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Designing and Cloning Guide RNA Plasmids for Targeted Editing of Mammalian RNAs by Using CRISPR-Cas13b

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ABSTRACT

Background/Purpose: CRISPR/Cas13 expands the CRISPR/Cas9-mediated DNA editing approaches to the RNA editing. In this system, a guide RNA (gRNA) targets a specific region in the RNA of interest and recruits Cas13. gRNA can be designed with little restriction to cover almost the whole transcriptome and various engineered Cas13 enzymes with unique added features can be utilized at the region of interest.

Methods: Plasmids were obtained from Addgene plasmid repository and their integrities were first confirmed by restriction enzyme digestions. An oligo that is complementary to the region surrounding the start codon of *PATZ1* mRNA was designed and cloned into a gRNA plasmid by using a golden gate reaction. The cloned plasmid was confirmed by Sanger-sequencing.

Results: A 45-nucleotide long sequence that is complementary to *PATZ1* mRNA around the AUG start codon with a mismatched cytosine for the corresponding adenine at the 30th nucleotide from the 3' end of the sequence was designed and cloned into gRNA plasmid.

Conclusion: We designed and cloned a gRNA plasmid that targets the start codon of human *PATZ1* mRNA. When this plasmid is co-transfected into cells with a catalytically inactivated Cas13 fused to an adenosine deaminase encoding plasmid, the adenine nucleotide in the canonical start codon of *PATZ1* is expected to be edited to inosine. This change might be functionally important to study the decrease in protein translation or the truncation of N-termini in future studies.

Keywords: CRISPR, Cas13, ADAR, *PATZ1*, RNA editing

ÖZET

Giriş/Amaç: CRISPR/Cas13, CRISPR/Cas9 aracılı DNA düzenleme yaklaşımlarını RNA düzenlemede kullanıma izin verir. Bu sistemde, bir kılavuz RNA (gRNA) hedef RNA'daki belirli bir bölgeyi bulur ve Cas13'ü beraberinde getirir. gRNA, neredeyse tüm transkriptomu kapsayacak şekilde çok az kısıtlama ile tasarlanabilir ve benzersiz ek özelliklere sahip tasarlanmış çeşitli Cas13 enzimleri hedef bölgede kullanılabilir.

Yöntemler: Plazmidler Addgene plazmid deposundan alındıktan sonra ilk olarak bütünlükleri restriksiyon enzim kesimiyle doğrulandı. *PATZ1* mRNA'sının başlangıç kodonunu çevreleyen bölgeye tamamlayıcı olan bir oligo tasarlandı ve golden gate reaksiyonu kullanılarak bir gRNA plazmidine klonlandı. Klonlanan plazmid Sanger dizilimiyle doğrulandı.

Bulgular: *PATZ1* mRNA'sının AUG başlangıç kodonu çevresine tamamlayıcı olan 45 nükleotid uzunluğunda bir dizi, dizinin 3' ucundan itibaren 30. nükleotide karşılık gelen adenin için uyumsuz bir sitozin ile tasarlanmış ve gRNA plazmidine klonlanmıştır.

Sonuç: İnsan *PATZ1* mRNA'sının başlangıç kodonunu hedefleyen bir gRNA plazmidini tasarladık ve klonladık. Bu plazmid, adenozin deaminaz kodlayan bir plazmide kaynaşmış katalitik olarak inaktif edilmiş bir Cas13 ile birlikte hücrelere aktarıldığında, *PATZ1*'in kanonik başlangıç kodonundaki adenin nükleotidinin inozine düzenlenmesi beklenmektedir. Bu değişiklik, gelecekteki çalışmalarda protein translasyonundaki azalmayı veya N-ucu kırık protein incelemek için işlevsel olarak önemli olabilir.

Anahtar Kelimeler: CRISPR, Cas13, ADAR, *PATZ1*, RNA Düzenleme

Engineered CRISPR/Cas systems are now widely applied for genome editing. Among these, the most famous is CRISPR/Cas9, in which a bacterial complementary CRISPR RNA (crRNA) and the trans-activating crRNA (tracrRNA) are combined into one intact RNA called as single guide RNA (gRNA) (1). gRNA binds Cas9, which is a DNA endonuclease, and guides it to the target DNA locus. In this system, gRNAs may require a pre-defined short stretch of flanking DNA sequence, which is called as protospacer adjacent motif (PAM). While gRNA binds to target DNA and forms a short hairpin, Cas9 is guided to this site to cleave the DNA. In eukaryotic cells, cleaved DNA initiates DNA damage response and cells edit the target DNA while repairing it (2).

Various other CRISPR/Cas systems were later discovered that utilize different Cas proteins or gRNA structures. CRISPR/Cas13 system has expanded the genome editing to RNA editing. This system takes advantage of the type VI CRISPR-associated RNA-guided ribonuclease Cas13 (3). Cas13 enzymes consist of four protein families that are smaller in size compared to Cas9: Cas13a, Cas13b, Cas13c and Cas13d (4). These enzymes cleave the target RNAs with their two higher eukaryotes and prokaryotes nucleotide-binding (HEPN) endoRNase domains. CRISPR/Cas13 also requires a gRNA to bind to target sequence and this gRNA forms a hairpin structure near a protospacer flanking site (PFS) to guide Cas13. Subsequently, Cas13 cleaves the target RNA with the activated HEPN domains. This catalytic activity of CRISPR/Cas13 can be harnessed to knock-down RNA expression in eukaryotic cells in a way that is similar to RNA interference (5).

CRISPR/Cas systems are very versatile tools to be utilized for various molecular biology approaches. One of the engineered versions of CRISPR/Cas13 has a catalytically inactive or so-called "death" Cas13 ortholog from *Prevotella sp.* (dPspCas13b) that is still capable of being guided by gRNAs. Cox, et al., further engineered dPspCas13b by fusing a modified human adenosine deaminase acting on RNA 2 enzyme (ADAR2) to it (3). ADARs are enzymes that edit double stranded RNAs at adenine:cytosine (A:C) mismatches by converting A to inosine (I) to form I:C Watson-Crick pairs. Inosine is a nucleobase functionally equal to

guanine (G) during RNA splicing and protein translation (6). The chimeric dPspCas13b - ADAR2DD [E488Q/T375G] protein is highly capable of editing target RNAs with very low number of off-targets and does not require any strict sequence constraints such as a PFS. With this type of precise RNA editing, disease causing mutations can be corrected, single nucleotide polymorphisms can be modelled, or protein translation start codons can be altered among many other applications.

In the current study, we designed and cloned a gRNA that would target the start codon of *PATZ1* mRNAs. Because *PATZ1* is an important DNA damage responsive transcription factor and is an important inhibitor of the p53 tumor suppressor protein functions, studying the functions of *PATZ1* is crucial for understanding tumorigenesis (7). The cloned plasmid may be used to destroy the canonical start codon of *PATZ1* mRNA.

Materials and Methods

Plasmids

pC0052 (REPAIR non-targeting guide clone into pC0043) (Addgene plasmid #103868), pC0043 (PspCas13b crRNA backbone) (Addgene plasmid #103854), and pC0054 (CMV- dPspCas13b- longlinker- ADAR2DD [E488Q/T375G]) (Addgene plasmid #103870) plasmids were gifts from Feng Zhang (3). MiniPrep Plasmid DNA isolation was performed using the alkaline lysis protocol (8).

Restriction Enzyme Digestion

The integrity of the plasmids was confirmed based on their expected fragment size patterns on an agarose gel after their digestion with different restriction enzymes. 500 ng of a plasmid was used with each restriction enzyme (New England Biolabs Inc.) and the reactions were performed according to the manufacturer protocols. The resulting DNA fragments were resolved on a 0.7% agarose gel for 60 min at 100V. Ethidium Bromide (EtBr) -stained DNA bands were captured using a ChemiDoc Imaging System (Bio-Rad).

Annealing of gRNA Insert

Two complementary DNA oligonucleotides were designed to express the gRNA against the target RNA, and flanked with additional nucleotides to create sticky ends: PspCas13bPATZ1top (5'- cac cCG TTC ACC CGC TCC AcG GCC GCC GCC CCC TCC CAC TAG CCC GGC C -3') and PspCas13bPATZ1bot (5'- caa cGG CCG GGC TAG TGG GAG GGG GCG GCG GCC **g**TG GAG CGG GTG AAC G -3'). The oligos were annealed at 10 μ M final concentration for each in 10 μ L final reaction volume with 1X T4 ligase buffer (NEB, #B0202S) and 1 unit/ μ L T4 Polynucleotide Kinase (NEB, #M0201S) by the following parameters (37°C 30min, 95°C 5min, ramp-down to 25°C (5°C / 5min)). The success of the annealing reaction was confirmed by resolving the single stranded and double stranded oligos on an agarose gel with EtBr.

Cloning of gRNA Insert into the Plasmid

The double stranded DNA oligo coming from the annealing reaction was diluted 1:200 with ddH₂O and 6 μ L of this dilution was mixed with 100 ng of pC0043, 2 μ L of 10X T4 ligase buffer, 10 units of BbsI restriction enzyme (NEB, #R0539S), 2 μ L of BSA (1 μ g/ μ L), 200 units of T4 DNA ligase (NEB, #M0202S) and ddH₂O up to 20 μ L total volume. Linearization of the plasmid followed by the ligation of the insert was performed by a golden gate reaction by the following parameters: (37°C 5min, 21°C 5min) \times 12. Unligated free oligos in the reaction mixture was later removed by treating the sample with exonuclease V. For this, the 20 μ L of ligation reaction yield was supplemented with 3 μ L NEBuffer 4 (NEB, #B7004S), 3 μ L of 10mM ATP (NEB, #P0756S), 10 units of T5 Exonuclease (NEB, #M0363S) and ddH₂O up to 30 μ L total volume. The treatment was performed at 37°C for 30 min and stopped by supplementing 3.5 μ L of 100mM EDTA and 1.5 μ L ddH₂O followed by an incubation at 70°C for another 30 min.

Colony PCR

10 μ L of the golden gate reaction product was used to transform DH5 α Chemically Competent E. coli. Eight colonies were picked from the agar plate and bacteria cultures

were propagated from them for miniprep DNA using alkaline lysis protocol (8). For colony PCR, 1 μ L of the miniprep DNA was mixed with 14.5 μ L of ddH₂O, 2 μ L of 2.5 μ M U6 forward primer (5'- GAG GGC CTA TTT CCC ATG ATT CC -3'), 2 μ L of 2.5 μ M PspCas13bPATZ1bot primer, 5 μ L of 5X MyTaq buffer, and 0.5 μ L of 5u/ μ L MyTaq polymerase (Bioline, #BIO-21105). PCR was performed in a thermocycler machine with the following parameters: 95°C 1 min (95°C 15 sec, 62°C 15 sec, 72°C 18sec) \times 35. The PCR products were visualized by resolving the DNA samples on an agarose gel with EtBr. Selected plasmid clones were sent out for Sanger sequencing using U6 forward primer. Sequencing results were visualized and analyzed by using QIAGEN CLC Main Workbench bioinformatics tool.

Results

Confirmation of Plasmid Integrities

Three important plasmids are used for the dPsp-Cas13b-ADAR2-mediated CRISPR/Cas13b RNA editing system. pC0043 is the backbone required for expressing the desired gRNA cloned into it. pC0054 is a eukaryotic protein expression plasmid that encodes dPsp-Cas13b-ADAR2DD fusion protein in mammalian cells. pC0052 is actually identical to pC0043 except for an already cloned non targeting guide RNA sequence that has no possible target site on mammalian RNAs and is used as negative control. After the plasmids were isolated by miniprep from the transformed bacterial stab cultures purchased from Addgene plasmid repository, the plasmids were first run on an agarose gel to visualize their integrity (Fig. 1a). The most intense bands observed on the image pointed out the expected size of the corresponding plasmid and confirmed that plasmids were intact. The integrity of the plasmids was further assessed by restriction enzyme digestion. For this, the plasmids were digested using appropriate restriction enzymes that would produce distinctive DNA fragments (Fig. 1b). Accordingly, resolving the digestion reaction on an agarose gel revealed the expected DNA bands at the expected sizes and confirmed the plasmid integrities.

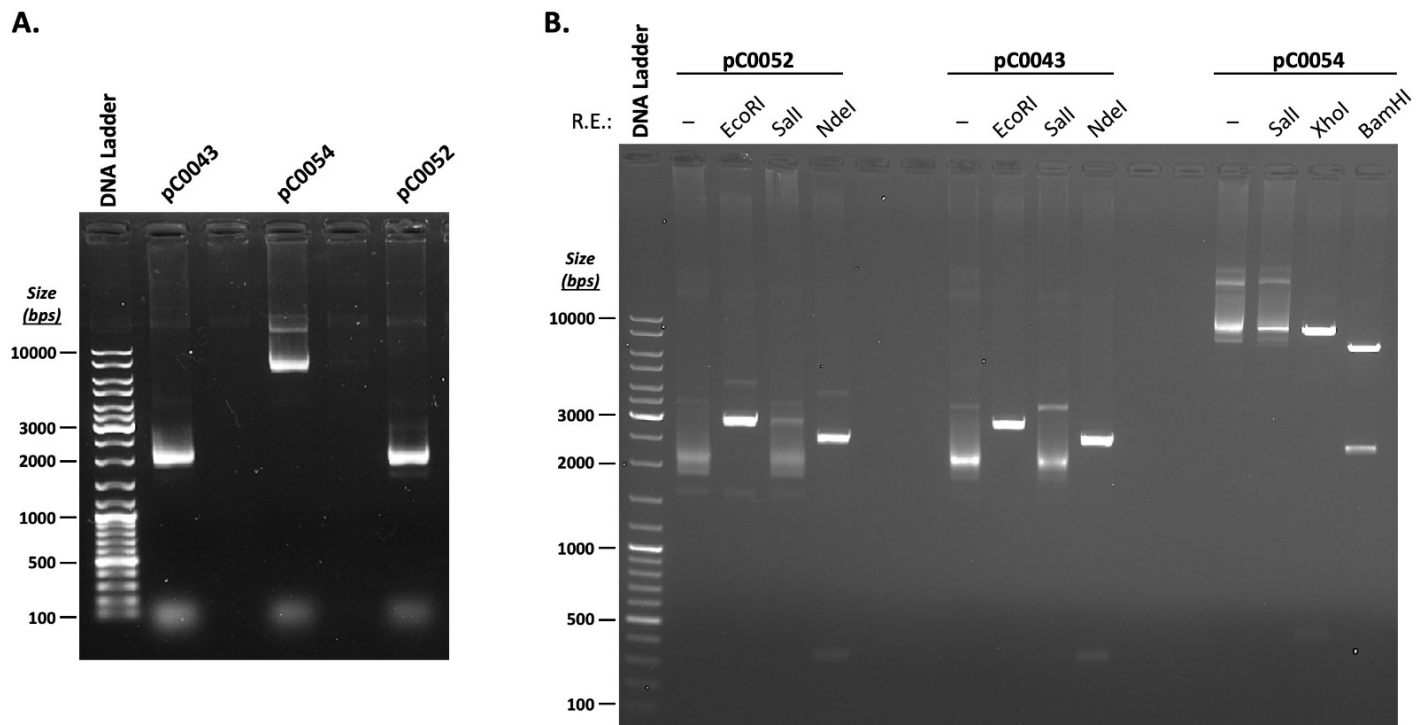


Figure 1: The plasmids required for CRISPR-Cas13b RNA editing system were intact. **A.** Miniprep DNAs were run on a 0.7% agarose gel for 60 min at 100V. EtBr-stained DNA bands were captured using a ChemiDoc Imaging System (Bio-Rad). Expected bands (bp: base pairs) are 2962bp for pC0043, 9864 bp for pC0054 and 2970 bp for pC0052. **B.** Plasmids were digested by restriction enzymes (R.E.) and DNA fragments were analyzed by agarose gel electrophoresis. For PC0052: EcoRI (2962bp), Sall (2962bp) and NdeI (372bp and 2602bp). For pC0043: EcoRI (2962bp), Sall (2962bp) and NdeI (364bp and 2602bp). For pC0054: Sall (2192bp and 7680bp), XhoI (489bp and 9383bp) and BamHI (2475bp and 7397bp). Note that the digestion reactions with Sall were apparently not to the completion. Also, DNA fragments shorter than 500bp were not easily visible under the current exposure settings.

Designing and Cloning Guide RNA Sequence

In order to edit the AUG start codon of *PATZ1* mRNA via deamination of adenosine to inosine, a gRNA that is complementary to the region encompassing the target adenine was designed (Fig. 2a). For this a 45-nucleotide long sequence was selected in such a way that the 30th nucleotide from the 3' end of the gRNA sequence would correspond to the adenine of the AUG codon and this specific nucleotide was replaced with a cytosine in the oligo. The DNA oligonucleotide that is expected to encode this guide RNA from the cloned plasmid was created by adding additional overhangs for cloning purposes. For the

cloning into pC0043 plasmid, firstly, two complementary DNA oligos were annealed that was confirmed by running the reaction yield on an agarose gel in the presence of ethidium bromide, which would bind DNA by exceedingly intercalating between base pairs (Fig. 2b). Subsequently, the double stranded DNA insert was cloned into pC0043 plasmid via golden gate reaction by digesting the plasmid with BbsI restriction enzyme and ligating the insert with T4 DNA ligase. The final plasmid construct was named as pC0043-PATZ1-gRNA. The sequence was annotated with all the important features and schematically represented in figure 2c.

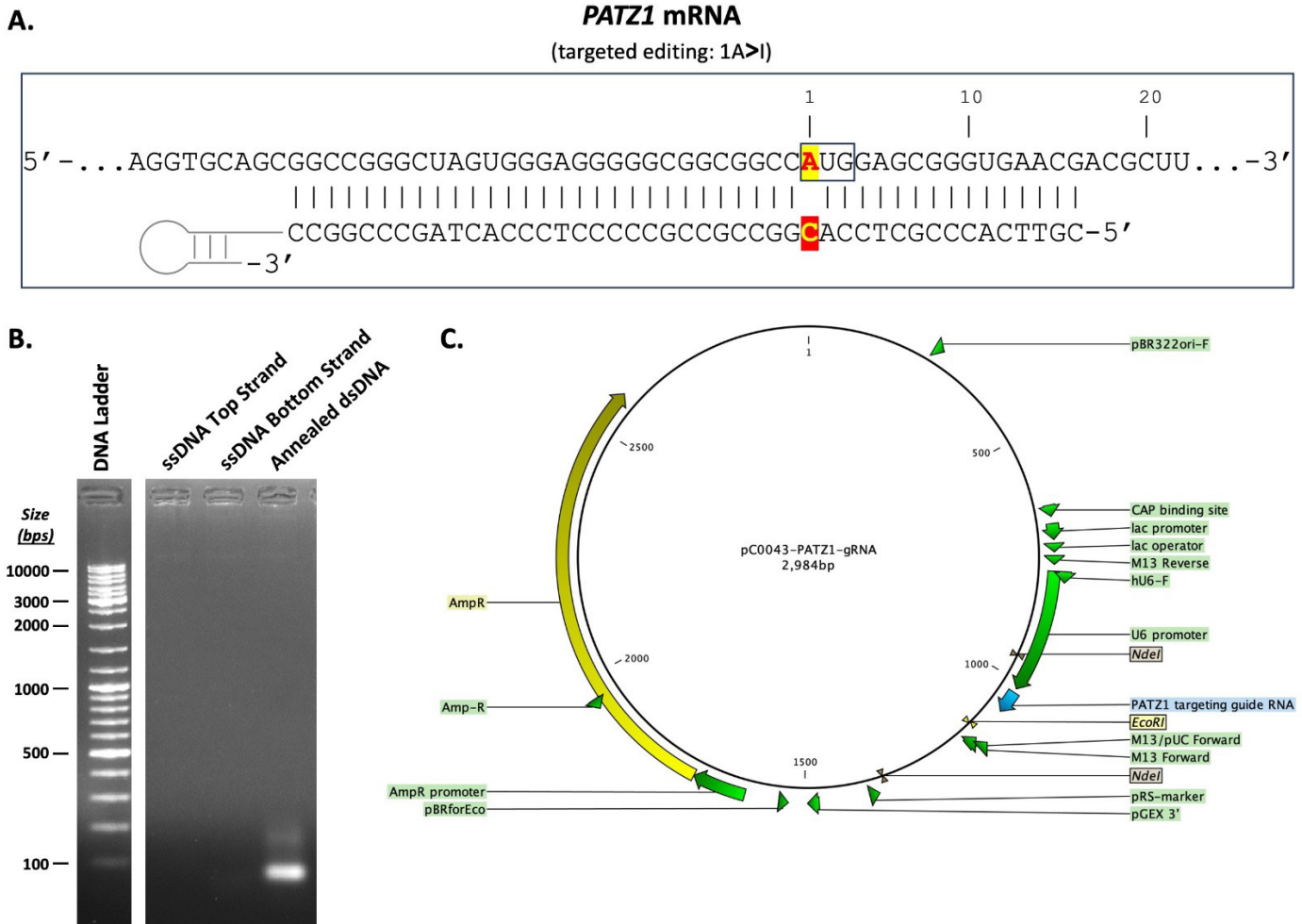


Figure 2: *PATZ1* mRNA targeting gRNA was designed and cloned into pC0043 plasmid. **A.** The mRNA sequence of *PATZ1* was acquired from Ensembl database (ENST00000266269.10). The gRNA sequence (below) complementary to the *PATZ1* mRNA (above) was shown. The adenine of the start codon (highlighted with a box) was numbered 1. **B.** The annealing success of the single stranded complementary DNA oligos encoding the gRNA was revealed by ethidium bromide staining of the agarose gel. **C.** The schematic representation of the final cloned plasmid, pC0043-PATZ1-gRNA, was generated by QIAGEN CLC Main Workbench software. Annotations on the map represent primer binding sites, antibiotic resistance gene, restriction enzyme cut sites and gRNA insert.

Confirmation of the Cloned Plasmid

The golden gate reaction was transformed into bacteria to select for individual clones. For this, first a colony PCR was performed to quickly screen for the presence of the insert using a PCR primer pair that includes an oligo that targets the U6 promoter as the forward primer and the specific bottom oligo used for the gRNA insert as the reverse primer (Fig. 3a). The colony PCR showed that all selected colonies from the agar plate contained the gRNA

insert. Plasmids were extracted from the expanded bacteria cultures and submitted for Sanger sequencing using U6 forward primer. This gave greater insight into the confirmation of the exact insert sequence in the plasmids. 5 plasmid samples were sequenced in total but only the sequence of colony #2 is included here as a representative result (Fig. 3b). According to the sequence, the corresponding insert was missing one nucleotide at the downstream end that is next to the hairpin structure of the encoded RNA.

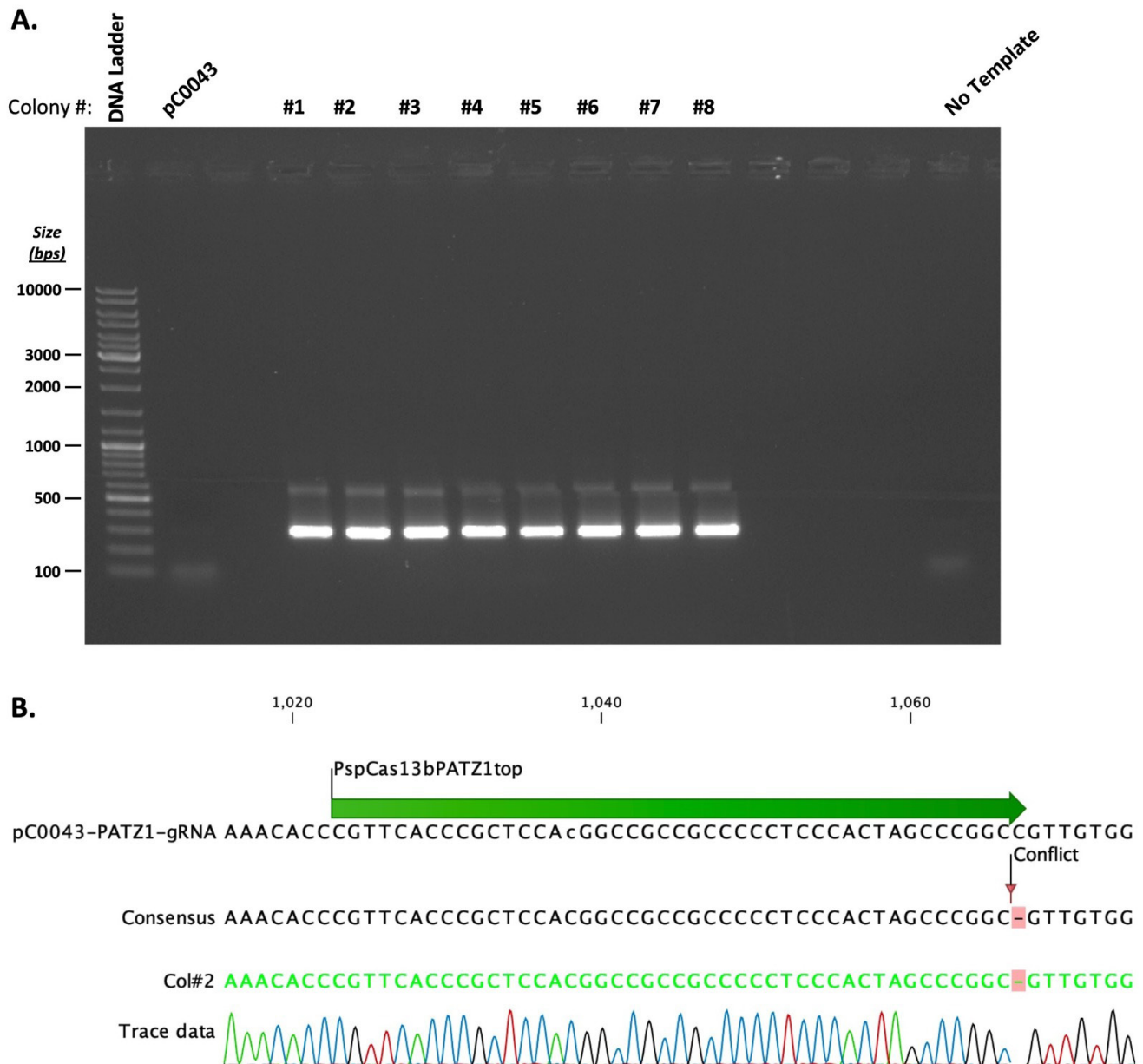


Figure 3: The final plasmid construct sequence. **A.** The transformed bacteria colonies were initially screened by using colony PCR with U6 forward and PspCas13bPATZ1bot reverse primers. A 298bp PCR product was expected from the successful transformants. **B.** The plasmids were extracted from the corresponding colonies using alkaline lysis miniprep method and submitted for sanger sequencing with U6 Forward primer. The colony shown here was missing the last nucleotide, which was indicated as a conflict on the alignment. Sequencing peaks were visualized by using QIAGEN CLC Main Workbench.

Discussion

There are catalytically impaired Cas9 proteins fused to adenine or cytidine base editors that can alter a specific start codon on DNA level (9). Alternatively, CRISPR/Cas13 system is another technology for altering gene expression by targeting, skipping or editing RNAs. This technology is

advantageous over Cas9 as it does not damage DNA (10). PspCas13b, which was also used in the current study, does not require a predefined PFS sequence on the target RNAs, potentially making it to be used across the whole mammalian transcriptome (3). CRISPR/Cas13 was proven to eliminate or correct pathogenic mRNAs. Powell, et al., (11) utilized RfxCas13d, a Cas13 ortholog, to knock-down

mutant *superoxide dismutase 1 (SOD1)* mRNA, which otherwise cause amyotrophic lateral sclerosis, in mouse spinal cord and brain via adeno-associated virus delivery. They also targeted *huntingtin (HTT)* mRNA, which causes Huntington's disease, with a similar approach.

Adenosine deaminases acting on RNA (ADAR2) can convert A to I in a targeted double stranded RNA at the site of a mismatch between A and C. Moreover, novel evolved ADARs can even act as cytidine deaminase to edit C to U (10). Cas13-based ADAR mediated RNA editing should still prove itself for its therapeutic potential, however, there are uses of ADARs to correct disease causing single nucleotide mutations already. Sinnamon, et al., (12) used an alternative approach to direct ADAR2 to a mutation site on *Methyl CpG Binding Protein 2 (MECP2)* mRNA that causes Rett syndrome, a neurological disease, and efficiently repaired the mutation to reverse its pathological consequences.

PATZ1 is an architectural transcription factor belonging to POZ domain Krüppel-like (POK) zinc finger family. It has multiple roles in variety of biological processes such as cellular proliferation, apoptosis, T-cell differentiation, and embryogenesis (13). PATZ1 inhibits the function of the p53 tumor suppressor protein by binding p53 to modulate its DNA binding capacity (7). Recently, *PATZ1* gene locus is also indicated in various gene fusions including the famous *EWSR1* gene locus that results in the production of chimeric *EWSR1::PATZ1* protein that causes round cell sarcoma (15). In order to elucidate the contributions of PATZ1 protein to tumorigenesis and to its other biological roles, utilizing recent molecular biology tools to manipulate PATZ1 expression in mRNA and protein levels would be beneficial.

In the current study, we first designed a gRNA targeting the human *PATZ1* mRNA. This gRNA would guide ADAR2-fused PspCas13b protein to alter the AUG start codon to IUG, which is supposed to inhibit the protein translation initiation from this start codon. Cox, et al., (3) suggests that an effective size of gRNA should be about 50 nucleotide long and the target A should be positioned at around 34th nucleotide. Therefore, with all these variabilities, we also recommend that it is best to design and

clone several different guide RNAs surrounding the target nucleotide and test editing efficiencies of these plasmids in an easy-to-transfect human cell line such as HEK293 by co-transfecting them with the plasmid encoding dPsp-Cas13b-ADAR2DD (pC0054) before transitioning to more challenging cell lines or *in vivo* studies. The efficiency of RNA editing at the start codon might be assessed by western blot for the protein production or by qRT-PCR using Taqman probes for the wildtype and mutated start codon on mRNA. The gRNA expressing plasmid we cloned in the current study is 1 nucleotide shorter than the intended sequence. This was probably due to the impurities in the initial oligo synthesis. We had ordered only standard de-salting for the synthesis of our oligos, however, now we recommend that researchers should select for an additional HPLC purification to get the precise length of the oligo before cloning it into the plasmid. *PATZ1* mRNA has other in-frame start codons downstream of canonical start codon that we also targeted in the current study. Therefore, it is important to keep in mind that skipping the initial start codon might not halt the protein translation completely but might yield in N-terminal truncated PATZ1 protein production as well. PATZ1 protein has an N-terminal BTB domain that is important for its activities including dimerization and co-repressor interactions (14). Therefore, skipping the canonical start codon by editing AUG to IUG might be useful for molecular biology studies in various ways.

Conclusion

Here, we report that we designed and cloned a gRNA plasmid that is expected to edit the start codon of human *PATZ1* mRNA when co-transfected with an ADAR2-fused catalytically inactive PspCas13b expressing plasmid into human cells. ADAR2 can edit adenine to inosine with high efficiency and therefore any adenine that is of interest might potentially be edited to inosine with this particular CRISPR/Cas13 approach. Designing and cloning gRNA plasmids are very straightforward and many other gRNAs targeting different RNA sequences may be cloned in a similar way with a limited budget and in a short time frame.

Declarations

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Conflict of Interest

The authors have declared no conflict of interest.

Ethics Approval

The current design and the execution of this study do not require an ethics approval.

Availability of Data and Material

All data have been presented here. Material may be available upon request.

Authors' Contributions

CG and ED performed the research, analyzed the data, and wrote the paper; ED conceived of and designed the overall study.

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Clinical Characteristics and Treatment Outcomes of Pediatric Patients with Non-Hodgkin Lymphoma: a Single-Center Experience From Southern Turkey

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ABSTRACT

Purpose: Non-Hodgkin lymphoma (NHL) accounts for 8-10% of all childhood cancers. In this study, we aimed to describe the epidemiological and clinical characteristics and treatment outcomes of pediatric NHL patients treated at a tertiary center.

Methods: The oncologic records of the patients diagnosed and followed up as NHL between 2013 and 2023 were reviewed retrospectively.

Results: A total of 36 patients were enrolled in this study. The most common pathologic subtype was lymphoblastic lymphoma (LL) (n=21, 58.3%) followed by Burkitt lymphoma (BL) (n=10, 27.8%), diffuse large B-cell non-Hodgkin lymphoma (DLBCL) (11.1%, n=4), and anaplastic large cell lymphoma (ALCL) (2.8%, n=1). Overall survival (OS) and event-free survival (EFS) were significantly longer in patients without bone marrow (BM) involvement (p=0.001 and p=0.02, respectively). EFS was significantly longer in patients without central nervous system (CNS) involvement (p=0.038). OS and EFS did not differ significantly according to NHL subtypes. There was no significant difference in OS according to age groups (p=0.7).

Conclusion: The OS with NHL has significantly improved. With the development of effective treatment regimens based on various pathologic subtypes, the result of pediatric NHL has significantly improved in recent years. The survival rates have reached >90%.

Keywords: cancer, pediatric, non-Hodgkin lymphoma

ÖZET

Amaç: Non-Hodgkin lenfoma (NHL), tüm çocukluk çağı kanserlerinin %8-10'unu oluşturur. Bu çalışmada üçüncü basamak bir merkezde tedavi gören pediatrik NHL hastalarının epidemiyolojik ve klinik özelliklerini ve tedavi sonuçlarını tanımlamayı amaçladık.

Yöntemler: 2013-2023 yılları arasında NHL tanısı konularak takip edilen hastaların onkolojik kayıtları geriye dönük olarak incelendi.

Bulgular: Bu çalışmaya toplam 36 hasta dahil edildi. En sık görülen patolojik alt tip lenfoblastik lenfoma (LL) (n=21, %58,3) olup bunu Burkitt lenfoma (BL) (n=10, %27,8), diffüz büyük B hücreli non-Hodgkin lenfoma (DLBCL) (n=4, 11.1%) ve anaplastik büyük hücreli lenfoma (ALCL) (%2,8, n=1) izledi. Genel sağkalım (OS) ve olaysız sağkalım (EFS), kemik iliği (BM) tutulumu olmayan hastalarda anlamlı derecede daha uzundu (sırasıyla p=0,001 ve p=0,02). Santral sinir sistemi (CNS) tutulumu olmayan hastalarda EFS anlamlı olarak daha uzundu (p=0,038). OS ve EFS, NHL alt tiplerine göre anlamlı farklılık göstermedi (p>0,05). Yaş gruplarına göre OS açısından anlamlı farklılık yoktu (p=0,7).

Sonuç: NHL'li hastalarda genel sağkalım gelişmeler oldu. Çeşitli patolojik alt tiplere dayalı etkili tedavi rejimlerinin geliştirilmesiyle, son yıllarda pediatrik NHL'nin sonuçları önemli ölçüde iyileşti. Hayatta kalma oranları >%90'a ulaştı.

Anahtar Kelimeler: kanser, pediatrik, non-Hodgkin lenfoma

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NHL is a group of lymphoid malignancies originating from the lymphoid tissues, mostly the lymph nodes. They often extend to other organs, including the spleen, bone marrow, or central nervous system. It is the second most frequent malignancy second among childhood cancers after leukemias, according to Türk Pediatrik Hematoloji Derneği (TPHD) and Türk Pediatrik Onkoloji Grubu (TPOG) cancer registry data. [1]. Compared to adult NHLs, pediatric NHLs are known to exhibit distinct clinical characteristics and distributions of pathologic subtypes. The NHL subtypes occurring in children are primarily high-grade tumors including BL, DLBCL, LL, and ALCL. Persistent weight loss, headaches, nausea, increased skeletal system edema and pain, and the presence of a lump or mass in the abdomen or cervical region are among the typical signs and symptoms. Radiological imaging, laboratory testing, and clinical evaluation are all part of the diagnosis process for NHL. The definitive diagnosis of NHL is made by histopathological and immunohistochemistry examination of the biopsy material. Administering biological subtype-directed chemotherapy is the key to success in childhood NHL as radiation and surgery have limited therapeutic benefits. In the current literature, available data on NHL among children in developing countries are limited. With the development of effective treatment regimens based on various pathologic subtypes, the result of pediatric NHL has significantly improved over the past thirty years [2]. The survival rates have reached >90% [3]. The purpose of this study is to assess the treatment modalities, results, and clinical and demographic features of our pediatric NHL patients treated in a single tertiary center in Turkey.

Methods

This study was approved by the Ethical Committee for Acibadem University, with the assigned decision no: 2024-6/233 and date: 18.04.2024. Data from children with NHL who were diagnosed and treated at the Acibadem Adana Hospital Pediatric Hematology-Oncology Department between 2013 and 2023 were analyzed. Patients with missing information or patients with blasts of 25% in BM were not included in this study. Retrospective analyses were conducted on the patients' age, gender, symptoms, physical examination results, complete blood count, lactate dehydrogenase concentration, histopathological features, stages at the time of diagnosis, treatments, and follow-up periods. NHL was diagnosed and classified according to the World Health Organization Classification of Hematological Malignancies [4]. A diagnosis of central nervous system disease was made if any of the following

conditions were met: lymphoma cells in the CSF (> 5 cells/ μ L CSF), cerebral infiltrates on cranial MRI, or cranial nerve palsy. Radiotherapy was administered for central nervous system involvement-positive patients. LMB-96 chemotherapy regimens for BL and DLBCL; BFM-95 chemotherapy regimen for LBL; and modified BFM-NHL90 chemotherapy regimen for ALCL were used [5]. In the OS analysis performed according to age groups, patients were divided into three groups: 0-5 (n=4), 6-11 (n=15) and 12-18 (n=17).

Statistical Analysis

Data were analyzed using IBM SPSS V23. Descriptive statistics including frequencies and percentages for categorical (ordinal and nominal) data; and averages (means, medians, and/or ranges) and standard deviations used for all study variables. The OS and the EFS probabilities were calculated using the Log-rank and Kaplan–Meier method. The entire period of patient follow-up from the time of diagnosis was referred to as OS; EFS was defined as relapse, tumor progression, sepsis, or death from any cause from the time of diagnosis. p values of < 0.05 were considered statistically significant.

Results

A total of 36 patients with NHL were included in this study. Demographic and clinical of the patients' characteristics are summarized in Table 1. There were 23 boys (63.9%) and 13 girls (36.1%). The median age at diagnosis was 11.17 ± 4.16 years. The most common pathologic subtype was LL (n=21, 58.3%) followed by BL (n=10, 27.8%), DLBCL (11.1%, n=4), and ALCL (2.8%, n=1). Most patients (66.7%) had advanced disease (stage III or IV) at diagnosis. Central nervous system (CNS) involvement and BM involvement were observed in 5 (13.9%) and 6 (16.7%) patients, respectively. In 13 (36.1%) of the patients, the primary site of the disease was the mediastinum, whereas in 12 (33.3%) abdomen, and 11 (30.6%) of the patients, it was cervical/peripheral lymph nodes. Various complications were observed at the time of admission to our hospital in four patients, one of which was tumor lysis syndrome, one was paralysis due to peripheral nerve compression, one was dyspnea due to a mediastinal mass, and one was "acute abdomen" from an intussusception. Patients were diagnosed via biopsy performed under general anesthesia. In a patient with a large anterior mediastinal mass, the diagnosis was made by tru-cut biopsy under local anesthesia. In another patient with pleural effusion, the diagnosis was made by pathological evaluation of the thoracentesis material.

Table 1: Patients' characteristics.	
	(N: 36), n (%)
Age (yr)	11.17±4.16
Sex	
Male	23 (63.9)
Female	13 (36.1)
Pathologic subtype	
LL	21 (58.3)
BL	10 (27.8)
DLBCL	4 (11.1)
ALCL	1 (2.8)
B Symptoms	
Yes	23 (63.9)
No	13 (36.1)
BM involvement	
Yes	6 (16.7)
No	30 (83.3)
CNS involvement	
Yes	5 (13.9)
No	31 (86.1)
Primary site	
Mediastinum	13 (36.1)
Abdomen	12 (33.3)
Cervical/peripheral lymph nodes	11 (30.6)
St. Jude stage	
I	4 (11.1)
II	8 (22.2)
III	13 (36.1)
IV	11 (30.5)
Complication	
Yes	4 (11.1)
No	32 (89.9)
Relapse	
Yes	4 (11.1)
No	32 (89.9)
LDH level (IU/mL) %50 (%25-%75 percentiles)	258 (201-535)
Follow up time (yr) %50 (%25-%75 percentiles)	3 (2-5.75)
Abbreviations: BL, Burkitt lymphoma; LL, lymphoblastic lymphoma; DLBCL, diffuse large B-cell lymphoma; ALCL, anaplastic large cell lymphoma; BM, bone marrow; CNS, central nervous system; LDH, lactate dehydrogenase.	

Four patients relapsed at the primary disease site. Of these four (11.1%) patients who relapsed, two (5.5%) received chemotherapy and survived, one (2.7%) underwent auto-HSCT and survived, and one (2.7%) died due to disease progression after the salvage regimen. There was no difference between NHL pathological subtypes in terms of BM, CNS involvement, or advanced-stage status (Table 2). The mean follow-up time was 3.83±2.39 years (median 3 years). 5-year EFS was 77.8% and OS 91.7% (Figure 1, Figure 2). OS and EFS were significantly longer in patients without BM involvement (p=0.001 and p=0.02, respectively). EFS was significantly longer in patients without CNS involvement (p=0.038). There was no significant difference in OS in patients without CNS involvement compared to those with CNS involvement (p=0.739). All patients were divided into 3 age groups: 0-5 years (4 patients), 6-11 years (15 patients), and 12-18 years (17 patients). There was no significant difference in OS according to age groups and gender (p=0.7 and 0.774, respectively) (Figure 3 and Figure 4). OS, EFS, and LDH levels did not differ significantly according to NHL subtypes (p>0.05).

Table 2: BM, CNS involvement and disease extent at diagnosis according to pathologic subtype.					
	LL n (%)	BL n (%)	DLBCL n (%)	ALCL n (%)	P
BM involvement					
Yes	3 (50)	2 (33)	1 (16)	0 (0)	0.871
No	18 (60)	8 (26.7)	3 (10)	1 (3.3)	
CNS involvement					
Yes	3 (60)	1 (20)	1 (20)	0 (0)	0.853
No	18 (58.1)	9 (29)	3 (9.7)	1 (3.2)	
Advanced disease (Stage≥3)					
Yes	15 (62.5)	6 (25)	2 (8.3)	1 (4.2)	0.658
No	6 (50)	4 (33.3)	2 (16.7)	0 (0)	
Abbreviations: BL, Burkitt lymphoma; LL, lymphoblastic lymphoma; DLBCL, diffuse large B-cell lymphoma; ALCL, anaplastic large cell lymphoma; BM, bone marrow; CNS, central nervous system.					

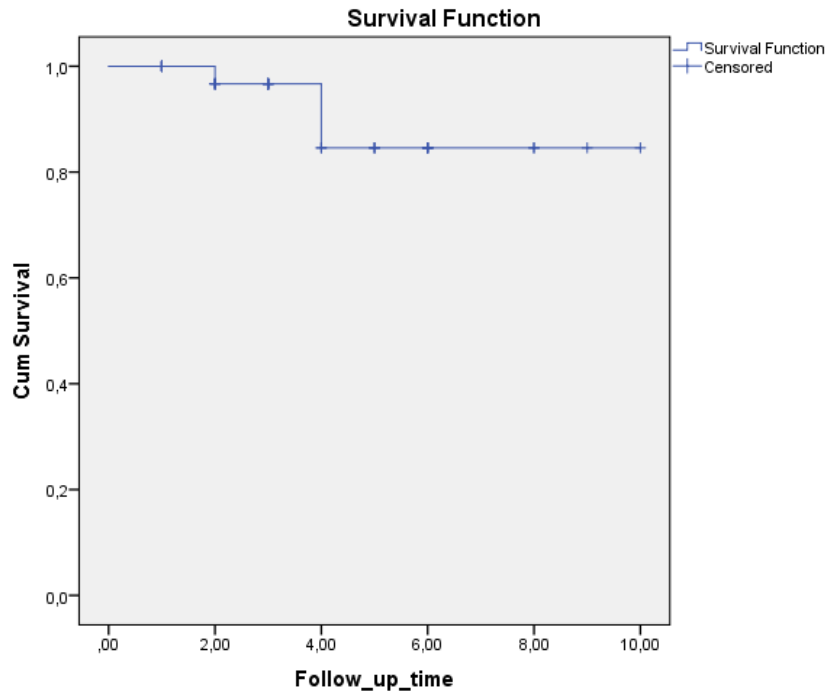


Figure 1: Kaplan-Meier estimate of overall survival (n=36; 5-year OS = 91.7 %).

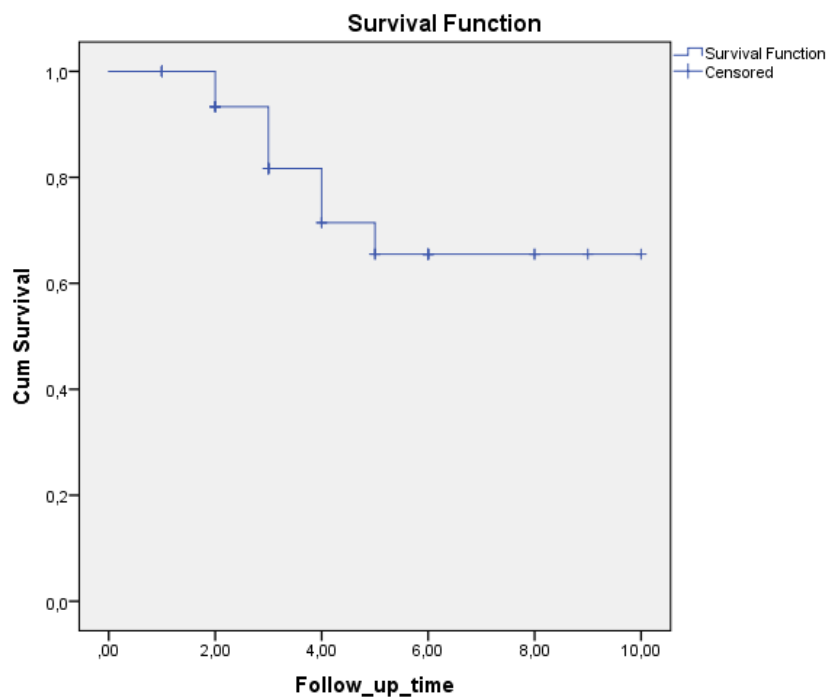


Figure 2: Event free survival (events: Mortality, progresyon, complication)

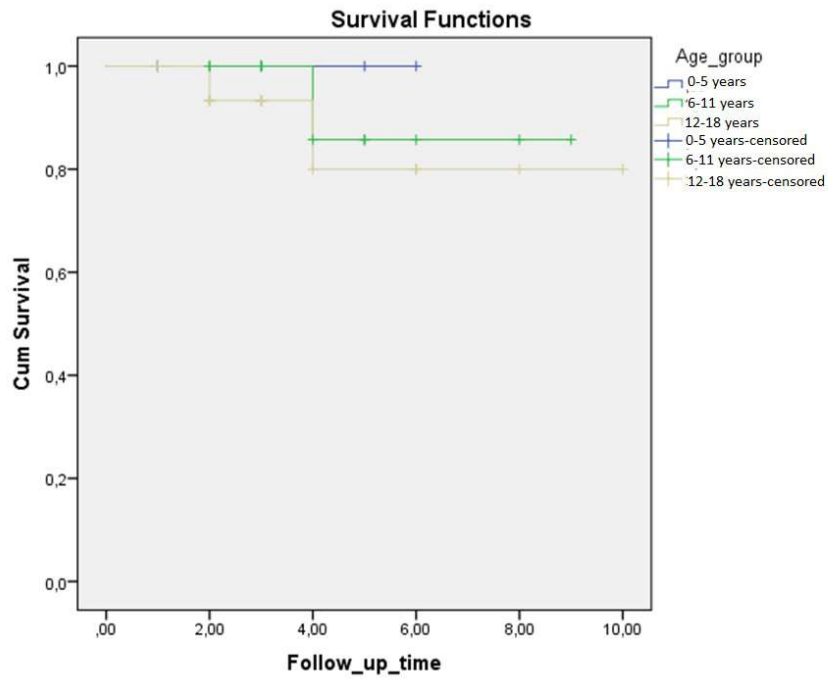


Figure 3: Figure shows OS according to age groups.

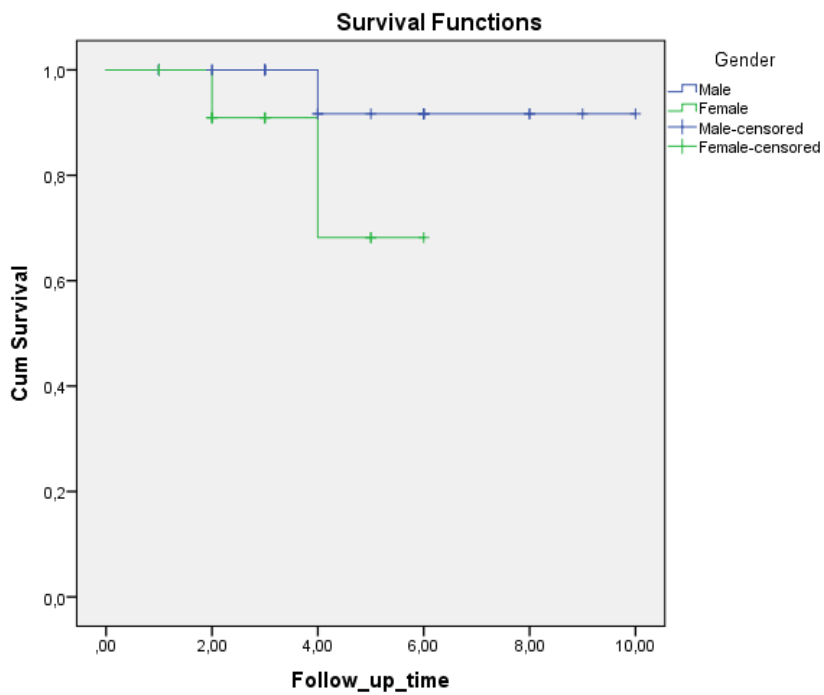


Figure 4: Figure shows according to gender groups.

Discussion

The second most prevalent childhood cancer is NHL, which even in children with advanced disease has a good long-term survival rate. Although the exact cause is unknown, infections, environmental stressors, immunodeficiency, and chronic inflammation are held responsible for etiology [6,7]. The prognosis for pediatric NHL has significantly improved during the last decades [8]. Improvements in treatment approaches, supportive care, and diagnostic techniques may be an explanation of this development. In the present study, we aimed to show the characteristics, treatment, and long-term follow-up of 36 children with NHL in a pediatric hematology-oncology unit in Turkey. The median age in our study was 11.1 years at diagnosis (ranging from 4 to 18 years). It is already known that the median age of presentation of NHL in childhood is 10 years. Cases involving children less than three are uncommon [9]. In a study conducted by Kara et al. with 80 children with NHL aged between 2 and 18, the median age was found to be 11.1 years, similar to our study [10]. The most prevalent pathogenic groups in children are ALCL, DLBCL, LBL, and BL. Marginal zone, cutaneous, follicular, and peripheral T-cell lymphomas, which are common NHL subtypes in the adult population, constitute the remaining 10% of the whole [11]. When the distribution of subtypes of NHL in our patients was evaluated, LL was seen most frequently, contrary to the literature [12]. There were no patients diagnosed with the rare NHL subtype in our study. NHL in our study affected (63.9%) boys and (36.1%) girls with male to female ratio of 1.76. These findings support the male predominance of childhood lymphoma that has been previously established [13].

Rapidly growing tumors may exhibit symptoms specific to their size and location. Part of patient management is being able to deal with these complications alongside chemotherapy. One of our cases diagnosed with T-cell LL presented with hemiparesis in the right upper extremity due to nerve compression in the paravertebral region (Figure 5). In cases with such neurological deficits, immediate radiotherapy in addition to chemotherapy contributes positively to morbidity. It is suggested that field radiation involved may also be considered for palliation of pain or mass effect [14]. In addition, surgery has a limited role in treating NHL, although being crucial for the initial diagnosis, evaluating the presence of residual masses, and determining the efficacy of therapy. In our study, there were no patients who underwent surgery other than diagnostic purposes (palliative, etc.).



Figure 5: Contrast enhancement in leptomeningeal structures at the C4-C7 level in the cervical vertebrae (white arrow).

In the present study, 5-year EFS was 77.8% and OS 91.7%, respectively. With current treatment, children with Stages I to II disease have 2-year EFS rates of 85-98% and 85-90%, respectively. 85-90% and 85-90% 2-year EFS are seen in children with stage III and stage IV illness with BM involvement, respectively, and those with CNS disease (BL) have an 80% EFS [15]. Our retrospective study indicated that pediatric NHL patients responded well to our treatment approaches. The better treatment outcomes for pediatric NHL may have been brought about by the emergence of effective treatment regimens for various histologic subgroups. In our study, OS and EFS did not differ significantly by age and gender. In the retrospective study conducted by Karadoğan et al. with 47 children with NHL were treated with BFM-95 protocol. Four-year EFS, and OS was 78.7% and 80.8%, respectively, similar to our study [16]. Furthermore, in the cross-sectional retrospective study conducted by Sherief et al. with 142 children with NHL, regarding OS and EFS, there was no difference between gender and age [17]. However, the distribution of age and sex varied depending on the pathologic subtype and had distinct implications on treatment outcomes according to a BFM study on pediatric NHL [18]. In a recent study by Özdemir et al. with 65 children diagnosed with NHL (treated with NHL-BFM, ALL-BFM, and ALCL-99 protocols), the median follow-up time was 86.4 months and OS and EFS for five years were 94.6% and 90.3%, respectively. Relapse was observed in 6 (9.2%) patients, 4 of whom were at the

primary site [19]. In this heterogeneous disease group with many subtypes, larger patient groups and separate analyses for each subtype may be needed. BM and CNS involvement were rarely identified, although the majority of patients had advanced-stage diagnoses. However, in our series of patients, OS and EFS were significantly longer in patients without BM involvement. Compared to other subtypes, patients with BL and LL had higher rates of BM and CNS involvement. Consistent with our study, in the large cohort study conducted by Salzburg et al. with children and adolescents diagnosed with NHL, in 141 (5.9%) out of 2381 patients, CNS involvement was identified; it was more common in BL patients. Also, CNS involvement was associated with an advanced stage of NHL. EFS was $64\% \pm 5\%$ and $86\% \pm 1\%$ for the 112 CNS-positive patients and for the 1927 CNS-negative patients, respectively ($p < .001$) [20].

NHL patients who experience a relapse have a low probability of survival [21]. Only one (25%) of our 4 patients with relapse died due to disease progression following treatment with ifosfamide, carboplatin, and etoposide (ICE). In contrast to our results, in a recent study conducted with 639 relapsed NHLs in children and adolescents, the eight-year probability of OS was found to be $34 \pm 2\%$ [22]. This may be explained by the relatively small number of patients in our study. Moreover, one of our patients (LL) who relapsed underwent auto-HSCT using the conditioning regimen consisting of carmustine (BCNU), etoposide, cytarabine, and melphalan and survived. In a study with 36 relapsed and refractory pediatric patients with NHL who underwent allogeneic HSCT, OS at 3 years was 67% in all subtypes and 17% for LL [23]. In another study, a 5-year OS in relapsed cases was found 33% [24]. Furthermore, this suggests that traditional salvage regimens were not efficacious enough, and enhancing the survival rate is critically needed in relapsed and/or refractory NHL. Recent studies have shown that blinatumomab treatment and CAR-T cell-based immunotherapy appear to be promising treatment options for pediatric NHL patients [25,26].

Conclusion

In conclusion, the OS of children with NHL has significantly improved. More than 80% of children achieve long-term EFS with current treatments. In this study, we presented the clinical, demographic, and treatment results of the patients we followed for 10 years in a tertiary care center. Our results are comparable with the reports mentioned above. To better understand the biology and treatment of NHL, collaborative study is needed.

Declarations

Funding

This study had no external funding.

Conflicts Of Interest

The authors declare that they have no conflicts of interest.

Ethics Approval

This study was approved by the Ethical Committee for Acibadem University, with the assigned decision no: 2024-6/233 and date: 18.04.2024.

Availability Of Data And Material

Data are available from medical records.

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Measuring the Gamma Band Entropy Variance is a Novel Method to Compare the Efficacy of Neurofeedback in the Left Temporal Region and in the right Temporal Region for Dyslexia: Pilot Study

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ABSTRACT

Purpose: The smartphone application called Auto Train Brain aims to improve reading comprehension and speed for people with dyslexia through neurofeedback. Clinical trials have been conducted to examine the efficacy of neurofeedback on dyslexia. However, accurately measuring long-term outcomes with rapidly changing electroencephalogram (EEG) data can be challenging without the use of psychometric tests. To overcome this issue, a novel measurement method was developed using the sample entropy variance calculated in the gamma band to compare different sessions.

Methods: 40 children with dyslexia aged 7 to 10 consisted of the experimental group that was randomly assigned and they used Auto Train Brain for six months.

Results: Results of the study showed that after 100 sessions, the 14-channel neurofeedback with Auto Train Brain was more effective in increasing the gamma band entropy variance in the left temporal lobe (T7) compared to that of the right temporal lobe (T8).

Conclusion: Using the measurement of gamma band entropy variance was identified as a suitable approach to assess the success of neurofeedback.

TİTÇK (Nbr: 71146310-511.06,2.11.2018)

Keywords: Neurofeedback, entropy, learning disorders, dyslexia, EEG.

ÖZET

Amaç: Auto Train Brain adlı akıllı telefon uygulaması, disleksi olan kişilerin okuduğunu anlama ve okuma hızını nörogeribildirim yoluyla artırmayı amaçlamaktadır. Disleksi üzerindeki nörogeribildirim etkinliğini incelemek için klinik deneyler yapılmıştır. Ancak, hızla değişen elektroensefalogram (EEG) verileriyle uzun vadeli sonuçları doğru bir şekilde ölçmek, psikometrik testler kullanılmadan zor olabilir. Bu sorunu aşmak için, farklı seansları karşılaştırmak amacıyla gama bandında hesaplanan örnek entropi varyansı kullanılarak yeni bir ölçüm yöntemi geliştirilmiştir.

Metodlar: 7 ile 10 yaşları arasında disleksi olan 40 çocuk deney grubunu oluşturdu ve rastgele atanarak altı ay boyunca Auto Train Brain kullandılar.

Sonuçlar: Çalışmanın sonuçları, 100 seans sonrasında Auto Train Brain ile yapılan 14 kanallı nörogeribildirim, sol temporal lobdaki (T7) gama bandı entropi varyansını sağ temporal loba (T8) göre artırmada daha etkili olduğunu gösterdi.

Özet: Gama bandı entropi varyansının ölçülmesi, nörogeribildirim başarısını değerlendirmek için uygun bir yaklaşım olarak bulunmuştur.

TİTÇK (Nbr: 71146310-511.06,2.11.2018)

Anahtar Kelimeler: Nörogeribildirim, entropi, öğrenme bozuklukları, disleksi, EEG.

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Dyslexia is a subcategory of Specific learning disorders according to Diagnostic and Statistical Manual of Mental Disorders (DSM) V criteria (1). Some people struggle with reading, despite having Intelligence Quotients (IQs) that are normal or above average (2). Regarding the underlying cause of dyslexia, numerous theories have been proposed. The genetic origin of dyslexia is the most well-known of these explanations (3). Children who have dyslexia are more likely to have dyslexic parents (4). According to (5), dyslexia is distinguished by significant under activity in the reading network, disturbed functional connections, and variations in structural connections in specific fiber tracts.

Even if children with dyslexia receive the necessary supportive education and adequate nutrition, it takes a very long time to close the gap between their peers (6). Sometimes this difference cannot be closed during their lifetime. One or more parts of phonological processing are missing, such as the ability to consciously manipulate speech sounds (phonological awareness), to temporarily store phonological information in the working memory, and to quickly retrieve phonological representations from the long-term memory (6).

It is hypothesized that there is a disconnection syndrome in the left temporal lobe of dyslexia (7). The slow brain waves in the left temporal region are increased for dyslexia (8) and/or there may be general EEG slowing. Temporal lobes are important for brain maturation and functional connectivity, and this connectivity seems missing in dyslexia (9).

Dyslexia causes problems in understanding words, pronunciation, and syllables. Because of this, a child with dyslexia frequently struggles with language and verbal expression and is unable to distinguish between words based on their phonemes due to poor hearing and comprehension skills. These children are normal in other aspects or just a little smarter than average. They might be daydreamers dealing with low self-esteem, anxiety, and despair as a result of their academic struggles (10).

Studies have indicated that dyslexic children have slow brain waves at the left frontal, and do not exhibit beta-1 activity desynchronization while performing reading tasks in regions associated with the Angular gyrus, the Broca region, and the left parieto-occipital region have an important role in semantics and mathematics

comprehension (11), while the right temporal and parietal areas exhibit elevated sluggish activity (12,13). According to researchers, there is a disruption in the left temporal region (14). Furthermore, individuals with dyslexia and Attention-Deficit/Hyperactivity Disorder (ADHD) may experience high levels of frontal sluggish activity and increased coherence in the delta and theta bands symmetrically at temporal regions, while the alpha and beta bands show a distinct right-temporal central increase in coherence (13). Bi-hemispheric hyper-coherence (between T3 and T4) is observed in the delta and theta bands, whereas hypo-coherence in the delta, theta, and alpha bands is present between P7 and O1. Dyslexia is also associated with gamma band issues and less functional connections, with the left and right temporal lobes being the sources of healthy functional connections. (15,16).

Neurofeedback has been established as a technique that can improve the consequences of dyslexia by allowing the subject to gain more control over their brain through operant conditioning (17). This phenomenon has been shown to add weak connections that can help the subject pay attention and learn better when they learn to manage a specific brain area (18). The American Psychological Association (APA) recognizes neurofeedback as a “possibly efficacious” technique (19). While demonstrating the effectiveness of neurofeedback can be challenging, clinical studies have shown advancements in psychometric tests used before and after the investigation (20). Furthermore, several studies have shown that neurofeedback leads to improvements in brain structure, including improved functional connectivity of the sensorimotor resting state network and increased fractional anisotropy (FA) in the corpus callosum after one hour of Neurofeedback (NFB) training. The default mode network also showed increased functional connectivity (21). While functional Magnetic Resonance Imaging (fMRI) is typically used in these studies to display strongly linked brain regions following neurofeedback, it is challenging to demonstrate changes in the brain using Quantitative electroencephalography (QEEG). However, research has shown a causal relationship between neurofeedback and cognitive improvement (22-25).

Auto Train Brain contains modules of multi-channel neurofeedback, multimodal learning, and special education principles (26). It also contains dyslexia biomarker software which is built with Machine Learning (ML) methods.

In this research, we have compared the gamma band entropy variance in the temporal lobes during 14-channel neurofeedback for dyslexia with Auto Train. Due to the challenges of measuring long-term results with rapidly changing EEG data, a new measurement method was developed using the sample entropy variance in the gamma band.

Materials and Methods

A. Subjects

40 children with dyslexia (aged 7 to 10, 34 males, 6 females) participated in the experiments providing their written consent. They have used Auto Train 100 times to improve their reading abilities for 6 months.

The children in the experimental group were diagnosed with dyslexia by psychiatric professionals, who then recommended using Auto Train Brain. The Test of Integrated Language & Literacy Skills (TILLS) tests were used by psychologists and psychiatrists to examine whether the individuals met the DSM-V dyslexia criteria. The children chosen to participate in the experiment were chosen at random. The participant's primary goal in the retrospective study is to use Auto Train Brain software as a neurofeedback device at home.

The participants utilized Auto Train Brain before leaving for school in the morning. The study's inclusion requirements stipulated that participants must be of middle socioeconomic status, be drug-free, and have dyslexia as their only comorbid condition, and be aged between 7-10. They lived all around Turkey in various cities. A socioeconomic position survey was conducted among parents of children, wherein questions related to their employment, education (primary, secondary, and tertiary), and income were asked. The income categories were defined as follows: low income (< 6,000 TL), middle income (6,000 TL to 20,000 TL), and high income (> 20,000 TL). The participants' occupation was categorized into three groups: white-collar, blue-collar, and staff.

B. Qeeg Recording

The experiments utilized EMOTIV EPOC-X headsets to gather data from 14 channels: AF3, F3, F7, FC5, T7, P7, O1, O2, P8, T8, FC6, F8, F4, and AF4. The EEG data was captured at 2048 samples per second per channel, then downsampled to 128 samples per second per channel.

The raw EEG data was transformed to the frequency band using Fast Fourier Transform (FFT). A low pass filter (<100Hz) and high pass filter (4Hz) were used to eliminate noise. The frequency band was then classified into Theta (4-8 Hz), Alpha (8-12 Hz), Beta-1 (12-16 Hz), Beta-2 (16-25 Hz), and Gamma (25-45 Hz). Calibration was performed using EMOTIV LAUNCHER to ensure high-quality EEG data was collected from each electrode. The EMOTIV EPOC-X, a commercially available wearable EEG device, was utilized. It has 14 sensors, felt pads, and two rubber electrodes were placed in the mastoids following the International 10-20 system. The electrodes were connected to the scalp using saline liquid solution. The sampling frequency was 128 Hz.

C. Auto Train Brain Patented Neurofeedback Protocol

The Auto Train Brain mobile application uses the EMOTIV EPOC-X headset and employs principles of neurofeedback to improve brain performance in both children and adults. The system real-time online reads QEEG signals from 14 channels, processes them, and delivers real-time visual and auditory online neurofeedback. The unique protocol of multi-sensory learning and EEG neurofeedback aims to improve reading ability and cognitive functions. It reduces the theta waves in the Broca and Wernicke areas of the brain if they exceed the threshold, identifying channels with the highest absolute power of theta waves in each hemisphere, and reducing absolute theta for those channels. Feedback is provided through green and red arrows on the screen, and a "beep" sound to indicate positive and negative feedback, respectively. Auto Train Brain stands out from other neurofeedback systems because it combines neurofeedback with multi-sensory learning principles.

D. Study Design

Forty participants, aged between 7 and 10 years, utilized the Auto Train Brain mobile phone application for over 100 sessions. During each session, their brain waves were monitored using the EMOTIV EPOC-X headset for 14 channels and were given visual and auditory neurofeedback for 30 minutes. Following the neurofeedback session, the participants engaged in a 15-minute multi-sensory alphabet learning study.

With some assistance from their families at home, the participants completed the 30-minute neurofeedback sessions. Each participant utilized it while seated at a table at home throughout the neurofeedback session. As their parents are told to do in advance, there were 40 centimeters between the subject and the smartphone app. The participants used Auto Train Brain's arrow neurofeedback interface.

Upon completion of each session, the session average data for every frequency band was saved to the database. Additionally, sample entropy was computed for the data of each frequency band during the neurofeedback session. (12).

E. Variance of Sample Entropy for Gamma Band as the Measure

Sample entropy is a complexity measure used to evaluate physiological time-series signals and identify disease states. It is represented by $\text{SampEn}(m, r, N)$, which is the negative natural logarithm of the probability that two sets of simultaneous data points of length m and $m+1$ have distances less than a given tolerance r , given an embedding dimension of m and a number of data points of N .

Variance, on the other hand, is a dispersion measure that represents the expected value of the squared deviation of a random variable from its population or sample means. It reflects how far a set of numbers deviates from their average value.

For every session, the sample entropy of the gamma band frequency is computed and saved. The gamma band entropy variances is then calculated for a group of sessions. Although sample entropy is typically calculated based on EEG data series, we used QEEG data for our computations since we lacked access to the raw data from the EMOTIV EPOC-X. The feature set comprises 14 variables containing gamma band values mapped from the 14 channels of the EMOTIV EPOC-X. Finally, the sample entropy variance in the gamma band is measured for each group of activities.

F. Statistical Analysis

The statistical analysis was performed with SPSS 22. The regression analysis has been performed and R square values are reported. The increase in gamma band entropy variance (y-axis) in the left posterior region in the 100

sessions (x-axis, 1 bin= 10 sessions) was tested for the significance of the regression slope coefficient. It was checked whether our model is a significant predictor of the outcome variable using the results of ANOVA for regression (The change in the gamma band entropy variance(y-axis) in the left (T7) and right temporal(T8) regions versus session groups (x-axis)).

Results

A regression statistical method is applied to the two-dimensional data (session numbers versus the sample entropy variance). The findings suggest that long-term neurofeedback use increased the gamma band sample entropy variance.

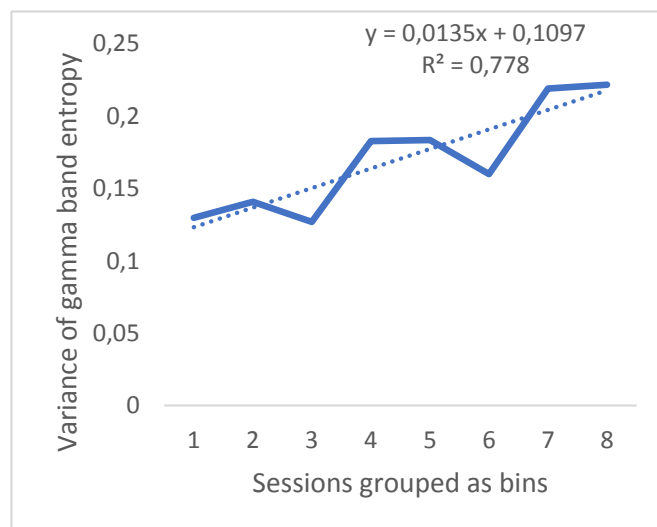


Figure 1: The increase in the gamma band entropy variance (y-axis) y in the left posterior region after 30 sessions (x-axis, 1 bin=10 sessions) for a 14-channel EEG headset

The 100 consecutive sessions have been merged into 10 bins. Next, we determined the variance of each bin's gamma band sample entropy. Ten bins were present. We have shown the sample entropy values' bin number vs variance. In both headsets' left posterior regions, the sample entropy variance in the gamma band rose over time (T7).

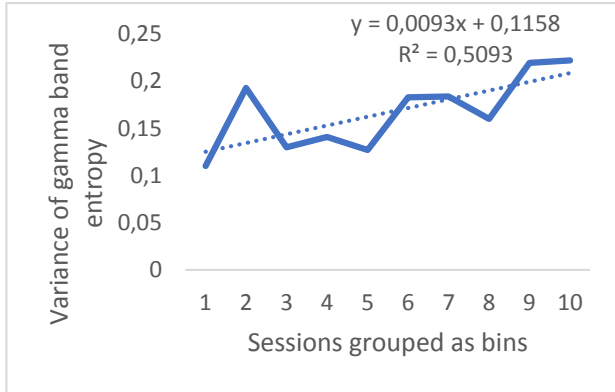


Figure 2: The change in the gamma band entropy variance (y-axis) in the left temporal region for a 14-channel EEG headset in the 100 sessions (x-axis, 1 bin= 10 sessions)

For a 14-channel EEG headset, the regression line yields $R^2=0.78$ when the first 30 sessions are excluded [$F_{(1,7)} = 15.38, p=.01$] (Figure I). R^2 for the regression line is 0.50 when the first 30 sessions are also included [$F_{(1,10)} = 8.97, p=.01$] (Figure II). In both instances, the linear regression lines' slopes were upward statistically significantly.

For a 14-channel headset, the gamma band entropy variance changes in the left temporal and the right temporal regions in the 100 sessions are plotted in Figure III.

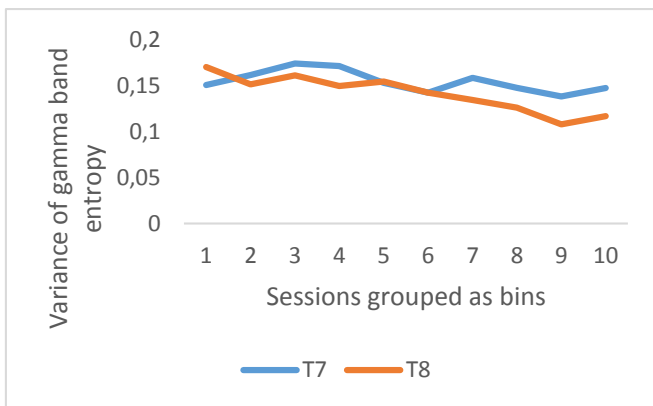


Figure 3: The change in the gamma band entropy variance (y-axis) in the left (T7) and right temporal(T8) regions for a 14-channel EEG headset in the next 100 sessions (x-axis, 1 bin=10 sessions)

Figure III shows that at around 20th sessions, the gamma band entropy variance becomes permanently dominant for the left temporal region after 60 sessions [$F_{(1,6)} = 20.79, p=.0038$]. Figure IV shows the user interface of Auto Train Brain.

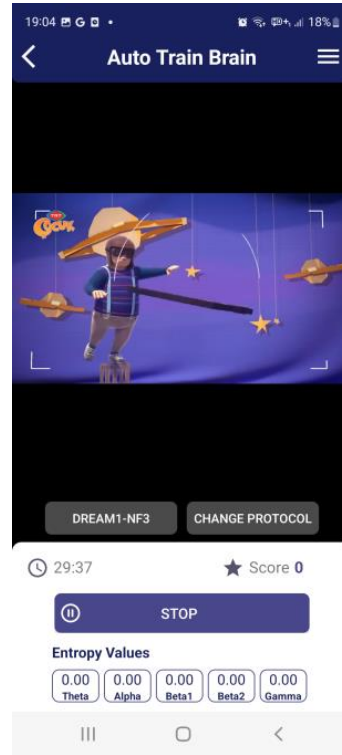


Figure 4: Auto Train Brain “youtube” interface

As the participant’s ages were 7-10 years old, the result is generalizable to 7-10-year-old children with dyslexia only.

Discussion

This research is unique in its approach to measuring the long-term outcomes of neurofeedback using a novel measurement method. While clinical trials have been conducted to examine the efficacy of neurofeedback on dyslexia, the use of the sample entropy variance calculated in the gamma band to compare different sessions is a unique approach. Additionally, the focus on the left temporal lobe (T7) compared to the right temporal lobe (T8) is a specific aspect that sets this research apart from previous studies.

In the first 20 sessions of use, 14-channel neurofeedback in the left posterior region causes a sharp increase in the sample entropy variance in the gamma band. The sample entropy variance in the gamma band is reduced after the 20 sessions for 14-channel neurofeedback with Auto Train Brain, and we assume that the functional networks prune and stabilize after some building and optimization. In the following sessions, there is an increase in the gamma band entropy variance. There are two further steps of pruning for both headsets in the remaining sessions. Moreover, the sample entropy variance in the left temporal lobe becomes dominant after 60 sessions of usage.

In a prior clinical study that assessed the efficacy of Auto Train Brain for children with dyslexia (26), pre- and post-TILLS test comparisons were conducted. The experimental group demonstrated a substantial increase in reading speed, from 38 to 65, following the 60-session clinical trial. Moreover, compared to the control group that received special education, the experimental group exhibited a statistically significant improvement ($p = .042$) in reading comprehension. Further posthoc tests indicated that the training with Auto Train Brain led to a noteworthy enhancement in reading comprehension (26).

According to Wu's research (27), neural stability plays a crucial role in supporting behavioral stability and reading automaticity. Nazari (28) administered neurofeedback to six dyslexic children and noted a normalization of coherence in the theta band at temporal, delta band at the frontocentral, and beta band at central electrodes, despite no significant changes in the power bands. Hypo coherence, indicating a disconnection syndrome, was observed. The author suggests that the significant improvement in reading ability and phonological awareness is attributable to the substantial changes in coherence, indicating the integration of sensory and motor domains. Coherence neurofeedback, as demonstrated by Coben (29), can raise reading scores by 1.2-grade levels for individuals with reading problems. fMRI has been utilized in the literature to show an increase in functional connectivity after neurofeedback (29). In order to assess the enhanced functional connectivity after coherence neurofeedback, it is necessary to compute the coherence and phase lag on the EEG. Nevertheless, performing real-time coherence calculations utilizing QEEG and EMOTIV headsets is difficult. Therefore, the gamma band entropy variance throughout the neurofeedback sessions is a suitable indicator of the changes in functional connectivity networks during the sessions.

This study has several limitations that need to be considered. Firstly, placebo effects could be a factor, where children receiving specialized interventions may exhibit improved functioning simply due to those interventions' social and environmental impact. Secondly, the experiment spanned over 6 months, which could introduce a maturation effect. Thirdly, the number of participants was limited, given that this was a pilot study, and further research with a larger cohort is warranted. Lastly, the absence of a control group is another limitation of the study.

For future research, we will investigate new calculation methods of coherence and functional connectivity based on QEEG and test our hypotheses with this calculation. The gamma band entropy variance over neurofeedback sessions presents promising results to explain electrophysiological changes and adaptations in the brain. Auto Train Brain has high efficacy in improving reading comprehension and reading speed beforehand. Now, with the new calculation method, we have investigated the electrophysiological changes in the left temporal region compared with the right temporal region after neurofeedback efficiently.

Conclusion

Accurately measuring long-term outcomes with rapidly changing electroencephalogram (EEG) data can be challenging without the use of psychometric tests. To overcome this issue, a novel measurement method was developed using the sample entropy variance calculated in the gamma band to compare different sessions. Using the measurement of gamma band entropy variance was identified as a suitable approach to assess the success of neurofeedback.

Declarations

Funding

None

Conflicts Of Interests

The author declares the following financial interests which may be considered as potential competing interests. Auto Train Brain has been developed at Sabanci University laboratories. This work has led to the formation of a company aimed to make Auto Train Brain available to users (www.autotrainbrain.com).

Ethical Approval

After the experimental procedure was explained to them following the guidelines established by the research ethics committee, all participants provided their informed consent. Yeditepe University Ethics Committee approved it, and the clinical trial was registered with the TITÇK (Nbr: 71146310-511.06,2.11.2018).

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Availability of Data and the Material

Upon a reasonable request, the datasets generated and/or analyzed during the current study will be provided by the corresponding author.

Authors Contributions

GE has written the whole manuscript by herself.

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Comparison of Anxiety Levels in Spontaneous Pregnancies and Assisted-Reproductive Techniques

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ABSTRACT

Purpose: Anxiety observed in the perinatal period can have adverse outcomes for the health of the mother and baby. The use of assisted reproductive techniques (ART) has been increasing in recent years for various reasons. In our study, we aimed to compare the anxiety levels of women, who had conceived spontaneously with women who had conceived by ART in these two groups.

Methods: 60 pregnant women in their pregnancy, who had applied to the pregnancy and in vitro fertilization (IVF) outpatient clinics, were divided into two groups as follows: those who became pregnant by ART and those who became pregnant spontaneously. The study employed the Beck Anxiety Inventory (BAI), the State and Trait Anxiety Inventory (STAI), and the Perinatal Anxiety Screening Scale (PASS) to assess and identify symptoms of anxiety.

Results: Among 60 pregnant women in the study, twenty-four (40%) conceived by ART, and 36 (60%) conceived spontaneously. When the groups were compared with regard to anxiety symptoms, the state anxiety levels of those who became pregnant via ART were significantly higher according to the STAI-S and PASS.

Conclusion: As a result, each population should present its own results, and in the event of increased anxiety, appropriate medical assistance should be provided.

Keywords: anxiety; assisted reproductive techniques; pregnancy; psychiatry

ÖZET

Amaç: Perinatal dönemde görülen anksiyete anne ve bebek sağlığı açısından olumsuz sonuçlar doğurabilmektedir. Yardımcı üreme tekniklerinin (ART) kullanımı son yıllarda çeşitli nedenlerden dolayı artmaktadır. Çalışmamızda bu iki grupta kendiliğinden gebe kalan kadınlar ile YÜT ile gebe kalan kadınların kaygı düzeylerini karşılaştırmayı amaçladık.

Yöntemler: Gebelik ve tüp bebek (IVF) polikliniğine başvuran, gebeliğindeki 60 gebe, YÜT ile gebe kalanlar ve kendiliğinden gebe kalanlar olmak üzere iki gruba ayrıldı. Çalışmada anksiyete semptomlarını değerlendirmek ve tanımlamak için Beck Anksiyete Envanteri (BAI), Durumluk ve Sürekli Kaygı Envanteri (STAI) ve Perinatal Anksiyete Tarama Ölçeği (PASS) kullanıldı.

Bulgular: Çalışmaya katılan 60 gebeden 24'ü (%40) YÜT ile, 36'sı (%60) spontan olarak gebe kaldı. Gruplar anksiyete belirtileri açısından karşılaştırıldığında, YÜT ile gebe kalanların durumluk kaygı düzeyleri STAI-S ve PASS'a göre anlamlı derecede yüksekti.

Sonuç: Sonuç olarak her popülasyon kendi sonuçlarını sunmalı ve kaygının artması durumunda uygun tıbbi yardım sağlanmalıdır.

Anahtar Kelimeler: anksiyete; yardımcı üreme teknikleri; gebelik; psikiyatri

In many societies today, particularly in industrialized societies, infertility has become an undeniable reality as a result of the postponement of marriage and fertility, changing eating habits, smoking, and alcohol consumption (1). With technological developments, the clinical use of assisted reproductive techniques (ART), particularly in-vitro fertilization (IVF), is increasing (2). Despite technological developments, the success of ART is still limited. In the UK, on average one quarter of couples undergoing ART cycles are successful (3). Cost, hormonal injections, physiological changes and medical interventions may cause stress in couples, especially women. If pregnancy occurs, increased prenatal risks may also cause anxiety (4).

Physiological, hormonal, and psychological changes during pregnancy, as well as environmental factors, and pregnancy complications, may cause anxiety in couples (5-7). The prevalence, and effects of anxiety symptoms in the perinatal period are increasingly emphasized (7). As supported by the literature, anxiety observed in the prenatal period has adverse effects on the mother and the baby. It has been reported that anxiety in the perinatal period can cause perinatal and postnatal problems such as low birth weight, preterm birth, and mental health problems in the child (8).

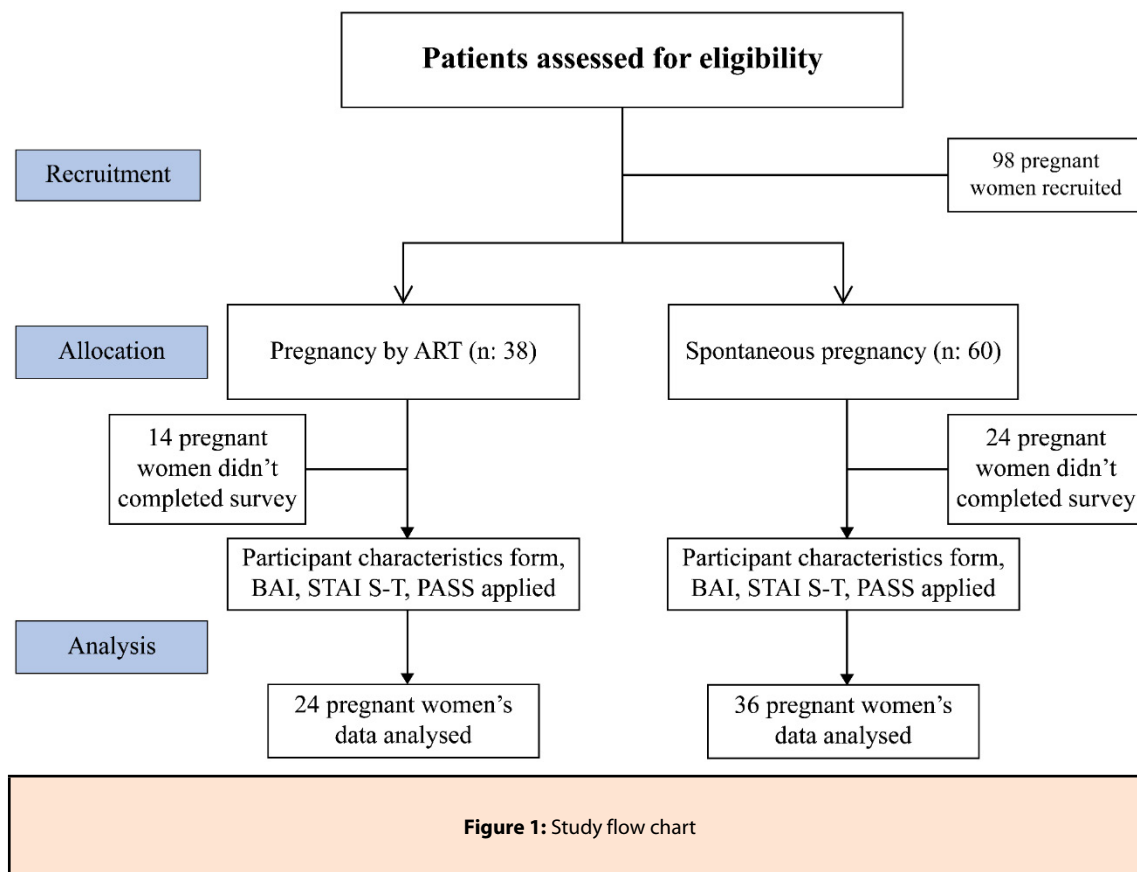
In the literature, contradictory findings were obtained regarding anxiety levels between women, who became pregnant via ART and those who became pregnant spontaneously. Although studies report that anxiety levels are higher in women, who become pregnant via ART than in women who conceive spontaneously (9, 10), there are also studies in which no difference was observed between the two groups (11). Emphasis is placed on the significance of identifying and addressing anxiety during the antenatal period, highlighting a clear need for research in this domain. In this study, we used various anxiety level assessment tests to compare the anxiety levels of pregnant women, who had received ART via IVF with those of pregnant women who had conceived naturally.

Material and Methods

The study included pregnant women, who applied to Acibadem Atakent Hospital Pregnancy and IVF outpatient clinics. Recruitment took place between March 20, 2023, and May 10, 2023. Pregnant women, who applied to the pregnancy outpatient clinic for antenatal care, met the inclusion criteria, and were between the 12th and 18th gestational weeks, were invited to participate in the study. Women with simultaneous spontaneous pregnancies and IVF pregnancies were invited to participate in the study. In total, 98 women's data (38 IVF, and 60 spontaneous) were obtained, but 14 IVF and 26 spontaneous pregnancies were excluded from the analysis due to incomplete data collection forms. Data from 24 IVF-pregnant women and 36 spontaneous-pregnant women were analyzed, for a total of 60 pregnant women.

All the pregnant women completed the questionnaire independently. An information form containing socio-demographic, clinical, and pregnancy-related features, which was prepared by the researchers in line with the purpose of the study, was filled in. Then, the Beck Anxiety Inventory (BAI), the State and Trait Anxiety Inventory (including State and Trait subscales) (STAI, STAI-S, STAI-T), and the Perinatal Anxiety Screening Scale (PASS) were used (Figure 1).

The study's inclusion criteria were set to include pregnant individuals seeking assistance from Acibadem Atakent Hospital IVF and Pregnancy outpatient clinics, having a singleton pregnancy, being fluent in Turkish, and having no fetal anomalies in the current pregnancy. Exclusion criteria involved illiteracy, severe psychiatric conditions like acute psychotic episodes, mental retardation, and dementia, hindering the ability to provide informed consent. The study received ethical approval from the Acibadem University Ethics Committee under application number 2019-9/9. Verbal informed consent was obtained from all subjects involved in the study. The study data collection was carried out approximately six months after ethics committee's approval.



Data Collection Forms

Participant characteristics form

The questionnaire used to determine the pregnant women's basic demographics was designed by the team before conducting the study. The form encompassed age, education level, infertility period, family income, and partner support.

The Beck Anxiety Inventory (BAI)

It is a Likert-type self-assessment scale consisting of 21 items in total and scored between 0-3. A high total score on the scale, designed to assess the severity of anxiety symptoms, indicates an elevated level of experienced anxiety. The validity and reliability study of the scale in Türkiye was performed by Ulusoy et al. (12). The State and Trait Anxiety Inventory (STAI)

A Likert-type scale consisting of 40 questions and two subscales, each containing 20 questions. While State Anxiety (STAI-S) expresses an individual's anxiety related

to a specific stressful situation, Trait Anxiety (STAI-T) indicates the individual's general anxiety level. High scores obtained from the scale indicate a high level of anxiety. The Turkish validity and reliability study of the scale was performed by Öner and Le Compte (13). The Cronbach's alpha value of the scale, validated by Öner and Le Compte, was .83 (13). In our study, the Cronbach's alpha value of the STAI-I was .072.

The Perinatal Anxiety Screening Scale (PASS)

The Likert-type scale developed to screen for anxiety symptoms in the perinatal period consists of 31 items. The Turkish validity and reliability study was performed by Yazıcı et al. (14). In our study, the Cronbach's Alpha coefficient of the scale was found to be 0.92.

Statistical Analysis

The SPSS 26.0 (IBM Corporation, Armonk, New York, United States) program was used to analyze the variables. Cronbach's Alpha coefficient was calculated for the consistency of the scales. The conformity of the data to the

normal distribution was evaluated using the Kolmogorov-Smirnov test. The Mann-Whitney U test was used together with the Monte Carlo results to compare two independent groups according to the quantitative variables. The Fisher Exact test was tested with the Monte Carlo Simulation technique in the comparison of groups according to the categorical variables. Spearman's Rho test was used to examine the correlations of the variables with each other. The Enter method was used in conjunction with the logistic regression test to determine the cause-effect relationship of the groups with the explanatory variables. Quantitative variables were expressed as mean (standard deviation) and median (IQR) (Inter-quartile Range) in the tables, while categorical variables were shown as n (%). The variables were analyzed at a 95% confidence level and a p-value of less than 0.05 was considered significant.

Results

The mean age of 60 pregnant women included in the study was 32.1 ± 4.3 . Twenty-four (40%) conceived by ART, and the rest (n: 36, 60.0%) were spontaneous pregnancies (planned n: 25, 41.7%; unplanned n: 11, 18.3%). The

majority of the patients had a university/masters-level education (n: 52, 86.7%) and had a moderate income (n: 49, 81.7%). Almost all (n: 58, 96.7%) were nuclear families. Ten women (16.7%) reported a chronic medical illness requiring treatment, while only one (1.7%, Generalized Anxiety Disorder (GAD)) reported receiving treatment for a psychiatric disorder. Although 7 (11.6%) participants did not disclose a diagnosis, FMF was the most common medical disease among patients, who disclosed their diagnosis (n: 2, 3.4%). Of the patients, 9 of them (15%) stated that they had previously received psychiatric treatment. Seven (11.6%) of them reported that they had received treatment for GAD. Most of the sample rated the support they had received from their spouses and peers as "good" (n: 51, 87.9% and n: 46, 79.3%, respectively). Participants, who conceived by ART, were pregnant at a median of 15 weeks (IQR: 13.3), and those, via spontaneous pregnancy, were at a median of 16.5 weeks (IQR: 21.0). There was no significant difference between the groups in terms of gestational times (Mann-Whitney U Test, Z: -0.18, p:0.86). The sociodemographic characteristics of the participants separated by pregnancy method are given in Table 1.

Table 1: Sociodemographic characteristics and anxiety symptoms according to the scales applied in women, who conceived spontaneously or by ART.

	Spontaneous	IVF	Impact value	P
	(n: 36)	(n: 24)		
	n (%)	n (%)		
Education			0.32 ^a	0.017 ^f
High school	8 (22.2%)	0 (0.0%)		
Bachelor's-Master's Degree	28 (77.8%)	24 (100.0%)		
Income level			-	0.173 ^f
Median	27 (75.0%)	22 (91.7%)		
High value	9 (25.0%)	2 (8.3%)		
Family structure			-	0.512 ^f
Core	34 (94.4%)	24 (100.0%)		
Large	2 (5.6%)	0 (0.0%)		
Medical diseases	3 (8.3%)	7 (29.2%)	-	0.073 ^f
Psychiatric disorders	1 (2.8%)	0 (0.0%)	-	0.999 ^f
Past psychiatric treatment	3 (8.3%)	6 (25.0%)	-	0.137 ^f
Mate support			-	0.999 ^f
Median	4 (11.1%)	3 (13.6%)		
High value	32 (88.9%)	19 (86.4%)		
Social environmental support			-	0.182 ^f
Median	10 (27.8%)	2 (9.1%)		
High value	26 (72.2%)	20 (90.9%)		
	Median (IQR)	Median (IQR)		
STAI-S	39.0 (5.3)	50.0 (13.0)	1.4 ^d	<0.001 ^u
STAI-T	45.0 (9.0)	49.0 (6.0)	-	0.490 ^u
PASS	31.5 (8.0)	21.0 (19.0)	0.7 ^d	0.010 ^u
BAI	9.0 (14.0)	17.0 (27.0)	-	0.210 ^u

^f Fisher Exact Test (Monte Carlo), ^u Mann Whitney U Test, ^d Cohen's d, ^a Phi, IQR: Inter-quartile Range

ART: assisted reproductive techniques; IVF: In vitro fertilization; STAI: State and Trait Anxiety Inventory; S: State; T: Trait; PASS: Perinatal Anxiety Screening Scale; BAI: Beck Anxiety Inventory

None of the women, who became pregnant with ART, were high school graduates and did not live with a large family. Only one (1.66%) of the mothers with spontaneous pregnancy reported a psychiatric disorder requiring treatment during evaluation. The groups' education, income level, family structure, social support, and medical/psychiatric diseases were similar. Most of the participants from the sample had their second (n: 32, 53.3%) or first (n: 26, 43.3%) pregnancies. The median number of pregnancies was found to be 2.0 (IQR: 1.0). Most of the participants (n: 42, 70%) had no children. Seventeen participants (28.3%) had one child, while one participant (1.7%) had two children. All patients, who had successful previous pregnancies, had had children via spontaneous pregnancies. Among the participants with spontaneous pregnancies (n: 36), preterm birth in previous pregnancies was reported in 8 (13.1%), abortion in 15 (24.6%), threatened abortion in 2 (3.3%), and induced abortion due to medical complication in 1 (1.6%). The deliveries were spontaneous in 1 (1.6%) of the participants and by caesarean section in 22 (36.1%) participants. In five (8.2%) cases, the baby had a history of inpatient treatment in the Paediatric Intensive Care Unit.

Sixteen participants (26.6%) stated that they breastfed their children for a median of 12 months after previous pregnancies (IQR: 0.0). Two of them (3.3%) reported that they had problems during breastfeeding. Ten (41.7%) of the patients, who had pregnancies via ART reported that they had previously unsuccessful pregnancies. Eight (33.3%) of these resulted in abortion, and two (8.3%) resulted in premature birth and infant loss. There was no significant difference between the groups regarding previous unsuccessful pregnancies (Chi-square (3): 4.9, p: 0.18, Likelihood Ratio). When the participants were evaluated with STAI-S, STAI-T, PASS, and BAI, it was found that the scores of these scales were not generally distributed between the groups (p:0.003, 0.006, 0.001, and 0.01; all Kolmogorov-Smirnov test). Cronbach's alpha was 0.92, 0.88, 0.90, and 0.95 for all sampled scales. Therefore, non-parametric tests were used for comparisons. Scale scores according to pregnancy types are given in Table 1.

As they observed the participants' perspectives, the state anxiety levels of those who became pregnant via ART were found to be high. Pregnancy-related anxieties were found to have a high productivity level in those who conceived spontaneously. For the entire sample, STAI-S scores correlated significantly with PASS (Rho: -0.57, p: 0.00) and BAI (Rho: 0.42, p: 0.04) scores. Controlling gestational age eliminated the association with BAI, but decreased the

association with PASS (Rho: -0.51, n: 0.01; all Spearman's Rho). For participants, who conceived spontaneously, STAI-S correlated significantly with PASS (Rho: -0.42, p: 0.01). However, the significance was not preserved by controlling the gestational age. When the correlations in the participant group, who became pregnant via ART were evaluated, STAI-S scores were found to be associated only with STAI-T scores (Rho: 0.50, p: 0.03). Controlling the gestational age eliminated this association and revealed a significant correlation with PASS scores (Rho: -0.68, p: 0.05).

When the cut-off point for clinically significant anxiety on the PASS was accepted as 16 points [14], 53 (88.3%) participants scored above this cut-off point, finally, logistic regression was applied to evaluate predictors of clinically significant PASS scores. As predictors, STAI-S, gestational age (weeks), pregnancy type (spontaneous vs. ART), complications in previous pregnancies, medical illnesses, and past psychiatric treatment were considered. Each predictor was entered in a separate step, and in the last step, all predictors were analyzed with the Enter method. Although the model was adequate (χ^2 : 2.1, dF: 7, p: 0.95, Nagelkerke R²: 0.41), none of the predictors, alone or in combination, was significant for a clinically significant PASS score (Table 2).

Table 2: Predictors of a PASS score above the cut-off point among ART and spontaneous pregnancy samples according to logistic regression analysis.

Predictor	Odds Ratio	95 % CI	p
Previous complications in pregnancy	0	0-	0.999
ART vs spontaneous pregnancy	35.80	0.3-4297.7	0.140
Medical disorder	0.10	0-	0.999
Past psychiatric disorder	0.00	0-	0.999
STAI-S	1.60	0.8- 3.2	0.210
Pregnancy period (week)	1.20	0.8- 1.6	0.420

Logistic Regression (Enter)

STAI-S: The State-Trait Inventory- Self; ART: assisted reproductive techniques; PASS: Perinatal Anxiety Screening Scale

Discussion

Every woman should spend the pregnancy period peacefully and comfortably. For a pregnant woman, this journey is filled with uncertainties, and as the pregnancy advances, curiosity may heighten, leading to increased anxiety (15). In the literature, there are many anxiety studies that utilize different scales related to pregnancy and the postpartum period (16, 17). In our study, we aimed to investigate the differences in anxiety levels during pregnancy between women, who spontaneously conceived and women, who conceived with ART and the variables that may be effective.

The importance of screening anxiety symptoms during pregnancy at least once with a standardized method with accepted validity has been emphasized (18). In studies on anxiety during pregnancy, scales commonly used in the general population were used (BAI, STAI) (12, 13). Recently, Somerville et al. developed the PASS, an anxiety screening scale specialized for this period, based on the importance of anxiety in the perinatal period (19). It has been reported that the PASS can detect anxiety in pregnant women at a rate that overlaps with clinical interviews (20). In our study, these three scales were used together to evaluate the level of anxiety in pregnant women.

Gourounti et al. reviewed studies between 2000 and 2014 examining the anxiety levels of women, who conceived spontaneously and of women, who conceived via ART (21). As a result, she discovered that women, who became pregnant following ART experienced increased pregnancy-specific anxiety, a lower quality of life, the same or fewer depressive symptoms, and the same level of self-confidence. In addition, it was found that prenatal attachment levels were higher. Oftedal et al. conducted a cohort study in Norway comparing 2,960 ART pregnancies with 108,183 spontaneous pregnancies (22). Accordingly, both females and males had lower levels of anxiety and depression in ART pregnancies compared to those in spontaneous pregnancies.

Since the PASS scale includes worries and fears about the baby and pregnancy and general questions about anxiety, it suggests the existence of primary concerns about the baby's health and the pregnancy process. As pregnancy progresses, anxiety may increase due to uncertainty, and studies show that anxiety decreases as the gestation period progresses (18). In our study, sociodemographic

and pregnancy-related variables that may predict perinatal anxiety were analyzed, and it was found that variables such as gestation period (weeks), complications in previous pregnancies, and medical diseases alone were insufficient to predict perinatal anxiety. When these variables were considered together, it was thought that they could be used as a model for determining perinatal anxiety. In our study, when the cut-off point for perinatal anxiety assessed by PASS was accepted as 16 points (14), it was found that most participants (88.3%) had high anxiety levels. This rate is generally higher than the literature, suggesting that the PASS is a sensitive tool in determining perinatal anxiety (23, 24). As stated in our study, perinatal anxiety levels determined by PASS were high in both groups. However, the pregnancy-related anxiety of the spontaneously pregnant participants was significantly higher than the other group. Since the PASS scale includes worries and fears about the baby and pregnancy and general questions about anxiety, it suggests the presence of primary concerns about the baby's health and the pregnancy process in this group. The literature has reported that some sociodemographic and pregnancy-related variables may be related to anxiety.

The study of Stevenson et al. was conducted with a smaller number of patients (25). STAI and PRAM questionnaires were administered to men and women in all trimesters. The study's results revealed that the anxiety levels of couples, who conceived through IVF and couples, who conceived naturally were comparable. Stress levels were also found to increase in men as the trimester progressed while decreasing in women. In our study, anxiety in men was not examined and a questionnaire was applied only once for pregnant women. Darwiche et al. also compared IVF/ICSI pregnancies with spontaneous pregnancies before first-trimester screening on a more limited number of pregnant women (26). A study using STAI and several different samples discovered that the group, who became pregnant with ART, had higher STAI scores. Our study found that the state anxiety scores determined by STAI-S were significantly higher in women, who conceived via ART (mean 50 points vs 39 points). The state anxiety score of those who conceived via ART was also significantly higher than those who conceived spontaneously.

In the literature, a history of psychiatric illness has been reported as a risk factor for anxiety (18), and in our study, only one pregnant woman had a history of psychiatric illness. Furthermore, the sociodemographic, clinical, and

pregnancy-related characteristics of the patients in our study allowed for the formation of comparable groups, facilitating a meaningful comparison between the two groups. The fact that most of the patients had bachelor's/master's degrees increased the likelihood of an adequate response. Although studies in the literature show that prenatal screening tests performed to evaluate fetal health increase anxiety (27, 28), the relationship of this variable with anxiety was not investigated in our study. If anxiety symptoms are detected in pregnant women, seeking help from psychiatry for detailed evaluation and follow-up is essential.

Limitations

The study's cross-sectional design, the fact that it was conducted in a single center, being exclusively for women and applied only once, and the small number of cases do not allow for generalization of the results.

Conclusions

When the literature is examined, anxiety assessments of women, who conceived via ART and women, who conceived spontaneously show different results with different tests. Accordingly, each population should evaluate its own results. If anxiety symptoms are detected in pregnant women, it would be appropriate to seek help from the psychiatry department.

Declarations

Funding

There is no funding.

Conflict of Interest

There is conflict of interest.

Ethic Approval

The study received ethical approval from the Acibadem University Ethics Committee under application number 2019-9/9.

Availability of data and material

All data available.

Author Contributions

Aygün EG: Original draft, formal analysis, writing. Agirbas Ozer U: Study design and protocol, data curation, writing. Sancak B: Study design and protocol, data curation

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Optimizing Lower Extremity Amputation Outcomes: The Impact of Multidisciplinary Consultations on Revision Rates in Non-Traumatic Lower Extremity Amputations

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ABSTRACT

Purpose: This study aims to identify factors leading to revision after non-traumatic lower extremity amputations and assess the accuracy of initial amputation levels based on multidisciplinary consultations (MDC).

Methods: This retrospective study included diabetic foot patients undergoing below-knee amputations. Two groups were formed: the revision group (35 patients from transtibial to transfemoral amputation) and the control group (35 without revisions). Gender, etiology, amputation levels, time to revision, follow-up, vascular status, and multidisciplinary consultations were analyzed. The MDC team included specialists from orthopedics, cardiovascular surgery, plastic surgery, and infectious diseases. Each patient's adherence to MDC recommendations was evaluated.

Results: The average follow-up time was 4.84 years. All amputations in the revision group were transtibial. In control group, 20% were transfemoral, and 80% transtibial. MDC recommended transfemoral amputation (TFA) to 80% and transtibial amputation (TTA) to 20% in the revision group, and TFA to 20% and TTA to 80% in control group. Overall, 60% adhered to MDC guidelines, while 40% didn't. All patients who deviated from MDC recommendations underwent revision. Among those adhering to recommendations, 83.3% didn't require revision, while 16.7% did, indicating a significant reduction in revision need with MDC adherence ($p < 0.0001$). Patients under 65 ($p = 0.0001$), males ($p = 0.028$), and those recommended transtibial amputations by MDC ($p = 0.036$) had longer revision-free intervals.

Conclusion: Non-compliance with MDC recommendations was strongly linked to revisions, while adherence significantly reduced the need for them. These findings emphasize the importance of following MDC recommendations to aid patients and their families in making informed decisions about initial amputation levels.

Level of Evidence: Level 3 (a retrospective cohort study)

Keywords: Amputation, diabetic foot, surgical revision, amputation stump, multidisciplinary recommendation

ÖZET

Amaç: Bu çalışma, travma dışı alt ekstremitte amputasyonları sonrası revizyon gerektiren faktörleri belirlemeyi ve multidisipliner konsültasyonlar (MDK) temelinde ilk amputasyon seviyelerinin doğruluğunu değerlendirmeyi amaçlamaktadır.

Gereç ve Yöntemler: Bu retrospektif çalışmada, diz altı amputasyon geçiren diyabetik ayak hastaları incelenmiştir. İki grup oluşturulmuştur: diz altından diz üstü amputasyona geçen 35 hastanın bulunduğu revizyon grubu ve revizyon gerektirmeyen 35 hastanın bulunduğu kontrol grubu. Cinsiyet, etiyoloji, amputasyon seviyeleri, revizyon süresi, takip süresi, vasküler durum ve MDK önerileri analiz edilmiştir. MDK ekibi, ortopedi, kalp ve damar cerrahisi, plastik cerrahi ve enfeksiyon hastalıkları uzmanlarından oluşmuştur. Her hastanın tedavisinde MDK seviye önerilerine uyum değerlendirilmiştir.

Bulgular: Ortalama takip süresi 4,84 yıl olarak belirlenmiştir. Revizyon grubundaki tüm amputasyonlar diz altı seviyede yapılmıştır. Kontrol grubunda ise hastaların %20'si diz üstü, %80'i diz altı amputasyon geçirmiştir. MDK, revizyon grubunda %80 oranında diz üstü amputasyon (TFA), %20 oranında diz altı amputasyon (TTA) önermiştir. Kontrol grubunda ise TFA %20, TTA %80 oranında önerilmiştir. Genel olarak, hastaların %60'ında MDK rehberliğine uyulurken, %40'ında uyulmamıştır. MDK önerilerine uyulmayan tüm hastalar revizyon geçirmiştir. MDK önerilerine uyulan hastaların %83,3'ü revizyon geçirmemiş, %16,7'si revizyon geçirmiştir, bu da MDK önerilerine uyumun revizyon ihtiyacını önemli ölçüde azalttığını göstermektedir ($p < 0,0001$). 65 yaş altındaki hastalar ($p = 0,0001$), erkek hastalar ($p = 0,028$) ve MDK tarafından TTA önerilen hastalar ($p = 0,036$) daha uzun revizyonsuz dönemlere sahip olmuştur.

Sonuç: MDK önerilerine uyumsuzluk, revizyonlarla güçlü bir şekilde ilişkilendirilmiş, uyum ise revizyon ihtiyacını önemli ölçüde azaltmıştır. Bu bulgular, hastaların ve ailelerinin önerilen amputasyon seviyeleri hakkında bilinçli kararlar almasına yardımcı olmak için MDK önerilerine uyumun önemini vurgulamaktadır.

Kant Düzeyi: Düzey 3 (retrospektif kohort çalışma)

Anahtar Kelimeler: Amputasyon, diyabetik ayak, cerrahi revizyon, amputasyon güdümü, multidisipliner iletişim

The diabetic foot represents a profoundly debilitating complication in patients afflicted with diabetes. Its pathophysiological basis comprises a confluence of factors, including neuropathy, vascular insufficiency, mechanical deformities in foot architecture, hyperglycemia, and susceptibility to infection (1). Individuals presenting with an acute diabetic foot in the emergency department often manifest hyperglycemia, sepsis, acute renal failure, and cardiac decompensation (2,3). To prevent septic shock and its complications, consequently, the decision for acute amputation is warranted.

Amputation surgeries serve not only as limb salvage procedures but also pose psychological challenges and impose financial burdens on healthcare systems due to potential long-term and recurrent hospitalizations. Despite progress in industry, technology, and medicine, amputation remains a significant contributor to disability (4). Losing a limb is becoming more common worldwide (5,6), and those who experience it often face various health challenges and comorbidities. To ensure the best possible care, it's crucial to assemble a diverse team of experts who can collaborate to meet the patient's needs effectively (7). This multidisciplinary team should start working with the patient early on, ideally before the amputation and continue after the surgery, to provide guidance, education, and support throughout the process of recovery and beyond (8). Despite advancements, revisions following lower extremity amputations remain prevalent. Re-amputation following major lower limb amputation is a frequent and severe complication (9). Infections, wound detachment due to uncontrolled metabolic status or nutrition level of the patients etc. might be the reasons for the amputation revision. The revision surgery hampers functional rehabilitation, prolongs hospital stays, and is linked to notable morbidity and mortality rates (10).

In our study, we hypothesize that multidisciplinary consultations (MDC) conducted prior to amputation surgeries lead to a decrease in the requirement for revision surgeries. Our study seeks to identify specific factors contributing to revision surgeries in non-traumatic lower extremity amputations and explore the relationship between these revisions and recommendations from multidisciplinary consultations. Thus, our objective is to assess the accuracy of the initial determination of the level of amputation.

Material and Methods

The study included patients from 2016 till 2021 in our clinic who underwent below knee amputations due to diabetic foot and consented to participate in the research. Patients who we cannot contact, who did not come to

regular examinations, who refused to participate, those who had undergone any minor or major surgical operation, such as skin grafting, on the lower extremity other than amputation following a diabetic foot wound, and patients who had undergone amputation for reasons unrelated to diabetes like traumatic amputations were excluded from the study. Our focus remained solely on major amputations necessitated by diabetic foot complications. In this study, two groups were determined, one of which was the revision group, and the other was the control group. Patients were evaluated retrospectively. A total of 70 patients meeting the inclusion criteria were included in our study. The revision group consisted of 35 patients who firstly underwent transtibial amputation and as a revision surgery transfemoral amputation and the control group of 35 patients who underwent either transtibial or transfemoral amputation. The control group did not encounter any revision procedures and was determined randomized. We evaluated patients' gender, etiology, amputation levels, the time interval between the first operation and revision, follow-up time, vascular status via computerized tomography or doppler ultrasound, and multidisciplinary consultation recommendations. The relationship between surgeon's amputation level and those factors were evaluated meticulously. The determination of amputation levels was carried out through a multidisciplinary approach involving evaluations from the departments of orthopedics, cardiovascular surgery, plastic surgery, and infectious diseases. For the decision of amputation, the patients were consulted the plastic surgery whether they decide to perform minor amputation. If they reject minor amputation decision, cardiovascular surgery was consulted for determining the level of amputation by analyzing the imaging modalities to determine the efficient vascular supply. As multidisciplinary consultations for major amputations, doctors for infectious diseases and internal medicine were included preoperatively for the proper antibiotic treatment and blood glucose regulation. We as orthopedists perform the amputation procedure. Physical therapy and rehabilitation doctors were consulted postoperatively for timely rehabilitation. Preoperative antibiotic prophylaxis was administered with 2 grams of cefazolin sodium before general anesthesia and maximum 1 hour before the surgery. 5 patients had cefazolin allergy, therefore 600mg clindamycin was used instead of it. Tourniquets were not used during surgery for all patients and surgical procedures commenced at the predetermined level of amputation, without deviation during the operation for all the patients. After the bone cut and removal of the amputate the myodesis procedure was implemented as part of the surgical protocol. Closure techniques varied depending on the level

of amputation. The fish-mouth technique was utilized for transfemoral amputations, while the posterior flap method was employed for transtibial cases. Skin closure was achieved using staples. Hemovac drainage was employed intraoperatively and subsequently removed either after 24 hours or once drainage decreased to less than 50 cc/day. Postoperative infectious disease consultations guided antibiotic therapy for each patient. Following surgery, hospitalized patients received continuous monitoring, while those discharged underwent weekly outpatient follow-ups for wound assessment during the initial three weeks postoperatively. Stitch removal was scheduled for the third week. General controls were conducted at the 6th, 12th weeks, and 6th, and 12th months postoperatively. Within the scope of the study, the number of samples was calculated with power analysis. As a result of the power analysis performed with G*Power (Version 3.1.9.6), the reliability was 95%, the effect level was 0.70 and the power value was 0.80. In this context, the minimum number of samples was calculated as 68. Accordingly, the study can be conducted by taking at least 34 samples from each group. In this study, IBM SPSS Statistics 24.0 software was used for analysis and statistical evaluation of the data. The following methods and tests were applied during statistical analysis: Descriptive Statistics: Frequency, percentage, mean (X), standard deviation (SD), minimum, maximum and median (M) values were calculated to present the demographic and clinical characteristics of the participants. The distributions of these variables are given through tables. Cross Tables and Chi-Square Test: Cross tables were created to examine the relationship between two categorical variables and the chi-square test was applied to determine whether the relationships were significant. Particularly in terms of amputation level, patient group and MDC level recommendation variables, the relationships with factors such as gender, age group and follow-up year were examined. Mann-Whitney U Test and Kruskal-Wallis Test: To compare the median differences between groups, the non-parametric Mann-Whitney U test (for two groups) and the Kruskal-Wallis test (for more than one group) were used to evaluate the differences between categorical variables and duration variables. With these tests, the time to revision and follow-up times were compared in terms of factors such as age group, gender, amputation level and group. Significance Level: In all analyses, $p < 0.05$ was accepted as the statistical significance level. With these analyses, it was evaluated whether there were differences between the groups according to the demographic and clinical characteristics of the participants in the study and statistical findings were presented.

Results

The demographic and clinical characteristics of the patients included in the study are comprehensively detailed in Table 1. The chi-square test yielded no statistical significance between the amputation level, revision/control group status, MDC recommendation and variables such as year, age group, and gender (detailed in Table 2). 100.0% ($n = 35$) of amputations in the revision group were transtibial. There is no amputation at the transfemoral level. Of the participants in the control group, 20.0% ($n = 7$) were at the transfemoral level and 80.0% ($n = 28$) were at the transtibial level. MDC recommended TFA to 80.0% ($n = 28$) and TTA to 20.0% ($n = 7$) of participants in the revision group. MDC recommended TFA to 20.0% ($n = 7$) and TTA to 80.0% ($n = 28$) of participants in the control group (Table 2).

Table 1: The demographic and clinical characteristics of the patients included in the study.							
		n	%	MIN	MAX	X	SD
Year	2016	6	8.6				
	2017	16	22.9				
	2018	24	34.3				
	2019	14	20.0				
	2020	5	7.1				
	2021	5	7.1				
Age				40	96	64.84	13.12
Age groups	<65	36	51.4				
	>65	34	48.6				
Gender	Male	44	62.9				
	Female	26	37.1				
Level of amputation	TFA	7	10.0				
	TTA	63	90.0				
Group	Revision	35	50.0				
	Control	35	50.0				
Etiology of amputation	Diabetes	70	100.0				
Time till revision in months				1	15	6.11	4.15
Follow-up time				2	7	4.84	1.30
MDC recommendation	TFA	35	50.0				
	TTA	35	50.0				
TFA= transfemoral, TTA= transtibial, MDC= multidisciplinary consultation, X= mean value, SD= standard deviation, MIN= minimum, MAX= maximum							

Table 2: The relationships between the amputation level, the group (revision or control), the MDC recommendations (for amputation levels TFA or TTA) variables and year, age group, and gender.

	LEVEL OF AMPUTATION				p value of chi-square test	AMPUTATION GROUP				p value of chi-square test	MDC RECOMMENDATION				p value of chi-square test	
	TFA		TTA			REVISION		CONTROL			TFA		TTA			
	n	%	n	%		n	%	n	%		n	%	n	%		
Year	2016	2	33.3	4	66.7	1.000	3	50.0	3	50.0	1.000	5	83.3	1	16.7	0.195
	2017	0	0.0	16	100.0		8	50.0	8	50.0		7	43.8	9	56.3	
	2018	3	12.5	21	87.5		12	50.0	12	50.0		13	54.2	11	45.8	
	2019	0	0.0	14	100.0		7	50.0	7	50.0		4	28.6	10	71.4	
	2020	1	20.0	4	80.0		3	60.0	2	40.0		4	80.0	1	20.0	
	2021	1	20.0	4	80.0		2	40.0	3	60.0		2	40.0	3	60.0	
Age groups	<65	3	8.3	33	91.7	0.467	19	52.8	17	47.2	0.632	17	47.2	19	52.8	0.632
	>65	4	11.8	30	88.2		16	47.1	18	52.9		18	52.9	16	47.1	
Gender	Male	4	9.1	40	90.9	0.521	21	47.7	23	52.3	0.621	19	43.2	25	56.8	0.138
	Female	3	11.5	23	88.5		14	53.8	12	46.2		16	61.5	10	38.5	

TFA= transfemoral, TTA= transtibial, MDC= multidisciplinary consultation

As a result of the Kruskal-Wallis test, no significant difference was found between years in terms of time to revision ($p = 0.488$). The Mann-Whitney test revealed a significant difference in time until revision between age groups (<65 vs. ≥ 65) ($p = 0.0001$), indicating that patients under 65 experienced longer periods (8.37 vs. 3.44 years) without revision. The average time until revision for male participants was 7.24 months ($SD = 4.06$, $M = 8$), whereas for female participants, it was 4.43 months ($SD = 3.82$, $M = 3$) on average. Additionally, a statistically significant difference was found between men and women in terms of time until revision ($p = 0.028$), with male participants showing longer durations without revision. Among patients who underwent TTA in the revision group, the average time to revision was calculated as 6.11 months ($SD = 4.15$, $M = 5$). The average time until revision was 5.39 months (SD

$= 4.15$, $M = 4$) for patients recommended TFA by MDC, and 9.00 months ($SD = 2.83$, $M = 9$) for those recommended TTA. A significant difference was found between TFA and TTA recommendations in time until revision ($p = 0.036$), indicating longer periods without revision for TTA-recommended patients. The average follow-up period for participants under 65 was 4.86 years ($SD = 1.13$, $M = 5$), and for those aged 65 and over, it was 4.82 years ($SD = 1.49$, $M = 5$). No statistically significant difference in follow-up time between age groups was found ($p = 0.875$), suggesting similar follow-up durations. Moreover, there were no statistically significant differences in follow-up period among age groups, genders, types of amputations, groups, and MDC level recommendations ($p > 0.05$) (details and exact p values in Table 3), indicating similarity in follow-up duration across these factors.

Table 3: The results of Mann-Whitney and Kruskal-Wallis tests comparing the variables Year, age groups, gender, amputation level, group (revision or control), and MDC recommendation with time till revision in months, and follow-up time in years.

		TIME TILL REVISION IN MONTHS			p value	FOLLOW-UP TIME IN YEARS			p value
		X	SD	M		X	SD	M	
YEAR	2016	4.33	1.53	4	0.488	7.00	0.00	7	0.0001
	2017	4.50	4.69	2		6.00	0.00	6	
	2018	5.83	3.74	5		5.00	0.00	5	
	2019	8.14	4.22	9		4.00	0.00	4	
	2020	7.33	4.73	9		3.00	0.00	3	
	2021	8.00	7.07	8		2.00	0.00	2	
AGE GROUPS	<65	8.37	3.71	9	0.0001	4.86	1.13	5	0.875
	>65	3.44	2.90	3		4.82	1.49	5	
GENDER	Male	7.24	4.06	8	0.028	4.77	1.08	5	0.334
	Female	4.43	3.82	3		4.96	1.64	5	
AMPUTATION LEVEL	TFA	-	-	-	-	4.86	1.86	5	0.888
	TTA	6.11	4.15	5		4.84	1.25	5	
GROUP	Revision	6.11	4.15	5	-	4.86	1.29	5	0.976
	Control	-	-	-		4.83	1.34	5	
MDC RECOMMENDATION	TFA	5.39	4.15	4	0.036	4.97	1.38	5	0.376
	TTA	9.00	2.83	9		4.71	1.23	5	

TFA= transfemoral, TTA= transtibial, MDC= multidisciplinary consultation, X= mean, SD= standard deviation, M= median

In the revision group, 80% (n = 28) of patients who underwent TTA were recommended TFA by the MDC, while 20% (n = 7) received a TTA recommendation. This discrepancy indicates that the majority (80%) of the patients needing revision were initially operated on at a lower level than recommended. Of the total sample, 60.0% (n = 42) underwent surgery aligning with MDC guidelines, while 40.0% (n = 28) underwent procedures deviating from the recommended level. Notably, revision was required for 50.0% (n = 35) of participants, indicating a significant occurrence rate (Table 4). All patients (n = 28, 100%) not adhering to MDC recommendations underwent revision, highlighting a strong association between non-compliance with the

MDC recommendation and revision necessity. Conversely, among those adhering to recommendations, 83.3% (n = 35) did not require revision, while only 16.7% (n = 7) required it, showcasing a significant decrease in revision need when adhering to the MDC recommendation. The obtained p-value (<0.0001) from the statistical test signifies an exceptionally high level of significance, emphasizing the relationship between compliance with the MDC recommendation and revision necessity (Table 5). These results advocate for strict adherence to MDC recommendations to reduce revision need and postoperative complications.

Table 4: The Distributions of Multidisciplinary Consultation Recommendations by Amputation Level in Revision and Control Groups.

		AMPUTATION LEVEL IN REVISION GROUP				AMPUTATION LEVEL IN CONTROL GROUP			
		TFA		TTA		TFA		TTA	
		n	%	n	%	n	%	n	%
MULTIDISCIPLINARY CONSULTATION RECOMMENDATION	TFA	0	0.0	28	80.0	7	100.0	0	0.0
	TTA	0	0.0	7	20.0	0	0.0	28	100.0

TFA= transfemoral, TTA= transtibial

Table 5: The relationship between adherence to MDC recommendations and whether a revision was performed, along with the statistical significance of this relationship.

		ADHERENCE TO MDC RECOMMENDATION				p value
		NO		YES		
		n	%	n	%	
REVISION PERFORMED	NO	0	0.0	35	83.3	<0.0001
	YES	28	100.0	7	16.7	

MDC= multidisciplinary consultation

Discussion

In this study, we examined whether multidisciplinary consultations conducted prior to amputation surgeries lead to a decrease in the requirement for revision surgeries. Non-compliance with MDC recommendations was strongly associated with revision necessity, while adherence significantly reduced the need for revision. Moreover, patients under the age of 65 and male patients remained without revision for longer periods of time. Besides, patients for whom MDC recommended a TTA remained without revision for longer than those for whom TFA was recommended. These results highlight the importance of following MDC recommendations to determine appropriate amputation levels and reduce postoperative complications.

In 2005, 1.6 million Americans lived with limb loss, largely due to dysvascular disease and diabetes. By 2050, this number is expected to double to 3.6 million. Reducing dysvascular disease rates by 10% could lower this estimate by 225,000. These findings stress the importance of addressing limb loss and its causes to curb the projected increase in affected individuals (6). Globally, approximately 131 million people have diabetes-related lower-extremity

complications, leading to diabetic foot ulcers and lower extremity amputations (LEA) (11). Around 6.8 million amputations, comprising 61% to 69%, were LEAs. Diabetic patients face a significantly higher risk of LEAs—up to 39 times more than non-diabetic patients—and have a higher mortality rate within five years post-amputation, ranging from 40% to 79% according to the study by Tuglo in 2022 (11). Re-amputation, a frequent and severe complication following major lower limb amputation (9), significantly impedes functional recovery, often prolongs hospital stays, and is linked to substantial morbidity and mortality (10). Many authors emphasize notable re-amputation rates following transmetatarsal and transtibial amputations, with diabetes identified as a critical risk factor for unsuccessful healing specifically at the transmetatarsal level (9,12,13). A multidisciplinary team approach to patients with acute diabetic foot is essential and has been demonstrated to lower the amputation rate by Cahn et al. (1). A retrospective study by Huizing et al. (14) revealed that a dedicated multidisciplinary team for diabetic foot care significantly improved limb salvage and ulcer healing rates. In managing diabetic foot ulcerations, teams consistently addressed glycemic control, local wound management, vascular disease, and infection promptly

and cohesively to mitigate the occurrence of major amputations (15). Although a multidisciplinary team was intended to decrease the LEAs rate due to the diabetic foot, if LEA is still required, MDCs have to be conducted prior to surgery to exactly determine the level of the LEA. So, a multidisciplinary team approach is an obligation both prior to the surgery to prevent it (16) and for preparation and aftercare of the surgery. Keszler et al. stated continuous lifelong care to be essential to monitor for complications arising from comorbidities or the emergence of secondary disabling conditions, aiming to improve the overall quality of life (5). Lepaentalo et al. emphasized the importance of cardiovascular surgeons consultation, who possess expertise in various revascularization methods, prior to the amputation decision to enhance leg salvage rates in diabetic patients with foot lesions (17). Poehler et al. developed a multiple criteria decision analysis tool to understand patient preferences for amputation-level selection and compare them with healthcare providers' perceptions of these preferences (18). They suggested that shared decision making process shall be improved with patient priorities and provider perceptions of them to reach the optimal, and patient-centered amputation results (19). In the decision-making process regarding amputation for diabetic foot complications, families also play a significant role by providing emotional support and evaluating the financial implications. They participate in seeking multiple opinions and considering the impact on the family's well-being before patients ultimately decide to undergo amputation (20). In our study, the determination of amputation levels and pre- and postamputation care involved a multidisciplinary approach consistent with the literature, with input from orthopedics, cardiovascular surgery, plastic surgery, and infectious diseases departments. Patients were consulted by plastic surgery for minor amputation decisions; if rejected, cardiovascular surgery analyzed imaging modalities to determine the appropriate amputation level based on vascular supply. For major amputations, infectious diseases and internal medicine doctors were consulted preoperatively for antibiotic treatment and blood glucose regulation, while we performed the procedure. Postoperatively, physical therapy and rehabilitation doctors were involved for timely rehabilitation. Although we recommended patients' families the MDC results, 28 of them rejected the recommended level and gave informed consent for lower levels. All patients not following MDC recommendations underwent revision, while among those adhering, 35 (83.3%) did not require revision, highlighting the significant decrease in revision need with MDC recommendation adherence.

Conclusion

In conclusion, the present study examined the impact of multidisciplinary consultations on the necessity for revision surgeries following amputation procedures. Our findings underscore a robust association between non-compliance with multidisciplinary consultation (MDC) recommendations and the need for revisions, while adherence to MDC guidelines significantly reduces the likelihood of revisions. These results emphasize the critical importance of adhering to MDC recommendations in determining appropriate amputation levels and mitigating postoperative complications. Furthermore, our study suggests that younger patients and male patients generally experience longer durations without requiring revision surgeries after amputation procedures. Additionally, patients recommended transtibial amputations through multidisciplinary consultations tend to have extended revision-free periods compared to those recommended transfemoral amputations. These findings are expected to inform patients and their families regarding the importance of following MDC-recommended levels, facilitating informed consent for higher amputation levels as the initial surgery, thus potentially reducing financial burdens associated with revision rates. One notable limitation of our study is its retrospective design, which inherently restricts our ability to control for all potential confounding factors. Moreover, this retrospective study contributes to the literature by prompting future research into prospective studies in this domain. Notably, existing literature primarily focuses on multidisciplinary teams' roles in preventing amputations or providing post-amputation care, rather than specifically addressing amputation level determination. Future research should explore prospective cohort studies or randomized controlled trials to validate our findings, particularly focusing on the long-term benefits of adhering to MDC recommendations in diverse populations. Additionally, investigating the specific barriers to adherence, including patient and provider perspectives, could provide valuable insights for improving compliance rates and patient outcomes.

Declarations

Funding

NONE

Conflicts of Interest/Competing Interests

The authors declare that they have no conflicts of interest.

Ethics Approval

This study was approved by the ISTANBUL UNIVERSITY-CERRAHPAŞA RECTORATE Clinical Research Ethics Committee with the number E-83045809-604.01-1016540.

Availability of Data and Material

The data that support the findings of this study are available from the corresponding author, C.D.D. upon reasonable request.

Authors' Contributions

C.D.D. contributed to the conception and design of the study, data collection, data analysis, manuscript drafting and critical revision of the manuscript.

M.Y.A. contributed to the conception and design of the study, data collection, data analysis, manuscript drafting and critical revision of the manuscript.

All authors read and approved the final manuscript.

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Outcome of Displaced Proximal Humerus Fractures Treated Surgically by Locking Plate- a Retrospective Case-Series Study

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ABSTRACT

Objectives: To evaluate functional outcomes, radiographic findings and complications of displaced proximal humerus fractures (PHFs) treated surgically by osteosynthesis with locking plate (OLP), to determine unpredictable results after surgery and to suggest essential surgical tips and tricks.

Methods: Twenty-five patients were evaluated retrospectively. Constant shoulder score, ASES shoulder score and range of motion (ROM) were used to evaluate clinical outcome. Preoperative and final follow-up radiographs were used and humeral neck-shaft inclination angle described by Boileau and avascular necrosis (AVN) of the humeral head evaluated by Cruess classification were recorded to judge radiological outcome.

Results: Patients were 58(28-92) years old. The median Constant and ASES scores were 80(60-89) and 80(60-95) respectively. Neck-shaft inclination angle was 135(120-144) degrees at the final follow-up. 11 patients (44%) had complications. Major complications were AVN and varus malunion and both had a rate of 12% individually. Technical errors during surgery, mainly placing the plate high and screw-related complications, had adverse effect on AVN and varus malunion. Functional scores were not affected significantly by age, gender, AO and Neer fracture types and concomitant injuries. The clinical outcome has significantly become worse if varus malunion and/or AVN proceeded. Revision rate was 20% and its leading cause was AVN.

Conclusion: Age, gender, fracture type and additional fracture elsewhere did not affect clinical outcome significantly. OLP for PHFs had favorable radiological and clinical outcomes unless varus malunion and/or AVN of the humeral head proceeded postoperatively. To avoid the complication of screw cutout and varus; only the cortical bone and 2cm further were drilled and spongios bone allograft was used in case of comminution in the metaphysis and "strut" bone allograft was used in case of non-integrity in the medial metaphysis

Keywords: proximal humeral fracture; bone plate; orthopedic procedures; outcome assessment

ÖZET

Amaç: Kilitli plak ile osteosentez (OLP) ile cerrahi olarak tedavi edilen deplase proksimal humerus kırıklarının (PHF) fonksiyonel sonuçlarını, radyografik bulgularını ve komplikasyonlarını değerlendirmek, cerrahi sonrası öngörülemeyen sonuçları belirlemek ve temel cerrahi ipuçları ve püf noktaları önermek.

Yöntemler: Yirmi beş hasta retrospektif olarak değerlendirildi. Klinik sonuçları değerlendirmek için Constant omuz skoru, ASES omuz skoru ve eklem hareket açıklığı (EHA) kullanıldı. Ameliyat öncesi ve son takip radyografileri kullanıldı ve radyolojik sonucu değerlendirmek için Boileau tarafından tanımlanan humerus boyun-şaft eğim açısı ve Cruess sınıflamasına göre değerlendirilen humerus başı avasküler nekrozu (AVN) kaydedildi.

Bulgular: Hastalar 58(28-92) yaş arasındaydı. Ortanca Constant ve ASES skorları sırasıyla 80(60-89) ve 80(60-95) idi. Son takipte boyun-şaft inklinasyon açısı 135(120-144) derece idi. 11 hastada (%44) komplikasyon görüldü. Başlıca komplikasyonlar AVN ve varus malunionu idi ve her ikisi de ayrı ayrı %12'lik bir orana sahipti. Başta pate'in yükseğe yerleştirilmesi ve vidaya bağlı komplikasyonlar olmak üzere ameliyat sırasındaki teknik hatalar AVN ve varus malunionu olumsuz etkiledi. Fonksiyonel skorlar yaş, cinsiyet, AO ve Neer kırık tipleri ve eşlik eden yaralanmalardan önemli ölçüde etkilenmemiştir. Varus malunion ve/veya AVN ilerlediğinde klinik sonuç anlamlı derecede kötüleşmiştir. Revizyon oranı %20 idi ve bunun önde gelen nedeni AVN idi.

Sonuç: Yaş, cinsiyet, kırık tipi ve başka bir yerdeki ek kırık klinik sonuçları anlamlı olarak etkilememiştir. Ameliyat sonrası humerus başında varus malunionu ve/veya AVN gelişmediği sürece, PHF'ler için OLP olumlu radyolojik ve klinik sonuçlara sahipti. Vida kesilmesi ve varus komplikasyonundan kaçınmak için; sadece kortikal kemik ve 2 cm daha fazla delindi ve metafizde komünite durumunda spongios kemik allogrefti ve medial metafizde bütünlük olmaması durumunda "strut" kemik allogrefti kullanıldı.

Anahtar Kelimeler: proksimal humerus kırığı; kemik plağı; ortopedik prosedürler; sonuç değerlendirmesi

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Surgical treatment options for proximal humerus fractures (PHFs) can be separated basically into two groups; osteosynthesis and arthroplasty. Although arthroplasty has become popular nowadays by the new designs- namely reverse shoulder arthroplasty- especially in the elderly people, osteosynthesis with locking plate (OLP) is still a reliable option for treating these fractures. Both treatment modalities are fraught with complications; on the OLP site, the major ones being varus malunion, avascular necrosis (AVN), technical errors in surgery or late implant-related complications.^[1,2]

Varus malunion is attributed to osteoporotic bone and/or medial cortex comminution.^[1] Intramedullary cortical bone support^[3], medial calcar screws driven through the plate^[4], cement augmentation of humeral head screws^[5], double plating^[6] are defined to get rid of this complication. On the other hand, technical errors and/or AVN can lead to this complication as well and these major complications can happen in a vicious circle.

AVN of the humeral head in traumatic cases is related to the type of the fracture and type and timing of the surgery. Neer type 4 fractures and fracture-dislocations, open reduction and internal fixation and surgery performed after 48 hours are reported as risk factors.^[1,7]

Locking plates are preferred to conventional plates for the osteosynthesis of proximal humeral fractures because of less mechanical complications which was reported as 11% and 50% respectively.^[2] These mechanical complications are usually screw-related, namely screw perforation, screw cut-out, screw loosening, screw pull-out.^[2] Screw-related complications can be lowered by respect of technical tips and tricks while performing locking plates.

Thus, the purpose of this study is to evaluate functional outcomes, radiographic findings and complications of proximal humerus fractures (PHFs) treated surgically by osteosynthesis with locking plate (OLP) to determine unpredictable results after surgery and to suggest essential surgical tips and tricks. The hypothesis is that OLP has favorable results in PHF if surgical tips and tricks are performed and major complications are avoided.

Materials and Methods

The study retrospectively evaluated 25 patients who underwent OLP surgical treatment for PHFs between 2005 and 2011 at our clinic. Institutional Review Board (IRB) (E-62977267-771-209014806) was obtained from the ethics committee of Haydarpasa Numune training and research hospital before starting the study. All the surgeries were performed by a single surgeon who is specialized in shoulder surgery. The indication for surgery was based on Neer criteria^[8], namely angulation of the humeral head greater than 45 degrees and displacement of the fragments greater than 1 cm. The exclusion criteria were the cases under bone-maturity, minimal displaced fractures according to Neer classification, open fractures, pathologic fractures and isolated fractures of the humeral tubercles. The preoperative radiological examination consisted of true anteroposterior (AP) and axillary X-Ray and computerized tomography (CT) and 3-dimensional CT of the shoulder. Neer and AO classification were used for fracture classification.^[9] The patients were evaluated radiologically and clinically in the postoperative final follow-up. The criteria for radiological assessment were malunion which was depicted by the neck-shaft inclination angle defined by Boileau^[10] and avascular necrosis which was evaluated by Cruess classification^[11]. Boileau proposed that if inclination angle is <120 degree, it is a varus malunion; if the inclination angle is >150 degree, it is a valgus malunion. Cruess classification delineates AVN stages as Stage 1: normal on the X-Ray, changes on magnetic resonance imaging (MRI), Stage 2: sclerotic changes in the humeral head where the sphericity of the humeral head is preserved, Stage 3: subchondral collapse or the sphericity of the humeral head is distorted, Stage 4: chondral collapse and osteochondritis dissecans, Stage 5: osteoarthritic changes in the glenoid fossa. Constant and ASES shoulder scores calculated at the final follow-up were used and ROM at the final follow-up was measured for clinical assessment.^[12,13]

Surgical Technique

The patients were positioned in beach chair position under general anesthesia. Anterior approach was performed. Cephalic vein was found and protected and the fracture site was exposed through the deltopectoral interval. If the fracture was a Neer 2-part fracture, it was directly accessed. If the fracture was a Neer 3-part or a 4-part

fracture or a fracture-dislocation, deltopectoral fascia was opened, long head of biceps tendon was found and suspended by a penrose drain. By opening the rotator interval, one can not only access the fractured tubercles but also by opening the tubercles as a book page expose the humeral head as well. Humeral head was reduced to anatomical position and was temporarily fixed with Kirschner (K) wires. The tubercles were reduced thereafter. Before the plate placement, two no2 vicryl sutures were passed through the upper holes of the plate and two through the holes prepared on the distal shaft of the humerus. The plate was placed just lateral to the long head of biceps tendon and approximately 1 cm below to the humeral head. The plate was stabilized proximally by K wires placed into the holes at the top of the plate. It was also fixed distally to the shaft of the humerus by a screw placed through the oval hole of the plate. Intra-operative imaging was used by taking 3 shots, namely true AP, AP in external rotation and AP in internal rotation, to determine that the plate and the screws were placed in appropriate height and length respectively. In order to prevent screw cut-out only the cortical bone and 2cm further were drilled and the gauge to measure the length of the screw was advanced till its advancement was blocked by the hard subchondral bone. The last distal screw of the proximal part of the plate was always used keenly in a fashion to support the inferomedial part of the humeral head to prevent further varus malalignment. no2 vicryl sutures which were formerly placed through the upper holes of the plate were passed into the tubercles, first through the bone and then through the rotator cuff in an over-and-over fashion and the tubercles were closed and stabilized by these sutures. The two no2 vicryl sutures coming from the distal shaft were passed through the tubercles one by one and tied to fix the tubercles to the shaft of the humerus. Spongios bone allograft was used in case of comminution in the metaphysis and "strut" bone allograft was used in case of non-integrity in the medial metaphysis.

Postoperative Management

All the patients used a sling for the first 3 weeks postoperatively. Shoulder pendulum exercises, full active ROM exercises of the elbow and grip exercises of the hand were begun in this period. After 3 weeks postoperatively, patients stopped using the sling and active assistive forward flexion and abduction exercises of the shoulder

were started, but shoulder rotation was not allowed. After 6 weeks postoperatively all active ROM exercises including rotation were allowed. Weight lifting was inhibited till 12 weeks postoperatively. The patients were evaluated clinically and radiologically in 3-week, 6-week, 3-month, 6-month, 1-year and final follow-up sequentially.

Statistical Analysis

In this study statistical analyses have been carried out by NCSS (Number Cruncher Statistical System) and package programme of 2007 Statistical Software (Utah. USA). The data were statistically evaluated not only by means of definitive methods (average, standard deviation, median, interquartile range) but also comparative methods such as Mann-Whitney U test for comparing two groups, Kruskal Wallis test for the groups more than two, Dunn's multiple-test for sub-groups, Ki-square test for categorical data. P values less than 0.05 is identified as statistically significant.

Results

Fourteen(56%) patients were male, eleven(44%) were female; mean age was 58(28-92). There were 7(%28) two-part, 6(%24) three-part, 12(%48) four-part fractures according to Neer classification and 8 (%32) Type A, 2 (%8) Type B, 15 (%60) Type C fractures according to AO classification. Philos® locking plate was applied to all of the patients. The mean follow-up duration was 25(14-82) months. There were 7(%28) patients who had concomitant injuries. 1-ipsilateral humerus distal fracture, 2-Cruris type 3 open fracture 3-ipsilateral humerus fracture 4-ipsilateral olecranon fracture 5- ipsilateral olecranon fracture 6-contralateral floating elbow 7-hemotoraks+ head trauma. Bone allograft was used in 3 (%12) patients- femoral strut in 1 patient, spongios allograft in 2 patients.

Clinical Results

Shoulder ROM values were measured as mean 130 (IQR 107-165) degrees of flexion, 125 (IQR 100-145) degrees of abduction and 40 (IQR 20-60) degrees of external rotation. The internal rotation degree was detected according to the level of the hand reaching to the body and measured as the dorsum of the hand at gluteus maximus in 3 patients, L5 in 1 patient, L3 in 10 patients, T12 in 7 patients and between the scapulas in 4 patients.

The median Constant score was 80(IQR 60-89). There were 7(28%) excellent, 9(36%) good, 5(20%) fair, 4(16%) poor results according to Constant shoulder score (Fig. 1). The median ASES score was 80(IQR 60-95). There were 10 (40%) excellent, 5 (20%) good, 7(28%) fair, 3(12%) poor results according to ASES shoulder score (Fig. 2).

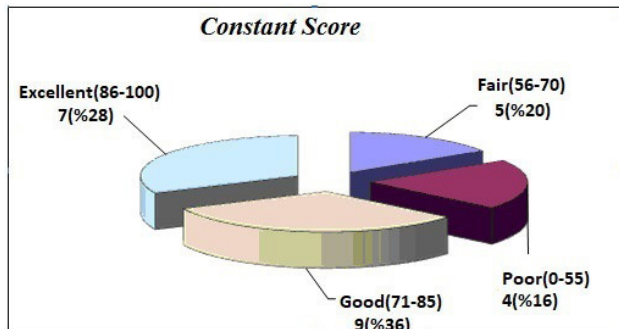


Figure 1

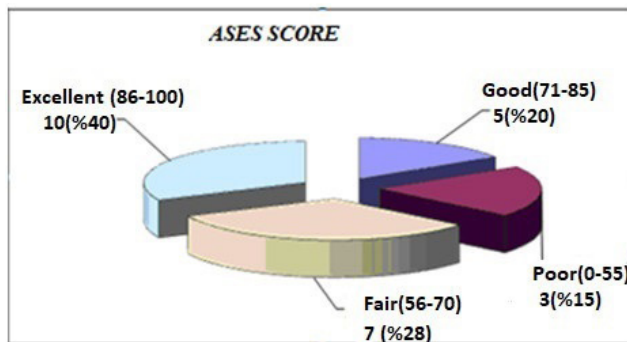


Figure 2

Age, gender, fracture type and concomitant injuries had no effect significantly neither on Constant nor on ASES scores (Tables I,II,III).

Table 1: Statistical analysis showing the effect of age and gender on Constant and ASES shoulder scores.

		N:18	N:7		
		<60 Age	≥60Age	MW	P
	Ort±SS	76,18±18,6	72,88±18,76		
Constant Score	Median	82 (60-91)	77 (58-85,25)	56,5	0,502
	Ort±SS	76,35±18,25	81,13±18,47		
ASES	Median	80 (60-93)	84 (61-99,5)	56,5	0,501
		N:14	N:11		
		Male	Female	MW	P
	Ort±SS	79,43±16,21	69,64±20,13		
Constant Score	Median	82,5 (63,75-92)	79 (55-83)	53	0,188
	Ort±SS	81,57±14,8	73,18±21,36		
ASES	Median	82,5 (67,5-95,75)	80 (55-95)	56,5	0,260

*MW: Mann-Whitney

Table 2: Statistical analysis showing the effect of Neer and AO fracture types on Constant and ASES shoulder scores.

		N:7	N:6	N:12		
		NEER 2	NEER 3	NEER 4	KW	P
Ort±SS		79,14±14,39	82,83±15,94	68,92±20,48		
Constant Score	Median	80 (75-87)	84 (65,25-100)	73 (55,25-88,75)	2,53	0,282
Ort±SS		85,86±13,98	79,17±16,56	72,58±20,25		
ASES	Median	88 (80-98)	77,5 (66,25-96,25)	75 (58,5-90,25)	2,33	0,312
		N:8	N:2	N:15		
AO Type		A	B	C	KW	P
Ort±SS		79,63±13,39	92,50±10,61	70,40±19,98		
Constant Score	Median	81,50 (76,25-86)	92,5 (63,75-95)	67 (56-91)	3,62	0,164
Ort±SS		84,50±13,50	87,50±10,61	73,07±19,95		
ASES	Median	84 (76,25-97,25)	87,5 (66-91,25)	70 (58-91)	2,28	0,320

Dunn's Multipl Comparing Test	Constant Score	ASES
A / B	0,115	0,895
A / C	0,301	0,174
B / C	0,117	0,370

*KW: Kruskal-Wallis

Table 3: Statistical analysis showing the effect of concomitant injuries on Constant and ASES shoulder scores.

		N:7	N:18		
		PHFs with concomitant injuries	Isolated PHFs	MW	P
Ort±SS		75,83±17,36	73,28±21,99		
Constant Score	Median	79,5 (61,5-89)	83 (51-91)	63	0,999
Ort±SS		79,72±16,77	73,14±21,76		
ASES	Median	82,5 (60-95,75)	80 (60-91)	52	0,504

*MW: Mann-Whitney

Radiological Results

Boileau neck-shaft inclination angle was found to be mean 135 (IQR 120-144) degrees. Three patients (12%) had varus malunion and three patients (12%) developed AVN which was evaluated as Stage 4 according to Cruess Classification.

Complications

Eleven patients (44%) had complications. 4 patients had more than one complication. Totally there were 15 complications which can be listed (Table IV). Revision surgery was proposed to 5 of the 11 patients complicated; 1 had AVN+high placed plate, 1 had varus malunion+high placed plate, 1 had AVN+screw cut-out, 1 had arthrosis due to neglected glenoid fracture and 1 had lysis of the greater tubercle. 3 patients refused further surgery and AVN+high placed plate case had hemiarthroplasty and arthrosis case had total shoulder arthroplasty. 2 patients with screw cut-out and 1 patient with metaphyseal angulation did not need any further surgical intervention as the complications noted did not worsen the clinical outcome. The brachial plexus palsy was transient, it healed completely. Of the remaining 3 patients, one had AVN and 2 had varus malunion with "moderate" results finally. The main complaint was restriction of motion in these patients and they were doing the daily activities without difficulty. No further intervention was planned eventually. The patients with complications had significant worse clinical results (lower Constant and ASES shoulder scores) than the patients without complications ($p=0,005$ and $p=0,005$ respectively) (Table V).

	N	%
AVN	3	12
Varus Mal-union	3	12
Screw cut-out	3	12
High placed plate	2	8
Artrosis	1	4
Brachial plexus palsy	1	4
Metaphyseal angulation	1	4
Lysis of the greater tubercle	1	4

*AVN: avascular necrosis

Table 5: Statistical analysis showing the effect of complications on Constant and ASES shoulder scores.

		N:14	N:11		
		Complication (-)	Complication (+)	MW	P
	Ort±SS	81,53±13,45	57,83±17,63		
Constant Score	Median	83 (75-91)	56,1 (38,5-70,75)	13	0,005
Ort±SS		83,84±14,27	63±16,52		
ASES	Median	88 (75-95)	63,1 (49-72,5)	13,5	0,005

*MW: Mann-Whitney

Discussion

This study had three noteworthy findings. One was dealing with the tips of surgical technique which informed that one should never place the plate high. The other one concluded that the outcome after locking plate osteosynthesis of PHFs had favorable results. The last one was about the complications delineating that AVN and varus malunion led to worse results.

It has been reported that functional results of patients under 65 years of age were better than patients over 65 years of age and this difference was related to osteoporosis seen in elderly patients which lead to "screw-cut out" complication¹⁴. On the other hand, another study found no difference between the functional results of two groups of patients who were under and over 60 years of age.^[15] In the present study, there was no significant difference between the clinical results (Constant and ASES shoulder scores) of the patients who were <60 years of age and the patients who were =>60 years of age. This result can be attributed to stable fixation of the fractures by locking plates and beginning the rehabilitation programme earlier.

It has been reported in various studies that Constant shoulder scores were "good" in Neer type 2 and type 3 fractures and "fair" in type 4 fractures treated surgically by locking plates.^[16,17,18,19,20,21] Robert el al informed that as the number of fracture pieces increased, the functional outcome of the patients treated surgically by locking plates get worse.^[18] In the current study, there was no significant difference between the Constant or ASES shoulder scores of Neer type 2, 3 and 4 fractures or AO type A, B and C

fractures. This can be interpreted as the clinical results of PHFs were not dependent on the fracture type, but on the complications recorded and complications can be seen in all of these fracture types.

Avascular necrosis of the humeral head after surgical treatment of PHFs with locking plates was reported as 0-15% in various studies.^[14,15,16,17,18,19,20] It was related to the arterial insufficiency due to the comminution at the fracture site or fracture-dislocation of the humeral head, or to excessive manipulation to reduce the fracture and excessive stripping of the soft tissues.^[15] The AVN rate was found to be 12% in the present study. All of the 3 patients had collum anatomicum fractures which could be a factor preceding AVN. Another factor to be considered was the age of 2 patients which was greater than 70; the remaining patient was 58 years of age but she had a fracture-dislocation as a stunning feature. We concluded that the fracture type, namely collum anatomicum fracture and fracture-dislocation and old age could be predisposing factors for AVN. The surgical tip we advocate to lower the AVN rate is to use the rotator interval to reach the humeral head which allows minimal stripping of the soft-tissues and reduce the humeral head gently with a periosteal elevator.

Screw cut-out was reported to be the most frequent complication leading revision surgery with an occurrence rate of 21%; 14% was primary screw cut-out (placing a long screw preoperatively) and 7% was secondary screw cut out (collapse of the humeral head due to metaphyseal osteoporosis during follow-up).^[22] It was recorded as 12% in the present study and all of the 3 screw cut-outs were secondary. The reason why we did not have any primary screw cut-out can be attributed mainly to the surgical technical tip performed, which was drilling only the cortex and the first 2-cm of the screw pathway and then measuring the screw length by the gauge to the point where the gauge engaged the hard subchondral bone. The other technical tip was taking 3 successive scopy images, namely AP, AP in external rotation and AP in internal rotation to determine the screw length and position were appropriate.

In another study, varus malunion was reported the most frequent complication with a rate of 16%¹⁸. It was detected with a rate of 12% in this study. When the 3 patients with varus malunion analyzed, it was detected that one had a technical error in surgery; the plate was placed high. The other two had short inferomedial screws that did not support the humeral calcar. We concluded that

the proper placement of the plate 1cm below the tip of the greater tuberosity and the use of inferomedial calcar screw long enough are two important factors that avoid varus malunion.

Revision surgery rates for surgical treatment of PHFs with locking plates were informed as %9-25.^[23] The complications which required revision surgery were reported in frequency order as screw cut-out, varus mal-union, AVN, subacromial and implant failure.^[14,15,18] The revision surgery rate was 20% in the present series. Among the 5 patients who needed revision surgery, 2 AVN, 2 technical errors in surgery (1 high placement of the plate, 1 screw cut-out), 1 neglected glenoid fracture and 1 lysis of the greater tubercle were noted. We concluded that in order to avoid revisions after locking plate of PHFs, a keen surgical technique delineated by the surgical tips of this manuscript, precautions to avoid AVN and a detailed glenoid fracture examination preoperatively with CT should be carried out.

A considerable issue to be discussed for the management of PHFs is when to choose fixation or arthroplasty options primarily. Hemiarthroplasty which was first introduced by Neer can be a solution for Neer 3 or 4 part comminuted fracture or fracture dislocations. The key point for success is tuberosity healing and best results can be obtained in younger patients and patients with less tuberosity comminution. Besides, reverse shoulder arthroplasty proposed by Grammont has become a pioneer treatment for the comminuted PHFs in the elderly people who have dysfunctional rotator cuffs additionally. On the other hand, prosthetic options have plenty serious complications; mainly aseptic loosening, instability, infection, reflex sympathetic dystrophy and periprosthetic fractures.^[24,25] Looking at the fixation site, it has sufficient results if anatomic reduction and stable fixation can be obtained. However, it is fraught with complications^[26,27], the rate of which was reported as 44% in this study. On the other hand, the revision rate was 20% which denoted that all of the complications did not require any further intervention as they did not bother daily activities of the patients and so were well tolerated. It was concluded that favorable results were obtained by locking plates in the management of PHFs in all fracture types and age groups if the surgical tips delineated in this study were accomplished and AVN complication did not proceed. AVN was the major complication leading poor results and revisions.

The pros of the study are the outcomes given after a minimum follow-up of 14 months and mean follow-up of 2 years. Limitations of this study include its retrospective design and the small number of patients being involved. The number of patients in the subgroups of the collected data on certain variables- age, gender, fracture type, concomitant injury- could make reaching statistically significant differences difficult which would lead to type II error. The other limitation is that the confounding factors such as smoking, diabetes, chronic kidney disease were not questioned. Lastly, the whole number of patients who were treated operatively or non-operatively for PHF in the study period and the patients who had surgery but were lost to follow-up were not recorded.

Conclusions

The treatment of PHFs by locking plates had favorable results in all fracture types and age groups if complications were being avoided. Major complications leading to poor results were AVN, varus malunion and technical errors in surgery. AVN was the leading cause for revisions and poor results.

Declarations

Conflict of interest

The authors declare that they have no conflict of interest.

Funding Statement

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Ethics Approval

Ethical approval (Date/Number: 2023/) was obtained from the ethical committee of a university.

Ethical Approval

The study was approved by the Haydarpasa Numune Education and Research Hospital Ethical Committee (date 09.02.2023 and number E-62977267-771-209014806)

Availability of Data And Material

Available.

Authors' Contributions

All authors have made substantial contributions to this article being submitted for publications. All authors critically reviewed the manuscript and approved the final form.

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Helicobacter Pylori Might be a Contributing Factor in Gallbladder Polyps or Gallstones: A Single Center Case-Control Matching Study of Turkish Individuals

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ABSTRACT

Background/Purpose: In recent studies, *Helicobacter pylori* (Hp) infection has been shown to be associated with diseases such as obesity, diabetes, chronic obstructive pulmonary disease and kidney failure. In our study, we aimed to examine the relationships between Hp infection and gallstones or gallbladder polyps.

Methods: Patients who underwent elective cholecystectomy between January 2017 and December 2021 were retrospectively examined. Patients were divided into those with only polyps in the gallbladder (Group P), those with polyps and stones together (Group SP), and those with only stones (Group S). The control group consisted of patients who underwent gastroscopy due to dyspeptic complaints (Group No). The groups were screened for the presence of *Helicobacter pylori*. Demographic data, comorbidities, the presence of hepatosteatosis and laboratory values were recorded and compared.

Results: A total of 244 patients were included in the study. HP was positive in 141 (57.8%) of the patients and negative in 103 (42.2%). There were 58 (23.8%) patients in Group P, 22 (9%) in Group SP, 90 (36.9%) in Group S, and 74 (30.3%) in Group No. There was a significant difference in age between Group P and Group No ($P = 0.012$). Female sex was significantly more common in Group S ($P=0.009$). The *Helicobacter pylori* positivity rate was significantly greater in Group P and Group SP ($P = 0.012$).

Conclusion: HP infection may be associated with gallbladder polyps. We recommend that prospective randomized controlled studies be supported by large sample data.

Keywords: Case-control study, gallstones, gallbladder polyp, gallbladder disease, *Helicobacter pylori*

ÖZET

Giriş/Amaç: Son yıllarda yapılan çalışmalarda *Helicobacter pylori* (Hp) enfeksiyonu; Obezite, diyabet, kronik obstrüktif akciğer hastalığı ve böbrek yetmezliği gibi hastalıklarla ilişkili olabileceği belirtildi. Çalışmamızda Hp enfeksiyonu ile safra taşı ve safra kesesi polipleri arasındaki ilişkiyi incelemeyi amaçladık.

Yöntem: Ocak 2017 ile Aralık 2021 tarihleri arasında elektif kolesistektomi yapılan hastalar retrospektif olarak incelendi. Hastalar safra kesesinde sadece polip olanlar (Grup P), polip ve taşı birlikte olanlar (Grup SP) ve sadece taş olanlar (Grup S) olarak ayrıldı. Kontrol grubunu hazımsızlık şikayeti nedeniyle gastrokopi yapılan hastalardan oluşturdu (Grup No). Gruplar *Helicobacter pylori* varlığı açısından tarandı. Demografik veriler, komorbiditeler, hepatosteatoz varlığı ve laboratuvar değerleri kaydedilip karşılaştırıldı.

Bulgular: Çalışmaya 244 hasta dahil edildi. Hastaların 141'inde (%57,8) HP pozitif, 103'ünde (%42,2) negatifti. Grup P'de 58 (%23,8), Grup SP'de 22 (%9), Grup S'de 90 (%36,9), Grup No'da 74 (%30,3) hasta vardı. Grup P arasında yaş farkı anlamlıydı. ve Grup No ($P = 0,012$). Kadın cinsiyet Grup S'de anlamlı derecede yüksekti ($P=0.009$). *Helicobacter pylori* pozitiflik oranı Grup P ve Grup SP'de anlamlı derecede yüksekti ($P=0,012$).

Sonuç: HP enfeksiyonu safra kesesi polipleri ile ilişkili olabilir. Prospektif randomize kontrollü çalışmaların geniş örneklem verileriyle desteklenmesini öneriyoruz.

Anahtar Kelimeler: *Helicobacter pylori*, safra taşı, safra kesesi polipi, safra kesesi hastalığı, vaka kontrol çalışması

Helicobacter pylori (*H. pylori*) infection affects more than 50% of the world's population, and its close relationship with gastric diseases is well known (1). In our country, although this rate is not clear, in a study conducted in 2003 in which the 13C urea breath test was applied, the general prevalence was found to be positive in 82.5% of the participants (2). In recent years, an increasing number of studies have reported that this infection may also be associated with obesity (3), diabetes (4), chronic obstructive pulmonary disease and renal failure (5).

The incidence of gallbladder polyps has been reported to be 6% in cholecystectomy series (6). Similarly, this rate is 3-7% on ultrasonographic imaging of the gallbladder (7). Gallbladder polyps are usually clinically asymptomatic. There are studies in the literature indicating that they may carry a malignancy risk of approximately 2%. For this reason, some approaches have been adopted in the treatment of gallbladder polyps by evaluating their characteristics, such as size and number (8). The prevalence of gallstones in the community varies between 10% and 15%, and features such as age, sex, genetic factors, hypercholesterolemia, diabetes, and alcohol use are responsible for the formation of gallstones (9).

There are few studies in the literature investigating the relationships between *H.pylori* infection and gallbladder polyps and stones. In this study, we aimed to investigate the relationships between *H.pylori* infection and gallbladder polyps and stones.

Methods

Patients who underwent elective cholecystectomy at the general surgery clinic between January 2017 and December 2021 were retrospectively reviewed. Patients who underwent gastroscopy for dyspeptic complaints and whose pathology slides revealed gallstones or polyps in the gallbladder were included in the study. The control group consisted of patients who did not have luminal or mural pathology in the gallbladder on ultrasonography (USG) due to dyspeptic complaints or who underwent gastroscopy for screening purposes.

Patients younger than 18 years of age, patients who had undergone *Helicobacter pylori* eradication therapy, pregnant or breastfeeding patients, patients with a history of malignancy, patients without abdominal USG data and patients with missing data were excluded.

Patients were divided into those with only polyps in the gallbladder (Group P), those with polyps and stones (Group SP), and those with only stones (Group S) in the cholecystectomy slides. The control group was named Group No.

Biopsies of the groups taken under gastroscopy were screened for the presence of *Helicobacter pylori* according to the Sydney classification by hematoxylin and eosin (H&E) and modified Giemsa methods under light microscopy.

Demographic data (age, sex, BMI (body mass index)), comorbidities (no comorbidity, 1 comorbidity, 2 or more comorbidities), presence of hepatosteatosis according to USG measurement, alanine aminotransferase (ALT), aspartate aminotransferase (AST), low-density lipoprotein (LDL), triglyceride levels (normal or high), and high-density lipoprotein (HDL) levels (normal or low) were recorded.

Ethical approval for the study was granted by the hospital in which the procedures were performed (IRB No:KAEK/2024.04.73).

Statistical Analysis

The Shapiro-Wilk test was used to assess whether the variables followed a normal distribution or not. Continuous variables are presented as median (minimum:maximum) and mean±standard deviation values. Categorical variables are reported as n(%). According to the normality test results, the Kruskal-Wallis test or ANOVA test was used if the number of groups was greater than two. Multiple comparison procedures were performed via the Dunn-Bonferroni approach to identify different groups or groups after the Kruskal-Wallis test. Pearson's chi-square test and Fisher's Freeman-Halton test were used to compare categorical variables. SPSS (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0, Armonk, NY: IBM Corp.) was used for statistical analysis and a p value <0.05 was considered to indicate statistical significance.

Results

The study included 244 patients. The mean age was 49.7 ± 12.52 years and the male/female ratio was 144 (59%)/100 (41%).

HP was positive in 141 (57.8%) patients and negative in 103 (42.2%) patients. Demographic data (Table 1) and laboratory data (Table 2) are given below.

Table 1: Demographic data	
Age (mean±SD)	49.7±12.52
Sex (n/%)	
Female	144 (59%)
Male	100 (41%)
BMI (mean±SD)	27.27±5.09
Comorbidity (n/%)	
None	142 (58.2%)
<2	49 (20.1%)
≥2	53 (21.7%)
Hepatosteatois (n/%)	
No	160 (65.6%)
Yes	84 (34.4%)
SD: Standard deviation	

Table 2: Laboratory data	
ALT (n/%)	
Normal	234 (95.9%)
High	10 (4.1%)
AST (n/%)	
Normal	229 (93.9%)
High	15 (6.1%)
TG (n/%)	
Normal	142 (58.2%)
High	102 (41.8%)
LDL (n/%)	
Normal	221 (90.6%)
High	23 (9.4%)
HDL (n/%)	
Normal	216 (88.5%)
Low	28 (11.5%)

There were 58 (23.8%) patients in Group P, 22 (9%) in Group SP, 90 (36.9%) in Group S and 74 (30.3%) in Group No.

When the groups were compared, a significant difference was found between Group P and Group No in terms of age (P=0.012). The proportion of females was significantly greater in Group S (P=0.009) (Table 3).

Table 3: Comparison of groups					
	Group P 58 (23.8%)	Group SP 22 (9%)	Group S 90 (36.9%)	Group No 74 (30.3%)	P value
Age (mean±SD)	46.06±11.73	52.27±10.71	49.15±11.75	52.74±13.82	0.015
Sex (n/%)					
Female	33 (56.9%)	10 (45.5%)	65 (72.2%)	36 (48.6%)	0.009
Male	25 (43.1%)	12 (54.5%)	25 (27.8%)	38 (51.4%)	
BMI (mean±SD)	28.03±4.74	27.95±4.40	27.13±5.41	26.63±5.13	0.443
Comorbidity (n/%)					
None	35 (60.3%)	10 (45.5%)	55 (61.1%)	42 (56.8%)	0.349
<2	8 (13.8%)	4 (18.2%)	21 (23.3%)	16 (21.6%)	
≥2	15 (25.9%)	8 (36.4%)	14 (15.6%)	16 (21.6%)	
Hepatosteatois (n/%)					
No	41 (70.7%)	15 (68.2%)	57 (63.3%)	47 (63.5%)	0.779
Yes	17 (29.3%)	7 (31.8%)	33 (36.7%)	27 (36.5%)	
SD: Standard deviation					

There were no significant differences between the groups in terms of ALT ($P=0.212$), AST ($P=0.802$), TG ($P=0.289$), LDL ($P=0.442$) or HDL ($P=0.343$) levels.

The *Helicobacter pylori* positivity rate was significantly greater in Group P and Group SP ($P=0.012$) (Table 4).

Table 4: HP relationships across groups					
	Group P 58 (23.8%)	Group SP 22 (9%)	Group S 90 (36.9%)	Group No 74 (30.3%)	P Value
H.P					
No	19 (32.8%)	5 (22.7%)	41 (45.6%)	38 (51.4%)	0.012
Yes	39 (97.2%)	17 (77.3%)	49 (54.4%)	36 (48.6%)	

Discussion

H. pylori is the main pathogen responsible for the development of various diseases, especially gastric cancer (10). In some studies, *H. pylori* was detected in the skin, nose, gallbladder, and stomach (11). However, few studies have explored the relationships between *H. pylori* and the formation of gallstones and cholecystitis. However, in a study in which Pandey M and Shukla M. (12) investigated the relationship between biliary tract diseases and *H. pylori*, they reported that the incidence of *H. pylori* was 42.9%.

In some studies, the frequency of *H. pylori* infection varies between 30% and 70% (13-14). Bulajic et al. (14) reported that *H. pylori* detected in the gastric mucosa via the ¹³C urease breath test was also detected in the biliary tract in 81% of patients. Similarly, in our study, 57.8% of all patients were positive for *H. pylori*.

In another meta-analysis, Zhou et al. (15-16) reported the relationship between the presence of *H. pylori* in the gallbladder and cholelithiasis and reported that premalignant lesions were observed more frequently in *H. pylori* positive patients. Hassan et al. (17) reported that *H. pylori* infection may increase the number of mucosal precancerous lesions.

Several mechanisms have been used to explain this relationship in the literature. First, the inflammatory

response, which is due to oxidative reactions and free radicals, is blamed (15, 18). Additionally, *H. pylori* acts as a foreign body and increases the risk of stone formation (19). Another publication reported that the ability of urease-positive *H. pylori* bacteria to precipitate calcium and substances involved in the formation of gallstones may be effective (20). Finally, it has been suggested that it may play a role in brown bile pigment stone formation by inducing beta-glucuronidase, bacterial hydrolase, and phospholipase enzymes (21).

We believe that these mechanisms might be effective and we found that there are publications in support of our article in our literature review.

Fatemi et al. (22) examined the relationship between *H. pylori* strains and acute and chronic cholecystitis with/without stones and reported a high incidence of *H. pylori* in cases of calculous cholecystitis, whereas they did not find a statistical relationship between gallstones and *H. pylori*. A meta-analysis including 18 studies by Cen et al. (23) reported that cholecystitis and *H. pylori* were related. In the same study, the *H. pylori* density was reported to be significantly greater in patients who underwent cholecystectomy for chronic cholecystitis and had stones in the gallbladder than in the control group. Although the rate of *H. Pylori* infection in patients with acute calculous cholecystitis was not evaluated in our study, no significant difference was found between *H. Pylori* infection in the group with only gallstones in the gallbladder and the control group. We believe that this difference may be because the pathology results of the groups did not differ between acute and chronic cholecystitis patients.

In two separate studies by Zhou et al. (15) and Helaly et al. (24), a statistically significant correlation was found between *Helicobacter* positivity in the stomach and gallbladder. Similarities between gallbladder diseases and *H. pylori* symptoms are frequently encountered in the clinic. In a study conducted by Takahashi et al. (25) in 2013 in which 15551 patients were examined with a ¹³C urease breath test, *H. pylori* was found to be positive in 4493 (28.8%) patients with stones in the gallbladder, and this was also shown to be significant in their multivariate analysis.

In some studies, no significant relationship was found between *H. pylori* positivity in patients with gallstones and preoperative upper gastrointestinal tract endoscopy (11, 26). In a retrospective study including a large population conducted by Xu et al. (3), no relationship was found between patients with positive *Helicobacter* antibodies in

the blood and gallstones. However, in the same study, a statistically significant relationship was found between gallbladder polyps and *H. pylori* positivity. In our study, similar to these results, we found significantly greater *H. pylori* positivity in 39 (97.2%) polyp and 17 (77.3%) polyp-stone coexistence groups than in the control group. *Pylori* positivity, which suggests that *H. pylori* may increase polyp formation in the gallbladder. Since our results did not cover a long follow-up period, the mechanisms of gallstone and gallbladder polyp formation were not evaluated in detail. For this reason, our study does not include the effect of the presence of *H. pylori* on the formation of gallstones and gallbladder polyps, but only the data related to their association. For definitive results on this subject, studies involving larger samples and pathophysiological investigations are needed.

In studies on the incidence of *H. pylori*, the prevalence of *H. pylori* increases with age in Eastern countries, but the sex difference is not significant. Colonization has been reported to increase, especially in people over 70 years of age (14, 27). Gallstones are more common in women than in men. Some sources have reported that approximately 6% of men and 9% of women in the United States have gallstones (28). When sex differences were evaluated, the proportion of women was greater in the group with only gallstones in our study ($p=0.009$). No significant sex-related differences were found in the other groups, and our findings are consistent with the literature.

There are publications mentioning the relationship between obesity and biliary tract diseases (29). Zhang et al. (30) reported that BMI was greater in patients with *H. Pylori* infection ($p=0.048$), whereas no significant difference was found between the groups in terms of BMI in our study ($p=0.043$).

We believe that our study will make an important contribution to the literature in terms of evaluating the relationships among gallstones, polyps and their associations with the incidence of *H. pylori*. Indeed, our results show this association.

Our study has important limitations. First, because this was a retrospective study without a good preparation, selection bias was possible. Second, the presence of *H. pylori* in gallbladder slides was not analyzed. Our findings imply that the development of gallbladder polyps or gallstones is influenced by *H. pylori* infection.

Declarations

Conflict of interest

The authors do not declare any

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Author Contributions

Cenk Ozkan, Serhan Yilmaz, Emre Bozdog, Osman Sibic and Erkan Somuncu are responsible for the design of the manuscript. Cenk Ozkan, Emre Bozdog and Erkan Somuncu collected the data, and Serhan Yilmaz, Cenk Ozkan and Osman Sibic analyzed the data. All the authors discussed the results and wrote, reviewed, and edited the manuscript and title page. Approval of final manuscript: Cenk Ozkan, Serhan Yilmaz, Emre Bozdog, Erkan Somuncu and Osman Sibic

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Effect of Spinal Surgery on Quality of Life in Patients with Chronic Low Back Pain, Clinical Study Evaluated with The SF-36 Quality of Life Scale

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ABSTRACT

Aim: Chronic low back pain is a disabling condition degrading peoples quality of life. Low back pain is the most common disease that neurosurgeons encounter in practice and the most common complaint that requires admission to outpatient clinics. Although the incidence of low back pain in the general population is 5% and 90% of the cases heal spontaneously within one month. In our study, the results of the quality of life scale of the patients who applied with the complaint of chronic low back pain within the clinical course and who had undergone spinal surgery and those who did not, were compared.

Material and Methods: 110 patients with chronic low back pain (chronic low back pain: lasting more than 12 weeks), who had undergone lumbar spinal surgery and who had not, were included in the study. Patients with chronic low back pain who underwent spinal surgery and not undergoing spinal surgery were compared with SF-36 quality of life outcome scale. The statistical significance level was accepted as $p < 0.05$ in the calculations.

Results: Physical functionality, emotional role difficulty, social functionality, pain and general health perception sub-dimensions of quality of life were found to be statistically significantly higher in males ($p < 0.05$). In our study, physical functionality (for example, activities that require physical effort such as walking), physical role difficulty, emotional role difficulty and general health perception scores were found to be significantly lower in patients with a history of spinal surgery ($p < 0.05$), and also social functionality (for example, going to a neighbor's), scores were found to be significantly lower in those with a history of surgery ($p: 0.087$).

Conclusion: When the early results of the surgical treatment for chronic low back pain are evaluated, it is seen that the pain is reduced and often eliminated, but it has been observed that it does not help the patients regain the correct body image, improve their functional abilities, and improve their quality of life in long-term follow-ups. In this case, before the surgery, especially the histories of the patients should be taken well, their expectations should be questioned, the benefits they can gain from surgery according to their age should be taken into account, the expectations and lifestyles of the people in the postoperative process are also extremely effective in well-being, no matter how good surgery is performed.

Key words: Spinal surgery, chronic low back pain, quality of life scale.

ÖZET

Amaç: Kronik bel ağrısı, insanların yaşam kalitesini düşüren ve sosyal yaşamlarını kısıtlayan bir durumdur. Bel ağrısı, beyin cerrahlarının pratikte ve özellikle polikliniklerde en sık karşılaştığı şikayettir. Genel popülasyonda bel ağrısı insidansı %5 tir ve vakaların %90'ı bir ay içinde kendiliğinden iyileşir. Çalışmamızda, klinik seyir ve radyolojik bulgular dahilinde kronik bel ağrısı şikayeti ile başvuran ve, spinal cerrahi geçirmiş ve geçirmemiş hastaların yaşam kalite ölççeği sonuçları, hastaların Beden Kitle İndeksleri de çalışmaya dahil edilerek karşılaştırılmıştır.

Gereç ve Yöntem: Çalışmaya kronik bel ağrısı olan (kronik bel ağrısı: 12 haftanın üzerinde süren), lomber spinal cerrahi geçirmiş ve geçirmemiş 110 hasta dahil edilmiştir. Çalışmamızda, lomber spinal cerrahi geçiren ve geçirmeyen hastaların yaşam kaliteleri, SF-36 yaşam kalite ölççeği kullanılarak karşılaştırılmış ve sonuçları değerlendirilmiştir. İstatistiksel olarak farkın önemliliği $p < 0.05$ olarak kabul edilmiştir.

Bulgular: Yaşam kalitesinin fiziksel işlevsellik, emosyonel rol zorluğu, sosyal işlevsellik, ağrı ve genel sağlık algısı alt boyutlarının erkeklerde istatistiksel olarak anlamlı düzeyde yüksek olduğu belirlendi ($p < 0.05$). Çalışmamızda omurga cerrahisi öyküsü olan hastalarda fiziksel işlevsellik (örneğin yürüme gibi fiziksel efor gerektiren aktiviteler), fiziksel rol zorluğu, emosyonel rol zorluğu ve genel sağlık algısı puanları anlamlı olarak düşük bulunmuştur ($p < 0.05$), ve ayrıca sosyal işlevsellik (örneğin komşuya gitmek) skorlarının ameliyat öyküsü olanlarda anlamlı olarak daha düşük olduğu belirlenmiştir ($p: 0.087$).

Tartışma ve Sonuç: Kronik bel ağrılı hastalara, ağrıyı azaltmaya yönelik yapılan cerrahi tedavinin erken dönem sonuçları değerlendirildiğinde ağrıyı azalttığı ve çoğu zaman ortadan kaldırdığı görülmekle birlikte uzun dönem takiplerde tek başına, hastaların doğru vücut algısını yeniden kazanmalarına, fonksiyonel yeteneklerini geliştirmelerine, yaşam kalitelerini iyileştirmelerine yardımcı olmadığı gözlenmiştir. Bu durumda ameliyat öncesi özellikle hastaların öyküleri iyi alınmalı, beklentileri sorgulanmalı, yaşlarına göre ameliyattan elde edebilecekleri faydalar dikkate alınmalı, bölgedeki kişilerin beklentileri ve yaşam tarzları dikkate alınmalıdır. Ameliyat ne kadar iyi yapılırsa yapılıns ameliyat sonrası süreç de sağlık açısından son derece etkilidir.

Anahtar Kelimeler: Spinal cerrahi, kronik bel ağrısı, yaşam kalitesi ölççeği.

Low back pain, commonly referred to as lumbalgia, is a prevalent condition encountered by treating surgeons and is a leading cause of outpatient clinic referrals. Sciatica, often associated with compression of sciatic nerve-forming roots, is a common manifestation. Originating from the 4th century by Hippocrates, the term 'sciatica' underscores the historical significance of this ailment (1). Lumbar disc herniation stands out as the primary cause of low back pain, with additional contributors such as degenerative spine disease, lumbar stenosis, spondylolisthesis, malignancies, and infections. The risk factors for disc herniation are similar to those seen in low back pain. Low back pain is among the first diseases that cause loss of work power (2).

The economic impact of low back pain is substantial, emphasizing the need for a comprehensive understanding, especially in developing societies. It is obvious that if a healthy database is created in developing and industrializing societies like our country, the results will not be much different (3).

In developed societies, a large financial resource has been allocated to degenerative spine disease, which is one of the causes of low back pain, and treatment algorithms for this disease are applied quite regularly. Despite significant attention and resources allocated to degenerative spine disease in developed societies, low back problems persist as almost intrinsic to modern lifestyles. The conscious and comfortable access of these high socio-cultural communities to hospitals also reveals the sufficient number of patients (3). While the prevalence of low back pain is 5%, approximately 80% of individuals experience it at some point in their lives (4). The challenge lies in the fact that only 15% of cases receive an etiological diagnosis. A majority of patients don't seek medical consultation due to natural resolution within a month. The risk of disc herniation is 2-5%, with surgical intervention limited to a mere 2% (5). Young-middle age, male gender, familial predisposition, environmental factors and previous trauma are common risk factors. Although there is a significant increase in low back pain with age, the incidence of disc herniation decreases (5).

In patients presenting with low back pain, examination begins with inspection. Especially if there is a disc herniation, patients try to take a suitable position to relax the nerve root. This posture is called the 'antalgic' posture. The Laseque test, the "opposite leg stretch" test described

by Fajerszdahn, is used in the examination of disc herniations. In the muscle strength examination, all muscle groups are examined one by one. Trauma, neoplasia, and signs of infection are also questioned while taking a history. In the differential diagnosis of low back pain, radiological evaluation can also be performed in addition to the history and physical examination. These are, in order; direct radiographs, computed tomography (CT), Magnetic Resonance Imaging (MR), Myelography. In fact, chronic pain is often described as an unpleasant sensory or emotional experience, and low back pain is also extremely common and is cited as the second most common reason people seek medical attention.

Low back pain or lumbalgia is one of the most common types of chronic pain in neurosurgery practice; It has been proven in clinical studies that it also causes anxiety, depression, sleep disorders, low quality of life and high health services (6,7). Low back pain is the most common cause of disability in people under the age of 45. It constitutes 15% of the workforce losses caused by the disease. Lifetime prevalence estimates range from 80-90%, with an annual incidence of 5% (8). Both chronic pain and deterioration of functional status can reduce the quality of life of patients. Quality of Life is defined as "subjective well-being" or, in other words, "the state of being satisfied with one's own life". The World Health Organization has similarly defined quality of life as "the way an individual perceives his/her own situation in life in the context of both the cultural and the value judgments of the environment, as well as his/her own goals, expectations, standards and interests".

There are many reasons to evaluate health-related quality of life in patients with low back pain. It provides potentially useful information for the clinician in assessing care needs, establishing treatment goals and planning treatment, monitoring the patient out of hours, and evaluating treatment outcomes (9). The scale consists of 36 items and these provide the measurement of 8 dimensions:

Physical functions, social functions, inhibition in roles due to physical problems, physical pain, mental health, inhibition in roles due to emotional problems, life energy, general health perception. The QOLS is scored by adding up the score on each item to yield a total score for the instrument. Scores can range from 16 to 112. There is no automated administration or scoring software for the QofLS (10).

Recognizing the socio-demographic factors and the scarcity of studies in the country, an investigation into the quality of life for chronic low back pain patients becomes imperative. Therefore, this study aims to fill the existing gap in the literature by evaluating the quality of life, physical and social functions of patients experiencing chronic low back pain (lasting more than 12 weeks) by utilizing the SF-36 scale. By raising awareness among health professionals, the study aspires to contribute to preventive measures and minimize workforce losses associated with this prevalent health issue.

Material and Method

Patient Population

This epidemiologic retrospective correlational study was conducted among suitable patients with chronic low back pain who sought treatment at the Neurosurgery Clinic of Kayseri City Hospital between April and July 2022. A power analysis during the biostatistical preliminary assessment indicated a study population 110 cases to show a clinically important difference for lumbar surgery. Research data were collected from patients attending the outpatient clinic of the University of Health Sciences, Kayseri City Hospital, Neurosurgery Clinic.

Inclusion-Exclusion Criteria and Demographic Data

The study included 110 patients with chronic low back pain, aged between 18-75, irrespective of gender, and both those who had experienced and not experienced chronic low back pain. Demographic data encompassed parameters such as height (cm), body weight (kg), and Body Mass Index (BMI). These measurements were taken with precision using a weight and height measurement device while patients were barefoot and dressed in sportswear.

Evaluation Criteria

Patient groups were evaluated through one-on-one interviews with physicians using the SF-36 Quality of Life form. This form assesses positive and negative aspects of life quality, where a higher score indicates a better quality of life. Additionally, patients' spinal surgery history was considered. The study aims to compare and evaluate the results of patients who underwent single or two-level

microdiscectomy, posterior stabilization, and arthrodesis surgery within 2 to 6 segments, patients who underwent spinal stenosis surgery without single-level arthrodesis, and those who did not undergo spinal surgery using the SF-36 Quality of Life scale. Minimally invasive procedures (kyphoplasty, vertebroplasty, endoscopic discectomy) were not included in the study. None of the patients included in the study were found to have early surgical complications, the need for a second surgery, or that not reducing the pain. All of the patients were discharged with surgical cure.

Statistical Analysis

Data for the study were recorded and analyzed using the SPSS 22 program. The Shapiro-Wilk test was employed to assess the normal distribution of data. For the statistical analysis of quantitative data, Unpaired t-Test was utilized for normally distributed values, and Mann Whitney-U test for non-normally distributed values. One-Sample t-test was applied to evaluate mean scores of Quality-of-Life Scale (QoLS) for patients in comparison to the Turkish population. Pearson Chi-square test was used for the statistical analysis of categorical data, and Pearson Correlation coefficient was employed to demonstrate relationships between variables. Statistical significance was accepted at $p < 0.05$.

Results

A total of 110 patients suffering from chronic low back pain, with a duration exceeding 12 weeks, were enrolled from the Neurosurgery outpatient clinic at Kayseri City Hospital. Among these participants, 71.8% were female, and the mean age was 45.79 ± 15.29 years. Notably, 30.9% of the patients had a history of previous spinal surgery, including procedures such as lumbar discectomy, spinal stenosis treatment, and posterior instrumentation.

The overall mean Body Mass Index (BMI) for the entire cohort was calculated as 28.22 ± 5.35 kg/m². Demographic analysis revealed no significant age or BMI differences between genders, yet a higher prevalence of previous spinal surgery among women was observed (**Table 1**).

Table 1: Surgical history, age and average BMI are given by gender.

Feature	Gender				p	
	Female (n:79)		Male (n:31)			
	Mean	SD.	Mean	SD:		
Age	45.86	15.38	45.61	15.30	0,939*	
BMI	28.66 Hydrangea:28.65	5.73	27.11 Hydrangea:27.14	4.11	0,174**	
		n	%	n	%	p
BMI group	Normal	25	31.6	8	25.8	0,010***
	Slightly fat	28	35.4	20	64.5	
	Obese	26	32.9	3	9.7	
Surgical history	There is	27	34.2	7	22.6	0,236***
	None	52	65.8	24	77.4	

*Unpaired t Test **, Mann Whitney U Test, *** Pearson Chi-Square Test
 BMI:Body Mass Index, LDL:Quality of Life Scale

A comprehensive evaluation of the patients' quality of life included a comparison with Turkish society values and revealed significantly lower scores in all sub-dimensions for the study participants. Gender-based analysis indicated

that males exhibited higher scores in physical functionality, emotional role difficulty, social functionality, pain, and general health perception sub-dimensions, with statistical significance ($p < 0.05$) (Table 2).

Table 2: Comparison of Quality of Life scores by gender and Turkish population averages

QoL sub dimensions	Female				Male				p ¹
	Patients		Turkish people		Patients		Turkish People		
	Mean	SD.	Mean	SD.	Mean	SD.	Mean	SD.	
Physical Functionality	50.18	24.34	80.6	21.7	60.48	22.03	87.2	17.1	0,043**
	p<0,001*				p<0,001*				
Physical Role Difficulty	29.74	33.74	82.9	28.6	36.29	35.84	89.8	19.3	0,386***
	p<0,001*				p<0,001*				
Emotional Role Difficulty	30.37	35.88	89.0	22.5	44.08	35.88	92.8	15.1	0,048***
	p<0,001*				p<0,001**				
Energy Vitality	35.94	21.88	63.4	13.7	42.41	18.34	65.7	11.9	0,148***
	p<0,001*				p<0,001*				
Mental Health	48.05	21.73	70.1	11.4	53.67	20.46	71.0	10.6	0,217**
	p<0,001*				p<0,001*				
Social Functionality	49.20	24.13	90.1	12.9	59.27	20.40	91.7	12.8	0,026***
	p<0,001*				p<0,001*				
Pain	20.60	15.77	81.0	20.2	29.35	19.68	85.1	16.4	0,015***
	p<0,001*				p<0,001*				
General health	37.08	18.33	69.1	16.9	45.64	18.56	73.6	14.9	0,030**
	p<0,001				p<0,001				

(p: patients according to Turkish population averages, p¹: between female and male patients) *One Sample-t Test, **Unpaired t Test ***Mann Whitney U Test
 QoLS:Quality of Life Scale

However, in other sub-dimensions, while males displayed higher mean scores, the differences were not statistically significant ($p > 0.05$). Further scrutiny into patients with a history of spinal surgery unveiled lower scores in physical functionality, physical role difficulty, emotional role difficulty, and general health perception ($p < 0.05$). Social functionality scores were also lower in this subgroup, though not statistically significant ($p: 0.087$). Moreover, a negative correlation was established between patients' age and their physical functionality scores ($p: 0.005$, Correlation Coefficient: -0.267), as well as a negative correlation between age and general health perception scores ($p: 0.019$, Correlation Coefficient: -0.233) (Table 3).

Table 3: Quality of life scale (QoLS) scores and surgical history of the patients

QoLS sub Dimensiones	Surgical history			
	There is		None	
	Mean	SD.	Mean	SD.
Physical functionality	41.47	21.76	58.28	23.34
	$p < 0,001^*$			
Physical Role Difficulty	20.58	30.44	36.51	34.98
	$p: 0,020^*$			
Emotional Role Difficulty	22.54	30.39	39.47	37.59
	$p: 0,026^*$			
Energy Vitality	33.08	23.90	39.86	19.47
	$p: 0,119^{**}$			
Mental Health	47.64	23.08	50.52	20.76
	$p: 0,518^{**}$			
Social Functionality	45.58	25.35	54.93	22.18
	$p: 0,087^*$			
Pain	20.22	16.46	24.34	17.66
	$p: 0,135^*$			
General Health	34.26	19.38	41.84	18.05
	$p: 0,049^{**}$			

**Mann Whitney U Test, **Unpaired t Test
QoLS: Quality of Life Scale*

Discussion

In the study, the quality of life of patients who had or had not undergone spine surgery was evaluated with the SF-36 scale, and the Body Mass Index (BMI) values of the patients were also included in the study. The most important finding of this study is that it was obtained by evaluating the results of obesity, low back pain and previous spine surgery together. As a result, it has been observed that

patients who have undergone spine surgery and obesity are more common in the female patient population.

While we may not desire it, this study has certain limitations. Firstly, due to its retrospective design, there may be limitations in accessing and verifying retrospective data. Secondly, the reliance on patients' self-reports for the data used in the study may lack objectivity. Evaluations of patients' symptoms or quality of life can be subjective, potentially impacting the reliability of the results

Lastly, although the text mentions that patients with a history of spinal surgery were evaluated in a general category, these patients may have undergone different surgical procedures. This situation could pose challenges in separating the effects of various surgical types. Patients have to be evaluated together with their physical examinations, radiological findings and complaints in deciding the surgical treatment. Although 80% of individuals complain of low back pain at some point in their lives, only 2% of them are treated surgically.

Acutely presented pains that if it is less than 12 weeks old is treated with non-surgical conservative methods, with satisfactory results in most of them. In a study by Chou et al. in the treatment of chronic low back pain; showed that physical therapy, exercise, functional and spinal surgery are also effective and reduce low back pain (12). Alemanno et al. clinically demonstrated that physical therapy applied to 20 patients with chronic low back pain in 2019 reduced their pain and increased their quality of life using the SF-36 scale (13). In our study, although it is expected that surgery may have a positive effect on the quality of life in patients with chronic low back pain who underwent spinal surgery, although their pain decreased in patients of both genders who underwent spinal surgery, their physical functionality, physical role difficulty, emotional role difficulty and general health perception improved in their postoperative follow-up. scores were found to be significantly lower ($p < 0.05$).

Rodrigues et al. randomized sixty-three patients with lumbar canal stenosis into two groups: the patients underwent surgery group and control group. The role of the physical field of SF-36 also showed significant differences between groups. It was observed that lumbar stenosis surgery did not improve pain in the short and medium term, but in the medium term, function and vitality were better in the operated group and patients were more satisfied with the surgical treatment. Researchers emphasize

that appropriate diagnostic procedures and treatments must be implemented to prevent further deterioration of physical functionality and quality of life (14).

In study of Almeida et al. a prospective study was conducted on 9 patients of both genders, aged between 18 and 60, who were scheduled for spine surgery due to degenerative disease in the lumbar segment, and found that the improvement achieved with spine surgery did not have a statistically significant relationship with fatigue, pain and fatigue in the lower extremities and lower back pain (15).

Yamamoto et al. in their study on lumbar spinal stenosis patients who underwent decompression surgery with and without fusion, they determined the medical outcomes before and 6 months after surgery using the SF-36 quality of life scale. Less severe preoperative low back pain was thought to be associated with patient dissatisfaction with lumbar surgery, but not with poorer mental health and higher levels of anxiety, depression, pain-catastrophizing pain or fear avoidance beliefs. The psychological state before and after surgery must be carefully evaluated and managed appropriately (16). Silverplats et al. the quality of life scales of 117 patients who were operated with the diagnosis of lumbar disc herniation between 1998 and 2002 were evaluated at the 2nd and 7th years after surgery. In 85% of the cases, improvement was found in the quality of life scale in the 2nd year after surgery, while improvement was found in 91% of the cases at the end of 7 years (17).

As a result, it seems that a successful surgical intervention and the surgical treatment of the existing pathological condition do not result in a complete perception of well-being in the patient. Of course, from a different perspective, knowing that the disease has relapsed or developed a relapse causes patients to consciously restrict their physical and functional activities. There are many factors such as choosing the right patient before surgical intervention and the information the patient receives about the intervention, the socioeconomic status of the patient and his family and their perception of the disease, the current health status of the patients and the comorbidities they bring with them. Patients have different expectations for recovery from surgical treatment, their professions and working conditions. In addition, our study has shown that choosing the right patient before surgical intervention and informing the patient about the intervention to be performed are of great importance.

Conclusion

In our study, when the patients' quality of life scale scores were compared with the values of Turkish society according to gender, their quality of life scores were found to be significantly lower than in the general population. When the early results of the surgical treatment for chronic low back pain are evaluated, it is seen that the pain is reduced and often eliminated, but it has been observed that it does not help the patients regain the correct body image, improve their functional abilities, and improve their quality of life in long-term follow-ups. In this case, before the surgery, especially the histories of the patients should be taken well, their expectations should be questioned, the benefits they can derive from surgery according to their age should be taken into account, and it should not be forgotten that the expectations and lifestyles of the people in the postoperative process are also extremely effective in well-being, no matter how well the surgery is performed.

Declarations

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This study has not received any financial support.

Conflicts of interest

The authors declare that they have no conflicts of interest regarding this study.

Ethical Consent

The study was approved by the local ethics committee of Nuh Naci Yazgan University (permission dated 22/04/2022 and numbered 2022-8146) and informed consent was obtained from all participants in accordance with the Declaration of Helsinki before they were permitted to complete the survey. Furthermore, approval for the study was granted by the local ethics committee of Kayseri City Hospital, with the ethics committee approval dated 10/05/2022 and numbered 61.

Availability of data and material

The data and material are available upon request.

Author Contributions

In their respective contributions, Op.Dr. GÖKTÜRK Ş. and Op.Dr. GÖKTÜRK Y. have provided insights into the intricacies of the project, encompassing the intricacies of project preparation, data collection, data analysis and statistics, preparation of tables, and the composition of scientific papers.

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Comparative Analysis of the Clinical and Criminal Characteristics of Male and Female Perpetrators of Homicide or Homicide Attempts in the Detention Ward

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ABSTRACT

Background: The aim of the study is to compare male and female cases who were in the prisoner service and committed murder/attempted murder in terms of clinical and criminal characteristics.

Methods: Information about 101 female and 101 male cases who were admitted to the prisoner service for murder and/or attempted murder were collected through a data form as a result of examining the hospitalization files.

Results: The rate of men having psychotic disorders (50.8%) was found to be higher than the rate of women (20.4%). While men's rates of having antisocial personality disorder are higher than women's rates, women's borderline personality disorder rates are significantly higher than men's rates. The rate of women's previous history of suicide (50.5%) is higher than the rate of men's history (35.6%). It was seen that the rate of women admitted to the service to be their first crime was higher (87.1%) than men (46.5%).

Conclusion: It is important to take gender-based differences into account and organize personalized treatment during the forensic treatment process. More clinical research on gender differences in homicide crimes is needed.

Key Words: Forensic psychiatry, homicide, gender

ÖZET

Amaç: Çalışmanın amacı tutuklu servisinde yatmış olan, cinayet/cinayete teşebbüs suçu işlemiş kadın ve erkek olguların klinik ve suça ilişkin özellikler bakımından karşılaştırılmasıdır.

Yöntem: Araştırma için tutuklu servisine cinayet ve/veya cinayete teşebbüs suçu ile yatışı olan 101 kadın olgu ve 101 erkek olguya ait sosyodemografik, klinik ve suça ilişkin bilgiler, yatış dosyalarının incelenmesi sonucu bir veri formu aracılığı ile toplanmıştır.

Bulgular: Psikotik bozukluğu olan erkeklerin oranı (%50,8) kadınların oranından (%20,4) daha yüksek bulunmuştur. Erkeklerin antisosyal kişilik bozukluğuna sahip olma oranları kadınlara göre daha yüksekken, kadınların borderline kişilik bozukluğu oranları erkeklerle göre anlamlı derecede yüksektir. Kadınların geçmiş intihar öyküsü oranları (%50,5), erkeklerin intihar öyküsü oranlarından (%35,6) daha yüksektir. Servise ilk suçu nedeniyle başvuran kadınların oranının (%87,1) erkeklerden (%46,5) daha yüksek olduğu görülmüştür.

Sonuç: Adli tedavi sürecinde cinsiyete dayalı farkların gözlemlenmesi ve kişiye özgü tedavi düzenlenmesi önemlidir. Homisid suçlarında cinsiyet farklılıklarına ilişkin daha fazla klinik araştırmaya ihtiyaç duyulmaktadır.

Anahtar Kelimeler: Adli psikiyatri, cinsiyet, cinayet

Murder is one of the most serious violent behaviors, and it has been reported that psychiatric disorders may also have an impact on homicidal behavior (1). Researches have focused on male perpetrators and less attention has been paid to female offenders (2, 3). The average murder rate, defined as the number of intentional homicides per 100,000 people in Turkey between 1997 and 2015, is 4.52. Only 10.84% of perpetrators were women (4).

The rate of psychiatric disorders in prisoners is significantly higher than the general population (1). Although the most common diagnoses are antisocial personality disorder (ASPD) and alcohol and/or substance use disorder, many psychiatric disorders are more common in prisoners than in the general population (5). The rate of men in terms of crime prevalence is found to be higher than women, therefore the literature in this field is based mostly on male case data (6, 7). Many studies on homicide report that the rate of major psychiatric disorders is higher in female criminals than in men (1, 8). It is stated that men are diagnosed with personality disorders at a higher rate and have a higher rate of alcohol/substance abuse (9). It is reported that the victim is more often a family member or an acquaintance in those with severe psychiatric disorders than in those without, and the rate of committing crimes against acquaintances is higher in women than in men (10).

The aim of this research was to collect and evaluate data on the demographic, clinical and criminological characteristics of male and female cases who committed murder or attempted murder, as well as data on clinical practices in psychiatric services; since such a study has not been conducted in our country before, it was thought that it could create a resource in this field in the future.

Material and Methods

The research population includes those who were hospitalized at Bakırköy Research & Training Hospital for Psychiatry, Neurology and Neurosurgery Prisoner Service between 01 January 2010 and 01 April 2017 for diagnosis, treatment and forensic procedures, and who are in prison for murder and/or attempted murder. It consists of 111 female and 481 male patients. The study was conducted through a retrospective examination of the case files. The sample of the research consists of 101 female and 101 male patients. The study started by accessing the files of female patients. First of all, the names of female cases with murder and/or attempted murder crimes were

taken retrospectively from April 2017, and those with recurrent hospitalizations were not included. 111 female cases who were incarcerated for related crimes between January 2010 and April 2017 were reached. The file of 1 case could not be accessed. The data of a total of 9 cases could not be included in the study due to the fact that the crime information in the hospital registration and the inpatient file did not match. Of the 110 female case files examined, 101 were found to meet the inclusion criteria for the study. To identify male cases, the registrations were examined, starting from April 2017 until January 2010, and those with similar recurrent hospitalizations were not included in the study for the second time. When those with recurrent hospitalizations were excluded, the names of 481 male cases related to the relevant crimes were obtained from the registration archive.

In order to equalize the number of male and female cases in the sample, 120 male cases were selected from 481 male cases in the study population by simple random sampling method. The hospitalization files of 5 of 120 male cases could not be accessed. Of the remaining 115 male cases, 14 cases were not included in the study because the information about the crime did not match in the protocol book and the inpatient file. It was determined that 101 of the 115 male cases examined in total met the inclusion criteria for the study. A total of 202 files, 101 files belonging to female cases and 101 files belonging to male cases, were examined and a data form prepared by the researcher was filled in.

The information of all cases was obtained by retrospective review from the inpatient registration book and the data in the inpatient files. A data form containing sociodemographic, clinical and criminal characteristics created by the researcher was used to obtain target data from the cases. Since participants who were hospitalized since 2010 were included in the study and DSM-IV was used until 2013, the diagnoses were classified in accordance with the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV).

Approval was received from Bakırköy Research & Training Hospital Ethical Committee on 04.04.2017 with the protocol number 4.

The questionnaire

The data form consists of demographic questions, clinical questions, and crime-related questions.

Data analysis

SPSS (version 26) program was used for statistical analysis of the data. Independent samples t-test was used to determine whether continuous variables differed in terms of gender, and Pearson chi-square test was used to compare categorical variables in terms of gender. While effect sizes in independent sample t-tests were presented as Cohen's d coefficient, effect sizes in chi-square tests were presented as Phi coefficient(ϕ) if the cross-tabs were 2x2 in size, and as Cramer's V coefficient if the cross-tabs were larger. Statistical significance was accepted as $p < 0.05$ in all analyses.

Results

Comparison of sociodemographic characteristics in terms of sex

As a result of comparing the demographic characteristics of the participants included in the study in terms of sex, age ($t(200)=1.290, p=0.198, d=0.18$), education period ($t(200)=0.742, p=0.459, d=0.11$) and it was determined that social support status ($\chi^2=0.181, p=0.671, \phi=0.03$) did not differ between women and men. The findings are included in Table 1.

Table 1: Comparison of sociodemographic characteristics in terms of sex

	Male (n= 101)	Female (n= 101)	Statistics	p	Effect size
Age (year), Mean \pm SD	30.53 \pm 12,32	32.58 \pm 10,15	$t(200)= 1.290$	0.198	0.18
Education (year), Mean \pm SD	7.50 \pm 2.98	7.11 \pm 4.30	$t(200)= 0.742$	0.459	0.11
Marital status			$\chi^2(2)= 42.058$	< 0.001	0.46
Married	20 (%19.8)	45 (%44.6)			
Single	58 (%57.4)	14(%13.8)			
Divorced	23 (%22.8)	42 (%41.6)			
Working status			$\chi^2(2)= 8.680$	0.013	0.21
Unemployed	52 (%51.5)	72 (%71.3)			
Not regular	17(%16.8)	12 (%11.9)			
Employed	32 (%31.7)	17 (%16.8)			
Social support			$\chi^2= 0.181$	0.671	0.03
Sufficient	43 (%42.6)	46 (%45.5)			
Insufficient/ none	58(%57.4)	55 (%54.5)			

SD: Standard deviation, p < 0.05

Comparison of crime-related characteristics in terms of sex
While the rate of women being admitted to the service due to the risk of suicide (65.4%) is higher than the rate of men (47.4%), the rate of men being admitted to the

service for other treatments (52.6%) is higher than the rate of women being admitted to the service for other treatments (34.6%) ($\chi^2= 5,211, p= 0,022, \phi=0,18$). Crime-related findings are included in Table 2.

Table 2: Comparison of crime-related characteristics in terms of sex

	Male (n= 101)	Female (n= 101)	Statistics	p	Effect size
Reasons for admission to the prisoner service			$\chi^2= 1.013$	0.314	0.07
Treatment	75 (%74.3)	81 (%80.2)			
Criminal responsibility	26 (%25.7)	20 (%19.8)			
Reason for treatment			$\chi^2= 5.211$	0.022	0.18
Suicide	36 (%47.4)	53 (%65.4)			
Other treatments	40 (%52.6)	28 (%34.6)			
Crime			$\chi^2= 1.836$	0.175	0.10
Murder	87 (%86.1)	93 (%92.1)			
Attempted murder	14 (%13.9)	8 (%7.9)			
Previous crime			$\chi^2= 37.541$	<0.001	0.43
Yes	54 (%53.5)	13 (%12.9)			
No	47 (%46.5)	88 (%87.1)			
Duration of stay in prison (days), Mean \pm SD	1916.9 \pm 1573.4	754.5 \pm 1023.8	$t(200)= 6.224$	<0.001	0.88
Repeated incarceration			$\chi^2= 53.989$	<0.001	0.52
No	49 (%48.5)	96 (%95.0)			
Yes	52 (%51.5)	5 (%5.0)			
Who the crime was committed against			$\chi^2= 30.606$	<0.001	0.39
Acquaintance	56 (%55.4)	91 (%90.1)			
Unknown	45 (%44.6)	10 (%9.9)			
Psychiatric history before treatment			$\chi^2= 4.063$	0.044	0.14
No	69 (%69.0)	54 (%55.1)			
Yes	31 (%31.0)	44 (%44.9)			

SD: Standard deviation, p < 0.05

Comparison of diagnosis and clinical features according to sex

Findings regarding the comparison of diagnoses are summarized in Table 3.

Table 3: Comparison of diagnosis of cases according to sex

	Male (n= 101)	Female (n= 101)	Statistics	p	Effect size
Malingering					
No	91 (%90.1)	100 (%99.0)	$\chi^2= 7.788$	0.005	0.20
Yes	19 (%9.9)	1 (%1.0)			
Substance use					
No	42 (%41.6)	83 (%82.2)	$\chi^2= 35.279$	<0.001	0.42
Yes	59 (%58.4)	18 (%17.8)			
Diagnosis in Axis I					
No	36 (%35.6)	8 (%7.9)	$\chi^2= 22.780$	<0.001	0.34
Yes	65 (%64.4)	93 (%92.1)			
Type of diagnosis in the Axis I	(n = 65)	(n = 93)	$\chi^2(3)= 18.808$	<0.001	0.35
Psychotic disorders	33 (%50.8)	19 (%20.4)			
Mood disorders	17 (%26.2)	26 (%28.0)			
Anxiety disorders	13 (%20.0)	44 (%47.3)			
Others	2 (%3.1)	4 (%4.3)			
Diagnosis in Axis II					
No	47 (%46.5)	69 (%68.3)	$\chi^2= 9.800$	0.002	0.22
Yes	54 (%53.5)	32 (%31.7)			
Type of diagnosis in the Axis II	(n = 54)	(n = 32)	$\chi^2(2)= 45.032$	<0.001	0.72
Antisocial personality disorder	50 (%92.6)	7 (%21.9)			
Borderline personality disorder	2 (%3.7)	15 (%46.9)			
Mental retardation	2 (%3.7)	10 (%31.3)			

p < 0.05

Men and women did not differ in terms of total number of hospitalizations ($t(199)=1.448$, $p=0.149$, $d=0.21$), number of hospitalizations to the forensic service ($t(199)=1.086$,

$p=0.279$, $d=0.15$) and length of stay in the forensic service ($t(199)=0.536$, $p=0.593$, $d=0.08$). Other findings regarding the comparison of clinical features are summarized in Table 4.

Table 4: Comparison of clinical features of cases according to sex

	Male (n= 101)	Female (n=101)	Statistics	p	Effect size
Total number of hospitalizations, Mean ± SD	3.12 ± 2.88	2.59 ± 2.23	$t(199)= 1.448$	0.149	0.21
Number of hospitalizations to the forensic service, Mean ± SD	2.47 ± 2.50	2.13 ± 1.93	$t(199)= 1.086$	0.279	0.15
Length of stay in the forensic service (days), Mean ± SD	117.21 ± 207.36	137.78 ± 323.67	$t(199)= 0.536$	0.593	0.08
Treatment during hospitalization					
Follow-up without medication	13 (%12.9)	9 (%8.9)	$\chi^2(2)= 0.821$	0.663	0.06
Pharmacological treatment	74 (%73.2)	77 (%76.2)			
Pharmacological + ECT	14 (%13.9)	15 (%14.9)			
Need for close observation during hospitalization					
No	38 (%37.6)	22 (%21.8)	$\chi^2= 6.069$	0.014	0.17
Yes	63 (%62.4)	79 (%78.2)			
Self mutilation history					
No	69 (%68.3)	82 (%81.2)	$\chi^2= 4.433$	0.035	0.15
Yes	32 (%31.7)	19 (%18.8)			
Suicide attempt just before hospitalization					
No	75 (%74.3)	73 (%72.3)	$\chi^2= 0.101$	0.751	0.02
Yes	26 (%25.7)	28 (%27.7)			
Suicide history					
No	65 (%64.6)	50 (%49.5)	$\chi^2= 4.543$	0.033	0.15
Yes	36 (%35.6)	51 (%50.5)			
Suicide during hospitalization					
No	101 (%100.0)	99 (%98.0)	$\chi^2= 2.020$	0.155	0.10
Yes	0	2 (%2.0)			
Recidivism					
No	48 (%47.5)	53 (%52.5)	$\chi^2= 0.495$	0.482	0.05
Yes	53 (%52.5)	48 (%47.5)			

SD: Standard deviation, p < 0.05

Discussion

The rates of being married or divorced among women included in the study were found to be higher than male participants. In a study from Finland in which 91 female and 658 male cases who committed the crime of homicide found that 67% of the female cases were in a relationship, 50% were living with their partners, and 41% of the male cases were found to be living with their partners at the time of the crime (11). The fact that the marriage rate of female cases is higher than male cases' in our sample may be due to factors such as prioritizing the concept of traditional family in Turkey and encouraging women to get married (12); it is thought that this may be related to the higher history of repetitive crime in male cases, and therefore the longer time spent in prison (13).

In the sample of our study, there is no difference between male and female subjects in terms of education period, but it is noteworthy that most of the general sample's education period is 8 years or less. It is known that the risk of committing crime is associated with low education level (14). It has been thought that low education level may be associated with the risk of committing crime in patient groups, regardless of sex (15).

51.5% of the male subjects and 71.3% of the female subjects included in the study did not work in any job before going to prison. In the study by Türkcan et al., where they examined 1831 cases applying to forensic psychiatry, the unemployment rate was 50.2% (16). In Öncü et al.'s (2007) study, in which they compared 70 male cases followed in the forensic ward due to preventive treatment and 70 male cases followed in the acute ward in terms of socioeconomic factors in the patients' committing crimes, unemployment and social insecurity were found to be two separate independent variables that increase the risk of committing crimes (17). The high unemployment rates in our study, consistent with research, can be explained by the low education level of the subjects, a history of repeated crimes and prisons, a higher incidence of psychiatric disorders, alcohol and substance use disorders, and ASPD.

Social support was found to be inadequate in more than half of the cases in the study. Just as negative socioeconomic factors are effective in both the emergence and prognosis of psychiatric disorders, cases with psychiatric disorders may be deprived of this support due to their illness (18). It was thought that it became difficult for them to receive visits due to the presence of a pre-existing psychiatric disorder and the fact that our hospital accepts cases from many provinces of Turkey, as it is a high security service,

and therefore the physical distance between patients and their relatives increases.

In our study, 78.2% of female cases and 62.4% of male cases were kept under close observation. It is reported that antisocial characteristics and criminal history increase rates of physical restraint (19). Since nearly half of our patients hospitalized for treatment were referred due to the risk of suicide or homicide, it was thought that the rate of close observation was high in relation to these risks.

The average length of stay in prison for female cases was lower than males'. It was thought that the longer sentence periods were due to the crime of murder being punished with long-term imprisonment, and the fact that the average sentence period in male cases was found to be longer than in female cases was related to the higher rates of repeat crime in male cases. Studies examining hospital readmissions and recidivism emphasize the negative impact of unemployment, lack of education, and inadequacy of social support systems (19). It is thought that one of the reasons for the high rate of repetitive crime in male cases is the higher number of individuals diagnosed with ASPD in this group.

In a study examining the psychiatric hospitalizations of prisoners, 45.1% of the cases were detainees and convicts brought for emergency treatment; while 26.8% of the cases were sent by the court to determine the risk to society, 12.7% were the convicts who will complete their sentences in the hospital after trial, it was stated that these cases were transferred to various psychiatric units and medium security services (20). Since the prisoner service, where we conducted our study, there may be differences in the indications for hospitalization and diagnosis distribution. The majority of our sample consists of cases hospitalized for treatment purposes. In high security services of developed countries, the majority of cases consist of psychiatric patients who have committed a crime and whose criminal liability has been removed, and people who may or may not have committed a crime but are dangerous (18).

It was stated that being in prison increased the risk of suicide by 9 times in women and 3 times in men compared to those in the general population (21). It is emphasized that weakness in social support, previous suicide attempts, and previous psychiatric history should be taken into consideration to prevent the risk of suicide in prisons (22). Although the lack of social support stands out for both genders in our sample, the fact that the female cases were entering prison for the first time and that almost all of them were diagnosed with an Axis I psychiatric disorder may explain the higher past suicide rates in women than in men.

It was observed that 92.1% of female cases were diagnosed in the Axis I. Of those diagnosed on Axis I, 20.4% were diagnosed with psychotic disorders, 28% with mood disorders, and 47.3% with anxiety disorders. Most of the 31.7% women diagnosed in the Axis II were diagnosed with BPD. It was observed that 64.4% of male cases were diagnosed in the Axis I field. Of those diagnosed on Axis I, 50.8% were diagnosed with psychotic disorders, 26.2% were diagnosed with mood disorders, and 20% were diagnosed with anxiety disorders. Of the 54 men diagnosed in the Axis II field, 92.6% were diagnosed with ASPD. In a study examining 961 male and 126 female homicide offenders, 77.4% of males and 70.8% of females were diagnosed with schizophrenia, 15.1% of males and 29.2% of females were diagnosed with major depressive or manic episodes. In another study examining 4572 homicide offenders found that 7% of female cases had schizophrenia, 14% had a mood disorder, and 11% had a personality disorder, and in male cases, these rates were 6%, 5%, and 6%, respectively (23). Although there are different rates from country to country, it is noteworthy that ASPD is more common in men and BPD in women, in line with our study. Other studies have used psychosis spectrum differences, probably due to differences in sample selection and forensic psychiatric functioning (24). Substance use disorder and ASPD diagnoses have been shown to be strongly associated with criminal behavior (25). Recidivism rates of individuals with both ASPD and substance use disorder have significantly increased, and as is known, the coexistence of these two diagnoses is quite common (25). Our results support the relationship between alcohol/substance use and homicide.

In a study examining the behavior of malingering in 20 homicide offenders sent to forensic psychiatry to determine criminal responsibility, it was determined that almost half of the cases had personality disorders and substance use, and 30% of the cases malingered (26). In our sample, criminal responsibility was asked for 24 out of 101 female cases and 27 out of 101 male cases. Only 1 out of the female cases and 19 out of the male cases were diagnosed with malingering behavior. It is thought that the higher rate of malingering behaviors diagnosed in male cases is related to the higher rate of ASPD in male cases.

In the study of Rossegger et al. (2009) examining female cases who committed violent crimes, it was stated that 46.7% of female cases had a previous criminal record, while this number was stated to be 60.8% for men (14). It is thought that the higher rate of repetitive crime in male cases than in female cases in our sample is related to the higher number of cases with ASPD, the lower number of

Axis I diagnoses in men than in female cases, the lower number of past treatment histories than in female cases, and the higher rate of alcohol/substance abuse.

In studies conducted on serious psychiatric illnesses and violent crimes against individuals, it has been found that the victim is more often a family member or acquaintance in those with severe psychiatric illness than in those without, and the rate of committing crimes against acquaintances is higher in women than in men (10, 27-29). Women who use violence are also reported to be more likely to have experienced trauma, substance abuse and mental health problems, and to target people they are in close relationships with or know (7, 14). In our female sample, the rate of crime committed against acquaintances is 90.1%. The higher rate of committing a crime against acquaintances in female cases than in male cases is due to the higher rate of major psychiatric disorders in women, the higher rate of diagnosis in the Axis I area, the lower rate of Axis II diagnoses, and the lower rate of major psychiatric disorder in male cases. It was thought that factors such as the relatively low rate of Axis I diagnosis, the high rate of Axis II diagnosis and especially the ASPD, and the high rate of alcohol/substance abuse may be related to the higher rate of crime committed against strangers.

This study has some important limitations. First of all, our study was designed as a retrospective file scan. This caused us to only benefit from file information while collecting data. For this reason, some data may have been missing. Personality disorder diagnoses may not be written on the file in order to prevent stigmatization, and this may have affected the statistics regarding the distribution of diagnoses. In the operation of the Prisoner Service, the treatment team changes periodically, so different physicians made the diagnosis. The study data are between January 2010 and April 2017. Until 2013, diagnoses were made according to DSM-IV TR, and after 2013, they were diagnosed according to DSM-5. Since most of the data were diagnosed according to DSM-IV, this was taken as the basis when collecting the data.

Conclusion

Female cases are more likely to have attempted suicide before coming to the service and have a history of attempted suicide, while male cases are more likely to have a history of self-mutilation. While the rate of women having a diagnosis in the Axis I field is higher than men, the rate of men having a diagnosis in the Axis II field is higher than women. It has been observed that most of the crimes

committed by women are against acquaintances. Based on these results, it is thought that more gender-sensitive treatment strategies are needed in forensic psychiatry. Repeating our findings on male and female cases who committed murder and were hospitalized for forensic psychiatric treatment in larger sample groups where they are evaluated cross-sectionally or prospectively will increase our knowledge in this field.

Declarations

Ethics Approval

Ethical approval was received from Bakırköy Research & Training Hospital Ethical Committee (04.04.2017;4).

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Conflicts of Interest

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Authors' Contributions

AK: Writing–review&editing, Writing–original draft, Methodology, Formal analysis, Data curation, Conceptualization. **EC:** Writing–review&editing, Writing–original draft, Validation, Conceptualization. **ÖDB:** Writing–review&editing, Validation, Supervision, Resources, Methodology, Data curation, Conceptualization.

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Evaluation of the Quality and Reliability of YouTube Videos on Gender Dysphoria

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ABSTRACT

Purpose: Many people search for information on YouTube on almost every medical topic. The aim of this study was to assess the quality and reliability of YouTube videos concerning Gender Dysphoria.

Methods: We searched for Gender Dysphoria on YouTube on June 7, 2023 and conducted a detailed evaluation of the first 100 unique English videos by two expert observers. The videos were evaluated using modified DISCERN scale, Global Quality Scale (GQS), and Video Power Index (VPI).

Results: The kappa coefficient for interobserver agreement was 0.892. For all 100 videos, the median value of the modified DISCERN score was 2.5 (1-4.8), and GQS score was 3 (1-5), and 68% of the videos rated as poor to moderate reliability and quality (modified DISCERN score ≤ 3 , GQS ≤ 3). Reliable videos were uploaded by professional sources in a higher rate than unreliable videos (48% vs 12%, $p < 0.001$). Reliable videos had significantly higher modified DISCERN and GQS scores (3 vs 1.6, $p < 0.001$, 3.5 vs 2, $p < 0.001$; respectively). There were some significant correlations between some video characteristics and scores of quality and reliability scales. However, there was no significant difference between reliable and unreliable videos in terms of the popularity of video and no significant correlation between modified DISCERN and GQS scores and VPI ($p = 0.664$, $p = 0.201$, $p = 0.566$; respectively).

Conclusion: YouTube video quality for Gender Dysphoria was low to moderate, with a remarkable number of unreliable videos. There was no relation between video quality and popularity.

Keywords: Gender dysphoria, youtube, internet, video, quality, reliability

ÖZET

Amaç: Birçok kişi YouTube'da hemen hemen her tıbbi konuda bilgi aramaktadır. Bu çalışmanın amacı, Cinsiyet Hoşnutsuzluğu ile ilgili YouTube videolarının kalitesini ve güvenilirliğini değerlendirmektir.

Yöntemler: YouTube'da 7 Haziran 2023 tarihinde Cinsiyet Hoşnutsuzluğu ile ilgili arama yaptık ve ilk 100 İngilizce videoyu iki uzman gözlemci tarafından ayrıntılı olarak değerlendirdik. Videolar modifiye DISCERN, Global Kalite Ölçeği (GQS) ve Video Güç Endeksi (VPI) ile değerlendirildi.

Bulgular: Gözlemciler arası uyum için kappa katsayısı 0.892'dir. Yüz videonun tamamı için modifiye DISCERN skorunun medyan değeri 2,5 (1-4,8) ve GQS skoru 3 (1-5) olup videoların %68'i zayıf ila orta derecede güvenilir ve kaliteli olarak değerlendirilmiştir (modifiye DISCERN skoru ≤ 3 , GQS ≤ 3). Güvenilir videolar, güvenilir olmayan videolara kıyasla daha yüksek oranda profesyonel kaynaklar tarafından yüklenmiştir (%48'e karşı %12, $p < 0,001$). Güvenilir videoların modifiye DISCERN ve GQS puanları önemli ölçüde daha yüksektir (sırasıyla, 3'e karşı 1,6, $p < 0,001$, 3,5'e karşı 2, $p < 0,001$). Bazı video özellikleri ile kalite ve güvenilirlik ölççeklerinin puanları arasında bazı anlamlı korelasyonlar vardı. Ancak, güvenilir ve güvenilir olmayan videolar arasında videonun popülerliği açısından anlamlı bir fark bulunmamış ve modifiye DISCERN ve GQS puanları ile VPI arasında anlamlı bir korelasyon görülmemiştir (sırasıyla, $p = 0,664$, $p = 0,201$, $p = 0,566$).

Sonuç: Cinsiyet Hoşnutsuzluğu için YouTube video kalitesi düşük ila orta düzeydeydi ve kayda değer sayıda güvenilir olmayan video vardı. Video kalitesi ile popülerlik arasında bir ilişki bulunmamıştır.

Anahtar Kelimeler: Cinsiyet hoşnutsuzluğu, youtube, internet, video, kalite, güvenilirlik

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Gender identity is a profound internal sense of affiliation with a man, or male, a woman, or female, or other gender (such as gender non-conforming, genderqueer, gender neutral, etc.) (1). The distress experienced by the individual due to the incongruence between their physical sex and gender identity is called gender dysphoria (2). The diagnosis of Gender Dysphoria (GD) was defined in the latest version of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) (3). Individuals with GD feels their gender identity that does not match the gender roles and societal expectations to their birth-assigned gender roles. This incongruence can lead to feelings of unease, restlessness, or internal conflict, which can have negative effects on mental health (4). The rate of people diagnosed with GD in the adult population is approximately one in a thousand individuals (3). Gender Dysphoria usually starts in early childhood, but it takes up to more than 20 years to seek transition (5,6). In order to alleviate the distress experienced by individuals due to GD, gender-affirming psychotherapy, hormone use, and surgical interventions may be recommended to appropriate individuals (7).

Individuals with GD and their families often turn to the internet for more information about GD (8). Video-sharing platforms also play a pivotal role in this information-seeking endeavor. YouTube is one of the most-watched internet platforms that has billions of users. Although it has significant potential to provide people with health-related information, the videos are uploaded not only by health professionals but also by non-professionals and there is no control mechanism for uploaded videos. There are numerous studies in the literature investigating the reliability and quality of YouTube videos addressing various health-related conditions (9,10,11,12). Previous research on YouTube videos showed that between one-third to half of videos about various medical conditions contain misleading information (13,14,9,15). Therefore, health-related videos should be questioned for accuracy, reliability, and quality before viewing.

However, there are currently no studies on the quality of videos on GD on YouTube of particular interest to individuals with gender dysphoria and their families. The aim of this study was to evaluate the content, reliability, and quality of YouTube videos on GD.

Material and Methods

Procedures

The YouTube website was searched for the term “gender dysphoria” using Google Chrome in incognito browser

mode without any filters (default mode) on June 7, 2023. The first 100 videos in English were included in the study. Two observers independently and simultaneously rated each video using the Qualtrics survey program. One of them was a psychiatrist and the other a clinical psychologist and both were EFS & ESSM certified psycho-sexologists. The videos were evaluated for reliability using the modified DISCERN scale, for quality using the Global Quality Scale (GQS), and for popularity using the Video Power Index (VPI). In addition, we assessed the degree of misinformation (containing information contradictory to established literature and/or current guidelines) in the videos using a 4-point scale (1-4), with numbers corresponding to none, low, medium, and high. This method has already been used in several previous studies (13,10,16). The YouTube videos were classified as reliable if they contained medically accurate information about GD. Medically accurate information about GD is seen as the definition, management, and social and medical transition processes of GD according to the DSM-V by the American Psychiatric Association, Standards of Care for the Health of Transgender and Gender diverse People by the World Professional Association for Transgender Health, and guidelines for psychological practice with transgender and gender nonconforming people by American Psychological Association (1,3,7). If a video contained both unreliable and reliable information, it was classified as unreliable.

Video characteristics such as the duration of the video, the total number of views, likes, dislikes, comments, and days, and the source of the video (uploader) and speaker of the video were recorded. Video Power Index that indicates the popularity of videos based on daily views, like, and dislike counts. The like rate was calculated using the formula $(\text{number of likes} \times 100) / (\text{number of likes} + \text{number of dislikes})$ and daily views were calculated using the formula $\text{total views} / \text{number of total days}$. Then, the Video Power Index of the video was calculated according to the formula $(\text{like rate} \times \text{daily views}) / 100$ based on the previous studies (10,11,17,18).

The uploaders of the videos were classified into professional sources (university, hospital, physician/psychologist) and non-professional sources (TV-YouTube channel, foundation, others). The speakers of the videos were classified as physician/psychologist, individuals with GD, others (YouTuber, TV speaker), and animation (no speaker).

Measurements

The DISCERN scale is a reliable and validated tool designed to help consumers of health information in assessing the quality of healthcare literature (19). It can be used by anyone without the requirement of specialized expertise. We used a modified 5-question DISCERN scale, with each question scored on a 5-point scale (16). The total score for the modified DISCERN is averaged and scaled to range between 1 and 5. Modified DISCERN scores within the range of video scores of 3-5 points indicate good, a score of 3 points indicate moderate, and scores 1-3 points indicate to poor reliability (Table 1). All videos were evaluated for the reliability of their content using the modified DISCERN scale.

Table 1: Modified DISCERN and Global Quality Scale		
Modified DISCERN		Reliability
1-Were aims clear and achieved?	1	Poor
2-Were the sources of information reliable?	2	Poor
3-Is the information balanced and unbiased?	3	Moderate
4-Are additional resources to learning provided?	4	Good
5-Does the video address areas of controversy/uncertainty?	5	Good
Global Quality Scale		Quality
Poor quality, very unlikely to be of any use to patients.	1	Poor
Poor quality but some information present, of very limited use to patients.	2	Limited
Suboptimal flow, some information covered but important topics missing, somewhat useful to patients.	3	Moderate
Good quality and flow, most important topics covered, useful to patients.	4	High
Excellent quality and flow, highly useful to patients	5	Excellent
<p><i>DISCERN scores: 1 and 2: poor reliability, 3: moderate reliability and 4 and 5: good reliability.</i></p> <p><i>Global Quality Scale: 1: poor quality, 2: limited quality, 3: moderate quality, 4: high quality and 5: excellent quality.</i></p>		

The GQS (Global Quality Score) scoring system which is introduced by Bernard et al. (2007) is used to assess the overall quality of the video (20). The scale provides information about the adequacy of the information in the video, the quality of that information, the overall flow of information, and how useful the author found the video for the audience. The observer should be qualified in the subject area. The quality of the video is evaluated through a 5-point scale. GQS scores within the range of 1-3 are classified as low quality, a score of 3 as medium quality, and a score of 4-5 as high quality (Table 1).

Statistics

Descriptive statistics of the data obtained from the study are given with median and range for numerical variables, while frequency and percentage analyses were employed for categorical variables. Modified DISCERN and GQS scores of the observers were averaged to calculate the mean scores. To assess the normal distribution of GQS and modified DISCERN scores, Kolmogorov–Smirnov and Shapiro–Wilk tests were conducted. Inter-rater agreement was determined using the kappa coefficient. Inter-rater reliability was measured by calculating the intraclass correlation coefficient. The data were not compatible with a normal distribution ($p < 0.05$). To explore the correlation between numerical variables, Spearman correlation analysis was implemented. In addition, for categorical variables featuring two groups, the Mann–Whitney U test was used to analyze GQS and modified DISCERN scores. The analyses were carried out with SPSS 22.0 software with a selected significance level of $p < 0.05$.

Ethical approval was not obtained since the study utilized publicly accessible videos and no human or animal subjects were used. Since all data used in this study were publicly available, permission from YouTube was not required. All confidential information, such as the name of the uploader, was maintained in strict confidence.

Results

The first 100 unique English videos about GD on YouTube were analyzed. One video was excluded due to duplication, while 5 videos were excluded owing to non-English content. The level of agreement between the 2 observers when classifying the videos as reliable and unreliable was highly positive (kappa coefficient= 0.892). The intraclass correlation coefficient was 0.908 for modified DISCERN and 0.873 for GQS, indicating a great reliability between the 2 observers for both tools.

Among the 100 videos, 61 videos were categorized as reliable, while 39 of them as unreliable that including inaccurate or misleading information concerning GD. The duration of the video, the number of followers, total views, likes, dislikes, and comments, daily views, like rate, VPI, source of video, and speaker of the video were shown in

Table 2. A notable rate of videos (67%) was uploaded by non-professional sources. Sixty-eight % of the videos rated as poor to moderate reliability and quality (modified DISCERN score ≤ 3 , GQS ≤ 3). For all 100 videos, the median value of the modified DISCERN score was 2.5(1-4.8), and GQS score was 3(1-5).

Table 2: Comparison of video engagement metrics and evaluation scales according to reliable and unreliable videos.

	Total (n=100) Median (range) or n (%)	Reliable (n=61) Median (range) or n (%)	Unreliable (n=39) Median (range) or n (%)	Z / χ^2	P
Characteristics of videos					
Duration (m)	10 (1-114)	9.7 (1-114)	11.3 (1.7-95.8)	-1.707	0.088
Number of followers	28,000 (36-38,400,000)	28,000 (36-38,400,000)	11,300 (36-38,400,000)	-1.313260	0.189
Number of total views	7,990 (100- 1741892)	13,815 (100-1741892)	5,243 (270-1330230)	-1.862150	0.063
Number of likes	342 (0-201,851)	537 (0-201,851)	181 (8-75,694)	-2.010605	0.044
Number of dislikes	13.5 (0-5137)	16 (0-3698)	7 (0-5137)	-1.217043	0.224
Number of comments	104.5 (0-13456)	141 (0-12521)	53 (1-13456)	-1.067717	0.286
Number of total days	737,5 (17-4897)	866 (17-4897)	591 (20-2506)	-0.872344	0.034
Number of daily views	144.443 (0233-18773,177)	18,440 (0,233-18773,177)	11.825 (0.295-1068,650)	-0.462887	0.643
Like rate	97.893 (0-100)	98.371 (0-100)	96.154 (50-100)	-0.998993	0.318
Video Power Index	13.741 (0-1540.171)	15.549 (0-15400.171)	10.706 (0.204-1021.875)	-0.434619	0.664

Uploader of video					
Professional account	33	29 (48%)	4 (12%)	14.957674	< .001
Non-professional account	67	32 (52%)	35 (88%)		
Speaker of video					
Professionals	52	29 (47.5%)	23 (59%)	8.417280	0.038
Subject	33	25 (41%)	8 (20.5%)		
Others	10	3 (5%)	7 (8%)		
Animation (no speaker)	5	4 (6.5%)	1 (2.5%)		

Scales					
Modified DISCERN	2.5 (1-4.8)	3.00 (1.8-4.8)	1.6 (1-3.6)	-6.429754	< 0.001
Global Quality Scale	3 (1-5)	3.5 (2-5)	2.0 (1-3)	-7.496546	< 0.001

Values of $p < 0.05$ were accepted as significant and marked in bold.

The number of likes and total days were significantly higher in the reliable videos than in the unreliable ($p < 0.05$). However, there was no significant difference between reliable and unreliable groups according to the VPI value ($p = 0.664$). Reliable videos were uploaded by professional sources in a higher rate than unreliable videos, and unreliable videos were uploaded by non-professional sources at a higher rate than reliable sources (48% vs 12%, $p < 0.001$, 88% vs 52%, $p < 0.001$; respectively). There were significant differences in speaker type of the video between reliable and unreliable groups ($p < 0.05$). Especially the proportions of physician/psychologist and individuals with GD as speakers in the reliable group differed from the proportions in the unreliable group (%47.5 and %41 vs %59 and

%20.5). Reliable videos had a significantly higher modified DISCERN and GQS scores than the unreliable videos (3 vs 1.6, $p < 0.001$, 3.5 vs 2, $p < 0.001$; respectively).

Videos uploaded by professional sources had greater modified DISCERN and GQS scores ($p < 0.001$, $p < 0.001$; respectively) in comparison to those uploaded by non-professional sources (Table 3). There were significant correlations between modified DISCERN score and number of followers, total views, likes, dislikes, comments, and total days. Similarly, there were correlations between the GQS score, and the number of total views and total days. However, there was no significant correlation between modified DISCERN and GOQ scores and the VPI value ($p = 0.201$, $p = 0.566$; respectively) (Table 4).

Table 3: Comparison of video evaluation tool scores according to professional and non-professional sources.

Scales	Professional n=33 Median (range)	Non-professional n=67 Median (range)	Z	P
Modified DISCERN	3.8 (1-4.8)	2.3 (1.1-4.2)	-5.921161	< 0.001
Global Quality Scale	3.5 (1-5)	2.5 (1-4)	-4.540107	< 0.001

Values of $p < 0.05$ were accepted as significant and marked in bold.

Table 4: Correlation analyses for Global Quality Scale and modified DISCERN scores of the videos.

Scales	Modified DISCERN		Global Quality Scale	
	r	p	r	p
Duration	-0.016	0.874	0.190	0.848
Number of followers	0.199597	0.046	0.093731	0.354
Number of total views	0.265951	0.007	0.234169	0.019
Number of likes	0.215394	0.031	0.192575	0.055
Number of dislikes	0.231448	0.020	0.168928	0.093
Number of comments	0.203002	0.049	0.129506	0.214
Number of total days	0.207169	0.038	0.232559	0.012
Number of daily views	0.134341	0.182	0.048907	0.629
Like rate	-0.121679	0.227	-0.064007	0.527
Video Power Index	0.129001	0.201	0.058037	0.566

Values of $p < 0.05$ were accepted as significant and marked in bold.

Discussion

In this study, we aimed to analyze the 100 most relevant videos concerning GD on the YouTube channel to evaluate these videos in terms of reliability and quality. Previous studies have evaluated the quality and reliability of YouTube videos for different medical conditions, such as premature ejaculation, erectile dysfunction, rheumatologic disease, body dysmorphic disorder, gender-affirming surgery, self-breast examination, and rheumatoid arthritis (9,10,11,13,14,17,18). To our knowledge, this was the first in-depth study to assess the reliability and quality of information regarding GD on YouTube.

Our results showed that 39% (n=39) of videos that containing misleading and/or unreliable information were identified as unreliable and, 68% (n=68) of videos exhibited a level of reliability and quality ranging from poor to moderate based on modified DISCERN and GQS scores. We found that reliable videos had significantly higher quality and reliability scores than unreliable videos. Consistent with our study, two separate studies that analyzed the quality of information on YouTube regarding premature ejaculation and erectile dysfunction, demonstrated that 30% and, 28% of the videos, respectively, were not reliable (10,13). In another study analyzing the quality and reliability of YouTube videos on a rheumatologic disease indicated that 46% of the videos were of low to moderate reliability and 56% of low to moderate quality (11). In a study that analyzed erectile dysfunction videos on TikTok, it was reported that 80% of the videos were not reliable (16). Another study of Vulvodynia videos on YouTube reported that 58% of the videos were of low quality (21). A recent systemic review assessing the reliability of health-related videos on YouTube showed that YouTube is not a reliable source of medical and health-related information (22). A study reported that many popular YouTube videos about prostate cancer contain biased and/or low-quality information (23). Currently, there were reported some misconceptions and scientific misinformation about gender dysphoria and gender-affirming care. (24,25).

We found that reliable videos were uploaded by professional and non-professional sources with nearly equal proportions, while unreliable videos were mostly uploaded by non-professional sources. Our study findings were in accordance with findings of previous studies that showed the better video quality in content uploaded by professional sources (21,26). Physician/psychologists were the most frequent speakers in the videos, while individuals

with GD coming second. Although the proportion of physician /psychologists as speakers in unreliable videos was higher than in reliable videos, the proportion of individuals with GD as speakers was higher in reliable videos. In previous studies, it was shown that video uploaders were primarily professional sources, and secondarily patients (10,22,27). A study that analyzed YouTube videos on gender affirmation surgery showed that videos uploaded by professional sources were of higher quality than compared to those uploaded by patients (17). Principally, professional sources should provide more reliable videos. It was found that videos uploaded by professional sources had greater reliability and quality than those uploaded by non-professional sources. Nevertheless, our investigation revealed that physician/psychologists also played a role in generating unreliable content. These results were similar to outcomes observed in a few studies evaluating the effects of YouTube videos (13,14). We found that unreliable videos have a higher rate of physician/psychologists as speakers, thereby the source of the uploader is more important for reliability.

When we compared the reliable and unreliable groups based on video characteristics, we found that the reliable videos had a higher number of likes and total days. However, there was no difference between the two groups in terms of video popularity. Additionally, we showed correlations between reliability scores and the number of views, likes, dislikes, comments, followers, and total days. Similarly, there were some correlations between quality scores and the number of views, and total days. However, there was no correlation between reliability and quality, and video popularity. Consistent with our results, previous studies have similarly not found a relationship between video popularity and quality (10,18,22). Furthermore, another study revealed an inverse relationship between video quality and popularity (23). These results showed that unreliable videos that disseminated misinformation were as popular as reliable videos.

YouTube, boasting an extensive user base, stands as one of the most prevalent social media platforms. With the widespread use of the internet, the number of people watching video content on these platforms is steadily increasing. Individuals dealing with gender dysphoria often face obstacles when trying to access crucial healthcare services (28). As a result, they might choose to navigate social media platforms in search of information about their dysphoria, aiming to avoid instances of discrimination. Moreover, these platforms are used for sharing experiences where individuals can benefit from the experiences of

other individuals with gender dysphoria (29). However, health-related information gleaned from the internet can be incomplete and misleading (9,22). Although it is impossible to control all the data available on YouTube, further research into assessing video quality could lead people to use these platforms more appropriately.

This study has some limitations. Firstly, we only included videos in English, therefore generalizations cannot be possible in other languages. Additionally, there is no clear consensus on how to evaluate the quality of the videos on health-related videos. However, we used two scales that are commonly used in previous studies (22). Finally, we should also acknowledge the possibility of obtaining different results when conducting similar searches at different times. Despite these limitations, the current study can be considered an assessment of the GD on YouTube videos at a specific time.

Conclusion

In this study, it was determined that YouTube videos concerning GD are mainly uploaded by non-professional sources and exhibiting a range of low to moderate video quality. More than one of third of videos are unreliable that contain misleading information. There is no relation between the video quality and popularity. The quality of the video is not always be determined by the speaker; the source of the video is very crucial for video quality. Therefore, universities, health organizations and other professional sources specialized in this field should produce high quality videos with accurate insights into GD.

Declarations

Disclosure of Interest

The authors declare that they have no conflict of interest.

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No financial support or scholarship has been received for this research.

Ethics Committee Approval

This study was exempt from ethical approval of the study institution because it involved the use of public access data only.

Data-Sharing

The data that support the findings of this study are available from the corresponding author with request.

Authors' Contributions

Concept – A.B.Ş., O.Ç.; Design – A.B.Ş., O.Ç.; Supervision – A.B.Ş.; Resources – A.B.Ş., O.Ç.; Materials – A.B.Ş., O.Ç.; Data Collection and Processing - A.B.Ş., O.Ç.; Analysis and/or Interpretation A.B.Ş., O.Ç.; Literature Review – A.B.Ş., O.Ç.; Writing – A.B.Ş., O.Ç.; Critical Review - A.B.Ş., O.Ç.

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Consultation-Liaison Psychiatry (CLP): Examination of the Psychiatric Consultations for Inpatients and from the Emergency Medicine in a University Hospital

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ABSTRACT

Objective: Consultation liaison psychiatry (CLP) manages the psychiatric care of patients admitted to a general hospital for somatic reasons. Improvements in CLP ensure that the treatment process is effective.

Methods and Methods: In two years, 1398 patients consulted from inpatient services were included in the psychiatry service. In the study, descriptive statistical analysis showed the number of patients in inpatient services, the reasons for consulting the psychiatry clinic of these patients, the results of psychiatrist evaluations, and the quantitative and qualitative characteristics of interdepartmental psychiatric consultations.

Results: According to the number of inpatients, it was determined that psychiatry consultation requests were more frequent in intensive care units (5.60%), internal services (3.36%), and surgical services (1.23%). The most common consultation result was delirium (21.1%). As a result of the consultation evaluation, the diagnoses were determined as delirium, depression, and anxiety disorder, respectively; It was found that all three diagnoses were made in patients in the internal medicine service.

Conclusion: A lower rate of mental illness was detected in the general hospital sample compared to epidemiology studies. This situation is experienced in the process of recognizing and defining a psychiatric disorder; It may be due to features such as the primary treatment department of the patient, the nature of the patient's primary disease, and the presentation of the mental disorder.

With the study, awareness of CLP was raised, and descriptive features were emphasized.

Keywords: Consultation–liaison psychiatry; general hospital; psychosomatic medicine; inpatients.

ÖZET

Amaç: Konsültasyon liyezon psikiyatrisi (KLP), somatik nedenlerle genel hastanelere başvuran hastaların psikiyatrik bakımını yönetir. KLP'deki iyileşmeler tedavi sürecinin efektif olmasını sağlamaktadır.

Gereç ve Yöntem: Çalışmaya 2 yıllık süreçte psikiyatri servisine, yataklı servislerden konsültasyon yolu ile danışılan 1398 hasta dahil edildi. Tanımlayıcı istatistiksel analizler kullanılarak aynı süreçte yataklı servislerde yatan hasta sayıları, bu hastaların psikiyatri kliniğine danışılma nedenleri, psikiyatrist değerlendirme sonuçları ve departmanlar arası psikiyatri konsültasyonlarının nicel ve nitel özellikleri gösterildi.

Bulgular: Yatan hasta sayısına göre; yoğun bakım servislerinde (%5,60), dahili servisler (%3,36) ve cerrahi servislere (%1,23) göre daha sık psikiyatri konsültasyon talebi olduğu tespit edildi. Çalışma sonucunda en sık psikiyatri kliniğine danışılma nedeni ajitasyon (%13,6) iken en sık konulan konsültasyon sonucu tanı ise deliryum (%21,1) oldu. Konsültasyon ile değerlendirme sonrası en sık konulan tanıları sırasıyla deliryum, depresyon ve anksiyete bozukluğu olarak tespit edildi; her üç tanın da en sık konulduğu klinik servis dahiliye servisiydi.

Sonuç: Çalışma sonucunda, epidemiyoloji çalışmalarına oranla, genel hastane örnekleminde daha düşük oranda ruhsal hastalık tespit edilmiştir. Psikiyatrik bozuklukları tanıma ve tanımlama sürecinde yaşanan bu durum; hastanın primer tedavi departmanı, hastanın primer hastalığının niteliği, ruhsal bozukluğun prezantasyonu gibi özelliklerden kaynaklanabilir.

KLP çalışmaları hem hastaların hem sağlık hizmet sunucularının sağlık sonuçlarını iyileştirmek için önemli bir araçtır. Bu çalışma ile örneklemdaki hastaların tanımlayıcı nitelikleri özellikleri vurgulanarak KLP alanına katkı sağlanmıştır.

Anahtar Kelimeler: Konsültasyon–liyezon psikiyatrisi; genel hastane, psikosomatik tıp; yatan hastalar

Consultation-liaison psychiatry (CLP) is a relatively young but dynamic and developing field of psychiatry. CLP, known as psychosomatic medicine, studies the interaction of biological and psychosocial factors in all diseases' development, course, and outcome. By providing an integrative healthcare service, CLP aims at the most appropriate treatment for the needs of patients and healthcare providers (1-4).

The probability of having a mental disorder increases in people with a physical illness, and the likelihood of a physical disease increases in people with a mental illness (5, 6). Difficulties experienced in the field of CLP during the disease process lead to an unfavorable course of the disease process (7, 8). Disruptions in the CLP process cause chronic diseases, prolonged hospitalizations, increased treatment costs, and decreased quality of life for the patient (9, 10).

There are difficulties in recognizing and managing mental illness that accompany the physical illness process in general hospitals (11). It is emphasized that studies and hospital-based training in this field will contribute positively to the main goals of CLP (12). This study highlighted CLP by examining the demographic characteristics of the patients consulted by a psychiatry clinic and their distribution according to the clinics requesting consultation, the reasons for seeking consultation, and the psychiatric diagnoses.

Materials and Methods

The Universe and Sample of the Study

The study population consisted of 50528 patients hospitalized at University Hospital between 01.03.2021 and 01.03.2023, and 126712 (total, 177240) who applied to the emergency outpatient clinic. 1398 of these patients requested psychiatry consultation from the relevant clinic and these patients formed the sample of the study.

Data Collection and Statistical Evaluation

After the mental health specialist evaluated the consulted patients, the patient files were analyzed retrospectively, and the study data were created. The sociodemographic characteristics of the patients included in the study, the reason for consulting psychiatry in the relevant clinic, and the diagnoses made according to the DSM-5 diagnostic criteria after the evaluation by the psychiatry specialist

were used in the study. After the reasons for consulting the psychiatry clinic were determined, they were grouped as agitation, suicide attempt or **suicidal ideation**, treatment arrangement, impairment of sleep delirium, depressive symptoms and signs, anxiety signs and symptoms, conversion signs and symptoms (psychogenic seizures, paresthesia, motor dysfunction, etc.), assessment pre-operatively, psychotic signs and symptoms, and other causes. After consulting the psychiatry clinic, the diagnoses made by the psychiatrist are delirium, depression, anxiety disorders, psychotic disorders, bipolar disorder attack period, alcohol and substance use disorders, conversion signs and symptoms, no psychiatric disorders, dementia, trauma-related mental disorders, impulsive act of self-harm, mental disorders due to organic reasons, and primary insomnia. Descriptive statistics on research data were analyzed by SPSS 21.0.

Inclusion and Exclusion Criteria for the Study

All patients aged 18 years and older who were consulted to psychiatry from the clinic where they were treated were included in the study. Patients whose diagnosis was not reported in the consultation file, repetitive consultations, consultations on patients younger than 18, and patients whose psychiatric opinion was requested through Forensic Medicine were excluded from the study. Some of the descriptive statistics regarding the emergency polyclinic were not made, assuming the density of admissions to the emergency outpatient clinic, and the emergency polyclinic records were made for triage purposes.

Results

Distribution of Inpatient Numbers and Consultation Requests by Departments

The number of hospitalizations and consultation requests by departments is given in Table 1. Accordingly, while 17251 patients were hospitalized in internal clinics, consultation was requested from 581 (3.36%) of these patients. While 33277 patients were hospitalized in surgical services, psychiatric consultation was requested from 412 (1.23%) of these patients. While 3087 patients were hospitalized in intensive care units, psychiatric consultation was requested from 173 (5.6%) of them.

Table 1: Distribution of the number of inpatients and consultation requests by the departments

Department	Number of inpatients	Number of consultation requests	Percentage(%)
Internal clinics	17251	581	3.36
Internal medicine service	9508	317	3.33
Palliative care service	764	83	10.86
Physical medicine and rehabilitation service	897	79	8.8
Neurology service	2.229	37	1.65
Infectious disease service	776	22	2.83
Pulmonary disease service	1.764	23	1.3
Dermatology service	1.313	20	1.52
Surgical clinics	33277	412	1.23
General surgery service	4.854	94	1.93
Orthopedic and traumatology service	4.752	105	2.2
Neurosurgery service	1.724	83	4.81
Obstetrics and gynecology service	8.693	40	0.46
Plastic and reconstructive surgery service	447	21	4.69
Thoracic surgery service	325	22	6.76
Ophthalmology service	5.483	19	0.34
Urology service	4.086	17	0.41
Ear, nose and throat service	2.913	11	0.37
Intensive care services	3087	173	5.60

Distribution According to the Reason for the Consultation Request and the Results of the Consultation

When the reasons for requesting a consultation were examined in general, 190 (13.6%) of all patients were consulted because of agitation and 168 (12%) because of suicide attempt attempt/suicidal ideation. It was determined

that 152 (10.9%) of them were consulted for the regulation of their existing psychiatric treatment and 143 (10.2%) were consulted for impair of sleep.. When the distribution of consultation diagnoses was examined in general, 295(21.1%) were diagnosed with delirium, 283 (20.2%) were diagnosed with depression, and 222 (15.9%) were diagnosed with anxiety disorder. In contrast, no mental disorder was detected in 165 patients (Table 2).

Table 2: Distribution according to the reason for the consultation request and the results of the consultation

Reason for consultation request	Diagnosis considered by psychiatrist as a result of consultation	
	n	%
Agitation	190	13.6
Suicide Attempt/Suicidal ideation	168	12.0
Treatment Arrangement	152	10.9
Impairment of sleep	143	10.2
Delirium	141	10.1
Depressive Signs and Symptoms	138	9.9
Anxiety Signs and Symptoms	128	9.2
Conversion signs and symptoms	63	4.5
Preoperative Evaluation	57	4.1
Psychotic Signs and Symptoms	55	3.9
Other reasons	79	5.6
Alcohol and Substance Use Disorders	34	2.4
Bipolar disorder	25	1.8
Trauma Associated Signs and Symptoms	18	1.3

Distribution of Patients by Clinics, Reasons for Consultation Request, and Diagnosis at the Results of Consultation

Of the 1398 patients included in the study, 708 (50.6%) were male, and 690 (49.4%) were female. The mean age of the participants was 50.9±15.53 (minimum 18-maximum 96). When the distribution of departments requiring psychiatric consultation is evaluated, it is observed that internal departments requested 581 patients (41.6%), surgical departments requested 412 patients (29.5%), emergency medicine outpatient clinics requested 232 patients (16.6%), and intensive care services requested 173 patients (12.4%). In two years, psychiatric consultation was requested from 317 (22.7%) patients, with clinical internal diseases requiring psychiatric consultation most frequently (Table 3).

Considering the distribution of the departments according

to the most common reasons for consultation request, agitation was the most common reason for requesting consultation in internal departments, surgical departments and intensive care units. In the emergency medicine outpatient clinic, it was determined that the most common reason for requesting consultation was suicide attempt/suicidal ideation. The most common reasons for requesting psychiatric consultation in the clinics are shown in Table 3.

When the most common diagnoses made according to the desired departments were examined, delirium was the most common diagnosis in the internal departments, intensive care services and emergency medicine outpatient clinics. Depression was found to be the most common diagnosis in the surgical departments. The diagnoses made after the psychiatrist's evaluation of the departments are shown in Table 3.

Table 3: Distribution of patients by clinics, reasons for consultation request, and diagnosis at the results of consultation

Department	n	%	Reason for consultation	n	%	Diagnosis	n	%
Internal clinics	581	41.6	Agitation	80	13.8	Delirium	123	21.2
			Treatment Arrangement	68	11.7	Depression	113	19.4
				62	10.7	Anxiety Disorders	96	16.5
Internal medicine service	317	22.7	Agitation	44	13.9	Depression	69	21.8
			Suicide Attempt/Suicidal ideation	39	12.3	Delirium	62	9.6
			Treatment Arrangement	38	12.0	Anxiety Disorders	52	16.4
Palliative care service	83	5.9	Anxiety Signs and Symptoms	13	15.7	Delirium	18	21.7
			Agitation	12	14.5	Anxiety Disorders	18	21.7
			Delirium	9	10.8	No mental disorder	15	18.1
Physical medicine and rehabilitation service	79	5.7	Impairment of sleep	12	15.2	Delirium	19	24.1
			Treatment Arrangement	12	15.2	Depression	16	20.3
			Depressive Signs and Symptoms	10	12.7	Anxiety Disorders	12	15.2
Neurology service	37	2.6	Suicide Attempt/Suicidal ideation	6	16.2	Delirium	7	18.9
			Treatment Arrangement	5	13.5	Depression	6	16.2
			Delirium	5	13.5	No mental disorder	6	16.2
infectious disease service	22	1.6	Delirium	5	22.7	Depression	8	36.4
			Agitation	3	13.6	Delirium	6	27.3
			Impairment of sleep	3	13.6	Anxiety Disorders	3	13.6
Pulmonary disease service	23	1.6	Agitation	6	26.1	Delirium	7	30.4
			Impairment of sleep	3	13.0	Bipolar disorder	4	17.4
			Bipolar disorder attack period	3	13.0	No mental disorder	4	17.4
Dermatology service	20	1.4	Anxiety Signs and Symptoms	4	20.0	Depression	5	25.0
			Impairment of sleep	4	20.0	Anxiety Disorders	4	20.0
			Delirium	3	15.0	Delirium	4	20.0
surgical clinics	412	29.5	Agitation	50	12.8	Depression	91	23.3
			Suicide Attempt/Suicidal ideation	47	12.1	Delirium	73	18.7
			Delirium	42	10.8	Anxiety Disorders	55	14.1
General surgery service	94	6.7	Depressive Signs and Symptoms	13	13.8	Depression	21	22.3
			Delirium	12	12.8	Delirium	18	19.1
			Impairment of sleep	12	12.8	Anxiety Disorders	15	16.0

Orthopedic and traumatology service	105	7.5	Suicide Attempt/Suicidal ideation	16	15.2	Depression	28	26.7
			Agitation	14	13.3	Anxiety Disorders	17	16.2
			Treatment Arrangement	13	12.4	Delirium	13	12.4
Neurosurgery service	83	5.9	Depressive Signs and Symptoms	13	15.7	Depression	21	25.3
			Anxiety Signs and Symptoms	12	14.5	Delirium	17	20.5
			Agitation	10	12.0	Anxiety Disorders	11	13.3
Obstetrics and gynecology service	40	2.9	Suicide Attempt/Suicidal ideation	6	18.8	Depression	8	25.0
			Delirium	4	12.5	Delirium	7	21.9
			Anxiety Signs and Symptoms	4	12.5	Anxiety Disorders	3	9.4
Plastic and reconstructive surgery service	21	1.5	Agitation	4	19.0	Delirium	5	23.8
			Suicide Attempt/Suicidal ideation	4	19.0	Alcohol and Substance Use Disorders	3	14.3
			Delirium	3	14.3	Organic Reason	3	14.3
Thoracic surgery service	22	1.6	Delirium	2	20.0	No mental disorder	3	30.0
			Other reasons	2	20.0	Delirium	2	20.0
Ophthalmology service	19	1.4	Agitation	6	31.6	Delirium	7	36.8
			Delirium	3	15.8	No mental disorder	4	21.1
			Anxiety Signs and Symptoms	2	10.5		3	15.8
Urology service	17	1.2	Impairment of sleep	3	17.6	Depression	4	23.5
			Anxiety Signs and Symptoms	2	11.8	Delirium	3	17.6
			Agitation	2	11.8	Anxiety Disorders	3	17.6
Ear, nose and throat service	11	.8	Impairment of sleep	2	22.2	Anxiety Disorders	3	33.3
			Suicide Attempt/Suicidal ideation	2	22.2	Depression	2	22.2
Intensive care services	173	12.8	Agitation	22	12.7	Delirium	42	24.3
			Delirium	21	12.1	Depression	41	23.7
			Depressive Signs and Symptoms	20	11.6	Anxiety Disorders	30	17.3
Emergency medicine outpatient clinics	232	16.6	Suicide Attempt/Suicidal ideation	39	16.8	Delirium	50	21.6
			Agitation	32	13.8	Anxiety Disorders	36	15.5
			Treatment Arrangement	25	10.8	Depression	35	15.1

Mean Age of Diagnoses and Gender Distribution of Diagnoses

Considering the average age according to the diagnoses, the mean age of the patients diagnosed with delirium was 71.9 ± 13.8 , the mean age of the patients diagnosed with depression was 17.6 ± 17.2 , the mean age of the patients diagnosed with anxiety disorders was 53.2 ± 18.1 , and the mean age of the patients without any psychiatric disorder was 52.2 ± 18.4 (Table 4).

When the distribution of diagnoses by gender is examined, 172 (58.3%) patients diagnosed with delirium were male, 121 (42.8%) patients diagnosed with depression were male, 96 (43.2%) patients diagnosed with anxiety disorder were male. On the other hand, 80 (48.5%) of the patients who did not have psychiatric disorders as a result of the evaluation were male. (Table 4).

Diagnosis(n)	Age(\pm)	Gender(Male)
Delirium (n:295)	71.9 ± 13.8	172;58.3%
Depression (n:283)	52.7 ± 17.2	121;42.8%
Anxiety Disorders (n:222)	53.2 ± 18.1	96;43.2%
No mental disorder (n:165)	52.2 ± 18.4	80;48.5%

Discussion

The benefits CLP will provide with its effective use have encouraged researchers to deal with this field. In this study, descriptive features that can lead to improvements in the area of CLP are presented. In this context, it has been determined how the awareness and identifiability of psychiatric illness are realized in a hospital.

The main evidence-based objectives of CLP can be listed as follows: It can be summarized as raising awareness of psychiatric illness, recognizing and suspecting mental illness, ensuring the predictability of possible mental illness based on the findings before the active illness period, and achieving the goals mentioned above even in changing situations, in cooperation with non-psychiatric clinics (13). Considering the inter-departmental distribution in terms of awareness of psychiatric illness in line with CLP goals, the most frequent consultation request in our study was from intensive care clinics. Although internal and surgical branches showed different demands for consultation among themselves, it was seen that internal clinics generally demanded higher consultation. Studies in this area have determined that the reasons for requesting consultation between departments in different hospitals may differ (14, 15). The difference in psychiatric consultation demand rates between departments may be due to the difference in the treatment plan of the department and the potential interaction with psychiatric drugs, the psychological needs of the patients in the departments, the clinical experience of the physician in the department and the approach to psychiatric diseases, and the general medical condition of the patient. Awareness of consultation demand between hospitals may be due to the hospital's operating system or training attention for in-hospital CLP. Patients in intensive care units are frequently followed up with more severe health problems and receive more intensive and invasive treatments. This high stress level may cause secondary psychiatric issues such as anxiety and depression in patients. At the same time, delirium can be seen frequently in intensive care patients because of the severity of the disease and the risk group of patients. All these reasons may explain the relatively higher rate of psychiatric consultations in intensive care units. In the surgical departments, the treatment of patients is focused on surgical interventions, and surgical specialists work intensively and at a fast pace. This situation may have caused psychiatric problems to be missed and prompted less request for psychiatric consultation. Different rates of consultation requests may be associated with the severity of the disease and the length of hospital stay in services with shorter hospitalization rates, such as ophthalmology and otolaryngology services, and services with chronic and long-term hospitalizations, such as palliative services. Pre-and post-operative periods in surgical departments may affect the individual's self-expression and prepare the ground for difficulty in awareness of the mental state.

Recognition of mental illness and interdepartmental collaboration is another goal of CLP. The importance of harmony between physicians regarding psychiatric terminology was also emphasized by the World Health Organization (16). The reasons for the consultation, the examinations to be made over the evaluations, and the harmony between the physicians are suggestive about this issue. In this study, although there may be differences within the departments, it was determined that agitation was the most common reason for requesting consultation in internal, surgical, and intensive care services. The most common reason for requesting consultation in the emergency clinic was suicide attempt or suicidal ideation. In a study conducted in Turkey in this area, the most common reason for requesting consultation was depression, while the most frequently requested department was surgical clinics. In another study, it was seen that the most frequent consultation was on the state of agitation, and the most commonly requested consultation was internal clinics (17, 18). In a hospital in Italy, during the 20 years, the most frequent consultation request was due to depression, followed by agitation. In another study, delirium was the most frequent consultation request, followed by depression. (19, 20). Among the reasons for the consultation request, the difference between departments may be related to the differences in the severity of the diseases of the patients, the different medical conditions and needs, and the different educational experiences and attitudes of the physicians in the relevant specialties about psychiatric disorders. The fact that agitation was the most common reason for requesting consultation in our study may be because the physicians quickly noticed the agitated patient because of his restless and inappropriate behaviors.

Conclusion

Studies in the field of CLP emphasize the difficulties in detecting mental comorbidity and its unfavorable effects. Our study's results indicate differences in diagnostic terminology between psychiatry and non-psychiatry departments, and non-psychiatry departments have difficulty detecting psychiatric diagnoses. In general, low psychiatric consultation requests and differences between departments indicate the need for more cooperation, coordination, and information in CLP. Considering the potential of the efficient use of CLP, improvements in this area will contribute to more holistic and effective clinical practices.

Conducting prospective studies in the future may ensure that the process is followed more systematically and comprehensively and that the data collection process is more accurate and complete. In addition, multicentre studies including larger patient groups from different geographical regions may increase the generalisability of the results.

Limitations and Strengths

The limitation of this study may be the lack of information in some patient files. Incomplete or unclear information about the psychiatric diagnosis or the reasons for the consultation may have affected the accuracy of the data analysis. In addition, the fact that the data included in the study were obtained from a single hospital limits the generalisability of the results. On the other hand, the fact that the data were obtained using a retrospective method may make it difficult to document the results in a complete and consistent manner.

The strengths of this study include its detailed examination of the most common symptoms of psychiatric disorders and the difficulties experienced by non-psychiatric clinics in defining mental disorders. In addition, these findings, which were retrospective and analysed data from a relatively large number of patients, emphasise the need for cooperation, coordination and information sharing within the CLP.

Declarations

Funding

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Conflicts of interest

The authors declare that they have no conflict of interest.

Ethics Committee Approval

This study was approved by Tokat Gaziosmanpaşa University Clinical Research Ethics Committee, with decision number 83116987-794.

Peer-review

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Author Contributions

Research idea: SA,AES,İG

Design of the study: SA,İG

Acquisition of data for the study: SA,AES

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The Effect of Bruxism on the Severity of Temporomandibular Dysfunction and Chewing Functionality: A Cross-Sectional Study

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ABSTRACT

Objective: The study was conducted to investigate the effect of bruxism on the severity of Temporomandibular Dysfunction (TMD) and chewing functionality in individuals with TMD.

Methods: This cross-sectional study was conducted with 91 individuals diagnosed with TMD, with a mean age of 31.14 (7.35) years, 65 (71.4%) of whom were female. TMJ pain was assessed with the Numeric Pain Scale (NPS), maximum mouth opening (MMO), TMD severity was evaluated with the Fonseca Anamnestic Questionnaire (FAQ), and chewing functionality was considered with the Jaw Functional Limitation Scale-20 (JFLS-20).

Results: The NPS ($p=0.002$), MMO ($p=0.000$), FAQ ($p=0.000$) and JFLS-20 ($p=0.000$) score results of TMD patients with bruxism were significantly worse than those of TMD patients without bruxism. The probability of having moderate-severe TMD ($FAQ \geq 50$) increased statistically significantly 16.236 times (95% CI: 3.485-75.651) with bruxism ($p=0.000$). Limitation in chewing functionality ($JFLS-20 > 5$) was significantly increased 4.364 times (95% CI: 1.127- 16.906) in the presence of bruxism ($p=0.033$).

Conclusion: The study results showed that pain, TMD severity, and chewing functionality limitation were higher in individuals with TMD accompanied by bruxism. Knowing the bruxism and its effects that may accompany TMD, which is very common and increasing in number and severity daily, in the evaluation or treatment phase is essential in improving rehabilitation success.

Keywords: Temporomandibular dysfunction, bruxism, chewing functionality.

(Trial registration number: NCT06053723)

ÖZET

Amaç: Çalışma, Temporomandibular Disfonksiyonu (TMD) olan bireylerde bruksizmin TMD şiddeti ve çiğneme fonksiyonelliği üzerine etkisini incelemek amacıyla yapıldı.

Yöntem: Bu kesitsel çalışma, TMD tanısı almış, yaş ortalaması 31.14 (7.35) yıl, 65'i (%71.4) kadın olan 91 birey ile yürütüldü. Araştırmada TME ağrısı Numerik Ağrı Skalası (NAS) ile, maksimum ağız açıklığı (MAA), TME rahatsızlığının şiddeti Fonseca Anamnestic Anketi (FAA) ile ve çiğneme fonksiyonelliği Çenenin Fonksiyon Kısıtlanma Skalası-20 (ÇFKS-20) ile değerlendirildi.

Bulgular: Bruksizmi olan TMD'li bireylerin NAS ($p=0.002$), MAA ($p=0.000$), FAA ($p=0.000$) ve ÇFKS-20 ($p=0.000$) sonuçları bruksizmi olmayan TMD'li bireylere kıyasla anlamlı derecede daha kötüydü. Orta-ciddi şiddette TMD'ye sahip olma olasılığının (FAA ≥ 50) bruksim varlığı ile birlikte istatistiksel olarak anlamlı şekilde 16.236 kat (%95 GA: 3.485-75.651) arttığı görüldü ($p=0.000$). Çiğneme fonksiyonelliğinde kısıtlanmanın (ÇFKS-20 >5) ise bruksizm varlığında anlamlı şekilde 4.364 kat (%95 GA: 1.127- 16.906) arttığı görüldü ($p=0.033$).

Sonuç: Çalışma sonuçları bruksizmin eşlik ettiği TMD'li bireylerde ağrı, TMD şiddeti ve çiğneme fonksiyonelliğinde kısıtlanmanın daha yüksek olduğunu göstermiştir. Çok yaygın olarak görülen, her geçen gün sayısı ve şiddeti artan TMD'nin değerlendirilme ya da tedavi aşamasında eşlik edebilecek bruksizm ve etkilerinin bilinmesinin rehabilitasyon başarısını artırma açısından önemli olduğu düşünülmelidir.

Anahtar sözcükler: Temporomandibular disfonksiyon, bruksizm, çiğneme fonksiyonelliği.

(Trial registration number: NCT06053723)

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Temporomandibular Joint Dysfunction (TMD) refers to dysfunctions caused by temporomandibular joint (TMJ) and musculoskeletal structure irregularities. (1). Bruxism, known as clenching and grinding of teeth, is the most common parafunctional activity in the etiology of TMD and affects the quality of life the most (2).

Bruxism is a parafunctional activity in sleep or wakefulness characterized by clenching and teeth grinding, most commonly seen in the age range of 20-50 years (3). Clinical findings of sleep bruxism include hypertrophy of the masseter muscle, abnormal wear and fracture of the teeth, limitation in the range of motion of the jaw joint, tenderness and pain in the masticatory muscles, especially in the morning (4).

Since the use of polysomnographic records, which provide definitive detection of bruxism in sleep, is limited due to high cost and lack of well-equipped sleep laboratories, clinical or self-report approaches are frequently used in the clinic as an alternative (5, 6). The prevalence of self-reported bruxism was found to be 39.6% in a study using the self-report method, and it was reported that self-reported bruxism was associated with TMD symptoms and signs related to pain, as well as TMD diagnoses (7). In two studies investigating the prevalence of bruxism in individuals diagnosed with TMD, the prevalence was approximately 80% and 57% (8,9).

Although there seems to be some debate in the literature as to whether bruxism, as a risk factor for TMD, is a potential cause of masticatory muscle disorders and/or joint overload, it has been proposed that bruxism can cause peripheral sensitization. It has been hypothesized that prolonged myofascial pain may constitute a risk for TMD (10,11). It is known that bruxism may accompany TMD in studies (7-13). Still, no study has been found to examine in detail how the presence of concomitant bruxism affects the severity of TMD and chewing functionality in individuals with TMD. Therefore, this study aimed to investigate the effect of bruxism on TMD severity and chewing functionality in individuals with TMD.

Methods

Design

This cross-sectional study was conducted between April 2023 and September 2023 with individuals aged 20-55 years with TMD. Approval for this study was granted by the Non-Interventional Research Ethics Committee of

Bandırma Onyedi Eylül University (decision no: 2023-54). The clinical trial number of the study is NCT06053723. All study methods conform to the Helsinki Declaration of the World Medical Association. All participants provided written informed consent.

Participants

Individuals aged 20-55 years with TMD who volunteered to participate in the study were included. Exclusion criteria included having a non-reducible disc problem, undergoing surgical operation related to the spine, and TMJ problem, cancer, trauma, congenital anomalies, neurological problems, musculoskeletal problems, facial paralysis, and receiving any treatment related to the spine and TMJ in less than six months.

Sample Size

The sample size was calculated using a population of 20000 and a prevalence of 15% (14) with a 95% confidence interval with the Rasoft sample size calculator. Considering the two-sided alpha value of 0.05, a power of 0.80, and dropout, 84 individuals were planned to be included in the study. The study included 91 individuals diagnosed with TMD.

Outcome Measurements

Those who volunteered to participate in the study completed the Descriptive Data Form, including demographic characteristics. Diagnostic classification (myofascial, disc and joint disorder) of the individuals diagnosed with TMD were recorded. The presence of bruxism in individuals with TMD was questioned, and the maximum mouth-opening measurement was recorded. TMD severity was assessed with Fonseca's Anamnestic Questionnaire (FAQ), pain severity was evaluated with the Numeric Pain Scale (NPS), and TMJ functionality was set with the Jaw Functional Limitation Scale-20 (JFLS-20). The evaluations of the participants were performed only once.

Bruxism: Sleep bruxism reported by the individual was recorded. As clinical diagnostic criteria for bruxism, the presence of regular or frequent teeth clenching and grinding sounds followed by pain or fatigue in the jaw muscles on waking up in the morning, temporal headache, masseter muscle hypertrophy, abnormal tooth abrasion and/or jaw locking was questioned. The presence of one or more clinical findings was recorded as bruxism (15).

Maximum mouth opening (MMO): Maximum pain-free mouth opening was measured with a 15 cm ruler (16).

Fonseca's Anamnestic Questionnaire (FAQ): It assessed TMD severity. The questionnaire includes ten questions about joint, head, and neck pain, pain during masticatory activity, parafunctional habits, decreased joint motion, impaired occlusion, and emotional stress. As a result of the questionnaire, the presence of TMD is accepted in those with 25 points and above. At the same time, severity can be classified as mild TMJ disorder (25-45), moderate TMJ disorder (50-65), and severe TMJ disorder (70-100). The Turkish validity and reliability of the questionnaire were performed by Kaynak et al. in 2020 (17).

Numeric Pain Scale (NPS): It is a simple, reliable, and short-term method frequently used to measure pain intensity in the clinic. The patient was told that the most severe pain they felt in the TMJ region was 10, and if they had no pain, the pain intensity was 0. The participant was asked to give a number between 0 and 10 corresponding to the intensity of pain felt in the TMJ region (18).

Jaw Function Limitation Scale-20: It assessed chewing functionality, including 20 items, with "0" indicating no limitation and "10" indicating a severe limitation in each item, about the function of the TMJ during different activities, difficulty in chewing, and jaw limitation. As a result of the questionnaire, it has been reported that TMJ functionality is limited in those with a score of 5 and above. Acceptable reliability and validity have been reported for the scale (19).

Statistical Analysis

IBM-SPSS 25.0 for the macOS package program was used to evaluate the participants' findings. In parametric testing, variables determined by measurements were reported as mean±standard deviation (SD), median (minimum-maximum) in nonparametric testing, and distributions for variables defined by counting were calculated as (%). The conformity of the variables to normal distribution was analyzed using the Shapiro-Wilk test. Mann-Whitney U Test for age, Independent Samples t Test for BMI, NPS, MMO, JFSL-20, and FAQ were used between the groups with and without bruxism. The relationship between TMD severity and diagnostic classification with the presence of bruxism and gender was compared by the Chi-Square Test. The Kruskal Wallis test evaluated TMD severity and JFSL-20 variability in diagnostic classification. After adjusting for

age and gender, multiple logistic regression analysis was performed to determine whether the presence of bruxism was a statistically significant determinant of TMD severity (FAQ≥50) and limitation of chewing functionality (JFSL >5). The degree of statistical significance was determined as $p < 0.05$.

Results

65 (71.4%) were female, 26 (28.6%) were male were included in the study and the median age was 29.0 (20-55) years. In the study, 63 (69%) individuals with TMD reported bruxism (Table 1). The NPS ($p=0.002$), MMO ($p=0.000$), FAQ ($p=0.000$) and JFSL-20 ($p=0.000$) score results of TMD patients with bruxism were significantly worse than those of TMD patients without bruxism (Table 2).

Table 1: Participants' descriptive and clinical data

Table 1: Participants' descriptive and clinical data			
N=91	Min-Max	Mean	SD
Age (years)	20.0- 55.0	31.14	7.35
BMI (kg/m ²)	15.47- 36.24	24.19	4.30
NPS (cm)	2.0- 8.0	4.53	1.57
MMO (mm)	22.0- 58.0	36.94	6.99
JFSL-20	3.0- 85.0	36.18	19.89
FAQ	25.0- 85.0	44.78	17.07
n (%)			
Gender	Female Male	65 (71.4%) 26 (28.6%)	
Bruxism	Yes No	63 (69%) 28 (31%)	
RDC/TMD	• Myofascial • Disc • Joint	34 (37.36%) 31 (34.06%) 26(28.58%)	
TMD Severity	• Light • Medium • Serious	54 (59.34%) 22 (24.17%) 15 (16.49%)	
Min:Minimum, Max: Maximum, SD: Standard Deviation, BMI= Body Mass Index, NPS: Numeric Pain Scale, MMO: Maximum Mouth Open, JFSL-20: Jaw Functional Limitation Scale-20, FAQ: Fonseca Anamnestic Questionnaire, RDC/TMD: Research Diagnostic Criteria/ Temporomandibular Disorders.			

Table 2: Comparison of chewing function in TMD diagnostic classification and severity difference

N=91	n	JFSL-20 median (min-max)	p
RDC/TMD n (%)			
• Myofascial	34	30.0 (3.0- 85.0)	0.000*
• Disc	31	33.0 (6.0-85.0)	
• Joint	26	45.0 (17.0- 83.0)	
TMD Severity n (%)			
• Light	54	29.0 (3.0- 47.0)	0.000*
• Medium	22	44.0 (26.0- 85.0)	
• Serious	15	63.0 (33.0- 85.0)	

*= p<0.05, p= Kruskal-Wallis Test, RDC/TMD: Research Diagnostic Criteria/ Temporomandibular Disorders.

Table 3: Pain, maximum mouth opening, chewing functionality and dysfunction score in participants with and without bruxism

	TMD with bruxism (n=63)	TMD without bruxism (n=28)	p
NPS (cm) X (SD)	4.87 (1.61)	3.78 (1.19)	0.002*
MMO (mm) X (SD)	35.63 (7.03)	39.89 (6.13)	0.000*
JFSL-20 X (SD)	42.87 (19.02)	21.14 (12.20)	0.000*
FAQ X (SD)	50.23 (16.88)	32.50 (9.57)	0.000*

*= p<0.05, p=Mann-Whitney U test, X:Mean, SD: Standard Deviation, NPS: Numeric Pain Scale, MMO: Maximum Mouth Open, JFSL-20: Jaw Functional Limitation Scale-20, FAQ: Fonseca Anamnestic Questionnaire.

In Table 3, JFSL-20 values in different diagnostic classifications and severity of TMD were compared. Chewing

functionality was significantly more limited in individuals with joint TMD and individuals with severe TMD (p=0.000).

Table 4: The effect of bruxism on TMD severity and chewing functionality

N=91	OR	%95 CI	Wald	p	Model Summary
FAQ ≥50					
Age (years)	0.992	[0.932- 1.056]	0.062	0.803	-2 Log likelihood: 100.142 Nagelkerke R ² : 0.299 Hosmer Lemeshow: 0.574
Gender (female)	0.625	[0.231- 1.839]	0.728	0.394	
Bruxism (no)	16.236	[3.485- 75.651]	12.602	0.000*	
JFSL >5					
Age (years)	1.028	[0.920- 1.149]	0.241	0.623	-2 Log likelihood: 59.934 Nagelkerke R ² : 0.145 Hosmer Lemeshow: 0.517
Gender (female)	0.450	[0.114- 1.784]	1.290	0.256	
Bruxism (no)	4.364	[1.127- 16.906]	4.548	0.033*	

*p<0.05, Multivariate logistic regression analysis, OR: Odds Ratio, CI: Confidence Interval, FAQ: Fonseca Anamnestic Questionnaire, JFSL-20: Jaw Functional Limitation Scale-20,

In Table 4, when age and gender were included, multivariate logistic regression analysis analyzed whether bruxism effectively affected TMD severity and limitation in chewing functionality. TMD severity was defined into two groups: mild and moderate-severe. The probability of having moderate-severe TMD increased statistically significantly 16.236 times (95% CI: 3.485-75.651) with bruxism (p=0.000). Limitation in chewing functionality was significantly increased 4.364 times (95% CI: 1.127- 16.906) in the presence of bruxism (p=0.033). Age and female gender were not statistically significant determinants of TMD severity and limitation in chewing functionality (p>0.05).

Discussion

In our study examining the effectiveness of bruxism on TMD severity and chewing function, pain, TMD severity and chewing function limitation were higher in individuals with TMD accompanied by bruxism.

Trauma, occlusal disorders, emotional stress, deep pain, and parafunctional activities are prominent in the etiology of TMD (20). Bruxism is an oral condition characterized by repetitive jaw muscle activity such as supporting or pushing the mandible and/or clenching or grinding the teeth

known as clenching and teeth grinding, the most common parafunctional activity associated with TMD (2). In epidemiological studies, bruxism is highest between the ages of 20-50, and its prevalence is similar in women and men. Still, bruxism with TMD is four times higher in women than men (3,21). In a study conducted by Magnusson et al. in which 420 individuals were followed for 20 years, it was reported that bruxism and TMD were most commonly seen in the same age range, with a significant correlation between bruxism and TMD (12). In this study, we studied individuals between the ages of 20 (min) and -55 (max), which is expected to be shared in TMD and bruxism, and among individuals with TMD accompanied by bruxism, women were approximately three times more than men. In this context, the study aligns with the literature regarding age and gender.

Pathophysiologically, the definitive detection of bruxism in sleep can only be achieved through polysomnographic records. Still, the use of these records is limited due to the need for more adequately equipped sleep laboratories and high costs (5). Therefore, clinical or self-report approaches are among the most accessible and widely adopted methods as an alternative to diagnosing bruxism (6). A recent study with 1962 participants looked at the prevalence of self-reported bruxism and its connection to TMD; the frequency of self-reported bruxism was 39.6%. According to the study's findings, self-reported bruxism was linked to TMD symptoms and indicators of discomfort, as well as TMD diagnoses (7). In two studies investigating the prevalence of bruxism in individuals diagnosed with TMD, bruxism was found to be approximately 80% and 57%, while it was found to be 37% in healthy individuals (8,9). In this study, 69% of individuals with TMD reported the presence of bruxism, which is consistent with the literature. Although there seems to be uncertainty in the literature as to whether bruxism is a risk factor for TMD as well as a potential cause of masticatory muscle disorders and joint overload or, muscle damage, or both, it has been proposed that bruxism can cause peripheral sensitization, and it has been hypothesized that long-standing myofascial pain may constitute a risk for TMD (10,11). In this context, bruxism, one of the parafunctional activities that play an essential role in the etiology of TMD, can be observed at high rates in individuals with TMD.

A population-based study showed a positive relationship between bruxism and a series of orofacial and temporomandibular joint pain symptoms (13). A study found that experimental and continuous jaw clenching caused acute muscle tenderness in the masticatory muscles, and

bruxism led to a positive relationship with jaw pain (6). Another study found that pain-related TMD symptoms and signs were significantly higher in individuals with bruxism than those who did not report bruxism (7). In this study, it was found that the pain level of individuals with bruxism was higher. This expected situation can be explained by non-physiological continuous clenching causing more pain due to fatigue and sensitivity in the masticatory muscles. In addition, as stated in other studies, the hypothesis that myofascial pain formation in individuals with bruxism may be due to lower resistance to fatigue comes to the fore (22).

While the limitation of mouth opening is among the most frequently observed findings in TMD, bruxism is also known to cause limitation in the jaw joint range of motion (1,4). A study found that individuals with bruxism had 30.3% difficulty opening/closing their mouths wide (13). This study found that the range of motion decreased more in individuals with TMD accompanied by bruxism. In the literature, this situation is expressed as tension in bruxism, which starts to restrict functions by damaging the joint and related tissues more after a while. This situation supports the result of this study (23). This may be explained as bruxism, which may further increase the limitation of the TMD in the range of motion with pain in the TMJ and facial region.

Bruxism may cause problems such as tooth wear, jaw joint and face pain, and limitation in jaw movements (23). In a study, 19.7% of individuals with bruxism had difficulty chewing, and 18.4% had pain in chewing (13). This study found chewing functionality decreased more in individuals with TMD accompanied by bruxism. It was also observed that chewing functionality was affected by the TMD diagnostic classification; the most limitation was observed in TMD originating from the joint, and the functionality decreased more in severe TMD. This study observed that chewing functionality was more limited in individuals with TMD accompanied by bruxism; chewing functionality limitation in individuals with TMD increased 4.364 times with bruxism. This shows that tooth wear, TMJ, facial region pain, and limitation in jaw movements with bruxism also negatively affect chewing. Therefore, based on the results of this study, concomitant bruxism affects the limitation of chewing functionality at high rates in individuals with TMD.

Bruxism has been suggested to be a continuous factor for TMD (7-13). According to two recent studies, TMD

symptoms were more common in individuals who clench their teeth while awake (23, 24). Another study discovered that individuals with bruxism had significantly more pain-related TMD symptoms and signs than those who did not report bruxism (7). A study by Leketas et al. (25) showed that bruxism was associated with a 10.83 times higher risk of TMD. This study observed that the dysfunction scores and TMD severity of individuals with TMD with bruxism were higher; when age and gender were included, the probability of having high-severity TMD increased 16.236 times with bruxism. Considering the study's other findings, this situation can be explained in the direction of increased severity of TMD in individuals with bruxism due to more intense pain in the TMJ region and more decreased range of motion and functionality. The literature shows that pain associated with muscle fatigue in bruxism is a serious risk factor for TMD by increasing peripheral sensitivity (10,11). However, based on the results of the study, it can be said that bruxism is not only a serious risk factor for TMD but also increases the severity of TMD significantly.

The long course of the disease and the variability of symptoms in TMD create a difficult situation for patients, physicians, and therapists. Therefore, it is essential to determine the etiological factor when making a treatment plan for TMD to ensure that recovery occurs in the shortest time (26). At this point, evaluating bruxism, frequently encountered in parafunctional activities that have an essential place in the etiology of TMD, should be critical in effective rehabilitation. This study aimed to investigate the effect of bruxism on TMD severity and chewing functionality in individuals with TMD. As a result, it was observed that pain, TMD severity, and chewing functionality limitation were higher with accompanying bruxism in individuals with TMD who had a high rate of bruxism.

Limitations and Strength

The limitation of the study was that pain assessment was performed only in the TMJ region, and objective assessment methods, including the cervical region, were not used. In addition, although it will not affect the primary effect analysis of our study, the difference in the number of individuals in the analysis comparing individuals with and without bruxism is a situation that may affect the statistics and is among our limitations. On the other hand, the study's strength is that it holistically examines the effect of bruxism, which has a significant role in the etiology of TMD, on TMD severity and chewing functionality.

Recommendations

It is recommended that future studies be conducted with a larger sample size, including evaluation methods, including the cervical region and comparative examination of the effects of sleep and wakefulness bruxism on TMD severity and chewing functionality.

Conclusion

In the study, it was observed that bruxism was honored at a high rate in individuals with TMD, and bruxism accompanying TMD increased pain, TMD severity, and chewing functionality limitation. While it is known that the relationship with TMD, which is an essential problem in bruxism studies and bruxism treatment, should be evaluated, it should be considered that knowing the bruxism and its effects that may accompany TMD, which is very common and increasing in number and severity day by day, in the evaluation or treatment phase is essential in terms of growing rehabilitation success.

Declarations

Funding

The author reports no financial support.

Conflict of Interest

The author declares that she has no conflict of interest.

Ethics Approval

This cross-sectional study was approved by the Ethics Committee. (Decision no: 2023-54). All study procedures comply with the provisions of the World Medical Association Declaration of Helsinki. Written informed consent was obtained from all participants.

Availability of Data and Material

The data supporting this study's findings are available from the corresponding author upon reasonable request.

Clinical Trials Number

The study is registered in the WHO International Clinical Trials Registry Platform: NCT06053723.

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Author Contributions

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Investigation of Sleep Quality and Kinesiophobia Levels in Individuals with Fibromyalgia with Physical Activity Levels

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ABSTRACT

Purpose: It is known that physical activity is necessary for all dimensions of the disease in individuals with Fibromyalgia. This study investigated how sleep quality and kinesiophobia levels were affected in individuals with Fibromyalgia according to their physical activity levels.

Methods: Our study was planned as a cross-sectional study of fibromyalgia individuals who applied to Ankara Medipol University's physiotherapy and rehabilitation department. The sample consists of one hundred sixty-eight volunteer participants. Physical activity levels of individuals, using the International Physical Activity Questionnaire (IPAQ), sleep quality, using the Pittsburg Sleep Quality Index (PSQI), and kinesiophobia levels, using the Tampa Kinesiophobia Scale (TKS), were evaluated.

Results: It was determined that the total physical activity of fibromyalgia patients was 1213.21±141.19 METmin/week; that is, they had a low physical activity level, and 50.6% were not physically active. The mean PSQI total score was 8.23±1.32, and the mean TKS total score was 43.12±2.19. It was determined that, a weak negative correlation was observed between IPAQ and PSQI ($r=-0.26$) ($p<0.05$), and a moderate negative correlation was observed between IPAQ and TKS ($r=-0.32$) ($p<0.05$). When individuals were evaluated at three different levels according to their physical activity levels, a significant difference was found between different physical activity levels and PSQI and TKS scores ($p<0.05$).

Conclusion: As a result, as the physical activity levels of individuals with fibromyalgia increase, sleep quality, and kinesiophobia levels are positively affected. This study highlights the importance of adequate regular physical activity to improve sleep health and prevent kinesiophobia in individuals with Fibromyalgia.

Keywords: Fibromyalgia, Physical Activity, Sleep quality, Kinesiophobia.

ÖZET

Amaç: Fibromiyalji bireylerde hastalığın tüm boyutları için fiziksel aktivitenin gerekli olduğu bilinmektedir. Bu çalışmada, fiziksel aktivite düzeylerine göre Fibromiyalji bireylerde uyku kalitesi ve kinezyofobi düzeylerinin nasıl etkilendiği araştırılmıştır.

Yöntem: Kesitsel olarak planlanan çalışmamız Ankara Medipol Üniversitesi Fizyoterapi ve Rehabilitasyon bölümüne başvuran fibromiyalji bireylerde planlandı. Örneklem yüz altmış sekiz gönüllü katılımcıdan oluşmaktadır. Bireylerin fiziksel aktivite düzeyleri Uluslararası Fiziksel Aktivite Anketi (UFAA) ile, uyku kalitesi Pittsburg Uyku Kalitesi İndeksi (PUKİ) ile, kinezyofobi düzeyleri ise Tampa Kinezyofobi Ölçeği (TKÖ) kullanılarak değerlendirildi.

Bulgular: Fibromiyalji hastalarının total fiziksel aktivite miktarının 1213.21±141.19 METmin/hafta olduğu, yani düşük fiziksel aktivite düzeyi olduğu ve %50.6'sının fiziksel olarak aktif olmadığı belirlendi. PUKİ toplam puanı ortalaması 8.23±1.32, TKS toplam puanı ortalaması ise 43.12±2.19 idi. UFAA toplam skor ile PUKİ arasında zayıf negatif korelasyon ($r=-0.26$) ($p<0.05$), UFAA toplam skor ile TKS arasında ise orta derecede negatif korelasyon ($r=-0.32$) ($p<0.05$) olduğu belirlendi. Bireyler fiziksel aktivite seviyelerine göre üç farklı düzeyde değerlendirildiğinde, farklı fiziksel aktivite düzeyleri ile PUKİ ve TKÖ puanları arasında anlamlı farklılık bulundu ($p<0.05$).

Sonuç: Sonuç olarak fibromiyalji bireylerin fiziksel aktivite düzeyleri arttıkça uyku kalitesi ve kinezyofobi düzeyleri olumlu yönde etkilenecektir. Bu çalışma, Fibromiyalji bireylerde uyku sağlığını iyileştirmek ve kinezyofobi önlemek için yeterli düzenli fiziksel aktivitenin önemini vurgulamaktadır.

Anahtar Kelimeler: Fibromiyalji, Fiziksel Aktivite, Uyku kalitesi, Kinezyofobi.

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Fibromyalgia Syndrome (FMS) is a disease that affects approximately 2.7% of the world's population, accompanied by widespread body pain and psychosomatic findings. Although it is more common in women than men, it is most common in the age group of 25-55 (1). Pathologies such as pain, sleep disturbance, anxiety, depression, fatigue, cognitive dysfunction, and gastrointestinal system disorders, which are among the most common findings of FMS, impair functionality and cause deterioration in quality of life (2). Published multidisciplinary publications emphasize the importance of patient education and physical activity (PA) in improving health in individuals with fibromyalgia (3). Despite these proven benefits, many individuals with fibromyalgia do not practice PA regularly (4). Many FMS patients believe physical activity will reduce their perceived pain levels. However, it is still reported that the physical activity levels of patients with FMS are generally lower than those of healthy controls (5). Various factors, such as fatigue, pain, and fear of movement, cause physical inactivity.

Kinesiophobia, defined as a fear of movement, means avoidance of physical activity due to excessive fear and anxiety about pain, which reduces mobility and muscle strength and subsequently triggers the fear of moving more. Kinesiophobia is present in more than 38% of FMS patients (6).

Anxiety about increased pain in patients with FMS prevents the individual from moving and reduces activities of daily living, which causes more injury avoidance and fear of movement in individuals. This vicious cycle of fatigue in fear of movement increases the risk of chronic pain and depressive mood (7). Due to chronic pain, individuals may adopt a more sedentary lifestyle by limiting their physical activities. Chronic pain and sleep disturbance, among the most common symptoms of FMS, may be related (8). However, there is no consensus on whether pain triggers sleep disturbance or whether sleep disturbance causes pain. Sleep disturbance is typically seen in 80% of patients with FMS. Frequent waking at night, restless sleep, and weakness and fatigue are among the complaints. Although patients with FMS have shorter sleep durations than healthy subjects, the shortened sleep duration seen in these individuals is also associated with low physical activity levels (9).

According to the results of a review published in 2023, it was stated that PA is still insufficient in individuals with fibromyalgia, and interventions are needed to prevent

physical inactivity and to make individuals physically active (10). The relationship between sleep quality and disease symptoms has been demonstrated in individuals with fibromyalgia, and studies indicate that high levels of physical activity positively affect sleep quality (11,12). Studies have reported that kinesiophobia levels are higher in individuals with fibromyalgia than in healthy individuals, which may affect other symptoms (13,14). The literature has reported that the absolute evaluation of kinesiophobia in individuals with FMS and the necessity of developing protective techniques against this condition will provide helpful information when creating a treatment program (15,16).

Few studies show that physical activity positively affects sleep quality and kinesiophobia in individuals with fibromyalgia (17,18). Small sample sizes and methodological inadequacy are standard limitations of literature studies. In addition, the effect of different levels of physical activity, which is an essential factor, on sleep quality and kinesiophobia levels has not been examined. Additionally, in most studies that examined the relationship, the sample group was only women.

Our study aims to examine the effects of physical activity levels on sleep quality and kinesiophobia levels in individuals with fibromyalgia and to emphasize the importance of developing individuals' awareness of increasing their physical activity levels, especially by drawing attention to the effects of a lack of physical activity on individuals with fibromyalgia.

Material and Methods

Study Design and Population

In the power analysis performed in the G*power program with Pearson correlation coefficient $r = 0.30$ and 80% power ($\alpha = .05$, bidirectional), it was determined that 148 people were needed to complete the analyses. Considering the 20% dropout assumption, 178 volunteers aged between 29-55, diagnosed with FMS according to the 2010 American College of Rheumatology criteria by a specialist physician and admitted to the Ankara Medipol University Department of Physiotherapy and Rehabilitation, were invited to our cross-sectional study between 21/06/2023 and 21/09/2023. After 10 participants did not want to complete the evaluation, our study was completed with 168 participants. The patients were excluded from our study were patients with systemic

infectious and inflammatory rheumatic diseases, fractures, orthopedic surgery in the last year, cancer patients, vestibular problems, neurological problems, psychiatric diseases, pregnancy, breastfeeding status, and metabolic and endocrine system diseases. The Principles of the Declaration of Helsinki conducted our study. Ethics Committee approval was obtained from Ankara Medipol University Non-Interventional Clinical Research Ethics Committee (Date: 14/02/2023 Decision No: 021) before the start of the study. After the participants were informed about the study, the consent form was signed, and an evaluation was made with data collection questionnaires.

Measuring Methods

After the participants' demographic information was obtained, physical activity levels, sleep quality, and kinesiophobia levels were evaluated through questionnaires.

The International Physical Activity Questionnaire (IPAQ), which evaluates the physical activity levels of individuals with a total of 7 questions in 4 separate sections, classifies individuals according to their physical activity levels as being physically inactive (<600 MET min/week), having low physical activity (600-3000 MET- min/week), and having sufficient physical activity (>3000 MET-min/week) (19). We used the Turkish version of IPAQ (20). The Pittsburgh Sleep Quality Index (PSQI), which we use to determine sleep quality, comprises 19 questions and seven subcomponents (21). The total score obtained from the 4-point Likert-type scale ranges from 0 to 21, and the Turkish version of the questionnaire was used in our study (22). Higher scores indicate poor sleep quality.

Tampa Kinesiophobia Scale (TKS), a four-Likert type, measures individuals' injury/re-injury and fear-avoidance status with 17 questions (23). The scores obtained from the scale, which we used the Turkish version in our study, ranged from 17 to 68, while high scores indicate a high level of kinesiophobia (24).

Statistical Analysis

Statistical analysis was performed with the Social Science Statistical Package (SPSS) version 26.0 (SPSS et al., USA). We determined whether the variables were normally distributed using visual and analytical methods. Mean±standard deviation was used for normally distributed numerical variables. The relationship between physical activity levels, sleep quality, and kinesiophobia levels

was determined using Pearson correlation analysis. The sign of the correlation coefficient gives the direction of the relationship. The (-) sign indicates a negative relationship and the (+) sign indicates a positive relationship. The correlation coefficient gives the magnitude of the relationship. 0.00 – 0.19: very low, 0.20 – 0.39: Low, 0.40 – 0.59: medium, 0.60 – 0.79: high, 0.80 – 1.00: very high (25). A one-way ANOVA analysis was used to determine the relationship between three levels of physical activity, sleep quality, and kinesiophobia.

Results

The age, BMI, and gender of the participants who participated in the study we completed with 168 individuals with fibromyalgia are shown in Table 1.

Table 1: Demographic characteristics of participants

Participants (n=168)			
X±SD			
Age (years)		42.12±3.62	
BMI (kg/m ²)		23.10±1.79	
Gender (%)		n	%
	Female	144	86.71
	Male	24	13.29

X±SD: mean±SD, m: meter, kg: kilograms, BMI: body mass index, n:sample size

While the average physical activity value of individuals with fibromyalgia was 1213.21±141.19 MET-min/week, the average PSQI scores were 8.23±1.32, and the average TKS results were 43.12±2.19 (Table 2).

Table 2: Participants' physical activity, sleep quality and kinesiophobia scale measurement results

Participants (n=168)	
X ± SD	
IPAQ Total physical activity (MET-min/week)	1213.21±141.19
PSQI Total (0-21)	8.23±1.32
TKS Total (17-68)	43.12±2.19

X±SD: mean±SD, IPAQ: International Physical Activity Questionnaire, MET: metabolic equivalent, min: minute, PSQI Pittsburgh Sleep Quality Index, TKS: Tampa Kinesiophobia Scale n:sample size

Table 3 shows that 50.6% of the participants were not physically active, 20.24% had low physical activity, and only 29.16% had sufficient physical activity. In our study, a weak negative correlation was observed between IPAQ total physical activity and PSQI ($r=-0.26$) ($p<0.05$), and a moderate negative correlation was observed between IPAQ total physical activity and TKS ($r=-0.32$) ($p<0.05$, Table 4).

Table 3: Physical activity levels of Participants		
	Participants (n=168)	
	n	%
Physical activity level		
Physically Inactive (<600 MET- min/week)	85	50,6
Low Physical Activity Level (600 – 3000 MET-min/ week)	34	20,24
Physical Activity Level Sufficient (>3000 MET-min/ week)	49	29,16
<i>MET: metabolic equivalent, min: minute, n: sample size</i>		

Table 4: The relationship between average value of total physical activity of participants' and sleep quality and depression total scores	
	Participants (n=168)
	IPAQ Total Physical Activity (MET-min/week)
PSQI Total	r: -0.26 p: 0.001*
TKS Total	r: -0.32 p: 0.001*
<i>*p < 0.05, IPAQ: International Physical Activity Questionnaire, PSQI: Pittsburgh Sleep Quality Index, TKS: Tampa Kinesiophobia Scale,</i>	

Table 5 compares the PSQI and TKS mean scores of the participants according to different physical activity levels, and a significant difference was found between the three levels according to physical activity levels ($p<0.05$, Table 5).

Table 5: Comparison of sleep quality and kinesiophobia levels according to participants Physical Activity Levels.				
Physical Activity Level				
	Physically Inactive n=85	Low Physical Activity Level n=34	Physical Activity Level Sufficient n=49	Test and p-value
PSQI Total	9.71±3.15	8.89±2.11	6.31±3.22	F=7.166 p=0.012
TKS Total	51.76±1.27	46.11±1.61	32.89±4.21	F=8.291 p=0.022
<i>Bold values indicate p < 0.05, MET: metabolic equivalent, min: minute, PSQI: Pittsburgh Sleep Quality Index, TKS: Tampa Kinesiophobia Scale, n: sample size</i>				

Discussion

This study showed that the physical activity levels of individuals with fibromyalgia are not sufficient, and their sleep quality and kinesiophobia levels are negatively affected.

Our study determined that the average physical activity of individuals with fibromyalgia was 1213.21 ± 141.19 MET-min/week, and only 29.16% had sufficient physical activity. Studies in the literature have observed that the physical activity levels of individuals with fibromyalgia are insufficient (10,23). Additionally, it has been stated that their inability to engage in physical activity causes many negative situations, especially physical ones. Physical activity levels of individuals with fibromyalgia were found to be insufficient in our study, similar to the literature, and it was determined that this insufficiency negatively affected the sleep quality and kinesiophobia levels of the participants.

We found the mean PSQI total score to be 8.23 ± 1.32 . Additionally, a weak negative correlation was found between IPAQ total physical activity and PSQI, and the average sleep quality levels of individuals with high physical activity levels were better than others. The literature contains studies similar to ours, showing that physical activity affects sleep quality in individuals with fibromyalgia (26-27). In a review, they stated that physical activity had a negligible effect on sleep levels and pointed out that more meditative exercises may be more effective (27). Similarly, a published meta-analysis showed that more meditative exercises, including traditional Chinese exercises, were influential in affecting sleep quality (26). We think that individuals with fibromyalgia who engage in physical activity feel more energetic and robust, which may have caused them to be more active in daily life and need more energy, affecting their ability to sleep more comfortably at night. In addition, physical activity may have helped individuals improve their sleep quality by affecting many physical parameters, especially pain. However, since we did not question the type of physical activity they did in our study, we may have found the correlation value to be lower. Additionally, no studies in the literature show how different physical activity levels affect sleep quality. Based on our study's results, we can say that the participants with sufficient physical activity has the best sleep quality.

Although a few studies address the importance of kinesiophobia in individuals with fibromyalgia (11,13,28,29), no study has evaluated its relationship with different physical

activity levels. As a result of our research, the average TKS total score was found to be 43.12 ± 2.19 . Additionally, a moderate negative correlation was found between IPAQ total physical activity and TKS, and it was observed that the kinesiophobia levels of individuals with fibromyalgia were negatively affected by the decrease in physical activity. In correlation with our study, it has been shown in the literature that kinesiophobia levels are positively affected by physical activity in individuals with fibromyalgia (6,13,30). Particularly in studies, it has been stated that physical activity affects kinesiophobia levels in individuals with fibromyalgia, with its psychosocial benefits (11), its relevance to pain control models, and its positive effects on quality of life (28,29). Our study found that kinesiophobia levels were lower, especially in individuals with high physical activity levels. We think the most important reason for this is the physical and psychosocial gains from physical activity, especially pain. In addition, adequate physical activity improves individuals' self-confidence and increases their mobility. We think that all these affected the results of our study.

This study once again emphasizes the importance of increasing physical activity and living an active life. One of the strengths of our study is that we classified the outcome measures according to different physical activity levels. The most important limitation of our study is that the types of physical activity individuals did were not questioned. Another limitation is that pain was not evaluated, which may affect physical activity levels. Another limitation is that the numbers of men and women are not homogeneous.

Conclusion

Our study emphasizes the importance of directing individuals with fibromyalgia to adequate physical activity to improve sleep health and prevent kinesiophobia and guides the literature. While individuals with fibromyalgia are referred to physical activities, their kinesiophobia levels should also be evaluated and led to appropriate actions. Future studies may investigate the effects of different types of physical activity on different dimensions in individuals with fibromyalgia.

Declarations

Funding

None

Conflicts of Interest/ Competing Interests

None

Ethics Committee Approval

Ethics committee approval was obtained from the Ankara Medipol University Non-Interventional Clinical Research Ethics Committee before starting the study (Date: 14/02/2023 Decision No: 021).

Availability of Data

Available upon request.

Authors' Contributions

HIB created the study idea, reached the individuals who participated, and brought it to the literature. MB organized the study method, created evaluation forms, made necessary evaluations of the individuals for the study, collected the data, analyzed the data, entered it into the system, and brought them to the literature. Both authors have read and approved the final version of the manuscript.

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The Difficulties Experienced by Tradesmen According to the Situation of Closing Their Businesses During the Pandemic Period and Their Depression Status

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ABSTRACT

Purpose: COVID 19, which continues to have a global impact, poses many challenges to small businesses. Due to the measures taken against the pandemic, tradesmen closed their small businesses and faced many difficulties. As a result of the difficulties experienced by the tradesmen, they have been adversely affected in terms of economic, social, and health factors. Based on these situations, the study was conducted to determine the depression level of the tradesmen during the pandemic, to determine the difficulties they experienced in their own words, and to determine its relationship with depression.

Methods: The population of the cross-sectional study consisted of 1100 people working as tradesmen in the Bitlis city center. The sample of the study, 285 individuals, was reached by the simple random method. Data were collected using the "Personal Information Form" and "Beck Depression Inventory".

Results: 17.2% of small business owners have severe depression, and 37.9% have moderate depression symptoms. Small businesses stated that they experienced difficulties such as family problems, laying off personnel, and experiencing physical and mental problems during the lockdown measures. Layoffs and family problems in business owners due to lockdown measures are more associated with depression symptoms.

Conclusion: During the pandemic, the depression level of tradesmen was higher than that of the general population. Challenges, particularly family problems, have emerged that may increase the level of depression symptoms among business owners.

Keywords: coronavirus, pandemic, infectious disease, depression

ÖZET

Amaç: Küresel düzeyde etkileri hala devam eden Covid 19 küçük işletmelere pek çok zorluklar yaşatmaktadır. Pandemi önemleriyle esnafın küçük işletmelerini kapatmış ve pek çok zorlukla yüzleşmiştir. Esnafın yaşadığı güçlükler ekonomik, sosyal ve sağlık yönünden onları etkilemiştir. Bu durumlardan yola çıkarak çalışma pandemide esnafın depresyon düzeyini saptamak, kendi ifadeleriyle yaşadıkları zorlukları tespit etmek ve depresyon durumuyla ilişkisini saptamak amacıyla yapılmıştır.

Yöntem: Kesitsel nitelikte çalışmanın evrenini Bitlis il merkezinde esnafın yapan 1100 kişi oluşturmaktadır. Çalışmanın örneklemini olan 285 kişiye basit rastgele yöntemle ulaşılmıştır. Veriler "Kişisel Bilgi Formu" ve "Beck Depresyon Envanteri" ile toplanmıştır.

Bulgular: Küçük işletmelerin %17,2'sinde şiddetli depresyon ve %37,9'unda orta düzey depresyon belirtileri vardır. Küçük işletmeler pandemi önlemlerine bağlı kapanma sürecinde ailesel problemler yaşama, işten personel çıkarma ve bedensel problemler yaşama gibi zorluklar yaşadıklarını ifade etmişlerdir. İşletmelerde işten personel çıkarmalar olması ve işletme sahiplerinde kapanmaya bağlı ailesel problemler ortaya çıkması depresyon belirtileriyle daha fazla ilişkilidir.

Sonuç: Pandemi sürecinde küçük işletme sahibi olan esnafın depresyon düzeyi genel topluma göre daha yüksektir. Başta aile problemleri olmak üzere işletme sahiplerinin depresyon belirtileri düzeyini arttırabilecek zorluklar ortaya çıkmıştır.

Anahtar Kelimeler: Koronavirüs, Pandemi, Bulaşıcı Hastalıklar, Depresyon

When the epidemiological data of COVID-19 for 2023 are examined at the global level, it is noticed that its effects on public health continue with new cases and deaths. Globally, a total of 13.9 million new cases and more than 49.000 new deaths were reported between December 12, 2022, and January 8, 2023. There has been an increase in the number of illnesses and deaths compared with the previous month (1). This pandemic surrounding the world continues to harm people's lives and the economy. One of the groups facing the most challenges in the pandemic is business owners and employees. Businesses are experiencing great losses due to the damages brought by the pandemic, mandatory measures, and other reasons. Businesses are hesitant to take risks during this period due to the decreasing purchasing power of consumers and supply problems. Thus, there is a decrease in the number of small businesses that want to start their own business and become entrepreneurs (2).

This change in small businesses also poses challenges for employees. Businesses may lay off employees or have challenging demands from their employees (3). During the pandemic, layoffs, workplace closures, and the search for new jobs forced small businesses to change. Yet, during this period of change, they are faced with challenges in adapting to mandatory epidemiological measures. Failure to adapt to these measures leads to disruptions in maintaining the economic activities of enterprises. Those who adapt to these economic changes, both macro and micro-enterprises, overcome difficulties more easily (4). In addition to economic adaptation, social adaptation, revisions in lifestyle and working conditions, development, digital technology innovations, and alternative employment opportunities are also useful in combating the challenges of the pandemic (5, 6).

Failure to adapt to the challenges posed by the COVID-19 pandemic has also affected the health of small business owners and employees. The problem of adaptation to the pandemic and the increasing economic losses of entrepreneurs have brought not only physical problems but also mental problems. Depression, anxiety, and stress have increased in small business owners and entrepreneurs due to economic impacts (7, 8). In addition to operators, the elderly, healthcare workers, infected people, relatives of infected people, and the poor are the groups most affected by the pandemic (9, 10). Based on these situations, the study was conducted to determine the depression level of small businesses during the pandemic, identify the difficulties they experienced in their own words, and determine the relationship with depression.

Research Questions

What is the frequency of depression symptoms among tradesman in the pandemic period?

Are the difficulties experienced by tradesmen during the pandemic related to depression?

Materials and Methods

Bitlis

Bitlis province is located in the Eastern Anatolia region of Turkey. The province is situated in a mountainous region and has a high altitude. The income levels and education rates of the province's residents have not yet reached the desired standards. In addition, the family type is traditional and crowded (11).

Research Design

It is a cross-sectional study.

Population and Sample

The population of the study consisted of 1100 tradesmen working as tradesmen in the central district of Bitlis province. From the formula used when the population is known ($n = [n \cdot t^2 \cdot p \cdot q] / [d^2(n-1) + t^2 \cdot p \cdot q]$), the number of people to be included in the sample was determined to be 285. In the formula, the calculation was made according to the confidence level of 95%, the population of 1100, $p=0.5$, and $q=0.5$. In the study, 285 people were reached by a simple random method between April 12 and June 24, 2022.

Inclusion Criteria

Those who were tradesmen in the central district of Bitlis during the pandemic, who were 18 years of age or older, and who agreed to participate in the study were included.

Data Collection

Data were collected using the Personal Information Form and Beck Depression Inventory (BDI) (12). The BDI was developed by Beck et al. in 1961. The Turkish validity and reliability study of the BDI was conducted by Hisli in 1989 (13). Based on self-assessment, the BDI consists of 21 items, and each item is scored between 0 and 3. According to the scores of the participants on the scale, it is considered minimum depression for 0–9 points, mild

depression for 10–16 points, moderate depression for 17–29 points, and severe depression for 30–63 points (14). The Cronbach alpha value (internal consistency coefficient) of the BDI items used in the study was 0.861.

Statistical Analysis

In the visual and statistical analysis of the data, it was determined that they did not fit the normal distribution. Therefore, the Kruskal-Wallis H test, Mann-Whitney U test, multivariate ordinal logistic regression analysis, and Spearman correlation analysis were used for statistical analysis.

Results

Socio-Demographic Characteristics

The mean age of the tradesmen was 36 (min. 18–max. 80), the mean income was 459.70 USD (United States dollar) (min. 55.91 USD – max. 2124.47 USD), and the mean BDI was 19.01 (min. 0.00–max. 58.00). Table 1 shows the socio-economic status of the participants and the comparison of these variables with the BDI score. No significant difference was found between gender, marital status, educational status, monthly income, and BDI ($p > 0.05$).

Table 1: Distribution of tradesmen by their socio-demographic characteristics and BDI comparison

		n	%	Median	Min-Max	Test	p
Gender	Male	236	82.8	17.00	0.00-58.00	5229.00 [‡]	0.292
	Female	49	17.2	19.00	2.00-39.00		
Marital status	Single	102	35.8	17.00	0.00-58.00	8567.00 [‡]	0.250
	Married	183	64.2	18.00	0.00-57.00		
Educational status	Primary school graduate	23	8.1	19.00	9.00-37.00	5.150 [§]	0.161
	Secondary school graduate	48	16.8	20.00	0.00-51.00		
	High school	119	41.8	18.00	0.00-58.00		
	University graduate	95	33.3	16.00	0.00-50.00		
Monthly income	0-279.54 USD †	129	45.3	17.00	0.00-50.00	3.042 [§]	0.219
	279.54-559.07 USD	133	46.7	19.00	0.00-58.00		
	Over 559.07 USD	23	8.0	17.00	0.00-45.00		

†; USD - United States dollar, ‡; Mann-Whitney Test, §; Kruskal-Wallis Test, n; Number, %; Percentage

Table 2: The difficulties experienced by the tradesmen during the pandemic their own words and BDI comparison

Pandemic Challenges		n	Median	Min-Max	Test	p
I borrowed money from acquaintances	Yes	88	19.500	(0.00-51.00)	7419.00 [‡]	0.052
	No	197	17.000	(0.00-58.00)		
I took loans from banks	Yes	113	18.000	(0.00-58.00)	8847.50 [‡]	0.201
	No	172	17.000	(0.00-50.00)		
I changed jobs	Yes	27	20.000	(4.00-50.00)	2731.00 [‡]	0.065
	No	258	17.000	(0.00-58.00)		
Physical problems arose	Yes	47	23.000	(2.00-58.00)	3701.00 [‡]	<0.001*
	No	238	17.000	(0.00-57.00)		
Familial problems occurred	Yes	111	23.000	(0.00-58.00)	5447.00 [‡]	<0.001*
	No	174	14.000	(0.00-46.00)		
I asked relatives for support	Yes	109	17.000	(0.00-58.00)	9460.00 [‡]	0.845
	No	176	18.000	(0.00-57.00)		
I laid off the employees	Yes	40	27.500	(7.00-58.00)	3362.50 [‡]	0.001*
	No	245	17.000	(0.00-51.00)		

* $P < 0.05$, ‡; Mann-Whitney Test,

Table 2 presents the difficulties experienced by tradesmen in their own words while their businesses were closed during the pandemic and the comparison of these difficulties with the BDI level. Some of these difficulties were statistically significant compared with the BDI level. A significant difference was found between BDI and those who had family problems (< 0.001), physical problems (< 0.001), and those who dismissed employees (0.001) during the pandemic.

Table 3: Spearman correlation matrix between the variables of the tradesmen

	1	2	3	4	5	6
1. Experience year as a tradesman	-					
2. Average monthly income	0.005	-				
3. Number of people cared for	0.438**	-0.014	-			
4. Number of employees in the enterprise	0.058	0.193**	0.091	-		
5. Shutting down the business during the pandemic (days)	-0.063	0.186**	0.023	-0.069	-	
6. BDI	-0.016	0.090	0.117*	0.009	0.264**	-

** $p < 0.01$, * $p < 0.05$, BDI, Beck Depression Inventory

Table 3 shows that there is a significant correlation between BDI and the number of days the business is closed. The increase in the number of days that businesses are closed affects the level of depression.

The Incidence of depression symptoms

Table 4 shows the depression symptoms of the participants according to their BDI scores. Severe depression symptoms were observed in 17.2% of the tradesmen, and moderate depression symptoms were observed in 37.9% of them.

Table 4: Classification of depression symptoms in participants

Symptoms	n	%
Minimal	54	18.9
Mild	74	26.0
Moderate	108	37.9
Severe	49	17.2
Total	285	100

Challenges faced by tradesmen associated with symptoms of depression

Table 5: Explanatory variables predicting depression symptoms of tradesmen

Predictive	Prediction	SE	Wald	p	Odds Ratio	95% CL		
						LL	UL	
Workplace closure (Days)		0.045	0.015	9.380	0.002	1.046	1.016	1.076
I made a job change during the pandemic	Yes	0.292	0.379	0.594	0.441	1.339	0.637	2.817
	No	0*						
Physical problems arose	Yes	0.792	0.308	6.621	0.010	2.208	1.208	4.036
	No	0*						
I laid off the employees	Yes	0.931	0.328	8.036	0.005	2.536	1.333	4.825
	No	0*						
I had family problems	Yes	1.107	0.241	21.176	<0.001	3.026	1.888	4.849
	No	0*						

CL; Confidence Interval, LL; Lower, UL; Upper, SE; Standard Error, *Reference category; response variable reference category minimum depression symptoms

In ordinal logistic regression analysis, the categories of the dependent variable are required to meet the assumption of parallel lines. According to the Test of Parallel Lines, the parallelism condition is met ($-2 \log \text{likelihood} = 415.799$, $\text{chi-square} = 15.20$, $p=0.125$). The model is statistically significant ($-2 \log \text{likelihood} = 431,008$, $\text{chi-square} = 57.351$, $p<0.001$). All independent variables in the model account for 20% of the dependent variable ($R^2=0.182$, Cox and Snell; $R^2=0.196$, Nagelkerke) (Table 5).

The odds of depression symptoms are 2.5 times higher for those who laid off workers than for those who did not, and the odds of depression symptoms are 3 times higher for those who started having family problems than for those who did not. A one-unit increase in the duration of workplace closure during the pandemic increases the odds of depression symptoms by 5% (Table 5). Based on the statements of tradesmen, the emergence of physical problems due to closing the workplace during the

pandemic, the emergence of family problems, the fact that business owners had to lay off workers, and the duration of the workplace closure are correlated with depression symptoms ($p<0.05$).

Discussion

Pandemics such as COVID-19 have psychologically affected every segment of society. While some individuals in society adapted to this new life change, others could not. Mental disorders such as anxiety and depression have increased in individuals who cannot adapt. The disruption of family communication, physical problems, and economic difficulties due to the impact of the pandemic have increased psychological problems (15). The patriarchal family structure is at the forefront in Bitlis. Tradesmen are important sources of income for the family. From this perspective, we found in our study that depression was more prominent in tradesmen affected by the pandemic.

In this study on tradesmen, the main difficulties that come to the fore are the emergence of family problems. In the ordinal regression analysis, it was observed that those who had family problems during the pandemic had a greater effect on depression. Restrictions brought about by the COVID-19 pandemic, lockdown, restriction of social opportunities, unemployment, and economic difficulties have negatively affected communication within the family (16). During the pandemic, the businesses of tradesmen were closed for a certain period of time. Another challenge faced by tradesmen during the pandemic was that they had to lay off their employees. It was observed that the tendency for depression symptoms increased in those who permanently dismissed their employees during the compulsory closure of businesses. The closure of a business, the dismissal of employees, and the bankruptcy of businesses may be due to being in the bankruptcy stage or depleting their economic resources. This may have increased the upward trend in depression. In a study conducted in the USA, the closure of small businesses during the pandemic was found to be associated with the prevalence of anxiety but not with the prevalence of depression. Reduced urban mobility and restricted access to social spaces as a result of social distancing measures have led to the closure of small businesses. Ultimately, anxiety and depression levels increased in American society (17).

Business owners stated that physical ailments arose due to the difficulties they experienced during the closure of their businesses. In our study, symptoms of depression were more common in tradesmen who stated that they had physical problems due to the pandemic. Depression may have also increased physical complaints. Physical complaints are common with depression. The most common complaints include joint pain, limb pain, gastrointestinal problems, fatigue, and changes in appetite (18).

In our study, no significant correlation was found between depression and the tradesmen's thoughts of starting another business due to the difficulties experienced during the closure of the business during the pandemic. Uncertainties such as fear and a lack of awareness of change can affect the motivation of businesses to start another business (19). The thought of starting another job may cause fear or uncertainty, but not depression.

In our study on tradesmen, the level of depression during the mandatory lockdown period was also examined. The prevalence of depression was found to be high among tradesmen. Severe depression and moderate depression

symptoms were observed in 17.2% and 37.9% of the tradesmen, respectively, which is higher than the general adult population in Turkey. During the pandemic, the prevalence of severe depression symptoms in the adult population was 5%, and the prevalence of moderate depression symptoms was 22.3% (20). In a study on the Chinese general population during the pandemic, the prevalence of depression symptoms was found to be 27.9% (10).

In our study, the sociodemographic characteristics and depression levels of the tradesmen were compared. There was no significant correlation between the gender, marital status, educational status, and monthly income of the participants and depression symptoms. In a study conducted in a Turkish adult population, a significant difference was found between these variables and depression (20). In a study conducted on the Chinese population during the pandemic, it was found that income and age were associated with depression symptoms (10). Results in groups with a high prevalence of depression symptoms, such as tradesmen, may differ from those in the general population.

Conclusion

During the pandemic, it was observed that the depression level of tradesmen was higher than that of the general population. Challenges, particularly family problems, have emerged that may increase the level of depression symptoms among business owners. In a pandemic that has devastating effects on society, providing family support to tradesmen, helping them overcome economic difficulties, and counseling on innovations can contribute to overcoming difficulties. Providing tradesmen with support during the period when they experienced difficulties during the pandemic could contribute to reducing the level of depression that they experienced.

Limitations of the Study

The results of the study are about the tradesmen who have small businesses in a city center. One of the limitations of the study is that the data were collected from small business owners in a provincial center. Although the study was conducted at the regional level, it can contribute to systematic reviews. Moreover, the self-report-based nature of the data collection tools and the cross-sectional nature of the study are other limitations.

Declarations

Financial Disclosure

This study was not funded by any company or individual.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Ethical Approval

Ethical approval of the study was obtained with the decision of the Bitlis Eren University Ethical Principles and Ethics Committee numbered 22/04-2.

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Contribution of the Authors

CÖ; Contributed to the Design of the Study, Introduction, Materials and Methods, Evaluation of the Results, Discussion, and Conclusion. AI; Contributed to the Design of the Study and Evaluation of the Results.

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Relationship between Postpartum Depression, Parental Perfectionism, and Social Media Use in First-Time Mothers: A Descriptive Study

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ABSTRACT

Purpose: The aim of this study was to examine the relationship between postpartum depression, parental perfectionism, and social media use in first-time mothers, and to determine the factors affecting postpartum depression.

Methods: This descriptive and correlational study was conducted with 229 mothers in the postpartum period of one year. The study conducted between January and June 2023 at the pediatric outpatient clinic of a Medical Faculty Hospital in a province in the Central Anatolia Region of Turkey. Data were collected using a participant information form, the Edinburgh Postnatal Depression Scale (EPDS), the Multidimensional Parenting Perfectionism Scale (MPPS), and the Social Media Use Scale (SMUS).

Results: 28.4% of the mothers are at risk group for depression (EPDS \geq 13). 45% of the mothers reported using their phones for four or more hours daily, and 80.8% of the mothers reported a decrease in mobile phone use after giving birth. Social media was predominantly used to obtain information (75.5%), and Instagram (88.2%) was the most used social media platform. In the study, the identified risk factors for PPD included mothers' age (OR = 0.835; $p < 0.001$); Multidimensional Parenting Perfectionism Scale total score (OR = 0.851; $p < 0.001$), including sub-dimension scores of personal parenting standards (OR = 1.212; $p = 0.053$), doubts about parenting activity (OR = 1.341; $p < 0.001$), and partner's parenting expectations and criticisms (OR = 1.219; $p < 0.001$); and social integration and emotional connection sub-dimension scores of the social media use scale (OR = 0.928; $p = 0.010$).

Conclusion: In the study, mother's age and parenting perfectionism were found to increase the risk of postpartum depression, while social media use was observed not to have an effect. Assessing perfectionism could be considered in identifying women at risk of postpartum depression during the postpartum period.

Keywords: Perfectionism; postpartum depression; social media; parenthood

ÖZET

Amaç: Bu çalışmanın amacı ilk kez anne olan kadınlarda postpartum depresyon, ebeveyn mükemmeliyetçiliği ve sosyal medya kullanımı arasındaki ilişkiyi incelemek ve postpartum depresyonu etkileyen faktörleri belirlemektir.

Gereç ve Yöntemler: Bu tanımlayıcı ve ilişkisel çalışma postpartum bir yıllık dönemde olan 229 anne ile yürütüldü. Çalışma, Ocak-Haziran 2023 tarihleri arasında İç Anadolu Bölgesi'ndeki bir ilin Tıp Fakültesi Hastanesinin çocuk polikliniğinde gerçekleştirildi. Veriler, katılımcı bilgi formu, Edinburgh Postpartum Depresyon Ölçeği (EPDÖ), Çok Boyutlu Ebeveynlik Mükemmeliyetçiliği Ölçeği (ÇBEMÖ) ve Sosyal Medya Kullanımı Ölçeği (SMKÖ) kullanılarak toplandı.

Bulgular: Annelerin %28.4'ü depresyon için risk grubundadır (EPDÖ \geq 13). Annelerin %45'i günde dört saat ve üzerinde telefon kullandıklarını ve %80.8'inin doğumdan sonra telefon kullanımının azaldığını ifade etmiştir. Sosyal medyayı en çok bilgi edinmek (%75.5) amacıyla ve sosyal medya araçlarından en fazla Instagram'ı (%88.2) kullanmaktadırlar. Çalışmada annelerin yaşı (OR:0.855, $p = p < 0.001$), Çok Boyutlu Ebeveynlik Mükemmeliyetçiliğinin alt boyutlarından ebeveynlik yeteneğinden şüphe duyma (OR:1.196, $p = 0.002$) ve ebeveynlikte düzen (OR:0.894, $p < 0.001$) postpartum depresyon için risk faktörleri olarak bulundu.

Sonuç: Çalışmada annenin yaşı ve ebeveynlik mükemmeliyetçiliği postpartum depresyon riskini artırırken, sosyal medya kullanımının etkili olmadığı görülmüştür. Postpartum dönemde postpartum depresyon riski taşıyan kadınların belirlenmesinde mükemmeliyetçilik değerlendirmesinin de dahil edilmesi düşünülebilir.

Anahtar Kelimeler: Mükemmeliyetçilik; postpartum depresyon; sosyal medya; ebeveynlik

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The transition to parenthood is a challenging time for mothers. Although the birth of a baby brings joy and happiness, women experience a sudden and dramatic change in their roles and responsibilities (1). This makes mothers highly susceptible to postpartum depression (PPD) (2). PPD may start approximately 1–3 weeks after birth and may occur up to 1 year later (3). PPD negatively affects the mother's quality of life; her relationship with her baby, spouse, and relatives (1); the baby's growth and development; and feeding of and attachment to the baby (4). Common risk factors for PPD include maternal/family history of depression, number of pregnancies, income status, number of children (5), lack of social support, current or past abuse, prenatal depression, and marital or spousal dissatisfaction (6). In addition to external factors, numerous internal factors including personality traits have also been emphasized as risk factors for PPD (7). Perfectionism may be considered one such factor (8).

Perfectionism can be defined as the effort of an individual to reach high standards and to be perfect (7, 9). Perfectionism complicates parental adjustment in the postnatal period and negatively affects maternal health by creating differences between parenting goals and realities (9). Mothers with perfectionist traits were reported to experience low self-efficacy, stress, and PPD (8, 9). First-time mothers may feel that they have to meet high standards for parenting. Accordingly, new mothers may use social media to get support, information, and advice in fulfilling their maternal responsibilities (10) or to show that they are fulfilling their maternal role (11).

Social media includes various platforms such as Facebook, Instagram, and Twitter along with a range of online services such as blogs and messaging sites (12). New social support models including social media networks have emerged considering the ubiquitous nature of the Internet and the fact that the family structure has considerably evolved in recent years, i.e., individuals no longer live in extended families and mothers are employed (13). Social media is commonly used by mothers to obtain information on motherhood and childcare, and it enables mothers to stay in touch with their friends and create the façade of an active social life (14). Most parents, especially young mothers, actively use social media (15). First-time mothers need more information on the Internet than multiparous mothers because they have no previous experience in child care (16). Furthermore, mothers who are unable to receive support from friends and parents seek support from online communities via social media (12, 17). However,

although social media provides sources of support and information for new mothers, excess and/or irrelevant information can cause confusion and misunderstandings (10). Notably, seeing examples of “ideal mothers” on social media may negatively affect the mental health of mothers who strive for perfection and compare themselves with the ideals presented on social media (18). Padoa and Berle (17) showed that social comparison with other mothers is a cause of anxiety and depression in mothers with self-oriented parenting perfectionism. This is because social media users tend to share and showcase the positive aspects of parenting, trying to create an illusion that they are happier and/or more successful than they actually are (18). Difficulties of parenting, i.e., parental frustration, exhaustion, and fatigue, are rarely shown on social media (19). Taking these challenges of the postpartum period into consideration, nurses should assess perfectionism and social media use, among other factors, in women at risk of PPD.

Objective

The aim of this study was to examine the relationship between PPD, parental perfectionism, and social media use in first-time mothers and to determine the risk factors affecting PPD.

Research questions

1. What is the level of PPD in mothers?
2. Is there a relationship between PPD, parental perfectionism, and social media use in mothers?
3. What are the risk factors affecting PPD in mothers?

Materials and Methods

Study Design

The present study was performed as a descriptive and correlational research.

Place and Time of the Study

The study was performed between January 2023 and June 2023 in the pediatric outpatient clinic of a Medical Faculty Hospital of a province in the Central Anatolia Region.

Population and Sample of the Study

The study population consisted of mothers who applied to the pediatric department for examination and check-up of their infants between January 2023 and June 2023. First-time mothers aged ≥ 18 years, who were literate in Turkish, and were in the first year postpartum period were included in the study. Mothers with any known psychiatric or neurological problems (self-reported) were excluded from the study. Gpower 3.1.9.2 program was used to calculate the minimum sample size. Using the F-test, a minimum sample size of 227 participants was calculated with 95% confidence ($1-\alpha$), 85% test power ($1-\beta$), and $d = 0.04$ effect size (17). The study was completed with 229 mothers who met the inclusion criteria.

Data Collection Tools

Participant Information Form, Edinburg Postpartum Depression Scale (EPDS), Multidimensional Parenting Perfectionism Scale (MPPS), and Social Media Use Scale (SMUS) were used for data collection.

Participant Information Form

The participant information form has been created by researchers based on the literature (12, 16-18). This form consisted of 18 questions on the sociodemographic characteristics and social media use of the participants.

Edinburg Postpartum Depression Scale (EPDS)

EPDS was developed by Cox and Holden (20) to measure symptoms of PPD, and the Turkish adaptation and validity study for this scale was performed by Engindeniz et al. (21) EPDS is a 4-point Likert type scale that consists of 10 items. Items are scored between 0 and 3, and the total score ranges from 0 to 30. Engindeniz et al. reported that Cronbach's alpha coefficient was 0.79. The cut-off point was identified as 13, and a scale score of ≥ 13 indicated risk for PPD (21). In the present study, Cronbach's alpha coefficient was 0.85.

Multidimensional Parenting Perfectionism Scale (MPPS)

MPPS was developed by Snell et al. (22) to measure multiple components of parenting perfectionism. Turkish validity and reliability study was conducted by Taluy and Maraş (23). Form B of the MPPS consists of the following four sub-dimensions: (1) Partner's Parenting Expectations and Criticisms, (2) Doubts about Parenting Activity, (3) Parenting Organization, and (4) Personal

Parenting Standards. MPPS is a 23-item, 5-point Likert-type self-report scale. The responses are scored between 1 and 5, and the sub-dimension scores are calculated by calculating the sum of the item scores in each sub-dimension. Higher scores in each sub-dimension indicated a stronger perfectionist parenting tendency defined in the sub-dimension. Cronbach's alpha internal consistency coefficients of the scale were between 0.83 and 0.93 (23). In the present study, Cronbach's alpha coefficient of the total scale was 0.89.

Social Media Use Scale (SMUS)

The SMUS was developed by Jenkins-Guarnieri et al. (24) and adapted into Turkish by Akin et al. (25). The scale consists of 10 items and two sub-dimensions (social integration and emotional connection and integration into social routines). It is a 6-point Likert-type self-report scale. The 8th item of the scale is scored in reverse. Higher scores indicate an increased level of social media use. Cronbach's alpha coefficients of the Social Media Use Scale were 0.87 for the social integration and emotional connection sub-dimension, 0.71 for the integration into social routines sub-dimension, and 0.87 for the whole scale (25). In the present study, Cronbach's alpha coefficient was 0.82.

Ethical Aspects of the Research

Ethical approval and institutional permission were obtained from Necmettin Erbakan University Health Sciences Scientific Research Ethics Committee before the research. Before initiating the study, the study's purpose was explained to the participants and their informed written consent was obtained. The study was performed in accordance with the principles of the Declaration of Helsinki.

Statistical Analysis

The IBM SPSS V29 software was used for data analysis. Percentage, mean, standard deviation, median, and minimum and maximum values were used to evaluate and present descriptive statistics. The Spearman correlation test was used to determine the relationship between the EPDS, MPPS, and SMUS. Binary Logistic Regression Analysis was used to identify risk factors for PPD. Multivariate regression analysis was performed with the Backward Wald method. Variables in the model were presented with odds ratio (OR) and 95% confidence interval (CI) values. $P < 0.05$ indicated statistical significance.

Table 1: Descriptive Characteristics of Mothers (n=229)

Independent variables	Postpartum Depression		
	No	Yes	Total
	n (%)	n (%)	n (%)
Age (Mean±SD)	28.57±4.87	25.60±3.65	27.73±4.74
Education			
Literate	12 (7.3)	20 (30.8)	32 (14)
Primary education	28 (17.1)	13 (20)	41 (17.9)
High school graduate	40 (24.4)	14 (21.5)	54 (23.6)
University and above	84 (51.2)	18 (27.7)	102 (44.5)
Working status			
Not Working	108 (65.9)	51 (78.5)	159 (69.4)
Working	56 (34.1)	14 (21.5)	70 (30.6)
Education of the spouse			
Literate	12 (7.3)	13 (20)	25 (10.9)
Primary education	24 (14.6)	18 (27.7)	42 (18.3)
High school graduate	48 (29.3)	18 (27.7)	66 (28.8)
University and above	80 (48.8)	16 (24.6)	96 (42.0)
A place where you live for a long time			
Village	31 (18.9)	12 (18.5)	43 (18.8)
District	46 (28.1)	23 (35.3)	69 (30.1)
Province	87 (53)	30 (46.2)	117 (51.1)
Perceived economic status			
Poor	18 (11)	10 (15.4)	28 (12.2)
Medium	116 (70.7)	46 (70.8)	162 (70.7)
Good	30 (18.3)	9 (13.8)	39 (17.1)
Chronic illness			
No	146 (89)	58 (89.2)	204 (89.1)
Yes	18 (11)	7 (10.8)	25 (10.9)
Drug use			
No	147 (89.6)	58 (89.2)	205 (89.5)
Yes	17 (10.4)	7 (10.8)	24 (10.5)
Smoking			
No	143 (87.2)	52 (80)	195(85.2)
Yes	21 (12.8)	13 (20)	34(14.8)
Phone usage time (h/day)			
1-2	36 (22)	13 (20)	49(21.4)
3	53 (32.3)	24 (36.9)	77(33.6)
4 and above	75 (45.7)	28 (43.1)	103(45.0)
Frequency of phone use			
Unchanged	16 (9.8)	17 (26.2)	33(14.4)
Decreased	139 (84.8)	46 (70.8)	185(80.8)
Increased	9 (5.4)	2 (3)	11(4.8)

SD: Standard deviation

Results

A total of 229 first-time mothers in the first year postpartum period participated in the study. The descriptive characteristics of the participants are presented in Table 1. The mean age of the mothers was 27.73 ± 4.74 years and 44.5% had university education or higher. Of the mothers, 30.6% stated that they were employed in an income-generating job and 70.7% stated that their income level was medium. 45% of the mothers reported using their phones for four or more hours daily, while 33.6% stated

they used their phones for three hours daily. Additionally, 80.8% of the mothers reported a decrease in mobile phone use after giving birth. Social media was mostly used to obtain information (75.5%) and Instagram (88.2%) was the most commonly used social media platform.

Mean EPDS, MPPS, and SMUS scores were 10.42 ± 5.83 , 63.13 ± 15.46 , and 25.52 ± 9.4 , respectively (Table 2). Accordingly, 28.4% of the mothers were in the risk group for depression (EPDS score ≥ 13). No significant correlation was found between EPDS, MPPS, and SMUS scores (Table 3).

Table 2: Distribution of total and subscale scores of Edinburg Postpartum Depression Scale, Multidimensional Parenting Perfectionism Scale and Social Media Use Scale

Scale and sub-dimensions		Mean±SD	Median	(Minimum-Maximum)
Edinburg Postpartum Depression Scale Total Score		10.42±5.83	10	(0-25)
Multidimensional Parenting Perfectionism Scale Total Score		63.13±15.46	65	(22-100)
Sub-dimensions	Personal parenting standards	15.3±4.71	15	(5-25)
	Doubts about parenting activity	7.57±3.08	7	(3-15)
	Partner's parenting expectations and criticisms	20.36±7.38	20	(9-40)
	Parenting organization	21.95±6.3	23	(6-30)
Social Media Use Scale Total Score		25.52±9.45	25	(10-60)
Sub-dimensions	Social integration and emotional connection	12.73±7.05	10	(6-36)
	Integration into social routines	13.79±4.35	14	(4-24)

SD: Standard Deviation

Table 3: Correlations between Edinburgh Postpartum Depression Scale, Multidimensional Parenting Perfectionism Scale and Social Media Use Scale

	EPDS		MPPS	
	r	p	r	p
EPDS	1.000			
MPPS	0.127	0.056	1.000	
SMUS	0.100	0.131	0.090	0.176

r: Spearman correlation, EPDS: Edinburg Postpartum Depression Scale, MPPS: Multidimensional Parenting Perfectionism Scale, SMUS: Social Media Use Scale

Table 4: Risk factors for postpartum depression (n=229)

Independent variables	Postpartum Depression			
	Univariate		Multiple	
	OR(%95 CI)	p	OR(%95 CI)	p
Age	0.855(0.793-0.921)	<0.001	0.835(0.766 - 0.911)	<0.001
Education				
Literate	7.778 (3.232 - 18.719)	<0.001		
Primary education	2.167 (0.943 - 4.978)	0.068		
High school graduate	1.633 (0.739 - 3.611)	0.226		
University and above	Reference			
Working status				
Working	1.889 (0.963 - 3.705)	0.064		
Not working	Reference			
Education of the spouse				
Literate	5.417 (2.093 - 14.015)	<0.001		
Primary education	3.75 (1.663 - 8.458)	0.001		
High school graduate	1.875 (0.875 - 4.02)	0.106		
University and above	Reference			
Chronic illness				
No	1.022 (0.405 - 2.575)	0.964		
Yes	Reference			
Drug use				
No	0.958 (0.378 - 2.431)	0.928		
Yes	Reference			
Smoking				
No	0.587 (0.274 - 1.257)	0.171		
Yes	Reference			
MPPS				
Personal parenting standards	0.993(0.934 - 1.055)	0.813	1.212 (0.997 - 1.474)	0.053
Doubts about parenting activity	1.193(1.081 - 1.316)	<0.001	1.341 (1.142 - 1.575)	<0.001
Partner's parenting expectations and criticisms	1.072(1.029 - 1.117)	0.001	1.219 (1.111 - 1.337)	<0.001
Parenting organization	0.944(0.902 - 0.988)	0.014		
MPPS total score	1.009(0.99 - 1.028)	0.375	0.851 (0.78 - 0.928)	<0.001
SMUS				
Social integration and emotional connection	1.011(0.972 - 1.053)	0.580	0.928 (0.877 - 0.983)	0.010
Integration into social routines	0.97(0.907 - 1.037)	0.369		
SMUS Total Score	1.000(0.970-1.031)	0.999		
Constant			288.902	0.001
Cox & Snell R Square=0.211; Nagelkerke R Square=0.303; Accuracy=0.734				
MPPS: Multidimensional Parenting Perfectionism Scale, SMUS: Social Media Use Scale				

Risk factors associated with PPD are presented in Table 4. Evaluation of these variables in the univariate model revealed that PPD increased 0.855-fold with increasing maternal age ($p < 0.001$). The risk of PPD was higher in literate women (no primary education) than in those with a university degree or higher (OR = 7.778; $p < 0.001$). This trend was observed in PPD risk for partners, and showed higher risk for participants who were literate (no primary education) and primary education level than for those who were university level or higher (OR = 5.417, 3.75; $p < 0.001$, $p = 0.001$, respectively). PPD risk increased 1.193-, 1.072-, and 0.944-fold with one unit increase in parameters such as doubts about parenting activity, partner's parenting expectations and criticisms, and parenting organization scores, which are sub-dimensions of MPPS ($p < 0.001$, $p = 0.001$, $p = 0.014$).

When all variables were analyzed in the multivariate model, it was found that PPD risk increased 0.835-fold with one unit increase in maternal age ($p < 0.001$). Similarly, PPD risk increased 1.212, 1.341, 1.219, and 0.851-fold with one unit increase in personal parenting standards, doubts about parenting activity, partner's parenting expectations and criticisms, and total MPPS scores ($p = 0.053$, $p < 0.001$, $p < 0.001$, and $p < 0.001$, respectively). One unit increase in the social integration and emotional connection sub-dimension score of the Social Media Use Scale increased the risk of PPD 0.928-fold ($p = 0.010$). The correct classification rate obtained using the generated model was 73.4%.

Discussion

The present study was performed to examine the relationship between PPD, parental perfectionism and social media use in first-time mothers and to determine the factors affecting PPD.

The results showed that mean EPDS score was 10.42 (± 5.83) and 28.4% of the mothers were at risk of PPD (EPDS score ≥ 13). PPD prevalence in the postpartum period was reported to be between 14% and 17% (2, 26). In Turkey, the prevalence of PPD was reported to be 24% (27). The results obtained in the present study were consistent with the results of other studies performed in Turkey.

Maternal age was identified as a risk factor for PPD in the present study. This finding was consistent with other studies in the literature (27, 28). Parents with a low education level were at a higher risk of developing PPD. This observation was also consistent with the

results of meta-analyses performed by Karaçam, Çoban (27). However, the multivariate analysis revealed that educational level of the parents had no effect on PPD. Thus, other risk factors may offset the negative effect of educational level.

In the present study, the three sub-dimensions of maternal perfectionism, namely (personal parenting standards, doubts about parenting activity, and partner's parenting expectations and criticisms), as well as total MPPS score were identified as risk factors for PPD. A similar relationship between perfectionism and depression was reported in the literature (8, 29). In their meta-analysis, Lea and Richardson (29) reported positive correlations between the sub-dimensions of concerns about mistakes, doubts about behavior, perfectionism towards others, parental criticism, self-oriented perfectionism, and socially determined perfectionism and depression symptoms. Consistent with the findings of the present study, Oddo-Sommerfeld, Hain (30) performed a longitudinal study and reported that the concerns about mistakes dimension of the scale increased the risk of PPD. In the present study, univariate analysis revealed parenting organization sub-dimension of MPPS as a risk factor for PPD; however, this effect disappeared in the multivariate analysis. Similar to this finding, Gelabert and Subirà (8) observed no relationship between parenting organization and PPD. Considering that perfectionism increases the risk of depression, the results obtained in the present study confirmed its importance for PPD and contributed to the existing literature.

Mothers frequently use social media for obtaining information about parenting and receiving support from others (19). First-time mothers can set high parenting standards (11). Therefore, they may be more inclined to present themselves as the perfect mother to show that they meet these standards or they may be more influenced by the "ideal/perfect mother" posts shared on social media (18). This can affect the mental health of mothers. In the present study, the social integration and emotional connection sub-dimension of the Social Media Use Scale was identified as a risk factor for PPD. Similarly, Padoa, Berle (17) found that perfectionist new mothers tend to make comparisons on social media and develop symptoms of anxiety. Schoppe-Sullivan, Yavorsky (11) reported that mothers with parenting perfectionism traits exhibited more depressive symptoms indirectly through Facebook activity. Considering the relationship between perfectionism and depression, social media use may be an important risk factor for PPD.

The increase in tasks and responsibilities associated with parenthood may lead to social withdrawal during the transition to parenthood and consequently contribute to symptoms of depression.

Limitations of the Study

Limitations of the present study include the fact that the research was performed in a single center. Furthermore, the obtained data were representative of the mothers who participated in the study; thus, the results cannot be generalized. Lastly, the reported findings are valid for the time period during which this study was performed, and the results may change over time.

Conclusion

The results obtained in the present study reported that 28% of mothers were in the risk group for PPD. Maternal age, parental perfectionism, and the social integration and emotional connection subscale of social media use were identified as risk factors for PPD. Examining risk factors for PPD can facilitate early diagnosis and treatment by identifying women at risk. Based on the results of the present study, we recommend that perfectionism and social media use should also be assessed for identifying women at risk of PPD in the postpartum period. Furthermore, interventions that address perfectionism may be effective in reducing PPD.

Declarations

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Conflict of Interest

All authors declare no conflict of interest.

Ethics approval

Approval was obtained from the ethics committee of Necmettin Erbakan University Health Sciences Scientific Research. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Availability of data and material

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions

Conceptualization: SK, SB; Methodology: SK, SB; Formal analysis and investigation: SK, SB; Writing - original draft preparation: SK, SB; Writing - review and editing: SK, SB; Supervision: SK, SB

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Evaluation of Mediterranean Diet Quality and Hedonistic Eating Status in Regularly Exercising Individuals

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ABSTRACT

Purpose: The aim of this study is to evaluate the hedonistic eating behaviors and adherence to the Mediterranean diet of individuals who exercise regularly.

Method: This study was conducted between June and September 2023. 200 individuals who exercised >150 minutes per week and continued this exercise for 3 months participated in the study. After the demographic questions in the first part of the survey, the Mediterranean Diet Adherence Scale (MEDAS) and the Nutrient Power Scale (PFS) were applied to the participants.

Results: As a result of our study, all subgroups of the food power scale were found to be greater than the cut-off value of 2.5. When the level of adherence to the Mediterranean diet increased, a statistically significant decrease was observed in terms of hedonistic eating sub-factors of food availability, food present and total score ($p<0.05$). A positive correlation was observed between the physical activity level and the total score of the MEDAS ($p<0.05$).

Conclusion: When the adherence to the Mediterranean Diet of individuals who exercise regularly was evaluated according to the cut-off point, it was found to be moderately adherent. It was also determined that the participants exhibited hedonistic eating behavior.

Keywords: Regular exercise, Mediterranean diet model, hedonistic eating behavior

ÖZET

Amaç: Bu araştırmanın amacı düzenli egzersiz yapan bireylerin, Akdeniz diyetine bağlılıklarını saptayarak, hedonistik yeme davranışları ile arasındaki ilişkiyi incelemektir.

Yöntem: Bu çalışma Haziran-Eylül 2023 tarihleri aralığında yapılmıştır. Araştırmaya haftada >150 dakika egzersiz yapan ve 3 ay yaptığı bu egzersize devam eden 200 birey katılmıştır. Anketin ilk kısmındaki demografik soruların ardından katılımcılara Akdeniz Diyeti Bağlılık Ölçeği, Besin Gücü Ölçeği uygulanmıştır.

Bulgular: Çalışmamızın sonucunda besin gücü ölçeğinin tüm alt grupları kesme noktası olan 2,5 değerinden daha fazla bulunmuştur. Akdeniz diyetine uyum seviyesi arttığında hedonistik yeme alt faktörleri olan besin bulunabilirliği, besin mevcudiyeti ve toplam puan bakımından istatistiksel olarak anlamlı bir azalma gözlemlenmiştir ($p<0.05$). Fiziksel aktivite düzeyi ile Akdeniz diyetine bağlılık ölçeği toplam puanında istatistiksel olarak pozitif korelasyon gözlemlenmiştir ($p<0.05$).

Sonuç: Düzenli egzersiz yapan bireylerin Akdeniz Diyetine bağlılıkları kesim noktasına göre değerlendirildiğinde orta düzeyde bağlı olarak bulunmuştur. Ayrıca katılımcıların hedonistik yeme davranışı gösterdiği saptanmıştır.

Anahtar Kelimeler: Düzenli egzersiz, Akdeniz diyet modeli, hedonistik yeme davranışı

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Nutrition, physical activity and sleep status of individuals are effective in maintaining health (1). Various studies have shown that regular exercise can reduce the risk of many chronic diseases, including obesity, depression, type II diabetes, cardiovascular diseases, neurological diseases, and various types of cancer (2-4).

The Mediterranean diet model is defined as a nutritional model in which animal foods are consumed at low-moderate levels, plant foods are consumed at high levels, olive oil is the basis of dietary fat, and wine is consumed moderately with meals in the routine diet (5). Studies have shown that compliance with the Mediterranean diet is associated with exercise performance (6,7). Mediterranean diet and regular exercise contribute to reducing the risk of chronic diseases such as heart disease, diabetes, and obesity, while also promoting longevity and a higher quality of life. This combination of healthy eating and physical activity reflects the holistic approach to health that characterizes the Mediterranean lifestyle (8,9).

Individuals' nutrition is maintained by homeostatic and non-homeostatic (hedonistic, emotional eating, etc.) mechanisms. In homeostatic fasting, the individual meets the individual's required energy level by covering a minimum of eight hours of fasting and reversing the individual's acute negative energy balance (10). Today, eating behavior is affected by many triggering factors such as stress, emotional change, rewarding behaviors, and the appeal of the food consumed to the sensory organs. Hedonistic eating behavior is characterized by the behavioral pattern that occurs with hedonic hunger, and the main priority in hedonic hunger is to trigger the urge for pleasure and enjoyment that individuals will get from the food they eat (11,12). Hedonic mechanisms overtake homeostatic mechanisms as individuals prefer delicious foods that appeal to the senses. The risk of diseases such as obesity increases due to the effects of factors such as sugar and fat, which are high in delicious foods (13).

Exercise can play a significant role in modulating hedonic hunger, which is the desire to eat for pleasure rather than to satisfy physiological hunger. Engaging in physical activity can help regulate the brain's reward system, reducing the intensity of cravings and the appeal of high-calorie, palatable foods often associated with hedonic hunger. Additionally, exercise can improve mood and reduce stress, factors that frequently contribute to emotional eating. Thus, regular physical activity may help in managing hedonic hunger by balancing the body's

need for energy with the brain's reward signals, promoting healthier eating habits (14). There are not enough studies in the literature about the use of the Mediterranean diet model in people who exercise regularly and associating these individuals with hedonistic eating situations. In this context, our research was conducted to evaluate the relationship between hedonistic eating behaviors and the adherence to the Mediterranean diet of individuals who exercise regularly.

Material and Methods

Population and Sample

In this cross-sectional planned study; the sample of the study consists of 200 individuals who exercise >150 minutes a week and continue this exercise for 3 months.

Data Collection Tools

Survey form: The survey presented to individuals was filled out via the online platform. The first part of the survey included demographic questions. In the second part of the survey, the Mediterranean Diet Adherence Scale (MEDAS) was used to evaluate individuals' adherence to the Mediterranean diet, and the Food Power Scale (FPS) was used to evaluate hedonistic eating behaviors.

Mediterranean diet adherence scale (MEDAS): The Mediterranean Diet Adherence Scale (MEDAS) consists of 14 questions, and 1 or 0 points are taken for each question depending on the amount of consumption, and these points are summed. The score is categorized as follows: 5 or less indicates low adherence, 6 to 9 indicates medium adherence, and 10 or higher indicates high adherence (15).

Power of Food Scale (PFS): A PFS score of 2.5 points or above indicates that hedonic hunger has increased. High scores psychometrically indicate increased motivation to consume delicious foods in the environment (16).

Results

The study was completed with 200 participants, 145 (72.5%) of whom were women and 55 (27.5%) of whom were men. The education level of 56% of the individuals participating in the study is at undergraduate level. While 33.5% of the participants go to sports 3 times a week; 50% of them do sports between 30-59 minutes daily. Demographic information about the participants is shown in Table 1.

Table 1: Demographic Information of Participants (n=200)

	N	%
Gender		
Women	145	72.5
Men	55	27.5
Education		
Primary school	7	3.5
High school	49	29.5
University	112	56.0
Postgraduate	32	16.0
Marital status		
Married	80	40.0
Single	120	60.0
Total activity frequency / Weekly		
1	45	22.5
2	71	35.5
3	67	33.5
>4	17	8.5
Total activity time / Daily		
less than 30 minutes	45	22.5
30-59 minutes	100	50.0
60-120 minutes	55	27.5

When the age and anthropometric measurements of the individuals were evaluated, it was observed that their median age was 29.5 (16-71) years, median height was 168.74 (151-190) cm, median body weight was 64 (43-114) kg and median body mass index (BMI) was 22.79 (14.20-35.19) kg/m². Data regarding the participants' age and anthropometric measurements are shown in Table 2.

Table 2: Age and Anthropometric Measurements of Participants

Variables	Mean± Standard deviation	Median	Min-Max
Age (years)	32.16±11.50	29.50	18-65
Height (cm)	168.74±8.60	168.00	151.-190
Weight (kg)	65.65±12.87	64.00	43-114
Body mass index (kg/m ²)	22.90±3.39	22.79	14.2-35.1

The scores of the participants from the Mediterranean diet adherence and nutritional strength scales are given in Table 3. The median total score of MEDAS was found to be 6 (2-11). 65% of the participants were low; 28% are at medium and 7% at high level of adherence. Additionally, when their scores from the power of food scale are examined, the median score for food availability is 3 (1-5); food present median score 3.5 (1-5); the median score for tasting the food was determined as 3.6 (1-5) and the total median score was 3.30 (1-5).

Table 3: Participants' Scale Scores

Variables	Mean± Standard deviation	Median	Min-Max
Mediterranean Diet Adherence Scale			
Total score	5.83±1.84	6.00	2-11
Power of Food Scale			
Food available	3.01±1.04	3.00	1-5
Food present	3.31±1.04	3.50	1-5
Food tasted	3.36±1.01	3.60	1-5
Total score	3.23±0.93	3.30	1-5
	N	%	
Mediterranean Diet Adherence Scale Categories			
Low	130	65	
Medium	56	28	
High	14	7	

The relationships between individuals' age, anthropometric measurements, number of main meals and snacks, power of food scale and Mediterranean diet adherence scale are shown in Table 4. It was determined that there was a weak negative ($R = -0.214$) significant relationship between total score of the PFS and MEDAS score ($p < 0.05$). When food availability and the total score of MEDAS were evaluated, a statistically significant negative ($R = -0.219$) relationship was found between them.

Table 4. Relationships Between Age, Anthropometric Measurements, Power of Food Scale and Mediterranean Diet Adherence Scale

	1	2	3	4	5	6	7	8	9	10
1. Age		R= 0,349 p= 0,000	R= 0,439 p= 0,000	R= -0,015 p= 0,835	R= -0,075 p= 0,298	R= -0,122 p= 0,085	R= -0,071 p= 0,319	R= -0,118 p= 0,096	R= -0,120 p= 0,090	R= 0,173 p= 0,014
2. Weight	R= 0,349 p= 0,000		R= 0,840 p= 0,000	R= 0,137 p= 0,055	R= 0,038 p= 0,598	R= 0,064 p= 0,368	R= -0,008 p= 0,907	R= -0,157 p= 0,026	R= -0,037 p= 0,601	R= 0,012 p= 0,868
3. Body mass index	R= 0,439 p= 0,000	R= 0,840 p= 0,000		R= 0,103 p= 0,150	R= -0,064 p= 0,368	R= 0,021 p= 0,772	R= -0,005 p= 0,941	R= -0,171 p= 0,015	R= -0,068 p= 0,342	R= 0,040 p= 0,578
4. Number of main meals	R= -0,015 p= 0,835	R= 0,137 p= 0,055	R= 0,103 p= 0,150		R= 0,045 p= 0,524	R= 0,093 p= 0,189	R= 0,219 p= 0,002	R= 0,125 p= 0,078	R= 0,150 p= 0,034	R= -0,040 p= 0,570
5 Number of snacks	R= -0,075 p= 0,298	R= 0,038 p= 0,598	R= -0,064 p= 0,368	R= 0,045 p= 0,524		R= 0,100 p= 0,159	R= 0,117 p= 0,100	R= 0,153 p= 0,030	R= 0,158 p= 0,025	R= -0,028 p= 0,690
Power of Food Scale										
6. Food available	R= -0,122 p= 0,085	R= 0,064 p= 0,368	R= 0,021 p= 0,772	R= 0,093 p= 0,189	R= 0,100 p= 0,159		R= 0,734 p= 0,000	R= 0,729 p= 0,000	R= 0,909 p= 0,000	R= -0,219 p= 0,002
7. Food present	R= -0,071 p= 0,319	R= -0,008 p= 0,907	R= -0,005 p= 0,941	R= 0,219 p= 0,002	R= 0,117 p= 0,100	R= 0,734 p= 0,000		R= 0,684 p= 0,000	R= 0,881 p= 0,000	R= -0,243 p= 0,001
8. Food tasted	R= -0,118 p= 0,096	R= -0,157 p= 0,026	R= -0,171 p= 0,015	R= 0,117 p= 0,100	R= 0,153 p= 0,030	R= 0,729 p= 0,000	R= 0,684 p= 0,000		R= 0,895 p= 0,000	R= -0,112 p= 0,114
9. Total score	R= -0,120 p= 0,090	R= -0,037 p= 0,601	R= -0,068 p= 0,342	R= 0,150 p= 0,034	R= 0,158 p= 0,025	R= 0,909 p= 0,000	R= 0,881 p= 0,000	R= 0,895 p= 0,000		R= -0,214 p= 0,002
Mediterranean Diet Adherence Scale										
10. Total score	R= 0,173 p= 0,014	R= 0,012 p= 0,868	R= 0,040 p= 0,578	R= -0,040 p= 0,570	R= -0,028 p= 0,690	R= -0,219 p= 0,002	R= -0,243 p= 0,001	R= -0,112 p= 0,114	R= -0,214 p= 0,002	

Discussion

This study aims to assess the adherence of regular exercisers to the Mediterranean diet through the Mediterranean Diet Adherence Scale (MEDAS) and the Power of Food Scale, and to explore the connection between their hedonistic eating behaviors.

In our current study, it was found that 65% of the participants had a low level of adherence to the Mediterranean diet, 28% had a medium level, and 7% had a high level (Table 3). In a study conducted by Manzano-Carrasco et al. consisting of 1676 adolescent participants, adherence with the Mediterranean diet was examined. While 35.7% of the individuals participating in the study had high or optimal compliance with the Mediterranean diet, 64.3% had low compliance with the Mediterranean diet (17). Another study evaluated compliance with the

Mediterranean diet in university students. 65.4% of the participants were found to have low MEDAS score (18). It was observed that the percentage compliance with the Mediterranean diet data obtained in the studies was similar to our current study.

In our study, all subgroups of the nutrient power scale (food availability, food present, food taste, total score) were found to be higher than the cut-off point of 2.5 (Table 3). A study was conducted to evaluate hedonic hunger. In a study evaluating hedonic hunger, all subgroup scores of the nutrient power scale were found to be statistically significantly higher in overweight or obese individuals compared to healthy individuals (19). In our present study, the food tasted score—a sub-factor of the Power of Food Scale—was observed to be higher among overweight and obese individuals compared to those of normal weight (Table 4).

In our study, it was observed that when the MEDAS score increased, the hedonistic eating sub-factors of food availability, food present and total score decreased at a statistically significant level (Table 4). Additionally, PFS score was negatively correlated with the total score MEDAS ($R = -0,214$). This negative correlation supports the hypothesis of our research. In a study investigating hedonic hunger and nutritional patterns among university students, a statistically significant negative correlation was found between the total scores of MEDAS and PFS, consistent with the findings of our research (20). Altinsoy conducted a study investigating the relationship between adherence to the Mediterranean diet and levels of hedonic hunger in adults. This study identified a negative correlation between the total score of the PFS, including the food availability subscale, and the total score of the MEDAS ($p < 0,05$) (21).

In our current study, it was observed that the total score of the MEDAS increased statistically significantly when the level of physical activity increased. A large-scale study measuring adherence to the Mediterranean diet was conducted in Greece among 22,043 participants. A positive relationship was identified between the participants' Mediterranean diet scores and their levels of physical activity (22). In another study, it has been found that individuals who engage in high levels of physical activity have a high score of MEDAS. Furthermore, participants who reported not engaging in physical activity exhibited a moderate level of adherence to the Mediterranean diet (23). It has been observed in the studies that similar results were obtained with our current study.

In our study, no statistically significant relationship was found between the body mass index value and the nutritional power scale sub-factors (except for food tasted) and total score ($p > 0,05$) (Table 4). One study evaluated the nutritional habits of adults with different body mass indexes. It was stated that participants with a body mass index of 30 kg/m² and above had higher scores on the emotional eating scale than individuals with a healthy body mass index (24). In another study, it was found that the average power of food scale score of obese individuals was statistically higher than other individuals (25). It has also been stated that each increase in the scores on the nutritional strength scale doubles the individual's risk of becoming obese (26). Various studies have been conducted examining the power of food scale and body mass index and different results have been found. The variations in the results are believed to stem from factors such as differences in the study population,

the demographic characteristics of the participants, and the environment in which the research was conducted.

A potential limitation of this study is the reliance on self-reported data for both the Mediterranean Diet Adherence Scale (MEDAS) and the Power of Food Scale (PFS). Self-reported data can be subject to bias. Additionally, the study's cross-sectional design limits the ability to establish causality between adherence to the Mediterranean diet and hedonistic eating behaviors.

Conclusion

In our research, which seeks to assess the adherence to the Mediterranean diet and the hedonistic eating behaviors of individuals who exercise regularly, it was found that a significant proportion of participants had a low level of adherence to the Mediterranean diet. In our study, power of food scale scores were found to be higher than the cut-off point of 2.5 in all subgroups. A negative correlation was identified between adherence to the Mediterranean diet and the hedonistic eating sub-factors, including food availability, food presence, and the total score. Additionally, it was found that adherence to the Mediterranean diet improved as physical activity levels increased.

Declarations

Ethical Statement

Ethics committee approval was received for this study from the ethics committee of Bahcesehir University (Ethics number: E-85646034-604.02.02-60527).

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Disclosures of Financial or Other Potential Conflicts of Interest

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Authors Contribution

AB: Study design, data collection, analysis of data, literature search, writing of the manuscript.

EBK: Study design, literature search, editing of the manuscript.

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Evaluation of the Integration of Simulation-Based Training Program into the Anesthesia Technician Curriculum : A Mixed Method Study

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ABSTRACT

Background: The aim of this research is to assess the experiences of graduates from the anesthesia technician program with simulation-based training. By gathering their perspectives as learners who went through the simulation curriculum, the study seeks to identify potential improvements for better integrating simulation into the program.

Method: The research examined the experiences of 68 graduates from the Anesthesia Program at Acibadem Mehmet Ali Aydınlar University's Vocational School of Health Sciences. The focus was on the simulation-based education program that was incorporated into their curriculum during their studies. The study employed a mixed-methods research approach, gathering both quantitative data through surveys and qualitative data through focus group discussions. The data from these different methods were integrated and interpreted using Creswell's Convergent Design

Results: The majority of participants (95.16%) stated that the simulation training significantly contributed to increasing their knowledge and skills, additionally, 93.55% of the participants stated that debriefings and the group discussion environment contributed to their learning processes. Participants who responded to the survey stated that the simulated cases were similar to the cases encountered in the clinic (79.09%), and that the features of the simulators and the environment were realistic (91.94%). However 43.55% of the participants also stated that the time allocated for training was not sufficient. The opinions of the participants in the focus group discussions were also similar.

Conclusion: The simulation-based training program for anesthesia technicians found to be effective. However, based on participant feedback suggesting more time should be devoted to training, it was determined that opportunities for self-directed learning need to be implemented.

Keywords: Medical Simulation, Anaesthesia Training, Curriculum, Development, Mixed Method, Clinical Transfer

ÖZET

Amaç: Bu araştırmanın amacı, anestezi teknikerliği programı mezunlarının simülasyona dayalı eğitim yöntemi ile ilgili deneyimlerini değerlendirmektir. Öğrencilerin simülasyona dayalı eğitim programı ile ilgili görüş ve deneyimleri üzerinden programın geliştirilmesi hedeflenmiştir.

Yöntem: Acibadem Mehmet Ali Aydınlar Üniversitesi Sağlık Hizmetleri Meslek Yüksekokulu Anestezi Programı'ndan mezun olan 68 kişinin, öğrencilik dönemlerinde müfredatlarına dahil edilen simülasyona dayalı eğitim programına dair deneyimleri incelendi. Veri toplama anketler yoluyla nicel veri, odak grup tartışmaları yoluyla nitel veri toplanarak karma yöntem yaklaşımı kullanıldı. Farklı yöntemlerden elde edilen veriler Creswell'in Birleşik Desen Tasarımı kullanılarak entegre edildi ve yorumlandı.

Bulgular: Katılımcıların çoğunluğu (%95,16), simülasyon eğitiminin bilgi ve becerilerini artırmada önemli katkı sağladığını belirtmiş; ayrıca %93,55'i geribildirimler ve grup tartışma ortamının öğrenme süreçlerine katkıda bulunduğunu ifade etmiştir. Anketi yanıtlayan katılımcılar, simüle edilmiş vakaların klinikte karşılaşılan vakalara benzediğini (%79,09) ve simülatörlerin özellikleri ile ortamın gerçekçi olduğunu (%91,94) belirtmiştir. Ancak katılımcıların %43,55'i de eğitim için ayrılan sürenin yeterli olmadığını ifade etmişlerdir. Odak grup tartışmalarındaki katılımcıların görüşleri de nicel bulgular ile benzerlik göstermiştir.

Sonuç: Anestezi teknikerleri için simülasyona dayalı eğitim programının etkili olduğu belirlenmiştir. Ancak, katılımcı geri bildirimlerine dayanarak eğitime daha fazla zaman ayrılması gerektiği önerilmiş ve öz yönelimli öğrenme fırsatlarının sağlanması gerektiği belirlenmiştir.

Anahtar Kelimeler: Medikal Simülasyon, Anestezi Eğitimi, Müfredat Geliştirme, Karma Yöntem, Klinik Transfer

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As stated in the standards recommended by the World Health Organization (WHO) for safe anesthesia practices; all anesthesia providers involved in anesthesia care should be trained according to a nationally recognized standard (1). The safe administration of anesthesia requires coordinated team-based care, with the anesthesiologist physician leading the team that includes anesthesia technicians as vital members (2, 3).

In Turkey, students can enroll in a 2-year anesthesia technician program at Vocational Schools of Health Sciences after high school, without prior health education. This program trains students as assistant healthcare personnel in anesthesia and is classified at Level 5 (short cycle) according to the Qualifications Framework for the European Higher Education Area (QF-EHEA), which standardizes higher education qualifications across Europe (4).

There is a disparity among Vocational Schools of Health Sciences some have well-developed infrastructure and provide good training, while others lack proper facilities (5). Beyond having the right infrastructure for skills training, it is crucial to properly structure and integrate those facilities/resources into the curriculum (6).

In recent years, clinical simulation applications have started to be used increasingly in training health professionals for skills training (7, 8). Simulation training provides the opportunity to practice repeatedly in a controlled and safe environment towards specific goals (9, 10). The prominence of patient safety, the need for new educational methodologies for the new generation, and the limitations in providing standardized training and assessment environments necessitate education in simulated settings (10, 11).

As with all educational modalities, the effectiveness of simulation applications varies depending on how, to

whom, and for what purpose they are used (12). When creating a program, the target audience and learning needs must be identified, and the planned time, resources, instructor profile, simulation method, and assessment methods must be planned (13).

Since the 2013-2014 academic year, Acibadem Mehmet Ali Aydınlar University's Anesthesia Program has integrated simulation-based learning into its practical courses. Simulation-based education, which is widely used in medical and nursing education (14), has been implemented for the first time in Anesthesia Programs in Turkey at Acibadem University. First-year students engage in skills-focused simulations, while second-year students participate in advanced clinical simulations. This study evaluates graduates' experiences with this training, using a mixed-methods approach, to inform future curriculum enhancements.

Method

The study evaluated the perspectives and experiences of graduates from the Anesthesia Program at Acibadem Mehmet Ali Aydınlar University's Vocational School of Health Sciences. The focus was on the simulation-based education program that was integrated into their curriculum during their studies. A mixed-methods research approach was utilized, combining both quantitative (survey) and qualitative (focus group discussions) data collection methods. The aim was to gain insights from the graduates about their views and first-hand experiences with the simulation-based training they received as part of the anesthesia technician education program. In this study, the mixed-method approach was preferred in order to provide a more holistic perspective when aiming to develop the implemented educational program. The data were integrated and interpreted using Creswell's Convergent Design (15). The flow diagram of the study is shown in Figure 1.

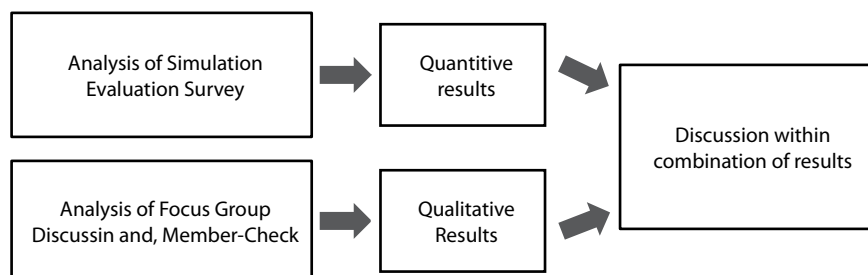


Figure 1: Flow diagram of the study

Participants:

The population of this research consists of students who have completed the Anesthesia Program at Acibadem University Vocational School of Health Services. The sample is 70 graduates who completed the Anesthesia Program in 2019.

Ethical Approval:

Prior to starting the research, ethical approval was obtained from the local ethics committee (decision no. ATADEK-2024-6/240). The content of the study was explained to the graduates, and consent was obtained from those participating in the study.

Data Collection

In this research, a mixed-methods approach was used for data collection. The survey method was employed for quantitative data, while focus group discussions were conducted for qualitative data. Out of 70 graduates, 62 graduates participated in the survey, and 14 graduates volunteered for the focus group discussions.

Quantitative data:

The survey sent online consists of questions whose validity and reliability have been established and it has been previously used in the evaluation of simulation education programs in the university (Appendix 1). The validity of the survey was assessed using exploratory factor analysis. The Kaiser-Meyer-Olkin value was calculated as 0.902. Cronbach's alpha was calculated for reliability, resulting in a value of 0.849. The survey comprises 22 questions regarding the content of the education, the effectiveness of the educational method, the safety of the educational environment, the contribution of the education to teamwork, and the realism of the simulation environment. The evaluation was conducted using a four-point Likert scale (1- Strongly Disagree, 2-Disagree, 3-Agree, 4-Strongly Agree).

Qualitative data:

The survey participants were invited to a focus group discussion to share their experiences regarding the simulation-based education program, which was a part of their educational process. In reporting the focus group discussions conducted to understand the participants' experiences in this research, the criteria in the Consolidated Criteria for Reporting Qualitative Research (COREQ) guideline were taken into consideration (16).

The interviews with volunteer graduate students were conducted in two separate sessions by a simulation educator who had not previously attended their classes, was experienced in simulation education, was familiar with the anesthesia simulation education program, and had prior experience conducting focus group discussions. No prior relationship was established between the interviewer and the participants. However, the participants were familiar with the research team that designed and implemented the educational program.

The focus group discussions were held at the simulation center's dedicated meeting room facilities on a single day, with different groups of participants scheduled at separate times. Proper arrangements were made to ensure a private, controlled environment with only the focus group moderator and student participants in attendance during each session.

In the focus group discussion, participants were asked five questions regarding the simulation education program:

1. What were your expectations from the simulation-based learning education?
2. Were your expectations met?
3. Were you able to transfer your experiences to clinical practice?
4. What are the best and worst aspects of the program?
5. How would you plan it if you were in charge?

These questions were formed based on the reaction evaluation criteria from Kirkpatrick's first level of the program evaluation models (17). Participants were informed prior to the interviews that the discussions would be recorded, and that no information revealing their identities would be included in the research, and their written consent was obtained. The focus group discussions lasted 35 and 40 minutes

Data Analysis:

Audio recordings from the focus group discussions were transcribed into written form by the second researcher involved in the study.

These transcriptions were then cross-verified by the researchers by listening to the recordings again to ensure accuracy and reliability of the transcription process. The coding process involved in analyzing the focus group discussions was performed manually. This manual coding

was done by the second researcher involved in the study. No software tools were used in the coding process. The researcher identified all the main themes, sub-themes, and concepts that emerged during the focus group discussions. The data were organized and grouped according to the coding system established at the end of the discussions, and a thematic analysis was conducted based on the main and sub-themes. The codings were checked by the first researcher. The findings that emerged were compared with the survey results, included in the findings section, and discussed in the conclusion part. As the transcribed interviews underwent the coding and analysis process, participants' opinions were revisited (member-check). The data were returned to the participants to verify the accuracy of their experiences, and they were asked to revise, clarify, and elaborate on their statements using their own words. The additions made by participants during the member-check were included in the data analysis.

Simulation based training program:

Simulation-based practical training has been integrated into the curriculum for both regular and second-shift education, with a total of 280 hours for first-year skills training and an additional 168 hours of clinical simulation training outside of clinical practice hours for the second year. These trainings are conducted by instructors

competent in simulation-based education at Center of Advanced Simulation and Education (CASE).

The first-year program focuses on basic skills training; it includes manually measuring vital signs on simulated patients, performing intramuscular and intravenous interventions on skill models, endotracheal intubation and laryngeal mask airway placement, drug dosage calculations and applications, basic monitoring, and anesthesia equipment preparation during twenty-eight weeks.

In the second year program focuses on advanced skills training; that includes preoperative patient assessment with simulated patients, preoperative preparation, anesthesia induction, difficult airway management, advanced life support training, intraoperative and postoperative complications with manikin based simulators during twenty-eight weeks.

Results

The 'Simulation Evaluation Survey', which consists of questions whose validity and reliability have been established and has been previously used in the evaluation of simulation education programs, was sent online to students who completed the Anesthesia Program in 2019. The survey included an assessment of the two-year simulation practices. 62 graduates responded to the survey, and the survey results are presented in Table 1.

Table 1: Simulation Evaluation Survey Results

Simulation Evaluation Survey	Strongly disagree(%)	Disagree(%)	Agree (%)	Strongly agree(%)
Simulation education contributed to increasing my knowledge and skills.	1,61	3,23	20,97	74,19
The time allocated for the training was sufficient	16,13	27,42	32,26	24,19
The scenario duration and equipment used in the scenario were sufficient for crisis management skills.	0,00	11,29	41,94	46,77
Simulation trainings should be a part of in-service trainings	1,61	1,61	12,90	83,87
Observing other participants during the training contributed to my learning	4,84	6,45	40,32	48,39
Planned practical training under the guidance of an instructor was important for acquiring new skills.	0,00	4,84	24,19	70,97
Watching myself during debriefing increased my awareness and enabled self-evaluation	6,45	8,06	27,42	58,06
Debriefing and group discussion contributed to my learning.	4,84	1,61	41,94	51,61
The instructor's feedback helped me understand the subject better	1,61	1,61	24,19	72,58
Seeing the mistakes in the video recordings contributed to my learning	8,06	4,84	40,32	46,77
Self/peer/team evaluation contributed to my learning	1,61	3,23	35,48	59,68
The simulated cases were similar to the cases I encounter in the clinic.	4,84	16,13	48,39	30,65
I found the features of the simulators realistic	1,61	6,45	33,87	58,06
The realism of the environment was effective in making the scenario more convinic	4,84	3,23	41,94	50,00
I observed that teamwork positively affected clinical outcomes	3,23	11,29	35,48	50,00
I better understood the responsibility that falls on the leader in teamwork	1,61	3,23	33,87	61,29
I saw that equal knowledge and skill levels of individuals in the team affected success.	4,84	4,84	37,10	53,23
I realized how important communication skills are	1,61	1,61	12,90	83,87
The fact that the scenario applications were being recorded caused stress in me	35,48	37,10	12,90	14,52
Being under stress negatively affected my performance	30,65	29,03	25,81	14,52
I had difficulty recalling the information I knew theoretically while under stress	19,35	29,03	32,26	19,35
The deterioration of the simulated case's clinical condition during the simulation training caused me stress	32,26	25,81	20,97	20,97
Mean	3,85	6,72	32,53	56,90

Table 2: Focus Group Data Analysis

Themes	Subthemes	Participants Comments
1. Expectations from simulation-based learning education	1.1. Practical experience	"My expectation was to acquire practical hands- on experience "(K-5)
	1.2. Contribution to theoretical education	"I thought that practical applications would contribute to my theoretical knowledge."(K-7)
	1.3. No expectations	"I had no expectations when coming here, because I did not research the school. I did not come and see this place beforehand, I just happened to end up here. I did not know that such programs existed here."(K-4)
2. Meeting Expectations	2.1. Structured content	"(...) For example, we cover a topic in theoretical classes for a week or during that week, and then we come here and practice it. Since we are adding practical knowledge on top of the theoretical knowledge, it becomes more memorable. What we practice here completely complements and overlaps with the theoretical knowledge, our practical applications here reinforce it." (K-1)
	2.2. Gaining experience	"Perhaps we may not encounter such complicated cases throughout our lives, but here we do. So, we at least get to experience them. If such a case were to come our way, we would have some idea about it. We would be able to handle the crisis situation, at the very least." (K-5) "In the practical courses here, I learned things like 'what I should do when touching a patient, how I should behave, how my communication should be during an operation, etc.' I didn't know any of these things before coming here. And after coming here, I was taught what I need to do when I go out into the field. So when I went out there, at least I didn't freeze up or get flustered. In this way, it was extremely beneficial for me."(K-4) "I gained the most self-confidence here(...) I learned what I need to do during crisis situations." (K-6)
	2.3. Instant Feedback	"With every practical application I did, I received feedback from my instructors regarding my errors, and this situation led to an increase in my theoretical knowledge as well." (K-7)
3. Clinical transfer	3.1. Transfer of knowledge and skills	"Let me put it this way, from the very beginning, I personally practiced everything there, from how we should behave with a patient, to medications, monitoring, and what to do in difficult situations. I even assisted the instructors. When I was asked questions like 'Do you know how to draw up this medication? How many units per dose? How many will we give this patient?' and I could answer those kinds of questions, that's when I realized the value of this place." (K-4)
	3.2. Confidence	"When we see the same scenario in a real setting that we've seen here, it feels very ordinary now. I can think logically, remember the steps I need to follow, and I get less anxious." (K-8) "Previously, because I didn't know about it, I used to blow the difficult airway situation out of proportion in my mind. But here, through the scenarios, I learned and practiced what I needed to do, and after doing those things, I realized that it's not something to be so afraid of" (K-8)
	3.3. Teamwork	"We saw teamwork in action. I thought that everything would be expected from me and that I would have to do it all alone, but in the scenarios here, I saw that tasks are carried out through teamwork."(K-9)
4. The good and bad aspects of the program	4.1. Time	"Time is limited. That's the biggest problem." (K-1)
	4.2. Stress	"The manikins were very realistic. The advanced life support and intubation training was so realistic that I became stressed." (K-10) "More than anything, it's making mistakes that causes stress. The sense of responsibility weighs heavily. If you don't do it (properly), the patient (simulator) dies" (K-2) "The limited time and being observed put me under stress." (K-6)
		4.3. Realism of the environment
	4.4. Taking Responsibility	"The situations I enjoyed the most were when I had to be alone, think quickly, and make rapid decisions. When I was left alone at the patient's bedside, I learned what to do and how to ask for help. I had not experienced this at the clinic since I was never given sole responsibility." (K-8) "Although we caused to death of our simulators here, we learned that human life is more important than anything else in real life, and how seriously we need to be in such a situation. We learned that here." (K-3)
5. Suggestions for planning	5.1. Time	"I would form groups based on each person's areas of deficiency, and provide them with the opportunity to practice independently through an appointment system" (K-7) "We come once a month. We should come 3-4 times." (K-13)
	5.2. Content	"The preparation of the room should be learned in the first year. Before going to the hospital for the summer internship, (...) the room preparation should be done in the first year. It needs to be added to a course that is close to the summer internship"(K-12) "There was nothing that needed to be removed, but there were things that needed to be added. Everyone needs to learn the awakening stage as well. We did the preparation, induction, monitoring, and postop, but we didn't do the awakening and extubation, and I think that was the most important deficiency. The awakening process is very different for some patient groups, and it would have been great if we could have experienced that too." (K-8) "It was quite good, it was sufficient. There was nothing that needed to be removed." (K-13)

The analysis of the responses from the 14 participants who volunteered and were invited to the focus group discussion is presented in Table 2.

During the coding and analysis process of the interviews, participants' views were re-obtained (member-check). The data was returned to the participants to verify the accuracy

of their experiences. Participants were asked to rephrase their own words, clarify, and provide more details in their narratives. Two of the participants who started the study stated that they wanted to make additions regarding the details they wanted to elaborate on. The other participants indicated that they did not have any data they wanted to change or remove at this stage (Table 3).

Table 3: Comments after Member-Check	
Content suggestions for planning after member-check	<i>"At the end of our conversation, apart from the infusion pump, I thought it would be beneficial to demonstrate procedures such as PCA devices, cerebral and BIS monitoring applications, and arterial line flushing in the simulations. This way, when a student goes into the field and sees these devices, they will at least have some idea about them." (K-3)</i>
	<i>"Thanks to the knowledge and experience gained from the practical courses, I had full confidence and self-assurance when starting the job. Since you showed me everything from monitoring the patient to induction and post-op follow-up, I am very comfortable in my professional life right now." (K-6)</i>

The additions made by the participants during the member-check were included in the data analysis.

Discussion

In this study, it was aimed to evaluate the views and experiences of the graduates from the Anesthesia Program at Acibadem Mehmet Ali Aydınlar University concerning the simulation-based educational program incorporated into their curriculum, utilizing a mixed-methods approach. Additionally, it aimed to enhance the educational program within this context. The graduates' perspectives were examined quantitatively via a survey and qualitatively through focus group discussions.

Acquiring Knowledge and Skills

The participants' expectations from the simulation-based learning training were to contribute to their theoretical knowledge and gain practical experience. They stated that their expectations were met due to the well-structured content, the opportunity to gain experience through individual and team work, and receiving feedback on their performance. The majority of participants (95.16%) stated that the simulation training significantly contributed to increasing their knowledge and skills. The focus group interviews also supported the responses given in the survey.:

"When I was left alone at the patient's bedside, I learned what to do and how to ask for help. I had not experienced this at the clinic since I was never given sole responsibility. This was the aspect I enjoyed the most about the training here." (K-8)

According to this, it has been observed that the simulation-based training method applied in a safe environment before clinical practices in anesthesia technician education allows participants to gain experience (18, 19).

The proportion of participants who think that the process of self-monitoring and receiving feedback during debriefing contributes to learning is high (85.48%). Additionally, 93.55% of the participants stated that debriefings and the group discussion environment contributed to their learning processes.

"I received feedback from my instructors about my mistakes in every performance I did, and this situation led to an increase in my theoretical knowledge as well." (K-7)

Receiving immediate feedback on performance during simulation-based training highly contributes to learning (20).

Additionally, the realism of the learning environment also increases the effectiveness of the simulation-based learning method. Participants who responded to the survey stated that the simulated cases were similar to the cases encountered in the clinic (79.09%), and that the features of the simulators and the environment were realistic (91.94%).

"Here we see the same scenario, but when we see it in the real environment, it seems very ordinary now. I can think logically and remember the steps I need to follow, and I get less excited." (K-8)

"The manikins were very realistic. The advanced life support and intubation training was very realistic, I got stressed." (K-10)

The opportunity to engage in teamwork in a simulation-based learning environment has increased participants' awareness of this subject. The responses given in the survey showed that participants had a high level of awareness, especially regarding communication and teamwork (96.77%).

"We saw teamwork. I thought everything would be expected from me and I would have to do it alone, but in the scenarios here, I saw that things work with teamwork"(K-9)

With this study, the importance of communication skills and the positive effect of teamwork on clinical outcomes have been emphasized in line with the literature (21, 22).

The study results also showed that the duration of the scenarios applied in education and the equipment used in the scenario are considered sufficient for crisis management skills (88.71%), and the rate of those who agree that simulation trainings should be a part of in-service trainings (96.97%) is high. The opinions expressed by the participants in the focus group discussions support this situation.

"I learned what to do during crisis situations. I learned to make decisions quickly." (K-6)

"We may not encounter such complicated cases throughout our lives, but here we do. So, we are at least trying. If such a case comes our way, we will have some idea. We will be able to experience the crisis moment according to that situation, at least." (K-5)

Simulation-based training is effective, especially in gaining experience regarding crisis management and rare cases that are not frequently encountered (23).

Ultimately, the various characteristics of the simulation-based training program appear to make it easier to apply the learned skills and knowledge in actual clinical settings (24, 25).

Course time

According to the survey results, 43.55% of the participants stated that the time allocated for training was not

sufficient. The opinions of the participants in the focus group discussions are also similar:

"We come once a month. We should come 3-4 times." (K-13)

These results indicate that the training duration needs to be increased. However, considering the increased workload for trainers and resource constraints that come with extending the training duration, increasing self-learning activities of the participants could be an effective solution to this problem (26).

Stress Factor

Some of the participants stated that being under stress did not negatively affect their performance (59.68%), while others indicated that being under stress negatively impacted their performance and they had difficulty recalling theoretical knowledge under stress (51.61%).

"It's more that making mistakes causes stress. The responsibility piles up. If you don't do it (the procedure), the simulator-patient " (K-2)

"Being observed and having limited time put me under " (K-6)

During the simulation-based training method, being observed during performance, deterioration of the patient's condition, and time pressure put the participants under stress(30).

Conclusion

The simulation-based training program for anesthesia technicians proved to be effective. However, based on participant feedback suggesting more time should be devoted to training, it was determined that opportunities for self-directed learning need to be implemented. Further research is required to mitigate the stress participants experience from being observed during their performance evaluations.

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Data Availability

The data sets generated during or analyzed during this study are available from the corresponding author on request.

Authors' Contributions

DK was responsible for study conceptualization, methodology, writing, reviewing and editing the manuscript.

TU was responsible for recruitment of the participants, data collection, data analyses methodology, writing, reviewing and editing the manuscript.

Disclosure

The authors did not use generative AI to write any portion of the manuscript.

Conflicts of Interest

None declared.

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The relationship of adult food addiction with obesity, the desire to be admired and being ego-centric

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ABSTRACT

Objective: The research was carried out as a descriptive cross-sectional study to determine the relationship between food addiction, obesity, desire to be admired, and egocentrism in adults.

Material and Methods: The research was carried out with 678 adults living in Turkey who voluntarily agreed to participate in the study. The research data were collected via Google Form between October 2021 and March 2022, with an online questionnaire consisting of Sociodemographic Data Form, Yale Food Addiction Scale, Desire to Be Admired Scale, and Inflated Sense of Self Scale.

Results: In the research, 80.8% were female of the adults who participated, on average 30.41±10.0 years old, 24.2% were overweight and 11.5% were obese and weighed an average of 24.13±4.71 kg/m² body mass index and 16.7% of them had food addiction. In the study, the majority of adults with food addiction were overweight or obese; A significant relationship was found between the diagnosis of psychiatric illness and body mass index characteristics of adults and food addiction. In the study, it was determined that there were positive and low-level significant relationships between adults' food addiction and total scores of body mass index, desire to be admired and inflated sense of self.

Conclusion: As a result of the research, it was found that there were positive significant relationships between adult food addiction and obesity, desire to be admired and inflated sense of self; It has been determined that obesity, desire to be admired and inflated sense of self increase with the increase of food addiction.

Keywords: Adult; ego; egocentrism; food addiction; obesity

ÖZET

Amaç: Araştırma, Yetişkinlerde yeme bağımlılığının obezite, beğenilme arzusu ve benmerkezçilik ile ilişkisinin belirlenmesi amacıyla tanımlayıcı kesitsel olarak gerçekleştirilmiştir.

Gereç ve Yöntemler: Araştırma, Türkiye'de yaşayan çalışmaya katılmayı gönüllü olarak kabul eden 678 yetişkin ile gerçekleştirilmiştir. Araştırma verileri, Google Form üzerinden Ekim 2021-Mart 2022 tarihleri arasında, Sosyodemografik Veri Formu, Yale Yeme Bağımlılığı Ölçeği, Beğenilme Arzusu Ölçeği ve Şişirilmiş Benlik Duygusu Ölçeğinden oluşan çevrimiçi anket ile toplanmıştır.

Bulgular: Araştırmaya katılan, yetişkinlerin %80,8'inin kadın, ortalama 30,41±10,0 yaşında, %24,2'sinin fazla kilolu ve %11,5'inin obez olduğu ve ortalama 24,13±4,71 kg/m² beden kitle indeksinde olduğu ve %16,7'sinde yeme bağımlılığı olduğu belirlenmiştir. Araştırmada, yeme bağımlılığı olan yetişkinlerin çoğunluğunun fazla kilolu veya obez olduğu; yetişkinlerin psikiyatrik hastalık tanısı ve beden kitle indeksi özellikleri ile yeme bağımlılığı arasında anlamlı ilişki olduğu saptanmıştır. Araştırmada, yetişkinlerin yeme bağımlılığı ile beden kitle indeksi, beğenilme arzusu ve şişirilmiş benlik duygusu toplam puanları arasında pozitif yönde ve düşük düzeyde anlamlı ilişkilerin olduğu belirlenmiştir.

Sonuç: Araştırma sonucunda, yetişkinlerin yeme bağımlılığı ile obezite, beğenilme arzusu ve şişirilmiş benlik duygusu arasında pozitif yönde anlamlı ilişkilerin olduğu; yeme bağımlılığının artmasıyla obezite, beğenilme arzusu ve şişirilmiş benlik duygusunun da arttığı belirlenmiştir.

Anahtar Kelimeler: Benmerkezçilik; ego; obezite; yeme bağımlılığı; yetişkin

Food addiction is the feeling of not being able to resist foods containing high sugar, carbohydrate and fat and wanting them too much (1). Associated with palatable foods, it is often an explanation for irritating cravings, loss of control, and overconsumption, and has been with us for many years (2). Research on food addiction was started by Randolph in 1956 (3).

The “stop eating” response to satiety signals is delayed or inhibited by consuming delicious foods containing high sugar and high fat. Therefore, an insensitivity to satiety signals occurs over time. In addition, after a decrease in serotonin levels, people desire to eat carbohydrates in order to improve their mood (4,5). People with high reward sensitivity tend to consume foods that are especially sweet and high in fat. Because with the consumption of foods high in sugar and fat, dopamine and opioid release increases and activates the brain’s reward system (6).

Among the risk factors of food addiction; high sugar and high fat foods, obesity, genetic factors, mood and stress. In a meta-analysis study by Bao et al. (7), it was reported that the prevalence of food addiction in overweight or obese adults and adolescents is higher than in individuals with normal body weight. The results of a study conducted in Germany show that the incidence of food addiction is higher in obese individuals worldwide (8).

Genetic predisposition is shown among the risk factors for food addiction (9). People with a genetic predisposition may lose control of their eating behavior due to emotional stress factors (10).

Food addiction is associated with emotion dysregulation, negative affect, mood disorders, difficulty coping with stress, and low self-esteem. It has been observed that the process leads to depression in individuals with these characteristics, revealing their tendency to addiction, and food addiction emerges in coping with these mood changes (11).

Which diet or which aesthetic intervention is necessary under the physical beauty standards offered by the media is given in many media content, and many individuals can be harmed physically and psychologically in this way. It is observed that individuals with eating disorders such as anorexia nervosa, bulimia nervosa, and obesity have a desire to be admired by other individuals in the society (12).

In addition, stress has generally been found to have different effects on eating, depending on the type of consumer. Restricted eaters (those who deliberately control or restrict their food intake to maintain or lose weight) and emotional eaters (those who overeat in response to negative emotional arousal) have been found to consume more energy and fat under stressful conditions, especially those involving ego threat. It has been observed that both restrained and emotional eaters consume significantly more after the ego-threatening stressor than after the control condition (13).

In this study, examining the relationship between obesity, which develops with overeating as a result of individuals having difficulty in resisting the consumption of certain foods, desire to be liked and the level of egocentrism will provide a different perspective to the literature.

Material and Methods

This cross-sectional study was conducted with 678 adults aged 18-65 years living in Turkey who agreed to participate in the study. The research data were collected with the “Sociodemographic Data Form” prepared by the researcher, and the online questionnaire consisting of the Yale Food Addiction Scale (YFAS), the Desire to Be Admired Scale (DBAS), and the Inflated Sense of Self Scale (ISSS).

1. Sociodemographic Data Form

The Sociodemographic Data Form was prepared by the researcher and consisted of 10 questions and two parts. In the first part of the form; It consisted of 8 questions describing personal and health-disease characteristics related to gender, marital status, age, educational status, diagnosis of psychiatric disease, and psychiatric drug use. In the second part of the form; It consisted of 2 questions describing height (cm) and body weight (kg) of adults. Body mass index (BMI) was calculated from the body weight and height data entered by the individuals. The classification of the World Health Organization was used to group BMIs (14).

2. Yale Food Addiction Scale (YFAS)

The Yale Eating Addiction Scale was developed by Gearhardt et al. in 2009 in order to identify individuals with symptoms of addiction to certain foods (15). The validity and reliability study of the scale, which was adapted into Turkish, was performed by Bayraktar et al. (16). YFAS is a

27-item scale used to detect dependence on certain foods and define its sub-criteria based on the DSM-IV diagnostic criteria for substance addiction. In the YFAS, 7 sub-criteria analyzed in the diagnosis of substance addiction are calculated and there is an 8th clinical significance score.

The number of criteria met constitutes the symptom count scoring. The number of symptoms varies between 0 and 7 (16). In the study, the number of symptoms was calculated and if at least three of the seven criteria were met in addition to the clinical significance criteria, individuals were evaluated as food addicts. In this study, the reliability coefficient of the YFAS was calculated as Cronbach's Alpha 0.86.

3. *Desire to Be Admired Scale (DBAS)*

In the research, the Desire to Be Appreciated Scale, which was developed by Kaşıkara and Doğan by applying it to university students in 2016-2017, aimed to determine the desire of individuals to be admired. The validity and reliability studies of the scale were also done by the same people. DBAS does not contain reverse items and is a one-dimensional scale. It is a self-assessment scale consisting of 9 items and answered with a 4-point rating as '1' I totally disagree, '2' I disagree, '3' I agree, '4' I totally agree. The score obtained from the scale varies between 9-36, and the higher the score, the higher the desire to be admired. In order to prove the validity of the scale, explanatory and confirmatory factor analyzes were performed and the single factor structure of the scale consisting of 9 items was confirmed. In addition, the cronbach alpha internal consistency coefficient calculated with to prove the reliability of this scale was found to be 0.82 (17). In this study, the same coefficient was calculated as 0.92.

4. *Inflated Sense of Self Scale (ISSS)*

The Inflated Sense of Self (Ego Inflation) Scale was developed by Yılmaz (2018). The scale is a self-evaluation scale consisting of a total of 15 items and answered with a 5-point rating. The score that can be obtained from the scale is between 15-75, and the higher the score, the higher the Inflated Sense of Self. The scale has 4 sub-dimensions. These; Inflation in Social Orientation, Inflation in Selfishness, Inflation in Manipulation, and Inflation in Self-Exaggeration. The Cronbach Alpha internal consistency coefficient ranged between 0.76 and 0.79 for the four sub-dimensions. The internal consistency coefficient calculated for the entire scale was found to be 0.90. The values found show that this scale is a reliable tool for

measuring the inflated sense of self (18). In this study, Cronbach's Alpha reliability coefficient of ISSS and its sub-dimensions was calculated between 0.66 and 0.89. The general reliability coefficient of ISSS was calculated as Cronbach's Alpha 0.89.

Data Analysis

The data of the research were evaluated with the SPSS (ver:23.0) program. In the study, the number, frequency distribution, mean, standard deviation, minimum and maximum values of the sociodemographic and anthropometric characteristics of the adults participating in the research were determined by using descriptive statistics tests on the data obtained from the Sociodemographic Data Form. Whether the data fit the normal distribution or not was determined by Kolmogorov-Smirnov (K-S) and Shapiro Wilks tests. The mean score, standard deviation, median, maximum and minimum values of the scales used in the study were determined. Cronbach's alpha coefficient for the scale and its sub-dimensions was calculated by reliability analysis. In the research, at the stage of comparing whether there is a difference between the averages of the independent groups; Independent Groups t-test was used for two groups and One-Way Analysis of Variance was used for more than two groups for normally distributed data. After testing their homogeneity, analysis of variance was performed between homogeneous groups. In the analysis of variance, the difference between the groups was examined with Tamhane's T2 test. In order to determine the relationship between the variables in the study, Pearson Correlation Coefficient analysis was applied to the variables conforming to the normal distribution. In the evaluation of the data, the level of significance was accepted as $p < 0.05$. The skewness and kurtosis values of the scales were checked; The skewness and kurtosis values of the YFAS, BAI and SBAS and their sub-dimensions were found to be within the normal distribution limits (+1.5, -1.5). For this reason, it was decided to use parametric tests in the analysis of scales and their sub-dimensions.

Ethical Approval

Ethics committee approval, dated 28.09.2021 and decision number 09, was obtained from Üsküdar University Non-Interventional Clinical Research Ethics Committee before the data were collected in the study. At the meeting numbered 04 held on 28.03.2022, it was decided that the research whose revision was requested was ethically appropriate.

Results

The distribution of sociodemographic, anthropometric characteristics and food addiction status of the adults participating in the study is given in Table 1. 80.8% (n=548) of the participants were female and 19.2% (n=130) were male. Adults participating in the study are on average 30.41 ± 10.00 (between 18-65 years old). It was determined

that 16.7% (n=113) of the adults participating in the study had food addiction and 83.3% (n=565) did not have food addiction. When the BMI characteristics of the adults participating in the research are examined; 57.4% (n=389) of the participants were normal, 24.2% (n=164) were overweight, 11.5% were obese (n=78), 6.9% were underweight (n =47) and a mean BMI of 24.13 ± 4.71 (between 15.20-42.20 kg/m²) kg/m² (Table 1).

Table 1: Distribution of adults' sociodemographic, anthropometric characteristics and food addiction status (n=678)

Variable	Category	n	%
Gender	Female	548	80,8
	Male	130	19,2
Marital status	Married	269	39,7
	Single	409	60,3
Age Group	18-25 years	313	46,2
	26-35 years	182	26,8
	36 years and older	183	27,0
Educational Status	High school graduate and below	144	21,2
	Graduate	365	53,8
	Postgraduate	169	24,9
Psychiatric Disease Status	Available	43	6,3
	Not available	635	93,7
Psychiatric Drug Use Status	Uses	28	4,1
	Not using	650	95,9
Eating Addiction Status	Has an addiction to food	113	16,7
	No food addiction	565	83,3
Variable	Min,-Max,	Median	$\bar{X} \pm SD$
Age	18,00-65,00	26,00	$30,41 \pm 10,00$
Variable	Category	n	%
BMI Group	Underweight	47	6,9
	Normal BMI	389	57,4
	Overweight	164	24,2
	Obesity	78	11,5
Variable	Min,-Max,	Median	$\bar{X} \pm SD$
Length (cm)	150,00-192,00	165,00	$166,22 \pm 8,28$
Body Weight (kg)	39,00-125,00	64,00	$66,88 \pm 14,90$
BMI (kg/m ²)	15,20-42,20	23,30	$24,13 \pm 4,71$

n: Number, \bar{X} : Average; BMI: Body Mass Index; SD: Standard Deviation; Min.: Minumum; Max.: Maximum; \pm : plus-minus

It was determined that the adults participating in the study got an average of 2.87 ± 1.82 (Median: 3.00; Min.-Max.: 0-7 points) on the YFAS and had a low level of food addiction. It was determined that they got an average score of 19.38 ± 6.37 (Median: 19.00; Min.-Max.: 9.00-36.00) from

the total of DBAS and the level of desire to be admired by adults was low. It was determined that the adults participating in the study scored an average of 30.32 ± 10.52 (Median: 28.00; Min.-Max.: 15.00-75.00) from the total ISSS, and their inflated sense of self was low (Table 2).

Table 2: Mean scores of the YFAS, DBAS, and ISSS and its sub-dimensions

Scales and Sub-Dimensions	N	Min.	Max.	Median	$\bar{X} \pm SD$
YFAS Total	678	0,00	7,00	3,00	2,87±1,82
DBAS Total	678	9,00	36,00	19,00	19,38±6,37
ISSS Total	678	15,00	75,00	28,00	30,32±10,52
ISSS-Inflation in Social Orientation	678	3,00	20,00	9,00	9,11±3,48
ISSS-Inflation in Selfishness	678	4,00	20,00	6,00	6,59±2,97
ISSS-Inflation in Manipulation	678	4,00	20,00	9,00	9,43±3,63
ISSS-Inflation in Self-Exaggeration	678	3,00	15,00	4,00	5,18±2,47

n: Number, \bar{X} : Average, SD: Standard Deviation, Min.: Minimum, Max.: Maximum; ±: plus-minus

Table 3 shows the relationships between Adults' YFAS Scores and the mean scores of BMI, DBAS, and ISSS. There was a positive and low-level significant relationship between the YFAS total mean score of the adults participating in the study and the mean BMI ($r=0.317$; $p<0.001$);

There was a positive and low-level significant correlation between the YFAS total score average and the DBAS total score average ($r=0.333$; $p<0.001$); A positive and low-level significant correlation was found between the YFAS total score average and the ISSS total score average (Table 3).

Table 3: Relationships between adults' YFAS scores and the mean scores of BMI, DBAS, and ISSS

BMI and Scales	N	r / p	1	2	3	4	5	6	7	8
1- YFAS Total	678	r^a	-							
		p								
2- BMI	678	r^a	,317**	-						
		p	,000							
3- DBAS Total	678	r^a	,333**	,028	-					
		p	,000	,468						
4- ISSS Total	678	r^a	,258**	-,055	,377**	-				
		p	,000	,152	,000					
5- ISSS-Inflation in Social Orientation	678	r^a	,213**	-,050	,308**	,843**	-			
		p	,000	,189	,000	,000				
6- ISSS-Inflation in Selfishness	678	r^a	,188**	-,001	,251**	,842**	,629**	-		
		p	,000	,987	,000	,000	,000			
7- ISSS-Inflation in Manipulation	678	r^a	,211**	-,136**	,338**	,843**	,606**	,628**	-	
		p	,000	,000	,000	,000	,000	,000		
8- ISSS-Inflation in Self-Exaggeration	678	r^a	,245**	,017	,352**	,806**	,562**	,592**	,546**	-
		p	,000	,657	,000	,000	,000	,000	,000	

^aPearson correlation analysis was applied, * $p<0.001$. BMI: Body Mass Index; YFAS: Yale Food Addiction Scale; DBAS: Desire to Be Admired Scale; ISSS: Inflated Sense of Self Scale

Table 4 shows the comparison of the adults' YFAS, DBAS, ISSS and sub-dimension scores according to BMI level with One-Way ANOVA Analysis of Variance. In the study, it was determined that the total YFAS scores of adults differed significantly according to the BMI level ($F=22.465$; $p=0.001$). According to the results of the variance analysis of Tamhane's T2 test, which was carried out to determine which group the difference originated from; YFAS total scores of obese adults (3.97 ± 2.05), underweight adults (1.89 ± 1.10), adults with normal BMI (2.58 ± 1.67) and overweight adults (3.31 ± 1.87); YFAS total scores of obese

adults (3.97 ± 2.05) compared to adults with normal BMI (2.58 ± 1.67) and overweight adults (3.31 ± 1.87), and YFAS total scores of obese adults (3.97 ± 2.05) were found to be statistically significantly higher than overweight adults (3.31 ± 1.87) ($p<0.05$). In the study, it was determined that DBAS total scores of adults did not differ significantly according to BMI level ($F=0.110$; $p=0.954$; $p>0.05$). In the study, it was determined that ISSS total scores of adults did not differ significantly according to BMI level ($F=0.506$; $p=0.679$; $p>0.05$) (Table 4).

Table 4: Comparison of adults' YFAS total score, DBAS total score, and ISSS total and sub-dimension scores according to BMI level with one-way ANOVA analysis of variance						
Scales and Sub-Dimensions	BMI Level	N	$\bar{X}\pm SD$	F*	p	Difference
YFAS Total	(1) Underweight	47	1,89±1,10	22,465	0.001	1-2,3,4 ^a 2-3,4 ^a 3-4 ^a
	(2) Normal BMI	389	2,58±1,67			
	(3) Overweight	164	3,31±1,87			
	(4) Obesity	78	3,97±2,05			
DBAS Total	(1) Underweight	47	19,40±6,45	0,110	0.954	-
	(2) Normal BMI	389	19,27±6,30			
	(3) Overweight	164	19,52±6,29			
	(4) Obesity	78	19,65±6,96			
ISSS Total	(1) Underweight	47	31,17±12,07	0,506	0.679	-
	(2) Normal BMI	389	30,52±10,34			
	(3) Overweight	164	30,23±10,32			
	(4) Obesity	78	28,98±10,91			
ISSS-Inflation in Social Orientation	(1) Underweight	47	9,74±3,80	0,764	0.515	-
	(2) Normal BMI	389	9,08±3,42			
	(3) Overweight	164	9,15±3,53			
	(4) Obesity	78	8,78±3,55			
ISSS-Inflation in Selfishness	(1) Underweight	47	6,51±3,24	0,041	0.989	-
	(2) Normal BMI	389	6,58±2,96			
	(3) Overweight	164	6,65±2,90			
	(4) Obesity	78	6,57±2,89			
ISSS-Inflation in Manipulation	(1) Underweight	47	9,74±4,13	1,601	0.114	-
	(2) Normal BMI	389	9,72±3,56			
	(3) Overweight	164	9,09±3,52			
	(4) Obesity	78	8,48±3,77			
ISSS-Inflation in Self-Exaggeration	(1) Underweight	47	5,17±2,64	0,228	0.877	-
	(2) Normal BMI	389	5,13±2,41			
	(3) Overweight	164	5,32±2,47			
	(4) Obesity	78	5,14±2,70			

**ANOVA Analysis of Variance, **p<0.05, ^aTamhane's T2 Testi. YFAS: Yale Eating Addiction Scale; DBAS: Desire to Be Admired Scale; ISSS: Inflated Sense of Self Scale*

Table 5 shows the comparison of adults' YFAS, DBAS, ISSS and sub-dimension scores by gender with Independent Groups t-test. In the study, it was determined that the total YFAS scores of adults differed significantly by gender ($t=2.878$; $p=0.004$). It was determined that the YFAS total scores of adult males (2.97 ± 1.85) were statistically

significantly higher than adult females (2.46 ± 1.62) ($p<0.05$). It was determined that the total DPS scores of adults differed significantly by gender ($t=2.691$; $p=0.004$). It was determined that the total DBS scores of adult female (19.70 ± 6.47) were statistically significantly higher than that of adult male (18.04 ± 5.77) ($p<0.05$) (Table 5).

Table 5: Comparison of adults' total score of YFAS, total score of DBAS, and total and sub-dimension scores of ISSS in independent groups by t-test

Scales and Sub-Dimensions	Gender	N	$\bar{X}\pm SD$	t*	p
YFAS Total	Female	548	2,97±1,85	2,878	0,004**
	Male	130	2,46±1,62		
DBAS Total	Female	548	19,70±6,47	2,691	0,004**
	Male	130	18,04±5,77		
ISSS Total	Female	548	30,38±10,68	0,192	0,848
	Male	130	30,06±9,83		
SBSS-Inflation in Social Orientation	Female	548	9,12±3,54	0,262	0,793
	Male	130	9,03±3,24		
SBSS-Inflation in Selfishness	Female	548	6,59±3,00	-0,549	0,583
	Male	130	6,72±2,83		
SBBS-Inflation in Manipulation	Female	548	9,56±3,65	1,971	0,059
	Male	130	8,86±3,53		
SBDÖ-Inflation in Self-Exaggeration	Female	548	5,12±2,51	-1,302	0,193
	Male	130	5,43±2,29		

* Independent Groups t-Test, ** $p<0.005$. YFAS: Yale Eating Addiction Scale; DBAS: Desire to Be Admired Scale; ISSS: Inflated Sense of Self Scale

Discussion

Food addiction has become a subject of increasing interest in recent years, especially in societies where the prevalence of obesity has increased (19). The relationship between food addiction and obesity has been increasing in recent years. However, whether obesity is a real cause of food addiction is a controversial issue (20). It is thought that food addiction may be caused by obesity and various psychological reasons, so it is essential to determine the risk factors of food addiction and to create treatment plans for them.

In this study, a positive and low-level significant correlation was found between the mean YFAS total score of adults and the mean BMI (Table 3). In addition, it was determined that YFAS total scores differed significantly according to the BMI level of adults. YFAS total scores of obese adults ($3,97\pm2.05$), were found to be statistically

significantly higher than underweight adults ($1,89\pm1,10$), adults with normal BMI ($2,58\pm1,67$), and overweight adults ($3,31\pm1,87$) (Table 4). Studies have found a positive relationship between food addiction and BMI, and it has been reported that food addiction is associated with higher BMI (21, 22, 23, 24, 25). In the study of Oktay (26), the relationship between food addiction and BMI was found to be significant; it has been found that food addiction is more common in obese individuals. In the study conducted by Öztatar (27), it was observed that participants with food addiction had higher BMI values. In other words, it has been reported that as BMI increases, food addiction also increases. In the literature review, the majority reported that there is a relationship between BMI and food addiction and this relationship is positive. In line with the information obtained from this study and the literature, it can be said that the prevalence of food addiction increases as BMI increases.

In the study, it was determined that the YFAS total scores of adults differed significantly by gender. It was determined that the YFAS total scores of adult female (2.97 ± 1.85) were statistically significantly higher than adult males (2.46 ± 1.62) (Table 5). In the study of Pedram et al. (28), the prevalence of food addiction in women was found to be higher than in men, and it was reported that women are at higher risk for food addiction than men. In the study of Burrows et al. (29), it was reported that food addiction differs significantly according to gender, with a higher prevalence in women (24.4%) than in men (13.3%). In the study conducted by Bilgi (30) in Isparta, food addiction was found to be higher in women. However, this difference was not statistically significant. In the study conducted by Başar (25), it was reported that food addiction was significantly more common in women (16.8%) than in men (5.7%). In this study and studies in the literature, it has been reported that food addiction is higher in women than in men. It can be said that women have higher food addiction than men.

In the study, it was found that there was a positive and low-level significant relationship between the YFAS total score average and the DBAS total score average (Table 3). There is no study in the literature examining the relationship between food addiction and the desire to be admired. This study will be the first. More research is needed to confirm this relationship.

A positive and low-level significant correlation was found between the YFAS total score average and the ISSS total score average (Table 3). More work is needed in this area to support this relationship.

A positive and low-level significant correlation was found between the DBAS total score average of the adults participating in the study and the ISSS total score average (Table 3). More work is needed in this area to support this relationship.

Some limitations should be considered when evaluating study data. The sample of this study is limited to individuals aged 18-65 between the years 2021-2022. The research is limited to the question items included in the "Socio-Demographic Information Form", "Eating Addiction Scale", "Desire to Be Admired Scale", "Inflated Sense of Self Scale" data measurement tools. The study is limited to the answers given by the participants to the questions. The study is limited to the perceptions and thoughts of the participants in a certain time period, it is not possible to detect

the changes over time. The results of the study are limited to the data analysis method used by the researcher.

Conclusion

As a result, food addiction can be a major problem in our society. It can be said that obesity, desire to be admired and egocentrism are positively related to food addiction. It has been determined that obesity, desire to be admired and inflated sense of self increase with the increase in food addiction. Results from the study may shed light on developing better treatment programs for eating behavior problems. While targeting body weight loss in overweight and obese individuals, treatment efficacy can be increased by considering food addictions and reducing food addiction. Collaboration of dietitian and psychologist in the treatment of food addiction can help to achieve more positive results.

Conflict of Interest

The author has no funding or conflicts of interest to disclose.

Declarations

Funding and Conflicts of Interest

During this study, material and moral support was not received from any pharmaceutical company that has a direct connection with the subject of the research, from a company that provides and produces medical instruments, equipment and materials, or from any commercial company, which may adversely affect the decision to be made regarding the study during the evaluation process of the study. Regarding this study, the authors and their family members did not have a potential conflict of interest, scientific and medical committee membership or relationship with its members, consultancy, expertise, employment in any company, shareholding or similar situations. While preparing the study; No conflict of interest was found during the data collection, interpretation of the results and writing of the article.

Ethics Approval

Ethics committee approval, dated 28.09.2021 and decision number 09, was obtained from Üsküdar University Non-Interventional Clinical Research Ethics Committee before the data were collected in the study. At the

meeting numbered 04 held on 28.03.2022, it was decided that the research whose revision was requested was ethically appropriate.

Authors' contributions

Idea/Concept: ER Laciner, ÖÖ Özcan, M Karahan; **Design:** ER Laciner; **Supervision/Consulting:** ÖÖ Özcan, M Karahan; **Data Collection and/or Processing:** ER Laciner; **Analysis and/or Interpretation:** ER Laciner, ÖÖ Özcan, M Karahan; **Literature Review:** ER Laciner; **Writing of the Article:** ER Laciner; **Critical Review:** ÖÖ Özcan, M Karahan.

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Validation Of Hospital Information System Quality Scale Into Turkish

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ABSTRACT

Purpose: This study aims to translate and validate the Hospital Information System Scale developed by Kuo, Liu, Talley, and Pan (2018) into Turkish within the hospital information system quality and satisfaction framework.

Metarial and Method: The study data were completed between 15 September - and 15 October 2023 through a survey link shared online with consenting and volunteering participants via an online survey. The study was conducted with healthcare professionals, and the online forms were filled out in Turkish. Hospital information system quality is measured by three dimensions: system, information and service quality, while satisfaction is measured by a single dimension. The research sample consists of data collected from 299 healthcare professionals by survey. The construct and relationship validity of the scale were tested by taking into account the variance structure and covariance relationships. The reliability of the scales was assessed through internal consistency tests.

Results: The scale's system, service, and information quality dimensions were observed to have significant relationships in the same direction as the satisfaction scale. According to all analyses, the scale was valid and reliable.

Conclusion: It is expected that this scale will be guiding and supportive in future studies on this subject to add patient satisfaction in health institutions that are aware of the importance of hospital information systems developed within the scope of the research.

Keywords: Information Quality, Hospital Information System, Satisfaction, Scale Validation, System Quality, Service Quality.

ÖZET

Amaç: Bu çalışmanın amacı Kuo, Liu, Talley ve Pan (2018) tarafından geliştirilen Hastane Bilgi Sistemi Ölçeğinin hastane bilgi sistemi kalitesi ve memnuniyeti çerçevesinde Türkçeye çevrilmesi ve geçerliliğinin sağlanmasıdır.

Materyal ve Metot: Çalışma verileri, çevrimiçi bir anket aracılığıyla izin veren ve gönüllü katılımcılarla çevrimiçi olarak paylaşılan bir anket bağlantısı aracılığıyla 15 Eylül - 15 Ekim 2023 tarihleri arasında tamamlandı. Çalışma sağlık profesyonelleri ile yürütülmüş olup online formlar Türkçe olarak doldurulmuştur. Hastane bilgi sistemi kalitesi; sistem, bilgi ve hizmet kalitesi olmak üzere üç boyutla ölçülürken, memnuniyet tek boyutla ölçülmektedir. Araştırmanın örneklemini 299 sağlık çalışanından anket yoluyla toplanan veriler oluşturmaktadır. Ölçeğin yapı ve ilişki geçerliği, varyans yapısı ve kovaryans ilişkileri dikkate alınarak test edilmiştir. Ölçeklerin güvenilirliği iç tutarlılık testleri ile değerlendirilmiştir.

Bulgular: Ölçeğin sistem, hizmet ve bilgi kalitesi boyutlarının memnuniyet ölçeği ile aynı yönde anlamlı ilişkilere sahip olduğu görülmüştür. Yapılan tüm analizlere göre ölçek geçerli ve güvenilirlidir.

Sonuç: Araştırma kapsamında geliştirilen hastane bilgi sistemlerinin öneminin bilincinde olan sağlık kuruluşlarında hasta memnuniyetinin artırılması açısından bu ölçeğin bundan sonra bu konuda yapılacak çalışmalara yol gösterici ve destekleyici olması beklenmektedir.

Anahtar kelimeler: Bilgi Kalitesi, Hastane Bilgi Sistemi, Memnuniyet, Ölçek Doğrulama, Sistem Kalitesi, Servis Kalitesi.

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In today's technological age, there are changes in many economic, political, cultural, social, and agricultural fields. The impact of rapid advances in information and communication technologies is also evident in the health sector. The introduction of communication and information technologies in health institutions facilitates the work of health service recipients and health professionals. Digital transformation in healthcare institutions has brought about significant changes in the follow-up and delivery of healthcare services (1). With digitalization in healthcare services, the systems in the sector are computerized, and information flow is provided by establishing connections between all channels. In this way, information about patients and other areas in the institution is quickly delivered to the point where it is needed, processed, used, analyzed, and made ready for presentation (2). With the spread of technology in the health sector, digital applications have manifested themselves in many areas of hospitals. However, the rapid advancement of technology has increased the need to use information technologies to solve numerous problems in the health sector with resource constraints, cost pressure, and increased demand (3). Modern developments in information technology have completely changed the face of the world, and information technology-based services have significantly improved healthcare (4). Among these, hospital information systems are one of the most widely used health information systems. HIS (Hospital Information System) is a comprehensive software that integrates patient information to send and share health information between departments in order to provide quality service, accelerate patient care and treatment, and increase satisfaction (5). In other words, a HIS is defined as a system that undertakes the functions of information collection and information dissemination to assist decision-makers at various levels of hospital enterprises, as a system that can integrate data obtained from different sources, realization of services through computer; automatic exchange of information in an electronic environment; recording and converting detailed information arising in terms of medical financial/financial services into details with a computer-based information system (6). HIS is a vital part of contemporary hospital infrastructure and the effective delivery of quality healthcare services in healthcare. Hospital Information Systems (HIS) is a needful efficiently providing high-quality healthcare services in hospitals (7). Hospital information systems support hospital activities in technical, practical, and strategic terms and provide better service to patients, reduce medical costs, and shorten service delivery time. It also helps minimize medical errors by ensuring that patients' medical and organizational

processes are used separately and in an integrated manner. A quality information system is needed to control costs, meet the needs of service users, and assist the medical process (8). A quality health information system; it can effectively increase the relevance of information, readable health information, and subsequent results, and lead users to develop a positive attitude towards information systems (9). Although there are limited studies on hospital information systems and quality in the literature, in the domestic literature, according to healthcare workers, hospital information systems are mainly used for easier access to information, providing better quality medical services, preventing loss of time, facilitating communication between employees, making appointments for outpatients and assigning patients, the use of information technologies in hospitals contributes positively to the quality-efficiency of the information management system (10), the use of information systems facilitates the workload of health sector employees, the realization of the medical equipment supply chain quickly and with minimum cost, accounting, and financial records, human resources management, workforce planning, etc. In healthcare institutions using HIS, these factors appear to positively affect patient satisfaction and loyalty in terms of efficiency (11), reliability, patient satisfaction, quality, and corporate image (12). In foreign literature, it is seen that hospital information quality can significantly predict physician satisfaction (13). The hospital information system has a significant impact on user satisfaction (14), the interaction of services, the availability of information, and the usability of the system have a substantial impact on the quality of services (15) and the effect on the quality of health services and hospital information systems (16). This study aims to examine the hospital information system quality to evaluate each variable's effect on satisfaction and contribute to the local literature with the Turkish validation of the hospital information system quality scale so that researchers can directly measure the hospital information system quality. In this way, it can help ensure the success of the information system and provide the desired service quality, such as ease of contact, system response time, ease of use, and learning. The quality of these systems is mainly related to customer satisfaction. HIS can improve the work process of staff, reduce the possibility of errors, and improve the quality of healthcare services by better communication in the work of healthcare professionals and increasing their precision in daily tasks (8).

Materials and Methods

This study used a quantitative research method and was conducted with a relational research design. The population of this study consists of health professionals in Turkey. The research is a cross-sectional study, and the data was collected using the convenience sampling method. In order to reach the required sample size, the criterion suggested by Hair et al. is that it should not be less than five times the total number of items in the survey. As a result, the required sample size was achieved. Data was provided from consenting and voluntary participants via the online survey and the survey link shared online between September 15 and October 15, 2023. According to the age variable of the healthcare professionals participating in the research, 154 (51.5%) are between the ages of 20-30, 88 (28.4%) are between the ages of 31-40, and 47 (15.7%) are between the ages of 41-50. range and 10 (3.3%) were over 50 years old. According to the gender variable, 200 (64.9%) of the participants were women and 99 (35.1%) were men. According to the marital status variable, 133 (44.5%) were married and 166 (55.5%) were single. According to the work organization variable, 254 (84.9%) of the participants work in public hospitals and 45 (15.1%) work in private hospitals. It was determined that 119 (39.8%) of the participants used hospital information systems for 0-5 hours, 104 (34.8%) for 6-15 hours, and 72 (24.4%) for 16 hours or more. The professions of the healthcare professionals participating in the research are as follows: 42 (14%) doctors, 92 (30.7%) nurses, 89 (29.8%) medical secretaries, 76 (25.4%) other healthcare personnel (dentists, psychologists, dietician), laboratory, radiology, administrative unit).

Measurement Tool

Kuo et al. developed a three-dimensional and 10-item measurement tool for hospital information system quality. The scale consists of information, service, and system quality dimensions. System quality and information quality consist of three statements and service quality consists of four statements. The satisfaction scale consists of five statements. The scale consists of a 7-point Likert-type scale ranging from strongly disagree to strongly agree.

Process

The scale was first translated into Turkish by taking the opinions of two linguists who are experts in their field. The understandability of the sentences and the suitability

of words and sentence structures were also evaluated by three academics who are experts in health management and were not involved in the translation. The research questions were created in consultation with the researcher to determine whether they reflected the purpose of the research and whether the number of questions was sufficient. In data analysis, SPSS Amos software focused on the covariance-based features of the measurement tools, and Smart PLS software was used to look at the variance-based features. The frequency tables were examined before starting the data analysis to check whether the data was entered correctly. The reliability of the scale was determined by Cronbach's alpha (α) coefficient. In factor analysis, considering the sufficient sample size and missing data, 50 is considered very poor, 100 is poor, 300 is good, 500 is very good, and 1000 is excellent (17). In the literature, it is seen that a sample of 200 people is sufficient for factor analysis, and 5 or 10 times the number of items may be enough for sample size (18, 19). There are studies stating that the minimum number of observations should be 300 (20). Considering all these, it can be said that the sample size in this study is sufficient. Firstly, the validity and then the reliability analyzes of the scale were conducted. For validity analysis, structure and criterion-related validity were tested and the partial least squares method (Smart PLS program) was used. Construct validity was ensured by testing the explained variance and the proposed factor structure using the observed covariance matrix (IBM AMOS program). SmartPLS is also a variance-based partial least squares structural equation modeling (PLSSEM) software that does not require a normal distribution assumption. In other words, predictions can be made regardless of whether the data is normally distributed or not (21). It also can effectively test complex models (22). In this way, the validity of the proposed structure was tested using both structural tests. Cronbach's alpha coefficient and split-half reliability coefficient (IBM SPSS program) were used to test reliability and internal consistency of the scale items.

Results

Validity Findings of the Scale

Construct and concurrent validity were tested for the validity of the scale. For construct validity, two different structural tests were conducted, taking into account both the explained variance structure and the observed covariance structure of the scale. In these tests, the structures of three-dimensional hospital information system

quality and one-dimensional satisfaction scales were tested. Reliability analysis was performed using the Cronbach alpha method to determine the internal consistency of the scales. The results obtained are shown in Table 1. Another method used to evaluate the scales' reliability in this study is the "corrected item-total score correlations" analysis, one of the correlation-based item analysis methods. When the corrected item-total correlation coefficients of each item of the scales are above 0.30, it is seen that the relationship between the scales and the main structures to which the items belong is satisfactory (23). These results show the reliability of the scales.

Table 1. Results of the reliability analysis

Measures	Number of items	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
System Quality	Item 1	9.52	9.103	.608	.737
	Item 2	10.19	7.135	.673	.672
	Item 3	9.40	9.227	.625	.722
Information Quality	Item 4	10.70	5.580	.689	.845
	Item 5	11.05	5.333	.783	.752
Service Quality	Item 6	10.80	5.995	.731	.805
	Item 7	15.14	15.356	.817	.810
	Item 8	15.11	15.588	.821	.810
	Item 9	15.8	15.619	.618	.899
Satisfaction	Item 10	14.96	17.169	.722	.849
	Item 11	20.7	22.297	.751	.896
	Item 12	20.46	22.585	.825	.878
	Item 13	20.91	21.664	.814	.881
	Item 14	20.39	24.421	.750	.894
	Item 15	20.33	25.767	.748	.897

Variance Structure Findings: The convergent and divergent validity of the scale was tested using the Smart PLS program. In the tests, the factor loadings of each item in the scale must be higher than 40%, the AVE (average variance explained) must be equal to or higher than 50% ($AVE \geq 0.50$), and the CR (combined reliability) value must be equal to or higher than 70%. It should be high ($CR \geq 0.70$), and the multicollinearity coefficient should be less than 5. In addition, rho_A should be a minimum of 0.70 ($\rho_A \geq 0.70$) to evaluate the internal consistency reliability of the model. According to the reliability and convergent validity results of the scales in Table 2, Cronbach's alpha coefficients (α), rho_A, and CR (combined reliability)

criteria above .70 indicate the scale's reliability. The AVE (average variance explained) shows the concurrent validity. Fornell and Larcker stated that to ensure internal consistency, the average variance explained (AVE) of the variables in the scale should be equal to or higher than 50% ($AVE \geq 0.50$), while Henseler et al. (25) also reveal this situation and argue that in determining discriminant validity, cross-loadings should be checked and it should be examined whether there are overlapping items between the statements measuring the research variables (24, 25). After discriminant validity, the Heterotrait-Monotrait Ratio (HTMT) test was performed. Table 3 shows the HTMT results. The reliability results of the scale, as seen in Table 1, showed that the total reliability value (Cronbach's Alpha value) and data consistency coefficient (rho-A) of the hospital information systems scale and satisfaction scale were .934. The internal consistency coefficient of the rho-A results of the three-factor hospital information system quality and satisfaction scales was found to be acceptable (27). According to the results obtained in Table 1, the hospital information system quality satisfaction scale is confirmed to have four sub-dimensions.

Table 2: Convergent Validity and Reliability Results

Constructs	Indicators	IL	CA	CR	AVE	rho_A
System Quality	1	0,815				
	2	0,845	.792	.877	.705	.801
	3	0,857				
Information Quality	1	0,831				
	2	0,916	.860	.914	.780	.881
	3	0,900				
Service Quality	1	0,815				
	2	0,845	.884	.920	.744	.898
	3	0,857				
	4	0,815				
Satisfaction	1	0,859				
	2	0,897	.913	.934	.740	.921
	3	0,881				
	4	0,833				
	5	0,831				
HISQ		.815-.916	.863	.898	.730	.934

Note: n = 299, IL: Indicator loadings, p: Statistical significance level, α : Cronbach's alpha, AVE: Average variance extracted, CR: Composite reliability.

Table 3: Discriminant Validity (Fornell-Larcker Criterion)

Constructs	1	2	3	4
System Quality(1)	.839			
Information Quality(2)	.746	.883		
Service Quality(3)	.663	.655	.863	
Satisfaction(4)	.711	.669	.725	.860

As seen in Table 3, inter-factor correlations were compared with the square root of the AVE of each factor to check the validity of the distinction between factors (24). According to this comparison, the condition that the square roots of the AVE values are greater than the inter-factor correlation values was met. In other words, when the relationship between each sub-dimension of the job shaping scale and the other factors was analysed, it was seen that the square root of AVE was much higher than the other factor values and that it was well separated from the other factors. In the Fornell-Larcker Criterion evaluation, the fact that all values in the rows and columns are smaller than the bolded values and the Heterotrait-Monotrait Ratio values are between 0 and 1 (Table 2) indicates that the discriminant validity between the research dimensions is ensured (26). In their study, Henseler et al. (25), stated that discriminant validity between a certain pair of reflective constructs is realised when the HTMT value is below 0.90. It is seen in Table 4 that all HTMT values are below 0.90 and discriminant validity has been achieved.

Table 4: Discriminant Validity (Heterotrait-Monotrait Ratio Criterion)

Constructs	1	2	3	4
System Quality(1)		.880		.820
Information Quality(2)	.880		.783	
Service Quality(3)	.783	.729		.797
Satisfaction(4)	.820		.797	

Covariance Structure Findings: The construct validity of the scale was conducted by confirmatory factor analysis with maximum likelihood calculation using the IBM AMOS program. According to Kline (18), the data were normally distributed and the covariance matrix was created according to the maximum likelihood method (28). From this point of view, the criteria which take into account as follows: the ratio of chi-square value to degrees of freedom ($\chi^2/sd < 3$), root mean square of prediction error (SMRM ≤ 0.8), comparative fit index (CFI $> .90$) and Turker Lewis

index (TLI $> .90$) criteria were used for the goodness of fit of the tested models. The three-factor structure of the hospital information system quality scale ($\chi^2 = 122.971$, $p < .000$, $sd = 32$, $\chi^2/sd = 3.843$, SMRM = 0.80, IFI = .946, CFI = .931, TLI = .914) and the single-factor structure of the satisfaction scale ($\chi^2 = 18.037$, $p < .000$, $sd = 4$, $\chi^2/sd = 4.509$, SMRM = 0.61, CFI = .986, TLI = .966, IFI = .986). To test the relationship validity of the scale, the relationships between the scale and the satisfaction scale were analyzed. As a result of the correlation analysis, Table 5 shows that all of the scale's system, information, and service quality dimensions have the same directional and significant relationships with the satisfaction scale. Based on this, it provides evidence for the relationship-dependent validity of the scale.

Table 5: Relationship Validity

Constructs	1	2	3	4
System Quality(1)	1			
Information Quality(2)	0.712**	1		
Service Quality(3)	0.651**	0.627**	1	
Satisfaction(4)	0.698**	0.686**	.720**	1

Discussion

This study was conducted to introduce the three-dimensional hospital information system quality scale developed by Kuo et al. (13) to the national literature based on the understanding of establishing a balance between hospital information system quality and the satisfaction perceptions of the users of these systems. However, in the translation of the scale questions, the closest equivalents of the theory and dimensions in the national culture were tried to be revealed in intercultural studies. Subsequently, two different construct validity and relationship validity of the scale were tested within the scope of the analysis, taking into account the variance structure and covariance relationships. In the light of the results obtained, sufficient evidence was provided for the validity of the scale. Two different internal consistency analyses were performed for the reliability of the scale and the results showed that the items were consistent at high levels. In the context of all these results, it was evaluated that the hospital information system quality scale can be used in future studies to be conducted in the national literature with the three-dimensional structure proposed in its original form.

In the health sector, studies can be carried out to increase the system quality for those who use hospital information systems, as well as to make the data more suitable for application areas with measurements to increase the quality of information. These studies can provide information from lower to upper levels about how information systems should be structured in the health sector by all users. Today, especially the important role of the health sector for sustainable innovation of information technologies will always remain important. In addition, if health sector organisations want to ensure patient satisfaction and patient loyalty in service delivery processes, regardless of private or public sector, they should take into account these factors obtained from the scale.

We believe that it is important to evaluate all the results obtained in the study with the constraints of single source and single time data collection. At the same time, the number of participants in this study is small and the findings do not reflect the opinions of all healthcare professionals in Turkey. It is expected that this scale will be guiding and supportive in future studies to increase patient satisfaction in health institutions that are aware of the importance of hospital information systems developed within the scope of the research.

Declaration

Funding

None

Conflict of interest/Conflict of interest

The author declares that he has no conflict of interest.

Ethical Approval

Tokat Gaziosmanpaşa University Social And Biberl Sciences Research Ethics Committee approved the study on June 17, 2023 with decision number 01-45.

Availability of data and material

The data file is available as an SPSS and Smart PLS document upon request.

Authors' contributions

Not applicable. I'm the only author (M.A).

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