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ORIGINAL ARTICLE / ARAŞTIRMA YAZISI

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Comparison of Dyspnea, Quality of Life and Fatigue Levels in Heart Failure Patients with and without Pacemakers - A Preliminary Study

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ABSTRACT

Background/Purpose: The main purpose of this study was to compare dyspnea, quality of life, and fatigue levels in heart failure patients with and without pacemaker. In addition, the aim of our study was to examine whether there was a relationship between dyspnea, quality of life and fatigue levels in heart failure patients, as well.

Methods: A total of 20 patients with heart failure, 10 with and 10 without pacemaker, who were diagnosed with heart failure by a cardiologist at the Corum-Hitit University Erol Olcok Training and Research Hospital, Cardiac Rehabilitation Unit were included in our study. Dyspnea, quality of life, and fatigue levels were measured with "Modified Medical Research Council Dyspnea Scale (MmRC)", "Minnesota Heart Failure Life Scale (MHF)" and "Fatigue Severity Scale (FSS)" questionnaire, respectively.

Results: A total of 20 heart failure patients, 10 with pacemakers with a mean age of 61.90±8.49 years and 10 without pacemakers with a mean age of 59.30±10.68 years, were included in our study. There was no significant difference in terms of dyspnea, quality of life and fatigue levels in heart failure patients with and without pacemaker ($p>0.05$). In 20 heart failure patients, it was observed that there was a moderate correlation in the same direction between the level of dyspnea and the level of fatigue ($p<0.05$).

Conclusion: According to the results of our study, it was found that using a pacemaker in heart failure patients had no effect on dyspnea, quality of life and fatigue levels. In addition, it was found that while the level of dyspnea was associated with the level of fatigue in heart failure patients, it was not correlated with the quality of life.

Keywords: Heart Failure, Artificial Pacemaker, Outcome Assessment, Dyspnea, Quality of Life, Fatigue

ÖZET

Amaç: Bu çalışmanın temel amacı kalp pili olan ve olmayan kalp yetmezliği hastalarında dispne, yaşam kalitesi ve yorgunluk düzeylerini karşılaştırmaktı. Ek olarak, çalışmamızın bir diğer amacı, kalp yetmezliği hastalarında dispne, yaşam kalitesi ve yorgunluk düzeyleri arasında da bir ilişki olup olmadığını incelemekti.

Yöntemler: Çalışmamıza Çorum-Hitit Üniversitesi Erol Olçok Eğitim ve Araştırma Hastanesi Kardiyak Rehabilitasyon Ünitesi'nde kardiyolog tarafından kalp yetmezliği tanısı konulan 10'u kalp pili olan ve 10'u kalp pili olmayan toplam 20 kalp yetersizliği hastası dahil edildi. Dispne, yaşam kalitesi ve yorgunluk düzeyleri sırasıyla "Modified Medical Research Council Dyspnea Scale (MmRC)", Minnesota Heart Failure Life Scale (MHF)", and "Fatigue Severity Scale (FSS)" anketleri ile ölçüldü.

Bulgular: Çalışmamıza yaş ortalaması 61,90±8,49 yıl olan kalp piline sahip 10, yaş ortalaması 59,30±10,68 yıl olan kalp piline sahip olmayan toplam 20 kalp yetersizliği hasta dahil edildi. Kalp pili olan ve olmayan kalp yetersizliği hastalarında dispne, yaşam kalitesi ve yorgunluk düzeyleri açısından anlamlı farklılık saptanmadı ($p>0,05$). 20 kalp yetersizliği hastasında dispne ile yorgunluk düzeyi arasında aynı yönde orta düzeyde bir korelasyon olduğu görüldü ($p<0,05$).

Sonuçlar: Çalışmamızın sonuçlarına göre kalp yetmezliği hastalarında kalp pili kullanımının dispne, yaşam kalitesi ve yorgunluk düzeylerine etkisinin olmadığı belirlendi. Ayrıca, kalp yetersizliği hastalarında dispne düzeyinin yorgunluk düzeyiyle ilişkili olduğu ancak yaşam kalitesiyle ilişkili olmadığı belirlendi.

Anahtar Kelimeler: Kalp Yetmezliği, Yapay Kalp Pili, Çıktıların Analizi, Dispne, Yaşam Kalitesi, Yorgunluk

Heart failure is a condition in which the heart does not work properly. This can be caused by a problem with the heart's structure or the way it functions. This can lead to a shortage of oxygen in the body (1). It is thought that heart failure, which affects approximately 1 to 2 percent of the adult population in developed countries, may affect more people in the coming years due to the aging of the population (2). It is estimated that the prevalence of heart failure will increase by 46 percent by 2030 (3). Heart failure affects about 2% of the Australian population as the prevalence, and about 30,000 new people are diagnosed with it each year (1).

In addition to the significant economic cost of heart failure disease on the health system, heart failure patients are also significantly affected by the disease (1). In this patient group, problems such as depression, anxiety, cognitive impairment, increased shortness of breath with exertion, decreased independence in activities of daily living, and sleep problems were found to be common (1, 2). These symptoms are also accompanied by stress, including the use of multiple medications, fluid management, and multiple medical appointments (1).

The main problems seen in clinically stable patients with heart failure are decreased exercise tolerance and worsened quality of life (3). Exercise intolerance, defined as the inability to perform physical activities with prominent dyspnea and/or fatigue symptoms, is the main feature of heart failure and is associated with low quality of life (4).

Pacemakers are medical devices used for treating cardiac arrhythmias by implanting for the body internally (5). Cardiac implantable electronic devices, including permanent pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy (CRT), which play an important role in the treatment of cardiac arrhythmias, are increasingly used by cardiologists (6). Pacemakers enable heart failure patients to achieve a consistent quality of life compared to their healthy peers and in most cases reduce mortality (7). Patients undergoing pacemaker treatment may experience changes in different aspects of their lives in terms of physical, social, emotional and psychological factors. (8). Therefore, it is extremely important to examine these parameters in patients with a diagnosis of heart failure and especially those receiving pacemaker therapy. On the other hand, although there are a limited number of studies examining the quality of life after pacemaker treatment in patients with heart failure (8), it is thought that there is a need for studies examining parameters such as dyspnea and fatigue in patients with heart failure with pacemakers and examining the factors affecting these parameters.

Although the comparison of various symptom and patient-focused outcomes such as health-related quality of life in patients with heart failure and healthy individuals in the literature has been the subject of some studies (5, 9, 10), the number of studies comparing heart failure patients with and without a pacemaker is limited. While it was found that exercise intolerance accompanied by dyspnea and fatigue, which is the main problem of patients with heart failure, is associated with poor function and reduced quality of life (4), whether there is a difference between these parameters according to the use of a pacemaker has not been examined. In addition, similar cardiac rehabilitation programs can often be applied in clinics for patients with and without a pacemaker. The difference in dyspnea, quality of life and fatigue parameters between patients with and without a pacemaker may create significant differences in the content of cardiac rehabilitation programs for both groups of patients.

In the light of this information, the main purpose of our study is to compare the levels of dyspnea, quality of life and fatigue in heart failure patients with and without a pacemaker. In addition, in this study, we examined whether there is a relationship between dyspnea, quality of life and fatigue levels in patients with heart failure.

2. Material and Methods:

2.1. Ethics:

Ethics committee approval of the study was obtained by Hitit University Faculty of Medicine Clinical Research Ethics Committee on 11.03.2020 with Decision Number 188. All subjects were informed about the study prior to their participation and written informed consent was obtained from each subject. In addition, institutional permission was obtained from the hospital to conduct the study.

2.2. Participants:

A total of 20 patients with cardiac failure, 10 with and 10 without a pacemaker, who were diagnosed with heart failure by a cardiologist in Çorum-Hitit University Erol Olçok Training and Research Hospital, Cardiac Rehabilitation Unit were included in our study. Patients with Class I, II and III according to New York Health Association (NYHA) classification were participated in the present study. All patients included in the study were clinically stable patients with good cognitive function with a score of 24 or higher on the Mini Mental State Scale.

The patients with the following conditions were excluded from the study: patients with diastolic heart failure or had moderate and severe lung diseases (COPD, etc.), patients with Class IV according to NYHA classification, geriatrics with a score of 23 or less on the Mini Mental State Scale, patients who did not understand the assessment test protocol or did not wish to participate in the study.

2.3. Study Procedures

Sociodemographic data included age, weight, height, gender, and educational level. Heart Failure risk factors data included medical history, obesity, alcohol consumption, smoking, comorbidities, ejection fraction. The following parameters were assessed as outcome measurements: Medical Research Council Dyspnea Scale for dyspnea, Minnesota Heart Failure Life Questionnaire for quality of life, Fatigue Severity Scale for fatigue. In addition, Mini-Mental State Examination (MMSE) was used to assess for any cognitive mental status in patients (11). All patients were classified by New York Heart Association (NYHA) functional classification (12). All measurements for outcome parameters were performed by the same researcher.

***Outcome Measures**:*

Dyspnea:

Dyspnea was measured using Medical Research Council Dyspnea Scale (MmRC). The MmRC dyspnea scale is based on various physical activities that cause shortness of breath. It is a 0-4 point scale in which one of the 5 statements that best describes the dyspnea levels of the patients is selected. Higher score in MmRC represents the more severe perceived levels of dyspnea. While "0 points" is defined as no dyspnea, "4 points" is defined as very severe dyspnea during basic activities of daily life (13).

Quality of Life:

The disease-specific health-related quality of life was evaluated using The Minnesota Living with Heart Failure Questionnaire (MLHFQ). The MLHFQ scale represents a self-administered, 21-item, 6-point Likert scored, patient-based and disease-specific questionnaire for patients with heart failure.

According to this scale, total score could range from 0 to 105 points, with lower scores for total score, physical and emotional domains present better health-related quality of life. (14).

Fatigue:

Fatigue level was determined by using Fatigue Severity Scale (FSS). This scale can be given as one of the best example of the unidimensional scales in the field. The scale, which was introduced in 1989 by Krupp, is a nine-item self-administered questionnaire that asks the patients to rate each statement according to their level of agreement. (15). Each item can range between 0 (strongly disagree) and 7 (strongly agree).

***2.4. Statistical Analyses**:*

All statistical analyses were performed using IBM SPSS version 11.5 software (IBM Corporation, USA), with a p value of <0.05 considered statistically significant. All numerical data were expressed as mean ± standard deviation. Data were summarized using tables, frequency, percentage, mean, standard deviation, maximum and minimum value.

Shapiro-Wilk Test were used to analyze the normality. Non-parametric tests were used in the study because of sample numbers and abnormal distribution. In order to examine associations between quantitative variables including dyspnea, quality of life, and fatigue, Spearmen's correlation coefficient (r), non-parametric test, was used. There were five different subgroups to examine the strength of relationship between variables according to Guilford's criteria (14). They were very high (r: 0.81–1.00), high (r: 0.61–0.80), moderate (r: 0.41–0.60), low (r: 0.21–0.40), and very low (r: 0.00–0.20).

In addition, Mann-Whitney U test was used to compare the study variables in both two different groups (patients with and without a pacemaker).

3. Results:

3.1. Descriptive Statistics:

This controlled clinical trial enrolled 20 patients of both genders aged between 39 and 73 years in Çorum-Hitit University Erol Olçok Training and Research Hospital, Cardiac Rehabilitation Unit.

Although 23 patients were screened, a total of 20 patients diagnosed with heart failure participated in the study due to the inclusion criteria. The patients were almost male (n=19; 95.0%). 10 out of 20 patients had a pacemaker. Of the patients with pacemakers, 8 were implantable cardioverter defibrillators (ICD), while 2 were patients with cardiac resynchronization therapy (CRT). The flow chart of the study protocol and exclusion diagram for the participants are presented at Figure 1.

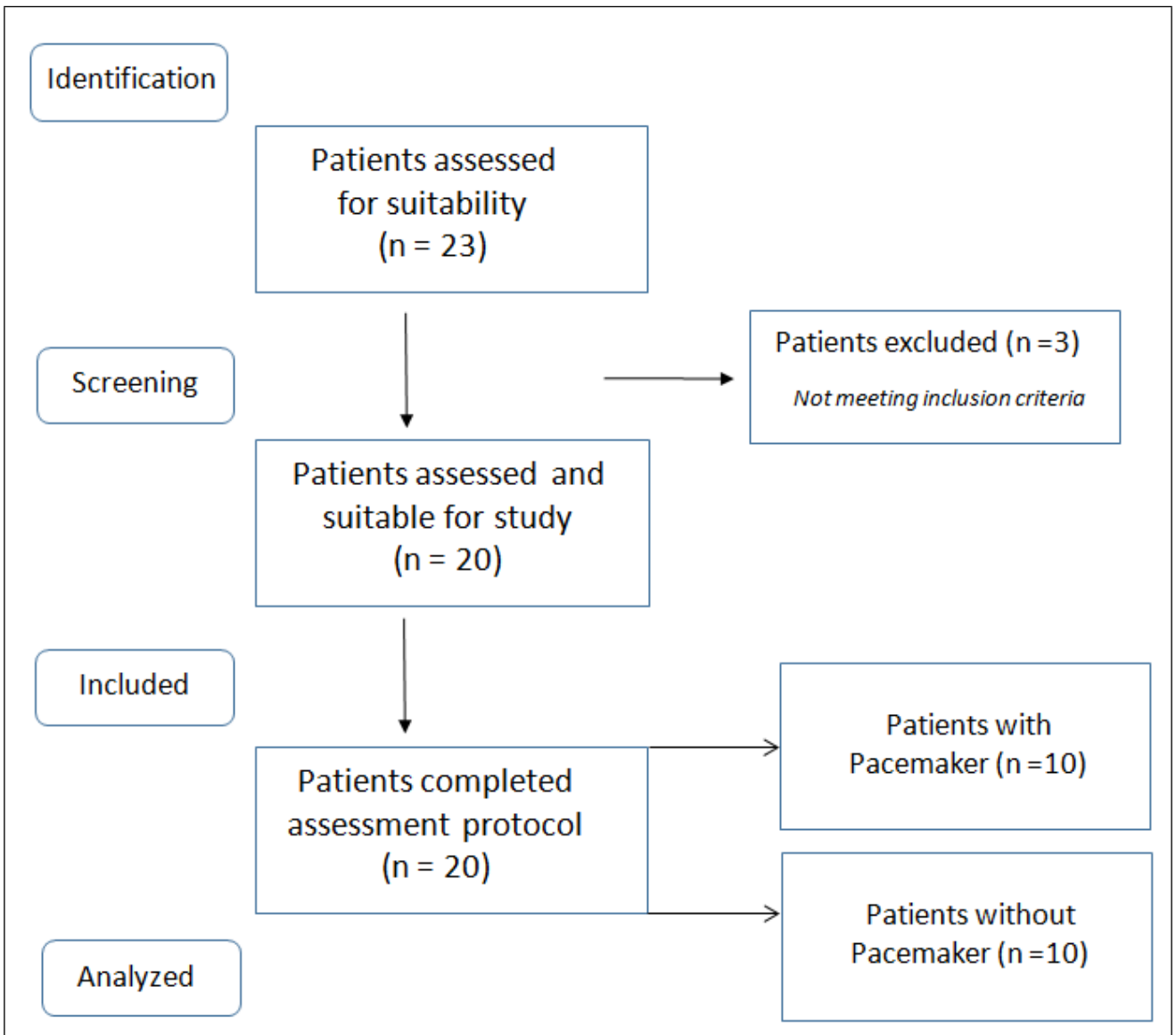

Figure 1: Flow chart of the study protocol and exclusion diagram for the participants

Table 1. Demographic characteristics of both groups

	Group I (With Pacemaker) Mean±SD	Group II (Without Pacemaker) Mean±SD	p-value
Age (year)	61.90±8.49	59.30±10.68	0.554
Body Height (cm)	167.90±4.90	167.50±5.33	0.863
Body Weight (kg)	83.59±12.98	80.33±11.42	0.559
BMI (kg/m^2)	29.73±4.73	28.70±4.02	0.609
Gender (F/M)	0 / 10	1 / 9	-

SD: Standard Deviation, BMI: Body Mass Index, F: Female, M: Male

Table 2. Clinical characteristics and comorbidities of patients in both groups

		Group I (With Pacemaker) Mean±SD	Group II (Without Pacemaker) Mean±SD
Education Level	Primary School	4	7
	High School	5	2
	University	1	1
Smoking	Yes	2	1
	No	8	9
Alcohol	Yes	3	2
	No	7	8
Psychological Issue	Yes	6	7
	No	4	3
Mini Mental	-	27.00±1.56	27.40±1.95
Pacemaker Type	ICD (n - %)	8 (80%)	-
	CRT (n - %)	2 (20%)	
Ejection Fraction (LVEF %)	-	31.00±8.09	36.00±3.16
NYHA	Class 2	6 (60%)	9 (90%)
	Class 3	4 (40%)	1 (10%)

SD: Standard Deviation, NYHA: New York Health Association

Demographic and clinical characteristics are shown in Table 1 and Table 2, respectively. The mean age of the patients with and without pacemaker was 61.90±8.49, 59.30±10.68, respectively. The mean of Ejection fraction of patients with and without pacemaker was 31.00±8.09 and 36.00±3.16, respectively. While 6 of the patients with pacemaker were Class 2 according to the NYHA, 9 of the patients without pacemaker were Class 2.

3.2. Examining the Relationship Between Clinical Evaluation Parameters:

Table 3 presents values of dyspnea, quality of life and fatigue for all patients with heart failure. There was statistically correlation between dyspnea and fatigue (r=0.479, p=0.033) in all patients participated in the study.

No significant correlation was found between dyspnea and quality of life (r=0.422, p=0.064) in all patients participated in the study. In addition, it was found that fatigue was not correlated to quality of life (r=0.262, p=0.265) for 20 patients with heart failure in the study, as well (Table 3).

3.3. Examining the Difference of Clinical Evaluation Parameters Between Patients with and without Pacemaker:

There was no significant difference in terms of dyspnea, quality of life and fatigue levels in heart failure patients with and without pacemaker (p>0.05) (Table 4).

Table 3. The correlation between data of dyspnea, quality of life and fatigue for all patients with heart failure

		Quality of Life (Minnesota)	Fatigue (FSS)
Dyspnea (MmRC)	r	0.422	0.479
	p	0.064	**0.033***
	n	20	20
Fatigue (FSS)	r	0.262	
	p	0.265	-
	n	20	

Abbreviations: *MmRC, Medical Research Council Dyspnea Scale; FSS: Fatigue Severity Scale; Minnesota: The Minnesota Living with Heart Failure Questionnaire*
**Spearmen Correlation Test*
**p<0.05*

Table 4. The differences between both groups in terms of dyspnea, quality of life and fatigue

	Group I (With Pacemaker) Mean±SD	**Group II (Without Pacemaker) Mean±SD**	**Z**	**p-value**
Dyspnea (MmRC)	1.60±1.17	1.80±1.39	-0.312	0.755
Quality of Life (Minnesota)	38.10±21.99	39.90±18.26	-0.303	0.762
Fatigue (FSS)	3.34±1.49	3.78±1.11	-0.871	0.384

Abbreviations: *MmRC: Medical Research Council Dyspnea Scale; FSS: Fatigue Severity Scale; Minnesota: The Minnesota Living with Heart Failure Questionnaire*
**Mann Whitney U Test*
**p<0.05*

4. Discussion:

Dyspnea, quality of life, fatigue are among the most common clinical findings in patients with heart failure. However, there are a limited number of studies investigating the relationship between these parameters. No study has been encountered in the literature, which examines patient-specific parameters and compares the differences according to the use of pacemakers in patients with a diagnosis of heart failure. To our knowledge, this is the first study to compare key clinical findings such as dyspnea, quality of life, and fatigue in patients with heart failure with and without a pacemaker. In addition to this purpose, we also investigated whether the level of dyspnea is associated with quality of life and fatigue levels in patients with heart failure.

There is an increase in chronic diseases with the aging population and the change in lifestyle in the world. Among these chronic diseases, cardiovascular diseases play a serious role (16). Nowadays, life expectancy can be prolonged by preventing deaths due to myocardial infarction, cardiovascular disease, heart valve diseases, hypertension and diabetes with advanced and modern treatment methods. However, with the aging of populations, there is a significant increase in the rate of heart failure. Nearly half of heart failure patients consist of individuals over the age of sixty (17). A total of 20 patients with a mean age of 60.60±9.48 years participated in our study. Of the patients, 19 (95%) were male and 1 (5%) was female. Lam et al. (2018) and Sciomer et al. (2020) examined in terms of gender, it was found that preserved ejection fraction as a type of heart failure was more common in female patients, and heart failure type with low ejection fraction was more common in male patients (18, 19). Consistent with the literature, the rate of female patients with heart failure was also less in our study, and the gender distribution of heart failure patients with low ejection fraction included in our study was predominantly male.

In our study, there were 15 people (75%) who were class II and 5 people (25%) who were class III according to the New York Heart Association classification (NYHA), and the mean EF of these 20 patients was 33.50±6.50%. It is stated that two parameters frequently used in patients with heart failure according to the criteria for inclusion in clinical trials in the literature are NYHA classification and left ventricular ejection fraction (20). NYHA Class II and III heart failure patients were included in our study, which is similar to the literature. In addition, when the samples of the studies were examined, it was seen that the number of Class I heart failure patients included in the study and the number of studies that included Class I patients were relatively low (21-23). This showed us that the clinical incidence of Class I patients is low due to the absence/less complaints of fatigue and dyspnea during daily activities compared to other groups. The clinical incidence of Class I heart failure patients is therefore low, as failure patients generally seek treatment as a result of shortness of breath and fatigue during exertion.

One of the main findings of our study is that the level of dyspnea is associated with fatigue in patients with heart failure. Fatigue is one of the main symptoms of heart failure (23). In a study, 59% of patients with heart failure reported moderate to severe fatigue (24). One of the main clinical features of heart failure is limited exercise tolerance. Patients with heart failure often experience dyspnea and fatigue at relatively low workloads and reduced physical work capacity (25). Like dyspnea, fatigue reduces daily performance and quality of life by limiting self-care in heart failure patients (26). Ramasamy et al. showed that there is a positive and moderate relationship between dyspnea and fatigue levels in heart failure patients (27). In the literature, no other study examining the relationship between the level of dyspnea and fatigue in heart failure patients has been encountered. Parallel to the results of our study, there are studies conducted in other disease groups showing that dyspnea and fatigue levels affect each other. One of these, in the study of Tütün-Yümin et al. in coronary artery patients, it was found that dyspnea and fatigue levels were correlated with each other (28). In the light of this information, the positive and moderate relationship between dyspnea and fatigue levels in patients with heart failure in our study is an expected result and is consistent with limited studies in the literature.

In patients with systolic heart failure, the ejection fraction of the heart is reduced. The main problems seen in clinically stable patients with heart failure are decreased exercise tolerance and worsened quality of life (3). Depending on the decrease in exercise tolerance, the effects of physical inactivity and sedentary life may be observed. In addition, inspiratory muscle strength and endurance are decreased in heart failure patients, and as this weakness increases, patients also experience dyspnea. As respiratory muscle weakness progresses, this symptom begins to be seen even at rest in daily life (29). In a study conducted with heart failure patients, the

incidence of severe dyspnea was reported as 69% (24). Dyspnea is a distinctive symptom of chronic heart failure and significantly impairs functional capacity and quality of life, regardless of the severity of the disease (30). As far as we know, there is no study in the literature examining the relationship between quality of life and dyspnea in patients with heart failure, whereas a study by Borges et al found a negative correlation between quality of life and functional classification in patients with pacemaker (7). On the other hand, in our study, no correlation was found between dyspnea level and quality of life in patients with heart failure. We consider this finding as an unexpected result compared to the literature. We attribute this to the less number of patients included in our study as the main reason for this findings. Because the correlation value between dyspnea level and quality of life is 0.064 and is very close to the level of significance.

Another important finding of our study is that the use of a pacemaker in patients with heart failure did not statistically affect the level of dyspnea, quality of life and fatigue levels. We attribute the fact that dyspnea, quality of life and fatigue parameters do not differ in heart failure patients with and without pacemakers, due to the functional classification of heart failure, the small number of samples and the variability of the duration of using pacemakers. Because, it has been revealed that functional classification in addition to age affects the level of quality of life and that functional classification scales are one of the important assessment tools in patients with pacemaker (7). In a study by Barros et al. examining the quality of life of patients after pacemaker implantation, it was shown that men had a better quality of life than women. In the same study, it was emphasized that age, gender, and duration of pacemaker implantation affect quality of life (8). In our study, patients with and without a pacemaker showed a similar distribution in terms of age and gender. However, in terms of functional classification, 40% of patients with pacemakers were in Class 3, while only 10% of patients without a pacemaker were in Class 3.

In our study, although there was no statistically significant difference between patients with and without a pacemaker in terms of basic clinical findings, it was observed that patients with pacemakers had relatively kinesiophobia and were more cautious while performing certain movements in terms of clinical observation. For this reason, it was thought that partial attention should be paid in determining the rehabilitation program in heart failure patients with pacemakers compared to those without pacemakers.

4.1. Limitations:

Our study has several limitations. The main limitation of our study is the small sample size. The main reason for this is that the case inclusion process of our study coincided with the peak period of the pandemic and the highest risk of transmission. Another important limitation is that the sample is not a homogeneous group in terms of time and type of pacemaker implantation, gender, and distribution of functional classification.

The strengths of our study are that, as far as we know, it is the first study to compare the basic clinical findings of individuals with and without a pacemaker in heart failure patients, and that it sets an example for future studies. It is also important that patients with heart failure have an equal distribution in terms of age, gender and BMI in both groups. In addition, we used disease-specific questionnaires, such as the Minnesota Living with Heart Failure Questionnaire, whenever possible, to monitor patients' clinical conditions such as dyspnea, fatigue, and quality of life.

5. Conclusion:

According to the results of our study, it was found that using a pacemaker in heart failure patients had no effect on dyspnea, quality of life and fatigue levels. In addition, it was found that the level of dyspnea in heart failure patients was associated with the level of fatigue, but not with the level of quality of life.

Declarations:

Sources of Support

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Conflict of Interest

Authors declare that there is no conflict of interest.

Author Contributions

All authors have read and approved the paper, they have met the criteria for authorship.

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Ethics approval

All the procedures performed in the studies involving human participants were in accordance with the ethical standards of the Clinical Research Ethics Committee of the Faculty of Medicine, Hitit University. All subjects were informed about the study prior to their participation and written informed consent was obtained from each subject.

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