

Vitamin and Micronutrient Deficiency and Peripheral Polyneuropathy Following Intra-gastric Balloon Technique Used For Obese People: Preliminary Study

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ABSTRACT

Aim: Complications from malnourishment when treating obesity are common, especially following bariatric surgery. Peripheral polyneuropathy due to vitamin and micronutrient deficiency is the most commonly encountered complication of bariatric surgery. The objective of this study was to investigate if this technique may lead to peripheral polyneuropathy due to vitamin B1, B2, B6, B12, folate, zinc, iron, and copper deficiency.

Material and Methods: In this study nine patients whose obesity was treated with the Spatz3 intra-gastric balloon technique were investigated for vitamin and micronutrient deficiencies and any consequent peripheral polyneuropathy. Vitamin B1, B2, B6, B12, zinc, copper, iron and folate were measured. Electromyography (EMG) was used to evaluate peripheral polyneuropathy, based on the Toronto Clinical Neuropathy Score (TCNS).

Results: None of the patients had vitamin B1, B2 or B6 deficiency, whereas one patient (11%) had vitamin B12 and another one patient (11%) had folate deficiency. Copper deficiency was seen in five patients (55.6%), iron deficiency was seen in seven patients (77.8%) and zinc deficiency was seen in eight patients (88.9%). Two patients (22.2%) had abnormal sensory nerve velocity and were diagnosed with polyneuropathy. However, these two had normal concentrations of B vitamins and folate but were deficient for copper, iron, and zinc.

Conclusion: The intra-gastric balloon technique does not appear to be associated with peripheral polyneuropathy due to vitamin B deficiency. In our opinion it is a safe approach for obesity treatment in terms of the risk of peripheral polyneuropathy due to vitamin B deficiency.

Keywords: Obesity, Gastric balloon, Malnourishment, Vitamin B deficiency, Polyneuropathy

Obez Kişilerde Kullanılan İntra-gastrik Balon Tekniği Sonrası Vitamin ve Mikrobesein Eksikliği ve Periferik Polinöropati: Ön Çalışma

ÖZ

Amaç: Obezite tedavisi sırasında yetersiz beslenmeden kaynaklanan komplikasyonlar, özellikle bariatrik cerrahiyi takiben yaygındır. Vitamin ve mikrobesein eksikliğine bağlı periferik polinöropati, obezite cerrahisinin en sık karşılaşılan komplikasyonudur. Bu çalışmanın amacı, bu tekniğin vitamin B1, B2, B6, B12, folat, çinko, demir ve bakır eksikliğine bağlı periferik polinöropatiye yol açıp açmayacağını araştırmaktır.

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Gereç ve Yöntemler: Bu çalışmada, obezitesi Spatz3 intragastrik balon tekniği ile tedavi edilen dokuz hasta, vitamin ve mikrobesein eksiklikleri ve buna bağlı periferik polinöropati açısından araştırıldı. Vitamin B1, B2, B6, B12, çinko, bakır, demir ve folat değerleri ölçüldü. Toronto Klinik Nöropati Skoru (TCNS)'na göre periferik polinöropatiyi değerlendirmek için elektromiyografi (EMG) kullanıldı.

Bulgular: Hastaların hiçbirinde vitamin B1, B2 veya B6 eksikliği yoktu, bir hastada (%11) vitamin B12 ve başka bir hastada (%11) folat eksikliği vardı. Beş hastada (%55.6) bakır eksikliği, yedi hastada (%77.8) demir eksikliği ve sekiz hastada (%88.9) çinko eksikliği görüldü. İki hastada (%22.2) anormal duyu siniri hızı vardı ve polinöropati tanısı konuldu. Bununla birlikte bu ikisinin B vitamini ve folat konsantrasyonları normaldi ancak bakır, demir ve çinko eksikliği vardı.

Sonuç: İnteragastrik balon tekniği, B vitamini eksikliğinden kaynaklanan periferik polinöropati ile ilişkili görünmemektedir. B vitamini eksikliğine bağlı periferik polinöropati riski açısından obezite tedavisi için güvenli bir yaklaşım olduğunu düşünüyoruz.

Anahtar Sözcükler: Obezite, Mide balonu, Yetersiz beslenme, B vitamini eksikliği, Polinöropati

INTRODUCTION

Obesity is an abnormal or excessive amount of fat accumulation, according to the World Health Organization (WHO)'s definition. Obesity affects more than 400 million adults worldwide and approximately 78 million adults in the United States of America (USA) (1). In 2015 among all the Organization for Economic Co-operation and Development (OECD) Countries, 19.5% of the adult population was obese (22.3% in Turkey) and this figure is expected to rise in the coming years (2).

Bariatric surgery is currently the only modality that provides a significant, sustained weight loss for morbidly obese patients, with resultant improvement in obesity-related comorbidities (3, 4). The most important long-term adverse effects are deficiencies of vitamins and micronutrients, especially after diversionary malabsorptive operations. Gastric-restrictive operations have mostly caused iron deficiency in menstruating women, owing to reduced intake of meat. Also, excessive vomiting can cause thiamine deficiency, resulting in neuropathy (5, 6).

Due to the high risk of complications, safer and effective treatments have been developed. There are several different techniques based on the same principle, and intragastric balloon technique is one of the most effective ones (7). Intragastric balloon technique is a minimally invasive and temporary method of inducing weight loss. It relies upon a soft, saline-filled balloon being placed in the stomach to promote the feeling of satiety and restrict food ingestion. Another possible mechanism of action that may also contribute to weight loss is by delaying gastric emptying (8, 9). Any balloon with a volume of 400 mL or greater can induce satiety (10). There are six different procedures available for the intragastric balloon technique. These are; Fluid-supplied Orbera (Apollo Endosurgery, Texas, USA), Spatz Adjustable Balloon system (Spatz FGIA, New York, USA), ReShape DualBalloon System (Reshape Medical, San Clemente, CA, USA), The Eclipse (Allurion Technologies,

Massachusetts, USA), Air-supplied Obalon (Obalon Therapeutics, California, USA) and Heliosphere BAG (Sante Actions, Vienna, France) (11). The intragastric balloon technique may play diverse roles in obesity treatment; as a preliminary therapy for bariatric surgery, a metabolic therapy, or a primary therapy for obesity for the patients who are contraindicated for the surgical procedures (12).

Micronutrient deficiencies are major concerns after bariatric surgeries (13). Evidence shows that micronutrient deficiencies such as iron, vitamin B6 and vitamin B12 occur among obese individuals after surgeries worldwide (14, 15).

Neurological complications may result from these vitamin and micronutrient deficiencies. Neurologic complications occur in the months and years succeeding the surgery in 5-16% of all patients undergoing any type of bariatric surgery. More than half (54%) of these neurologic complications are peripheral neuropathies, 9% comprise one or more cranial neuropathies, 2% are myelopathies and 35% are encephalopathies (16, 17). Carpal Tunnel Syndrome is seen in 7% of patients who underwent gastric bypass surgery (18, 19). Deficiency of vitamin B1 may cause both acute and chronic complications such as Wernicke's encephalopathy (20). Vitamin B2 deficiency is associated with burning feet syndrome (21). Deficiency of vitamin B6 may cause peripheral neuropathies, optical neuropathy and myopathies (22).

The aim of this study was to identify if the intragastric balloon technique, which is used as an alternative in obesity treatment, may cause peripheral polyneuropathy due to deficiency of vitamins and micronutrients.

MATERIAL and METHODS

Study Design

Patients were analyzed between November 2017 and March 2020 retrospectively. Morbidly obese patients who were treated with the Spatz3 intragastric balloon (Spatz FGIA, New York, USA) technique at Kocaeli University School

of Medicine, Bariatric Unit of the Department of General Surgery were included in the study.

Ethical approval was received for this study from The Ethical Committee of the Research, Health & Science Center-Kocaeli University with 18.10.2017/KOGOEK01.2 approval number. Written informed consent was obtained from patients prior to recruitment to the study.

Inclusion and Exclusion Criteria

Patients were eligible for the study if they had been treated with the Spatz3 Adjustable Intra-gastric Balloon System® (Spatz FGIA, New York, USA) for morbid obesity and the balloon was still in situ., were aged between 18 – 60 years and had body mass index (BMI) over 35. Only patients who had the intra-gastric balloon for more than six months were included. Patients having the balloon for lesser than six months or who had finished the treatment period and balloons had been taken out were excluded. All patients had a multidisciplinary obesity team examination- including chest, cardiac and endocrinological tests before the procedure. No supplementary multivitamins were given to those patients during the study period. Exclusion criteria also included any patients having type 2 diabetes mellitus, any neurological disorders detected through neurological physical examination or any vitamin and micronutrient deficiency prior to intra-gastric balloon insertion.

Outcomes/Endpoints

Patients taking part in the study were investigated for vitamin and micronutrient deficiencies and peripheral polyneuropathy.

Objectives

The main objective was to determine if vitamin and micronutrient deficiency occurred during obesity treatment with the intra-gastric balloon technique. In addition, as a secondary objective, the presence of peripheral polyneuropathy, possibly due to vitamin deficiency was assessed.

Data

Patients' demographic and clinical data were retrieved from their hospital files in Nucleus Medical Information System- XCE (Monad Software and Consulting, Çankaya, Ankara). Demographic data included gender, age and BMI before intra-gastric balloon insertion, and at the time of data collection were recorded.

Blood Collection/Analysis

Blood samples were taken after overnight fasting in the Department of General Surgery, Kocaeli University Hospital. Blood levels of vitamins B1, B2, B6, B12 and

folate, also copper, iron, zinc were measured. Total blood Ethylenediaminetetraacetic acid (EDTA) samples were obtained for vitamin B1 and B2 assays. All other vitamins and elements were assessed in serum samples. Serum samples were prepared immediately after drawing by centrifugation at 3500 rpm for 15 minutes and then transferred to the laboratory. Vitamin B12 and folate were both measured using the chemiluminescent enzyme immunoassay method. High-performance liquid chromatography method was used for analysis for vitamins B1, B2 and B6. Copper, iron, and zinc were measured with using an inductively coupled plasma (ICP) Optical Emission Spectrometry analyser.

Electromyography (EMG)

Polyneuropathy assessment was based on the Toronto Clinical Neuropathy Score (TCNS). Polyneuropathy grade results were scored out of 36. Findings were accepted as polyneuropathy if TCNS score was 7 or above. Quantitative sensory testing findings were exempted from this study. The Nicolet® EDX Synergy System (Natus Neurology Inc, Middleton, Wisconsin, USA) was used for EMG. The right extremities of all patients were used because all of their dominant sides were the right. During the EMG examination; right ulnar nerve to the fifth digit (antidromic) velocity, right sural nerve to ankle (calf) velocity, right ulnar nerve to abductor digiti minimi muscle (ADMM) velocity, right peroneal nerve to extensor digitorum brevis muscle (EDBM) velocity were recorded as meter per second (m/s). Also, F minimum waves of the right median nerve to abductor pollicis brevis muscle (APBM) and right tibial nerve to abductor hallucis muscle (AHM) were recorded in milliseconds. Patients' extremity temperature, lower and upper extremities' sensory and motor nerve conductions were examined carefully.

Intra-gastric Balloon Technique

The Spatz3 Adjustable Balloon System (Spatz FGIA, New York, USA) was used. Balloon volume may range from 400 -700 milliliters. The maximum placement period for the Spatz3 Adjustable Balloon System (Spatz FGIA, New York, USA) is 12 months. All patients were treated endoscopically after the approval of the multidisciplinary obesity treatment team which included the surgeon, nutritionist and endocrinologist. All patients were also requested to regularly report back for check-up after the procedure by the obesity treatment team.

Statistical Analysis

Statistical analysis was performed using IBM-SPSS 20 (IBM Inc, Chicago, Ill, USA). Kolmogorov-Smirnov Test was used to compare normally distributed continuous variables.

Median (25th – 75th Percentiles) were used for non-normally distributed numeric variables and categorically distributed variables are shown as Frequency (Percentage).

RESULTS

Over a period of three years, 12 patients have undergone an intragastric balloon technique. Nine patients (8 female) in whom the balloon was still in situ and who also met the other inclusion criteria for the study consented to participate. Eight of the subjects (89%) were female. Three patients were excluded from the study because the intragastric balloon had been removed before the study period. The pre-operative median BMI was 41.80. Median BMI at data collection was 35.29. The time elapsed from balloon emplacement in patients to the time of data collection was 11.3 months. Demographic data are shown in Table 1. There were no patients with vitamin B1, B2 or B6 deficiency. Vitamin B12 and folate deficiencies were seen in one patient each (11%). Copper (Cu), iron (Fe) and zinc (Zn) deficiency was investigated. Copper deficiency was seen in five patients (55.6%), iron deficiency was seen in seven patients (77.8%), and zinc deficiency was seen in eight patients (88.9%). All findings related to vitamins and micronutrients are shown in Table 2.

Nerve conduction studies showed two patients (22.2%) appeared to have weakened nerve velocity at the right ulnar nerve to the fifth digit (antidromic). The sural nerve to ankle (calf) velocity was found to be abnormal in two patients (23.2%). At the motor nerves, no patient presented with the abnormal right ulnar nerve to ADMN or the right peroneal nerve to EDBM. With regard to the results of F minimum waves, neither the right median nerve to APBM nor the right tibial nerve to AHM were found to be in the pathological range in any of the patients. Nerve conduction data are shown in Table 2.

DISCUSSION

EMG results show that two patients (22.2%) were diagnosed with polyneuropathy. Thus seven patients (78%) had no evidence of polyneuropathy and had normal results. The two patients who had polyneuropathy indicated by abnormal EMG findings were investigated for vitamin and micronutrient concentrations and their results are shown in Table 3. Both were found to be deficient for copper and zinc. In addition one suffered from iron deficiency and the other from vitamin B12 deficiency.

According to WHO reports, more than 1.9 billion adults aged 18 years and older are overweight and of these, over 650 million adults are obese (23). Bariatric surgery is an effective procedure for weight loss in morbidly obese

Table 1: Description of study patients.

Parameters	Findings (n = 9)
Age, year [Median (IQR 25 – 75)]	40 (36.5 – 54.5)
Pre-operative BMI, kg/m ² [Median (IQR 25 – 75)]	41.8 (39.5 – 45.0)
Pre-operative weight, kg [Median (IQR 25 – 75)]	120 (95 – 127)
Weight at blood collection, kg [Median (IQR 25 – 75)]	102 (75 – 111)
BMI at blood collection, kg [Median (IQR 25 – 75)]	35.3 (31.2 – 38.6)
Sex,	
Female [n (%)]	8 (89)
Male [n (%)]	1 (11)
Elapsed time since balloon emplacement, months [Median (IQR 25 – 75)]	11.3 (9 – 14)

IQR: Interquartile Range, **BMI:** Body mass index, **kg:** kilograms

patients, refractory to diet and/or exercise programs. However neurological complications have been reported to be associated with bariatric surgery. There are a number of neurological complications that can result from bariatric surgery, with most of them being irreversible (17, 24). Neurological complications can involve the entire nervous system ranging from diffuse encephalopathy to peripheral neuropathy, to myopathy. Among the neurological complications seen after bariatric surgery, peripheral neuropathies are the most commonly reported and may affect up to 16% of operated patients (18).

Malnutrition is not uncommon for morbidly obese patients prior to bariatric surgery. Twenty-nine percent of patients were thiamine-deficient among 379 consecutive patients undergoing bariatric surgery, as reported by Flancbaum (25). The most common nutrient deficiencies following bariatric surgery are deficiencies of thiamine, vitamin B12 and copper (26). Bariatric procedures cause or worsen malnutrition by restriction of intake or combined restriction of intake and impaired absorption. Peripheral neurological complications after bariatric surgery are probably related to multiple nutritional deficiencies but especially to vitamin and micronutrient deficiency.

The most common vitamin deficiency seen after bariatric surgery is thiamin deficiency. In this study, the thiamin levels of patients undergoing intragastric balloon, rather than bariatric surgery were monitored. Since thiamine levels of all patients were found in the normal range, it suggests that the intragastric balloon technique does not cause Korsakoff syndrome or other chronic complications resulting from thiamine deficiency.

In this study none of the patients with peripheral polyneuropathy had vitamin B1 deficiency. Neither were they deficient in vitamin B2 or B6, regardless of whether they had peripheral polyneuropathy or not. This suggests that the intragastric balloon technique does not cause any peripheral polyneuropathy due to B vitamin deficiency.

Table 2: Vitamins and micronutrients status and nerve conduction study of patients.

Vitamins and Micronutrients		Values (n=9)
Vitamin B1 [Thiamine] ($\mu\text{g/L}$)	Reference Value	25 – 75
	Median (IQR 25 – 75)	49 (34.5 – 53.5)
	Deficiency [n (%)]	0 (0)
Vitamin B2 [Flavin Adenine Dinucleotide (FAD)] ($\mu\text{g/L}$)	Reference Value	137 – 370
	Median (IQR 25 – 75)	234 (201.5 – 262.5)
	Deficiency [n (%)]	0 (0)
Vitamin B6 [Pyridoxal Phosphate (PLP)] ($\mu\text{g/L}$)	Reference Value	5 – 50
	Median (IQR 25 – 75)	13 (10 – 19)
	Deficiency [n (%)]	0 (0)
Vitamin B12 (ng/mL)	Reference Value	145 – 505
	Median (IQR 25 – 75)	214 (174.0 – 251.5)
	Deficiency [n (%)]	1 (11)
Folate (ng/mL)	Reference Value	3.1 – 19.9
	Median (IQR 25 – 75)	7 (6 – 11)
	Deficiency [n (%)]	1 (11)
Copper (mg/L)	Reference Value	0.70 – 1.40
	Median (IQR 25 – 75)	0.69 (0.57 – 0.77)
	Deficiency [n (%)]	5 (55.6)
Iron (mg/L)	Reference Value	0.8 – 1.8
	Median (IQR 25 – 75)	0,76 (0.50 – 0.84)
	Deficiency [n (%)]	7 (77.8)
Zinc (mg/L)	Reference Value	0.7 – 1.2
	Median (IQR 25 – 75)	0.5 (0.45 – 0.54)
	Deficiency [n (%)]	8 (88.9)
Nerve Data		
R Ulnar - Digit V (Antidromic) Velocity (m/s)	Reference Value	50
	Median (IQR 25 – 75)	53 (51.5 – 58.0)
	Slacked [n (%)]	2 (22.2)
R Sural - Ankle (Calf) Velocity (m/s)	Reference Value	40
	Median (IQR 25 – 75)	45 (39 – 51)
	Slacked [n (%)]	2 (22.2)
R Ulnar - ADM Velocity (m/s)	Reference Value	50
	Median (IQR 25 – 75)	61 (56.5 – 64.0)
	Slacked [n (%)]	0 (0)
R Peroneal - EDB Velocity (m/s)	Reference Value	40
	Median (IQR 25 – 75)	45 (43.5 – 53.5)
	Slacked [n (%)]	0 (0)
R Median - APB F min (ms)	Reference Value	32
	Median (IQR 25 – 75)	27 (24 – 30)
	Pathological [n (%)]	0 (0)
R Tibial - AH F min (ms)	Reference Value	56
	Median (IQR 25 – 75)	47 (43.0 – 54.5)
	Pathological [n (%)]	0 (0)

Deficiencies were defined based on the number of subjects below the lower limit of normal.

Neuropathy was defined based on the number of subjects above the low limit of normal values

R: Right; **IQR:** Interquartile Range, **m/s:** meters per second, **ms:** millisecond, **ADMM:** Abductor digiti minimi muscle, **EDBM:** Extensor digitorum brevis muscle, **APBM:** Abductor pollicis brevis muscle, **AHM:** Abductor hallucis muscle, **F min:** Minimum F waves

Table 3: Deficiencies and pathological findings in patients diagnosed with polyneuropathy.

	Age	Sex	Deficient Vitamins and Micronutrients	EMG Pathologies
Patient 1	65	F	Copper (Cu)	R Ulnar - Digit V (Antidromic) Velocity m/s
			Iron (Fe)	R Sural - Ankle (Calf) Velocity m/s
			Zinc (Zn)	
Patient 2	40	F	Vitamin B12	R Ulnar - Digit V (Antidromic) Velocity m/s
			Copper (Cu)	R Sural - Ankle (Calf) Velocity m/s
			Zinc (Zn)	

EMG: Electromyography, m/s: meters per second

One patient (11%) had folate deficiency with a measured concentration of 2,97 ng/mL which is just below our laboratory reference range of 3.1 – 19.9 ng/mL. This patient was not diagnosed with peripheral polyneuropathy. Another one patient (11%) was deficient in vitamin B12 with a concentration of 115 ng/mL (reference range 145 – 505 ng/mL). This patient was diagnosed with peripheral polyneuropathy. This subject also had copper and zinc deficiency. Of our nine subjects, five (55.6%) had low copper levels and this included both patients who were diagnosed with peripheral polyneuropathy. Eight patients (88.9%) had zinc deficiency, again including both patients diagnosed with peripheral polyneuropathy. Iron deficiency was present in seven (77.8%) which again included one of the patients diagnosed with peripheral polyneuropathy but, interestingly, not the other.

It is a known issue that comparisons between intragastric balloon and bariatric surgery can not be carried out. Because intragastric balloon technique is a transient procedure while surgical procedures are definitive procedures. The comparisons might be done if the balloons were left in place for many years paradoxically, like a bariatric operation, whether they would cause hypovitaminosis or not. Also weight loss between the two procedures are different, and therefore the consequent possible hypovitaminosis and/or micronutrient deficiency, is different. But in this experimental study we just tried to show the effect of intragastric balloon technique on peripheral neuropathy and vitamin and mineral deficiency as a separate treatment not as a comparison of surgical procedures.

The main limitation of this study is the small sample size making detailed statistical analysis of the outcome unreliable. However this study is the most comprehensive to date as a search for literature on the intragastric balloon technique in relation to neurological complications and peripheral polyneuropathy reveals only two other articles. One of these is a case report and the other article has only one intragastric balloon patient (20). We suggest that this study

is therefore timely and valuable although there is a need for larger sample-sized, prospective randomized studies of the association between intragastric balloon placement and neuropathies in the treatment of obese patients. In this preliminary study, we realized that we should examine the pre-procedural EMG findings in the next study.

Peripheral polyneuropathy is a significant complication resulting from vitamin and micronutrient deficiency, which has been reported to arise from bariatric surgery. It is unclear if the intragastric balloon technique, which appears to be an effective alternative for obesity treatment also induces peripheral polyneuropathy complications due to vitamin and micronutrient deficiency. There was no evidence that the intragastric balloon technique caused polyneuropathy due to vitamin B1, B2, B6, folate and B12 deficiency in this study. However the intragastric balloon technique appears to lead to micronutrient deficiencies including a high prevalence of zinc, iron, and copper deficiency. For this reason, it is suggested that routine micronutrient investigation and appropriate replacement are needed during intragastric balloon treatment.

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Conflicts of Interest

The authors declare that they have no conflict of interest.

Financial Disclosure

The authors declared that this study has received no financial support.

Ethical Approval

Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects" (amended in October 2013).

Ethical approval was received for this study from The Ethical Committee of the Research, Health & Science Center-Kocaeli University with 18.10.2017/KOGOEK01.2 approval number.

Peer Review Process

Extremely peer-reviewed and accepted.

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