EURASIAN JOURNAL OF EMERGENCY MEDICINE
Original Article
DOI: 10.4274/eajem.galenos.2024.47113
Eurasian J Emerg Med. 2024;23(4): 270-7

Factors Influencing Mortality in Patients with Pacemaker/ICD Dysfunction Presenting to Emergency Departments

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Abstract

Aim: Management of patients with heart failure and implanted cardioverter defibrillators (ICDs) is as important as ICD placement. Inappropriate shocks and factors affecting mortality are the factors determining management. Appropriate intervention and detection improve the quality of life of patients. We aimed to investigate the complaints, medication use, electrocardiography findings, symptoms, laboratory findings and body mass index affecting mortality in patients with pacemaker/ICD dysfunction who presented to the emergency department.

Materials and Methods: Our study is a single-center, prospective, observational cohort. It included patients aged 18 years and older with pacemakers of both genders who gave their consent between 09/01/2022 and 09/01/2023.

Results: Ninety-one patients were included. The mean age was 65.02±13.71 years and 61 (67.0%) were male. The most common diseases were hypertension (86.8%) and congestive heart failure (76.9%). The most commonly used drugs were beta blockers (70.3%) and antiplatelet agents (59.3%). ICD shock rates were higher in men and those with dyspnea did not experience inappropriate ICD shocks. There was a significant correlation between in-hospital mortality and systolic blood pressure (BP), diastolic BP, partial oxygen saturation (sPO_2) and potassium (K) levels.

Conclusion: We found that ICD shock rates were higher in men and in patients without diabetes mellitus. The incidence of infection due to pacemaker/ICD use was low. We found that ICD patients with low partial sPO_2 and hypotensive patients had a worse prognosis. We found that K levels above 4.65 mEq/L were associated with increased mortality.

Keywords: Body mass index, emergency department, implantable cardioverter defibrillators, pacemaker, pacemaker dysfunction.

Introduction

The use of pacemaker/implanted cardioverter defibrillator (ICD) implantation is on the rise due to increasing life expectancy and the prevalence of cardiovascular disease.

Recent technological advancements and studies have led to significant changes in medical practice. Pacemaker/ICD therapy has expanded to include the concept of "rhythm control for quality of life". The indications for pacemaker/ICD implantation have expanded, and the programable features have diversified. The accumulation of data from well-designed randomized clinical trials has ushered in an era in which patients can be offered the most appropriate treatment options (1,2).

Clinical trials have demonstrated that implantable cardioverter defibrillators are effective for preventing sudden death caused by ventricular arrhythmias in patients with left ventricular dysfunction (3-5).

However, the increasing use of implantable cardiac devices has led to a rise in complications, such as battery pocket infection, lead malfunction, improper positioning, or dislodgement (6).

As the number of patients receiving pacemakers/ICDs increases, the likelihood of emergency physicians encountering these patients also increases. The purpose of our study was to examine the presenting complaints, medication usage, electrocardiography findings, symptoms, laboratory results, body mass index (BMI), and conditions affecting mortality in pacemaker dysfunction among patients with pacemaker-implanted emergency department.

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Received: 05.09.2024
Accepted: 03.12.2024
Published: 19.12.2024

Cite this article as: Yolay İF, İşler Y, Kaya H, Yüksel M, Ay MO, Ocak U. Factors Influencing Mortality in Patients with Pacemaker/ICD Dysfunction Presenting to Emergency Departments. Eurasian J Emerg Med. 2024;23(4): 270-7.

Materials and Methods

This was a single-center prospective study approved by the Ethics Committee of Health Sciences University, Bursa Faculty of Medicine, Bursa High Specialty Training and Research Hospital (decision no.: 2011-KAEK-25, date: 24.08.2022).

The study included emergency department patients aged 18 years and older, of both sexes, who had pacemaker implants, consented to participate, and had fully accessible data. The patients were admitted to the Emergency Department of Bursa High Specialty Training and Research Hospital between 09.01.2022 and 09.01.2023. Patients aged below 18 years, pregnant women, those who did not provide informed consent, and those with incomplete study data were excluded from the study. The hospital automation system, patient examination cards, and routine blood parameters were used.

The study assessed the relationship between BMI and several factors, including age, sex, admission complaints, comorbidities, medication use, fever, blood pressure (BP), pulse, respiratory rate, saturation, electrocardiogram, physical examination findings, complete blood count, and biochemical tests. A data collection form was prepared for the patients included in the study to record their age, sex, height, and weight.

Statistical Analysis

The statistical analysis was performed using IBM SPSS Statistics for Windows (version 21.0. Descriptive statistics were presented as mean ± standard deviation (minimum-maximum), median and range, and/or interquartile range (IQR) for numerical variables. For categorical variables, the number and percentage (%) of cases were reported. The Kolmogorov-Smirnov test was used to determine the normal distribution of the data. Levene's test was used to assess the homogeneity of variances. The significance of differences between groups for continuous numerical variables was tested using the Student's t-test, where the assumptions of parametric test statistics were met.

Where the statistical assumptions of parametric tests were not met, differences between continuous numerical variables were assessed using the Mann-Whitney U test. For comparisons between three or more groups, we used either one-way ANOVA or the Kruskal-Wallis test. Pearson correlation analysis was used to assess the relationships between parametrically distributed data, whereas Spearman's rank correlation analysis was preferred for non-parametrically distributed data. To analyze the relationship between categorical variables, we used either the chi-square test or Fisher's exact test. We considered a significance level of $p<0.05$ to be statistically significant. Results were presented with a 95% confidence interval.

Results

A total of 91 patients were included. The mean age of the patients was 65.02±13.71 years and 61 (67.0%) patients were male. The most common presenting complaints were dyspnea (n=22, 24.2%) and ICD shock (n=16, 17.6%).

All patients had a history of comorbidities. The most common comorbidities were hypertension (HT) (n=79, 86.8%) and congestive heart failure (n=70, 76.9%). The most common medications were beta-blockers (n=64, 70.3%) and antiplatelets (n=54, 59.3%). The most commonly used pacemaker was DDD, which was implanted in 28 (30.8%) of the patients, while 73 (80.2%) had been implanted 5 years or more previously. Of the patients who presented to the emergency department, 51 (56.0%) were discharged and 20 (22.0%) were admitted to the coronary intensive care unit. In-hospital mortality occurred in 6 (15.8%) patients (Table 1).

Table 1. Clinical and demographic findings

Age (years)*		**65.02±13.71**
Gender#	Male	61 (67.0)
	Woman	30 (33.0)
Application complaints#	Dyspnea	22 (24.2)
	ICD shock	16 (17.6)
	Chest pain	12 (13.2)
	Palpitation	9 (9.9)
	Stinging in the chest	5 (5.5)
	Headache/dizziness	4 (4.4)
	Syncope	3 (3.3)
	Cough	3 (3.3)
	Speech disorder	2 (2.2)
	Leakage at the battery place	1 (1.1)
	Other	8 (8.8)
Additional diseases#	Hypertension	79 (86.6)
	Congestive heart failure	70 (76.9)
	Coronary artery disease	67 (73.6)
	Diabetes mellitus	40 (44.0)
	Chronic kidney failure/disease	17 (18.7)
	Chronic obstructive pulmonary disease	8 (8.8)
	Malignancy	3 (3.3)
	Asthma	1 (1.1)
	Other	17 (18.7)

Table 1. Continued		
Medical drugs used#	Beta blocker	64 (70.3)
	Antiplatelet	54 (59.3)
	Anticoagulant	47 (51.6)
	Calcium channel blocker	37 (40.7)
	Angiotensin-converting enzyme ınhibitors	35 (38.5)
	Angiotensin 2 receptor blocker	25 (27.5)
Pace-maker type#	DDD	28 (30.8)
	ICD	25 (27.5)
	CRT	21 (23.1)
	VVI	17 (18.7)
	Biventricular pace	1 (1.1)
	VDD	0 (0)
	5 Years and before	73 (80.2)
	6 Years and above	18 (19.8)
History of pace dysfunction	Yes	15 (16.5)
	No	76 (83.5)
	Discharge	51 (560)
Emergency department outcome	Intensive care hospitalization	20 (22.0)
	Service hospitalization	18 (19.8)
	Extinction Other	0 (0) 2 (2.2)
Hospital outcome#	Discharge Extinction	32 (84.2) 6 (15.8)
Diagnosis of cardiac pacemaker dysfunction		4 (4.4)
Total#		91 (100)

ICD: Implanted cardioverter defibrillator, DDD: Dual dual dual, CRT: Cardiac resynchronization therapy, VVI: Ventriculer ventriculer inhibition, VDD: Ventriculer dual dual

The mean BMI was 36.52±0.57, the mean pulse rate was 80 (IQR: 25-75: 72-100) beats/min, the mean SBP was 137 (IQR: 25-75: 122-160) mm/Hg, the mean implant duration was 2 (IQR: 25-75: 1-5) years, the mean hemoglobin level was 12.4±2.3 g/dL, and the mean troponin level was 174.07±1034.38 ng/L.

Chi-square/Fisher's exact analysis to determine the relationship between sex, presenting complaints, comorbidities, and medications with pacemaker dysfunction showed no statistical significance. Chi-square/Fisher's exact analysis to determine the relationship between emergency department and hospital outcomes with pacemaker dysfunction showed no statistical significance.

The ICD shock rate was significantly higher in men. However, the ICD did not shock any patient with shortness of breath ($p<0.05$) (Table 2).

In the analysis performed to determine the relationship between comorbidities and ICD shock, a significant relationship was found between diabetes mellitus (DM) and ICD shock ($p<0.05$). ICD shock rates were significantly higher in non-diabetic patients (Table 3).

The chi-square/Fisher's exact analysis performed to determine the relationship between patients' medications, emergency department, and hospital outcomes in patients with ICD shock showed no statistical significance.

Mann-Whitney U and Student t-tests, which were performed to determine the relationship between age, BMI, vital signs, duration of pacemaker implantation, and laboratory findings with pacemaker dysfunction, showed no statistical significance.

The Mann-Whitney U test and Student's t-test were performed to determine whether there was a difference between age, BMI, vital signs, pacemaker implantation time, and laboratory findings with ICD shock status of the patients. The age of the patients whose ICD was shocked was significantly different ($p<0.05$). The mean age of patients whose ICD was shocked was 57.38±15.01 years, whereas the mean age of patients who did not experience shock was 66.65±12.94 years, which was significantly different.

The Mann-Whitney U and Student's t-tests were performed to investigate whether there was a relationship between age, BMI, vital signs, duration of pacemaker implantation, laboratory findings, and in-hospital mortality in patients with pacemakers. Accordingly, systolic BP (SBP), dibutyl phthalate (DBP), oxygen saturation (sPO_2), and potassium levels were significantly different in patients with pacemakers who developed in-hospital mortality [($p<0.05$), ($p<0.05$), ($p<0.05$), ($p<0.05$), ($p<0.05$), ($p<0.05$)] (Table 4).

When the cut-off values for potassium in the diagnosis of in-hospital mortality in patients with pacemakers were 4.50, 4.65, and 4.85, the sensitivity and specificity values were as follows, respectively (83.3%, 59.4%; 66.7%, 78.1%; 66.7%, 81.3%) (Table 5).

Discussion

Despite increased life expectancy and technological advances, cardiovascular disease remains the leading cause of mortality and morbidity. Accordingly, the need for pacemaker/ICD use is increasing. The main findings of our study are as follows: (a) the incidence of infection associated with pacemaker/ICD use is low; (b) the rate of ICD shock is higher in men and in patients without a diagnosis of DM; (c) low partial sPO_2 and hypotension in patients with ICDs should be considered with regard to mortality; and (d) a potassium level above 4.65 mEq/L increases mortality.

In the study by Jacob et al. (7), the mean age of patients with inappropriate shock was 56.05±12.68 years, whereas the mean age of patients without inappropriate shock was 55.57±12.64 years. In our study, the mean age of patients who received shock was 57.38±15.01 years, whereas the mean age of patients who did not receive shock was 66.65±12.94 years, which was significantly different.

In the study by Tompkins et al. (8), male and female patients were analyzed to determine the incidence of inappropriate shocks and their effects on outcomes. The results showed that 13.5% of men and 9.2% of women received inappropriate shocks. This finding showed that the incidence of inappropriate shocks was lower in women. A study including data from 14 centers across 11 European countries found that ICD shock rates were higher in men (9). In our study, the ICD shock rates were 23% in men and 6.7 % in women.

In a study by Rautiio et al. (10), the need for ICD was higher in patients with DM. In a study by Junttila et al. (11), 28% of patients with ICD implantation had DM, and mortality was higher in patients with DM. In our study, ICD shock rates were higher in patients with HT than in those with DM. We believe that this result was obtained because only patients with ICD shock were included in the study.

The infection rates after permanent transvenous pacemaker implantation range from 0.03% to 7.9% in small studies (12). These rates range from 0.3% to 2.2% in multicentre registries (13-15). Infection can affect any part of the pacemaker system, but the most common cause is infection in the pacemaker pocket (16). In our study, we found one case of infection in the pacemaker pocket (1.1 %).

Low SBP is a well-known independent predictor of morbidity and mortality in patients with relatively reduced or preserved systolic HF. Studies have shown an association between low BP

Table 2. Analysis of variables with implanted cardioverter defibrillator shocking

Variables			ICD shock		Total	Fisher's exact test
			No	Yes		
Gender	Woman	n (%)	28 (93.3)	2 (6.7)	30 (100)	**p<0.05**
	Male	n (%)	47 (77.0)	14 (23.0)	61 (100)	
Chest pain	No	n (%)	63 (79.7)	16 (20.3)	79 (100)	p>0.05
	Yes	n (%)	12 (100)	0 (0)	12 (100)	
Palpitation	No	n (%)	66 (80.5)	16 (19.5)	82 (100)	p>0.05
	Yes	n (%)	9 (100)	0 (0)	9 (100)	
Dyspnea	No	n (%)	53 (76.8)	16 (23.2)	69 (100)	**p<0.05**
	Yes	n (%)	22 (100)	0 (0)	22 (100)	
Stinging in the chest	No	n (%)	70 (81.4)	16 (18.6)	86 (100)	p>0.05
	Yes	n (%)	5 (100)	0 (0)	5 (100)	
Syncope	No	n (%)	72 (81.8)	16 (18.2)	88 (100)	p>0.05
	Yes	n (%)	3 (100)	0 (0)	3 (100)	
Leakage at the battery place	No	n (%)	74 (82.2)	16 (17.8)	90 (100)	p>0.05
	Yes	n (%)	1 (100)	0 (0)	1 (100)	
Cough	No	n (%)	72 (81.8)	16 (18.2)	88 (100)	p>0.05
	Yes	n (%)	3 (100)	0 (0)	3 (100)	
Headache/dizziness	No	n (%)	71 (81.6)	16 (18.4)	87 (100)	p>0.05
	Yes	n (%)	4 (100)	0 (0)	4 (100)	
Dysarthria	No	n (%)	73 (82.0)	16 (18.0)	89 (100)	p>0.05
	Yes	n (%)	2 (100)	0 (0)	2 (100)	
Other	No	n (%)	67 (80.7)	16 (19.3)	83 (100)	p>0.05
	Yes	n (%)	8 (100)	0 (0)	8 (100)	
Total		n (%)	75 (82.4)	16 (17.6)	91 (100)	

ICD: Implanted cardioverter defibrillator

Table 3. Analysis of additional diseases with ICD shock

Variables			ICD Shock		Total	Fisher's exact test
			No	Yes		
Hypertension	No	n (%)	11 (91.7)	1 (8.3)	12 (100)	p>0.05
	Yes	n (%)	64 (81.0)	15 (19.0)	79 (100)	
Diabetes mellitus	No	n (%)	38 (74.5)	13 (25.5)	51 (100)	**p<0.05**
	Yes	n (%)	37 (92.5)	3 (7.5)	40 (100)	
Coronary artery disease	No	n (%)	18 (75.0)	6 (25.0)	24 (100)	p>0.05
	Yes	n (%)	57 (85.1)	10 (14.9)	67 (100)	
Congestive heart failure	No	n (%)	18 (85.7)	3 (14.3)	21 (100)	p>0.05
	Yes	n (%)	57 (81.4)	13 (18.6)	70 (100)	
Asthma	No	n (%)	74 (82.2)	16 (17.8)	90 (100)	p>0.05
	Yes	n (%)	1 (100)	0 (0)	1 (100)	
Chronic obstructive pulmonary disease	No	n (%)	68 (81.9)	15 (18.1)	83 (100)	p>0.05
	Yes	n (%)	7 (87.5)	1 (12.5)	8 (100)	
Chronic kidney failure/disease	No	n (%)	62 (83.8)	12 (16.2)	74 (100)	p>0.05
	Yes	n (%)	13 (76.5)	4 (23.5)	17 (100)	
Malignancy	No	n (%)	73 (83.0)	15 (17.0)	88 (100)	p>0.05
	Yes	n (%)	1 (66.7)	1 (33.3)	3 (100)	
Other	No	n (%)	60 (81.1)	14 (18.9)	74 (100)	p>0.05
	Yes	n (%)	15 (88.2)	2 (11.8)	17 (100)	
Total		n (%)	75 (82.4)	16 (17.6)	91 (100)	

ICD: Implanted cardioverter defibrillator

Table 4. Analysis of Variables with In-Hospital Mortality

Variables	In-Hospital Mortality	n	Value	p-value
Age	No	32	62.66±14.28	>0.05*
	Yes	6	71.50±8.80	
BMI	No	32	27.43±4.12	>0,05*
	Yes	6	27.99±5.09	
Implantationt time	No	32	1 (1-5)	>0.05#
	Yes	6	3.5 (0-6)	
Fever	No	32	36.3 (36.12-36.5)	>0.05#
	Yes	6	36.15 (36.07-36.3)	
Pulse rate	No	32	81.5 (72.5-102.25)	>0.05#
	Yes	6	83 (73.25-143)	
Systolic blood pressure	No	32	134 (120-154.75)	**<0.05#**
	Yes	6	102.5 (77.5-128.5)	
Diastolic blood pressure	No	32	84.5 (76.25-94.5)	**<0.05#**
	Yes	6	69.5 (55.75-79.25)	
Oxygen saturation	No	32	97 (96-98)	**<0.05#**
	Yes	6	93 (82-95.25)	

Table 4. Continued				
Variables	**In-Hospital Mortality**	**n**	**Value**	**p value**
Glucose	No	32	136.5 (112.75-180.25)	>0.05#
	Yes	6	157.5 (125.5-285.25)	
Hemoglobin	No	32	12.48±2.50	>0.05*
	Yes	6	11.85±2.17	
Sodium	No	32	137 (134-139)	>0.05#
	Yes	6	134 (131.75-142.25)	
Potassium	No	32	4.3 (3.7-4.6)	**<0.05#**
	Yes	6	5.05 (4.5-5.8)	
INR	No	32	1.09 (0.99-1.54)	>0.05#
	Yes	6	1.16 (1.04-1.33)	
Troponin	No	32	29.2 (14.6-129)	>0.05#
	Yes	6	59.25 (42-2865)	

*Student's t-test, #Mann-Whitney U test, INR: International normalized ratio, BMI: Body mass index

Table 5. In-hospital mortality diagnosis of potassium based on receiver operating characteristic analysis					
AUC (95% CI)	**p value**	**Risk factor**	**Cut-off value**	**Sensitivity %**	**Specificity %**
0.786 (0.607-0.966)	<0.05	Potassium	4.50	83.3	59.4
			4.65	66.7	78.1
			4.85	66.7	81.3

AUC: Area under the curve; CI: Confidence interval

and adverse clinical outcomes in patients with HF. BP <120 has been shown to be an independent predictor of morbidity and mortality (17).

In the National Registry of Acute Decompensated Heart Failure study, BP <115 mm Hg was the second-best independent predictor of mortality after renal failure in patients with preserved and reduced left ventricular ejection fraction (LVEF) (18). In another study, BP <110 mm Hg was a predictor of mortality and the need for heart transplantation in patients considering heart transplantation (19). In the Multicenter Automatic Defibrillation Study, BP <100 mm Hg was a predictor of mortality and the need for heart transplantation among patients considering heart transplantation.

The Multicentre Automatic Defibrillator Implantation Trial reported that SBP and DBP levels were inversely associated with sudden cardiac mortality in patients with ischemic left ventricular dysfunction (20). We found that low SBP and DBP were significant predictors of mortality.

In previous studies, weight loss in patients with left bundle branch block treated with cardiac resynchronization therapy with a defibrillator (CRT-D) was associated with a particularly high risk of HF or death. Although being underweight was associated with a higher risk of death and hospitalization, overweight and obese patients were found to have a lower risk of death after CRT-D (21). Another study comparing patients with low and high BMIs with ICDs found that mortality was higher in patients with low BMIs (22). Hsu et al. (23) also found that patients with low BMI and ICDs had higher rates of complications, hospital stay, and mortality compared with those with normal BMI patients. In our study, although our patients were overweight according to BMI, we did not find any significant value in terms of mortality.

Hyperkalemia is the most common electrolyte abnormality, leading to loss of capture. Hyperkalemia causes two important clinical abnormalities in pacemaker patients: First, when the K level exceeds 7 mEq/L, intraventricular conduction velocity is usually decreased, and the QRS complex widens. Second, it increases the atrial and ventricular pacing thresholds (24). Koul et al. (25) reported that hyperkalemia-induced T-wave oversensing leads to the loss of biventricular pacing and inappropriate ICD shocks. Kiamanesh et al. (26) reported that hyperkalemia-induced T-wave oversensing leads to the loss of biventricular pacing and inappropriate ICD shocks. A 33-year-old male patient with dilated cardiomyopathy (EF: 25%) and

end-stage renal disease on hemodialysis and an ICD with a low LVEF, missed a scheduled hemodialysis session and had a serum potassium level of 7.0 mmol/L. It was reported to cause inappropriate shock and ventricular fibrillation. Chua et al. (27) reported that hyperkalemia (9.7 mmol/L) in a patient with an ICD with non-ischemic cardiomyopathy and end-stage renal failure due to hemodialysis caused a large ventricular escape rhythm and T-wave complexes that caused the device to overdetect and fall into the tachycardia detection range, resulting in inappropriate shocks. The patient was placed on emergency dialysis due to a missed hemodialysis session and rapid correction of hyperkalemia. There were no inappropriate shocks after the correction of hyperkalemia. Botrus et al. (28) reported an inappropriate shock due to T-wave oversensing caused by hyperkalemia (7.4 mmol/L) in a patient with ICD. The patient was found to have hyperkalemia due to excessive banana consumption despite regular dialysis, and inappropriate shocks improved after dialysis.

In our study, inappropriate shock was observed in 17.58% of patients. In contrast to other studies, the K value in patients with inappropriate shocks was within the normal range of 4.45 (4.12-4.67). We could not find any reports on the relationship between inappropriate shocks and K value in patients with ICDs in the emergency department. To the best of our knowledge, this is the first study on this topic. The articles in the literature on inappropriate shock are mostly case reports, and K values were found to be higher than our measurements. In these cases, K elevation and rhythm disturbances were observed, and these patients often required urgent dialysis.

Interestingly, in our study, the sensitivity and specificity between serum potassium and mortality were 66.7% and 78.1%, respectively, when the potassium cutoff value was 4.65. Previous studies have reported that hyperkalemia may cause overdetection in ICD patients. In our study, we found that a potassium level >4.65 mEq/L, including normal limits, was significant for mortality. Further multicenter studies with larger numbers of patients are needed to investigate the relationship between K levels and both inappropriate shocks and mortality. Based on the results of our study, we believe that potassium levels should be rapidly detected by blood gas, and appropriate treatment should be initiated if the potassium level is above 4.65.

Study Limitations

The main limitation of this study was that it was conducted in a single center. This resulted in a relatively smaller number of patients compared with larger studies in the literature. The limited number of participating patients made it difficult to obtain statistically significant results. In addition, due to the prospective study design, some patients dropped out of follow-up or refused treatment before the end of the follow-up period and were referred to other healthcare facilities in emergencies, resulting in incomplete and inadequate data. In addition, the inability to contact some patients due to errors in contact information was also a limitation of our study.

Conclusion

We found that the rate of ICD shock in pacemaker/ICD patients presenting to the emergency department was significantly higher among males and patients without DM diagnosis. When a patient with a pacemaker/ICD presents to the emergency department with low sPO_2 and hypotension, more attention should be paid to mortality. We believe that mortality may be higher in patients with potassium levels >4.65. We believe that potassium levels in patients with pacemakers and ICDs could be revised to set a lower limit for hypopotassemia.

Ethics

Ethics Committee Approval: This was a single-center prospective study approved by the Ethics Committee of Health Sciences University, Bursa Faculty of Medicine, Bursa High Specialization Training and Research Hospital (decision no.: 2011-KAEK-25, date: 24.08.2022).

Informed Consent: An informed consent form was obtained from all patients before their inclusion in the study.

Acknowledgments

We would like to thank Ayşe Kılıç, Ayşen Zeybek, Kübra Sezgin, and Hasan Can Memiş for their contributions to the article.

Footnotes

Authorship Contributions

Surgical and Medical Practices: İ.F.Y., M.Y., U.O., Concept: Y.İ., M.Y., M.O.A., Design: İ.F.Y., Y.İ., U.O., Data Collection or Processing: Y.İ., H.K., U.O., Analysis or Interpretation: H.K., M.Y., M.O.A., Literature Search: İ.F.Y., H.K., M.O.A., U.O., Writing: İ.F.Y., Y.İ., U.O.

Conflict of Interest: The authors declare that they have no conflict of interest.

Financial Disclosure: The authors declared that this study received no financial support.

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