Original Article

Evaluation of Right Ventricular Function in the Acute Period Following Lead Extraction by Strain Echocardiography in Patients with Cardiovascular Implantable Electronic Devices

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ABSTRACT

Objective: The growing population and broadening indications have led to a surge in cardiovascular implantable electronic devices (CIEDs) implantations. Concurrently, there is a rising need for lead extractions due to various reasons. Yet, there is a lack of studies highlighting the immediate impact of lead removal on right ventricular (RV) functions. This study aims to evaluate the immediate effects of lead extraction on RV functions using strain echocardiography.

Methods: A total of 64 patients were included, who were scheduled for CIED lead extractions due to various reasons, and were admitted to the cardiology service or coronary intensive care unit. Detailed physical examinations were conducted, routine blood tests and wound and blood cultures were collected. All patients underwent detailed transthoracic echocardiography upon admission and within 24 hours post lead removal. Right ventricular functions in TTE were assessed using 2-dimensional Doppler and strain/ strain rate echocardiography.

Results: The mean age of the study participants was 61.3 ± 15 years, with 51 (79.7%) being male. The primary reasons for battery removal were infection in 89.1% (n = 57) and lead dysfunction in 10.9% (n = 7). Transthoracic echocardiography results indicated a significant reduction in strain echocardiography at the base of the RV free wall (-20.5% vs. -18.6%, P < .001) and the apex (-17.4% vs. -16%, P < .001) post procedure. There was also a notable decrease in the tricuspid annular plane systolic excursion post procedure (1.6 vs. 1.5 cm, P < .016).

Conclusion: Lead extraction results in an acute decline in RV function, making it essential for clinicians to anticipate complications such as hypotension, dizziness, congestion, and syncope post-extraction in CIED patients and tailor treatments accordingly.

Keywords: Implantable cardiac electronic device, lead extraction, lead removal outcomes, post-extraction complications, right ventricular function, strain echocardiography

INTRODUCTION

For over 6 decades, cardiac implantable electronic devices (CIEDs) have played a pivotal role in the treatment of cardiovascular conditions such as bradycardia, tachycardia, and heart failure (HF).¹ These devices can be categorized into 3 primary types: permanent pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices. Permanent pacemakers are employed for managing symptomatic bradycardia, ICDs target patients at risk of sudden cardiac death due to ventricular arrhythmias, and CRT devices aim to improve quality of life and reduce morbidity and mortality in HF patients.²

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The adoption of CIEDs has increased in recent years, driven by factors such as rising life expectancy, population growth, and improved access to healthcare services.³ Globally, an estimated 1.2-1.4 million CIEDs are implanted each year.¹

However, the increasing use of CIEDs has introduced new challenges, including device infections, lead failures, and displacement or misplacement issues. These issues often necessitate transvenous lead extraction (TLE).⁴ Among these, device infection is the most frequent cause for TLE, and the rate of such infections has been rising disproportionately compared to the rate of device implantations.⁵ The risk of infection ranges from 0.5% to 1% for initial implantation, and increases to 1%-5% for device replacement or upgrade.⁶ Such infections could manifest in the generator pocket, leads, or endocardium around the lead, and early device removal is associated with better patient outcomes.⁷ Complete device removal is associated with lower rates of reinfection and mortality in patients with CIED infections, emphasizing the importance of timely and thorough removal of infected devices.8

Despite the general view of TLE as a safe procedure, it is not without life-threatening complications, including myocardial avulsion, tricuspid valve injury, cardiac tamponade, vascular rupture, hemothorax, pneumothorax, and pulmonary embolism.⁹

Conventional and/or Doppler echocardiography offer accessible methods for evaluating right ventricular (RV) functions. Most evaluations of cardiac systolic functions are based on the radial (horizontal) fibers. However, the initial deterioration in cardiac functions begins with the heart's longitudinal fibers. A new method, called strainstrain rate, studies this aspect and has shown promise in identifying impaired longitudinal systolic functions even when radial functions appear normal.¹⁰ Right ventricular functions are crucial for the prognosis of various cardiovascular diseases. Assessing these functions using advanced methods can detect subtle changes that are vital for patient management.

MAIN POINTS

- The immediate effects of lead extraction on right ventricular (RV) functions were evaluated using strain echocardiography in this study.
- This study showed that implantable cardiac electronic device extractions may adversely impact RV functions in the acute phase.
- Post-procedure of implantable cardiac electronic device extraction, patients should be closely followed for right ventricle functions.

The aim of this study is to investigate the immediate impact of TLE on RV functions in patients with CIEDs using the strain/strain rate echocardiography method. This could provide insights into the actual rates of complications and help in the development of new treatment protocols for minimizing risks.

MATERIAL AND METHODS

Study Setting and Population

The study was conducted at the clinic from November 2021 to May 2022. A total of 64 patients were enrolled, all of whom presented to the adult emergency department or cardiology outpatient clinic with symptoms including erythema, discharge, malodor, or skin separation at the site of the implanted cardiac device. Subsequent evaluations led to these patients being scheduled for cardiac implantable electronic device (CIED) extraction, and all patients were informed about the study upon hospitalization in the cardiology service or coronary intensive care unit. Data collected included age, gender, height, body weight, existing medical conditions, and medications. A detailed medical history was taken, and physical examinations were conducted. All the information was recorded on a designated patient form.

Age >18 years, presence of a cardiac implantable device, and scheduled for device extraction for any reason were criteria for inclusion in the study, assuming voluntary participation. Patients with severe chronic obstructive pulmonary disease, pregnancy, co-existing autoimmune diseases, chronic liver or kidney disease, immunosuppressed status, cognitive impairment, moderate to severe mitral stenosis, anomalies affecting RV function (e.g., Ebstein anomaly, arrhythmogenic RV dysplasia), urgent need for surgical intervention due to the extraction procedure, body mass index >30 kg/m², unwillingness to participate in the study were excluded.

Ethical Approval

This study was approved by the Ethics Committee of Ankara Bilkent City Hospital (Date: 17/11/2021; Approval Number: 2146) in accordance with institutional and international guidelines and was conducted in accordance with the principles of the Declaration of Helsinki.

Data Collection and Laboratory Tests

Baseline laboratory evaluations included fasting blood glucose, liver and kidney function tests, and complete blood counts. Biomarkers for infection—erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), procalcitonin, and N-terminal brain natriuretic peptide (NT-proBNP) were measured for all participants. Blood and wound swab cultures were obtained, and intravenous empirical antibiotic therapy was initiated, later to be adjusted based on culture results. Battery pocket swab samples were taken from all patients under suspicion upon admission.

Echocardiographic Evaluation

All patients underwent transthoracic echocardiography (TTE) examinations both before and within 24 hours following the extraction procedure using the IE33 echocardiography system (Philips Medical Systems, Eindhoven, The Netherlands) by an echocardiography cardiologist, in adherence to the guidelines of the American Society of Echocardiography.¹¹

The echocardiographic examinations were conducted by 2 seasoned operators while the patients lay in the left lateral decubitus position, after a minimum 15-minute rest. All readings were taken over 3 consecutive cycles, and averages were determined. Standard viewing windows included the parasternal long and short axis views as well as apical views. M-mode measurements in the parasternal longaxis view captured the left ventricular (LV) end-diastolic/ end-systolic diameters (LVEDd, LVESd). The left ventricular ejection fraction (LVEF) was computed from the apical window via the modified Simpson's method. The left atrial diameter was gauged from M-mode echocardiographic images using the end-to-end method, and the maximum span between the posterior aortic root wall and posterior left atrial wall was captured at systolic end. Diastolic functions were assessed by measuring the peak velocities of the early diastolic (E) and late diastolic (A) waves at the mitral leaflet coaptation point in apical 4-chamber views. PW [Pulsed Wave (Doppler)] tissue Doppler imaging (TDI) was employed to measure the peak velocities of the early diastolic waves (septal e' and lateral e') from the lateral and septal mitral annulus. For RV TDI measurements, PW tissue Doppler was placed in the lateral corner of the tricuspid annulus. The tricuspid annular plane systolic excursion (TAPSE) represents the distance between end-diastolic and end-systolic points at the tricuspid annulus's lateral corner. Systolic pulmonary artery pressure was deduced by summing the tricuspid valve pressure gradient and the right atrial pressure, as derived from Bernoulli's equation.

Right Ventricular Strain/Strain Rate Imaging

For 2-dimensional (2D) strain imaging of the right ventricle, the patient's heart rhythm was monitored echocardiographically. A 2D video data was captured from the modified apical 4-chamber (A4C) image. Right ventricular-focused imagery containing at least three cardiac cycles was secured with regular electrocardiogram (ECG) signals in tissue velocity imaging mode. Analysis of the stored images was executed with QLAB-CMQ (Philips Healthcare, Andover, MA, USA). Post identification of the 3 reference points (RV apex, medial, and lateral tricuspid annulus), the software auto-traced the endocardial and epicardial borders in the modified A4C perspective. For some patients, tracking points were manually adjusted. The 2D longitudinal strain and strain rate curves for each myocardial segment were derived. Peak negative longitudinal systolic strain metrics were sourced from these curves. Measurements for RV global longitudinal strain (RV-GLS) and RV free-wall longitudinal strain (RV-FWLS) were made in alignment with contemporary guidelines¹² (Figure 1).

Extraction Process

Informed consent was obtained from all patients after fully explaining the procedure and its associated risks.



Figure 1. 2D strain images of the right ventricle in a patient included in our study. Image format: JPEG, dimensions: 1132 × 753.

Following a minimum fasting period of 8 hours, patients were escorted to the catheter laboratory within the angiography unit.

All extraction procedures took place in the specialized electrophysiology laboratory. In anticipation of potential emergencies, the cardiac surgery team was informed in advance. For every patient undergoing lead extraction, an 8-French venous sheath, suitable for rapid administration of blood products and intravenous fluids, was positioned in the femoral vein. Following this, the patients were transferred to the cardiac intensive care unit for a comprehensive 24-hour observation period.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) for Windows 20 (IBM SPSS Corp.; Armonk, NY, USA) and MedCalc 11.4.2 (MedCalc Software, Mariakerke, Belgium). The Kolmogorov–Smirnov test was employed to assess the normality of data distribution. Numerical variables following a normal distribution were expressed as mean \pm SD, while those not adhering to a normal distribution were depicted as the median. Categorical variables were described in terms of numbers and percentages. To compare categorical variables, either the chi-square test or Fisher's exact chi-square test was applied, as appropriate. A *P*-value < .05 was deemed statistically significant for all analyses.

RESULTS

The average age of the cohort was 61.3 ± 15 years, with males constituting 79.7% (n = 51). The baseline characteristics of the participants are delineated in Table 1.

Table 1. Baseline Characteristics of Patients				
Variables	n (64)			
Age, years	61.3 ± 15			
Gender, male	51 (79.7)			
Height, cm	170 (150-185)			
Weight, kg	74.1 ± 11.8			
Body mass index, kg/m ²	25.6 (18.5-35.1)			
Hypertension, n (%)	38 (59.4)			
Diabetes mellitus, n (%)	25 (39.1)			
Coronary artery disease, n (%)	29 (45.3)			
Atrial fibrillation, n (%)	11 (17.2)			
Chronic obstructive pulmonary disease, n (%)	10 (15.6)			
Chronic kidney disease, n (%)	12 (18.8)			
Cerebrovascular event, n (%)	6 (9.4)			
Heart failure, n (%)	31 (48.4)			

Infections emerged as the predominant rationale for CIED extraction, comprising 89.1% of the cases, while lead dysfunction accounted for the remaining 10.9%. The average duration from CIED implantation to extraction stood at 6 years, with the range spanning from 1 to 22 years. Single leads were extracted in 34.4% of the cases, double leads in 45.3%, and 3 leads in 20.3%. Notably, 60.9% of patients had not previously undergone a battery replacement. However, 25% had 1 replacement, 4.2% had 2, 3.1% had 3, 4.7% had 4, and 1.6% underwent 6 replacements. Post-extraction, 37.5% of patients necessitated new batteries. The average hospitalization duration was 22 days.

A mere 10.9% of patients exhibited no signs of battery pocket infection during the preliminary assessment. However, the majority (89.1%) manifested infectious symptoms: 37.5% displayed both discharge and skin erosion, 21.9% only discharge, 18.8% solely skin erosion, 7.8% abscess formation, and 3.1% had visible lead infections/vegetations on echocardiography.

The laboratory results of the patients before and after the CIED extraction procedure are shown in Table 2. Notably, there was a significant decrease in patients' hemoglobin (12.9 \pm 2.3 vs. 12.1 \pm 2.2 g/dL, *P* < .001) and albumin (40.9 \pm 4 vs. 38.2 \pm 3.8 g/L, *P* < .001) levels after the procedure compared to pre-procedure levels. In contrast, patients' ESR (24 vs. 34.8 mm/hr, *P* < .001), CRP (0.009 vs. 0.017 g/L, *P* < .001), procalcitonin (0.03 vs. 0.06 µg/L, *P* < .001), and NT-proBNP (927 vs. 1827 ng/L, *P* = .035) values were significantly higher after the procedure compared to pre-procedure compared to pre-procedure slaves.

Table 2.Changes in the Blood Parameters of Patients Beforeand After the Procedure

Parameters	Before the Procedure	After the Procedure	Р
Hemoglobin, g/dL	12.9 ± 2.3	12.1 ± 2.2	<.001
Platelet, X10 ⁹ /L	248.6 ± 73	245.3 ± 73.2	.658
eGFR, mL/min/ 1.73/m²	78.4 ± 27.3	81.6 ± 34.3	.316
Albumin, g/L	40.9 ± 4	38.2 ± 3.8	<.001
WBC, X10 ⁹ /L	8 (3.6-16.6)	9 (5-25)	.004
Creatinine, mg/dL	0.94 (0.62-3.7)	0.94 (0.48-3.6)	.859
CRP, g/L	0.009 (0-0.2)	0.017 (0-0.8)	<.001
ESR, mm/hr	24 (3-103)	34.8 (3-114)	<.001
Procalcitonin, µg/L	0.03 (0-13.4)	0.06 (0-46.2)	<.001
NT-proBNP ng/l	927 (35-35000)	1827 (35-35000)	.035

CRP, C-reactive protein; eGFR, estimated glomerular filtration rate; ESR, erythrocyte sedimentation rate; NT-proBNP, N-terminal brain natriuretic peptide; WBC, white blood cell. The post-procedure mitral A value witnessed a significant escalation (68.6 vs. 76.1 m/s, P=.001) relative to its preprocedure counterpart. Post-procedure metrics revealed a marked reduction in left atrium volume (23.2 vs. 21.9 mL, P=.049), left atrial volume index (LAVI) (12.3 vs. 11.7 mL/m², P=.014), and the mitral E/A ratio (1.14 vs. 1.04, P=.034).

The fraction of patients with pronounced tricuspid regurgitation surged significantly post-procedure (18.75% vs. 6.25%, P < .001). The post-procedure TAPSE value, an M-mode echocardiography metric indicative of RV systolic function, experienced a statistically significant downturn compared to its pre-procedure value (1.6 vs. 1.5 cm, P=.016). However, the RV TDI metric, a Doppler-derived echocardiography measure reflective of RV systolic function, remained stable when comparing pre- and post-procedure data (10.9 vs. 11.8 cm/s, P=.267) (Table 3).

Table 3.Changes in Echocardiographic Parameters Beforeand After the Procedure in Patients				
Parameters	Before the Procedure	After the Procedure	Р	
LVEF, %	37.6 (15.4-62)	37.3 (12.3-63)	.725	
Septal E', cm/s	6.8 (2-50.3)	6.3 (3-10.9)	.763	
Lateral E', cm/s	8.1 (3-16.8)	8.6 (3.1-15.5)	.093	
Mitral E, m/s	78.3 (15-232)	79.4 (30-180)	.669	
Mitral A, m/s	68.6 (20-150)	76.1 (26-180)	.001	
Mitral E/A	1.14 (0.22-4.5)	1.04 (0.33-4.38)	.034	
LVGLS, %	-12.2 (-21 to -4.5)	12.2 (-21.2 to -4.1)	.666	
LA volume, mL	23.2 (10.3-86)	21.9 (9.9-75)	.049	
LAVI, mL/m ²	12.3 (6.3-41.7)	11.7 (6.4-36.4)	.014	
Severity of tricuspid insufficiency				
Mild	48 (75%)	44 (68.75%)	<.001	
Moderate	12 (18.75%)	8 (12.5%)		
Severe	4 (6.25%)	12 (18.75%)		
sPAB, mm Hg	30.3 (14-63)	31.9 (13-76)	.300	
TAPSE, cm	1.6 (0.7-2.7)	1.5 (0.7-2.4)	.016	
RV TDI S', cm/s	10.9 (-29.1 to 21.1)	11.8 (5.7-18)	.267	
AVC, ms	377.8 (235-619)	385 (277-580)	.768	
RAV, mL	18 (8-33.5)	18 (7.4-40)	.907	
RVFWB, %	-20.5 (-35.3 to -9.3)	-18.6 (-34.6 to 27.5)	.001	
RVFWM, %	-18.4 (-41 to -3.1)	-17.2 (-52 to -6)	.197	
RVA, %	-17.4 (-33.8 to -6.3)	-16 (-29.9 to -3)	.001	
RVGLS, %	-19.5 (-33.6 to -9.7)	-17.3 (-33.3 to -2.4)	.001	

LVEF, left ventricular ejection fraction; A, late mitral inflow velocity; AVC, aortic valve closure time; E, early mitral inflow velocity; E', early diastolic annular velocity; LA, left atrium; LAVI, left atrial volume index; LVGLS, left ventricular global longitudinal strain; RAV, right atrial volume; RVA, right ventricular apical; RVFWB, right ventricular free wall basal; RVFWM, right ventricular free wall mid; RVGLS, right ventricular global longitudinal strain; RV TDI, right ventricular tissue Doppler imaging; sPAB, systolic pulmonary artery pressure; TAPSE, tricuspid annular plane systolic excursion. Regarding strain echocardiography assessments of the right ventricle, there were notable reductions in the post-procedure values of RVFWB (-20.5% vs. -18.6%, P = .001), RVA (-17.4% vs. -16%, P = .001), and RVGLS (-19.5% vs. -17.3%, P = .001) subsequent to lead extraction.

DISCUSSION

There is a gap in literature regarding the acute impact of implantable electronic device extractions on RV functions. This study aimed to explore this acute effect on RV functions. This investigation is pioneering in the literature, evaluating RV systolic functions through strain/ strain rate echocardiography in the immediate aftermath of extraction in patients with CIED. The most salient discovery from our research is the discernible decrease in RV systolic functions shortly after CIED extraction. Although not the initial purpose of the study, it was found that the predominant reason for CIED extractions was infection.

Cardiovascular implantable electronic devices first emerged for clinical use in the 1960s, and today's repertoire includes ICDs, CRTs, and cardiac pacemakers. Cardiovascular implantable electronic devices provide a plethora of beneficial therapeutic options, and when used judiciously, can enhance life expectancy and the quality of life.¹³ This has resulted in a surge in global CIED indications and implantation rates. However, this uptrend is shadowed by an increase in complications related to CIED. Device infection and endocarditis are among the more pressing complications that electrophysiologists encounter.

Though relatively uncommon, CIED infection presents a grave complication, manifesting either as a generator pocket infection or a lead wire infection, which might subsequently involve endocardial structures. At present, CIED infections contribute to 10% of all endocarditis cases.¹⁴ An early sign of device infection could be wound dehiscence, warranting vigilant monitoring. Such patients often endure extended hospitalizations, sometimes repeatedly.¹⁵ Additionally, addressing infected systems frequently requires prolonged antibiotic regimens.¹⁶ In this cohort, the mean hospital stay for patients subjected to CIED extraction was 22 days, with certain cases necessitating even lengthier durations.

Incomplete CIED removal or mere antibiotic therapy results in a 50%-100% recurrence of infection. This recurrence rate plummets to between 0% and 4.2% with total system removal.¹⁷ Solely relying on antibiotic therapy without device removal is associated with a sevenfold surge in mortality within 30 days. Transvenous lead extraction procedures are associated with high success rates and low major complication rates in patients

with CIED infections, but the presence of infection may increase 30-day mortality rates.¹⁸

This underscores the necessity to preemptively avert device infections rather than merely addressing them post facto. Present guidelines from eminent institutions like the American Heart Association, American College of Cardiology, and Heart Rhythm Society advocate for the extraction of the entire system (device and leads) for patients with confirmed CIED infection, lead endocarditis, pocket abscess, device erosion, or bacteremia.¹⁹ Transvenous lead extraction is considered the benchmark treatment for infections associated with cardiac CIEDs. Although other factors, such as lead dysfunction and device upgrades, complicate device and lead extraction protocols, infection remains the primary impetus for TLE.⁴ The findings corroborate this, revealing that device infection was the predominant rationale for device extraction in 89.1% of instances.

The RV is pivotal for the prognosis of numerous cardiovascular conditions. As with the left ventricle, RV function is determined by factors like preload, afterload, and contractility. Echocardiography has historically been the preferred non-invasive imaging technique for assessing RV systolic function. Therefore, this study assessed RV systolic function using echocardiographic measures like TAPSE, RV TDI S' wave, and, importantly, strain/strain rate imaging.

Tricuspid annular plane systolic excursion provides an easily executed, consistent quantitative assessment reflecting the RV's longitudinal contraction. This onedimensional metric, derived from M-mode, captures the lateral tricuspid annulus's displacement from end-diastole to end-systole and is taken from the RV-focused apical 4-chamber view. The longitudinal contraction, majorly due to the RV's deep subendocardial fibers, constitutes 80% of the RV's cardiac output.²⁰ The descent of the base towards the apex during systole is a marker of RV systolic function. The TAPSE has shown reliability in assessing RV dysfunction and ejection fraction, with sound correlations to magnetic resonance imaging, right heart angiography, radionuclide studies, fractional area change, and the biplane Simpson's method.²¹ According to American Society of Echocardiography (ASE) guidelines, a TAPSE value <16 mm indicates abnormal RV systolic dysfunction,²² a value later revised to <17 mm by the ASE and European Association of Cardiovascular Imaging (EACVI).23 The study found the mean TAPSE value postextraction in the acute period to be 15 mm, a significant drop from the pre-procedure value, suggesting a deterioration in RV functions after extraction. Yet, the RV S' wave exhibited no significant change post-procedure.

The complexities in assessing RV functions via conventional echocardiography arise due to factors like delineation of the endocardial line because of trabecular structures and imaging the RV free wall given its thoracic location. Thus, diverse techniques are crucial for an in-depth visualization of RV functions. Strain echocardiography, which can depict regional deformations due to the RV's heterogeneity, has gained traction. The "speckle" method was favored for strain value analysis in this study, due to its angle-independence and other benefits. Using specialized software (EchoPAC 6.3.6), the software identified the endocardial border, tracked the "speckle," and calculated the strain ²⁴ Speckle tracking echocardiography is considered to be a more sensitive and objective assessment method compared to conventional echocardiography. In this context, changes in RV strain were also detected in the study, which are believed to aid in clinical approaches by evaluating earlystage RV functions in patients who underwent lead extraction. A notable reduction in RVFWB and RVFWA was observed during the acute phase post-extraction, along with a significant decline in the RVGLS value. The decrease in these values may be associated with symptoms in patients that cannot be attributed to any other events clinically. Clinicians, keeping in mind that these symptoms could be related to changes in RV function, can approach accordingly.

Extractions of implantable cardiac electronic devices are paramount in device management. This study posits that implantable cardiac electronic device extractions may adversely impact RV functions in the acute phase. Hence, in postoperative follow-up, any symptoms like hypotension, dizziness, swelling in extremities, or abdominal discomfort should warrant thorough investigation. If such symptoms surface, RV systolic function impairment should be on the radar, necessitating timely interventions.

This study possesses several constraints. Its sample size is limited. As a single-center and non-randomized research, the findings might not be universally applicable. The limited sample size and single-center design of the study may restrict the generalizability of the findings. Future largescale, multi-center studies are needed to validate these results and provide broader clinical insights. No categorization was made based on the number of extracted leads when assessing acute RV functions, which might influence results. Furthermore, though a combination of conventional and strain echocardiography could have yielded richer insights, our study predominantly employed the latter. Larger, randomized, multi-center studies are requisite to scrutinize RV systolic functions in CIED patients scheduled for extraction, ensuring findings are generalizable and categorizations are based on lead count.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Ankara Bilkent City Hospital (Date: 17/11/2021; Approval Number: 2146).

Informed Consent: Written informed consent was obtained from all patients who participated in this study.

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