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Predictive value of the frontal QRS-T angle for a permanent pacemaker requirement in patients undergoing transcatheter aortic valve implantation

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Abstract. – OBJECTIVE: Despite recent advances, the requirement for permanent pacemaker (PPM) implantation after transcatheter aortic valve implantation (TAVI) remains high. The frontal QRS-T angle (fQRS-Ta) indicates ventricular electrical instability as well as ventricular depolarization and repolarization heterogeneity. The predictive value of fQRS-Ta for the PPM requirement after TAVI is lacking. Therefore, we aimed to investigate the predictive value of baseline fQRS-Ta for the requirement of PPM after TAVI.

PATIENTS AND METHODS: This is a retrospective study conducted at a single tertiary care center. The patients were divided into two groups: those who required a pacemaker (PPM group) and those who did not (No-PPM group). The optimal fQRS-Ta cut-off value for predicting a PPM requirement was determined by using receiver operating characteristic (ROC) curve analysis. Univariate and multivariate Cox regression analyses were used to determine the independent predictors of post-TAVI PPM placement.

RESULTS: Final study population consisted of 184 patients. The mean age of the patients was 79.41 ± 7.88 years, and 61% (n = 113) were women. Twenty-seven patients who required PPM after TAVI were considered as the 'PPM group'. The baseline frontal QRS and T axes did not differ between the groups, but the fQRS-Ta was significantly higher in the PPM group. ROC analysis performed for the prediction of post-TAVI PPM need, the fQRS-Ta cut-off value was found to be 100.5 with a sensitivity of 74.1% and a specificity of 60.5% [AUC (95% CI): 0.637 (0.520 - 0.755), *p*: 0.023]. In multivariate analysis, age [HR (95% CI): 1.071 (1.005 - 1.142), *p*: 0.034] and fQRS-Ta [HR (95% CI): 2.509 (1.084 - 6.399), *p*: 0.044] were identified as independent risk factors for PPM requirement after TAVI.

CONCLUSIONS: This study demonstrated that age and baseline fQRS-Ta were independent predictors of PPM requirements after TAVI in patients with aortic stenosis.

Key Words:
Frontal QRS-T angle, Predictors, Permanent pacemaker, Transcatheter aortic valve implantation.

Introduction

In Europe and North America aortic stenosis is the most common primary valve lesion requiring surgery or transcatheter intervention[1]. The prevalence of severe aortic stenosis is increasing rapidly as a result of the aging population[2]. Transcatheter aortic valve implantation (TAVI) is a standard therapy with low mortality and complication rates for inoperable, high-risk, and intermediate-risk patients with severe aortic stenosis[3-5]. Studies[6,7] examining the efficacy and safety of TAVI in low-risk patients are still ongoing. TAVI is being applied with an increasingly minimalist approach and the rate of periprocedural complications is decreasing over time.

Unfortunately, atrioventricular (AV) heart block is a common complication of the procedure, which can be observed in up to 30% of different valve systems[8]. In a subgroup analysis of the PARTNER study[9], the requirement for a permanent pacemaker after TAVI was associated with increased hospitalization and mortality at 1-year follow-up. The incidence of conduction disorders (complete heart block) requiring permanent pacemaker implantation has not recently decreased, unlike other procedural complications. While 8.5%-25.9% of patients undergoing TAVI require a permanent pacemaker (PPM) within 30

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days, depending on the type of prosthesis, only 7% of patients undergoing surgery require PPM after the procedure[10,11]. Predictors of PPM implantation after TAVI may be electrocardiographic, patient-related, and procedural factors. Pre-existing right bundle branch block, periprocedural AV block, prolonged QRS duration, longer PR at baseline, and pre-existing left anterior fascicular block have been reported as electrocardiographic factors. Of these, the pre-existing right bundle block is the most predictive[10].

The frontal QRS-T angle (fQRS-Ta) is calculated by the absolute difference between the QRS and T axes and expresses the absolute difference between the ventricular depolarization and repolarization axes[12]. It is commonly used to illustrate ventricular electrical instability and ventricular depolarization, and repolarization heterogeneity. The relationship between fQRS-Ta and the prognosis of cardiovascular disease has also been demonstrated in previous studies[13,14]. Increased fQRS-Ta was related to increased mortality rates in patients with congestive heart failure, coronary artery disease, and patients with severe AS undergoing transcatheter aortic valve replacement therapy[15-17].

Despite the increasing importance and utility of the procedure, risk stratification for postprocedural complications in patients undergoing TAVI is of great interest to clinicians. Although many risk factors have been identified, new risk factors are still needed to predict arrhythmic complications after TAVI procedure. To the best of our knowledge, there are no clinical studies in the literature evaluating the predictive value of fQRS-Ta for the possibility of post-TAVI PPM implantation due to complete heart block and hemodynamic unstabilizing malignant bradyarrhythmia in patients undergoing the TAVI procedure. Therefore, we aimed to analyze the baseline (pre-operative) fQRS-Ta in patients undergoing the TAVI procedure to predict the requirement for post-TAVI PPM.

Patients and Methods

Study Population

This is a retrospective study conducted at a single tertiary care center. Patients with complete and incomplete right or left bundle brunch block or pathological Q wave on surface electrocardiography (ECG), atrial fibrillation, left anterior fascicular block, left posterior fascicular block, bifascicular block and nonspecific intraventricular conduction defects, type I or III antiarrhythmic usage, ECGs without clearly analyzable, history of cardiac pacemaker implantation, history of myocardial infarction, severe non-revascularized coronary artery lesions (left main coronary artery > 50% or other coronary arteries > 70% stenosis) and heart failure with reduced ejection fraction were excluded from the study. A total of 326 patients were screened and a total of 184 consecutive patients who underwent TAVI due to severe aortic stenosis were included (Figure 1). Indications for PPM placement in post-procedure TAVI patients were complete heart block or high-grade AV block, Mobitz 2 second-degree AV block, trifascicular heart block; if causing hemodynamic unstabilization: LBBB, sick sinus syndrome, and symptomatic bradycardia. These indications were named malignant bradyarrhythmias. Study groups were divided into two groups as follows: 27 patients requiring post-TAVI PPM due to malignant bradyarrhythmias (PPM group) and 157 patients who underwent TAVI with no malignant bradyarrhythmias (TAVI group). Furthermore, ECG recordings were analyzed by two clinical cardiologists, who were unaware of the study results. All patients who received a permanent pacemaker (PPM) within a hospital stay and a 30-day follow-up period of the valve procedure were included in the study. In this cohort study, patient selections and data collection were obtained retrospectively. Demographic, clinical, electrocardiographic, and echocardiographic evaluations were recorded before TAVI from all subjects. Written informed consent was obtained from all patients before TAVI and PPM implantation. This study conforms to the ethical principles outlined in the Declaration of Helsinki. An ethics committee approval was obtained from the hospital's Institutional Review Board (IRB date and number: 21.03.2017-2017/04).

Electrocardiography

A 12-lead surface ECG (Nihon Kohden Corporation, Cardiofax M Model ECG-1250, Tokyo, Japan) with a 25 mm/s paper speed and a voltage of 10 mm/s, was obtained in a supine position before TAVI was performed. All ECG recordings were scanned and transferred to the digital platform. Measurements were evaluated by two different cardiologists who were blinded to the patient data. The frontal QRS-Ta was calculated as the absolute value of the difference between the frontal plane QRS and T axes (Figure 2). If such

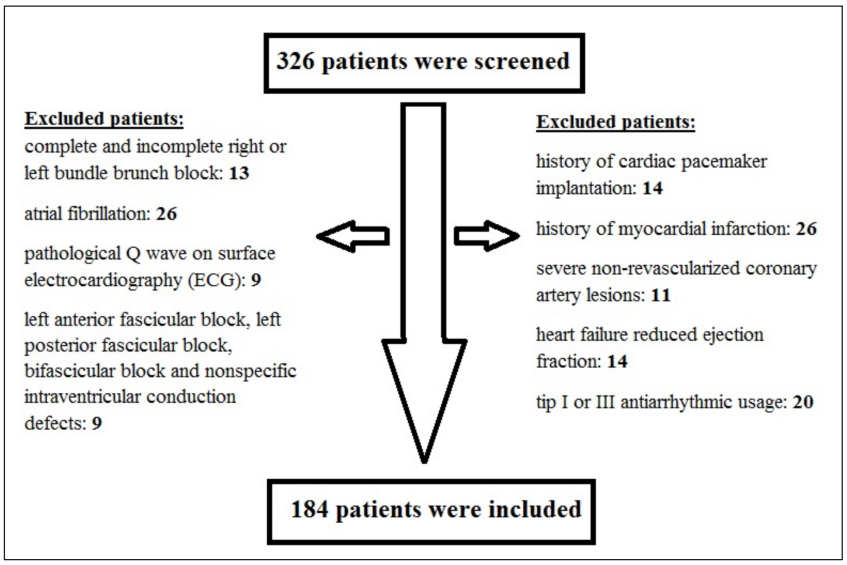

Figure 1. Flowchart of the study population selection.

a difference was > 180°, QRS-Ta was adjusted to the minimal angle of 360° minus the absolute value of the difference between the frontal plane QRS and T axes[12]. Intraobserver and interobserver differences for fQRS-Ta measurements were 2.4% and 2.5%. This systematic error was similar for both groups.

Echocardiography

Transthoracic 2-D echocardiography was performed for each patient before TAVI and repeated on post-TAVI by using commercially available equipment (VIVID 7 Dimension Cardiovascular Ultrasound System) (Vingmed-General Electric, Chicago, IL, USA) with a 3.5 MHz transducer.

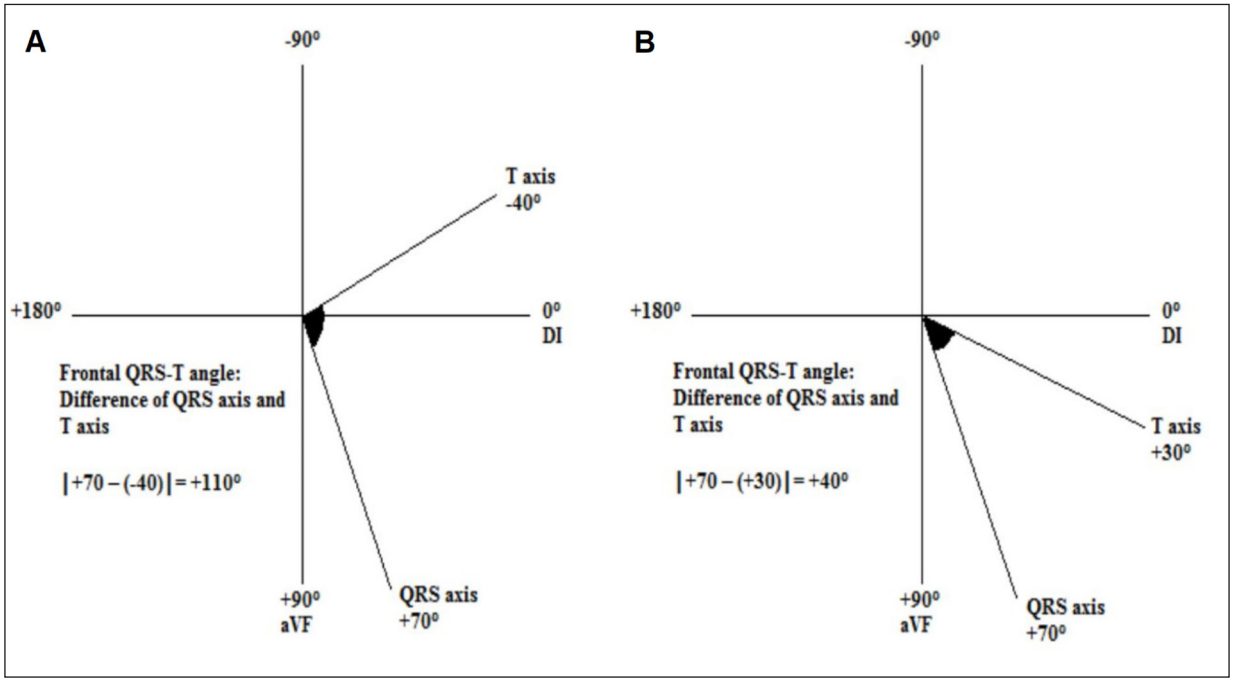

Figure 2. Illustrations (**A**) and (**B**) show the calculations of the frontal QRS-T angle at different QRS and T axes.

Table I. Baseline demographic, clinical, electrocardiographic, and echocardiographic variables of patients.

Variables	PPM group (n = 27, 14.6%)	No-PPM group (n = 157, 85.4%)	p
Age, years	82.41 ± 5.69	78.89 ± 8.10	0.032
Female Gender, n (%)	14 (52%)	99 (63%)	0.269
Body mass index (kg/m^2)	26.8 (22.4 - 31.2)	27.2 (20.8 - 31,9)	0.326
COPD, n (%)	14 (52%)	98 (62%)	0.299
Diabetes mellitus, n (%)	10 (37%)	64 (41%)	0.715
Hypertension, n (%)	25 (93%)	126 (80%)	0.123
Dyslipidemia, n (%)	11 (41%)	64 (41%)	0.862
Previous CVA, n (%)	2 (7%)	15 (10%)	0.284
Creatinine (mg/dl)	1.01 ± 0.39	1.07 ± 0.63	0.612
Hemoglobin (g/dl)	11.48 ± 1.51	11.52 ± 1.74	0.902
Leukocytes × 10^3/mm^3	7.58 (2.72 - 18.42)	7.74 (3.25 - 18.87)	0.245
Thrombocyte × 10^3/mm^3	234 (99 - 399)	230 (124 - 490)	0.284
Valve type, n (%)			0.059
Balloon expandable	17 (63%)	130 (83%)	
Self-expandable	7 (26%)	19 (12%)	
Mechanically expanded	3 (11%)	8 (5%)	
Valve size, n (%)			0.011
23	3 (11%)	57 (36%)	
25	4 (15%)	11 (7%)	
26	10 (37%)	59 (38%)	
27	0	6 (4%)	
29	10 (37%)	24 (15%)	
Logistic EuroSCORE, %	26.02 ± 5.03	26.21 ± 4.94	0.965
STS score, %	10.64 ± 2.17	10.68 ± 2.22	0.969
LVEF, %	59.36 ± 8.49	59.08 ± 10.63	0.104
LVEDD, mm	49 (33 ± 58)	50 (35 ± 59)	0.756
LVESD, mm	33.12 ± 6.49	35.67 ± 6.73	0.246
LA diameter, mm	38.34 ± 7.16	38.62 ± 7.28	0.136
Preoperative PAG, mm Hg	78.28 ± 14.76	82.92 ± 15.35	0.297
Preoperative MAG, mm Hg	48.80 ± 9.76	51.34 ± 10.06	0.373
Preoperative AVA, cm^2	0.82 ± 0.19	0.77 ± 0.15	0.084
Postoperative PAG, mm Hg	23 (19 ± 46)	25 (21 ± 48)	0.539
Postoperative MAG, mm Hg	13 (9 ± 27)	12 (8 ± 25)	0.086
Heart rate, bpm	79.28 ± 18.81	75.43 ± 14.65	0.244
PR interval, ms	183.29 ± 33.06	172.61 ± 29.76	0.219
QRS interval, ms	112.32 ± 27.15	108.98 ± 28.27	0.069
QT interval, ms	414.24 ± 35.57	416.41 ± 44.42	0.817
QTc interval, ms	438.80 ± 32.93	435.43 ± 40.12	0.691
Preop fQRS	10.85 (-24.75 - 30)	8.67 (-26.17 - 24.26)	0.690
Preop fT	105.74 (40 - 155.04)	95.64 (36.82 - 127)	0.225
Preop fQRS-Ta	115.81 ± 23.16	87 ± 16.73	0.015

AVA: aortic valve area, COPD: chronic obstructive pulmonary disease, CVA: cerebrovascular accident, EuroSCORE: european system for cardiac operative risk evaluation, LA: left atrium, LVEDD: left ventricular end-diastolic diameter, LVEF: left ventricle ejection fraction, LVESD: left ventricular end-sistolic diameter, MAG: mean aortic gradient, PAG: peak aortic gradient, QTc: QT corrected, STS: society of thoracic surgeons.

Left ventricular (LV) and left atrial diameters were measured using M-mode imaging. The ejection fraction was calculated by using modified Simpson biplane method. Aortic valve area, maximum, and mean aortic gradient were measured to assess the severity of aortic stenosis (AS). Aortic jet velocity was calculated by Doppler echocardiography. AS was defined as severe if the mean systolic transaortic gradient was greater than 40 mm Hg or jet velocity was greater than 4.0 m/s. All echocardiographic examinations were performed by an experienced cardiologist.

Transcatheter Aortic Valve Implantation (TAVI)

Transthoracic and transesophageal echocardiography were performed for each patient to determine valve morphology and disease severity as well as cardiac functions and calcification of the aortic valve. Also, multislice computed tomogra-

Table II. Univariate and multivariate regression analyses of predictors of PPM requirements in patients undergoing TAVI.

	Univariate analysis		Multivariate analysis	
Variables	**Hazard ratio (95% CI)**	***p***	**Hazard ratio (95% CI)**	***p***
Age, years	1.064 (1.003 - 1.129)	**0.039**	1.071 (1.005 - 1.142)	**0.034**
Gender	0.648 (0.305 - 1.379)	0.260		
Body mass index	1.029 (0.951 - 1.118)	0.318		
COPD	0.661 (0.311 - 1.407)	0.283		
Diabetes mellitus	0.848 (0.388 - 1.852)	0.679		
Hypertension	2.870 (0.680 - 12.119)	0.151		
Dyslipidemia	0.866 (0.448 - 1.614)	0.580		
Previous CVA	4.708 (0.626 - 13.635)	0.104		
Creatinine	0.814 (0.358 - 1.853)	0.624		
Valve type	2.498 (1.035 - 6.030)	**0.042**	1.020 (0.225 - 4.621)	0.980
Valve size	5.923 (1.325 - 26.476)	**0.020**	3.647 (0.134 - 23.113)	0.587
Logistic EuroSCORE	1.000 (0.982 - 1.018)	0.999		
STS score	0.998 (0.924 - 1.079)	0.965		
LVEF	1.033 (0.992 - 1.076)	0.120		
Peak aortic gradient	0.988 (0.967 - 1.010)	0.277		
Mean aortic gradient	0.985 (0.953 - 1.017)	0.350		
AVA	0.957 (0.317 - 9.705)	0.422		
Heart rate	1.014 (0.990 - 1.039)	0.255		
PR interval	1.008 (0.996 - 1.020)	0.212		
QRS interval	1.012 (1.002 - 1.024)	**0.046**	0.998 (0.982 - 1.015)	0.857
QT interval	0.999 (0.990 - 1.008)	0.824		
QTc interval	1.002 (0.992 - 1.012)	0.716		
Preop fQRS	1.001 (0.994 - 1.009)	0.700		
Preop fT	1.003 (0.998 - 1.008)	0.228		
fQRS-T angle	3.787 (1.601 - 8.959)	**0.002**	2.509 (1.084 - 6.399)	**0.044**

AVA: aortic valve area, CI: confidence interval, COPD: chronic obstructive pulmonary disease, CVA: cerebrovascular accident, EuroSCORE: european system for cardiac operative risk evaluation, LVEF: left ventricle ejection fraction, QTc: QT corrected, STS: society of thoracic surgeons.

phy was used to evaluate the aortic valve, aortic annulus, and aorta anatomy, besides the peripheral vascular anatomy and coronary ostium-annulus distance. Then, each patient was evaluated by our heart team to assess suitability for TAVI. In all patients, a retrograde transfemoral technique was used, and the procedure was performed under general anesthesia. The Amplatz Extra Stiff Guide Wire was advanced to the apex of the left ventricle using 16-F sheath through the femoral artery. A balloon valvuloplasty was applied on the aortic valve with ventricular pacing at a rate of 80-200 beats/min. The procedure was performed by using the balloon-expandable Edwards Sapien XT valve (Edwards Lifesciences; Irvine, CA, USA), the self-expandable Medtronic CoreValve (Medtronic Inc.; Minneapolis, MN, USA), Evolut R (Medtronic Inc.; Minneapolis, MN, USA) and Portico (St. Jude Medical; St Paul, MN, USA) valves and mechanically expanded Lotus valve (Boston Scientific; Marlborough MA, USA). After achieving optimal opening, the aortic root, aortic valve, and pericardium were visualized. After the TAVI procedure, dual antiplatelet therapy, including 100 mg acetylsalicylic acid plus 75 mg clopidogrel, was administrated to all subjects for 6 months.

Statistical Analysis

Statistical analysis was made using the computer software Statistical Package for Social Sciences [IBM SPSS Statistics for Windows, version 21.0 released 2012, (IBM Corp., Armonk, NY, USA)]. Data were expressed as 'n (%)' for categorical variables and as 'mean + standard deviation (SD)' for quantitative variables. Pearson Chi-square and Fisher exact tests were performed for categorical variables. After fitness to normal distribution was analyzed with the Kolmogorov-Simirnov test, data were expressed as 'median (25^{th}-75^{th} percentiles)' for variables without normal distribution. Mann-Whitney U test was used for comparing quantitative variables without normal distribution. Differences between independent groups were assessed by Student's *t*-test for normally distributed quantitative variables. Univari-

ate and multivariate Cox regression analyses were used to determine the independent predictors of post-TAVI PPM placement. A *p*-value lower than 0.05 was considered statistically significant.

Results

The mean age of the patients included in our study was 79.41 ± 7.88 years, and 61% (n = 113) were women. 27 patients who received post-TAVI PPM therapy were considered as the 'PPM group'**.** Complete heart block or high-grade AV block causing hemodynamic instability (63%; n = 17), Mobitz 2 second degree AV block (19%; n = 5), trifascicular heart block (11%; n = 3), and sick sinus syndrome (7%; n = 2) were the indications for PPM implantation after TAVI. Although the mean age of the PPM group was higher than that of the No-PPM group, no significant difference was found between the groups in other demographic characteristics and laboratory results. The comparison of demographic data, laboratory, echocardiography, and electrocardiography results between groups is shown in Table I.

While the rate of self-expandable and mechanically expanded valves was higher in the PPM group, the use of balloon-expandable valves was higher in the No-PPM group. While valve sizes were higher diameters in the PPM group, it was lower in the No-PPM group. There was no significant difference between the groups in terms of EuroSCORE, society of thoracic surgeons (STS) score, pre- and post-procedure echocardiography measurements. No significant difference was also observed between the groups in baseline electrocardiographic measurements. It was found that the frontal QRS and T angle before the procedure did not differ between the groups, but the fQRS-Ta was significantly higher in the PPM group (Table I).

As a result of the ROC analysis performed for the prediction of post-TAVI PPM need, the fQRS-Ta cut-off value was found to be 100.5 with a sensitivity of 74.1% and a specificity of 60.5% [AUC (95% CI): 0.637 (0.520 - 0.755), *p*: 0.023] (Figure 3).

The 30-day post-TAVI PPM need events were evaluated by Kaplan-Meier analysis of the groups formed according to the fQRS-Ta cut-off value. The need for PPM was found to be significantly higher in the patient group with fQRS-Ta ≥ 100.5 [Log Rank Chi-Square: 10.761 (*p*: 0.001)] (Figure 4).

With Cox regression analysis, the risk factors for post-TAVI PPM needs were determined for 30-day follow-up. The analysis details are presented in Table II. Age, valve type, valve size, QRS interval, and fQRS-Ta were modeled as a result of Univariate analysis. In multivariate analysis, age [HR (95% CI): 1.071 (1.005 - 1.142), *p*: 0.034] and fQRS-Ta [HR (95% CI): 2.509 (1.084 - 6.399), *p*: 0.044] were identified as independent risk factors for post-TAVI PPM need.

Discussion

In this study, 27 patients (14.6%) required PPM after TAVI; age and fQRS-Ta were found to be independent predictors of post-TAVI PPM requirements.

PPM requirement is a common complication after TAVI and has been reported to range between 8.5% and 25.9% in previous studies[10,18,19]. The incidence of PPM requirement after TAVI varies in the literature because of electrocardiographic, patient-related, and procedural factors. The incidence of PPM requirement in this study is consistent with the literature.

Periprocedural mechanical trauma to the conduction system is the main cause of the need for a PPM after TAVI[20]. Parts of the conduction system, particularly the His bundle and the left bundle branch, are located near the bases of the non-coronary and right coronary leaflets. This proximity explains why periprocedural conduction disorders occur. Damage to the AV node, the

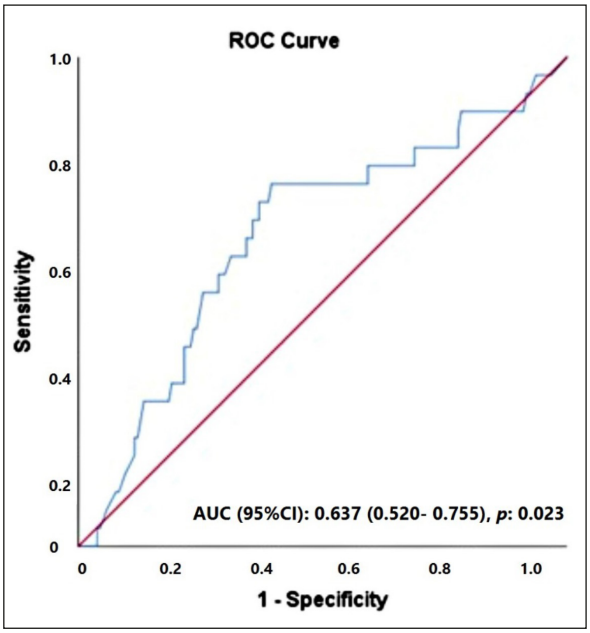

Figure 3. ROC analysis to determine the optimal frontal QRS-T angle cut-off value for postprocedural PPM prediction.

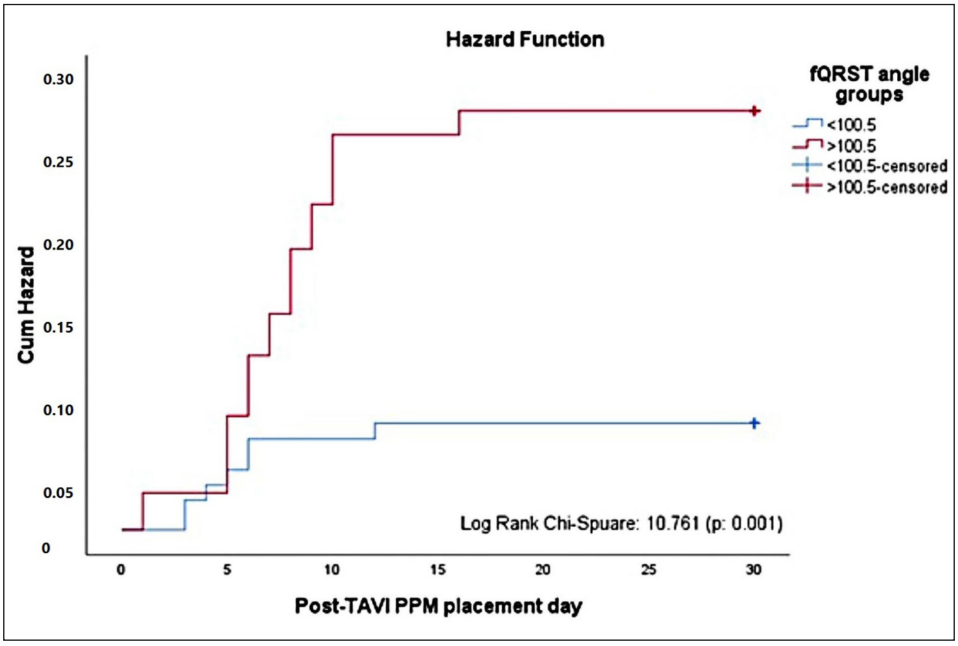

Figure 4. Kaplan-Meier event rates of fQRS-Ta groups.

His, and the infra-His system has been shown in electrophysiological investigations conducted following TAVI[21]. In essence, the conduction system suffers mechanical trauma during the procedure due to three main causes. These are the size and type of valve chosen, the size of the balloon used for pre- and post-dilatation, and the depth and strategy of implantation.

In a meta-analysis by Mahajan et al[18], it was found that implantation of a self-expandable valve was associated with a 3.47-fold increased risk of PPM implantation compared with the balloon-expandable valve. Also, higher rates of PPM implantation after TAVI are associated with larger valve size/annulus diameter (1.14-fold) and deeper implantation (1.24-fold)[18]. Another meta-analysis by Abu Rmilah et al[19] revealed that when a self-expandable valve was implanted, the risk of PPM implantation was 2.4 times higher than when a balloon-expandable valve was used. Additionally, increasing annulus diameter and implantation depth are associated with higher rates of PPM implantation after TAVI[19]. In this study, using univariable analysis, we found that the valve type (self-expandable *vs*. balloon-expandable) and valve size were associated with an increased risk of a need for PPM. However, in multivariable analysis, they were not found to be independent risk factors for a PPM. This could be due to the relatively small number of patients included in this study.

Demographic risk factors such as age and gender have been linked to a requirement for PPM after TAVI[18,19]. Fadahunsi et al[22] found that age was an independent risk factor for PPM need (OR: 1.07; $p < 0.05$, per 5-year increment). Mahajan et al[18,] in their meta-analysis, also reported that age was an independent risk factor for a need for PPM (OR: 1.15; $p < 0.05$, per one unit increase). Similarly, Abu Rmilah et al[19], found that an age ≥80 years was independently associated with an increased risk for a need for PPM (OR: 1.07; $p < 0.05$). In line with previous research[18-19,22], we found that age was an independent risk factor for the need for PPM (OR: 1.071; $p < 0.05$) in this study.

The predictive value of baseline ECG characteristics for the requirement for a PPM has been investigated in many studies[8,18,19]. Baseline electrocardiographic changes, including first-degree AV block, left anterior hemiblock, and RBBB, were significantly associated with the requirement for PPM implantation. There is no information regarding the predictive value of the fQRS-Ta for the requirement for a PPM in the literature. However, the prognostic value of fQRS-Ta and its association with mortality have been demonstrated in patients with congestive heart failure, coronary artery disease, and severe AS undergoing transcatheter aortic valve replacement therapy[13-17]. The relationship between the fQRS-Ta and the requirement for a PPM after TAVI has never been

studied before. This is the first study investigating the predictive value of the baseline fQRS-Ta for the requirement for a PPM after TAVI. We found that baseline fQRS-Ta was an independent risk factor for the requirement for PPM (OR: 2.509; p <0.05) in this study.

Limitations

There are some limitations in our study. First, this is a retrospective study from a single center. Second, a relatively small sample population was enrolled in this study to clarify the relationship between fQRS-Ta parameters and post-TAVI PPM implantation probability due to malignant bradyarrhythmias in patients undergoing TAVI procedure.

Conclusions

This study demonstrated that age and baseline fQRS-Ta were independent predictors of PPM requirements after TAVI in patients with aortic stenosis. Large multicenter prospective studies are needed to clarify the exact pathophysiological mechanism and relationship between this parameter on the ECG and the probability of PPM need in TAVI patients.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Ethics Approval

The study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the Clinical Research Ethics Committee of Health Sciences University Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training Research Hospital (Approval No.: 2017/04).

Informed Consent

All patients provided written informed consent.

Informed Consent

Not applicable due to the retrospective nature of the study.

Authors' Contributions

Concept - ST, EY; Design - ST, EY; Supervision - ST; Resources - ST, EY; Materials - ST, EY; Data Collection and/or Processing - ST, EY; Analysis and/or Interpretation - ST, EY; Literature Search - ST, EY; Writing Manuscript - ST, EY; Critical Review - ST, EY.

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Availability of Data and Materials

Data are available upon request to the corresponding author.

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