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Fluoroscopic predictors of acceptable capture threshold during the implantation of the micra transcatheter pacing system

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Abstract

Introduction: Few predictors of low capture threshold before the deployment of the Micra transcatheter pacing system (Micra TPS) have been determined. We aimed to identify fluoroscopic predictors of an acceptable capture threshold before Micra TPS deployment.

Methods: Sixty patients were successfully implanted with Micra TPS. Before deployment, gooseneck appearance of the catheter shaft was quantified using the angle between the tangent line of the shaft and the cup during diastole in the right anterior oblique (RAO) view. The direction of the device cup toward the ventricular septum was evaluated using the angle between the cup and the horizontal plane in the left anterior oblique (LAO) view.

Results: Of the 95 deployments we evaluated, 56 achieved an acceptable capture threshold of ≤2.0 V at 0.24 ms. In this acceptable threshold group, the deflection angle of the gooseneck shaft was significantly larger and the device cup was placed more horizontally with a lower elevation angle compared with those in the high threshold group. A deflection angle of ≥6° and an elevation angle of ≤30° were identified as the predictors of an acceptable capture threshold after deployment. An acceptable capture threshold was achieved in 24/31 (77.4%) patients in whom either angle criterion was satisfied at the first deployment.

Conclusions: Diastolic gooseneck appearance of the delivery catheter in the RAO view or near-horizontal direction in the LAO view predicts an acceptable capture threshold after deployment. The shape of the delivery catheter before deployment should be evaluated using multiple fluoroscopic views to ensure successful implantation of Micra TPS.

KEYWORDS
capture threshold, fluoroscopic view, gooseneck appearance, leadless pacemaker, pacemaker implantation

1 | INTRODUCTION

The Micra transcatheter pacing system (Micra TPS; Medtronic) was introduced to reduce the complications associated with the transvenous pacing lead system.[1–3] Although the safety and feasibility of the Micra TPS have been reported, cardiac perforation remains a major complication of this new technology. Deployment to the apex was recommended in the IDE study.[2] However, it was altered to the right ventricular (RV) septum in the post-approval registry, resulting in a reduction in the incidence of cardiac injury.[3]

The number of Micra TPS deployments is related to the incidence of cardiac injury.[4] The main reasons for multiple attempts are a high capture threshold and unstable fixation. The capture threshold cannot be measured before deployment. The contact force toward the myocardium is regarded as an important factor in achieving an acceptable capture threshold. A gooseneck appearance of the delivery catheter, which probably implies sufficient contact force, is recommended for successful deployment.[5] However, the degree of gooseneck appearance and other angiographic markers for an acceptable capture threshold before deployment remain unclear.

We hypothesized that the deflection and direction of the delivery catheter before deployment may predict an acceptable capture threshold after fixation.

2 | METHODS

This study was a single-center, retrospective, observational registry-based study. The study protocol was approved by the local institutional review committee. Overall, 60 consecutive patients with a Class I or Class IIa indication for pacemaker implantation who underwent Micra TPS implantation between March 2014 and November 2020 were included. Saved fluoroscopic images of multiple views and the electrical parameters, such as pacing impedance, intracardiac ventricular amplitude, and capture threshold that were measured at least 5 min after deployment were evaluated. A previous study indicated that pacing capture threshold of >2.0 V at 0.24 ms at implantation was associated with a high capture threshold at 6 months.[6] Therefore, in the present study, the acceptable capture threshold was defined as ≤2.0 V at 0.24 ms and a high capture threshold as >2.0 V. An unstable fixation held with <2 tines was also regarded as a high capture threshold.

The need for informed consent for inclusion in the study was waived because the analysis used anonymous clinical data obtained after the patients consented for the procedures. We used the opt-out method for consent using the poster described later. The poster was approved by our institutional review committee.

2.1 | Implant procedure

Micra TPS implantation procedures have been described previously.[5] Briefly, the procedure was performed under mild sedation and local anesthesia. The femoral vein was punctured under ultrasound guidance, and the Micra introducer (outer diameter, 27 Fr; inner diameter, 23 Fr) was inserted into the right atrium using a stiff guidewire. The deflectable delivery catheter, in which the device was mounted, was advanced into the apex of the RV. The puff of the contrast media through the delivery catheter was used to visualize the RV border. The direction and curve of the delivery catheter were evaluated using two fluoroscopic views before deployment. The perpendicular direction of the device cup to the RV septum was estimated in the left anterior oblique (LAO) view at an angle of 35°. The gooseneck appearance of the catheter shaft was evaluated in the right anterior oblique (RAO) view at an angle of 30°. Micra TPS was affixed to the myocardium using four flexible nitinol tines. After confirming that at least two tines were engaged in the pull-and-hold test, the electrical parameters were repeatedly measured during the procedure. If the capture threshold after 5 min was >2.0 V at 0.24 ms, it was repositioned. Finally, the tether was cut, and the delivery system was removed. A figure-eight femoral suture was used and was removed the next day.

2.2 | Analysis of the deflection and direction of the delivery catheter

The direction and deflection of the delivery catheter before deployment were analyzed using the saved LAO and RAO images. The direction of the device cup toward the ventricular septum was evaluated using the LAO view. The elevation angle was measured between the device cup and the horizontal line (Figure 1A). The deflection angle of the gooseneck shaft was defined as the angle between the axis of the device cup and a tangential line connecting the curved catheter shaft to the device cup during diastole in the RAO view (Figure 1B). Implantation sites were classified into three locations: right ventricular outflow tract (RVOT), mid-septum, and apical septum in the RAO view (Figure 1C). The RVOT was defined as the area above the tricuspid annulus. The RV septum was divided into three parts using vertical lines. The apical third was determined as the apical septum, and the middle third was defined as the mid-septum.

2.3 | Statistical analysis

Continuous variables were presented as mean ± standard deviation, while categorical data were presented as the actual number or percentage. The Student t test and the Mann Whitney U test were used to compare continuous variables, whereas the chi-square test was used to compare categorical variables. A receive-operator characteristic (ROC) curve analysis was used to determine the optimal values at implantation for predicting an acceptable pacing capture threshold. All statistical analyses were performed using EZR v1.52 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R v3.4.1 (The R Foundation for Statistical Computing).
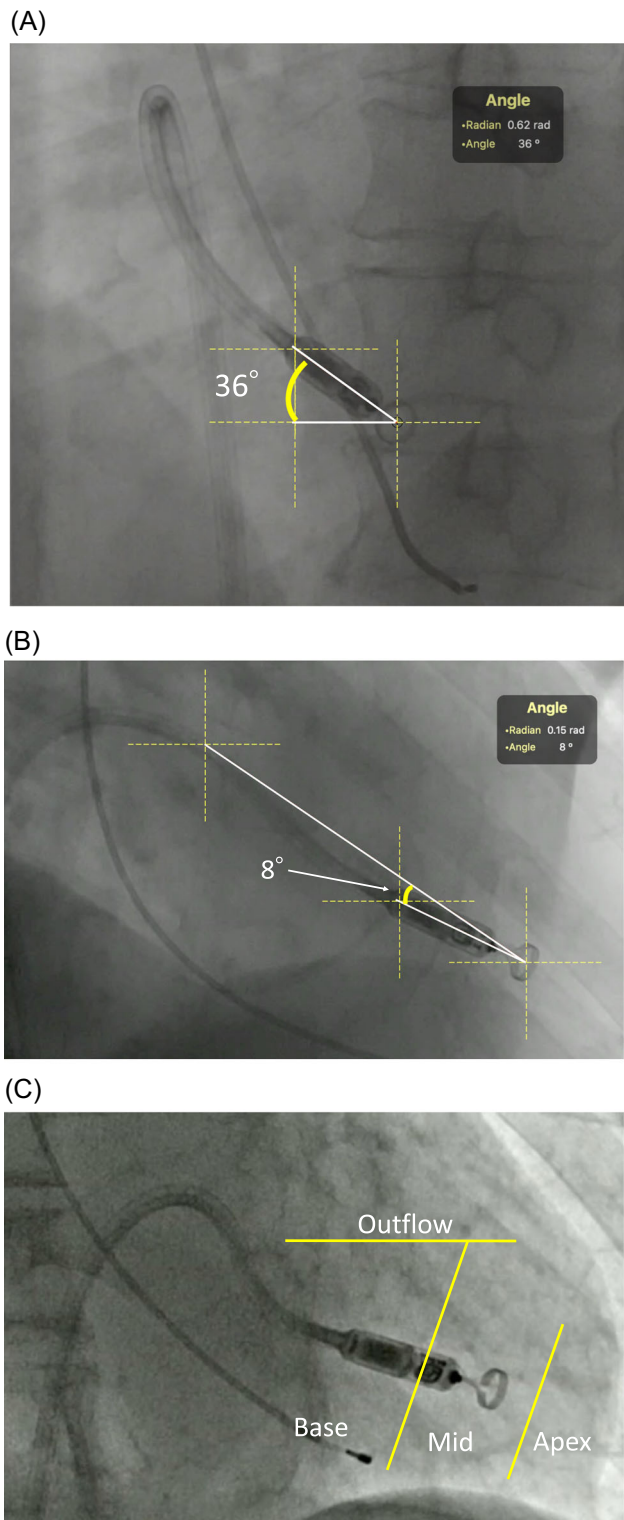
FIGURE 1 Fluoroscopic images during the right ventricle (RV) septal implantation of the Micra transcatheter pacing system. (A) The elevation angle between the device cup and the horizontal line measured in the LAO view is 36°. (B) The deflection angle between the axis of the device cup and the tangential line connecting the device cup to the curve of the catheter shaft during diastole measured in the RAO view is 8°. The gooseneck appearance of the delivery catheter is usually observed at good forward pressure against the myocardium. (C) The device cup locations at the RV septum were classified into three locations: right ventricular outflow tract (RVOT), mid-septum, and apical septum in the RAO view. LAO, left anterior oblique; RAO, right anterior oblique

3 | RESULTS

3.1 | Patients

The clinical characteristics of the 60 patients who underwent implantation with Micra TPS are shown in Table 1. The mean age was 80 ± 9 years, and 36 (60%) patients were male. The mean body mass index was $21.8 \pm 3.3 \, kg/m^2$. Congestive heart failure and coronary artery disease were recorded in 18 (30%) and 10 (17%) patients, respectively. The mean left ventricular ejection fraction was $63.0 \pm 7.6\%$.

The indications for pacemaker implantation were sinus node dysfunction in 33 (55%) patients and atrioventricular (AV) block in 27 (45%) patients. Forty-five patients (75%) had bradycardia related to atrial fibrillation (AF): bradycardia-tachycardia syndrome ($n = 28$), persistent AF with AV block ($n = 12$), and AV block during paroxysmal AF ($n = 5$).

3.2 | Implantation procedures and electrical measurements

A total of 104 deployments (1.7 per patient; median: 1) were performed in 60 patients (Figure 2). The final position of the device was achieved after one, two, three, and four attempts in 53% ($n = 32$), 27% ($n = 16$), 13% ($n = 8$), and 7% ($n = 4$) of the patients, respectively. Recapturing and repositioning was required in 44 deployments in 28 patients due to high pacing thresholds (32 deployment; mean capture threshold before recapturing: 3.9 ± 3.0 V at 0.24 ms), unstable fixation (10 deployments), and complaint of chest pain upon deployment at the tip of the cardiac apex (2 deployments). Final measurements were pacing impedance of $712 \pm 213 \, \Omega$, intracardiac ventricular amplitude of 7.9 ± 4.8 mV, and capture threshold of 0.72 ± 0.51 V at 0.24 ms. In two patients, the final capture threshold was >2.0 V at 0.24 ms after the third deployment; however, a reposition was not attempted due to the multiple risk factors for cardiac injury and the patients were anticipated to be nonpacer dependent. Micra TPS was placed at the apical septum in 29 patients, mid-septum in 29 patients, and RVOT in 2 patients. No major complications, including device dislodgement or cardiac tamponade, were observed.

3.3 | Deflection and direction of the delivery catheter

The deflection and direction of the delivery catheter before deployment were evaluated. Nine deployments were excluded from the analysis as the reason for repositioning was believed to be unrelated to the deflection and direction of the delivery catheter in seven deployments (two cases of thrombus formation, two cases of pain during deployment, two unstable fixations due to inappropriate catheter manipulation, and one case of unstable fixation probably due to an interaction with the tricuspid subvalvular apparatus). Two deployments at the RVOT were excluded from the analysis.

TABLE 1 Baseline characteristics

Age (years)	80 ± 9
Male	36 (60%)
BMI (kg/m²)	21.8 ± 3.3
LVEF (%)	63.0 ± 7.6
Indication for implant	
SND	33 (55%)
AV block	27 (45%)
Atrial fibrillation	45 (75%)
BTS	28
Persistent AF	12
AV block with PAF	5
Comorbidity	
Hypertension	40 (67%)
Diabetes mellitus	21 (35%)
Myocardial infarction	3 (5%)
Congestive heart failure	18 (30%)
Coronary artery disease	10 (17%)
Valvular heart disease	13 (22%)
Chronic kidney disease	25 (42%)
COPD	3 (5%)
Cerebral infarction	15 (25%)

Note: Values are presented as *n* (%) or mean ± standard deviation.

Abbreviations: AF, atrial fibrillation; AV, atrioventricular; BMI, body mass index; BTS, bradycardia-tachycardia syndrome; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; PAF, paroxysmal atrial fibrillation; SND, sinus node dysfunction.

In total, 95 deployments were evaluated and divided into two groups: acceptable (*n* = 56) and high capture threshold (*n* = 39). The parameters and device locations were compared between the two groups (Table 2). In the acceptable threshold group, the delivery catheter exhibited a stronger "gooseneck" appearance in the RAO view and a near-horizontal direction in the LAO view. During diastole, the deflection angle of the acceptable threshold group was significantly larger than that of the high threshold group (7.4 ± 5.0° vs. 4.5 ± 4.3°, respectively; *p* = 0.005). In the LAO view, the elevation angle of the acceptable threshold group was significantly smaller than that of the high threshold group (30 ± 21° vs. 40 ± 16°, respectively; *p* = 0.01), thus suggesting more vertical contact against the septum in the acceptable threshold group. The pacing impedance of the acceptable threshold group was significantly higher than that of the high threshold group (722 ± 202 Ω vs. 614 ± 116 Ω, respectively; *p* = 0.04).

The ROC curve analysis showed that a deflection angle of ≥6° during diastole was a cut-off value for an acceptable threshold with a sensitivity of 0.61 and specificity of 0.69 (Figure 3). An elevation angle of ≤30° was an optimal value with a sensitivity of 0.57 and specificity of 0.72. Thus, the gooseneck appearance during diastole in the RAO view or the near-horizontal direction of the delivery catheter in the LAO view may predict an acceptable capture threshold after deployment.

3.4 | Analysis of the deflection and direction of the delivery catheter at first deployment

In 31/57 first deployments, either criterion of a deflection angle ≥6° or an elevation angle ≤30° was satisfied. In 24 (77.4%) of these, an acceptable capture threshold was achieved. This rate was
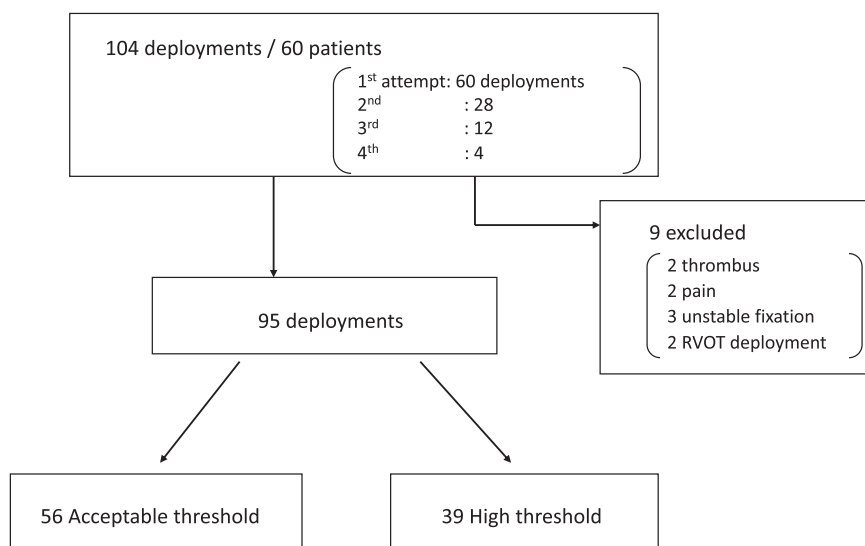

FIGURE 2 Details of the deployments. A total of 104 deployments were performed in 60 patients. Nine deployments were excluded from the analysis because of various reasons and unusual locations of the Micra transcatheter pacing system. Of the remaining 95 deployments, 56 achieved at an acceptable capture threshold, while 39 had high capture thresholds

significantly higher than that in the other 26 first deployments in which neither criterion was satisfied (30.8%, $p < 0.001$). The sensitivity and specificity of either angle criterion for predicting an acceptable capture threshold were 0.75 and 0.72, respectively.

TABLE 2 Comparison of parameters and the locations between the acceptable threshold and the high threshold groups

	Acceptable threshold (N = 56)	High threshold (N = 39)	p value
Deflection angle in the RAO view (°)	7.4 ± 5.0	4.5 ± 4.3	0.005
Elevation angle in the LAO view (°)	30 ± 21	40 ± 16	0.01
Site of deployment			
Apical septum	28 (50%)	27 (69%)	
Mid-septum	28 (50%)	12 (31%)	
Electric parameter			
Impedance (Ω)	722 ± 202	614 ± 116	0.04
Amplitude (mV)	7.4 ± 5.1	5.2 ± 2.6	0.05
Threshold (V/0.24 ms)	1.03 ± 0.70	3.90 ± 3.04	<0.001

Note: Values are presented as *n* (%) or mean ± standard deviation.
Abbreviations: LAO, left anterior oblique; RAO, right anterior oblique.

3.5 | Pacing capture threshold during follow-up periods

At 1 month after implantation, an acceptable capture threshold of ≤2.0 V at 0.24 ms was maintained in all patients, and all electrical parameters remained stable (pacing impedance: 604 ± 152 Ω, intracardiac ventricular amplitude: 9.7 ± 4.9 mV, and capture threshold: 0.62 ± 0.32 V at 0.24 ms). In two patients with an initial high capture threshold at implantation, the capture threshold decreased to <2.0 V at 0.24 ms. The average follow-up period was 33.4 ± 26.1 months (median, 29 months; range: 1–87 months). At the final measurement, the capture threshold was 0.60 ± 0.23 V at 0.24 ms. No patient underwent pacemaker reimplantation due to an elevated capture threshold.

4 | DISCUSSION

We analyzed angiographic markers, such as the deflection and the direction of the delivery catheter to predict acceptable capture threshold before the deployment of Micra TPS. Our main findings are as follows:

1. In the acceptable capture threshold group, the delivery catheter exhibited a stronger "gooseneck" appearance during the diastolic phase in the RAO view and a near-horizontal direction in the LAO view, compared to those in the high threshold group.
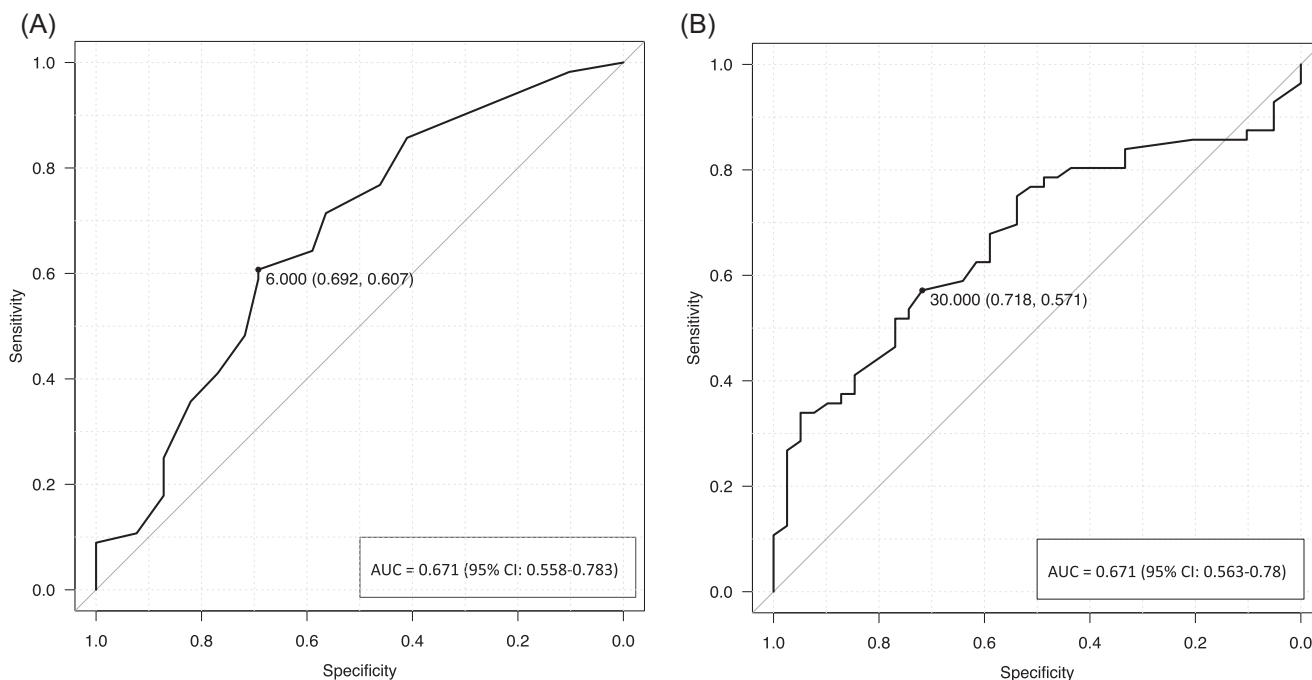

FIGURE 3 Receiver-operating characteristic curves of the angles in RAO and LAO views. (A) A stronger gooseneck appearance of the delivery catheter in RAO during diastole, the deflection angle ≥6° between the device and the catheter, was related to an acceptable threshold with a specificity of 0.69 and sensitivity of 0.61. (B) A near-horizontal direction of the delivery catheter in LAO, the elevation angle of ≤30° between the device and the catheter, was related to an acceptable threshold with a specificity of 0.72 and sensitivity of 0.57. AUC, area under curve; CI, confidence interval; LAO, left anterior oblique; RAO, right anterior oblique

2. A deflection angle ≥6° and an elevation angle ≤30° were determined to be predictors of an acceptable capture threshold after deployment. Either angle criterion was satisfied at the first deployment in 31 patients; among them, an acceptable capture threshold was achieved in 24 (77.4%) patients. The achievement rate of an acceptable threshold was significantly greater than that in the remaining patients in whom neither criterion was satisfied (30.8%).

Cardiac injury remains a major complication of Micra TPS implantation and may require surgical intervention in almost 20% of patients.[7] Several risk factors for cardiac injury have been identified, including older age, female sex, low body mass index, congestive heart failure, chronic lung disease, and non-AF indications.[2,3] The number of risk factors in a patient is directly proportional to the risk of cardiac injury.[4] Japanese patients have been reported to have more risk factors than non-Japanese patients.[8] The median number of risk factors was found to be two in Japanese patients who underwent implantation with Micra TPS.[8] To minimize the risk of cardiac injury, the number of deployments should be kept low because more deployments in high-risk patients significantly increase the incidence of cardiac injury.[4]

One of the main reasons for multiple attempts is a high capture threshold. However, the capture threshold cannot be estimated before deployment. Therefore, we aimed to identify the predictors of an acceptable capture threshold before deployment. It should be noted that the deflection and direction of the delivery catheter before deployment may predict an acceptable capture threshold after fixation. We demonstrated that an acceptable capture threshold was achieved in 77.4% of attempts if either criterion was fulfilled. The angle criteria in multiple views before deployment can help reduce the incidence of cardiac injury.

A "gooseneck" appearance of the delivery catheter probably implies sufficient contact force, and is, therefore, recommended for successful deployment.[5] A larger deflection angle indicates a greater contact force with the myocardium. In this study, the delivery catheter exhibited a stronger "gooseneck" appearance in not only the systolic but also the diastolic phase and was associated with an acceptable capture threshold after deployment of the Micra TPS. It should be noted that a near-horizontal direction of the delivery catheter also indicates good contact with the myocardium. Previously, a delivery catheter presenting a halo shape in the LAO view was reported to suggest good contact, which can result in an acceptable threshold.[9] The halo shape of the delivery catheter implied a near-horizontal direction toward the RV septum.

The pacing impedance after fixation has been reported to be associated with the capture threshold during the follow-up period.[10–12] Kiani et al.[10] showed that a pacing impedance of <800 Ω at implantation was related to an elevated capture threshold at 12 months. Other reports have identified a pacing impedance at implantation of >600 Ω or 660 Ω as a predictor of an acceptable threshold.[11,12] The low impedance may indicate a poor contact of the Micra TPS with the myocardium. In the present study, pacing impedance was significantly higher in the acceptable threshold group than that in the high threshold group. These results also suggest the importance of the contact force for an acceptable capture threshold.

Previous reports have shown that the capture threshold tends to decrease over time after implantation in most cases. Half of the patients with capture threshold >2.0 V at 0.24 ms did not demonstrate a decrease in the pacing capture threshold,[6] whereas Piccini et al.[6] reported that an implant capture threshold of approximately 1.5 V at 0.24 ms decreased to <1.0 V at 0.24 ms in 80% of patients at 6 months after implantation. One of the reasons for the improvement in the capture threshold might be the resolution of local tissue injury induced by the tines. Predictors of an acceptable long-term capture threshold have not been identified. In this study, predictors of chronic acceptable capture threshold could not be evaluated because the acceptable capture threshold was maintained in all patients during the follow-up.

Therefore, the shape of the delivery catheter should be evaluated using multiple fluoroscopic views to achieve an acceptable threshold and reduce the number of deployments, thus resulting in successful deployment.

4.1 | Limitations

This was a retrospective, single-center, observational study. The sample size was small. Larger multicenter studies are needed to establish the cut-off for the angles of the delivery catheter and confirm our results. The acceptable capture threshold was defined as ≤2.0 V at 0.24 ms in this study. Proper deflection and elevation angle can change depending on the definition of acceptable capture threshold. We could not measure the angles using our fluoroscopic system during implantation. We will need to assess the septal orientation and tissue contact using RAO and LAO angles before the deployment. The capture threshold can be affected by local myocardial injury. In our study, most patients had a preserved ejection fraction, and only 5% of the patients had myocardial infarction. Local fibrosis may have affected the capture threshold in patients with cardiomyopathy. The direction of the device cup toward the ventricular septum was estimated using the horizontal angle in the LAO view because the septal surface was only confirmed using the local puff of the contrast and not right ventriculogram. We did not evaluate deployments at sites other than the septum and excluded two RVOT deployments from the analysis. The delivery catheter might be less curved during RVOT deployment.

5 | CONCLUSION

The gooseneck appearance during diastole in the RAO view and the horizontal direction of the delivery catheter in the LAO view may predict an acceptable capture threshold. The shape of the delivery catheter should be evaluated using multiple fluoroscopic views to ensure successful implantation of the Micra TPS.

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