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ORIGINAL ARTICLE

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Individualized left anterior oblique projection based on pigtail catheter visualization facilitates leadless pacemaker implantation

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Abstract

Background: Pacemaker positioning on the right ventricular (RV) septum during implantation is conventionally conducted utilizing two fixed fluoroscopy angles, a 45° left anterior oblique (LAO) and 35° right anterior oblique projection. However, placement location can be suboptimal, especially for leadless pacemakers (LPMs).

Objective: To evaluate the safety and ease of LPM implantation using individualized LAO projection.

Methods: Consecutive patients undergoing LPM implantation were prospectively included. The angle of the RV septum was recorded for each patient by studying the angle at which an RV pigtail catheter (RV-PC) could be seen edge on. This was then used as the preferred LAO projection angle for that patient. We evaluated the success rate and safety of this method. We also compared the RV septum angle as measured by this method versus that measured by chest CT.

Results: Of the 31 patients (mean age 80.6 ± 7.0 years, 15 females), LPM implantation was successful in 30. The pacemaker was implanted on the RV septum in 29 and on the free wall in one. LPM implantation was abandoned for anatomical reasons in one. Complications were limited to a groin arteriovenous fistula and one deep vein thrombosis. The angle of RV septum as measured by pigtail catheter and chest CT was not significantly different (CT: 54.8 ± 6.0°, RV pigtail catheter: 52.9 ± 6.1°, $P = .07$).

Conclusions: Using an RV-PC to determine the preferred angle of LAO projection facilitates differentiation between the RV septum and free wall, which in turn facilitates optimal LPM placement.

KEYWORDS

individualized LAO projection, leadless pacemaker, right ventricular pigtail catheter

Abbreviations: LAO, left anterior oblique; LPM, leadless pacemaker; RV, right ventricular; RV-PC, right ventricular pigtail catheter.

1 | INTRODUCTION

Pacemaker therapy is a well-established and safe treatment for bradycardic heart disease. Pacemaker implantation on the right ventricular (RV) septum is now standard practice because it carries less risk of acute cardiac perforation and tamponade, and decreases the incidence of delayed pacing-induced cardiomyopathy compared with nonseptal positions.[1]

The left anterior oblique (LAO) projection of 40-45° is the most commonly used angle to locate the interventricular septum. It is believed that this angle best captures the septum in profile. However, some studies have questioned and demonstrated the unreliability of classical fluoroscopic projection criteria,[2-4] and one study has gone so far as to recommend adjusting the angle of LAO projection for each patient to increase accuracy.[5] Leadless pacemakers (LPMs), in particular, have been frequently found to be implanted on the RV free wall upon postoperative evaluation by ultrasound.[6] Currently, there is no established method of employing fluoroscopy for LPM implantation on the RV septum. The goal of our study was to assess whether the use of an RV pigtail catheter (RV-PC) (Figure 1) to guide the determination of the best angle of LAO projection for LPM implantation was advantageous and safe.

2 | METHODS

2.1 | Study population

We prospectively enrolled 31 consecutive patients who underwent implantation of LPMs (Micra™, Medtronic, US) from October 2018 to April 2020 at our institution. This study was approved by the institutional ethics committee. The study complied with the Declaration of Helsinki.

The indications for LPMs at our institution were elderly patients with (i) permanent atrial fibrillation with bradycardia, (ii) long pauses after termination of paroxysmal atrial fibrillation, or (iii) paroxysmal complete AVB.

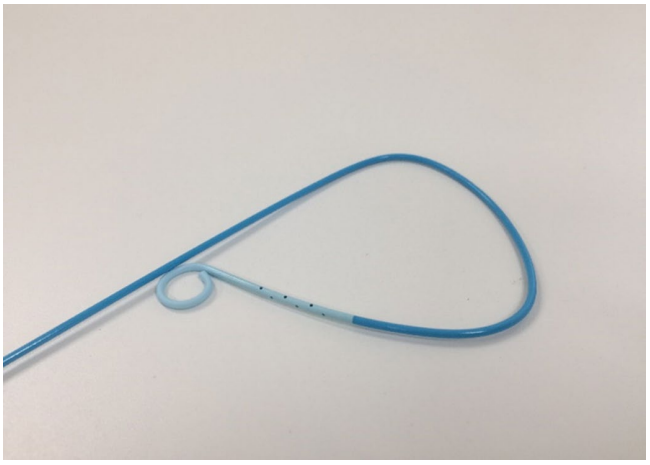

FIGURE 1 Right ventricular pigtail catheter. There is one hole at the tip and 12 holes around the distal side of the shaft of the catheter for contrast medium delivery

2.2 | Implantation procedure

The LPMs were implanted using the following methods. Access was obtained from the right femoral vein with a 25 cm 8-Fr sheath. Contrast medium was injected to inspect contours of the right heart. After obtaining the venogram, a stiff guide wire (Amplatz Extra Stiff guide wire, Cook Medical) was guided into the super vena cava (SVC). A 5Fr RV-PC (Nishiya SoftNAV catheter, Technowood, Tokyo, Japan) was introduced from the same sheath with a wire in it, and the tip of the RV-PC was advanced to the SVC. As soon as the wire was withdrawn and the RV-PC was slightly retracted, the RV-PC attempted to return to its original shape, making it easier to place the RV-PC tip near the RV apex. Individualized LAO projection was used to determine the angle of RV septum in each patient. The angle was defined as the LAO angle that allowed the perfect overlapping of the RV-PC body in the inferior vena cava (IVC) and the RV-PC tip in the RV apex, while the RV-PC shaft was in contact with the RV septum. This provided a true edge on view of the RV septum and indicated the route of the delivery catheter (Figure 2). Then, contrast medium was injected from the RV-PC tip to confirm the inner contours of the right ventricle including septum, apex, and inferior free wall (Figure 3). These images (LAO and RAO projections) were saved and used as references during the implantation procedure. After removing the RV-PC, the 8-Fr sheath was removed and replaced with an exclusive 23-Fr hydrophilic material coated sheath over the stiff wire under fluoroscopic guidance. The tip of the sheath was positioned at the junction of the right atrium and IVC. Then, a delivery catheter mounted with an LPM was inserted via the 23-Fr sheath and its tip was manipulated into the right ventricle. After adjusting the bi-plane fluoroscopy to the 35° RAO and individualized LAO views, the catheter tip was pushed onto the RV septum until the catheter shaft formed a “gooseneck” shape in the right cardiac cavity. If an optimal location was confirmed by injecting contrast medium via the delivery catheter, the LPM was deployed and then the electrical parameters were checked to determine whether to sever the connecting tether or not. If the parameters were suboptimal, the LPM was retracted from the cardiac muscle and implantation was attempted again. After successful implantation was achieved, the system was withdrawn, and the puncture region in the groin was sutured. Transthoracic echocardiography (TTE) was repeatedly performed to detect any postprocedural pericardial effusions.

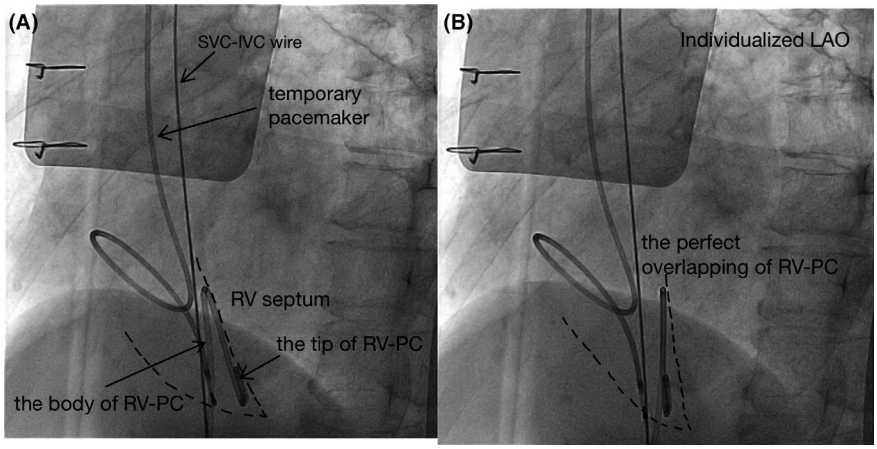

FIGURE 2 Individualized LAO determination method. (A) The RV pigtail catheter (RV-PC) tip is positioned so that it is in contact with the RV septum. The body and tip of the RV-PC are visible and distinguishable in this left anterior oblique (LAO) projection angle. (B) The angle of the X-ray generator arm is then adjusted so that the RV-PC body in the inferior vena cava (IVC) and the tip in the RV apex overlap completely. The LAO angle at which this occurs is recorded. SVC, superior vena cava

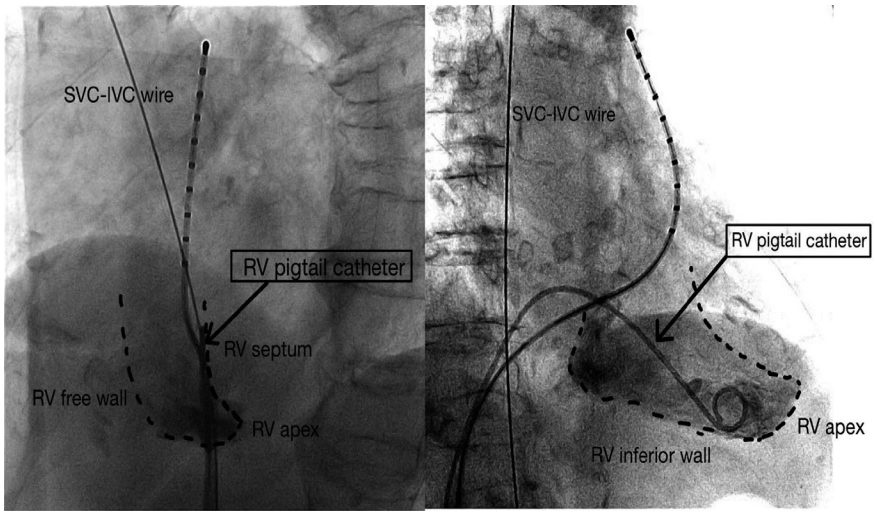

FIGURE 3 Images during right ventricular fluoroscopy. Left panel: Individualized LAO view. An example of an individualized LAO projection with the tip of the LPM pointing to the right, along the RV septum, suggesting RV septal position. The dotted line outlines the RV cavity. Right panel: RAO 35° view. RV ventriculography with an RV-PC shows the inner contours of the apex and inferior wall. LAO, left anterior oblique; RAO, right anterior oblique; RV, right ventricular; RV-PC, right ventricular pigtail catheter

2.3 | RVS angle measured by CT

We compared the RV septum angle (RVS angle) measured using the RV-PC with that measured by preprocedural multidetector row computed tomography (MDCT).

2.4 | Location of the LPM

The RAO view was used to determine the region where the device was implanted. The individualized LAO was further used to distinguish the free wall from the septum. Images obtained postoperatively by TTE or MDCT were evaluated to recognize the location of the implanted LPM. The location of the device was ascertained by two independent observers blinded to the procedures.

We calculated the peak deflection index (PDI) in lead V1 as an objective way to confirm whether the LPMs were implanted at the septum.[6]

2.5 | Postprocedural care and follow-up

The first outpatient clinic visit was 1 week after the procedure. Subsequent follow-up visits consisted of a clinical interview, check of electrical measurements from the device, and TTE as needed, at our cardiology clinic.

2.6 | Statistical analysis

All statistical analyses were performed using PASW Statistics 18 software. Continuous data are expressed as mean ± SD for normally and non-normally distributed variables, and were compared using Student's *t*-test or Mann-Whitney *U*-test, respectively. Categorical variables were compared using the chi-squared or Fisher's exact test. Statistical significance was established at $P < .05$.

3 | RESULTS

3.1 | Patient characteristics and implantation procedures

We enrolled 31 consecutive patients (mean age, 80.6 ± 7.0 years; 15 females) who underwent implantations of LPMs (Micra™, Medtronic, USA) from October 2018 to April 2020 at our single institution. Patient characteristics are summarized in Table 1. The patients were

of small stature and of slight build on average with mean height and BMI of 156.7 ± 8.4 cm and 21.1 ± 3.2 kg/m^2, respectively. Chronic lung disease was seen in 19.4%.

Contrast medium was used to check for possible stenosis along the access route from the inguinal area to the RV, to confirm RV contours using the RV-PC, and testing before pacemaker implantation. Total contrast medium used was 10 to 20 cc. The fluoroscopic time was about 11 minutes.

3.2 | Outcomes and complications

Thirty (96.8%) of the 31 patients successfully received implantation of a LPM in the right ventricle. However, one patient had elevated pacing capture threshold the day after the operation. No cases of cardiac tamponade occurred. No life-threating complications occurred. One arteriovenous fistula and one deep vein thrombosis occurred at the right femoral access site within a week after the operation. No complications occurred later than a week after surgery.

3.3 | Difference in the RVS angle as measured by the RV-PC and MDCT

We compared the angle of the RV septum using RV-PC with the angle of the RV septum measured by chest CT. There was no significant difference between the two angles (CT: 54.8 ± 6.0°, RV-PC: 52.9 ± 6.1°, $P = .07$).

TABLE 1 Patient characteristics

	Leadless pacemaker, N = 31
Age, y	80.6 ± 7.0
Female, n (%)	15 (48.4)
Height (cm)	156.7 ± 8.4
Body mass index (kg/m^2)	21.1 ± 3.2
Comorbidity, n (%)	
Hypertension	17 (54.8)
Diabetes mellitus	9 (29.0)
Dyslipidemia	5 (16.1)
Chronic lung disease	6 (19.4)
Chronic heart failure	11 (35.5)
Coronary artery disease	2 (6.5)
Permanent atrial fibrillation	9 (29.0)
Hemodialysis	6 (19.4)
Pacing indication, n (%)	
Sick sinus syndrome	12 (38.8)
Bradycardia atrial fibrillation	6 (19.4)
Atrioventricular block	14 (45.2)
Antiplatelet therapy	8 (25.8)
Anticoagulant therapy	18 (58.1)
Right groin approach	29 (93.5)

3.4 | Localization of the device

The LPM was successfully implanted on the RV septum in 29 patients (Mid-septum: 8, Apical septum: 21). The LPM was implanted on the apical free wall in one case (3.2% of 31). In that patient, the tip of the delivery catheter was directed rightward in the individualized LAO projection, and the LPM location was expected to be in the RV apical septum (Figure 4). However, postprocedural TTE proved that the LPM placement was on the free wall (Figure 5). In one patient, we failed to implant an LPM. That patient was of small stature with a small right ventricle and the delivery catheter could not be directed toward the spine (rightward) at the RV septum. After several attempts, the decision was made to implant a conventional pacemaker to avoid pericardial effusion and perforation.

The PDI in lead V1 in all patients is summarized in Figure 6 as box and whisker plots. The PDI values were mid-septum: 0.415 ± 0.072 (n = 8), apical septum: 0.435 ± 0.061 (n = 21), and free wall: 0.633 (n = 1).

3.5 | Electrical measurements of the device

The mean pacing threshold was within the appropriate range both at implantation (0.8 ± 0.4 V/0.24 ms) and 1 month after the operation (0.7 ± 0.4 V/0.24 ms). One patient had an elevated pacing capture threshold the day after the operation, so the patient subsequently received a conventional pacemaker.

4 | DISCUSSION

To the best of our knowledge, this is the first time an RV-PC has ever been used to determine the angle of the RV septum. We validated the safety and utility of using this angle to individualize LAO fluoroscopy angle for LPM implantation. This method has several advantages over using contrast to determine RV septal location. First, using the RV-PC to determine the preferred angle of the LAO projection facilitates the differentiation between the RV septum and free wall, which in turn facilitates optimal LPM placement. Second, right ventriculography with the RV-PC with a small amount of contrast medium shows more clearly the contour of the RV septum and apex than conventional ventriculography from the right atrium. Third, the shape of the RV-PC fitted well with the angle between the RV and IVC, allowing it to be delivered smoothly to the RV septum and apex. We do, on the other hand, caution against pushing the RV-PC forcibly into the RV apex instead of sliding it against the septum, because doing so often causes the shaft of the RV-PC to detach from the RV septum toward the free wall and have a different angle from the tip.

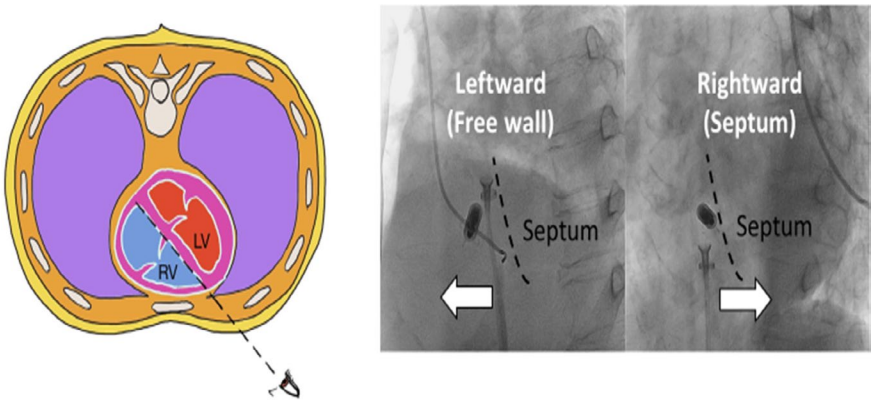

FIGURE 4 Individualized LAO projection applied to an LPM implantation. Left panel: Schematic diagram showing individualized LAO angle. Right panel: Two fluoroscopic images using individualized LAO projection. In the left image, the tines of the LPM are caught in the trabeculae of the right ventricle and angle away from the septum and toward the free wall, whereas in the right image, the tines face the septum

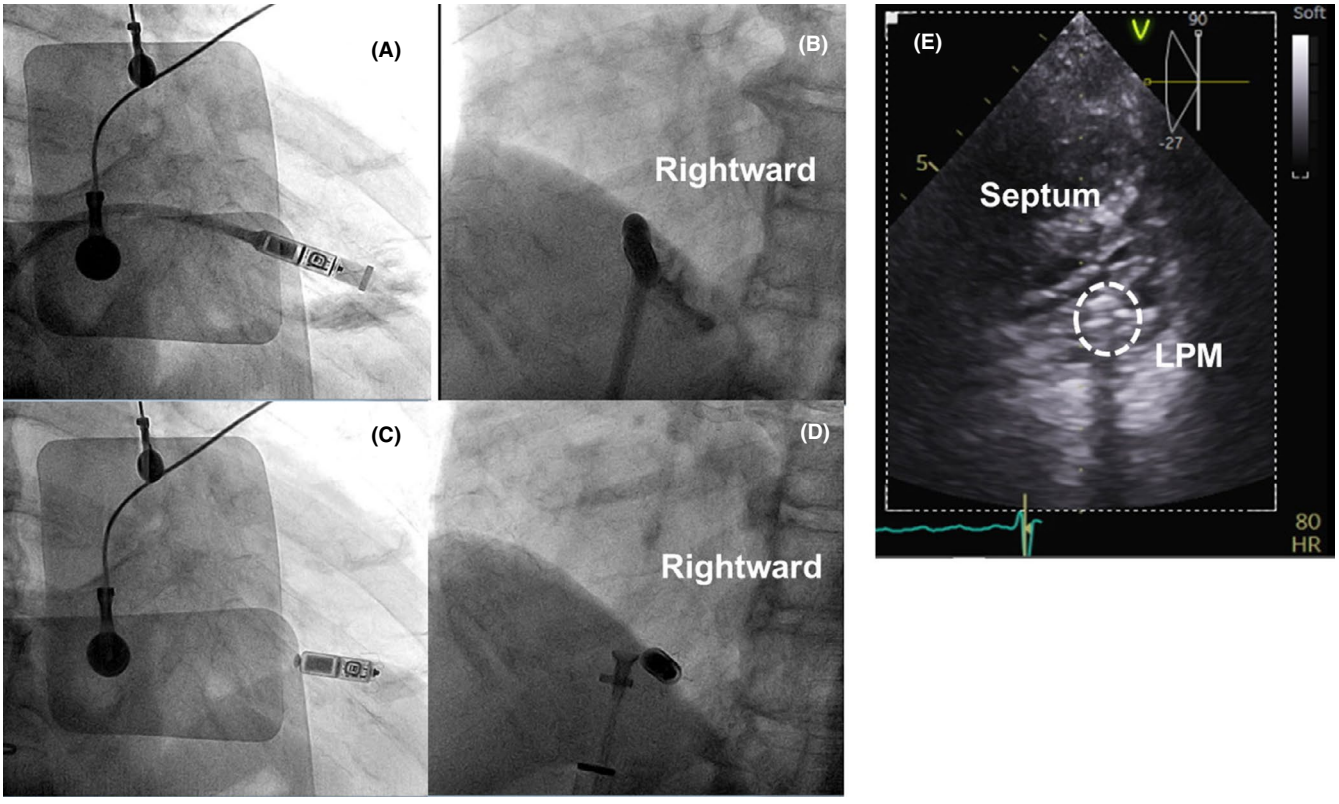

FIGURE 5 Free wall implantation case. During contrast medium injection (A, B). After the deployment of LPMs (C, D). In this case, the target was an apical septal site shown in the fluoroscopic images (A-D). However, the interventricular septum was curved toward the apex of the heart, and the septal wall of the apex and free wall were very close. This led to LPM implantation in the apical free wall, but this was a rare case (E). LAO: left anterior oblique; LV: left ventricle; LPM: leadless pacemaker; RAO: right anterior oblique

We demonstrated feasibility of our procedure. Understanding the anatomy allowed for more accurate device positioning during implantation.

The angle of the RV septum derived from the RV-PC did not differ significantly from the angle derived from the CT. The *P* value for the difference was 0.07, but even if it had been significant, the difference was less than 2°. This result validates our method for determining the optimal LAO projection angle for LPM placement.

The interventricular septum is curved rather than flat, especially near the apex. Compared to targeting the mid-septum, targeting of the apical septum is difficult because the tip of the delivery catheter tends to slip. The position of the tip is difficult to discern with the usual 40-45° LAO projection. Individualized LAO can be useful. Although it has been reported that fluoroscopy from the left lateral view can be used to determine the tip position of the delivery catheter,[7] we believe that a patient-tailored angle is more useful than a preset angle because of patients' anatomical diversity.

The association between the position of the Micra LPM and number of Micra relocations and risk of pericardial bleeding is unknown, as previous large studies have not confirmed even postoperatively the location of the Micra.[8] However, repeated repositioning has been reported to be a risk factor for bleeding complications[9] and it is believed

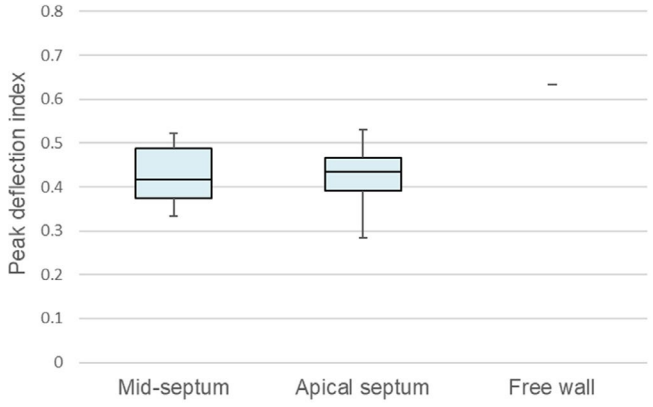

FIGURE 6 Peak deflection index in lead V1

that LPM should not be repositioned even if implantation occurs on the apex or free wall. In the current study, there was one case in which the LPM became implanted on the apical free wall of the heart, but the fixation and threshold were good, and cardiac effusion did not occur. Even in the apex of the heart, if thick trabeculae carneae can be confirmed by RV ventriculography with an RV-PC in advance, there is less concern about applying force to the delivery catheter.

Kajiyama et al reported that the PDI at V1 could be useful for predicting implantations of LPMs on the free wall, and their PDI values were septum: 0.505 ± 0.010, apex: 0.409 ± 0.052, and free wall: 0.617 ± 0.043, $P = .004$. In their data, the best cut-off value of the PDI was 0.571 in lead V1 (sensitivity = 0.875, specificity = 1.000).[6] The PDI in lead V1 was 0.633 in our single case of apical free wall implantation. In our septal implantation cases, the PDI in lead V1 was lower (0.427 ± 0.064) than their proposed cut-off value (Figure 6).

Most of the physicians in this study had previously performed fewer than five LPM implantations, including some who were performing the procedure for the first time. We believe our method of visualizing the RV septum can be particularly useful for doctors who are inexperienced with fluoroscopic visualization. The fluoroscopic time in this study (11 minutes) seemed to be a little longer than that in a previous report[10] (range: 9.8-10.7 minutes).

In addition, physicians can use our method with individualized LAO projection for conventional pacemaker implantation. However, this method requires an additional groin puncture, so the method should be limited to cases with thin ventricular muscle walls or special anatomy, where screw-in leads are used at the RV septum.

5 | STUDY LIMITATIONS

The study was a single-center study and the population was relatively small. Secondly, the follow-up was limited to 3 months. Third, our method may be less accurate for determining actual LPM implantation site in boundary areas such as the tip of the apex or at the hinge between the anterior wall and septum. Fourth, this method uses an additional single RV catheter, so the procedural cost would be somewhat higher. Nevertheless, we believe the advantages of accurate positioning outweigh this extra cost. This is particularly true of patients with atypical anatomy. Finally, our patients were mostly elderly Japanese, many of whom were of small stature and correspondingly smaller hearts. This led to two cases in which we had difficulty implanting LPM onto the RV septum, resulting in implantation onto the free wall in one, and conventional pacemaker placement in another. In patients with larger stature, we believe RV septum implantation success rates could be nearly 100% using our method, but this would have to be proven in a future study.

6 | CONCLUSIONS

Adjusting radiographic projection angle so an RV-PC is visualized entirely to be edge on determines a preferred angle of LAO projection such that the interventricular septum is also visualized edge on. LAO projection using that angle makes it easy to distinguish between the septum and the free wall, and facilitates safe LPM implantation.

DISCLOSURE

All authors have no disclosure associated with this manuscript.

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