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DEVICES

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Leadless pacing: Going for the jugular

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Abstract

Background: Leadless pacing is generally performed from a femoral approach. However, the femoral route is not always available. Until now, data regarding implantation using a jugular approach other than a single-case report were lacking.

Methods: The case records of all patients who underwent internal jugular venous (IJV) leadless pacemaker implantation (Micra, Medtronic, Dublin, Ireland) at our center were analyzed retrospectively.

Results: Nineteen patients underwent IJV leadless pacemaker implantation, nine females, mean age of 77.5 \pm 9.6 years; permanent atrial fibrillation in all patients with normal left ventricular ejection fraction. Implant indication was atrioventricular conduction disturbance in 10, pre-AV node ablation in seven, and replacement of a conventional VVI pacemaker in two (infection in one and lead malfunction in the other). The device was positioned at the superior septum in seven patients, apicoseptal in seven patients, and midseptal in five patients. In 12 patients, a sufficient device position was obtained at the first attempt, in three at the second, in one at the third, in one at the fourth, and in two at the sixth attempt.

The mean pacing threshold was 0.56 \pm 0.39V at 0.24-ms pulse width, sensed amplitude was 9.1 \pm 3.2 mV, mean fluoroscopy duration was 3.1 \pm 1.6 min. There were no vascular or other complications. At follow-up, electrical parameters remained stable in 18 of 19 patients.

Conclusion: Although experience is minimal, we suggest that the IJV approach is safe and may be considered in patients where the femoral approach is contraindicated.

KEYWORDS jugular vein, leadless pacing, pacemaker

1 | INTRODUCTION

Leadless pacemaker (PM) implantation has until now been performed from the femoral vein with the exception of a single case via the jugular vein, published by Kolek et al.¹ These authors described a patient who had a caval filter for prevention of thromboembolism, and in whom they successfully implanted a leadless PM (Micra, Medtronic, Dublin, Ireland) using the internal jugular vein. In the two cases described below, where femoral approach was not possible, the jugular approach was used instead. Based on this favorable experience, the jugular approach was used more frequently. This study describes 19 patients who underwent leadless PM implantation from the internal jugular vein.

1.1 | Case 1

The index patient was a 58-year-old female patient, who presented with a highly symptomatic longstanding persistent atrial fibrillation (AF). Several antiarrhythmic drugs were not effective. Echocardiography showed a normal left ventricular function and a dilated left

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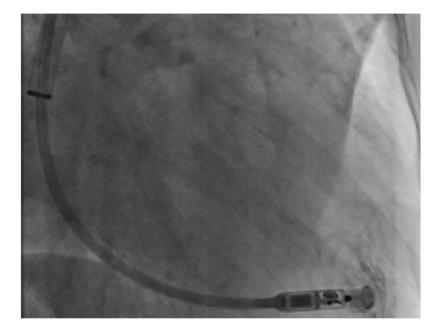


FIGURE 1 Right anterior oblique fluoroscopic images to confirm the device position on the apical septum

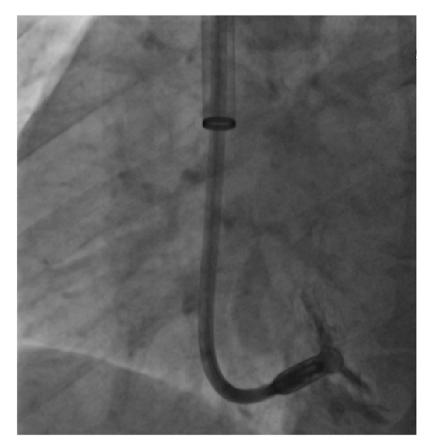


FIGURE 2 Left anterior oblique fluoroscopic images of the device positioned on the apical septum with contrast injection to confirm septal localization. The delivery tool enters the right atrium from the superior caval vein

atrium, with left atrial volume index of 64.3 mL/m². The patient was referred for pulmonary vein isolation. A preparatory computed tomography scan showed an azygos vein in continuation of the inferior vena cava, along with a polysplenia and a ventricular septal defect (Swiss cheese septum). A right heart catheterization with oximetry runs demonstrated that the ventricular septal defect was not hemodynamically significant and a coronary angiogram showed normal coronary arteries. The azygos continuation precluded routine

femoral vein access for pulmonary vein isolation. Therefore, a thoracoscopic maze procedure was performed. Unfortunately, after maze surgery, AF recurred. Subsequent catheter ablation using remote magnetic navigation (Stereotaxis, St. Louis, MO, USA) using a retrograde aortic approach was also not successful. Pharmacological rate control did not provide adequate relief of symptoms. After 5 years of unsuccessful treatment, the patient elected to undergo a PM implantation followed by atrioventricular (AV) node ablation. Implantation options were discussed with the patient, including implantation of a regular VVI pacing system. The patient strongly preferred a leadless pacing system. Internal jugular venous (IJV) access was obtained and the 23 = F introducer sheath was positioned in the right atrium. The leadless PM was deployed at the right ventricular apical septum (Figures 1 and 2). Excellent sensing and pacing threshold values were obtained.

1.2 | Case 2

The second patient was an 80-year-old female, who had a history of aortic valve replacement with a bioprosthesis, mitral valve and tricuspid valve repair with implantation of annuloplasty rings, and concomitant maze procedure. The AF recurred and became permanent. The patient presented to another hospital with third-degree AV block. Conventional transvenous PM implantation was attempted at that hospital. From a left cephalic vein approach, the right ventricular lead could be passed into the right ventricle with difficulty, but right atrial dilatation (102×57 mm) made it impossible to obtain an adequate wall contact to screw the lead in position. The implantation was abandoned and the patient was transferred to our center. Due to the previously unsuccessful implantation attempt, a second conventional implant attempt was rejected and a leadless pacing system was chosen. A lack of support from femoral access was anticipated due to the severely dilated atrium. In addition, the presence of a tricuspid annuloplasty ring was thought to cause axial catheter pressure to be diverted superiorly instead of to the right ventricular wall when using the femoral route. So, a straighter approach to the right ventricle from the jugular vein was used. Despite the severely dilated right atrium, the leadless PM was implanted without any complications and excellent sensing and pacing threshold values were obtained.

2 | METHODS

Case files of all patients who underwent leadless PM implantation at our center were retrospectively analyzed. The study was reviewed by the regional medical ethical committee. All patients consented to their case records being reviewed and consented to use of the data for publication. A consistent implant technique was used in all cases.

2.1 | Implant procedure

In all cases, a central approach to the jugular vein was used as described by Daily et al.² Both the sternal and clavicular head of the sternocleidomastoid muscle were identified. After the skin was appropriately disinfected and the patient draped, lidocaine 1% was used to infiltrate the skin between the two heads of the sternocleidomastoid muscle using a 22-gauge needle. Then the internal jugular vein was entered with the 22-gauge needle, which was left in place as a landmark. Next, the vein was entered with an 18-gauge needle directly adjacent to the 22-gauge needle and a guide wire was introduced. Echography with a linear probe was available but not needed in any of the cases. The

guide wire was passed through the right atrium into the inferior cava under fluoroscopic guidance to demonstrate venous placement and exclude inadvertent arterial entry. The access site was dilated with a 6-F dilator and the puncture site was carefully observed for any arterial bleeding. In the last 16 cases, two Perclose Proglide sutures (Abbott, Santa Clara, CA, USA) were placed at 90 degrees and secured with hemostats. A 6-F introducer was placed and a 0.035 stiff Amplatzer wire (Cook Medical, Bloomington, IN, USA) was passed into the inferior caval vein. Finally, the puncture site was dilated in stages with 10 F, 14 F, and 18 F dilators and the 23 F (outer diameter = 27 F) introducer sheath was placed, double flushed, and connected to an intravenous drip. Heparin 2500 IE was administered intravenously (IV). The delivery tool was flushed with heparinized saline and connected to a continuous IV drip. The device was introduced into the delivery sheath and biplane fluoroscopy (right anterior oblique 45/left anterior oblique [LAO] 45) was used to enter the right ventricle with the device; septal placement was confirmed using the LAO projection. In order to minimize the chance of excessive force being applied to the device tip, the delivery tool was maintained in a flexed position at all times. After a satisfactory position was reached, the device was deployed and electrical measurements were obtained. If adequate electrical parameters were obtained, device fixation was verified with the pull and hold test. If a minimum of two out of four tines had engaged the myocardium, the device was released by cutting the tethering wire. The delivery tool and the sheath were removed, the access site was closed with a figure of 8 suture in two patients and with ProGlide (Abbott, Abbott Park, IL, USA) in 17 patients. All patients were ambulated immediately after the procedure and were observed overnight. The following morning, chest x-ray and device interrogation were performed and the patient was discharged.

3 | RESULTS

A total of 19 patients underwent leadless PM implantation with the jugular approach. Table 1 summarizes baseline characteristics, as well as implant data. There were nine female patients. The mean age was 77.5 ± 9.6 years. All patients had permanent AF with normal left ventricular ejection fraction >50%. Implant indication was AV conduction disturbance in 10 patients, pre-AV node ablation in seven patients, replacement of a conventional VVI system in two patients (infection in one and lead malfunction in the other). Eleven patients used new oral anticoagulants, whereas the other eight patients used vitamin K antagonists.

The device was positioned at the superior septum in seven patients, apicoseptal in seven patients, and midseptal in five patients. In 12 patients, a sufficient device position was obtained at the first attempt, in three at the second, in one at the third, in one at the fourth, and in two at the sixth attempt.

The mean pacing threshold was 0.56 ± 0.39 V at 0.24-ms pulse width, sensed amplitude was 9.1 ± 3.2 mV, mean fluoroscopy duration was 3.1 ± 1.6 min. There were no vascular or other complications. At follow-up, electrical parameters remained stable in 18 of 19 patients;

Pt. no	Age (years)	Sex	Implant indication	OAC	Attempts (n)	Final position	Sense (mV)	Threshold (V)	Tines (n)	Fluoroscopy (min)
1	59	F	Pre-AVNA	NOAC	1	Apicoseptal	12.9	0.75	3	2.83
2	81	F	Brady	VKA	4	Apicoseptal	9.5	0.63	2/3	7.55
3	71	F	Pre-AVNA	VKA	1	Apicoseptal	15.5	0.38	2/3	0.9
4	84	F	Brady	NOAC	1	Apicoseptal	7.3	0.5	3	2.68
5	77	F	Pre-AVNA	NOAC	1	High septal	11.7	0.38	3	2.46
6	93	М	Brady	NOAC	1	High septal	8.1	0.25	2/3	3.03
7	95	М	Brady	VKA	6	High septal	6	0.5	3	4.93
8	79	М	Brady	NOAC	1	High septal	12.5	0.25	2/3	3.03
9	81	F	Brady	VKA	1	Midseptal	2.4	0.5	2/3	3.97
10	67	М	Brady	NOAC	1	High septal	11.1	0.25	2	1.78
11	90	F	PM dysfunction	VKA	1	Midseptal	12	0.62	2	1.95
12	77	F	Brady	VKA	2	Apicoseptal	6.6	0.25	2/3	4.58
13	85	М	Pre-AVNA	VKA	1	High septal	7.3	1.25	2	3.07
14	73	М	Pre-AVNA	NOAC	1	Apicoseptal	11.1	0.38	3	1.63
15	66	М	Pre-AVNA	NOAC	2	High septal	6.6	1.88	3	2.37
16	75	М	Pre-AVNA	NOAC	1	Midseptal	11.6	0.38	3	2.54
17	61	М	Brady	NOAC	2	Midseptal	8	0.38	2	0.85
18	80	М	Pocket infection	VKA	6	Midseptal	5.6	0.38	3	6.08
19	79	М	Brady	NOAC	3	Apicoseptal	6.5	0.75	3	3.37

TABLE 1 Baseline characteristics and implant data

attempts = number of attempted device deployments to reach final position; biplane system = duration of both fluoroscopes added; brady = bradycardia/atrioventricular conduction disturbances; fluoro = fluoroscopy duration in minutes; NOAC = new oral anticoagulants; OAC = oral anticoagulant usage; PM dysfunction = pacemaker dysfunction; pre-AVNA = pre-atrioventricular node ablation; Pt. no = patient number in order of implantation; sense = sensing value in millivolts; threshold = pacing threshold in volts, 0.24-ms pulse width; tines = number of tines engaging the myocardium as determined by pull and hold test; VKA = vitamin K antagonists.

in one patient a threshold rise occurred at 1 month, which was managed by increasing the pacing output.

4 | DISCUSSION

To our knowledge, the jugular venous approach was reported previously in only one patient, who had an implanted inferior vena cava filter.¹ After the first two cases, where femoral approach was impossible or considered difficult, we decided to expand the usage of jugular approach to other patients. We now report a case series with 19 patients, in which the IJV approach was successful in all implantations. There were no vascular or other complications. Although a conventional pacing system may have been used, recent data showed leadless pacing systems to be associated with a lower complication rate, the main difference being caused by freedom of pocket related complications and infections.³ Large-bore IJV cannulation has previously been shown to be safe for extracorporeal circulation.⁴ The implantation procedure was relatively straightforward and uncomplicated.

Furthermore, the IJV approach may offer several advantages. For instance, septal sites were easier to reach. The septal site is nowadays a preferred site for lead insertion as Bongiorni et al showed long-term stability of nonapical pacing sites.⁵ The jugular approach also avoids the His bundle and right bundle branch area, which may be safer in patients with left bundle branch block.

A potential source of concern is that the jugular route is straighter than the femoral route, potentially increasing the risk of inadvertent tip pressure. To avoid this, the delivery tool was kept in the flexed position and biplane fluoroscopy was used to ensure that the device was always positioned septally.

Finally, all patients could be ambulated immediately after the procedure allowing for a shorter hospital stay. Although experience is minimal, these data suggest that the internal jugular approach is safe and may be considered in patients where the femoral approach is impossible or considered undesirable.

AUTHOR CONTRIBUTIONS

All authors critically revised the manuscript. All authors were involved in the implantation procedures and patient care.

CONFLICT OF INTEREST

Tanja Nikolic is employed by Medtronic and Harry van Wessel is employed by Abbott. Other authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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