CASE SERIES

Leadless pacing: First experience and outcomes in an isolated area in the setting of the Greek financial crisis

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Abstract

Background: Leadless pacing (LP) is a novel permanent pacing modality without transvenous leads that is increasingly applied in certain circumstances. We aimed to report our preliminary experience in LP implementation.

Case series: This observational study represents a simple registry of LP systems implanted in our tertiary center from April 2018 until November 2019 in the setting of the Greek financial crisis. Consecutive patients from the isolated area of Northwestern Greece referred to our center for LP were included. Patients' clinical and procedural data, as well as follow-up events, were carefully recorded. Nine patients (mean age: 75 years; six men) were included and were followed for a median period of 20 months. The commonest indication for LP implantation was increased patient infection risk (n: seven), while in the remaining patients (n: two), the indication was problematic vein access along with concomitant comorbidities that increase infection risk. Most of the patients (6/9) were in sinus rhythm, while the rest had slow atrial fibrillation. During the follow-up period, two patients with end-stage renal disease suffered sudden cardiac death, two patients died due to pneumonia, and one patient died due to metastatic cancer. However, no device-related death occurred during the follow-up.

Conclusions: Our data indicate that LP's long-term cost-effectiveness is limited in patients with several comorbidities due to increased mortality. Indeed, considering its increased financial cost, well-defined patients' selection criteria should be developed and applied, especially in medium/low-income countries. HIPPOKRATIA 2021, 25 (2):75-78.

Keywords: Cardiac pacing, leadless pacemaker, bradycardia, cardiac implantable electronic devices

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Introduction

Leadless pacing (LP) represents a novel modality of permanent pacing having significant advantages over conventional cardiac implantable electronic devices (CIEDs)[1-4]. LP systems consist of a single device implanted in the right ventricle through the central vein system without transvenous part. The Achilles' heel of transvenous CIEDs is mainly related to the leads and the pocket of the device. In the LP systems, there is no pocket, and there are no lead-related complications such as lead endocarditis, venous obstructions, lead dislodgements, and lead failures[1-4]. Of note, a considerable amount of clinical data indicate that LP systems provide effective single chamber (right ventricular) rate-responsive pacing in the long-term[1-4]. Despite the small size of these devices, their battery longevity may last 12-15 years[4]. Also, the implantation success rate has been significantly improved over time, reaching the level of 99 % in experienced centers[5]. Remarkably, a 3-axis accelerometer-based technology has been recently developed[6,7]. Last generation LP systems can detect atrial mechanical contractions using this technology, providing effective atrioventricular synchronous pacing[6,7]. However, as with every innovating technology, financial cost represents an obstacle for the wider clinical application of LP.

Case series

This is a case series of LP systems implanted in our tertiary center from April 2018 until November 2019. Consecutive elderly adult patients from the isolated area of Northwestern Greece were included in this registry. University Hospital of Ioannina is a high-volume tertiary center that is the sole referral center for CIEDs implantation in Northwestern Greece, covering a population of half a million inhabitants. Patients' clinical data and follow-up events were carefully recorded. Specifically,

four patients were implanted in the year 2018 and five patients in the year 2019. Commercially available Micra™ devices (Medtronic, Minneapolis, MN, USA) were implanted in all patients. The last follow-up was performed in December 2020; the median follow-up period was 20 months.

The implantation procedure was performed via the right femoral vein under local anesthesia and mild sedation with midazolam. The standard delivery system of the Micra® LP system was used in all patients. Closure of the insertion site after the procedure was performed with non-absorbable sutures using the figure of eight technique. Pressure dressings for 16-24 hours were also applied in all patients.

The demographic and clinical characteristics of the nine patients and the pacing indications are presented in Table 1. The commonest reason for selecting LP over conventional CIEDs was the presence of conditions that significantly increase the infection risk[8,9]. These included diabetes, renal insufficiency, recurrent infections, and immunosuppression (cortisone therapy for rheumatic disease and myelodysplastic syndrome) (Table 1). This reason was particularly true in seven patients. Specifically, one patient had previous CIED infections, five patients had recurrent infections, and one had multiple risk factors for infection (immunosuppression). Regarding patients with recurrent infections, one had recurrent respiratory infections, and two had recurrent upper urinary tract infections. Another two patients had chronic open chest wounds (that could not be healed) with purulent discharge after cardiothoracic operations and had experienced frequent flares. In the remaining two patients, the decision for LP implantation was mainly driven by problematic vein access. Specifically, one dialysis patient had an occluded arteriovenous fistula and an occluded subclavian vein (diagnosed by triplex ultrasonography) on the right side and a central vein catheter on the left side. The other patient had morbid obesity while an unsuccessful attempt for conventional pacemaker implantation had been performed. Additionally, these latter two patients had concomitant comorbidities.

Table 1: Baseline demographic, clinical characteristics, and pacing indications of the nine studied patients who were implanted leadless pacing systems.

Age (years)	75.2 ± 6.4
Males (%)	6 (67 %)
BMI (kg/m^2)	30.9 ± 4.2
Pacing indication	
Slow AF with pauses	3
Tachy-brady syndrome	1
Sick sinus syndrome (sinus arrest)	1
Complete heart block	2
Mobitz II AV block	1
Paroxysmal high-grade AV block	1
Permanent AF (%)	3 (33 %)
Paroxysmal AF (%)	1 (11 %)
Hypertension (%)	7 (78 %)
Diabetes (%)	6 (67 %)
CAD (%)	1 (11 %)
CHF (%)	3 (33 %)
CKD (%)	8 (89 %)
ESRD (%)	3 (3 %)
Chronic immunosuppression	2 (22 %)
History of recurrent infections	5 (56 %)
Previous CIED infections	1 (11 %)
Problematic vein access	2 (22 %)
LVEF (%)	56 ± 5

AF: atrial fibrillation, BMI: body mass index, CAD: coronary artery disease, CHF: congestive heart failure, CIED: cardiac implantable electronic device, CKD: chronic kidney disease, ESRD: end stage renal disease, LVEF: left ventricular ejection fraction

Details regarding the procedure and the baseline pacing parameters at implantation are presented in Table 2. We must notice that all devices were implanted in the right ventricular apex. No significant variation in the LP systems' electrical parameters was observed during the follow-up. Moreover, no patient developed pacemaker syndrome after the LP system implantation. This was true both for patients with Mobitz II or complete heart block who had >80 % ventricular pacing as well as for the other patients who had <20 % ventricular pacing during follow-up.

Regarding periprocedural adverse events, only one patient suffered a postoperative complication. Specifically, a female patient with morbid obesity, COPD, and diabetes, manifested fever the day after the operation without a clear origin of the infection, having negative blood cultures. She was treated with broad-spectrum antibiotics; she became afebrile two days later and was discharged home on the seventh postprocedural day. She remained well 22 months after the implantation without any fever relapse. All the other patients were discharged the day after the index procedure on a good clinical condition.

During the follow-up period, five patients died. Specifically, two patients with end-stage renal disease (ESRD) experienced sudden cardiac death; two patients died due to severe pneumonia, and one patient due to metastatic cancer. Of note, no device-related death occurred during the 20-month follow-up period.

Table 2: Procedure characteristics and parameters at implantation of the leadless pacemakers.

Procedure time (min)	66 ± 12
Fluoroscopy time (min)	9 [7-12]
Number of device deployments (%)	
1	5 (56 %)
2	3 (33 %)
3	1 (11 %)
Sensing amplitude (mV)	11.4 ± 6.8
Pacing threshold (V at 0.24ms)	0.43 ± 0.16
Pacing impedance (Ω)	789 ± 118

Discussion

LP is an increasingly used mode of permanent pacing, especially in cases with high infection risk and/or in patients with problematic subclavian venous access[1-4]. Given that LP systems do not provide atrial pacing, most candidates are patients with atrial fibrillation (AF)[1-4]. However, LP represents a suitable option in patients with sinus rhythm and is preserved left ventricular systolic function, especially in instances where low ventricular pacing rates are anticipated[4]. The same is true in those with a very high risk for infection and those with missing venous access for conventional leads implantation[4]. An increasing body of evidence suggests that current LP systems provide consistent clinical performance in real-life patients while their use is associated with significantly fewer major complications compared to conventional pacing systems[5].

Our patient population had very high infection risk characteristics for conventional CIED placement. Possibly, this high infection risk as well as the high prevalence of comorbidities, including obesity, accounted for the high mortality rate during this short-term follow-up period. Indeed, 2/5 deaths were due to severe pneumonias, whereas 2/5 were sudden deaths in patients with ESRD, a condition associated with increased cardiovascular risk, including sudden cardiac death. However, the mortality was not driven by procedure-related complications. Interestingly, it has been reported that severe infectious events during the first few months after the LP system implantation occur in 2.2 % of patients[10]. However, these infections seem to have a favorable outcome while no vegetation on the LP device is detectable[10]. Patients with ESRD represent a challenging population, but it has been demonstrated that LP in these patients carries a low infection risk and can be safely performed[11].

In our report, the mean procedural time was quite long (66 minutes) compared to other studies. However, it should be acknowledged that, despite our limited experience, the procedural success and the number of procedural deployments were acceptable and comparable with other registries[12,13]. In fact, the operator's learning curve is an important factor affecting the procedure duration in LP system implantations[12]. Interestingly, recent evidence suggests that implantation of LP systems in the right ventricular outflow tract (RVOT) can be effectively accomplished without complications while it is associated with a narrower QRS complex compared to mid-ventricular or apical pacing[14]. Whether this favorable electrophysiologic performance translates into better clinical outcomes remains to be investigated.

The first Greek series of LP patients was reported by Sideris et al in 2017[15]. In this series of six patients, five had vascular access problems rendering them unsuitable for conventional lead placement[15]. Regarding pacing indications, only one patient had slow AF while the other five had sinus activity in the context of sick sinus syndrome or complete heart block[15]. Of note, none of these latter patients developed pacemaker syndrome after LP[15]. In the same line, 6/9 patients in our series had sinus activity while three patients had slow AF. However, in contrast to the Sideris et al series, the decision for LP implantation was mainly driven by the increased infection risk in our population.

We must acknowledge that our case series is a small registry from the isolated area of Northwestern Greece. However, this limitation should be viewed in the light of restricted resources of the Greek National Health Service in the era of the ongoing financial crisis. It should be stressed that the supply cost of an LP system in a Greek hospital is almost ten times greater than the cost of a conventional pacing system. Therefore, the decision to implant an LP system in the setting of the Greek financial crisis is at least difficult.

Conclusion

LP is a valuable and safe permanent pacing modality in patients with high infection risk or vascular access abnormalities. Our data indicate that its long-term cost-effectiveness is limited in elderly patients with several comorbidities due to increased mortality. Indeed, considering its increased financial cost, well-defined patients' selection criteria should be developed and applied, especially in medium/low-income countries.

Conflict of interest

The authors declare that they have no conflicts of interest.

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