

Use of leadless pacemakers in Europe

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Use of leadless pacemakers in Europe: results of the European Heart Rhythm Association survey

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The purpose of this European Heart Rhythm Association (EHRA) survey is to provide an overview of the current use of leadless pacemakers (LLPM) across a broad range of European centres. An online questionnaire was sent to centres participating in the EHRA Electrophysiology Research Network. Questions dealt with standards of care and policies used for patient management, indications, and techniques of implantation of LLPM. In total, 52 centres participated in the survey. Most (86%) reported using LLPM, although 82% of these centres implanted <30 LLPM devices during the last 12 months. Non-availability (36%), lack of reimbursement (55%), and cost of the device (91%) were factors limiting the use of LLPM. The most commonly reported indications for LLPM were permanent atrial fibrillation (83%), a history of complicated conventional pacemaker (87%), or an anticipated difficult vascular access (91%). Implantation of LLPM is perceived as an easy-to-do and safe procedure by most implanters (64%), while difficult or risky in 28%, and comparable to conventional pacemakers by only a few (8%). Local vascular complications were the most frequently reported major problems (28%), but a significant number of respondents (36%) have never encountered any issue after LLPM implantation. Although cost and reimbursement issues strongly influence the use of LLPM, most respondents (72%) anticipate a significant increase in device utilization within next 2 years.

Keywords

Leadless pacemakers • Standards of care • European Heart Rhythm Association survey • EP Wire

Introduction

Cardiac pacing has been used for more than 50 years for the management of bradycardias.^{1–3} Whereas the efficacy and overall safety of these devices are high, complications often related to the use of endovascular leads, including fracture, insulation breakdown, and infections may occur.^{4,5} In the FOLLOWPACE study, the reported incidence of perforations, pericardial effusions, pocket complications, and pulse generator-related technical issues was 12.4% at 2 months and additional 9.2% at 5.9 years.⁶ In addition, the extraction of the endovascular leads may be challenging and particularly risky. Furthermore, transvenous pacing may sometimes be very difficult or impossible because of venous thrombosis or occlusions.^{4,5,7,8}

For a long time, these considerations have motivated research into pacing systems free of endovascular leads. Currently, two devices are routinely used in many European centres: the NanostimTM (St. Jude Medical, Inc., St. Paul, MN, USA)⁹ and the MicraTM (Medtronic, Inc., Minneapolis, MN, USA)^{10,11} which are both totally free-standing, intracardiac, single-chamber ventricular-only (VVIR) pacing devices, implanted in the right ventricular endocardium. All these leadless pacemakers (LLPM) are introduced via the femoral approach, using large (18–25 Fr) vascular sheaths, and they are screwed or anchored in the endocardium. The currently available pacemakers are only single-chamber devices, pacing in VVIR mode.¹² Several manufacturers are also working on the development of dual-chamber devices, with two ‘modules’ implanted independently, which are able to

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communicate and interact with each other. These dual-chamber devices will include a right ventricular pacemaker, probably very similar to those already available, and a pacemaker implanted in the right atrium. Leadless pacing is just at the beginning, new systems are being developed, and the choice of devices will likely broaden in the near future. This technological breakthrough will most probably impact the future of the patients and the implanters.¹³ The aim of this European Heart Rhythm Association (EHRA) survey was to provide better insight into current LLPM utilization across a broad range of the European centres, and to anticipate what direction future trends may follow.

Methods and results

A questionnaire was sent via the internet to 151 centres that participate in the EHRA Electrophysiology (EP) Research Network. In this survey, 25 questions focused on standards and policies concerning patients' management, indications, and techniques of implantation of LLPM in the participating EP centres.

Participating centres

Overall, 52 out of the 151 centres from 21 countries that were contacted (34% response rate), responded, with a wide geographical distribution of respondents: 15 centres from Poland, 8 centres from France and Spain, 6 centres from Germany, 3 centres from Sweden, 2 centres from Italy and from UK, and 1 centre each from Austria, Belgium, Georgia, Netherlands, Estonia, Lithuania, Czech Republic, and Switzerland. Among these 52 centres, 75% were university hospitals, 17% were non-university hospital, and 8% were private hospitals.

Respondents were mostly high-volume centres: during the last 12 months 16% of them had implanted >500 dual or single chamber conventional pacemakers (CPM), 54% had implanted 300–500 CPMs, 28% had implanted 100–299 CPMs, 2% had implanted 50–99 CPMs, and none reported <50 implantations.

Use of leadless pacemakers

At least once, LLPM has been implanted at 86% of the responding centres. Of all CPM implantations per centre, LLPMs represented <10% in 80% of the centres, 10–20% in 4% of the centres, 21–50% in 2% of the centres, and >50% in 0% of the centres, while 14% of the responding centres reported to have never implanted LLPM.

Regarding the number of patients implanted with LLPMs during the last 12 months, 4% of the responding centres implanted the device in 50–100 patients, 4% in 30–49 patients, 44% in 10–29 patients, 39% reported <10 implantations, and 9% of did not implant LLPM (Figure 1).

Implantation strategies and techniques

In the majority of responding centres (79%), LLPM implantation procedures are performed during a short hospitalization (1–2 days), in 18% of centres peri-procedural hospitalization lasts 3–5 days, and never >5 days. Only in 3% of the centres are LLPM implantations being performed on an outpatient basis. In 72% of the centres, LLPM implantations are performed in an EP laboratory, and in 8% the procedure is done in a surgical theatre. In the remaining 20% of the centres, a hybrid operating room is routinely used for these implantations.

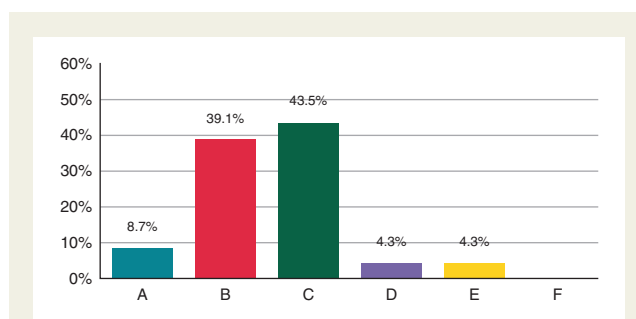


Figure 1 Proportion of respondents to the question: 'How many patients were equipped with a LLPM during the last 12 months in your centre?' Each bar represents one possible answer. A, None; B, <10 patients; C, 10–29 patients; D, 30–49 patients; E, 50–100 patients; and F, >100 patients. LLPM, leadless pacemaker.

In the majority of centres, LLPM implantations are always performed by an electrophysiologist (90%), by an interventional cardiologist or surgeon alone in 2% of the centres (each), and by both cardiologists and surgeons in the remaining 6% of the centres. Most of the responding centres routinely implant LLPM under local anaesthesia (56%), or deep sedation (36%), and only 8% of the centres perform the procedure under general anaesthesia. Among the two devices currently available in most countries, the Medtronic Micra was reportedly used in 87% of the respondents, the Abbott Nanostim in 5%, and both devices in 8%.

Implantation of LLPM is perceived as 'an easy-to-do and safe procedure' by 64% of the operators, 'an easy-to-do and risky procedure' by 15%, 'a difficult and safe procedure' by 5%, 'a difficult and risky procedure' by 8% of the operators, and 'a procedure which is comparable with CPM implantation' by further 8%. The mean implantation duration of LLPM from femoral vein puncture to sheath removal was reported as <30 min by 18% of the centres, 30–45 min by 46%, 45–60 min by 23%, and >60 min by 13%.

Repositioning of the device was required during the implant procedure in <10% of cases by 36% of the implanters, in 11–30% of cases by further 36%, in 31–50% of cases by 13%, in >50% of cases by 2% and was never required by 13% of the implanters. Finally, 72% of the responding centres declared having experience with LLPM retrieval.

Reasons for not implanting leadless pacemakers

As stated previously, 14% of the responding centres do not implant LLPM. The main reasons reported for not implanting these devices included the limited availability (36%), economic issues, such as lack of reimbursement (55% of not implanting centres), high cost of the device (91% of centres), issues associated with patient selection, such as the lack of dual-chamber or cardiac resynchronization therapy (CRT) pacing functions (27% of centres), or the absence of eligible patients (18% of centres). Lack of training was infrequently reported as the reason for not implanting LLPM (9%). Interestingly, physicians' scepticism towards device efficacy, the complexity of the implantation procedure, the need of surgical back-up, or patients' choice, were not reported as a potential obstacle for the use of this system (Figure 2).

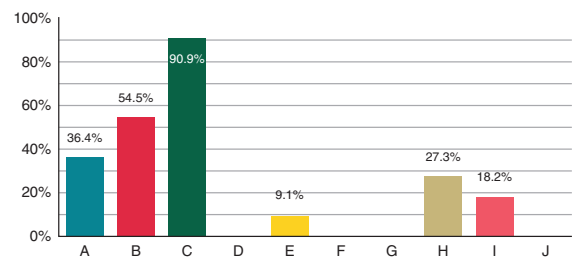


Figure 2 Proportion of respondents to the question: 'If you don't implant leadless pacemakers in your centre, the reasons are (multiple answers)?' A, Not available; B, not reimbursed; C, price too high; D, 'I don't believe in this system'; E, 'I've not been trained to this procedure'; F, procedure too complex; G, need for a surgical back-up; H, lack of dual chamber or CRT pacing function; I, no patients who qualify; J patients rather opt for a conventional pacemaker. CRT, cardiac resynchronization therapy.

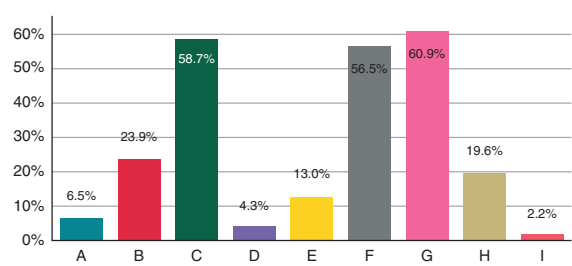


Figure 3 Proportion of respondents to the question: 'Which features in your opinion could represent an obstacle to leadless pacemaker use (multiple answers)?' A, Overweight; B, underweight; C, age < 20 years old; D, age > 75 years old; E, pacing dependency; F, underlying sinus rhythm; G, tricuspid valvular prosthesis; H, patient's preference; I, no particular feature.

Apart from device availability and reimbursement, the obstacles to LLPM use reported by most of the centres—users and non-users—were mainly linked to the presence of a tricuspid valvular prosthesis (61% of the respondents), age < 20 years (59%), underlying sinus rhythm (57%). More mitigating factors were being underweight (24%), patient's preference for CPM (20%), patient dependency (13%), followed by being overweight or age > 75 years (7% and 4%, respectively) (Figure 3).

Features favouring leadless pacemaker over conventional pacemaker use

Among responding centres routinely implanting LLPMs, the choice of LLPM system instead of CPM was mainly dictated by an anticipated difficult vascular access (91%), a history of complicated CPM (87%), a pacing indication in patients with permanent atrial fibrillation (83%), and an anticipated higher risk of infection (70%). Less commonly reported factors favouring LLPM implantation were patient's advanced age (48% of the centres), or preference (33%), no pacing dependency (22%), and young age (17%) (Figure 4).

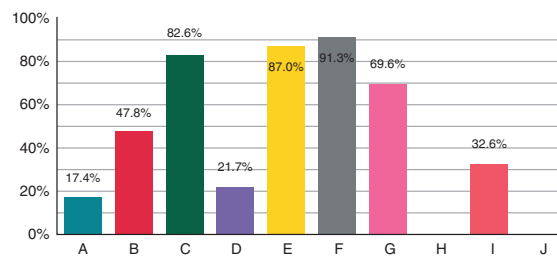


Figure 4 Proportion of respondents to the question: 'Which features would make you more inclined to use leadless pacemaker, rather than conventional pacemaker implantation (multiple answers)?' A, Young age; B, elderly; C, permanent atrial fibrillation; D, no pacing dependency; E, previous complicated endovascular conventional pacemaker; F, anticipated difficult vascular access; G, anticipated higher risk of infection; H, short anticipated survival; I, patient's preference; J, no particular feature.

Current perception of indications for leadless pacemakers

Among the responding centres, 77% undertake implantation of LLPMs only for very restricted indications, while in 10% discussion with the patient and shared decision-making (after both transvenous and leadless devices alternatives have been proposed) is the basis for device use. When no dual chamber pacing or CRT is needed, only few centres (5%) propose LLPMs as a first-choice therapy. Finally, 8% of the centres did not adopt any particular policy on the decision between transvenous CPM and LLPM devices.

More interestingly, LLPM is also considered in patients with otherwise standard indications for dual-chamber pacemakers, when anticipated pacing burden is expected to be very low (74%), in patients with very advanced age (61%), in very active or non-cooperative patients, presenting with high risk of damage to the leads (39%), in patients with a normal left ventricular ejection fraction (28%), or in those with short anticipated survival, apart from age (26%). Only 11% of the respondents would never implant LLPM in a patient with indication for dual-chamber pacing (Figure 5).

Outcomes after leadless pacemaker implantation

Overall, 79% of survey participants reported very rare occurrence (<3%) of adverse events while managing patients with LLPM. More than one-third (36%) of the centres never encountered any issue after LLPM implantation. Among the major problems were local vascular complications (28%), high pacing thresholds at implant or during follow-up (23% and 8%, respectively), and pericardial effusion or tamponade requiring an intervention (20%). Less common problems included device dislodgement requiring recapturing and extraction (7%), and post-implant need for dual-chamber pacing or CRT requiring an up-grade (5%).

Anticipated use of leadless pacemakers in the future

The majority of respondents (63%) anticipated that the number of LLPM implantations will increase in their centre in the next 2 years,

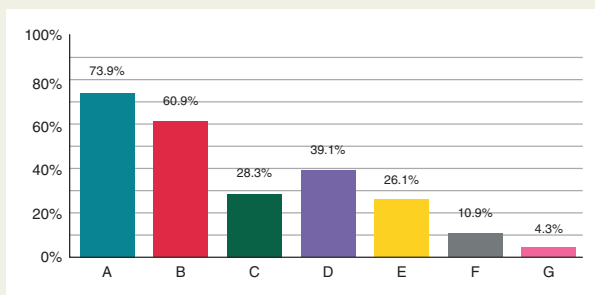


Figure 5 Proportion of respondents to the question: 'In a patient with otherwise standard indications for dual chamber pacemaker implant, which one or more of the following would sway your opinion towards the use of a leadless pacemaker (multiple answers)?' A, Low anticipated pacing burden; B, very advanced age; C, normal left ventricular ejection fraction; D, very active or not cooperating patient (high risk of damage to the leads); E, short anticipated survival, apart from age; F, 'I would never implant a leadless pacemaker in a patient with indications for dual-chamber pacing'; G, vascular or infectious issues.

while 22% and 4% of centres estimate that the volume of LLPM patients in their centre will remain the same or will decrease, respectively. Many also expect that LLPM will be introduced in their centres (9%), while only 2% did not expect introduction of this technology within the next 2 years (Figure 6).

Discussion

This EP Wire provides an insight into contemporary European practice regarding LLPM implantation and management several years after its introduction in our countries. The main findings of this survey are: (i) the vast majority of the responding centres implant—however, often sparingly—LLPMs; (ii) the absence of reimbursement, limited availability, and device cost seem to be the main factors restricting the use of LLPM; (iii) the most commonly reported reasons for preferring LLPM over CPM are an anticipated difficult vascular access, previous complicated CPM, a pacing indication in a patient with permanent atrial fibrillation, or an anticipated high risk of infection; (iv) one-third of respondents have not encountered any problems following LLPM implantation; the most frequently reported major problems were local vascular complications; (v) most of the respondents to this survey consider LLPM in patients with otherwise standard indications for dual-chamber pacemaker implant, and they anticipate that LLPM implantation rates will increase in their centre within the next 2 years.

The LLPM system was developed to reduce the morbidity associated with endovascular leads (e.g. lead dislodgement or rupture, venous thrombosis, infection, etc.), while providing effective pacing function.^{4,5} Although LLPM was introduced 3–5 years ago in most of the European countries,^{9,14} its use is still not routine, even if it has already been implanted in most tertiary hospitals. In our survey, more than 80% of the respondents have already implanted LLPM. However, LLPM have been implanted in <10, or <30 patients during the last year in 48% and 91% of these high-volume centres, respectively. This emphasizes the very low proportion (<10% in 80% of the

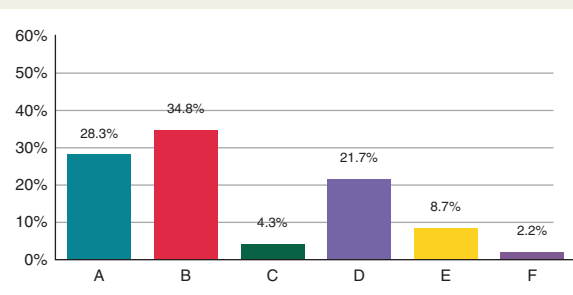


Figure 6 Proportion of respondents to the question: 'Do you think that the volume of patients equipped with leadless pacemakers in the next 2 years at your centre?' A, Will increase by more than 20%; B, will increase by less than 20%; C, will decrease; D, will remain the same; E, leadless pacemakers will be introduced in your centre within the next 2 years; F, leadless pacemakers will not be used in your centre within the next 2 years.

centres in this survey) of LLPMs among all pacemakers implanted in the majority of the European centres.

There are many potential reasons for such discrepancy and slow penetration rate of LLPM across European countries. The LLPM is often considered as 'a niche' for rare indications or difficult patients. On the other hand, LLPM is basically a substitute for a single-chamber CPM, providing same function by delivering endocardial VVIR pacing mode.^{12,15} In this setting, one could theoretically expect that the LLPM would progressively replace the endovascular CPM in common indications, for example, in conduction disturbances.^{15,16} Furthermore, most of respondents to this survey would consider LLPM in a patient with otherwise standard indications for dual-chamber pacemaker under some circumstances¹⁷ such as low expected pacing burden or advanced age. This highlights the gap existing between the wide theoretical LLPM indications and the far lower real implantation rate across European centres.

Implantation of LLPM involves a completely new technique,^{12,18} which requires specific training, posing a potential barrier to many operators who may have years of experience in implantation of CPMs. In addition, the femoral sheath used for introducing LLPM is particularly large^{12,18} (18–25 Fr), which engenders reluctance on the part of many implanters. Finally, this procedure needs to fit into the routine, everyday hospital regime, and at the moment most centres still appear to be in a learning phase. Increased organizational and logistic efforts are called for, in addition to, nursing training, requirements for a hybrid or a surgical theatre, anaesthetists, and surgical backup.¹² In this context, LLPM implantations lead to more complexity, which may ultimately discourage some teams. Last but not least, cost issues, largely reported by the responding centres in this survey, will indisputably negatively impact the availability of LLPM and its uptake across Europe.

While one-third of the centres using LLPM in our survey reported no complications during or after implantation, local vascular complications were the most frequently reported adverse event. Importantly, pacemaker syndrome and/or infection were not reported as a major problem encountered with LLPM. These findings are consistent with the data from the literature, showing that LLPM short-term outcomes are mostly related to the implant procedure itself: cardiac perforation, device dislocation, and femoral vascular access site complications. It is

also clear, that the complication rate is significantly influenced by implanter experience with this new procedure.^{10,15}

It is surprising that the most reported obstacle to implant was considered to be the presence of a tricuspid valvular prosthesis. Paradoxically, some data suggest, that crossing a prosthetic tricuspid valve for LLPM placement is possible and can be facilitated by the valve visualization.¹⁹ In addition, this option could offer the advantage of preventing tricuspid insufficiency and bioprosthesis chronic damages due to the implantation of a permanent endovascular ventricular pacing lead.²⁰ The risk of future infection is also expected to be lower in this setting. Other limitations for LLPM use are related to the risk of battery replacement after depletion in young patients and the need for atrial pacing in case of sinus node disease.^{12,18}

Leadless pacemaker is a major technological step forward in the world of cardiac pacing, and current first generation single-chamber devices represent the initial step of this new venture. Many further important enhancements are expected, such as multi chamber systems, and enhancements allowing for easier retrieval, for battery replacement for example.^{12,15,18} It seems highly probable that LLPM implantations will significantly increase in the European countries, as anticipated by the participants of this survey.

Limitations

This survey has some limitations. First, because it is fully based on a voluntary participation, it is non-exhaustive. Second, because questions had a limited number of options to be chosen, some situations may have not been completely covered. Third, this questionnaire was launched before Abbott paused the distribution of the Nanostim LLPM. Finally, because purely declarative, it may not be entirely representative of the whole activity or decisions of the responding centres. However, the purpose of this survey was reached by providing an overview of the current use of LLPMs across a broad range of the European centres.

Conclusion

This survey provides an insight into LLPM implantation and management strategy in the European centres. The use of this device is influenced by cost issues and lack of reimbursement which currently limit its uptake in clinical practice. However, most respondents anticipate that LLPM implantation rates will increase significantly in the next 2 years.

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