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EHRA SURVEY

Peri-procedural management, implantation feasibility, and short-term outcomes in patients undergoing implantation of leadless pacemakers: European Snapshot Survey

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The aim of this European Heart Rhythm Association (EHRA) prospective snapshot survey is to assess procedural settings, safety measures, and short-term outcomes associated with implantation of leadless pacemakers (LLPM), across a broad range of tertiary European electrophysiology centres. An internet-based electronic questionnaire (30 questions) concerning implantation settings, peri-procedural routines, complications, and in-hospital patient outcomes was circulated to centres routinely implanting both LLPMs and transvenous pacemakers (TV-PM). The centres were requested to prospectively include consecutive patients implanted with either LLPMs or TV-PMs during the 10-week enrolment period. Overall, 21 centres from four countries enrolled 825 consecutive patients between November 2018 and January 2019, including 69 (9%) implanted with LLPMs. Leadless pacemakers were implanted mainly under local anaesthesia (69%), by an electrophysiologist (60%), in the electrophysiology laboratory (71%); 95% of patients received prophylactic antibiotics prior to implantation. Most patients on chronic oral anticoagulation were operated on-drug (35%), or during short-term (to 48 h) drug withdrawal (54%). Implantation was successful in 98% of patients and the only in-hospital procedure-related complication was groyne haematoma in one patient. This EHRA snapshot survey provides important insights into LLPM implantation routines and patient outcomes. These findings suggest that despite the unfavourable clinical profile of pacemaker recipients, LLPM implantation is associated with relatively low risk of complications and good short-term outcomes.

Keywords European Heart Rhythm Association • Cardiac pacing • Leadless cardiac pacemaker • Snapshot survey

Introduction

Since 1958, when a 'fully implantable' pacemaker (PM) was first implanted, next generations of implantable cardiac PMs have been widely used to manage bradycardias.[1–4] Despite more sophisticated electrical circuits and smaller and more efficient devices, this therapy is not free of complications, most of which being related to a presence of endovascular leads.[5,6] In the National Swedish Pacemaker and Implantable Cardioverter-Defibrillator Registry, the reported incidence of PM-related complications equalled 5.4% per year, with

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lead displacement and dysfunction being the two leading types of complications (2.2% and 0.7%/year, respectively).[7] Furthermore, the extraction of infected or damaged leads remains a difficult task with significant procedural risks, and re-implantation of new leads sometimes may be challenging,[5,6,8,9] with complete occlusion of venous access observed in 3–26% of upgrade procedure cases.[10,11]

Those limitations of transvenous pacemakers (TV-PM) initiated the development of pacing systems free of endovascular leads—leadless pacemakers (LLPM). Currently, one device is routinely used in many European centres: the Micra™ (Medtronic, Inc., Minneapolis, MN, USA),[12] which is a totally freestanding, intracardiac, single-chamber ventricular-only pacing device (VVI), implanted into the right ventricular endocardium. This European Heart Rhythm Association (EHRA) survey was designed to provide an insight into LLPM utilization across a broad range of European centres, to examine implantation settings, equipment, peri-procedural routines, and safety measures, as well as implantation-related in-hospital complications.

Methods

The European Snapshot Survey on Leadless Pacemaker Implantation (ESSS-LLPM) was a prospective, observational, multicentre survey of consecutive patients undergoing PM implantation between 5 November 2018 and 18 January 2019. Electronic link to the online questionnaire, prepared by the EHRA Scientific Initiative Committee members, was sent to all centres participating in the EHRA Electrophysiology (EP) Scientific Research Network who routinely implant both types of PMs (conventional and leadless). All European countries were invited to participate, with a particular focus was placed on the 17 largest countries, in which >8000 PMs were implanted in 2014 or 2015.[13] The indications for PM, as well as implantation techniques, equipment, and peri-procedural treatment, were all left entirely to the discretion of the responsible physicians, but had to conform to current standards of good clinical practice and clinical routine. Each participating centre was responsible for obtaining ethics committee approval, as required by national or local rules.

The questionnaire consisted of four general questions (centre characteristics and number of procedures), and 26 specific questions about individual patient demographics, functional class, underlying heart disease and left ventricular ejection fraction, co-morbidities, electrocardiogram, indications for PM implantation, procedural details, and in-hospital outcomes. All data were entered anonymously.

Statistical analyses

Continuous variables were presented as mean ± standard deviation (SD), or as median [25th to 75th percentile], if not normally distributed. Categorical variables were reported as counts with percentages. The Student's *t*-test was used for comparison of continuous variables with a normal distribution, and Mann–Whitney *U* test for those with non-normal distribution. Differences in categorical variables were tested by the χ^2 test. A value of $P < 0.05$ was considered statistically significant in all analyses.

Results

Enrolment and participating centres

Twenty-one centres from four countries (France: $n = 12$, Spain: $n = 4$, the Netherlands: $n = 3$, and Italy: $n = 2$) enrolled a total of 825 patients. Most (86%) participating centres were university hospitals; this percentage was even higher (94%) considering only centres implanting LLPMs. The median number of LLPMs implanted in the year 2018 was 17 [6–26] per participating centre, 8 centres (33%) implanted <10, and 2 (8%) >30 LLPMs/year.

Patients' characteristics

Of the 825 patients enrolled during the 10-week study period, 69 (9%) patients were implanted with LLPMs (74% males, 43% aged 76–85 years, 12% older than 85 years, and 3% younger than 55 years) (*Table 1*). Most patients ($n = 41$, 59%) had an underlying heart disease, most frequently valvular ($n = 19$, 45%) or ischaemic heart disease ($n = 15$, 36%). Patients presented predominantly with NYHA class II (43%), and median left ventricular ejection fraction was 55% [54–60%]. Permanent atrial fibrillation with slow ventricular rate (45%) and intermittent (18%) or permanent high degree atrioventricular block (14%) were the most common indications for pacing; bi- or trifascicular block, sick sinus syndrome, or syncope without documented bradycardia (8% each) were less common.

Anaesthesia, operator, and settings

Out of 67 LLPM patients with available data on operation settings, 46 (69%) patients were implanted under local anaesthesia, 19 (28%) patients under sedation, and within 2 (3%) patients under general anaesthesia. An electrophysiologist was an operator in 40 patients (60%), whereas interventional cardiologist was involved in the remaining implantations. None of LLPMs was implanted by a surgeon. Patients were most commonly implanted in EP laboratory (71%), less frequently (27%) in hybrid catheter lab, and only incidentally (2%) in a surgical theatre (*Figure 1*).

Implantation feasibility and success rate

Among 66 patients with data reported, LLPM implantation was successful in 65 (98%). The reason for the implantation failure was lack of vascular access in a female patient, aged between 76 and 85, with diabetes and chronic renal failure, implanted for chronic atrial fibrillation with a slow ventricular rate. This procedure took place in the hybrid cath lab and was performed by an interventional cardiologist/electrophysiologist. Procedure duration (skin-to-skin time) was <45min in most cases (43 patients; 65%).

Peri-operative routines and safety measures

Among the 20 centres in which LLPMs were implanted during the study period (one centre implanted TV-PMs only), 19 (95%) had cardiac surgery on-site. Sixty-four patients (95%) received a prophylactic dose of antibiotic peri-procedurally. Most patients (77%) were taking oral anticoagulants (OACs) prior to implantation, of whom 59% were on vitamin K antagonists (VKA) and 41% on non-VKA oral anticoagulants (NOAC). Patients taking anticoagulants were most commonly operated on uninterrupted OACs (35%), or during transient (24–48 h) interruption of an antithrombotic drug (35%). Less frequently, OACs were discontinued for <24 h (19%), or for >48 h (6%). Anticoagulation was only permanently withdrawn prior to the procedure in 2%, or temporarily replaced with fractionated heparin (2%) (*Figure 2*).

Table 1 Baseline characteristics of LLPM patients

N (%)	LLPM (*n* = 69)
Age, in years	
18–30	0
31–45	1 (1.45)
46–55	1 (1.45)
56–65	7 (10.14)
66–75	22 (31.88)
76–85	30 (43.48)
86 and over	8 (11.59)
Female	18 (26.09)
Body mass index, kg/m^2	
Underweight	2 (2.90)
Normal	30 (43.48)
Overweight	30 (43.48)
Obese	7 (10.14)
NYHA class	
I	26 (37.68)
II	30 (43.48)
III	11 (15.94)
IV	2 (2.90)
LVEF %; median [25; 75 percentile]	55 [54; 60]
Underlying heart disease	
Ischaemic	15 (35.71)
Dilated	2 (4.76)
Hypertrophic	0
Valvular	19 (45.24)
Congenital	1 (2.38)
Other	4 (9.52)
Unknown	1 (2.38)
Co-morbidities[a]	
Coronary artery disease	16 (23.88)
Chronic renal failure	19 (28.36)
Diabetes	23 (34.33)
COPD	11 (16.42)
Neoplasm	7 (10.45)
None	23 (34.33)
Cardiac rhythm at implant[a]	
Sinus rhythm	19 (28.36)
Atrial fibrillation	43 (64.18)
Atrial flutter	1 (1.49)
Other	4 (5.97)
LBBB	8 (11.59)
RBBB	9 (13.04)
PQ duration; median [25; 75 percentiles]	160 [110; 186]
QRS duration; median [25; 75 percentiles]	103 [85; 140]
Indication for implantation[b]	
Syncope without documented bradycardia	5 (7.69)
Sick sinus syndrome	5 (7.69)
Permanent AF with slow ventricular rate	29 (44.62)
Permanent high degree AV block	9 (13.85)
Paroxysmal high degree AV block	12 (18.46)
Bi- or tri-fascicular block	5 (7.69)

Data presented as numbers (%), unless stated otherwise.
AF, atrial fibrillation; AV, atrioventricular; COPD, chronic obstructive pulmonary disease; LBBB, left bundle branch block; LVEF, ejection fraction of left ventricle; NYHA, New York Heart Association; RBBB, right bundle branch block.
[a]Data available for 67 patients.
[b]Data available for 65 patients.

In-hospital outcomes

The in-hospital period was uneventful for 97% of patients (62/64 patients with available data). One male patient developed groyne haematoma after the procedure. The patient had a history of myocardial infarction and coronary artery by-pass grafting and was taking NOAC prior to the procedure, and the anticoagulant has been discontinued for >48 h, without bridging. One patient died 1 day after unsuccessful implantation, presumably due to pulmonary embolism.

Discussion

This prospective, multicentre, international survey provides insight into European implantation routines and short-term outcomes in LLPMs patients. Although the relatively small number of patients included, unlike most previous documents based on data derived from clinical trials or national registers, this survey provides valuable information on contemporary clinical practices across a broad range of European centres and consecutive patients. The main findings are as follows: (i) typical procedure of LLPM implantation in European tertiary centre is carried out mostly under local anaesthesia, by an electrophysiologist in the electrophysiological laboratory; the involvement of surgeon is imperceptible and the use of the operating theatre is only anecdotal, despite the fact, that almost all implanting centres are equipped with cardiac surgery on-site; (ii) the success rate of implantations was very high, and the lack of vascular femoral access may be the main reason of implantation failure; (iii) perioperative safety measures (use of prophylactic antibiotic or no 'bridging' of oral anticoagulation prior to procedure) are mostly in line with the current recommendations; (iv) despite very unfavourable clinical profile of LLPM patients (older age, many co-morbidities), the short-term outcomes after implantation are good and the proportion of in-hospital, procedure-related complications remains very low.

Procedural settings and feasibility of the procedure

The results of the present survey indicate that currently only anecdotally implantations are performed using surgical room, and what is of note, no surgeon was involved in any of the implantation procedures despite the fact that almost all centres implanting LLPMs reported to have a surgery on-site. Such surgical backup is quite

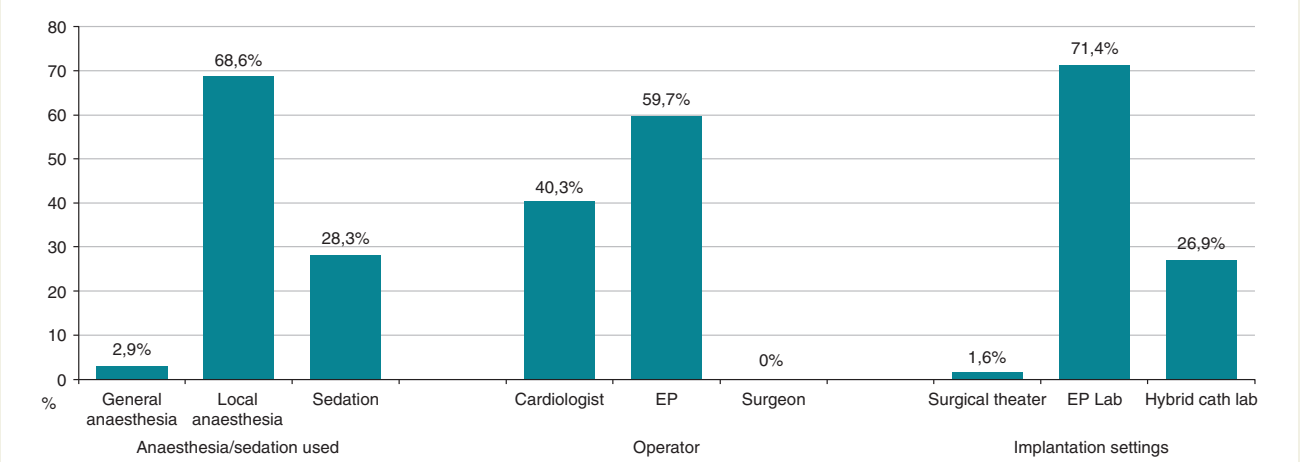

Figure 1 Anaesthesia used, operator, and implantation settings in patients undergoing implantation of leadless pacemakers. EP, electrophysiology. Data on operation theatre were reported for 63 LLPM patients.

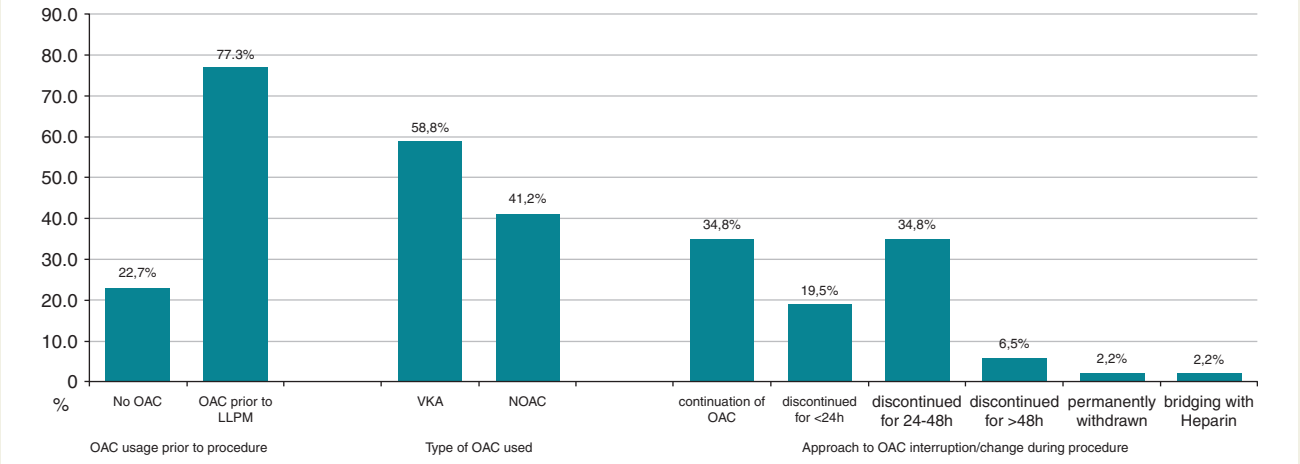

Figure 2 Anticoagulation prior to and during pacemaker implantation. LLPM, leadless pacemaker; NOAC, non-vitamin K oral antagonist; OAC, oral anticoagulants; VKA, vitamin K antagonist.

typical in many countries for the early stages of implementation of new invasive procedures. Probably, with the growth in experience of the operators, greater availability of LLPMs and with the spread of these methods to non-tertiary centres, the proportion of sites which implant LLPMs, and have on-site surgery will decrease. Implantation success rate was close to 99% in this survey, and majority of procedures lasted <45min; these data are very similar to previously published data on LLMPs implantations.[14] Noteworthy is that the only failure was due to lack of adequate vascular access. Compared with historical TV-PM procedures, LLPMs implantations turned out to be at least similarly feasible. In a retrospective German analysis of 610 procedures, VVI implantation performed by operators with different levels of experience lasted roughly 40 and 30 min (less experienced vs. more experienced, respectively).[15] As shown previously, in case of LLPMs, procedure and fluoroscopy duration (but not complication rates, which remain low, even with unexperienced operator) decrease with the number of implantations performed by an operator, and the learning curve is rather steep (procedure duration decrease by 2%, and fluoroscopy time by 3.2% per case).[16]

Peri-procedural safety measures

Almost all patients in the current survey were given prophylactic dose of antibiotics before the procedure. This peri-procedural routine has become a Class I recommendation for patients undergoing TV-PM implantations, since the 2015 Guidelines on Infective Endocarditis were issued by the European Society of Cardiology.[17] Effectiveness of such prophylaxis in LLPM patients remains currently unknown yet, given the potential possibility of developing systemic

bacteraemia\infection with this procedure, it seems reasonable to use the same prevention measures, as in the case of TV-PMs.[18]

Over three-quarters of patients implanted with LLPMs were treated chronically with OAC before the procedure, what is not surprising given that the main indication for a VVI PM implantation is permanent atrial fibrillation. Of these, over 95% were implanted on either uninterrupted OAC (one-third), or during short-term (mainly up to 48 h) interruption of anticoagulants. Only in 2% 'bridging' with heparin was used prior to implantation. Facing the data on the safety of TV-PM implantations on uninterrupted OAC (which by far overwhelms safety of bridging with Heparin), such approach is fully justified and recommended by current guidelines.[19] The 2015 EHRA position document on Antithrombotic Management in Patients Undergoing Electrophysiological Procedures proposes that TV-PMs are implanted on uninterrupted VKA in patients with AF and a CHA_2DS_2-VASc score of ≥3, or with a CHA_2DS_2-VASc score of 2 resulting from stroke or transient ischaemic attack within 3 months. It suggests also, that NOACs should be temporarily discontinued for a period of 24–48 h in most cases, depending on the characteristics of the anticoagulant.[20] No recommendations are provided to date pertaining to OAC use in LLPM procedures; however, the growing amount of data on safety of implantations under uninterrupted VKA and temporarily withdrawn NOACs suggest that the approach recommended in TV-PMs patients may be safely used also in this group, until reliable data are available.[21,22]

In-hospital outcomes

In comparison to several European national registries of cardiac electronic implantable devices, patients in this study presented with substantially more unfavourable clinical profile (i.e. were aged mostly >75 years, burdened with diabetes in one-third, and renal failure in one-fourth of the patients).[6,7,23] Patients' baseline risk profile remained unfavourable in this survey even when limiting the analysis to patients with VVI PMs, who usually constitute the oldest and the sickest group of TV-PMs patients, and typically present with chronic atrial fibrillation. However, despite significant proportion of patients remaining under anticoagulation, complications rate after LLPMs implantation was surprisingly low (indeed, only one procedure-related complication was recorded). These results are in line with results of the Micra Transcatheter Pacing Study, which suggested (by comparing LLMPs with a historical TV-PM group) that the 1-year risk associated with LLPM implantation can be 48% lower as compared with patients with TV-PMs.[24] Even greater reduction of complications (by 63%) with LLPMs, as compared with TV-PMs, was found by another study, based on Micra Investigational Device Exemption Study and Micra Post-Approval Registry.[25] Overall, available data indicate that in the near future, LLPMs can not only become a reasonable alternative to single-chamber TV-PMs, but due to safety reasons, may become a preferred option.

Study limitations

The small number of patients included in this survey is the main limitation. In addition, the number of questions was limited due to constraints associated with the format of online questionnaire, and some important issues (e.g. another co-morbidities, procedural details, like fluoroscopy exposure) may have been omitted. Furthermore, most participating centres were tertiary, highly specialized cardiology centres, what makes data generalization more difficult.

Conclusions

This EHRA survey provided the opportunity to prospectively evaluate current practice on management and in-hospital outcomes of patients implanted with LLPM, in a broad range of European tertiary electrophysiology centres. Our study suggests that LLPM implantation, despite relatively unfavourable clinical profile of patients (including frequent need for anticoagulation), remains safe and is associated with a low risk of complications.

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References

1. Larsson B, Elmqvist H, Ryden L, Schuller H. Lesons from the first patient with an implanted pacemaker: 1958-2001. *Pacing Clin Electrophysiol* 2003;**26**:114–24.
2. Brignole M, Auricchio A, Baron-Esquivias G, Bordachar P, Boriani G, Breithardt OA *et al.*; European Heart Rhythm Association (EHRA). ESC guidelines on cardiac pacing and cardiac resynchronization therapy: the task force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). *Europace* 2013;**15**:1070–118.
3. Epstein AE, DiMarco JP, Ellenbogen KA, Estes NAM, Freedman RA, Gettes LS *et al.* 2012 ACCF/AHA/HRS focused update incorporated into the ACCF/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol* 2013;**61**:e6–75.
4. Boveda S, Lenarczyk R, Haugaa KH, Iliodromitis K, Finlay M, Lane D *et al.* Use of leadless pacemakers in Europe: results of the European Heart Rhythm Association survey. *Europace* 2018;**20**:555–9.
5. Hauser RG, Hayes DL, Kallinen LM, Cannom DS, Epstein AE, Almquist AK *et al.* Clinical experience with pacemaker pulse generators and transvenous leads: an 8-year prospective multicenter study. *Heart Rhythm* 2007;**4**:154–60.
6. Kirkfeldt RE, Johansen JB, Nohr EA, Jørgensen OD, Nielsen JC. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. *Eur Heart J* 2014;**35**:1186–94.
7. Gadler F, Valzania C, Linde C. Current use of implantable electrical devices in Sweden: data from the Swedish pacemaker and implantable cardioverter-defibrillarot registry. *Europace* 2015;**17**:69–77.
8. Kutarski A, Czajkowski M, Pietura R, Obszański B, Polewczyk A, Jacheć W *et al.* Effectiveness, sefety, and long-term outcomes of non-powered mechanical sheats for transvenous lead extraction. *Europace* 2018;**20**:1324–33.
9. Narducci ML, Di Monaco A, Pelargonio G, Leoncini E, Boccia S, Mollo R *et al.* Presence of 'ghosts' and mortality after transvenous lead extraction. *Europace* 2017;**19**:432–40.
10. Abu-El-Haija B, Bhave PD, Campbell DN, Mazur A, Hodgson-Zingman DM, Cotarlan V *et al.* Venous stenosis after transvenous lead placement: a study of

outcomes and risk factors in 212 consecutive patients. *J Am Heart Assoc* 2015;**4**: e001878.
11. Sweeney MO, Shea JB, Ellison KE. Upgrade of permanent pacemakers and single chamber implantable cardioverter defibrillators to pectoral dual chamber implantable cardioverter defibrillators: indications, surgical approach, and long-term clinical results. *Pacing Clin Electrophysiol* 2002;**25**:1715–23.
12. Roberts PR, Clementy N, Al Samadi F, Garweg C, Martinez-Sande JL, Iacopino S *et al*. A leadless pacemaker in the real-world setting: the Micra Transcatheter Pacing System Post-Approval Registry. *Heart Rhythm* 2017;**14**:1375–9.
13. Raatikainen MJ, Arnar DO, Merkely B, Camm AJ, Hindricks G. Access to and clinical use of cardiac implantable electronic devices and interventional electrophysiological procedures in the European Society of Cardiology Countries: 2016 Report from the European Heart Rhythm Association. *Europace* 2016; **18**(Suppl. 3):iii1–79.
14. Reynolds D, Duray GZ, Omar R, Soejima K, Neuzil P, Zhang S *et al*. A leadless intracardiac transcatheter pacing system. *N Engl J Med* 2016;**374**:533–41.
15. Eberhardt F, Bode F, Bonnemeier H, Boguschewski F, Schlei M, Peters W *et al*. Long term complications in single and dual chamber pacing are influenced by surgical experience and patient morbidity. *Heart* 2005;**91**:500–6.
16. El-Chami M, Kowal RC, Soejima K, Ritter P, Duray GZ, Neuzil P *et al*. Impact of operator experience and training strategy on procedural outcomes with leadless pacing: insights from the Micra Transcatheter Pacing Study. *Pacing Clin Electrophysiol* 2017;**40**:834–42.
17. Habib G, Lancellotti P, Antunes MJ, Bongiorni MG, Casalta JP, Del Zotti F *et al*. ESC Scientific Document Group. 2015 ESC Guidelines for the management of infective endocarditis: the Task Force for the Management of Infective Endocarditis of the European Society of Cardiology (ESC). Endorsed by: European Association for Cardio-Thoracic Surgery (EACTS), the European Association of Nuclear Medicine (EANM). *Eur Heart J* 2015;**36**:3075–128.
18. El-Chami MF, Soejima K, Piccini JP, Reynolds D, Ritter 5, Okabe T *et al*. Incidence and outcomes of systemic infections in patients with leadless pacemakers: data from the Micra IDE study. *Pacing Clin Electrophysiol* 2019;**42**:1105–10.
19. Sant'anna RT, Leiria TL, Nascimento T, Sant'anna JR, Kalil RA, Lima GG *et al*. Meta-analysis of continuous oral anticoagulants versus heparin bridging in patients undergoing CIED surgery: reappraisal after the BRUISE study. *Pacing Clin Electrophysiol* 2015;**38**:417–23.
20. Sticherling C, Marin F, Birnie D, Boriani G, Calkins H, Dan GA *et al*. Antithrombotic management in patients undergoing electrophysiological procedures: a European Heart Rhythm Association (EHRA) position document endorsed by the ESC Working Group Thrombosis, Heart Rhythm Society (HRS), and Asia Pacific Heart Rhythm Society (APHRS). *Europace* 2015;**17**:1197–214.
21. Kiani S, Black GB, Rao B, Thakkar N, Massad C, Patel AV *et al*. Outcomes of Micra leadless pacemaker implantation with uninterrupted anticoagulation. *J Cardiovasc Electrophysiol* 2019;**30**:1313–8.
22. Antonio RS, Chipa-Ccasani F, Apolo J, Linhart M, Trotta O, Pujol-López M *et al*. Management of anticoagulation in patients undergoing leadless pacemaker implantation. *Heart Rhythm* 2019;**16**:1849–54.
23. Tuppin P, Neumann A, Marijon E, de Peretti C, Weill A, Ricordeau P *et al*. Implantation and patient profiles for pacemakers and cardioverter-defibrillators in France (2008-2009). *Arch Cardiovasc Dis* 2011;**104**:332–42.
24. Duray GZ, Ritter P, El-Chami M, Narasimhan C, Omar R, Tolosana JM *et al*.; for the Micra Transcatheter Pacing Study Group. Long-term performance of a transcatheter pacing system: 12-month results from the Micra Transcatheter Pacing Study. *Heart Rhythm* 2017;**14**:702–9.
25. El-Chami MF, Al-Samadi F, Clementy N, Garweg C, Martinez-Sande JL, Piccini JP *et al*. Updated performance of the Micra transcatheter pacemaker in the real-world setting: a comparison to the investigational study and a transvenous historical control. *Heart Rhythm* 2018;**15**:1800–7.