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EHRA SURVEY

Factors influencing the use of leadless or transvenous pacemakers: results of the European Heart Rhythm Association Prospective Survey

Serge Boveda [1,2,3]*†, Eloi Marijon[3,4]†, Radoslaw Lenarczyk[5], Konstantinos E. Iliodromitis[6], Francisco Marin[7,8], Pascal Defaye[9], Aude Solnon[10], Nikolaos Dagres[11], and Tatjana S. Potpara[12,13]

[1]Cardiology, Cardiac Arrhythmias Management Department, Clinique Pasteur, 45, Avenue de Lombez, 31076 Toulouse, France; [2]Postgraduate Program in Cardiac EP and Pacing, Universiteit Ziekenhuis Brussel, Vrije Universiteit Brussel (VUB), Brussels, Belgium; [3]INSERM U970, Paris Descartes University, Paris, France; [4]Cardiology Department, European Georges Pompidou Hospital, Paris Cardiovascular Research Center, Paris, France; [5]First Department of Cardiology and Angiology, Silesian Centre for Heart Disease, Curie-Sklodowskiej Str 9, 41-800 Zabrze, Poland; [6]Electrophysiology Section, Department of Cardiology, Cardiovascular Center, OLV, Aalst, Belgium; [7]Department of Cardiology, Hospital Clínico Universitario Virgen de la Arrixaca, Murcia, Spain; [8]IMIB-Arrixaca, CIBERCV, University of Murcia, Murcia, Spain; [9]University Hospital of Grenoble-Alpes, 38043 Grenoble, France; [10]Cardiology Department – CHU Laennec, Nantes, France; [11]Department of Electrophysiology, Heart Center Leipzig, Leipzig, Germany; [12]School of Medicine, University of Belgrade, Belgrade, Serbia; and [13]Cardiology Clinic, Clinical Center of Serbia Visegradska 26, 11000 Belgrade, Serbia

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To study the proportion of leadless pacemaker (LL-PM) implants and the factors influencing the choice of LL-PM vs. transvenous pacemaker (TV-PM) across tertiary centres in Europe with routine availability of the LL-PM. A European Heart Rhythm Association (EHRA) prospective snapshot survey using electronically distributed questionnaire sent to participating centres. Participating tertiary cardiac pacing centres prospectively included consecutive patients implanted between November 2018 and January 2019. Questions covered standards of care and policies used for patient management, focusing particularly on the reasons for choosing LL-PM vs. TV-PM. Overall, 21 centres from four countries (France, Netherlands, Spain, and Italy) participated, with eventual data from 798 patients ($n = 472$, 59% male). With 69 implants, LL-PM represented only 9% of all implants and 36% of the single-chamber pacing group; double-chamber transvenous pacemakers were implanted in 528 patients and biventricular (cardiac resynchronization pacemaker) in 79. The two major reasons reported in favour of LL-PM implantation were an anticipated high risk of infection or low rate of ventricular pacing. Compared to TV-PM, LL-PM patients were more often male (74% vs. 54%, $P = 0.009$), with greater proportion of valvular heart disease (45% vs. 35%, $P = 0.01$) and atrial fibrillation (AF; 65% vs. 23%, $P < 0.0001$), with significantly more comorbidities (≥ one comorbidity, 66% vs. 52%, $P = 0.02$). This contemporary multicentre European survey shows that LL-PM constitutes a small proportion of all PM implants. Patients implanted with LL-PM were more likely to have AF and a high anticipated risk of infection.

Keywords European Heart Rhythm Association survey • Leadless pacing • Atrial fibrillation • Infection

Introduction

Implantable transvenous pacemakers (TV-PMs) have been used since >50 years for the management of bradycardias.[1,2] Whereas the efficacy and overall safety of these devices is high, it has been shown that almost 90% of TV-PM complications are related to the presence of endovascular leads and device pocket issues, such as erosion and infection.[3–5] In addition, the extraction of endovascular leads, most commonly for infection, is challenging and fraught with risks. Lastly, transvenous pacing may sometimes be very difficult or impossible because of venous thrombosis or occlusions.[3,4,6]

* Corresponding author. Tel: +33 562 211 645; fax: +33 562 211 641. *E-mail address*: sboveda@clinique-pasteur.com

† The first two authors contributed equally to the study.

What's new?

- The leadless pacemaker (LL-PM) implantation rates remain small, covering less than about a third of all single-chamber pacemaker implantations in everyday clinical practice in Europe.
- Lack of reimbursement, non-availability, and cost of the device seem to limit the use of the LL-PM.
- Patients implanted with LL-PM were more likely to present with atrial fibrillation and had a high anticipated risk of infection.

For a long time, these considerations have motivated the research for pacing systems free of endovascular leads,[7,8] which has resulted in the development of leadless pacemakers (LL-PMs). Completely intracardiac, miniature, single-chamber ventricular (VVIR) pacing devices, implantable directly in the right ventricular endocardium are now available.[9] These LL-PMs are introduced *via* femoral approach, using large (18–25 Fr) vascular sheaths, and they are screwed or anchored with tines into the endocardium, commonly at the right ventricular apical septum. Several manufacturers are also presently working on the development of dual-chamber devices, with one[10] or two 'modules' implanted independently, which are able to communicate and interact with each other. Leadless pacing is just at the initial stages of its clinical use; cardiac resynchronization systems are also being developed to pace the left ventricle,[11] and this broad technological breakthrough will certainly make a major difference to both patients and implanters.[12]

The aim of this European Heart Rhythm Association (EHRA) international snapshot survey was to provide an insight into both TV-PM and LL-PM utilization, better understand the current impact of LL-PM and underlying reasons for choosing this device and to anticipate future trends.

Methods

An electronic questionnaire for the collection of individual patient data was sent to selected tertiary centres participating in the EHRA electrophysiology (EP) research network. Local ethics committee approval was obtained where needed, as per local policy. Participating centres were selected according to the following criteria: (i) a referral centre for pacemaker implantation and management in respective region and (ii) routine access to both the TV-PM and the LL-PM.

The questionnaire included a total of 30 questions (see the Supplementary material online, Appendix) focusing on the standards and policies concerning patient management and indications for and techniques of pacemaker implantation in the participating EP centres. Many of the questions were focused on factors that could influence the choice of device: TV-PM [including VVI, DDD, and cardiac resynchronization pacemaker (CRT-PM)] or LL-PM. The remaining questions were focused on information that allowed for better understanding of utilization of both types of devices in current practice.

The participating centres were requested to prospectively include consecutive patients admitted for and implanted with a pacemaker (either TV-PM or LL-PM) during a 10-week time period, between November 2018 and January 2019 (*Figure 1*). All patient data were anonymously collected.

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

Results

Participating centres

Overall, there were 21 centres from four countries: 12 centres in France, 4 centres in Spain, 3 centres in Netherlands, and 2 centres in Italy. Of 21 participating centres, 18 were university hospitals, two were non-university hospitals, and one was a private institution. Only one centre did not implant any LL-PM during the survey period. During 12 months preceding this survey, the total number of LL-PM implantations ranged from 3 to 44 per centre; 11 centres (52%) reported to have implanted <20, and 7 centres (33%) implanted between 20 and 29 devices per year.

Patients' characteristics

A total of 825 consecutive patients were included. After a preliminary data review, 27 patients were excluded from further analysis due to incomplete data and 798 patients were included in the present study.

Devices were implanted for symptomatic sinus node disease ($n = 150$, 20%), severe atrioventricular conduction disease ($n = 538$, 70%), or cardiac resynchronization ($n = 79$, 10%).

Only 104 patients (13%) were aged ≤65 years, with a greater proportion of males ($n = 472$, 59%). Most patients were New York Heart Association (NYHA) Class I ($n = 292$, 37%) or II ($n = 370$, 46%), whereas 119 patients (15%) were NYHA III and only 17 (2%) NYHA IV. The overall mean left ventricular ejection fraction was 55 ± 10%. Most patients ($n = 466$, 58%) had underlying structural heart disease (HD): ischaemic HD ($n = 123$, 26%), dilated cardiomyopathy ($n = 36$, 8%), hypertrophic cardiomyopathy ($n = 23$, 5%), valvular HD ($n = 186$, 40%), or other HD ($n = 79$, 21%). Atrial fibrillation (AF) was present in 199 patients (25%), including 92/199 patients (46%) with permanent AF and slow ventricular rate. Left bundle branch block was reported in 175 (26%) and right bundle branch block in 144 (21%) of the patients. The mean QRS duration was 115 ± 31 ms. Other characteristics are listed in *Table 1*.

Factors associated with leadless pacemaker implantation

The total number of LL-PM implanted during the survey period was 69 (9% of all implants). The distribution of other implanted devices was CRT-PM ($n = 79$, 10%), DDD ($n = 528$, 66%), and VVI ($n = 122$, 15%).

Factors associated with LL-PM implantation vs. TV-PM were male sex (74% vs. 58%, $P = 0.009$), valvular HD (45% vs. 35%, $P = 0.01$), and chronic renal failure and diabetes (28% vs. 16%, $P = 0.01$ and 34% vs. 21%, $P = 0.01$, respectively). Overall, LL-PM patients presented with

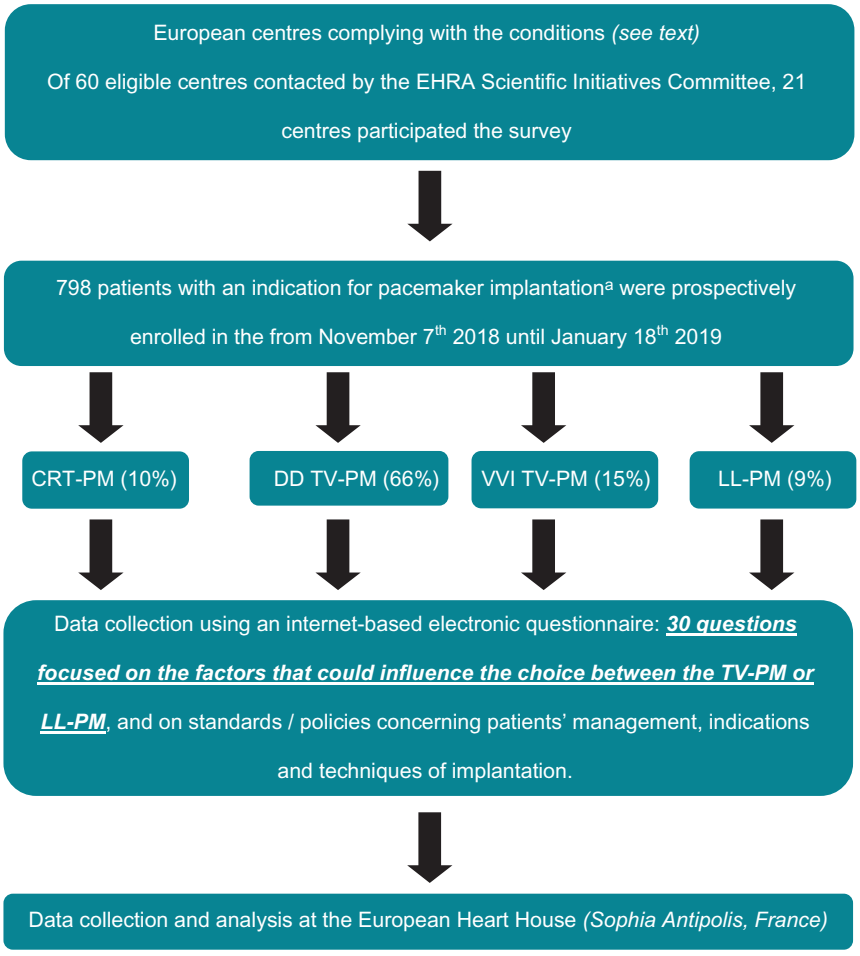

Figure 1 A flowchart of patients included in the pacemaker prospective survey from EHRA. CRT-PM, cardiac resynchronization pacemaker; DD TV-PM, double-chamber transvenous pacemaker; LL-PM, leadless pacemaker; VVI TV-PM, single-chamber transvenous pacemaker. [a]According to the 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy.[1]

significantly more comorbidities than those in the TV-PM group (≥ one comorbidity, 66% vs. 52%, $P = 0.02$; *Table 1*). No significant interaction was observed with age ($P = 0.12$).

When compared with TV-PM implanted patients, LL-PM patients were significantly more often in AF/atrial flutter (65% vs. 23%, $P < 0.0001$). The LL-PM and VVI TV-PM: single-chamber transvenous pacemaker (VVI TV-PM) implantation indications showed a very similar profile, with severe conduction diseases constituting >80% of total pacing indications in each group.

Reasons leading to implantation of a leadless pacemaker

No specific factor was overwhelmingly reported to prioritize LL-PM implantation in this survey. The most commonly declared settings favouring the LL-PM implantation were old age (38%), anticipated high risk of infection or previous device infection with removal (46%), previous or anticipated lead-related complications (19%), or anticipated low rate of ventricular pacing (25%) (*Figure 2*).

The most common factors favouring the use of a TV-PM were the need for resynchronization (in 100% of CRT TV-PM) and atrial pacing (90% of DDD TV-PM). In addition, advanced age and anticipated high rate of ventricular pacing were also reported to be barriers in 53% and 34% of the VVI TV-PM patients, respectively, for which the use of an LL-PM could have been a viable alternative (*Figure 3*).

Discussion

Our prospective multicentre international study of 798 patients implanted with a PM added information to better understand the criteria governing the choice between LL-PM and TV-PM in contemporary European practice.

The main findings are as follows: (i) the LL-PM implantation rates remain small, covering less than about a third of all single-chamber pacemaker implantations in everyday clinical practice in Europe; (ii) in addition to reimbursement issues, patients implanted with LL-PM

Table 1 Baseline characteristics of TV-PM vs. LL-PM patients

	N	CRT-PM (*n* = 79)	DD TV-PM (*n* = 528)	VVI TV-PM (*n* = 122)	LL-PM (*n* = 69)	*P*-value
Type of centre	798					
University hospital		60 (76.0)	466 (88.3)	110 (90.2)	65 (94.2)	0.2
Private hospital		19 (24.1)	61 (11.6)	12 (9.8)	4 (5.8)	
Non-university hospital		0	1 (0.2)	0	0	
Age (years)						
18–30	798	0	4 (0.8)	1 (0.8)	0	0.12
31–45		0	12 (2.3)	0	1 (1.5)	
46–55		3 (3.8)	21 (3.9)	0	1 (1.5)	
56–65		6 (7.6)	45 (8.5)	3 (2.5)	7 (10.1)	
66–75		19 (24.1)	115 (21.8)	18 (14.8)	22 (31.9)	
76–85		42 (53.2)	226 (42.8)	37 (30.3)	30 (43.5)	
>85		9 (11.4)	105 (19.9)	63 (51.6)	8 (11.6)	
Sex (male)	798	41 (51.9)	321 (60.8)	59 (48.4)	51 (73.9)	0.009
BMI	798					
<18.5		5 (6.3)	16 (3.0)	12 (9.8)	2 (2.9)	0.58
18.5–24.9		34 (43.0)	236 (44.7)	53 (43.4)	30 (43.5)	
25–34.9		31 (39.2)	247 (46.8)	50 (40.9)	30 (43.5)	
>35		9 (11.4)	29 (5.5)	7 (5.7)	7 (10.1)	
LVEF (%), median (IQR)	749	35 (30–40)	60 (55–60)	58 (52–60)	55 (54–60)	0.53
NYHA	798					
I		4 (5.1)	227 (43.0)	35 (28.7)	26 (37.7)	0.94
II		32 (40.5)	242 (45.8)	66 (54.1)	30 (43.5)	
III		37 (46.8)	53 (10.0)	18 (14.8)	11 (15.9)	
IV		6 (7.6)	6 (1.1)	3 (2.5)	2 (2.9)	
Heart disease	798	72 (91.1)	275 (52.1)	77 (63.1)	42 (60.9)	0.66
Ischaemic		15 (20.8)	67 (24.4)	26 (33.8)	15 (35.7)	0.32
Dilated		30 (41.7)	3 (1.1)	1 (1.3)	2 (4.8)	
Hypertrophic		2 (2.8)	16 (5.8)	5 (6.5)	0	
Valvular		18 (25.0)	120 (43.8)	29 (37.7)	19 (45.2)	
Congenital		0	9 (3.3)	1 (1.3)	1 (2.4)	
Other		7 (9.7)	55 (20.1)	13 (16.9)	4 (9.5)	
Unknown		0	4 (1.5)	2 (2.6)	1 (2.4)	
Comorbidities	789					
Coronary artery disease		17 (21.5)	87 (16.7)	27 (22.3)	16 (23.9)	0.25
Chronic renal failure		20 (25.3)	67 (12.8)	29 (23.9)	19 (28.4)	0.01
Diabetes		10 (12.7)	109 (20.9)	32 (26.5)	23 (34.3)	0.01
Chronic obstructive pulmonary disease		6 (7.6)	55 (10.5)	17 (14.1)	11 (16.4)	0.16
Neoplasms		5 (6.3)	20 (3.8)	6 (5.0)	7 (10.5)	0.02
None		39 (49.4)	269 (51.5)	45 (37.2)	23 (34.3)	0.02
Cardiac rhythm at implantation	789					
Sinus		46 (58.2)	390 (74.7)	48 (39.7)	19 (28.4)	<0.0001
Atrial fibrillation		27 (34.2)	62 (11.9)	67 (55.4)	43 (64.2)	
Atrial flutter		4 (5.1)	9 (1.7)	1 (0.8)	1 (1.5)	
Other		2 (2.5)	61 (11.7)	5 (4.1)	4 (6.0)	
PR duration (ms), median (IQR)	387	204 (188–240)	189 (160–220)	240 (205–280)	160 (110–186)	0.05
QRS duration ms, median (IQR)	676	142 (120–160)	110 (90–132)	110 (90–134)	103 (85–140)	0.28
Bundle branch block						
Right		6	107	23	8	
Left		54	88	24	9	

Continued

Table 1 *Continued*

	N	CRT-PM (n = 79)	DD TV-PM (n = 528)	VVI TV-PM (n = 122)	LL-PM (n = 69)	P-value
Cardiac arrhythmia	761					
Syncope without documented bradycardia		2 (3.1)	57 (11.1)	9 (7.6)	5 (7.7)	<0.0001
Sick sinus syndrome (mostly in sinus rhythm)		6 (9.2)	125 (24.4)	14 (11.8)	5 (7.7)	
Permanent atrial fibrillation with slow ventricular rate		13 (20.0)	11 (2.2)	39 (32.8)	29 (44.6)	
Permanent high degree AV block		16 (24.6)	137 (26.8)	28 (23.5)	9 (13.8)	
Paroxysmal high degree AV block		5 (7.7)	137 (26.8)	24 (20.2)	12 (18.5)	
Bi- or tri-fascicular block		23 (35.4)	45 (8.8)	5 (4.2)	5 (7.7)	

Values are expressed as *n* (%) or in mean ± SD unless stated otherwise.
AV, atrioventricular block; BMI, body mass index; DD TV-PM: double-chamber transvenous pacemaker; EP, electrophysiological; IQR, interquartile range; LBBB, left bundle branch block; LL-PM, leadless pacemaker; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PM, pacemaker; RBBB, right bundle branch block; SD, standard deviation; VVI TV-PM: single-chamber transvenous pacemaker.
- *P*-value for comparisons LL-PM vs. TV-PM.
- Data are available for 798 patients in total, but device type specified in 383.
- Data are available for 69 LL-PM patients.
- Data are available for 729 TV-PM patients.

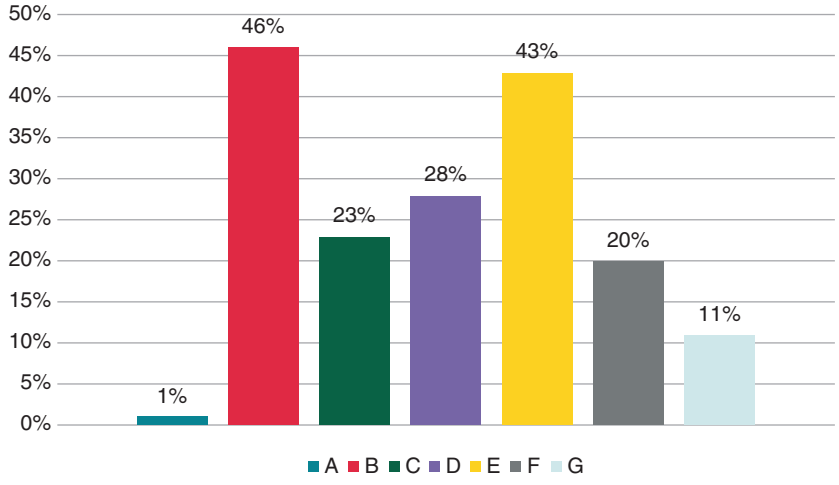

Figure 2 Factors in favour of an LL-PM implantation (multiple answers): each bar represents one possible answer (proportion of responders to each question). A, young age; B, old age; C, anticipated low rate of pacing; D, previous or anticipated lead-related complications; E, previous device infection or anticipated infection risk; F, vascular issues; G, patient preference. LL-PM, leadless pacemaker.

were more likely to present with AF and had a high anticipated risk of infection.

Current global pacemaker implantation practice in European tertiary centres

Our survey provides a picture of the current pacemaker implantation activity in European high-reference centres. Probably the most noteworthy finding is a low rate of LL-PM implantation showing low penetration of this treatment in everyday clinical practice.

The characteristics of the patients in this survey are broadly concordant with those in previously published reports from 'real-world' registries,[4] including a greater proportion of male patients undergoing PM implantation, with a two-fold higher implantation rate among men.[4,5] In addition, more than half of the patients implanted during our study period were suffering from structural HD, which is also consistent with other registries.[4–6]

Considering indications, the main reason to implant a pacemaker in this survey was symptomatic severe atrioventricular block conduction disease (more than two-thirds of patients), with less than one-third of patients implanted for sinus node dysfunction. This distribution has also been observed in many other surveys.[4–6]

Regarding the distribution of implanted device types, dual-chamber implantations were most commonly observed in our cohort. This survey demonstrates well that the subgroup of single-chamber pacemaker patients now includes a significant, but still minor proportion

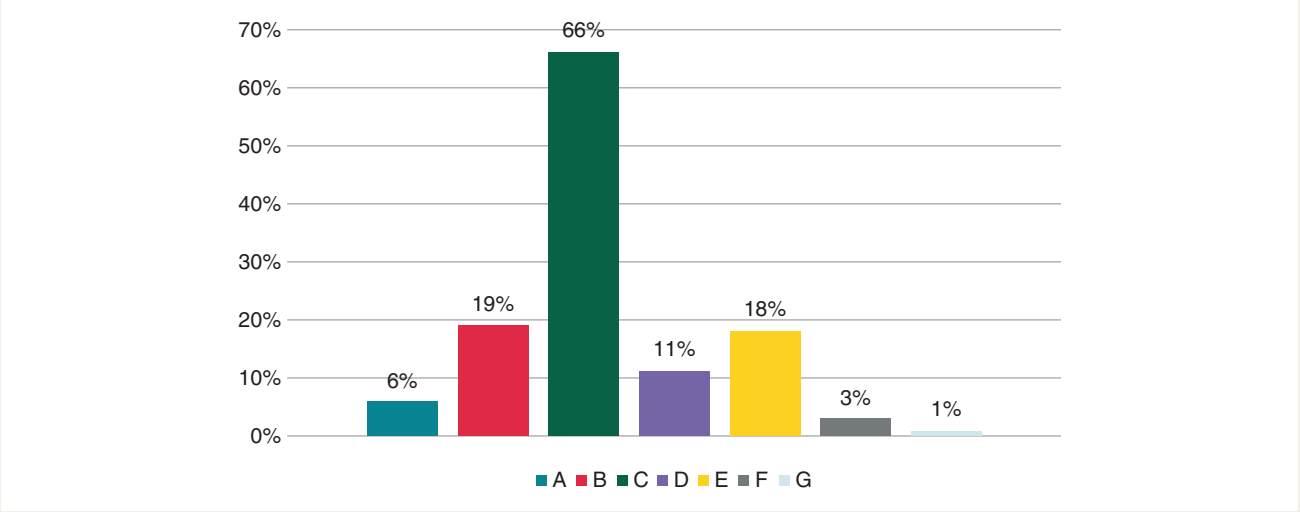

Figure 3 Factors in favour of a transvenous pacemaker implantation (multiple answers): each bar represents one possible answer (proportion of responders to each question). A, availability of LL-PM or cost issues; B, need for permanent pacing; C, need for dual-chamber pacing; D, need for CRT pacing; E, too elderly patient; F, too young patient; G, patient preference. CRT, cardiac resynchronization; LL-PM, leadless pacemaker.

of subjects with LL-PM, covering less than a third of the total number of single-chamber pacemaker implantations in selected centres with the possibility to implant all types of devices.

Reasons for choosing leadless pacemaker vs. transvenous pacemaker

Although the LL-PM device is routinely available, reimbursement issues are likely a major factor still limiting the LL-PM implantation rate across Europe. Since the hospitals participating in this study can afford the cost, our survey reports—for the first time in real-world practice—other important reasons favouring one type of pacemaker over another.

The first reported reason that favoured decision towards LL-PM implantation in our survey was advanced patient age. Nevertheless, older age was also reported to be a factor favouring VVI TV-PM implantation. These conflicting observations currently pose some challenge in choosing the ideal subject for an LL-PM regarding age. While the best candidates for this device, with regard to lead and endovascular complications,[13] are theoretically the youngest, battery longevity, and replacement management makes it difficult to diffuse it routinely in this group of patients, while the cost considerations and comorbidity limit the use of LL-PM in the elderly. This will likely improve in the near future, with improving battery longevity and device extraction possibilities (allowing several replacements). Cost of this device should also gradually decrease.

The anticipation of low rate of ventricular pacing has also been reported in this survey as a factor favouring the LL-PM, which is closely related to the battery longevity concern: a low pacing rate will significantly increase the battery longevity, and consequently, the duration between replacements of the device will be prolonged. In this setting, an anticipated low rate of pacing will encourage the use of LL-PM in younger patients.

Lastly, as expected, an elevated risk of device infection or vascular issues were also noted to be factors favouring choice of an LL-PM implantation.[14,15]

The main reasons for choosing TV-PM systems included the need for CRT and/or atrial pacing. Obviously, the LL-PM cannot still compete in these fields, and it is likely that such reasons will remain valid until the achievement of currently developing technological breakthroughs, which will allow atrial and left ventricular pacing by leadless technology.[10,11,16]

Future perspectives

It seems reasonable to assume that, in the absence of technical issues, the LL-PM could progressively replace a significant proportion of single-chamber pacemaker implantation procedures in patients who do not need resynchronization therapy. Already developing technical improvements will probably allow expanding the leadless pacing solution to other indications such as dual-chamber pacing or resynchronization in the future. However, the use of LL-PM is still considerably limited by reimbursement issues and availability of the device in many European countries.

Limitations

The limitations of this prospective observational study include a voluntary participation of the centres (the survey is, therefore, not exhaustive and the centre selection process could be biased). Second, the multiple-choice questions in the survey's electronic questionnaire could have not completely covered all relevant options. Finally, owing to the declarative description of the reasons for choosing specific treatment options, the survey may not be entirely representative of the treatment decision-making process in the participating centres.

Conclusion

This snapshot survey provides a contemporary insight into pacemaker implantation and management across European EP centres and shows a gradual, but still small increase in LL-PM implantation rate with the implantation of an LL-PM was more likely in patients presenting with AF or a high anticipated risk of infection.

Supplementary material

Supplementary material is available at *Europace* online.

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