ESC European Society of Cardiology

Europace (2020) **22**, 939–946
doi:10.1093/europace/euaa097

Leadless pacemaker implantation quality: importance of the operator's experience

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Received 16 December 2019; editorial decision 2 April 2020; accepted 4 April 2020; online publish-ahead-of-print 3 May 2020

Aims Leadless cardiac pacemaker (PM) implantation differs from conventional PM implantation. While the procedure has been considered safe, recent real-world data raised concerns about the learning curve of new operators and their implantation quality. The goal of this study was to investigate the influence of the first operator's experience on leadless PM implantation quality and procedural efficiency.

Methods and results We performed a bicentric analysis of all Micra TPS™ implantations in two large tertiary referral hospitals. We assessed both leadless PM implantation quality based on the absence of complications (requiring intervention or prolonged hospitalization), good electrical performance (pacing threshold ≤ 1.5 V/0.24 ms, R-wave amplitude > 5 mV), and acceptable fluoroscopy duration (<10 min) as well as procedural efficiency in relation to the operator's experience. Univariate and multivariate logistic regression analyses were performed to identify predictors for implantation quality and procedural efficiency. Leadless PM implantation was successful in 106/111 cases (95.5%). Three patients (2.7%) experienced acute complications (one cardiac tamponade, one femoral bleeding, one posture-related PM exit block). Multivariate analysis showed that implantation quality of more experienced first operators was higher [odds ratio 1.09 (95% confidence interval 1.00–1.19), $P = 0.05$]. Procedural efficiency increased with operator experience as evidenced by an inverse correlation of procedure time, time to the first deployment, fluoroscopy time, and the number of procedures performed (all $P < 0.05$).

Conclusion The operator's learning curve is a critical factor for leadless PM implantation quality and procedural efficiency.

Keywords Leadless pacemaker • Micra • Experience • Learning curve • Implantation quality • Safety

Introduction

Leadless cardiac pacemakers (PMs) have been introduced to overcome the Achilles heel of conventional systems, the pacing lead. Initial results from the most widely used leadless PM, the Micra TPS™ (Medtronic, Minneapolis, MN, USA), showed that the implantation procedure is feasible and safe.[1] This was confirmed subsequently in the Micra Investigational Device Exemption study, where 3.4% of patients experienced acute relevant complications, which was lower than in a historical cohort of conventional transvenous systems.[2] Due to these promising results and encouraging reports on electrical long-term efficacy,[3] leadless PMs became implanted more frequently despite limited experience with this technology.

These initial results from multicentre registries have been questioned more recently by 'real-world reports'. Alarming acute major complication rates of 6.5–20%[4,5] (including mortality rates of up to

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What's new?

- A significant leadless cardiac pacemaker (PM) implantation learning curve exists.
- Leadless cardiac PM implantation quality is significantly higher if more experienced first operators perform the implantation.
- Overall procedure duration, fluoroscopy duration, and radiation dose decrease with increasing operator experience.

1.5%[6]) and 1-year serious adverse event rates of almost 10%[5] have been reported. These publications give rise to concern. Notably, leadless PM implantations are in many ways not comparable to conventional PM implantations. An operator's individual learning curve, appropriate training, and the implantation technique may affect the quality of the procedure and outcomes. Noteworthy, the required skills are very different from the ones needed for conventional PM implantations. Implanters, who are not also invasive electrophysiologists, need to acquire a new skill set. Accordingly, widespread adoption of this new technology might potentially increase overall complication rates, lower implantation quality, and jeopardize leadless PM technology *per se*. The apparent influence of operator experience on acute complications has already been reported for the Nanostim™ leadless PM (Abbott, Chicago, IL, USA),[7] whereas data for the Micra TPS™ remain conflicting and the effect of the operator's learning curve on implantation quality remains unclear.[8]

In this study, we present transparent data on the learning curves of individual first operators. We investigate the impact of increasing experience on implantation quality and procedural efficiency and report data on outcomes after leadless PM implantation.

Methods

Study design and patient population

In this investigator-initiated observational study from the two largest tertiary electrophysiology referral centres in Switzerland, we analysed all implantation procedures of a Micra TPS™. All attempted implantation procedures from June 2015 (first implantation in any of the two sites) until January 2019 were analysed and no exclusion criteria applied. All patients had a PM indication according to current guidelines.[9] The decision to implant a leadless system was made individually based on the patient's co-morbidity. The study was reviewed and approved by the local ethics committees and conducted according to the principles of the Declaration of Helsinki. The authors designed the study, gathered and analysed the data, and vouch for the data and analysis.

Implantation procedure and implanter training

The Micra TPS™ is a miniaturized single-chamber PM that is implanted transvenously via a steerable catheter directly in the right ventricle, according to a previously described standard implantation procedure.[2] All implantations were performed in the catheterization laboratories of our institutions by seven different first operators. All operators were electrophysiologists performing catheter ablations and device implantations for two up to 20 years. Moreover, they all had undergone the implantation training recommended by the manufacturer prior to their first implantation. This also included at least several simulated implantations on a bench simulator. The first two implantations in one centre were assisted by a proctor. In the other centre, the manufacturer's technical field representative was present during the first 30 implantations. In addition, all procedures were assisted by a second physician. The implantations were performed via femoral venous access. Most implantations were performed under conscious analgosedation using fentanyl, propofol, and/or benzodiazepines. The Micra TPS™ was advanced under fluoroscopic guidance into the right ventricle. Right and left anterior oblique (LAO) fluoroscopic projections and contrast medium injections were used to identify a suitable position for PM deployment. After deployment, the stability of the mechanical fixation was verified by a 'pull-and-hold test' and device interrogation was performed. Whenever the tests showed appropriate results, the PM was released definitely. The femoral access site was closed with a suture ('figure-of-eight' or 'Z-stitch') to achieve haemostasis. After the implantation, the patients were monitored overnight on the ward or the intermediate care unit. Chest radiography and device interrogation were performed the next morning.

Data acquisition and follow-up

Detailed implantation procedure data were acquired prospectively (e.g. procedure duration from venipuncture to final wound closure, radiation duration and dose, amount of used contrast medium, electrical parameters, cumulative experience of the operator). Post-procedural and follow-up data were collected from the hospitals' electronic files and from external cardiologists. Perioperative complications were defined as any events that prolonged hospital stay due to further treatment, ongoing monitoring, or further investigations. Follow-up visits were scheduled 1–3 months after the implantation and in at least yearly intervals thereafter.

Assessment of pacemaker implantation quality and procedural efficiency

To analyse the impact of patient- and operator-specific variables on acute implantation quality, all implantation procedures were categorized by the investigators into two groups ('good implantation quality' or 'impaired implantation quality') using objective criteria. The adjudication of the implantation quality factored in acute complications, electrical performance, and fluoroscopy duration. In detail, good implantation quality was reached if (i) no complication occurred, (ii) electrical device performance was acceptable (pacing threshold $\leq$ 1.5 V/0.24 ms, sensed R-wave > 5 mV), and (iii) fluoroscopy duration was short (<10 min).

Procedural efficiency was assessed by analysing overall implantation time, time to first PM deployment, the number of required PM deployments, fluoroscopy duration, cine time, and radiation dose (dose-area-product) for each implantation procedure.

Statistical analysis

For statistical analysis R version 3.6.1 for Windows (R Foundation, Vienna, Austria) was used. Categorical variables are expressed as numbers and corresponding percentages. Continuous variables are shown as mean ± 1 SD or median and interquartile range (IQR) after assessing the data distribution (using Q–Q plots and Shapiro–Wilk's test). We assessed the correlation of operator experience (the number of leadless PM implantations) and procedural efficiency using Spearman's rank correlation coefficient ($\rho_{Spearman}$). Comparisons between patient groups were performed using Wilcoxon's rank-sum test. Electrical PM follow-up parameters were analysed with respect to initial implantation values using Wilcoxon's signed-rank test.

Univariate and multivariate binary logistic regression models were fitted to quantify the association between selected baseline variables and procedure quality. Variables were selected a priori based on previously described patient-specific risk factors for leadless PM implantation [age,

gender, body mass index (BMI), heart failure, implantation indication not related to atrial fibrillation].[10] In addition, procedure-related factors were assessed. The full multivariate model included all variables from the univariate models with a *P*-value <0.1. This was an exploratory analysis within an observational study, and sample size of the overall cohort was not determined specifically for this analysis. A *P*-value ≤0.05 was considered significant.

Results

Patient and procedural data

Implantation was successful in 106/111 cases (95.5%). Baseline patient characteristics are shown in *Table 1*, details on procedural characteristics in *Table 2*. The device was implanted septally in 65%, apically in 28%, in the right ventricular outflow tract in 6%, and at other sites in 1% of cases. Five implantations were aborted prematurely as the implantation catheter could not be safely placed in the right ventricle [three cases due to venous vessel anatomy (tortuosity, compression), two cases due to thoracic/cardiac anatomy (kyphoscoliosis)]. Patients with aborted implantation were less heavy than patients, who successfully underwent implantation [median weight 64 kg (IQR 58–64 kg) vs. 78 kg (IQR 67–87 kg), $P = 0.05$] and showed a trend towards smaller body height [1.60 m (IQR 1.55–1.62 m) vs. 1.7 m (IQR 1.63–1.75 m), $P = 0.07$]. The BMI was not different between patients with and without aborted implantation [25.9 kg/m^2 (IQR 21.6–26.6 kg/m^2) vs. 27.0 kg/m^2 (IQR 23.5–30.1 kg/m^2), *P* = not significant].

Impact of operator experience on leadless pacemaker implantation quality

The implantation quality depended on procedure-related factors (*Table 3*). In the univariate and multivariate analyses, the overall implantation quality of experienced operators was higher ($P = 0.05$). The experience of the second operator or continued anticoagulation had no effect on procedure quality.

In total, 29 implantations (27%) were of impaired quality according to our definition. This was related to three complications (2.7%, see section 'Acute perioperative complications'), 19 cases (17.9%) with high fluoroscopy duration, 6 patients (5.7%) with low R-wave amplitude, and 2 patients (1.9%) with insufficient pacing thresholds.

Impact of operator experience on procedural efficiency

The total number of implanted leadless PMs as first operator ranged from 5 to 20 implantations. Individual operator-dependent learning curves are shown in *Figure 1*.

We observed a significant impact of the first operator's experience with Micra TPS^{TM} implantations on procedural efficiency (*Figure 2*). Increasing experience correlated inversely with overall implantation time ($\rho_{Spearman} = -0.2$, $P = 0.05$), time to the first PM deployment ($\rho_{Spearman} = -0.40$, $P = 0.004$), fluoroscopy duration ($\rho_{Spearman} = -0.29$, $P = 0.003$), cine time ($\rho_{Spearman} = -0.37$, $P = 0.009$), and radiation dose ($\rho_{Spearman} = -0.30$, $P = 0.002$). The number of required PM deployments showed no significant correlation with the operator's experience ($\rho_{Spearman} = -0.03$, *P* = not significant).

Table 1 Patient baseline characteristics

Patient characteristics	*n* = 111
Clinical patient characteristics	
Age (years)	80 (75–85)
Female gender (*n*)	30 (27%)
Body height (m)	1.69 (1.63–1.75)
Body mass index (kg/m^2)	26.6 (23.5–29.1)
NYHA class	2 (1–2)
CHA_2DS_2-VASc score	4 (3–5)
Uninterrupted oral anticoagulants or therapeutic heparin (*n*)	76 (68%)
Bundle branch block (*n*)	48 (44%)
LBBB (*n*)	14 (13%)
RBBB (*n*)	21 (19%)
Incomplete LBBB or RBBB (*n*)	9 (8%)
Temporary ventricular pacing, complete AV block (*n*)	4 (4%)
Patient comorbidities	
Coronary artery disease (*n*)	46 (42%)
Arterial hypertension (*n*)	86 (80%)
Diabetes (*n*)	29 (27%)
Dyslipidaemia (*n*)	47 (46%)
Chronic kidney disease (eGFR < 60 mL/min) (*n*)	58 (59%)
Echocardiography data	
LVEF (%)	58 (53–60)
TAPSE (mm)	18 (14–23)
LVEDD (mm)	47 (43–54)
PM indication	
Atrial arrhythmia with intermittent bradycardia (*n*)	42 (38%)
Permanent or intermittent third degree AV block (*n*)	35 (32%)
Atrial tachyarrhythmia, planned AV node ablation (*n*)	18 (16%)
Permanent or intermittent other AV block (*n*)	7 (6%)
Sick sinus syndrome (*n*)	7 (6%)
Carotis sinus hypersensitivity (*n*)	2 (2%)

Median values with interquartile ranges in brackets and absolute numbers with percentages are shown.
AV, atrioventricular; eGFR, estimated glomerular filtration rate; LBBB, left bundle branch block; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PM, pacemaker; RBBB, right bundle branch block; TAPSE, tricuspid annular plane systolic excursion.

Acute perioperative complications

In total, we observed three perioperative complications (2.7%):

- A 65-year-old male haemodialysis patient with intermittent complete atrioventricular (AV) block developed cardiac tamponade ~6 h after implantation (10th implant of operator #4, *Figure 1*). The procedure had been uneventful with a single PM deployment, three engaged tines, and acceptable electrical parameters (pacing

threshold 0.5 V/0.24 ms, sensed R-wave 18.6 mV, impedance 1370 Ω). The procedure had been performed under oral anticoagulation (phenprocoumon, INR 2.04) that was stopped after the tamponade became apparent. He required pericardial drainage, which was removed the following day. The patient stayed in the hospital for 3 days and was released without further sequelae.

- A 66-year-old female with left bundle branch block and first degree AV block after transcatheter aortic valve implantation developed femoral bleeding. The complication became apparent after the withdrawal of the introducer. The patient was under dual platelet inhibition. This was the first implantation of operator #5 (*Figure 1*). Sonography and thrombin injection was performed; no further therapies were required otherwise.
- An 84-year-old male with tachycardiomyopathy due to atrial fibrillation underwent Micra implantation and AV node ablation directly afterwards. The implantation had been uneventful with three engaged PM tines, a pacing threshold of 0.38 V/0.24 ms, and an R-wave amplitude of 7.1 mV. The patient developed intermittent posture-dependent exit block and syncope during mobilization. This was the first implantation of operator #1 (*Figure 1*). While standing, the patient repeatedly showed pacing thresholds ≥1.75 V/0.24 ms, the pacing threshold in recumbent position was still 0.38 V/0.24 ms. The pacing output was adjusted and the patient was released 4 days later on maximum stimulation output.

Table 2 Procedural data

Procedural characteristics	*n* = 111
Procedure times	
Procedure duration (min)	45 (33–63)
Time to first 'pull-and-hold' test (min)	30 (22–41)
Mechanical implantation characteristics	
Number of engaged tines (*n*)	2 (2–3)
Number of required PM deployments (*n*)	1 (1–2)
1 deployment (*n*)	63 (63%)
2–4 deployments (*n*)	29 (29%)
>4 deployments (*n*)	8 (8%)
Used volume of contrast medium (mL)	25 (16–40)
Acute electrical performance at the final device implantation site	
Pacing threshold (V/0.24 ms)	0.5 (0.38–0.86)
Sensed R-wave amplitude (mV)	9.6 (6.5–14.0)
Pacing impedance (Ω)	690 (580–790)
Imaging	
Fluoroscopy duration (min)	5.9 (3.3–9.0)
Cine image acquisition time (s)	20 (11–28)
Radiation dose (cGycm^2)	1413 (658–3120)

Median values with interquartile ranges in brackets and absolute numbers with percentages are shown.
PM, pacemaker.

Complications and trends during follow-up

Mean follow-up duration was 13 ± 10 months (range 0–34 months). During the follow-up, 25 patients died, however, no death was procedure- or device-related. We observed no new complications during follow-up. The patient with intermittent exit block did not develop syncope anymore, and repeated device interrogation showed a stabilization of the pacing threshold around 1.0 V/0.24 ms, which allowed lowering the pacing output.

At 1-year follow-up, median pacing thresholds remained stable and were not different with respect to the initial thresholds at implantation (0.5 vs. 0.5 V/0.24 ms, P = not significant). Median sensed R-waves increased (12.9 vs. 9.6 mV at implantation, $P < 0.001$) and median stimulation impedance decreased (570 vs. 690 Ω at implantation, $P < 0.001$).

Discussion

In this investigator-initiated bicentric observational study, we assessed the course and impact of detailed individual learning curves of leadless PM implanters, which has not been done previously. Acute implantation quality and procedural efficiency clearly improve with increasing experience of an operator.

Table 3 Predictors for good leadless PM implantation quality

Variables	Univariate analysis		Multivariate analysis	
	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Patient-related factors				
Age	1.00 (0.95–1.05)	0.90	–	–
Male gender	1.35 (0.53–3.44)	0.53	–	–
Body mass index	1.02 (0.93–1.12)	0.70	–	–
LVEF	1.03 (0.98–1.08)	0.20	–	–
AF-related implantation indication	2.08 (0.88–4.94)	0.10	2.07 (0.86–4.99)	0.11
Procedure-related factors				
Experience first operator	1.09 (1.00–1.19)	0.045	1.09 (1.00–1.19)	0.05
Experience second operator	0.99 (0.96–1.03)	0.66	–	–
Therapeutic anticoagulation	1.49 (0.61–3.64)	0.38	–	–

AF, atrial fibrillation; CI, confidence interval; LVEF, left ventricular ejection fraction; OR, odds ratio; PM, pacemaker.

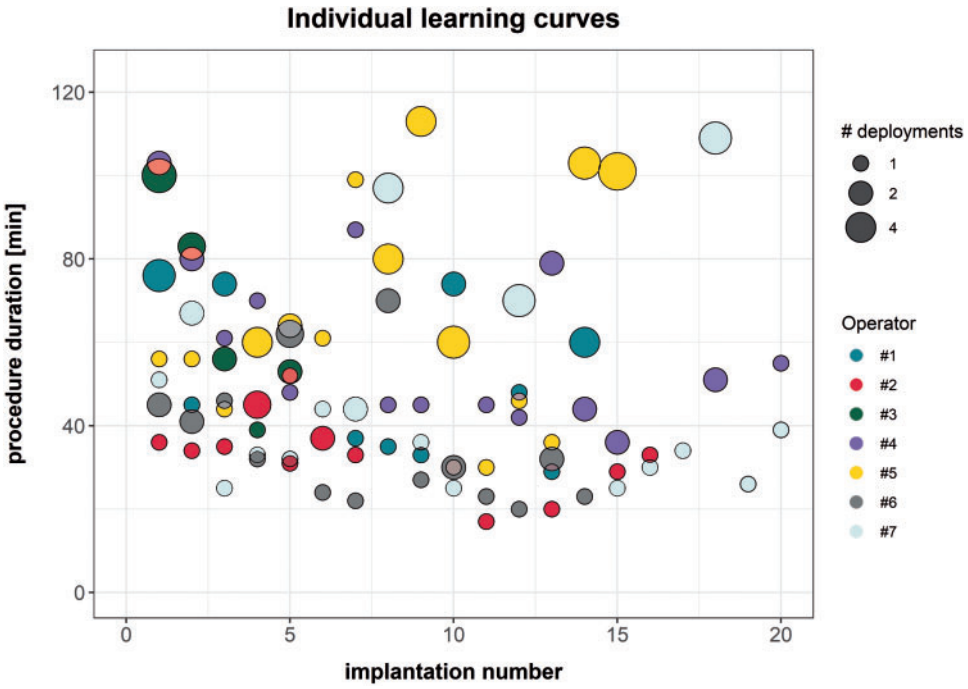

Figure 1 Learning curves of individual operators: colours denote the seven different operators, point sizes the number of required pacemaker deployments. Intervention number 18 of operator #7 is described further in *Figure 3*.

Role of experience on procedural quality

Two of three complications occurred during the first implantation of an operator. However, the overall number of complications in our cohort was low and no significant correlation of operator experience and incidence of complications was found. Interestingly, despite a relatively limited patient number, our data show that procedural quality depends on the first operator's experience in the multivariate analysis.

The key question of how many implantations an operator must perform to reach full implantation competency is challenging and cannot be answered based on our results. Some authors argue that leadless PM implantation proficiency may be reached after just 10 implantations.[7] This is based on reports from studies investigating the learning curve after introduction of other new device technologies, e.g. subcutaneous defibrillators (S-ICD) or cardiac resynchronization therapy (CRT). The learning curve of an operator was steepest during the first 10 CRT implantations[11] and in case of S-ICD implantations, complication rates remained stable after 13 procedures.[12] However, these studies mainly focused on acute procedural success and infection rates and not general implantation quality. In addition, the implantation of a leadless PM differs significantly from conventional PM implantations. This poses an additional challenge for physicians without experience in catheter-based interventions and may increase the number of implantations required to obtain a good implantation quality. Other complex invasive cardiovascular procedures such as transcatheter aortic valve implantation showed significantly prolonged learning curves of 40–80 required procedures when accounting for a more complex quality-based endpoint.[13] Thus, appropriate training and expertise of operators are required to gain familiarity with the procedure. In addition, non-standard implantation approaches such as implantations via the jugular vein may require supplementary training.[14] As single-chamber PMs do not preserve AV synchrony, they are required in ~15% of patients only. Due to the relatively low caseload, full implantation proficiency is difficult to achieve and maintain for more than two operators even in large implantation centres.

The nature of the training itself (laboratory setting or on-site hospital formation) seems to have no direct impact on acute outcome.[8] However, the provided implantation advice by the manufacturer matters. It has been shown that after adaption of the Nanostim™ implantation training, procedures were performed differently (more septal than apical implantations) with a trend towards lower complication rates.[15]

Role of experience on procedural efficiency

Familiarity with the leadless PM implantation procedure increases procedural efficiency. In particular, the time to the first PM deployment decreased, indicating that operators became increasingly familiar with system preparation, and gained confidence to implant the device at a site considered suitable. Our findings are in line with previous reports showing a decreased overall procedure duration[7,8] and fluoroscopy time[8] of leadless PM implantation with increasing procedural experience. However, due to the large interpatient variability, even experienced operators can face significant challenges prolonging implantation duration, radiation dose, or the number of required PM

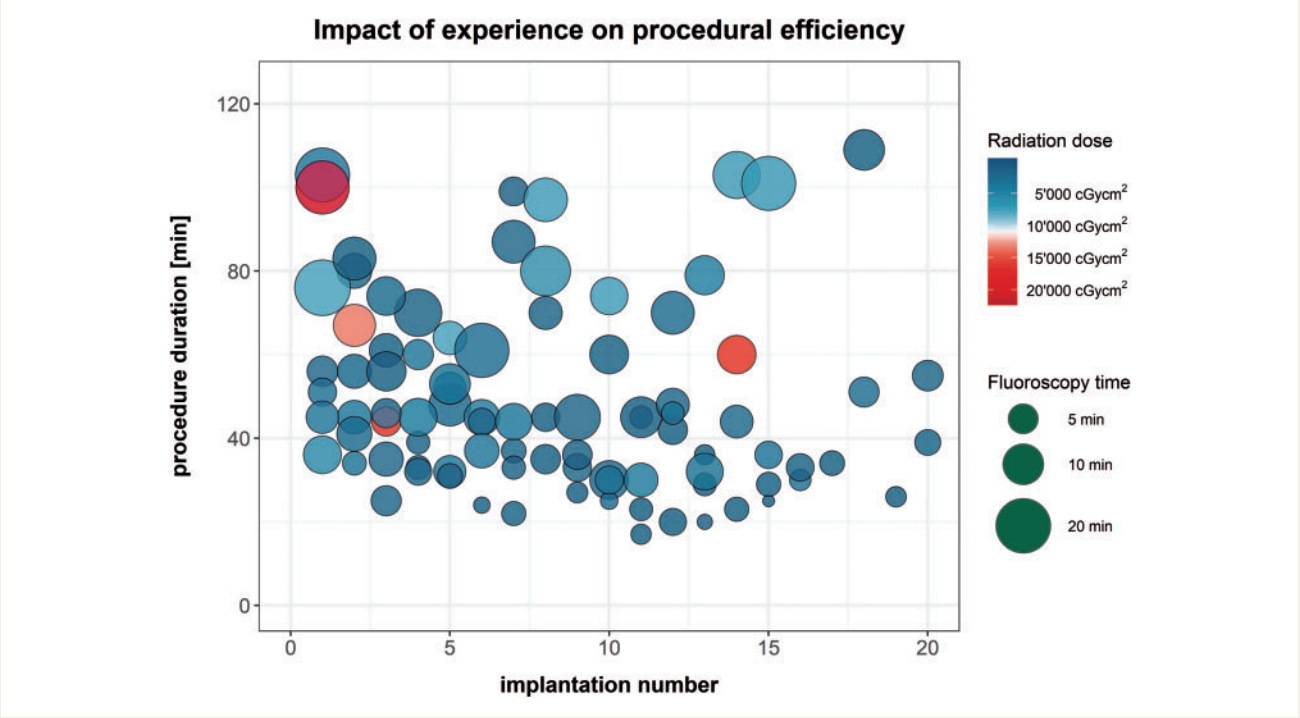

Figure 2 Learning curve and procedural efficiency: impact of operator experience (number of implanted devices) on procedural efficiency (procedure duration, fluoroscopy time, and radiation dose).

deployments (*Figure 1*). For instance, special anatomical constraints may limit manoeuverability of the implantation catheter, negatively affecting procedural efficiency and safety [e.g. PM implantation after tricuspid valve repair (*Figure 3*), or in the presence of congenital heart disease[16]]

Clinical implications

The implantation of a leadless PM differs in many ways from the implantation of conventional PMs. The catheter-based intervention is a novel and—for certain operators—an unusual intervention. Accordingly, high acute complication rates have been reported.[4,5] In addition, we found a significant experience-implantation quality relationship in our study. In contrast to other studies reporting higher complication rates, all implantations at our institutions were performed by trained electrophysiologists with experience both in device implantation and catheter ablation. All physicians had undergone proper training and were assisted by a colleague, who was also familiar with the procedure.

Subsequently, we summarize implications from our data (see points 1 and 2) and current literature recommendations (points 3–6). Even though the latter were not directly assessed in our study, the meticulous compliance with these recommendations might contribute to the lower complication rates:

(1) *Operator experience* is a crucial factor to obtain good implantation results. Thus, limiting the number of implanters per centre is reasonable to obtain and maintain an adequate caseload per operator.[17] The French Working Group on Cardiac Pacing and Electrophysiology states that ≥10 implantations per year and operator should be targeted.[18] Specific training goals and advice for good implantation practice are crucial and presented in more detail in the next paragraph. Two trained operators should participate in the implantations according to the MHRA Expert Advisory Group,[17] which seems reasonable although the second operator may have only minimal impact on overall implantation quality.

(2) *Patient selection criteria* for leadless PM implantation and procedural success have not yet been established. Catheter manoeuverability, e.g. in patients with extreme kyphoscoliosis or after pneumonectomy can be severely restricted and prevent successful implantation. Thus, careful patient selection is crucial to avoid implantation abortion. In general, smaller body size and lower weight may predict implantation failures. Risk factors for complications such as advanced age, female gender, BMI <25 kg/m^2, heart failure, and an implantation indication not related to atrial fibrillation should be considered by operators prior to implantation.[10]

(3) *Familiarity with large-bore catheter-based procedures* via femoral access may be beneficial to avoid implantation pitfalls as emphasized previously[7,8] and to improve implantation safety. The implantation results of physicians only performing conventional PM implantations and no catheter-based interventions may be inferior.

(4) *Visiting the manufacturer-recommended implantation courses* is crucial as it has an effect on the procedure and complications.[15] Proctoring and on-site technical support may further optimize the quality of the implantation procedure, help avoiding potentially harmful catheter manipulations, correct minor handling mistakes, and improve the learning effect.

(5) *Minimal implantation facility requirements* comprise a cardiac catheterization lab, echocardiography and pericardiocentesis equipment,

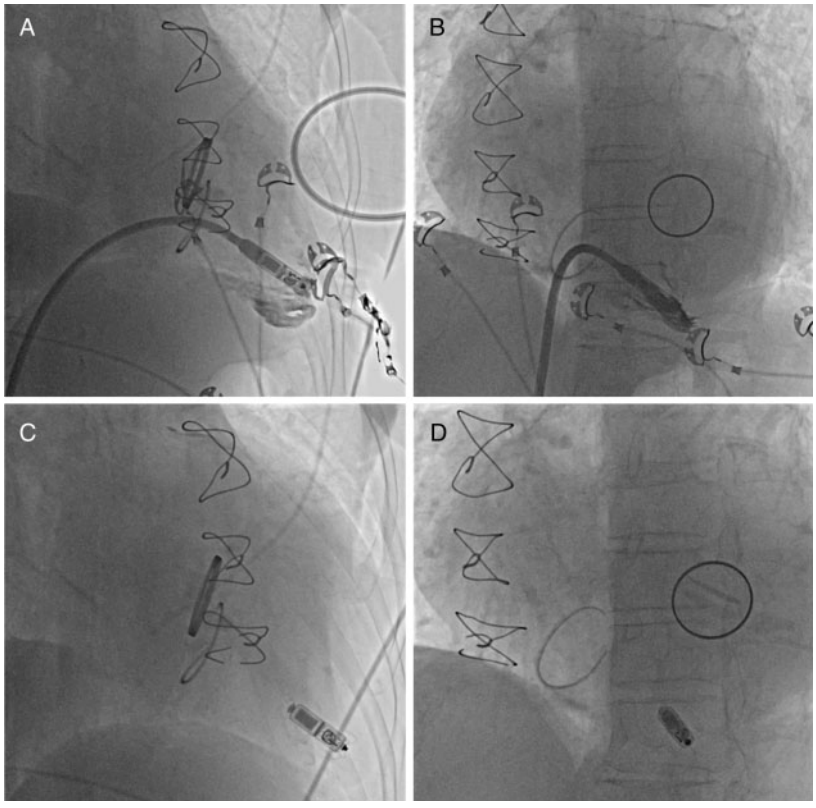

Figure 3 The 18th intervention of operator #7 (*Figure 2*): this 75-year-old female had a complete atrioventricular block after tricuspid valve repair (Edwards Lifesciences 32 mm) and mitral valve replacement (SJM 29 mm). The catheter manoeuverability was impaired by the reconstructed tricuspid valve. (*A*) (RAO view, 38°) and (*B*) (LAO view, 32°) show a relatively apical position with tangential septal alignment—a suboptimal and questionable implantation site. Multiple deployments resulted in high pacing thresholds. Finally, only a slightly different position with acceptable values was found [*C* (RAO) and *D* (LAO), pacing threshold 1.38 V/0.24 ms, sensed R-wave 5.4 mV]. LAO, left anterior oblique; RAO, right anterior oblique; SJM, St. Jude Medical.

tools for leadless PM retrieval, and an on-site cardiac surgery.[17,18] Leadless PM implantation numbers of ≥20 per year and centre should be targeted.[18]

Advice for new operators on good implantation practice

When beginning leadless PM implantations, operators should ensure that at least their co-operator has sufficient expertise in leadless PM implantation. The above implications on experience, education, and patient selection should be considered as well as the manufacturer's manual. Subsequently, we provide additional specific advice for new operators that may help to ensure good implantation practice:

- Prepare the implantation system appropriately (de-airing, ensure that the PM is completely inside the device cup, connect heparinized saline drip to the femoral sheath and catheter).[19]
- Make a skin incision large enough not to hinder the sheath insertion. Administer 1 mg atropine i.v. prior to sheath insertion and flushing as this may prevent excessive vagal reactions.[20]
- Navigate carefully to the target site. A right anterior oblique (RAO) projection facilitates the tricuspid valve passage and allows avoiding too apical sites. An LAO projection helps ensuring a position/direction aimed towards the septum.
- Try to minimize the number of deployments. Invest enough time to find an appropriate septal (not too apical) target site. Contrast medium injections in RAO and LAO projection will help verifying the position. Ensure good tissue-device contact immediately before the implantation and start retracting the implantation catheter early once the device exits the catheter's cup.[20]
- After PM release, a pull-and-hold test with magnified fluoroscopic views at ≥15 frames/s is indicated and electrical parameters should be measured.[19] Waiting times of 5–10 min can be helpful and electrical parameters should be checked repetitively and at least once after the pull-and-hold test. Mind the electrical target values proposed by the manufacturer (R-wave ≥ 5 mV, impedance 400–1500 Ω, and stimulation threshold ≤ 1 V/0.24 ms).[19] During the waiting time, flush the catheter to remove contrast medium.
- Flush the catheter extensively with saline water before cutting the retraction tether. Once the latter is cut, do not flush the catheter to avoid knot formation.[21] Slow tether retraction is advised.
- In case of a difficult procedure (e.g. anatomical constraints), consult experienced team members/proctors. Instead of accepting an excessive implantation risk, a 'bailout implantation' of a conventional PM or even an epicardial system might be preferable.

Study limitations

This is an observational study of a relatively limited number of patients and operators. As clear indications and guidelines for leadless PMs instead of conventional systems are lacking, patient selection depended on individual decisions. Implantation outcomes may vary in different patient populations. All operators were electrophysiologists with ample experience in transfemoral procedures, limiting the generalizability of the results. Moreover, the training prior to the first implantation in humans differed between the operators. Some operators underwent more extensive training in cadaver models or had experience from animal studies.

Ultimately, long-term performance comparisons of leadless against conventional transvenous systems are strongly desired. Leadless PMs may outperform conventional systems over long-term[22] but data remain sparse at the moment. Controlled trials with a composite long-term outcome are deemed necessary.

Conclusion

Leadless PM implantation has a low complication rate if performed by operators with experience in catheter-based endocardial interventions using a transfemoral venous approach. The first operator's experience is the single most critical factor determining leadless PM implantation quality and procedural efficiency.

Acknowledgements

We would like to thank Lea Streich and Sara Giesebart for their assistance during the data collection process. We acknowledge the grant to Dr Haeberlin from the Swiss Heart Rhythm Foundation.

Conflict of interest: A.H. has received travel grants from Medtronic. He was a consultant for Cardiac, co-founder of Act-Inno and has received research funding from Novartis. H.T. has received travel grants from Abbott. F.N. has received travel grants and speaker honoraria from Medtronic and Abbott. S.O. has received institutional support from Medtronic, Boston Scientific, Biotronik, Abbott, and Microport. S.B. has received travel grants from Microport. J.S.'s spouse works for Boston Scientific. C.S. is a proctor and consultant for Medtronic. He has received speaker/consulting honoraria/travel or institutional support from Abbott, Biotronik, Biosense Webster, Boston Scientific, Medtronic, and Microport. M.K. has received grants from Bayer and Pfitzer-BMS. He has received consulting fees from Bayer, Daiichi-Sankyo, Boehringer-Ingelheim, Novartis, MSD, Sanofi, Boston Scientific, Abbott, Medtronic, Biotronik, Zoll, and Biosense Webster. L.R. has received travel grants from Boston Scientific. T.R. is a consultant for Medtronic. He has received speaker's honoraria or travel support from Abbott, Bayer, Biotronik, Biosense Webster, BMS, Boston Scientific, Daiichi, Medtronic, and Pfizer. He has received institutional support from Abbott, Biotronik, Biosense Webster, Boston Scientific, Medtronic, and Microport. All other authors declared no conflict of interest.

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