Comparative study of acute and mid-term complications with leadless and transvenous cardiac pacemakers

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BACKGROUND Leadless cardiac pacemakers (LCPs) aim to mitigate lead- and pocket-related complications seen with transvenous pacemakers (TVPs).

OBJECTIVE The purpose of this study was to compare complications between the LCP cohort from the LEADLESS Pacemaker IDE Study (Leadless II) trial and a propensity score–matched real-world TVP cohort.

METHODS The multicenter LEADLESS II trial evaluated the safety and efficacy of the Nanostim LCP (Abbott, Abbott Park, IL) using structured follow-up, with serious adverse device effects independently adjudicated. TVP data were obtained from Truven Health MarketScan claims databases for patients implanted with single-chamber TVPs between April 1, 2010 and March 31, 2014 and more than 1 year of preimplant enrollment data. Comorbidities and complications were identified via *International Classification of Diseases, Ninth Revision* and Current Procedural Terminology codes. Short-term ($\leq$1 months) and mid-term (>1–18 months) complications were compared between the LCP cohort and a propensity score–matched subset of the TVP cohort.

RESULTS Among 718 patients with LCPs (mean age 75.6 $\pm$ 11.9 years; 62% men) and 1436 patients with TVPs (mean age 76.1 $\pm$ 12.3 years; 63% men), patients with LCPs experienced fewer complications (hazard ratio 0.44; 95% confidence interval 0.32–0.60; $P < .001$), including short-term (5.8% vs 9.4%; $P = .01$) and mid-term (0.56% vs 4.9%; $P < .001$) events. In the short-term time frame, patients with LCPs had more pericardial effusions (1.53% vs 0.35%; $P = .005$); similar rates of vascular events (1.11% vs 0.42%; $P = .085$), dislodgments (0.97% vs 1.39%; $P = .54$), and generator complications (0.70% vs 0.28%; $P = .17$); and no thoracic trauma compared to patients with TVPs (rate of thoracic trauma 3.27%). In short- and mid-term time frames, TVP events absent from the LCP group included lead-related, pocket-related, and infectious complications.

CONCLUSION Patients with LCPs experienced fewer overall short- and mid-term complications, including infectious and lead- and pocket-related events, but more pericardial effusions, which were uncommon but serious.

KEYWORDS Complications; Leadless; Comparative Study; Pacemakers; Transvenous

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Introduction

Approximately 1 million transvenous pacemakers (TVP) are implanted annually worldwide.[1] Despite technological advances, the implantation technique involving a subcutaneous pulse generator and transvenous lead has remained unchanged and is the most common source of complications, occurring in up to 12% of device recipients.[2,3] Acute complications are related to implantation and include pneumothorax,

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hemothorax, cardiac perforation, pocket hematoma, and lead dislodgment.[4] Most long-term complications are associated with the pulse generator or lead and include pocket erosion, infection, lead fracture or insulation failure, tricuspid valve regurgitation, and venous thrombosis.[2,3,5–7]

Leadless cardiac pacemakers (LCPs) represent a new paradigm in cardiac pacing developed to mitigate complications by eliminating the need for a subcutaneous pocket and transvenous leads. These devices are small ($\sim$1 cm^3), entirely self-contained units that are delivered via a transfemoral venous catheter and affixed in the right ventricle using either an active (Nanostim, Abbott, Abbott Park, IL) or a passive (Micra, Medtronic, Minneapolis, MN) fixation mechanism.[8–13] The short-term safety and efficacy of these devices at 6 months have been established in nonrandomized comparisons to prespecified historical performance measures of TVPs.[8,9] Complications occurred in 4.0%–6.7% of patients, with cardiac perforation being the most common adverse event. While the quantity and type of complications were fewer and different from those reported with TVPs, comparison is limited by differences in patient comorbidities and study characteristics.

In this study, short-term and mid-term complications of the Nanostim LCP (Abbott, Abbott Park, IL) are compared with those of conventional single-chamber TVPs. The LCP safety data are obtained from the extended follow-up of the previously reported LEADLESS II IDE study.[8] Comparative safety data for TVPs are reported from a propensity score–matched cohort obtained from a large US real-world insurance claims database.

Methods

LCP study

The LEADLESS Pacemaker IDE Study (Leadless II) trial is a prospective, nonrandomized, multicenter clinical study conducted in the United States, Canada, and Australia. The trial design has been described in detail previously.[8] Patients with indications for permanent single-chamber ventricular pacing were implanted with a Nanostim LCP between February 1, 2014 and January 31, 2016. Full inclusion and exclusion criteria for the LEADLESS II trial are described in the Supplement. The LCP is a self-contained, active-fixation, rate-adaptive single-chamber pacemaker. The 42-mm-long, 5.99-mm-diameter device contains a helical screw-in fixation electrode at the distal end. A specially designed delivery catheter is used to percutaneously implant the LCP in the right ventricular apex or apical septum. Patients were evaluated before hospital discharge with device interrogation, chest radiography, and standard 12-lead electrocardiography. Subsequently, patients were followed at 2 weeks, 6 weeks, 3 months, 6 months, and every 6 months thereafter.

LCP safety data

All complications in the LEADLESS II trial were reported as part of the active clinical study follow-up and adhered to the International Standard Organization definition of a serious adverse device effect (SADE). A *SADE* is any untoward but not unanticipated medical occurrence that is related to the investigational device or procedure and that is classified as serious. A *"serious" event* is defined as any event that led to death or to a serious health deterioration that resulted in either a life-threatening illness or injury or a permanent impairment of a body structure or body function. It also includes events that led to an inpatient or prolonged hospitalization or medical or surgical intervention that was required to prevent the above-mentioned effects. All adverse events were adjudicated by an independent clinical events committee. SADEs were categorized into those related to cardiac perforation, vascular complications, device dislodgment, pacing threshold elevation, or other types of events. Complications were evaluated from implantation until 18 months or the time of withdrawal from the study, last available follow-up visit, or death.

TVP study

TVP data were extracted from the Truven Health MarketScan Research Databases, which contain more than 20 billion de-identified, person-specific health insurance claims from approximately 350 US private sector payers.[14] Data for this study were extracted from 2 MarketScan databases—the Commercial Claims and Encounters database and the Medicare Supplemental database—spanning the time period from April 1, 2010 to March 31, 2014. The Commercial Claims and Encounters database contains data from active employees, dependents, and early retirees covered by employer-sponsored health plans. The MarketScan database contains data from Medicare-eligible retirees with employer-sponsored Medicare Supplemental plans.

The study population included patients 18 years and older implanted with single-chamber pacemakers from any device manufacturer. Patients with pacemaker were identified as those having the *International Classification of Diseases, Ninth Revision* procedure code 37.81 (initial insertion of a single-chamber device, not specified as rate responsive) or 37.82 (initial insertion of a single-chamber device, rate responsive) or the Current Procedural Terminology code 33207 (insertion or replacement of a permanent pacemaker and lower-chamber electrodes). Patients with any implantable cardiac rhythm management device-related codes at any time before pacemaker implantation (Supplemental Table S1) were excluded from the analysis to eliminate non–de novo implants.

To characterize baseline comorbidities in the study population with TVPs, relevant inpatient and outpatient diagnostic and procedure codes were identified over the entire available time period before implantation. To ensure completeness of baseline data, patients with less than 1 year of MarketScan enrollment data were excluded from the analysis. Codes that indicated a history of atrial fibrillation, hypertension, diabetes, coronary artery disease, vascular disease, or tricuspid valve disease were included in the baseline characterization (comorbidity codes are listed in Supplemental Table S2).

TVP safety data

Pacemaker-related complications were identified for the TVP cohort using inpatient and outpatient billing codes recorded

from the day of implantation onward. Complications were compiled into the following categories (detailed in Supplemental Table S3): (1) infection, including endocarditis and other device-related infection; (2) thoracic trauma, including pneumothorax and hemothorax attributed to lead insertion; (3) pocket complication, including hematoma and pocket revision; (4) electrode dislodgment; (5) other lead complication requiring revision; (6) venous embolism or thrombosis; (7) cardiac perforation and its downstream clinical manifestations; and (8) generator complications. Generator explants were considered generator complications since they occurred within 30 days for acute and within 18 months for mid-term time frames, which are earlier than expected longevity of these devices.

To avoid overestimating complication rates, multiple codes from the same complication category that occurred on the same or consecutive dates were counted as a single event. In cases in which a pacemaker implantation and a complication occurred on the same date, the implantation was assumed to have preceded the complication. Thoracic trauma, cardiac perforation, and venous embolism/thrombosis occurring more than 1 month after implantation were not included in the TVP mid-term complication analysis, as they could not be definitively attributed to the pacemaker implant beyond the first month of implantation. Complications were evaluated from implantation until 18 months or the time of device upgrade, removal, or replacement or the patients' withdrawal from MarketScan.

Safety data comparison

Both LCP and TVP complications were classified as short- or mid-term relative to device implantation. Short-term complications occurred within 1 month, while mid-term complications occurred between 1 and 18 months after pacemaker implantation. In order to compare complication rates between LCP and TVP groups, a subset of patients with TVPs with similar baseline comorbidities to patients with LCPs was identified. Patients with TVPs were 2:1 propensity score matched to patients with LCPs using the nearest-neighbor method without replacement. The 2:1 ratio was the highest ratio for which resulting groups were well-matched on all baseline parameters. Propensity scores were computed on the basis of age, sex, and relevant baseline comorbidities including atrial fibrillation, coronary artery disease, diabetes, hyperlipidemia, hypertension, tricuspid valve disease, and peripheral vascular disease. The overall freedom from complications was evaluated in the matched cohort. In addition, the proportion of patients experiencing each prespecified short-term complication type was compared between patients with LCPs and patients with TVPs. In the mid-term time frame, rates of complications per patient-year were compared between the groups.

Statistical analysis

Continuous variables were compared using the Student *t* test. Categorical variables were compared using the χ^2 test. Complication rates were quantified by the number of patients with pacemaker who experienced at least 1 instance of a particular complication. Percentages were calculated relative to the total number of patients with pacemaker available within each time frame. Proportions were compared using the Fisher exact test, and event rates were compared using Poisson regression. Freedom from complications was computed using the Kaplan-Meier method and compared between patients with TVPs and patients with LCPs using the weighted Cox proportional hazards regression, adjusted for age, sex, and baseline comorbidities. All calculations were performed in R version 3.1.1, augmented with the following R packages: survival,[15] MatchIt,[16] and coxphw.[17]

Results

LCP cohort

The baseline clinical characteristics of the patient cohort enrolled in the multicenter LEADLESS II trial (n = 718) between February 2014 and January 2016 with a minimum follow-up of 180 days and a median follow-up of 323 days (interquartile range 197–489 days) are listed in Table 1. Single-chamber pacemaker indications in the LCP cohort were atrial fibrillation with atrioventricular block (n = 407 [56.7%]), sinus rhythm with high-grade atrioventricular block (n = 61 [8.5%]), and sinus bradycardia with infrequent pauses or syncope (n = 250 [34.8%]). *Acute implantation success*, defined as the patient leaving the implant procedure

Table 1 Baseline demographic characteristics of propensity score–matched patients

Characteristic	Patients with leadless pacemaker (n = 718)	Patients with transvenous pacemaker (n = 1436)	*P*
Age (y)	75.6 ± 11.9	76.1 ± 12.3	.39
Follow-up (d)	323 (197–489)	408 (167–547)	<.001
Sex: male	447 (62.3%)	905 (63.0%)	.77
Atrial fibrillation	425 (59.2%)	881 (61.4%)	.36
Coronary artery disease	262 (36.5%)	485 (33.8%)	.23
Diabetes mellitus	178 (24.8%)	335 (23.3%)	.49
Hyperlipidemia	475 (66.2%)	970 (67.5%)	.55
Hypertension	557 (77.6%)	1146 (79.8%)	.25
Tricuspid valve disease	150 (20.9%)	266 (18.5%)	.21
Peripheral vascular disease	91 (12.7%)	163 (11.4%)	.41

Values are presented as mean ± SD, as median (interquartile range), or as n (%).

with an implanted and functioning device, was achieved in 692 patients (96.4%) with the mean implantation time of 27.5 ± 17.0 minutes, which included 13.4 ± 9.3 minutes of fluoroscopy. Most of the failed implants were due to inability to deliver the LCP to the desired location in the right ventricle. Five of the failed implantations were due to pericardial effusion with tamponade and 1 (0.14%) due to pericardial effusion without tamponade. These events are included in the overall complication analysis. The pacemaker required repositioning more than 2 times in 25 patients (3.6%), and the mean hospital stay was 1.1 ± 1.0 days.

Short-term LCP complications occurred in 42 patients (5.8%), including 7 dislodgments (0.97%) requiring percutaneous retrieval, vascular-related events in 8 patients (1.11%), pericardial effusion with tamponade in 7 patients (0.97%), and pericardial effusion without tamponade in 4 patients (0.56%). Of the 8 vascular events, 2 (0.28%) required surgery; and of the 7 pericardial effusion with tamponade events, 3 (0.42%) required surgery. Pacing threshold elevation requiring percutaneous retrieval occurred in 5 patients (0.70%) within 1 month of implantation and in 1 patient (0.14%) after the first month. Overall, there were only 4 patients (0.56%) with a complication beyond 1 month. There were no reported dislodgments beyond 1 month. There were no infections in this patient cohort at short- and mid-term follow-up. The overall freedom from SADEs was 95.7% at implantation (95% confidence interval [CI] 94.2%–97.2%), 94.1% at 1 month (95% CI 92.4%–95.9%), and then remained at 93.5% (95% CI 91.7%–95.3%) starting at 100 days onward up to 18 months.

TVP cohort

The MarketScan database query yielded 120,556 patients with pacemaker, from whom we excluded 33,126 (27.4%) patients with less than 1 year of preimplant clinical data, 7442 (6.17%) patients with indeterminate pacemaker type, 7174 (5.95%) patients with evidence of preexisting devices, 113 (0.094%) patients less than 18 years of age, and 63,325 (52.5%) patients with dual-chamber devices. Ultimately, 9376 (7.78%) patients with single-chamber pacemaker (5323 [56.8%] men; mean age 80.4 ± 9.6 years; median follow-up 393 days [interquartile range 166–547 days]) were included in the unmatched analysis. The unmatched transvenous cohort was older and had fewer men and higher incidence of comorbidities including atrial fibrillation, coronary artery disease, diabetes, hyperlipidemia, hypertension, tricuspid valve disease, and peripheral vascular disease. A summary of complications in the unmatched TVP cohort and a comparison with LCPs are presented in Supplemental Figure S1.

Propensity score–matched analysis

After applying 1:2 propensity score matching to the 9376 patients with TVPs from the unmatched analysis, the 718 patients with LCPs were matched with 1435 (15.3% of unmatched cohort) patients with TVPs with clinical characteristics as listed in Table 1. As shown in Figure 1, there were

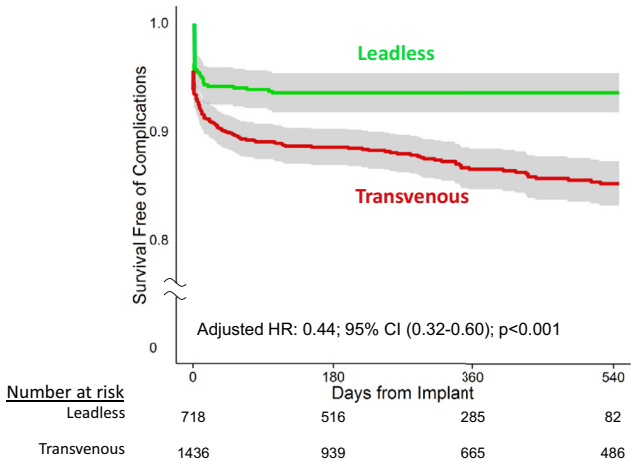

Figure 1 Kaplan-Meier curve (with 95% CI) illustrates that patients with LCPs were at a lower risk of experiencing a complication than were patients with TVPs. The Cox proportional hazards result is adjusted for age, sex, and baseline comorbidities. The starting point for the curves is the implantation of the device for both the LCP and TVP cohorts. CI = confidence interval; HR = hazard ratio; LCP = leadless pacemaker; TVP = transvenous pacemaker.

fewer overall complications in the leadless group when compared with the propensity score–matched transvenous group (adjusted hazard ratio 0.44; 95% CI 0.32–0.60; $P < .001$). This reduction persisted in all demographic and comorbidity subgroups (Figure 2).

Short-term complications were greatly reduced in the LCP cohort (42 [5.8%] vs 165 [9.4%]; $P = .0095$) despite a higher rate of pericardial effusions (11 [1.53%] vs 5 [0.35%]; $P = .0056$) in the leadless group. Of the 5 patients with TVPs with pericardial effusions, 4 (0.28%) were identified with the code for cardiac tamponade (423.3). There were no statistical differences between the leadless and transvenous groups with regard to rates of vascular complications (8 [1.11%] vs 6 [0.42%]; $P = .085$), electrode dislodgment (7 [0.97%] vs 20 [1.39%]; $P = .54$), and generator complications (5 [0.70%] vs 4 [0.28%]; $P = .17$). In the leadless group, there was a complete absence of lead-related complications, infections, and pocket complications, which were seen in 52 (3.62%), 25 (1.74%) and 6 (0.42%) TVP patients, respectively (Figure 3). In the LCP group, there was a single case of hemothorax associated with a perforation and cardiopulmonary resuscitation performed during the procedure, while in the TVP group, there were 47 (3.27%) occurrences of thoracic trauma. There were several complications in patients with LCPs that could not have been quantified in patients with TVPs because of limitations of insurance claims data. These included 5 instances of arrhythmia during implantation (0.70%), 2 acute migrations during implantation (0.28%), 1 angina event (0.14%), and 3 transient neurological events (0.42%). Of the 25 patients in the TVP cohort experiencing infection, 20 (1.39%) used an insurance code indicative of endocarditis while the other 5 (0.35%) used only the 996.61 code (infection and inflammatory reaction due to cardiac device, implant, and graft). Of the 6 patients experiencing pocket complications, none had an infection.

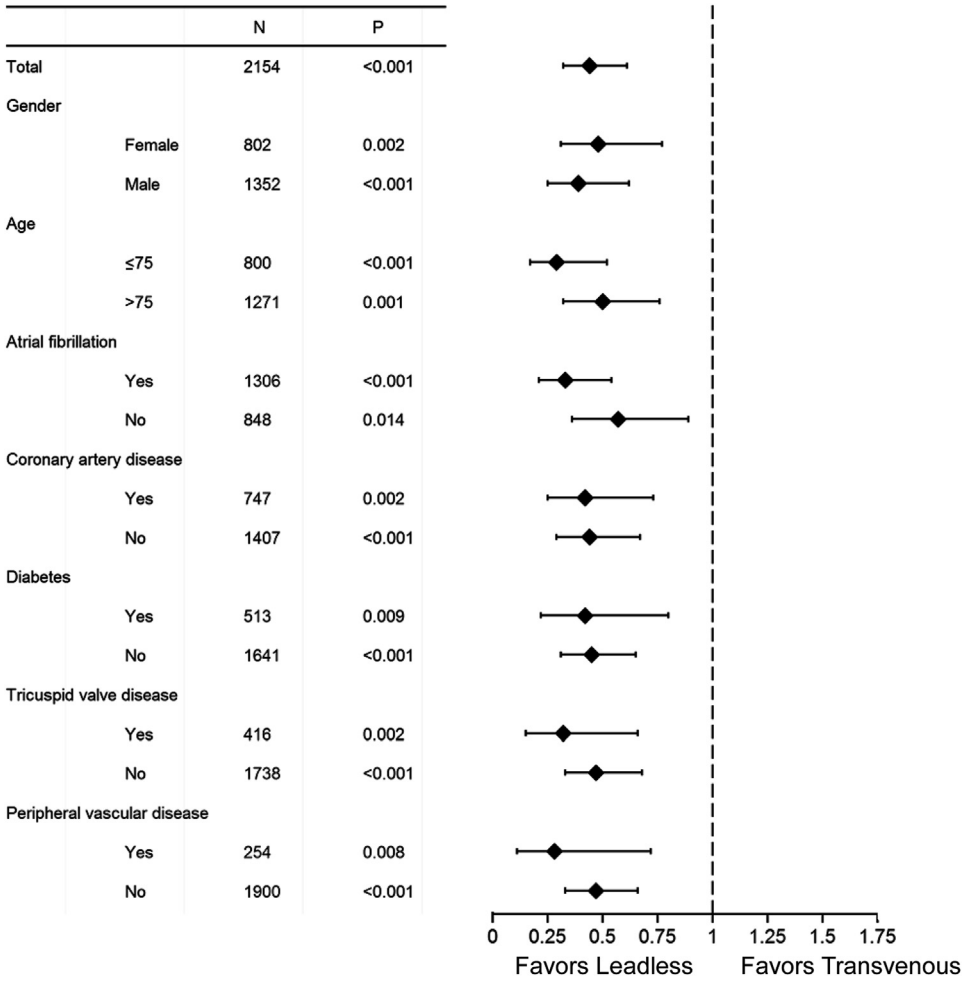

Figure 2 Plot presents adjusted hazard ratios and 95% confidence intervals for the risk of complication with the leadless pacemaker vs transvenous pacemaker in various patient subgroups.

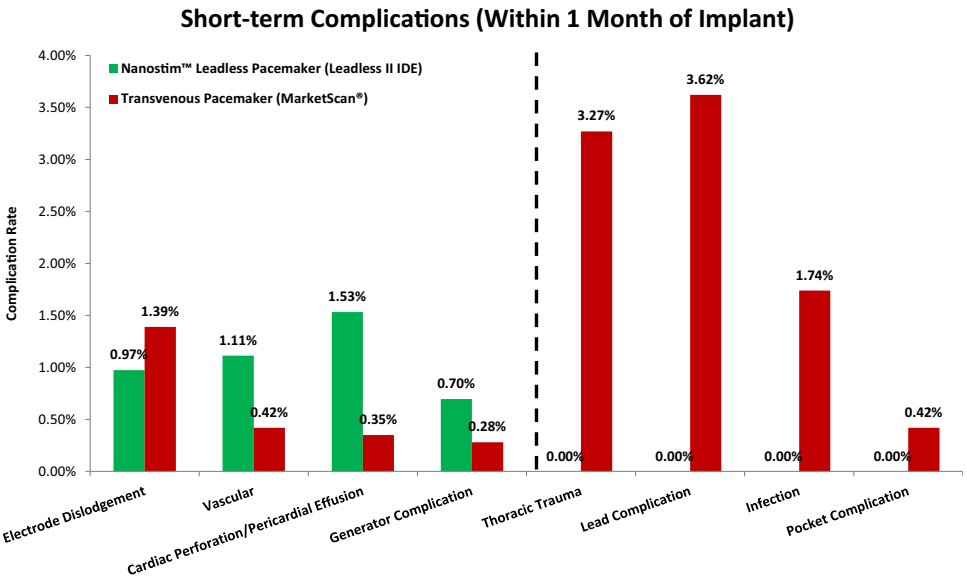

Figure 3 Short-term complication rates presented per category for patients with leadless pacemaker and patients with transvenous pacemaker. The exact rate is shown at the top of each bar.

Beyond 1 month, there were only 4 patients (0.56%) experiencing 4 complications in the leadless group (0.62 per 100 patient-years) vs 71 patients (4.94%) experiencing 127 complications in the TVP group (9.12 per 100 patient-years) ($P < .001$). In the leadless group, the mid-term complications included 1 instance of threshold elevation requiring revision (0.16 per 100 patient-years) and 1 temporary loss in pacing and sensing during ablation (0.16 per 100 patient-years) as compared to 5 (0.36 per 100 patient-years) generator complications in the TVP cohort. The leadless group also experienced 2 instances of new-onset heart failure (0.31 per 100 patient-years). In the transvenous group, there were a number of complications that were wholly absent in the leadless group, including lead-related complications (n = 36; 2.59 per 100 patient-years), electrode dislodgment (n = 4; 0.29 per 100 patient-years), infection (n = 66; 4.74 per 100 patient-years), and pocket complications (n = 16; 1.15 per 100 patient-years) (Figure 4). Most of the infectious complication encounters contained a code indicative of endocarditis, while only 10 (0.72 per 100 patient-years) contained only the 996.61 code. Of the 16 patients with pocket complications, 4 (0.29 per 100 patient-years) patients also had an infection, with only 2 (0.14 per 100 patient-years) of these infections occurring during the same hospital stay as the pocket complication.

Discussion

The principal finding of this analysis is that patients from the LEADLESS II IDE trial demonstrated fewer short- and mid-term complications when compared with a large propensity score–matched cohort of patients with single-chamber TVPs. The overall reduction in both short- and mid-term events was driven by a virtual elimination of lead, pocket, and infectious complications, suggesting that this disruptive technology has successfully targeted the most common sources of traditional pacemaker complications observed over the past 50 years. The TVP complications in this study are consistent with an extensive body of literature, showing that lead-related problems, thoracic trauma, vascular injury, pocket hematoma, and infection drive short-term complications and that lead-related problems dominate the mid-term complications.[2–7] The latter relate to electrical phenomena involving sensing, pacing, or insulation failures. These findings reinforce the use of a leadless pacemaker as an alternative to TVPs in patients requiring single-chamber ventricular pacing.

Both the short-term and mid-term TVP complication rates of 9.40% and 4.94% reported in our study exceeded those reported in The Mode Selection Trial (MOST) (4.8% at 30 days and 2.1% at 3 years)[18] and were slightly lower than those reported in the FOLLOWPACE study (12.4% at 2 months and 9.2% by 5 years).[3] Both MOST and FOLLOWPACE studies investigated dual-chamber devices, which are expected to have more complications than do single-chamber devices.[2,3,19,20] In addition, the FOLLOWPACE study did not exclude non–de novo systems while our study focused only on new implants. Similar to the FOLLOWPACE study and in contrast to the MOST trial, claims data capture complications occurring across the full spectrum of operators performing pacemaker surgery at community and urban hospitals and are not limited to the academic or tertiary medical centers with highly experienced operators. Furthermore, the MOST trial was performed between 1995 and 2001 and the FOLLOWPACE study between 2003 and 2007 while our patients were implanted between 2010 and 2014. A report from a large national survey demonstrates that the population receiving pacemakers has greatly expanded, and has become older and sicker,[21] which could lead to higher rates of complications.

The categories in which TVPs fared better had slightly lower rates of uncommon but potentially serious complications of pericardial effusion and vascular events. It should

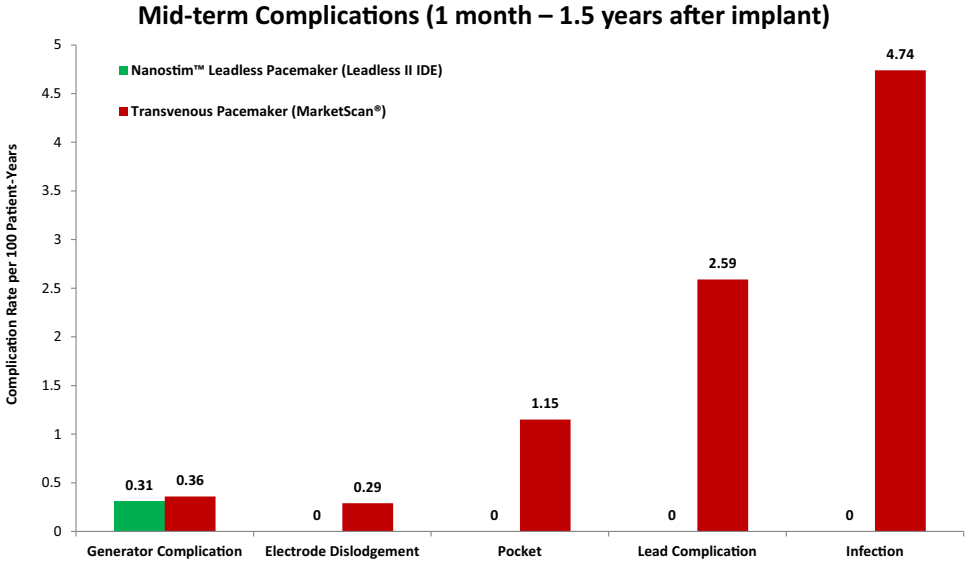

Figure 4 Mid-term complication rates presented per category for patients with leadless pacemaker and patients with transvenous pacemaker. The exact rate is shown at the top of each bar. One of the reported cardiac perforation complications also had an associated hemothorax as a result of a cardiopulmonary resuscitation performed during the procedure.

be noted that the introduction of femoral vascular complications with LCPs represents a true trade-off created by the paradigm shift away from pectoral surgical incisional access to percutaneous femoral vascular access; the introduction of an 18-F vascular delivery sheath provides challenges to achieving hemostasis after use of femoral instrumentation. However, the elimination of pocket-related and infection-related acute complications arguably more than compensates for the small increases in rates of vascular events in LCPs. The possibility of cardiac perforation and pericardial effusion exists with both technologies since decades of innovation in lead design and fixation mechanisms have not eliminated this problem even with transvenous leads.[22] The 0.35% pericardial effusion rate in this transvenous group is similar to other published data involving transvenous leads (0.3%–0.8%) and is lower than the 1.5% event rate in the leadless cohort.[3,18,22,23] It is concerning that 3 of the 7 patients with pericardial effusion in the LCP group required surgery. This suggests more traumatic tearing-type injuries that need to be mitigated by future iterations of LCP technology, as well as improvements in operator technique. Previous studies have associated acute pacemaker complications with operator experience and training.[2,4] Encouragingly, the original LEADLESS II study investigators reported a reduction in complications from 6.8% to 3.6% after 10 operator implants.[8] While the future performance of subsequent iterations of leadless delivery systems is unknowable, it is expected that design changes incorporating operator feedback as well as greater experience will improve acute implantation safety. It is possible that LCP delivery systems will always remain stiffer and more traumatic to cardiac tissue than will transvenous leads because of the support needed to introduce and steer the catheter-based device. Even in this scenario, it would be premature to equate small absolute differences in pericardial effusions to a net clinical benefit of avoiding complications associated with transvenous systems. Transvenous lead extractions carry significant risk in the event of vascular or cardiac tears.[24] Some of these complications may arise with LCPs if there is a need for extraction. No incidents of tricuspid valve injury occurred during the placement of LCPs in the trial, but there could be such incidents associated with LCP extraction. However, fully eliminating lead, pacemaker pocket, and infectious complications beyond the acute period will obviate the need for at least some of these procedures and extend some degree of still unknown benefit in avoiding procedure-related catastrophes. Finally, this field is simply too young to judge and compare the long-term implications that remain, as of yet, unknown; indeed, the end-of-service clinical experience of the leadless device will not be fully understood for another 10–15 years.

Development of a new technology can be accompanied by unexpected challenges. Field safety advisories were issued for the Nanostim leadless pacemaker due to battery malfunction and docking button detachments. The replacement battery for the Nanostim LCP has been approved by several regulatory agencies and the next generation LCP will include an updated docking button design.

Study limitations

Limitations of the present analysis include limitations of the MarketScan databases, which do not contain a random sample of patient claims data, but rather a cohort that is primarily drawn from large employers. Patients who are self-insured and those insured through small and medium employers are underrepresented, and those covered by Medicare Advantage and traditional Medicare plans are excluded. To avoid overestimating complication rates in the transvenous cohort, multiple diagnostic and procedure codes observed on the same or consecutive service dates were treated as a single occurrence; however, these could only have resulted in repeat occurrences to be undercounted in some scenarios. Similarly, single complications with encounters on nonconsecutive service dates could be overcounted. Furthermore, it was not possible to definitively associate every complication with the pacemaker implant. Some complications may have wrongly been attributed to pacemaker implants, and others may not have been identified if unanticipated claims codes were used. Finally, the severity of a complication could not be ascertained, as there is not a systematic way to identify cases requiring surgical management.

Another limitation of the analysis is lack of specific data on atrial fibrillation in the TVP cohort. Insurance claims do not distinguish between AF of different severities. Therefore, the distribution of various severities of AF may not have been the same between the matched TVP and LCP groups.

Limitations related to comparison of the 2 data sets include the differing definitions of complications and different types of complications that can occur with the different pacemaker systems. The LEADLESS II study included complications deemed serious by an independent committee. The TVP complications were not adjudicated and could have included both more and less severe events. One can only be sure that patients experiencing these complications had active encounters with the medical system, and the encounters resulted in the filing of insurance claims. Furthermore, since the LEADLESS II study was a clinical trial, it may have had more experienced implanters operating at academic centers and research hospitals as compared with TVP implanters from a full spectrum of US hospitals and with varying degrees of experience. Despite these limitations, the magnitude of the difference between complications in the LCP and TVP groups suggests that future studies will confirm the advantage of leadless technology.

Conclusion

This propensity score–matched analysis of leadless pacemakers from the LEADLESS II IDE study and TVPs from the MarketScan claims database suggests that leadless

pacemakers are associated with significant reduction in overall short- and mid-term complications, particularly among infectious, pocket-related, and lead-related events, but can be accompanied by more pericardial effusions, which are uncommon but may be serious enough to require surgery. Additional data about the long-term risk and complication profile of these devices are needed.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2018.04.022.

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