Leadless pacemakers: leading us into the future?

Theofanie Mela and Jagmeet P. Singh*

Cardiac Arrhythmia Service, Cardiology Division, Massachusetts General Hospital Heart Center, Harvard Medical School, Boston, MA, USA

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This editorial refers to ‘Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study’ by P. Ritter et al., on page 2510.

If at first the idea is not absurd, then there will be no hope for it.
A. Einstein

Since the first permanent pacemaker implant, almost 60 years ago, there has been continued progress and evolution of these devices. The technology has advanced on many fronts, with longer battery lives, smaller sized generators, with an intelligent ‘adaptive functionality’ closely mimicking the human physiology. However, contemporary implant technology has been disadvantaged by the need for a subcutaneous implantable device (with a risk for infection or erosion) and an attached pacing electrode system within the cardiac vasculature that itself is at risk for fracture and infection. The additional hazard of extracting malfunctioning or infected leads poses further challenges. Notably, almost 10% of the ~700,000 pacemakers implanted annually are worldwide are associated with lead-related problems.1,2 This, in turn, has created the need for a leadless pacemaker system.

Although Spickler et al. first reported the theory of a totally self-contained leadless intracardiac pacemaker in 1970,3 it is only through recent technological advancements in battery energy, endocardial fixation, and delivery systems that this concept has become a reality. The leadless device not only has improved the aesthetics of an implant through eliminating the visible lump and scar of a conventional pectoral pacemaker implant but also has potentially reduced the risk of complications, related to infections and lead failure.

In this issue of the journal, we learn about the short- and intermediate-term performance of the Medtronic Micra leadless cardiac pacemaker.4 This device was implanted in 140 patients, 60 of who had completed their 3-month follow-up when the data were collected. The device (~2.5 cm in length and 0.7 cm in diameter) is delivered via the right femoral vein utilizing a 27 French outer diameter introducer. It is fixated via four electrically inactive protractible nitinol tines located on the distal end of the device. Of note, the fixation mechanism may present its own challenges, as it may occasionally be difficult to obtain a stable position. The investigators were requested to check fluoroscopically that at least two tines were engaged within the myocardium before releasing the device; otherwise, the device had to be retracted and repositioned to another position within the right ventricle.

The majority of implants (81%) were successfully completed with one or two positioning attempts, with an isolated case requiring many more deployments for a successful pacing site. Evidently, the delivery catheter is large and the size by itself explains the increased vascular complications in 10 patients, including two pseudoaneurysms, one requiring thrombin injection. The continued need for anticoagulation in some high-risk patients with atrial fibrillation could pose some challenges, where physician discretion will need to be judiciously exercised. Although, the procedure duration for the first 60 implants (37.9 ± 24.8 min) and for the total 140 implants (36.7 ± 20.7 min) is probably equivalent to or shorter than the implantation of a transvenous VVI pacemaker, the fluoroscopy time was significantly longer (10.1 ± 7.8 and 9.1 ± 7.0 min, respectively). Although there was no marked reduction in fluoroscopy time with experience, it is quite likely that radiation exposure of the operator is less compared with the conventional pectoral implant (due to distance from the image intensifier). For this single-chamber ‘right ventricular pacing-only’ device, the battery longevity is quite remarkable and estimated at an average 12.6 years (range 8.6–14.4 years). Accelerometer-based, rate response (VVIR) was programmed on in 54% (76/140) of patients, programmed to where the delivery of a subcutaneous device (with a risk for infection or erosion) and an attached pacing electrode system within the cardiac vasculature that itself is at risk for fracture and infection. The additional hazard of extracting malfunctioning or infected leads poses further challenges. Notably, almost 10% of the ~700,000 pacemakers implanted annually are worldwide are associated with lead-related problems.1,2 This, in turn, has created the need for a leadless pacemaker system.

In comparison, the other leadless cardiac pacemaker (Nanostim, St. Jude Medical, St Paul, MN, USA) made an earlier appearance in the clinical arena, but in a smaller proportion of patients.5 The recent report of the 1-year experience shows good results of the pacing and sensing parameters in 31 patients.6 The early clinical experience in Europe and the USA has been punctuated with a few cardiac perforations and tamponade. In the recent study from Knops et al.,6 one patient was excluded from the analysis because he developed a fatal complication, a myocardial perforation, which subsequently resulted in a massive stroke. The Nanostim differs
from the Micra leadless pacemaker in that it is thinner and longer (~4 cm long and 6 mm in diameter) and can be delivered via a smaller 18 French introducer. The fixation is achieved via a distal non-retractable, single-turn (screw-in) steroid-eluting helix that affixes the device to the endocardium.\(^5,6\) In the majority of patients (n = 22, 71%), the initial deployment of the device was successful; nine patients (29%) required more than one reposition(s) during implantation due to inadequate electrical measurements (mean of two repositions; range 1–3). The rate response strategy for this device is different and is driven by the central venous temperature, and could be slower and potentially suboptimal at low workloads.\(^7\)

The results of the Micra Transcatheter Pacing Study from Ritter et al.\(^4\) are very encouraging, with early evidence that the safety of this device is on the right track. There were no unforeseen events, i.e. no device migration, dislodgements, device telemetry issues, infections, re-operations, or related deaths. All the pacing and sensing parameters remained optimal throughout the follow-up. Of course, the longer follow-up will be of interest, to assess the durability of these findings and the concern around the retrieval or subsequent additional device implantation when it is considered. It is unclear as to which is the better sensor, which is the more superior fixation strategy, and what is the most appropriate way of managing these patients in the setting of systemic infections. Another recurring question that comes up is whether this is a niche product, or will it have a wider market appeal. The worldwide need for single-chamber devices is large and especially so in regions of the developing world.\(^4\) The device was most often used in patients where the extent of pacing requirement was less, in those of advanced age, and with a sedentary lifestyle, and in patients with anatomical limitations or co-morbidities. As longer term data become available attesting to the safety and efficacy of the leadless device and technical advances make the implant easier, there will be a lower threshold amongst implanting physicians to reach out for the leadless pacemaker.

The future of leadless pacing

The natural advancement of the leadless single chamber device will be to a dual-chamber and then to a three-chamber resynchronization device with left ventricular pacing (Figure 1). To allow this evolution to take place, it is quite likely that in the near future there will be the continued need for a subcutaneous generator to (i) facilitate the communications between the chambers; (ii) serve as an energy source for the battery;\(^8\) or (iii) to provide the additional role of serving as a defibrillator. Although in its current form the ‘Micra’ has a self-contained battery, leadless pacing of the left ventricle has been demonstrated with the use of external ultrasound energy.\(^8\) Alternative energy sources, i.e. radiofrequency, magnetic fields, etc., along with newer scavenging technology to derive battery power from blood flow, motion, and temperature changes are under investigation. Advances in functionality, fixation strategies, incorporation of sensors, and remote monitoring will undoubtedly occur and make the leadless approach more mainstream. The leadless technology has made it into clinical practice and is here to stay. The investigators of the Micra Transcatheter Pacing Study should be congratulated on a very well conducted study with technology from the future. As has been said before, ‘the best way to predict the future is to create it.’

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References


