

Predictive Modeling of Lead Durability, An Important Step Forward

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The authors present an eloquent description of an analysis of the durability of a cable-based lead for use in directly pacing the human conduction system ¹.

There has long been interest in pacing the conduction system to normalize the ventricular activation sequence in patients requiring ventricular pacing² and clear detriment has been demonstrated from ventricular pacing, especially when not needed³. The first forays into this were performed by pacing the AV nodal tissues or the His bundle directly ⁴. Over time, it was noted that the stimulation thresholds of His bundle leads often rose over time. Interest was then developed in the direct stimulation of the arborized tissues of the Left Bundle Branch. This was initially aimed at the proximal portions of the left anterior fascicle, but it was soon found that the early arborization of the left posterior fascicle was much easier to approach. In this technique, a lead is placed perpendicular to the RV septal endocardium. The lead is drilled into the septum until it is near the LV endocardium. At this level, there is marked arborization of the left bundle tissues. A very narrow QRS is often obtained. The adoption of this technique spread quickly. While this technique is medically very attractive, it presents new and different stressors of the pacing lead used to accomplish

this. Additionally, since this technique is often used in patients with heart block, it is imperative that the implanting physician have confidence in the reliability of the lead.

Dr. Wilkoff eloquently expressed, in 2007, that “what has become clear is that there are three contributing factors to lead failures. First, lead construction is critical, including materials, design, and manufacturing. Second is implantation technique, which continually evolves slowly

over time. Lastly, there are patient factors, such as size, peculiar anatomic variations, and activities such as power weightlifting, and the potential for trauma during exercise or accidents.”⁵

The differences between this technique and the usual technique of RV endocardial pacing created a great deal of concern among the community of lead design engineers. The most common lead used for this technique is the Medtronic 3830 lead which has several unique features: a small diameter, a lumenless design and a very flexible central cable with a tight weld to the tip electrode. While the durability of this lead has been extensively studied and analyzed, it has never been studied when used in this manner. The unique features of this implant technique include that the lead is rotated many more times than a standard implant and that the implantation deep into the tissue creates a fulcrum point at the surface of the RV endothelium, near the ring electrode. Bending at a fulcrum point, as is seen with lead implantation through the subclavious tendon structure, has been associated with conductor fracture. While the deleterious effect of a fulcrum point on leads has long been recognized ⁶, the specific stressors involved in Left Bundle pacing have never been studied that have never been studied.

The authors used techniques that were developed during the analysis of the Fidelis® lead failure to study the specific use conditions for a given lead with given implantation techniques ⁷. Prior to that analysis, the stressors that were induced by skeletal motor activity on the lead in the pocket had largely been ignored and the impact of prolapsing the lead across the valve had not been appreciated.

Using these techniques, the authors studied the Medtronic 3830 lead when used in left bundle pacing. They demonstrated that the 10-year durability of the lead will likely be very high. This is not only useful in the analysis of this lead when used in this manner, but it also demonstrates a very useful set of techniques that can help with the conundrum of studying the long-term durability of an implanted device that is expected to last many years without doing a 10 – 20 year clinical study. Fortunately, this approach is becoming standard in the cardiac rhythm management field, and we certainly hope that it will lead to improved performance of leads in general⁸.

One caveat of this analysis is that it should not be extended to other leads as other leads until they are studied in a similar manner. The most important unique feature of this lead is that there is no central lumen. This reduces a common mechanism of lead fracture caused by acute bending when the lead is flexed. That make extrapolation of these results to lumen-based leads inappropriate.

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