Learning from ICD Leads in Children

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If you want to break something, give it to your kid. That truism applies to many items from toys to technology. The paper describing the results of the PLEASE study (Pediatric Lead Extractability and Survival Evaluation Study) from Berul et al in this issue of Circulation provides sobering but important evidence that this also applies to implantable cardioverter-defibrillator (ICD) leads.¹

Most ICD systems are implanted in adults, but many are implanted in children. These pediatric patients with ICD systems now participate in larger ICD registries,² but an earlier specific pediatric registry is the target of this study. This study encompasses 874 patients and 965 ICD leads, spanning 24 centers. The initial ~1/5th of the patients were enrolled in a randomized study comparing two specific lead designs: the smaller Medtronic Fidelis lead, and a larger but ePTFE coated Boston Scientific alternative. This portion of the study was terminated when concerns about Fidelis lead performance surfaced, and these and all subsequent patients entered into a registry, with more patients and nearly inclusive entry for the latter portion of the enrollment. Although not pre-specified, I think this flexibility was laudatory, allowing the salvage of useful and generalizable information, and does not appear to be an obvious source of bias or scientific compromise. The study design however is essentially that of a registry rather than a randomized study.

ICD's work in children,³ and transvenous ICD systems appear superior to epicardial systems.⁴ Smaller patient size allows novel non-vascular lead configurations for leads usually placed transvenously,⁵ but these were presumably not targeted in this study.

The authors accurately summarize: “There were 139 (14%) ICD lead failures in 132 (15%) patients at mean lead age of 2.0±1.4 years, causing shocks in 53 (40%) patients.” The failure rate in “thin” leads was significantly higher, but this was dominated by the failure of
Fidelis leads. However, even in non-Fidelis leads, “good” leads showed disappointing performance: the actuarial yearly failure rate was 2.3%. The average time to failure was 2 years, although finite study follow up will necessarily bias this estimate. Thus, while flawed leads failed, even our best available leads show a disconcertingly high failure rate in younger patients. Possibly a small lead other than a Fidelis lead might prove superior, or inferior; for purposes of this study thin is inescapably confounded with Fidelis. One smaller lead is the Riata and its derivatives. There were not enough Riata leads in this study to draw essential conclusions. The absence of longer term follow up means that questions about asymptotic durability are not addressed by this study.

Multivariate analysis showed that younger age at implant was an independent predictor of lead failure. Younger patients may be more active, more flexible, or simply smaller, forcing their ICD leads to take tighter turns and experience more component stress. This again emphasizes the engineering challenges as implantable devices are increasingly used in smaller, and larger, patients. The failure rate was not predicted by procedural volume, suggest that lead failure was a function of intrinsic and patient factors, not obviated by special wizardly implant techniques known only to a small set of high volume operators.

Extraction was accomplished for 143 leads without mortality, but with a 4.3% rate of major complications. Half of the extractions required advanced tools, either locking stylets, a powered sheath, or both. These data join with a small but consistent set of other evidence suggesting that pediatric lead extraction is feasible, reasonably safe, and difficult.6,7

One limitation not discussed is the absence of a precise definition of “lead failure.” The meaning may have seemed self-evident at the time this study was initiated. It is less obvious now, when some leads have known mechanical failure (specifically, fluoroscopic or physical
conductor externalization), or electrical failure, with an imperfect correlation between these. Registries and studies will need to accommodate this with greater precision going forward.

There is one important “glass half full” conclusion that can be drawn from this study. Larger leads were used in nearly half the patients, spanning all age ranges. Patient size is often cited as a rationale for downsizing ICD leads. However, while smaller leads for smaller people may be nice, they are clearly not essential. Perhaps subcutaneous ICD systems can improve set of options available for younger patients or result in superior performance, but rigorous trials are needed, and trials are currently underway. Delaying the initial implantation of a transvenous system may have significant benefit greater than just the actuarial number of years.

Learning from children is often professed and less often experienced. The presence of large and inclusive registries with good follow up is an important element in drawing clinically useful conclusions. The cohesive pediatric EP community provides a model, which the larger EP community could well emulate. You can see a lot by looking, and what we can see is still significant room for improvement in lead survival.

Conflicts of Interest Disclosures: Dr. Rottman is on the advisory board at Spectranetics (non-compensated), is a non-compensated speaker for Medtronic, and reports administrative activity with Nashville VA Medical Center. He has received grant support from St. Jude Medical.

References:


