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

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, 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 approximately one fifth of the patients were enrolled in a randomized study comparing 2 specific lead designs: the smaller Medtronic Fidelis lead and a larger but ePTFE (expanded polytetrafluoroethylene)-coated Boston Scientific alternative. This portion of the study was terminated when concerns about Fidelis lead performance surfaced, and these and all subsequent patients were entered into a registry with more patients and nearly inclusive entry for the latter portion of the enrollment. Although not prespecified, I think this flexibility was laudatory, allowing the salvage of useful 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.

ICDs work in children, and transvenous ICD systems appear superior to epicardial systems. Smaller patient size allows novel nonvascular lead configurations for leads usually placed transvenously, but these were presumably not targeted in this study.

The authors accurately summarize: “There were 139 ICD lead failures (14%) in 132 patients (15%) at mean lead age of 2.0±1.4 years, causing shocks in 53 patients (40%).” The failure rate in thin leads was significantly higher, but this was dominated by the failure of Fidelis leads. However, even non-Fidelis “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, although 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. Smaller leads include 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 implantation 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, suggesting that lead failure was a function of intrinsic and patient factors, not obviated by special wizardly implantation techniques known only by 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, ie, locking stylets, a powered sheath, or both. These data join a small but consistent set of other data suggesting that pediatric lead extraction is feasible, reasonably safe, and difficult.

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 electric failure, with an imperfect correlation between them. Registries and studies will need to accommodate this with greater precision going forward.

An important glass half-full conclusion 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, although smaller leads for smaller people may be nice, they are clearly not essential. Perhaps subcutaneous ICD systems can improve the 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

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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with good follow-up is an important element in drawing clinically useful conclusions. The cohesive pediatric electrophysiology community provides a model that the larger electrophysiology 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.

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

References

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