Supraventricular Tachycardia Treatment Efficacy in Infants
On Further Review

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In this issue of Circulation: Arrhythmia and Electrophysiology, Sanatani et al report a randomized, double-blind study of a comparison of digoxin and propranolol for chronic therapy of supraventricular tachycardia (SVT) in infants <4 months of age. The key findings in 61 patients were that there were no differences in SVT recurrence for the 2 drug treatment groups and that there were no recurrences of SVT after 4 months of therapy with either antiarrhythmic agent. Another salient point to be taken includes an expectation that perhaps 10% of infants diagnosed with SVT can be expected to require subsequent hospitalization for management of SVT recurrences.

As is often the case with even thoughtful attempts to perform these types of clinical trials in pediatric electrophysiology, and pediatric cardiology generally, the study is underpowered to make feasible many of the desired statistical analyses between the 2 treatment groups. As a result of the relatively small numbers of patients in a given institution, multicenter studies in our field are frequently required to achieve the requisite N for these study designs. As the authors note, issues of patient enrollment, physician biases, parental consent, and inadequate follow-up plague this and other similar efforts. The history of this specific article is telling, in its attempts to clear the hurdle of peer review: it was submitted to 4 journals, critiqued by 12 reviewers, and underwent 8 revisions in response to seemingly unachievable demands for the statistical rigor of a large, randomized clinical trial. The study and its lead author became fixtures for a plea to the masses for patient enrollment at the Pediatric and Congenital Electrophysiology Society business meeting at Heart Rhythm Society for each of the past 6 years. With its key features intact, it has reached its well-deserved publication.

From a practical standpoint, yes, the study is underpowered. It is still worthy of our attention and publication, even in its descriptive terms, for its effects on what we do, how we educate families, and how we lay the foundation of their expectations going forward. Personally, over the years, I have scaled back the duration of therapy for infants with SVT from 12 months to 8 months and then to 6 months. As a result of this current report, I have been stopping therapy for SVT in these non–Wolff-Parkinson-White, common SVT mechanism patients at 4 months. The data from Sanatani et al have been available in review form for the better part of a year, and (anecdotally!) over that time period we have not seen an SVT recurrence. That aspect of the current article raises another value of this data: it provides us with a data set from which we can pose new questions, such as “do all infants with SVT warrant ongoing treatment, and if not, which patients?” As the authors query, do we need (or want) a placebo study for this population?

This all brings us to an important consideration for the design of studies for rare (ie, low N) conditions. A valid critique of randomized clinical trials and group comparisons is that the value for an individual patient of one therapy versus another can be lost in the statistical comparison of means. As Sanatani et al state, “There are no randomized clinical trials addressing the most effective medicine for preventing recurrent SVT.” Perhaps, for the majority of pediatric electrophysiology and pediatric cardiology questions, there should not be. In our attempts to adhere to the stringent requirements of randomized clinical trial study design, with rare exception, we bemoan the difficulties, never embark on the studies, and wind up accomplishing…nothing new.

There has been renewed interest in the N-of-1 clinical trial study design, particular for rare diseases. In these studies, patients serve as their own controls, and their responses to therapies are quantified for that individual patient. These types of trials seem to require a constant, measurable background disease variable (eg, arthritis, attention deficit hyperactivity disorder) or frequent symptom event (eg, asthma) to assess individual treatment effects. Pediatric SVT could meet these requirements in some study populations with measurable frequencies of SVT recurrences. The overall construct of this study design has appeal as a general modus operandi for pediatric electrophysiology.

As many of us in the Pediatric and Congenital Electrophysiology Society group asked Dr Sanatani several years ago, “Who cares about a study of digoxin versus propranolol?” The answer is, we all should. So much of what we do in the clinical practice of pediatric electrophysiology is based on anecdote, mythology, and institutional and training center biases. In our clinics, patients and families now routinely come armed with often erroneous, preconceived notions of their rhythm problems based on Web site information, but they ask simple and reasonable questions such as, “How do you know this is the best drug to give my child?” or “How do you know how long we should treat?” and “Are you sure?” In 2012, when we are awash in precise, but difficult to apply wireless data dumps
and the complexities of genomic effects emerging for many diseases, we owe these people honest answers about what we profess to know about simple issues. We run into the prideful complication illustrated by the following quote attributed to Leo Tolstoy:

I know that most men—not only those considered clever, but even those who are very clever and capable of understanding the most difficult scientific, mathematical, or philosophic problems—can seldom discern even the simplest and most obvious truth, if it be such as obliges them to admit the falsity of conclusions they have formed, perhaps with much difficulty—conclusions of which they are proud, which they have taught to others, and on which they have built their lives.

Sanatani et al\(^1\) remind us that the seemingly simple truths that form the basis of how we practice pediatric electrophysiology do warrant investigation, reexamination, and publication. They are to be applauded for their persistence in seeing this study through to print (and the Circulation: EP Editors as well). The end result is an article that can have direct clinical impact on what we do and what we think we know and teach to others. Perhaps it is time we get over our obsession with emulating the adult cardiology heart failure and ischemia clinical trial study design, pursue more viable and appropriate study options for our unique and smaller patient population, and hope the editors and reviewers are equally open-minded.

**Disclosures**

None.

**References**


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