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Intravenous Sotalol in Pediatric and Congenital Patients: A Multi-center Registry

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Background:

Though intravenous sotalol has been used outside the US for over thirty years, it was only recently approved by the Food and Drug Administration (FDA; 2009) and reintroduced to the US market (2015). Sotalol is a class III antiarrhythmic agent that prolongs action potential duration while also blocking beta-adrenergic receptors. Intravenous (IV) sotalol has been used for many different types of tachyarrhythmias with the distinct advantage of having an oral equivalent with more tolerable side effects. This is of particular importance in pediatric patients as well as young adults with congenital heart disease who will likely remain on antiarrhythmic therapy for long periods of time (potentially a lifetime). Additionally, collateral damage to developing organ systems by other class III antiarrhythmics makes sotalol an important alternative in this population.

Currently, IV sotalol is indicated for substitution of oral sotalol in patients who are unable to take oral medications per the FDA. Infusion options are based on the current adult literature, FDA guidance, and modeling with reported infusion times between one and thirty minutes, most commonly five minutes^{1,2}. Typical IV sotalol doses have been reported around 1-1.5mg/kg/dose³. However, pediatric dosing for IV sotalol has not been well studied, with a single case series from Zhang⁴ et al using IV sotalol in children with normal left ventricular function.

The purpose of this study is to evaluate the safety and efficacy of IV sotalol being given for tachyarrhythmias to pediatric patients as well as adults with congenital heart disease. Our goal is to collect approximately 100 patients from 10 centers over an 18 month time period. To facilitate this, a multicenter prospective nonrandomized registry study will be performed to address specific aims.

If you are interested in this study, please see the [Registry Proposal](#) and [Data Collection Form](#); contact Lindsey Malloy-Walton at lemalloywalton@cmh.edu for more information.