

Sugammadex, Same Dose across All Age Groups: Does One Size Fit All?

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The article titled "Sugammadex for Reversal of Neuromuscular Blockade in Neonates and Infants Less than 2 Years Old: Results from a Phase IV Randomized Clinical Trial" by Mensah-Osman *et al.* in this issue of *ANESTHESIOLOGY* is a welcome addition to the literature regarding the use of the novel pharmacologic agent sugammadex for reversal of neuromuscular blockade in pediatric-aged patients, specifically those less than 2 yr of age.¹ To date, the available information on the clinical use of sugammadex in this age category is indeed scarce. It consists primarily of data from the first study on sugammadex in a total of 26 children (6 infants) published by Plaud *et al.*,² and by similar cohorts from a limited number of subsequent studies in infants.^{3,4} Although still not approved the U.S. Food and Drug Administration (Silver Spring, Maryland) for use in this age group, sugammadex is indeed used by many practitioners in neonates and infants, often in a nonstandard dose, without specific train-of-four (TOF) data.⁵ Current Food and Drug Administration–approved indications include the reversal of neuromuscular blockade induced by rocuronium bromide or vecuronium bromide in adults (December 2015) with a more recent expanded indication for patients at least 2 yr of age (July 2021).

Although sugammadex is frequently administered "off-label" in patients less than 2 yr of age, neonates and infants are at increased risk of residual neuromuscular blockade or even recurarization because of various clinical factors including differences in neuromuscular junction physiology, pharmacodynamics, excessive dosing of



"Now that easy-to-use and reliable electromyography-based monitoring is available even for the smallest patients, we suggest that we should monitor neuromuscular blockade from the start..."

neuromuscular blocking agents (NMBAs), drug interactions, developmental pharmacokinetics, or absent TOF monitoring.^{3,6,7} The primary finding of the current study is that sugammadex in doses of 2 mg/kg or 4 mg/kg is well tolerated and rapidly reverses moderate (presence of second twitch on TOF stimulation) or deep (posttanic twitch count greater than 1 or 2) neuromuscular blockade, respectively, in pediatric patients less than 2 yr of age.¹ These preliminary data suggest that the same dosing schedule as in adults, based on qualitative neuromuscular (TOF) monitoring, may be used in patients less than 2 yr of age. However, this study raises some specific methodologic concerns that must be considered before widespread application of these findings can be recommended in current clinical practice.

First, the absence of uniformity in neuromuscular monitoring

among the participating centers is a surprising limitation given the rigorous methodology usually applied in industry-sponsored randomized clinical trials or studies. Time to recovery of neuromuscular function, the main outcome of the study, was variable across the study sites as recovery was assessed by one of four methods, selected by the investigator for each site, based on their judgment of what was technically feasible and clinically appropriate for the individual participant's procedure and their clinical practice. The methods used to judge recovery were (1) ability to sustain head lift against resistance for at least 5 s, (2) ability to sustain hip flexion against resistance for at least 5 s, (3) four twitches without fade (or, for neonates, four twitches comparable

Image: J. P. Rathmell.

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