Off-label sugammadex use in neonates and infants for reversal of non-depolarizing neuromuscular blockade

Allison Thoeny MD, Andrew Costandi MD, and Abhishek Karnwal MD

Introduction

- Sugammadex is attractive for reversal of aminosteroid non-depolarizing neuromuscular blockers (NDMB) as it produces rapid reversal after deep paralysis without notable adverse effects.
- Pediatric use is limited due to lack of FDA approval under age 18 and few randomized-controlled trials (RCTs) in young children[1,2]. Support in neonates is even more scarce, though a cohort study[3] demonstrated use without adverse events.
- *Aim:* To report our observations and experiences with off-label use of sugammadex for neuromuscular blockade reversal in neonates and infants < age 1.

Methods

- Retrospective study using pharmacy database of sugammadex dispensed from January-October 2017.
- Inclusion criteria:
  - ✓ age < 1 year
  - ✓ ASA I-IV
  - ✓ documented sugammadex administration after rocuronium or vecuronium-induced paralysis
- Primary outcome was incidence of adverse effects determined by intraoperative and post-anesthesia records.

Table 1. Demographic data of study patients

Age (days)	114.43 ± 94.88, n = 35
Neonate (< 30 days)	19.29 ± 10.83, n = 8
Infant (30 days to 1 year)	142.26 ± 90.68, n = 27
Sex (male/ female)	20/ 15
Weight (kg)	5.16 ± 2.06
ASA	
I	5
II	12
III	13
IV	5

*Expressed as Mean ± SD or n

Results

Figure 1. Procedural Categories

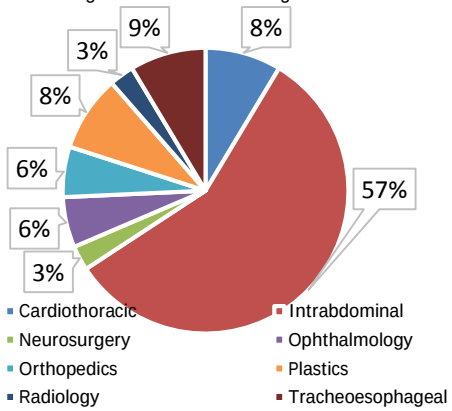

Table 2. Sugammadex given as reversal of neuromuscular blockade by dose, indication and adverse effects observed, n = 35

Dose (mg/kg)	
16	7
8	3
4	17
3	5
2	3
Indication	
Planned primary agent for routine neuromuscular reversal	16
Residual neuromuscular weakness after reversal with neostigmine/ glycopyrrolate	9
Neuromuscular weakness with no TOF/PTC or need for immediate reversal	10
Adverse effects	
Hypotension	0
Bradycardia	0
Nausea or vomiting	0
Hypersensitivity	0
Anaphylaxis	0

*TOF= train-of-four; *PTC= post-tetanic count

- 35 patients (8 neonates, 27 infants) were enrolled; 9 patients without dose documentation were excluded. Age, sex, weight and ASA classifications are shown in Table 1.
- Most patients underwent intra-abdominal surgeries (57%); variety of procedural categories are seen in Figure 1.
- Sugammadex dosing ranged from 2-16 mg/kg without adverse effects; indication for reversal included routine agent (46%), residual weakness (26%) and no TOF /PTC or need for immediate reversal (28%) (Table 2).

Discussion

- We observed safe clinical use of sugammadex for routine, residual, and urgent neuromuscular blockade reversal in neonates and infants under age 1.
- Bradycardia after sugammadex was not observed in this study, supporting prospective evidence that it may provide a more hemodynamically stable alternative to neostigmine in infants[1].
- Study limitations: nature of retrospective design, small sample size, non-uniform anesthetic, not powered to assess drug safety, and unaddressed efficacy.
- Further study with RCTs is needed to draw formal conclusions about safety and efficacy in this population.

Conclusion

Sugammadex was well tolerated in 35 infants (ages 4 days to 1 year) to provide reversal of rocuronium or vecuronium-induced neuromuscular blockade without any clinically detectable adverse effects.

References:
1. Liu et al. The efficacy and safety of sugammadex for reversing postop residual neuromuscular blockade in pediatric patients: A systematic review. Sci Rep 2017, 7: 5724.
2. Ozmete et al. Sugammadex given for rocuronium-induced neuromuscular blockade in infants: a retrospective study. J Clin Anesth 2016, 35: 497-501.
3. Alonso et al. Reversal of rocuronium-induced neuromuscular block by sugammadex in neonates. Eur J Anaesth 2014, 31: 163.