Could Sugammadex be an Option in Children Younger than 3 Years Old?

A case series summarizing our experience at Cleveland Clinic

Nicholas Fawley DO, Sanchit Ahuja MD, Pilar Castro MD MsED
Department of Anesthesiology, Cleveland Clinic, Cleveland Ohio

Introduction

- Sugammadex is indicated for reversal of neuromuscular blockade (NMB) in adult anesthesia
- Sugammadex offers **advantages** compared to acetylcholinesterase inhibition
  - Full and rapid reversal
    - Including during profound blockade
    - May benefit in a “cannot intubate, cannot ventilate” scenario
  - Lower incidence of residual NMB
  - Can be used when acetylcholinesterase inhibitors are contraindicated
  - Absence of muscarinic cholinergic adverse effects
- These advantages may extend to the pediatric population
- Limited experience regarding the safety and efficacy of sugammadex in pediatric patients
  - Especially below age 2
- The aim of this case series is to describe the use of sugammadex in pediatric patients younger than 3 years of age at our institution

Methods

- Retrospective descriptive analysis of medical records was completed at Cleveland Clinic
- Inclusion criteria: children less than age 3, ASA Physical Status 1-4, undergoing general anesthesia, during which rocuronium or vecuronium was administered
- Surgical encounters included within the dates of Sept 2016 to Sept 2017.
- Sugammadex reversal of neuromuscular blockade (Bridion; Merck & Co, 12/2015)
- Primary evaluation was time from sugammadex administration to extubation
- Adverse effects reported
- Medical record review was approved by Institutional Review Board

Results

Table 1. Patient Characteristics (N = 118)

Age	N (%)
0 to 31 days	19 (16)
1 to 6 months	35 (30)
7 to 12 months	14 (12)
12 to 24 months	27 (23)
24 to 35 months	23 (19)
Gender	N (%)
Female	48 (41)
Male	70 (59)
ASA Physical Status (in 138 cases)	N (%)
1	18 (13)
1E	9 (7)
2	34 (25)
2E	0 (0)
3	54 (39)
3E	13 (9)
4	10 (7)
4E	0 (0)

Table 2. Procedure Characteristics (N = 138)

Procedure category	N (%)
General surgery	43 (31.2)
Cardiac	11 (7.9)
Neurosurgery	28 (20.0)
ENT	12 (8.7)
Orthopaedic	2 (1.4)
Urologic	8 (5.8)
Endoscopy	20 (14.5)
Other	3 (2.2)
Case type	N (%)
Elective	116 (84.1)
Emergency	22 (15.9)
Mean duration of procedure in minutes (range)	191 (28-718)
Sugammadex Dose in mg/kg	N (%)
0.5	1 (0.7)
1.0	1 (0.7)
2.0	78 (56.5)
2.5	8 (5.8)
3.0	9 (6.5)
4.0	38 (27.5)
5.0	2 (1.4)
6.0	2 (1.4)
10.0	1 (0.7)

Table 3. Outcomes of 118 patients who received sugammadex for 138 procedures

Mean time to extubation in minutes	8.1
Minutes to extubation	N (%)
> 2 to ≤ 4	31 (22.5)
> 4 to ≤ 6	28 (20.3)
> 6 to ≤ 10	31 (22.5)
> 10	25 (18.1)
Not extubated intraoperatively	23 (16.6)
Bradycardia	N (%)
Decrease in heart rate >10 bpm	14 (10)
Decrease in heart rate requiring treatment	2 (1.4)
Anaphylaxis or anaphylactoid reactions	0
Respiratory events	N (%)
Laryngospasm	2 (1.4)
Bronchospasm	2 (1.4)
Desaturation	2 (1.4)
Re-intubation	1 (0.7)

Discussion

- The use of sugammadex for NMB reversal in pediatric patients in the United States has been “off-label”
- Europe – sugammadex approved for routine rocuronium reversal NMB in pediatric patients age 2-17
- Systematic reviews and meta-analysis of pediatric patients age 2 - 18 receiving sugammadex in comparison to placebo or neostigmine
  - Reduced time to return of train-of-four ratio
  - Reduced time to extubation
  - No increase in adverse effects when compared to neostigmine
  - No increase in incidence of post-anesthetic adverse events
- In patients under age 2, evidence is limited to case reports and retrospective studies which comprise approximately 50 infants
  - Ozmete et al. – Retrospective study of 26 pediatric patients under age 2 who received 3mg/kg of sugammadex for reversal of deep neuromuscular blockade
    - Suggested efficacy and safety of sugammadex
- Our observations in 118 cases of children younger than 3 (including 95 younger than 2) who received sugammadex suggest a short time to extubation with limited adverse outcomes.
- Decrease in heart rate was observed in 10% of the patients
- Future studies are necessary to further characterize the efficacy and safety profile of sugammadex in this population.

References

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