

SOCIETY FOR AMBULATORY ANESTHESIA
Outpatient • Office Based • Non-Operating Room

ASC Medical Directors & Leaders Virtual Summit
Saturday, January 22, 2022

Pediatric Outpatient Anesthesia: Current Issues



Rosalie F. Tassone, MD, MPH
Envision Physician Services
Palms West Hospital and Palms West Children's Hospital



1

SOCIETY FOR AMBULATORY ANESTHESIA
Outpatient • Office Based • Non-Operating Room

www.SAMBAhq.org

Objectives

- Review the updated guidelines for pediatric patients undergoing tonsillectomy
- Present discussion perspectives regarding NPO guidelines in pediatric patients
- Refresh recommendations regarding neuromuscular blockade in pediatric patients



SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

2

SOCIETY FOR AMBULATORY ANESTHESIA
Outpatient • Office Based • Non-Operating Room

www.SAMBAhq.org

I have nothing to disclose



SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

3

SOCIETY FOR AMBULATORY ANESTHESIA
Outpatient • Office Based • Non-Operating Room

www.SAMBAhq.org

Introduction





SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

4

SOCIETY FOR AMBULATORY ANESTHESIA
Outpatient • Office Based • Non-Operating Room

www.SAMBAhq.org

Starting at the End

- Population based retrospective cohort
 - Patients <18 years of age
 - Ontario 2014-2018
 - 3 days post surgery
- 83,468 surgeries
 - 2588 (3.1%) ED visit
 - 608 (0.7%) hospital admission



SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

5

SOCIETY FOR AMBULATORY ANESTHESIA
Outpatient • Office Based • Non-Operating Room

www.SAMBAhq.org

Starting at the End

- Majority of ED visits for **pain and bleeding**
- Majority of hospital admissions for **bleeding, dehydration, pain**
- Most common surgeries
 - Tonsillectomy and cholecystectomy



Sawhney M, VanDenKerkhof EG, Goldstein DH, Wei X, Pare G, Mayne I, Tranmer J. Emergency department use and hospital admission in children following ambulatory surgery: a retrospective population-based cohort study. *BMJ Paediatr Open*. 2021 Nov 23;5(1):e001188. doi: 10.1136/bmop-2021-001188. PMID: 34901470; PMCID: PMC8311446.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

6

Predictors of Unanticipated Admission

Pediatric Anesthesia

Pediatric Anesthesia ISSN 155-5646

RESEARCH REPORT

Predictors of unanticipated admission following ambulatory surgery in the pediatric population: a retrospective case-control study

Armands Whikey, Gregory Kostandoff, Heung K. Ma, Ji Cheng, Lehana Thabane & James Paul

Department of Anesthesia, McMaster University, Hamilton, ON, Canada

What is already known

- The rate of unanticipated admission following adult ambulatory surgery is almost 2% and can be used as a marker of patient safety, quality of care, and to identify appropriate patients for ambulatory surgery.
- Little is known about the incidence of and potential risk factors for unanticipated admission in the pediatric population.

What is added

- The incidence of pediatric unanticipated admission is low (0.97%) but significant.
- Anesthesia-related causes accounted for the majority of admissions.
- Predictive factors include age, ASA 3 class, type, duration, and time to completion of surgery as well as presence of OSA.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

7

Predictors of Unanticipated Admission

Case control study of ambulatory patients requiring unanticipated admission between 2005 and 2013

Incidence of unanticipated admission was 0.97%

- 47% (98) was anesthesia related
- Hypoxia, pain, PONV

Factors associated with unanticipated admission

- Age <2 years
- ASA 3 class
- duration of surgery >1 h
- completion of surgery >3 pm
- orthopedic, dental, ENT
- Intraoperative events
- OSA

Whikey A, Kostandoff G, Ma HK, Cheng J, Thabane L, Paul J. Predictors of unanticipated admission following ambulatory surgery in the pediatric population: a retrospective case-control study. *Pediatr Anesth*. 2016 Aug;26(8):831-7. doi: 10.1111/paa.12937. Epub 2016 Jun 1. PMID: 27247224.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

8

Case presentation

14-year-old girl presents for adenotonsillectomy

5' 3" 75 kg BMI 29

sleep disordered breathing

PMH for mild asthma

Meds- albuterol prn, oral contraceptives

Clear nasal discharge for past 1 day

Younger brother at home just recovered from URI

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

9

Guidelines for Tonsillectomy

Clinical Practice Guideline: Tonsillectomy in Children (Update)—Executive Summary

Ron B. Mitchell, MD¹, Sanford M. Archer, MD², Stacey L. Ishman, MD, MPH³, Richard M. Rosenfeld, MD, MPH, MBA⁴, Sarah Coles, MD⁵, Sandra A. Finestone, PsyD⁶, Norman R. Friedman, MD⁷, Terri Giordano, DNP⁸, Douglas M. Hildrew, MD⁹, Tae W. Kim, MD, MPH¹⁰, Robin M. Lloyd, MD¹¹, Sanjay R. Parkh, MD¹², Stanford T. Shulman, MD¹³, David L. Walner, MD¹⁴, Sandra A. Walsh¹⁵, and Lorraine C. Nnacheta, MPH¹⁵

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

10

Guidelines for Tonsillectomy

5. Indications for polysomnography

Before performing tonsillectomy, the clinician should refer children with obstructive sleep-disordered breathing (OSDB) for polysomnography (PSG) if they are <2 years of age or if they exhibit any of the following obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or myopathies.

9. Perioperative pain counseling

The clinician should counsel patients and caregivers regarding the importance of managing tonsillectomy pain as part of the perioperative educational process and should reinforce this counseling at the time of surgery with reminders about the need to avoid nonsteroidal anti-inflammatory drugs (NSAIDs) after surgery.

10. Perioperative antibiotics

Clinicians should not administer or prescribe perioperative antibiotics to children undergoing tonsillectomy.

11. Intraoperative steroids

Clinicians should administer a single intraoperative dose of intravenous dexamethasone to children undergoing tonsillectomy.

12. Inpatient monitoring for children after tonsillectomy

Clinicians should arrange for overnight inpatient monitoring of children after tonsillectomy if they are <3 years old or have severe obesity, a history of obstructive sleep-disordered breathing (OSDB), or obstructive events after oxygen saturation nadir <80% or both.

13. Postoperative ibuprofen and acetaminophen

Clinicians should recommend ibuprofen, acetaminophen, or both for pain control after tonsillectomy.

14. Postoperative codeine

Clinicians must not administer or prescribe codeine, or any medication containing codeine, after tonsillectomy in children younger than 12 years.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

11

Opioid sparing anesthetics

• Codeine no longer routinely used

• Patients often sensitive to narcotics

• More opioid sparing approaches in literature

- Ketorolac, dexmedetomidine, ketamine
- However, some intraoperative narcotic use

• Peritonsillar local anesthetic injection

1 Aldamijil, N., Burgess, A., Pogatzki-Zahn, E., Rader, J., Bellotti, H. and (2021). PROSPECT guideline for tonsillectomy: systematic review and procedure-specific recommendations. *Anesthesia & Analgesia* 124: 924-934. <https://doi.org/10.1213/ANE.0000000000004626>

2 Franz, AM, Dahl, JP, Huang, H, et al. The development of an opioid sparing anesthesia protocol for pediatric ambulatory tonsillectomy and adenotonsillectomy surgery—A quality improvement project. *Pediatr Anesth*. 2019; 29: 682- 689. <https://doi.org/10.1111/paa.13562>

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

12

ERAS in Adenotonsillectomy

Received 28 May 2020 | Revised 24 September 2020 | Accepted 17 September 2020

DOI: 10.1111/j.1365-2760.2020.15646.x

© 2020 The Authors. *Journal of Clinical Pharmacy and Therapeutics* © 2020 Society for Adenotonsillectomy and Non-Operating Room Anesthesia (SAMBAhQ)

Original Article

An enhanced recovery programme improves the comfort and outcomes in children with obstructive sleep apnoea undergoing adenotonsillectomy: A retrospective historical control study

Yu Zhang¹ | Dawei Liu¹ | Xiumei Chen¹ | Jiahui Ma² | Xicheng Song³

¹Department of Otolaryngology Head and Neck Surgery, Xuzhou Key Laboratory of Pediatric Otolaryngology, Xuzhou Children's Hospital, Xuzhou, China

²Department of Anesthesiology, Xuzhou Children's Hospital, Xuzhou, China

³Department of Otolaryngology Head and Neck Surgery, Xuzhou Key Laboratory of Pediatric Otolaryngology, Xuzhou Children's Hospital, Xuzhou, China

Correspondence

Xicheng Song, Department of

Otolaryngology Head and Neck Surgery,

Xuzhou Children's Hospital, Xuzhou, China.

E-mail: songxicheng@163.com

Published online

© 2020 The Authors. *Journal of Clinical Pharmacy and Therapeutics* © 2020 Society for Adenotonsillectomy and Non-Operating Room Anesthesia (SAMBAhQ)

Printed in China, Quarto Board Member

15646

SOCIETY FOR
SAMBA
HQA
Department of Office-Based Non-Operating Room
Anesthesia

www.SAMBAhQ.org

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

13

ERAS in Adenotonsillectomy

• 294 children with OSA

• 208 in ERAS group, 186 controls

• ERAS protocol included

- ERAS education, nutritional assessment,
- Periop anxiety management,
- Standardized anesthetic, multimodal pain management
- Drink 10% glucose (5 mL/kg) 2 hrs before surgery

• ERAS patients had less pain, anxiety, complications

Zhang, Y, Liu, D, Chen, X, Ma, J, Song, X. An enhanced recovery programme improves the comfort and outcomes in children with obstructive sleep apnoea undergoing adenotonsillectomy: A retrospective historical control study. *Clin Otorhinolaryngol.* 2021; 46: 249–255. <https://doi.org/10.1111/cot.13655>

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

14

NPO guidelines



SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

15

ASA current guidelines

• 2 hrs for clears

• 4 hrs for breast milk

• 6 hrs for formula, light meal

• 8 hrs for heavy meal

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

16

NPO concerns in children

- Instruction standardization
- Poor compliance
- Surgical case shuffling
- Aspiration risk
- Dehydration
- Patient and parent satisfaction
- Difficult IV access
- New studies related to gastric emptying

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

17

1 hour fast for clears?

Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children

Nicola Dismas, MD, Peter Frykholm, MD,† Scott D. Cook-Sather, MD, FCPP,‡ and Jerrold Lerman, MD, FRCRCP, FANZCA§

See Article, p 578

Perioperative fasting guidelines are designed to minimize the risk of pulmonary aspiration of gastrointestinal contents. The current recommendations from the American Society of Anesthesiologists (ASA) and the European Society of Anesthesiology and Intensive Care (ESAC) are for a minimum 2-hour fast for ingesta, including clear liquids, before surgery. This is based on the assumption that procedural sedation and analgesia. Nonetheless, in children, fasting guidelines also have consequences as regards to child and parent satisfaction, hemodynamic stability, the ability to achieve adequate sedation, and the cost of the procedure. The debate is whether the current guidelines recommend a relatively short fasting time for clear fluids of 2 hours, the actual duration of fasting time can be significantly longer. This may be the result of deficiencies in communication regarding the duration of the fast, the meaning of clear liquids, and the definition of a clear liquid. This may also be due to poor parent and patient adherence to the 2-hour guidelines. Prolonged fasting can result in children arriving in the operating room for an elective procedure being thirsty, hungry, and generally in an uncomfortable state. This can result in increased anxiety and decreased parent and child cooperation and can result in parental dissatisfaction with the perioperative experience. In this PRO and CON presentation, the authors debate the premise that reducing the nominal minimum fasting time from 2 hours to 1 hour for clear liquids before surgery may provide significant benefits to children, with no increased risks. (Anesth Analg 2021;133:581–91)

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

18

1 hour fast for clears: Pro

- Underlying concepts of preoperative fasting
 - ensure “safety” from aspiration
 - smooth and comfortable perioperative experience
- Often fasting times exceed recommended times
- Incidence of pulmonary aspiration is 0.6-9 cases/10,000 children undergoing anesthesia

Disma, Nicola MD¹; Frykholm, Peter MD²; Cook-Sather, Scott D. MD, FCP³; Lerman, Jerrold MD, FRCP⁴; FANZCA⁵ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005549

www.SAMBAhq.org

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

19

1 hour fast for clears: Pro

- During a fasting period of 1 hour, the greater part of any ingested fluid will empty from the stomach in healthy children
- Is endorsed and implemented already by some institutions and societies

Disma, Nicola MD¹; Frykholm, Peter MD²; Cook-Sather, Scott D. MD, FCP³; Lerman, Jerrold MD, FRCP⁴; FANZCA⁵ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005549

www.SAMBAhq.org

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

20

1 hour fast for clears: Con

- Often fasting times exceed recommended times
- Gastric emptying is complex
- In context of 1-hour fast pulmonary aspiration has increased to 12-18:10,000

Disma, Nicola MD¹; Frykholm, Peter MD²; Cook-Sather, Scott D. MD, FCP³; Lerman, Jerrold MD, FRCP⁴; FANZCA⁵ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005549

www.SAMBAhq.org

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

21

1 hr fast for clears: Con

Disma, Nicola MD¹; Frykholm, Peter MD²; Cook-Sather, Scott D. MD, FCP³; Lerman, Jerrold MD, FRCP⁴; FANZCA⁵ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005549

www.SAMBAhq.org

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

22

1 hour fast for clears: Con

- Clear liquids of varying composition and unlimited volumes are INCONSISTENTLY and UNRELIABLY emptied from the stomach in 1 hr
- Focus on improving compliance of 2-hour fast

Disma, Nicola MD¹; Frykholm, Peter MD²; Cook-Sather, Scott D. MD, FCP³; Lerman, Jerrold MD, FRCP⁴; FANZCA⁵ Pro-Con Debate: 1- vs 2-Hour Fast for Clear Liquids Before Anesthesia in Children, Anesthesia & Analgesia: September 2021 - Volume 133 - Issue 3 - p 581-591 doi: 10.1213/ANE.0000000000005549

www.SAMBAhq.org

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

23

Back to our case

- 14-year-old girl presents for adenotonsillectomy
- 5' 3" 75 kg BMI 29
- sleep disordered breathing
- PMH for mild asthma
- Meds- albuterol prn, oral contraceptives

www.SAMBAhq.org

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

24

Reversal of Neuromuscular Blockade



- Current literature with more attention toward reversal of neuromuscular blockade
- Full reversal not always achieved
- Sugammadex FDA approved in children
- Sugammadex vs Neostigmine
- Counseling patients on oral contraceptives who receive sugammadex about utilizing alternate form of contraception postoperatively

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

25



SUPPLEMENT APPROVAL FULFILLMENT OF POSTMARKETING REQUIREMENT

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
126 E. Lincoln Avenue, PO Box 2000
Rt34-B-186
Rahway, NJ 07065

Attention: Dori Glassner
Director, Global Regulatory Affairs
Dear Ms. Glassner:

Please refer to your supplemental new drug application (sNDA) dated and received, August 26, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bridion (sugammadex) injection.

This Prior Approval supplemental new drug application proposes changes to the Package Insert based on data to fulfill the requirements of postmarketing requirement (PMR) 3003-8 in pediatric patients ages 2 to less than 17 years old. The data is from Study 0003-8, a 4-period, 4-treatment, randomized, double-blind, placebo-controlled, crossover Clinical Trial to Study the Efficacy, Safety, and Pharmacokinetics of Sugammadex (MK-8616) for Reversal of Neuromuscular Blockade in Pediatric Participants.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

26

Sugammadex in children



- Randomized a total of 288 pediatric participants aged 2 to <17 years
 - sugammadex 2 mg/kg
 - sugammadex 4 mg/kg
 - neostigmine 50 µg/kg
- Recovery from rocuronium- or vecuronium-induced moderate neuromuscular blockade faster with sugammadex 2 mg/kg than with neostigmine
- Reversal of deep neuromuscular blockade with sugammadex 4 mg/kg was consistent with that of moderate neuromuscular blockade reversal

Voss, T, Wang, A, DeAngelis, M, et al. Sugammadex for reversal of neuromuscular blockade in pediatric patients: Results from a phase IV randomized study. *Pediatr Anesth*. 2021; 00: 1–10. doi:10.1111/poa.13370.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

27

Residual neuromuscular block



- impaired regulation of ventilation during hypoxia
- impaired pharyngeal function and airway protection
- is a risk factor for the development of postoperative pulmonary complications
- To assure normal vital muscle function and normal ventilatory regulation, an adductor pollicis TOF ratio of 0.90 should ideally be achieved before a patient is allowed to breath spontaneously after tracheal extubation
- This can only be reliably detected using objective monitoring techniques of neuromuscular function, such as accelerometry or electromyography

Eriksson, Lars I, MD, PhD The Effects of Residual Neuromuscular Blockade and Volatile Anesthetics on the Control of Ventilation, Anesthesia & Analgesia: July 1999 • Volume 89 • Issue 1 • p 243-251 doi: 10.1213/000039199070000004

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

28

Residual neuromuscular block



- Monocentric prospective observational cohort
 - 291 patients ages >29 weeks and <19 years
- Incidence of residual neuromuscular block
 - 48.2% in OR
 - 26.9% in PACU
- Pharmacological reversal of neuromuscular block was administered in 23.3% of patients
 - 41% of these after the TOF measurement in the OR (due to residual blockade)
- Quantitative monitoring of neuromuscular blockade should be implemented in all patients when NMBAs are administered

Klucka J, Kosinova M, Krikava I, Stoudek R, Toukalova M, Stourac P. Residual neuromuscular block in paediatric anaesthesia. *Br J Anaesth* 2019;122(01):e1–e2.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

29

Reversal Agents and Postoperative Pulmonary Complications in Children



Association of Sugammadex or Neostigmine With Major Postoperative Pulmonary Complications in Children

Robert J. Bellini, MD, Jonathan Moody, MD, PhD, MBA, MPH, Oshubhika O. Nafsu, MD, FRCR, MS, and John D. Stoudek, MD

BACKGROUND: Previous data in adult patients suggest that the use of sugammadex compared to neostigmine for reversal of neuromuscular block (NMB) was associated with a significant reduction in the incidence of pulmonary complications in children, although the role of NMB reversal in the development of postoperative pulmonary complications is not well understood.

METHODS: We performed a propensity score-matched retrospective study using the Pediatric Health Information System (PHIS) dataset to compare the incidence of postoperative pulmonary complications in children who received sugammadex or neostigmine for reversal of NMB.

RESULTS: We identified 23,610 children, of whom 22,312 (94.5%) received sugammadex and 10,207 (4.5%) received neostigmine. After propensity score matching, there was no difference in the rate of postoperative pulmonary complications (3.1% vs 3.0%, $P = 0.87$).

CONCLUSION: The choice of reversal agent appears to impact the incidence of major postoperative pulmonary complications. Further research is needed to determine whether our findings are generalizable to other patient populations, including those with complex medical conditions, and anesthesia techniques.

Anesth Analg 2021;122(01):200–205.

KEY POINTS:
Question: What is the association between the choice of neuromuscular block reversal and the incidence of major postoperative pulmonary complications in children?
Answer: In this large multicenter cohort of 23,610 children undergoing noncardiac surgery, there was no difference in the risk-adjusted incidence of postoperative pulmonary complications between children who received sugammadex or neostigmine for reversal of NMB.

Meaning: Compared to neostigmine, the use of sugammadex for reversal of NMB was associated with a reduced incidence of major postoperative pulmonary complications in children who underwent a wide variety of pediatric surgical procedures.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

30

Reversal Agents and Postoperative Pulmonary Complications in Children

- 33,819 children
 - 23,312 (68.9%) received neostigmine
 - 10,507 (31.1%) received sugammadex
- No evidence of a statistically significant association between the NMB reversal agent and the incidence of pulmonary complications
- Choice of NMB reversal agent does not appear to impact the incidence of major postoperative pulmonary complications

Beltran, Ralph J. MD; Mopdy, Christian MD, PhD, MBA, MPH; Nafiu, Olubukola O. MD, FRCA, MS; Tobias, Joseph D. MD Association of Sugammadex or Neostigmine With Major Postoperative Pulmonary Complications in Children. *Anesthesia & Analgesia*: January 12, 2022 - Volume - Issue - 10.1213/ANE.0000000000005872

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

31

Sugammadex and hormonal contraceptives

- Sugammadex may interfere with hormonal contraception
- Counsel patients about decreased effectiveness of hormonal contraceptives with use of sugammadex for reversal of neuromuscular blockade
- Revise informed consent
- Documentation

Corda, David M. MD; Roberts, Christopher B. MD Sugammadex and Oral Contraceptives: Is It Time for a Revision of the Anesthesia Informed Consent? *Anesthesia & Analgesia*: February 2018 - Volume 126 - Issue 2 - p 730-731 doi: 10.1213/ANE.0000000000002627

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

33

Summary



- Choose your patients wisely
- Keep them hydrated
- Keep them strong
- Keep them informed
- Stay thoughtful in how you care for them

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

35

Sugammadex and hormonal contraceptives

- According to the package insert from Merck & Co, Inc.
- "5.6 Due to the administration of Bridion, certain drugs, including hormonal contraceptives, could become less effective due to a lowering of the (free) plasma concentrations"
- "7.3 In vitro binding studies indicate that Bridion may bind to progestogen, thereby decreasing progestogen exposure. Therefore, the administration of a bolus dose of Bridion is considered to be equivalent to missing dose(s) of oral contraceptives containing an estrogen or progestogen."
- If an oral contraceptive is taken on the same day that Bridion is administered, the patient must use an additional, non-hormonal contraceptive method or back-up method of contraception for the next 7 days."

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

32

Sugammadex and hormonal contraceptives

Informed Consent for Sugammadex and Oral Contraceptives: Through the Looking Glass

To the Editor: Recently, along with many others across the country, have revised protocols to address potential issues for women on oral contraceptives who have received sugammadex for reversal of neuromuscular blockade. According to the package insert from Merck & Co, Inc., "5.6 Due to the administration of Bridion, certain drugs, including hormonal contraceptives, could become less effective due to a lowering of the (free) plasma concentrations." The insert also states, "7.3 In vitro binding studies indicate that Bridion may bind to progestogen, thereby decreasing progestogen exposure. Therefore, the administration of a bolus dose of Bridion is considered to be equivalent to missing dose(s) of oral contraceptives containing an estrogen or progestogen. If an oral contraceptive is taken on the same day that Bridion is administered, the patient must use an additional, non-hormonal contraceptive method or back-up method of contraception for the next 7 days." Given these warnings, it is our understanding that many anesthesia providers are considering the potential risk to patients of this potential risk by providing both counseling and a written informed consent suggesting alternative contraceptive use for these patients. Interestingly, a similar potential risk exists with the administration of neostigmine for reversal of neuromuscular blockade. The package insert for a common oral contraceptive (OVC), NARVIK, states, "Contraceptive effectiveness may be reduced when neostigmine is taken on the same day that a patient receives neostigmine, anticholinergics, and other drugs that increase the metabolism of oral contraceptives." Commonly used neostigmine medications include antibiotics that are frequently

- Women in their teens and 20s are about twice as likely as older women to have an unintended pregnancy while using birth control
- Adolescents with parents in tow may not be forthcoming regarding contraceptive use
- Consider using using neostigmine in lieu of sugammadex in these patients

Wesber AM, Krebs M. Informed Consent for Sugammadex and Oral Contraceptives: Through the Looking Glass. *Anesth Analg*. 2018 Sep;127(3):e52. doi: 10.1213/ANE.0000000000005868. PMID: 29979198.

SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

34

Questions



SAMBA ASC Medical Directors & Leaders Virtual Summit • Saturday, January 22, 2022

36