

Pre-Sedation Fasting

An update of the evidence and the new ICAPS guidelines

Mark G. Roback, MD

Professor of Pediatrics

University of Colorado School of Medicine

Section Head, Emergency Medicine

Children's Hospital Colorado



Disclosure Information

- I have no relevant personal financial relationships
- I will be discussing sedation drugs, some of which are not FDA approved for children in the U.S.



Objectives

1. Examine the history of pre-sedation fasting
 - Goals, guidelines, actual practice
2. Review the literature: “best evidence” regarding pre-sedation fasting and aspiration risk
3. Consider ICAPS fasting guidelines

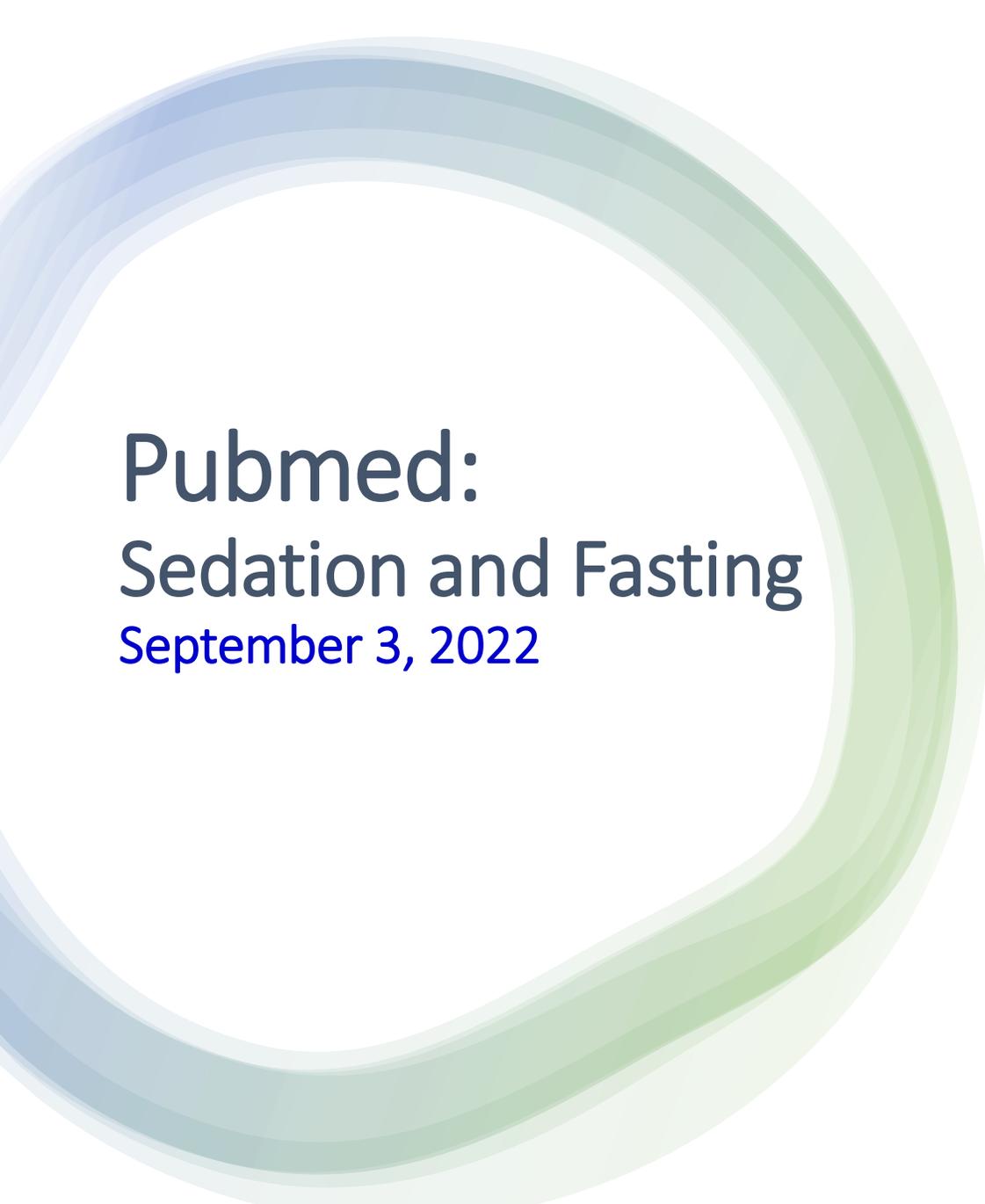


Pre-Sedation Fasting

Years of Multidisciplinary Consideration and Collaboration

1. Agrawal D, Manzi SF, Gupta R, **Krauss B**. Preprocedural fasting state and adverse events in children undergoing procedural sedation and analgesia in a pediatric emergency department. *Ann Emerg Med*. 2003;42(5):636-46.
2. **Roback MG**, Bajaj L, Wathen J, Bothner J. Preprocedural fasting and adverse events in procedural sedation and analgesia in a pediatric emergency department – are they related? *Ann Emerg Med*. 2004;44:454-459.
3. **Green SM**, **Roback MG**, Miner JR, Burton JH, **Krauss B**: Fasting and emergency department procedural sedation and analgesia: A consensus-based clinical practice advisory. *Ann Emerg Med*. 2007;49:454-461.
4. **Bhatt M**, Johnson DW, Chan J, Taljaard M, Barrowman N, Farion KJ, Ali S, Beno S, Dixon A, McTimoney CM, Dubrovsky AS, Sourial N and **Roback MG**; Sedation Safety Study Group of Pediatric Emergency Research Canada (PERC). Impact of preprocedural fasting on outcomes of emergency department sedation in children. *JAMA Pediatr*. 2018;172(7):678-685.
5. **Green SM**, **Leroy PL**, **Roback MG**, Irwin MG, Andolfatto G, Babl FE, **Barbi E**, Costa LR, Absalom A, Carlson DW, **Krauss BS**, Roelofse J, Yuen VM, Alcaino E, Costa PS, **Mason KP**. An international, multidisciplinary consensus statement on fasting before procedural sedation in adults and children. *Anaesthesia*. 2020;75(3):374-385.





Pubmed: Sedation and Fasting September 3, 2022

Is NPO (Nil Per Os) Order Helping or Hindering Elective Cardiac Procedures?

Alexander J, Castelow C, Cieker C, Wilbanks D, Asbeutah AA, Melton CD, Khouzam RN.

Curr Probl Cardiol. 2022 Mar 25;101179. doi: 10.1016/j.cpcardiol.2022.101179. Online ahead of print.

PMID: 35341803 Review.

Decreasing pre-procedural fasting times in hospitalized children.

Carroll AR, McCoy AB, Modes K, Krehnbrink M, Starnes LS, Frost PA, Johnson DP.

J Hosp Med. 2022 Feb;17(2):96-103. doi: 10.1002/jhm.12782. Epub 2022 Feb 14.

PMID: 35504576

Pre-operative fasting times for clear liquids at a tertiary children's hospital; what can be improved?

Schmidt AR, Fehr J, Man J, D'Souza G, Wang E, Claire R, Mendoza J.

Anesth Pain Med (Seoul). 2021 Jul;16(3):266-272. doi: 10.17085/apm.21025. Epub 2021 Jul 21.

PMID: 34289299 **Free PMC article.**

Quality improvement project to reduce pediatric clear liquid fasting times prior to anesthesia.

Isserman R, Elliott E, Subramanyam R, Kraus B, Sutherland T, Madu C, Stricker PA.

Paediatr Anaesth. 2019 Jul;29(7):698-704. doi: 10.1111/pan.13661. Epub 2019 Jun 2.

PMID: 31070840

A prospective study of paediatric preoperative fasting times at Red Cross War Memorial Children's Hospital, Cape Town, South Africa.

Kouvarellis AJ, Van der Spuy K, Biccard BM, Wilson G.

S Afr Med J. 2020 Sep 30;110(10):1026-1031. doi: 10.7196/SAMJ.2020.v110i10.14814.

PMID: 33205733

CONTROVERSY!!

- Historically, pre-sedation fasting guidelines have been **consensus-** rather than **evidence-based**
 - Do not provide consistent recommendations
 - Practice is highly variable
- Potential risks to patients due to extended fasting time have not be closely examined nor emphasized
- Appropriate duration of pre-sedation fasting to support best practice/outcomes remains controversial
 - Is this the correct question?



Why do we fast before sedation?

- **Pulmonary aspiration**

- Inhalation of oropharyngeal or gastric contents into the larynx and lower respiratory tract
- Silent vs symptomatic
 - New cough, crackles, tachypnea, wheeze, decreased breath sounds, respiratory distress, hypoxia

- **Aspiration pneumonitis**

- Acute lung injury after the inhalation of regurgitated gastric contents



Preprocedural Fasting Guidelines

- Founded on assumption: *waiting a specific amount of time after eating and drinking prior to general anesthesia or procedures sedation reduces aspiration risk*
 - Let's examine the evidence!



Anesthesia Fasting Guidelines

- For healthy patients undergoing **elective surgery**

Clear Liquids	at least 2 hours
Breast milk	at least 4 hours
Light meal, cow's milk, formula	at least 6 hours
Full meal	at least 8 hours

- Supported by:
 - American Academy of Pediatric Dentistry
 - American Academy of Pediatrics
 - **American Society of Anesthesiologists (ASA)**



Anesthesia Fasting Guidelines

- For healthy patients undergoing **elective surgery**

Clear Liquids	at least 1 hour
Breast milk	at least 4 hours
Light meal, cow's milk, formula	at least 6 hours
Full meal	at least 8 hours

- Supported by:
 - Association of Paediatric Anaesthetists of Great Britain and Ireland
 - European Society for Paediatric Anaesthesiology
 - L'Association des Anesthésistes-Reanimateurs Pédiatriques d'Expression Française



ASA Physical Status Classification

- **Class I:** Normal healthy patient
- **Class II:** Mild systemic disease (controlled asthma)
- **Class III:** Severe systemic disease (actively wheezing)
- **Class IV:** Disease that is a constant threat to life (status asthmaticus)
- **Class V:** Moribund patient not expected to live without the operation

ASA. Anesthesiology. 1963



Aspiration

General Anesthesia vs. Procedural Sedation

- Literature review procedural sedation (all ages): 1985 to 2017
 - **Goal:** Estimate aspiration incidence general anesthesia vs. procedural sedation
- Results: 35 articles reporting aspiration events
 - Aspiration is uncommon in children
 - General anesthesia **1 : 4,800**
 - Procedural sedation **0.8 : 10,000**
 - Aspiration risk in procedural sedation outside of the OR is < 50% of GA
 - No reported mortality in children

Pulmonary aspiration during procedural sedation: a comprehensive systematic review.

Green SM, Mason KP, Krauss B. *BJA* 2017



Clinical Studies in Children

Major Adverse Events and Relationship to *Nil per Os* Status in Pediatric Sedation/Anesthesia Outside the Operating Room *Anesthesiology* 2016

A Report of the Pediatric Sedation Research Consortium

Michael L. Beach, M.D., Ph.D., Daniel M. Cohen, M.D., Susan M. Gallagher, B.S., Joseph P. Cravero, M.D.

JAMA Pediatrics | [Original Investigation](#) 2018

Association of Preprocedural Fasting With Outcomes of Emergency Department Sedation in Children

Maala Bhatt, MD, MSc; David W. Johnson, MD; Monica Taljaard, PhD; Jason Chan, MSc; Nick Barrowman, PhD; Ken J. Farion, MD; Samina Ali, MD; Suzanne Beno, MD; Andrew Dixon, MD; C. Michelle McTimoney, MD; Alexander Sasha Dubrovsky, MD; Mark G. Roback, MD; for the Sedation Safety Study Group of Pediatric Emergency Research Canada

**Largest Pediatric
Elective
Sedation Study**

**Largest Pediatric
Emergency Department
Sedation Study**



Major Adverse Events and Relationship to *Nil per Os* Status in Pediatric Sedation/Anesthesia Outside the Operating Room

A Report of the Pediatric Sedation Research Consortium

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- **139,142** sedations; **107,947 (78%)** documented NPO
 - Most received propofol (70%) for elective procedures
 - 24% did not meet ASA fasting guidelines
 - 17% were ASA III or IV



Major Adverse Events and Relationship to *Nil per Os* Status in Pediatric Sedation/Anesthesia Outside the Operating Room

- **10 aspirations**

- 8 out of 10 cases fasted 8 hours prior to sedation

OR 1.07 (95% CI: 0.26 to 4.51)

- **61 major complications**

- Aspiration, death, cardiac arrest, unplanned hospital admission
 - *NO deaths*
- 46 of 61 (75.4%) cases met fasting guidelines

OR 0.76 (95% CI: 0.40 to 1.39)



Major Adverse Events and Relationship to *Nil per Os* Status in Pediatric Sedation/Anesthesia Outside the Operating Room

- **Conclusions**

- Aspiration is uncommon
- *Fasting status for liquids and solids is not an independent risk factor for aspiration*



Major Adverse Events and Relationship to *Nil per Os* Status in Pediatric Sedation/Anesthesia Outside the Operating Room

- **Risk Factors for aspiration**
 - Age < 12 months
 - Procedures
 - Bronchoscopy
 - Endoscopy
 - History of obstructive sleep apnea
 - ASA class III or IV



JAMA Pediatrics | Original Investigation 2018

Association of Preprocedural Fasting With Outcomes of Emergency Department Sedation in Children

Maala Bhatt, MD, MSc; David W. Johnson, MD; Monica Taljaard, PhD; Jason Chan, MSc; Nick Barrowman, PhD; Ken J. Farion, MD; Samina Ali, MD; Suzanne Beno, MD; Andrew Dixon, MD; C. Michelle McTimoney, MD; Alexander Sasha Dubrovsky, MD; Mark G. Roback, MD; for the Sedation Safety Study Group of Pediatric Emergency Research Canada

- Multi-centre prospective cohort in 6 Canadian pediatric emergency departments (ED)
 - Pediatric Emergency Research Canada (PERC)
- Patients: **6,295 ED sedations**
 - 99.7% ASA class I or II

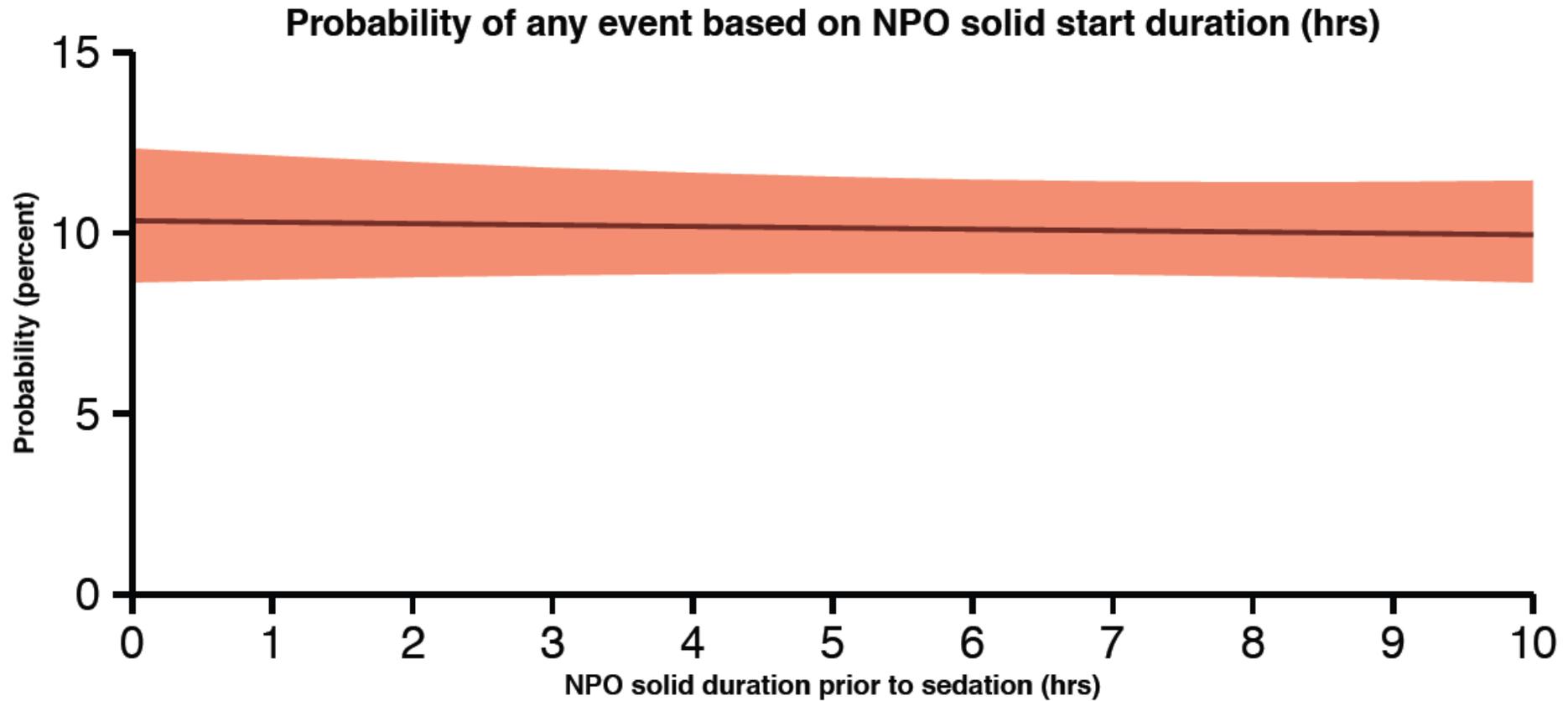


Association of Preprocedural Fasting With Outcomes of Emergency Department Sedation in Children

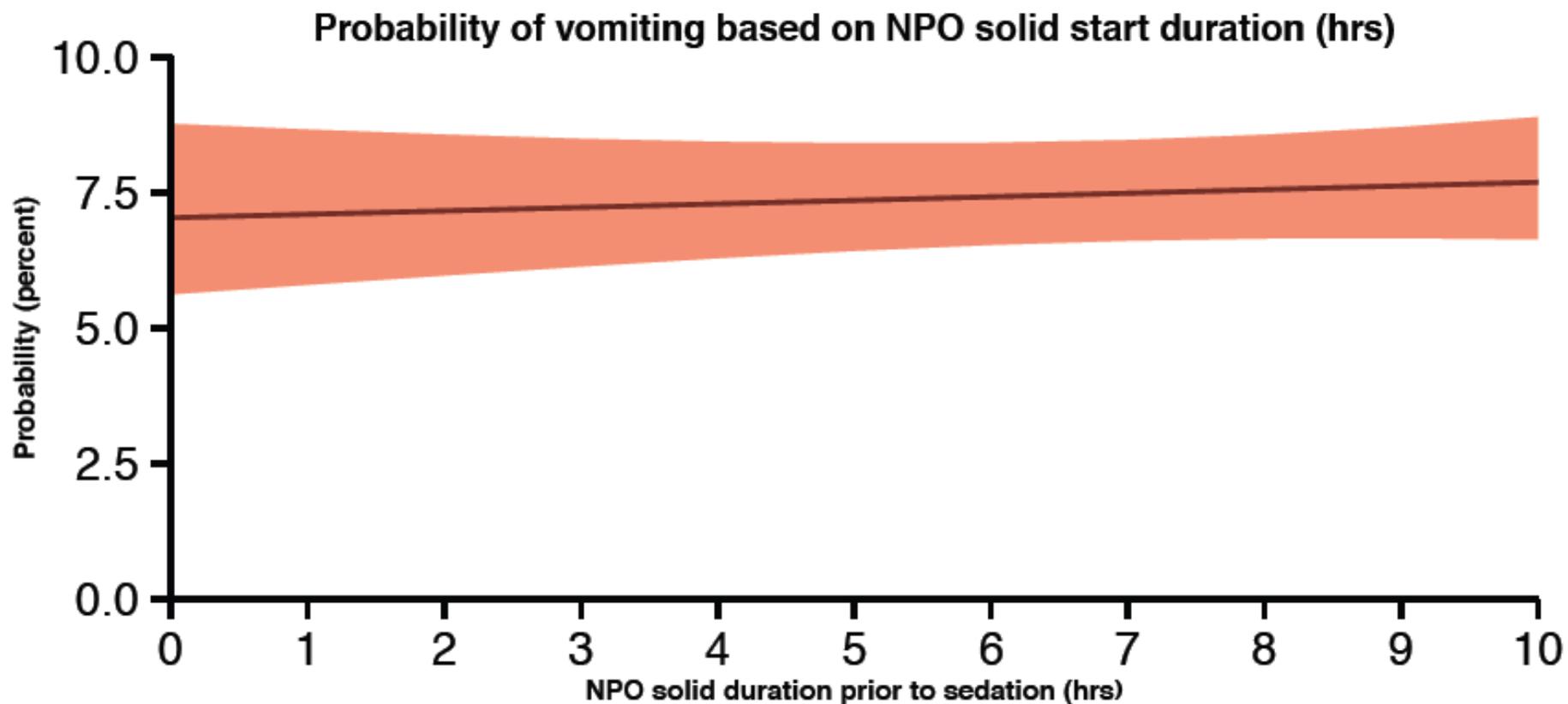
- Procedures: short, painful
 - Orthopedic, laceration repair, abscess I+D, FB removal, LP
- Fasting status
 - Documented in 6,183 (98%)
 - 48% did not meet ASA elective sedation NPO guidelines
- 68 (1.1%) serious adverse events – received PPV
 - No cases of pulmonary aspiration



Probability of Any Adverse Event Occurring Based on Fasting Duration



Probability of Vomiting Occurring Based on Fasting Duration



Conclusions

- No association between fasting duration and any type of adverse event was detected
- These findings do not support delaying sedation to meet established fasting guidelines



Downside to Prolonged Fasting

- Patients present for elective procedures having fasted much longer than recommended
- Fasting can promote dehydration and hypoglycemia in young children
 - Smaller glycogen stores
- Majority of children report being extremely hungry or thirsty
 - When children are irritable risk of poor sedation efficacy, and increases in sedation failures





What is the Solution?

- European organizations support shorter fasting times for clear liquids
 - **No change in aspiration risk**
- **Decrease required fasting time for clear liquids**





ICAPS

International Committee for the Advancement of Procedural Sedation



www.proceduralsedation.org

- ICAPS: Multidisciplinary, international, and independent consensus committee
 - Mission: advancing optimal, evidence-based practice for procedural sedation and analgesia
 - 20 prominent sedation researchers
 - 9 countries, 6 continents
 - Anesthesia, emergency medicine, pediatrics, critical care, hospital medicine, dentistry and gastroenterology
 - Institute of Medicine
 - “Clinical Practice Guidelines We Can Trust”



Guidelines

An international multidisciplinary consensus statement on fasting before procedural sedation in adults and children

S. M. Green,¹ P. L. Leroy,² M. G. Roback,³ M. G. Irwin,⁴ G. Andolfatto,⁵ F. E. Babl,⁶ E. Barbi,⁷ L. R. Costa,⁸ A. Absalom,⁹ D. W. Carlson,¹⁰ B. S. Krauss,¹¹ J. Roelofse,¹² V. M. Yuen,¹³ E. Alcaino,¹⁴ P. S. Costa,¹⁵ K. P. Mason¹⁶ and on behalf of the International Committee for the Advancement of Procedural Sedation



- Literature search from 1985-2019
 - Sedation, monitored anesthesia care, aspiration,
- **Procedural sedation** - outside the operating room administered with the intent of maintaining the patient's own airway
- **Pulmonary aspiration** - "inhalation of oropharyngeal or gastric contents into the larynx and lower respiratory



ICAPS Findings

- Fasting duration often substantially exceeds recommended time thresholds
 - Potential Consequences: irritability, dehydration, hypoglycemia
- Fasting does NOT guarantee an empty stomach
 - No observed association between aspiration and compliance with common fasting guidelines
- Probability of “clinically important aspiration” during procedural sedation is negligible
 - Zero pediatric deaths
 - Zero adult deaths in ASA I and II patients



ICAPS Risk-Stratification Algorithm

- Patient characteristics
- Comorbidities
- Nature of the procedure
- Nature of the sedation technique



ICAPS Aspiration Risk Factors

- **Mild Risk**

- Severe systemic disease
- Moderate obesity (BMI 30-39)
- Age \leq 12 months
- Hiatal hernia
- Procedure/Sedation
 - Upper endoscopy
 - Bronchoscopy
 - Propofol

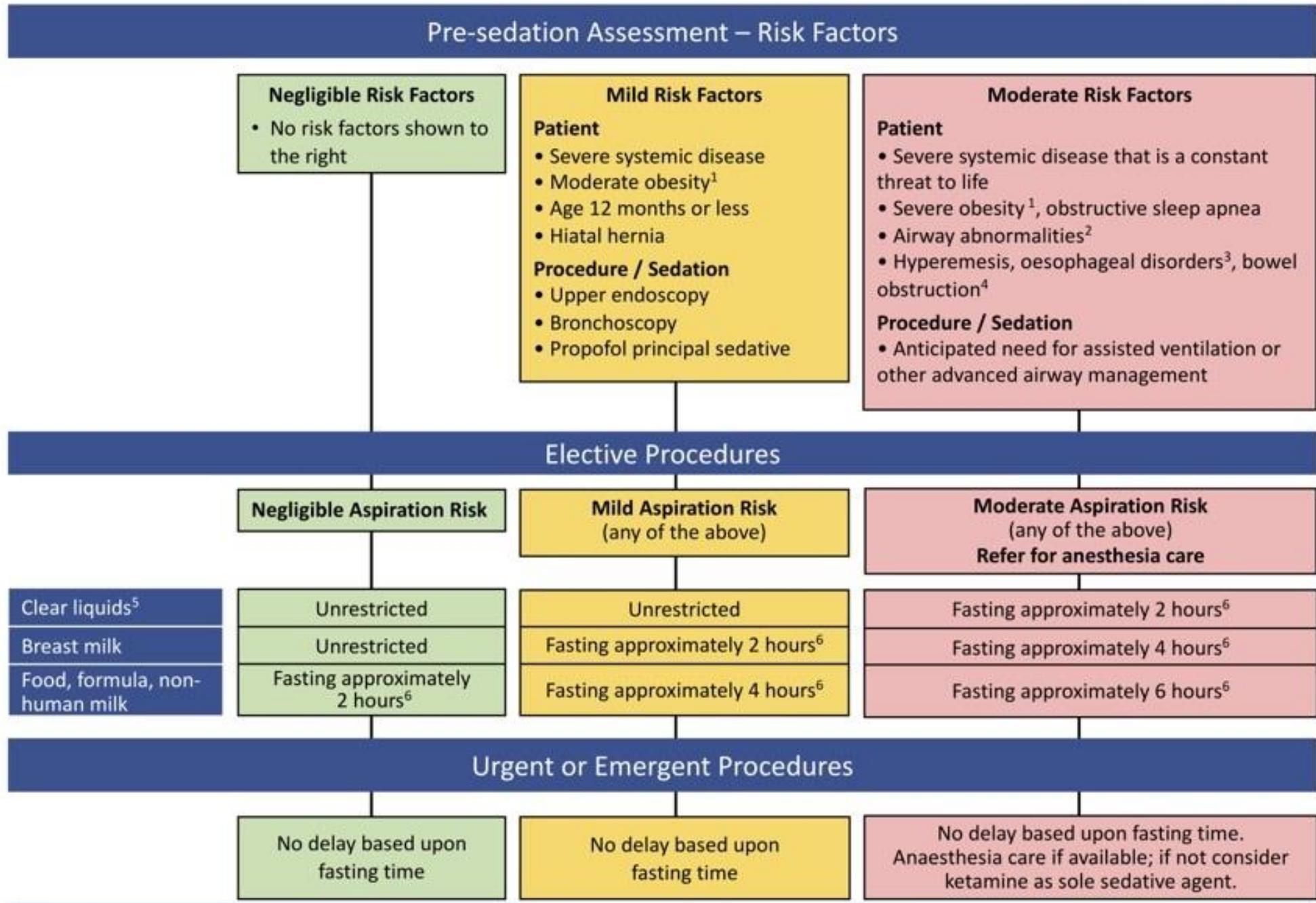


ICAPS Aspiration Risk Factors

- **Moderate Risk**

- Severe systemic disease: constant threat to life
- Severe obesity (BMI ≥ 40)
- Obstructive Sleep Apnea
- Airway abnormalities
- Hyperemesis, esophageal disorders, bowel obstruction
- Procedure/Sedation
 - Anticipated need for assisted ventilation or other advanced airway





NPO time and Aspiration Risk Summary

- Patient factors appear to have the most significant impact on aspiration risk
 - Severe systemic disease
 - Age under 1 year
 - Obesity and OSA
 - Airway abnormalities





Response to ICAPS Fasting Guidelines

Consensus statement on **fasting** before procedural **sedation** - underestimating the threat to patient safety?

Zdravkovic M, Hagberg CA, Chrimes N.

Anaesthesia. 2020 Jun;75(6):829-830. doi: 10.1111/anae.15052.

Consensus statement on **fasting** before procedural **sedation** - underestimating the threat to patient safety? A reply.

Green SM, Irwin MG, Mason KP; International Committee for the Advancement of Procedural Sedation.

Anaesthesia. 2020 Jun;75(6):830-832. doi: 10.1111/anae.15061.

Anaesthesia 2020, 75, 1010-1013

doi:10.1111/anae.15018

Editorial

Breaking the fast for procedural sedation: changing risk or risking change?

G. C. McCracken¹ and **A. F. Smith**²

¹ Specialty Registrar, Department of Anaesthesia, Royal Victoria Hospital, Belfast, UK

² Consultant, Department of Anaesthesia, Royal Lancaster Infirmary, Lancaster, UK

Conclusion

The consensus statement is compelling progress in the direction of the evidence. It has implications for widespread practice. At the very least, before changing local policy, it will fuel a very active debate, providing a reference point to which many will hold. It could also spur new research into this simple practice with widespread implications for the millions of patients it affects globally each year.

Response to ICAPS Fasting Guidelines

Anaesthesia 2020, 75, 1010-1013

doi:10.1111/anae.15018

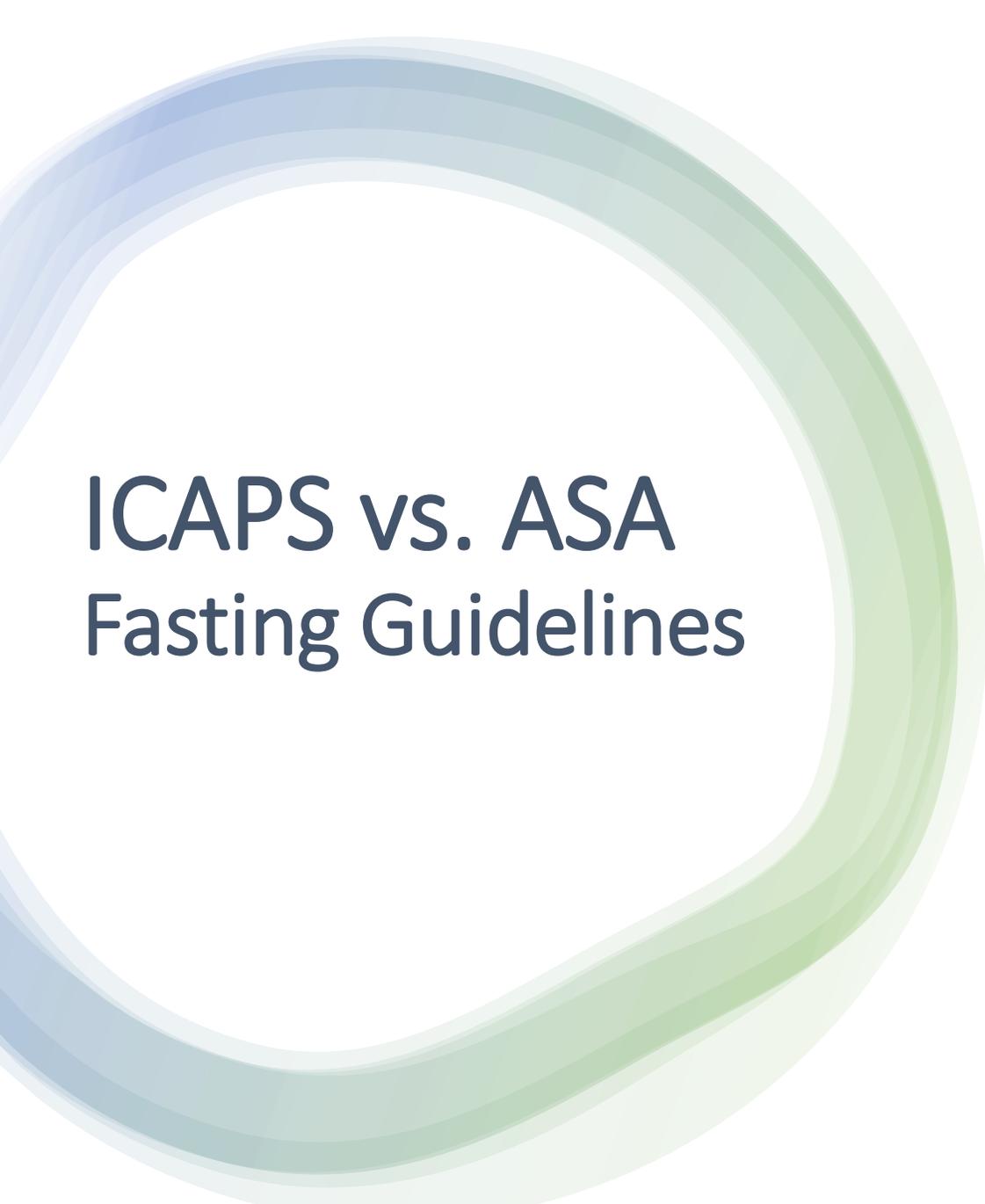
Editorial

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ICAPS vs. ASA Fasting Guidelines

> *Pediatr Int.* 2021 May 15;64(1):e14840. doi: 10.1111/ped.14840. Online ahead of print.

Effects of the new fasting standard on sedation in the pediatric emergency room

Yutaro Hara ¹, Yusuke Hagiwara ¹, Nobuaki Inoue ²

Affiliations + expand

PMID: 33991157 DOI: 10.1111/ped.14840

Abstract

Background: This study compared adherence to the fasting-time guidelines of the International Committee for the Advancement of Procedural Sedation (ICAPS) and the North American Society of Anesthesiologists (ASA) and complication rates in pediatric patients requiring procedure sedation and analgesia during treatment in the emergency room (ER).

Methods: This retrospective, single-center study was performed between 2016 and 2020, and enrolled patients who received procedural sedation and analgesia in the ER with the fasting times recommended in the ICAPS and ASA guidelines.

Results: In total, 857 patients were included. The most frequent indication for procedural sedation and analgesia was fracture reduction in 420 patients (49.0%). Ketamine, the most commonly administered drug, was given to 710 patients (82.8%). Adherence to the ICAPS guidelines was higher ($P < 0.01$), with 772 (95.7%) and 351 (41.0%) patients, respectively, adhering to the ICAPS and ASA recommendations for food and drink fasting times. Complications occurred in 130 patients (15.2%), including $SpO_2 < 90\%$ in 75 patients (8.7%) and vomiting in 20 patients (2.3%). No serious complications, such as aspiration, cardiac arrest, or death, occurred. The complication rate between the two groups did not differ significantly, with 50 (14.2%) and 127 (15.5%) patients experiencing complications according to the ICAPS and ASA guidelines, respectively ($P = 0.586$).

Conclusions: The fasting recommendations of the ICAPS guidelines, which propose risk stratification to determine the appropriate fasting time for procedural sedation and analgesia, are more tolerable to patients and the rate of adverse events did not appear to be different from that experienced when following the ASA guidelines.

Summary

- Aspiration risk in procedural sedation is less than general anesthesia and rare in children
 - 0.8 per 10,000
- Fasting status is not an independent risk factor for aspiration
 - Fasting duration not associated with risk for adverse events
- Patient characteristics, procedure type and sedation technique have been shown to be predictors of risk for aspiration



Safe and Effective Procedural Sedation Care for Children

