

Nil per os (NPO) Times and Pulmonary Complication Rates in Pediatric Sedation: Results from the Pediatric Sedation Research Consortium (PSRC)

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General Background

Givens

- Pediatric sedation is practiced by multiple specialties in many different environments in a given institution/office.
- Serious problematic events are rare – and thus difficult to detect in standard sedation studies (50 – 1000 patients).

Current Literature

- Single institution; Single type of provide; Small numbers (30-1000 patients); Observational or retrospective; Always end with “technique X is safe and effective for Y”.

Pediatric Sedation Research Consortium (PSRC)

Development

- Membership solicited through the readership of the *Pediatric Sedation Newsletter* – readership approximately 5000 internationally (no selection criteria for institutions).
- Each site has a PI – obtains IRB approval – maintains the integrity of the data (audits).

Participating Institutions

1. Alfred I Dupont Children's Hospital	Wilmington DE	13. DeVos Children's Hospital	Grand Rapids MI
2. Avera McKennan Hospital	Sioux Falls, SD	14. Eastern Maine Medical Center	Bangor, ME
3. Cape Fear Valley Medical Center	Fayetteville, NC	15. Gundersen Lutheran	LaCrosse, WI
4. Children's Healthcare of Atlanta (Egleston)	Atlanta, GA	16. Jackson Memorial Hospital	Miami, FL
5. Children's Healthcare of Atlanta (Scottish Rite)	Atlanta, GA	17. Kosair Children's Hospital	Louisville, KY
6. Children's Hospital of Philadelphia	Philadelphia, PA	18. LeBonheur Children's Medical Center	Memphis, TN
7. Children's Hospital Omaha	Omaha, NE	19. Medical University of South Carolina	Charleston, SC
8. Children's Mercy Hospital	Kansas City MO	20. New York University School of Medicine	New York, NY
9. Chris Ever Children's Hospital	Fort Lauderdale, FL	21. Rainbow Babies and Children's Hospital	Cleveland, Ohio
10. Columbus Children's Hospital	Columbus, OH	22. UMass Memorial Medical Center	Worcester, MA
11. Dartmouth Hitchcock Medical Center	Lebanon, NH	23. University of Virginia	Charlottesville, VA
12. Denver Children's Hospital,	Denver, CO	24. Yale New Haven Children's Hospital	New Haven, CT

Structure

- 24 institutions submit data on web-based data collection tool – securely stored at Dartmouth Bioinformatics Group ; all data is de-identified meeting HIPAA regulations.
- Participants include 8 free standing children’s hospitals, 7 children’s hospitals within hospitals, 6 general hospitals/medical centers and 3 community hospitals. Equal partners – use data for QA purposes and research.
- Data is entered on a web-based tool that takes ~3 minutes to complete.

PSRC Data Elements

- The result of over 30 hours of discussion and 3 general meetings of the active participants.
- Balance between what we want to know and what is possible to complete in 2-3 minutes.

Age	Provider type monitoring the patient
Weight	Planned airway management strategy
Gender	Planned depth of sedation
ASA status	Actual depth of sedation
Primary medical condition	Sedation start time
Coexisting medical problems	Procedure end time
Procedure performed	Discharge time
Location of procedure	NPO status of the patient
Medications used for sedation	Complications encountered during sedation
Monitors employed during sedation	Unexpected airway management required
Provider type responsible for the sedation	Transport during sedation
	Assessment of patient state during the procedure

PSRC Complication Data

- Apnea – unintended pause in breathing for more than 20 seconds (obstructive or central).
- Aspiration – gastric contents suctioned – respiratory sequelae documented.
- Cardiac Arrest, Death.
- Delirium during or after the procedure – requiring restraint of medication.
- Oxygen desaturation – further defined as mild, moderate or severe.
- Emergency consultation called for airway management
- Hypothermia – Temp < 35C in a previously normothermic patient.
- Required positive pressure ventilation when not intended, Unplanned intubation
- Prolonged recovery time/prolonged sedation – greater than 2X expected for drug and child.
- Unexpected change in heart rate, blood pressure or respiratory rate > 30% change from baseline.
- Unintended deep level of sedation.
- Vomiting – during or after the (non-gastrointestinal) procedure.
- Unplanned admission to the hospital or increase in the level of care. Other.

NPO Study

Limited evidence has been published on the risk of aspiration in children during pediatric sedation and in particular the role of pre-procedural fasting guidelines.

Hypothesis: This study evaluates adherence to fasting guidelines and examines its relationship to pulmonary complications.

Methods

PSRC data from 7/14/2004 to 11/15/2005 were evaluated. 30,037 sedations were recorded by the 24 participating institutions. Patients were considered NPO if intake for solids was > 8 hours and intake for liquids was > 2 hours. Primary outcomes were pulmonary aspiration or pulmonary complication (defined as: apnea, aspiration, desaturation, emergency anesthesia consult, bag-mask ventilation or intubation). We adjusted for ASA level, emergency status, provider type, and age using generalized linear models to estimate relative risk (RR).

Results

No pulmonary aspirations were recorded. NPO status was known for 28,941 patients. Pulmonary complications were more common when NPO guidelines were violated for solids but not liquids, however this difference did not persist in multivariate models (see Table). Age less than 6 months (RR=1.82; 95% CI 1.38-2.41), ASA classification greater than II (RR=2.41; 95% CI 1.93-3.02), and provider specific differences (p<0.0001) remained statistically significant, while emergency status was not a statistically significant predictor of risk. Tables 1 and 2 below present the multivariate model results.

Table 1:

Pulmonary Complication for various risk factors:	N	n	rate	RR	95% CI	p-value	Global
Liquids >= 2hrs	29611	607	0.020	ref			0.353
< 2 hrs	426	6	0.014	0.69	(0.31-1.53)	0.353	
Solids >= 8hrs	23463	455	0.019	ref			0.019
< 8hrs	6574	158	0.024	1.24	(1.04-1.48)	0.019	
Liquids >= 2hrs	23180	452	0.019	ref			0.041
Solids <2hrs	6857	161	0.023	1.20	(1.01-1.44)	0.041	
ASA > I, II	25675	451	0.018	ref			0.000
>II	4362	162	0.037	2.11	(1.77-2.52)	0.000	
Emergency No	27648	569	0.021	ref			0.473
Yes	2389	44	0.018	0.89	(0.66-1.21)	0.473	
Provider Anesthesiologist	5781	87	0.012	ref			0.000
APRN/ENP/PA	2907	32	0.011	0.95	(0.62-1.44)	0.809	
ER MD	8378	178	0.021	1.83	(1.39-2.42)	0.000	
Fellow	1172	21	0.018	1.55	(0.95-2.51)	0.077	
Housestaff	316	2	0.006	0.55	(0.13-2.22)	0.389	
Intensivist	8535	264	0.031	2.67	(2.05-3.48)	0.000	
Pediatrician	2071	28	0.014	1.17	(0.75-1.81)	0.491	
Radiologist	616	13	0.021	1.82	(1.01-3.28)	0.043	
Other	256	8	0.031	2.70	(1.31-5.55)	0.005	
age Less than 6 months	1930	66	0.034	ref			0.000
6 months-2years	6944	149	0.021	0.63	(0.47-0.83)	0.001	
More than 2years	14108	221	0.016	0.46	(0.35-0.60)	0.000	

Pulmonary complications are a function of solids, ASA, provider, and age. (Individuals variables are evaluated, without any adjustments).

Results (continued)

Table 2:

Adjusted model for Pulmonary Complications and Solids less than 8 hours Or liquids less than 2 hours				
	Variable	Relative Risk	95% CI	p-value
Solids or Liquids Age	Less than 8/2 hours	1.11	(0.89 - 1.39)	0.36
	Less than 6 months	ref		
	6 months-2years	0.69	(0.51 - 0.93)	0.02
Provider	More than 2years	0.47	(0.35 - 0.64)	0.00
	Anesthesiologist	ref		
	APRN/ENP/PA	1.16	(0.74 - 1.84)	0.52
	ER MD	1.89	(1.35 - 2.63)	0.00
	Fellow	1.98	(1.05 - 3.74)	0.04
	Housestaff	0.56	(0.08 - 4.08)	0.57
	Intensivist	3.15	(2.33 - 4.27)	0.00
Emergency ASA >II	Pediatrician	1.34	(0.82 - 2.20)	0.24
	Radiologist	1.46	(0.66 - 3.24)	0.35
	Other	3.79	(1.69 - 8.48)	0.00
		0.58	(0.36 - 0.94)	0.03
		2.64	(2.11 - 3.30)	0.00

Discussion

- 1) This is the largest database of pediatric procedural sedation available.
- 2) The rate of pulmonary aspiration events in pediatric sedations is unknown, though reportedly rare. In this data set, we found no pulmonary aspiration events in 30,037 sedations. The statistical “rule of 3s” predicts that the rate for this complication is 0 to 1:10,000 with a 95% confidence interval.
- 3) Remarkably, NPO status was not as strong a determinant of pulmonary complications as were age, ASA status and provider type. This suggests that patient characteristics may be of primary importance, not the duration of NPO.
- 4) With time and on-going data collection, the rate of these risks will be further clarified.

Conclusions

In this study, NPO status is not associated with pulmonary aspiration. Risk stratification for pediatric procedural sedation based on age, ASA status and provider type may be more useful predictors of pulmonary complication risk than NPO status.