Black Box Analysis of Pediatric Sedation Tragedies

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No financial disclosures or conflicts of interest
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- Saddleback Memorial Medical Center, Laguna Hills
How do you spell/pronounce YUN?

Yen

Jung

Yoon

Jun

Yuen

Joon

Young

Yung

Yum

Yuh
Deadly Dental Procedure Has Heartbroken Family Pushing For New State Law

March 31, 2016 at 10:01 am   Filed Under: anesthesia, Caleb Sears, California law, Dentistry, Tim Sears
ADA Recognizes Dentists Anesthesiologists as 10th Dental Specialty, March 11, 2019
“Blame is an oversimplification driven by biases in the human brain...Undermining our capacity to learn.”

Author
Matthew Syed
The confidence people have in their beliefs is not a measure of the quality of evidence but of the coherence of the story the mind has managed to construct.

— Daniel Kahneman —
The first principle is that you must not fool yourself - and you are the easiest person to fool.

- Richard Feynman
“Everything we know in aviation, 
Every rule in the rule book, 
Every procedure we have, 
We know because someone somewhere died. 

We cannot have the moral failure of forgetting these lessons and having to re-learn them.”
Air accident experts examining Boeing 737 Max 8 'black boxes'
Finley Boyle
Dec. 2013  Admitted to “Island Dentistry for Children in Kailua”

Oral sedation  Demerol 31 mg

Hydroxyzine 10 mg
Chloral hydrate 824 mg
Patient weight = 38 lbs

Dentist **NOT** present during initial administration of sedatives

26 minute gap in the sedation record. Last SpO2 65%.

During middle of procedure - **LARYNGOSPASM**
Dentist tried to “pump oxygen into Finley using a mask”

Dental assistant asked if she should call 911 three times. (No response or dentist said no?) Ultimately **13 minute delay**.

Pediatrician next door asked to help rescue the patient.

MD found the patient “sitting upright, not breathing, unresponsive, and pulseless.”

Finley died one month later (hypoxic encephalopathy)
Key Issues?

Chloral hydrate?

URI?

Pediatric Dentist?
Laryngospasm

Reflexive forceful closure of the vocal cords

Usually occurs during excitement stage of anesthetic, noxious stimulation, often preceded by coughing/breath holding.
The CCDB and POCA Registries

CCDB = Pediatric Closed Claims Database (1973-2000; 532 claims)
POCA = PeriOperative Cardiac Arrest Database (1998-2004; 193 cases)

Respiratory events are a leading cause of pediatric legal claims and anesthesia related cardiac arrest.

Laryngospasm is the #1 cause of respiratory events leading to those outcomes.
Chloral Hydrate

Long duration of action (>24 hr)

Active metabolite (trichloroethanol)

Chloral hydrate ----> laryngospasm?
CHLORAL HYDRATE ORAL SOLUTION USP
DISCONTINUED
500 mg/5 mL

Anna Nicole Smith (1967-2007)
Playboy model and sex-symbol died from a mixed drug overdose including the sleep-aid chloral hydrate.

Marilyn Monroe (1926-1962)
Hollywood movie star and sex-symbol died from taking a sleep-aid consisting of chloral hydrate and a barbiturate (Nembutal®).
Laryngospasm Can Occur Anytime!

PEDIATRICS/CASE REPORT

Laryngospasm With Apparent Aspiration During Sedation With Nitrous Oxide

Franz E. Babi, MD, MPH+; Joanne Grindlay, MBBS, FACEM; Michael Joseph Barrett, MB, MRCPI

*Corresponding Author. E-mail: hanz.babi@rch.org.au.

Nitrous oxide and oxygen mixture has become increasingly popular for the procedural sedation and analgesia of children in the emergency department. In general, nitrous oxide is regarded as a very safe agent according to large case series. We report a case of single agent nitrous oxide sedation of a child, complicated by laryngospasm and radiographically confirmed bilateral upper lobe pulmonary opacities. Although rarely reported with parenteral sedative agents, laryngospasm and apparent aspiration has not been previously reported in isolated nitrous oxide sedation. This case highlights that, similar to other sedative agents, nitrous oxide administration also needs to be conducted by staff and in settings in which airway emergencies can be appropriately managed. [Ann Emerg Med. 2015;66:475-478.]

0196-0644/© 2015 by the American College of Emergency Physicians.
http://dx.doi.org/10.1016/j.annemergmed.2015.04.029
Risk Factors for Perioperative Adverse Respiratory Events in Children with Upper Respiratory Tract Infections

Alan R. Tait, Ph.D.,* Shobha Malviya, M.D.,* Terri Voepel-Lewis, M.S.N., R.N.,† Hamish M. Munro, M.D., F.R.C.A.,‡ Monica Siewert, B.A.,§ Uma A. Pandit, M.D.*

Background: Anesthesia for the child who presents for surgery with an upper respiratory infection (URI) presents a challenge for the anesthesiologist. The current prospective study was designed to determine the incidence of and risk factors for adverse respiratory events in children with URIs undergoing elective surgical procedures.

Methods: The study population included 1,078 children aged 1 month to 18 yr who presented for an elective surgical procedure. Parents were given a short questionnaire detailing their child’s demographics, medical history, and presence of any symptoms of a URI. Data regarding the incidence and severity of perioperative respiratory events were collected prospectively. Adverse respiratory events (any episode of laryngospasm, bronchospasm, breath holding > 15 s, oxygen saturation < 90%, or severe cough) were recorded. In addition, parents were contacted 1 and 7 days after surgery to determine the child’s postoperative course.

Results: There were no differences between children with active URIs, recent URIs (within 4 weeks), and asymptomatic children with respect to the incidences of laryngospasm and bronchospasm. However, a higher incidence of adverse perioperative respiratory events was observed in children with recent URIs compared to children with no URI or with a URI more than 4 weeks prior to surgery. The current prospective study was therefore designed to examine the incidence of and independent risk factors for perioperative respiratory complications in children who present for elective surgery with a URI. The hypothesis to be tested is that children undergoing elective surgical procedures with symptoms of an active URI or history of a recent (within 4 weeks) URI have a higher incidence of adverse perioperative respiratory events.
URI & Adverse Airway Events (AAE)

1,078 patients receiving general anesthesia

Children with current URI at the time of anesthesia had nearly twice the incidence of adverse airway events compared to patients with no URI findings.
URI & Adverse Airway Events (AAE)

RISK FACTORS FOR CHILDREN WITH URIs

Fig. 1. Incidence of adverse events by upper respiratory tract infection (URI) status and days since recent URI. *P < 0.05 versus no URI.
Table 3. Incidence of Perioperative Adverse Respiratory Events by URI Status [n (%)]

<table>
<thead>
<tr>
<th></th>
<th>Breath Holding</th>
<th>Laryngospasm</th>
<th>Bronchospasm</th>
<th>Severe Cough</th>
<th>Spo₂ &lt; 90%</th>
<th>Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>URI (n = 407)</td>
<td>124 (30.5)†</td>
<td>8 (2.0)‡</td>
<td>9 (2.2)§</td>
<td>23 (5.7)</td>
<td>40 (9.8)†</td>
<td>64 (15.7)*</td>
</tr>
<tr>
<td>Recent URI (n = 335)</td>
<td>78 (23.3)</td>
<td>9 (2.7)‡</td>
<td>5 (1.5)§</td>
<td>9 (2.7)</td>
<td>19 (5.7)</td>
<td>49 (14.7)*</td>
</tr>
<tr>
<td>No URI (n = 336)</td>
<td>60 (17.9)</td>
<td>8 (2.4)‡</td>
<td>5 (1.5)§</td>
<td>11 (3.3)</td>
<td>14 (4.2)</td>
<td>26 (7.8)</td>
</tr>
</tbody>
</table>

* P < 0.05 versus no URI. † P < 0.05 versus recent URI. ‡ Laryngospasm requiring positive airway pressure. § Laryngospasm requiring succinylcholine.
URI = upper respiratory infection; Spo₂ = oxygen saturation measured by pulse oximetry.
Over 83,000 patients with thick URI, clear URI, recent URI (2 weeks ago), and no URI. (Pediatrics 2017)
Patients with a current URI with thick secretions demonstrated the highest rate of AE:

- 9.0% required suctioning
- 8.7% developed cough
- 8.1% had desaturation
- 22.2% overall developed some type of AAE
<table>
<thead>
<tr>
<th></th>
<th>No URI (n = 70830)</th>
<th>Recent URI (n = 3354)</th>
<th>Current URI With Clear Secretion (n = 9307)</th>
<th>Current URI With Thick URI (n = 658)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any complication</td>
<td>5560 (7.9)</td>
<td>348 (10.4)</td>
<td>1381 (16.0)</td>
<td>158 (24.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>AEs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheezing</td>
<td>29 (0.04)</td>
<td>8 (0.2)</td>
<td>26 (0.3)</td>
<td>12 (1.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Secretions requiring treatment</td>
<td>482 (0.7)</td>
<td>48 (1.4)</td>
<td>352 (4.1)</td>
<td>59 (9.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Cough</td>
<td>1026 (1.5)</td>
<td>113 (3.4)</td>
<td>508 (5.9)</td>
<td>57 (8.7)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Stridor</td>
<td>100 (0.1)</td>
<td>10 (0.3)</td>
<td>37 (0.4)</td>
<td>2 (0.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Desaturation</td>
<td>1213 (1.7)</td>
<td>72 (2.2)</td>
<td>325 (3.8)</td>
<td>53 (8.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Emergent AI</td>
<td>111 (0.2)</td>
<td>10 (0.3)</td>
<td>23 (0.3)</td>
<td>1 (0.2)</td>
<td>.058</td>
</tr>
<tr>
<td>Airway obstruction</td>
<td>1364 (1.9)</td>
<td>77 (2.3)</td>
<td>341 (3.9)</td>
<td>45 (6.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Snoring</td>
<td>1220 (1.7)</td>
<td>60 (1.8)</td>
<td>297 (3.4)</td>
<td>39 (5.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>229 (0.3)</td>
<td>16 (0.5)</td>
<td>63 (0.7)</td>
<td>6 (0.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Apnea &gt; 15 s</td>
<td>605 (0.9)</td>
<td>24 (0.7)</td>
<td>94 (1.1)</td>
<td>9 (1.4)</td>
<td>.054</td>
</tr>
<tr>
<td>Any airway-related adverse event</td>
<td>4433 (6.3)</td>
<td>304 (9.1)</td>
<td>1258 (14.6)</td>
<td>146 (22.2)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
Laryngospasm and URI

“Despite the statistically significant relationships that we found, the rates of major AAEs such as laryngospasm, aspiration, emergent AI, unplanned admission and emergent call for anesthesia all remained <1% regardless of URI status. In many instances, the increased rate of AAEs and AIs that we document reaches statistical significance, but is of questionable clinical relevance,”

Mallory et al, Pediatrics 2017
**Laryngospasm and URI**

**Multivariate Data from Prospective Case Control Study of 15,183 children & 123 Laryngospasms**

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.92</td>
<td>0.87-0.99</td>
<td>0.01</td>
</tr>
<tr>
<td>Airway Surgery (vs non-airway surgery)</td>
<td>1.3</td>
<td>1.0-1.7</td>
<td>0.042</td>
</tr>
<tr>
<td>Active Upper Respiratory Infection (URI)*</td>
<td>2.05</td>
<td>1.21-3.34</td>
<td>0.01</td>
</tr>
<tr>
<td>Supervisor (Fellow vs Consultant)</td>
<td>1.69</td>
<td>1.04-2.7</td>
<td>0.03</td>
</tr>
</tbody>
</table>

* parent’s definition

Schreiner et al, Anesth 1996
“Despite this, it appears with careful management, most of these children can undergo elective procedures safely without increased morbidity. This does not imply that all children with URIs should be anesthetized, but that decisions to proceed with elective surgery be individualized with careful consideration for the... anesthesiologist’s overall comfort with anesthetizing children with URIs.”
Concluding Points

1. Postpone if current URI that (a) fever, (b) malaise, © productive rhinorrhea or cough.
2. Consider the airways skills of the anesthetist.
3. Document informed consent

“I always make a note in the record that these issues have been discussed with both the surgeon and the family and that everyone has been informed of the risk and agreed to proceed.” Charles Cote, MD (The upper respiratory tract infection dilemma: fear of complication or litigation? Anesthesiology Aug 2001.)

Was Finley’s URI a major factor in this case?
Beware!

40-60 LPM (up to 60 cm pressure)

No oxygen reservoir (FRC)

Cannot “feel” the lungs

Needs oxygen flow to work
Proper Technique

Optimize airway position

PULL face UP to the mask

C & E Clamp

Consider 2 hands
Head Extension – Sniffing Position
Use of a swimming pool noodle

**PROPER POSITION**
- In the absence of neck injury, tilt the forehead back and lift the chin (Figure 9a)

**TIGHT SEAL**
- Use the “E-C clamp,” which is the letters E and C formed by the fingers and thumb over the mask (Figure 9b)

**VENTILATE**
- Squeeze the bag over one second until the chest rises (Figure 9c)
- Do not over ventilate
BMV is the most critical skill...

If BMV is NOT working, then

BAG BETTER!
Larson’s Maneuver

“This notch is behind the lobule of the pinna of each ear. It is bounded anteriorly by the ascending ramus of the mandible adjacent to the condyle, posteriorly by the mastoid process of the temporal bone, and cephalad by the base of the skull.”
Traditional Airway Management

“Education is not the learning of facts, but training the mind to think”

Albert Einstein
Vortex Model of Airway Management

The Vortex

For each lifeline consider:

- Manipulations:
  - Head & Neck
  - Larynx
  - Device

- Adjuncts

- Size / Type

- Suction / O₂ Flow

- Muscle Tone

Maximum three attempts at each lifeline (unless gamechanger)
At least one attempt should be by most experienced clinician
CICO status escalates with unsuccessful best effort at any lifeline
Vortex Model of Airway Management
When should you call 911?
Are we ready to treat laryngospasm?
“Recently, I was fortunate to be able to audit and participate in a “Maintenance of Certification in Anesthesia” course (MOCA, American Board of Anesthesiology [ABA], Raleigh, NC) with 6 medical anesthesiologists. Simulation is a major part of the recertification process to maintain ABA board certification in anesthesia. I was immediately struck that even experienced, board-certified anesthesiologists can underperform in high-stress, simulated cardiac arrest situations. The first arrest simulation of the day was videotaped and studied by the participants, the MOCA course director, and myself. Hyperventilation is very deleterious in low-flow arrest states. The course director gently pointed out to the 6 participants that the SimMan was being ventilated at a rate of 44 breaths/minute with the bag valve mask.”
“Temporary Autism” (eg. failure to call 911)

‘everyone has a plan, until they get punched in the face’
- Mike Tyson, World Heavyweight Boxing Champion
If you say you know, but do not do....

Then you really do not know
Key Issues
- Chloral hydrate?
- URI?
- Pediatric dentist?

FAILURE TO RESCUE THE...
ABC15 EXCLUSIVE

BREAKING NEWS

AZ BOY DIES AFTER DENTAL WORK
December 16, 2017  Pulpotomies, crowns under GA

GA
Ultane
Propofol 50 mg
Alfentanil 50 mcg
DILAUDID 0.2 mg

8:22 am  Procedure start
9:07 am  Procedure ended
9:15 am  To recovery bay

An oxygen mask was placed at 5 LPM

Next child may have been intubated within as little as 2 minutes after Zion’s extubation.
Left alone for approximately 5 minutes

The oxygen taken was **EMPTY and/or NOT WORKING**

9:20 am  Mother brought back. She noted that pulse oximeter alarm was beeping. Assistant silenced the alarm several times and remarked that the probe often doesn’t work on children.

“Not to worry, Zion just needs a little more oxygen”

Anesthesiologist immediately recognized the situation and initiated rescue breaths. No improvement.
Oxygen disconnected from intubated patient and Zion re-intubated.

No improvement.

9:24 am  EMS called
9:27 am  EMS arrived

Died 4 days later due to

SEVERE HYPOXIC ISCHEMIC ENCEPHALOPATHY
Potency of Dilaudid

Comparison of Peak Effect Times

Onset and duration of action of each opioid depend on their lipid solubility and ionization.

- Hydromorphone
- Morphine
- Fentanyl
- Alfentanil
- Remifentanil

Percent of peak effect site concentration vs. Minutes since bolus injection.
Potency of Dilaudid

1:7 dilaudid/morphine potency ratio, BUT.... the ratio may vary as much as 1:4 to 1:10 (Mahler et al 1975)

May be affected by co-administration of propofol

$T_{\frac{1}{2}} = 1-2 \text{ h BUT duration of analgesia} = 4-6 \text{ h}$
Hydrophilic Dilaudid vs Lipophilic Fentanyl

DON’T BE FOOLLED BY $T\frac{1}{2}$

Adapted from Lehmann 2011: “Teaching from Catastrophe: Using Therapeutic Misadventures from Hydromorphone to Teach Key Principles in Clinical Pharmacology”
Pharmacokinetics ≠ Pharmacodynamics
Children do not read the textbook!
Neonates take longer to metabolize sedatives
Re-think our traditional aphorisms

Children are not small adults...

Children are OLD babies
Consider use of neonatal monitors
The alveolar gas equation estimates the pressure of oxygen in our lungs:

\[ P_{A_O_2} = F_{I_O_2} (P_{ATM} - P_{H_2O}) - P_{a CO_2} / R \]

NORMAL CONDITIONS:
- \( F_{I_O_2} \) = 0.21 (760 − 47) − 40 / 0.8
- = 100 mmHg
\[
P_{A \text{O}_2} = F_{i \text{O}_2} \left( P_{\text{ATM}} - P_{\text{H}_2\text{O}} \right) - P_{a \text{CO}_2} / R
\]

OPIOID OVERDOSE with NASAL CANNULA

\[= 0.30 \left( 760 - 47 \right) - 90 / 0.8\]

\[= 100 \text{ mmHg}\]
Pitfalls of Oxygen
Pitfalls of Oxygen
The most dangerous person in the office?
Be Present in the Post-Anesthesia Recovery

4-Year-Old Boy Dies After Anesthesia Used in Dental Procedure

VANCOUVER, Wash. -- A 4-year-old Vancouver boy has died after what seemed like a routine dentist visit last week.
Figure 3. Cause of arrest by phase of care

“Decreased stimulation from the proceduralist, delayed drug absorption after non-intravenous administration, and slow drug elimination may contribute to residual sedation and cardiorespiratory depression during the recovery period.”

Waiting for a child to recover is... BORING
Pressure from Corporate Office?

DOJ: Kool Smiles dental clinics to pay $23.9 million, allegedly submitted false claims

Posted: 11:25 AM, Jan 10, 2018   Updated: 5:50 PM, Jan 10, 2018
By: abc15.com staff
“High pressure, high volume work environment...the scheduling of these patients was absolutely RIDICULOUS for what was being asked of a dental anesthesiologist”

“The anesthesiologist forgot what he had learned in his training kind of based on the PEER PRESSURE of that what was already happening in the office...”
Top 3 reasons why employees don't speak up:

- Fear of being viewed negatively
- Feeling as if they don't have enough experience
- Feel that the organisation's hierarchy is intimidating/unsupportive
Use Your CUS words...

I am Concerned
I am Uncomfortable
This is a Safety issue

If you SEE something, SAY something
Concluding Points

Patients, esp. young children, should never be left alone until the patient is AWAKE.

Always check primary AND emergency sources of oxygen.

SEE - SAY - FIX (better than at trial)
Avoid Long-Acting Narcotics in the Dental Office

SEE NO DILAUDID

HEAR NO DILAUDID

SPEAK NO DILAUDID
“Most large failures have multiple causes, and some of these causes are deeply embedded in organizations...Small failures are early warning signs that are vital to avoiding catastrophic failure in the future.”
Example: Cystic Fibrosis

99.95 % vs 99.5 % daily chance of staying well

But over the course of a year, small differences add up....

83% vs 16%
Hard Stop Rule
Sometimes quitting is the best option

Take 10 seconds...

Rule of 3

Prospective Hindsight

Think about the way you think!
Heinrich’s Pyramid

1
30
300
Dental Patient Safety Foundation (DPSF)

Once submitted, all data is...

- CONFIDENTIAL
- PRIVILEGED
- CANNOT BE USED IN ANY DISCIPLINARY HEARING
www.dentalpatientsafety.org

Sign up for safety updates
Shared Learning
from the Dental Patient Safety Foundation Reporting Tool

"What gets measured gets managed" is the DPSF philosophy to encourage reporting. All recorded information about patient safety events (unscheduled, near misses, or adverse events) are de-identified (full confidentiality is preserved) aggregated, analyzed, and abstracted by selected experts from our DPSF committees. Reports are generated and disseminated as the only means to learn from our errors. The information in these peer-reviewed reports is provided for its educational value only, and does not purport to establish any legally binding standard of care. Feedback is encouraged.

Case 2017.12: Wrong Site Surgery

Situation: A 44 y/o female was referred on an emergent basis to a specialist for extraction of three teeth as indicated. Undated bitewing was sent with the patient, which necessitated a panoramic radiograph, provided at no charge to the complaining patient. Examination confirmed that #13 and #14 were non-restorable, and that pain in the lower right quadrant was due to non-vital discomfort of the distal most tooth. No attempt was made to contact the referring source, as the surgeon was distracted, in a hurry, and not particularly pleased to manage this situation from an infrequent referral source. Teeth #13, #14 and the most posterior tooth on the lower right quadrant were removed. On return to the dentist, he contacts the specialist indicating that #32 was extracted and not #31, which was clearly indicated on the referral slip due to a lingual fracture and poor restorative prognosis.

What we learned: In cases of previous extractions and drifting of teeth, any currently used numbering system can become unclear, especially in the absence of obvious pathology. In spite of common knowledge that wrong site extraction is the most frequent claim against dental surgeons, the frequency of this claim has not improved.

Welcome to the inaugural DPSF safety report. Information received on the reporting tool. Future reports will be released on a monthly basis and catalogued on the...

Recommendations and action:

Referral sources should actively engage and educate their patients regarding planned procedures at outside offices, facilitating a proactive stance to ensure successful completion of desired treatment. Referral forms should be clear and complete. Verbal communication can be most helpful, especially when difficulties are anticipated. A request for a current panoramic or other films should replace the transmittal of outdated or anatomically insufficient radiographs.
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24/7/365

#SoCalBulldogRescue
Healthy Smiles for Kids of Orange County Spring Forum
“So others may learn, and even more may live...”