### Intranasal Dexmedetomidine & Midazolam: A Novel Sedation Technique for Infant PFT DiSilvio G, Jacoby M, Weiner D, Broussard A, Callahan P, Cain J Abstract accepted by the Society for Pediatric Anesthesiology with poster presented at Annual Spring Meeting (~ 1100 attendees) Phoenix 2015 Pulmonologists have been satisfactorily utilizing oral chloral hydrate for infant PFT for > 30 yrs. A recent shortage has forced them to utilize alternatives. While Callahan, et al (Pediatr Pulmonol 2014), recently described the use of IV

Pulmonologists have been satisfactorily utilizing oral chloral hydrate for infant PFT for > 30 yrs. A recent shortage has forced them to utilize alternatives. While Callahan, et al (Pediatr Pulmonol 2014), recently described the use of IV dexmedetomidine for iPFT, this case report describes for the first time its intranasal use for iPFT. A 2 year old female with cystic fibrosis, dx'd with and tx'd for pneumonia 3 wks previously, required sedation for iPFT. The patient was an anxious two-year old standing 88.3cm and weighing 12.3kg. She received 3.25 mcg/kg of dex & 0.325 mg/kg of midaz intranasally, tolerating it well. At 40 min she reached a -4 on the Richmond Agitation Sedation Scale (RASS) and was deemed adequately sedated to undergo the iPFT. The doses of 3.25 mcg/kg of dexmed and 0.325 mg/kg of midaz Were based upon previous sedation experience with intranasal dex and versed as well as conversions of dex and midaz IV dosing to intranasal equivalents. The patient tolerated the stimulation PFT's very well, was hemodynamically appropriate and maintained spontaneous ventilation at a respiratory rate not less than 22 BPM with oxygen saturation >93% (pts baseline) throughout. The pulmonologist performed the most stimulating part of the procedure, the "hug" with the fitted airtight mask first. Adequate sedation was provided for successful performance of all prebronchodilator tests. At approximately 35 minutes, it was determined that the patient required rescue sedation and she received 1.625 mcg/kg IV dex and 0.325 mg IV midaz over 5 minutes, successfully tolerating the remaining 30 minutes of the procedure. Post procedure, she was immediately arousable to voice and comfortable. She was transferred back to her floor bed awake and alert, in no distress within 1 hour of her PACU stay.

Intranasal dex + midaz provided an excellent noninvasive sedation technique for PFT's should the procedure be less than 35 minutes. Should the procedure be anticipated to require sedation longer than 35 minutes, either larger initial IN doses, a second IN dose timed to overlap with the initial dose, or invasive methods such as IM or IV (in this case) may be necessary.

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## Intranasal Dexmedetomidine & Midazolam A Novel Sedation Technique for Infant PFT

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#### Introduction:

- Pulmonologists have used oral chloral hydrate for infant PFTs for >30 years.
- Recent shortage due to manufacturing forced them to utilize alternatives.
- Callahan et al (Ped Pulmonology, 2014), described IV dexmedetomidine for iPFT,
- This case report describes for the first time intranasal dexmedetomidine for iPFT.

#### Discussion:

- 3.25 mcg/kg of dexmedetomidine & 0.325 m provided excellent, noninvasive sedation for
- Should the procedure be require sedation to initial IN doses, additional IN dose/s timed to invasive methods such as IM or IV (as in this

#### Case Presentation:

- Anxious 2 yo female with cystic fibrosis, dx'd and tx'd for pneumonia 3 weeks prior to iPFT,
- Sedation required for iPFT.
- In pre-op area, 3.25 mcg/kg of dexmedetomidine & 0.325 mg/kg of midazolam administered intranasally with atomizer
  Tolerated well.
- Doses based upon prior clinical intranasal experience and conversions of prior IV dex for iPFT to intranasal equivalents.
- At 40 minutes, reached a -4 on the Richmond Agitation Sedation Scale (RASS) → adequately sedated to undergo the iPFT.
- Pulmonologist performed the most stimulating part of the procedure, the "hug" with the fitted airtight mask first.
- Tolerated iPET very well, hemodynamically appropriate, and maintained spontaneous ventilation at a respiratory rate not less than 22 BPM with oxygen saturation >93% (pts. baseline) throughout.
- Adequate sedation for successful performance of all prebronchodilator tests.
- At approximately 35 minutes, it was determined that she required additional sedation
  - 1.625 mcg/kg IV dexmedetomidine and 0.325 mg/kg IV midazolam over 5 minutes
    - Tolerated remaining 30 minutes of the procedure.
  - Post procedure, immediately arousable to voice and comfortable.
- Transferred to floor bed awake, alert and in no distress within 1 hour of completion of procedure and PACU admission.

#### References:

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- Callahan, P., Pinto, S. J., Kurland, G., Cain, J. G., Motoyama, E. K. and Weiner, D. J. (2015), Dexmedited to infant pulmonary function testing. Pediatr. [ doi: 10.1002/ppul.23100
- FDA Drug Shortages: http://www.fda.gov/drugs/drugsafety/drugshortages/ucm050794.htm. Volume 2014.



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### Dexmedetomidine in Children: Current Knowledge and Future Applications

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More than 200 studies and reports have been published regarding the use of dexmedetomidine in infants and children. We reviewed the English literature to summarize the current state of knowledge of this drug in children for the practicing anesthesiologist. Dexmedetomidine is an effective sedative for infants and children that only minimally depresses the respiratory system while maintaining a patent airway. However, dexmedetomidine does depress the cardiovascular system. Specifically, bradycardia, hypotension, and hypertension occur to varying degrees depending on the age of the child. Hypertension is more prevalent when larger doses of dexmedetomidine are given to infants. Consistent with its 2-hour elimination half-life, recovery after dexmedetomidine may be protracted in comparison with other sedatives. Dexmedetomidine provides and augments analgesia and diminishes shivering as well as agitation postoperatively. The safety record of dexmedetomidine suggests that it can be used effectively and safely in children, with appropriate monitoring and interventions to manage cardiovascular sequelae. (Anesth Analg 2011;113:1129–42)

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# A Comparison of Intranasal Dexmedetomidine and Oral Midazolam for Premedication in Pediatric Anesthesia: A Double-Blinded Randomized Controlled Trial

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Man K. Yuen, MBBS, FANZCA, FHKCA, FHKAM **BACKGROUND:** Midazolam is the most commonly used premedication in children. It has been shown to be more effective than parental presence or placebo in reducing anxiety and improving compliance at induction of anesthesia. Clonidine, an  $\alpha_2$  agonist, has been suggested as an alternative. Dexmedetomidine is a more  $\alpha_2$  selective drug with more favorable pharmacokinetic properties than clonidine. We designed this prospective, randomized, double-blind, controlled trial to evaluate whether intranasal dexmedetomidine is as effective as oral midazolam for pre-medication in children.

METHODS: Ninety-six children of ASA physical status I or II scheduled for elective minor surgery were randomly assigned to one of three groups. Group M received midazolam 0.5 mg/kg in acetaminophen syrup and intranasal placebo. Group D0.5 and Group D1 received intranasal dexmedetomidine 0.5 or 1  $\mu$ g/kg, respectively, and acetaminophen syrup. Patients' sedation status, behavior scores, blood pressure, heart rate, and oxygen saturation were recorded by an observer until induction of anesthesia. Recovery characteristics were also recorded.

**RESULTS:** There were no significant differences in parental separation acceptance, behavior score at induction and wake-up behavior score. When compared with group M, patients in group D0.5 and D1 were significantly more sedated when they were separated from their parents (P < 0.001). Patients from group D1 were significantly more sedated at induction of anesthesia when compared with group M (P = 0.016).

CONCLUSIONS: Intranasal dexmedetomidine produces more sedation than oral midazolam, but with similar and acceptable cooperation.

(Anesth Analg 2008;106:1715-21)

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