Efficacy and Safety of Intranasal Dexmedetomidine for Pediatric Sedation Dentistry

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PURPOSE

- This prospective and cohort study will compare the safety and efficacy intranasal dexmedetomidine with oral midazolam, and oral midazolam/hydroxyzine all with nitrous oxide when used for sedation during pediatric dental procedures

BACKGROUND

- Dental fear and anxiety are common among children.
- Moderate sedation provides a safe alternative to general anesthesia and is used routinely to facilitate dental treatment in anxious patients.[1]
- The discontinuation of commercial production of chloral hydrate and the avoidance of opioids has left a void in the sedation protocols of many pediatric sedationists.
- Dexmedetomidine is a selective alpha-2 agonist that provides sedation, anxiolysis, and mild analgesia without suppressing respiratory drive or compromising airway integrity.[2]
- Dexmedetomidine has been successfully used for pediatric procedural imaging sedation as well as a premedication before general anesthesia.[3-5]
- Retrospective studies demonstrate that intranasal dexmedetomidine is safe and effective when combined with nitrous oxide for moderate pediatric dental sedation.[6,7]
- Our objective was to add to the growing body of information regarding the efficacy and safety of intranasal dexmedetomidine for moderate pediatric dental sedation.

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Sedation Score	
0	None (typical response/cooperative for this patient)
1	Mild (anxiolysis), tired, verbally responsive
2	Moderate (purposeful response to verbal commands light tactile sensation), somnolent
3	Deep (purposeful response after repeated verbal or painful physical stimulation), deep sleep
4	General anesthesia (unarousable)
Behavior Score	
0	Excellent (quiet and cooperative)
1	Good (mild objections and/or whimpering but treatment not interrupted)
2	Fair (crying with minimal disruption to treatment)
3	Poor (struggling that interfered with operative procedures)
4	Prohibitive (active resistance and crying, treatment cannot be rendered)

Figure 1: Modified AAPD scale used to assess efficacy of sedation

METHODS

- A prospective multi-site randomized control study.
- Inclusion criteria: 3-6 years old, ASA I or II, and English speaking
- Children were randomized and received one of the following regimens:
  - 3 mcg/kg intranasal dexmedetomidine with ≥65% nitrous oxide/oxygen at a calculated flow rate.
  - 0.7 mg/kg oral midazolam with ≥65% nitrous oxide/oxygen at a calculated flow rate.
  - 1 mg/kg oral hydroxyzine with 0.7 mg/kg oral midazolam with ≥65% nitrous oxide/oxygen at a calculated flow rate.
- Demographic data, procedural times, minor and major adverse events, and quality of sedation were identified and recorded.
- Efficacy of sedation was determined by utilizing a scale modified from the AAPD (see figure 1).
- For the sedation to be considered effective, the treatment needed to be completed, and the patient could only receive a behavior score of 0-2 (see figure 1). Those who received a score of 3 or 4 in either category were considered to have ineffective sedations regardless of completion status.
- For the sedation to be considered safe, no minor nor major adverse events were recorded (see figure 2).

DATA ANALYSIS

- Data analysis for categorical data will be performed by Fisher's exact test or chi-square test
- Analysis of variance will be performed to compare the difference between the sedation groups. The level of statistical significance will be taken as *p-values* <0.05.

RESULTS

- Two children were recruited into this study: 1 in the oral midazolam group and 1 in the intranasal dexmedetomidine group
- There was no statistical difference in the efficacy between sedation groups
- No minor nor major adverse events were recorded

CONCLUSIONS

- Based on this study's current tentative data, no conclusions can be reported at this time

LIMITATIONS

- Limitations include:
  - Small sample size
- Ongoing data collection must be continued to determine statistical support

Minor Adverse Events
Apnea
Desaturation ≤ 92% SpO_2
Airway obstruction
Bradycardia≤ 60 bpm
Hypotension (defined by PALS & Aldrete)
Major Adverse Events
Death
Aspiration
Cardiac arrest
Respiratory arrest
Laryngospasm
Level of care increase
Unplanned hospital admission

Figure 2: Minor and Major Adverse Events