Efficacy and Safety of Intranasal Dexmedetomidine for Pediatric Sedation Dentistry

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PURPOSE

The purpose of the study was to evaluate the safety and efficacy of intranasal dexmedetomidine as a sedative agent for pediatric dental treatment in comparison to oral midazolam alone and oral midazolam in combination with hydroxyzine.

BACKGROUND

- Children and adolescents in the dental office frequently exhibit dental fear and anxiety.[1]
- Moderate sedation is routinely used to facilitate dental treatment in anxious patients.[2]
- Alternative medications for dental sedation are needed since the discontinuation of the commercial production of chloral hydrate and the increased risk associated with opioids. [3]
- Dexmedetomidine is a selective alpha-2 agonist that provides sedation, anxiolysis, and mild analgesia without suppressing respiratory drive or compromising airway integrity.[4]
- Dexmedetomidine has been used successfully for pediatric procedural imaging as well as a premedication before general anesthesia.[5,6]
- Retrospective studies demonstrate that intranasal dexmedetomidine is safe and effective when combined with nitrous oxide for moderate pediatric dental sedation.[7,8]
- A prospective study of dexmedetomidine is needed in sedation dentistry to assess effectiveness and safety.

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METHODS

- A prospective, one site, randomized control trial.
- Inclusion criteria: 3-6 years old, ASA I or II, English speaking.
- Patients were randomized and received one of the following medication regimen:
  - 3 µg/kg intranasal dexmedetomidine[a] (DEX).
  - 0.7 mg/kg oral midazolam[a] (MID).
  - 1 mg/kg oral hydroxyzine[a] with 0.7 mg/kg oral midazolam (MIDHYD).
- All patients received nitrous oxide sedation during treatment with a concentration of 65% at a calculated flow rate during treatment.
- Demographic data, procedural times, minor and major adverse events, and quality of sedation were identified and recorded.
- Effectiveness of sedation was determined by utilizing a scale modified from the American Academy of Pediatric Dentistry (AAPD) (Figure 1).
- Sedation was considered effective if the treatment was completed and had a behavior score of 0 to 2. A score of 3 or 4 in either category was graded as ineffective.

[a] maximum dose for intranasal dexmedetomidine is 100 µg, for oral hydroxyzine is 25 mg, and for oral midazolam is 20 mg.

DATA ANALYSIS

Due to the ongoing nature of this study, only descriptive statistics were conducted. Confidence intervals and hypothesis testing will be conducted at the conclusion of the trial.

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 resistant and crying, treatment cannot be rendered)

Figure 1: Modified AAPD Score

RESULTS

- Thirty-eight children were included in the preliminary analysis. The sedation modality groups, demographic distribution, and treatment completion rates are shown in Tables 1 and 2.
- The sedation level and efficacy for the DEX group was consistent with the other sedation modalities.
- No episodes of bradycardia occurred in any group.
- In the dexmedetomidine group, the PALS score indicated hypotension in 2 cases, however no intervention was needed.
- **There were no major adverse events for any group.**

Males	66%
Females	34%
Black	50%
White	29%
Middle Eastern	8%
Asian	8%

Table 1: Patient Demographics

Medication	Distribution	Treatment Effective
MID	36.8%	57%
DEX	26.3%	70%
MID/HYD	36.8%	57%

Table 2: Sedation Modality Distribution & Treatment Completed

CONCLUSIONS

- Thus far, dexmedetomidine has proved to be an effective and safe medication for pediatric dental sedation.
- In comparison to oral midazolam and oral midazolam in combination with hydroxyzine, dexmedetomidine provides adequate sedation treatment.
- Limitations include small sample size, restricted inclusion criteria, and different residents completing dental treatment.