Efficacy and Safety of Intranasal Dexmedetomidine for Pediatric Sedation Dentistry

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PURPOSE

The purpose of the study aimed to assess the safety and effectiveness of intranasal dexmedetomidine as a sedative for pediatric dental procedures, comparing it to oral midazolam alone and in combination with hydroxyzine.

BACKGROUND

- Moderate in-office sedation is commonly used to facilitate dental treatment in anxious, fearful, and uncooperative patients.[1,2]
- Due to the discontinuation of commercially produced chloral hydrate and the heightened risks associated narcotics, such as respiratory depression, alternative medications for dental sedation are needed.[3]
- Dexmedetomidine is a selective alpha-2 agonist that induces sedation, mild analgesia, anxiolysis while preserving respiratory function and maintaining airway integrity.[4]
- A key characteristic of dexmedetomidine based sedation is its similarity to natural sleep, allowing the patient to remain easily arousable. [5]
- Dexmedetomidine has been effectively used for pediatric procedural imaging and as a premedication before general anesthesia. [6,7]
- Retrospective studies show that intranasal dexmedetomidine, when combined with nitrous oxide, is a safe and effective option for moderate sedation in pediatric dental procedures.[8,9]
- A prospective study of dexmedetomidine is needed in pediatric moderate sedation dentistry to assess effectiveness and safety.

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METHODS

- A prospective 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 behavior scale modified from the American Academy of Pediatric Dentistry (AAPD) (Figure 1). Sedation was 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.
- Per Michigan Sedation Scale, sedation was considered effective if it scored 0-2

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

DATA ANALYSIS

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

- Sixty-seven 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 7 cases, however no intervention was needed.
- **There were no major adverse events for any group.**

Males	54%
Females	46%
Black	54%
White	22%
Middle Eastern	6%
Asian	7%

Table 1: Patient Demographics

Medication	Distribution	Treatment Effective
MID	35.8%	62%
DEX	28.3%	74%
MID/HYD	38.8%	54%

Table 2: Sedation Modality Distribution & Treatment Completed

CONCLUSIONS

- Dexmedetomidine shows potential to be an effective and safe medication for pediatric dental sedation.
- Dexmedetomidine provides adequate sedation treatment In comparison to oral midazolam and oral midazolam in combination with hydroxyzine.
- Limitations: small sample size, restricted inclusion criteria, and different residents completing dental treatment and sedation.