Efficacy and Safety of Intranasal Dexmedetomidine for Pediatric Sedation Dentistry

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PURPOSE

The purpose of the study was to compare the safety and efficacy of intranasal dexmedetomidine with oral midazolam and oral midazolam/hydroxyzine as a sedative agent for pediatric dental treatment.

BACKGROUND

- Dental fear is a frequent encountered problem among children and adolescents in the dental office.[1]
- Moderate sedation provides a safe alternative to general anesthesia and is used routinely to facilitate dental treatment in anxious patients.[1]
- The discontinuation of the commercial production of chloral hydrate and the increased avoidance of opioids has left a void in dental sedation protocols.
- 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]

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METHODS

- A prospective multi-site randomized control study.
- Inclusion criteria: 3-6 years old, ASA I or II, and 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 ≥65% nitrous oxide/oxygen at a calculated flow rate during treatment.
- 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 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

Kruskal-Wallis tests for continuous variables and Fisher's exact tests for categorical variables were used to analyze the data.

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

- Seventeen children were included into this study. The sedation modality groups, demographic distribution, and treatment completion rates are shown in Tables 1 and 2.
- The sedation level for the DEX group was consistent with the other sedation modalities.
- There were no major adverse events for any group.
- There were significant differences in mean systolic blood pressure (SBP) (p=0.012), minimum overall SBP (p=0.044), mean recovery SBP (p=0.003), minimum recovery SBP (p=0.022), and mean recovery HR (p=0.030) across the three groups.
- Specifically, patients receiving DEX had a significantly lower SBP and recovery HR as compared with the other two groups.
- No statistically significant differences were observed for treatment effectiveness (p>.999).

Males	70.6%
Females	29.4%
Black	64.7%
White	17.6%
Middle Eastern	11.8%
Asian	5.9%

Table 1: Patient Demographics

Medication	Distribution	Treatment Completed
MID	41.2%	66.7%
DEX	23.5%	75.0%
MID/HYD	35.3%	71.4%

Table 2: Sedation Modality Distribution & Treatment Completed

CONCLUSIONS

- Dexmedetomidine is an effective and safe medication for pediatric sedation for dentistry.
- Dexmedetomidine provides adequate sedation effects compared to oral midazolam and oral midazolam combined with hydroxyzine.
- Limitations include small sample size and on-going study.