



Efficacy and Safety of Intranasal Dexmedetomidine for Pediatric Dental Sedation

Christina Sun, DMD¹, Caleb Widner, DDS¹, Bethany K White, DDS¹, Jacqueline Yip, DMD,¹ Yanelis Mestre, DMD,¹ John H Unkel, DDS, MD,² Elizabeth J Berry DDS, MSD, MPH¹

¹Bon Secours St. Mary's Hospital of Richmond, Richmond, VA

PURPOSE

This multi-year, single-site, prospective clinical study was completed to examine the effectiveness and safety of intranasal dexmedetomidine (DEX) when used in moderate sedations for pediatric dental treatment., compared to oral midazolam (MID), and oral midazolam with hydroxyzine (MIDHYX).

BACKGROUND

- Dental fear and anxiety (DFA) is a significant hurdle for children receiving dental treatment.¹
- Moderate sedation has been widely used by pediatric dentists to manage DFA, improve cooperation, and provide an opportunity to complete treatment for these patients.^{2,3}
- Various pharmacological agents have been historically used, but consideration of potential adverse effects pose limitations for their use.⁴
- Dexmedetomidine has been widely accepted for use in many procedures in medical fields, notably for procedural sedations in pediatric populations.^{5,6,7,8,9}
- Retrospective studies show that intranasal dexmedetomidine, when combined with nitrous oxide, is a safe and effective option for moderate sedation in pediatric dental procedures.^{10,11}
- A prospective study of dexmedetomidine for pediatric moderate sedation dentistry is needed to assess its effectiveness and safety.

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METHODS

- This is an ongoing, randomized, blinded, clinical study
- Inclusion criteria: 3-6 yo, ASA I or II, English speaking, no prior history of dental sedations.
- Patients were randomized and received one of the following medication regimens for their treatment:
 - 3 µg/kg* intranasal dexmedetomidine (DEX).
 - 0.7 mg/kg* oral midazolam (MID).
 - 1 mg/kg oral* hydroxyzine with 0.7 mg/kg oral midazolam (MIDHYD).
 - * maximum dose for intranasal dexmedetomidine is 100 µg, for oral hydroxyzine is 25 mg, and for oral midazolam is 20 mg.
- All patients received nitrous oxide sedation during treatment with a concentration of 65% at a calculated flow rate.
- Demographic data, procedural times, minor and major adverse events, and quality of sedation were identified and recorded by one provider while another completed the treatment.
- Effectiveness of sedation was assessed with a scale modified from the American Academy of Pediatric Dentistry (AAPD) (Figure 1). A behavior score of 0 to 2 was considered effective. A score of 3 or 4 in either category was graded as ineffective.
- 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

Males	53%
Females	47%
Black	54%
White	25%
Middle Eastern	5%
Asian	7%
Other	9%

Table 1: Patient Demographics

Medication	Distribution	Treatment Effective
MID	35.8%	59%
DEX	29.6%	71%
MID/HYD	34.6%	46%
Overall	100%	58%

Table 2: Sedation Modality Distribution & Treatment Completed

RESULTS

- To date, 91 subjects have been enrolled. Of the 91, 10 are excluded due to patients being sick, parents refused, or being unable to take the meds. Therefore, the analytic sample is 81 subjects: 24 received DEX, 29 MID, and 28 MID/HYD.

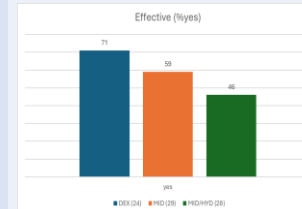
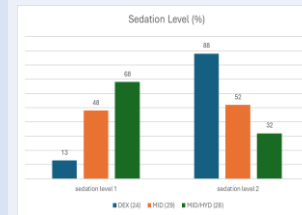


Figure 2: Sedation level and percent effectiveness for all sedation modalities

- The sedation modality groups, demographic distribution, and treatment completion rates are shown in Tables 1 and 2.
- The sedation efficacy for the DEX group was consistent with the other sedation modalities.
- There was one bradycardia event in both the DEX and MID groups but none that required intervention.
- There were no major adverse events for any group.**

CONCLUSIONS

- Intranasal dexmedetomidine combined with nitrous oxide is a safe and effective sedation option for children undergoing dental treatment.
- Additional studies need to be done to assess how dexmedetomidine compares to traditional pediatric sedation drugs.
- Due to the limitation of DEX in painful procedures, studies that combine DEX with other sedation medications to investigate safety and effectiveness should also be conducted.
- Limitations: small sample size, restricted inclusion criteria, different providers completing dental treatment and assessing sedation and behavior scores.