Evaluating the Safety and Efficacy of 3.5-3.7 mg/kg Hydroxyzine for Pediatric Conscious Sedation in a South Florida Population: A Retrospective Study

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BACKGROUND

Conscious sedation is an essential behavior management modality in pediatric dentistry, particularly for young or anxious children who are unable to tolerate dental treatment using conventional techniques alone. Hydroxyzine, a first-generation antihistamine with sedative, anxiolytic, anticholinergic, and antiemetic properties, is commonly used in pediatric dental sedation due to its favorable safety profile. Current AAPD guidelines typically recommend hydroxyzine at doses of 0.5–1.0 mg/kg, often in combination with other sedative agents. However, international studies have reported improved sedation efficacy and treatment completion using higher doses of hydroxyzine (approximately 3.5–3.7 mg/kg) without an associated increase in clinically significant adverse events. Despite these findings, limited U.S. data exist evaluating the safety and effectiveness of higher-dose hydroxyzine when used as a sole sedative agent in pediatric dental patients. This study seeks to address this gap by evaluating clinical outcomes associated with high-dose hydroxyzine in a U.S. outpatient pediatric dental setting.

OBJECTIVE

The objective of this study was to evaluate the safety and clinical efficacy of oral hydroxyzine administered at a dosage of 3.5–3.7 mg/kg as a sole sedative agent for pediatric dental conscious sedation.

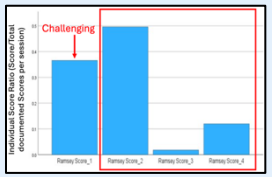
METHODS

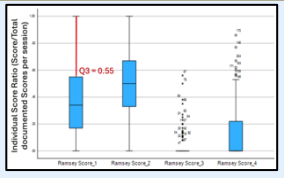
A retrospective cohort study was conducted of pediatric patients aged 3–10 years who underwent dental treatment with oral hydroxyzine as the sole sedative agent between January 2022 and January 2025. Cases in which the medication was not fully administered were excluded.

Sedation efficacy was assessed using:

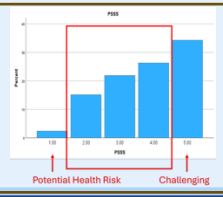
1. Planned treatment completion as the primary outcome.
2. Appropriate sedation depth was defined as a Ramsay Sedation Scale (RSS) score ≥2 for more than half of the treatment duration, with poorly sedated patients defined as RSS1 occurring at a rate ≥0.55, or a Pediatric Sedation State Scale (PSSS) score of 2-4.
3. Behavioral response was assessed using pre- and post-treatment Frankl Behavior Rating Scale (FBRS) with good behavioral response defined as a FBRS ≥2.

RSS – Stratification Strategy





PSSS – Stratification Strategy



Safety outcome included documented adverse events and continuous vital sign monitoring. Heart rate and respiratory rate abnormalities were analyzed as event rates per hour to account for variable sedation duration. A PSSS1 was considered unsafe deep sedation.

RESULTS – SEDATION EFFICACY

Table 1. Demographic Characteristics and Treatment Completion

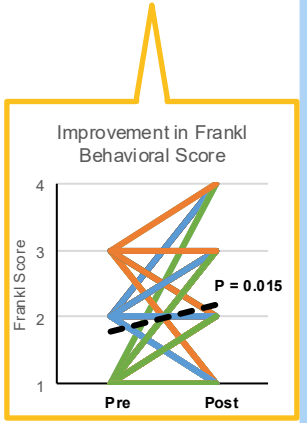
Characteristic		Total Sample (N=263)	Complete (N=249)	Not Complete (N=14)	P-Value
Gender - n(%)					
	Female	101 (38.4)	97(39)	4(28.6)	0.437
	Male	**162 (61.6)**	152(61)	10(71.4)	
Tonsil Score - n(%)					
	0	5 (2.0)	5(2.1)	0(0)	
	1	70 (27.8)	67(28.2)	3(21.4)	0.743
	2	**128 (50.8)**	119(50)	9(64.3)	
	3	49 (19.4)	47(19.7)	2(14.3)	
Mallampati Score - n(%)					
	1	87 (39.4)	81(38.2)	6(66.7)	
	2	**114 (51.6)**	111(52.4)	3(33.3)	0.357
	3	19 (8.6)	19(9)	0(0)	
	4	1 (0.5)	1(0.5)	0(0)	
Age (years) - x̄ (SD)		5.5 (1.3)	5.5(1.3)	5.0(1.3)	0.701
Concentration (mg/kg) - x̄ (SD)		3.6 (0.1)	3.6(0.1)	3.6(0.1)	0.921
Total drug (mg) - x̄ (SD)		71.9 (12.2)	71.9(12.2)	69.3(13.0)	0.838
No. of Teeth - x̄ (SD)		5.2 (2.3)	5.3(2.3)	3.1(1.9)	**<0.001**
No. of Interventions - x̄ (SD)		5.0 (2.40)	5.2(2.3)	3.1(1.9)	**<0.001**
Tx Duration (mins) - x̄ (SD)		82.3 (29.4)	83.3(28.7)	73.5(39.2)	**0.055**

Table 2. Sedation Depth and Behavioral Outcomes

Characteristic		Total Sample (N=263)	Complete (N=249)	Not Complete (N=14)	P-Value
PSSS - n(%)					
	1	6 (2.4)	6(2.5)	0(0)	
	2	38 (15.1)	38(16.0)	0(0)	
	3	55 (21.8)	55(23.1)	0(0)	**<0.001**
	4	66 (26.2)	65(27.3)	1(7.1)	
	5	87 (34.5)	74(31.1)	13(92.9)	
Ramsey Score Ratio - mean (SD)					
	1	0.37 (0.25)	0.35(0.24)	0.6(0.2)	**<0.001**
	2	0.50 (0.24)	0.5(0.2)	0.4(0.2)	0.242
	3	0.02 (0.07)	0.02(0.1)	0(0)	**<0.001**
	4	0.12 (0.18)	0.1(0.2)	0(0)	**<0.001**
PRE Frankl Score - n(%)					
	1	66 (30.8)	63(31.3)	3(23.1)	
	2	127 (59.3)	120(59.7)	7(53.8)	0.244
	3	21 (9.8)	18(9.0)	3(23.1)	
POST Frankl Score - n(%)					
	1	69 (33.0)	56(28.6)	13(100)	
	2	70 (33.5)	70(35.7)	0(0)	**<0.001**
	3	53 (25.4)	53(27.0)	0(0)	
	4	17 (8.1)	17(8.7)	0(0)	

Table 3. Association of Sedation Outcomes with Patient Characteristics, Treatment Variables, and Procedural Completion

Characteristic	RSS <75th (N=181)	RSS ≥75th (N=56)	RSS P-Value	PSSS 2 - 4 (n=158)	PSSS 5 (n=74)	PSSS P-Value	Post-Frankl 1 (n=56)	Post-Frankl 2 - 4 (n=140)	Post-Frankl P-Value
Age in years - x̄ (SD)	5.3 (1.2)	5.6 (1.4)	0.072	5.6 (1.3)	5.3 (1.2)	**0.026**	5.2 (1.2)	5.7 (1.4)	**0.006**
Concentration (mg/kg) - x̄ (SD)	3.6 (0.1)	3.6(0.1)	0.254	3.6 (0.1)	3.6 (0.1)	0.614	3.6 (0.1)	3.6 (0.1)	0.4
Total drug (mg) - x̄ (SD)	68.9 (11.4)	68.8 (11.4)	**0.018**	72.2 (12.2)	69.8 (11.9)	0.145	68.4 (10.5)	73.2 (12.4)	**0.006**
Txt Duration minutes - x̄ (SD)	90.2 (32.5)	81.3 (27.0)	**0.033**	83.7 (28.1)	79.6 (29.8)	0.522	76.7 (27.6)	79.3 (25.1)	0.261
No. of interventions - x̄ (SD)	5.1 (2.4)	5.3 (2.3)	0.275	5.4 (2.2)	4.6 (2.5)	**0.046**	4.5 (2.4)	5.6 (2.3)	**0.001**
D1510 (counts per patient)									
1	17 (9.4)	5 (8.9)	0.619	16 (10.1)	6 (8.1)	**0.037**	4 (7.1)	17 (12.1)	0.383
2	3 (1.7)	0 (0)		3 (1.9)	0 (0)		0 (0)	2 (1.4)	
D2940 (counts per patient)									
1	2 (1.1)	2 (3.6)	0.088	0 (0)	4 (5.4)	**0.011**	4 (7.1)	0 (0)	**0.006**
2	0 (0)	1 (1.8)		-	-		-	-	
D2392 (counts per patient)									
1	35 (19.3)	7 (12.5)		33 (20.9)	10 (13.5)		7 (12.5)	28 (20.0)	
2	26 (14.4)	4 (7.1)		22 (13.9)	6 (8.1)		2 (3.6)	19 (13.6)	
3	15 (8.3)	1 (1.8)	0.079	11 (7.0)	3 (4.1)	0.062	2 (3.6)	10 (7.1)	**0.013**
4	8 (4.4)	1 (1.8)		9 (5.7)	0 (0)		0 (0)	8 (5.7)	
5	1 (0.6)	0 (0)		1 (0.6)	0 (0)		0 (0)	1 (0.7)	
7	1 (0.6)	0 (0)		1 (0.6)	0 (0)		-	-	



RESULTS – SAFETY

Ratio	Mean	Median	Max
High HR	0.8662	0.4054	8.18
Low HR	0.0067	0.0000	1.00
Low RR	**3.9063**	**3.2727**	**19.00**
High RR	0.8662	0.4054	8.18

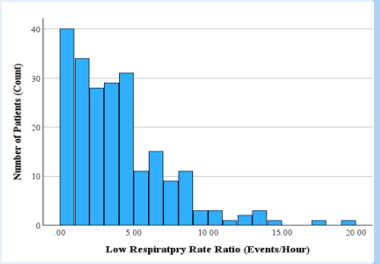


Figure. Distribution of low respiratory rate events per hour during sedation encounter. The mean low respiratory rate was 3.9 events per hour, with no hypoxia, airway intervention, or prolonged recovery observed.

DISCUSSION

Planned dental treatment **was successfully completed in 95% of sedation encounters using high-dose oral hydroxyzine.** Effective sedation was reflected by clinically useful Pediatric Sedation State Scale scores (PSSS 2-4) and favorable Ramsay Sedation Scale findings, defined as RSS1 occurring less than 55% of the treatment duration, allowing completion of definitive dental treatment under conscious sedation. Sedation effectiveness was not uniform across all patients. **Younger age and longer treatment duration were significantly associated with reduced sedation effectiveness**. Greater sedation effectiveness was also associated with the completion of more technique sensitive procedures, including posterior composite restorations and sealants, suggesting that effective sedation supports completion of more technique-sensitive procedures. From a safety perspective, **no severe intra- or immediate post-procedural adverse events were observed**. These findings provide U.S.-based clinical evidence supporting higher-dose hydroxyzine as an effective oral sedative agent for pediatric dental conscious sedation in appropriately selected patients.

CONCLUSIONS

- High-dose oral hydroxyzine (3.5–3.7 mg/kg) allowed completion of planned dental treatment in 95% of pediatric sedation encounters.
- Sedation effectiveness was lower in younger patients and during longer treatment appointments.
- Effective sedation was supported by favorable PSSS scores (2-4) and Ramsay sedation scale findings.
- No severe intra- or immediate post-procedural adverse events were documented.
- These findings support higher-dose oral hydroxyzine as a safe and effective option for pediatric dental conscious sedation in appropriately selected patients.