



# A Randomized Controlled Trial Comparing Two Triple Oral Conscious Sedation Regimens

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## ABSTRACT

- **Purpose:** The goal of this study was to assess the success rate of these two oral conscious sedation regimens as well as evaluate other factors that could influence the sedation experience such as age, gender, pre-treatment behavior, behavior during administration of sedation drugs and degree of dental treatment.
- **Methods:** A double-blind randomized controlled trial was performed on a group of thirty patients from 4 to 7 years of age to evaluate the success rate of two oral conscious sedation regimens. The participants were randomly assigned to be sedated using either a combination of midazolam, meperidine and hydroxyzine (midazolam triple regimen) or a combination of chloral hydrate, meperidine and hydroxyzine (chloral hydrate triple regimen). The evaluation of the child’s behavior was assessed every 10 minutes for a period of 40 minutes using a behavior scale.
- **Results and Conclusion:** The success rate of chloral hydrate was 80% and midazolam 73.3% and there was no statistically significant difference between the two drug regimens. Demographic factors, pre-treatment behavior, behavior during the administration of the medication, and the amount of dental work that needed to be completed did not influence the success of sedations in either regimen groups.

## METHODS

### Ethical Considerations

- This research was submitted and approved by the Pediatric Dental Associates IRB committee (Protocol Number: 2021-015).
- The families were contacted before the sedation visit to discuss their voluntary participation in our study.
- A written informed consent was obtained from the legal guardian of each child that participated in this study.

### Study Design

- Double-blind randomized controlled trial.
- 30 patients in total (15 patients in each group).
- Evaluate the success rate of two oral conscious sedation regimens.

Chloral hydrate: 25mg/kg (maximum dose of 550 mg)	Midazolam: 0.5mg/kg (maximum dose of 10 mg)
Hydroxyzine (Vistaril): 2mg/kg (maximum dose of 44 mg)	Hydroxyzine (Vistaril): 2mg/kg (maximum dose of 44 mg)
Meperidine: 2mg/kg (maximum dose of 44 mg)	Meperidine: 2mg/kg (maximum dose of 44 mg)

### Inclusion Criteria

- Children ages 4 to 7 years old; weight up to 50 lbs/22.7 kg; healthy individuals (ASA I); children with a Mallampati score of I to III and a Brodsky score of I or II.

### Exclusion Criteria:

- History of obstructive sleep apnea; children with special physical/psychological needs; children who did not voluntarily drink the full amount of sedation drugs; children that had a history of dental treatment performed under sedation or general anesthesia.

### Study Protocol:

- Patients were administered nitrous oxide during operative treatment based on patient’s behavior, within a range of 30- 40%.
- Vital signs were monitored throughout the sedation (blood pressure cuff, pulse oximeter, capnograph, precordial stethoscope).
- The behavior was recorded every 10 minutes for the first 40 minutes of the sedation. The dental provider who assessed the behavior of the child was also the operator of the dental treatment.

## METHODS

Sleep - 1 (awake), 2 (drowsy), 3 (asleep).

Movement - 1 (violent), 2 (continuous), 3 (controllable), 4 (no movement).

Crying - 1 (hysterical), 2 (continuous), 3 (intermittent), 4 (no crying).

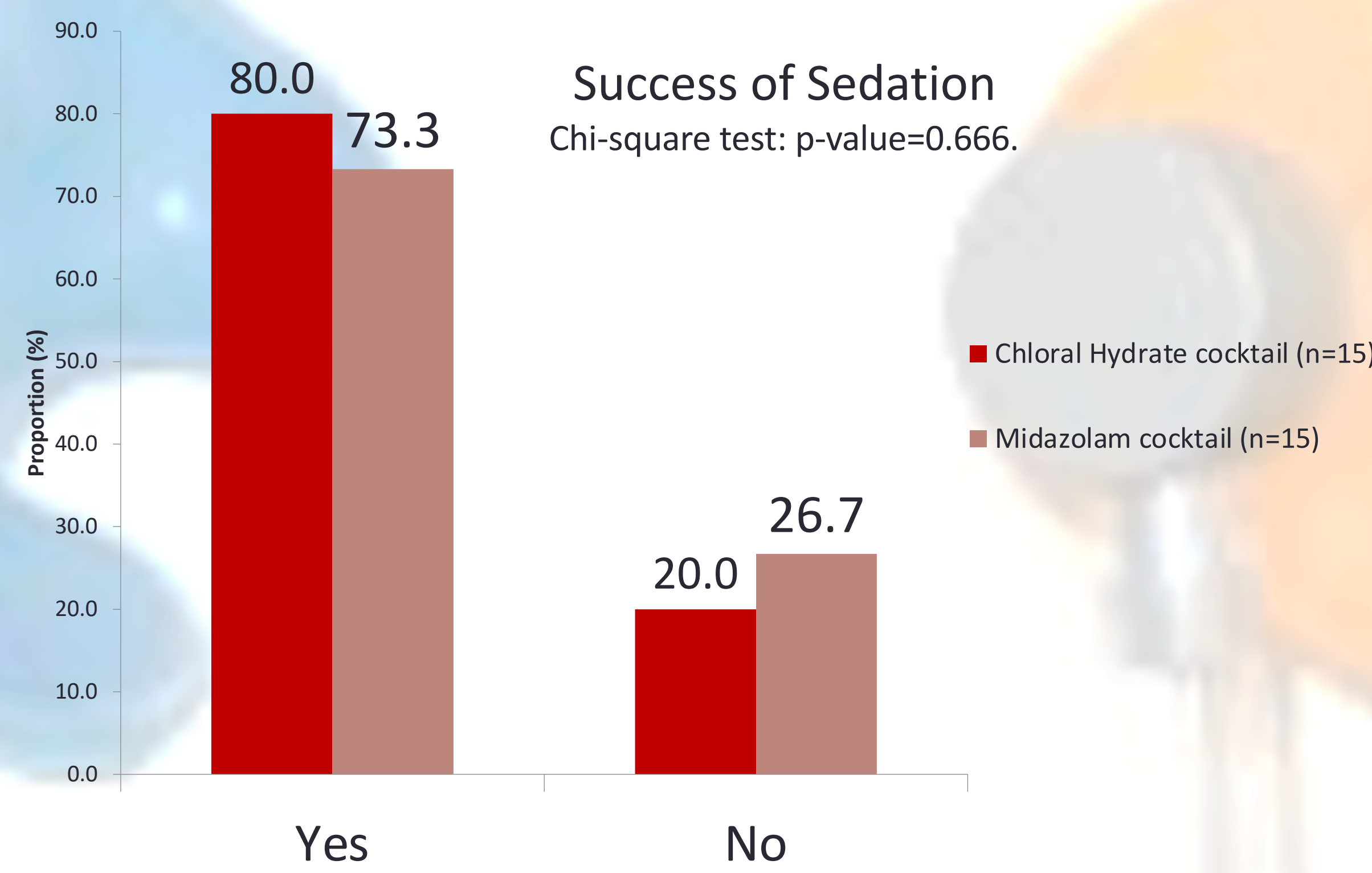
- A sedation was considered successful when no adverse reactions were observed in the vital signs during treatment, and the overall behavior was 5 or 6.

### Overall behavior:

- 1 (Aborted – no treatment rendered)
- 2 (Poor – treatment interrupted, only partial treatment completed)
- 3 (Fair – treatment interrupted, but eventually all completed)
- 4 (Good – difficult but all treatment performed)
- 5 (Very good – limited crying or movement)
- 6 (Excellent – no crying or movement)

## RESULTS

- 30 participants total, 15 females and 15 males.
- 56.6% (n=16) were 4-5 years old, and 43.3% (n=14) were 6-7 years old.
- African-American was the most prevalent race (33.3%).



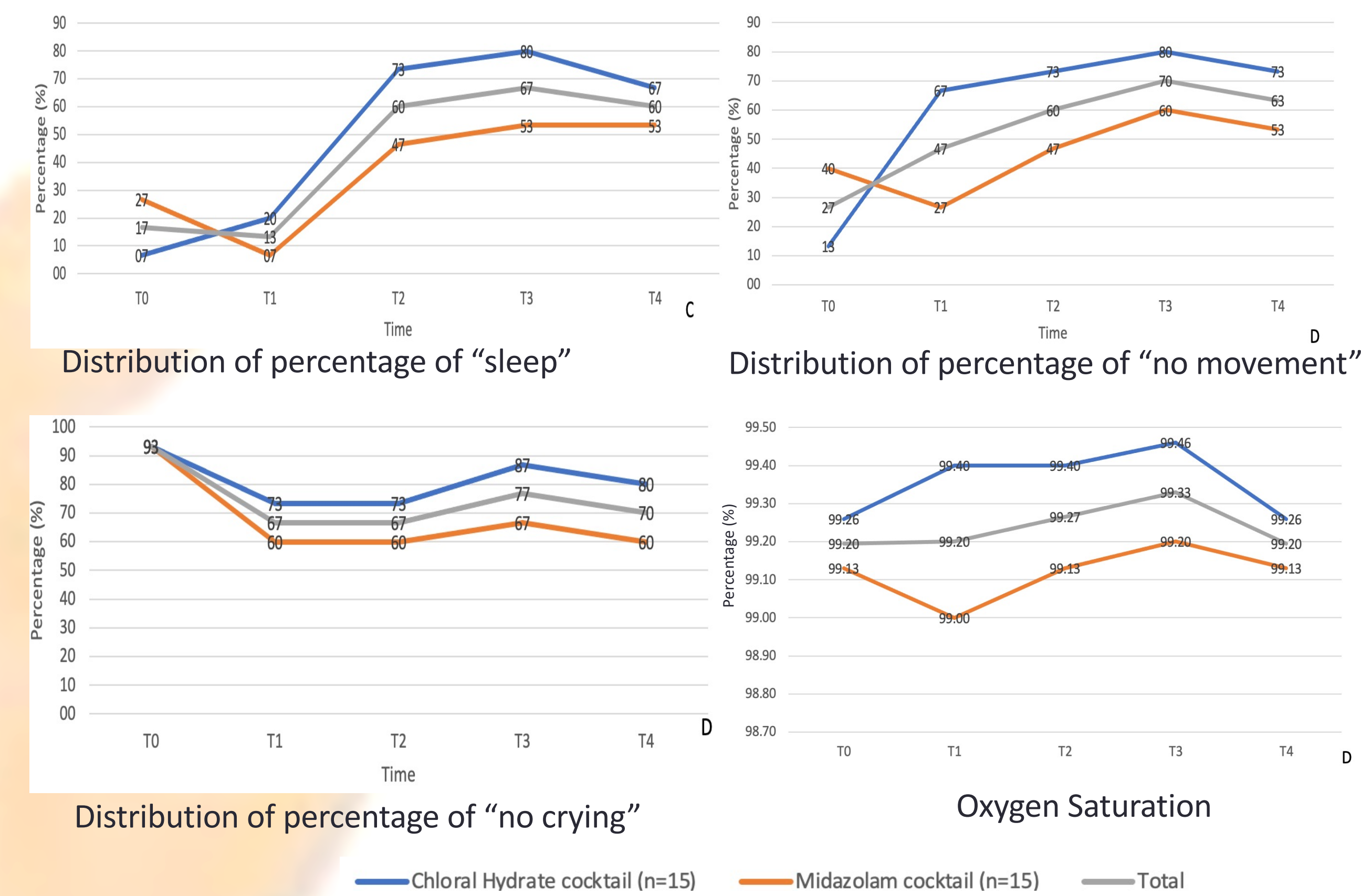
	Type of sedation drug (groups)			
	Total (n=30)	Chloral hydrate regimen (n=15)	Midazolam regimen (n=15)	P-value
Gender				
Female	15 (50.0)	9 (60.0)	6 (40.0)	0.273*
Male	15 (50.0)	6 (40.0)	9 (60.0)	
Age (mean)	5 (1.0)	5 (0.88)	5 (1.16)	>0.999**
Age (group)				
4-5 years old	17 (56.7)	8 (53.3)	9 (60.0)	0.713*
6-7 years old	13 (43.3)	7 (46.7)	6 (40.0)	
Race				
White	9 (30.0)	5 (33.3)	4 (26.7)	0.719***
African American	10 (33.3)	4 (26.7)	6 (40.0)	
Asian	3 (10.0)	1 (6.7)	2 (13.3)	
Hispanic/Latino	8 (26.7)	5 (33.3)	3 (20.0)	

\*Chi-square (p<0.05) \*\* Independent t-test (p<0.05) \*\*\*Fisher’s exact (p<0.05)

Most patients didn’t have any post-sedation complications (90%). Two patients vomited after the treatment, one from each one of the sedation groups. One patient that received the midazolam regimen had a paradoxical reaction (3.3%).

	Type of sedation drug			
	Total (n=30)	Chloral Hydrate regimen (n=15)	Midazolam regimen (n=15)	P-value
Behavior pre-treatment				
Definitely positive (++)	18 (60.0)	11 (73.3)	7 (46.7)	0.083*
Positive, but with reservations (+)	9 (30.0)	2 (13.3)	7 (46.7)	
Negative (-)	3 (3.3)	0 (0.0)	1 (6.6)	
Definitely negative (--)	2 (6.7)	2 (13.3)	0 (0.0)	
Behavior during medication				
Child took the medicine willingly	27 (90.0)	12 (80.0)	15 (100.0)	0.224*
Child had to be coaxed	3 (10.0)	3 (20.0)	0 (0.0)	
Size of dental case (amount of work that needed to be done)				
Small	3 (10.0)	0 (0.0)	3 (20.0)	0.050
Medium	18 (60.0)	8 (53.3)	10 (66.7)	
Large	9 (30.0)	7 (46.7)	2 (13.3)	
Sedation Level*				
Level I	3 (10.0)	2 (13.3)	1 (6.7)	0.830
Level II	25 (83.3)	12 (80.0)	13 (86.7)	
Level III	2 (6.7)	1 (6.7)	1 (6.7)	
Treatment completion				
All treatment was completed	23 (76.7)	12 (80.0)	11 (73.3)	0.502
Treatment only partially completed due to behavior	4 (13.3)	1 (6.7)	3 (20.0)	
No treatment completed due to behavior	3 (10.0)	2 (13.3)	1 (6.7)	

\*Chi-square (p<0.05)



There were no statistically significant differences between the groups in regards to consciousness, movement or crying (p>0.05). The vital signs recorded stayed within the normal range for both groups throughout the sedations and didn’t show any significant differences between the chloral hydrate and midazolam groups (p>0.05).

## LIMITATIONS

- Small sample size.
- Different treatments performed. Example: extractions vs fillings.
- Two different clinicians subjectively evaluating behavior.

## CONCLUSIONS

- Both sedation regimens showed high success rates without a statistically significant difference between the chloral hydrate and midazolam groups.
- Demographic factors and the amount of dental work that needed to be completed did not influence the success of sedations in both regimen groups.
- Based on the vital signs and number and nature of complications, both sedation regimens demonstrated to be safe options to treat children.