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## COMPARISON OF ORAL KETAMINE-MIDAZOLAM AND CHLORAL HYDRATE-MEPERIDINE-HYDROXYZINE SEDATION REGIMENS IN PEDIATRIC DENTISTRY

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COMPARISON OF ORAL KETAMINE-MIDAZOLAM AND CHLORAL HYDRATE-  
MEPERIDINE-HYDROXYZINE SEDATION REGIMENS IN PEDIATRIC DENTISTRY

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science  
in Dentistry at Virginia Commonwealth University

by

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## **Abstract**

### **COMPARISON OF ORAL KETAMINE-MIDAZOLAM AND CHLORAL HYDRATE-MEPERIDINE-HYDROXYZINE SEDATION REGIMENS IN PEDIATRIC DENTISTRY**

By David W. Merrell, D.D.S.

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University

Virginia Commonwealth University, 2013

Director: Malinda M. Husson, D.D.S., M.S.D.  
Assistant Professor, Department of Pediatric Dentistry

**Purpose:** The purpose of this study was to create an experimental design to compare the regimen of ketamine-midazolam to chloral hydrate-meperidine-hydroxyzine for moderate oral conscious sedation.

**Methods:** Patients between 36 and 83 months of age have been randomly assigned to receive 1 of the 2 regimens. Dosages, times, and vital signs will be recorded. Procedures will be recorded on video for assessment of sedation level and behavior. Patients will be contacted to evaluate postoperative sleeping, discomfort, and amnesia. Data will be analyzed using two-group t-tests (TOST) of equivalence in means to compare the two groups across the study period.

**Results:** Patient enrollment of the study has begun. In order not to break the blind randomized code, future data analysis is pending final data collection.



**Conclusions:** This study will assist clinicians by establishing if a regimen of ketamine-midazolam is a comparable alternative to a regimen of chloral hydrate-meperidine-hydroxyzine for sedations.

## **Introduction**

Oral medications for minimal and moderate sedation of young, uncooperative dental patients are common, largely because drugs can easily and conveniently be administered via this route by the practitioner. The oral route is also economical in that no additional equipment is needed other than that required for monitoring.<sup>1</sup> Oral medications are easily accepted by patients and parents due to ease of administration. If therapeutic doses are calculated for each individual patient, the oral route of sedation is relatively safe.

Many drugs can be used for sedation, alone or in combination. The most commonly used medications are the benzodiazepines (ex. midazolam), chloral hydrate, meperidine, and hydroxyzine. The physiological and behavioral effects of these drugs are well documented.<sup>2-6</sup> For a patient with moderate to severe anxiety, a single medication given at therapeutic dosage may not be sufficient. Clinicians may choose to use drug combinations, or “cocktails”, to take advantage of different drug properties. For example, a sedative can be combined with an analgesic (such as an opioid) to provide both anxiolysis and pain control.<sup>7</sup> An anti-emetic can be given to offset nausea caused by certain drugs. However, if drug combinations are used or if 2 routes are combined, the chance of an adverse side effect increases.

Practitioners considering sedation must be very knowledgeable about the medications they intend to use and they must have the skills to rescue the patient from a deeper level of sedation than intended. For example, if the desired level of sedation is moderate, the practitioner must be able to rescue the patient from deep sedation. Sedation guidelines for children have been

endorsed and published by the American Academy of Pediatric Dentistry and the American Academy of Pediatrics. The recognized levels of sedation are minimal, moderate, and deep.<sup>7-9</sup> Beyond deep sedation is general anesthesia, a drug-induced loss of consciousness. Minimal sedation (formerly termed “anxiolysis”) is a drug-induced state where patients respond normally to verbal commands. Ventilatory and cardiovascular functions are unaffected. An example of minimal sedation is the use of nitrous oxide to assist a slightly anxious patient in a routine dental setting. With moderate sedation (formerly termed “conscious sedation” or “sedation/analgesia”), patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation (light tap, not a sternal rub). Reflex withdrawal, a normal response to pain, must be accompanied by another response such as pushing away the stimulus as to confirm higher cognitive function. Spontaneous ventilation is adequate and cardiovascular function is usually maintained. Deep sedation (formerly termed “deep sedation/analgesia”) describes a level of consciousness where patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation. Independent ventilatory function may be impaired and protective airway reflexes may be lost. Cardiovascular function is usually maintained.<sup>8</sup> Our intention is to achieve a level of moderate sedation for the patients included in this study.

Nitrous oxide is often used as an adjunct to other sedatives to assist with anxiolysis, sedation, and analgesia. Nitrous oxide is an inhalation sedative shown to be safe and effective when used by a well-trained clinician. In addition to providing mild anxiolysis, nitrous oxide helps create a psychologically receptive mindset for the child patient and it complements oral sedatives by acting as a titrating and settling agent. During initiation of a procedure under sedation, nitrous oxide is often used in high concentration (50-70%) to settle the patient. Once the patient calms, it is usually reduced to below 50% for the duration of the procedure.<sup>7</sup>

## **Chloral Hydrate**

One of these medications, chloral hydrate, is a sedative hypnotic with a long history of relative safety. Chloral hydrate is often selected for sedations involving more lengthy dental procedures. This is due in part to its elimination half-life of 8-11 hours. In therapeutic doses chloral hydrate has minimal cardiovascular or respiratory effect, has an onset of 30 to 60 minutes, peak of 60 minutes, and duration of 4-8 hours. Chloral hydrate is metabolized to trichloroethanol (TCE) in the liver and is excreted by the kidneys. Undesirable aspects of the drug are lack of a reversal agent, gastric irritation, and an unpleasant taste. Chloral hydrate is often combined with other medications such as meperidine and hydroxyzine to enhance level of sedation and offset certain side effects, such as gastric irritation.

Recommended therapeutic dosing of chloral hydrate for sedative procedures ranges from 25-100 mg/kg for children although doses more than 75 mg/kg have been shown to cause central nervous system instability.<sup>10</sup> One study concluded that doses of 40 mg/kg or less had no more effect than placebo. This same study concluded that 60 mg/kg was required to improve behavior.<sup>11</sup> A combination of chloral hydrate 40 mg/kg, meperidine 0.5 mg/kg, hydroxyzine 25 mg, and 50% nitrous oxide resulted in 85% good (some difficulty, but all treatment performed) or better behaviors according to another study.<sup>5</sup> Yet another study deemed a combination of chloral hydrate 55 mg/kg, and hydroxyzine 1 mg/kg to be just under 74% effective.<sup>4</sup> Differences in research methods and differences in defining what constitutes an effective sedation make comparing results difficult.<sup>12</sup> A regimen of chloral hydrate (Gallipot®, Inc.) 35 mg/kg, meperidine (Demerol®) 1.5 mg/kg, and hydroxyzine (Vistaril®) 1.5 mg/kg was chosen for this study based on a history of successful sedations within the Virginia Commonwealth University Pediatric Dentistry clinic. In this triple “cocktail”, chloral hydrate acts as the sedative agent,

meperidine is added as a narcotic pain reliever, and hydroxyzine is added to counteract the side effect of gastric irritation and nausea caused by the chloral hydrate. Hydroxyzine also acts as a mild sedative.

Chloral hydrate oral solution had been available in 16 full oz. retail packages and 5 mL unit dose packages that were convenient for record keeping in multi-doctor settings such as residency programs. However, in May 2012 manufacture of chloral hydrate oral solution was discontinued. Chloral hydrate is still available in crystal form, but the dentist or participating pharmacy must compound the drug into oral solution. Prior to securing a pharmacy that would compound chloral hydrate into oral solution, VCU Pediatric Dentistry looked at alternative medications that might work well for oral conscious sedations involving lengthy dental procedures. Oral ketamine seemed promising and was used successfully, in conjunction with oral midazolam, for a number of oral sedations in the VCU Pediatric Dentistry clinic. A literature review evaluating the use of oral ketamine with other medications and a review of equivalence studies were completed and reviewed prior to further consideration.

## **Ketamine**

Ketamine is a dissociative anesthetic that has been shown to be a safe and effective oral sedative.<sup>13-19</sup> Ketamine is a derivative of the hallucinogen phencyclidine.<sup>14,20</sup> It has a fast onset, approximately 20 minutes, because of its high lipid solubility and quick entry into the CNS.<sup>13,15,16,18,21,22</sup> Working time is adequate at around 36 minutes.<sup>23</sup> Oral ketamine produces sedation, analgesia, maintains the protective airway reflex, maintains or stimulates the cardiorespiratory system, and has a wide safety margin.<sup>13,14,24-26</sup>

Dissociative sedation describes a state of consciousness where the patient feels disconnected or unaware of his or her surroundings. Nystagmus, or the vacant, glassy-eyed “ketamine stare” marks the onset of this state. Patients may experience nonpurposeful movement independent of verbal or painful stimulation but are still able to independently maintain their own protective reflexes.<sup>13,14,27</sup> This cataleptic state is caused by dissociation between the thalamoneocortical and limbic systems. This dissociation prevents the higher brain centers from perceiving visual, auditory, or painful stimuli.<sup>13,28</sup> Ketamine binds to N-methyl-D-aspartate (NMDA) receptors in the CNS, a subgroup of sigma opioid receptors. This causes ketamine’s analgesic effect.<sup>29</sup> Termination comes about due to redistribution to the peripheral compartment. Ketamine is also metabolized by the cytochrome P450 system to norketamine, an active metabolite, which has one-third the potency of ketamine itself.<sup>14</sup>

Ketamine enhances upper airway muscular tone and preserves spontaneous respiration.<sup>13,14</sup> Bronchodilation and decreased airway resistance due to inhibition of vagal outflow, increased circulating catecholamines, and smooth muscle relaxation, may lead to increases in O<sub>2</sub> saturation. However, ketamine stimulates salivary and airway secretions increasing the risk of laryngospasm. This can be controlled by concomitant use of an antisialogogue. Ketamine has a mild to moderate stimulatory effect on the cardiovascular system. The sympathomimetic effects are due to the inhibition of catecholamine reuptake at adrenergic nerve terminals. Increased myocardial O<sub>2</sub> consumption causes an increase in coronary perfusion. Therefore, ketamine is relatively contraindicated in patients with heart disease or uncontrolled hypertension. Other side effects include skeletal muscle rigidity and hyper tonicity.<sup>14</sup> Random movements unrelated to stimuli have been mistaken for seizure activity although ketamine has been shown to not alter the seizure threshold in epileptics. Ketamine even possesses anticonvulsive properties. Ketamine has

been shown to elevate intracranial pressure due to increased cerebral blood flow. Therefore, ketamine is also relatively contraindicated in patients with hydrocephalus or intracranial lesions since apnea, ataxia, or dizziness may persist for up to 4 hours after ketamine administration. Reports indicate that 0-10% of children experience hallucinogenic reactions such as strange dreams, feelings of detachment, or out of body experiences. Risk for hallucinogenic reactions increases for patients over 10 years of age, of female gender, and having a history of personality disorders; hallucinogenic reactions may be experienced if patients are excessively stimulated during recovery. Concomitant use of benzodiazepines, opioids, or propofol may attenuate these reactions.<sup>13,14</sup> 0-43% of adults and 0-10% of children also experience nausea and vomiting upon emergence from sedation. This usually happens in the late recovery phase when the patient is alert.<sup>13-16,23,26</sup> Post-operatively, children have been reported to sleep at home for up to 6 hours; one study reported an average of 3 hours.<sup>13,15</sup>

Literature reports oral ketamine dosages ranging from 3-10 mg/kg with varying success rates.<sup>13,15-19,26</sup> A regimen of 3 mg/kg oral ketamine with 0.4 mg/kg midazolam was chosen for this study. Earlier trial sedations at VCU Pediatric Dentistry using 4 or 5 mg/kg ketamine with 0.5 mg/kg midazolam resulted in longer recovery times than desired. As mentioned previously, midazolam (a benzodiazepine) is being used in this study to help offset possible ketamine-induced hallucinogenic reactions during emergence from sedation. Benzodiazepines also contribute to sedative drug combinations with their sedative, anxiolytic, amnestic, hypnotic, and anticonvulsive properties.<sup>7</sup>

The goal of this study is to answer if a regimen of ketamine-midazolam (K-M) is as effective or more effective than a regimen of chloral hydrate-meperidine-hydroxyzine (CH-D-H)

for oral conscious sedations. This study also attempts to compare recovery times, postoperative sleeping, discomfort, and amnesia involved with use of the two regimens.

## **Methods**

### **Subject Selection**

In order to properly determine the number of subjects necessary to determine equivalence, a power calculation was completed. The VCU Human Subjects IRB approved the study prior to starting (# HM14735). An experimental design was developed to determine equivalence utilizing the programs nQuery Advisor + nTerim<sup>®</sup> (Statistical Solutions, Saugus, MA) and SAS software (SAS Institute Inc., Cary, NC). Residents of the Virginia Commonwealth University Pediatric Dentistry residency program will perform 50 oral conscious sedations. Patients included in the study will have been previously selected for sedation and will range in age between 36-83 months. Other inclusion criteria include a history of fearful or refractory behavior at previous dental appointments as documented by Frankl behavior rating scores of 1 or 2. Patients to be included must have a classification of ASA 1 and less than 50 percent tonsillar obstruction (rating of Brodsky 1 or 2). Brodsky rating is a standardized tonsillar hypertrophy grading scale (0= tonsils are entirely within the tonsillar fossa, 1= tonsils occupy less than 25% of the lateral dimension of the oropharynx as measured between the anterior tonsillar pillars, 2= less than 50%, 3= less than 75%, 4= 75% or more). Patients will be required to obtain a history and physical from their primary care physician to determine if the patient is healthy and well for dental treatment under moderate oral conscious sedation. All patients will have an NPO (nil per os, Latin for “nothing through the mouth”) status of more than 8 hours prior to sedation.



## Procedure

Patients will be moderately sedated using 1 of 2 oral drug regimens: a combination of ketamine (Ketalar<sup>®</sup> – JHP Pharmaceuticals, Parsippany, NJ) 3 mg/kg and midazolam (Hospira, Inc., Lake Forest, IL) 0.4 mg/kg (K-M) or a triple combination of chloral hydrate (Chloral Hydrate Crystal USP – Gallipot/Fagron, St. Paul, MN) 35 mg/kg (1g maximum), meperidine (Demerol<sup>®</sup> – Winthrop/Breon, New York, NY) 1.5 mg/kg, and hydroxyzine (Vistaril<sup>®</sup> – Pfizer, New York, NY) 1.5 mg/kg (CH-D-H).

Children from both groups will receive between 30-50% nitrous oxide during treatment. Twenty-five patients in the study have been randomly assigned to receive the (K-M) combination and 25 have been randomly assigned to receive the (CH-D-H) combination using SAS software (SAS Institute Inc., Cary, NC). A description of the assigned regimen will be concealed in a folder labeled with the patient number and will be revealed to the operator just prior to drug administration.

Each procedure will be video recorded on a DVD (Sony DCR-DVD308 Handycam<sup>®</sup>, Sony Electronics Inc., San Diego, CA) labeled with the assigned patient number and date. Sedation visits will involve these common procedures after patients are brought to the operatory: Video recording, review of informed consents including consent for the study, review of the history and physical form, review of the medical history and review of systems update (to ensure no changes in health), confirmation of NPO status, airway assessment to evaluate Brodsky score (tonsillar tissues), and baseline vital signs (heart rate, SpO<sub>2</sub>, and blood pressure). If patients are assessed as being healthy for the procedures, oral medications will be administered via a cup or oral syringe. The patients will be observed in the dental chair for 20 minutes (for K-M sedations) or 60 minutes (for CH-D-H sedations) with a parent present. Patients will be placed on a Papoose

Board<sup>®</sup> (Olympic Medical Corp., Seattle, WA) and left unsecured, partially secured, or fully secured for protective stabilization depending on the operator's discretion. The parents will be escorted to the reception area. Patients will initially receive 100% O<sub>2</sub> for 2-5 minutes, then will be given an inhalation mixture ranging from 30-50% N<sub>2</sub>O via a nitrous hood over the nose prior to initiating the dental procedure. Dental procedures will include the use of a mouth prop, rubber dam, or Isodry<sup>Ti</sup> (Isolite Systems, Santa Barbara, CA).

The following will be recorded before, during, or after the procedure by an assigned monitor: patient number, age, weight, indication for sedation, ASA classification, pre-operative medication dosages and times, nitrous oxide dosage and times, local anesthesia dosage and times, procedure times (start to finish), recovery time (end of procedure to discharge), O<sub>2</sub> saturation, blood pressure, and heart rate. Vital signs will be taken every 5 minutes (Appendix 1).

### **Behavior and Sedation Level Evaluation**

Two pediatric dentists, who are not operators in the study, will independently watch the recorded procedures and assess protective stabilization (no wrap, partial wrap, full wrap), sedation level, and behavior (amount of sleep, body movement, head/oral resistance, crying, verbal responsiveness, followed by an overall sedation rating) (Table 1). Both dentists will be blind to the sedation regimens given. Sedation level and behavior will be recorded at the following times: 1) medication administration, 2) entrance of the operator into the treatment room, 3) local anesthetic administration, 4) procedure start, 5) every 10 minutes until 6) procedure stop (Appendix 2). The behavior rating criteria is similar to the criteria used by Reinemer et al (1996),<sup>15</sup> a modified version of the scale developed by Houpt et al (1985).<sup>5,30</sup> To establish reliability and permit rater training, 10 DVD behavior and sedation level evaluations

Table 1. BEHAVIOR AND SEDATION LEVEL

<b>PAPOOSE</b>	<b>HEAD/ORAL RESISTANCE</b>	<b>OVERALL</b>
1. No wrap	1. Turns head, refuses to open mouth	1. Aborted – no treatment performed
2. Partial wrap	2. Mouth closing, must request to open	2. Very poor – Tx interrupted, partial treatment completed
3. Complete wrap	3. Choking, gagging, spitting	3. Poor – Tx interrupted, all treatment completed
	4. No head/oral resistance present	4. Fair – difficult, all treatment performed
<b>SLEEP</b>	<b>CRYING</b>	5. Good – some limited crying or movement
1. Awake, alert	1. Hysterical, demands attention	6. Excellent – no crying or movement
2. Drowsy, disoriented	2. Continuous, making treatment difficult	
3. Intermittently asleep	3. Intermittent, mild, does not interfere	
4. Sound asleep	4. No crying present	
<b>BODY MOVEMENT</b>	<b>VERBAL</b>	<b>SEDATION LEVEL</b>
1. Violent, interrupting treatment	1. Verbal abuse, threats	1. <u>N</u> one
2. Continuous, making treatment difficult	2. Verbal protest	2. <u>M</u> inimal
3. Controllable, does not interfere with treatment	3. Statement of discomfort	3. <u>M</u> oderate
4. No body movement present	4. Occasional talking or silence	4. <u>D</u> eep
		5. <u>G</u> eneral <u>A</u> nesthesia

will be selected to calibrate examiners. We expect the kappa statistic for inter-examiner reliability to be between 0.7 and 0.9.

Criteria for discharge will include the following: satisfactory and stable cardiovascular function, airway patency, easy arousability, responsiveness near presedation levels, intact protective reflexes, ability to talk, ability to sit up unaided, and adequate state of hydration. Patients will be released to the care of their guardians after they meet these discharge criteria. The guardians will be given written and verbal post-operative care instructions and a copy of the Wong-Baker FACES Pain Rating Scale<sup>31</sup> (Figure 1) for reference during the post-op phone call. Patients will then be transported to their cars in a wheelchair. Patients will be called approximately 7 hours following the procedure to evaluate postoperative sleeping, discomfort, and amnesia (Appendix 3).

## Wong-Baker FACES Pain Rating Scale



Figure 1. Pain rating scale recommended for children 3 years and older developed by Donna Wong and Connie Baker

## Data Analysis

Data will be collected for numerous variables. However, the primary variable to be analyzed will be the overall sedation score. Patients were randomly assigned to a group,  $n=25$  per group. It is thought that if the 2 overall sedation behavior scores have a difference of 0.1 (SD = 1.5 per group), then the study has 75% power to claim equivalence to within  $\pm 1.25$  units (Figure 2). We feel that 75% power is enough to claim that the 2 regimens are equivalent. Data will be analyzed using two-group t-tests (TOST) of equivalence in means to compare the 2 groups across the study period.

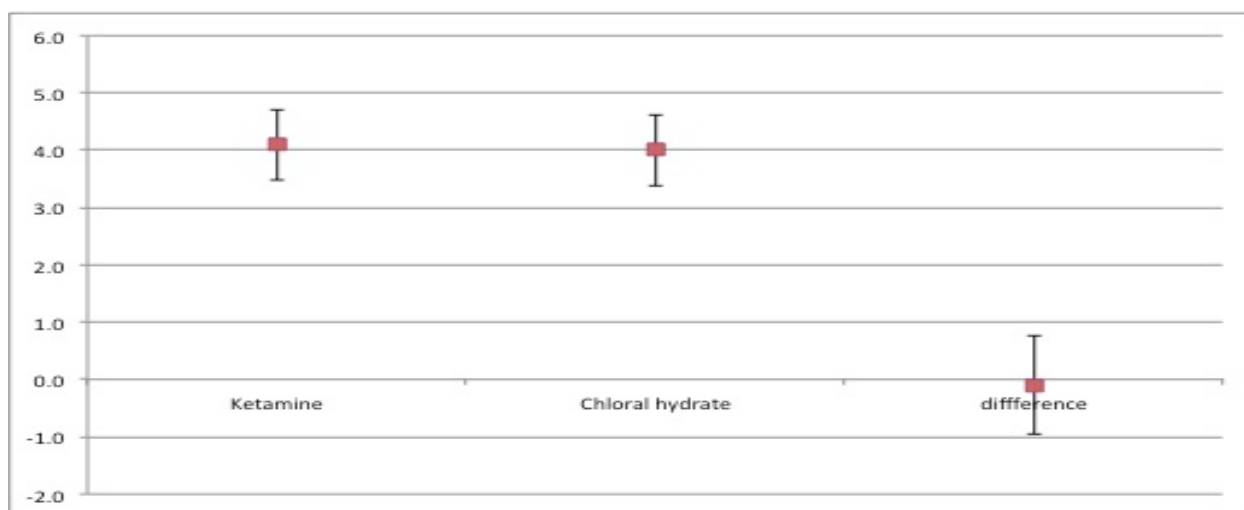


Figure 2. Equivalence Study Design Analysis

## **Results**

Patient enrollment of the study has just begun. In order not to break the blind randomized code, future data analysis is pending final data collection. We will continue the study and post results in the near future.

## **Discussion**

Unlike most randomized controlled trials, equivalence trials do not try to determine if one intervention is superior to another. The goal of an equivalence trial is to show that there are no significant differences between 2 or more treatments.<sup>32</sup> Typically a new intervention is compared to an existing treatment (active control).<sup>33</sup> Investigators must determine how much difference can be tolerated as clinically irrelevant. Relevant differences must be stated in the protocol.<sup>32</sup> For this study, the primary outcome to be analyzed will be the (overall) behavior and sedation score (Table 1). Based on experience, it is expected that the CH-D-H sedations will have a mean of 4 (Fair – difficult, all treatment performed). It is our expectation that the K-M sedations will have a very similar, possibly higher mean, expected to be around 4.1 (Figure 2). Our power analysis, using these numbers, determined we would need a minimum of 50 study participants. These expected means differ from some found in the literature. Poorman et al<sup>5</sup> found an overall behavior rating mean of 5 (Table 1) with CH-D-H regimens. Reinemer et al<sup>15</sup> found an overall behavior rating mean of 3.1 when using 4 mg/kg of ketamine for sedations. A power analysis comparing these very different means would have required a minimum of 700 patients, a number

not feasible for a 2-year residency program. We attribute these different means to differences in study design and methods as mentioned previously.

One limitation of the study is the multi-doctor setting in which the sedations will take place. Ten residents will be acting as operators in the sedations and each comes with a varying level of experience and each has his or her own style of behavior management. These differences could impact patient behavior during the sedations. In addition, resident interpretation of pre-sedation behavior (Frankl rating) at work-up appointments could vary potentially affecting who is and who is not included in the study. Residents might also vary on determination of when a patient has met discharge criteria affecting calculated recovery times.

Another limitation of the study might be the strictness of the inclusion and exclusion criteria. The majority of patients undergoing sedation at VCU do not meet inclusion criteria. The study design calls for only patients rated as ASA I to be included. This was done in effort to omit some potentially complicating variables such as illnesses and medication interactions. However, many patients undergoing sedation at VCU Pediatric Dentistry have an ASA II rating due to health histories that include such diagnoses as asthma, eczema, ADHD, etc. Additionally, the study design only includes patients with behavior rated as Frankl 1 or 2 in an effort to ensure all study participants have similar dispositions (negative behavior). Numerous patients who will undergo sedation at VCU will be excluded because they will be rated as having Frankl 3 behavior (somewhat cooperative), and will be sedated to assist with mild anxiety not controllable with nitrous oxide alone. With the majority of patients being sedated not meeting inclusion criteria, the study could potentially extend for a great length of time in order to include all 50 needed participants. Discussion about alteration of inclusion criteria for our study model is continuing. It has also been suggested that the study may benefit from including intraoperative

complications such as laryngospasms, excessive salivation, respiratory depression, nausea, or vomiting.

If our experimental design was developed correctly, the statistical analysis will show that the regimen of ketamine-midazolam is equivalent to chloral hydrate-meperidine-hydroxyzine. Most children can achieve dental care in a routine setting. Some children require an advanced behavioral management technique, including pharmacological management, for the completion of dental treatment. We continue to strive to find a safe alternative to the use of CH.

### **Conclusions:**

This study will assist clinicians by establishing if a regimen of ketamine-midazolam is an equivalent alternative to a regimen of chloral hydrate-meperidine-hydroxyzine for oral conscious sedations.

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## Clinical Monitoring Data Collection Sheet

CLINICAL MONITORING – ATTACHMENT A

### Comparison of oral ketamine-midazolam and chloral hydrate-meperidine-hydroxyzine sedation regimens in pediatric dentistry

Age _____ mos	Procedure Time <sup>1,2</sup> _____ min	Chloral Hydrate (35mg/kg) _____mg	Ketamine (3mg/kg) _____mg
Weight _____kg	Recovery Time <sup>2,3</sup> _____ min	Meperidine (1.5 mg/kg) _____mg	Midazolam (0.4 mg/kg) _____mg
		Hydroxyzine (1.5 mg/kg) _____mg	

Record vital signs every 5 minutes. Use an "X" to document times for each part of procedure.

[illegible]

Continue here if necessary

[illegible]

## Appendix 2

### Video Monitoring Data Collection Sheet

PATIENT # \_\_\_\_\_ EVALUATOR \_\_\_\_\_

VIDEO MONITORING – ATTACHMENT B

**Comparison of oral ketamine-midazolam and chloral hydrate-meperidine-hydroxyzine sedation regimens in pediatric dentistry**

TIME		Papoose Board	Sedation Level	BEHAVIOR					
				Sleep	Body Movement	Head/Oral Resistance	Crying	Verbal	Overall
Drug Administration	:								
Entrance Operator	:								
Local Anesthesia	:								
Procedure Start <sup>1</sup>	:								
10 min	:								
10 min	:								
10 min	:								
10 min	:								
10 min	:								
10 min	:								
10 min	:								
10 min	:								
10 min	:								
10 min	:								
Procedure Stop <sup>2</sup>	:								

#### PAPOOSE

1. No wrap
2. Partial wrap
3. Complete wrap

#### SLEEP

5. Awake, alert
6. Drowsy, disoriented
7. Intermittently asleep
8. Sound asleep

#### BODY MOVEMENT

1. Violent, interrupting treatment
2. Continuous, making treatment difficult
3. Controllable, does not interfere with treatment
4. No body movement present

#### HEAD/ORAL RESISTANCE

1. Turns head, refuses to open mouth
2. Mouth closing, must request to open
3. Choking, gagging, spitting
4. No head/oral resistance present

#### CRYING

1. Hysterical, demands attention
2. Continuous, making treatment difficult
3. Intermittent, mild, does not interfere
4. No crying present

#### VERBAL

1. Verbal abuse, threats
2. Verbal protest
3. Statement of discomfort
4. Occasional talking or silence

#### OVERALL

1. Aborted – no treatment performed
2. Very poor – Tx interrupted, partial treatment completed
3. Poor – Tx interrupted, all treatment completed
4. Fair – difficult, all treatment performed
5. Good – some limited crying or movement
6. Excellent – no crying or movement

#### SEDATION LEVEL

1. None
2. Minimal
3. Moderate
4. Deep
5. General Anesthesia

## Appendix 3

### Follow-Up Data Collection Sheet

PATIENT # \_\_\_\_\_

4-6 HOUR FOLLOW-UP PHONE CALL

Comparison of oral ketamine-midazolam and chloral hydrate-meperidine-hydroxyzine sedation regimens in pediatric dentistry

#### POST-OPERATIVE SLEEPING

1. None (Awake, alert)
2. Drowsy, disoriented
3. Intermittent sleep
4. Sound asleep

#### SLEEP DURATION (if applicable)

1. Less than 1 hour
2. 1-3 hours
3. 4-6 hours
4. 7 or more hours

#### DISCOMFORT

Wong-Baker FACES Pain Rating Scale



#### PAIN MEDS REQUIRED

1. Yes If yes, what given (ex. Ibuprofen, Tylenol, etc) \_\_\_\_\_
2. No

#### AMNESIA

1. Entire procedure remembered
2. Most of procedure remembered
3. Little of procedure remembered
4. Nothing of procedure remembered

#### COMPLICATIONS (circle if any)

1. Psychic phenomena / nightmares
2. Headache
3. Nausea/vomiting
4. Skin rash



### **Vita**

David Webber Merrell was born on March 8, 1973, in Bitburg, West Germany, and is an American citizen. He graduated from Guthrie High School, Guthrie, Oklahoma in 1991. David graduated Cum Laude with a Bachelor of Science in Biology from the University of Central Oklahoma, Edmond, Oklahoma in 2007. He then graduated with distinction from the University of Oklahoma College of Dentistry in 2011 earning the degree of Doctor of Dental Surgery. David has been a resident in the Virginia Commonwealth University pediatric dentistry residency program since 2011 and is a candidate for graduation in June 2013 with a certificate in the specialty of pediatric dentistry and a Master of Science in Dentistry degree.