



Editorial

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The Disappearance of Chloral Hydrate as an Effective Sedation for Management of Challenging Child Dental Behavior: An Inappropriate and Unfortunate Outcome



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Editorial

For the greater part of four decades, the use of chloral hydrate in combination with other agents (hydroxyzine and meperidine) has served as the primary agent for management of moderately to severely apprehensive and disruptive child dental behavior for in-office sedation. Over the past few years, however, its misuses have resulted in both terminations of manufacture in an oral elixir form as well as diminished use in the pediatric dental setting for procedures requiring moderate to lengthy working times. Several institutions and states have removed it from its formularies or discouraged its use leaving a huge void in sedation arsenals previously used safely for many years. At present, the end result has been for less experienced clinicians and training programs to rely on a limited arsenal of shorter acting agents with reversal capabilities that fall seriously short with respect to efficacy and working time. This editorial seeks to explore support, or in actuality the lack thereof, for evidence based support for this unfortunate occurrence.

Having served as a clinician, researcher, and academician for almost forty years, it has been this observer's impression that no agent or combination remotely compares to the effectiveness and safety of Chloral hydrate combined with hydroxyzine and meperidine for managing challenging child behaviors of 2-5-year old's when moderate or extensive treatment needs exist. Heavy reliance on short and ultrashort-acting benzodiazepines such as Midazolam has for reasons which lack credibility and evidence based support become the drug of choice. Despite considerable study to illustrate the safety but short acting effects of this agent and variable efficacy, it appears the decision to abandon chloral hydrate has been made by contemporary training programs to simply eliminate or reduce the occurrence of mishaps that have appeared in the literature or been addressed by litigation. The sequelae for having eliminated CH from their arsenal of management approaches has been both acceptance and reliance on the frequent need for physical restraint when alternative oral

agents or strategies prove inadequate to overcome interfering behaviors [1,2]. In addition to sedation failures to control resistive behaviors from sub-therapeutic dosing, are adverse reactions resulting from excessive dosing. In any event, the loss of CH from available sedatives leaves a huge void when longer durations of action are needed. Mishaps which have tainted this time tested agent, however, appear to be multifactorial in origin. The etiology and historical misuse of CH are described below.

Historical Use of Chloral Hydrate

Clinician impression prior to 1980 seemed consistent that use of the hypnotic dosage (twice the sedative dose of 25mg/kg) of chloral hydrate, alone, or in combination with an anti-emetic was necessary to produce adequate levels of sedation to obtund interfering child behaviors. This aspect, however, did not include predictable outcomes, particularly for instances where anxiety and disruptive behaviors ran high. Nevertheless, its range of safety even under conditions where somnolence occurred still considered CH among the safest and most predictable agent to permit avoidance of general anesthesia. Trapp [3] in a prominent textbook suggested elevation of the hypnotic dosage to 70mg/kg (exceeding the maximum recommended hypnotic dosage of 50mg/kg or 1000mg, maximum single dose).

Use of high-end dosing of CH, however, created problems associated with enhanced somnolence without evidence to suggest the quality, predictability or safety were improved. Research during the 1980's by several institutions might best be characterized as flawed methodologies that included confounded variables using fixed concentrations (50%) nitrous oxide, arbitrary and mandatory use of restraining devices for all subjects and an absence of pre-treatment behavioral selection criteria precluded assessment of primary agent efficacy in a meaningful way [4-8]. Despite these shortcomings during this period, of favorable note, was a shifting of attention toward

airway patency, assessment and monitoring of physiologic responses, protective reflexes, and levels of sedation achieved.

Retrospective study of Nathan and West [9] and prospective study of Hasty et al [10] reported significant improvement and safety from reduced somnolence by reducing CH dosage and by the addition of meperidine. These studies reported significantly improved quality of sedations and no need for higher-end dosing of CH. This regimen became the most frequent regimen for difficult behaviors requiring moderate to long durations of action (30-75minutes) for the next two plus decades. Despite the development of safety guidelines and increased emphasis on patient monitoring, instances of abuses and misuse of CH have since appeared. No records of compliance and documentation following such guidelines have yet to be developed or enforced [11,12].

Analysis of mishaps has revealed several common denominators from misuse of CH resulting in morbidity and mortality [13-15]. These have included

- a) Over dosage of CH beyond 50mg/kg.
- b) Gross over dosage of local anesthetic extending well beyond the maximum toxic limits.
- c) Inadequate patient monitoring to detect abnormalities in vital signs, airway patency, or early recognition of an adverse reaction.
- d) Lack of proficiency in either recognition of a developing adverse reaction/response or management of a medical emergency.
- e) Failure to monitor recovery parameters and premature discharge before satisfying appropriate discharge criteria.

Regardless of the regimen being used, violation of any of the preceding has potential to impact on the use of sedative agents or combinations. This author has been in search of an alternative agent to CH over the past fifteen years. To date, nothing has been found to compare to the predictability, efficacy, and safety of this "triple combination". Of note is also the fact that considerable retrospective assessment of reduction in dosage to a maximum of 30-35 mg/kg has virtually eliminated all occurrences of somnolence pre-operatively, intra-operatively, and post-operatively. A long term 35 year retrospective look at CH looking at over 3000 sedation visits, using various dosages for variations in anxiety is underway. Long duration of action appears retained with early satisfaction of discharge criteria achieved. In rare occasions, treatment efforts have been abandoned for use of general anesthesia due to heightened levels of apprehension and/or pre-cooperative behaviors. Subtle changes in delivery of compounded concentrations which significantly reduce the quantity of oral suspension to be ingested have resulted in enhanced compliance; similarly, allowing for greater latency periods for medication absorption and effect up to 75 minutes,

(due to variable GI absorption) appear to have resulted in higher success rates and smoother sedations. Compounding of CH formulations from tablet form with flavoring agents have contributed to greater patient acceptance.

Alternatives to CH for moderate to long duration of action

There are few agents that offer the ability to obtund moderate to severely anxious and disruptive behaviors of young children. These include anti-histamines which carry mild anti-anxiety effects, and mild sedation (hydroxyzine, promethazine). Benzodiazepines such as diazepam (which offer mild anti-anxiety effect) are of long duration of action up to 24-36 hours by virtue of having long acting metabolites. Limited study on young children has demonstrated variable and unpredictable levels of sedation. As result, it is more commonly chosen alone or in combination for older children >6 yrs of age. Midazolam, while perhaps the most studied compared to CH, has yet to identify predictable dosing efficacy alone or in combination with agents such as hydroxyzine with and without meperidine, when used in dosing under 0.7 mg/kg; duration of action remains ultra-short to short [16]. There has been virtually no study of longer term agents such as Lorazepam in young children. This agent warrants study.

Ketamine, a dissociative anesthetic, has been minimally studied in young children; at present, there are no p.o. guidelines for oral use in young children despite favorable ability to obtund disruptive behaviors of profound neurologically challenged individuals with limited cardiovascular or respiratory effects. Oral absorption is subject to significant first pass metabolism rendering oral dosing as high as 8-10mg/kg in comparison to its parenteral IM or IV dosing of 2-5mg/kg. Airway, respiratory and depressed consciousness can be expected to serve as in-office deterrents to use in this population.

In Summary, removal of CH from the arsenal of sedation of agents for whatever reason, appears to be premature if not without justification. Blaming this agent solely as result of clinician misuse, abuse, and poor judgment is both inappropriate and by this observer, represents a step backward to securing evidence based support for what is currently used for pediatric in-office sedation.

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