A retrospective study of chloral hydrate, meperidine, hydroxyzine, and midazolam regimens used to sedate children for dental care

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Abstract

Purpose: *The purpose of this retrospective study was twofold: a) to examine the behavior and physiology of pre-school children each sedated with 1 of 3 drug regimens based on patient age, dental needs, and pre-operative clinical impression; and b) to determine the association between pre-operative behaviors to the behavior and physiology of the sedated children.*

Method: *Records of more than 600 patients sedated at Columbus Children's Hospital dental clinic over a two-year period were culled for patients who ranged in age from 2 to 5 years of age and had received one of three different drug regimens: a) chloral hydrate and hydroxyzine (CH-H), b) chloral hydrate, meperidine, and hydroxyzine (CH-D-H), or c) midazolam (M). A minimum of 300 patients (100/drug regimen) were randomly selected. The standard sedation sheet used in all sedations at the clinic included, among other factors, pre-operative assessments of patient behavior, interaction, and cooperation. Physiological and behavioral variables during the intraoperative sedation periods were also available. These periods included initial baseline vitals, vitals following drug administration, topical and local drug administration, rubber dam placement, and a minimum of the first 15 minutes of restorative procedures. The three drug regimens were compared for these variables. Data were entered into SPSS for data analysis using one-way ANOVA, Chi-square, regression analysis, and descriptive statistics.*

Results: *The results indicated significant mean differences in patient age, weight, and duration by drug regimen (F=20.3, P<0.001; 16.2, P<0.001; and 48.7, P<0.001, respectively). ANOVA indicated a significant difference among drug regimens for percent of quiet, sleeping, and struggling behaviors. Quiet behavior accounted for 26%, 41%, and 67% of all behaviors for CH-H, CH-D-H, and M, respectively. Sleep accounted for 50%, 43%, 0.4% and struggling 11%, 8%, and 19% for CH-H, CH-D-H, and M, respectively. Pre-operative behaviors were also significantly different and patient cooperation was the only variable found minimally predictable of intra-operative behaviors (R = 0.32, P<0.001). Significant differences among drug regimens were found for heart rate (HR) and mean arterial blood pressure (MAP) during certain procedures (e.g., CH-H produced lower MAP compared to the other drug regimens); however, all physiological variables were within normal limits for the children.*

Conclusion: *Significant differences were found for behavioral and physiological variables among the drug regimens (e.g., CH-D-H produced significantly more quiet and sleeping behaviors than M). Prospective studies are needed to confirm these findings. (Pediatr Dent 22:107-112, 2000)*

Various drug regimens delivered orally are used to sedate children during the delivery of dental care.[1-10] The oral route is the most frequently used by pediatric dentists, primarily because of its ease of administration in most cases and training of the practitioners.[11] Likewise, the drugs and dosages included in the regimens vary significantly, most likely due to practitioner training and experience.[12-15]

Physiological and behavioral effects of many of these regimens are fairly well-known;[16-20] however, differences in research methodology continue to obfuscate interpretation among studies.[21] Preoperative variables, including aspects of the child's behavior, are less understood as predictors of sedation outcome. Nonetheless, preoperative behaviors, cooperation, and other child characteristics (e.g., temperament) may offer clues for predicting behaviors occurring during the intraoperative phase of treatment. Further, a clinician's knowledge of such clues could be important in both the selection of drug regimens and the dosages of drugs.

Although not studied as yet in any systematic clinical format, a working hypothesis of the selection of orally administered drug regimens and dosages to match the degree of patient cognitive and coping abilities can be proffered at this point. Preschool children appear to begin comprehending, albeit to a limited extent, the concept of mutual participation with outcome goals in a social setting such as the dental operatory.[22] The age at which this concept and the resulting cooperation occur is estimated to be around the third year of

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Table 1. Mean Age, Weight, and Duration of Each Drug Regimen Studied

Variable	Drug Regimens	Mean±SD	F	*P*
Age (months)	CH-H	35.9±12.5	20.3	0.001
	CH-D-H	48.5±13.5		
	M	43.1±15.6		
Weight (kg)	CH-H	13.7±2.3	16.2	0.001
	CH-D-H	16.6 3.8		
	M	15.8±4.7		
Duration (minutes)	CH-H	40.7±16.7	48.7	0.001
	CH-D-H	42.4±14.1		
	M	23.1±9.2		

life. Prior to 36 months of age, most children tend to display escape behaviors and cry to cope when fearful or angry.[23] Management of the latter behaviors often can be accomplished with sedation or general anesthesia. But the degree of sedation required is usually significant if the extent of dentistry to be done and disruptive behaviors are also significant.

One could hypothesize that children younger than 36 months of age and requiring, as a minimum, quadrant restorative dentistry may be poor candidates for levels I and II sedation of the American Academy of Pediatric Dentistry (AAPD) sedation guidelines.[29] Such children would be expected to cry and struggle on a more frequent basis due to immature cognitive development, unless more deeply sedated. By contrast, children older than 36 months, on average, may be expected to display more cooperative behaviors during level II or III sedation theoretically, because of more refined coping skills.

The purpose of this preliminary, retrospective study was to test portions of the above hypothesis by analyzing sedation-related data collected in a format consistent with our standardized operating procedures at Columbus Children's Hospital.[17,20,25-28] Specifically, preoperative assessment of patient behavior, interaction, and cooperation during patient work-up immediately prior to sedation were studied as a function of drug regimen selected on the basis of this hypothesis. Additionally, intraoperative behavioral and physiological data were analyzed to determine any significant differences of the drug regimens.

The selection of drug regimens was based on three factors: a) age of the patient at the time of the sedation; b) the perceived temperament based on the interaction with the child; and c) the extent of dental needs of the child. The drug regimens included: a) the triple combination of chloral hydrate, meperidine, and hydroxyzine (CH-D-H); b) chloral hydrate and hydroxyzine (CH and H); and c) midazolam alone (M).

Methods and materials

The sedation sheets of 300 children were randomly selected from a pool of over 600 sedation cases completed over a two-year period at the dental clinic of Columbus Children's Hospital. The pool of cases was culled to identify only children who were preschoolers and who had received one of the three drug regimens (e.g., CH-D-H, CH-H, or M). An attempt was made to identify more than 100 cases in each of the categories of the drug regimens and then randomly select 100 per category for data analysis.

All children were healthy and sedated because of behaviors displayed during dental visits prior to the sedation. Children were excluded if they had not met preoperative requirements of nothing by mouth or had a medical condition that contraindicated sedation (e.g., the flu).

Each sedation visit shared common procedures. Each parent or guardian gave informed consent for the sedation appointment. All patients had their medical history reviewed and a physical assessment was done preoperatively by a dentist. The physical assessment included preoperative auscultation of the chest, and oral and oropharyngeal examinations to determine extent of dental need and tonsil size. The patients were weighed (final weight was in kg and was always 1 kg less than the weight of the child fully clothed) using a standard hospital scale that is calibrated yearly. The child's heart rate and oxygen saturation were obtained in most cases, depending on patient cooperation, using a Nellcor oximeter. Likewise, blood pressure was determined using a Dinamap automatic blood pressure cuff.

The patient's preoperative behaviors were assessed by the dentist sedating the child and recorded on the front page of the clinic's standardized sedation sheet. The sheet contained several scales, including patient interaction with the dentist, cooperation when asked to do some activity (e.g., open their mouth), and behavior in general during the preoperative assessment. For each scale, at least four descriptors were available for the dentist to categorize the patient. For instance, the scale for patient interaction had five descriptors, including: 1) talks freely without prompting: 2) talks most of time after initial prompting; 3) talks only when prompted; 4) refuses to talk; and 5) unable to talk (age or foreign language).

Following patient preoperative assessment, the drug regimen and individual drug dosages were selected that corresponded to the scheme mentioned previously. The drugs were drawn and administered to the child by the parent via a cup, or if uncooperative or the parent unwilling, orally by a needleless 10 cc syringe into the buccal vestibule. Depending on the drug regimen, the start time for separating the child from the parent and beginning patient preparation for dental care was as follows: a) for CH-D-H—45 minutes; b) CH-H—45 minutes; and c) M—10 minutes.

When separated from the parent, the child was placed on a papoose board but usually not immobilized initially. An

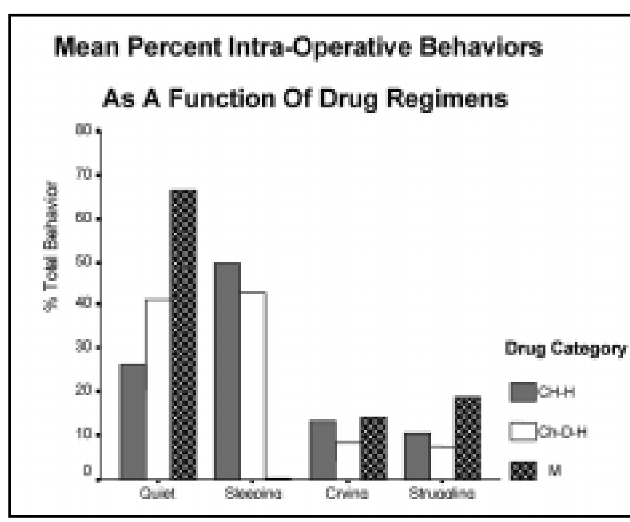

Fig 1. Mean percent intra-operative behaviors as a function of drug regimens.

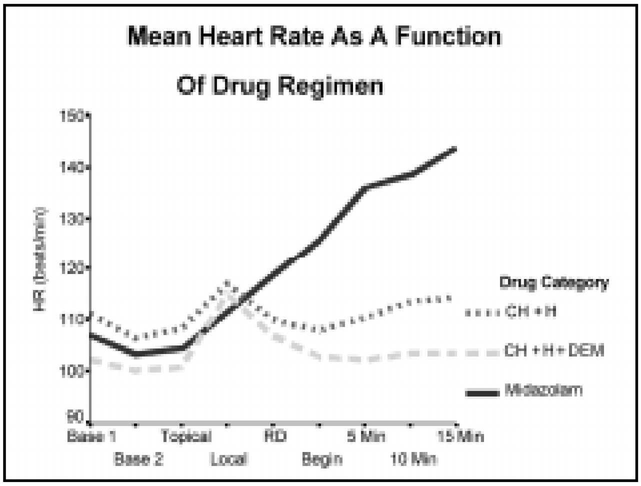

Fig 2. Mean heart rate as a function of drug regimen.

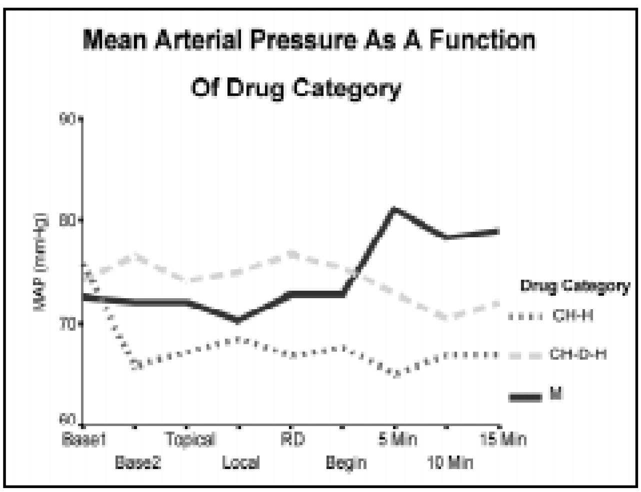

Fig 3. Mean arterial pressure as a function of drug category.

oxisensor probe was attached to the toe adjacent to the big toe. An appropriate sized blood pressure cuff was placed on the right arm, and a capnograph line placed next to the nostril if the child was in level III of the AAPD guidelines on sedation and general anesthesia.[2-9]

A nitrous oxide/oxygen (N_2O/O_2) nasal hood was placed over the child's nose and N_2O/O_2 was administered at 50% ± 10% at 3 to 6 liters/minute depending on the size of the child. A settling period was initiated that usually lasted 2 to 5 minutes in duration, depending on the behavior of the child. Children who became uncooperative and not responsive to directives of maintaining their hands on their stomach and keeping their head still, were immobilized in the papoose board. The patient's physiological parameters were recorded at each major procedural event (e.g., injection) and otherwise every five minutes.

The behavior of the child was also recorded simultaneously with the physiological parameters and included the standardized clinical scale of: C, for crying; Q for quiet, but awake; M for movement without crying; Sl for sleep-like behaviors (e.g., eyes closed) but arousable; and St for struggling. The dentistry was completed and the dentist rated the difficulty of the sedation and the global intraoperative behavior displayed by the child.

The frequency of occurrence of each behavioral category of quiet, sleeping, crying, and struggling recorded intraoperatively was recorded during determination of baseline vital signs following sedation, topical, and local administration, rubber dam application, and minimally through the first 15 minutes of the restorative phase. The percentage of each behavioral category was computed for each of the above phases. Furthermore, the percents of quiet and sleeping for each phase were summed and arbitrarily labeled as "good" behaviors. Likewise, the percents of crying and struggling were summed for each phase and arbitrarily labeled as "bad" behaviors.

The data were entered into a computer and analyzed using SPSS+ for PCs. Analysis included ANOVA, Chi-square, and regression analysis. For statistical purposes, any procedures lasting longer than 15 minutes beyond the beginning of restorative procedures were not analyzed because the number of cases in the M group decreased significantly beyond the 15 minute period due to its short duration of action.

Results

The sedation sheets of 300 children were reviewed with 100 each included in the 3 drug regimens of 1) CH-H, 2) CH-D-H, and 3) M. The mean age and weight of the sample of children were 42.5±14.8 months and 15.3±3.9 kgs. The mean age, weight, and duration of each drug regimen were significantly different. (Table 1)

A one-way ANOVA indicated a significant difference in the percent of quiet, sleeping, and struggling behaviors as a function of drug regimens (Fig 1). Crying behavior was not significantly different among regimens. Quiet behavior accounted for 26%, 41%, and 67% of all behaviors for CH-H, CH-D-H, and M, respectively. Sleep accounted for 50%, 43%, 0.4%, and struggling 11%, 8%, and 19% for CH-H, CH-D-H, and M, respectively. Also, significant differences were observed among the drug regimens for the good and bad behaviors. Good and bad behaviors were the percent of quiet and sleeping behaviors summated and the percent of struggling and crying summated, respectively. A post-hoc analysis indicated that the triple combination of CH-D-H had significantly more "good" and less "bad" than the M regimen. CH-H was not significantly different from either of the other two drug regimens. The mean percent good behaviors were 76%, 84%, and 67% for CH-H, CH-D-H, and M, respectively. The mean percent bad behaviors were 24%, 16%, and 33%, for CH-H, CH-D-H, and M, respectively.

Chi-square analysis indicated significant differences in distribution of patients expressing measured preoperative behavioral responses (χ^2=21.1, P<0.007), interactions with the dental personnel (χ^2=34.0, P<0.001), and cooperation as per requests of the dental personnel (χ^2=14.0, P<0.03) as a function of drug regimens. There were no significant differences among groups in the distribution of patient behaviors intraoperatively and in dentist ratings of difficulty in performing the sedations.

A stepwise regression analysis was done to see if preoperative behavioral responses, interactions with dental personnel, and cooperation with requests by dental personnel were predictive of the percent of "good" or "bad" behaviors. Cooperation was the only variable found to minimally predict the percent of these behaviors (R=0.32, P<0.001).

One-way ANOVA indicated that significant differences among drug regimens were found for heart rate, mean arterial blood pressure (MAP), but not for oxygen saturation. The heart rate increased during local anesthetic injection for all three regimens. The heart rate continued to be significantly higher for

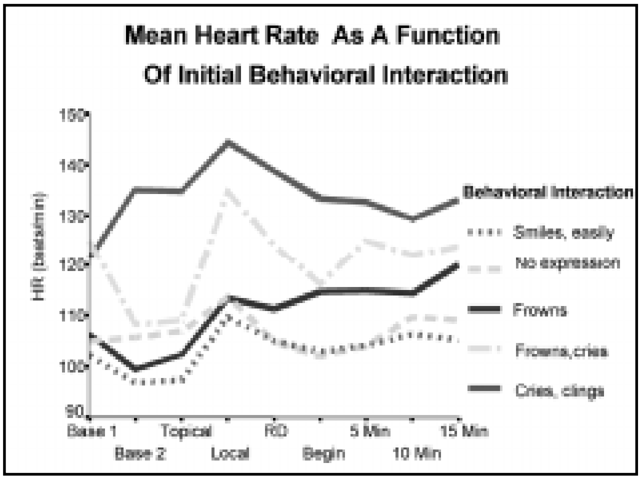

Fig 4. Mean heart rate as a function of initial behavioral interaction.

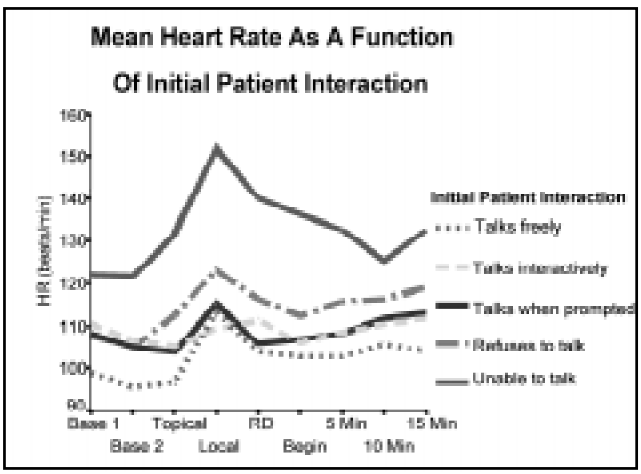

Fig 5. Mean heart rate as a function of initial patient interaction.

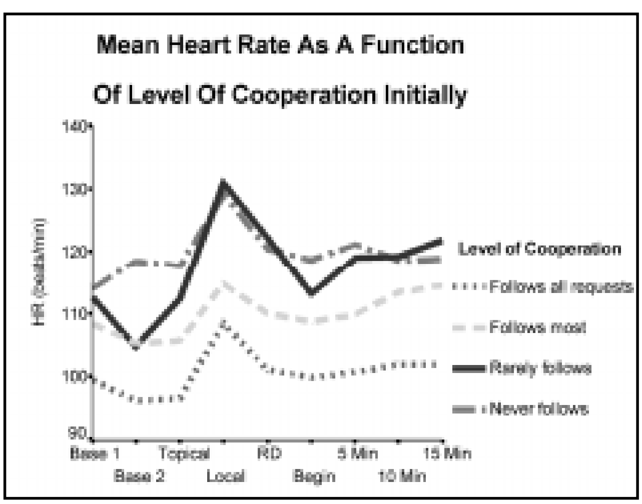

Fig 6. Mean heart rate as a function of level of cooperation initially.

M, compared to the other two regimens, following local anesthetic injection. Also, the heart rate in the CH-D-H group was significantly lower than either of the other two regimens after the rubber dam was placed. CH-H consistently produced significantly lower MAP throughout the sedation compared to the other regimens. Also, M produced a significantly higher MAP than the other regimens after five minutes into the restorative period. (Figs 2 and 3)

A one-way ANOVA indicated that heart rate during various procedures and times varied significantly with preoperative behavioral interaction, patient behaviors, and level of cooperation. Generally, children who were not approachable failed to follow instructions, and those who cried and struggled preoperatively were found to have higher resting heart rates and higher heart rates during operative procedures. (Figs 4, 5, and 6)

MAP was shown to be significantly different for baseline vitals prior to drug administration for behavioral interaction and level of cooperation. Again, children who failed to follow instructions and cried and struggled preoperatively were found to have a higher MAP (Figs 7 and 8).

Discussion

Several factors were found to be significant in this study. The mean age, weight, and duration of each drug regimen were significantly different from each other and this is consistent with the hypothesis proposed and evaluated in this study. For instance, some children received the drug regimen of CH-H because of their young age and the increased likelihood of their inability to cope in a dental setting unless in a non-interactive, but arousable mode of sedation. Consequently, these children would be younger, weigh less, and have a different duration of treatment than an older child who requires only enough sedation to overcome or assist coping with the dental treatment and thus remains fully interactive. In some cases where minimal treatment was completed (e.g., extraction of maxillary primary incisors only), M may have been used, thus increasing the variance for the factor of age. CH-D-H, on average, provided the longest duration for operative procedures.

Compatible with the significant difference in age among the drug regimens was the finding that the preoperative behavioral measurements had significantly different distributions. As mentioned in the hypothesis above, the older children who received the triple combination of CH-H-D were expected to have better coping and language skills. In general, they responded more frequently to directed requests, were more approachable, and exhibited less overtly combative behaviors than the younger children who received the CH-H regimen. Two goals of pharmacological management (e.g., sedation) of children are to assist children in inducing their own coping skills and to promote acceptance of the dental environment.[29] The selection of sedative agents that increase the likelihood of rendering interactive behaviors as opposed to noninteractive behavior is reasonable for the older, more mature child. The results of this study seem to provide support for this concept.

It is interesting that almost two-thirds of the patients were somewhat approachable, a component of temperament,[26,30] with only 9% demonstrating behaviors classified as crying and clinging to parents. However, the children in the group receiving the triple combination (CH-H-D) had the highest percentage of all patients of behaviors characterized as easily approachable and smiling. In fact, 71% in this group were characterized as smiling and either easily approachable or approachable, compared to the group receiving CH-H (60%) and the group receiving M alone (55%). Nonetheless, children who appear approachable during the initial phases of a dental visit may exhibit strongly disruptive behaviors either during examination or restorative procedures. Further prospective studies

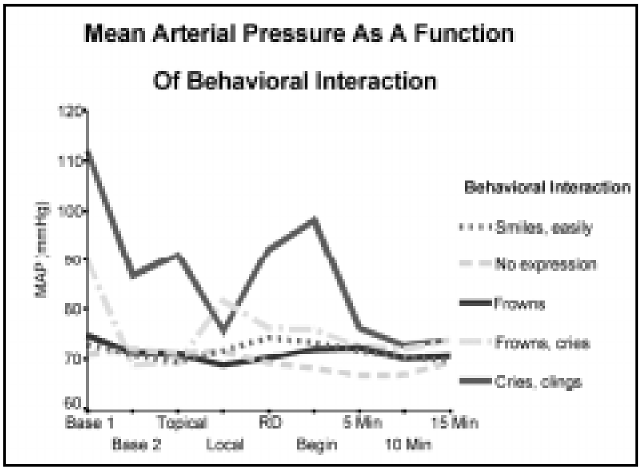

Fig 7. Mean arterial pressure as a function of behavioral interaction.

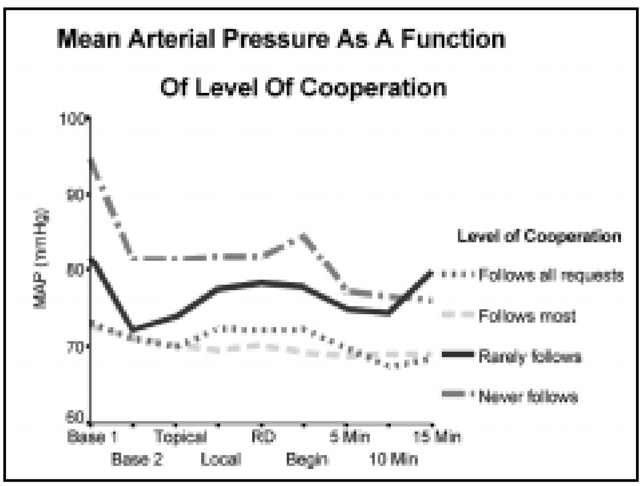

Fig 8. Mean arterial pressure as a function of level of cooperation.

are required to confirm this finding and determine elements contributing to individual variance related to this aspect of temperament.

Differences in intraoperative behaviors were noted among the three drug regimens. M seemed to be consistent with a pattern of quiet behaviors until the local anesthetic was administered. Following this procedure, the behaviors were noted to shift to crying and struggling activities consistent with the findings of others.[31] Heart rate was notably elevated during and after local anesthetic administration, reflecting the crying and struggling behaviors. On the contrary, CH-H-M resulted in mainly quiet and sleeping behaviors after these procedures. CH-H was noted to be somewhere in between the other two regimens for this portion of the restorative visit. The M regimen produced the least percent of "good" behaviors compared to CH-D-H and CH-H (67% vs. 84%, and 76%, respectively) and obviously the most "bad" behaviors (33% for M compared to 24% and 16% for CH-H and CH-D-H, respectively).

In fairness to the M regimen, the drug's duration of action is short and occasionally causes the "angry" child syndrome.[27] If a clinician was interested in a very short procedure (e.g., extraction of a single tooth), then M seems to be ideally suited. It has a rapid onset of action when administered orally (approximately 10 minutes) and causes minimal crying or struggling until 10 to 15 minutes following the injection of local anesthetic. However, M has no analgesic properties.[8] To the contrary, CH-D-H takes approximately 45 minutes for onset of good clinical working conditions which lasts for approximately 40 minutes, is often associated with a mellow-like affect during which interactive states and some degree of analgesia are notable. Hence, it is a good combination of agents to use when one or more quadrants of dentistry are required on a child who has potentially reasonable coping skills.

Significant differences among the three drug regimens were noted for the physiological variables of heart rate and mean arterial blood pressure. It is not clear whether the differences were due to the sedative regimens themselves or to differences in the age and thus age-specific values for these physiological parameters. Average heart rate for the drug regimens were consistent with the mean age of the groups with the exception of dramatic increased heart rate following the administration of local anesthetic which was also associated with struggling behaviors. Average MAP for each regimen suggested consistency with the age group of the children during baseline vitals. Following the administration of the agents, CH-H produced a mild depressive effect consistent with settling of an anxious child. CH-D-H produced little change throughout the procedures and in the M group, MAP increased during the restorative phases. What is important is that none of these variables were found to be outside of normal physiological ranges for the children in the study. Hence, in support of findings of others,[3,9,17,20,32] these drug regimens when used in the dosages reported in this study do not appear to adversely affect children.

One of the more promising findings was related to preoperative behavioral findings and their relationship with heart rate and MAP prior to and with heart rate during sedation. Children who had relatively higher heart rates and MAP tended to have poor abilities in coping with the dental visit. They were least cooperative, most often refused to comply with requests, and demonstrated the most disruptive behaviors. There is some evidence that children with a high resting heart rate for their age tend to be poorer candidates for a smooth, quiet sedation (S. Wilson: unpublished observations). It is possible that the child who has poor social skills or a high degree of fear may also have a higher likelihood of having a higher heart rate. Further testing of this hypothesis is needed but, if found true, may provide the clinician with a clue as to expectations of the sedated child's behavior during routine restorative procedures.

The limitations of this study are consistent with the characteristics of retrospective studies. Several dental providers were involved in the pre-, intra-, and post-operative evaluations of the children and were not trained specifically for standardization of patient assessment congruent with a prospective study. However, all providers had a minimum of one year of pediatric dental training and extensive experience with the behaviors and characteristics of difficult to manage children. Likewise, detailed recording of every phase of treatment was sometimes compromised by the clinical demands of the sedation and acquisition of every potential data point was not always possible. Data were collected according to the AAPD guidelines for sedation, but disruptive clinical behaviors of the patient sometimes prevented data collection. The time of sedation for each visit was different because the sedative regimens have varying onset and working times and the children had varying personality characteristics. Neither patient nor provider was blinded to the agents being used and dosages were based on empirically derived factors and clinical experience.

Conclusions

Based on the results of this study the following conclusions can be offered.

1. The drug regimen that appears to maximize quiet and sleeping behaviors while producing more interactive and cooperative children is CH-D-H.
2. Children who preoperatively follow instructions are minimally predictive of intraoperative quiet and sleeping behaviors. Children who preoperatively refuse to follow instructions were minimally predictive of intraoperative crying and struggling.
3. Heart rate was consistent with the age of the children for the three drug regimens; however, heart rate increased significantly following local anesthesia, reflecting disruptive and crying behaviors in the M group.
4. Preoperative heart rate, in addition to patient age, seems consistent with the degree of child cooperation and interaction with dental personnel. Uncooperative children had higher heart rates and MAP pre- and intraoperatively.

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