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# The evaluation of child behavior during dental examination and treatment using premedication and placebo

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## Abstract

*The purpose of this study were to determine the association of scores on the North Carolina Behavior Rating Scale (NCBRS) to those of the Frankl scale during restorative visits; and to quantify and compare rated behavior of children during an oral examination and restorative visits involving either a placebo or a combination of chloral hydrate (CH) and hydroxyzine. Fifteen patients 21–37 months old participated in this institutionally approved study. The study was a double-blind, crossover design. Following an examination using a mirror, explorer, and prophylaxis cup, the child received either a placebo or a combination of chloral hydrate and hydroxyzine. The sequence was reversed at the next appointment. All exam and treatment visits were videotaped and analyzed using the NCBRS. In addition, all treatment visits were rated with the Frankl scale. The data were analyzed using a repeated ANOVA and correlation coefficients. The results showed a high interrater reliability (> 86% agreement) and a significant correlation between the NCBRS and Frankl scale ( $P < 0.001$ ). No significant difference was found for the amount of disruptive behavior among oral examination, placebo, and medication visits ( $P \leq 0.097$ ), although a consistent decrease in mean disruptive behavior for that order of visits was observed most frequently. The findings suggest the importance of rating behavior during a pretreatment visit before placebo or sedation visits. (Pediatr Dent 13:339–43, 1991)*

## Introduction

Several studies have investigated chloral hydrate's (CH) effect on children's behavior in the dental operatory (Evans et al. 1966; Robbins 1967; Tobias et al. 1975; Barr et al. 1977; Sheskin et al. 1983; Houpt et al. 1984; Houpt et al. 1985; Moody et al. 1986; Moore et al. 1986; Nathan 1987). A lack of consistency in behavioral measurements and research designs makes interpretation of CH's effect on behavior ambiguous. Two literature reviews that detail the shortcomings of the studies were published (Moore 1986; Nathan 1987).

Whitehead et al. (1988) are the only investigators who have reported the use of a rating scale (Frankl) in selecting patients for CH studies. They did not relate the children's behavior during premedication screening to that of the sedation period. Many studies have selected patients because of behavior that was "uncooperative," "apprehensive," or "difficult to manage" (Evans et al. 1966; Barr et al. 1977; Moody et al. 1986; Moore et al. 1986).

No studies have been reported that quantify behavior during an oral examination with mirror and explorer, and relate that to a subsequent restorative visit where a sedative agent is used. Similarly, no sedation studies have determined the degree of association between two behavior rating scales simultaneously used to evaluate behavior during a restorative visit.

The purposes of this study were to determine the degree of association of the North Carolina Behavior

Rating Scale (NCBRS) to the Frankl scale when both are used to evaluate the behavior of toddlers during restorative procedures; and to relate the rated behavior of children using the NCBRS during an oral examination to that during restorative visits involving either a placebo or a combination of CH and hydroxyzine in a crossover design.

## Materials and Methods

### Sample

Fifteen children between the ages of 21 and 37 months (mean  $29.53 \pm 4.01$  months), weighing between 11.4 and 15.5 kg (mean  $13.57 \pm 1.40$  kg) were involved in the study. All children were American Society of Anesthesia Class I and had nursing bottle caries that required at least two restorative visits. The children were referred to the study by pediatric dentists or residents who indicated that their behavior was "uncooperative."

### Clinical Procedure

A crossover, double-blind design was used in this study. Following parental consent of an institutionally approved protocol, the child's weight and vital signs were obtained, and an examination with a mirror and explorer and a rubber cup prophylaxis was performed with the parent present. Operators and assistants did not provide behavior guidance; this allowed a baseline of behavior representing the child's means of coping in

this situation to be established. Additionally, no restraints were used during this phase.

Each patient was assigned randomly to one of two groups. Group A received 40 mg/kg CH (Noctec<sup>®</sup>, E.R. Squibb and Co., Princeton NJ) and 2 mg/kg hydroxyzine pamoate (Vistaril<sup>®</sup>, Pfizer Inc., New York, NY) respectively) mixed with Tang<sup>®</sup> (Kraft General Foods, White Plains, NY) on the first visit and an equal volume of Tang<sup>®</sup> alone on the second visit. Group B received the reverse order. Both drug and placebo were administered blindly, then the patient and parent were taken to the waiting room for 45 min. The patient then was returned to the operatory, monitors were attached, and restorative dentistry was performed using local anesthesia.

During the restorative visit, the operator used tell-show-do and voice control to control behavior. If the child's behavior became excessively disruptive and repeatedly interfered with treatment, the child was restrained using a PediWrap<sup>®</sup> (Clark Association, Charlton City, MA). If this was insufficient, a Papoose Board<sup>®</sup> (Olympic Medical Group, Seattle, WA) was used.

After treatment, the child was returned to the parent and observed until stable. The child's behavior was videotaped during the oral examination and restorative visits.

### Rating of Behavior

Two trained raters performed the rating of recorded behavior. Oral examination and restorative visits were rated using the NCBRS (Chambers et al. 1981). The raters independently viewed the videotapes and recorded the occurrence of each of four disruptive behaviors (Table), every 10 sec. Subsequently, an overall score defined as per cent disruptive behavior (DB) was calculated by dividing the occurrence of the disruptive behavior by the total number of disruptive behaviors that could occur during each visit.

All treatment visits were rated for the first 30 min, beginning with placement of monitors on the patient, to allow for a relatively continuous assessment of behavior over time and dental procedures (e.g., administration of local anesthesia). Oral examination and prophylaxis visits were rated for their full duration, as this phase was brief (mean time = 3.55 min) and without the occurrence of a painful procedure.

The Frankl scale was used to rate patient behavior using categories of "definitely positive," "positive," "negative," or "definitely negative."

Each rater used the Frankl scale and the NCBRS to categorize the behavior over the entire treatment phase to compare the Frankl scale ratings with those of the NCBRS.

### Analysis

The association between rated behavior during the examination and restorative visits using the NCBRS was determined by a Pearson product-moment correlation coefficient. A contingency coefficient, a measure of relationship when at least one variable is nonparametric (i.e., Frankl scale), was used to determine the relationship between NCBRS and Frankl scales for behavior during placebo and medication visits.

Statistical analysis with a repeated measures ANOVA was performed to determine if significant differences existed in overall ratings of child behavior using the NCBRS among examination, medication, and placebo visits averaged across both raters.

## Results

### Interrater Relationships

The per cent agreement between raters using the NCBRS was 86.1%. When not in agreement, raters differed by one occurrence 94.1% of the time. A Pearson product-moment correlation coefficient analysis of the DB scores for the raters yielded an  $r = .994$  ( $P < .001$ ). The overall agreement between raters using the Frankl scale was 80%.

### Frankl and NCBRS Relationship

The association between NCBRS and Frankl scores for overall behavior during restorative phases of treatment was statistically significant for the medication (contingency coefficient = .8165,  $P < .001$ ) and placebo (contingency coefficient = .8864,  $P < .001$ ) visits.

The range of DB scores over all visits was 0 to 50.3. When the placebo and medication visits were considered together and both raters were in agreement, a DB score between 0 and 17.2 was rated "positive" on the Frankl scale for 15 visits. A DB score between 33 and 51 was rated "definitely negative" on four visits. DB scores between 20.8 and 32.7 were rated "negative" on four visits. The raters were split between ratings of "posi-

**Table. Modified North Carolina Behavior Rating Scale**

High hand movement	Hands or hand above level of armpits or arm extension angle less than 90° — physical restraints used
Leg movement	Any movement of the legs including kicking, lifting, postural change — physical restraints used
Crying	Crying, screaming, whining, asking for parents while crying
Oral physical resistance	Choking, gagging, coughing, spitting, clenching of teeth

tive"/"negative" for one visit when the DB score was 19.7. Also, they were split between "negative"/"definitely negative" when the DB score ranged from 25.8 to 31.7 (four visits). The remaining two visits did not fit into any scheme, as both raters gave Frankl ratings of "negative" and "positive" for DB scores of 15 and 28.3, respectively.

### Placebo vs. Medication

The mean DB scores for examination, placebo, and medication visits were 27.8 ( $\pm 20.3$ ), 20.3 ( $\pm 13.4$ ), and 14.8 ( $\pm 16.2$ ), respectively (Fig 1). A repeated ANOVA indicated that there was no significant difference in the averaged rated behavior among examination, placebo, and medication visits ( $F = 2.54$ ,  $df = 2$ ,  $P \leq 0.097$ ). Decreasing mean disruptive behavior in the order of examination, placebo, and medication visits was the most commonly observed pattern across patients (40%); however, other patterns were observed (e.g., 20% of the patients had more mean disruptive behavior during the placebo than either examination or medication visit).

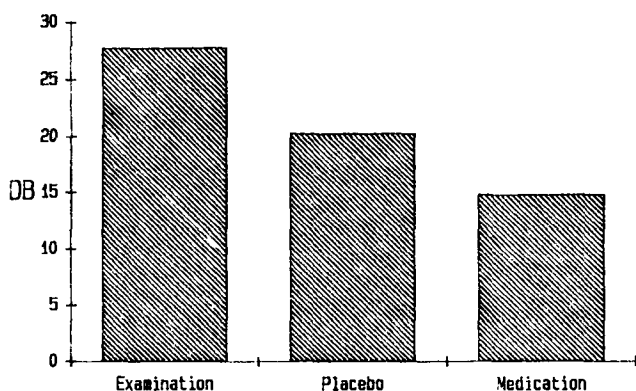


Fig 1. Mean disruptive behavior (DB) scores as a function of examination, placebo, and medication visits.

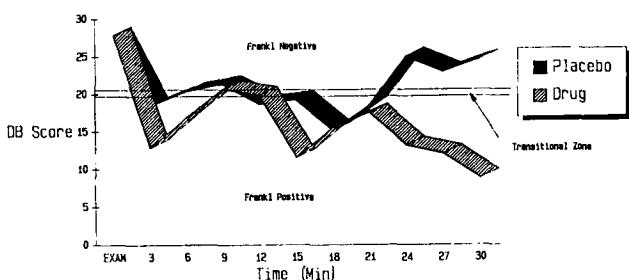


Fig 2. Disruptive behavior (DB) scores for placebo and medication visits as a function of time. DB scores below 19.7 were considered "positive" according to the Frankl scale. Frankl "negative" ratings were equivalent to DB scores of 21 or above. A transitional zone consisting of DB scores between 19.7 and 21 could not be consistently labeled as either "positive" or "negative" with the Frankl scale.

DB scores during placebo and medication visits revealed different behavioral trends over the first 30 min of treatment (Fig 2). For the initial 21 min, the trend in DB scores for placebo and medication visits was similar, although the medication visits appeared to show a slight lag phase compared to the placebo. After 21 min, a divergence in DB scores between these two groups occurred. Placebo DB scores began to rise and in general, corresponded to Frankl "negative" at approximately 22 min, reaching their peak at 24 min before leveling off. Medication DB scores continued to decline for the remainder of time that rating occurred. No significant difference was found in DB scores related to first and second visit, nor orders effect of placebo and medication visits.

## Discussion

### Interrater Relationships

The per cent of interrater agreement for all trials using the NCBRS was 86.1%; this is excellent, considering that at least 5400 time intervals were rated for the occurrence of specific behaviors. This percentage compares favorably to the interrater agreement ranging from 83 to 91% reported by Chambers et al. (1981) in their study describing the reliability of the NCBRS.

The degree of agreement between raters using the Frankl scale was comparable, but slightly less than that of the NCBRS. Since the Frankl scale was used to evaluate cumulative and generalized behavior occurring over an extended period of time, raters may have lost or collapsed information, or have been influenced by more extreme behaviors during their ratings. The very brief intervals during which the NCBRS was used to record occurrences of specific behavior would not be subject to this effect.

### Frankl and NCBRS Relationships

The highly significant relationship between Frankl ratings and DB scores provides a means to express, in a more global and descriptive fashion, the meaning of behavior rated in numerical units. A DB score ranging from 0 to 19 consistently was rated as "positive" behavior according to the Frankl scale, and would not be expected to interfere with the delivery of dental treatment.

A DB score greater than 25 is equivalent on the average to a minimum of one disruptive movement every 10 sec and corresponded to a "negative" or "definitely negative" Frankl rating. This would suggest that interfering movements occurring at a rate of at least six times per min are detrimental to the efficient delivery of dental care. The DB score of around 20 represented a transitional zone of behavior which was not easily rated as either "positive" or "negative."

## Medications vs. Placebo

No significant difference in overall DB scores for the examination, placebo, and medication visits was found. There was a 27.1 and 46.8% mean reduction in DB scores (*viz.*, a decrease in disruptive movements) for the placebo and medication visits, respectively, compared to the examination visit. This observation may justify a commonly held clinical impression that uncooperative children may behave better during sedation visits. Increasing the sample size may have lent support to such an impression.

It is possible that the reduction in disruptive behavior during the placebo visit compared to the oral examination was due to operator guidance of behavior during the former. This speculation cannot be concluded definitively because of the design of the study; direct comparisons between the examination visit and those of the restorative visits are not possible due to differences in procedures.

The additional reduction in DB scores of medication compared to placebo visits probably represents the added effect of the medication on the children's activity. However, it should be noted that some children had more disruptive behavior during the medication visit than either the placebo or examination visit. It has been our experience that CH can cause some children to become disruptive rather than sedated during treatment.

Behavior was rated for the first 30 min of each child's visit. The DB scores for the placebo and medication visits were similar for the first two-thirds of this period and then began to diverge. The DB scores during the medication visit continued to decline, indicating less behavioral responsiveness, whereas the placebo DB scores leveled off. This pattern probably represents the concentration of more stressful events (*e.g.*, injection, rubber dam placement, and initiation of drilling) in the earlier period of each visit, resulting in the children becoming tired or exhausted from their reaction to the stress. Thereafter, minimal stimulation and potentiation effects of the medication resulted in a less active reactive state (*i.e.*, sleep) compared to the placebo.

Although this study did not use the Frankl scale for rating the oral examination phase of the study, the mean DB score during this phase was 27.8. This would suggest that the mean behavior during the oral examination would have been classified as "negative." Support for this extrapolation is noted in that the children were referred by dentists who said the children's behavior was "uncooperative." Previous studies using CH have not attempted to quantify the degree of pre-treatment anxiety or disruptive behavior, with an exception involving monitoring (Whitehead *et al.* 1988). Further study of the variables influencing the child's

behavior during initial examinations, and their relationship to behavior during sedative trials is warranted.

It is possible that learning in this repeated measures design may have influenced the children's behavior. However, this seems unlikely, since no statistical difference was found between DB scores for first and second visits or for order effects of the medication and placebo visits. This supports the view of Kleinknecht *et al.* (1973) that younger children are not likely to benefit from sequential visits.

The age range of children in this study is narrow and representative of a "precooperative" child. This inclusion criterion would necessarily contribute to a homogeneity of behavior which may afford an increased probability of discriminating treatment effects. Rud and Kislning (1973) have shown that children with mental ages less than or equal to 29 months are less receptive to dental treatment than those with mental ages greater than 29 months. Additionally, they reported that children younger than 3 years old required 20% more time to accept dental treatment than children older than 3.

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- Barr ES, Wynn RL, Spedding RH: Oral premedication for the problem child: placebo and chloral hydrate. *J Pedod* 1:272-80, 1977.
- Chambers WL, Fields HW, Machen JB: Measuring selected disruptive behaviors of the 36- to 60-month-old patient. Part I: development and assessment of a rating scale. *Pediatr Dent* 3:251-56, 1981.
- Evans WO, Tannenbaum K, Turek B, Alling EF: A method for evaluating the use of premedicating agents in difficult pedodontic patients. *ASDC J Dent Child* 33:317-23, 1966.
- Haupt M, Koenigsberg S, Weiss NJ, Desjardins P: A comparison of chloral hydrate with and without promethazine in the premedication of young children. *Pediatr Dent* 6:176, 1984.
- Haupt MI, Sheskin RB, Koenigsberg SR, Desjardins PJ, Shey Z: Assessing chloral hydrate dosage for very young children. *ASDC J Dent Child* 52:364-69, 1985.
- Kleinknecht RA, Klepac RK, Alexander LD: Origins and characteristics of fear of dentistry. *J Am Dent Assoc* 86:842-48, 1973.
- Moody EH, Mourino AP, Campbell RL: The therapeutic effectiveness of nitrous oxide and chloral hydrate administered orally, rectally and combined with hydroxyzine for pediatric dentistry. *ASDC J Dent Child* 53:425-29, 1986.
- Moore PA, Mickey EA, Hargreaves JA, Needleman HL: Sedation in pediatric dentistry: a practical assessment procedure. *J Am Dent Assoc* 109:564-69, 1986.
- Moore PA: Pharmacologic research and methodologic needs for child dental patients. *Anesth Prog* 33:40-43, 1986.
- Nathan JE: Management of the refractory young child with chloral hydrate: dosage selection. *ASDC J Dent Child* 54:22-29, 1987.
- Robbins MB: Chloral hydrate and promethazine as premedicants for the apprehensive child. *ASDC J Dent Child* 34:327-31, 1967.
- Rud B, Kislning E: The influence of mental development on children's acceptance of dental treatment. *Scand J Dent Res* 81:343-52, 1973.

Sheskin R, Desjardins P, Houpt M, Koenigsberg S, Shey Z: Assessing chloral hydrate dosage for young children. *J Dent Res* 62:198 (Abstr 259), 1983.

Tobias MG, Lipschultz DH, Album MM: A study of three preoperative sedative combinations. *J Dent Child* 42:453-59, 1975.

Whitehead BG, Durr DP, Adair SM, Proskin HM: Monitoring of sedated pediatric dental patients ASDC *J Dent Child* 55:329-33, 1988.

## Toy labels should warn against choking hazard

Most toy warning labels don't specifically mention potential choking hazards, according to a study published in the *Journal of the American Medical Association*.

"With few exceptions, current warning labels on toys may not be sufficiently explicit to alert buyers of toys with small parts to the potential choking hazard to children under 3 years of age," wrote Jean A. Langlois, MPH, from The Johns Hopkins University Injury Prevention Center, Baltimore, MD with colleagues. As a result, parents and other toy buyers who read the label may erroneously interpret the age recommendation only as a guide to the age at which children might find the toy interesting or intellectually stimulating, and not as a warning.

In 1980, the Consumer Products Safety Commission (CPSC) issued its 'small parts' guidelines, which prohibit "the manufacture and marketing of toys to children below 3 years of age if the toys themselves or their detachable components fit the definition of small parts. To meet that standard, manufacturers generally place age labels on toy packages. However, there are no requirements for label contents, so potential choking hazards often are not mentioned.

The authors surveyed 199 toy buyers in a mall in Baltimore, MD. Participants were shown three commonly used warning labels: "Recommended for 3 and up;" "Not recommended for below 3;" and "Not recommended for below 3 — small parts."

After viewing each label, participants were asked if they would buy a toy bearing that label for a child between 2 and 3 years old.

Forty-four per cent said they would buy a toy with the first label for a child between 2 and 3, 8% would buy it with the second label, and 5% would buy it with the third.

"When shown label 1, only 7% of those surveyed said they would not buy the toy specifically because of concerns regarding small parts or safety," the authors noted. "However, when shown label 3, a total of 70% said that they would not buy the toy because of small parts or safety."

The authors recommended a change in the CPSC guidelines to require specific labeling, such as "Not recommended for children under 3 due to danger of choking from small parts." This labelling might significantly reduce inappropriate toy purchases without imposing substantial costs on the consumer, the government, or the manufacturer.