The effects of nitrous oxide on behavior and physiological parameters during conscious sedation with a moderate dose of chloral hydrate and hydroxyzine

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Abstract

The purpose of this study was to determine differences in heart rate (HR), blood pressure (BP), peripheral oxygen saturation (pO_2), expired CO_2 (CO_2), and behavior (using two scales) comparing nitrous oxide/oxygen (N_2O) with oxygen (O_2) alone in 20 children (mean age 45 ± 5.1 months) sedated with chloral hydrate (CH) and hydroxyzine in a double-blind crossover design. Administration of CH (40 mg/kg) and hydroxyzine (2 mg/kg) was held constant for each patient visit; however, N_2O (50%) was administered during one visit and O_2 (100%) at the other in a randomly determined manner. Physiologic and behavioral parameters were collected during eight specific procedural events (e.g., administration of local anesthesia). Data were analyzed with a repeated-measures ANOVA, one-way ANOVA, t-test, Kruskal Wallis ANOVA, and descriptive statistics. There was no statistically significant difference in any physiologic or behavioral parameter as a function of inhalation agent. However, significant differences were found for certain physiological parameters (i.e., HR [F = 5.41, P < 0.001], pO_2 [F = 6.04, P < 0.001], and CO_2 [F = 2.33, P < 0.027]) and all behavioral measures (% crying [F = 2.82, P < 0.008], % quiet [F = 5.38, P < 0.001], % movement [F = 3.88, P < 0.001], and % struggle [F = 2.83, P < 0.007]) of one scale (Ohio State University Behavioral Rating Scale [OSUBRS]) as a function of procedural events. Although no statistically significant differences were attributable to inhalation agent, evidence suggests that N_2O resulted in less crying and struggling and more quiet behaviors than O_2. Significant correlations existed between sub-categories of the two behavioral rating scales, suggesting some association between the scales. One may conclude from the results of this study that moderate doses of CH and hydroxyzine in combination with nitrous oxide are not associated with any significant potentiation effects on physiologic parameters compared with the same oral agents with oxygen alone. Certain procedural events (e.g., administration of local anesthesia) do result in patient responses that affect specific behaviors and physiology. Although the effects of N_2O may not be statistically significant, generally it produces an attenuation in physiological and behavioral responses as measured under the conditions of this study. (Pediatr Dent 18:35–41, 1996)

The most commonly used drug combination for the sedation of pediatric dental patients is CH and hydroxyzine supplemented with nitrous oxide (N_2O).[1,2] A variety of studies have evaluated pediatric dental sedations utilizing various drugs or drug combinations supplemented with N_2O.[3–13] All used sedative agents in doses consistent with the recognized upper limits of therapeutic ranges, and none reported any significant adverse effects despite some probability of such.

Few studies have focused on the effects of N_2O on behavioral and physiological responses in young children sedated with a combination of common sedative agents used in a relatively moderate dose range. In theory, under most circumstances, the addition of N_2O to a combination of sedative agents should result in the reduced need for higher doses of the other agents, attaining the same sedation end-point because of the potentiation effect of N_2O. Concerns of N_2O as a potentiating agent during pediatric dental sedations have become widely discussed in light of the recently revised American Academy of Pediatrics guidelines concerning sedation procedures.[14]

Houpt et al.[10] studied the effects of N_2O on CH sedation in 20 children, (mean age of 32 months) by evaluating behavior at two appointments. Patients randomly received 50 mg/kg CH dose as a sedative agent with either 50% N_2O/O_2 for the first 20 min of treatment then 100% O_2 for the remainder of treatment; or 100% O_2 for the first 20 minutes, switching to 50% N_2O/O_2 for the remainder. The alternate inhalation agent regimen pairing was used during the second appointment. Results indicated improved sedative effects in about half of

patients when N_2O was combined with CH. Behavior assessment involved a subjective rating scale for overall behavior during visits, which increased the likelihood of either a halo effect or a loss of procedurally related changes or both. Vital signs remained unchanged throughout treatment with the exception of slight pulse and respiratory rate elevations during episodes of increased oral stimulation (i.e., mouth prop insertion and local anesthetic administration). Similar physiologic responses have been noted in other studies.[4, 5, 15–17]

Shapira et al.[11] also reported behavior improvement in patients receiving N_2O during sedation in a study comparing the effects of hydroxyzine alone, hydroxyzine with N_2O, and N_2O alone. However, the effects on physiology were not addressed. The limited knowledge of potentiating effects of N_2O following administration of sedative agents warrants further investigation. To gain a better understanding of the effects of N_2O on physiologic and behavioral responses during sedations of young children, this study had the following objectives:

1. To monitor and evaluate physiologic functions (HR, BP, CO_2 levels, and pO_2) following a moderate dose of CH/hydroxyzine comparing N_2O with O_2 alone

2. To evaluate the quality of sedations, based on operationally defined patient behavior, following CH/hydroxyzine administration comparing N_2O with O_2 alone.

Methodology

Sample and design

Consent was obtained for 20 children (ages 36–60 months) to participate in this institutionally approved study. All were ASA class I, required more than one sedation visit for completion of operative dentistry, and exhibited a variety of the following behaviors during examination by a pediatric dentist or resident:

1. Failure to open mouth following directions to do so

2. Active attempts to escape from the dental chair

3. Extraneous flailing of arms or legs

4. Excessive interfering head movements.

A standardized dose of CH (40 mg/kg) and hydroxyzine (2 mg/kg) was used during each patient visit. N_2O was administered at a ratio of 50% nitrous oxide and 50% oxygen.

Physiologic monitoring included: Critikon Dinamap Vital Signs Monitor (Dinamap™, Tampa, FL), 1846SX (BP); Nellcor Pulse Oximeter and Printer (Nellcor®, Hayward, CA), Model N-100 and N-9000, respectively (HR and pO_2); Datex Carbon Dioxide Monitor (Datex™, Helsinki, Finland), Model 223 (CO_2). The Porter MXR nitrous oxide delivery system was used. Monitoring of behavioral patterns was carried out by vid-

eotaping each treatment session and analyzing the tapes later.

Patients were assigned randomly to one of two groups (A or B) in a double-blind cross-over design. At the first appointment, group A received CH (40 mg/kg) and hydroxyzine (2 mg/kg) PO, was observed for a 45-min latency period, then treated with N_2O via the nasal hood. Group B participants received equivalent dosages of CH and hydroxyzine PO, were also observed for a 45-min latency period, and were treated with 100% O_2 administration via the nasal hood. The alternate regimen was administered at the second appointment. Scheduled appointments were at the same time of day (8–12 am) and were no more than 4 weeks apart.

Preoperative steps

Baseline physiologic values (BP, HR, pO_2, and CO_2 levels) were obtained. The BP cuff was placed on the right arm, and the HR and pO_2 probe was affixed to the right index finger during baseline and the right middle toe during treatment. Baseline CO_2 values were obtained from a cannula in the right naris and recordings from patient's normal respiratory pattern. Treatment values were obtained similarly irrespective of regimen.

Parent or operator administered medications mixed with syrup and carbonated beverage. Parents and patient waited in the reception room for 45 min then a secondary operator escorted the child to the treatment room without the primary operator and started videotaping. Either N_2O (titrated initially, then to 50% at 5 L/min) or O_2 (100% at 5 L/min), depending on the child's assigned group, was started using tell-show-do and positive reinforcement. During this initial titration phase, the need for a Papoose Board™ (Olympic Medical Group, Seattle, WA) was determined based on the patient exhibiting one of the following three behaviors: 1) excessive struggling/fighting without use of voice control; 2) high hands and attempts to escape from the chair; or 3) arm and/or leg flailing/kicking that did not cease following tell-show-do or voice control requests. Patients were not wrapped in the Papoose Board unless behavior warranted it. The N_2O delivery system was placed out of view of the primary operator who returned to the treatment room and initiated treatment once the patient was stabilized.

Physiological parameters were recorded throughout the treatment session by automated monitor recorders and manually by another assistant. Operative or extraction procedures were limited to posterior quadrants and lasted approximately 60 min.

Data analysis

Behavior was rated and analyzed later based on the following eight segments of each session:

1. Start of videotape until topical application

2. Topical anesthetic application

3. Local anesthetic injection

4. Rubber dam placement

5. Initiation of operative procedures

6. 5 min following treatment initiation

7. 10 min following treatment initiation

8. 15 min following treatment initiation.

The study used the Ohio State University Behavior Rating Scale (OSUBRS), which involves four behavioral categories based on head or bodily movements, crying and oral/physical resistance as follows:

1. Q = quiet behavior, no movement

2. C = crying with no struggling

3. M = movement with struggling only, no crying

4. S = crying and struggling exhibited simultaneously, disruptive behavior. Struggling is defined as rapid or intense head, foot, or hand movements.

The Automated Counting System (ACS)™ (Version 1.0 JAGTECH, Rockville, MD) computer software program, was used to quantify behavioral categories by the rater who recorded each behavioral category by pressing its respective keyboard key (i.e., Q, C, M, S). Any change from one behavioral category to another was noted by pressing the appropriate key. Behavioral categories were mutually exclusive and only one was identified for any given time period. A computerized printout of data provided information on the frequency, duration, and mean duration of each category of behavior during any defined segment of the treatment session.

Previous studies indicated that intra- and inter-rater reliability as measured by a correlation analysis was 95–99%.[19,20] Intrarater reliability was measured by a random selection of three treatment visits, which were initially rated and, following the 20th rating session, rated again. Additionally, behaviors were rated intraoperatively by the operator or assistant using a simple ordinal scale that categorized behavior as either quiet, struggling, or crying. For statistical purposes, the following scores were assigned to the behavioral categories: 1 = quiet; 2 = struggling; and 3 = crying. These ratings occurred at every procedural event identified previously and referred only to the observed behavior at the time of the event.

The mean, standard deviation, and frequency distribution were used to characterize the age and sex of the sample population. Intrarater reliability was evaluated by t-test analysis comparing the first to the second rating for each behavioral category for the OSUBRS. A repeated-measures ANOVA was used to determine individual significant changes in the OSUBRS categories and physiological parameters across the eight procedural events as a function of inhalation agent (N_2O versus O_2). The nonparametric Kruskal-Wallis one-way ANOVA was utilized to analyze behavior ratings associated with the intraoperative ordinal scale. Finally, a correlation coefficient was used to determine any sig-

nificant association between the two behavioral rating scales used across the procedural events.

Results

Physiologic and behavioral data were collected from 40 sedation visits involving 26 males and 14 females, ages 36 to 55 months (mean = 45 months). Weight ranged from 13.0 to 20.5 kg (mean = 16.07 kg). Utilizing a set dosage per kg body weight for chloral hydrate (40 mg/kg) and hydroxyzine (2 mg/kg), the mean dosage administered was 637 mg and 32 mg, respectively.

Physiologic response

A repeated-measures ANOVA revealed no statistically significant differences in any physiologic parameter as a function of inhalation agent; however, significant differences for procedural events were found for HR ($F = 5.41$, $P < 0.001$), pO_2 ($F = 6.04$, $P < 0.001$), and CO_2 ($F = 2.33$, $P < 0.027$, see [Table 1]). Although no significant difference was found comparing inhalation agents, Figs 1 and 2 demonstrate generally that N_2O tended to have an attenuating effect compared with O_2 on mean HR and CO_2 (actually CO_2 was within normal limits compared with pO_2 which decreased due to crying), although not as consistent as the behavioral data.
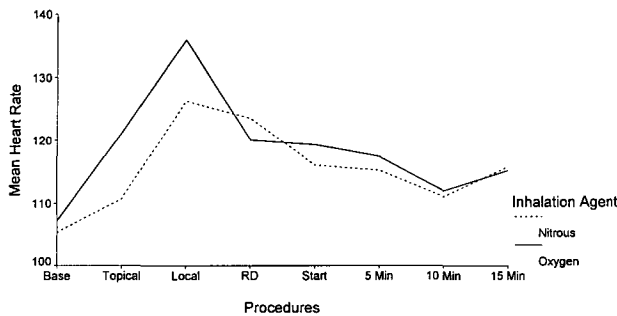
Behavioral response

Behavior categories of quiet (Q), crying (C), struggling (S), and movement (M) were quantified by a single rater viewing videotapes of each sedation appointment. A t-test comparing first and second reliability sessions for each behavioral category revealed no significant difference ($P = 0.05$).

Parameter	Variable	df	F-Value	P
Heart rate	N_2O	1	0.64	0.43
	Procedure	7	5.41	0.001*
	N_2O x Proc	7	0.63	0.63
Systolic BP	N_2O	1	0.09	0.76
	Procedure	7	1.77	0.093
	N_2O x Proc	7	0.078	0.078
Diastolic BP	N_2O	1	0.15	0.70
	Procedure	7	1.11	0.356
	N_2O x Proc	7	1.12	0.353
O_2 sat	N_2O	1	0.15	0.70
	Procedure	7	6.04	0.001*
	N_2O x Proc	7	0.72	0.658
Expired CO_2	N_2O	1	0.58	0.45
	Procedure	7	2.33	0.027*
	N_2O x Proc	7	0.98	0.44

TABLE 1. REPEATED MEASURES ANOVA OF PHYSIOLOGIC PARAMETERS AS A FUNCTION OF PROCEDURE AND INHALATION AGENT

* Significant.

Fig 1. Mean heart rate across procedures as a function of inhalation agent.
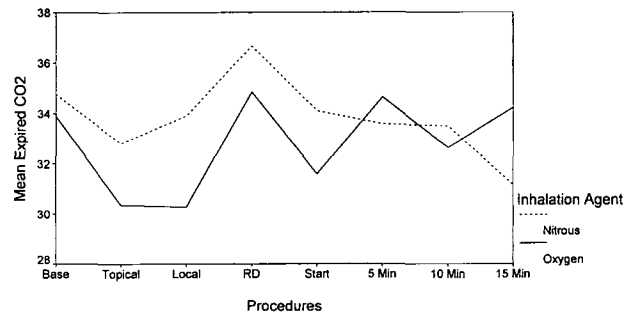
Fig 2. Mean expired CO_2 across procedures as a function of inhalation agent.

TABLE 2. MEAN (± SD) PERCENT BEHAVIORS OF OSUBRS* ACROSS PROCEDURES BY INHALATION AGENTS

	Baseline		Topical		Local		Rubber Dam		Start		5 Min		10 Min		15 Min	
Behavior	N_2O	O_2	N_2O	O_2	N_2O	O_2	N_2O	O_2	N_2O	O_2	N_2O	O_2	N_2O	O_2	N_2O	O_2
% Cry	8.3[†]	18.8	12.6	14.6	28.1	33.3	12.6	20.1	19.5	14.5	13.3	24.0	11.7	10.4	4.7	21.6
	18.0[‡]	25.6	28.9	31.6	31.3	31.8	29.8	35.9	35.0	30.0	28.1	35.9	27.4	25.9	13.4	34.4
% Movement	4.8	5.7	2.0	2.8	4.1	2.7	3.7	1.5	0.2	0.3	2.4	0.5	1.4	0.3	0.4	1.69
	6.7	6.0	6.5	9.9	8.8	5.0	9.8	5.0	0.9	1.6	5.8	2.1	4.5	1.4	1.1	4.3
% Quiet	85.1	70.3	81.9	72.6	51.7	47.6	74.0	72.2	75.2	78.5	82.4	66.8	83.2	84.6	94.5	73.7
	20.3	29.8	36.5	39.6	40.1	39.6	41.8	43.6	41.5	39.9	31.5	46.4	34.3	36.5	14.2	38.3
% Struggle	1.6	5.0	3.4	9.8	15.9	16.2	9.61	6.0	4.9	6.5	1.8	8.5	3.5	4.5	0.23	2.9
	5.1	8.5	10.5	29.5	26.0	24.0	25.4	17.2	16.7	15.9	5.1	18.0	9.75	11.9	1.0	6.4

Procedure

* Ohio State University Behavioral Rating Scale.
† Mean.
‡ SD.

Percent duration of each behavioral category of the OSUBRS was calculated. A repeated-measures ANOVA indicated that there were no statistically significant differences in any behavioral category as a function of N_2O versus O_2. However, significant differences for procedural events were found for all categories (%C [F = 2.82, P < 0.008], %Q [F = 5.38, P < 0.001], %M [F = 3.88, P < 0.001], and %S [F = 2.83, P < 0.007]). Table 2 shows a summary of the mean occurrence of each behavioral category over the rated procedural periods. Of note is the wide variability observed across all categories of behavior, especially for infrequently occurring behaviors (M and S).

Intraoperative behaviors were recorded, coincidental to physiological data, based on the following scale: 1 = Q; 2 = S; 3 = C (the scale was not evaluated for reliability). From these data, Kruskal Wallis one-way ANOVA revealed no statistically significant differences in behavior with respect to inhalation agent. However, Fig 3 demonstrates a lower mean score for the N_2O visit interpreted as more quiet behavior compared with O_2. There was a statistically significant and modest association between the categories of the OSUBRS and the simple clinical scale. Table 3 shows the correlation co-

efficients. The Papoose Board was required for 10 visits when N_2O was used and for 14 visits with O_2.

Discussion

We found no statistical difference between N_2O and O_2 conditions for the physiologic and behavioral parameters measured. Graphically, N_2O appeared to limit behavioral responsiveness and some physiological parameters and this trend may contribute to a common conviction that N_2O has beneficial effects during sedation. Certain physiological parameters and all behavioral categories of the OSUBRS were influenced significantly by procedural events.

Physiology

Although no statistical difference in physiological parameters as a function of inhalation agent was detected, a consistent trend was observed graphically for mean HR and CO_2. Data from this study suggest that N_2O decreases mean HR, and that pO_2 decreases mean CO_2 (due to crying) in response to procedural events. It is not likely that these trends were due directly to the pharmacologic action of N_2O alone. A slight depressing effect on myocardial contractility has been reported with N_2O, but N_2O in a therapeutic range used in den-

TABLE 3. CORRELATION COEFFICIENTS SHOW MODEST ASSOCIATION BETWEEN BEHAVIORAL CATEGORIES OF THE OSUBRS* AND THE SIMPLE CLINICAL SCALE

Behaviors	Baseline	Topical	Local	Rubber Dam	Start	5 Min	10 min	15 min
Crying	0.58[†]	0.67[†]	0.71[†]	0.82[†]	0.82[†]	0.34	0.73[†]	0.53[‡]
Struggle	0.21	0.39	0.36	0.71[†]	0.55[†]	0.33	0.66[†]	0.40
Quiet	-0.57[†]	-0.74[†]	-0.74[†]	-0.96[†]	-0.84[†]	-0.33	-0.73[†]	-0.52[†]

* Ohio State University Behavioral Rating Scale.
[†] $P < 0.001$.
[‡] $P < 0.01$.
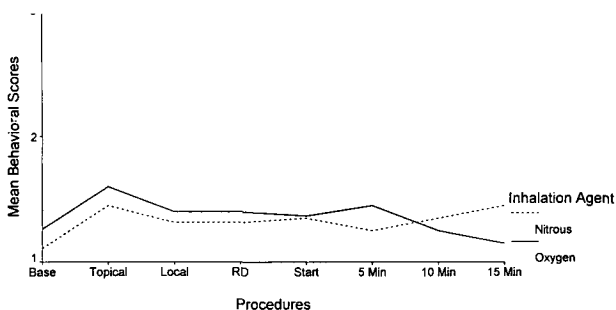
Fig 3. Mean behavior scores of simple clinical scale across procedures as a function of inhalation agent.

tistry has no known effect on HR or cardiac output.[21] More than likely, the observed mean physiologic parameters during N_2O conditions would not be attributed to direct cardiovascular depression, but to greater patient relaxation.

Minimal variability existed for pO_2 values and no desaturation episodes of clinical consequence (< 95%)[13, 22] were observed without simultaneous foot\toe movements in this study. Procedural effects did cause significant but clinically irrelevant fluctuations in pO_2. Patient movement has been shown to be a cause of false peripheral oxygen desaturations as measured by pulse oximetry.[23, 24] Because pO_2 normally demonstrates very little variability, minor fluctuations associated with conditions unrelated to pharmacological influence (e.g., Valsalva's maneuver and crying) can lead to erroneous and inappropriate conclusions.

Various studies have implicated advantages of sidestream capnography during pediatric dental sedations.[25-28] These advantages focus on the ability of capnography to detect apnea, airway obstruction and developing hypoventilation.[28, 29] Classical waveform patterns with normal respiratory rates are more typically observed in the quiet or sleeping patient. Changes in the waveform pattern can reflect many distinct conditions and require vigilance in monitoring. Any patient displaying waveform deviations was immediately postured with the head-tilt/chin-lift maneuver and evaluated with readjustments of the sampling port location in the naris or re-assessment of patient status. These precautions, along with 50–100% oxygen supple-

mentation, may have precluded desaturation episodes detected by pulse oximetry.

Slight differences in trends of CO_2 levels may be attributed to differences in clinical behavior (i.e., decreased means associated with increased crying bouts) rather than to pharmacologic-induced conditions. In this study, patterns of CO_2 levels in both N_2O and O_2 groups coincided with other physiological parameters measured and patient behavior, suggesting the latter's influence rather than a pharmacologic effect. These findings and interpretation support the findings of others.[17, 25]

HR and CO_2 monitoring are expected to best reflect children's responsiveness to procedures based on characteristics associated with stressful experiences. Salient stimuli will result in increased HR, the common mode of cardiovascular response to perceived stressful conditions in young children. Similar trends in clinical behavior have been reported by Houpt et al.[10] Likewise, under such conditions, children also respond by crying, resulting in decreased CO_2 concentration due to oral shunting of expired air.

Behavior

Compared with O_2 alone, improved clinical behavior was observed during N_2O visits in the categories of crying, quiet, and struggling. Movement occurred infrequently and was essentially equivalent for both agents. Fewer patients required restraint in the Papoose Board with N_2O compared with O_2. Increased Q and decreased C behaviors in the majority of patients occurred when N_2O was used. From a clinical standpoint, the results indicate N_2O used in combination with a modest dose of CH and hydroxyzine may improve intraoperative behavior for patients 36–60 months of age without significantly affecting physiologic function.

In a dose-response study, Wilson[17] found that during low doses of CH, accentuated physiologic responses notably occurred during local anesthetic injection and/or tooth preparation, but responses were dampened as doses increased. This observation was attributed to a deeper level of sedation imparted by increased CH dosage. He noted that significantly high doses of CH would be necessary to overcome more discomforting stimuli of certain dental procedures in many young children and that such a practice may lead to deep sedation, compromising patient safety.

Results of this study indirectly suggest that improved responses to procedures may not require significantly higher doses of CH. Although no statistical difference was detected as a result of inhalation agent, definitive clinical conclusions should be cautioned because of wide variation in patient responses (i.e., large standard deviations of the mean percent of each behav-

ioral category of the OSUBRS) and operator expectations. This study concurs with findings by Houpt et al.,[10] which imply that N_2O does improve behavioral responses to stimuli in some individuals (viz., sedation augmentation was not consistently observed among subjects). Larger sample sizes, more refined patient selection techniques, and more sensitive behavioral and physiologic measures might demonstrate both clinical and statistically significant differences.

Although no scales were used in this study to rank sedation in terms of success/failure, the high percentage of quiet behavior (compared with crying, struggling, and movement) is an indirect indication that sedation efforts were effective, regardless of inhalation agent used. Treatment planned for each visit was completed without compromise; no physiologic aberrations were observed; and no vomiting occurred intraoperatively. Furthermore, no postoperative complications were noted or reported by parent/guardian.

One interesting finding was the association between the OSUBRS and a clinically relevant and simple technique of rating behavior. Correlations between the two scales involving Q and C categories were high and modest with S as a function of procedural events. Since the OSUBRS requires the tedious and costly procedure of videotaping and playback review, a simple technique such as rating behavioral response for each procedure occurring as either quiet, crying, or struggling may be economically advantageous and more feasible. It is not clear how much information is "lost" because only a brief moment in time is rated for the simple clinical rating scale, whereas the OSUBRS collects raw data continuously. It's analogous to the situation of comparing the output of an automated BP cuff set to record BP and HR every 5 min with that of continual output of HR and pO_2 of a pulse oximeter. In the former, a significant amount of information is not retrievable. Further study into this issue is warranted.

Conclusions

In pediatric dental sedations, utilizing 40 mg/kg CH plus 2 mg/kg hydroxyzine:

1. No physiologic parameters were significantly affected by the addition of inhalation agents to a dose of chloral hydrate and hydroxyzine in the moderate therapeutic range

2. HR, pO_2, and CO_2 were affected significantly by dental procedures. HR increased and CO_2 decreased reflecting patient discomfort and crying, particularly during procedural phases of injection and tooth preparation

3. OSUBRS categories of percent crying increased during O_2 visits while percent quiet increased during N_2O visits. A simple clinical rating scale correlated well with the OSUBRS and reflected similar changes.

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