

EFFICACY OF TRIMEPRAZINE TARTRATE IN BEHAVIOR MANAGEMENT OF UNCOOPERATIVE PEDIATRIC DENTAL PATIENTS

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أجريت هذه الدراسة الإكلينيكية للتحقق من تأثير جرعات مختلفة من المهديء طرطرات ثلاثي المبرازين (الفالرجان) على سلوك الأطفال الخائفين وغير متقبلين لعلاج الأسنان.

أختير الأطفال من العيادات الخارجية لكلية طب الأسنان - جامعة الملك سعود وكان من شروط الاختيار أن يكونوا أصحاء وغير متقبلين لعلاج الأسنان وتراوح أعمارهم بين ثلاثين وستين شهراً.

أخذت موافقة كتابية من أولياء الأمور على علاج أطفالهم واستخدام عقار الفالرجان كمهديء بعد شرح تأثيره على سلوكهم. وأعطيت لهم التعليمات التي يجب اتباعها قبل وبعد العلاج.

قسم الأطفال إلى ٥ مجموعات بطريقة عشوائية وخصصت جرعة معينة من المهديء لكل مجموعة ولم يكن للطبيب المعالج أي خلفية عن الجرعة المعطاة لكل طفل.

أعطيت التعليمات لأولياء الأمور بعدم إطعام الطفل لمدة ٦ ساعات قبل الموعد.

في يوم العلاج تم وزن الأطفال وقيس كل من ضغط الدم والنبض وتركيز الأكسجين في الدم الشرياني.

أعطى المهديء عن طريق الحقن أو عن طريق الفم بكميات قليلة ثم ترك الطفل مع والديه في غرفة هادئة ولمدة ساعتين. وفي خلال هذه الفترة دونت تصرفات الطفل وبدأ نومه. عند استغراق الطفل في النوم نقل إلى غرفة العلاج وأخذت قياسات للمؤشرات الحيوية باستخدام جهاز الديناماب ثم قيدت حركة الطفل جزئياً باستخدام غطاء حوله.

كان التخدير الموضعي المستخدم لكل الأطفال هو ليدوكائين ٢٪ مع ابنفرين تركيز ١ : ٨٠٠٠٠٠، كما استخدم الحاجز المطاطي للفم، ثم عولج جميع الأطفال بواسطة طبيب واحد.

كما تم تقييم تأثير المهديء على تصرفات الأطفال بواسطة طبيب متدرب على القياسات واستخدمت طريقة هويت لرصد القياسات جدول ١، ٢، ٣.

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لتقدير درجة النوم، البكاء أو الحركة أثناء كل من العمليات التالية:

- ١ - قبل العلاج مباشرة .
- ٢ - أثناء حقن المخدر الموضعي .
- ٣ - أثناء وضع العازل المطاطي .
- ٤ - أثناء حفر السن .
- ٥ - أثناء الحشو .

بعد الانتهاء من العلاج قام الطبيب المعالج بتقييم نجاح أو فشل المهديء المعطىء لتمام العلاج .

* دلت النتائج على أن سلوك الأطفال تحسن لدى ٨٨٪ من الأطفال الذين تناولوا جرعة ٤ مجم /كجم من وزنهم و ٧٥٪ من الأطفال الذين تناولوا جرعة ٥ , ٣٪ مجم /كجم و ٣٨٪ من الأطفال الذين تناولوا ٣مجم /كجم . أما جرعة ٥ , ٢ /كجم فلم يكن لها أي تأثير على سلوك الأطفال .

لم يكن للمهديء أي تأثير على نبضات القلب أو تركيز الأكسجين في الدم أو ضغط الدم .

لوحظ زيادة في نبضات القلب عند البدء في كل من العمليات التالية :
الحقن ، وضع الحاجز المطاطي ، البديء في حفر الأسنان .

This study was carried out to determine the effectiveness of different doses of trimeprazine tartrate (Vallergan®) when uncooperative and fearful children were sedated for dental treatment, Thirty children took part in the study, ranging in age from 30 months to 60 months with a mean age of 42.8 months. The subjects were randomly assigned to receive 0.0 mg, 2.5 mg, 3.0 mg, 3.5 mg and 4.0 mg of the medication per kilogram body weight, respectively, Behavior was assessed in terms of the degree of sleep, crying and body movements during specific treatment procedures. Significant improvement in behavior as evidenced by tack of crying and/or body movement in which interrupted treatment was found in 88% and 75% of the children administered 4.0 mg and 3.5 mg, respectively in contrast to 38%, 0% and 0% of those administered 3.0 mg, 2.5 mg and 0.0 mg of trimeprazine, respectively. No significant effect on vital signs was observed during the course of treatment.

Introduction

The provision of qualitative dental care for the fearful or uncooperative child can be an arduous task for the pediatric dentist. When conventional behavior modification techniques do not achieve satisfactory control of the patient's behavior, pharmacologic sedation is frequently used. The aim of using sedatives is to diminish anxiety, hence promoting behavior that will facilitate provision of dental care and help the child to get through a difficult treatment without a negative psychological response.¹

Drugs used to premedicate a child patient may be administered orally, parentally or submucosally. Due to its relative simplicity, oral administration is most often sued. It is the oldest, safest, most

convenient and most economic route for drug administration.² It is also reported to have low incidence of adverse reactions.² The main disadvantages include unpredictable absorption rate of drugs from the gastro-intestinal tract which may affect the adequacy of the therapeutic effect, inability to readily lighten or deepen the level of sedation and dietary restrictions.^{2,5} Other disadvantages include prolonged duration of anxiety, reliance on patient compliance and patient cooperation.

Sedative-hypnotic, anxiolytic or narcotic agents have been used by several investigators to control inappropriate behaviors in children during dental treatment. There is apparently no consensus among pediatric dentist as to which drug or combination of drugs produces the best effects. However, any drug required for premedication should,

among other things, (a) alter the mood of patient so that the child is more receptive to dental procedures, (b) minimally depress the level of consciousness for the patient to retain ability to maintain a patent airway, respond appropriately to physical stimulation or verbal command, and (c) maintain normal and stable vital signs.^{6,7}

Trimeprazine tartrate (Vallergran®)* is a phenothiazine derivative antihistamine which is also a sedative-hypnotic. It has weak anti-cholinergic action and slight anti-emetic and anti-muscarinic effects. It is well absorbed when taken orally with onset of action within 15-60 minutes and takes 1-2 hours to attain peak effect.⁸ It also has a wide safety margin.⁸ It has been widely used as preoperative medication for children to induce sedation in patients undergoing ENT surgery since the late 1950's when it was introduced to clinical practice.⁹⁻¹² Adverse effects, such as CNS depression, hypotension and bradycardia resulting from high doses have been reported.¹³ Many investigators have used different dosages ranging from 2 mg/kg to 6 mg/kg body weight^{10-12,14,15} and each had reported varying degrees of success. For sedative and hypnotic effects, doses of 2 mg/kg and 4 mg/kg body weight, respectively, have been suggested.^{16,17} Davis and Dougherty¹⁸ reported that sedation was unreliable with a dose of 2.2 mg/kg body weight when given with hyoscine as premedication.

All previous investigations were aimed at the effectiveness of trimeprazine as preoperative sedation in children before induction of anesthesia in ENT surgery. Although the drug is also used as oral premedication for fearful and uncooperative children seeking dental treatment, the sedative efficacy and optimal dose appear not to have been established in any clinical studies.

The objective of this study was to evaluate the changes in behavior of uncooperative pediatric dental patients who had received one of the four doses of trimeprazine or a placebo in order to verify the efficacy and establish an optimal dose to use for dental procedures. Adverse effects, rate of recovery and details of vital signs would appear in our next report.

Materials and Methods

The subject consisted of thirty children with ages ranging between 30 and 60 months. They were selected from the pediatric dentistry clinic at the Dental College of the King Saud University. The children were from a group of patients who, during screening or first appointment procedures, were considered to require treatment with sedation due to their uncooperative behavior. All children fell within the American Society of Anesthesia (ASA) Class 1 anesthesia risk. Parental consent was obtained for all sedation procedures after which written pre- and post-appointment instructions were given to each patient.

On the appointment day, each child was required to have nothing by mouth (NPO) for 4-6 hours before the appointment. Preoperative assessment was carried out by the attending anesthetist. The patients were weighed and baseline values were obtained for the blood pressure, pulse rate and oxygen saturation (SaO₂) for each child. The children were randomly assigned to one of the five study groups made up as follows:

Group A	Control	(mixed fruit juice)
Group B	2.5 mg/kg	trimeprazine tartrate syrup
Group C	3.0 mg/kg	trimeprazine tartrate syrup
Group D	3.5 mg/kg	trimeprazine tartrate syrup
Group E	4.0mg/kg	trimeprazine tartrate syrup

The medication was dispensed in a cup but where the child refused, a syringe was used and the medication was carefully deposited in the back of the mouth in small quantities to avoid aspiration but allowed swallowing and prevented spitting. After drug administration, the child was left with parent in a quiet room during which behavior and onset of sleep (defined as closure of eyes and lack of visible movement) were evaluated. Two hours following drug administration, the child was taken into the operatory and restrained after the monitors were placed. Vital signs were monitored and recorded during the course of treatment using Dinamap 1846 SX vital signs monitor with Oxytrak pulse oximeter*.

Local anesthetic was administered using 2% lidocaine (maximum dose of 3.8 mg/kg body weight) with 1:80,000 epinephrine after which the

* May and Baker Ltd, Dagenham, Essex, England. The Saudi Dental

* Critikon, Tampa, Florida, USA.

rubber dam was placed and treatment started. All restorative procedures were carried out by the same operator.

Evaluation

The child's behavior was evaluated by a trained observer using a scoring system suggested by Houpt *et al*⁹ (Tables 1, 2 and 3). Rating scales were used to evaluate degrees of sleep, crying and head or body movements during each of the following five specific treatment procedures.

1. Preoperative (2 hours after drug administration)
2. During local anesthetic injection
3. During rubber dam placement
4. During cavity preparation
5. During filling and carving

At the end of each session, a subjective appraisal of the overall quality of the sedation was made by the operator (who was blind to the dose of medication given) to determine the relative effectiveness of the premedication. A four-point scale was used with one being the worst and four, the ideal (Table 4). Since ordinal scale of measurement was used in the rating scale, the effectiveness of sedation of different dosages of Vallergran® as measured by the degree of crying and body movement which interfered with treatment was analyzed using the nonparametric Friedman two-way analysis of variance by ranks.

Results

Ten of the patients required additional visit to complete their treatment, hence, a total of 40 sedations were carried out and analyzed. The distribution of patients by age, weight and sex is given in Table 5.

The mean age and weight for all subjects combined were 42.8 months and 14.7 kg, respectively. There were no significant differences for these parameters among any of the study groups.

Table 1. Rating scale for sleep.

	Score
Fully awake, alert	1
Drowsy, disoriented	2
Asleep but easily aroused	3
Deep sleep, difficult to arouse	4

Table 2. Rating scale for crying.

	Score
Hysterical crying that demands attention	1
Continuous crying that makes treatment difficult	2
Intermittent mild crying that does not interfere with procedure	3
No crying	4

Table 3. Rating scale for movement.

	Score
Violent movement, interrupting treatment	1
Continuous movement, making treatment difficult	2
Controllable movement that does not interfere with procedure	3
No movement	4

Table 4. Rating scale for overall behavior.

	Score
Very bad - treatment aborted or interrupted and only partial treatment rendered	1
Bad-treatment interrupted but eventually all completed	2
Good-moderate crying or movements which did not interrupt treatment	3
Very good - no crying or movement, or some limited crying or movement, e.g. during anesthesia	4

Evaluation of Sleep

There was a significant difference in ratings for sleep between the groups that received different drug regimens (Table 6). Two hours following drug administration, all the eight subjects (100%) in Group A were fully awake. In Group B, one patient (13%) was awake; five (63%) were drowsy and two (25%) fell asleep. In each of Groups C and D, two patients (25%) were drowsy and six (75%) fell asleep. In Group E, only one patient (13%) was drowsy, all other seven (88%) fell asleep. The averages of the mean ratings during the 5-period evaluation were 1.00, 1.43, 2.35, 2.65 and 2.90 for Groups A, B, C, D and E, respectively.

Evaluation of Crying

The summary of ratings of crying for all subjects in the operatory is shown in Table 7. Over 80% of the patients in Groups D and E did not cry or cried

Table 5. Age, weight and sex of subjects.

Treatment Groups	Age (months)		Weight(kg)		Sex	
	Mean	Range	Mean	Range	Male	Female
0.0 mg/kg (control)	43	46-48	15.1	12-17	3	5
2.5 mg/kg	41	30-60	14.7	12.1-17	4	4
3.0 mg/kg	42	30-54	14.7	12-18	5	3
3.5 mg/kg	45	30-60	14.5	10-17.4	5	3
4.0 mg/kg	43	30-58	14.4	12-20	4	4

Table 6. Summary of ratings of sleep during treatment.

Time	Regimen	1	2	3	4	Mean Rating**
		Fully awake	Drowsy	Light Sleep	Deep Sleep	
Preoperative	A	8(100)*	-	-	-	1.00
	B	1(13)	5(63)	2(25)	-	2.13
	C	-	2(25)	6(75)	-	2.75
	D	-	2(25)	6(75)	-	2.75
	E	-	1(13)	7(88)	-	2.88
During LA	A	8(100)	-	-	-	1.00
	B	5(63)	3(38)	-	-	1.38
	C	1(13)	3(38)	4(50)	-	2.38
	D	-	2(25)	6(75)	-	2.75
	E	-	1(13)	7(88)	-	2.88
During RD	A	8(100)	-	-	-	1.00
	B	5(63)	3(38)	-	-	1.38
	C	1(13)	3(38)	4(50)	-	2.38
	D	-	2(25)	6(75)	-	2.75
	E	-	1(13)	7(88)	-	2.88
During cavity preparation	A	8(100)	-	-	-	1.00
	B	7(88)	1(13)	-	-	1.13
	C	1(13)	4(50)	3(38)	-	2.25
	D	1(13)	2(25)	5(63)	-	2.50
	E	-	-	8(100)	-	3.00

*** Pooled rating: A = 1.00^a; B= 1.43^a; C = 2.35^b; D = 2.65^b; E = 2.90^b

* Number of subjects receiving this rating, bracketed number = percentage of total (may not equal 100% due to rounding)

** Mean rating for all subjects in each group

*** Pooled rating for all subjects during the treatment procedures

Regimen A: 0.0 mg/kg trimeprazine (control); Regimen B: 2.5 mg/kg; Regimen C: 3.0 mg/kg; Regimen D: 3.5 mg/kg; Regimen E: 4.0 mg/kg

Statistics: Friedman ANOVA by ranks at 0.05 level of significance, a & b denote different levels of significance.

wildly and intermittently which did not interfere with treatment. Continuous and persistent crying which demanded the operator's attention was recorded in 30% of the patients in Group C and over 90% of the patients in Groups A and B. The averages of the mean ratings over the period of treatment for Groups A, B, C, D and E were 1.56, 1.68, 2.53, 2.32 and 3.70, respectively. Statistical analysis showed that only Groups D and E were significantly different from others ($df = 2$; $F = 2.49$) (Table 7).

Evaluation of Movement

Table 8 indicates the mean ratings of movement of all subjects during treatment. In Group A, more than 90% of the patients exhibited violent or uncontrollable movements which made treatment difficult and, in most cases, treatment had to be aborted. In Group B, 87% of the patients made continuous movements which interfered with treatment while movements in 13% of the cases were intermittent and controllable. In Group C, movements in 50% of the cases were mild and controlla-

Table 7. Summary of ratings of crying during treatment.

Time	Regimen	1 Hysterical Crying	2 Continuous Crying	3 Intermittent Crying	4 No Crying	Mean Rating**
Preoperative	A	2(25) ^a	6(75)	-	-	1.75
	B	-	5(63)	3(38)	-	2.38
	C	-	2(25)	1(13)	5(63)	3.38
	D	-	1(13)	3(38)	4(50)	3.38
	E	-	-	1(13)	7(88)	3.38
During LA	A	5(63)	3(38)	-	-	1.38
	B	3(38)	5(63)	-	-	1.63
	C	1(13)	4(50)	3(38)	-	2.25
	D	-	2(25)	6(75)	-	2.75
	E	-	-	7(88)	1(13)	3.13
During RD	A	5(63)	3(38)	-	-	1.38
	B	4(50)	4(50)	-	-	1.50
	C	1(13)	4(50)	3(38)	-	2.25
	D	-	1(13)	7(88)	-	2.88
	E	-	1(13)	3(38)	4(50)	3.76
During cavity preparation	A	5(63)	3(38)	-	-	1.38
	B	5(63)	3(38)	-	-	1.38
	C	1(13)	5(63)	2(25)	-	2.13
	D	-	2(25)	1(13)	5(63)	3.38
	E	-	-	2(25)	6(75)	3.75
During filling and carving	A	2(25)	5(63)	1(13)	-	1.88
	B	5(63)	2(25)	1(13)	-	1.50
	C	2(25)	1(13)	3(38)	2(25)	2.63
	D	1(13)	1(13)	-	6(75)	3.76
	E	-	-	-	8(100)	4.00

*** Pooled rating: A = 1.56^a; B = 1.68^a; C = 2.53^b; D = 3.23^b; E = 3.70^b

* Number of subjects receiving this rating, bracketed number = percentage of total (may not equal 100% due to rounding)

** Mean rating for all subjects in each group

*** Pooled rating for all subjects during the treatment procedures

Regimen A: 0.0 mg/kg trimeprazine (control); Regimen B: 2.5 mg/kg; Regimen C: 3.0 mg/kg; Regimen D: 3.5 mg/kg; Regimen E: 4.0 mg/kg

Statistics: Friedman ANOVA by ranks at 0.05 level of significance, a & b denote different levels of significance.

Table 8. Summary of ratings of movement during treatment.

Time	Regimen	1 Violent Movement	2 Continuous Movement	3 Controllable Movement	4 No Movement	Mean Rating**
Preoperative	A	1(13)*	6(75)	1(13)	-	2.00
	B	-	5(63)	3(38)	-	2.38
	C	1(13)	-	4(50)	3(38)	3.13
	D	-	1(13)	2(25)	5(63)	3.50
	E-	-	-	8(100)	4.00	
During LA	A	6(75)	2(25)	-	-	1.25
	B	3(38)	4(50)	1(13)	-	1.75
	C	-	6(75)	2(25)	-	2.25
	D	-	1(13)	7(88)	-	2.88
	E	-	-	3(38)	5(63)	3.38
During RD	A	6(75)	2(25)	-	-	1.25
	B	4(50)	4(50)	-	-	1.50
	C	-	5(63)	2(25)	1(13)	2.50
	D	-	2(25)	3(38)	3(38)	3.13
	F	-	-	4(50)	4(50)	3.50
During cavity preparation	A	6(75)	2(25)	-	-	1.25
	B	4(50)	4(50)	-	-	1.50
	C	2(25)	4(50)	2(25)	-	2.00
	D	-	1(13)	3(38)	4(50)	3.38
	E	-	-	2(25)	6(75)	3.75
During filling and carving	A	3(38)	4(50)	1(13)	—	1.75
	B	3(38)	4(50)	1(13)	-	1.75
	C	-	2(25)	4(50)	-	3.00
	D	-	1(13)	1(13)	6(75)	3.63
	E	-	-	1(13)	7(88)	3.88

*** Pooled rating: A = 1.50^a; B = 1.76^a; C = 2.58^a; D = 3.30^b; E = 3.70^b

* Number of subjects receiving this rating, bracketed number = percentage of total (may not equal 100% due to rounding)

** Mean rating for all subjects in each group

*** Pooled rating for all subjects during the treatment procedures

Regimen A: 0.0 mg/kg trimeprazine (control); Regimen B: 2.5 mg/kg; Regimen C: 3.0 mg/kg; Regimen D: 3.5 mg/kg; Regimen E: 4.0 mg/kg

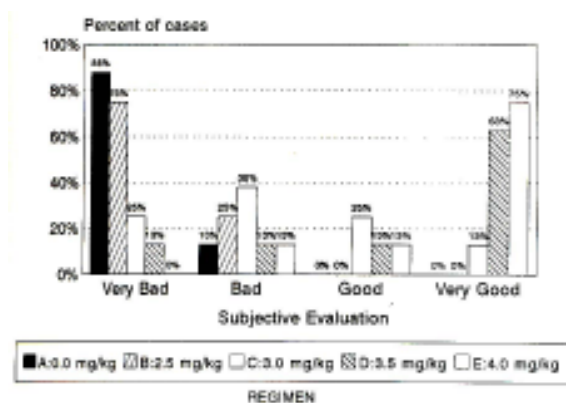
Statistics: Friedman ANOVA by ranks at 0.05 level of significance, a & b denote different levels of significance.

ble while for Groups D and E, the values were 85% and 100%, respectively. The averages of the mean ratings of Groups A, B, C, D and E were 1.50, 1.76, 2.58, 3.30 and 3.70, respectively. Friedman two-way analysis of variance by ranks indicated Groups D and E as being significantly different from others (df = 2; F = 2.63)

Overall Evaluation of Behavior

Most subject in Groups D and E were classified as good or very good and less than 20% were classified

as bad or very bad (i.e., behavior was difficult and treatment aborted or partial treatment rendered). In Group C, 38% of the patients experienced good or very good effects of the sedation with more than 60% as bad or very bad. Virtually, all subject in Groups A and B were classified as bad or very bad [Fig. 1]. The average of the mean ratings for the drug regimens A, B, C, D and E were 1.13, 1.25, 2.20, 3.25 and 3.75, respectively. Only groups D and E showed significant differences among the groups as indicated by Friedman analysis.



Regimen A: 0.0 mg/kg trimeprazine (control)

Figure 1. Overall evaluation of behavior.

Vital Signs

The systolic and diastolic pressures, pulse rate and oxygen saturation were recorded and evaluated overtime and in relation to the dose of VallerGAN®. Initial drop in blood pressure was observed two hours following drug administration but later rose during the treatment procedures. On the average, no significant changes were observed in the vital signs except for the pulse rate which increased significantly (Table 9) during periods of stimulation, such as local anesthetic injection, rubber dam application and cavity preparation. The changes returned to normal as soon as the stimulus discontinued.

Table 9. Average pulse rate.

Regimen	PUISE RATE (beats/min.)			
	Baseline		During Procedure	
	Mean ± SD	Range	Mean±SD	Range
A	110 + 8	105-129	143 ±6*	133-153
B	117 = 7	109-129	142 ±8*	131-155
C	111 ±15	89-135	144 + 12*	123-160
D	107±13	94-131	137 + 5*	120-149
E	106+ 11	91-120	130 + 9*	125-144

Regimen A: 0.0 mg/kg trimeprazine (control); Regimen B: 2.5 mg/kg trimeprazine; Regimen C: 3.0 mg/kg trimeprazine; Regimen D: 3.5 mg/kg trimeprazine; Regimen E: 4.0 mg/kg trimeprazine

Statistics: One way ANOVA and least significant multiple range test *P<0.05.

Discussion

The result of this study indicated that 3.5 mg/kg and 4.0 mg/kg dosage level of trimeprazine produced significant improvement in the behavior of uncooperative pediatric dental patients than doses of 3.0 and 2.5 mg/kg. Of the sedation with 4.0 mg/kg, 88% (7 out of 8) were judged as good or very good, compared to 75% for the 3.5 mg/kg dose. In contrast, 63% of the cases with 3.0 mg/kg dose and all cases with 2.5 mg/kg and the control group were judged as bad or very bad.

Unlike in the control group, all patients in the experimental group were either drowsy or in light sleep just before the operative procedure started. However, the 2.5 mg/kg dose was only able to make the patients drowsy but not enough to calm them down for treatment to be carried out. The greater effect of sedation became more evident when the degree to which crying and body movement interfered with treatment and the amount of work accomplished at each dosage level was evaluated. The state of hypnosis created by the higher dosages of trimeprazine resulted in little or no movements as well as crying by the subjects which could interrupt treatment. A lower dose of the medication could not provide similar effect. The results were similar to those reported by Layfield and Walker,⁹ Van der Walt *et al*¹¹ and Davis and Doughty¹⁸ although their studies were aimed at the effectiveness of trimeprazine as preoperative sedation before induction of general anesthesia. The present study was intended to evaluate its use as a sedative in children undergoing dental treatment.

Unexpected, however, was the findings that there was no significant difference in the pulse rate recorded during the procedure between the different treatment groups. One would have expected a significant decrease in the average pulse rate corresponding to the level of sedation provided by the 3.5 mg/kg and 4.0 mg/kg doses as against the control group. It is quite possible that deeply sedated children who are disturbed or exposed to noxious stimuli, such as local anesthetic injection or cavity preparation, tend to be irritable once aroused. This could result in increased amount of sympathetic nervous system activity as well as the release of

catecholamines which could sustain the high pulse rate despite the level of sedation. The fact that the average pulse rate recorded during the procedure is significantly higher than baseline values indicate that the medication has a poor anti-anxiety effect even though it is a good sedative.

Further studies are needed to compare the efficacy of this medication with other well established oral premedications such as chloral hydrate.

Conclusion

The results of this study demonstrate that trimeprazine tartrate at a dosage level of 3.5 and 4.0 mg/ kg body weight provide better effect than 3.0 and 2.5 mg/kg in behavior management when young uncooperative children are sedated for dental treatment. No significant effect on the vital signs was observed for the trimeprazine doses studied. Further studies are needed to compare the efficacy of trimeprazine with other well established drugs, such as chloral hydrate.

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