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Intra-nasal midazolam in conscious sedation of young paediatric dental patients

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Summary. *Objectives*. To compare the effects of 3 different doses of intra-nasal midazolam in the conscious sedation of young paediatric dental patients and to compare the effectiveness of the sedation in the fasting and non-fasting child.
Design. Double blind random controlled trial.
Sample and Methods. Thirty-eight uncooperative young children aged 2–5 years (mean age 4·02 years) were randomly assigned to one of 3 groups. The groups and the doses of midazolam administered intra-nasally were A: 0·3 mg/kg, B: 0·4 mg/kg, and C: 0·5 mg/kg body weight. Each child in each group had two visits for restorative treatment: one without food (fasting) and the other with soft drink and light food (non-fasting) before treatment. Child behaviour and sedative effects were evaluated using the scoring system of Houpt. The vital signs were monitored continuously using a pulse oximeter and Dinamap machine.
Results. There was rapid onset of sedation with the maximal effect between 8 and 15 minutes. This sedation lasted for 25–40 minutes in Groups A and B and for 60 minutes in Group C. Conscious sedation and dental treatment were achieved in 79%, 96% and 100% of the children in Groups A, B and C, respectively. Consistently higher Houpt scores were seen in Groups B and C, with statistically significant differences between Groups A and C, and B and C (Tukey's range test, $P < 0{\cdot}05$). There were no significant differences in the general behaviour of the child, the onset and the duration of sedation between the fasting and the non-fasting child (nonparametric ANOVA $P > 0{\cdot}05$). All the vital signs were within normal physiological limits and there were no significant adverse effects either with or without fasting.
Conclusions. All 3 doses of intranasal midazolam were effective in modifying the behaviour of the uncooperative child patient to accept dental treatment. This was irrespective of fasting.

Introduction

An exaggerated perception of pain and anxious behaviour is more closely related to dental treatment than any other type of health care [1]. A child with normal behaviour will readily accept dental treatment but others will require some form of behaviour modification before allowing treatment to be carried out. Children between 15 months and six years of age are perhaps the most difficult patients to manage in dentistry [2]. The children may be anxious and fearful because of the lack of past experiences. Coping skills may be either underdeveloped or non-existent and there may be no incentive to co-operate [2]. A large number of patients with anxiety can be managed with a combination of behavioural approaches and non-invasive pharmacologic methods. A safe and commonly used anxiety control technique for paediatric patients in the dental office is 'conscious

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sedation', defined by the American Academy of Paediatric Dentistry (AAPD) [3] as a controlled pharmacologically induced, minimally depressed level of consciousness that retains the patient's ability to maintain a patent airway independently and continuously and to respond appropriately to physical stimulation and/or verbal command. The drugs, dosages, and techniques used should carry a margin of safety which is unlikely to render the child non-interactive and non-arousable. Sedation is indicated for children who are uncooperative, fearful of the dental environment, have a dental phobia or are unable to cope because of physical or mental handicaps [4–6].

Sedative agents are frequently administered by the oral, rectal, intra muscular and intravenous routes. The oldest, safest and most convenient route at present is the oral route [7]. However, the oral route has some disadvantages, which include the long onset of action and the parental compliance for the need to starve the child for 4–6 hours before the dental treatment.

Recommended alternatives for the pre-anaesthetic sedation of pre-school children include intra-nasal administration of midazolam. Intra-nasal midazolam offers the great advantage of being a quick-acting drug. The few studies on intra-nasal midazolam also suggest a quick recovery from the effect of the drug [8–11]. Intra-nasal administration is simple and relatively painless. Although it may be objectionable, less patient cooperation is required than with oral administration, in which the child must swallow the medication. The drug has been used as a pre-anaesthetic sedative for elective surgery in adults and more recently in children [8–10,12–21] but there are very few studies concerning its use in paediatric dentistry [10]. Much interest has now been focused on the use of midazolam for conscious sedation in paediatric dentistry [11,23–26].

The objectives of this study are: to compare the effect of 3 different doses of intranasal midazolam in the conscious sedation of young paediatric dental patients, and to compare the effectiveness of intranasal midazolam in the conscious sedation of the fasting and the non-fasting children.

Methods

The study involved 38 uncooperative children aged 3–5 years, who attended the paediatric clinic of the College of Dentistry in King Saud University, Riyadh, in Saudi Arabia. The research protocol was also reviewed and approved by the Ethics Committee of the College of Dentistry Research Centre at the University.

Children were recruited to the study if they could not cooperate sufficiently to permit simple restorative dental treatment to be provided and scored 1 or 2 on the Frankl scale [27]. All the children were healthy ASA classification I [28], had no contra-indications to midazolam and needed at least two restorative visits. Those with upper respiratory tract infection and nasal discharge were excluded. The risks and possible discomforts as well as the benefits of the procedure were explained to parents and their informed consent was obtained before the study commenced.

The 38 children (18 males and 20 females) were randomly assigned to one of three groups, each having a different dose of midazolam administered intra-nasally (IN). Group A received 0·3 mg/kg body weight; Group B, 0·4 mg/kg body weight; and Group C, 0·5 mg/kg body weight.

The *first visit* required that each child should have nothing by mouth (NPO) for 4–6 hours before the appointment. The *second visit* required that each child had a glass of milk or soft drink and one sandwich or small piece of cake at least 2 hours before coming for dental treatment. The two visits were scheduled at similar times during the morning sessions. The drug used was the normal undiluted solution for parenteral administration. (Dormicum® 15 mg/3 mL F. Hoffman La Roche Ltd, Basel, Switzerland). Pre-operative assessment was carried out by the attending anaesthetist. The children were weighed and the baseline readings of the blood pressure, heart rate, respiratory rate and peripheral oxygen saturation were recorded for each child using the pulse oximeter and Dinamap vital signs monitoring equipment (Critikon, Johnson and Johnson Company, Dinamap vital signs monitor with oxytrak pulse oximeter).

The drug was administered using a nasal atomizer (Apoteksbolaget, Order Department Box 26S-401 20, Gothenburg, Sweden), with the child sitting reclined on the dental chair or parent's lap. With each pump, the atomizer released 0·1 ml of the medication as slow spray into alternating nares, with brief moments of pause in order to give the children rest and prevent sneezing. Following IN administration of the sedative, the child was observed for the onset of sedation as evidenced by

slurred speech, glazed look and delayed eye movement. Then, the child was placed in a restraint device (Papoose Board, Olympic Medical Group, Seattle). Thereafter, the vital signs were continuously monitored and recorded every 10 min until the patient was ready for discharge. Evaluation of hypoxemia was based on pulse oximeter recordings; normal oxygen saturation was considered as above 95%, mild hypoxemia as between 91 and 95%, moderate hypoxemia 75–90%, and below 75% was considered severe hypoxemia [29]. The operator was blind to the dose regimen received.

Evaluation

The general behaviour of the child during treatment was evaluated by a trained observer who was also blind to the drug regimen used, using a scoring system described by Houpt [6]. At the end of each treatment the operator also evaluated the general behaviour of the child and discussed this with the trained observer. Whenever there was a difference in the Houpt score, the lower score was chosen. The degree of alertness, movement and crying of the child was assessed before, during and after the operative procedures. The drug effects at different doses were evaluated as follows: IN administration, depth of sedation, effect following IN administration, level of anxiety and complications/side-effects.

The acceptability of IN administration of midazolam by the children was evaluated at four code levels: (1) Good -when the child accepted the drug without any refusal or resistance; (2) Fair -when the child accepted the drug administration with some verbal resistance; (3) Poor -when the child accepted the drug with some physical resistance; (4) Refused, crying -when the child refused and drug administration was possible only after much persuasion.

The side-effects of IN administration were evaluated as follows: (1) No effect; (2) Sneezing; (3) Coughing; (4) Vomiting. The degree of anxiety of each child after the IN midazolam was evaluated at three levels: (1) Very anxious; (2) Not anxious; (3) Calm and prepared.

Post-operative patient discharge was based on the child's ability to sit unaided, talk and with intact protective reflexes. Each patient's mother was requested to complete a questionnaire as to adverse effects noted within the first 24 hours post-operatively.

The patient's behaviour during treatment was scored using the scale described by Houpt *et al.* [6] and considered acceptable in sessions when the scores ranged from 3 to 6 and unacceptable when the score was 1 or 2.

Data analysis

Tukey's range test was used to compare the mean general behaviour score of Houpt in the three groups. Non-parametric two factor analysis of variance was used to compare the sedative effects of the three different doses of IN midazolam (as reflected by the general behaviour scores) in the fasting and the non-fasting child. Repeated measures analysis of variance was used to determine the effects of the three doses and fasting/non-fasting on the diastolic blood pressure (BPD) with the interaction of time.

Results

Out of the 38 uncooperative young children selected for this study, there were 12 (6 boys, 6 girls) in group A (0·3 mg/kg) and 13 each (6 boys, 7 girls) in groups B (0·4 mg/kg) and C (0·5 mg/kg). The mean/SD for age (years) and weight (kg) in Groups A, B and C were $3{\cdot}75 \pm 0{\cdot}75$, $15{\cdot}0 \pm 1{\cdot}38$; $4{\cdot}3 \pm 0{\cdot}65$, $15{\cdot}7 \pm 2{\cdot}90$ and $4 \pm 0{\cdot}71$, $16 \pm 2{\cdot}47$, respectively.

The mean values of onset of sedation, recovery and the general behaviour rating scores of Houpt [6] for each dose are shown in Table 1. Out of the 75 pairs of rating scores recorded by the trained observer and the operator, 69 were identical giving a 92% agreement between the two sets of scores.

For group A, treatment was accomplished in 19 out of 24 attempts (79%). In group B, 25 out of 26 attempts (96%) were successful. In group C, treatment was completed in all the children (100%) both when they were fasting and not fasting (scores 4–6).

Table 2 shows the results of using non-parametric two factor analysis of variance. There were no statistically significant differences in general behaviour scores with fasting ($P = 0{\cdot}8286$). However, there was a statistically significant difference in general behaviour rating scores between groups ($P = 0{\cdot}0001$). There were no statistically significant interaction between dosage and fasting/non-fasting in general behaviours ($P = 0{\cdot}8719$).

There were no significant differences in mean diastolic Blood Pressure (BPD), either with fasting or in the three different doses (Table 3) using repeated measures analysis of variance.

Table 1. Mean periods onset of sedation, recovery and mean general behaviour score (Houpt[6]) by dose.

	Group A 0·3 mg/kg		Group B 0·4 mg/kg		Group C 0·5 mg/kg	
	F	NF	F	NF	F	NF
Mean Period Onset of Sedation in minutes	10·3	10·2	10·8	1·06	12·3	12·6
SD:	1·44	1·03	1·01	0·99	2·06	2·40
Mean Period of Recovery in minutes	31·6	31·3	42·3	42	57·7	58·5
SD:	5·37	4·03	2·60	2·57	3·84	3·15
Mean Rating Scale of Houpt[6] Mean Houpt Score	3·4	3·5	3·9	3·7	49	5·2
SD:	1·31	1·31	1·26	1·38	0·64	0·80

F = Fasting; NF = Non-Fasting; SD = Standard Deviation
Tukey's Range Test: General Behaviour Score Vs. Dosage.
0·3 mg V 0·4 mg: $P = 0·620$
0·3 mg V 0·5 mg: $P < 0·0001$*
0·4 mg V 0·5 mg: $P < 0·01$*

Table 2. Comparison of the general behaviour score in the fasting/nonfasting with the interaction of dosage.

General behaviour score compared with	DF	P Value
Fasting/Non-fasting	1	0·8286 (NS)
Dosage	2	0·0001*
Fast vs. Dosage	2	0·8719 (NS)

(Non-parametric two factor analysis of variance).
*Significant
NS = Not Significant

Table 3. Comparison of diastolic blood pressure (BPD) with the effect of the three doses and fasting/non-fasting with the interaction of time.

Source	DF	P Value
BPD	4	0·67 NS
BPD vs. Fast/Non-Fast	4	0·34 NS
BPD vs. Dosage	4	0·48 NS

(Repeated Measures Analysis of Variance)
NS = Not Significant

The mean values for oxygen saturation were within normal physiological levels in all three groups and with and without fasting. There was no hypoxemia with levels maintained between 99 and 97%. Details of the effects on vital signs are being reported elsewhere, along with the acceptability of IN midazolam by the children.

Sneezing and coughing on in administration occurred in 8–17% of the children. No effects were observed in the 0·4 mg/kg body weight group. There was no vomiting by any of the children who participated in the study and no evidence of allergic response to the drug.

Depth of sedation was evaluated and is presented in Fig. 1. Only one child in each of the two groups (A & B) was awake crying while none were asleep. Drowsiness was achieved in 92% in Group A, in 92% in Group B and 100% in Group C.

Other observations

Other observations recorded following the administration of IN midazolam included one child restless and irritated, three emotional and actually crying. There was diplopia or double vision in 62% (fasting) and 69% (non-fasting) of the children in Group C but this did not occur in children in the other two groups.

Discussion

This study demonstrates that in all the three doses, IN midazolam is an effective anxiolytic and sedative drug in the dental management of pre-school children. However, the degree of sedation varied with the three doses. The 0·3 mg/kg body weight dosage in Group A in this study did not appear to be as effective as the 0·2 mg/kg or 0·3 mg/kg body weight doses used in earlier studies [8,11,26]. No statistically significant differences were observed in the effect of any of the three drug doses on the behaviour rating with fasting. This is an interesting finding as no previous studies have evaluated the use of IN midazolam in the fasting and non-fasting child.

The maximum time for onset of sedation was between 8 and 15 minutes, with most cases occurring within 10 minutes of administration irrespective of fasting. This is comparable to earlier studies [30–32] which reported that the average time to peak plasma concentration was 10 minutes. Nasal administration of a sedative has the advantage of rapid absorption of the drug directly into the

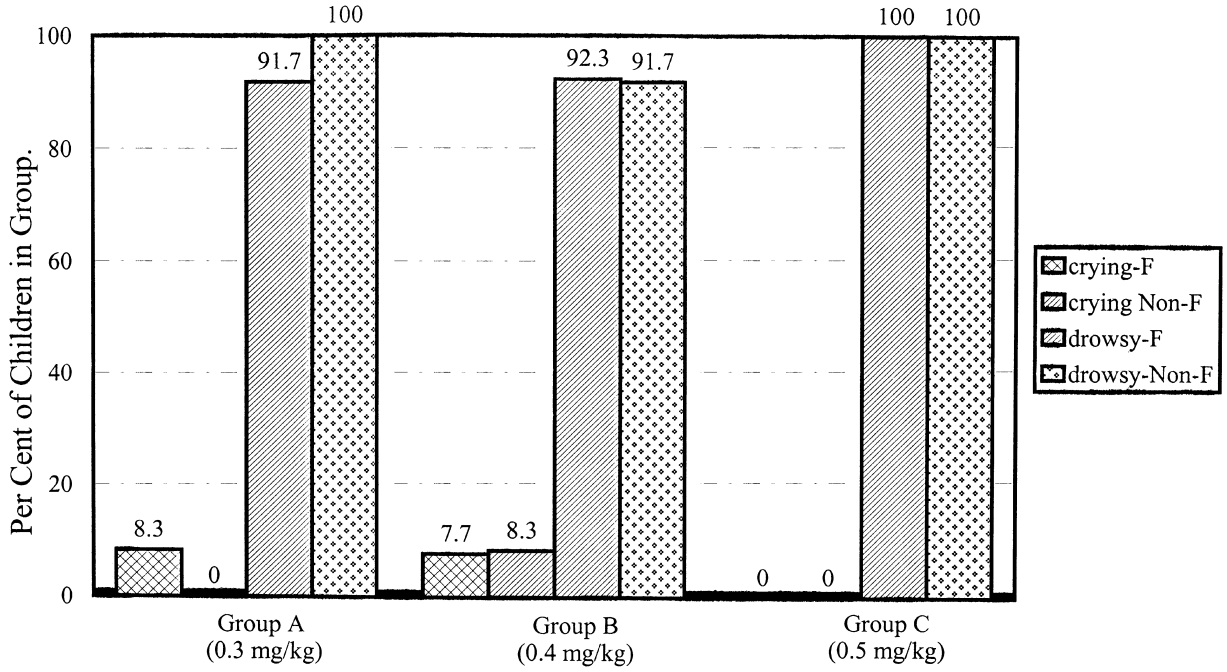

Fig. 1. Depth of sedation in fasting (F) and non-fasting (non-F) children with intra-nasal midazolam.

systemic circulation, with greater accuracy than oral administration since it diffuses directly into the vessels, due to the rich vascularity of the nasal mucosa rather than being transported via the portal vein, as is the case in per rectal or oral administration [24].

The children who received the dose of 0·3 mg/kg and 0·4 mg/kg IN midazolam had recovery periods of 31–42 min. This interval is similar to values seen in earlier studies [30–32]. In the children who received the dose of 0·5 mg/kg body weight, the sedative effect was maintained for longer, between 45 and 60 min. Fukuta *et al.* [24] obtained satisfactory sedative effects from 15 minutes up to 55 minutes post administration of 0·2 mg/kg IN midazolam but in conjunction with nitrous oxide/oxygen analgesia. Therefore, the decision to treat a child using different doses of IN midazolam should be based on: the child's ability to communicate; the amount of restorative treatment required and the behaviour exhibited at the initial appointment. In the case of a simple treatment, such as composite restorations or simple extractions or excavation of caries, adequate sedation of sufficient duration may be obtained by a dose of 0·3 mg/kg or 0·4 mg/kg body weight. However, where comprehensive treatment is needed, including pulpotomy, stainless steel crowns and perhaps extractions, a dose of 0·5 mg/kg body weight may be preferred. There should be no need to use nitrous oxide/oxygen analgesia in addition to these doses unlike the smaller doses of 0·2 mg/kg and 0·3 mg/kg body weight used by Fukuta *et al.* [24,33] where it was still necessary to use nitrous oxide and oxygen analgesia to obtain a treatment period of 55–60 min

Analysis of the vital signs was carried out to provide a comprehensive assessment of the physiological parameters during the appointment. There were significant differences in the mean systolic blood pressure (BPS) before administration and 10 minutes following administration. The BPS would decrease and then elevate after 10 min but with no significant long-term changes from baseline readings even after 60 minutes. Similar findings were observed in the diastolic blood pressure (BPD). These changes were not influenced either by the differences in the dose or by fasting.

The oxygen saturation (SaO_2) of the children decreased slightly with time but remained at levels between 99% and 97% indicating that there was neither hypoxemia nor respiratory depression. In contrast, Noguchi and Amemiya [34] reported respiratory depression as demonstrated by significant decrease in SaO_2 after intravenous use of midazolam.

There were no reports of nausea, vomiting or seizure from parents of the children in the study

during the 24 hours after treatment. The findings in this study, in which all the vital signs remained stable during sedation, also confirm conclusions of earlier studies [14,15] that intranasal midazolam is a safe and effective sedative for short-term procedures.

Coughing and sneezing with the expulsion of part of the dose has been reported previously with IN midazolam [8,11,12,26] and has been attributed to the probable large volume of the drug applied [18]. The careful method of administering IN midazolam in this study may have helped to reduce sneezing and coughing to a minimum.

Only one child in each of groups A and B was awake, and drowsiness was achieved in 91%–92%. All the children in group C (0·5 mg/kg) were drowsy. No child in any group was asleep. In contrast, level of anxiety in the children differed in the three groups; the higher the dosage the less the anxiety. Nearly all the children in the 0·5 mg/kg group were considered 'calm and prepared' for the dental treatment compared to pre-medication state. This result shows not only that the lower doses were less effective in calming the child but also that drowsiness of the child does not mean lack of anxiety.

Diplopia affected 61–69% of the children who had 0·5 mg/kg body weight of IN midazolam but this finding was transient and had disappeared before the patient left the clinic. Fukuta *et al*. [33] had reported slight dizziness or disorientation in two adults who were given 0·3 mg/kg IN midazolam.

The absence of nausea, vomiting and respiratory depression in the child who had a light breakfast appears to suggest that it may not be essential to subject a child to the discipline of fasting for 4–6 hours before the administration of IN midazolam and dental treatment. This represents an advantage since it means the technique may be used effectively for children who require emergency dental treatment, are young and/or uncooperative and who have eaten. Such children may be given IN midazolam without the risk of a respiratory complication.

This study agrees with and confirms the findings of Hartgreaves and Primosch [25]. IN midazolam proved to be easy to administer, had a rapid onset of sedation, and was safe and effective in aiding modification of behaviour of the uncooperative child dental patient to accept treatment.

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Résumé. *Objectifs*. Comparer les effets de 3 différentes doses de midazolam intra-nasal pour une sédation consciente chez les jeunes patients de dentisterie pédiatrique, et comparer la réalité de la sédation chez l'enfant à jeun ou non à jeun.
Protocole. Etude randomisée en double aveugle.
Echantillon et Méthodes. Trente-huit enfants non-coopératifs âgés de 2 à 5 ans (âge moyen 4,02 ans) ont répartis par randomisation dans l'un des trois groupes. Les groupes et les doses de midazolam administrées en intra-nasal étaient de A: 0,3 mg/kg, B: 0,4 mg/kg, and C: 0,5 mg/kg de poids de corps. Chaque enfant de chaque groupe a bénéficié de deux visites pour des traitement conservateurs: un sans alimentation (à jeun), et l'autre avec boisson et nourriture légère (non à jeun) avant traitement. Le comprtement des enfants et les effets sédatifs ont été évalués selon le système de score de Houpt. Les indices vitaux ont été contrôlés en continuité à l'aide d'un tensiomètre et d'un appareil Dinamap.
Résultats. La sédation a été rapide avec effet maximal entre 8 et 15 minutes. Cette sédation a duré pendant 25-40 minutes dans les groupes A et B, et 60 minutes dans le groupe C. La sédation consciente et le traitement dentaire ont été effectués chez 79%, 96% et 100% des enfants respectivement dans les groupes A, B et C. Des scores de Houpt plus élevés ont été obtenus dans les groupes B et C, avec des diférences statistiquement significatives entre les groupes A et C et B et C (Turkey's range test, $p < 0{,}05$). Il n'y avait pas de différence significative concernant le comportement général de l'enfant, la mise en place et la durée de la

sédation entre les enfants à jeun ou non (ANOVA non paramétrique, $p > 0{,}05$). Tous les signes vitaux ont été à l'intérieur des normales physiologiques, et il n'yavait de différence significative dans les effets indésirables entre les enfants à jeun ou non.
Conclusions. Les trois doses de midazolam intranasal sont efficaces pour modifier le comportement de l'enfant non coopératif afin qu'il accepte les soins dentaires. Le fait d'être ou non à jeun n'avait pas d'influence.

Zusammenfassung. *Ziel*. Vergleich des Effektes von 3 unterschiedlichen Dosierungen von intra-nasal appliziertem Midazolam zur Sedierung von jungen Kindern vor Zahnbehandlung und Untersuchung des Einflusses von Nüchternheit.
Design. Doppelblindstudie, randomisiert.
Kollektiv und Methoden. Achtunddreißig unkooperative Kinder im Alter von 2 bis 5 Jahren (Mittelwert 4.02 Jahre) wurden randomisiert einer von 3 Gruppen zugeordnet. Die Gruppen und die Dosierungen an intranasal appliziertem Midazolam waren A: 0.3 mg/kg, B: 0.4 mg/kg und C: 0.5 mg/kg Körpermasse. Jedes Kind in jeder Gruppe hatte 2 Termine zur restaurativen. *Behandlung*. Einen ohne Nahrungsaufnahme (nüchtern) und einen mit leichter Kost und Getränk vor der Behandlung (nicht müchtern). Das Verhalten der Kinder und der sedierende Effekt wurden mit dem scoring System nach Houpt bewertet. Das Monitoring der Vitalfunktionen erfolgte mit Pulsoximetrie und einer Dinamap Apparatur.
Ergebnisse. Es war ein rascher Wirkeintrit mit einem Wirkmaximum nach 8-15 min zu verzeichnen. Die Sedierung hiel an für 25-40 min in Gruppe A und B und für 60 min in Gruppe C. Eine tiefe Sedierung und eine restaurative Zahnbehandlung wurden erreicht in 79%, 96% und 100% bei den Gruppen A, B und C.
Durchgängig höhere Houpt-Scores wurden in den Gruppen B und C beobachtet mit statistisch signifikanten Unterschieden zwischen A und C sowie B und C (Turkeys Test, $p < 0.05$). Keine Unterschiede hinsichtlich dem Verhalten, Wirkeintritt sowie Wirkdauer ergab sich zwischen den Behandlungen die 'nüchtern' und 'nicht nüchtern' durchgeführt worden waren (ANOVA $p > 0.05$). Die Vitalfunktionen waren innerhalb der Normwerte und es zeigten sich keine unerwünschten Reaktionen, weder in der 'nüchtern' noch in der 'nicht-nüchtern' Gruppe.
Schlussfolgerung. Alle 3 Dosierungen von intranasal appliziertem Midazolam waren effektiv in der Verhaltensbeeinflussung unkooperativer Kinder vor zahnärztlicher Therapie, unabhängig von Nüchternheit.

Resumen. *Objetivo*. Comparar los efectos de tres dosis diferentes de midazolam intranasal sobre la sedación consciente en pacientes odontopediátricos y comparar la efectividad de la sedación en el niño en ayunas y sin ayunas.
Diseño. Prueba controlada aleatoria a doble ciego.
Muestra y métodos. Treintaiocho niños pequeños no cooperadores entre 2 y 5 años de edad (edad media 4,02 años), se asignaron aleatoriamente a uno de los tres grupos. Los grupos y las dosis de midazolam intranasal administrado fueron A: 0,3 mg/Kg, B: 0,4 mg/Kg y C: 0,5 mg/Kg de peso corporal. Cada niño en cada grupo tenía dos visitas para tratamiento restaurador: uno sin comida (en ayunas) y el otro con refresco y comida ligera (sin ayunas) antes del tratamiento. El comportamiento del niño y los efectos sedantes se evaluaron usando el sistema de valoración de Houpt. Los signos vitales se monitorizaron de forma continua usando un pulsioxímetro y una máquina Dinamap.
Resultados. Hubo un comienzo rápido de la sedación con el efecto máximo entre 8 y 15 minutos. Esta sedación duró 25-40 minutos en los grupos A y B y durante 60 minutos en el grupo C. La sedación consciente y el tratamiento dental se realizaron en el 79%, 96% y 100% de los niños en los grupos A, B, y C respectivamente.
Los valores de Houpt más altos se vieron en los grupos B y C con diferencias estadísticamente significativas entre los grupos A y C Y B y C (Test de rangos de Tukey, $p < 0{,}05$). No hubo diferencias significativas en el comportamiento general del niño, el comienzo y la duración de la sedación entre el niño en ayunas y no ayunas (ANOVA no paramétrica $p > 0{,}05$). Todos los signos vitales estuvieron en los límites fisiológicos normales y no hubo efectos adversos significativos con o sin ayunas.
Conclusiones. Las tres dosis de midazolam intranasal fueron efectivas en la modificación del comportamiento del niño no cooperador para aceptar el tratamiento odontológico. Esto fue independiente del estado de ayuno.

References

1 Troutman KC. Pharmacologic management of pain and anxiety for paediatric patients. In: *Wei, SHY. Pediatric Dentistry total patient care*. Philadelphia. Lea and Febiger., pp 156–186., 1988.

2 Giovannitti JA. Regimens for pediatric sedation. *Compendium of Continuing Education in Dentistry*, 1993; **8:** 1002–1004.

3 American Academy of Pediatric Dentistry (AAPD). Guidelines for the elective use of pharmacologic conscious sedation and deep sedation in pediatric dental patients. *Reference Manual. Pediatric Dentistry*, 1997–98; **19:** 48–52.

4 Barr ES, Wynn RL, Spedding RH. Oral premedication for the problem child: placebo and chloral hydrate. *Journal of Pedodontics* 1977; **1:** 272–280.

5 Creedon RL. Pharmacologic management of patient behavior. In *Dentistry for the Child and Adolescent*. 6th edn. REMcDonald DR. Avery. eds., Philadelphia. CV Mosby Co., 1994: pp 307–334.

6 Houpt M, Koenigsberg SR. Weiss no. Comparison of chloral hydrate with and without promethazine in the sedation of young children. *Pediatric Dentistry* 1985; **7:** 41–48.

7 Malamed SF. *Sedation. A guide to patient management*. 3rd edn. St. Louis, CV Mosby Co., 1995: p 101.

8 Wilton NCT, David JL, Rosen R, Pandit UA. Pre-anesthetic sedation of pre-school children using intranasal Midazolam. *Anesthesiology* 1988; **69:** 972–975.

9 Walbergh EJ, Wills RJ, Eckhert J. Plasma concentration of Midazolam in children following intranasal administration. *Anesthesiology* 1991; **74:** 233–235.

10 Kupietzky A, Houpt M. Midazolam. A review of its use for conscious sedation of children. *Pediatric Dentistry* 1993; **15:** 237–241.

11 Fukuta O, Braham RL, Yanase H, Kurosu K. The sedative effects of nasal Midazolam administration in the dental treatment of patients with mental disabilities. Part 2. Optimal concentration of intranasal Midazolam. *Journal of Clinical Pediatric Dentistry* 1994; **18:** 259–265.

12 Rice TL, Kyff JV. Intranasal administration of midazolam to a severely burned child. *Burns* 1990; **16:** 307–308.

13 Saint-Maurice C, Landais A, Delleur MM, Esteve C, MacGee Murat I. The use of midazolam in diagnostic and short surgical procedures in children. *Acta Anaesthesiologica Scandinavica* 1990; **92:** 39–41.

14 Gobeaux D, Sardnal F, Cohn H, Lequoy O. Intranasal midazolam in pediatric ophthalmology. *Cashiers D Anesthesiologic* 1991; **39:** 34–36.

15 Yealy DM, Ellis JH, Hobbs GD, Moscati RM. Intranasal Midazolam as a sedative for children during laceration repair. *American Journal of Emergency Medicine* 1992; **10:** 584–587.

16 Karl HW, Keifer AT, Rosenberger JL, Larch MG, Ruffle JM. Comparison of the safety and efficacy of intranasal midazolam or sufentanil for pre-indication of anesthesia in pediatric patients. *Anesthesioology* 1992; **76:** 209–215.

17 Malinovsky JM, Lejus C, Servin F, Lepage JY, Le Normand Y, Testa S, Cozian A, Pinaud M. Plasma concentrations of midazolam after I.V. nasal or rectal administration in children. *British Journal of Anaesthesia* 1993; **70:** 617–620.

18 Theroux MC, West DW, Corddry DH, Hyde PM, Bachrach SJ, Cronan KM, Kettrick RG. Efficacy of intranasal midazolam in facilitating suturing of lacerations in pre-school children in the emergency department. *Pediatrics* 1993; **91:** 624–627.

19 Connors K, Terndrup T. Nasal versus oral midazolam for sedation of anxious children undergoing laceration repair. *Annals of Emergency Medicine* 1994; **24:** 1074–1079.

20 Louon Reddy. Nasal midazolam and ketamine for pediatric sedation during computerized tomography. *Acta Anaesthesiologica Scandinavica* 1994; **38:** 259–261.

21 Otsuka Y, Yusa T, Higa M, Terada T. Intranasal midazolam for sedation before anesthesia in pediatric patients. *Masui Japanese Journal of Anaesthesia* 1994; **43:** 106–110.

22 Malinovsky JM, Populaire C, Cozian A, Lepage JY, Lejus C. Premedication with midazolam in children. Effect of intranasal, rectal and oral routes on plasma midazolam concentrations. *Anesthesia* 1995; **50:** 351–354.

23 Abrams R, Morrison J Jr, Villasenor A, Hencmann D, Da Fonseca M, Mueller W. Safety and effectiveness of intranasal administration of sedative medications (Ketamine, Midazolam or Sufentanil) for urgent brief pediatric dental procedures. *Anesthesia Progress* 1993; **40:** 63–66.

24 Fukuta O, Braham RL, Yanase H, Atsumi N, Kurosu K. The sedative effect of intranasal midazolam administration in the dental treatment of patients with mental disabilities. Part I. The effect of a 0.2 mg/kg dose. *Journal of Clinical Pediatric Dentistry* 1993; **17:** 231–237.

25 Hartgraves PM, Primosch RE. An evaluation of oral and nasal midazolam for pediatric dental sedation. *ASDC Journal of Dentistry for Children* 1994; **61:** 175–181.

26 Fuks AB, Kaufman E, Ram D, Hovav S, Shapira J. Assessment of two doses of intranasal midazolam for sedation of young paediatric dental patients. *Pediatric Dentistry* 1994; **16:** 301–305.

27 Frankl SN, Shiere FR, Fogels HR. Should the parent remain in the operatory? *ASDC Journal of Dentistry for Child* 1962; **29:** 150–163.

28 American Society of Anesthesiologist Classification. Guidelines for the elective use of conscious sedation, deep sedation and general anesthesia in pediatric patients. *Pediatric Dentistry* 1985; **7:** 334–337.

29 Mueller WA, Drummond JN, Pribisco TA, Kaplan RF. Pulse oximetry monitoring of sedated pediatric dental patients. *Anesthesia Progress* 1985; **32:** 237–240.

30 Latson LA, Cheatham JP, Gumbiner CH, Kugler JD, Danford DA, Hosfschire PJ, Honts J. Midazolam nose drop for out-patient echocardiography sedation in infants. *American Heart Journal* 1991; **121:** 209–210.

31 Rose E, Simon D, Haberer JP. Premedication with intranasal midazolam in pediatric anesthesia. *Annales Francaises D. Anesthesie et de Reanimation* 1990; **9:** 326–330.

32 Bunz R, Gozzler M. Intranasal premedication of young children using midazolam. *Clinical Experience. Anaesthesiol Intensive Not Fallmed Schmerzther* 1991; **26:** 76–78.

33 Fukuta O, Braham RL, Yanase H, Kurosu K. Intranasal administration of midazolam: Pharmacokinetics and Pahrmacodynamic Properties and Sedative Potential. *ASDC Journal of Dentistry for the Child* 1997, **64**, 89–98.

34 Noguchi I, Ameniya Y. Study on arterialization of peripheral venous blood by midazolam. *Journal of Dental Society for Anesthesia* 1993; **21:** 558–569.