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Midazolam conscious sedation in a large Danish municipal dental service for children and adolescents

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Objective. The aim of this study was to describe the introduction and the first six years use of midazolam for conscious sedation in a municipal dental service in Denmark.

Methods. In 1998, all dentists were introduced to midazolam conscious sedation. A sedation chart was filled in for each session, and parents' assessment was obtained. In 2004, all clinical materials were collected.

Results. Six hundred and eighty sessions were performed; 63.7% of the children were between 2 and 6 years of age; 88.5% belonged to American Society of Anesthesiologists grade 1; 74.8% of the sedations performed used the oral route of administration. Restorations were performed during 60.3% of the sessions, and extractions during 38.4%. Complications during the sessions were rare, the most frequent being double vision (6.1%), hiccups (2.7%), and paradoxical reaction (2.0%). Using Wilton's sedation scale, 42.9% were calm and 27.7% were agitated during treatment, whereas after treatment 61.7% were calm; 80.4% of the parents were very positive towards this sedation method.

Conclusion. Sedation with midazolam for dental treatment of children with dental fear and anxiety is a feasible and an efficient method with a low rate of complications. It can probably reduce the need for dental treatment under general anaesthesia.

Introduction

Conscious sedation with benzodiazepines during dental treatment of children with dental fear and anxiety, and behaviour management problems has been used successfully for several decades by paediatric dentists. In Denmark and in Scandinavia, the drug of choice was for many years diazepam[1,2]. However, because of its long elimination half-life[3] and because it has an active metabolite[3,4], diazepam is less suitable for dental treatment of children. The Municipal Dental Service for Children and Adolescents in Copenhagen therefore decided to introduce midazolam (Dormicum, F. Hoffmann–La Roche AG, Basel, Switzerland) as an alternative to diazepam in 1998. This decision was primarily based upon this drug's rapid onset and short duration of action[5,6]. Furthermore, successful use of midazolam in other Scandinavian countries is well-documented[2,7–9].

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Aim

The purpose of this paper was to describe the introduction and the first 6 years (1999–2004) of using midazolam in conscious sedation for dental treatment of children and adolescents in the Municipal Dental Service for Children and Adolescents in Copenhagen, Denmark.

Materials and methods

Introducing midazolam conscious sedation

In 1998, all dentists employed by the Municipal Dental Service for Children and Adolescents in Copenhagen participated in a 1-day introductory course in the use of midazolam conscious sedation. The course included general aspects, that is, the pharmacological properties of the drug, indications, and contraindications, and a practical guideline for using midazolam. After

the course, it was left to each dentist to become acquainted with and implement the technique. In case of uncertainties concerning the use of the technique, it was possible to refer the child to a specialist clinic, staffed with dentists with longer experience in using the method.

A sedation chart was developed. The chart had to be filled in for each sedation session (i.e. one child could have more than one sedation chart). The sedation chart contained personal data, body weight, American Society of Anesthesiologists (ASA) classification[10], medication, indication for sedation, planned treatment, dose and route of administration, complications, level of sedation according to Wilton's sedation scale.[11], acceptance of sedation, and overall acceptance of treatment (adapted from Holst *et al*.[12–14]) and strategy for future sedation in case the treatment was not successful (i.e. a new sedation session or referral to treatment under general anaesthesia).

In order to obtain the parents' assessment of the sedation session, they were asked to fill in a questionnaire 24 h after the session. This questionnaire contained information on how long the sedative effect had persisted, whether or not they would prefer the technique if the child should need dental treatment again, and a 10 cm visual analogue scale (VAS) on how the parents had perceived the sedation and the treatment. In the scale, 0 indicated a very positive and 10 a very negative parental response.

The following protocol for sedation was adopted: i) Prior to sedation, the parents received oral and written information. ii) Medical contraindications were observed, and children in ASA grade 2 and 3 were only sedated after consultation with the children's physician. iii) The following fasting rules were adopted: no solid foods or non-clear liquids (including milk) 4 h before sedation, and no clear liquids 2 h before sedation. iv) The recommended dose for oral administration was 0.5 mg/kg body weight, and for rectal administration 0.3 mg/kg body weight. v) The child stayed in the clinic at least 1 h after midazolam administration (but parents and children could stay in the recovery room until they felt able to leave the clinic).

Data collection

In 2004, clinical dental records, sedation charts, and parents' questionnaires were collected from all the midazolam sedation sessions that had been performed during the 6-year period. The following data were extracted from these files: i) The dentists and the clinics: identification of dentist and clinic, number of sedations performed, access to nitrous oxide/oxygen, ii) The children: age, gender, ASA grade, acceptance of dental treatment prior to sedation[15], body weight, and number of sessions received, iii) The sedations: indication for sedation, dental treatment performed, route of administration and dose, complications, level of sedation, acceptance of sedation and treatment[12–14], and strategy if treatment was not possible during sedation, iv) The parents' assessment: VAS scale on the parents' perception of the session, information on whether or not they would choose the technique again, and whether or not they had received enough information prior to the session

Data entry was done using EpiData. Double entry of the data was performed, and the analysis was performed using SPSS1.0.

Results

The dentists and clinics

During the 6-year period, 69 dentists had performed 680 sedation sessions in 29 clinics. One clinic did not have access to nitrous oxide/oxygen. Table 1 shows that the number of sedation sessions per dentist varied considerably. One dentist performed 166 (24.2%) of the sedation sessions.

Table 1. Distribution of dentists according to number of sedation sessions during a six-year period.

Number of sessions	Number of dentists (%)
< 10	50 (72.5%)
10–19	13 (18.8%)
20–59	5 (7.2%)
≥ 60	1 (1.5%)
Total	69 (100%)

Table 2. Distribution of children (%) according to age in months at first sedation, and gender.

Gender	Number	Age in months				
		< 24 mo	24–47 mo	48–71 mo	72–95 mo	>95 mo
Boys	138	4.3%	24–47%	40.6%	13.8%	14.5%
Girls	219	3.2%	26.5%	34.7%	20.5%	15.1%
Total	357	3.6%	26.6%	37.1%	17.9%	14.8%

The children

During the 6-year period, a total of 357 children and adolescents were sedated. Table 2 shows that there were more girls than boys in the study population, and that 67.3% of the children were below 6 years of age. The mean age of boys and girls at first sedation was almost identical: boys 65.7 months [standard deviation (SD) 35.44] and girls 65.5 (SD 29.65).

In this study, 52.5% of the children were sedated once, 42.2% received two to four sedation sessions, whereas 5.3% were sedated five to nine times (only one child was sedated nine times); 88.5% of the children ($n = 316$) belonged to ASA grade 1, whereas 9.0% ($n = 32$) belonged to ASA grade 2 and very few ($n = 3$; 0.8%) to ASA grade 3.

For 93 children (26.1%), the acceptance grade was not recorded prior to sedation. In children where the acceptance grade was noted, 210 (79.5%) of the children presented with acceptance grade 0 when exposed to behaviour-shaping techniques (including 'tell–show–do' and in some cases nitrous oxide/oxygen sedation), 21 (8.0%) presented with acceptance grade 1, 12 (4.5%) with grade 2, and 21 (8.0%) with grade 3. Of all children, 58.3% ($n = 208$) were considered too young or immature to cope with the treatment that they needed, and 34.5% ($n = 123$) had been diagnosed with dental fear and anxiety[16].

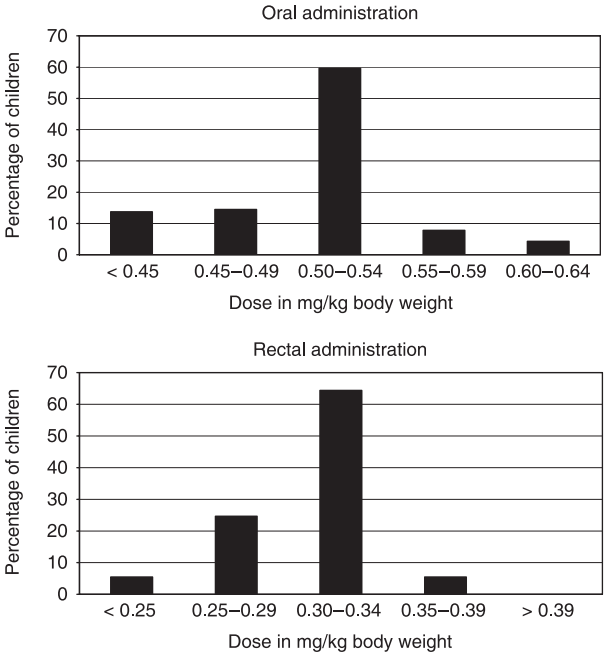

Fig. 1. Distribution of children (%) according to dose in milligrams per kilogram body weight for oral administration ($n = 272$) (top) and rectal administration ($n = 84$) (bottom) at first sedation session.

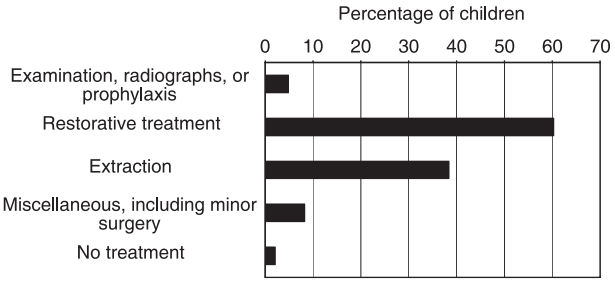

Fig. 2. Distribution of sedation sessions (%) ($n = 680$) according to type of treatment performed.

The sedations

In 74.8% ($n = 509$) of the 680 sedation sessions, the oral administration was used, and in the rest of the cases, rectal administration was used.

Figure 1 shows that the recommended dose for the oral administration was used for 59.6% ($n = 162$) of the children at their first visit, and the recommended dose for the rectal administration was used for 64.6% ($n = 54$) of the children also at their first visit.

The treatment provided during sedation is illustrated in Fig. 2. In 2.1% ($n = 14$) of the 680

Table 3. Complications (number and %) observed during the sedations sessions.

Complications	During treatment	After treatment
None	539 (84.6%)	551 (88.0%)
Double vision	39 (6.1%)	25 (4.0%)
Nausea	3 (0.5%)	3 (0.5%)
Vomiting	7 (1.1%)	3 (0.5%)
Hick-ups	17 (2.7%)	25 (4.0%)
Headache	5 (0.8%)	1 (0.2%)
Paradoxical reaction	13 (2.0%)	7 (1.1%)
Reduced respiration	2 (0.3%)	0 (0%)
Other	19 (3.0%)	17 (2.7%)

sedation sessions, treatment was not possible, and 31 children (4.6%) had to be referred to treatment under general anaesthesia.

Complications, either during or after treatment, were rare. Complications appear from Table 3. Paradoxical reactions were found in 20.0% of the cases when treatment was not possible.

During treatment, 42.9% were calm, 27.7% were agitated, and 17.6% were alert, whereas the rest were euphoric, drowsy, or asleep. After treatment, 61.7% were calm, 13.0% were euphoric, 10.8% were agitated, whereas the rest were alert, drowsy, or asleep.

Data on acceptance were available from 659 of the 680 sedation sessions. Of these, 10.2% ($n = 67$) showed no acceptance, 10.2% ($n = 67$) showed negative acceptance, 39.9% ($n = 263$) showed reluctant acceptance, and 39.8% ($n = 262$) showed positive acceptance of sedation or treatment.

The parents' assessment

Parents returned the questionnaires after 52.7% ($n = 357$) of the sedation sessions. In case their child should need dental treatment again, 88.2% would prefer midazolam conscious sedation, whereas the rest were either indifferent (9.3%) or did not wish their child to be subjected to this procedure again (2.5%); 80.4% of the parents scored between 0 and 2 on the VAS scale on how the parents had perceived the sedation and the treatment, whereas 5.7% of the parents scored between 8 and 10.

Among the parents, 95.4% ($n = 333$) felt that they had received sufficient information about the technique prior to sedation.

Discussion

This study is based on data collected retrospectively during the first 6-year period after the introduction of midazolam for sedation for dental treatment in a large Danish municipal dental service for children and adolescents. The study describes the dentists' use of the method, the children receiving sedation, and parental assessment of the method.

An optimal sedation technique should be accessible and easy to use; it should have a documented effect and produce few complications. Furthermore, the clientele (children as well as parents) must accept it. In this study, dentists taking part in the study were introduced to midazolam through an introductory course. We observed much variation in the use of the method (ranging from use several times a week to once or twice in the 6-year period) which suggests that its applicability was conceived very differently by the participating dentists.

Jensen and Matsson[7] suggested that a more regular use of sedation is advantageous for achieving better results. One single dentist performed more than one-fourth of all the sessions recorded, and we have not been able to demonstrate the association between regular use and outcome.

The effectiveness of midazolam conscious sedation has been demonstrated in numerous studies[2,7,8,17]. In this study, the most frequent reason for choosing this kind of sedation was found to be behaviour management problems and dental fear and anxiety, often combined with low age. As only approximately 5% of the children had to be referred for treatment under general anaesthesia, sedation with midazolam was found to be a valuable method in solving behaviour management problems that could not be solved using behaviour management techniques. The sedation level obtained in this study is in accordance with that obtained in similar studies[2,9].

The route of administration was predominantly oral. Jensen[4] found no difference in acceptance of procedures between the oral and the rectal route. If there is any doubt whether the young child might spit out the oral preparation, the rectal route should be preferred.

We found that the recommended dose for both oral and rectal administration had been followed very closely. A recent study by Day *et al.*[18] demonstrated that the doses (0.5–0.7 mg/kg or 0.2–0.3 mg/kg) had no effect on whether the treatment was successfully carried out or not. As mentioned earlier, Jensen and Matsson[7] suggested that a high volume of sedation sessions is important to achieve satisfactory sedation outcome. In a survey by Klingberg *et al.*[19], it is reported that the number of patients treated using sedation and general anaesthesia has increased in Sweden since 1983. In the same period, referrals to dentists with special skills in this field, that is, paediatric dentists, have increased. In 37% of the referrals in 2003, the main reason for referral was dental treatment need in combination with behaviour management problems. These observations lead us to suggest that in order to obtain high quality, children in need of conscious sedation should be offered this treatment by dentists having extensive experience in the method. We furthermore suggest that this is part of the reason why we need a postgraduate training programme for specialist paediatric dentist in Denmark.

In accordance with Erlandsson *et al.*[9], we found only few complications. The small number of children that presented with paradoxical reactions was anticipated[8,20]. For these children, general anaesthesia must be considered if there is an immediate need for comprehensive dental treatment.

As only half of the parents returned the questionnaire, the results on parental acceptance of the method should be assessed with caution. One reason for the low response rate could be that a questionnaire had to be filled in after each sedation session, and that parents who were satisfied with the method may not find it necessary to fill in the same questionnaire at subsequent sessions. On the other hand, it may also be assumed that unsatisfied parents would not be willing to spend time on issues of no importance to them, and therefore chose not to return the questionnaire.

The method does, however, seem to be well-accepted by the parents as evidenced by the fact that 88.2% of parents who returned the questionnaire would choose the technique again for their child if needed. This stands in contrast to what Alammouri[21] reported in a study on parental attitudes towards behaviour management techniques, where only 27.5% preferred conscious sedation.

As mentioned earlier, we found very few complications related to midazolam sedation. The law in Denmark does not presently require monitoring by pulse oximeter in connection with conscious sedation, and it was therefore not used in this study. In a study by Krafft *et al.*[20], low respiratory function (≤ 80% oxygen saturation) was diagnosed by pulse oximeter in two of 72 children sedated with midazolam, but they had administered higher doses (0.7 mg/kg body weight) than in this study. In a study by Lindh-Strömberg[8] of 120 children sedated with rectal midazolam, 50% were monitored. None of these children had an oxygen saturation below 92%. The use of pulse oximeter, however, should be investigated further.

Conclusion

We found that midazolam conscious sedation during dental treatment of children and adolescents with dental fear and anxiety, and behaviour management problems is a feasible, an efficient, and an acceptable method with a low rate of complications. The number of children who have to be referred to general anaesthesia could probably be reduced by using this method. In order to obtain high-quality assurance, midazolam conscious sedations should be performed by dentists who will have a sufficient volume of sedation sessions to gain high competency in the use of this method.

What this paper adds

- Knowledge about the process of implementation of midazolam conscious sedation in an organization with a large number of dentists, and the importance of training in the use of the method.
- It confirms that midazolam conscious sedation during dental treatment of children and adolescents with dental fear and anxiety, and behaviour management problems is a feasible, an efficient, and an acceptable method with a low rate of complications.

Why this paper is important to paediatric dentists

- Midazolam conscious sedation should be considered an alternative to general anaesthesia.
- It illustrates the need for further research into the use of pulse oximetry.

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