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Parental Recall of Post-Sedation Effects of Oral Midazolam in Paediatric Dental Patients

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Abstract **Objectives:** To assess parental recall of post-sedation effects of Oral Midazolam (OM) in paediatric dental patients and its association with patients' age, gender and type of dental treatment. **Methods:** This cross-sectional study used structured phone interviews involving parents or guardians of children treated with OM from February 2023 to February 2024 at the Paediatric Dental Specialist Clinic, Universiti Sains Malaysia (USM) Specialist Hospital, Malaysia. The structured phone interview contained sociodemographic data and OM post-sedation effects. **Results:** Fifty-four respondents participated in this study. On sedation day, most children slept on the way home (48.1%), taken a prolonged nap (29.6%) and experienced difficulty awakening (7.4%). A few experienced fevers (7.4%), eating problems (3.7%) and nausea (1.9%). By the next day, only 1.9% (n = 1) children had a post-sedation effect, each for prolonged naps, fever and difficulty awakening. The most common treatment was tooth extraction (96.3%), with only 2 (3.7%) cases involving stainless steel crown placement. A significant correlation was found between fever and the patient's gender (p = 0.004). **Conclusion:** Post-sedation effects of OM sedation include sleeping on the way home, prolonged naps and difficulty awakening. OM sedation is relatively safe since most children recover within a day of post-sedation. Further prospective research is needed to explore its safety margin among paediatric dental patients.

Key Words Oral Midazolam, Post-Sedation Effects, Dental, Children, Parents

INTRODUCTION

The delivery of diagnostic or therapeutic procedures to the young, uncooperative and anxious paediatric patients poses numerous challenges to the dental practitioner. Collectively, 30% of global younger children are experiencing dental anxiety or fear [1]. Conventional non-pharmacological behaviour management, along with local anaesthesia, is commonly applied to most paediatric patients in dental clinics [2]. However, sedation may be required to properly administer dental treatment to certain paediatric patients who struggle with behavioural management issues, including fear and anxiety. This is to prevent psychological distress, avoid dental treatment and deteriorate oral health [3].

There are various ways to give sedative medications, including intramuscular, intravenous, oral and intranasal. The oral route is the most commonly utilised approach in dentistry, as it is child-friendly, convenient and bearable [2]. Midazolam is one of the benzodiazepine derivatives, which has sedative, anxiolytic and anterograde amnesia effects [4]. The efficacy and safety of Oral Midazolam (OM) for minimal to moderate sedation in paediatric patients were reported at doses ranging from 0.25 mg to 1.5 mg per kilogram body weight, with demonstrated concordance of side effects at increasing doses [5]. According to specific research, paediatric patients receiving dental treatment under OM in addition to other sedative medications improve their behaviour and level of sedation [6].

Dental sedation for children has an outstanding safety record. Nevertheless, complications can still occur, including those related to post-sedation. A thorough preoperative evaluation of the patient's medical status, consideration of how these conditions might affect the sedation and adherence to the discharge criteria outlined in the American Academy of Pediatric Dentistry (AAPD) guidelines before discharging the patient could all help to minimise, if not eliminate, the possibility of unfavourable effects during and after sedation [7]. Hence, the parents' role is crucial in continuously monitoring the child after sedation and leaving the dental surgery. In children, the recovery time after oral sedation, which returns to baseline physiological status according to caregivers, ranges from a few hours to the following morning [8].

Post-sedation effects and adverse effects may occur in patients who have undergone dental treatment under OM sedation. This effect includes excessive somnolence post-discharge, nausea, vomiting, fever, restlessness, irritability, trouble speaking or walking and changes in activity or behaviour [8]. Parents or legal guardians are often used as proxies to report information on behalf of their children in observational health research. Despite the frequent use of OM sedation, limited evidence exists on parental recall of OM post-sedation effects among Malaysian children population in the dental settings.

Thus, the aims of this study include:

- To assess parental recall of post-sedation effects of OM in paediatric dental treatment till day one OM post-sedation
- To determine the associations between OM post-sedation effects with patients' age, gender and type of dental treatment

METHODS

Study Design and Setting

This study employed a cross-sectional design that involved one parent or legal guardian of each child who underwent dental treatment under OM sedation at the Paediatric Dental Specialist Clinic, Universiti Sains Malaysia (USM) Specialist Hospital, Malaysia.

Participants and Sampling

This study applied the total sampling method that involved 54 parents or legal guardians of paediatric patients that underwent dental treatment under OM sedation in Paediatric Dental Specialist Clinic, USM, Malaysia, from February 1, 2023, to January 31, 2024. The list of paediatric patients who underwent dental treatment under OM sedation was retrieved from the appointment book. By using this list, the patient's medical record was retrieved from the Record Unit at USM Specialist Hospital to collect relevant details related to the research criteria, including the parent's contact number. The inclusion criteria included one parent who was fluent in either Malay or English and parents of patients with a physical classification of ASA 1 or ASA 2, as classified by the American Society of Anesthesiologists (ASA) physical classification system. The exclusion criteria were parents with mental and hearing disability, unsuccessful oral midazolam sedation and treatment was not completed and using oral sedation in combination with other types of sedation or drugs.

Data Collection Tools

Phone Interview: Parents were contacted via the USM landline phone by the main researcher to briefly explain the study's objectives and obtain verbal consent for participation. Consequently, a soft copy of consent was sent to each verbally consented parent via WhatsApp Messenger or email for an official agreement. Once the consent is retrieved, the main researcher would contact the parents back via the same landline phone number. Essentially, all the data was collected through phone interviews, which lasted less than 15 minutes per call. For any data that the parent could not recall, it was noted as 'Not sure'.

Interview Script and Format

A script for verbal consent was prepared in Malay and English versions. The phone interview was conducted by the first author only, hence no inter-rater reliability applied. The first author was not involved in any sedation treatment for the whole sample size. Initially, the first author would use this script to provide brief information about this study, including the researchers involved, study aims, interview procedure, voluntary participation, confidentiality of data provided by parents and verbal agreement for participation. The parents have also been allowed to ask any questions at any time during the interview that is relevant to this study.

The parent was interviewed using a structured questionnaire to examine their recollection of their child's post-sedation effects. This questionnaire was adapted from Huang and Tanbonliong [8]. This questionnaire served as a guide for the main researcher to ask questions about post-sedation during the phone survey. It consists of two parts, with Part 1 containing sociodemographic data and Part 2 detailing post-sedation effects. Examples of questions in part 1 include the child's age during sedation, gender, race and the child's past medical history. Examples of questions in part 2 include the following:

- Slept on the way home
- Difficult to awaken upon reaching home
- Prolonged nap
- Breathing difficulty
- Problems with eating
- Nausea
- Vomiting
- Diarrhoea
- Constipation
- Fever

The Malay version of the questionnaire had been translated with the assistance of a professional Malay translator but not validated. The pre-test of this questionnaire content was conducted by distributing it to 10 parents or guardians of patients attending the Paediatric Dental Specialist Clinic at the USM Specialist Hospital, which were not included in the total sample size of this study.

Statistical Analysis

All data was entered in SPSS version 29. The computed frequency and percentage were used to assess the likelihood of unfavourable events following discharge. For comparing the percentage of participants reporting post-sedation effects and adverse events in this sedation regimen, Fisher's exact test was used. A priori, the significance level was set at $p<0.05$.

RESULTS

A total of 54 out of 60 parents agreed to participate in this interview. Table 1 shows the demographic data of 54 patients who had undergone dental treatment under OM sedation within the period of one year.

Based on Table 2, most parents claimed that their child did not sleep (n = 28) on the way back home after the OM sedation on the day of sedation. The number of children who slept on the way back home was almost similar (n = 26). This was followed by the majority of them do not having prolonged naps at home after the sedation and had neither difficulty awakening from sleep upon reaching home nor problem with eating. Only 1 (1.8%) child experienced nausea on the day of sedation. No other sedation effects were reported, such as breathing difficulties, diarrhoea, constipation and vomiting.

On day 1 post-sedation, as shown in Table 3, parents reported that 98.1% (n = 53) of children experienced neither prolonged nap nor eating problems. Only 1 (1.9%) developed fever on day 1 post-sedation and 1 (1.9%) reported as 'not sure'. No other side effects were observed by the parents in these children.

Based on the results in Figure 1, the most common dental treatment performed under OM sedation was tooth extraction, with a percentage of 96.3% (n = 52), followed by stainless steel crown placement which consists of 2 patients.

Table 4 presents the correlation between OM post-sedation effects and patients' age, gender and type of dental treatment. There is a correlation between fever and the patient's gender; however, no correlation is found between other post-sedation effects and age or type of dental treatment. For post-sedation effects such as vomiting, diarrhoea and breathing difficulty, no correlation analysis could be performed since no parents reported these effects.

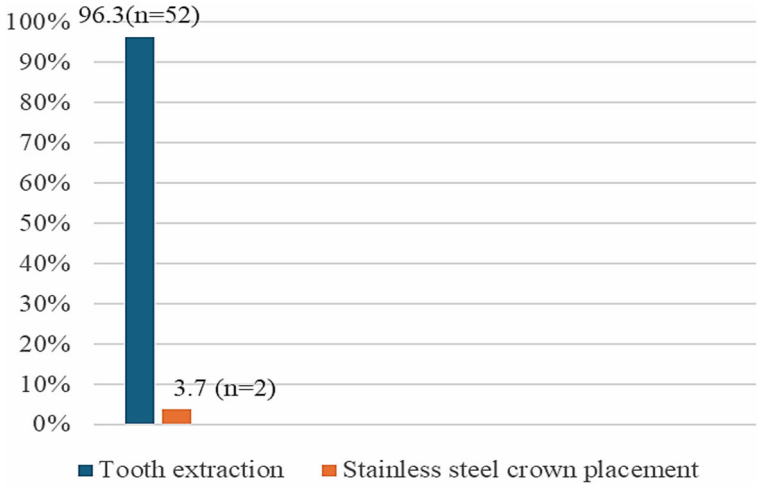

Figure 1: Type of Dental Treatment done Under Oral Midazolam Sedation (N = 54)

Table 1: Demographic data (N = 54)

Demographic data		Frequency (%)	Mean (SD)
Patient's age during sedation	(1- to 5-year-old	30 (55.5)	5.44 (1.701)
	(6- to 10-year-old	24 (44.5)	
Gender	Male	27 (50)	0.48 (0.504)
	Female	27 (50	
Race	Malay	54 (100%)	1.00
	Chinese	-	
	Indian	-	
Past Medical History	Yes	2 (3.7%)	0.04 (0.191)
	No	52 (96.3%)	

Table 2: Parental Recall of Type of Post-Sedation Effects on Sedation Day in Paediatric Dental Patients who Received OM Administration (N = 54)

Recall incidence of post-sedation on sedation day	Yes Frequency (%)	No Frequency (%)	Not Sure Frequency (%)
Slept on the way home	26 (48.1%)	28 (51.9%)	0
Prolonged nap	16 (29.6%)	37 (68.5%)	1 (1.9%)
Difficult to awaken upon reaching home	4 (7.4%)	50 (92.6%)	0
Fever	4 (7.4%)	50 (92.6%)	0
Problems with eating	2 (3.7%)	52 (96.3%)	0
Nausea	1 (1.8%)	53 (98.1%)	0
Breathing Difficulty	0	54 (100%)	0
Diarrhoea	0	54 (100%)	0
Constipation	0	54 (100%)	0
Vomiting	0	54 (100%)	0

Table 3: Parental Recall of Type of Post-Sedation Effects at Day 1 Post-Sedation in Paediatric Dental Patients who Received OM Administration (N = 54)

Recall incidence of day 1 post-sedation	Yes Frequency (%)	No Frequency (%)	Not Sure Frequency (%)
Prolonged nap	1 (1.9%)	53 (98.1%)	0
Problems with eating	1 (1.9%)	53 (98.1%)	0
Fever	1 (1.9%)	52 (96.3%)	1 (1.9%)
Breathing difficulty	0	54 (100%)	0
Difficult to awaken	0	54 (100%)	0
Vomiting	0	54 (100%)	0
Diarrhoea	0	54 (100%)	0
Constipation	0	54 (100%)	0
Nausea	0	54 (100%)	0

Table 4: Correlation between Post-Sedation Effects and the Patient's Age, Gender and Type of Dental Treatment using Fisher's Exact Test (N = 54)

	Sociodemographic and dental treatment type		
Post-sedation symptoms	Patient's age	Gender	Type of dental treatment
Prolonged Nap	0.229	0.132	0.27
Eating problem	0.143	0.143	0.27
Fever	0.267	0.004*	0.38
Difficult to awaken	-	-	-
Nausea	-	-	-
Vomiting	-	-	-
Diarrhoea	-	-	-
Constipation	-	-	-
Breathing difficulty	-	-	-

Analysis using Fisher's exact test with a significant $p<0.05$

DISCUSSION

A total of 54 parents of paediatric patients who received OM sedation during dental treatment were involved in recalling the post-sedation effects after the sedation and on day 1 post-sedation. More than half of these children (55.5%) were toddlers. It shows that young children who are aged below 6 years tend to display dental anxiety, particularly with previous dental experience [9]. The use of sedation as part of behaviour management in children during dental treatment is inevitable. Parents play a vital role in continuing to monitor post-sedation effects on their child once they being discharged from the dental setting.

Sedation Day

The most reported post-sedation effect on the sedation day was drowsiness, with almost half of children (48.1%) slept on the way home. These findings are almost similar to a previous study by Huang and Tanbonliong (2015) [6], who discovered that more than half (60.1%) of patients slept upon reaching home after oral sedation, apart from majority of them also had prolonged naps at home on the same day of sedation. The latter study evaluated multiple regimes of sedative drugs in paediatric dental patients, which only minority used OM. Likewise, research by Ritwik *et al.* [10] found that about half of the sedated children slept in the car on the ride back home for both regimes, namely meperidine with hydroxyzine pamoate or midazolam alone. It should be noted that the difference in OM dosage was applicable in this current study and other previous studies. Higher dose of OM exhibits more post-sedation adverse events such as excessive napping, irritation, dizziness and vomiting [11]. When comparing the use of a regime of multiple drugs, such as chloral hydrate, meperidine and hydroxyzine, with OM alone, children tend to have prolonged post-sedation sleeping all the way home and difficulty in awakening [12]. The infrequent occurrence of other post-sedation effects, such as nausea and eating problems, is aligned with other studies [10-12]. In summary, on the same day of OM sedation, the common post-sedation effects are sleeping on the way back home, prolonged nap and difficult to awaken.

Day 1 Post Sedation

By the first day after sedation, most side effects occurred in merely 2% of instances, closely resembling the findings by previous studies [8,10,11]. It means that these children would return to normal physiological condition on day 1 post-sedation. Approximately 18 out of 53 paediatric patients who underwent dental treatment under OM sedation showed excessive sleep at 24 hours post-sedation, compared to 13 patients in chloral hydrate group [11]. This might be due to the higher dosage of OM used during dental treatment, averaging from 1.0 to 1.5mg/kg bodyweight. Contrast to this current study which capped OM dosage of 0.5mg/kg bodyweight, only one (1.9%) of 54 paediatric patients had prolonged naps at day 1 OM post-sedation. The use of OM alone produces earlier normal baseline behaviour, which is within 6 hours from discharge compared to a combination of drugs [2,10,11]. In comparison, an earlier pilot study revealed no difference in post-sedation effects within 24 hours after discharge from dental surgery between OM alone and a combination of sedative drugs [12]. The lower occurrence of side effects the next day may be linked to the liver's primary metabolism of midazolam, facilitating its effective removal in children. Moreover, children's capacity to resume their normal activities indicates that the sedation effects do not extend beyond the anticipated duration, further supporting its safety profile.

Pharmacokinetic of Midazolam in Children

Understanding the pharmacokinetic and metabolism of midazolam is imperative when developing the sedation plan that suits the patient and dental procedure. The quick reduction in post-sedation effects corresponds to the pharmacokinetics of midazolam, which features a comparatively short half-life, resulting in its swift removal from the body, particularly in older children [13]. A microtracer pharmacokinetic study of OM shows that with increasing age of a child, the oral bioavailability of OM is decreasing with the range of 25% to 85% due to higher Cytochrome P3A (CYP3A) enzyme activity in both the intestinal wall and liver [14]. This highlights the elevated risk of subtherapeutic or toxic exposure to orally administered midazolam and potentially other CYP3A substrates, in the paediatric population. Higher doses of midazolam, especially 1.0 to 1.5 mg/kg bodyweight, are associated with a greater frequency of adverse events such as paradoxical reaction and respiratory event, as well as over-sedation [5].

Dental Treatment under OM Sedation

A comparable pattern was noted in the study by Day *et al.* [15], where extractions constituted the most frequently conducted procedures under OM sedation, followed by restorations, which are consistent with the current study. Moreover, their research indicated that the placement of stainless steel crowns constituted half of the extraction numbers. In contrast, a recent study using OM and paediatric hypnosis technique shows that the majority of treatments performed were stainless steel crowns with pulpotomy or root treatment (26%, n = 81) and 19.8% (n = 62) underwent tooth extraction during the first sedation visit [16]. In this present study, stainless steel crown placement using Hall's technique was used, without root treatment. In view of the OM sedation period lasting less than 30 minutes, which may be inadequate for long restorative treatments that require significant cooperation from the child [17]. Thus, OM is more suitable for paediatric dental treatment, such as simple extractions and restorations [15]. There is no further definitive explanation about 'simple' in the context of dental treatment provided by the author. The length of treatment also affects sedation results. However, a review had shown that OM produced a lower success rate of sedation and analgesia during tooth extraction when compared with nitrous oxide inhalation [18]. Since midazolam's complete sedative effect may last after the procedure is over, shorter treatments may paradoxically result in more evident post-sedation effects [19].

Correlation of OM Post-Sedation Effects with Age, Gender and Dental Treatment

Additionally, no notable correlations were identified between post-sedation effects and age or type of dental treatment. However, there is a significant correlation with the patient's gender and post-sedation effects. Differences in sedation response between genders may be associated with physiological aspects, such as variations in fat distribution, hormonal effects, body water volume and enzyme activity, that impact drug metabolism [20]. Nevertheless, the reasons behind the differences in post-sedation effects between genders remain unclear [13,21]. Future research is valuable for investigating the biological foundations of gender disparities in OM sedation responses and evaluating whether changes in dosage or sedation protocols could enhance favourable patient outcomes.

The post-sedation effects of OM, particularly regarding recovery duration and sedation depth, can be influenced by several factors. It is essential to comprehend these elements to maximise patient care and guarantee safety. First and foremost, the dosage and method of administration are crucial. In contrast to intranasal methods, OM administration typically has a more extended recovery period and a slower onset [22]. More extended recovery periods and more profound sedation are usually linked to higher dosages. Second, the patient's age is a significant consideration. Older patients typically have a higher sensitivity to midazolam, which can result in longer-lasting sedative effects, while younger children may metabolise medications differently than older children or adolescents [23].

Based on our limited knowledge, this is the first study that focuses and assesses the post-sedation effect of OM in Malaysian children on the day of sedation (after discharge from dental surgery) till the first day of post-sedation. It also includes the type of dental treatment performed under OM sedation alone, using the same dose of 0.5 mg/kg body weight. This study contrasts with previous studies that have included comparisons of OM with other sedative drugs and using various OM dosages [2,4,8,10-12,24].

Findings in this current study support the safety of OM with minimal residual effects, emphasizing the importance of post-sedation parental monitoring and adherence to AAPD discharge protocols [7]. For instance, parents can be advised regarding the position of their child's head to prevent respiratory disruption during post-sedation sleep.

Strengths and Clinical Implications

Parents are the main figure for further monitoring their children after the sedation starting from the trip back home. This study provides data that focuses on the real-world parental recall of OM post-sedation effects. The evaluation is limited to the use of OM without any additional sedative drug, to ensure minimal adverse reactions from the polypharmacy effects. Our findings support the crucial information regarding the OM post-sedation effects till day one after discharge to dental practitioners. This will reinforce counselling values that may assist them in preparing parents to monitor their children closely on the way home and at home. Any adverse events need to be addressed immediately by bringing the child for emergency management.

CONCLUSION

In summary, OM sedation remains a safe and effective sedative for paediatric dental treatments, with tolerable post-sedation effects during the sedation day and on the first post-sedation day. Most children reach the baseline physiology

condition on day one OM post-sedation. The most frequently mentioned symptoms are drowsiness, prolonged naps and difficulty waking up from sleep. These findings emphasize the significance of comprehensive pre-sedation counselling and post-operative guidance for parents or caregivers. Keeping them aware of potential effects after sedation may help alleviate parents' anxiety and enhance overall satisfaction with the dental treatment done under sedation. Additional studies involving larger and multi-centre validation samples are suggested to confirm these results and to help formulate better sedation protocols and parent education guidelines.

Limitations and Recommendations

The outstanding limitation of this study is that it depends on the recall capability of parents. Given that each child reacts differently to midazolam sedation, these contributing factors may be partially responsible for the variation in parental recollection. Parents may notice variations in post-sedative behaviours due to changes in metabolism, surgical kinds and preoperative anxiety levels. A time span of up to one year is commonly used for observational studies in dental health research, as it is often considered adequate for proxy in recalling post-sedation effects [25]. In this present study, the maximum duration for recalling the OM post-sedation effects by the parents was one year. A prospective observational design study is crucial for gaining a better understanding of OM post-sedation effects in children, particularly with larger sample sizes. A more extended observational period may help to assess the length of OM post-sedation impact in children. In addition, baseline behaviour assessment and dental anxiety evaluation are essential factors. Higher doses of sedation may be necessary for children with high levels of dental anxiety and they may also lengthen the recovery period [26]. Thus, dental anxiety assessment can be determined before OM sedation for more conclusive findings. Additionally, recall bias inherent to parent-reported data may affect accuracy of the collected data.

Declaration of Patient Consent

All parents involved had given their consent before the interview.

Ethical Statement

The study was approved by the Internal Review Board of Human and Ethics Committee, USM (USM/JEPeM/KK/24040327).

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