

Effectiveness and acceptability of intravenous sedation in child and adolescent dental patients: report of a case series at King's College Hospital, London

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VERIFIABLE CPD PAPER

IN BRIEF

- Provides information on the safety of IV sedation in clinical paediatric dentistry.
- Provides information on the efficacy of IV sedation when providing care to children.
- Demonstrates the broad range of procedures in young children who would otherwise have had general anaesthesia.

Introduction Conscious sedation for young patients continues to be challenging. Few studies have shown positive results using intravenous midazolam when sedating young patients. This case series reports an investigation of conscious sedation using intravenous midazolam for young patients receiving dental treatment. **Objective** To determine acceptance, safety and efficacy of intravenous midazolam for conscious sedation in children and adolescent patients undergoing dental treatment. **Patients and methods** Patients from seven to 16 years of age, ASA I, II and III, opted to have extractions, minor oral surgery and/or conservative treatment with IV midazolam and local anaesthesia. A pulse oximeter was used to monitor vital signs and the Houpt scale to assess overall behaviour. **Results** A total of 552 patients, 234 boys and 318 girls with mean ages of 13.3 years and 13.5 years respectively, were included. Three hundred and sixty-five patients (66%) claimed to be anxious or very anxious before treatment. The average dose given was 5.7 mg and dosage ranged from 2 to 10 mg. Four hundred and fifty-seven patients (83%) scored 'very good' and 'excellent' for overall behaviour. Side-effects included crying, drowsiness and amnesia. **Conclusions** Intravenous midazolam is accepted by patients and is a safe and effective method of sedation for use in children and adolescents, producing some level of tearfulness.

INTRODUCTION

The use of intravenous sedation in paediatric dentistry has been evolving over the years. A report from the General Dental Council on professional conduct and fitness to practice¹ in 1993 indicated that intravenous sedation in children was unpredictable, has a narrow safety margin, and carries with it the ever-present risk of a paradoxical reaction. Lately, the Standing Committee on Sedation for Dentistry² reporting in 2007 described forms of sedation other than inhalation sedation as an 'alternative technique', although they limited this caveat to children below 12 years of age.

In 1993 the Royal College of Surgeons issued guidelines on sedation by

non-anaesthetists,³ stating that 'intravenous sedation is hazardous in children as the therapeutic margin between sedation and anaesthesia is narrow'.

The British Society for the Study of Paediatric Dentistry published *A policy document on sedation for paediatric dentistry*⁴ in 1996, making recommendations for the role of sedation in paediatric dentistry, including IV sedation.

In 2000, the *A conscious decision* document encouraged the use of conscious sedation as an alternative to general anaesthesia.⁵ The 2002 UK National Clinical Guidelines in Paediatric Sedation⁶ recommended single-agent intravenous sedation for adolescents administered in an appropriate setting by an experienced sedationist with a sedation-trained nurse and monitoring of pulse rate and tissue oxygenation with a pulse oximeter. It was also recommended that for children under the age of 14 years intravenous sedation should be carried out in hospital.

A report from the Expert Group on Sedation for Dentistry commissioned by the Department of Health in 2003 and

guided by the Standing Dental Advisory Committee⁷ (SDAC) followed the same principles as the Royal College of Surgeons guidelines. However, some evidence is beginning to materialise, as stated in an article entitled *Recent advances in conscious sedation*⁸ showing midazolam and propofol intravenous sedation to be of assistance for unpleasant or lengthy dental procedures. The authors did not report any paradoxical reactions to the sedative technique.

A further study reported that children 11 to 15 years of age were successfully managed using intravenous midazolam. It is of note that sedation was administered by an anaesthetist. It concluded that '... further research into the use of intravenous conscious sedation in patients under of 16 is required. There is insufficient evidence currently available to support the routine use of conscious sedation in the age group, but equally there is sufficient doubt to make an absolute prohibition of the use of these techniques in this age group of patients unjustifiable.'⁹

Evidence in the paediatric medical literature shows favourable use of intravenous

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conscious sedation for endoscopy, oesophageal manometry and biopsy.¹⁰ The degree of invasion and time taken to provide these procedures may correspond to that of routine dental treatment for a child.

A pilot study and a randomised controlled trial used IV midazolam combined with or without inhaled nitrous oxide or with nitrous oxide plus sevoflurane for dental treatment. It reported these as effective techniques, with the sevoflurane combination being the one most likely to result in successful treatment in children between six and 14 years of age. In these studies an anaesthetist was involved in providing sedation.^{11,12} Intravenous midazolam was also compared to nitrous oxide in a crossover study on dental treatment in children between 12 and 16 years old. The authors concluded that IV midazolam appeared to be as effective as nitrous oxide, with 51% of children preferring IV sedation.¹³ This study also showed acceptability of cannulation in this age group.

An Indian study included children aged three to six years using midazolam 0.1 mg/kg bolus plus 0.004 mg/kg/min infusion *versus* propofol 1 mg/kg bolus plus 0.06 mg/kg/min infusion *versus* ketamine 0.5 mg/kg bolus plus 0.01 mg/kg/min infusion. Furthermore, all children had premedication one hour before of 0.5 mg/kg midazolam and atropine (0.6 mg).¹⁴ This is clearly not minimal or moderate sedation as described in the 2010 NICE (National Institute for Health and Clinical Excellence) guidelines.¹⁵ In the UK, in dentistry, the recommendation is the use of a single agent. Sedation other than with nitrous oxide for children under 12 is to be carried out in hospital by a trained sedationist, as reported by the Standing Committee on Sedation for Dentistry.²

The NICE guidelines also support the clinical scenario of the operator-sedationist. This is important as sedation for dental practice is now regarded as minimal to moderate sedation as defined in the NICE guidelines. The essential criterion indicating that the patient is conscious is the ability to respond appropriately to verbal communication and to maintain a patent airway.

One of the comments in the NICE guidelines is that there is little evidence on the efficacy and safety of IV midazolam and

more research is recommended. This case series addresses these issues.

PATIENTS AND METHODS

The sample comprised of young patients aged between 7 and 16 years referred to the Paediatric Sedation Department over the period of October 2006 to May 2010. Initial diagnosis and treatment planning was carried out at new patient clinics and casualty clinics in the Department of Paediatric Dentistry at King's College Hospital. The options for pain control were explained and discussed with patients and their parents or carers. All dentists assessing these patients discussed with them and/or the parents the six methods of encouraging patients to accept pain control with local anaesthesia:

1. Behaviour management only
2. Behaviour management plus inhalation sedation
3. Behaviour management plus oral sedation
4. Behaviour management plus intravenous sedation
5. Behaviour management and intranasal sedation
6. General anaesthesia.

The following criteria were used:

- Young patients identified as anxious, uncooperative or with need of complex dental treatment. The level of anxiety was judged by a combination of factors such as self- or parental report and/or information provided by the referring dental surgeon. The complexity of treatment was judged by the clinician performing the assessment
- Clinical ratings of I, II or III were made using the scale of the American Society of Anesthesiologists,¹⁶ using child's medical history as provided by parents and information sent with the referral letter
- Not allergic to benzodiazepines.

The patients whose choice was intravenous sedation were included in the study. A full verbal and written explanation of the study was given, informed written consent was obtained and an appointment arranged after a topical cream (EMLA or AMETOP) and an adhesive had been given to parents to place on the skin one hour before the sedation appointment. It was

explained that an adult escort was needed for each patient attending for treatment.

On the day of treatment a pre-sedation list was checked including reconfirmation of consent for procedure and sedation and whether pre-sedation instructions were followed: light meal, being well, appropriate escort, medication taken and confirmation of medical history. Patients were encouraged to empty their bladder. Patients' baseline anxiety was recorded by asking them to rate how they were feeling before the procedure as very anxious, anxious, a bit anxious or not anxious.

Blood pressure, heart rate and arterial oxygen saturation were taken and noted at baseline. In the case of extractions, patients were given an appropriate dosage of analgesic, following the Oral Surgery Department protocol.

All dental treatment and sedation was provided by one dentist (LLM), who had advanced training in intravenous sedation and paediatric life support.

Syringes were marked with midazolam labels, the ampoules' batch number and expiry date, and time and site of administration; dosage used was noted.

The anterior cubital fossa and the dorsum of the hand were the most common sites for cannulation. If a topical cream was not used, ethyl chloride was sprayed before venipuncture. A tourniquet was used to help cannulation. A Y-can or a Venflon paediatric cannula for thin veins was used. Acceptance of cannulation was noted.

Midazolam ampoules (10 mg/5 ml) were used in titration of 1 mg over 30 seconds, waiting for 90 seconds and then giving increments of 1 mg every 30 seconds until the appropriate level of sedation was achieved according to child's response, without exceeding 10 mg. The concentration of the ampoules was later changed to 5 mg/5 ml owing to new safety regulations.

A pulse oximeter was attached to the patient's finger throughout sedation, dental treatment and recovery. This measured the peripheral arterial oxygen (SpO₂).

Dental treatment included extraction of unrestorable teeth, roots of permanent molars, retained primary molars and orthodontic extractions; exposure and bonding of impacted canines; root canal therapy; removal of odontomes and supernumeraries; apicectomies and conservative treatment.

Rating scale	Score
A. Rating scale for sleep	
Fully awake, alert	1
Drowsy, disoriented	2
Asleep	3
B. Rating scale for movement	
Violent movement interrupting treatment	1
Continuous movement making treatment difficult	2
Controllable movement that does not interfere with treatment	3
No movement	4
C. Rating scale for crying	
Hysterical crying that demands attention	1
Continuous, persistent crying that makes treatment difficult	2
Intermittent, mild crying that does not interfere with treatment	3
No crying	4
D. Rating scale for overall behaviour	
Aborted - No treatment rendered	1
Poor - treatment interrupted, only partial treatment completed	2
Fair - treatment interrupted, but eventually all completed	3
Good - difficult, but all treatment performed	4
Very good - some limited crying or movement, for example, during anaesthesia or mouth prop insertion	5
Excellent - no crying or movement	6

Fig. 1 The Houpt Scale used for rating patient behaviour during treatment

The complexity of dental treatment was rated. 'Simple', for example, could include extraction of a single-rooted tooth or conservation without local anaesthetic. 'Moderate' included conservation of a permanent tooth using a rubber dam or extraction of one broken-down molar or four premolars. 'Moderate/complex' was a mixture of conservation and extraction or a difficult broken-down molar extraction. 'Complex' treatment included minor oral surgery or surgical extractions. Following completion of treatment, heart rate and oxygen saturation were recorded.

Patients were placed in a recovery area until the operator-sedationist assessed fitness for discharge and final blood pressure was taken. A child was fit to be discharged when vital signs (heart rate, blood pressure and respiratory rate) had returned to normal levels, the child was awake, alert and responsive and there was no risk of further reduced level of consciousness, and nausea, vomiting and pain had been adequately managed, if present.

Full written and verbal postoperative sedation and surgical instructions were provided. The behaviour of the patient during treatment was rated by the operator using the Houpt Scale (Fig. 1) for level of sedation, movement, crying and overall behaviour.¹⁷

Completion of planned dental treatment was recorded as 'YES' or 'NO' and drop-outs were reported and reasons given. Side-effects such as nausea, vomiting, diplopia, hiccups and crying were recorded.

All data subsets, for example, boys and girls, were tested for normality using the Shapiro-Wilk test. The Mann-Whitney U test was used for continuous variables and the chi-square or Fisher's exact probability test for categorical variables. The statistical software used was Stata.¹⁸

RESULTS

A total of 564 patients were referred for dental treatment using intravenous sedation. The patients were first assessed by consultants (130, 23%), senior staff (203,

36%) and junior staff or trainees (231, 41%). Sedation was requested by patients/parents (48), by general dental practitioners (47) and by King's consultants (130). Thirteen patients were initially referred to have treatment under GA. Indication for sedation also included patients who were perceived as very anxious at the assessment (147), possible surgical extractions (87), complex treatment (29) and special needs patients (31). No indication of the need for sedation was recorded for 20 patients.

Cannulation was accepted by 128 boys (55%), whereas 71 (30%) were a bit reluctant and 35 (15%) very reluctant at cannulation. For girls, 180 (57%) accepted cannulation, 86 (27%) were a bit reluctant and 52 (16%) very reluctant at cannulation. No statistically significant difference was found ($p = 0.68$). Two patients had IV sedation but were over 16 years of age on the day of the treatment. Three patients refused cannulation: two had treatment under GA and one refused any treatment. Venous access was not possible in four patients who then had treatment under inhalation sedation. Three patients had intranasal sedation to allow cannulation. These last 12 patients were not included in this report.

The final sample was 234 boys (42%) and 318 girls (58%). The mean ages were 13.3 years (range 7.4 to 16.5 years) and 13.5 years (range 8.1 to 16.7 years) for boys and girls respectively. No statistical differences were found regarding age ($p > 0.4358$). The ethnicity was divided into Caucasians (178, 32%), Afro/Caribbean (230, 42%) and Asians and others (174, 26%). No statistical differences were found ($p = 0.602$).

The majority of patients were ASA I (499, 90%): this included patients with learning difficulties, such as autism, ADHD, Asperger's syndrome and Down syndrome. The ASA II group (46, 8.5%) included patients with sickle cell trait, sensory integration dysfunction, neurofibromatosis type 2, Marfan's syndrome, type 1 diabetes, hypothyroidism, rickets, cerebral palsy, excess weight, liver transplant and controlled epilepsy. In the ASA III group (7, 1.5%) there were patients with sickle cell disease, severe asthma and uncontrolled epilepsy. All ASA III patients were in good health at the time of their sedation appointment. Supplemental oxygen was readily available.

All patients were given sedation and doses were titrated in relation to their

Table 1 Patients' characteristics

	Age (years)				ASA			Self-rated anxiety			Dosage (mg)			Ethnicity		
	N	Mean	SD	Range	I	II	III	VA	A	BA, NA	Mean	SD	Range	Caucasion	Black	Other
Boys	234	13.3	1.8	7.4 - 16.5	208	23	3	74	62	43.55	5.2	1.0	2.5-9	71	99	64
Girls	318	13.5	1.8	8 - 16.7	291	23	4	175	54	49.40	5.2	1.1	2-10	107	131	80

Table 2 Patients' movement and crying using Houpt scale

	Movement				Crying			
	Violent	Continuous	Controllable	None	Hysterical	Continuous	Intermittent	None
Boys	7	11	46	162	7	11	41	167
Girls	5	23	64	217	7	36	78	188

Table 3 Patient's overall behaviour using the Houpt scale

	Overall behaviour (Houpt scale)					
	Aborted	Poor	Fair	Good	Very good	Excellent
Boys	0	2	13	17	49	153
Girls	1	4	23	35	79	176

Table 4 Patients' overall behaviour and their self-rated anxiety

Self-rated anxiety	Overall behaviour (Houpt scale)									
	Poor		Fair		Good		Very good		Excellent	
	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls
Very anxious	2	3	4	18	12	29	18	46	38	78
Anxious	0	0	5	4	3	6	15	13	35	31
A bit anxious	0	1	0	1	0	0	6	12	37	35
Not anxious	0	0	4	0	2	0	10	8	39	32

response. Dosages ranged from 2 to 10 mg and no statistical differences were found between the two groups ($p = 0.935$). Patient demographics are shown in Table 1.

Boys' self-rating of their anxiety showed that 136 (58%) were anxious or very anxious compared to 229 girls (72%). Girls claimed more anxiety than boys before treatment and this was statistically significant ($p < 0.001$).

There was no significant difference between girls and boys for the level of sedation. Only 1 girl remained alert and treatment was aborted. Statistical differences were found for crying ($p = 0.002$), with girls crying more than boys. No statistical differences were found for movement ($p = 0.391$, Table 2).

The overall behaviour during dental treatment under sedation was recorded. 'Good' (difficult but all treatment performed) and

Table 5 Complexity of dental treatment by gender

	Simple	Moderate	Moderate to complex	Complex
Boys	14	128	66	26
Girls	14	195	81	28

'very good' scores reflected some level of crying/verbalisation and movement. There were no significant differences regarding overall behaviour among boys and girls ($p = 0.245$, Table 3).

One girl had treatment aborted and was referred for GA. Six patients in the 'poor' overall behaviour category (two boys and four girls) had part of their treatment under IV sedation but were later referred to continue dental treatment under general anaesthesia. The patients' overall behaviour and their self-rated anxiety showed significant statistical differences, $p = 0.0006$ and $p = 0.0002$ for boys and girls respectively.

Four boys in the 'not anxious' group were rated as having 'fair' overall behaviour and two girls from the 'a bit anxious' group had 'poor' and 'fair' overall behaviour (Table 4). From the 365 patients (66%) who claimed to be 'anxious' or 'very anxious' before treatment, 278 (50%) were scored as having 'very good' or 'excellent' overall behaviour. The higher numbers in the 'poor' and 'fair' overall behaviour groups were from the 'very anxious' and 'anxious' groups.

The complexity of treatment is shown in Table 5. No statistical differences were found between the groups, with both groups having treatment from 'simple' to 'complex',

Table 6 Level of self-rated anxiety and complexity of treatment

Self-rated anxiety	Complexity of dental treatment							
	Simple		Moderate		Moderate/complex		Complex	
	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls
Very anxious	5	8	41	104	22	50	6	13
Anxious	5	5	35	29	15	15	7	5
A bit anxious	2	0	22	10	13	10	6	6
Not anxious	2	1	30	6	16	6	7	4

Table 7 Complexity of treatment and dosages administered for boys and girls

Gender	Mean dosages administered in mg											
	Complexity of treatment											
	Simple			Moderate			Moderate/Complex			Complex		
	Number	mg	SD	Number	mg	SD	Number	mg	SD	Number	mg	SD
Boys	14	4.57	1.05	128	5.02	0.79	66	5.29	0.97	26	5.8	1.44
Girls	14	4.42	0.99	195	4.95	0.89	81	5.55	1.09	28	5.9	1.39

SD = standard deviation

Table 8 Level of self-rated anxiety and dosages administered for boys and girls

Gender	Mean dosages administered in mg											
	Complexity of dental treatment											
	Very anxious			Anxious			A bit anxious			Not anxious		
	Number	mg	SD	Number	mg	SD	Number	mg	SD	Number	mg	SD
Boys	74	5.33	(1.05)	62	5.16	(0.86)	43	5.08	(0.97)	55	5.02	(1.06)
Girls	175	5.26	(1.08)	54	4.97	(1.21)	49	5.07	(0.95)	40	5.18	(0.91)

SD = standard deviation

$p = 0.426$. The patient's self-rated anxiety and the complexity of their dental treatment showed that the 'very anxious' and 'anxious' patients had more 'moderate', 'moderate to complex' and 'complex' treatment than the other groups but no significant differences were found: $p = 0.971$ for boys and $p = 0.262$ for girls (Table 6).

For complexity of treatment and dosage it was found that a slightly higher dose for both girls and boys was required when the treatment was more complex. Statistical differences were found when comparing complex to simple treatment and dosages, $p < 0.0004$ and $p < 0.0006$ for boys and girls respectively (Table 7).

There was no significant difference across the four levels of self-rated anxiety and dosage, $p = 0.107$ for boys and $p = 0.664$ for girls (Table 8).

Side effects were present in 110 patients (19%). These included hiccups (11), crying/

agitation (73) and diplopia (14). Crying and being agitated may be described as paradoxical reactions, as well as the seven patients who refused treatment. One patient vomited and one patient passed water in recovery.

The lowest arterial oxygen saturation recorded was 94%. Only patients with sickle-cell status were given supplemental oxygen throughout sedation as a preventive measure. Blood pressure readings showed no patient had abnormally high or low blood pressure.

DISCUSSION

The 'Poswillo Report'¹⁹ included recommendations such as to avoid general anaesthesia whenever possible and to use sedation in preference to GA. This brought about a renewed interest in more effective conscious sedation techniques and drugs for behavioural and anxiety control in children.

Intravenous sedation has the advantage of not requiring fasting. For most cases a one-hour appointment was allowed for induction, treatment, and preliminary recovery. Once treatment was complete, further recovery took place in the recovery area. The patient was under supervision of the accompanying adult. In practice all patients were treated and recovered in less than two hours. This is a significantly reduced amount of time compared to children and adolescents treated under GA.

Current government guidelines have also highlighted the importance of the use of alternative of pain and anxiety control techniques for dental treatment in place of general anaesthesia where appropriate, including the use of different conscious sedation techniques, such as inhalation sedation.²⁰ At present there is no alternative for patients who may not accept nitrous oxide sedation.

Midazolam is used extensively in adult patients and in children, in whom it produces similar effects such as anxiolysis, sedation, anticonvulsant, muscle relaxant and anterograde amnesia.^{21,22} This report was designed to assess the acceptance, safety and effectiveness of midazolam as an alternative to nitrous oxide sedation in paediatric dental patients.

Side-effects included hiccups, being very tearful and diplopia, none of which was reported as being of major concern to the patient or parent.

The 2007 report from the Standing Committee on Sedation for Dentistry² states that for children under 12 years of age, this technique falls under 'alternative techniques'. Practitioners must have documented experience (at least 100 cases over the last two years). Anyone undertaking this technique must be appropriately trained. This would include the ability to identify adverse events early and to be able to use reversal agent flumazenil if required. It is also essential that the operator/sedationist and the sedationist nurse be proficient in delivering paediatric life support in the unlikely event of an emergency.

In this report, parents were allowed to be present in the surgery. The majority chose to be present. This is important because it gives the parents some insight into the problems caused as a result of uncontrolled dental caries. It was noted that even after signing the consent form on the assessment visit, a few parents and patients still thought 'they were going to be put completely out'. This misunderstanding was solved by a new clinical assessment and sedation was then carried out when appropriate. Many patients who stated at baseline that they were not anxious, were indeed very anxious. In order to improve data collection and reliability, it would be important to use more thoroughly validated scales to assess anxiety, behaviour management and sedation levels. A better way to measure patients' fear should be used and assessment made of whether this fear is translated into behaviour problems during treatment. Some of the patients rated as having 'good' or 'fair' sedation behaviour had continuous movement and persistent loud crying. Parents were asked to help by holding the patient gently if required.

Dental treatment provided should be matched whenever possible. In this study, the dental treatment was graded according to its severity and complexity, ranging from conservative treatment to minor surgical procedures. Complex treatment required slightly higher dosages.

Ideally, intravenous sedation should be compared with nitrous oxide in a randomised, controlled manner; however, blinding would be difficult.

The safety of the patient is paramount so monitoring the arterial oxygen saturation with a pulse oximeter is essential. It is also recommended that the patient's blood pressure be taken and recorded at baseline and immediately before discharge.

More evidence-based research should be carried out to add reliable information to the literature on what seems to be a safe and effective technique for paediatric patients.

CONCLUSIONS

Midazolam sedation was well tolerated and accepted by the patients. The use of a topical anaesthetic decreases the fear of cannulation. Needle phobia was common among this patient group and many patients were reluctant to allow cannulation. Inhalation sedation may be used to relax the patient in order to aid cannulation.

Most patients exhibited good to excellent overall behaviour and acceptance of treatment. This report supports evidence from other studies that paradoxical reactions may occur, but this should not discourage its possible use for paediatric dental sedation. Young patients tend to be very vocal and tearful when sedated, but treatment may be carried out with reassurance, appropriate behaviour management techniques and parents' support. Patients were asked to complete a questionnaire when fit to be discharged. Partial or total amnesia was prevalent. Only seven treatment sessions (1.3%) in this study failed as patients became very restless, tearful and uncooperative, so parents requested treatment to be stopped.

As no clinical hypoxic effect was experienced it suggests that IV midazolam anaesthesia appears to be a safe technique.

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