Can intravenous conscious sedation with midazolam be effective at facilitating surgical dentistry in adolescent orthodontic patients? A service evaluation

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In brief

- Describes the use of intravenous conscious sedation (IVCS) with midazolam in adolescents within a primary-care setting.
- Illustrates the potential for conscious sedation to provide a viable alternative to general anaesthesia for some adolescents undergoing surgical dental procedures.
- Identifies the need for appropriate assessment of patient suitability to receive treatment under conscious sedation.
- Highlights the potential for IVCS midazolam to facilitate care for young people both within other areas of dentistry and medical specialities.

Background Surgical dentistry during orthodontic care often occurs in adolescence and may involve surgical removal or exposure of teeth. The invasive nature of treatment, combined with dental anxiety, means care can often be provided under general anaesthesia (GA). Best-practice guidelines however endorse conscious sedation as an alternative, where appropriate. Although a limited number of studies have shown safe and effective use of intravenous conscious sedation (IVCS) with midazolam in this cohort, robust evidence to support routine use is lacking. **Aim** To assess whether IVCS with midazolam can effectively facilitate surgical dentistry in adolescent orthodontic patients in primary care. **Method** A retrospective service evaluation was undertaken reviewing clinical records of adolescents (aged 12–15 years) undergoing surgical exposure and/or surgical removal of teeth under IVCS with midazolam. **Results** A total of 174 adolescents (mean age 14.2 years) attended for treatment between 2009 and 2015. Of these adolescents, 98.9% (N = 172) allowed cannulation, with all surgical dentistry completed during a single visit. Midazolam dose ranged from 2–7 mg with 79.1% of patients having good or excellent cooperation and three minor adverse events occurring. **Conclusion** This service evaluation shows IVCS with midazolam can effectively facilitate surgical orthodontics in carefully selected adolescents. There is however a distinct need to further explore potential for this technique to provide a viable alternative to GA.

Introduction

Surgical dental procedures are sometimes a necessity while patients are undergoing orthodontic treatment and may involve management of impacted, ectopic or supernumerary teeth. Failure to address impactions, in particular maxillary canines, can result in detrimental effects before patients reach their mid-teens with evidence supporting adolescence as the optimal time to address these teeth.[1,2] Management may involve surgical removal, exposure or transplantation of teeth and although some adolescents accept treatment under local anaesthetic (LA),[3] for many, anxiety and the invasive nature of treatment necessitates use of additional management techniques.[1,2]

Surgical removal or exposure of teeth in adolescents are recognised as 'suitable' justifications for provision of general anaesthetic (GA).[4,5] Although this technique has been shown to be extremely successful in facilitating such treatment in children and adolescents,[2,3] owing to associated risks, best-practice guidelines recommend that conscious sedation is endorsed as an alternative, where appropriate.[4,6,7]

Relative analgesia (RA) nitrous oxide/oxygen inhalational sedation has proven safety and efficacy for children with mild to moderate anxiety and elective simple orthodontic extractions.[7–10] Limitations are however apparent for invasive treatment[9,11] and for patients unable to cooperate under LA alone it appears an alternative patient management technique may be required.

Midazolam has favourable properties as a sedative in that it is anxiolytic, short-acting and can often produce anterograde amnesia.[12] In 2007, the Standing Committee on Sedation in Dentistry (SCSD) described the use of single-drug intravenous conscious sedation (IVCS) with midazolam for those aged 12 years and over in primary care as a standard sedation technique to facilitate dental treatment.[13] More recent guidance by the Intercollegiate

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Refereed Paper. Accepted 26 October 2016
DOI: 10.1038/sj.bdj.2017.78
©British Dental Journal 2017; 222: 113-119

Advisory Committee for Sedation in Dentistry (IACSD),[7] reiterated this sentiment with particular emphasis on the need for appropriate training, experience and facilities. The use of this technique in adolescents has however been subject to debate, with a 2009 questionnaire sent to specialists in paediatric dentistry finding only 54% of respondents believing such treatment was appropriate in primary care.[14]

IVCS with midazolam is routinely employed in adult dentistry and a small number of studies have shown its safe and effective use in children and adolescents to facilitate a variety of dental procedures, including surgical dentistry.[12,15–18] In 2003, a randomised controlled cross-over trial by Wilson *et al.*[12] demonstrated IVCS with midazolam to be a safe, effective and well-accepted alternative to RA sedation for 12–16-year-olds requiring simple orthodontic extractions. The same year, a small retrospective study by Robb *et al.*[17] demonstrated successful and safe IVCS with midazolam in eighteen 11–15-year-olds receiving wide-ranging treatment with good patient cooperation and willingness to receive IVCS at subsequent visits suggesting adolescent acceptance of this technique.

In 2007, Dorman *et al.*[19] published a retrospective case review of 28 patients aged between 11 and 15 years who underwent surgical orthodontic treatment under IVCS with midazolam. A broad range of procedures were provided (often multiple teeth during each visit) by a suitably trained, experienced and equipped non-anaesthetist operator-sedationist, with 89% of patients completing treatment as planned. Owing to the small number of subjects, firm conclusions cannot be drawn. This study however provides foundations upon which to build further research whilst also highlighting potential limitations of this technique.

Although there is a large body of literature reporting surgical orthodontic procedures, this largely focuses on surgical and orthodontic outcomes and can fail to document the method used to facilitate treatment.[2] This limits ability to accurately identify current practice with regard to different behavioural management techniques and evidence to inform decision-making in anaesthetic choice is lacking.[9,20,21]

In summary, there is currently a lack of robust evidence demonstrating effective use of IVCS with midazolam in adolescents. Despite published recommendations supporting the use of this sedation modality in this cohort, there is a lack of evidence to support its routine use in primary care. This service evaluation will attempt to add to the evidence base for use of IVCS with midazolam in adolescents.

Aim

To assess whether IVCS with midazolam, in combination with local anaesthesia, can be employed effectively as a behavioural management tool to facilitate surgical dental treatment in adolescent orthodontic patients in primary care.

Table 1 Descriptors of patient level of sedation – 'Wilson Scores'[24]. Reproduced with permission from E. Wilson *et al.*, 'Sedation during spinal anaesthesia: comparison of propofol and midazolam', *Br J Anaesth* 1990; 64: 1, by permission of Oxford University Press

Score	Degree of sedation
1	Fully awake and orientated
2	Drowsy
3	Eyes closed but rousable to command
4	Eyes closed but rousable to mild physical stimulation (earlobe tug)
5	Eyes closed but unrousable to mild physical stimulation

Table 2 Descriptors of patient cooperation

Level of cooperation	
Rating	**Description**
Excellent	Patient fully cooperative, all treatment completed
Good	Minimal interference from patient, (for example, crying with cannulation or local anaesthetic), all treatment completed
Fair	Some patient disruption during treatment or additional management steps required to facilitate treatment (for example, mouth prop). All treatment eventually completed.
Poor	Patient very disruptive during treatment making provision of care very difficult/impossible

Methods

A retrospective service evaluation was undertaken based on a review of computer and paper-based clinical records at Queensway Teesside Oral Surgery Service (QTOSS). QTOSS is a primary care-based NHS specialist oral surgery referral service offering IVCS with midazolam to facilitate surgical dentistry for adolescents as part of orthodontic treatment.

In this service, all participants adhered to the following pathway:

Patient assessment

Patients were assessed on a separate day to treatment by one specialist oral surgeon holding a Diploma in Conscious Sedation (MD), with planned treatment being confirmed following appropriate patient examination. Formal assessment of dental anxiety was made using an in-house dental anxiety questionnaire (first 25 patients) or Modified Dental Anxiety Scale (MDAS)[22] (subsequent 149 patients – MDAS was only introduced in the practice after the first 25 patients). Vital signs were recorded (blood pressure, oxygen saturation, heart rate), body mass index (BMI) calculated and the American Society of Anaesthesiologists[23] (ASA) physical classification system score assigned to determine fitness to receive sedation in primary care.

Assessment of physical and psychological aptitude to undergo treatment under IVCS with midazolam was made and management options explained; including their risks and benefits. These included non-pharmacological behavioural management plus care under:

- LA alone
- RA sedation and LA
- IVCS with midazolam (including cannulation) and LA.

The option of treatment under GA was also discussed, with patients opting for GA discharged to their referring practitioner to consider referral to secondary care. Adolescents played a key role in the consent process and for those proceeding with care, informed written consent was gained from a legal guardian with additional adolescent consent/assent as appropriate. Clear pre- and post-sedation instructions were given verbally and in written form including a request for patients to starve for two hours before treatment.

Patient treatment

The operator-sedationist providing treatment (MD) was assisted by two sedation-qualified dental nurses. Baseline vital signs were recorded and venous cannulation achieved in the dorsum of the hand or antecubital fossa. Midazolam was titrated in 1 mg/minute increments with continuous assessment of patient response to sedation by the operator-sedationist. In some cases the decision was made to provide final increments at 0.5 mg/minute (individual dependent), until the patient was happy to begin treatment and deemed optimally sedated. The option was given for escorts to be present during treatment, with patient consent.

Patients were continuously monitored visually during treatment to assess level of sedation and cooperation, using descriptors detailed in Tables 1 and 2, respectively. Continual pulse oximetry was undertaken and blood pressure measured pre- and post-sedation and at appropriate intervals during treatment. In recovery, patients were monitored by a sedation-trained dental nurse and fitness for discharge assessed at least one hour after the last increment of midazolam.

Patient sample

Criteria used to identify adolescents for the evaluation are detailed below:

Inclusion criteria:

- Patients aged 12 years and over but less than 16 years of age
- At least one tooth requiring surgical removal or exposure
- Treatment performed under IVCS with midazolam and LA.

Exclusion criteria:

- Patients aged less than 12 years or 16 years and over
- No teeth requiring surgical removal or exposure
- Treatment not performed under IVCS with midazolam and LA.

Data collection

A consecutive sample of clinical records was reviewed for adolescents meeting the inclusion criteria between December 2009 and December 2015. Information collected included: patient demographics and details of sedation provided, treatment performed, sedation or treatment-related complications or adverse events, and any additional procedural comments. Data were entered into a Microsoft Excel spreadsheet.

Table 3 Sedation-related complications categorised by severity

Sedation-related complications	
Severity	**Description**
Mild	Managed in clinic
	Treatment completed
	Patient discharged home
	For example, nausea, vomiting, faint, transient oxygen desaturation SaO_2 ≤90% corrected with verbal stimulus/supplemental oxygen, paradoxical response, minor/transient changes to vital signs
Moderate	Managed in clinic
	Treatment completed
	Prolonged recovery/medical advice sought
	Patient discharged home
	For example, allergic reaction without anaphylaxis, more pronounced change to vital signs, over-sedation requiring reversal
Severe	Treatment stopped
	Medical intervention required
	Patient admitted to hospital
	For example, respiratory depression with oxygen desaturation prolonged or SaO_2 <75%, airway obstruction, aspiration, laryngospasm, bronchospasm, allergic reaction with anaphylaxis, loss of consciousness

Sedation-related complications or adverse events were noted with reference to the World SIVA Adverse Sedation Event Reporting Tool[25] and additional complications commonly reported in the literature (Table 3).[18] The severity of such events was categorised into either mild, moderate or severe, using the approach reported by Wilson *et al.*[26]

Ethical considerations

Ethical approval was not required for this service evaluation.

Data analysis

Data were analysed and results are presented as descriptive statistics.

Results

Patient demographics

One hundred and seventy-four patients attended appointments for surgical orthodontic treatment under IVCS with midazolam. Patients were ASA I (n = 129) or ASA II (n = 45) with a mean BMI of 21.0 (range 15.0–31.0). Figure 1 shows the distribution of patient age ranging from 12.1 to 15.9 years (mean 14.2 years, standard deviation (SD) 0.96). One hundred and fourteen patients were female and sixty male (mean ages 14.3 years and 14.1 years, respectively).

One hundred and forty-nine adolescents completed MDAS questionnaires with Figure 2 showing their self-perceived anxiety towards dental treatment. This was seen to be wide-ranging and skewed to the lower end of the anxiety spectrum with a median of 13/25.

Acceptance of cannulation

Two patients (1.1%) did not permit any attempt at cannulation and were discharged for onward referral for treatment under GA. Of the remaining 172 patients, all were cannulated successfully (94.2% on the first attempt) with no more than two cannulation attempts being required. Cannulation adjuncts, provided only on patient request, were employed in 39 adolescents (Table 4). If requested the following options were available: topical ethyl chloride spray, topical eutectic mixture of local anaesthetic (EMLA) or RA sedation.

Midazolam dose

The dose of midazolam administered ranged from 2–7 mg (Figure 3) with median and mode dosages being 4.0 mg and 5.0 mg for each gender and the cohort as a whole.

Level of sedation

Throughout treatment and recovery all patients except one were responsive to verbal stimuli (Wilson Scores 1–3). One patient was initially

Fig. 1 Age and gender of adolescents attending for treatment

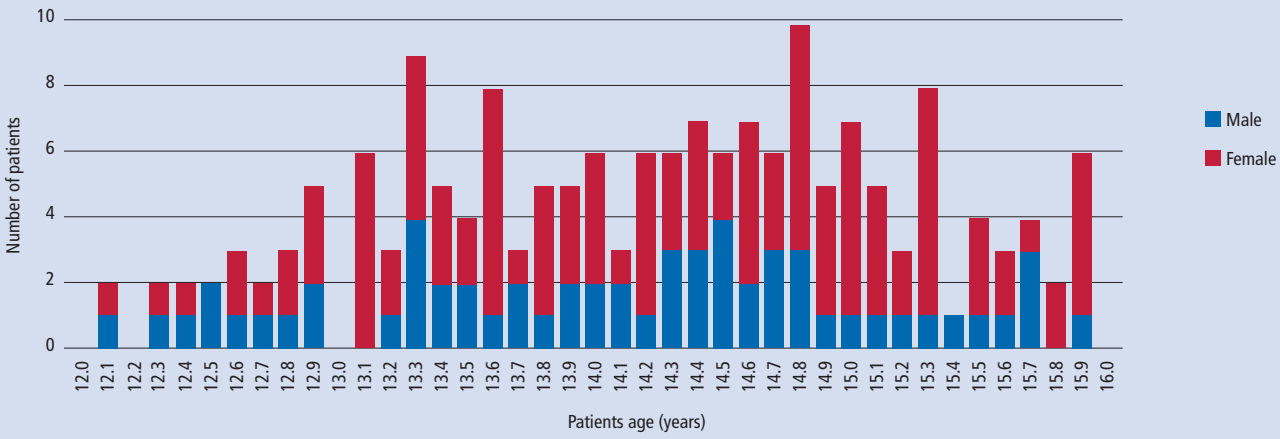

Fig. 2 Reported anxiety of adolescents attending for treatment under IVCS with midazolam

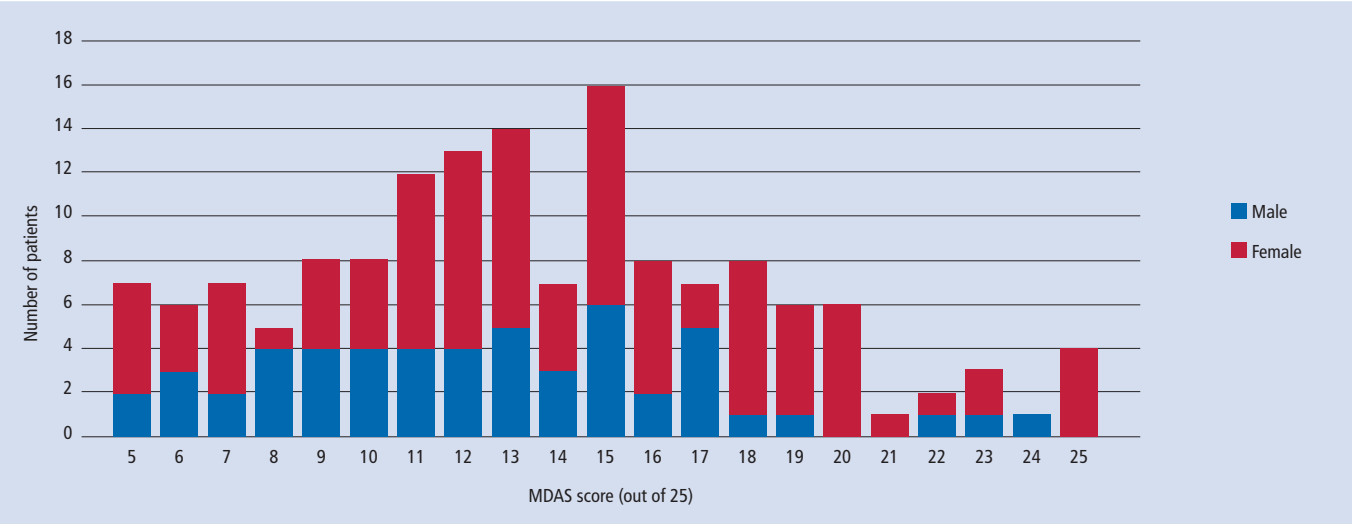

Table 4 Adjuncts used to assist with cannulation

Cannulation adjunct	Number of patients
None	133
Ethyl chloride spray	32
Eutectic mixture of local anaesthetic (EMLA)	4
Nitrous oxide/oxygen	3
	Total = 172

only responsive to light tactile stimuli (Wilson Score 4) after the last midazolam increment (5 mg in total). As vital signs were normal, the decision was made to proceed with treatment and after five minutes the patient became responsive to verbal stimuli.

Patient cooperation

Once sedated, all 172 adolescents were happy to proceed with treatment with Table 5 showing patient cooperation. 77.9% males and 79.7% females had good or excellent cooperation, with that of the cohort as a whole being 79.1%. Twenty-eight patients (16.3%) were noted as being very nervous or teary on cannulation, exhibiting anxiety related to this aspect of care; once sedated, 19 (67.9%) settled well and had good or excellent cooperation.

A number of factors made provision of treatment more challenging. There were fifteen instances of tears during treatment, eight of increased head movement, ten of reduced mouth opening and five reports of the patient being talkative. Some patients exhibited more than one of these behaviours. In addition to this, one patient had a profound gag reflex.

Adverse events

During treatment, for all patients, physiological parameters remained within normal limits. As previously noted, for a period of time, one adolescent exhibited a lower level of responsiveness than required under the definition of conscious sedation. In recovery following treatment, one patient was verbally abusive to staff and another was tearful, both potential examples of recovery agitation. Clinical records reported both patients had been a little teary during treatment, but all surgery was completed without difficulty. These three events give an overall adverse event rate of 1.7%

Dental treatment provided

For all sedated patients, all planned dental treatment was completed successfully in a single visit. The median time taken in surgery for sedation and treatment was 45 minutes (interquartile range 39–55 minutes). Patients received at least one of the following four procedures:

- Surgical canine exposure
- Surgical exposure of another permanent tooth
- Surgical removal of a primary tooth
- Surgical removal of a permanent tooth.
-

The number of teeth undergoing surgical treatment per patient ranged from one to four (mean = 1) with eight patients undergoing surgical exposure and surgical removal of teeth during the same visit. Of the procedures, 75.6% required bone removal. For 93 patients, treatment was performed in combination with other less complex additional procedures, such as simple extraction of deciduous and/or permanent teeth (Table 6). The most common procedure was canine exposure (66.9% patients with 45% buccal and 55% palatal) with 79% requiring bone removal.

Surgical treatment complications

Three patients required further treatment for re-exposures (four teeth) giving a re-exposure rate of 2.3% of patients (2.6% teeth). A more detailed review of records showed the need for re-exposure being the result of gold chain de-bond (two upper canines in one patient, one lower premolar in another patient) and mucosal overgrowth (of a palatally exposed canine in one patient). Considering the most commonly performed procedure, canine exposure, the re-exposure rate was 2.3% of canines (1.8% patients).

Fig. 3 Dose of midazolam administered

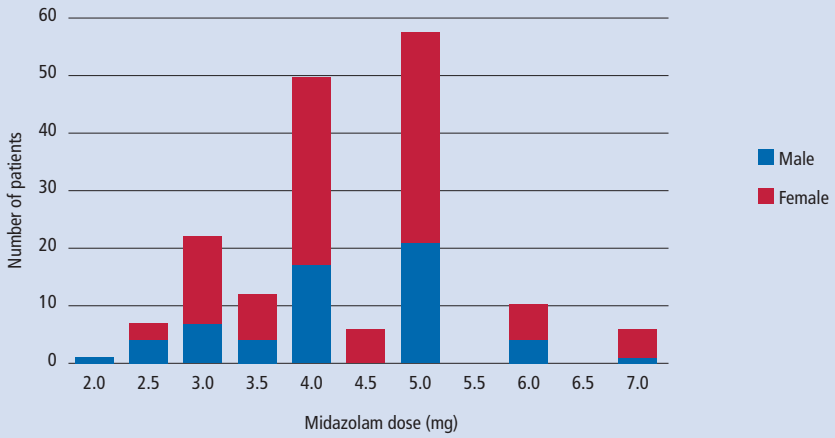

Table 5 Patient cooperation during treatment

		Patient cooperation			
		Excellent	Good	Fair	Poor
Number of patients	Male (% all males)	10 (16.9%)	36 (61%)	9 (15.3%)	4 (6.8%)
	Female (% all females)	7 (6.2%)	83 (73.5%)	19 (16.8%)	4 (3.5%)
	Total (% cohort)	17 (9.9%)	119 (69.2%)	28 (16.3%)	8 (4.6%)

Table 6 Summary of treatment provided (note: some patients received multiple procedures in terms of both volume and type

Procedure	Number of teeth	Number of patients	% Patients
Primary procedure(s)			
Surgical removal of deciduous tooth/teeth	2	2	1.2%
Surgical removal of permanent tooth/teeth	52	47	27.3%
Canine exposure(s)	134	115	66.9%
Other permanent tooth exposure(s)	21	16	9.3%
Additional/secondary procedures(s)			
Simple deciduous tooth extraction(s)	80	55	32.0%
Simple permanent tooth extraction(s)	106	52	30.2%

Discussion

The age group studied was designed to reflect 'adolescence', with twelve years chosen as a minimal age in-line with SCSD and IACSD guidance.[7,13] Patient age was wide-ranging but skewed to the older end of the spectrum; similar to findings of others.[16,19] This could be explained by older patients having the greater maturity required to accept care under IVCS or perhaps some explanation lies with the time at which orthodontic and/or oral surgery treatment begins. Approximately two thirds of patients were female. Recognised gender differences such as: rate of impaction;[27] perceived maturity during adolescence; and motivation for treatment may play a role in this trend, however, the potential for referral tendencies of orthodontists to influence patient characteristics must be remembered.

Male anxiety was skewed to the lower end of the MDAS spectrum and of those deemed to have 'high anxiety' (MDAS 19–25),[22] females had greater representation suggesting females are more anxious than males, or perhaps more prepared to admit it. This trend has been noted in young adults and adolescents and could lead to greater proportions of females opting for treatment under sedation or GA.[22,28,29]

Although MDAS has been employed in adolescents aged 12 years and over, as a means of assessing dental anxiety,[28,30] cut-off scores for sedation-need are based on research with adult populations and its use in adolescents must be carefully considered. Using MDAS, twenty-three patients (15.4%) were deemed to be highly dentally anxious, greater than that reported by the Children's Dental Health Survey in 2013 (14% of 12-year-olds and 10% of 15-year-olds).[28] This could be explained by high female representation in the cohort, however, MDAS does not assess anxiety in relation to oral surgery procedures; likely to be at the forefront of the minds of this cohort.

IVCS midazolam was employed in this patient group, despite many being deemed to have 'low anxiety' using MDAS. The Indicator of Sedation Need (IOSN) attempts to objectively assess sedation need and addresses failure of MDAS to appreciate the impact of medical history and treatment complexity on patient management.[31] Although IOSN has been reported as useful to sedation decision-making in adults,[32] Gerrard[33] recently questioned its validity and reliability in defining sedation need in adults undergoing oral surgery procedures. Even in adult populations, with evidence supporting the safe and effective use of IVCS with midazolam, decision-making in relation to sedation provision is not always clear and evidence is lacking for appropriate management of adolescents. It is however clear that anxiety should not be used as the sole means of determining sedation need.

What is of interest is that 77% of patients were cannulated without the use of cannulation adjuncts. Although shown not to guarantee cannulation acceptance, they may reduce anxiety and cannulation did pose a significant barrier to care for some patients, confirming findings of others.[10,15] In such cases the potential for gaseous induction of GA has a clear advantage over a sedation modality relying on the IV route. GA is a highly effective behavioural management tool and will always have a role in facilitating dental care for some patients.

Paediatric morbidity and mortality have occurred using techniques and drugs outwith the strict United Kingdom (UK) regulation of dental conscious sedation;[6,18,20] raising concerns about sedation safety. Although there has been limited research in children and adolescents within dentistry in the UK, the National Institute for Health and Care Excellence has reported midazolam as a sole-agent used in children in dentistry and other medical specialities to have a 'good' safety profile.[20] This evaluation showed effective use of IVCS with midazolam in a primary care environment with very few adverse events, all of which were minor. The patient in this case series initially unresponsive to verbal stimuli was slightly over-sedated, demonstrating the need for careful titration.

A wide-range and volume of surgical dentistry was provided under IVCS with midazolam for carefully selected patients in an effective manner, with the canine re-exposure rate comparing favourably with those of GA[34,35] and Dorman *et al.*,[19] suggesting high quality care. The time taken to provide treatment (sedation and surgery) was longer than that cited for similar procedures under GA.[36] Such reports however tend to cite surgical time only, without anaesthetic induction or recovery. Treatment under IVCS with midazolam in primary care by a non-anaesthetist sedationist is considerably less costly than under GA in a secondary care setting.[20] With success rates seen in this study, provision of care under IVCS with midazolam in primary care has the potential to save NHS resources, increase access to care at local clinics and free-up hospital services.[37,38]

Limitations and further research

This evaluation describes only one cohort undergoing surgical orthodontic treatment with midazolam IVCS, and the trends seen in patient characteristics cannot be considered stead-fast indicators of suitability to undergo such care. It is clear a number of factors acting in unison impact on adolescent suitability for and acceptance of this treatment modality and more robust research is required to aid decision-making regarding behavioural management techniques. Although Germain *et al.*[36] found surgeons could not accurately predict difficulty of exposure of palatal maxillary canines using radiographic findings alone, quantification of the invasiveness of treatment undertaken in this service evaluation would have been advantageous.

Although a number of behavioural management techniques were offered, there is potential for referring and treating clinician preference or bias to influence characteristics of patients assessed and attending for care. Additionally, the impact of service facilities, location and contract may influence the patient cohort and forms of behavioural management available. Although this evaluation showed a suitably qualified team, led by one highly experienced operator-sedationist, could provide effective adolescent care under IVCS with midazolam, there is a distinct need for other dental teams to reproduce this success through prospective study.

Sub-optimal cooperation can negatively impact provision of care in both adults and children.[16,19,26] Disruptive behaviour exhibited by adolescents could be explained by paradoxical reaction, disinhibition or similar phenomena and characterised as adverse events. Assessment to ensure suitability and preparation for sedation can reduce incidence of such occurrences, with recognition that physiological and psychological maturity can vary widely in adolescents of a similar age. Owing to the retrospective nature of this study, it is not possible to deduce the exact cause of behavioural traits displayed and although cooperation was recorded prospectively, this was not using a validated scale. A system such as the Houpt Scale[39] would enable more reliable behavioural assessment and standardisation of adverse incident reporting should enable robust assessment of sedation safety.[18,25]

Almost 80% patients exhibited excellent or good cooperation, with relaxation of those highly anxious before treatment demonstrating the role of anxiolysis in facilitating care. Although treatment success was high in those attending for elective orthodontic procedures, its relevance to those receiving urgent dental care or with dental decay and sepsis must be carefully considered and could explain lower success rates seen by Averley *et al.*[15] With some patients noted to be tearful during treatment, there is a distinct need to ensure this sedation technique provides sufficient anxiolysis. The three patients requiring re-exposures opted for treatment under LA alone or in combination with IVCS midazolam at the second visit, suggesting good acceptance of this technique. Assessment of adolescent experience through qualitative study would provide evidence relating to patient-perceived acceptability of IVCS with midazolam.

Retrospective review of records has potential to reduce accuracy of results obtained.[16] Well-designed prospective studies providing surgical orthodontics using techniques across the behavioural management spectrum, not just IVCS midazolam and GA, with subsequent evaluation of safety and success, would allow comparison of different techniques. A Cochrane systematic review identified that randomised allocation would allow assessment of IVCS as an alternative to GA; ethical dilemmas posed by doing so are however clear with inability to blind operators to techniques used likely to limit the strength of evidence directly comparing these techniques.[21]

Conclusion

This service evaluation has shown IVCS with midazolam, in combination with effective LA, can successfully facilitate surgical orthodontic treatment in carefully selected adolescents in primary care. This supports the appropriate use of this technique by suitably trained, experienced and equipped teams to facilitate not only surgical orthodontic treatment, but also less complex dental procedures.

There is a distinct need to further explore the potential of this technique to provide a safe and effective alternative to GA and benefit a significant proportion of adolescent patients, particularly those undergoing elective orthodontic procedures.

Acknowledgements

CRV is funded by a Clinician Scientist Award supported by the National Institute for Health Research. This paper details independent research and the views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

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