SVOA Dentistry

ISSN:2753-9172

ScienceVolks Open Access

Research Article

Intranasal (IN) Midazolam Sedation to Facilitate Dental Treatment for Adults with Autism and Learning Disabilities: An Audit of Efficacy and Safety in Primary Care

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***Received:** December 09, 2021 **Published:** December 29, 2021*

Abstract:

The provision of dental care for adults with leaning disabilities and autism is often provided under general anaesthesia in a hospital setting, tending to result in increased waiting times and additional costs to the NHS. An alternative to the use of general anaesthesia in Secondary Care services, is to use intranasal Midazolam with intravenous Midazolam as a conscious sedation technique which has been widely used in the UK. The aim of this audit is to assess the use of intranasal mediated conscious sedation and assess its effectiveness in the management of dental care of patients with learning disabilities and autism in Primary Care. The standards based from previous research were decided that planned treatment completed would be >90%, IV accessed achieved in >96% and adverse events<6%. The level of cooperation obtained should aim to be: 50% Ellis grade 1, 30% Ellis grade 2, 15% Ellis grade 3 and 6% Ellis grade 4/5. The first cycle audit demonstrated that all the standards were met, except 12% of sedation episodes were successfully achieved without difficulty (Ellis sedation score 1), compared to the standard of 50%. Recommendations included the use a team of four (involving 2 sedation trained dentists and 2 sedations trained nurses) for more challenging cases and regular peer review. The second cycle audit results showed that 20% of cases successfully achieved sedation episodes with an Ellis score 1 using intranasal sedation. 11% of patients were unable to be treated and required referral for general anaesthesia. The results demonstrate the safety and cost effectiveness of the combined intranasal and intravenous midazolam sedation technique for providing dental treatment for majority of adults with severe learning disabilities and autism. While acknowledging that there will still be a need for general anaesthesia, the technique of utilising two sedation trained dentists has the potential to make dental treatment more accessible in primary care for most patients with autism and learning disabilities.

***Keywords:** Intranasal, intravenous sedation, autism, learning disability, dental*

Introduction

The General Dental Council defines conscious sedation as: "A technique in which the use of a drug or drugs produces a start of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact is maintained throughout the period of sedation. The drugs and techniques used to provide conscious sedation for dental treatment should carry a margin of safety wide enough to render loss of consciousness unlikely". (GDC, 1999) For those individuals who are unable to respond to verbal contact even when fully conscious, the normal method used for communicating with them must be maintained (IACSD, 2015).

For individuals with severe learning disabilities the management of their oral health can be demanding. Many patients with learning disabilities may not be sufficiently able to cooperate with a dental examination or, indeed, with any form of dental treatment other than that provided under general anaesthesia (Tiller et al, 2001). Challenges in gaining cooperation from adults with learning disabilities may have contributed to the well-documented oral health inequalities experienced by adults with learning disabilities when compared with the oral health of the general population (Tiller et al, 2001; Manley et al, 2000; Manley et al, 2008). The inequitable distribution of dental disease in this population has the potential for additional National Health Service cost implications and the need for dental treatment can lead to an increase in waiting times for Community Dental Services (CDS) and Special Care Dentistry in secondary care.

Treatment for adults with learning disabilities has previously been reported to be limited to the extraction of carious or symptomatic teeth under general anaesthetic rather than the provision of comprehensive restorative dental treatment. Many patients with more severe learning disabilities and autism tend to be referred for treatment under general anaesthesia (Holland and O'Mullane, 1990). Whilst general anaesthesia is commonly used to facilitate dental treatment for both adults and children, it does have a risk of mortality as well as associated morbidity including post-operative nose bleeds, sore throat, nausea, and the need for social support including an escort, carers and sometimes a side room or an inpatient bed. General anaesthesia, therefore, may be difficult to justify on a regular basis for routine examinations and scaling for the asymptomatic patient or for treatment that requires multiple visits such as periodontal therapy and endodontics (Manley et al, 2000). Evidence of a multi-disciplinary approach for patients with learning disabilities under general anaesthesia could also be adopted for patients under sedation who would benefit from additional medical interventions such as blood investigations and ECG (Clough et al, 2016).

As an alternative to general anaesthesia, the use of intravenous sedation with Midazolam provided in primary care has been shown to be an effective management strategy for people with learning disabilities (Manley et al, 2000) (Manley et al, 2008) (Ransford et al, 2010).

Intravenous sedation is not without its challenges, and some patients with learning disabilities may struggle to co-operate with the cannulation process required to administer Midazolam intravenously. IN sedation using 0.25mls of 40mg/ml Midazolam via a Mucosal Atomising Device (MAD) delivering a standard 10mg dose has become a more commonly used adjunctive method to allow the cannulation procedure necessary for the intravenous administration of midazolam. The IN transmucosal use of Midazolam is at present an off license technique; however, existing literature has described IN sedation as a successful means to providing comprehensive dental care to uncooperative patients in both the primary and secondary care setting (Fukuta et al, 1993; Fukuta et al, 1994;BNF 2017) . The aim of the IN midazolam is to make the patient more co-operative and relaxed, thereby allowing intravenous access to be obtained. For some patients it may be beneficial for appropriately trained staff to make use of clinical holding techniques during the administration of IN midazolam and whilst gaining intravenous access. A concentration of 1mg/ml midazolam is administered intravenously and titrated until the patient is adequately sedated to allow examination and treatment.

The guideline document 'Transforming care: A national response to Winterbourne View Hospital Department of Health Review: Final Report' outlined the need for patients with learning disabilities and autism to be managed in more community-based setting in order to have the right support and care. This review outlined the specialist management of individuals with learning disabilities and autism with the aim to deliver high quality care in local community based primary care services.

The availability of the IN-sedation technique across the UK depends on the training, skills and experience of the staff within each local service. IN midazolam has been used effectively within primary care in various CDS for several years (Ransford et al, 2010). As a result of the increasing popularity of the IN technique, this audit seeks to understand for what proportion of patients IN administration of midazolam is successful in enhancing cooperation sufficient to provide dental treatment and whether the IN technique is associated with an increased number of adverse events. The purpose of this audit is to assess the pre-defined success criteria of this techniques judged by the provision of dental treatment and the patient's level of cooperation relative. Additionally, it will seek to identify ways in which practice may be standardised to meet the reference standards described in the methodology section and ultimately to improve the quality of care for patients.

Aim

To assess the effectiveness and safety of IN sedation for the dental care of patients with learning disabilities and autism within a Primary Care Dental Service when compared with the outcomes of previously published audits as well as local and national guidelines.

Objectives

The objectives of this audit include:

1. Identification of patients who have been managed with IN midazolam in the CDS setting.
2. Recording the ASA classification and nature of disability of those who received the IN midazolam.
3. Recording of any adverse outcomes and their management.
4. Assessment of the level of cooperation obtained during the treatment procedure
5. Documentation of types of treatments carried out and if they were successfully carried out.

6. Reporting of the doses of intravenous and IN Midazolam administered by clinicians.
7. Considering ways in which to improve the future practice
8. Performing a re-audit following action taken to comply with the audit recommendations.

Methodology: Audit cycle

A clinical audit consists of five stages: preparing for audit, selecting the criteria, measuring performance, making improvements, and sustaining improvements by repeating the audit (NICE, 2004). The five-stage methodology has been adopted for the auditing of IN midazolam technique as follows:

1) **Preparing for audit**: Clinicians informed that audit was taking place. Identified logbook as source of cases for inclusion in audit. Identified appropriate period for the selection of cases.
2) **Selecting the Criteria**: An initial literature review of previous audits examining the efficacy and safety of midazolam sedation techniques. The results of these papers were adapted to provide standards for this audit. The latest IACSD, SDCEP and local trust guidelines were also used to develop a composite audit tool (Table 3).
3) **Measuring performance**: A first cycle of the audit was undertaken with continuous cases over a 24 month period. All patients receiving IN Midazolam were logged in a Controlled Drug book as per local Trust policy. Therefore, each IN case was identified using the Controlled Drug book. The additional information was located retrospectively from the computer patient database and clinical notes. Data were collected over a 2-year period on all patients who met the inclusion criteria (Table 4) and were treated by dentists experienced in conscious sedation. All dentists had appropriately recognised qualifications or seniority, skills, and expertise.
4) **Making improvements**: After the completion of the first cycle of the audit a series of recommendations were made and disseminated to the team. A future date for the second cycle of the audit was planned.
5) **Sustaining improvements**: A second cycle of the audit was undertaken after a 12-month period to assess whether there had been any improvements in the success and safety of the IN technique for delivering midazolam.

Table 1: Ellis Grading

Grade	Description
I	No uninvited limb movement; total co-operation and no restlessness.
II	Small amount of uninvited limb movement; still total cooperation and no restlessness
III	More uninvited limb movement; small degree of restlessness and anxiety. Patient less co-operative; still able to perform all dental procedures.
IV	Considerable degree of limb movement; perhaps also unhelpful head movements; co-operation poor; patient quite restless and anxious; able to perform only basic dentistry;
V	Restlessness, anxiety and limb movements severe; impossible to perform any dentistry.

Table 2: The DS TG scale of operating conditions (Dental Sedation Teachers Group)

Grade	Description
1	Good: patient fully cooperative
2	Fair: minimal interference from patient
3	Operating difficult: physical intervention required
4	Impossible: general anaesthesia required to complete treatment.

Table 3: Combined audit standards.

Audit Standards		
Planned treatment completed		>90%
IV access achieved		>96%
Adverse events		<6%
Level of Cooperation	Ellis 1	>50%
	Ellis 2	>30%
	Ellis 3	<15%
	Ellis 4/5	<6%

Standards used (Table 3)

Reference standards were set across a series of domains relevant to demonstrate the level of success and safety of IN midazolam to facilitate the provision of dental treatment:

1. **Treatment completion**: Manley et al (2008) demonstrated that in 90% of cases, planned dental treatment was completed when IN sedation was undertaken; this audit has therefore used 90% as their reference point.
2. **Cannulation:** Ransford et al (2010) reported that in 96.2% of cases, cannulation was achieved. This study found that the incidence of adverse events occurred was 6.01% of those receiving IN sedation. The doses of intravenous midazolam required after IN midazolam administration in this study were 10mg or less in 90.3% of episodes and intranasal doses were 10mg in 88% cases and 8.2% used a higher dose. The authors of the study have therefore selected 96% as the minimum standard for obtaining IV access.
3. **Level of cooperation:** The Community Dental Service in which this audit was undertaken has historically used the Ellis sedation scoring as opposed to the DSTG sedation scoring. Therefore, to allow for comparison with existing data, the sedation scoring was changed from DSTG to Ellis sedation scoring. The Ellis sedation scoring exhibited a more detailed scoring system when compared with the DSTG (Ellis, 1996) (Tables 1 & 2). The level of cooperation obtained should aim to be 50% dental teachers' sedation group (DSTG) grade 1, 28.8% DSTG grade 2, 15.7% DSTG grade 3 and 5.6% DSTG grade 4 (Dental Sedation Teachers Group).
4. **Adverse outcomes**: Adverse outcomes were defined in this audit as an Oxygen saturation level repeatedly falling below 90%, evidence of extreme paradoxical effects, vomiting, delayed recovery, failure to recover and urinary incontinence. The standards were established by combining the standards used by previous audits but altering the sedation scoring to the Ellis sedation score (Table 3).

Table 4: Inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
Patients who would not tolerate cannulation	Needle phobic with no disability
Use of IN and IV sedation	Patient records with insufficient data
Adults >12years	

Table 5: First Cycle of results.

Results			Standard
Planned treatment completed		95%	>90%
IV access achieved		96%	>96%
Adverse events		5%	<6%
Level of Cooperation	Ellis 1	12%	>50%
	Ellis 2	33%	<30%
	Ellis 3	49%	<15%
	Ellis 4/5	5%	<6%

Results

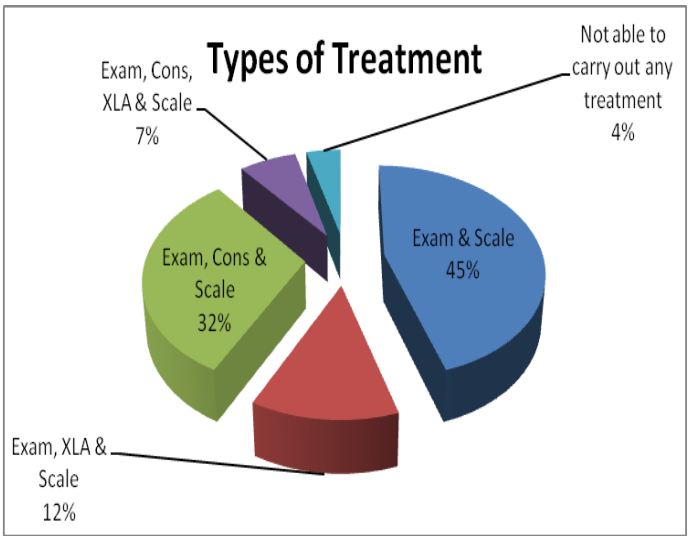
First cycle

Cases identified	A total of 73 IN sedation episodes were identified over a 2 year period.
Learning disability	72 of the patients had a learning disability or autism and one patient had Alzheimer's
ASA 1	77%
ASA2	23%

ASA 3 & 4	No patients were classified as ASA III or IV
Midazolam dose	For 70% (51) of patients a dose of or less than 10mg midazolam was used. The highest IV dose given was 20mg midazolam in 7% episodes
Dental procedures	
Non-dental procedures	5% of cases required bloods to be taken as requested by their medical practitioner.

1. **Cannulation**: Cannulation was achieved after administration of IN midazolam in 96% (69) episodes 53% (39) of patients received a dose of 10mg midazolam. 47% (34) of patients received a dose of 20mg midazolam. No patients exceeded an IN dose of 20mg midazolam (Table 5).
2. **Treatment completion**: 95% of treatment was completed using the IN technique. Most treatments (77%) were examination and scaling alone or examination, scaling and placing of direct restorations.
3. **Level of cooperation**: 5% could not have the planned treatment carried out due to a lack of cooperation (Ellis 4/5) and had to be referred for treatment under general anaesthesia.
4. **Adverse outcomes**: (a) *Repeated episodes of oxygen saturation below 90%:* A single case had oxygen saturation repeatedly drop below 90% and were reversed using Flumazenil. The patient made a full recovery in surgery and was discharged on the same day, but the dental treatment had to be aborted. (b) *Delayed recovery*: 4% of cases experienced a delayed recovery and required the use of Flumazenil as well as additional time to allow further recovery. The patients eventually made a full recovery.

Figure 1: Types of treatment provided in first cycle of audit.



Recommendations from first cycle

1. Regular training and peer review at 6 monthly intervals to ensure a more uniform approach to recording and managing cases.
2. For more challenging cases, consider using a team of 4 members of staff (2 dentists and 2 nurses). The staff should be trained in clinical holding and sedation as well as having experience in special care dentistry. This approach may enable a more effective and safer use of sedation by having a separate sedationist and operator. Having additional staff would also ensure a safer and more effective delivery of any clinical holding and manual handling techniques. It would also provide additional support should any best interest decision making be required during treatment.

The IACSD (2015) and more recently, the SCDEP (2017), reiterates that operator-sedationist techniques may at times be more effective and/or safer when the sedation is provided by a dedicated sedationist and a separate operator. They have listed several examples, such as:

- The patient is medically compromised, has a physical disability or is emotionally challenging
- The patient has a history of being particularly difficult to manage
- The dental procedure is complex or prolonged

3. Undertake a second audit cycle after recommendations have been implemented.

Second cycle: Summary of cases

Cases identified	A total of 52 IN sedation episodes were carried out over a 2 year period.
Learning disability	All patients had autism and a learning disability as well as some additional medical comorbidity such as epilepsy, hypertension and Schizophrenia.
ASA 1	23%
ASA2	77%
ASA 3 & 4	No patients were classified as ASA III or IV
Midazolam dose	The dose of Midazolam used for IN and intravenous sedation during the 2nd cycle was less.
Dental procedures	
Non-dental procedures	10% of cases required bloods to be taken as requested by their medical practitioner.
Treatment using 4 member team	44% were treated by a team of 4 staff members (2 Dentists, 2 Dental Nurses)

The results of the first and second cycles of the audit can be found in Tables 3,4,5.

1) **Cannulation:** There was no change in the number of patients where IV access was successfully achieved between the first and second cycle of the audit; in both first and second cycle of the audit 96% of patients were successfully cannulated.
2) **Treatment completion:** There was a 3% decrease in the number of planned dental procedures that were completed during the sedation episodes. 8% of those patients who were unable to be treated under sedation due to a lack of cooperation required referral for general anaesthesia.
3) **Cooperation:** There was an improvement in the percentage of Ellis 1 from 12% to 23% and Ellis 2 scores from 33% to 37%.
4) **Adverse outcomes:** There were no adverse outcomes encountered in the second cycle of the audit. No patient had repeated oxygen desaturation below 90% and there were no episodes of delayed recovery. No flumazenil was used for emergency reversal in the second cycle of the audit.

Results		2nd Cycle	1st Cycle	Standard
Planned treatment completed		92%	95%	>90%
IV access achieved		96%	96%	>96%
Adverse events		0%	5%	<6%
Level of Cooperation	Ellis 1	23%	12%	>50%
	Ellis 2	37%	33%	>30%
	Ellis 3	33%	49%	<15%
	Ellis 4/5	6%	5%	<6%

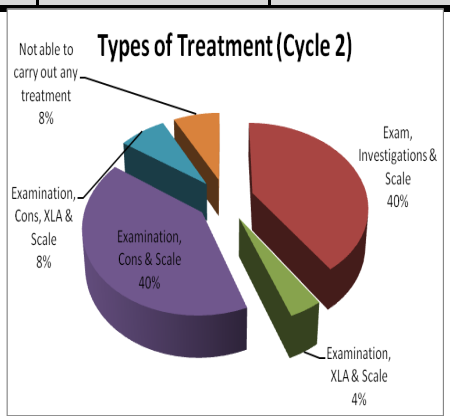


Figure 2: Types of treatment carried out in second cycle

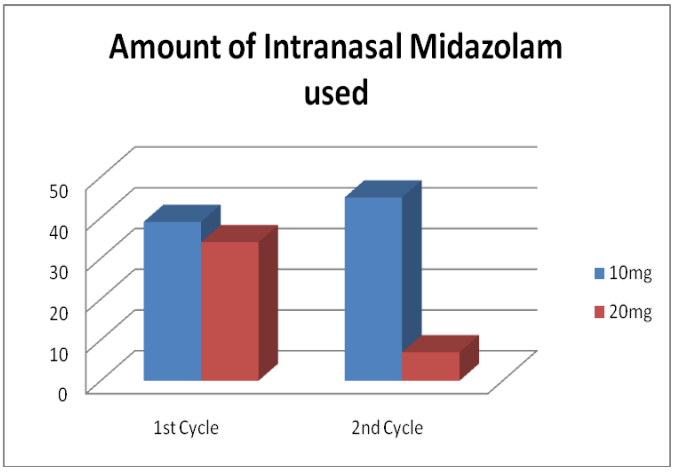


Figure 3: Amount of Intranasal sedation used for each cycle .

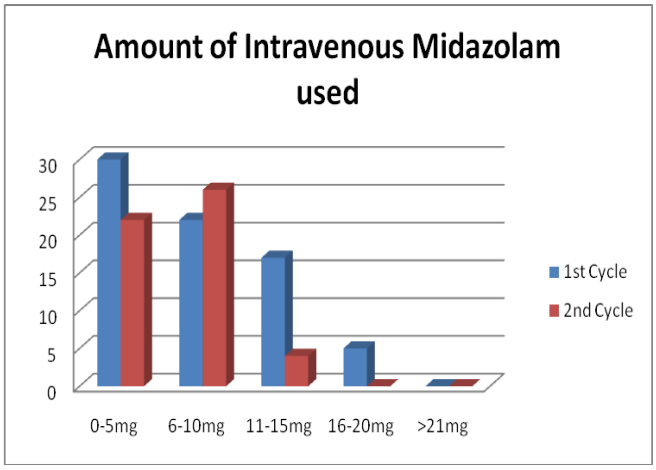


Figure 4: Amount of intravenous Midazolam used in each cycle

Recommendations from second cycle

- Consider further research on utilising a team of 4 members of staff to manage more challenging cases under sedation.
- Standardise the sedation scoring among staff by carrying out calibrated training.
- Contemplate refining the computerised patient database to allow more accurate clinical records for further audits.
- Re-audit in 12 months' time

Discussion

The audit process effectively addresses the initial objectives patients were identified successfully by using the clinic log-book, the majority of patients who were provided with care using the IN midazolam technique had learning disabilities, autism and other medical co-morbidities that may have implications for the delivery of their care. All patients undergoing sedation were ASA 1 or 2. The success of treatment provision met or exceeded the audit standards. Cannulation was consistently above 96% and therefore complied with the standards set for the audit. For both cycles of the audit adverse events were recorded and none were considered emergencies. The authors of the audit can conclude that in this local service providing sedation using the IN technique there appears to be consistent efficacy and safety of the technique when used to facilitate the provision of dental care for patients who may otherwise be unable to receive dental treatment.

The results demonstrate that a wide range of dental procedures can be carried out successfully. The technique also allowed repeated visits for longer treatment plans as well as the ability to carry out routine examinations and scaling on a regular basis to prevent the need for a general anaesthetic. This was highlighted in this audit as most of the treatment carried out in both cycles was examination and scaling followed by examination, scaling and routine restorative care.

The changes introduced following the first cycle included the use of 4 members of staff; 44% of cases requiring IN sedation were undertaken using this approach. Other recommendations included additional training and peer review of staff to have a more uniformed approach. Both recommendations may have contributed to the outcomes as well as reducing the amount of IN Midazolam required to facilitate cannulation and subsequently a reduction in intravenous midazolam used to during the delivery of dental treatment.

With regards to the level of co-operation during sedation, there was an increase in the Ellis 1 sedation score and a reduction in the Ellis 3 scores from the first cycle. Although this may be an incidental finding, it could be explained by the change in local sedation practice where complex sedation cases were planned and carried out with care by a team of four members of staff. The results for Ellis 1 and Ellis 3 scores for co-operation did not meet the set standard for this audit. It may be that the standard may have been set too high for the nature of the patients managed as they would have a degree of involuntary movement due to their lack of understanding and difficulty with co-operation. There may also be a variation in the reporting of the Ellis scores between dentists. However, 92% of patients had their planned treatment completed in cycle 2, despite 33% of patients scoring an Ellis 3. This may have resulted from having the ability to utilise more staff to manage the more challenging cases.

The number of IN midazolam doses of 20mg were considerably fewer in cycle 2 than in cycle 1. Furthermore, the of higher doses (above 10mg) of intravenous Midazolam used in the second cycle was less when compared with the first cycle.

The reduction of midazolam dosages may have been related to adopting a four-person approach to delivering sedation, thereby facilitating effective clinical holding as opposed to using higher doses of midazolam in order to improve the level of co-operation. The disadvantages of using 4 members of staff for this technique are the limited availibility of having to coordinate all appropriately trained staff to be available at the same time. Another issue is the loss of clinical time incurred by making use of a second dentist, especially when there are monitored activity targets in operation within some primary care services.

Adverse outcomes

The adverse outcomes in both cycles met the set standard with 5% in cycle 1 and no reported adverse outcomes in cycle 2. Henthorne and Dickinson (2010) identified the benefits of the judicious use of flumazenil in several selected cases. The authors recommended that if flumazenil is administered for reasons other than an emergency, then the decisions should be made for each individual case and documented appropriately. They also identified that Flumazenil use for patients with special needs or learning disabilities would be appropriate as they may display fractious and unpredictable behaviour that can be difficult for their carer to manage.

Conclusion

The results demonstrate a high level of safety and effectiveness using the combined IN and intravenous Midazolam sedation technique for providing a variety of dental treatment for many adults with severe learning disabilities and autism within primary care. The results of this audit suggest that the recommendations suggested have improved the delivery of sedation by improving treatment outcomes for patient care by a reduction in adverse events and resulting in lower titrations of midazolam. Further research is recommended to explore the cost effectiveness of these recommendations when contrasted with general anaesthesia as well as understanding in larger trials whether the impact of having a larger sedation team supporting the patient does indeed improve the outcomes and reduce the amount of midazolam required in undertaking dental treatment.

While acknowledging that there will still be a need for general anaesthesia in some cases, the technique of utilising a larger team of t clinical staff and regular training has the potential to make dental treatment more manageable and accessible in primary care. The ability to manage regular dental care for patients with learning disabilities and autism in primary care allows dental treatment to be carried out in more familiar surroundings as well as increasing the level of access. Further research may be required on a larger scale to determine the overall success of these techniques.

Conflict of Interest

The authors would like to declare there are no conflicts of interest.

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Citation: Hossenally H, Doughty J. "Intranasal (IN) Midazolam Sedation to Facilitate Dental Treatment for Adults with Autism and Learning Disabilities: An Audit of Efficacy and Safety in Primary Care". SVOA Dentistry 3:1 (2022) Pages 38 -46.