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# Intranasal midazolam for management of down syndrome patient: A case report

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**Abstract**
Down syndrome (DS) is a congenital autosomal disorder characterized by generalized growth and mental deficiency. Patients with down syndrome may be anxious and uncooperative during dental treatment thus oral health professionals may need to use physical restraints, which causes further emotional trauma.
Intranasal sedation is a non-invasive, safe and well tolerated method by children. This paper presents a case report of a 12-year-old female patient with known diagnosis of Down syndrome, who was treated successfully under intranasal sedation using midazolam (0.5 mg/kg), in which multiple extractions were performed. Satisfactory levels of sedation were achieved with no adverse effects. Post-operative healing of socket was seen without any complications after 7 days of follow up.

**Keywords:** Down syndrome (DS), Intranasal Midazolam, Sedation

## Introduction
Down Syndrome (DS), also referred to as Trisomy 21, is a congenital autosomal anomaly that was first described by Esquirol in 1838 and later named mongolism by John Langdon Down in 1866. The incidence of Down syndrome is estimated to be per 800 to 1000 births [1]. It is characterised by generalized hypotonia, neurological changes with intellectual impairment, a great risk of respiratory problems and infections, as well as dental anomalies. The condition manifests as a deficiency of central growth and delayed mental and physical development, along with various medical issues such as cardiovascular, immunological, haematological, pulmonary, neurological, and musculoskeletal abnormalities, motor disorders, and dysmorphology challenges [2]. Dental care for individuals with Down syndrome (DS) can be challenging due to a wide range of behaviours observed in the dental setting, including different levels of cooperation, mild to moderate anxiety, phobias, and a complete lack of cooperation. Although treatment follows the same principles as for the general population, additional measures may be required based on behavioural challenges, IQ, medications, and physical status [3]. For many children with DS, simple restorative and preventive treatments can be performed using the Tell, Show, and Do technique with short and focused appointments. However, less cooperative patients may require reasonable restraint, sedation, or general anaesthesia for safe and effective treatment. Dental practitioners should collaborate with the patient's physician to manage any medical risks [4].
Oral and intranasal sedation offer an alternative method for examinations and simple or quick treatment in paediatric dentistry. The intranasal route of midazolam administration has been found to have a faster onset of action than other routes, as it avoids hepatic first-pass metabolism and rapidly enters the brain through the cribriform plate, leading to increased bioavailability. It has been shown to be as effective and safe as the intramuscular route. Midazolam has also been found to produce partial anterograde amnesia and provide tranquil sedation, effectively reducing anxiety related to dental treatment. However, the choice of the route of administration should be based on individual patient factors, and practitioners should be aware of the advantages and disadvantages of each route [5]. This paper presents a case report of a 12-year-old female patient with a known diagnosis of Down syndrome who was treated under intranasal midazolam sedation undergoing multiple dental extractions.

## Case report

A 12-year-old female child was brought to the Department of Pedodontics and Preventive Dentistry with a known diagnosis of Down syndrome. The patient reported a chief complaint of pain in the upper right and left back tooth regions for the past 3-4 months. History revealed that pain was chronic, dull, and aching in nature and aggravated upon mastication. Past dental history revealed that the patient had undergone pulp therapy and restorative procedures and had been treated under general anaesthesia twice in the past two years. A review of the patient's medical history showed that the patient was diagnosed with Down syndrome at birth. On general examination, the patient was conscious and moderately cooperative but did not respond well to questions. On Extraoral examination, the patient had a small head (brachycephaly), epicanthic folds, a flat nasal bridge, lip incompetency, an open mouth, a hypotonic upper lip, and an enlarged tongue. (Fig. 1) On intraoral examination, high-arch palate, macroglossia, and deep dental caries were present in relation to 55, 65, a stainless-steel crown in relation to 75, and amalgam restorations were present in relation to 26, 46. Radiographic evaluation was further done to evaluate carious teeth, which revealed that there was periapical radiolucency involving enamel, dentin, and pulp in relation to 55 and 65. Both teeth showed physiologic root resorption greater than 2/3 of the length of the tooth. Deep occlusal caries involving pulp were present in relation to 65. (Fig. 2) In the treatment plan, extraction for both 55 and 65 were planned as they were over retained and showed physiological root resorption.

**Fig 1:** Extraoral features of down syndrome patient

**Fig 2:** IOPA of 55, 65

## Treatment Plan

The treatment plan involved a step-by-step approach, with behaviour modification techniques such as tender love and care, communicative management, voice control, and tell-show-do being recommended as the first step. However, the patient displayed reluctant behaviour and exhibited a limited level of communication and understanding. Intranasal midazolam conscious sedation was planned, and the parents were provided with written and informed consent before initiating the treatment. A medical consultation with a pediatrician was conducted to determine the appropriate dosage of medication. Throughout the procedure, blood pressure, pulse rate, and oxygen saturation levels were monitored using a pulse oximeter.

Based on the patient's weight of 28 kg, the recommended dosage for the drug was 0.25-0.5 mg/kg, which calculates to a dose of 14 mg that can be given for the patient. However, the maximum safe daily midazolam drug dose was determined to be 10 mg.

To administer the medication, a midazolam spray was used, (Fig. 3) with each puff containing 0.5 mg of the drug. To achieve the appropriate dosage, a total of 20 puffs were calculated to be sprayed for this patient. (Table 1), (Table 2). The tip of the nozzle was carefully positioned within the nostril, and a single spray was delivered. (Fig. 4) Following a 5-minute interval, an additional puff of midazolam spray was applied, this time into the alternative nostril. After a subsequent 10-minute period, four puffs of midazolam spray were administered in the same manner. The level of sedation was assessed using the paediatric sedation score, which was determined to be a score of 2 under moderate sedation. Slow administration of local anesthesia was performed, followed by a traumatic extraction of both 55 and 65 tooth. (Fig. 5, Fig. 6) Complete irrigation and haemostasis were achieved, and post-operative instructions were given. The dental procedures were successfully completed within approximately 20 minutes, and recovery was smooth following the procedure. The post-sedation instructions were given to the parents to walk along with the patient, considering the potential occurrence of drowsiness throughout the remainder of the day. After a 7-day follow-up appointment, it was observed that the socket had successfully healed without any complications, and no adverse effects were reported.


**Fig 3:** Midazolam spray

**Table 1:** Specification for dosage

| Specification for dosage | Measures (unit) |
|---|---|
| Recommended dosage | 0.25 - 0.5 mg/kg |
| Maximum safe drug dose | 10 mg/d |
| Midazolam spray | 50 puffs of spray |
| 1 puff | 0.5 mg drug |

**Table 2:** Dosage calculation for patient

| Dosage calculation for patient | Measures (unit) |
|---|---|
| Patient's weight | 28 kg |
| Calculated dose (0.5 × 28) | 14 mg |
| No. of puffs (n) to be sprayed: 1/0.5 × 10 | 20 puffs |

**Fig 4:** Administration of intranasal midazolam spray

**Fig 5:** Administration of LA

**Fig 6:** Extraction of 55

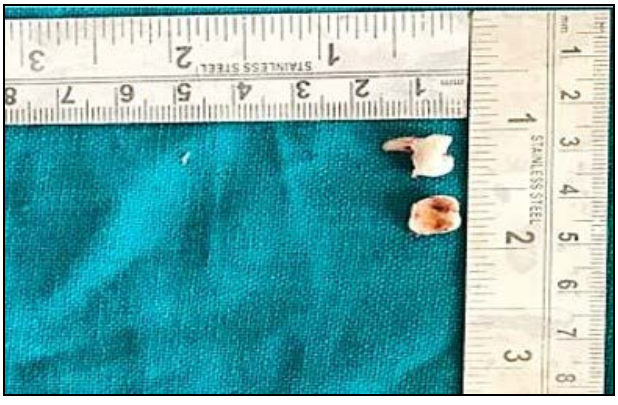

**Fig 7:** Extracted teeth: 55.65

## Discussion

Down syndrome is one of the leading causes of intellectual disability, and millions of individuals suffer from a variety of health difficulties, including learning and memory impairments and congenital heart disease. Individuals with down syndrome commonly encounter dental issues such as delayed eruption of teeth, malocclusions, periodontal disease, and enamel hypoplasia [4]. These oral health concerns may be attributed to factors such as altered craniofacial growth and development, decreased muscle tone, and impaired immune function. Proper dental care and management are crucial for individuals with down syndrome to maintain good oral health and prevent further complications. Regular dental check-ups, oral hygiene instructions, and preventive measures, including fluoride treatments and dental sealants, play a vital role in minimising the risk of dental problems [1]. The ability to communicate effectively with individuals who have Down Syndrome (DS) can be influenced by their level of learning disability, any hearing or visual impairment, and speech difficulties. Non-verbal communication, such as smiling and a reassuring touch, plays an important role. Additionally, a collaborative approach involving the patient's carers, dental professionals, and healthcare providers is essential to address the specific needs and challenges associated with dental care for individuals with down syndrome [6].

Midazolam is a commonly used short-acting benzodiazepine with a wide therapeutic ratio and safety margin that makes it an ideal sedative agent. It exerts anxiolytic, anticonvulsant, muscular relaxant, and amnesic effects. Sedation using midazolam can be administered via various routes, including orally, intranasally, sublingually, rectally, or intravenously [7]. Among these, the intranasal route is particularly advantageous due to its faster onset of action and increased bioavailability, making it as effective and safe as the intramuscular route. the use of intranasal midazolam as a premedication for preschool children was originally introduced and endorsed by Wilton *et al*. (1988) [8]. A randomized, double-blind, placebo-controlled study conducted by Shapiro *et al*., established that the administration of midazolam spray effectively alleviates distress in Pediatric patients experiencing fear during routine medical procedures such as venous blood sampling and venous cannulation, involving the insertion of a needle into a subcutaneous intravenous port [9].

A double-blind, randomised, controlled trial conducted in 2011 by Rakaf *et al*. concluded that 91% to 100% of dental procedures were successfully completed after IN midazolam delivery. However, to ensure its effective utilisation, efforts must be made to alleviate the associated unpleasant sensations such as burning and bitter taste [10].

There are different routes of drug administration to provide sedation in children. In this case, the administration of oral sedation was not considered due to the challenges associated with determining an appropriate dosage and the documented risks of over sedation. The use of intramuscular or intravenous (IM/IV) sedation was avoided to prevent discomfort caused by needle placement as well as increased anxiety for the child. General anaesthesia (GA) had been employed twice before, but parents expressed apprehension regarding its usage. Conscious sedation was not planned due

to the patient's inability to cooperate, comprehend, and communicate effectively. Therefore, the intranasal midazolam sedation was chosen in this case, taking into account the limitations of other administration methods and considered as non-invasive and convenient route of sedation that minimizes the patient's discomfort and anxiety during dental extraction procedures, particularly in individuals with Down syndrome.

## Conclusion

It is important to note that individuals with Down syndrome (DS) may exhibit intellectual impairments and potentially present with complex medical conditions. Nevertheless, it is essential for Pediatric dentists to possess the necessary competence and expertise to provide comprehensive dental care to these individuals within the confines of their private practices. Intranasal administration of midazolam offers several advantages, including ease of use, reduced technique sensitivity, minimal patient cooperation requirements, rapid onset of action, and painless administration. The utilization of intranasal midazolam in dental practice represents a significant advancement, providing a well-tolerated and effective alternative to oral or intravenous routes. By incorporating such techniques, Pediatric dentists can ensure the delivery of needle-free, patient-friendly sedation, thereby addressing the unique needs of individuals with DS and facilitating their consistent access to comprehensive dental care within the private practice setting.

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