Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 6, 2021, Pages. 2043 - 2047
Received 25 April 2021; Accepted 08 May 2021.

Evaluation of Different Sedatives used to Achieve Conscious Sedation during Pediatric Dental Procedures: An Original Research

[1]Dr SubhasmitaBhol, [2]Dr Mohammed Muzammil Khan, [3]Dr Shrinivas T R, [4]Dr. Rahul VC Tiwari, [5]Dr. Sourabh Ramesh Joshi, [6]Dr. MastanShaik

[1]Reader, Dept of Pediatric& Preventive dentistry, Hi tech Dental college& Hospital, Bhubaneswar, drsubha81@gmail.com
[2]Specialist Pedodontist, Ministry of health, Taif, Kingdom of Saudi Arabia.mdmuzammil.khan8@gmail.com
[3]Associate professor, Department of Anaesthesia, Koppal institute of medical sciences, Gangavathi Road, Koppal, Karnataka.
[4]OMFS, FOGS, PhD Scholar, Dept of OMFS, Narsinbhai Patel Dental College and Hospital, Sankalchand Patel University, Visnagar, Gujarat, 384315. drrahulvctiwari@gmail.com
[5]Reader, Department Of Pediatric Dentistry, Rural Dental College, Pravara Institute Of Medical Sciences, Loni, TalukaRahata, Ahmednagar, Maharashtra
[6]Department of Oral and Maxillofacial Surgery, St. Joseph Dental College, Eluru, Andhra Pradesh. drmastanshaik@gmail.com

Corresponding Author: Dr SubhasmitaBhol, Reader, Dept of Pediatric& Preventive dentistry, Hi tech Dental college& Hospital, Bhubaneswar, drsubha81@gmail.com

ABSTRACT

Aim: The primary aim of this study is to investigate the efficacy of intranasally administered ketamine plus midazolam for the dental treatment of children.

Methodology: Two- to six-year-old healthy children, came for dental treatment in our institutional setting and due to uncooperative behavior and requiring restorative dental procedures, were recruited for conscious sedation after taking consent form from their parents/guardians. Each child was randomly assigned to one of the two groups: A – Intranasal (IN) administration of ketamine (4.0 mg/kg, maximum 100 mg) and midazolam (0.2 mg/kg, maximum 5.0 mg); B – Oral administration of ketamine (4.0 mg/kg, maximum 100 mg) and midazolam (0.5 mg/kg, maximum 20 mg). The primary outcome was the child's behavior which was assessed through an observational scale using acceptance of sedative administration; memory of intraoperative events; the child's stress; adverse events; the child's pain during the procedure. Descriptive statistical analysis was carried out on the data recorded.

Results:'Adequate' depth of sedation was achieved in 93% and 'satisfactory' completion of treatment was achieved in 89% of cases with intranasal midazolam-ketamine combination. However, sedation effect was deeper in case of oral route sedation procedures (98%), with recovery time of 45 mins-1 hour, which was longer than that of Intra nasal route.

Conclusion

Intranasal route was effective for modifying behavior in mild to moderately anxious children, however, for more invasive or prolonged procedures oral routes is recommended.

Keywords: Conscious sedation, Midazolam, Ketamine, Intranasal, Pain assessment

INTRODUCTION

Conscious sedation is an effective method of reducing preoperative anxiety in children and in adult patients who suffer from anxiety, especially prior to surgical procedures requiring

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 6, 2021, Pages. 2043 - 2047
Received 25 April 2021; Accepted 08 May 2021.

general anesthesia. When administered before dental treatments, conscious sedation methods have been shown to aid in the reduction of patient pain and anxiety. Conscious sedation is very useful in encouraging patient cooperation and improving overall patient satisfaction with dental treatment. However, conscious sedation methods do involve some level of risk for patients and dental practitioners.[1]It is well known that conscious sedation allows dental practitioners to treat uncooperative patients.[2]

Some patients simply cannot be treated with locoregionalanesthesia alone for various reasons, generally due to behavioral problems resulting from some form of disability or because the patient is a child. In these cases, procedures must be performed with the patient under conscious sedation. However, in some cases requiring very complex dental procedures, or if the patient is in poor condition, conscious sedation may be inadvisable or the class of drugs used may be contraindicated.[3]

The adverse effects associated with conscious sedation are a result of the class of drugs used, with hallucinations being the most frequently observed adverse reaction [4,5] linked to the use of benzodiazepines, propofol and nitrous oxide. Nitrous oxide may also cause damage to immune and hematologic systems, and it can cause fertility problems in women.[6-9] However, the biggest disadvantage of conscious sedation is that it can mask symptoms of a medical emergency, so clinicians should remain very conscious of proper methods of sedation for dental procedures and their importance.[10]

The research concerning intranasal procedural sedation has been highlighted due to its faster onset of action and recovery time and less discomfort and cost compared to other routes of sedative administration.[11] In line with the aforementioned efficacy of orally administered ketamine/midazolam,[12] we did a search in PubMed and found only one study in pediatric dentistry that used intranasally administered ketamine plus midazolam. Based on a crossover design with 45 children aged 2–6 years, that study [13] revealed high success rates for intranasal sedation as follows: ketamine (6.0 mg/kg) – 89%; midazolam and ketamine (0.2 mg/kg and 4.0 mg/kg) – 84%; and midazolam (0.3 mg/kg) – 69%. In the medical pediatric field, the combination of ketamine and midazolam to perform gastric aspirates has been successful. However, there is a lack of RCTs investigating the intranasal route to deliver ketamine-midazolam in procedural sedation.[14]

Pediatric dental sedation outcomes have primarily been assessed through children's behavior during the procedure, but the assessment of other "core variables," including baseline anxiety, completion of treatment, and patient satisfaction or preference, is advisable. However, there are other assessments that can be beneficial for the evaluation of sedation success if performed using a systematic method. Given the lack of evidence on which a sedative regimen is more effective for pediatric dental patients and the requirement for more well designed studies, the development of a RCT on pediatric dental sedation comprising multiple assessments is timely.[15]

While IN sedatives do not relieve pain, they are a useful adjunct to analgesics, particularly in preparing patients for surgery, and are commonly given to patients before general anesthesia, known as premedication, or before invasive procedures. As a premedication, IN sedatives are effective in reducing anxiety associated with separation from parents and induction of anesthesia. Delivery of IN sedatives can be either via drops using a syringe/ dropper or a sprayed/atomized medication delivery system that delivers a unit dose through a syringe, or a unit dose pump usually with a spray tip that fragments the IN sedative into fine particles as it is being sprayed into the nose. [13]

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 6, 2021, Pages. 2043 - 2047
Received 25 April 2021; Accepted 08 May 2021.

AIM OF THE STUDY

The primary aim of this study is to investigate the efficacy of intranasally administered ketamine plus midazolam for the dental treatment of children and understand the after effects of the treatment with this kind of conscious sedation on pediatric patients.

METHODOLOGY

Two- to six-year-old healthy children, came for dental treatment in our institutional setting and due to uncooperative behavior and requiring restorative dental procedures, were recruited for conscious sedation after taking consent form from their parents/guardians. Each child was randomly assigned to one of the two groups:

A – Intranasal administration of ketamine (4.0 mg/kg, maximum 100 mg) and midazolam (0.2 mg/kg, maximum 5.0 mg)

B – Oral administration of ketamine (4.0 mg/kg, maximum 100 mg) and midazolam (0.5 mg/kg, maximum 20 mg).

The primary outcome was the child's behavior which was assessed through an observational scale using acceptance of sedative administration; memory of intraoperative events; the child's stress; adverse events; the child's pain during the procedure.

The medical examination was performed to confirm the health history and obtain vital signs at baseline. Necessary treatment was carried out by the dental professionals while noticing the behavior patterns of the children according to the Frankl scale.

The pediatric dentists are trained in the application of the Frankl scale, which classifies the child's behavior as follows: (1) Definitely negative – refusal of treatment; intense crying, fear or any other evidence of extreme negativism, (2) Negative – reluctance to accept treatment; lack of cooperation; any other negative attitude, (3) Positive – acceptance of treatment; willingness to cooperate with the dentist despite some caution; followed instructions from the dentist, (4) Definitely positive – good behavior toward the dentist interested in dental procedures; had fun with the situation.

Descriptive statistical analysis was carried out on the data recorded which helped to verify the success of sedation based on the child's behavior (primary outcome) comparing the two groups.

RESULTS

'Adequate' depth of sedation was achieved in 93% and 'satisfactory' completion of treatment was achieved in 89% of cases with intranasal midazolam-ketamine combination.There were no major adverse effects reported. Medication administration was reasonably well tolerated, with no reduction in heart rate and blood pressure.5% showed increased lacrimation, vomiting post the sedation during the recovery period.

However, sedation effect was deeper in case of oral route sedation procedures (98%), with recovery time of 45 mins-1 hour, which was longer than that of Intra nasal route. In case of oral route, adverse effects ranged from vomiting, lacrimation, sneezing, coughing post the treatment and in the recovery period (8%). (Table 1)

Table 1 – Data recorded in the present study

Variables	Intranasal route	Oral route
Onset of sedation	5-6 mins	15 -30 mins
Adverse effects post recovery	5% showed increased lacrimation, vomiting	vomiting, lacrimation, sneezing, coughing post the treatment and in the

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 6, 2021, Pages. 2043 - 2047
Received 25 April 2021; Accepted 08 May 2021.

		recovery period (8%)
Deeper sedation achieved	93%	98%
Level of professional training required	Less	more
Length of treatment	Useful for shorter treatment period	Useful for longer treatment period

DISCUSSION

Intranasal sedation is becoming more popular given the rapid onset and offset and the relative safety of the sedation of patients without the need for intravenous catheters. This phenomenon is accomplished by avoiding the gut and thus avoiding first-pass metabolism. This allows for greatly increased bioavailability compared with oral administration. In addition, the nasal mucosa is in near direct contact with the CSF via the cribriform plate, allowing for rapid and effective action. To maximize the effectiveness of intranasal sedation, low volumes with high concentrations, atomization, and minimal nasal occlusion are vital. The ideal volume per nostril is approximately 0.5 ml as using any greater volume results in oversaturation and minimal additional absorption. Thus, concentrating the medications into minimal volumes provides for more efficacious usage. Atomization aids in ensuring thorough surface area coverage and higher absorption. This is a far more efficacious method of delivery than liquid/drop administration.[16] Because intranasally administered agents have a delayed and widened serum peak compared to IV, IN sedation carries less of a chance to reach serum levels high enough to cause respiratory depression, though monitoring is still necessary. When compared to IV sedation, IN does have a delay in onset, but also provides for a more gentle recovery process, often resulting in a less disorienting recovery for the patient, while also providing for a wider safety profile. Intranasal midazolam was effective for modifying behavior in mild to moderately anxious children, however, for prolonged procedures, stronger sedatives (for example, IN ketamine, IN sufentanil) are recommended. IN ketamine was considered to be more successful for conscious sedation when compared with IN midazolam and IN midazolam-ketamine combination. However, when IN sufentanil was used in combination with IN midazolam, patients experienced less pain when compared with a IN midazolam-ketamine combination. [17] Burstein et al, reported that a combination of sedatives resulted in over sedation leading to loss of consciousness and laryngospasm. It should be noted that dentists administering IN sedatives should not only be competent at basic life support, but they should also be prepared for other complications in general. While dentists can and do provide safe and effective IN conscious sedation without the need for general anesthesia training, it is vital that they abide by the American Dental Association's definition of conscious sedation.[18]

CONCLUSION

Intranasal route was effective for modifying behavior in mild to moderately anxious children, however, for more invasive or prolonged procedures oral routes is recommended. However, the IN route of sedation administration to achieve conscious sedation is reliable, successful, and invaluable when treating anxious and un-cooperative children needing dental care.

REFERENCES

1. Almenrader N, Passariello M, Coccetti B, Haiberger R, Pietropaoli P. Premedication in children: a comparison of oral midazolam and oral clonidine. PaediatrAnaesth. 2007;17:1143-9.

2. Wilson TD, McNeil DW, Kyle BN, Weaver BD, Graves RW. Effects of conscious sedation on patient recall of anxiety and pain after oral surgery. Oral Surg Oral Med Oral Pathol Oral Radiol. 2014;117:277-82.
3. O'Halloran M. The use of anaesthetic agents to provide anxiolysis and sedation in dentistry and oral surgery. Australas Med J.2013;6:713-8.
4. Saraghi M, Badner VM, Golden LR, Hersh EV. Propofol: an overview of its risks and benefits. CompendContinEduc Dent. 2013;34:252-8.
5. Lambert C. Sexual phenomena hypnosis and nitrous oxide sedation. J Am Dent Assoc. 1982;105:990-1.
6. Sweeney B, Bingham RM, Amos RJ, Petty AC, Cole PV. Toxicity of bone marrow in dentists exposed to nitrous oxide. Br Med J (Clin Res Ed). 1985;291:567-9.
7. Nunn JF, Sharer NM, Gorchein A, Jones JA, Wickramasinghe SN. Megaloblastichaemopoiesis after multiple short-term exposure to nitrous oxide. Lancet. 1982;1:1379-81.
8. Pasha H, Basirat Z, Hajahmadi M, Bakhtiari A, Faramarzi M, Salmalian H. Maternal expectations and experiences of labor analgesia with nitrous oxide. Iran Red Crescent Med J. 2012;14:792-7.
9. Lahoud GY, Averley PA. Comparison of sevoflurane and nitrous oxide mixture with nitrous oxide alone for inhalation conscious sedation in children having dental treatment: a randomised controlled trial. Anaesthesia. 2002;57:446-50.
10. Todd DW. Pediatric sedation and anesthesia for the oral surgeon. Oral MaxillofacSurgClin North Am. 2013;25:467-78.
11. Wolfe TR, Braude DA. Intranasal medication delivery for children: a brief review and update. Pediatrics. 2010;126(3):532–7.
12. Moreira TA, Costa PS, Costa LR, Jesus-França CM, Antunes DE, Gomes HS, et al. Combined oral midazolam-ketamine better than midazolam alone for sedation of young children: a randomized controlled trial. Int J Paediatr Dent. 2013;23(3):207–15.
13. Bahetwar SK, Pandey RK, Saksena AK, Chandra G. A comparative evaluation of intranasal midazolam, ketamine and their combination for sedation of young uncooperative pediatric dental patients: a triple blind randomized crossover trial. J ClinPediatr Dent. 2011;35(4):415–20.
14. Buonsenso D, Barone G, Valentini P, Pierri F, Riccardi R, Chiaretti A. Utility of intranasal ketamine and midazolam to perform gastric aspirates in children: a double-blind, placebo controlled, randomized study. BMC Pediatr. 2014;14:67.
15. Lourenço-Matharu L, Ashley PF, Furness S. Sedation of children undergoing dental treatment. Cochrane Database Syst Rev. 2012;3:CD003877.
16. AlSarheed MA. Intranasal sedatives in pediatric dentistry. Saudi Med J 2016; Vol. 37 (9): 948-95.
17. Wilton NC, Leigh J, Rosen DR, Pandit UA. Preanesthetic sedation of preschool children using intranasal midazolam. Anesthesiology 1988; 69: 972-975.
18. Burstein AH, Modica R, Hatton M, Gengo FM. Intranasal midazolam plasma concentration profile and its effect on anxiety associated with dental procedures. AnesthProg 1996; 43: 52-57.