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Comparison of sedative effects of midazolam and dexmedetomidine in paediatric dentistry-A randomized controlled trial

Dr. Deepashree Sawkar[1*], Dr. Nitin Khanduri[2], Dr. Kalpna Chaudhry[3], Dr. Mridul[1]
[1] Department of Pediatric and Preventive Dentistry, Seema Dental College and Hospital, Rishikesh, Uttarakhand, India
[2] Professor, Department of Pediatric and Preventive Dentistry, Seema Dental College and Hospital, Rishikesh, Uttarakhand, India
[3] Head & Professor, Department of Pediatric and Preventive Dentistry, Seema Dental College and Hospital, Rishikesh, Uttarakhand, India

Abstract
Background: To check for better and faster effectiveness of nasal sedation achieved by dexmedetomidine and midazolam on fearful children needing dental treatment.
Aim: The aim of the study was to compare the nasal sedative effects of dexmedetomidine and midazolam on fearful children needing dental treatment.
Methodology: This *In vitro* study was conducted in Seema dental college and hospital, Rishikesh. Patients aged 2-10yrs were included with at least two similar teeth needing pulp therapy. Standard vital signs would be measured pre and post administration of sedative. Frankel's rating and Sedation Scale will be used to analyse the fearfulness and level of sedation respectively. Cases would be referrals/outpatient in college for arrangement to receive dental treatments under sedation. The combination of drugs will be administered at the start of each dental session by dental operator under the guidance of anaesthesiologist and patient will be blinded to the drugs combination during the visit.
Conclusion: Both the drugs produced satisfactory results in behaviour modification from pretreatment to post treatment. Sedation level was significant in Group II (Dexmedetomidine) with p-value=0.014 then group I (Midazolam) with p value=0.206.

Keywords: Dexmedetomidine, midazolam, frankel's rating scale, sedation scale

Introduction

Dental fear and anxiety are the commonest cause of compromised and complicated oral health status in an individual. Dental anxiety refers to uneasiness of outcome coupled with sense of losing control. Around 5-20% prevalence rate in dental fear across the country is noted [1].
A comprehensive behaviour methodology needs to be formulated between patient/child and the dentist along with dental environment. When approached in friendly and encouraging way, the majority of individuals voluntarily accept treatment. But, the other half, needs continuous effort and time by the expert clinician in behaviour modification. Thus, behaviour management is considered an integral part in pediatric dentistry [2].
Children in which basic behaviour guidance is not effective, pharmacological aids such as conscious sedation can be used. Methods routinely used for administration of sedatives are inhalational, oral, intramuscular, intravenous and submucosal. Sub-mucosal (Intranasal) sedation involves deposition of drug beneath the mucosa. It is the commonly used method in children as it painless, easily accepted and inexpensive with rapid duration of onset. Various drugs used are Opiods (Meridine), Anti-anxiety drugs (Midazolam) and sedative hypnotics (Chloral hydrate, Dexmedetomidine, Ketamine) [3].
Midazolam is common choice of sedation in pediatrics to perform dental procedures. It has sedative and anxiolytic effect. Effect of sedation is rapid within 10mins of administration. Prescribed dosage intranasally is 0.2-0.4mg/kg and is well established as a premedication for anaesthesia. [4]
Dexmedetomidine is relatively a newer intranasal drug. It is highly selective alpha2-adrenergic agonist, with a short duration of action. Dosage for I.V administration is 0.2-0.7µg/kg/hr. This drug has the unique ability to mimic natural sleep like state, provide rapid and stable hypnosis, analgesia while maintaining patient arousability and respiratory function [5].
The aim of this study was to evaluate and compare the sedative effects of midazolam and dexmedetomidine in a group of uncooperative child dental patients aged 2–10years.

Material and method

The study was conducted in Seema Dental College and Hospital, Rishikesh. This *in-vitro* study was a double blinded randomised study approved by institution ethical committee. All patients were informed about the study and prior consent was signed by participants parent or guardian.
Frankl Dental anxiety of participant was taken into consideration based on uncooperative nature in the first dental appointment. This study included 25 patients aged 2-10yrs which required pulpal therapy in bilaterally two similar teeth. Sample size of 25 in each group I (Midazolam) and group II (Dexmedetomidine) was calculated using 90% power and 0.05 level of significance. Patients with known allergies, blood disorders, cardiac or respiratory diseases and mental disabilities were excluded from the study.

Table 1: Frankel's behavior rating scale

Score	Attitude	Signs
1	Definitely negative	Refusal of treatment, crying forcefully, fearful or any other overt evidence of extreme negativism.
2	Negative	Reluctant to accept treatment, uncooperative, some evidence of negative attitude.
3	Positive	Acceptance of treatment, at times cautious, willingness to comply with the dentist, at times with reservation but patient is co-operative with the dentist.
4	Definitely positive	Good rapport with the dentist, interested in the dental procedures, laughing and enjoying the situation.

Prior to sedation, patient's vital signs such as pulse rate, oxygen saturation were recorded. Dental anxiety was assessed based on Frankel's rating scale [Table no.1] i.e. definitely negative, negative, positive and definitely positive [Figure no.1]

Fig 1: patient with dental anxiety and fear
a. Definitely negative behavior **b.** Negative behaviour

Table 2: Wilson's sedation scale

Score	Signs
1	Fully aware and oriented
2	Drowsy
3	Eyes closed but responsive to command
4	Eyes closed but responsive to mild physical stimulation (earlobe tug)
5	Eyes closed but unresponsive to mild physical stimulation

Wilson's sedation rating scale [Table no: 2] was used in sedation assessment pre-treatment post sedation, during treatment and post treatment and recovery time was recorded. Patients received either of the drug, Dexmedetomidine or Midazolam [Figure no.2]. The Pediatric dentist and the observer were blind to the drug administered. Dexmedetomidine nasal spray was prepared by diluting intravenous formulation into 0.9% normal saline for final diluted volume of 1ml. One of the sedative drug was intra nasally given to the patient based on patients weight Dex (group II) received 1mcg/kg of sedative and mid (group I) received 0.2mg/kg through nasal spray. Pulpal treatment was carried out under local anaesthesia 2% lignocaine. Vital signs were recorded at every interval of 15mins during treatment.

Fig 2: Nasal administration of sedative drug

Data was subjected to statistical analysis using SPSS software. Mann Whitney U test and Wilcoxon's signed rank test were performed to compare scores during treatment and post treatment. The significance level was less than 5%.

Result

The study consisted 25 patients with mean age of 6.057yrs of age with 52.4% males and 47.6% females. Amongst the participants, 94% was the least level of oxygen saturation noted in the study. Frankel's behavioral scale showed a positive outcome after administration of selected individual drugs, midazolam and dexmedetomidine [Table no.3]. When comparison was carried out, intranasal use of midazolam proved to be quick and faster in onset then dexmedetomidine. There was decrease in patient's anxiety level on Wilson's sedation scale post drug administration [Table no.4].

Table 3: Comparison of Group I and Group II during and post treatment in each group

Group	Parameter	Z statistic	p value
Midazolam (Group I)	Wilsons sedation scale post treatment -during treatment	-1.265	0.206
	Frankel's behaviour rating post treatment-during treatment	-2.646	0.008
Dexmedetomidine (Group II)	Wilsons sedation scale post treatment -during treatment	-2.449	0.014
	Frankel's behaviour rating post treatment-during treatment	-2.333	0.020

Z statistics and p value obtained from Wilcoxon's signed rank test. p value ≤ 0.05 is significant

Table 4: Comparison of Group I and Group II during and post treatment in both groups

Parameter	Intervention	Mean rank	Mann Whitney U test	P Value
Wilson Sedation rating -During treatment	Midazolam (Group I)	23.17	185.500	0.348
	Dexmedetomidine (Group II)	19.83		
Wilson Sedation rating -Post treatment	Midazolam (Group I)	22.33	203.000	0.641
	Dexmedetomidine (Group II)	20.67		
Frankel's Rating scale -During treatment	Midazolam (Group I)	21.05	211.000	0.797
	Dexmedetomidine (Group II)	21.95		
Frankel's Rating scale -post treatment	Midazolam (Group I)	21.50	220.500	1.000
	Dexmedetomidine (Group II)	21.50		

Discussion

Due to intense anxiety and terror, many youngsters continue to experience serious dental issues. There are still lots of paediatric dentists and even dental colleges who utilise commonplace office behavioural control methods such as physical constraints, as their only option. Conscious sedation is a good strategy used in child's behaviour management in the dental clinic, according to more current, in-depth research.

Children are susceptible to drug reactions including sedatives hence it is crucial to take all reasonable steps to minimize the risks during treatment. This is beneficial if the potency of the medications employed can offer the best level of cooperation for the intended dental surgery to be carried out in a safe manner. The combination of drug use consists of a strategy that lower doses of the known sedative agents can be administered safely in children while achieving maximum re-quired sedation level to satisfactorily carry out the procedure.

Amongst various studies, Kaya *et al*. conducted a similar study on dexmedetomidine and midazolam. They found the level of sdation achieved was better with Dexmedetomidine then midazolam. Muttu *et al*. and Cheung *et al*. mentioned that several patients became restless, aggressive or agitated after midazolam administration accompanied by nasal irritation. This reaction was not reported in dexmedetomidine-treated patients in any of the included studies.

Discussion

This study aimed to evaluate and compare the sedative effects of intranasal midazolam and dexmedetomidine in pediatric dental patients exhibiting high levels of anxiety. Both drugs are commonly used for sedation in uncooperative children, yet their effectiveness and onset times can vary significantly.The results indicated that both midazolam and dexmedetomidine were effective in reducing dental anxiety, as evidenced by improvements in Frankel's behavior rating and Wilson's sedation scale scores. Midazolam demonstrated a faster onset of sedation compared to dexmedetomidine. This aligns with its pharmacokinetic profile, which includes a rapid onset of action and a well-established track record as a premedication for anesthesia [4]. The observed decrease in anxiety levels in the midazolam group could be attributed to its quicker sedative effect, which is crucial in managing acute anxiety during dental procedures.

On the other hand, dexmedetomidine, despite its slower onset, was effective in achieving a calm state similar to natural sleep, as noted in previous studies [5]. This unique property might make dexmedetomidine preferable for longer or more complex procedures where maintaining a stable, relaxed state is beneficial.

Both the Frankel's behavioral scale and Wilson's sedation scale showed significant improvements in the patients' anxiety levels post-treatment. The Wilcoxon signed-rank test revealed significant reductions in anxiety as per Frankel's scale for both groups, with midazolam demonstrating a marginally more significant reduction in behavioral negativity compared to dexmedetomidine (p=0.008 vs. 0.020). This suggests that while both sedatives are effective, midazolam may provide a more immediate impact on patient behavior, which is a crucial factor in pediatric dentistry.

The choice between midazolam and dexmedetomidine should consider not only the onset time but also the duration of sedation required for the procedure. Midazolam's rapid onset makes it a preferable choice for short dental treatments, while dexmedetomidine's ability to induce a sleep-like state may be advantageous for more prolonged

procedures. Additionally, dexmedetomidine's potential for maintaining patient arousability while ensuring stable sedation could offer advantages in complex cases where continuous monitoring is feasible.

Study limitations

Several limitations must be acknowledged. The sample size of 25 patients per group, while calculated for adequate power, is relatively small and may limit the generalizability of the findings. Additionally, the study's focus on a single institution's patient population might introduce biases related to specific clinical practices or patient demographics. Further studies with larger and more diverse samples are necessary to validate these findings and assess the long-term effects and safety profiles of these sedatives in broader pediatric populations.

Future research

Future research should explore the comparative effectiveness of midazolam and dexmedetomidine in different age groups and for various types of dental procedures. Investigating the long-term effects of these sedatives on children's dental health and behavioral outcomes could provide more comprehensive insights into their suitability for routine pediatric dental care.

Conclusion

Both midazolam and dexmedetomidine are effective for managing dental anxiety in uncooperative pediatric patients, but they offer different benefits. Midazolam provides a quicker onset of sedation, while dexmedetomidine offers a more stable, sleep-like state. The choice of sedative should be tailored to the specific needs of the dental procedure and the patient's response to the drug. Further research with larger sample sizes and diverse patient groups is needed to enhance our understanding of these sedative options in pediatric dentistry.

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