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Comparison of Midazolam, Ketamine and Dexmedetomidine as Premedications for Radiological Imaging in Children Under 10 Years of Age - A Randomised Controlled Trial

(Sedative agents as Pre-Medication)

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The data sets generated and analysed during the current study are available from the corresponding author upon reasonable request.

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KEYWORDS

Premedication, Children under 10 years, Midazolam vs Ketamine vs Dexmedetomidine.

ABSTRACT:

Background: Successful radiological imaging in young children often requires pharmacologic sedation to alleviate anxiety and ensure immobility. The optimal sedative agent balancing rapid onset, safety, and recovery profile remains a subject of debate. This study aims to directly compare the efficacy and safety of midazolam, ketamine, and dexmedetomidine for this purpose.

Methods: A prospective, randomized, comparative study was conducted on children under 10 years of age scheduled for non-invasive radiological imaging. Patients were randomly allocated to receive intravenous midazolam, ketamine, or dexmedetomidine as premedication. The outcomes included time to onset of sedation, total sedation duration, and the number of doses required and PAED score.

Results: Our results demonstrated statistically significant differences among the agents. Ketamine provided the most rapid onset of sedation (16.9 minutes) and required the fewest doses (1.1), while Dexmedetomidine offered the longest duration of action (121.4 minutes). Critically, Ketamine exhibited the most favorable safety profile, with 96.3% of patients experiencing no adverse effects. No significant difference was found in the incidence of emergence delirium between the three groups. Conclusion: Ketamine is a preferred choice for radiological imaging in children due to its rapid onset, low dosing requirements, and minimal adverse effects, while Dexmedetomidine offers longer sedation.

Introduction:

Children undergoing radiological imaging procedures often experience significant anxiety and distress, which can compromise the quality of imaging due to movement and lack of cooperation. To ensure optimal conditions for diagnostic accuracy and minimize psychological trauma, effective premedication is crucial in the pediatric population, particularly in those under 10 years of age (1,2). A recent study stated that Approximately 18% of children had difficulty undergoing investigation without sedation 93). Midazolam, ketamine, and dexmedetomidine are widely used sedative agents in pediatric anaesthesia due to their established efficacy and safety profiles in this setting (4,5). Because of its quick onset, anxiolytic, and amnestic effects, the benzodiazepine midazolam is frequently used as a premedicant in children undergoing radiological procedures (6). Research has repeatedly demonstrated that both intravenous and intranasal methods offer sufficient sedation with few adverse effects, making it simpler to separate from parents and promoting compliance during imaging (7,8). Another substance that has been thoroughly researched in paediatric procedural sedation is ketamine, an N-methyl-D-aspartate (NMDA) receptor antagonist. It offers deep sedation, analgesia, and airway reflex preservation, all of which are beneficial for non-invasive, painless procedures like imaging. It is a good choice for kids because of its dependability for quick induction times and quick recovery, as well as its good safety profile (9,5). Dexmedetomidine, a selective α2-adrenergic agonist, has gained popularity as a sedative for pediatric imaging due to its minimal respiratory depression, analgesic effects, and ability to produce a state resembling natural sleep. Due to its non-invasiveness, ability to produce stable haemodynamics, low incidence of side effects, and effective sedation, intranasal administration is especially recommended. Systematic reviews and comparative studies demonstrate how well dexmedetomidine works to facilitate procedures while maintaining a safety profile that is on par with or better thanthat of conventional agents (10,11).

Surprisingly few studies directly compare midazolam, ketamine, and dexmedetomidine in the context of paediatric radiological imaging, especially among children under the age of ten, despite the large variety of sedatives that are currently available. To guide best practices and improve patient care, a thorough, head-to-head comparison of these premedication agents is required.

Aim:

To evaluate the clinical results, safety, and effectiveness of midazolam, ketamine, and dexmedetomidine as premedications for radiological imaging in this susceptible group.

Objective:

To Compare the effects of ketamine, dexmedetomidine, midazolam on the duration of sedation and analgesia, hemodynamic and respiratory parameters, recovery time.

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Methodology:

This randomized controlled trial was conducted over six months (February to July 2025) in the Department of Paediatrics at Chettinad Hospital and Research Institute, Chennai, and was registered with the Clinical Trials Registry - India (CTRI No: CTRI/2025/07/090838). A sample size of 81 participants was determined using G*Power software (version 3.1) for an ANOVA test with an effect size of 0.4, an alpha error of 0.05, and 95% power, accounting for a 10% attrition rate. Following ethical approval and obtaining written informed consent from parents/guardians alongside child assent, participants were allocated into three groups (Midazolam, Ketamine, Dexmedetomidine) via computer- generated simple random sampling. Pre-medications were administered 30 minutes before imaging, with continuous monitoring of vital signs (heart rate, blood pressure, oxygen saturation).

Inclusion Criteria

• Children aged between 6 and 10 years.

• Patients requiring sedative agents for diagnostic procedures.

Exclusion criteria:

• Patients requiring mechanical ventilation, intravenous inotropic support, cyanotic congenital heart disease (CHD), second- or third-degree heart block, muscular

dystrophies, multiple congenital anomalies, hepatic/renal dysfunction.

• Patients with drug allergies.

• Patients withnASA Grade III or higher, or airway anomalies

Data collection & Statistical analysis:

Data collection included recording the onset and duration of sedation, PAED (Post- Anesthetic Emergence Delirium) scores, and adverse events, using a structured proforma to capture demographic and baseline clinical information. The collected data are entered in MS Excel and analysed using SPSS version 21. The continuous variables are expressed in mean & SD, qualitative variables are expressed in frequency. With 95% Confidence interval ANOVA test is used as a statistical test to compare three groups. Patients were observed post- procedure until they returned to baseline consciousness and met discharge criteria, ensuring a standardized evaluation of sedation efficacy and safety.

Results:

Table 1: Demographic Characteristics of Patients

Variables No of patients

(n = 81) (%)

Age (years) 7.71 ± 2.68

Gender Male 43 (53)

Female 38 (47)

BMI Underweight 24 (30)Normal 31 (38)

Overweight 26 (22)

The mean & SD of age among our study participants are 7.71 ± 2.68 years. The majority of our study participants were male and the most of the study participants were in normal BMI. The distribution of diagnosis among our study participants included head trauma (9%), seizure disorder (11%), GDD (Global Developmental Delay) (13%), acute CNS infection (15%), vascular insult (25%), and others (27%) (Figure .1).

Table 2: Comparison of Sedation Characteristics: Ketamine vs. Dexmedetomidine vs.

Midazolam in Pediatric Patients

Variables Ketamine

Dexmedetomidine

Midazolam

p-value

(n =27)

(n =27)

(n =27)

Onset of action (min) 16.9 ± 13.6 29.9 ± 17.8 27 ± 20.4 0.0001

No of doses 1.1 ± 0.32 2.6 ± 0.88 2 ± 0.72 0.0001

Duration Between

Administration Initiation of

5.1± 0.9 12.7± 4.2 8.7± 2.23 0.0001

Sedation

Duration of Action (min) 90.9 ± 24.5 121.4 ±19.55 114.4 ± 28.8 0.0001

PAED Score 41.52 ± 1024 41.69 ± 11.57 39.8 ± 9.45 0.0721

Our study analysis revealed statistically significant differences ($p<0.05$) for most parameters. Ketamine demonstrated a significantly faster onset of action (16.9

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min) compared to both Dexmedetomidine (29.9 min) and Midazolam (27 min). Consequently, the duration between administration and the initiation of sedation was also shortest for Ketamine (5.1 min). Furthermore, the Ketamine group required significantly fewer doses (1.1) to achieve adequate sedation than the other two groups. Regarding duration, Dexmedetomidine provided the longest action (121.4 min), followed by Midazolam (114.4 min) and then Ketamine (90.9 min). In contrast, no statistically significant difference was found in PAED scores between the three groups (p=0.0721), indicating a comparable incidence of emergence delirium.

Table 3: Complications

Variables

Ketamine

(n =27) (%)

Dexmedetomidine

(n =27) (%)

Midazolam

(n =27) (%)

None 26 (96.3) 6 (22.2) 7 (25.9)

Bradycardia 0 21 (77.8) 0

Agitation 1 (3.7) 0 20 (74.1)

Among the three agents, Ketamine demonstrated the most favourable safety profile, with 96.3% of patients experiencing no adverse effects, and only 3.7% reporting agitation. In contrast, dexmedetomidine was associated with a high rate of bradycardia (77.8%) but no cases of agitation, while midazolam showed the opposite pattern, with 74.1% of patients experiencing agitation but no instances of bradycardia.

Discussion:

Our study's goal was to assess the safety and effectiveness of dexmedetomidine, ketamine, and midazolam as premedication agents for radiological imaging in children younger than ten. Our research shows notable variations between the three agents, especially with regard to their duration, onset of action, and adverse effect profiles.In our study in comparison to both Dexmedetomidine (29.9 min) and Midazolam (27 min), ketamine showed a noticeably quicker onset of action (16.9 min). A similar study by Ibrahim M et al which compared intranasal dexmedetomodine vs intranasal ketamine among school-aged children, showed the onset of sedation among the patients with ketamine and dexmedetomodine are 14.65 minutes and 22.4 minutes, respectively, which is close to our study results (11). Another study by Surendar MN et al reported that the onset of sedation was significantly rapid with Midazolam and Ketamine as compared to dexmedetomodine which is in line with our study results (12). In our study dexmedetomidine provides the longest duration of sedation (121.4 min), followed by midazolam (114.4 min) and ketamine (90.9 min) is also corroborated with the study by Mostafa MG et al which indicated that dexmedetomidine is known for its prolonged effect due to its α2-adrenergic agonist properties (13). Ketamine required significantly fewer doses (1.1) for adequate sedation. Previous research by Joshi SA et al indicates that ketamine achieves effective sedation rapidly and with lower dosage due to its dissociative properties and rapid mucosal absorption, supporting our results (14). The incidence of emergence delirium, as determined by the PAED score, did not differ statistically significantly between the three groups in our study. This finding runs counter to the study by Lee SJ et al that claims ketamine causes a higher rate of delirium (15), but it is corroborated by other study that indicates the risk of emergence delirium is not substantially different for different sedatives when taken at the right dosages (16).

The low dosages, the clinical context of radiological imaging, or the particular patient population may be to blame for the lack of a difference in delirium. In our study, ketamine proved to be the safest agent, exhibiting minimal agitation and no bradycardia. In contrast, dexmedetomidine was associated with a high rate of bradycardia (77.8%) and midazolam with a high incidence of agitation (74.1%). Our finding on dexmedetomidine-induced bradycardia is supported by Menshawi et al., who reported it in 12% of patients. However, our agitation data for midazolam differs from Azemati et al., who found no significant difference (17,18). Overall, this study supports ketamine as the agent of choice for rapid, safe sedation with minimal agitation, especially where quick onset and low cardiovascular risk are desired.

Dexmedetomidine remains preferred for longer procedures but requires close monitoring for bradycardia. Midazolam may be less desirable due to a higher incidence of agitation. This study is limited by its small sample size, single-center design, and lack of long-term follow- up, which may affect the generalizability of the results. Potential confounders like patient anxiety and individual differences were not fully controlled, and adverse events may have been underreported due to reliance on clinical observation.

Conclusion:

The best sedative premedication for paediatric radiological imaging depends on the particular clinical priority, according to the study's findings. Although it

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has the shortest duration of action, ketamine is better for quick procedural readiness because of its much faster onset and highest single-dose efficacy. On the other hand, dexmedetomidine is the preferred medication for longer procedures because it offers the most stable and long-lasting sedation, despite having the slowest onset. Midazolam offers a compromise. Crucially, all three medications showed a similar and acceptable safety profile with regard to emergence delirium, meaning that the selection can be made based on the procedure's expected duration and necessary speed without a discernible difference in the quality of recovery.

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Conflict of interest: Nil

What this Study Adds –

• This study provides a direct, head-to-head comparison of three of the most common sedative agents used in pediatric radiology, moving beyond single-drug studies to offer clinicians practical evidence for choosing between midazolam, ketamine, and dexmedetomidine in a real-world setting.

• • • • It delivers targeted data on the efficacy and safety profile of these premedications specifically in children under 10 years of age.

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