BIOMEDICINE AND CHEMICAL SCIENCES
AN INTERNATIONAL PEER-REVIEWED JOURNAL

BIOMEDICINE AND CHEMICAL SCIENCES

Website: https://journals.irapa.org/index.php/BCS
e-ISSN: 2790-296X | p-ISSN:2957-5826

Original Article

Ketamine Versus Midazolam as Premedication in Paediatric Surgery

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Article History:
Received on: May 12, 2026
Revised on: May 20, 2026
Accepted on: June 19, 2026
Published on: Aug 01, 2026

Citation: Dr Shazia Banoo *et al.* Ketamine Versus Midazolam as Premedication in Paediatric Surgery. *Biomedicine and Chemical Sciences, 5 (3): 8-15, 2026*

ABSTRACT

Background: Preoperative anxiety is a common problem in pediatric patients undergoing surgery and anesthesia. Anxiety can result in difficult parental separation, poor cooperation during induction, increased perioperative stress response, emergence delirium, and adverse postoperative behavioral changes. Premedication is therefore an essential component of pediatricanesthesia. **Aim**: To compare the efficacy and safety of ketamine and midazolam as premedication agents in pediatric patients undergoing elective surgery under general anesthesia. **Methods**: This prospective randomized comparative study was conducted in the Department of Anesthesiology, Government Medical College, Doda, over a period of six months. Sixty pediatric patients aged 2–10 years, belonging to ASA physical status I and II and scheduled for elective surgical procedures under general anesthesia, were randomly allocated into two equal groups. Group K received intravenous ketamine (1 mg/kg), while Group M received intravenous midazolam (0.05 mg/kg) as premedication. Sedation scores, parental separation scores, mask acceptance scores, hemodynamic parameters, recovery profiles, and adverse events were recorded and statistically analyzed. **Results**: Adequate sedation was achieved in 26 patients (86.7%) in Group K compared with 20 patients (66.7%) in Group M (p=0.041). Satisfactory parental separation was observed in 27 children (90.0%) in the ketamine group versus 21 children (70.0%) in the midazolam group (p=0.048). Good mask acceptance was noted in 25 patients (83.3%) receiving ketamine and 18 patients (60.0%) receiving midazolam (p=0.036). Mean recovery time was significantly longer in Group K (42.5 ± 8.3 minutes) compared with Group M (35.1 ± 6.7 minutes) (p=0.002). Postoperative nausea and vomiting occurred in 4 patients (13.3%) in Group K and 2 patients (6.7%) in Group M. Excessive salivation was observed in 5 patients (16.7%) receiving ketamine compared with 1 patient (3.3%) receiving midazolam. **Conclusion**: Ketamine provided superior sedation, smoother parental separation, and better acceptance of anesthesia induction compared with midazolam. Although recovery was slightly prolonged and minor adverse effects were more frequent with ketamine, its overall efficacy as a premedication agent was superior. Ketamine can therefore be considered a valuable alternative to midazolam for pediatric surgical patients requiring effective preoperative sedation.

Keywords: Ketamine; Midazolam; Pediatric Surgery; Premedication; Sedation; General Anesthesia.

INTRODUCTION

Pediatric patients frequently experience significant anxiety before surgical procedures and anesthesia. Preoperative anxiety has been reported in up to 60–80% of children undergoing elective surgery and is associated with difficult parental separation, resistance during induction of anesthesia, increased postoperative pain, emergence delirium, sleep disturbances, and maladaptive behavioral changes that may persist for several weeks after surgery [1]. The perioperative period is particularly stressful for young children because of separation from parents, unfamiliar surroundings, fear of pain, and apprehension regarding surgical procedures. Consequently, effective premedication forms an essential component of modern pediatricanesthetic practice.

The ideal premedicant should provide anxiolysis, sedation, amnesia, ease of parental separation, and smooth induction of anesthesia without causing significant cardiorespiratory depression or delaying postoperative recovery. Numerous pharmacological agents have been investigated for this purpose, including benzodiazepines, ketamine, dexmedetomidine, clonidine, and opioid medications. Among these agents, midazolam remains one of the most commonly used premedicants worldwide because of its rapid onset of action, short duration, anxiolytic properties, and favorable safety profile [2].

Midazolam is a short-acting benzodiazepine that acts by enhancing gamma-aminobutyric acid (GABA)-mediated inhibitory neurotransmission within the central nervous system. It produces anxiolysis, sedation, muscle relaxation, and anterograde amnesia while generally preserving cardiovascular stability. Intravenous midazolam has a rapid onset of action and is widely used in pediatricanesthesia because of its predictable clinical effect and ease of administration in children who already have intravenous access. Nevertheless, paradoxical reactions, inadequate sedation in highly anxious children, and occasional behavioral disturbances during recovery have been reported following intravenous administration [2,3].

Ketamine, a phencyclidine derivative, is another widely used sedative and analgesic agent in pediatricanesthesia. Unlike benzodiazepines, ketamine primarily acts through antagonism of N-methyl-D-aspartate (NMDA) receptors within the central nervous system. It produces a unique dissociative state characterized by profound analgesia, sedation, amnesia, and preservation of spontaneous respiration and airway reflexes [4]. Because of these properties, ketamine has attracted considerable attention as a potential alternative premedicant in pediatric patients, particularly in situations where deeper sedation and improved cooperation are desirable.

Several investigators have demonstrated that intravenous ketamine provides effective preoperative sedation, facilitates easier parental separation, and improves cooperation during induction of anesthesia. These effects are attributed to its rapid onset, dissociative sedation, and preservation of spontaneous respiration and airway reflexes, making it a valuable premedicant in pediatricanesthesia [5–7].The preservation of protective airway reflexes and maintenance of cardiovascular stability make ketamine particularly useful in pediatric populations. Furthermore, its intrinsic analgesic properties may contribute to reduced perioperative discomfort and improved postoperative outcomes. Nevertheless, ketamine is associated with certain adverse effects, including excessive salivation, postoperative nausea and vomiting, prolonged recovery, and emergence phenomena such as vivid dreams or hallucinations [4].

The relative advantages and disadvantages of intravenous ketamine and intravenous midazolam have been evaluated in several clinical studies. Ketamine generally provides deeper sedation and improved perioperative cooperation, whereas midazolam is associated with a faster recovery profile and fewer psychomimetic adverse effects. Variations in drug dosage, patient characteristics, timing of administration, and outcome assessment have contributed to differences in published results. Therefore, further comparative studies are required to identify the most appropriate intravenous premedication strategy for pediatric surgical patients.Differences in study design, route of administration, dosage schedules, patient populations, and outcome measures have contributed to variability in reported findings. Consequently, there remains no universal consensus regarding the optimal premedicant for pediatric surgical patients.

Recent systematic reviews and meta-analyses have highlighted the continuing importance of optimizing premedication strategies in pediatricanesthesia. Evidence suggests that effective anxiolysis and sedation before surgery significantly improve perioperative experiences for both children and their caregivers while facilitating smoother anesthetic management [8]. Given the widespread use of both ketamine and midazolam in clinical practice, direct comparisons between these agents remain highly relevant.

In resource-constrained settings and tertiary-care hospitals serving large pediatric populations, identifying the most effective and safe premedicant has important clinical implications. Improved sedation and cooperation may reduce induction-related stress, enhance operating room efficiency, and improve patient and parent satisfaction. Therefore, the present study was undertaken at Government Medical College, Doda, to compare ketamine and midazolam as premedication agents in pediatric patients undergoing elective surgery under general anesthesia.

MATERIALS AND METHODS

Study Design

This study was designed as a prospective, randomized, comparative study.

Study Setting
The study was conducted in the Department of Anesthesiology, Government Medical College, Doda, in collaboration with the Department of General Surgery.
Study Duration
The study was conducted over a period of six months.
Study Population
The study population consisted of pediatric patients scheduled for elective surgical procedures under general anesthesia.
Sample Size
A total of 60 pediatric patients were enrolled in the study. The patients were randomly allocated into two groups of 30 patients each.

Group K (Ketamine Group): 30 patients received ketamine as premedication.
Group M (Midazolam Group): 30 patients received midazolam as premedication.

Inclusion Criteria
1. Children aged between 2 and 10 years.
2. Patients belonging to American Society of Anesthesiologists (ASA) physical status I and II.
3. Patients scheduled for elective surgical procedures under general anesthesia.
4. Patients whose parents or legal guardians provided written informed consent.

Exclusion Criteria
1. Children with known hypersensitivity or allergy to ketamine or midazolam.
2. Patients with significant cardiovascular disease.
3. Patients with severe respiratory disorders.
4. Patients with neurological or psychiatric disorders.
5. Patients with developmental delay or cognitive impairment affecting assessment of sedation.
6. Patients receiving sedative or psychoactive medications before surgery.
7. Patients requiring emergency surgical procedures.
8. Patients with upper respiratory tract infection at the time of surgery.

Randomization
Patients fulfilling the inclusion criteria were randomly allocated into two groups using a computer-generated randomization sequence. Allocation concealment was maintained using sealed opaque envelopes opened immediately before administration of the study drug.

Preoperative Assessment
All children underwent detailed pre-anesthetic evaluation one day before surgery. Demographic data including age, sex, weight, ASA physical status, and type of surgical procedure were recorded.

A thorough history was obtained and physical examination was performed. Relevant laboratory investigations were reviewed. Parents were informed regarding the study protocol and written informed consent was obtained.

Study Drug Administration
An intravenous cannula was secured in all patients in the preoperative holding area before administration of the study drug.
Children in Group K received intravenous ketamine 1 mg/kg, administered slowly over approximately 60 seconds.
Children in Group M received intravenous midazolam 0.05 mg/kg, administered slowly over approximately 60 seconds.
Following drug administration, all patients were continuously monitored for heart rate, blood pressure, respiratory rate, and oxygen saturation. Patients were transferred to the operating room after achieving adequate sedation, approximately 5–10 minutes after intravenous premedication.

Observation Parameters
Sedation Score
Sedation was assessed 5 minutes after intravenous administration of the study drug using a four-point sedation scale. This interval was selected because both intravenous ketamine and intravenous midazolam have a rapid onset of action and achieve effective sedation within a few minutes of administration.

Parental Separation Score
The quality of parental separation was assessed approximately 10 minutes after intravenous premedication, immediately before transfer to the operating room, using the following four-point scale.
Score 1 – Excellent (easy separation without crying)
Score 2 – Good (minor apprehension but cooperative)

Score 3 – Fair (crying but can be reassured)
Score 4 – Poor (crying and resisting separation)

Mask Acceptance Score
Acceptance of the anesthesia face mask was assessed during induction of general anesthesia using the following four-point grading system.
Score 1 – Excellent acceptance
Score 2 – Good acceptance with minimal resistance
Score 3 – Moderate resistance
Score 4 – Poor acceptance requiring restraint

Hemodynamic Monitoring

The following parameters were recorded:
1. Heart rate
2. Systolic blood pressure
3. Diastolic blood pressure
4. Oxygen saturation

Hemodynamic parameters were recorded at baseline (before administration of the study drug), 5 minutes after intravenous premedication, at induction of anesthesia, and immediately after induction to evaluate the cardiovascular effects of both study drugs.

Anesthetic Technique
All patients were kept fasting according to standard fasting guidelines.
After intravenous premedication and adequate sedation, patients were shifted to the operating room.
Standard monitoring including electrocardiography, non-invasive blood pressure, pulse oximetry, and capnography was instituted.

General anesthesia was induced using a standardized anesthetic protocol with inhalational sevoflurane in oxygen. Intravenous access, already secured in the preoperative area, was utilized for administration of anesthetic drugs. Appropriate muscle relaxants and analgesics were administered according to institutional protocol.
Anesthesia was maintained using oxygen, nitrous oxide, sevoflurane, and additional muscle relaxants as required.

Recovery Assessment
Recovery characteristics were assessed in the post-anesthesia care unit.

The following parameters were evaluated:
1. Time to spontaneous eye opening.
2. Time to response to verbal commands.
3. Time to achieve recovery room discharge criteria.
4. Presence of emergence agitation or delirium.

Assessment of Adverse Effects
Patients were monitored for adverse effects including:
1. Nausea and vomiting.
2. Excessive salivation.
3. Respiratory depression.
4. Oxygen desaturation.
5. Hallucinations or emergence reactions.
6. Excessive sedation.
7. Hemodynamic instability.

Data Collection
All observations were recorded in a predesigned data collection proforma by the investigator. The collected data were entered into a master chart and analyzed systematically.
Statistical Analysis
The collected data were compiled and analyzed using appropriate statistical software.
Continuous variables were expressed as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages.
Student's t-test was used for comparison of quantitative variables between groups. Chi-square test or Fisher's exact test was used for comparison of qualitative variables.A p-value less than 0.05 was considered statistically significant.

RESULTS

Both groups were comparable with respect to demographic characteristics and baseline clinical variables. Table 1 presents the demographic profile of the study population. No statistically significant differences were observed between the two groups regarding age, gender distribution, weight, ASA physical status, or duration of surgery, indicating adequate comparability between the study groups.

Table 1: Demographic Characteristics of Study Population

Variable	Group K (n=30)	Group M (n=30)	p-value
Age (years)	5.9 ± 2.1	6.1 ± 2.3	0.724
Weight (kg)	18.6 ± 4.7	19.1 ± 5.2	0.689
Male	18 (60%)	17 (56.7%)	0.793
Female	12 (40%)	13 (43.3%)	0.793
ASA I	24 (80%)	23 (76.7%)	0.754
ASA II	6 (20%)	7 (23.3%)	0.754
Duration of Surgery (minutes)	54.8 ± 15.2	56.3 ± 14.7	0.698

Table 2 shows the distribution of sedation scores in both groups. Adequate sedation (Score 3 or 4) was achieved in 86.7% of patients in the ketamine group compared with 66.7% in the midazolam group. This difference was statistically significant. P = 0.041

Table 2: Comparison of Sedation Scores

Sedation Score	Group K (n=30)	Group M (n=30)
Score 1 (Alert and active)	1 (3.3%)	4 (13.3%)
Score 2 (Calm and awake)	3 (10.0%)	6 (20.0%)
Score 3 (Drowsy but responsive)	18 (60.0%)	15 (50.0%)
Score 4 (Asleep but arousable)	8 (26.7%)	5 (16.7%)
Adequate Sedation (Score 3 & 4)	26 (86.7%)	20 (66.7%)

Table 3 demonstrates parental separation scores in both groups. Excellent or good parental separation was achieved in 90% of children receiving ketamine compared to 70% receiving midazolam. P = 0.048

Table 3: Comparison of Parental Separation Scores

Separation Score	Group K (n=30)	Group M (n=30)
Excellent	18 (60.0%)	11 (36.7%)
Good	9 (30.0%)	10 (33.3%)
Fair	2 (6.7%)	6 (20.0%)
Poor	1 (3.3%)	3 (10.0%)
Excellent + Good	27 (90.0%)	21 (70.0%)

Table 4 illustrates mask acceptance scores. Children premedicated with ketamine showed significantly better mask acceptance than those receiving midazolam (P = 0.036).

Table 4: Comparison of Mask Acceptance Scores

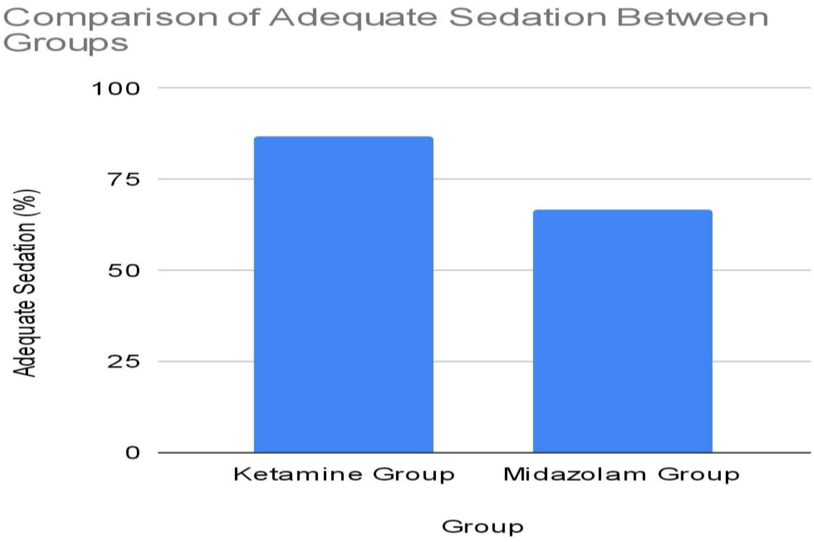
Mask Acceptance Score	Group K (n=30)	Group M (n=30)
Excellent	16 (53.3%)	9 (30.0%)
Good	9 (30.0%)	9 (30.0%)
Moderate Resistance	4 (13.3%)	8 (26.7%)
Poor Acceptance	1 (3.3%)	4 (13.3%)
Excellent + Good	25 (83.3%)	18 (60.0%)

Although intravenous ketamine produced superior sedation and perioperative cooperation, it was associated with a slightly prolonged recovery period and a somewhat higher incidence of minor adverse effects compared with intravenous midazolam. No episodes of respiratory depression or oxygen desaturation were observed in either group, confirming the safety of both intravenous premedication regimens.
Table 5 summarizes recovery characteristics and adverse events observed in both groups.

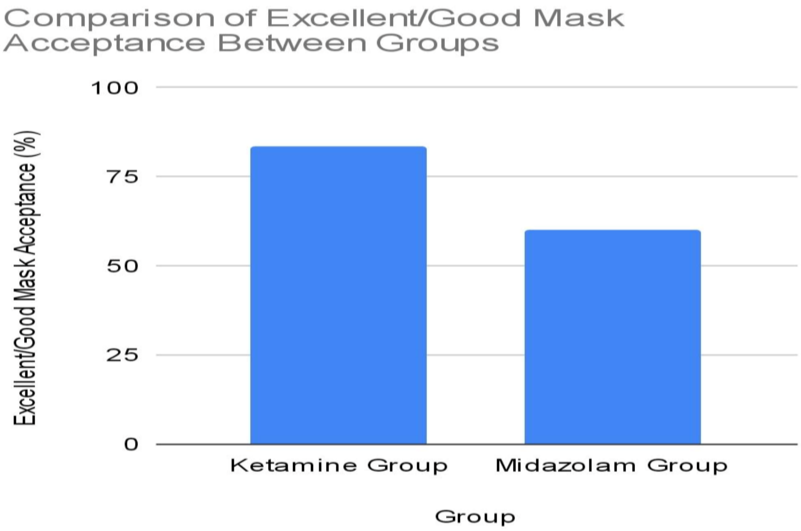
Table 5: Recovery Characteristics and Adverse Effects

Variable	Group K (n=30)	Group M (n=30)	p-value
Recovery Time (minutes)	42.5 ± 8.3	35.1 ± 6.7	0.002
Nausea and Vomiting	4 (13.3%)	2 (6.7%)	0.389
Excessive Salivation	5 (16.7%)	1 (3.3%)	0.085

Emergence Reaction	2 (6.7%)	0 (0%)	0.150
Oxygen Desaturation	0 (0%)	0 (0%)	--
Respiratory Depression	0 (0%)	0 (0%)	--



Bar graph: Comparison of Adequate Sedation Between Groups .



Bar graph: Comparison of Excellence/ Good Mask Acceptance Between Groups.

DISCUSSION

Preoperative anxiety remains a major concern in pediatricanesthesia because it may adversely affect induction of anesthesia, perioperative hemodynamic stability, postoperative recovery, and behavioral outcomes. Appropriate premedication facilitates smooth parental separation, improves cooperation during induction, and reduces perioperative psychological stress. In the present prospective randomized comparative study, intravenous ketamine was compared with intravenous midazolam as premedication in pediatric patients undergoing elective surgery under general anesthesia.

The demographic characteristics of both study groups were comparable with respect to age, gender distribution, body weight, ASA physical status, and duration of surgery. The absence of statistically significant differences between the groups ensured baseline homogeneity and minimized the influence of confounding variables on the study outcomes.

The primary outcome of the present study was the assessment of preoperative sedation. Adequate sedation (sedation score 3 or 4) was achieved in 86.7% of patients receiving intravenous ketamine compared with 66.7% receiving intravenous midazolam ($p = 0.041$). These findings indicate that intravenous ketamine provided significantly deeper sedation than intravenous midazolam. Ketamine produces a dissociative state through antagonism of N-methyl-D-aspartate (NMDA) receptors while preserving spontaneous respiration and airway reflexes, thereby making it an effective premedication agent in children. Similar observations were reported by Hosseini Jahromi et al. [9], who demonstrated that intravenous ketamine produced greater sedation than intravenous midazolam, although the combination of both drugs provided the highest sedation scores.

Successful parental separation is an important indicator of effective pediatric premedication. In the present study, satisfactory parental separation (excellent or good) was achieved in 90% of patients receiving intravenous ketamine compared with 70% of those receiving intravenous midazolam ($p = 0.048$). The superior parental separation observed with ketamine is most likely related to its deeper sedative and anxiolytic effects, which reduce fear and resistance during transfer to the operating room. These findings are comparable with those reported by Hosseini Jahromi et al. [9], who observed improved preoperative behavior and reduced anxiety following intravenous ketamine administration compared with intravenous midazolam.

Mask acceptance during induction is another clinically important parameter because poor cooperation may lead to difficult induction and increased perioperative stress. In the present study, excellent or good mask acceptance was observed in 83.3% of children in the ketamine group compared with 60.0% in the midazolam group ($p = 0.036$). Better mask acceptance reflects improved anxiolysis and patient cooperation before induction of anesthesia. Similar findings have been reported in previous pediatricanesthesia studies, where ketamine premedication resulted in smoother induction conditions and better patient cooperation than midazolam alone [9,10].

Recovery characteristics are equally important while selecting an ideal premedicant. In the present study, the mean recovery time was significantly longer in the ketamine group (42.5 ± 8.3 minutes) compared with the midazolam group (35.1 ± 6.7 minutes) ($p = 0.002$). Although recovery was prolonged with ketamine, the difference was clinically acceptable and did not delay discharge from the recovery room. Similar observations have been reported by Kim et al. [10], who demonstrated that ketamine may prolong early recovery because of its dissociative properties while simultaneously reducing emergence agitation during the immediate postoperative period.

Both drugs maintained satisfactory hemodynamic stability throughout the perioperative period. No episodes of respiratory depression, oxygen desaturation, or clinically significant cardiovascular instability were observed in either group. These findings confirm the favorable safety profile of both intravenous ketamine and intravenous midazolam when administered in recommended doses under appropriate monitoring. Similar safety outcomes have been reported in previous randomized clinical trials comparing these intravenous agents in pediatricanesthesia [9].

Minor adverse effects were more frequent in the ketamine group. Excessive salivation was observed in 16.7% of patients receiving ketamine compared with 3.3% receiving midazolam, while postoperative nausea and vomiting occurred in 13.3% and 6.7% of patients, respectively. Emergence reactions were noted in two children receiving ketamine but were mild, transient, and required no specific treatment. These adverse effects are well recognized with ketamine and are attributable to its pharmacological profile. Previous investigators have also reported increased salivation and occasional emergence reactions following intravenous ketamine, although these effects are generally self-limiting [10].

Overall, the findings of the present study demonstrate that intravenous ketamine provided superior preoperative sedation, easier parental separation, and better mask acceptance than intravenous midazolam. Although ketamine was associated with a modest increase in recovery time and a slightly higher incidence of minor adverse effects, no serious complications were encountered. Therefore, intravenous ketamine may be considered an effective and safe alternative to intravenous midazolam for pediatric premedication, particularly in children requiring deeper sedation and improved perioperative cooperation.

The present study has certain limitations. The sample size was relatively small, and the study was conducted at a single tertiary care center, which may limit the generalizability of the findings. Furthermore, long-term postoperative behavioral outcomes and parental satisfaction were not evaluated. Future multicenter studies with larger sample sizes are warranted to further establish the optimal intravenous premedication regimen for pediatric surgical patients.

CONCLUSION

The present prospective randomized comparative study evaluated the efficacy and safety of intravenous ketamine and intravenous midazolam as premedication agents in pediatric patients undergoing elective surgical procedures under general anesthesia. Both drugs were found to be effective and safe for preoperative sedation; however, intravenous ketamine demonstrated superior overall performance in several clinically important parameters.

Children receiving intravenous ketamine achieved significantly better sedation scores than those receiving intravenous midazolam. Intravenous ketamine also facilitated smoother parental separation and improved acceptance of the anesthesia face mask during induction, thereby providing better perioperative cooperation and a smoother induction of anesthesia. These findings are consistent with previous studies evaluating intravenous premedication in pediatric patients.

Intravenous midazolam also proved to be an effective premedication agent and offered the advantage of a comparatively faster recovery with fewer postoperative adverse effects. However, its sedative efficacy, parental separation scores, and mask acceptance rates were lower than those observed with intravenous ketamine.

Further multicenter randomized studies with larger sample sizes and longer follow-up are recommended to validate these findings and to assess long-term postoperative behavioral outcomes, patient and parent satisfaction, and the optimal dosing strategies for intravenous pediatric premedication.

In conclusion, intravenous ketamine (1 mg/kg) is a safe and effective alternative to intravenous midazolam (0.05 mg/kg) for premedication in pediatric patients undergoing elective surgery under general anesthesia. It provides superior preoperative sedation, facilitates easier parental separation, and improves mask acceptance while maintaining an acceptable safety profile, making it a valuable option for achieving optimal perioperative conditions in pediatric anesthesia.

Conflict of interest: Nil
Funding: Nil

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