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Original Research Article

ASSESSMENT OF NEBULIZED DEXMEDETOMIDINE VERSUS NEBULIZED KETAMINE FOR PREOPERATIVE PREMEDICATION IN CHILDREN UNDERGOING SURGERY

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ABSTRACT

Background: Preoperative anxiety in pediatric patients can lead to difficult parental separation, poor mask acceptance, and adverse perioperative outcomes. Nebulized dexmedetomidine and ketamine have emerged as effective non-invasive premedication options for children undergoing surgery. **Aim:** To compare the effectiveness of nebulized dexmedetomidine and nebulized ketamine as premedication before general anesthesia in pediatric surgical patients. **Materials and Methods:** This prospective randomized comparative study included 150 pediatric patients undergoing elective surgeries under general anesthesia. Patients were randomly allocated into three groups of 50 each: Group D received nebulized dexmedetomidine (2 µg/kg), Group K received nebulized ketamine (2 mg/kg), and Group C received normal saline nebulization. Sedation was assessed using the Ramsay Sedation Scale at 15 and 30 minutes. Parental separation, mask acceptance, recovery profile, discharge time, and perioperative complications were also evaluated. **Results:** Demographic characteristics were comparable among the three groups. At 15 minutes, Ramsay Sedation Score 2 was achieved in 62.0% of Group D, 48.0% of Group K, and 20.0% of Group C participants. At 30 minutes, Ramsay Sedation Score 3 was observed in 54.0%, 32.0%, and 6.0% of patients, respectively ($p<0.001$). Excellent parental separation and mask acceptance were achieved in 74.0% of Group D compared with 52.0% of Group K and 20.0% of Group C ($p<0.001$). Recovery and discharge times were comparable among groups. Excessive salivation occurred more frequently in the ketamine group (8.0%) than in the dexmedetomidine group (0.0%) ($p=0.038$). **Conclusion:** Nebulized dexmedetomidine provides superior sedation, improved parental separation, and better mask acceptance compared with nebulized ketamine and placebo while maintaining a favorable safety profile and comparable recovery characteristics. It represents an effective and well-tolerated non-invasive premedication strategy for pediatric surgical patients.

INTRODUCTION

Preoperative anxiety is a common phenomenon among pediatric patients undergoing surgical procedures and may adversely affect the perioperative experience. Anxiety before surgery can result in difficult parental separation, poor acceptance of anesthetic masks, increased anesthetic requirements, emergence delirium, postoperative pain, and negative behavioral changes. The prevalence of preoperative anxiety among children has been reported to range from 40% to 75%, making effective premedication an essential component of pediatric anesthesia practice.[1]

An ideal pediatric premedicant should provide adequate anxiolysis and sedation while preserving spontaneous ventilation and cardiovascular stability. It should be non-invasive, painless, acceptable to children, easy to administer, and associated with minimal adverse effects. Traditional premedication techniques such as oral or injectable agents often present challenges including delayed onset, variable absorption, unpleasant taste, needle-related anxiety, and reduced patient compliance.[2]

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Dexmedetomidine is a highly selective α2-adrenergic receptor agonist that produces sedation, anxiolysis, and analgesia without significant respiratory depression. Its unique sedative profile closely resembles natural sleep, allowing patients to remain easily arousable while maintaining protective airway reflexes. Recent studies have demonstrated the effectiveness of dexmedetomidine in reducing preoperative anxiety, improving parental separation, facilitating mask acceptance, and decreasing postoperative emergence agitation in pediatric patients.[3,4]

Ketamine is a dissociative anesthetic that acts primarily through antagonism of N-methyl-D-aspartate receptors. It possesses sedative, analgesic, and amnestic properties while maintaining cardiovascular stability and preserving spontaneous respiration. These characteristics have led to its widespread use in pediatric anesthesia. Nebulized ketamine has emerged as an attractive alternative route for pediatric premedication because it is painless, non-invasive, and well tolerated by children.[5]

Nebulization has gained considerable attention as a route for pediatric premedication because it avoids the discomfort associated with injections and circumvents the challenges related to oral administration. Drug absorption occurs through the highly vascular respiratory mucosa, resulting in rapid onset and satisfactory bioavailability. Furthermore, nebulized medications are generally well accepted by children, thereby improving compliance and reducing preoperative distress.[6]

Several clinical studies have investigated nebulized dexmedetomidine and nebulized ketamine as premedicants before surgery. Both agents have demonstrated effectiveness in improving sedation levels and reducing perioperative anxiety. However, variations in study design, drug dosages, patient populations, and outcome measures have resulted in inconsistent findings regarding their comparative efficacy.[7]

Assessment of sedation quality is an important aspect of pediatric premedication studies. The Ramsay Sedation Scale is a validated tool frequently used to evaluate the depth of sedation in pediatric and adult patients. Similarly, parental separation and mask acceptance scores provide clinically relevant measures of the effectiveness of premedication in facilitating smooth transfer to the operating room and induction of anesthesia.[8]

Postoperative recovery also plays a crucial role in determining the overall effectiveness of a premedication regimen. Recovery quality can be objectively assessed using the Modified Aldrete Score, which evaluates activity, respiration, circulation, consciousness, and oxygen saturation. A rapid return to baseline physiological status with minimal complications is desirable in pediatric surgical patients.[9]

Although both dexmedetomidine and ketamine have shown promising results when administered via nebulization, there remains limited evidence directly comparing these agents with a control group in pediatric surgical patients. Therefore, the present study was undertaken to evaluate and compare the effectiveness of nebulized dexmedetomidine and nebulized ketamine with a control group as premedication before general anesthesia in pediatric surgeries. The study aimed to assess sedation level, parental separation, mask acceptance, postoperative recovery, discharge profile, hemodynamic stability, and perioperative complications.[10]

MATERIALS AND METHODS

This prospective randomized controlled comparative study was conducted in the Department of Anesthesiology at a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from the parents or legal guardians of all participating children before enrollment in the study. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

A total of 150 pediatric patients scheduled for elective surgery under general anesthesia were included in the study. Children aged between 2 and 12 years belonging to American Society of Anesthesiologists (ASA) physical status I and II were eligible for participation. Patients with known hypersensitivity to dexmedetomidine or ketamine, significant cardiovascular disease, respiratory disease, neurological disorders, hepatic dysfunction, renal dysfunction, developmental delay, active upper respiratory tract infection, or current use of sedative medications were excluded from the study.

The enrolled patients were randomly allocated into three equal groups comprising 50 patients each using a computer-generated randomization sequence. Group D received nebulized dexmedetomidine at a dose of 2 μg/kg diluted with normal saline to a total volume of 4 mL. Group K received nebulized ketamine at a dose of 2 mg/kg diluted with normal saline to a total volume of 4 mL. Group C received 4 mL of normal saline nebulization and served as the control group. The study medication was administered through a standard jet nebulizer approximately 30 minutes before induction of anesthesia.

Demographic variables including age, sex, weight, ASA status, type of surgery, and duration of surgery were recorded. Baseline heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, respiratory rate, and oxygen saturation were documented before nebulization and monitored periodically throughout the perioperative period.

Sedation was assessed using the Ramsay Sedation Scale at 15 minutes and 30 minutes following nebulization. Parental separation and mask acceptance were evaluated immediately before transfer to the operating room and during induction of anesthesia. The quality of parental separation and

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mask acceptance was categorized as excellent, good, fair, or poor.

All patients underwent standardized general anesthesia according to institutional protocols. Following completion of surgery, patients were transferred to the post-anesthesia care unit. Recovery status was assessed using the Modified Aldrete Score, which evaluates activity, respiration, circulation, consciousness, and oxygen saturation. Recovery time and discharge time were recorded for all patients.

Patients were monitored for adverse events including nausea, vomiting, hypotension, hypertension, tachycardia, bradycardia, hypoxia, excessive salivation, laryngospasm, bronchospasm, and emergence agitation. All complications occurring during the perioperative and recovery periods were documented and analyzed.

Data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) version 26.0. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were expressed as frequency and percentage. One-way analysis of variance (ANOVA) was used for comparison of quantitative variables among the three groups. Post hoc pairwise comparisons were performed using Tukey's test where appropriate. The Chi-square test or Fisher's exact test was used for categorical variables. A p-value less than 0.05 was considered statistically significant.

RESULTS

Table 1 shows the demographic and baseline characteristics of the study population. A total of 150 pediatric patients were included and equally distributed among Group D (Nebulized Dexmedetomidine), Group K (Nebulized Ketamine), and Group C (Control), with 50 patients in each group. The mean age was 6.84±2.01 years in Group D, 6.67±2.18 years in Group K, and 6.51±2.07 years in Group C (p=0.762). Male children constituted 58.0%, 54.0%, and 56.0% of Groups D, K, and C, respectively (p=0.912). The mean body weight was comparable among the groups, being 21.62±5.14 kg in Group D, 20.98±5.46 kg in Group K, and 21.31±5.29 kg in Group C (p=0.845). Distribution according to ASA grade and type of surgery was also similar among groups, indicating successful randomization. The mean duration of surgery ranged from 61.38±11.84 to 63.42±12.65 minutes without significant difference (p=0.658).

Table 2 demonstrates the comparison of Ramsay sedation scores at 15 and 30 minutes after nebulization. At 15 minutes, Ramsay score 2 was observed in 62.0% of Group D, 48.0% of Group K, and 20.0% of Group C participants, while Ramsay score 1 was highest in the control group (80.0%). The difference was statistically significant (p<0.001). At 30 minutes, deeper sedation was observed in Group D, where 54.0% achieved Ramsay score 3 compared to 32.0% in Group K and only 6.0% in Group C. Excellent parental separation and mask acceptance were recorded in 74.0% of Group D patients, compared with 52.0% in Group K and 20.0% in Group C (p<0.001), demonstrating superior premedication efficacy with nebulized dexmedetomidine.

Table 3 compares postoperative recovery characteristics and complications among the study groups. The mean recovery time was 8.16±2.54 minutes in Group D, 8.42±2.68 minutes in Group K, and 8.58±2.72 minutes in Group C, showing no significant difference (p=0.691). Similarly, mean discharge time was 31.82±7.45, 32.34±7.96, and 32.88±8.12 minutes, respectively (p=0.804). No patient developed nausea, vomiting, bradycardia, hypotension, hypertension, or hypoxia. Excessive salivation was observed in 4 patients (8.0%) in Group K and 1 patient (2.0%) in Group C, whereas no case was observed in Group D. This difference reached statistical significance (p=0.038).

Table 1: Comparison between the studied groups according to demographic data (n = 150)

Demographic Data	Group D (n=50)	Group K (n=50)	Group C (n=50)	P value
Age (years)	6.84 ± 2.01	6.67 ± 2.18	6.51 ± 2.07	0.762
Male	29 (58.0%)	27 (54.0%)	28 (56.0%)	0.912
Female	21 (42.0%)	23 (46.0%)	22 (44.0%)	
Weight (kg)	21.62 ± 5.14	20.98 ± 5.46	21.31 ± 5.29	0.845
ASA I	41 (82.0%)	40 (80.0%)	39 (78.0%)	0.887
ASA II	9 (18.0%)	10 (20.0%)	11 (22.0%)	
Cochlear Implant	11 (22.0%)	10 (20.0%)	12 (24.0%)	0.963
Laparoscopic Hernia Repair	15 (30.0%)	17 (34.0%)	16 (32.0%)	
Tonsillectomy	24 (48.0%)	23 (46.0%)	22 (44.0%)	
Duration of Surgery (min)	62.74 ± 12.11	63.42 ± 12.65	61.38 ± 11.84	0.658

Table 2: Comparison between the studied groups according to Ramsay sedation scale and parental separation with mask acceptance

Variable	Group D (n=50)	Group K (n=50)	Group C (n=50)	P value
Ramsay Sedation Score after 15 min				<0.001*
Score 1	11 (22.0%)	18 (36.0%)	40 (80.0%)	
Score 2	31 (62.0%)	24 (48.0%)	10 (20.0%)	
Score 3	8 (16.0%)	8 (16.0%)	0 (0.0%)	
Ramsay Sedation Score after 30 min				<0.001*

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Score 1	2 (4.0%)	8 (16.0%)	26 (52.0%)	
Score 2	21 (42.0%)	26 (52.0%)	21 (42.0%)	
Score 3	27 (54.0%)	16 (32.0%)	3 (6.0%)	
Parental Separation and Mask Acceptance				<0.001*
Excellent	37 (74.0%)	26 (52.0%)	10 (20.0%)	
Good	10 (20.0%)	16 (32.0%)	15 (30.0%)	
Fair	3 (6.0%)	7 (14.0%)	17 (34.0%)	
Poor	0 (0.0%)	1 (2.0%)	8 (16.0%)	

Table 3: Comparison between the studied groups according to recovery profile and complications

Variable	Group D (n=50)	Group K (n=50)	Group C (n=50)	P value
Recovery Time (min)	8.16 ± 2.54	8.42 ± 2.68	8.58 ± 2.72	0.691
Discharge Time (min)	31.82 ± 7.45	32.34 ± 7.96	32.88 ± 8.12	0.804
Nausea	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Vomiting	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Hypotension	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Bradycardia	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Tachycardia	0 (0.0%)	0 (0.0%)	1 (2.0%)	0.364
Hypoxia	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Salivation	0 (0.0%)	4 (8.0%)	1 (2.0%)	0.038*

DISCUSSION

The present study compared the efficacy of nebulized dexmedetomidine, nebulized ketamine, and normal saline as premedication in pediatric patients undergoing elective surgeries under general anesthesia. The demographic variables including age, gender distribution, body weight, ASA physical status, type of surgery, and duration of surgery were statistically comparable among the three groups, confirming the homogeneity of the study population and minimizing the influence of confounding factors on study outcomes.

One of the most important findings of the present study was the significantly superior sedation achieved with nebulized dexmedetomidine. At 15 minutes following nebulization, 62.0% of children in Group D achieved Ramsay Sedation Score 2 compared with 48.0% in Group K and only 20.0% in the control group. Furthermore, at 30 minutes, deeper sedation reflected by Ramsay Sedation Score 3 was observed in 54.0% of children receiving dexmedetomidine compared with 32.0% receiving ketamine and 6.0% in the control group. The difference was highly significant ($p<0.001$). These findings indicate that nebulized dexmedetomidine produces more satisfactory and predictable preoperative sedation than nebulized ketamine. Similar observations were reported by Abdel-Ghaffar et al,[11] who compared nebulized dexmedetomidine, ketamine, and midazolam in preschool children and found that dexmedetomidine produced significantly better sedation scores with improved perioperative cooperation and reduced anxiety.

Parental separation and mask acceptance represent clinically important indicators of successful pediatric premedication. In the present study, excellent parental separation and mask acceptance were achieved in 74.0% of patients receiving dexmedetomidine compared with 52.0% receiving ketamine and only 20.0% in the control group. Poor acceptance was absent in Group D and was observed in only 2.0% of Group K patients, whereas 16.0% of control patients exhibited poor acceptance. These findings emphasize the effectiveness of nebulized dexmedetomidine in facilitating smoother induction of anesthesia. Shereef et al,[12] similarly reported that nebulized dexmedetomidine provided superior parental separation and mask acceptance compared with nebulized ketamine and midazolam. The authors attributed this advantage to the anxiolytic and sedative properties of dexmedetomidine, which promote a calm and cooperative state in pediatric patients.

The superiority of dexmedetomidine over ketamine observed in the present study is also supported by Geetha et al,[13] who compared nebulized dexmedetomidine and ketamine in children undergoing magnetic resonance imaging. They demonstrated that dexmedetomidine produced a higher rate of satisfactory sedation and procedural success while maintaining hemodynamic stability. Although their study involved imaging procedures rather than surgery, the findings support the notion that nebulized dexmedetomidine provides more effective sedation than nebulized ketamine in pediatric settings.

The current study also demonstrated that recovery time and discharge time were comparable among all groups. The mean recovery times were 8.16±2.54 minutes, 8.42±2.68 minutes, and 8.58±2.72 minutes in Groups D, K, and C, respectively, whereas discharge times were 31.82±7.45 minutes, 32.34±7.96 minutes, and 32.88±8.12 minutes. No statistically significant differences were observed. These findings suggest that despite producing superior sedation, dexmedetomidine did not prolong postoperative recovery. Similar conclusions were reported by Elshafeey et al,[14] who observed that nebulized dexmedetomidine provided effective preoperative sedation without adversely affecting recovery characteristics or delaying discharge readiness in pediatric surgical patients.

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Assessment of perioperative safety revealed excellent tolerability of both study medications. No cases of nausea, vomiting, hypotension, hypertension, bradycardia, or hypoxia were observed in either intervention group. Excessive salivation occurred in 8.0% of children receiving ketamine and 2.0% in the control group, while no child in the dexmedetomidine group developed this complication. The difference was statistically significant (p=0.038). Increased salivary secretion is a known adverse effect of ketamine and has been reported in previous investigations. Dharamkhele et al,[15] similarly observed a greater incidence of salivation among pediatric patients receiving nebulized ketamine-based premedication compared with dexmedetomidine-containing regimens. Their findings further support the favorable safety profile of dexmedetomidine in pediatric anesthesia.

Overall, the findings of the present study demonstrate that nebulized dexmedetomidine is superior to nebulized ketamine and placebo in providing effective preoperative sedation, facilitating parental separation, and improving mask acceptance while maintaining a favorable recovery profile and excellent safety. The non-invasive nature of nebulization, combined with the pharmacological advantages of dexmedetomidine, makes it a highly attractive option for pediatric premedication before general anesthesia.

CONCLUSION

Nebulized dexmedetomidine was found to be a more effective premedicant than nebulized ketamine and normal saline in pediatric patients undergoing elective surgeries under general anesthesia. Children receiving nebulized dexmedetomidine achieved significantly better sedation scores, superior parental separation, and improved mask acceptance while maintaining comparable recovery and discharge times. Both dexmedetomidine and ketamine demonstrated acceptable safety profiles; however, excessive salivation was observed more frequently with ketamine. Therefore, nebulized dexmedetomidine may be considered a safe, effective, and well-tolerated non-invasive premedication option for pediatric surgical patients.

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