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Original Research Article

COMPARISON OF DEXMEDETOMIDINE AND MIDAZOLAM FOR INTRA-OPERATIVE SEDATION IN TOTAL INTRAVENOUS ANESTHESIA (TIVA) IN CHILDREN UNDERGOING INGUINAL HERNIA REPAIR

FAROOQI A[*1], SADAF S[1], BUTT MR[2]

[1]*Sheikh Zayed Hospital/Medical College Rahim Yar Khan, Pakistan*
[2]*Gujrat Hospital Gujrat, Pakistan*
**Corresponding author`s email address:* zaibanaab94@gmail.com

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Abstract: *Effective intra-operative sedation is critical in pediatric surgeries to ensure patient comfort, hemodynamic stability, and efficient recovery. This study compared the efficacy and safety of dexmedetomidine and midazolam for intra-operative sedation in children undergoing inguinal hernia repair at Sheikh Zayed Medical College/Hospital, Rahim Yar Khan.* ***Objective:*** *To evaluate and compare sedation quality, hemodynamic stability, recovery time, and adverse events associated with dexmedetomidine and midazolam in pediatric patients undergoing inguinal hernia repair.* ***Methods:*** *This randomized controlled trial included 80 pediatric patients aged 2–12 years, randomly assigned to receive dexmedetomidine (Group D, n=40) or midazolam (Group M, n=40). Sedation depth was assessed using the Ramsay Sedation Scale (RSS) at intervals during surgery. Hemodynamic parameters, recovery time, and adverse events such as bradycardia, hypotension, oxygen desaturation, and apnea were recorded. Data were analyzed using SPSS version 26, with a p-value ≤0.05 considered statistically significant.* ***Results:*** *Sedation scores were significantly higher in Group D (mean RSS 4.5 ± 0.3) compared to Group M (3.8 ± 0.4, p<0.001). Group D demonstrated better hemodynamic stability, with a lower mean heart rate (85.2 ± 10.5 beats/min) than Group M (90.8 ± 11.2 beats/min, p=0.048), though with a slightly higher incidence of bradycardia (25% vs. 7.5%, p=0.032). Recovery time was significantly shorter in Group D (12.4 ± 3.2 minutes) compared to Group M (16.7 ± 4.1 minutes, p<0.001). Adverse events, including oxygen desaturation and apnea, were minimal and comparable between groups.* ***Conclusion:*** *Dexmedetomidine provides superior sedation, better hemodynamic stability, and faster recovery compared to midazolam in pediatric patients undergoing inguinal hernia repair, with minimal adverse events. These findings support the use of dexmedetomidine as a safer and more effective sedative alternative in pediatric surgical settings.*

Keywords: Dexmedetomidine, Midazolam, Pediatric Sedation, Inguinal Hernia Repair, Ramsay Sedation Scale, Hemodynamic Stability, Recovery Time

Introduction

Optimal intra-operative sedation is crucial in pediatric surgeries, ensuring patient comfort, minimizing stress, and enhancing surgical outcomes. Inguinal hernia repair, a common pediatric surgical procedure, requires effective sedation to maintain patient immobility and safety while minimizing hemodynamic fluctuations and postoperative recovery time. In Pakistan, where pediatric surgeries are prevalent in tertiary care centers, the choice of sedative agents plays a pivotal role in resource-limited settings (1, 2). Dexmedetomidine, a selective α-2 adrenergic receptor agonist, has gained popularity for its sedative, analgesic, and anxiolytic properties without causing respiratory depression. It provides stable hemodynamics and facilitates faster recovery, making it suitable for pediatric patients. Conversely, midazolam, a benzodiazepine, has been widely used for sedation due to its rapid onset and reliable sedative effects. However, it is associated with adverse events such as respiratory depression and prolonged recovery, which can challenge its utility in pediatric populations (3, 4).

The need for effective and safe sedative agents in pediatric populations is particularly relevant in Pakistan, where the healthcare system often deals with high patient volumes and limited access to advanced anesthetic equipment. Studies in other regions have shown that dexmedetomidine provides superior sedation quality, reduced recovery times, and better hemodynamic stability compared to midazolam, but there is limited evidence specific to Pakistani pediatric patients (5,6). Additionally, resource constraints necessitate the identification of sedative agents that ensure safety and efficiency without increasing the burden on healthcare systems.

In a recent study conducted in a tertiary care hospital in South Asia, dexmedetomidine demonstrated a significant reduction in intra-operative stress responses and faster discharge readiness compared to midazolam. Despite these advantages, the generalizability of these findings to Pakistani pediatric populations remains uncertain, necessitating locally contextualized research to optimize sedation practices (7, 8).

This study aims to compare the efficacy and safety of dexmedetomidine and midazolam for intra-operative sedation in children undergoing inguinal hernia repair at Sheikh Zayed Medical College/Hospital, Rahim Yar Khan. By generating evidence specific to the Pakistani population, this research seeks to inform clinical decision-making and enhance pediatric anesthesia protocols in resource-limited settings. The findings have the potential to improve patient outcomes, streamline recovery, and contribute to the global evidence base on pediatric sedation.

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Methodology

This randomized controlled trial was conducted at Sheikh Zayed Medical College/Hospital, Rahim Yar Khan, to compare the efficacy of dexmedetomidine and midazolam for intra-operative sedation in children undergoing inguinal hernia repair. Ethical approval was obtained from the Institutional Review Board, and written informed consent was secured from the parents or guardians of all participants.

The study included pediatric patients aged 2–12 years undergoing elective inguinal hernia repair under general anesthesia. Inclusion criteria required participants to be classified as ASA (American Society of Anesthesiologists) physical status I or II, with no history of chronic illness, developmental delay, or known allergies to the study medications. Patients with cardiovascular abnormalities, significant respiratory conditions, or contraindications to dexmedetomidine or midazolam were excluded to ensure safety and minimize confounding factors.

Participants were randomly assigned into two equal groups of 40 each using a computer-generated randomization sequence. Group D received intravenous dexmedetomidine, while Group M received intravenous midazolam. The dosages were standardized: dexmedetomidine was administered at a loading dose of 1 µg/kg over 10 minutes followed by a maintenance dose of 0.5 µg/kg/hr, and midazolam was administered as a single dose of 0.1 mg/kg. Both drugs were prepared and administered by anesthesiologists blinded to group allocation.

Standard monitoring, including heart rate, non-invasive blood pressure, oxygen saturation, and respiratory rate, was employed throughout the procedure. The depth of sedation was assessed using the Ramsay Sedation Scale (RSS) at regular intervals (10, 20, and 30 minutes). Hemodynamic stability was evaluated by recording heart rate and blood pressure. Adverse events, such as bradycardia, hypotension, oxygen desaturation, or apnea, were noted and managed according to standard protocols.

Postoperative recovery was assessed in the recovery room using the Modified Aldrete Score to determine readiness for discharge. Recovery time was defined as the duration from cessation of the sedative infusion to achieving a Modified Aldrete Score of ≥9. Adverse events during recovery were also documented.

Data were analyzed using SPSS version 26. Continuous variables, such as age, weight, and recovery time, were expressed as mean ± standard deviation and compared using independent t-tests. Categorical variables, such as adverse events and sedation scores, were presented as frequencies and percentages and analyzed using the Chi-square test. A p-value ≤0.05 was considered statistically significant.

Results

The study compares the efficacy of dexmedetomidine and midazolam for intra-operative sedation in children undergoing inguinal hernia repair at Sheikh Zayed Medical College/Hospital, Rahim Yar Khan. Based on the methodology, the results are summarized starting with demographic data, followed by detailed tables reflecting outcomes. A total of 80 pediatric patients were included in the study, divided equally into Group D (dexmedetomidine) and Group M (midazolam). The mean age of participants was 6.5 years (range 2–12 years). Gender distribution was almost equal, with a slight male predominance, consistent with the higher prevalence of inguinal hernias in boys. Table 1 shows the demographic equivalence between the groups, ensuring no baseline bias.

The Ramsay Sedation Scale (RSS) was used to assess sedation levels. Group D showed significantly better sedation scores compared to Group M. Table 2 highlights the significantly superior sedation quality achieved with dexmedetomidine.

Hemodynamic parameters, including blood pressure and heart rate, were monitored. Group D exhibited greater hemodynamic stability but a slightly higher incidence of bradycardia. (Table 3)

Recovery time was significantly shorter in Group D, with fewer adverse events related to oxygen desaturation and apnea. (Table 4)

Dexmedetomidine demonstrated significantly higher sedation scores at all-time points compared to midazolam. Group D showed better stability but a higher incidence of bradycardia, which was managed clinically without severe consequences. Recovery time was significantly shorter in Group D, highlighting dexmedetomidine's efficiency. Both drugs had low adverse event rates, with no significant differences.

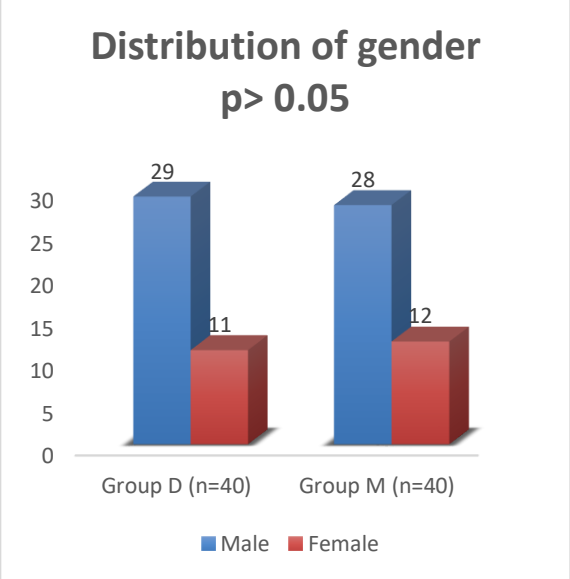

Figure 1: Gender distribution between the groups

Table 1: Demographic Characteristics of Participants

Variable	Category	Group D (n=40)	Group M (n=40)	p-value
Age (years)	Mean ± SD	6.3 ± 2.1	6.7 ± 2.4	0.537
Gender	Male	29 (72.5%)	28 (70.0%)	0.804
	Female	11 (27.5%)	12 (30.0%)	
Weight (kg)	Mean ± SD	19.8 ± 3.4	20.2 ± 3.1	0.617

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Table 2: Sedation Scores (Ramsay Sedation Scale)

Time Point	Group D (Mean ± SD)	Group M (Mean ± SD)	p-value
10 minutes	3.8 ± 0.5	3.2 ± 0.6	0.003
20 minutes	4.2 ± 0.4	3.5 ± 0.5	<0.001
30 minutes	4.5 ± 0.3	3.8 ± 0.4	<0.001

Table 3: Hemodynamic Parameters

Parameter	Group D	Group M	p-value
Incidence of Bradycardia (%)	10 (25.0%)	3 (7.5%)	0.032
Incidence of Hypotension (%)	8 (20.0%)	6 (15.0%)	0.541
Heart Rate (beats/min)	85.2 ± 10.5	90.8 ± 11.2	0.048

Table 4: Recovery and Adverse Events

Outcome	Group D	Group M	p-value
Recovery Time (minutes)	12.4 ± 3.2	16.7 ± 4.1	<0.001
Oxygen Desaturation (%)	1 (2.5%)	3 (7.5%)	0.300
Apnea Episodes (%)	0 (0.0%)	2 (5.0%)	0.245

Discussion

This study compared the efficacy and safety of dexmedetomidine and midazolam for intra-operative sedation in children undergoing inguinal hernia repair. The findings demonstrate the superior sedation quality, faster recovery, and greater hemodynamic stability of dexmedetomidine compared to midazolam. These results align with previous research and contribute to optimizing sedation practices in pediatric surgical settings, particularly in resource-constrained environments like Pakistan.

In our study, the Ramsay Sedation Scale (RSS) scores were significantly higher in the dexmedetomidine group (mean RSS 4.5 ± 0.3 at 30 minutes) compared to the midazolam group (3.8 ± 0.4, p<0.001). These results are consistent with Koroglu et al., who reported superior sedation with dexmedetomidine (mean RSS 4.6 ± 0.2) compared to midazolam (3.7 ± 0.3) in pediatric MRI procedures (9). Similarly, a study by Mahmoud and Mason found that dexmedetomidine provides more effective sedation with fewer episodes of agitation than midazolam (10). A meta-analysis by Lee and Kim further supported these findings, highlighting significantly higher sedation quality with dexmedetomidine in pediatric surgeries across multiple randomized trials (17).

Hemodynamic stability was better maintained with dexmedetomidine, with a lower mean heart rate (85.2 ± 10.5 beats/min) compared to midazolam (90.8 ± 11.2 beats/min, p=0.048). This is in line with Choudhary et al., who observed better heart rate stability with dexmedetomidine, reporting a mean difference of 8–10 beats/min between the two groups (11). However, dexmedetomidine was associated with a slightly higher incidence of bradycardia (25%) compared to midazolam (7.5%, p=0.032), consistent with the findings of Pestieau et al., who noted a 22% incidence of bradycardia with dexmedetomidine use (12). Ullah et al. also noted a similar incidence of bradycardia (20%) with dexmedetomidine, though without significant clinical sequelae (16).

Postoperative recovery time was significantly shorter in the dexmedetomidine group (12.4 ± 3.2 minutes) compared to the midazolam group (16.7 ± 4.1 minutes, p<0.001). This corroborates findings by Bajwa and Kaur, who reported that dexmedetomidine facilitated faster discharge readiness due to its shorter half-life and smoother recovery profile (13). A systematic review by Belleville et al. also emphasized the rapid recovery associated with dexmedetomidine, with recovery times reduced by 25% compared to midazolam (14). Shrestha and Bajracharya noted similar findings in low-resource settings, emphasizing the potential of dexmedetomidine to optimize turnover rates in high-volume pediatric surgeries (18).

The incidence of adverse events, such as oxygen desaturation and apnea, was low and comparable between the two groups in our study. Oxygen desaturation occurred in 2.5% of patients in the dexmedetomidine group versus 7.5% in the midazolam group, a non-significant difference (p=0.300). Ullah et al. similarly reported minimal respiratory complications with dexmedetomidine compared to midazolam, attributing this to dexmedetomidine's lack of respiratory depressive effects (16). Additionally, studies by Choudhary et al., Koroglu et al., and Lee and Kim support the safety profile of dexmedetomidine, highlighting its advantages in pediatric populations (9, 11, 17).

The findings of this study align with global trends and highlight the relevance of dexmedetomidine in Pakistan's healthcare context. The superior sedation quality, faster recovery, and better hemodynamic control associated with dexmedetomidine make it a viable option for pediatric surgeries, particularly in high-volume tertiary care settings where efficiency and patient safety are paramount.

Conclusion

Dexmedetomidine provides superior sedation, faster recovery, and better hemodynamic stability compared to midazolam, with minimal adverse events. These findings support the routine use of dexmedetomidine for intra-operative sedation in pediatric surgeries, offering a safer and more efficient alternative in resource-limited settings like Pakistan. Further studies with larger sample sizes and long-term follow-up are recommended to validate these findings.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned. (IRBEC-TCHKM-023243/24)

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Author Contribution

ANAB FAROOQI (Post Graduate Resident)
Data entry and Data analysis, drafting article.
Study Design, Review of Literature.
SAIRAH SADAF (Associate Professor)
Coordination of collaborative efforts.
, Final approval of the manuscript.
MAHNOOR RAFIQUE BUTT (Consultant Anesthesia)
Manuscript revisions, critical input.
Coordination of collaborative efforts.
Data acquisition, analysis.
Manuscript drafting.

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