

Comparison of effect of intravenous Dexmedetomidine and Midazolam on preoperative sedation in paediatric patients undergoing elective surgery under general anaesthesia

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Abstract:

Background: One of the difficulties in paediatric anaesthesia is reducing stress for children and ensuring a smooth induction of anaesthesia. This is typically achieved by administering a sedative medication before transferring the child to the operating room.

Aim: To compare the efficacy and effects of intravenous Dexmedetomidine and Midazolam on preoperative sedation in paediatric patients undergoing elective surgery under general anaesthesia.

Methods: A prospective, randomized study was conducted on 96 paediatric patients undergoing elective surgery under general anaesthesia. They were randomly allocated into two groups, Group A and B, which included 48 patients each. Group A received Dexmedetomidine 1 mcg/kg diluted to 50 ml normal saline IV over 10 minutes and patients in group B received Midazolam 0.05mg/kg in 50 ml normal saline IV over 10 minutes. Injection Glycopyrrolate 4 mcg/kg IV was given to both groups. Sedation score and Mask Acceptance Score were noted at 10 minutes. Haemodynamic parameters and pain score were also noted.

Results: The study revealed that at 10 minutes, the mean sedation score was 3.58 ± 0.50 in the Dexmedetomidine group and 3.81 ± 0.39 in the Midazolam group, with a statistically significant difference ($t = 2.499$, $p = 0.01$). The mean MAS in the Dexmedetomidine group was 1.38 ± 0.49 , while that in Midazolam group was 1.63 ± 0.67 . The difference in MAS between the two groups was statistically significant, as indicated by independent t-test value of 2.083 and a p-value of 0.04. There was no statistically significant difference between the groups in terms of haemodynamic parameters. However, pain scores were lower in the Dexmedetomidine group. No adverse effects were seen in either of the study groups.

Conclusion: Dexmedetomidine has a slightly better preoperative sedative effect on paediatric patients as compared to Midazolam, along with a better mask acceptance during induction, without causing any serious adverse effects.

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Introduction

Preoperative anxiety affects nearly 60% of paediatric patients undergoing elective surgery, often leading to poor cooperation during induction, increased postoperative pain, and behavioural disturbances [1]. Although non-pharmacological measures such as parental presence and distraction techniques help, sedative premedication remains the most reliable means of reducing anxiety and ensuring smooth induction [2].

Several routes of administration have been explored, each with limitations. The oral route, though common, is associated with variable bioavailability and delayed onset, while rectal and intramuscular

routes are painful and poorly accepted. Intranasal and sublingual routes offer faster absorption but may cause local discomfort. The intravenous route provides the most rapid and predictable onset, particularly useful when IV access is already in place.

Midazolam, a benzodiazepine, is widely used for paediatric premedication due to its rapid onset, anxiolysis, and amnesia [3]. However, it can cause respiratory depression, paradoxical agitation, and postoperative behavioural changes [4]. Ketamine, though effective, is limited by side effects such as hypersalivation, hallucinations, and nausea [1].

Dexmedetomidine, a selective α_2 -adrenergic agonist, offers sedation, anxiolysis, and analgesia without respiratory depression [5]. Acting on receptors in the locus coeruleus, it induces a sleep-like, calm, and cooperative sedation similar to natural non-REM sleep [6]. Though bradycardia and hypotension can occur, these effects are typically mild and dose-dependent [7].

Given the limited data from our setting, this study was undertaken to compare the efficacy and safety of intravenous Dexmedetomidine and Midazolam as premedicants in paediatric patients undergoing elective surgery under general anaesthesia.

Objectives:

- **Primary objective:** To compare the sedation with IV Dexmedetomidine and IV Midazolam in paediatric patients.
- **Secondary objective:**
 - a) To compare the mask acceptance score.
 - b) To compare the occurrence of any perioperative adverse outcome.

Methodology

Ethical clearance: This study was conducted in different operation theatres and wards under the Department of Anaesthesiology and Critical Care, GMCH, Guwahati, within 1 year (14th October, 2023 to 13th November, 2024). Our research plan was carefully reviewed and approved by the Institutional Ethics Committee before commencement of the study (via number – MC.No. 190/2007/Pt II/Oct 2023/26).

Study Design: Randomized controlled study.

Study Setting: This study was taken up in the Department of Anaesthesiology & Critical Care in collaboration with the Departments of Paediatric Surgery and Urology, Gauhati Medical College and Hospital, Guwahati

Study Population: We included paediatric patients aged 5 to 12 years, both boys and girls, who were scheduled for elective surgeries requiring general anaesthesia.

Inclusion Criteria:

1. Children aged 5-12 years
2. ASA grade I
3. An intravenous cannula was inserted pre-operatively.
4. Patients whose parents/guardians consented to participate in the study

Exclusion Criteria:

1. Obese children with a BMI > 30
2. Children with an anticipated difficult airway
3. Children with associated hepatic or renal dysfunction

4. Patients with congenital heart disease
5. Patients with known allergy to study drugs
6. Patients with sedation score < 5

Sample Size Calculation: The sample size was calculated based on the study by Bhadla et al. [3] A total of 43 subjects per group were required to detect a mean difference of 0.5 in sedation scores between the two groups, with 80% power and a 5% level of significance. Considering a 10% attrition rate, 48 subjects were included in each group. Thus, 96 patients meeting the inclusion criteria were enrolled and allocated to Groups A and B according to the treatment planned.

Plan of the Study: This prospective, randomized study included 96 children (5–12 years) of either sex undergoing elective surgery under general anaesthesia. After obtaining parental consent, eligible patients were randomly allocated into two groups (A and B) using a computer-generated sequence. Allocation concealment was ensured with opaque sealed envelopes opened on the day of surgery by a resident anaesthesiologist uninvolved in data analysis.

Patient Preparation: All patients underwent standard pre-anaesthetic evaluation, including medical history, general and systemic examination, airway assessment, and routine investigations. They were kept nil per oral for at least six hours. The anaesthetic process and postoperative pain assessment using the Wong-Baker FACES scale were explained to parents and children. In the preoperative area, baseline heart rate, blood pressure, ECG, and SpO₂ were recorded in the presence of a parent.

Procedure: An independent anaesthesiologist administered the study drug after baseline sedation and vital parameters were recorded.

- **Group A:** Dexmedetomidine 1 μ g/kg IV, diluted to 50 ml with normal saline, infused over 10 min.
- **Group B:** Midazolam 0.05 mg/kg IV, diluted to 50 ml with normal saline, infused over 10 min.

All patients received Glycopyrrolate 4 μ g/kg IV. Sedation scores and vitals were noted 10 minutes post-infusion before transfer to the operating room.

Anaesthetic Technique: Mask acceptance was assessed using the Mask Acceptance Scale. Induction was achieved with Fentanyl 1 μ g/kg, Propofol 2 mg/kg, and Atracurium 0.5 mg/kg IV. Anaesthesia was maintained with O₂: N₂O (2:4) and Sevoflurane (MAC 0.9–1.2). Muscle relaxation was maintained with Atracurium 0.1 mg/kg as needed. Ventilation was adjusted to keep EtCO₂ between 35–45 mmHg.

Fluids were administered per the Holliday–Segar formula. Hypotension and bradycardia were

managed with fluid bolus (10 ml/kg) and Atropine 0.6 mg IV, respectively. All patients received Paracetamol (7.5–15 mg/kg) and Ondansetron 0.1 mg/kg IV.

Haemodynamic parameters were recorded 10 minutes after intubation. At skin closure, Sevoflurane was discontinued; neuromuscular blockade was reversed with Neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg IV. Extubation was performed after adequate recovery.

Postoperative Assessment: Sedation and pain scores, along with vitals, were recorded immediately after extubation and one hour postoperatively. Patients were observed for adverse effects including hypotension, bradycardia, nausea, vomiting, or agitation.

Statistical Analysis: After completion of the study, data were entered into Microsoft Excel and analyzed using SPSS version 22. Descriptive statistics were presented as tables, bar diagrams, and graphs. The Kolmogorov–Smirnov and Shapiro–Wilk tests were used to assess normality. Independent t-tests compared means of normally distributed continuous variables, while the Mann–Whitney test was applied for non-normal data. Associations between categorical variables were analyzed using the Chi-square or Fisher's exact test.

Results

A. Demographic variables

Table 1: Age distribution

Parameter	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Independent t-test value	P value
Age	7.85 $\pm$ 2.07	8.13 $\pm$ 2.45	0.58	0.56

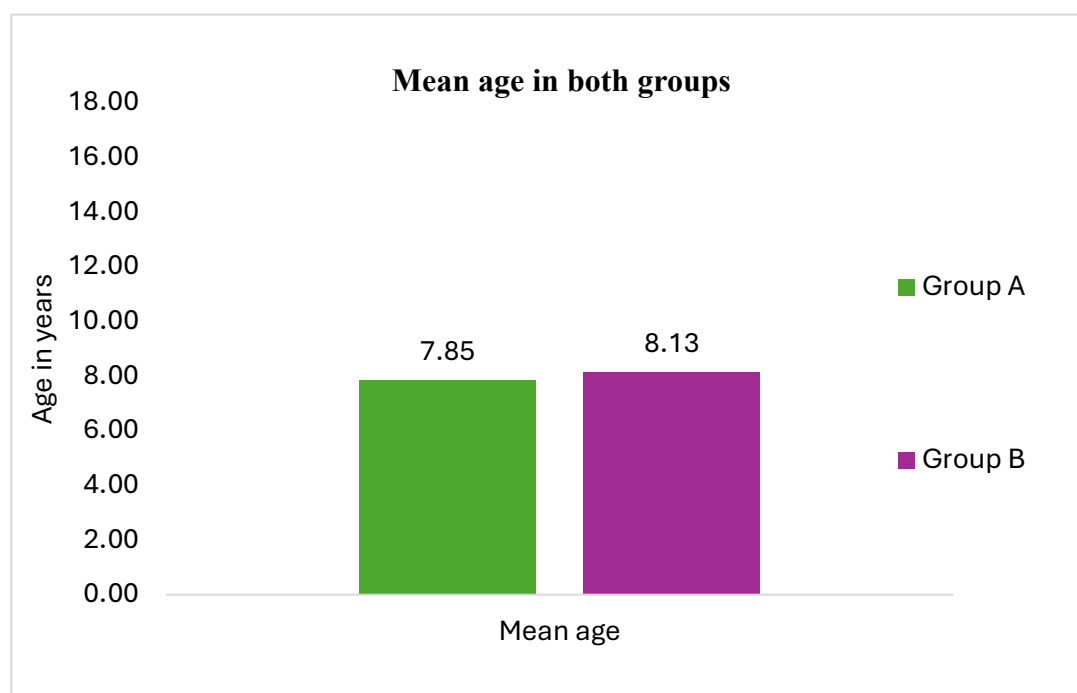


Figure 1: Mean age in both groups

Gender distribution in both groups:

Table 2: Gender distribution

Gender	Group A	Group B	Total	Chi-square Value	P Value
Female	16 (33.3%)	17 (35.4%)	33 (34.4%)	0.04	0.83
Male	32 (66.7%)	31 (64.6%)	63 (65.6%)		
Total	48 (100.0%)	48 (100.0%)	96 (100.0%)		

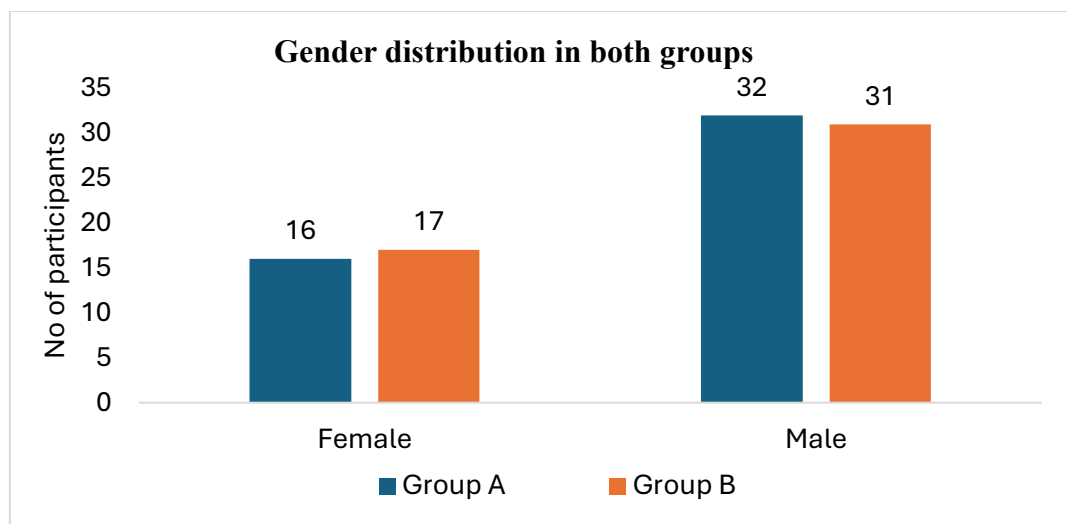


Figure 2: Gender distribution in both groups

Weight of the children in both groups:

Table 3: Weight of the children in both groups

Parameter	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Independent t-test value	P value
Weight	21.19 $\pm$ 6.66	22.42 $\pm$ 8.31	0.79	0.42

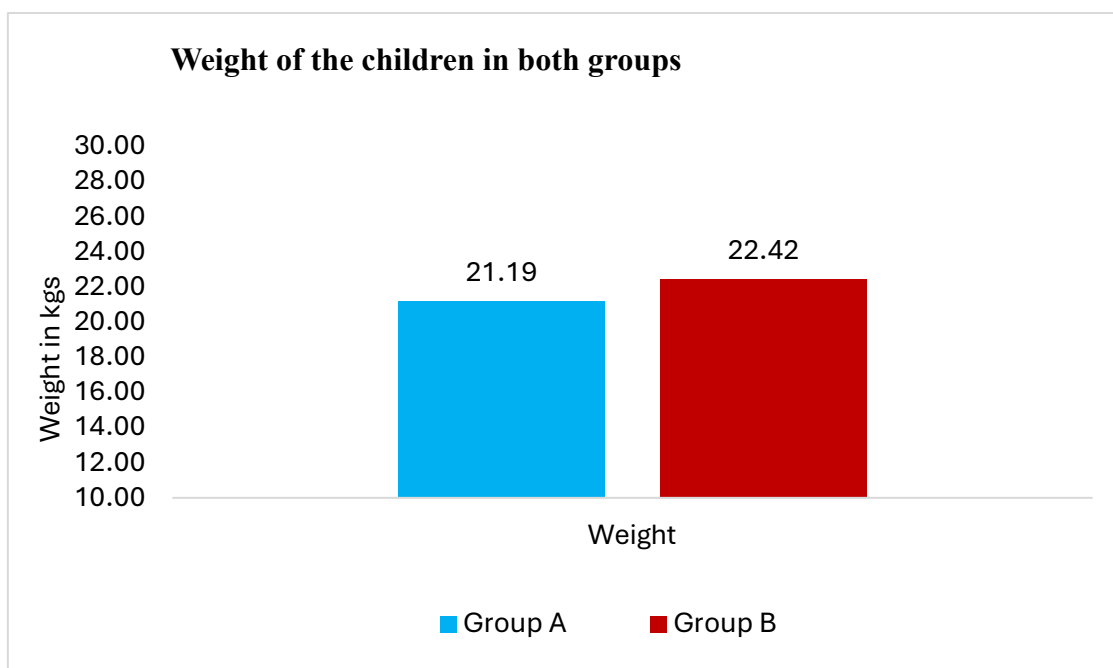


Figure 3: Weight of the children in both groups

B. Haemodynamic parameters:

Mean systolic blood pressure at various time points in both groups:

Table 4: Mean systolic blood pressure at various time points in both groups

Systolic Blood Pressure	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Independent t-test value	P value
0 minute	99.31 $\pm$ 8.16	100.75 $\pm$ 9.61	0.790	0.432
10 minutes	97.42 $\pm$ 7.90	98.96 $\pm$ 9.29	0.876	0.383
Intra-op	93.75 $\pm$ 7.11	94.88 $\pm$ 8.02	0.727	0.469
Post extubation	101.19 $\pm$ 7.22	101.00 $\pm$ 8.36	0.118	0.907
After 1 hour	95.71 $\pm$ 14.24	100.17 $\pm$ 7.97	1.893	0.061

The difference in mean systolic blood pressure was not statistically significant at all time points.

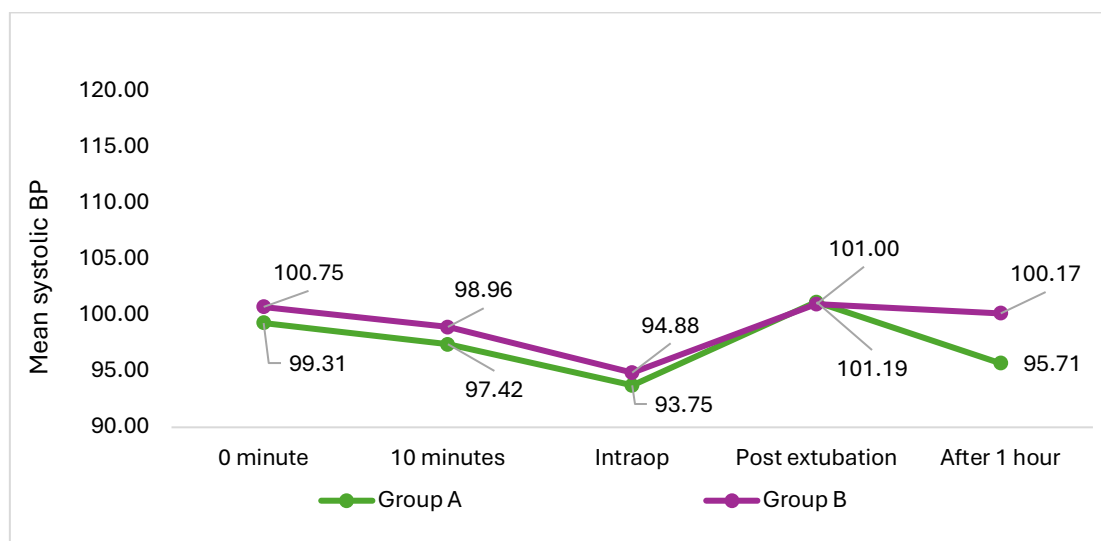


Figure 4: Mean systolic blood pressure at various time points

Mean diastolic blood pressure at various time points:

Table 5: Mean diastolic blood pressure at various time points

Diastolic Blood Pressure	Group A (Mean ± SD)	Group B (Mean ± SD)	Independent t-test value	P value
0 minute	63.04 ± 5.30	63.10 ± 5.85	0.055	0.956
10 minutes	61.27 ± 5.16	61.15 ± 5.94	-0.110	0.913
Intra-op	58.23 ± 4.86	58.04 ± 5.07	-0.185	0.854
Post extubation	64.42 ± 5.27	62.54 ± 5.31	-1.737	0.086
After 1 hour	62.10 ± 8.17	61.42 ± 5.14	-0.493	0.623

The differences in mean diastolic blood pressure were not statistically significant at any time interval.

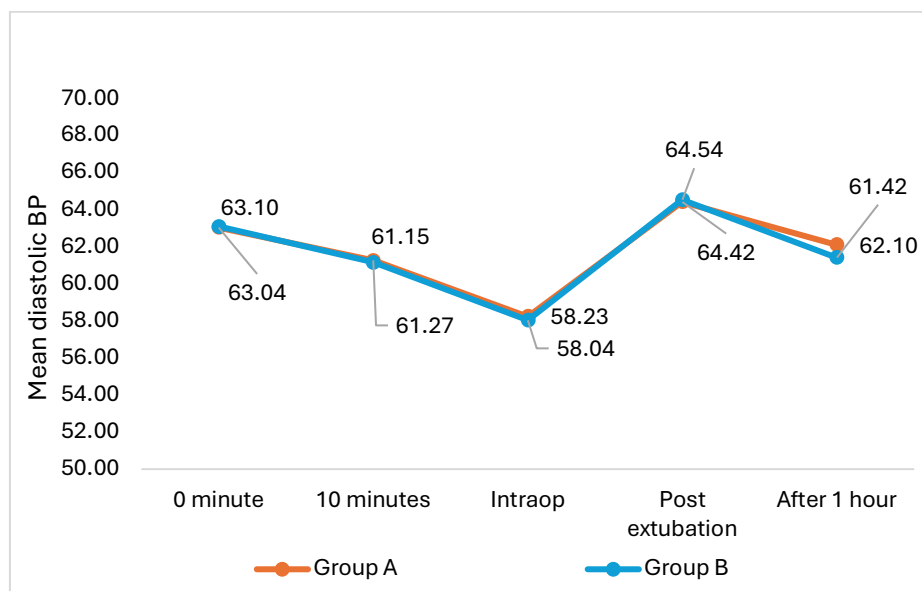


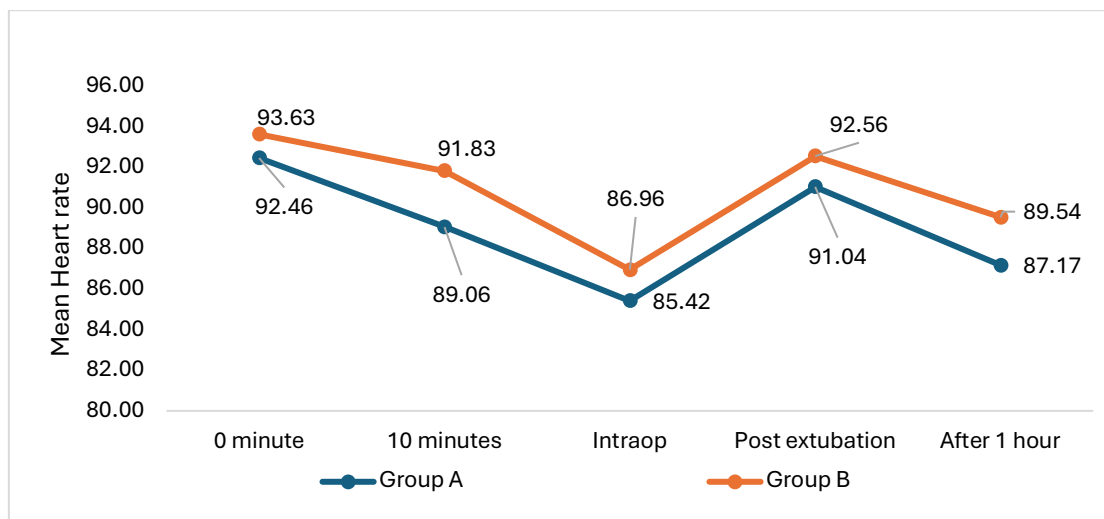
Figure 5: Mean diastolic blood pressure at various time points among both groups

Mean heart rate at various time points among both groups:

Table 6: Mean heart rate at various time points among both groups

Heart rate	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Independent t-test value	P value
0 minute	92.46 $\pm$ 6.60	93.63 $\pm$ 8.35	0.759	0.450
10 minutes	89.06 $\pm$ 6.50	91.83 $\pm$ 8.78	1.757	0.082
Intra-op	85.42 $\pm$ 6.08	86.96 $\pm$ 7.40	1.115	0.268
Post extubation	91.04 $\pm$ 5.30	92.56 $\pm$ 6.83	1.219	0.226
After 1 hour	87.17 $\pm$ 6.33	89.54 $\pm$ 7.13	1.725	0.088

The differences in mean heart rate were not statistically significant at any of the time points.

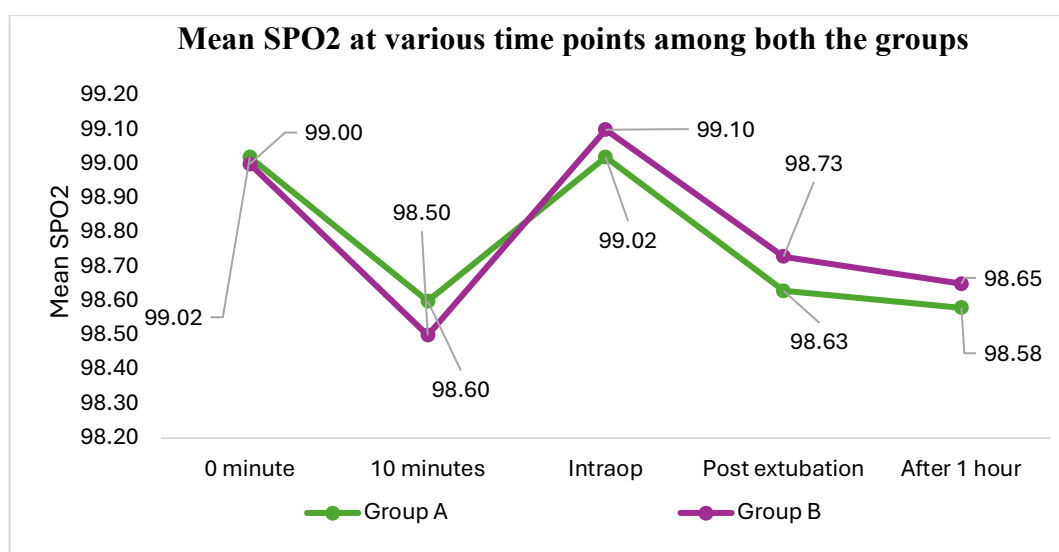
**Figure 6: Mean heart rate at various time points among both groups**

Mean SPO₂ at various time points among both groups:

Table 7: Mean SPO₂ at various time points

SPO ₂	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Independent t-test value	P value
0 minute	99.02 $\pm$ 0.93	99.00 $\pm$ 0.88	-0.113	0.910
10 minutes	98.60 $\pm$ 0.87	98.50 $\pm$ 0.90	-0.577	0.565
Intra-op	99.02 $\pm$ 0.86	99.10 $\pm$ 0.78	0.497	0.620
Post extubation	98.63 $\pm$ 0.84	98.73 $\pm$ 0.77	0.635	0.527
After 1 hour	98.58 $\pm$ 0.85	98.65 $\pm$ 0.70	0.394	0.694

The differences in mean SpO₂ were not statistically significant at any of the time intervals.

**Figure 7: Mean SPO₂ at various time points among both groups**

C. Sedation Score:

Sedation score in both groups in the study participants:

Table 8. Modified Observer's Assessment of Alertness/Sedation Scale

Sedation score	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Independent t-test value	P value
10 minutes	3.58 $\pm$ 0.50	3.81 $\pm$ 0.39	2.499	0.01*
Post extubation	4.21 $\pm$ 0.58	4.42 $\pm$ 0.50	1.884	0.03*
After 1 hour	4.81 $\pm$ 0.39	4.96 $\pm$ 0.20	2.280	0.02*

*- statistically significant by independent t-test

At all-time points, the Midazolam group demonstrated significantly higher sedation scores compared to the Dexmedetomidine group.

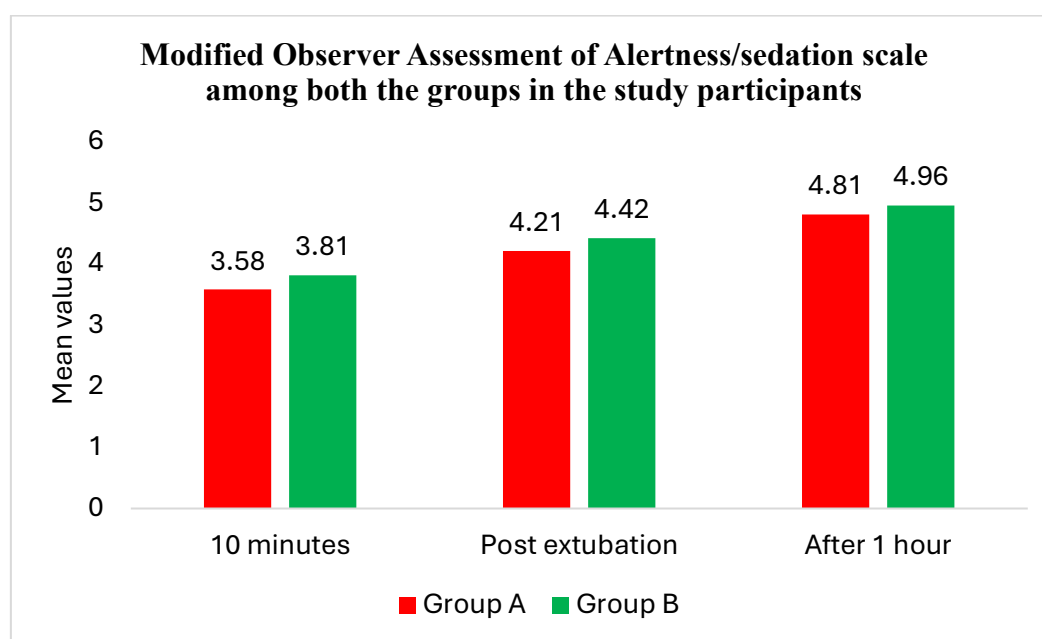


Figure 8: Modified Observer's Assessment of Alertness/Sedation Scale among both groups in the study participants

D. Mask Acceptance Score:

Mask Acceptance Score (MAS) among both groups in the study participants:

Table 9: Mask Acceptance Score (MAS) among both groups

Parameter	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Independent t-test value	P value
MAS	1.38 $\pm$ 0.49	1.63 $\pm$ 0.67	2.083	0.04*

*- statistically significant by independent t-test

The average MAS in the Dexmedetomidine group was 1.38 $\pm$ 0.49 and 1.63 $\pm$ 0.67 in the Midazolam group. This difference was statistically significant,

as shown by an independent t-test value of 2.083 with a p-value of 0.04. This suggests that the variation between the two groups is unlikely to have happened by chance.

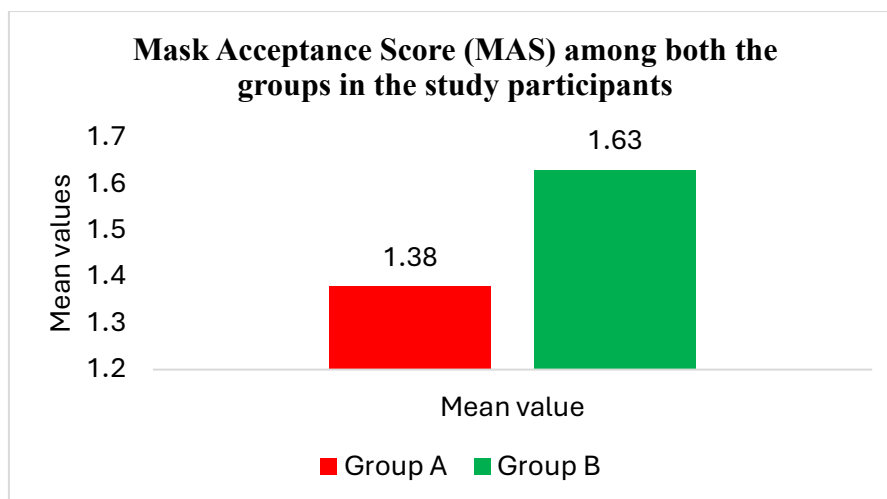


Figure 9: Mask Acceptance Score (MAS) among both groups in the study participants

E. Pain Score:

Pain score among both groups:

Table 10: Pain score among both groups

Pain score	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Independent t-test value	P value
Immediate postop	5.60 $\pm$ 0.84	6.25 $\pm$ 0.89	3.654	0.001*
After 1 hour	5.10 $\pm$ 0.59	5.98 $\pm$ 0.73	6.455	0.001*

*- statistically significant by independent t-test

The Dexmedetomidine group experienced significantly lower pain scores compared to the Midazolam group at both time points.

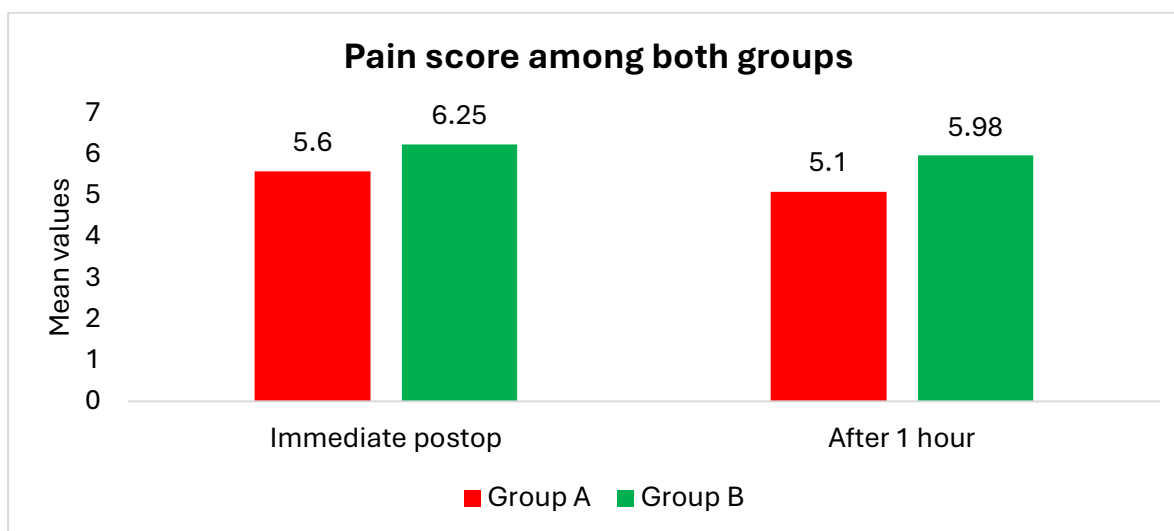


Figure 10: Pain score among both groups

F. Incidence of Adverse Effects:

Table 11: Incidence of adverse effects in both groups

Adverse Effects	Group A	Group B
Hypotension	0	0
Bradycardia	0	0
Postoperative nausea and vomiting	0	0
Agitation	0	0

Adverse effects were not seen in the study population.

Discussion

The demographic characteristics of the two groups in our study were found to be well-matched. The patients across groups were similar as for factors such as age, sex, ASA classification, weight, and type of surgery performed, and statistical analysis revealed no significant differences,

The average age of subjects in the Dexmedetomidine group was 7.85 ± 2.07 years, while in the Midazolam group it was 8.13 ± 2.45 years. Overall, 33 participants (34.4%) were female, and 63 participants (65.6%) were male.

The primary objective was to compare sedation scores between two groups: intravenous (IV) Dexmedetomidine and IV Midazolam. At 10 minutes, the mean sedation score was 3.81 ± 0.39 in the Midazolam group and 3.58 ± 0.50 in the Dexmedetomidine group, showing a significant difference ($t = 2.499$, $p = 0.01$), indicating deeper sedation with Dexmedetomidine. Sedation was assessed using the MOAAS scale, where lower scores indicate deeper sedation.

Our findings align with Bhadla et al. [3], who also observed greater sedation in the Dexmedetomidine group (mean scores 3.63 ± 0.04 vs. 3.12 ± 1.2 , $p = 0.038$). Similar results were reported by Sheta et al. [8], Singla et al. [9], Kumar et al. [10], and Shereef et al. [11] using varied administration routes. Hojjat et al. [12], using the Ramsay Sedation Scale, found no significant difference, though 10% of Midazolam cases required repeat dosing. Other studies (Akin et al. [13], Mostafa et al. [14], Surendar et al. [15]) also reported comparable sedation between both drugs.

Conversely, Chatrath et al. [16] and Kamal et al. [17] noted a faster onset with Midazolam. Such discrepancies may be due to differences in dosage, administration route, and sedation scoring systems.

In our study, IV Dexmedetomidine was administered at $1 \mu\text{g/kg}$ over 10 min, a dose shown to provide effective and rapid sedation. Midazolam was given at 0.05 mg/kg , based on evidence from Qiao et al. [18] indicating faster onset with this dose.

The mean Mask Acceptance Score (MAS) was 1.63 ± 0.67 with Midazolam and 1.38 ± 0.49 with Dexmedetomidine, a significant difference ($t = 2.083$, $p = 0.04$), favouring Dexmedetomidine. Similar observations were made by Bhadla et al. [3], Akin et al. [13], Sheta et al. [8], Singla et al. [9], Chatrath et al. [16], and Shereef et al. [11]. In contrast, Jannu et al. [19], Mountain et al. [20], Peng et al. [1], and Sathyamoorthy et al. [21] found no significant difference, likely due to differing routes of administration.

Both groups maintained stable haemodynamics with no significant intergroup differences. Minor decreases in systolic and diastolic pressures responded to IV fluids. Bhadla et al. [3] observed a greater fall in BP with Dexmedetomidine, likely due to faster IV bolus administration in their study. Heart rate was consistently lower in the Dexmedetomidine group but not significantly so; no bradycardia occurred. These effects are attributed to sympathetic inhibition and reduced catecholamine release.

No respiratory depression or desaturation ($<95\%$) occurred in either group, probably due to slow, diluted infusion over 10 minutes.

Postoperative pain, assessed using the Wong–Baker scale, was significantly lower in the Dexmedetomidine group both immediately and one hour after extubation, confirming its superior analgesic effect. Akin et al. [13] and Kamal et al. [17] also reported lower pain scores and reduced need for rescue analgesics with Dexmedetomidine.

The trial drugs in our study were well tolerated by the patients, and adverse effects such as hypotension, bradycardia, postoperative nausea and vomiting, and agitation were not seen in either group. This was probably due to the careful dosing and meticulous administration of the drugs during the study.

Our study's biggest strength is its thoughtful design, which uses randomization and keeps both the observers and patients blind to certain details. This method enables reducing bias, thereby ensuring that the findings are both reliable and precise.

Conclusion

Our study was on “Comparison of effect of intravenous Dexmedetomidine and Midazolam on preoperative sedation in paediatric patients undergoing elective surgery under general anaesthesia”.

From our study, we can conclude that –

- Intravenous Dexmedetomidine provides better preoperative sedation than intravenous Midazolam in paediatric patients, along with a better mask acceptance during induction, without causing any serious perioperative adverse effects.

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