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Original Research Article

Dexmedetomidine Versus Midazolam for Sedation in Patients Undergoing Procedures Under Spinal Anaesthesia: A Randomized Controlled Study

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Abstract

Introduction: Sedation during spinal anaesthesia improves patient comfort, reduces anxiety, and enhances surgical conditions. Among commonly used sedatives, dexmedetomidine and midazolam differ in their pharmacodynamic profiles, particularly in terms of sedation quality, hemodynamic stability, and respiratory effects.

Aims: This study aimed to compare the efficacy and safety of dexmedetomidine versus midazolam for intraoperative sedation in patients undergoing procedures under spinal anaesthesia.

Materials and Methods: Prospective, randomized, double-blind controlled study conducted in the department of anaesthesiology at ils dumdum, kolkata, over a period of 12 months. The study included 100 adult patients undergoing elective surgeries under spinal anaesthesia.

Results: The sedation scores differed significantly between the dexmedetomidine and midazolam groups. In the dexmedetomidine group (n = 50), 5 patients (10.0%) had a sedation score of 2, 20 patients (40.0%) had a score of 3, 18 patients (36.0%) had a score of 4, and 7 patients (14.0%) had a score of 5. In the midazolam group (n = 50), 12 patients (24.0%) had a sedation score of 2, 25 patients (50.0%) had a score of 3, 10 patients (20.0%) had a score of 4, and 3 patients (6.0%) had a score of 5. The difference in sedation scores between the two groups was statistically significant (p = 0.042).

Conclusion: Dexmedetomidine is a superior alternative to midazolam for sedation during spinal anaesthesia due to its better sedation quality, analgesic-sparing effect, and minimal respiratory depression, although careful monitoring for bradycardia is required.

Keywords: Dexmedetomidine; Midazolam; Spinal Anaesthesia; Sedation; Randomized Controlled Trial; Hemodynamic Stability; Ramsay Sedation Scale; Analgesia.

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Introduction

Spinal anaesthesia is widely used for lower abdominal, pelvic, and lower limb surgeries due to its rapid onset, reliable sensory and motor blockade, and avoidance of airway manipulation. Despite these advantages, many patients remain anxious, uncomfortable, or aware of the surgical environment during procedures performed under regional anaesthesia. This has led to the routine use of intraoperative sedation as an adjunct to spinal anaesthesia, aimed at improving patient comfort, providing anxiolysis, and ensuring better cooperation during surgery. An ideal sedative agent in this setting should provide adequate sedation without causing respiratory depression, maintain hemodynamic stability, allow easy arousability, and have minimal side effects [1,2]. Traditionally, benzodiazepines such as midazolam have been widely used for procedural sedation due to their anxiolytic, amnestic, and hypnotic properties. Midazolam acts on gamma-aminobutyric acid (gaba) receptors, producing dose-dependent sedation and anterograde amnesia. It has a rapid onset and relatively short duration of action, making it suitable for intraoperative use. However, midazolam is associated with certain limitations, including the risk of respiratory depression, oxygen desaturation, and variability in sedation levels, especially when used in higher doses or in

combination with other sedatives or opioids. Additionally, it lacks intrinsic analgesic properties and may not provide optimal patient satisfaction in all cases [3,4]. In recent years, dexmedetomidine, a highly selective α2-adrenergic receptor agonist, has emerged as an attractive alternative for sedation during regional anaesthesia. It produces sedation by acting on the locus coeruleus in the brainstem, resulting in a state that closely resembles natural sleep. Unlike benzodiazepines, dexmedetomidine provides both sedative and analgesic effects without significant respiratory depression. Patients sedated with dexmedetomidine are typically easily arousable and cooperative, which is particularly advantageous during procedures under spinal anaesthesia. Furthermore, it has been shown to prolong the duration of sensory and motor blockade when used as an adjunct, thereby enhancing the overall quality of anaesthesia [5,6]. Hemodynamic effects are an important consideration when selecting a sedative agent during spinal anaesthesia. Dexmedetomidine is known to cause dose-dependent bradycardia and hypotension due to its sympatholytic action, whereas midazolam may also lead to hypotension but generally has less pronounced effects on heart rate.

The balance between adequate sedation and hemodynamic stability is crucial, especially in patients with comorbid conditions. Several studies have compared these two agents, suggesting that dexmedetomidine provides more consistent sedation and better patient satisfaction, albeit with a higher incidence of bradycardia, while midazolam may result in less predictable sedation and a higher likelihood of respiratory compromise [7,8]. Another important aspect is the recovery profile and postoperative outcomes associated with these sedatives. Rapid recovery and early ambulation are desirable in modern anaesthetic practice. Midazolam, although short-acting, may occasionally lead to delayed recovery or residual sedation, particularly in elderly patients.

Dexmedetomidine, on the other hand, has been associated with smoother recovery profiles and reduced postoperative analgesic requirements due to its opioid-sparing effect. Additionally, its minimal impact on respiratory function makes it particularly advantageous in patients at risk of hypoventilation or airway compromise [9]. Given these differences in pharmacological profiles and clinical effects, there is a growing interest in determining the optimal sedative agent for patients undergoing procedures under spinal anaesthesia. While both dexmedetomidine and midazolam are commonly used, comparative evidence regarding their efficacy, safety, and overall patient outcomes remains an area of active research. Therefore, this randomized controlled study was designed to compare dexmedetomidine and midazolam in terms of sedation quality, hemodynamic stability, respiratory effects, and recovery characteristics in patients undergoing surgeries under spinal anaesthesia, with the aim of identifying the more suitable agent for routine clinical use [10].

Materials and Methods

Study Design: Prospective, randomized, double-blind, controlled study.

Study Place: Department of anaesthesiology, ILS Dumdum, Kolkata.

Study Duration: 12 months.

Study Population: Adult patients scheduled for elective surgeries under spinal anaesthesia.

Sample size: total of 100 patients.

Inclusion criteria

- Patients aged between 18–65 years
- Patients of either sex
- American society of anesthesiologists (asa) physical status i and ii
- Patients undergoing elective surgeries under spinal anaesthesia
- Patients willing to provide informed written consent

Exclusion criteria

- Patients with known hypersensitivity to dexmedetomidine or midazolam
- Patients with severe cardiac disease (e.g., heart block, severe bradycardia)
- Patients with uncontrolled hypertension or hypotension
- Patients with respiratory disorders (e.g., copd, sleep apnea)
- Patients with hepatic or renal impairment
- Patients on sedatives, opioids, or psychiatric medications
- Pregnant or lactating women
- Patients with contraindications to spinal anaesthesia

Study variables

- Age group (years)
- Gender
- ASA status
- Sedation score
- Adverse effect

Statistical Analysis: For statistical analysis data were entered into a microsoft excel spreadsheet and then analyzed by spss (version 27.0; spssinc., chicago, il, usa) and graphpad prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved

independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for pearson's chi-squared test. Unpaired proportions were compared by chi-square test or fischer's exact test, as appropriate. Explicit expressions that can be used to carry out various t-tests are given below.

In each case, the formula for a test statistic that either exactly follows or closely approximates a t-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test.

Once a t value is determined, a p-value can be found using a table of values from student's t-distribution .if the calculated p-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis. P-value $\leq$ 0.05 was considered for statistically significant.

Result

Table 1: Age distribution

Age Group (Years)	Dexmedetomidine (n=50)	Midazolam (n=50)	Total
18–30	12 (24.0%)	10 (20.0%)	22
31–45	18 (36.0%)	20 (40.0%)	38
46–60	14 (28.0%)	12 (24.0%)	26
>60	6 (12.0%)	8 (16.0%)	14
Total	50 (100%)	50 (100%)	100
P-value	0.839		

Table 2: Gender distribution

Gender	Dexmedetomidine (n=50)	Midazolam (n=50)	Total
Male	28 (56.0%)	30 (60.0%)	58
Female	22 (44.0%)	20 (40.0%)	42
Total	50 (100%)	50 (100%)	100
P-value	0.688		

Table 3: ASA physical status

Asa Status	Dexmedetomidine (n=50)	Midazolam (n=50)	Total
Asa I	30 (60.0%)	28 (56.0%)	58
Asa II	20 (40.0%)	22 (44.0%)	42
Total	50 (100%)	50 (100%)	100
P-value	0.689		

Table 4: Sedation score (Ramsay sedation scale)

Sedation Score	Dexmedetomidine (n=50)	Midazolam (n=50)	Total
2	5 (10.0%)	12 (24.0%)	17
3	20 (40.0%)	25 (50.0%)	45
4	18 (36.0%)	10 (20.0%)	28
5	7 (14.0%)	3 (6.0%)	10
Total	50 (100%)	50 (100%)	100
P-value	0.042		

Table 5: Adverse effects

Adverse Effect	Dexmedetomidine (n=50)	Midazolam (n=50)	Total
Bradycardia	10 (20.0%)	2 (4.0%)	12
Hypotension	6 (12.0%)	10 (20.0%)	16
Respiratory depression	1 (2.0%)	8 (16.0%)	9
None	33 (66.0%)	30 (60.0%)	63
Total	50 (100%)	50 (100%)	100
P-value	0.021		

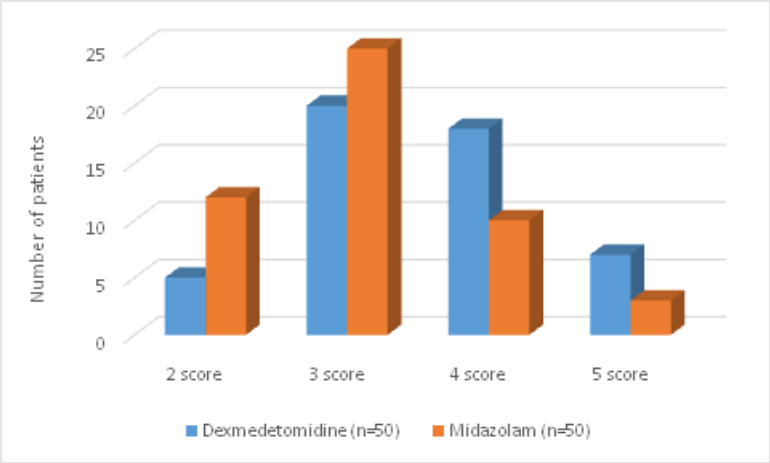

Figure 1: Sedation score (Ramsay sedation scale)

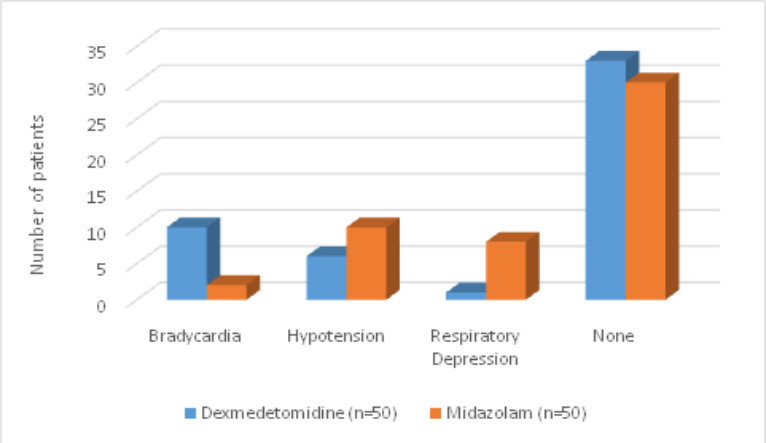

Figure 2: Adverse effects

The age distribution between the dexmedetomidine and midazolam groups was comparable and showed no statistically significant difference. In the dexmedetomidine group (n = 50), 12 patients (24.0%) were aged 18–30 years, 18 patients (36.0%) were 31–45 years, 14 patients (28.0%) were 46–60 years, and 6 patients (12.0%) were >60 years. In the midazolam group (n = 50), 10 patients (20.0%) were aged 18–30 years, 20 patients (40.0%) were 31–45 years, 12 patients (24.0%) were 46–60 years, and 8 patients (16.0%) were >60 years. The difference in age distribution between the two groups was not statistically significant (p = 0.839).

In the dexmedetomidine group (n = 50), 28 patients (56.0%) were male and 22 patients (44.0%) were female. In the midazolam group (n = 50), 30 patients (60.0%) were male and 20 patients (40.0%) were female. The difference in gender distribution between the two groups was not statistically significant (p = 0.688).

In the dexmedetomidine group (n = 50), 30 patients (60.0%) were ASA I and 20 patients (40.0%) were ASA II. In the midazolam group (n = 50), 28 patients (56.0%) were ASA I and 22 patients (44.0%) were ASA II. The difference in ASA status between the two groups was not statistically significant (p = 0.689).

The sedation scores differed significantly between the dexmedetomidine and midazolam groups. In the dexmedetomidine group (n = 50), 5 patients (10.0%) had a sedation score of 2, 20 patients (40.0%) had a score of 3, 18 patients (36.0%) had a score of 4, and 7 patients (14.0%) had a score of 5. In the midazolam group (n = 50), 12 patients (24.0%) had a sedation score of 2, 25 patients (50.0%) had a score of 3, 10 patients (20.0%) had a score of 4, and 3 patients (6.0%) had a score of 5. The difference in sedation scores between the two groups was statistically significant (p = 0.042).

The incidence of adverse effects showed a statistically significant difference between the dexmedetomidine and midazolam groups. In the dexmedetomidine group (n = 50), bradycardia was observed in 10 patients (20.0%), hypotension in 6 patients (12.0%), respiratory depression in 1 patient (2.0%), while 33 patients (66.0%) had no adverse effects. In the midazolam group (n = 50), 2 patients (4.0%) developed bradycardia, 10 patients (20.0%) had hypotension, 8 patients (16.0%) experienced

respiratory depression, and 30 patients (60.0%) had no adverse effects. The difference in overall adverse effect profile between the two groups was statistically significant (p = 0.021).

Discussion

Our findings are consistent with the work of Riker et al., who demonstrated that dexmedetomidine provides effective sedation with a lower incidence of respiratory depression compared to benzodiazepines such as midazolam in ICU patients [11]. Similarly, Jakob et al. in the SPICE III trial reported that dexmedetomidine-based sedation was associated with comparable or improved clinical outcomes compared to standard sedatives including midazolam, particularly with respect to ventilatory safety and arousability [12].

Belleville et al. also observed that dexmedetomidine produces a more cooperative form of sedation without significant respiratory compromise, unlike midazolam which is more associated with dose-dependent respiratory depression [13].

In terms of hemodynamic effects, Venn and colleagues reported that dexmedetomidine may be associated with bradycardia and hypotension, which aligns with our observation of higher bradycardia incidence in the dexmedetomidine group [14]. However, these effects are generally manageable and do not outweigh its sedative advantages. Hall et al. further supported that dexmedetomidine allows sedation resembling natural sleep with minimal respiratory depression, whereas midazolam often results in deeper sedation levels and prolonged recovery [15].Pandharipande et al. highlighted that benzodiazepines like midazolam are associated with prolonged sedation and increased delirium risk in critically ill patients, which limits their use compared to dexmedetomidine [16]. In another study by Jakob et al., dexmedetomidine showed improved patient interaction and reduced mechanical ventilation duration compared to conventional sedatives [17].Further studies comparing both agents concluded that while midazolam is effective for achieving deep sedation, it is associated with a higher risk of respiratory depression and delayed recovery. Maze and Scarfini explained the pharmacologic advantage of dexmedetomidine as an α2-adrenergic agonist providing sedation without significant respiratory suppression, which explains its safety profile seen in our study [18]. Finally, dexmedetomidine is associated with a more favorable sedation profile compared to midazolam, despite a higher incidence of mild cardiovascular side effects.

Conclusion

In this study, dexmedetomidine and midazolam were comparable in terms of baseline demographic and clinical characteristics. However, dexmedetomidine demonstrated a more favorable sedation profile with better distribution of higher-quality sedation scores and reduced incidence of respiratory depression compared to midazolam. Although dexmedetomidine was associated with a higher incidence of mild hemodynamic side effects such as bradycardia and hypotension, these were generally manageable. Overall, dexmedetomidine appears to be a safer and more effective sedative agent than midazolam, particularly in terms of sedation quality and respiratory safety.

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