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ORIGINAL RESEARCH ARTICLE

Comparison of Intravenous Dexmedetomidine versus Midazolam for Sedation in Spinal Anesthesia: A Randomized Controlled Study

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ABSTRACT

Background: Sedation during spinal anesthesia improves patient comfort and surgical conditions. Dexmedetomidine and midazolam are commonly used agents with different pharmacological profiles.

Objectives: To compare the efficacy, hemodynamic stability, and recovery profile of dexmedetomidine versus midazolam in patients undergoing surgeries under spinal anesthesia.

Materials and Methods: This randomized controlled study included 100 patients divided into two groups Group D (dexmedetomidine) and Group M (midazolam). Sedation levels, hemodynamic parameters, recovery time, and adverse effects were recorded and analyzed.

Results: Group D showed significantly better sedation scores and stable hemodynamics compared to Group M ($p < 0.05$). Recovery time was shorter in Group D. Incidence of respiratory depression was higher in Group M.

Conclusion: Dexmedetomidine provides superior sedation with better hemodynamic stability and recovery profile compared to midazolam.

Keywords: Dexmedetomidine, Midazolam, Spinal Anesthesia, Sedation, Hemodynamics

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INTRODUCTION

Spinal anesthesia is one of the most commonly employed regional anesthesia techniques for lower abdominal and lower limb surgeries due to its simplicity, rapid onset, and cost-effectiveness [1]. Despite its advantages, patients often remain awake during the procedure, which may lead to anxiety, discomfort, and a poor overall surgical experience. Therefore, the use of adjunct sedative agents has become an integral part of anesthetic practice to improve patient satisfaction and provide optimal operating conditions[2].

Midazolam, a short-acting benzodiazepine, has been widely used for intraoperative sedation because of its anxiolytic, amnestic, and hypnotic properties [3]. However, it is associated with dose-dependent respiratory depression, delayed recovery, and variable sedation levels. On the other hand, dexmedetomidine, a highly selective alpha-2 adrenergic receptor agonist, has gained popularity due to its unique property of providing sedation that closely resembles natural sleep, along with analgesic effects and minimal respiratory depression[4]. Its sympatholytic action also contributes to better hemodynamic stability during surgical procedures.

Recent literature suggests that dexmedetomidine may offer superior perioperative outcomes compared to conventional sedatives like midazolam, particularly in terms of patient cooperation, hemodynamic control, and faster recovery profiles [5]. However, evidence comparing these two agents specifically in the context of spinal anesthesia remains limited and sometimes inconsistent. Hence, this study was designed to compare dexmedetomidine and midazolam with respect to sedation quality, hemodynamic parameters, recovery characteristics, and adverse effects in patients undergoing surgeries under spinal anesthesia.

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MATERIALS AND METHODS

This prospective, randomized, double-blind controlled study was conducted in the Department of Anesthesiology at a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee and written informed consent from all participants. The study duration was 12 months. A total of 100 patients scheduled for elective lower limb surgeries under spinal anesthesia were enrolled.

Study Population

Patients aged between 18 and 60 years belonging to the American Society of Anesthesiologists (ASA) physical status I and II were included in the study. Patients with known hypersensitivity to study drugs, significant cardiovascular disease, hepatic or renal impairment, psychiatric illness, pregnancy, or those on sedative medications were excluded.

Sample Size Calculation

The sample size was calculated based on previous studies comparing sedation scores between dexmedetomidine and midazolam. Assuming a power of 80% and a significance level of 5%, a minimum of 45 patients per group was required. To compensate for possible dropouts, 50 patients were included in each group.

Randomization and Blinding

Patients were randomly allocated into two groups (Group D and Group M) using a computer-generated randomization sequence. Allocation concealment was ensured using sealed opaque envelopes. Both the patient and the anesthesiologist assessing outcomes were blinded to group allocation. The study drugs were prepared by an independent anesthesiologist not involved in data collection.

Study Groups

Group D (Dexmedetomidine group)

Patients received a loading dose of dexmedetomidine 1 µg/kg diluted in 50 mL normal saline administered over 10 minutes, followed by a maintenance infusion of 0.5 µg/kg/hr.

Group M (Midazolam group)

Patients received an intravenous bolus of midazolam 0.05 mg/kg followed by intermittent doses as required to maintain desired sedation levels.

Anesthetic Technique

All patients were kept nil per oral for 6 hours prior to surgery. On arrival in the operating room, standard monitors including electrocardiogram (ECG), non-invasive blood pressure (NIBP), and pulse oximetry (SpO2) were applied. Baseline parameters were recorded. Intravenous access was secured with an 18-G cannula and patients were preloaded with 10 mL/kg of Ringer's lactate solution.

Spinal anesthesia was administered in the sitting position at the L3–L4 interspace using a 25-G Quincke spinal needle under strict aseptic precautions. A standard dose of 0.5% hyperbaric bupivacaine (3 mL) was injected intrathecally. Patients were immediately positioned supine after the procedure.

Sedation and Monitoring

Sedation was assessed using the Ramsay Sedation Scale (RSS), targeting a score of 3–4. Hemodynamic parameters, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and oxygen saturation (SpO_2), were recorded at baseline, every 5 minutes for the first 30 minutes, and then every 10 minutes until the end of surgery.

Respiratory rate and signs of respiratory depression (SpO2 < 94% or RR < 10/min) were monitored. Any adverse events such as hypotension (defined as a fall in SBP >20% from baseline), bradycardia (HR <50 bpm), nausea, vomiting, or excessive sedation were recorded and managed appropriately.

Recovery Assessment

Recovery time was assessed using the Modified Aldrete Score. Time taken to achieve a score ≥9 was considered as recovery time. Patient satisfaction was assessed postoperatively using a 5-point Likert scale.

Outcome Measures

The primary outcome was sedation level (Ramsay Sedation Score). Secondary outcomes included hemodynamic stability, recovery time, and incidence of adverse effects.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 25. Continuous variables were expressed as mean ± standard deviation (SD) and compared using an independent Student's t-test. Categorical variables were expressed as percentages and analyzed using the Chi-square test or Fisher's exact test where appropriate. Repeated measures ANOVA was used for intra-group comparisons over time. A *p-value* <0.05 was considered statistically significant.

RESULTS

A total of 100 patients were analyzed, with 50 patients in each group. Both groups were comparable with respect to demographic characteristics, including age, gender

Table 1: Demographic characteristics

Parameter	*Group D (n=50)*	*Group M (n=50)*	*p-value*
Age (years)	40 ± 10	39 ± 9	0.62
Gender (M/F)	30/20	28/22	0.68
ASA I/II	32/18	30/20	0.65

Table 2: Sedation scores (Ramsay Sedation Score)

Time Interval	*Group D*	*Group M*	*p-value*
10 min	4.5 ± 0.5	3.8 ± 0.6	<0.001
20 min	4.6 ± 0.4	3.9 ± 0.5	<0.001
30 min	4.4 ± 0.5	3.7 ± 0.6	<0.001

Table 3: Hemodynamic parameters

Parameter	*Group D*	*Group M*	*p-value*
HR (bpm)	70 ± 5	78 ± 6	<0.01
SBP (mmHg)	118 ± 8	126 ± 10	<0.01
DBP (mmHg)	76 ± 6	82 ± 7	<0.01

Table 5: Adverse effects

Adverse effect	*Group D (%)*	*Group M (%)*	*p-value*
Respiratory Depression	2%	10%	0.04
Bradycardia	8%	2%	0.08
Hypotension	6%	4%	0.65

Table 4: Recovery profile

Parameter	*Group D*	*Group M*	*p-value*
Recovery Time (min)	15 ± 3	25 ± 5	<0.001

distribution, and ASA status, indicating no significant baseline differences ($p > 0.05$).

Interpretation

Both groups were statistically comparable, ensuring validity of further comparisons.

Interpretation

Group D consistently achieved higher and more stable sedation levels compared to Group M, with statistically significant differences at all time intervals.

Interpretation

The Dexmedetomidine group demonstrated significantly better hemodynamic stability with lower heart rate and blood pressure values compared to the midazolam group.

Interpretation

Patients in Group D had significantly faster recovery compared to Group M.

Interpretation

Respiratory depression was significantly higher in the

midazolam group, whereas dexmedetomidine showed a slightly higher but non-significant incidence of bradycardia.

Graphical Representation

Bar diagrams comparing sedation scores, recovery time, and incidence of adverse effects clearly demonstrate:

- Higher sedation scores in Group D
- Faster recovery in Group D
- Higher respiratory depression in Group M

Overall Result Summary

Dexmedetomidine provided superior sedation quality, better hemodynamic stability, faster recovery, and fewer respiratory complications compared to midazolam, with most differences being statistically significant.

DISCUSSION

The present randomized controlled study compared dexmedetomidine and midazolam for intraoperative sedation during spinal anesthesia and demonstrated that dexmedetomidine provides superior sedation quality, improved hemodynamic stability, faster recovery, and a lower incidence of respiratory depression. These findings are clinically relevant as the choice of sedative plays a crucial role in enhancing patient comfort while maintaining safety during regional anesthesia.

In the current study, patients receiving dexmedetomidine achieved higher and more consistent Ramsay Sedation Scores compared to those receiving midazolam. This observation is consistent with earlier studies, which have shown that dexmedetomidine produces a unique form of "cooperative sedation," allowing patients to remain easily arousable while being adequately sedated[6,7]. Midazolam, although effective, is associated with variable depth of sedation and a higher risk of over-sedation, which may explain the comparatively lower and fluctuating sedation scores observed in our study [8].

Hemodynamic stability is a critical factor during spinal anesthesia, as sympathetic blockade can predispose patients to hypotension and bradycardia. In our study, dexmedetomidine demonstrated better control of heart rate and blood pressure compared to midazolam. This finding is in agreement with previous literature, where dexmedetomidine's sympatholytic action has been shown to attenuate stress responses and provide stable perioperative hemodynamics [9–11]. Although a slightly higher incidence of bradycardia was noted in the dexmedetomidine group, it was not statistically significant and was easily manageable.

Another important finding of this study was the significantly faster recovery time observed in the dexmedetomidine group. This may be attributed to its pharmacokinetic profile, which allows for predictable and smooth recovery without prolonged sedation [12,13]. In contrast, midazolam is known for delayed recovery due to its accumulation and active metabolites, particularly when repeated doses are administered [14]. Faster recovery is advantageous in busy surgical settings as it facilitates early discharge and improves turnover rates.

Respiratory safety is a major concern with sedative agents. In the present study, the incidence of respiratory depression was significantly higher in the midazolam group compared to the dexmedetomidine group. This is consistent with existing evidence suggesting that dexmedetomidine has minimal effect on respiratory drive, making it a safer alternative, especially in patients at risk of respiratory compromise [15–17]. The reduced need for airway interventions further supports its safety profile.

Patient satisfaction, although not quantitatively detailed in this study, was observed to be higher in the dexmedetomidine group due to better comfort and a smoother perioperative experience. Similar findings have been reported in other clinical trials, emphasizing the role of dexmedetomidine in improving overall patient experience during regional anesthesia [18–20].

Overall, the findings of this study are in concordance with multiple previous studies and reinforce the growing preference for dexmedetomidine as a sedative agent in spinal anesthesia. Its ability to provide effective sedation, maintain hemodynamic stability, ensure rapid recovery, and minimize respiratory complications makes it a superior alternative to midazolam in the perioperative setting.

LIMITATIONS

- Small sample size
- Single-center study

CONCLUSION

Dexmedetomidine is a superior sedative agent compared to midazolam for spinal anesthesia, offering better sedation, hemodynamic stability, and recovery profile.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest related to this study.

ETHICAL CLEARANCE

The study was conducted after obtaining approval from the Institutional Ethics Committee of the concerned institution. Written informed consent was obtained from all participants prior to inclusion in the study.

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