

Comparative Evaluation of Efficacy of Propofol and Midazolam during Spinal Anesthesia: A Hospital Based Study

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ABSTRACT

Background: Spinal anesthesia offers many advantages over general anesthesia, however, the fear of surgery, the unfamiliar environs of operation room, the sight and sounds of sophisticated instruments, and the masked faces makes the patient panic.

Aim of the study: To comparatively evaluate efficacy of Propofol and Midazolam during spinal anesthesia.

Materials and Methods: The present study was conducted in the Zanana Hospital, R.B.M. Hospital, Bharatpur, Rajasthan, India. For the study, we selected 20 patients with American Society of Anesthesiologist (ASA) I-II for which abdominal surgical procedures were planned. The time interval for surgery was about 40-60 minutes. A written informed consent was obtained from each patient preoperatively.

Results: We included 20 patients for the study. Patients were randomly grouped into two groups, Group A and Group B. We observed that there was no statistically significant difference between demographic characteristics of the patients of both groups. The anesthesia onset time for Group A was 12.21 ± 10^{-1}

1.96 minutes as compared to 11.22 ± 1.45 minutes for Group B (P=0.32).

Conclusion: Midazolam is more efficacious as compared to Propofol, however, both the agents can be used effectively during spinal anesthesia.

Keywords: Midazolam, Spinal Anesthesia, Propofol.

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INTRODUCTION

Spinal anesthesia offers many advantages over general anesthesia, however, the fear of surgery, the unfamiliar environs of operation room, the sight and sounds of sophisticated instruments, and the masked faces makes the patient panic.1, 2 The intense sensory and motor block, continuous supine position and the inability to move the body also brings a feeling of discomfort and phobia in many patients. Spinal anaesthesia also has disadvantages, like haemodynamic disturbances, unsuitable for psychologically disturbed patients, inability to last for the duration of prolonged surgery, and failed spinal block. The complications associated with it, are total spinal or high spinal anaesthesia, Postdural Puncture Headache (PDPH), urinary retention, and waist and back pain.^{3,4} An ideal supplemental sedative should provide, effective anxiolysis, an easily controllable level of sedation, predictable depth of amnesia, a rapid and clear headed recovery, minimal intraoperative side effects, no evidence of cumulation and minimal postoperative side effects. Numerous agents ranging from methohexitone to etomidate and droperidol to dexmedetomidine have been used as sedative adjuvants to spinal anesthesia, with their very own advantages and disadvantages over one another.⁵ Propofol, with its early metabolism to inactive

metabolites, has a rapid onset of action and an extremely short recovery. It has a context sensitive half time of 25 minutes for a three hour long infusion and 50 minute for a prolonged infusion and thus can also be easily titrated for achieving conscious sedation.⁶ Midazolam, with fast onset and short recovery time is a near ideal supplemental sedative that provides effective anxiolysis, predictable depth of amnesia, a rapid and clear headed recovery, with minimal side effects and no evidence of cumulation.^{7, 8} Hence, we planned the study to comparatively evaluate efficacy of Propofol and Midazolam during spinal anesthesia.

MATERIALS AND METHODS

The present study was conducted in the Zanana Hospital, R.B.M. Hospital, Bharatpur, Rajasthan, India.. The ethical approval for the study was obtained from the ethical committee of the institute. For the study, we selected 20 patients with American Society of Anesthesiologist (ASA) I-II for which abdominal surgical procedures were planned. The time interval for surgery was about 40-60 minutes. A written informed consent was obtained from each patient preoperatively.

Exclusion Criteria

- 1. History of long-term steroid therapy
- 2. Allergic to drugs
- 3. Uncontrolled hypertension
- 4. Alcohol abuse
- 5. Addiction to opium or other drugs

The patients were randomly grouped into two groups, Group A and Group B with 10 subjects in each group. Administration of Midazolam 0.1% infusion was done in Group A patients and Propofol 1% infusion was administered to Group B. Administration of spinal anaesthesia was done in the desk-bound projection at L 4 -L 5 level through a midline approach by means of a 25-gauge spinal needle. Patients of Group A were administered Midazolam 0.1% infusion starting with 0.5 mg.kg-1.h-1 till BIS level reached

75 and then dose reduced and titrated to maintain a BIS of 65-85. Patients in Group B were administered Propofol 1% infusion starting with 6mg.kg-1.h-1 till BIS level reached 75 and then dose was reduced and titrated to maintain a BIS of 65-85. For the evaluation of efficacy of anesthesia, assessment of pain intraoperatively was done using visual analogue pain scale (VAS) every hour. Anesthesia onset time, sensory block time period, pain free time-period was recorded for each patient. Also, demographic data (age, sex, weight, height) of the patients were recorded.

The statistical analysis of the data was done using SPSS software for windows. Chi-square test and Student's T-test were used to assess the significance of the data. Statistical significance level was defined as P value less than 0.05.

Table 1: Demographic characteristics of patients					
Variables	Group A (n=10)	Group B (n=10)	P-value		
Age (years)	33.11 <u>+</u> 10.21	35.26 <u>+</u> 12.11	-		
Sex (male/female)	1.5	2.33	0.54		
Weight (kg)	78.43 <u>+</u> 11.33	79.45 <u>+</u> 10.22	0.87		
Height (cm)	162.23 <u>+</u> 3.74	167.56 <u>+</u> 4.23	0.43		

Table 2: Comparative analysis of different parameters of anesthesia between Group A and Group B

Parameters	Group A	Group B	P-value
No. of subjects (n)	10	10	
Anesthesia Onset Time (Minutes)	12.21 <u>+</u> 1.96	11.22 <u>+</u> 1.45	0.32
Sensory Block Time Period (Minutes)	122.21 <u>+</u> 12.43	94.11 <u>+</u> 9.16	0.006
Pain Free Time-Period (Minutes)	388.65 <u>+ </u> 56.43	198.45 <u>+ </u> 49.23	0.004

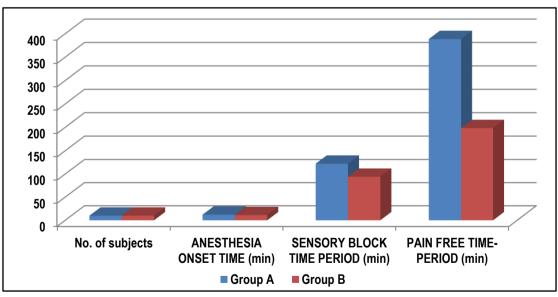


Figure 1: Comparative analysis of different parameters of anesthesia between Group A and Group B

RESULTS

We included 20 patients for the study. Patients were randomly grouped into two groups, Group A and Group B. Table 1 shows different demographic characteristics of the patients. We observed that there was no statistically significant difference between demographic characteristics of the patients of both groups (P>0.05). Table 2 shows the comparative analysis of different parameters of anesthesia between Group A and Group B. The

anesthesia onset time for Group A was 12.21 ± 1.96 minutes as compared to 11.22 ± 1.45 minutes for Group B (P=0.32). The sensory block time period for Group A was 122.21 ± 12.43 minutes in comparison to Group B that was 94.11 ± 9.16 minutes with a P value of 0.006. Also, pain free time-period for Group A was 388.65 ± 56.43 minutes as compared to Group B that was 198.45 ± 49.23 minutes with a P value of 0.004 (Fig 1).

DISCUSSION

In the present study we compared efficacy of Propofol and Midazolam during spinal anesthesia. We observed that the sensory block time period for Midazolam was more in comparison to Group B. Also, pain free time-period for Midazolam was more as compared to Group B. On comparing the results, the results were statistically significant. The results were compared with previous studies and results were consistent with previous studies. Tarhan O et al evaluated the efficacy of subhypnotic doses of midazolam and propofol for peripartum nausea and vomiting during regional anesthesia for elective cesarean section in order to prevent emesis in at least 50% of patients. A prospective, double blind, placebo-controlled study was carried out. Patients were randomly allocated to one of three groups to receive placebo (saline, N=28), propofol (20 mg bolus and 1.0 mg x kg(-1) x h(-1) infusion, N=30), and midazolam (1 mg bolus and 1.0 mg x h(-1) infusion, N=30) at subhypnotic doses intravenously (i.v.) immediately after the umbilical cord was clamped. Bupivacaine hydrochloride (8-10 mg) and fentanyl (10 microg) were injected into the intervertebral space for spinal anesthesia. Blood pressure was monitored at 2 min intervals and intraoperative postdelivery emetic episodes and ephedrine consumption were recorded. The study was carried out at the Anesthesiology Department, Hacettepe University, Turkey, hospitalized care. We included 90 parturients with ASA physical status I and II between the ages of 20 and 38 years undergoing spinal anesthesia for elective cesarean delivery to evaluate the efficacy of subhypnotic doses of propofol and midazolam and, in particular, the incidence of nausea, retching, and vomiting intraoperatively. The incidence of nausea, retching, and vomiting was significantly higher in the control group, compared to the propofol and midazolam groups. Total ephedrine consumption was significantly higher in the control group compared to the propofol and midazolam groups. They concluded that a subhypnotic dose of midazolam (1 mg x h(-1)) was as effective as the subhypnotic dose of propofol (1 mg x kg(-1) x h(-1)) for the prevention of nausea and vomiting in parturients undergoing cesarean section under spinal anesthesia. Khurana P et al compared midazolam and propofol in terms of onset & recovery from sedation, dosage and side effects of both the drugs using Bispectral Index monitoring. Ninety eight patients were randomly divided into two groups, one group received midazolam infusion while the other recieved propofol infusion until BIS reached 75. We observed Time to reach desired sedation, HR, MABP, time for recovery, dose to reach sedation and for maintenance of sedation and side effects if any. The time to reach required sedation was 11 min in Midazolam group(Group I) while it was 6 min in Propofol group(Group II) (p=0.0). Fall in MABP was greater with propofol. Recovery in with midazolam was slower than with propofol (18.6 ± 6.5 vs 10.10±3.65 min) (p=0.00). They concluded that both midazolam and propofol are effective sedatives, but onset and offset was quicker with propofol, while midazolam was more cardiostable.9, 10

Jo YY et al compared the effects of bispectral index (BIS)-guided intravenous sedation using midazolam or dexmedetomidine on hemodynamics and recovery profiles in patients who underwent spinal anesthesia. One hundred and sixteen adult patients were randomly assigned to receive either midazolam (midazolam group; n = 58) or dexmedetomidine (dexmedetomidine group; n=58) during spinal anesthesia. Systolic, diastolic, and mean arterial pressures; heart rates; peripheral oxygen saturations; and bispectral index scores were recorded during surgery, and Ramsay sedation scores and postanesthesia care unit (PACU) stay were monitored. Hypotension occurred more frequently in the midazolam group and bradycardia occurred more frequently in the dexmedetomidine group. Mean Ramsay sedation score was significantly lower in the dexmedetomidine group after arrival in the PACU and PACU stay was significantly longer in the dexmedetomidine group. They concluded that BIS-guided dexmedetomidine sedation can attenuate intraoperative hypotension, but induces more bradycardia, prolongs PACU stay, and delays recovery from sedation in patients during and after spinal anesthesia as compared with midazolam sedation. Nishizawa T et al conducted a meta-analysis of data from randomized controlled trials that compared dexmedetomidine with propofol. They searched PubMed, the Cochrane library, and the Igaku-chuo-zasshi database for randomized trials eligible for inclusion in our meta-analysis. They identified six eligible randomized trials from the database search, and compared the effect of propofol versus dexmedetomidine with respect to: (a) patient's satisfaction level, (b) body movement or gagging, (c) cardiopulmonary complications, and (d) change in heart rate. Data from eligible studies were combined to calculate pooled risk difference (RD) or weighted mean difference (WMD). Compared to propofol, dexmedetomidine significantly decreased the patient's satisfaction level, and there was no significant heterogeneity among the trial results. The pooled RD for developing body movement or gagging when using dexmedetomidine was 0.107, with no significant differences. Compared with propofol, the pooled RD for hypotension, hypoxia, and bradycardia with dexmedetomidine sedation were -0.029, -0.080, and 0.022, respectively, with no significant differences. Compared to propofol. dexmedetomidine significantly decreased the heart rate, without significant heterogeneity. It was concluded that in gastrointestinal endoscopy, patient satisfaction level was higher in propofol administration, when compared to dexmedetomidine. The risk of complications was similar.^{10, 11}

CONCLUSION

Within the limitations of the study we conclude that Midazolam is more efficacious as compared to Propofol, however, both the agents can be used effectively during spinal anesthesia.

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