A Clinical Study of Dexmedetomidine under Combined Spinal Epidural Anaesthesia at a Tertiary Care Hospital

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ABSTRACT

Introduction: *Sedation has been shown to increase patient satisfaction during regional anesthesia and may be considered as a means to increase the patient's acceptance of regional anesthetic techniques. For surgery under regional anesthesia, sedation is a valuable tool to make it more convenient for the patient, the anesthetist, and the surgeon. This study focuses sedative property of Dexmedetomidine in regional anesthesia.*

Material and Method: *This study was conducted in the Department of anaesthesiology, Banaras Hindu University. A randomized prospective study was conducted on 60ASA grade I and II patients of age 20 to 60 years undergoing elective gynaecological surgery. Dexmeditomidine was administered intravenously for sedation. Group A sedation was monitored by BIS and Group B by Ramsay sedation score (RSS).*

Results: *The induction, maintenance and total dose of Dexmedetomidine in group A was significantly less than in group B (28.77±4.44 vs 35.43±6.90, 12.24±2.70 vs 18.57±4.74, and 41.01±5.97 vs 54.00±9.62 mcg p< 0.001). Recovery time was prolonged in group B in comparison to group A (37.87±3.35 vs 22.17±3.19 mins p<0.001). Vitals like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were significantly less than baseline in both groups. Respiratory rate and SPO2 did not change significantly from baseline in both groups.*

Conclusions: *Dexmedetomidine provides effective sedation. Use of BIS during Dexmedetomidine infusion reduces the dose required for sedation.*

Keywords: *Dexmedetomidine, BIS, RSS, Combined spinal epidural anaesthesia, Sedation*

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INTRODUCTION

A large proportion of the gynaecological surgeries are performed under regional anaesthesia.For surgery under regional anesthesia, sedation is a valuable tool to make it more convenient for the patient, the anesthetist, and the surgeon. The depth of sedation should be clearly defined and the infusion of sedative drug precisely targeted to this clinical endpoint. By defining the sedation level and carefully controlling the sedation infusion to meet this endpoint, the dangers of over or under sedation are minimized. Bispectral (BIS) monitoring provides an objective, non-invasive measure of the level of consciousness in sedated patients.BIS guidance has a definite role in modifying the requirement of intravenous sedative agents.[1]

Dexmedetomidine is a novel sedative, providing sedation while patients remain cooperative and can be easily aroused. As a α2-adrenoceptor agonist, dexmedetomidine has both sedative and analgesia effects without respiratory depression. These favourable properties have encouraged use for a wide range of clinical conditions such as an anaesthetic adjunct, intra operative and postoperative sedation and paediatric premedication.[2, 3]

Aim and objective of this prospective study was to compare the sedative property of dexmedetomidine, recovery time and dose requirement with and without BIS monitoring during gynaecological surgeries under combined spinal epidural anaesthesia.

MATERIALS AND METHOD

This study was conducted in the department of anaesthesiology, Sir Sunderlal Hospital, Banaras Hindu University. Prior to commencing the study approval was obtained from the ethical committee. Participants in this study were explained about the anaesthetic procedure and informed consent was taken. A randomized prospective study was conducted on 60 ASA grade I and II patients of age 20 to 60 years undergoing elective gynaecological surgery. All patients received combined spinal epidural anaesthesia. Group A (n=30) included patients receiving Dexmedetomidine with BIS monitoring and group B (n=30) patients received Dexmedetomidine and sedation was monitored with Ramsay sedation score

(RSS). Patients having history of allergy to Dexmedetomidine, any contraindications of spinal anaesthesia, and patients with known psychiatric illness or any previous neurological deficit were excluded from the study.

All participants were premedicated with oral alprazolam 0.5mg at 12 hours and 2 hours before the surgery. Intravenous access was established with 18gauge cannula. Ringer lactate 10ml/kg was administered over 15minutes. Patient's baseline heart rates, systolic blood pressures, diastolic blood pressure, mean arterial pressure, oxygen saturation, and respiratory rate were noted and continous ECG monitoring was instituted.

Patient was put in lateral decubitus position. With all aseptic precautions, skin was cleaned and draped. The L3-L4 space was palpated and the skin and interspinous area was infiltrated with 2% lignocaine with adrenaline to render the procedure pain free. Then a 16 gauge combined spinal epidural needle (B-BRAUN) was put in the interspinous area and epidural space was located by Loss of Resistance with Saline technique. Through the needle a 16 gauge epidural catheter was passed and 3ml of 2.5% lignocaine with adrenaline was administered as a test dose. Patient was observed for 5minutes to rule out any inadvertent intravascular or intrathecal injection. After that, subarachnoid block was given with 2.5 ml of 0.5% bupivacaine heavy.

If the duration of surgery exceeds 2hrs then epidural catheter was charged with 8 ml of 0.25% bupivacaine plain. Epidural catheter was used for maintainance of post operative analgesia. Post operative analgesia was maintained with 8 ml of 0.125% bupivacaine plain through epidural catheter every 6hours for 48 hours.

After confirming the sensory and motor effect of subarachnoid block, BIS sensor was applied and sedation was monitored. Dexmedetomidine loading dose 0.5-1mcg/kg was given over 10 minutes to attain BIS value of 80-85 in patients of Group A. Maintenance dose was in the range of 0.2-0.7mcg/kg was administered all through the procedure to maintain BIS value between 65-85. Dexmede-tomidine infusion was stopped at the end of the surgery.

In group B patients, after confirming the sensory and motor effect of subarachnoid block, Dexmeditomidine sedation was monitored with Ramsay Sedation Scale (RSS).[4] Dexmedetomidine loading dose 0.5- 1mcg/kg was given initially over 10 minutes to attain RSS 3, maintenance dose was in the range of 0.2-0.7mcg/kg to maintain score RSS 3.

Onset time and the Dexmedetomidine dose required for the onset of required level of sedation were recorded. Heart rate, mean arterial blood pressure and oxygen saturation were recorded at 15 minutes interval time. Dexmedetomidine infusion was stopped ten minutes before completion of surgery and recovery time (BIS value 90, or Ramsay sedation score 2) was noted.

STATISTICAL ANALYSIS

Power of the study was 92% (.92) as calculated by two tailed test. The statistical analysis was done using SPSS for Windows version 16.0 software. For non-continuous data Chi-square test was used. The mean and standard deviation of the parameters studied during observation period were calculated for two treatment groups and compared using Student 't' test. The critical value of 'p' indicating the probability of significant difference was taken as <0.05 for comparisons.

OBSERVATION AND RESULTS

The two groups were similar with respect to age and weight (Table 1;p >0.05). The induction dose of dexmedetomidine in group A (28.77±4.44 mcg) was significantly less than in group B (35.43±6.90 mcg p<0.001). Maintenance dose of dexmedetomidine was significantly less in group A (12.24±2.70 Vs 18.57±4.74 mcg p<0.001). Total dose of dexmedetomidine consumed throughout the surgery was significantly less in group A (41.01±5.97Vs 54.00±9.62 mcg p<0.001). Recovery time was prolonged in group B (37.87±3.35Vs 22.17±3.19 mins p<0.001).Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were significantly less than baseline in both groups during intra operative period and the inter group changes in these parameters were not significant. Respiratory rate and SPO2 did not change significantly from baseline in both groups and inter group changes were also not significant. Incidence of bradycardia in both the groups was same; whereas incidence of hypotension was more in group B than in group A. There were no incidences of other adverse effects like hypertension hypoxia, Post operative nausea and vomiting, urinary retention, atrial fibrillation in both the groups.

Table 1: Demographic Data

Groups	Group A N = 30	Group B N = 30	t-value	p-value
Mean Age ± SD (Years)	38.10±9.034	40.40±9.761	0.947	0.347
Mean Weight ±SD (Kg)	54.73±6.275	52.13±7.186	1.493	0.141

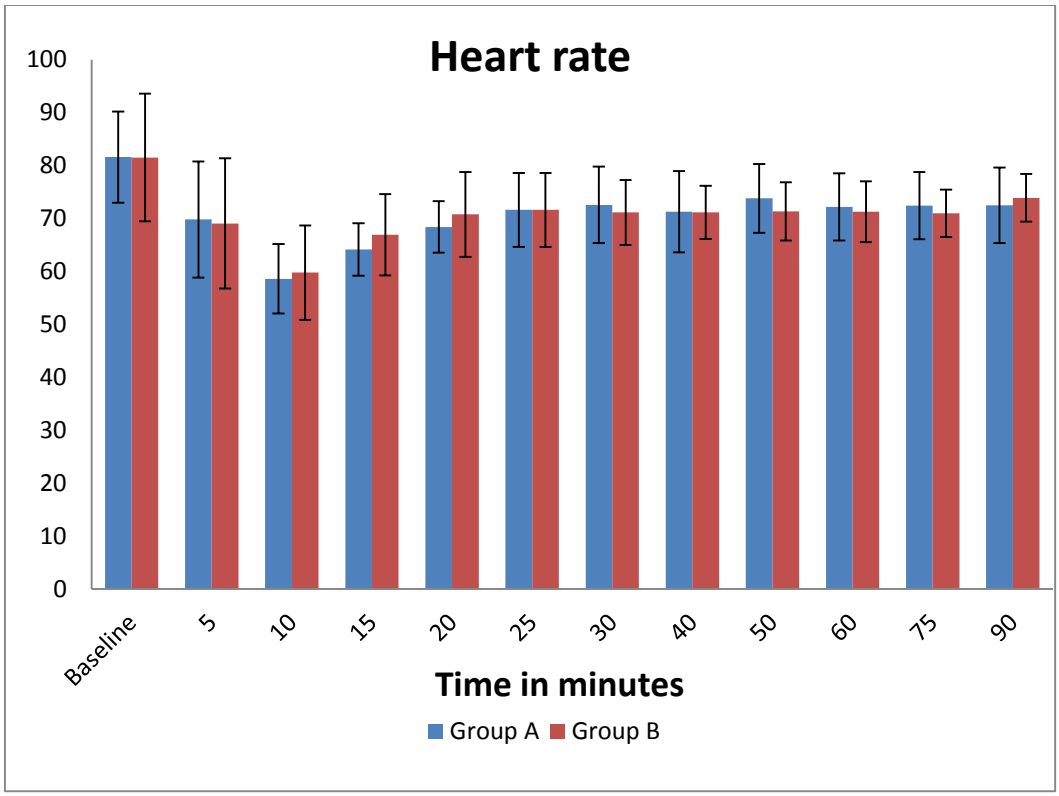


Figure1: Comparison of mean heart rate (HR) in both groups at various intervals

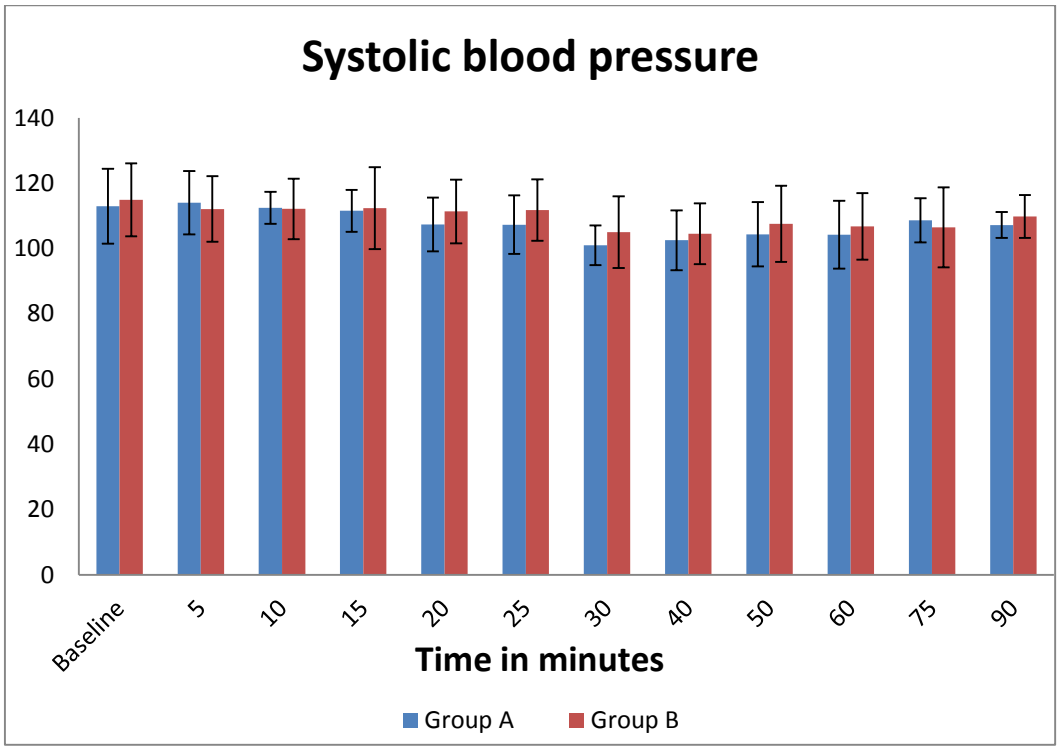


Fig. 2: Comparison of mean systolic blood pressure (SBP) in both groups at various intervals

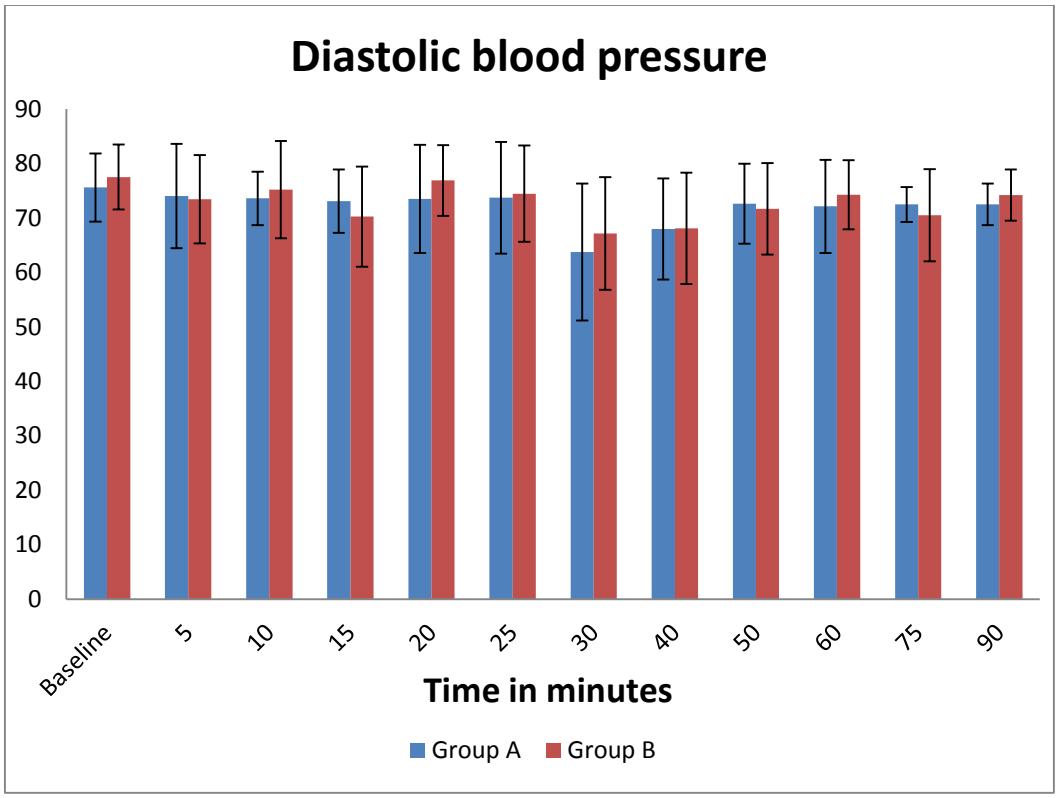


Fig. 3: Comparison of mean diastolic blood pressure (DBP) in both groups at various intervals

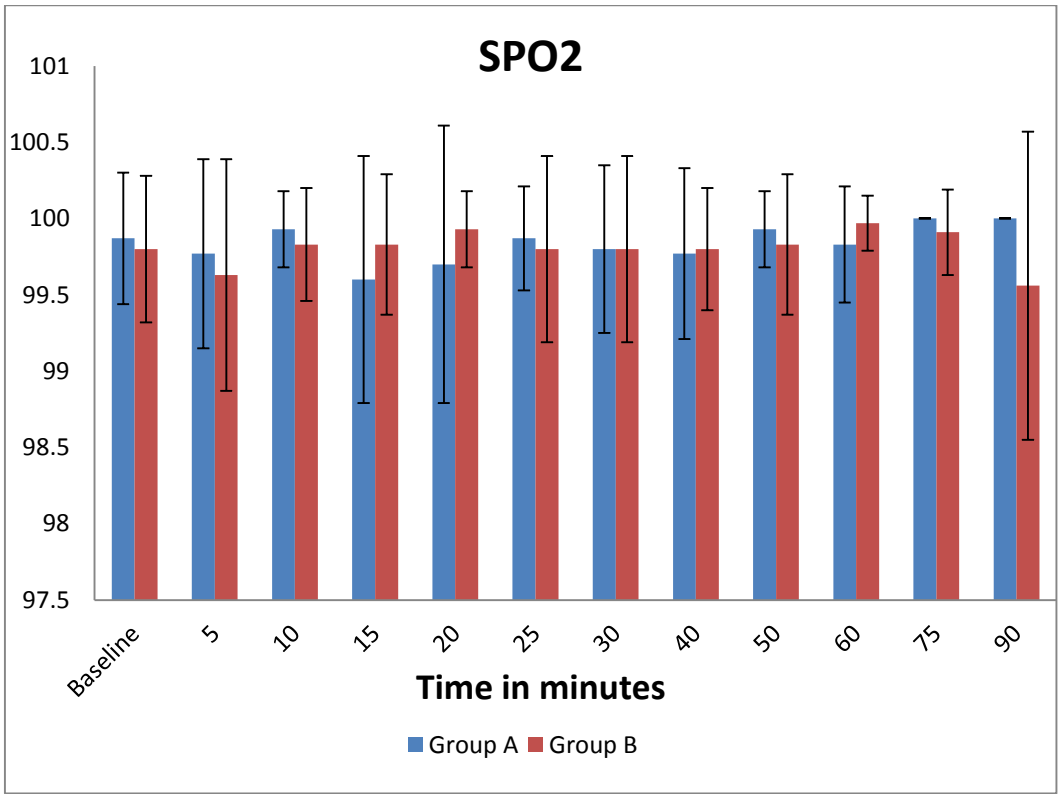


Fig. 4: Comparison of mean peripheral oxygen saturation (SPO2) in both groups at various intervals

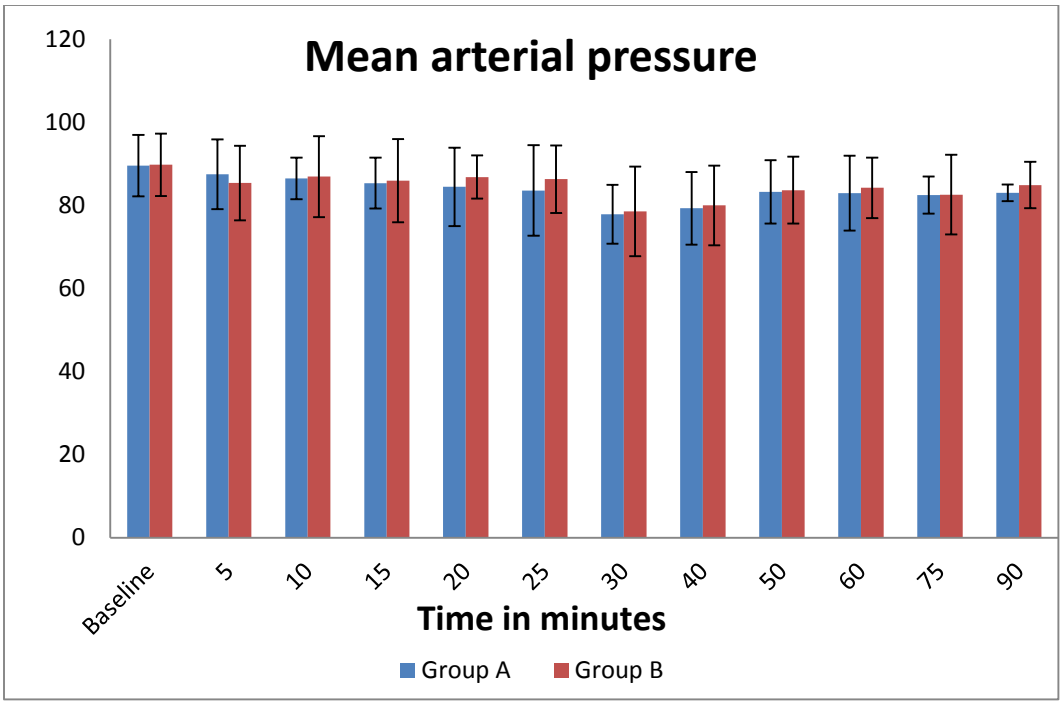


Fig. 5: Comparison of mean arterial pressure (MAP) in both groups at various intervals

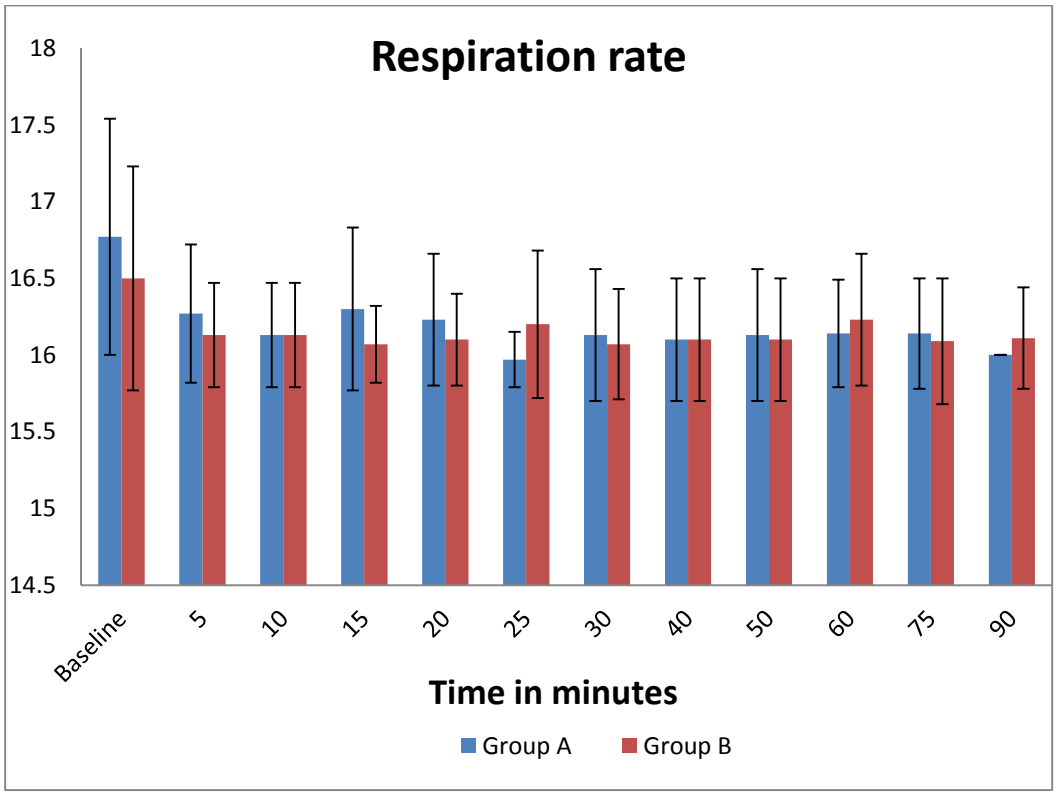


Fig. 6: Comparison of mean respiratory rate (RR) in both groups at various intervals

Table2: Comparison of induction dose (mcg) in both groups

Group	Induction of Sedation (Mean±SD) (mcg)	t-value	p-value
A	28.77±4.44	4.445	<0.001
B	35.43±6.90		

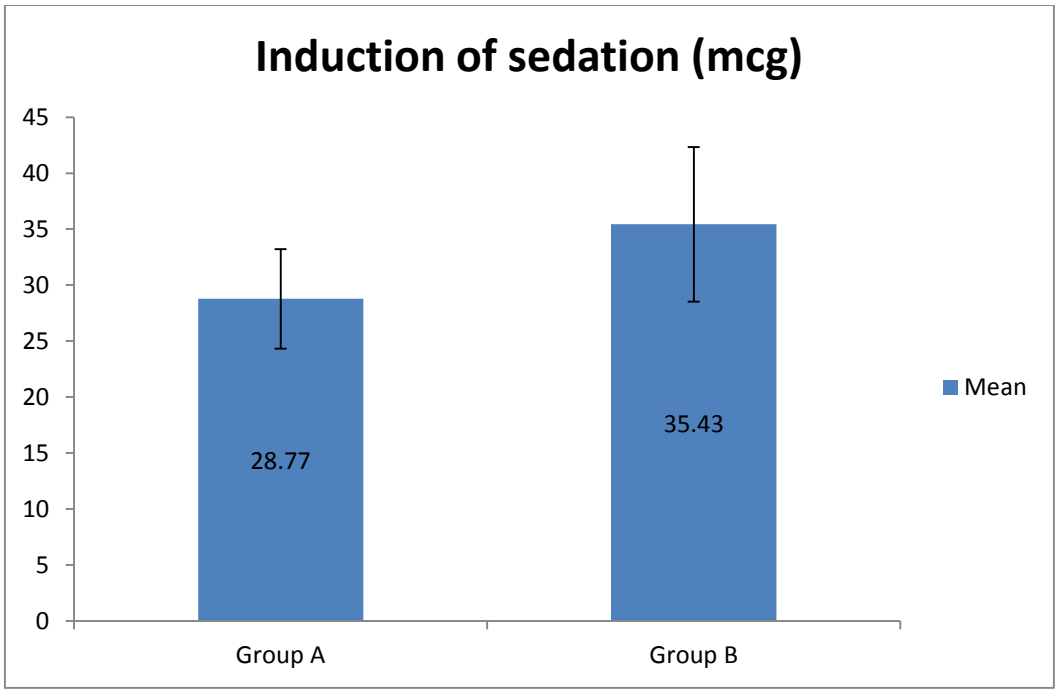


Table4: Comparison of total dose (mcg) in both groups

Group	Total dose (Mean±SD)(mcg)	t-value	p-value
A	41.01±5.97	6.279	<0.001
B	54.00±9.62		

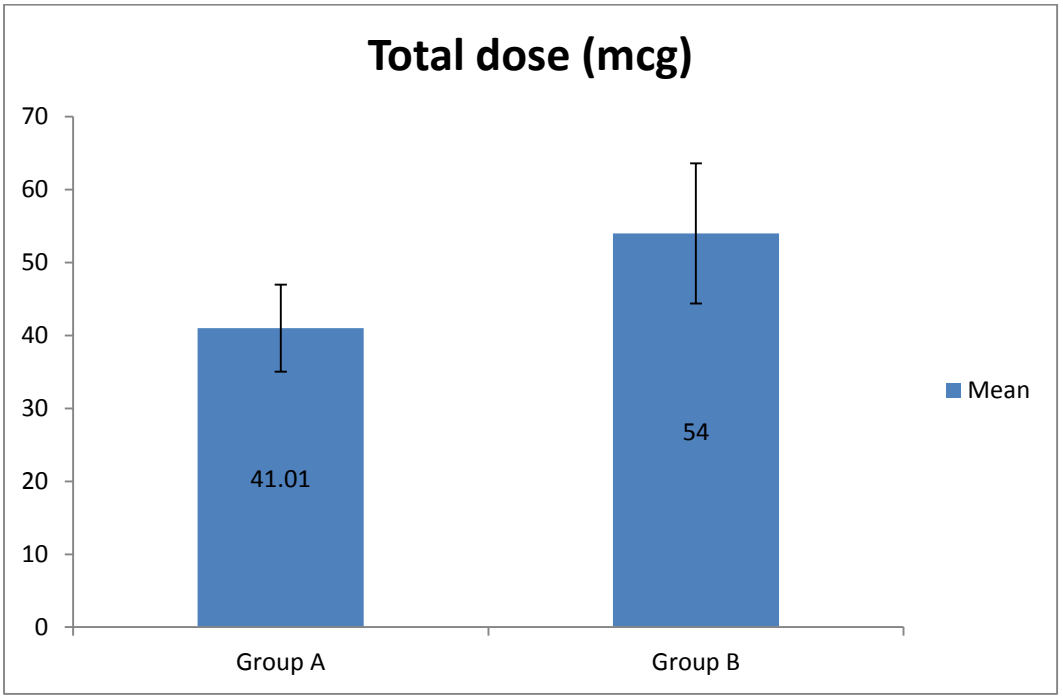


Table3: Comparison of maintenance dose (mcg) in both groups

Group	Maintenance dose (Mean±SD) (mcg)	t-value	p-value
A	12.24±2.70	6.338	<0.001
B	18.57±4.74		

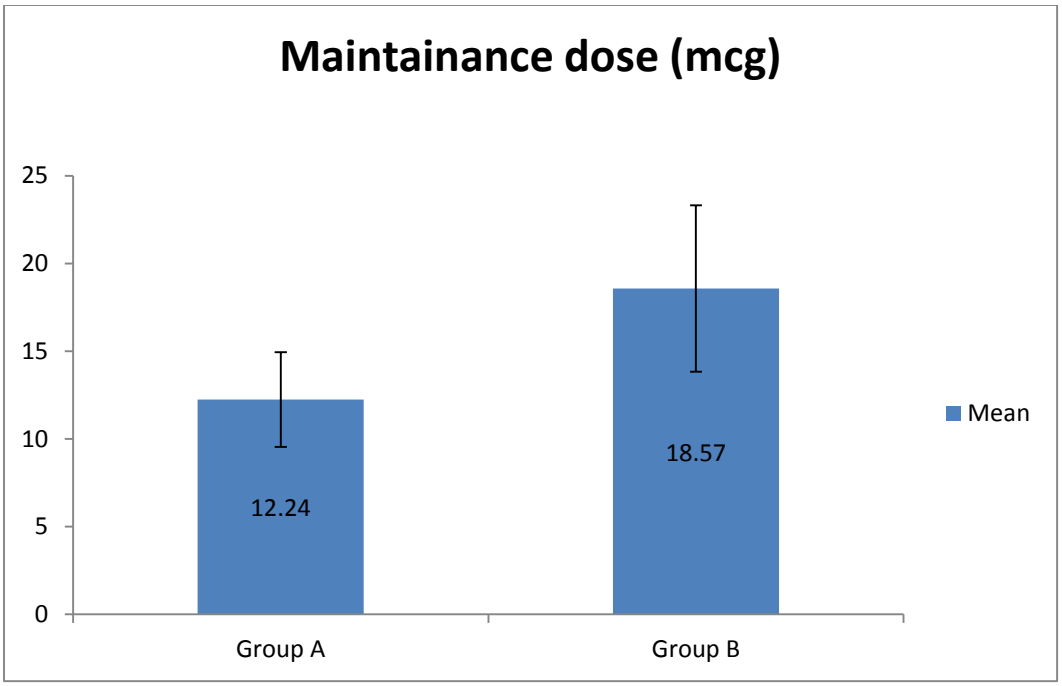
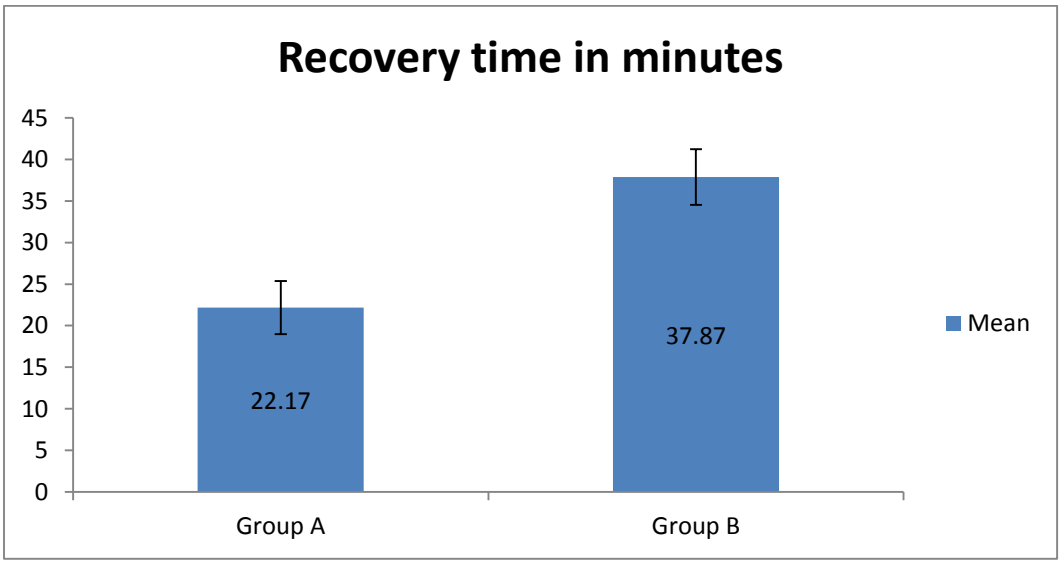


Table5: Comparison of recovery time (minutes) in both groups

Group	Recovery Time (Mean±SD) (Minutes)	t-value	p-value
A	22.17±3.19	18.573	<0.001
B	37.87±3.35		



DISCUSSION

Regional anaesthesia has many advantages over general anaesthesia. Regional anaesthesia is associated with lower incidence of respiratory and cardiovascular complications, better postoperative pain management, lower incidence of deep vein thrombosis and pulmonary embolism.

The assessment of depth of sedation can be done by Ramsay sedation scale, motor activity assessment scale, sedation agitation scale. More recently an objective assessment of depth of sedation, BIS monitor has been invented. The bispectral index (BIS), an EEG derivative, has been shown to be a sensitive and simple monitor to assess the hypnotic component of anaesthesia, and the level of consciousness during dexmedetomidine sedation.[5]

There is dearth of validating studies of monitoring dexmeditomidine sedation with RSS and BIS monitoring. However we have found that some studies comparing dexmedetomidine with other

sedative agents like midazolam, propofol using BIS and RSS[5,7,8]. Pollock and colleagues[6] reported that in volunteers, spinal anesthesia leads to a significant decrease in BIS level. Several studies have shown that the interaction between spinal local anesthetics and sedatives leads to an augmentation of the sedation causing a decrease in the required dose of intravenous anaesthetic agents.[7,8] Supplement of intravenous dexmedetomidine in patients receiving combined spinal epidural anaesthesia may provide a good sedative effect without any clinically important untoward cardio respiratory reactions.[9]

Yongixn liang et al (2011)[10] reported that there was no respiratory depression with dexmedetomidine. In our study in both group A and group B, respiratory rate and SPO2 did not change significantly from baseline throughout the intra operative period. Respiratory depression was not noted. In the same study[10] they reported that there was bradycardia noted in 11% of patients during dexmedetomidine infusion and the definition of bradycardia was heart rate (HR) less than 50 per min. In present study we found 76.6% of patients in group A and 80% patients in group B had bradycardia during induction dose. However the definition of bradycardia in our study was HR less than 60 per min and the bradycardia noted during induction got settled automatically and no treatment was required. Judith et al (2000)[11] in their study mentioned that with small (0.2mcg/kg/hr) and moderate doses (0.6mcg/kg/hr) of dexmedetomidine they noticed 20% and 16% decrease in heart rate from baseline during initial 10minutes of initial dose (6mcg/kg/hr) respectively. In our study heart rate was significantly less than baseline throughout intra operative period in both the groups

Yongixn liang et al[10] reported hypotension in 8% of patients. In their study definition of hypotension was <30% of MAP from baseline. The large percentage in our study might be because we had kept the definition of hypotension as mean arterial pressure (MAP) < 20%.In present study we had noticed hypotension in 56% in group A and 80% in group B. Ashraf et al (2011)[12] mentioned that the MAP during intra operative period with dexmedetomidine sedation was significantly less than baseline. They also mentioned HR was significantly less from baseline throughout the surgery. In our study MAP was significantly less than baseline in both the groups after 15mins till end of the surgery.

Bell et al (2004)[13] compared RSS with BIS and found that BIS monitoring enables more effective titration of sedatives to maintain a suitable level of consciousness, while reducing procedure time. The BIS offers an objective, safe and reliable measure of sedation, without disturbing either patient or operator. In our study the BIS group required significantly less dose of dexmedetomidine for both induction and maintainance and total dose for throughout the surgery was also significantly less in comparison to RSS group. The cause of decreased dose requirement and lowered recovery time in BIS group could be due to the continuous graphical monitoring with BIS monitor and BIS is non intrusive. Recovery time was significantly lower in BIS group. From present study, it is concluded that Dexmedetomidine provides effective sedation following combined spinal epidural anaesthesia without any significant side effects.

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Conflict of interest; - There was no conflict of interest from any author.

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