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Original Research Article

COMPARISON BETWEEN INTRAVENOUS DEXMEDETOMIDINE AND MIDAZOLAM FOR SEDATION DURING ORTHOPEDICS SURGERIES UNDER SUPRA CLAVICULAR BRACHIAL PLEXUS BLOCK

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Abstract

Background: Brachial plexus block (BPB) is a popular and widely employed regional nerve block of the upper extremity. Midazolam and Dexmedetomidine are commonly used drugs for sedation during BPB. Present study was aimed to compare intravenous dexmedetomidine and midazolam for sedation during orthopedics surgeries under supra clavicular brachial plexus block. **Materials and Methods:** Present study was double-blind, randomized, comparative study, conducted in patients of Age-18 to 50 years, either sex, with ASA I, undergoing upper extremity surgery under supraclavicular brachial plexus blockpatients were divided in 2 equal groups as Group D (Dexmedetomidine Infusion)&Group M (Midazolam infusion). **Result:** Both groups were comparable regarding their age, body weight, duration of surgery, baseline MAP, SPO2 and RSS value. Intraoperative HR values were significantly lower in group D.Intraoperative MAP values were comparable up to 30 mins between the groups. Subsequently MAP values were significantly lower in group M in comparison to group D. The onset of sedation (BIS 75) was earlier in group D in comparison to group M which was statistically significant. Intraoperative BIS values were lower ingroup D. After discontinuation of the study drug, higher BIS value (BIS 90) wasachieved earlier in dexmedetomidine group which was statistically significant. At BIS 90, RSS values were comparable between the groups.There was no episode of desaturation in group D. However desaturation was observed among 4 patients of group M. Higher patient satisfaction score was found in group D in comparison to group M, which was statistically significant. The onset of sensory and motorblock was quicker in the dexmedetomidine group than in the midazolam group. The duration of sensory as well as motor block was more prolonged in the dexmedetomidine group than in the midazolam group. **Conclusion:** Dexmedetomidine is superior than midazolam for intraoperative sedation during upper limb surgery under BPB.

INTRODUCTION

Brachial plexus block (BPB) is a popular and widely employed regional nerve block of the upper extremity. Various approaches to brachial plexus block have been described but supraclavicular approach is the easiest and most consistent method for anaesthesia and perioperative pain management in surgery below the shoulder joint. Supraclavicular brachial plexus block is an excellent technique in experienced hands. Pneumothorax (1-6%), Hemothorax, Horner's syndrome and phrenic nerve block are the potential complications. It provides good surgical condition, prolongs analgesia and decreased opioid administration during postoperative period.[1]

Sedation should be administered along with BPB, which will provide amnesia, anxiolysis, freedom from recall of surgery, about the procedure and postural discomfort.[2] Loud noises, untoward remarks in the operating room perceived by the

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patients, may have long term undesirable psychological effects.[3] So administration of sedation is essential during surgeries performed under regional anesthesia.[4] Various drugs may be used for sedation during BPB, but the preferred drugs are those which produce sedation and maintain cardiovascular stability with minimum respiratory depression.[5]

Midazolam and Dexmedetomidine are commonly used drugs for sedation during BPB. Midazolam is a benzodiazepine with relatively early onset of action and early recovery time due to its short half-life, as compared to diazepam. The primary drawback of midazolam is potential accumulation of drug that can cause prolonged sedation and hangover effect when used as infusion over prolonged time.[6] At therapeutic level it provides sedation, reasonable patient satisfaction, less opioid requirement and less respiratory depression without affecting cardiovascular stability.[7] Present study was aimed to compare intravenous dexmedetomidine and midazolam for sedation during orthopedics surgeries under supra clavicular brachial plexus block.

MATERIALS AND METHODS

Present study was double-blind, randomized, comparative study, conducted in department of Anaesthesiology & Critical Care, SCB Medical College and Hospital, Cuttack, India. This study was conducted from August 2017 to November 2019. Study was approved by institutional ethical committee.

Inclusion Criteria

- Patients of Age-18 to 50 years, either sex, with ASA I, undergoing upper extremity surgery under supraclavicular brachial plexus block, willing to participate in present study

Exclusion Criteria

- Patients who refused to participate
- Difficult airway anticipated in preoperative assessment.
- Patients with known contraindications to brachial plexus block (coagulopathy or local infection)
- Patients with known allergy to bupivacaine, midazolam or dexmedetomidine
- Patients not having adequate block or requiring other drugs as supplement or conversion to general anaesthesia.
- Patients who failed brachial plexus block
- Patients ASA physical status II, III and IV.
- History of significant systemic illness like Bronchial asthma, Chronic Obstructive Pulmonary Disease, Liver diseases, Conduction blocks, Hypertensive patients, Renal diseases, Neurological illnesses, myopathies,
- Pregnant and lactating females.

Patients on any opioid or sedative medication or those medications in the week prior to surgery. All patients were assessed for pre-anaesthetic check-up and airway assessment before admission to the ward. A written informed consent was taken for enrolment in study after proper explanation of the procedure of the study and different aspects of BPB under peripheral nerve stimulator (PNS) guidance. Sample assignment was done by sequential allocation using sealed opaque envelope in to 2 equal groups: —

- Group D (Dexmedetomidine Infusion)
- Group M (Midazolam infusion)

All patients were premedicated with oral ranitidine 150 mg and oral alprazolam 0.25 mg night before surgery. All were kept nil per oral 6 hour prior to surgery. On arrival to the operation theatre, intravenous access was established with 18G/20G cannula on the dorsum of the non-operative hand. Routine monitoring in the form of electrocardiography, non-invasive arterial pressure, pulse oximetry and respiration was done, and baseline values were noted. Oxygen at a rate of 5 l /min through a face mask was administered to all patients.

The infusions were prepared by an independent clinician not involved in the study. The anaesthesiologist performing the block and observing the patient was blinded to the treatment group. Neither the patient nor the attending anaesthesiologist who also collected the data was aware of group allocation.

Group D patients were given 0.5 mcg/kg IV dexmedetomidine over 10 min. bolus followed by 0.1 mcg/kg/hr infusions as maintenance until the end of surgery. Group M were given 0.05 mg/kg IV midazolam over 10 min. bolus followed by 0.01 mg/kg/hr infusion as maintenance until the end of surgery.

Variation of BIS scores after starting of infusion was recorded every 10 mins till completion of surgery between the study groups. After starting of the infusion, when BIS score reaches down to 75, with prior aseptic preparation of the area, brachial plexus block was given with local infiltration of injection site with injection bupivacaine 0.5% plain by supra clavicular approach under PNS guidance. Surgeons were allowed to give incision, 30 min after the block.

Time to reach BIS score 75 was also noted and was considered as onset of sedation. Patient not having adequate block or requiring other drugs as supplement and or conversion to general anaesthesia was excluded from the study. Hemodynamic parameters like MAP (Mean arterial pressure), Heart rate and SpO2 were recorded at the point of time when BIS reaches 75 and in every 10 mins, from the starting point of infusion to completion of surgery.

Infusion was stopped at completion of surgery and Ramsey sedation score was recorded at that point. Duration of postoperative analgesia was recorded when the patient was complaining of pain, first time after surgery. Time to reach BIS score of 90 (taken as recovery point from sedation) in both groups was

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recorded. At that point, Ramsay sedation score was recorded.

Data were compiled and subjected to statistical analysis using the Statistical Package for Social Sciences(SPSS Inc.; Version20.0. Chicago, IL, USA). Categorical variables were expressed as Number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes. Continuous variables were expressed as Mean ± Standard Deviation and compared across the 2 groups using unpaired t test. P value was less than 0.05, was considered as statistically significant.

RESULTS

100 patients were enrolled and randomised to either of the two groups, 50 patients in each. The mean age, mean body weights & duration of surgery of the study participants was not found to be statistically significant (p> 0.05) and were thus comparable among both groups. There was a total of 60 males (60%) and 40 females (40%) as study participants, and the groups were not found to have significant (p=0.414) with respect to gender.

Haemodynamic parameters, i.e., heart rate and mean arterial pressure, in both the groups were compared at an interval of 10 min during maintenance infusion. The baseline value of mean arterial pressure was comparable in both groups and remained so until the end of the infusion.

Intraoperative MAP values were significantly lower in group M at 60 minutes interval and onwards.

Table 1: General characteristics.

Gender	Group D	Group M	P value
Age (years).	33.58 ±9.2	35.8 ± 9.26	0.232
Body weight (kg).	54.82 ± 5.92	54.32 ± 5.79	0.670
Duration of surgery (minutes).	97.6 ±29.39	86.3 + 29.53	0.058
Gender			
Female	22 (44%)	18 (36%)	0.414
Male	28 (56%)	32 (64%)	

Table 2: Intraoperative MAP (mm Hg) at different time intervals.

	Group D (Mean+ SD)	Group M (Mean+ SD)	P Value
MAP 0	94.65 ±5.87	96.77 ± 5.28	0.061
MAP BIS 75	92.44 ± 5.63	93.5 ±4.91	0.318
MAP 10	92.11 ±5.65	93 ±4.74	0.394
MAP 20	90.87 ± 5.52	91.39 ± 4.36	0.597
MAP 30	90.09 ± 5.62	89.56 ± 4.39	0.598
MAP 40	89.35 ± 5.81	88.09 ±5.19	0.258
MAP 50	88.83 ±5.55	86.98 ±4.71	0.075
MAP 60	88.7 ±5.71	85.83 ±5.28	0.011
MAP 70	88.19 ±5.24	85.48 ±4.93	0.009
MAP 80	87.48 ±5.54	84.09 ±5.2	0.002
MAP 90	87.33 ±5.54	83.22 ± 4.94	<0.001
MAP 100	86.96 ±6.02	83.12 ± 4.98	0.004
MAP 110	86.81 ±5.56	83.1 ±4.48	0.007
MAP 120	85.94 ± 5.74	82.28 ±4.86	0.024

The mean heart rates were found to be lower in the dexmedetomidine group after 20 min of infusion until the end of the infusion. The baseline values of mean heart rate were comparable in both groups and remained so during the initial infusion of sedatives and up to 10 min thereafter.

Table 3: Intraoperative HR (bpm) at different time intervals.

	Group D (Mean+ SD)	Group M (Mean+ SD)	P value
Heart Rate 0	90.54 ± 11.01	100.4 ± 13.06	<0.001
Heart Rate Bis75	85.86 ± 10.6	95.44 ± 11.66	<0.001
Heart Rate 10	85.18 ± 10.43	94.94 ± 11.84	<0.001
Heart Rate 20	81.5 ± 9.82	9 1.9 ±10.98	<0.001
Heart Rate 30	79.34 ± 10.44	89.94 ± 11.18	<0.001
Heart Rate 40	78.2 ± 10.68	88.94 ± 10.82	<0.001
Heart Rate 50	76.52± 10.69	88.3 ± 10.86	<0.001
Heart Rate 60	74.96 ± 10.51	87.52 ± 10.64	<0.001
Heart Rate 70	73.8 ± 10.81	86.26 ± 9.85	<0.001
Heart Rate 80	72.7 ± 10.47	85.53 ±9.73	<0.001
Heart Rate 90	72.68 ± 10.5	85.48 ± 9.69	<0.001
Heart Rate 100	70.73 ± 10.03	85.54 ± 8.97	<0.001
Heart Rate 110	71.5 ±8.85	85.54 ± 9.01	<0.001
Heart Rate 120	71.59 ± 8.57	85.21 ±9.91	<0.001

Intraoperative SpO2 values were comparable between the groups.

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Table 4: Intraoperative SpO2 (%) at different time intervals.

	Group D (Mean+ SD)	Group M (Mean+ SD)	P Value
$Sp0_20$	100 ± 0	100 ±0	NA
$Sp0_2$ BIS75	99.96 ±0.28	99.9± 0.42	0.401
$Sp0_2$ 10	99.98±0.14	99.82 ± 0.56	0.053
$Sp0_2$ 20	99.96 ±0.28	99.9±0.42	0.401
$Sp0_2$ 30	99.96 ±0.28	99.86±0.5	0.218
$Sp0_2$ 40	99.94±0.42	99.68 ± 1.46	0.230
$Sp0_2$ 50	99.96± 0.28	99.82± 1.27	0.450
$Sp0_2$ 60	99.96±0.28	99.96 ± 0.2	1.000
$Sp0_2$ 70	99.98±0.14	100±0	0.320
$Sp0_2$ 80	99.96±0.28	99.96±0.29	0.989
$Sp0_2$ 90	99.96 ± 0.28	99.96 ± 0.29	0.953
$Sp0_2$ 100	99.91±0.43	99.74±1.52	0.501
$Sp0_2$ 1 10	99.97 ±0.1 7	100±0	0.393
$Sp0_2$ 120	99.94±0.35	100±0	0.453

Intraoperative BIS values were lower in group D, which was statistically significant.

Table 5: Intraoperative BIS values at different time intervals.

	Group D(Mean + SD)	Group M(Mean + SD)	P value
BIS 10	73.4 ± 1.23	75.38 ± 2.82	<0.001
BIS20	70.8 ±1.32	71.14 ±2.68	0.423
BIS30	68.4 ± 1.28	70.02 ± 3.63	0.004
BIS40	67.34 ± 1.41	68.34 ± 3.11	0.041
BIS50	66.6 ±1.36	67.38 ± 2.95	0.092
BIS60	65.44 ± 2.12	66.42 ±3.1	0.068
BIS70	64.54 ± 2.33	65.5 ± 3.45	0.106
BIS80	63.64 ± 3.18	65.29 ± 3.7	0.019
BIS90	62.96 ± 3.69	64.93 ± 3.63	0.010
BIS 100	62.73 ± 3.76	64.71 ± 3.36	0.019
BIS110	62.76 ± 4.06	65.38 ± 3.1	0.008
BIS 120	63.16 ± 3.82	66.25 ± 2.34	0.002

Significantly more time was required to reach BIS value 75 in group M patients as compared to group D.

Table 6: Time (minutes) of onset of sedation (BIS 75) & recovery from sedation (BIS 90).

	Group D (Mean+SD)	Group M (Mean+SD)	P value
Time BIS 75	7.98 ±1.41	12. 14 ±2.36	<0.001
Time BIS 90	15.78±2.74	28.8 ±5.21	<0.001

Significantly a greater number of patients had higher sedation score in group M compared to group D.

Table 7: RSS at different time intervals.

RSS at different time interval	RSSvalues	Group D	Group M	P value
RSS I (anxious and agitated or restless)	RSS 2	50 (100%)	50 (100%)	NA
RSS II (co-operative, oriented, and tranquil)	RSS 2	26 (52%)	46 (92%)	<0.001
	RSS 3	24 (48%)	4 (8%)	
RSS III (responds to commands only)	RSS 1	0 (0%)	1 (2%)	0.315
	RSS 2	50 (100%)	49 (98%)	

The onset of sensory and motor block was quicker in the dexmedetomidine group than in the midazolam group. The mean sensory block onset time was 15.7 ±1.8 min in the dexmedetomidine group and 18.9 ±1.7 min in the midazolam group (p<0.001). The mean motor block onset time was 18.6 ±2.8 min in the dexmedetomidine group and 22.7 ±1.5 min in the midazolam group (p<0.001).

The duration of sensory as well as motor block was more prolonged in the dexmedetomidine group than in the midazolam group. The duration of sensory block in the dexmedetomidine group was 699.0 ± 56.9min, whereas in the midazolam group, it was 337.9 ±41.8min (p<0.001). The duration of motor block in the dexmedetomidine group was also prolonged; it was 610.3 ± 72.5min in the dexmedetomidine group and 298.1 ± 29.5min in the midazolam group (p<0.001). Significantly a greater number of patients developed intraoperative desaturation in group M.

Table 8: Block Characteristics in Minutes

Block characteristics	Group D (Mean +SD)	Group M (Mean+ SD)	P Value
Onset of sensory block (min)	15.7 ±1.8	18.9 ±1.7	<0.001
Onset of motor block (min)	18.6 ±2.8	22.7 ±1.5	<0.001
Duration of sensory block (min)	699.0 ± 56.9	337.9 ±41.8	<0.001
Duration of motor(min)	610.3 ± 72.5	298.1 ± 29.5	<0.001
Intraoperative desaturation	50 (100%)	46 (92%)	0.041

Significantly a greater number of patients had higher patient satisfaction score in group D.

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Table 9: Patients satisfaction score.

Patient Satisfaction Score	Group		Total	
	Group D	Group M		P Value
Satisfied Somewhat	4 (8%)	25 (50%)	29 (29%)	<0.001
Satisfied	32 (64%)	23 (46%)	55 (55%)	
Extremely Satisfied	14 (28%)	2 (4%)	16 (16%)	

DISCUSSION

Although general anesthesia continues to be used for most of the surgical procedures, regional anesthesia has been increasing in popularity in recent years. This is mainly because of the fact that the regional anesthesia techniques can be utilized for analgesia not only during the operative period, but during the postoperative period as well and avoids complications of general anaesthesia. A regional technique should always be considered whenever general condition of the patient is poor, or the patient is not adequately prepared or in the presence of associated conditions like uncontrolled diabetes, cardiovascular or respiratory diseases.

The brachial plexus block consists of injecting local analgesic drugs in the fascial spaces surrounding the nerve plexus, thereby blocking the autonomic, sensory and motor fibers supplying the upper extremity. It is a simple, safe and effective technique of anesthesia having distinct advantages over general and intravenous regional anesthesia.

Sedation during regional blocks is routinely employed. It would be beneficial if such an agent also prolonged the duration of block. Various studies had been performed to compare dexmedetomidine and midazolam for intraoperative sedation.[7] Propofol produces rapid onset and offset of sedation. However, it produces hypotension, respiratory depression and airway obstruction.[8,9] So this study was conducted to compare dexmedetomidine and midazolam for intraoperative sedation during upper limb surgeries under BPB.

The onset and intraoperative sedation and recovery from sedation was compared between dexmedetomidine and midazolam. Time to reach BIS 75 was considered as onset of sedation which was significantly ($p < 0.001$). Earlier in group D (7.98±1.41) in comparison to group M (12.14 ± 2.36). At BIS 75 RSS(RSS-I) was also recorded which was comparable between the groups. This finding was also supported by study performed by Jo Y, Lee D, Jung W et al,[8] comparison between intravenous dexmedetomidine and midazolam for bispectral index guided sedation during spinal anesthesia.

In this study we observed that intraoperative BIS value was lower with dexmedetomidine infusion in comparison to midazolam infusion. This findings corroborates with other studies like study by Liang Y, Gu M et al,[9] on dexmedetomidine vs midazolam for sedation in gynaecologic surgery under epidural anesthesia showing dexmedetomidine significantly reducing fentanyl requirement and both drugs showing similar patient and surgeon satisfaction scores and no difference in time to recovery.

Intraoperative MAP values were comparable between the groups from initial 50 mins, but subsequent values were significantly lower in group M in comparison to group D. However, all recorded values of HR were significantly lower in group D ($p<0.01$) in comparison to group M. Dexmedetomidine reduces the release of norepinephrine induced by presynaptic alpha 2-receptor activation and inhibits sympathetic activity induced by postsynaptic receptors in the central nervous system, and these can decrease blood pressure and heart rate. Given its anxiolytic and sedative properties, midazolam has negative inotropic activity in atrial tissues mediated by the inhibition of L-type calcium channels. However, although dexmedetomidine and midazolam reduce blood pressure and heart rate, a previous comparative study demonstrated lower heart rate and blood pressure during third molar surgery for dexmedetomidine compared to midazolam during monitored anesthesia care.[10]

However, in this present study, blood pressure was significantly higher in the dexmedetomidine group during the sedation period. Dexmedetomidine provokes an initial transient increase in blood pressure because of alpha 2- adrenoceptor-mediated vasoconstriction in peripheral vessels, and a diminished heart rate could increase blood pressure mediated by the baroreceptor reflex. However, midazolam causes a transient baroreflex depression and a sustained decrease of sympathetic tone in humans. It has been reported that the preserved baroreflex and transient biphasic hemodynamic response observed during dexmedetomidine administration can attenuate hemodynamic changes induced by thoracolumbar sympathetic block and venous pooling during spinal anesthesia in the study performed by Jo Y, Lee D et al,[8] comparing iv dexmedetomidine and midazolam for bispectral index guided sedation during spinal anesthesia.

These results suggest that dexmedetomidine has clinical advantage over midazolam in providing a better operative field for microscopic surgery. Durmus et al have evaluated this property of dexmedetomidine for providing controlled hypotension in general anesthesia for tympanoplasty cases and concluded that it is a useful adjuvant to decrease bleeding when a bloodless surgical field is required.[11]

In a randomized controlled study, Kathuria et al,[12] evaluated dexmedetomidine as an adjuvant to ropivacaine in supraclavicular brachial plexus block. Perineural addition and intravenous co-administration of dexmedetomidine both led to a decrease in the onset time and an increase in the duration of motor and sensory blockade. They

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observed that these effects were more prominent in patients who had received dexmedetomidine perineurally. However, they administered dexmedetomidine infusion over 15 min only, whereas in our study, it was continued until the end of surgery. Similar to our study, there were no significant side effects such as excessive sedation, hypotension or bradycardia.

Agarwal S et al,[13] evaluated the effect of perineural dexmedetomidine added to 0.325% bupivacaine compared to that of bupivacaine solution with normal saline. Perineural dexmedetomidine as an adjuvant significantly shortened the onset and prolonged the duration of sensory and motor blockade.

Higher patient satisfaction score was found in group D in comparison to group M, which was statistically significant. Other study also corroborates with a study done by Alhashemi J et al,[14] showed that dexmedetomidine failed to elicit any hemodynamic changes with significant sequelae, but provided a favourable respiratory profile.

A possible limitation of this study could be that amnesia scoring & cognitive function testing for psychomotor impairment was not done. Midazolam has a potent anterograde amnestic effect and dexmedetomidine also results in memory impairment.[15]Another limitation could be that effects of the drugs were seen only in ASA 1 patients. The effects of alpha 2 agonist on cardiovascular system may be beneficial in high risk patients. Further studies need to be carried out recruiting high risk patients.

Dexmedetomidine infusion resulted in stable haemodynamic parameters with a better block profile, without significant side effects. This was in agreement with the findings of other studies where dexmedetomidine was found to be a valuable addition for sedation in patients undergoing upper limb surgeries under brachial plexus block.[16,17]

CONCLUSION

In this study, the early onset, rapid recovery and better intraoperative sedation, hemodynamic stability without episode of desaturation were observed in dexmedetomidine group in comparison to midazolam group. So we conclude dexmedetomidine is superior than midazolam for intraoperative sedation during upper limb surgery under BPB.

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