Comparison of hemodynamic and analgesic effects of interscalene block with bupivacaine versus bupivacaine-dexmedetomidine combination for shoulder arthroscopy under general anesthesia

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ABSTRACT

Background: The interscalene block in shoulder arthroscopy is a well-established procedure. Many drugs have been used as adjuvants to local anesthetics to increase the quality of block in regional anesthesia, with variable results. **Aims and Objectives:** The present study was designed to evaluate the effect of dexmedetomidine as an adjuvant to bupivacaine during interscalene block in terms of intraoperative hemodynamic changes and postoperative analgesia. **Materials and Methods:** Thirty patients, aged 20–55 years of either sex, American Society of Anesthesiologists physical status I-II, scheduled for shoulder arthroscopic surgery for <2 h, were allocated into two equal groups to receive inj. bupivacaine (0.25%) with inj. dexmedetomidine 1 μg/kg (Group BD, n=15) or inj. bupivacaine (0.25%) with 1 mL normal saline (Group BS, n=15), total volume 20 mL in each case. After settlement of the interscalene block, both groups received general anesthesia as per standard protocol. Hemodynamic parameters (heart rate [HR] and systolic blood pressure [SBP]) were assessed in the intraoperative period, and postoperative pain was assessed using a visual analog scale score in the postoperative period at stipulated time points. **Results:** The mean values of HR and SBP were considerably low at all observed time points in the intraoperative period (i.e., at 10 min, 30 min, 60 min, 90 min, and 120 min), in comparison with the saline group (P<0.0001). VAS scores between the two groups were considerably lower only at 8, 12, and 18 h in patients receiving dexmedetomidine (P<0.001). **Conclusion:** Dexmedetomidine as an adjuvant with bupivacaine can achieve a better hemodynamic profile (lower HR and SBP) in the intraoperative period. Also, the use of dexmedetomidine provides better postoperative analgesia profiles in the later part of the postoperative period (8–18 h), and the effect usually wanes by 24 h.

Key words: Bupivacaine; Dexmedetomidine; Interscalene block; Shoulder arthroscopy

INTRODUCTION

Arthroscopic surgery recently appeared as a booming advancement in the field of orthopedic surgery.[1] Shoulder arthroscopy is a minimally invasive technique that is used for diagnostic and various therapeutic procedures such as rotator cuff tears, recurrent joint instability, and sub-acromial pathology.[2] Shoulder surgery can be performed under either regional or general anesthesia, or both.[3] Until 70's almost all the procedures for shoulder surgery were performed under general anesthesia. The interscalene brachial plexus block can be an alternative

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anesthesia technique for shoulder surgery.[3] Various local anesthetics such as lidocaine, bupivacaine, and ropivacaine are commonly used for this block.[3] Various adjuvants have been used to prolong the duration of nerve block, including clonidine, epinephrine, fentanyl, and dexmedetomidine.[4]

Dexmedetomidine is a highly selective α_2-adrenergic receptor agonist and can be expected to have a longer duration of action than other adjuvants.[4-6] Dexmedetomidine is the focus of interest for its sedative, analgesic, perioperative sympatholytic, and cardiovascular stabilizing effects with reduced anesthetic requirements.[7,8] Some studies[9-11] reported the incidence of bradycardia and hypotension with alpha-2 adrenoreceptor agonists, but most are transient, isolated, and uncomplicated. Dexmedetomidine has been used in a wide range of doses (20-150 μg), and a comprehensive guideline or recommendation is still lacking in this regard; there are no relevant published dosing recommendations.[12] Recent literature provides insufficient safety data about the use of perineural dexmedetomidine and thereby warrants further evaluation.[13] With this background knowledge, it was felt that further evaluation regarding the effect of dexmedetomidine as an adjuvant during interscalene block would be fruitful. Hence, the present study was designed to evaluate the effect of dexmedetomidine as an adjuvant to bupivacaine in interscalene block on changes in systolic blood pressure (SBP) as well as other hemodynamic parameters and perioperative analgesic effects in comparison with bupivacaine alone.

Aims and objectives

The aim of the study was to compare the effect of dexmedetomidine as an adjuvant to bupivacaine for interscalene block in terms of changes in systolic arterial pressure in patients undergoing shoulder arthroscopic surgery under general anesthesia. This was the primary outcome. The changes in heart rate (HR) in the intra-operative period and the quality of post-operative analgesia were also compared. Adverse events, if any, were also observed in our study between the two groups.

MATERIALS AND METHODS

This experimental study was conducted in the orthopedic surgery operating room. The study was started after getting approval from the institute's ethics committee and spanned over 1 year (January' 2018–December' 2018). Patients, aged 20–55 years, of either sex, conforming to American Society of Anesthesiologists physical status (ASA-PS) class I-II, scheduled for shoulder arthroscopic surgery, were recruited for the study.

Exclusion criteria

Patients having pre-operative Hb% level <11 g% and those having a history of allergy to any of the anesthetic drugs were excluded from the study. Patients with unstable hemodynamics, those having contraindications to interscaelene block, and those with an anticipated difficult airway were not included. Those who were non-cooperative and refused to participate were also excluded from the study.

Sample size

Sample size was calculated based on a previous similar study[14], where the authors noted the first significant difference in SBP as early as 5 min after the administration of block, and it was reported to be 125.47±10.55 versus 119.47±6.53 in the dexmedetomidine adjuvant group and the bupivacaine alone group, respectively. Therefore, according to the previous study, the standard deviation (SD) of the first group (σ_1)=10.55 and that of the second group (σ_2)=6.53. We assumed that a difference of 10 mm of Hg in the SBP at 10 min after the interscaelene block would be the minimal clinically significant difference to detect (i.e., M1-M2=d=10 mm of Hg). The following formula[15] was used for sample size calculations: n (sample size in each group)=$(\sigma_1^2+\sigma_2^2)$ $[Z_{1-\alpha/2}+Z_{1-\beta}]^2/(M_1-M_2)^2$.

Setting the power of the study at 80% and allowing an alpha error of 5%, the sample size for each group (N) was calculated to be 12 (approx.). Considering a 1:1 allocation, the total sample for the two groups came to 24. Assuming the possibility of a 10% attrition rate, it was rounded off to 30. Hence, a total of 30 patients were recruited, 15 in each group.

Routine investigations were carried out on all patients as per our institutional protocol and as per the patients' needs. All the patients were informed about the study in their own language. They were also explained that participation in this study was not mandatory for them and that they would get the best possible treatment from the institute even if they did not participate in it. Subsequently, written consent was obtained from each patient. Patients' current medications were reviewed, and optimization of the drug therapy was achieved in all selected patients. Tab. alprazolam 0.5 mg was given orally the night before surgery to reduce anxiety in all patients.

The patients were randomly allocated into two groups to receive either inj. bupivacaine plus normal saline (Group-BS, n=15) or inj. bupivacaine plus inj. dexmedetomidine (Group-BD, n=15) for interscalene block. For randomization, the sealed envelope technique was used. Patients in both groups also received general anesthesia. After randomization, the patients in two groups

received drugs for interscalene block as follows: Group-BS received 19 mL of bupivacaine (0.25%) with 1 mL of normal saline. The dose of bupivacaine was calculated as per body weight, not exceeding the maximum safe dose. Group-BD received 19 mL of bupivacaine (0.25%) with 1 mL of dexmedetomidine (1 mcg/kg body weight plus normal saline). Identical syringes containing 1 mL of either normal saline or dexmedetomidine and labeled only with the randomization number were prepared by an investigator who was neither involved in the administration of the interscalene block nor in the follow-up of patients.

Baseline demographic parameters (age, sex, and body weight) were noted. After receiving patients in the operating room, monitors were attached and a peripheral intravenous channel was secured. All patients remained fasted as per standard guidelines. Intravenous (iv) fluid Ringer's lactate was started and received predication with injections (inj.) of ondansetron (4 mg slow iv) and glycopyrrolate (0.2 mg iv) before induction.

Baseline measurements of HR, SBP, and SpO_2 were recorded before the interscalene block was started. Under all aseptic precautions, the interscalene block was performed in a supine position. Neural localization was performed using a nerve stimulator. The block was performed following Winnie's technique. The plexus was approached at the C6 vertebral level (at the cricoid cartilage), where the roots of the brachial plexus pass between the anterior and middle scalene muscles in the interscalene groove. Local skin anesthesia was provided for the area to be operated upon with 1 mL of 2% lidocaine. A 22 G, 50 mm needle connected to a peripheral nerve stimulator was introduced near the plexus sheath. Its position was judged adequate when a group of muscles distal to the deltoid was stimulated with a threshold stimulation of 0.5 mA. After a negative aspiration test for blood, the drug was injected. An evaluation of motor and sensory blocks was carried out. The level of sensory block was evaluated with a pinprick test on the shoulder using a 3-point scale (0=normal sensation, sharp to pin prick; 1=pin prick felt but not sharp; 2=no sensation, pin prick not felt). Motor function was evaluated by shoulder abduction (0=normal abduction; 1=decreased movement; moves shoulder but not normal; 2=unable to abduct shoulder). The onset of sensory block was defined as the time from injection of local anesthetic to no response to a pin prick, whereas a onset of motor block was defined as the time between injection and motor paralysis. The duration of sensory block was considered as the time interval from complete sensory block until the first postoperative pain, and the duration of motor block was the time interval between complete paralysis and complete recovery of motor function. The duration of analgesia was recorded from

the interscalene block to VAS >3. Parameters obtained from visually assessing blood loss, urine output during the operation, total volume of IV fluid, or blood transfusion (if any) Adverse events were recorded.

After the interscalene block, all patients received standard general anesthesia care. It started with pre-oxygenation with 100% O_2 for 5 min, then IV induction with propofol 1.5–2 mg/kg of bodyweight and midazolam 0.03 mg/kg. Following induction, patients were intubated with the proper size ET tube, facilitated by the muscle relaxant atracurium 0.5 mg/kg. After confirming the ET tube position, they were put on mechanical positive pressure ventilation with set parameters. Maintenance of anesthesia was done with a $N_2O–O_2$ gas mixture; sevoflurane and atracurium were the muscle relaxants in all cases at a dose of 0.5 mg/kg body weight as the loading dose, followed by a 0.1 mg/kg intermittent maintenance dose. At the end of surgery, residual neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg, and extubation was done when patients were fully awake and breathing spontaneously.

After the establishment of block, the hemodynamic parameters were noted in intervals of 5 min after block, then after 10 min, 30 min, 60 min, 90 min, 120 min of surgery. During surgery, increases in BP and HR were controlled by inj. propofol and inj. esmolol. Hypotension was defined as a 20% drop in mean arterial pressure (MAP) of <65 mm of Hg. Bradycardia was defined as HR <60 min. A hypoxemic episode was defined as SpO_2 <90%. Adverse events were noted, if any.

After the operation was over, all the parameters were re-checked in the immediate postoperative period and after 30 min. Then, patients were soon transferred to the recovery room with all monitors attached. Patients were examined, and any adverse reaction or complaints were noted. Pain was assessed by a visual analog scale (VAS) score after the completion of surgery up to 24 h postoperative period. Initially, at baseline (0 h), just after surgery and extubation; after that, at 2 h, 4 h, 8 h,12 h,18 h, and 24 h after surgery. Rescue analgesia in the form of inj. diclofenac sodium 75 mg i.m. was advised to all patients when their VAS score was >3, and then these patients were not considered for continuing for further hours of study.

Continuous data are expressed as mean±SD and are analyzed using Student's t-test. Categorical data (gender and ASA status) is expressed as the number of patients and is analyzed using the Chi-square test. The demographic parameters in both groups were not statistically significant. P<0.05 is statistically significant.

RESULTS

The study spanned over 12 months. Data from all patients were available for analysis. Demographic parameters were comparable between the two groups (Table 1).

The baseline HR between the groups remained comparable. In the group receiving dexmedetomidine as adjuvant, the mean HR is considerably low at all observed time points in the intraoperative period (i.e., at 10 min, 30 min, 60 min, 90 min, and 120 min), in comparison with the saline group (Table 2).

The mean values of baseline SBP between the two groups were found to be comparable. Considerable differences in mean values of SBP were observed between the groups at other observed time points in the intraoperative period (i.e., at 10 min, 30 min, 60 min, 90 min, and 120 min). In the group receiving dexmedetomidine, the mean SBP are considerably low at all observed time points in comparison with the saline group (Table 3).

VAS scores at baseline and 2 h and 4 h after surgery were found to be comparable between the groups. There were considerable differences in VAS scores between the two groups at other observed time points (i.e., at 8 h, 12 h, and 18 h). Again, VAS scores became comparable at 24 h in the postoperative period between the groups (Table 4).

In the BD group, two patients had bradycardia. In the BS group, all 15 patients had no bradycardia. The association of bradycardia in two groups was not statistically significant (P=0.143). In the BD group, only one patient had hypotension. In the BS group, all 15 patients had no episode of hypotension. The association of hypotension in two groups was not statistically significant (P=0.3091). In both groups, no episode of hypoxemia was observed (Table 5).

In the BD group, all 15 patients didn't receive any rescue therapy with inj. propofol and inj. esmolol to treat increased BP and HR. In the BS group, 8 (53.3%) patients received such therapy. This difference was found to be statistically significant P=0.0009.

At 0 h, 2 h, and 4 h of the postoperative period in both groups, no patient received rescue analgesia, which was found to be comparable. However, at 8 h, 12 h, and 18 h, there was a considerable difference in the number of patients receiving rescue analgesia between the two groups. No patients receiving rescue analgesia were found to be comparable again at 24 h after surgery between the groups (Table 6).

Table 1: Demographic parameters

Parameters	Group BD (n=15)	Group BS (n=15)	P-value
Age (years)	29.13±7.50	31.07±9.58	0.543
Weight (kg)	59.73±6.29	61.07±5.92	0.555
Duration of surgery (min)	112.13±6.43	113.21±5.01	0.619
Sex (M/F)	10/5	12/3	0.409
ASA status (I/II)	10/5	8/7	0.456

Data are presented here as Mean±Standard deviation (SD) and analyzed using t-test except gender distribution and ASA, which are categorical data and presented as number of patients and analyzed using Chi-square test. Group BD, patients receiving dexmedetomidine as adjuvant to bupivacaine, Group BS, patients receiving bupivacaine plus saline

Table 2: Comparison of HR at different time points

Time points	Group BD (n=15)	Group BS (n=15)	P-value
HR Baseline (0 min)	86.6±14.2	85.7±5.6	0.814
HR 10 min	71.2±6.3	91.1±6.6	<0.0001
HR 30 min	65.7±4.2	95.9±10.1	<0.0001
HR 60 min	66.3±3.9	101.3±12.3	<0.0001
HR 90 min	67.8±3.7	102.0±14.6	<0.0001
HR 120 min	78.1±5.8	105.9±11.9	<0.0001

HR: Heart rate

Table 3: SBP between the two groups at different time points

Time points	Group BD (n=15)	Group BS (n=15)	P-value
SBP Baseline (0 min)	120.93±4.88	120.80±6.75	0.951
SBP 10 min	108.20±6.83	124.87±7.42	<0.0001
SBP 30 min	106.27±7.68	132.07±8.92	<0.0001
SBP 60 min	108.20±6.31	136.47±9.28	<0.0001
SBP 90 min	113.60±5.77	138.33±10.98	<0.0001
SBP 120 min	120.27±4.13	136.40±7.71	<0.0001

SBP: Systolic blood pressure

Table 4: Visual analog scale (VAS) scores at different time points

Time points	Group BD (n=15)	Group BS (n=15)	P-value
VAS Baseline- (Postoperative 0 h)	0.07±0.00	0.13±0.00	0.558
VAS at 2 h	0.07±0.00	0.13±0.13	0.559
VAS 4 h	0.27±0.46	0.33±0.49	0.702
VAS 8 h	0.47±0.52	3.93±1.43	<0.0001
VAS 12 h	1.53±0.52	3.60±0.89	<0.0001
VAS 18 h	2.40±0.91	4.33±1.53	0.008
VAS 24 h	4.46±0.78	6.00±0.00	0.080

DISCUSSION

The present study finds that the mean HR and SBPs between the two groups at 10 min, 30 min, 60 min, 90 min, and 120 min time points in the intraoperative period were statistically significant. The mean VAS scores immediately after extubation were comparable. Similarly, it

Table 5: Incidence of adverse events			
Adverse effects	Group BD (n=15)	Group BS (n=15)	P-value
Bradycardia	2	0	0.143
Hypotension	1	0	0.301
Hypoxia	0	0	NA

Table 6: Consumption of rescue analgesia in the postoperative period			
Time points	Group BD (n=15) (%)	Group BS (n=15) (%)	P-value
0 h	0/15 (0)	0/15 (0)	NA
2 h	0/15 (0)	0/15 (0)	NA
4 h	0/15 (0)	0/15 (0)	NA
8 h	0/15 (0)	10/15 (66.67)	0.0001
12 h	0/15 (0)	12/15 (80)	<0.0001
18 h	2/15 (13.33)	14/15 (93.33)	<0.0001
24 h	14/15 (93.33)	15/15 (100)	0.143

was comparable at 2 h and 4 h after extubation. However, there were considerable differences in VAS scores between the two groups at 8, 12, and 18 h after extubation, and again, they became comparable at 24 h in the postoperative period.

Dexmedetomidine is useful as an adjuvant to local anesthetics for a variety of regional analgesias. It can yield its analgesic properties through multiple mechanisms in each stage of the perioperative period.[16] Dexmedetomidine as an adjuvant to bupivacaine for supraclavicular block can considerably shorten the block onset time and prolong the duration of both sensory and motor block, thereby yielding the benefit of prolonged analgesia in the postoperative period.[6] The use of dexmedetomidine as an adjuvant to ropivacaine (0.75%) for interscalene brachial plexus block was found to considerably shorten the block onset time and prolong the duration of sensory and motor blockade.[17] Similarly, in a recent study[18] dexmedetomidine as an adjuvant to bupivacaine for supraclavicular blocks was found to reduce the onset time of sensory and motor blocks, and use of dexmedetomidine yielded benefits in terms of considerable reduced postoperative pain. Meena et al.,[14] found that dexmedetomidine is a useful adjuvant to local anesthetics in terms of achieving prolonged sensory and motor blockade, prolonged analgesia, and satisfactory hemodynamic stability. As an adjuvant to bupivacaine during supraclavicular brachial plexus block, dexmedetomidine was found to prolong the durations of sensory block, motor block, and postoperative analgesia considerably more than clonidine. Dexmedetomidine was found to yield a better quality of anesthesia compared with clonidine.[19]

In the present study, the postoperative hemodynamics and duration of analgesia were evaluated. The effect of dexmedetomidine on block-onset properties was not assessed in the present study and can be a future scope.

In the present study, SBP was observed as one of the parameters of hemodynamic stability. Compared with MAP, perioperative SBP monitoring and prompt detection of abnormal SBP remain important elements in the early detection of hemodynamic abnormalities.[20] A raised HR and SBP from baseline to hospital discharge was found to be associated with increased 30-day mortality.[21] The present study was not designed to assess long-term mortality and remains to be a future's scope.

It was observed that the need for rescue analgesia was much earlier in the bupivacaine alone group compared with those who received dexmedetomidine adjuvant. This may be attributed to extended postoperative analgesia in the dexmedetomidine adjuvant group compared with the control (saline) group. In the present study, the incidences of adverse events (bradycardia and hypotension) with the use of dexmedetomidine as an adjuvant were not significant when analyzed between the two groups.

Limitations of the study

This was a single-center study involving a small sample size. The benefits of maintaining postoperative hemodynamics and analgesia were studied. However, the onset of block characteristics and quality of block were observed before general anesthesia for patient management only but not evaluated. Long-term follow-up to determine 30-day mortality in a large sample may reveal other aspects.

CONCLUSION

The study concludes that the use of dexmedetomidine as an adjuvant with bupivacaine yields benefits in terms of lower HR and SBP in the intraoperative period. Use of dexmedetomidine can't give any extra benefit regarding postoperative analgesia in the early postoperative period (up to 4 h), while improved pain control was observed in the later period (8–18 h) just to wane up the effect by 24 h.

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