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Original Article

Comparison between the Effects of Dexmedetomidine and Nalbuphine as an Adjuvant to 0.5% Levobupivacaine in Interscalene Brachial Plexus Block – A Prospective Randomized Double-blind Study

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Abstract

Introduction: Regional/peripheral nerve blocks are commonly used nowadays for upper limb orthopedic surgeries as an alternative to general anesthesia, as it provides ideal operating conditions with complete muscle relaxation and stable intraoperative hemodynamics. This study was carried out to compare the effectiveness of dexmedetomidine and nalbuphine as an adjuvant to interscalene brachial plexus block.

Materials and Methods: Sixty adult patients of either sex aged 18–65 years of American Society of Anesthesiologist Physical Status I-II, scheduled for shoulder surgeries which were randomly allocated to Group A (n = 30) receiving 30 ml levobupivacaine plus 50 mg dexmedetomidine and Group B (n = 30) receiving 30 ml levobupivacaine plus 10 mg nalbuphine. The onset and duration of sensory and motor blockade and the duration of post-operative analgesia were studied.

Results: Statistically highly significant difference (P = 0.001) was seen between Group A and Group B, regarding the onset and duration of sensory and motor blockade. Significantly prolonged duration of post-operative analgesia was seen in Group A.

Conclusion: The study concluded that dexmedetomidine is a better adjuvant than nalbuphine in interscalene brachial plexus block as it reduces the onset time for sensory and motor blockade and prolonged the duration of sensory and motor blockade.

Key words: Dexmedetomidine, Interscalene brachial plexus block, Nalbuphine

INTRODUCTION

Pain is an unpleasant phenomenon which has both sensory and affective components.[1] Regional anesthesia can be used alone, either as an anesthetic or can be combined with general anesthesia for perioperative analgesia. Upper limb nerve blocks are used in orthopedic procedures as a substitute to general anesthesia, as it provides good operating conditions and complete muscle relaxation, stable hemodynamics intraoperatively. It also provides associated sympathetic block along with post-operative analgesia. Due to early recovery from anesthesia, it provides less systemic side effects.[2-4] Regional anesthesia has minimum interaction with metabolic process of the body. Hence, it is better to use regional anesthesia in metabolic disorders such as diabetes mellitus, hypertension, cardiovascular diseases, and also in respiratory and renal diseases. It also gives post-operative analgesia.

Interscalene approach provides reliable anesthesia of the shoulder and areas of upper arm. In this technique, the interscalene groove is palpated right at the level of cricoid cartilage and local anesthetic is injected between the anterior and middle scalene muscles. Due to possible

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ulnar nerve sparing and close proximity of carotid artery, its use is restricted to surgeries of upper arm and shoulder.[5] Complications include hoarseness of voice because of blockade of recurrent laryngeal nerve mainly on the right side and Horner's syndrome.

Interscalene block is performed either by conventional, nerve stimulator (NS) guided, or ultrasonography guided. Using NS or ultrasound, we can reduce the complications of interscalene block to minimum. In NS-guided technique, once the needle is in proximity with the plexus, the NS is attached to stimulating needle and a preset current and frequency are delivered. With stimulation of motor fibers, motor twitch is elicited. When the desired twitch is obtained, amplitude is decreased ensuring that muscle twitch is still present.

Drug is usually injected in proximity to lower trunk identified as finger twitch. As motor fibers have a lower electrical threshold than sensory fibers, so the patient need not be subjected to the discomfort of paresthesia when the nerve is stimulated to produce a motor twitch. Applicability of NS-guided blocks in uncommunicative patients due to coma or language barrier provides an extra edge of benefit to the anesthesiologist.

Levobupivacaine is the local anesthetic which can block the transmission of action potential reversibly in both sensory and motor and also in sympathetic nerve fibers. It inhibits the passage of sodium through voltage sensitive ion channel in neuronal membrane. Levobupivacaine is metabolized in liver, primarily by cytochrome P450, specially the CYP1A2 and CYP3A4 isoforms. Clearance reduces when hepatic function is damaged.[6,7]

Adjuvants are pharmacological agents that are added to local anesthetics to enhance the potency and reduce the total dose of local anesthetics needed. Dexmedetomidine is a novel FDA approved (1999) alpha2 adrenergic receptor agonist for short-term sedation and analgesia. It is a category C drug with diverse action. Primary analgesia and potentiation of opioid-induced analgesia results from the activation of alpha 2 adrenergic receptors in the dorsal horn of the spinal cord and further inhibition of the release of substance P. Dexmedetomidine is also a neuroprotective drug.

Nalbuphine belongs to the class of synthetic opioid agonist – antagonist. It belongs to phenanthrene group. Its molecular formula is $C_{21}H_{27}NO_4HCL$ (nalbuphine hydrochloride). It is a potent analgesic basically identical to that of morphine on milligram basis.

We hypothesized that administration of dexmedetomidine as an adjuvant to levobupivacaine will quicken the onset of sensory and motor blockade in interscalene brachial plexus block and lengthen the duration of blockade as compared to nalbuphine as an adjuvant.

MATERIAL AND METHODS

It was a prospective, randomized, double-blind study. Following approval by the Institutional Ethical Committee (Government Medical College, Amritsar, Punjab, India, ECC/TH-03716/05/2019 dated: May 16, 2019), all patients underwent written informed consent (which included the risks, benefits, and explanation of process) to participate in the study. Randomization was performed centrally by a statistician using a random number table generated by Microsoft Excel to ensure proper concealment of the study management from the patients and investigators until the release of final statistical results.

The study was carried out prospectively in 60 patients of American Society of Anesthesiologists (ASA) Grade I and II of age group 18–65 years of either sex, admitted in the orthopedic department of Guru Nanak Dev Hospital, Amritsar, and scheduled to undergo shoulder and arm surgeries under interscalene brachial plexus block with levobupivacaine and dexmedetomidine mixture and with levobupivacaine and nalbuphine mixture. Non-cooperating patients, patients with ASA grade more than II, coagulation disorders, pulmonary and cardiac disease, and morbidly obese and previously brachial plexus injured patients were kept out from the study.

Duration of analgesia was taken as the outcome measure of interest for the purpose of sample size calculation. Sample size was calculated keeping in view at most 5% risk, with minimum 80% power and 5% significance level (significant at 95% confidence interval). Patients were divided into two Groups A and B of 30 each in a random and unbiased manner [Figure 1].

Group A (n = 30): Thirty subjects received 30 mL of 0.5% levobupivacaine plus 50 mg dexmedetomidine.

Group B (n = 30): Thirty subjects received 30 mL of 0.5% levobupivacaine plus 10 mg nalbuphine.

Patients recruited in study were given complete information about the procedure, potential side effects, complications, and alternative techniques. Then, the informed written consent was taken from the patients in their vernacular language. A day before surgery, a thorough pre-anesthetic check-up of all patients was conducted. Assessment of patient airway was done. Patients were instructed to fast for 4–6 h for clear fluids and 6–8 h for semi-solids and solids before the surgery. All basic investigations were carried out

and documented before procedure. The interpretations of visual linear analog scale were explained at the time of pre-anesthetic check-up. The patients were asked to point out the severity of pain experienced at that time in the post-operative period. Rescue analgesia was given if visual analog scale (VAS) score was >4.

In the operating room, 20 G I/V cannula was secured and an IV infusion of ringer lactate started. All the monitors (NIBP, pulse rate, respiratory rate, ECG, and SpO_2) were attached. The baseline readings were noted and were monitored intraoperatively.

The patient was made to lie in supine position, arms by the side, and head turned away toward the opposite side. The interscalene groove was palpated by rolling the fingers posterolaterally from the posterior border of the sternocleidomastoid over the belly of anterior scalene muscles into the groove. Cricoid cartilage palpated and bisecting point of an imaginary line was drawn from cricoid cartilage toward interscalene groove. This was the point of entry. This point lies directly opposite to C6 vertebra. An insulated needle compatible with NS was inserted almost perpendicular to floor of gutter on the superior aspect of transverse process of C6 vertebra that is 45 degrees caudal, posterior, and in medial direction. After inserting the needle, contractions were elicited with the help of peripheral NS starting from 1.2 mA and going down to 0.3–0.4 mA at a frequency of 1–2 Hz. When the contractions were elicited at a current of 0.3 mA, at this point, needle was fixed and local anesthetic solution was injected after repeated aspiration. The assessment of sensory block was done by loss of sensation to pin pricks using 27-gauge blunt hypodermic needle. The degree of motor block was assessed by modified bromage scale. Analgesia was considered satisfactory if score is 3 or less. If score is more than 4, rescue analgesia was given in form of injection diclofenac 75 mg iv. Time to first analgesia and total doses required for post-operative analgesia for 24 h were noted. Oxygen was routinely administered through oxygen mask at 4 L/min.

Bradycardia (heart rate <60 bpm) was treated with I/V atropine 0.4 mg. Hypotension (systolic blood pressure <100 mmHg or 20% less than the base value) was treated with I/V ephedrine 10 mg and additional ringer lactate solution. Ondansetron I/V was given for post-operative nausea and vomiting.

Patients were monitored for 24 h in the post-operative period for total duration of sensory and motor blockade. The patients were monitored for side effects and complications of technique and drugs throughout intraoperative and post-operative period. Side effects and complications such as accidental intravascular injection, pneumothorax, phrenic nerve block, neuropathy, and Horner's syndrome were recorded and if any occurred were followed postoperatively.

Statistical Analysis

Data were recorded in a Microsoft Excel spread sheet and analyzed using Statistical Package for the Social Sciences (SPSS version 24.00). Continuous data were presented as mean with standard deviation. Categorical data were expressed as percentages. Numerical variables were normally distributed and were compared using Chi-square test for non-parametric data and Student's "*t*"-test for parametric data. *P* value was then determined to evaluate the level of significance. The results were analyzed and compared to the previous studies to draw relevant conclusions. The blinding was opened at the end of the study.

RESULTS

Sixty patients were enrolled in the present study in two different groups. No patients were lost in follow-up and excluded from analysis. All the two groups were comparable in terms of demographic parameters [Table 1]. In Group A, the mean onset of sensory block was 9.02 ± 1.07 min. In Group B, the mean onset of sensory block was 10.02 ± 1.21. Group A shows early onset of sensory block as compared to Group B, and it was found to be statistically highly significant ($P = 0.001$).

In Group A, the mean onset of motor block was 9.15 ± 0.98 min. In Group B, the mean onset of motor block was 14.13 ± 1.39 min. Group A showed early onset of motor block as compared to Group B and it was found to be statistically highly significant ($P = 0.001$)

[Table 2 and Figure 2]. The mean duration of sensory block in Group A was 13.32 ± 0.80 h. The mean duration of sensory block in Group B was 12.00 ± 0.65 h. Group A showed prolonged duration of sensory block as compared

Table 1: Demographic parameters

Parameters	Group A	Group B	*P* value
Age (years)	42.10±18.14	38.39±15.87	0.240
Gender (female/male)	14/16	12/18	0.602
Weight (kilograms)	66.08±14.10	64.93±10.95	0.370
ASA (I/II)	27/3	24/6	0.278

Table 2: Onset of blocks

Parameters	Group A	Group B	*P* value
Onset of sensory block	9.02±1.07	10.02±1.21	0.001
Onset of motor block	9.15±0.98	14.13±1.39	0.001

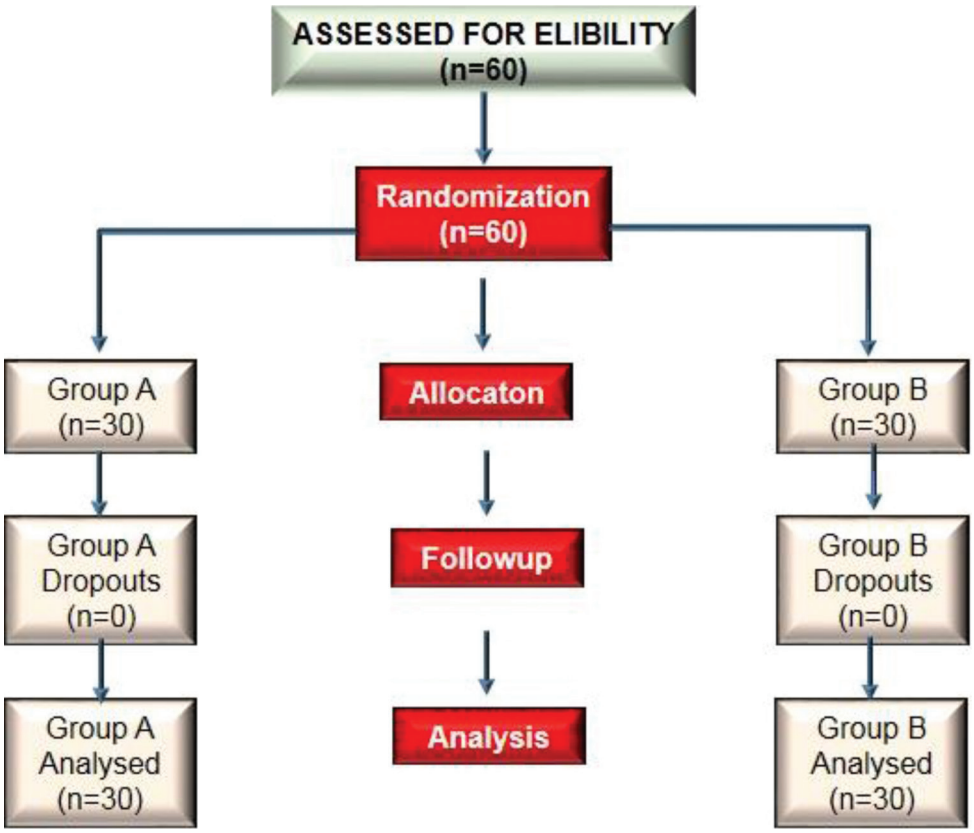

Figure 1: Consort diagram

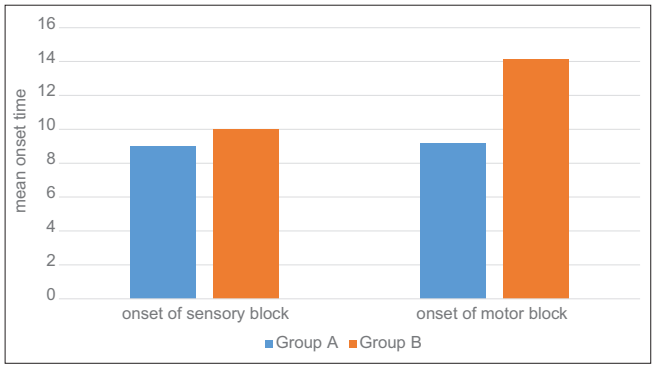

Figure 2: Mean onset time of blocks

to Group B, and it was found to be statistically highly significant ($P = 0.001$).

The mean duration of motor block in Group A was 12.00 ± 0.49 h. The mean duration of motor block in Group B was 7.97 ± 1.05 h. Group A showed prolonged duration of motor block as compared to Group B and it was found to be statistically highly significant ($P = 0.001$)

[Table 3 and Figure 3]. The comparison of VAS for both groups at different time intervals was done. At 8 h, the mean VAS score of Group A was 3.20 and that of Group B was 3.67. It showed statistically significant difference ($P = 0.001$). At 12 h, the mean of Group A was 4.07 and that of Group B was 4.50 and it showed statistically significant difference ($P = 0.03$). At 24 h, the mean VAS score of Group A was 4.50 and that of Group B was 6.07 and it showed statistically significant difference ($P = 0.001$)

[Table 4 and Figure 4]. No adverse effects such as respiratory depression, hypotension, bradycardia, nausea, and vomiting were reported in both the groups in the study.

DISCUSSION

Brachial plexus block has emerged as one of the most popular esthetic technique for upper limb surgeries. This regional technique avoids untoward effects of general anesthesia related to airway instrumentation and poly pharmacy. Ideally, regional anesthesia should have faster sensory onset, differential offset, with an earlier return of motor activities than sensory functions, enabling early ambulation or movements with prolonged analgesia.

Dexmedetomidine, an α2-receptor agonist, with α2/α1 selectivity 8 times than that of clonidine has also been reported to improve the quality of intrathecal and epidural anesthesia when used along with local anesthetics as adjuvant.[8]

Table 3: Mean duration of blocks

Parameters	Group A	Group B	*P* value
Duration of sensory block	13.32±0.80	12.00±0.65	0.001
Duration of motor block	12.00±0.49	7.97±1.05	0.001

Table 4: Visual analog scale score

Time interval	Group A		Group B		t-value	*P*-value
	Mean	SD	Mean	SD		
2 h	1.93	0.64	2.10	0.66	−0.90	0.16
4 h	2.47	0.68	2.53	0.57	−0.36	0.34
6 h	2.83	0.38	2.97	0.56	−1.44	0.14
8 h	3.20	0.61	3.67	0.61	−2.84	0.001
12 h	4.07	0.69	4.50	0.97	−1.90	0.03
24 h	4.50	0.97	6.07	0.91	−6.33	0.001

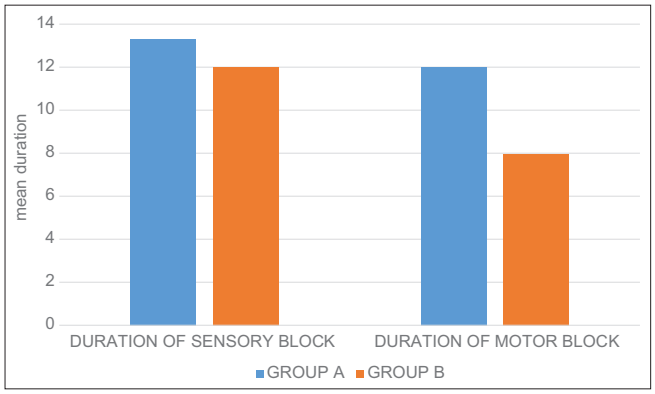

Figure 3: Mean duration of blocks

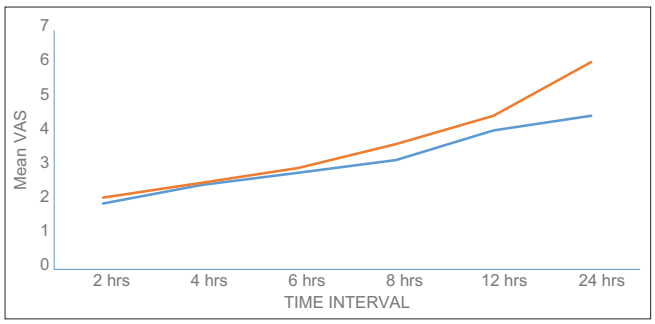

Figure 4: Visual analog scale score

Nalbuphine is a synthetic opioid agonist – antagonist. It is primarily a κ agonist and partial mu antagonist. κ opioid receptors are distributed throughout the brain and spinal cord areas involved in nociception.[9]

In our study, the mean onset of sensory block for Group A was 9.02 min. The mean onset of sensory block for Group B was 10.02 min. Highly significant difference was observed between mean onset time of sensory block among two groups ($P = 0.001$). The findings of our study were in accordance with studies conducted by Esmaoglu *et al.*,[10] Kathuria *et al.*,[11] and Gupta *et al.*[12]

In our study, the mean onset of motor block for Group A was 9.15 min. The mean onset of motor block for Group B was 14.13 min. Highly significant difference was observed between mean onset time of motor block among two groups ($P = 0.001$). The findings of our study were in consistent with studies conducted by Esmaoglu *et al.*,[10] Gupta *et al.*,[12] and Chiruvella *et al.*[13]

The mean duration of sensory block in our study was 13.32 ± 0.80 h (approximately 799.2 min) for Group A and 12.00 ± 0.65 h (approximately 720 min) for Group B. Highly significant difference was observed between duration of both the groups ($P = 0.001$). The results of our study were consistent with studies conducted by Kathuria *et al.*[11] and Chiruvella *et al.*[13]

The mean duration for motor block in our study was 12.00 ± 0.49 h (720 min approximately) for Group A and 7.97±1.05 h (478.2 min approximately) for Grou B. Highly significant difference was observed between both the groups ($P = 0.001$). These findings were in accordance with studies conducted by Kathuria *et al.*[11] and Chiruvella *et al.*[13]

All the hemodynamic parameters were comparable among both the groups. There were no significant differences between the two groups with respect to hemodynamic parameters preoperatively, intraoperatively, and postoperatively. Our observations were in accordance with studies by Kathuria *et al.*[11] and Gupta *et al.*[12]

On comparing the VAS score, significant difference was observed at 8 h, 12 h, and 24 h with mean VAS score of Group B being significantly more than Group A, thus showing that dexmedetomidine is a better analgesic than nalbuphine. The mean VAS score was observed to be 3.2, 4.07, and 4.50 for Group A at 8, 12, and 24 h, respectively, and it was 3.67, 4.50, and 6.07 at 8, 12, and 24 h, respectively, for Group B.

CONCLUSION

From our study, we concluded that the onset of sensory and motor block with dexmedetomidine was significantly earlier as compared to nalbuphine, as an adjuvant. Dexmedetomidine prolongs the duration of sensory block, motor block, and post-operative analgesia.

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