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Original Article

Anaesthesia Section

Comparison of Levobupivacaine 0.5% versus Ropivacaine 0.75% with Dexmedetomidine as an Adjuvant in Ultrasound-guided Supraclavicular Brachial Plexus Block: A Randomised Clinical Study

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ABSTRACT

Introduction: Peripheral nerve blocks not only provide surgical anaesthesia but also minimise the stress response, in addition to providing postoperative analgesia. The addition of adjuvants augments the anaesthetic action of the drug and reduces the dose required, thus improving the safety margin. However, no single drug can be considered the optimum local anaesthetic or adjuvant at this time. In the quest to find a better local anaesthetic and adjuvant combination, dexmedetomidine has recently emerged as a promising adjuvant to local anaesthetics during regional anaesthesia procedures.

Aim: To study the efficacy of levobupivacaine and ropivacaine with dexmedetomidine as an adjuvant using ultrasound in the Supraclavicular Brachial Plexus Block (SCPB).

Materials and Methods: A randomised, double-blinded clinical study was conducted in the Department of Anaesthesiology, Jagjivan Ram Railway Hospital, Mumbai Central, Maharashtra, India from November 2019 to April 2021 on 60 adults aged 21-65 years with American Soceity of Anaesthesiology (ASA) class I and II, scheduled for upper limb surgery. Patients were randomised into two groups, each containing 30 patients. Group A received 20 mL of levobupivacaine 0.5% with 50 mcg of dexmedetomidine, while Group B received 20 mL of ropivacaine 0.75% with 50 mcg of dexmedetomidine. A comparison was made regarding the efficacy in terms of the onset of sensory and motor blockade, duration of sensory and motor blockade, haemodynamics, any adverse effects, and postoperative analgesia. Categorical covariates were compared using the Chi-square test, and continuous covariates were compared using the unpaired t-test.

Results: The groups were comparable concerning demographic data and baseline haemodynamic parameters. There was no statistically significant difference when comparing the mean Heart Rate (HR), mean blood pressures, and mean oxygen saturations at different time intervals between the groups. The mean time±Standard Deviation (SD) for the onset of sensory block and motor block in the levobupivacaine group was 19.13±1.87 min and 29.53±2.86 min, respectively; this was statistically faster at 11.26±1.92 min and 7.53±1.35 min in the ropivacaine group (p-value <0.05). The mean duration of sensory and motor block in the levobupivacaine group was 459.83±26.40 min and 539.33±23.77 min, respectively, while it was longer at 878.66±17.46 min and 786.16±17.50 min in the ropivacaine group (p-value <0.05).

Conclusion: The use of dexmedetomidine with ropivacaine for SCPB results in a quicker onset and longer anaesthetic effect compared to levobupivacaine. Dexmedetomidine should be utilised as an adjuvant to reduce anaesthesia induction time in SCPB.

Keywords: Anaesthesia, Brachial plexus block, Postoperative analgesia, Regional anaesthesia, Upper limb surgery

INTRODUCTION

Peripheral nerve blocks, as an anaesthetic technique, play an important role in modern regional anaesthesia as they are devoid of the side effects of intubation and muscle relaxants [1]. This type of anaesthesia mainly helps achieve ideal operating conditions by producing muscular relaxation, maintaining stable intraoperative haemodynamic conditions, and providing sympathetic block, which reduces vasospasm. Peripheral nerve blocks not only provide intraoperative anaesthesia but also minimise the stress response in addition to providing postoperative analgesia [2].

Upper limb surgeries below the shoulder joint are mostly performed under brachial plexus block and are often referred to as central neuraxial blockade of the upper limb. A number of approaches for brachial plexus block have been described in the literature. The supraclavicular block has gained importance as a technique of choice, as the nerves are most compactly arranged, requiring less anaesthetic solution to achieve a block. It provides ideal conditions for surgery, maintains stable intraoperative haemodynamics, and prolongs postoperative analgesia with a high success rate [3].

With the recent expansion in the practice of ultrasound-guided techniques for performing regional anaesthetic procedures through proper nerve localisation and optimal needle placement techniques, there is a lower incidence of neural damage, thereby reducing unpleasant paresthesia, and a higher rate of block success with faster onset times [4-6]. Due to bupivacaine's long duration of action, it is the most frequently used local anaesthetic drug for brachial plexus block. Bupivacaine is available in a commercial preparation as a racemic mixture (50:50) of its two enantiomers: levobupivacaine (S (–) isomer) and dextrobupivacaine (R (+) isomer) [7].

The physicochemical properties of the two enantiomeric molecules are identical, but the two enantiomers can have substantially different behaviours in their affinity for either the site of action or the sites involved in the generation of side effects. Thus, the cardiotoxicity of local anaesthetic drugs shows enantioselectivity, which is more pronounced with R (+) racemic bupivacaine. The pure S (–) enantiomer of bupivacaine, levobupivacaine, was introduced into clinical anaesthesia practice due to fewer central nervous system and cardiovascular adverse reactions and having a wider safety

margin, as reported in the literature. Since this drug is relatively new, its clinical properties are the least studied [8].

Ropivacaine is also less cardiotoxic and less central nervous system toxic than other long-acting local anaesthetics like bupivacaine, making it an interesting alternative for procedures requiring large doses of local anaesthetic. In addition, ropivacaine also has a vasoconstrictive effect, thereby reducing the absorption of the drug into the plasma and leading to a prolonged Duration of Analgesia (DOA). This drug is also one of the ideal anaesthetics to relieve a variety of postoperative pain [9-11].

The addition of adjuvants not only augments the anaesthetic action of the drug but also reduces the dose required, thus improving the safety margin. Dexmedetomidine is a highly selective (eight times more selective than clonidine), specific, and potent α2-adrenergic agonist with analgesic, sedative, antihypertensive, and anaesthetic-sparing effects when used via the systemic route [12,13]. Adding dexmedetomidine to local anaesthetics during peripheral nerve blockade and regional anaesthesia procedures has been shown to prolong the duration of the block and postoperative analgesia when added to local anaesthetic in various regional blocks [14,15].

However, no single drug can be considered an optimum local anaesthetic or adjuvant. In the quest to find a better combination of local anaesthetic and adjuvant, numerous research studies have been conducted for individual drugs, but few have compared these two [16-17]. A clinical trial was conducted to study the efficacy between levobupivacaine and ropivacaine with dexmedetomidine as an adjuvant, using ultrasound in the supraclavicular block in terms of DOA, the onset of sensory and motor blockade, and possible complications, if any.

MATERIALS AND METHODS

A randomised, double-blinded clinical study was conducted at the Department of Anaesthesiology, Jagjivan Ram Railway Hospital, Mumbai Central, Maharashtra, India from November 2019 to April 2021, following approval by the Institutional Ethics Committee (IEC/JRH/25/09/2019).

Sample size calculation: Sample size of 27 was calculated by using formula $N=2*SD^2*(Z_{\alpha/2}+Z_{\beta})^2/d^2$. Where, $Z_{\alpha/2}$ is the critical value of normal distribution curve at $\alpha/2$(1.96), Z_{β} is the critical value of normal distribution at β (0.84), SD^2 is population variance and d is difference in mean. Mean of and Standard Deviation (SD) of 'the time for first rescue analgesia' (13.23±1.1651 hr) obtained from a study done by Kulkarni SB et al., is computed in this formula at confidence interval 95% and power 80%, 27 patients will be required per group [1]. Total 30 patients are taken per group for possible dropouts after taking written informed consent and explaining it in their language.

Inclusion criteria: Adult patients of either gender between the ages of 21-65 years with ASA class I or II, scheduled for unilateral below-shoulder upper limb surgery, were included in the study.

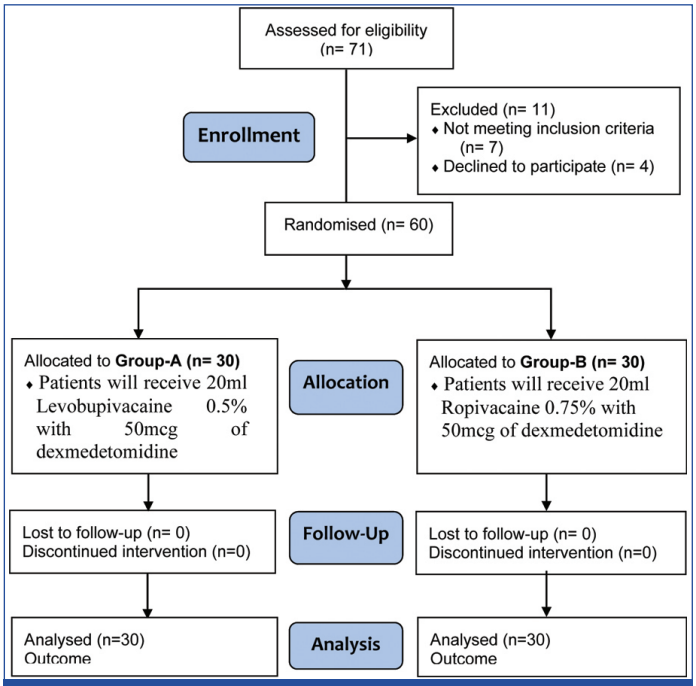
Exclusion criteria: Exclusion criteria included patient refusal, allergy to local anaesthetics or any included medications, localised infection at the site of the supraclavicular block, allergy or intolerance to local anaesthetics and adjuvants, and a history of significant co-existing diseases such as ischaemic heart disease, impaired renal function, severe liver disease, coagulopathy, peripheral neuropathy, pregnancy, chronic alcoholism, and malnourishment.

Patients were randomised into two groups using a computerised random sequence generator through 'random.org,' a popular tool for generating random sequences.

Group A: Patients received 20 mL of levobupivacaine 0.5% with 50 mcg of dexmedetomidine.

Group B: Patients received 20 mL of ropivacaine 0.75% with 50 mcg of dexmedetomidine [18].

The patients were not informed about the particulars of the local anaesthetic drug, and the investigator assessed the outcome variables without being involved in the brachial plexus block; therefore, all participants and the investigator were blinded to the anaesthetic technique. Allocation concealment was done using Sequentially Numbered Opaque Sealed Envelopes (SNOSE technique). The blocks were performed by experienced consultants from the department, and the drug was provided by the operating theatre technician according to the random allocation sequence generated. Observations were made by one of the authors who was not aware of the study drug. The patients were also not aware of the specific study drug used. A total of 71 patients were selected, out of which 7 were excluded for not meeting the inclusion criteria, and 4 did not provide consent. In total, 60 patients were included in the study. The Consolidated Standards of Reporting Trials (CONSORT) flowchart has been presented in [Table/Fig-1]. They were observed for the onset and duration of sensory and motor block, as well as the DOA, which was indicated by the demand for rescue analgesia, as the primary objectives. Secondary objectives included sedation scores, haemodynamic parameters (heart rate, blood pressure, and SpO_2), and any adverse reactions.



[Table/Fig-1]: CONSORT flowchart of the study.

Study Procedure

Preoperative anaesthetic assessment, including history, physical examination, and routine investigations, was conducted. The patient was explained the supraclavicular block procedure, the use of either study drug, and the Visual Analogue Scale (VAS). After arriving in the operating room, Nil per Oral (NPO) status was confirmed, and a 20G peripheral intravenous catheter was secured in the patient's non-operating forearm, starting intravenous crystalloids. Standard monitoring was used throughout the procedure. Haemodynamic parameters, such as heart rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and SpO_2 baseline, were recorded. The patient was positioned supine with the head turned approximately 30 degrees to the contralateral side. The anaesthesiologist then performed the SCPB using the ultrasound machine Sonosite Edge II (Fujifilm Sonosite, India) with a high-frequency probe (13-6 MHz, linear probe). The site of the block was prepared with 5% betadine solution, and the skin and subcutaneous tissue at the puncture site were anaesthetised with 2% lignocaine. Brachial plexus anatomy was assessed using ultrasound, and any deviation from normal anatomy was noted. A 22 G, 80 mm peripheral nerve block needle was inserted using an in-plane approach. The tip of the needle was maneuvered into the fascial plane. The location of the needle tip was confirmed by

hydro-dissection with 2 mL of normal saline, separating nerve fibers in the plexus on ultrasonographic imaging. A volume of 20 mL of the study drug was injected. The onset of sensory block was assessed by pinprick and was defined as the time from the completion of local anaesthetic injection to the time to achieve a grade of 3/4 on the Hollmen scale (pinprick recognised as touch with a blunt object/no perception of pinprick). The time to complete resolution of sensation in the distribution of the median, radial, ulnar, and musculocutaneous nerves was noted for the duration of sensory anaesthesia. The onset of motor block was defined as the time from the completion of local anaesthetic injection to the achievement of score 0 (complete block at the elbow joint) on the Bromage scale. The duration of motor block was measured by the time taken to recover to grade 4 (no block) [19].

If anaesthesia was found to be inadequate after 30 minutes, such patients were excluded from the study. The total duration of sensory block was measured as the duration between the onset of complete sensory block and the appearance of pain. The total duration of motor blockade was calculated as the time between the onset of motor blockade and the complete recovery of motor activity. The Visual Analogue Scale (VAS) was noted in the postoperative period, and any patient showing a VAS score of three or higher was administered supplemental rescue analgesia; the duration from the time the block was given was also noted.

The incidence of pruritus, nausea, vomiting, arrhythmia, hypotension, respiratory depression, intravascular puncture, pneumothorax, or any other adverse event was recorded. During the procedure and intraoperative period, bradycardia (heart rate less than 60 beats per minute) was recorded and treated with Inj. Atropine 0.6 mg. Hypotension (blood pressure less than 90/50 mmHg) was recorded and treated with crystalloid fluids and Inj. Mephentermine 6 mg boluses. Local anaesthesia systemic toxicity was treated with a 20% lipid emulsion, 1.5 mL/kg bolus over one minute, followed by a 15 mg/kg/hr infusion or crystalloid fluids. A heart rate of less than 60 beats per minute was corrected using 0.6 mg of intravenous atropine. Respiratory depression (respiratory rate <8 or SpO_2 <95%) was treated with oxygen supplementation and respiratory support, if required. Intraoperative sedation was determined using the Ramsay sedation scale as follows: 1 - Patient anxious and agitated or restless or both; 2 - Patient cooperative, oriented, and tranquil; 3 - Patient responds to commands only; 4 - Brisk response to light glabellar tap or loud auditory stimulus; 5 - Sluggish response to light glabellar tap or loud auditory stimulus; 6 - No response to light glabellar tap or loud auditory stimulus. The maximum score was noted.

STATISTICAL ANALYSIS

The data obtained were tabulated and analysed using IBM® Statistical Package for Social Science (SPSS)® Statistics (version 21.0). Data are expressed as mean and SD. Categorical covariates (gender, ASA class) were compared using the chi-square test. Continuous covariates (onset of motor and sensory block, duration of sensory and motor block, duration of surgery) were compared using the unpaired t-test. Non parametric data, such as the sedation score, are presented as median and Interquartile Range (IQR) and were assessed using the Mann-Whitney U-test for pair-wise comparison. The significance threshold for the p-value was set at <0.05 (95% confidence interval).

RESULTS

No difference was observed between the study groups regarding mean age, mean weight distribution, and mean height distribution [Table/Fig-2]. Overall, a male predominance was observed in the cases undergoing upper limb surgery, with 45 male patients and 15 female patients. Out of the total 60 cases undergoing surgery, 40 patients were in ASA grade II and 20 patients were in ASA grade I. No difference was observed between the study groups with regard to gender distribution or ASA grade distribution [Table/Fig-3].

Variables	Groups		Unpaired t-test p-value
	A (n=30)	B (n=30)	
Age (years)	47.60±16.736	46.93±15.222	0.769
Weight (kg)	65.43±6.765	66.4±6.032	0.386
Height (cm)	163.43±6.811	163.53±6.962	0.991

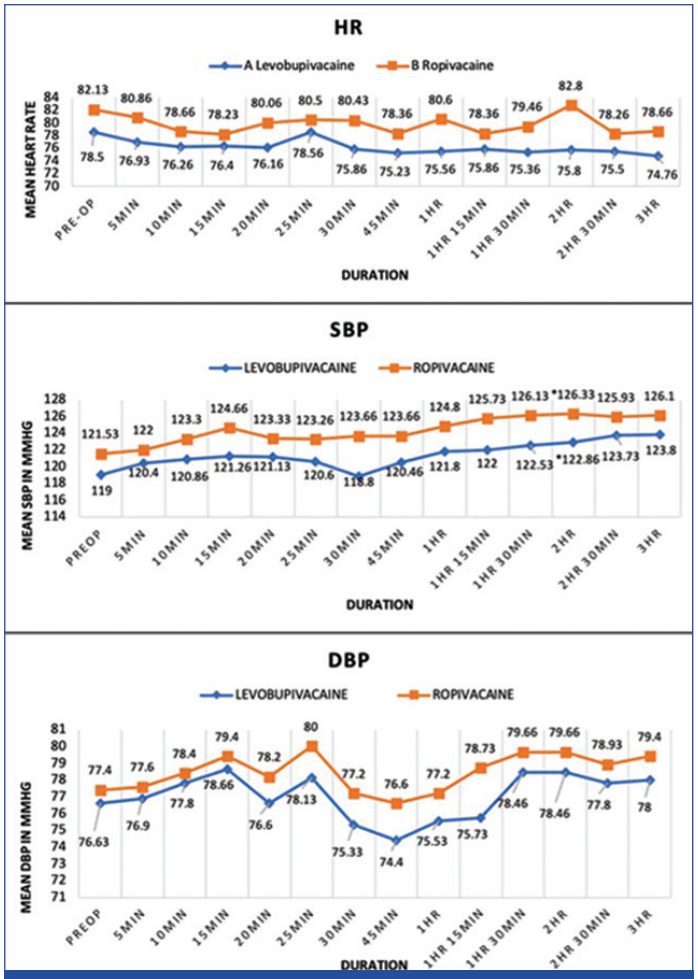
[Table/Fig-2]: Comparison of demographic profile and patient characteristics (N=60).

Gender	Groups		Total (N=60)	Chi-square test
	A (n=30)	B (n=30)		p-value
Male/Female	22/8	23/7	45/15	0.089
ASA I/II	9/21	11/19	20/40	0.30

[Table/Fig-3]: Gender and ASA grade distribution in study groups (N=60).

At preoperative evaluation and at five-minute intervals after the block, the mean Heart Rate (HR) of both groups was comparable. Throughout the assessment, the comparison of HR remained non significant.

The difference in mean SBP at different time intervals between the Levobupivacaine and Ropivacaine groups was not statistically significant; however, there was a significant difference (p-value <0.05) between the two groups in SBP at two hours post-block. The difference in mean DBP at different time intervals between Group A and Group B was not statistically significant [Table/Fig-4].



[Table/Fig-4]: Chart showing comparison of Haemodynamic data between both the group. a) Heart Rate (HR); b) Systolic Blood Pressure (SBP); c) Diastolic Blood Pressure (DBP).

The mean time of onset of sensory block in the levobupivacaine group was 19.13 minutes, while it was 7.53 minutes in the Ropivacaine group. This difference in the onset of sensory block was statistically significant between the two groups. The mean duration of sensory block in the levobupivacaine group was 539.33 minutes, and it was 878.66 minutes in the ropivacaine group. This difference in duration of sensory block was also statistically significant between

the two groups. The mean time of onset of motor block in the levobupivacaine group was 29.53 minutes, compared to 11.26 minutes in the ropivacaine group. This difference in the onset of motor block was statistically significant between the two groups. The mean duration of motor block in the levobupivacaine group was 459.83 minutes, while it was 786.16 minutes in the ropivacaine group. This difference in duration of motor block was statistically significant between the two groups [Table/Fig-5].

Variables	Groups		Unpaired t-test p-value
	A (n=30)	B (n=30)	
Onset of sensory block (minutes)	19.13±1.87	7.53±1.35	0.036
Onset of motor block (minutes)	29.53±2.861	11.26±1.92	0.033
Duration of motor block (minutes)	459.83±26.40	786.16±17.50	0.001
Duration of sensory block (minutes)	539.33±23.77	878.66±17.46	0.044
Duration of first rescue analgesia (minutes) interval between time to complete block and time when patient first complain of VAS >3	624.16±21.45	933.5±18.48	0.001

[Table/Fig-5]: Characteristics outcomes of the blocks in study groups.

The mean and standard deviation of oxygen saturation in both groups at various intervals were comparable and found to be statistically not significant (p-value >0.05). A significant p-value (<0.05) was noted at three hours post-block, with a mean SpO_2 of 97.86±0.68 in Group A versus 98.46±0.81 in Group B. The incidence of nausea and vomiting was 2 (6.7%) in Group A and 7 (23.3%) in Group B, out of a total of nine cases (p-value=0.14). No other adverse events were noted in any cases.

Both groups had a median sedation score of 3 (2-3), but there was no statistically significant difference upon comparison [Table/Fig-6]. No respiratory depression was noted in any patient, and no intervention was required.

Variable	Group		Mann Whitney test p-value
	A (n=30)	B (n=30)	
Sedation score (median range)	3 (2-3)	3 (2-3)	0.36

[Table/Fig-6]: Comparison of sedation scores in study groups (N=60).

DISCUSSION

The present study aimed to compare levobupivacaine and ropivacaine with dexmedetomidine as an adjuvant, used for SCPB block, in terms of anaesthetic effect, haemodynamic parameters, and complications. The groups were comparable with regard to demographic data and baseline haemodynamic parameters. The mean age of the cases undergoing upper limb surgery was 47.60 years in Group A and 46.93 years in Group B, with no statistically significant difference between the study groups (p-value=0.769). Out of the total 60 cases, 66.6% were in ASA grade II and 33.3% were in ASA grade I. Subjects in the present study were also comparable regarding their ASA grades in both groups.

In present study, SBP and DBP were compared at baseline and after administering the block (post-block) at intervals of 5, 10, 15, 20, 25, 30, 45, 60, 75, 90, 180, 210, and 270 minutes after the block. The difference in mean SBP at different time intervals between Group A and Group B was not statistically significant; however, there was a significant difference between the two groups in SBP at two hours post-block. The difference in mean DBP at different time intervals between the levobupivacaine and ropivacaine groups was not statistically significant (p-value >0.05).

Oxygen Saturation (SpO_2) was comparable between both groups at baseline and throughout the procedure. There was no significant difference between the two groups (p-value >0.05) throughout the procedure, but a statistically significant difference was observed at the third hour post-block, which can be considered a trivial finding. Similar results related to haemodynamic parameters were found in a study conducted by Kulkarni SB et al., which reported that there was no significant difference between the two groups; heart rate, blood pressure, and SpO_2 were maintained throughout the surgery [1]. Batool S et al., also reported that the groups with levobupivacaine and dexmedetomidine and ropivacaine and dexmedetomidine did not significantly differ concerning haemodynamic parameters, except for heart rate at 180, 210, and 240 minutes [20].

The mean onset of sensory and motor blockade was statistically significant and faster in Group B (ropivacaine with dexmedetomidine) compared to Group A (levobupivacaine with dexmedetomidine), with p-values of 0.036 and 0.033, respectively, in the present study. Similar findings regarding the effect of dexmedetomidine with levobupivacaine on reducing the onset of sensory and motor blockade were reported in studies conducted by Agarwal S et al., and Biswas S et al., [21,22]. The addition of 20 mL of 0.75% ropivacaine with 1 mcg/kg dexmedetomidine was observed in studies conducted by Mangal V et al., and Singh N et al., [17,23]. Thalamati D et al., compared ropivacaine and levobupivacaine in SCPB and found that ropivacaine had a faster sensory onset compared to levobupivacaine. The duration of sensory and motor blockade was longer with levobupivacaine than with ropivacaine [24].

In the present study, the duration of sensory and motor blockade was prolonged in the ropivacaine group compared to the levobupivacaine group. This difference in the duration of sensory and motor blockade was found to be statistically significant (p-values of 0.04 and 0.001, respectively). Similar durations of sensory and motor blockade were observed in studies conducted by Kaur H et al., and Liu X et al., with ropivacaine [25,26]. A similar prolongation of the duration of sensory and motor blockade was observed in studies conducted by Mangal V et al., and Singh N et al., [17,23]. Additionally, the inclusion of dexmedetomidine with levobupivacaine prolonged the duration of sensory and motor blockade, as noted in studies by Agarwal S et al., and Biswas S et al., [21,22].

Batool S et al., found that the onset and completion of sensory and motor blocks were comparable for both groups [20]. However, the duration of sensory and motor blocks was significantly longer in the levobupivacaine and dexmedetomidine group, resulting in a delayed requirement for rescue analgesia.

Limitation(s)

The present study had a fixed dose of the local anaesthetic agent as well as the adjuvant. Another limitation is that VAS score of patients was monitored only until the first dose of rescue analgesia was administered. Additionally, present study did not have a control group.

CONCLUSION(S)

Ropivacaine 0.75% 20 mL with dexmedetomidine 50 mcg had a faster onset of sensory blockade, providing anaesthesia, and a faster onset of motor blockade, resulting in longer muscle relaxation for surgery when compared to levobupivacaine 0.5% 20 mL with dexmedetomidine 50 mcg. The prolonged duration of sensory blockade makes it an excellent choice for providing analgesia and a considerable level of sedation. Ultrasound guidance reduces the required volume of the drug. It is quite safe to perform brachial plexus block while avoiding complications such as pneumothorax and local anaesthetic systemic toxicity. The supraclavicular brachial plexus block with ultrasound guidance has become a predictable, secure, and safe option for upper limb surgeries, providing superior analgesia with a significant impact on perioperative wellness.

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