RESEARCH

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COMPARISON OF SAFETY AND EFFICACY OF VARYING DOSES OF BUTORPHANOL COMBINED WITH LEVOBUPIVACAINE IN SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK- A PROSPECTIVE STUDY

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Abstract

Background: Supraclavicular brachial plexus block is the most common technique for upper limb surgeries to anaesthetize the brachial plexus. Butorphanol is effective in increasing the duration of block and analgesia compared to the other drugs used for anaesthesia. As very limited studies are available on the use of varying doses of butorphanol, this study is an attempt to assess the onset of sensorimotor block, duration of sensorimotor block and period of analgesia with varying doses of butorphanol combined with levobupivacaine. Materials and Methods: A prospective, randomized, doubleblinded study was conducted in a tertiary care hospital among patients posted for elective upper limb orthopaedic surgeries from November 2019 to November 2021. Patient selection was made by consecutive sampling, and they were randomized into two groups of 30 patients each. Group LB1 was receiving 29ml of 0.375% Inj. Levobupivacaine + 1mg of Inj. Butorphanol and Group LB2 were receiving 29ml of 0.375% Ini. Levobupivacaine + 2mg of Ini. Butorphanol. The double blinding method was adopted, and the patients followed up until they rescued analgesia. Result: Inj. Butorphanol 2 mg added with 0.375% Inj. Levobupivacaine in 1ml Normal saline / 1mg in 1ml Normal Saline had a significant onset of motor block, prolonged duration of the sensorimotor block, and a more extended period of analgesia when compared to Inj. Butorphanol 1 mg with 0.375% Inj. Levobupivacaine in 1ml Normal saline. However, the use of Butorphanol 2mg + 0.375% Inj. Levobupivacaine in 1ml Normal saline is associated with adverse effects like nausea, vomiting and pruritis. Conclusion: Butorphanol significantly impacted the duration of sensorimotor block and the period of analgesia. Therefore, it could be used as an adjuvant in supraclavicular plexus block for upper limb surgeries. 2 mg of butorphanol produces more significant effects than 1 mg of butorphanol.

INTRODUCTION

Anaesthesia for the upper limb from the shoulder to the fingertips can be achieved by blocking the brachial plexus. Blocking the brachial plexus can be done in various ways, depending on the need for the block, the surgery or treatment performed, the patient's body habitus, medical comorbidities, and individual anatomy variances.^[1] Halsted and Crile, two well-known surgeons, were the first to conduct a brachial plexus block in 1884 and 1887, respectively. Both doctors opened the brachial plexus surgically before injecting cocaine into the neural system under direct vision.^[2] Hirschel and Hulenkampff reported the first percutaneous brachial plexus blockades in 1911. Brachial plexus blockade has become one of the most commonly procedures regional anaesthetic utilized in contemporary Anaesthesia practice, thanks to approaches, several adjustments, and developments.^[3] Winnie A et al. recent work has clarified the clinically relevant anatomy of the brachial plexus, allowing for further development of the method and acknowledgement of the relevance of brachial plexus blockade in the treatment of sympathetically sustained upper extremity pain syndromes. Interscalene, supraclavicular, infraclavicular, and axillary approaches are typically

used for brachial plexus blocks. Since this plexus stays rather tightly packed at this level, the supraclavicular level is ideal for achieving anaesthesia of the entire upper extremity, only distal to the shoulder.^[4]

The supraclavicular block is referred to as the "spinal of the arm" because of its results in a prompt and high-quality block.^[5] The shoulder, arm, forearm and hand surgical procedures were held using the supraclavicular approach to the brachial for regional anaesthesia.^[6] plexus Various anaesthetic drugs are used for Supraclavicular brachial plexus block surgeries in the upper limb 2ml of Dexamethasone (8mg), combined with the standard local anaesthetics 15ml of bupivacaine 0.5% and 15ml of 2% lignocaine, as well as adrenaline, is an effective and safe choice for quick onset and increases the duration of sensory and motor block in the brachial plexus.^[7] When 0.5% with 1ml of dexmedetomidine is used with 35cc of levobupivacaine with 1ml of isotonic saline is a supraclavicular brachial plexus block; the block lasts longer, and the duration of postoperative analgesia lasts longer.^[8] Butorphanol (2 mg) as an 0.5% of levobupivacaine adiuvant to in supraclavicular block hastens the onset of action. It prolongs the block's duration and postoperative analgesia compared to 100 mg tramadol.^[9] In brachial plexus block, a higher dose of 2mg of butorphanol accelerates the onset and prolongs the duration of sensory block, motor block and analgesia.^[10]

The brachial plexus block is the standard block used for upper limb surgeries. The Supraclavicular particularly gives ideal anaesthesia to the entire upper extremity distal to the shoulder. Many orthopaedic surgeries involving the upper limb require regional anaesthesia rather than general anaesthesia. Several drugs are used for regional Anesthesia. However, Inj Butorphanol of varying doses in addition to an adjuvant leads to prolongation of the duration of sensorimotor block and increases postoperative analgesia. There are minimal studies on the effect of different doses of Inj Butorphanol. This study attempts to assess and compare doses of Inj Butorphanol (1mg and 2mg) used in addition to Inj Levobupivacaine for upper limb orthopaedics surgeries.

Aim

To compare the onset and duration of the sensory and motor block, duration of analgesia and adverse effects between doses of Inj Butorphanol (1mg and 2mg) combined with Inj.Levobupivacaine. Inj Levobupivacaine is used in the Supraclavicular Brachial plexus block for upper limb orthopaedic surgeries.

MATERIALS AND METHODS

A Prospective, randomized, double-blinded study was conducted in the Department of Anesthesia,

Govt Villupuram Medical College and Hospital, Mundiyampakkam, for two years (November 2019 to November 2021). Institutional Ethics Committee approved this study. The patients undergoing plexus blockade were explained about the research, and a written consent form was obtained.

Inclusion Criteria

All the patients in this study are between 18 to 65 years of age. All the patients were posted for elective elbow, forearm and hand orthopaedic surgeries. All the patients belonged to Physical status 1 and 2 as per the American Society of Anesthesiologists (ASA).

Exclusion Criteria

The following patients were excluded from the study with a rib fracture, Patients with comorbidities like psychological disorders, coagulopathies, neuropathy and nerve injury. Patient posted for emergency surgeries, known allergy to local anaesthetics, and any infection at the puncture site. Patients who are unwilling and non-cooperative.

The sample size was calculated based on Bharath et al.^[10] studies using the mean difference between the two groups based on the duration of analgesia (-131.82). Open epi software was used to calculate the sample size, and the sample size was 30 in each group.

To make the sizes of groups similar, Block Randomization was adopted. The Participants were randomized using random allocation software version 1.0.0. 60.

The participants were allocated into two groups, and each group consisted of 30.

Members. Group LB1 was receiving 29ml of 0.375% Inj. Levobupivacaine + 1mg of Inj. Butorphanol was diluted in 1ml of normal saline. Group LB2 was receiving 29ml of 0.375% Inj. Levobupivacaine + 2mg of Inj. Butorphanol was diluted in 1ml of normal saline. Seventy-six patients were assessed for eligibility, and 60 met the inclusion and exclusion criteria. (5 patients were excluded, seven did not meet inclusion criteria, and four were unwilling to participate). The 60 patients included in the study were divided into two groups of 30 patients each (Group LB1 and Group LB2). The two groups were included in the final analysis.

The patients were premedicated with Inj. Ranitidine 50 mg and Inj. Ondansetron 4mg 30 minutes before surgery. In the Operating room, patients were received and connected to operating room monitors like pulse oximeter, non-invasive blood pressure monitor and patient baseline values. Then, an IV infusion (Ringer Lactate solution 500ml) was started in the contralateral forearm using an 18G intravenous cannula. For emergency resuscitation of the patient, emergency drugs and intubation, kits were kept ready.

A successful blockade was considered when there was motor function according to the modified

Bromage scale and absent sensation to pinprick in the regions.^[11]

Sensory and motor blockade were assessed every two minutes. After completion of injection till 30 minutes and then every 30 minutes after the end of the surgery till the first 12 hours, after that hourly, until the blockade had completely worn off.

The onset of sensory blockade was defined as the period between the end of the injection and the onset of sensory blockade, which was demonstrated by loss of sensation to pinprick or a pinprick response score of 1.

Every hour until the block wore off, postoperative pain was measured using the Visual Analogue Scale [VAS] (0–no pain to 10–worst pain) scale. The first 6 hours of postoperative vitals (heart rate [HR], systolic blood pressure [SBP], diastolic blood pressure [DBP], mean arterial pressure [MAP], and SpO2 were monitored every 2 hours, then every 4 hours until rescue analgesia was required.

Data analyzed were performed using SPSS software 16, using quantitative and qualitative variables. Quantitative variables were measured as Mean and standard deviation and analyzed using the Independent T-test to compare LB1 and LB2 groups. Qualitative variables were calculated as proportions and analyzed using the chi-square test to compare LB1 and LB2 groups.

RESULTS

The mean age of participants in the LB1 group was 39.10 ± 9.589 ranging from 18 - 56 years, and the LB2 group was 41.90 ± 9.553 , ranging from 24 - 57 years. LB1 and LB2 groups follow the normal distribution. The mean age of participants in the LB1 group was 39.10 ± 9.589 ranging from 18 - 56

years, and the LB2 group was 41.90 ± 9.553 , ranging from 24 - 57 years. The difference between study groups based on age was not significant.

The majority were males in the LB1 (66.7%) and LB2 (60%) groups. The difference between gender among LB1 and LB2 groups was found to be insignificant.

The mean weight of participants in the LB1 group was 71.60 ± 7.262 kgs and in the LB2 group was 73.93 ± 6.817 kgs; the difference shows insignificant results.

The mean onset of sensory block in the LB1 group was 7.77 ± 1.547 ranging from 5 - 11 minutes, and in the LB2 group was 7.87 ± 1.525 minutes ranging from 6 - 11 minutes. There was no difference among LB1 and LB2 groups statistically based on the onset of sensory block.

The mean onset of motor block in the LB1 group was 14.83 ± 1.367 from 12 - 18 minutes, and in the LB2 group was 13.17 ± 1.821 minutes from 10 - 16 minutes. There was a significant difference among LB1 and LB2 groups statistically based on the onset of motor block.

The mean duration of sensory block in the LB1 group was 401.1 ± 28.835 , ranging from 340 - 490 minutes, and in the LB2 group was 508.73 ± 24.866 minutes ranging from 456 –560 minutes. The difference based on the duration of the sensory block between LB1 and LB2 groups was significant statistically.

The mean duration of motor block in the LB1 group was 299.9 ± 17.695 ranging from 264 - 330 minutes, and in the LB2 group, it was 408.3 ± 19.846 , ranging from 356 - 438 minutes. There was a significant difference among LB1 and LB2 groups based on the duration of motor block.

Table 1: Distribution of patients' demographic characteristics						
		LB 1	LB 2	P value		
Age		39.10±9.59	41.90±9.55	0.262		
Gender	Male	20	18	0.592		
	Female	10	12			
Weight		71.60±7.26	73.93±6.82	0.205		

Table 2: Distribution of study parameter				
Variables	LB1	LB 2	P value	
The onset of sensory block	7.77 ± 1.547	7.87 ± 1.525	0.802	
The onset of motor block	14.83 ± 1.367	13.17 ± 1.821	0.001	
Duration of sensory block	401.1±28.835	508.73 ± 24.866	< 0.0001	
Duration of motor block	299.9 ± 17.695	408.3 ± 19.846	< 0.0001	
Duration of analgesia	510.13 ± 17.632	608.33 ± 21.290	< 0.0001	

Table 3: Distribution of Adverse effects				
Effects	LB1	LB2	P value	
Nil	27	22	0.372	
Nausea	2	5		
Vomiting	1	2		
Pruritis	0	1		

The mean duration of analgesia in the LB1 group was 510.13 ± 17.632 ranging from 480 - 556 minutes, and in the LB2 group, it was 608.33 ± 21.290 minutes ranging from 564 - 642 minutes.

The difference based on the duration of analgesia between the LB1 and LB2 groups was significant statistically.

The everyday adverse events reported in the LB1 group were nausea (6.7%) and vomiting (3.3%). LB2 group reported nausea (16.7%), vomiting (6.7%) and pruritis (3.3%) among participants. There was no significant association between LB1 and LB2 based on adverse events.

DISCUSSION

This double-blinded, randomized, prospective study was conducted among 60 patients, 30 patients allocated to each group LB1 and LB2; Group LB1 was administered with 29ml of 0.375% Inj. Levobupivacaine + 1mg of Inj. Butorphanol was diluted in 1ml of normal saline. Group LB2 was administered 29ml of 0.375% Inj. Levobupivacaine + 2mg of Inj. Butorphanol was diluted in 1ml of normal saline.

The mean onset of sensory block in the LB1 group was 7.77 ± 1.547 ranging from 5 -11 minutes, and in the LB2 group was 7.87 ± 1.525 minutes ranging from 6 -11 minutes, and there was no difference in both groups statistically.

Bharathi B et al. study conducted among 80 patients found that the mean score based on onset of sensory block was 12.57 \pm 3.5 minutes in the (29 ml of 0.375% levobupivacaine + 1mg of butorphanol) group and $8.04\pm$ 0.65 minutes in the (29 ml of 0.375% levobupivacaine + 2mg of butorphanol) group. The onset of motor and sensory block was higher in (29 ml of 0.375% levobupivacaine + 1mg of butorphanol) group than in (29 ml of 0.375% levobupivacaine + 2mg of butorphanol) group, and this result was significant statistically.^[10] The results were similar to our study results as the fastest onset was seen among the LB2 group than in the LB1 group. This was contradictory to our results as there was no difference among both groups based on the onset of sensory block.

The duration of sensory block was 396.23 ± 90.5 minutes in the (29 ml of 0.375% levobupivacaine + 1mg of butorphanol) group and 521.67 ± 71.3 minutes in the (29 ml of 0.375% levobupivacaine + 2mg of butorphanol) group which was significantly higher among the group. In addition, our study found that the mean duration of motor block in the LB1 group was 299.9 ± 17.695 , ranging from 264 - 330 minutes, and in the LB2 group was 408.3 ± 19.846 , ranging from 356 - 438 minutes, and the difference was found to be significant.

The duration of motor block was 305.60 ± 66.6 minutes in (29 ml of 0.375% levobupivacaine + 1mg of butorphanol) group and 418.40 ± 73.8 minutes in (29 ml of 0.375% levobupivacaine + 2mg of butorphanol) group, which was significant. This result was similar to our study as Inj. Butorphanol 2 mg produces a longer duration of the motor block than Inj. Butorphanol 1 mg.

Bommalingapa B et al. study showed Mean score of onset of sensory block was 12.3 ± 2 minutes in (24mL of 0.5% levobupivacaine + 1mL (1mg)

Butorphanol) group and 16.4± 3.2 minutes in (24mL of 0.5% levobupivacaine + 1mL normal saline) group. The onset sensory block was higher in (24mL of 0.5% levobupivacaine + 1mL normal saline) group than in (24mL of 0.5% levobupivacaine + 1mL (1mg) Butorphanol) group, which was significant.^[12] statistically (24mL of 0.5% levobupivacaine + 1mL (1mg) Butorphanol) Group used Inj. Butorphanol 1 mg and (24mL of 0.5% levobupivacaine + 1mL normal saline) group used only Inj. Levobupivacaine drugs and this result were similar to our study results. Inj. Butorphanol 1 mg added as adjuvant results in a lower time of onset of sensory block.

The motor block onset in (24mL of 0.5%)levobupivacaine + 1mL (1mg) Butorphanol) group was 10.1 ± 2.1 minutes, and in (24mL of 0.5%)levobupivacaine + 1mL normal saline) group was 12.3 ± 2.8 minutes. The motor block onset was higher in (24mL of 0.5%) levobupivacaine + 1mL normal saline) group than (24mL of 0.5%)levobupivacaine + 1mL (1mg) Butorphanol) group, which was not statistically significant. This study results were similar to our study results as Inj. Butorphanol added as an adjuvant produces the fastest onset of action (12 minutes).

Our study reported that the mean duration of sensory block in the LB1 group was 401.1 ± 28.835 ranging from 340 - 490 minutes, and in the LB2 group was 508.73 ± 24.866 minutes, ranging from 456 - 560 minutes, and the difference was found to be significant. In a survey, the duration of motor block in (24mL of 0.5% levobupivacaine + 1mL (1mg) butorphanol) group was 256.6 ± 14.6 minutes, and in the (24mL of 0.5% levobupivacaine + 1mL normal saline) group was 168.8 ± 11.4 , and the difference was significant. Inj. Butorphanol (24mL of 0.5% levobupivacaine + 1mL (1mg) Butorphanol) Group produces a prolonged duration of the motor block than Inj. Levobupivacaine.

Sharan R et al. found that the mean sensory block duration was 4.27 ± 0.51 hours in (Bupivacaine) group and 9.10 ± 0.71 hours in (Inj.Butorphanol+ Bupivacaine) group; it was discovered that the difference between the two groups was statistically significant. Furthermore,^[13] (Inj. Butorphanol+ Bupivacaine) group had an increased duration of the sensory block than the (Bupivacaine) group, similar to our study results.

Kujur DS et al. reported that the onset was 25 ± 7.07 sec and peak effect 312.5 ± 12.4 sec in (2mg of butorphanol) group patients as compared to (3mg of butorphanol) group where it was 12.81 ± 21.68 sec and 162.8 ± 21.68 sec respectively, which is statistically significant (P<0.05).^[14] The varying doses of Inj. Butorphanol (1 mg & 2 mg) had effective fastest action in the onset of motor block. However, there was a difference in both groups statistically in our study.

Gupta R et al. reported the duration of analgesia was 5.35 ± 0.29 hrs, and 6.25 ± 1.58 hrs in Butorphanol and Tramadol groups, respectively and the

difference was found to be statistically significant.^[15] In our study, research showed Inj. Butorphanol 2 mg had more prolonged duration analgesia compared with Inj. Butorphanol 1 mg.

Pokharel K et al. study showed the onset and duration of analgesia in (0.5 mg of butorphanol) group (4.1±2.6 min and 202.4±62.8 min) and (0.75 mg of butorphanol) group $(4.0\pm2.5 \text{ min and})$ 192.3 \pm 69.1 min) were significantly different.^[16] Our study showed Inj. Butorphanol 2 mg had a longer duration of analgesia compared with Ini. Butorphanol 1 mg. which is statistically significant. Wajima Z et al. reported that After upper limb surgery, continuous Inj. Butorphanol 2 mg day-1 with 0.5 percent mepivacaine produced adequate postoperative analgesia.^[17] For Supraclavicular brachial plexus block in upper limb surgeries, they used Inj. Butorphanol had a prolonged duration of analgesia compared with other drugs like bupivacaine and Inj. Levobupivacaine. The varying doses of Inj. Butorphanol (1 mg & 2 mg) had a significantly prolonged duration of analgesia in our study.

In addition, Side effects such as hypotension (17.5%), pruritis (12.5), and sedation (15%). (0.5% hyperbaric bupivacaine) group was recorded in the research of Kumar B et al.^[18] In our study, Group LB1 presented with adverse events like nausea (6.7%) and vomiting (3.3%). The LB2 group reported nausea (16.7%), vomiting (6.7%) and pruritis (3.3%) as adverse effects.

CONCLUSION

The varying doses of Inj.Butorphanol (1mg & 2mg) significantly prolonged sensory block duration. Inj.Butorphanol had a prolonged duration of analgesia compared with drugs bupivacaine and Inj.Levobupivacaine. The varying doses of Inj.Butorphanol (1mg & 2mg) had a significantly prolonged duration of analgesia. Therefore, it could be an adjuvant in the Supraclavicular brachial plexus block for upper limb surgeries 2 mg of Inj. Butorphanol produces the more significant effects, i.e. faster onset of motor block, prolonged duration of sensory and motor block, and prolonged duration of analgesia when compared to 1mg of Inj Butorphanol. Thus, it can be used as an adjuvant in the supraclavicular brachial plexus block for upper limb surgeries. The 29ml of 0.375% Inj.Levobupivacaine + 2mg of Inj.Butorphanol (LB2) group recorded nausea, vomiting and pruritis as adverse effects. There is no significant difference between the groups.

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