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Original Research Article

Comparative Study of 0.5% Levobupivacaine with and without Fentanyl in Ultrasound Guided Supraclavicular Brachial Plexus Block: A Randomized, Prospective Study

Rajib Hazarika[1], Pallavi Ghose[2], Smitakshi Das[3]

[1]Professor, Department of Anaesthesiology, Gauhati Medical College and Hospital, Guwahati, Assam
[2]Associate Professor, Department of Anaesthesiology, Gauhati Medical College and Hospital, Guwahati, Assam
[3]Post Graduate Trainee, Department of Anaesthesiology, Gauhati Medical College and Hospital, Guwahati, Assam

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Corresponding Author: Dr. Rajib Hazarika
Conflict of interest: Nil

Abstract:

Background and Objectives: Supraclavicular brachial plexus block is a popular and widely employed regional nerve block technique for upper limb surgeries. Adjuvants are often added to local anaesthetics to prolong or enhance their action. This study was conducted to evaluate the anaesthetic and analgesic efficacy of addition of 50mcg fentanyl to 0.5% levobupivacaine in ultrasound guided supraclavicular brachial plexus block.

Methods and Materials: In this prospective, double blind, randomised control study, 110 patients (aged 18-65 years) belonging to ASA physical status I/II undergoing elective orthopaedic upper-limb surgery under ultrasound-guided SCBP block were randomised into 2 groups. GROUP A (n = 55) received 25ml levobupivacaine 0.5% + 1ml(50mcg) fentanyl diluted to a volume of 30ml with normal saline. GROUP B (n = 55) received 25ml levobupivacaine 0.5% diluted to a volume of 30ml with normal saline.

Results: The duration of sensory blockade in Group A was longer than Group B ($P < 0.05$). The onset of sensory and motor blockade in Group A was faster than Group B. The duration of motor blockade and duration of analgesia in Group A was prolonged compared to Group B. Hemodynamic parameters were similar between the two groups. 24 hours analgesic consumption postoperatively was less in group A than group B. 3 patients in group A and 1 patient in group B complained of nausea, vomiting.

Conclusion: Fentanyl added to levobupivacaine for supraclavicular brachial plexus block reduces the time to onset and duration of sensory and motor blockage and prolongs the duration of analgesia.

Keywords: Supraclavicular Brachial Plexus, Levobupivacaine, Fentanyl, Analgesia, Anaesthetic Adjuvant.

Introduction

One of the primary aims of anaesthesia is to relieve a patient's pain and discomfort during surgery and in the postoperative period. Peripheral nerve blocks have proved to be a good alternative to general anaesthesia for upper limb orthopaedic surgeries as they provide prolonged postoperative analgesia while reducing the side effects of general anaesthesia.

The supraclavicular block, often referred as the 'spinal of the arm' is commonly used for upper limb surgeries and provides excellent anaesthesia and analgesia from distal arm to fingertips.

A variety of local anaesthetics (LAs) have been studied for brachial plexus blockade. Earlier Bupivacaine was commonly used for brachial plexus block. Bupivacaine, an amide local anaesthetic is a racemic mixture (50:50) of its two enantiomers Levobupivacaine (S-) and dextrobupivacaine (R+). Levobupivacaine, S-enantiomer of bupivacaine, has a better safety profile with respect to both cardiovascular system (CVS) and central nervous system compared with racemic bupivacaine. Levobupivacaine provides a faster onset of sensory block and longer duration of analgesia compared to ropivacaine but the return of motor activity is earlier with ropivacaine.[1–3]

Perineural use of adjuvants is a commonly used measure in regional nerve block. Fentanyl is a synthetic opioid which acts on μ-opioid receptors. It is 50-100 times more potent than morphine as an analgesic. [4] The use of fentanyl as an adjuvant to local anaesthetic in peripheral nerve blocks has presented with conflicting results. While some studies have established a prolonged analgesic effect with fentanyl, others have failed to show any benefit.

The present study was done to evaluate the efficacy of levobupivacaine and fentanyl in USG guided supraclavicular brachial plexus block.

Aims and Objectives

Aim of the study: To determine the efficacy of 0.5% levobupivacaine alone and levobupivacaine with fentanyl in supraclavicular brachial plexus block.

Primary Objective: To compare the duration of sensory block in each group.

Secondary objectives:

1. Onset of sensory block
2. Onset and duration of motor block
3. Duration of analgesia
4. Hemodynamic changes following block
5. Side effects and complications

Methods and Materials

This is a prospective, randomised, double-blinded study conducted under the Department of Anaesthesiology and Critical Care, Gauhati Medical College and Hospital, Guwahati in association with the Department of Orthopaedics, Gauhati Medical College and Hospital, Guwahati. The study was carried out for a period of one year from 1st November 2023 till 31st October 2024 with prior approval from the Institutional Ethical Committee (No.MC/190/2007/Pt-11/Oct.2023/27). The study was also registered with the Clinical Trials Registry of India (CTRI/2024/04/065128).

Sample Size Calculation: The sample size was calculated based on a previous study by Paramaswamy et al.(5) Considering a mean difference of 15.6 minutes in the duration of sensory block between two groups as per the previous study, a total of 108 (round off 110) samples will be required for the study to detect 80% power at 5% level of significance.

Selection of Cases for the Study: Our study included adult patients of both sexes who fulfilled the inclusion and exclusion criteria as mentioned below.

Inclusion Criteria:

1. Age: 18-65years
2. ASA grade 1 and 2
3. Patient posted for elective orthopaedic elbow, forearm and hand surgeries under USG guided supraclavicular brachial plexus block
4. Patients giving consent to participate in the study

Exclusion Criteria:

1. Coagulation disorders and patients on anticoagulants
2. Infection at the site of injection
3. History of anaphylaxis to local anaesthetics and allergy to the study drugs
4. Patients with peripheral neuropathy.
5. Patients on chronic analgesic medications
6. Patients with contralateral phrenic nerve palsy.
7. Block failure or partial blocks
8. Pregnant and lactating patients

Procedure:

For our study, the patients admitted under the Department of Orthopaedics, GMCH were assessed for eligibility. After obtaining informed written consent, patients were randomised into two equal groups- GROUP A and GROUP B using computer generated random sequencing software. Sealed, opaque envelope was used for concealment of allocation.

On the day of surgery, the sealed envelope was opened by an OT technician and drugs were prepared by an anaesthetist not involved in the study. The person performing the block was not aware of the drug being administered.

- GROUP A received 25ml levobupivacaine 0.5% + 1ml(50mcg) fentanyl diluted to a volume of 30ml with NS
- GROUP B received 25ml levobupivacaine 0.5% diluted to a volume of 30ml with NS

The drug volume in both the groups was same.

All patients were subjected to detailed pre-anaesthetic check-up with routine investigations the day before surgery. Special investigations were done wherever needed. During the pre-anaesthetic check-up, patients were also explained regarding pain assessment using the NRS scale postoperatively.

On the day of surgery, after arrival in the operation theatre waiting room, standard monitors such as pulse oximetry, ECG and non-invasive blood pressure were connected. Baseline pulse rate, oxygen saturation and blood pressure were recorded. An intravenous access with 18-gauge cannula was established. After this, the brachial plexus block was performed via supraclavicular approach under ultrasound guidance.

Study Parameters

After injecting the local anaesthetic, the following parameters were noted-

1. Onset and duration of sensory block
2. Onset and duration of motor block
3. Duration of analgesia
4. Total analgesic consumption in 24 hours
5. Hemodynamic changes following block
6. Side effects and complications
7. Intra-operative Ramsay Sedation Score

The sensory block was evaluated along the distribution of four nerves – musculocutaneous,

median, radial and ulnar by pinprick sensation and compared with same area on contralateral arm by Hollmen scale Score.

[1] = Normal sensation of pinprick

[2] = Weaker sensation of pinprick felt as compared with another upper limb

[3] = Pinprick recognised as touch with a blunt object

[4] = No perception of pinprick.

The findings were recorded at an interval of 2 min till a complete sensory block is achieved i.e. Hollmen Score=4.

Onset of sensory block was taken as the time interval between end of total local anaesthetic administration to complete sensory block (Hollmen score =4).

Duration of sensory block was taken as the period between onset of sensory blockade to reappearance of pinprick sensation.

The motor block was evaluated for flexion of elbow (musculocutaneous nerve), opposition of thumb (median nerve), abduction of finger (ulnar nerve), extension of thumb (radial nerve) by using the Modified Bromage Scale (MBS) for the upper extremity on a 3-point scale.

- Grade 0 - normal motor function with full flexion and extension of elbow, wrist and fingers
- Grade1 - decrease motor strength with the ability to move fingers and/or wrist only
- Grade 2 - complete motor blockade with inability to move fingers

The onset of motor block was considered from the injection of the drug till to the time of grade 1 of Modified Bromage Scale.

Duration of motor block was taken as the interval between successful block completion till full recovery of motor function (Grade=0).

After achieving an adequate sensory block of score 4 using Hollmen scale and motor block of grade 2 using Modified Bromage Scale, surgery was started. The block was considered to have failed if desired sensory and motor block is not achieved after 30 minutes of administration of the block. All failed blocks were converted to general anaesthesia.

During the intraoperative period hemodynamic parameters (heart rate, Non-invasive blood pressure, oxygen saturation) were monitored every 15 minutes.

Procedural complications associated with supraclavicular block like vessel injury, hematoma, pneumothorax, Horner's syndrome, phrenic nerve block, if any, were noted. Any adverse effects like hypotension, bradycardia, nausea and vomiting, respiratory depression, fall in oxygen saturation, any signs or symptoms of local anaesthetic toxicity, ECG changes, etc. were recorded and appropriately managed. Hypotension was defined as ≥20% decrease of mean arterial pressure (MAP) from baseline value and bradycardia was defined as HR <50 beats/min.

Hypotension was treated with IV fluids and if still uncorrected, vasopressors like mephentermine and ephedrine were used. In case of bradycardia, injection atropine 0.6 mg iv was used. Nausea and vomiting were treated with 4 mg intravenous ondansetron injection.

Degree of sedation was monitored every 15 minutes during the surgery using the Ramsay Sedation Scale -

- 1: anxious and agitated or restless or both
- 2: Co-operative, oriented and tranquil
- 3: responding 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 stimulus

Postoperatively, pain assessment was done using numerical rating scale (NRS). Pain assessment was done every 3 hours up to 24 hours post-operatively. The score was interpreted as follows:

- 1-3: mild pain
- 4-6: moderate pain
- 7-10: severe pain

Duration of analgesia was taken as the time interval between complete sensory block to NRS score ≥4. NRS score ≥4 was managed with rescue analgesia in the form of 1g paracetamol intravenous infusion. Total analgesics given during the 1st 24 hours postoperative period was also recorded.

Statistical Analysis: After completion of study, the data obtained was entered into Microsoft Excel and analysed with SPSS version 21. The Chi-square or Fisher's Exact Test have been used to determine associations between categorical data. The Kolmogorov-Smirnov test and Shapiro-Wilk test were used to checked data normality. The Student's t-test assessed significant mean differences for normal data while the Mann-Whitney U test had been applied for non-normal data. Statistical significance was interpreted as follows:

- P-value > 0.05 – not significant
- P-value < 0.05 – significant
- P-value < 0.001 – highly significant

Results and Observation: For this study, 146 patients were screened for inclusion criteria. 132 patients meeting the inclusion criteria were randomized into 2 groups- Group A and Group B.

There were 2 cases of block failure in group A and 3 in group B. 9 patients in group A and 8 patients in group B were excluded from the study due to loss to follow up in the postoperative period. In the end, 55 patients were analysed in each group.

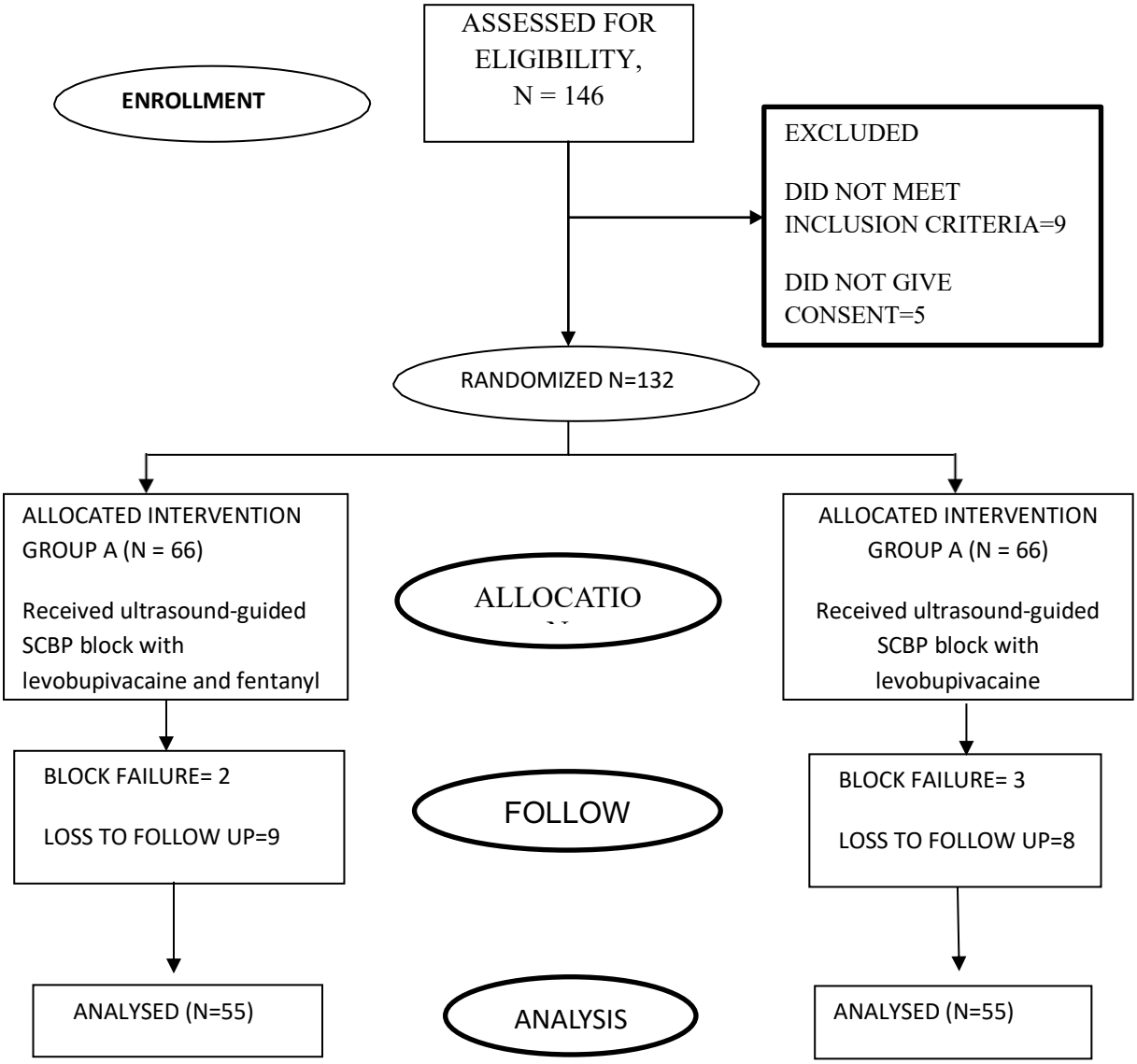

Table 1: Consort Flow Diagram

A. **Demographic Variables**

Table 1: Demographic Variables

Demographic Characteristics		Group A (Mean± S.D.)	Group B (Mean± S.D.)
Age (Yrs)		38.49±13.63	38.93±13.5
Sex	**Male**	33	32
	Female	22	23
Weight (kgs)		61.8±7.7	62.4±8.7
Height(cm)		161.8±6.3	162.4±5.8
ASA Grade	**I**	41	36
	II	14	19
Duration of Surgery(mins)		72±21.6	68.5±19.5

The demographic characteristics of patients in both the study groups were comparable. There was no significant difference with respect to age, sex, weight, height, ASA physical status and duration of surgery.

B. **Block Characteristics**

Table -2: Block characteristics

	Group A	Group B	p value
Onset of sensory block (mins)	9.5±1.6	12±2	<0.001
Onset of motor block (min)	11.6±1.8	14.6±1.8	<0.001
Duration of sensory block (mins)	497.1±28.8	425.7±40.2	<0.001
Duration of motor block (mins)	435.7±31.3	366.2±27.4	<0.001
Duration of analgesia (mins)	696.4±58.2	590.6±66.4	<0.001

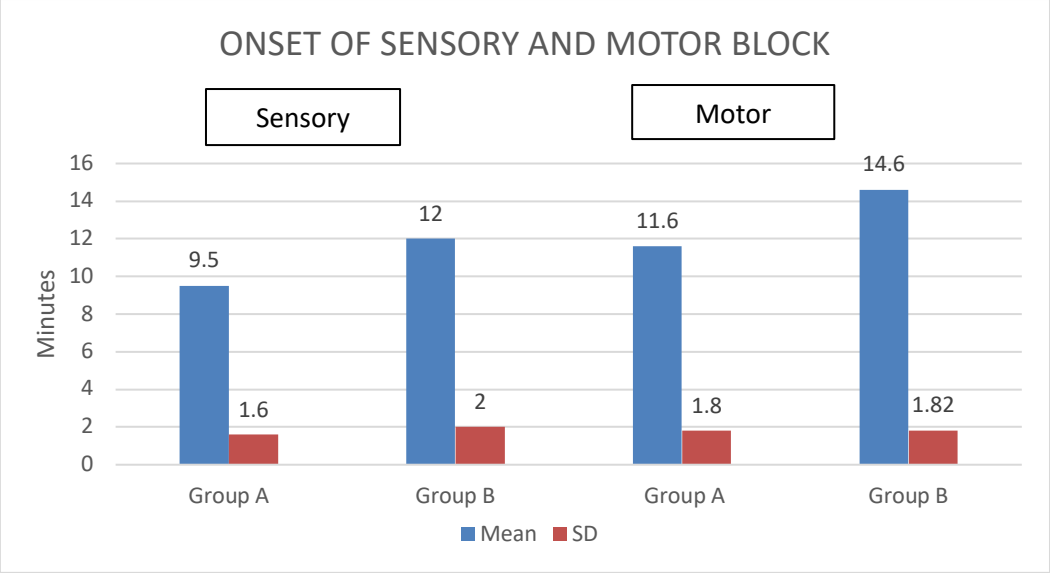

Figure 1: Distribution of onset of sensory block and motor block in both groups

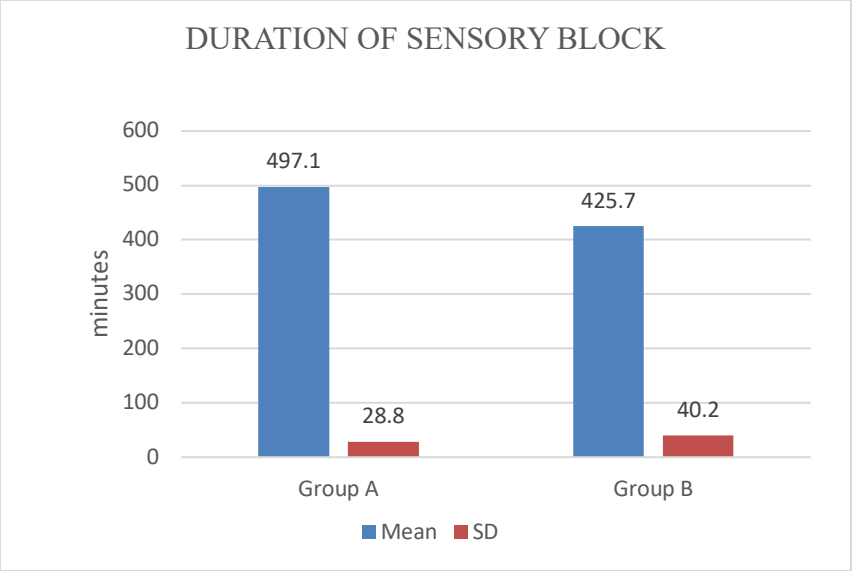

Figure 2: Duration of sensory block in both groups

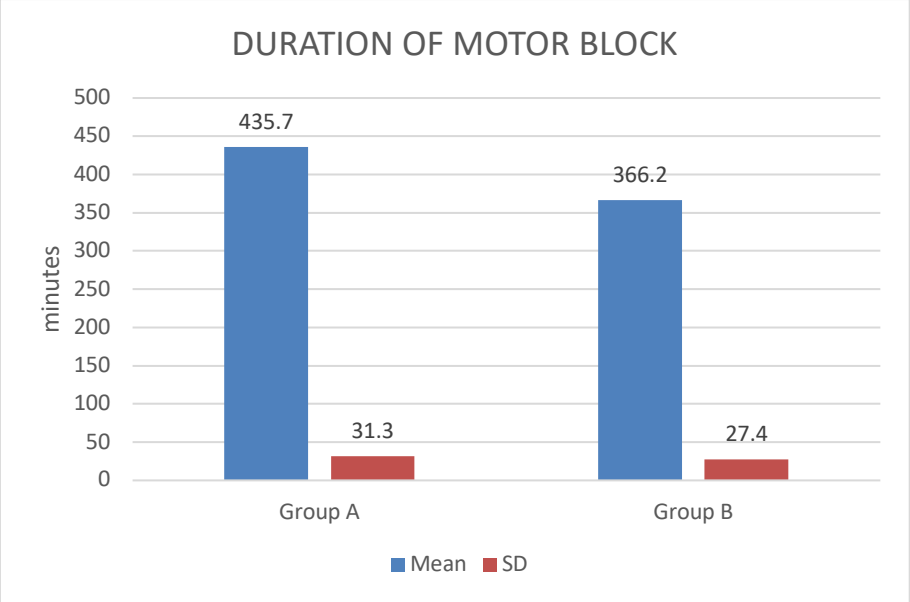

Figure 3: Distribution of duration of motor block

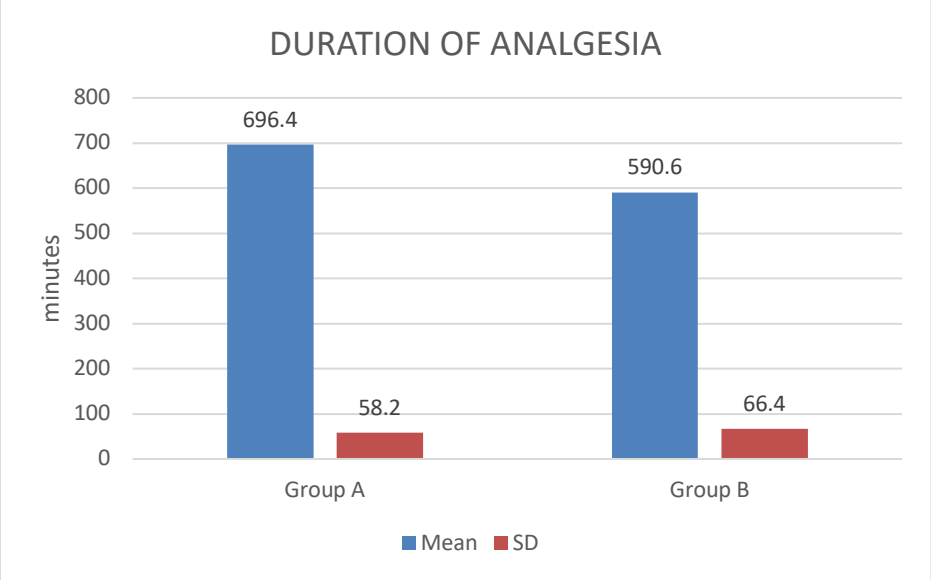

Figure 4: Distribution of duration of analgesia in both groups

C. **NRS Scores**

In our study, we found that from the 3rd postoperative hour onwards, there is a significant statistical difference of NRS score between group A and B. However, in the 12th[th] postoperative hour, the difference was not significant. A highly significant statistical difference of NRS score was noted at 3rd, 9th, 15th and 24th postoperative hours. Overall, lower pain scores were seen in group A.

Table 3: Comparison of NRS between the two groups

Post-op NRS score	Group A	Group B	p value
0 HRS	0±.0	0±.0	1.000
3 HRS	0.4±0.5	0.8±0.4	<0.001
6 HRS	1.7±0.6	2±0.4	.003
9 HRS	2.4±0.7	3.1±0.5	<0.001
12 HRS	3.7±0.7	3.9±0.6	.264
15 HRS	3.9±0.7	4.7±0.8	<0.001
18 HRS	4.4±0.8	4.8±0.7	.006
21 HRS	4.8±1	5.1±0.8	.024
24 HRS	4.7±1	5.5±0.7	<0.001

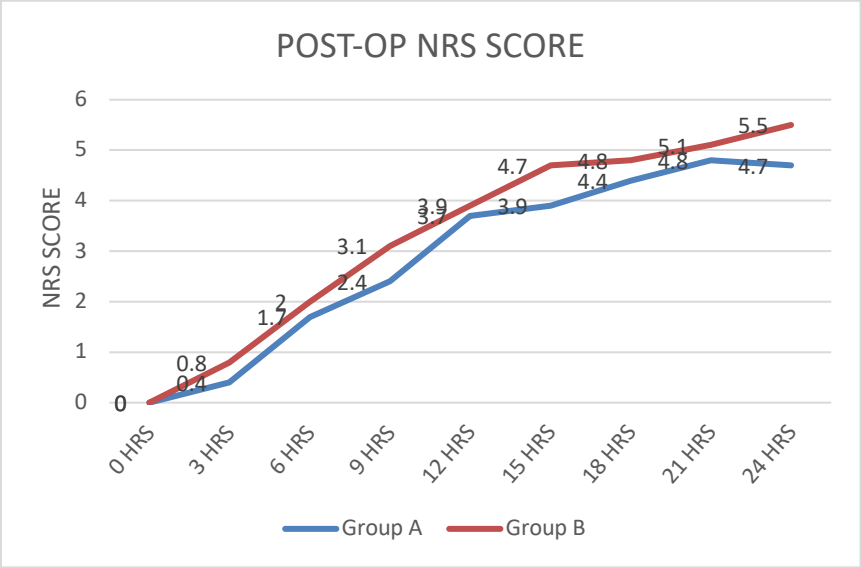

Figure 5: Distribution of mean NRS between the two groups

D. **Total Analgesic Requirement in 24 Hours**

1g paracetamol was used as rescue analgesia for NRS score ≥ 4. The mean total analgesic consumption in 24hrs postoperatively in group A was 1.9g whereas it was 2.1g in group B. This difference was not statistically significant.

Table 4: Comparison of total analgesic requirement in 24 hours between the two groups

	Group A	Group B	p value
Total Analgesic (in gm)	1.9±0.5	2.1±0.6	0.056

E. **Hemodynamic Parameters:** The mean arterial pressure, heart rate and oxygen saturation was measured every 15 minutes intraoperatively in both groups. There is no statistically significant difference between the two groups with respect to intraoperative hemodynamics.

Table 5: Comparison of Mean Arterial Pressure between the two groups

MAP	Group A	Group B	p value (t-test)
Pre-Op	80.3±5.3	82.1±5.9	0.098
0 min	81.1±5.5	82.7±4.8	0.117
15 mins	81.3±4.7	82.2±5.9	0.367
30 mins	80.6±4.9	82.5±5.5	0.059
45 mins	80.5±4.8	81.8±5.3	0.183
60 mins	80.3±5.1	81.2±5.8	0.415
75 mins	79.9±4.5	82.8±5.4	0.059
90 mins	80.5±5.4	84.1±4.8	0.058
105 mins	79.3±2.4	81.8±3.3	0.092
120 mins	78±0.0	85±5.7	0.497

Table 6: Comparison of Heart Rate between the two groups

Heart Rate (HR)	Group A	Group B	p value (t-test)
Pre-OP	81.8±7.9	83.3±6.8	0.299
0 min	82.3±7.6	84±5.8	0.178
15 mins	81.3±8.4	83.1±6.5	0.226
30 mins	80.9±7.6	82.3±6.9	0.306
45 mins	81.1±7.7	82.1±7.1	0.465
60 mins	81.2±7.2	81.4±6	0.861
75 mins	81.3±7	81±7.1	0.907
90 mins	79.9±6.8	81.9±5.4	0.371
105 mins	81.1±5.9	82±5	0.761
120 mins	86±0.0	83.5±0.7	0.212

Table 7: Comparison of Oxygen Saturation between the two groups

	Group A	Group B	p value (Mann Whitney test)
Pre_Op_SPO2 (%)	98.6±0.8	98.7±0.7	0.707
0 min_SPO2	98.5±0.8	98.6±1	0.533
15 mins_SPO2	98.6±0.8	98.5±0.8	0.348
30 mins_SPO2	98.4±1	98.6±0.8	0.389
45 mins_SPO2	98.6±0.7	98.7±0.8	0.454
60 mins_SPO2	98.1±3.1	98.5±0.8	0.916
75 mins_SPO2	98.5±0.6	98.3±0.9	0.188
90 mins_SPO2	98.4±0.6	98.2±0.7	0.526
105 mins_SPO2	98.5±0.5	98.5±0.5	1.000
120 mins_SPO2	99±0.00	98±1.4	0.480

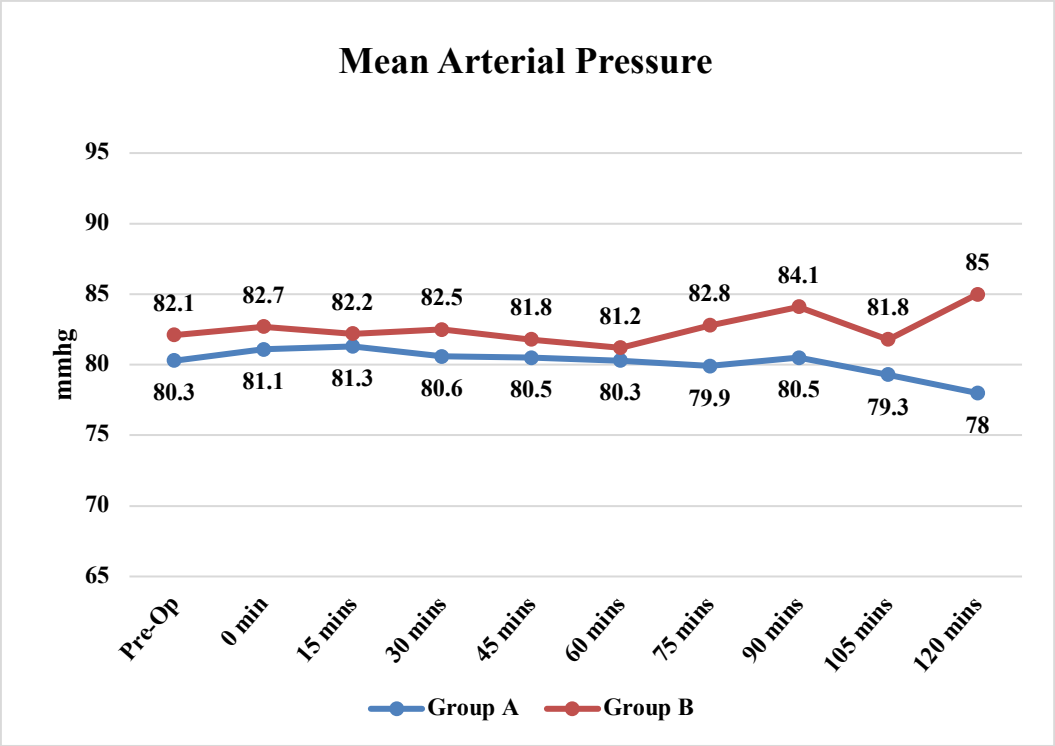

Figure 6: Distribution of Mean Arterial Pressure between the two groups

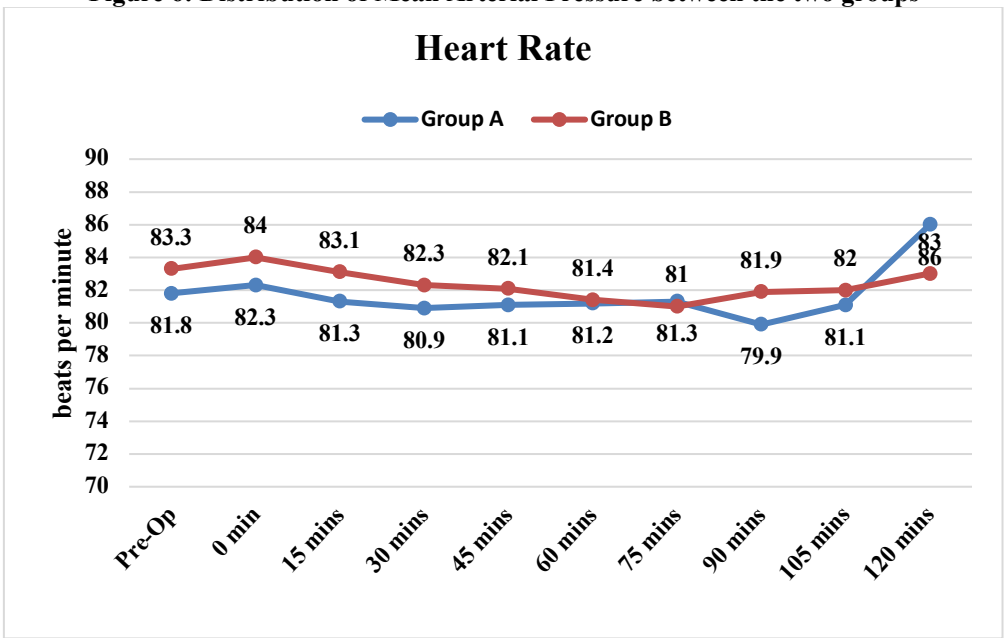

Figure 7: Distribution of Heart Rate between the two groups

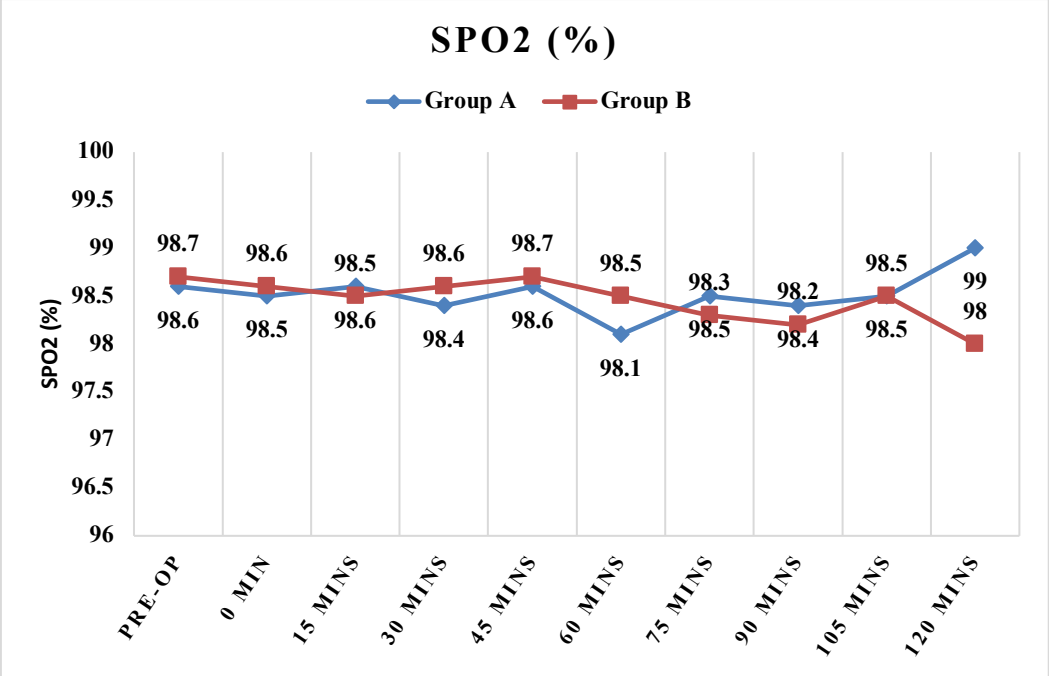

Figure 8: Distribution of Oxygen Saturation between the two groups

The mean arterial pressure, heart rate and oxygen saturation was measured every 15 minutes intraoperatively in both groups. There is no statistically significant difference between the two groups with respect to intraoperative hemodynamics.

F. **Adverse Effects**

Table 8: Incidence of adverse effects in both groups

Complications	Group A	Group B	Total	p value
nausea, vomiting	3	1	4	0.308
None	52	54	106	
Total	55	55	110	

3 patients in group A and 1 patient in group B complained of nausea and vomiting which was statistically insignificant. This was treated with injection 4mg ondansetron intravenously.

G. **Ramsay Sedation Score**

The Ramsay sedation score of both groups was in the range 2-3 throughout the intraoperative period. This was statistically not significant.

Table 9: Comparison of Ramsay Sedation Score between the two groups

Intra-OP Ramsay sedation score	Group A	Group B	p value
0 mins	2±0.0	2±0.0	1.000
15 mins	2.05±0.23	2.04±0.19	0.436
30 mins	2.07±0.26	2.05±0.23	0.436
45 mins	2.05±0.23	2.04±0.19	0.436
60 mins	2.03±0.16	2.05±0.23	0.417
75 mins	2.04±0.21	2.06±0.24	0.480
90 mins	2.06±0.24	2.08±0.29	0.456
105 mins	2±0.0	2±0.0	1.000
120 mins	2±0.0	2±0.0	1.000

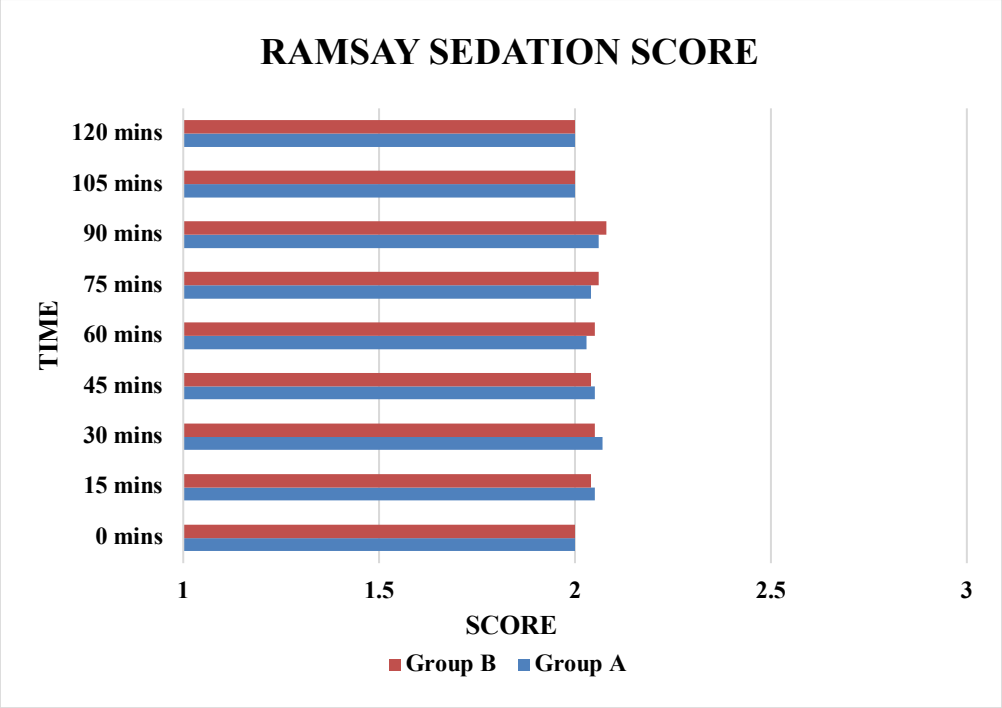

Figure 9: Distribution of mean Ramsay Sedation Score between the two groups

Discussion

The primary aim of our study was to evaluate and compare the duration of sensory block between the two groups. The duration of sensory block in group A was 497.1 ± 28.8 minutes while in group B it was 425.7 ± 40.2 minutes. Thus, the duration of sensory block was significantly prolonged in group A compared to group B (p value <0.001).

The study conducted by Sesham et al [6] comparing 0.5% levobupivacaine and 0.5% ropivacaine with and without 50 mcg fentanyl for supraclavicular brachial plexus block also reported a prolonged sensory block on using fentanyl with levobupivacaine (13 hrs) compared to ropivacaine with fentanyl (9 hrs). Jajjari P et al [7] carried out a similar study comparing ropivacaine and levobupivacaine with fentanyl as adjuvant and found similar results. The duration of sensory block was more prolonged in their studies compared to ours. This difference could be attributed to the higher volume of levobupivacaine (29 ml) used in these studies. This could also be due to a different definition of duration of sensory block in these studies. The criteria for end point of sensory block duration were return of pin prick sensation in our study whereas in the above-mentioned studies it was the same as duration of analgesia, i.e. till the time when VAS score was < 4. Levobupivacaine has vasoconstrictive properties which may account for the longer duration of block observed when compared to ropivacaine. The sensory blockade duration was also prolonged in the fentanyl group in the studies conducted by Hembrom et al [8] and Mahmoud Hala et al [9]. Hembrom et al used 30 ml 0.5% levobupivacaine with 100 mcg fentanyl and the end point of sensory block was return of dull pain and VAS score <3. This could again explain the more prolonged sensory block duration (995.10 ± 46.090 mins) in their study compared to ours. Mahmoud Hala et al. had used 22.5 ml levobupivacaine 0.5% and 1ml Fentanyl (50 µg). The mean duration of sensory block in this study was 658.4 minutes in the fentanyl group and 524.8 mins in the group receiving only levobupivacaine.

The mean onset of sensorimotor block was faster in group A compared to group B. Our results were in agreement with studies conducted by Mahmoud H et al, Paramaswamy R et al [5], Kaur et al [10] and Roy G et al [11]. Delay in onset of block was seen in studies carried out by Nishikawa K et al [12], Chavan SG et al [12], Rajkhowa et al [13], Kaniyil S et al [14], Gupta M et al [15] and Hembrom et al. On the other hand, as per the research by Jajjari P et al no significant difference was detected with respect to the onset time of block when fentanyl was added as an adjuvant to local anaesthetics. Such conflicting results could be due to the use of different local anaesthetics in some of the studies or due to a change in the pH of the drug solution on adding fentanyl.

A meta-analysis conducted by Song et al [16] on the effect of fentanyl as an adjuvant to brachial plexus block observed that a delayed onset of sensory anaesthesia was seen with fentanyl in earlier studies, while a faster onset was observed in latter studies. They speculated that such variation may be due to a change in drug formulations and pH of solution.

The duration of motor block was significantly longer in group A (435.7 ± 31.3 mins) compared to group B (366.2 ± 27.4). The duration of sensory block was longer than motor block which was similar to previous studies. This is probably due to a higher volume and concentration of local anaesthetic required to block the large motor fibres than the small sensory fibres. The motor block duration on addition of fentanyl to levobupivacaine was found to be significantly longer than the groups using only levobupivacaine in studies conducted by Sesham et al, Mahmoud Hala et al and Hembrom et al. The studies using local anaesthetics other than levobupivacaine also reported extended motor block duration on using fentanyl except the studies conducted by Fletcher et al [17] and Fanelli G et al [18].

In our study, the duration of analgesia was greater in group A (696.4 ± 58.2 mins) compared to group B (590.6 ± 66.4 mins) and this was statistically highly significant. Our findings were consistent with the studies conducted by Sesham et al, Jajjari P et al, Paramaswamy R et al, Kaur et al, Roy G et al, Mahmoud Hala et al, Hembrom et al and Nishikawa et al who also reported enhanced analgesia with fentanyl. In contrast to our findings, Fletcher et al and Fanelli G et al did not report any additional benefit on addition of fentanyl in axillary block.

Nishikawa et al hypothesized that the beneficial effects of fentanyl in peripheral nerve blocks can be ascribed to three reasons. Firstly, there is a direct action of fentanyl on peripheral opioid receptors. Secondly, fentanyl may diffuse from the brachial plexus sheath to subarachnoid and epidural spaces which can then bind to opioid receptors in dorsal horn. Also, following systemic absorption, fentanyl may have an effect on central opioid receptors.

There was a significant difference in the NRS score between the two groups in our study with group A reporting lower pain scores. The group receiving fentanyl attained a NRS score of 4 at around 11.6 hours whereas the group receiving only levobupivacaine attained a NRS score of 4 at around 9.8 hours. Our results were in concurrence with the studies conducted by Sesham et al, Mahmoud Hala et al, Jajjari P et al. The studies conducted by Sesham et al and Jajjari P et al observed that the group receiving only levobupivacaine attained a VAS score of 4 at around 10 hours which was earlier than the group receiving levobupivacaine with fentanyl. The fentanyl group attained a VAS score of 4 at around 13 hours. The 24 hours VAS scores in the studies conducted by Khan I et al and Gupta M et al also indicated better pain control on perineural administration of fentanyl with local anaesthetics. But at 12th postoperative hours the NRS score between the 2 groups in our study was not significant. This is probably due to a higher number of patients receiving analgesic between the 9th-12th postoperative hours in group B.

The rescue analgesic used in our study was 1g intravenous paracetamol infusion. The mean total analgesic consumption for 24 hours postoperatively was higher in group B compared to group A but this was statistically insignificant. But the studies conducted by Mahmoud Hala et al, Paramaswamy et al and Kaur et al reported a significantly lower consumption of analgesics postoperatively when fentanyl was used as an adjuvant. On analysing the impact of fentanyl on postoperative analgesic requirement, Song et al found conflicting results with some studies reporting better analgesic effects while others reported no difference. This variation could probably be due to the different analgesics used in these studies compared to ours. Moreover, pain is subjective and the extent of surgical procedures can also influence the postoperative analgesic consumption.

The intraoperative hemodynamic parameters were comparable between the groups with respect to mean arterial pressure, heart rate and oxygen saturation. Our findings were similar to those of the studies conducted by Hembrom et al and Mahmoud Hala et al. The study conducted by Roy G et al reported a lower heart rate in patients given fentanyl compared to those receiving plain local anaesthetic solution. They attributed this to the higher dose of fentanyl (1mcg/kg) used in their study.

The Ramsay sedation score between the groups was also comparable and statistically insignificant. On comparing the sedation score, Kaur et al too did not observe any significant difference when when fentanyl was added to levobupivacaine.

Incidence of adverse effects was more when fentanyl was added to levobupivacaine. 3 patients in group A and 1 patient in group B complained of nausea vomiting but this difference was statistically insignificant. This was in agreement with previous studies. But the systemic review and meta-analysis of RCTs conducted by Song et al found a two-fold increase in the incidence of complications when fentanyl was used as an adjuvant. Nausea, vomiting and pruritus were the most common complications reported. But the individual analysis of adverse effects in each RCT was insignificant probably due to the small sample size of the studies.

Limitations of our study-

1. It is a single hospital study. A multi-hospital study is considered to be better for the purpose of evaluation of the parameters that we have used in our study.
2. Our study included patients aged 18-65 years and belonging to ASA I/II status, and hence, the findings of our study cannot be validated in older, as well as, non ASA I/II patients.

3. The research sample was not large enough to adequately assess the difference in the occurrence of complications. A larger sample size would have added more precision to our results.

Conclusion

From our study, we concluded that addition of fentanyl as an adjuvant to levobupivacaine improves the onset of sensory and motor blockade and significantly prolongs the duration of sensory and motor blockade. It also provides prolonged analgesia while maintaining stable hemodynamics. Even though no statistically significant difference has been observed in the occurrence of adverse effects on addition of fentanyl, it is important to be cautious while using it due to a higher number of patients reporting nausea/ vomiting on receiving fentanyl.

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