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Original Research Article

A Comparative Study of Analgesic Effectiveness between Tramadol Plus Levobupivacaine versus Fentanyl Plus Levobupivacaine in Ultra Sound Guided Supraclavicular Brachial Plexus Block

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Abstract:

Introduction: The brachial plexus block is a frequently utilized nerve plexus block for providing perioperative anaesthesia and pain relief during upper limb surgeries. Levobupivacaine, an S (-) enantiomer of bupivacaine and part of the amino-amide group, has a favourable clinical profile with a better safety margin for cardiovascular and central nervous system effects. To improve the effectiveness of supraclavicular brachial plexus blocks, adjuvants like tramadol, fentanyl, dexamethasone, and butorphanol are added to local anaesthetics. The study was conducted to compare the analgesic effectiveness between Tramadol plus Levobupivacaine versus Fentanyl plus Levobupivacaine in ultra sound guided supraclavicular brachial plexus block."

Methods: The present prospective, observational, and comparative study was conducted in the Department of Anaesthesiology at a tertiary care hospital, from January 1, 2023, to June 30, 2024 amongst 100 patients, aged 18 to 70 years, who were scheduled for elective upper limb surgeries. They were randomly assigned into two equal groups (Group I and Group II) using the Complete Enumeration method, with 50 patients in each group. Group I – This group of patients received inj. 0.5% Levobupivacaine 20 mL + Fentanyl 100mcg(2mL) + NS making a total of 30 ml. Group II – This group of patients received inj. 0.5% Levobupivacaine 20 mL + Tramadol 100 mg (2 mL) + NS making a total of 30 ml.

Results: For onset of sensory block the tramadol group exhibited a mean onset time of 11.92 ± 1.957 minutes, while the fentanyl group had a significantly shorter sensory block onset time of 3.80 ± 0.990 minutes. For onset of motor block the tramadol group showed a mean onset time of 11.78 ± 1.941 minutes, while for onset of motor block the fentanyl group had a notably shorter onset time of 4.48 ± 0.886 minutes. The total duration of motor block in the tramadol group had a mean duration of 461.80 ± 27.15 minutes, whereas the fentanyl group had a shorter total duration of motor block of 369.80 ± 16.22 minutes. Both tramadol and fentanyl are effective in inducing sensory and motor blocks, fentanyl demonstrates a faster onset of action, whereas tramadol provides a longer duration of block. While some fluctuations were noted, overall, tramadol and fentanyl groups maintained comparable MAP values for most of the study duration.

Conclusion: The present study concludes that despite differences in the onset and duration of sensory and motor blocks, both tramadol and fentanyl showed comparable effects on patient demographics and cardiovascular stability.

Key Words: Tramadol, Fentanyl, Levobupivacaine, Bupivacaine, Brachial plexus block

Introduction

The brachial plexus block is a frequently utilized nerve plexus block for providing perioperative anaesthesia and pain relief during upper limb surgeries. It is a viable alternative to general anaesthesia for these procedures due to its enhanced effectiveness, safety margin, lower overall costs, shorter hospital stays, fewer side effects compared to general anaesthesia, and excellent postoperative

pain relief [1]. As brachial plexus closely run superficially over the first rib, the onset and quality of anesthesia is fast and complete [2].

In a supraclavicular brachial plexus block, the anaesthetic effect is primarily on the middle and lower trunks of the brachial plexus, affecting the median, radial, and ulnar nerves [3,4]. Due to the dense clustering of nerves in this area, the block can be administered rapidly and deeply, earning it the nickname "the spinal anaesthesia of the arm [5].

Numerous local anaesthetics have been investigated for use in brachial plexus blocks. Levobupivacaine, an S (-) enantiomer of bupivacaine and part of the amino-amide group, has a favourable clinical profile with a better safety margin for cardiovascular and central nervous system effects compared to racemic bupivacaine, primarily due to its quicker protein binding rate [1,6].

To improve the effectiveness of supraclavicular brachial plexus blocks, adjuvants like tramadol, fentanyl, dexamethasone, and butorphanol are added to local anaesthetics. These adjuvants enhance the quality of the nerve block, prolong the duration of analgesia, and reduce the total dose of local anaesthetic needed [1]. Fentanyl is a potent opioid agonist that provides strong analgesia without affecting neurotransmitters like serotonin or norepinephrine [7]. Tramadol, a synthetic analgesic, has both opioid-like effects and influences serotonin-norepinephrine reuptake, offering a dual mechanism for pain relief. Both drugs are readily available and used as adjuvants. Studying the analgesic effectiveness of tramadol versus fentanyl in combination with levobupivacaine is important for effective postoperative pain management. This research can lead to improved patient comfort, quicker recovery, and better overall outcomes. Hence, the study was conducted to compare the analgesic effectiveness between Tramadol plus Levobupivacaine versus Fentanyl plus Levobupivacaine in ultra sound guided supraclavicular brachial plexus block."

Material and Methods

The present prospective, observational, and comparative study was conducted in the Department of Anaesthesiology at a tertiary care hospital, from January 1, 2023, to June 30, 2024 amongst 100 patients, aged 18 to 70 years, who were scheduled for elective upper limb surgeries. All patients were evaluated for normal hemodynamic stability, as well as haematological, biochemical, and radiological parameters. Informed written consent for the procedure was obtained from each participant.

Patients were classified as ASA grade I and II, aged 18-70 years, scheduled for upper limb surgery under ultrasound-guided supraclavicular brachial plexus block were selected for the study. They were randomly assigned into two equal groups (Group I and Group II) using the Complete Enumeration method, with 50 patients in each group.

Group I – This group of patients received inj. 0.5% Levobupivacaine 20 mL + Fentanyl 100mcg(2mL) + NS making a total of 30 ml. **Group II –** This group of patients received inj. 0.5% Levobupivacaine 20 mL + Tramadol 100 mg (2 mL) + NS making a total of 30 ml.

Inclusion Criteria: Patients undergoing elective surgery under Supraclavicular Brachial plexus block, ASA grade 1 & 2 patient, age between 18 to 70 yrs, Weight between 30 to 70 kg, either gender patient, Written informed consent given by patient
Exclusion Criteria: Allergy to drugs to be used in study, Patient taking adrenergic or psychotropic drugs, Myasthenia gravis and musculoskeletal disorder, Pregnant patient

Methodology: for Data Collection

The procedure for the brachial plexus block was explained to them in their native language. Patients were briefed on the Visual Analogue Pain Score, where 0 represented "no pain" and 10 indicated "the worst pain imaginable." The method of using a pinprick to assess sensory onset was also explained. The patient was Premedicated with Inj. Ondansetron, Inj. Glycopyrrolate, Inj. Midazolam and Inj. Pentazocine.

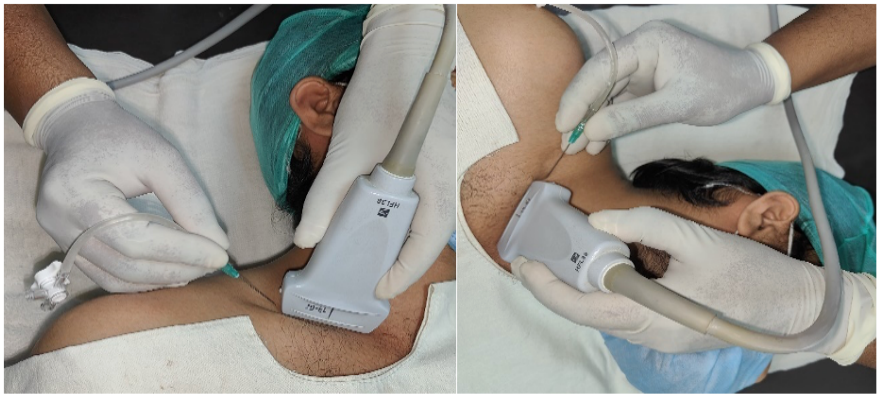

Figure1:

Supraclavicular brachial plexus block; transducer position and needle insertion

For the supraclavicular plexus block, patients were positioned supine with their heads turned away from the side of the block. After local anaesthetic skin infiltration, a 5 cm, 22-gauge needle was inserted laterally to medially in line with the ultrasound beam, targeting the brachial plexus. Upon reaching the nerve cluster as visualized on the ultrasound, 30 mL of the anaesthetic mixture depending on the group of the patient was injected gradually, with intermittent aspiration to avoid intravascular injection, for each group of 50 patients.

Measurement:

Time 0 was considered as the moment the injection was fully administered. Sensory and motor blockades were assessed every minute until both blocks were successfully achieved, followed by hourly checks for complete regression of the block. Sensory block was evaluated using the pinprick method over the four nerve distributions—musculocutaneous, median, radial, and ulnar. Baseline and intraoperative heart rate (HR), non-invasive blood pressure (NIBP) and oxygen saturation (SpO2) was monitored every 5 min and their average calculated.

Data analysis:

The data was coded and entered into Microsoft Excel Worksheet. The categorical data was expressed as rates, ratios, and proportions and the continuous data was expressed as mean ± standard deviation. The comparison of categorical data was performed using the Chi-square test and Fisher's exact test. $P \leq 0.05$ at a 95% confidence interval was considered as statistically significant.

Results:

Table 1. Comparison of time of onset of sensory block (in minutes.) Between two groups.

	GROUP TRAMADOL	GROUP FENTANYL	t-value	P- Value
Number of Cases	50	50	3.934	0.001
TIME OF ONSET OF SENSORY BLOCK. (MINUTES) Mean + SD	11.92+1.957	3.80+0.990		

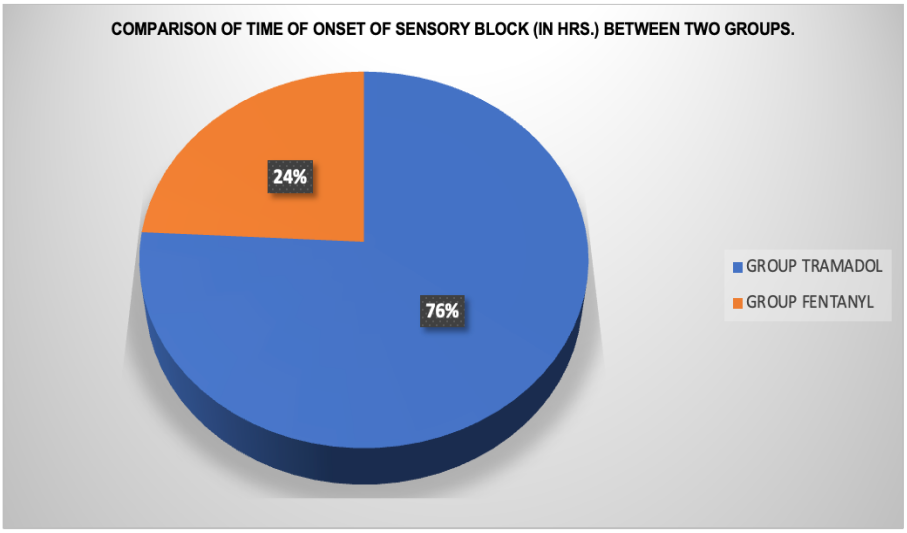

Figure 1. Comparison of time of onset of sensory block (in minutes.) Between two groups.

Table no.1 shows that the Fentanyl group had a much faster average onset time of sensory block compared to Tramadol. On average, sensory block began in just 3.8 minutes (SD: 0.990) for the Fentanyl group. In contrast, the Tramadol group experienced an average onset time of 11.92 minutes (SD: 1.957), nearly triple the time of Fentanyl. This difference is statistically significant (p-value = 0.001), indicating a strong likelihood that Fentanyl truly leads to a quicker numbing effect.

Table 2: comparison of time of onset of motor block (in minutes.) Between two groups.

	GROUP TRAMADOL	GROUP FENTANYL	t-value	P- Value
Number of Cases	50	50	6.022	0.001
TIME OF ONSET OF MOTOR BLOCK. (MINUTES)	11.78 +1.941	4.48 +0.886		

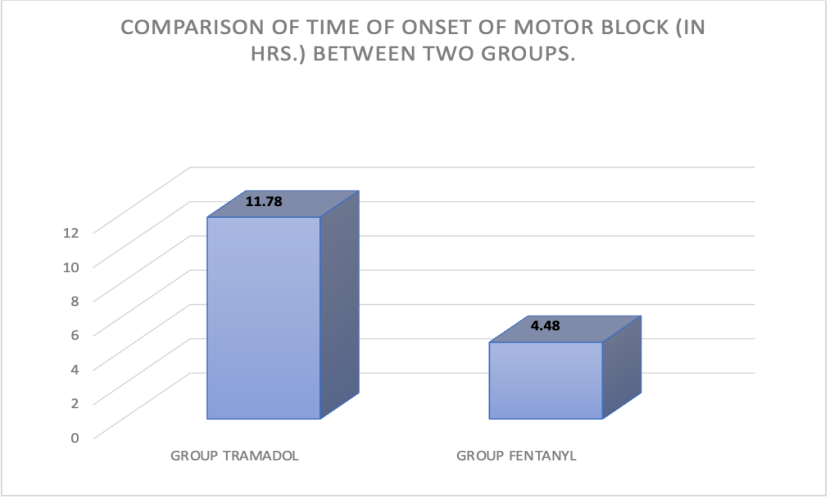

Figure 2: Comparison of time of onset of motor block (in minutes.) Between two groups.

Table no.2 shows that the Fentanyl once again led to a much faster block, with an average onset time of only 4.48 minutes (SD: 0.886). The Tramadol group experienced a considerably slower onset time, averaging 11.78 minutes (SD: 1.941) to achieve motor block. This substantial difference is statistically significant (p-value = 0.001), suggesting that Fentanyl provides a quicker onset of motor block compared to Tramadol.

Table 3: Time of duration of sensory block (in min.) Between two groups.

	GROUP TRAMADOL	GROUP FENTANYL	t-value	P- Value
Number of Cases	50	50	13.022	0.001
Time of Duration of Sensory Block (In Min.) Mean + SD	461.80+ 27.15	369.80 +16.22		

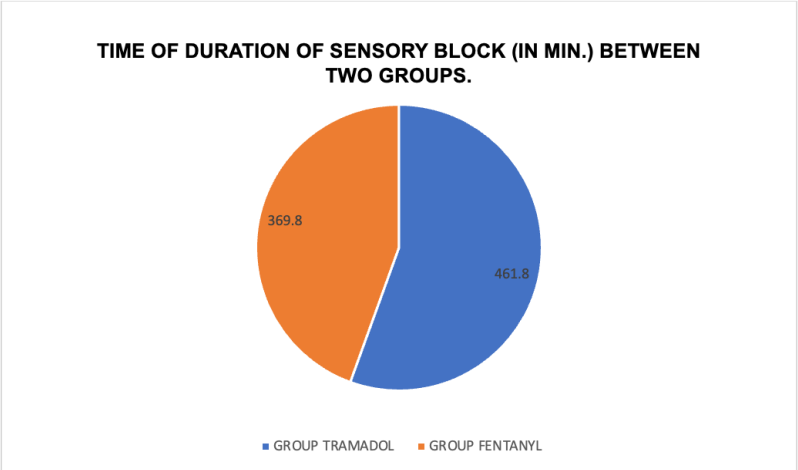

Figure 3: Time of duration of sensory block (in min.) Between two groups. Table no.3 shows that the Tra

madol appears to provide a longer-lasting effect. The table shows the average duration of sensory block was 461.8 minutes (SD: 27.15) for the Tramadol group, compared to 369.8 minutes (SD: 16.22) for the Fentanyl group. This difference is statistically significant (p-value = 0.001), indicating a strong likelihood that Tramadol offers a longer period of sensory numbing.

Table 4: Comparison of time of duration of motor block (in min.) Between two groups.

	GROUP TRAMADOL	GROUP FENTANYL	t-value	P- Value
Number of Cases	50	50	9.022	0.001
Time of Duration of Motor Block (In Min.) Mean + SD	461.20+ 27.15	370.80 +13.974		

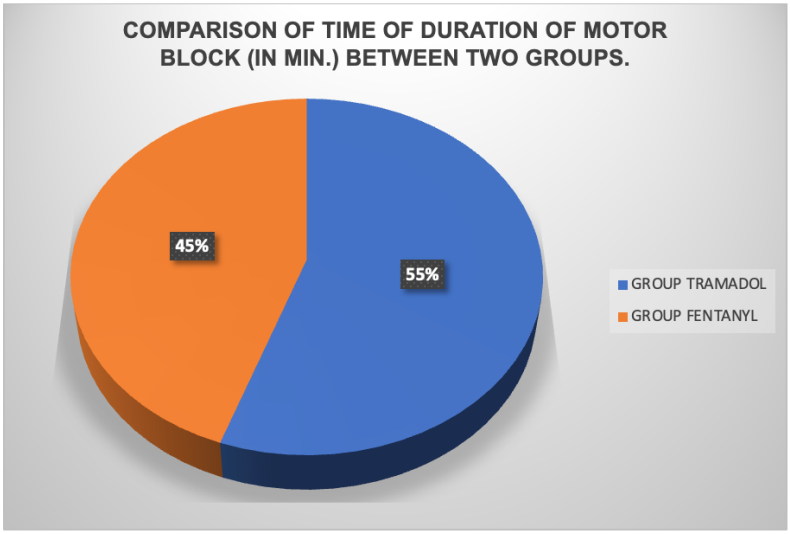

Figure 4: Comparison of time of duration of motor block (in min.) Between two groups.

Table no.4 shows that the duration of motor block between the Tramadol and Fentanyl groups. Here, the pattern is reversed. Tramadol appears to provide a longer duration of motor block compared to Fentanyl. On average, the Tramadol group experienced a duration of 461.2 minutes (SD: 27.15) for motor block, whereas the Fentanyl group averaged 370.8 minutes (SD: 13.97). This difference is statistically significant (p-value = 0.001), indicating a strong likelihood that Tramadol leads to a longer-lasting motor block effect.

Discussion:

Ultrasound guided Supraclavicular block for upper limb surgery is becoming the popular technique and are commonly used by anaesthetist, giving an advantage to regional block over general anaesthesia.

In the present study the mean age for the Tramadol group was 37.34 years with a standard deviation (SD) of 12.0, while the Fentanyl group has a mean age of 37.16 years with an SD of 11.81 with no statistically significant difference. **Dr Boniface Hembrom Et al (2018) [8]** study showed no significant difference between the two groups in terms of age and it tally with our study.**Kumari A Et al (2019) [1]** showed that the demographic study was similar like our study.

In our study the mean time of onset for the sensory block in the Tramadol group was 11.92 minutes with a standard deviation (SD) of 1.957, while in the Fentanyl group, it was considerably shorter at 3.80 minutes with an SD of 0.990 with a statistically significant difference suggesting that Fentanyl induces sensory block much more rapidly. In the previous study **Kaur M Et al (2018) [2]** showed that fentanyl group onset time of sensory block was 8.513 + 0.4001min. It was longer than the mean time of our study. Shorter duration of onset of sensory can be explained by dose of local anaesthesia used in our study. In our study we used 100mcg of fentanyl while in study of **Kaur M Et al (2018) [2]** used 25 ml of 0.5% levobupivacaine with 1 mcg/kg fentanyl diluted to the volume of 5 ml NS. **Dr Boniface Hembrom Et al (2018) [8]** study showed delayed onset of sensory blockade (0.50% levobupivacaine-30cc +(2ml) Fentanyl(100mcg) while our study showed faster onset of sensory blockade (inj. 0.5% Levobupivacaine 20 mL + Fentanyl 100mcg(2mL) + NS making a total of 30 ml). **Kumari A Et al (2019) [1]** this study showed tramadol group had onset of sensory blockade was 10.9 + 1.97 min which tallied with our study (11.92 + 1.957 min). **Hala Mahmoud Et al (2020) [9]** The sensory onset was significantly faster in Fentanyl group (10.8±3.6 min) which was longer as compared to our study (3.80 + 0.990 min). **Hala Mahmoud Et al (2020)[50]** used 22.5ml levobupivacaine 0.5 % + 1ml Fentanyl (50µg) + 6.5ml normal saline in their study.

In the present study, the mean time of onset for motor block in the Tramadol group was 11.78 minutes with a standard deviation (SD) of 1.941, while in the Fentanyl group, it was significantly shorter at 4.48 minutes with an SD of 0.886 with a statistically significant difference suggesting that Fentanyl induces motor block much more rapidly. **Nashat Ali W Et al (2023) [10]** study showed that onset of Motor Blockade for tramadol group was 15.9 ± 2.9 min which was almost similar to our study i.e. 11.78 + 1.941 min. **González, S Et al (2024) [11]** study showed onset of sensory block for fentanyl group (13.58 + 7.48min) which is also different than the mean time of our study.

In this study the mean duration of sensory block was significantly longer in the Tramadol group, with an average duration of 461.80 minutes (±27.15), compared to the Fentanyl group, which had an average duration of 369.80 minutes (±16.22). **S.**

Aravind Raj Et al (2017) [12] study showed that the duration of analgesia for tramadol was 820.47 min which was much more than the result of our study. **Hala Mahmoud Et al (2020) [9]** this study showed duration of sensory block for fentanyl group showed highly significant difference (658.4±14.08 min). This study results were longer than our study.

This study showed the mean duration of the motor block in the Tramadol group (n=50) was significantly longer, with an average of 461.20 minutes (SD = 27.15), compared to the Fentanyl group (n=50), which had a mean duration of 370.80 minutes (SD = 13.97) demonstrating a clear and substantial distinction between the effects of the two drugs. **S. Aravind Raj Et al (2017) [12]** study showed that the duration of analgesia for tramadol was 820.47 min which was much more than the result of our study. **Nashat Ali W Et al (2023) [10]** They found that the tramadol group Motor block duration lasted for 11.7 ± 1.19 hr which was similar to our study.

The present study results, compare heart rates per minute at various time intervals between two groups: one receiving Tramadol and the other receiving Fentanyl shows no significant differences. Comparatively, another study by **Regmi NK et al [13]**. also found no significant differences in heart rates between their two study groups over various time points.

Overall, both studies consistently show that there are no significant differences in heart rates between the groups receiving different treatments at various time intervals, suggesting that neither Tramadol nor Fentanyl significantly affects heart rate.

In the presented study, the comparison between systolic blood pressure (SBP) at different time intervals in two groups, one administered with tramadol and the other with fentanyl, reveals interesting findings. Initially, at 0 minutes, both groups had SBP values, with the tramadol group at 121.7 ± 7.137 mmHg and the fentanyl group slightly higher at 121.9 ± 6.59 mmHg. Then it persistently decreased although the differences were not statistically significant, the fentanyl group tended to have higher SBP compared to the tramadol group. Nevertheless, the p-values were greater than 0.05, indicating a lack of statistical significance. The SBP remained relatively stable in both groups.

Similarly, the comparison of diastolic blood pressure (DBP) between the tramadol and fentanyl groups over various time intervals also showed no significant differences ($p > 0.05$) throughout the study period. Despite some fluctuations observed at different time points, the overall pattern suggests that the administration of tramadol or fentanyl did not significantly affect DBP compared to baseline values.

In summary, the study results indicate that neither tramadol nor fentanyl significantly altered SBP or DBP compared to baseline values over the observed time intervals. **Kumari A Et al (2019) [1]** also showed results as our study with no any significant difference.

The comparison between mean arterial pressure (MAP) at different time intervals in two groups, one administered with tramadol and the other with fentanyl. Both studies show no significant differences in MAP between the study groups at baseline and throughout the observation period, except for a few time points. In contrast to the presented study, where significant differences were noted at specific time intervals. **Dr Boniface Hembrom Et al (2018) [8]** found no significant variations between the fentanyl and levobupivacaine groups at any time point ($p > 0.05$).

Conclusion:

The present study concludes that despite differences in the onset and duration of sensory and motor blocks, both tramadol and fentanyl showed comparable effects on patient demographics and cardiovascular stability. These results indicate that both drugs are effective and safe for clinical use, with each offering specific benefits in anesthesia management**.**

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