

Comparative Evaluation of Tramadol and Butorphanol as an Adjuvant to Bupivacaine for Supraclavicular Block: A Randomised Clinical Study

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# ABSTRACT

**Introduction:** Brachial plexus blocks have become useful alternatives to general anaesthesia for forearm surgeries. When used as a sole agent, Local Anaesthetics (LA) do not provide adequate pain relief. Tramadol and Butorphanol are synthetic opioid analogues that, when added to Bupivacaine, improve the quality of the block and reduce the need for supplementary postoperative opioids.

**Aim:** To evaluate the effect of Tramadol and Butorphanol as adjuvants to Bupivacaine for supraclavicular brachial plexus block on sensory and motor block characteristics.

**Materials and Methods:** This double-blinded randomised clinical study was conducted in the Department of Anaesthesiology, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India, from January 2021 to June 2022. The patients were randomly allocated into two groups of 30 each: group T received 0.5% Bupivacaine 25 mL with 50 mg Tramadol, and group B received 0.5% Bupivacaine 25 mL with 1 mg Butorphanol. The primary objective was to study the onset and duration of sensory and motor blockade. The secondary objectives were to study

the duration of postoperative analgesia, requirements of rescue analgesia, and drug-related adverse effects in supraclavicular brachial plexus block. Fisher's exact test and the Chi-square tests were used to compare categorical variables.

**Results:** Demographic data were comparable in both groups. A faster onset of sensory block and motor block was seen with Tramadol than with Butorphanol (p-value <0.001). The duration of sensory and motor block was longer with Butorphanol than with Tramadol (p-value <0.001 and p-value=0.01, respectively). The time to first rescue analgesia was longer with Butorphanol (p-value <0.001). Beyond six hours, the Visual Analog Scale (VAS) score was significantly lower in group B, except at the 12<sup>th</sup> hour. Very few incidents of adverse events were recorded in both groups.

**Conclusion:** The authors concluded that adding Butorphanol in a dose of 1 mg to Bupivacaine showed a delayed onset for sensory and motor block but prolonged duration of sensory and motor block, as well as the duration of postoperative analgesia, compared to the addition of 50 mg Tramadol, without producing any significant adverse effects.

Keywords: Analgesia, Local anaesthetics, Nerve block, Postoperative pain

# INTRODUCTION

Supraclavicular brachial plexus block is a method used prevalently for perioperative anaesthesia and pain relief in upper limb surgeries [1]. Hence, it is also known as the spinal anaesthesia of the upper extremity [2]. It can be safely used as a substitute for general anaesthesia, even for American Society of Anaesthesiologists (ASA) grade III patients, for any upper limb surgery, as it has the advantage of rapid onset, dense anaesthesia, and prolonged postoperative analgesia [3].

William Halsted first used the brachial plexus block in 1885 when cocaine was directly applied to the brachial plexus, which was exposed during surgery [1]. There are various techniques to perform the block, such as the blind technique, which uses surface landmarks and positioning, nerve stimulator, and ultrasound-guided technique [3]. Ultrasound allows visualisation of the structures, thus increasing the success rate of the block. It also causes less injury to nerves and adjacent structures and allows administration of a lesser volume of LA solutions, thus decreasing their toxicity [3].

Bupivacaine, an amide LA when used alone, usually provides postoperative analgesia for a shorter time. To provide a rapid, dense block and prolong the time of postoperative analgesia, several adjuvants are used. Drugs like Tramadol, Butorphanol,  $\alpha 2$  adrenergic agonists, and Dexamethasone are widely utilised. Opioids lengthen

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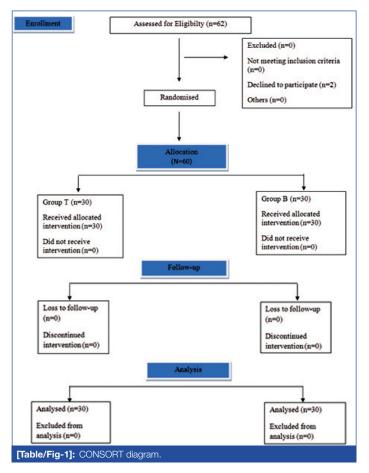
the analgesic duration postoperatively and intensify the depth of the block when added as adjuncts to LA [4]. Tramadol is a synthetic codeine analog with moderate affinity for the  $\mu$  receptor and weak  $\kappa$  and  $\delta$  opioid receptors. It acts as an analgesic by inhibiting the reuptake of Serotonin and Norepinephrine from nerve endings. This enhances the action of LA. It causes less respiratory depression as it has weak  $\mu$  receptor affinity [5]. Butorphanol is a synthetic opioid. It belongs to the phenanthrene series. It acts like Morphine, having partial  $\mu$  receptor antagonistic activity and  $\kappa$  receptor agonistic activity [6].

Very few trials have been done to study the efficacy of Tramadol and Butorphanol as an adjuvant [5-7]. Previous studies have used 2 mg/kg to 100 mg Tramadol and 40 µg/kg to 2 mg Butorphanol with different combinations of LA. As Bupivacaine is one of the most commonly used drugs in practice and to the best of the authors' knowledge, they could not find any study that used 50 mg Tramadol and 1 mg Butorphanol as an adjuvant to Bupivacaine. Therefore, the present study aimed to study the effectiveness of these adjuvants in supraclavicular block. The primary objective was to study the onset and duration of sensory and motor blockade. The secondary objectives were to study the duration of postoperative analgesia, VAS scoring, the number of rescue analgesics, haemodynamic parameters, and drug-related adverse effects.

## **MATERIALS AND METHODS**

This was a double-blind randomised clinical study conducted in the Department of Anaesthesiology, Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha, India, from January 2021 to June 2022. After obtaining approval from the ethics committee (KIIT/KIMS/ IEC/409/2020) and registering with CTRI (CTRI/2021/01/030500).

**Sample size calculation:** The sample size was calculated with reference to a previous study by Kumari A et al., where the mean±SD of duration of analgesia was 12.8±0.86 hours for group T and 13.8±1.46 hours for group B, which was statistically significant [7]. Assuming these reference values, the minimum required sample size at a 5% level of significance, 90% power, and 95% confidence interval was at least 31 in each group. Patients were randomly divided into two groups of thirty each, as shown in the Consolidated Standards of Reporting Trials (CONSORT) diagram [Table/Fig-1].



**Inclusion criteria:** Patients aged 18-60 years, ASA physical status I and II, and patients scheduled for elective upper limb orthopaedic surgeries under supraclavicular brachial plexus block were included in the study.

**Exclusion criteria:** Patients who refused to participate in the study, morbidly obese patients (Body Mass Index [BMI] >35 kg/m<sup>2</sup>), pregnant or lactating women, patients with a history of allergy or addiction to study drugs were excluded from the study. Patients receiving chronic analgesic therapy, patients with a history of coagulopathies, and those with pre-existing peripheral neuropathy were also excluded from the study.

## **Study Procedure**

Patients were randomly allocated into two equal groups using a computer-generated table of random numbers, and opaque envelopes were used for concealment. Sixty-two patients were recruited for the study, but only sixty patients were randomised as two patients refused to participate. All patients underwent a preanesthetic assessment the day before surgery, during which they were also informed about the study and the anesthetic procedure in their preferred language. They were explained the VAS score, ranging from 0 to 10, with an image to assess their postoperative pain. In the operating theatre, baseline parameters such as Pulse Oximetry (SpO<sub>2</sub>), Heart Rate (HR), and blood pressure were recorded. HR and Mean Arterial Pressure (MAP) were monitored every five minutes for the first 30 minutes and then every two hours for 12 hours postoperatively. An intravenous access, preferably with an 18G cannula, was placed in the non-operating hand, and Ringer's lactate solution was started. Based on the group allocation, the required drug was prepared by an anaesthesiologist who was not part of the study. Another blinded anaesthesiologist performed the ultrasound-guided supraclavicular block and recorded the block parameters intraoperatively.

Group T received 0.5% Bupivacaine (25 mL) and 1 mL (50 mg) Tramadol diluted to 30 mL with saline, while group B received 0.5% Bupivacaine (25 mL) and 1 mL (1 mg) Butorphanol diluted to 30 mL with saline. The ultrasound-guided supraclavicular block was performed using a high-frequency linear probe (Fujifilm Sonosite M-turbo portable ultrasound machine). The subclavian artery was identified as a hypoechoic pulsating structure above the hyperechoic first rib, confirmed by colour doppler. The supraclavicular brachial plexus was identified as a cluster of grapes located laterally and superficially to the artery. Local infiltration with 1 mL of 2% Lidocaine was administered 1 cm lateral to the transducer. An insulated Stimuplex needle (B. Braun, Germany) was introduced using an inplane technique until the brachial plexus sheath was penetrated. The study drug was deposited after ensuring no blood aspiration, and its spread around the brachial plexus was visualised. The onset time of both sensory and motor block was noted immediately after.

Sensory block was tested using the spirit swab method [8]. The onset was defined as the time required for the loss of sensation in all the nerve areas of the forearm and hand after drug administration. The duration was measured from the time the drug was administered until the VAS score reached 1. Similarly, motor block was tested using a modified Bromage score [9]. A score of '0' indicated no block with total arm and forearm flexion, a score of '1' indicated partial block with partial arm and total forearm flexion, a score of '2' indicated almost complete block with the inability to flex, and a score of '3' indicated complete block with the inability to flex both the arm and forearm. The onset of motor block was measured from the administration of the LA mixture until the loss of motor function, defined as a modified Bromage score of 3. The duration was measured from a modified Bromage score of '3' until '0'. If a modified Bromage score of 3 was not achieved within 30 minutes, the supraclavicular block was considered a failure and converted to general anaesthesia. These patients were considered dropouts in the study. Pain assessment was done using VAS scores every two hours up to 12 hours, followed by every four hours up to 24 hours in the postoperative period. The VAS score was checked at the first complaint of pain postoperatively, and if it was found to be ≥4, injection Diclofenac 75 mg diluted in 100 mL normal saline was given slowly intravenously as the first rescue analgesia. The group allocation was revealed at the end after collecting all the data.

## STATISTICAL ANALYSIS

The data was collected on a data sheet and later transferred to a master chart. Statistical analysis was performed using Microsoft Excel and Statistical Package for the Social Sciences (SPSS) software version 20.0. The quantitative data were described using the arithmetic mean±SD. Fisher's exact test and chi-square test were used to assess the relationships between qualitative or quantitative variables, while the t-test was used to compare the means of the two study groups for continuous data. A p-value of  $\leq$ 0.05 was considered statistically significant.

## RESULTS

The demographic profile data were comparable in both groups (p-value >0.05) [Table/Fig-2]. There was no significant difference in

MAP [Table/Fig-3] and HR [Table/Fig-4] variability between the two study groups (p-value >0.05).

		Group T	Group B	p-value	
Age (in years) (Mean±SD)		38.30±13.75	38.30±14.79	1.00	
Gender (n)	Males	23	20	0.00	
	Females	7	10	0.39	
ASA status (n)	1	23	19	0.06	
	II	7	11	0.26	
BMI (in kg/m <sup>2</sup> ) (Mean±SD)		24.44±3.09	24.88±2.83	0.56	

[Table/Fig-2]: Comparison of demographic data.

Age, BMI: paired t-test

MAP (in mmHg)	Group T (Mean±SD)	Group B (Mean±SD)	p-value
Before block	94.43±8.431	97.23±9.115	0.22
0 min after block	81.70±7.125	85.43±8.799	0.07
5 min after block	78.80±6.930	80.93±7.991	0.27
10 min after block	81.27±6.108	82.73±7.353	0.40
15 min after block	83.37±10.817	86.17±10.014	0.30
20 min after block	82.07±7.061	78.83±7.711	0.09
25 min after block	86.53±9.605	88.20±7.694	0.46
30 min after block	96.47±8.488	95.77±9.637	0.76
2 h postoperatively	80.90±7.814	79.77±6.786	0.55
4 h postoperatively	92.67±8.676	90.53±7.200	0.31
6 h postoperatively	84.30±6.899	83.63±6.441	0.70
8 h postoperatively	84.00±8.120	81.40±7.257	0.20
10 h postoperatively	94.63±5.696	93.80±6.744	0.62
12 h postoperatively	atively 82.50±7.417 83.60±8.838		0.60
[Table/Fig-3]: Mean MAP in both the study groups at different time interval.			

Heart rate	Group T (BPM in Mean±SD)	Group B (BPM in Mean±SD)	p-value
Before block	71.03±8.739	71.60±9.167	0.81
0 min after block	67.47±18.904	66.70±9.147	0.84
5 min after block	73.47±6.942	73.73±6.496	0.88
10 min after block	76.00±8.514	73.20±8.401	0.21
15 min after block	74.00±7.235	74.13±9.923	0.95
20 min after block	74.00±7.235	74.13±9.923	0.95
25 min after block	72.17±6.497	71.33±8.417	0.67
30 min after block	70.40±6.311	70.47±8.169	0.97
2 h postoperatively	70.87±6.474	69.50±7.519	0.45
4 h postoperatively	69.97±6.333	68.93±7.661	0.57
6 h postoperatively	69.27±6.710	68.30±7.662	0.60
8 h postoperatively	69.33±6.599	67.93±6.782	0.42
10 h postoperatively	71.03±6.133	69.20±5.340	0.22
12 h postoperatively	71.27±4.331	71.53±4.890	0.82
<b>[Table/Fig-4]:</b> Mean HR in both the study groups at different time interval. BPM: Beats per minute; min: Minutes; h: Hours; Paired t-test			

The mean time of onset of sensory and motor block [Table/Fig-5] was earlier in group T compared to group B, with a significant difference (p-value <0.001). The duration of sensory and motor block [Table/Fig-6] was prolonged in group B, with a significant difference (p-value <0.001 and p-value=0.01, respectively). Beyond six hours postoperatively, the VAS score [Table/Fig-7] was significantly lower in group B (p-value <0.05). The time to first rescue analgesia [Table/Fig-8] was faster in group T compared to group B, with a significant difference (p-value <0.01). Fewer doses of analgesics were given in group B, with a significant difference (p-value <0.01).

When comparing the two groups for drug-related reactions [Table/ Fig-9] in the perioperative period, there was no significant difference (p-value=0.75). In group T, three study subjects experienced postoperative nausea and vomiting, while in group B, two patients had the same symptoms. No patients experienced sedation in either group. One patient in group B had an episode of hypotension, and no patients in either group had respiratory depression.

Parameters	Group	Mean±SD	p-value
	Т	6.60±2.42	<0.001
Time of onset of sensory block (in min)	В	9.18±1.24	<0.001
Time of anost motor block (in min)	Т	6.00±1.21	<0.001
Time of onset motor block (in min)	В	9.44±1.64	<0.001

[Table/Fig-5]: Comparison of onset of sensory and motor block in both groups. Paired t-test; The p-value in bold font indicates statistically significant values

	Group	Mean±SD	p-value
Duration of concern (block (in min)	Т	313.12±79.56	-0.001
Duration of sensory block (in min)	В	443.6±51.99	<0.001
	Т	378.44±55.28	0.01
Duration of motor block (in min)	В	434.76±68.76	0.01

[Table/Fig-6]: Comparison of duration of sensory and motor block in both the groups. Paired t-test; The p-value in bold font indicates statistically significant values

VAS score	Group T (Mean±SD)	Group B (Mean±SD)	p-value
Before block	6.47±1.73	5.83±1.41	0.12
0 min after block	6.47±1.73	5.83±1.41	0.12
5 min after block	5.30±1.55	5.43±1.19	0.71
10 min after block	0.90±0.40	0.93±0.36	0.73
15 min after block	0.60±0.49	0.53±0.57	0.63
20 mins after block	1.76±0.93	1.6±0.72	0.45
25 min after block	1.70±0.83	1.8±0.71	0.61
30 min after block	1.96±0.80	1.7±0.70	0.18
2 h postoperatively	1.63±0.85	1.46±0.89	0.98
4 h postoperatively	0.93±0.25	0.93±0.25	1.00
6 h postoperatively	1.50±1.35	1.03±0.61	0.09
8 h postoperatively	2.87±2.08	1.27±0.86	0.0001
10 h postoperatively	4.23±1.69	1.57±1.40	0.0001
12 h postoperatively	1.33±1.15	2.77±1.85	0.001
16 h postoperatively	3.00±1.68	2.6±1.89	0.39
20 h postoperatively	3.03±1.27	2.00±1.55	0.006
24 h postoperatively	3.03±1.73	2.2±1.60	0.05

[Table/Fig-7]: VAS of both the study group at different time interval. VAS: Visual analogue scale; min: Minutes; h: Hours; Paired t-test; The p-value in bold font indicate statistically significant values

Parameters	Group T (Mean±SD)	Group B (Mean±SD)	p-value		
Time to first rescue analgesia ( in hours)	8.33±1.06	10.93±1.23	<0.001		
Total number of analgesics in 24 hours	2.03±0.41	1.33±0.54	<0.001		
[Table/Fig-8]: Time to first rescue analgesia and total number of analgesics given in 24 hours in both groups. The p-value in bold font indicates statistically significant values					

Group B Total Group Parameters T (n) (n) (n) p-value PONV З 2 5 Hypotension 0 1 1 0.75 NS 27 27 54 Total 30 30 60

[Table/Fig-9]: Complications found in both the study groups. PONV: Postoperative nausea and vomiting; NS: No side-effects; Chi-square test used

# DISCUSSION

Supraclavicular block delivers the most consistent and time-efficient anaesthesia for upper limb surgeries [3]. Bupivacaine alone provides stable surgical conditions, but its duration of analgesia is maintained for no more than four to six hours [9]. The primary concern as an anaesthesiologist should be to prolong the total span of pain relief in the postoperative period. Any patient undergoing orthopaedic surgery experiences severe pain in the postoperative period, which should be adequately treated to avoid impairment of body functions.

In the present study, Tramadol showed a quicker onset time of sensory block than Butorphanol. A study by Kumari A et al., also reported a decreased onset time of sensory block with the addition of both 100 mg Tramadol and 2 mg Butorphanol, compared to a placebo, with no significant difference between the two adjuvants [7]. Bhatia U et al., and Wakhlo R et al., also concluded that Butorphanol caused a delay in the onset time of sensory block compared to Tramadol [10,11]. This similarity may be attributed to using the same doses of Tramadol. Another study by Regmi NK et al., demonstrated that Tramadol did not affect the onset of sensory block, but it was compared to a placebo [12].

The present study also showed an early onset of motor block with Tramadol. Shah S et al., demonstrated a similar time of onset of motor block with Tramadol (2 mg/kg) compared to Dexamethasone (0.15 mg/kg) as adjuvants to Bupivacaine [13]. Another study by Vinaya R et al., stated that there is a delayed onset of motor block with Butorphanol at a higher dosage of 40 mcg/kg compared to a lower dose of 30 mcg/kg or Fentanyl at 1 mcg/kg [14].

The duration of sensory block and motor block in the present study was shorter with Tramadol than with Butorphanol. Similarly, a study by Apte VY and Jamkar MA showed less prolongation of the duration of sensorimotor block with Tramadol compared to Dexamethasone [15]. Kumari A et al., concluded that the duration of motor block was prolonged but comparable when adding 100 mg Tramadol and 2 mg Butorphanol [7]. The similarity in volume and the dose of the additive added could have resulted in the same outcome.

In this trial, the VAS scores in the two groups showed no statistical significance at different points in time from the beginning of block administration up to six hours postoperatively. Beyond six hours, the VAS score was significantly lower in group B, except at the 12<sup>th</sup> hour where the VAS was significantly lower in group T. This occurred because rescue analgesics had been given between the 8<sup>th</sup> and 10<sup>th</sup> hour in group T, indicating an early requirement for analgesics in the Tramadol group. Madhusudhana R et al., demonstrated a significant decrease in VAS scores postoperatively when Tramadol was added as an adjuvant to local anaesthesia during supraclavicular block [16]. Wajima Z et al., showed that a bolus of Butorphanol followed by a continuous intravenous infusion of Mepivacaine-Butorphanol in the brachial plexus for postoperative period [17].

The present study demonstrated that the time till first rescue analgesia with Tramadol was shorter than with Butorphanol. A study conducted by Bhatia U et al., found that the duration of analgesia after surgery (when the first rescue analgesic was given) was prolonged with Butorphanol [10]. Kumari A et al., also concluded that the analgesia duration was significantly increased by adding Butorphanol compared to Tramadol [7].

The total number of analgesics given in a 24-hour period with Tramadol was  $2.03\pm0.41$ , whereas in group B, it was  $1.33\pm0.54$ , with a statistically significant difference (p-value <0.001). Kumari A et al., and Bhatia U et al., also showed a reduced requirement for rescue analgesia with Butorphanol [7,10].

The mean arterial blood pressure in the Butorphanol group during the preoperative period was  $97.23\pm9.1$  mmHg, which decreased to  $78.83\pm7.7$  mmHg at 20 minutes after the block was given (p-value=0.09) and remained low thereafter. Both groups were statistically comparable (p-value >0.05) after that. A study by Wakhlo R et al., reported a similar fall in blood pressure after 15 minutes, and the early onset of action of lignocaine with adrenaline might explain this finding [11]. In the present study, there was no overall difference between the two groups with respect to complications observed preoperatively (p-value=0.75). However, Bhatia U et al., and Wajima Z et al., noted a higher incidence of sedation with Butorphanol [10,16]. This difference could be possible as they used 2 mg as opposed to 1 mg in the present study.

### Limitation(s)

The blocks could not be performed by a single anaesthesiologist, although they were performed by equally experienced ones. Additionally, there was limited availability of similar studies for contrast or comparison.

## CONCLUSION(S)

Opioids are commonly added to LA to improve the quality and duration of the block. In conclusion, 1 mg of Butorphanol and 50 mg of Tramadol can be used as adjuvants with 0.5% Bupivacaine for supraclavicular block to enhance its perioperative efficacy. Both adjuvants provided similar haemodynamic stability and surgical anaesthesia. Tramadol showed an early onset of sensory and motor block, while Butorphanol significantly prolonged the duration of the block, reducing the number of analgesics given in the postoperative period with minimal side effects.

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#### AUTHOR DECLARATION:

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- For any images presented appropriate consent has been obtained from the subjects. NA

#### PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Apr 07, 2023
- Manual Googling: Jun 02, 2023
- iThenticate Software: Jul 04, 2023 (15%)

ETYMOLOGY: Author Origin

**EMENDATIONS:** 6

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