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Original Research Article

Comparative study of tramadol and nalbuphine as an adjuvant to ropivacaine in supraclavicular block: A cross sectional observational study

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ABSTRACT

Background: Brachial plexus block via supraclavicular approach performed with the help of ultrasound assistance, is a promising anaesthetic alternative for upper limb surgery, when compared with general anaesthesia. It provides good surgical anaesthesia and better post-operative analgesia. We compared the anaesthetic and analgesic efficacy of two additives, nalbuphine and tramadol with 0.375% ropivacaine.

Materials and Methods: A double-blind, cross-sectional study, performed prospectively on 82 patients who were randomly assigned into Group N (41) and Group T (41). Patients were posted for surgical procedure of upper limb under supraclavicular brachial plexus block. Group N received inj. Ropivacaine 0.375% 25 ml plus 1ml (10 mg) of Nalbuphine plus 1ml of normal saline. Patients in Group T received inj. Ropivacaine 0.375% 25 ml with Inj. Tramadol 2 ml (100 mg). Total volume was 27 ml in both groups. Duration of postoperative analgesia was the primary outcome of our study. The secondary outcomes were the sensory and motor block characteristics (onset and duration), change in hemodynamic parameters and side effects.

Results: A statistically significant difference was noted in the duration of postoperative analgesia [Group N: 648.27 (± 124.69) minutes, Group T: 514.73 (± 43.15) minutes; P <0.001]. In terms of onset of both sensory and motor block no statistically significant difference was noted. A significant difference was noted in duration of sensory block (Group N: 545.85 ± 118.13 min; Group T: 416.71 ± 50.43 min; P <0.001). The mean duration of motor block was 482.93 ± 120.07 min in nalbuphine group and 356.59 ± 43.74 min in tramadol group; P <0.001.

Conclusion: Nalbuphine 10mg is a better adjuvant to 0.375% ropivacaine when compared with tramadol 100 mg. It prolongs the duration of sensory block and motor block and increases the duration of analgesia postoperatively.

1. Introduction

Brachial plexus is formed from the anterior primary rami of C5-C8 and T1 nerve root. There are different approaches to block the plexus. The target or level of block varies with each approach. In interscalene approach, we target the trunks. In supraclavicular approach, the trunk and divisions are in close proximity as they pass over the first rib. At this level, the whole sensory, motor and sympathetic innervation of the upper limb is blocked. The accurate deposition of local anaesthetic at this site leads to a predictable, dense block of upper extremity, which is helpful for surgical anaesthesia and post-operative analgesia for upper limb surgeries; distal to shoulder joint.[1] The infraclavicular approach blocks the three cords, by local anaesthetic

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deposition around the axillary artery. The axillary approach will block the individual nerves placed around the axillary artery.

The technique of brachial plexus block can be performed by blind or classic paraesthesia technique, peripheral nerve stimulator guided or by using ultrasound guidance. At supraclavicular level; the pleura, thoracic cavity and subclavian artery are in close proximity to the trunks. The dorsal scapular artery crosses the plexus at this level.[2,3] Suprascapular artery and transverse cervical artery are in the vicinity of plexus.[4] Ultrasound guidance helps in imaging of these structures, locates the needle trajectory and position of needle tip and shows the real time drug deposition; thus increases the success rate of block and reduces the complications. The total volume of drug required for block is also reduced.

Ropivacaine acts by reversible inhibition of sodium ion influx through voltage gated sodium channels in neuronal membrane. Thus, action potential cannot be created and nerve conduction is inhibited. Unlike the racemic bupivacaine, ropivacaine is manufactured as a pure S (-) enantiomer. It is less lipophilic, which makes it less neurotoxic and cardiotoxic than bupivacaine.[5]

Postoperative analgesia after brachial plexus block can be increased, either by placing an indwelling perineural catheter for prolonged infusion or by adding adjuvants to local anaesthetics. Dexamethasone,[6] fentanyl,[7] buprenorphine,[8] epinephrine,[9] alpha-2 agonist (clonidine, dexmedetomidine),[10] midazolam, magnesium sulphate[11] are the various adjuvants studied.

Nalbuphine is a mixed opioid; agonist at κ (kappa) receptor and antagonist at μ opioid receptor. κ agonism causes sedation and analgesia. Compared to morphine, it has more cardiovascular stability and minimal respiratory depression.[12] It potentiates local anaesthetic action by activating the spinal and supraspinal opioid receptors.

Tramadol is a weak μ-opioid agonist. It has local anaesthetic effect by blocking sodium channels at peripheral nerve endings. It activates descending inhibitory pain pathway, by inhibiting the central neuronal reuptake of norepinephrine (NE) and serotonin which inhibits transmission of pain in the dorsal horn.

There were only few studies comparing the two additives, nalbuphine and tramadol with 0.375% ropivacaine in brachial plexus block by supraclavicular approach. Our aim was to study, postoperative analgesic efficacy of the two drugs.

2. Materials and Methods

We conducted this randomized, double-blind study prospectively; on 82 patients of either sex, in the age group 20-65 years, American Society of Anaesthesiologists class I and II, posted for upper extremity surgical procedures under supraclavicular brachial plexus block. Patients were enrolled, after approval of the study from Institutional Ethical Committee. Written informed consent was signed by all participants. Data confidentiality was maintained throughout the study. Patients were informed about the procedure, its outcome and the purpose of study. Patients not willing to give consent, those having infection at the site of block, those with coagulopathy, known allergy to study drugs, pre-existing peripheral neuromuscular or neurological disease, significant organ dysfunction, and those with incomplete action of block were excluded from the study.

For calculating the sample size, the duration of postoperative analgesia was considered as the primary objective. We assumed a pooled standard deviation of 40 units. For finding a true difference in mean between the two groups of 25 units; for achieving a power of 80% and level of significance of 5% (two sided), we would need to include 82 patients in our study, 41 patients in either group.

[Formula used: $n = (Z_{\alpha/2} + Z_{\beta})^2 * 2 * \sigma^2 / d^2$).

At 5% level, $Z_{\alpha/2} = 1.96$, $Z_{\beta} = 0.84$, $\sigma = 2.5$, $d = 5$]

Patients were randomized into two groups: nalbuphine group (Group N) and tramadol group (Group T), using computer generated table of random numbers. Closed opaque-sealed envelope, which were numbered sequentially were used for allocation concealment. The drug used for patients in Group N was inj. Ropivacaine 0.375% 25 ml with 1ml (10 mg) of Nalbuphine plus 1ml of Normal Saline and that in Group T was inj. Ropivacaine 0.375% 25 ml with Inj. Tramadol 2 ml (100 mg). Total volume was 27 ml in the two groups. The intended drug solution for block was prepared by anaesthesia resident, who was not a part of study. Another anaesthesiologist performed the block and assessed the results.

Pre-anaesthetic evaluation was done a day before surgery and patients were educated about reporting the severity of pain using numerical rating scale (NRS) and kept nil per mouth 6 hours before surgery. Securing intravenous access and preloading with Lactated ringer solution (6-8 mL/Kg) was done in preoperative room. Baseline pulse rate (PR), mean arterial pressure (MAP), oxygen saturation (SpO2), electrocardiogram (ECG) and respiratory rate (RR) were noted. Patients were premedicated with inj.ondensetron 80 μg / kg and inj.midazolam 30 μg / kg intravenous (IV).

During performing the block in the operation theatre, patients were in supine position with head turned away from the side to be blocked. Linear, high frequency (6-13 MHz) ultrasound probe (Sonosite EDGE II) and SonoPlex echogenic needle (gauge 22 and length 60 mm) was used for the block. Under all aseptic precautions, the probe was placed in the supraclavicular fossa, posterior to midpoint of clavicle with a slight caudal tilt. Brachial plexus was visualised as collection of hypoechoic oval structures (like the bunch of grapes) posterior and superficial to the pulsating hypoechoic subclavian artery. Color Doppler was

used to rule out the presence of blood vessels in the needle trajectory. To reduce the discomfort during needle insertion, 1 ml of local anaesthetic was infiltrated. The needle was inserted in plane towards the plexus aided by hydro-localization. After negative aspiration, the prepared drug solution was injected, achieving the spread of drug around the brachial plexus. The end of injection was noted as 'time 0'. Oxygen supplementation was done with face mask at 5 L/minute.

After completing the block, hemodynamic parameters and sensory and motor characteristics were noted at 5, 10, 15, 30, 45 and 60 minutes and then half hourly till complete recovery of sensory and motor block; thereafter at 2 hourly intervals for 24 hours.

Hypodermic needle was used for pinprick, to assess the sensory block in the appropriate dermatomal area. The onset of sensory block was considered from 'time 0' to dull response to pinprick in any dermatome (C5-T1). The duration of sensory block was noted from complete sensory block to reappearance of pinprick sensation.

Modified Bromage scale was used for assessment of motor block.:[13] As per the scale, the block will be graded as: grade 0- where patient is able to lift the extended arm to 90°. In grade 1- patient will not be able to raise the extended arm but will be able to flex the elbow and move the fingers while in grade 2- only the fingers can be moved. Complete motor block will be considered as Grade 3.

Onset of motor block was the time duration from, the end of drug injection i.e. from 'time 0'till achievement of grade 2 modified Bromage scale. Time from grade 2 motor power to complete motor recovery (Bromage grade 0) was considered as duration of motor block. Patients were instructed to note the time when they were able to move their fingers. Patients having inadequate sensory and motor block, after 45 minutes of block were excluded from the study.

At the end of surgery, patients were shifted to recovery room. Postoperative pain was assessed using NRS (0 - no pain to 10 - worst possible pain). Duration of analgesia was considered from the onset of sensory block to the first rescue analgesic demand by the patient (Numeric Rating Scale, NRS $\geq$ 4). Inj.Paracetamol 1 gm intravenous was given as rescue analgesic. Patients were monitored for nausea, vomiting, hypotension, bradycardia, chest pain, convulsion or any other adverse side effect.

The primary outcome was the duration of postoperative analgesia while the sensory and motor block characteristics (onset and duration), change in hemodynamic parameters and side effects were the secondary outcomes.:

2.1. Statistical analysis

The study data was analysed using SPSS (Statistical Package for Social Sciences, Chicago, USA) version-23 (IBM Corp.). Continuous variables were analysed using mean / standard deviation and sample't' test analysed the continuously distributed data. Categorical variables were analysed by frequencies and percentages and Chi-squared test applied for categorical data. Wilcoxon test was applied for data which was not normally distributed. Fisher's Exact test was used, in case the expected frequency in the contingency tables was <5, for >25% of the cells. For normally distributed data, the linear correlation between two continuous variables was analysed using Pearson's correlation. In case the data is not normally distributed then Spearman's correlation was used. For paired analysis of continuous variables, paired t-test was used. ANOVA/ Friedman test was used when comparing more than two continuous variables. $P < 0.05$ indicates statistical significance.

3. Results

No difference was noted in patient demographic characteristics (Table 1). The hemodynamic parameters were comparable among the groups (Table 2).

No statistical significance was noted amongst the groups with respect to onset of both sensory (W =1029.500, P - 0.070) and motor block (W = 886.500, P = 0.666) (Table 3).

Patients in nalbuphine group showed the duration of sensory block as 545.85(± 118.13) minutes which was longer than the duration in tramadol group, 416.71(± 50.43) minutes. The duration of motor block in nalbuphine group was more than the tramadol group; 482.93(±120.07) minutes and 356.59 (± 43.74) minutes respectively. The difference showed statistical significance; W = 1571.000, P =<0.001 for sensory block and W =1549.000, P <0.001 for motor block duration (Table 3).

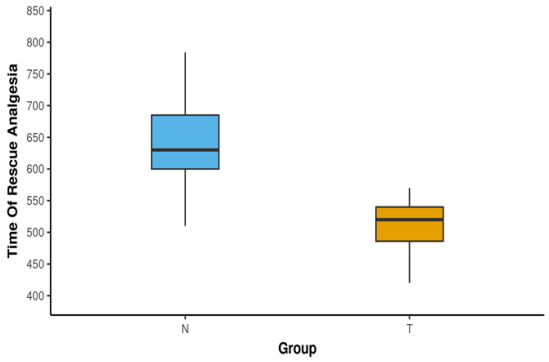

Figure 1: Box-and-Whisker plot showing association between duration of analgesia in the groups
Middle horizontal line: represent median duration of analgesia; upper and lower bounds of the box: represent the 75^{th} and 25^{th} centile of duration of analgesia; upper and lower extent of the whiskers: represent the Tukey limits for duration of analgesia

The duration of analgesia in nalbuphine group was 648.27(± 124.69) minutes which was longer than tramadol

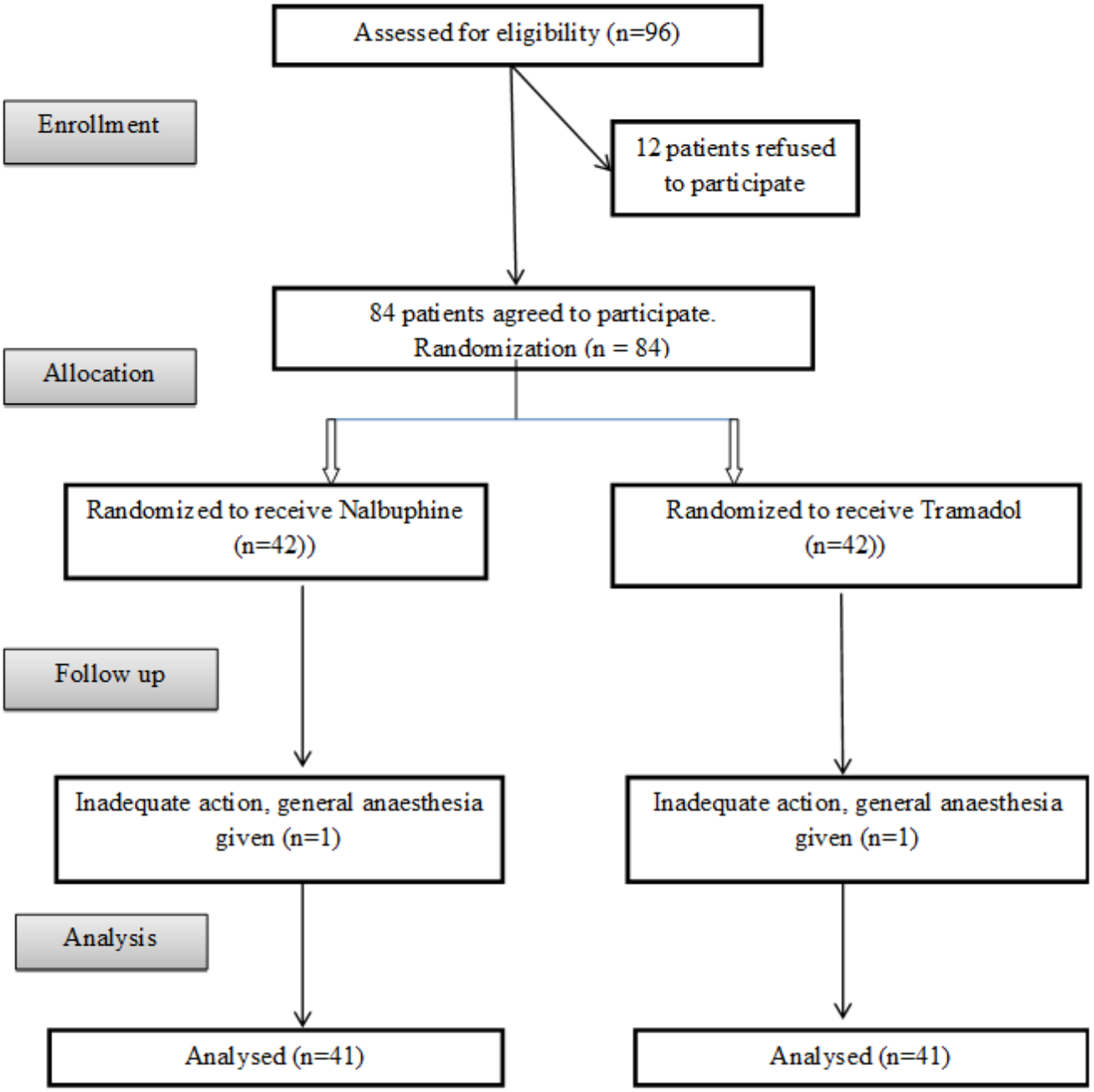

Diagram 1: Consort flow chart

group, 514.73(± 43.15) minutes (W =1527.500, P <0.001) (Table 3), (Figure 1).

None of the patient in either group reported any side effects. The two groups differed significantly in terms of NRS at 6, 8 and 10 hours. In Group N, the mean NRS increased from 0 at 2 hours to a maximum of 2.89 at 12 hours time-point while in Group T it increased from 0 at 2 hours to a maximum of 3.00 at 12 hours time-point. Friedman Test (Group N $\chi 2$ =88.2, P <0.001; Group T $\chi 2$ =19.2, P =0.002) showed a statistical significant difference (Table 4, Figure 2).

4. Discussion

Precise local anaesthetic deposition around the brachial plexus under ultrasound guidance not only increases the success of block but also makes it a cost effective technique. Stable intraoperative hemodynamics, excellent surgical anaesthesia and better post-operative analgesia leads to improved surgical conditions and patient satisfaction.

Table 1: Demographic parameters

Demographic parameter	Group		n	Mean (SD)	P value
Age (years)	N		41	36.88 ± 11.71	0.297
	T		41	33.34 ± 7.96	
Gender	N	M	29 (70.7%)	-	0.810
		F	12 (29.3%)		
	T	M	28 (68.3%)	-	
		F	13(31.7%)		
Height (m)	N		41	1.62 ± 0.05	0.532
	T		41	5.61 ± 25.51	
Weight (Kg)	N		41	59.41 ± 5.74	0.807
	T		41	59.12 ± 5.08	
BMI (Kg / m2)	N		41	22.52 ± 1.50	0.391
	T		41	22.33 ± 1.55	

Table 2: Hemodynamic parameters

			Mean Heart Rate (HR) (per min)			Mean Arterial Pressure (MAP) (mm of Hg)			Respiratory rate (RR)		
Time (min)	**Group**	**n**	**Mean**	**SD**	**P value**	**Mean**	**SD**	**P value**	**Mean**	**SD**	**P value**
0	N	41	78.05	5.35	0.937	92.24	5.91	0.745	15.00	2.12	0.659
	T	41	77.98	6.75		91.88	6.33		14.78	1.75	
5	N	41	78.32	5.80	0.945	93.33	6.23	0.735	15.66	2.22	0.684
	T	41	78.24	6.70		92.28	5.86		14.88	1.86	
10	N	41	76.03	6.25	0.867	92.32	5.98	0.747	15.20	1.64	0.637
	T	41	77.85	5.84		93.36	6.38		14.26	1.68	
15	N	41	77.80	5.14	0.727	91.88	5.46	0.989	14.49	1.08	0.817
	T	41	76.93	6.55		92.05	5.64		14.41	1.28	
30	N	41	78.32	5.84	0.985	91.88	5.42	0.457	14.24	1.65	0.628
	T	41	78.54	8.08		92.88	5.69		14.41	1.67	
45	N	41	77.24	6.37	0.943	91.78	6.43	0.756	14.68	1.24	0.817
	T	41	78.26	6.55		92.22	5.92		15.02	1.44	
60	N	41	78.56	6.97	0.784	91.88	5.44	0.970	16.54	1.63	0.763
	T	41	79.15	8.13		92.15	5.29		16.66	1.71	
90	N	41	78.46	6.34	0.726	93.64	5.24	0.547	15.28	1.76	0.267
	T	41	79.05	8.10		92.65	5.96		14.26	1.80	
120	N	41	78.46	6.24	0.989	92.83	5.36	0.784	15.10	1.62	0.268
	T	41	78.49	8.81		92.20	6.12		15.51	1.66	
150	N	41	77.82	6.05	0.937	94.84	6.36	0.782	14.56	1.65	0.628
	T	41	76.84	6.50		93.42	5.39		14.98	1.67	
180	N	41	78.62	6.42	0.972	91.78	6.33	0.745	13.24	1.58	0.660
	T	41	78.48	8.13		92.25	5.32		14.22	1.78	
			Comparison of change in HR over time between the two groups			Comparison of change in MAP over time between the two groups			Comparison of change in RR over time between the two groups		
P value			0.379			0.227			0.735		

Table 3: Showing onset and duration of sensory and motor block and duration of analgesia

Parameters	Group		Wilcoxon-Mann-Whitney U Test	
	N	T	W	P value
	Mean (SD)	Mean (SD)		
Onset of sensory block (mins)	11.27 (3.41)	9.78 (4.10)	1029.5	0.070
Onset of motor block (mins)	20.51 (7.04)	20.15 (7.56)	886.50	0.666
Duration of sensory block (mins)	545.85 (118.13)	416.71 (50.43)	1571	< 0.001
Duration of motor block (mins)	482.93 (120.07)	356.59 (43.74)	1549.0	< 0.001
Duration of analgesia (mins)	648.27 (124.69)	514.73 (43.15)	1527.500	<0.001

Table 4: Showing onset and duration of sensory and motor block and duration of analgesia

NRS Numeric rating scale	Group		P value
	N	T	
	Mean (SD)	Mean (SD)	
2 Hours	0.00 (0.00)	0.00 (0.00)	-
4 Hours	0.00 (0.00)	0.07 (0.26)	0.082
6 Hours	0.15 (0.42)	0.73 (0.92)	0.001
8 Hours	1.51 (0.64)	2.24 (0.86)	<0.001
10 Hours	2.50 (0.60)	2.83 (0.39)	0.025
12 Hours	2.89 (0.32)	3.00 (0.00)	0.550
P value for change in NRS over time within each group (Friedman Test)	< 0.001	0.002	(Wilcoxon-Mann-Whitney Test)
Overall P value for comparison of change in NRS over time between the two groups (Generalized Estimating Equations)	< 0.001		

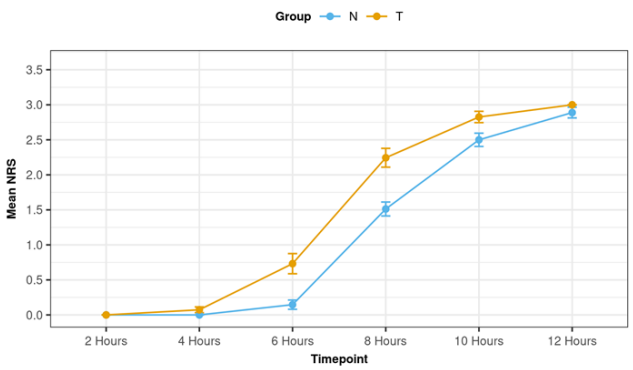

Figure 2: Line diagram depicting the change in Numeric Rating Scale over time in the two groups

Compact arrangement of trunks and divisions of brachial plexus produces dense and reliable anaesthesia with optimal tourniquet coverage even with less volume of local anaesthetic. A total volume of 27 mL was used in our study. Only one patient in each group had to be given general anaesthesia due to inadequate action of block.

Accurate drug placement near the plexus leads to prolonged duration of postoperative analgesia. As per Raghove et al., since there is more precise drug deposition near the nerve plexus, the duration of postoperative analgesia is more in ultrasound- guided supraclavicular block compared to landmark-guided technique.[14]

The demographic and hemodynamic parameters of the two groups were comparable. There was no difference in the onset times of sensory block (P =0.070) and motor block (P =0.666). The mean duration of sensory block was more in nalbuphine group compared to tramadol [545.85(±118.13) minutes and 416.71(±50.43) minutes respectively], which showed statistical significance (P <0.001). Similarly, the duration of motor block was longer in nalbuphine group [482.93(±120.07) minutes] than tramadol group [356.5 (±43.74) minutes], (P <0.001).

Similar results were noted by Abdelhaq M.M et al. in their study, using 20 mg nalbuphine as an adjuvant with 0.5% bupivacaine for brachial plexus block using supraclavicular approach.[15] Jadeja et al. compared 10 mg nalbuphine with 0.5% ropivacaine and noted early onset of sensory and motor block, and a significant increase in the duration of sensory and motor block.[16] Similar increase in the period of sensory and motor block was noted by Akhtar et al. using 100 mg tramadol as adjuvant to 0.5% ropivacaine.[17]

Opioids are used as adjuvant to local anaesthetics in regional anaesthesia, including nerve blocks with the aim of improving the quality of block and prolong the postoperative analgesic period. Opioids penetrate the nerve membrane and act at the substantia gelatinosa of dorsal horn of spinal cord. Laudren demonstrated that opioids

act directly on peripheral nervous system by showing that proteins undergo bidirectional axonal transport.[18]

In the postoperative period, the analgesic duration of block was more in nalbuphine group (648.27 ±124.69 minutes) compared to tramadol group (514.73 ±43.15 minutes), (P <0.001). This may be due to peripheral uptake of nalbuphine to systemic circulation and the central opioid receptor mediated analgesia. Youssef et al. compared nalbuphine and tramadol as additives with lignocaine for intravenous regional anaesthesia.[19] They noted that the analgesic duration of nalbuphine was better than tramadol. Abdelhaq et al. studied 20 mg nalbuphine as additive in their study and found similar results in terms of postoperative analgesia.[15] We used 10 mg nalbuphine in our study, yet a significant increase in postoperative analgesic effect was noted. The total dose of local anaesthetic used in our study was also less. We used 0.375% ropivacaine.

Looking at the trend of NRS over time, pain scores were on lower side in nalbuphine group at all time points, than tramadol group (P <0.001). No side effects were noted in either group. Nalbuphine is a κ agonist and antagonist at μ receptor, hence nausea, vomiting, pruritus and respiratory depression was less. Tramadol does not cause respiratory depression like other μ opioid agonist. None of the patient in group T had nausea and vomiting. Similar results were noted by Akhtar et al.[17] Only one patient complained of nausea in their study.

Ultrasound imaging helps in identification of anatomical variations. Complications like pleural puncture and resulting pneumothorax, vascular puncture are avoided due to imaging. Inadvertent intravascular injection is less with Color Doppler assistance. In addition to this, one should never inject against high resistance to avoid nerve injury. All these factors add to the safety of the procedure. No procedure related complications were noted in our study.

5. Limitations

We had relatively small sample size in comparison to large burden of post operative pain. Because of unavailability of similar studies we could not compare our results with others.

6. Conclusion

10 mg Nalbuphine is a better additive with 0.375% ropivacaine when compared with 100 mg tramadol, for upper limb surgical procedures performed under brachial plexus block. It prolongs the time duration of sensory and motor block and has better analgesic effect in postoperative period.

7. Source of Funding

None.

8. Conflicts of Interest

None.

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