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A comparative clinical study between nalbuphine and buprenorphine as an adjuvant to ropivacaine in ultrasound-guided interscalene brachial plexus block

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Abstract

Background and aims: The present study was undertaken to compare the effect of nalbuphine and buprenorphine as an adjuvant to ropivacaine on duration of block and postoperative analgesia during ultrasound-guided interscalene block for upper limb surgeries.

Subject and methods: This study design was a prospective, randomised double blind study involving sixty patients of either sex undergoing elective orthopedics surgeries were divided into two groups. Group N, 20ml of 0.5% ropivacaine with 1ml of nalbuphine (10mg) and group B, 20ml of 0.5% ropivacaine with 1ml of buprenorphine (100µg) were used for giving inter scalene block (ISB) under ultrasound guidance. Onset and duration of sensory and motor blockade was considered as primary outcome, duration of analgesia and adverse effects were considered as secondary outcome. Statistical data was analysed using SPSS software version -16.0. P value <0.05 was considered as statistic ally significant.

Results: Group B had significant early onset of sensory blockade, longer duration of sensory and motor block, shorter onset time to achieve motor block and prolonged duration of analgesia compared to group A.

Conclusion: Addition of buprenorphine as an adjuvant to ropivacaine in interscalene brachial plexus block (ISB) prolonged the duration of sensory, motor blockade along with the duration of postoperative analgesia without any side effects as compared to nalbuphine.

Keywords: Brachial plexus block, interscalene block, ropivacaine

Introduction

Interscalene brachial plexus (ISB) block is most widely practiced peripheral nerve blocks for the procedures

involving shoulder, lateral 2/3rd of clavicle, proximal humerus, and shoulder joint. It can be used as sole anaesthetic technique or combination with general anesthesia for intraoperative and postoperative analgesia. [1]

Adjuvants are often used with local anaesthetics for synergistic effect that reduces cumulative dose requirement of local anaesthetics by prolonging the duration of sensory-motor block. [2,3] With the development of ultrasound, it became feasible to disseminate the local Anaesthetic and reduce the amount of local Anaesthetic needed.[4]

Ropivacaine is a long-acting amide local Anaesthetic agent with a great degree of motor to sensory differentiation, reduced lipophilicity along with anticipated central nervous system toxicity and cardiotoxicity. Nalbuphine, a kappa agonist and partial μ antagonist enhance the duration of analgesia and results in sedation, analgesia, and cardiovascular stability with minimal respiratory depression. Buprenorphine is highly lipid soluble thebaine derivative with partial agonist activity at μ opioid receptor that possess higher affinity for opioid receptor and its slow dissociation from these receptor accounts for prolonged action.

Literature on effect of nalbuphine as an adjuvant to ropivacaine and buprenorphine as an adjuvant to Ropivacaine on assessment of onset, duration of block and post operative analgesia during ultrasound-guided inter scalene block for upper limb surgeries were scare and however the assessment of the same was not much commonly done in South Indian population. Hence this study was undertaken with an objective to check the exact prevailing effects nalbuphine and buprenorphine as an adjuvant to ropivacaine on onset, duration of block and postoperative analgesia during ultrasound-guided interscalene block for upper limb surgeries. Primary outcome includes assessment of duration of sensory and motor block and secondary outcome includes assessment of post operative analgesia during ultrasound-guided inter scalene block for upper limb surgeries.

Material and methods

After obtaining clearance from institutional ethical committee the study was conducted in a prospective, randomised, double blind manner during March 2019 to April 2022. Sixty consenting patients with American society of anesthesiologists (ASA) physical status grade I and II, aged 18–70yrs, scheduled for various elective orthopaedic surgeries on the upper extremities were included in the study.

Nonconsenting patients, patients with coagulopathy and on anticoagulant, neurologic deficit in the upper limb, allergy to any of the study drug (i.e., nalbuphine, Ropivacaine, or buprenorphine), infection at the site of block, patients on chronic opioid use, pregnant women or lactating women and body mass index (BMI) >35kg/m^2 were excluded from the study. The sample size was calculated based on the outcomes of previously published study with mean onset of time of 6.6 and 6.7 in two groups and SD of 0.1, considering 5% level of significance (type 1 error probability) and 95% power, the sample size was calculated to be 26 in each group. So we took 30 patients in each group. Patients were randomised according to computer-generated random number tables into two equal groups of thirty patients each. Group N received 20ml of 0.5% ropivacaine with 1ml of nalbuphine (10mg) and patients of group B received 20ml of 0.5% ropivacaine with 1ml of buprenorphine (100μg) for brachial plexus blockade under ultrasound guidance by interscalene approach. After preanaesthetic evaluation, physical examination,

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and routine investigations patients were enrolled a day before surgery. Visual analogue scale (VAS) was explained to all patients where 0 corresponds to no pain and 10 indicated the worst imaginable pain. After explaining the procedure and its safety a written, valid, informed consent was obtained. All patients were fasted overnight (8 hours and more) and premedicated with tablet pantoprazole 40mg on the night before surgery.

On arrival of patients in the operation theater standard American Society of Anesthesiologists (ASA) monitors were attached for monitoring. An intravenous (IV) access were established using 18-20gauge (G) IV cannula on the nonoperative arm and crystalloid infusion (ringer lactate) was started at the rate of 6–8ml/kg. All patients received interscalene brachial plexus block under ultrasound guidance (GE healthcare LOGIQ, Chicago, New York). A high-frequency linear probe (13-16 MHZ) was placed transversely over the supra clavicular fossa and the brachial plexus was seen as honeycomb cluster, superior and lateral to the subclavian artery. After tracing the nerves in a proximal fashion toward the interscalene groove, the nerve structures (roots/trunks) was visualised in a sagittal oblique section as three oval-shaped hypoechoic with a few internal punctate echoes, lying between the scalenus anterior and Medius muscles. After infiltration of local anaesthetics to the skin, 50mm, 22 G stimulating needle was inserted in plane, in a lateral to medial direction.

The predetermined volume of 21ml of drug solution was administered around the brachial plexus as per group allocation and drug spread was observed in real time. All the patient were given supplemental oxygen using face mask.

The groups were compared for onset, duration of sensory- motor block, and duration of analgesia along with side effects. Assessments of the block were done by the investigator blinded to the study group. Sensory block evaluation was done by pin prick method for the presence or absence of sensation along the dermatomal distribution and it is compared with the contralateral arm [4]. Complete loss of sensation to pin prick was considered as complete sensory block. Motor block evaluation was done by modified bromage scale and also by inability to abduct the shoulder [5]. Complete inability to move the limb and fingers was considered as complete motor block. Ineffective blockade was considered as failure to achieve complete loss of sensation and motor block along the dermatomal distribution beyond 15min. These patients were excluded from the study and surgery was done under general anaesthesia. The time interval between injection and complete recovery of sensation was considered as duration of sensory block and the time interval between completion of injection and complete recovery of motor power.

Intraoperative monitoring of vitals parameters as heart rate, respiratory rate, oxygen saturation, blood pressure (systolic, diastolic, and mean arterial) were recorded and patient was observed for any incidence of hypotension, brady cardia, fall in peripheral saturation, nausea, vomiting, shivering, pain, or any other adverse effects and were managed according to clinical protocol.

Post operative analgesia was assessed every hour post operatively using VAS score. The time from completion of injection to the time when VAS>3 was considered as total duration of analgesia.

Data was analysed using SPSS software version 16.0. Analysed data presented in appropriate tabular and graphical forms.

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Data expressed as mean and standard deviation for quantitative data and proportions were used for qualitative data. Chi-square test was used as a test of significance for comparing qualitative data (sex and ASA grading).

Unpaired t test was used as test of significance for comparing quantitative data (age, BMI, duration of surgery, sensory and motor blockade, rescue analgesia, HR, SBP, DBP, MAP). P value <0.05 was considered as statistically significant.

Results

The demographic profiles in both groups were com parable (Table 1).

There were no significant differences between both groups with respect to demographic data and duration of procedure.

The mean time of onset of sensory blockade in group N and group B was 10.80 ± 1.16min and 7.86 ± 1.15min, respectively. The mean onset of motor block was 15.30 ± 1.42 and 10.86 ± 1.09. Both were significantly delayed in group N and is presented in Table 2 and Figure 1.

Table 1: Comparison of sensory and motor block onset and duration in both the groups

Variables	Group N	Group B	P value
Onset of sensory block (mins)	10.80 ± 1.16	7.86 ± 1.15	<0.001
Onset of motor block (mins)	15.30 ± 1.42	10.86 ± 1.09	<0.001
Duration of analgesia (hours)	9.42 ± 0.82	12.19 ± 1.26	<0.001
Duration of motor blockade (hours)	7.74 ± 0.90	10.65 ± 1.36	<0.001
Rescue analgesia time (hours)	10.09 ± 0.89	12.38 ± 1.29	<0.001

Figure 1: Comparison of onset of sensory and motor block

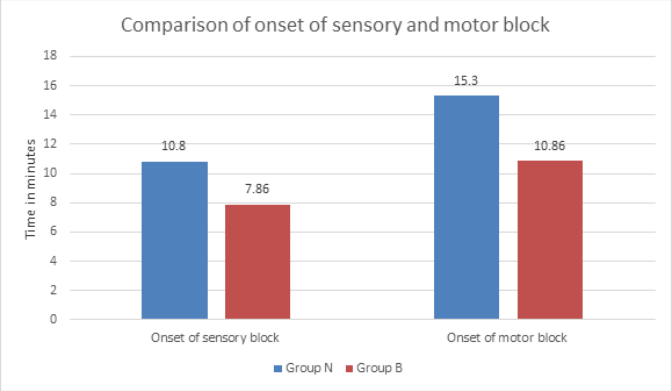

Figure 2: comparison of block characteristics

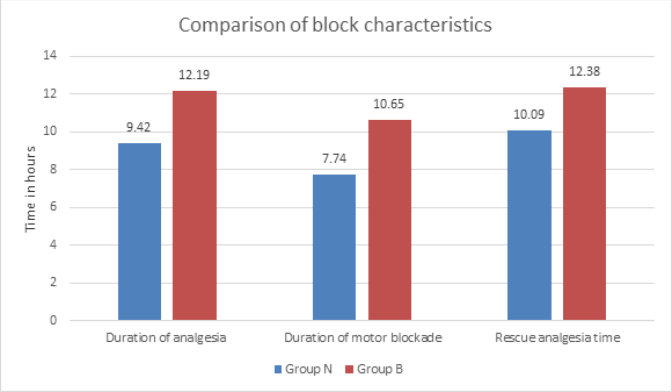

Table 2: Comparing heart rate at various time interval in both the groups.

Heart rate at various time interval	Group N		Group B		P value
	Mean	SD	Mean	SD	
HR at 5 min	85.63	16.16	85.37	10.06	0.939
HR at 15 min	83.60	15.49	85.87	10.29	0.507
HR at 30 min	80.23	14.35	81.90	9.74	0.601
HR at 1 hr	78.37	13.06	80.57	10.66	0.478
HR at 1 hr 30 min	77.13	12.91	79.00	9.10	0.520
HR at 2 hr	78.03	12.71	80.93	10.93	0.347
HR at 2 hr 30 min	79.53	12.44	82.07	11.27	0.412
HR at 3 hr	77.03	10.91	80.97	10.21	0.155

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HR at 3 hr 30 min	76.13	11.26	80.20	9.69	0.139
HR at 4 hr	75.43	10.54	79.73	8.54	0.088
HR at 6 hr	76.27	10.39	80.87	10.67	0.096
HR at 8 hr	77.53	12.34	81.47	10.65	0.191
HR at 12 hr	77.57	11.32	82.57	9.47	0.069
HR at 24 hr	76.30	11.01	77.57	9.93	0.642

Table 3: Comparing MAP at various time interval in both the groups

MAP at various time interval	Group N		Group B		P value
	Mean	SD	Mean	SD	
MAP at 5 min	99.06	14.10	93.99	6.69	0.081
MAP at 15 min	100.18	13.39	97.10	9.78	0.314
MAP at 30 min	95.09	12.87	94.12	6.59	0.716
MAP at 1 hr	91.43	12.21	90.82	6.88	0.812
MAP at 1 hr 30 min	91.16	12.45	90.18	7.01	0.709
MAP at 2 hr	91.56	11.35	89.42	8.24	0.408
MAP at 2 hr 30 min	93.38	13.36	90.37	6.60	0.273
MAP at 3 hr	91.93	13.09	92.09	7.78	0.956
MAP at 3 hr 30 min	92.12	12.66	90.08	7.97	0.457
MAP at 4 hr	92.57	12.22	88.67	11.14	0.201
MAP at 6 hr	91.71	12.19	90.99	8.50	0.791
MAP at 8 hr	92.68	12.13	90.68	8.31	0.459
MAP at 12 hr	92.14	11.51	87.84	13.54	0.190
MAP at 24 hr	91.28	11.50	87.77	8.17	0.178

The mean duration of sensory block in group N and group B was 9.42 ± 0.82min and 12.19 ± 1.26 mins, respectively and the mean duration of motor block was 7.74 ± 0.90min and 10.65 ± 1.36 mins, respectively. Both parameters were remarkably prolonged in group B and is presented in Table 2 and Figure 2.

The mean duration of rescue analgesia in group N and group B was 10.09 ± 0.89min and 12.38 ± 1.29min, respectively. It was markedly prolonged in group B and is presented in Table 2.

Both the groups were hemodynamically comparable at all times of surgery. None of the patients were having side effects.

Discussion

In the present study is undertaken to study the effects of nalbuphine and buprenorphine as an adjuvant to 0.5% ropivacaine for USG-guided ISB. We chose a constant dosage of nalbuphine 10mg and buprenorphine 100µg as an adjuvant to ropivacaine. The patients were divided into two groups and both groups were received equal volume of drug (20ml of 0.5% ropivacaine with 1ml of adjuvant.

It has been hypothesised that opioids act directly on the peripheral nervous system due to possible centripetal axonal transport of opioids into substantia gelatinosa after perineural injection.[6] Adjuvants have been tried with local anaesthetics to prolong the intraoperative anaesthesia and postoperative analgesia. Wajimaet al, demonstrated that continuous infusion of butorphanol into the brachial plexus sheath provided a better analgesic effect versus continuous IV systemic injection.[7]

At the mu opioid receptor, butorphanol and naibuphine both have narcotic antagonistic actions. Pentazocine's antagonist action is 30 times stronger than butorphanol's

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[8]. It's interesting to note that higher doses of naloxone are required to counteract butorphanol's effects than morphine. When used on people who are dependent on 60 mg of morphine per day, nalbuphine is just as strong as nalorphine and ten times more effective than Pentazocine as a narcotic antagonist [9].

After stopping the narcotics, Magruder et al found significant nalbuphine analgesia that persisted well into the postoperative period [9].

When antidotal naloxone is used to reverse narcotic CNS depression but, unfortunately, also reverses the narcotic analgesia, adverse cardiovascular stimulation occasionally occurs in patients in pain. This is where nalbuphine's differential mu (opioid antagonism) and kappa (agonist analgesia) opioid receptor actions may be useful. For the emergency treatment of opioid CNS depression, nalbuphine is used as a narcotic antagonist in place of naloxone.

The rationale of choosing 0.5% ropivacaine in the present study for ISB is that it can be safely used as an good alternative to bupivacaine 0.5% in supraclavicular block.[8] The failure in achieving the block by increasing the concentration of ropivacaine from 0.5% to 0.75% was reported [10] Lower volumes of local anaesthesia in ultra sound guided ISB is associated with lower incidence of hemi-diaphragmatic paresis with a similar success rate and duration of postoperative analgesia.[11] Thus with all these advantages over bupivacaine we used 20ml ropivacaine 0.5 % considering maximum dose of 3mg/kg. In a meta-analysis, nalbuphine was found to be comparable to morphine in terms of effective pain relief with significantly lower incidences of pruritis, nausea, vomiting, and respiratory depression.[12] Various study conducted have reported the effect of buprenorphine as an adjuvant to local Anaesthetic in supraclavicular block [13,14].

Addition of nalbuphine to local anaesthetics increases the duration of block, postoperative analgesia, and mechanism of action to describe the analgesic effect. [13-16] In the present study, the onset of sensory and motor block was significantly earlier in buprenorphine group as compared to nalbuphine group. Neena Jain et al [17] reported that onset of sensory block was significantly faster in buprenorphine group than the control group [17].

Conclusion

ISB under ultrasound guidance with 0.5% ropivacaine and buprenorphine prolonged the duration of both sensory and motor block without significantly increasing the side effects as compared with nalbuphine.

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