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Comparison of Two Different Doses of Buprenorphine as an Adjuvant to Ropivacaine in Ultrasonography (USG) Guided Supraclavicular Brachial Plexus Block for Upper Limb Surgeries

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ABSTRACT

Buprenorphine an opioid with mixed agonist antagonist property has been shown to provide longer duration of analgesia among all the opioids when used as an adjuvant for peripheral nerve block. The exact dose of the drug to be used is not studied much with head to head comparison of different doses. We compared two different doses of Buprenorphine 3 µg kg^{-1} Vs 4µg kg^{-1} as an adjuvant to Ropivacaine in ultrasonography (USG) guided supraclavicular block. The primary outcome of the study was to compare characteristics of sensory, motor blockade and duration of analgesia in both the groups. This prospective randomized double blind controlled trial was conducted in 60 patients of both sexes between age group of 18-70 yrs, with ASA class 1, 2, 3, undergoing surgery under supraclavicular block. Group 1 received 0.5% ropivacaine 20ml + Buprenorphine (3mcg kg^{-1}) Group 2 received 0.5% ropivacaine 20ml+ Buprenorphine (4mcg kg^{-1}). We observed time of onset of sensory block, motor block, their duration and duration of analgesia. All statistical analysis was done using SPSS 21 for Windows (Statistical Package for Social Science). If $p<0.05$, it was considered as significant and $p>0.05$ as non-significant. The mean dose of drug used in Group 1 was 176.8±23.4µg and in Group 2 was 240.5±41.5µg. The mean time of onset of sensory block was faster in Group 2 (4.08±1.29 min) than Group 1 (4.92±1.82 min), (p-value = 0.067).The mean duration of sensory block was more in Group 2 (514.8±136.4 min) than Group 1 (457.8±135.65 min) (p-value = 0.1450) The mean onset of motor block was earlier in Group 2 (15.24±1.81 mins) than Group 1 (15.64±1.78 mins) (p-value = 0.4342). The mean duration of motor block was more in Group 2 (445±143 min) than in Group 1 (376±121min).The mean duration of analgesia was longer in Group 2 (954.40±88.60 mins) than Group 1 (834.92±65.31 mins), P value 0.0001 which shows statistically highly significant difference. Buprenorphine when used as an adjuvant with 20 ml ropivacaine in USG guided supraclavicular block, in the dose of 3µg kg^{-1} and 4µg kg^{-1} has comparable sensory and motor block characteristics, without any side effects although 4µg kg^{-1} provides longer duration of analgesia and reduced requirements of postoperative rescue analgesics, hence it may be preferred over 3µg kg^{-1} dose.

INTRODUCTION

Regional Anaesthesia in the form of brachial plexus block is the common technique used for upper limb surgeries. which provides excellent surgical conditions along with best postoperative analgesia[1,2]. Ultrasound guided brachial plexus block given by supraclavicular approach offers a rapid onset and dense sensory and motor blockade of upper extremity among all other approaches and so called as "Spinal for upper limb"[3,4]. The duration of single shot supraclavicular nerve block can be increased by adding various adjuvants like dexamethasone, opioids and alpha two agonists. along with different local anaesthetics.

Buprenorphine an opioid with mixed agonist antagonist property has been shown to provide longer duration of analgesia among all the opioids. There are various studies available in literatures who have observed the safety and efficacy of buprenorphine in different peripheral nerve blocks in different doses[8]. There are no consensus on the effective dose of Buprinorphine as an adjuvant to local anesthetic in peripheral nerve block. Hence, we decided to undertake the study where we have compared two different doses of buprenorphine 3µg kg^{-1} Vs 4µg kg^{-1} as an adjuvant to ropivacaine in ultrasonography (USG) guided supraclavicular block. The primary outcome of the study was to compare characteristics of sensory, motor blockade and duration of analgesia in both the groups. Our secondary outcome was to compare intra operative haemodynamics, requirement of rescue analgesics and side effects if any.

MATERIAL AND METHODS

This prospective randomized double blind controlled study was conducted after obtaining written permission of the institutional ethics committee of MGM Medical College and hospital Aurangabad, Maharashtra. The patients admitted to MGM hospital for upper limb surgeries during the period October 2019 to October 2021 were considered for study. The sample size was calculated with the formula after setting a error at 0.06 and ß error at 0.9.

The number of patients required in each group (n) was 25 as per power analysis. The study was registered in the clinical trial registry (Reg. no-CTRI/2020/06/026126). Patients of both sexes, between age group 18-70 yrs, weight 45-70kg and belonging to American Society of Anesthesiologists (ASA) physical status grade 1, 2 and 3 scheduled for elective upper limb surgeries under supraclavicular block were included in study. Exclusion criteria used were patients with known allergy to local anaesthetics, infection at the site of block, peripheral neuropathy and on chronic opioid therapy. Pre-operative examination was done one day before the scheduled surgery. Informed consent was taken from all the eligible and willing patients. Fifty patients randomly divided into two groups using sealed envelope method. Group 1: Received 0.5% ropivacaine 20ml+buprenorphine 3mcg kg^{-1} and Group 2: Received 0.5% ropivacaine 20ml+buprenorphine 4mcg kg^{-1} on arrival in pre-operative room, ASA standard monitors like Electrocardiography (ECG) for Heart Rate (HR beats/min), NIBP (mm Hg) for blood pressure, and probe for oxygen saturation. (SpO2) were applied. Baseline pre-operative parameters were recorded. Intravenous (IV) access was secured with 20G cannula and an infusion of ringer's lactate was started. Inj. midazolam 1mg IV was given for anxiolysis.

Technique: The patient was placed in supine position with a pillow under head, arm to be operated was adducted and head was tilted 45 degrees to opposite side. Supraclavicular brachial plexus block was performed using (SONOSITE M-TURBO) an ultrasound machine with high frequency transducer (9-12 Hz linear probe) in transverse plane.After maintaining proper ergonomics probe was placed in supraclavicular region above the clavicle. Stimuplex needle (22 G, 100mm) was inserted by "in plane" approach placed above the plexus. A predetermined volume as per the group allocation of local anaesthetic solution was injected after negative aspiration into the corner pocket (Fig.1).

The person who had given the block, observed the parameters and recorded the findings was blind to the study drug prepared. Thus both the patient and observer (participant and investigator) were blind to the study drug used making the study double blind. Patients were assessed for onset of sensory and motor block every 5 mins for first 20 mins. The motor blockade was assessed using modified Bromage's scale. Grade 0: Normal motor function with full extension of elbow, wrist and fingers. Grade 1: Ability to flex and extend wrist and fingers. Grade 2: Ability to flex and extend only fingers Grade 3: Complete motor block with the inability to move elbow, wrist and finger.

- **The time of onset of Sensory block:** Time between injection of the drug (T0) to loss of pin prick sensation over C5-T1 dermatomes
- **The time of onset of Motor block:** Time between injection of the drug (T0) and achieving grade 1 motor block

Surgical incision was allowed only when loss of sensation over surgical site and motor block of modified Bromage scale 2 was achieved. Failure to achieve this within 20 mins was considered as failure of

block and general anaesthesia was supplemented. Any patient who needed administration of general anaesthesia was excluded from study. Intra-operatively HR, mean arterial blood pressure (MAP), Spo2, ECG was recorded every 5 mins. After completion of the procedure, patients were assessed for recovery of motor and sensory block every 1 hour for first 8 hours and every 2 hrs thereafter till 24 hrs.

- **Duration of sensory block:** This was time taken from onset of sensory block to return of pinprick sensation over hand
- **Duration of motor block:** This was time taken from onset of motor block to complete recovery (Grade 0 Modified Bromage Scale)
- VAS assessment was done every h for first 8 h then 2 hourly for 24 hr
- **Duration of analgesia**: It was the time from onset of sensory block till the time patient complained of pain

Rescue analgesics in the form of Inj. Tramadol 1mg kg^{-1} IV was given only after the patient complained of pain. Additional analgesic Inj. Paracetamol was used if VAS>4 even after receiving Inj. Tramadol. Total number of rescue analgesics required in 24 hrs was noted. VAS Score: 0: No Pain, 1-3: Mild Pain, 4-6: Moderate Pain, 7-10: Severe Pain.

Statistical analysis: Quantitative data were expressed in form of Mean±SD, for statistical analysis the unpaired t-test was used for comparison of mean between two groups. Qualitative data were expressed in form of Frequency and Percentage. The chi-square test was used for qualitative data. Non-Normal data were compared using Mann-Whitney test. All statistical analysis was done using SPSS 21 for Windows (Statistical Package for Social Science). If p>0.05, it was considered as non significant.

RESULTS

Both the groups were comparable with respect to age, sex and weight distribution. (Table 1) The mean time of onset of sensory block was faster in Group 2 (4.08±1.29 min) than Group1 (4.92±1.82 min), with no statistically significant difference seen between two groups (p-value = 0.067). The mean duration of sensory block was more in Group 2 (514.8±136.4 min) than Group 1 (457.8±135.65 min) the difference being statistically non significant. (p-value = 0.1450) The mean onset of motor block was earlier in Group 2 (15.24±1.81 mins) than Group 1 (15.64±1.78 mins), with p-value 0.4342, which shows no statistically significant difference between two groups. The mean duration of motor block was more in Group

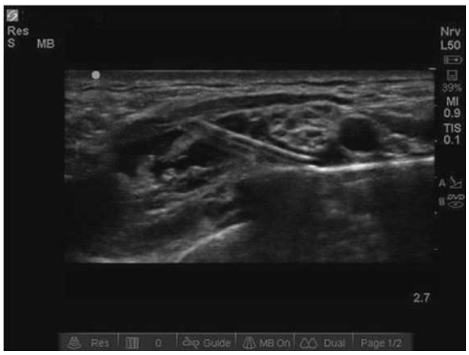

Fig. 1: USG Image of Supra clavicular block

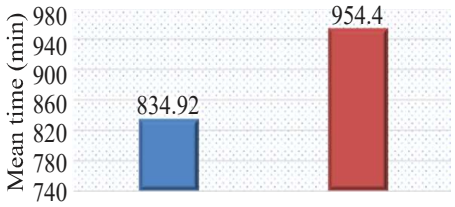

Fig. 2: Comparison of Duration of Analgesia

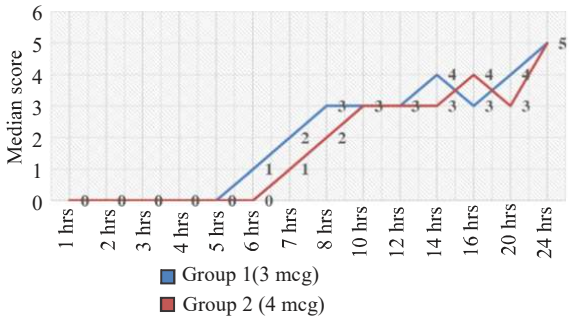

Fig. 3: VAS Distribution in both the groups

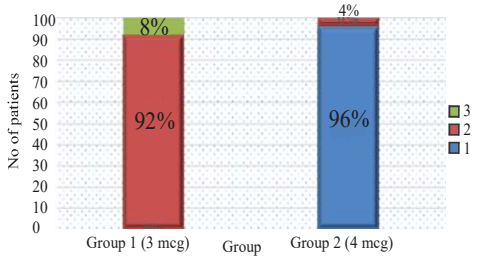

Fig. 4: Comparison of Doses of Rescue Analgesics required

2 (445±143 min) than in Group 1 (376±121min). The difference being statistically insignificant with p value 0.069. The intra-operative hemodynamic parameters (heart rate, blood pressure, saturation) were maintained throughout surgery and were comparable

Table 1: Demographic parameters

Parameter	Group 1 (3 Mcg)	Group 2 (4 Mcg)	t-Value	p-Value	
Age (Yrs)	34.3±11.9	39.7±16.6	1.33	0.191	p>0.05, Not Sig
Weight (Kg)	58.76±7.39	59.28±9.79	0.21	0.833	p>0.05, Not Sig

Table 2: Sensory and Motor Block characteristics

Parameter	Group 1 (3 Mcg)	Group 2 (4Mcg)	t-Value	p-Value	
Onset of Sensory Block (Min.)	4.92±1.82	4.08±1.29	1.88	0.067	p>0.05, Not Sig
Duration of Sensory Block (Min.)	457.8±135.65	514.8±136.4	1.4815	0.1450	
Onset of Motor Block (Min.)	15.64±1.78	15.24±1.81	0.7887	0.4342	
Duration of Motor Block (Min.)	376±121	445±143	1.86	0.069	
Duration of Analgesia (Min.)	834.92±65.31	954.40±88.60	5.4275	0.0001	High Sig. p 0.05

in both the groups. (p>0.05) (Table 2). The mean duration of analgesia was longer in Group 2 (954.40±88.60 mins) than Group 1 (834.92±65.31 mins), (p value 0.0001) which shows statistically highly significant difference. (Table 2) (Fig. 2). Till 10 hrs there was no statistically significant difference in VAS in both the groups. From 10-24 hrs there was statistically significant difference noted in both the groups VAS being less in Group 2 than Group 1. (Fig. 3) Maximum number of patients in Group 2 required only one rescue analgesic while 92% patients in Group 1 required two rescue analgesics in 24 hrs which shows statistically significant difference (p = 0.000) (Fig.4)None of the patients in either of the study groups had adverse effects like nausea, vomiting, and respiratory depression.

DISCUSSIONS

Buprenorphine an opioid analgesic, strong agonist of μ receptor, is used by many researchers for peripheral nerve block. Perineural action of buprenorphine includes non-specific local anaesthetic effect which includes a decrease in K+ conduction and an increase in Ca++ conduction in the cell body of sensory neuron. It also acts via μ receptors located on C fiber axons and blocks sodium channels in a concentration-dependent manner[5]. Opioids also inhibit the release of excitatory neurotransmitter substance P from the peripheral sensory nerve endings[4,6].

Despite of many studies comparing efficacy of buprenorphine in peripheral nerve block no research is available demonstrating dose dependent effect on duration of analgesia. Similarly, dose finding studies are also lacking for this adjuvant[7]. Various doses of buprenorphine as adjunct with local anaesthetics are used in different studies ranging from 0.1mg, 0.15 mg, 0.2mg, 0.3mg[7]. As fixed rather than per kg dose. Some studies have used the dose of 3μg kg^{-1} for post-operative analgesia and found it effective in[6,7,1]. improving quality of sensory block and postoperative analgesia[8]. The maximum perineural dose used in these studies was 300ug. Considering the average weight of our patients we decided to study 3μg kg^{-1} and 4μg kg^{-1} dose to compare its effect on post-operative analgesia. Our study demonstrated faster onset of sensory block in Group 2 (4.08±1.29) min than Group 1 (4.92±1.82) but the difference was statistically non-significant. (p-value = 0.067) This shows earlier onset of sensory block after increasing the per kg dose of buprenorphine. Vinod *et al*.[9] compared effect of dexmedetomidine and buprenorphine as an adjuvant to 0.5% bupivacaine for ultrasound guided supra clavicular brachial plexus block. Buprenorphine group received 24ml 0.5% bupivacaine with 100 μg buprenorphine. Onset time of sensory block was 5.2±1.6 min which is delayed than our study the difference in the actual value may be due to less dose of buprenorphine used. Duration of sensory block in our study was more in Group 2 (514 ±136.4 min) than Group 1 (457.8±135.65) with p value 0.145, which was statistically non-significant. Jain et al.[4] conducted study of buprenorphine as an adjuvant to 0.5% Ropivacaine for ultrasound guided supraclavicular brachial plexus block. Duration of sensory block was 8.76±0.83 h, in the group where they used ropivacaine 30 cc with buprenorphine 0.3mg. Even after using long acting local anaesthetic like bupivacaine Vinod et al.[9] observed shorter duration of sensory block (395.7±15min.) may be due to lower dose of buprenorphine used.

In our study the mean onset of motor block was earlier in Group 2 (4μg kg^{-1}) 15.24±1.81 min. Than Group 1 (3μg kg^{-1}) 15.64±1.78 min. p-value 0.43 with statistically insignificant difference. Jain *et al*.[4] conducted study of buprenorphine as an adjuvant to 0.5% Ropivacaine for ultrasound guided supra clavicular brachial plexus block a randomized, double blind, prospective study two groups Patients received 30ml 0.5% ropivacaine with 1ml buprenorphine (0.3 mg). Onset of motor block was 11.13±1.89 min.; it suggests that buprenorphine as an additive when given in more doses causes earlier onset of motor block. In our study the mean duration of motor block in Group 2 was 445±143 min and Group 1 was 376±121 min.with p-value 0.069; which was statistically insignificant.

Vinod *et al*.[9] noted duration of motor block in Group B (24ml 0.5% bupivacaine + 1ml (100 µg) buprenorphine) as 334.3±23.8 min. We have better duration of motor block with more dose of buprenorphine than this study. Our study demonstrated significantly longer duration of analgesia in Group 2 (954.40±88.60 min) receiving buprenorphine 4µg kg^{-1} as an adjunct than Group 1 (834.92±65.31) where dose of buprenorphine was 3µg kg^{-1} (p-value 0.0001).

We have more duration of analgesia than Jain *et al*.[4] where they noted 868.2±77.78 min duration with 300µg of buprenorphine and 30ml ropivacaine in USG guided block of post-operative analgesia than this study even when we used less dose of ropivacaine and buprenorphine. Vinod *et al*.[9] used 100µg buprenorphine with 24ml bupivacaine in USG guided supra clavicular block and observed duration of analgesia as 579.0±41.4 min. We have longer duration of analgesia than this study where we used more dose of buprenorphine. VAS was compared in both the groups. In Group 1 median VAS< 4 was observed till 14 hrs and in Group 2 till 16 hrs respectively. When compared shows statistically significant difference. This shows improved quality of post-operative analgesia with use 4µg kg^{-1} dose of buprenorphine. Patil *et al*.[6] observed VAS <4 for 24 hrs in the group where they have used buprenorphine 300 MCG as an adjuvant. This low value of VAS for such a long duration was may be due to use of maximum dose of buprenorphine, hyaluronidase, large volume of 30ml and combination of local anaesthetics. Most of the references have not included details of VAS comparison in their studies. So it is difficult to compare our findings related to VAS and specific dose of buprenorphine. In our study Group 1 -92% patients required two rescue analgesics and Group 2: 96% patients required only one rescue analgesics which show statistically significant p-0.000, it shows that lesser requirement of rescue analgesics and good pain relief with increased dose of buprenorphine.

Dixit *et al*.[10] mentioned consumption of analgesics in first 24 hrs as 1.3±0.59 in bupivacaine with buprenorphine 3µg kg^{-1} group. Shaji *et al*.[1] mentioned in metanalysis that patients treated with 0.1-0.3 mg buprenorphine combined with local anaesthetics required rescue analgesia around 9 h later compared to those receiving only local anaesthetic, indicating a larger effect. In our study in Group 2 rescue analgesics required less may be due to increased dose of buprenorphine i.e. 4µg kg^{-1} which shows better postoperative analgesia with less requirement of rescue analgesics In our study we have found no side effects like nausea, vomiting and respiratory depression. Safety of perineural buprenorphine in peripheral nerve blocks overall showed the lesser adverse events[7]. There was no statistically significant difference in the heart rate between the two group at various time intervals There was no statistically significant difference in the mean arterial pressure between the two groups at various time intervals throughout the study period.

CONCLUSION

Buprenorphine when used as an adjuvant with 20 ml Ropivacaine in USG guided supraclavicular block, in the dose of 3µg kg^{-1} and 4µg kg^{-1} has comparable sensory and motor block characteristics, good haemodynamic stability, without any side effects although 4µg kg^{-1} provides longer duration of analgesia and reduced requirements of postoperative rescue analgesics, hence it may be preferred over 3µg kg^{-1} dose.

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