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Original Research Article

Efficacy of 0.5% levobupivacaine with clonidine 30 µg versus 0.5% levobupivacaine with 150 µg buprenorphine for USG guided interscalene brachial plexus block for shoulder, upper and middle humerus surgeries: a prospective randomized double blinded comparative study

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ABSTRACT

Background: Ultrasound imaging is increasingly used for peripheral nerve blocks, offering real-time visualization of nerves, surrounding structures, and needle tips. Levobupivacaine, a local anesthetic, provides excellent intraoperative and postoperative analgesia. Buprenorphine, a partial µ-opioid receptor agonist, and clonidine, an α2 adrenergic agonist, also offer postoperative analgesia. We aimed to compare levobupivacaine with clonidine versus levobupivacaine with buprenorphine for ultrasound-guided interscalene block for shoulder and upper-arm surgeries. This study aimed to determine the onset and duration of sensory and motor block, duration of postoperative analgesia, hemodynamics, complications, and sedation.
Methods: Patients scheduled for elective shoulder and upper-middle humerus surgeries received either levobupivacaine with clonidine or levobupivacaine with buprenorphine. Assessments include onset and duration of sensory and motor blockade, analgesia duration, sedation, side effects, and block quality. Onset and duration of sensory and motor blockade, and analgesia duration was analyzed using unpaired T-Test.
Results: Levobupivacaine with clonidine group showed longer duration of analgesia (595±148 mins) compared to levobupivacaine with buprenorphine group (445±44.16 mins), with a significant difference (P<0.039).
Conclusions: Levobupivacaine with clonidine provided excellent blockade quality, and both clonidine and buprenorphine added to levobupivacaine offered good surgical and postoperative analgesia. However, levobupivacaine with clonidine significantly prolonged postoperative analgesia compared to buprenorphine.

Keywords: Buprenorphine, Clonidine, Interscalene block, Levobupivacaine

INTRODUCTION

The ultrasonography guided interscalene block has a greater success rate when compared to nerve-stimulation technique. Ultrasound imaging is increasingly used to guide peripheral nerve blocks, nowadays because of its safety and success rate.[1] USG guidance allows real time visualization of nerves surrounding structure & needle tip to maximize block success and minimize complications.[2] Peripheral nerve blocks provide both excellent intraoperative and postoperative analgesia. To prolong the postoperative analgesia and improve the quality of blockade we can add additives to local anaesthetic agents.

Adjuvants like dexamethasone, buprenorphine, dexmedetomidine, clonidine etc., can be used with varying efficacies.

Levobupivacaine is an amino-amide local anaesthetic drug belonging to the family of n-alkyl substituted pipecoloxylidide. It is S-enantiomer of bupivacaine with slightly longer block duration. It acts by blocking sodium channels, thereby preventing nerve impulse conduction. It is commonly employed in regional anesthesia, particularly for procedures requiring prolonged analgesia for upper and lower limb surgeries.[3]

Buprenorphine is a weak partial μ-opioid receptor agonist and kappa-opioid receptor antagonist. It provides excellent postoperative analgesia. It is a synthetic opioid with a thebaine derivative structure. It acts as a partial agonist at the mu-opioid receptor, providing analgesia with a lower risk of respiratory depression compared to full agonists. It is widely used for pain management, particularly in postoperative settings. It can be administered transdermally or as an injectable formulation.[4] Its long duration of action is because of its high affinity for opioid receptors.

Clonidine is an α_2 adrenergic agonist. It provides excellent postoperative analgesia. It acts on alpha-2 receptors in the central nervous system, leading to decreased sympathetic outflow, resulting in analgesic effects. It is also often used in combination with local anesthetics for regional anesthesia, as it enhances the duration and quality of the block.[5] It provides prolonged analgesia and is known for its sympatholytic effects.

Buprinorphine and Clonidine are FDA approved for perineural administration along with local anaesthetic agents.[6] Various clinical trials proved that both of the agents provide prolonged and excellent analgesia when combined with local anesthetic agents.[7,8] The proposed study aimed to compare the efficacy of 0.5% levobupivacaine with clonidine 30μg versus 0.5% levobupivacaine with 150μg buprenorphine for USG guided interscalene brachial plexus block for shoulder, upper and middle humerus surgeries.

METHODS

This randomized, double blind clinical trial was performed at tertiary care, Government General Hospital, Siddhartha Medical College, Vijayawada, Andhra Pradesh, for a duration of 6 months, from June 2023 to December 2023. The study included patients of both genders scheduled for elective shoulder, upper, and middle humerus surgeries under ultrasound-guided interscalene block.

Inclusion criteria

Inclusion criteria comprised patients in the ASA-I and ASA-II categories, aged between 20 and 60 years.

Exclusion criteria

This included individuals with a weight exceeding 80 kilograms, those classified as ASA-III and ASA-IV, presence of comorbid conditions such as diabetes, hypertension, asthma, or other systemic diseases, coagulopathy, and heart rate less than 60 beats per minute.

Methodology

After obtaining IEC approval, written and informed consent, patients of ASA-1 and ASA-2 of both genders were scheduled for elective shoulder, upper and middle humerus surgeries under USG interscalene block. They were randomly divided into two equal groups. Group-C was assigned to receive 20 ml of 0.5% levobupivacaine + 1ml (30μg) clonidine. Group-B was assigned to receive 20 ml 0.5% levobupivacaine + 1ml (150μg) buprenorphine. Both groups were given 21ml of equal volume.

On arrival of patient on OR table

18G IV access was secured to the non operating hand. Patients baseline parameters like HR, NIBP, RR and SPO2 were recorded in each patient preoperatively. No sedative premedication was administered in both the groups. All the patients were preloaded with 10 ml/kg crystalloids before the procedure. After explaining blockade procedure, patients were positioned in supine with the arms placed on the side of the body and head was turned to contralateral side at an angle of 45° and the pillow was placed under the shoulder blade to optimize the position for interscalene block. Under strict aseptic conditions a senior Anaesthesiologist who is unaware of group allocation has performed the interscalene block. The chief anesthesiologist who is aware of group allocation provided the study drugs in sealed covers just before the procedure is being done.

USG guided procedure was done using a linear probe (15hz) placed in the transverse plane at the supraclavicular area just above the midpoint of the clavicle. Supraclavicular brachial plexus were identified initially and then the probe was slowly drawn in cephalad direction until the level of C6 vertebra where scalene muscles and interscalene brachial plexus, nerve roots were distinctly identified as traffic light signal appearance in majority of cases. Once the plexus were identified, probe is fixed at that point, skin was infiltrated with LA and 23G 10 cm spinal needle was introduced in plane from lateral to medial direction and study drugs were deposited after piercing the sheath under real time visualization and spread up the study drugs were observed usually. The total drug was slowly injected while taking care to aspirate in between. After completion of the block procedure, evaluation was done for onset of sensory and motor blockade by an alcohol swab and modified bromage scale (Table 1), respectively.

Table 1: Modified Bromage scale for upper limb.

Gradings for shoulder surgery	
4	N Motor function(full power in arm and shoulder)
3	↓ strength with ability to move arm and shoulder against resistance
2	Ability to move arm and shoulder against gravity but inability to move against resistance
1	Flicker of movement in arm and shoulder muscles
0	No movement in arm and shoulder muscles

Table 2: QAGA.

Grade	Criteria
Excellent	No complaint from the patient
Good	Minor complaints (small dose of anxiolytic only)
Tolerable	Requires supplemental analgesics
Unsuccessful	Failed. GA is required

Table 3: Four point sedation.

Point	Criteria
1	Spontaneous eye opening awake and alert
2	Drowsy (response to verbal stimuli)
3	Drowsy (arousable to physical stimuli)
4	Unresponsive

The quality of the block was evaluated throughout the procedure by using QAGA grading which is described in Table 2. Sedation levels were also monitored using a 4 - point sedation score in Table 3. Intra operatively all patients were monitored for hemodynamics and any complications. After the completion of surgery, patients were monitored for 2 hours in the post anesthesia care unit. Duration of sensory and duration of motor blocks, VAS scores and postoperative analgesia duration were evaluated in PACU stay of two hours. Then patients were shifted to postoperative wards. Continuous evaluation of sensory and motor block duration, VAS scores and any postoperative complications were done in the post operative ward. Study period is completed at the end of 24hours. Post-operative rescue analgesia was administered with inj. diclofenac 70 mg I.M + inj. tramadol 1.5 mg/kg slow I.V when VAS Score ≥ 4.

Statistical analysis

Sample size was calculated based on a pilot study conducted with 10 subjects per group. The main difference in the primary outcome i.e. time to first request of pain medication between groups is accounted to be more than 25%, α-value is taken as 0.05 β-error is taken as 0.20 (power of 80%). So the calculated sample size is 25 per group as per the above α and β values. Margin of error taken as 5%. In order to account for dropouts the total number of subjects per group is taken as 30.

All the data was recorded by a senior postgraduate who is blinded to the study drugs. The data was analyzed statistically as onset time and duration of sensory, motor-blockade, and duration of analgesia analyzed by unpaired T-Test. P value <0.05 will be considered statistically significant. Data was represented as mean±SD.

RESULTS

Both the groups were comparable in the terms of age, sex, weight, ASA grade and duration of surgery and no statistical significant difference was found in Table 4.

Table 4: Demographic data, data presented as mean ± SD.

	Buprenorphine (n=30) Mean±SD	Clonidine (n=30) Mean±SD	Total (n=60) Mean±SD	P value
Age	39.50±14.3	45.66±17.7	42.58±16	0.5100
Weight	67.33±12.2	55.66±12.8	61.49±12.5	0.1370
Duration of surgery (in mins)	113.50±64.5	108.33±68.8	110.91±66.6	0.8952

Note: P>0.05, statistically not significant. Data expressed as mean±SD

The mean onset times of sensory block in Group B is 4.33±1.21 mins and in Group C is 3.67±0.82 mins. There is no significant difference in mean onset times of sensory block in between Group B and group C (P>0.28). The mean onset time of motor block in Group B is 6.33±1.97 mins and Group C is 5.83±0.98 mins. There is no significant difference in mean onset of motor block between Group B and group C (P>0.58). In comparison to the mean duration of sensory blockade between the two groups, the mean duration of sensory blockade for Group B is 198.33±34.74 mins and for Group C is 237.50±121.64 mins. There is no significant difference in mean duration of sensory blockade in between Group B and Group C (P>0.46). In comparison of mean duration of motor blockade between the two groups, Group B is 440±140.29 mins and Group C is 670±95.98 mins. There is a highly significant difference in mean duration of motor blockade in between Group B and Group C (P<0.008), showing that duration of motor blockade is longer in Group C. Onset times of sensory motor blockade and duration of sensory and motor blockade are represented in Table 5. The mean duration of analgesia in between Group B is 445±44.16 mins and Group C is 595±148 mins. There is a highly significant difference in mean duration of analgesia in between Group B and group C (P<0.039), showing that the duration of analgesia was longer in Group C. The duration of

postoperative analgesia is represented in Table 7 and Figure 1. Mean pulse rate of mean arterial blood pleasure were also comparable in both the groups as represented in Figure 2.

Table 5: Characteristics of sensory and motor block.

	Buprenorphine (n=30) Mean±SD	Clonidine (n=30) Mean±SD	P value
Sensory onset	4.33±1.21	3.67±0.82	0.28
Motor onset	6.33±1.97	5.83±0.98	0.58
Duration of sensory	198.33±34.74	237.50±121.64	0.46
Duration of motor	440±140.29	670±95.98	0.008*

* P value <0.05 statistically significant. Data expressed as Mean±SD

Table 6: QAGA grading and sedation score.

	QAGA – I (Excellent)	QAGA – II (Good)	4 point sedation score - 1
Group-B, n=30	n=20, 66.6%	n=10, 33.3%	n=30, (100%)
Group-C, n=30	n=25, 82.5%	n=5, 17.5%	n=30, (100%)

Data expressed as absolute numbers and percentage

Table 7: Duration of postoperative analgesia.

	Buprenorphine (n=30), Mean±SD	Clonidine (n=30), Mean±SD	P value
Duration of analgesia (in mins)	445±44.16	595±148	0.039*

***** P value <0.05, statistically significant. Data expressed as mean ± SD

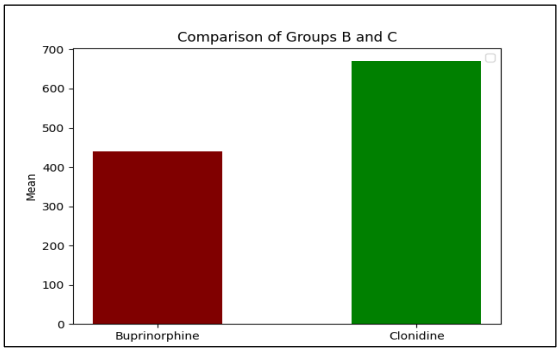

Figure 1: Comparison of duration of postoperative analgesia in Group B and Group C.

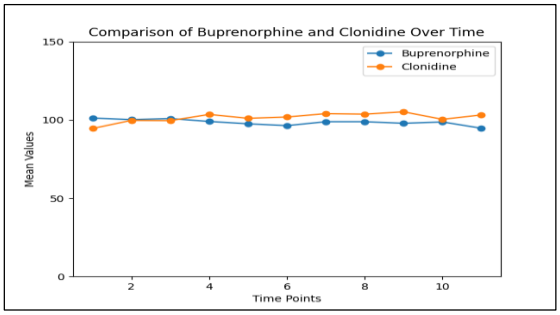

Figure 2: Comparison of mean arterial pressure between Group B and Group C.

On comparison of quality of anesthesia by QAGA grading, Group C showed Grade - 1 (excellent) in 82.5% while Group B showed Grade - 1 in 66.6% which is represented in Table 6. On assessment of sedation in the two groups, all the patients are awake and alert and 4-point sedation score is 1 in both the groups which is comparable, represented in Table 6. Postoperative pain was assessed by VAS scores and which is represented in Table 8.

Table 8: VAS scoring.

	Buprenorphine (n=30) Mean±SD	Clonidine (n=30) Mean±SD	P value
1 hr	0.0±0.0	0.0±0.0	0
2 hrs	0.0±0.0	0.0±0.0	0
4 hrs	1.00±1.26	1.16±0.98	0.81
6 hrs	2.00±1.89	2.16±1.32	0.86
8 hrs	4.20±0.63	2.80±0.63	0.0001*
10 hrs	2.10±0.57	4.10±0.32	0.0001*
12 hrs	2.00±0.89	2.66±1.21	0.30
14 hrs	2.33±0.81	1.50±1.04	0.15
16 hrs	3.00±0.89	3.00±1.26	1
18 hrs	3.83±1.16	2.83±1.47	0.22
20 hrs	4.10±0.57	2.20±0.63	0.0001*
22 hrs	2.33±0.52	4.17±0.41	0.0001*
24 hrs	2.00±0.89	2.66±1.21	0.30

*P value <0.05, statistically significant. Data expressed as Mean ± SD

After some time, VAS ≥ 4 was recorded between 6-8 hours in the buprenorphine group, and between 8-10

hours in the clonidine group. The second rise in VAS score occurred after rescue analgesia, above the 20th hour in the buprenorphine group and the 24th hour in the clonidine group. Perioperative complications like postoperative nausea and vomiting, failed block and inadequate block, pneumothorax respiratory depression etc., were not reported in any of the patients.

DISCUSSION

Interscalene brachial plexus block provides excellent surgical anesthesia for shoulder and upper arm surgeries.[9] However, the ulnar nerve is spared (C_8-T_1) sometimes with an interscalene block. Hence ideally indicated for shoulder proximal and mid humerus surgeries with the advent of ultrasonography in the preoperative arena ISB block can be given with precision producing excellent analgesia and high success rate without any complications in most of the patients.[10,11] Numerous studies reported that bupivacaine with various adjuvants produced excellent surgical analgesia and prolonged postoperative analgesia.[12,13]

In this study we compared levobupivacaine with clonidine vs levobupivacaine with buprenorphine for shoulder, upper and mid humerus surgeries by interscalene block using USG guidance. The duration of motor blockade (P = 0.008) and the duration of postoperative analgesia (P = 0.039) were significantly high in clonidine groups. Clonidine is an α_2 agonist and buprenorphine is an opioid which proved to improve the quality of analgesia and increase the duration of postoperative pain relief when administered with local anesthetic agents.[14,15] This study demonstrated that both clonidine and buprenorphine when administered perineurally along with levobupivacaine produced excellent analgesia in clonidine (QAGA-1, excellent-82%) and in buprenorphine (QAGA-1, excellent 66.6%) groups as evaluated by QAGA Scale. Onset time of sensory block, onset time of motor block and duration of sensory blockade were comparable in both the groups. The duration of motor blockade (P=0.008) and duration of postoperative analgesia (P=0.03946) were significantly high in the clonidine groups.

Dass et al evaluated the effect of adding 0.5 µg/kg clonidine to 0.5% levobupivacaine during interscalene brachial plexus block for shoulder arthroscopy and concluded that 0.5 µg/kg clonidine with 0.5% levobupivacaine is well tolerated and produces better and prolonged analgesia than 0.5% levobupivacaine alone.[16] The mean time to first request pain medication was 13.5 hours in the clonidine with levobupivacaine group, while in this present study it was observed to be 9 hours 55 minutes, the difference in the duration of post operative analgesia could be due to increased dose of levobupivacaine 30 ml in their study contrary to 20 ml in the present study and also difference in the dose of clonidine 0.5 µg/kg in their study on contrary to 30 µg of standard dose in this present study.

Gupta et al evaluated the effect of adding clonidine to levobupivacaine in supraclavicular brachial plexus block and concluded that there is decrease in the onset times of sensory and motor blocks (P<0.05) and increase in the duration of sensory and motor block (P<0.05) and prolonged duration of analgesia (P<0.001) when compared to levobupivacaine alone.[17] The duration of sensory motor and postoperative analgesia were significantly prolonged in clonidine with the levobupivacaine group compared to levobupivacaine group alone. In comparison with the present study, the duration of sensory, motor and postoperative analgesia were prolonged as 880.16±55.48 mins versus 237.50±121.64 mins, 771.83±54.19 mins versus 670±95.98 mins, 1013.5±39.01 mins versus 595±148; respectively.

The prolonged duration in the Gupta et al study can be attributed to larger doses of levobupivacaine i.e., 30 ml and clonidine 150 µg only. The present study uses levobupivacaine 20 ml only and the standard doses of clonidine are 30 ml.

Amany and Arafa conducted a study on clonidine plus levobupivacaine for patient controlled interscalene analgesia after shoulder surgery and concluded that clonidine improved the quality of analgesia and increased the degree of patient satisfaction, decreased the consumption of LA during PCIA and also decreased sleep disturbances and the postoperative oral narcotics use when compared to levobupivacaine alone.[18] In their study, levobupivacaine with clonidine improved the quality of ISB compared to levobupivacaine alone. The results are comparable to the present study, where the quality of ISB blockade as assessed by QAGA scale was rated as excellent in 82.5% in levobupivacaine with clonidine Group versus 66.6% in levobupivacaine with buprenorphine group.

Behr et al compared levobupivacaine (0.75%) for ISB block with epineural buprenorphine (0.15 mg) versus intramuscular buprenorphine (0.15 mg) versus saline intramuscularly (0.5 cc) and concluded that epineural buprenorphine prolonged postoperative analgesia of middle inter scale block most effectively than intramuscular buprenorphine which can be compared to the observation of this present study.[19] They also administered high doses of levobupivacaine 0.75% of 29.5 ml compared to levobupivacaine 0.5% of 20 ml in our study. The doses of buprenorphine were similar to that of our study.

Yadeau et al did a dose response study by adding of buprenorphine, clonidine, dexamethasone and ropivacaine for interscalene nerve blockade and concluded that for maximum pain reduction combining perineural additives with ropivacaine 0.375% or ropivacaine 0.2% is suggested.[20] In this study, they compared varying doses of ropivacaine 0.375% versus 0.2% versus 0.1% with perineural additives, while in the

present study standard dose of 0.5% levobupivacaine was administered.

Behar et al and Yadeau et al studies proved that perineural buprenorphine significantly prolongs pain duration when added to levobupivacaine or ropivacaine whose findings are comparable to our study.[19,20] Levobupivacaine is chosen in the present study as it is now easily available, equipotent with bupivacaine and has cardiac and CNS safety profile which might reduce the severity of complications when inadvertent intravascular injections may happen. A prescribed dose of levobupivacaine 0.5% of 20 ml is sufficient for USG guided blocks as there will be deposition of drug into the sheath of the plexus which will be appreciated on real time visualization while performing the blockade moreover larger doses are unnecessary with USG guidance.

This study was meticulously done as per the standard protocols in both the groups. The quality of the block is graded as excellent and good as per QAGA scaling. None of the patients in both the groups had any complications to the study drugs. All patients were alert and awake in both the groups.

The main limitation of the study was that a limited sample size was taken.

CONCLUSION

Most of the patients had excellent quality of blockade in levobupivacaine with clonidine group. Both buprenorphine and clonidine added to levobupivacaine provide excellent surgical and postoperative analgesia. However; levobupivacaine with clonidine prolong duration of postoperative analgesia significantly compared to buprenorphine.

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