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Comparison between Bupivacaine vs. Bupivacaine plus Potassium Chloride in Supra clavicular Brachial Plexus Block: Double Blind Randomized Controlled Trial

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ABSTRACT

Pain, an unpleasant sensory and emotional experience linked to tissue damage, is a key concern for anesthesiologists. Regional anesthesia, blocking peripheral nerve conduction with local anesthetics, is now established as effective and accepted as general anesthesia. The supra clavicular brachial plexus block is a widely used technique, offering safe, effective and cost-efficient anesthesia with prolonged post-operative pain relief. Adding adjuvants to the local anesthetic can further extend the pain-free period. This study compares plain bupivacaine with bupivacaine plus potassium chloride in brachial plexus block. Sixty patients aged 18-60 years, of ASA Grade I-III, scheduled for upper limb surgeries, were randomly assigned to two groups. Group I received 30 ml of 0.375% bupivacaine with 0.2 mmol of potassium chloride, prepared by adding 0.1 ml of potassium chloride and 10 ml of distilled water to 20 ml of 0.5% bupivacaine. Group II received 30 ml of 0.375% plain bupivacaine. The study assessed the onset and duration of sensory and motor blockade, along with the duration of effective post-operative analgesia following supra clavicular brachial plexus block in both groups. The onset of sensory and motor blockade was early in potassium group when compared to plain bupivacaine group, the duration of the blockade was prolonged in potassium group when compared to other group, the duration of effective post-operative analgesia was better in potassium group when compared to other group. Potassium chloride as an adjuvant to bupivacaine has advantages in supra clavicular brachial plexus block for upper limb surgeries.

INTRODUCTION

Pain functions as a protective and defensive mechanism. According to the International Association for the Study of Pain (IASP), pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"[1]. Anaesthesiologists have a moral obligation to promptly alleviate pain and ensure that patients are free from pain. Peripheral nerve blockade is a fundamental component of contemporary regional anesthesia. Its popularity has increased over time due to advancements in nerve blockade techniques, including the availability of drugs and the use of nerve stimulators and ultrasound for safe and successful block execution. This approach ensures excellent operative anesthesia and prolonged postoperative analgesia without causing undesirable systemic effects[2].

The supra clavicular approach to brachial plexus block is a commonly employed regional anesthesia technique for upper limb surgeries. It is preferred due to its rapid onset, ease of technique and effectiveness in relieving tourniquet pain. This approach is considered a superior alternative to general anesthesia because it minimizes physiological alterations, eliminates the need for airway manipulation, provides prolonged postoperative analgesia, reduces postoperative nausea and vomiting, allows for early ambulation and is cost-effective for both patients and hospitals[3]. Local anesthetics administered for supra clavicular brachial plexus block offer effective intra operative conditions but result in a shorter duration of postoperative analgesia. To address this limitation, adjuvants have been combined with local anesthetics for years to prolong analgesia following peripheral nerve blocks. Various adjuvants, such as opioids, clonidine, neostigmine, dexamethasone and midazolam, have been used in combination with local anesthetics for brachial plexus block to achieve rapid, dense and prolonged block[4-8].

Potassium chloride is a compound consisting of potassium and chloride ions. Potassium plays a crucial role in maintaining intracellular tonicity, nerve conduction, muscle contraction (including cardiac, skeletal and smooth muscle), energy production, nucleic acid synthesis, blood pressure regulation and normal kidney function. The addition of potassium chloride in physiological amounts offers several advantages, such as shortening the onset period of nerve block and prolonging its duration. Despite limited studies on potassium chloride as an adjuvant to local anesthetics, we decided to use it in supra clavicular block. The aim of our study is to compare the effects of bupivacaine alone versus bupivacaine plus potassium chloride in supraclavicular brachial plexus block for patients undergoing elective upper limb surgeries.

MATERIALS AND METHODS

After receiving approval from the institutional ethical committee (approval number 1083/2021), this double-blinded, prospective randomized, interventional study was registered in the Clinical Trials Registry India (CTRI) under registration number CTRI/2021/11/038337. The study was conducted from November 1, 2021 to August 1, 2022. Following explanation of the procedure, written informed consent was obtained from patients in the local language. The study was conducted in an orthopedic operating theater at SIR T Hospital, Bhavnagar, involving 60 patients. Patients were included or excluded based on thorough pre-anesthetic evaluation according to specific criteria.

Inclusion criteria: Patients posted for all elective or emergency orthopaedic surgeries of age group between 18-60 years with ASA physical status I-III, either gender were included.

Exclusion criteria: Patient with clinically significant coagulopathy, Infection at the injection site, with peripheral neuropathy, Uncooperative and patients who were Allergy to local anesthetics drugs were excluded.

Procedure: On the day of surgery patient was shifted to pre-anesthetic preparation room. written informed consent was taken in local language. Patients were randomly allocated to one of the two groups of 30 patients each by distributing computer-generated random sequences into either of two groups.

- Group I- received 30ml of 0.375% Bupivacaine with 0.2 mmol potassium chloride
- Group II- Received 30ml of 0.375% Bupivacaine

In pre-operative care room: Standard monitoring for heart rate (ECG), Mean arterial blood pressure (NIBP), Respiratory rate (RR) were established and baseline vital parameters were recorded. An appropriate size intravenous cannula was secured in a nonoperative hand and ringer lactate infusion was started slowly. Injection ondansetron 4mg, injection midazolam 1mg IV was given as premedication 15 min before induction. In the preoperative preparation room only, patients were randomized to one of the two groups by random number list. The doctor performing the randomization prepared the solution as per the group assigned and no other member of research team knew about the contents of the solution. In operation theater, supra clavicular brachial plexus block was performed with aid of Nerve Locator (B. Braun Melsungen, Germany).

After giving position for supraclavicular brachial plexus block, 22G short beveled 1.5inch insulated needle was introduced just lateral to subclavian artery

pulsation a cm above mid-point of clavicle and advanced in backward, inward and downward direction. The current was initially set to deliver 0.5 milli amperes at 2Hz stimulation frequency. The needle was advance till we get contraction of forearm muscle. Once the contraction is seen, current was reduced in 0.02 milli amperes decrements while advancing the needle, till we get maximum contraction with minimum possible current. At this point, solution as per group assigned, was injected after careful aspiration so as to avoid intravascular injection of drug.

The doctor performing the block was unaware of the drug combination administered. End of the injection was taken as Time '0'. Immediately after the block, sensory and motor characteristics of the blockade, hemodynamic variables, SpO2 was assessed by the same doctor who performed block at 1,5,10,20,30 mins and then at hourly intervals till 4 hours and then at two hourly interval for 24 hours. Post operatively, the time of first rescue analgesia required at VAS = 4 was the effective duration of post op analgesia. Injection Diclofenac sodium 1.5 mg/kg i.v was given as rescue analgesics. The territories supplied by the following nerves were evaluated by pinprick for the presence or absence of pain sensation with a 25gauge needle.

The sensory block will be assessed by Hollmen scale:

- Grade-1 full sensation,
- Grade-2 weak sensation,
- Grade-3 recognized as light touch
- Grade-4 loss of sensation

The motor block was evaluated by examining the following response:

- I Musculocutaneous nerve - elbow flexion
- II Median nerve-3 rd. finger flexion
- III Radial nerve-thumb abduction
- IV Ulnar nerve-little finger flexion

The motor blockade will be assessed by modified bromage scale:

- 0- Normal motor function,
- 1- Ability to move fingers only,
- 2- Complete motor block with an inability to move the elbow, wrist and finger

Sensory characteristics: Onset was taken as time duration from the end of injection to dull response to pin pinprick sensation. Duration was taken as time duration from the onset of sensory block to a feeling of pinprick sensation.

Motor characteristics: Onset was taken as time duration from end of injection to decreased finger movements. Duration was taken as time duration from the onset of motor a block to the reappearance of finger movements.

The quality of block was evaluated in the intraoperative time:

- **Satisfactory block:** Surgery without patient discomfort or the need for supplementation
- **Unsatisfactory block:** A sensory region involved in the surgery not completely anaesthetized and the block was supplemented by local infiltration, continuous infusion of propofol at 50µg/kg/min and inj. fentanyl 1-2µg/kg IV as per requirement

Duration of post operative analgesia: It is as time duration from onset of sensory block to first rescue analgesia requested by the patient at VAS = 4.

Statistical analysis: Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analyzed with the T test and categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $p<0.05$. The data was analyzed using IBM SPSS 22.0 version software and Microsoft Excel 2010.

RESULTS AND DISCUSSIONS

We compare demographic parameters between two groups, each with 30 participants. Age and weight were similar between Group I (39.73 years, 60.56 kg) and Group II (41.66 years, 60.03 kg), with no statistically significant differences ($p = 0.5254$, $p = 0.8343$, respectively). Gender distribution also showed no significant difference, with Group I having 16 males (53.33%) and 14 females (46.66%) and Group II having 17 males (56.66%) and 13 females (43.33%) ($p = 0.7957$). ASA grade distribution was comparable, with Group I having 17 Grade I (56.66%), 9 Grade II (30%) and 4 Grade III (13.33%) and Group II having 18 Grade I (60%), 10 Grade II (33.33%) and 2 Grade III (6.66%) participants, with no significant difference between the groups ($p = 0.6879$) (Table 1). Table 2 compares sensory and motor characteristics of Brachial Plexus Blockade between Group I ($n = 30$) and Group II ($n = 30$). Group I showed significantly faster onset and longer duration of sensory block (8.73 vs. 22.4 minutes, 417.5 vs. 239.33 minutes, respectively, both $p<0.0001$) and motor block (11.63 vs. 26.73 minutes, 392.33 vs. 217.33 mins, respectively, both $p<0.0001$) compared to Group II. On comparison, group I (potassium group)

produced statistically significant prolonged duration of effective post-op analgesia as compared to group II (plain bupivacaine group) (p<0.0001) (Table 3, Fig. 1).Changes in the heart rate were comparable in both the groups- group I (potassium group) and group II (plain bupivacaine group), without any statistical significance (p >0.05) (Table 4, Fig.2). Changes in the Mean Arterial Blood Pressure were comparable in both the groups- group I (potassium group) and group II (plain bupivacaine group), without any statistical significance (p >0.05) (Table 5, Fig. 3). Changes in the respiratory rate were comparable in both the groups- group I(potassium group) and group II(plain bupivacaine group), without any statistical significance (p >0.05)

In the current study, a comparison of age and weight distribution between the groups revealed mean and standard deviation values of age (39.73±12.81 years vs. 41.66±10.47 years) and weight (60.56±10.02 kg vs. 60.03±9.51 kg) for both groups, respectively, which were not statistically significant (p>0.05). Similar observations were made by Swetha *et al*.[9], who found comparable demographic parameters (age: 41.03±10.30 years vs. 38±10.39 yrs; weight: 56.37±4.47 kg vs. 58.27±6.61 kg) in both groups, with no statistical significance (p>0.05). These findings align with those of studies by Shreedhar *et al* [10], Shivani *et al*.[11] and Kumar *et al*.[12]. In this study, the onset of sensory blockade was 8.73±2.50 min in group I (KCL group) and 22.4±3.69 min in group II (control group), which was statistically significant (p<0.0001). Group I exhibited a faster onset of sensory block compared to the control group. This finding is consistent with a study by Swetha *et al*[9], where the onset of sensory blockade was 10.43 min vs. 26.33 min in group I (KCL group) and group II (control group), respectively, which was also statistically significant (p<0.0001). Similar results were observed by Shreedhar *et al*.[10], Kumar *et al*.[12] and Shivani *et al*.[11]. In the current study, the onset of motor blockade was determined to be 11.63±2.51 min in group I (KCL group) and 26.73±3.61 min in group II (control group), which was statistically significant (p<0.0001). Group I exhibited a faster onset of motor block compared to the control group. This finding is consistent with a study by Swetha *et al*.[9], where the onset of motor blockade was 9.46 min vs. 23.93 min in group I (KCL group) and group II (control group), respectively, which was also statistically significant (p<0.0001). Similar results were observed in studies by Shreedhar *et al*.[10], Kumar *et al*.[12] and Shivani *et al*.[11].

In this study, the duration of sensory blockade was found to be 417.5±17.30 min in group I and 239.33±21.64 min in group II, which was statistically significant (p<0.0001). This indicates that the duration of sensory block was prolonged in group I. This finding aligns with a study by Swetha *et al*.[9], where they also observed a prolonged duration of sensory blockade of 467.67 min vs. 205.67 min in group I and group II, respectively, which was statistically significant (p<0.0001). Similar results were reported in studies by Shreedhar *et al*.[10], Kumar *et al*[12] and Shivani *et al*.[11].

In this study, the duration of motor blockade was observed to be 392.33±20.75 min in group I and 217.33±21.48 min in group II, which was statistically significant (p<0.0001). Group I exhibited a prolonged duration of motor block compared to group II. This finding is consistent with a study by Swetha *et al*.[9], where they also observed a prolonged duration of motor blockade of 477.67 min vs. 215.67 min in group I and group II, respectively, which was statistically significant (p<0.0001). Similar results were reported in studies by Shreedhar *et al*.[10], Kumar *et al*[12] and Shivani *et al*.[11].

In this study, the mean duration of effective postoperative analgesia in group I (KCL group) was 438±20.53 min, whereas it was 272±28.81 min in group II (control group), showing a statistically significant difference (p<0.0001). Group I exhibited a longer duration of motor block compared to group II. The time to first rescue analgesic for most patients was between 7-8 hours in group I and 4-5 hours in group II. These findings are consistent with a study by Neeraj Solanki *et al*[13], where the duration of effective analgesia was 512.04±28.8 min in group I (KCL group) and 240.9±19.42 min in group II (control group), also showing a statistically significant difference (p<0.0001). The time to first rescue analgesic for most patients was between 8-9 hours in group I and 4-5 hours in group II. In this study, the changes in heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, respiratory rate and SPO2 were assessed at various time points (1, 5, 10, 20, 30 mins, then at two-hour intervals up to four hours and finally at four-hour intervals for 24 hours) in both groups. The results showed no statistically significant differences between the groups, indicating that the changes in these parameters were comparable. This finding is consistent with other studies by Swetha *et al*.[9], Shreedhar *et al*.[10] and Kumar *et al*.[12], which also reported non-significant changes in heart rate, mean arterial pressure, respiratory rate and SPO2 at various time points after surgery.

In this study, no serious complications such as pneumothorax, dyspnea, neurological issues like convulsions or nerve injuries were observed in either group. This finding is consistent with a study by Shreedhar *et al*[10], which evaluated the use of

Table 1: Demographic parameters

Parameters		Group-I (n = 30)	Group-II (n = 30)	p-value
Mean Age (yrs)		39.73±12.81	41.66±10.47	0.5254
Gender	Male	16 (53.33%)	17 (56.66%)	0.7957
	Female	14 (46.66%)	13 (43.33%)	
Weight (Kg)		60.56±10.02	60.03±9.51	0.8343
ASA Grade	Grade-I	17 (56.66%)	18 (60.00%)	0.6879
	Grade-II	09 (30%)	10 (33.33%)	
	Grade-III	04 (13.33%)	02 (6.66%)	

Table 2: Sensory and motor characteristics of Brachial Plexus Blockade

Parameters		Group-I (n = 30)	Group-II (n = 30)	p-value
Sensory Characteristics	Onset (Minutes)	8.73± 2.50	22.4 ± 3.69	<0.0001
	Duration (Minutes)	417.5 ± 17.30	239.33 ± 21.64	<0.0001
Motor Characteristics	Onset (Minutes)	11.63± 2.51	26.73 ± 3.61	<0.0001
	Duration (Minutes)	392.33 ± 20.75	217.33 ± 21.48	<0.0001

Table 3: Duration of effective post-op analgesia.

	Group-I (n = 30)	Group-II (n = 30)	p-value
Effective analgesia (Mins)	438 ± 20.53	272 ± 28.81	<0.0001

Table 4: Mean Heart Rate Changes

Time	Group I (mean ± SD)	Group II (mean ± SD)	Intergroup p-value
Baseline	86.2 ± 9.02	84 ± 8.03	0.32
1min	86.2 ±6.48	84.3 ±6.9	0.28
5min	87.06 ± 7.96	85.46 ± 7.86	0.43
10min	86.06 ± 7.95	85.35 ± 7.00	0.58
20min	87.2 ± 9.04	85.2 ± 6.94	0.34
30min	86.28 ± 8.65	85.46 ± 8.13	0.73
2hr	86.53 ± 7.66	85.83 ± 6.93	0.71
4hr	86.6 ± 7.26	84.6 ± 7.19	0.238
6hr	87.73± 7.36	84.46 ± 8.83	0.55
8hr	86.8 ± 8.25	87.13 ± 7.85	0.87
12hr	87 ± 7.46	86.33 ± 7.81	0.73
16hr	88.27 ± 6.34	86.8 ± 7.29	0.41
20hr	86.87 ± 6.09	86.73 ± 6.64	0.93
24hr	87.06 ± 6.47	86.26 ± 8.08	0.67

Table 6: Mean Arterial Blood Pressure Changes

Time	Group I (mean ± SD)	Group II (mean ± SD)	Intergroup p-value
Baseline	92.23 ± 9.39	90.46 ± 8.69	0.45
1min	91.63 ± 9.02	89 ± 6.82	0.207
5min	91.77 ± 8.23	89 ± 7.04	0.16
10min	90.83 ± 8.1	89.3 ± 8.43	0.47
20min	90.76 ± 7.80	89.36 ± 8.31	0.50
30min	90.6 ± 7.92	88.93 ± 7.07	0.39
2hr	90.56 ± 3.03	88.43 ± 2.76	0.24
4hr	91.2 ± 7.26	90.2 ± 7.01	0.62
6hr	90.9± 7.39	88.36 ± 7.83	0.202
8hr	90.73 ± 7.14	89.36 ± 7.26	0.46
12hr	90.43 ± 6.82	89.43 ± 7.50	0.59
16hr	90.3 ± 7.19	89.03 ± 6.80	0.48
20hr	90.23 ± 7.61	88.27 ± 6.36	0.28
24hr	89.53 ± 6.60	88.9 ± 6.80	0.71

Table 7: Mean Respiratory Rate Changes

Time	Group I (mean ± SD)	Group II (mean ± SD)	Intergroup p-value
Baseline	15.6 ± 1.22	14.2 ± 1.518	0.09
1min	14.06 ±1.23	14.13 ±1.16	0.83
5min	14.06 ± 1.43	14.6 ± 1.5	0.16
10min	13.8 ± 0.8	14.33 ± 1.49	0.09
20min	13.67 ± 1.06	14.33 ± 1.49	0.003
30min	14.06 ± 1.78	13.93 ± 1.11	0.73
2hr	13.67 ± 1.66	13.53 ± 1.13	0.71
4hr	13.73 ± 1.14	13.67 ± 1.06	0.81
6hr	13.86± 1.04	14.26 ± 1.28	0.18
8hr	13.67 ± 1.4	14 ± 1.4	0.36
12hr	14 ± 1.05	14.06 ± 1.11	0.81
16hr	13.67 ± 0.92	13.93 ± 0.82	0.24
20hr	13.8 ± 1.21	14.13 ± 1.38	0.32
24hr	13.73 ± 1.25	13.93 ± 1.11	0.51

potassium chloride as an adjuvant to bupivacaine in brachial plexus block and found no complications such as nausea, vomiting, pneumothorax. Although ultrasonography is considered the ideal technique for localizing the brachial plexus, we used a nerve locator due to the unavailability of ultrasonography equipment in the departmen. The use of a nerve locator is preferred over the blind approach as it allows

for the deposition of the drug solution in close proximity to the neurons, which is essential for studying the drug's effects. In our study, the initial stimulus for advancing the needle was set at 0.5 milliamperes. This current was gradually decreased in 0.02 milliampere decrements while advancing the needle further, until we achieved maximum muscle contraction with minimal current. This technique ensures that the needle tip is in close proximity to the brachial plexus trunks, maximizing the chances of satisfactory blocks. We determined that 0.5 milliamperes is a safe level to start with and there is no benefit to increasing the current beyond this point. Higher currents are not advantageous and can cause discomfort and pain to the patient.

CONCLUSION

In conclusion, the use of 0.375% Bupivacaine with potassium chloride 0.2mmol as an adjuvant in supra clavicular brachial plexus block significantly shortens the onset of both sensory and motor blockades, prolongs the duration of sensory and motor blockade and extends the duration of effective postoperative analgesia. Importantly, no complications or side effects were observed, suggesting that this approach can be safely used in both routine and emergency upper limb surgeries.

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