A Prospective Randomised Controlled Double-Blinded Comparative Study of Plain Bupivacaine versus Bupivacaine and Dexamethasone for Supraclavicular Brachial Plexus Block, Government General Hospital, Nizamabad

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ABSTRACT

BACKGROUND

Dexamethasone (DES) is a very potent anti-inflammatory and analgesic glucocorticoid with very strong activity. The current study is randomised to determine the onset time, duration, and analgesic potency of bupivacaine (BUC) 0.5 percent, relative to BUC 0.5 percent and DES 8 mg by supraclavicular approach for brachial plexus block.

METHODS

In patients posted for upper limb surgery under a supraclavicular block, a prospective, randomised, double-blinded study was conducted. 60 Class I and II American Society of Anesthesiologists (ASA) patients were randomly divided into two classes. Group A received 0.5 percent of 30 ml BUS and group B received 0.5 percent of 28 ml BUS and 8 mg of 2 ml DES combined. For a single shot blockade of the supraclavicular brachial plexus, 30 ml of a solution was required.

RESULTS

The mean age of patients who received BUS was 36.9 ± 10.4 years and those who received BUS + DES was 34.7 ± 7.1 years (P = 0.328), there was no statistically significant difference between the mean ages of two groups (P > 0.05). The mean time of onset of sensory block in the BUS group was 8.6 ± 1.2 minutes and 5.6 ± 0.7 minutes in the BUS + DES group. There was a statistically significant difference between the onset of motor block in minutes among BUS and BUS + DES groups, there was a statistically significant difference between the mean ages of the two groups (P < 0.001). There was no statistically meaningful difference between the BUS and BUS + DES classes at various time intervals in the mean heart rate, difference in systolic blood pressure and diastolic blood pressure, and oxygen saturation.

CONCLUSIONS

The start of sensory and motor blockade also prolongs the length of DES 8 mg to BUS 0.5 percent speeds, thereby supplying improved analgesia and reducing the rescue analgesic requirements.

KEYWORDS

Bupivacaine, Dexamethasone, Brachial Plexus, Supraclavicular, Sensory Block

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BACKGROUND

For upper limb surgery, brachial plexus blocks offer a valuable alternative to general anaesthesia.[1] By achieving full muscle relaxation, preserving a healthy intraoperative hemodynamic state, and sympathetic block, which decrease postoperative pain, vasospasm, and oedema,[2,3] they attain near-optimal operating conditions.

Bupivacaine is one of the most widely available local anaesthetics, as it ranges from 3 to 8 hours with a prolonged time of operation.[4] It has constraining variables, however, such as delayed onset, patchy or imperfect analgesia. Many medications have been applied to local anaesthetics to reduce these disadvantages, such as dexamethasone, neostigmine,[5] opioids, hyaluronidase, midazolam, clonidine,[6] etc., to enhance the efficiency and length of operation and postoperative analgesia.[7]

Dexamethasone is a glucocorticoid that is very active and extremely selective. It is used mainly as an anti-inflammatory and immunosuppressant. Its power is about 40 times that of hydrocortisone.[8] DES is clinically used to treat certain inflammatory and allergic disorders, but glucocorticoids are also used to treat people with neuropathic pain and complicated regional pain syndromes (CRPS). So, steroids have anti-inflammatory as well as analgesic effects.[9] Many studies have successfully proved the usefulness of DES as an effective analgesic.[10]

The current study is randomised to determine the onset time, duration, and analgesic potency of BUC 0.5 percent, relative to BUC 0.5 percent, and DES 8 mg by supraclavicular approach for brachial plexus block.

METHODS

A prospective, randomised, double-blinded study was conducted following ratification by the internal ethics committee (ECR / 951 / Inst / TG / 2017) and in writing (ECR / 951 / Inst / TG / 2017) in the Department of Anaesthesiology, General Government Hospital, Nizamabad. Research duration was from September 2017 to November 2018. American Society of Anaesthesiologists grade I and II patients between the age range of 18 and 65 years and those undertaking elective upper-limb surgery were the inclusion criterion for our research (i.e. elbow, forearm and hand).[11]

Patients with ASA grade III and IV, bleeding disorders, respiratory compromise, known allergies to local anaesthetics and those with infections at the site of block or documented neuromuscular disorders were excluded from the study.

Sample Size (n)

The sample size was estimated from the data available from previous research, using a formula based on mean and standard deviation, as follows:

$$d = (\mu^2 - \mu^1)/\sigma$$

$$n \geq \left(\frac{1+\mathrm{r}}{r}\right) + \frac{\left(---Z_{1\text{-}\alpha/2} + Z_{1\text{-}\beta}\right)^2}{d^2} + \frac{Z^2{}_{1\text{-}\alpha/2}}{2(1+r)}$$

Where $z_{1\text{-}\alpha}$ is linked with the level of significance and $z_{1\text{-}\beta}$ is linked with the power of the test, d is half-length of confidence interval d = 0.96; alpha error of 5 %; 95 % confidence interval. A beta error of 10 %; power of 90 %. The ratio of cases in each group = 1. Substituting the above values in the formula we obtained a minimum sample of 24 patients in each group.

Thus, using the thumb rule for the minimum sample size for a randomised controlled trial (RCT), i.e., 30 patients in each group, the total sample size was taken as 60. Patients were randomised with the help of computer randomisation to one of the two groups. Group A received intrathecally 30 ml of 0.5 % BUC and group B received intrathecally 28 ml of 0.5 % BUC + 8 mg (2 ml) of DES.

Once the patient fulfilled the inclusion criteria, history, clinical examination, and informed consent were taken from the patient. Every patient was subjected to routine investigations like complete haemogram, ribosome-binding site (RBS), chest x-ray, and electrocardiography (ECG).

The anaesthesiologist involved in the data collection as well as the patient was blinded to the content of the study solution.

Upon arrival in the operation area, the intravenous line was secured by an 18- or 20-gauge cannula and an injection of Ringer's lactate was started. During the perioperative time, patients were checked for heart rate (HR), non-invasive systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP), continuous electrocardiographic (ECG), and oxygen saturation (SpO2) measurements. The patient was put in a propped-up location of 30 with the face bent to the opposite side and the ipsilateral upper arm positioned by the patient.[12]

Under strict aseptic precautions, the area between the mandible and the ipsilateral nipple was painted and draped. The carotid artery was palpated, and a skin wheal was raised by injecting 2 ml of lidocaine 2 %.

Under ultrasound guidance, a 23G spinal needle was used to localise the brachial plexus which is present posterolateral to the brachial plexus. A 23G spinal needle was inserted from the right side of the probe for the right-side shoulder and vice versa. Aspiration was done for checking the absence of blood. The spinal needle was inserted into the nerve sheath and the drug was injected under ultrasonological view. The infused volume gently extends the connective tissue, which is called hydrodissection, circling the nerves. This makes a direct direction for the needle.[12]

Sensory block was assessed by pinprick test using a 3-point scale as a 0 = sharp pin felt; 1 = dull sensation felt (analgesia); 2 = no sensation felt (anaesthesia).[13]

Motor block was tested on a 3-point scale for motor function by thumb abduction (radial nerve), thumb adduction (ulnar nerve), thumb opposition (median nerve), and elbow flexion (musculocutaneous nerve), which is defined as 0 = regular motor function with a complete elbow, wrist and finger flexion and extension; 1 = reduced motor

strength but able to move fingers; 2 = full motor block function.[14]

The sensory and motor blocks were tested every 3 minutes until 30 minutes after injection, and again every 30 minutes after surgery until they were done. The time of onset was described as the interval between the end of the final administration of local anesthetic and the full sensory block. Total sensory block in all nerve regions was characterised by anesthetic block (score 2). The period between the end of local anesthetic administration and the full resolution of the effect of anaesthesia on all nerves was defined as the length of the sensory block.

The onset of the motor block was described as the time between local anesthetic solution administrations for lack of motion. The absence of voluntary movements in the hand and forearm was described as the full engine block (score 0). The length of the motor block was described as the time between the end of local anesthetic administration and the recovery of the hand and forearm's full motor control. At 0, 5, 10, 15, 30, 45, 60, 90, 120 min and 6, 12, 24 hours, heart rate, systolic arterial BP, and diastolic arterial BP were registered. Adverse events such as hypotension have been described as a 20 percent reduction in systolic BP from baseline values. To ensure the block was blinded by the anaesthetist, research medicine was prepared by an individual who was not interested in inpatient treatment or supervision. A single reviewer, who was also blinded to the drugs administered, performed all findings. The examined patients and anaesthesiologists were unsure of the drugs used in the study. All the parameters were reported and statistically analysed.

Statistical Analysis

The average ± SD was reflected by the quantitative figures. It was a percentage reflecting categorical and nominal data. The observations reported in both classes was tabulated, and the student t-test, unpaired for intergroup comparison. Chi-square test used to conduct statistical analysis of demographic data and group comparison. To be statistically relevant, P of < 0.05 was taken. With SPSS v 18, all the statistical research was carried out.

RESULTS

About 60 patients of ASA I and II posted for upper limb surgeries were enrolled in this study as study subjects. They were arbitrarily divided into two equal groups where the first group received 30 ml of 0.5 % BUC (Group A) and the second group received 28 ml of a mixture of 0.5 % BUC with DES (8 mg) 2 ml (Group B) by supraclavicular approach.

The mean comparison of sensory block parameters between study groups are shown in Table 1.

The mean age of patients receiving BUC was 36.9 ± 10.4 years and the mean age of patients receiving BUC + DES was 34.7 ± 7.1 years (P = 0.328), with no statistically meaningful difference between the two-groups (P > 0.05). Around 43.3 percent of group 1 patients and 70.0 percent of group 2 patients were in the 31 - 40 age group. The groups were equal in age, as the age groups were identical.

In the BUC + DES group, the meantime of sensory block onset was 8.6 ± 1.2 minutes and 5.6 ± 0.7 minutes. This discrepancy between the two classes was statistically important in the onset of the sensory block (P = 0.001).

In this analysis, the meantime of motor block onset was 16.7 ± 2.1 minutes in the BUC group and the meantime of motor block onset in the BUC + DES group was 10.3 ± 1.4 minutes. There was a statistically important discrepancy between the minute onset of the motor block and the groups of BUC and BUC + DES; the mean difference between the two groups was statistically significant (P = 0.001).

The mean duration of sensory block in the BUC group was 4.00 ± 6.3 hours and in the BUC + DES group was 5.9 ± 0.7 hours. This difference was not statistically significant between the BUC and BUC + DES groups, there was no statistically significant difference between the mean ages of the two groups (P > 0.05).

In the BUC group, the mean motor block length was 1.9 ± 0.5 hours and the mean motor block period in the BUC + DES group was 4.3 ± 0.9 hours. Differences in motor block length between the BUC and BUC + DES groups were statistically important.

The distribution of study groups in the number of rescue analgesic doses in 24 hours; patients of the BUC group had received 2.5 ± 0.5 doses and patients of the BUC + DES group received 1.3 ± 0.4 mean doses of rescue analgesic. The difference in receiving the mean doses of rescue analgesia was statistically significant between the BUC and BUC + DES groups.

Variables (Mean ± SD)	Group-A (N = 30)	Group-B (N = 30)	P-Value
Onset of sensory block in mins	8.6 ± 1.2	5.6 ± 0.7	< 0.001**
Onset of motor block in mins	16.7 ± 2.1	10.3 ± 1.4	< 0.001**
Duration of sensory block in hours	4.0 ± 6.3	5.9 ± 0.7	> 0.05ns
Duration of motor block in hours	1.9 ± 0.5	4.3 ± 0.9	< 0.001**
No. of RA in 24 hours	2.5 ± 0.5	1.3 ± 0.4	< 0.001**

Table 1. Mean Comparison of Sensory Block Parameters between the Study Groups

*P < 0.05 was considered statistically significant; **P < 0.001 was highly significant; NSP = not significant

In the BUC community, the mean heart rate was about 76 to 78 beats per minute. The mean heart rhythm was about 78 to 79 beats per minute in the BUC + DES community (Table 2). In the heart rate classes at various periods, there was no statistically meaningful difference between BUC and BUC + DES.

Pulse	Group-A (N = 30) (Mean ± SD)	Group-B (N = 30) (Mean ± SD)	P-Value
0 min	77.3 ± 6.4	79.7 ± 6.4	0.151ns
5 min	77.2 ± 5.7	79.3 ± 6.1	0.168ns
15 min	77.3 ± 6.0	79.3 ± 5.8	0.211ns
30 min	77.1 ± 6.0	79.1 ± 5.7	0.206ns
60 min	76.6 ± 6.1	79.5 ± 5.4	0.055ns
2 hours	77.7 ± 5.9	78.7 ± 6.3	0.527ns
6 hours	78.0 ± 6.1	78.6 ± 6.5	0.714ns
12 hours	77.8 ± 5.4	78.3 ± 6.6	0.766ns
24 hours	78.3 ± 5.8	79.3 ± 6.5	0.505ns

Table 2. Pulse Rate at Different Time Intervals between the Study Groups

*P < 0.05 was considered statistically significant; **P < 0.001 was highly significant; NSP = not significant

The mean systolic blood pressure in the population of BUC ranged from 114.1 ± 8.8 mm Hg to 115.2 ± 9.4 mm Hg. The mean systolic blood pressure ranged from 119.3 ± 12.8 mm Hg to 120.9 ± 13.1 mm Hg in the BUC + DES group at various periods (Table 3). The disparity in systolic blood pressure at various periods between the groups of BUC and BUC + DES was not statistically important at baseline, although there was a significant difference in systolic blood pressure between the two groups after 2 h to 24 h.

SBP	Group-A (N = 30) (Mean ± SD)	Group-B (N = 30) (Mean ± SD)	P-Value
0 min	114.9 ± 9.3	119.9 ± 12.8	0.093 ^{ns}
5 min	114.8 ± 8.7	119.3 ± 12.7	0.112 ^{ns}
15 min	115.1 ± 9.0	119.6 ± 12.8	0.118 ^{ns}
30 min	115.2 ± 9.4	119.9 ± 12.9	0.115 ^{ns}
60 min	115.1 ± 8.0	120.4 ± 12.7	0.056 ^{ns}
2 hours	114.1 ± 8.8	120.1 ± 12.5	0.036*
6 hours	114.4 ± 8.8	120.4 ± 13.2	0.043*
12 hours	114.5 ± 8.9	120.9 ± 13.1	0.035*
24 hours	114.3 ± 9.1	121.6 ± 13.0	0.014*

Table 3. Systolic Blood Pressure at Different Time Intervals between the Treatment Groups

*P < 0.05 was considered statistically significant; **P < 0.001 was highly significant; ^{ns}p = not significant

The mean diastolic pressure in the group of BUC ranged from 75.7 ± 6.5 mm Hg to 76.9 ± 6.6 mm Hg. In the BUC + DES group, it ranged from 77.5 ± 7.3 mm Hg to 78.7 ± 7.6 at various periods (Table 4). Diastolic blood pressure variations between the BUC and BUC + DES classes at various time ranges were not statistically important.

DBP	Group-A (N = 30) (Mean ± SD)	Group-B (N = 30) (Mean ± SD)	P-Value
0 min	76.3 ± 7.4	77.7 ± 7.3	0.465 ^{ns}
5 min	76.1 ± 6.8	78.0 ± 7.1	0.302 ^{ns}
15 min	75.7 ± 6.4	78.4 ± 7.0	0.119 ^{ns}
30 min	76.9 ± 6.5	78.7 ± 7.4	0.34 ns
60 min	75.8 ± 6.3	78.3 ± 7.5	0.174 ^{ns}
2 hours	76.7 ± 6.0	77.9 ± 7.9	0.536 ^{ns}
6 hours	76.5 ± 6.7	77.6 ± 7.9	0.573 ^{ns}
12 hours	75.5 ± 5.9	77.5 ± 7.2	0.261 ^{ns}
24 hours	75.9 ± 6.1	77.5 ± 6.9	0.365 ^{ns}

Table 4. Diastolic Blood Pressure at Different Time Intervals between the Treatment Groups

*P < 0.05 was considered statistically significant; **P < 0.001 was highly significant; ^{ns}p = not significant

Oxygen Saturation	Group-A (N = 30) (Mean ± SD)	Group-B (N = 30) (Mean ± SD)	P-Value
0 min	98.7 ± 0.5	98.7 ± 0.5	1.0 ns
5 min	99.0 ± 0.0	98.5 ± 0.5	0.001 **
15 min	98.4 ± 0.5	98.3 ± 0.5	0.599 ^{ns}
30 min	98.3 ± 0.7	98.5 ±0.5	0.407 ^{ns}
60 min	98.3 ± 0.5	98.7 ± 0.5	0.002*
2 hours	98.5 ± 0.5	98.7 ± 0.5	0.122 ^{ns}
6 hours	98.9 ± 0.3	98.6 ± 0.5	0.019*
12 hours	98.7 ± 0.5	98.7 ± 0.5	0.581 ^{ns}
24 hours	98.8 ± 0.4	98.5 ± 0.5	0.007 *

Table 5. Oxygen Saturation at Different Time Intervals in the Study Groups

*P < 0.05 was considered statistically significant; **P < 0.001 was highly significant; ^{ns}p = not significant

Table 5 shows the oxygen saturation at dissimilar time intervals in BUC and BUC + DES group. The oxygen saturation was ranging from 98.3 ± 0.5 percent to 99.0 percent in the BUC group and it was ranging from 98.3 ± 0.5 percent to 98.7 ± 0.5 percent in BUC + DES groups. The difference between the oxygen saturation was not statistically significant between BUC and BUC + DES groups in most of the time intervals except at 5 mins, 60 mins, 6 hours and 24 hours after injection of the anaesthetic.

DISCUSSION

The brachial plexus block has emerged as a common technique for upper limb surgery among anaesthesiologists. This form of anaesthesia, such as complications linked to upper airway instrumentation, prevents the untoward effects of general anaesthesia. The research has also shown that this approach is attractive and effective in terms of cost, performance, a margin of safety and also provides good postoperative analgesia.[15] Several brachial plexus block methods are also identified, and the available literature has demonstrated that supraclavicular block is the safest and simplest anaesthesia and post-operative pain relief technique.

Several drugs have been tried as anaesthetics in brachial plexus block and BUC was consistently used for its longer duration of action. However, the BUC is condemned for its delayed onset, patchy or incomplete analgesia. Many drugs are in turn used to treat the side effects of BUC also make the drug more effective for surgery and postoperative analgesia.

DES, being glucocorticoid, has emerged as a potent corticosteroid when used along with BUC.[16] Many studies have successfully proved the usefulness of DES as an effective analgesic. However, the studies are scant to evaluate the efficacy of BUC alone and when used in combination with corticosteroids like DES.

Hence, this study was undertaken in this part of the country to evaluate the efficacy of it. The mean age of the recorded patients was 36.9 years for BUC and 34.7 years for BUC + DES. The age gap between the two groups is not statistically important. Therefore, the two classes were close in terms of age. Most of the patients in this study belonged to 31 - 40 years in both groups. In a study by Shrestha et al.[17,18] the mean age was 25.5 ± 12.02 years in the local anesthetic group and 28.05 ± 16.1 in the DES group. In a related survey, the mean age was 33.8 years in the local anesthetic group and 30.3 years in the DES group, contrary to the results of this study.

In comparison with the BUC + DES group, the meantime of sensory block onset was later in the BUC group. The mean time of motor block onset in this study was also lower in the DES group than in the local anesthetic group. This dissimilarity was also statistically significant between the two groups. In a study by Shreshtha et al.[17,18] the mean onset of action was 18.15 ± 4.25 minutes while it was 14.5 ± 2.1. However, the mean onset of sensory anaesthesia was slightly lesser in this study, contrary to the findings of Shreshtha et al. In another study, Yadav et al.[19] compared three different drugs by supraclavicular brachial plexus block. However, the onset of anaesthesia in the DES group was faster than the other two groups of drugs. In a study by Islam et al. the onset of sensory blocks was also lesser in the DES group than in the plain local anesthetic group.

The mean sensory block length in the BUC and BUC + DES classes was 4 ± 6.3 hours and 5.9 ± 0.7 hours,

respectively. The mean motor block length was 1.9 ± 0.5 hours in the BUC group and 4.3 ± 0.9 hours in the BUC + DES group. There was a statistically important difference in the period of operation between the BUC and BUC + DES groups. Similar finds found that the duration of action of the local anesthetic was 3.16 hours in the local anesthetic group and 12.75 hours in the steroid group[5]. In a study by Shreshtha et al.[17,18] the mean duration of postoperative analgesia was around 16 hours in a group who received BUC with DES and it was around 8 hours in BUC – tramadol group. This shows that the addition of steroids certainly prolongs the duration of anaesthesia and also produces earlier onset of action. This might be the due anti-inflammatory effect of DES. It has also been proved in many studies that the addition of DES to local anesthetic prolongs the duration of action. However, another study also noted that the mean duration of analgesia was more in the DES group than the plain anesthetic group.

The mean number of rescue analgesic doses in the DES group was slightly smaller than in the BUC group alone. In the Yadav et al.[19] reports, the mean number of rescue analgesic doses in the DES group was also smaller than for the other two groups.

The mean heart rate in the BUC group was around slightly higher in the DES group than the local anesthetic group. The pulse patterns of the DES group did not vary statistically substantially from those of the local anesthetic group. But it was within normal limits. The mean systolic and diastolic pressure was also almost similar in both the groups within normal limits. The mean oxygen saturation did not differ much in both groups. In summary, the haemodynamic responses are crucial in the maintenance of patients during anaesthesia. However, the BUC has already proved its safety, especially when used as a local anesthetic in supraclavicular brachial plexus block. Since the hemodynamic responses were similar, the study concludes that the BUC + DES combination was also safer to use in supraclavicular brachial plexus block. The adverse effects were not reported in both the groups in this study.

This research found that the addition of 4 - 8 mg of DES prolongs the length of analgesia successfully and substantially by inducing an early onset of action as well. This research has also demonstrated that the early onset of activity in the steroid community can be due to local anesthetic synergistic action on nerve fiber blockage. The prolongation of the duration of the block is the local effect of the steroid than the systemic action. The effects are mainly mediated by glucocorticoid receptors. The blockade is not produced by the action of steroids alone. Hence it should be used in addition to a local anesthetic.

CONCLUSIONS

The brachial plexus block supraclavicular method has become a common anaesthesia delivery technique in patients undergoing upper limb surgery. Elegance of the procedure allows anaesthesia to be administered safely and thus, guarantees sustained analgesia while avoiding the side effects of general anaesthesia. Steroids are commonly used now a days along with local anaesthetics due to their anti-inflammatory and analgesic effects. DES being a potent corticosteroid is becoming popular for the regional blocks. This study has made an effort to compare the BUC alone with BUC + DES. But this study has shown the beneficial effect of the addition of steroid to a local anesthetic in terms of onset and duration of anaesthesia.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
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