Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v31i7.7089

"A COMPARATIVE STUDY BETWEEN 0.25% BUPIVACAINE AND 0.25% BUPIVACAINE WITH DEXAMETHASONE FOR ULTRASOUND-GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK IN UPPER LIMB SURGERIES IN INDIAN POPULATION FOR POST OPERATIVE PAIN RELIEF"

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Abstract-

Background- Brachial plexus blockade has proven a versatile regional anesthetic. It has been given in many ways using blind approach, or using a Peripheral nerve stimulator or under ultra sound guidance. Bupivacaine which has commonly been used has an advantage of being a Long-acting analgesic. Dexamethasone has been widely studied to have an effect on the action of local anesthetic by prolonging their action. Dexamethasone also acts by blocking pain signal transmission and nerve block prolonging effects.

Aim- A comparative study between 0.25% bupivacaine and 0.25% bupivacaine with dexamethasone for ultrasound guided supraclavicular brachial plexus block in upper limb surgeries in Indian population for postoperative pain relief.

Method and materials- this is a prospective randomized comparative study done in department of Anesthesiology, K.E.M. Hospital, Pune in 60 patients from February 2018 to November 2018. Participants will be recruited as patients undergoing upper limb surgery under Brachial Plexus Block Regional anaesthesia in General surgery and orthopedic surgery OT of KEM Hospital, Pune included this study. Informed consent was taken one day prior to surgery while doing pre-anesthetic evaluation from all patients. On the day of surgery all ASA standard monitors were attached which included pulse oximeter, Electrocardiogram, non-invasive blood pressure. An intravenous line appropriate for the surgical procedure was secured. Pre-operative baseline values of heart rate (HR) ,systolic and diastolic blood pressure (BP) and SpO2 were noted. Patients were the randomly assigned in two groups (30 each) using computer generated sequences. Group A- Patients receiving (30ml 0.25% bupivacaine + 2 ml of N/S) perineurally in the Brachial Plexus using supraclavicular approach. Group B - Patients receiving (30ml of 0.25% Bupivacaine+ 8mg (2ml) Dexamethasone) perineurally with same approach.

Result- The present study comprised of 60 ASA1, 2 patients. The mean ± SD of age of in Group A and Group B was 48.83 ± 18.74 years and 41.77 ± 12.85 years respectively. 30 cases studied in

Group A, 13 (43.3%) had Grade 1 ASA, 17 (56.7%) had Grade 2 ASA. Of 30 cases studied in Group B, 15 (50.0%) had Grade 1 ASA, 15 (50.0%) had Grade 2 ASA. (P-value>0.05). The mean ± SD of onset of sensory blockade in Group A and Group B was 22.90 ± 1.79 Mins and 19.85 ± 1.83 Mins respectively. The distribution of mean onset of motor blockade was significantly higher in Group A compared to Group B (P-value<0.001). The mean ± SD of time to rescue analgesia in Group A and Group B was 5.35 ± 1.38 Hrs and 10.58 ± 0.92 Hrs respectively. The minimum – maximum time range in Group A and Group B was 4 – 9 Hrs and 9 – 13 Hrs respectively. The distribution of mean time to rescue analgesia was significantly higher in Group B compared to Group A (P-vale<0.001).

CONCLUSION: It is seen in this study that Single shot Supraclavicular Brachial Plexus Block analgesia was of longer duration in Bupivacaine plus Dexamethasone group than plain Bupivacaine Group. There were statistically significant lower values of VAS PAIN score at various points in Bupivacaine plus Dexamethasone Group. The SBP, DBP and Heart Rate were Significantly on lower side in Bupivacaine with Dexamethasone group which was hemodynamically more stable. Intraoperative and postoperative bradycardia or hypotension was not observed in any group, Postoperative nausea /vomiting were not observed in any group. Hence Dexamethasone added to Bupivacaine for single shot Brachial Plexus Blockade was efficient in prolonging duration of analgesia compared to Bupivacaine only with minimum or no side effects.

Keywords- supraclavicular brachial plexus, bupivacaine,

INTRODUCTION

Increasing the duration of local anaesthetic action is often desirable as it prolongs the surgical anaesthesia and analgesia. A patients most dreaded fear is the pain of the surgery. And the second anxiety is that of receiving anaesthesia. Apart from general anaesthesia the best alternative that can be given the patient is with regional anaesthesia that is peripheral nerve blocks. Regional blocks even if used with general anaesthesia result in decreased requirement of anaesthetic and analgesic agents with less pain on awakening and respiratory depression post operatively. In outpatient surgery regional anaesthesia has always facilitated early mobilization both in general and orthopedic surgery patients. It is also advocated that it should always be considered in case of severe cardio respiratory diseases(5).

Brachial plexus blockade has proven a versatile regional anaesthetic. It has been given in many ways using blind approach, or using a Peripheral nerve stimulator or under ultra sound guidance. Ultrasound guided single shot has proven to be a safe and a reliable technique. It involves injecting local anaesthetic in the facial planes around the nerves thus blocking autonomic motor and sensory fibers (5).

Drugs in local anesthetics which have been commonly used for blocks are Lignocaine or Bupivacaine. These drugs have their own respective advantages and side effects. Bupivacaine which has commonly been used has an advantage of being a Long-acting analgesic. But it also has its own cardiotoxic side effects in case it is used beyond allowable limit. Challenge always remains to increase the duration of analgesia with decreasing the side effects (5)

To overcome this many adjuvants have been used recently to prolong the action of Bupivacaine so that the total dose as well as the concentration of bupivacaine used can be brought down. Many Adjuvants have been used including opioids such as Morphine Fentanyl, Tramadol, Buprenorphine, Sufentanyl and Calcium channel blockers (eg. Verapamil) and alpha agonists like clonidine and dexmedetomidine (13).

Many of them esp. opioids and dexmedetomidine are associated with side effects of sedation respiratory depression and psychomimetic effects

Steroids recently have been used as an adjuvant to LA in peripheral nerve block. Dexamethasone has been widely studied to have an effect on the action of local anesthetic by prolonging their action. Dexamethasone also acts by blocking pain signal transmission (14) and nerve block prolonging effects .It is not known to have any imminent effect on heart rate. It has powerful anti-inflammatory and analgesic property as well.
In our study we have intended to compare the clinical profile of 0.25 % bupivacaine and 0.25 bupivacaine+dexamethasone.

AIMS: -
A comparative study between 0.25% bupivacaine and 0.25% bupivacaine with dexamethasone for ultrasound guided supraclavicular brachial plexus block in upper limb surgeries in Indian population for postoperative pain relief.

OBJECTIVES OF THE STUDY:
Primary objective-
To evaluate the difference between the duration of action on postoperative analgesia using Dexamethasone as an additive in one group as compared to plain 0.25% bupivacaine in the other group.

Secondary objective-
To evaluate
1. Requirement of other modalities of Analgesia
2. Analgesia satisfaction
3. Sedation
4. Nausea
5. Pruritis
6. Postoperative hemodynamic changes
7. Watch for Hematomas, Organ Injuries, Infection
8. Hypersensitivity reaction for the study drug.

The Brachial plexus is formed by the union of the anterior primary divisions (Ventral rami) of the fifth through the eighth cervical nerves and the first thoracic nerve. Contribution from C4 and T2 are often minor or absent. The Brachial plexus is ensheathed by the prevertebral fascia and lies above the subclavian artery, close to the first rib.

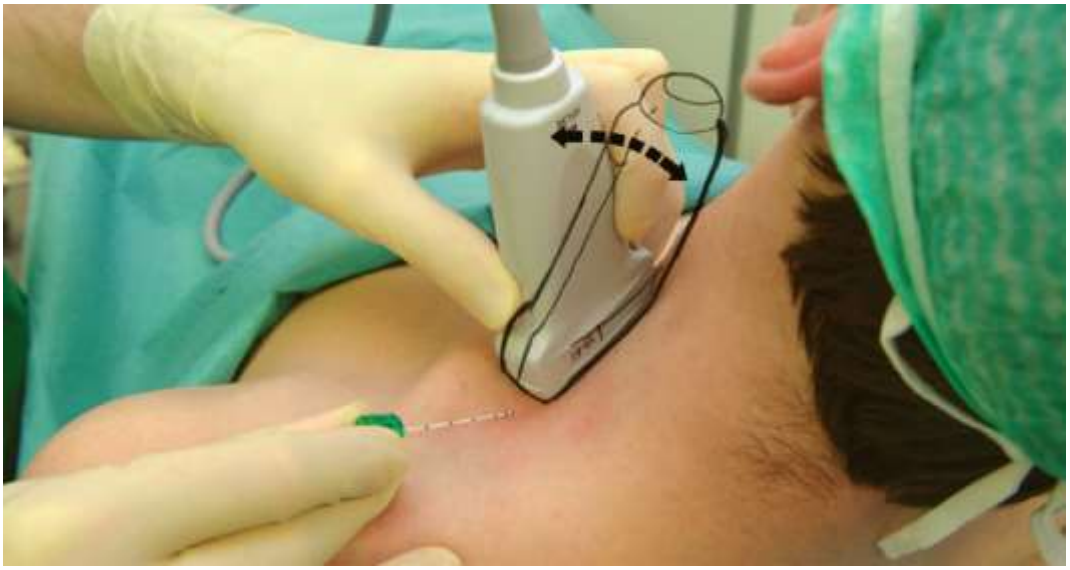


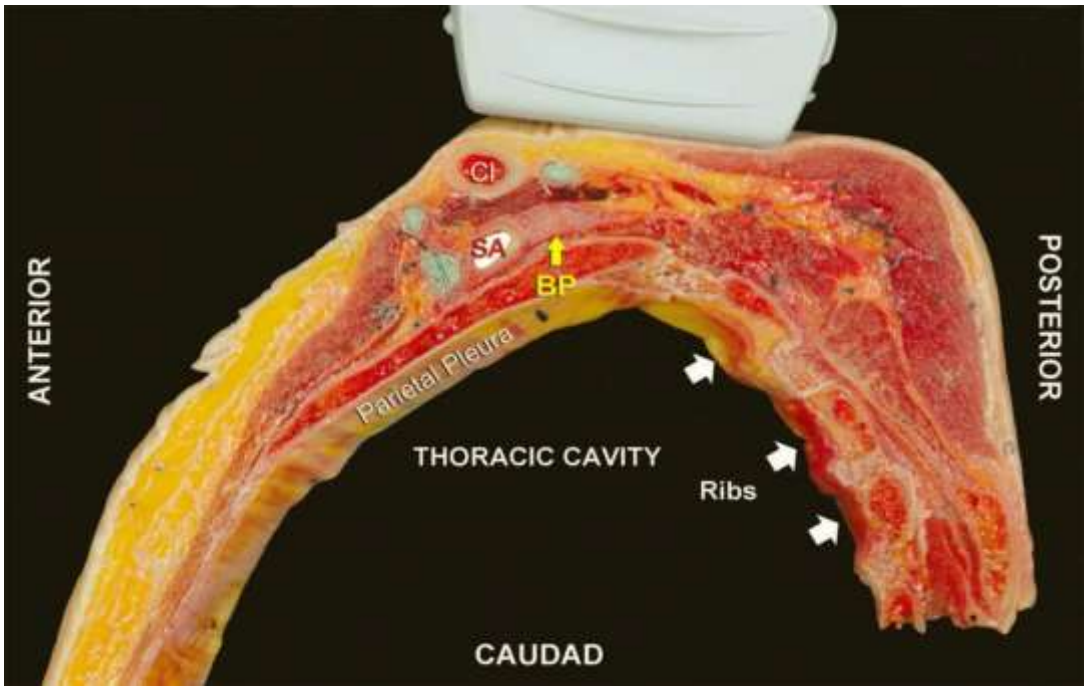
Figure showing Placement of probe in relation to the patient's anatomy.

Several techniques for blocking the Brachial plexus have been described: interscalene, supraclavicular, infraclavicular, axillary and blocking the specific terminal nerves. The anatomy of interest for supraclavicular block is the relationship between brachial plexus and the first rib, subclavian artery and cupola of the lung. As the subclavian artery and brachial plexus pass over the first rib, they do so between the insertion of the anterior and middle scalene muscles on to the first rib. The nerves lie in a cephalon-posterior relationship to the artery.

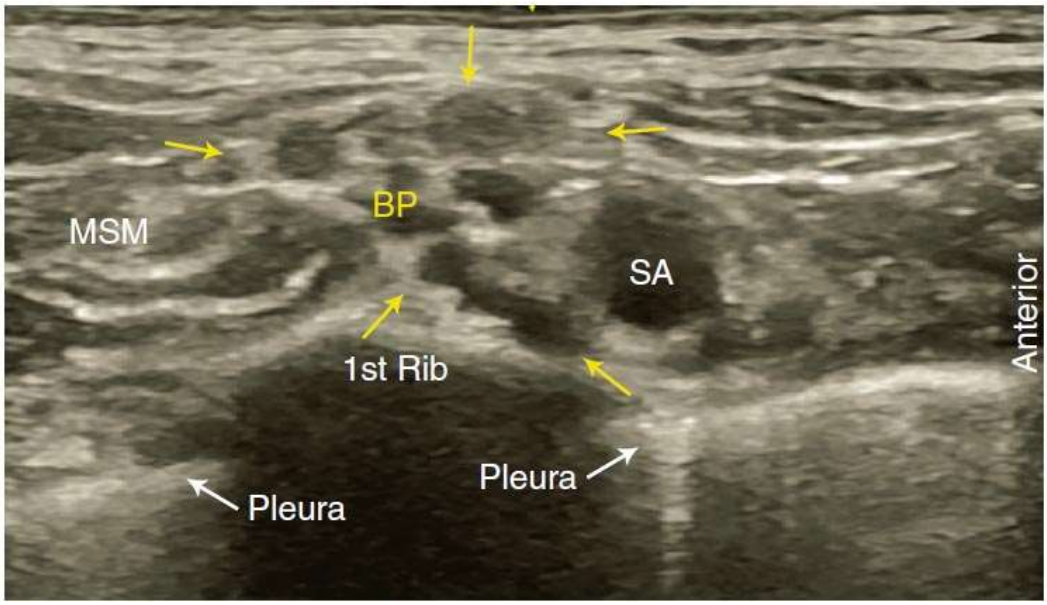
ULTRASOUND ANATOMY FOR BRACHIAL PLEXUS BLOCK

The subclavian artery crosses over the first rib between the insertions of the anterior and middle scalene muscles, posterior to the midpoint of the clavicle. The subclavian artery is readily apparent as an anechoic round structure, whereas the parietal pleura and the first rib can be seen as a linear hyperechoic structure immediately lateral and deep to the subclavian artery. The rib casts an acoustic shadow so that the image field deep to the rib appears anechoic. The brachial plexus can be seen as a bundle of hypoechoic round nodules just posterior and superficial to the artery. It is often possible to see the fascial sheath of the muscles surrounding the brachial plexus. Sometimes the upper, middle and lower trunks of the brachial plexus can be individually identified, as they join together at the costoclavicular space. Anterior or posterior to the first rib is the hyperechoic pleura, with lung tissue deep to it. It is confirmed by observing a "sliding" motion of the visceral pleura in synchrony with the patient's respiration. The brachial plexus is typically visualized at a 1- to 2-cm depth at this location.

Sometimes two separate clusters of elements of the brachial plexus may be present with a separation by a blood vessel. It is important to recognize that the more superficial and lateral branches come from C5–C7 (shoulder, lateral aspect of arm, and forearm) and can be tracked up to the interscalene area, whereas the deeper and more medial contingent are branches of C8 and T1 (hand and medial aspect of forearm). Adequate spread of local anesthetic in both areas is necessary for successful block of the arm and hand. (14)



Anatomy of the supraclavicular brachial plexus with proper transducer placement slightly oblique above the clavicle (Cl). Yellow arrow: brachial plexus (BP). SA, subclavian artery.



Supraclavicular brachial plexus (BP; yellow arrows) seen slightly superficial and postero-lateral to the subclavian artery (SA). The brachial plexus is enveloped by a connective tissue sheath. Note the intimate location of the pleura and lung to the brachial plexus and subclavian artery. MSM, middle scalene muscle.

MATERIAL AND METHODS:

Study area:

The present study was carried out in department of anesthesiology, K.E.M. Hospital, Pune.

Study population:

Patients undergoing elective surgery in operation theatre requiring regional anaesthesia for Upper Limb Surgeries.

Study design: Prospective Randomized Comparative Study.

Sample size: 60

Justification of sample size

Sample Size calculation

$$n(\text{Per Group}) = \left[\frac{Z_{\alpha/2}\sqrt{2pq} + Z_{\beta}\sqrt{p1q1+p2q2}}{p1-p2}\right]^2$$

p1 = 0.13 (Approximate incidence of requirement of rescue analgesia in first 24Hrs group I (group BDex)),

p2 = 0.47 (Approximate incidence of requirement of rescue analgesia in first 24Hrs in group II (group B)),

q1 = 1 – p1 = 0.87, q2 = 1 – p2 = 0.53.

$Z_{\alpha/2}$ = 1.96 (score at 95% confidence interval), Z_{β} = Cut-off value for Power (1 - β). = 0.8416

n (Per Group) = ((1.96*SQRT(2*0.3*0.7)+0.8416*SQRT(0.13*0.87+0.47*0.53))/(0.13-0.47))^2

= 27.30 Per group

Thus, the **minimum** sample size required according to this formula is 27 per group (54 total in 2 groups).

Reference used for sample size calculation:

Sample size was determined by using the effect sizes from the previously published study (Fredrickson MJ et al., Reg Anesthesia Pain Med, 2013) and with the help of following formula:

Duration of study:

Total duration of Study: 10 Months (February 2018-November 2018)

Selection Criteria:

A. Inclusion criteria:

Participants will be recruited as patients undergoing upper limb surgery under Brachial Plexus Block Regional anaesthesia in General surgery and orthopedic surgery OT of KEM Hospital, Pune

1.Age: 18 – 60 years
2.American society of anesthesiologists (ASA) physical status: I-II
3.Elbow, forearm and hand surgeries
4.Body mass index of 18.5 – 30 kg/m2

B. Exclusion criteria:

Patient refusal for procedure
2.History of Any bleeding disorder or patients on anticoagulants
3.Neurological deficits involving brachial plexus
4.Patients with known allergy to local anesthetics/ Dexamethasone
5.Local infection at injection site
6.History of pneumothorax
7.Pregnant women, Pre-eclampsia
8.ASA grade III-IV
9. Patients with uncontrolled Type 2 diabetes
10 History of Psychological disorders

11. Chronic use of pain medications
12. History of tolerance to opiates
13. BMI >30 kg/m2

Methods:

This is a Prospective Randomized Comparative study conducted on a total of 60 patients who were given Regional Anesthesia (Brachial Plexus Block) for Elective Upper Limb Surgeries between February 2018 and November 2018. For all patient's, Informed consent was taken one day prior to surgery while doing pre-anaesthetic evaluation. On the day of surgery all ASA standard monitors were attached which included pulse oximeter, Electrocardiogram, non-invasive blood pressure. An intravenous line appropriate for the surgical procedure was secured. Pre-operative baseline values of heart rate (HR), systolic and diastolic blood pressure (BP) and SpO2 were noted. Patients were the randomly assigned in two groups (30 each) using computer generated sequences.

Group A- Patients receiving (30ml 0.25% bupivacaine + 2 ml of N/S) perineurally in the Brachial Plexus using supraclavicular approach

Group B - Patients receiving (30ml of 0.25% Bupivacaine+ 8mg (2ml) Dexamethasone) perineurally with same approach.

Supraclavicular brachial plexus block was performed under aseptic precautions with the patient lying supine and head turned 45degrees to contralateral side. The brachial plexus and its relationship to surrounding structures will be imaged using 5-12 MHz linear array ultrasound probe. The probe was placed in coronal oblique plane in supraclavicular fossa to visualize the subclavian artery and brachial plexus in the transverse section view. Brachial plexus was approached with a 22G 50mm insulated block needle (Stimuplex; Braun Medical) using in plane method. The Block needle is inserted at a point 1 cm away from the lateral end of the probe. The probe is adjusted accordingly to visualize the needle. Once the needle reaches the brachial plexus cluster, pre decided study medication as mentioned above will be injected incrementally following negative aspiration. Spread of study medication at the time of injection will be observed in real time. Needle will be repositioned to ensure that the drug reaches all the imaged parts of the plexus. The onset and duration of sensory and motor blockade will be studied. Sensory blockade will be assessed using a pin prick sensation every 5 minutes till the onset of loss of sensation then every 30 minutes by the surgeon during the surgery. The motor blockade will be assessed every 5 minutes till the attainment of surgical anaesthesia and thereafter every 30 min during the surgery. Both the sensory and motor blocks assessed using modified bromage scale. (Annexure)

After the surgery is over the sensory and motor blockade will be assessed every 30 min for the first 4 hours then hourly up till 8 hours and then 2 hourly up to 24 hours. The contralateral upper limb will be used as control. Block success was defined as attainment of surgical anaesthesia - a motor score of 2 or more according to modified Bromage scale for upper limb, with absent appreciation of cold swab sensation. (15) Block failure is defined as absence of surgical anaesthesia at 30 min.

In addition, the following parameters were noted:

1. Onset of the Sensory and motor Blockade
2.Duration of the Sensory and motor Blockade
3. Duration of surgery
4.Any other complications namely - nausea, vomiting, motor weakness, respiratory depression, sedation, hypotension and bradycardia, fall in SpO2.

At the onset of pain, (VAS >3,4) rescue analgesia was given as appropriate (i.v. Paracetamol 1 gm) and the total duration of analgesia was noted. Also monitoring done after giving rescue analgesia till 24 hours post-operatively the final results of the study were tabulated and analyzed for significance using standard statistical techniques (sample t test). Sedation score was analysed by using Ramsay Sedation Score

7.10 Statistical data analysis:

The data on categorical variables will be presented as n (% of cases) and the values on continuous variables will be presented as Mean ± Standard deviation (SD). The significance of difference of distribution of prevalence of clinical outcome across two study groups will be tested using Chi-Square test of Fisher's exact probability test. Independent sample 't' test will be used to test the significance of difference in the continuous variables across two study groups. The underlying assumption of normality will be tested before subjecting the study variables to t test. P-values less than 0.05 will be considered to be statistically significant. All the hypotheses will be formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data will be statistically analysed using Statistical Package for Social Sciences (SPSS ver 21.0, IBM Corporation; NY, USA) for MS Windows.

Observation and results:

The present study comprised of 60 ASA1,2 patients

1.The mean ± SD of age of cases studied in Group A and Group B was 48.83 ± 18.74 years and 41.77 ± 12.85 years respectively.

2.Of 30 cases studied in Group A, 13 (43.3%) had Grade 1 ASA, 17 (56.7%) had Grade 2 ASA. Of 30 cases studied in Group B, 15 (50.0%) had Grade 1 ASA, 15 (50.0%) had Grade 2 ASA.

The distribution of ASA grades among the cases studied did not differ significantly between two study groups (P-value>0.05).

3. The mean ± SD of body weight among the cases studied in Group A and Group B was 59.5 ± 9.9 kg and 61.7 ± 8.0 kg respectively.

4. The mean ± SD of duration of surgery in Group A and Group B was 1.92 ± 0.67 Hrs and 2.02 ± 0.74 Hrs respectively

5. The mean ± SD of onset of sensory blockade in Group A and Group B was 22.90 ± 1.79 Mins and 19.85 ± 1.83 Mins respectively.

The distribution of mean onset of sensory blockade is significantly higher in Group A compared to Group B (P-value<0.001).

The mean ± SD of onset of motor blockade in Group A and Group B was 28.88 ± 1.74 Mins and 27.27 ± 1.82 Mins respectively.

The distribution of mean onset of motor blockade is significantly higher in Group A compared to Group B (P-value<0.001).

The mean ± SD of time to rescue analgesia in Group A and Group B was 5.35 ± 1.38 Hrs and 10.58 ± 0.92 Hrs respectively. The minimum – maximum time range in Group A and Group B was 4 – 9 Hrs and 9 – 13 Hrs respectively.

The distribution of mean time to rescue analgesia is significantly higher in Group B compared to Group A (P-value<0.001).

Discussion-

The mean ± SD of age of cases studied in Group A and Group B was 48.83 ± 18.74 years and 41.77 ± 12.85 years respectively. Results of our study were consistent with the findings **of Ritu Baloda et al 2016**. In the results in their study, they found that the mean onset of sensory blockade in Group2-Dexamethasone was 8.1667±0.985 min and in Group 1 Normal saline group 10.20±1.min. They also found that time of onset of motor blockade was 15.033±0.889mins in Dexamethasone group as compared to 13.7667±2.045 min in only Bupivacaine + normal saline group. (4)

Of 30 cases studied in Group A, 13 (43.3%) had Grade 1 ASA, 17 (56.7%) had Grade 2 ASA. Of 30 cases studied in Group B, 15 (50.0%) had Grade 1 ASA, 15 (50.0%) had Grade 2 ASA. The distribution of ASA grades among the cases studied did not differ significantly between two study groups (P-value>0.05).

The mean ± SD of body weight among the cases studied in Group A and Group B was 59.5 ± 9.9 kg and 61.7 ± 8.0 kg respectively.
The mean ± SD of duration of surgery in Group A and Group B was 1.92 ± 0.67 Hrs and 2.02 ± 0.74 Hrs respectively.
The mean ± SD of onset of sensory blockade in Group A and Group B was 22.90 ± 1.79 Mins and 19.85 ± 1.83 Mins respectively. The distribution of mean onset of sensory blockade is significantly higher in Group A compared to Group B (P-value<0.001).
The mean ± SD of onset of motor blockade in Group A and Group B was 28.88 ± 1.74 Mins and 27.27 ± 1.82 Mins respectively. Results of our study were consistent with the findings **of Ritu Baloda et al 2016**. In the results in their study, they found that the mean onset of sensory blockade in Group2- Dexamethasone was 8.1667±0.985 min and in Group 1 Normal saline group 10.20±1.min. They also found that time of onset of motor blockade was 15.033±0.889mins in Dexamethasone group as compared to 13.7667±2.045 min in only Bupivacaine + normal saline group. (4)
The distribution of mean onset of motor blockade is significantly higher in Group A compared to Group B (P-value<0.001). Our Results were also consistent with the study done by **Smita R Engineer et al in**. In the results in their study, they also found that mean onset of sensory blockade in group C (Bupivacaine +normal saline) was 14.32 min and that in Group D (Bupivacaine+Dexathasone) was 7.12 min. Also, the onset of motor blockade in Group C was 18.64min and in Group D was 11.46min. [11]

The mean ± SD of time to rescue analgesia in Group A and Group B was 5.35 ± 1.38 Hrs and 10.58 ± 0.92 Hrs respectively. The minimum – maximum time range in Group A and Group B was 4 – 9 Hrs and 9 – 13 Hrs respectively.
The distribution of mean time to rescue analgesia is significantly higher in Group B compared to Group A (P-value<0.001). Our study results were consistent with that of the results of **Islam SM Hossain**. There was markedly prolonged duration of analgesia in group-B (Dexamethasone group), 11.87± 0.53 hour compared to group-A (without Dexamethasone), 3.43±0.49 hours. [12] The result was statistically highly significant (p<0.001)(14). Their findings also endorsed that dexamethasone does increase the duration of analgesia as well as the duration of motor blockade. Although they had used 0.5 % of bupivacaine in their mixture still the values of the results were quite similar to ours.

CONCLUSION:
It is seen in this study that Single shot Supraclavicular Brachial Plexus Block analgesia was of longer duration in Bupivacaine plus Dexamethasone group than plain Bupivacaine Group. There were statistically significant lower values of VAS PAIN score at various points in Bupivacaine plus Dexamethasone Group. The SBP, DBP and Heart Rate were Significantly on lower side in Bupivacaine with Dexamethasone group which was hemodynamically more stable. Intraoperative and postoperative bradycardia or hypotension was not observed in any group, Postoperative nausea /vomiting were not observed in any group. Hence Dexamethasone added to Bupivacaine for single shot Brachial Plexus Blockade was efficient in prolonging duration of analgesia compared to Bupivacaine only with minimum or no side effects.

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