

**TO COMPARE EFFICACY OF BUPIVACAINE AND
BUPIVACAINE WITH DEXAMETHASONE FOR
SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK
IN PATIENTS UNDERGOING UPPERLIMB
SURGERIES – A ONE YEAR RANDOMISED
CONTROLLED TRIAL**

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ENDORSEMENT

This is to certify that the dissertation entitled “**TO COMPARE EFFICACY OF BUPIVACAINE AND BUPIVACAINE WITH DEXAMETHASONE FOR SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING UPPERLIMB SURGERIES – A ONE YEAR RANDOMISED CONTROLLED TRIAL**” is a bonafide and genuine research work carried out by
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ABBREVIATIONS

USG	--	Ultrasonography
NSAIDs	--	Non Steroidal Anti Inflammatory Drugs
kHz	--	Kilo Hertz
MHz	--	Mega Hertz
2 -D	--	2 Dimentional
pKa	--	pH of dissociation constant of acid
mg	--	milligram
Kg	--	Kilogram
mcg	--	microgram
ml	--	mililiters
COX -2	--	Cyclooxygenase 2
IV	--	Intravenous
IM	--	Intramuscular
HPA	--	Hypothalamo Pituitary Axis
ASA	--	American Society of Anaesthesiologists
RBS	--	Random Blood Sugar
SD	--	Standard Deviation
AMP	--	Adenosine Monophosphate
ECG	--	Electrocardiography
RR	--	Respiratory Rate

DM	--	Diabetes Mellitus
SBP	--	Systolic Blood Pressure
DBP	--	Diastolic Blood Pressure
HTN	--	Hypertension

ABSTRACT

INTRODUCTION:

Brachial plexus block has become a viable alternative to general anaesthesia for upper limb surgeries as it provides adequate muscle relaxation, excellent intra-operative and post-operative analgesia. Bupivacaine is a commonly used local anaesthetic in such blocks. Dexamethasone, a synthetic glucocorticoid was combined with local anaesthetics to prolong the effects of local anaesthetics.

AIMS AND OBJECTIVES:-

This study was conducted to compare the onset and duration of sensory and motor block following administration of either bupivacaine and bupivacaine-Dexamethasone in patients undergoing upper limb surgeries following supraclavicular brachial plexus block performed under USG guidance.

MATERIALS AND METHODS :-

This prospective randomised controlled study was carried out in the Department of Anaesthesiology at KLE's Dr Prabhakar Kore Hospital and Medical Research Center, Belagavi which included 60 ASA grade I and II patients between the ages of 18 and 60 who underwent elective upper limb surgeries. After obtaining ethical committee clearance and informed consent, the patients were randomly allocated into two groups of 30 each by a sealed envelope technique to receive 30 ml of 0.5 % Bupivacaine and 2 ml of normal saline in Group BS and 30 ml of 0.5% Bupivacaine with 2ml (8mg) of Dexamethasone in Group BD. The onset and duration of sensory and motor blockade were observed between the two groups.

RESULTS:-

The onset of sensory and motor blockade was faster in Group BD when compared to Group BS ($p < 0.0001$). The duration of sensory and motor blockade was longer in Group BD when compared to Group BS ($p < 0.0001$). There were no significant haemodynamic changes in the study group

CONCLUSION:-

Dexamethasone when added to Bupivacaine for supraclavicular block shortens the onset time and prolongs the duration of sensory and motor blockade without any systemic side effects.

KEYWORDS:-

Dexamethasone, Supraclavicular, Brachial plexus block, upper limb surgeries, bupivacaine

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INTRODUCTION

Surgeries on the upper limb have traditionally been done under general anaesthesia. However this has its own demerits like airway instrumentation, exposure to multiple drugs¹ and chances of aspiration if inadequate nil oral status is there.

Brachial plexus block has become a viable alternative to general anaesthesia as it provides adequate muscle relaxation, excellent intra-operative and post operative analgesia¹ without above mentioned complications.

It is also helpful for sick patients or in those with co-morbidities which can render the patient unfit for general anaesthesia.²

Blind/landmark based technique had a high rate of failure and complications and thus the technique was not very popular .However the advent of USG guidance for locating the brachial plexus has increased the success rate and has renewed the interest in brachial plexus block.

The most common surgeries on the upper limb include orthopaedic and plastic surgery reconstructive procedures. These procedures can be long and painful and sometimes requiring long operative time and good post operative analgesia.

Therefore prolonging the duration of sensory and motor blockade of regional anaesthetic techniques is often desirable³.

The four routes to block the brachial plexus are axillary, supraclavicular, infraclavicular and interscalene Blocking the brachial plexus using these routes can provide effective anaesthesia for surgeries from the shoulder upto the fingers.

In this study we plan to use the Supraclavicular brachial plexus block under USG guidance which can provide good anaesthesia for surgeries extending from mid arm upto the fingers. .This approach is associated with a rapid onset of anaesthesia and a high rate of success.

The first supraclavicular block was performed by Kullenkampff in 1911-12.⁴

This block is given at the level of the trunks where the plexus is most compact and thus spread of local anaesthetic is uniform and leads to dense block in the area supplied .

Ultra sound guided supraclavicular brachial plexus block is a safe reliable anaesthetic techniques for upper limb surgeries with less complications .¹ Ultrasound guidance leads to decreased procedure time,faster onset of action and higher block success rates without neural injuries ,thereby improving efficacy by better nerve localisation.

Bupivacaine is a long acting local anaesthetic, commonly used in brachial plexus blocks .Its effects last from 3 to 6 hours .¹ This can provide for the intraoperative anaesthesia but may fall in –sufficient to provide post operative analgesia.

Postoperative pain causes the patient to demand rescue analgesia commonly provided by opioids and NSAIDs.

Prolonging the effect of Bupivacaine can help avoid this need for rescue analgesia and avoid the side effects of these analgesics.

Various adjuncts have been used to prolong brachial plexus block. These include epinephrine¹, magnesium sulphate, alpha-2agonists (i.e. clonidine⁵ and dexmedetomidine⁶) and midazolam¹.

Corticosteroids have been studied recently as adjuncts to local anaesthetics in regional blockade³. Steroids induce a degree of vasoconstriction and therefore the first theory states that they act by reducing local anaesthetic absorption⁶.

The more accepted theory states that dexamethasone increases the activity of inhibitory K⁺ channels on nociceptive c-fibers (via glucocorticoid receptors) and thereby decreases their activity^{7,8}.

Dexamethasone also decreases the release of inflammatory mediators and reduces ectopic neuronal discharges and this too adds to the prolongation of local anaesthetic action.

Dexamethasone is a derivative synthetic glucocorticoid and is 25-30 times more potent than hydrocortisone and lacks mineralocorticoid activity⁹. Hence it is safe and devoid of potential side effects.

There have been some studies comparing the effect of dexamethasone in interscalene block and transverses abdominis block. Only a few studies have been done to study the role of dexamethasone in supraclavicular block.

These studies show that dexamethasone prolongs the effect of local anaesthetic solutions but the duration of this block is varied.

This study aims at finding the effect of dexamethasone when used in supraclavicular block and thereby addressing this knowledge gap.

OBJECTIVE

The objective of the study is:-

To compare the onset and duration of sensory and motor block following administration of either Bupivacaine and Bupivacaine- Dexamethasone in patients undergoing upper limb surgeries following Supraclavicular brachial plexus block performed under Ultrasound guidance.

REVIEW OF LITERATURE

BRACHIAL PLEXUS BLOCK

The idea of reducing sensations in the operative site has been present since the earliest surgical documentations. But the research and development of a local anaesthetic for this purpose started in the 1800s.

The first breakthrough in this regard came with the introduction of ether local spray in 1846 by Benjamin Richardson¹⁰.

The next significant event was when in 1884 Hall injected 4% cocaine (15mg) into his forearm and theorised that it blocks neural transmission in cutaneous nerves. This knowledge was then applied to other nerve blocks¹⁰.

In 1909, intravenous regional anaesthesia was described by Dr. August Bier. He applied two tourniquets and injected procaine intravenously which caused analgesia which persisted until the tourniquets were released.

Koller demonstrated that cocaine has local anaesthetic properties by instillation into the eye of the patient. Using this idea William Halstead performed the very first Brachial plexus block in the year 1885.

Using a similar approach to Halstead, Crile in 1897 first exposed the plexus under local anaesthesia and then cocaine was injected under direct vision to anaesthetise the nerve roots. This technique was then utilised for the surgeries on the upper limb.

This first percutaneous brachial plexus block was done by G Hirschel in 1911 following which D. Kullenkampff performed the supraclavicular block in 1912. M. Kappis in 1912 performed the brachial plexus block through a posterior para vertebral approach to reduce the incidence of pneumothorax, a common complication of the supraclavicular block ¹⁰.

This posterior approach was associated with failures and thus others like J.Etienne, V.Pauchet and others attempted anterior approaches.

Ohen Labat used axillary approach in 1922 and then described interscalene approach too in 1927.

These techniques were modified by Murphy in 1944 by using the clavicle, subclavian artery, scalene muscles and 1st rib as land marks.

Rorie DK, Thompson G studied the brachial plexus in 1983 and found that it is a multi-compartmental structure, made up of connective tissue surrounding the plexus. This study also showed that injected anaesthetic solutions spread vertically around the nerves ¹¹.

The peripheral nerve stimulator was invented in the 19th century, which made the localisation of nerves better ¹².PNS use in regional anaesthesia was first demonstrated in 1984 by Pither , Raj and Ford.

Now with the advent of ultrasound guided block even better localisation of nerves due to direct visualisation of nerve bundles and needle during insertion has

been made possible. This has helped in reducing nerve trauma and other complications¹³.

Walid Trabelsi et al in a study compared overall success rate , procedure time and onset of sensory and motor blockade between Nerve stimulator guided and ultrasound guided infraclavicular brachial plexus block .

They used 10-12 MHz linear probe (Logic 7 GE Health care, USA) in ultrasound group and in nerve stimulator group Stimuplex Dig RC, B.Braun, Melsungen Germany.

They injected 15 ml of 0.5% Bupivacaine into the brachial plexus sheath. They concluded that there was no significant difference between the two groups regarding the procedure time but success rate of block was 100% for ultrasound group compared to 73-100% in the Nerve stimulator group and that the onset of block both motor and sensory was faster in the Ultrasound group¹⁴.

De Jose Maria B. et al in 2007 in a study compared the success rate, complications and time of performance of Ultrasound guided Supraclavicular Vs Infraclavicular Brachial plexus blocks in children aged 5- 15 years. They used Ropivacaine 0.5% upto a maximum of 0.5ml/kg body weight .They concluded that Ultrasound guided supraclavicular and infraclavicular blocks are both effective in children and no pneumothorax (a common side effect) was reported as the anaesthesiologist performing the blocks were trained in the “In the Plane” for children in this group .They also concluded that Supraclavicular approach was easier and faster to perform than the Infraclavicular approach¹⁵.

In an attempt to prolong the effect of brachial block and provide adequate post operative analgesia and thereby reduce demand for additional rescue analgesics various adjuvants have been added to local anaesthetic solutions.

Prashant A Biradar , Padmanabha Kaimar and Kannapady Gopalkrishna in 2013 conducted a prospective, randomised double blinded study to evaluate the effect of Dexamethasone added to lidocaine on the onset and duration of Supraclavicular Brachial plexus Block. The control group C received 1.5% lidocaine (7mg/kg) with adrenaline (1:200,000) and 2 ml of normal saline and Group D received 1.5% lidocaine (7mg/kg) with adrenaline (1:200,000) and 2ml of Dexamethasone (8mg)

It was concluded that both sensory and motor blockade was more rapid in onset and the duration of sensory (326 minutes) and motor (290 minutes) blockade were prolonged in Dexamethasone group ³

K.C.Cummings III et al in a double blinded clinical trial between 2008 -2010 used single injection interscalene block where patients were randomised into four groups.

The first group received 0.5% ropivacaine, the second group received 0.5% Bupivacaine, the third group was given 0.5% ropivacaine with 8mg dexamethasone while the last group received 0.5% Bupivacaine with 8 mg dexamethasone. They concluded that Dexamethasone prolonged the duration of analgesia with both ropivacaine (11.8hrs Vs 22 hrs, $p<0.001$) and bupivacaine (14 hrs Vs 22.4 hrs, $p<0.001$) but the prolongation seen was more with ropivacaine than bupivacaine ($p=0.0029$)⁸.

S.Choi et al studied the effects of dexamethasone as a local anaesthetic adjuvant for brachial plexus block in a systematic review and meta – analysis of randomized trials.

They used three electronic databases MEDLINE (1946- April 2013), EMBASE (1980 – April 2013) and Cochrane central Register (2005- April 2013) .All available abstracts from major international meetings including the American Society of Regional Anaesthesia (ASRA 2005- 2012), the European Society of Regional anaesthesia (ESRA 2007 – 2012) and the American society of Anaesthesiologists (ASA 2000- 2012) annual meetings were also examined .They included nine trials of 801 patients out of which 393 received dexamethasone (4-10mg) .

They concluded that Dexamethasone prolonged the analgesic duration for long acting local anaesthetic from 730 to 1306 minutes while motor block was prolonged from 664 to 1102 minutes without any observed adverse events ⁷ .

Ghada F. El- Baraday and Nagat S-Elshma in 2010 -2012 conducted a prospective randomised controlled observer – blinded study to assess the effectiveness of adding either midazolam or Dexamethasone in comparison with epinephrine addition to 0.5% bupivacaine in supraclavicular brachial plexus block.

The study population was divided into three groups. Group E received 30ml of 0.5% bupivacaine with 1:200,000(5mcg/ml), Group M received 30ml of 0.5% bupivacaine and midazolam 50mcg/kg while Group D received 30ml of bupivacaine with 8 mg of Dexamethasone .They concluded that in comparison with epinephrine and midazolam addition of Dexamethasone to Bupivacaine had rapid onset of block and longer time to first analgesic request with fewer side effects ¹ .

Feroz Ahmed et al in a randomised double –blinded study evaluated the effect of adding dexamethasone to ropivacaine for supraclavicular brachial blockade. They included eighty patients scheduled for various elective orthopaedic surgeries on the forearm and around the elbow under supraclavicular brachial block. The patients were randomised into Group R where patients received 0.5% ropivacaine(30ml) + 2ml of Normal saline and Group RD where the patients received 0.5% ropivacaine (30ml)+ 2ml (8mg) of Dexamethasone .

From the 6th postoperative hour, onwards patients who received Dexamethasone showed a significantly lower VAS score than those who received ropivacaine alone .It was concluded that Dexamethasone added to Ropivacaine prolonged the duration of sensory and motor blockade ($p<0.001$)⁹ .

Vieira PA et al in a randomised, prospective, double blinded study evaluated the effects of dexamethasone on analgesia in patients undergoing shoulder arthroscopy under Interscalene Block with 0.5% Bupivacaine .

They included 88 patients and the each group received 20 ml of 0.5% Bupivacaine with Epinephrine and clonidine 75mg. The patients were randomised and Normal saline 0.9% was added to the control group where as 8 mg (2ml) of Dexamethasone was added to the study group .After discharge, patients recorded pain scores and analgesic consumption in a diary and estimated the time at which they perceived that the sensory block from the interscalene brachial plexus block resolved. This was based on pain, recovery of sensation and strength in the arm. Demographics, timed pain intensity measurements, postoperative analgesic consumption, duration of analgesia and patient satisfaction were recorded.

They concluded that Dexamethasone prolonged median sensory (1457 vs. 833 min, $P < 0.0001$) and motor (1374 vs. 827 min, $P < 0.0001$) blockade compared with the control.

At 24 h, the dexamethasone group had lower median verbal analogue scale scores compared with control (3.0 vs. 6.0). At 48 h, the two groups had similar median pain scores (4.0 vs. 5.0, dexamethasone vs. control, respectively). The opioid requirement in oxycodone equivalency was lower in the dexamethasone group than in the control group for the first 24 h.¹⁶

E. Albrecht et. al in a meta analysis of controlled trials reviewed the safety and efficacy of Dexamethasone as an adjuvant to perineural nerve blockade. They included 29 controlled trials with a total of 1695 patients. The trials were then grouped were one group included studies on short and medium duration action local anaesthetics while the other group included the studies using the long acting. They used the PRISMA guidelines and the databases used were PUBMED, CENTRAL and EMBASE upto May 16th 2014.

They concluded that dexamethasone shortens the onset of sensory and motor blockade. It also prolongs the duration of local anaesthetic actions.

Dexamethasone increased the mean (95% CI) duration of analgesia by 136 (127–145) min, when injected with local anaesthetics with short- or medium-term action, $p < 0.00001$, and by 406 (400–413) min when injected with local anaesthetics with long-term action, $p < 0.00001$.¹⁷

Thi Mum Huynh et. al in a meta analysis of randomised controlled trials studied the effect of combining dexamethasone with the local anaesthetics on the

sensory and motor peripheral nerve blocks in adult patients .They searched Medline, Embase, Google Scholar and Cochrane Controlled Trials Register up to December 2013. They included Twelve trials (1054 patients,with 512 receiving perineural dexamethasone) were included. Dexamethasone was added in doses ranging between 4 mg to 10 mg. 10 studies among the 12 included were on brachial plexus block.

They concluded that adding dexamethasone caused faster onset of time to onset of sensory and motor blocks was significantly reduced with dexamethasone (WMD -78 s, 95% CI -112 to -44 , and -90 s, 95%CI -131 to -48 , respectively).block and increased the duration of analgesia [weighted mean difference (WMD) 351 min, 95% confidence interval (95% CI) 288 to 413, $P<0.001$]. This result was statistically significant even when only studies using upper extremity nerve blocks were pooled (WMD 420 min, 95% CI 326 to 511, $P<0.001$). The median duration of motor blockade was 202 min (range 130 to 1500 min), (WMD 277 min, 95% CI 167 to 387, $P<0.001$) compared with local anaesthetic solutions alone.¹⁸

B.R. Shreshtha et al in a prospective, randomised, double blind study compared the effects of adding tramadol and dexamethasone to bupivacaine for supraclavicular block. Their study included a total of 60 ASA I or II patients who were undergoing surgeries on the upper limb under brachial plexus block, were randomly divided into two groups. The first group received Bupivacaine + Tramadol (2mg/Kg) and the second group received Bupivacaine + Dexamethasone (8mg). The duration of post operative analgesia was studied using VAS scores and it was defined as the time when the patient's VAS score was 8-10 and they demanded extra analgesics.

The mean duration of post- operative analgesia was found to be 1028.00 minutes for the Dexamethasone group while for the Tramadol group it was 453.17 minutes. They concluded that addition of Dexamethasone to bupivacaine increased the duration of block more than Tramadol ($p < 0.05$) when these drugs were used as adjuvants to Bupivacaine for patients undergoing upper limb surgeries .¹⁹

Ali Movafegh et al in a prospective randomised double blind study analysed the effect of addition of dexamethasone to Lignocaine on the onset and duration of axillary brachial plexus block. They included 60 patients who were undergoing surgeries on hand and fore arm under axillary brachial plexus block and randomly divided them into two groups . The first group received 34 ml of 1.5 % Lignocaine and 2ml of isotonic normal saline (control group) while the second group received 34ml of 1.5% Lignocaine 2ml of Dexamethasone (8mg). After giving the block the sensory and motor blockade radial, median, musculocutaneous, and ulnar nerves were recorded at 5, 15 and 30 minutes. The onset time of sensory and motor blockade was taken to be the time between the last injection and total abolition of pin prick response and complete paralysis. The duration of sensory and motor block were taken as first pain response and complete motor recovery.

16 patients were excluded due to unsuccessful block. The onset time was found to be similar in the two groups but the duration of sensory block was 242 ± 76 mins in dexamethasone group while it was 98 ± 33 mins in the control group. The duration of motor block was 310 ± 81 mins in dexamethasone group compared to 130 ± 31 mins in the control group .($p < 0.01$) .

They concluded that adding dexamethasone to lignocaine 1.5% in axillary brachial plexus block prolongs the duration of sensory and motor block .²⁰

Ammar Amany S. and Mahmoud Khaled M in a prospective randomised controlled trial studied the effect of adding dexamethasone on transverse abdominis plane block for abdominal hysterectomy.

They included 60 adult patients under going elective open abdominal hysterectomy and randomly divided into two groups the first of which received 20 ml of bupivacaine 0.25% + 2ml of 0.9 % normal saline (control group) . The second group received 20 ml of bupivacaine 0.25% and 2ml (8mg) dexamethasone. They assessed the post- operative pain by the visual analogue scale (VAS) at 1,2,4,12,24 and 48 hrs. They also studied the time to first analgesia, morphine consumption and the incidence of post- operative nausea and vomiting or somnolence. They found that the VAS scores were significantly lower at 2, 4 and 12 hrs post-operatively. The time for first analgesic was significantly longer in dexamethasone group with significantly lower morphine requirement in the 48 hours post-operatively

The incidence of of nausea and vomiting post – operatively were also found to be lower in the dexamethasone group.

They concluded that addition of dexamethasone to bupivacaine in TAP block prolonged the duration of the block and decreased the incidence of nausea and vomiting.²¹

BASIC SCIENCES

ANATOMY OF BRACHIAL PLEXUS ²²

To administer successful anaesthesia for the upper limb surgeries, a thorough knowledge about the anatomy of brachial plexus i.e. its formation, muscular and cutaneous distribution and surface anatomy is paramount for the anaesthesiologist.

FORMATION OF THE BRACHIAL PLEXUS

This plexus is formed by joining of the ventral rami of the C5, C6, C7, C8 nerves and the first thoracic (T1) nerve with variable contributions from C4 and T2.

If the C4 contribution is large then the plexus is termed “prefixed” whereas if the contribution from the thoracic T2 is large then the plexus is termed “post fixed”.

These variations are more commonly seen in presence of a cervical rib or first rib anomaly. The plexus is composed of roots, trunks, divisions, cords and branches

Roots:-

They are made by the anterior primary rami of C4-C8 and T1 nerves. After they exit from the foramina they join to form the trunks

Trunks:-

There are three trunks in the brachial plexus. The “upper trunk” is formed by union of C5 and C6 at the lateral border of the scalenus medius muscle. Behind the scalenus anterior C8 and T1 rami fuse to form the “lower trunk” whereas the C7 ramus continues as the “middle trunk”.

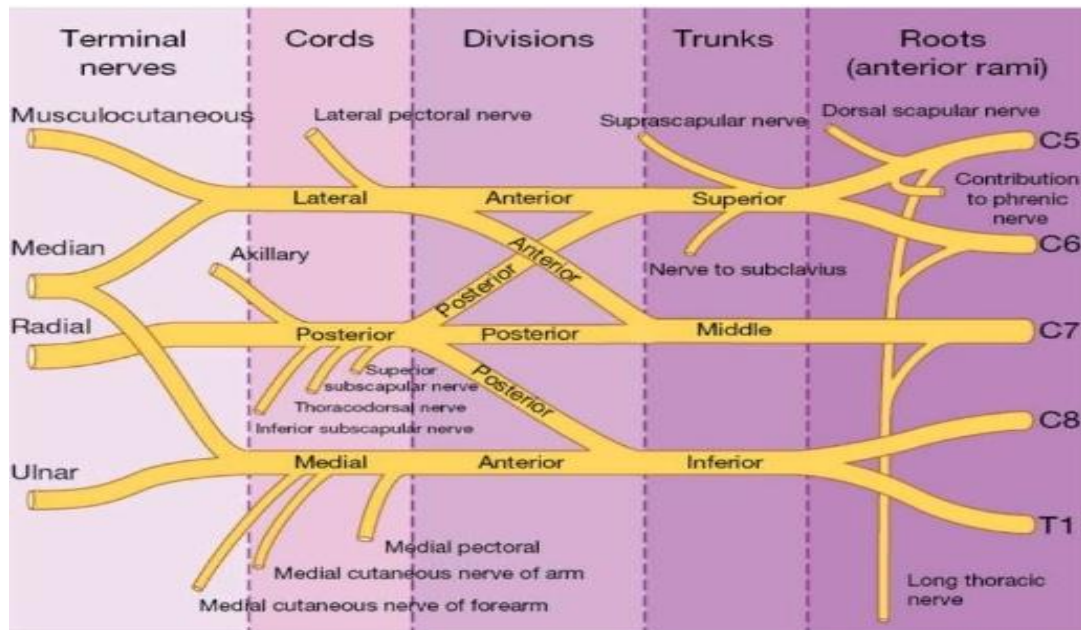


Figure 1. Formation of brachial plexus

Divisions:-

These three trunks travel inferiorly and behind the clavicle each of them gets bifurcated into anterior and posterior divisions

Cords:-

These divisions rejoin to form the cords. Anterior divisions of the upper and middle trunks join to form the “lateral cord” which lies lateral to the axillary artery. On the medial side of the axillary artery the anterior division of the lower trunk continues as the medial cord. Posterior divisions of all three trunks join to form the “posterior cord”, behind the axillary artery.

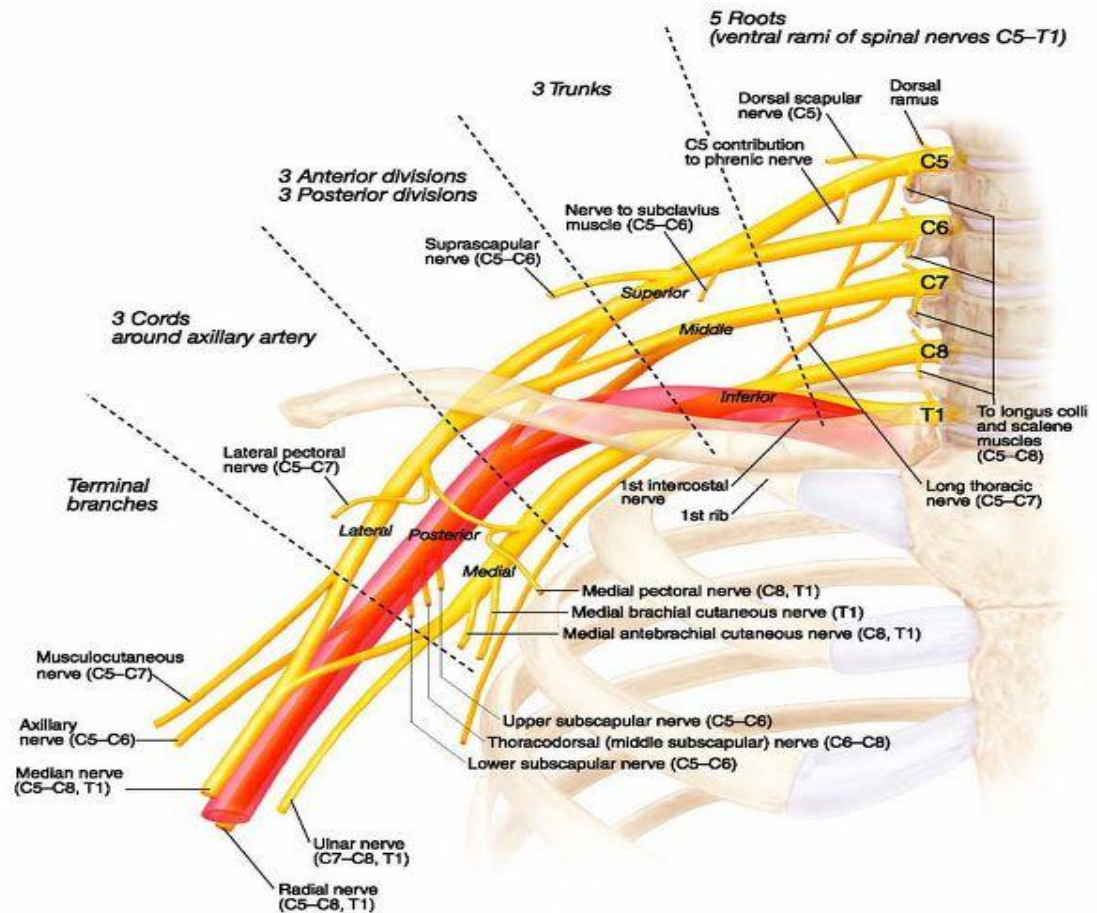


Figure 2 .Relations of brachial plexus

In the neck:-

Here the plexus is located in the posterior triangle between the clavicle and lower posterior border of sternocleidomastoid. It exists between the scalenus anterior and medius muscle and passes posterior to the medial two thirds of the clavicle and the suprascapular vessels.

The proximal part of the plexus is superior to the third part of the subclavian artery.

In the axilla :-

Here the lateral and the posterior cords lie lateral to the first part of the axillary artery while the medial cord is present behind it . In the lower axilla cords divide into nerves for the upper limb .

Branches of brachial plexus:-

They are divided into supraclavicular and infraclavicular branches

Supraclavicular branches: include From the Roots:-

- a) Nerves to scalene and longus colli- C5,6,7,8
- b) Dorsal scapular nerve – C5
- c) Branch to phrenic nerve – C5
- d) Long thoracic nerve – C5,6,(7)

From the trunks :-

- a) Nerve to subclavius – C5,6
- b) Suprascapular nerve – C5,6

Infraclavicular branches :- include

Medial cord :

- a) Medial pectoral nerve – C8,T1
- b) Ulnar nerve – C7,T1
- c) Medial cutaneous nerve of arm – C8
- d) Medial cutaneous nerve of forearm – C8,T1
- e) Medial root of median nerve – C8,T1

Lateral cord :

- a) Lateral pectoral nerve C5,6,7
- b) Musculocutaneous nerve – C5,6,7
- c) Lateral root of median nerve C5,6,7

Posterior cord :

- a) Upper scapular nerve – C5,6
- b) Thoracodorsal nerve – C6,7,8
- c) Axillary nerve – C5,6
- d) Radial nerve – C5,6,7,8,T1
- e) Lower scapular nerve – C5,6

Supraclavicular nerves:

The nerves to longus colli and scalene (C5,6,7,8):-

They arise from lower cervical ventral rami just after coming out of intra-vertebral foramina. They supply longus colli (C2-C7), Anterior scalene muscle (C4-C6), Medial scalene muscle (C6-C8), Posterior Scalene muscle (C6-C8), Scalene minimus muscle (C7-C8).

Branch to phrenic nerve :(C5)

This nerve joins the phrenic nerve anterior to scalenus anterior.

Dorsal scapular nerve :-(C5)

It arises from C5 and pierces scalenus medius and supplies the rhomboids and levator scapulae

Long thoracic nerve (C5,6(7)):

It is formed by roots from C5-C7 but C7 may sometimes be absent. The C5 and C6 roots pierce the scalenus medius and join each other. They then traverse dorsal to remaining plexus and the axillary artery the superior border of serratus anterior supplying branches to it.

It supplies serratus anterior muscle.

Injury to this nerve manifests as winging of scapula due to unopposed action of rhomboids and levator scapulae

Branches from trunks:

Nerve to subclavius :

It is a small branch arising from the fifth and sixth rami and is commonly connected to the phrenic nerve. It descends above the subclavian vein and supplies the subclavius muscle.

Suprascapular nerve:

It is a branch of the superior trunk and traverses deep to the trapezius and omohyoid entering the suprascapular notch and supplies supraspinatus and infraspinatus muscles and gives articular branches to the shoulder joint. It sometimes has a cutaneous branch which pierces the deltoid muscle and supplies the area also supplied by the axillary nerve.

The lesions of this nerve include neuralgic amyotrophy, entrapment neuropathy near the suprascapular notch and damage due to shoulder trauma.

Infraclavicular branches :

These are branches from the cords but they also contain certain fibers from spinal nerves

Branches from the cords :

A. Lateral cord :

1. Lateral pectoral nerve (C5,6,7):

This branch arises from either the anterior divisions of upper and middle trunks or from a single root from the lateral cord . It crosses anterior to the axillary artery and vein and pierces the clavipectoral fascia and supplies the pectoralis major muscle and also gives some fibers to the pectoralis minor muscle .

2. Musculocutaneous nerve :

This branch starts from opposite the lower border of pectoralis minor. It pierces the coracobrachialis muscle and descends between the biceps and brachialis. It then pierces the deep fascia lateral to the tendon of biceps and continues as lateral cutaneous nerve of the forearm .

It supplies the coracobrachialis ,both heads of biceps and major portion of brachialis.

Injury to this nerve causes major weakness of flexion of the elbow due to paralysis of biceps and most of brachialis. This is accompanied by sensory loss along the extensor aspect of the forearm in the area supplied by the lateral cutaneous nerve of the forearm.

3. Lateral head of the Median nerve .

The Median Nerve :C6,7,8,T1

This nerve is comprised of two roots one from lateral and one from medial cords. These two roots join each other either in front of or lateral to the third part of axillary artery.

It enters the arm lateral to the brachial artery but becomes medial to it in the cubital fossa lying just behind the brachial aponeurosis. It enters the forearm between the two heads of pronator teres and descends further between the humero-ulnar and radial heads of flexor digitorum superficialis .

About 5 cms proximal to the flexor retinaculum it becomes superficial lying between the tendons of flexor digitorum superficialis and flexor carpi radialis

Branches in the arm:

These include a vascular branch to brachial artery and a muscular branch to the pronator teres.

Branches in the forearm:

These include articular, muscular, anterior interosseous and posterior communicating.

Muscular branches: include branches to

1. Flexor pollicis longus
2. Flexor pollicis bravis
3. Flexor digitorum superficialis
4. Flexor digitorum profundus
5. Pronator quadrates

6. Pronator teres
7. Flexor carpi radialis
8. Opponens pollicis

Articular branches : include one branch each to the elbow joint and radio ulnar joints.

It terminates in the hand after giving muscular branch to abductor pollicis brevis ,in the form of various palmar digital branches which supply the second and third lumbricals and give cutaneous supply to the hand .

Injury to this nerve in the forearm before it gives the muscular branches causes loss of flexion of second phalanges of all four digits .The cutaneous sensation in the area supplied is also lost ²³.

Carpal tunnel syndrome: It is an entrapment neuropathy caused due to compression of the nerve while passing below the flexor retinaculum.The dominant hand is usually affected first.

There is wasting and weakness of abductor pollicis brevis and impairment of sensation in the thumb, index, middle and median side of the ring finger ²⁴.

Median cord

1. The medial pectoral nerve –This nerve joins the lateral pectoral nerve and makes a loop around the artery and then supplies the pectoralis minor muscle. It also supplies some fibers to the pectoralis major muscle .

2. The medial cutaneous nerve of arm – This nerve begins in the axilla by coming out of the axillary sheath. It supplies the medial portion of the upper arm upto the medial epicondyle.
3. The medial cutaneous nerve of the forearm - It lies between the axillary artery and vein and gives cutaneous supply to skin over the biceps upto the elbow. It descends downwards and divides into anterior and posterior branches supplying the skin over the medial side of forearm upto the wrist joint.
4. The medial head of median nerve
5. The Ulnar Nerve –It starts from the medial cord but commonly receives fibers from the ventral ramus of C7. It travels between the axillary artery and vein upto the mid arm,where after it pierces the medial inter-muscular septum and descends anterior to the medial head of the triceps .

It enters the forearm between the two heads of the flexor carpi ulnaris superficial to the posterior part of the ulnar collateral ligament.

About 5 cm before the wrist joint it gives a dorsal branch which continues distally into the hand anterior to the flexor retinaculum and posteromedial to the ulnar artery.

Its branches include – articular branches ,muscular ,palmar cutaneous, dorsal, superficial terminal and deep terminal.

Articular branches – these supply the elbow joint

Muscular branches – they innervate

1. Abductor digiti minimi
2. Abductor pollicis

3. Palmar interossei
4. Dorsal interossei
5. Flexor digiti minimi brevis
6. Flexor carpi ulnaris
7. Ulnar head of flexor digitorum profundus

Dorsal branch – It descends along the medial side of the back of the wrist and then divides into two or three branches . The first of these supplies the medial side of the little finger, second branch supplies the adjacent sides of little and ring fingers while the third supplies the adjoining sides of the middle and ring fingers.

Superficial terminal branch – It supplies the Palmaris brevis and medial palmar skin and then divides into two palmar digital nerves.

Deep terminal branch— It traverses with the deep branch of the ulnar artery supplies the abductor digiti minimi ,opponens digiti minimi and flexor digiti minimi. It then crosses the hand and supplies the interossei and the third and fourth lumbricals. It ends by supplying the abductor pollicis and first palmar interossei. It also gives articular branches to the wrist joint.

In case the ulnar nerve is injured in the forearm , it causes impaired abduction. Due to the paralysis of the dorsal interossei ,the fingers cannot be spread or flexed at the metacarpophalangeal joints or extended at the interphalangeal joints. the hypothenar muscles are wasted and area of cutaneous supply is lost .
Posterior cord:-

1. The thoracodorsal nerve :- this nerve arises from the C6-C8 between the subscapular nerves .It accompanies the subscapular artery along the posterior axillary wall and supplies the latissimus dorsi muscle.
2. The upper subscapular nerve
3. The lower subscapular nerve :-
 - a. It supplies the lower part of the subscapularis muscle and teres major.
4. The axillary nerve :- It is in the early portion it lies lateral to the radial nerve and posterior to the axillary artery . At the lower border of the subscapularis muscle it curves back and traverses the quadrangular space and divides into anterior and posterior branches .

The anterior branch curves around the deltoid muscle and supplies it .It also gives cutaneous branches to skin overlying the lower part of the muscle . The posterior branch supplies the teres minor and gives the upper lateral cutaneous nerve of the arm.

The axillary nerve is susceptible to injury around the surgical neck of humerus causing the paralysis of the deltoid and anaesthesia in the skin overlying the deltoid (regimental patch anaesthesia)

The radial nerve :- It is made up of contributions from the C5,6,7,8 and is the largest branch of the brachial plexus . It is behind the third part of the axillary artery. Along with the profunda artery it lies between the long and medial heads of the triceps muscle and then passes obliquely across the back of the humerus in the spiral groove . Anterior to the lateral epicondyle it divides into superficial and deep terminal rami.

The branches of radial nerve include articular ,muscular , cutaneous, superficial terminal and posterior interosseous nerves

Articular branches – they supply the elbow joint Muscular branches – they supply

- a) Supinator
- b) Triceps brachii
- c) Extensor carpi radialis brevis
- d) Extensor pollicis longus
- e) Extensor indicis
- f) Extensor pollicis brevis
- g) Abductor pollicis longus
- h) Brachioradialis
- i) Extensor carpi ulnaris
- j) Extensor digitorum
- k) Extensor digiti minimi
- l) Extensor carpi ulnaris longus

Cutaneous branches :- They include the posterior and lower lateral cutaneous nerves of the arm and the posterior cutaneous nerve of the forearm .

Superficial terminal branch :- It starts from the lateral epicondyle and descends anterolaterally behind the brachioradialis close to the artery.

Just before the wrist it leaves the artery and curves around the lateral side of the radius and pierces the deep fascia and divides into four to five digital nerves.

These digital branches supply the skin of the thumb, the index finger, adjoining sides of ring and the middle fingers. They also supply the metacarpophalangeal and proximal interphalangeal joints.

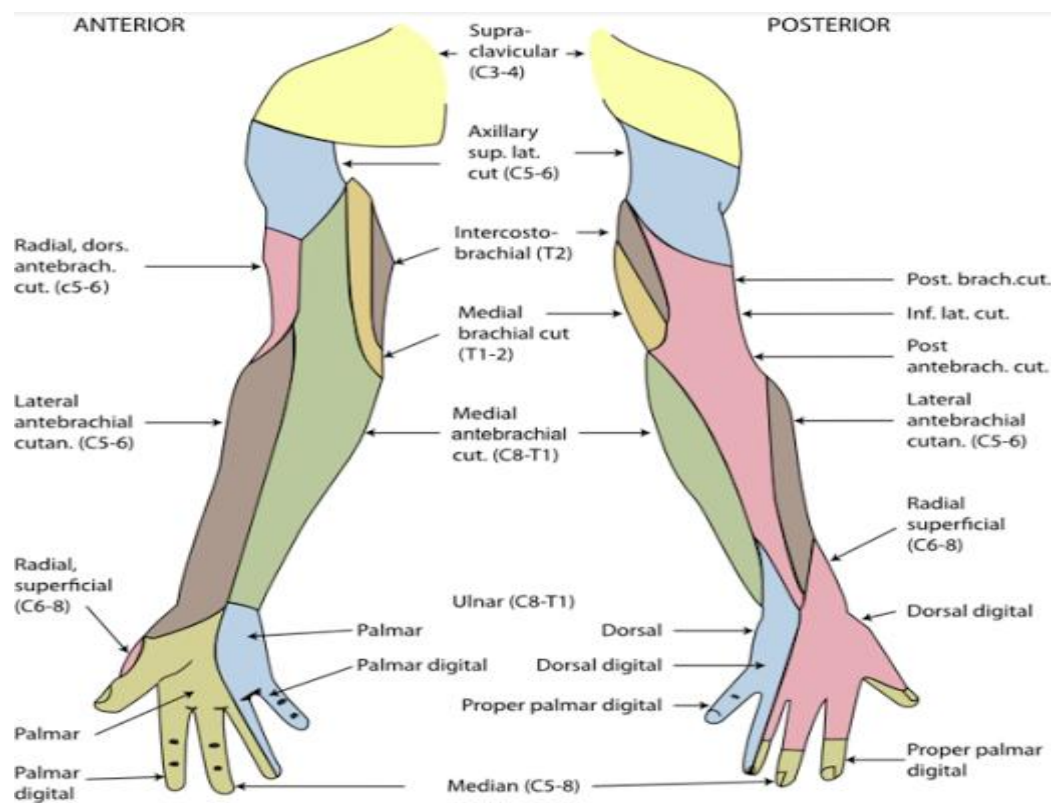


Figure 3. Dermatomal distribution in the upper limbs

Sympathetic innervations in the Brachial Plexus : The sympathetic nerves for the upper limb are derived from spinal segments T2-T6. The vasoconstrictor fibers emerge from the T2 and T3 segments while the pre-ganglionic fibers arise from the lateral horn cells and passing through the white rami communicans they reach the sympathetic chain and end in the middle and inferior cervical and first thoracic ganglia.²⁵

The post ganglionic fibers from the cervical ganglion pass through the grey rami communicans to reach the C5-C6. They pass through the roots, trunks, divisions, cords and the branches.

The arteries of skeletal muscles are dilated by sympathetic activity and for the skin they are pilomotor, pseudomotor and vasomotor .

The Brachial Plexus Sheath

The prevertebral fascia and the anterior and middle scalene muscles envelope the brachial plexus and the subclavian vessels in a sheath known as the “Brachial Plexus Sheath”.

It is cylindrical to conical in shape with a volume of approximately 42ml. It is 8-10 cms in length. Proximally it is densely packed and becomes more loosely arranged once it moves distally.

There are fibrous septae present in the sheath which can impair the even distribution of the local anaesthetic drug when giving blocks.

ULTRA SONOGRAPHY AND SUPRACLAVICULAR BLOCK

P. La Grange and his colleagues were the first Anaesthesiologists to publish a case series report of Ultrasound application for peripheral nerve blockade in 1978 .

In 1989, P. Ting and V. Sivagnanaratnam used B- Mode ultrasonography to demonstrate the anatomy of the axilla and to observed the spread of local anaesthetics during axillary brachial plexus block .²⁶

Ultrasound waves are high frequency waves in the range of more than 20 kHz . These are emitted from the transducer and travel through the tissue and are reflected or absorbed . Based on this the image is created .

A coupling medium (usually a gel) is a must between the transducer and the skin to displace the air .

The frequency to be used depends on the structure to be visualised . Frequencies between 6 and 12 MHz yield better resolution for imaging of the peripheral nerves as they are superficial .

There are 3 modes of ultrasound :-

- A – Mode
- B - Mode
- Doppler Mode

The B – Mode supplies a 2-D image of the area by simultaneous scanning from a linear array of 100-300 piezoelectric elements .This mode provides a cross sectional image through the area of interest and hence is the primary mode currently used in regional anaesthesia.

Doppler Mode is based on the work of Austrian physicist Johann Christian Doppler. Colour Doppler produces a colour coded map of Doppler shifts superimposed on a B- Mode ultrasound image.

Blood flow towards the transducer is seen as red while blood flow away from transducer is seen as blue.

This mode helps to identify the vascular structures in the area of interest . Thus it helps to avoid accidental intravascular injection of local anaesthetic .

Two types of scan transducers are used in Regional anaesthesia i.e. Linear and Curved. Linear transducer produces parallel scan lines and rectangular display whereas a Curved transducer produces an arc- shaped image .

ULTRASOUND GUIDED SUPRACLAVICULAR BLOCK

Anatomy:- The most important landmark for the supraclavicular block is the subclavian artery , which is readily imaged in the cross – section as it lies atop the bright hypoechoic first rib and itself is anechoic , hypodense ,round and pulsatile .²⁷

The plexus is identified as a “cluster of grapes” like appearance of 3 or more hypoechoic nodules located superolateral to the artery.

Patient position :- Supine with head turned away from the side of the block .

Transducer :- 25 or 38 mm linear transducer oscillating at 13 MHz is used . It is placed in the Coronal Oblique plane.

The needle is inserted immediately above the clavicle in a lateral to medial direction with a slight cephalad angle . This approach will ensure that the needle approaches the nerve structure before reaching the Subclavian artery.

25 to 40 ml of Local Anaesthetic solution will produce adequate analgesia .

PHARMACOLOGY

PHARMACOLOGY OF BUPIVACAINE^{28,29} :

Local Anaesthetic Drugs : These drugs produce reversible conduction blockade of nerve conduction along the central and peripheral nerve pathways . When the concentration is increased gradually the transmission of autonomic.somatic sensory and somatic motor impulses are interrupted in the same sequence. This produces autonomic blockade ,sensory anaesthesia, and muscle paralysis in the area supplied . Gradual removal by absorption into systemic circulation causes the reversal of this blockade .

Molecular Structure:These drugs have two portions. One is lipophilic while the other is hydrophilic and the two are connected by a hydrocarbon chain. The hydrophilic portion is usually a tertiary amine while the lipophilic portion is an unsaturated aromatic ring.

This lipophilic portion is essential for anaesthetic activity.

BUPIVACAINE³⁰ :Bupivacaine is a long acting, amide-type local anaesthetic. It was prepared by A.F. Ekenstam in 1957 and introduced by Telivuo in 1963.

Chemically related to lignocaine and its structure is similar to that of Mepivacaine except that the amine-containing group is a butyl piperidine. Its potency is approximately four times that of lignocaine.

Its long duration of action plus its tendency to provide both sensory and motor block has made it a popular drug for providing prolonged analgesia during labor or the postoperative period.

By taking advantage of indwelling catheters and continuous infusions, bupivacaine can be used to provide several days of effective analgesia.

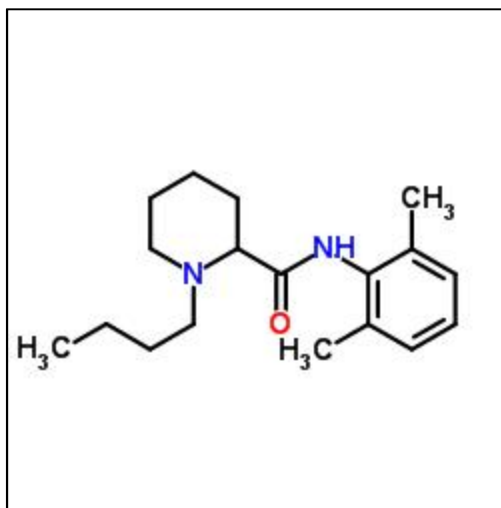


Figure 4 Structure of Bupivacaine

Physiochemical Properties :

1. Chemical name : 1-N-butyl-DL-piperidine 2 carboxylic acid-2,6 dimethyl anilide hydrochloride
2. Molecular weight : 324.9
Solubility : 28
3. pka : 8.1
4. Half life : 1.5 -5.5 hours in adults and 8.1 in neonates.
5. Specific gravity : 1.026 at 37°C
6. Volume of Distribution = 73 liters

Pharmacology ³¹ :

The addition of a butyl group to the piperidine Nitrogen of Mepivacaine makes Bupivacaine 35 time more lipid soluble

Potency :

It is approximately 3 to 4 times more potent than Mepivacaine or Lignocaine

Onset and Duration :

The onset of action of Bupivacaine is between 5 and 7 minutes and maximum anaesthesia is achieved in between 15 and 25 minutes .

The duration varies according to the type of block ; average duration of epidural block is – 2.5 to 4 hours average duration of spinal block is – 2 to 3 hours

Mechanism of Action :

The mechanism of action of bupivacaine is similar to lignocaine.

Local Anaesthetics bind to specific site in the voltage gated sodium channels and block Na⁺ current and reduce the excitability of Neuronal ,Cardiac or CNS Tissue.

The large transient increase in permeability to sodium ions necessary for propagation of the impulse is prevented .

Thus the resting membrane potential is maintained and depolarisation in response to stimulation is also prevented.

The mechanism of sodium conductance blockade :-

a) The cationic form of Local anaesthetics acts on the receptors within the Na⁺ Channel on the cell membrane and block it. The local anaesthetics can reach the

Na⁺ channel either via the lipophilic pathway directly across the lipid membrane or via the axoplasmic opening .

b) The second mechanism is a non specific action i.e. by membrane expansion .

Available concentrations of Bupivacaine: - 0.25% and 0.5%

Dosage of Bupivacaine: - Maximum dosage – 3mg /Kg body weight Bupivacaine is less likely to produce vasoconstriction unless sufficiently dilute³² . Adrenaline prolongs its action only marginally, if at all.

Tachyphylaxis is much less likely than with Lignocaine .

Metabolism and Elimination :-

Bupivacaine gets metabolised by the following mechanisms –

- a) Aromatic Hydroxylation
- b) N- dealkylation
- c) Amide Hydrolysis
- d) Glucuronide – conjugation

The chief mechanism is N- dealkylation and the metabolite is N-desbutyl Bupivacaine .

The mean total of urinary excretion of Bupivacaine and its dealkylation and hydroxylation metabolites account for >40% of the total anesthetic dose.

Systemic Actions :-

Central Nervous System:-

Over dosage concentrations of Bupivacaine produce dizziness and light headedness followed by visual and auditory disturbances such as difficulty to focus and tinnitus .

Shivering , muscular tremors and tremors of facial muscles can occur.

The plasma concentration of Bupivacaine associated with seizures is 4.5 to 5.5 mcg/ml

Cardiovascular System :-

Usually cardiovascular system is more resistant to the toxic effects of high plasma concentrations of local anaesthetics.

Lignocaine concentration <5mcg/ml is devoid of adverse effects but causes decrease in automaticity. Lignocaine concentrations 5-10 mcg/ml can produce profound hypotension due to arteriolar vascular smooth muscle relaxation and direct myocardial depression.

Blockade of cardiac sodium channels by local anaesthetics contributes to anti dysrhythmic properties.

With increase in concentration more Na⁺ channels become blocked and conduction and automaticity become affected adversely ³³. This is evident by prolongation of PR interval and QRS Complexes.

Accidental IV injection of bupivacaine may result in precipitous Hypotension , cardiac dysrhythmias and AV Heart block.

Most common dysrhythmias include Widening of QRS Complex, Premature Ventricular contractions and Ventricular tachycardia³⁴.

Cardiotoxicity of Bupivacaine is seen when plasma concentrations are 8 – 10 mcg/ml³⁵

Pregnancy may increase sensitivity to cardiotoxic effects of Bupivacaine³⁶.

Cardiotoxic threshold of Bupivacaine may be decreased in patients being treated with drugs like digitalis, calcium channel blockers and beta blockers³⁷.

Epinephrine and phenylephrine can increase cardiotoxicity of Bupivacaine induced inhibition of catecholamine induced production of cyclic AMP³⁸.

Bupivacaine blocks cardiac Na⁺ ion channels during systole but due to its high lipid solubility ,it gets dissociated during diastole . This explains its persistent depressant effect on V_{max} and hence greater cardiotoxicity³⁹. The R- enantiomer of Bupivacaine is more cardiotoxic.

Tachycardia can enhance frequency dependent blockade of cardiac sodium channels by Bupivacaine⁴⁰.

Treatment :-

Bretyllium 20mg/Kg IV reverses Bupivacaine induced cardiac depression and hence increases the threshold for ventricular tachycardia⁴¹.

Lipid emulsion infusion is also used for Treatment of cardiotoxicity . Its use is recommended at the earliest sign of toxicity .

Initial bolus of 1.5 ml/Kg 20% lipid emulsion followed by 0.25ml/Kg/min. the infusion should be continued for atleast 10 minutes after circulatory stability is achieved.

Respiratory System :-

Local Anaesthetics in very high plasma levels depress medullary respiratory center which can precipitate decreased oxygenation

Toxicity :-

The toxic plasma concentration is $>3\text{mcg/ml}$ ³⁰ but cardiotoxicity of Bupivacaine becomes evident when plasma concentration are 8 – 10 mcg/ml.

Pharmacokinetics³⁰ :-

Levels of Bupivacaine are detectable in blood 5 minutes after infiltration. Peak blood concentrations depend on the total dosage given and range between 0.14-0.18mcg/ml.

These levels are from 5 mins to 2hrs and slowly reduce to 0.1 to 0.34 mcg/ml in approximately 4 hrs .

Being an amide the liver is the primary site of metabolism of Bupivacaine.

Bupivacaine is secreted in the breast milk and also crosses the placenta but in very less concentrations with feto-maternal concentration ratios ranging from 0.2-0.4⁴²

PHARMACOLOGY OF DEXAMETHASONE

The adrenal cortex synthesizes two classes of steroid :-

- a) Corticosteroids – (Glucocorticoids and Mineralocorticoids). They have 21 carbon atoms.
- b) Androgens – 19 carbon atom

Cortisol is the main glucocorticoid and aldosterone is the main mineralocorticoid.

Corticosteroids are grouped according to their relative potencies in sodium retention, effects on carbohydrate metabolism and anti inflammatory properties.

General Mechanism for Corticosteroid Effects⁴³ :-

Corticosteroids bind to specific receptor proteins in target tissues to regulate the expression of corticosteroid responsive genes , thereby changing the levels and array of proteins synthesized by the various target tissues .

As a result of time required to modulate gene expression and protein synthesis , the effects of corticosteroids are not immediate.

Glucocorticoid receptors:-

The receptors for corticosteroids are members of the nuclear receptor family of transcription factors .These receptors share two highly conserved domains .

- a) Zinc Fingers: - for interaction of the receptor with specific gene sequences.
- b) A region at the carboxyl terminus that interacts with ligands (Ligand Binding Domain) Steroid binding results in receptor activation and translocation to the nucleus whereas the inactive receptor is complexed with other proteins

,including the heat shock protein (HSP).Two genes for corticosteroid receptors are present :-

1. GR- Glucocorticoid Receptor gene
2. MR- Mineralocorticoid Receptor gene

The metabolic effects of glucocorticoids generally are mediated by the transcriptional activation , whereas the anti inflammatory effects are mediated by the transrepression.

Systemic Effects of Glucocorticoids :-

Glucocorticoids have effect on most of the organ systems of the body and also on the metabolism .

- A) Carbohydrate and Protein Metabolism :-**They protect the glucose dependent tissues (brain and heart) from starvation . They stimulate gluconeogenesis and glycogenesis meanwhile also decreasing glucose utilisation ,increasing lipolysis and protein breakdown leading to release of amino acids.The increased serum levels insulin release and.Thus they precipitate the onset of hyperglycaemia in susceptible patients.
- B) Lipid Metabolism :-**corticosteroids cause redistribution of body fat and lead to permissive facilitation of the lipolytic effect of other agents like growth hormone and beta agonists .
- C) Cardiovascular System :-** The main effect is via mineralocorticoid receptors causing changes in sodium excretion by kidneys. They also enhance vascular reactivity to other vasoactive substances eg. Norepinephrine and angiotensin II.

D) Anti Inflammatory and Immunosuppressive Actions: - Corticosteroids profoundly alter the immune responses of lymphocytes . This effect is responsible for the anti inflammatory and immunosuppressive actions. In addition there is decreased release of vasoactive and chemoattractive factors, diminished secretion of lipolytic and proteolytic enzymes , decreased extravasation of leukocytes to areas of injury and finally decreased fibrosis . Glucocorticoids also reduce expression of pro inflammatory cytokines as well as COX 2 and NOS 2.

DEXAMETHASONE

Dexamethasone is a long acting synthetic glucocorticoid with negligible mineralo corticoid activity . It is a 9-Alpha Fluro derivative.

Physiochemical Properties :

Chemical name :- 9 -fluoro-11 ,17 ,21-trihydroxy-16 -methylpregna-1,4-diene-3,20-dione .

Molecular Weight :- 392.4g/mol

Water Solubility :- 89 g/L at 25 °C⁴²

Melting point :- 262 °C

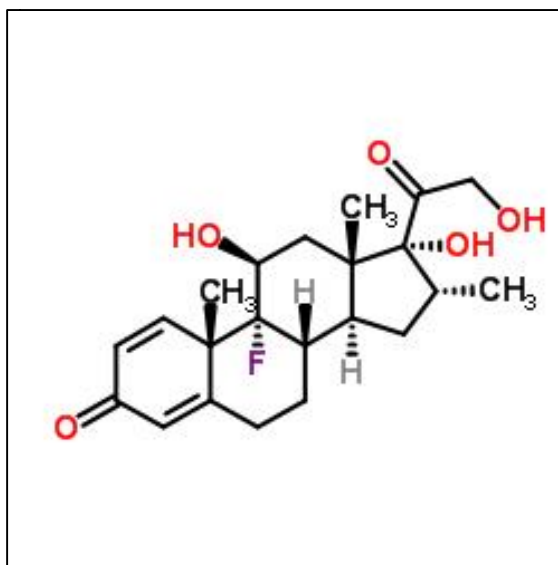


Figure 5. Chemical Structure of Dexamethasone

Pharmacology :-

Introduction of an additional double bond in the position of ring A selectively increases glucocorticoid activity and enhanced glucocorticoid- mineralocorticoid ratio. It also results in compounds that are metabolized more slowly than Hydrocortisone.

Flourination at the 9 α position on ring B enhances both gluco and minrealocorticoid activity .

When combine with the 1,2 double bond in the ring A plus othe substitutions at C16 on ring D the9 α Fluro derivatives like Dexamethasone are formed .

Dexamethasone has marked glucocorticoid activity and the substitutions at C16 have virtually eliminated mineralocorticoid activity ,thus reducing salt retaining properties and thereby the cardiovascular adverse effects .

Potency :- Dexamethasone is 25- 30 times more potent in its anti inflammatory actions compared to Hydrocortisone . whereas when applied topically it is 10 times as potent as Hydrocortisone ⁴³.

Mechanism of action :-The systemic effects of dexamethasone are mediated via its actions on the Glucocorticoid receptors just like the other naturally occurring and synthetic steroids . In addition to binding to specific nuclear steroid receptors, dexamethasone also interferes with NF-kB activation and apoptotic pathways.

Mechanism of action in Regional Anaesthesia :-The use of Dexamethasone as adjuvant in regional anaesthesia is a relatively newer concept and the actual mechanism is under study .

But the present concepts state that :-

- a) Steroids induce a degree of vasoconstriction and hence reduce systemic absorption of local anaesthetic and prolong their actions⁸.
- b) Dexamethasone increases the activity of inhibitory potassium channels on nociceptive C-fibers (via glucocorticoid receptors),reducing their activity and prolonging local anaesthetic activity ^{7,46,47} .

It also reduces ectopic neuronal discharge .

The above mentioned effects of dexamethasone are supplemented by the local anti- inflammatory actions mediated by attenuating the release of inflammatory mediators ^{7,48} .

Pharmacokinetics :-Synthetic steroids are usually synthesized from cholic acid . They are rapidly and completely absorbed when given orally. They are transported and metabolized in a fashion similar to that of the endogenous steroids.

When given IV synthetic steroids achieve high concentrations in the body fluids .

Glucocorticoids are also applied locally(topical). This administration if prolonged or involves large surface area the systemic absorption can be sufficient to cause suppression of HPA axis.

Metabolism and Elimination :-

After absorption >90% of cortisol in plasma is bound to protein. The unbound fraction is active and can enter cells.

Two proteins are responsible for binding i.e. Transcortin and albumin .The metabolism of steroids hormones involves sequential additions of oxygen or hydrogen atoms , followed by conjugation to form water soluble derivatives .

The steroid hormones metabolites formed are conjugated with sulphate or Glucuronide in the liver and to a lesser extent in the kidneys .

The resultant sulphate esters and glucuronides are water soluble and form the predominant forms excreted in urine.

Toxicity :- A single dose of glucocorticoid ,even a large one ,is virtually without harmful effects . Instead abrupt cessation of glucocorticoids after prolonged therapy is associated with the risk of adrenal insufficiency .

Perineural administration of Dexamethasone with local anaesthetics prolongs the duration of analgesia without observed adverse effects ⁷.

Uses of Dexamethasone :-

1. Primary Generalised Glucocorticoid Resistance (Chrousas Syndrome):- High dose of Synthetic glucocorticoids such as Dexamethasone with no inherent mineralocorticoid activity are used.
2. Chronic Adrenal Insufficiency :-4 mg Dexamethasone subcutaneous or IM if patient cannot take orally is given.
3. Congenital Adrenal Hyperplasia :-To suppress foetal adrenal androgen production effectively and consequent virilisation, Dexamethasone 20 mcg/Kg orally is given for mothers at risk starting from before the 10th week of gestation.
4. Bronchial Asthma and other Pulmonary conditions:-Long term glucocorticoid therapy is reserved for patients who have failed to respond to adequate regimens of other medications.
5. Antenatal Glucocorticoids are used frequently in the setting of premature labour, decreasing the incidence of respiratory Distress Syndrome ,intraventricular haemorrhages and death. Dexamethasone 6mg IM every 12 hours for 4 doses, should be given only once .
6. Ocular Diseases :-Used to suppress the inflammation in the eyes , 0.1% Dexamethasone 2 drops is given every 4 hours for awake patients and 0.05% Dexamethasone ointment is applied at bed time.
7. Dexamethasone is used as a first line agent to diagnose Hypercortisolism and to differentiate among various causes of Cushing's Syndrome .

8. Airway edema .
9. Regional Anaesthesia :- Relatively it is a newer application of dexamethasone properties. In combination with Local Anaesthetics, Dexamethasone is used as an adjuvant to prolong the duration of block. Dexamethasone appears to be the best method to prolong analgesia over clonidine , epinephrine or midazolam ⁷.
Dosage :- 4-10 mg of Dexamethasone has been used for this purpose.

The most common is 8 mg of dexamethasone .

Glucocorticoid Antagoists :-

Certain drugs can inhibit the actions of glucocorticoids . They include :-

1. Ketoconazole
2. Mitotane
3. Mifepristone
4. Etomidate
5. Metyrapone
6. Aminoglutethimide

METHODOLOGY

The present study titled **“TO COMPARE EFFICACY OF BUPIVACAINE AND BUPIVACAINE WITH DEXAMETHASONE FOR SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING UPPERLIMB SURGERIES – A ONE YEAR RANDOMISED CONTROLLED TRIAL”** was conducted in the Department of Anesthesiology, Jawaharlal Nehru Medical College KLE University during the period January 2016 to December 2016. A total of 60 patients Belonging to ASA grade I and II between the age group of 18-60 years of either gender scheduled for upper limb surgeries under supraclavicular brachial plexus block at K.L.E`S society Dr. Prabhakar Kore hospital and medical research center, Nehrunagar , Belgaum were included in the study .

a) Selection Criteria :

Inclusion

1. Patients undergoing elective upper limb surgeries (i.e elbow, forearm and hand).
2. Age: 18 to 60 years.
3. ASA Grade I and Grade II patients.

Exclusion

1. Patient refusal to consent.
2. Patients with history of bleeding disorders.
3. Patients with local infection at the site of block.
4. Patients with documented neuromuscular disorders.
5. Patients with respiratory compromise.

6. Patients with known allergy to local anaesthetic drugs.
7. ASA grade III and IV patients.

b) Sample size (n):

From the data available from the previous studies

Using the formula based on mean and standard deviation

$$n = \frac{(z_{\alpha} + z_{\beta})^2 (s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

Where z_{α} is linked with the level of significance and z_{β} is linked with the power of the test.

For 5% level of the significance $z_{\alpha} = 1.96$ and $z_{\beta} = 0.84$ for 80% power of the test.

\bar{X}_1 is the mean of the first group -326

\bar{X}_2 is the mean of the second group -159

s_1 is the standard deviation of the first group -58.6

s_2 is the standard deviation of the second group - 20.1.

For these values the minimum sample size calculated is just 1.

Thus using the thumb rule for minimum sample size for a randomized control trial i.e. 30 patients in each group the total sample size was taken as 60 .

c) Sample procedure:

After obtaining institutional review board and ethical committee clearance 60 patients were allocated in a randomised manner on a sealed envelope technique into one of the two groups of 30 each .

- **Group BS:** Will receive 30ml of 0.5% bupivacaine +2ml of normal saline
- **Group BD:** Will receive 30ml of 0.5% bupivacaine +2 ml (8Mg) of dexamethasone

d) Methodology :

After having met inclusion and exclusion criteria's and having obtained informed consent, a meticulous history and clinical examination was carried out and all the patients were subjected to the routine blood investigations ,

- **Complete Blood count**
- **RBS**
- **Serum creatinine**
- **Urine routine**
- **Chest Xray , ECG**

Anaesthesiologist involved in the data collection as well as the patient will be blinded to the content of the study solution.

Preoperatively the patient's intravenous (IV) line was secured with either 18 G or 20 G branula and IV ringer lactate solution is started at 5 ml/kg/hr. The patient then was shifted to the operation theater and monitors like electrocardiograph (ECG), pulse oximeter and non-invasive blood pressure were attached and baseline reading

was taken. The patient was placed in supine position with upper arm placed by the side of the patient.

Under strict aseptic precautions and preparation of parts the carotid artery was palpated and a skin wheal was injected using a 2ml of lidocaine 2%.

Under ultrasound guidance 23G spinal needle was used to localize the brachial plexus. At this location the subclavian artery is seen beating above the first rib. The brachial plexus lateral to the artery appears like a honeycomb.

23 Gauge spinal needle used was inserted from right side of the probe for right side shoulder and vice versa. Aspiration is done for checking the absence of blood. The spinal needle is inserted into the nerve bundle and nerve sheath and drug was injected and USG view.

The injected volume gently expands the connective tissue surrounding the nerves which is called hydrodissection. This allows the needle a clear path.

Sensory block was assessed by pinprick test using a 3-point scale:

0=sharp pin felt

1=dull sensation felt (analgesia)

2=no sensation felt (anaesthesia).

Motor block was assessed by thumb abduction(radial nerve),thumb adduction(ulnar nerve),thumb opposition(median nerve),and flexion at the elbow (musculocutaneous nerve) on a 3-point scale for motor function

0=normal motor function with full flexion and extension of elbow, wrist and fingers

1=reduced motor strength but able to move fingers

2=complete motor blocks with inability to move fingers.

Sensory and motor block was assessed every 3 minutes until 30 minutes after injection, and then every 30 minutes after the surgery, until they had resolved.

Onset time was defined as the time interval between the end of total local anaesthetic administration and complete sensory block.

Complete sensory block=defined by anaesthetic block (score 2) on all nerve territories.

Duration of sensory block=defined as the time interval between the end of local anaesthetic administration and the complete resolution of anaesthesia on all nerves.

Onset of motor block - the time interval between administration of local anesthetic solution to loss of movements.

Complete motor block=absence of voluntary movements in hand and forearm (score 0).

Duration of motor block= defined as the time interval between the end of local anaesthetic administration and the recovery of complete motor function of the hand and forearm.

Heart rate, systolic arterial blood pressure(SAP),and diastolic arterial blood pressure(DAP) were recorded at 0,5,10,15,30,45,60,90,and 120minutes. Adverse events such as Hypotension were defined as decrease in systolic B.P by 20% from baseline values.

Bradycardia was defined as decrease in heart rate less than 50 beats per minute and hypoxia defined as $SPo_2 < 90\%$,or nausea and vomiting.

Pain was assessed using a visual analog scale(0-10).Nursing staff administered IM diclofenac 75mg when the visual analog scale >4 .

Statistical Analysis:

All the data are expressed as mean +/- SD. Quantitative data was compared using student's unpaired t test while Qualitative data was compared using student's paired t test .

The p value of <0.05 was considered significant.

OBSERVATIONS AND RESULTS

The objective of the present study was to compare the onset and duration of sensory and motor block following administration of either Bupivacaine and Bupivacaine- Dexamethasone in patients undergoing upper limb surgeries following Supraclavicular brachial plexus block performed under Ultrasound guidance. 60 patients were randomly allocated into two groups of 30 each:-

Group BS	Recieved 30 ml of 0.5% bupivacaine + 2 ml of normal saline
Group BD	Recieved 30 ml of 0.5% bupivacaine + 2ml(8mg) Dexamethasone

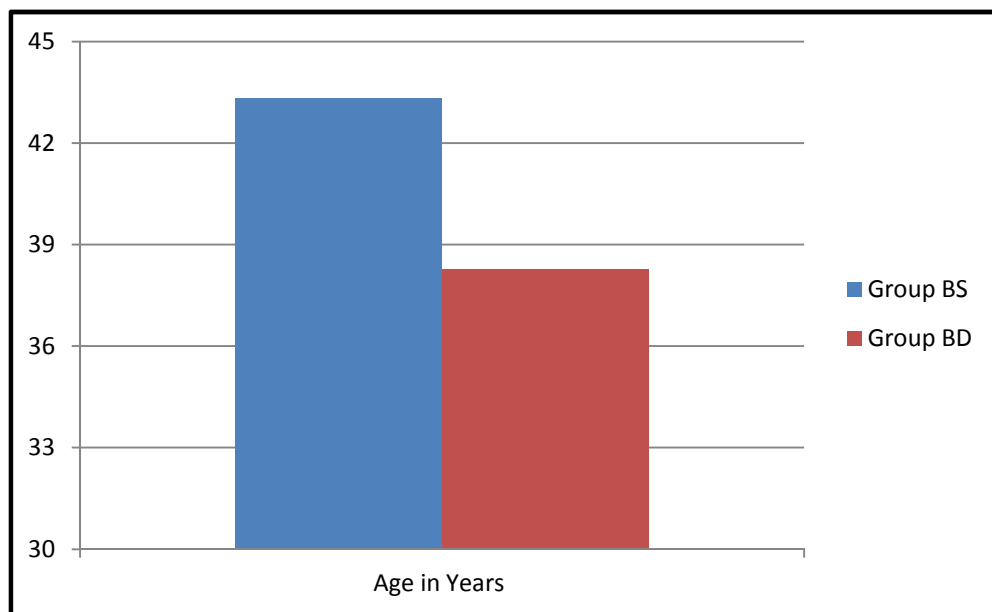
The data obtained were analysed and the observations and results are tabulated as below:

Demographic data:-

AGE – Table 1: Mean age of patients

GROUP	Mean age(in years) + Standard deviation	P- value	Statistical Significance
BS	38.27 ± 13.38	0.1899	NS
BD	43.30 ± 15.90		

Graph 1 – Age Distribution



The mean age in years was 38.27 ± 13.38 in Group BD and 43.30 ± 15.90 in Group BS.

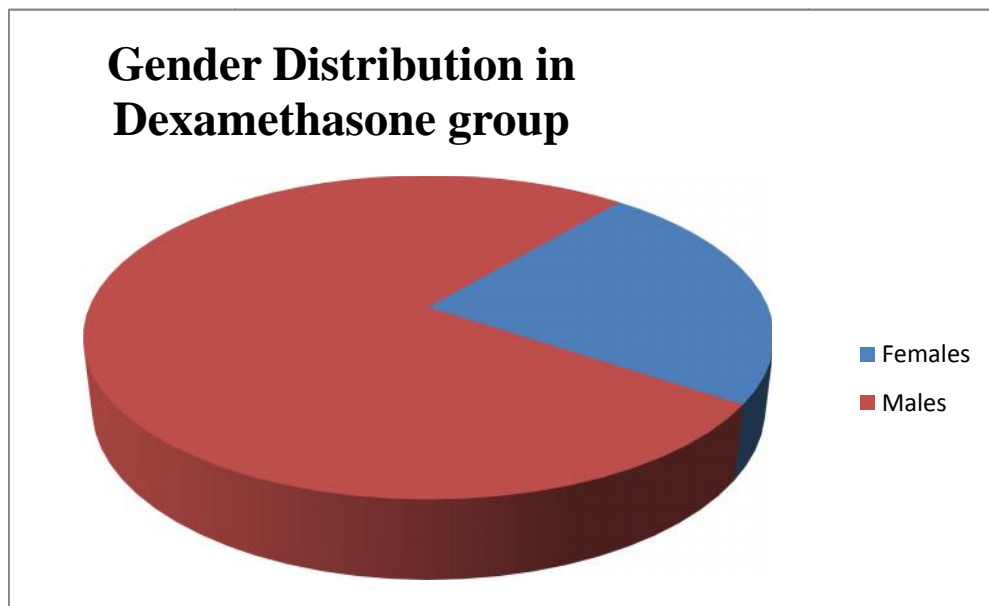
The 2 groups did not differ significantly with respect to their age .

SEX DISTRIBUTION

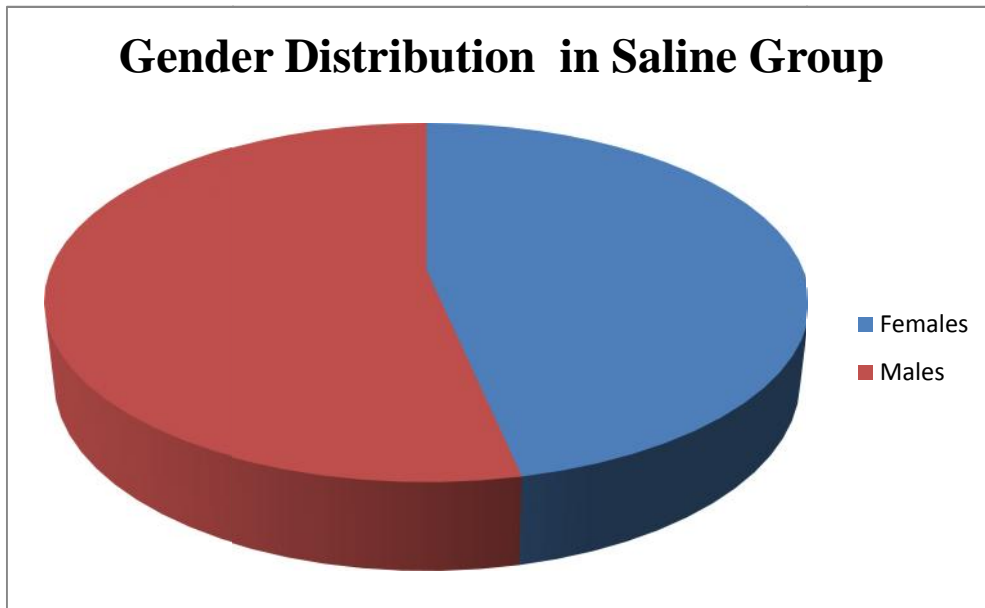
Table 2 : Sex Distribution

GROUP	Group BD	Group BS	TOTAL
FEMALE	7	14	21
MALE	23	16	39
TOTAL	30	30	60

Graph 2 A :-



Graph 2B :



There were 7 females and 23 males in Dexamethasone group and 14 females and 16 males in the Saline group .

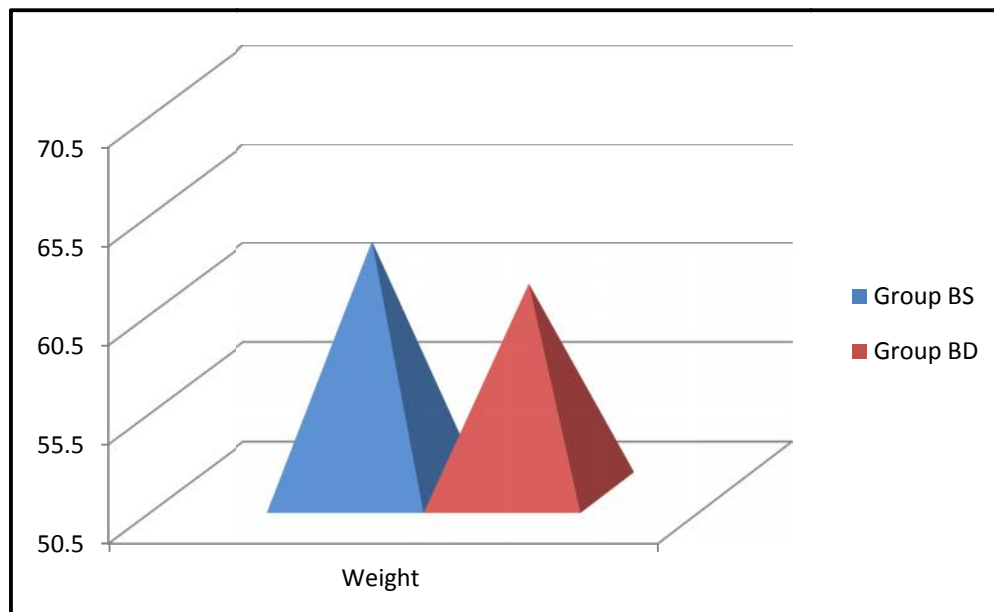
The two groups were comparable with respect to sex distribution with no significant difference between the groups .

Comparison of mean weight between the groups:

Table 3: Mean weight of Patients

Group	Mean Weight (Kg) ± Standard deviation	p-Value	Statistical Significance
Group BS	61.00 ± 6.48	0.2166	NS
Group BD	63.13 ± 6.75		

Graph 4:- Weight Distribution



The mean weight was 61.00 ± 6.48 in Group BS and 63.13 ± 6.75 Kgs in Group BD.

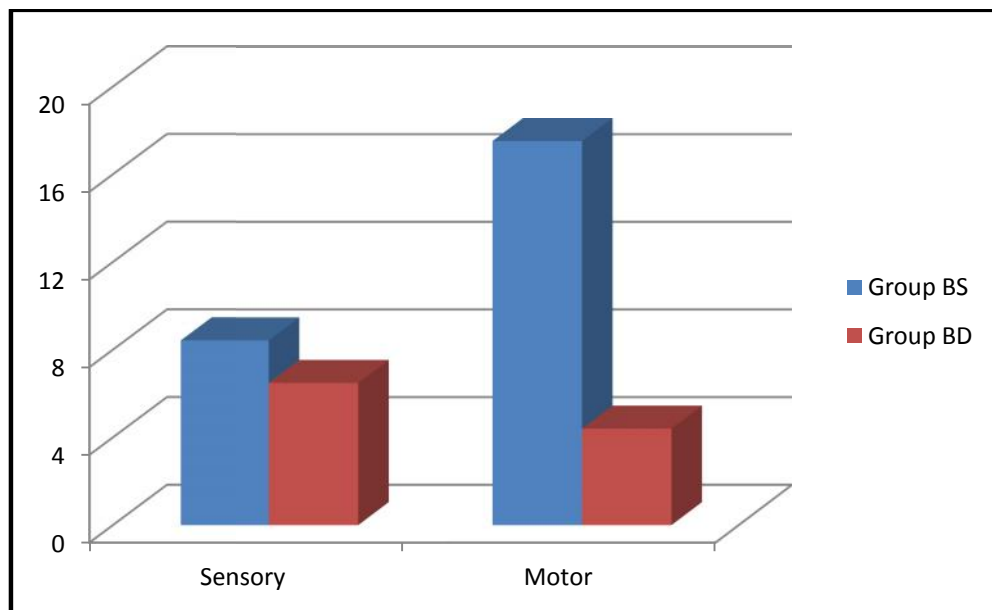
The two groups did not differ significantly with respect to weight of the patients.

BLOCK CHARACTERISTICS

Table 4: Onset time of sensory and motor blockade

	Group BS	Group BD	p-Value	Significance
Onset of Sensory Blockade (min)	8.43 ± 1.04	6.49 ± 1.09	<0.0001	HS
Onset of motor blocked (min)	17.53±1.70	14.63 ± 2.79	<0.0001	HS

Graph 4 :- Onset Times of Sensory and Motor Blockade

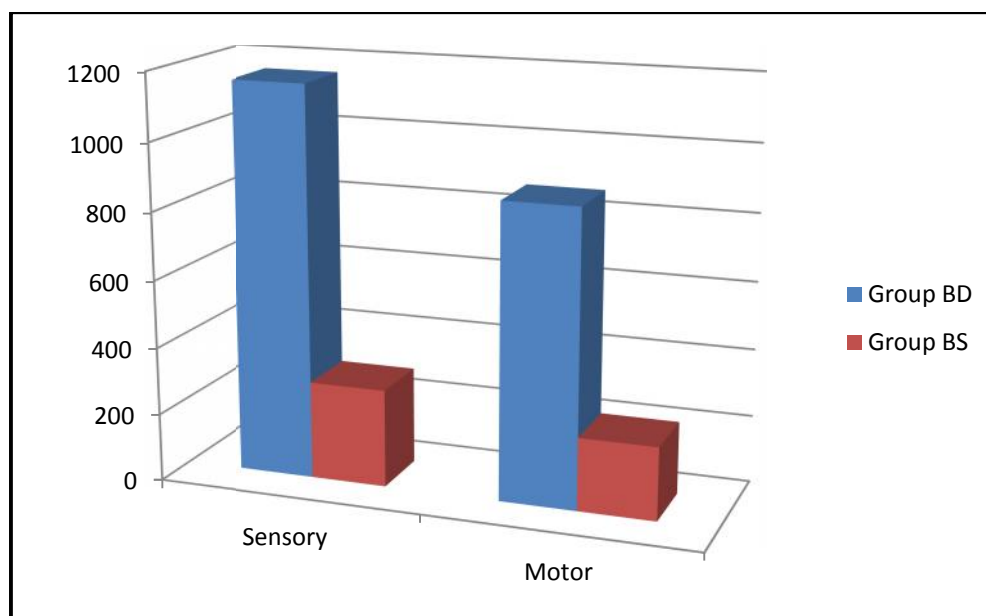


The mean time for onset of sensory blockade was 8.43 ± 1.04 min in Group BS and 6.49 ± 1.09 in Group BD

The mean time for the onset of motor block was 17.53 ± 1.70 in Group BS and 14.63 ± 2.79 the statistical analysis by students unpaired t test showed that there is a significant difference in the mean onset times of sensory and motor block between the two groups with the p-value <0.0001 which was statistically Highly Significant.

Table 5 :- Duration of sensory and Motor Blockade.

	Group BS	Group BD	p-Value	Significance
Duration of sensory Blockade (mins)	289.50 \pm 45.71	1160 \pm 143 .10	<0.0001	HS
Duration of motor Blockade (mins)	216.27 \pm 37.73	870.87 \pm 101.14	<0.0001	HS

Graph 5 :- Duration of Sensory and Motor Blockade

The mean time of duration of sensory Blockade was 289.50 \pm 45.71 in Group BS and 1160 \pm 143.10 in Group BD .

The mean time for the duration of motor Blockade was 216.27 \pm 37.73 in Group BS and 870.87 \pm 101.14 in Group BD.

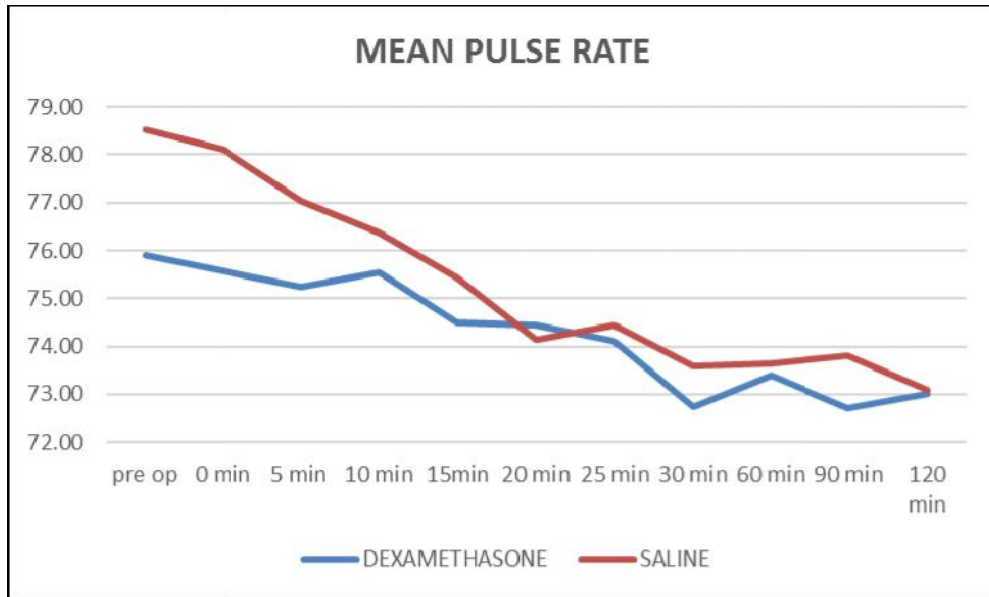
The statistical analysis by Students Unpaired t test showed that there is a significant difference in the duration of sensory and motor block between the two groups with p- value < 0.0001 which was Highly Significant .

Table 6 :- Mean Pulse Rate

	Group BD		Group BS			
GROUP	MEAN	S.D.	MEAN	S.D.	p VALUE	INFERENCE
pre op	75.90	6.50	78.53	8.06	0.1690	NS
0 min	75.57	7.88	78.10	8.27	0.2294	NS
5 min	75.23	7.88	77.03	8.91	0.4104	NS
10 min	75.53	8.57	76.37	9.56	0.7235	NS
15min	74.50	7.50	75.43	9.04	0.6651	NS
20 min	74.43	7.87	74.13	8.05	0.8845	NS
25 min	74.10	6.11	74.43	8.16	0.8584	NS
30 min	72.73	5.51	73.60	8.08	0.6294	NS
60 min	73.40	5.40	73.63	7.84	0.8937	NS
90 min	72.70	5.77	73.80	7.57	0.5294	NS
120 min	73.00	5.65	73.10	7.23	0.9526	NS

NS – Not Significant

Graph 6:- Mean Pulse Rate



The above table shows that the intraoperative mean pulse rate was comparable between the two groups at all points of observation. The difference in the two groups was found to be statistically not significant.

However there was a decline in the mean pulse rates from 0 min to the 120 minutes.

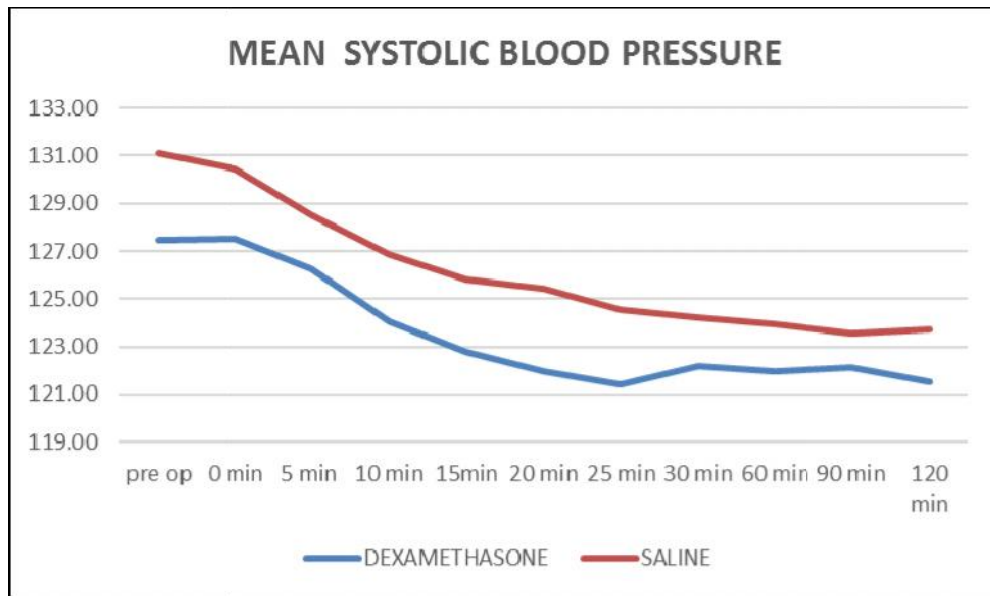
At 0 minutes the mean pulse rate in Group BS was 78.10 ± 8.27 while in Group BD was 75.57 ± 7.88 while at 120 minutes the mean pulse rate was 73.10 ± 7.23 in Group BS and 73.0 ± 5.65 in Group BD.

Table 7 : Mean Systolic Blood Pressure

GROUP	GROUP BD		GROUP BS		p VALUE	INFERENCE
	MEAN	S.D.	MEAN	S.D.		
pre op	127.47	8.72	131.10	6.10	0.0667	NS
0 min	127.53	8.30	130.47	6.88	0.1415	NS
5 min	126.23	8.02	128.53	6.34	0.2230	NS
10 min	124.07	8.78	126.87	6.10	0.1566	NS
15min	122.77	8.83	125.80	6.83	0.1421	NS
20 min	121.97	7.63	125.43	7.18	0.0752	NS
25 min	121.40	7.45	124.53	5.61	0.0709	NS
30 min	122.20	7.28	124.20	5.97	0.2495	NS
60 min	121.93	7.34	123.97	5.67	0.2347	NS
90 min	122.13	7.16	123.53	5.22	0.3904	NS
120 min	121.50	7.28	123.70	5.78	0.2002	NS

NS- Not Significant

Graph 7 :- Mean Systolic Blood Pressure



The above table and graph show that intraoperative systolic Blood Pressure was comparable between the groups at all points of observation .

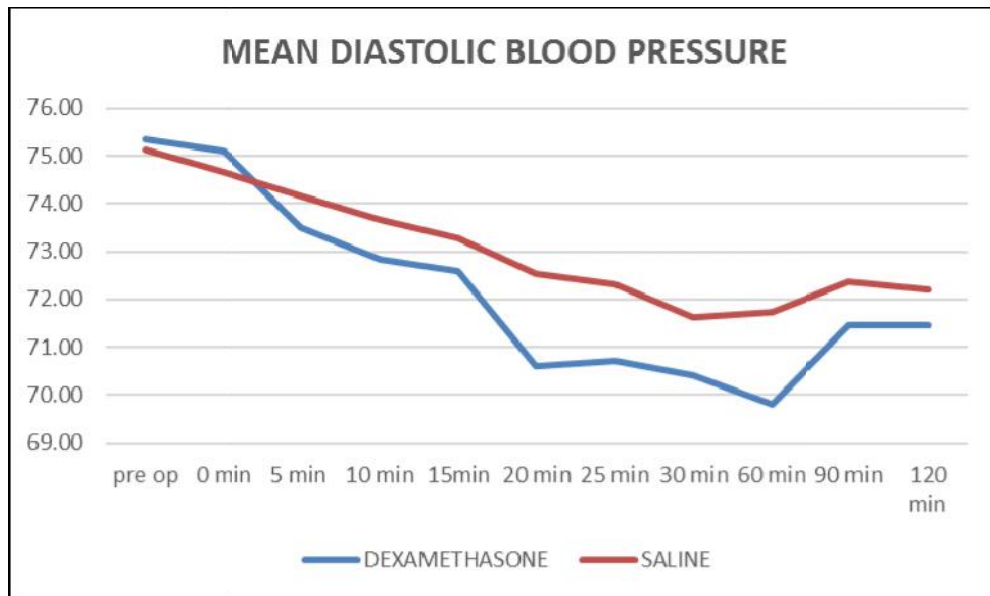
The difference in the two groups was found to be statistically Not Significant .

Table 8 : Mean Diastolic Pressure :

GROUP	GROUP BD		GROUP BS		p VALUE	INFERENCE
	MEAN	S.D.	MEAN	S.D.		
pre op	75.33	6.08	75.13	7.77	0.9120	NS
0 min	75.10	6.42	74.67	6.11	0.7899	NS
5 min	73.50	6.78	74.17	6.47	0.6980	NS
10 min	72.83	6.83	73.67	6.74	0.6361	NS
15min	72.60	7.10	73.27	5.81	0.6921	NS
20 min	70.60	5.85	72.53	6.26	0.2217	NS
25 min	70.70	5.34	72.30	5.84	0.2728	NS
30 min	70.40	5.54	71.63	5.00	0.3693	NS
60 min	69.80	6.53	71.73	4.65	0.1914	NS
90 min	71.47	5.58	72.37	5.10	0.5168	NS
120 min	71.47	5.22	72.20	5.26	0.5901	NS

NS – Not Significant

Graph 8 – Mean Diastolic Pressure



The above table and Graph show that the intraoperative diastolic blood pressure was comparable between both the groups at all points of observation.

The difference observed was found to be statistically Not Significant.

DISSCUSION

Supraclavicular Block is a commonly performed anaesthetic technique for patients under going surgeries on the upper limb. It blocks the plexus at the level of trunks leading to high rates of success making it a popular choice among the anaesthesiologists.

The addition of Ultrasonography has revolutionised the field of anaesthesia more so the field of regional anaesthesia. It has increased the success rates of peripheral nerve blocks and helped avoid complications like inadvertent intravascular injection, pneumothorax and trauma to nerves which was seen with the classical “Blind”/ “Landmark” techniques. It also helps to reduce the total volume of drug required to be injected for anaesthetising the plexus and thereby decreases chances of systemic toxicity of local anaesthetics.

Several studies have compared the effects of Bupivacaine, Ropivacaine and Levobupivacaine in peripheral nerve blocks. Bupivacaine is a long acting local anaesthetic suitable for its use in regional anaesthesia. It blocks transmission of nerve impulses by inhibiting the passage of sodium ions in the nerves and produces a conduction block.

Various adjuvants like midazolam, clonidine, tramadol, neostigmine, Dexmedetomidine etc. have been tried to increase the duration of supraclavicular blocks to provide post-operative analgesia.

The addition of Dexamethasone to regional anaesthesia with local anaesthetics has added a newer aspect to medical uses of corticosteroids. Steroids have very strong

anti-inflammatory and immunosuppressive effects .Perineural injection was found to be safe , devoid of adverse effects , Dexamethasone is a synthetic glucocorticoid , preferred as it is 25- 30 times more potent than hydrocortisone and lacks any mineralocorticoid activity .

The present study is a one year randomised controlled study which was undertaken at Department of Anesthesiology, KLES Prabhakar Kore Charitable Hospital, Belagavi between January 2016 to December 2016. A total of 60 patients were randomised into two groups of 30 each.

Group BS: received 30 ml of Bupivacaine + 2 ml of Normal Saline

Group BD: received 30 ml of Bupivacaine + 2 ml (8mg) of Dexamethasone

The mean Age, Weight, Sex were all found to be comparable and the differences were proven statistically Not Significant.

In our study the mean time of onset of sensory block was 8.43 ± 1.04 min in Group BS and 6.49 ± 1.09 min in Group BD . This was found to be clinically Highly significant with a p -Value <0.0001 . The results of our study are similar to the results of a study conducted by Feroz A Dar et al (2012)⁹ who added dexamethasone to ropivacaine and observed that the onset time in Dexamethasone group for sensory block was 14.65 ± 3.31 mins which was significantly shorter than the control group (17.5 ± 4.2 mins).

In another study by Thi Mum Huynh et. al (2013)¹⁸ in a meta analysis of randomised controlled trials studied 12 trials where dexamethasone was added to local anaesthetic . They concluded that time of onset of sensory block was significantly reduced from 10 mins (control group) by Weighted mean difference

(WMD – 78 secs , 95 % CI , p <0.001) with the addition of dexamethasone to local anaesthetic . This was in concordance with the results of our study.

In our study the mean time for the onset of motor block was 17.53 ± 1.70 in the Group BS and 14.63 ± 2.79 in the Group BD.

A study was conducted by El-Baraday and Elshmaa (2012)¹ where they observed the onset time for motor block with Bupivacaine and Dexamethasone was 11.4 ± 3.6 mins. This result is similar to the findings of our study.

Feroz A Dar et al (2012)⁹ in his study observed that the onset time for motor block was 18.01 ± 4.5 mins in dexamethasone group which was significantly shortened from the control group (20.67 ± 3.03 mins) . This result is similar to that observed in our study.

In our study the mean duration of the duration of sensory block was 289.50 ± 45.71 min in Group BS and 1160 ± 143.10 min in the Group BD. This difference was statistically Highly Significant with a p –Value of < 0.0001. The mean duration of the duration of motor block was 216.27 ± 37.73 min in Group BS and 870.87 ± 101.14 min in the Group BD. This too was found to be statistically Highly Significant with a p- Value of <0.0001.

This result was similar to a study by S.Choi et al ⁷ who conducted a meta analysis of randomised controlled trials and included 9 trials having 801 patients. They observed that that Dexamethasone prolonged the analgesic duration for long acting local anaesthetic from 730 to 1306 minutes while motor block was prolonged from 664 to 1102 minutes without any observed adverse events. The minor differences in the results between our studies can be due to use of varying

concentrations of Dexamethasone i.e. 4- 10 mg whereas we used 8mg for all patients in Group BD.

Similar results were also seen in a study by Vieira PA et al (2008) ¹⁶ who in a randomised study evaluated the effect of Dexamethasone on analgesia with 0.5%Bupivacaine with Epinephrine and Clonidine .The median sensory block duration was (1457 vs.833 min, $P<0.0001$) and motor block duration was (1374 vs. 827 mins $p<0.0001$) when compared with the control .These results though similar are slightly higher than ours .This difference could be due the added vasoconstrictive effects of Epinephrine and also due to addition of Clonidine .

E. Albrecht et. al (2014) ¹⁷ in their study concluded that addition of dexamethasone to local anaesthetic prolonged the duration of both sensory and motor block . The median duration of analgesia (sensory blockade) was increased by 488 mins, when dexamethasone was combined with long action local anaesthetics. This result is in concordance with our findings where the difference due to adding dexamethasone was 871 mins for sensory block.

The difference can be due to the fact that their study included RCTs on all peripheral blocks and also that they studied and compiled the results considering overall all local anaesthetics i.e. both short and medium duration on one side and long duration in the other whereas we studied only Bupivacaine which is a long acting local anaesthetic in only supraclavicular block. Another source of difference in the results can be that the inclusion of multiple studies caused the nerve location methods to vary i.e. Anatomical landmarks , nerve stimulator or ultrasound whereas in our study we standardised it by using ultrasonography for nerve location in both groups of patients .

Thi Mum Huynh et. al (2013)¹⁸ in another meta analysis studied 12 randomised controlled trials and concluded that combining Dexamethasone with local anaesthetics causes prolongation of block . Further on subgroup analysis they concluded that dexmethasone in combination with intermediate or long action local anesthetics nearly doubles the duration of action of the block. .This is similar to the findings in our study where sensory block was increased by 871 mins and motor block was increased by 654 mins.

Prashant A Biradar et al (2013)³ in their study concluded that dexamethasone caused prolongation of action of lignocaine for both sensory and motor block. This is similar to findings in our study where action of Bupivacaine was prolonged.

The addition of dexamethasone induces vasoconstriction, blocks ectopic neuronal discharges and prevents the release of inflammatory mediators. The prolonged duration of sensory and motor blockade and analgesia observed in dexamethasone group can be attributed to the fact that dexamethasone increases the activity of inhibitory potassium channels on nociceptive C- fibres (via glucocorticoid receptors) reducing their activity and prolonging local anaesthetic activity .The different mechanisms of action of the two drugs when combined have an additive effect .

The haemodynamic parameters like heart rate, systolic and diastolic blood pressures were stable in both the groups in our study. This was similar to the results of the study conducted by El Baraday and S Elshmaa¹.

Thus ultrasound guided supraclavicular brachial plexus block using 0.5% bupivacaine and 8 mg dexamethasone can provide adequate intra-operative and post – operative analgesia when used for patients undergoing upper limb surgeries .

LIMITATIONS OF THE STUDY

The volume of injection was 32 ml in our study. Now that ultrasonography is being used commonly in regional anaesthesia it increases the efficacy and the reliability of blocks. Further studies can be undertaken to identify the benefit of adding dexamethasone to smaller volumes of local anaesthetic.

CONCLUSION

In conclusion, Dexamethasone shortens the onset and prolongs the duration of sensory and motor blockade effectively and enhances the quality of blockade when used as an adjuvant to Bupivacaine in Supraclavicular block, with minimal haemodynamic changes thus making Dexamethasone a potential adjuvant for peripheral blocks

SUMMARY

In this prospective randomised control trial , 60 ASA grade I and II patients were randomly enrolled to receive 30 ml of 0.5% Bupivacaine with 2 ml of normal saline (Group BS) and 30 ml of 0.5% Bupivacaine with 2 ml (8mg) Dexamethasone (Group BD). The onset, duration of sensory and motor block were compared between the two groups.

There was observed a significant decrease in the onset of sensory block in Group BD (6.49 ± 1.09 min) compared to Group BS (8.43 ± 1.04 min). There was also a significant decrease in the onset of motor block in Group BD (14.63 ± 2.79 min) compared to Group BS (17.53 ± 1.70 min).

The mean duration of sensory and motor block was prolonged in Group BD (1160 ± 143.10 min and 870.87 ± 101.14 min) compared to Group BS (289.50 ± 45.71 min and 216.27 ± 37.73 min) respectively.

The haemodynamic changes between the two groups were both statistically and clinically not significant.

Hence we conclude that dexamethasone shortens the onset and prolongs the duration of sensory and motor blockade enhancing the quality of block when it is used as an adjuvant to bupivacaine in supraclavicular brachial plexus block for upper limb surgeries.

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ANNEXURE-I

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. _____ we are requesting you to enroll yourself in study titled **“TO COMPARE THE EFFICACY OF BUPIVACAINE AND BUPIVACAINE WITH DEXAMETHASONE FOR SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING UPPERLIMB SURGERIES – A ONE YEAR RANDOMISED CONTROLLED TRIAL”**, conducted by Dr. _____, Post Graduate in M.D. Anaesthesiology under the guidance of Dr. _____, Professor, Department of Anaesthesiology, J.N. Medical College, Belgaum under KLE university, Belgaum.

Respected Sir/Madam we request you to enroll yourself to participate in our study as you are eligible for participating in the study. During the study you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide to participate you are free to withdraw at any time.

The purpose of research is to compare efficacy between bupivacaine and bupivacaine – dexamethasone on onset and duration of motor block, onset and duration of sensory block, upper limb surgeries under SUPRACLAVICULAR brachial plexus block.

Procedure Involved:

If you agree to enroll yourself in my study, you will be interviewed regarding your present, past and family history, then you will be clinically examined in detail and investigated accordingly. You will be randomly allocated either into study Group A or Group B, and be given the study drug as per the randomisation protocol. You will receive 30 cc of 0.5% bupivacaine (Plain) or 30 cc of 0.5% bupivacaine (plain) plus 2 cc dexamethasone for SUPRACLAVICULAR brachial plexus block.

Risks and Benefits:

The benefits of taking part in this research are that we can avoid General Anaesthesia with good quality of Analgesia during and after the surgery. The risks of the procedure as such are minimal but with the use of the new drug dexamethasone you may have mild side effects which include, paraesthesia and sedation.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change present or future health care services offered to you at K.L.E.S hospital.

Alternatives:

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality:

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of any side effects related to the study, treatment will be made available through KLES Hospital & MRC, Belgaum. There is no compensation or payment for such medical treatment by law.

Questions:

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact Dr. _____ Department of Anaesthesiology, KLES Hospital and MRC, Ph. No. _____ or phone number: 8150947091. Or Dr. _____, Professor, Dept. Of Anaesthesiology, KLES Hospital and MRC, Belgaum Ph.: _____

If you have any queries about your rights as a study subject, you may call Dr. _____, Prof. of Pathology as Chairman of J. N. Medical College Institutional Ethical Committee on Human Subjects Research, Phone No. _____ at J. N. Medical College, Belgaum.

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL

I, _____ voluntarily agree for the participation as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read form in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or the Left Thumb Print of Subject : _____ Date :

Witness Name: _____ Signature: _____ Date :

Investigators Name: _____ Signature: _____ Date :

Place : _____

ANNEXURE-II

PROFORMA

“TO COMPARE EFFICACY OF BUPIVACAINE AND BUPIVACAINE WITH DEXAMETHASONE FOR SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK IN PATIENTS UNDERGOING UPPERLIMB SURGERIES – A ONE YEAR RANDOMISED CONTROLLED TRIAL”

Name & Address of the patient: _____

Age of the Patient: _____

IP. No. _____

Weight of Patient: _____

Random No. _____

Anaesthesiologist : _____

Surgeon : _____

PREANAESTHETIC EVALUATION:

Chief Complaints:

Past History:

1. HTN/ DM/Asthma/Drug allergy:
2. Drug therapy:
3. Previous exposure to anaesthesia:

Family History

I. General Physical Examination:

Weight: Temperature:

Pallor/ Icterus/ Cyanosis/Clubbing/ Lymphadenopathy/ Oedema

Pulse : B.P: RR:

M.P Grading

Teeth: Mouth opening:

Jaw examination:

SYSTEMIC EXAMINATION:

Respiratory System:

Cardiovascular System:

Central Nervous system:

Per Abdomen:

Spine assessment:

INVESTIGATIONS:

Complete Blood count: RBS: Serum Creatinine:

Urine routine: Chest X-ray:

ECG:

Any others:

Pre-operative physical status: ASA grade **I** **II**

Diagnosis:

Proposed Surgery:

Selection Criteria:

Inclusion

1. Patients undergoing upper limb surgeries.
2. Age: 18 to 60 years.
3. ASA Grade I and Grade II patients

Exclusion

1. Patients who refuse.
2. Patients with history of bleeding disorders.
3. Patients with local infection at the site of block.
4. Patients with documented neuromuscular disorders.
5. Patients with respiratory compromise.
6. Patients with known allergy to local anaesthetic drugs.
7. ASA grade III and IV patients.

Procedure: After having met inclusion and exclusion criteria's and having obtained informed consent, patients will be randomized based on a sealed envelope technique into one of the two groups.

- **Group BS:** Will receive 30ml of 0.5% bupivacaine +2ml of normal saline

- **Group BD:** Will receive 30ml of 0.5%BUPIVACAINE +2 ml (8Mg) of dexamethasone

Anaesthesiologist involved in the data collection as well as the patient will be blinded to the content of the study solution.

Preoperatively the patient's intravenous (IV) line will be secured with either 18 G or 20 G branula and IV ringer lactate solution is started at 5 ml/kg/hr. The patient then will be shifted to the operation theater and monitors like electrocardiograph (ECG), pulse oximeter and non-invasive blood pressure will be attached and baseline reading is taken. The patient will be placed in supine position with upper arm placed by the side of the patient.

Under strict aseptic precautions and preparation of parts the carotid artery will be palpated and a skin wheal was injected using a 2ml of lidocaine 2%.

Under ultrasound guidance 23G spinal needle was used to localize the brachial plexus. At this location the subclavian artery is seen beating above the first rib .The brachial plexus lateral to the artery appears like a honeycomb.

23 Gauge spinal needle used was inserted from right side of the probe for right side shoulder and vice versa. Aspiration is done for checking the absence of blood. The spinal needle is inserted into the nerve bundle and nerve sheath and drug was injected and USG view.

The injected volume gently expands the connective tissue surrounding the nerves which is called hydrodissection. This allows the needle a clear path.

Sensory block will be assessed by pinprick test using a 3-point scale:

0=sharp pin felt

1=dull sensation felt (analgesia)

2=no sensation felt (anaesthesia).

Motor block will be assessed by thumb abduction (radial nerve),thumb adduction(ulnar nerve),thumb opposition(median nerve),and flexion at the elbow (musculocutaneous nerve) on a 3-point scale for motor function

0=normal motor function with full flexion and extension of elbow, wrist and fingers

1=reduced motor strength but able to move fingers

2=complete motor blocks with inability to move fingers.

Sensory and motor block was assessed every 3 minutes until 30 minutes after injection,and then every 30 minutes after the surgery,until they had resolved.

Onset time will be defined as the time interval between the end of total local anaesthetic administration and complete sensory block.

Complete sensory block=defined by anaesthetic block (score 2) on all nerve territories.

Duration of sensory block=defined as the time interval between the end of local anaesthetic administration and the complete resolution of anaesthesia on all nerves.

Onset of motor block - the time interval between administration of local anesthetic solution to loss of movements.

Complete motor block=absence of voluntary movements in hand and forearm (score 0).

Duration of motor block= defined as the time interval between the end of local anaesthetic administration and the recovery of complete motor function of the hand and forearm.

Heart rate, systolic arterial blood pressure(SAP),and diastolic arterial blood pressure(DAP) were recorded at 0,5,10,15,30,45,60,90,and 120minutes. Adverse events such as Hypotension will be defined as decrease in systolic B.P by 20% from baseline values.

Pain will be assessed using a visual analog scale(0-10).Nursing staff administered IM diclofenac 75mg when the visual analog scale>4.

Preoperative baseline values

HR:

SBP:

DBP:

Monitors attached

Pulse oximetry :

NIBP :

ECG:

II. Vital parameters:

Time	HR	SBP	DBP
0 min			
5 min			
10 min			
15 min			
20 min			
25 min			
30 min			
60 min			
90 min			
120 min			

Sensory and motor block onset time,block and analgesia duration in groups

Time(mins)	Group BS	Group BD
Time of giving block		
Onset time of sensory block(mins)		
Onset time of motor block(mins)		
Time of onset of pain		
Duration of sensory block (mins)		
Time of starting movements in the limb		
Duration of motor block (mins)		

ANNEXURE III – PHOTOGRAPHS



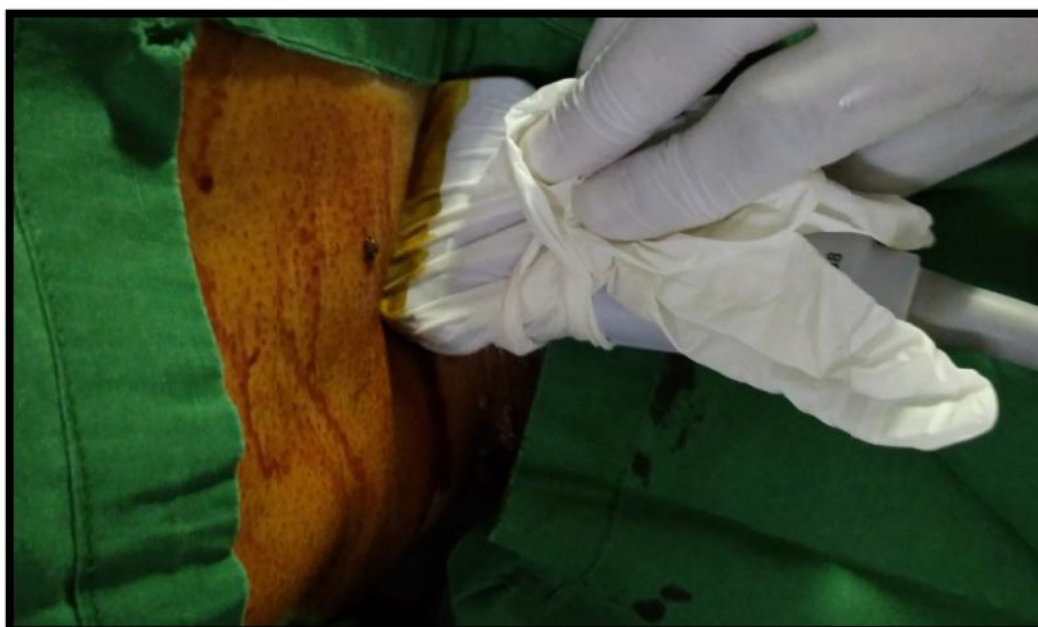
Photograph : 1. Dexamethasone Ampule



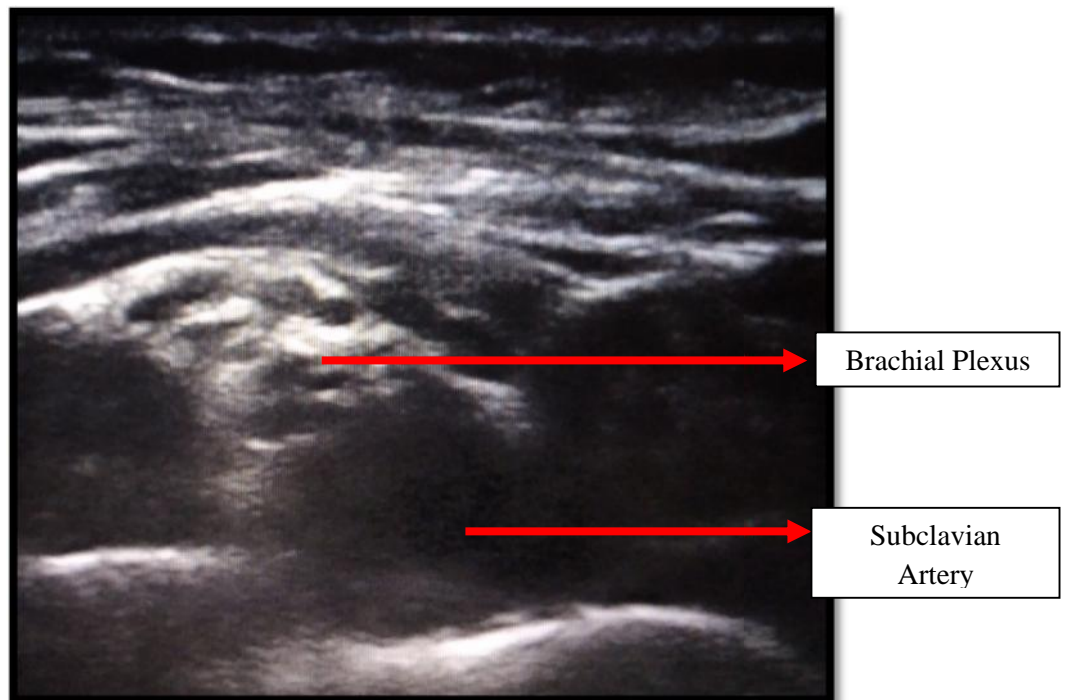
Photograph :2. Bupivacaine Ampule



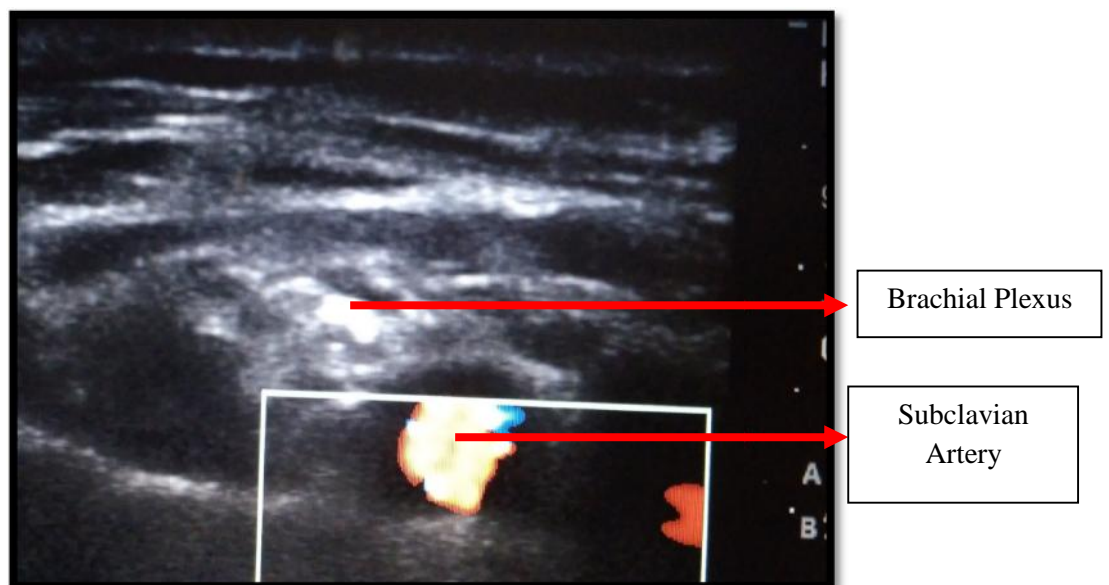
Photograph :3 . SonoSite Ultrasound Machine



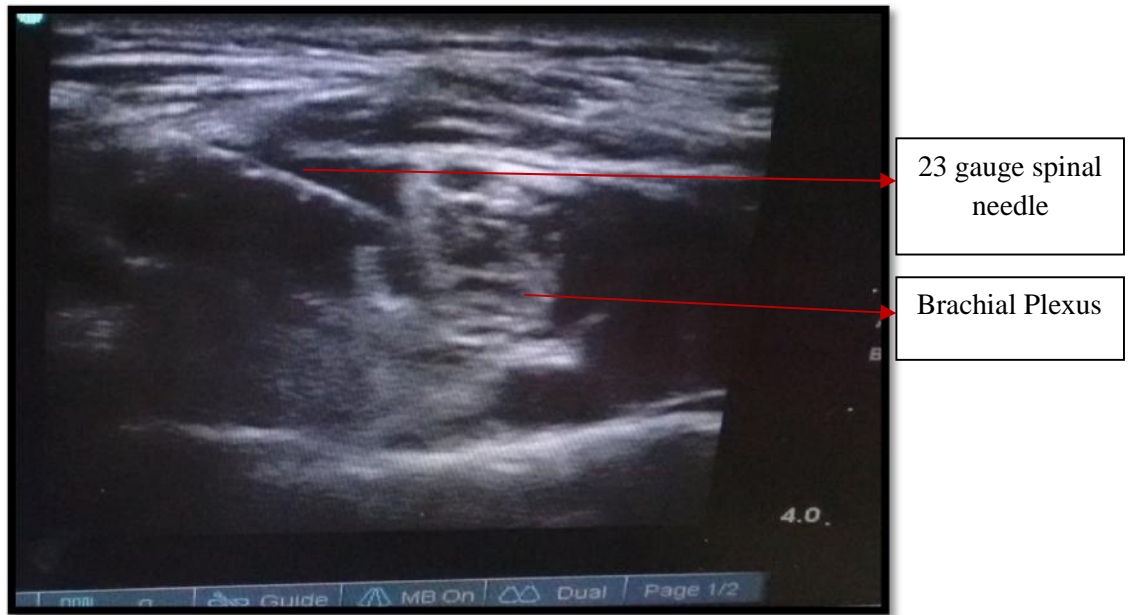
Photograph: 4 . Position of the Ultrasound Probe



Photograph 5. Brachial Plexus Under Ultrasound



Photograph:6. Doppler mode for confirmation of Subclavian Artery



Photograph: 7. Injection of Local anaesthetic under Usg Guidance



Photograph 8. Brachial Plexus with local anaesthetic

S.No.	Age(years)	Sex	IP Number	Randomisation No	Weight(Kgs)	Time of Onset(mins)	Duration of Block (mins)	Pre op		Systolic Blood Pressure (mmHg)												Diastolic Blood Pressure (mmHg)																								
								Sensory	Motor	pre op	0 min	5 min	10 min	15 mins	20mins	25 mins	30 mins	60 mins	90 mins	120 mins	pre op	0 min	5min	10 min	15mins	20mins	25mins	30 min	60 mins	90 mins	120 mins	pre op	0 mins	5mins	10 mins	15 mins	20 mins	25 mins	30 mins	60 mins	90 mins	120 mins				
1	41	M	763005	28	68	6	15	1164	924	70	68	70	##	66	66	68	70	66	68	68	130	130	126	126	126	126	124	126	120	126	122	70	70	70	68	66	66	68	68	66	66	68	68	66	66	68
2	18	M	762181	24	57	6	14	1064	964	70	70	72	##	70	68	68	68	70	70	72	120	120	118	118	118	118	114	114	112	114	116	70	70	68	68	70	66	66	66	70	72	70	72	70	72	
3	45	M	760681	25	68	5	17	1180	910	76	76	74	##	74	70	70	68	68	66	68	130	130	120	120	118	120	120	118	116	116	116	76	76	76	70	68	68	70	68	70	70	74	74			
4	25	F	759891	20	56	6	18	1229	955	84	84	80	##	80	88	80	84	80	82	84	124	120	124	118	120	120	120	124	122	124	110	79	76	72	74	74	74	79	72	70	74	74	74			
5	48	F	693174	1	68	6	12	1424	984	70	70	72	##	64	70	70	72	72	74	68	114	114	110	118	110	118	118	110	114	114	70	70	60	62	70	64	68	68	60	62	62	62				
6	31	M	757037	30	60	8	15	1102	855	80	80	76	##	76	72	74	74	70	72	72	136	136	136	130	130	128	130	130	126	120	120	72	72	72	72	74	72	70	70	68	70	70				
7	36	M	758519	19	68	5	12	1187	1077	80	80	70	##	74	76	74	76	80	80	80	114	120	118	114	114	118	118	118	114	114	114	70	70	68	68	72	76	70	68	70	76	76				
8	18	M	755125	18	60	5	17	1075	950	80	80	76	##	80	78	78	74	78	80	78	130	130	124	124	124	120	120	122	124	118	118	80	80	72	72	78	70	72	72	64	72	70	70			
9	36	F	721441	9	65	8	12	1390	880	68	68	70	##	84	76	80	74	82	70	70	110	124	124	122	118	110	110	112	12	130	138	70	70	68	70	62	72	64	60	62	72	82	82			
10	60	M	731662	31	63	8	12	1042	788	80	80	82	##	84	90	82	76	78	74	76	140	140	130	136	136	136	130	130	130	136	130	90	90	88	88	88	84	84	80	82	84	80	80			
11	35	M	719304	8	50	6	12	1008	798	80	80	88	##	78	78	70	74	70	72	70	130	130	128	128	120	120	118	120	130	130	130	80	80	76	76	64	64	66	66	70	74	74	74			
12	55	F	761180	15	50	5.3	10	1380	840	80	78	72	##	74	70	82	78	78	70	78	150	150	152	150	152	140	140	140	140	140	138	80	80	80	76	80	70	70	68	70	80	78	78			
13	27	M	771625	34	70	7	16	996	816	73	70	74	##	73	74	73	72	73	74	74	130	130	128	118	128	118	120	120	120	118	116	70	70	70	70	70	70	68	68	68	70	70	70			
14	37	F	751154	16	56	5	11	1435	1025	78	80	78	##	76	80	84	74	76	74	80	118	114	120	118	118	112	110	112	118	118	120	78	78	76	80	76	74	68	68	64	70	72	72			
15	26	M	774974	46	60	7	17	1516	1066	90	95	90	##	85	84	84	83	80	78	78	120	120	120	115	115	118	118	118	118	116	116	75	75	75	78	78	70	72	80	78	78	76	76			
16	28	M	720771	17	62	7	15	1183	993	66	62	58	##	62	62	60	62	65	68	68	110	110	118	112	118	112	114	112	114	120	114	76	76	70	74	70	72	70	68	68	70	76	76			
17	38	M	733945	12	68	5	11	1080	860	80	88	88	##	85	72	72	68	70	68	70	130	128	130	110	110	114	114	112	114	110	112	80	80	80	76	78	70	68	70	68	70	68	70	68		
18	20	M	713471	2	60	6	13	1040	865	68	65	60	##	62	64	68	64	62	60	60	120	120	110	110	110	118	110	114	112	112	114	68	60	58	60	59	62	60	58	58	60	60	60			
19	24	M	717669	3	66	7	18	1015	695	70	70	72	##	74	72	72	74	76	76	72	130	130	132	132	128	126	126	124	126	126	126	70	72	74	78	78	70	70	70	70	70	68	68			
20	28	M	782766	54	69	8	15	1182	875	88	88	82	##	80	82	80	78	78	78	76	130	130	126	126	126	126	124	126	120	120	120	70	70	68	68	68	66	68	68	64	64	64	64			
21	25	M	718456	4	70	7	13	1058	692	80	80	78	##	88	90	80	74	76	80	80	130	130	124	130	120	124	130	132	132	130	130	80	80	80	70	68	68	70	68	68	70	68	68	68		
22	57	M	784514	55	68	6	15	1084	755	70	68	68	##	68	64	68	64	68	68	68	130	130	128	126	118	118	120	122	122	122	118	70	70	72	70	72	70	70	68	72	70	70	70			
23	60	F	773753	43	58	8	18	1050	870	64	64	66	##	60	62	64	66	68	62	62	130	130	132	128	130	126	126	126	124	124	124	72	72	74	72	72	70	70	72	72	72	72	72			
24	32	M	718630	7	65	5	9	995	686	80	80	88	##	80	84	80	82	80	84	80	130	128	128	130	124	134	122	122	118	120	124	86	86	80	82	80	74	72	80	80	76	76	76			
25	60	F	711211	47	60	8	17	1126	796	80	72	80	##	72	73	73	78	80	78	78	130	134	130	132	130	128	130	130	132	128	128	76	76	77	76	70	70	70	70	72	80	80	76	76		
26	60	M	784060	53	60	7	17	1233	853	70	69	69	##	68	70	72	68	68	68	72	128	128	128	126	126	126	120	120	118	118	119	72	72	72	70	72	70	70	70	72	72	74	74			
27	48	M	784161	48	70	7	15	1158	820	80	80	82	##	80	82	80	74	76	74	74	130	130	128	126	128	126	126	128	122	124	122	76	76	72	72	74	74	72	74	74	76	72	72			
28	48	M	784328	56	78	6	18	1102	862	74	74	72	##	72	70	72	68	70	68	70	132	132	132	132	120	120	130	130	130	124	126	76	76	76	75	72	72	70	70	72	68	68	68			
29	39	M	771625	39	70	8	20	1052	842	78	80	80	##	78	75	75	75	74	75	76	138	138	135	132	133	133	130	132	134	132	130	90	90	91	90	92	90	86	86	84	78	72	72			
30	43	M	706118	60	51	6.5	15	1265	830	70	68	70	##	68	71	70	70	70	70	68	130	120	128	115	115	114	110	114	118	120	120	68	70	70	60	63	60	80	72	58	62	62	62			

S.No.	Age(years)	Sex	IP Number	Randomisation No.	Weight(Kgs)	Onset of Block (mins)		Duration of Block (mins)		Pulse Rate (per min)		Systolic Blood Pressure (mmHg)												Diastolic Blood Pressure (mmHg)																					
						Sensory	Motor	Sensory	motor	pre op	0 min	5 min	10 min	15min	20 min	25 min	30 min	60 min	90 min	120 min	pre op	0 min	5 min	10 min	15min	20 min	25 min	30 min	60 min	90 min	120 min														
1	45	F	760804	22	55	9	18	322	262	85	84	88	78	74	70	70	72	68	67	68	140	141	138	138	138	138	130	130	132	128	130	88	80	84	90	90	82	84	80	78	82	82			
2	18	F	747546	14	56	10	20	350	260	88	82	84	86	88	80	82	84	86	84	84	130	128	128	126	126	126	120	122	124	120	118	70	72	72	73	74	74	72	74	74	74	74	74		
3	19	M	726480	11	78	8	20	265	220	78	78	80	76	78	86	80	82	76	78	77	130	130	125	120	122	122	118	122	120	118	118	70	70	72	70	72	70	72	72	68	70	72	72		
4	43	F	766288	57	59	10	19	270	220	80	80	82	78	76	70	70	72	70	70	70	130	130	128	128	128	118	119	118	118	116	116	80	80	78	78	74	74	74	72	76	74	72	72		
5	46	M	720009	10	58	8	15	285	225	78	80	76	82	88	78	80	80	80	78	80	130	118	118	116	118	118	116	120	120	122	126	70	70	70	72	72	68	70	70	72	72	74	74		
6	60	M	711105	5	52	8	15	248	215	90	92	90	100	88	88	90	84	90	90	84	118	120	118	120	110	110	118	118	120	120	118	60	64	60	64	62	60	64	64	70	80	80	80		
7	57	F	701030	59	61	10	21	272	195	90	88	84	84	82	84	86	78	78	78	74	136	136	130	132	132	130	128	130	130	130	132	76	74	74	72	72	72	68	70	70	72	72	72		
8	60	M	761777	26	60	9	16	253	193	62	60	62	60	58	56	60	58	63	62	60	136	130	130	128	128	130	128	124	126	126	128	76	76	70	70	76	76	78	76	72	74	74	74		
9	23	M	714397	6	60	10	18	270	205	80	80	84	84	78	76	78	78	79	80	80	126	126	120	128	128	118	120	118	118	120	118	80	80	78	80	80	82	76	68	70	68	70	68	68	
10	58	M	766709	27	56	9	18	293	248	78	70	66	66	65	66	64	62	64	66	68	136	130	130	128	126	126	128	126	122	122	126	70	70	76	68	68	64	66	66	62	64	64	64		
11	60	M	769825	32	65	8	15	242	182	70	70	72	68	65	64	64	64	62	63	64	130	134	134	130	130	130	132	130	132	132	132	78	78	72	73	73	78	78	76	74	74	72	72		
12	19	F	710610	58	57	10	16	280	190	90	90	92	90	91	88	86	86	78	78	78	130	130	130	124	124	124	120	120	124	124	124	70	70	72	64	66	66	64	64	66	64	66	64	66	
13	58	M	771186	33	69	8	16	262	187	70	70	64	66	62	64	64	62	63	64	64	138	136	132	132	136	133	130	132	125	128	128	80	80	80	80	82	83	82	80	80	80	80	82	82	
14	58	F	729399	50	50	7	18	333	253	80	80	82	82	83	82	80	80	82	82	82	117	117	120	110	112	112	113	111	112	112	113	70	70	70	72	73	72	73	74	73	73	73	74	74	
15	60	F	780842	52	58	9	18	423	315	66	66	66	64	64	64	64	62	63	64	65	130	132	130	132	132	126	126	122	123	124	124	78	78	78	74	74	72	72	74	76	76	76	76	76	
16	60	F	769631	36	60	8	18	257	197	74	73	72	70	72	73	72	72	73	73	72	126	126	126	124	120	122	122	120	118	118	118	80	80	82	82	80	80	82	80	80	82	80	80	82	82
17	35	M	765900	41	62	8	19	302	242	80	80	70	78	78	76	77	77	76	76	72	130	130	128	130	130	136	130	132	132	130	132	70	70	70	70	72	76	74	74	74	74	72	72	72	
18	35	M	777522	51	67	8	19	312	211	72	72	70	72	74	70	68	68	70	72	70	132	130	128	128	125	128	128	128	126	126	126	68	68	68	64	64	65	64	64	65	66	66	66	66	
19	60	F	769637	35	60	8	16	287	202	73	73	72	70	72	73	74	73	72	72	70	126	126	126	124	120	122	122	118	118	120	120	80	80	80	82	80	80	80	78	76	76	74	74	74	
20	44	M	760124	21	70	10	16	210	149	66	66	64	60	62	62	64	62	60	62	60	120	120	118	118	114	116	116	115	115	114	114	70	70	66	66	66	62	64	64	64	64	62	60	60	
21	48	M	772176	42	68	7	15	293	233	90	90	88	89	84	80	80	82	82	80	80	130	130	130	130	125	128	128	130	128	122	120	76	76	74	76	72	74	74	70	72	76	76	76	76	
22	18	M	761129	37	60	7	18	313	225	76	76	74	80	76	76	78	80	78	78	76	130	130	132	120	122	122	122	124	122	124	122	70	70	70	72	70	70	72	76	74	74	74	72	72	
23	18	F	734634	13	50	8	20	232	172	90	90	88	82	86	80	82	82	80	84	86	130	130	120	122	118	118	118	116	116	118	118	70	70	70	70	74	70	70	70	74	74	74	74	74	
24	45	F	772957	44	68	7	18	233	165	70	70	68	64	66	66	66	64	66	62	66	130	130	132	132	130	130	130	128	130	128	122	70	70	68	68	72	72	70	70	72	72	72	70	70	
25	37	F	798822	38	58	8	18	302	190	82	80	76	76	74	76	74	72	80	76	76	142	140	140	136	136	130	130	130	130	132	130	90	90	88	82	76	76	76	72	72	72	72	70	70	
26	29	M	799150	49	65	8	17	382	283	80	80	78	72	72	76	78	76	74	74	76	136	136	132	132	130	130	130	132	128	128	128	72	72	72	74	72	72	72	70	69	70	72	72	72	
27	22	M	774464	40	72	8	19	337	247	80	80	78	82	82	78	76	77	74	77	74	138	138	130	130	128	128	128	126	128	126	126	76	76	77	76	72	74	72	73	73	72	72	72		
28	54	F	763038	29	56	8	16	254	179	70	70	68	68	66	68	65	65	66	70	65	130	130	128	130	128	122	124	122	122	122	130	70	70	70	66	66	60	60	62	62	64	64	64	64	
29	60	F	773198	45	58	7	16	283	173	88	88	88	84	84	80	86	80	82	82	80	136	130	130	128	128	130	130	130	128	128	122	76	76	74	74	74	76	72	72	70	70	70	68	68	
30	50	M	762810	23	62	10	18	320	250	80	85	85	80	75	74	75	74	74	72	72	140	150	145	130	130	140	132	132	130	130	100	90	90	88	80	76	74	74	74	74	74	72	72	72	

ANNEXURE – VI – ETHICAL CLEARANCE LETTER



K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
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Ref: MDC/DOME/366

Date: 16/11/2015

To,

PG student in Anaesthesiology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled "COMPARISON OF BUPIVACAINE AND BUPIVACAINE WITH DEXAMETHASONE FOR SUPRACLAVICULAR BLOCK IN PATIENTS UNDERGOING UPPER LIMB SURGERIES – A ONE YEAR RANDOMIZED CONTROLLED TRIAL", is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Ganga Pilli)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.