"A STUDY ON THE EFFECT OF NALBUPHINE AS AN ADJUVANT TO BUPIVACAINE IN ULTRAOUND GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS NERVE BLOCK"

Dissertation submitted in partial fulfillment of the requirements for award of the degree M.D. (Anaesthesiology) Branch X

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MAY 2019

DECLARATION BY THE GUIDE

This is to certify that this dissertation entitled **"A STUDY ON THE EFFECT OF NALBUPHINE AS AN ADJUVANT TO BUPIVACAINE FOR ULTRAOUND GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS BLOCKS "** submitted by **Dr.SHALINI LAL**

in partial fulfillment for the award of the degree Doctor of Medicine in Anaesthesiology by **The Tamilnadu Dr.M.G.R. Medical University, Chennai** is a bonafide work done by her at **GOVERNMENT KILPAUK MEDICAL COLLEGE, CHENNAI** during the academic year 2016-2019, under my guidance and supervision.

Prof.Dr.A.Chandrasekhar M.D;D.A,

Professor Of Anaesthesiology ,

Department of Anaesthesiology,

Govt. Kilpauk Medical College,

Chennai – 10.

DECLARATION

I, **Dr.SHALINI LAL,** solemnly declare that this dissertation, entitled **"A STUDY ON THE EFFECT OF NALBUPHINE AS AN ADJUVANT TO BUPIVACAINE FOR ULTRASOUND GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS NERE BLOCKS"** has been prepared by me, under the expert guidance and supervision of Prof. A.Chandrasekhar M.D;D.A, Professor, Department of Anaesthesiology, Government Kilpauk MedicalCollege and Hospital, Chennai and submitted in partial fulfillment of theregulations for the award of the degree **M.D.(Anaesthesiology)** by **TheTamil Nadu Dr. M.G.R. Medical University** and the examination to be held in May 2019.

This study was conducted at Government Kilpauk Medical College Hospital and Government Royapettah Hospital, Chennai. I have not submitted this dissertation previously to any university for the award of any degree or diploma.

Place: Chennai

Date:

DR.SHALINI LAL

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INTRODUCTION

Brachial plexus nerve block is a regional anaesthesia technique which is developing in the day to day anaesthesia practice. It is sometimes used as an alternative to or along with general anaesthesia for upper extremity surgeries. It is a safer alternative to general anaesthesia for upper limb surgery and also works excellently in relieving post operative pain and also proving excellent hemodynamic stability . Its becoming increasingly popular because the field of regional anaesthesia has improved over time. Several newer adjuvant drugs and many advanced techniques like ultrasound /peripheral nerve stimulator for successful and safe block. The main advantages are it avoids the adverse effects of general anaesthesia. It creates less financial burden to the patient and hospital stay is lessened.

Many adjuvants to local anaesthetics like clonidine, dexmeditomidine, Nalbuphine, buprenorphine, dexamethasone etc have been developed to increase the quality of the nerve block as well as hastening the onset of blockade and increasing the duration of blockade. Nalbuphine is a novel drug classified under opioid agonist- antagonist and it is now being increasingly used as an adjuvant in brachial plexus nerve blocks. It acts as an antagonist at mu-receptors and agonist at kappa receptors, to provide reasonably potent and adequate analgesia. Also,there is no supportive documentary evidence of neurotoxicity following the use of Nalbuphine in peripheral nerve blocks.

In human beings, Nalbuphine is usually added to local anaesthetics while

performing peripheral nerve blocks. This has been proved to increase the duration of post operative analgesia.

Bupivacaine is a local anaesthetic being used commonly in practice for giving peripheral nerve blocks. The aim of this studysis to try to prove the efficacy of Nalbuphine, when it is added as an adjuvant to Bupivacaine while performing supraclavicular brachial plexus nerve blocks.

AIMS AND OBJECTIVES OF THE STUDY

The aim and objective of the study is to prove the efficacy of Nalbuphine when it is added as an adjuvant to Bupivacaine while performing supraclavicular brachial plexus blocks. This is done by observing and assessing the

1. Time to the Onset of the sensory block
2. Time to the onset of the motor block
3. How long is the duration of motor block?
4. How long is the duration of sensory block

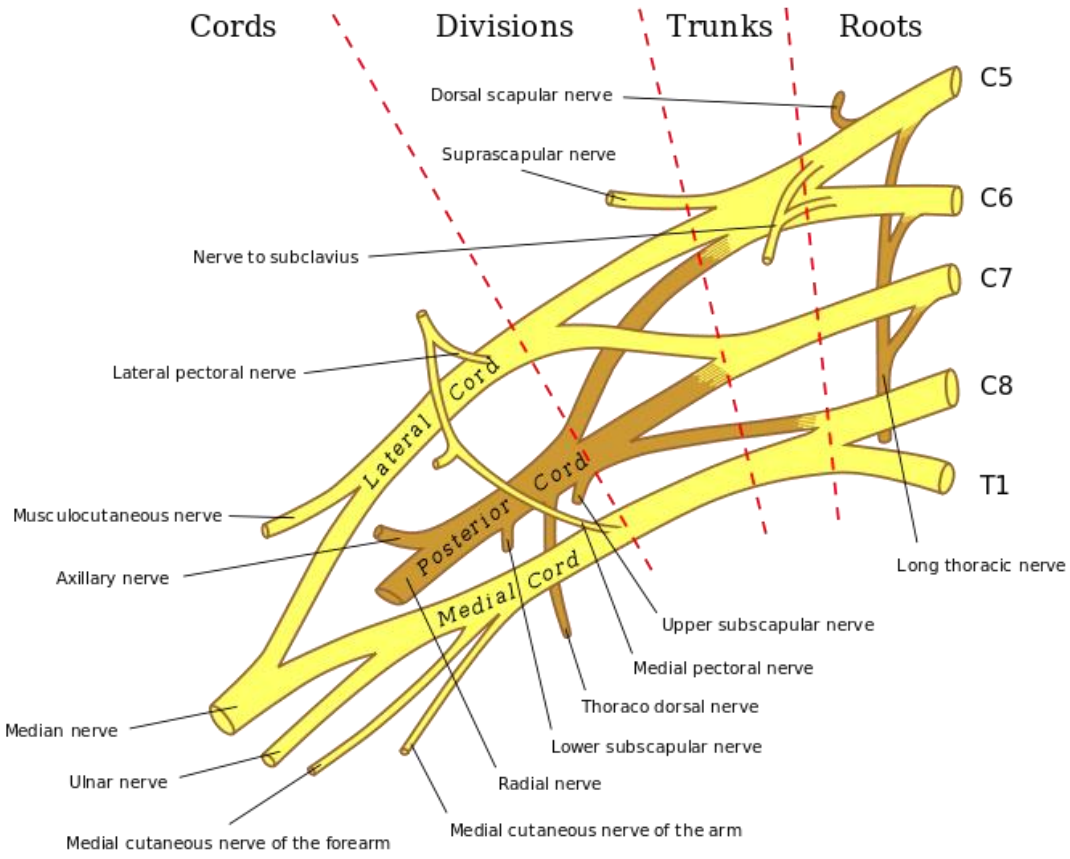
3. Quality of anaesthesia

5. Time of request of first rescue analgesic (which indicates the duration of post operative analgesia)

ANATOMY OF BRACHIAL PLEXUS

To perform a successful brachial plexus blockade, we must be thorough about the detailed anatomy of the brachial plexus and its distribution. An in-depth knowlwdge on the muscular, vascular and the fascial relationship of the brachial plexus beginning from its formation and distribution is needed. This only helps us in successfully performing the various techniques of brachial plexus block at the various levels.

The brachial plexus gives innervation to the upper limb it is constituted by Roots ,Trunks, Cords And divisions.



The major contribution to brachial plexus comes from the ventral ramus of C5 to C8 and T1 nerves.

T2 below and C4 nerve also contributes to form the brachial plexus.

The roots join to form the trunks, that lies above the clavicle.

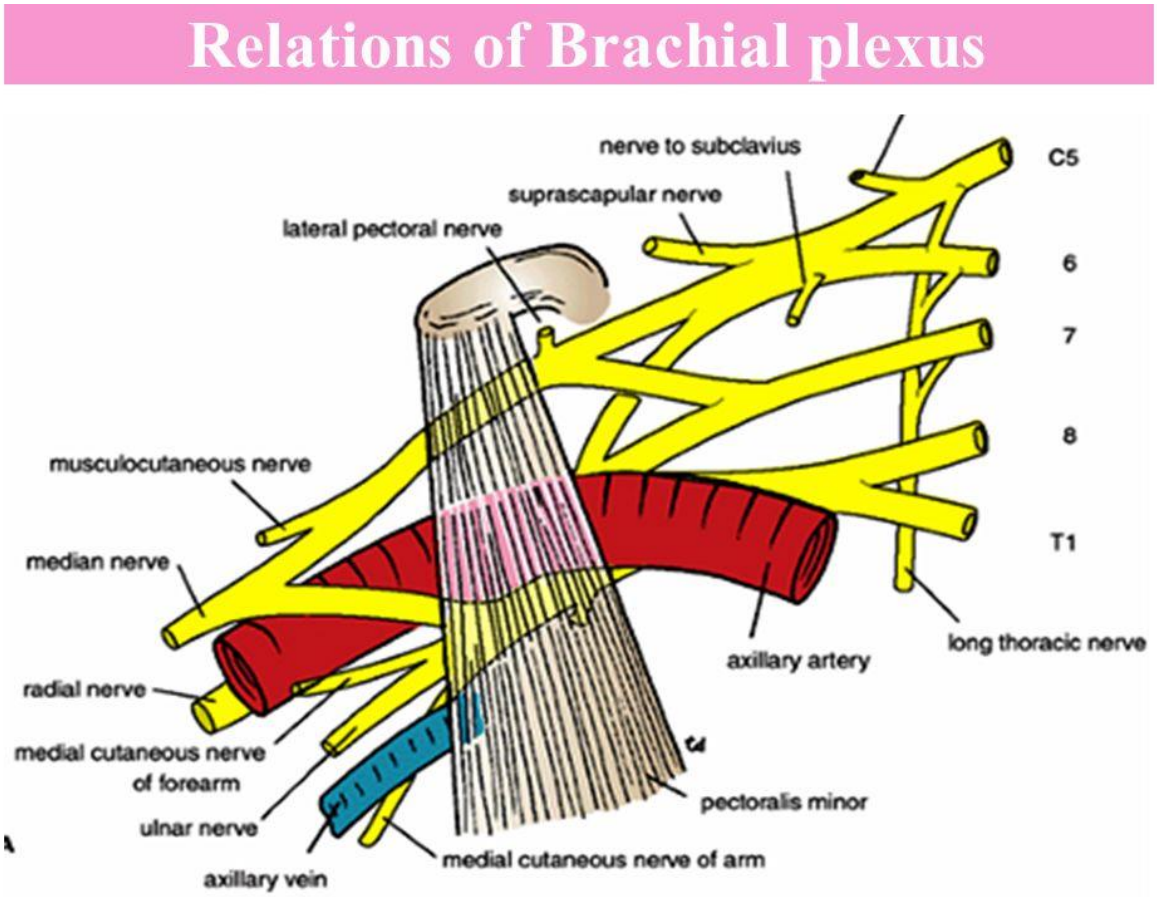
The brachial plexus nerves are very much compacted at the level of supraclavicular area. It travels through the fascia enclosed space which lies between the scalenus medius and scalenus anterior muscle.

At this level , the brachial plexus is accompanied by the subclavian artery. There it enters the fascia that lies over the muscle. They together forms the neurovascular bundle. This fascia continues as the axillary sheath in the axilla.

RELATIONS OF THE BRACHIAL PLEXUS

ANTERIOR RELATIONS

The skin, the superficial fascia, platysma, supraclavicular branches of the superficial cervical plexus, the deep fascia and the external jugular vein.Anterior to the upper part lies the scalenus anterior. the clavicle lies inthe lower part.



POSTERIOR RELATIONS

Scalenus medius muscle, the long thoracic nerve of Bell

INFERIOR RELATIONS

Inferiorly, the plexus is related to the fourth rib

SUPERIOR RELATIONS

Initially the brachial plexus lies above and then it is lateral to the subclavian artery.

FORMATION OF THE BRACHIAL PLEXUS

The upper trunk is formed by C5 to C6. The middle trunk is formed by C7 . The inferior trunk is contributed by C8-T1. Before it enters the axilla, the plexus goes down to lie between the clavicle and the first rib at the level of the anterior scalene muscle.

The trunks are compacted over the first rib, just posterior to the subclavian artery. Each trunk splits to form anterior and posterior divisions. A total of 6 divisions are formed., these six divisions regroups to form lateral, medial and posterior cords below the clavicle. At this level They are related to the axillary artery .

The subclavian artery continues as the axillary artery . Lateral cord is formed by the anterior divisions of the middle and the superior trunks. Medial cord is formed by the anterior division of inferior trunk. Posterior divisions of superior, middle and inferior trunks form the posterior cord. At the lateral margin of pectoralis minor, Every cord gives off a large branch, before ending as a terminal nerve.

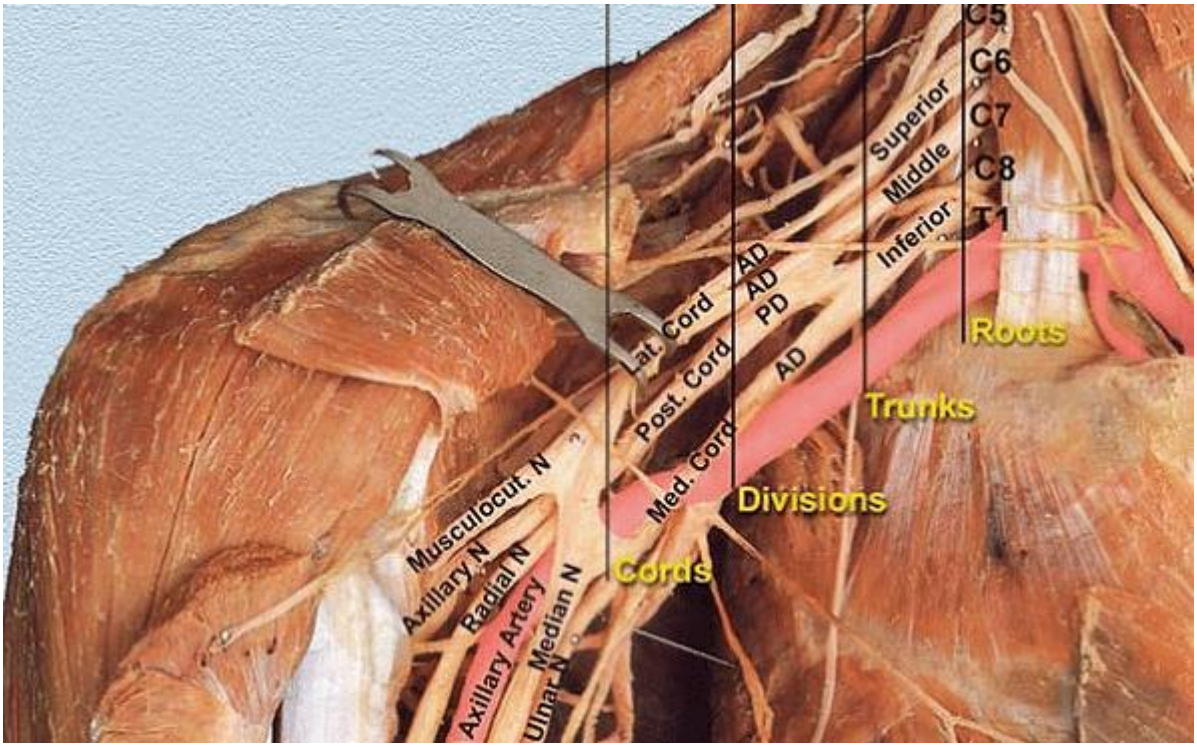
Lateral cord forms the lateral branch of median nerve. the cord terminates as the musculocutaneous nerve.

Medial cord forms the medial branch of median nerve . it terminates to form the ulnar nerve. The posterior cord forms the axillary nerve and terminates as the radial nerve.

Before entering the axilla, the musculocutaneous nerve leaves the sheath . then it lies in the coracobrachialis muscle.

Thus the brachial plexus nerve blocks can be performed at various levels ie; the level of roots, trunks, cords, or at the level of peripheral branches .

Brachial plexus block at each level possess its own merits as well as demerits.



SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK

The Supraclavicular brachial plexus block is otherwise known as the spinal of the arm.

HISTORY

The history dates back to 1884. William Steward Halsted performed the first brachial plexus block.

Crile performed the supraclavicular block in 1887.

In 1911,Hulenkampff explained the percutaneous technique of brachial plexus block by supraclavicularApproach.

Hirshel described the brachial plexus block via axillary nerve in 1911

F. Paul Ansbro described the concept of continuous brachial block technique in 1946.

Many approaches are being developed since the beginning to block the brachial plexus. Newer approaches tend to reduce the complications as well as the failiure rate of the procedure.

The most commonly used approaches are

1. The classical technique By Patrician
2. Brown's Vertical plumb bob method
3. Bonica and Moore explained the First rib walkover technique
4. Subclavian perivascular technique (Winnie&Collins)
5. Parascalene approach (Vongvises and Panijayanond) in 1979.
6. Infraclavicular brachial plexus approach using peripheral nerve stimulator

1. CLASSICAL SUPRACLAVICULAR BLOCK OF HULENKAMPFF

   First, infiltrate the puncture site with local anaesthetic. The needle is inserted 1cm above the midpoint of the clavicle. The needle is inserted in such a waythet it is parallel to the long axis of patient head and neck. The rib is reached at depth of 3 to 4 cm . the needle is then walked off over the first rib until the elicitation of paraesthesia . Inject the local \anaesthetic solution after careful negative aspiration of blood to rule out inadvertent intravascular injection.

2. SUBCLAVIAN PERIVASCULAR APPROACH OF WINNIE AND COLLINS

   Identify the interscalene groove just posterior to the subclavian artery . Insert the needle just posterior and superior to the subclavian artery pulsation. then direct the needle caudally at a flat angle against the skin. Inject the local anaesthetic after elicitation of paraesthesia.

3. Plumb BOB SUPRACLAVICULAR BLOCK

The trunks of the brachial plexus lies cephalic and posterior to the subclavian artery at the level of the first rib. Turn the patient's head to an angle of 30 degrees to the contralateral side. Direct the needle in a perpendicular fashion at the lateral border of the sternocleidomastoid muscle and immiediately above the clavicle. After eliciting paraesthesia, local anaesthetic is injected after confirming negative aspiration of blood

COMPLICATIONS

- Pneumothorax
- Horners syndrome
- Paralysis of Ipsilateral phrenic nerve
- Paralysis of the Recurrent laryngeal nerve
- Haemothorax
- Puncture and injury to the Subclavian artery

ULTRASONOGRAPHY

Ultrasound are high frequency sound waves over 20000 cycles per second(20 KHz). These waves are used for scanning various tissues of human body , inaudible to humans and can be transmitted as beams.

PRINCIPLES OF ULTRASONOGRAPHY

Ultrasound works on the principle known as Piezoelectric effect. The piezoelectric crystals are arranged in the transducer. They have the property of changing the shape on application of electrical voltage . they convert electrical energy into sound energy, when electrical voltage is applied to them. The intensity of the sound waves can be either inhibited or amplified.

The rate of absorption of sound waves is highest in solid structures and it is least in liquids. The reflected waves enter the transducer. They strike the piezoelectric crystals . Thus, it converts sound energy to electrical energy. The reflectivity of the object is computed from the amplitude of the reflected sound.

The difference in the acoustic impedence among the tissues forming the interface determines the proportion of sound reflected or transmitted.

The acoustic impedance is measured in the Rayls unit. It is the product of velocity and density of the tissue in which it propagates sound. Bone and air have different impedance when compared to other tissues. Therefore, majority of sound is reflected. Hence, ultrasound cannot be used to image structures which are deep to bone or air.

Low frequency transducers(2 to 8 MHz) have poor resolving power. But they have higher penetration.

penetration. High frequency transducers (10 to 20 MHz) produce higher

resolution . They produce clear view for the superficial structures. They cannot penetrate further into the tissue.

COMPONENTS OF ULTRASOUND

1. TRANSDUCER
2. RECEIVER AND PROCESSOR
3. IMAGE AND DISPLAY

TRANSDUCER

The transducer can convert mechanical energy into electrical energy and vice

versa. It possess the ability to receive the echoes which are reflected.

RECEIVER AND PROCESSOR

The scattered energy is detected and amplified. They adjust the signals for providing display.

IMAGE DISPLAY

It shows the received ultrasound waves in various modes. The various modes

In use are:

A mode:

Amplitude modulation. It shows the voltage developed

across the transducer and is shown as a vertical deflection on the face of

the oscilloscope. The strength and position of a reflecting structure can only be

recorded.

M Mode:

It is also known as Motion modulation. It displays echo amplitude . It shows the position of moving reflections. It is employed for evaluation of Chambers of the heart, heart valves and the walls of the vessels.

B Mode:

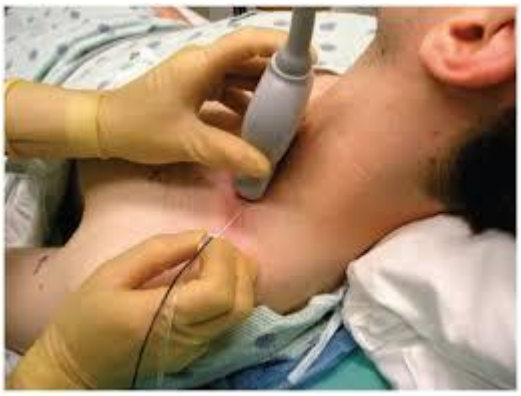
It is also known as Brightness modulation. It uses multiple ultrasound pulses and generates a two dimensional image.

ULTRASOUND IN ANAESTHESIA

In anasesthesia, ultrasound is employed :

1. For obtaining intravascular access
2. regional anaesthesia
3. Transesophageal echocardiography

PERIPHERAL NERVE BLOCK



A successful regional block needs a better and precise distribution of local anaesthetic

solution around the nerve and the nerve plexus. Ultrasound imaging has the following advantages.

- Directly Visualise the nerve structures
- Directly visualise the related structures like tendons and blood vessels.
- Better guidance of needle
- Better monitoring of the drug spread

- Less incidence of intraneuronal and intravascular puncture
- Can reposition The needle if needed
- Can be used in patients with low response to nerve stimulation

The nerves appear as “honeycomb appearance” on high resolution ultrasonography. They appear as hyperechoic fascicles which are surrounded by hyperechoic tissues. Different blocks are performed with different frequencies.

The brachial plexus is blocked at the interscalene and the supraclavicular levels by 10 to 15 MHz probe.

The sciatic, popliteal and infraclavicular block is performed with 4 to 8 MHz probe.

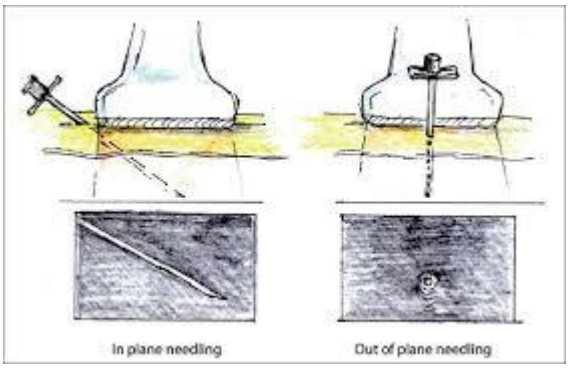
To perform an ultrasound guided nerve block, the entire anatomical structures need to be visualised in the field. To achieve this, optimisation of frequencies, positioning of the focal zones and the depth of penetration is necessary. Place the needle appropriately and then administer the local anaesthetic solution. The spread of the drug is visualised sonographically. Bicarbonate containing solution is better avoided since it interferes with the imaging due to its carbondioxide production.

NEEDLE APPROACH:

There are 2 ways of inserting the needle. They are in plane(parallel) and out of plane(not parallel) to the ultrasound waves. In the in plane

technique, the needle entry is from the side of the probe, whereas the needle entry is away from the probe in out of plane technique.

The entire needle shaft is seen in the in plane technique whereas, only the needle tip is visualised in the out plane approach.



ERGONOMICS:

The operator stands on the same side, where the nerve is to be blocked. Position the ultrasound machine on the opposite side. Hold the needle with the dominant hand and the probe is held with the non dominant hand. Place the monitor in the front of the operator in such a way that he is able to visualise the entire screen without any kind of physical strain.

PROBE ORIENTATION:

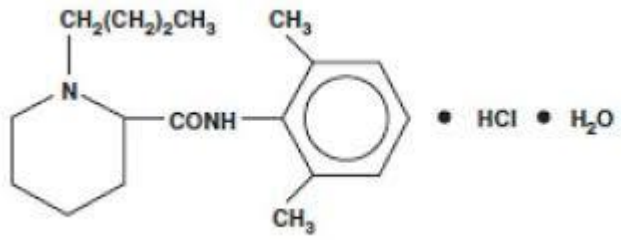
A marker is present on one end of the transducer probe. The operator needs to be oriented about the marker. This avoids confusion, in case of manipulation of the probe.

BUPIVACAINE

Bupivacaine is a member of the pipecoloxylidide member of amide local anaesthetics. They possess the property of chirality as they have an assymetric carbon atom. Hence, Bupivacaine has a left and right sided configuration. It is while, odourless, soluble in water and 95% ethanol, and less

soluble in chloroform or acetone

CHEMICAL STRUCTURE:



Solution of Bupivacaine hydrochloride is clear and colourless. It is used for peripheral nerve blocks, local infiltrations, epidural and caudal blocks. Bupivacaine hydrochloride injection solution can be autoclaved.

Bupivacaine is a member of aminoacyl group of local anaesthetics. It is a

homologue of mepivacaine and is chemically related to lignocaine. All these 3 local anaesthetics possess an amide linkage btween the aromatic nucleus and the amino or piperidine group. These tHRee differ in this respect from the procaine type of local anaesthetics, which possess an ester linkage.

It is available in 4ml ampoules where each ml contains 5 mg of hyperbaric Bupivacaine hydrochloride.

It is also available in 15 ml vials , where each ml contains 5mg anhydrous Bupivacaine Hydrochloride.

CLINICAL PHARMACOLOGY:

Bupivacaine acts by binding to the intracellular portion of the voltage gated sodium channels , thereby blocking the sodium ion influx into the nerve cells, which prevents depolarisation.

It blocks the generation and conduction of nerve impulses by:

1. Amplifying the threshold for electrical excitation in the nerve
2. Decreasing the speed of the propogation of the impulse through the nerve
3. Decreasing the rate of rise of the action potential

Compared to the other local anaesthetics, Bupivacaine is highly cardiotoxic.

At low therapeutic doses, Bupivacaine does not cause much cardiovascular changes or changes cardiac contractility or conduction. But, toxic blood concentrations of Bupivacaine can result in major abnormalities in cardiac conduction and excitability, which in turn leads to major ventricular arrythmias, atrioventricular blocks and bradycardia. Depression of myocardial contractility leads to decreased cardiac output and arterial

blood pressure leading to cardiac arrest and death. But, these changes have been reported mostly due to inadvertent intravascular injection of Bupivacaine. But, its racemic mixture, S- enantiomer is relatively less cardiotoxic.

Adverse effects on the central nervous system include circumoral numbness, facial tingling, vertigo, tinnitus, tremors and convulsions.

PHARMACOKINETICS:

The rate of absorption of bupivacaine is dependent on its route of administration, site of administration, total dose, and concentration of the drug administered and the presence or absence of epinepH.Rine in the solution.

EpinepH.Rine in concentrations of 1:200000 in the anaesthetic solution prolongs the duration of action and permits usage of larger total doses by reducing the rate of absorption and peak plasma concentratiion of bupivacaine.

Certain clinical studies have found that the peak plasma concentrations, maximum spread of analgesia, and motor blockade produced by Bupivacaine is found in elderly when compared to young subjects.

1. The duration of anaesthesia is about 240 to 480 mins
2. Half life of the drug is 210 minutes
3. The Maximum single dose for infiltration is 175 mg
4. Toxic plasma concentration is more than 3 microgram/dl
5. pKa: 8.1
6. the drug is 95% bound to plasma proteins
7. fraction of unionised bupiacaine at pH7.4 is 17% and pH 7.6 is 24 %.
8. Volume of distribution is 73 L
9. Clearence : 0.47 L/min. The total plasma clearence is decreased in elderly patients

The rate and degree of diffusion of any local anaesthetic is dependent on:

1. Plasma protein binding capacity of the drug
2. Degree of ionisation of the drug
3. The lipid solubility of the drug

The fetal to maternal circulation of local anaesthetics is inversely proportional to their plasma protein binding capacity. Hence, only the unbound or free fraction of the drug in the maternal circulation is available for placental transfer. The plasma protein binding capacity of bupivacaine is 0.9%. hence, the ration of fetal umbilical vein to maternal arterial concentration of Bupivacaine is only 32 %.

Likewise, lipid soluble or water soluble drugs which occur in non ionised form in the circulation readily crosses maternal circulation to enter the fetal circulation, whereas the water soluble or ionised drugs do not readily cross the placental barrier. The lungs are also capable of extracting bupivacaine from the circulation.

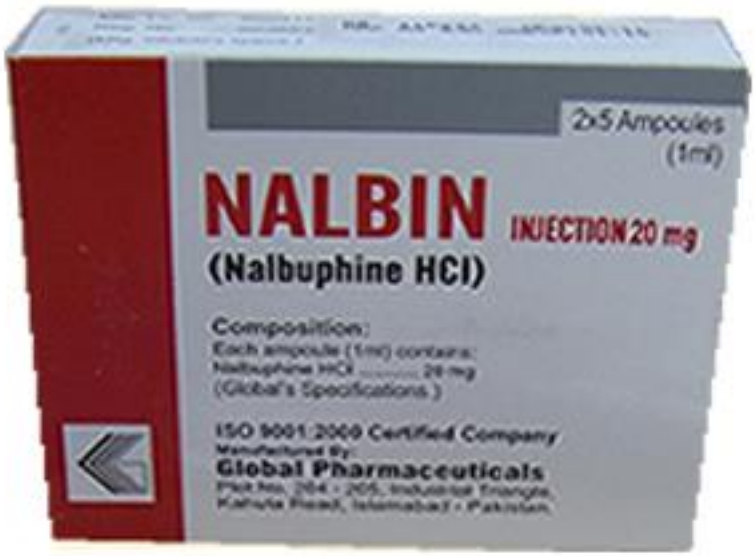
Possible pathways of Bupivacaine metabolism include Aromatichydroxylation, N- dealkylation, amide hydrolysis, and conjugation. Alpha acid glycoprotein is the most important plasma protein binding site of Bupivacaine. The major metabolite of Bupivacaine is Pipecoloxylidide, which is mainly

catalysed by cytocH.Rome p450 3A4.

Pipecoloxylidide is then further hydroxylated to form glucuronide conjugates.

The kidney is the major excretory organ for most of the local anaesthetics and their metabolites. Urinary excretion is affected by the urinary perfusion and factors affecting the urinary ph .

NALBUPHINE



Nalbuphine hydrochloride is a synthetic opioid agonist- antagonist analgesic. It belongs to

Phenantherene series. Chemically, it is related to the widely used opioid

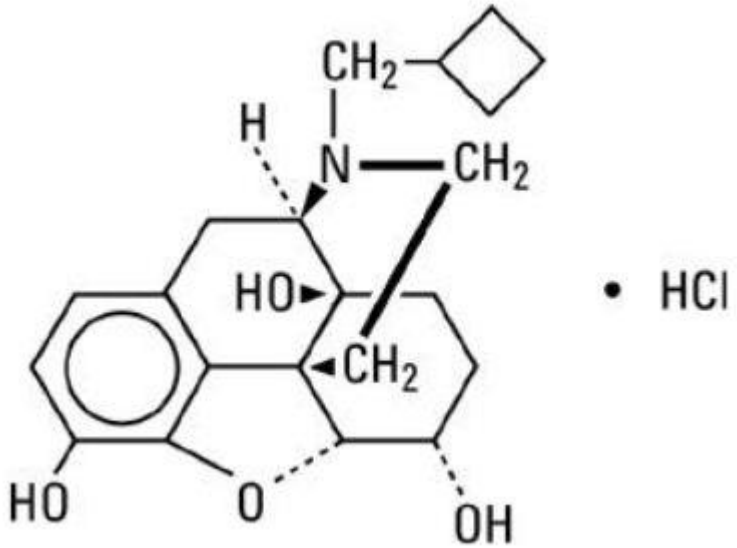
antagonist naloxone and the potent opioid agonist cymorphone. Chemically, Nalbuphine hydrochloride is 17-cyclobutylmethyl 4, alpha epoxy morphinan-3,6 alpha 14 triol hydrochloride.

The molecular weight of Nalbuphine hydrochloride is 393.91 . it is soluble in water(35.mg/ml at 2 degrees) and ethanol (0.8%) and is insoluble in CHCl3 and ether. Nalbuphine hydrochloride has pKa values of 8.71 and 9.96. the molecular formula is C21H27NO4 HCl.

COMPOSITION:

Each ml contains clear, odourless solution of Nalbuphine hydrochloride dihydrate equivalent to anhydrous Nalbuphine hydrochloride 10mg/20mg.

The structural formula is



PROPERTIES:

- It binds to mu as well as kappa and delta opioid receptors.
- Nalbuphine acts as an antagonist at mu receptors ans ad an agoinist at kappa receptors.

- Activation of supraspinal and spinal kappa receptors results in linited analgesia, respiratory depression and sedation.
- In rats, administration of Nalbuphine with morphine dose dependently blocked the development of morphine tolerance without attenuation of the antinociceptive effect of morphine.
- It is equally potent asan analgesic to morphine. Nalbuphine has no euphoriant effects.
- It is about one fourth as potent as morphine as an antagonist.
- Naloxone reverses the agoist effects of Nalbuphine
- Nalbuphine 10 mg im produces analgesia with an onset of effect and duration of action is simillar to that of morphine.
- Depression of ventilation is similar to morphine. But it shows a ceiling effect at the dose of 0.5 mg/kg.it antagonises the respiratory depressant effects of co administered pure mu opioid agonists, but the analgesic effect is additive in nature.
- The incidence of dysphoria is less in comparison to butorphanol and pentazocine
- In contrast to pentazocine, Nalbuphine does not increase systemic blood pressure, pulmonary artery blood pressure, heart rate or atrial filling pressures.
- Withdrawal symptoms are milder compared to that of morphine, but similar to that produced by pentazocine.
- Abuse potential is low
- Nalbuphine causes lesser incidence of gastrointestinal side effects when compared to other opioids
- The antagoinist effects of Nalbuphine occurs due to its action on mu receptors. This could be an advantage in the post operative period to reverse the ventilatory depressant effects of opioid agonists, while still maintaining the analgesia.
- Onset of action is rapid within 5 to 10 mins
- Duration of action is long 3 to 6 hours
- Plasma elimination half life is hours

PHARMACOKINETICS

Absorption:

The bio availability by oral route is 12 to 17 % due to a significant first pass

metabolism. The bioavailability is about 80 % by the intramuscular and subcutaneous routes.

Distribution:

Nalbuphine is 25 to 40 % plasma protein bound. The volume of distribution is 162- 498 litres.

Metabolism:

It is metabolised predominantly in the liver to two inactive conjugates which are secreted in to the bile.

Excretion:

The metabolites of Nalbuphine are excreted mainly in the faeces. A small fraction is excreted in the urine. The clearence is 0.8 to 2.3 liter per minute. Elimination half life is 110 to 160 minutes.

Side effects:

Sedation, dizziness, vertigo, dry mouth, headache. Nalbuphine cause less nausea and vomiting.

Psychomimetic effects and dependence are less as compared to morphine.

ULTRASOUND GUIDED SUPRACLAVICULAR NERVE BLOCK:

Place the patient in a supine position . Turn the patient's head to 30 degree towards the opposite side. Place a linear high frequency probe over the supraclavicular fossa Just above the clavicle. Angulate the probe slightly towards the thorax . Identify the subclavian artery by

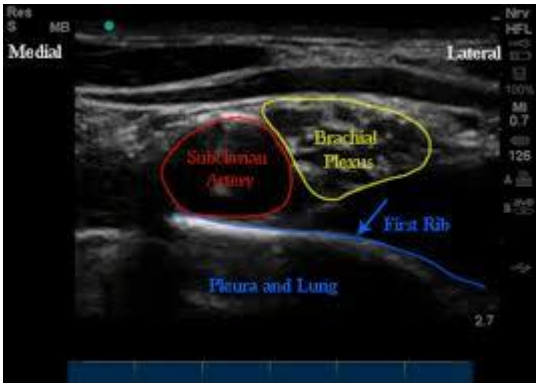
its visible pulsation. Just above and lateral to the subclavian artery, multiple hyperechoic Disks are seen. This confirm the brachial plexus.

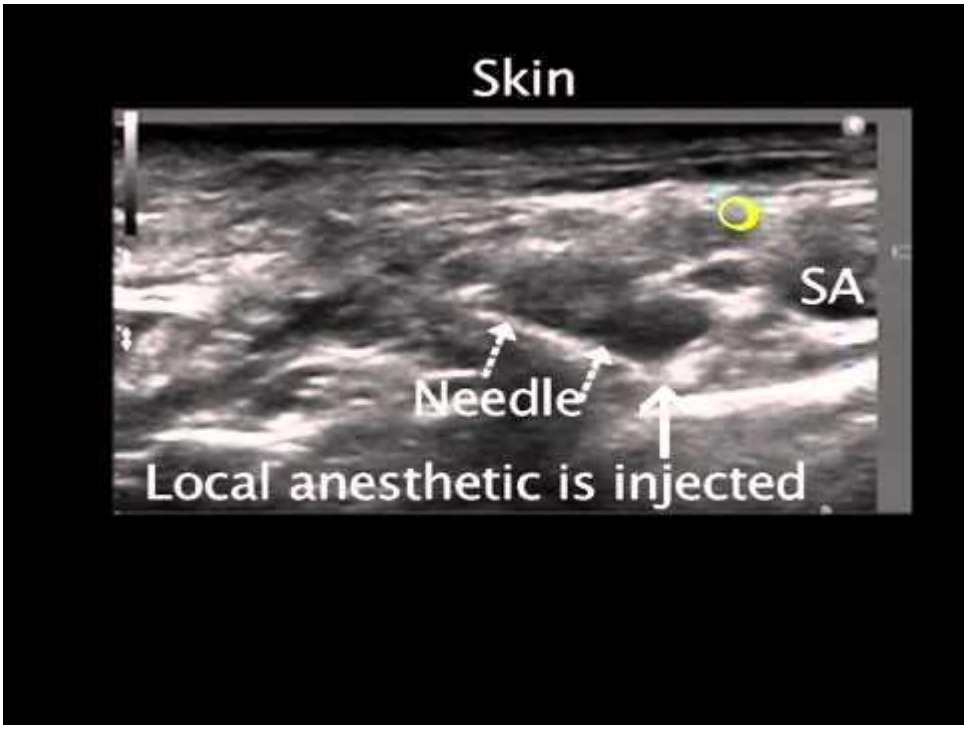
The first rib is visualised as a Hyperechoic line just deep to the artery. Identify the pleura, adjacent to the rib. It is differentiated from bone by its movement with respiration.

To perform, an out of plane technique,a 22 gauge short tip, blunted tip needle is used.

The skin is first anaesthetised with 1-2 ml of lignocaine. Then, the needle is introduced just above to the ultrasound probe in a posterior and caudal fashion. Inject about 30 ml of local anaesthetic solution, after careful aspiration to rule out an accidental and inadvertent intravascular injection. The spread of the drug around the brachial plexus is visualised.

For an in plane technique, a longer needle is required. The skin is first anaesthetised. Introduce the needle just lateral to the ultrasound beam. The needle is then advanced through the subclavian artery medially, until the tip is visualised near the brachial plexus, just lateral and superficial to the subclavian artery. Inject 30 ml of local anaesthetic solution after careful aspiration to rule out intravascular injection.





REVIEW OF LITERATURE:

Mohammed et al conducted a study on the effect of Nalbuphine as an adjuvant

with Bupivacaine in supraclavicular brachial plexus blocks.

The test group(Nalbuphine) revealed a greater increase in the duration of motor block,

while comparing with the control group. Significant increase was also shown in

the duration of sensory block in Test(Nalbuphine) group, when compared to control

Group. The onset time of blockade was unaffected in both the groups.

An increase was noted in the duration of analgesia in the Test group.

Cenklham et al conducted a study on the effectiveness of bupivacaine and

levobupivacaine for supraclavicular block. It was shown that equal volumes of 0.5%

Bupivacaine and levoBupivacaine produce nearly similar features of

supraclavicular block. Bupivacaine causes faster motor and sensory

block onset. But the duration of

postoperative analgesia is nearly the same.

Rohit et al conducted a study comparing 0.5% ropivacaine and 0.5%

Bupivacaine in supraclavicular brachial plexus block. They concluded that the

mean onset time of motor blockade was nearly similar in both the groups. The Ropivacaine group produced a

mean pain relief duration of 688 +/- 86.78 minutes . In bupivacaine group, it was 664.37 +/- 109mins. The sensory and motor

block Onset was nearly the same in both groups.

Mithun et al performed a study comparing the effectiveness of nerve stimulator vs ultrasound

guided supraclavicular brachial plexus block. They concluded that there was no

significant difference between these groups with regard to demographic data, time of onset of motor and sensory block. A failure of 10% in ultrasound group and 20 % in nerve stimulator group observed and is statistically insignificant.

B**assant mohammed et al** conducted a study on the efficacy of Nalbuphine as an adjuvant to 0.25% levobupiacaine in ultrasound guided supraclaicular brachial plexus blocks. They concluded that adding 20 mg of a Nalbuphine to 25 ml of 0.25% levobupivacaine provided prolonged duration of sensory block with similar duration of motor block.

Sunil chiruvella et al conducted a study comparing the various doses of Nalbuphine combined with levobupivacaine for supraclavicular brachial plexus blocks. They concluded that higher doses of Nalbuphine in brachial plexus block fastened the onset , prolonged the duration of sensorimotor blockade and analgesia, without any significant side effects.

Nazir et al conducted a randomised control trial for analysing the Effect of Nalbuphine as an adjunct to Bupivacaine while performing supraclavicular block under ultrasound guidance. Results: When Nalbuphine is added to Bupivacaine as an additive, it greatly reduced the onset of sensory and motor block . It also raised(increases) the duration of sensory and motor block and even the

duration of post operative analgesia.

MATERIALS AND METHODOLOGY

SOURCE OF DATA:

Patients who undergo surgeries on the upper limb done under supraclavicular brachial plexus block at Govt.Kilpauk medical college hospital and Govt. Royapettah Hospital, Chennai between a time period of November 2017 and April 2018 will be assessed for inclusion and exclusion criteria . Written, informed conent is then obtained from them.

SAMPLE SIZE CALCULATION:

Sample size was determined based on the

STUDY: Effect of Nalbuphine as an adjunct to Bupivacaine for ultrasound guided brachial plexus blocks.

AUTHORISED BY: Mohammed et al

PUBLISHED IN: OJ Anaes 2016; vol 06(8): 1199-1203

This study revealed the following findings.There was a significant increase in the duration of motor block(412.559 +/- 18.63)in the Nalbuphine group in comparison to the control group(353.70 +/-29.019). Sensory duration was greatly increased in Nalbuphine group(718.14 +/-21.04) in comparison to control group (610.18 +/- 26.33). But the onset time of blockade remained unaffected. The analgesic effect was significantly increased in the Nalbuphine group(835.18 +/- 42.45), in comparison to to control group (708.14 +/- 54.57)

DESCRIPTION:

The formula for detecting sample size is given as:

$$n = \left(\frac{Z_{\alpha/2} \cdot \sigma}{E}\right)^2$$

Where n= sample size

E= margin of error

Z= margin given for each confidence interval

- The confidence interval is estimated at 95%

- Standard deviation 59.31
- With a Z value of 1.96
- The confidence interval or margin of error is estimated at +/- 16.

Taking into consideration 80 as the power of the study, minimum of

56 was calculated to be the sample size.

- In my study. I will choose 60 patients(as 10% attrition rate is taken into consideration).
  Group B: 30
  Group N: 30

STUDY DESIGN:

A Prospective, Randomised, double arm, double blind controlled study.

INCLUSION CRITERION:

1. Patients who undergo elective orthopaedic forearm fracture surgeries under supraclavicular block.
2. Age between 30 to 60 years.
3. Patients Who weigh more than 50 kg
4. Males and females
5. ASA physical status class 1 and 2
6. Patients from whom valid informed consent was obtained

EXCLUSION CRITERION:

1. Patients who do not fulfil the inclusion criteria
2. Patients with a history of allergy or hypersensitivity to either local anaesthetic or opioid group of drugs
3. Any contraindication to peripheral nerve block
4. Impaired ability to communicate(eg: confusion, poor hearing or language barrier)
5. Patients who are unconscious
6. Patients who are severely ill
7. Pregnancy
8. Patients with coagulation disorders
9. Local infection at the place of injection
10. Patients who are taking any sedatives or antipsychotics

MATERIALS:

1. Boyles apparatus
2. Working laryngoscope with different blade sizes
3. Other airway gadgets used in case of difficult intubation
4. Endotracheal tubes
5. Drugs for administering general anaesthesia
6. Ultrasound machine
7. 18 G iv cannula needle, tH.Ree way adapter with 10 cm extension
8. 10 ml syringes
9. Inj. Nalbuphine, available as ampoules(one ampoule contains 1ml, each ml contains 10 mg of Nalbuphine)
10. Inj. Bupivacaine , available as vials in the concentration of 0.5%(each vial contains 20 ml, each ml contains 5 mg of Bupivacaine)

METHODOLOGY:

Patients in the above mentioned inclusion criteria will be selected and counselled about the risks and advantages that are involved in the study. After getting their valid informed consent, patients who are willing to be in the study will be enrolled and analysed. 60 patients in total will be included. Divide the patients into two groups

Group B: Control group. 30 Patients Given 25 ml of 0.5% Bupivacaine + 1 ml of normal saline

Group N: Nalbuphine group. 30 patients given 25 ml of 0.5% Bupivacaine + 1 ml (10 mg)of Nalbuphine

A thorough preoperative examination including history taking, physical examination, and

Routine and relevant investigations were done for all patients . Visual analogue pain score was explained to all

candidates Where "0" denotes no pain . "10" denotes the worst pain. An 18 G venflon is

inserted into a peripheral vein in the opposite forearm. 0.01-0. 05 mg/kg of intravenous midazolam is given.

Intravenous fentanyl 1 microgram/kg is given if necessary (tomoderately

Sedate the patient; patient is arousable on command). Basic monitoring consisting of

electrocardiography, non invasive blood pressure and pulse oximetry were attatched.

Baseline heart rate, blood pressure and oxygen saturation were noted as pre-block values. Place the patient in supine position . Turn the patient's head to 45 degrees to the opposite side. An ultrasound machine (Mindray

M7) and a 10 MHz linear type probe used. All aseptic precautions are taken. The skin is first cleaned and draped. Local anaesthetic infiltration of the skin is done. scan the supraclavicular fossa.

Locate the subclavian artery , the 1st rib, pleura and brachial plexus cluster.

Then an echogenic 22 Gauge , 5 centimeters ,B.Braun Needle is advanced from the lateral

to medial direction along the long axis of ultrasound beams. Advance the needle

towards the "corner pocket". The lower trunk frequently lies in this

area (between the subclavian artery In the medial position , first rib below and the plexus

above) . Then half the volume of the prepared local anaesthetic mixture

either with 1ml of normal saline or 10mg of Nalbuphine was injected. Then, the

needle was repositioned cranially towards the neural cluster so as to infiltrate

the rest volume of the local anaesthetic just above and lateral to the

subclavian artery. Intraoperatively, the patient's heart rate, mean arterial pressure was noted down every 5 minutes during the first 15 minutes. Then it was noted every15

minutes till the end of the surgery. If sensory and motor blockade is inadequate even

after 30 minutes of administration of local anaesthetic ,it is

taken as an unsuccessful block. After the local anaesthetic administration,surgery was proceeded . The onset of both motor and sensory blockade was noted.

The duration of both motor and sensory blockade and duration of analgesia was evaluated by enquiring the patient in the early

postoperative period. We routinely monitored the patientts. Side effects if any,

are noted.

In the post operative period, if patients started to complain of pain (VAS>3),

rescue analgesia was given as pethidine 1 mg /kg, paracetamol 1gram iv infusion or diclofenac sodium 75 mg intramuscular, until VAS<3.

CRITERIA FOR ASSESSMENT	Group B	Group N	
sensory blockade Onset			
motor Blockade onset			
sensory blockade duration			
motor blockade duration			
Heart Rate			
Blood pressure (mean arterial pressure)			
Respiratory rate			
Oxygen saturation			
Duration of post operative analgesia(time of first requisition of analgesic)			

METHOD OF COLLECTION OF DATA:

After administering the block, The evaluation of motor and sensory block was done every 5 minutes, till complete sensory and motor block was achieved or 30 minutes, whichever is earlier. To assess the sensory block, pinprick sensation by a 23 G hypodermic needle was used in the distribution of ulnar, median, musculocutaneous and radial nerves. A 3 point scale was used. In the 3 point scale , Zero denotes normal sensation, One denotes loss of prick sensation. Two denotes loss of sensation of touch.

To evaluate Motor block . thumb adduction(radial nerve), opposition of thumb (median nerve), adduction of thumb(ulnar nerve) and elbow

flexion(musculoctaneous nerve) is used. Similar to sensory evaluation, a 3 in one point scale is used . zero indicates thet motor function is normal, One indicates decreased motor strength, 2 indicates thet motor block is complete.

The time interval between the end of infiltration of local anaesthetic and the complete motor and sensory block is defined as the onset time for motor and sensory block respectively. Anaesthetic block on all the 4 nerve territories indicate complete sensory block. The absence of voluntary movements of the hand and forearm indicates complete motor block.

The quality of anaesthesia was assessed at the end of the surgery. This was graded by:

EXCELLENT(4): If Patient gives no complaints. GOOD(3): Few vague complaints from the patient, but there is no need for any supplementation of drug.

MODERATE(2): complaint from the patient which necessitate need for supplemental analgesics .

UNSUCCESSFUL: requirement of general anaesthesia.

Postoperatively, Patients were asked to rate their pain on a 11 point visual analogue scale. After discharge from the recovery room, pain was regularly assessed every 30 minutes for the first two hours, and thereafter 1 hourly till 24 hours. The sensory and motor regression was tested every 15 minutes until complete resolution. The time from the end of infiltration of local anaesthetic till the full motor power recovery of the hand and forearm is the duration of motor block. The duration of analgesia was recorded as the time between the end of administration of the

local anaesthetic solution and the time of first request of rescue analgesic.

Data Analysis

Statistical Analysis was done by Statistical Package for Social Sciences (SPSS Version 16.0) statistical analysis software. The values were represented in number (%) and mean ± standard deviation. Acceptable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test and ANOVA. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$.

Sample Size Estimation

Sample size was determined based on

Study

Effect of nalbuphine as an adjuant to bupivacaine for ultrasound guided supraclaicular brachial plexus blocks

Authored by

Mohammed et al

Published in

OJ Anaes 2016; Vol 06(8); 1199-1203

This study revealed the following findings.There was a significant increase in the duration

of motor block(412.559 +/- 18.63)in the Nalbuphine group in comparison to the control group(353.70 +/-

29.019). Sensory duration was greatly increased in Nalbuphine

group(718.14 +/-21.04) in comparison to control group (610.18 +/-

26.33). But the onset time of blockade remained unaffected. The analgesic effect was significantly increased in the Nalbuphine

group(835.18 +/- 42.45), in comparison to to control group (708.14 +/- 54.57)

Description:

- The confidence level is estimated at 95%
- with a z value of 1.96
- the confidence interval or margin of error is estimated at +/-17
- Assuming p% =29 and q%=71

$n = p\% \times q\% \times [z/e\%]^2$
$n = 29 \times 71 \times [1.96/17]^2$
n= 28 per group

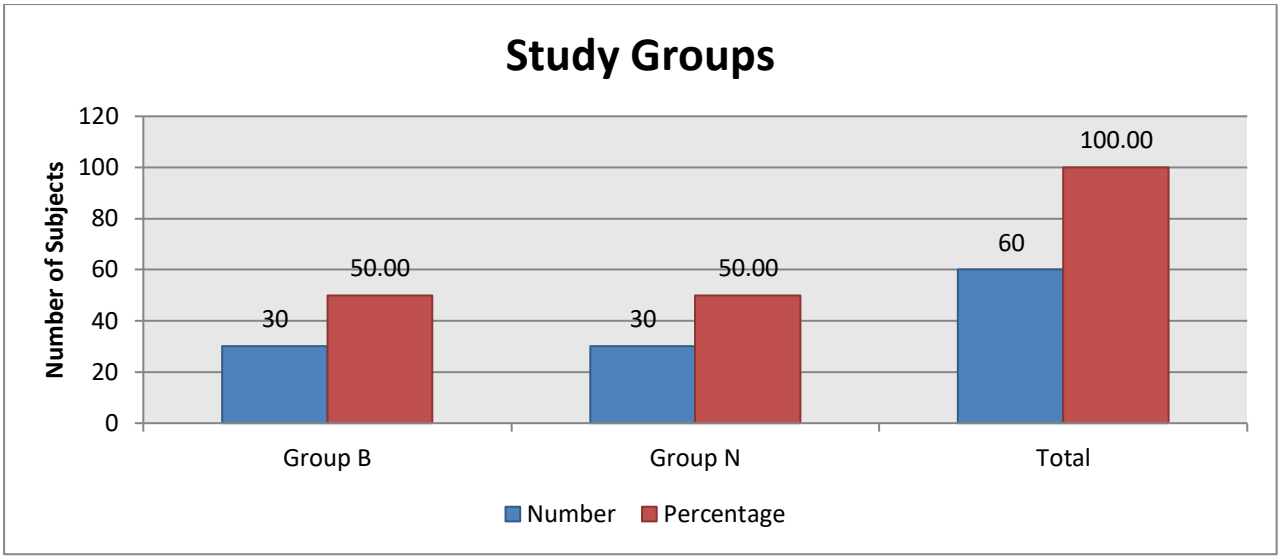
Therefore 56 is the minimum sample size required (28 per group) for the study.

In my study I plan to recruit a minimum of 60 subjects (30 per intervention arm)

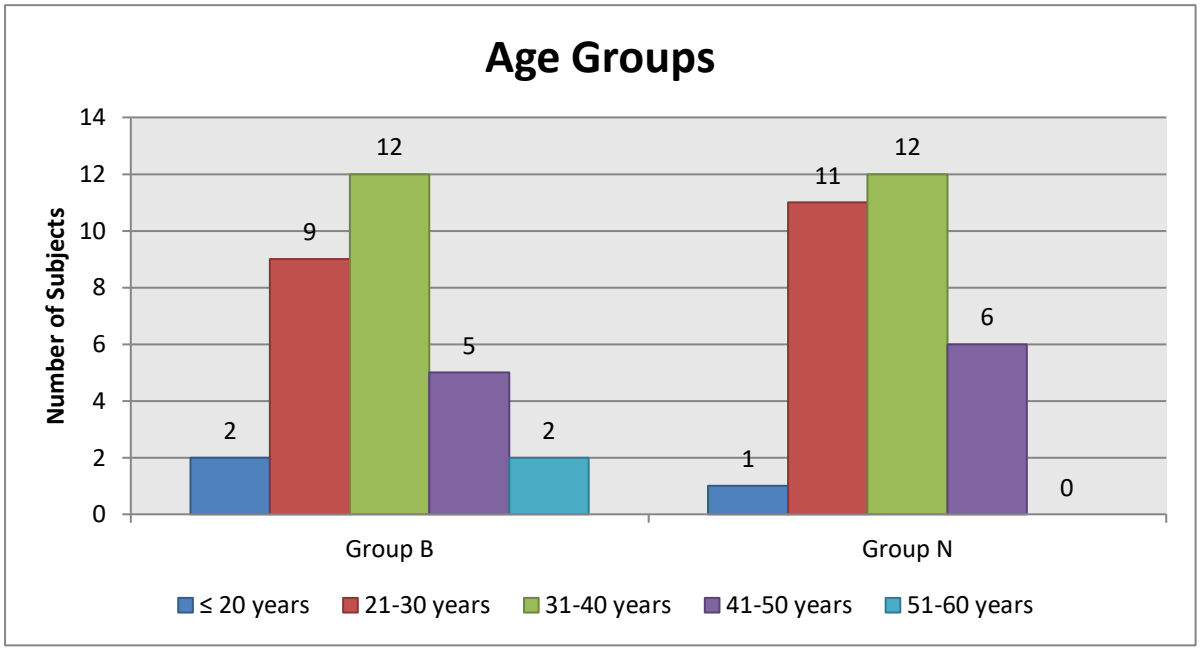
The present study was carried out at the Department of Anaesthesiology, Kilpauk Medical College, Chennai and Government Royapettah hospital, chennai, with an aim to compare the efficacy of 0.5% Bupivacaine alone vs 0.5%Bupivacaine with Nalbuphine as adjuvant for ultrasound guided supraclavicular brachial plexus block

A total of sixty patients were recruited and data collected was internally compared, tabulated, analysed and interpreted by using descriptive and inferential statistics based on the formulated objectives of the study.

Study Groups	Intervention	Number	%
Group B	0.5% Bupivacaine alone as adjuvant for ultrasound guided supraclavicular brachial plexus block	30	50.00
Group N	0.5%Bupivacaine with Nalbuphine as adjuvant for ultrasound guided supraclavicular brachial plexus block	30	50.00
Total		60	100.00



Age



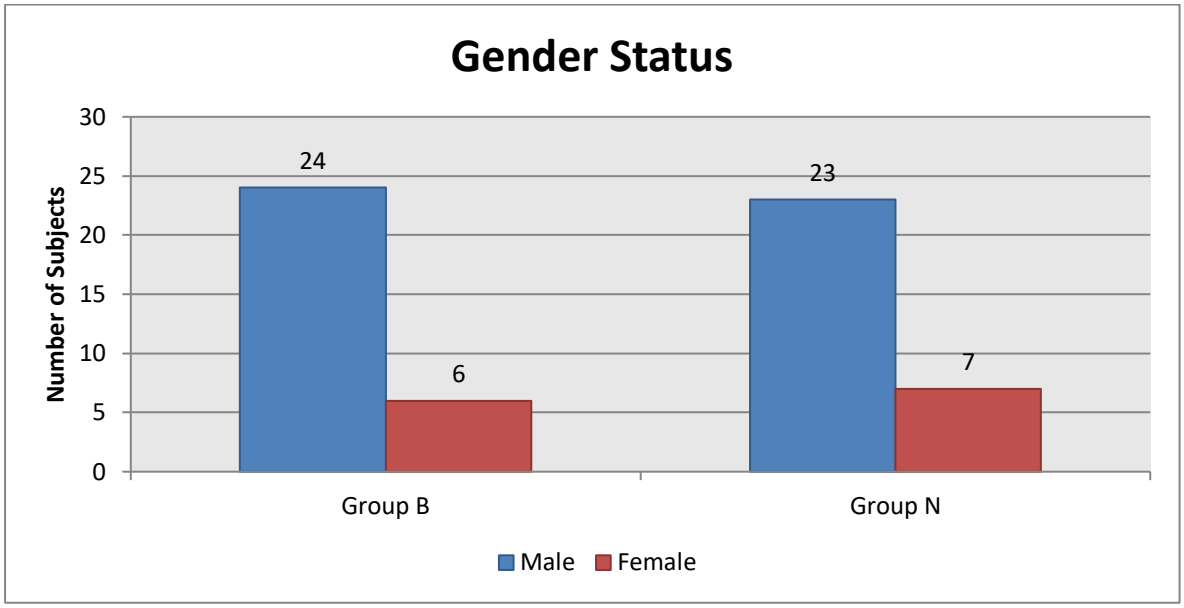
Age Groups	Group B	%	Group N	%
≤ 20 years	2	6.67	1	3.33
21-30 years	9	30.00	11	36.67
31-40 years	12	40.00	12	40.00
41-50 years	5	16.67	6	20.00
51-60 years	2	6.67	0	0.00

Total	30	100.00	30	100.00

Age Distribution	Group B	Group N
Mean	34.53	33.33
SD	10.04	7.95
P value Unpaired t Test		0.610

On analysis of age distribution table It was evident that most of the group B subjects were in 31-40 years age category (40.00%) with a mean age of 34.53 years. In group N majority were in 31-40 years age category (40.00%) with a mean age of 33.33 years.($p= 0.610$). The data subjected to unpaired t test reveals the existence of statistically non-significant association between age distribution and intervention groups ($p > 0.05$)

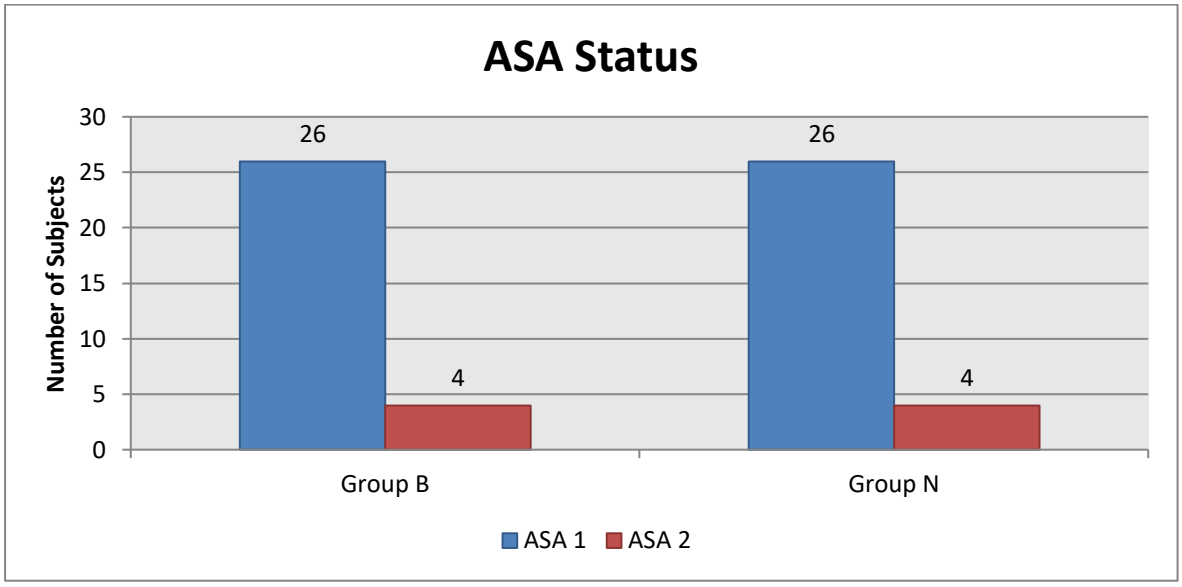
Gender



Gender Status	Group B	%	Group N	%
Male	24	80.00	23	76.67
Female	6	20.00	7	23.33
Total	30	100.00	30	100.00
P value Chi Squared Test	>0.999			

On analysis of the gender status table It is evident that most of the group B subjects were males (80.00%) and in group N too majority were males (76.67%) (p= >0.999). The data subjected to chi squared test reveals the existence of statistically non-significant association between gender status and intervention groups (p >0.05)

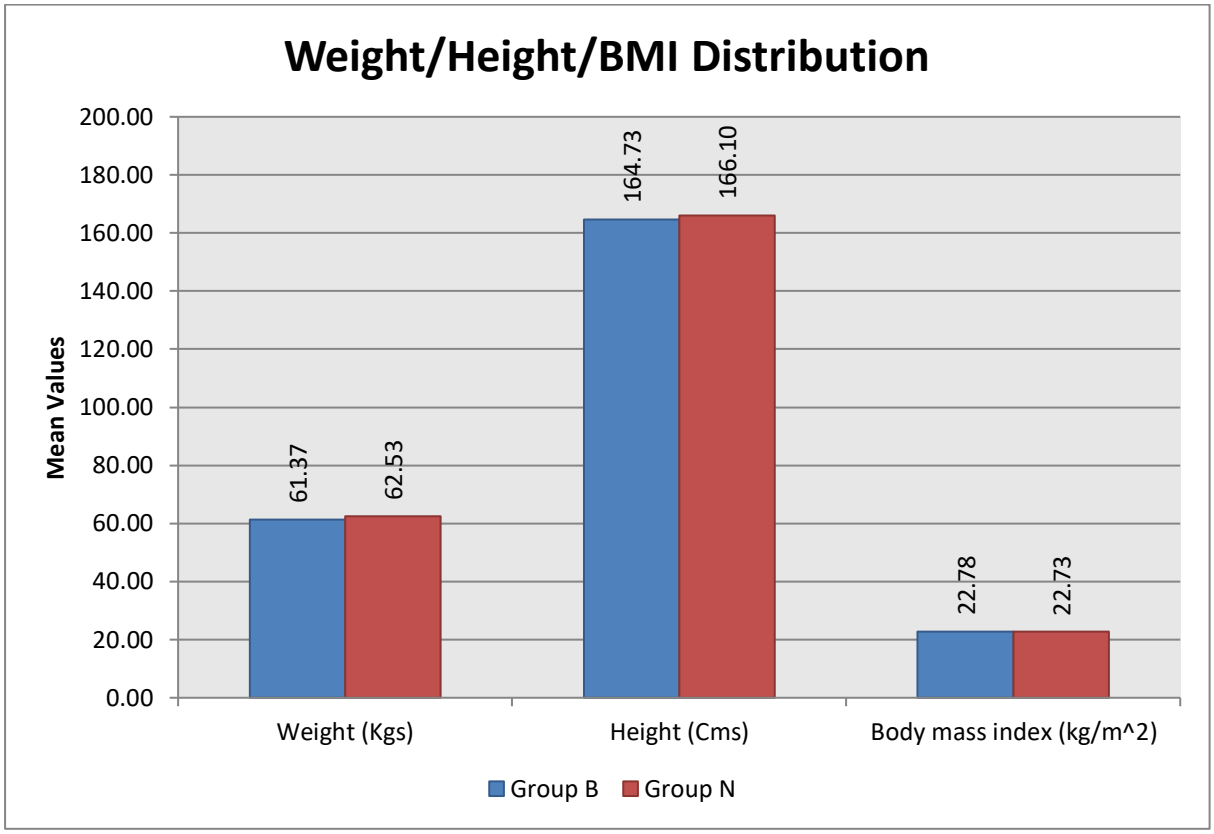
ASA



ASA Status	Group B	%	Group N	%
ASA 1	26	86.67	26	86.67
ASA 2	4	13.33	4	13.33
Total	30	100.00	30	100.00
P value Chi Squared Test	>0.999			

On analysis of the ASA status table It is evident that most of the group B subjects were in ASA 1 category (86.67%) and in group N too majority were in ASA 1 category (86.67%) (p= >0.999). The data subjected to chi squared test reveals the existence of statistically non-significant association between ASA status and intervention groups (p >0.05)

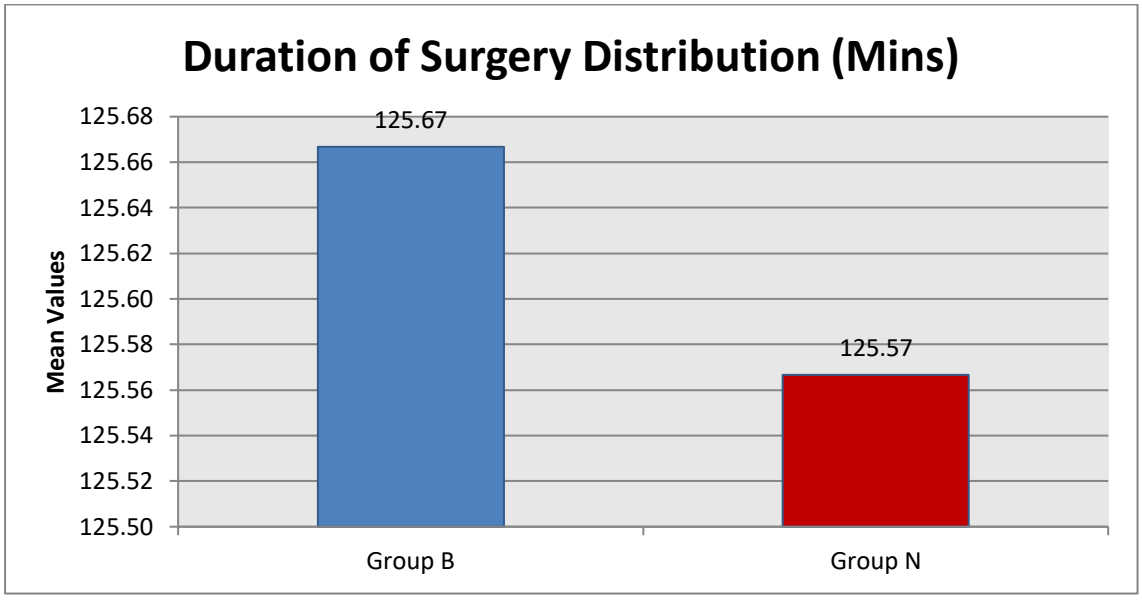
Weight/Height/BMI



Weight/Height/BMI Distribution		Weight (Kgs)	Height (Cms)	Body mass index (kg/m^2)
Group B	*Mean*	61.37	164.73	22.78
	SD	5.37	5.45	2.00
Group N	*Mean*	62.53	166.10	22.73
	SD	6.20	5.17	1.97
P value Unpaired t Test		0.439	0.323	0.916

On analysis of weight distribution table it was evident that group B subjects had a mean weight of 61.37 kgs and group N subjects had a mean weight of 62.53 kgs (p= 0.439).. In relation to height distribution group B subjects had a mean height of 164.73 cms and group N subjects had a mean height of 166.10 cms (p= 0.323)..Similarly in BMI distribution group B subjects had a mean BMI of 22.78 and group N subjects had a mean BMI of 22.73 (p= 0.916). The data subjected to unpaired t test reveals the existence of statistically non-significant association between weight/height/BMI distribution and intervention groups (p > 0.05)

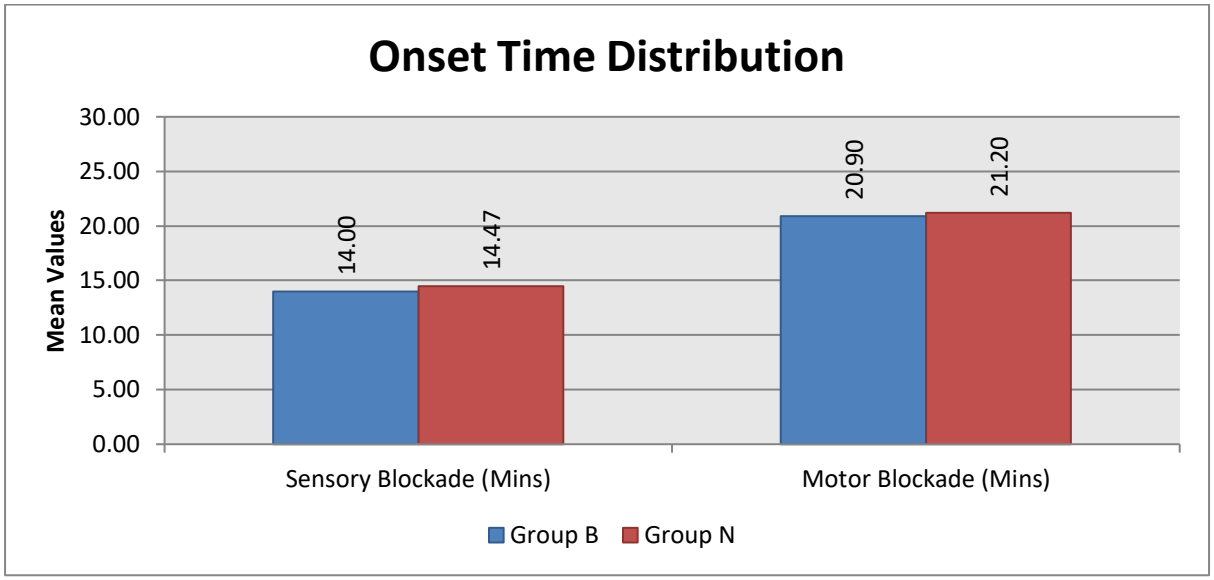
Duration of Surgery



Duration of Surgery Distribution (Mins)	Group B	Group N
Mean	125.67	125.57
SD	17.01	18.82
P value Unpaired t Test		0.983

On analysis of duration of surgery distribution table it was evident that group B subjects had a mean DOS of 125.67 mins and group N subjects had a mean DOS of 125.57 mins (p= 0.983). The data subjected to unpaired t test reveals the existence of statistically non-significant association between duration of surgery distribution and intervention groups ($p > 0.05$)

Onset Time



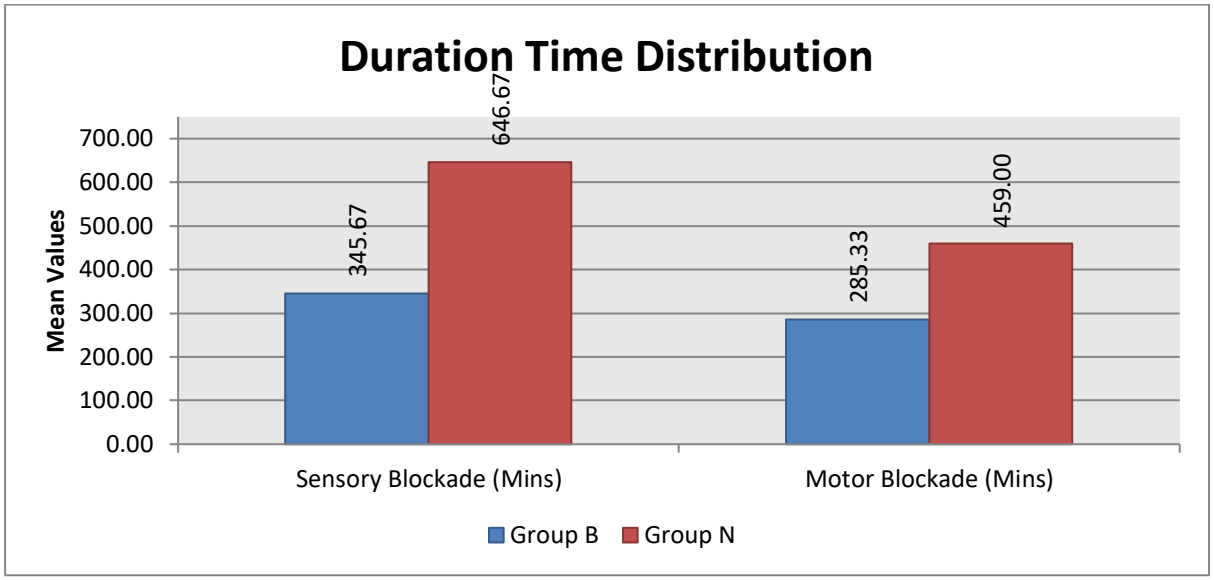
Onset Time Distribution		Sensory Blockade (Mins)	Motor Blockade (Mins)
Group B	*Mean*	14.00	20.90
	SD	1.46	2.17
Group N	*Mean*	14.47	21.20
	SD	1.46	1.85
P value Unpaired t Test		0.220	0.566

On analysis of motor blockade onset time distribution table it was evident that group B subjects had a mean onset time - sensory blockade of 14.00 mins and group N subjects had amean onset time - sensory blockade of 14.47 mins ($p = 0.220$).

On analysis of motor blockade onset time distribution table it was evident that group B subjects had a mean onset time - motor blockade of 20.90mins and group N subjects had amean onset time of 21.20mins ($p = 0.566$).

The data subjected to unpaired t test reveals the existence of statistically non-significant association between onset time – sensory/motor distribution and intervention groups ($p > 0.05$)

Duration Time



Duration Time Distribution		Sensory Blockade (Mins)	Motor Blockade (Mins)
Group B	*Mean*	345.67	285.33
	SD	14.55	14.79
Group N	*Mean*	646.67	459.00
	SD	23.24	19.36
P value Unpaired t Test		<0.001	<0.001

On analysis of motor blockade duration time distribution table it was evident that group B subjects had a mean duration time - sensory blockade of 345.67 mins and group N subjects had a mean duration time - sensory blockade of 646.47 mins (p= <0.001).

On analysis of motor blockade duration time distribution table it was evident that group B subjects had a mean duration time - motor blockade of 285.33 mins and group N subjects had amean duration time of 459.00 mins (p= <0.001).

The data subjected to unpaired t test reveals the existence of statistically significant association between duration time – sensory/motor blockade distribution and intervention groups ($p < 0.05$)

Discussion

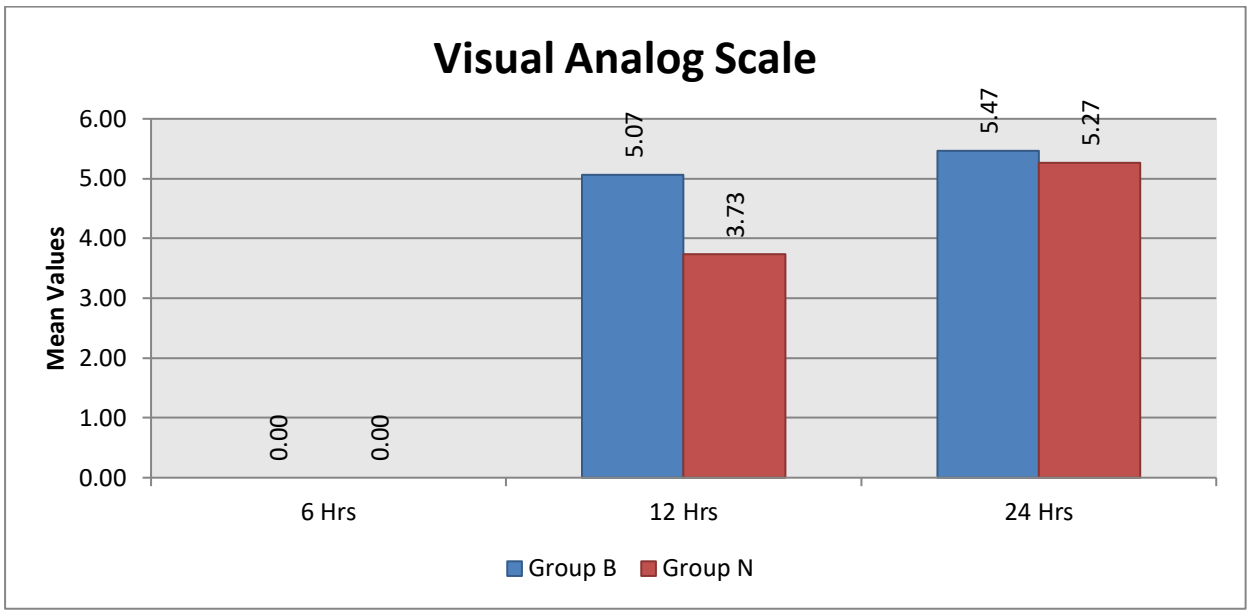
In our study the duration time – sensory/motor blockade distribution between the group B and group N was meaningfully significant. This is evident by:

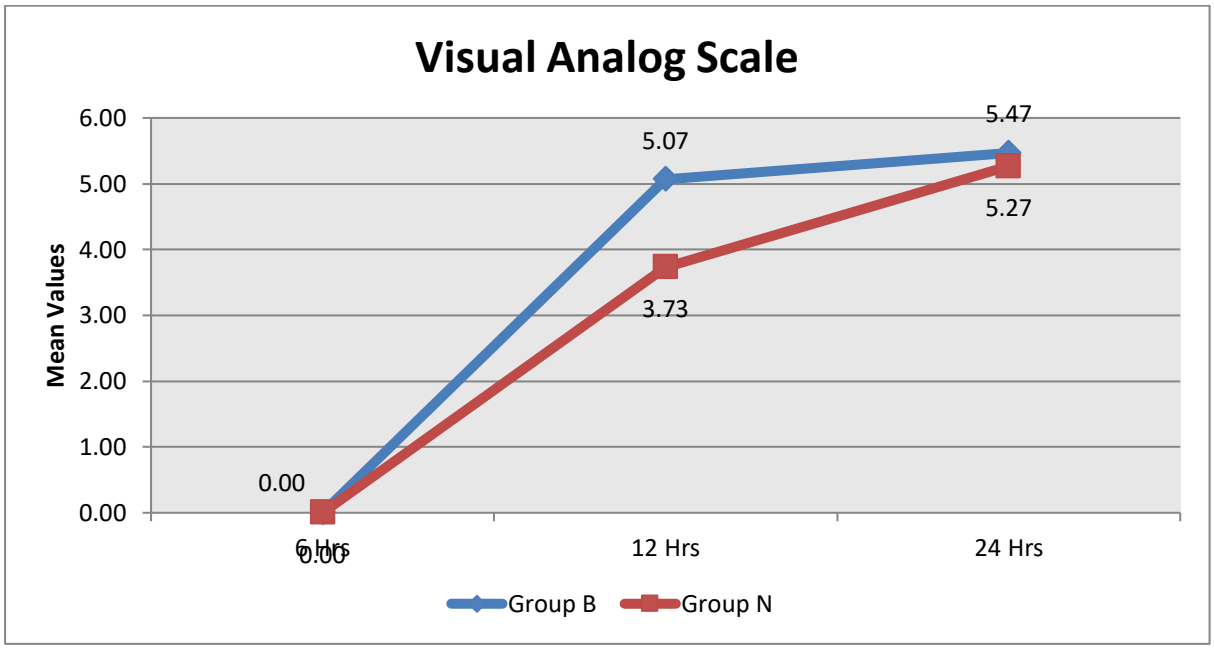
- Decreased mean duration time – sensory blockade in group B compared to group N (mean reduction difference of 301mins, 47% shorter). The same view was echoed by A study conducted by Mohammed et al on the effectiveness of adding Nalbuphine to Bupivacaine while performing supraclavicular brachial plexus blocks.
- Decreased mean duration time – motor blockadein group B compared to group N (mean reduction difference of 173.67 mins, 38% shorter). The same view was echoed by A study conducted by Mohammed et al on the effectivensss of adding Nalbuphine to Bupivacaine while performing supraclavicular brachial plexus blocks.

Conclusion

Anesthetic agent 0.5%Bupivacaine with Nalbuphinehad a longer duration of sensory and motor blockadecompared to 0.5% Bupivacaine alone as adjuvant for ultrasound guided supraclavicular brachial plexus block

VAS


Visual Analog Scale
Mean Values
6.00
5.00
4.00
3.00
2.00
1.00
0.00
0.00
0.00
5.07
3.73
5.47
5.27
6 Hrs
12 Hrs
24 Hrs
Group B
Group N


Visual Analog Scale
Mean Values
6.00
5.00
4.00
3.00
2.00
1.00
0.00
0.00
5.07
3.73
5.47
5.27
6 Hrs
12 Hrs
24 Hrs
Group B
Group N

Visual Analog Scale		6 Hrs	12 Hrs	24 Hrs
Group B	*Mean*	0.00	5.07	5.47
	SD	0.00	0.91	0.97
Group N	*Mean*	0.00	3.73	5.27
	SD	0.00	0.98	1.39
P value Unpaired t Test		>0.999	<0.001	0.521

On analysis of pain score (VAS) distribution table it was evident that group B subjects had a mean pain score of 0.00, 5.07 and 5.47 at 6, 12 and 24 hours respectively. Similarly in Group N subjects had a mean pain score of 0.00, 3.73 and 5.12 at 6, 12 and 24 hours respectively

(6 hrs - p= >0.999). (12 hrs - p= <0.001). (24 hrs - p= 0.521).

The data subjected to unpaired t test reveals the existence of statistically non-significant association between pain scores at 6 and 24 hours PO and intervention groups ($p > 0.05$) and reveals the existence of statistically significant association between pain scores at 12hours Post operatively and intervention groups ($p < 0.05$)

Discussion

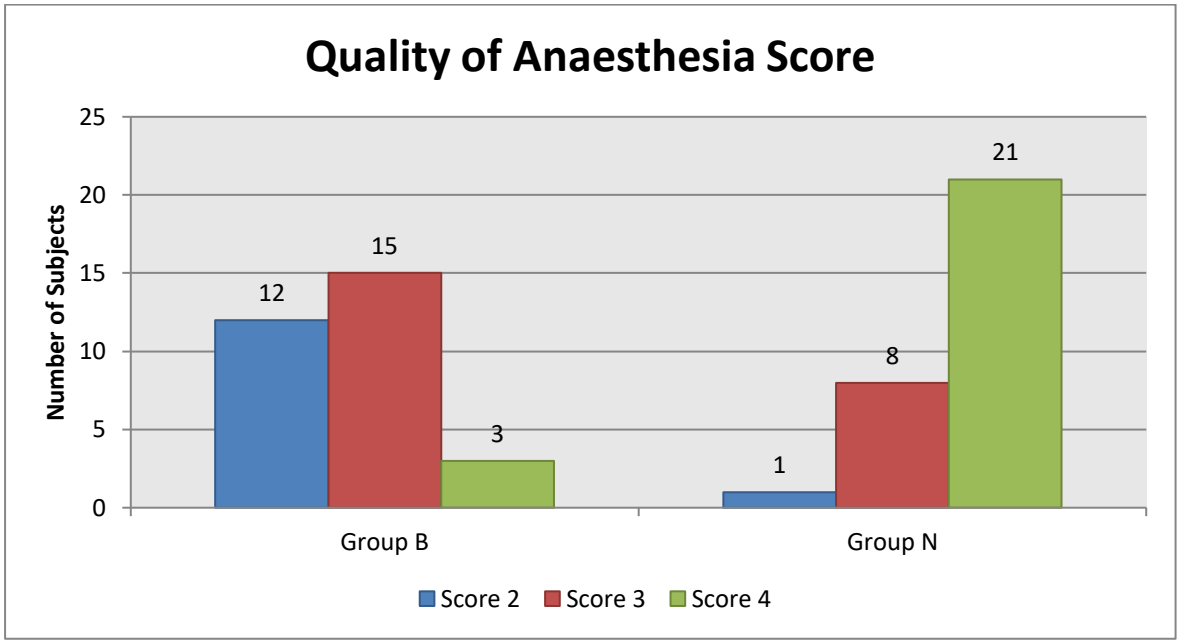
In our study the pain score distribution between the group B and group N was meaningfully significant. This is evident by increased mean pain score in group B compared to group N (mean elevation difference of 1.33 points,26% higher).

The same view was echoed by A study conducted by Mohammed Et al on the effectiveness when Nalbuphine is added as an adjunct to Bupivacaine while performing supraclavicular brachial plexus blocks.

Conclusion

There were no differences in pain scores between intervention groups during immediate and late postoperative period. Anesthetic agent 0.5%Bupivacaine with Nalbuphineproduced better medium term pain control at 12 hours postoperative period compared 0.5% Bupivacaine alone as adjuvant for ultrasound guided supraclavicular brachial plexus block.

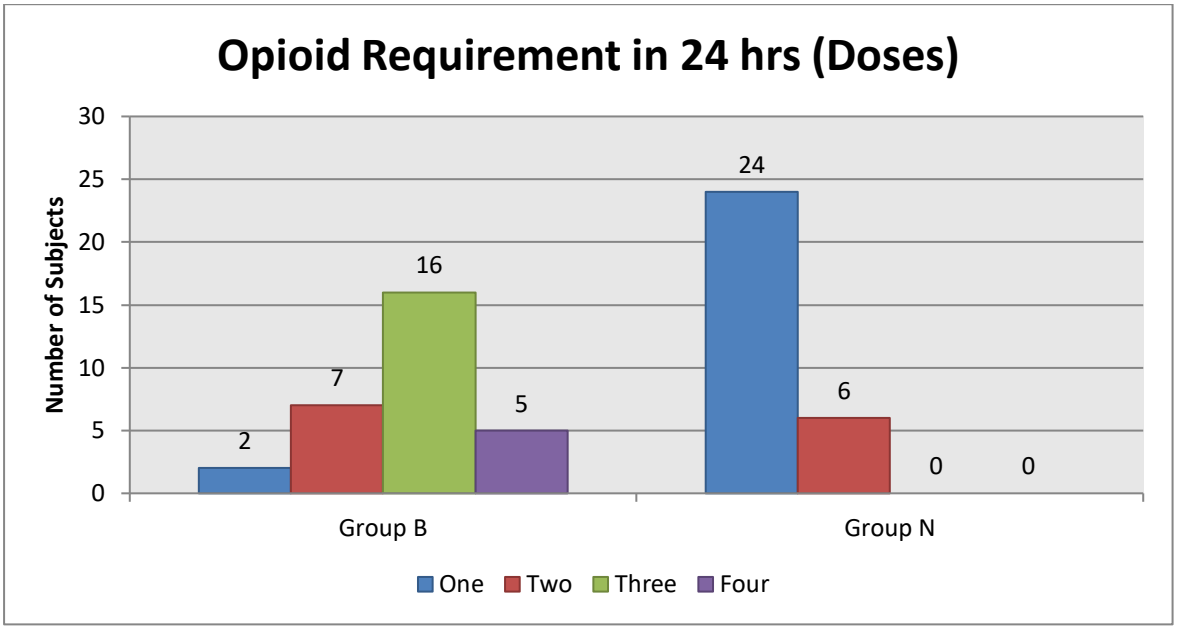
Quality of Anaesthesia



Quality of Anaesthesia Score	Group B	%	Group N	%
Score 2	12	40.00	1	3.33
Score 3	15	50.00	8	26.67
Score 4	3	10.00	21	70.00
Total	30	100.00	30	100.00
P value Chi Squared Test	0.071			

On analysis of quality of anaesthesia score distribution table it was evident that majority of group B subjects had QAS of score 3 (50,00%) and majority of group N subjects had QAS of score 4 (70,00%) ($p = 0.071$). The data subjected to chi squared test reveals the existence of statistically non-significant association between quality of anaesthesia scores and intervention groups ($p > 0.05$)

Opioid Requirement in 24 hrs



Opioid Requirement in 24 hrs (Doses)	Group B	%	Group N	%
One	2	6.67	24	80.00
Two	7	23.33	6	20.00
Three	16	53.33	0	0.00
Four	5	16.67	0	0.00
Total	30	100.00	30	100.00
P value Chi Squared Test	<0.001			

On analysis of opioid requirement for 24 hours distribution table it was evident that majority of group B subjects were given three doses of opioid (53,33%) and majority of group N subjects were given one dose of opioid (80,00%) (p= <0.001). The data subjected to chi squared test reveals the existence of

statistically significant association between opioid requirement for 24 hours and intervention groups ($p < 0.05$)

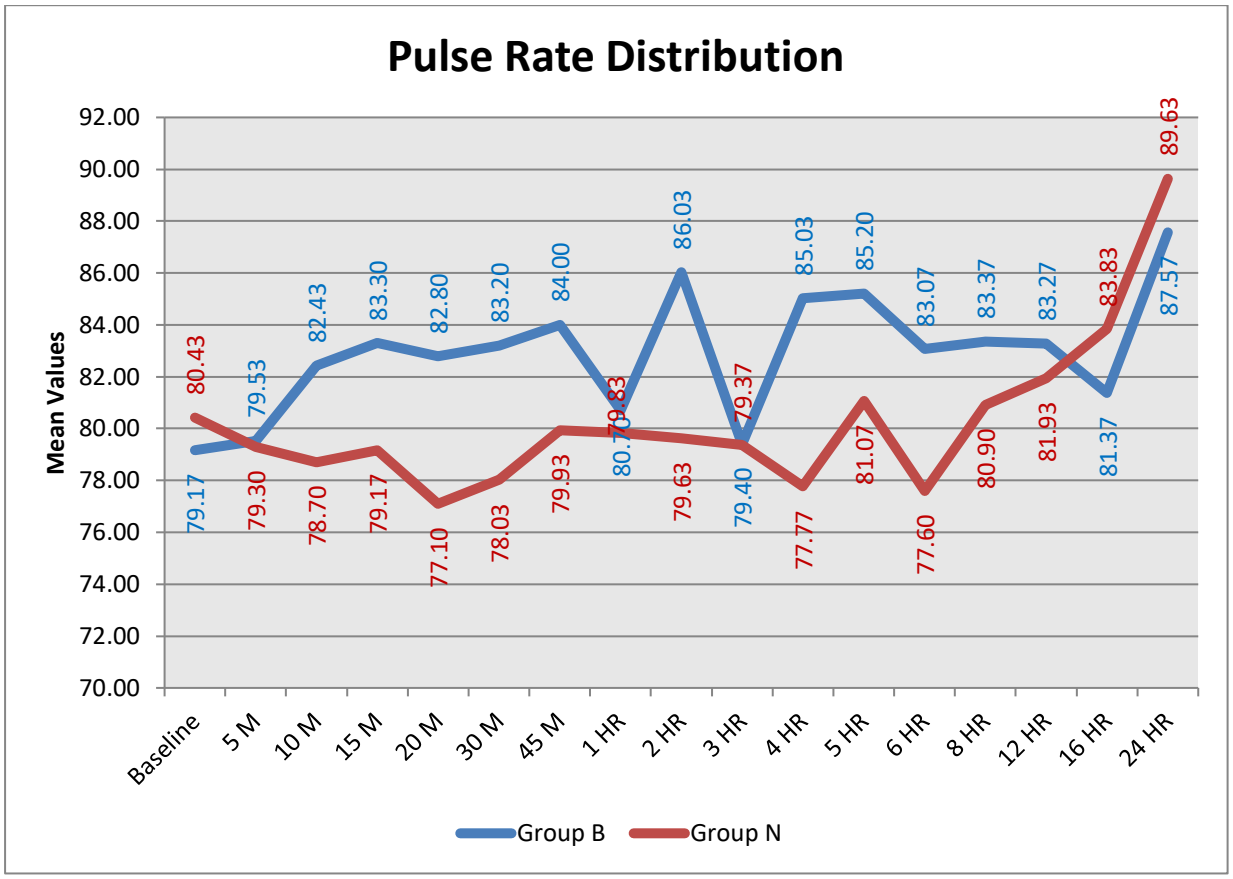
Discussion

In our study the opioid requirement for 24 hours distribution between the group B and group N was meaningfully significant. This is evident by increased opioid requirement for 24 hours in group B compared to group N (mean increased difference of 73.33 points at one dose level, 92% higher). The same view was echoed by The study conducted by Mohammed et al on the effectiveness of Nalbuphine when added to Bupivacaine as adjunct while performing supraclavicular brachial plexus blocks.

Conclusion

Anesthetic agent 0.5%Bupivacaine with Nalbuphine produced better pain management compared to 0.5% Bupivacaine as adjuvant for ultrasound guided supraclavicular brachial plexus block

PR


Pulse Rate Distribution
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88.00
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82.00
80.00
78.00
76.00
74.00
72.00
70.00
Baseline
5 M
10 M
15 M
20 M
30 M
45 M
1 HR
2 HR
3 HR
4 HR
5 HR
6 HR
8 HR
12 HR
16 HR
24 HR
79.17
79.53
82.43
83.30
82.80
83.20
84.00
80.70
86.03
79.37
85.03
85.20
83.07
83.37
83.27
81.37
87.57
80.43
79.30
78.70
79.17
77.10
78.03
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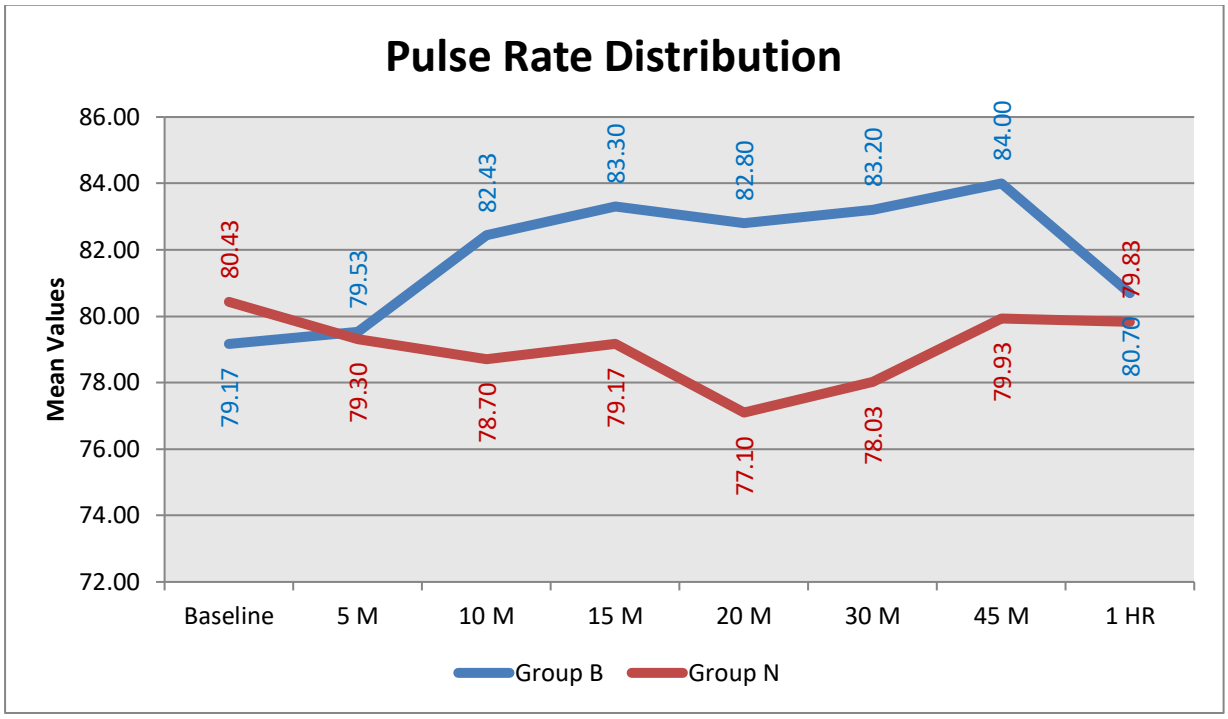
81.07
77.60
80.90
81.93
83.83
89.63
Group B
Group N


Pulse Rate Distribution
Mean Values
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80.00
78.00
76.00
74.00
72.00
Baseline
5 M
10 M
15 M
20 M
30 M
45 M
1 HR
79.17
79.53
82.43
83.30
82.80
83.20
84.00
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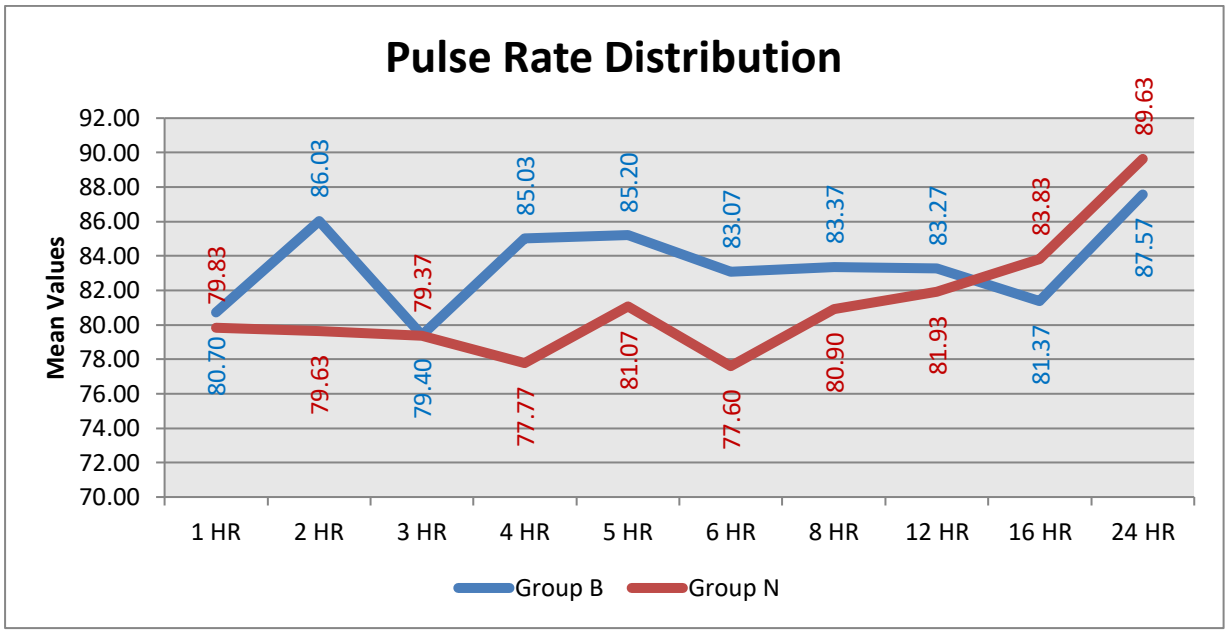
80.43
79.30
78.70
79.17
77.10
78.03
79.93
79.83
Group B
Group N


Pulse Rate Distribution
Mean Values
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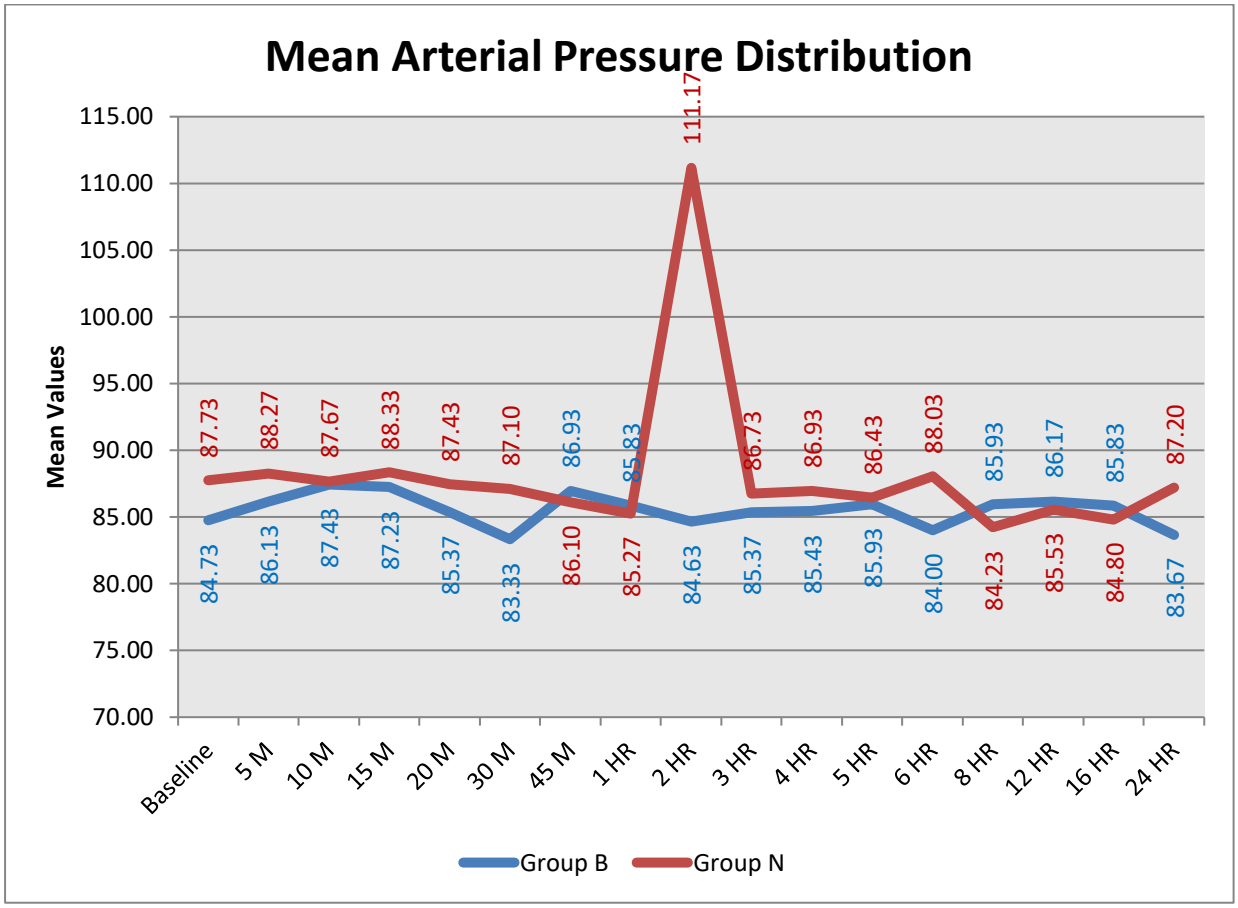
86.00
84.00
82.00
80.00
78.00
76.00
74.00
72.00
70.00
1 HR
2 HR
3 HR
4 HR
5 HR
6 HR
8 HR
12 HR
16 HR
24 HR
80.70
86.03
79.40
85.03
85.20
83.07
83.37
83.27
81.37
87.57
79.83
79.63
79.37
77.77
81.07
77.60
80.90
81.93
83.83
89.63
Group B
Group N

Pulse Rate Distribution	Group B		Group N		P value Unpaired t Test
	Mean	*SD*	*Mean*	*SD*	
Baseline	79.17	7.71	80.43	6.81	0.503
5 M	79.53	6.54	77.37	7.52	0.238
10 M	82.43	6.93	80.37	8.14	0.294
15 M	83.30	6.25	77.17	7.36	0.456
20 M	82.80	5.68	80.07	7.70	0.123
30 M	83.20	5.07	76.90	7.91	0.582
45 M	84.00	6.52	78.27	10.18	0.712
1 HR	80.70	7.03	78.63	7.75	0.284
2 HR	86.03	7.24	76.50	6.70	0.445
3 HR	79.40	7.70	79.50	8.06	0.961
4 HR	85.03	6.54	81.20	7.12	0.682
5 HR	85.20	8.09	81.57	6.00	0.065
6 HR	83.07	5.00	80.00	8.15	0.084
8 HR	83.37	4.67	80.37	7.25	0.062
12 HR	83.27	6.64	82.13	7.92	0.550
16 HR	81.37	6.19	83.83	6.21	0.129
24 HR	87.57	8.32	90.20	8.91	0.242

On analysis of pulse rate distribution table it was evident that group B subject had a mean overall PR of 82.91 bpm and group N subjects had a mean overall PR of 80.94 bpm ($p= 0.216$). The data subjected to unpaired t test reveals the existence of statistically non-significant association betweenpulse rate and intervention groups ($p > 0.05$)

MAP


Mean Arterial Pressure Distribution
Mean Values
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105.00
100.00
95.00
90.00
85.00
80.00
75.00
70.00
Baseline
5 M
10 M
15 M
20 M
30 M
45 M
1 HR
2 HR
3 HR
4 HR
5 HR
6 HR
8 HR
12 HR
16 HR
24 HR
87.73
88.27
87.67
88.33
87.43
87.10
86.93
85.83
111.17
86.73
86.93
86.43
88.03
85.93
86.17
85.83
87.20
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86.13
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87.23
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83.33
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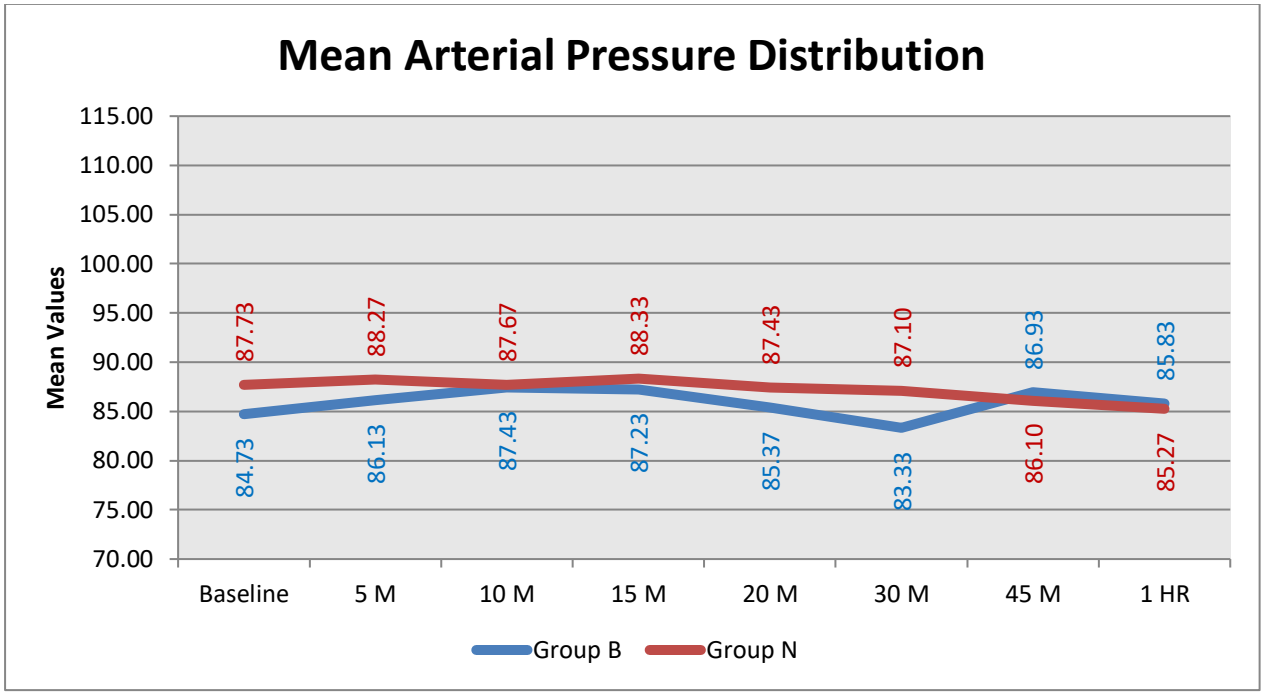
83.67
Group B
Group N


Mean Arterial Pressure Distribution
Mean Values
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90.00
85.00
80.00
75.00
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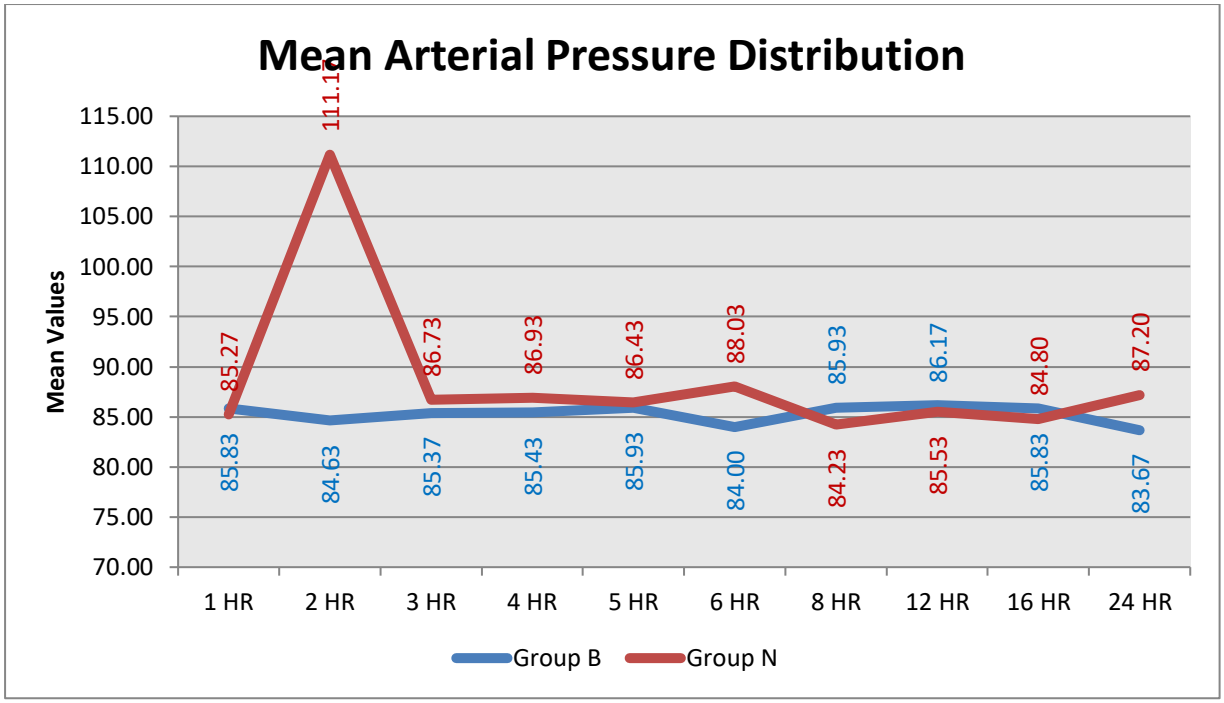
87.67
88.33
87.43
87.10
86.93
85.83
84.73
86.13
87.43
87.23
85.37
83.33
86.10
85.27
Baseline
5 M
10 M
15 M
20 M
30 M
45 M
1 HR
Group B
Group N


Mean Arterial Pressure Distribution
Mean Values
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100.00
95.00
90.00
85.00
80.00
75.00
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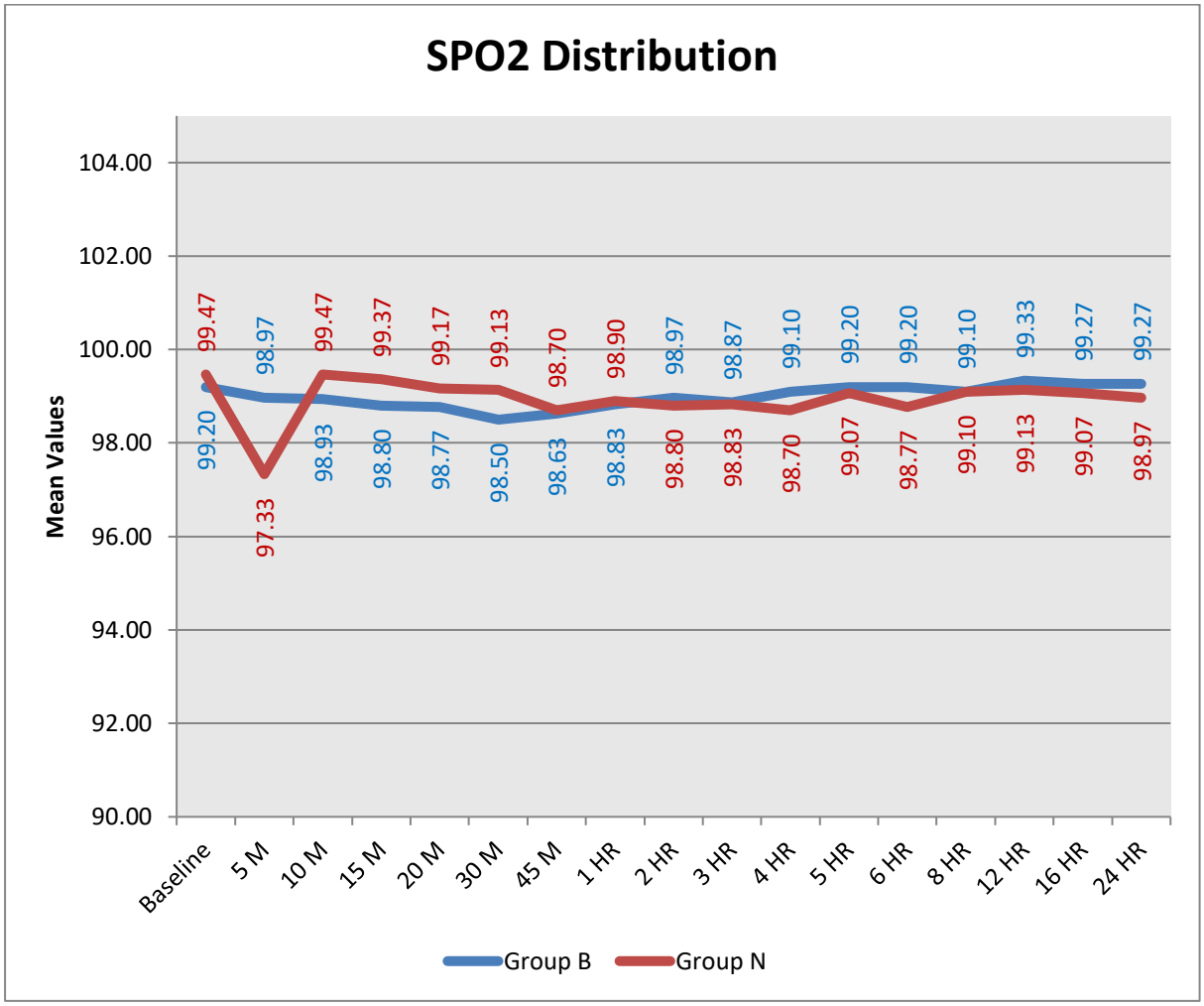
85.27
111.13
86.73
86.93
86.43
88.03
85.93
86.17
84.80
87.20
85.83
84.63
85.37
85.43
85.93
84.00
84.23
85.53
85.83
83.67
1 HR
2 HR
3 HR
4 HR
5 HR
6 HR
8 HR
12 HR
16 HR
24 HR
Group B
Group N

Mean Arterial Pressure Distribution	Group B		Group N		P value Unpaired t Test
	Mean	*SD*	*Mean*	*SD*	
Baseline	84.73	5.58	87.73	7.60	0.087
5 Minutes	86.13	7.03	88.27	8.21	0.284
10 Minutes	87.43	6.95	87.67	8.51	0.908
15 Minutes	87.23	6.80	88.33	8.47	0.581
20 Minutes	85.37	6.24	87.43	8.84	0.300
30 Minutes	83.33	16.11	87.10	7.59	0.251
45 Minutes	86.93	7.14	86.10	7.25	0.655
1 Hour	85.83	6.33	85.27	6.82	0.740
2 Hours	84.63	7.56	111.17	140.70	0.307
3 Hours	85.37	6.57	86.73	7.47	0.455
4 Hours	85.43	6.33	86.93	6.91	0.384
5 Hours	85.93	7.72	86.43	6.33	0.785
6 Hours	84.00	15.40	88.03	7.34	0.200
8 Hours	85.93	6.03	84.23	15.26	0.573
12 Hours	86.17	6.11	85.53	8.55	0.743
16 Hours	85.83	5.83	84.80	7.81	0.564
24 Hours	83.67	5.82	87.20	6.12	0.026
Overall	85.53	4.99	88.17	9.78	0.192

On analysis of mean arterial pressure distribution table it was evident that group B subject had a mean overall MAP of 85.53 mm Hg and group N subjects had a mean overall MAP of 88.17 mm Hg ($p= 0.192$). The data subjected to unpaired t test reveals the existence of statistically non-significant association between mean arterial pressure and intervention groups ($p > 0.05$)

SPO2


SPO2 Distribution
Mean Values
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102.00
100.00
98.00
96.00
94.00
92.00
90.00
Baseline
5 M
10 M
15 M
20 M
30 M
45 M
1 HR
2 HR
3 HR
4 HR
5 HR
6 HR
8 HR
12 HR
16 HR
24 HR
99.20
98.97
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98.80
98.77
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98.63
98.83
98.97
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99.10
99.20
99.20
99.10
99.33
99.27
99.27
99.47
97.33
99.47
99.37
99.17
99.13
98.70
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98.83
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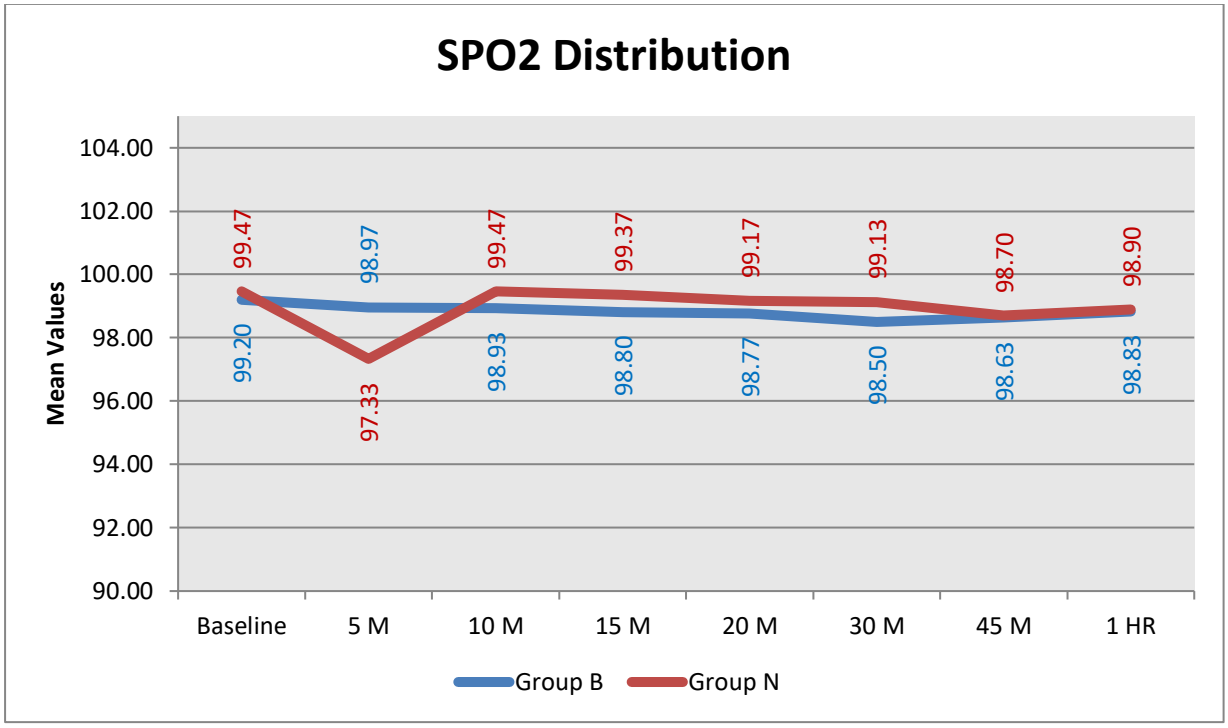
99.07
98.77
99.10
99.13
99.07
98.97
Group B
Group N


SPO2 Distribution
Mean Values
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99.37
99.17
99.13
98.70
98.90
99.20
97.33
98.93
98.80
98.77
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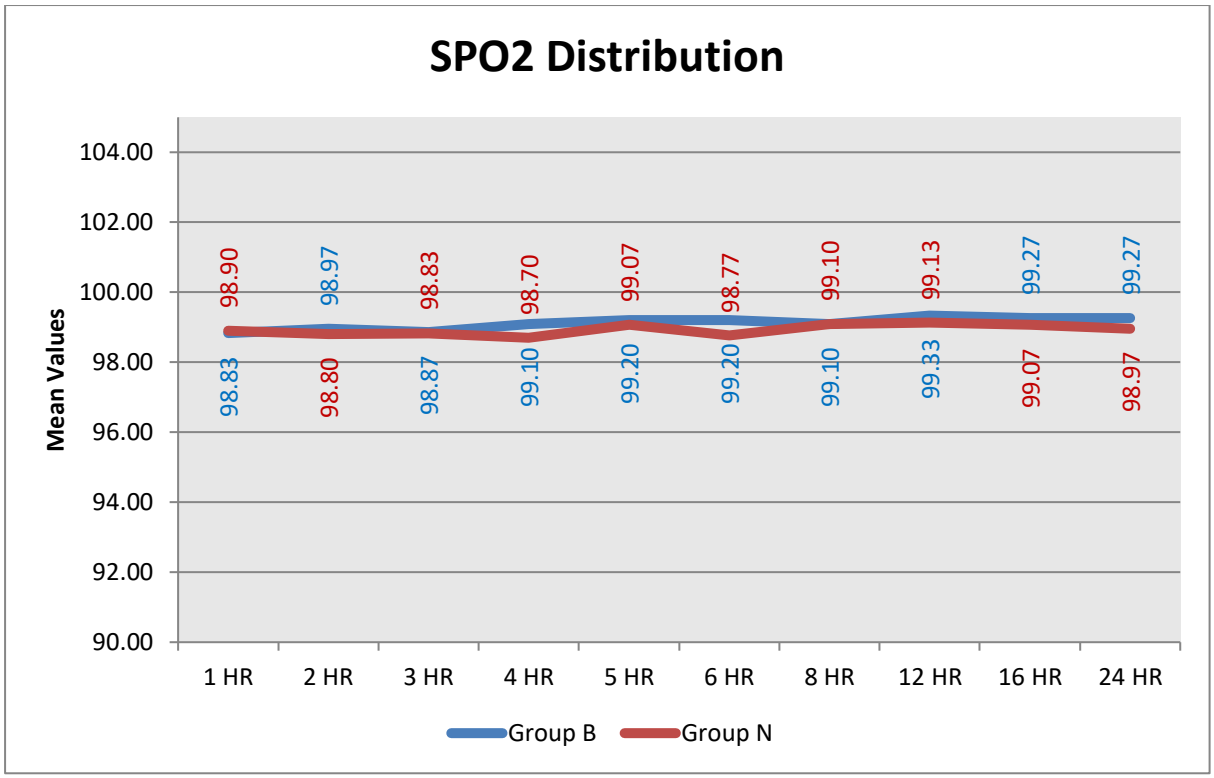
98.63
98.83
Baseline
5 M
10 M
15 M
20 M
30 M
45 M
1 HR
Group B
Group N


SPO2 Distribution
Mean Values
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98.70
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99.27
98.83
98.80
98.87
99.10
99.20
99.20
99.10
99.33
99.07
98.97
1 HR
2 HR
3 HR
4 HR
5 HR
6 HR
8 HR
12 HR
16 HR
24 HR
Group B
Group N

SPO2 Distribution	Group B		Group N		P value Unpaired t Test
	Mean	*SD*	*Mean*	*SD*	
Baseline	99.20	0.85	99.47	0.63	0.171
5 Minutes	98.97	2.37	97.33	5.70	0.152
10 Minutes	98.93	2.89	99.47	0.63	0.327
15 Minutes	98.80	2.54	99.37	0.72	0.244
20 Minutes	98.77	2.24	99.17	0.87	0.366
30 Minutes	98.50	2.45	99.13	0.78	0.182
45 Minutes	98.63	2.40	98.70	1.02	0.889
1 Hour	98.83	0.83	98.90	1.12	0.795
2 Hours	98.97	0.85	98.80	1.00	0.489
3 Hours	98.87	0.97	98.83	0.91	0.892
4 Hours	99.10	0.92	98.70	0.99	0.111
5 Hours	99.20	0.81	99.07	0.83	0.530
6 Hours	99.20	0.92	98.77	1.01	0.088
8 Hours	99.10	0.88	99.10	0.71	>0.999
12 Hours	99.33	0.76	99.13	0.97	0.378
16 Hours	99.27	0.78	99.07	0.94	0.376
24 Hours	99.27	0.91	98.97	0.89	0.201

On analysis of SPO2 distribution table it was evident that group B subject had a mean overall SPO2 of 99.00% and group N subjects had a mean overall SPO2 of 98.94% ($p= 0.808$). The data subjected to unpaired t test reveals the existence of statistically non-significant association betweenSPO2and intervention groups ($p > 0.05$)

Overall Conclusion

Anesthetic agent 0.5%Bupivacaine with Nalbuphine in comparisin to 0.5%Bupivacaine alone as adjuvant for ultrasound guided supraclavicular brachial plexus block:

- Equivocal duration of surgery
- Equivocal sensory blockade onset time
- Equivocal motor blockade onset time
- Longer duration of sensory blockade
- Longer duration of motor blockade
- Equivocal immediate postoperative pain scores
- Lower postoperative pain scores at 12 hours
- Equivocal Quality of anaesthesia
- Lower opioid requirement
- Better immediate and midterm postoperative pain management
- Equivocal hemodynamic stability

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PROFORMA

"A STUDY ON THE EFFECT OF NALBUPHINE AS AN ADJUVANT TO BUPIVACAINE FOR ULTRASOUND GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS NERVE BLOCK"

Name:

Age/Gender:

IP Number:

Height: cm

Weight: kg

BMI:

Date of surgery:

ASA Physical status:

Co morbidity:

Drug history:

Group(Tick any one)

Group B : 25 ml Bupivacine 0.5% and 1 ml normal saline (control group).

Group N : 25 ml Bupivacaine 0.5% plus 10 mg Nalbuphine (test group)

ASSESSMENT CRITERIA	Group B	Group N	
Onset of sensory blockade			
Onset of motor blockade			
Duration of sensory blockade			
Duration of motor blockade			
Heart rate			
Blood pressure(mean arterial pressure)			
Respiratory rate			
Oxygen saturation			
Duration of post operative analgesia(time of first requisition of analgesic)			

INFORMED CONSENT FORM

STUDY: "A STUDY ON THE EFFECT OF NALBUPHINE AS AN ADJUVANT TO BUPIVACAINE FOR ULTRASOUND GUIDED SUPRACLAVICULAR BRACHIAL PLEXUS NERVE BLOCK".

STUDY CENTRE: GOVT. KILPAUK MEDICAL COLLEGE HOSPITAL & GOVT ROYAPETTAH HOSPITAL, CHENNAI.

PATIENT'S NAME:

PATIENT'S AGE:

I.P NO :

Patient may check (✓) these boxes

I confirm that I understood the purpose of the procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction ☐

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ☐

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will ☐

need not my permission to look at my health records, both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law.

I agree not to restrict the use of any data or results that arise from the study.I agree to take part in the above study and to comply with the instructions given during the study and faithfully co operate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ☐

I hereby consent to participate in this study. ☐

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests. ☐

Signature / thumb impression:

Patient’s name and address: place:
date:

Signature of the investigator:

Study investigator's name: place: date:

PARTICIPANTS INFORMATION SHEET

Investigator :

Name of the participant :

Title: " A STUDY ON THE EFFECT OF NALBUPHINE AS AN ADJUVANT TO BUPIVACAINE FOR ULTRASOUND GUIDED

SUPRACLAVICULAR BRACHIAL PLEXUS NERVE BLOCK".

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria.

What is the purpose of this research?

In this study, efficacy of Nalbuphine as adjuvant to Bupivacaine for supraclavicular block will be evaluated so that the patient will have increased duration of postoperative analgesia without much effect on the onset of sensory or motor blockade.

BENEFITS:

This study will help us in determining the effect of Nalbuphine as an adjuvant to Bupivacaine for supraclavicular brachial plexus blocks.Nalbuphine causes better postoperative analgesia without much affecting the onset of motor and sensory block.

DISCOMFORTS AND RISKS:

Nalbuphine may also cause nausea, vomting, pruritus and dizziness in some patients.

CONFIDENTIALITY:

Patients who participated in the study and their details will be maintained confidentially and at any cost, those details will not be let out

RIGHT TO WITHDRAW :

Patients will not be forced to complete the study. At any cost, in such circumstances the treatment will not be compromised.

Date : Signature of the investigator:

Place :

Signature/Thumb impressionof the participant

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

கீழ்ப்பாக்கம் மற்றும் ராயப்பேட்டா அரசு பொது மருத்துவமனையில் மேல் மூட்டு அறுவை சிகிச்சையில் கமுத்துப்பட்டை எலும்புக்கு மேல்நிலையான நரம்புகளை சுற்றியுள்ள பகுதியில் nalbuphine+bupivacaine ஆகியவற்றின் வலி நிவாரணி பண்புகளின் ஒப்பிட்டு ஆய்வு.

ஆராய்ச்சி நிலையம்: மயக்கவியல் மருத்துவத் துறை,

கீழ்ப்பாக்கம் மருத்துவக்கல்லூரி மற்றும் ராயப்பேட்

அரசு பொது மருத்துவமனை,

சென்னை

பங்கு பெறுபவரின் பெயர்: **உறவு முறை:**

பங்கு பெறுபவரின் எண்:

பங்கு பெறுபவர் இதனை (√) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும் அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்மந்தமாகவும், மேலும் இது சார்ந்த ஆய்வு மேற்கொள்ளும்போதும், இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்துகொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும், அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்துகொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறாக நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன். ☐

இந்த ஆய்வில் எனக்கு மருத்துவப் பரிசோதனை, மேல் மூட்டு அறுவை சிகிச்சையில் கமுத்துப்பட்டை எலும்புக்கு மேல்நிலையான நரம்புகளை சுற்றியுள்ள பகுதியில் nalbuphine+bupivacaine ஆகியவற்றின் வலி நிவாரணி பண்புகளின் ஒப்பிட்டு ஆய்வுகுறித்து ஆராய்ச்சி செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன். ☐

பங்கேற்பவரின் கையொப்பம் ..... இடம் .....
தேதி .....

கட்டைவிரல் ரேகை:

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்
.....

ஆய்வாளரின் கையொப்பம் ..... இடம்
.....தேதி .....

ஆய்வாளரின் பெயர் .....

ஆராய்ச்சி தகவல் தாள்

கீழ்ப்பாக்கம் மற்றும் ராயப்பேட்டா அரசு பொது மேல் மூட்டு அறுவை சிகிச்சையில் கமுத்துப்பட்டை எலும்புக்கு மேல்நிலையான நரம்புகளை சுற்றியுள்ள பகுதியில் nalbuphine+bupivacaine நிவாரணி பண்புகளின் ஒப்பிட்டு ஆய்வு செய்ய உள்ளோம்.

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் பங்கேற்பதால் தங்களது நோயின் ஆய்வறிக்கையோ அல்லது சிகிச்சையோ பாதிக்கப்படாது என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துகளை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியில் இருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த சிறப்புப் பரிசோதனைகளின் முடிவுகளை ஆராய்ச்சியின் போதோ அல்லது ஆராய்ச்சியின் முடிவின் போதோ தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கோள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி:

S.NO	Name	Age	Sex	ASA status	Wt in Kg	Height in Cm	Body mass index in kg/m^2	Duration of Surgery (Minutes)	Onset Time (Minutes)		Duration
									sensory blockade	Motor blockade	Sensory blockade
1	kathir	28	male	1	61	161	23.82	125	14	20	340
2	Pandi	25	male	1	56	165	20.57	140	15	23	350
3	jagadeesh	22	male	1	54	158	21.68	155	16	18	330
4	ravi	44	male	2	68	163	25.66	100	12	19	370
5	santhakumari	42	male	1	59	169	21.93	110	15	21	340
6	lawrence	28	male	1	64	174	22.14	95	13	20	360
7	karthick	17	male	1	52	162	19.84	125	14	22	350
8	shakul ahmed	32	male	1	63	155	26.25	130	16	23	330
9	thulasi	40	female	2	65	167	23.38	145	12	19	340
10	lakshmi	38	female	1	61	174	20.19	120	13	18	340
11	murugayan	40	male	1	64	169	22.45	135	15	23	350
12	ranjithkumar	30	male	1	65	159	25.79	145	12	20	330
13	ramya	26	female	1	57	168	20.21	150	14	21	320
14	jeeva	32	female	1	61	171	20.89	135	14	18	350
15	mani	24	male	1	62	168	21.98	125	15	19	340
16	vignesh	19	male	1	46	159	18.25	110	16	20	370
17	mohan	35	male	1	64	163	25.29	90	13	24	360
18	praveen	36	male	1	63	170	21.79	120	12	23	350
19	chinnapa	33	male	1	64	168	22.69	130	11	20	370
20	tirupathi	34	male	1	65	163	24.52	125	14	21	360
21	kalaiseli	34	female	1	56	152	24.2	130	16	24	350
22	muthukumar	33	male 1	1	68	163	25.62	145	14	20	360
23	harish	25	male	1	60	167	21.53	135	15	23	330
24	kumar	45	male	2	68	167	24.43	140	16	24	360
25	poongodi	28	female	1	54	154	22.78	120	13	18	340
26	kumaravel	60	male	1	60	165	22	130	14	18	330
27	kannadasn	56	male	1	65	167	23.32	140	12	18	320
28	kanniyappan	45	male	2	60	166	21.79	120	14	23	360
29	manish	40	male	1	66	167	23.71	105	16	24	330
30	lalu	45	male	1	70	168	24.82	95	14	23	340