COMPARISON OF SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK BY NERVE STIMULATOR AND ULTRASOUND GUIDED METHOD

Dissertation submitted to The Tamilnadu Dr. M. G. R. Medical University Chennai – 600032

With fulfillment of the regulations for the award of Degree

M.D. ANAESTHESIOLOGY BRANCH- X



DEPARTMENT OF ANAESTHESIOLOGY, K.A.P.V. GOVERNMENT MEDICAL COLLEGE, TRICHY.

April-2017

CERTIFICATE

This is to certify that this dissertation titled "COMPARISON OF SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK BY NERVE STIMULATOR AND ULTRASOUND GUIDED METHOD" is a bonafide work of DR.C.SENTHIL, Post Graduate in M.D. Anaesthesiology, Department of Anaesthesiology, K.A.P.V. Government Medical College, Trichy and has been prepared by him under our guidance. This has been submitted in partial fulfilment of regulations of The Tamil Nadu Dr. M.G.R Medical University, Chennai-32 for the award of M.D. Degree in Anaesthesiology.

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DECLARATION

I, Dr. C.SENTHIL, solemnly declare that this dissertation titled, "COMPARISON OF SUPRACLAVICULAR BRACHIAL PLEXUS BLOCK BY NERVE STIMULATOR AND ULTRASOUND GUIDED METHOD" is a bonafide work done by me at K.A.P.V. Government Medical College during 2015-2016 under the guidance and supervision of Prof. Dr.R. SELVAKUMAR, M.D.,D.A.,DNB Professor and Head of the Department of Anaesthesiology. The dissertation is submitted to the Tamilnadu Dr. M. G. R. Medical University, towards the partial fulfilment of requirement for the award of M.D. Degree in Anaesthesiology Branch X.

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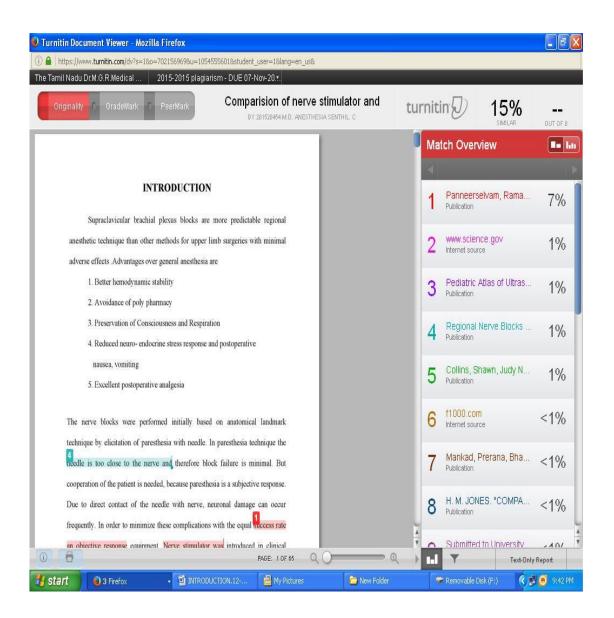
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INTRODUCTION

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ABBREVATIONS

μg	-	MicroGram	
ASA	-	American society of Anaesthesiologist	
DBP	-	Diastolic Blood pressure	
ECG	-	Electrocardiogram	
HR	-	Heart rate	
I.M	-	Intramuscular	
I.V	-	Intravascular	
Inj	-	Injection	
kg/Bw	-	Kilogram/ body weight	
MHz	-	Mega hertz	
Min	-	Minutes.	
Ml	-	Milli Litre	
MmHg	-	Milli meter of mercury	
NIBP	-	Non invasive blood pressure	
PR	-	Pulse rate	
SBP	-	Systolic Blood pressure	
SD	-	Standard deviation .	
SAo2	-	Saturated arterial oxygen tension	
NS	-	Nerve stimulator	
US	-	Ultrasound	

INTRODUCTION

Supraclavicular brachial plexus blocks are more predictable regional anesthetic technique than other methods for upper limb surgeries with minimal adverse effects .Advantages over general anesthesia are

- Better hemodynamic stability
- Avoidance of poly pharmacy
- Preservation of Consciousness and Respiration
- Reduced neuro- endocrine stress response and postoperative nausea, vomiting

Excellent postoperative analgesia

The nerve blocks were performed initially based on anatomical landmark technique by elicitation of paresthesia with needle. In paresthesia technique the needle is too close to the nerve and therefore block failure is minimal. But cooperation of the patient is needed, because paresthesia is a subjective response. Due to direct contact of the needle with nerve, neuronal damage can occur frequently. In order to minimize these complications with the equal success rate an objective response equipment, Nerve stimulator was introduced in clinical practice.

In peripheral nerve stimulator the electrical current required to elicit muscle contractions which well correlates with the distance between the tip of the needle and nerve. The needle malposition was minimal and localization of individual nerve was without elicitation of a paresthesia, thus guaranteeing a better blockade than the conventional paresthesia elicited method. It is also a anatomical landmark oriented technique and may lead to residual neuronal damage.

The real time imaging Ultrasonogram was used in direct visualization of nerves and vessels. Ultrasonogram added focus over the conventional paresthesia elicited methods. Though it is a real time imaging device the incidence of success rate and adverse effects has to be detailed before performing the block.

The scarcity of appropriate instruments, high cost and lack of training are the reasons for the hindrance in their usage in routine clinical practice till the last few years. Nowadays economical, portable ultrasound machines and more <u>teaching programme</u> are accessible enabling us to achieve the peripheral nerve blocks successfully.

The introduction of Ultrasonogram has generated a yearning of identifying the better technique with more success and least complication rate.. Therefore we conducted a study to compare the usefulness of ultrasound and nerve stimulator for supra clavicular brachial plexus block in upper limb surgeries.

AIMS & OBJECTIVES

- To compare the effects of supraclavicular brachial plexus block using nerve stimulator and USG technique in terms of:
- Time taken for the procedure (Block execution time)
- Onset of sensory blockade
- Onset of motor blockade.
- Success rate
- Incidence of complications
- Total duration of analgesia

PHYSIOLOGICAL BASIS OF PERIPHERAL NERVE STIMULATON

The efficacy of nerve stimulator corresponds to the intensity, duration, and polarity of the current used for nerve stimulation and the distance between needle (stimulus) and the nerve. For nerve propagation, a certain stimulus should be applied to the nerve, below that threshold propagation does not occur. Commonly, rectangular pulse of current is used for peripheral nerve stimulation. When stimulation occurs with square pulse of the current, the charge delivered is the product of strength and the pulse interval of current.

RHEOBASE-is the minimal threshold current that is needed to stimulate a nerve with long pulse width.

CHRONAXIE- is the time duration of the stimulus needed to stimulate at twice the rheobase. A- α (motor) fibres can be stimulated without stimulating A- δ and C fibres that transmit pain. Moreover mixed nerves can be identified by evoking a motor response without causing patient discomfort. It measures threshold of nerve fibres and compare different types



FIGURE -1 : NERVE STIMULATOR

PHYSIOLOGICAL BASIS OF ULTRASOUND

PHYSICAL PRINCIPLE OF ULTRASOUND

The fundamental behind the Ultrasound imaging technique is transmission and reflection of longitudinal high-frequency ultrasonic waves of frequency more than20 kHz in tissues. When voltage is applied to the transducer produces ultrasonic waves and vice versa works on the principle of PIEZOELECTRIC EFFECT.

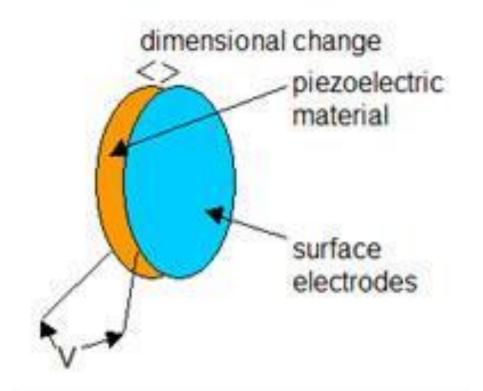


FIGURE-2: PIEZOELECTRIC EFFECT (v-potential difference)

The transducer modifies electrical energy into very rapid mechanical vibrations that are extreme high-pitched sounds to hear. The electrical field required is formed when a voltage is applied between the two electrodes, producing a dimensional change in the crystals. Conversely, when the reflecting mechanical vibrations from the tissues returns back to the transducer they compress the crystals and create an electrical potential.

ANISOTROPY IN NERVE IMAGING

When the angle of the transducer is altered, the echogenicity of soft tissues, such as nerves and tendons also changed significantly, this major property of ultrasound imaging is called Anisotropy. When the transducer is perpendicular, nerve fibre looks hyper echoic (white), but it appears hypo echoic (black) when the transducer is placed obliquely.

IMAGE RESOLUTION

A good resolution is the main aim of the ultrasound technique after image formation. The resolution includes axial/lateral resolution, contrast of the image, spatial and temporal resolution.

Axial resolution: It specifies the proximity of two objects along the axis of the beam and is depends on frequency.

Lateral resolution: It indicates the proximity of two objects perpendicular to the axis of the beam and is depends on beam width.

Spatial resolution :(detail resolution) is the sum of Lateral and Axial resolution.

Contrast Resolution: It is the capacity to resolute two adjacently placed objects into two separate objects whose intensity and reflective properties are same.

SPATIAL COMPOUND IMAGING

Spatial compound imaging adds multiple lines of insonation within a planar scan to give a single image. It illustrates the nerve borders and tissue planes very well. It also improves the appreciation of needle tip over a limited range of needle angles (<30 degrees).

ULTRASOUND TRANSDUCERS AND MANIPULATION

For imaging of nerves, transducers with high-frequency, broad band linear probe producing linear array have proven the most useful. Picture from linear arrays are visualized in rectangular shape format .Transducer probe orientation and manipulation skills plays the vital role for success of regional nerve blocks. The manipulations are:

1. Sliding (moving contact):

The probe should move along the anatomical course of the nerve using a short-axis view to visualize the nerve plexus.

2. Tilting (side-to-side):

The contrast of peripheral nerves will vary with the degree of tilt. The visibility of nerve depends on optimizing this angle.

3. Compression:

Mainly used to locate the venous structures.Compression provides better contact and the structures closer to the probe surface. Soft tissue is more susceptible to compression and therefore estimates of tissue distances will vary.

4. Rocking (in-plane):

Rocking is important to visualize the needle and anatomic structures, when the working room is narrow range.

5. Rotation:

The true short-axis views obtained from rotation rather than long-axis or oblique views.

NERVE IMAGING WITH ULTRASOUND

The peripheral nerve fascicles can be visualized with high-resolution image of the ultrasound. This echo texture of nerve fascicles is the most distinguishing feature of nerves ("honeycomb" shape). Ultrasound frequencies of 10 MHz or more are needed to differentiate nerves from tendons based on echo texture lone.

In short axis view to slide a broad linear probe over the anatomical course of a peripheral nerve to visualize the nerve. Along with nerve imaging notify the adjacent structures is also critical. During injection of local anaesthetic the favourable distribution of drug and separation of nerve fibres can also be seen. Nerves appear circle, elliptical, or triangular.

ULTRASOUND ARTIFACTS IN REGIONAL ANESTHESIA

In presence of local heterogeneities, artifactual bending of the block needle can be seen with sonography , the so-called 'bayonet artefact'¹⁰.Sound waves are assumed to take a straight path in and out from the tissue. When this does not occur, reverberation artefacts occur from the multipath echoes, Ex; comet tail artefact. Reverberation echoes are seen when the block needle is near parallel to the active face of the probe when strong specular reflections are received.

BLOCK NEEDLES FOR ULTRASOUND-GUIDED PROCEDURES

Needle tip visibility is good, when the needle path is parallel to the active face of the transducer and is straight to the sound beam so strong specular reflections will be created. As the angle of incidence is increased, the mean brightness will decrease.

ANATOMY OF BRACHIAL PLEXUS

Thorough knowledge about anatomy of brachial plexus is essential for to achieve an optimal brachial plexus block.

Brachial plexus consists of

- Roots
- Trunks
- Divisions
- Cords.

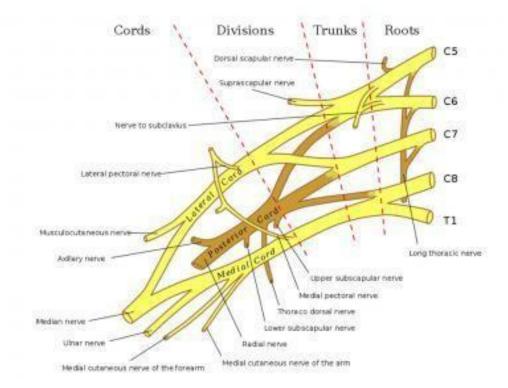


FIGURE 3: ANATOMY OF BRACHIAL PLEXUS

ROOTS:

The roots emerged from the anterior primary rami of the spinal nerves. 5^{th} , 6^{th} , 7^{th} , 8th cervical nerve and 1st thoracic nerve and also from the C4 to T2. The formation of brachial plexus may be one segment higher (or) one segment lower which results prefixed or post fixed plexus respectively.

In Prefixed plexus C4 contributes more than T2.Sometimes T2 totally is absent.

In Post fixed plexus T1 is large, T2is always present ,C4 is absent and C5 is very minimal in size

TRUNK:

Trunks are derived from roots, which lies among the anterior and medial scalenus muscles .C5 and C6 roots unite to form the upper trunk, C7 gives middle trunk, C8 and T1 unites to form the lower trunk.

DIVISIONS:

Trunks are branched into anterior & posterior division, which is located in between lateral border of first rib and posterior aspect of clavicle after that it descend into axilla.

CORDS:

The six divisions make up the lateral, medial and posterior cords. The cords are named according to relationships to the axillary artery. Lateral cord formed by ventral division of upper and middle trunks Medial cord formed by the anterior division of lower trunk. The posterior division of all the three trunks unite to form posterior cord

TERMINAL BRANCHES:

In distal axilla the cord gives rise to terminal branches namely the ulnar, medial and radial nerves.

(1). Branches of the roots:

- Nerve to serratus anterior C5, C6 C7
- Nerve to rhomboids

(2) Branches of the trunk :(arise from the upper trunk)

- Supra scapular nerve (C5, C6)
- Nerve to subclavius (C5, C6)

(3) Branches of the cord:

Lateral cord:

- Lateral pectoral nerve (C5, C6,C7)
- Median nerve (lateral root)(C5,C6,C7)
- Musculo cutaneous nerve (C5, C6,C7)

Medial cord:

- Medial pectoral nerve C8, T1)
- Medial cutaneous division of arm (C8, T1) (3).Medial cutaneous division of forearm C8,T1 (4).Ulnar nerve (C8, T1)
- Median nerve(medial root) (C8, T1)

Posterior cord:

- Upper and lower subscapular nerve (C5,C6)
- Nerve to Latismus dorsi (C6, C7, C8) (Thoraco dorsal nerve)
 (4).Axillary nerve (C5, C6)
- Radial nerve (C5, C6, C7,C8)

In addition to branches of brachial plexus:

- Upper limb also supplied by supraclavicular branch of cervical plexus.
- By the 2nd intercostal nerve.
- Sympathetic nerves are also distributed through the brachial plexus

ROOTS:

The roots lie between the inter scalenus (anterior&medial) muscles. It is situated cephalo posterior to the second part of subclavian artery. It is the ideal landmark for Classical interscalene block.

TRUNKS:

In the posterior triangle, upper and middle trunks emerges above the subclavian artery as they traverses the first rib, but the lower trunk passes behind the artery. The trunks are enclosed by the skin, platysma and deep fascia superficially. Trunks are over lied by external jugular vein, inferior belly of omohyoid and supraclavicular nerves. The trunks are easily identified by palpation. This landmark is often used for perivascular approach of brachial plexus block.

DIVISIONS:

The divisions emerge from the trunks at the lateral border of first rib and exists behind the clavicle, and then descends into axilla. The rib hitching technique of brachial plexus is performed in this area.

CORDS:

The cords lies around the axillary artery at the apex of axilla. The medial cord lies behind the artery, but the posterior and lateral cord are situated lateral to the artery. The infra clavicular approach causes the blockade at the junction of divisions & cords.

TERMINAL BRANCHES:

Formation occurs in the lateral aspect of axilla. Radial, ulnar and median nerves are blocked by the axillary approach.

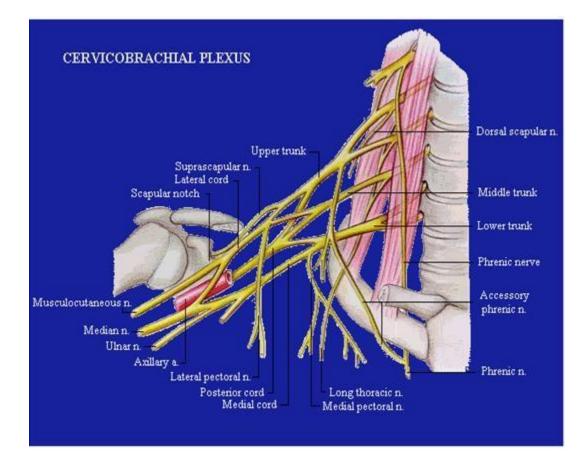


Figure – 4 : RELATIONSHIP OF THE BRACHIAL PLEXUS

SONOANATOMY OF BRACHIAL PLEXUS

Ultrasound is a recently emerging technique for regional anesthesia. Ultrasound guided peripheral nerve blockade was first performed in supraclavicular region by La Grange and colleagues in 1978. Later developed by Kapral et al in 1994. Advantages of supraclavicular block are that brachial plexus is compact (proximal trunks and distal division), structures are shallow and easily visible.

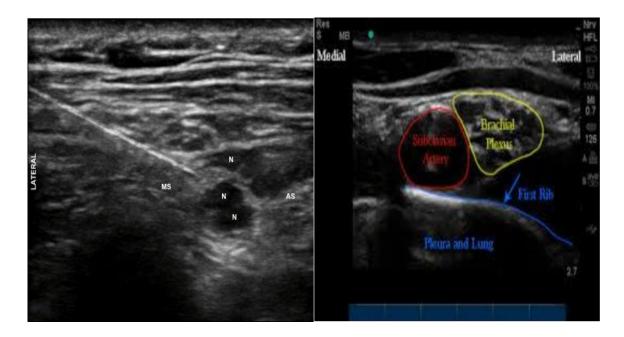


FIGURE -5 : SONOANATOMY OF BRACHIAL PLEXUS

Advantages of Ultrasound:

- Enabling real time visualization of brachial plexus, rib, pleura and pulsating subclavian artery.
- Increase in safety because we can appreciate the needle placement and local anesthetic spread during the injection and enables further needle repositioning if needed.
- Rapid of onset of nerve block occurs due to drug deposition near the plexus.
- Lesser volume of drug is needed than conventional techniques

Structural characteristic in ultrasound:

- Subclavian artery pulsation should be appreciated.
- First rib is seen as hyper-echoic linear structure.
- Parietal pleura is identified by its hyper-echoic nature its movement with respiration (Sliding sign) and by its position lateral and medial to the first rib.
- Lung tissues are underneath the plexus.
- Brachial plexus can be visible in between scalenus muscle and superior-lateral to the subclavian artery as hypo-echoic round nodules. (Honeycombs or bunch of grapes) at 1-2 cm depth

PHARMACOLOGY

BUPIVACAINE:

Bupivacaine was introduced in the year 1957 by Ekenstom. Its chemical structure is 1-butyl-2⁻, 6⁻ pipecoloxylidide hydrochloride.

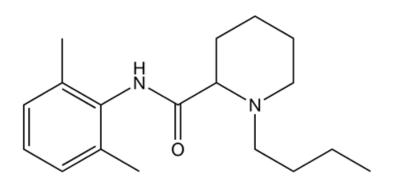


Table-1: Pharmacokinetics

Molecular Weight	288 daltons
Pka	8.1
Lipid solubility	28
Partition Coefficient (octanol/buffer)	346,0
Protein Binding	95%
Volume of distribution	73 L
T1/2	210 minutes
Clearance	0.58L/min

It is available as 0.25%, 0.5% and 0.75% injection for use in peripheral nerve blocks.

Effects on Cardiovascular system:

Due to its high affinity for the sodium channel, bupivacaine is considered to be cardio toxic. A plasma concentration between 0.5-5 micrograms/ml depresses cardiac conduction and contractility.

Effects on Central nervous system:

It is a highly protein bound, highly lipid soluble drug. The central nervous system effects occur in two stages. In low plasma concentrations it produces circum oral numbness and dizziness. In high intravascular concentrations can cross blood brain barrier and produces tinnitus, vertigo, restlessness, skeletal muscle twitching followed by convulsions. The second stage is state of CNS depression followed by suppression of inhibitory and excitatory pathways. The toxic dose is said to be 3mg/kg. Inadvertent intravascular injection leads to cardiovascular collapse and central nervous system toxicity.

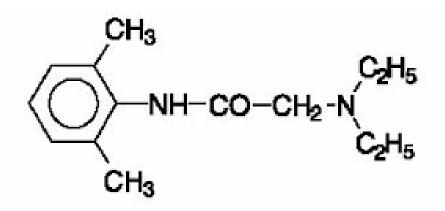
Metabolism –

It is metabolized in the liver by N- dealkylation and glucouronide conjugation of hydroxylated parent compound, and renally excreted.

Treatment of Local Anaesthetic Systemic Toxicity (LAST)

1.	Get help
2.	Initial attention
3.	Maintain patent airway and ventilate with 100% oxygen
4.	Benzodiazepines are preferred to treat seizure activity
5.	Make sure the nearest cardiopulmonary bypass facility
б.	Basic and Advanced Cardiac Life Support (ACLS) will require adjustment of medications.
7.	AVOID vasopressin, calcium channel blockers, beta blockers or local Anaesthetics
8.	DECREASE the individual inj. adrenaline doses to <1mcg/kg
9.	Lipid emulsion (20%) Therapy.
10.	Bolus 1.5ml/kg/body weight intravenously over 1 min (~ 100ml)
11.	Infusion of 0.25ml/kg/min (~18ml/min) continuously
12.	If persistent cardiovascular collapse, repeat bolus doses.
13.	If blood pressure remains low, ensures the infusion rate 0.5ml/kg/min
14.	Continue infusion after attaining circulatory stability at least 10 minutes
15.	Approximately 10ml/kg lipid emulsion over the first 30 minutes are recommended.

Lignocaine: Lignocaine was introduced in the year 1943 by LofgrenIt is an amide local anesthetic, and its chemical structure is 2- (diethyl amino)-N-(2,6dimethylphenyl) acetamide



Pharmacokinetics:

Molecular Weight	234.34g/mol
Pka	7.86
Lipid solubilty	2.9
Protein Binding	60-80%
Volume of distribution	91L
T1/2	60-120 mts
Clearance	0.95L/mt

It is available as 2% injection for use in peripheral nerve blocks.

USES:

Surface application, infiltration, nerve block, epidural, spinal and intravenous regional block anesthesia.

CNS effects:-

Basic action:- Neuronal inhibition. Due to inhibition of inhibitory neurons the apparent stimulation seen initially. At over doses all Neurons are inhibited and flattening of EEG waves is seen. Early effects are depressant, i.e. drowsiness, dysphoria, mental confusion, altered taste and tinnitus.

CVS effects:

Small effect on contractility and conductivity. It abbreviates ERP and has minimal pro arrhythmic potential and used as an anti arrhythmic drug.

Overdose:

Produces muscle twitching, convulsions, cardiac arrhythmias, hypotension, coma and respiratory arrest.

REVIEW OF LITERATURE

1.Duncan et al and his colleagues compared the efficacy of nerve stimulator with ultrasound in supra clavicular brachial plexus block. The study group was divided in to NS and US. (60 patients, each had 30). Both groups received 30 ml of local anesthetic (mixture of 0.5% bupivacaine and 2% lignocaine) with Inj. adrenaline(1:200000) They concluded that both US and NS group guidance for carrying out Supra clavicular brachial plexus blocks confirm a high success rate and a lesser frequency of adverse effects that are accompanying with the Conventional landmark methods. However, that study did not prove the Superiority of one technique over the other. The US-guided technique Seemed to have an edge over the NS-guided technique.

2.SinghG.Saleem et al done a prospective randomized comparative study between conventional landmark technique and ultrasound guided supraclavicular brachial plexus block in elective upper limb surgeries. There were 60 patients haphazardly assigned into two groups of 30 each. Both groups received 1:1 mixture of 0.5% bupivacaine and 2%lignocaine with Inj. adrenaline(1:200000) The result showed that US guided supraclavicular brachial plexus block has more success rate, longer duration of analgesia and very few complications compared to conventional technique.

3. Raghove P et al and colleagues have compared the landmark technique with ultrasound guided technique for brachial plexus block in patients undergoing upper limb surgeries They studied 60 patients, 30 in each group All patients received 10 ml each of 2% lignocaine with adrenaline, 10 ml 0.5% bupivacaine and 10 ml of saline. They concluded that ultrasound guidance was more helpful to provide supraclavicular brachial plexus nerve blocks. It allows real time visualization of brachial plexus and blood vessels, movement of needle, local anesthetic diffusion resulting in safer and more effective block as compared to landmark technique.

4.Ahmed A.El Daba et al worked to compare between ultrasonic guided supraclavicular plexus block and nerve stimulator guided block in elective upper limb surgery. The study was conducted on 50 patients prepared for upper limb orthopedic and plastic surgery. In both groups block was done with 20ml 2% lidocaine and 20ml 0.5% bupivacaine It was much better to block the brachial plexus with help of ultrasonography. The time of the block procedure is shorter; the success rate was higher and usually from first trial. Lastly there was almost no complication because they did the block under vision.

5. "Williams et al studied and assessed the quality of block, safety, and Performance time for supraclavicular approach of brachial plexus Using ultrasound guidance compared with anatomical landmark technique. Both the techniques were confirmed by using nerve stimulator. Blocks were done using Inj.bupivacaine 0.5% and lidocaine 2% (1:1) with adrenaline 1:200000 as the anesthetic mixture. They concluded that ultrasound-guided neurostimulator-confirmed supraclavicular block performed quickly and resulted in a complete block than anatomic landmark technique and neurostimulator confirmation. It was concluded that ultrasonic guidance would give more successful blocks, decrease block performance time, and decrease the incidence of complications(pneumothorax and neuropathy etc..)"

6. " Kapral S et al p studied 40 patients those who undergoing operation in arm, forearm and wrist, to note how for ultrasonic cannula helpful in supraclavicular brachial plexus block and studied efficacy and occurrence of complications. Patients were divided into Group S (paravascular approach; n = 20) and Group A (axillary route; n = 20). Plexus

block was executed using 30 mL of 0.5% bupivacaine. The study of the plexus sheath was done with Ultrasonogram. After visualization of the brachial plexus, the sheath was penetrated through a 24-gauge cannula. In Group A, 25% of patients sensory block was inadequate , whereas in Group S all patients had a complete sensory block . The sensory block of the radial, median, and ulnar nerves was completed approximately 40 min without a major difference between the two groups. They had no cases of pneumothorax because in real time imaging cervical pleura can be easily identified. Also accidental puncture of subclavian or axillary vessels, and neurologic impairment was minimal. They concluded that ultrasound-guided supraclavicular block combines the safety of axillary block".

7. "Liu FC et al compared an ultrasound technique to the peripheral nerve stimulation in axillary nerve blocks. 60 patients scheduled for upper limb surgeries of were randomized into two groups. For Group 1; US, and for Group 2 PNS was applied. The time consumed to perform the axillary brachial plexus block is almost equal in both groups. But dense motor blockade was obtained in Group 1 than in Group II They concluded that ultrasound-guided axillary approach brachial plexus block is a safe

technique with rapid onset time and good quality of motor blockade compared to conventional peripheral nerve stimulation".

8.Singh S et al evaluated the difference efficacy, safety margin, and the side effects of doing brachial plexus nerve blocks by using a nerve stimulator when compared to ultrasound (US).They studied 102 were randomly allocated into two groups, one with US and the other with nerve stimulator (NS). In both groups 40 ml of 0.25% bupivacaine solution was injected around the brachial plexus.

.Results: About 90% patients in US group and 73.1% in NS group, had successful blocks. The block onset was more rapid in the Group US than Group NS and significant change in the radial nerve territory. In Group US the mean duration was prolonged compared to Group NS. Unintentional injury to the blood vessels occurred in 7 patients in the NS group and only 1 in the US group. Finally they evaluated that the block performed with Ultrasound results early onset, has an improved quality and lasts extended duration when related with similar dose delivered by conventional methods. **9. "Chan VW et al** conducted the study about state-of-the-art using ultrasound guided technique for supraclavicular approach of brachial plexus blocks. They studied 40 patients undergoing upperlimb surgery Ultrasound real time imaging was used to locate the brachial plexus before execute the block, direct the block needle to get target nerves, and analyze the pattern of local anaesthetic spread. Needle position was further redirected by the nerve stimulator before injection of drug. The technique we describe aligned the needle path with the narrow ultrasound beam. In 95% of the cases the block performed in first attempt, with one failure due to subcutaneous injection and one to partial intravascular injection. They suggested that the real-time ultrasound imaging can facilitate better nerve localization and placement of needle and visualize the distribution of local anaesthetic spread".

STUDY MATERIALS AND METHODS

This is a prospective, randomized, observer blinded study in Supraclavicular brachial plexus blocks using nerve stimulator and ultrasound guidance to evaluate the effectiveness, safety and to compare different parameters. The study was intended and ethical committee approval was obtained.

(i)Inclusion criteria:

- a) Patients of both sex, aged in the middle of 18 and 60 years
- b) Patients with ASA-PS Grade I and II physical status
- c) Elective upper limb surgeries

(ii)Exclusion criteria:

- a) Patients <18 years and >60 years of age.
- b) Patient refusal
- c) Patients with significant coagulopathy or peripheral neuropathy
- d) ASA Grade III and IV patients
- e) Allergy to local anesthetics

SAMPLE SIZE AND RANDOMIZATION:

The sample size was scheduled to be 60 based on the pilot study. They were randomly selected to 30(n=30) in each group and named as Group US (ultrasound) and Group NS (Nerve stimulator). The performer made 60 lots and numbered serially from 1-60. A chart was prepared that selected each number randomly to a group. The observer took a lot and the number was noted in the proforma chart. Then the observer was hided for the block being done. The investigator performed the block and then the observer was allowed to note the outcomes. After the study was completed the proforma chart was revealed.

(iii)**PROCEDURE:**

A.DESCRIPTION OF PARAMETERS:

1. Block Execution time US GROUP:

The time duration between the primary scanning to identify the plexus and the withdrawal of the needle at the end of the procedure.

NS GROUP:

The time duration between the subclavian artery landmark palpation to the withdrawal of the needle at the end.

2. Success

We declared our block to be successful when the patient had a dense block of all the sensory dermatomes and unable to move shoulder, elbow and wrist joints.

Failure was defined as the presence of sensation in at least one or more dermatomes.

PREPARATION:

Informed consent must be obtained from patient and relatives with adequate documentation of the risk and complications.

PREPARATION OF THE O.T:

- I. Anesthesia machine check.
- II. Avail resuscitation equipment, laryngoscope, endotracheal tube and Laryngeal mask and oro pharyngeal airways
- III. Keep ready the emergency drugs with preloaded syringes like, Inj.Adrenaline, Inj.Atropine Inj.Midazolam Inj.Thiopentone sodium and general anesthesia drugs.
- IV. Ultrasound machine and probe check (Linear array probe (9-18MHZ).
- V. Check the monitors (ECG, NIBP,Sp02 and ETCO₂).

MATERIALS

GROUP NS:

- Sterile sheets and 4"x4" gauze pieces
- Two 10-mL syringes filled with local anaesthetic drug
- Surface electrode leads and sterile gloves
- One 1¹/₂" 25-gauge needle to infiltrate skin, povidone iodine.
- Peripheral nerve stimulator
- 5 cms long, 21G, stimuplex needle (Braun).

GROUP US:

- Sterile sheets and 4"x4" gauze pads.
- Two 10-mL syringes with local anaesthetic.
- Sterile gloves
- One 1¹/₂" 25-G needle for local infiltration.
- A 38mm long and 7-11 MHz linear probe (SONO RAY)
- The needle used is 18 G intravenous needle

Drug:

1:1 mixture of 15 ml Inj.Lidocaine (2%) and 15 ml of Inj.Bupivacaine

(0.5%) with adrenaline (1:200000) dilution.

STERILE PREPARATION AND ACOUSTIC COUPLING

(with povidone iodine)



Fig-6: Sterile preparation

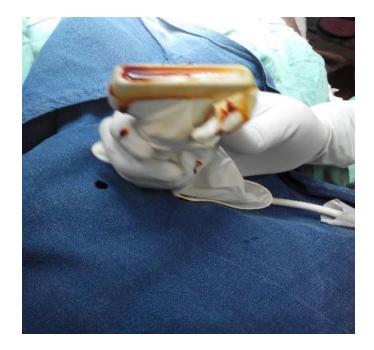


Fig-7: Acoustic coupling

Sterility during the procedure was obtained with sterile drape and gloves. Acoustic coupling was prepared by a sterile jelly applied over the footprint and applying sterile glove and tie it to the probe (Fig-6). Then the gloved probe is soaked with povidone iodine along its foot print to result acoustic coupling between the gloved probe and interface of skin. (Fig-7)

DESCRIPTION OF TECHNICAL PROCEDURE:

After preoperative assessment of the patient, they were shifted to operation theatre. After arrival in the operating room, intravenous access was gained with 18G intravenous cannula and intravenous premedication was given (midazolam0.03mg/kg). Continuous blood pressure monitoring was done with NIBP with automated cuff, heart rate and Pulse Oximetry during the entire period.

PREPARATION OF THE PATIENT:

- Preoperative assessment
- Premedication
- Ensure adequate fasting

POSITIONING:

Position should allow comfortable placement of patient in supine position in O.T table with arm placed by side. Head is positioned without head rest and head turned 45 degree opposite side.

PROCEDURE:

AIM:

Placement of needle around the brachial plexus sheath adjacent to the subclavian artery and real time visualization of the local anesthetic spread, displacement of trunk and divisions.

- After proper positioning, skin preparation done with povidoneiodine and draping with sterile sheet, Transducer is placed in coronal plane just above the clavicle at approximately its midpoint.(Land mark: subclavian artery, scalenus muscle, first rib).
- The probe should be focused acutely down the neck, as if scanning the image deep to the thorax, do not across the neck.
- Attempts are made to appreciate the subclavian artery: Artery is hypo echoic (black circle), pulsation is visible. The artery lies on the hyper echoic line of pleura or first rib. If difficult to find the artery, slide the probe medially (or) laterally parallel to clavicle. Scanning to be done cautiously, to avoid inadvertently mistaking the carotid artery for subclavian artery

- Brachial plexus is posterior-lateral to the artery (or) superior to the artery, looks like bunch of grapes, hypo echoic structure encases hyper echoic fascia.
- Before insertion of needle, change to color Doppler to differentiate blood vessel (either artery or vein) and to know the needle pathway.During In plane technique, needle placed medial to lateral (or) lateral to medial towards and below the transducer.
- Needle should be advanced at the junction of the artery and rib.
 To make sure the needle does not cross beyond the hyper echoic line (pleura, rib).
- After the injection of local anesthetic mixture, the plexus will separate away from the artery and is displaced.
- Remaining LA injected on the superficial aspect of the plexus after change the needle position



Fig-8: Anatomical landmark for Supraclavicular block

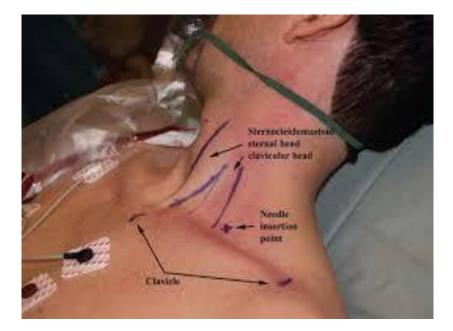


Fig-9: Marked dot indicates site of needle puncture



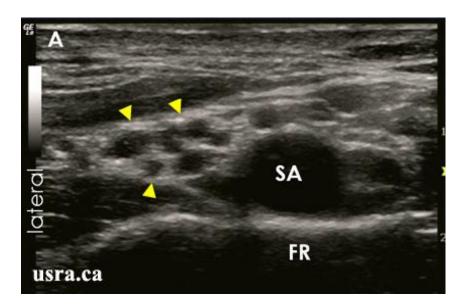


Fig-10: 'positioning of needle and probe to perform block in US group



Fig-11: 'positioning of needle to perform block in NS group

Group NS

Under all aseptic precaution local site was prepared. The Positive electrode of the nerve stimulator was connected to an ECG lead and fixed on the ipsilateral arm. The subclavian artery was then palpated 1-1.5 cm above the mid clavicular point, immediately lateral to the sternomastoid muscle and was pushed medially by the thumb and an intradermal wheal was raised with 1% lignocaine (2 mL) using a 24 G needle. A 20 G insulated needle attached to the negative electrode of the NS was then pierced through the skin wheal in a posterior, medially, and caudally. NS was set to deliver a current of 1.5 current at 1Hz frequency and 0.1ms of pulse duration.

After finger flexion was obtained with stimulation, the current was reduced in to 0.2 mA till the presence of a muscle twitch with 0.6mA was observed and no twitch with a current of 0.2 mA was observed. This ensures the proximity of the needle tip to the nerve and the drug was injected after negative aspiration of air or blood Sensory block was evaluated every 5 minutes until 30 minutes after the last local anaesthetic injection by the observer blinded to technique.

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The Sensory blockade is defined as the loss of pinprick pain over the medial and lateral aspect of arm, forearm and the hand.

Sensory onset time is the time interval between the last drug injected to loss of pinprick pain sensation. It is scored as follows:

Normal-Intact touch and pain sensation,

Incomplete block-Touch sensation is present with no pain Complete block-No sensation

As defined above, complete block and incomplete block surgery was proceeded. When the surgery could not be completed in patients with incomplete block without discomfort, requiring more than 100 mcg fentanyl we administered general anaesthesia (GA) with endotracheal tube and was noted as a failed block. When the patient experienced pain on pinprick by 30 minutes after block completion suitable alternate anaesthesia was provided, declaring the block failed. After the sensory block, motor block was assessed every 5 minutes to rule out any painful restriction by the same observer blinded to technique. The onset of motor blockade was evaluated every 2 min till the onset of motor block. It is the time of withdrawal of the block needle to the time when the patient had weakness of any of the three joints Shoulder, elbow, or wrist, upon trying to achieve active movements .

No block: full power

Incomplete block: able to move active movements

Complete block: No power

OBSERVATION AND RESULTS

This is study comparing the nerve stimulator and ultrasound on the duration of block execution time ,time taken for sensory and motor onset, success rate and complications in supraclavicular brachial plexus blocks. After performing the study, the results were compiled and analysed.

For analysing comparison among groups Chi square test was used. Student t test helped to quantify the variables.

The p value of less than 0.05 was declared as statistically significant. The statistical analysis was carried out using statistical software package SPSS 20

Table 4-: GENDER COMPARISON BETWEEN GROUP US AND

Sex	Statistical inference			
	US	NS		
Male	22	21		
	73.3%	70.0%		
Female -	8	9	X ² =.082 Df=1	
	26.7%	30.0%	.774>0.05	
	30	30	Not Significant	
Total	100.0%	100.0%		

GROUP NS

The distribution of gender among both Group NS and Group US were analyzed and there is no significance difference between the two groups hence they are comparable.(P>0.05)

Graph-1: BAR CHART OF GENDER COMPARISON BETWEEN GROUP US AND GROUP NS

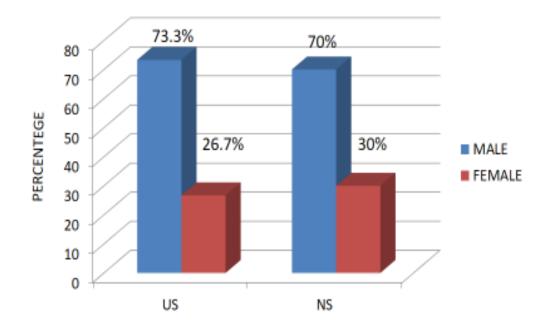


Table 5: COMPARISON OF MEAN AGE BETWEEN GROUP NS

AND GROUP US

Age	Mean	S.D	Statistical inference
US (n=30)	46.70	13.455	T=.751 Df=58
NS (n=30)	44.10	13.361	.456>0.05 Not Significant

Graph 2: BAR CHART COMPARING GROUP NS AND GROUP

US IN MEAN AGE

AGE(in YEARS)



AGE(in YEARS)

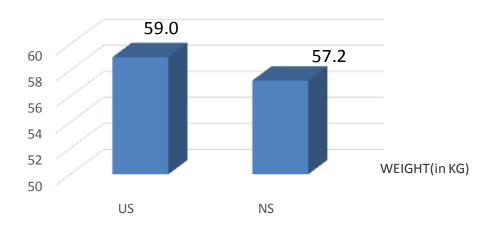
Table 6: COMPARISON OF MEAN WEIGHT BETWEEN

Weight (kg)	Mean	S.D	Statistical inference
US (n=30)	59.00	8.317	T=.898 Df=58
NS (n=30)	57.20	7.175	.373>0.05 Not Significant

GROUP NS AND GROUP US

On analysing the data statistically, the p value was calculated as p=.456, p=.373 for age and weight respectively. For both variables P value>0.05 value which is statistically insignificant and comparable.

Graph-3: BAR CHART COMPARING GROUP NS AND GROUP US IN MEAN WEIGHT



WEIGHT(in KG)

WEIGHT(in KG)

Table 7: COMPARISON OF ASA - PS STATUS BETWEEN

ASA-PS	Statistical inference			
	US	NS		
Ι	19	15		
	63.3%	50.0%		
II	11	15	X ² =1.086 Df=1	
	36.7%	50.0%	.297>0.05	
Total	30	30	Not Significant	
	100.0%	100.0%		

GROUP US AND GROUP NS

On analyzing the statistics p value=.297, i.e. $p \square 0.05$, therefore no statistical insignificant difference between the Group NS and Group US.

Graph 4: BAR CHART COMPARING THE ASA STATUS BETWEEN

GROUP US AND GROUP NS

ASA-PS

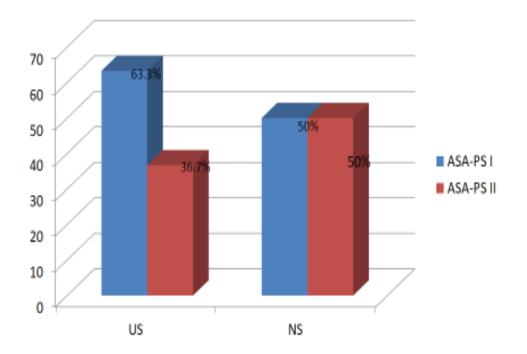


Table 8: COMPARISON OF "BLOCK EXECUTION TIME" IN

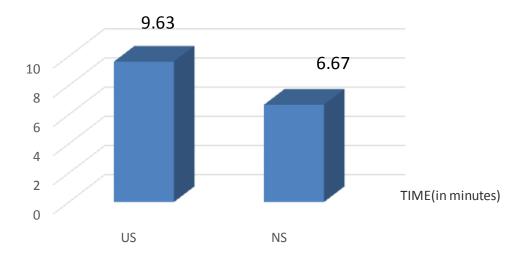
Block execution time(min)	Mean	S.D	Statistical inference
US (n=30)	9.63	2.470	T=5.606 Df=58
NS(n=30)	6.67	1.516	.000<0.05 Significant

T-Test

The duration of technique in Group US=9.63 min and Group NS=6.67 min The calculated p value=.000 which is <0.05, hence the difference is statistically significant. Therefore the time taken to execute the block in Group NS is significantly lesser than the Group US

Graph 5: BAR CHART COMPARING THE "BLOCK EXECUTION TIME" IN GROUP NS AND GROUP US

BLOCK EXECUTION TIME(in minutes)



TIME(in minutes)

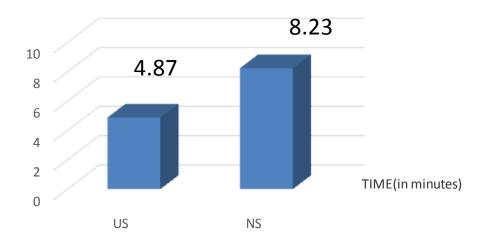
Table 9: COMPARISON OF ONSET OF SENSORY BLOCKADE BETWEEN GROUP NS AND GROUP US

Sensory onset (min)	Mean	S.D	Statistical inference
US (n=30)	4.87	3.256	T=-3.416 Df=58
NS (n=30)	8.23	4.305	.001<0.05 Significant

The onset of sensory blockade in Group NS=8.23 minutes Group US=4.87 minutes, whose p value is **0.001**, which is statistically significant. Therefore the onset of the sensory blockade is significantly faster in Group US than Group NS

Graph:6 COMPARISON OF ONSET OF SENSORY BLOCKADE BETWEEN GROUP NS AND GROUP US

SENSORY ONSET TIME(in minutes)



TIME(in minutes)

Table 10 COMPARISON OF ONSET OF MOTOR BLOCKADE

Motor onset (min)	Mean	S.D	Statistical inference	
US (n=30)	8.47	5.501	T=-2.863 Df=58	
NS (n=30)	12.67	5.857	.006<0.05 Significant	

BETWEEN GROUP NS AND GROUP US

The onset of motor blockade in Group NS=12.67 minutes and Group US=8.47 minutes, whose p value is **0.006**, which is statistically significant. Therefore the onset of the motor blockade is significantly faster in Group US than Group NS

Graph 7: BAR CHART OF ONSET OF MOTOR BLOCKADE BETWEEN GROUP NS AND GROUP US

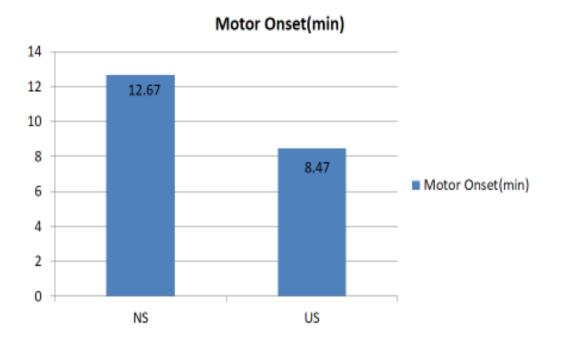


Table 11: COMPARISON OF SUCCESS RATE OF

	SUCCESS	FAILURE	TOTAL	Statistical inference
GROUP NS	25(83.33%)	5(16.67%)	30	X ² =1.456 Df=1
GROUP US	28(93.33%)	2(6.67%)	30	.228>0.05 Not Significant

GROUP NS AND GROUP US

The success rate in Group NS =83.33% and Group US =93.33%providing a numerical difference. But on statistical analysis, the calculated P value=.228 i.e. (p>0.05)

Graph 8: BAR DIAGRAM COMPARING THE SUCCESS RATE OF GROUP NS AND GROUP US

SUCCESS RATE %

93.33



Success rate %

Table 12: COMPLICATIONS OCCURED AMONG

Complications	Statistical inference					
Complications	US	NS				
Failure	2	3				
ranure	6.7%	16.67				
Par aesthesia	2	6	X^2 =6.089 Df=3 .107>0.05			
Far aestnesia	6.7%	20.0%	Not Significant			
Vaganlar musatura	0	3				
Vascular puncture	0	10.0%				

GROUP NS AND GROUP US

Analyzing above values showed complications observed in both groups, US group shows less adverse effects compared to NS group which is statistically insignificant p value .107(>0.05) though appears numerical difference.

Graph 9: BAR DIAGRAM COMPARING THE COMPLICATIONS OF GROUP NS AND GROUP US

Chart Title 20 18 16 14 12 10 10% 8 16.7% 6 4 z -8 0 US NS Failure Paresthesia Vessel puncture

Complications

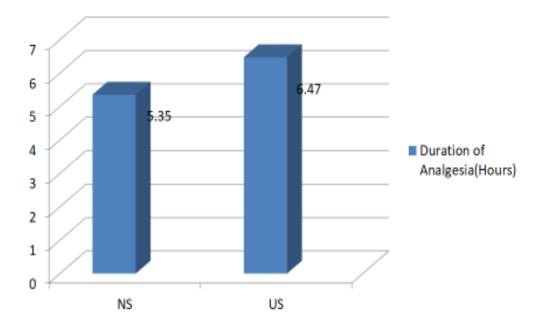
Table 13: MEAN DURATION OF ANALGESIA BETWEEN

Analgesic duration (hours)	Mean	S.D	Statistical inference
US (n=30)	6.47	1.299	T=4.539
			Df=58 .000<0.05
NS (n=30)	4.95	1.289	Significant

GROUPNS AND GROUP US

The mean duration of analgesia increased in US group (6.47 hours) compared to NS group which is (4.95 hours). The p value .000(<0.05) is highly significant.

Graph:10 BAR DIAGRAM OFMEAN DURATION OF ANALGESIA BETWEEN GROUP NS AND GROUP US



DISCUSSION

In our study, supraclavicular brachial plexus block was done under both ultrasound guidance and nerve stimulator. Most of the patients had successful brachial plexus block and hence satisfactory surgical anesthesia.

The real time ultrasound imaging showed better visualization of the brachial plexus, accurate position of the needle placement and spread of local anesthetic around the brachial plexus. Identification of the adjacent structures like blood vessels (Subclavian artery and vein), first rib and pleura was useful to avoid procedure related complications.

We observed that 15 ml of Inj. Lignocaine (2%) and Inj. Bupivacaine (0.5%) with Adrenaline(1:200000), resulted in excellent quality of supraclavicular brachial plexus block for upper limb surgeries.

In our study, we observed that block execution time was significantly decreased in NS group when compared to US group. The mean duration of block performance in NS group was 6.67 min and in US group 9.63 min.

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It is statistically significant. Singh G Saleem MY et al. showed the mean time required to administer a block was 5.43 min in NS group, whereas using ultrasound, the time needed for the same was 10.1 min. They suggested that the use of ultrasound in brachial plexus block requires good knowledge about sono anatomy and skills by anesthesiolgists.

In our study, we observed that onset time of sensory blockade was significantly decreased in US group when compared to NS group. The mean onset time of sensory blockade in US group was 5.27 min and in NS group.

Group 8.23 min. Danelli et al showed the mean onset time for sensory block with the use of ultrasound was 10.86 min and 11.60 min for conventional paresthesia eliciting techniques. This is almost same to the study performed by Marhofer et al. The real time imaging of ultrasound give better visualization of brachial plexus, underlying structures and deposition of local anesthetic in the appropriate place could minimize the sensory onset time in ultrasound guided blocks. The mean onset time of motor blockade in US group was 8.47 min. as compared to NS group 12.67 min which was statistically significant. Duncan et al .showed the mean onset time of motor blockade in group US was 10.83 ± 2.94 min and in NS group was 11.60 ± 3.48 min.The reason for early onset of motor blockade in our study would have been due to accuracy of needle placements close to the plexus, higher volume of local anesthetic (30ml). Williams et al(2003) found that the motor onset paralleled that of onset of sensory blockade.

The duration of analgesia was significantly prolonged in US group than NS group which was statistically highly significant. The mean duration of analgesia in US group is 6.47 hours as compared to NS group 4.95 hours (p<.000) .Singh S et al Showed that Group US the mean duration of analgesia was prolonged 286.22 \pm 42.339 compared to 204.37 \pm 28.54-min in Group NS (*P*< 0.05).The prolonged duration of analgesia was due to synergistic effect of lignocaine and bupivacaine and decreased absorption of local anesthetic due to vaso constrictive effect of adrenaline.

In US group the drug was injected under direct visualization and equal distribution around the brachial plexus assured, may be the reason for extended duration of block than NS group. Even though proximity ensured in NS group the even drug distribution is doubtful.

Kapral et al studied that there was no complications such as vessel puncture, paresthesia or pneumothorax in his study of ultrasound guided brachial plexus block through supraclavicular approach. In our study we found that there was no incidence of pneumothorax or vascular puncture during ultrasound guided block. In 3 patients (10%)we had accidental vascular puncture when we followed the NS technique. Three patients in both the groups , the block was 'patchy' or inadequate , which was considered as 'Block failure'(6.7%). Incidence of accidental paresthesia was higher - 20% (6 patients) in NS group compared to US group 6.7 %. though this was not statistically insignificant.

Our study showed that the block success was 93.33% in US group (28/30) where as it was 83.33% in NS group (25/30).All the block failures were managed with general anesthesia. Although there was some difference in the success rates between the groups it was statistically insignificant We monitored hemodynamic vital parameters such as Pulse rate, Systolic and Diastolic blood pressure and oxygen saturation percent periodically with appropriate monitors. There was no obvious changes between two groups during all over the study. This results no significant difference between two groups clinically and statistically(P>0.05)

SUMMARY

This prospective, randomized, comparative study was done in Mahatma Gandhi Memorial Government Hospital, Trichy from the period of 2015 to 2016. A total of 60 patients belonging to ASA I& II, aged between 18 to 60 years were scheduled for upper limb surgeries were included in the study.

Patients receiving anticoagulants, H/O coagulopathy and peripheral neuropathy, and age < 18 years, > 60 years, H/O uncontrolled hypertension, refusal of patient's participation were excluded from this study. Patients were divided into two groups, each group consisting of 30 patients (n=30).

NS Group: Supraclavicular brachial plexus block performed with the guidance of Nerve Stimulator

US Group: Supraclavicular brachial plexus block performed through Ultrasound guidance.

The parameters observed were

- Block Execution time,
- Time taken for sensory Onset
- Total Duration of analgesia
- Time duration for motor Onset
- Success rate and complications

In this study we concluded that Ultrasound guided supraclavicular brachial plexus block for patients undergoing upper limb surgeries provided rapid onset of sensory and motor blockade than NS group and also extends the duration of analgesia with good hemodynamic stability. Block execution time by US group was longer than NS group. Success rate achieved by both methods are almost similar and occurrence of complications such as vascular puncture and paresthesia was seen more in NS group.

CONCLUSION

We concluded that Ultrasound guided supraclavicular brachial plexus block for patients undergoing upper limb surgeries provided rapid onset of sensory and motor blockade than NS group and also extends the duration of analgesia with good hemodynamic stability. Block execution time by US group was longer than NS group. Success rate achieved by both methods are similar and occurrence of complications such as vascular puncture and paresthesia was seen more in NS group.

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Comparison of Supraclavicular brachial plexus block by nerve stimulator vs ultrasound guided method

Proforma:	NS US			
Name:	Age: Sex;	I.P. No:	Date:	Case no:
Diagnosis:	Surgery:		I	Duration:

Drug: Bupivacaine(0.5%) 15 ml and 15 ml lignocaine(2%) with adrenaline(1:200000) for both Group US and Group NS

Needle insertion/Initial scanning time:

Needle withdrawal time:

Procedural time:

Sensory	C5	C6	C7	C8	T1
onset time	dermatome	dermatome	dermatome	dermatome	dermatome
1 minute					
2 mts					- annia h
3 mts		00.1	a Casta 24.1	towned I former 2	time 2
4 mts				1	
6 mts					
7 mts			1		
8 mts			shole	eteuneh	ani \ent
9 mts	~				
10 mts					
15mts	s rate:	Succes	199	ns:	otteatio
20 mts					
30 mts					
45 mts					
1 hour					

Sensory onset:

Sensory duration:

Motor Onset:

Motor duration:

Motor onset time	Loss of shoulder abduction	Loss of elbow flexion	Loss of wrist movements	Loss of finger movements
1 mt			0 64	
2 mts				
3 mts	12850	1071 (1.1)2.94		
4 mts	0	Superior		gnosis
5 mts				
6 mts	ne(2%) with	id 15 ml lignore	e(0.6%) 15 ml a	ig: Bupivacuu
8 mts	64.0	noto tem co de	NO BOUIDION	Week Prove
10 mts	A Street March	Series Company	science laitin	de insertion
15 mts				
20 mts				COLUMN LINE, O
30 mts				
40 mts	80	0	C6	Sansbary CS
50 mts	demistome	e dematome	ome dermatou	dernab leeno
1 hour				Ampin I

Vital signs:

Time	5 mt	15 mts	30 mts	45 mts	1 hour	1.30	2 hours	2.30	3 hours
PR									6101.9
BP									S mits
SPO2									stm (

Failure/ Inadequate block:

Complications:

Success rate:

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

சுப்ரா க்ளாவிக்குளார் ப்ரேக்கியள் ப்ளக்ஸஸ் பிளாக் போடுவதற்கு நர்வ் ஸ்டிமுலேட்டர் மற்றும் அல்ட்ராசவுண்டு கருவிகளை கொண்டு ஒப்பிடும் ஆய்வு.

ஆராய்ச்சி நிலையம்	:	மகாத்மாகாந்தி நினைவு அரசு மருத்துவமனை, திருச்சிராப்பள்ளி.
பங்கு பெறும் நோயாளியின் பெயர்	:	ഖധத്വ :
பங்கு பெறும் நோயாளியின் எண்	:	பாலினம்: பெண்

பெற்றோர்/உடனிருப்பவர் பெயர் விலாசம்:

பெற்றோர்/உடனிருப்பவர் இதனை (√) குறிக்கவும்.

- மேலே குறிப்பிட்டுள்ள மருத்தவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.
- நான் நோயாளியை இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்க வைக்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நோயாளியை இவ்வாய்வில் இருந்து விலக்கி கொள்ளலாம் என்று அறிந்து கொண்டேன்.
- இந்த ஆய்வு சம்பந்தமாகவோ இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும். இந்த ஆய்வில் பங்குபெறும் மருத்துவர் நோயாளியுடைய மருத்தவ அறிக்கைகளை பார்ப்தற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நோயாளியை ஆய்வில் இருந்து விலக்கிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.
- இந்த ஆய்வின் மூலம் கிடைக்கம் தகவல்களையும் பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.
- இந்த ஆய்வில் நோயாளியை ஈடுபடுத்த முழுமனதுடன் ஒப்புக்கொள்கிறேன். இந்த மயக்க மருந்துகள் மற்றும் மயக்க முறையினால் ஏற்படக்கூடிய பின் விளைவுகள் மற்றுமு எதிர்பாராத விளைவுகள் பற்றி எனக்கு விளக்கமாக தெரிவிக்கப்பட்டது.
- இந்த ஆய்வில் நோயாளிக்கு தோல்பட்டையின் அருகில் சிறு ஊசியின் மூலம் மயக்க மருந்துகளை அல்ட்ராசவுண்டு அல்லது நர்வ் ஸ்டிமுலேட்டர் கொண்டு கொடுக்க சம்மதம்
- நோயாளிகளின் நலன் கருதியே இந்த ஆய்வு மேற்கொள்ளப்பட்டது என்று தெரிந்து இந்த ஆய்விற்கு ஒப்புதல் அளிக்கின்றேன்.

பெற்றோர்/உடனிருப்பவர் கையொப்பம்..... இடம்......தேதி.....தேதி.....

கட்டைவிரல் ரேகை (இந்த படிவம் படித்து காட்டப்பட்டு புரிந்து கைரேகை அளிக்கின்றேன்)

ஆய்வாளரின் கையொப்பம்.....தேதி

ஆய்வாளரின் பெயர்.....

சுப்ரா க்ளாவிக்குளார் ப்ரேக்கியள் ப்ளக்ஸஸ் பிளாக் போடுவதற்கு நர்வ் ஸ்டிமுலேட்டர் மற்றும் அல்ட்ராசவுண்டு கருவிகளை கொண்டு ஒப்பிடும் ஆய்வு.

ஆராய்ச்சியின் நோக்கம்

உங்களை ஈடுபடுத்த திட்டமிட்டுள்ள இந்த ஆராய்ச்சியானது, அல்ட்ராசவுண்டு, அல்லது நர்வ் ஸ்டிமுலேட்டர் கொண்டு சுப்ரா க்ளாவிக்குளார் ப்ளாக் செலுத்தப்பட்டு அதில் உங்களுக்கு ப்யுபிவெக்கெய்ன், லிக்னோகெய்ன் மற்றும் அட்ரிணலின் மருந்துகள் உட்செலுத்தபடும். இம்மருந்துகள் மிகவும் பாதுகாப்பனவை. இந்த பிளாக் மூலம் கை முழுவதும் செயல் இழக்க செய்யமுடியும். இதற்கு அல்ட்ராசவுண்டு மற்றும் நர்வ் ஸ்டிமுலேட்டர் பயன்படுத்தும் போது மிக துல்லியமாகவும், பக்கவிளைவுகள் குறைவாக இருக்கும்.

மாந்நு மயக்க மருத்துவ முறை

இந்த அறுவை சிகிச்சையை முழு மயக்கம் கொடுத்தும் செய்யலாம் அப்படி கொடுக்கும் போது முழுமயக்கத்திற்கு செலுத்தப்படும் மருந்துகளால் ஏற்படும் பக்கவிளைவுகள் அதிகம் மற்றும் அறுவைசிக்சை பிறகு முழுமையான வலி நிவாரணமும் கிடைக்காது.

உண்டாக கூடிய இடர்கள்

மற்ற மயக்க மருத்துவ முறைகளை போலவே இந்த முறையிலும் எதிர்பாராத பக்கவிளைவுகள் ஏற்பட வாய்ப்புகள் உண்டு. இந்த பிளாக் செலுத்தும் போது மருந்து நேரடியாக இரத்தத்தில் கலக்க வாயப்புகள் உண்டு. இதனால் மூளை மற்றும் இதயம் செயல் இழக்கலாம் இந்த ஊசி போடும் போது தவறுதலாக நுரையீரலை சுற்றி உள்ள ப்ளுராவில் குத்தும் போது நியுமோதொராக்ஸ், வலிப்பு மற்றும் இதயதுடிப்பு நின்று போக வாய்ப்பு உண்டு. ஆனால் அல்ட்ராசவுண்டு மற்றும் நர்வ் ஸ்டிமுலேட்டர் பயன்படுத்தும் போது பக்கவிளைவுகள் மிகவும் குறைவாகவே ஏற்படும். இந்த ப்ளாக் தகுந்த முன்னெச்சரிக்கையுடன் உங்களுக்கு செலுத்தப்படும்.

ஆராய்ச்சிமுறை:

இந்த ஆராய்ச்சிக்கு உங்களை அறுவை சிகிச்சை அரங்கிற்கு அழைத்து சென்று தகுந்த முன்னெச்சரிக்கை நடவடிக்கையுடன் சுப்ரா க்ளாவிக்குளார் ப்ளாக் அல்ட்ராசவுண்டு அல்லது நர்வ் ஸ்டிமுலேட்டர் கொண்டு போடப்படும் இந்த ப்ளாக் முறை தோல்வி அடையும் பட்சத்தில் உங்களுக்கு முழு மயக்கம் கொடுத்து வாயில் E.T டியுப் மூலம் மயக்க வாயு செலுத்தப்படும். உங்களது இதயதுடிப்பு, இரத்தகொதிப்பு மற்றும் இரத்த ஆக்ஸிசன் அளவு சீராக ஆய்வு செய்யப்படும். அறுவை சிகிச்சை முடிந்தவுடன் வாயிலிருந்து டியுபை எடுத்து விட்டு உங்களை அறுவை சிகிச்சை பின் வார்டிற்கு அனுப்புவோம். உங்களது இதயதுடிப்பு, இரத்தகொதிப்பு 12 மணி நேரத்திற்க்கு தொடர்ந்து கண்காணிக்கப்படும்.

உங்களின் உரிமை

உங்கள் மருத்துவப் பதிவேடுகள் மிகவும் அந்தரமாக வைத்து கொள்ளப்படும். இந்த ஆய்வின் முடிவுகள் அறிவியல் பத்திரிகைகளில் பிரசுரிக்கப்படலாம். ஆனால் பெயரை வெளியிடுவது மூலம் நோயாளி அடையாளம் காட்டப்படமாட்டார். இந்த ஆய்வில் நோயாளியின் பங்களிப்பு தன்னிச்சையானது மற்றும் காரணங்கள் எதையும் கூறாமலேயே நீங்கள் இந்த ஆய்விலிருந்து எந்த நேரத்திலும் விலகிக் கொள்ளலாம். எப்படியிருந்தாலும் நோயாளிக்கு தகுந்த சிகிச்சை அளிக்கப்படும். இந்த ஆய்வில் ஏதேனும் பக்க விளைவுகள் ஏற்பட்டால் நோயாளிக்கு முழு சிகிச்சை மருத்துவ குமுவினரால் அளிக்கப்படும்.

உடன் இருப்போர் / நோயாளி கையொப்பம்

நாள்

இடது பெரு விரல் ரேகை

PATIENT INFORMATION SHEET

Title : Comparison of supraclavicular brachial plexus block by nerve stimulator and ultrasound guided method

Aim of the study & Advantages of the techniques

You will undergo Supraclavicular brachial plexus block with the guidance of either Ultrasound or Nerve stimulator before the surgical procedure. You will receive long acting drugs with adrenaline which will provide good intra operative and postoperative analgesia up to 8 hours. These drugs lignocaine and bupivacaine are standard drugs used for anesthesia and are known to be safe in adults.

Supraclavicular block is given to block pain in the upper limbs. This block is known to provide good pain relief and complete anesthesia in arm, fore arm and hand. Since the Supraclavicular block is administered either under Ultrasound guidance or nerve stimulator, there is less risk associated with administering the block with high success rate.

Alternate plan of anesthesia management:

The procedure can also be done under only general anesthesia, but that will not provide adequate pain relief after surgery. It will result in administering opioid analgesics frequently which can cause side effects such as respiratory depression, nausea and vomiting. Inadequate pain relief causing discomfort to the patients.

Possible Complications associated with the techniques:

Just as the possibility of complications with any anesthesia technique, unexpected complications can occur with these procedures too. In supraclavicular block technique, inadvertent injection of the drug into the blood can occur, which in that case will affect the heart and brain. The anesthesia technique as such can cause side effects such as pneumothorax, seizures, arrhythmias and cardio respiratory arrest. In Supraclavicular brachial plexus block, accidental entry of the needle into the pleural cavity can occur resulting in injury to pleura and lung which is best avoided by ultrasound guidance. The anesthesiologist will ensure utmost care in administering the blocks and will take all necessary precautions to avoid and also treat such complications.

Study Procedure:

In this research, you will be taken to operating room, and under aseptic precaution supraclavicular block will be performed with guidance of either Ultrasound or Nerve stimulator as decided by the investigator will be administered. In case of a failed or inadequate block, general anesthesia will be given through the intravenous line and endotracheal tube will be inserted through the mouth to secure the airway and administer anesthesia gases through it. The Blood pressure, heart rate and Oxygen saturation will be monitored. At the end of the procedure, after the patient has recovered from the general anesthesia, the ET tube will be removed and the patient will be shifted to recovery room. The patient will be monitored for 12hrs after the surgery and if he/she feels pain, will be given intramuscular analgesics.

You're Rights in the Study

Patient's medical records will be maintained confidential. The results of the study may be published in journals, but will not disclose the identity of the participants. The participation in this study is voluntary and not under any compulsion and you are free to withdraw from the study without giving any reasons at any time, you will be given the same medical care as provided to patients normally.

If in case any complication arises, patient will be adequately taken care of by the medical crew.

Date:

Signature/Thumb Impression of the parent/guardian

PARENT/GUARDIAN CONSENT FORM

Title of the study: Comparison of Supraclavicular brachial plexus block by Ultrasound and Nerve stimulator guided method

Study Centre: Mahathma Gandhi Memorial Government Hospital, Trichy

Patient's name:

Age/Sex:

Parent/Guardian's Name:

Address:

- □ The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions about the anesthetic techniques to be administered to he/she for surgery and postoperative pain relief.
- □ I understand that my..... participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without affecting the medical care that will normally be provided by the hospital.
- □ I understand that the doctor involved in the study does not require my permission, to monitor and assess my...... for various medical parameters
- □ I agree not to restrict the use of any data or results that arise from this study, provided such a use is only for scientific purpose(s).
- □ I fully consent for my.....to take part in the study and I have also been explained about the complications that may arise due to the anesthesia techniques
- □ As the parent/ guardian of the patient, I give my consent for him/her to undergo the anesthesia procedures involving Supraclavicular block by guidance of Ultrasound or Nerve stimulator followed by injecting of anesthetic drug, bupivacaine and Lignocaine mixture in the supraclavicular space of my...... for the study as mentioned in the patient information sheet.
- □ I consent wholeheartedly after understanding that the study is taken up for the benefit of my......

Signature/Thumb impression of the parent/ guardian:

Date: Place:

Signature of the investigator: