"EFFECTIVE VOLUME OF LOCAL ANAESTHETIC FOR ULTRASOUND-GUIDED INFRACLAVICULAR BRACHIAL PLEXUS BLOCK: A PROSPECTIVE RANDOMIZED CONTROL TRIAL"

By

Dr. BHARATH C J

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

Under the Guidance of

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EFFECTIVE VOLUME OF LOCAL ANAESTHETIC FOR ULTRASOUND-GUIDED INFRACLAVICULAR BRACHIAL PLEXUS BLOCK: A PROSPECTIVE RANDOMIZED CONTROL TRIAL I ABSTRACT Background: Fractures of the upper limb are a frequent orthopedic issue that often necessitate surgical management, typically performed under general anesthesia or through a regional technique such as a brachial plexus block. Despite its widespread use, the ideal volume of local anesthetic for achieving optimal ICB remains unclear. This study aims to compare the effectiveness of 25 ml versus 30 ml of ropivacaine (0.5%) administered via ultrasound-guided ICB. Materials and Methods: This study was conducted on 60 patients undergoing upper limb surgery below the mid-humerus at "R.L. Jalappa Hospital and Research Centre. Patients were randomly allocated into two groups: Group A received 25ml of ropivacaine (0.5%), and Group B received 30ml of ropivacaine (0.5%)." The onset and duration of sensory and motor block, postoperative analgesia, and visual analog scale (VAS) scores were analyzed using appropriate statistical methods. Results: The onset of sensory and motor block was similar among groups (p>0.05). Group B had substantially longer periods of sensory (12.9±1.6 min vs. 10.9±3.0 min, p<0.05) and motor block (13.5±2.4 min vs. 10.2±3.0 min, p<0.05). Group B had longer analgesia (14.13±1.22 hours vs. 12.77±2.45 hours, p<0.05) and lower VAS scores across several postoperative time periods. Conclusion: While 30ml of ropivacaine (0.5%) provides longer sensory and motor block duration and superior postoperative analgesia, 25ml remains a viable alternative with a comparable onset, adequate anesthesia, reduced toxicity risk, and cost-effectiveness. It is recommended in cases where early motor recovery and resource optimization are priorities. II Keywords: Infraclavicular brachial plexus block, Ropivacaine, Regional anesthesia, Ultrasound-guided block, Postoperative analgesia, Upper limb surgery. III INTRODUCTION Upper limb fractures are common orthopaedic problem and as a definitive treatment most of the patients undergo open reduction and internal fixation. Patients would undergo either general anaesthesia or brachial plexus block for orthopedic procedures on upper limb1. Previously, brachial plexus blocks were performed by landmark-guided techniques. However, in recent years, ultrasound-guided approaches have become increasingly popular for orthopedic surgeries involving upper limb fractures. For such procedures, brachial plexus blocks are considered a preferable alternative to general anesthesia. When surgeries involve the distal humerus, elbow, forearm, or hand, regional anesthesia techniques such as supraclavicular, axillary, infraclavicular, and interscalene brachial plexus blocks are commonly utilized2,3. Among them, distal humeral, elbow, forearm, and

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ABBREVIATIONS

AEC – Absolute Eosinophil Count

ALP – Alkaline Phosphatase

ALT – Alanine Aminotransferase

ASA – American Society of Anesthesiologists

AST – Aspartate Aminotransferase

BP – Brachial Plexus

CI – Confidence Interval

C – Cervical

CTRI – Clinical Trials Registry - India

ECG – Electrocardiogram

ESR – Erythrocyte Sedimentation Rate

FS – Febrile Seizures

HBsAg – Hepatitis B Surface Antigen

HCV – Hepatitis C Virus

HR – Heart Rate

ICB – Infraclavicular Brachial Plexus Block

IDA – Iron Deficiency Anemia

IEC – Institutional Ethical Clearance

INR – International Normalized Ratio

IV – Intravenous

K^+ – Potassium Ion

LA – Local Anesthetic

LSIB – Lateral Sagittal Infraclavicular Block

MAP – Mean Arterial Pressure

MCV – Mean Corpuscular Volume

MEV – Minimum Effective Volume

MEV90 – Minimum Effective Volume required for 90% success

Na^+ – Sodium Ion

NIBP – Non-Invasive Blood Pressure

OP – Organophosphorus

ORIF – Open Reduction and Internal Fixation

PT – Prothrombin Time

SBP – Systolic Blood Pressure

SSN – Suprascapular Nerve

T – Thoracic

URTI – Upper Respiratory Tract Infection

US – Ultrasound

VE90 – Minimum Effective Volume required for 90% success

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ABSTRACT

Background: Upper limb fractures are a common orthopedic condition requiring surgical intervention, often performed under general anesthesia or regional anesthesia via a brachial plexus block. Ultrasound-guided infraclavicular brachial plexus block (ICB) is widely used for procedures involving the distal humerus, elbow, forearm, and hand due to its efficacy and safety. However, the optimal volume of local anesthetic for effective ICB remains uncertain. This study compares the efficacy of 25ml and 30ml of 0.5% ropivacaine in ultrasound-guided ICB.

Aim: To evaluate the quality of anesthesia, onset, and duration of postoperative analgesia using 25ml and 30ml of 0.5% ropivacaine in ultrasound-guided infraclavicular brachial plexus block.

Materials and Methods: A randomized controlled trial was conducted on 60 patients undergoing upper limb surgery below the mid-humerus at R.L. Jalappa Hospital and Research Centre. Patients were randomly allocated into two groups: Group A received 25ml of 0.5% ropivacaine, and Group B received 30ml of 0.5% ropivacaine. The onset and duration of sensory and motor block, postoperative analgesia, and visual analog scale (VAS) scores were analyzed using appropriate statistical methods.

Results: The onset of sensory and motor block was comparable between the groups ($p>0.05$). However, Group B exhibited a significantly longer duration of sensory (12.9±1.6 min vs. 10.9±3.0 min, $p<0.05$) and motor block (13.5±2.4 min vs. 10.2±3.0 min, $p<0.05$). Group B also demonstrated prolonged analgesia (14.13±1.22 hours vs. 12.77±2.45 hours, $p<0.05$) and lower VAS scores at multiple postoperative time points.

Conclusion: While 30ml of 0.5% ropivacaine provides longer sensory and motor block

duration and superior postoperative analgesia, 25ml remains a viable alternative with a comparable onset, adequate anesthesia, reduced toxicity risk, and cost-effectiveness. It is recommended in cases where early motor recovery and resource optimization are priorities.

Keywords: Infraclavicular brachial plexus block, Ropivacaine, Regional anesthesia, Ultrasound-guided block, Postoperative analgesia, Upper limb surgery.

INTRODUCTION

INTRODUCTION

Upper limb fractures are common orthopaedic problem and as a definitive treatment most of the patients undergo open reduction and internal fixation. Patients would undergo either general anaesthesia or brachial plexus block for orthopedic procedures on upper limb[1].

Previously, brachial plexus blocks were performed by landmark-guided techniques. However, in recent years, ultrasound-guided approaches have become increasingly popular for orthopedic surgeries involving upper limb fractures. For such procedures, brachial plexus blocks are considered a preferable alternative to general anesthesia. When surgeries involve the distal humerus, elbow, forearm, or hand, regional anesthesia techniques such as supraclavicular, axillary, infraclavicular, and interscalene brachial plexus blocks are commonly utilized[2,3].

Among them, distal humeral, elbow, forearm, and hand procedures are performed with infraclavicular brachial plexus block (ICB). The cords are the site of an infraclavicular brachial plexus block. prior to the axillary and musculocutaneous nerves emerging. Therefore, for distal humerus, forearm, and hand surgery, infraclavicular brachial plexus block is preferable to supraclavicular brachial plexus block, interscalene block, and axillary brachial plexus block[4].

ICB plexus block is associated with reduced risk of intravertebral, intrathecal and epidural injection, when compared to supraclavicular brachial plexus block and interscalene block. There is limited evidence in the literature specifying the optimal volume of local anesthetic required for an effective infraclavicular brachial plexus block. Therefore, in this study, we aim to perform infraclavicular brachial plexus blocks for upper limb orthopedic surgeries involving regions distal to the humerus, using two different volumes of local anesthetic (25

ml and 30 ml), to determine the minimum effective volume necessary for successful blockade.

OBJECTIVES

AIMS & OBJECTIVES

Objectives of the study

Primary objectives:

To compare efficacy of 25ml of 0.5%ropivacaine with 30ml of 0.5%ropivacaine on quality of anaesthesia following ultrasound-guided infraclavicular brachial plexus block

Secondary objectives:

To compare onset and duration of postoperative operative analgesia using 25ml and 30ml of 0.5% ropivacaine following ultrasound-guided infraclavicular brachial plexus block

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Nerve anatomy and physiology

Myelinated fibers enable quicker conduction of electrical impulses, which are effectively transferred by nerves to and from the central nervous system, since the action potential leaps across the nodes of Ranvier[5]**.** Myelinated A fibers come in four different functional forms: Aα fibers innervate skeletal muscles, Aβ fibers govern muscle spindles, Aδ fibers transmit pain and cold sensations, and Aα fibers communicate tactile sensations[6].

Depolarization triggered by the stimulation of nociceptors activates voltage-gated sodium (Na^+) channels, which are protein structures located in the cell membranes of nerve and heart muscle cells. These channels have a complicated structure made up of one or two β subunits and a big α subunit that forms pores. "Each of the four domains (I–IV) that make up the α subunit has six segments grouped around a central bell-shaped channel. The S5 and S6 segments, as well as the brief amino acid loops that join them, make up the pore[7]. Positively charged amino acids like arginine or lysine are found in each domain of the S4 segment, the voltage-sensitive Na+ channel section"[8].

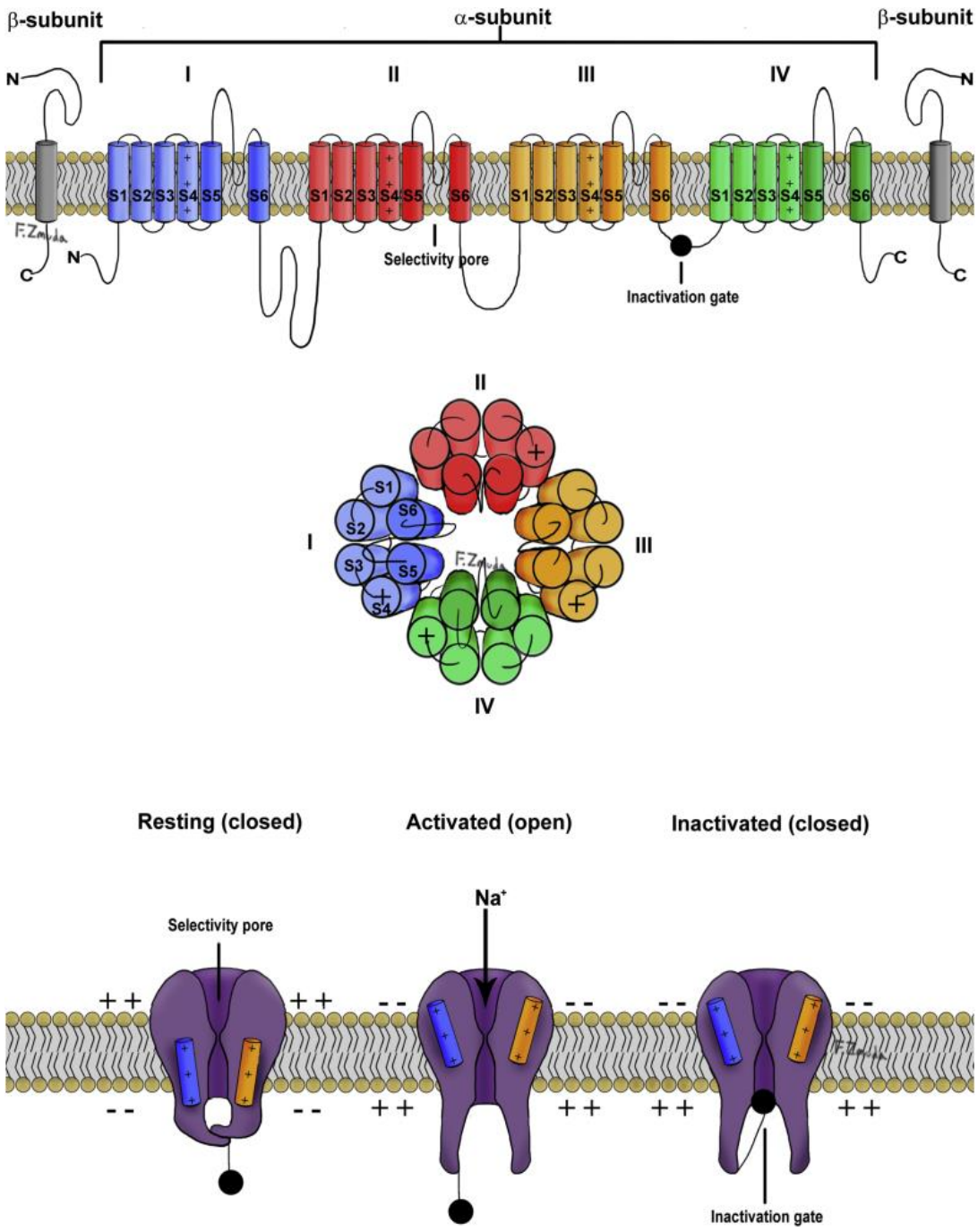

Figure 1: Structure and configuration of voltage gated Na+ channel[5]

The Na^+ channel exists in three distinct states: resting, open, and inactivated. During the resting state, the membrane potential is approximately –70 mV, maintained by K^+ ions moving outward along their concentration gradient while negatively charged anions, primarily proteins, remain inside the cell. The S4 segments are oriented inward in this

resting condition, which stops the channel from conducting. The S4 segments spiral outward during depolarization, which causes the Na+ channels to open and permits a quick inflow of Na+ ions propelled by chemical and electrical gradients. The channel is inactivated as a result of this movement, which reveals the inactivation gate's receptor location, which is situated between domains III and IV. Only after the cell membrane repolarizes can the channel transition back to its resting state from the inactivated state[9].

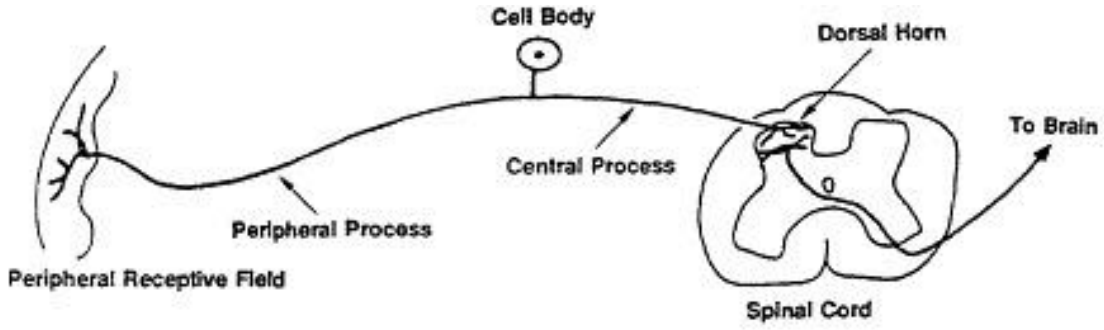

Figure 2: Primary afferent nociceptors

Selective ion channels regulate the flow of Na^+ and K^+ ions during impulse generation along a neuron, allowing Na^+ ions to flow rapidly inward and K^+ ions outward. The resting membrane potential is then reestablished by the sodium-potassium pump, which restores the original ion gradients[9].

Brief anatomy of brachial plexus

Originating from the cervical (C5–C8) and upper thoracic (T1) nerve roots, the brachial plexus is a complex network of nerve fusions and divisions that culminate in distinct nerves that supply the shoulder and arm muscles and skin. While a detailed understanding of its components is essential for distinguishing radiculopathy from mononeuropathy, a syndromic approach is more effective for diagnosing conditions affecting the plexus itself. Structurally, the brachial plexus is organized into regions, including roots, cords,

divisions, trunks, branches, and nerves, arranged from proximal to distal[10]. “The trunks—middle, upper, and lower—and the cords—posterior, lateral, and medial—are further classified based on their anatomical relationships with other structures in the upper extremity.

- The upper trunk is made up of the C5 and C6 roots.
- The central trunk is formed by the C7 root.
- The lower trunk is formed by the junction of the C8 and T1 roots[11].
- The upper stem branches out to the lateral and posterior cords.
- The lower trunk splits away to generate the posterior and medial cords.
- The lateral cord contributes to the median nerve and splits to produce the musculocutaneous nerve.
- The axillary nerve, which eventually develops into the radial nerve, is formed when the posterior cord splits.
- Various nerves originate from different elements of the brachial plexus. The C5 root gives rise to the dorsal scapular nerve, while the C5, C6, and C7 roots contribute to the formation of the long thoracic nerve. The suprascapular nerve arises from the upper trunk.
- Within the brachial plexus, the distribution of motor and sensory fibers varies. Additionally, sympathetic nerve fibers from the vertebral ganglia pass through the brachial plexus”[12].

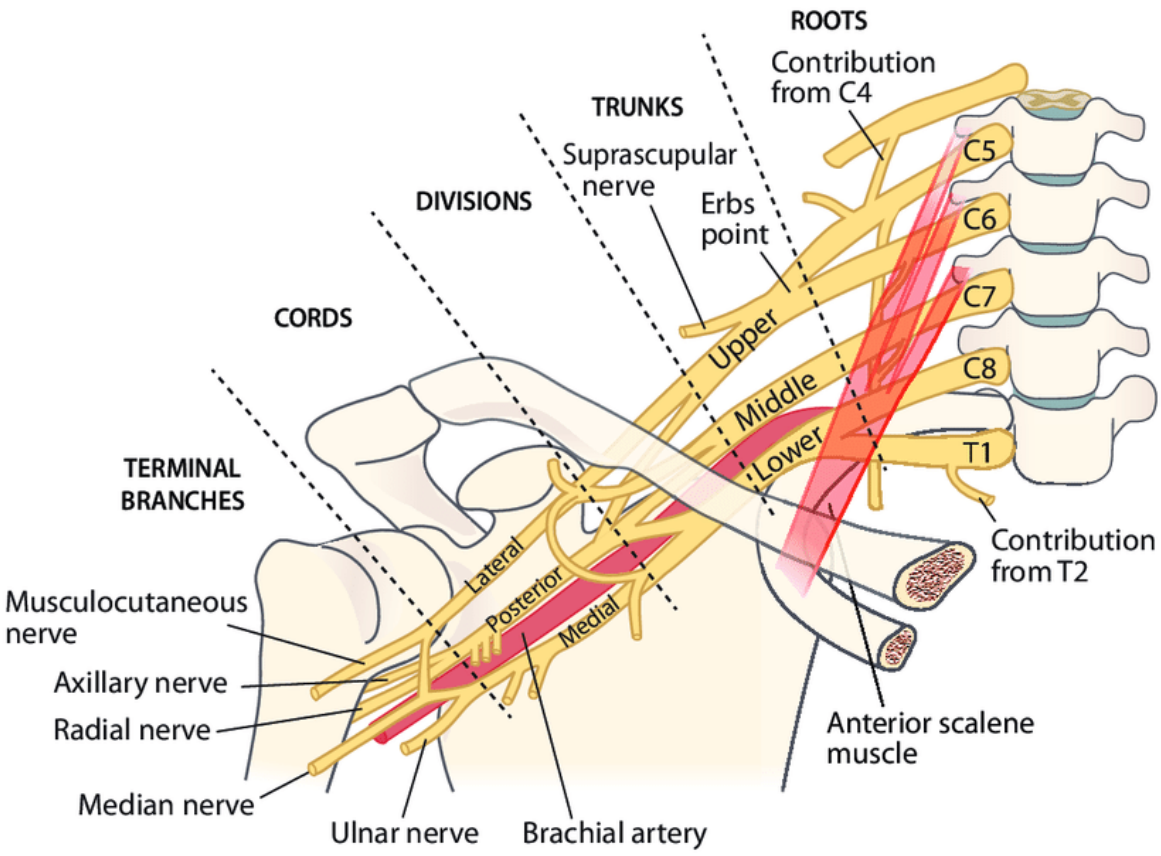

Figure 3: Brachial plexus[13]

The brachial plexus is created by the union of the ventral rami of the upper thoracic and lower cervical nerve roots. It passes behind the subclavian artery and the cephalad as it approaches the first rib[14].

Specific branches of branchial plexus

Supraclavicular branches

From roots

- Dorsal scapular nerve – C5
- Branch to phrenic nerve – C5
- Nerves to scalene and longus colli – C5,6,7,8
- Long thoracic nerve – C5,6

From trunk

- Suprascapular nerve – C5,6
- Nerve to subcalius – C5,6

Infraclavicular branches:

Lateral cord:

- Lateral root of median nerve – C5,6,7
- Musculocutaneous nerve – C5,6,7
- Lateral pectoral nerve – C5,6,7

Medial cord:

- Ulnar nerve – C7,8,T1
- Medial pectoral nerve – C8, T1
- Medial root of median nerve – C8,T1
- Medial cutaneous nerve of forearm – C8,T1
- Medial cutaneous nerve of arm – C8,T1

Posterior cord:

- Thracodorsal nerve – C6,7,8
- Upper subscapular nerve – C5,6
- Lower subscapular nerve – C5,6
- Axillary nerve – C5,6
- Radial nerve – C5,6,7,8,T1

After passing beneath the first rib, the three trunks descend deeply to the collarbone. The brachial plexus cords are referred to as posterior, lateral, or medial depending on where they lie in relation to the axillary artery. They emerge from the trunks just after the first rib. The five main nerves of the upper extremities originate from the cords:

- Musculocutaneous nerve
- Radial nerve

- Axillary nerve
- Ulnar nerve
- Median nerve
- Brachial plexus blocks are performed not only for facilitating upper limb surgical procedures but also for providing postoperative analgesia.

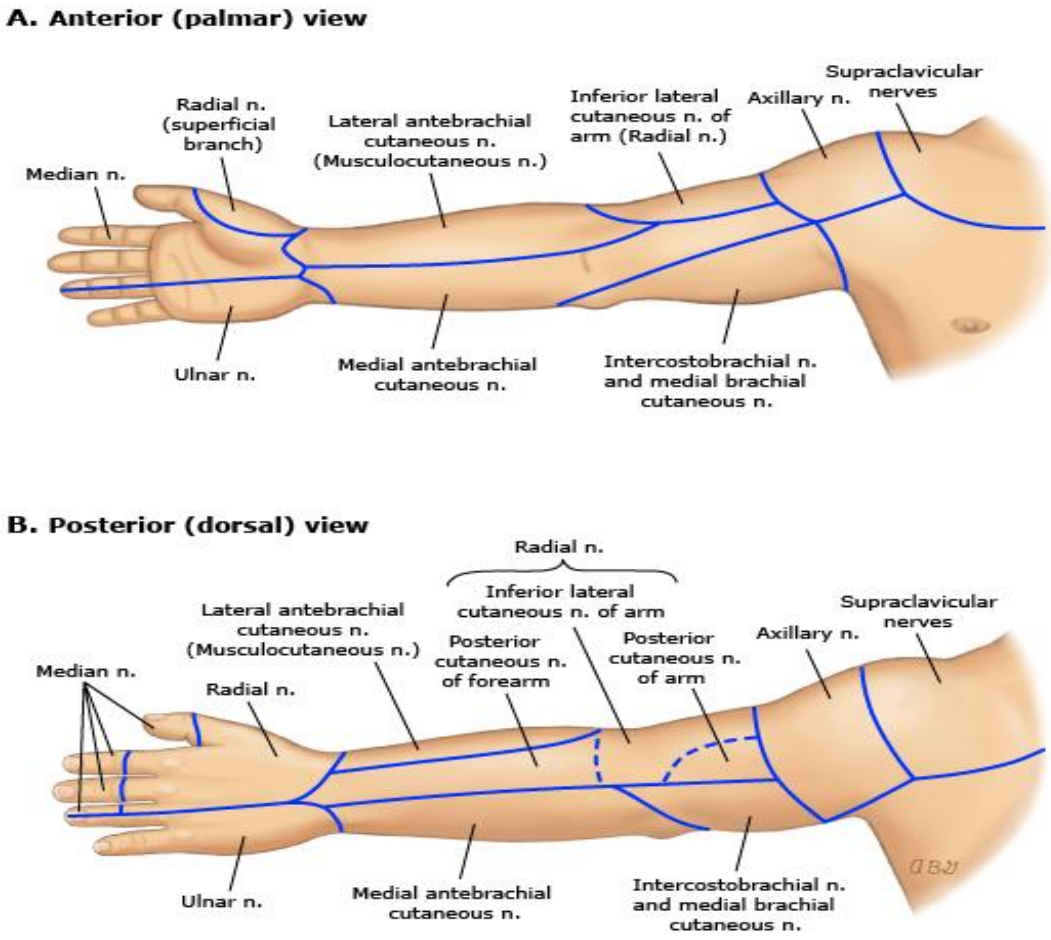

Figure 4: Cutaneous innervation of the arm

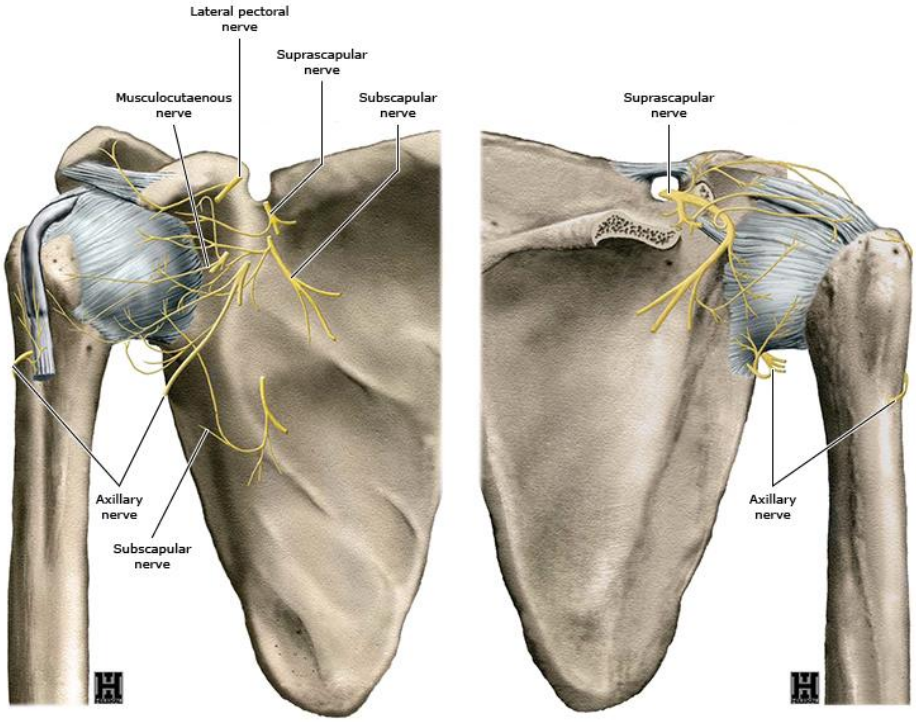

Figure 5: Innervation of the capsule and shoulder joint.

For a range of upper extremity operations, peripheral nerve blocks are utilised for operating anaesthesia and/or postoperative analgesia.

Brachial plexus blocks

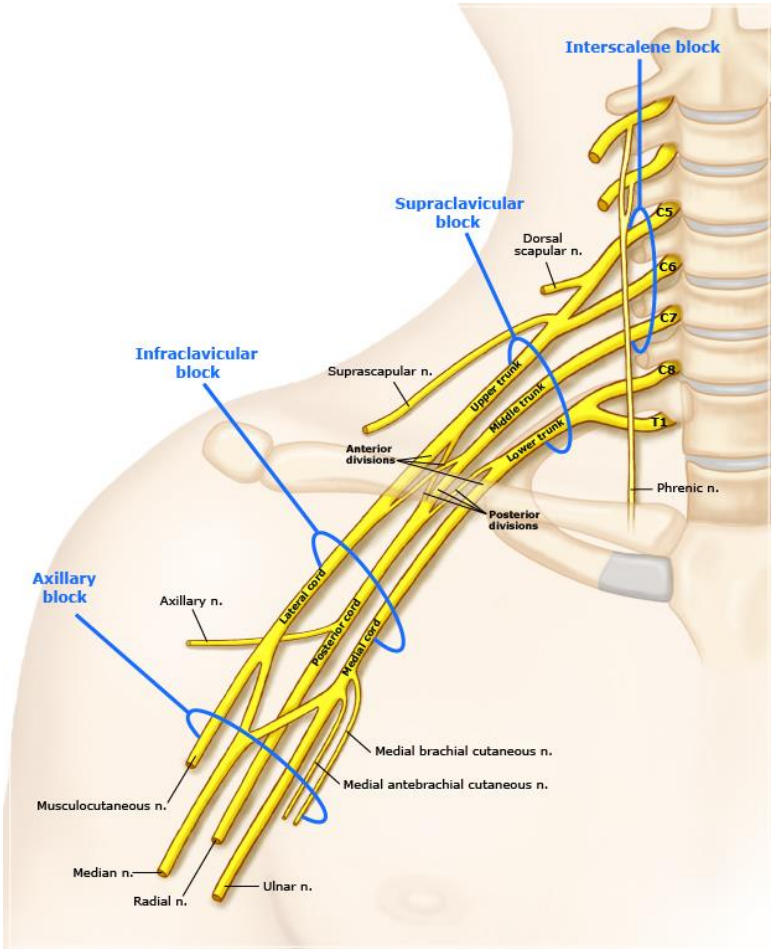

Figure 6: Brachial plexus blocks

- Interscalene block[15].
- Suprascapular block[16–21].
- Axillary block
- Supraclavicular block
- Infraclavicular block
- Axillary block[22].
- Ulnar block
- Digital block

- Wrist block
- Radial block
- Median block

Supraclavicular brachial plexus block: This technique offers a fast and effective onset of anesthesia, making it well-suited for surgeries on the distal 2/3rd of the upper limb, including hand operations, even when an upper extremity tourniquet is applied.

Infraclavicular block – In addition to giving anesthesia to the distal two-thirds 0f the arm, it consistently blocks the axillary and musculocutaneous nerves, which is more reliable than a supraclavicular block, by targeting the lateral, posterior, and medial cords 0f the brachial plexus[4]. This method is more commonly utilized for indwelling catheter placement than supraclavicular blocks because the infraclavicular site gives greater efficacy, secure location, and easier catheter management. "The patient is placed in a supine posture, with the head tilted away from the block's side. The arm is abducted with the elbow flexed in order to detect the coracoid process"[23].

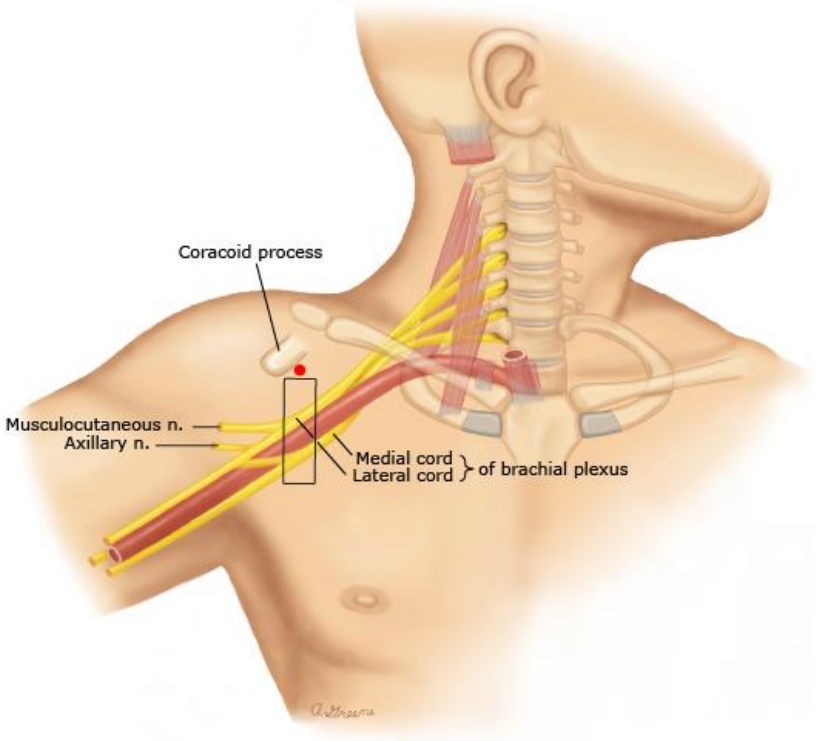

Figure 7: Infraclavicular branchial plexus block guided by ultrasound

Landmark technique

It is particularly advantageous in acute trauma patients, as it provides effective anesthesia and block can also be performed with minimum movement 0f the affected limb. This makes it especially useful when access to the neck is limited or when minimizing patient movement is crucial for administering the block safely and effectively.

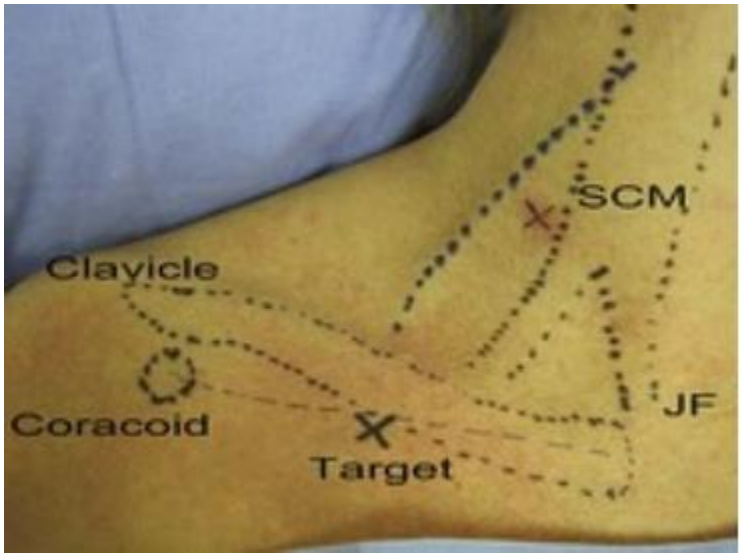

Figure 8: The surface anatomy for the infraclavicular block.

"To do the block, the patient should be in a supine position with their head turned away from the side that is being blocked. To preserve regular landmark linkages with the brachial plexus and enable unambiguous observation of hand twitches, the arm should preferably be abducted at the shoulder and flexed at the elbow. The medial end of the clavicle, the coracoid process (which is felt medial to the shoulder when the arm is raised and dropped), and the midpoint of a line between these two sites are important anatomical landmarks to identify for assistance. The needle insertion point is located 30 mm inferior and perpendicular to this midpoint"[24].

Mark the most anterior portion 0f the acromion, the jugular fossa, and the midpoint 0f the line that connects these two areas for the mid-clavicular vertical needle approach. Place the needle one fingerbreadth (10 mm) medial to the infraclavicular fossa, immediately inferior to the clavicle. As an alternative, mark the coracoid process and a location 20 mm inferior and 20 mm medial to it as the needle insertion site for the sub-coracoid vertical needle approach. For a nerve block to be successful, these procedures guarantee

precise placement and execution.

Ultrasound guided block

"It is carried out by locating the arterial pulse on the sonogram, which acts as a distinct and simple marker. Additionally, the chest wall muscle reduces the chance of dislodgement and aids in holding the catheter in place, making this approach particularly well-suited for the catheter technique in comparison to the more superficial interscalene and supraclavicular procedures"[25,26].

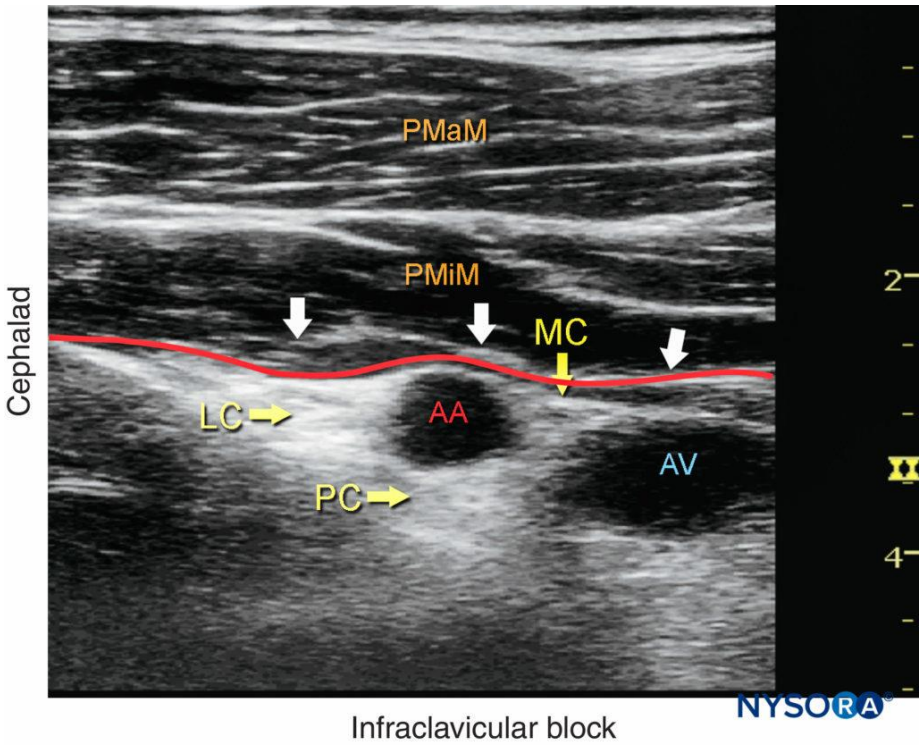

Figure 9: Ultrasound picture 0f block

Equipment

The following equipment is recommended for performing block:

- **Ultrasound machine**: Equipped with a 8–14 MHz linear transducer,
- **Standard nerve block tray**: Includes necessary preparation and procedural tools.
- **Local anesthetic**: 20–30 mL, pre-filled in syringes.
- **Needle**: An 8- to 10-cm, 21- to 22-gauge, short-bevel needle.
- **Sterile gloves**: To maintain aseptic technique.

Positioning

"In order to better visualize the pectoralis muscles, brachial plexus cords, and needle, as well as to elevate the clavicle and shorten the distance between the skin and the plexus for easier block performance, the patient is positioned supine with the head turned away from the side to be blocked and the arm on the blocked side abducted to 90 degrees with the elbow flexed"[27].

The coracoid process lines up with the palpating fingers when the arm is dropped. The transducer is moved medially and laterally in a parasagittal plane to locate the pleura and chest wall. The ultrasound scanning for an infraclavicular block usually starts just below the clavicle and medial to the coracoid process. To reduce the risk 0f pneumothorax, the probe is positioned lateral to the pleura during the block.

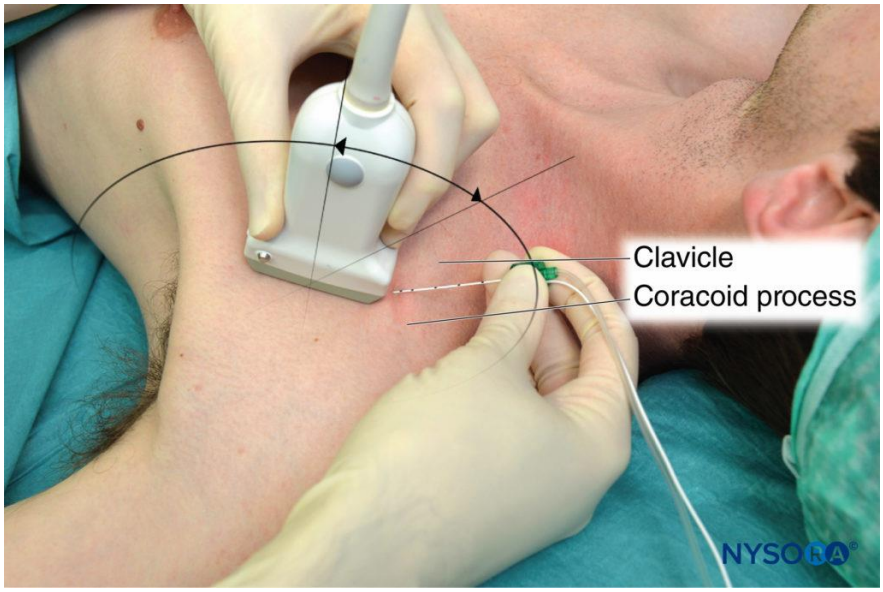

Figure 10: Patient position during needle insertion in ICB nerve block

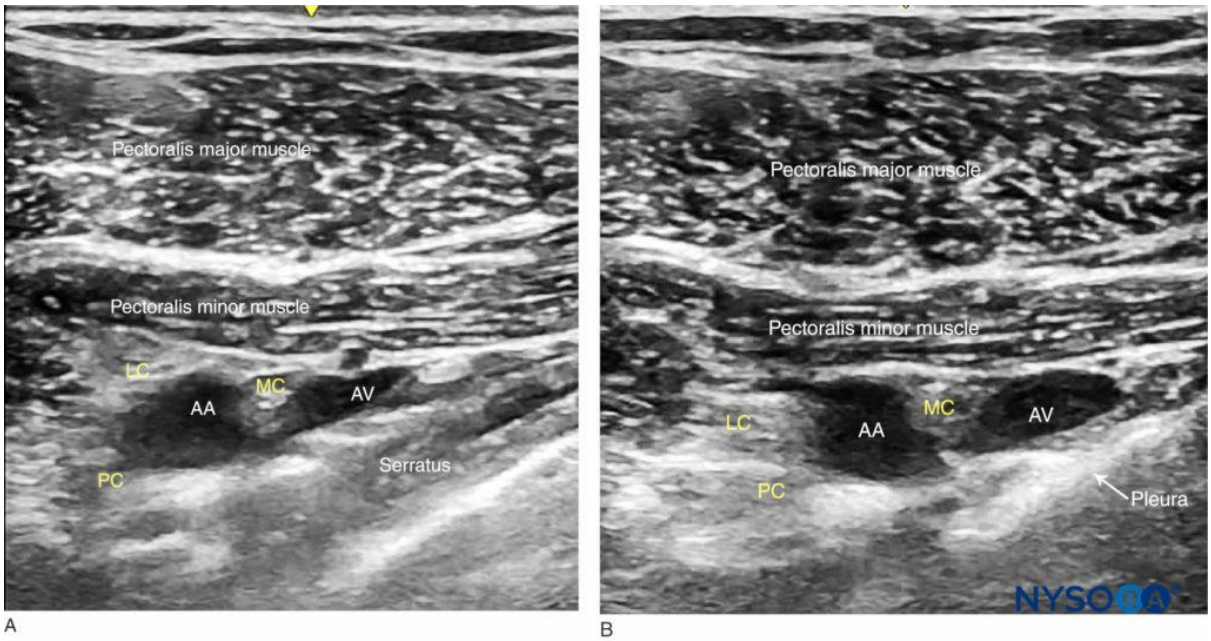

Figure 11: US guided infraclavicular nerve block

After identifying the artery, an effort is made to locate the brachial plexus's hyperechoic cords and determine where they are in relation to the artery. Successful blocking does not, however, depend on the visualization 0f these cords, which may not always be readily apparent. The ultrasound probe's cephalad end is used to enter the needle in-plane, with the insertion site situated immediately below the clavicle. “It targets the posterior side 0f the axillary artery and passes through the pectoralis major and minor muscles. To ensure correct needle insertion and dissemination, 1-2 mL of local anesthetic is administered following cautious aspiration to prevent artery puncture. In order to sufficiently cover the lateral and medial cords, the injectate should extend both cephalad and caudad”[27].

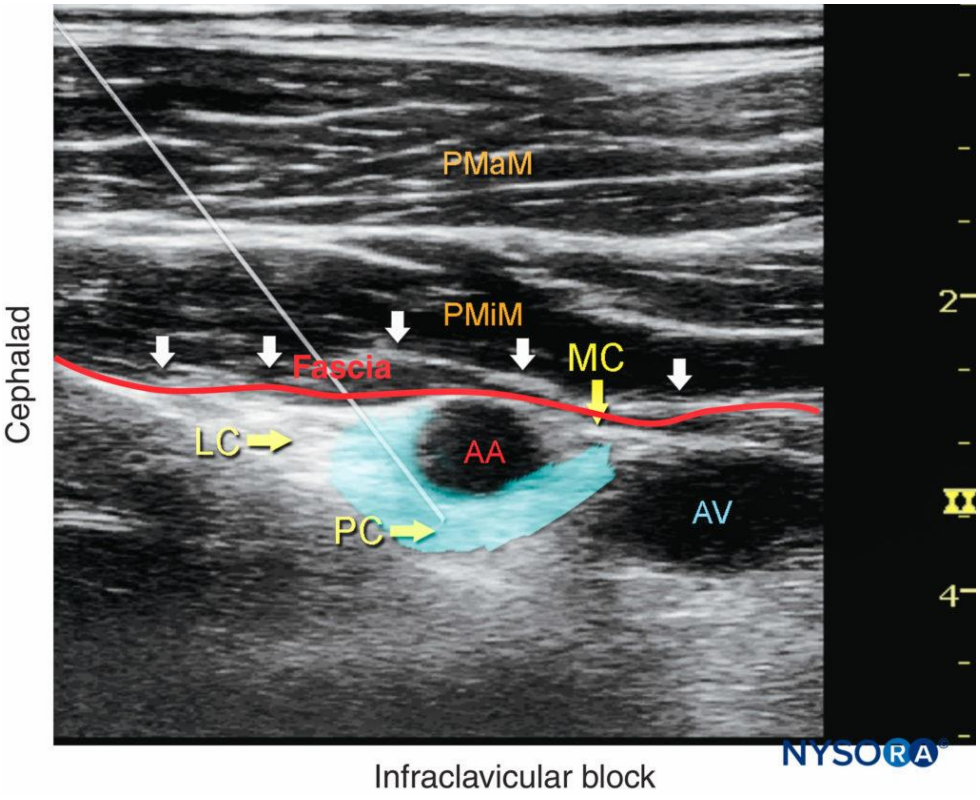

Figure 12: Ideal needle path during procedure

There have also been other methods for obstructing the brachial plexus distal to the collarbone. This method 0ffers yet another practical way to achieve anesthesia that works.

Various articles;

Tran DQ et al., (2010) conducted study to assess the MEV of lidocaine in ultrasound guided infraclavicular blocks. "The study included 55 patients, and isotonic regression combined with bootstrap confidence intervals (CIs) was used to estimate the minimum effective volume required for 90percent success (MEV90) in single-injection ultrasound-guided infraclavicular block (ICB). The best dosages for different lidocaine concentrations, other local anesthetics, and methods like numerous injections, a more medial approach to ICB, or specific targeting of all three cords of the brachial plexus require more investigation"[28].

To determine the lowest effective volume of ropivacaine in the ultrasound-guided infraclavicular brachial plexus block technique, Flohr-Madsen S et al. (2013) carried out a study. Roprivacaine was given to patients in amounts varying from 12.5 to 30 ml, at a concentration of 7.5 mg/ml. For 50percent and 95percent of patients, respectively, the minimum effective volumes (MEVs) needed to attain favorable results were 19 ml. For procedures performed distal to the elbow, the MEV required for a successful LSIB in 95percent of patients was estimated to be 31 ml. The variables affecting the amount of local anesthetic required to achieve an effective infraclavicular block require more investigation[29].

In order to determine the lowest effective volume for US guided brachial plexus block, Ferraro L. et al. (2014) conducted a study. The MEV of 0.5percent bupivacaine with 1:200,000 epinephrine needed per nerve was found to be 1.56 ml in the study, which involved 19 patients. In summary, these results are consistent with earlier research, showing that ultrasound-guided peripheral nerve blocks can produce surgical anesthesia with small amounts of local anesthetic[30].

In order to evaluate the volume on duration of a single injection US guided block, Fenten M et al. (2015) conducted a study. Fifteen patients each group were included in the analysis after 45 individuals were randomly selected, four of whom were removed and replaced. According to the results, a higher dose and concentration of mepivacaine during axillary brachial plexus blocks extend the duration of sensory and motor blockade, but the volume given has no effect[31].

Ince I et al., (2017) conducted study to assess the low volume anesthetic for US guided infraclavicular brachial plexus block. Pain scores, assessed using the Wong-Baker Face Scale, were found to be similar at all time points. "These results suggest that similar block success, postoperative sensory block durations, and pain scores can be achieved in pediatric patients undergoing infraclavicular brachial plexus block using lower volumes of local anesthetic"[32].

A retrospective analysis was carried out by Yeniocack T et al. in 2019 to evaluate the US guided infraclavicular block. Group I received a considerably larger volume of local anesthetic (LA) (33.7 ± 4.2 mL) than groups II, III, and IV ($p < 0.05$). Furthermore, group I had a considerably higher failure rate (3.2percent) than the other groups ($p < 0.05$). According to these results, a high success rate is guaranteed by sonographic supervision, and more anesthesiologist expertise is linked to fewer problems, lower failure rates, and the avoidance of LA overdose[33].

In order to determine the MEV of ropivacaine in US guided brachial plexus block, Mittal K et al. (2019) did a study. "This study shows that 8.64 mL of 0.5 percent ropivacaine can be used to produce surgical anesthesia utilizing ultrasound-guided ISB with a multiple-injection approach without sacrificing the duration of analgesia or the onset of block"[34].

A research by Kim JH et al. (2021) found that ICB plexus block with 0.375percent

ropivacaine or 0.25percent levobupivacaine was proven to give sufficient surgical anesthetic in a research with 46 participants. "The sensory onset time for 0.375 percent ropivacaine was much shorter than that of 0.25 percent levobupivacaine. However, there were no appreciable differences between the two groups in other block characteristics or clinical outcomes. Therefore, 0.375 percent ropivacaine is preferable when a quicker block onset is required"[35].

Baskan S et al., (2022) conducted study to assess the MEV of bupivacaine for US guided ICBP block. In nine volume groups, ranging from 30 mL to 14 mL, all patients (n = 45) experienced successful blocks; however, three blocks in the 12-mL group failed. The 30-mL group saw a block onset time of 15 (10–15) minutes and a first postoperative analgesic administration period of over 24 hours, respectively.In contrast, these times increased to 40 (30–45) minutes and 14 (10–24) hours in the 14-mL group. While a volume of 14 mL is effective, it is associated with a significantly longer onset time of approximately 40 minutes on average[36].

Aguilera G et al., (2024) conducted study to assess the US guided infraclavicular brachial plexus block. Bupivacaine alone resulted in a longer sensory block duration, with an average of 29.3 (5.8) hours versus 18.7 (4.0) hours, with a mean difference of 10.6 hours. Additionally, the duration of postoperative analgesia was substantially longer for bupivacaine alone (38.3 (7.4) hours) than for the mixture (24.3 (6.6) hours), with a mean difference of 14 hours. But bupivacaine alone delayed the median (IQR) onset time by 35 (15) minutes, while the combo took 20 (10) minutes ($p<0.001$). There were no other noteworthy variations found. Compared to the bupivacaine-lidocaine mixture, 0.5% bupivacaine significantly prolongs the duration of sensory and motor blocks and enhances postoperative analgesia, but with the drawback of a slower onset time[37].

METHODOLOGY

MATERIAL & METHOD

SOURCE OF DATA:

Study Design: A Randomized control trial

Sample size: 23 in each group

Study Duration: From May 2023 to November 2024

Study Participants: This study was conducted on patients posted for upper limb surgeries at R. L. Jalappa Hospital and Research Centre, Tamaka, Kolar.

Sampling Method: Computer generated random sequence of numbers concealed by closed envelope technique.

Sample size calculation

As per Das et al., (2026) the sample size formula is given below [11]

$$n = \frac{2 \times \left(z_{1-\alpha/2} - z_{1-\beta}\right)^2 \times \sigma^2}{d^2}$$

Where n = minimum required sample size

$z_{1-\alpha/2}$= The critical value (Table value) from a standard normal distribution that the test statistic must exceed in order to show a statistically significant result at 'α' level of significance.

$z_{1-\beta}$= Standard normal table value for the power of the test $(1-\beta)$

σ = Standard deviation of the response variable (obtained from previous study

d = the effect size = the minimum clinically important difference that the investigator wishes to detect.

In the present case, $z_{1-\alpha/2} = 1.96$ at 5 % level of significance

$z_{1-\beta}$ = 0.84 at 80 % power

Assuming a minimum difference of 5 min in time to onset of successful block would be clinically important to detect significance. So, d = 5 (Bashan et al., 2022) and σ = 6

Then the minimum required sample size in each group was computed as **22.6 ≅ 23**

Inclusion Criteria

- Patients who have given valid written consent
- Patients above 18 years of age with American society of Anesthesiologists (ASA) physical status 1-3 posted for ORIF upper limb for fractures below mid humerus

Exclusion Criteria

- Patient refusal
- Coagulopathy-Decreased platelets, increased PT, aPTT and INR
- Allergy or hypersensitivity to local anesthetics
- Active infection at the site of block, where needle is inserted
- Uncooperative or noncompliant patients
- Neurological or neuromuscular disorders involving upper extremities

Methodology:

- The study was started after Institutional Ethical Clearance (IEC) and CTRI. Patients were included in the study after obtaining written, informed consent. Study was conducted on patients more than 18 years of age undergoing ORIF for fractures below mid humerus. Necessary investigations like Platelet count, PT, INR and APTT are done prior to surgical procedure.

- Peripheral Intravenous cannula was secured and maintenance IV fluids (Ringer's Lactate) was initiated before giving block

- Monitors: ECG, SPO2, NIBP, Heart Rate connected before block was monitored throughout the procedure including adverse effects if any were noted

- Patients in both groups were premedicated with INJ. Midazolam 1MG I.V 5minutes before the procedure

- Patients were divided into two groups using computer generated random number table

- Group A: Receiving Infraclavicular brachial plexus block with 25ml of local anaesthetic (Ropivacaine 0.5%)

- Group B: Receiving Infraclavicular brachial plexus block with 30ml of local anaesthetic (Ropivacaine 0.5%)

Method of collection of data:

- Number of patients in each group 28.

- Informed consent was taken from the patient
- Result values were recorded using a proforma

Parameters to be observed

- Heart rate
- SBP and Mean arterial pressure (MAP)
- Oxygen saturation
- ECG
- Sensory block
- Motor block

STATISTICAL ANALYSIS

"Collected data was coded and entered into an excel data base. Percentage analysis in terms of frequency and percentages was done for representing qualitative characteristics. Descriptive statistics like Mean, standard deviation and standard error was calculated for representing quantitative variables like age and other variables. Comparison of quantitative variables between two groups can be done by using either independent t-test or Mann Whitney U test depending on normality assumptions satisfied by the data. Comparison of Qualitative data between two groups was done by using either chi-square test or Fisher's exact test. For all statistical purpose, a p-value of <0.05 was considered statistically significant."

RESULTS

RESULTS

Present study included total of 60 patients with 30 in group A and 30 patients in group B.

- Group A: Receiving Infraclavicular brachial plexus block with 25ml of local anaesthetic (Ropivacaine 0.5%)
- Group B: Receiving Infraclavicular brachial plexus block with 30ml of local anaesthetic (Ropivacaine 0.5%)

Table 1: Comparison of mean age between the groups

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Age in year	39.8	16.0	35.0	14.4	0.28

The mean age between the groups were comparable with no significant difference noted.

The mean age in group A was 39.8yrs and group B was 35yrs.

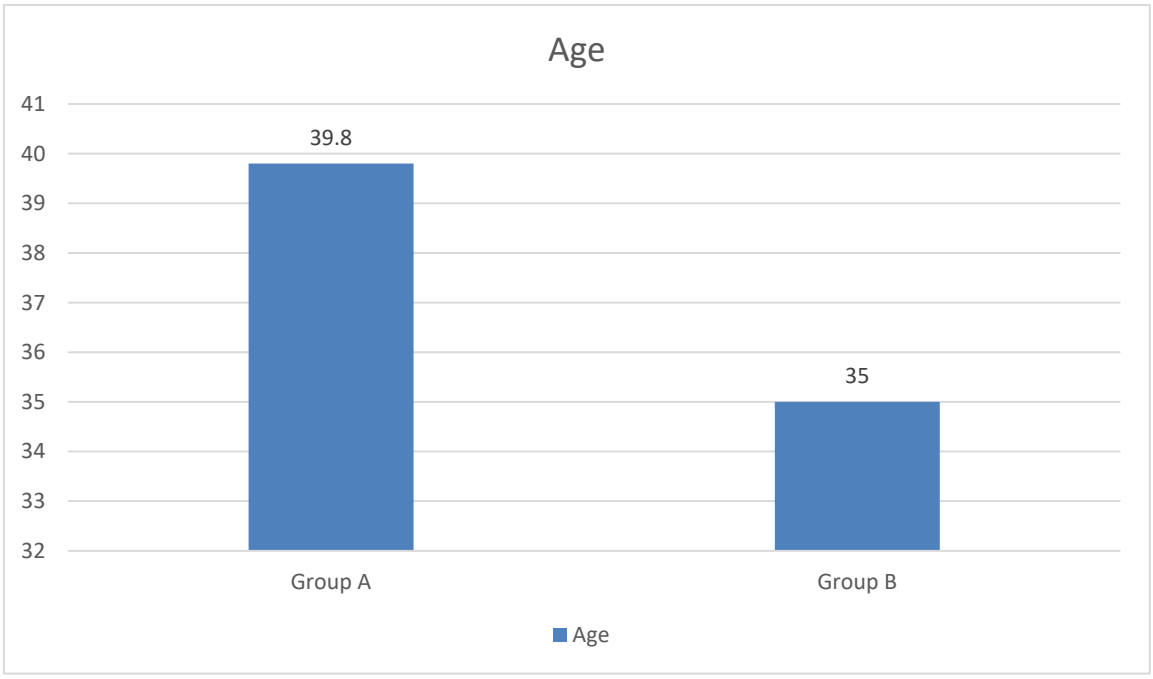

Figure 13: Comparison of mean age between the groups

Table 2: Gender distribution between the groups

		Group A		Group B		Chi-square (p-value)
		Count	N %	Count	N %	
Gender	Female	9	30.0%	6	20.0%	0.88 (0.37)
	Male	21	70.0%	24	80.0%	

The gender distribution between the group was comparable with no significant difference, however there is male preponderance in both the group with 70% male in group A and 80% in group B.

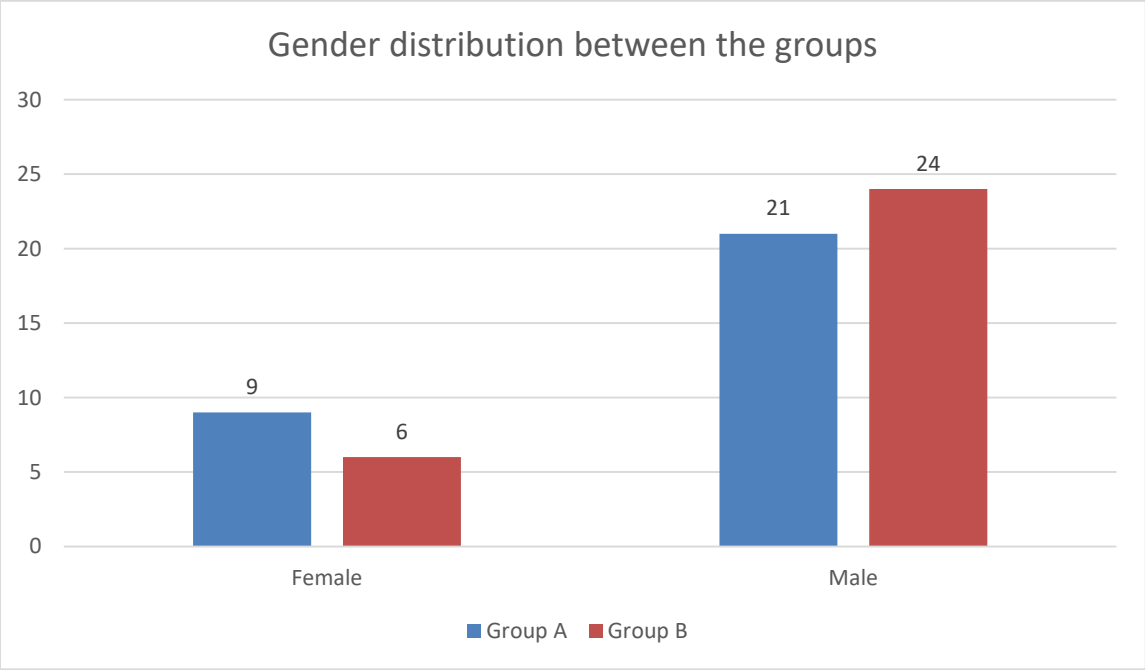

Figure 14: Gender distribution between the groups

Table 3: ASA grade between the groups

		Group A		Group B		Chi-square (p-value)
		Count	N %	Count	N %	
ASA	1.0	19	63.3%	21	70.0%	0.174 (0.455)
	2.0	11	36.7%	8	26.7%	
	3.0	0	0.0%	1	3.3%	

ASA grade showing the similar distribution between the groups, with no significant difference between two groups.

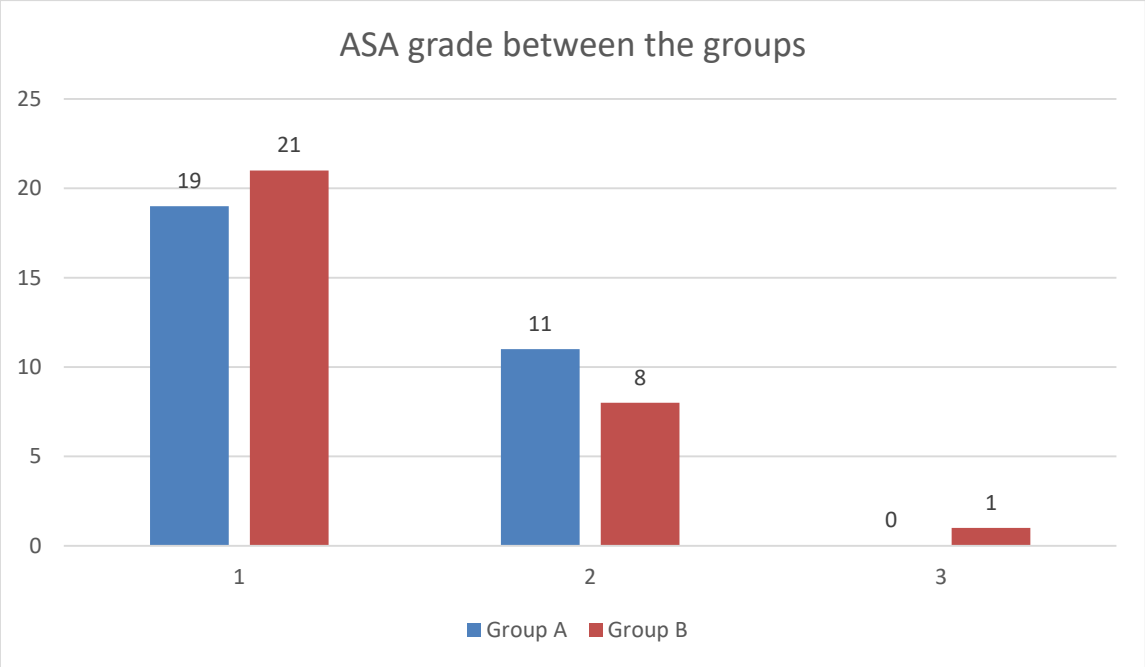

Figure 15: ASA grade between the groups

Table 4: Comparison of onset and duration of sensory block between the groups

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Onset of sensory Block(mins)	9.4	2.4	10.1	2.1	0.19
Duration of sensory block(hrs)	10.9	3.0	12.9	1.6	0.05*

The onset of sensory block was found to be similar between the group. The mean onset of sensory block was 9.4mins in group A and 10.1min in group B. ($p>0.05$) There is significant longer duration of sensory block in group B (12.9±1.6min) compared to patients in group A (10.9±3.0min).($p<0.05$)

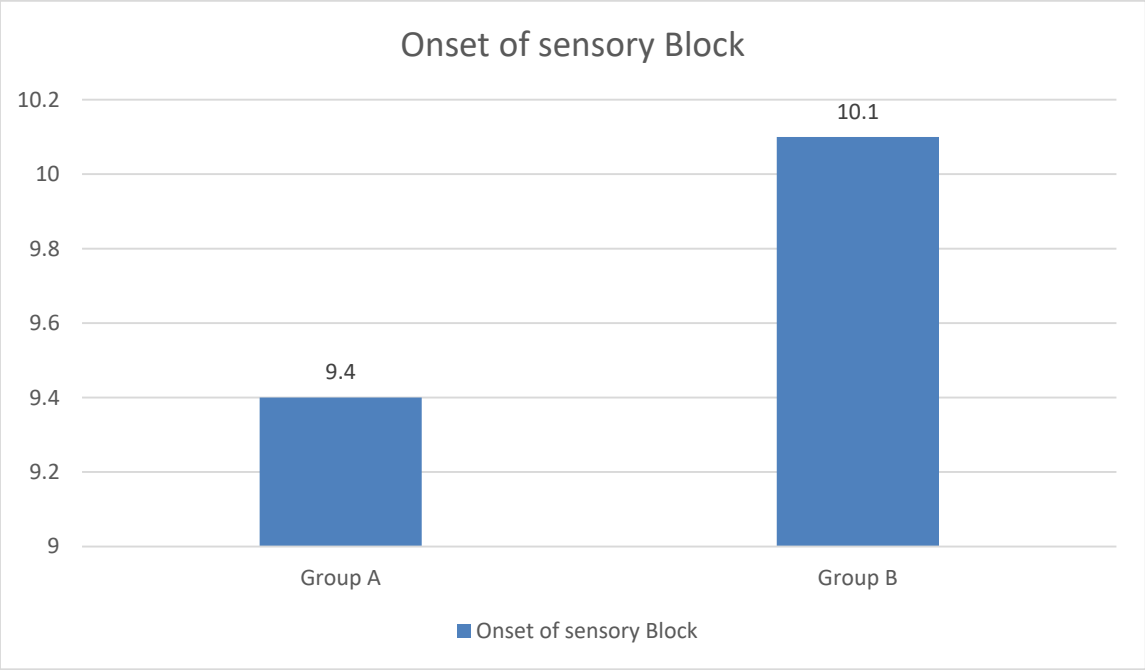

Figure 16: Comparison of onset of sensory block between the groups(mins)

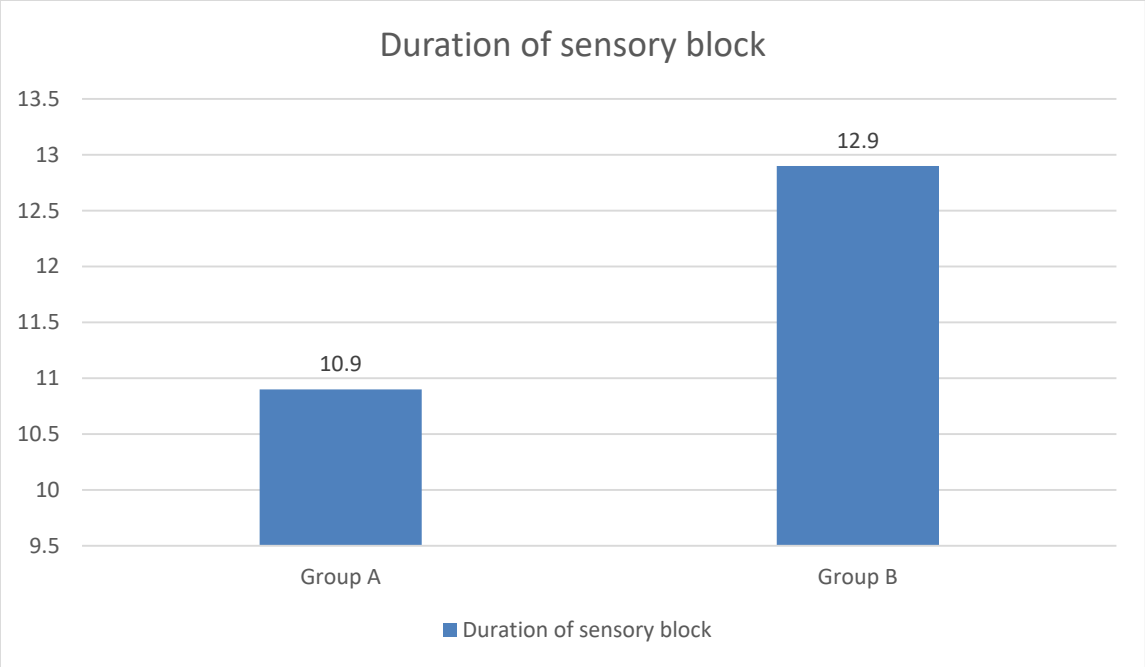

Figure 17: Comparison of duration of sensory block between the groups(hrs)

Table 5: Comparison of onset and duration of motor block between the groups

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Onset of Motor Block(mins)	12.9	3.4	12.3	2.6	0.32
Duration of motor block(hrs)	10.5	2.0	13.5	2.4	0.05*

The onset of motor block was found to be similar between the group. The mean onset of motor block was 12.9mins in group A and 12.3min in group B. ($p>0.05$) There is significant longer duration of motor block in group B (13.5±2.4min) compared to patients in group A (10.2±3.0min).($p<0.05$)

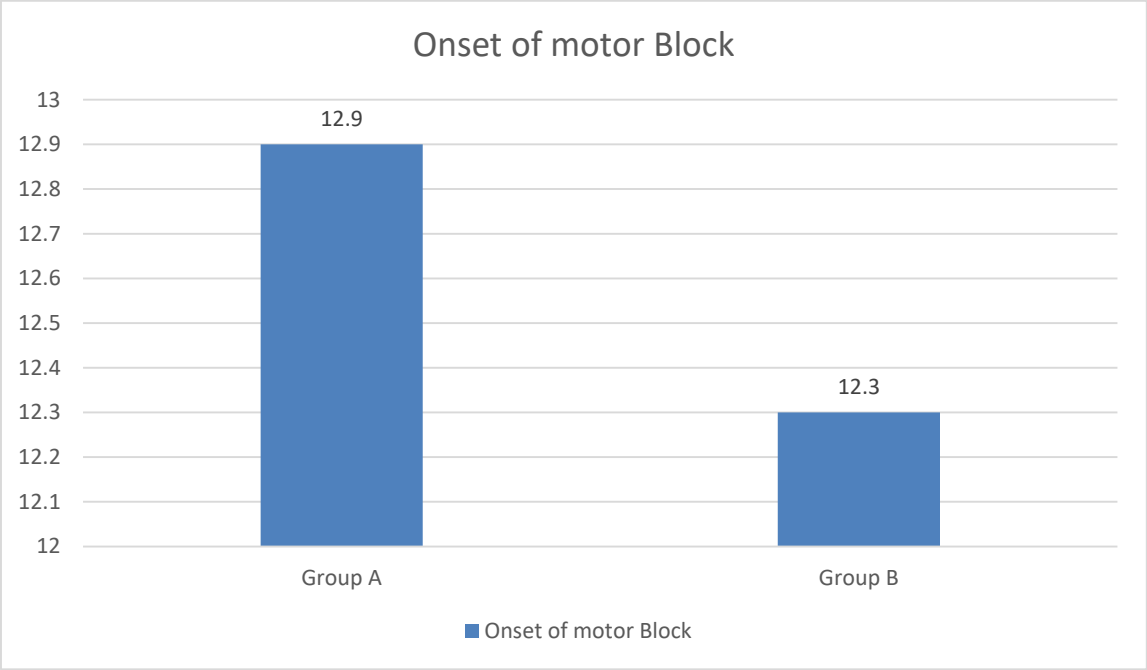

Figure 18: Comparison of onset of motor block between the groups(mins)

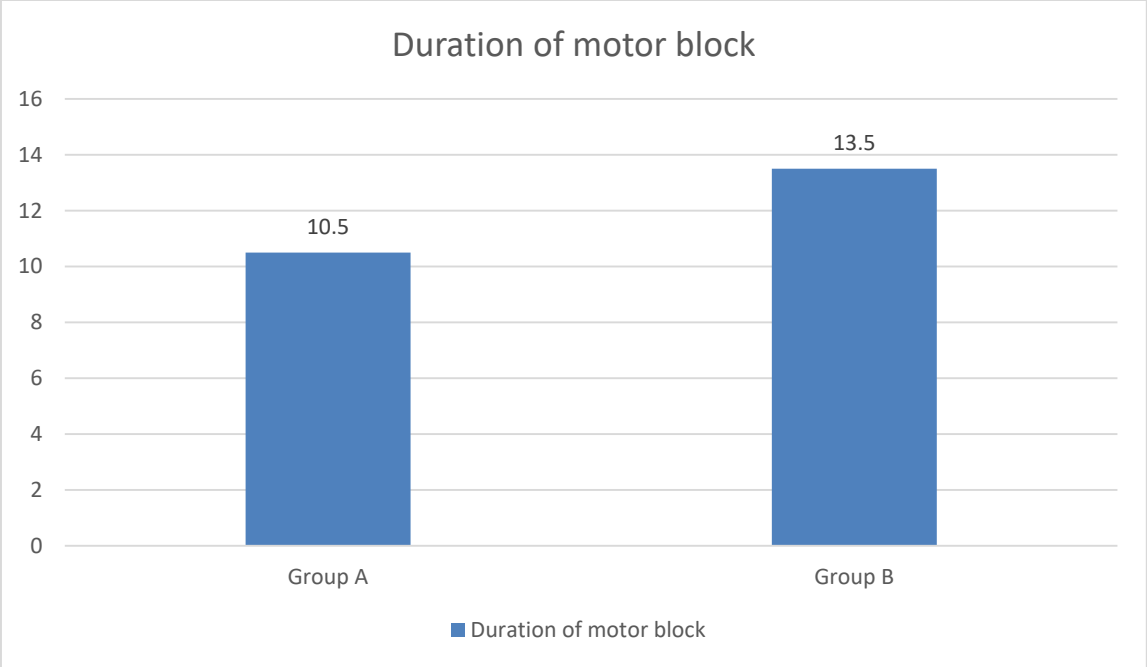

Figure 19: Comparison of duration of motor block between the groups(hrs)

Table 6: Comparison of Sensory block establishment time between the groups

Sensory block establishment time	Group A		Group B		p-value
	Mean	SD	Mean	SD	
0min	1.00	.02	1.00	.04	0.95
5min	2.27	.64	2.17	.46	0.49
10min	3.93	.25	3.97	.18	0.56
15min	3.92	.22	3.93	.25	0.155
20min	4.00	.00	4.00	.00	-
25min	4.00	.00	4.00	.00	-
30min	4.00	.00	4.00	.00	-

There is no significant difference in the sensory block establishment between the groups.

(p>0.05)

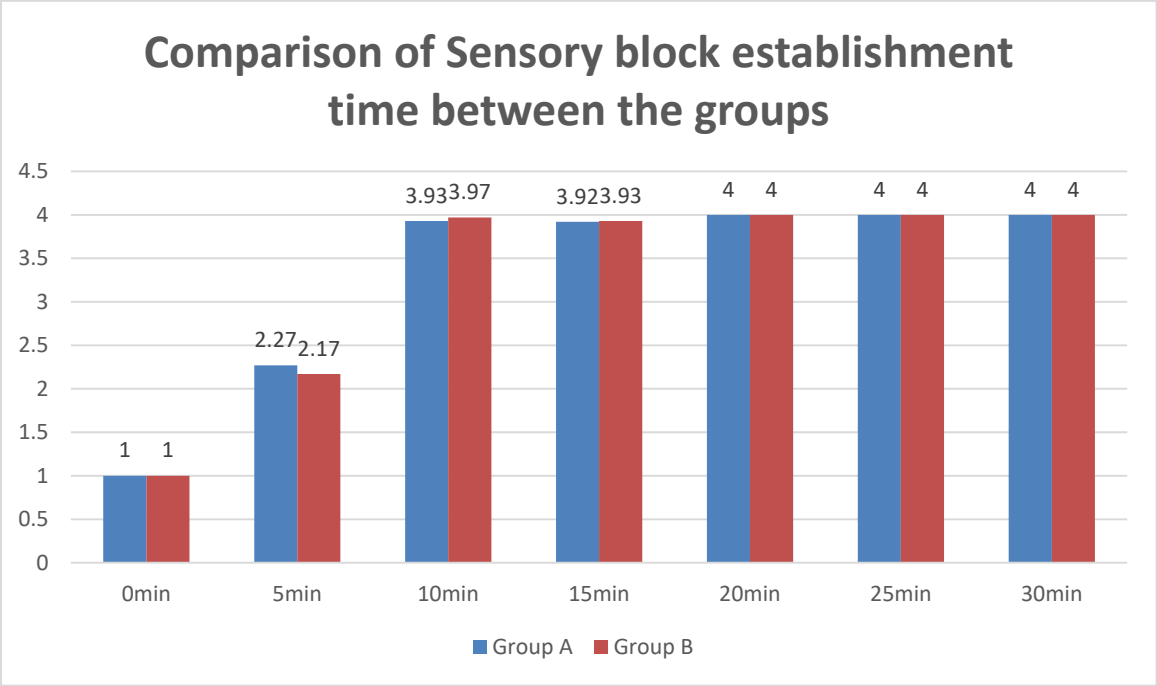

Figure 20: Comparison of Sensory block establishment time between the groups(mins)

Table 7: Comparison of motor block establishment time between the groups

Motor block establishment time	Group A		Group B		p-value
	Mean	SD	Mean	SD	
0min	1.00	.00	1.00	.00	0.56
5min	2.13	.43	2.10	.31	0.15
10min	3.43	.50	3.13	.35	0.73
15min	3.73	.18	3.93	.45	0.01*
20min	3.75	.12	3.97	.18	0.01*
25min	3.9	.11	3.97	.18	0.321
30min	4.00	.02	4.00	.02	0.32

There is significant difference in motor block establishment at 15min, and 20min in group B with mean higher compared to group A patients. ($p<0.05$) other interval time, the establishment of motor block was comparable between the groups.

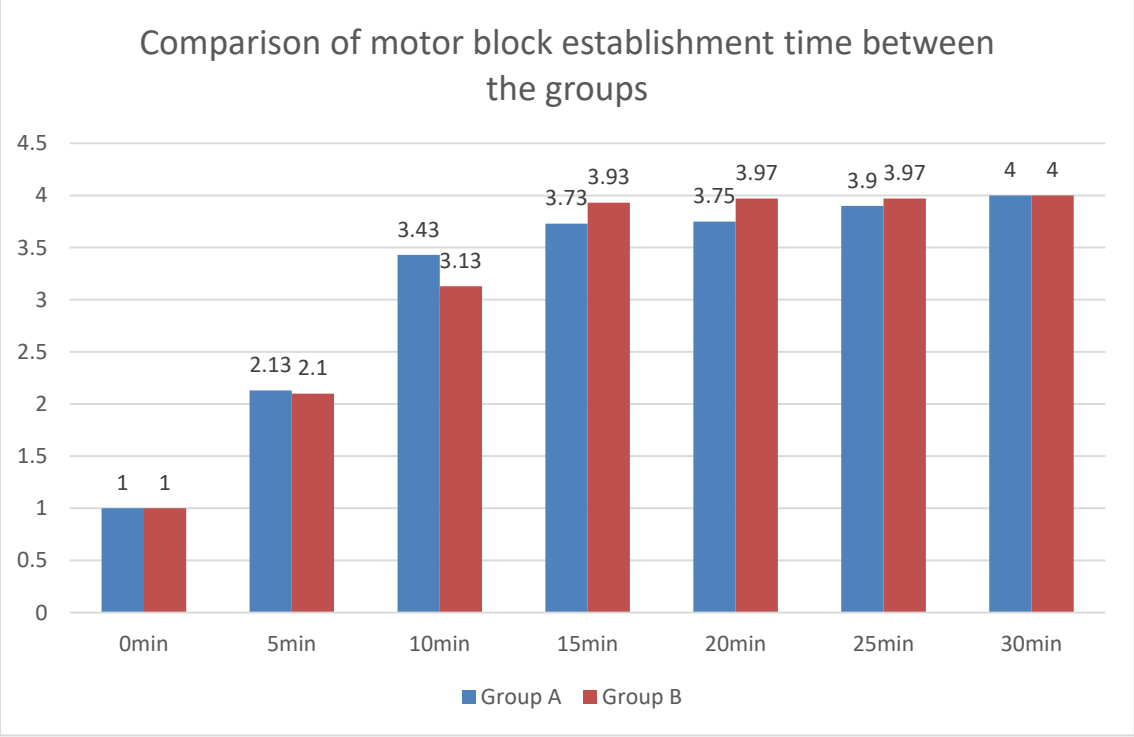

Figure 21: Comparison of motor block establishment time between the groups(mins)

Table 8: Comparison of mean duration of analgesia between the groups

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Duration of analgesia(hrs)	12.77	2.45	14.13	1.22	0.05*

The mean duration of analgesia was found to be significantly higher in group B (14.13±1.22hr) compared to patients in group A (12.77±2.45hr). ($p<0.05$)

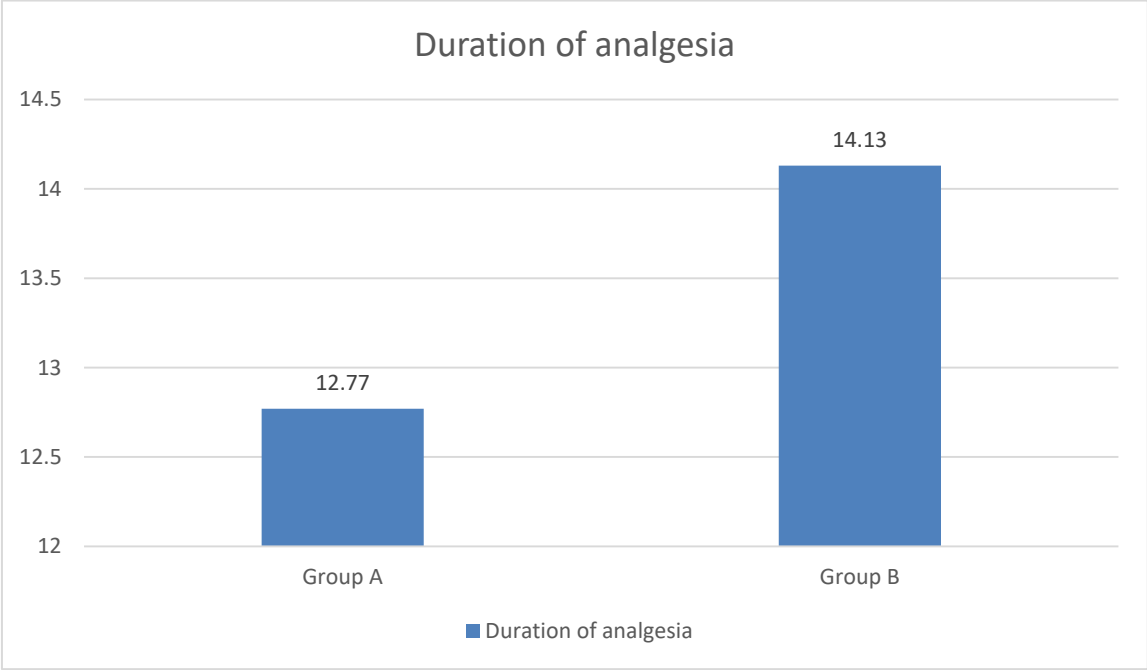

Figure 22: Comparison of mean duration of analgesia between the groups(hrs)

Table 9: Comparison of mean post-operative VAS score between the groups

Post Op VAS	Group A		Group B		p-value
	Mean	SD	Mean	SD	
1st hour	1.10	.55	1.00	.00	0.32
2nd hour	1.17	.91	1.00	.00	0.32
4th hour	1.20	.92	1.00	.00	0.24
6th hour	1.60	1.07	1.03	.18	0.01*
8th hour	1.70	1.06	1.33	.48	0.08
10th hour	1.87	1.11	1.50	.51	0.104
12th hour	2.30	1.37	1.80	.55	0.06
14th hour	2.63	1.69	1.90	.71	0.05*
16th hour	3.00	1.72	2.20	.55	0.05*
18th hour	3.53	1.80	2.97	.96	0.13
20th hour	4.07	1.87	3.33	.96	0.05*
24 hour	3.10	2.17	2.00	.00	0.05*

During post operative period, the mean VAS score was found to be significantly lower in group B at 6th hour, 14th, 16th, 20th and 24th hour compared to patients in group A. Showing the longer analgesic effect of group B compared to group A, with longer pain free period and lower mean VAS score. ($p<0.05$)

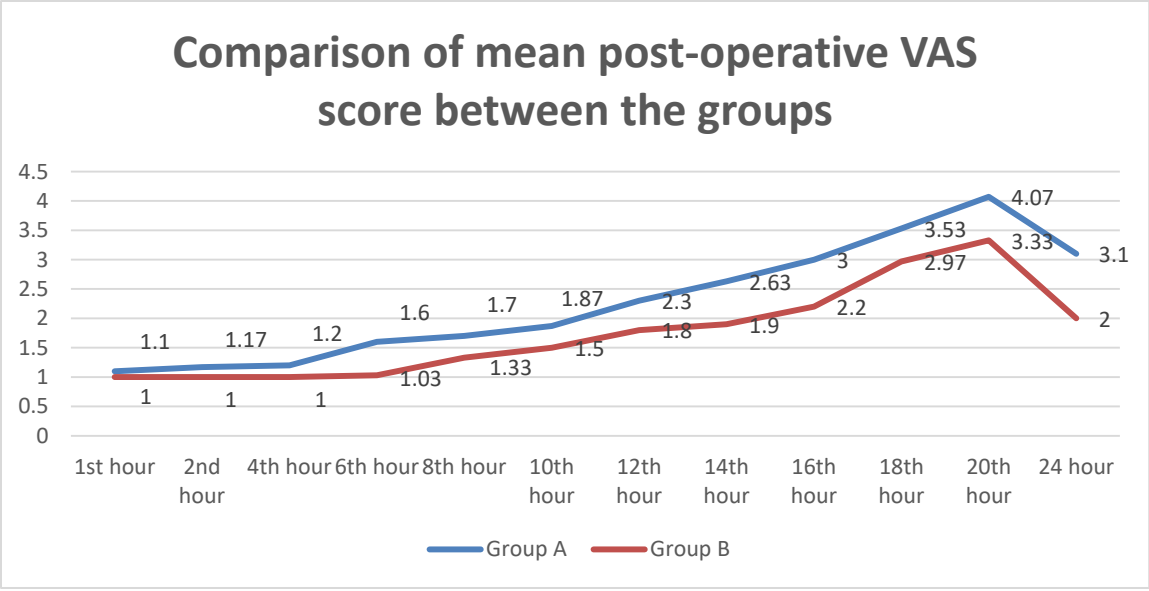

Figure 23: Comparison of mean post-operative VAS score between the groups(hrs)

DISCUSSION

DISCUSSION

Ultrasound-guided infraclavicular brachial plexus block (ICB) is a widely utilized regional anesthesia technique for upper limb surgeries, offering effective surgical anesthesia and postoperative analgesia. “This approach targets brachial plexus cords at infraclavicular fossa level, offering advantages such as improved success rates, reduced complications, and faster onset compared to landmark-based techniques”[36].

The volume of local anesthetic (LA) plays a crucial role in determining the effectiveness, duration, and safety of the block. Studies have explored various LA volumes, ranging from high doses (30-40 mL) for reliable blockade to lower doses (15-25 mL) aimed at reducing side effects while maintaining efficacy. However, the ideal volume for achieving a balance between efficacy and safety remains an area of ongoing research. Factors influencing the effective LA volume include anatomical variations, nerve distribution, concentration and type of anesthetic used, and patient characteristics such as body habitus and comorbidities. Modern ultrasound guidance has significantly improved precision, allowing anesthesiologists to use lower LA volumes with better spread and fewer complications.

Determining the MEV of local anesthetic for US guided ICB is essential for optimizing patient outcomes. A well-calibrated volume ensures sufficient anesthesia while reducing unnecessary drug exposure. This study aims to evaluate the effective volume of local anesthetic required for a successful ultrasound-guided infraclavicular brachial plexus block, contributing to safer and more efficient regional anesthesia practices.

“There was no discernible difference in the mean age across the groups. Group A's mean age was 39.8 years, whereas Group B was 35yrd. The gender distribution was also similar

between the groups, with no significant difference; however, there was a male predominance in both groups, with 70% males in group A and 80% in group B. The distribution of ASA grades was similar between the groups, with no significant difference between them. The mean age of patients was similar to present study with 37.3yrs among the patients, with 66.7% were male (male preponderance). The ASA grade was found with 83.3% with grade II and 16.7% with grade I"[36].

The two groups' onsets of sensory and motor block did not differ statistically significantly in this investigation. The mean time for the start of sensory block was 9.4 minutes in group A and 10.1 minutes in group B ($p>0.05$), which was almost the same in both groups. "Similar to this, the groups' mean times for the start of motor block were 12.9 minutes for group A and 12.3 minutes for group B ($p>0.05$). However, group B's sensory block lasted 12.9 hours, which was substantially longer than group A's (10.9 hours) ($p<0.05$). Similarly, group B's motor block duration (13.5 hours) was substantially longer than group A's (10.2 hours) ($p<0.05$). No significant difference was found in the establishment of sensory block between the groups" ($p>0.05$).

On the contrary there is significant increase in the duration of both sensory and motor block in patients receiving 30ml of ropivacaine (0.5%) (Group B) when compared to patients receiving 25ml of ropivacaine (0.5%) (Group A)

There is significant difference in onset of motor block at 15min, and 20min in group B with mean higher compared to group A patients. ($p<0.05$) other interval time, the establishment of motor block was comparable between the groups.

The study conducted by Baskan S. et al. found that in nine volume groups, ranging from 30 mL to 14 mL, all patients (n = 45) experienced successful blocks; however, three blocks in the 12-mL group failed[36]. "In Ince I et al., the average motor block duration was 168 (±16) minutes for Group L and 268 (±15) minutes for Group S, indicating a

significant difference between the groups ($p < 0.001$). Nonetheless, there was no statistically significant difference in the length of sensory block ($p = 0.064$), with Group L averaging 385 (±26) minutes and Group S 402 (±39) minutes"[32].

Chadha et al. found no difference between the mean start of sensory block and motor block, which is similar to the current investigation. In groups 20 and 35, the average onset of sensory block was 18.06 and 17 minutes, respectively. Similarly, group 20 and group 35 had mean motor block onset times of 23.89 and 23.75 minutes, respectively[38].

The mean duration of analgesia was found to be significantly higher in group B (14.13±1.22hr) compared to patients in group A (12.77±2.45hr). ($p<0.05$) "During post operative period, the mean VAS score was found to be significantly lower in group B at 6^{th} hour, 14^{th}, 16^{th}, 20^{th} and 24^{th} hour compared to patients in group A. Showing the longer analgesic effect of group B compared to group A, with longer pain free period and lower mean VAS score." ($p<0.05$)

"The 30-mL group's time to block onset and time to first postoperative analgesic administration were 15 (10–15) minutes and more than 24 hours, respectively, in accordance with the current study by Baskan S et al"[36].

In similar, study by Chadha M et al., found significant longer duration of analgesia in group 35 (730.75mins) compared to group 20 (575.56min)[38].

Recommendations

1. **Comparable Onset of Sensory and Motor Block**: Since the onset of both sensory and motor block was similar between the two groups ($p>0.05$), 25ml of ropivacaine (0.5%) can be effectively used without compromising the initiation of anaesthesia.

2. **Sufficient Duration of Anaesthesia**: Although the duration of sensory and motor block was slightly longer in the 30ml group, the 25ml dose still provided an adequate duration of anaesthesia for most surgical procedures, making it a viable alternative.
3. **Adequate Postoperative Analgesia**: The 25ml dose provided a clinically acceptable duration of postoperative analgesia (12.77±2.45 hours), which may be sufficient for many procedures, especially when supplemented with multimodal analgesia.
4. **Reduced Risk of Local Anaesthetic Toxicity**: Using 25ml instead of 30ml reduces the total local anaesthetic dose, potentially lowering the risk of systemic toxicity while still achieving effective anaesthesia and analgesia.
5. **Resource Optimization**: A lower volume of local anaesthetic reduces drug consumption and cost without significantly affecting the quality of anaesthesia, making it a cost-effective alternative in clinical settings.
6. **Faster Motor Recovery**: In circumstances when early mobilization and functional recovery are crucial, like in outpatient or ambulatory surgery, the 25ml group may be favored because the length of motor block was noticeably shorter..

LIMITATIONS OF THE STUDY

1. Smaller sample size.
2. Equipment Limitations
3. Anatomical Variations
4. Variability in defining and assessing block success (e.g., sensory and motor block scales) can introduce subjectivity, affecting the study's outcomes.
5. The success of ultrasound-guided blocks can be significantly influenced by the clinician's experience. Inexperienced operators may require higher volumes of local anesthetic to achieve effective blocks, potentially skewing results.

CONCLUSION

CONCLUSION

This study aimed to compare the efficacy of 25ml and 30ml of 0.5% ropivacaine on the quality of anesthesia following ultrasound-guided infraclavicular brachial plexus block. Additionally, the study assessed the onset and duration of postoperative analgesia between the two groups.

The results indicate that the onset of both sensory and motor block was comparable between the two groups, with no statistically significant difference. However, the duration of sensory and motor block was significantly longer in Group B (30ml) compared to Group A (25ml), suggesting that a higher volume of ropivacaine prolongs the anesthetic effect. Furthermore, the mean duration of postoperative analgesia was significantly longer in Group B, with a prolonged pain-free period and lower VAS scores at multiple time points postoperatively. This indicates that a 30ml volume of 0.5% ropivacaine provides superior analgesia compared to 25ml.

Based on these findings, while both volumes are effective in producing ultrasound-guided infraclavicular brachial plexus block, the use of 30ml of 0.5% ropivacaine results in a prolonged duration of sensory and motor block, as well as extended postoperative analgesia, making it a more effective option for prolonged pain relief. While 30ml of 0.5% ropivacaine provides a longer duration of block and postoperative analgesia, 25ml remains an effective alternative, offering comparable onset, sufficient duration, reduced toxicity risk, and cost benefits. Therefore, 25ml can be recommended, especially in cases where early motor recovery and resource optimization are priorities.

SUMMARY

SUMMARY

Present study included total of 60 patients with 30 in group A and 30 patients in group B.

- Group A: Receiving Infraclavicular brachial plexus block with 25ml of local anaesthetic (Ropivacaine 0.5%)
- Group B: Receiving Infraclavicular brachial plexus block with 30ml of local anaesthetic (Ropivacaine 0.5%)

The mean age between the groups were comparable with no significant difference noted. The mean age in group A was 39.8yrs and group B was 35yrs.

The gender distribution between the group was comparable with no significant difference, however there is male preponderance in both the group with 70% male in group A and 80% in group B.

ASA grade showing the similar distribution between the groups, with no significant difference between two groups.

The onset of sensory block was found to be similar between the group. The mean onset of sensory block was 9.4mins in group A and 10.1min in group B. ($p>0.05$) There is significant longer duration of sensory block in group B (12.9±1.6min) compared to patients in group A (10.9±3.0min).($p<0.05$)

The onset of motor block was found to be similar between the group. The mean onset of motor block was 12.9mins in group A and 12.3min in group B. ($p>0.05$) There is significant longer duration of motor block in group B (13.5±2.4min) compared to patients

in group A (10.2±3.0min).($p<0.05$)

There is no significant difference in the sensory block establishment between the groups. ($p>0.05$)

There is significant difference in motor block establishment at 15min, and 20min in group B with mean higher compared to group A patients. ($p<0.05$) other interval time, the establishment of motor block was comparable between the groups.

The mean duration of analgesia was found to be significantly higher in group B (14.13±1.22hr) compared to patients in group A (12.77±2.45hr). ($p<0.05$)

During post operative period, the mean VAS score was found to be significantly lower in group B at 6^{th} hour, 14^{th}, 16^{th}, 20^{th} and 24^{th} hour compared to patients in group A. Showing the longer analgesic effect of group B compared to group A, with longer pain free period and lower mean VAS score. ($p<0.05$)

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ANNEXURES

ANNEXURE

PROFORMA

EFFECTIVE VOLUME OF LOCAL ANAESTHETIC FOR ULTRASOUND-GUIDED INFRACLAVICULAR BRACHIAL PLEXUS BLOCK: A PROSPECTIVE RANDOMIZED CONTROL TRIAL

1.Personal Details:

NAME: AGE: SEX:

ADDRESS:

OCCUPATION:

HEIGHT:

IBW:

TELEPHONE NO:

UHID NO:

ASA GRADING:

SITE OF OPERATION:

2.Co-Morbidities:

3.General physical examination :

HEIGHT: WEIGHT: PULSE RATE: BP:

Pallor/icterus/cyanosis/clubbing/lymphadenopathy/edema

4.Systemic examination:

RS - CVS –

CNS - P/A –

5.Investigations:

Platelet count:
PT:
aPTT:
INR:

6.CLINICAL DIAGNOSIS:-

7.PROPOSED OPERATION:-

8. SENSORY BLOCK ESTABLISHMENT TIME (min) IN DIFFERENTNERVE TERRITORIES:-

Grades:-

Grade 2-Normal
Grade 1-Reduced
Grade 0-Absent to pinprick

TIME(min)	0	5	10	15	20	25	30
Musculocutaneous nerve							
Radial nerve							
Median nerve							
Ulnar nerve							
Medial cutaneous nerve of arm							
Medial cutaneous nerve of forearm							

9.MOTOR BLOCK ESTABLISHMENT TIME (min) IN DIFFERENTNERVE TERRITORIES:-

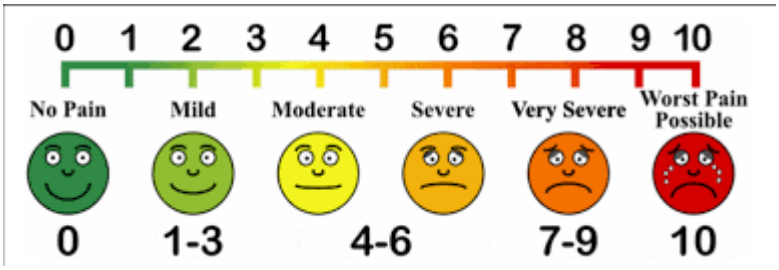
Grades:-

Grade 2-Normal
Grade 1-Reduced
Grade 0-Absent to pinprick

NERVE	0	5	10	15	20	25	30
Musculocutaneous nerve							
Radial nerve							
Median nerve							
Ulnar nerve							

11.DURATION OF ANALGESIA:-

VAS SCORE



12.TOURNIQUET PAIN:-

INFORMATION SHEET

TITLE: EFFECTIVE VOLUME OF LOCAL ANAESTHETIC FOR ULTRASOUND-GUIDED INFRACLAVICULAR BRACHIAL PLEXUS BBLOCK (ICBPB):A PROSPECTIVE RANDOMIZED CONTROL TRIAL

I, Dr.Bharath C J post graduate in the department of Anaesthesiology, Sri Devaraj Urs Medical College, Kolar . We are carrying out above mentioned study at RLJH, Tamaka, Kolar. The study has been reviewed and approved by the institutional ethical review board. We will be checking the effective volume of local anaesthetic 0.5%ropivacaine for ultrasound-guided infraclavicular brachial plexus block.

Participation in this study doesn't involve any added cost to the patient. There is no compulsion to participate in this study and you will not be affected with regard to patient care, if you wish not to be part of this study.

All the information collected from the patient will be kept confidential and will not be disclosed to any outsider, unless compelled by the law. The information collected will be used only for this study. I request your kind self to give consent for the above mentioned research project.

For any further clarification you are free to contact,

Dr.BHARATH C J

(Post Graduate in Anaesthesiology)

Mobile no:9591170080

Dr.SURESH KUMAR N

(Professor and HOD in Anaesthesiology)

Mobile no:9008222550

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ಮಾಹಿತಿ ಹಾಳೆ

ಶೀರ್ಷಿಕೆ: ಅಲ್ಟ್ರಾಸೌಂಡ್-ಗೈಡೆಡ್ ಇನ್‌ಫ್ರಾಕ್ಲಾವಿಕ್ಯುಲರ್ ಬ್ರಾಚಿಯಲ್ ಪ್ಲೆಕ್ಸಸ್ ಬ್ಲಾಕ್‌ಗಾಗಿ ಸ್ಥಳೀಯ ಅರಿವಳಿಕೆಗಳ ಪರಿಣಾಮಕಾರಿ ಪರಿಮಾಣ: ಪ್ರಾಸ್ಪೆಕ್ಟಿವ್ ರ್ಯಾಂಡಮೈಸ್ಡ್ ಕಂಟ್ರೋಲ್ ಟ್ರಯಲ್

ನಾನು**,** ಡಾ.ಭರತ್ ಸಿ ಜೆ **,** ಕೋಲಾರದ ಶ್ರೀ ದೇವರಾಜ್ ಅರ್ಸ್ ಮೆಡಿಕಲ್ ಕಾಲೇಜಿನ ಅರಿವಳಿಕೆ ವಿಭಾಗದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ಪದವೀಧರ. ನಾವು ಮೇಲೆ ತಿಳಿಸಿದ ಅಧ್ಯಯನವನ್ನು **RLJH,** ಟಮಕ**,** ಕೋಲಾರದಲ್ಲಿ ನಡೆಸುತ್ತಿದ್ದೇವೆ.

ಅಧ್ಯಯನವನ್ನು ಸಾಂಸ್ಥಿಕ ನೈತಿಕ ಪರಿಶೀಲನಾ ಮಂಡಳಿಯು ಪರಿಶೀಲಿಸಿದೆ ಮತ್ತು ಅನುಮೋದಿಸಿದೆ.

ಅಲ್ಟ್ರಾಸೌಂಡ್-ಗೈಡೆಡ್ ಇನ್‌ಫ್ರಾಕ್ಲಾವಿಕ್ಯುಲರ್ ಬ್ರಾಚಿಯಲ್ ಪ್ಲೆಕ್ಸಸ್ ಬ್ಲಾಕ್‌ಗಾಗಿ ನಾವು ಸ್ಥಳೀಯ ಅರಿವಳಿಕೆ 0.5% ರೋಪಿವಕೈನ್‌ನ ಪರಿಮಾಣವನ್ನು ಪರಿಣಾಮಕಾರಿಯಾಗಿ ಪರಿಶೀಲಿಸುತ್ತೇವೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ರೋಗಿಗೆ ಯಾವುದೇ ಹೆಚ್ಚುವರಿ ವೆಚ್ಚವನ್ನು ಒಳಗೊಂಡಿರುವುದಿಲ್ಲ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಯಾವುದೇ ಬಲವಂತವಿಲ್ಲ ಮತ್ತು ನೀವು ಈ ಅಧ್ಯಯನದ ಭಾಗವಾಗದಿರಲು ಬಯಸಿದರೆ ರೋಗಿಗಳ ಆರೈಕೆಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.ರೋಗಿಯಿಂದ ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಕಾನೂನಿನಿಂದ ಒತ್ತಾಯಿಸದ ಹೊರತು ಯಾವುದೇ ಹೊರಗಿನವರಿಗೆ ಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಈ ಅಧ್ಯಯನಕ್ಕಾಗಿ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ. ಮೇಲೆ ತಿಳಿಸಿದ ಸಂಶೋಧನಾ ಯೋಜನೆಗೆ ಒಪ್ಪಿಗೆ ನೀಡುವಂತೆ ನಾನು ವಿನಂತಿಸುತ್ತೇನೆ. ಯಾವುದೇ ಹೆಚ್ಚಿನ ಸ್ಪಷ್ಟೀಕರಣಕ್ಕಾಗಿ ನೀವು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ**.**

ಯಾವುದೇ ಹೆಚ್ಚಿನ ಸ್ಪಷ್ಟೀಕರಣಕ್ಕಾಗಿ ನೀವು ಸಂಪರ್ಕಿಸಲು ಮುಕ್ತರಾಗಿದ್ದೀರಿ

ಡಾ.ಭಾರತ್ ಸಿ ಜೆ

(ಅರಿವಳಿಕೆ ಶಾಸ್ತ್ರದಲ್ಲಿ ಸ್ನಾತಕೋತ್ತರ ಪದವಿ)

ಮೊಬೈಲ್ ಸಂಖ್ಯೆ:9591170080

ಡಾ.ಸುರೇಶ್ ಕುಮಾರ್ ಎನ್

(ಅರಿವಳಿಕೆ ಪ್ರೊಫೆಸರ್ ಮತ್ತು **HOD)**

ಮೊಬೈಲ್ ಸಂಖ್ಯೆ:9008222550

INFORMED CONSENT FORM

EFFECTIVE VOLUME OF LOCAL ANAESTHETIC FOR ULTRASOUND-GUIDED INFRACLAVICULAR BRACHIAL PLEXUS BLOCK(ICBPB):A PROSPECTIVE RANDOMIZED CONTROL TRIAL

Date:

I,_____aged _____,after being explained in my own vernacular language about the purpose of the study, risks and complications of the procedure, hereby give my valid written informed consent without any force or prejudice for ultrasound-guided infraclavicular brachial plexus block-using different drug volumes. The nature and risks involved have been explained to me to my satisfaction. I have been explained in detail about the study being conducted. I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I consent voluntarily to participate in this research. I hereby give consent to provide my history, undergo physical examination, investigations, procedure and provide its results and documents to the doctor / institute etc. All the data may be published or used for any academic purpose. I will not hold the doctors / institute responsible for any untoward consequences during the procedure / study.

A copy of this Informed Consent Form and Patient Information Sheet has been provided to the participant.

_____

(Name & Signature of Patient / patient Attendant)

_____

(Signature/Thumb impressions and name of the patient) (Relationship with patient)

Witness 1:

Witness 2:

_____

(Signature & Name of Research person /doctor)

ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ನಮೂನೆ

ಅಲ್ಟ್ರಾಸೌಂಡ್-ಗೈಡೆಡ್ ಇನ್‌ಫ್ರಾಕ್ಲಾವಿಕ್ಯುಲರ್ ಬ್ರಾಚಿಯಲ್ ಪ್ಲೆಕ್ಸಸ್ ಬ್ಲಾಕ್‌ಗಾಗಿ ಸ್ಥಳೀಯ ಅರಿವಳಿಕೆಗಳ ಪರಿಣಾಮಕಾರಿ ಪರಿಮಾಣ: ಪ್ರಾಸ್ಪೆಕ್ಟಿವ್ ರ್ಯಾಂಡಮೈಸ್ಡ್ ಕಂಟ್ರೋಲ್ ಟ್ರಯಲ್

ದಿನಾಂಕ:

ನಾನು, _____ ವಯಸ್ಸಿನ _____, ಅಧ್ಯಯನದ ಉದ್ದೇಶ ಮತ್ತು ಕಾರ್ಯವಿಧಾನದ ಅಪಾಯಗಳು ಮತ್ತು ತೊಡಕುಗಳ ಬಗ್ಗೆ ನನ್ನ ಸ್ವಂತ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಿದ ನಂತರ, ಇನ್‌ಫ್ರಾಕ್ಲಾವಿಕ್ಯುಲರ್ ಬ್ರಾಚಿಯಲ್ ಪ್ಲೆಕ್ಸಸ್ ಬ್ಲಾಕ್ ಅನ್ನು ನಿರ್ವಹಿಸಲು ಯಾವುದೇ ಬಲ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆ ನನ್ನ ಮಾನ್ಯ ಲಿಖಿತ ತಿಳುವಳಿಕೆಯ ಒಪ್ಪಿಗೆಯನ್ನು ಈ ಮೂಲಕ ನೀಡುತ್ತೇನೆ. ಒಳಗೊಂಡಿರುವ ಸ್ವರೂಪ ಮತ್ತು ಅಪಾಯಗಳನ್ನು ನನ್ನ ತೃಪ್ತಿಗೆ ವಿವರಿಸಲಾಗಿದೆ. ನಡೆಸುತ್ತಿರುವ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ನನಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ನಾನು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಪ್ರಶ್ನೆ ಕೇಳುವ ಅವಕಾಶ ನನಗೆ ಸಿಕ್ಕಿದೆ. ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪುತ್ತೇನೆ. ನನ್ನ ಇತಿಹಾಸವನ್ನು ಒದಗಿಸಲು, ದೈಹಿಕ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಲು, ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಒಳಗಾಗಲು, ತನಿಖೆಗೆ ಒಳಗಾಗಲು ಮತ್ತು ಅದರ ಫಲಿತಾಂಶಗಳು ಮತ್ತು ದಾಖಲೆಗಳನ್ನು ಇತ್ಯಾದಿಗಳನ್ನು ವೈದ್ಯರಿಗೆ / ಸಂಸ್ಥೆಗೆ ನೀಡಲು ನಾನು ಈ ಮೂಲಕ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ. ಶೈಕ್ಷಣಿಕ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಕಾರ್ಯಾಚರಣೆ / ಕಾರ್ಯವಿಧಾನ ಇತ್ಯಾದಿ ವೀಡಿಯೊ ಆಗಿರಬಹುದು ಗ್ರಾಫ್ ಅಥವಾ .ಾಯಾಚಿತ್ರ. ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ ಪ್ರಕಟಿಸಬಹುದು ಅಥವಾ ಬಳಸಬಹುದು. ಕಾರ್ಯವಿಧಾನ / ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಅಹಿತಕರ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳನ್ನು ಹೊಂದಿಲ್ಲ.

ಭಾಗವಹಿಸುವವರಿಗೆ ಈ ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ನಮೂನೆ ಮತ್ತು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯ ನಕಲನ್ನು ಒದಗಿಸಲಾಗಿದೆ.

_____ _____

(ಸಹಿ ಮತ್ತು ಪಂ. ಅಟೆಂಡೆಂಟ್) (ಸಹಿ / ಹೆಬ್ಬೆರಳು ಅನಿಸಿಕೆ ಮತ್ತು ರೋಗಿಯ ಹೆಸರು) (ರೋಗಿಯೊಂದಿಗಿನ ಸಂಬಂಧ)

ಸಾಕ್ಷಿ 1:

ಸಾಕ್ಷಿ 2:

(ಸಹಿ ಮತ್ತು ಸಂಶೋಧನಾ ವ್ಯಕ್ತಿ / ವೈದ್ಯರ ಹೆಸರು)

KEY TO MASTER CHART

SBP Systolic Blood Pressure

DBP Diastolic Blood Pressure

HR Heart Rate

ASA American Society of Anesthesiologists

MIN Minutes

Group A 25 ml of 0.5% Ropivacaine

Group B 30 ml of 0.5% Ropivacaine

MIN Minutes

HR Heart rate

MASTERCHART

MASTERCHART

GROUP A:0.5%ROPIVACAINE OF 25ML

Sl.no	Group	UHID.NO	Age(year)	GENDER	ASA	Onset.Of.sensory.Block	Onset.of.Motor.Block	Duration.of.sensory.block	Duration.of.motor.block	SENSORY BLOCK ESTABLISHMENT	ESTABLISHMENT	ESTABLISHMENT	ESTABLISHMENT	ESTABLISHMENT	ESTABLISHMENT	ESTABLISHMENT	ESTABLISHMENT	ESTABLISHMENT
1	A	367447	58	M	2	10	15	6	8	1	2	4	4	4	4	4
2	A	362727	28	M	2	10	10	9	10	1	2	4	4	4	4	4
3	A	363245	25	M	1	10	10	10	9	1	2	4	4	4	4	4
4	A	296393	35	M	1	10	10	8	10	1	2	4	4	4	4	4
5	A	373121	66	F	2	10	15	15	11	1	2	4	4	4	4	4
6	A	371860	68	M	2	10	15	14	12	1	2	4	4	4	4	4
7	A	367847	20	F	1	10	10	9	8	1	2	4	4	4	4	4
8	A	374165	45	F	1	10	15	13	11	1	2	4	4	4	4	4
9	A	366727	22	F	1	5	5	10	14	1	2	4	4	4	4	4
10	A	380085	46	M	1	8	15	16	13	1	2	4	4	4	4	4
11	A	379587	55	M	2	10	15	19	15	1	2	4	4	4	4	4
12	A	379579	43	M	1	10	16	10	13	1	2	4	4	4	4	4
13	A	381020	60	M	2	12	14	12	12	1	2	4	4	4	4	4
14	A	380869	61	M	2	12	18	12	8	1	2	4	4	4	4	4
15	A	390578	44	F	1	10	16	8	7	1	2	4	4	4	4	4
16	A	397259	50	M	1	10	14	11	10	1	2	4	4	4	4	4
17	A	397861	21	M	1	6	10	13	14	1	4	4	4	4	4	4
18	A	402965	22	F	1	8	10	8	9	1	4	4	4	4	4	4
19	A	400790	54	F	2	15	20	9	11	1	2	3	4	4	4	4
20	A	415435	63	M	2	15	15	14	10	1	2	3	4	4	4	4
21	A	415395	23	M	1	8	15	11	12	1	2	4	4	4	4	4
22	A	364850	34	M	1	10	16	6	8	1	2	4	4	4	4	4
23	A	410971	24	F	1	10	10	8	8	1	2	4	4	4	4	4
24	A	364850	23	M	1	6	10	7	9	1	2	4	4	4	4	4
25	A	410971	38	M	1	10	15	11	10	1	2	4	4	4	4	4
26	A	433334	24	M	2	8	10	10	11	1	2	4	4	4	4	4
27	A	432121	29	M	1	5	8	10	10	1	2	4	4	4	4	4
28	A	321345	42	M	1	8	10	11	10	1	3	4	4	4	4	4
29	A	43212	52	F	2	10	15	13	11	1	3	4	4	4	4	4
30	A	456268	18	M	1	5	10	13	10	1	4	4	4	4	4	4

GROUP B:0.5%ROPIVACAINE OF 30ML

Sl.no	Group	UHID.NO	Age(year)	GENDER	ASA	Onset.Of.sensory.Block	Onset.of.Motor.Block	Duration.of.sensory.block	Duration.of.motor.block	SENSORY BLOCK ESTABLISHMENT	SENSORY BLOCK ESTABLISHMENT	SENSORY BLOCK ESTABLISHMENT	SENSORY BLOCK ESTABLISHMENT	SENSORY BLOCK ESTABLISHMENT	SENSORY BLOCK ESTABLISHMENT	SENSORY BLOCK ESTABLISHMENT	SENSORY BLOCK ESTABLISHMENT	SENSORY BLOCK ESTABLISHMENT
1	B	406476	58	F	2	10	15	10	9	1	2	4	4	4	4	4
2	B	439083	45	M	1	10	13	12	10	1	2	4	4	4	4	4
3	B	439847	20	M	1	10	15	11	9	1	2	4	4	4	4	4
4	B	442927	24	M	1	9	20	11	11	1	2	4	4	4	4	4
5	B	436734	45	M	2	9	15	12	10	1	2	4	4	4	4	4
6	B	442466	48	M	2	9	16	13	12	1	2	4	4	4	4	4
7	B	445304	30	M	1	11	18	14	14	1	2	4	4	4	4	4
8	B	448550	28	M	2	12	15	15	15	1	2	4	4	4	4	4
9	B	448294	45	M	2	11	14	13	14	1	2	4	4	4	4	4
10	B	448652	30	M	1	9	14	13	11	1	2	4	4	4	4	4
11	B	450469	41	F	1	10	15	12	10	1	2	4	4	4	4	4
12	B	455119	18	M	1	12	16	12	11	1	2	4	4	4	4	4
13	B	458804	72	M	3	11	18	14	14	1	2	4	3	4	4	4
14	B	460987	19	M	1	9	17	14	13	1	2	4	4	4	4	4
15	B	462952	20	F	1	8	16	12	10	1	2	4	4	4	4	4
16	B	475986	30	M	1	9	15	11	11	1	2	4	4	4	4	4
17	B	476795	27	M	1	11	18	10	12	1	2	4	4	4	4	4
18	B	479913	62	F	2	12	15	14	14	1	2	4	4	4	4	4
19	B	475028	38	M	1	10	15	13	10	1	2	4	4	4	4	4
20	B	496137	29	M	1	11	14	16	15	1	2	4	4	4	4	4
21	B	496136	29	M	1	11	15	10	7	1	2	4	4	4	4	4
22	B	502497	30	M	1	12	16	14	9	1	2	4	4	4	4	4
23	B	505561	28	M	1	10	17	13	9	1	2	4	4	4	4	4
24	B	513221	59	M	2	17	22	14	8	1	2	3	3	4	4	4
25	B	535959	28	M	1	11	15	12	9	1	2	4	4	4	4	4
26	B	206191	22	F	1	11	15	13	8	1	2	4	4	4	4	4
27	B	256725	19	M	1	8	10	15	15	1	3	4	4	4	4	4
28	B	432243	25	M	1	5	10	15	15	1	4	4	4	4	4	4
29	B	432256	51	F	2	10	15	15	14	1	3	4	4	4	4	4
30	B	432235	29	M	1	6	10	14	13	1	3	4	4	4	4	4