INCIDENCE AND RISK FACTORS OF DIAPHRAGMATIC PARALYSIS AFTER ULTRASOUND-GUIDED SUPRACLAVICULAR BLOCK AT KENYATTA NATIONAL HOSPITAL OPERATING THEATRES.

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STUDENT'S DECLARATION

I, **Dr. Gakuo Daniel**, do hereby declare that this dissertation is my original work and has not been presented for a degree in any other university.

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LIST OF ABBREVIATIONS

AV:	Atrioventricular
COPD:	Chronic Obstructive Pulmonary Disease
EMG:	Electromyogram
HDP:	Hemi-diaphragmatic Paralysis
ICU:	Intensive Care Unit
KNH:	Kenyatta National Hospital
LA:	Local Anesthetic
LAST:	Local Anesthetic Systemic Toxicity
MRI:	Magnetic Resonance Imaging
POCUS:	Point of Care Ultrasound
SCNB:	Supraclavicular Nerve Blocks
SCM:	Sternocleidomastoid
SPSS:	Statistical Package for Social Sciences
US:	Ultrasound

ABSTRACT

Background: For upper limb procedures, peripheral nerve blocks can be used instead of, or in addition to, general anesthesia. The supraclavicular block gives a quick onset, dense block that is surgically acceptable, although it has been linked to an increased incidence of hemi-diaphragmatic paralysis, particularly in high-risk populations. For some patients, inadvertent hemi-diaphragmatic paralysis has resulted in prolonged hospital stays. The incidence of diaphragmatic paralysis globally varies widely, and we do not have local data. Determining the incidence of hemi-diaphragmatic paralysis and the associated risk factors assists in adequate planning for the perioperative care of patients undergoing supraclavicular nerve block.

Broad Objectives: To determine the incidence of diaphragmatic paralysis in patients undergoing ultrasound-guided supraclavicular nerve block in KNH theatres.

Methodology: This was a descriptive cross-sectional study. Participants were recruited by consecutive sampling methods from the elective and emergency theatre lists. Ethical approval was granted by KNH-UoN Ethics and Research Committee before recruitment of study subjects and data collection. For the enrolled participants with duly signed informed consent, observations were recorded preoperatively on patient characteristics, intra-operatively on the supraclavicular block technique, respiratory rate, oxygen saturations, supplemental oxygen requirement, diaphragmatic excursion, and velocity before and after the block. Pre-block and post-block data were compared.

Data Analysis: Excel and SPSS software were used for data analysis. Descriptive statistics were used to provide information on the variables. Chi-square tests, multivariate analysis, and logistic regression were used for prediction of significant risk factors for hemi-diaphragmatic paralysis.

Conclusion: There was a 57.1% incidence of hemi diaphragmatic paralysis following ultrasound guided supraclavicular blocks in patients undergoing upper limb surgeries in KNH operating theatres. Patients require close monitoring after supraclavicular block since oxygen supplementation was required in a subset of patients (18.4%). Most patients will not develop clinically significant respiratory symptoms following hemi diaphragmatic paralysis. There could be an association between female gender and development of hemidiaphragmatic paralysis.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background Information

Supraclavicular nerve blocks provide a fast onset and dense block for anesthesia or postoperative analgesia of the fore extremity. This block is used for a wide variety of upper limb surgeries including open reduction and fixation of fractured bones, AV fistula fashioning and takedown, and skin grafting. Historically the risk of pneumothorax was an impediment to this block but with the advent of ultrasound guidance there's been a resurgence in its use. As with a few brachial plexus blockade techniques, there is a varying risk of ipsilateral phrenic nerve paralysis leading to diaphragmatic paralysis(1).

Phrenic nerve paralysis after brachial plexus blockade may occur indirectly (due to the local anesthetic tracking upwards within the nerve sheath to the C3 – C5 nerve roots), or directly by blocking the phrenic nerve in the anterior scalene fascia. Interscalene block almost always results in an ipsilateral phrenic nerve block(2) as opposed to supraclavicular and costoclavicular blocks. In a subset of patients with reduced cardiorespiratory reserves (obesity, elderly patients, obstructive sleep apnea, COPD) even slight diaphragmatic paresis could lead to significant respiratory compromise(3–5). This would be reflected by hypercapnia with retention of carbon dioxide leading to prolonged mechanical ventilation time and ICU stay.

The occurrence of phrenic nerve paralysis with supraclavicular block has a wide variability(67-100% incidence) from the available data(6–11)**.** This variability could be due to the difference in volumes of anesthetic used. Local studies in this area are still needed to inform the perioperative care of patients undergoing supraclavicular nerve block. For those patients who develop hemi-diaphragmatic paralysis, there could be indicators or predictors of decompensation inherent in the patients' characteristics.

Excursion of the diaphragm is an objective way of detecting changes in the motion of the diaphragm. The use of point of care ultrasound (POCUS), is a useful tool used to make this assessment.

This study aimed to determine the incidence of diaphragmatic paralysis in patients undergoing supraclavicular nerve block at Kenyatta National Hospital. The current practice relating to the conduct of supraclavicular nerve block: the common approaches used, variability in volumes of local anesthetic used and the outcomes were observed. We also analyzed the risk factors or predictors of phrenic nerve blockade in our patient population.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1. Anatomy of the Brachial Plexus and Phrenic Nerve

The brachial plexus forms the main innervation of the upper limb and consists of the ventral rami of the spinal nerves from the C5-T1 spinal segments. The plexus may be referred to as either being prefixed or post-fixed depending on the presence of an additional contribution cranially(C4) or caudally (T2, T3). The brachial plexus passes through four anatomical areas namely the interscalene gap, posterior triangle of the neck, infraclavicular fossa and axillary fossa(12). The interscalene gap is bound ventrally by the anterior scalene muscle and dorsally by the middle scalene muscle. The interscalene gap is a lateral continuation of the epidural space; thus, local anesthetic can track into the epidural space during an interscalene block. The prevertebral fascia envelopes both the prevertebral muscles and the nerves(figure1).

The phrenic nerve originates from the C3-C5 spinal segments and descends on the ventral surface of the anterior scalene muscle. It is closely related to the C5 ventral rami (covered by the prevertebral fascia). The phrenic nerve is initially close to the brachial plexus(18-20mm) at the level of the cricoid cartilage but as it descends it moves 3mm further away for each 1cm it descends over the anterior scalene muscle(1). Finally, at the root of the neck it lies between the subclavian artery and vein. Caudally in the interscalene gap, the ventral rami of C8 and T1 are closely related to the subclavian artery and the first rib. The interscalene gap consists of the prevertebral space laterally and the scalenovertebral triangle medially, separated by the anterior scalene muscle. During an interscalene block, local anesthetic could potentially track medially to block the recurrent laryngeal nerve, sympathetic chain and autonomic innervation of the heart(12). The long thoracic nerve and dorsal scapular nerve emerge directly from the ventral rami of C5-C7.

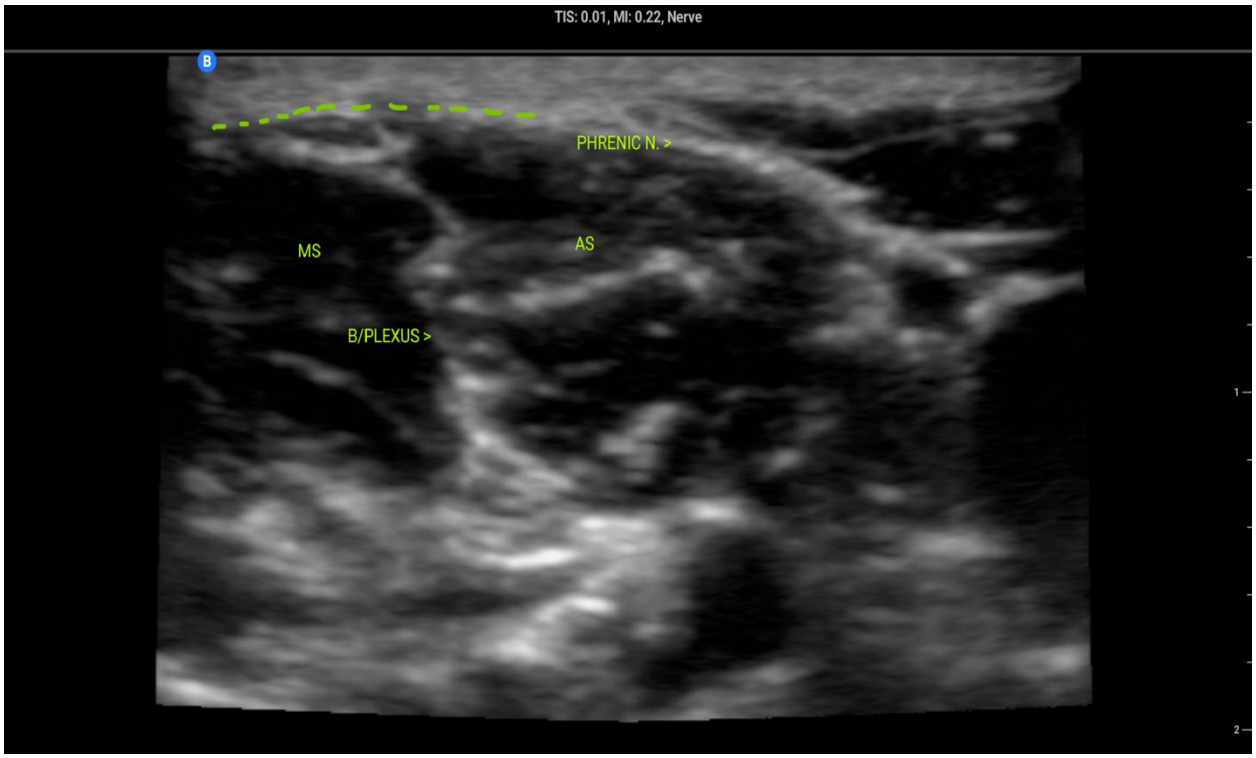

Figure 1:Interscalene gap: Ultrasonographic illustration of the interscalene gap with the prevertebral fascia indicated as a discontinuous line. AS, anterior scalene; MS, middle scalene; B/plexus, brachial plexus; Phrenic N, phrenic nerve.

In the supraclavicular area, the ventral rami forming the brachial plexus merge into trunks. The ventral rami of C5 and C6 form the superior trunk, C7 forms middle trunk and C8 and T1 form the inferior trunk. This is in the posterior triangle of the neck (separated by the sternocleidomastoid muscle from the anterior triangle). The posterior triangle is bounded anteromedially by the sternocleidomastoid muscle and posterolaterally by the trapezius muscle. The brachial plexus continues into this area, still covered by the prevertebral fascia and fuses inferiorly with fascia covering the subclavius muscle. The brachial plexus is related medially to the subclavian artery and inferiorly to the first rib and pleura(figure2). The trunks are tightly arranged lateral to the artery as shown and can be blocked easily, giving a dense block.

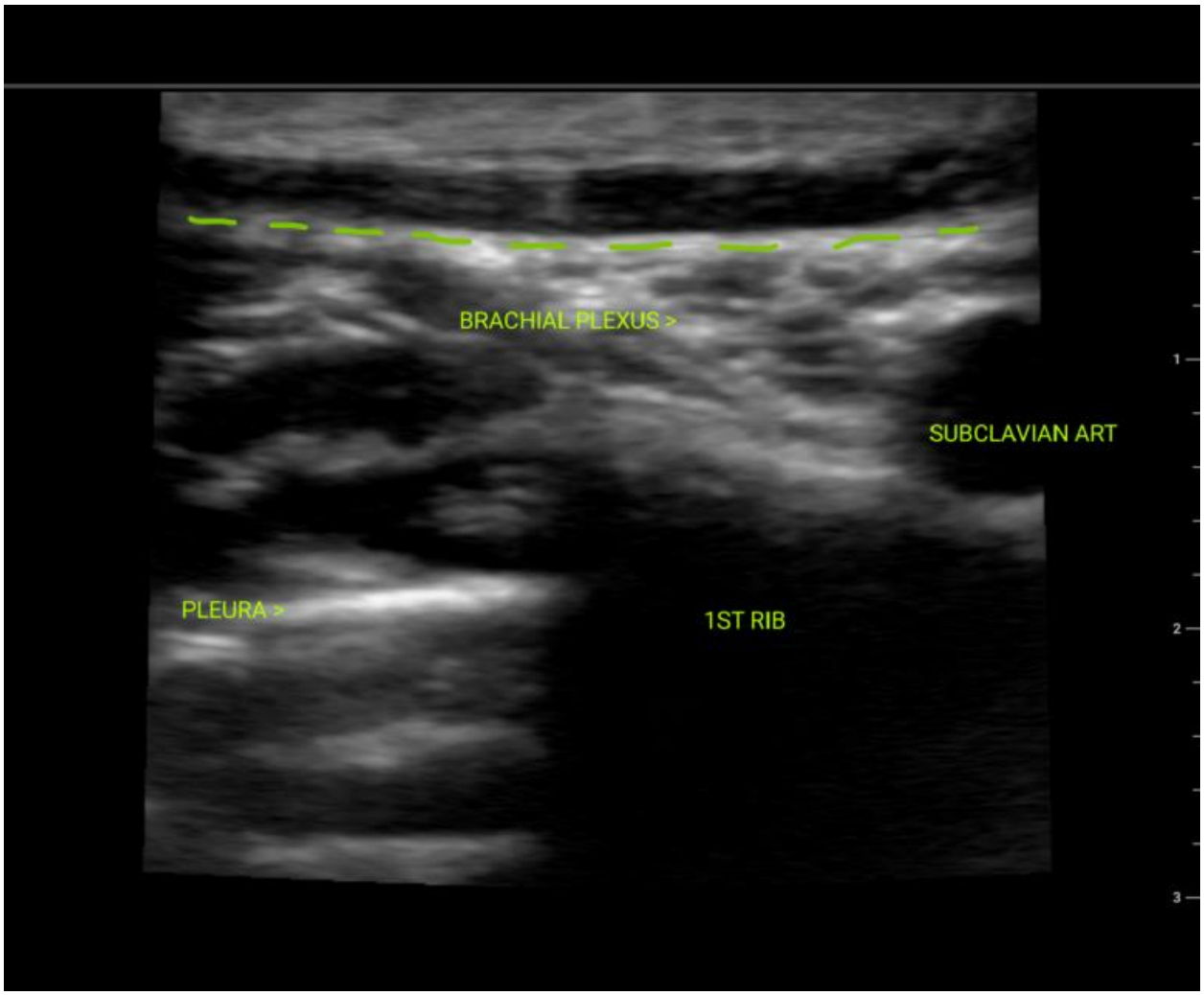

Figure 2:Sonoanatomy of the brachial plexus in the supraclavicular region. Prevertebral fascia is indicated as a discontinuous line. Subclavian ART, Subclavian artery

The suprascapular and subclavian nerve branch off the brachial plexus at the level of the clavicle. The suprascapular nerve supplies the supraspinatus and infraspinatus muscles and sensory innervation to the acromioclavicular and glenohumeral parts of the shoulder joint. The subclavian nerve supplies the subclavius muscle and the middle and medial thirds of the clavicle.

The infraclavicular fossa is bounded by the clavicle, deltoid muscle, pectoralis major muscle and the upper part of the thorax. In the infraclavicular fossa, at or below the clavicle, the brachial plexus trunks separate into anterior and posterior divisions which then come together to form lateral, medial, and posterior cords. The clavipectoral fascia which continues laterally as the prevertebral fascia and is joined to the fascia of the subclavius muscle, divides this space into a superficial and deep part (figure 3). The cords of the brachial plexus are in the deep part of the infraclavicular fossa, arranged around the subclavian artery.

The lateral cord is most superficial and ventrolateral to the artery, posterior cord is dorsolateral, and the medial cord is dorsal to the artery(figure3). The cords are named for their position around the axillary artery(13). The cords change position winding around the artery as the plexus progresses through the infraclavicular fossa and into the axillary fossa(12). The lateral cord is formed by the anterior divisions of the superior and middle trunks, the medial cord is formed by the anterior division of the inferior trunk and the posterior cord is formed by the posterior divisions of all the three trunks.

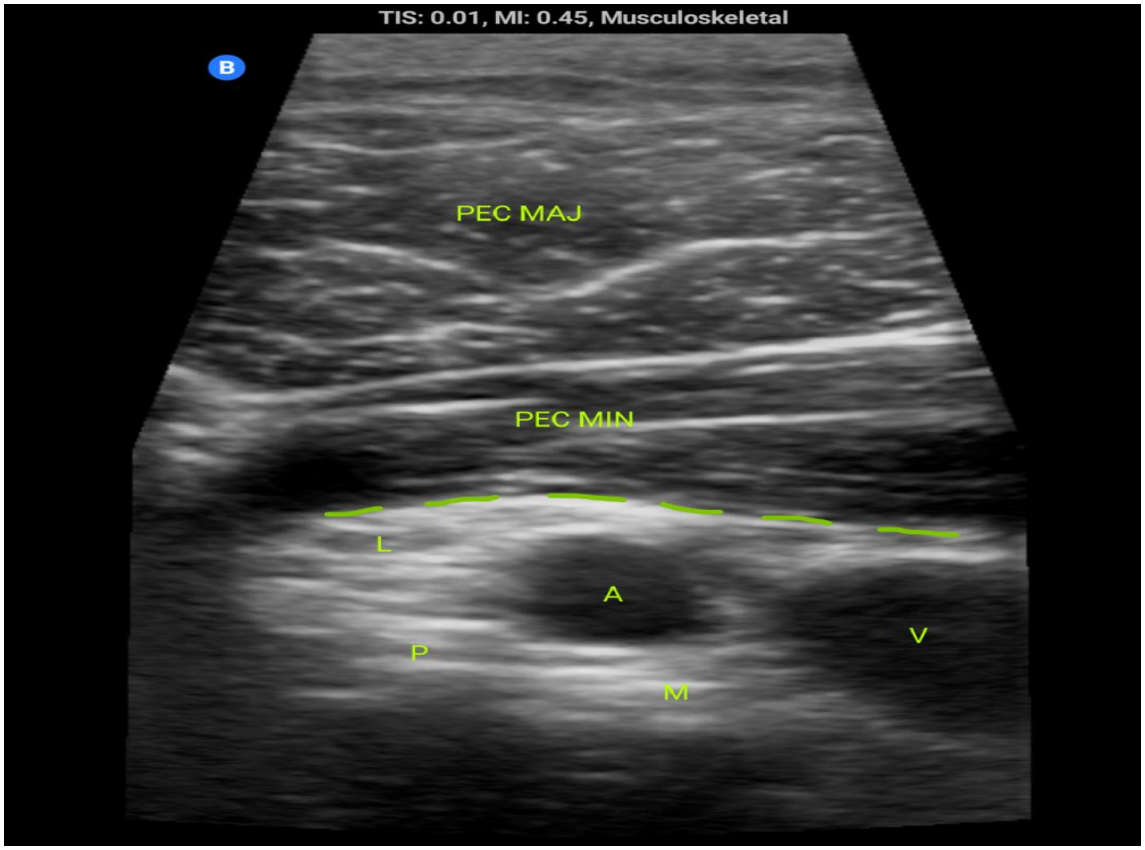

Figure 3:Infraclavicular arrangement of the cords around the subclavian artery, clavipectoral fascia as the broken line. PEC MAJ, pectoralis major; PEC MIN, pectoralis minor; A, subclavian artery; V subclavian vein; L lateral cord; P posterior cord; M medial cord

The lateral cord gives off the lateral pectoral nerve supplying the pectoralis major muscle while the medial cord gives off the medial pectoral nerve supplying the pectoralis minor muscle; these branches are given off just before the plexus enters the axillary fossa. The axillary fossa is a pyramid shaped space with the apex at the coracoid process and the base at the superficial axillary fascia. The space has a dorsal, medial and ventral wall. The nerves enter the space underneath the deep axillary fascia which is a continuation of the clavipectoral fascia and lie in the deep axillary space which is a continuation of the deep layer of the infraclavicular fossa. The cords then divide into terminal branches. The lateral cord splits into the

musculocutaneous nerve and part of the median nerve, the medial cord splits into the other part of the median nerve and the ulnar nerve, and the posterior cord splits into the radial and axillary nerves. The nerves have been shown to run in separate fascial tunnels facilitated by branching of the epineural sheaths(12). Figure 4 summarizes the innervation of the brachial plexus to the upper limb.

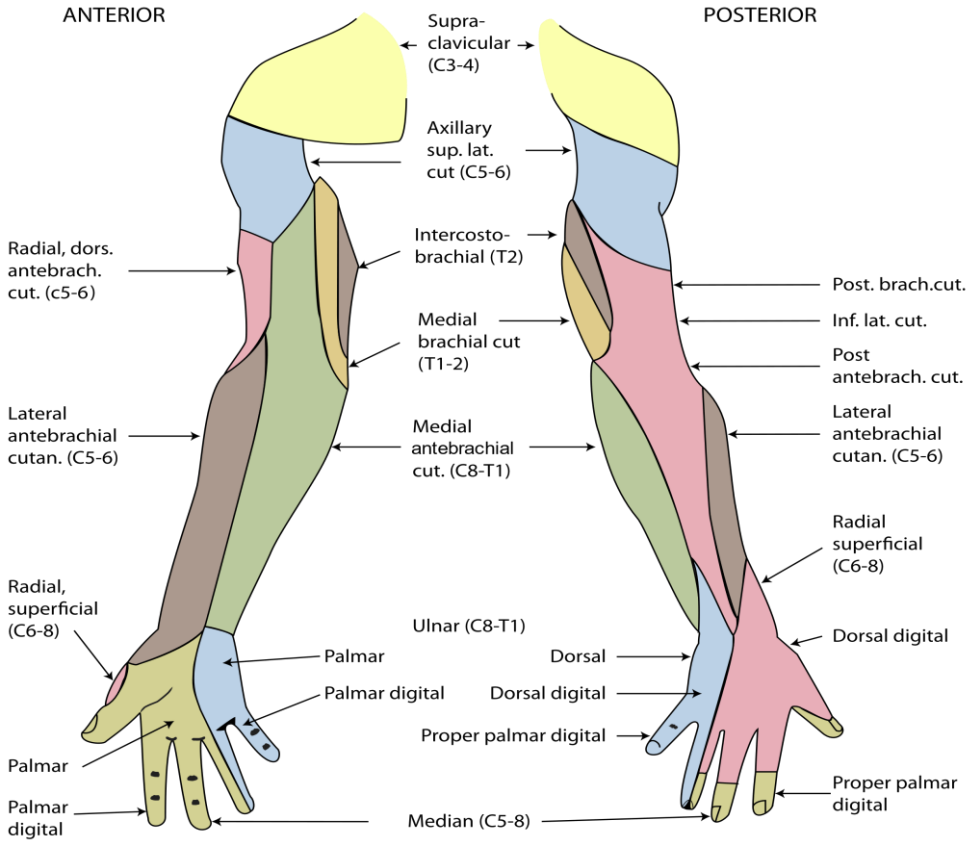

Figure 4:Schematic innervation of the upper limb

(Henry Gray. (1918) Anatomy of the Human Body. https:// commons. wikimedia. org/wiki/ File: Gray 812 and 814.svg)

2.2 Historical Background of Brachial Plexus Blockade

The supraclavicular technique for brachial plexus block was first introduced in 1911 by Kulenkampf(14). He recommended advancing the needle towards the first rib in the direction of the spinous processes of T2&T3. The risk of pneumothorax was high leading to the supraclavicular block gradually falling out of favor especially with the introduction of the axillary block of the brachial plexus in 1949. In 1978 La Grange described the use of doppler ultrasound to image the arteries which aided in locating the brachial plexus(15). Kapral et al(1994) then described the first ultrasound guided supraclavicular block(16).

The use of ultrasound guidance is now widely established and has markedly reduced the occurrence of pneumothorax with supraclavicular blocks. This has contributed to the wide resurgence of the use of

supraclavicular blocks for upper limb surgeries(17). Ultrasound guidance is employed to locate the brachial plexus, direct the needle thus avoiding injury (to nerve, blood vessels & pleura) and to observe or direct the spread of local anesthetic.

2.3 Evaluation of Diaphragmatic Function After Brachial Plexus Blockade

Early studies employed the use of fluoroscopy and X-rays to assess diaphragmatic paralysis following SCNB. Knoblanche found an incidence of 67% following successful SCNB under landmark technique using 30mls 0.5% Bupivacaine with 1: 200,000 adrenaline. Diaphragmatic paralysis was assessed using fluoroscopy within 3 hours after the block(6). Fluoroscopy involves significant radiation exposure and requires transport of the patient to the fluoroscopy unit.

Epelman et al in a retrospective analysis of M-mode sonograms evaluated diaphragmatic motion in children with suspected diaphragmatic paralysis and compared it to chest radiography and clinical correlation(18). Abnormal diaphragmatic motion was shown in 63% of children in whom chest radiography indicated normal hemi-diaphragms. Chest radiography may indicate elevation of the diaphragm unilaterally, but is insensitive and poorly predicts normal motion(18). Dynamic Magnetic Resonance Imaging, considered as the gold standard for quantitative and synchronous assessment of the diaphragm(19), is relatively expensive, not widely available and involves transporting the patient to the MRI suite.

Non-imaging modalities include pulmonary function testing, spirometry, phrenic nerve testing and diaphragmatic electromyogram (EMG). Pulmonary function tests are limited in accuracy and reproducibility as they are dependent on the patient's effort and are highly variable. EMG is highly specific and accurate but technically challenging to perform and interpret.

Sarwal et al notes that neuromuscular ultrasound is increasingly being used to image the diaphragm(20). The anterior subcostal view could be used for measurement of both diaphragmatic excursion and velocity. Ultrasound is portable, does not involve radiation exposure and is able to image structures adjacent to the diaphragm(20).

It is also important to note the ease and applicability of these techniques being applied in the surgical setting, for quick interpretation and appropriate intervention, may only be achieved with non-invasive and portable ultrasonography at best.

2.4 Techniques of The Brachial Plexus Blockade

The brachial plexus can be blocked at various levels for surgeries to the shoulder, humerus, elbow, forearm, wrist, and hand. An interscalene block performed in the interscalene gap at the level of the roots of the brachial plexus provides surgical anesthesia or analgesia to the clavicle, shoulder, and humerus. The superior trunk block is a modification of the interscalene block that provides anesthesia to the capsule of the shoulder and the proximal humerus. The supraclavicular block is performed in the supraclavicular region at the level of the trunks of the brachial plexus and provides anesthesia to the whole upper limb from the humerus distally. The infraclavicular block performed in the infraclavicular fossa at the level of the cords of the brachial plexus provides anesthesia from the humerus to the fingertips while sparing the intercostobrachial nerve. The axillary block performed in the axillary fossa at the level of the terminal branches of the brachial plexus and provides anesthesia from the mid-humerus to the fingertips and also spares the intercostobrachial nerve(21). Selective blocks to the individual terminal branches of the brachial plexus could be done for minor surgeries to the wrist and hand.

The ease of performance for the ultrasound guided SCNB is one of the reasons why it is a commonly performed block for upper limb surgeries. Kim SC et al in a study of 18 medical students performing ultrasound guided nerve blocks in simulation showed that while good hand eye coordination is a prerequisite for performing good quality peripheral nerve blocks, inexperienced ultrasound users can improve their hand eye coordination and quality of block to an acceptable level after 5 attempts(22). Time to successful injection was measured and the quality of injection was rated by two independent observers. Time to successful injection was significantly shortened after 5 attempts. Lewis SR et al in a Cochrane systematic review looked at whether ultrasound guidance had any merits over other methods of nerve location, and found that it was superior(either alone or in combination with nerve stimulation) in terms of improved sensory and motor block, reduced need for supplementation and reduced complications(23).

2.5 Complications of Brachial Plexus Blocks

There are various complications that are common to peripheral nerve blocks and some that are unique to brachial plexus nerve blocks:

Nerve Injury: may occur from direct trauma to the nerve and the incidence is estimated retrospectively at 0.5-1%. The symptoms may include paresthesia in the immediate days after the block and mostly transient. The quoted incidence will vary with the working definition for nerve injury. Ultrasound directly visualizes whether the injection is perineural(outside the epineurium), intraneural(inside epineurium), or

intrafascicular(within perineurium)(24). Neurological follow up is important inasmuch as nerve injury is uncommon(24).

Block Failure: Failure of a block may involve total failure (no numbness or change in sensation), incomplete block (numbness present but not adequate for surgical incision), patchy block(incomplete block in certain areas within the intended surgical field), or secondary failure(when surgery is longer than the duration of the block)(25). Despite improving the success of blocks, ultrasound is dependent on the skills of the operator. Adequate duration of time should be observed before declaring block failure, depending on the expected onset of local anesthetic used(25).

Infections: This may occur mostly from translocation of skin flora during needling. Good skin preparation and aseptic technique is important while performing peripheral nerve blocks and the use of chlorhexidine is recommended. In developed economies it is common to place a perineural nerve catheter for continuous analgesia. There's paucity of data comparing rates of infection between single shot injections and peripherally placed nerve catheters. For neural catheters, local inflammation is uncommon(0-13.7%), while local infection (0-3.2%), abscess formation (0-0.9%), and sepsis is even less common(24). The site of block is important, with femoral and axillary catheters having higher colonization rates(26).

Vascular Puncture: Inadvertent vascular puncture may occur leading to hematoma formation. This is dependent on the vascularity of the site of block, the supraclavicular block is performed in an area where the nerves are closely related to the subclavian artery; the dorsal scapular and transverse cervical vessels can also be seen while performing brachial plexus blocks and can be identified by doppler ultrasound. Ultrasound guidance has the potential to reduce rates of vascular injury. Guidance pertaining to anticoagulation and thrombocytopenia in peripheral nerve blocks is similar to guidance for neuraxial blocks(27).

Local Anesthetic Systemic Toxicity (LAST): This is a life-threatening systemic side-effect of the use of local anesthetics. It has a low incidence, currently estimated at 0.03% (0.27/1000 nerve blocks)(1) .Although neurological manifestations are more common, it can present as isolated cardiovascular instability. Definitive treatment is by early administration of intralipid emulsion, supportive measures including seizure treatment and cardiovascular support as needed. Preventive measures include restriction of the dose of local anesthetic, the use of ultrasound guidance to avoid intravascular injection, and vigilance in monitoring patients' vital signs after nerve block(28).

Complications specific to the brachial plexus nerve blocks include:

Phrenic Nerve Block: results in diaphragmatic paralysis, which may cause respiratory compromise. Higher rates of phrenic nerve block (up to 100%) are seen with interscalene block as opposed to supraclavicular block. This is discussed further below.

Horner's Syndrome: this is a rare side-effect (approximately 1%). It is characterized by unilateral miosis (constricted pupil), partial ptosis (drooping eyelid), anhidrosis (reduced sweating) and apparent enophthalmos (sunken eyeball). It occurs due to interruption of the impulses between the brain and the affected side of the eye and face. This is caused by a unilateral block of the sympathetic trunk presumably due to the local anesthetic tracking upwards. Studies on the rates of occurrence are lacking as it is a rare side effect. However it is known to occur commonly with interscalene block(29) and may also occur following infraclavicular blocks(30). Risk factors have yet to be identified but it may be more common in younger patients(31). It causes no adverse clinical consequence, and the effects disappear within 2-3hours(29).

Recurrent Laryngeal Nerve Block: This is a rare side effect (1.3% occurrence)(32,33) that leads to hoarseness of the voice due to unilateral paralysis of the recurrent laryngeal nerve that supplies the vocal cords. It has been reported exclusively on the right side following supraclavicular nerve block. This is because the right recurrent laryngeal nerve is closely related to the subclavian artery and curves around it while the left one is much further from the artery(32). In addition to hoarseness of voice, theoretically the patient may develop cough, dyspnea, dysphonia, aspiration or may even be asymptomatic(34). Depending on the clinical presentation, the supportive care offered will vary from reassurance to ventilatory support(34). The effects are usually transient as the local anesthetic wears off.

Pneumothorax: Occurs when air is trapped within the pleura due to pleural puncture and may lead to lung collapse and obstructive shock. This is a rare complication especially with the use of ultrasound guidance during the block, which aids in visualization of the pleura. It may occur for periclavicular (supraclavicular and infraclavicular) blocks due to the proximity to the pleura with an occurrence rate of 6.1%(without ultrasound guidance) and 0.06%(with ultrasound guidance)(35). Treatment involves insertion of a chest tube and underwater seal. Risk factors may include poor needle tip visualization(35).

Ulnar Nerve Sparing: In supraclavicular block in case there's inadequate spread of local anesthetic between the brachial plexus and the first rib, ulnar nerve sparing may occur causing an incomplete block in the area of interest. However this has not yet been reported with the current techniques utilizing the corner pocket and intertruncal approaches(36). It can be remedied by performing rescue blocks or converting to general anesthesia.

2.6 Phrenic Paresis: Risk Factors and Consequences

Phrenic nerve paralysis leading to diaphragmatic paralysis occurs either by direct spread to the phrenic nerve, especially when large volumes of local anesthetic are used, or by upward spread to the C4&C5 ventral rami/roots. This results in transient phrenic nerve paralysis (1).The use of large volumes of local anesthetic has thus been shown to increase the incidence of phrenic nerve paralysis (10).The duration of the paralysis is determined by the type of local anesthetic used. This is in turn affected by the degree of protein binding for the anesthetic used, and the additives used in the block(37,38).

Persistent phrenic nerve paralysis can also occur following brachial plexus blocks especially with interscalene block. Prolonged paralysis could be caused by direct nerve trauma, intraneural injection, inflammatory scarring causing nerve entrapment, nerve traction, nerve compression, reduced blood flow to the nerve during surgery or postsurgical inflammatory neuropathy(1,39,40). Prior cervical spine stenosis aggregated with nerve trauma (double crush mechanism) or additionally the increased pressure on the nerve from high volume of local anesthetic (triple crush mechanism) could lead to persistent phrenic nerve paralysis in interscalene blocks(1).

The diaphragm is the main muscle of respiration contributing to 75% lung volumes in quiet breathing, the intercostal muscles and neck muscles (scalene & sternocleidomastoid) contribute to the additional 25%(1).There is minimal cross-over innervation and thus each hemi-diaphragm can contract independently following unilateral phrenic nerve palsy. On the affected side, there will be reduced lung ventilation, especially in the lower lobe. In healthy individuals this is compensated for by the intercostal muscles and the ribcage bucket-handle mechanism resulting in minimal changes in measured tidal volumes. In morbidly obese patients and patients with preexisting respiratory comorbidities, however, tachypnea, hypoxia and dyspnea may be observed. Dyspnea is the main observable complication of phrenic nerve paralysis but it is neither sensitive nor specific for phrenic nerve paralysis; phrenic nerve paralysis may occur without accompanying dyspnea and alternatively dyspnea may occur in the absence of phrenic nerve paralysis(1).

2.7 Supraclavicular Block

2.7.1 Indications and contraindications:

The supraclavicular block is utilized for surgeries of the upper limb, below the shoulder(17). This includes surgeries on the hand, forearm, elbow, and lower humerus e.g., supracondylar fractures, radioulnar fractures, hand and wrist injuries, skin grafting, arteriovenous fistula fashioning and takedown. This could be compared to the interscalene block which is utilized for shoulder, clavicle and humerus surgeries(21).

A recent meta-analysis(41) indicates that ultrasound-guided supraclavicular block is as effective as interscalene block for shoulder surgeries including rotator cuff repair, adhesiolysis and decompression with a lower rate of phrenic nerve paralysis.

The contraindications include patients with preexisting respiratory failure, local infection, allergies to local anesthetics, lack of patient cooperation or refusal, significant coagulopathies, and preoperative nerve deficits(17,42)**.**

2.7.2 Techniques:

The supraclavicular nerve block (SCNB) is performed at the level of the trunks of the brachial plexus and at this point the entire sensory, motor, and sympathetic supply to the upper limb is situated in the three trunks. This provides a dense blockade with rapid onset and a high success rate. There are several ways of performing a supraclavicular nerve block, blind (without ultrasound) or with ultrasound. The blind techniques (Vongvises, plumb-Bob, Dalens & inter-SCM)(43) are falling out of favor due to the high risk of pneumothorax. The ultrasound guided techniques include the intra-cluster approach, intertruncal approach and the corner pocket technique.

The intra-cluster approach(44,45)involves injection of the local anesthetic within the main and satellite cluster of nerves and may lead to sub perineural injection(45,46). In a cadaver study of single intra-cluster injection, it was shown that there's a high rate (24%) of sub epi-neural injection and intrafascicular(90%) injection and thus caution is advised(45) .

The corner pocket approach described in 1997 involves depositing 15mls LA between the lower trunk and the first rib thus lifting the brachial plexus off the first rib; an optional further 10mls is injected between the upper trunk and prevertebral fascia (25). The corner pocket method prevents ulnar nerve sparing due to the needle proximity to the lower trunk. Soares et al described in line visualization of the brachial plexus trunks lateral to the subclavian artery and superior to the first rib. These are the components of the 'corner pocket'. Deposition of as little as 15mls of local anesthetic here resulted in quick onset of a dense block within minutes (47). However, they were concerned that when the optimal position is not obtained the resulting block could be unpredictable. There were early concerns that the corner pocket method would result in a high incidence of pneumothorax and vascular puncture(48) but with continuous visualization of the tip of the needle and pleura, this is avoided(47,49). Macfarlane et al further reported a case of a patient who had undergone rib resection for thoracic outlet syndrome and presented for upper limb surgery more than 30 years later. Ultrasonographic visualization of the absence of the first rib informed abandonment of the supraclavicular block(49).

The intertruncal approach involves depositing 10mls LA between the lower and middle trunks, then an injection of 7.5mls LA between upper and middle trunks and a further 7.5mls between the upper trunk and the prevertebral fascia. The intertruncal technique involves careful visualization of the individual trunks, their epineurium and the investing adipose tissue(36,46). The local anesthetic is injected in the adipose tissue planes between the lower, middle, and upper trunks. It was observed that with the corner pocket approach there's need for the injection to be in the perineural space within the nerve sheath(50) for a reliable block, and this would require significant caudal tilting of the probe (12)which brings in challenges with needling, optimal image acquisition and continuous needle tip visualization. A further advantage is that the needle tip lies further away from the pleura than with the corner pocket approach and additionally this method respects the integrity of the epineurium as opposed to the intra-cluster approach(46). However, the intertruncal approach requires careful hydro dissection to avoid intrafascicular injection(46).

Jo et al in a double blinded randomized controlled trial involving 60 patients and using a 1:1 mixture of 0.75% ropivacaine and 1% lidocaine, compared intertruncal approach to the corner pocket method and concluded that the intertruncal approach may result in faster surgical readiness and comparable ulnar nerve blockade(36).

It is established that peripheral nerve blocks provide superior postoperative pain management compared to general anesthesia alone for a variety of upper limb surgeries (51,52). Intra-articular infiltration during shoulder surgery has also been shown to be less effective than brachial plexus blocks (53). Additionally, brachial plexus blocks when used as the sole anesthetic have been shown to be more cost-effective than general anesthesia(54).

2.7.3 Choice of anesthetic method

Traditionally, the preoperative assessment offers the anesthesia provider the opportunity to discuss with the patient the available modes of anesthesia and develop an anesthetic plan(55). This often includes a discussion on the advantages and disadvantages of each mode and the recommendation by the anesthesia provider. Involvement of the patient in such a manner has been shown to improve patient satisfaction(56,57). For the anesthesia provider the recommendation on mode of anesthesia will be informed mainly by the site of surgery, anesthetic risk, comorbidities and ensuring optimal conditions for surgery(58), in addition to the provider’s level of proficiency in performing the block if indicated.

2.8 Complications of Supraclavicular Block

A 2016 meta-analysis, looked at the effect of ultrasound-guidance on patient safety in regional anesthesia, concentrating on four important complications: peripheral nerve injury, local anesthetic systemic toxicity (LAST), hemi diaphragmatic paralysis (HDP) and pneumothorax. The conclusion was that while ultrasound(US) guidance may not have a significant effect on the incidence of postoperative neurological symptoms, it reduced the incidence and intensity of hemi diaphragmatic paralysis(HDP), but did this in an unpredictable way(59).

It is widely known that HDP from blockade of the roots of the phrenic nerve is a common complication of interscalene block(60–63), with some research finding 100% incidence(2).In addition to the possibility of nerve injury while performing the interscalene block, prolonged postoperative paralysis could be due to nerve traction, nerve compression, reduced blood flow to the nerve during surgery or postsurgical inflammatory neuropathy(39,40). As such, supraclavicular nerve block is now preferred for upper limb surgeries, especially for those below the shoulder. Schubert et al in a systematic review and meta-analysis comparing interscalene block to supraclavicular nerve block(SCNB) found higher occurrence of HDP with interscalene block (78.75% vs 42.6%) and equivalent 24hr postsurgical pain scores(64). All the studies used ultrasound as the main nerve localization technique, which is now widely practiced. The use of ultrasound improves safety of the block, considering none of the patients had a pneumothorax in all the studies in the systematic review. These findings were supported in Guo CW et al (2017) in a systematic review comparing SCNB to interscalene block(41).

The potential for HDP as a side effect of SCNB has only recently received greater attention (3,5,65). Several research studies have been conducted to evaluate the incidence and degree of HDP following SCNB. The incidence of HDP varies from 32.5% to 67% (8,59,66). Neal et al in a study involving 8 healthy volunteers demonstrated a 50% incidence using 30mls 1.5%lidocaine and assessing HDP with both ultrasound and pulmonary function testing(67). This study was limited by a small sample group. However, Subsequent studies have confirmed these findings, with varying incidences of HDP reported following SCNB(10,66). Ferret et al in a prospective cohort study comparing the incidence of HDP in SCNB to interscalene block while using 20mls 0.375% ropivacaine found an incidence of 59.5% in SCNB compared to 95.3%(65). The incidence varies depending on the volume of anesthetic used. Zhang et al in a randomized controlled trial comparing rates of HDP using 20mls versus 30mls of 0.375% ropivacaine found higher rate of HDP with the higher volume of LA(10). Johnson et al in a double-blinded randomized controlled trial of 60 patients where patients were randomized to receive different

volumes(20,25&30ml) of 0.375% Bupivacaine for SCNB, found the lowest incidence of 32.5% in the 20ml group(66). However, none of the patients in the 20ml group developed complete diaphragmatic paralysis. They demonstrated higher incidence of diaphragmatic paralysis with higher volumes of local anesthetic(10,66).

Renes et al hypothesized that diaphragmatic paralysis could be avoided altogether by limiting the spread of local anesthetic(LA) to the areas caudal and posterolateral to the brachial plexus trunks(68). The phrenic nerve descends on the anterior surface of the anterior scalene muscle and its paralysis during SCNB is thought to occur by direct spread as opposed to LA tracking upwards to the C4 root. By limiting LA spread caudal and posterolateral to the brachial plexus this should hypothetically avoid LA spread medial to the subclavian artery thus avoiding spread to the phrenic nerve(68).

In a prospective randomized observer-blinded controlled trial involving 60 patients undergoing upper limb elective surgery, patients were randomized to either ultrasound assisted SCNB, or nerve stimulator assisted SCNB. 20ml 0.75% ropivacaine was used and hemi diaphragmatic paralysis was avoided in the ultrasound assisted group while in the nerve stimulation assisted group there was a 53.3% incidence of hemi-diaphragmatic paralysis(68). However, the study was underpowered to detect the true incidence of avoidance of hemi diaphragmatic paralysis. They demonstrated that ultrasonography could effectively be used to target the deposition of LA and to assess diaphragmatic paralysis(68).

Various other phrenic sparing nerve blocks are being utilized to reduce or eliminate diaphragmatic paralysis from brachial plexus blocks (69,70). These include ultrasound guided supraclavicular blocks with LA injection posterolateral to the brachial plexus, selective C7 root blocks, combined axillary-suprascapular nerve blocks, combined infraclavicular-suprascapular nerve blocks. While some of the blocks are still under study, others are technically challenging and may present additional risks.

2.9 Point of Care Ultrasound Imaging for Diaphragm Function

Ultrasound is portable, has no risk of ionizing radiation, and can be used to assess both structure and function of the diaphragm. It has been shown to be as accurate as most other imaging methods that are used to assess diaphragmatic function(20).

The diaphragm can be identified on ultrasound by its anatomic location, curved geometry, and echogenic appearance (figure 5). It appears as two echogenic layers (the parietal pleura, and the peritoneum) with a hypoechoic line (muscular layer) in between them. Two ultrasound modes are used to assess the diaphragm. B-mode is a 2D mode used to check the thickness of the diaphragm and its echogenicity while M-mode (which has a time component) is used to check the excursion and velocity of the diaphragm. M-mode is a representation of the movement of a single point of the diaphragm over a certain duration. Ultrasonographic assessment of the diaphragm focuses on the lateral and posterior muscular components of the diaphragm(innervated by the phrenic nerve), as opposed to the less mobile(40% less mobile) and fibrous anterior central tendon(20).

The position and motion of the diaphragm are dependent on the position of the patient. The supine position is preferred because there is less general variability, and it is highly reproducible. Diaphragmatic excursion is also greater in this position because the abdominal viscera easily move the diaphragm, compensatory efforts are limited and thus any paralysis or paradoxical movement will be accentuated. The inspired volume and diaphragm movement have been shown to correlate better in the supine position as opposed to sitting position. The right hemi-diaphragm is visualized easily through the liver window while the left hemi-diaphragm is harder to visualize due to the smaller splenic window(20).

The diaphragm can be imaged in four views. The intercostal view at the anterior axillary line, 7th-9th rib, using a high frequency linear probe in a sagittal orientation; this view is ideal for diaphragm thickness measurements. The anterior subcostal view at the costal margin in between the anterior axillary and midclavicular lines using a low frequency curvilinear probe in sagittal orientation; this view is ideal for measurement of diaphragmatic excursion and velocity. The posterior subcostal view is a mirror image of the anterior subcostal view obtained at the costal margin posteriorly. The sub-xiphoid view is obtained at the xiphoid area with a low frequency curvilinear probe in transverse orientation and can view both hemi-diaphragms at the same time, however M-mode can only look at one hemi-diaphragm at a time(20). The anterior subcostal view will be used for this study and is demonstrated in the diagram below:

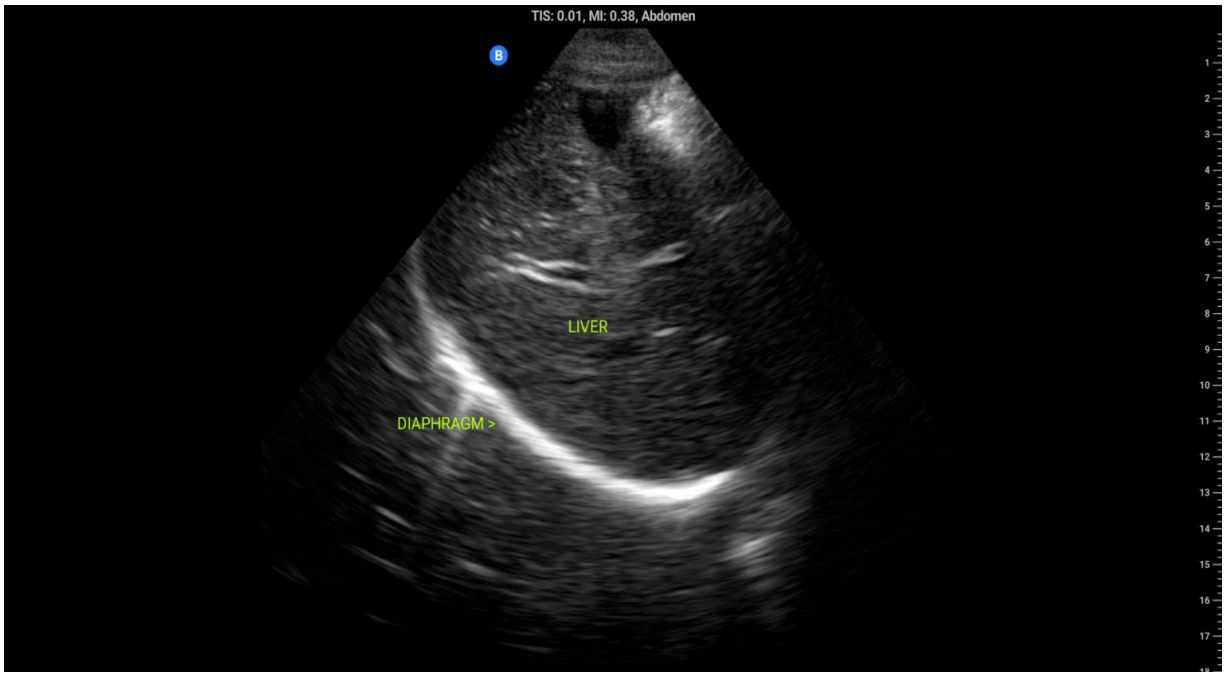

Figure 5:Anterior subcostal view of the diaphragm through the liver window. This is the image seen on B-mode.

Various measurements of the diaphragm can be made:

Diaphragm Thickness and Change in Thickness: may be used to identify chronic diaphragmatic paralysis and atrophy of the diaphragm. Normal thickness is 0.22-0.28cm and 0.13-0.19cm in diaphragm paralysis. Thickness of less than 0.2cm measured at end expiration is the cutoff for atrophy. However, standardization of measurement is difficult since a uniform point of measurement must be used. The inferior portions of the diaphragm are thicker than the superior portions. Change in thickness of less than 20% is consistent with paralysis(71).

Side to side variation: variation in excursion may also be used to compare diaphragmatic excursion between the two hemi-diaphragms. In standing patients, the excursion is asymmetrical with higher excursion on the left. Normal difference in excursion should be less than 50%(72). The range of motion of the diaphragm is greater posteriorly than anteriorly and greater laterally than medially.

Diaphragm Excursion: Using M-mode which can measure motion of the diaphragm against time, diaphragm excursion and velocity can be measured (Figure 6), and pre-block and post-block values compared. While monitoring excursion of the diaphragm it is important to correlate with inspiratory and expiratory phases of respiration to pick up on paradoxical breathing (diaphragm moves away from the probe during inspiration phase). Excursion is measured during quiet breathing, deep breathing, or sniff test. Normal range of motion has been observed at 1.9-9.0cm with higher range of motion during deep breathing and sniff tests. Complete diaphragmatic paralysis is indicated by absence of excursion on quiet

or deep breathing and paradoxical motion on sniff test. Incomplete paralysis is indicated by reduced excursion on quiet and deep breathing. Excursion greater than 2.5cm has been suggested as a cutoff to exclude diaphragmatic paralysis(73).

Diaphragmatic Velocity: Diaphragmatic muscle strength can be assessed by measuring velocity during a sniff test. The velocity is a calculation between the values on the y and x axis (excursion per unit time respectively) on an M-mode capture during a sniff test (Figure 7). Velocity has been shown to increase from 1.52cm/sec during quiet breathing to 10.4cm/sec during a sniff test(74). This increase would be absent in a paralyzed hemi-diaphragm.

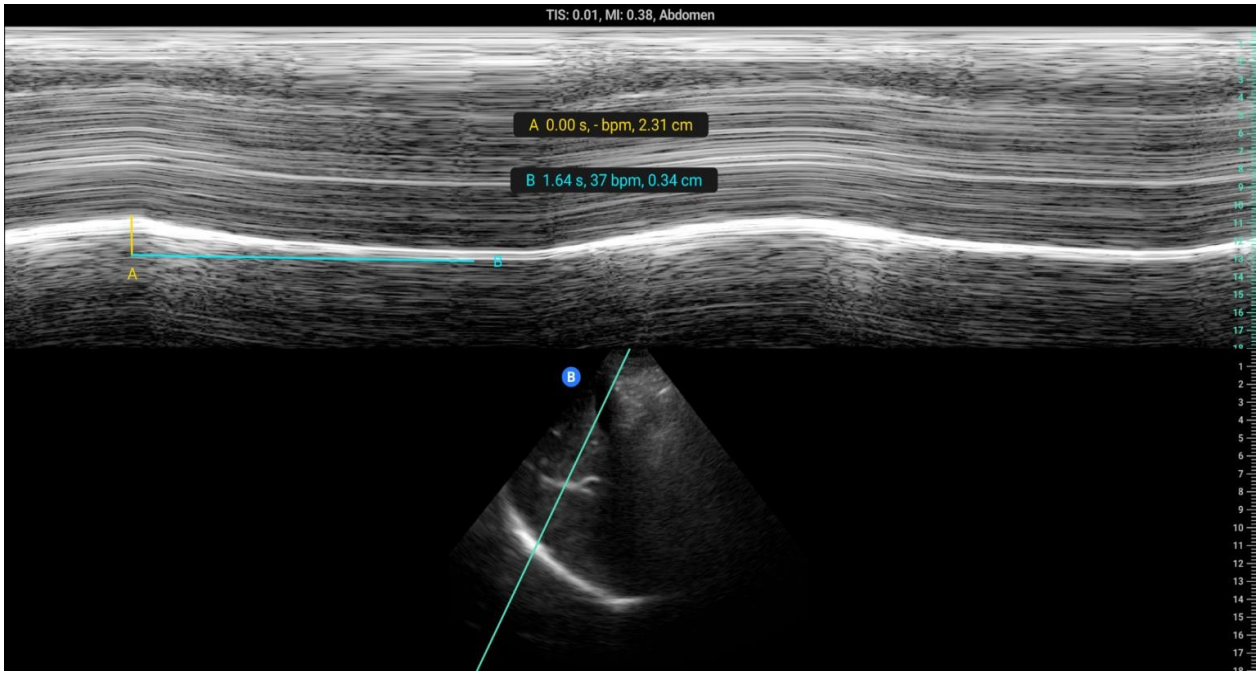

Figure 6: M-Mode image of diaphragmatic excursion and velocity during quiet breathing. Diaphragmatic excursion of 2.31cm is seen here, with a diaphragmatic velocity of A/B = 2.31cm/1.64s

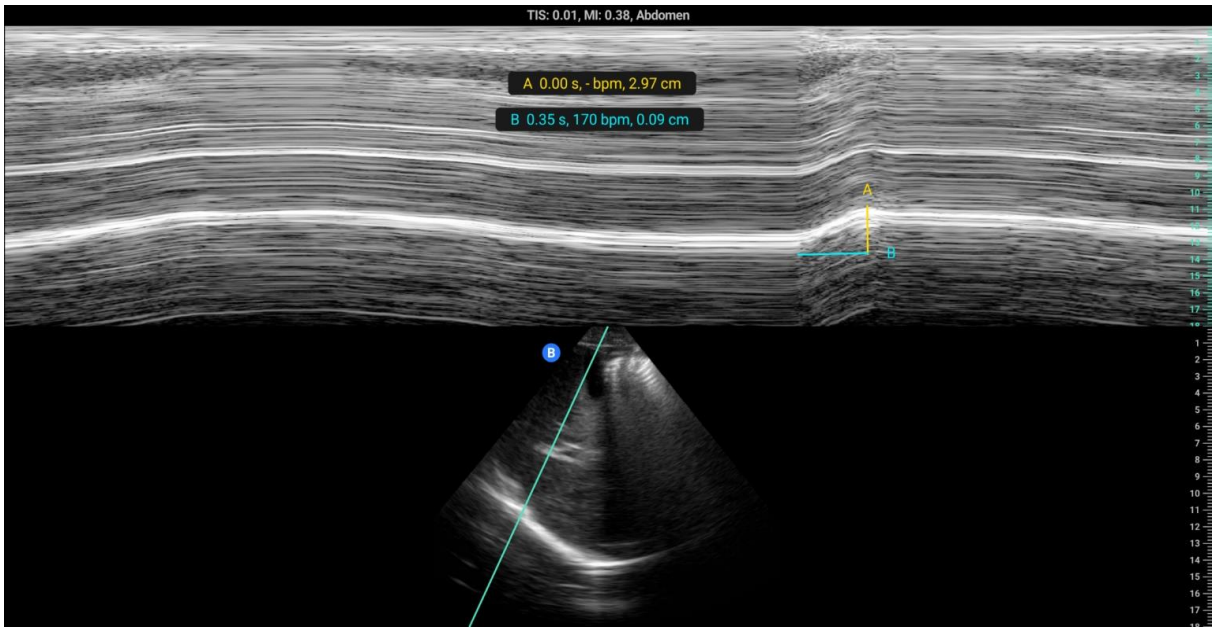

Figure 7:M-mode image of diaphragmatic excursion and velocity during a sniff test.

2.10 Study Justification

Peripheral blocks can save on operating costs as compared to general anesthesia and generally have a good safety profile. Peripheral blocks provide good surgical operative conditions and optimal analgesia. The resultant local vasodilation after regional anesthesia is beneficial for some procedures like upper limb AV fistula fashioning and skin grafting. Peripheral nerve/plexus blocks are preferable whenever indicated, either as the sole anesthetic, combined with general anesthesia, or for postoperative analgesia. This has generally seen an increased uptake of regional anaesthetic approaches to surgical facilitation and increased workflow in busy centers. However, the safety profile and ease of translating anaesthesia science does not negate the dangers that may be associated with these applications if not appropriately undertaken. Prevention, recognition, and early intervention in case of adverse effects are cornerstones and key in anaesthesia and pain medicine. In the cases in which unilateral diaphragmatic paralysis occurs after supraclavicular block in otherwise healthy individuals, insignificant needs for respiratory support occur.

There are however, various case reports that have documented a high risk of significant respiratory compromise following unilateral diaphragmatic paralysis in obese patients and patients with cardiorespiratory comorbidities(3–5). In such cases, there has been a need to convert from a regional anesthetic technique to general anesthesia with subsequent postoperative admission to ICU for mechanical ventilation. This confers significant additional cost and increased postoperative morbidity and possibly mortality.

Locally there is minimal data on the incidence of diaphragmatic paralysis following supraclavicular block and its sequelae. Theoretically, if a significant proportion of patients developed unilateral diaphragmatic paralysis following supraclavicular block with subsequent requirement for mechanical ventilation and possible critical care intervention, a recommendation for other technically challenging blocks which are phrenic nerve sparing would be appropriate.

Ascertaining the risk and incidence of diaphragmatic paralysis following supraclavicular block in our local population will assist in improving safety of the block and anticipating/preparing for complications. This would also help in formulating guidelines of care and protocol bundles.

2.11 Research Question

What is the risk of hemi diaphragmatic paralysis after ultrasound-guided supraclavicular brachial plexus blockade for upper limb surgical procedures in patients at the Kenyatta National Hospital?

2.12 Main Objective

To determine the incidence of diaphragmatic paralysis after undergoing ultrasound-guided supraclavicular nerve block in KNH theatres.

2.13 Specific Objectives

a) To determine the incidence of diaphragmatic paralysis in patients undergoing supraclavicular block in KNH theatres.
b) To determine respiratory profile of patients who develop ipsilateral diaphragmatic paralysis.
c) To determine risk factors for hemi diaphragmatic paralysis after ultrasound-guided supraclavicular block.

3.0 CHAPTER THREE: METHODOLOGY:

3.1 Study Design

The study was a descriptive cross-sectional study. The researcher observed the block technique and then the outcome of the supraclavicular blocks performed was observed.

3.2 Study Area

The study site was Kenyatta National Hospital's burns, orthopedic, trauma, cardiothoracic and emergency theatres. KNH is currently the largest teaching and referral facility in the country and the region (East Africa). It has a bed capacity of 2,400; catering to approximately 989,000 inpatients annually. It has 50 wards, 24 outpatient clinics, 26 operating theatres (16 specialized), 82 ICU beds and a busy accident and emergency department. Supraclavicular blocks are done routinely in KNH for isolated upper limb surgeries under the guidance of both portable and console ultrasound systems.

3.3 Study Population

ASA category I - III patients, undergoing below shoulder upper limb surgeries in KNH theatres, who received a supraclavicular block.

3.3.1 Inclusion Criteria

a) All patients scheduled for below shoulder upper limb surgeries in KNH theatres, who received a supraclavicular block and whose ASA category was I-III.
b) Patients who consented to participate in this study.

3.3.2 Exclusions Criteria

a) Patients scheduled to undergo below shoulder upper limb surgeries in KNH theatres but had contraindication(s) to local anesthetics or regional anesthesia.
b) Patients who met the inclusion criteria, but the primary anesthesia provider chose general anesthesia over supraclavicular block as the mode of anesthesia.
c) Patients with additional injuries (polytrauma) and undergoing multiple surgeries at one sitting, in whom supraclavicular block was not adequate as the sole anesthetic method.
d) Patients who met the inclusion criteria either declined the use of supraclavicular block as sole anesthetic or declined consent for participation in the study.

3.4 Sample Size Calculation

Sample size was calculated using the Fisher's formula.

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 85.0%, from several studies(6–11) with the quoted incidence ranging from as low as 67% to as high as 100% for paralysis of the hemi diaphragm (complete & incomplete); these studies looked at the incidence of diaphragmatic paralysis following supraclavicular brachial plexus block and the effect of various volumes on extent of diaphragmatic paralysis.

d = desired precision (0.1)

$$n_0 = \frac{1.96^2 x\ 0.85(1-0.85)}{0.1^2} = 49$$

A sample size of 49 patients was required for the study.

3.5 Sampling Technique:

Consecutive sampling was used to identify eligible study subjects from the emergency and elective theatre lists until the calculated sample population size was attained.

3.6 Study Procedure and Data Collection

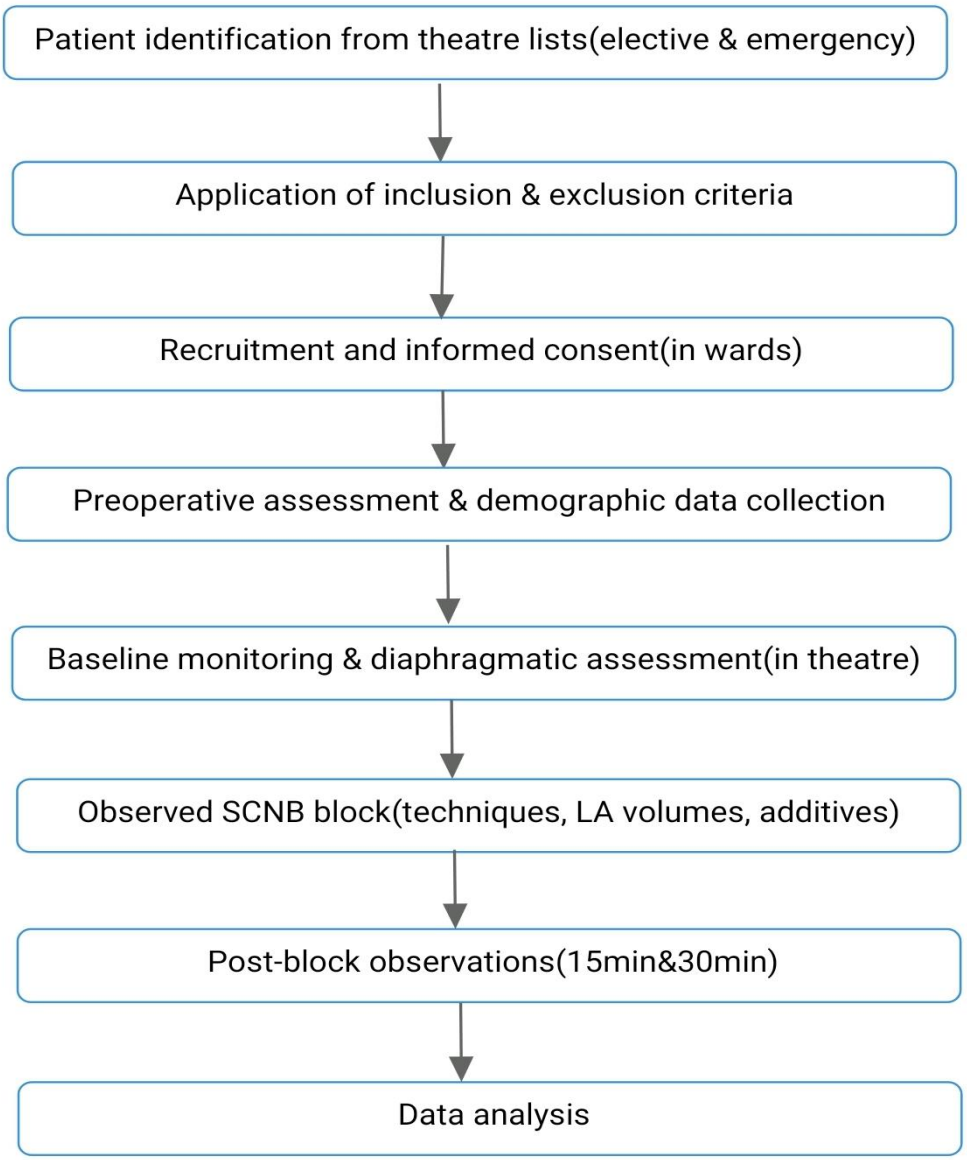

Figure 8:Study procedure diagram illustrating the flow from patient identification to data analysis.

3.6.1 Consenting & Recruitment Procedure

59 patients scheduled to undergo upper limb surgery were identified from the elective and emergency theatre lists. All patients scheduled to undergo upper limb surgeries were identified consecutively until sample size was attained. Once the inclusion and exclusion criteria were met, the patient was approached while in the ward. The study was explained to the patient by the principal researcher or research assistant. Informed written consent was then obtained once the patient agreed to participate in the study. On obtaining informed consent, the primary anesthesiologist was contacted, and the anesthetic plan was discussed with them. The patient's height and weight were measured and recorded. A preoperative assessment was done by the researcher or research assistant and any comorbidities noted as well as the ASA classification and smoking status.

3.6.2 Data Collection

Upon enrollment to the study, the height and weight of the patient was noted during the preoperative review. A full preoperative assessment was carried out on the day prior to the surgery for elective cases and on the day of surgery for emergency cases. The plan for the supraclavicular block was at this point discussed with the attending anesthesiologist.

On the day of surgery, the patient was received in theatre and connected to monitoring equipment. Baseline diaphragmatic assessment was done and recorded. Diaphragmatic paralysis was assessed by measurements of the diaphragmatic excursion (on quiet breathing) which were carried out on each patient while in the supine position before administration of block and at 15, and 30minutes after the block. The diaphragmatic excursion and velocity were measured in M-mode; excursion was recorded in centimeters while velocity was recorded in centimeters/sec. A Butterfly® IQ Portable ultrasound probe was used for the measurements. The block was performed by the attending anesthesiologist or anesthesia registrar. The blocks were ultrasound guided (high frequency linear probe) at mid-clavicular point; the block technique used was documented (intertruncal, corner-pocket or intra-cluster). Observations on the local anesthetic used, the concentration, volume and any additives used were made. Diaphragmatic excursion measurements were all done with the patient in supine position and quietly breathing. For diaphragmatic velocity, measurements were done following a sniff. A skin marking was placed anteriorly at the subcostal margin along midclavicular line to standardize subsequent measurements of the diaphragm.

Baseline vital signs (HR, BP, RR, O_2Sat) and patient oxygen use (or lack thereof) were recorded at baseline and 15 & 30 minutes. Symptoms that developed following diaphragmatic paralysis were recorded. The success of the block was also recorded, by assessment of motor blockade and sensory blockade to pinprick sensation. Pre-block and post-block data was compared.

3.7 Data Analysis

Data was collected via a data collection form. The data collected was continuously checked for completeness and lack of error. At the end of data collection, the data was entered into a Microsoft Excel Workbook 2017. Thereafter, the data were exported to the Statistical Package for Social Sciences version 23 for analysis.

The demographic and clinical characteristics of the patients was analyzed and presented as frequencies and percentages for categorical data, and as means with standard deviation for continuous data. The incidence of diaphragmatic paralysis in patients undergoing supraclavicular nerve block was calculated as a proportion of the patients having diaphragmatic paralysis over the total sample size and reported as a percentage. The respiratory symptoms of patients who had ipsilateral diaphragmatic paralysis was analyzed and presented as frequencies and percentages. Predictors of hemi-diaphragmatic paralysis were assessed with the use of Chi-square test, and those predictors found to be statistically significant were subjected to a multivariate analysis with the use of logistic regression. All statistical tests were considered significant where the p-value was less than 0.1.

3.8 Quality Assurance Procedures

The data collection form was designed to capture all the information relevant to this study. The design was simple and avoided ambiguity, to allow ease of use by the principal researcher and the research assistant.

The primary researcher examined the data collection form daily to ensure accuracy and completeness of data collected. The information contained in this form was uploaded daily by the principal researcher to avoid leaving out any of the entries.

The data variables collected were monitored to ensure completeness. This included the demographic data (collected preoperatively) and the pre-block and post-block diaphragmatic excursion data (collected in theatre). At the start of data collection, any challenges that arose were corrected immediately to prevent further errors in the data collection process. This included both logistic and procedural concerns in the data collection process.

3.9 Data Management

The data collected was entered into the data collection forms. Kobo Toolbox, an open source and free data collection platform was used for generation of the data collection form and upload of the data. The form could be used with or without a data connection. This data was uploaded daily into a digital format and stored in a password protected folder. This data was uploaded daily to a cloud-based storage drive

for backup purposes. Access to the data was only granted to the statistician and not to any other third party.

Data de-identification was achieved using unique patient identification numbers that had no relation to the patient's name or other patient details.

3.10 Ethical Considerations

Informed consent: The patients were fully informed by the researcher about the basis and aims of the study. They were also informed that their continuous involvement in the study was voluntary and that they were free to leave the study at any time if they so wished by informing the researcher. The informed consent form was signed by the patient and the researcher.

Confidentiality: All study participants remained anonymous and were only identified by a unique patient identification number. Privacy and confidentiality of the patient and the data collected was observed throughout the duration of the study.

Research approval: Approval was sought from the institution through the KNH/UoN Ethics and Research Committee.

Risk: The study did not constitute any extra cost to the patient or expose them to any harm or invasive procedures and interventions. It was an augmented standard of care in optimizing their treatment. In the event of a critical incidence or a near miss, all records pertaining to the incident were to be reviewed with the objective of identifying and rectifying the root cause at the equipment, process, or training level.

Benefits: No monetary benefits were offered to the patient. The patients did not incur any additional costs from their participation in this study.

4.0 CHAPTER FOUR: RESULTS

A total of 50 participants were recruited for the study; one patient was excluded, and analysis was conducted on the sample of 49 patients. The results are presented as per the study objectives.

4.1 Demographic characteristics of the study participants

The mean age of the study participants was 32.0 (SD 13.4) years, where the minimum age was 3.0 years, and the maximum was 73.0 years. The median age was 30.0 (IQR 26.0 – 39.0) years. Majority of the participants were aged between 21.0 to 30.0 years (44.9%), were male (75.5%), and had no comorbid condition (80.0%). The rest of the results is as shown on Table 1.

Table 1: Characteristics of the study participants

	Frequency *(n=49)*	**Percent**
Age in years		
≤20	5	10.2
21 – 30	22	44.9
31 – 40	14	28.6
>40	8	16.3
Gender		
Male	37	75.5
Female	12	24.5
BMI		
<18.5	5	10.2
18.5 – 24.9	33	67.3
25.0 – 29.9	11	22.4
Comorbidity		
Yes	10	20.0
No	40	80.0
ASA status		
1	30	61.2
2	16	32.7
3	3	6.1
Smoking status		
Smoker	10	20.4
Non-smoker	39	79.6

A total of 50 participants were recruited for the study. 1 patient was excluded due to aberrant anatomy that made the block technically challenging to perform safely, as shown in the figure below.

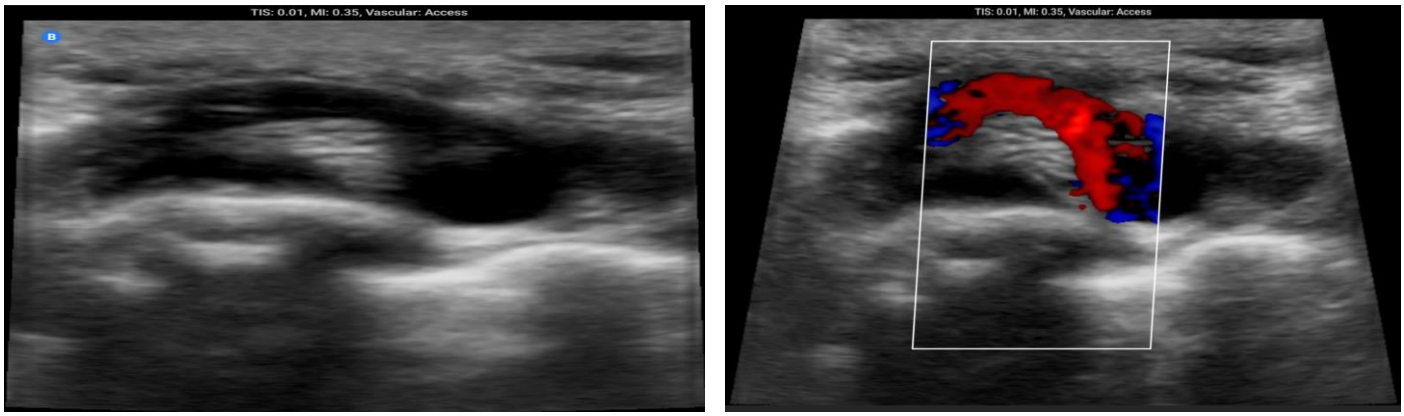

Figure 9: Aberrant anatomy indicating brachial plexus trunks surrounded by blood vessels.

4.2 Incidence of diaphragmatic paralysis

The incidence of diaphragmatic paralysis in patients undergoing supraclavicular block in KNH theatres is as shown on Table 2. The patients who had more than 50% decrease in either diaphragm velocity, excursion or both were categorized as having complete paralysis.

Table 2: Incidence of diaphragmatic paralysis

	Frequency *(n=49)*	**Percent**
Paralysis	28	57.1
No paralysis	21	42.9

A further breakdown of the grading of diaphragmatic paralysis is as shown in Table 3.

Table 3: Grading and incidence of diaphragmatic paralysis

	Total paralysis (>50%)	**Partial paralysis (25-50%)**	**No paralysis (<25%)**
Frequency (%)	28 (57.1)	12 (24.5)	9 (18.4)

4.3 Respiratory profile of patients who developed diaphragmatic paralysis.

The respiratory profile of patients who develop ipsilateral diaphragmatic paralysis is as shown on Table 4. For O2 supplementation, the results show the number of patients who had need for supplemental oxygen, distributed at the point they experienced paralysis. Additionally, the table shows the number of

patients who developed increased respiratory rate after the block and their respective levels of paralysis of the hemi diaphragm.

Table 4: Respiratory profile of patients who develop diaphragmatic paralysis.

O2 supplementation	Total paralysis (>50%)	Partial paralysis (25-50%)	No paralysis (<25%)
Yes	7	2	2
No	21	10	7
Increased Respiratory rate			
Yes	15	4	5
No	13	8	4

Among the patients who had debridement, the need for supplemental oxygen and the increase in respiratory rate was as shown on Table 5.

Table 5: Respiratory changes among patients who had debridement surgery.

Debridement	Oxygen supplementation	Total paralysis (>50%)	Partial paralysis (25-50%)	No paralysis (<25%)
Yes	Yes	2	1	1
	No	4	0	3
No	Yes	5	1	1
	No	17	10	4

4.4 Risk factors for diaphragmatic paralysis

The risk factors evaluated for association with hemi diaphragmatic paralysis after ultrasound-guided supraclavicular block were as shown in Table 6.

Table 6: Risk factors for diaphragmatic paralysis

	Yes *(n=28)*	No *(n=21)*	p-value
Age, *Mean ± SD*	34.1 ± 15.9	29.2 ± 8.6	0.176
Gender, *n (%)*			
Male	18 (64.3)	19 (90.5)	0.035
Female	10 (35.7)	2 (9.5)	
BMI, *Mean ± SD*	22.4 ± 3.9	22.6 ± 2.6	0.896
Smoking status, *n (%)*			
Smoker	5 (17.9)	5 (23.8)	0.609
Non-smoker	23 (82.1)	5 (76.2)	

4.5 Block performance practices

The blocks done were anesthetic blocks mostly using 0.5% Bupivacaine and performed mostly by anesthesia registrars (45) and some by consultant anesthesiologists (4). The local anesthetic mixture used was 0.5% Bupivacaine in 32 patients, a mixture of 2% Lidocaine with 0.5% Bupivacaine in 14 patients and purely 2% Lidocaine in 3 patients. Various additives were used, dexamethasone only was used in 29 patients, dexamethasone and adrenaline in 16 patients and no additives in 4 patients. The dose of dexamethasone used was 4mg in 32 patients, 8mg in 10 patients and 2mg in 3 patients.

The various local anesthetic concentrations and volumes used have been shown on Table 7

Table 7: Local anesthetic concentrations and volumes

	Frequency *(n=49)*	Percent
15mls 0.5% Bupivacaine	1	2.0
16mls 0.5% Bupivacaine (heavy)	1	2.0
16mls 0.5% Bupivacaine + 2mls 2%Lidocaine	1	2.0
18mls 0.5% Bupivacaine	2	4.1
18mls 0.5% Lidocaine	1	2.0
20ml: 4mls 0.5% Bupivacaine + 16mls 2% Lidocaine	1	2.0
20mls 0.5% Bupivacaine	24	49.0
20mls 0.5% Bupivacaine + 10mls 2% Lidocaine.	1	2.0
20mls 2% Lidocaine	2	4.1
20mls: 15mls 0.5% Bupivacaine + 5mls 2% Lidocaine	1	2.0
20mls: 16mls 0.5% Bupivacaine	1	2.0
20mls: 16mls 0.5% Bupivacaine + 2mls 2% Lidocaine	4	8.2
3.5mls 0.5% Bupivacaine	1	2.0
30mls: 20mls 0.5% Bupivacaine + 10mls 2% Lidocaine	5	10.2
8mls 0.5% Bupivacaine	1	2.0
Bupivacaine 0.33% & Lidocaine 1% 30mls	1	2.0
Bupivacaine, 0.5%, 25mls	1	2.0

The various techniques used have been shown on Table 8

Table 8: Techniques used for supraclavicular blocks.

	Frequency *(n=49)*	**Percent**
CP	36	73.5
IC	1	2.0
IT	12	24.5

5.0 CHAPTER FIVE: DISCUSSION

We found a 57.1% incidence of hemi diaphragmatic paralysis after supraclavicular nerve block at KNH. This is significant in that a moderate incidence of hemi diaphragmatic paralysis is to be expected after supraclavicular block despite using reduced anesthetic volumes and despite ultrasound guidance. This can be sometimes underappreciated by the anesthesia provider. This correlates with other incidence studies, where the incidence varies from 25% to 100%. Caution is thus needed in patients requiring supraclavicular block but would clinically deteriorate from reduced ventilation occasioned by the resulting hemi diaphragmatic paralysis.

The supraclavicular blocks we observed used relatively low volumes (15-20mls) of mostly 0.5% Bupivacaine, and this could explain the lower incidence of hemi diaphragmatic paralysis. In a study looking at the dose-response relationship between local anesthetic volume and incidence of hemi diaphragmatic paralysis, Tedore et al 2020(11) found an incidence of 33% at 5mls and 100% at 30-35mls. Mak et al 2001(8), found an incidence of 50%, using 0.5mls.kg-1 0.375% ropivacaine; Johnson et al 2022(66), found an incidence of 25-47.5% using 20-30mls of 0.375% Bupivacaine. Some studies have found a higher incidence i.e. 80% in Zhang et al 2020(10) using 20-30mls 0.375% ropivacaine and 70% in Georgiadis et al 2021(9).

There is no consensus as to the minimum effective volume of local anesthetic. In a study of minimum effective volume in 90% of patients (MEV90) using 1.5% Lidocaine, Tran et al 2011(75) determined the MEV90 for ultrasound-guided supraclavicular block, using corner pocket technique, to be 32mls. Jae Gyok Song et al 2013(76) determined the MEV90 to be 15mls, using 1.5% Mepivacaine. Direct observation of the spread of local anesthetic under ultrasound guidance could facilitate the use of less volumes. The patient's weight also influences the safe dose/volume of local anesthetic used. A balance between minimizing anesthetic volume to limit the incidence of hemi diaphragmatic paralysis, while still having an acceptable success rate especially for anesthetic blocks is necessary.

Out of 28 patients with complete paralysis, 7 patients required oxygen supplementation. Out of 21 patients with no paralysis, 4 patients required oxygen supplementation. All the patients had normal pulse oximetry reading off oxygen at the end of surgery, apart from one patient who needed supplementation for one hour postoperatively following debridement of electrical burns. Among the 28 patients with complete paralysis, 15 patients had increased respiratory rate after the block, while among the 21 patients with no paralysis, 9 patients had increased respiratory rate. There are few studies reporting specific respiratory rates or oxygen saturations, however Zhang et al 2020(10) and Johnson et al 2022(66) demonstrated no significant desaturation or increased respiratory rate following supraclavicular blocks. For this study, we had no control over the anesthesia provider's threshold for starting supplementation of oxygen. We noted that out of 8 patients who had debridement for burn wounds, 4 patients (50%) required oxygen supplementation. This high proportion could possibly be explained by pre-existing acute lung injury following burns. However, most patients were clinically unaffected apart from the one patient who required oxygen supplementation for up to one hour postoperatively.

We did not find any significant association between age, BMI & smoking status, and the development of hemi diaphragmatic paralysis. Female gender (p=0.035) was significantly associated with development of hemi diaphragmatic paralysis. Studies have not previously reported female gender to be a factor in developing hemi diaphragmatic paralysis following supraclavicular block. However, our sample size may not have been adequately powered for definitive association.

The blocks performed were anesthetic blocks (block used as the primary anesthetic) and 92% (45 of 49) were successful. 2 were supplemented with an axillary block and 2 were converted to general anesthesia. This is comparable to Bao et al 2019(7) where there was a success rate of 81% with 20mls and 91% with 30mls 0.375% ropivacaine. Higher volumes may therefore result in a higher success rate but consequently with higher incidence of hemi diaphragmatic paralysis.

For this study, the local anesthetic mixture used was 0.5% Bupivacaine in 32 patients, a mixture of 2% Lidocaine with 0.5% Bupivacaine in 14 patients and purely 2% Lidocaine in 3 patients. Various additives were used, dexamethasone only was used in 29 patients, dexamethasone, and adrenaline in 16 patients and no additives in 4 patients. The dose of dexamethasone used was 4mg in 32 patients, 8mg in 10 patients and 2mg in 3 patients. These results show that dexamethasone is a widely preferred additive among anesthesia providers in KNH. Dexamethasone is a potent anti-inflammatory corticosteroid with seven times the anti-inflammatory effect compared to prednisone. It exerts its perineural effect by attenuating the release of inflammatory mediators, reducing ectopic neuronal discharge and directly inhibiting potassium channel mediated discharge of nociceptive type C nerve fibers(77). In a cochrane review in 2017 looking at dexamethasone use in peripheral nerve blocks(78), dexamethasone has been proven to prolong the effect of peripheral nerve blocks. Additionally, pain intensity at 12 and 24 hours is less for perineural dexamethasone as compared to intravenous dexamethasone. Looking at the duration of block, perineural dexamethasone was slightly more effective than intravenous dexamethasone by an additional 2-3 hours and additionally both perineural and intravenous dexamethasone reduce postoperative opioid consumption. There was insufficient evidence to generalize the findings to lower limb surgeries and to children. Some studies show longer duration of block with 8 mg dexamethasone as opposed to 4 mg (Acharya R, Sriramka B, Panigrahi S. Comparison of 4 mg dexamethasone versus 8 mg dexamethasone as an adjuvant to levobupivacaine in fascia iliaca block-a prospective study(79) but this is an evolving research topic.

The injection techniques used included mostly the corner-pocket technique in 36 patients, intertruncal technique in 12 patients and intracluster technique in 1 patient. The intracluster technique is discouraged due to high rates of intrafascicular injection (90%) as shown in Retter et al 2019(45). For additional safety, pre-scanning the nerve trunks with doppler mode will identify vessels around the plexus and may even lead to abandonment of the block if there’s no safe path to the plexus as demonstrated in the excluded patient.

One patient developed Horner's syndrome lasting about 3 hours. This is a rare side-effect that is clinically without harm but can cause anxiety in the patient. The patient was reassured and 1mg IV midazolam was given for anxiolysis. Previous studies have reported Horner's syndrome commonly following interscalene

block, however Walid et al 2012(29) reported a case of Horner's syndrome following infraclavicular block. Therefore, Horner's syndrome may also be seen in some supraclavicular blocks.

6.0 CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusion:

1. There's a 57.1% incidence of hemi diaphragmatic paralysis following ultrasound guided supraclavicular blocks in patients undergoing upper limb surgeries in KNH theatres.
2. Patients require to be monitored closely after supraclavicular nerve blocks since oxygen supplementation will be required in a subset of patients (18.4%). Most patients will not develop clinically significant respiratory symptoms following HDP.
3. There could be an association between female gender and development of HDP.

6.2 Recommendations:

1. Further studies are needed to establish optimal local anesthetic block and techniques.
2. There is need for further controlled studies powered to establish a causal effect relationship between various factors and occurrence of hemi diaphragmatic paralysis.
3. An additional ultrasound machine is needed to facilitate use of regional blocks as an adjunct or an alternative to general anesthesia.

6.3 Limitations of the study:

1. This was a single center study and as such inferences can only be made to the patient population in KNH theatres.
2. The causal effect relationship could not be firmly established.

STUDY TIMELINE

	Sept-Dec 2022	Dec/Jan 2022	Feb/March 2023	Feb/April 2023	April 2023	April/May 2023
Proposal development						
Protocol presentation						
Ethics approval						
Data collection						
Data analysis						
Results presentation						

STUDY BUDGET AND JUSTIFICATION

ITEM	QUANTITY	UNIT COST	TOTAL
KNH/UoN ERC processing fees	1	2000	2000
Statistician	1	25000	25000
Research Assistant	1	25000	25000
Stationery			30000
Miscellaneous			30000
TOTAL			112000

A. PERSONNEL

1. The Statistician assisted in data cleaning, ensuring data completeness, analyzing, and interpreting the data, and providing valuable insights and trends in the data; as such he was considered as a key member in this study.

2. The research assistant assisted in preoperative review of patients, initial measurements of patient weights and heights, collecting of demographic and clinical data and ensuring completeness and daily uploading of the data; he was also considered a key member of this study.

B. STATIONERY

It was estimated that the typesetting, printing, binding, and other associated costs amounted to Ksh. 30,000 based on prior costs of postgraduate thesis process involving several copies at each level of the study.

C. MISCELLANEOUS

In the conduct of this study, various other miscellaneous costs included airtime, transport, conveyance of documents, internet usage charges, electricity related charges and other unanticipated charges amounted to approximately Ksh. 30,000.

REFERENCES

1. El-Boghdadly K, Chin KJ, Chan VWS. Phrenic Nerve Palsy and Regional Anesthesia for Shoulder Surgery. Anesthesiology. 2017 Jul 1;127(1):173–91.

2. Urmey WF, Talts KH, Sharrock NE. One hundred percent incidence of hemidiaphragmatic paresis associated with interscalene brachial plexus anesthesia as diagnosed by ultrasonography. Anesth Analg. 1991 Apr;72(4):498–503.

3. Sakuta Y, Kuroda N, Tsuge M, Fujita Y. Hypercapnic respiratory distress and loss of consciousness: a complication of supraclavicular brachial plexus block. JA Clin Rep. 2015;1(1):13.

4. Song JG, Kim SK, Jeon DG, Kwon MA, Yoo JH. Dyspnea after supraclavicular brachial plexus block in a morbidly obese patient due to phrenic nerve block: A case report. Korean J Anesthesiol. 2009 Oct;57(4):511–4.

5. Lang J, Cui X, Zhang J, Huang Y. Dyspnea induced by hemidiaphragmatic paralysis after ultrasound-guided supraclavicular brachial plexus block in a morbidly obese patient. Medicine (Baltimore). 2022 Jan 14;101(2).

6. Knoblanche GE. The incidence and aetiology of phrenic nerve blockade associated with supraclavicular brachial plexus block. Anaesth Intensive Care. 1979 Nov;7(4):346–9.

7. Bao X, Huang J, Feng H, Qian Y, Wang Y, Zhang Q, et al. Effect of local anesthetic volume (20 mL vs 30 mL ropivacaine) on electromyography of the diaphragm and pulmonary function after ultrasound-guided supraclavicular brachial plexus block: a randomized controlled trial. Reg Anesth Pain Med. 2019 Jan;44(1):69–75.

8. Mak PH, Irwin MG, Ooi CG, Chow BF. Incidence of diaphragmatic paralysis following supraclavicular brachial plexus block and its effect on pulmonary function. Anaesthesia. 2001 Apr;56(4):352–6.

9. Georgiadis PL, Vlassakov KV, Patton ME, Lirk PB, Janfaza DR, Zeballos JL, et al. Ultrasound-guided supraclavicular vs. retroclavicular block of the brachial plexus: comparison of ipsilateral diaphragmatic function: A randomised clinical trial. Eur J Anaesthesiol. 2021 Jan;38(1):64–72.

10. Zhang L, Pang R, Zhang L. Effect of different volumes of 0.375% ropivacaine on diaphragmatic paralysis by supraclavicular brachial plexus block under ultrasound guidance. Ann Palliat Med. 2020 Nov;9(6):3993–4001.

11. Tedore TR, Lin HX, Pryor KO, Tangel VE, Pak DJ, Akerman M, et al. Dose-response relationship between local anesthetic volume and hemidiaphragmatic paresis following ultrasound-guided supraclavicular brachial plexus blockade. Reg Anesth Pain Med. 2020 Dec;45(12):979–84.

12. Feigl GC, Litz RJ, Marhofer P. Anatomy of the brachial plexus and its implications for daily clinical practice: regional anesthesia is applied anatomy. Reg Anesth Pain Med. 2020 Aug;45(8):620–7.

13. Mian A, Chaudhry I, Huang R, Rizk E, Tubbs RS, Loukas M. Brachial plexus anesthesia: A review of the relevant anatomy, complications, and anatomical variations. Clin Anat N Y N. 2014 Mar;27(2):210–21.

14. Kulenkampff D. BRACHIAL PLEXUS ANAESTHESIA: ITS INDICATIONS, TECHNIQUE, AND DANGERS. Ann Surg. 1928 Jun;87(6):883–91.

15. la Grange P, Foster PA, Pretorius LK. Application of the Doppler ultrasound bloodflow detector in supraclavicular brachial plexus block. Br J Anaesth. 1978 Sep;50(9):965–7.

16. Kapral S, Krafft P, Eibenberger K, Fitzgerald R, Gosch M, Weinstabl C. Ultrasound-guided supraclavicular approach for regional anesthesia of the brachial plexus. Anesth Analg. 1994 Mar;78(3):507–13.

17. Franco CD. Chapter 26. Supraclavicular Brachial Plexus Block. In: Hadzic A, editor. NYSORA Textbook of Regional Anesthesia and Acute Pain Management [Internet]. New York, NY: The McGraw-Hill Companies; 2007 [cited 2023 Mar 24]. Available from: accessanesthesiology.mhmedical.com/content.aspx?aid=3501393

18. Epelman M, Navarro OM, Daneman A, Miller SF. M-mode sonography of diaphragmatic motion: description of technique and experience in 278 pediatric patients. Pediatr Radiol. 2005 Jul;35(7):661–7.

19. Yang X, Sun H, Deng M, Chen Y, Li C, Yu P, et al. Characteristics of Diaphragmatic and Chest Wall Motion in People with Normal Pulmonary Function: A Study with Free-Breathing Dynamic MRI. J Clin Med [Internet]. 2022 Jan [cited 2023 Jan 13];11(24). Available from: https://www.mdpi.com/2077-0383/11/24/7276

20. Sarwal A, Walker FO, Cartwright MS. Neuromuscular ultrasound for evaluation of the diaphragm. Muscle Nerve. 2013 Mar;47(3):319–29.

21. Pester JM, Hendrix JM, Varacallo M. Brachial Plexus Block Techniques. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 [cited 2022 Dec 16]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK470213/

22. Kim SC, Hauser S, Staniek A, Weber S. Learning curve of medical students in ultrasound-guided simulated nerve block. J Anesth. 2014 Feb;28(1):76–80.

23. Lewis SR, Price A, Walker KJ, McGrattan K, Smith AF. Ultrasound guidance for upper and lower limb blocks. Cochrane Database Syst Rev. 2015 Sep 11;2015(9).

24. Jeng CL, Torrillo TM, Rosenblatt MA. Complications of peripheral nerve blocks. Br J Anaesth. 2010 Dec;105 Suppl 1:i97-107.

25. Santosh Kumar Sharma. Failed Nerve Blocks: Prevention and Management [Internet]. Journal of Anaesthesia & Critical Care Case Reports. 2018 [cited 2022 Dec 20]. Available from: http://jaccr.com/failed-nerve-blocks-prevention-and-management/

26. Cuvillon P, Ripart J, Lalourcey L, Veyrat E, L'Hermite J, Boisson C, et al. The continuous femoral nerve block catheter for postoperative analgesia: bacterial colonization, infectious rate and adverse effects. Anesth Analg. 2001 Oct;93(4):1045–9.

27. Horlocker TT, Vandermeuelen E, Kopp SL, Gogarten W, Leffert LR, Benzon HT. Regional Anesthesia in the Patient Receiving Antithrombotic or Thrombolytic Therapy: American Society of Regional Anesthesia and Pain Medicine Evidence-Based Guidelines (Fourth Edition). Reg Anesth Pain Med. 2018 Apr;43(3):263–309.

28. El-Boghdadly K, Pawa A, Chin KJ. Local anesthetic systemic toxicity: current perspectives. Local Reg Anesth. 2018;11:35–44.

29. Walid T, Mondher BA, Mohamed Anis L, Mustapha F. A Case of Horner's Syndrome following Ultrasound-Guided Infraclavicular Brachial Plexus Block. Case Rep Anesthesiol. 2012;2012:1–3.

30. Schwalbert AM, Filho' D de PR. 189 A case of horner's syndrome after ultrassom-guided interscalene brachial plexus block. Reg Anesth Pain Med. 2021 Sep 1;70(Suppl 1):A99–100.

31. Stasiowski M, Zuber M, Marciniak R, Kolny M, Chabierska E, Jałowiecki P, et al. Risk factors for the development of Horner's syndrome following interscalene brachial plexus block using ropivacaine for shoulder arthroscopy: a randomised trial. Anaesthesiol Intensive Ther. 2018;50(3):215–20.

32. Naaz S, Asghar A, Jha NK, Ozair E. A unique case of hoarseness of voice following left supraclavicular brachial plexus block. Saudi J Anaesth. 2020;14(1):109–11.

33. Neal JM, Gerancher JC, Hebl JR, Ilfeld BM, McCartney CJL, Franco CD, et al. Upper extremity regional anesthesia: essentials of our current understanding, 2008. Reg Anesth Pain Med. 2009;34(2):134–70.

34. Sahu SK, Badole U. A rare complication in ultrasound-guided supraclavicular brachial plexus block. Res Innov Anesth. 2016;1:30–1.

35. Gauss A, Tugtekin I, Georgieff M, Dinse-Lambracht A, Keipke D, Gorsewski G. Incidence of clinically symptomatic pneumothorax in ultrasound-guided infraclavicular and supraclavicular brachial plexus block. Anaesthesia. 2014;69(4):327–36.

36. Jo Y, Park J, Oh C, Chung W, Song S, Lee J, et al. Comparison of the ulnar nerve blockade between intertruncal and corner pocket approaches for supraclavicular block: a randomized controlled trial. Korean J Anesthesiol. 2021 Dec;74(6):522–30.

37. Bailard NS, Ortiz J, Flores RA. Additives to local anesthetics for peripheral nerve blocks: Evidence, limitations, and recommendations. Am J Health-Syst Pharm AJHP Off J Am Soc Health-Syst Pharm. 2014 Mar 1;71(5):373–85.

38. Kirksey MA, Haskins SC, Cheng J, Liu SS. Local Anesthetic Peripheral Nerve Block Adjuvants for Prolongation of Analgesia: A Systematic Qualitative Review. PloS One. 2015;10(9):e0137312.

39. Bellew B, Harrop-Griffiths WA, Bedforth N. Interscalene Brachial Plexus Blocks and Phrenic Nerve Palsy. Anesthesiology. 2014 Apr 1;120(4):1056–7.

40. Staff NP, Dyck PJB, Warner MA. Postsurgical inflammatory neuropathy should be considered in the differential diagnosis of diaphragm paralysis after surgery. Anesthesiology. 2014 Apr;120(4):1057.

41. Guo CW, Ma JX, Ma XL, Lu B, Wang Y, Tian AX, et al. Supraclavicular block versus interscalene brachial plexus block for shoulder surgery: A meta-analysis of clinical control trials. Int J Surg. 2017 Sep;45:85–91.

42. Folino TB, Mahboobi SK. Regional Anesthetic Blocks. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 [cited 2023 Mar 24]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK563238/

43. Akpınar S, Açar Hİ, Cömert A, Şam B, Elhan A. Location of Needle Tips on Plexus Brachialis in Different Supraclavicular Block Techniques: A Cadaver Study. Turk J Anaesthesiol Reanim. 2016 Aug;44(4):169–76.

44. Choudhary N, Kumar A, Kohli A, Wadhawan S, Siddiqui TH, Bhadoria P, et al. Single-point versus double-point injection technique of ultrasound-guided supraclavicular block: A randomized controlled study. J Anaesthesiol Clin Pharmacol. 2019;35(3):373–8.

45. Retter S, Szerb J, Kwofie K, Colp P, Sandeski R, Uppal V. Incidence of sub-perineural injection using a targeted intracluster supraclavicular ultrasound-guided approach in cadavers. Br J Anaesth. 2019 Jun;122(6):776–81.

46. Siddiqui U, Perlas A, Chin K, Reina MA, Sala-Blanch X, Niazi A, et al. Intertruncal approach to the supraclavicular brachial plexus, current controversies and technical update: a daring discourse. Reg Anesth Pain Med. 2020 May;45(5):377–80.

47. Soares LG, Brull R, Lai J, Chan VW. Eight ball, corner pocket: the optimal needle position for ultrasound-guided supraclavicular block. Reg Anesth Pain Med. 2007;32(1):94–5.

48. Samet R, Villamater E. Eight ball, corner pocket for ultrasound-guided supraclavicular block: high risk for a scratch. Reg Anesth Pain Med. 2008;33(1):87.

49. Macfarlane AJR, Perlas A, Chan V, Brull R. Eight ball, corner pocket ultrasound-guided supraclavicular block: avoiding a scratch. Reg Anesth Pain Med. 2008;33(5):502–3; author reply 504.

50. Brull R, Chan VWS. The corner pocket revisited. Reg Anesth Pain Med. 2011;36(3):308.

51. Kalthoff A, Sanda M, Tate P, Evanson K, Pederson JM, Paranjape GS, et al. Peripheral Nerve Blocks Outperform General Anesthesia for Pain Control in Arthroscopic Rotator Cuff Repair: A Systematic Review and Meta-analysis. Arthrosc J Arthrosc Relat Surg Off Publ Arthrosc Assoc N Am Int Arthrosc Assoc. 2022 May;38(5):1627–41.

52. Boin MA, Mehta D, Dankert J, Umeh UO, Zuckerman JD, Virk MS. Anesthesia in Total Shoulder Arthroplasty: A Systematic Review and Meta-Analysis. JBJS Rev. 2021 Nov 10;9(11).

53. Yung EM, Got TC, Patel N, Brull R, Abdallah FW. Intra-articular infiltration analgesia for arthroscopic shoulder surgery: a systematic review and meta-analysis. Anaesthesia. 2021 Apr;76(4):549–58.

54. Marhofer P, Kraus M, Marhofer D. [Regional anesthesia in daily clinical practice: an economic analysis based on case vignettes]. Anaesthesist. 2019 Dec;68(12):827–35.

55. Lo SS. Chapter 1. Preoperative Evaluation. In: Atchabahian A, Gupta R, editors. The Anesthesia Guide [Internet]. New York, NY: The McGraw-Hill Companies; 2013 [cited 2023 Mar 24]. Available from: accessanesthesiology.mhmedical.com/content.aspx?aid=57260201

56. Hwang SM, Lee JJ, Jang JS, Gim GH, Kim MC, Lim SY. Patient Preference and Satisfaction with Their Involvement in the Selection of an Anesthetic Method for Surgery. J Korean Med Sci. 2014 Feb;29(2):287–91.

57. Nakahashi K, Kuzumoto N, Iwata T, Furuya H. [Effect of patient's choice of type of anesthesia or postoperative pain management]. Masui. 2007 Jun;56(6):720–7.

58. Kirkebøen KA, Lindholm E, Raeder J. [Choice of anaesthetic approach and anaesthetic drugs]. Tidsskr Den Nor Laegeforening Tidsskr Prakt Med Ny Raekke. 2010 Feb 25;130(4):388–91.

59. Neal JM. Ultrasound-Guided Regional Anesthesia and Patient Safety: Update of an Evidence-Based Analysis. Reg Anesth Pain Med. 2016;41(2):195–204.

60. Jariwala A, Kumar BCRP, Coventry DM. Sudden severe postoperative dyspnea following shoulder surgery: Remember inadvertent phrenic nerve block due to interscalene brachial plexus block. Int J Shoulder Surg. 2014 Apr;8(2):51–4.

61. Jules-Elysee K, Reid SC, Kahn RL, Edmonds CR, Urban MK. Prolonged diaphragm dysfunction after interscalene brachial plexus block and shoulder surgery: a prospective observational pilot study. Br J Anaesth. 2014 May;112(5):950–1.

62. Kaufman MR, Elkwood AI, Rose MI, Patel T, Ashinoff R, Fields R, et al. Surgical treatment of permanent diaphragm paralysis after interscalene nerve block for shoulder surgery. Anesthesiology. 2013 Aug;119(2):484–7.

63. Nickless JT, Waterman BR, Romeo AA. Persistent diaphragmatic paralysis associated with interscalene nerve block after total shoulder arthroplasty: a case report. JSES Open Access. 2018 Oct;2(3):165–8.

64. Schubert AK, Dinges HC, Wulf H, Wiesmann T. Interscalene versus supraclavicular plexus block for the prevention of postoperative pain after shoulder surgery: A systematic review and meta-analysis. Eur J Anaesthesiol. 2019 Jun;36(6):427–35.

65. Ferré F, Mastantuono JM, Martin C, Ferrier A, Marty P, Laumonerie P, et al. [Hemidiaphragmatic paralysis after ultrasound-guided supraclavicular block: a prospective cohort study]. Braz J Anesthesiol Elsevier. 2019;69(6):580–6.

66. Johnson JE, Daniel S. Ultrasonographic evaluation of incidence of diaphragmatic paralysis following different volumes of supraclavicular brachial plexus block- A prospective randomized double blinded study. Saudi J Anaesth. 2022;16(1):58–64.

67. Neal JM, Moore JM, Kopacz DJ, Liu SS, Kramer J, Plorde JJ. Quantitative Analysis of Respiratory, Motor, and Sensory Function After Supraclavicular Block. ANESTH ANALG. :6.

68. Renes SH, Spoormans HH, Gielen MJ, Rettig HC, van Geffen GJ. Hemidiaphragmatic Paresis Can Be Avoided in Ultrasound-Guided Supraclavicular Brachial Plexus Block: Reg Anesth Pain Med. 2009 Nov;34(6):595–9.

69. Hong B, Lee S, Oh C, Park S, Rhim H, Jeong K, et al. Hemidiaphragmatic paralysis following costoclavicular versus supraclavicular brachial plexus block: a randomized controlled trial. Sci Rep. 2021 Sep 21;11(1):18749.

70. Tran DQH, Elgueta MF, Aliste J, Finlayson RJ. Diaphragm-Sparing Nerve Blocks for Shoulder Surgery: Reg Anesth Pain Med. 2017;42(1):32–8.

71. Summerhill EM, El-Sameed YA, Glidden TJ, McCool FD. Monitoring recovery from diaphragm paralysis with ultrasound. 2008.

72. Urvoas E, Pariente D, Fausser C, Lipsich J, Taleb R, Devictor D. Diaphragmatic paralysis in children: diagnosis by TM-mode ultrasound. Pediatr Radiol. 1994;24(8):564–8.

73. Lerolle N, Guérot E, Dimassi S, Zegdi R, Faisy C, Fagon JY, et al. Ultrasonographic diagnostic criterion for severe diaphragmatic dysfunction after cardiac surgery. Chest. 2009;135(2):401–7.

74. Scott S, Fuld JP, Carter R, McEntegart M, MacFarlane NG. Diaphragm ultrasonography as an alternative to whole-body plethysmography in pulmonary function testing. J Ultrasound Med Off J Am Inst Ultrasound Med. 2006 Feb;25(2):225–32.

75. Tran DQH, Dugani S, Dyachenko A, Correa JA, Finlayson RJ. Minimum effective volume of lidocaine for ultrasound-guided infraclavicular block. Reg Anesth Pain Med. 2011;36(2):190–4.

76. Song JG, Jeon DG, Kang BJ, Park KK. Minimum effective volume of mepivacaine for ultrasound-guided supraclavicular block. Korean J Anesthesiol. 2013 Jul;65(1):37–41.

77. Stephen Choi CJLM. Analgesic Adjuvants in the Peripheral Nervous System [Internet]. NYSORA: Analgesic Adjuvants in the Peripheral Nervous System. Available from: https://www.nysora.com/topics/pharmacology/analgesic-adjuvants-peripheral-nervous-system/

78. Pehora C, Pearson AM, Kaushal A, Crawford MW, Johnston B. Dexamethasone as an adjuvant to peripheral nerve block. Cochrane Database Syst Rev. 2017 Nov 9;2017(11):CD011770.

79. Acharya R, Sriramka B, Panigrahi S. Comparison of 4 mg dexamethasone versus 8 mg dexamethasone as an adjuvant to levobupivacaine in fascia iliaca block-a prospective study. Korean J Pain. 2018 Oct;31(4):261–7.

APPENDICES

Appendix I: Consent Explanation and Consent Form (English)

PARTICIPANT INFORMATION AND CONSENT FORM

FOR ENROLLMENT IN THE STUDY

Title of Study: INCIDENCE AND RISK FACTORS OF DIAPHRAGMATIC PARALYSIS AFTER ULTRASOUND-GUIDED SUPRACLAVICULAR BLOCK AT KENYATTA NATIONAL HOSPITAL THEATRES.

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UNIVERSITY OF NAIROBI

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in medical research: i)

Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has been approved by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

WHAT IS THIS STUDY ABOUT?

Various upper limb procedures are currently done under supraclavicular block, and this is advantageous to the use of general anesthesia only. A side effect of the block is unilateral diaphragmatic paralysis. Determining how frequently this occurs and any associated respiratory compromise will promote perioperative care of these patients.
The researchers would like to ask some questions that will assist in planning your anesthetic plan. Participants will then get a supraclavicular block on the day of the surgery and thereafter their diaphragm will be assessed by use of ultrasound. They will also be observed for any development of respiratory symptoms. There will be approximately 59 participants in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:

You will be asked some questions that will help in your anesthesia plan. You will be interviewed in a private area where you'll feel comfortable, and the interview will last about 15 minutes. These questions will be on your prior exposure to anesthesia, any allergies you may have, any other chronic diseases you may have, and your current surgical condition.

After the interview, on the day of surgery a supraclavicular nerve block will be performed. This involves an injection above your collarbone under a local anesthetic, then local anesthetic will be introduced around your nerves to make your arm numb for the surgery.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional, and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be secure, so it is still possible that someone could find out you were in this study and could find out information about you.

You may feel some discomfort when the initial injection is made, and afterwards your arm will be numb, and this may be distressing for some patients. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

ARE THERE ANY BENEFITS IN THIS STUDY?

This study will help improve perioperative care of patients undergoing supraclavicular blocks. No monetary benefits will be offered to you. We will refer you to a specialist for care and support where necessary.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Participation in this study will not attract any additional cost that you would not have incurred in your treatment outside of this study.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

No monetary reward or compensation will be offered to you and you will not be required to give out any money or spend any additional cost that you would not have incurred in your treatment outside this study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the top of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study:	**Yes**	**No**
I agree to provide contact information for follow-up:	Yes	No

Participant printed name:

_____

Participant signature / Thumb stamp _____ **Date**

_____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher 's Name: _____ **Date**:

_____

Signature

_____

Role in the study: _____*[i.e., study staff who explained informed consent form.]*

Appendix II: Maelezo ya Idhini na Fomu ya Idhini (Swahili)

FOMU YA TAARIFA NA RIDHAA YA MSHIRIKI

KWA KUJIANDIKISHA KATIKA MAFUNZO

Kichwa cha Utafiti:

TUKIO NA MAMBO HATARISHI YA KUPOOZA KWA KIPINDUPIKO BAADA YA KITABU CHA SUPRACLAVICULAR IKIONGOZWA NA ULTRASOUND KATIKA TETESI ZA HOSPITALI YA TAIFA KENYATTA.

Mpelelezi Mkuu\na uhusiano wa kitaasisi:

GAKUO, DANIEL NJENGA (MBChB)
Anwani ya barua pepe: P. O. BOX 36161-00200 NAIROBI
Simu: 0726252513
Anwani ya barua pepe: dangakuo2018@students.uonbi.ac.ke
IDARA YA ANESTHESIA, CHUO KIKUU CHA NAIROBI

Wachunguzi-wenza na uhusiano wa kitaasisi:

MWITI TIMOTHY MURITHI (MBChB, MMed, Fell Pain, FCA)
Anwani ya barua: P.O. Sanduku 21586-00505
Simu: 0721366294
Anwani ya barua pepe: tmwiti@uonbi.ac.ke
MHADHIRI, IDARA YA ANESTHESIA
CHUO KIKUU CHA NAIROBI
IDARA YA ADABU, CHUO KIKUU CHA NAIROBI

CHOKWE THOMAS. M BSc, MBChB, MMed, FCA
Anwani ya barua: P.O. Sanduku 21586-00505
Simu: 0722528237
Anwani ya barua pepe: chokwe@uonbi.ac.ke
MHADHIRI MWANDAMIZI, IDARA YA ANESTHESIA
CHUO KIKUU CHA NAIROBI

Utangulizi:

Ningependa kukuambia kuhusu utafiti unaofanywa na watafiti walioorodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa utakayohitaji ili kukusaidia kuamua kama utakuwa mshiriki katika utafiti. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, nini kitatokea ikiwa utashiriki katika utafiti, hatari na manufaa yanayoweza kutokea, haki zako kama mtu wa kujitolea, na kitu kingine chochote kuhusu utafiti au fomu hii ambacho hakiko wazi. Wakati tumejibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kuwa katika utafiti au la. Utaratibu huu unaitwa 'ridhaa iliyoarifiwa'. Ukishaelewa na kukubali

kuwa katika utafiti, nitakuomba utie sahihi jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla zinazotumika kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni wa hiari kabisa ii) Unaweza kujiondoa kwenye utafiti wakati wowote bila kueleza sababu ya kujiondoa.
iii) Kukataa kushiriki katika utafiti hakutaathiri huduma unazostahili kupata katika kituo hiki cha afya au vituo vingine. Tutakupa nakala ya fomu hii kwa rekodi zako.
Naweza kuendelea? NDIO/ LA
Utafiti huu umeidhinishwa na Itifaki ya Kamati ya Maadili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Nairobi Na._____

SOMO HILI LINAHUSU NINI?

Taratibu mbalimbali za viungo vya juu kwa sasa zinafanywa chini ya kizuizi cha supraclavicular, na hii ni faida kwa matumizi ya anesthesia ya jumla tu. Athari ya upande wa kizuizi ni kupooza kwa diaphragmatic kwa upande mmoja. Kuamua ni mara ngapi hii hutokea na maelewano yoyote yanayohusiana na kupumua yatakuza utunzaji wa upasuaji wa wagonjwa hawa.
Watafiti wangependa kuuliza maswali kadhaa ambayo yatasaidia katika kupanga mpango wako wa ganzi. Washiriki watapata kizuizi cha supraclavicular siku ya upasuaji na baada ya hapo diaphragm yao itapimwa kwa kutumia ultrasound. Pia watazingatiwa kwa maendeleo yoyote ya dalili za kupumua. Kutakuwa na takriban washiriki 59 katika utafiti huu.

NINI KITAENDELEA UKIAMUA KUWA KATIKA UTAFITI HUU?

Ukikubali kushiriki katika utafiti huu, mambo yafuatayo yatafanyika:
Utaulizwa maswali kadhaa ambayo yatasaidia katika mpango wako wa anesthesia. Utahojiwa katika eneo la faragha ambapo utajisikia vizuri, na mahojiano yatadumu kama dakika 15. Maswali haya yatakuwa juu ya mfiduo wako wa awali wa ganzi, mizio yoyote ambayo unaweza kuwa nayo, magonjwa mengine sugu ambayo unaweza kuwa nayo, na hali yako ya sasa ya upasuaji.
Baada ya mahojiano, siku ya upasuaji kizuizi cha ujasiri cha supraclavicular kitafanywa. Hii inahusisha sindano juu ya mfupa wako wa shingo chini ya ganzi ya ndani, kisha ganzi ya ndani italetwa karibu na neva zako ili kufanya mkono wako ufe ganzi kwa ajili ya upasuaji.

JE, KUNA HATARI, MADHARA YOYOTE YANAYOHUSISHWA NA UTAFITI HUU?

Utafiti wa kimatibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili. Jitihada zinapaswa kuwekwa kila wakati ili kupunguza hatari. Hatari moja inayoweza kutokea ya kuwa katika utafiti
ni kupoteza faragha. Tutaweka kila kitu unachotuambia kama siri iwezekanavyo. Tutatumia nambari ya msimbo kukutambua katika hifadhidata ya kompyuta iliyolindwa na nenosiri na tutaweka rekodi zetu zote za karatasi kwenye kabati ya faili iliyofungwa. Hata hivyo, hakuna mfumo wa kulinda usiri wako unaoweza kuwa salama, kwa hivyo bado kuna uwezekano kwamba mtu anaweza kujua ulikuwa katika utafiti huu na kupata taarifa kukuhusu.
Unaweza kujisikia usumbufu wakati sindano ya kwanza inapotengenezwa, na baadaye mkono wako utakuwa na ganzi na hii inaweza kuwa ya kutaabisha kwa baadhi ya wagonjwa. Iwapo kuna jeraha, ugonjwa au matatizo yanayohusiana na utafiti huu, wasiliana na wafanyakazi wa utafiti mara moja kwa nambari iliyotolewa mwishoni mwa waraka huu. Wafanyikazi wa utafiti

watakushughulikia kwa masharti madogo au watakuelekeza inapohitajika.

JE, KUNA FAIDA YOYOTE KATIKA UTAFITI HUU?

Utafiti huu utasaidia kuboresha utunzaji wa upasuaji wa wagonjwa wanaopitia vitalu vya supraclavicular. Hakuna faida za kifedha zitatolewa kwako. Tutakuelekeza kwa mtaalamu kwa huduma na usaidizi inapobidi.

JE, KUWA KWENYE SOMO HILI LITAKUGHARIMU LOLOTE?

Kushiriki katika utafiti huu hakutavutia gharama yoyote ya ziada ambayo haungetumia katika matibabu yako nje ya utafiti huu.

JE, UTAREJESHWA KWA FEDHA ZOZOTE ULIZOTUMIA SEHEMU YA UTAFITI HUU?

Hakuna zawadi ya pesa au fidia itatolewa kwako na hutahitajika kutoa pesa yoyote au kutumia gharama yoyote ya ziada ambayo haungetumia katika matibabu yako nje ya utafiti huu.

VIPI IKIWA UNA MASWALI BAADAYE?

Ikiwa una maswali zaidi au wasiwasi kuhusu kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi wa maandishi kwa wafanyikazi wa utafiti kwa nambari iliyotolewa juu ya ukurasa huu.
Kwa maelezo zaidi kuhusu haki zako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu/Mwenyekiti, Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi Nambari 2726300 Ext. 44102 barua pepe uonknh_erc@uonbi.ac.ke.
Wafanyikazi wa utafiti watakulipa malipo yako kwa nambari hizi ikiwa simu ni ya mawasiliano yanayohusiana na masomo.

UCHAGUZI WAKO MENGINE NI GANI?

Uamuzi wako wa kushiriki katika utafiti ni wa hiari. Uko huru kukataa kushiriki katika utafiti na unaweza kujiondoa kwenye utafiti wakati wowote bila dhuluma au hasara ya manufaa yoyote.

FOMU YA RIDHAA (TAARIFA YA RIDHAA)

Kauli ya mshiriki

Nimesoma fomu hii ya idhini au nimesomewa maelezo. Nimepata nafasi ya kujadili utafiti huu na mshauri wa utafiti. Nimejibiwa maswali yangu kwa lugha ninayoielewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kujiondoa wakati wowote. Ninakubali kwa uhuru kushiriki katika utafiti huu.

Ninaelewa kuwa juhudi zote zitafanywa ili kuweka maelezo kuhusu utambulisho wangu wa kibinafsi kuwa siri.

Kwa kutia saini fomu hii ya idhini, sijaacha haki zozote za kisheria nilizo nazo kama mshiriki katika utafiti wa utafiti.

Ninakubali kushiriki katika utafiti huu:	**Ndiyo**	**Hapana**
Ninakubali kutoa maelezo ya mawasiliano kwa ufuatiliaji:	Ndiyo	Hapana

Jina lililochapishwa la mshiriki: _____

Sahihi ya mshiriki / Muhuri wa kidole gumba_____ **Tarehe**_____

Kauli ya mtafiti

Mimi, aliyetia sahihi hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kuwa mshiriki ameelewa na ametoa ridhaa yake kwa hiari na kwa uhuru.

Jina la Mtafiti:_____**Tarehe:**_____

Sahihi_____

Jukumu katika utafiti:_____ *[i.e., wafanyikazi wa utafiti ambao walielezea fomu ya idhini iliyo na taarifa.]*

Appendix III: Data Collection Form

Hemidiaphragmatic paralysis

1. Patient code: _____
2. Age: _____
3. Gender: _____
4. Weight (kgs): _____
5. Height(cms): :_____
6. Co-morbidities:

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   ……
   ……
   ……
   ……
7. ASA Status:

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8. Smoking status:

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……
……
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9. Type of surgery:

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10. Resprate0(b/min):

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11. O2sat_0(%):

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12. Supplemental oxygen_0(lpm):

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13. Diaphragmatic excursion_0(cm)

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14. Diaphragmatic velocity_0(cm/s):

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15. Resprate15:

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16. O2sat_15:

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17. oxygen_15(lpm):

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18. Diaphragmatic excursion_15:

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19. Diaphragmatic velocity_15:

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20. Resp rate_30:

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21. O2sat_30:

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22. Supplemental oxygen_30(lpm):

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23. Diaphragmatic excursion_30:

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24. Diaphragmatic velocity_30:

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25. Block technique (IT, CP, IC):

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26. Local anesthetic used (type, conc, volume):

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27. Adjuncts used (type, amount):

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28. Success of block motor (complete, incomplete, failed):

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29. Success of block sensory (complete, incomplete, failed):

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Appendix IV: Training Tool for Data Collection

Data collection will be facilitated by use of a data collection form attached in the appendix. The following details will be filled during preoperative assessment:

- Patient code
- Age(years)
- Gender(M/F)
- Weight(kgs)
- Height(cm)
- Comorbidities
- ASA status
- Smoking status
- Type of surgery

On the day of surgery (in theatre) the patient will be connected to a monitor prior to commencement of the supraclavicular nerve block. The research assistant will fill in the following baseline details:

- Respiratory rate(b/min)
- O2 saturation (%)
- Supplemental oxygen(lpm)

While the patient is in a supine position, the skin on the subcostal area at the midclavicular line on the ipsilateral side as the block will be cleaned with surgical spirit. The curvilinear ultrasound probe on abdominal setting, or the single butterfly probe on abdominal setting will be selected and adequate ultrasound gel applied. The probe will be placed in sagittal orientation pointing posteriorly and upwards on the midclavicular line in the subcostal region and an image of the diaphragm obtained. A skin marking will then be made on each side of the probe and inferior to the probe. Subsequent measurements of the diaphragm will be guided by these skin markings.

While in this position and having obtained an initial B-mode image of the diaphragm in quiet breathing, the mode will be changed to M-mode and a freeze image obtained; diaphragm excursion and velocity measurements will then be taken in quiet breathing. The patient will then be asked to sniff and a freeze image of this used to take measurements of diaphragm excursion and diaphragm velocity. The diaphragmatic velocity will be calculated as the excursion/time elapsed (as indicated on the M-mode freeze image). The data collected will be baseline:

- Diaphragmatic excursion 0(cm)
- Diaphragmatic excursion 0(cm/s)

The primary anesthesia provider will then proceed to position and administer the supraclavicular block. The following details will be observed and recorded about the block:

- Block technique (intertruncal, corner pocket, intracluster)
- Local anesthetic used (type, concentration, total volume)
- Adjuncts used (type, amount/dose)

Upon administration of block, a timer will be started, and the following measurements will be taken at 15minutes and at 30minutes following the block:

- Respiratory rate(b/min)
- O2 saturation (%)
- Supplemental oxygen(lpm)
- Diaphragmatic excursion 0(cm)
- Diaphragmatic velocity 0(cm/s)
- Success of block(motor)
- Success of block(sensory)

The measurements of diaphragm excursion and velocity will be measured on quiet breathing and on sniff maneuver with the probe placed at the existing skin markings. The success of block will be assessed by motor and sensory assessment at the 15minute and 30minute marks. Motor assessment will be by finger flexion, wrist flexion and forearm pronation; from the motor response the success of motor block will be recorded as either incomplete, complete, or failed. Sensory assessment will be by assessment of pain sensation to pin prick at 15minute and 30minute mark; Success of sensory block will be recorded as either incomplete, complete, or failed.