COMPARATIVE STUDY ON EFFICACY OF ULTRASOUND GUIDED SUPRACLAVICULAR VERSUS COSTOCLAVICULAR BRACHIAL PLEXUS BLOCK IN PATIENT FOR ARTERIOVENOUS FISTULA SURGERY

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First and foremost, I praise and thank Allah the Almighty for His blessing throughout my years in completing this research successfully.

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LIST OF SYMBOLS AND ABBREVIATIONS

ASA	American Society of Anesthesiologists
BMI	Body mass index
CAD	Coronary artery disease
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CVA	Cerebrovascular accident
DM	Diabetes mellitus
ESRF	End stage renal failure
HPT	Hypertension
HUSM	Hospital Universiti Sains Malaysia
ICU	Intensive care unit
IQR	Interquartile range
MI	Myocardial infarction
MSA	Malaysian Society of Anesthesiologists
OR	Odds ratio
SCB	Supraclavicular brachial plexus block
CCB	Costoclavicular brachial plexus block
CCS	Costoclavicular space
USG	Ultrasound

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ABSTRAK

Pengenalan: Kebanyakan pesakit yang menghidapi penyakit kegagalan fungsi buah pinggang memerlukan pembedahan untuk menghasilkan fistula arteriovena iaitu sebagai tapak tempat suntikan untuk menerima rawatan hemodialisis. Kebanyakan daripada pesakit ini menghidapi komplikasi kesihatan yang menyebabkan pembiusan setempat brachial plexus adalah pilihan yang lebih baik dan dapat mengelakkan pembiusan penuh seluruh badan. Objektif kajian ini dilakukan adalah untuk membandingkan keberkesanan diantara pembiusan setempat supraklavikular dan kostoklavikular brachial plexus dibawah bantuan pengimejan ultrasound dalam pembedahan fistula arteriovena.

Kaedah: Sejumlah 70 pesakit yang menghidapi penyakit kegagalan buah pinggang yang dijadualkan untuk pembedahan menghasilkan fistula arteriovena di bahagian lengan dibahagi secara rawak kepada dua kumpulan .Kumpulan supraklavikular 35 kes dan kumpulan kostoklavikular 35 kes. Untuk kedua-dua kumpulan, jumlah isipadu ubat bius setempat yang sama digunakan iaitu 20ml 0.5% ropivacaine dan 10ml 1% lignocaine. Data demografik, kelajuan masa untuk bius setempat berkesan, kadar kesakitan untuk setiap prosedur, kadar kesan perfusi setempat direkodkan.

Keputusan: Terdapat perbezaan ketara kelajuan masa untuk pembiusan setempat berkesan sepenuhnya di saraf sensori dimana menunjukkan kumpulan kostoklavikular lebih cepat (10 ± 5) berbanding kumpulan supraklavikular brachial plexus block (15 ± 10) ($p < 0.001$). Kajian juga menunjukkan lebih cepat masa untuk pembiusan setempat berkesan sepenuhnya di saraf motor dalam kumpulan kostoklavikular block (10 ± 5) berbanding dalam kumpulan supraclavicular block (15 ± 10) ($p = 0.01$). Selain itu, tiada perbezaan ketara kualiti pembiusan setempat diantara kedua-dua kumpulan kostoklavikular dan supraklavikular ($p=0.573$). Tiada perbezaan ketara berkaitan kadar

skala sakit untuk kedua-dua prosedur supraklavikular block (1 ± 0) dan kostoklavikular block (1 ± 1) (p = 0.117). Kadar pengaliran darah setempat lebih tinggi dalam kumpulan supraklavikular block (0.48 ± 0.19) (p=0.013).

Kesimpulan: Kaedah kostoklavikular brachial plexus block adalah lebih berkesan berbanding kaedah konvensional supraklavikular brachial plexus block kerana keputusan kajian menunjukkan lebih cepat masa yang diambil untuk pembiusan setempat berkesan sepenuhnya. Kaedah ini boleh digunakan sebagai alternatif dalam pembiusan setempat untuk pembedahan arteriovenal fistula di kalangan pesakit kegagalan buah pinggang.

Kata kunci: Kostoklavikular brachial plexus block, supraklavikular brachial plexus block, pembedahan arteriovenous fistula.

ABSTRACT

Background: Most patients with end stage renal failure (ESRF) require placement of arteriovenous fistula (AVF) creation for receiving maintenance haemodialysis (HD). Most of them usually have multiple comorbidities that make brachial plexus block a good choice for providing anaesthesia and as an alternative to avoid general anaesthesia. This study objective is to compare the efficacy of ultrasound guided supraclavicular and costoclavicular brachial plexus block in providing anaesthesia for creation of AVF.

Methods: 70 adult patients with ESRF, scheduled for creation of AVF of the distal upper extremity were randomly divided into two equal groups: supraclavicular brachial plexus block (Group SC, n = 35) and costoclavicular brachial plexus block (Group CC, n = 35). For both groups, 20 ml of 0.5% ropivacaine and 10ml of 1% lidocaine are used. The measured parameters were speed of onset of motor and sensory blockade, quality of blockade including procedural related pain score, the patient's satisfaction and regional perfusion.

Results: There were significant faster onset to achieve complete anaesthesia ($p < 0.001$), complete paralysis ($p = 0.01$) in all sensory and motor nerves in costoclavicular block compared to supraclavicular block. There were significant different of regional perfusion where there was higher perfusion in supraclavicular block compared to costoclavicular block ($p=0.013$). There were no significant differences in quality of block ($p=0.573$) and procedural related pain score ($p = 0.117$) between supraclavicular and costoclavicular brachial plexus block.

Conclusion: Costoclavicular brachial plexus block is superior compared to supraclavicular approach in term of faster onset of sensory and motor blockade. For quality of block and procedural related pain score, costoclavicular brachial plexus block

is comparable to supraclavicular brachial plexus block. We concluded that this new technique at costoclavicular brachial plexus block can be used as an alternative to supraclavicular approach for providing surgical anaesthesia in patients with ESRF undergoing creation of AVF.

Keywords: *costoclavicular brachial plexus block, supraclavicular brachial plexus block, arteriovenous fistula surgery,*

CHAPTER ONE

INTRODUCTION

1.1 Background

The prevalence of end-stage renal failure (ESRF) cases is rising worldwide. Placement of arteriovenous fistula (AVF) is the procedure of choice for patients with ESRF receiving maintenance haemodialysis (HD). Patients with ESRF may suffer from serious complications like congestive heart failure, systemic hypertension, electrolyte imbalances, metabolic acidosis, coagulopathy and unpredictable intravascular fluid volume status that obligate the anaesthesiologist to avoid general anaesthesia and to use other alternative methods (1).

Brachial plexus block is often used in ESRF patients to provide anaesthesia for the creation or revision of AVF for haemodialysis access. It provides analgesia, sympathetic blockade, optimal surgical conditions and adequate duration of postoperative block that prevents arterial spasm and graft thrombosis. It also provides higher blood flow in the radial artery and arteriovenous fistula than is achieved with infiltration anaesthesia (2).

Many approaches can be used for brachial plexus block, such as axillary, supraclavicular and infraclavicular approaches. They were commonly performed by blind techniques or neurostimulation which may be associated with high failure rate and serious complications.

Nowadays, the intraoperative use of ultrasonography (USG) becomes more popular and much easier. Its use in these blocks increases the success rate and decreases complications (3). Ultrasound guidance brachial plexus block (BPB) enhances the view

of nerve bundles, provides real-time assessment of needle advancement, assists with avoiding key structures such as blood vessels, pleura and facilitates spread of local anaesthetic along the targeted nerves. The use of this non-invasive technology to view nerve bundles while performing nerve blocks has significantly improved the success rate of the block as well as the safety of the procedure. Moreover, total volume of drug required is also reduced due to precise location and direct visualisation of nerves when using ultrasound.

The supraclavicular and costoclavicular brachial plexus block provides anaesthesia and analgesia to the upper extremity below the shoulder. It is an excellent choice for elbow and hand surgery.

Supraclavicular brachial plexus block is known as spinal anaesthesia of upper extremities, produce rapid onset of blockade however higher incidence of complications (1,2). Common risks and complications associated with this technique include phrenic nerve block with diaphragmatic paralysis and sympathetic nerve block with development of Horner's syndrome. But these complications are typically self-limiting and do not require intervention and this may be reduced by the use of ultrasound guidance. Intravascular injection with systemic local anaesthetic toxicity and hematoma formation can also occur. To reduce the risk, high level of vigilance is needed due to the rich vascularity of the supraclavicular region. Several small vessels and the cephalic vein can often be visualized between the insertion site and plexus with colour flow Doppler and care should be taken to avoid vascular puncture and inadvertent intravenous injection. Besides that, pneumothorax occurs as often as 6.1%, which was an incidence reported in 1961. This complication is rare in the modern literature as this may be reduced using ultrasound guidance. (3)

A recently developed approach of infraclavicular brachial plexus block at Costoclavicular brachial plexus, pioneered by Karmakar et al. (4), and performed at the costoclavicular space (CCS). Using ultrasound, at costoclavicular approach, all of 3 cords of brachial plexus are well visible in single plane, cords are relatively superficial and clustered together lateral to axillary artery within the costoclavicular space and exhibit a triangular arrangement. (5) It targets the centre of the three neural cords lateral to the axillary artery. This result in a very rapid onset of brachial plexus blockade similar with supraclavicular approach but with better surgical effectiveness and fewer adverse events, but there is a little data and consensus regarding this new approach. (6)

1.2 **Study Rationale**

The prevalence of end-stage renal failure (ESRF) cases is rising worldwide. Placement of a arteriovenous fistula (AVF) is the procedure of choice for patients with ESRF receiving maintenance haemodialysis. Anaesthetic modalities used for AVF creation such as monitored anaesthesia care with local infiltration, regional blocks and general anaesthesia.

During the recent years it has become evident that the use of regional anaesthesia techniques considerably improves patient outcome. It is used as an alternative or adjunct to general anaesthesia for upper extremity surgeries. Regional anaesthetic techniques have been used to improve the success of vascular access procedures because of sympatholytic effects. The technique produces significant vasodilatation whilst minimally altering the patient's haemodynamic parameters.

Malinzak and colleagues suggested that use of regional blocks may improve the success of vascular access procedures by producing significant vasodilatation, greater fistula blood flow, sympatholytic effects and decreased maturation time while minimally altering blood pressure and heart rate.

According to a recent study, authors observed that infraclavicular brachial plexus block at costoclavicular approach, provided higher blood flow in the radial artery and arteriovenous fistula (AVF) in a Turkish population as compared with infiltration anaesthesia.

This result in a very rapid onset of brachial plexus blockade similar with supraclavicular approach but with better surgical effectiveness and fewer adverse events, but there is a little data and consensus regarding this new approach. (4)

Ultrasound-guided costoclavicular approach can be an alternative way of providing effective analgesia and safe anaesthesia for vascular access surgery of the upper limb. In this study, we aim to prove that the new approach of costoclavicular brachial plexus block is more effective than supraclavicular brachial plexus block in arteriovenous fistula surgery.

1.2 Literature Review

In the past decade many studies have been done to compare the effectiveness of supraclavicular versus infraclavicular brachial plexus block. However not much data comparing directly between supraclavicular and the new approach of infraclavicular at costoclavicular brachial plexus block.

Supraclavicular brachial plexus block is known as spinal anaesthesia of upper extremities, produce rapid onset of blockade however significant incidence of Horner's syndrome and pneumothorax as a complication. (1,2) Hemidiaphragmatic paralysis, a frequent complication of the brachial plexus block performed above the clavicle, is rarely associated with an infraclavicular approach. The costoclavicular brachial plexus block is emerging as a promising infraclavicular approach.

Chahyun Oh et al found that the incidence of hemidiaphragmatic paralysis is significantly lower with costoclavicular than with supraclavicular brachial plexus block.

Karmakar et al. (5) The costoclavicular brachial plexus block (CCB) is a recently introduced infraclavicular approach that targets three cords located lateral to the axillary artery in the costoclavicular space. Cords in this space are located more superficially than with the classical approach at the lateral infraclavicular fossa and are clustered, while maintaining a consistent anatomical relationship with each other.

The costoclavicular approach (CC-approach), pioneered by Karmakar et al. (6), and performed at the costoclavicular space (CCS), targets the centre of the three neural cords lateral to the axillary artery, and has been reported to produce rapid onset times.

For the SC-approach, the trunks and divisions of the brachial plexus arrange compactly superolateral to the subclavian artery at the supraclavicular fossa. Alternately, at the CCS,

all three cords of the brachial plexus are clustered together lateral to the axillary artery. Because of these anatomical advantages, the CCB is emerging as a promising infraclavicular approach, with several studies showing that the CCB can provide a successful and rapid onset of the blockade with a single injection of a relatively small volume of local anaesthetic.

Chun Wu Yang et al. Both infraclavicular and supraclavicular brachial plexus block had similar effect. The infraclavicular approach may be preferred to the supraclavicular approach when considering complications.

Zhi Yuen Beh et al.Ultrasound-guided costoclavicular approach can be an alternative way of providing effective analgesia and safe anaesthesia for vascular access surgery of the upper limb.

A few studies have shown that when vascular access surgery is carried out under brachial plexus block (BPB), the resultant upper extremity vasodilation and improved blood flow. This hemodynamic boost increases the chances of the draining vein dilating past the 2.5-mm and 4-mm diameter threshold required for successful AVF placement and maturation respectively.

CHAPTER 2
STUDY PROTOCOL

Study Objectives

2.1 General Objective

To compare the efficacy of ultrasound guided supraclavicular versus costoclavicular approach of infraclavicular brachial plexus block in arteriovenous fistula surgery.

2.2 Specific objectives

1.To compare the effect of supraclavicular and costoclavicular brachial plexus block on the speed of onset of blockade.

The proportion of complete sensory blockade will be assessed within 30 minutes after LA injection. The sensory blockade at 4 nerves will be evaluated and graded using a 3 point of scale at every 5 minutes until 30 minutes after LA injection

2. To compare the effect of supraclavicular and costoclavicular plexus block on success rate of block.

3.To compare the effect of supraclavicular and costoclavicular plexus block on sympathectomy like effect and regional perfusion.

2.3 Null Hypothesis

The new approach costoclavicular brachial plexus block is comparable to supraclavicular brachial plexus block in arteriovenous fistula surgery.

2.4 **Research Methods and Methodology**

2.4.1 **Research Design**

This is an interventional randomised controlled trial.

2.4.2 **Study Period**

2020-2022

2.4.3 **Study Population**

Target population: Involve patients scheduled for elective Arteriovenous Fistula surgery in HUSM from 2020-2022

2.4.4 **Study Area**

The study will be carried out in Hospital Universiti Sains Malaysia (HUSM) involving the following operating theatres:

- General operating theatre
- Trauma operating theatre

2.5 **Subject Criteria**

2.1.1 **Inclusion Criteria**

1. Age > 18 years old -60 years old
2. ASA 1 – 3
3. Undergo elective arteriovenous fistula surgery

2.1.2 Exclusion Criteria

1. Patients' refusal
2. Allergy to local anaesthetic agent
3. Pre-existing active neuropathy of the arm of undergoing surgery
4. Urea level >25
5. Pregnancy
6. Clavicle fracture

2.6 **Sample Size Estimation**

Two proportion formula is used to determine the sample size of this study by using the Power and Sample Size Calculation program. Based on the literature review (ShyamMeena et al. 2015), the SD of percentage of doing block is 0.07 and the mean difference is 0.05. To calculate the required sample size, we use $\alpha = 0.05$, power = 0.8, $p_0 = 0.4$, $p_1 = 0.8$, m = 1

The sample size per group is about 32. Considering 10% of drop-out rate, the sample size is 35. Total sample size required is 35 x 2 = 70 patients. Therefore, 70 patients will be enrolled into the study with 35 candidates per arm.

Sample size was calculated using G* power version 3.1.

2.7 **Sampling Method and subject recruitment**

The study requires approval from Ethics Committee of Universiti Sains Malaysia (USM) prior to the enrolment of the patients. Eligibility of the patients will be screened during preoperative assessment in the ward one day prior to surgery and patients who fulfil the inclusion and exclusion criteria will be selected. Procedure will be explained in detail as well as patient is reassured of the privacy and confidentiality of the data obtained. A written informed consent will be taken from each patient and its confidentiality is assured.

All the patients were fasted for at least 6 hours. No premedication given prior to operation for both groups of patients. Patient's anti- hypertensive medication will be served as usual in the morning with sips of clear fluids.

Upon arrival to operation theatre, all patients will be monitored based on standard anaesthesia monitoring (non-invasive BP, pulse oximetry (Sp02), electrocardiography

(ECG) and baseline BP, heart rate will be documented before procedure. All patient will receive supplemental oxygen (nasal cannula 3L/min). IV access at least 20G will be inserted in non-operated hand and titrated conscious sedation with midazolam to prevent anxiety during procedure and surgery. Level of sedation will be monitor during procedure, provided response to verbal stimulus is maintain. There will be assistant who monitor patient's vital sign throughout the procedure.

Patients who met the criteria for the study will be randomly divided into two groups. The patient were randomized to receive either supraclavicular plexus block (Group SC) or costoclavicular plexus block (Group CC). All blocks will be performed by experienced anaesthesiologists who have had experience with ultrasound-guided SC- or CC-approach before the research. Regional anaesthesia for arteriovenous fistula workshop was held on 27^{th}-28^{th} December 2019 at HUSM. Adequate training for supraclavicular and costoclavicular brachial plexus block under ultrasound guided.

For both the approaches, block will be perform using a portable ultrasound machine, wisonic ultrasound and a 22-gauge, 50-80mm, short-bevelled stimulating needle, stimuplex will be used for all participants.

For supraclavicular approach, the first step was to initiate an ultrasound scan for a satisfactory image, which was a short-axis view of the supraclavicular fossa and elliptical hypoechoic trunks and divisions arranged compactly superolateral to the subclavian artery. The anaesthesia provider initially oriented the needle tip to the target location, called the 'corner pocket', using an in-plane technique in lateral to medial direction, ropivacaine was injected after the accurate position was confirmed by ultrasound.

Subsequently, the remaining volume was administered into the centre of the main neural cluster formed by the trunks and divisions. The local anaesthetic 20mls 0.5% ropivacaine will injected slowly with intermittent aspiration.

For costoclavicular approach, the patients were placed in a supine position with the arm abducted at 90 degrees. When initially scanning from the midpoint of the clavicle toward the CCS, the three cords (lateral, medial, and posterior) could be visualized and were clustered tightly lateral to the axillary artery. The needle was advanced from the lateral end of the probe, in plane with the ultrasound beam. The same type and volume of LA was first injected to the targeted nerves when the desired sensory-motor responses of the areas innervated by the medial cord (finger flexion) or UN (which derives entirely from the medial cord of the brachial plexus. Subsequently, the remaining volume was injected to the lateral cord under closely observation with real-time ultrasound guidance.

The sensory and motor blockade at 4 nerves will be evaluated and graded using a 3 point of scale at every 5 minutes until 30 minutes after LA injection. Both patient and observer will be double blinded, hence minimize assessment bias. Patient will be monitored in operation theatre post procedure by the medical officer in charge of respective OT. In case of fail block, rescue peripheral nerve block given (a second block after completion of an initial block). Infiltration of local anaesthetic agent (LA) into the surgical site. If still inadequate block, the case will be converted to general anaesthesia technique and if any emergency occur from the procedures will be treat accordingly.

At the end of the surgery, patients are transferred to the post anaesthesia care unit (PACU) for observation.

2.8 **Research Tool**

Patients were randomly allocated to one of the two study groups: supraclavicular (SC) or costoclavicular (CC) block. The drawing sequentially numbered, sealed, opaque envelopes were prepared, and they contained a card with the computer-generated allocation number:1 = SC-approach, 2 = CC-approach. The envelopes were prepared and announced by a research assistant who no longer engaged in further study. Outcome assessors were blinded to the randomization sequence and in charge of evaluating and recording clinical data. SPSS version 26 will be used for statistical analysis and independent t test will be used.

2.9 **Operational Definition**

SPEED OF ONSET

- The primary outcome was the proportion of complete sensory blockade at 30 min after LA injection.
- The sensory blockade of the four nerves was evaluated and graded every 5 min until 30 min after injection by double-blinded observers using a 3-point scale (0 = no block, 1 = partial anesthesia, 2 = complete anesthesia).
- Similarly, motor block was tested and graded according to a 3-point scale (0= no block; 1= paresis, 2= paralysis).
- The overall sensory and motor scores were calculated for every patient at the predetermined intervals. For purposes of standardization, the complete sensory or motor blockade were defined as score was equal to or greater than 7 points.
- The onset times were defined as the measured interval when a complete sensory or motor blockade was achieved.
- Sensory blockade was evaluated in the cutaneous distribution of each nerve using a cold test on the following: the lateral forearm for the musculocutaneous nerve

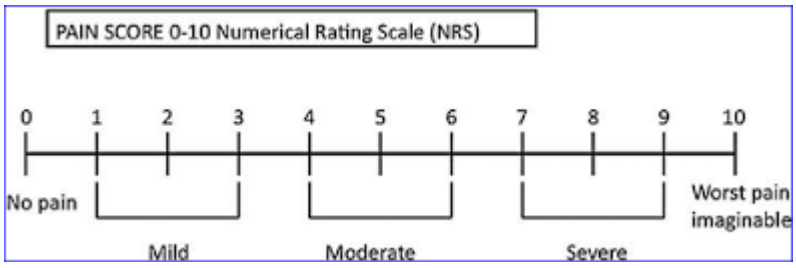
(MCN), the palmar aspect of the second finger for the median nerve (MN), the dorsum of the hand between the thumb and second finger for the radial nerve (RN), and the ventral side of the fifth finger for the UN.

- Motor blockade of each nerve was evaluated by elbow flexion (MCN), wrist flexion and opposition of the second and third fingers and the thumb (MN), wrist extension (RN), and flexion and opposition of the fifth finger toward the thumb (UN).

QUALITY OF BLOCK

- Successful of blockade 30 minute after needle withdrawal,
- Surgical anaesthesia Painless surgery without requirement for block supplementation
- Patient satisfaction -procedural related pain score

Pain scores describe as;



REGIONAL PERFUSION

Basilic Vein diameter will be evaluate using the colour doppler ultrasound before and 30 minute after administration of the LA regional block.

2.10 **Data Collection Method**

Patients' medical and anaesthesia records will be reviewed, and all relevant data will be identified and recorded into a data collection sheet. The following parameters are recorded:

The patients' sociodemographic data:

• Age, gender, weight, height, BMI

• ASA physical status classification

• Pre-existing co-morbidities: hypertension, diabetes mellitus, ischaemic heart disease, COAD, ESRF, active smoker, obesity, respiratory system disorder

Surgical data:

- Diagnosis and proposed operation
- Type of block
- Block performance time

Perioperative data

Vital signs Blood pressure, heart rate, SPO2

1. Speed of onset

   Sensory onset time: 0= no block, 1=partial anaesthesia, 2= complete anaesthesia

	5 min	10min	15min	20min	25min	30 min
Musculocutaneous nerve (Lateral forearm)						
Median nerve (Palmar aspect of second finger)						
Radial nerve (dorsum of hand between thumb and second finger)						
Ulnar nerve (Ventral side of fifth finger)						

Motor onset time: 0= no block, 1=paresis, 2=paralysis

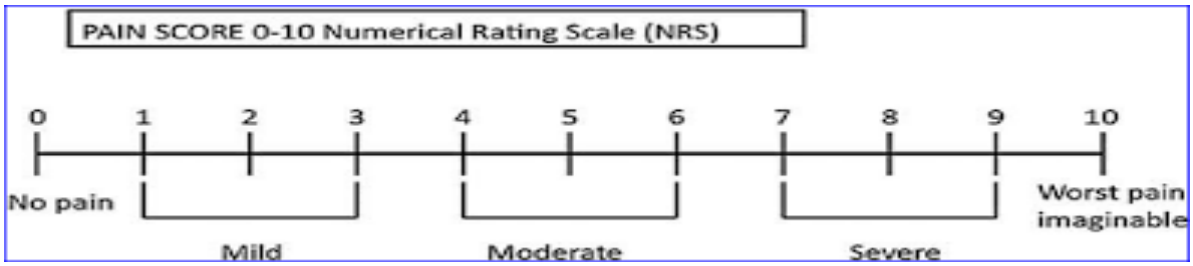
	5 min	10 min	15 min	20 min	25 min	30 min
Musculocutaneous nerve (Elbow flexion)						
Median nerve (Wrist flexion)						
Radial nerve (Wrist extension)						
Ulnar nerve (flexion and opposition of fifth finger toward thumb)						

2. Quality of block

Success rate of block

1	Complete block. Adequate block for surgery(sensory/motor)
2	Partial block. Require supplementation of LA
3	Failed block. Require conversion to GA

Procedural related pain score



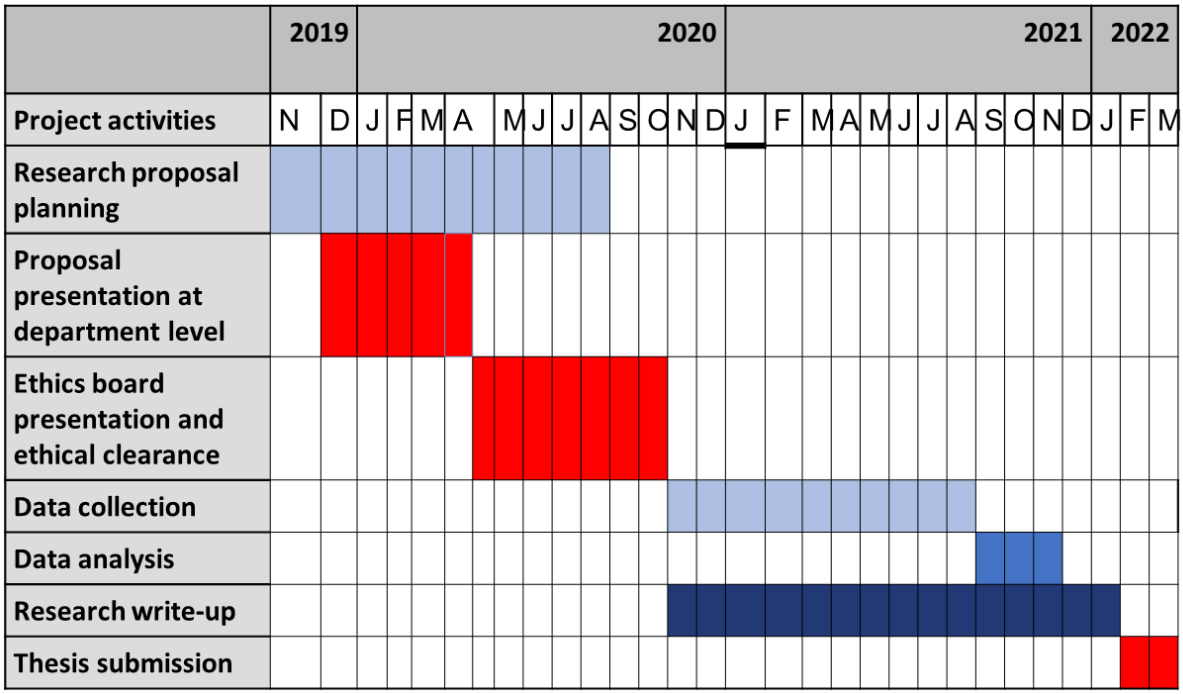
3. Regional perfusion

	Before blockade	30 minutes after blockade
Basilic vein diameter (cm)		

2.11 **Proposed Data Analysis**

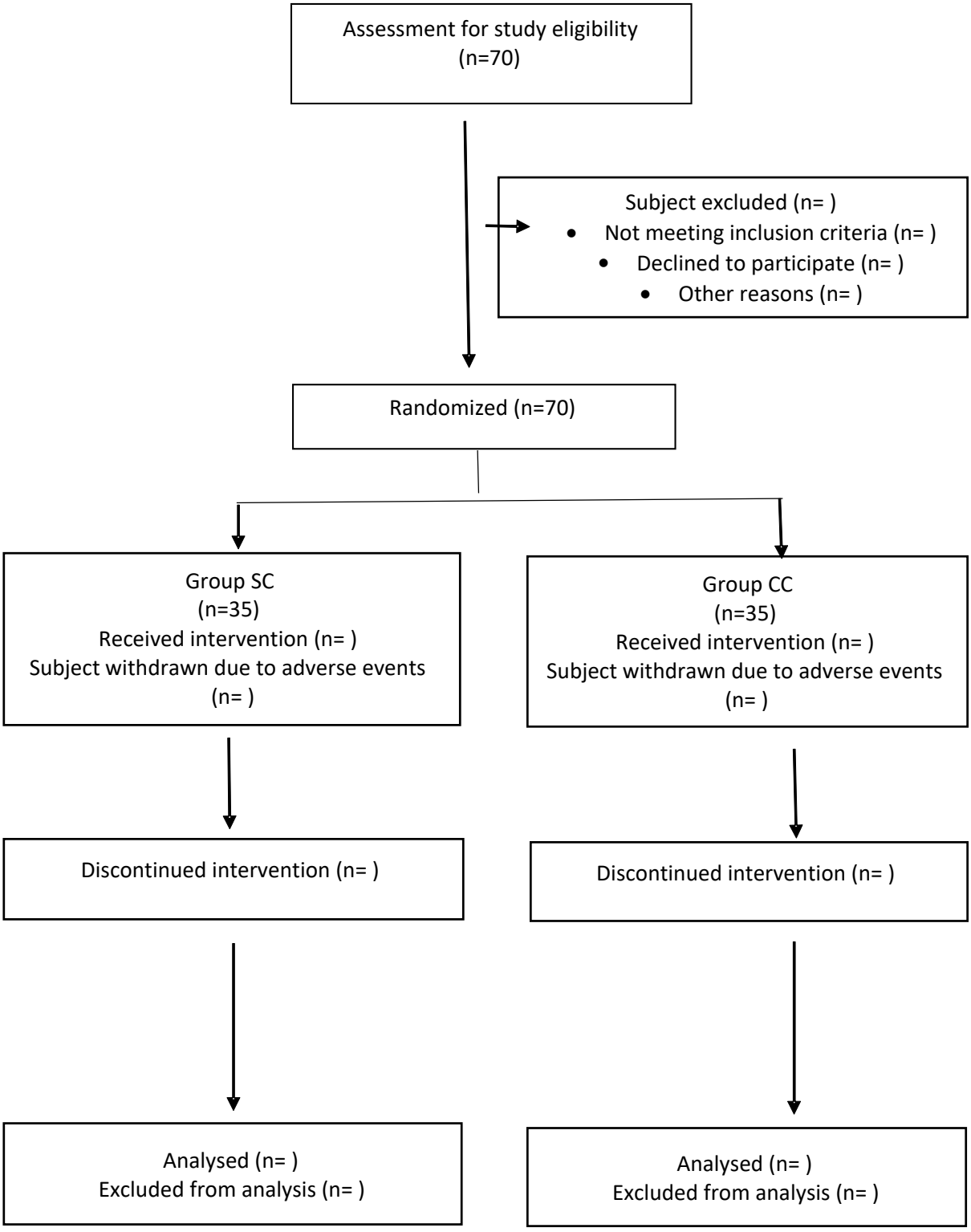
All data were entered and analyzed using IBM Statistical Package for the Social Sciences (SPSS) for macOS 26.0. Descriptive statistics was used to summarise the demographic and clinical characteristic of the patients. Numerical data was presented as mean (standard deviation, SD) or median (interquartile range, IQR) based on their normality distribution. Categorical data was presented as frequency (percentage, %)

2.12 **The Gantt chart**



2.13 **Study flow chart**

Study flow chart according to CONSORT guideline



2.14 **Ethical Consideration**

2.14.1 Subject *Vulnerability*

This study will commence only after a full review and authorisation from the ethics review panel of the Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM). The subject file is under the care of the investigator. The data will be independent and will not be disclosed to the management authority to be used for any achievement assessment and decision related to work. There is no direct potential harm to the participants as only the patient's file and anaesthesia record will be examined.

2.14.2 Declaration of conflict of interest

All investigators conducting this study are practising as anaesthesiology residents and specialist under the health and education ministry and are not affiliated with any third party that may influence the outcome of this study. Neither the patient nor the principal investigators will receive any form of reimbursement or incentives from the drug company.

2.14.3 Privacy and Confidentiality

All information obtained in this study will be kept and handled in confidential manner, in accordance with applicable laws and/or regulations. All forms are anonymous and will be entered using unique numbers into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the responders individually

2.15 Ethical Approval

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)

Human Research Ethics Committee USM (HREC)

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JEPeM Code : USM/JEPeM/20120629
Protocol Title : Comparison of Efficacy of Ultra-Sound Guided Supraclavicular Versus Costoclavicular Brachial Plexus Block in Arteriovenous Fistula Surgery.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/20120629**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **20th April 2021** until **19th April 2022.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:

1. Dr. Sanihah Che Omar
2. Assoc. Prof. Dr. Rhendra Hardy Mohd Zaini
3. Prof. Dr. Nik Abdullah Nik Mohamad

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical documents were included in the review on which this approval was based:

1. Patient Information Sheet and Consent Form (English version)
2. Patient Information Sheet and Consent Form (Malay version)
3. Data Collection Sheet

The list of JEPeM-USM members present during the full board meeting reviewing your protocol is attached.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form.**
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**

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4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019.**
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

Sincerely,

ASSOC. PROF. DR. AZLAN HUSIN
Deputy Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)

Human Research Ethics Committee USM (HREC)

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Date of meeting : 31st January 2021
Venue : Through WEBEX Application
Time : 9.00 a.m – 3.30 p.m
Meeting No : 493

Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name)		Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
Deputy Chairperson: Associate Professor Dr. Azlan Husin		Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Deputy Chairperson)
Secretary: Mr. Mohd Bazlan Hafidz Mukrim		Science Officer	M	✓
Members :				
1.	Assoc. Prof. Dr. Garry Kuan Pei Ern	Lecturer, School of Health Sciences	M	✓
2.	Mrs. Intan Rohani Tan	Community Representatives	F	✓
3.	Prof. Dr. Irfan Mohamad	Lecturer, School of Medical Sciences	M	✓
4.	Mr. Khairul Ithma Mahdi	Assistant Registry, School of Health Sciences	M	✓
5.	Assoc. Prof. Dr. Mohd Hashairi Fauzi	Lecturer, School of Medical Sciences	M	✓
6.	Dr. Munirah Mohd Adnan	Lecturer, School of Dental Sciences	F	✓
7.	Mrs. Normah Salleh	Community Representatives	F	✓
8.	Prof. Dr. Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	M	✓
9.	Assoc. Prof. Dr. Wong Kah Kang	Lecturer, School of Medical Sciences	M	✓
10.	Mrs. Zawiah Abu Bakar	Community Representatives	F	✓

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

ASSOC. PROF. DR. AZLAN HUSIN
Deputy Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
Universiti Sains Malaysia

CHAPTER 3: MANUSCRIPT

3.1 Title Page

Title

Comparative Study on Efficacy of Ultrasound guided Supraclavicular versus Costoclavicular Brachial Plexus Block in patients for Arteriovenous Fistula Surgery

Running head

Ultrasound guided Supraclavicular versus Costoclavicular Brachial Plexus Block in patients for Arteriovenous Fistula Surgery

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No conflict of interest between the authors and other research parties should be declared