“Ultrasound Guided Bilateral Pecto-intercostal Fascial Block: Role as a Preemptive Analgesic Adjunct in Fast-tracking for Mitigating Postoperative Sternotomy Pain.”

DISSERTATION

Submitted for partial fulfilment of the requirement for the Degree of Doctorate in Medicine in Cardio-Thoracic and Vascular Anaesthesiology

by

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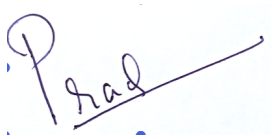
DECLARATION

I hereby declare that the thesis entitled ***"Ultrasound guided Bilateral Pecto-intercostal Fascial Block: Role as a preemptive analgesic adjunct in fast tracking for mitigating postoperative Sternotomy Pain."*** has been prepared by me under the capable supervision and guidance of **Dr. Subin Sukesan,** Associate Professor, Department of Cardio-thoracic and Vascular Anaesthesiology, **Prof. Senior Grade (Dr.) Rupa Sreedhar,** Professor & previous Head of Department of Cardio-thoracic and Vascular Anaesthesiology**, Prof. (Dr.) Shrinivas Gadhinglajkar,** Department of Cardio-thoracic and Vascular Anaesthesiology, **Prof. (Dr.) Prasanta Kumar Dash**, Department of Cardio-thoracic and Vascular Anaesthesiology, **Prof. (Dr.) Suneel P. R**, Department of Cardio-thoracic and Vascular Anaesthesiology, **Prof. (Dr.) Unnikrishnan K. P**, Department of Cardio-thoracic and Vascular Anaesthesiology, **Dr Saravana Babu**, Assistant Professor, Department of Cardio-thoracic and Vascular Anaesthesiology, **Dr. Varghese T.P**, Additional Professor, Department of Cardio-thoracic and Vascular Surgery, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram, Kerala.



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CERTIFICATE

This is to certify that the thesis entitled **"Ultrasound guided Bilateral Pecto-intercostal Fascial Block: Role as a preemptive analgesic adjunct in fast tracking for mitigating postoperative Sternotomy Pain."** is the bonafide work of Senior Resident, ***Dr. Pradeep A.P,*** conducted by the Department of Anaesthesiology, at Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram, under our supervision and guidance. He has shown keen interest in preparing this study for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology.

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1

INTRODUCTION

1

INTRODUCTION

Peri-operative pain from any surgery or pain perception threat from any surgery, are a major deterrent for any patient seeking treatment for treatable health conditions. Pain arising from skin incision and concerned operative sites are the corner stone for target by the treatment modalities in advanced modern day medical care scenarios.

Post-operative pain in patients are contributed by visceral and somatic components of afferent nerves. The perception regarding the severity of pain as experienced by patients, is directly proportional to the extent of tissue damage caused by the surgical trauma or inflammation.(1) In addition to the above mentioned factors for perceiving the severity of pain, the pre-operative anxiety level, the particular analgesic protocols, liberal use of analgesics followed on a case to case basis are all determining factors for the final outcome of the pain related experience.(2).

Cardiac surgery is one among many surgical situations, where there is an extensive damage occurring to the tissue, the ensuing inflammatory response to the exposure of extra corporeal circuit and the added insults from surgical trauma continues to remain profound.(3) Inadequate management of pain can result in serious derailment of not only the underlying deranged general conditions, but at the same time can affect the function of cardio-vascular, respiratory, metabolic and immunologic system functioning. Inadequate control of pain leads to a greatly reduced muscular and physical activity, which can directly be attributed to a prolonged rehabilitation phase, hospital stay and associated increased incidence of respiratory and cardiovascular complications. (3,4)

Despite the current advancements in the field of pain management, patients belonging to this subset of cardiac surgery with sternotomy incision, still can experience some pain postoperatively.

Currently Opioids are the mainstay of treatment for the pain management in almost all of the cardiac intensive care setups, even though they have side effects related to excess of sedation, nausea and vomiting (5) Adjuvant neuraxial block in cardiac surgery may definitely have an advantage of opioid sparing. However neuraxial techniques are not so popular because of the possibility of developing epidural haematoma, especially during the use of anticoagulation in cardiac surgery.(6) The other reason for the reluctance to use any neuraxial block technique in cardiac patients, are about the sympatholysis concerns, induced by the neuraxial analgesia techniques causing haemodynamic instability and the fear of infection in the infection. These above contributing factors resulted in reluctance or non-acceptance of this already established modality for Cardiac-surgery patients, which otherwise for non-cardiac surgeries are a standard norm for regional analgesia and anaesthesiology. We intended to use these studies for making these regional nerve block analgesia-anaesthesia techniques for getting commonly incorporated for adult cardiac surgery as an adjuvant or preemptive analgesic techniques in addition to standard opioid based intravenous analgesic techniques.

The ideal way to improve the quality of pain control for sternotomy pain with ensuing systemic heparinisation and nearly abolish postoperative breakthrough pain while curbing the side effects associated with systemic analgesics are still an enigma. Preemptive analgesia coupled with regional nerve blocks or other neuraxial blocks along with systemic analgesics can provide better postoperative pain control while sparing excess opioids usage.(7)

AIMS AND OBJECTIVES

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1. Primary Objective - To assess the quality and effectiveness of postoperative pain relief offered by ultrasound guided bilateral single shot parasternal pecto-intercostal fascial block after fast-tracking tracheal extubation, when the block administered is before surgical incision providing preemptive analgesia.

2. Secondary Objectives –
    a. Effects of the blockade on sedation-alertness, respiration-ventilation and requirement of concomitant analgesics during the post-operative care setting.

    b. To assess the patient cooperation and patient comfort while performing the deep inspiratory exercises, coughing, and incentive spirometry, in the immediate post Tracheal-extubation period.

Hypothesis:

1. We hypothesize that, a single shot ultrasound guided bilateral parasternal pecto-intercostal fascial plane block using long-acting anaesthetic (0.5% Levobupicaine preservative free), after the induction of anaesthesia will be having a preemptive analgesic and adjuvant effect to intravenous analgesics and facilitate fast tracking with mitigation of post operative pain.

2. This synergistic effect would be additive and will extend well into the postoperative period providing adequate analgesic cover, avoiding the need for the rescue analgesia with opioid sparing effect in post operative period.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

ACUTE POST-OPERATIVE PAIN

The acute pain in post operative period is directly proportional to the extent of tissue damage. Damage to the tissues result in release of chemical molecules like Substance P, Bradykinin, Leukotrienes, Cytokines which are directly involved in the pain perception.(8) Release of these chemical messengers has got regional and remote effect of sensitisation both at the site of injury as well as central nervous system. This leads to the activation of dormant nociceptors at the site of injury and surroundings. Peripheral sensitisation leads to excessive pain stimulus at the surgical wound site while central sensitisation leads to primary hyperalgesia ,pain at the wound site and secondary hyperalgesia ie; pain in the surroundings. This pain induced by sensitisation of pain receptors is of diffuse in nature and will last for longer duration. (9)Thus the pain response elicited depends directly on the amount of surgical trauma in inflammatory response.

Physiological effect of pain on different body systems are wide and profound. Pain can seriously derail the function of cardio-respiratory function. The muscular immobility and tension attributed to acute pain in post-operative cardiac surgical patients can result in a significant reduction in the functional residual capacity, acquired tidal volume per body weight, and vital capacity.(10) The compliance of the lungs are observed to be significantly reduced in such patients with poor control of post-operative pain. Naturally the end result in such scenario will be arterial blood desaturation.

Painful stimulus leads to activation of sympathetic nervous system. This leads to increase in heart rate, myocardial contractility, and causes increase in the tension of myocardial fibres. (11) This also ensues in defuse constriction of blood vessels and reduction the peripheral blood flow, which can result in decreased venous return and can cause deep vein thrombosis and related

embolic complications. Excessive sympathetic system activation can result in reduced bowel motility and sphincter spasm of bowel and urethra.(11)

Effect of acute pain stimulus on endocrine stimulus involves an up regulation of hormones like cortisol, ACTH, catecholamines. The production and secretion of insulin hormone is reduced significantly which leads to a state of relative insulin resistance, hyperglycaemia and leads to a general state of catabolism.(12) Pain results in activation of renin-angiotensin-aldosterone path way and results in vasoconstriction, hypertension. It also leads to salt and retention and can aggravate oedema. (13)

Pain can cause suppression of immune system results in poor wound healing and increased chances of infection. There can be increased platelet aggregation and an increased chance of thrombotic complications in the peri-operative period .The effect of severe pain can result in anxiety and sleep disorders and in extreme case results in depression.(14)

CHRONIC POST-OPERATIVE PAIN

Pain lasting more than the expected duration after cardiac surgery signifies development of Chronic Post-Operative Pain (CPOP). CPOP, by itself is an entity where in patients may suffer from varying degrees of pain.

According to the definition suggested by Werner and Kongsgaard Chronic Post-Operative Pain (CPOP) can be defined as a pain that occurs after the surgery or increases in intensity and necessarily lasts for at least a period of 3-6 months causing serious derailment of quality of life. The

pain may appear as a continuation of the acute pain or it may reappear after a period of asymptomatic phase. The pain may be localized to the surgical field or to the dermatomal level associated directly with one of the nerves injured in the surgery.(15) While diagnosing Chronic Post-Operative Pain (CPOP) it is important to rule out secondary causes of pain like myocardial ischemia, mediastinitis, or sternal instability.

Pathophysiology of Chronic Post-Operative Pain (CPOP) is still unclear. It was noted that the injury to the nerves causing altered afferent impulses could be a cause to this debilitating condition. (16) The need of effective pain control in the immediate post-operative hours may be very important in this regard. For every 10% increase in the time spent in severe pain in the post-operative period the risk of development of CPOP increases by about 30% (17) Female sex, younger age, prolonged surgery, anxiety are all possible risk factor for CPOP development. (16)Cardiac surgery is one situation associated with relatively high incidence of CPOP (30-55%). Hence our goal should be to achieve the best possible control over pain.

ANATOMY OF INTERCOSTAL SPACE & NERVE SUPLY OF THORACIC WALL

Intercostal Spaces and Intercostal Muscles

The spaces between the ribs anteriorly is occupied by three respiratory muscles. From outside to inside they are external intercostals muscle, internal intercostals muscle and the innermost intercostal muscle (transverses thoracic muscle) respectively. (18) External intercostals muscle arises from the inferior border of the rib above and its fibers run in a downward and forward direction and inserts to the superior border of the rib below. Anterior fibers of the muscle forms a

thin aponeurosis and forms the anterior or external intercostal membrane which lies deep to the pectoralis major muscle and is quite often not discernible as a separate muscle layer in ultrasound imaging.(18)

Internal intercostal muscle forms the intermediate layer .It arises from the subcostal grove of the rib above runs downward and backward and inserts to the upper border of the rib below. Posterior most portion of this muscle is forms the thin layer of aponeurosis forming the posterior intercostal membrane.(19)

Innermost intercostal muscle (Transversus thoracic) forms the deepest layer. It is frequently an incomplete layer of muscle and in many cases overlaps more than one intercostal spaces. Internal aspect of this muscle is lined by the endothoracic facia followed by the parietal pleura. The facial plane between internal intercostal muscle and the innermost intercostal muscle is traversed by the intercostal vessels and nerve. From above downwards they are in the order as intercostal vein, artery, and intercostal nerve.

Intercostal Arteries and Veins

Posterior intercostal arteries: In the first and second posterior intercostal arteries originate from the superior intercostal arteries which are branches of costo-cervical trunk of first part of subclavian artery. In the lower corresponding intercostal spaces the descending thoracic aorta give rise to the posterior intercostal arteries. Posterior intercostal veins drain to azygous and hemi azygous venous system.

Anterior intercostal arteries: First 6 pairs of anterior intercostal arteries are the braches of internal thoracic artery whereas the remaining six pairs are branches of musculo-phrenic artery ,which is the terminal branch of internal thoracic artery.(18) Anterior intercostal veins drain to the corresponding intercostal and musculo-phrenic veins.

Intercostal Nerves

Intercostal nerves are formed by the anterior rami of first 11 thoracic spinal nerves. The Anterior rami of the 12th thoracic spinal nerve lies in the abdominal wall forming the subcostal nerve. Each intercostal nerve enters the intercostal space between parietal pleura and posterior intercostal membrane. The intercostal nerves thus run forward and inferiorly along with the intercostal vessels in the corresponding intercostal space between the internal intercostal muscle and the innermost intercostal muscles. First 6 pairs of intercostal nerves lies in the corresponding intercostal spaces while the intercostal nerves 7-9 leaves the anterior ends of the intercostal spaces by penetrating deep to the costal cartilage. 10th and the 11th intercostal nerves pass directly to the abdominal wall since the respective ribs are floating.(19)

Branches of Intercostal nerves

- Sensory Branches: Supply the corresponding parietal pleural surface .
- Peritoneal sensory branches: Intercostal nerves 7 -11 supply the parietal peritoneum Rami Communicantis: connects the intercostal nerve to the corresponding sympathetic ganglion
- Collateral Branch: Connects the intercostal nerve the main nerve below.
- Lateral Cutaneous Branch: Originates at the angle of rib reaches on the side of the skin on chest and then divides in to anterior and posterior branches.

- Anterior Cutaneous Branch: Formed as a continuation of the main trunk of intercostal nerve, pierces the muscle layer in the parasternal area divides in to medial and lateral branches.
- Muscular Branches: Supply the intercostal muscles
- Pleural and peritoneal sensory branches.

Special Features

First Intercostal Nerve join to the brachial plexus by a large branch similar to lateral cutaneous nerve, it has no anterior cutaneous branch. The 2nd intercostal nerve is joined to the medial cutaneous nerve of arm and known as intercosto-bracheal nerve which supplies the skin of armpit and the upper medial aspect of arm.(19)

Regional Blocks for Pain Mitigation and Fast Tracking in Cardiac Surgery

The possibilities of regional anaesthesia are ever increasing in the cardiac anaesthesia. Greater numbers of regional anaesthesia techniques have been introduced in to the field of cardiac surgery in the past decade. The use of conventional thoracic epidural analgesia and the paraspinal nerve blocks are not quite widely accepted in cardiac surgery for fear of neuraxial bleeding related complications. Combinations of Pectoralis Nerve Block 1 (PEC1) and Pectoralis Nerve Block 2 (PEC2) nerve block have shown some efficiency managing pain due to sternotomy.

Epidural Analgesia in Cardiac Surgery:

Thoracic epidural anaesthesia and analgesia is now an established gold standard for the postoperative pain relief. All other regional anaesthesia modalities are in comparison to the efficacy and risk to benefit safety standards established in Thoracic epidural review given by various published scientific literatures.

Thoracic Epidural Analgesia provides superior analgesia compared to other regional methods. Incidence of respiratory complications and duration of mechanical ventilation are seen to be reduced in the patients receiving epidural underwent cardiac surgery.(20) In short, it helps in a better and speedy recovery and significantly shortened rehabilitation phase.

The settings involving perioperative Cardiac surgery, introduces a finite theoretical risk of encountering spinal haematomas in comparison to other comparative subset of non-cardiac surgery. The use of dual antiplatelet drugs, heparinization and Cardiopulmonary bypass run are a common contributing factor. The incidence of epidural hematoma is widely under reported in cardiac surgery.The risk of spinal hematoma is increased with repetitive puncture attempts, bloody tap, patient medications like anticoagulants and anti-platelet drugs The recent meta-analysis, currently availableshows that the risk of developing any spinal hematoma by itself, is not increased when compared to the settings of non-cardiac operation. However the incidence of serious complications like spinal hematoma albeit small is a precluding factor in the widely non acceptance of thoracic epidural analgesia in cardiac surgeries.

Paravertebral Nerve Block:

The use of paravertebral block is considered as an alternative to the Thoracic Epidural for Cardiac and robotic cardiac surgeries as an adjuvant for analgesia in anaesthesia practice.

Paravertebral block is widely used in thoracic surgeries and provides excellent pain relief. Bilateral paravertebral nerve block is used to mitigate sternotomy pain in cardiac surgeries, owing to the availability of ultrasound guided imaging and the ease of administration**.**(22)

Paravertebral space is a wedge space present lateral to the inter-vertebral foramen, where the spinal nerves emerge.This space is anatomically bounded by parietal pleura forming the anterior and lateral boundaries; base formed by posterior-lateral portion of the vertebral body, the

intervertebral discs and foraminae, and posterior border is formed by superior costo-transverse ligament. (23) The space is filled with fat and the nerves, which lack facial coverings and hence are highly sensitive to the action of local anaesthetics.(24) A single shot 15-20 ml bolous injection of the local anaesthetic drugs can effectively block both somatic and sympathetic output. Injection in this space allows cephalic and caudal spread of the drugs, and the ensuing block extension effect to cover at least 5 dermatomal levels. It can allow spread of local anaesthetic drugs also to the contra-lateral paravertebral space and laterally to the inter-costal spaces. This space can easily be accessed approximately 3 cm lateral to the spinous process. Ultrasound guided procedures allows nearly 100% success rate and the associated complication rate is also very low. However there are theoretical risks like pneumothorax, haematoma, dural puncture involved and can still persists, especially in inexperienced hands. (25,26)

The main drawbacks considered for the paravertebral block in perioperative Cardiac surgical settings are about the concerns involving the discomfort arising from the change in patient positioning with endotracheal tube in anaesthetised patients and with postoperative care settings with sternotomy pain; making the other regional nerve blocks, as an alternative being considered with the ease of ultrasound guided administration and rapid procedure planning execution.

Pectoral Nerve Blocks:

The use of ultrasound guided regional nerve block technique has gained a forefront in recent years for analgesia and anaesthesiology. Involving anaesthesia for cardiac surgeries there are limited randomised control studies using combined regional nerve blocks as preemptive analgesia modality for postoperative analgesia in fast tracking scenarios.

The combined Pectoral nerve block (PECS) 1& 2 can be used to provide analgesic cover in cardiac surgery. It is facial plane block. PECS-1 block targets the plane between Pectoralis major and

Pectoralis minor muscles opposite to 2nd and 3rd ribs where it blocks medial pectoral (C8, T1) and lateral pectoral nerve (C 5-7). PECS 2 block targets the plane between Serratus anterior muscle and pectoralis minor, opposite to 3rd and 4th ribs. This block intends the targeting of the 2nd to 6th intercostal nerves.(27)

The use of this block in regional anaesthesia analgesia techniques for non-cardiac perioperative settings made the renewed interest in the scenarios of cardiac post-operative settings where the ease of administration and the flexibility of prompt procedure execution option exists without any altering of the patient positioning.

Erector Spinae Plane Block:

This regional nerve block technique is considered easier to perform under ultrasound guidance and is associated with lesser procedural risk complications as compared to the Paravertebral nerve blocks.

This block is a fascial plane block. It targets the myofascial plane deep to the erector spinae muscles. For sternotomy pain, a bilateral single shot erector spinae plane block 3 cm lateral to T5/ T6 vertebral spine can be used. A single shot bolus injection of approximately 20 ml allows an anterior and cephalo-caudal spread. This facial plane block provides pain relief at T 2-T12 dermatomal levels. Ultrasound allows accurate placement of the needle for the anesthetic analgesic drug delivery for inducing nerve block and significantly reduce potentially associated complications and block failure. One major advantage apart from the ease of performance of this block is that, it is away from vascular structures and parietal pleura and it also allows catheter placement in the anatomical space for providing postoperative analgesia. (26)

Transversus Thoracic Plane Block:

This regional nerve block technique is a parasternal myofascial plane block. The myofascial plane between innermost intercostal muscle and internal intercostal muscles is targeted. The intercostal arteries and the main trunk of intercostal nerve travel in this plane. The main trunk of inter-costal nerve is pharmacologically blocked before it pierces the muscle planes and divides into medial and lateral branches. It allows effective pain control in the midline and para-median areas of skin and parietal pleural surfaces within the anterior six intercostal spaces.(29)

The major advantage of the block is that it allows a better vertical spread of the drug beyond intercostal spaces. One single bolus injection can give analgesic cover to the anterior six intercostal spaces.(29)

The major disadvantage about this block is that the procedure technique has the target site bearing proximity to the vascular structures. The first three pairs of anterior intercostal arteries are branches of internal thoracic artery. The Internal thoracic artery which is harvested for bypass grafting also courses in the compartment of the target anatomical space. This theoretically increases the chances of injury to vascular structures with haematoma formation and interference with potential failure concerning internal mammary artery harvest.(29)

The innermost intercostal muscle (Transversus - thoracic muscle) is generally very thin anteriorly and often is not appreciable as a separate layer from pleura, especially when imaged in long axis. This may increase the chances of pleural puncture. Hence short axis imaging is the preferred ultrasound guided axis being used to confirm the muscle planes. (30)

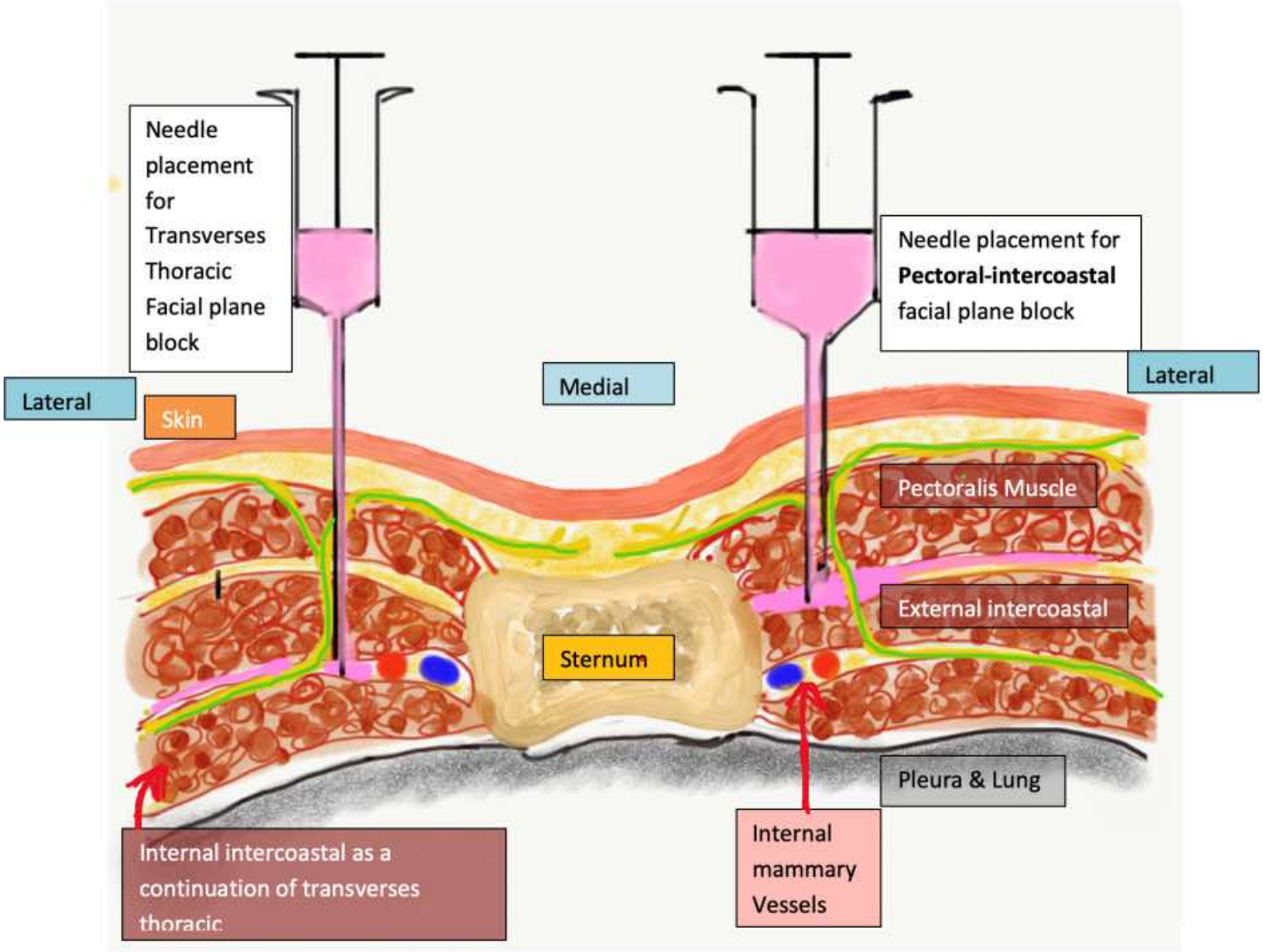
Pectero-Intercostal Fascial Plane Block:

This regional nerve block technique is another variation with parasternal myofascial plane nerve block. (Figure 1)Here the area targeted is myofascial plane between pectoralis major muscle and internal intercostal muscle. This is similar to Transversus thoracic plane block, but at a different muscle facial plane, which allows blocking the anterior intercostal nerve before it divides to medial and lateral terminal branches. This block ~~can~~ effectively give analgesic cover to midline and paramedian area supplied by the first six pairs of anterior cutaneous nerves.(33)

One major advantage of this block is that the target site of the injection is away from vascular structures, which reduces chances of haematoma and injury to intercostal vessels and internal mammary vessels. This is definitely a probable advantage for coronary artery bypass surgeries, where harvesting the internal mammary artery is the cornerstone for total arterial revascularisation. (31) Since the site of block is anterior, the patient lying in supine position for surgery or postoperative care is also an ideal for ultrasound guided block, making the administration quick, prompt easy. Under ultrasound guidance the internal intercostal muscle is clearly visible underneath pectoralis major muscle in long axis view and myofascial plane can be easily identified, accessed and delineated during sonogram visualisation on administration of the pharmacological drugs for block.

The major disadvantage documented in scientific literature is that the vertical spread is often incomplete, which implies that, at least three injections on either side of sternum is required for covering the six intercostal spaces anteriorly to mitigate the pain stimulus arising from the skin and sternotomy.(31)

Figure 1. Artistic impression demonstrating the myo-fascial plain for the drug injection in Pecto-intercostal facial plane for regional anaesthesia when compared to Transversus thoracic-fascial plane block.



MATERIALS AND METHODS

MATERIALS AND METHODS

Design: Prospective, Double Blinded, Randomised Intervention study.

Setting: A tertiary referral centre, a university super-speciality hospital and single-centre (SCTIMST). The study was approved by the institutional ethics committee (IEC registration number: ECR/189/Inst/KL/2013/RR-16). After registering in ctri@gov.in (**CTRI/ 2019/10/021591),** 90 patients posted for elective CABG surgeries from 10/10/2019 to 10/06/2021 were included in the study. Patients coming for elective CABG surgery were randomised into two groups and ultrasound guided bilateral parasternal pecto-intercostal fascial plane block was performed in the study group with 0.5% Levobupivacaine limited to total volume to 0.05ml - 0.06ml/Kg per site. All other routine standard anaesthetic and analgesic protocols were followed intraoperatively and postoperatively in both the groups. In the control group no intervention or block was given.

Inclusion criteria

- Adult patients coming for elective cardiac surgery having CAD for CABG
- > 40 years old and < 75 years old
- Median sternotomy
- Patient undergoing Coronary Artery bypass surgery.
- Single surgeon
- Planned Fast tracking

Exclusion Criteria

- Emergency Surgeries.
- Poor native vessel targets for grafting

- Re-exploration for surgical bleed
- Redo-surgeries.
- Open Sternum
- Left Ventricular Ejection Fraction < 35%
- Preoperative use of narcotics or illicit drug abuse.
- History of chronic intractable non-cardiac pain.
- Liver or Kidney disease
- Allergy to Amide group of anaesthetics, Morphine or Fentanyl.
- Arrhythmia Allergy to Amide group of anaesthetics, Morphine or Fentanyl.
- Arrhythmia history or rhythm disturbances documented in ECG.
- Haemodynamically unstable patients, already on preoperative inotropic support or Intra-arterial balloon pumps(IABP).
- Anticipated prolonged surgery or Surgery lasting more than 6hrs.
- History or rhythm disturbances documented in ECG preoperatively.
- Intubation time lasting more than 12hrs or planned for overnight ventilation.
- Elective ventilation beyond 6 hrs after shifting to ICU post-surgery.
- Patients refusing to participate.
- Patients refusing to share their medical data for analysis.
- Patients refusing to participate after the start of study and desire to leave the study at any point of time.
- Patients currently enrolled in another study.
- Patients with inability to provide written informed consent.
- Inability to complete Pain assessments.
- Post-operative complications with underlying cardio-respiratory cause requiring return to operative room for re-explorations or reinstitution of mechanical ventilation.
- Patients refusing the offered therapeutic options in either group.

Study Protocol:

The patients recruited for the study were randomised to one of the two groups (GROUP A & GROUP B) for post-operative analgesia evaluation, by a Computer generated randomised number, using Block Randomisation technique, with blocks of ten numbers. Group A recruited as the intervention study group and the Group B were recruited as the Control Group.

Method of Randomisation and Blinding

Using Block Randomisation technique with Computer generated randomised number, the recruited patients were randomised to Group A & Group B with blocks of ten numbers. On the day prior to the surgery, all the listed surgical patient were screened after the completion of Pre-anaesthetic checkup. Those patients who met the inclusion criteria and consented for the participation in this trial were recruited for the study by the principal investigator. After obtaining an informed written consent for the study, allocation concealment was done by the principal investigator using sealed opaque envelopes for allocation of patients into either Group A or Group B.

The master list containing the allocation of randomised serial number with patient hospital identity number was not shared to anybody nor the guide or even statistician during analysis. The serial number were written on the top of envelope along with the bar code sticker with patient name and hospital number. The envelopes were then opened sequentially, by the co-principal investigator-guide, and the guide thereafter dispatched the data collection forms to the ICU anaesthesia incharge for the case recruited. and the drugs prepared

Envelopes were opened by the guide not involved in the conduct of cases. Conduct of anaesthesia was done by separate consultant and resident team posted for that scheduled case, keeping the standard in the hospital anaesthesia protocols practiced in our institute. The

instructions to be followed in each group were given to them. Intra-operative anaesthesia and pecto-intercostal facial plane block were administered by the anaesthesiologist.

All the patients who were enrolled in this trial participation were made familiarised for using the pain scoring documentation methodology, incentive spirometry and deep breathing and coughing exercises a day prior to the procedure.

Group B : (The control group) The basic anaesthesia care and the analgesic protocols were maintained exactly similar in both groups except no regional anaesthesia techniques were used in the control group. None of the Anaesthesia Technicians or Senior Resident and Consultant of the concerned Operation theatre knew about the recruitment of the case for study intraoperatively. This was taken up as per suggestions from the Institutional Ethics committee for avoiding the injection or intervention on patients on placebo arm or Control group being injected with Normal saline having proven with no analgesic and anaesthetic effects.

Group A: (Intervention Group) The intervention drug was prepared under the supervision of Principal investigator, and marked as per the computer generated random number for the patient. The drug was handed as the study drug for administering the block, without disclosing the content (drug or placebo) to the concerned theatre Anesthesia Technician assisting the anaesthesiology Senior Resident and Operation Theatre Consultant, for the administration of block, blinded to the content within the loaded syringe. After standard anaesthesia induction for the cardiac patients as per in-hospital protocols, direct vision in plane Ultrasound guidance imaging was used for giving the Single shot bilateral Pecto-intercostal facial block. The drug was with closed label prepared using 0.5% preservative free Levobupivacaine volume of 3 to 5 ml, with instructions for injection to the co-guide investigator. The drug for regional nerve block were injected on at least 3 sites on both sides, keeping the maximum dose not exceeding 2 mg/ Kg of Levobupivacaine. A drug volume of 3 to 5 ml were injected on each site on both sides for a total of 6 sites. The time lag between the administration of block and surgical skin incision was

deliberately ensured and kept at a gap of 20min. At the end of surgery, skin entrance site before putting the incision for the chest tube insertion, was infiltrated using the 5 ml of the closed labelled drug supplied by the Principal investigator, in the interventional group (Group A).

The total duration of mechanical ventilation, doses of sedative drugs, rescue analgesics given perioperatively and in intensive care unit, cooperation with physiotherapy, incentive spirometry, deep breathing and intense physiotherapy coughing exercises upto 24 hrs of post fast tracking were noted. All patients were assessed for pain and sedation scoring, which were done by the resident doctor in ICU and the attending staff nurse on duty who were blinded to the intervention and the control group.

Any patients with prolonged surgery lasting for six hours, tracheal intubation time more than 12 hours, or any patient requiring re-exploration or endotracheal re-intubation were excluded from the study and subsequent analysis.

The linking of the randomised chart to patient identity were done by the guide to segregate and correlate patient data into either of the study group labeled A and B with final statistical analysis.

Intraoperative Protocol:

On wheeling the patient inside operation theatre, non-invasive blood pressure (NIBP), pulse oximetric probe for oxygen saturation (SpO2) and electrocardiogram (ECG) for monitors–ing were attached. One large bore peripheral Intravenous cannula 14-18G were inserted in either of the dorsum of hand or cubital fossa in the arm. A 20G Arterial cannula under local anaesthesia was placed in the radial artery in the wrist area of the forearm. Aanaesthesia for endotracheal intubation was induced with standard doses of drugs and according to institutional practice using balanced anesthesia, titrating the desired response using Midazolam 100 mcg /Kg, Fentanyl 10 mcg/Kg, Propofol 1-1.5 mg/Kg, Pancuronium 100 mcg/kg.

Once patient's airway was secured, anaesthesia was maintained with Sevoflurane at a MAC of 1 %, which was continued throughout on CPB also, through the oxygenator in both groups. All the intraoperative anaesthesia protocol for both the study groups were as per institution protocol and remained same. Patients belonging to both groups were given additional dose of 5 mcg/kg fentanyl before incision. This was immediately followed by infusion of Morphine at 60 mcg/Kg/ hrs intraoperatively and was continued throughout on CPB and post CPB. Additional doses of fentanyl 5 mcg/Kg were further repeated before sternotomy in both groups. Additional dose of 100 mcg/Kg of Midazolam and Pancuronium 0.05 mg/Kg was given in both groups just before instituting the CPB and 100 mcg/Kg of Midazolam was repeated again at the starting of rewarming phase. Infusion rate of morphine was reduced to 20 mcg/Kg/hrs once the patients was shifted to the post operative ICU unit. Infusion of Morphine was reduced again to 10 mcg/Kg/hrs at least 4hrs before the planned tracheal extubation in both the study (Group A) and control groups (Group B) and was continued at the same rate into the post tracheal extubation period.

Patients in study group (Group A) were administered bilateral Pecto-Intercostal facial plane block (Figure 2a, b, c, d & e) after the airway was secured. Patients were placed in supine position and a high-frequency linear ultrasound probe was placed in a parasagittal plane 3 cm lateral from the mid-sternum. The Pectoralis major muscle, Internal intercostal muscle (IIM), ribs, and pleura were identified. A 26-gauge, one and half inch, echogenic needle was inserted in plane from caudal to cephalad direction until the tip got positioned between Pectoralis major muscle and IIM, and ideal positioning was confirmed with fluid spread in the plane between these muscles (Figure 1). The needle was positioned superficial to the 5th–6th rib space and was repositioned in a cephalad direction to target each rib space up to the 1st–2nd rib space. A total of 3 needle insertions were performed on each side to cover the 3 interspaces ensuring adequate longitudinal spread was done. The block administering co-investigator was also blinded to the injected drug. Closed labeled Levobupivacaine 0.5%, a total volume 10 to15 ml was injected not exceeding the minimum dose for toxicity was issued by the Principal investigator to the block

administering anaesthesiologist. The time lag between the administration of block and surgical skin incision was deliberately ensured and kept at a gap of 20min. At the end of surgery, skin entrance site for the chest tube insertion was infiltrated with 5 ml of 0.5% preservative free Levobupivacaine before putting the incision in the interventional group.

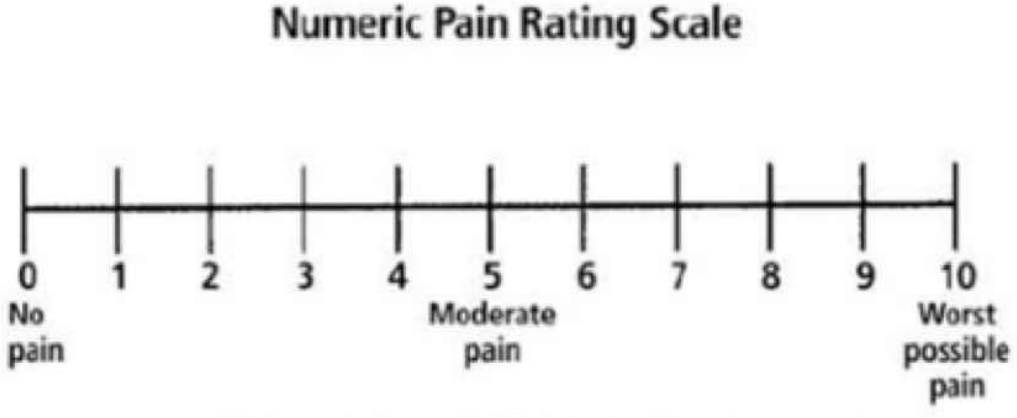
All patients were assessed for as per the proforma supplied along with the patient information chart. (Annexure 2.) This was done by the resident doctor in ICU and the attending staff nurse who were blinded.

Any additional need of sedative drugs, or rescue analgesia using intravenous Tramadol or Morphine bolus, determined from direct communication with the patient or by monitoring the altered vital signs of pain (e.g. sweating, increased blood pressure, and elevated heart rate above 20% or more of the patient's baseline values). Assessment of patient cooperation and patient comfort while performing the deep inspiratory exercises, physiotherapy coughing manoeuvres, and incentive spirometry, in the immediate post Tracheal-extubation period and thereafter at regular time interval were recorded.

Post-operative Protocol:

The quality and effectiveness of pain relief and effect of blockade on sedation were evaluated for 24 hrs at regular time intervals in all the fast tracked patients in either groups using following parameters:

A) Verbal Numeric Rating Scale (0-10) Figure. (3.)



B) Any postoperative requirement for additional supplemental analgesics.

C) Patient cooperation to deep inspiratory exercise and spirometry exercises at regular time periods after tracheal extubation.

D) Effects of the blockade on sedation was assessed by Ramsay Sedation Scale.

Ramsay Sedation Assessment Scale

Awake	Patient anxious or agitated or both	1
Levels:	Patient cooperative, oriented and tranquil	2
	Patient responds to commands only	3
Asleep	A brisk response to a light glabellar tap	4
Levels:	A sluggish response to a light glabellar tap	5
	No response	6

Data collection:

Intra-operative anaesthesia and ultrasound guided bilateral pecto-intercostal fascial plane block (PIFB) was administered by the anaesthesiologist not involved in the study unaware of the content of the drug preparation made for giving block and infiltration.

The data collection and assessment was done by separate Resident posted in Intensive Care Unit (ICU) under the supervision of Principal-investigator.

Figure 2a. Investigator's artistic impression of the Pecto-Intercostal Fascial Block, given in the fascial plane interposed between the Pectoralis Major muscle and the Internal Intercostal muscle.

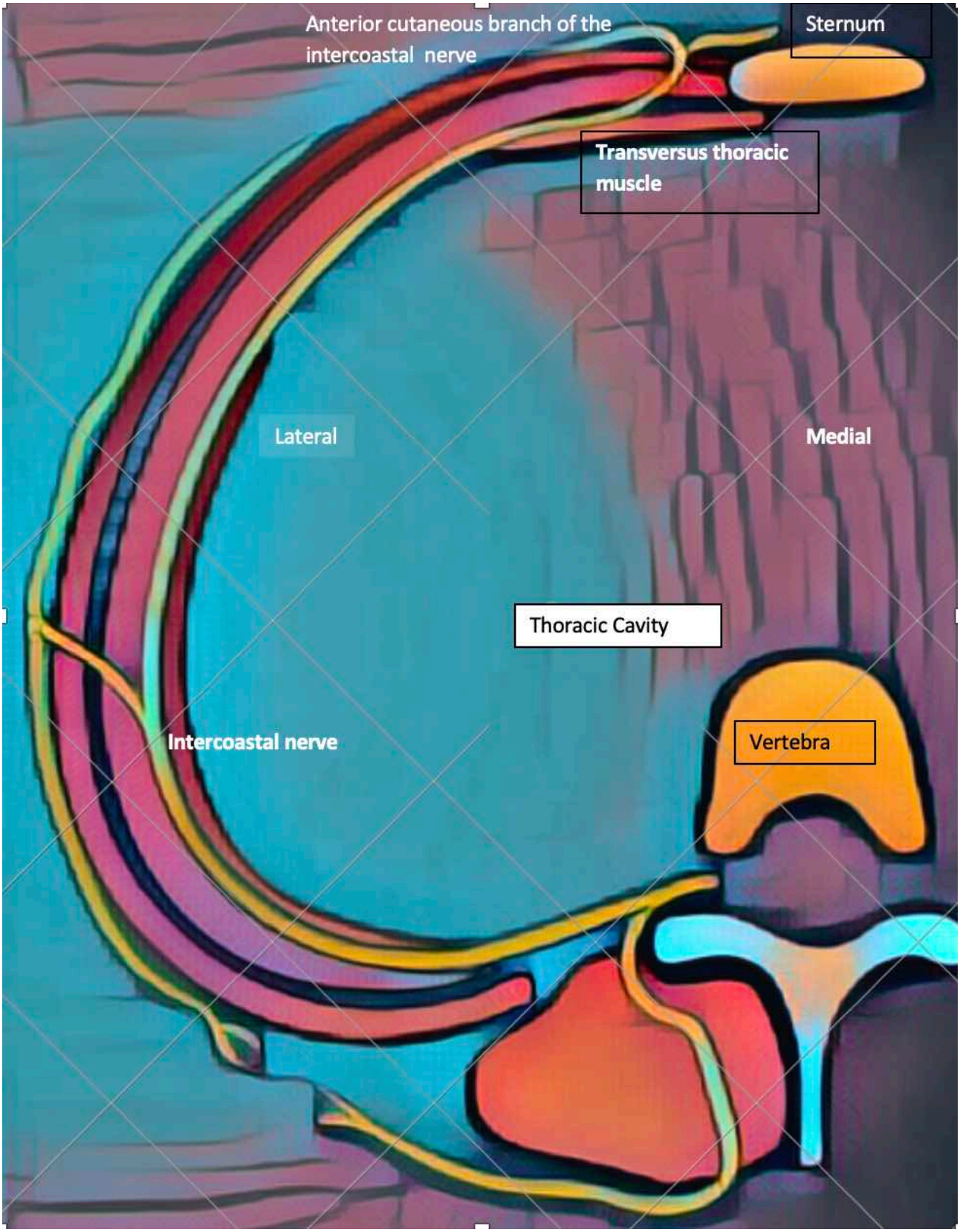


Figure 2b. Investigator's artistic impression of the anatomical plane of the pecto-intercostal Fascial Block, given in the facial plane between the Pectoralis Major muscle and the Internal Intercostal muscle.

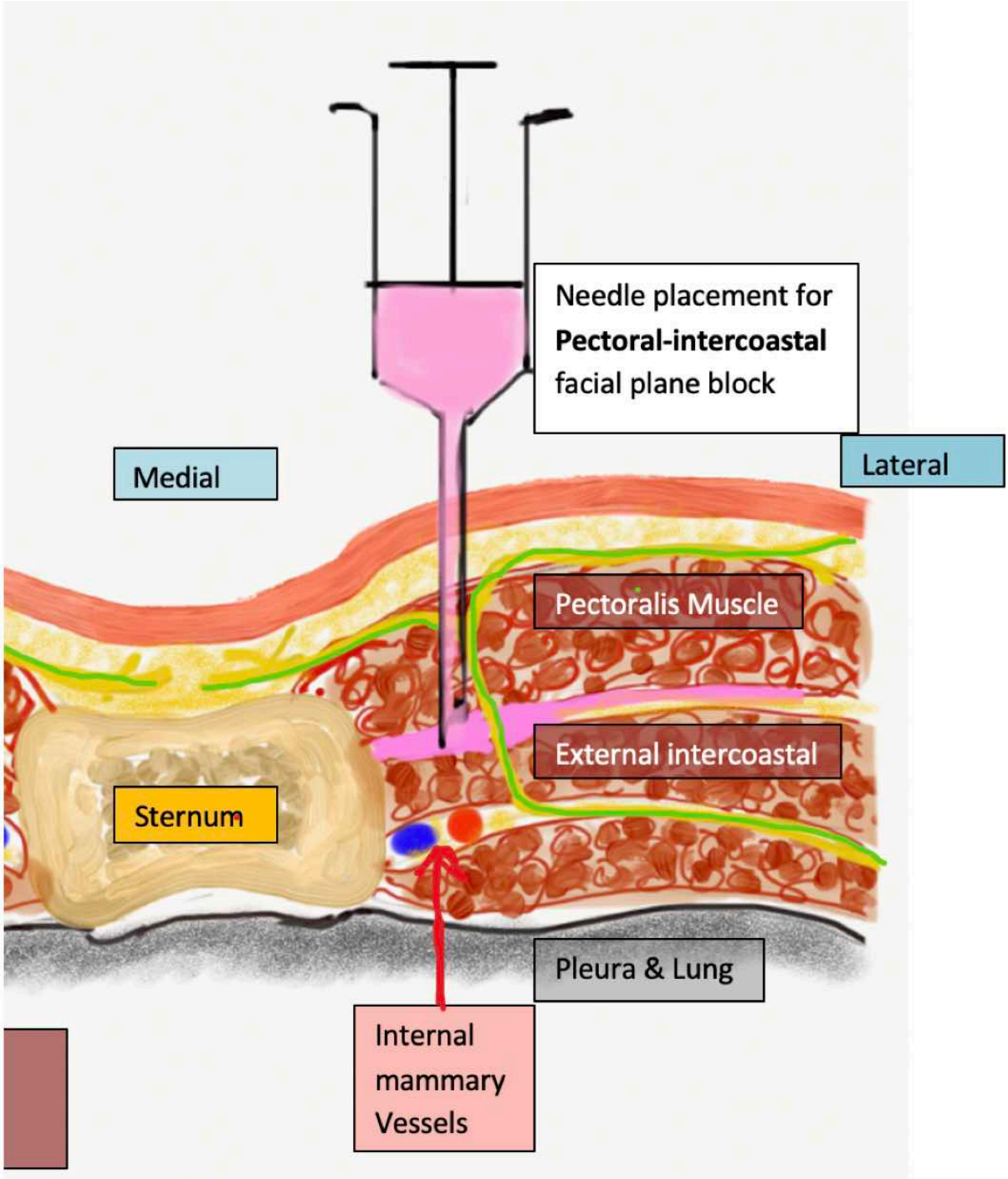
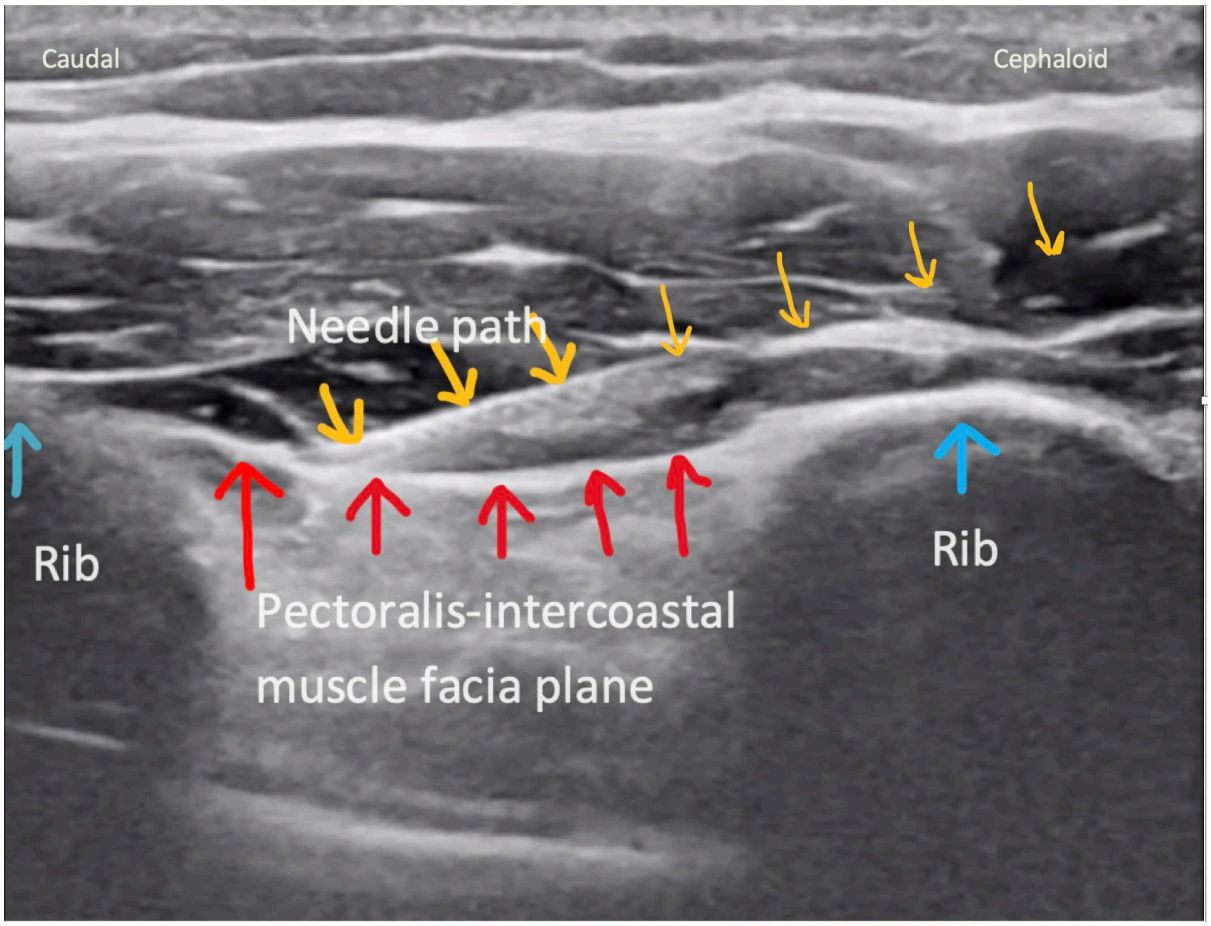


Figure 2c & d. Ultrasound imaging of the pecto-intercostal Fascial Block, given in the fascial plane interposed between the Pectoralis Major muscle and the Internal Intercostal muscle.



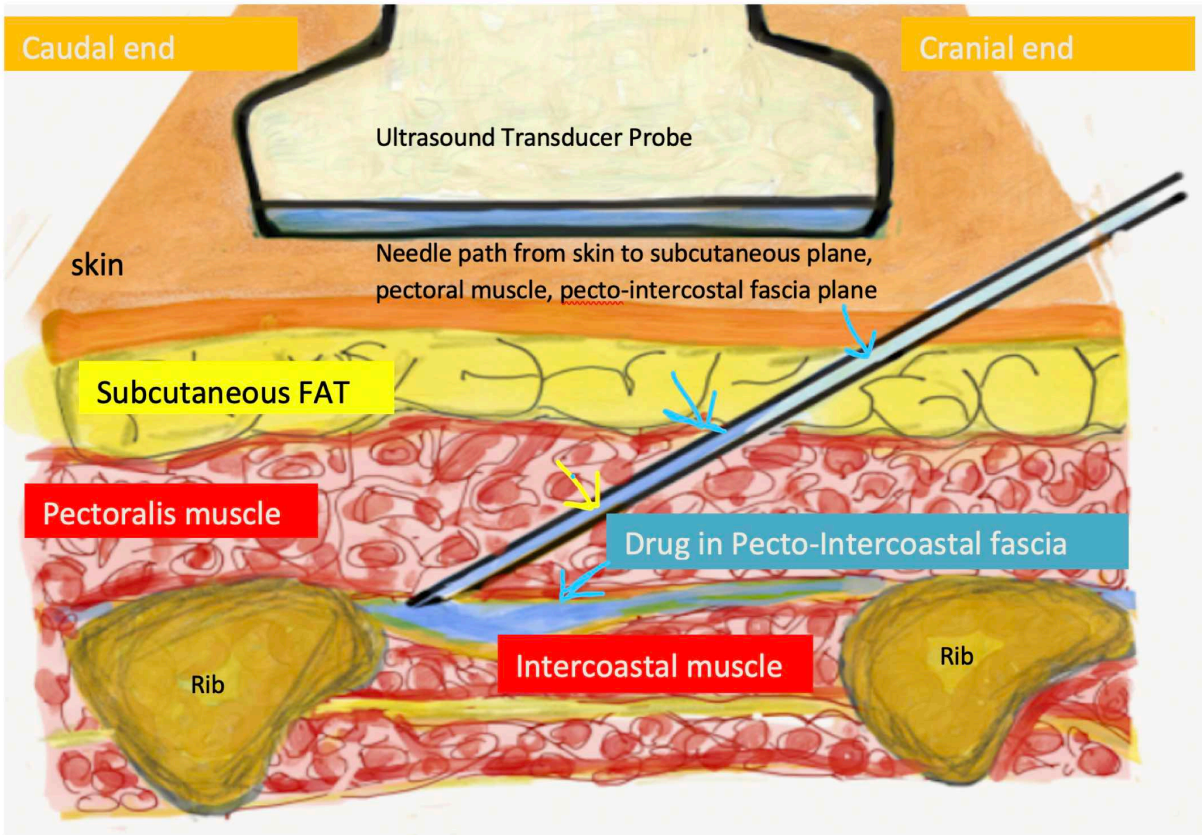


Figure 2e. Investigator's artistic impression about the six injection sites of drug infiltration in Pecto-intercostal Fascial block, with predicted area of drug spread and the anterior Thoracic chest wall anatomy.

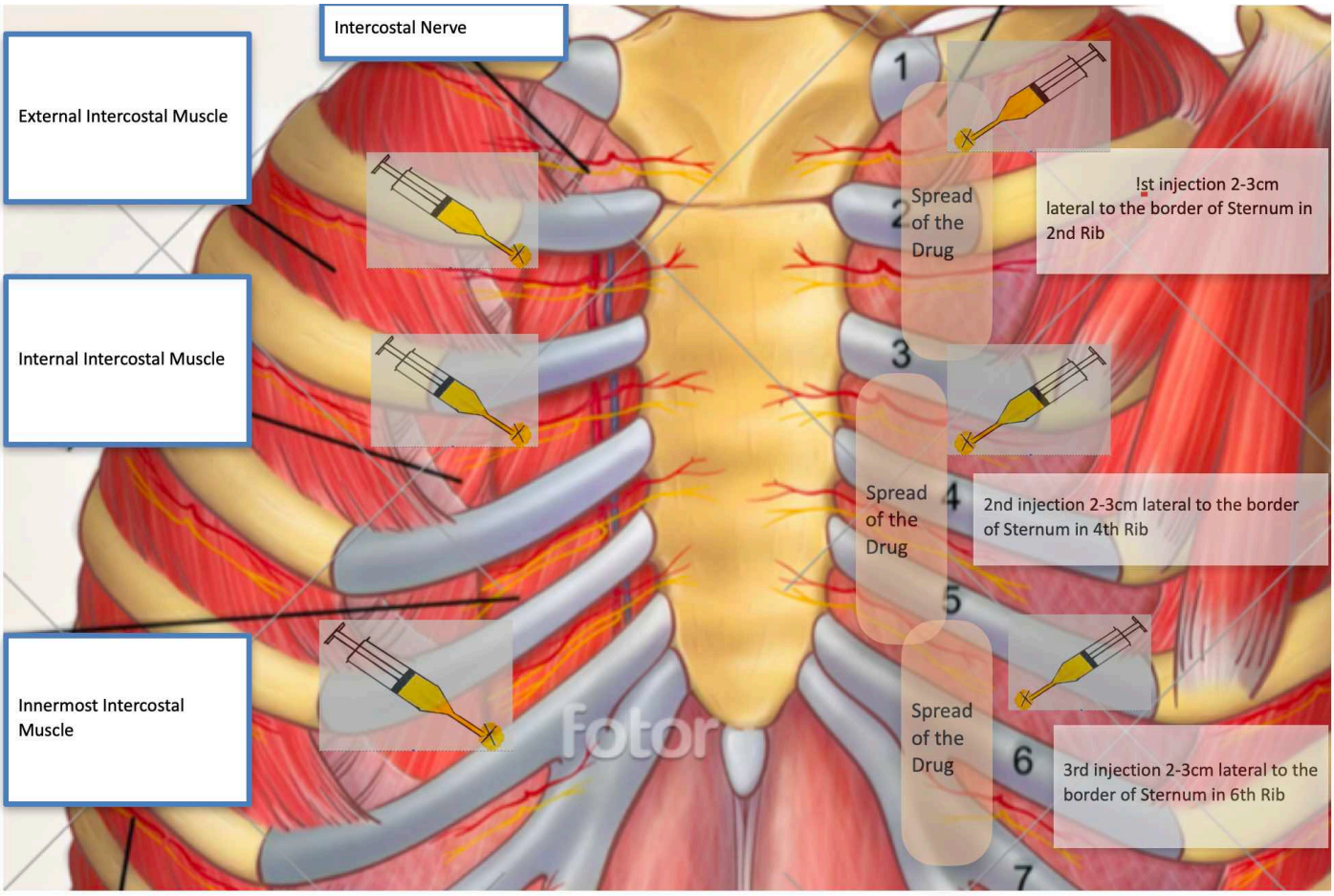
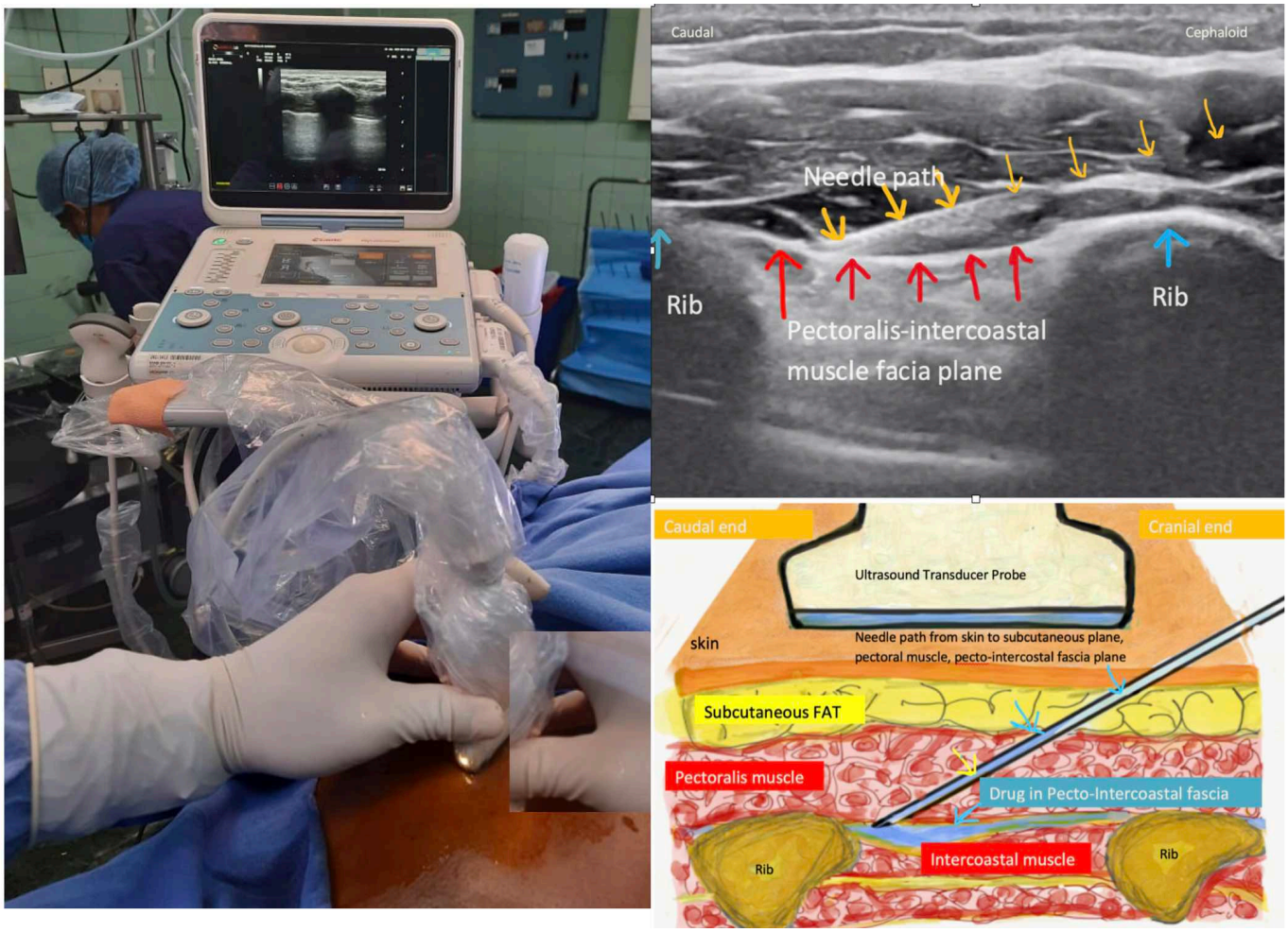


Figure 2f. Clinical picture depicting the administration of the Pecto-Intercostal Fascial Block under Ultrasound guidance in the fascial plane interposed between Pectoralis Major muscle and the Internal Intercostal muscle



OBSERVATIONS & RESULTS

Observations and Results

Comparison of Background Characteristics:

Table:1 Comparison of background characteristics based on group

	Group B			Group A			t	p
	Mean	SD	N	Mean	SD	N		
Age	64.2	3.6	45	63.7	4.2	45	0.59	0.555
Weight	72.0	4.3	45	71.7	4.7	45	0.3	0.762
Height	165.4	5.0	45	165.8	3.5	45	0.54	0.591
Body surface area	1.7	0.1	45	1.8	0.1	45	1.1	0.273
Ejection Fraction	60.0	2.9	45	59.4	4.0	45	0.79	0.431
Aortic cross clamp time	72.4	6.3	45	74.0	5.4	45	1.3	0.197
Total cardio pulmonary bypass time	115.6	5.9	45	114.2	6.3	45	1.14	0.256

Fig: 1 Comparison of age based on group

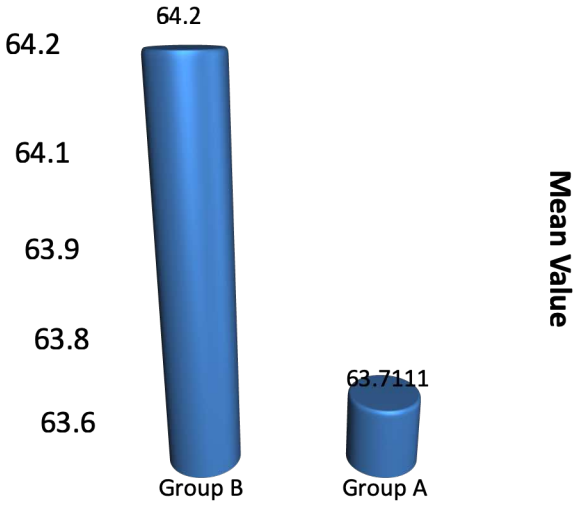


Figure 1. Comparison of age between the two groups shows uniform distribution with mean age of 64.2±3.6 in Group A (interventional) and 63.7±4.2 in Group B (control). Statistical analysis shows no significant difference between the groups regarding age distribution (P value 0.55)

Fig: 2 Comparison of weight based on groups

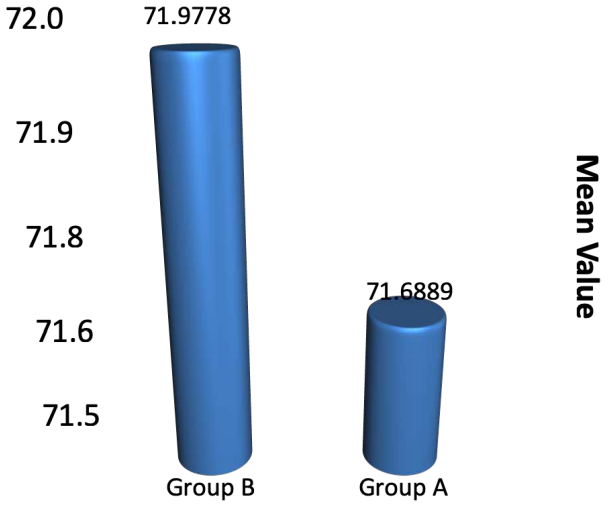


Figure 2. Comparison of weight between the two groups shows uniform distribution with mean weight of 72.0±4.3 in Group A (interventional) and 71.7±4.7 in Group B (control). Statistical analysis shows no significant difference between the groups regarding age distribution (P value 0.3)

Fig: 3 Comparison of height based on groups

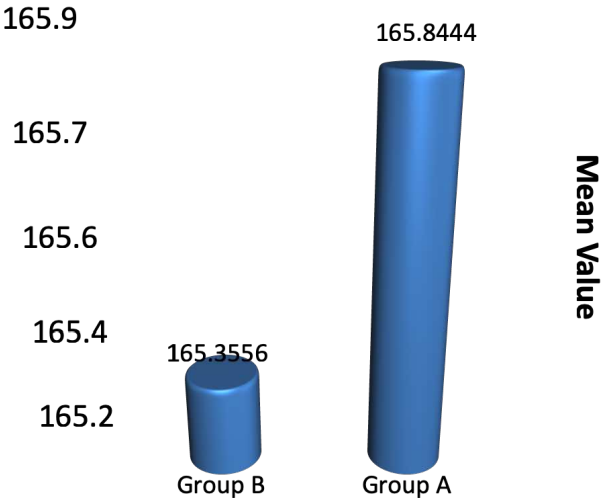


Figure 3. Comparison of height between the two groups shows uniform distribution with mean height of 165.4±5 i.0n Group A (interventional) and 165±3.5 in Group B (control). Statistical analysis shows no significant difference between the groups regarding height distribution (P value 0.54)

Fig:4 Comparison of Body surface area based on groups

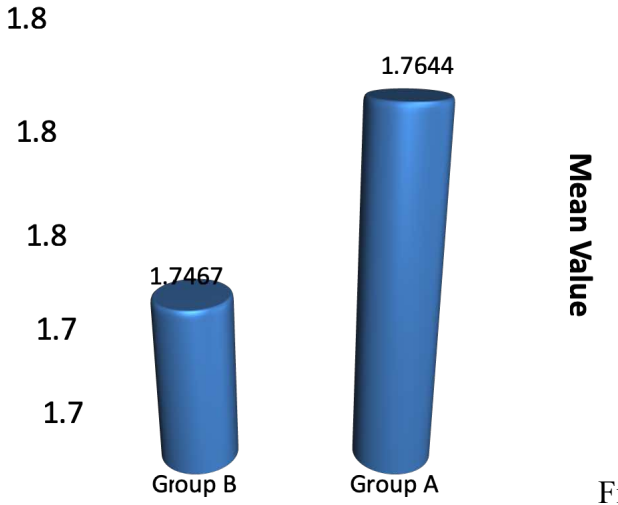


Figure 4. Comparison of body surface area between the two groups shows uniform distribution with mean value of 1.7±0.1 in Group A (interventional) and 1.8±0.1 in Group B (control). Statistical analysis shows no significant difference between the groups (P value 0.27)

Figure 5. Comparison of ejection fraction based on groups

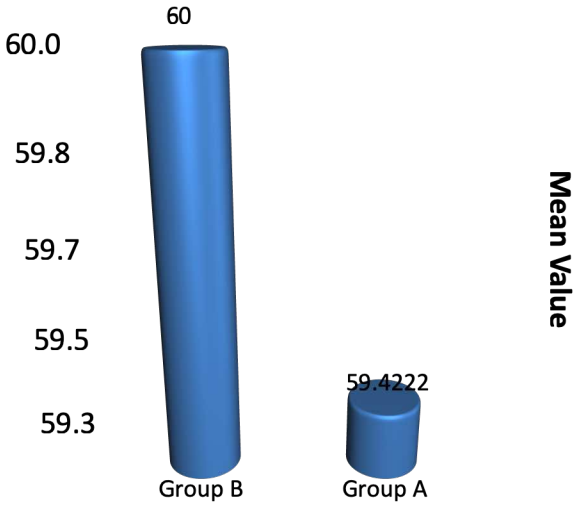


Figure 5. Comparison of ejection fraction between the two groups shows uniform distribution with mean value of 60.0±2.9 in Group A (interventional) and 59.4±4.0 in Group B (control). Statistical analysis shows no significant difference between the groups (P value 0.43).

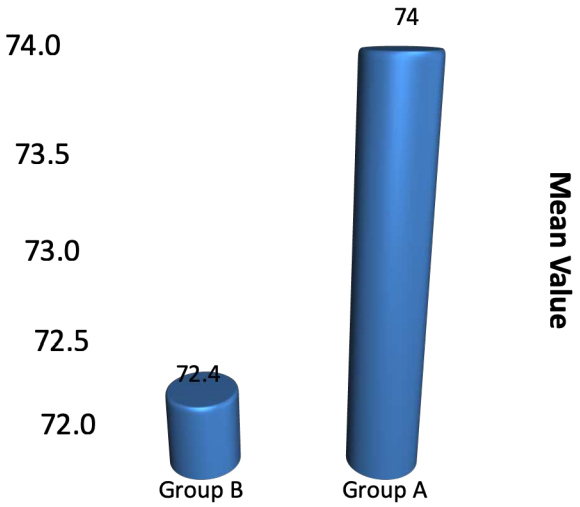


Figure 6. Comparison of aortic cross clamp time between the two groups shows uniform distribution with mean of 72.4±6.3 in Group A (interventional) and 74±5.4 in Group B (control). Statistical analysis shows no significant difference between the groups (P value 0.19)

Fig:7 Comparison of Total cardio pulmonary bypass time between the groups

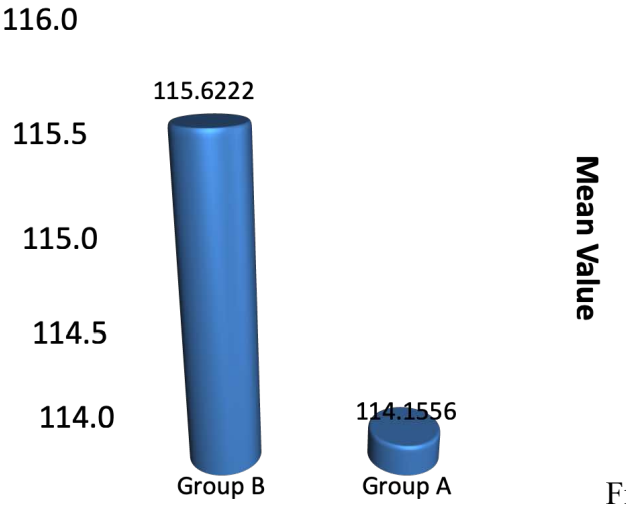


Figure 7. Comparison of the total CPB time between the two groups shows uniform distribution with mean of 115±5.9 in Group A (interventional) and 114.2±6.3 in group B (control). Statistical analysis shows no significant difference between the groups (P value 0.25)

Table: 2 Comparison of background characteristics based on groups

		Group B		Group A		χ^2	p
		Count	Percent	Count	Percent		
Sex	Male	38	84.4	38	84.4	0	1.000
	Female	7	15.6	7	15.6		
Recent Acute Coronary Insult	Yes	13	28.9	12	26.7	0.06	0.814
	No	32	71.1	33	73.3		

Fig: 8 Comparison of Sex based on groups

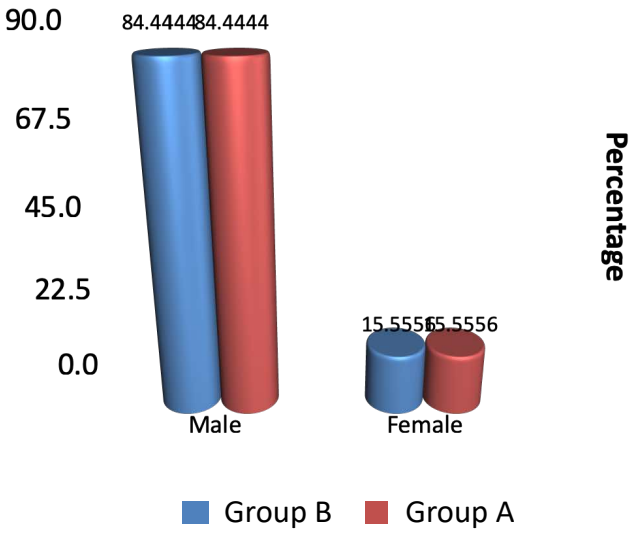


Figure 8. Comparison of sex distribution showed no significant difference between the groups with equal distribution of males and females in either group (P value of 1.00)

Fig:9 Comparison of incidence of recent acute coronary insult based on the groups.

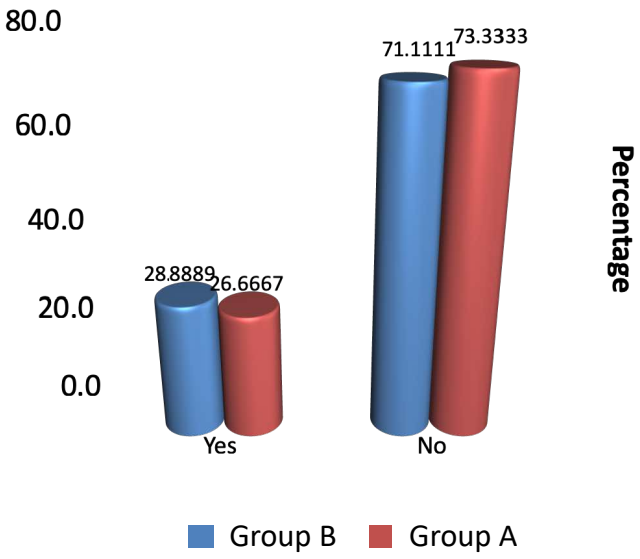
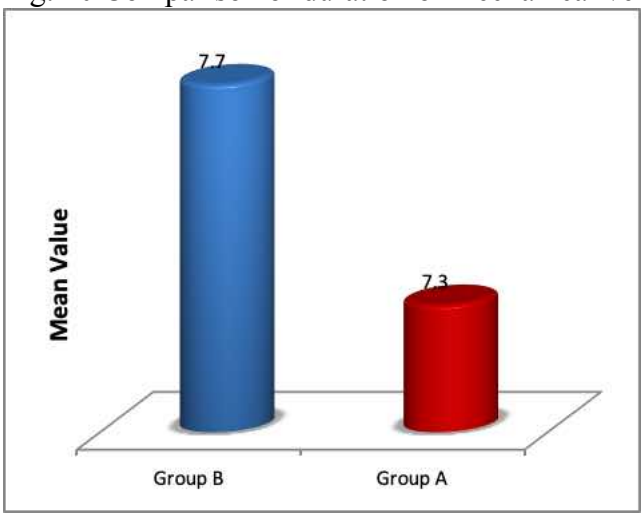


Figure 9. Regarding the incidence of recent acute coronary syndrome, 13 patients (28.9%) belonging to the interventional group and 14 patients (26.7%) of the control group had history of recent acute coronary syndrome with a p value of 0.8 suggesting no significant difference between the groups.

Table:3 Comparison of duration of mechanical ventilation in ICU

Group	Mean	SD	N	t	P
Group B	7.2	1.0	45	0.1	0.920
Group A	7.2	1.1	45		

Fig: 10 Comparison of duration of mechanical ventilation in ICU based on the groups.



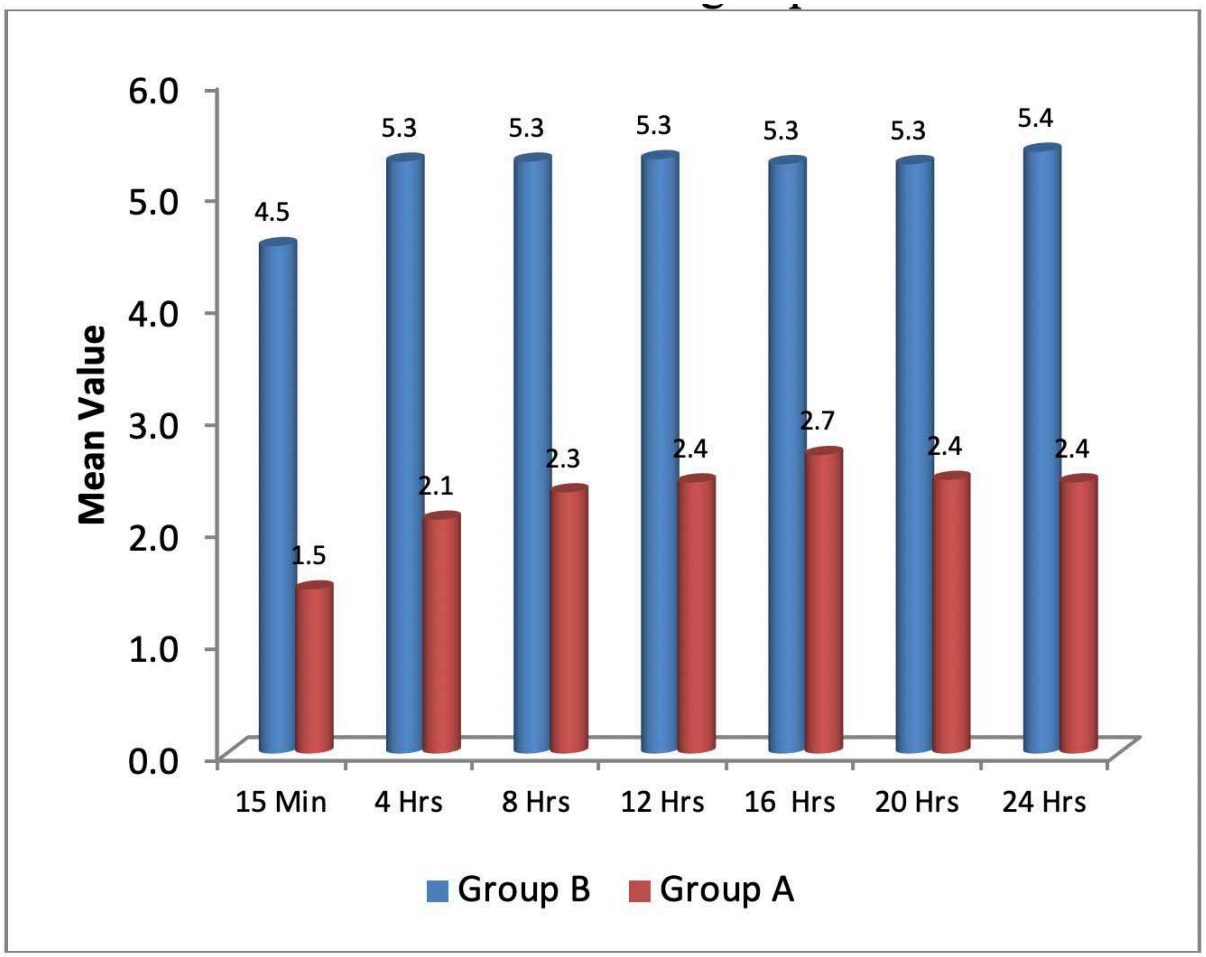
Comparison of the duration of mechanical ventilation between the two groups shows uniform distribution with mean of 7.7±1.2 hours in Group A (interventional) and 7.3±1.1 in Group B (control). Statistical analysis shows no significant difference between the groups (P value 0.92)

Table: 4 Comparison of Numeric Rating Scale for pain assessment after Extubation at different time interval between groups**.**

NRS Score After Extubation	Group B		Group A		Z#	p
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)		
15 Min	4.5 ± 0.9	5 (4 - 5)	1.5 ± 0.9	2 (1 - 2)	8.28	p<0.01
4 Hrs	5.3 ± 0.7	5 (5 - 6)	2.1 ± 0.8	2 (2 - 3)	8.32	p<0.01
8 Hrs	5.3 ± 0.7	5 (5 - 6)	2.3 ± 0.7	2 (2 - 3)	8.4	p<0.01
12 Hrs	5.3 ± 0.7	5 (5 - 6)	2.4 ± 0.6	2 (2 - 3)	8.4	p<0.01
16 Hrs	5.3 ± 0.7	5 (5 - 6)	2.7 ± 0.6	3 (2 - 3)	8.24	p<0.01
20 Hrs	5.3 ± 0.7	5 (5 - 6)	2.4 ± 0.5	2 (2 - 3)	8.39	p<0.01
24 Hrs	5.4 ± 0.6	5 (5 - 6)	2.4 ± 0.7	2 (2 - 3)	8.4	p<0.01

Mann-Whitney U Test

Fig:11 Comparison of Numeric Rating Scale Score for pain assessment after extubation at different time intervals between the groups.



Comparison of Numeric Rating Scale Score After Extubation at different time intervals between groups

Comparison of Numeric Rating Scale for pain assessment at 15 minutes post Tracheal extubation showed mean pain score of 4.5 ± 0.9 in Group B (Control) and a mean pain score of 1.5 ± 0.9 in group A (Interventional). Pain scores noted in interventional group was significantly lower ($p<0.01$)

Comparison of Numeric Rating Scale for pain assessment at 4 hours post Tracheal extubation showed mean pain score of 5.3 ± 0.7 in Group B (Control) and a mean pain score of 2.1 ± 0.8 in Group A (Interventional). Pain scores noted in interventional group was significantly lower ($p<0.01$).

Comparison of Numeric Rating Scale for pain assessment at 8 hours post Tracheal extubation showed mean pain score of 5.3 ± 0.7 in Group B (Control) and a mean pain score of 2.3 ± 0.7 in Group A (Interventional). Pain scores noted in interventional group was significantly lower ($p<0.01$).

Comparison of Numeric Rating Scale for pain assessment at 12 hours post Tracheal extubation showed mean pain score of 5.3 ± 0.7 in Group B (Control) and a mean pain score of 2.4 ± 0.6 in Group A (Interventional). Pain scores noted in interventional group was significantly lower ($p<0.01$).

Comparison of Numeric Rating Scale for pain assessment at 16 hours post Tracheal extubation showed mean pain score of 5.3 ± 0.7 in group B (Control) and a mean pain score of 2.7 ± 0.6 in Group A (Interventional). Pain scores noted in interventional group was significantly lower ($p<0.01$).

Comparison of Numeric Rating Scale for pain assessment at 20 hours post Tracheal extubation showed mean pain score of 5.3 ± 0.7 in Group B (Control) and a mean pain score of 2.4 ± 0.4 in group A (Interventional). Pain scores noted in interventional group was significantly lower ($p<0.01$).

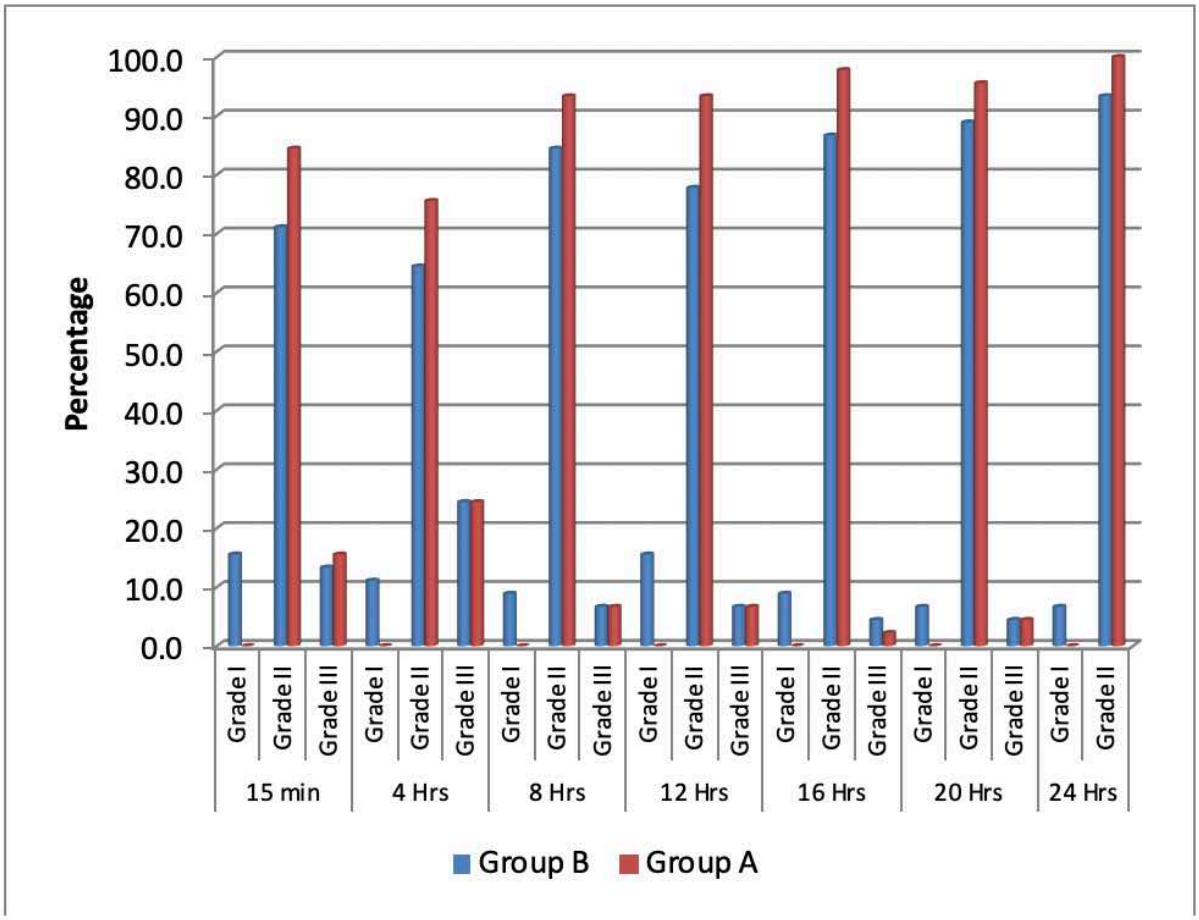
Comparison of Numeric Rating Scale for pain assessment at 24 hours post Tracheal extubation showed mean pain score of 5.4 ± 0.6 in Group B (Control) and a mean pain score of 2.4 ± 0.7 in Group A (Interventional). Pain scores noted in interventional group was significantly lower ($p<0.01$)

Table:5 Comparison of Ramsay Sedation Scale at different time intervals between groups after extubation

Group		Group B			Group A			Z#	P
		Count	Percent	Median	Count	Percent	Median		
15 min	Grade I	7	15.6	2.0	0	0.0	2.0	1.73	0.084
	Grade II	32	71.1		38	84.4			
	Grade III	6	13.3		7	15.6			
4 Hrs	Grade I	5	11.1	2.0	0	0.0	2.0	0.86	0.392
	Grade II	29	64.4		34	75.6			
	Grade III	11	24.4		11	24.4			
8 Hrs	Grade I	4	8.9	2.0	0	0.0	2.0	1.24	0.214
	Grade II	38	84.4		42	93.3			
	Grade III	3	6.7		3	6.7			
12 Hrs	Grade I	7	15.6	2.0	0	0.0	2.0	1.94	0.052
	Grade II	35	77.8		42	93.3			
	Grade III	3	6.7		3	6.7			
16 Hrs	Grade I	4	8.9	2.0	0	0.0	2.0	1.14	0.255
	Grade II	39	86.7		44	97.8			
	Grade III	2	4.4		1	2.2			
20 Hrs	Grade I	3	6.7	2.0	0	0.0	2.0	1.12	0.262
	Grade II	40	88.9		43	95.6			
	Grade III	2	4.4		2	4.4			
24 Hrs	Grade I	3	6.7	2.0	0	0.0	2.0	1.75	0.080
	Grade II	42	93.3		45	100.0			

Mann-Whitney U Test

Fig: 13 Comparison of Ramsay Sedation Scale at different time intervals between groups after tracheal extubation.



Comparison of Ramsay Sedation Scale at different time intervals between groups after tracheal extubation.

At 15 minutes post tracheal extubation, in control group (group B), 15 % (7 patients out of 45) showed score of 1, while 71 %(32 patients out of 45) showed a sedation score of 2 and the remaining 13.3% (6 patients) showed a sedation score of 3. In the interventional group, (group A), 0%, none showed a score of 1, while 84.4 %(38 patients out of 45) showed a sedation score of 2 and the remaining 15.6% (7 patients) showed a sedation score of 3. The mean value for sedation

score was 2.0 in either group which showed no statistically significant difference between the groups (p value of 0.08).

At 4 hours post tracheal extubation, in control group (group B), 11.1 % (5 patients out of 45) showed score of 1, while 64.4 % (29 patients out of 45) showed a sedation score of 2 and the remaining 24.4% (11 patients) showed a sedation score of 3. In the interventional group, (group A), 0%, none showed a score of 1, while 75.6 %(34 patients out of 45) showed a sedation score of 2 and the remaining 24.4% (11 patients) showed a sedation score of 3. The mean value for sedation score was 2.0 in either group which showed no statistically significant difference between the groups (p value of 0.39).

At 8 hours post tracheal extubation in control group (group B), 8.9 % (4 patients out of 45) showed score of 1, while 84 %(38 patients out of 45) showed a sedation score of 2 and the remaining 6.7% (3 patients) showed a sedation score of 3. In the interventional group, (group A), 0%, none showed a score of 1, while 93.3 %(42 patients out of 45) showed a sedation score of 2 and the remaining 6.7% (3 patients) showed a sedation score of 3. The mean value for sedation score was 2.0 in either group which showed no statistically significant difference between the groups (p value of 0.24).

At 12 hours post extubation in control group, (group B), 15.6 % (7 patients out of 45) showed score of 1, while 77.8 %(35 patients out of 45) showed a sedation score of 2 and the remaining 6.7 (3 patients) showed a sedation score of 3. In the interventional group, (group A), 0%, none showed a score of 1, while 93.4 %(42 patients out of 45) showed a sedation score of 2 and the remaining 6.7% (3 patients) showed a sedation score of 3. The mean value for sedation score was 2.0 in either group which showed no statistically significant difference between the groups (p value of 0.052).

At 16 hours post tracheal extubation, in control group (group B), 8.9 % (4 patients out of 45) showed score of 1, while 86.7 %(39 patients out of 45) showed a sedation score of 2 and the remaining 4.4% (2 patients) showed a sedation score of 3. In the interventional group, (group A), 0%, none showed a score of 1, while 97.8 %(44 patients out of 45) showed a sedation score of 2 and the remaining 2.2% (1 patient) showed a sedation score of 3. The mean value for sedation score was 2.0 in either group which showed no statistically significant difference between the groups (p value of 0.25).

At 20 hours post tracheal extubation in control group, (group B) 6.7 % (3 patients out of 45) showed score of 1, while 88.9 %(40 patients out of 45) showed a sedation score of 2 and the remaining 4.4% (2 patients) showed a sedation score of 3. In the interventional group, (group A), 0%, none showed a score of 1, while 95.6 % (43 patients out of 45) showed a sedation score of 2 and the remaining 4.4 % (2 patients) showed a sedation score of 3. The mean value for sedation score was 2.0 in either group which showed no statistically significant difference between the groups (p value of 0.26).

At 24 hours post tracheal extubation in control group (group B), 6.7 % (3 patients out of 45) showed score of 1, while 93.3 %(42 patients out of 45) showed a sedation score of 2. In the interventional group, (group A), all the patients (100 %) showed a sedation score of 2. The mean value for sedation score was 2.0 in either group which showed no statistically significant difference between the groups (p value of 0.08)

Fig: 14 Comparison of co-operation with deep inspiratory exercises and spirometry at different time intervals between the groups.

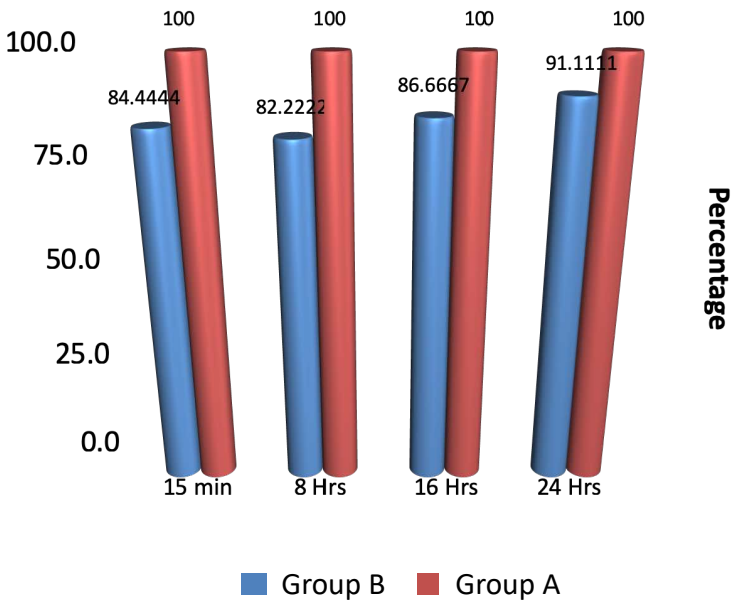


Table: 6 Comparison of co-operation with deep inspiratory exercises and spirometry at different time intervals between the groups.

Co-operation		Group B		Group A		χ^2	P
		Count	Percent	Count	Percent		
15 min	Yes	38	84.4	45	100.0	7.59**	0.006
	No	7	15.6	0	0.0		
8 Hrs	Yes	37	82.2	45	100.0	8.78**	0.003
	No	8	17.8	0	0.0		
16 Hrs	Yes	39	86.7	45	100.0	6.43*	0.011
	No	6	13.3	0	0.0		
24 Hrs	Yes	41	91.1	45	100.0	4.19*	0.041
	No	4	8.9	0	0.0		

**: - Significant at 0.01 level, *: - Significant at 0.05 level

Comparison of co-operation with deep inspiratory exercises and spirometry at different time intervals between the groups:

In control group (group B) at 15 minutes post extubation showed 84.4 %(38 patients) cooperating with inspiratory exercises and spirometry while 15.6% (7 patients) did not cooperate. In the

interventional group (group A) at 15 minutes post extubation all the patients (100%) cooperated well with the inspiratory exercises and spirometry. There was significant difference between the groups statistically with a p value of 0.006.

In control group (group B) at 8 hours post extubation showed 82.2 %(37patients) cooperating with inspiratory exercises and spirometry while 17.8% (8 patients) did not cooperate. In the interventional group (group A) at 8 hours post extubation all the patients (100%) cooperated well with the inspiratory exercises and spirometry. There was significant difference between the groups statistically with a p value of 0.0.003.

In control group (group B) at 16 hours post extubation showed 86.7 %(39 patients) cooperating with inspiratory exercises and spirometry while 13.3% (6 patients) did not cooperate. In the interventional group (group A) at16 hours post extubation all the patients (100%) cooperated well with the inspiratory exercises and spirometry. There was significant difference between the groups statistically with a p value of 0.01.

In control group (group B) at 24 hours post extubation showed 91.1 %(41 patients) cooperating with inspiratory exercises and spirometry while 13.3% (6 patients) did not cooperate. In the interventional group (group A) at 24 hours post extubation all the patients (100%) cooperated well with the inspiratory exercises and spirometry. There was significant difference between the groups statistically with a p value of 0.04.

Fig:16 Comparison of Rescue Analgesia After Extubation at different time interval between group

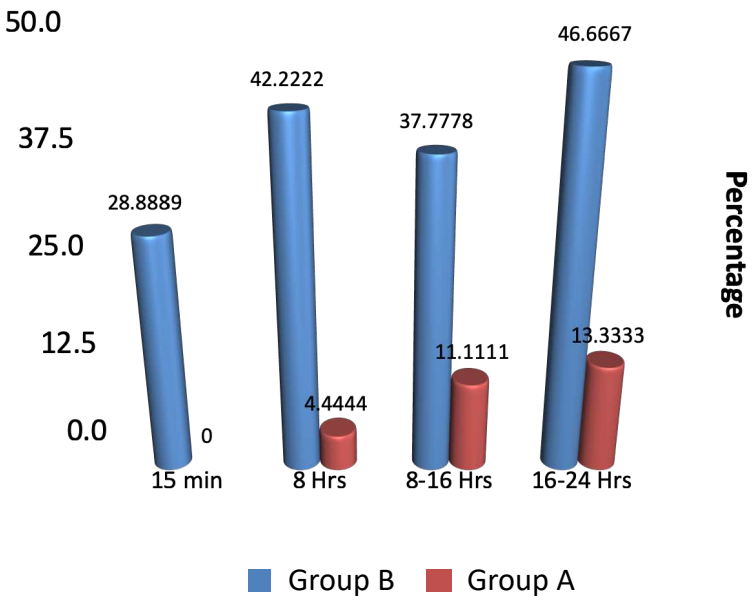


Table: 7 Comparison of Rescue Analgesia After Extubation at different time interval between the groups.

Rescue Analgesia After Extubation		Group B		Group A		χ^2	p
		Count	Percent	Count	Percent		
15 min	Yes	13	28.9	0	0.0	15.19	p<0.01
	No	32	71.1	45	100.0		
8 Hrs	Yes	19	42.2	2	4.4	17.95	p<0.01
	No	26	57.8	43	95.6		
8-16 Hrs	Yes	17	37.8	5	11.1	8.66**	0.003
	No	28	62.2	40	88.9		
16-24 Hrs	Yes	21	46.7	6	13.3	11.9	p<0.01
	No	24	53.3	39	86.7		

**: - Significant at 0.01 level

Comparison of rescue analgesia after extubation at different time intervals between the groups

At 15 minutes post Tracheal extubation patients in control group (group B) showed 28 %(13 patients) requiring rescue analgesia while 71% (32 patients) did not require any additional analgesic supplementation. In the interventional group (group A) at 15 minutes post Tracheal extubation all the patients (100%) did not require any additional supplementation of analgesia. There was statistically significant difference between the groups with a p value <0.01.

At 8 hours post Tracheal extubation patients in control group (group B) showed 42.2 %(19 patients) requiring rescue analgesia while 57.8% (26 patients) did not require any additional analgesic supplementation. In the interventional group (group A) at 8 hours post Tracheal extubation showed 4.4 %(2 patients) requiring rescue analgesia while 95.6% (43 patients) did not require any additional analgesic supplementation. There was statistically significant difference between the groups with a p value <0.01.

At 8-16 hours post Tracheal extubation patients in control group (group B) showed 37.8 %(17 patients) requiring rescue analgesia while 62.2% (28 patients) did not require any additional analgesic supplementation. In the interventional group (group A) at 8-16 hours post Tracheal extubation showed 11.6 %(5 patients) requiring rescue analgesia while 88.9% (40 patients) did not require any additional analgesic supplementation. There was statistically significant difference between the groups with a p value <0.01.

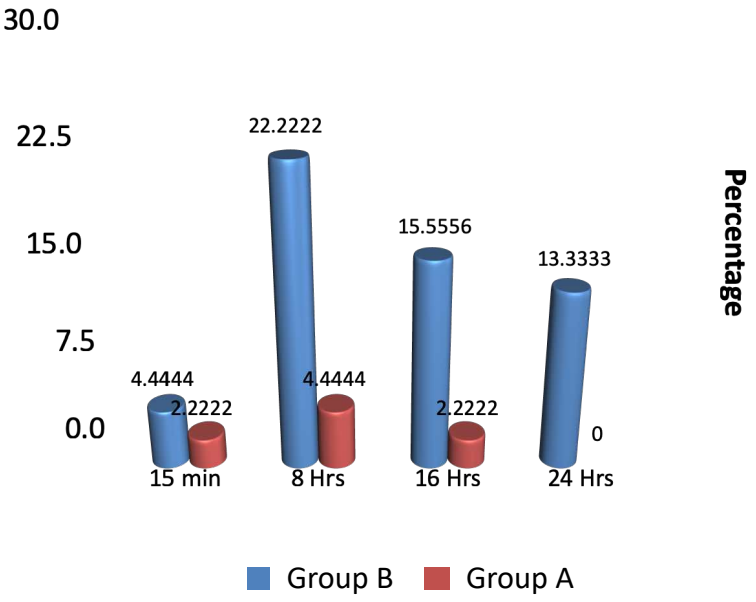
At 16-24 hours post Tracheal extubation patients in control group (group B) showed 46.7 %(21 patients) requiring rescue analgesia while 53.3% (24 patients) did not require any additional analgesic supplementation. In the interventional group (group A) at 16-24 hours post Tracheal extubation showed 13.3% (6 patients) requiring rescue analgesia while 86.7% (39 patients) did not

require any additional analgesic supplementation. There was statistically significant difference between the groups with a p value <0.01

Table :8 Comparison of Incidence of Nausea and Vomiting at different time interval between group

Incidence of Nausea and Vomiting		Group B		Group A		p#
		Count	Percent	Count	Percent	
15 min	Yes	13	28.9	0	0.0	p<0.01
	No	32	71.1	45	100.0	
8 Hrs	Yes	19	42.2	2	4.4	p<0.01
	No	26	57.8	43	95.6	
8-16 Hrs	Yes	17	37.8	5	11.1	0.003
	No	28	62.2	40	88.9	
16-24 Hrs	Yes	21	46.7	6	13.3	p<0.01
	No	24	53.3	39	86.7	

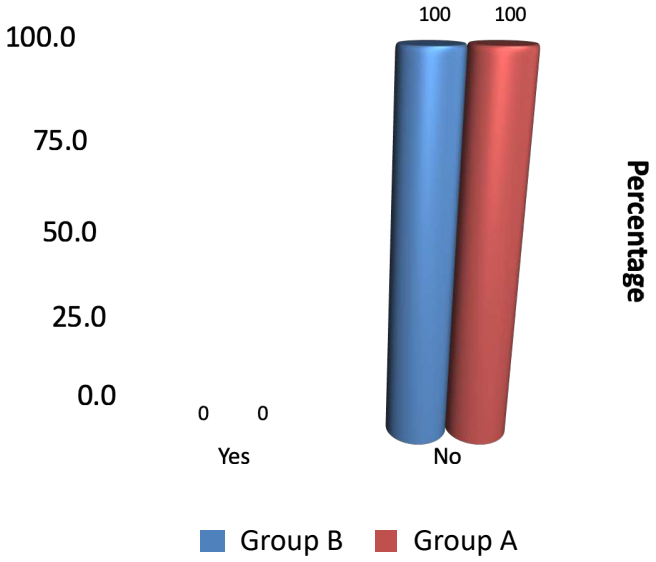
Fig.17 Comparison of Incidence of Nausea and Vomiting at different time interval between group



Comparison of Incidence of Nausea and Vomiting at different time interval between the groups

In the immediate post-Tracheal extubation period, 13% patients experienced side effects either in the form of nausea and vomiting, while there was no incidence of side effects in the interventional group which could be attributed to the better pain scores in this group. In the subsequent time intervals 42% at 8 hours, 37.8% at 8-16 hours and 46.7% at16-24 hours experienced side effects in the control group. Incidence of nausea and vomiting was comparatively low and statistically significant compared to control group in the interventional arm with 2%, 5% and 6% in the above mentioned time intervals respectively.

Fig: 18 Comparison of anticipated procedure linked complications related to intervention as compared between both the groups.



There was no incidence of complications documented during the study which were listed as a possible secondary objective findings as a theoretical possibility, such as haematoma, injury to vessels, pneumothorax, aspiration of bloody tap under ultrasound guidance in the intervention group.

DISCUSSION

Discussion

Cardiac surgery poses unique challenges in the field of pain management. The ideal modality to provide perioperative anaesthesia-analgesia on maintaining stable haemodynamics, stable myocardial oxygen consumption as shown with acceptable mean and diastolic blood pressure while avoiding hypertension and tachycardia especially while dealing with Ischemic and Valvular heart disease.(34) Pain in cardiac surgery comes from many sources. In conventional sternotomy surgeries, unlike minimally invasive surgeries, a new trend in the current world is about calling the skin incision is being quite lengthy. Also the pain arising due to full length sternotomy, bone pain on the other hand is very difficult to manage. Effective control of pain has got a multitude of advantages including the provision of postoperative avoiding rapid and frequent fluctuations in blood pressure and heart rate. It can effectively reduce the incidence of arrhythmias intraoperatively and in the post operative period. Effective control of pain allows the opportunity for pain free breathing efforts and allows early weaning practices, which can potentially reduce the duration of mechanical ventilation. Adequate pain control can also abate the potential derailment in the metabolic functions and hormonal responses associated with pain stimulation. In cardiac surgery the extensive tissue injury and the exposure of blood to extra-corporeal circuit leads to extensive activation of inflammatory cascade, the coagulation pathways and platelets. The prothrombotic environment prevailing in such situation can be attenuated to some extent by providing adequate and proper analgesia.

Even today, in most of the cardiac surgery centres in this era of ultrasound and regional blocks, intravenous opioids are the corner stone in managing pain. However the rising and compelling evidences related to iatrogenic opioids dependency, opioids induced hyperalgesia, opioid crisis, the possible delay in weaning phase from ventilator, related to carbon dioxide retention and possible side effects like excess sedation, nausea and vomiting have caused paradigm shift in the current management of sternotomy pain cardiac surgery recently.(35)

Multimodal analgesia is currently the favourite approach in cardiac surgery. The non-steroidal anti-inflammatory drugs, acetaminophen, alpha-2 receptor agonists, N-methyl-D-aspartate-receptor antagonists, gabapentanoids and the local anaesthetics forms a handful of medications currently used along with opioids for pain relief in cardiac surgery. (36,37) The optimum selection of drug combination and the dosage allows better pain control and opioid sparing while minimising the side effects associated with the individual drugs.

In our hospital protocol the adjuvants used are Tramadol, morphine, Paracetamol and Fentanyl. The primary objective focused on the quality of pain scale post fast tracking in intensive care unit.

The parasternal fascial plane blocks are relatively newer technique which includes transversus thoracic plane block and the pecto-intercostal fascial plane block. In both the blocks above mentioned local anaesthetic injection in the parasternal fascial plane targets the anterior cutaneous nerve, the terminal branch of main trunk of intercostal nerve which can effectively prevent the pain perception from midline sternotomy.

Our study chose Pecto-intercostal nerve block because of its additional advantage as compared to Transverses Thoracic Plane block (TTP) block. Pecto-intercostal fascial block (PIFB) is away from vascular structures and avoids possible injury to the internal mammary vessels and intercostal vessels. The vertical spread of the injectate is often incomplete in PIFB compared to TTP block, which mandates at least three injections on either side to cover for anterior six intercostal spaces. However the better safety profile and the prospect of easy and reliable block administration ensuring adequate spread of local anaesthetic drug with the help of ultrasound guided techniques made PIFB choice as an even more attractive regional technique compared to TTP block.

The concept of pre-emptive analgesia involves providing anti-nociceptive treatment well before the onset of pain stimulus i.e., before the surgical incision. The aim of this technique is to

prevent the afferent impulses of pain sensation from reaching central nervous system which could lead to central and peripheral sensitisation and leads to the development of allodynia, hyperalgesia, and chronic post-operative pain. Even though opioid based analgesia can provide excellent analgesia, it does not prevent complete transmission of the afferent nociceptive signals. Multimodal analgesia, especially systemic analgesia combined with a regional analgesia techniques is quite attractive in this regard.

The primary aim of our current study was to analyse whether the effect of bilateral ultrasound guided pecto-intercostal fascial block before the skin incision (adding to the preemptive analgesia) when combined with the routine dose of fentanyl and morphine infusion according to institutional practice could affect the post operative pain score.

We recruited sequential 90 patients who were posted for elective CABG surgery. Patients were randomised in to two groups, the control group (Group B) and the study group (interventional group-group A). Patients in both the groups received similar anaesthesia and analgesic care both intra-operatively and in ICU, except for the administration of PIFB in the interventional group providing preemptive analgesia. Patients were fast tracked and extubated once the patients were shifted to ICU after meeting the criteria for Tracheal extubation. Once extubated, patients were evaluated for the efficacy of preemptive analgesia in the interventional group by comparing the mean pain scores at regular time intervals. Patients were also monitored for the break through analgesia, or any side effects related to excess use of opioids in the post-operative period.

Comparison of Baseline Demographic Characteristics:

We recruited 90 patients who were posted for elective CABG surgeries after meeting the criteria for selection. Patients were randomised in to two groups-the control and the interventional group. The comparison of the baseline demographic data, age, sex, height, weight and BSA between the two groups yielded comparable results (p value ≥.0.05). Three (n=3)

patients recruited initially for the study were excluded from the trial in view of re-exploration and prolonged mechanical ventilation. The mean age of patients were between 64.2±3.6 in group B (control) and 63.7±4.2 in group A (interventional), while mean weight of patients were 72.0±4.3 and 71.7±4.7 in the control and the interventional group respectively. The mean height observed was 165.4±5 in group B (control) and 165±3.5 in group A (interventional) respectively. Comparison of body surface area between the two groups yielded mean values of 1.7±0.1 in group B (control) and 1.8±0.1 in group A (interventional) respectively.

Comparison of Patient Specific Baseline Cardiac Profile

Comparison of ejection fraction between the two groups showed uniform distribution. The mean values of ejection fractions were in range of 60.0±2.9 in group B (control) and 59.4±4.0 in group A (interventional) which was statistically insignificant.

While comparing the incidence of recent acute coronary syndrome, 28.9% (n=13) patients belonging to the control group and 27.6% (n=14) patients of the interventional group had history of recent acute coronary syndrome with a p value of 0.8 suggesting no significant difference between the groups.

Comparison of Baseline Intra-operative and Post-operative Characteristics.

Comparison of the intra-operative baseline characteristics like the total CPB exposure time and aortic cross clamp time showed comparable results suggesting no statistically significant difference between the groups.

The mean duration of CPB exposure was 115±5.9 minutes in group B (control) and 114.2±6.3 minutes in group A (interventional). Comparison of aortic cross clamp time between the two groups showed mean values of 72.4±6.3 in group B (control) and 74±5.4 in group A (interventional) respectively. Comparison of the duration of mechanical ventilation between the

two groups showed uniform distribution with mean of 7.2±1.0 hours in group B (control) and 7.2±1.0 in group A (interventional) respectively. There was no statistically significant difference between the groups

Assessment and Comparison of Post-operative pain

Comparison of for pain intensity after extubation was carried out using the 11 point Numeric pain Rating Scale at regular intervals till 24 hours in the post extubation period. Patients were also assessed for the incidence of break through analgesia, the co-operation with deep inspiratory exercises, intense coughing and incentive spirometry as a surrogate measure for the effectiveness of pain management strategy.

In control group the minimum value of pain score recorded as per the NRS was 4.5 ± 0.9 which was noted 15 minutes post-extubation and the maximum value 5.4 ± 0.6 recorded at 24 hours post extubation. The median value of pain score in control group was 5 (4-5) at all corresponding measuring points which signifies the moderate to severe pain experienced by the patients in this group.

In the interventional group the minimum value of pain score recorded as per the NRS was 1.5 ± 0.9 which was noted at 15 minutes post-extubation and the maximum value 2.4 ± 0.7 recorded at 24 hours post extubation. The median values of pain score in interventional group were 2 (2-3) at all corresponding measuring points except for at 16 hours (median 3).

Comparison of the rescue analgesia was done by calculating the percentage of the patients who required rescue analgesia at specific time intervals. In the control group 28% of the patients required rescue analgesia in the first 15 minutes after extubation while the incidence was 0% in the interventional group. In the initial 8 hours post extubation 42.4% of patients in control group and 4.4% in the interventional arm required rescue analgesia. Between 8-16 hour's post-extubation 37.8% and 11.1% patients required rescue analgesia in the control and interventional

groups respectively. At 16-24 hours saw the highest incidence (46%) of requirement of rescue analgesia in the control group while still maintaining a lower incidence (11.1%) in the interventional arm.

Comparison of the percentage of people who co-operated well with the deep inspiratory exercises, coughing and spirometry as a surrogate for the effectiveness of pain management showed significant difference between the groups. Patients in the control group witnessed more number of patients not co-operating with the above mentioned breathing exercises with 15.6% immediately post-tracheal extubation, 17.8% at 8 hours post-tracheal extubation, 13.3% at 16 hours and 8.9% 24 hours post tracheal extubation. Patients in the interventional group mean while showed 100 % cooperation in the respective time intervals till 24 hours with the respiratory exercises and spirometry which can be attributed to the superior pain management strategy in the interventional group.

While comparing the incidence of side effects related to opioid overuse 13% of patients experienced side effects either in the form of nausea and vomiting in the immediate post-tracheal extubation period in control group while there was no incidence of side effects in the interventional group which could be attributed to the better pain control in this group. In the subsequent time intervals, 15 minutes-8 hours, 8-16 hours and 16-24 hours the average incidence of side effects among the patients were approximately 40% or above in the control group while the incidence was significantly low in the interventional arm with the maximum incidence of nausea and vomiting, 6% noted in the time interval 16-24 hours.

Statistical analysis of the results suggested significant difference in the amount of pain experienced by the patients as measured by NRS, with superior pain scores, decreased incidence of rescue analgesia and the side effects associated with opioid usage in the interventional arm. Comparison of percentage of patients co-operating with deep inspiratory exercises and

spirometry, a surrogate for the effectiveness of analgesia technique showed far superior results in the interventional group.

In 2020 Thanvi Khera et al. did a Single-centre based, prospective, randomised, quadripledblinded, placebo-controlled trial. They recruited 80 adult cardiac surgical patients aged more than 18years, who required median sternotomy. Patients were randomly assigned to receive ultrasoundguided PIFB, with either 0.25% Bupivacaine or placebo, on postoperative days 0 and 1. There was a significant reduction in visual analog scale scores (4.8 ± 2.7 v 5.1 ± 2.6; $p < 0.001$). The 48-hour cumulative opioid requirement computed as morphine milligram equivalents was similar (40.8 ± 22.4 mg v 49.1 ± 26.9 mg; $p = 0.14$). Patients who received PIFB with Bupivacaine showed a decline in cumulative opioid consumption postoperatively, but this difference between the groups was not statistically significant. Low incidence of complications and improvement in visual analog scale pain scores suggested that the PIFB can be performed safely in this population. This study is comparable with our present study regarding the incidence of comparatively low pain scores in the interventional arm, except for the drug concentration used for block administration was 0.25% Bupivacaine and the administration of block was done twice and that too in post-operative period at intervals of 24 hours.(31) In our present study we did not restrict the total dose of intra-operative opioid dosage in either group. By administering PIFB in the interventional arm, we could ensure that the benefit of pre-emptive analgesia is at its best in the study group.

In 2021 Yang Zhang et al. did a double-blind, randomised, controlled study in which they recruited 108 patients in the age group between 20-70 years, those who underwent conventional valve replacement surgeries via midline sternotomy. Patients in the interventional arm received PIFB. Their observation was that patients in the PIFB group had better pain scores compared with the control group as measured by Numerical Rating Scale (NRS) pain scores at 24 h after operation both at rest and during coughing. The total peri-operative dosages of opioids and

NASIDS were also found to be significantly lower in the interventional arm. The time to tracheal extubation, length of ICU stay and length of hospital stay were also significantly decreased in the PIFB group compared with the control group.(39) The results of the study quoted above are co-relating with our present study.

Comparison of Ramsay Sedation Scale

The level of sedation was assessed using Ramsay sedation scale starting from immediately posttracheal extubation till 24 hours at regular intervals. Statistical analysis showed maximum numbers of patients having a sedation score of 2, with apparently more number of patients having sedation score of 2 in the interventional group. The median value on sedation scale was 2 in either groups on all the corresponding intervals. There was no statistically significant difference between the groups while comparing the sedation status.

The incidence of patients with sedation score of 2 was 71.8%(n=32), 84.4% (n= 32), 86.7% (n= 39) and 93.3% (n= 42) at regular intervals starting immediately post-tracheal extubation, at 8 hours post-tracheal extubation, 16 hours and at 24 hours post-tracheal extubation respectively in the control group. In the interventional group 84.4% (n=38), 93.3%(n=42), 97.8% (n=44) and 100% (n= 45) patients showed Ramsay sedation scale of 2 in the respective time intervals.

Comparison of patients showing sedation score of 3 did not show any difference between the groups. The maximum incidence of patients showing grade 3 sedation status was noted at 4 hours post extubation followed by the immediate post extubation period in either groups.

While no patients in the interventional arm showed sedation scale of 1 (anxious, agitated) at any point of time in the post-tracheal extubation period till 24 hours, incidence of sedation scale showing score of 1 were more in control group with 15.6%(n=7), 8.9%(n= 4), 8.9%(n=4) and 6.7%(n=3) respectively at 15 minutes, 8 hours,16 hours and 24 hours post Tracheal extubation.

The absolutely zero incidence of sedation scale of 1 in interventional arm might be attributed to the better pain control in this group, leading to lesser anxiety and pain in this group.

Our hypothesis was that, 1) a single shot ultrasound guided bilateral parasternal pecto-intercostal fascial plane block using long-acting anaesthetic (0.5% Levobupicaine preservative free), after the induction of anaesthesia would be having a preemptive analgesic and adjuvant effect to intravenous analgesics and facilitate fast tracking with mitigation of post operative pain. 2) This synergistic effect would be additive and would extend well into the postoperative period providing adequate analgesic cover, avoiding the need for the rescue analgesia with opioid sparing effect in post operative period.

Our observations in this study proved our hypothesis that Ultrasound guided PIFB is safe, without any procedural complications, easily performed and is a recommendable technique for providing a reliable block, which can be routinely used in the practice of anaesthesiology for cardiac surgery. In our experience, the incidence of procedure related complications were zero, which established the safety for internal mammary harvest profile with PIFB.

SUMMARY & CONCLUSION

Summary

The current study evaluated the efficacy of providing preemptive analgesia, incorporated by regional nerve block given as parasternal Pecto-intercostal fascial plane block (PIFB) coupled in addition to the conventional institutional practice of opioid based analgesia. With this study we were able to arrive at the following conclusions:-

- Patients in the intervention group who received Pecto-intercostal fascial plane block (PIFB) had a statistically significant pain relief when compared to the (non-intervention) control group, assessed during the first 24 hours of fast tracking. The average pain scale was significantly lower ($p < 0.01$) in the patient group who received Pecto-intercostal fascial plane block (PIFB) at all corresponding intervals from the point of Tracheal extubation unto 24 hours post tracheal extubation as the end point.
- The requirement of rescue analgesia and the incidence of side effects like nausea and vomiting were significantly lower ($p < 0.01$) in the interventional group.
- Comparison of the ability of patients to fully co-operate with the deep inspiratory exercises, coughing, and spirometry as a surrogate measure of the efficacy of the pain management strategy, showed better patient co-operation

in the interventional group with data analysis showing significant difference ($p<0.05$) as compared to the control group.

- The comparison of sedation status using Ramsay sedation scale in the extubated patients for a period of 24 hours showed a median sedation score of 2 in both the groups. There was no statistically significant difference between the groups. However a small percentage (4.4%–15.6%) of patients in control group persistently expressed grade 1 sedation status which was seen throughout the study period. Considering anxiety and agitation as a byproduct of poor management of pain, we can assume that the presence of Pecto-intercostal fascial plane block (PIFB) has resulted in a superior and clinically acceptable sedation scales in the interventional group. This was evident throughout the study period.

Conclusion

- **Regional nerve block technique for a pre-emptive analgesia using Pecto-Intercostal Fascial Block (PIFB) combination with standard opioid based analgesia in conventional Cardiac surgeries with median sternotomy, provides effective pain relief upto 24hrs post tracheal extubation in patients undergoing Fast tracking.**

- **Effective analgesia with Pecto-intercostal fascial plane block (PIFB), helped in patient cooperation with better conduct of deep-breathing inspiratory exercises, intense coughing physiotherapy manoeuvres and incentive spirometry. All the above mentioned factors resulted in better respiratory toileting and care.**

- **The incidence of break through analgesia with requirement of additional analgesics as supplement for pain and the anticipated opioid side effects nausea and vomiting, was significantly lower in patients who received Pecto-intercostal fascial plane block (PIFB) in addition to standard opioid based analgesia protocol.**

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ANNEXURES

i. PATIENT INFORMATION SHEET AND INFORMED CONSENT

SREE CHITRA TIRUNAL INSTITUTE OF MEDICAL SCIENCES AND TECHNOLOGY
DEPARTMENT OF CARDIAC ANAESTHESIOLOGY

Ultrasound guided Bilateral Pecto-intercostal Fascial Block: Role as a preemptive analgesic adjunct in fast tracking for mitigating postoperative Sternotomy Pain
Information sheet

You are being requested to participate in a study to see if a technique called *Pecto-intercostal Fascial Block* can help give you better pain relief after cardiac surgery.

Routine pain management after cardiac surgery

Post operative pain after heart surgery is treated with intravenous/oral pain killers usually opoids (like morphine) and NSAIDS (paracetamol, ketorolac, diclofenac). Some times these drugs can cause nausea, vomiting, drowsiness. Occasionally pain relief may not be complete.

Hence we are doing this study to Identify the best possible method with minimal side effects for post operative pain relief after heart surgery.

We hope to include about 90 patients in this study.

What is Pecto-intercostal Fascial Block?

The major source of pain for the patients after any cardiac surgery, is from the Sternotomy-incision and pleuro-mediastinal drain tube placement sites.

The intercostal space (ICS) is the space between 2 adjacent ribs of the thoracic cage
There are 11 ICSs on each side There are 11 pairs of ICNs (T1-T11) which are anterior divisions of the thoracic spinal nerves. They course through the intercostal spaces accompanied by the intercostal vessels. They provide sensory and motor innervation to the thoracic and abdominal wall and sensory innervation to the parietal pleura and peritoneum.

In pecto-intercostal fascial block (PIFB) Local anaesthetic is infiltrated into the interfascial plane between pectoralis major and the intercostal muscles lateral to the sternum to anaesthetise the anterior cutaneous branches of the intercostal nerves under Ultrasound guidance. This procedure can be undertaken very safely and anaesthetic drug injected around the nerves, that carry signal from that part of your body to spinal cord, could be instrumental in providing supplementary pain relief and preemptive analgesia at that operated site post surgically.

What are the potential problems with this technique?

There are very limited data on the safety profile of the PIFB or effectiveness compared to other regional analgesic techniques; however, it is arguably less invasive than thoracic epidural or paravertebral analgesia with no risk of serious complications like epidural or spinal hematoma in this patient population that is routinely anticoagulated during surgery.

If you take part in this study what will you have to do?

If you agree to participate in this study, you will be allotted by computer to receive either pecto-intercostal facial plane block with anaesthetic drug or no block with usual intravenous morphine for pain relief after surgery.

In the preoperative and postoperative period, you will be asked to grade your pain on a scale scientifically devised and practiced all over the world. In case pain relief is inadequate, you will be given supplemental pain killers.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide, to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way. In addition, If your recovery from surgery or postoperative course requires any additional surgical intervention for haemodynamic instability, bleeding or re-exploration, the study will be stopped and your routine treatment will continue as usual

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but, if you do develop any side effects in form of pain due to the study, these will be treated promptly at no cost to you. We are unable to provide any monetary compensation, however for participation in this study.

Will you have to pay for drugs/participating in this study?

Drugs (local anaesthetic) for intercostal nerve block will be given free and are a part of the routine anaesthetic medications.

All other protocols for post-operative patients will be followed strictly as done in routine cases.

What happens after the study is over?

You may or may not benefit from the study drug that you are given. Once this study is over, and the technique scientifically do show any benefit for the relief of post operative pain , then this method will be used in future for all the patients undergoing cardiac surgery.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal, but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please ask
Dr Pradeep A P (Senior resident, Department of Anaesthesiology), Telephone no. 8652360349, email id-pradeeppowers@gmail.com
Dr. Subin Sukesan (Associate Professor, Department of Anaesthesiiology)
Telephone no. 8289983726, email – subin@sctimst.ac.in

For any clarifications regarding the study's ethics clearance you may contact the Member Secretary of the SCTIMST-IEC – Dr Mala Ramanathan. The phone number is: 0471- 2524234 and the email id is iec.mem.sec@sctimst.ac.in

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: ***Ultrasound guided Bilateral Pecto-Intercostal facial Plane block: Role as a preemptive analgesic adjunct in fast tracking for mitigating postoperative Sternotomy Pain***

Study Number:
Participant's name:
Date of Birth / Age (in years):

I_____
_____, son/daughter of _____

(Please tick boxes)
Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]
I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]
I also understand that neither I, nor my doctors, will have any choice or knowledge of whether I will get intercostal block for analgesia[ ]
I understand that I will receive free treatment for any study related injury or adverse event but I will not receive and other financial compensation [ ]
I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial.
I agree to this access [ ]
I understand that my identity will not be revealed in any information released to third parties or published [ ]
I voluntarily agree to take part in this study [ ]

Name:
Signature:
Date:

Name of witness:
Relation to participant:
Date:

(Person Obtaining Consent) I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____ _____
Name and Signature of Person Obtaining Consent
(For Principal Investigator)

Witness:

If you have any further questions, please ask

Dr Pradeep A P (Senior resident, Department of Anaesthesiology), Telephone no. 8652360349, email id- pradeeppowers@gmail.com

Dr. Subin Sukesan (Associate Professor, Department of Anaesthesiology)

Telephone no. 8289983726, email – subin@sctimst.ac.in

For any clarifications regarding the study's ethics clearance you may contact the Member Secretary of the SCTIMST-IEC – Dr Mala Ramanathan. The phone number is: 0471- 2524234 and the email id is iec.mem.sec@sctimst.ac.in

i. PATIENT INFORMATION SHEET AND INFORMED CONSENT MALAYALAM

ശ്രീചിത്തിര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ്

ആൻറ് ടെക്നോളജി

തിരുവനന്തപുരം ,695011

കാർഡിയാക് അനെസ്തേസിയോളജി ഡിപ്പാർട്മെന്റ്

കാര്യവിവരണപത്രം

പഠന ശീർഷകം

ശാസ്ത്രക്രിയാനന്തരം സ്റ്റെർനോടോമി വേദന വേഗം ലഘൂകരിക്കാനുള്ള മുൻകൂർ വേദന സംഹാരിയുട അനുബന്ധമായി അൾട്രാസൗണ്ട് നിയന്ത്രിതമായ പെക്ടോ ഇന്റർകോസ്റ്റൽ ഫേഷ്യൽ ബ്ലോക്ക് എന്ന നെഞ്ചിന് കൂട്ടിലെ രണ്ടു സമീപസ്ഥ വാരിയെല്ലുകൾക്കിടയിലെ നാഡി തടസം

ശാസ്ത്രക്രിയാനന്തരം സ്റ്റെർനോടോമി വേദന വേഗം ലഘൂകരിക്കാനുള്ള മുൻകൂർ വേദന സംഹാരിയുട അനുബന്ധമായി അൾട്രാസൗണ്ട് നിയന്ത്രിതമായ പെക്ടോ ഇന്റർകോസ്റ്റൽ ഫേഷ്യൽ ബ്ലോക്ക് എന്ന നെഞ്ചിന് കൂട്ടിലെ രണ്ടു സമീപസ്ഥ വാരിയെല്ലുകൾക്കിടയിലെ നാഡി തടസം എന്ന പഠനത്തിൽ പങ്കെടുക്കാൻ തങ്ങളോട് അഭ്യർത്ഥിക്കുന്നു

എൻ്റെ പഠനത്തിലെ പങ്കാളിത്തം തികച്ചും സ്വമേധയാ ഉള്ളതും ,ഏതു സമയത്തും അനുവാദം പിൻവലിക്കാൻ എനിക്ക് സ്വാതന്ത്ര്യം ഉണ്ടെന്നും അങ്ങനെ സംഭവിക്യായ്കയാൽ എൻ്റെ ഈ ആശുപത്രിയിലെ പതിവ് ചികിത്സയെയോ നിയമാരമായ അവകാശങ്ങളെയോ ഒരു തരത്തിലും ബാധിക്കില്ല എന്നും ഞാൻ മനസിലാക്കുന്നു

എനിക്ക് വേദന സംഹാരിയായി പെക്ടോ ഇന്റർ കോസ്റ്റൽ ഫേഷ്യൽ ബ്ലോക്ക് ലഭ്യമാക്കുമോ ഇല്ലയോ എന്ന് എനിക്കോ എൻ്റെ ഡോക്ടർക്കോ മനസിലാക്കാൻ കഴിയില്ല എന്നും ഞാൻ മനസിലാക്കുന്നു .

പഠനവുമായി ബന്ധപ്പെട്ട ഏതു പരിക്കുകൾക്കും പാർശ്വ ഫലങ്ങൾക്കും എനിക്ക് സൗജന്യമായി ചികിത്സ ലഭിക്കുമെന്നും എന്നാൽ നഷ്ട പരിഹാരം ലഭിക്കുകയില്ലെന്നും ഞാൻ മനസിലാക്കുന്നു

ഞാൻ പഠനത്തിൽ നിന്നും പിന്മാറിയലും ക്ലിനിക്കൽ പരീക്ഷണത്തിന്റെ സംഘാടകർക്കോ ,പഠിതാക്കൾക്കോ സ്ഥാപനത്തിലെ നൈതിക കമ്മിറ്റി അംഗങ്ങൾക്കോ എൻ്റെ ഇപ്പോഴെത്തെയോ ,ഇതുമായി ബന്ധപ്പെട്ടുള്ള ഭാവി പഠനങ്ങൾക്കോ എൻ്റെ ചികിത്സ വിവരങ്ങൾ പരിശോധിക്കാൻ അനുവാദം ആവശ്യം ഇല്ലായെന്നും ഞാൻ മനസിലാക്കുന്നു .അതിനോട് ഞാൻ പൂർണമായും യോജിക്കുന്നു .മൂന്നാം കക്ഷിക്ക് വിവരങ്ങൾ കൈമാറുമ്പോഴും ,പ്രസിദ്ധീകരിക്കുമ്പോഴും എൻ്റെ വ്യക്തി വിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കും എന്നും എനിക്ക് മനസിലായിട്ടുണ്ട് .

ഞാൻ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതം നൽകുന്നു

സമ്മതം നൽകുന്ന ആളുടെ പേര് .....

രോഗിയുമായുള്ള ബന്ധം.....

ഒപ്പ്

തിയതി

സമ്മതം വാങ്ങുന്ന ആൾ

ഗവേഷണ പ്രബന്ധത്തിനായി കാര്യബോധത്തോടു കൂടിയുള്ള സമ്മതപത്രത്തിനായുള്ള എല്ലാ വിവരങ്ങളും ഈ പത്രികയിൽ നൽകിയത് തൃപ്തികരമാണെന്ന് ഞാൻ സാക്ഷ്യ പെടുത്തുന്നു

പങ്കാളിയുടെ രക്ഷ കർത്താവുമായി ചർച്ച ചെയ്യുകയും കാര്യബോധത്തോടു കൂടി തയാറാക്കിയ സമ്മത പത്രത്തിലെ വിവരങ്ങൾ ന്യായമായും ഉണ്ടായേക്കാമെന്നും , പ്രതീക്ഷിക്കുന്ന അപകട സാദ്ധ്യതകൾ ,പ്രതികൂല പ്രതികരണങ്ങളുമുൾപ്പെടെ സാങ്കേതിക പാദങ്ങൾ ഉൾപ്പെടുത്താതെ പറഞ്ഞു തന്നിട്ടുണ്ട് .

പങ്കാളിയുടെ രക്ഷ കർത്താവിനെ ചോദ്യങ്ങൾ ചോദിയ്ക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഞാൻ മറുപടി നൽകി എന്നും ഞാൻ സാക്ഷ്യപെടുത്തുന്നു

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര് ..... ഒപ്പ്.....

തിയതി

തങ്ങൾക്കു കൂടുതൽ എന്തെങ്കിലും ചോദ്യങ്ങൾ ഉണ്ടെകിൽ ചോദിക്കുക

ഡോ. പ്രദീപ് എ പി , സീനിയർ റസിഡന്റ്
ഫോൺ ;8652360349

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പഠനത്തിലെ നൈതിക അനുവാദവുമായി ബന്ധപ്പെട്ട വിവരങ്ങൾക്ക് വേണ്ടി ബന്ധപ്പെടാൻ
ഡോ . മാല രാമനാഥൻ
മെമ്പർ ,സെക്രട്ടറി ,IEC
SCTIMST തിരുവനന്തപുരം

CONSENT TO TAKE PART IN A CLINICAL TRIAL MALAYALAM

സമ്മത പത്രം

ശാസ്ത്രക്രിയാനന്തരം സ്റ്റെർനോടോമി വേദന വേഗം ലഘൂകരിക്കാനുള്ള മുൻകൂർ വേദന സംഹാരിയുടെ അനുബന്ധമായി അൾട്രാസൗണ്ട് നിയന്ത്രിതമായ പെക്ടോ ഇന്റർകോസ്റ്റൽ ഫേഷ്യൽ ബ്ലോക്ക് എന്ന നെഞ്ചിന് കൂട്ടിലെ രണ്ടു സമീപസ്ഥ വാരിയെല്ലുകൾക്കിടയിലെ നാഡി തടസം

പഠന നമ്പർ

പങ്കാളിയുടെ പേര്

ജനന തിയതി /വയസ്സ്

ഞാൻ .....പുത്രി / പുത്രൻ .....

പ്രസ്താവിക്കുന്നതെന്തെന്നാൽ

ശാസ്ത്രക്രിയാനന്തരം സ്റ്റെർനോടോമി വേദന വേഗം ലഘൂകരിക്കാനുള്ള മുൻകൂർ വേദന സംഹാരിയുടെ അനുബന്ധമായി അൾട്രാസൗണ്ട് നിയന്ത്രിതമായ പെക്ടോ ഇന്റർകോസ്റ്റൽ ഫേഷ്യൽ ബ്ലോക്ക് എന്ന നെഞ്ചിന് കൂട്ടിലെ രണ്ടു സമീപസ്ഥ വാരിയെല്ലുകൾക്കിടയിലെ നാഡി തടസം എന്ന പഠന സംബന്ധമായി എനിക്കുണ്ടായ എല്ലാ സംശയങ്ങളും പൂർണമായും പരിഹരിച്ചു .

എൻ്റെ പഠനത്തിലെ പങ്കാളിത്തം തികച്ചും സ്വമേധയാ ഉള്ളതും ,ഏതു സമയത്തും അനുവാദം പിൻവലിക്കാൻ എനിക്ക് സ്വാതന്ത്ര്യം ഉണ്ടെന്നും അങ്ങനെ സംഭവിക്യായ്കയാൽ എൻ്റെ ഈ ആശുപത്രിയിലെ പതിവ് ചികിത്സയെയോ നിയമാരമായ അവകാശങ്ങളെയോ ഒരു തരത്തിലും ബാധിക്കില്ല എന്നും ഞാൻ മനസിലാക്കുന്നു

എനിക്ക് വേദന സംഹാരിയായി പെക്ടോ ഇന്റർ കോസ്റ്റൽ ഫേഷ്യൽ ബ്ലോക്ക് ലഭ്യമാക്കുമോ ഇല്ലയോ എന്ന് എനിക്കോ എൻ്റെ ഡോക്ടർക്കോ മനസിലാക്കാൻ കഴിയില്ല എന്നും ഞാൻ മനസിലാക്കുന്നു .

പഠനവുമായി ബന്ധപ്പെട്ട ഏതു പരിക്കുകൾക്കും പാർശ്വ ഫലങ്ങൾക്കും എനിക്ക് സൗജന്യമായി ചികിത്സ ലഭിക്കുമെന്നും എന്നാൽ നഷ്ട പരിഹാരം ലഭിക്കുകയില്ലെന്നും ഞാൻ മനസിലാക്കുന്നു

ഞാൻ പഠനത്തിൽ നിന്നും പിന്മാറിയലും ക്ലിനിക്കൽ പരീക്ഷണത്തിന്റെ സംഘാടകർക്കോ ,പഠിതാക്കൾക്കോ സ്ഥാപനത്തിലെ നൈതിക കമ്മിറ്റി അംഗങ്ങൾക്കോ എൻ്റെ ഇപ്പോഴെത്തെയോ ,ഇതുമായി ബന്ധപ്പെട്ടുള്ള ഭാവി പഠനങ്ങൾക്കോ എൻ്റെ ചികിത്സ വിവരങ്ങൾ പരിശോധിക്കാൻ അനുവാദം ആവശ്യം ഇല്ലായെന്നും ഞാൻ മനസിലാക്കുന്നു .അതിനോട് ഞാൻ പൂർണമായും യോജിക്കുന്നു .മൂന്നാം കക്ഷിക്ക് വിവരങ്ങൾ കൈമാറുമ്പോഴും ,പ്രസിദ്ധീകരിക്കുമ്പോഴും എൻ്റെ വ്യക്തി വിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കും എന്നും എനിക്ക് മനസിലായിട്ടുണ്ട് .

ഞാൻ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതം നൽകുന്നു

സമ്മതം നൽകുന്ന ആളുടെ പേര് .....

രോഗിയുമായുള്ള ബന്ധം.....

ഒപ്പ്

തിയതി

സമ്മതം വാങ്ങുന്ന ആൾ

ഗവേഷണ പ്രബന്ധത്തിനായി കാര്യബോധത്തോടു കൂടിയുള്ള സമ്മതപത്രത്തിനായുള്ള എല്ലാ വിവരങ്ങളും ഈ പത്രികയിൽ നൽകിയത് തൃപ്തികരമാണെന്ന് ഞാൻ സാക്ഷ്യ പെടുത്തുന്നു

പങ്കാളിയുടെ രക്ഷ കർത്താവുമായി ചർച്ച ചെയ്യുകയും കാര്യബോധത്തോടു കൂടി തയാറാക്കിയ സമ്മത പത്രത്തിലെ വിവരങ്ങൾ ന്യായമായും ഉണ്ടായേക്കാമെന്നും , പ്രതീക്ഷിക്കുന്ന അപകട സാദ്ധ്യതകൾ ,പ്രതികൂല പ്രതികരണങ്ങളുമുൾപ്പെടെ സാങ്കേതിക പാദങ്ങൾ ഉൾപ്പെടുത്താതെ പറഞ്ഞു തന്നിട്ടുണ്ട് .

പങ്കാളിയുടെ രക്ഷ കർത്താവിനെ ചോദ്യങ്ങൾ ചോദിയ്ക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഞാൻ മറുപടി നൽകി എന്നും ഞാൻ സാക്ഷ്യപെടുത്തുന്നു

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര് ..... ഒപ്പ്.....

തിയതി

തങ്ങൾക്കു കൂടുതൽ എന്തെങ്കിലും ചോദ്യങ്ങൾ ഉണ്ടെകിൽ ചോദിക്കുക

ഡോ. പ്രദീപ് എ പി , സീനിയർ റസിഡന്റ്
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ഡോ . മാല രാമനാഥൻ
മെമ്പർ ,സെക്രട്ടറി ,IEC
SCTIMST തിരുവനന്തപുരം

ii. OBSERVATION CHART

Study Code Number of patient:

Age of the patient (yrs):

Weight (Kg):

Height (cm):

BSA (m^2):

Time of shifting to ICU:

Recent acute coronary syndrome:

Ejection Fraction:

Diagnosis:

Procedure:

Aortic cross clamp duration (min):

CPB duration (min):

Time of start - Incision:

Time of Tracheal Extubation:

Duration of mechanical ventilation (hours in ICU):

Pain score (Numeric Rating Scale): (After extubation)

	At 15 minutes	**At 4 hours**	**At 8 hours**	**At 12 hours**	**At 16 hours**	**At 20 hours**	**At 24 hours**
NRS							

Sedation score (after extubation)

	At 15 minutes	**At 4 hours**	**At 8 hours**	**At 12 hours**	**At 16 hours**	**At 20 hours**	**At 24 hours**
Ramsay sedation scale							

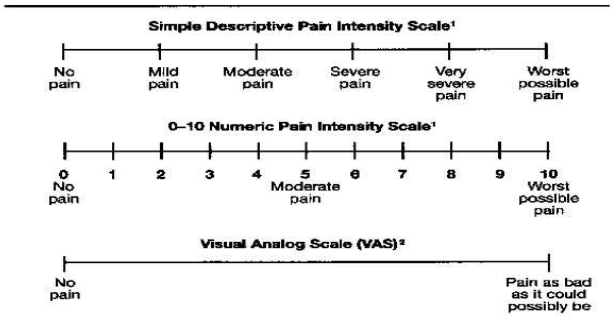
Rescue Analgesia at different time intervals

Rescue analgesia	At 15 minutes	15 min- 8 hours	8-16 hours	16-24 hours
Yes/No				

Incidence of Side Effects (nausea /vomiting)

Side effects	At 15 minutes	15 min- 8 hours	8-16 hours	16-24 hours
Yes/No				

Complications, related to procedure if any:



Ramsay Sedation Assessment Scale

Awake Levels:	Patient anxious or agitated or both	1
	Patient cooperative, oriented and tranquil	2
	Patient responds to commands only	3
Asleep Levels:	A brisk response to a light glabellar tap	4
	A sluggish response to a light glabellar tap	5
	No response	6

iii. INSTITUTIONAL ETHICS COMMITTEE APPROVAL

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1398/JULY-2019 07.09.2019

Dr. Pradeep A P
Senior Resident, Department of Anaesthesiology
SCTIMST, Thiruvananthapuram

Dear Dr. Pradeep,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "ULTRASOUND GUIDED BILATERAL PECTO-INTERCOSTAL FASCIAL BLOCK: ROLE AS A PREEMPTIVE ANALGESIC ADJUNCT IN FAST TRACKING FOR MITIGATING POSTOPERATIVE STERNOTOMY PAIN (IEC/1398)" on 26th July, 2019.

The following documents were reviewed:

Original submission

1. *Covering Letter addressed to the Chairman, IEC, SCTIMST with checklist*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Project Proposal*
5. *Proforma*
6. *Patient Information Sheet and Informed Consent Form in English and Malayalam*
7. *CV of Principal Investigator and Co-Principal Investigators*

Revised submission

1. *Covering Letter addressed to the Chairman, IEC, SCTIMST with checklist*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Project Proposal*
5. *Proforma*
6. *Patient Information Sheet and Informed Consent Form in English and Malayalam*
7. *CV of Principal Investigator and Co-Principal Investigators*

The following members of the Ethics Committee were present at the meeting held on 26th July, 2019 at Noshir H Wadia Conference Hall, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
2.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
3.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
4.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
5.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:
The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

iv. DATA COLLECTION MASTER CHART

Iou	ge	Se	eig	igS	E	FC	TOA	Mechare After Exation Scale Afte										Co-operation				gesia After Ext				PLICAT	of Nusea and			
	yea	M/	Kg	im	%	Y	Minut	n Hours	1	4	8	1	1	2	4	1	16	20	24	15	8 H	16	24	15	8 H	8-1	16-	Y/N	15	8 H	16	24
1	B	69	M	72	7	..	60	Y	62	114	6	5	5	5	5	5	5	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	Y	Y	N	N
2	B	56	M	75	7	..	68	N	62	118	8	4	5	5	4	3	6	6	2	2	2	2	2	Y	Y	Y	Y	N	N	N	y	N	N	N	N	Y
3	B	64	M	74	7	..	66	N	68	115	7	5	5	5	4	4	6	6	2	2	2	2	2	Y	Y	Y	Y	N	Y	y	N	N	N	N	Y	Y
4	B	66	F	76	6	..	62	N	82	122	7	4	6	5	5	4	5	6	1	1	1	1	1	N	N	N	N	N	y	N	y	N	N	Y	N	N
5	B	69	M	62	6	..	68	Y	91	128	8	7	5	5	5	5	5	1	1	1	2	2	2	2	Y	Y	Y	Y	Y	N	N	y	N	N	N	N	N
6	B	67	M	76	7	..	65	N	67	117	6	4	6	6	5	5	5	5	2	2	2	3	2	Y	Y	Y	Y	N	Y	y	N	N	N	N	N	N
7	B	62	F	63	5	..	62	N	64	116	6	5	6	5	5	5	6	6	2	2	3	2	2	2	Y	Y	Y	Y	Y	N	N	y	N	N	N	Y	N
8	B	63	M	72	6	..	60	Y	70	112	7	3	5	7	5	5	5	4	2	3	2	2	2	2	Y	Y	Y	Y	N	Y	N	y	N	N	N	N	N
9	B	69	M	66	6	..	65	N	68	116	6	5	5	6	5	6	5	5	1	2	1	2	2	2	N	Y	Y	Y	N	N	y	N	N	N	Y	N	N
10	B	67	M	69	6	..	68	N	66	118	6	5	6	7	5	6	5	6	3	2	2	2	1	2	2	Y	Y	N	N	N	Y	N	y	N	N	N	N	N
11	B	60	F	72	5	..	67	Y	64	112	8	4	5	5	5	6	6	4	2	2	2	2	2	2	Y	Y	Y	Y	N	N	y	N	N	N	N	N	N
12	B	61	M	75	6	..	64	N	72	122	9	7	5	6	5	6	4	5	1	2	2	2	2	2	Y	Y	Y	Y	Y	y	N	N	N	N	Y	Y	Y
13	B	69	M	76	6	..	63	N	70	118	6	5	5	5	5	5	6	2	3	3	2	2	2	1	Y	Y	Y	Y	N	y	N	y	N	N	N	N	N
14	B	64	M	79	6	..	61	Y	62	114	7	3	5	6	5	5	4	6	2	2	3	3	2	2	Y	N	Y	Y	N	Y	N	N	N	N	N	N	N
15	B	64	M	68	6	..	62	N	63	112	6	4	5	6	5	5	6	5	3	3	1	2	2	2	Y	N	Y	Y	N	Y	N	y	N	N	Y	N	N
16	B	68	F	68	6	..	64	N	68	118	6	5	6	5	5	7	5	5	2	1	3	2	1	2	2	N	N	N	N	Y	N	y	N	N	N	N	N
17	B	58	M	76	7	..	67	Y	73	118	9	4	5	5	6	5	6	6	2	3	2	1	2	1	2	Y	Y	Y	Y	N	N	y	y	N	N	N	N	Y
18	B	62	F	68	5	..	68	N	70	119	6	4	4	5	7	5	4	5	2	2	2	1	1	2	2	Y	Y	Y	Y	N	N	y	N	N	N	Y	N	N
19	B	66	M	77	6	..	69	N	74	118	6	3	5	6	6	5	6	6	3	2	2	2	2	2	Y	Y	Y	Y	N	Y	N	y	N	N	N	N	N
20	B	61	M	72	6	..	60	N	67	114	8	5	4	5	5	4	5	5	2	2	2	2	2	3	2	2	Y	Y	Y	Y	Y	N	y	N	N	N	N	Y	N
21	B	62	M	72	6	..	61	N	72	112	7	5	5	6	5	6	6	5	2	3	2	1	2	2	2	Y	N	N	N	N	N	y	N	N	Y	N	N	N
22	B	62	F	64	5	..	62	N	71	112	6	4	5	5	6	6	6	2	1	2	1	1	3	2	Y	Y	Y	Y	y	N	N	y	N	N	N	N	N
23	B	66	F	68	5	..	66	Y	79	112	8	5	5	5	5	5	6	3	2	3	2	2	2	1	Y	Y	Y	Y	N	N	N	N	N	N	N	N	Y
24	B	58	M	74	6	..	62	N	82	114	6	4	5	5	6	5	6	6	2	2	2	2	2	2	N	Y	Y	Y	Y	N	y	N	N	N	N	N	N
25	B	67	M	71	6	..	60	N	71	115	7	4	4	4	6	5	5	5	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	y	N	N	N	N	N
26	B	68	M	72	6	..	60	N	68	118	8	4	4	5	4	6	5	5	3	3	2	2	2	2	Y	Y	Y	Y	N	N	y	N	N	N	Y	N	N
27	B	66	M	68	6	..	58	N	74	120	6	4	5	6	5	6	6	6	2	1	2	3	2	2	Y	Y	N	Y	N	N	N	y	N	N	N	N	N
28	B	66	M	69	6	..	58	Y	71	111	9	5	6	5	6	5	5	1	2	2	2	2	2	2	Y	N	Y	Y	N	Y	N	N	N	N	N	N	N
29	B	67	M	79	7	..	68	N	75	98	8	5	6	6	6	5	5	2	3	3	2	2	2	2	Y	Y	Y	Y	N	Y	N	y	N	N	N	N	N
30	B	64	M	75	6	..	69	N	72	113	8	4	5	5	5	6	4	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	y	N	N	N	N	Y	N
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32	B	62	M	69	6	..	66	N	71	112	8	6	6	6	6	5	5	6	3	3	2	2	2	2	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N
33	B	68	M	70	6	..	56	Y	76	112	9	5	5	5	5	6	5	6	2	3	2	2	2	2	Y	Y	Y	Y	N	N	y	N	N	N	N	N	N
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36	B	66	M	74	6	..	64	N	81	114	8	5	7	6	6	5	5	5	2	3	2	1	2	2	2	Y	Y	Y	Y	N	Y	N	Y	N	N	N	N	N
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38	B	58	M	70	6	..	65	Y	80	102	8	4	4	5	5	6	4	5	2	2	2	2	2	2	Y	Y	Y	Y	N	N	y	N	N	N	N	N	N
39	B	69	M	68	6	..	63	N	78	112	7	4	5	5	6	5	6	6	2	2	2	2	2	2	Y	Y	Y	Y	N	Y	y	N	N	N	N	N	N

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41	B	58	M	71.	.60	.72	Y	76	128	9	5	6	5	5	5	6	6	2	2	2	2	2	2	2	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N
42	B	66	M	72.	.70	.82	Y	79	122	8	5	7	6	6	5	5	5	1	2	2	2	2	2	2	Y	N	Y	Y	Y	N	Y	N	N	N	N	N	N
43	B	64	M	77.	.68	.80	N	70	124	7	5	6	6	5	6	6	5	2	2	2	2	2	2	2	Y	Y	N	Y	N	Y	N	Y	N	N	N	Y	N
44	B	62	M	74.	.60	.82	N	72	118	7	4	6	5	5	6	5	5	2	3	2	2	2	2	2	N	N	Y	Y	Y	Y	N	N	N	N	N	N	N
45	B	58	M	68.	.61	.78	N	74	114	7	5	6	4	4	5	5	5	2	2	2	2	2	2	2	Y	Y	Y	Y	N	Y	N	N	N	N	N	N	N
46	A	66	F	64.	.68	.78	N	76	112	6	2	1	2	3	3	3	2	3	2	2	2	2	2	2	Y	Y	Y	Y	N	Y	N	Y	N	N	N	N	N
47	A	55	M	57.	.59	.69	N	70	115	8	0	0	3	2	3	2	3	2	2	2	2	3	2	2	Y	Y	Y	Y	N	N	Y	N	N	N	N	N	N
48	A	56	M	77.	.60	.87	N	81	122	8	1	2	2	2	3	3	2	2	2	2	3	2	3	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
49	A	63	M	73.	.70	.88	N	82	114	6	2	3	3	2	2	2	3	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	Y	N	N	N	N	N	N
50	A	64	M	72.	.69	.83	N	72	110	7	2	2	2	1	3	2	3	2	2	2	2	2	2	2	Y	Y	Y	Y	N	Y	N	Y	N	N	N	N	N
51	A	68	M	67.	.64	.76	N	74	112	8	1	1	2	3	2	2	1	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
52	A	64	M	73.	.61	.82	N	70	114	7	2	2	1	2	3	2	3	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
53	A	62	M	74.	.61	.84	Y	69	115	6	3	0	2	2	3	2	2	2	2	2	3	2	3	2	Y	Y	Y	Y	N	N	Y	N	N	N	N	N	N
54	A	64	M	72.	.68	.82	Y	64	119	7	1	2	2	3	2	2	2	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
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56	A	64	M	76.	.69	.92	N	64	104	8	2	2	2	3	3	3	3	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
57	A	62	M	68.	.70	.75	N	69	106	6	0	3	3	2	2	2	3	2	3	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
58	A	66	M	70.	.69	.80	Y	68	122	6	1	3	2	2	3	3	2	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
59	A	58	F	74.	.65	.82	Y	67	123	9	2	2	2	3	3	2	0	3	2	2	2	2	2	2	Y	Y	Y	Y	N	N	Y	N	N	N	N	N	N
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62	A	68	M	77.	.69	.94	N	69	112	7	2	2	3	1	3	3	2	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	Y	N	N	N	N	N
63	A	68	M	69.	.68	.89	N	66	105	8	2	2	2	2	3	2	3	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
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68	A	66	M	77.	.68	.92	N	79	122	6	1	2	2	3	3	2	3	3	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
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70	A	60	M	72.	.61	.82	Y	73	124	6	2	2	3	2	2	2	3	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
71	A	68	M	79.	.68	.95	N	82	117	8	0	3	3	2	3	2	2	3	2	3	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
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75	A	66	M	70.	.69	.89	Y	81	125	6	2	2	2	2	2	2	2	2	3	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
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89	A	68	F	68	.61	..	55	N	78	114	7	3	3	2	3	3	2	2	3	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	N	N	N	N	N	N
90	A	69	M	80	.60	..	65	N	78	115	8	1	1	2	2	2	2	3	2	2	2	2	2	2	2	Y	Y	Y	Y	N	N	N	Y	N	N	N	N	N

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