COMPARISON OF EFFICACY OF ULTRASOUND GUIDED BILATERAL ERECTOR SPINAE BLOCK AND PECTORALIS NERVE 2 BLOCK IN PEDIATRIC CARDIAC SURGERIES VIA MEDIAN STERNOTOMY

Dr. TONY JOSE JOSEPH

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A THESIS SUBMITTED BY

Dr. TONY JOSE JOSEPH

TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM.

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

Doctorate in Medicine in Cardio-Thoracic and Vascular Anaesthesiology

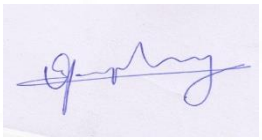
2020-2022

DECLARATION BY THE STUDENT

CERTIFICATE

I, Dr. Tony Jose Joseph hereby certify that I had personally carried out the work depicted in the thesis titled, ***"COMPARISON OF EFFICACY OF ULTRASOUND GUIDED BILATERAL ERECTOR SPINAE BLOCK AND PECTORALIS NERVE 2 BLOCK IN PEDIATRIC CARDIAC SURGERIES VIA MEDIAN STERNOTOMY."***

No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.



Dr. Tony Jose Joseph
Senior Resident
Dept. of Cardiovascular &
Thoracic Anesthesia
SCTIMST

Date: 25th July 2022

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

CERTIFICATE BY THE RESEARCH GUIDES

Name of the Guide: Dr. Rupa Sreedhar

Division/Department: Professor (senior grade), Dept. of Anaesthesiology

Name of the Guide: Dr. Subin Sukesan

Division/Department: Additional Professor, Dept. of Anaesthesiology

This is to certify that Dr. Tony Jose Joseph, Department of Anaesthesiology of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, "**Comparison of Efficacy of Ultrasound Guided Bilateral Erector Spinae Block and Pectoralis Nerve 2 Block in Pediatric Cardiac Surgeries via Median Sternotomy**" was carried out under our direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date. Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Rupa Sreedhar

Dr. Rupa Sreedhar

Date 10/8/2022

Dr. Subin Sukesan

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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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

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Shrinivas Gadhinglajkar

Department: Professor (senior grade) and Head, Dept. of Anaesthesiology

This is to certify that Dr. Tony Jose Joseph, Department of Anaesthesiology of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

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Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

S Gadhinglajkar

Dr. Shrinivas Gadhinglajkar

Date: 10-8-2022

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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(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

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Prasanta Kumar Dash
Division/Department: Professor, Dept. of Anaesthesiology

This is to certify that Dr. Tony Jose Joseph, Department of Anaesthesiology of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

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Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Dr. Prasanta Kumar Dash

Date: 3/8/2022

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
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Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Baiju S Dharan

Division/Department: Professor and Head, Dept. of Cardiothoracic & Vascular Surgery.

This is to certify that Dr. Tony Jose Joseph, Department of Anaesthesiology of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

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Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

Dr. Baiju S Dharan

Date: 10 - 8 - 2022

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide:. Dr. Saravana Babu M. S.

Division/Department: Assistant Professor, Dept. of Anaesthesiology

This is to certify that Dr. Tony Jose Joseph, Department of Anaesthesiology of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, "**Comparison of Efficacy of Ultrasound Guided Bilateral Erector Spinae Block and Pectoralis Nerve 2 Block in Pediatric Cardiac Surgeries Via Median Sternotomy**" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

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Dr. Saravana Babu M. S.

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Date: 25th July 2022

Place: Trivandrum

Dr. Tony Jose Joseph

Senior resident

Cardiothoracic & Vascular Anaesthesiology

SCTIMST, Trivandrum

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SYNOPSIS

BY

Dr. Tony Jose Joseph

For DM Cardiothoracic and Vascular Anesthesia

of

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

SYNOPSIS

Midline sternotomies for cardiac surgery can account to immense postoperative discomfort and pain. The usage of regional nerve blocks for postoperative pain control is becoming very popular and has become an integral part for fast tracking of patients. Various regional nerve blocks like Erector Spinae block, PECS 2 block, Transverse thoracic plane block, etc are gaining popularity

In this study we compare the postoperative pain in pediatric cardiac surgeries done through a median sternotomy, in those patients receiving either ultrasound guided Erector Spinae block or ultrasound guided Pectoralis Nerve 2 block along with a control group. Also we compare the intraoperative and postoperative fentanyl requirement, stress response assessed by glucose and lactate levels, duration of mechanical ventilation, postoperative lung complications and duration of ICU stay

.

A randomized controlled trial was carried out in the pediatric cardiothoracic and vascular surgery department of our institute over a period of 15 months. . Patients undergoing correction of elective congenital heart disease (acyanotic heart disease) will be consecutively recruited and randomized into three groups using a computer generated random number table. Group E (general anesthesia + ultrasound guided bilateral Erector Spinae block), Group P (general anesthesia + ultrasound guided bilateral PECS 2 block) and Group C (general anesthesia only). Following this pain score by MOPS score, intraoperative and postoperative fentanyl consumption, blood sugar and lactate values from serial arterial blood gases, time to first rescue

analgesia, and duration of mechanical ventilation were measured. Data was collected and statistical analyses wereperformed by using a statistical software package SPSS, version 20.0

From patients who underwent elective surgical procedures in the department of pediatric cardiac surgery, 90 patients were selected and randomized into 3 groups as mentioned above.

In our study the comparison of the baseline demographic data, age, sex, height, weight and BSA between the two groups yielded comparable results. Bilateral Erector Spinae Block and PECS 2 block resulted in lower pain scores after extubation of the trachea compared to control group in children undergoing cardiac surgery with median sternotomy. Lower pain scores and opioid consumption in Erector Spinae group compared to PECS 2 group suggests that it is a superior technique for sternotomy pain. Both, the regional anesthetic techniques resulted in similar hemodynamic parameters which were lower than the baseline in response to surgical stimulus.

The median duration of ventilation and length of stay in ICU was similar in all the three groups Ultrasound guided Erector Spinae and PECS 2 blocks are safe as there were no procedure related complications in our study.

INTRODUCTION

INTRODUCTION

Pain, as defined by International Association for study of pain, is an "unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage"(1). Pain arising from skin incision and concerned operative sites are the main intervention targets for treatment modalities in advanced pain management protocols. Pain at the operative site adversely affects the respiratory and cardiovascular systems, impair muscular mobility, general mobility, and physical fitness of the patient (2).

Cardiac surgery with cardiopulmonary bypass elicits inflammatory and stress response which extends to the immediate postoperative period (3). Midline sternotomies for cardiac surgery can account for immense postoperative discomfort and pain .The stress response to surgery leads to neurohumoral, immunologic, metabolic and endocrine derangements and secretion of catabolic hormones including cortisol and catecholamines (4). All these can cause adverse effects such as tachycardia, hypertension, increased oxygen consumption, catabolism, and impaired immune function. Poor control of postoperative surgical pain is associated with the development of chronic pain in 20-50% of the patients following sternotomy and thoracotomy (5).

Optimal dynamic pain management has become a prerequisite for early postoperative recovery. An appropriate anesthetic technique can alleviate perioperative stress. Currently Opioids are the mainstay of treatment for pain management in almost all cardiac intensive care units, even though they have side effects related to excess of sedation, nausea and vomiting(6). 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. The other reason for the reluctance to use any neuraxial block technique in cardiac patients, is about the sympatholysis concerns, induced by the neuraxial analgesia techniques, causing haemodynamic instability. One of the most intriguing aspects of regional anesthesia is its ability to attenuate the stress response to surgery (7). Ultrasound guided Erector Spinae block and Pectoralis Nerve 2 (PECS 2) blocks are superficial plane blocks with very few complications and can provide comparable analgesia with that of central neuraxial blocks.

The role of Erector Spinae block for postoperative analgesia has been well established in pediatric surgeries (8) including thoracic surgeries, abdominal surgeries such as laparoscopic cholecystectomy, nephrectomy etc (9). PECS 2 was originally described for analgesia in breast surgeries (10). Now PECS 2 is also used for adult cardiac surgical procedures including Coronary Artery Bypass Grafting (CABG), valve surgeries (11) and pediatric thoracotomies (12).

Erector Spinae block has been described in pediatric cardiac surgeries done via median sternotomy (8). PECS 2 block has been studied in adult cardiac surgeries performed via midline sternotomy (11) and in pediatric thoracotomies (12). However, there are no studies comparing the intraoperative and postoperative effects of Erector Spinae block and PECS 2 block in pediatric cardiac surgeries done via midline sternotomy.

We propose to assess the efficacy of ultrasound guided bilateral Erector Spinae block versus ultrasound guided bilateral PECS 2 block in children undergoing open heart surgery through a median sternotomy approach and to find out whether the addition of ultrasound guided bilateral Erector Spinae block/ PECS 2 block to the present institutional postoperative analgesia protocol will have a beneficial effect.

AIMS AND OBJECTIVES

Hypothesis

We hypothesize that the addition of a single shot ultrasound guided bilateral Erector Spinae block or bilateral Pectoralis Nerve 2 (PECS 2) block using Levobupivacaine (after the induction of anesthesia), along with the current institutional protocol of using postoperative morphine and paracetamol infusions will significantly reduce the postoperative pain in pediatric cardiac surgeries done through a median sternotomy, compared to the present institutional protocol of using morphine and paracetamol infusions for postoperative analgesia

Objectives

1. The **primary objective** of the study is to compare the postoperative pain in pediatric cardiac surgeries done through a median sternotomy, in those patients receiving either ultrasound guided Erector Spinae block or ultrasound guided Pectoralis Nerve 2 block along with the current institutional protocol of using postoperative morphine and paracetamol infusions, with those receiving only postoperative morphine and paracetamol infusions.

2. Our **secondary objectives** are to assess whether the addition of bilateral Erector Spinae or PECS 2 block to general anesthesia (GA) reduces intraoperative and postoperative analgesic requirement, the intraoperative and postoperative stress response as assessed by glucose and lactate levels, duration of mechanical ventilation, postoperative lung complications, and duration of ICU stay. We also propose to study the procedure related complications.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

All surgical interventions result in the patient's perception of pain. Postoperative pain is proportional to the extent of surgery and intraoperative damage to tissues (13). In cases of extensive surgical trauma, in addition to superficial and somatic pain, the visceral component of postoperative pain is also activated. This visceral component of pain is due to smooth-muscle contraction, compression and tension of the visceral structures, and inflammatory lesions. Postoperative pain is one among the prime reasons for deterioration of the general condition of the patient. It is manifested as disorders of the respiratory and cardiovascular systems, sympathetic nervous system stimulation, and impairment of muscular mobility, general mobility, and well-being of the patient.

Cardiac surgery on cardiopulmonary bypass evokes intense inflammatory response. Pain following cardiac surgery may be related to the sternotomy incision, intraoperative tissue dissection, vascular cannulation, and chest tube insertion. Postoperative pain is not merely a disturbing symptom, but it affects the whole body, causing hemodynamic instability as well as enhanced oxygen consumption, with an increased risk of myocardial ischemia (14).

Furthermore, pain might also restrain respiratory capacity. It affects the breathing mechanics (a phenomenon called "splinting"), and the ability to cough properly, promoting pulmonary infections and other complications (15). High-dose long-acting opioids was accepted as the primary means of analgesia that nullifies the sympathetic response from surgical pain and improves patient hemodynamics. This practice has led to patients requiring longer duration

of mechanical ventilation and duration of intensive care unit (ICU) stay. This practice has changed over the past two decades with the growing trend towards “fast-tracking” (16) which includes earlier tracheal extubation, shorter ICU stay, and earlier discharges. Regional anesthesia enables fast tracking by providing sufficient pain relief and early patient mobilization.

PAIN IN CARDIAC SURGERY

Pain following cardiac surgery is a multifaceted phenomenon resulting from a number of mechanisms.

ACUTE PAIN

Acute pain decreases day by day with healing of organic tissue and skin. This usually lasts up to 10 days, but can even last for a duration of 3 months. Acute sternotomy pain occurs as result of nociceptive input from direct tissue injury. An inflammatory response to sternotomy leads to the sensitization of peripheral and central pathways. Tissue injury in sternotomy occurs in the skin, subcutaneous tissues, bone, and cartilage. Intercostal nerves arising from thoracic nerve roots innervate the sternum, ribs, and surrounding subcutaneous tissue (17). The principal thoracic nerves supplying the sternum arise from nerves which originate at T2 to T6 spinal levels. The pericardium is innervated with pain fibers that arise from the vagus nerve, phrenic nerve, and sympathetic trunks. Injury to tissues causes release of numerous inflammatory mediators including ions (eg, sodium, potassium, and calcium), bradykinin, substance P, histamine, 5-hydroxytryptamine, adenosine triphosphate, nitric oxide,

prostanoids, and leukotrienes (18). Some of the mediators directly activate nociceptors, whereas others work through indirect mechanisms. They also play an important role in the sensitization of both peripheral and central neurons to subsequent stimuli. Acute tissue injury occurring after sternotomy is not only at the site of incision but also at more distant sites because of prolonged sternal retraction, which may lead to rib fracture, costochondritis, rib joint dislocation, or nerve injury. The presence of chest tubes and mediastinal tubes, which irritate the parietal pleura and pericardium, are also a significant source of pain for patients(19). Finally, pericarditis can occur after pericardiotomy, leading to significant pain.

CHRONIC PAIN

In 35 % of patients pain may persist for prolonged periods up to one year following cardiac surgery (20). Werner and Kongsgaard described Chronic Post-Operative Pain (CPOP) as "the pain that develops after a surgery or increases after the surgical intervention, lasts for a duration of minimum 3–6 months and significantly affects the quality of life; the pain is an extension of acute post-surgical pain or occurs following an asymptomatic period; the pain is confined to the area of surgery or projected to the innervation territory of a nerve located in the surgical field or referred to a dermatome; and other causes of pain should be excluded".(21)

The exact pathophysiology of Chronic Post-Operative Pain (CPOP) is still unclear. Intraoperative nerve injury is a major cause of pain which manifests postoperatively as hyperalgesia and allodynia, both typical symptoms of neuropathic pain. Chronic post-sternotomy pain is a result of various factors such as sternal osteomyelitis,

sternal fracture, incomplete bone healing, sternocostal chondritis, costal fracture, brachial plexus injury, nerve entrapment by sternal wire sutures or an allergic hypersensitivity reaction against the sternal wire (22).

Another possible mechanism is that visceral stimulation during surgery sensitizes the central nervous system, thus facilitating the development of somatic chronic pain via viscero-somatic convergent mechanisms. However, compared to adults the prevalence of chronic postoperative pain is lower in children. The lower prevalence of chronic pain after surgery in childhood may have several explanations. The peripheral and central nervous system is not fully mature and augmented neuronal plastic capacity of the child's brain (23) may impart a diminished risk of developing chronic pain. Bones, tendons and ligaments are more indulgent and compliant in children, and so sternotomy may impart lesser damage in children than in adults (5). Psychological aspects may also play an important role. Psychological aspects such as fear of surgery have been found to be associated with more acute pain in adults (24), but in children anxiety and parental separation fears are more worrisome factors rather than the fear about surgery.

ADVERSE EFFECTS OF POST OPERATIVE PAIN

Post-operative pain results in a number of harmful sequelae detrimental to patient recovery. Pain hampers satisfactory coughing and deep breathing, and leads to inadequate breaths. This can abolish the normal mucus clearance resulting in an increased risk of atelectasis and pneumonia, prolonged hospital stay, mechanical ventilation, and antibiotic therapy (25).

Also, postoperative pain adversely affects patient mobilization, and compliance to physiotherapy. This not only leads to atelectasis but also exacerbates disuse induced muscle atrophy and prolongs the time taken to return to a normal level of mobility for discharge. Pain also contributes to patient anxiety affecting normal sleep pattern resulting in exhaustion and low mood (13).

All surgical interventions leads to a stress response characterized by enhanced secretion of pituitary hormones and sympathetic nervous system activation, with subsequent effects on target organs including adrenal glands, that leads to a cascade of hormone secretion. The stressful situation further triggers the activation of the hypothalamic-pituitary-adrenal (HPA) axis whereby the hypothalamus releases a hormone called corticotrpin-releasing-hormone (CRH). This triggers the pituitary gland to secrete adrenocorticotropin (ACTH) which acts on adrenal glands to secrete cortisol (26). In parallel, the stress response involves hypothalamic stimulation of sympathetic nervous system resulting in secretion of catecholamines from adrenal medulla. In addition, there is release of growth hormone and prolactin. The circulating catecholamines, cortisol, and growth hormone result in elevated blood glucose levels. Consequently, synthesis and release of insulin is stimulated to maintain blood glucose levels within normal range. In the pancreas glucagon is released and insulin secretion may be diminished. The net effect of endocrine response to stress as a result of surgery is an elevated secretion of catabolic hormones. Blood glucose concentrations increase after surgery begins. Cortisol and catecholamines promotes glucose synthesis by accelerated glycogenolysis and gluconeogenesis. They also inhibit the peripheral utilization of glucose. Blood glucose concentration is directly related to the magnitude of the surgical trauma and this is less pronounced in minor surgeries whereas cardiac surgery with extensive

tissue injury and major hemodynamic fluctuations can result in altered glucose homeostasis. Lactate production occurs from pyruvate in the cytosol as a byproduct of glycolysis. Lactate is in equilibrium with pyruvate. This equilibrium is maintained by lactate dehydrogenase with a fairly constant lactate to pyruvate ratio of 10:1. Lactate accumulation might not imply a state of anaerobic glycolysis, but simply represent a state of accelerated glycolysis (glycolytic flux is higher than the tricarboxylic acid cycle flux) or of decreased pyruvate dehydrogenase activity with pyruvate accumulation (27).

Hyperlactataemia in patients who have undergone cardiac surgery is fairly common (28). Irrespective of whether hyperlactataemia is early (admission) or late (post-admission), it is strongly associated with mortality. Most studies refer to tissue hypoxia or organ oxygen debt as the main explanations for hyperlactataemia. Hyperglycaemia and administration of epinephrine, norepinephrine, and dobutamine are often associated with hyperlactataemia after cardiac surgery(29). Stimulation of β-adrenergic receptors increases plasma glucose concentration, thereby increasing the substrates for glycolysis and lactate production.

CHEST WALL INNERVATION

Sensory innervation of the chest wall arises mainly from thoracic intercostal nerves (T1–T11). A spinal nerve after its origin from the spinal cord exits the intervertebral foramen and divides into a dorsal and ventral rami. The dorsal rami supply the muscles, bones, joints, and skin of the mid back. The ventral rami courses together with blood vessels in the

beginning, runs between pleura and endothoracic fascia, and later on between the internal and innermost intercostal muscles, supplying the lateral and anterior chest wall. At the midaxillary line, a lateral cutaneous branch originates and runs between the intercostal muscles and serratus anterior muscle (SAM), innervating the lateral chest wall. Then it continues anteriorly toward the sternum and pierces the internal intercostal muscle, external intercostal membrane, and Pectoralis major muscle providing sensory innervation for the anterior chest wall. The adjacent intercostal nerves have overlapping segmental innervation requiring blockade of at least the nerve above and below a particular segment to achieve pain relief (30) (Figure 1). Nerves arising from the brachial plexus such as medial pectoral nerve, lateral pectoral nerve, long thoracic nerve and thoracodorsal nerve, and although primarily motor in function are known to carry sensory fibers that innervate the anterolateral chest wall.

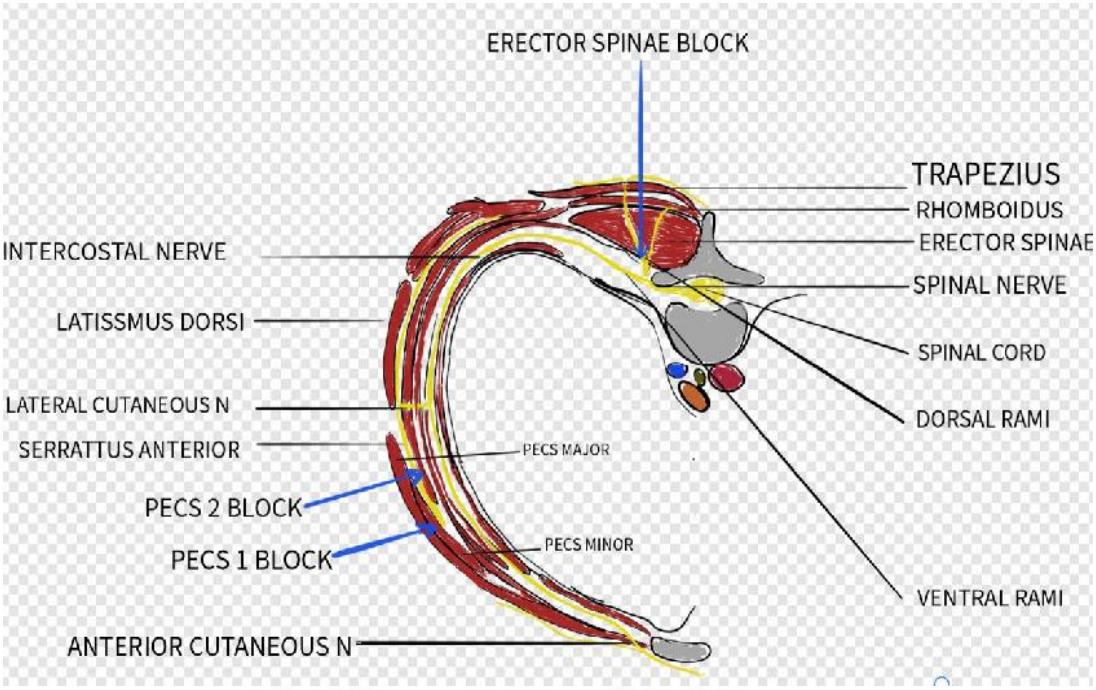


Figure 1: Anatomy of intercostal nerve and various sites of its blockade

For providing analgesia for surgery involving anterolateral or posterior chest wall, it is necessary to block intercostal nerves at their origin via a thoracic epidural blockade or thoracic paravertebral block; or block the posterior intercostal nerve; or block lateral/ anterior cutaneous branches of the intercostal nerves as they pierce their way into the subcutaneous tissue at around the anterior axillary line or sternal border (31).

PAIN RELIEF IN CARDIAC SURGERY: THE ROAD SO FAR

Intravenous opioids are considered to be the mainstay for managing pain during the perioperative period in children undergoing median sternotomy for cardiac surgery (32). High opioid dose can be associated with prolonged ventilation, tolerance and opioid related side effects including sedation, nausea and vomiting, gut dysfunction and immunosuppression (33). Today, lower doses are often used in order to achieve early tracheal extubation. At such doses, there is no guarantee that the stress response is completely abolished. Some of these children may require repeated operations and poorly controlled perioperative pain may lead to a suboptimal experience and be associated with chronic pain, although this is less common than in adults.

Central neuraxial blockade including spinal, epidural and caudal have been used since the 1980s but have not gained wide spread acceptance, unlike its use in non-cardiac surgery, due to the fear of potential associated complications in heparinized patients, especially epidural hematoma (34). The other reason for the reluctance to use any neuraxial block technique in cardiac patients, are about the fear of infection at the injection site and sympatholysis

concerns induced by the neuraxial analgesia techniques, causing haemodynamic instability. These 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. Hemmerling and colleagues reviewed the risk of catheter related epidural hematomas in all patients who had received epidural anesthesia for cardiac surgery from 1966 to 2012 (35). They concluded that the risk of catheter related hematoma in cardiac surgery was with the advent of similar to those undergoing non-cardiac surgery.

REGIONAL BLOCKS IN CARDIAC SURGERY

With ultrasound-guided regional anesthesia, it is now possible to achieve intraoperative conditions enabling tracheal extubation even in the operating room. Fascial plane chest wall blocks are gaining popularity in cardiac surgery due to their simplicity and safety. These are relatively simple techniques where the local anesthetic is deposited in the interfascial planes. They provide excellent postoperative pain control and reduce the requirement of intraopeartive and post-operative opioids. They also improve lung function parameters, reduce the incidence of post-operative hypoxemia, and provide good tolerance to physiotherapy, thus achieving better clinical outcomes after cardiac surgery. All these facilitates early patient tracheal extubation and "fast-tracking" in cardiac surgery patients. Various blocks that can be employed for the postoperative reduction in pain after cardiac surgery includes bilateral Pectoralis I/II (PEC I/II), Erector Spinae Block (ESB), Serratus Anterior Plane Block (SAPB), and the Paravertebral Block (PVB).

ERECTOR SPINAE BLOCK

The “erector spinae” are a group of three muscles which include Iliocostalis, Longissimus, and Spinalis muscles. They are situated on the back on either side of the spine. They originate from the spinous processes of T9 – T12 thoracic vertebrae and the medial slope of dorsal segment of iliac crest. They are inserted into the spinous processes of T1 and T2 vertebrae and cervical vertebrae. The Erector Spinae plane block (ESP) is a paraspinal fascial plane block that involves injection of local anesthetic deep in the Erector Spinae muscle and superficial to the tips of the thoracic transverse processes. The local anesthetic administered, blocks the dorsal and ventral rami of the thoracic and abdominal spinal nerves. This results in multi-dermatomal sensory block of the anterior, posterior, and lateral thoracic and abdominal walls. The proposed mechanism of action is the diffusion of local anesthetic through the underlying tissues into the spinal nerve roots. Another mechanism is the transforaminal and epidural spread of the local anesthetic.

SONOANATOMY

After selecting the site of block (T3 vertebral level in our study), the transducer is placed in a paramedian sagittal position about 2 cm away from the midline (Figure 2). At this level, the trapezius, rhomboid major and erector spinae muscles can be identified as three layers superficial to the transverse processes. In the lower and mid-thoracic levels, only the trapezius and erector spinae muscles can be seen. Typically, the rib-transverse process complex should be identified as a flat squared hyperechoic line with an acoustic shadow behind. This is referred to as the “tomb stone” appearance. The pleura should not be visualized at the level where the nerve block is performed (Figure 3).

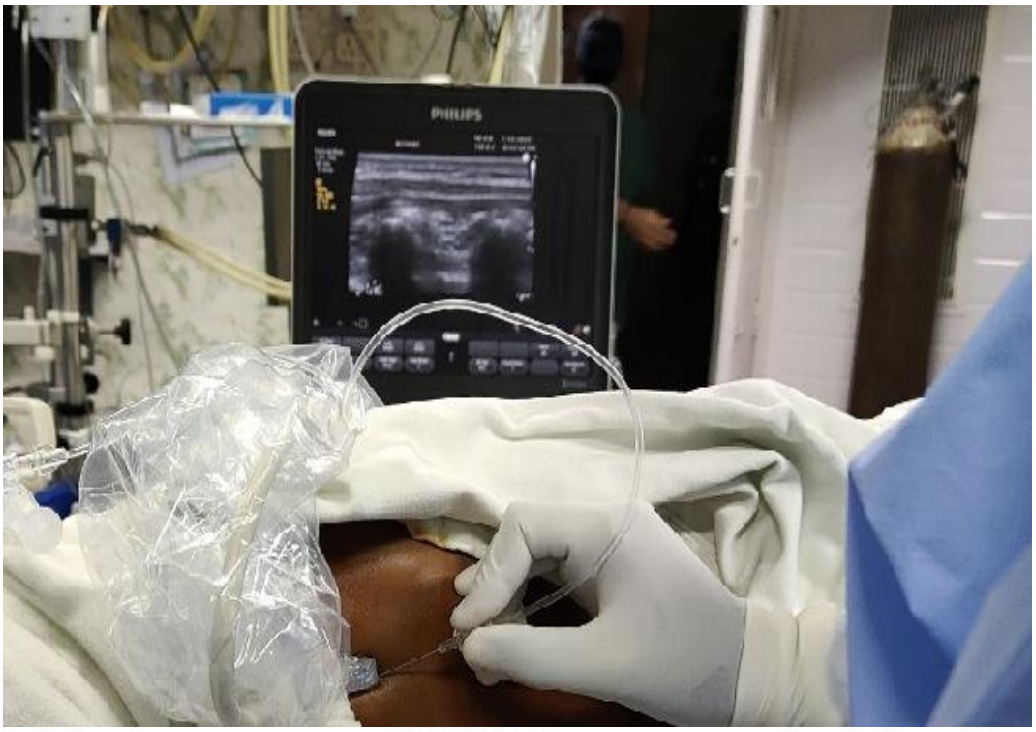


Figure 2: Patient positioning and probe placement for ultrasound guided Erector Spinae Block

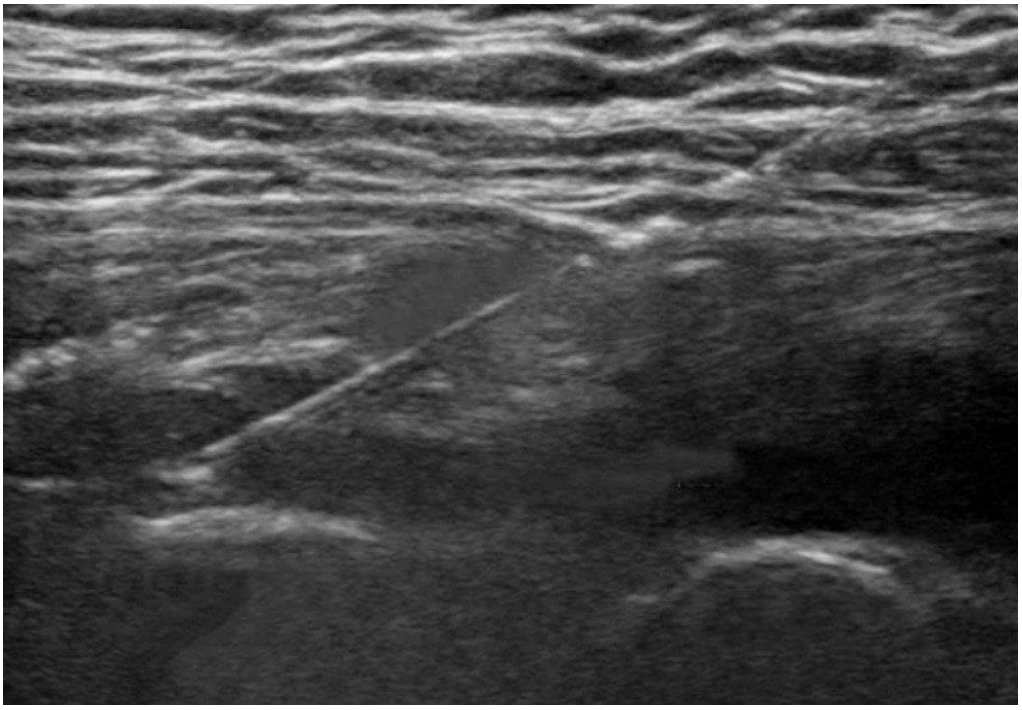


Figure 3: Erector Spinae Sonoanatomy

Approach

The needle is inserted from cranial to caudad direction until the needle tip contacts the transverse process. 1 to 2 ml of saline is injected to confirm the injection plane by visualization of saline spread deep to erector spinae muscles and superficial to transverse process. (Figure 4) If the transducer is placed **too much medial,** the thoracic laminae will be visualized as flat hyperechoic lines (Figure 3). If the transducer is placed too lateral, ribs will be visualized as rounded acoustic shadows with an intermediate hyperechoic pleural line. The block is completed by injecting the desired volume of local anesthetic in the confirmed injection plane.

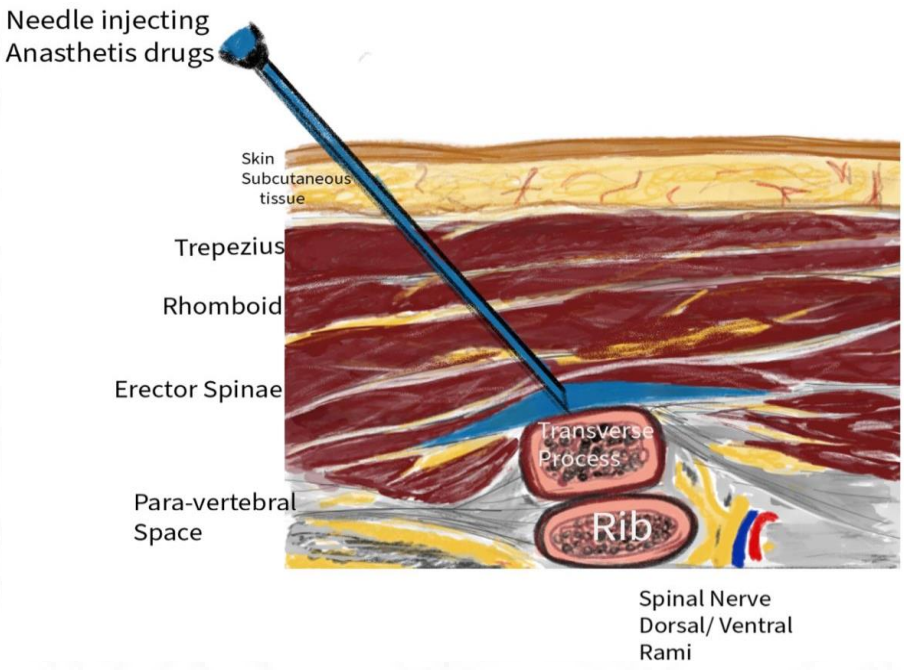


Figure 4: Artistic impression demonstrating the myo-fascial plane for drug injection in erector spinae block

Complications

The site of injection is far from the pleura, major blood vessels, and the spinal cord. So complications are quite rare. Infection at the needle insertion site, local anesthetic toxicity/allergy, vascular puncture, pleural puncture, pneumothorax, and failed block are the primary concerns.

PECS 2 BLOCK

PECS block was developed by Blanco *et al* for breast surgeries. PECS 2 block is a modified PECS 1 block and can be done with a single needle prick. The PECS 2 block targets the interfacial plane between the Pectoralis major muscle and the Pectoralis minor muscle and also between the Pectoralis minor muscle and the Serratus anterior muscle. PECS I block targets medial and lateral pectoral nerves, while PECS II block targets anterior divisions of the thoracic intercostal nerves from T2 to T6 spinal nerves, long thoracic nerve, and thoraco-dorsal nerve.

Sonoanatomy

The PECS 2 block is performed with the patient in the supine position. The patient's arm is placed next to the body or abducted 90 degrees. The transducer is positioned at the midclavicular line and angled inferiorly and laterally to visualize the axillary artery, axillary vein, and second rib. The transducer is then moved laterally until the pectoralis minor muscle, and serratus anterior muscle are visualized. The transducer is then moved further laterally so that the third and fourth rib are also viewed (Figure 5,6).

Figure 5. Patient positioning and probe placement for PECS 2 Block

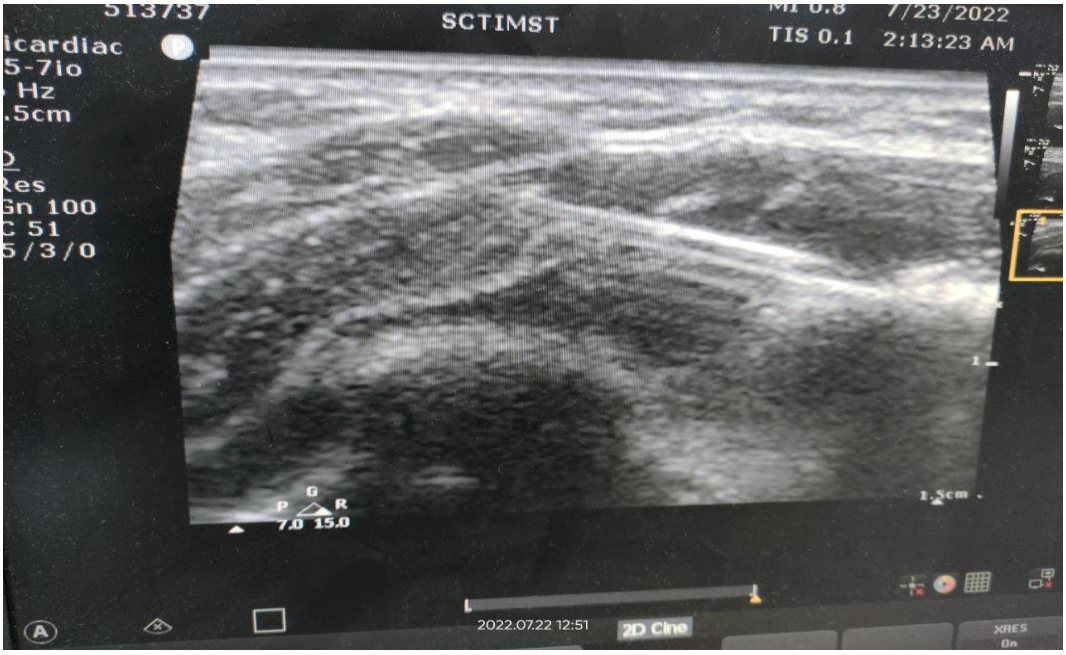


Figure 6. PECS 2 block Sonoanatomy

Approach

The local anesthetic is then deposited in two separate interfascial places. Using a 22 gauge needle the first injection of local anesthetic is deposited between the Pectoralis major and Pectoralis minor. The needle is then advanced using ultrasound guidance, and the second injection of local anesthetic is made between the pectoralis minor and serratus anterior (Figure. 7).

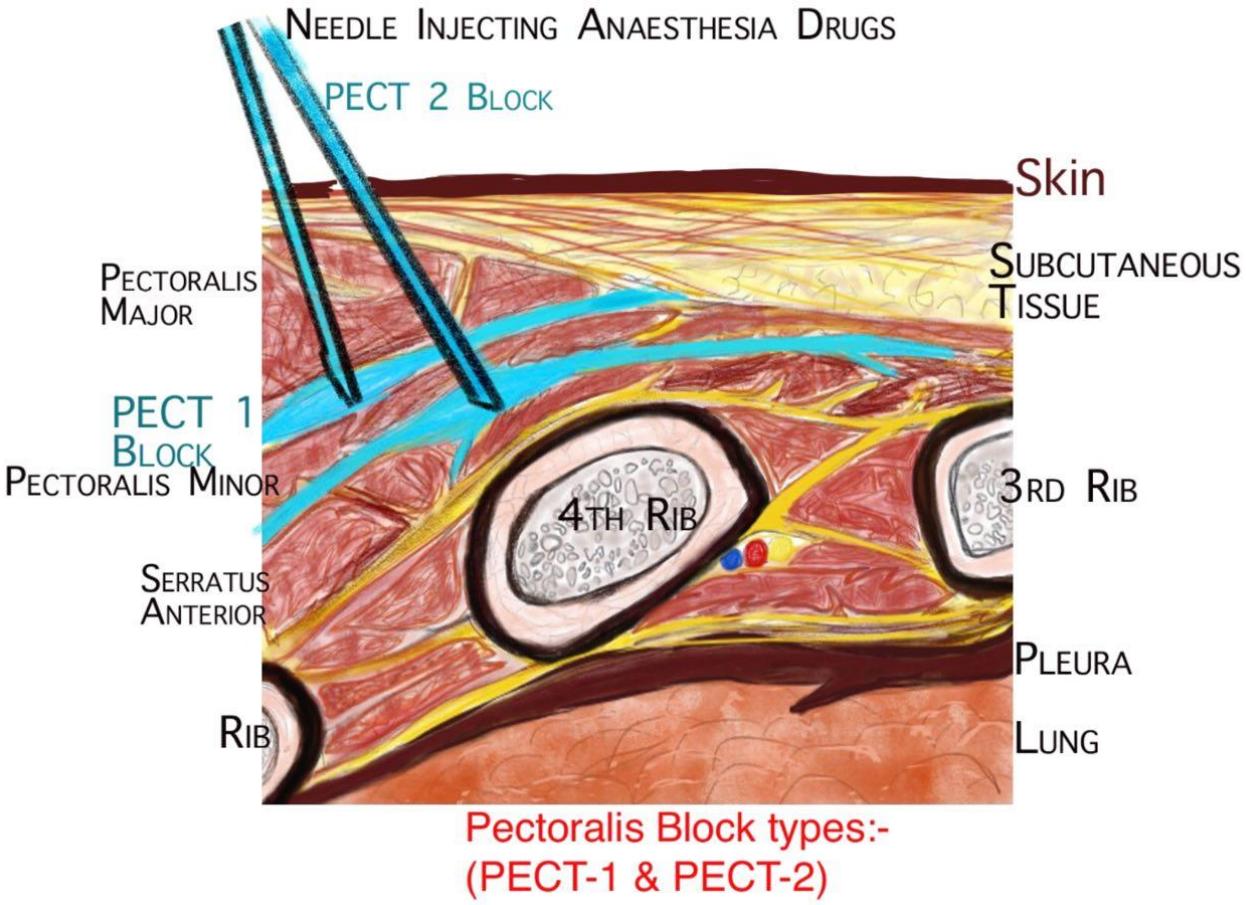


Figure 7: Artistic impression demonstrating the myo-fascial plane for drug injection in PECS 2 and PECS 1 block

Complications

Complications are rare with the use of ultrasound guidance, as the pleura and major blood vessels are visible throughout the procedure. The most common complications are pneumothorax, infection, local anesthetic toxicity/allergy, vascular puncture, and failed block.

MATERIALS AND METHODS

MATERIALS AND METHODS

Design:

Prospective randomized control study.

Setting:

Sree Chitra Tirunal Institute for Medical Sciences and Technology which is a Tertiary referral center performing 800-1000 congenital heart surgeries annually.

Participants:

All children below 18 years of age who were admitted to the Institute for the conduct of elective acyanotic congenital heart disease surgery. They were enrolled into the study once they were deemed eligible as per the inclusion criteria and after obtaining prior written informed consent from their parents or primary care givers.

Inclusion criteria:

All children less than 18 years old, who were diagnosed with acyanotic congenital heart disease in sinus rhythm, and requiring elective congenital heart surgery with median sternotomy and cardiopulmonary bypass were included.

Exclusion criteria:

- Emergency surgeries.
- Cyanotic congenital heart disease.
- Chest wall and vertebral deformities.
- Subjects having known contraindication or allergy to local anesthetics.
- Evidence of coagulopathy.
- Skin infection or any injury at the site of planned block.
- Severe pulmonary arterial hypertension (PAH).

Study protocol

The study commenced after the approval from IEC and registration with CTRI. Consecutive patients who were to undergo correction of elective congenital acyanotic heart disease were recruited and randomized into three groups using a computer-generated random number table.

- **Group E (general anesthesia + ultrasound guided bilateral Erector Spinae block)**
- **Group P (general anesthesia + ultrasound guided bilateral PECS 2 block)**
- **Group C (general anesthesia only)**
- All the patients were induced using standard general anesthesia techniques as per institutional protocols.
- All children received 0.2 mg/kg of oral diazepam one and a half hours prior to surgery. Upon arrival in the operating room, standard monitors were attached. Baseline hemodynamic parameters were noted. Intravenous access was obtained after an adequate depth of anesthesia was achieved with Sevoflurane. Once intravenous (IV) access was secured, fentanyl 2μg/kg and midazolam 0.1mg/kg were given. After confirming adequacy of mask ventilation, IV Pancuronium bromide 0.15 mg/kg was given and Sevoflurane maintained at 1%.
- Trachea was intubated and invasive arterial as well as central venous lines were secured. Bispectral index (BIS) electrodes were attached on the forehead of all children for depth of anesthesia monitoring.
- Once invasive lines were secured, patients were positioned for either of the blocks.

- Anesthesia was maintained with sevoflurane or isoflurane to maintain a MAC of 1 in a mixture of air-oxygen delivered through the circle breathing system using low flows and targeting a BIS value of 40 in all the three groups.
- Fixed dose of intravenous (IV) fentanyl, 2mcg/kg were administered during induction, and 2mcg/kg each before skin incision & sternotomy, before going on bypass, before rewarming, and before sternal closure.
- If BIS was above 40 or hemodynamic parameters were above 20% of baseline, IV fentanyl was administered in aliquots of 1mcg/kg.
- All patients received a background IV morphine infusion (40 mcg/Kg/hour) which was continued throughout the intraoperative period and was reduced thereafter to 20 mcg/kg/hour in the postoperative period.
- In the ICU, all patients received IV paracetamol 20 mg/Kg eighth hourly starting from half an hour prior to tracheal extubation.
- Esaote, MyLabOne^{TM} ultrasound machine were used in all cases for giving the blocks.

In group E:

After correct identification of T3 vertebral level (by counting down from C7 vertebra), the ESP block was performed under ultra sound guidance with Levobupivacaine 0.125% and the spread of local anesthetic in cranial and caudal direction visualized. A total dose of 2 mg/kg, 0.8ml/kg on each side was administered.

In group P:

After correct identification of the 4th rib, PECS 2 block was performed under ultrasound guidance and levobupivacaine 0.125% was injected. A total dose of 2mg/kg, 0.8ml/kg was given on each side.

In group C:

The patients in this group did not receive either of the blocks. They received similar anesthetics as group E and group P but without the blocks as per institutional protocol.

Observations:

The first sample (S0) for evaluation of baseline blood sugar and lactate was drawn from all patients after induction of anesthesia and placement of arterial line. Subsequent values were assessed along with arterial blood gas (ABG) samples taken at different intervals and a total of 7 samples were assessed including those sent from the ICU. These samples were labelled as S1, S2, S3, S4, S5 and S6 (Table 3).

- The additional fentanyl aliquots and the total fentanyl dose used in the intraoperative period & the postoperative period in each group were recorded.
- Post tracheal extubation, pain score was assessed at 15mins, 1, 2, 4, 6, 8, 10 and 12 hours using modified objective pain score (MOPS) (10). (Table 1,2)
- Rescue analgesia was provided with IV fentanyl 1mcg/kg if MOPS ≥4 was observed. If MOPS < 4 was not achieved within 5 minutes, the same dose was repeated

- Any complications related to the drugs used or the procedures performed, were noted. The length of ICU stay was also noted.

Table 1. MODIFIED OBJECTIVE PAIN SCORE

CRITERIA	FINDING	POINTS
Crying	**None** **Consolable** **Not Consolable**	**0** **1** **2**
Movement	**None** **Restless** **Thrashing**	**0** **1** **2**
Agitation	**Asleep** **Calm** **Mild** **Hysterical**	**0** **0** **1** **2**
Posture	**Normal** **Flexed** **Holds Injury site**	**0** **1** **2**
Verbal	**Asleep** **No Complaint** **Complains, but cannot localize** **Complains & localizes**	**0** **0** **1** **2**

Table 2. MOPS SCORE at various time intervals post tracheal extubation

TIME	15mins	1hr	2hrs	4hrs	6hrs	8hrs	10hrs	12hrs
MOPS								

Table 3: Blood sugar and Lactate values from ABG samples

Parameter	S0	S1	S2	S3	S4	S5	S6
Random blood sugar (mg%)							
Lactate (mmol/l)							

- **Intraoperative Fentanyl Consumption (mcg/kg):**
- **Duration of mechanical ventilation (hours):**
- **Time to first rescue analgesic(hours):**
- **Additional dose of Fentanyl used postoperatively(mcg/kg):**
- **Complications, if any:**
- **Length of ICU stay(days):**

Statistical analysis:

Based upon the previous study by Kausal et al. a sample size of 30 per group were required to get a comparison for MOPS (Modified objective Pain Score) among the 3 groups with an alpha error of 0.05 and power of 80%.

Categorical and quantitative variables were expressed as frequency (percentage) and mean ± SD respectively. One way ANOVA / Kruskal Wallis Test was used to compare quantitative/ ordinal parameters among groups. Chi-square test was used to find association between categorical variables. For all statistical interpretations, $p < 0.01$ was considered the threshold for statistical significance. Statistical analyses was performed by using a statistical software package SPSS, version 20.0.

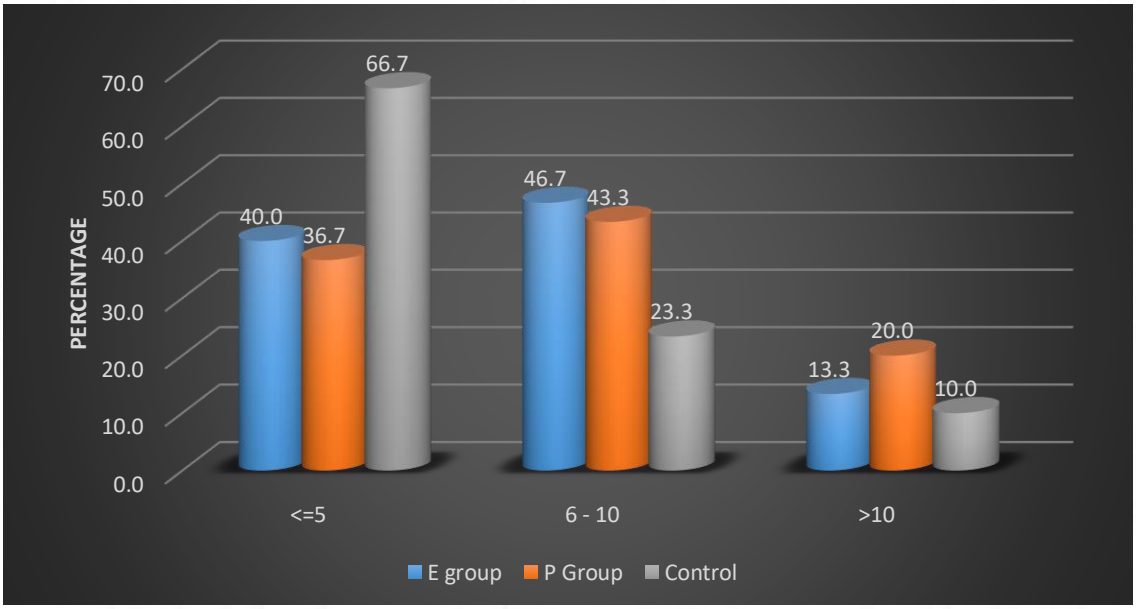
OBSERVATIONS & RESULTS

OBSERVATIONS AND RESULTS

Table 4. Comparison of age groups

Age (years)	E group		P Group		Control	
	Count	Percent	Count	Percent	Count	Percent
<=5	12	40.0	11	36.7	20	66.7
6 - 10	14	46.7	13	43.3	7	23.3
>10	4	13.3	6	20.0	3	10.0
Mean ± SD	6.8 ± 3		7.4 ± 3.5		5.5 ± 3.4	

Figure 8. Comparison of age groups

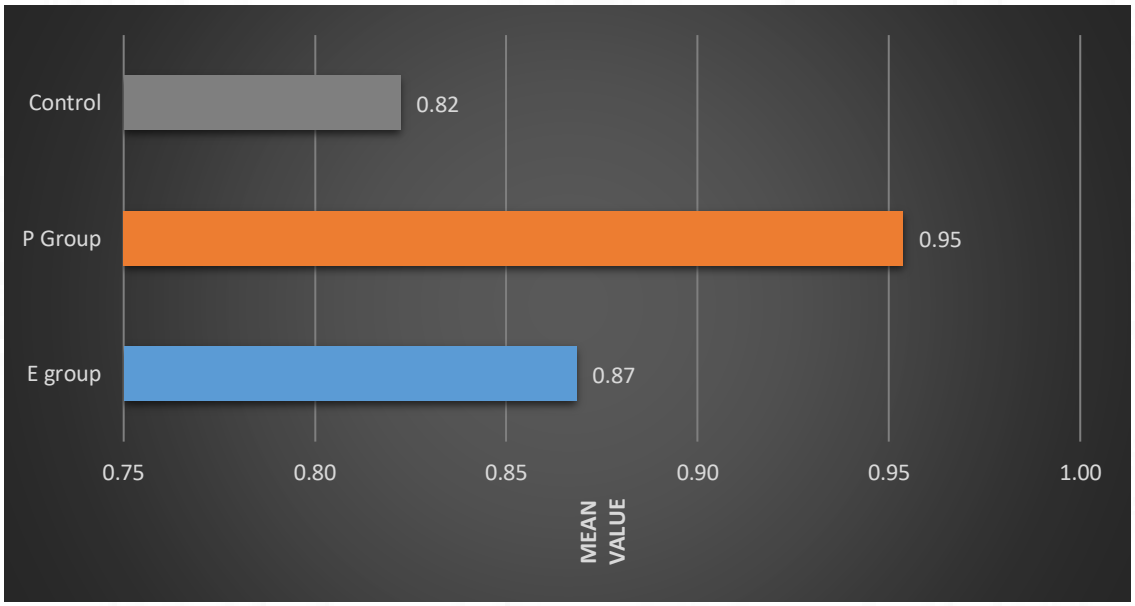


The mean age was 6.8 ± 3 years in Group E, 7.4 ± 3.5 years in Group P, and 5.5 ± 3.4years in group C. Statistical analysis showed no significant difference between the groups regarding age distribution (P value 0.07). (Table 4, Figure 8)

Table 5. Comparison of Body Surface Area based on group

Group	Mean (m^2)	SD	N	F	p
E group	0.87	0.27	30	2.29	0.107
P Group	0.95	0.21	30		
Control	0.82	0.24	30		

Figure 9. Comparison of BSA based on group

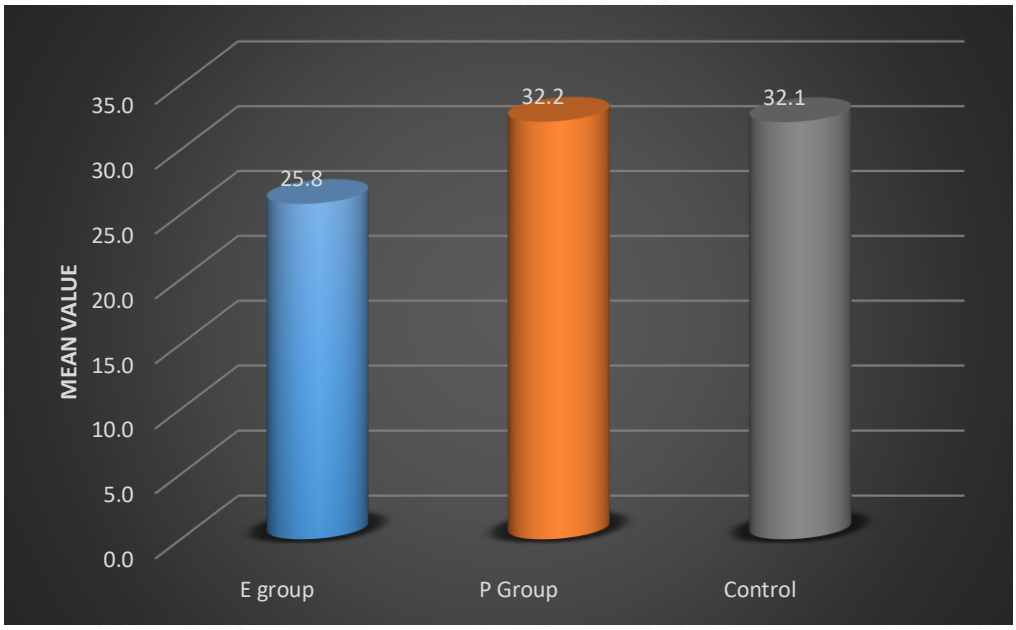


The mean body surface area was found to be 0.87 ± 0.27 m^2 in Group E (interventional), 0.95 ± 0.21 m^2 in Group P (interventional) and 0.82 ± 0.24 m^2 in group C(control) Statistical analysis showed no significant difference between the groups. (Table 5, Figure 9)

Table 6. Comparison of aortic cross clamp time based on group

Group	Mean (mins)	SD	N	F	p
E group	25.8	5.5	30	5.12	0.08
P Group	32.2	10.8	30		
Control	32.1	9.2	30		

Figure 10. Comparison of Aortic cross clamp time based on group

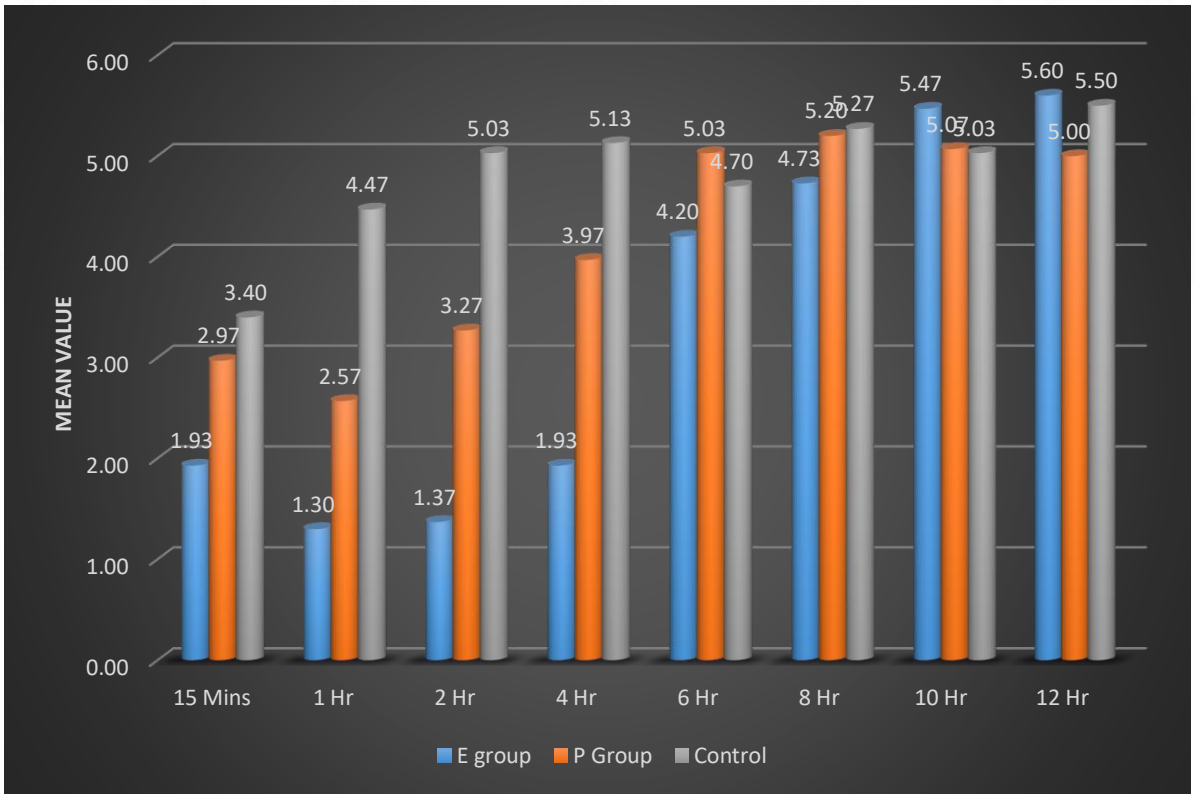


The mean Aortic Cross Clamp Time was found to be 25.8 ± 5.5minutes in Group E (interventional), 32.2 ± 10.8 minutes in Group P (interventional) and 32.1 ± 9.2 minutes in group C (control). Statistical analysis showed no significant difference between the groups. (P value 0.08) (Table 6, Figure 10)

Table 7. Comparison of MOPS at different interval of time based on group

MOPS	E group		P Group		Control		χ^2#	p
	Mean ± SD	Median	Mean ± SD	Median	Mean ± SD	Median		
15 Min	1.93 ± 0.69	2.00	2.97 ± 0.76	3.00	3.4 ± 0.77	3.50	36.54	p<0.01
1 Hr	1.3 ± 0.47	1.00	2.57 ± 0.68	2.00	4.47 ± 0.51	4.00	74.74	p<0.01
2 Hr	1.37 ± 0.49	1.00	3.27 ± 0.98	3.00	5.03 ± 0.72	5.00	71.31	p<0.01
4 Hr	1.93 ± 0.94	2.00	3.97 ± 0.93	4.00	5.13 ± 0.78	5.00	61.15	p<0.01
6 Hr	4.2 ± 0.41	4.00	5.03 ± 0.72	5.00	4.7 ± 0.7	5.00	21.56	p<0.01
8 Hr	4.73 ± 0.45	5.00	5.2 ± 0.61	5.00	5.27 ± 0.69	5.00	12.99	p<0.01
10 Hr	5.47 ± 0.51	5.00	5.07 ± 0.74	5.00	5.03 ± 0.67	5.00	7.29	0.026
12 Hr	5.6 ± 0.5	6.00	5 ± 0.83	5.00	5.5 ± 0.51	5.50	10.16	0.056

Figure 11. Comparison of MOPS at different interval of time based on group



MOP score for pain assessment at 15 minutes post tracheal extubation showed a mean pain score of 1.93 ± 0.69 in group E (interventional), 2.97 ± 0.76 in group P (interventional) and 3.4 ± 0.77 in group C (Control). This difference in pain scores between the groups was found to be statistically significant ($p < 0.01$). (Table 7, Figure 11)

MOP score for pain assessment at 1 hour post tracheal extubation showed a mean pain score of 1.3 ± 0.47 in group E (interventional), 2.57 ± 0.68 in group P (interventional) and 4.47 ± 0.51 in group C (Control). This difference in pain scores between the groups was found to be statistically significant ($p < 0.01$).

MOP score for pain assessment at 2 hours post tracheal extubation showed a mean pain score of 1.37 ± 0.49 in group E (interventional), 3.27 ± 0.98 in group P (interventional), and 5.03 ± 0.72 in group C (Control). This difference in pain scores between the groups was found to be statistically significant ($p < 0.01$).

MOP score for pain assessment at 4 hours post tracheal extubation showed a mean pain score of 1.93 ± 0.94 in group E (interventional), 3.97 ± 0.93 in group P (interventional), and 5.13 ± 0.78 in group C (Control). This difference in pain scores between the groups was found to be statistically significant ($p < 0.01$).

MOP score for pain assessment at 6 hours post tracheal extubation showed a mean pain score of 4.2 ± 0.41 in group E (interventional), 5.03 ± 0.72 in group P (interventional), and 4.7 ± 0.7 in group C (Control). This difference in pain scores between the groups was found to be statistically significant ($p < 0.01$).

MOP score for pain assessment at 8 hours post tracheal extubation showed a mean pain score of 4.73 ± 0.45 in group E (interventional), 5.2 ± 0.61 in group P (interventional), and 5.27 ± 0.69 in group C (Control). This difference in pain scores between the groups was found to be statistically significant ($p < 0.01$).

MOP score for pain assessment at 10 hours post tracheal extubation showed a mean pain score of 5.47 ± 0.51 in group E (interventional), 5.07 ± 0.74 in group P (interventional), and 5.03 ± 0.67 in group C (Control). There was statistically no significant difference in pain scores observed between the groups ($p > 0.01$).

MOP score for pain assessment at 12 hours post tracheal extubation showed a mean pain score of 5.6 ± 0.5 in group E (interventional), 5 ± 0.83 in group P (interventional), and 5.5 ± 0.51 in group C (Control). There was statistically no significant difference in pain scores observed between the groups ($p > 0.01$).

Table 8. Comparison of MOPS between Group E & Group P at different time intervals

MOPS SCORE	GROUP E		GROUP P			
	Mean± SD	Median	Mean± SD	Median	Z#	p
15 Min	1.93 ± 0.69	2.00	2.97 ± 0.76	3.00	4.46	p<0.01
1 Hr	1.3 ± 0.47	1.00	2.57 ± 0.68	2.00	5.96	p<0.01
2 Hr	1.37 ± 0.49	1.00	3.27 ± 0.98	3.00	6.23	p<0.01
4 Hr	1.93 ± 0.94	2.00	3.97 ± 0.93	4.00	5.71	p<0.01
6 Hr	4.2 ± 0.41	4.00	5.03 ± 0.72	5.00	4.56	p<0.01
8 Hr	4.73 ± 0.45	5.00	5.2 ± 0.61	5.00	3.09	p<0.01
10 Hr	5.47 ± 0.51	5.00	5.07 ± 0.74	5.00	2.14	0.032
12 Hr	5.6 ± 0.5	6.00	5 ± 0.83	5.00	2.9	0.004

Mann-Whitney U Test **: - Significant at 0.01 level,

Comparison of MOPS between group E and group P showed lower mean pain scores in group E at 15 minutes, 1hours, 2hours, 4hours, 6hours and 8hours post tracheal extubation. The difference in pain scores observed were statistically significant ($p<0.01$) at 15mins, 1hour, 2hours, 4hours, 6 hours and 8 hours. (Table 8)

Table 9. Comparison of MOPS between Group P & Group C at different time intervals

MOPS SCORE	GROUP P		GROUP C			
	Mean± SD	Median	Mean± SD	Median	Z#	p
15 Min	2.97 ± 0.76	3.00	3.4 ± 0.77	3.50	2.09	0.036
1 Hr	2.57 ± 0.68	2.00	4.47 ± 0.51	4.00	6.53	p<0.01
2 Hr	3.27 ± 0.98	3.00	5.03 ± 0.72	5.00	5.66	p<0.01
4 Hr	3.97 ± 0.93	4.00	5.13 ± 0.78	5.00	4.35	p<0.01
6 Hr	5.03 ± 0.72	5.00	4.7 ± 0.7	5.00	1.79	0.073
8 Hr	5.2 ± 0.61	5.00	5.27 ± 0.69	5.00	0.49	0.621
10 Hr	5.07 ± 0.74	5.00	5.03 ± 0.67	5.00	0.2	0.840
12 Hr	5 ± 0.83	5.00	5.5 ± 0.51	5.50	2.4	0.016

Comparison of MOPS between group P and group C showed lower mean pain scores in group P at 15 minutes, 1hour, 2hours, 4hours, 6hours and 8hours post tracheal extubation. The difference in pain scores observed were statistically significant ($p<0.01$) at 1hour, 2hours, and 4hours. (Table 9)

Table 10. Comparison of MOPS Score between Group E & Group C at different intervals

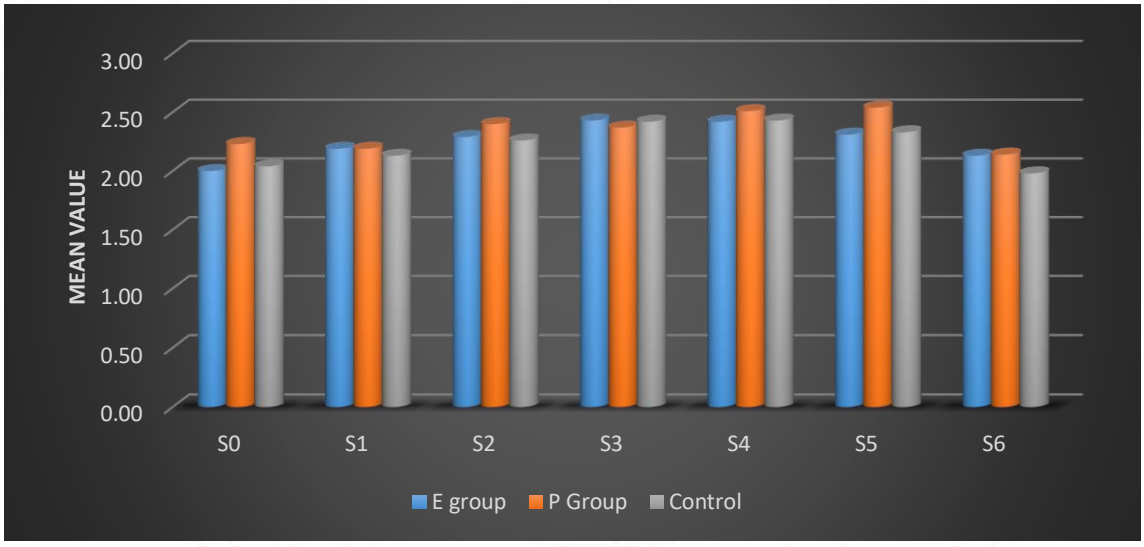
MOPS SCORE	GROUP E		GROUP C			
	Mean± SD	Median	Mean± SD	Median	Z#	p
15 Min	1.93 ± 0.69	2.00	3.4 ± 0.77	3.50	5.55	p<0.01
1 Hr	1.3 ± 0.47	1.00	4.47 ± 0.51	4.00	6.93	p<0.01
2 Hr	1.37 ± 0.49	1.00	5.03 ± 0.72	5.00	6.85	p<0.01
4 Hr	1.93 ± 0.94	2.00	5.13 ± 0.78	5.00	6.65	p<0.01
6 Hr	4.2 ± 0.41	4.00	4.7 ± 0.7	5.00	3.06	p<0.01
8 Hr	4.73 ± 0.45	5.00	5.27 ± 0.69	5.00	3.24	p<0.01
10 Hr	5.47 ± 0.51	5.00	5.03 ± 0.67	5.00	2.55	0.011
12 Hr	5.6 ± 0.5	6.00	5.5 ± 0.51	5.50	0.77	0.440

Comparison of MOPS between group E and group C showed lower mean pain scores in group E at 15 minutes, 1hour, 2hours, 4hours, 6hours and 8hours post tracheal extubation. The difference in pain scores observed were statistically significant ($p<0.01$) at 15mins, 1hour, 2hours, 4hours, 6 hours and 8 hours (Table 10).

Table 11. Comparison of lactate at different intervals of time based on group

Lactate (mmol/L)	E group		P Group		Control		χ^2#	p
	Mean ± SD	Median	Mean ± SD	Median	Mean ± SD	Median		
S0	2 ± 0.73	1.95	2.23 ± 0.32	2.25	2.04 ± 0.59	2.15	2.35	0.309
S1	2.19 ± 0.58	2.20	2.19 ± 0.35	2.20	2.13 ± 0.59	2.20	0.32	0.851
S2	2.29 ± 0.51	2.35	2.4 ± 0.38	2.50	2.26 ± 0.52	2.30	1.05	0.591
S3	2.43 ± 0.46	2.50	2.37 ± 0.35	2.40	2.42 ± 0.49	2.50	1.14	0.566
S4	2.42 ± 0.46	2.50	2.51 ± 0.34	2.60	2.43 ± 0.5	2.55	0.47	0.791
S5	2.31 ± 0.41	2.45	2.54 ± 0.47	2.50	2.33 ± 0.5	2.30	3.08	0.215
S6	2.13 ± 0.48	2.15	2.14 ± 0.34	2.10	1.98 ± 0.4	2.05	2.62	0.269

Figure 12. Comparison of lactate at different interval of time based on group

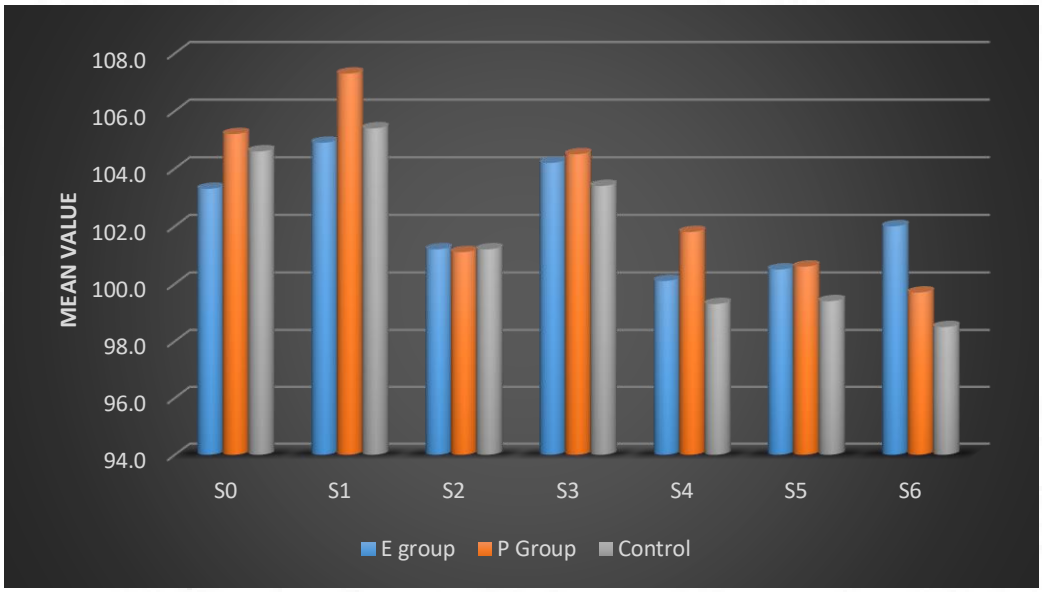


Lactate levels in all the 3 groups at different time intervals of observation remained within normal levels. There was no statistically significant difference between the lactate levels between all the 3 groups from samples taken at different time intervals of observation. (Table 11, Figure 12)

Table 12. Comparison of random blood sugar at different interval of time based on group

RBS (mg/dl)	E group	P Group	Control	F	P
S0	103.3 ± 13.3	105.2 ± 13.5	104.6 ± 12.3	0.18	0.836
S1	104.9 ± 9.5	107.3 ± 11.3	105.4 ± 8.9	0.5	0.606
S2	101.2 ± 9.5	101.1 ± 10.5	101.2 ± 9.5	0	0.999
S3	104.2 ± 8.9	104.5 ± 8.7	103.4 ± 9	0.13	0.876
S4	100.1 ± 8.7	101.8 ± 9.4	99.3 ± 8.9	0.61	0.545
S5	100.5 ± 9.4	100.6 ± 9.3	99.4 ± 9.5	0.14	0.871
S6	105.3 ± 8.5	102 ± 7.4	110 ± 9.2	0.56	0.564

Figure 13. Comparison of random blood sugar at different intervals of time based on group

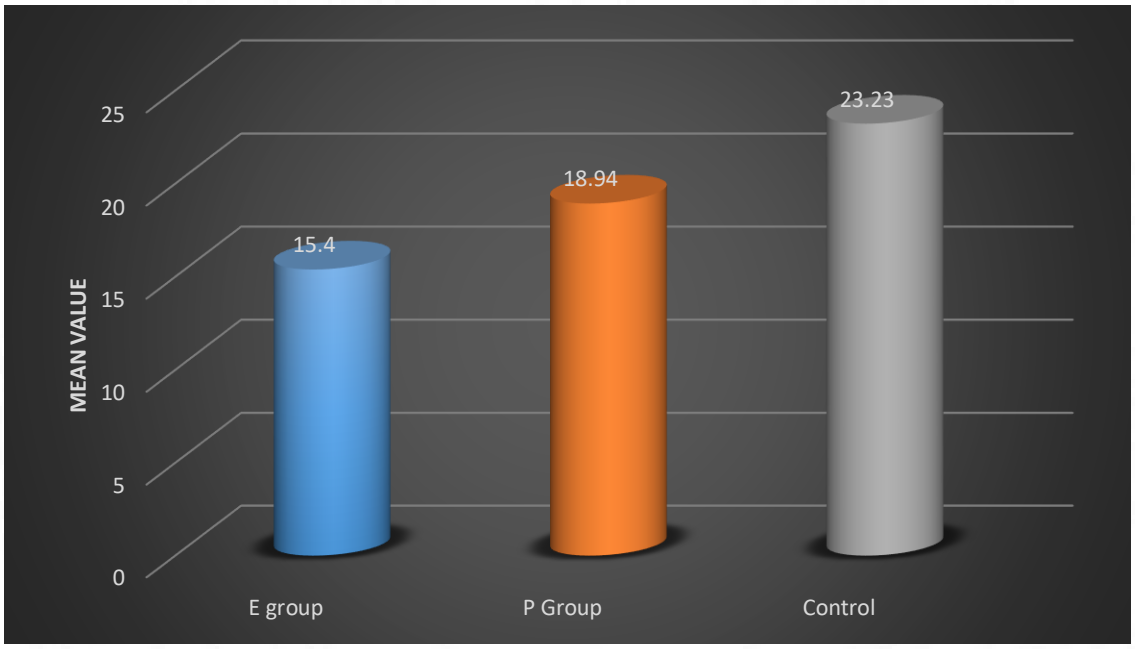


Blood sugar levels in all the 3 groups at different time intervals of observation remained within normal levels. There was no statistically significant difference between the blood sugar levels between all the 3 groups from samples taken at different time intervals of observation. (Table12, Figure 13)

Table 13. Comparison of Intraop Fentanyl Consumption based on group

Group	Mean ± SD (µg/kg)	SD	χ^2#	p	Mann-Whitney U Test		
					Pair	Z$	p
E group	15.4 ± 0.69	15.00	76.98	p<0.01	E &P	6.64	p<0.01
P Group	18.94 ± 1.27	18.50			E & C	6.7	p<0.01
C Group	23.23 ± 1.64	23.30			P & C	6.29	p<0.01

Figure 14. Comparison of Intraoperative Fentanyl Consumption based on group



The mean Intraoperative fentanyl consumption was 15.4 ± 0.69 µg/kg in group E, 18.94 ± 1.27 µg/kg in group P and 23.23 ± 1.64 µg/kg in group C. The higher mean value in the control group compared to the interventional groups was found to be statistically significant (p<0.01) (Table 13, Figure 14).

Comparison of intraoperative fentanyl consumption between group E 15.4 ± 0.69 µg/kg and group P 18.94 ± 1.27 µg/kg showed a lower mean value in group E. The difference in fentanyl consumption between the groups was found to be statistically significant (p<0.01)

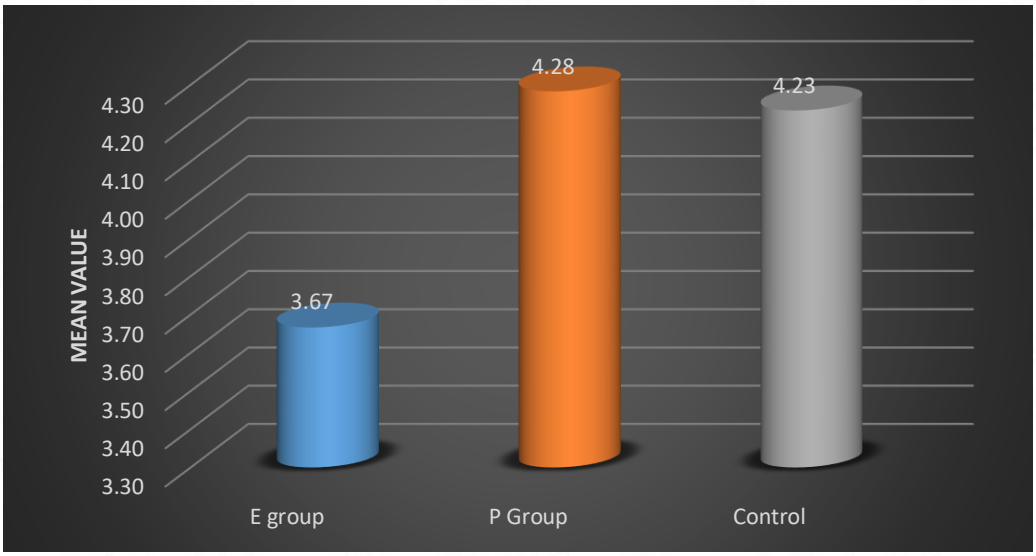
Comparison of intraoperative fentanyl consumption between group E 15.4 ± 0.69 µg/kg and group C 23.23 ± 1.64 µg/kg, showed a lower mean value in group E. The difference in fentanyl consumption between the groups was found to be statistically significant (p<0.01)

Comparison of intraoperative fentanyl consumption between group P 18.94 ± 1.27 µg/kg and group C 23.23 ± 1.64 µg/kg, showed a lower mean value in group P. The difference in fentanyl consumption between the groups was found to be statistically significant (p<0.01)

Table 14 Comparison of duration of ventilation between the groups in ICU

Group	Mean ± SD(hours)	Median	χ^2#	p
E group	3.67 ± 1.13	3.50	4.41	0.110
P Group	4.28 ± 1.48	4.00		
Control	4.23 ± 0.97	4.00		

Figure 15. Comparison of duration of ventilation in ICU based on group

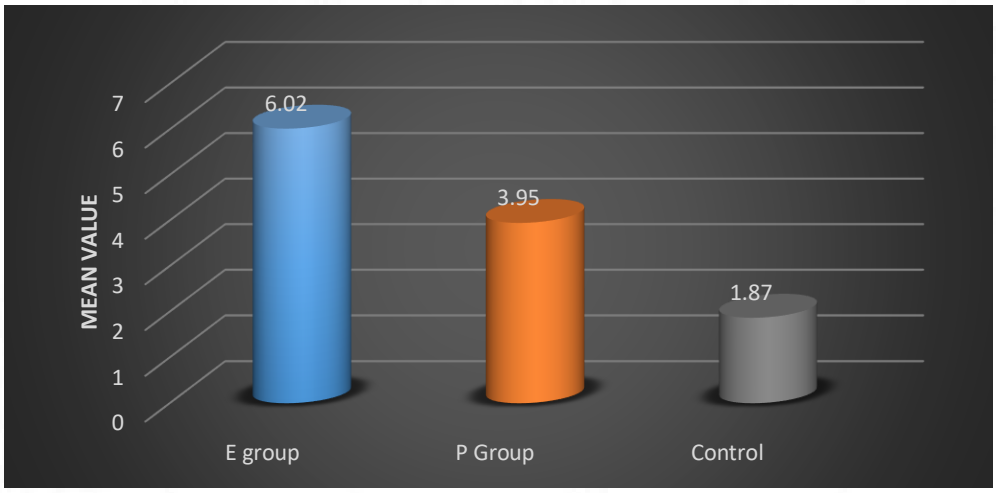


Comparison of duration of ventilation of patients between the groups showed a lower value in group E (3.67 ± 1.13) hours and group P (4.28 ± 1.48) hours compared to group C (4.23 ± 0.97) hours. However, there was no statistical significant variation (p > 0.01) in the duration of ventilation among the groups. (Table 14, Figure 15)

Table 15 Comparison of time to 1st Rescue Analgesic based on group

Group	Mean ± SD (hours)	SD	χ^2#	p	Mann-Whitney U Test		
					Pair	Z$	p
E group (A)	6.02 ± 1.04	6.00	74.47	p<0.01	A &B	6.04	p<0.01
P Group (B)	3.95 ± 0.68	4.00			A & C	6.7	p<0.01
Control (C)	1.87 ± 0.72	2.00			B & C	6.45	p<0.01

Figure 16. Comparison of time to 1st Rescue Analgesic based on group



The time to rescue analgesia among the groups showed a lower mean value in control group (1.87 ± 0.72) hours compared to group E (6.02 ± 1.04) hours and group P (3.95 ± 0.68 hours) which was statistically significant (p<0.01) (Table 15, Figure 16)

Comparison of time to rescue analgesia between group E (6.02 ± 1.04) hours and group P (3.95 ± 0.68) hours showed a higher value in group E. The difference observed between the groups was statistically significant (p<0.01).

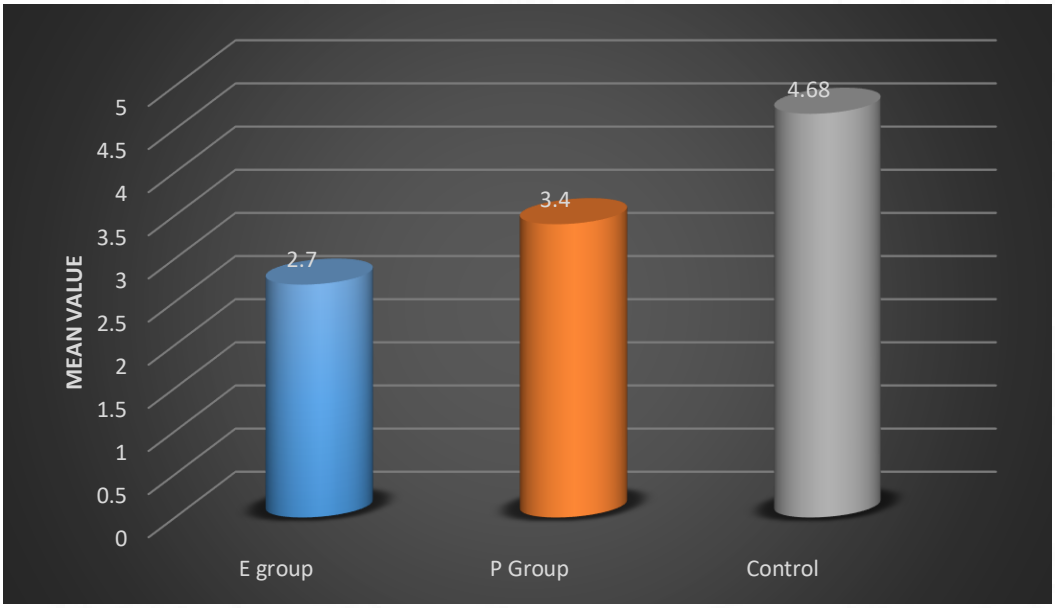
Comparison of time to rescue analgesia between group E (6.02 ± 1.04) hours and group C (1.87 ± 0.72) hours showed a higher value in group E. The difference observed between the groups was statistically significant (p<0.01).

Comparison of time to rescue analgesia between group P (3.95 ± 0.68) hours and group C (1.87 ± 0.72) hours showed a higher value in group P. The difference observed between the groups was statistically significant (p<0.01).

Table 16: Comparison of additional fentanyl doses bases on group

Group	Mean ± SD (mcg/kg)	Median	χ^2#	p	Mann-Whitney U Test		
					Pair	Z$	p
E group (A)	2.7 ± 0.64	3.00	52.5	p<0.01	A &B	3.61	p<0.01
P Group (B)	3.4 ± 0.72	3.00			A & C	6.38	p<0.01
Control (C)	4.68 ± 0.79	5.00			B & C	5.14	p<0.01

Figure 17. Comparison of additional fentanyl dose based on group



The additional fentanyl doses required in the ICU showed a lower value in group E (2.7 ± 0.64) µg/kg and group P (3.4 ± 0.72) µg/kg compared to group C (4.68 ± 0.79) µg/kg which was statistically significant (p< 0.01) (Table 16, Figure 17)

Comparison of additional fentanyl requirement between group E (2.7 ± 0.64) µg/kg and group P (3.4 ± 0.72) µg/kg showed a lower value in group E. The difference observed between the groups was statistically significant (p<0.01).

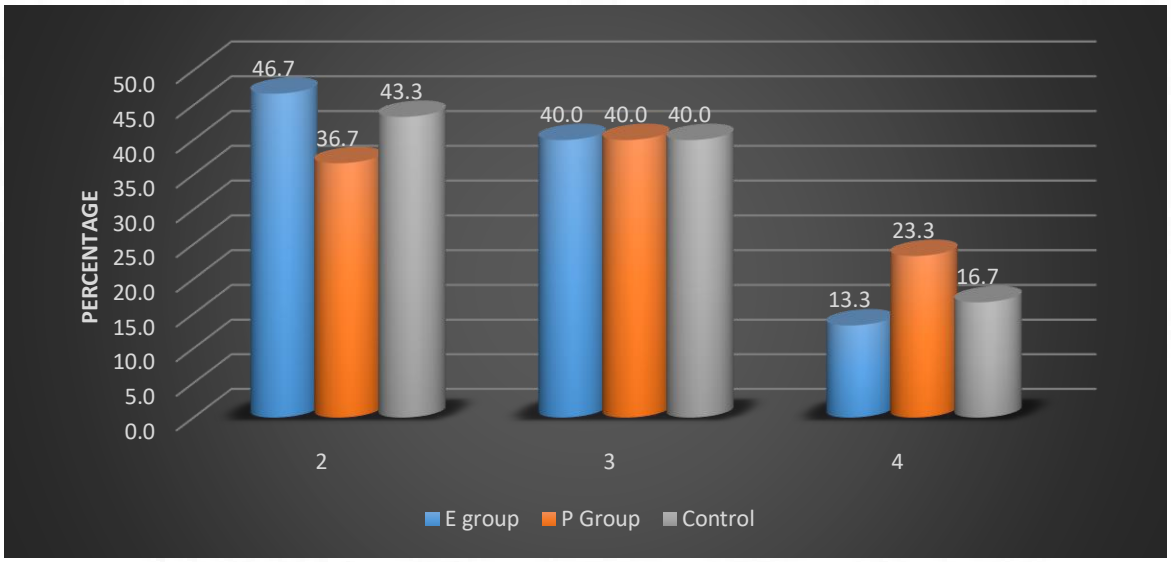
Comparison of additional fentanyl requirement between group E (2.7 ± 0.64) µg/kg and group C (4.68 ± 0.79) µg/kg showed a lower value in group E. The difference observed between the groups was statistically significant (p<0.01).

Comparison of additional fentanyl requirement between group P (3.4 ± 0.72) µg/kg and group C (4.68 ± 0.79) µg/kg showed a lower value in group E. The difference observed between the groups was statistically significant (p<0.01)

Table 17: Comparison of length of ICU stay

Length of ICU stay	E group		P Group		Control		χ^2	p
	Count	Percent	Count	Percent	Count	Percent		
2 days	14	46.7	11	36.7	13	43.3	1.24	0.871
3 days	12	40.0	12	40.0	12	40.0		
4 days	4	13.3	7	23.3	5	16.7		

Figure 18. Comparison of length of ICU stay based on group



The duration of ICU stay among all the 3 groups were 2 to 4 days. In group E 46.7% of the subjects stayed 2 days, 40% stayed for 3 days and 13.3% stayed for 4 days. In group P 36.7% of the subjects stayed 2 days, 40% stayed for 3 days and 23.3% stayed for 4 days. In group C 43.3% of the subjects stayed 2 days, 40% stayed for 3 days and 16.7% stayed for 4 days. There was no statistically significant difference observed among the three groups.

DISCUSSION

DISCUSSION

This prospective randomized control study compares the efficacy of ultrasound guided Erector Spinae block versus PECS 2 block for sternotomy pain in pediatric cardiac surgery.

Patients receiving ultrasound guided Erector Spinae block demonstrated significantly lower pain scores up to 8 hours after extubation, compared to the control group which didn't receive either of the blocks. Patients who received ultrasound guided PECS 2 block demonstrated significantly lower pain scores up to 4 hours after extubation compared to a control group which didn't receive either of the blocks. However, on comparison between the Erector Spinae group and PECS 2 group, there was significantly lower pain scores in Erector Spinae group for up to 8 hours after extubation. In a similar study by Kaushal et al(8) assessing the efficacy of bilateral Erector Spinae block in managing acute pain after cardiac surgery, they observed lower pain scores in the intervention group for up to 12 hours after tracheal extubation as compared to the control group. Another study by Kumar et al (11) in assessing the efficacy of bilateral PECS 2 block in postoperative in adult cardiac surgery, observed a lower pain score up to 12 hours in the intervention group as compared to the control group. Krishna et al (36) in their study of Bilateral Erector Spinae Plane block for Acute Post-Surgical pain in Adult Cardiac Surgical patients had demonstrated lower pain scores for up to 8 hours after tracheal extubation compared to the control group. Our observation and results were nearly comparable to the different intervention arms in the studies done by Kumar et al and Krishna et al.

In the present study there was a lower intraoperative consumption of Fentanyl in the interventional groups compared to the control group. Fentanyl consumption was observed to be lowest in Erector

Spinae group. The study done by Kaushal et al (12) for assessing the efficacy of bilateral Erector Spinae block for managing acute pain after cardiac surgery also showed a lower intraoperative consumption of fentanyl compared to the control group. Holland et al (37) in their case series study which aimed to determine the effect of Erector Spinae block in pediatric population for various surgical procedures, had also demonstrated a lower intraoperative opioid usage compared to control group. Kamal et al (38) also in their study assessing the efficacy of bilateral PECS 2 in postoperative analgesia in pediatric cardiac surgery showed a lower fentanyl consumption intra-operatively in the interventional group with respect to the control group. Gokhan et al (39) who studied the effect of bilateral PECS 2 block in Nuss procedure for Pectus Excavatum, found that PECS 2 block was associated with decreased opioid requirements in the postoperative period for up to 24 hours compared to the control group.

In our study, the additional fentanyl doses received in ICU as rescue analgesia, was demonstrated to be lower in the interventional groups as compared to the control group. The Erector Spinae group had demonstrated a lower requirement of rescue analgesic doses when compared to the PECS 2 group. Ghamry et al (40) who compared the efficacy of PECS 2 block versus fentanyl intravenous patient controlled analgesia for pain control after minimally invasive cardiac surgery demonstrated a significant lower fentanyl consumption in the PECS 2 group. Vaughan et al (41) studied the effect of bilateral Erector Spinae block on postoperative consumption of opioids and demonstrated a lesser consumption of opioids both intra operatively and post operatively, compared to the control group.

Garcia et al. (29) in their review article reported that hyperlactataemia is fairly common in patients who have undergone cardiac surgery, especially cardiac surgery with cardiopulmonary bypass. Our study showed that there was no statistically significant difference the blood sugar and lactate levels in all the three groups. The blood sugar and lactate levels were not of much contributory significance in assessing the stress response to the surgery.

In our study, the time to first rescue analgesia was found to be less in the control group when compared to the interventional groups. The time to first rescue analgesia was less in PECS 2 group with respect to the Erector Spinae group.

We did not find any significant difference in duration of ICU stay and duration of mechanical ventilation in the three groups in our study

We did not encounter any procedure related complication in our study patients.

CONCLUSION AND LIMITATIONS

CONCLUSION

- Bilateral Erector Spinae Block and PECS 2 block resulted in lower pain scores after extubation of the trachea when compared to control group in children undergoing cardiac surgery with median sternotomy.
- Administration of bilateral Erector spinae block and PECS 2 block lead to a significant reduction in the intraoperative and postoperative requirement of fentanyl compared to the control group
- The blood-sugar and lactate levels in the three study groups did not show any significant difference. They were not of any contributory significance in assessing the intraoperative and postoperative stress response
- The median duration of ventilation and length of stay in ICU was similar in all the three groups
- There were no procedure related complications in our study. This demonstrated that ultrasound guided Erector spinae block and PECS 2 block could be safely practiced in pediatric cardiac surgeries.
- Lower pain scores and lesser intraoperative and postoperative opioid requirement in Erector Spinae group compared to PECS 2 group suggests that it is a superior technique for control of postoperative sternotomy pain in pediatric cardiac surgery.
- Both the regional anesthetic techniques resulted in similar hemodynamic parameters which were lower than the baseline in response to surgical stimulus.

LIMITATIONS

- A larger sample size needs to be studied to prove a clinically relevant difference between the groups.
- Serum cortisol, which is a more reliable marker of surgical stress response, could not be used as it is more expensive

BIBLIOGRAPGHY

1. Treede RD. The International Association for the Study of Pain definition of pain: as valid in 2018 as in 1979, but in need of regularly updated footnotes. Pain Rep. 2018 Mar 5;3(2):e643.

2. Zubrzycki M, Liebold A, Skrabal C, Reinelt H, Ziegler M, Perdas E, et al. Assessment and pathophysiology of pain in cardiac surgery. J Pain Res. 2018 Aug;Volume 11:1599–611.

3. Corral-Velez V, Lopez-Delgado JC, Betancur-Zambrano NL, Lopez-Suñe N, Rojas-Lora M, Torrado H, et al. The inflammatory response in cardiac surgery: an overview of the pathophysiology and clinical implications. Inflamm Allergy Drug Targets. 2015;13(6):367–70.

4. Hernández-Avalos I, Flores-Gasca E, Mota-Rojas D, Casas-Alvarado A, Miranda-Cortés AE, Domínguez-Oliva A. Neurobiology of anesthetic-surgical stress and induced behavioral changes in dogs and cats: A review. Vet World. 2021 Feb 11;14(2):393–404.

5. Lauridsen MH, Kristensen AD, Hjortdal VE, Jensen TS, Nikolajsen L. Chronic pain in children after cardiac surgery via sternotomy. Cardiol Young. 2014 Oct;24(5):893–9.

6. Morton NS. Prevention and control of pain in children. Br J Anaesth. 1999 Jul;83(1):118–29.

7. Caruso TJ, Lawrence K, Tsui BCH. Regional anesthesia for cardiac surgery. Curr Opin Anaesthesiol. 2019 Oct;32(5):674–82.

8. Kaushal B, Chauhan S, Magoon R, Krishna NS, Saini K, Bhoi D, et al. Efficacy of Bilateral Erector Spinae Plane Block in Management of Acute Postoperative Surgical Pain After Pediatric Cardiac Surgeries Through a Midline Sternotomy. J Cardiothorac Vasc Anesth. 2020 Apr;34(4):981–6.

9. Aksu C, Gurkan Y. Defining the Indications and Levels of Erector Spinae Plane Block in Pediatric Patients: A Retrospective Study of Our Current Experience. Cureus [Internet]. 2019 Aug 8 [cited 2022 Jul 10];11(8). Available from: https://www.cureus.com/articles/22205-defining-the-indications-and-levels-of-erector-spinae-plane-block-in-pediatric-patients-a-retrospective-study-of-our-current-experience

10. Blanco R, Fajardo M, Parras Maldonado T. Ultrasound description of Pecs II (modified Pecs I): a novel approach to breast surgery. Rev Esp Anestesiol Reanim. 2012 Nov;59(9):470–5.

11. Kumar K, Kalyane R, Singh N, Nagaraja P, Krishna M, Babu B, et al. Efficacy of bilateral pectoralis nerve block for ultrafast tracking and postoperative pain management in cardiac surgery. Ann Card Anaesth. 2018;21(3):333.

12. Kaushal B, Chauhan S, Saini K, Bhoi D, Bisoi AK, Sangdup T, et al. Comparison of the Efficacy of Ultrasound-Guided Serratus Anterior Plane Block, Pectoral Nerves II Block, and

Intercostal Nerve Block for the Management of Postoperative Thoracotomy Pain After Pediatric Cardiac Surgery. J Cardiothorac Vasc Anesth. 2019 Feb;33(2):418–25.

13. Jayakumar S, Borrelli M, Milan Z, Kunst G, Whitaker D. Optimising pain management protocols following cardiac surgery: A protocol for a national quality improvement study. Int J Surg Protoc. 2019 Jan 1;14:1–8.

14. Mangano DT, Siliciano D, Hollenberg M, Leung JM, Browner WS, Goehner P, et al. Postoperative Myocardial Ischemia: Therapeutic Trials Using Intensive Analgesia Following Surgery. Anesthesiology. 1992 Mar 1;76(3):342–53.

15. Chanques G, Jaber S, Barbotte E, Violet S, Sebbane M, Perrigault PF, et al. Impact of systematic evaluation of pain and agitation in an intensive care unit*. Crit Care Med. 2006 Jun;34(6):1691–9.

16. MacLeod JB, D'Souza K, Aguiar C, Brown CD, Pozeg Z, White C, et al. Fast tracking in cardiac surgery: is it safe? J Cardiothorac Surg. 2022 Apr 6;17(1):69.

17. Mazzeffi M, Khelemsky Y. Poststernotomy Pain: A Clinical Review. J Cardiothorac Vasc Anesth. 2011 Dec 1;25(6):1163–78.

18. Kidd BL, Urban LA. Mechanisms of inflammatory pain. Br J Anaesth. 2001 Jul;87(1):3–11.

19. Weissbein AS, Heller FN. A Method of Treatment for Pericardial Pain. Circulation. 1961 Sep;24(3):607–12.

20. Bruce J, Drury N, Poobalan AS, Jeffrey RR, Smith WCS, Chambers WA. The prevalence of chronic chest and leg pain following cardiac surgery: a historical cohort study. Pain. 2003 Jul;104(1–2):265–73.

21. Werner MU, Kongsgaard UE. I. Defining persistent post-surgical pain: is an update required? Br J Anaesth. 2014 Jul;113(1):1–4.

22. Huang APS, Sakata RK. Pain after sternotomy – review. Braz J Anesthesiol Engl Ed. 2016 Jul;66(4):395–401.

23. Florence SL, Jain N, Pospichal MW, Beck PD, Sly DL, Kaas JH. Central reorganization of sensory pathways following peripheral nerve regeneration in fetal monkeys. Nature. 1996 May 2;381(6577):69–71.

24. Peters ML, Sommer M, de Rijke JM, Kessels F, Heineman E, Patijn J, et al. Somatic and psychologic predictors of long-term unfavorable outcome after surgical intervention. Ann Surg. 2007 Mar;245(3):487–94.

25. Lahtinen P, Kokki H, Hynynen M. Pain after Cardiac Surgery: A Prospective Cohort Study of 1-Year Incidence and Intensity. Anesthesiology. 2006 Oct 1;105(4):794–800.

26. Roth-Isigkeit A, Brechmann J, Dibbelt L, Sievers HH, Raasch W, Schmucker P. Persistent endocrine stress response in patients undergoing cardiac surgery. J Endocrinol Invest. 1998 Jan;21(1):12–9.

27. Proia P, Di Liegro C, Schiera G, Fricano A, Di Liegro I. Lactate as a Metabolite and a Regulator in the Central Nervous System. Int J Mol Sci. 2016 Sep 1;17(9):1450.

28. Maillet JM, Le Besnerais P, Cantoni M, Nataf P, Ruffenach A, Lessana A, et al. Frequency, risk factors, and outcome of hyperlactatemia after cardiac surgery. Chest. 2003 May;123(5):1361–6.

29. Garcia-Alvarez M, Marik P, Bellomo R. Stress hyperlactataemia: present understanding and controversy. Lancet Diabetes Endocrinol. 2014 Apr;2(4):339–47.

30. Roberts KP, Weinhaus AJ. Anatomy of the Thoracic Wall, Pulmonary Cavities, and Mediastinum. :26.

31. Sharma R, Louie A, Thai CP, Dizdarevic A. Chest Wall Nerve Blocks for Cardiothoracic, Breast Surgery, and Rib-Related Pain. Curr Pain Headache Rep. 2022 Jan 1;26(1):43–56.

32. Lowenstein E, Hallowell P, Levine FH, Daggett WM, Austen WG, Laver MB. Cardiovascular response to large doses of intravenous morphine in man. N Engl J Med. 1969 Dec 18;281(25):1389–93.

33. Benyamin R, Trescot AM, Datta S, Buenaventura R, Adlaka R, Sehgal N, et al. Opioid complications and side effects. Pain Physician. 2008 Mar;11(2 Suppl):S105-120.

34. Kowalewski R, Seal D, Tang T, Prusinkiewicz C, Ha D. Neuraxial anesthesia for cardiac surgery: thoracic epidural and high spinal anesthesia - why is it different? HSR Proc Intensive Care Cardiovasc Anesth. 2011;3(1):25–8.

35. Hemmerling T, Cyr S, Terrasini N. Epidural catheterization in cardiac surgery: The 2012 risk assessment. Ann Card Anaesth. 2013;16(3):169.

36. Krishna SN, Chauhan S, Bhoi D, Kaushal B, Hasija S, Sangdup T, et al. Bilateral Erector Spinae Plane Block for Acute Post-Surgical Pain in Adult Cardiac Surgical Patients: A Randomized Controlled Trial. J Cardiothorac Vasc Anesth. 2019 Feb;33(2):368–75.

37. Holland EL, Bosenberg AT. Early experience with erector spinae plane blocks in children. Veyckemans F, editor. Pediatr Anesth. 2020 Feb;30(2):96–107.

38. Kamal F, Abd El-Rahman A, Hassan RM, Helmy AF. Efficacy of bilateral PECS II block in postoperative analgesia for ultrafast track pediatric cardiac anesthesia. Egypt J Anaesth. 2022 Dec 31;38(1):150–7.

39. Sertcakacilar G, Kose S. Bilateral PECS II Block is Associated with Decreased Opioid Consumption and Reduced Pain Scores for up to 24 hours After Minimally Invasive Repair of Pectus Excavatum (Nuss Procedure): a Retrospective Analysis. J Cardiothorac Vasc Anesth

[Internet]. 2022 Jun 6 [cited 2022 Jul 15]; Available from: https://www.sciencedirect.com/science/article/pii/S1053077022004438

40. Ghamry MRE, Darwish JM, Anwar AG, Elghoneimy Y. Ultrasound Guided PECS II Block in Minimally Invasive Coronary Artery By-pass Grafting. 2019;10(3):7.

41. Vaughan BN, Bartone CL, McCarthy CM, Answini GA, Hurford WE. Ultrasound-Guided Continuous Bilateral Erector Spinae Plane Blocks Are Associated with Reduced Opioid Consumption and Length of Stay for Open Cardiac Surgery: A Retrospective Cohort Study. J Clin Med. 2021 Oct 28;10(21):5022.

ANNEXURES

Technical Advisory Committee (Clinical Studies)

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2020/1109

Date: 27.07.2020

Project title: COMPARISON OF EFFICACY OF ULTRASOUND GUIDED BILATERAL ERECTOR SPINAE BLOCK AND PECTORALIS NERVE 2 BLOCK IN PEDIATRIC CARDIAC SURGERIES VIA MEDIAN STERNOTOMY

Principal Investigator:
Dr. Tony Jose Joseph, First year DM Senior Resident, Department of Anaesthesiology SCTIMST Degree: MBBS, MD
Co-Principal Investigator(s):
Dr. Rupa Sreedhar, Professor (Senior Grade), Department of Anesthesiology, SCTIMST Degree: MBBS, DA, MD, DNB, PDCC.
Dr. Subin Sukesan, Associate Professor, Department of Cardiac Anesthesiology, SCTIMST Degree: MBBS, MD, DM.
Co- Investigator(s):
Dr Shrinivas VGadhinglajkar, Professor,Department of Cardiac Anesthesiology,SCTIMST Degree: MBBS, MD, PDCC
Dr. Prasanta Kumar Dash, Professor, Department of Cardiac Anesthesiology, SCTIMST Degree: MBBS, MD, PDCC.
Dr. Baiju S Dharan, Professor, Department of CVTS, SCTIMST Degree: MBBS, MS, MCH
Dr. Saravana Babu M S, Assistant Professor, Department of Cardiac Anesthesiology, SCTIMST Degree: MBBS, MD, DM, FTEE

Members who participated in the TAC meeting on 20/06/2020

Dr Harikrishnan S (Chairman)
Dr Manikandan S
Dr Narayanan Namboodiri
Dr Jayadevan E R
Dr Sylaja P N
Dr Ramshekhar N Menon
Dr Unnikrishnan K P
Dr Syam K
Dr Sanjay G
Dr Deepti A N
Dr Sabarinath Menon
Dr Jayanand Sudhir B
Dr Srinivas G (Member Secretary)

Dr Sabarinath Menon, Dr Ramshekhar N Menon, Dr Sylaja P N, Dr Deepti A N, Dr Manikandan S, Dr Narayanan Namboodiri, Dr Srinivas G, Dr Sanjay G, Dr Harikrishnan S, Dr Unnikrishnan K P, Dr Syam K and Dr Jayadevan E R stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#1072,1087, 1089, 1092, 1093, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1103, 1107, 1108, 1111, 1113, 1114, 1116, 1118, 1119, 1120, 1121, 1122, 1123, 1127, 1129, 1130)

Risk Classification of the project (Minimum/ Moderate/ High): Moderate

Requirement of DSMB: Yes

Recommended members of DSMB:

Dr Vivek V Pillai, Department cardiothoracic and Vascular Surgery, SCTIMST
Dr Sabarinath Menon, Department cardiothoracic and Vascular Surgery, SCTIMST
Dr Bineesh K Radhakrishnan, Department cardiothoracic and Vascular Surgery, SCTIMST
Dr Sowmya Ramanan, Department cardiothoracic and Vascular Surgery, SCTIMST
Dr Shivanesan P,Department cardiothoracic and Vascular Surgery, SCTIMST

Recommendations of TAC:

Recommended for consideration of IEC in the light of the responses received from the investigator
The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.

Dr Srinivas G
MEMBER SECRETARY
TAC (Clinical Studies)
SCTIMST

Note for IEC

Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-1).

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेंद्रम - 695 011, केरल, भारत
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY
TRIVANDRUM - 695 011, KERALA, INDIA
(एक राष्ट्रीय महत्व का संस्थान, विज्ञान एवं प्रौद्योगिकी विभाग, भारत सरकार)
(An Institution of National Importance, Department of Science and Technology, Government of India)
टेलीफॉन नं./Telephone No.: 0471-2443152 फैक्स/Fax: 0471-2446433, 2550728
ई-मेल/E-mail: sct@sctimst.ac.in वेबसाइट/Website: www.sctimst.ac.in

Institutional Ethics Committee

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

SCT/IEC/1622/DECEMBER-2020 19.12.2020

Dr.Tony Jose Joseph
Senior Resident ,Cardiac Anaesthesia, Department of Anaesthesiology
SCTIMST, Thiruvananthapuram

Dear Dr.Tony Jose Joseph,
Thank you for submitting documents related to your proposal titled"**COMPARISON OF EFFICACY OF ULTRASOUND GUIDED BILATERAL ERECTOR SPINAE BLOCK AND PECTORALIS NERVE 2 BLOCK IN PEDIATRIC CARDIAC SURGERIES VIA MEDIAN STERNOTOMY** (IEC/1622)"to the IEC for review.

The following documents were reviewed:

1. Checklist
2. Covering letter addressed to the Chairman, IEC, SCTIMST dated 14.11.2020
3. Full proposal
4. IEC Application Form
5. Covering letter addressed to the Chairman, IEC, SCTIMST dated 14.11.2020 forwarded by HOD
6. Proforma
7. TAC Approval Letter
8. Patient Information Sheet in English
9. Informed Consent Form in English
10. Patient Information Sheet in Malayalam
11. Informed Consent Form in Malayalam
12. Child Assent Form in English
13. Child Assent Form in Malayalam
14. CV of Dr.Tony Jose Joseph with TCMC registration number
15. CV of Dr. Srinivas V Gadhinglajkar with TCMC registration number
16. CV of Dr. Rupa Sreedhar with TCMC registration number
17. CV of Dr. Subin Sukesan with TCMC registration number
18. CV of Dr. Prasanta Kumar Das with TCMC registration number
19. CV of Dr. Saravana Babu with TNMC registration number
20. CV of Dr. Baiju S Dharan with TCMC registration number

The following members of the Students Sub-Committee of the Institutional Ethics Committee participated in the discussions held between August 23-October 29, 2020 at the offices and residences of the members

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
5.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
6.	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

PATIENT INFORMATION SHEET

Title of study:

COMPARISON OF EFFICACY OF ULTRASOUND GUIDED BILATERAL ERECTOR SPINAE BLOCK AND PECTORALIS NERVE 2 BLOCK IN PEDIATRIC CARDIAC SURGERIES VIA MEDIAN STERNOTOMY

What are Erector Spinae block and PECS 2 blocks?

The Erector Spinae plane block (ESP) is a paraspinal fascial plane block that involves injection of local anesthetic deep in the Erector Spinae muscle and superficial to the tips of the thoracic transverse processes

The PECS II block is a superficial thoracic wall block which through blockade of the pectoral and intercostal nerves can be used to provide analgesia for the chest wall.

How are the blocks performed?

The blocks will be performed while your child is unconscious.
Your child will receive either Erector Spinae block or the PECS 2 block. Your child will be turned to one side or put in the supine position and area is cleaned with antiseptic solution. The Erector Spinae muscle and the Pectoral muscles are identified with ultrasound. Under strict aseptic precautions and ultrasound guidance the local anesthetic will be delivered. For the Erector Spinae block local anesthetic will be delivered below the erector spinae muscle. For the PECS 2 block local anesthetic will delivered between the pectoralis major and pectoralis minor muscles and also between the pectoralis minor and serratus anterior muscles.

What are the risks and side-effects?

Erector Spinae and PECS 2 block are fascial plane blocks. The possible complications including infection, injury to pleura, blood vessels and nerves will be avoided by using strict aseptic precautions and ultrasound guidance.

Why are we doing this study?

Congenital heart disease repair with cardiopulmonary bypass induces a systemic inflammatory response and sternotomy causes severe pain. Regional anaesthesia (blocks) administered as part of a combined anaesthetic technique decreases the stress response associated with the cardiopulmonary bypass (CPB), reduces postoperative pain, improves lung function and aids in recovery.

Can you withdraw from this study after it starts?

Your child's participation in this study is entirely voluntary and your will be 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.

What will happen if you develop any study related injury?

We do not expect any injury to happen to your child but if he/she develops any side effects or problems due to the study, these complications will be treated at no additional cost to you.

Will you have to pay for the study?

No.

Will your personal details be kept confidential?

Your child's personal details will be kept confidential. The result of this study maybe be published in a medical journal but your child will not be identified by name in any publication or presentation of results.

If you have any further questions, please ask:

Dr. Rupa Sreedhar, Professor (Senior Grade), Department of Anesthesia (Tel:9446314043)

Dr. Subin Sukeshan, Associate Professor, Department of Anesthesia (Tel:8289983726)

Name of the PI: Dr. Tony Jose Joseph, Senior Resident, Department of Anesthesia (Tel: 8547292062 or email id: tonyj224@gmail.com

Signature of the PI:

For any clarifications regarding the study's ethics clearance you may contact the Member Secretary of SCTIMST- IEC, Dr. Mala Ramanathan, (phone number:2524-234,
email id : iec.mem.sec@sctimst.ac.in)

INFORMED CONSENT

I, _____ (Parent's or guardian's name), F/o or M/o or G/o _____ _____ aged _____ (in years), declare that I have read the above information provided to me regarding the study: COMPARISON OF EFFICACY OF ULTRASOUND GUIDED BILATERAL ERECTOR SPINAE BLOCK AND PECTORALIS NERVE 2 BLOCK IN PEDIATRIC CARDIAC SURGERIES VIA MEDIAN STERNOTOMY

Please tick the relevant boxes

- I confirm that I have read and understood the information sheet dated…….for the above study and have the opportunity to ask questions [ ]
- I also understand that my ward's 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 understand that the investigators and institutional ethics committee members will not need my permission to look at the health records even if I withdraw my ward from the trial. I agree to this access [ ]
- I understand that my ward's identity will not be revealed in any information released to third parties or published [ ]
- I voluntarily agree to allow my ward to take part in this study [ ]
- I received a copy of this signed consent form [ ]

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date:

Signature:

(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 parents/guardian/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)

Contact No: 8547292062

Dr. Tony Jose Joseph (Principal Investigator)

കാര്യവിവരണപത്രം

പഠനശീർഷകം: കുട്ടികളുടെ ഹൃദയ ശസ്ത്രക്രിയയ്ക്ക് അൾട്രാസൗണ്ട് മാർഗ്ഗനിർദ്ദേശത്തോടെ നട്ടെല്ലിനിരുവശവുമുള്ള ഇറക്ടർ സ്പിനൈയ് ബ്ളോക്കും പെക്ടറാലിസ് നെർവ് 2 ബ്ളോക്കും തമ്മിലുള്ള പ്രയോജനക്ഷമതയുടെ താരതമ്യം

എന്താണ് ഇറക്ടർ സ്പിനൈയ് ബ്ളോക്കും പെക്ടറാലിസ് നെർവ് 2 (പിഇസിഎസ് 2) ബ്ളോക്കും?

ഇറക്ടർ സ്പിനൈ പ്ലെയിൻ ബ്ളോക്ക് (ഇഎസ്പി) ഒരു പാരാസ്പൈനൽ ഫേഷിയൽ പ്ലെയിനാണ് അതിൽ ഇറക്ടർ സ്പിനൈ പേശിക്ക് ആഴത്തിലും തൊറാസിക് ട്രാൻസ്വേർസ് പ്രോസസിന്റെ അഗ്രഭാഗത്ത് ഉപരിതലത്തിലുമായി പ്രാദേശികമായി മയക്കൽ മരുന്ന് കുത്തിവയ്ക്കുന്നു

നെഞ്ചിൽ വേദനയില്ലാതാക്കാൻ പെക്റ്റോറലും ഇന്റർകോസ്റ്റലുമായ നെർവുകളിൽ ബ്ളോക്കുണ്ടാക്കി തിരശ്ചീനമായി തൊറാസിക് ഭിത്തിയുടെ ഉപരിതലത്തിൽ ബ്ളോക്കുണ്ടാക്കുന്നതാണ് പിഇസിഎസ് 2 ബ്ളോക്ക്.

തടസ്സങ്ങൾ എങ്ങനെയുണ്ടാക്കുന്നു?

താങ്കളുടെ കുട്ടി അബോധാവസ്ഥയിലായിരിക്കുമ്പോഴാണ് ബ്ളോക്കുകൾ ഉണ്ടാക്കുന്നത്
താങ്കളുടെ കുട്ടിക്ക് ഇറക്ടർ സ്പിനൈയ് ബ്ളോക്കോ പെക്ടറാലിസ് നെർവ് 2 ബ്ളോക്കോ ലഭിക്കും. താങ്കളുടെ കുട്ടിയെ ഒരു വശത്തേക്ക് തിരിച്ച് കിടത്തിയോ മലർത്തി കിടത്തിയ നിലയിലോ കുത്തിവയ്ക്കുന്ന സ്ഥലം അണുവിമുക്തമാക്കും. അൾട്രാസൗണ്ടിന്റെ സഹായത്താൽ ഇറക്ടർ സ്പിനൈ പേശിയും പെക്ടോറൽ പേശിയും കണ്ടെത്തും. കർശനമായ അണുവിമുക്ത മുൻകരുതലോടെയും അൾട്രാസൗണ്ട് മാർഗ്ഗനിർദ്ദേശത്തോടെയും പ്രാദേശികമായ മയക്കൽ നടത്തും. ഇറക്ടർ സ്പിനൈ ബ്ളോക്കിന് പ്രാദേശികമായ മയക്കൽ മരുന്ന് ഇറക്ടർ സ്പിനൈ പേശിയിർ കുത്തിവയ്ക്കും. പെക്ടോറാലിസ് നെർവ് 2 ബ്ളോക്കിന് പെക്ടോറാലിസ് മെജറിനും പെക്ടോറാലിസ് മൈനർ പേശിക്കുമിടയിലും പെക്ടോറാലിസ് മൈനറിനും സെറേറ്റസ് ആന്റീരിയർ പേശികൾക്കുമിടയിലും പ്രാദേശികമായ മയക്കൽമരുന്ന് കുത്തിവയ്ക്കും.

അപായങ്ങളും പാർശ്വഫലങ്ങളുമെന്തെല്ലാം?

ഇറക്ടർ സ്പിനൈയ് ബ്ളോക്കും പെക്ടറാലിസ് നെർവ് 2 ബ്ളോക്കും ഫേസിക്കൽ പ്ലെയിൻ ബ്ളോക്കുകളാണ്. അണുബാധ, പ്ലൂറയിലുണ്ടാകാവുന്ന പരുക്ക് എന്നിവയാണ് അപായങ്ങൾ, രക്തക്കുഴലുകളും നെർവുകളും ഒഴിവാക്കി അണുവിമുക്തമായ മുൻകരുതലുകളോടെ അൾട്രാസൗണ്ട് മാർഗ്ഗനിർദ്ദേശത്തോടെയാണ് ഇത് ചെയ്യുന്നത്.

എന്തിന് ഞങ്ങൾ ഈ പഠനം നടത്തുന്നു?

കാർഡിയോ പൾമനറി ബൈപാസിലൂടെ ജന്മനായുള്ള ഹൃദ് രോഗം പരിഹരിക്കാൻ മാറെല്ലിൽ ശസ്ത്രക്രിയനടത്തുമ്പോൾ ശരീരത്തിലാകെയുണ്ടാകുന്ന വീക്കത്തിന്റെ പ്രതികരണം തീവ്രമായ വേദനയുണ്ടാക്കും. കാർഡിയോ പൾമനറി ബൈപാസ്സിനോട് (സിപിബി) ബന്ധപ്പെട്ട

സമ്മർദ്ദത്തിന്റെ പ്രതികരണം കുറയ്ക്കാനുപയോഗിക്കുന്ന സംയുക്തമായ മയക്കൽ സങ്കേതത്തിന്റെ ഭാഗമായാണ് പ്രാദേശികമായ മയക്കൽ (ബ്ളോക്ക്) ഉണ്ടാക്കുന്നത്, അത് ശസ്ത്രക്രിയയ്ക്ക് ശേഷമുള്ള വേദനകുറയ്ക്കുകയും ശ്വാസകോശത്തിന്റെ പ്രവർത്തനം മെച്ചപ്പെടുത്തുകയും വേഗം സുഖം പ്രാപിക്കാൻ സഹായിക്കുകയും ചെയ്യുന്നു.

പഠനമാരംഭിച്ചശേഷം താങ്കൾക്ക് പിൻമാറാനാകുമോ?

താങ്കളുടെ കുട്ടിയുടെ പഠനത്തിലെ പങ്കാളിത്തം തികച്ചും സ്വമേധയായുള്ളതും സമ്മതം പിൻവലിക്കാൻ ഏതുസമയത്തും താങ്കൾക്ക് സ്വാതന്ത്യമുള്ളതുമാണ്. താങ്കളങ്ങനെ ചെയ്താലും ഈ ആശുപത്രിയിലെ താങ്കളുടെ കുട്ടിയുടെ പതിവ് ചികിത്സയെ ഒരു തരത്തിലും ബാധിക്കില്ല.

പഠനസംബന്ധിയായി എന്തെങ്കിലും പരിക്ക് താങ്കളുടെ കുട്ടിക്കുണ്ടായാലെന്ത് സംഭവിക്കും?

ഈ പഠനത്തിന്റെ ഭാഗമായി താങ്കളുടെ കുട്ടിക്ക് പരിക്കൊന്നും ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല, പക്ഷേ എന്തെങ്കിലും പാർശ്വഫലങ്ങളോ പ്രശ്നങ്ങളോ ഉണ്ടായാൽ ഈ ആശുപത്രിയിൽ താങ്കൾക്കധിക ചിലവില്ലാതെ ചികിത്സിക്കും.

പഠനത്തിനായി താങ്കൾ പണം മുടക്കണോ?

വേണ്ട

താങ്കളുടെ കുട്ടിയുടെ വ്യക്തിപരമായ വിവരങ്ങൾ രഹസ്യമായിരിക്കുമോ?

താങ്കളുടെ കുട്ടിയുടെ വ്യക്തിപരമായ വിവരങ്ങൾ രഹസ്യമായിരിക്കും. ഈ പഠനം പൂർത്തിയാകുമ്പോൾ ഫലങ്ങൾ ഒരു വൈദ്യശാസ്ത്ര ജേർണലിൽ പ്രസിദ്ധീകരിച്ചേക്കാം പക്ഷേ താങ്കളുടെ കുട്ടിയുടെ പേരുകൊണ്ട് പ്രസിദ്ധീകരണത്തിലോ പ്രദർശനത്തിലോ ഒരിടത്തും തിരിച്ചറിയാനാകില്ല.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ താഴെ നൽകിയിരിക്കുന്ന ഗവേഷകരോട് ചോദിക്കുക

1. ഡോ. രൂപാ ശ്രീധർ, പ്രൊഫസർ (സീനിയർ ഗ്രേഡ്), ഡിപ്പാർട്ട്മെന്റ് ഓഫ് അനസ്തീഷ്യ (ഫോൺ 9446314043)
2. ഡോ. സുബിൻ സുകേശൻ, അസോസിയേറ്റ് പ്രൊഫസർ, ഡിപ്പാർട്ട്മെന്റ് ഓഫ് അനസ്തീഷ്യ (ഫോൺ 8289983726)
3. പ്രധാന ഗവേഷകന്റെ പേര് ഡോ. ടോണി ജോസ് ജോസഫ്, സീനിയർ റെസിഡന്റ്, ഡിപ്പാർട്ട്മെന്റ് ഓഫ് അനസ്തീഷ്യ (ഫോൺ 8547292062) ഇമെയിൽ tonyj224@gmail.com

പ്രധാന ഗവേഷകന്റെ ഒപ്പ്

4. പഠനത്തിന്റെ നൈതീക അനുവാദവുമായി ബന്ധപ്പെട്ട വിശദീകരണങ്ങൾക്ക് ഡോ. മാലാ രാമനാഥൻ, മെമ്പർ സെക്രട്ടറി, SCTIMST *IEC*, അഡീഷണൽ പ്രൊഫസർ/ ഫോൺ 2524234 ഇമെയിൽ iec.mem.sec@sctimst.ac.in

പ്രസ്താവനയും കാര്യബോധത്തോടെയുള്ള സമ്മതപത്രവും

..... വയസ്സ്..... (വർഷത്തിൽ) കുട്ടിക്കുവേണ്ടി ഞാൻ ..... (അച്ഛൻ/അമ്മ അല്ലെങ്കിൽ രക്ഷിതാവിന്റെ പേര്) കുട്ടികളുടെ ഹൃദയ ശസ്ത്രക്രിയയ്ക്ക് അൾട്രാസൗണ്ട് മാർഗ്ഗനിർദ്ദേശത്തോടെ നട്ടെല്ലിനിരുവശവുമുള്ള ഇറക്ടർ സ്പിനൈയ് ബ്ളോക്കും പെക്ടറാലിസ് നെർവ് 2 ബ്ളോക്കും തമ്മിലുള്ള പ്രയോജനക്ഷമതയുടെ താരതമ്യം എന്ന പഠനസംബന്ധമായി നൽകിയ കാര്യവിവരണപത്രം വായിച്ചതായി പ്രഖ്യാപിക്കുന്നു.

(ദയവായി പ്രസക്തമായ കോളങ്ങളിൽ ശരിയടയാളമിടുക)

1. എനിക്കുണ്ടായ എല്ലാ സംശയങ്ങളും പരിഹരിച്ചു. [ ]
2. എന്റെ കുട്ടിയുടെ പങ്കാളിത്തം സ്വമേധയായാണെന്നും, എന്റെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളോയോ ബാധിക്കാതെ ഏതു സമയത്തും പങ്കെടുക്കുനനതിനുള്ള എന്റെ അനുവാദം പിൻവലിക്കാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
3. പഠനത്തിൽനിന്നും ഞാൻ പിൻമാറിയാലും ഈ പഠനവുമായി ബന്ധപ്പെട്ട ആരോഗ്യരേഖകൾ എന്റെ അനുവാദം കൂടാതെ പരിശോധിക്കാമെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിന് ഞാൻ സമ്മതിക്കുന്നു.
4. എന്റെ കുട്ടിയുടെ വ്യക്തിപരമായ വിവരങ്ങൾ മുന്നാം കക്ഷികൾക്കോ പ്രസിദ്ധികരണത്തിനോ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
5. ഞാൻ സ്വമേധയാ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. [ ]
6. സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. [ ]

പേര്

ഒപ്പ്

തീയതി

സാക്ഷിയുടെ പേര്

രോഗിയുമായുള്ള ബന്ധം

ഒപ്പ്

സമ്മതപത്രം വാങ്ങുന്ന ആൾ

മെഡിക്കൽ റിസർച്ച്പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണ പദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രംവാങ്ങുന്ന ആളുടെ പേര്

ഒപ്പ് തീയതി

പ്രധാന ഗവേഷകൻ

CHILD ASSENT FORM

Title of the study: COMPARISON OF EFFICACY OF ULTRASOUND GUIDED BILATERAL ERECTOR SPINAE BLOCK AND PECTORALIS NERVE 2 BLOCK IN PEDIATRIC CARDIAC SURGERIES VIA MEDIAN STERNOTOMY

Principal Investigator: Dr Tony Jose Joseph

My name is Dr Tony Jose Joseph. Right now, I am trying to study how to relieve pain after your surgery in the ICU.

If you agree we will be giving you two small injections either to your back or your chest before your operation. You will not feel any pain during this injections because you will be already put to sleep before this. You may be helping us to study how to reduce the pain after heart surgery in children

You should also know that if you decide to help us or if you decide to say "no," your choice will not affect your treatment in hospital.

Please talk this over with your parents before you decide if you want to be in my study or not. I will also ask your parents to give their permission for you to be in this study, but even if your parents say "yes," you can still say "no" and decide not to be in the study.

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me or ask your parents to call me at: 8547292062

Would you like to participate in this study?

YES/NO

_____

(Signature of child with date)
Name of the Child: _____
Parent's/Guardian's name: _____
Age of the Child: _____

(Study independent contact person)
Dr.Mala Ramanathan, Phone No: 04712524-234

രോഗിയുടെ സമ്മതപത്രം

പഠനശീർഷകം: കുട്ടികളുടെ ഹൃദയ ശസ്ത്രക്രിയയ്ക്ക് അൾട്രാസൗ മാർഗ്ഗനിർദ്ദേശത്തോടെ നട്ടെല്ലിനിരുവശവുമുള്ള ഇറക്ടർ സ്പിനെയ് ബ്ളോക്കും പെക്ടറാലിസ് നെർവ് 2 ബ്ളോക്കും തമ്മിലുള്ള പ്രയോജനക്ഷമതയുടെ താരതമ്യം

പ്രധാന ഗവേഷകൻ ഡോ. ടോണി ജോസ് ജോസഫ്

എന്റെ പേര് ഡോ. ടോണി ജോസ് ജോസഫ് എന്നാണ്. തീവ്രപരിചരണ വിഭാഗത്തിൽ വച്ച് വേദന താങ്കളുടെ ശസ്ത്രക്രിയയ്ക്ക് ശേഷമുള്ളയ്ക്ക് എങ്ങിനെ ആശ്യാസംമുണ്ടാക്കാം എന്ന പഠനമാണ് ഞാനിപ്പോൾ നടത്തുന്നത്.

താങ്കൾ സമ്മതിക്കുകയാണെങ്കിൽ ശസ്ത്രക്രിയയ്ക്കുമുമ്പ് താങ്കളുടെ പുറകിലോ നെഞ്ചിലോ രണ്ട് ചെറിയ കുത്തിവയ്പ്പുകൾ ഞങ്ങൾ നൽകും. താങ്കളെ മയക്കിയതിനുശേഷമാണ് ഈ കുത്തിവയ്പ്പുകൾ എന്നതിനാൽ താങ്കൾക്ക് അതിന്റെ വേദന തോന്നില്ല. കുട്ടികളിൽ ഹൃദയ ശസ്ത്രക്രിയയ്ക്ക് ശേഷം എങ്ങനെ വേദനയ്ക്ക് ആശ്വാസമുണ്ടാക്കാമെന്ന ഞങ്ങളുടെ പഠനത്തെ സഹായിക്കുകയാവാം താങ്കൾ ചെയ്യുന്നത്.

താങ്കൾ ഞങ്ങളെ സഹായിക്കാൻ തീരുമാനിച്ചാലോ ഇല്ല എന്ന് തീരുമാനിച്ചാലോ താങ്കളുടെ തീരുമാനം താങ്കലുടെ ഈ ആശുപത്രിയിലെ ചികിത്സയെ ഒരുവിധത്തിലും ബാധിക്കില്ല എന്നും താങ്കൾ അറിയണം.

ഈ പഠനത്തിൽ പങ്കെടുക്കമോ വേണ്ടയോ എന്ന് തീരുമാനിക്കുന്നതിനുമുമ്പ് താങ്കളുടെ രക്ഷിതാക്കളുമായി സംസാരിക്കണം. ഞാനും താങ്കളുടെ രക്ഷിതാക്കളോട് പഠനത്തിൽ പങ്കെടുക്കാൻ താങ്കളെ അനുവദിക്കണമെന്ന് പറയാം, പക്ഷേ താങ്കളുടെ രക്ഷിതാക്കൾ സമ്മതിച്ചാലും താങ്കൾക്ക് ഇല്ല എന്നു പറയാനും പഠനത്തിൽ പങ്കെടുക്കേണ്ട എന്ന് തീരുമാനിക്കനുമാകും.

ഈ പഠനത്തെ പറ്റി താങ്കൾക്ക് ഏത് ചോദ്യവും ചോദിക്കാം. ഇപ്പോൾ ആലോചിക്കത്ത ചോദ്യമുണ്ടെങ്കിൽ എന്നെ താങ്കൾക്കോ താങ്കളുടെ രക്ഷിതാക്കൾക്കോ എന്നെ ഫോണിൽ 8547292062 വിളിക്കാം.

താങ്കൾ ഈ പഠനത്തിൽ പങ്കെടുക്കാന താത്പര്യപ്പെടുന്നുണ്ടോ?

ഉണ്ട്/ഇല്ല

കുട്ടിയുടെ ഒപ്പും തീയതിയും

കുട്ടിയുടെ പേര്..... വയസ്സ്.....

അച്ഛന്റെ/അമ്മയുടെ രക്ഷിതാവിന്റെ പേര്.....

പഠനത്തിൽ നിന്നും സ്വതന്ത്രമായ ബന്ധപ്പെടാനുള്ള വ്യക്തി. ഡോ. മാലാ രാമനാഥൻ ഫോൺ : **04712524-234**

കുട്ടിയുടെ പ്രായം

MASTER CHART

SR No	Group	Weight(kg)	Height(cm)	BSA(m2)	Aort	CPB	MOPS(PAIN							LAC						RANDOM BLOOD							Int	Dura	Tim	Addi	CU	Com
							15m	1hr	2hr	4hr	6hr	8hr	10hr	12hr	S0	S1	S2	S3	S4	S5	S6	S0	S1	S2	S3	S4	S5	S6						
1	E	6	17	112	0.7	16	30	3	1	1	1	4	4	5	6	2	1.8	2	2	2.3	2	1.8	75	86	94	115	108	114	103	15	2.5	6	2	2	nil
2	E	6	13	107	0.6	24	38	2	2	2	2	4	5	6	5	3	3.8	3	3	3	3	1.6	113	115	108	116	95	100	98	15	1.5	7	3	2	nil
3	E	5	14	110	0.6	23	37	3	1	1	2	4	5	6	5	1	1.4	2	1	1.2	2	1.2	104	112	102	113	99	94	107	15	4	8	2.5	2	nil
4	E	7	22	124	0.9	22	60	2	2	2	3	4	5	6	6	2	2.4	2	3	2.6	2	2.1	92	94	98	110	104	110	94	15	3	6	2.5	2	nil
5	E	4	14	100	0.6	17	70	1	1	2	1	5	5	6	5	1	1.1	1	1	1.5	1	1.1	80	100	112	104	110	95	92	16	3	5	4	2	nil
6	E	#	41	151	1.3	18	49	1	2	2	3	4	5	5	5	2	2.3	2	2	1.4	1	1.1	85	111	104	94	92	112	104	16	4	5	3	3	nil
7	E	5	19	112	0.8	22	49	2	1	1	4	4	5	5	6	2	1.8	2	3	2.8	2	2.3	90	103	104	112	103	110	95	14	3	6	2	2	nil
8	E	7	16	120	0.7	30	55	2	1	1	1	4	5	6	6	1	1.5	2	3	3.1	3	2	98	112	100	114	102	92	103	18	4	5	3	3	nil
9	E	3	12	90	0.7	25	45	3	2	2	3	4	5	5	6	1	1.4	2	2	2	2	2.1	102	113	95	90	122	110	102	16	3.5	6	2	3	nil
10	E	5	15	110	0.7	22	47	1	2	1	3	4	4	5	6	2	2.5	3	3	2.9	3	2.1	98	102	107	98	86	92	90	15	4	7	2	3	nil
11	E	8	25	135	1	26	44	2	1	2	1	4	5	6	5	3	2.7	3	3	2.4	3	2.4	112	115	98	112	89	81	98	15	3	7	3	4	nil
12	E	4	13	104	0.7	32	50	2	1	1	3	5	4	6	5	2	1.7	2	2	2.1	2	1.8	104	121	82	114	102	94	115	15	4	5	3	3	nil
13	E	7	20	125	0.8	29	55	3	1	2	1	4	5	5	5	1	1.6	2	2	2.1	2	1.6	102	125	116	97	116	94	89	16	4	5.5	3	3	nil
14	E	3	14	104	0.6	34	58	1	2	1	2	4	5	6	6	2	2.5	3	3	3	2	1.9	94	100	112	104	110	95	92	15	4.5	6	3	4	nil
15	E	5	16	110	0.7	28	59	2	1	1	2	4	4	5	5	2	1.9	2	2	2.5	3	2	84	91	98	112	104	103	113	15	3	7	2	3	nil
16	E	6	25	125	0.9	22	48	2	1	1	1	4	5	5	6	2	2.3	3	3	2.4	2	2.9	106	118	102	98	94	109	102	15	3	6.5	3	4	nil
17	E	9	35	145	1.2	34	60	2	1	2	3	4	5	5	6	3	2.7	3	3	2.4	2	2.6	94	99	92	86	85	111	100	15	3.5	6	2	2	nil
18	E	#	46	160	1.4	33	65	1	1	1	1	4	5	5	6	3	2.8	3	3	2.6	3	3	98	100	112	103	98	91	87	16	5	6	3	3	nil
19	E	#	55	165	1.6	22	49	1	1	1	4	5	4	6	6	1	1.8	2	2	2.5	3	2.6	84	94	98	110	104	110	94	15	4	7	2	2	nil
20	E	7	20	127	0.8	26	56	3	1	1	2	4	5	6	6	2	2.5	3	3	2.2	3	2.4	94	104	96	91	88	83	111	15	3.5	6	3	2	nil
21	E	8	22	130	0.9	20	49	2	1	1	2	5	5	6	6	3	3	3	3	2.6	3	2.3	91	102	100	103	93	99	92	16	4	5.5	4	3	nil
22	E	4	14	110	0.7	24	55	2	2	1	1	4	5	5	6	3	3.1	3	3	2.9	3	2.3	93	103	82	103	111	102	100	16	3	5	3	4	nil
23	E	3	12	102	0.6	29	46	2	1	1	2	4	5	5	5	2	1.9	2	2	2.1	2	1.9	87	99	93	99	100	111	102	16	2	4	3	3	nil
24	E	5	16	106	0.7	19	44	2	1	2	2	4	4	5	5	3	2.5	3	3	2.8	2	2	112	95	98	90	99	112	119	14	3	7	2	2	nil
25	E	6	18	116	0.8	28	56	1	2	1	1	5	4	6	6	2	1.8	2	2	2.6	3	2.5	116	111	98	101	100	101	103	15	2	7.5	2	2	nil
26	E	4	13	105	0.6	22	45	2	1	1	2	4	5	6	6	2	2.2	3	3	2.7	3	2.4	102	112	117	98	90	93	95	15	1.5	5	3	2	nil
27	E	9	26	140	1	33	67	2	2	2	1	4	5	5	6	3	2.4	2	3	2.5	3	2.2	94	112	100	114	102	92	103	15	5	8	2	2	nil
28	E	8	22	135	0.9	37	68	1	1	1	1	5	4	5	6	2	1.8	2	2	2.2	2	2.6	93	103	109	118	98	93	87	15	6	4	4	3	nil
29	E	#	35	145	1.2	28	55	3	1	1	2	4	5	6	5	2	2.2	2	3	2.5	3	2.5	84	91	119	104	103	94	90	16	3	6	3	2	nil
30	E	#	40	153	1.3	30	66	2	1	2	1	4	5	5	5	2	2.2	2	3	2.6	3	2.5	99	103	102	104	95	99	110	16	3	5.5	2	3	nil
1	P	3	12	115	0.6	23	44	3	2	2	4	4	5	5	4	2	2.3	3	2	1.7	2	1.8	100	115	98	112	89	81	98	18	3	3	3	4	nil
2	P	6	17	134	0.8	28	48	3	2	3	5	5	5	6	5	2	2.4	2	2	2.5	2	1.7	102	121	82	114	102	94	115	18	4	3.6	5	3	nil
3	P	7	22	130	0.9	33	55	4	4	3	3	5	6	5	4	2	2.6	3	2	2.6	2	1.8	107	125	116	97	116	94	89	18	5	4	2	3	nil
4	P	#	36	141	1.2	19	40	3	3	5	4	5	5	4	6	2	2.1	3	2	2.4	3	2.4	112	100	112	104	110	95	92	19	4	4	3	4	nil
5	P	3	15	114	0.7	44	65	3	3	4	4	6	5	6	5	2	2.8	3	2	2.5	3	1.9	82	91	85	112	104	103	113	20	4	4.5	3	3	nil
6	P	#	40	157	1.3	34	66	2	3	3	3	6	5	5	6	2	1.8	2	3	2.6	2	2.2	112	118	102	98	94	109	122	21	3	5	2	4	nil
7	P	4	15	123	0.7	25	45	4	2	2	3	5	4	5	4	2	2.2	4	2	2.6	3	2.7	91	99	92	86	85	111	100	18	2	3	4	2	nil
8	P	9	24	136	1	22	43	4	2	3	4	6	4	6	6	2	2.4	3	3	2.9	2	2	90	100	112	103	98	91	87	19	1	5	3	3	nil
9	P	5	16	130	0.8	46	66	3	3	5	5	4	6	5	5	2	2	2	2	1.9	2	2.6	84	94	98	110	104	110	94	20	2	3	3	2	nil
10	P	#	26	145	1	55	75	4	3	4	5	5	5	5	4	3	2.2	2	2	2.6	2	2.4	112	115	98	112	89	81	98	18	4	3	3	2	nil
11	P	3	14	121	0.7	19	43	2	2	4	3	5	5	5	4	3	2.4	2	3	2.6	3	2.1	103	121	109	114	102	94	115	20	3	4.3	4	3	nil
12	P	5	18	126	0.8	60	94	3	2	4	4	6	5	5	6	3	2.2	3	3	2.5	4	3	102	125	116	97	116	94	89	20	2	3	4	4	nil
13	P	7	23	134	0.9	34	57	3	2	3	4	5	6	4	5	2	2.1	2	2	2.5	3	2.1	112	100	112	104	110	95	92	18	2.5	4	3	3	nil
14	P	8	28	148	1.1	24	50	2	3	4	5	4	5	6	4	3	2.4	3	3	2.8	2	2	82	91	85	112	104	103	113	21	4	3.5	3	2	nil
15	P	#	38	155	1.3	29	55	2	2	4	3	5	6	5	6	3	2.3	3	2	2.2	2	1.9	102	118	102	98	94	109	122	17	3	4.5	4	2	nil
16	P	#	41	166	1.4	21	45	4	3	4	5	5	5	6	4	2	2.2	3	3	2.2	3	1.9	94	99	92	86	85	111	100	19	3	3	5	2	nil
17	P	6	23	133	0.9	39	66	3	3	4	2	6	5	6	5	2	1.2	2	2	2.1	2	2.5	90	100	112	103	98	91	87	18	2	3.5	3	2	nil
18	P	8	24	141	1	44	75	3	2	2	5	5	5	5	6	3	2.2	3	3	2.9	3	1.9	84	94	98	110	104	110	94	19	3.5	4	4	3	nil
19	P	#	33	149	1.2	43	70	3	4	5	3	6	6	5	6	2	2.2	3	2	2.2	3	2	102	125	116	97	116	94	82	23	2	3	3	2	nil
20	P	5	16	134	0.8	26	49	4	2	4	4	5	5	6	5	2	2.2	2	3	2.8	2	2.2	93	100	112	104	110	95	116	18	2.5	5	3	3	nil
21	P	#	33	150	1.2	32	60	3	3	4	4	4	5	6	6	2	2.5	3	2	2.2	3	1.7	86	91	85	112	104	103	112	17	3	4.4	4	4	nil
22	P	5	16	126	0.8	38	59	2	2	3	2	6	6	5	5	2	2.1	3	3	2.7	2	2.1	111	118	102	98	94	109	85	19	2.5	3.5	3	3	nil
23	P	9	23	137	0.9	23	45	4	4	2	4	4	6	4	5	3	2.8	2	2	3.1	3	2.7	104	115	108	116	95	100	102	19	2	4.3	4	3	nil
24	p	7	25	132	1	27	51	3	2	3	5	4	5	4	4	2	2.3	3	3	2.8	3	2.2	100	112	102	113	99	112	92	20	2.5	4.2	3	4	nil
25	p	4	21	124	0.9	19	44	2	3	2	4	4	6	5	5	2	1.7	2	2	2.5	2	1.8	90	94	98	110	104	110	112	17	4	4.5	4	3	nil
26	p	8	28	133	1	23	46	2	2	2	3	5	5	4	6	3	2.2	2	2	2.8	3	2.1	85	100	112	104	110	95	98	18	3	5	3	4	nil
27	p	3	15	124	0.7	22	45	3	2	3	5	5	4	4	4	2	1.4	2	2	1.9	2	1.7	86	105	104	94	92	112	96	19	3	4	4	2	nil
28	p	5	24	127	0.9	41	66	2	2	2	4	6	5	5	5	2	2.2	3	2	2.7	3	2.6	90	103	104	112	103	110	100	19	4	4.6	4	3	nil
29	p	9	34	144	1.2	39	70	4	3	2	5	5	6	4	6	2	2.4	2	3	2.9	2	2	98	112	100	114	102	92	82	17	1	4	3	2	nil
30	p	6	38	135	1.2	33	64	2	2	3	5	5	4	6	4	2	1.8	2	3	2.7	3	2.2	100	113	95	90	122	110	93	19	3	4.1	3	2	nil
1	C	3	14	112	0.7	35	65	4	5	4	5	4	6	5	6	3	2.4	2	3	2.6	3	2.1	98	102	107	98	86	92	95	25	4	2	5	3	nil
2	C	4	16	123	0.7	22	55	4	5	5	6	5	6	5	6	3	2.2	3	3	2.5	4	3	100	115	98	112	89	81	107	25	4	3	4	4	nil
3	C	5	20	128	0.8	34	67	3	4	6	5	4	6	5	5	2	2.1	2	2	2.5	3	2.1	111	121	82	114	102	94	98	23	5	2	5	3	nil
4	C	2	11	96	0.7	23	48	4	4	5	5	4	6	5	5	3	2.4	3	3	2.8	2	2	102	125	116	97	116	94	82	22	5	1	4	2	nil
5	C	7	23	136	0.9	25	49	3	5	5	4	4	5	5	6	3	2.3	3	2	2.2	2	1.9	94	100	112	104	110	95	116	24	4	2	6	2	nil
6	C	8	25	138	1	38	77	4	4	6	6	5	5	6	6	2	2.2	3	3	2.2	3	1.9	102	113	85	112	104	103	112	20	4	1	6	2	nil
7	C	5	16	122	0.7	19	43	3	4	5	6	4	6	5	5	2	1.7	2	2	2.5	2	1.8	104	118	102	98	94	109	85	25	4	2	4	2	nil
8	C	4	13	117	0.7	21	49	2	5	5	5	5	5	5	6	3	2.2	2	2	2.8	3	2.1	94	115	108	116	95	100	102	27	4	1	5	3	nil
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13	C	#	44	155	1.4	44	80	4	5	5	4	4	5	6	5	3	3.8	3	3	3	3	1.6	90	103	104	112	103	110	100	23	4	2.5	4	3	nil
14	C	3	14	104	0.6	22	45	3	4	5	5	5	6	4	5	1	1.4	2	1	1.2	2	1.2	98	112	100	114	102	92	82	25	4	1	5	4	nil
15	C	5	16	118	0.7	23	51	4	4	6	5	4	5	5	6	2	2.4	2	3	2.6	2	2.1	103	113	95	90	122	110	93	24	3	3	4	3	nil
16	C	7	20	129	0.9	38	66	2	5	6	4	5	6	6	5	1	1.1	1	1	1.5	1	1.1	94	104	96	91	88	83	111	23	5	1.5	6	4	nil
17	C	3	13	110	0.6	32	64	4	4	5	6	4	5	5	5	2	2.3	2	2	1.4	1	1.1	93	102	100	103	93	99	92	25	5	2	5	2	nil
18	C	4	15	125	0.7	27	58	3	5	4	4	6	4	6	5	2	1.8	2	3	2.8	2	2.3	95	103	82	103	111	102	100	23	2	1	5	3	nil
19	C	3	12	107	0.6	45	74	5	4	5	5	4	5	5	6	1	1.5	2	3	3.1	3	2	91	99	93	99	100	111	102	25	4	3	6	2	nil
20	C	2	11	104	0.7	22	44	4	5	4	5	5	4	6	6	1	1.4	2	2	2	2	2.1	112	95	98	90	99	112	119	23	6	1	4	2	nil
21	C	5	14	122	0.7	41	69	3	4	5	6	4	6	5	5	2	2.5	3	3	2.9	3	2.1	116	111	98	101	100	101	103	21	5	2	5	3	nil
22	C	8	21	137	0.9	36	73	3	5	5	5	5	5	6	6	1	1.4	2	2	2	2	2.1	102	112	117	98	90	93	95	21	4	3	3	4	nil
23	C	#	52	164	1.5	30	55	4	4	5	5	4	5	4	5	2	2.5	3	3	2.9	3	2.1	94	112	100	114	102	92	103	19	3	1	4	3	nil
24	C	4	14	123	0.7	47	72	4	4	4	6	5	6	5	6	3	2.7	3	3	2.4	3	2.4	93	103	109	118	98	93	87	25	6	2.5	4	2	nil
25	C	6	18	127	0.8	44	78	2	4	4	5	5	5	4	5	2	1.7	2	2	2.1	2	1.8	85	91	119	104	103	94	90	22	5	1	4	2	nil
26	C	#	39	158	1.3	34	73	4	5	5	6	6	5	5	6	1	1.6	2	2	2.1	2	1.6	94	99	92	86	85	111	100	22	4	2.5	5	2	nil
27	C	2	12	99	0.6	56	88	4	5	4	5	6	5	6	5	2	2.5	3	3	3	2	1.9	93	100	112	103	98	91	87	23	6	2	6	2	nil
28	C	5	22	133	0.9	36	74	3	4	5	6	5	6	4	6	3	3	3	3	2.6	3	2.3	84	94	98	110	104	110	94	23	5	1.5	5	3	nil
29	C	4	15	122	0.7	29	64	4	4	5	4	5	5	5	5	3	3.1	3	3	2.9	3	2.3	94	104	96	91	88	83	111	23	4	3	4	2	nil
30	C	8	26	144	1	23	51	3	5	6	6	5	4	5	6	2	1.9	2	2	2.1	2	1.9	92	102	100	103	93	99	92	21	4	2	5	3	nil

Proforma

Name of the patient: Diagnosis:

Age of the patient (years): Procedure:

Weight (Kg): Aortic cross clamp duration (min):

Height (cm): CPB duration (min):

BSA (m^2): Regional anaesthetic technique:

BMI (Kg/m^2): Time of shifting to ICU:

Group (E/P/C):

Pain score: (After extubation)

TIME	**15mins**	**1hr**	**2hrs**	**4hrs**	**6hrs**	**8hrs**	**10hrs**	**12hrs**
MOPS								

Parameter	S0	S1	S2	S3	S4	S5	S6
Random blood sugar (mg%)							
Lactate (mmol/l)							

- **Intraoperative Fentanyl Consumption (mcg/kg):**
- **Duration of mechanical ventilation (hours):**
- **Time to first rescue analgesic(hours):**
- **Additional dose of Fentanyl used postoperatively(mcg/kg):**
- **Complications, if any:**
- **Length of ICU stay:**

MOPS (MODIFIED OBJECTIVE PAIN SCORE)

CRITERIA	FINDING	POINTS
Crying	**None** **Consolable** **Not Consolable**	**0** **1** **2**
Movement	**None** **Restless** **Thrashing**	**0** **1** **2**
Agitation	**Asleep** **Calm** **Mild** **Hysterical**	**0** **0** **1** **2**
Posture	**Normal** **Flexed** **Holds Injury site**	**0** **1** **2**
Verbal	**Asleep** **No Complaint** **Complaints But Cant Localize** **Complaints & Localize**	**0** **0** **1** **2**

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