

A Dissertation on

**“A PROSPECTIVE RANDOMISED OBSERVER BLINDED
COMPARATIVE STUDY OF SERRATUS PLANE BLOCK AND
THORACIC PARAVERTEBRAL BLOCK IN CONJUNCTION
WITH GENERAL ANAESTHESIA IN MODIFIED RADICAL
MASTECTOMY”**

Submitted to

THE TAMILNADU DR M.G.R.MEDICAL UNIVERSITY

in partial fulfilment

For the award of the degree of

DOCTOR OF MEDICINE in ANAESTHESIOLOGY

BRANCH X



DEPARTMENT OF ANAESTHESIOLOGY & CRITICAL CARE

STANLEY MEDICAL COLLEGE

CHENNAI-600 001

APRIL 2017

DECLARATION BY THE CANDIDATE

I hereby declare that the dissertation entitled “**A PROSPECTIVE RANDOMISED OBSERVER BLINDED COMPARATIVE STUDY OF SERRATUS PLANE BLOCK AND THORACIC PARAVERTEBRAL BLOCK IN CONJUNCTION WITH GENERAL ANAESTHESIA IN MODIFIED RADICAL MASTECTOMY**” has been prepared by me under the Guidance of **PROF.DR.PONNAMBALA NAMASIVAYAM**, Professor of Anaesthesiology, Department of Anaesthesiology, Stanley Medical College, Chennai, in partial fulfilment of the regulations for the award of the degree of M.D (ANAESTHESIOLOGY), examination to be held in April 2017.

This study was conducted at Department Of Anaesthesiology, Stanley Medical College, Chennai.

I have not submitted this dissertation previously to any university for the award of any degree or diploma.

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Place: Chennai

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ABBREVIATIONS

USG	-	Ultrasonogram
VAS	-	Visual Analog score
PECS Block	–	Pectoral nerve blocks.
PVB	-	Paravertebral Block
PONV	-	Postoperative nausea and vomiting.

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INTRODUCTION

The Postoperative Analgesia for Breast surgery is Challenging, Previously Thoracic Epidural Analgesia was gold standard for Breast surgeries which was Replaced by Paravertebral Block. But both these Techniques has complications Like Pneumothorax, Vascular Injection. Now regional Blocks like Pectoral Nerve Blocks has been gradually coming into practice.

With Recent use of USG in nerve blocks has improved the success rate of the blocks and less complications. More studies were conducted to compare USG guided Paravertebral block and pectoral nerve Blocks. Serratus plane block is now recently used technique for Postoperative Analgesia in breast Surgeries. We hypothesise that Serratus Plane block under USG guidance provides better analgesia and fewer complications compared to Thoracic Paravertebral block.

AIM OF THE STUDY

“TO COMPARE THE EFFICACY OF POSTOPERATIVE ANALGESIA OF USG GUIDED THORACIC PARAVERTEBRAL BLOCK AND USG GUIDED SERRATUS PLANE BLOCK IN CA BREAST PATIENTS UNDERGOING MRM SURGERY”.

Primary Outcome measures:

- Assessment of the postoperative analgesia by Visual Analogue pain score.

Secondary Outcome measures:

- Postoperative Nausea and vomiting
- Rescue Analgesic requirement
- Patient Satisfaction
- Incidence of side effects

ULTRASONOGRAM

Anesthesiologists have been performing many interventional procedures using anatomical landmarks over many years with variable success rates, risks, and consequences of complications. Recently Ultrasonogram has an increasing role in Regional Anaesthesia for nerve Blocks. It is a simple and non-invasive technique that provides accurate and localises the area. Modern USG machines are well compact with better Resolution and enhanced tissue penetration.^{4,5} Ultrasound Imaging can elucidate peripheral nerves and adjacent landmarks. The typical appearance of a nerve will be honey-comb formed by the nerve fibres. Many blind techniques can lead to complications like Pneumothorax can be avoided by USG, by full visualisation of the needle and its proximity to vital structures.

BASIC PRINCIPLE

Ultrasound is a sound above the audible range (20000 cycles per second). In clinical imaging with a frequency range of 1 – 20 MHz. Sound waves reflected by the tissues generate echoes. The ultrasound waves penetrate different tissues and are reflected by interfaces.

Parts of Ultrasound Machine

- Transducer
- Receiver & Processor and display

It works on the Principle of Pizelectricity, Transducers have Pizelectric Crystals which have property of changing shape when voltage is applied. Application of voltage at a Particular frequency converts electrical energy Into sound waves.

The waves strikes the tissues at different levels may reflected Or refracted. The reflected waves strike the transducer strike the piezoelectric Crystals converting sound into electrical energy. The Sound Reflected or transmitted depends on the Acoustic Impedance is Measured in rayls is product of density of tissue and velocity.

TABLE 1 Acoustic Impedance of Different Materials

Material	Acoustic Impedance
Air	400
Fat	1380000
Water	1430000
Soft tissue	1630000
Bone	780000

Ultrasonogram has the following advantages in peripheral nerve blocks

- Visualisation of neural structure & blood vessels
- Guidance of the needle under real time visualisation
- Avoid complications like pneumothorax and intravascular injection.

To Monitor the spread of local Anaesthetic

TYPES OF NEEDLES

18 G Tuohy Needle⁸

Tuohy Huber point needle – with a blunt leading edge and a lateral opening at the tip. This needle is a standard directional needle used for Thoracic Paravertebral Block and Serratus Plane Block. 22 G Tuohy needle can also be used.

FIGURE 1



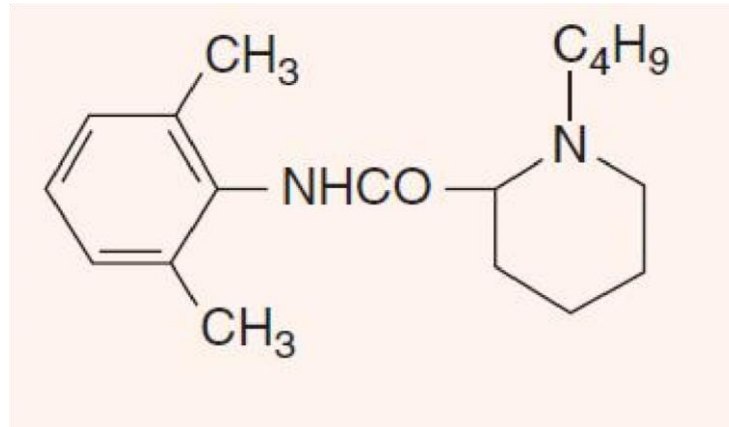
18G TUHOY NEEDLE

Various other needles used are

1. Crawford point needle
2. Hustead needle - Modified Tuohy needle with a rounded tip and a bevel opening which is located 2.7mm from the tip in 18G needle.
3. 22G venflon needles can also be used for both Thoracic Paravertebral block and Serratus plane block.

PHARMACOLOGY OF BUPIVACAINE

FIGURE 2.



CHEMICAL STRUCTURE OF BUPIVACAINE

It is an amide local anaesthetic characterized as piperidoxylidides. Addition of a butyl to the piperidine nitrogen of mepivacaine results bupivacaine. It is a chiral drug , because of possession of asymmetric carbon atom. Its was first synthesized in Sweden by Ekenstam and his colleagues in 1957 and used clinically by L.J. Telivuo in 1963. It has a molecular weight of 288.

MECHANISM OF ACTION¹

It prevents transmission of nerve impulses by inhibiting passage of sodium through ion selective sodium channels in nerve membranes. They do not alter the transmembrane potential or threshold potential.

PHARMACOKINETICS

It is a weak base that has a pKa value above physiologic pH 7.4. Lung is capable of extracting bupivacaine from circulation. This extraction limits the concentration of drug reaching systemic circulation and distribution to the coronary and cerebral circulations.

METABOLISM

Undergoes varying rate of metabolism by microsomal enzymes located primarily in the liver. ²Bupivacaine has the slowest metabolism among amide local anaesthetics, it undergoes aromatic hydroxylation, amide hydrolysis and conjugation. Only the N – desbutyl bupivacaine has been measured in blood or urine after epidural and spinal anaesthesia. Alpha -1 acid glycoprotein is the most important protein binding site of bupivacaine.

SIDE EFFECTS

The cardiotoxic effects of bupivacaine are more pronounced when compared to other drugs. This is manifested with severe ventricular arrhythmias, and myocardial depression. Bupivacaine blocks cardiac Na⁺ channels rapidly during systole and dissociates slowly during diastole,

so that significant fraction of Na channels remain blocked at the end of the diastole.

CLINICAL USE :

Onset of anaesthesia and duration of action are long. The ability to provide more sensory than preferential motor block has made it useful and effective for postoperative analgesia .

Used mainly for :

- Epidural anaesthesia
- Spinal anaesthesia
- Infiltration anaesthesia
- Field block anaesthesia
- Nerve block anaesthesia

THORACIC PARAVERTEBRAL SPACE

This space begins at the level of T1 and extends up to the level of T12³.

It is a wedge shaped in all three dimensions.

Medial wall - Vertebral Bodies and Intervertebral foramina

Anterolaterally- Parietal pleura and Intercostal Membrane

Posteriorly - Transverse Process of Thoracic vertebrae, Heads of the ribs.

The Paravertebral Space contains spinal nerves, grey and white communicants.

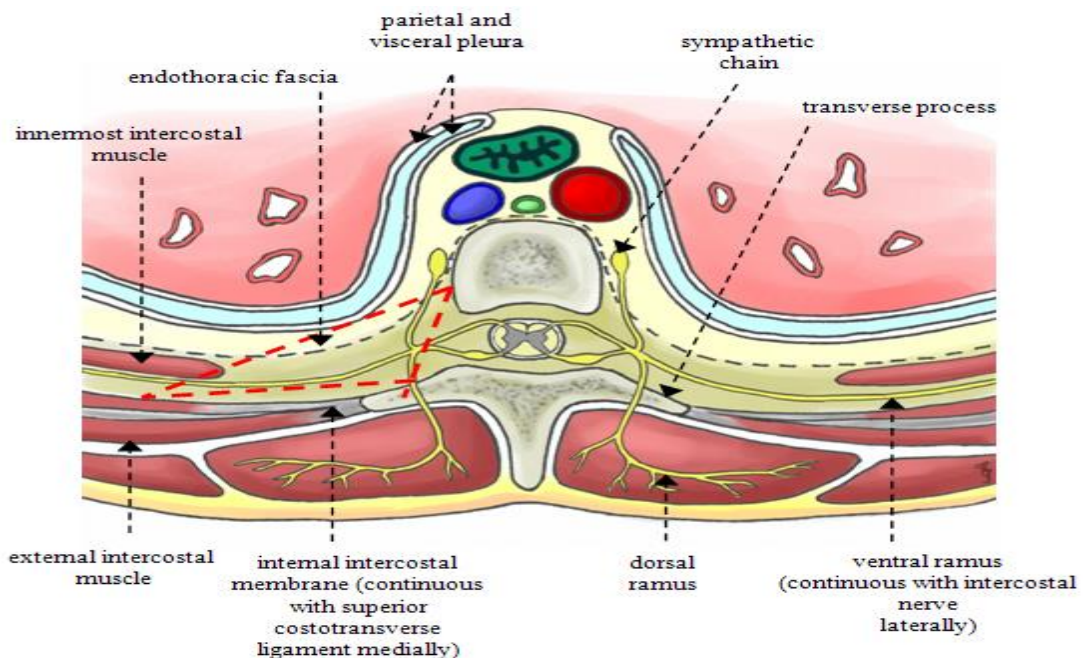


FIGURE 3

THORACIC PARAVERTEBRAL BLOCK

In 1979 land mark based Thoracic paravertebral block technique was introduced to provide analgesia for breast surgery. It provides unilateral block of the spinal nerves.

INDICATIONS

Breast Surgeries

Analgesia after thoracotomy

TECHNIQUE

Dermatome to be blocked should be identified, the inferior border of the scapula (T7) and C7 Prominence are identified as landmarks. By using 22G Tuohy needle after locating the spinous process, the needle is advanced after contacting the transverse process, then needle is withdrawn and directed in cephalad or caudal referred to as 'walking over' technique the needle is passed until there is a give away which is the puncture of costotransverse ligament, after aspiration 15-20ml of 0.125% bupivacaine is injected in paravertebral space.

COMPLICATIONS

- Pneumothorax
- Hypotension
- Vascular puncture
- Failed block

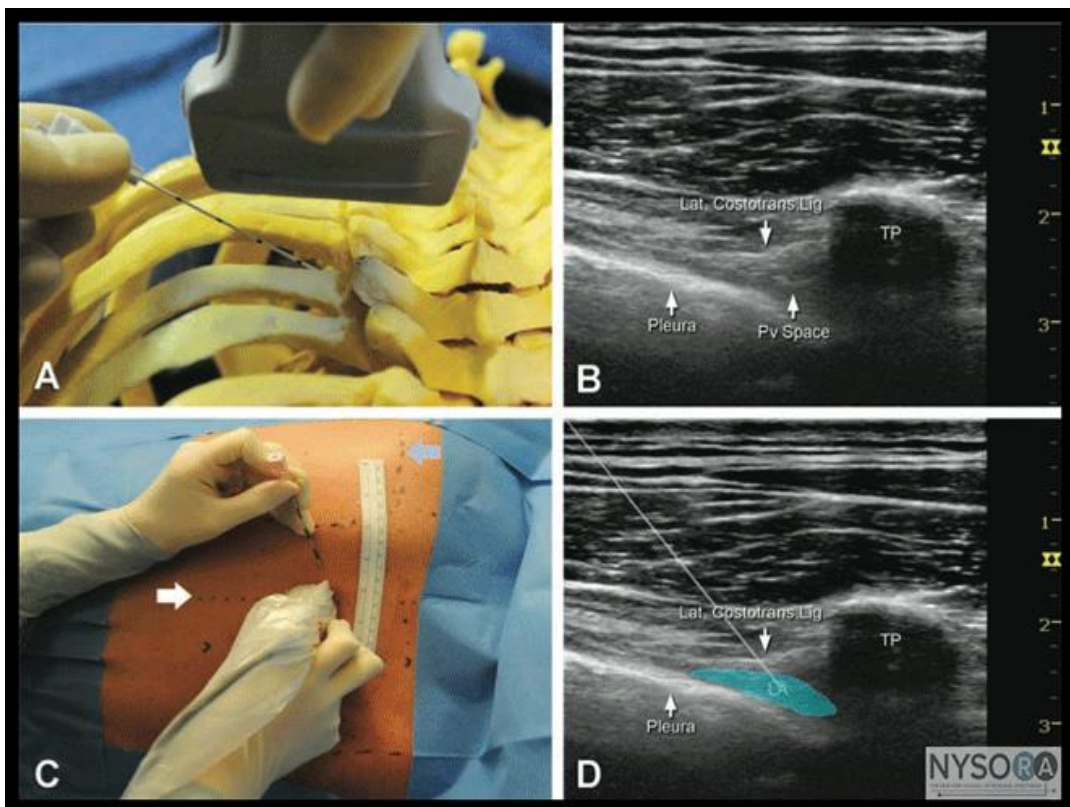


FIGURE 4

CONTRAINDICATIONS

- Patient refusal
- Severe Coagulopathy
- Local infection
- Allergy to Local Anaesthetics
- Severe hypovolemia

NERVE SUPPLY OF THE BREAST ³

Breast is a modified sweat gland in the pectoral region. The Breast lies in the Superficial fascia of the Pectoral region. It extends vertically from second to sixth rib. Horizontally it extends from lateral border of the sternum to mid-axillary line. The Nerve supply of the breast is by medial and lateral pectoral nerve and long thoracic nerve of bell. The cutaneous is by lateral and anterior cutaneous branches of 4th to 6th intercostal nerves. The Medial Pectoral nerve is a branch of medial cord of Brachial Plexus derived from C8-T1. It supplies Pectoralis minor and part of pectoralis major. The Lateral Pectoral Nerve is a branch of Lateral cord

of brachial plexus runs above pectoralis minor and supplies remainder of pectoralis major. The Long Thoracic Nerve of Bell derived from ventral rami of C5- C7 supplies Serratus Anterior Muscle Superficially.

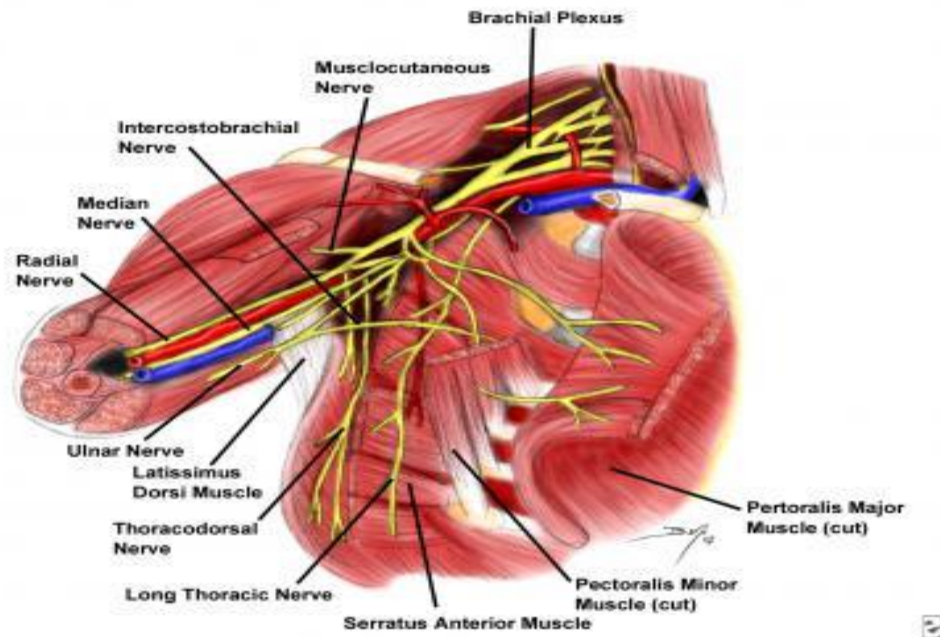


FIGURE 5

The Pectoralis Major Muscle originates from the anterior surface of the medial half of clavicle and surface of manubrium and sternum up to 6th costal cartilages inserted into bicipital groove of the humerus. It is supplied by medial and lateral pectoral nerves. The Pectoralis Minor muscle originates from 3,4,5 ribs near costochondral junction and is inserted into coracoid process, supplied by medial and lateral pectoral nerves.

SERRATUS ANTERIOR MUSCLE

The Serratus anterior muscle arises as eight digitations from upper 8 ribs and is inserted into the costal surface of the scapula³. The first digitation is inserted into the superior angle to the root of spine. The next two or three digitations are inserted lower down on the medial border. The lower four or five digitations are inserted into a large triangular area over inferior angle.

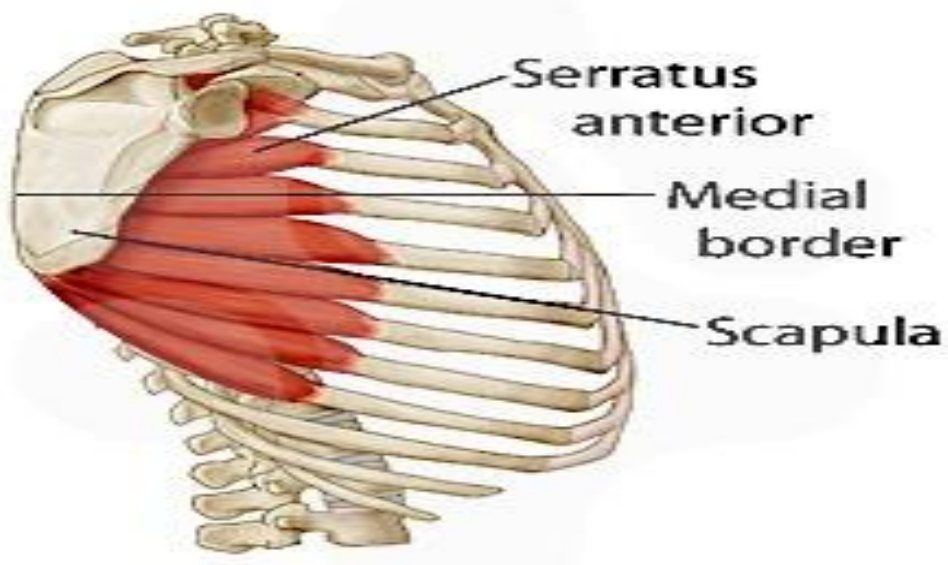


FIGURE 6

PECTORAL NERVE BLOCKS

Blanco described interfascial block for Breast Surgeries as a alternative to Paravertebral blocks, termed as PECS blocks. In this technique (PECS 1 Block) local anaesthetic is deposited in between Pectoralis major and minor. This block anaesthetises Medial and lateral pectoral nerves⁷.

To Perform Pecs1block Patient is Positioned supine with ipsilateral arm relaxed to the side. By using USG guidance Blanco Initially described a approach with high frequency probe(10 -12 MHZ) at the level of coracoid process, From superficial to deep subcutaneous tissue, pectoralis major muscle, Pectoralis minor muscle, Axillary artery, Axillary vein and pleura should be identified. Thoracoacromial artery and the lateral pectoral nerves lies between the pectoral muscles.20ml of 0.25% bupivacaine is injected between the pectoral muscles, Dose should be calculated based on patient's bodyweight.

Later Blanco modified this by injecting the local Anaesthetic between Pectoralis minor and Serratus anterior muscle named as (Pecs 2 block).

⁸This block Anaesthetises the Lateral branches of Intercostal nerves (T2 – T6) with Intercostobrachial, Thoracodorsal and the Long Thoracic Nerves. For Performing the pecs2 block the same anatomy is identified the probe is moved laterally until pectoralis minor and 3rd rib is visualised. Pleura is visualised between the ribs.

Local anaesthetic 20ml of 0.25% bupivacaine is injected between pectoralis minor and serratus anterior muscle.

Few complications like accidental intravascular injection in Thoracoacromial artery may be seen. Pleural puncture may be possible with Pecs 2 block.

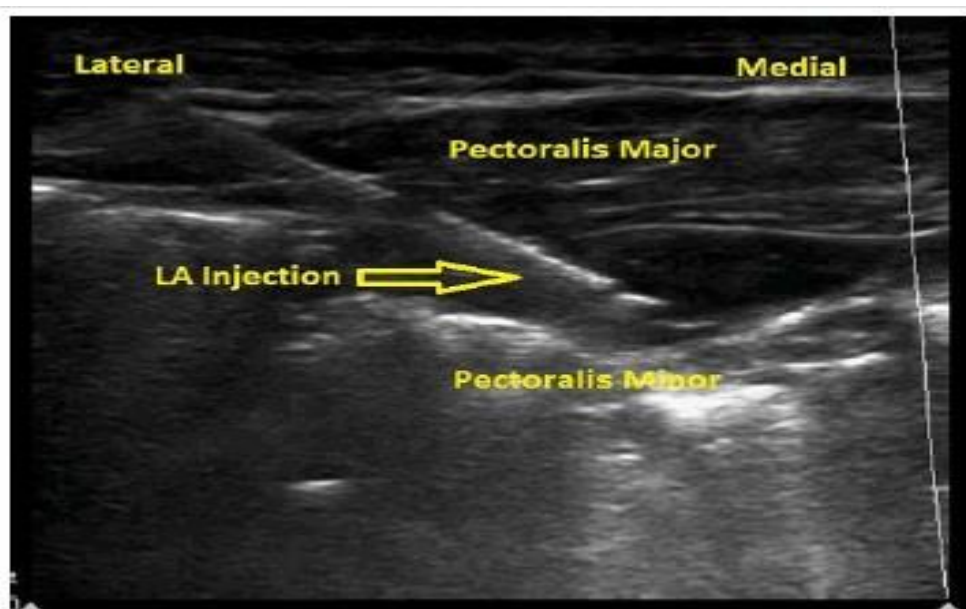


FIGURE 7

SERRATUS PLANE BLOCK ¹¹

This new Ultrasound guided new technique is an alternative to thoracic paravertebral block and thoracic epidural, while Pecs 1 and pecs 2 block are technically difficult to perform, Serratus plane block is easily Performed regional block for Breast surgeries. ¹²It also provides complete analgesia of hemithorax by blocking thoracic intercostal nerves. By using USG 5th rib is identified in the midaxillary line latissimus dorsi and serratus anterior muscle are identified, by 18G tuohy needle introduced by in-plane technique 30ml of 0.25 bupivacaine is injected superficial to serratus muscle. ¹⁴ After 30min the area of sensory loss is tested with pinprick.

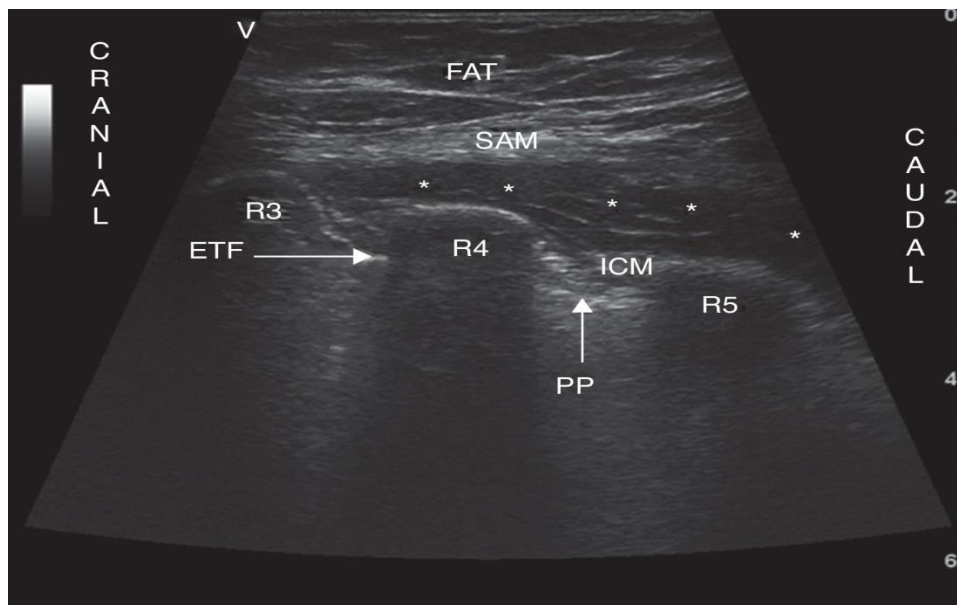


FIGURE 8

REVIEW OF LITERATURE

1. Sherif Samir wabha and sahar Mohammed kamal in Ain sams university, cairo, Egypt compared Thoracic paravertebral block and pectoral nerve blocks for analgesia in breast surgery patients. Sixty patients were randomly allocated into two groups of 30 each. In USG guided paravertebral block 15-20ml of 0.25% levobupivacaine at the level of fourth thoracic vertebra in paravertebral space. 30ml of 0.25% levobupivacaine given by USG guided pectoral nerve block. Primary outcome measures was morphine consumption in the first 24hrs while secondary outcome measures was VAS scores, fentanyl consumption in Intraop period, Postoperative nausea and vomiting (PONV).

Results: Post operative Morphine requirement 24hr was significantly lower in Pecs group [175 (155–220) min] than in paravertebral block [137.5 (115–165) min]. VAS scores was lower in Pecs group for 12hrs ($p < 0.001$) while at 18 & 24hrs it was significantly lower in PVB group ($p < 0.001$).

Conclusion: Pecs block reduces the requirement of postoperative morphine consumption in the first 24hrs in comparison and Lower VAS scores in first 12 hrs when compared to PVB group after MRM surgeries.

2. Blanco demonstrated USG guided Serratus plane block in four female volunteers. He performed block at two different levels in midaxillary line recorded the degree of paraesthesia lasting for 750-840 min.

3. Luca Guzzetti Giorgio danelli performed a observational analysis about novel chest wall blocks (pecs and serratus plane blocks) during breast surgery. 4 Italian hospitals participated in observational surgery in women undergoing breast surgeries. Postoperative pain onset and Postop nausea vomiting were monitored for 48hrs. 279 patients were divided based on the surgical procedures like ductectomy, mastectomy, mastectomy with lymphadenectomy, quadrantectomy, breast plastic surgery. In this study Pecs 2 block and serratus plane block were combined before administering General Anaesthesia. It was observed that postop VAS scores were less among breast surgery patients with pecs

block and General Anaesthesia, than in patients with General anaesthesia alone.

4. Harue Morioka, yoshinori kamiya did a retrospective comparison of breast surgery patients under TIVA with pecs block and without block. Retrospective analysis of intraoperative opioid requirement, postoperative pain, and postop nausea and vomiting (PONV) were analysed. 46 patients who underwent BCS at Niigata University Medical and Dental Hospital were included in the study from January 2013 to March 2014; 36 patients were included in the TIVA group, and 35 patients were included in TIVA with PECS group and the remaining Patients with TIVA group alone, it was found retrospectively that intraoperative fentanyl requirement and VAS scores were less in TIVA with Pecs group than TIVA group alone (TIVA: $10.9 \pm 2.9 \mu\text{g/kg/h}$; TIVA + PECSB: $7.3 \pm 3.3 \mu\text{g/kg/h}$; $p < 0.001$). Postoperative VAS scores during the 48 h after surgery were significantly lower in the TIVA with PECSB group than in TIVA group (TIVA: 2 [1–5]; TIVA + PECSB: 1 [0–5]; $p = 0.03$).

5. Naja, Klein and colleagues in sveti duh university hospitals assessed the efficacy of paravertebral blocks in thoracic, abdominal and

breast surgeries. Six randomised control trials, 386 patients were included. Out of which 120 patients of breast surgery patients was performed PVB by using Lidocaine 1%, bupivacaine 0.5% fentanyl, clonidine and epinephrine. The results were randomised they reported that the block was 100% effective failure rate was less than 9%, vascular puncture was 5.2%, hypotension 6%, pleural puncture 1.8% and pneumothorax 0.5%. Postoperative nausea and vomiting were lower in PVB patients than in GA.

6. James Simpson and Arun Ariyarthanam in south Devon healthcare hospitals, UK performed a randomised controlled study. 28 female patients were included in this study (mean age 73, range 27-93). Three patients received TPVB due to anxiety for GA, 21% on patients choice, 4% who were pregnant. TPVB was performed at two levels T3 and T5, T3 T5 and T6. The volume of local anaesthetic used was 24ml of 0.25% bupivacaine. Based on the study outcome of 28 patients were studied TPVB by USG guidance along with sedation appears to be effective and reliable analgesia for breast surgery patients.

7. Anis dizdarv and Anthony fernandes Performed Thoracic Paravertebral block with Multimodal Analgesia for 64 yr old CA breast patient with Primary Lateral Sclerosis in whom GA was contraindicated. Midazolam 1mg iv and fentanyl 25mcg was administered before the procedure, three single shot paravertebral blocks by USG guidance was given at the level of T3 T4 T5 using 35ml 0.5% ropivacaine. Dexmedetomidine infusion (0.4mcg/kg/hr) was started. Cold sensation was assessed by swab for dermatome level. During surgical incision the patient experienced mild pain 10ml of 1% lignocaine was given for surgical incision. The entire surgery was completed with paravertebral block under monitored anaesthesia care.

MATERIALS AND METHODS

This study was conducted at Government Stanley Medical College hospital, Chennai on 60 patients who have undergone elective Modified Radical Mastectomy surgeries for CA Breast. This study was conducted after obtaining approval from the institutional ethical committee. Patients were explained about the procedure in detail and informed written consent was obtained for the same.

Study Design:

This study is a randomized prospective interventional clinical Study Randomization was done by allocating the patients to either the Thoracic Paravertebral group (Group P) or Serratus Plane group (Group B) by sealed cover technique. Study was a single blinded study. The patients who met the inclusion and exclusion criteria were only included in the study. Patients were divided into 2 groups of 30 each.

Group P: Patients receiving USG guided paravertebral block

Group S: Patients Receiving USG guided Serratus Plane block

Sample size required for the study t tests - Means: Difference between two independent means (two groups)

Analysis: A priori: Compute required sample size

Input:

Tail(s) = Two

Effect size $d = 0.74$

α err prob = 0.05

Power ($1-\beta$ err prob) = 0.8

Allocation ratio $N2/N1 = 1$

Output:

Noncentrality parameter $\delta = 2.866077$

Critical $t = 2.0017175$

Df = 58

Sample size group 1 = 30

Sample size group 2 = 30

Total sample size = 60

Actual power = 0.8046348

SAMPLE PLOT

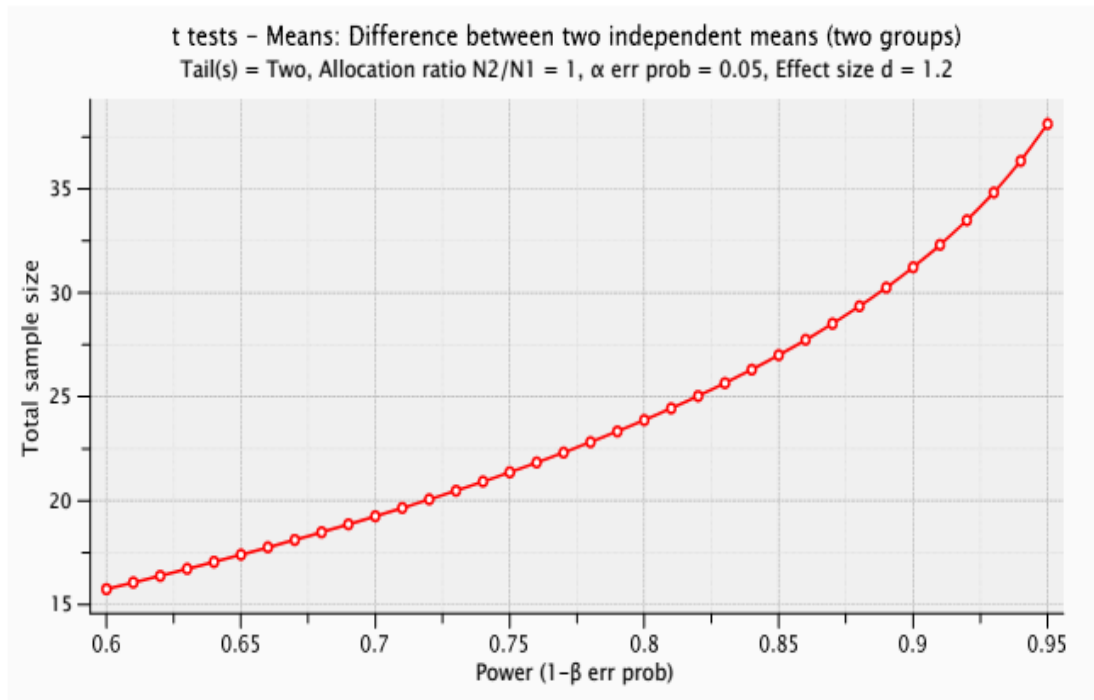


FIGURE 9

METHODOLOGY

INCLUSION CRITERIA

All consented adult patients aged between 20-60 yrs belonging to ASA I, ASA II and ASA III physical status diagnosed cases of breast cancer scheduled for elective modified radical mastectomy.

EXCLUSION CRITERIA

- Patient with known bleeding disorders
- Allergy to local anaesthetic
- Infection at the injection site
- Pregnancy or breast feeding females

EQUIPMENTS

- a) For the procedure
1. 10 cm, 18 G short bevel Tuohy's epidural needle
 2. 10 ml syringes
 3. 5 ml syringe with 1 ½ " 25 gauge needle for skin infiltration
 4. 10 cm extension tube
 5. Sterile towels and gauze packs
 6. Sterile gloves
 7. Antiseptic solution for cleaning and painting of part

8. Sponge holding forceps
9. Ultrasound machine and linear 11 Mhz probe
10. Local anaesthetic used- 20-30 mL bupivacaine 0.25% and 2%
lignocaine 3ml
11. Monitors: NIBP, ECG, PILSE OXIMETER

DRUGS 0.25% bupivacaine

STUDY METHOD

PROCEDURE

Written informed consent

The patients will be randomized and allocated to two groups by sealed envelope technique

Group P will be given Ultrasound guided Paravertebral block

Group S will be given Ultrasound guided Serratus Plane block

Monitors : Non-invasive Blood Pressure (NIBP), ECG, Pulse oximetry, Capnography

Intravenous access - starting of an intravenous line with 18G intravenous cannula on the under aseptic techniques.

Premedication Injection midazolam 0.02 mg/kg, Injection glycopyrolate 4µg/kg, Injection Fentanyl 1µg/mL and Inj. Ondansetron 0.1 mg/kg will be given intravenously before the procedure.

Block given according to the group allocated after randomisation

Ultrasound guided Paravertebral block will performed in patients of Group P

This block will be performed with the patient in sitting position. Under strict aseptic precautions, a high-frequency (11 MHz) transducer is used and the depth of field is set about 3 cm. The scanning process is started 5-10 cm laterally from the midline at the level between the third and fourth thoracic transverse process on the side to be blocked. The rounded ribs and parietal pleura underneath them are identified. The transverse processes and ribs are visualized as hyperechoic structures with acoustic shadowing below them. The transducer is then moved progressively more medially until transverse processes are identified as more squared structured and deeper to the ribs. Once the transverse processes are identified, the skin is infiltrated at puncture site with 3 ml of lignocaine 2%. An 18-gauge Tuohy needle will be inserted out-of-plane to contact the transverse process and then, walked off the transverse process 1-1.5 cm deeper to inject 20 mL of 0.25% bupivacaine in increments. The downward displacement of the pleura indicates the proper spread of the local anesthetic.

Ultrasound guided Serratus Plane block will be in patients of Group S

Serratus Plane block will be performed with the patient in supine position with placing the ipsilateral upper limb in abduction position with a 100 mm needle using a linear US probe of high frequency (11 MHz). Under strict aseptic precautions, the US probe will be first placed at midclavicular region after skin sterilization in a sagittal plane and we counted the ribs inferiorly laterally until we identified the fifth rib in midaxillary line. The Latissimus Dorsi (Superficial And Posterior), teres major (superior) and serratus muscles (deep and inferior) were then easily identifiable by ultrasound overlying the fifth rib . After infiltration of the skin at puncture site with 3 ml of lignocaine 2%, the needle will be inserted in plane with US probe to the fascial plane above Serratus Anterior by using thoracodorsal Artery as reference and 10 ml of bupivacaine 0.25% will be injected. Then, the US probe will be moved downwards till serratus anterior muscle deep plane be will be identified 20 ml of bupivacaine 0.25 % will be injected in increments of 5 ml after aspiration.

The sensory level will be tested with pin prick over the anterior chest wall before induction of general anesthesia.

General anesthesia will be induced thiopentone 5 mg/kg and endotracheal tube intubation will be facilitated with suxamethonium 2 mg/kg. Anesthesia will be maintained with desflurane 3% and O₂/N₂O mixture with a fraction of 40% inspired O₂. Muscle relaxation will be maintained with Injection Atracurium 0.5 mG/kG followed by intermittent doses of 0.1 mG/kG Fentanyl 25 µg in bolus doses will be given intravenously if the mean blood pressure (MBP) or heart rate exceeded 20% of the preoperative value. Hypotension is defined as a decrease of more than 20% of the base line MBP and will be treated with increments of 6 mg bolus doses of ephedrine iv and 250 ml of lactated ringer solution. At the end of surgery patient will be reversed with Neostigmine 0.5 mG/kG and glycopyrrolate 0.08 mG/kG and then extubated . The patients will be then shifted to post-anesthetic care unit (PACU) for the first 2 hours.

At 30 minutes, 60 minutes, 90 minutes, 2nd hour, 6th hour, 12th hour, 18th hour, 24th hour following surgery, level of postoperative pain will be assessed using Visual Analogue Scale (VAS) (starting from 0-no pain to 10-worst pain imaginable). Postoperative analgesia will be provided with tramadol 2mG/kG i.m , when VAS score exceeded 4. The level of postoperative nausea & vomiting will be assessed with Numerical

Rating Scale (NRS) at 30 minutes, 60 minutes, 90 minutes, 2nd hour, 6th hour, 12th hour, 18th hour, 24th hour.

Starting from 0-no nausea, 1-nausea, 2- retching, 3-vomiting and 4-severe vomiting (4-5 episodes). Ondansetron 0.1 mg/kg was given for anti emesis to patients with NRS score of two or more. All data will be recorded with residents of anesthesia not sharing in the study. Complications, if any, will also be recorded. Chest X-ray will be requested for any patient if they have any difficulty of breath, desaturation or had diminished air entry at any time after the block. Primary outcome is post operative pain scores. Secondary outcome measures are post-operative tramadol consumption, intraoperative fentanyl consumption, postoperative nausea and vomiting (PONV), and post-operative ondansetron consumption.

Primary Outcome measures:

Assessment of postoperative pain by visual analogue scale.

Secondary Outcome measures:

- Postoperative Nausea and vomiting
- Rescue Analgesic requirement
- Patient Satisfaction
- Occurrence of side effects

VISUAL ANALOGUE SCALE

Used to assess the severity of pain.

0- No pain

1-

2- Mild pain

3-

4- Moderate pain

5-

6- Severe pain

7-

8- Very severe pain

9-

10- Worst possible pain

VISUAL ANALOGUE SCORE

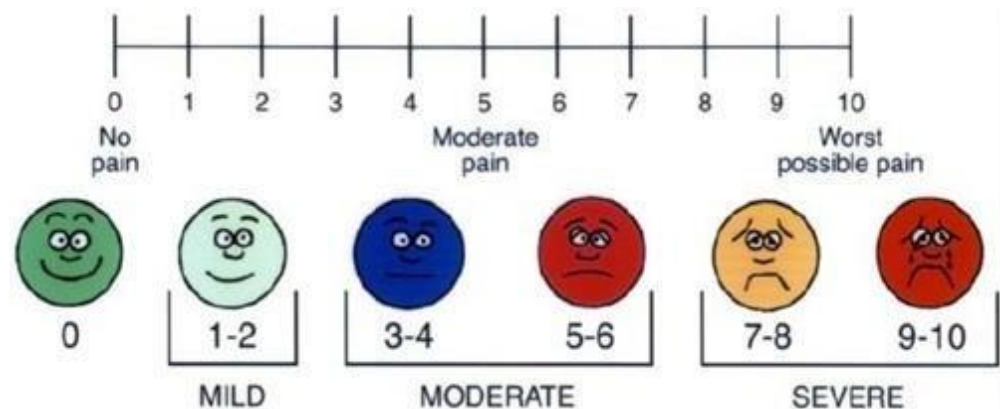


FIGURE 10

SECONDARY OUTCOME MEASURES:

a. Postoperative nausea and vomiting:

Patients were assessed for nausea and vomiting by the following score

None = 0

Mild = 1

Moderate = 2

Vomiting = 3

Rescue antiemetics were given to patients with nausea score greater than or equal to 2 with Injection Ondansetron 4mg.

Patient Satisfaction:

Patient satisfaction was assessed at the end of 48 hours.

Poor = 1

Fair = 2

Good = 3

Excellent = 4

Requirement of rescue analgesia: If the postoperative pain scores as measured by visual analogue scale is greater than or equal to 4, then rescue analgesia was given with intravenous tramadol 100mg.

FLOW CHART OF EVENTS

1. Written informed consent and explanation of procedure to patient
2. Patient shifted to premedication room
3. Monitors connected (NIBP,ECG,SpO2)
4. 18 Gauge Intravenous line secured on the non surgical limb
5. Ringer Lactate infusion 10ml/kg started
6. 0.02mg/kg Midazolam, Glycopyrrolate 4 μ G/mL, Fentanyl 2 μ G/mL, ondansetron 0.1 mG/kG given for premedication
7. Patient positioned- Sitting or supine
8. Area prepared with Betadine and draped
9. A) Under ultrasound guidance, patient is given paravertebral block at the level of T4 with 20 mL of 0.25% bupivacaine
B) Under ultrasound guidance, patient is given fascial block with 30 mL of 0.25% bupivacaine superficial to seratus anterior plane.

10. Sensory blockade is tested with pinprick over anterior chest wall
11. Induction of general anaesthesia with thiopentone 5mG/kG and Suxamethonium 2mG/kG
12. Intubation with appropriate size Cuffed endotracheal tube
13. Maintenance with N₂O and O₂ mixture with an FiO₂ of 0.4, Desflurane 3%,
14. Injection Atracurium 0.5 mG/kG bolus followed by intermittent doses of 0.1 mG/kG
15. Inj.Fentanyl 25µG iv given in Heart rate or mean blood pressure increases 20% of the preoperative value
16. Inj. Ephedrine 6 mG iv bolus and 250 mL of ringer lactate will be given if or mean blood pressure decreases 20% of the preoperative value
17. At the end of the procedure, patient reversed with neostigmine 0.05mG/kG and glycopyrrolate 8µG/kG and extubated

18. Continuous NIBP, ECG, SpO₂ monitoring, Capnography intraoperatively
19. Post operative pain score is recorded with Visual Analogue Scale at 30 minutes, 60 minutes, 90 minutes, 2nd hour, 6th hour, 12th hour, 18th hour, 24th hour following surgery
20. Injection tramadol 2mg/kg i.m given if score > 4.
21. Postoperative nausea & vomiting will be assessed with Numerical Rating Scale (NRS) at 30 minutes, 60 minutes, 90 minutes, 2nd hour, 6th hour, 12th hour, 18th hour, 24th hour. .
22. Ondansetron 0.1 mg/kg was given for anti emesis to patients with NRS score of two or more.
23. Patients will be monitored for complications for 24 hours

OBSERVATION & RESULTS

DEMOGRAPHIC PROFILE:

A randomized controlled study was conducted to compare the postoperative pain relief among USG guided Thoracic paravertebral block group and USG guided serratus plane block group in patients undergoing MRM surgery. The sample size were 60 patients and were randomly allocated into Group P Thoracic Paravertebral block and Group s Serratus plane block. The observation and results are as follows

AGE DISTRIBUTION:

Table 2. Age Distribution

Age in years	GroupS (yrs)	Group P (yrs)	p-value
Mean \pm SD	48.07 \pm 9.48	47 \pm 11.994	0.437

Mean age in group S was 48 years and the standard deviation was 9.48 years. In Group P, Mean age was 47 years and the standard deviation being 9.34 years. These data were computed using students t-test and the P value was found to be 0.437. This difference is considered to be not statistically significant.

AGE DISTRIBUTION

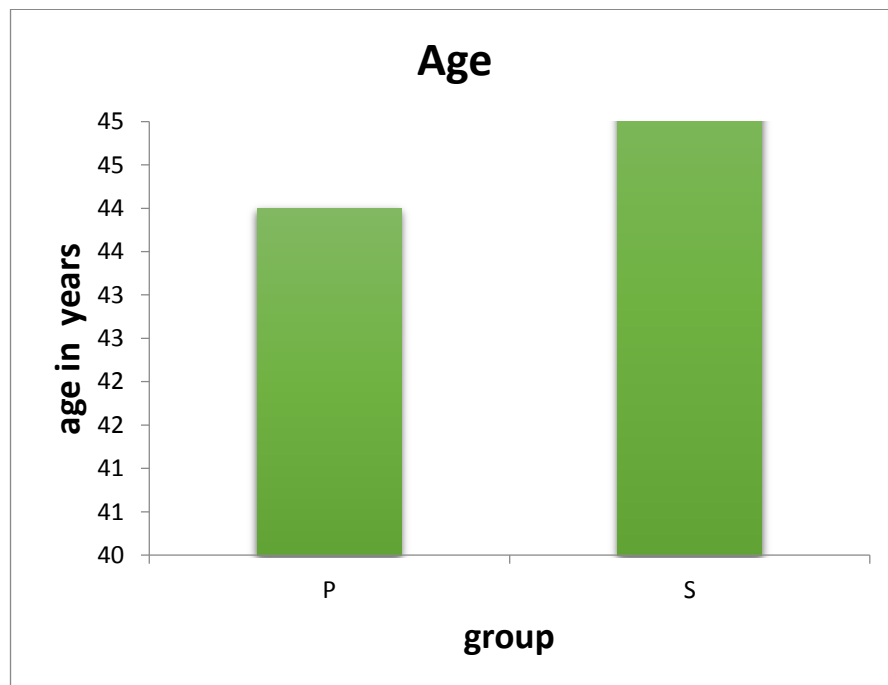


FIGURE 11

WEIGHT DISTRIBUTION

Maximum weight of the patient in Group P was 56.4 kg, with a minimum weight of 55 kg. Mean weight in Group P was 56.37 kg with a standard deviation of 5.41kg, maximum weight of group S patients was 59kg and the minimum weight was 52kg. Mean weight in Group S was 57.8kg with a standard deviation of 6.37 kg. Data was computed using students t-test. The two failed P-value equals 0.351, which is not statistically significant.

Table 3. WEIGHT DISTRIBUTION

Weight	Group P (kg)	Group S (kg)	Pvalue
mean±SD	56.37±5.41	57.8±6.37	0.351

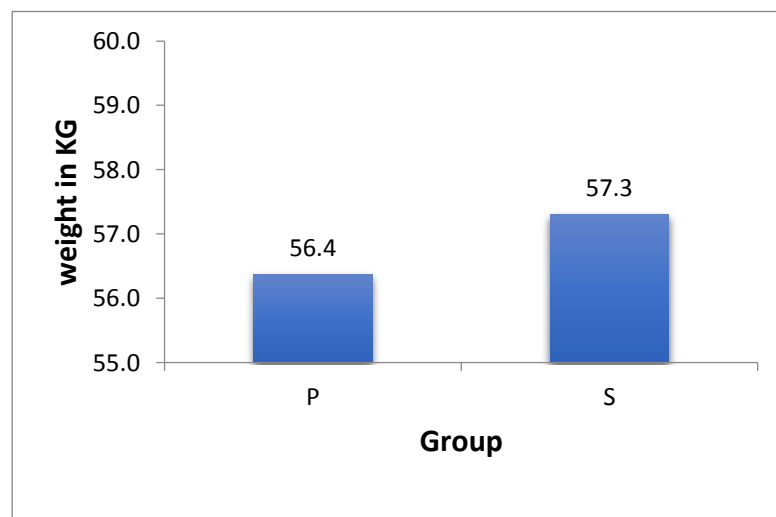


FIGURE 12.

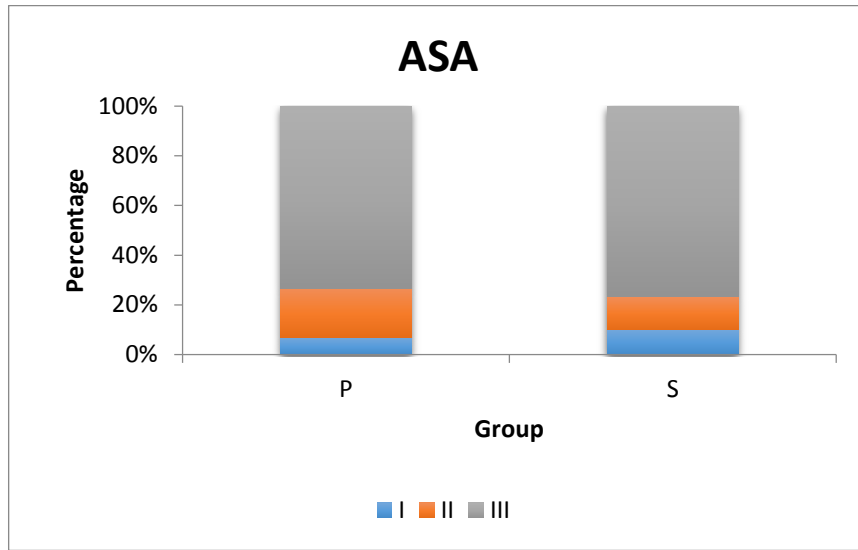
ASA PHYSICAL STATUS DISTRIBUTION

Table 4. ASA Physical Status Distribution

	ASA PS 1	% within group	ASA PS II	% within group	ASA PS III	% within group
Group P	2	6.7	6	20	22	73.3
Group S	3	10	4	13.3	23	76.7

In Group P, the number of patients assessed under ASA-PS I were 2 with ASA-PS II 6 in number, with ASA – PS III were 22 in number. In Group B, the number of patients assessed under ASA-PS I were 3, with ASA – PS II were 4, with ASA – PS III were 23 in number. The p value was computed as 0.733, which is not statistically significant. Figure 13. ASA Physical Status Distribution

FIGURE 13



DURATION OF SURGERY

TABLE 5.

Duration	Group P (min)	Group S (min)	Pvalue
mean±SD	152.27±16.70	152.17±15.24	0.981

The average duration of surgery in Group P was 152.27minutes with a standard deviation of 16.7.

The mean duration of surgery in Group B was 152.17 minutes with a standard deviation of 15.24. The data was computed using students t-test. The p value was 0.981 which was not statistically significant.

DURATION OF SURGERY

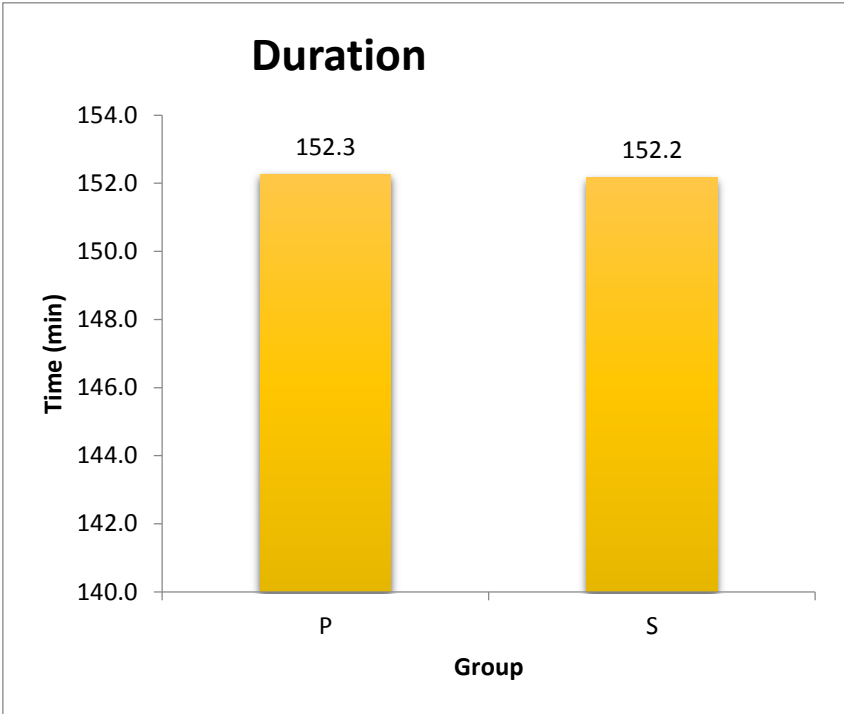


FIGURE 14

VAS SCORING:

TABLE 6

Group		N	Mean	Std. Deviation	Std. Error Mean	P value	
VASIpostop	P	30	3.03	.320	.058	Significant	
	S	30	2.13	.434	.079		
VAS 30 mins	P	30	3.23	.479	.088		
	S	30	2.56	.621	.113		
VAS 60 mis	P	30	3.35	.481	.088		
	S	30	2.85	.643	.117		
VAS 2 hrs	P	30	3.63	.711	.130		
	S	30	3.06	.664	.121		
VAS 6 hrs	P	30	4.13	.765	.140		
	S	30	3.47	.997	.182		
VAS 12 hrs	P	30	4.45	1.215	.222		0.167
	S	30	3.65	1.015	.185		
VAS 18 hrs	P	30	4.58	1.351	.247		0.176
	S	30	4.15	1.137	.208		
VAS24 hrs	P	30	4.76	1.418	.259	0.189	
	S	30	4.53	1.351	.247		

Postoperative pain scores were measured using visual analogue scores in a 0-10cm scale. The visual analogue scores were compared between the two groups, Group P and Group S VAS scores were measured at Immediate, 30 minutes, 1hour, 2 hours, 6 hours, 12 hours, 18hours, 24hours.

VAS SCORE

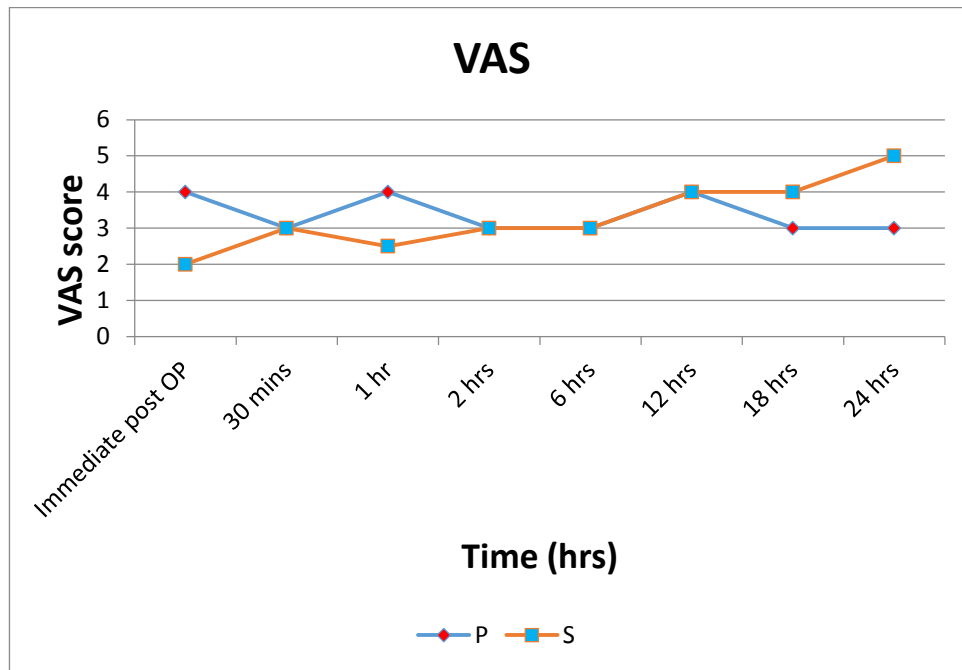


FIGURE 15

The average VAS scores at Immediate, 30 minutes, 1 hour, 2 hours, 6 hours, 12 hours, 18 hours, 24 hours, for both Group P and Group S are enumerated in table 6 and figure 6. The p-value between the two groups for first 12h was low for Serratus plane group, indicating that the analgesia in Group S was more effective than Paravertebral group. After 12 hr p value was comparable between two groups.

PULSE RATE

TABLE 7

TIME(min)	Group P mean±SD (mm)	Group S mean±SD (mm)	P value
Immediate postop	75.13±4.82	72.21±2.34	0.001
30 mins	76.23±5.12	73.33±3.51	0.001
60 mins	77.34±5.49	74.27±4.34	0.002
2 hrs	77.8±5.97	75.10±5.16	0.001
6 hrs	78.93±6.35	76.21±5.78	0.003
12 hrs	82.37±8.30	81.24±6.87	0.002
18 hrs	84.67±9.51	83.71±8.05	0.070
24 hrs	86.37±10.47	85.34±9.70	0.189

Pulse rate was monitored over a period of 24 hours, in the postoperative period in both Group P and Group S, at intervals of Immediate, 30 minutes, 1hour, 2 hours, 6 hours, 12 hours, 18hours, 24 hours, . The pulse rate was comparable in both the groups at all time intervals. The p-value was significant up to 12hrs after that p-value is comparable between two, indicating better postoperative analgesia in serratus plane group.

PULSE RATE

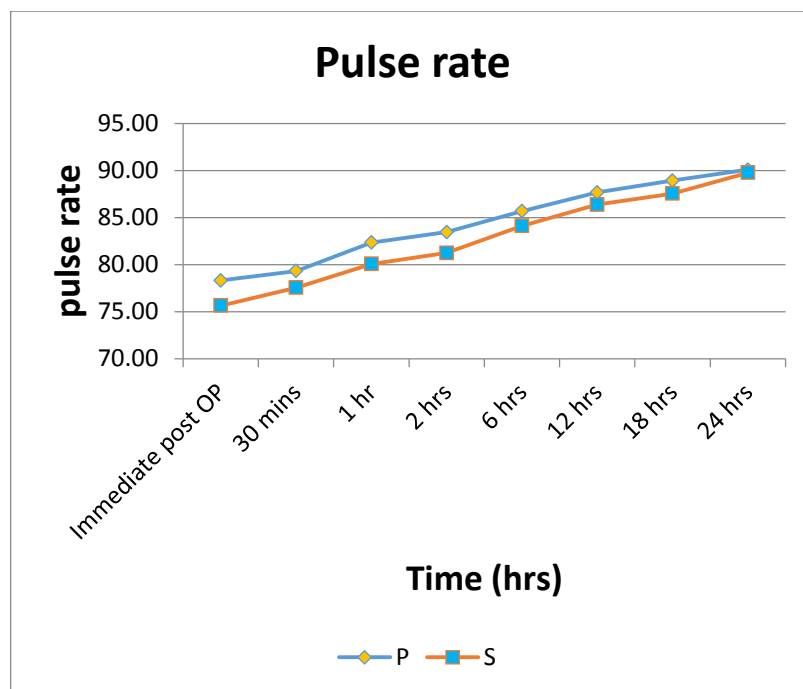


FIGURE 16

SYSTOLIC BLOOD PRESURE

TABLE 8

TIME (min)	Group P mean±SD (mm)	Group S mean±SD(mm)	P value
Immediate postop	118.97±7.28	110.33±5.76	0.755
30 mins	120.03±6.96	114±6.60	0.557
60 mins	122.27±7.17	117.67±6.98	0.160
2 hrs	125.77±8.01	119.27±6.90	0.023
6 hrs	129.37±6.45	122.83±7.98	0.001
12 hrs	132.10±6.21	129.67±7.41	0.001
18 hrs	135±7.75	134.13±8.85	0.157
24 hrs	138.5±6.63	137.97±9.73	0.175

Systolic blood pressure was monitored over a period of 24 hours, in the postoperative period in both Group P and Group S, at intervals of Immediate, 30 minutes, 1 hour, 2 hours, 6 hours, 12 hours, 18 and 24hrs. It was found that the systolic blood pressure was low for first 12hrs in serratus plane block which indicates the analgesic efficiency superior to paravertebral block ($P < 0.001$) thereafter the mean pvalue is comparable in both the groups after 12hrs.

SYSTOLIC BLOOD PRESSURE

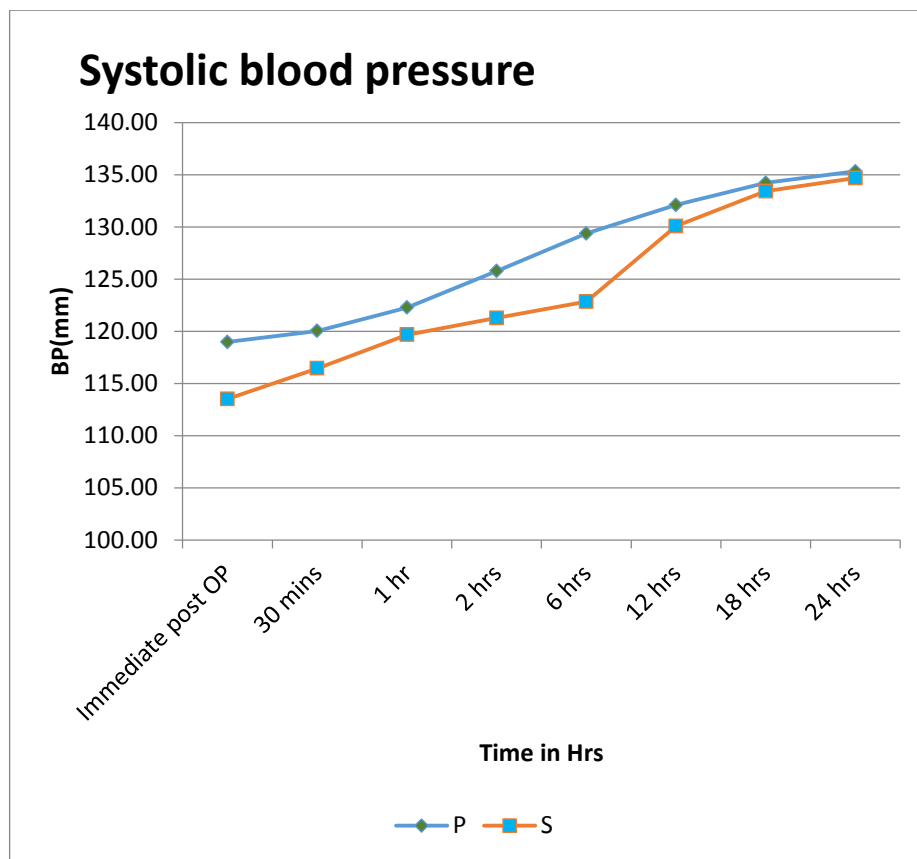


FIGURE 17

DIASTOLIC BLOOD PRESSURE

TABLE 9

TIME (min)	Group P mean±SD (mm)	Group S mean±SD (mm)	P value
Immediate postop	74.03±3.71	72.17±5.66	0.000
30 mins	74.37±6.00	72.45±5.33	0.001
60 mins	76.70±6.03	73.97±5.62	0.000
2 hrs	79.8±6.09	76.07±5.97	0.001
6 hrs	82.87±6.69	79.07±6.09	0.001
12 hrs	83.57±7.11	82.80±6.45	0.165
18 hrs	86.83±7.75	86.67±7.56	0.187
24 hrs	91.90±8.54	89.53±8.38	0.185

Diastolic BP was measured over the 24 hours post operative period, at specified time intervals. The P value was found to be statistically significant upto 6hrs after which p value was comparable between two groups.

DIASTOLIC BLOOD PRESSURE

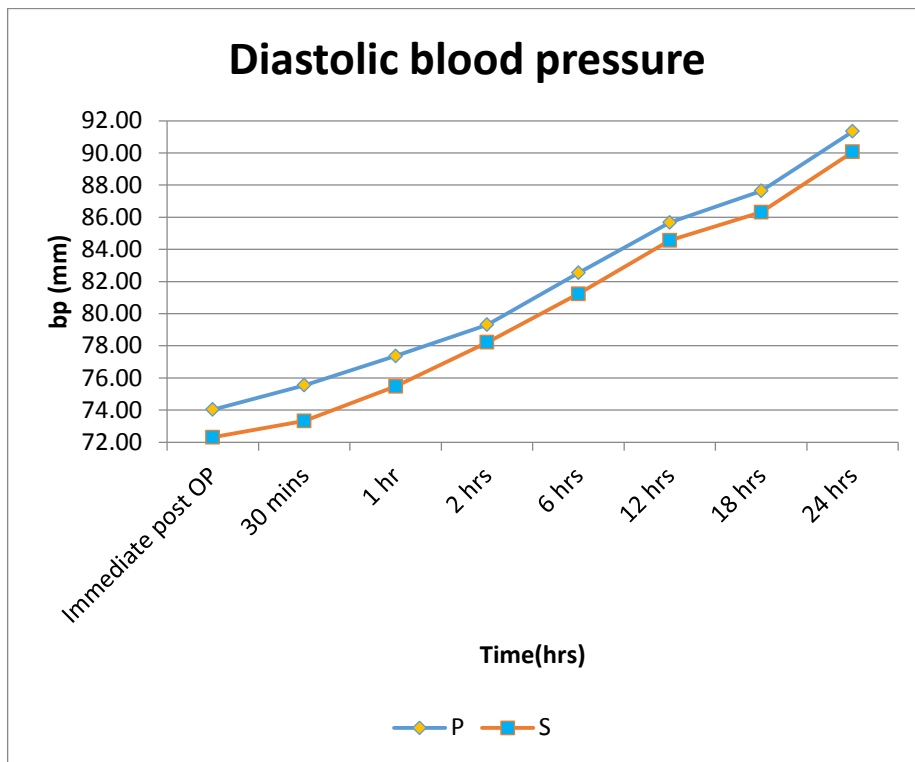


FIGURE 18

MEAN ARTERIAL PRESURE

TABLE 10

TIME (min)	GROUP P mean±SD (mm)	GROUP S mean±SD (mm)	P value
Immediate postop	74.23±5.98	73.19±6.97	0.011
-30 mins	77.60±4.64	76.20±5.78	0.008
60 mins	79.61±4.25	78.1290±5.49	0.006
2 hrs	81.31±4.70	79.23±6.42	0.011
6 hrs	84.37±5.34	82.31.99±7.30	0.002
12 hrs	86.8±5.74	85.09±7.47	0.198
18 hrs	87.56±6.58	86.63±7.42	0.179
24 hrs	89.43±6.25	88.68±7.33	0.198

MAP was measured over the entire 24 hours postoperative period, at specified time intervals. The mean arterial pressure was found to be comparable in both the groups at all time intervals as depicted in Table 11 figure 11. The P – value was found to be statistically significant upto 12hrs.

MEAN BLOOD PRESSURE

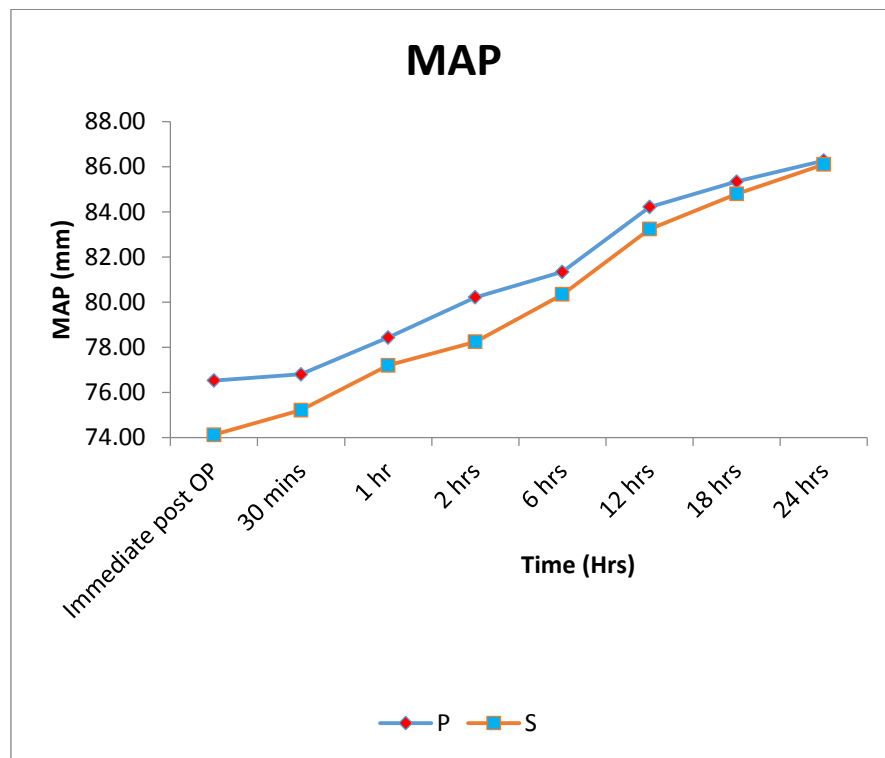


FIGURE 19

POST OPERATIVE NAUSEA AND VOMITING

TABLE 11

	Group P	Group S	Pvalue
0	5	6	0.687
1	11	13	
2	12	10	
3	2	1	

Postoperative nausea and vomiting scores were measured over the 24hours. The scores were : No nausea = 0, moderate nausea = 2, vomiting = 3. Rescue antiemetic's were given if nausea score \geq 2. Nausea score was 2 in 16patients in group P. Vomiting was present in 9 patients in Group P. Nausea score was 2 in 1 patient in Group S. 2 patients had vomiting in Group S The p value was found to be comparable between two groups.

POSTOPERATIVE NAUSEA AND VOMITING

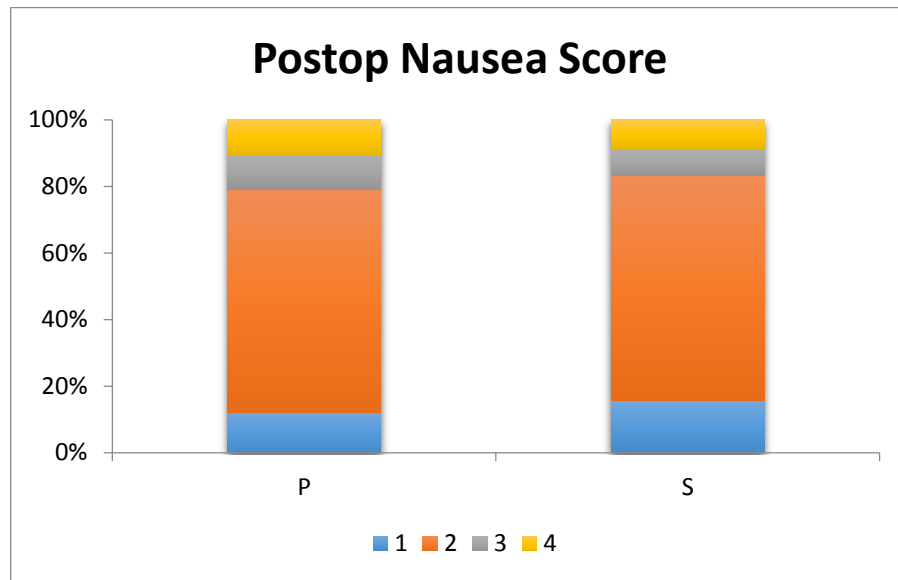


FIGURE 20

POST OPERATIVE SATISFACTION

Table 12. Postoperative Satisfaction

Score	Group P	Group S	Pvalue
1	4	2	0.001
2	22	0	
3	3	23	
4	1	5	

Postoperative satisfaction scores were poor = 1, fair = 2, Good = 3 and excellent = 4. In group P, 4 patients recorded 1 score and 22 patients scored 2.

In Group S, 2 patients recorded score 1 and 23 patients recorded score of 3.

POSTOPERATIVE SATISFACTION

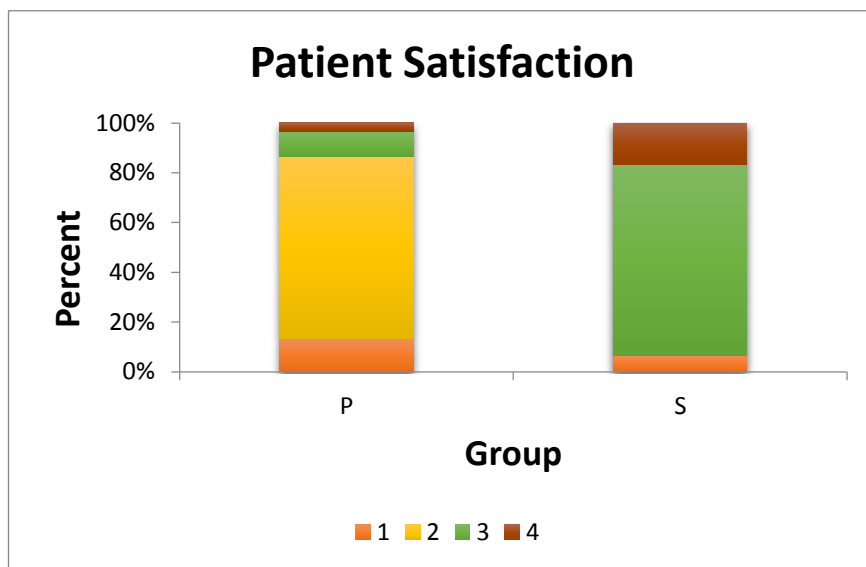


FIGURE 21

FAILURE

TABLE 13

	GROUP P	GROUP S	P value
YES	2	1	0.646
NO	28	28	

In group P patients, therapeutic failure rate was found in 2 out of 30 patients. In Group S therapeutic failure rate was found in 1 out of 30 patients.

FAILURE

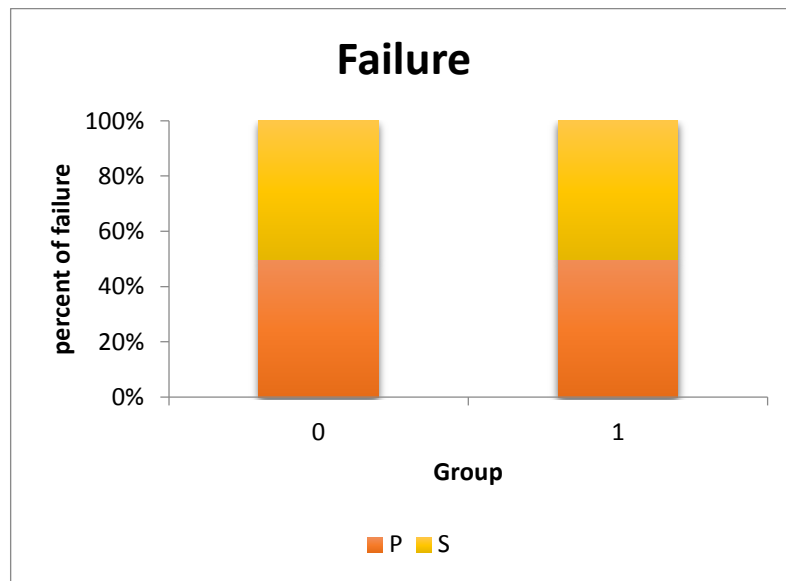


FIGURE 22

RESCUE ANALGESIC REQUIREMENT

TABLE 14

	GROUP P	GROUP S	Pvalue
NO	14	26	0.001
YES	16	4	

Rescue analgesics were provided when Visual Analogue Score (VAS) scores ≥ 4 , or on patient demand. Out of 30 patients in Group P, 16 of them required rescue analgesics, and in Group S also 4 patients required rescue analgesics.

RESCUE ANALGESIA

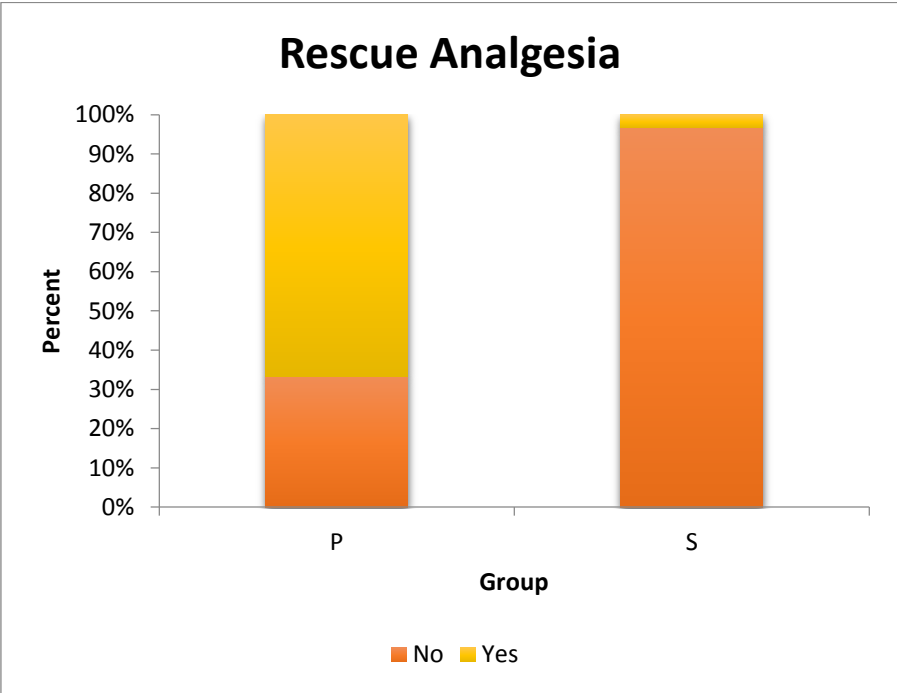


FIGURE 23

HYPOTENSION

TABLE 15

	Group P	Group S	Pvalue
NO	29	30	0.000
YES	1	0	

In Group P, 1 Patient developed hypotension out of 30 patients. Similarly in Group S, no patient developed hypotension. The P value was 0.000, which was statistically significant. The hypotension was treated with bolus of intravenous fluids after which Blood pressure returned to normal.

HYPOTENSION

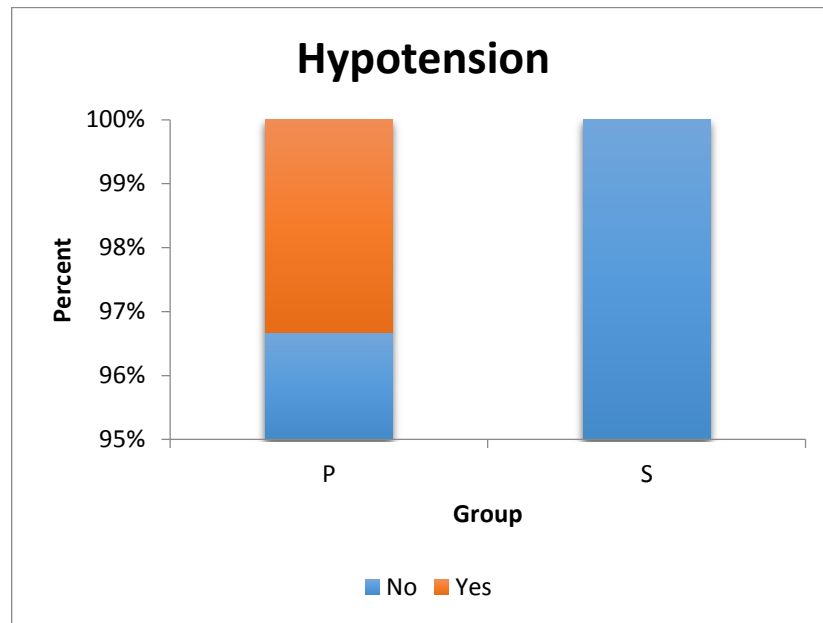


FIGURE 24

BRADYCARDIA&RESPIRATORY DEPRESSION:

There were no incidence of respiratory depression and bradycardia reported in both the groups S and P

DISCUSSION

Breast cancer surgeries are associated with severe pain in postoperative period and is associated frequently with nausea and vomiting. Postoperative Analgesia for breast surgery is a challenging task for an Anaesthetist. Nowadays Breast surgeries are done as a Day care Procedure, So Adequate control of Postop Pain remains crucial. A Lot of Regional Anaesthesia Techniques are used for both Intraoperative and Postoperative Pain Management. The Regional Anaesthesia techniques for breast surgery that were introduced earlier were Thoracic Epidural and Thoracic Paravertebral Block. Thoracic Epidural remains Gold Standard technique for Postoperative Analgesia in breast surgery patients. Because Thoracic Epidural anaesthesia provides better perioperative analgesia along with reduction in cardiac and sympathetic activity. It also helps in sooner recovery of patients at the end of surgery. Although adequate Relaxation is not necessary for breast surgery, Thoracic Epidural analgesia is used in conjunction with General Anaesthesia. But there are case reports of breast surgeries done under sole Thoracic Epidural analgesia Under Monitored Anaesthesia care. Several such studies are done the intraop and postop analgesia requirement were studied. Even though Thoracic Epidural infusion for breast surgery has its

own advantages, this technique has some adverse effects. The decision of using epidural Analgesia for breast surgery the advantages and its adverse complications should be weighed. While using Thoracic Epidural Anaesthesia there may be wide alteration in hemodynamic parameters, because of epidural local anaesthetic injection at the level of mid-thoracic level which may lead to hypotension. Strict monitoring of vital parameters is an important part in Thoracic epidural Analgesia. This technique cannot be used in patients with ischemic heart disease, also alteration in coagulation profile which is a contraindication for this technique. Also for patients with spine abnormalities and musculoskeletal disorders, thoracic epidural technique is difficult to administer.

Now Thoracic Paravertebral block has been used widely for this purpose. It has been found to decrease the response to surgical stress greater than thoracic epidural Analgesia. The Thoracic Paravertebral space is wedge shaped bounded by parietal pleura anteriorly and transverse process of thoracic vertebra posteriorly. The paravertebral space contains spinal nerves white and grey communicantes, vessels and sympathetic chain. So by blocking spinal nerves in the thoracic paravertebral space analgesia is achieved. The Paravertebral space at the thoracic level extends from the T1 level and extends to terminate at the

level of T12 vertebra. The desired thoracic level is chosen for block after placing the patient in lateral position. The spinous process is identified and the skin is punctured 3cm lateral from the midline after anaesthetic infiltration by using 22G needle the transverse process of the thoracic spine is struck at the depth of 3 to 3.5cm by using walk-off technique the needle is further withdrawn and redirected while a loss of resistance to costotransverse ligament indicates the entry of needle in the paravertebral space. Direct injection of local anaesthetic by using 18G needle leads to analgesia at the thoracic level. Also by using epidural catheter can also be introduced at the paravertebral space by keeping the catheter at the desired level ideally at T3 level, analgesia is achieved. Several advantages over Thoracic epidural technique are analgesia by this technique is comparable with that of thoracic epidural, less risk of neurological complication in paravertebral block, incidence of hypotension is less when compared to that of epidural, intense blockade of sympathetic discharge, tumour recurrence after surgery is inhibited, less perioperative morbidity. But this technique is associated with complications like Pneumothorax, Epidural spread of local anaesthetic is possible may lead to hypotension. total spinal anaesthesia is a rare but dreadful complication, also vascular injection of local anaesthetic, ipsilateral horner's syndrome may be seen in thoracic nerve blocks.

¹⁵Also certain contraindications to this technique like patient refusal, coagulopathy, tumours in the paravertebral space, severe respiratory disease, severe spinal deformity like scoliosis, kyphosis limits the use of this technique.

The use of Ultrasonogram in nerve blocks has revolutionised the success rate of Blocks and ¹⁶helps in reducing the incidence of complications. By using ultrasonogram the time for administering the block is minimised .

By using ultrasonogram the nerves and close proximity of other structures are also visualised. The nerves appears as characteristic honey comb appearance.

The echogenicity of the nerve is better visualised if the sound beam is perpendicular to the axis of the nerve.

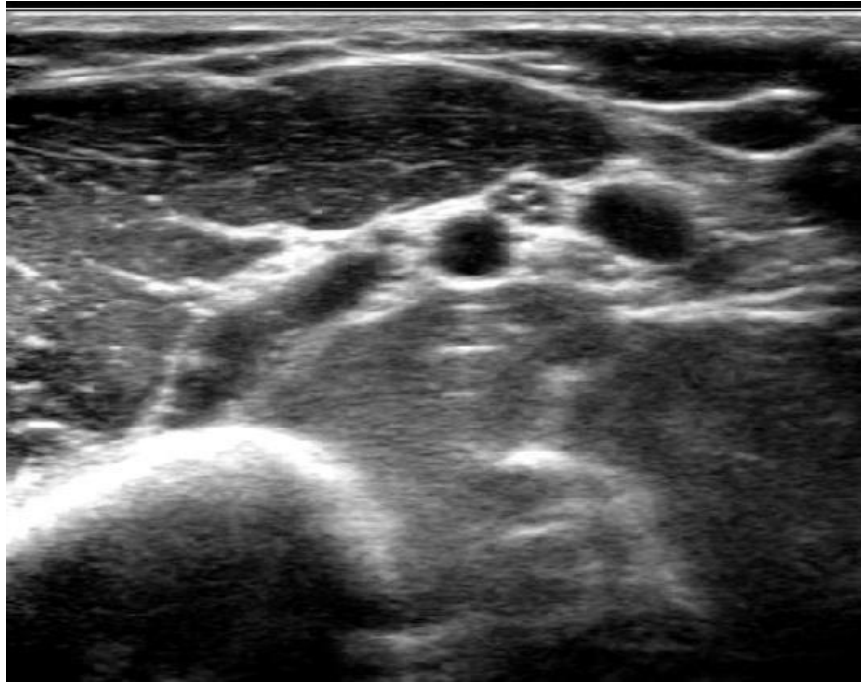


FIGURE 25

The characteristic structure of the nerves are seen, appearing like bunch of grapes. The pleura can be identified as a hyperechoic structure also vascular structures can be easily identified by its pulsatility, also by Doppler flow the vascular imaging is confirmed.

Ultrasonogram has the following advantages in peripheral nerve blocks

- Visualisation of neural structure & blood vessels
- Guidance of the needle under real time visualisation
- Avoid complications like pneumothorax and intravascular injection.
- Monitor the spread of local Anaesthetic

The technique of in-plane needle has advantages because the entire needle is visualised. So accidental vascular injection or pleural puncture may be prevented by using this technique.

The advantages of using ultrasonogram in nerve blocks are lower incidence of accidental puncture of vital structures like pleura, vascular structures, it minimises the number of needle passages, paresthesia occurring during block is reduced, volume of local anaesthetic used for nerve block is reduced using ultrasound because the spread of local anaesthetic is visualised while administering block, also provides long lasting analgesia.

So under the guidance of ultrasound the use of 18G thoracic paravertebral block to provide analgesia for breast surgery has increased recently.

The technique of ultrasound guided thoracic paravertebral block is by using a high frequency transducer the desired thoracic spine level is identified the transducer is positioned in such a way that it is lateral to the spinous process of the thoracic vertebra, then the ribs and the transverse process are visualised as hyperechoic structures after identification of these structures the thoracic paravertebral space²⁰ is identified as a wedge shaped which appears as a hyperechoic structure that is demarcated by the pleura below and the inner intercostal membrane above.

The ultimate goal of using ultrasound in thoracic paravertebral block is while injecting local anaesthetic in the thoracic paravertebral space there is a downward spread of the pleura²³ which indicates correct administration of the drug. The USG guided thoracic paravertebral technique is a simple and superficial technique but it is essential to visualise the entire needle path during administering the block because this space is bounded by pleura so accidental pleural puncture is possible so ideally in-plane needle technique is used frequently. So the idea is by using 18G needle in in-plane technique introducing the needle slowly

after identifying the pleura after the feeling of pop-off of piercing the costotransverse ligament aspiration²² should be done to avoid vascular puncture ideally 15-20ml of local anaesthetic is used.

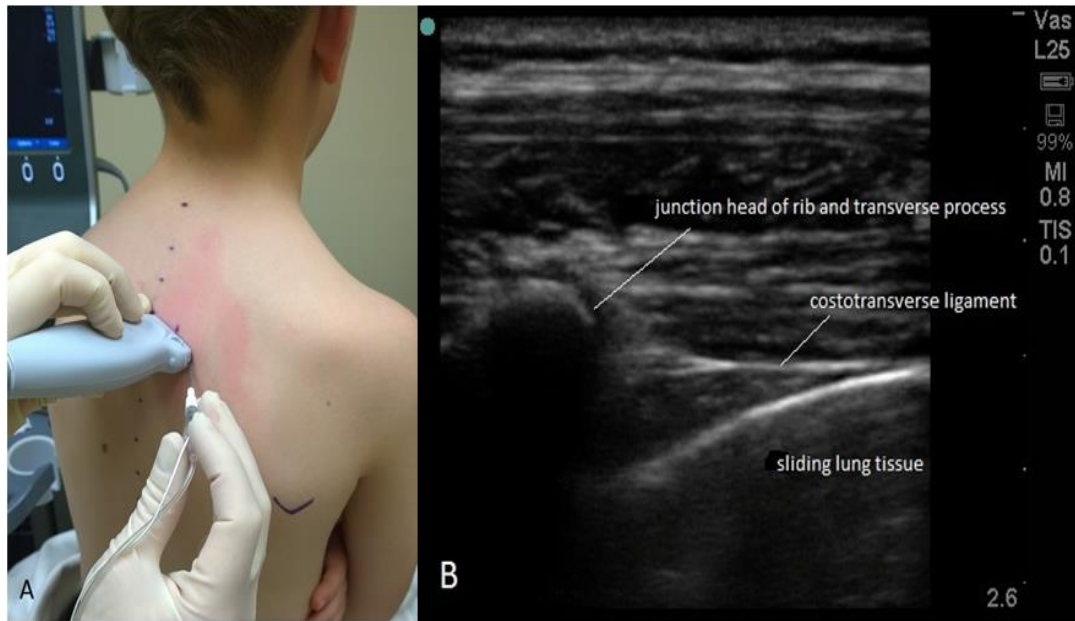


FIGURE 26

The use of USG guided Thoracic Paravertebral block has minimised the incidence of complications like Pneumothorax and vascular injections although these are not completely prevented, also hemodynamic instability is a fact to be considered in Paravertebral blocks and thoracic epidural techniques.

Even though use of ultrasonogram has reduced such complications there is no studies that this complications can be prevented completely.

Also technical difficulty in paravertebral block has lead to the use of newer regional anesthesia techniques to provide analgesia for breast surgery.

Considering this an, improvement in regional anaesthesia technique was introduced by Blanco, Pectoral Nerve Blocks by USG guidance.²⁵ Pectoral Nerve blocks has gained Popularity among Anaesthetists because of its easier technique , Avoiding complications of Paravertebral block and without Hemodynamic instability.

Pecs 1 block involves the Injection of local Anaesthetic between Pectoralis major and minor muscle.²⁷The main nerve supply of the breast is by medial and lateral pectoral nerve so pectoral nerve 1 blocks anaesthetise these two nerves, but in this block the analgesia does not extends into axillary region so there may be pain during axillary clearance.

For Pecs 1 block initially blanco used coracoid approach, the patient is placed in supine position, with ipsilateral arm placed by the side of the patient after getting informed consent from the patient the procedure is done. ²⁸With the help of ultrasonogram, block is performed a high frequency transducer probe is used. the transducer transverse to the sternum at the level of lateral 1/3 of the clavicle, similar to that of infraclavicular block.

Many other modifications of blanco's technique has been introduced. Then the anatomy of the chest wall from superficial to deep are identified like pectoralis major and minor muscle, axillary artery and axillary vein considering patient's body weight long acting local anaesthetic like ropivacaine or bupivacaine (0.125– 0.25%) is injected by using 18G needle between Pectoralis major and Pectoralis Minor muscle.

PECS 1 BLOCK

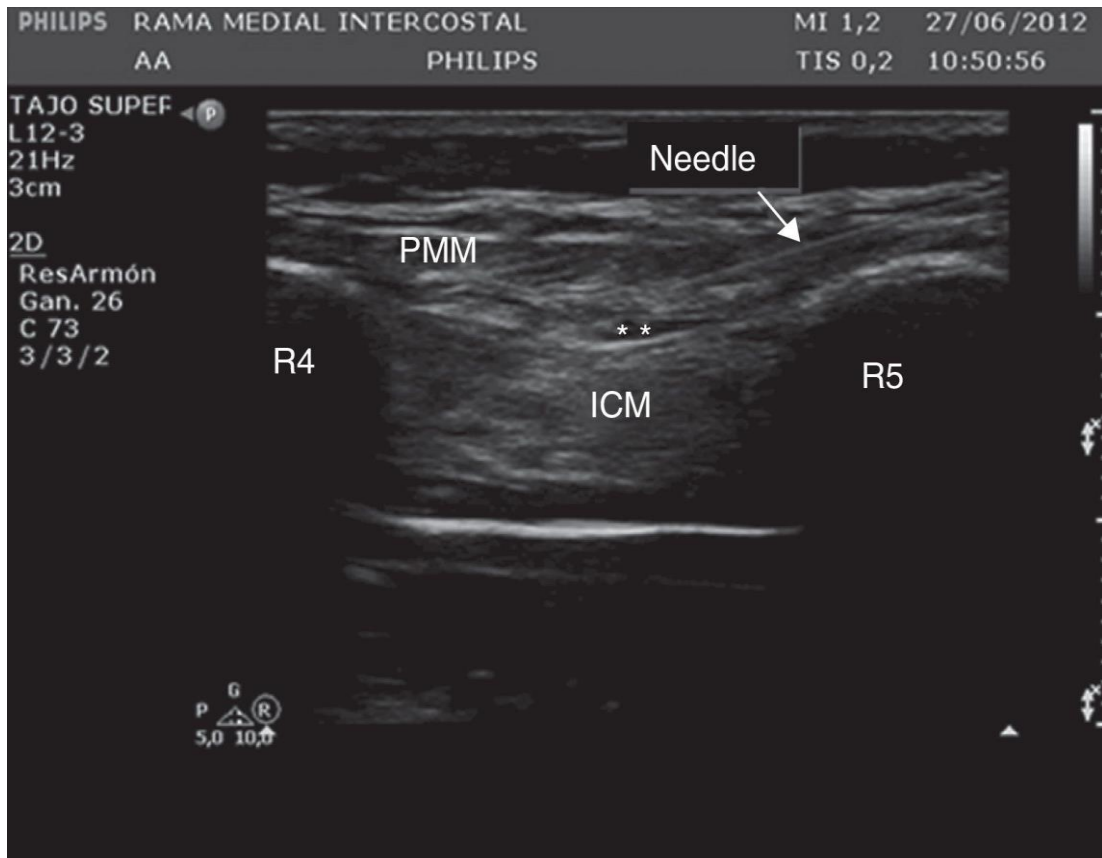


FIGURE 27

Actually Pecs 2 block is ideally combined with pecs1 block to improve analgesia for breast surgery with axillary dissection.³² The pecs 2 block involves injection of Local Anaesthetic additionally between pectoralis minor and serratus anterior muscle.

This block anaesthetises the intercostal nerves especially the lateral branches (T2-T6), other nerves like thoracodorsal nerve, intercostobrachial nerve, and Long thoracic Nerve of bell also blocked in this technique.

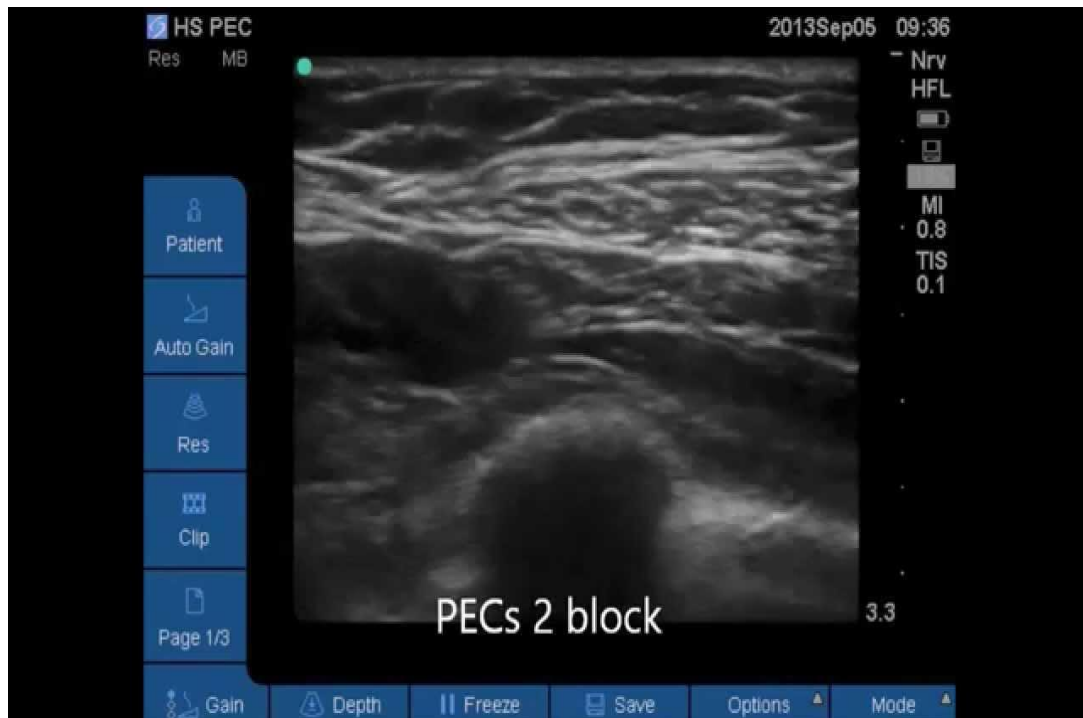


FIGURE 28

Recently Blanco modified the Pecs block by Serratus plane block which involves identifying the serratus anterior muscle by USG guidance injecting Local Anaesthetic either superficial or deep to the muscle plane.

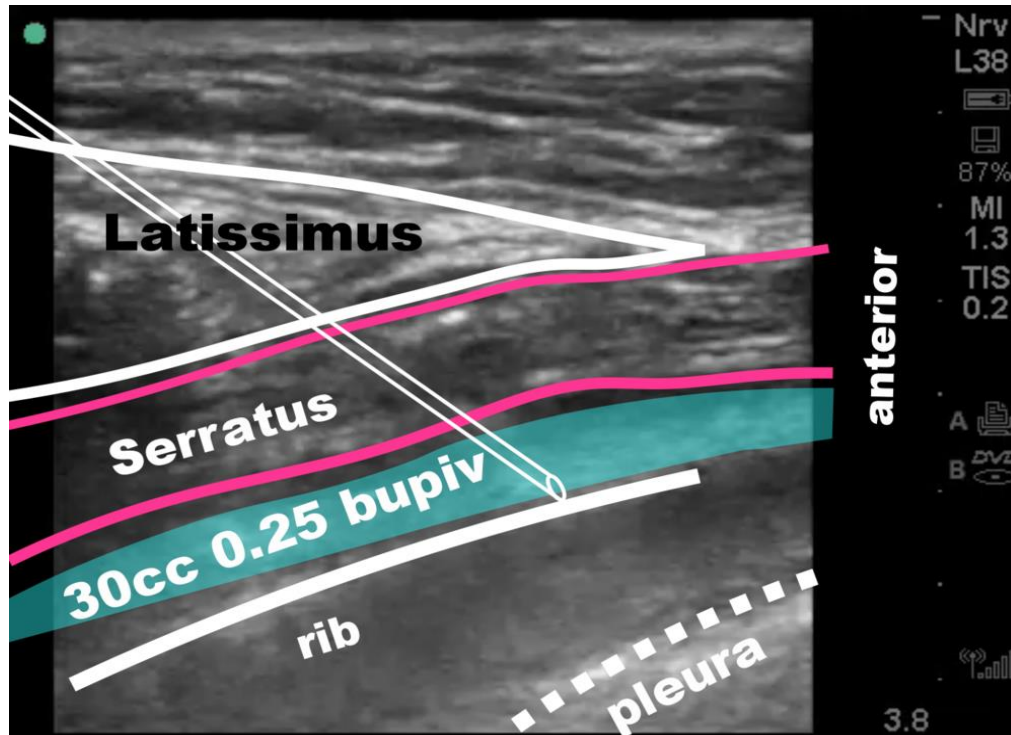


FIGURE 29

There is considerable Improvement in Postop Analgesia for breast surgery Patients who were given pecs block. ³⁴Serratus Plane block is technically easier than Pecs 2 block and provides entire anaesthesia of hemithorax. Ideally serratus plane block anaesthetises Long thoracic nerve of bell and Thoracodorsal nerve.

The technique of serratus plane block is similar to that of pecs block, after getting consent from the patient, patient is placed in supine position arm is placed by the side, by USG guidance transducer is placed in the midaxillary line at the level of 5th rib, similar anatomical structures identified the serratus anterior muscle and lattisimus dorsi muscle are

identified, based on patient's weight long acting local anaesthetic ropivacaine or bupivacaine (0.125-0.25%) is injected superficial to serratus anterior muscle. The technique of serratus plane block is technically easier when compared to pecs block 1 &2. Also serratus plane block provides anesthesia of entire hemithorax.

A study was done by Shamir and his colleagues in Ains sham university, cairo comparing ³⁷Thoracic paravertebral block and serratus plane block in patients undergoing Breast surgery patients. ³⁹They found that pectoral nerve block patients had minimal complications and better Postop Analgesia than Paravertebral group.

Based on these views we conducted a Randomised observer blinded study comparing the Analgesic Efficacy of USG guided Thoracic Paravertebral Block vs USG guided Serratus Plane Block in CA Breast patients undergoing MRM surgery.

The study was a randomized observer blinded study. Sample size selected was 60, based on previously published articles. As far as the inclusion criteria was concerned, all consented patients more than 18 years of age and less than 65 years, weighting more than 45 kg under ASA PS I/II/III diagnosed of breast cancer were only included in the study.

Patients who were excluded from the study were those allergic to local anaesthetics, on anti-coagulation therapy, with infections at the site of Injections, Severe obesity, psychiatric disorders, Pregnancy and breast feeding females, Musculoskeletal Disorders .

Patients from groups 'P' & 'S' were analyzed for the demographic profile. Patients' mean age and standard deviation were comparable between the two groups. Sex distribution was also comparable. The mean weights between the two groups were also similar and P value computed using Student's *t* test was insignificant.

USG guided Thoracic Paravertebral Block and serratus plane block were given before induction of anaesthesia in both the groups. After Extubation Patients were shifted to PACU for observation.

The primary outcome measures that were compared between both the groups were VAS scores. The VAS score was graded on a 0 to 10 cm scale. VAS scores were observed over a period of 24 hrs at the following intervals: immediate, 30 mins, 60 mins, 2 hrs, 6 hrs, 12 hrs, 18 hrs, 24 hrs. While the serratus plane block has a good Vas score till first 12hrs. This explains that Plane blocks always have good analgesic action when compared to paravertebral block.

The mean VAS scores at all the time intervals measured and was found that the P value was statistically significant and the VAS scores were lower in serratus plane group at 1h, 6h and 12h ($p = 0.008$ and <0.001 respectively). Also it has been observed that plane blocks have shorter duration of action when compared to paravertebral block.

The time for first request of analgesia was monitored it was found that it was more in serratus plane group when compared to thoracic paravertebral group.

One of the secondary outcome measures that was analyzed was the postoperative nausea and vomiting. Rescue antiemetics were given with injection Ondansetron, 4 mg intravenously, when PONV scores were ≥ 2 . It was found that PONV scores were comparable between two groups.

The next outcome measure was Postop patient satisfaction it was found that Patient satisfaction was better for Serratus plane Group than Paravertebral Group.

The therapeutic failure rates were comparable between both the groups, with the p value being 0.646. Out of the two patients who underwent failure, 1 patient in each group the patient was obese so the

anatomy could not be well established. For the patients who had failure, rescue analgesia was given.

Rescue analgesia was given as per the patient requirement and on patients demand. Rescue analgesia was given if VAS scores were greater than or equal to 4. Injection Ondansetron 4 mg intravenously was given before administering tramadol. Rescue analgesia was required in 19 of the 30 patients in the Paravertebral and 4 of the 30 patients in the serratus plane group. So requirement of rescue analgesia was more in paravertebral block.

There was no incidence of bradycardia, respiratory depression, urinary retention in both the groups. But there was recorded hypotension in 1 patient in paravertebral group. 1 of the 30 patients from Group P had hypotension that is defined as mean arterial pressure $< 20\%$ from baseline parameters. Episodes of hypotension were treated with fluid boluses of normal saline or ringer lactate. Patient responded to crystalloids.

³⁷The diffusion of local Anaesthetic into epidural space from paravertebral space is responsible for hypotension in paravertebral group.

As far as the hemodynamic parameters are concerned the systolic blood pressure, as well as mean arterial pressure and pulse rate were

recorded more inn PVB group was found to be better for serratus plane group when compared to thoracic paravertebral block first 12 hrs , indicating that plane blocks have good analgesic action when compared to thoracic paravertebral block .

Because of the proximity to the operating site and the nerves that are responsible for the pain sensation are blocked it has been found that serratus plane block has good patient acceptance and postoperative pain relief. ³⁸After 12 hrs the hemodynamic parameters were found to be similar between two groups after which parameters were comparable between two groups.

The hemodynamic parameters are assessed based on the intensity of pain and hypotension that may occur as a complication of the procedure.

Even though incidence of complications like Pneumothorax , inadvertent vascular injection of local anaesthetic are more when compared to that of serratus plane block, in this study there were no such complications. Because of the use of USG has minimised such complications although it could happen even with guidance of USG when needle tip is not visible accidental puncture of pleura is seen.

CONCLUSION

The randomized controlled study conducted to compare the analgesic efficacy of Thoracic Paravertebral block vs Serratus plane group in Cancer breast patients undergoing MRM surgery. By comparing the outcome measures between two groups, it was found that patients of ⁴⁴Serratus plane Group had better postop Analgesia and the time of requirement of analgesia was longer for serratus plane group when compared to thoracic paravertebral block group. Patient satisfaction score was better for serratus plane group when compared to paravertebral group. VAS scores were favourable in serratus plane group for first 12h, after which the scores were comparable.

Also the ⁴⁴technique of serratus plane group is easier when compared to USG thoracic paravertebral. There are case reports that serratus plane block provides good analgesia for ⁴⁵post thoracotomy pain and there is a decrease in incidence of recurrence of metastasis. Considering the complications associated with paravertebral block which is more likely to occur in Parvertebral block when compared to serratus plane block and also taking into account the technical feasibility, serratus plane block is a Potent alternative as a regional anaesthesia technique for breast surgery.

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INSTITUTIONAL ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : A prospective Randomised observer blinded comparative study of Serratus plane block and thoracic paravertebral block in conjunction with general Anaesthesia in modified radical mastectomy.

Principal Investigator : Dr. Krishna Kumar.M

Designation : PG MD (Anaesthesia)

Department : Department of Anaesthesiology)
Government Stanley Medical College,
Chennai-01

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 13.01.2016 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.


MEMBER SECRETARY, 15/1/16
IEC, SMC, CHENNAI

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Thoracic paravertebral block vs serratus plane block in breast surgery patients

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INTRODUCTION

The Postoperative Analgesia for Breast surgery is Challenging. Previously Thoracic Epidural Analgesia was gold standard for Breast surgeries which was Replaced by Paravertebral Block. But both these Techniques has complications Like Pneumothorax, Vascular Injection. Now regional Blocks like Pectoral Nerve Blocks has been gradually coming into practice.

With Recent use of USG in nerve blocks has improved the success rate of the blocks and less complications. More studies were conducted to compare USG guided Paravertebral block and pectoral nerve Blocks. Serratus plane block is now recently used technique for Postoperative Analgesia in breast Surgeries. We hypothesise that Serratus Plane block under USG guidance provides better analgesia and fewer complications compared to Thoracic Paravertebral block.

தகவல்தாள்

இந்த ஆராய்ச்சியை பற்றிய முக்கியமான தகவல்களை தெரிந்துகொண்டு, இதில் பங்கேற்க உங்கள் சம்மதத்தை தெரிவிக்குமாறு நாங்கள் விடுத்த வேண்டுகோளை ஏற்றுக்கொண்டமைக்கு நன்றி. இந்த ஆராய்ச்சி சம்மந்தமான தகவல்கள், இதில் பங்கு பெறுவதினால் உங்களுக்கு ஏற்படக்கூடிய அசௌகரியங்கள், பாதிப்புகள் மற்றும் நன்மைகள் அனைத்தும் இப்படிவத்தில் கொடுக்கப்பட்டிருக்கின்றன. இதை நீங்களாகவே படித்து தெரிந்து கொள்ளலாம் அல்லது நீங்கள் விருப்பப்பட்டால், நாங்கள் இதை உங்களுக்குப் படித்துக்காட்டி புரியும்படி சொல்வதற்கு தயாராக இருக்கிறோம். உங்களுக்கு ஏதேனும் புரியவில்லை என்றாலும் அல்லது கூடுதல் தகவல்கள் ஏதேனும் தேவை என்றாலும் நாங்கள் உங்களுக்கு உதவ தயாராக இருக்கிறோம்.

இந்த ஆய்வின் நோக்கம் என்ன?

இந்த ஆய்வின் நோக்கம், மார்பகபுற்றுநோய் அறுவைசிகிச்சைக்கு பிறகு வலிகுறைக்க, எந்த நுட்பம் நல்லது என்பதை கண்டுபிடிக்கதான்.

இந்த மருத்துவசோதனை முறையில் யார்பங்கேற்க முடியும்?

அறுவைசிகிச்சை திட்டமிடப்பட்டுள்ள மார்பகபுற்றுநோய் பாதிக்கப்பட்ட நோயாளிகள், வயது 20 முதல் 60 ஆண்டுகள்.

இந்த ஆய்வில், யார்பங்கேற்க கூடாது?

இரத்தம்வடிதல் சீர்கேடுகள், ஊசிதளத்தில் தோல்நோய், மயக்கமருந்து ஒவ்வாமை, கர்ப்பிணி, தாய்பால் கொடுக்கும் தாய்மார்கள், அதிகரித்த எடை, மனநலகோளாறு, தசைக்கூட்டுநோய்கள் மற்றும் மார்பு அறுவைசிகிச்சை முந்தைய வரலாறு உள்ள நோயாளிகள்.

இந்த மருத்துவசோதனை நடைமுறை என்ன?

நோயாளிகளுக்கு தோராயமாக இரண்டு உத்திகளில் ஒன்று ஒதுக்கீடு செய்தல்.

ஒரு செயல்முறையில்;

முதுகு எலும்பின் அருகில்,

அல்ட்ராசவுண்ட் உதவியில் ஒரு ஊசி பாரவேர்டேப்றல் இடத்தில் வைக்கப்பட்டு,

ரோபிவசைனேஎன்னும்மரத்துபோகும்ஊசிதரப்படும்.
இதனால்மார்புகுதிமறுத்துபோகும்.

மற்றுருசெயல்முறையில், அல்ட்ராசவுண்ட்ன்உதவியில், மார்புதசைகளின்நடுவில்,
ஊசிமூலம்ரோபிவசைனேமருந்துதரப்படும். இதனால்மார்புகுதிமறுத்துபோகும்.

இந்திசயல்முறைநன்மைகள்என்ன?

அறுவைசிகிச்சிகுபின்உங்களுக்குகுறைந்தவலிஇருக்கும்.
குமட்டல்,மற்றும்வாந்திவருகிறஅறிகுறிகளுக்குறையலாம்.

இந்திசயல்முறைன்பின்விளைவுகள்என்ன?

இந்திசயல்முறையில், அலற்றசெளண்ட்இன்உதவியில்செய்வதால்சிக்கல்களுக்குறைவு.
அப்படிநேர்ந்தால்இங்கேயேசிகிச்சைதரப்படும்..

இந்தமருத்துவசோதனையில்சேருவதுகட்டயமா ?

இல்லை , இந்தமருத்துவசோதனையில்சேருவதுஉங்கள்விருப்பம்.
நீங்கள்எந்தநேரத்திலும்இந்தமருத்துவசோதனையைவிட்டுசெல்லமுடியும்.

என்னைபற்றியதகவல்இரகசியமாகஇருக்குமா?

ஆம், உங்கள்பெயர்பற்றியதகவல்கள்உங்கள்தனிப்பட்டவிவரங்கள்ரகசியமாகஇருக்கும்

இந்த ஆராய்ச்சியின் முடிவுகள் எனக்கு தெரிவிக்கப்படுமா?

நீங்கள்விரும்பினால், எங்களிடம் பெற்றுக் கொள்ளலாம்.

ஆராய்ச்சியில்பங்குபெற ஒப்புதல் உறுதிமொழி அளிக்கும்படிவம்

ஆராய்ச்சியின்

பெயர்

மார்க்கஅறுவைசிகிச்சைபரவேர்டேப்றல்மயக்கமருந்துமாற்றம்பெக்டோரல்மயக்க மருந்துஒப்பீடு என்கிற எனக்கு இந்த ஆராய்ச்சியைப்பற்றியமுழுவிவரங்களும் என் தாய்மொழியில் தரப்பட்டன.

இந்த ஆராய்ச்சியை பற்றி முழுமையாக தெரிந்து கொண்டேன்.

இதில் நான் பங்கு பெறுவதினால் எனக்கு ஏற்படக்கூடிய அசௌகரியங்கள்மற்றும் நன்மைகள்பற்றியும் தெரிந்து கொண்டேன்.

இந்த ஆராய்ச்சியிலிருந்து என் சுய விருப்பப்படி, எந்த நேரமும் விலகிக் கொள்ளமுடியும் என்றும், அதனால் இம்மருத்துவமனையில் எனக்கு கிடைக்கவேண்டியமருத்துவ உதவிகள் அனைத்தும் எந்த பாரபட்சமும்இல்லாமல் தொடர்ந்து கிடைக்கும் என்றும் தெரிந்து கொண்டேன்.

இதில் பங்குபெற எனக்கு எந்தவித சன்மானமும் தரப்பட மாட்டாது என்று புரிந்துகொண்டேன்.

இந்த ஆராய்ச்சியின் முடிவுகள், என்னைபற்றிய தனிப்பட்ட தகவல் ஏதும் தராமல் இருந்தால், மருத்துவம் சார்ந்த பத்திரிக்கைகளில் பிரசுரமாவதற்கு எதிர்ப்பு தெரிவிக்கமாட்டேன்.

இந்த ஆராய்ச்சியில்பங்குபெற நான் என்ன செய்ய வேண்டும் என்று தெரிந்து கொண்டேன். அதன்படி முழு ஒத்துழைப்பு கொடுக்க தயாராக உள்ளேன்.

பங்கு பெறுபவரின் கையொப்பம் _____ தேதி _____

முகவரி : _____

ஆராய்ச்சியாளரின் கையொப்பம் _____ தேதி _____

PROFORMA

NAME

AGE/SEX

SERIAL NO :

I.P. NO

WEIGHT

HEIGHT

BMI

DIAGNOSIS

PROCEDURE

ASA GRADE

H/O OTHER MEDICAL/SURGICAL ILLNESS

DRUG H/O

ALLERGIC H/O

ON EXAMINATION Anemia/Icterus/Cyanosis/Clubbing/Pedal Edema

Pulse rate /min

Blood Pressure

mmHg

SpO₂

Cardiovascular system

Respiratory System

INVESTIGATIONS

Hb g%

MPC

BT

Dentition

CT

Neck

RBS

Back

Blood Urea

Serum Creatinine

ECG

Chest X-Ray

OTHERS

IV access with 18 gauge cannula

Premedication - Injection Glycopyrrolate 4 μ G/kg, Injection Midazolam 0.02mg/kg and Inj Fentanyl 1 μ G/mL & Injection Ondansetron 0.1 mg/kg

Monitors : Pulse oximetry/ Non-invasive Blood Pressure/ ECG

Block given after randomization according to envelope technique

Induction- Inj. Thiopentone 2.5% 5mg/kg _____mg IV+ Inj. Succinylcholine 2 mg/kg _____mg IV

Intubation- Under direct laryngoscopy with oral endotracheal tube (cuffed).

Maintenance – O₂ & N₂O with FiO₂ 0.4

Desflurane (3%)

Inj. Atracurium 0.5 mg/kg IV bolus followed by intermittent doses of 0.1 mg/kg

TIME	HEART RATE	BLOOD PRESSURE	SpO₂
Baseline			
5			
10			
15			
20			
25			
30			
45			
60			
75			
90			

Additional Drugs given :

Fentanyl given :

TI ME

DOSE GIVEN

Reversal

Inj. Neostigmine 0.05 mg/body weight kg IV and Inj. Glycopyrrolate
8µG /kG body weight IV

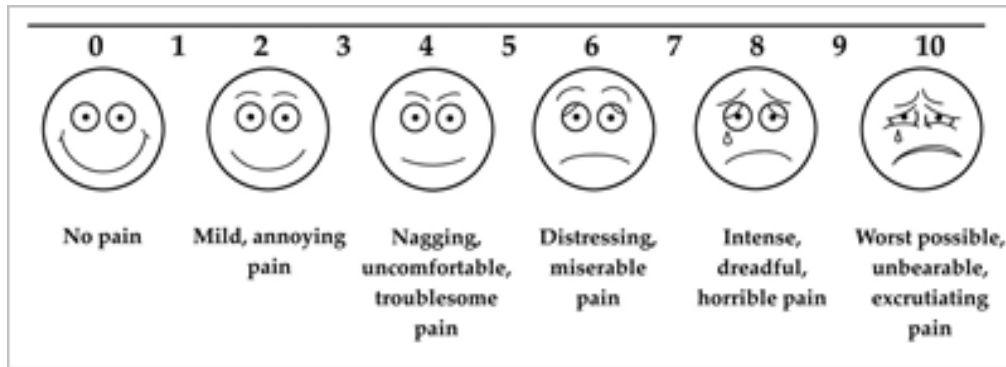
Reversal and extubation:

POST OPERATIVE MONITORING

	Immediate	30 minutes	60 minutes	90 minutes	2 nd hour	6 th hour	12 th hour	18 th hour	24 th hour
VISUAL ANALOGU E SCORE									
INJ. TRAMADO L (mG)									
NAUSEA/ VOMITING Numerical Rating Score									
INJ. ONDANSE TRON (mG)									

Time of request of first dose of tramadol :

VISUAL ANALOGUE SCALE FOR PAIN



Injection Tramadol 2mg/kg i.m will be given if pain score exceeds 5

NAUSEA/ VOMITING

The level of postoperative nausea & vomiting will be assessed with Numerical Rating Scale (NRS) at 30 minutes, 60 minutes, 90 minutes, 2nd hour, 6th hour, 12th hour, 18th hour, 24th hour.

SCORE	SYMPTOMS
0	No Nausea
1	Nausea
2	Retching
3	Vomiting
4	Severe Vomiting (More Than 4 Episodes)

Injection Ondansetron 0.1 mG/kG is given intravenously if score >2 .

COMPLICATIONS

1.

2.

MASTER CHART

ON S	NAME	AGE/SEX	SEX	GROUP	WEIGHT	DATE	IP	DURATION	DIAGNOSIS	ASA SCORE	
1	RATHINAMMAL	52	F	S	67	01-Mar-16	1614795	160	CA RT BREAST	MRM	3
2	KUMARI	43	F	S	50	03-Mar-16	1619752	140	CA LT BREAST	MRM	2
3	SAROJA	49	F	S	65	07-Mar-16	1618720	145	CA LT BREAST	MRM	2
4	MARIYAMMAL	45	F	P	56	28-Mar-16	1620001	150	CA LT BREAST	MRM	2
5	PRAMILA	36	F	P	51	04-Apr-16	1620740	135	CA RT BREAST	MRM	3
6	LAKSHMI	38	F	S	65	05-Apr-16	1620813	150	CA LT BREAST	MRM	2
7	SAROJA	60	F	P	60	07-Apr-16	1617132	120	CA RT BREAST	MRM	3
8	VIJAYA	60	F	S	50	12-Apr-16	1620418	125	CA LT BREAST	MRM	3
9	INDRA	63	F	P	65	14-Apr-16	1620001	130	CA LT BREAST	MRM	2
10	SARASWATHY	65	F	P	50	20-Apr-16	1620813	135	CA LT BREAST	MRM	3
11	MARY	55	F	S	65	22-Apr-16	1624430	140	CA RT BREAST	MRM	3
12	SINGARI	31	F	S	55	26-Apr-16	1624308	135	CA LT BREAST	MRM	2
13	LAKSHMI	35	F	P	58	28-Apr-16	1623941	150	CA RT BREAST	MRM	2
14	KASTHURI	54	F	P	60	02-May-16	1625321	130	CA RT BREAST	MRM	3
15	VINAYAKI	65	F	S	68	04-May-16	1622570	140	CA RT BREAST	MRM	3
16	JAHORABEE	54	F	S	55	06-May-16	1624159	145	CA LT BREAST	MRM	3
17	GAYATHRI	39	F	P	50	09-May-16	1623989	140	CA LT BREAST	MRM	3
18	VIJAYA	65	F	S	63	10-May-16	1626396	135	CA LT BREAST	MRM	1
19	JOTHI	65	F	P	63	12-May-16	1607579	135	CA RT BREAST	MRM	1
20	SURYAVATHY	51	F	P	66	13-May-16	1627945	140	CA LT BREAST	MRM	2
21	PERIYAMMAL	45	F	S	52	17-May-16	1628903	150	CA LT BREAST	MRM	1
22	TAMILSELVI	40	F	P	65	19-May-16	1627398	145	CA RT BREAST	MRM	2
23	DEVI	32	F	S	65	21-May-16	1629115	145	CA LT BREAST	MRM	1
24	JOTHI	55	F	S	70	24-May-16	1628549	140	CA LT BREAST	MRM	3
25	ABITHABEGUM	31	F	P	50	26-May-16	1629459	145	CA RT BREAST	MRM	1
26	RATHNA	32	F	S	65	27-May-16	1631993	140	CA LT BREAST	MRM	3
27	Banupriya	48	F	P	57	07-Jun-16	1631225	145	CA LT BREAST	MRM	2
28	KANNAMMAL	55	F	S	65	11-Jun-16	1631997	140	CA LT BREAST	MRM	3
29	PRIYA	36	F	S	55	14-Jun-16	1632564	145	CA RT BREAST	MRM	3
30	RAJAMMAL	45	F	P	54	17-Jun-16	1632452	180	CA LT BREAST	MRM	3
31	ANITHA	53	F	S	58	19-Jun-16	1634567	200	CA RT BREST	MRM	3
32	SIVAGAMI	49	F	S	53	22-Jun-16	1634721	170	CA RT BREAST	MRM	3
33	SELVI	52	F	P	54	24-Jun-16	1634819	180	CA LT BREAST	MRM	3
34	RAJESWARI	49	F	S	52	28-Jun-16	1634822	150	CA LT BREAST	MRM	3
35	MARIYAMMAL	48	F	S	53	30-Jun-16	1634829	160	CA RT BREAST	MRM	3
36	PANDIAMMAL	39	F	P	57	03-Jul-16	1634832	150	CA LT BREAST	MRM	3
37	SHANTHI	51	F	P	56	08-Jul-16	1634836	160	CA RT BREAST	MRM	3
38	VIJAYALAKSHMI	53	F	S	55	11-Jul-16	1634862	180	CA LT BREAST	MRM	3
39	MUTHULAKSHMI	60	F	S	49	13-Jul-16	1634873	150	CA RT BREAST	MRM	3
40	RANI	42	F	S	62	15-Jul-16	1634881	160	CA RT BREAST	MRM	3
41	MAHALAKSHMI	43	F	P	56	18-Jul-16	1634891	145	CA LT BREAST	MRM	3
42	MURUGESWARI	52	F	P	47	21-Jul-16	1634893	165	CA LT BREAST	MRM	3
43	KOLUNTHAI	40	F	S	51	25-Jul-16	1634899	155	CA LT BREAST	MRM	3

NO .S	NAME	AGE/SEX	SEX	GROUP	WEIGHT	DATE	IP	DURATION	DIAGNOSIS	ASA SCORE	
44	BABY	52	F	P	52	27-Jul-16	1634901	180	CA RT BREAST	MRM	3
45	SHAJITHA	40	F	S	53	30-Jul-16	1634912	155	CA LT BREAST	MRM	3
46	SARASWATHY	37	F	P	54	01-Aug-16	1634922	170	CA RT BREAST	MRM	3
47	LEELA	45	F	S	55	04-Aug-16	1634924	150	CA LT BREAST	MRM	3
48	SIVA	41	F	P	61	08-Aug-16	1634932	145	CA LT BREAST	MRM	3
49	MALAR	47	F	S	52	11-Aug-16	1634941	170	CA RT BREAST	MRM	3
50	MEENA	40	F	S	58	12-Aug-16	1634951	160	CA LT BREAST	MRM	3
51	NITHYA	34	F	P	51	17-Aug-16	1634955	145	CA RT BREAST	MRM	3
52	KUMUDHA	54	F	P	52	22-Aug-16	1634958	155	CA LT BREAST	MRM	3
53	MANGLAM	61	F	S	54	25-Aug-16	1634973	165	CA RT BREAST	MRM	3
54	PREMA	37	F	P	58	27-Aug-16	1634989	175	CA LT BREAST	MRM	3
55	GARPAGAM	39	F	P	51	28-Aug-16	1634993	163	CA LT BREAST	MRM	3
56	RAJEE	42	F	P	53	30-Aug-16	1635003	145	CA RT BREAST	MRM	3
57	PARAMESWARI	48	F	S	54	01-Sep-16	1635007	165	CA LT BREAST	MRM	3
58	KARTHIGAI	49	F	P	55	03-Sep-16	1635011	170	CA RT BREAST	MRM	3
59	BANU	40	F	P	62	05-Sep-16	1635012	175	CA LT BREAST	MRM	3
60	PRIYA	46	F	P	67	07-Sep-16	1635021	165	CA LT BREAST	MRM	3

SL.NO.	VAS SCORE								SECONDARY OUTCOME MEASURES				SIDE EFFECTS		
	IMMEDIATE POSTOP	30 MINS	60 MIS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS	POSTOP NAUSEA SCORE	PATIENT SATISFACTION	FAILURE	RESCUE ANALGESIA	HYPOTENSION	BRADYCARDIA	RESP DEPRESSION
1	2	2	3	3	3	4	4	4	1	3	0	No	no	Nil	nil
2	2	2	2	2	3	3	3	4	1	3	0	No	no	Nil	nil
3	2	2	3	3	3	4	5	5	2	4	0	No	nil	Nil	nil
4	3	3	3	4	4	5	5	5	3	2	0	No	no	Nil	nil
5	3	3	3	4	4	5	5	5	4	2	0	No	nil	Nil	nil
6	2	2	2	2	3	3	5	5	2	3	0	No	no	Nil	nil
7	3	3	3	4	4	5	5	7	3	2	0	Yes	no	Nil	nil
8	2	2	3	3	3	4	4	5	2	3	0	No	nil	Nil	nil
9	3	3	4	4	5	5	5	6	4	3	0	No	no	nil	nil
10	4	4	5	5	7	9	10	10	4	1	1	Yes	no	nil	nil
11	2	2	3	3	3	3	4	4	2	3	0	No	nil	nil	nil
12	2	3	3	3	3	4	4	5	2	3	0	No	nil	nil	nil
13	3	3	4	4	5	7	7	10	4	2	0	Yes	nil	nil	nil
14	2	3	3	3	4	4	5	5	2	4	0	no	nil	nil	nil
15	2	2	3	3	3	4	4	5	2	3	0	no	no	nil	nil
16	3	3	3	4	4	5	5	7	2	3	0	no	nil	nil	nil
17	3	4	4	4	5	5	7	7	3	2	0	yes	no	nil	nil
18	2	2	2	3	3	4	5	5	2	1	1	no	no	nil	nil
19	3	4	4	5	5	7	7	9	3	2	0	yes	no	nil	nil
20	3	3	4	4	5	5	7	7	4	2	0	no	nil	nil	nil
21	2	3	3	3	4	4	4	5	2	3	0	no	nil	nil	nil
22	3	3	4	4	5	5	5	7	4	2	0	yes	no	nil	nil
23	3	4	5	5	7	8	9	10	4	1	1	no	no	nil	nil
24	2	3	3	4	4	4	5	5	2	3	0	no	nil	nil	nil
25	3	3	4	4	5	5	7	7	3	3	0	yes	no	nil	nil
26	2	2	3	3	3	4	4	5	1	3	0	no	no	nil	nil
27	3	3	4	4	4	5	5	6	2	3	0	no	nil	nil	nil
28	2	2	3	3	3	4	4	4	1	3	0	no	nil	nil	nil
29	2	3	3	3	4	4	5	5	2	3	0	no	nil	nil	nil
30	3	3	4	4	5	5	7	7	3	2	0	yes	no	nil	nil
31	2	2	3	3	4	4	5	5	2	3	0	no	no	nil	nil
32	2	2	2	3	3	4	4	5	1	4	0	no	no	nil	nil
33	3	3	3	4	5	5	7	8	3	2	0	yes	no	nil	nil
34	2	3	3	4	4	5	5	5	1	4	0	no	no	nil	nil
35	2	2	3	3	4	4	5	5	1	3	0	no	no	nil	nil
36	3	3	4	4	5	5	7	7	2	2	0	yes	no	nil	nil
37	3	4	4	5	7	7	8	8	4	1	0	yes	no	nil	nil
38	2	2	3	3	4	4	5	5	2	3	0	no	no	nil	nil
39	2	3	3	3	4	4	5	5	2	3	0	no	no	nil	nil
40	2	2	3	3	4	4	5	5	1	4	0	no	no	nil	nil
41	3	4	4	4	5	5	5	6	3	2	0	no	yes	nil	nil
42	3	3	4	4	5	5	7	7	3	2	0	no	no	nil	nil
43	2	2	3	3	4	4	5	5	2	3	0	no	no	nil	Nil
44	3	4	4	5	5	7	8	8	3	2	0	yes	no	nil	Nil
45	2	3	3	4	4	5	5	7	2	3	0	no	no	nil	Nil

SL.NO.	VAS SCORE								SECONDARY OUTCOME MEASURES				SIDE EFFECTS		
	IMMEDIATE POSTOP	30 MINS	60 MIS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS	POSTOP NAUSEA SCORE	PATIENT SATISFACTION	FAILURE	RESCUE ANALGESIA	HYPOTENSION	BRADYCARDIA	RESP DEPRESSION
46	3	3	4	4	5	7	7	8	3	2	0	yes	no	nil	Nil
47	2	2	3	3	4	4	5	5	2	3	0	no	no	nil	Nil
48	4	4	5	7	7	8	9	9	3	2	0	yes	no	nil	Nil
49	2	2	3	3	4	4	5	5	2	3	0	no	no	nil	Nil
50	2	2	3	3	4	4	5	5	2	4	0	no	no	nil	Nil
51	3	3	4	4	5	5	7	7	2	1	0	yes	no	nil	Nil
52	3	3	4	4	5	5	5	6	3	2	0	no	no	nil	Nil
53	4	4	5	5	7	7	8	9	3	3	0	yes	no	nil	nil
54	3	4	4	5	5	7	7	9	4	2	0	yes	no	nil	nil
55	3	3	4	4	5	5	5	5	2	2	0	no	no	nil	nil
56	3	4	4	5	5	7	8	8	3	2	0	yes	no	nil	nil
57	2	2	3	3	4	5	5	7	2	3	0	no	no	nil	nil
58	3	3	4	5	5	7	8	9	4	1	1	yes	no	nil	nil
59	3	4	4	5	5	7	7	8	3	2	0	yes	no	nil	Nil
60	3	3	4	4	5	5	7	8	3	2	0	yes	no	nil	Nil

SL.NO.	SYSTOLIC BP								DIASTOLIC BP							
	IMMEDIATE POSTOP	30 MINS	60 MINS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS	IMMEDIATE POSTOP	30 MINS	60 MINS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS
1	114	120	120	128	124	130	128	134	77	80	80	72	75	73	82	81
2	113	116	119	112	122	124	120	133	77	71	70	73	75	70	69	83
3	110	116	122	112	108	124	118	135	85	82	72	78	73	70	82	82
4	114	108	117	106	120	124	138	132	71	68	68	70	72	82	89	85
5	117	119	124	128	132	128	122	136	66	68	64	70	82	88	91	94
6	114	121	123	130	128	125	134	132	85	81	80	80	78	77	74	83
7	113	118	121	128	136	138	140	133	74	70	68	72	78	82	86	90
8	119	122	125	132	135	130	136	139	74	79	80	72	68	75	70	83
9	112	118	122	125	128	132	136	138	82	66	75	82	86	92	94	84
10	117	119	121	138	142	144	148	141	75	60	68	66	68	64	70	85
11	112	119	120	120	125	121	130	135	79	72	74	73	81	77	72	82
12	116	122	124	115	118	128	125	135	68	65	66	62	60	73	64	80
13	119	122	121	124	128	132	133	133	73	69	72	77	81	84	88	85
14	113	121	124	128	130	118	115	132	68	77	76	72	72	74	70	83
15	117	120	125	120	118	114	118	134	68	67	70	69	66	70	72	82
16	114	118	119	132	127	128	126	132	82	81	80	78	73	72	75	85
17	117	121	124	126	132	134	138	134	75	70	72	75	78	82	86	86
18	112	122	123	133	139	144	147	135	75	79	82	84	83	82	81	83
19	114	123	125	115	122	128	132	134	75	69	75	77	82	86	89	84
20	117	125	125	138	127	125	130	132	79	72	76	77	68	74	70	82
21	117	121	124	117	115	113	128	134	64	68	70	60	72	70	67	89
22	112	122	122	132	136	138	140	132	80	82	84	92	82	85	88	89
23	110	119	125	138	142	144	148	135	77	80	83	87	89	87	88	88
24	114	120	120	122	128	117	110	136	81	78	76	74	77	72	69	82
25	112	119	122	131	134	136	140	133	78	80	85	81	82	85	87	88
26	116	120	122	118	115	127	122	136	71	65	66	64	70	66	68	82
27	111	121	124	130	132	133	138	140	78	80	83	82	84	85	92	84
28	110	118	121	114	118	126	122	137	73	78	76	70	69	80	74	81
29	112	119	122	116	115	110	118	138	78	80	82	78	73	77	81	83
30	118	122	124	132	136	139	140	142	75	78	81	84	87	92	94	82
31	112	119	121	118	122	124	126	130	69	75	79	78	82	84	86	88
32	108	122	123	119	122	124	120	132	72	74	77	81	80	83	84	87
33	117	121	124	131	133	137	141	134	72	76	79	83	85	87	89	84
34	111	114	120	118	121	122	127	139	68	72	75	79	80	82	83	86
35	109	112	121	117	113	124	122	138	71	74	77	79	81	83	80	82

SL.NO.	SYSTOLIC BP								DIASTOLIC BP							
	IMMEDIATE POSTOP	30 MINS	60 MINS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS	IMMEDIATE POSTOP	30 MINS	60 MINS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS
36	118	124	123	127	131	134	138	132	76	77	83	84	89	91	89	83
37	110	122	124	123	132	129	135	133	75	79	82	81	84	85	80	87
38	116	117	119	114	118	125	128	130	71	74	72	75	79	81	82	83
39	112	121	122	113	122	124	128	134	71	74	72	75	82	83	84	86
40	116	122	123	118	121	125	128	132	69	72	74	75	77	82	85	88
41	109	123	124	103	114	116	109	137	72	71	75	83	81	80	84	87
42	118	122	120	127	129	133	137	142	73	75	79	82	80	83	86	88
43	115	124	121	125	127	128	132	136	71	73	72	79	82	84	86	90
44	119	125	122	132	136	138	141	144	71	70	73	76	81	85	88	94
45	112	117	119	122	125	128	129	132	73	75	71	82	83	85	88	90
46	117	119	122	126	120	131	136	139	72	77	70	79	81	82	83	89
47	110	122	126	129	131	134	138	141	72	73	74	78	79	82	84	85
48	115	119	119	121	122	130	132	138	71	74	72	78	81	80	81	88
49	114	118	121	118	117	122	110	129	71	72	75	79	82	84	85	89
50	110	122	122	125	127	128	131	134	72	73	78	79	82	84	86	89
51	111	118	121	118	124	129	133	136	73	75	81	84	85	88	92	92
52	110	119	117	119	122	126	129	131	68	71	73	77	82	84	89	90
53	116	118	119	124	132	135	138	132	74	76	79	81	87	89	94	98
54	117	119	122	124	127	129	132	133	71	72	75	78	81	83	84	89
55	119	122	125	127	131	133	138	134	79	82	83	85	89	90	93	84
56	116	122	122	124	127	132	134	139	72	75	78	82	87	88	90	82
57	114	121	117	119	110	122	127	136	72	74	78	71	78	82	84	86
58	118	128	121	125	128	132	136	138	75	78	81	83	85	85	87	86
59	112	122	127	133	136	138	142	133	78	82	83	85	89	94	96	82
60	116	121	119	121	123	127	129	131	74	75	79	82	84	85	89	90

SL.NO.	MEAN ARTERIAL PRESSURE								PULSE RATE							
	IMMEDIATE POSTOP	30 MINS	60 MIS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS	IMMEDIATE OSTOP	30 MINS	60 MIS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS
1	93	93	93	91	91	92	97	87	99	98	88	84	88	90	92	88
2	92	86	83	86	91	88	86	86	88	80	82	88	92	84	86	82
3	93	93	86	89	85	88	94	89	88	88	84	90	92	99	86	85
4	87	81	82	82	88	99	105	108	87	86	90	92	96	84	78	76
5	88	89	84	89	99	101	105	110	90	88	86	90	92	90	86	84
6	99	98	97	97	95	93	94	91	89	94	90	92	88	90	84	86
7	95	87	85	91	97	101	104	107	88	86	80	84	86	88	80	82
8	94	98	99	92	90	93	92	98	91	82	78	70	75	77	74	68
9	97	81	91	96	100	105	108	111	90	80	76	78	72	68	66	64
10	97	81	90	90	93	91	96	97	86	78	72	70	68	66	78	70
11	94	89	89	89	96	92	91	97	91	88	84	85	89	82	76	78
12	85	81	83	80	79	91	84	84	92	90	88	84	86	86	78	86
13	91	82	85	93	97	100	103	107	86	80	78	82	88	78	82	84
14	89	93	93	91	91	89	85	88	94	90	88	92	80	86	88	85
15	85	85	87	86	83	85	87	87	82	76	74	70	82	88	84	80
16	97	97	97	96	91	91	92	91	81	80	88	84	92	86	84	90
17	94	87	88	92	96	99	103	110	92	88	80	78	86	76	86	80
18	103	102	104	107	112	116	100	98	91	84	88	80	82	86	84	86
19	91	83	87	90	95	100	103	110	80	78	76	74	78	76	74	70
20	95	91	93	97	88	91	90	99	86	88	76	78	76	80	78	80
21	81	85	86	79	86	84	87	88	80	82	86	84	82	84	82	78
22	99	98	99	105	108	110	112	115	74	74	76	74	86	84	80	84
23	102	102	106	109	113	116	118	95	80	84	86	82	84	82	86	88
24	97	92	91	90	94	87	83	90	72	80	84	82	78	74	80	82
25	97	97	99	102	106	107	110	113	78	80	86	78	76	78	80	74
26	86	83	84	82	85	86	86	89	66	64	66	62	60	64	66	62
27	96	95	98	98	100	101	107	110	72	76	74	72	70	70	72	74
28	88	89	87	85	85	95	90	90	72	70	72	70	76	72	78	78
29	90	93	93	91	87	88	93	84	88	90	94	92	90	92	88	86
30	95	93	96	100	103	108	109	111	86	84	89	91	90	93	88	89
31	87	89	92	91	95	97	99	102	89	90	91	94	98	103	104	106
32	89	87	90	94	94	97	96	100	78	83	85	87	89	101	103	104
33	88	89	92	99	101	104	106	109	89	92	94	96	98	99	102	103
34	81	87	88	93	94	95	98	100	77	79	81	83	88	90	90	91
35	85	89	91	90	92	97	94	100	76	78	82	84	87	89	91	92
36	81	87	92	98	103	105	105	109	87	89	91	92	94	97	99	102
37	85	89	91	92	100	100	98	104	87	88	93	95	97	99	101	103

SL.NO.	MEAN ARTERIAL PRESSURE								PULSE RATE							
	IMMEDIATE POSTOP	30 MINS	60 MIS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS	IMMEDIATE OSTOP	30 MINS	60 MIS	2 HRS	6 HRS	12 HRS	18 HRS	24 HRS
38	79	82	93	94	92	96	97	95	76	74	79	82	84	87	89	92
39	80	87	92	95	95	97	99	101	72	75	77	79	80	83	82	90
40	92	88	90	91	92	96	99	103	71	73	76	79	81	84	85	87
41	82	81	89	92	92	92	92	97	79	82	85	87	89	92	94	99
42	84	89	93	97	102	106	108	113	82	84	86	89	94	96	99	100
43	83	84	88	91	97	99	101	104	73	75	78	82	84	88	89	93
44	84	85	94	98	99	103	106	111	83	85	89	92	94	97	99	101
45	81	83	89	92	97	99	102	104	74	75	78	79	82	84	86	89
46	80	83	88	94	94	98	101	106	85	87	89	92	94	97	99	101
47	83	85	92	95	96	99	102	104	75	77	79	83	84	86	89	93
48	85	88	95	97	95	97	98	105	86	88	89	91	93	94	96	99
49	81	85	88	91	94	97	93	99	72	74	77	79	82	84	86	89
50	79	83	87	90	97	99	101	104	74	77	78	81	83	84	87	89
51	84	85	87	98	98	102	106	108	82	83	87	89	94	95	99	101
52	80	82	89	92	95	98	102	105	84	85	87	90	92	93	95	98
53	83	86	90	99	102	104	109	113	72	74	76	79	81	83	84	89
54	81	84	87	89	96	98	100	104	82	85	89	92	94	97	98	99
55	83	85	93	97	103	104	108	111	87	89	92	94	97	99	102	103
56	84	86	89	92	100	103	105	109	86	89	92	95	98	99	102	104
57	85	88	91	93	89	95	98	99	73	76	79	82	84	87	92	93
58	83	85	89	94	110	113	116	119	83	85	87	89	93	95	97	99
59	84	88	90	92	105	109	111	115	84	87	92	95	97	99	100	101
60	88	89	91	92	97	99	102	104	81	83	89	90	94	98	99	102