EFFECT OF 0.125% OF LEVOBUPIVACAINE VERSUS 0.125% OF LEVOBUPIVACAINE WITH NALBUPHINE AS AN ADJUVANT ON THORACIC PARAVERTEBRAL BLOCK TO MANAGE POSTOPERATIVE PAIN AFTER BREAST SURGERIES.

Dissertation submitted

IN THE PARTIAL FULFILMENT OF THE REQUIREMENTS

for award of the degree

M.D (Anaesthesiology) - BRANCH X

GOVERNMENT CHENGALPATTU MEDICAL COLLEGE

Reg. No. 201720259

THE TAMIL NADU DR.M.G.R MEDICAL UNIVERSITY,

CHENNAI, TAMIL NADU.

APRIL 2020

CERTIFICATE

This is to certify that this dissertation entitled **"EFFECT OF 0.125% OF LEVOBUPIVACAINE VERSUS 0.125% OF LEVOBUPIVACAINE WITH NALBUPHINE AS AN ADJUVANT ON THORACIC PARAVERTEBRAL BLOCK TO MANAGE POSTOPERATIVE PAIN AFTER BREAST SURGERIES"** submitted by **Dr.UVASRI.P** in partial fulfilment for the award of the degree Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai is a bonafide work done by her at Government Chengalpattu Medical College, during the academic year 2017-2020.

Dean,
Govt. Chengalpattu Medical College,
Chengalpattu.

Prof.Dr.R. Mala M.D.,D.A,
Professor & HOD,
Department of Anaesthesiology,
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BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled **"EFFECT OF 0.125% OF LEVOBUPIVACAINE VERSUS 0.125% OF LEVOBUPIVACAINE WITH NALBUPHINE AS AN ADJUVANT ON THORACIC PARAVERTEBRAL BLOCK TO MANAGE POSTOPERATIVE PAIN AFTER BREAST SURGERIES"** submitted by **Dr. UVASRI.P** in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology for the April 2020 examination by the Tamilnadu Dr. M.G.R. Medical University, Chennai. This is a bonafide original research work done by her in the Department of Anaesthesiology, Government Chengalpattu Medical College, under my guidance and supervision.

Prof.Dr.R. MALA M.D.,D.A.,
Professor & HOD,
Department of Anaesthesiology,
Govt. Chengalpattu Medical College,
Chengalpattu.

DECLARATION

I, **Dr. UVASRI.P** solemnly declare that this dissertation, entitled **"EFFECT OF 0.125% OF LEVOBUPIVACAINE VERSUS 0.125% OF LEVOBUPIVACAINE WITH NALBUPHINE AS AN ADJUVANT ON THORACIC PARAVERTEBRAL BLOCK TO MANAGE POSTOPERATIVE PAIN AFTER BREAST SURGERIES"** has been prepared by me under the expert guidance and supervision of Prof. **Dr. R.MALA M.D.,D.A** Professor and HOD, Department of Anaesthesiology, Government Chengalpattu Medical College and Hospital and submitted in partial fulfilment of the regulations for the award of the degree M.D.(Anaesthesiology) by The TamilNadu Dr. M.G.R. Medical University and the examination to be held in April 2020.

This study was conducted at Government Chengalpattu Medical College Hospital, Chengalpattu. I have not submitted this dissertation previously to any university for the award of any degree or diploma.

Place: Chengalpattu **(DR.UVASRI. P)**

Date:

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I wish to thank all the patients whose willingness and patience made this study possible.

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CONTENTS

ABBREVIATIONS

PVB	Paravertebral Block
TPVS	Thoracic Paravertebral Space
USG	UltraSonoGraphy
VAS	Visual Analog Scale
NRS	Numeric Rating Scale
HR	Heart Rate
MAP	Mean Arterial Pressure
IV	Intravenous
ASA	American Society of Anaesthesiologist
CPCR	Cardio Pulmonary Cerebral Resuscitation
CVS	Cardiovascular System
CNS	Central Nervous System
NIBP	Non Invasive Blood Pressure
ECG	Electrocardiography
ETCO2	End Tidal Carbon-di-oxide
GA	General Anaesthesia
LA	Local Anaesthesia
TPVB	Thoracic Paravertebral Block
PONV	Postoperative Nausea and Vomiting

INTRODUCTION

General anaesthesia is the traditional technique used for surgical treatment of breast surgeries. Incidence of postoperative pain in breast surgery patients is as high as 50% [1]. Since the last two decades, there is a search for the best and ideal regional techniques for operative procedures on the breast and axilla, which would reduce post-operative nausea and vomiting caused by drugs such as Tramadol and also to provide prolonged post-operative sensory block, reducing the systemic narcotic requirements.

Paravertebral block has been used for unilateral procedures such as thoracotomy, breast surgery, chest wall trauma, hernia repair and renal surgery. The cortical responses to thoracic dermatomal stimulation can be particularly eliminated by the paravertebral block. It is associated with a reduced need for opioids for controlling pain, decreased nausea and vomiting and reduced pulmonary complications in the postoperative period [2], improved patient outcome and finally decreased duration of stay in the post-anaesthesia care unit [3].

Postoperative pain is associated with increase in sympathetic activity leading to increase in heart rate, blood pressure, respiratory rate and even delirium.So there is a need for a study to find a drug which prolongs the duration of analgesia in the postoperative period without much side effects so that the

need for opioids and the occurrence of nausea and vomiting in the postoperative period can be reduced.

Establishment of a block necessary for the breast surgeries is easily done by the injection of local anaesthetic drug into the thoracic paravertebral space without any significant side effects. There are some studies going on to find out the effects of adding analgesic agents as an adjunct in paravertebral blockades. Adjuncts to local anaesthetics can add value to the superiority and time length of analgesia [(4).]

Though Nalbuphine is similar to Morphine in pain relieving property it is different from it in producing its less effect on respiratory depression. [(5).]

The present study is aimed at finding the effectiveness and safety of Nalbuphine as an adjuvant to Levobupivacaine in thoracic paravertebral block.

AIM AND OBJECTIVES

The aim and objectives of my study is to assess the following using 0.125% of Levobupivacaine versus 0.125% of Levobupivacaine with Nalbuphine as an adjuvant on thoracic paravertebral block given for breast surgeries.

Primary aim is to assess:

A. Duration of sensory blockade.

B. Reduction in the dose of opioids in the first 48 hours.

Secondary aim is to assess:

A) Adverse effects such as postoperative nausea and vomiting.

B) Complications associated with thoracic paravertebral block.

REVIEW OF LITERATURE

1. Jehan M. Kamal et al, in the year 2019, conducted a study about the continuous thoracic paravertebral block, an adjunct to general anesthesia in major breast surgery. Two groups of patients undergoing unilateral breast cancer surgery(each 20 patients) were randomly selected. Preoperative application of an epidural catheter by using the nerve stimulator at the fourth thoracic paravertebral space and injection of local anesthetic was started preoperatively in the study group. General anesthesia was started for the two groups. They concluded that TPVB provides effective pain relief, significant opioid sparing, prevents restricted shoulder movements due to pain [(40).]

2. Yu mao, Yuanyuan Cao et al, in the year 2017, studied the efficacy of Nalbuphine with Flurbiprofen compared to Sufentanil with Flurbiprofen in multimodal analgesia efficacy for elderly patients undergoing gastrointestinal surgery with a transverse abdominis plane block. They concluded that low dose of Nalbuphine combined with Flurbiprofen is superior for elderly patients undergoing elective open gastrointestinal surgery with TAPB in terms of the efficient postoperative analgesia, decreased incidence of postoperative nausea and vomiting and also enhanced recovery with fewer side effects [(41).]

3. Mohammmad et al, in the year 2017, studied the effectiveness and safety of Dexmedetomidine and Nalbuphine as an adjuvant to local anaesthetic, Bupivacaine in thoracic paravertebral block in breast cancer surgeries in a total of sixty female patients who were scheduled for mastectomy.They concluded that addition of Nalbuphine to local anaesthetic Bupivacaine in PVB increased the quality of the block and reduced postoperative analgesic requirements than the other two groups A) Bupivacaine only group, and B) Dexmedetomidine and Bupivacaine group. Also sedation was less in Bupivacaine and Nalbuphine group compared to other groups (42).

4. Kumkum Gupta et al, in the year 2016, conducted a meta analysis in sixty patients to assess the efficacy and safety of Nalbuphine as an adjuvant to Bupivacaine for ultrasound guided brachial plexus block. They found that Nalbuphine enhanced the duration of sensory and motor block without affecting the onset time of block.There were no hemodynamic instability, no associated complication of technique or adverse effects.Nalbuphine has extended the duration of analgesia of brachial plexus block significantly without any side effects (43).

5. VeenaChatrath et al, in the year 2015, compared Bupivacaine hydrochloride with Nalbuphine versus Bupivacaine with Tramadol for postoperative analgesia in lower limb orthopaedic surgeries under combined spinal epidural anesthesia.They found that addition of

Nalbuphine with Bupivacaine was effective for postoperative analgesia, lesser incidence of side effects, postoperative complications such as nausea, vomiting, sedation and patient satisfaction was better compared to tramadol [(5).]

6. Mohamed et al, in the year 2014, conducted a meta analysis on the efficacy of addition of adjunctive analgesia in paravertebral analgesia in 60 patients.They found that addition of adjunctive analgesic Dexmedetomidine to local anaesthetic Bupivacaine in thoracic paravertebral block in patients undergoing modified radical mastectomy increases the quality and duration of sensory neural blockade,provides analgesic sparing effect without any serious side effects and decrease the dose of local anaesthetic and supplemental analgesia [(44).]

7. Beyaz, HandeOzocak et al, in the year 2014, conducted a study about thoracic paravertebral block performed for open cholecystectomy compared to general anesthesia.They found that TPVB is an alternative method to general anaesthesia.TPVB provides high quality analgesia and safe anaesthesia with more hemodynamic stability and less side effects.They concluded that TPVB is an alternative method to general anesthesia for patients with serious comorbidities who were planned for open cholecystectomy and it is considered in patients who cannot tolerate the hemodynamic responses of general anesthesia or neuraxial blocks [(45).]

8. Pankaj kundra et al, in the year 2013, conducted a study about the comparison of paravertebral block and interpleural block in patients undergoing modified radical mastectomy. The study was to determine their effects on lung functions and postoperative pain in a total of 120 patients.They concluded that lung functions are well preserved in patients undergoing modified radical mastectomy under general anesthesia supplemented with PVB or IPB. But PVB has the added advantage of achieving a more complete block[46].

9. Schnabel A et al, in the year 2010, done a meta analysis about the effectiveness and safety of paravertebral block in breast surgery.Fifteen randomized controlled trials including 877 patients met the inclusion criteria.They found that PVB in addition to GA or alone provide better postoperative pain control with little adverse effects compared with other analgesic treatment strategies.The results of this study had limitations such as different surgical procedures, use of different types and doses of local anaesthetics [47].

10. Kotze A et al, in the year 2009, done a systematic review about the efficacy and safety of different techniques of paravertebral block after thoracotomy for analgesia. Primary aim was to determine whether local anesthetic dose influence the quality of analgesia from PVB.Secondary aims were to determine the choice of LA agent, continuous infusion, adjuvants, pre-emptive PVB or addition of patient controlled opioids

improve analgesia.They concluded that the definitive answer on how best to manage pain, rehabilitation, and risk in difficult group of patients were still not clear [48].

11. Ali Dabbagh and HedayatollahElyasi et al in the year 2007, done a meta analysis, in which sixty patients scheduled for breast cancer surgery were randomized to two groups of 30 patients in each group: general anaesthesia(control group) and paravertebral block(study group). The primary aim was to assess the postoperative pain in 1,3,6 hours postoperatively.It has been concluded that thoracic paravertebral block is an efficient method of anaesthesia as it blocks the pain pathways, suppress the acute stress response to surgical stress, induces preemptiveanalgesia,decreases the incidence of postoperative pain and complications.He also suggested that paravertebral block should be compared with other thoracic regional anaesthesia techniques with regard to postoperative pain management and cost-effectiveness for elective breast surgeries in a large scale meta-analysis [49].

12. Hadzic A et al, in the year 2006 done a randomized controlled trial that paravertebral blocks provide superior same day recovery over general anesthesia for patients undergoing inguinal hernia repair.Fifty patients were randomly assigned to receive either PVB or GA.Postoperative pain ,adverse events such as nausea, vomiting,and sore throat has occurred less frequently in patients who had received PVB than in those who had

received GA.Also PVB resulted in faster time to home readiness compared to GA[50].

13. Kairaluoma et al, in the year 2004, conducted a study on single injection paravertebral block before general anesthesia.They found that it increases analgesia after breast cancer surgery.They studied sixty patients scheduled for breast cancer surgery.Those patients given PVB needed 40% less IV opioid medication in the postanesthesia care unit, had a longer latency to the first dose of opioid and had less pain at rest.Thus they concluded that PVB before general anesthesia for breast cancer surgery reduced postoperative pain, opioid consumption, and occurrence of PONV and improved recovery from anesthesia [51].

14. Cheema et al, in the year 2003, conducted a study about the factors affecting the spread of Bupivacaine in the adult thoracic paravertebral space in patients undergoing paravertebral nerve blocks for the treatment of post-thoracotomy, post-herpetic, intercostal neuralgia and other chronically painful conditions.They found that the unpredictable block with single bolus of Bupivacaine can be overcome with multiple level injection with smaller individual boluses.Pre-emptive analgesia can overcome the prolonged onset of the block with Bupivacaine [52].

15. Klein SM,Bergh et al done a meta analysis in the year 2000 comparing thoracic PVB with general anaesthesia for breast surgery in a group of 60 women.Primary objective was to assess the postoperative pain.The secondary objectives were to assess the analgesic requirements and postoperative complications.The study demonstrated improved postoperative analgesia from PVB when compared with GA alone for breast surgery. They concluded that PVB is an alternative technique for breast surgery that offers superior pain relief and decreased nausea and vomiting than GA alone [53].

HISTORY

Hugo Sellheim of Leipzig was a pioneer in the concept of Paravertebral block in 1905 instead of neuraxial block for obstetric surgeries. It was further refined by Lawen (1911) and Kappis (1919). [6]

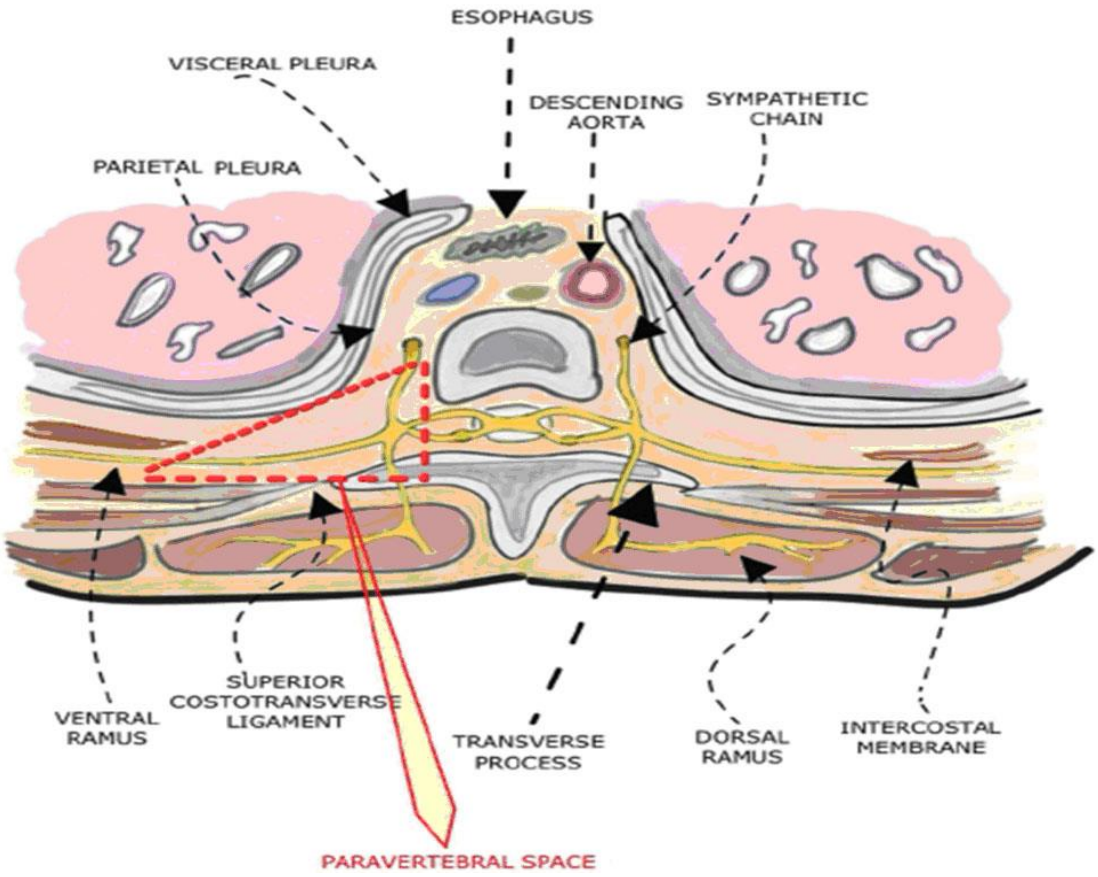
The technique however remained neglected till the late 1970s. Reappraisal on Thoracic Paravertebral Block was presented by Eason and Wyatt and renewed interest developed in the topic due to their efforts [7].

They found it to be an accurate, simple and safe method which carried significant advantages over intercostal or epidural block. It was initially utilized as an alternative to spinal anaesthesia which would minimise the cardiovascular and respiratory effects of central neuraxial blockade.

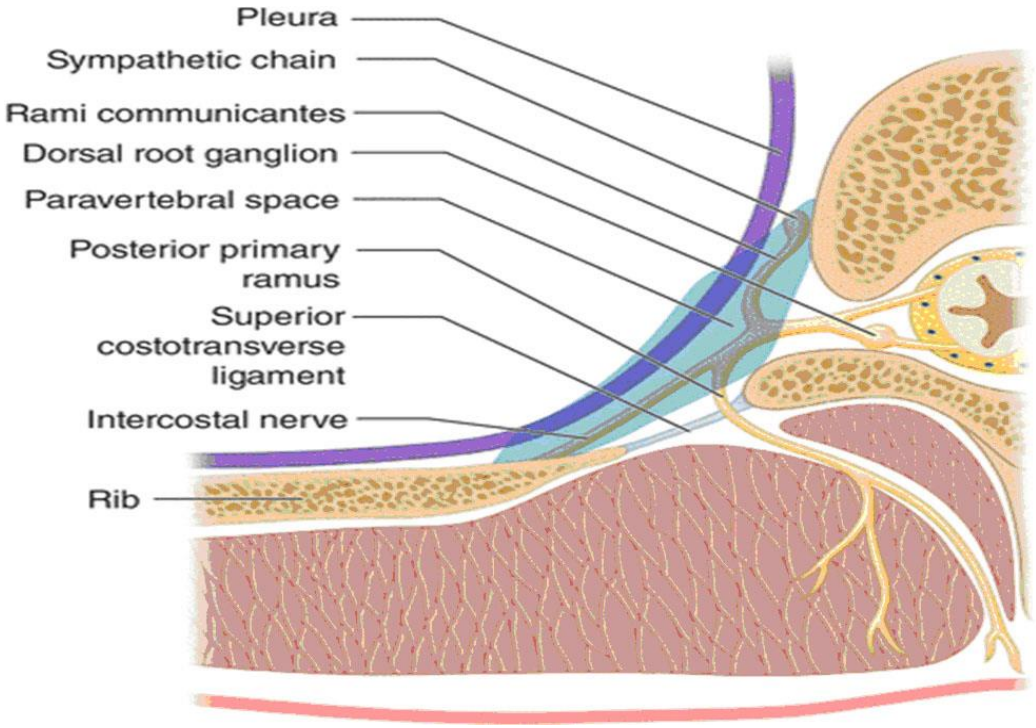
At a recent time, more interest has been developed in this technique for the management of acute and chronic pain. Paravertebral block has been successfully used in many abdominal and thoracic procedures to provide analgesia in both children and adults and can provide long-lasting unilateral anaesthesia.

ANATOMY OF PARAVERTEBRAL SPACE

Understanding about the anatomy of Paravertebral space is essential for an effective analgesia and to prevent the complications associated with it.



The thoracic paravertebral space commence at T1 and extends caudally to terminate at T12. Although PVBs can be done in the cervical and lumbar regions, there is no direct communication between adjacent levels in these areas. Most PVBs are therefore performed at the thoracic level, since there is direct communication between the adjacent areas.



The thoracic paravertebral space lies on either side of the vertebral column and it is wedge shaped in all three dimensions. Its wider on the left than on the right. The boundaries of the paravertebral space is as follows:

Anterolateral boundary: Parietal pleura and the innermost intercostal membrane.

Medial boundary: The bodies of the vertebrae, intervertebral discs, and intervertebral foraminae.

Posterior boundary : Transverse process of the thoracic vertebrae, heads of the ribs, and the superior costotransverse ligament. The apex of the space is continuous with the intercostal space lateral to the tips of the transverse processes.

The endothoracic fascia, a fibroelastic structure is interposed between the parietal pleura and the superior costotransverse ligament which is the deep fascia of the thorax and lines the inside of the thoracic cage. The endothoracic fascia is closely applied to the ribs in the paravertebral area and fuses medially with the periosteum at the midpoint of the vertebral body.

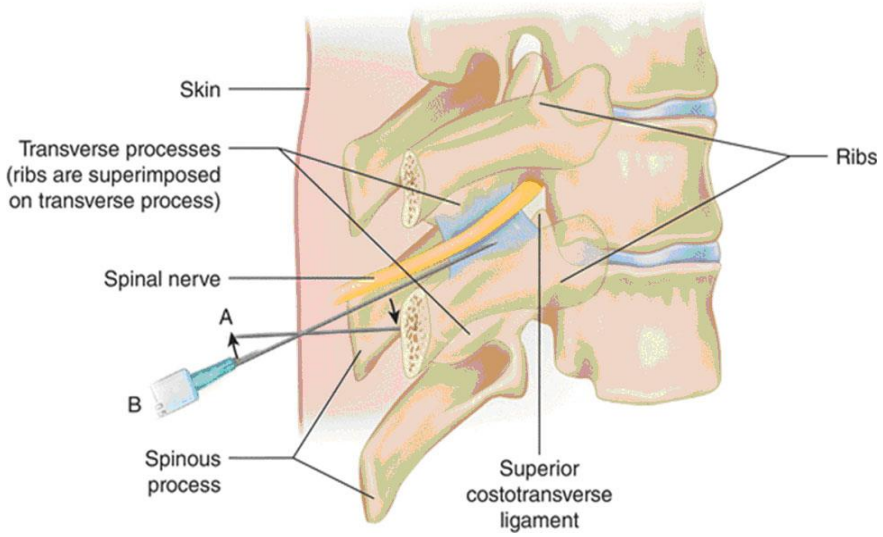
The thoracic paravertebral space is divided into subendothoracic compartment posteriorly and subserous compartment anteriorly by the endothoracic fascia. The “Subserous fascia”, an intervening layer of loose connective tissue is found between the parietal pleura and the endothoracic fascia. Thus the thoracic paravertebral space is divided into two potential fascial compartments, the anterior “extrapleural paravertebral compartment” and the posterior “subendothoracic paravertebral compartment” by the endothoracic fascia.

CONTENTS:

The contents of the paravertebral space are intercostal(spinal) nerves, white and grey rami communicantes, the sympathetic chain, intercostal vessels and fat. The spinal nerves in the thoracic paravertebral space are susceptible to local anaesthetic block since they are devoid of a fascial sheath and segmented into small bundles lying freely among the fat. The sympathetic trunk is located anterior to the endothoracic fascia in the thoracic paravertebral space, while the intercostal nerves and vessels are located behind the endothoracic fascia .

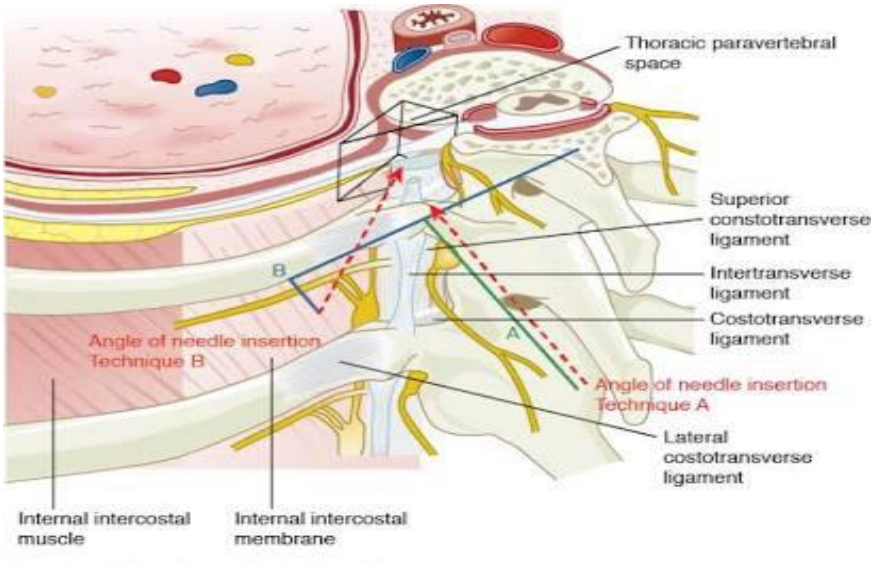
COMMUNICATIONS OF THE THORACIC PARAVERTEBRAL SPACE

Medially, the thoracic paravertebral space is continuous with the epidural space through the intervertebral foramen, intercostal space laterally and the contralateral paravertebral space *via* the prevertebral and epidural space. The fascia transversalis of the abdomen is the continuation of the endothoracic fascia inferiorly dorsal to the diaphragm through the medial and lateral arcuate ligaments and the aortic hiatus.



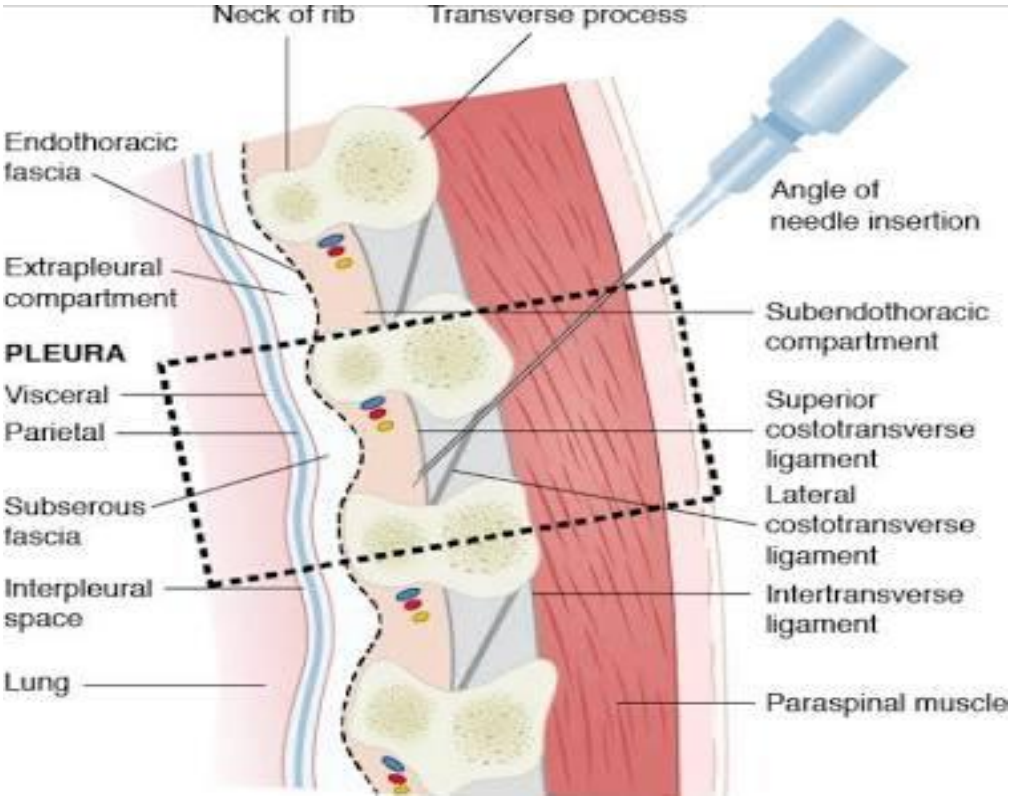
Extended Unilateral Anaesthesia:

An injection in the lower thoracic paravertebral space posterior to the endothoracic fascia can spread inferiorly to the retroperitoneal space through the medial and lateral arcuate ligaments behind the fascia transversalis where the lumbar spinal nerves lie and is the anatomic basis of the technique of “Extended unilateral anesthesia.”



TECHNIQUES OF THORACIC PARAVERTEBRAL BLOCK

Thoracic paravertebral block can be done with the patient in the sitting, lateral, or prone position. The patients are often more comfortable in the sitting position and allows easy identification of landmarks.



PREPARATION

Informed consent should be obtained from the patient and intravenous access is established. Block should be performed in an area where full resuscitation facilities and a trained assistant are available and a standard non-invasive monitoring should be connected. Full aseptic precautions should be taken during preparation and performance of the block.

POSITIONING

The patient should be seated with the neck and back flexed if awake. The patient is turned to the lateral position with the operating side uppermost if performed under sedation or general anaesthesia . Between the patient and the operating table surface a bag of saline or a pillow can be placed at the level of the intended block to open up the spaces between adjacent transverse process.

CHOOSING THE LEVEL

A single level paravertebral block at or below the mid-dermatomal level is usually sufficient if only one to four dermatomes need to be blocked. Multiple level injections are given if spread greater than four dermatomes are required and will block the area more reliably. Since the spread between adjacent levels is less reliable in the lumbar region than in the thoracic region, it is recommended that individual injections be performed at each level with small volumes of local anaesthetic for blocks in the lumbar region.

CATHETER INSERTION FOR CONTINUOUS ANALGESIA

For continuous postoperative analgesia**,** a catheter can be inserted into the paravertebral space. This is particularly useful for the management of unilateral rib fractures and after major surgeries. After the location of the paravertebral space, 5–10 ml of local anaesthetic or normal saline is injected to expand the space and a standard epidural catheter is then advanced not more than 2 cms into the space.

Slightly more force is required to thread a paravertebral catheter compared with epidural catheterization. The risk of intercostal or epidural cannulation is increased with deeper catheter insertion.

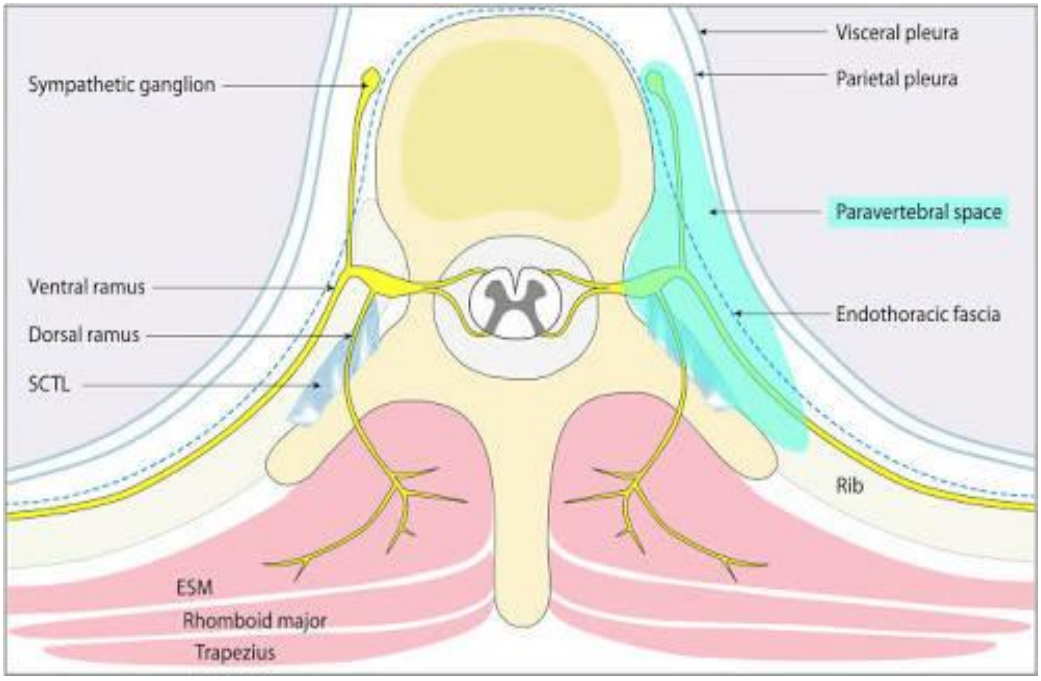
During thoracotomy, paravertebral catheters can be very reliably inserted under direct vision by the surgeon [(8).] If the tears and incisions in the medial parietal pleura are repaired before closure, the success rate is much higher. Paravertebral catheters insertion during video-assisted thoracoscopic surgery has also been described [(9).]

IDENTIFICATION OF PARAVERTEBRAL SPACE

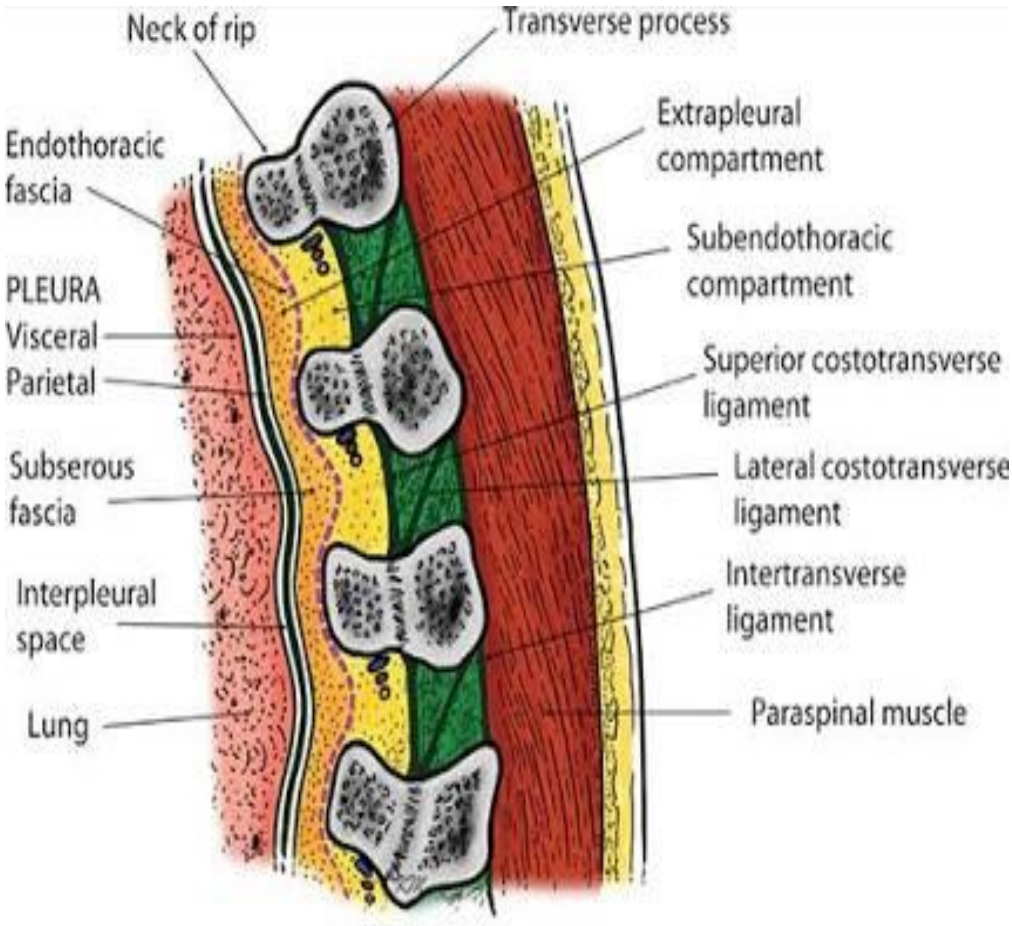
There are various techniques to identify paravertebral space such as:

1. Anatomical landmark technique.
2. Ultrasound guided technique.
3. Nerve stimulator technique.

In my study, I followed the anatomical landmark technique.



Classical technique involves eliciting loss of resistance [7] which is the most commonly used technique. Under strict aseptic precautions at the appropriate dermatome,2.5–3 cm lateral to the most cephalad aspect of the spinous process, 16-gauge, 8 cm Tuohy needle is inserted and advanced perpendicular to the skin to contact the transverse process of the vertebra below depending on the built of the individual at a variable depth (2–4 cm). It is possible that the needle tip is lying between adjacent transverse processes if bone is not encountered at this depth.



Before advancing the needle any further, it is important to locate the transverse process to prevent inadvertent deep insertion and possible pleural puncture. This is done by withdrawing the needle to the subcutaneous plane and redirecting it cephalad and caudad to the same depth until bone is encountered. The needle is advanced further centimetres if the bone is still not encountered, and the above process is repeated until the transverse process is contacted.

The needle is then walked above the transverse process and advanced gradually until a subtle “pop” or a loss of resistance to air or saline is felt as the

needle tip pierces the thin superior costotransverse ligament usually within 1–1.5 cm from the superior edge of the transverse process. Local anaesthetic is injected in the paravertebral space after gentle aspiration or a catheter is inserted so that 1–3 cm of the distal end of the catheter lies within the thoracic paravertebral space.

CONFIRMATION: Supplementary methods that are often used to confirm the position of the needle or catheter is fluoroscopy[10] and contrast chest radiography[11].Either a longitudinal or a cloud-like spread localized to the paravertebral region is produced when contrast is injected into the thoracic paravertebral space as depicted on frontal chest radiography.

PRESSURE MEASUREMENT TECHNIQUE

During inspiration, pressure in the erector spinae muscle is higher than that during expiration. There is a sudden lowering of pressure when the superior costotransverse ligament is traversed and the thoracic paravertebral space is entered and expiratory pressure then exceeds inspiratory pressure called as "pressure inversion"[12]. These are the objective signs which are described as an easy and reproducible method of locating the thoracic paravertebral space.If there is negative pressure during both phases of respiration, it would indicate interpleural placement.

MEDIAL APPROACH:

Medial approach is a modification of the classical approach in which the needle is inserted 1 cm from the midline and advanced perpendicularly to contact the lamina rather than the transverse process. It is followed by the lateral redirection to slip off the lamina into the thoracic paravertebral space [13]. It was developed initially by directing the needle away from the intervertebral foramen to avoid intrathecal injection but this approach has been associated with complications relating to dural puncture.

PARAVERTEBRAL-PERIDURAL BLOCK:

"Paravertebral–peridural block" is a recent variation of the medial approach in which the needle is inserted 3–4 cm lateral to the midline and advanced at a 45° angle to the coronal plane with medial direction to contact the lamina.The needle is then redirected laterally by gradual increase in the angle of entry to the coronal plane until the needle is walked off the lamina into the thoracic paravertebral space.

CONFIRMATION

Confirmation is done with the use of a nerve stimulator set at 2 Hz with a pulse width of 0.3 ms, and current of 2milliamperes. When the needle tip is in the appropriate position, intercostal or abdominal muscle contraction should be apparent.

INDICATIONS FOR PVB

Unilateral surgical procedures in the thoracoabdominal region [14] such as:

1. Breast surgery.
2. Thoracic surgery.
3. Cholecystectomy.
4. Renal surgery.
5. 5.Appendicectomy.
6. Inguinal hernia repair.
7. Relief of acute pain.
8. Fractured ribs.
9. Liver capsule pain (trauma or ruptured cysts).
10. Relief of chronic pain.
11. Neuropathic chest or abdominal pain (post-surgical or post-herpetic).
12. Complex regional pain syndrome.
13. Refractory angina pectoris.
14. Relief of cancer pain.

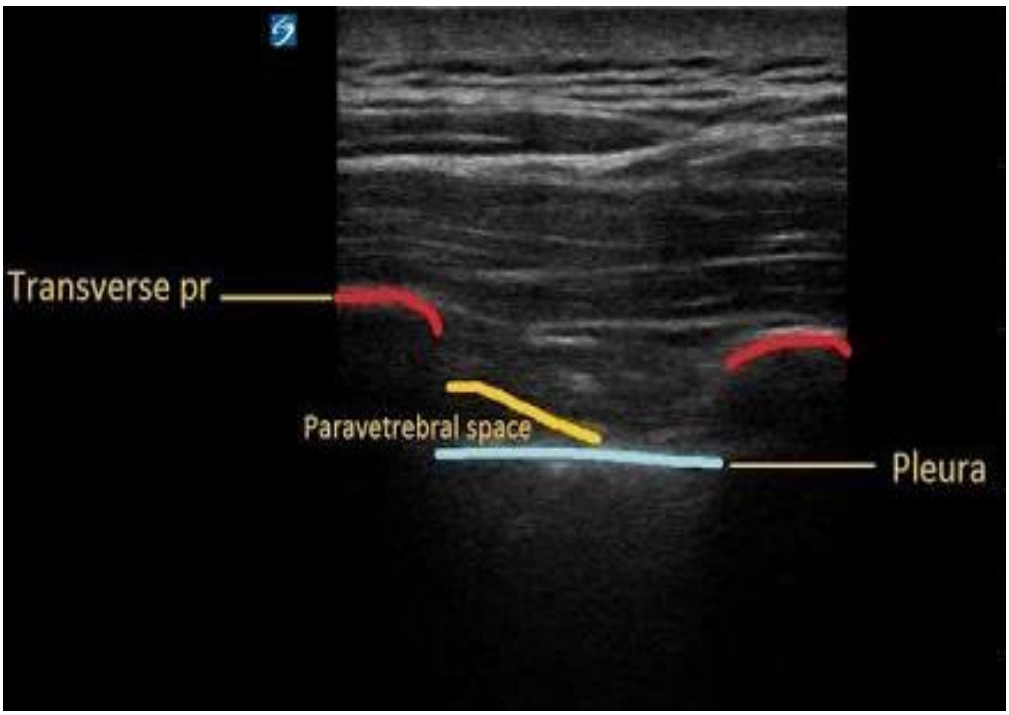
CONTRAINDICATIONS

1. Patient refusal.
2. Local sepsis .
3. Severe coagulopathy.
4. Tumours in the paravertebral space at the level of injection.
5. Allergy to local anaesthetic drugs.
6. Severe respiratory disease (where the patient depends on intercostals muscle function for ventilation).
7. Ipsilateral diaphragmatic paresis.

COMPLICATIONS

1. Incidence of pneumothorax when pleura is punctured [15].
2. Horner's syndrome (miosis, ptosis, anhydrosis) in blocks extending to T1 and T2.
3. Hypotension
4. Vascular puncture.

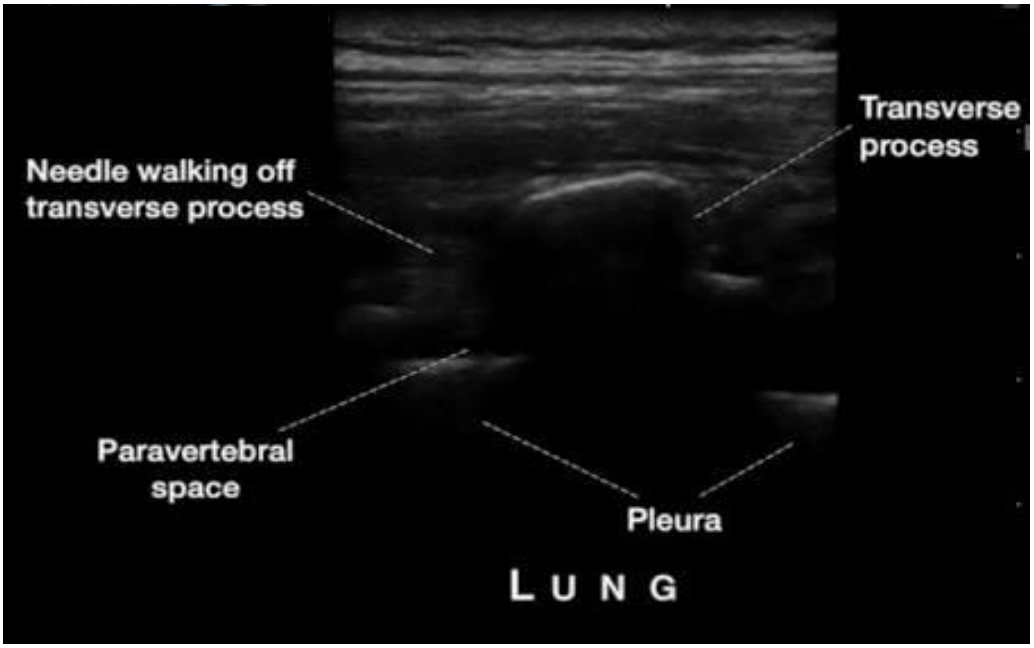
ULTRASOUND GUIDANCE FOR PARAVERTEBRAL BLOCK



A linear probe which is set at 5 MHz is selected and placed about 5 cms from the midline in a craniocaudal direction. Structures such as posterior (internal) intercostal membrane and pleura are identified. The probe is then moved medially to show the bony transition from rib to transverse process. The transverse process is always more superficial than the rib [(16).]

At this point the pleura will become less distinct so the probe is angulated laterally to improve the image and measure the distances between the skin, transverse process and pleura. Then the transverse process can be marked at the midpoint of the probe. In the ultrasound-guided approach, the probe is then removed and the paravertebral block is performed using the depth calculation to

improve needle placement. Due to tissue compression by the probe the actual needle to bone distance is usually slightly greater.



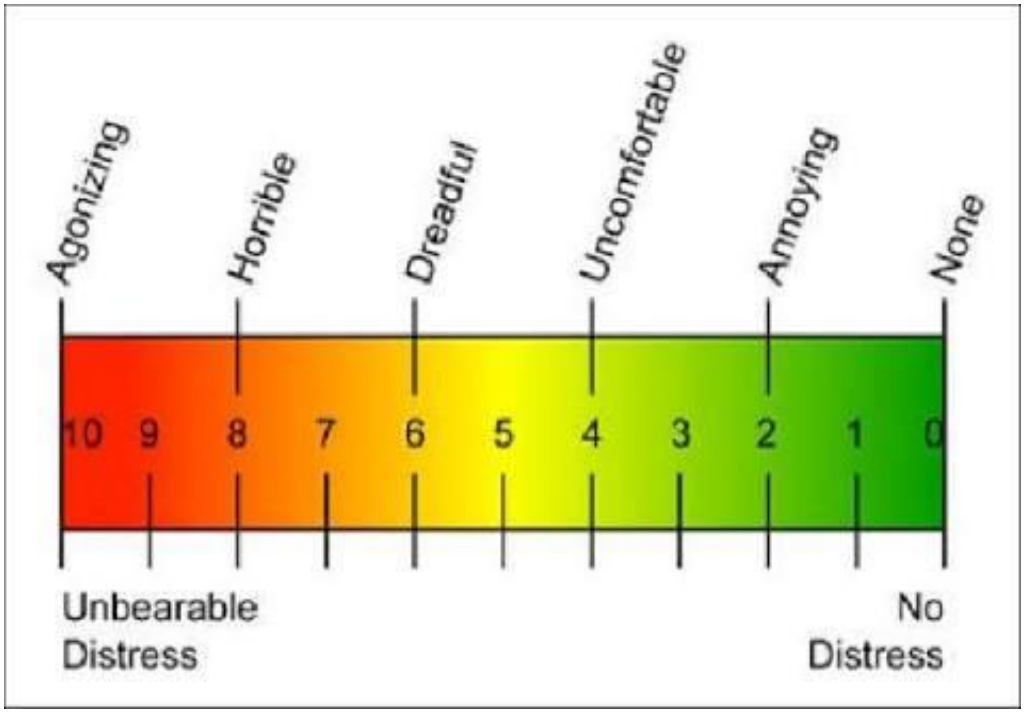
The needle is inserted into the paravertebral space alongside the probe in an ‘out-of-plane’ technique in the ultrasound-guided approach. The space between the pleura and costotransverse ligament will be seen to expand as local anaesthetic is injected. This expansion can be followed cranially and caudally to assess the need for additional injections. Insertion of the catheter can be done and the position is confirmed.

ASSESSMENT OF PAIN

In assessing acute pain after surgery, visual analogue scale (VAS) and numeric rating scale (NRS) are equally sensitive in assessment of pain intensity.

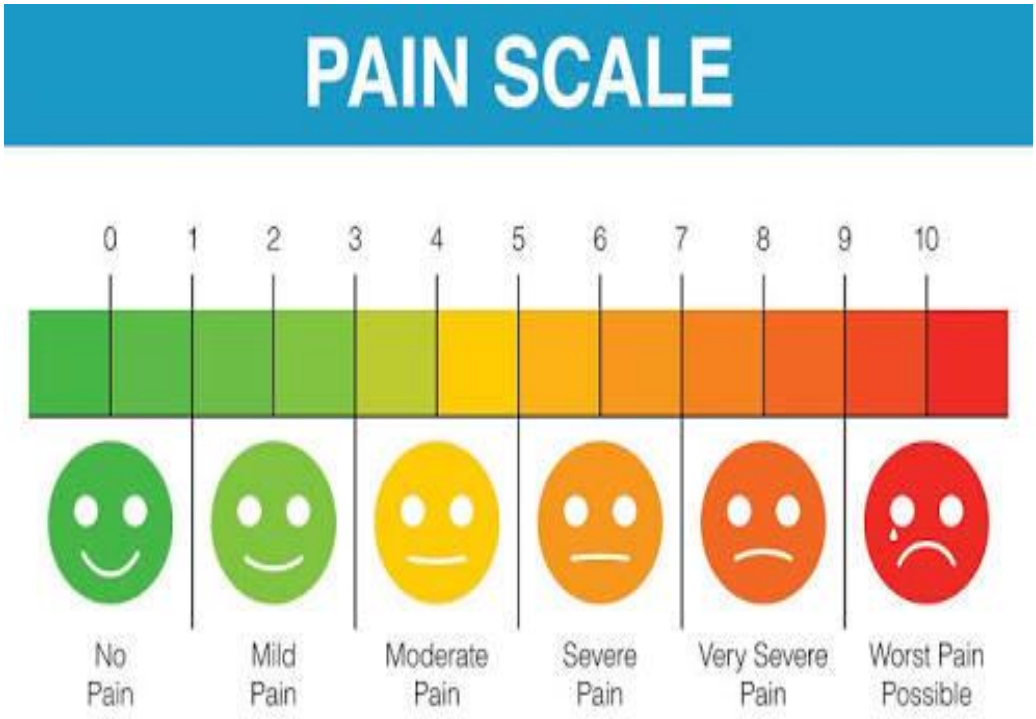
VISUAL ANALOGUE SCALE

It is usually presented as a 100-mm horizontal line. The patient's pain intensity is represented by a point between the extremes of "no pain at all" and "worst pain imaginable". VAS remains as the optimal tool for describing pain severity or intensity because of its simplicity, reliability, and validity as well as its ratio scale properties [17].



NUMERIC PAIN RATING SCALE

In adults it is an unidimensional measure of pain intensity for both acute and chronic pain.It is a segmented numeric version of the visual analog scale in which the patient selects a whole number (0-10) that best reflects the intensity of his/her pain. A horizontal bar or line is the common format.Scores range from 0-10 points. Greater pain intensity is indicated with higher scores [18].

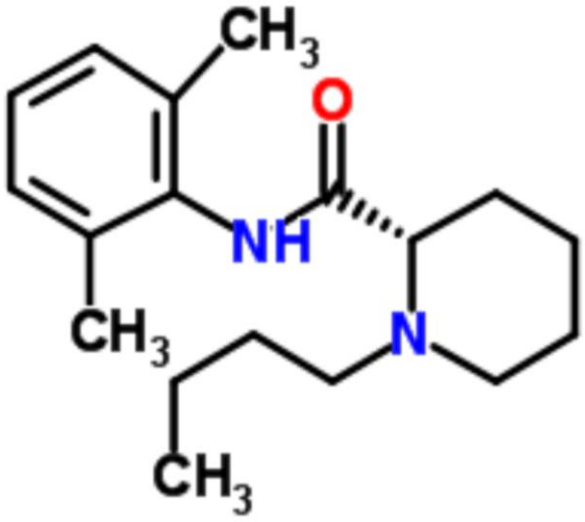


In my study I used the visual analog scale for the assessment of postoperative pain.

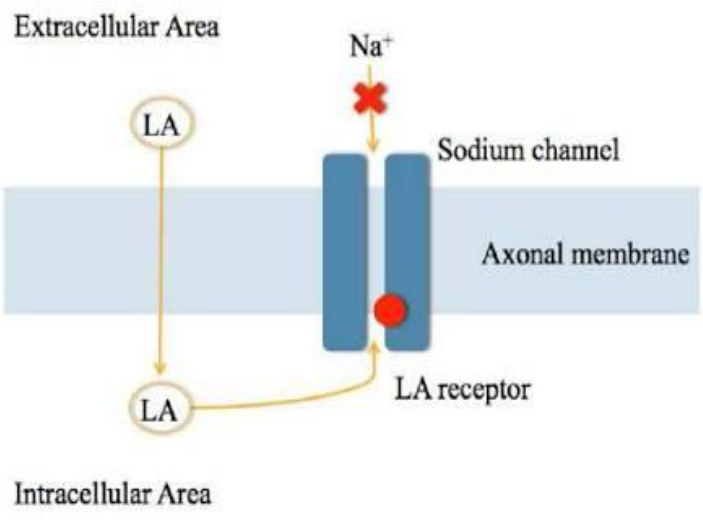
PHARMACOLOGY OF LEVOBUPIVACAINE

Levobupivacaine ([2S]-1-butyl-N- [2,6-dimethylphenyl] piperidine-2 carboxamide) is an amino-amide local anaesthetic drug belonging to the family of n-alkyl substitute pipecoloxylidide.It is the S-enantiomer of Bupivacaine [19].

Its chemical formula is C18H28N2O.Its structural formula is as follows:



MECHANISM OF ACTION



Levobupivacaine exerts its mechanism of action through blockade of sodium channels which is reversible[20]. Myelinated nerves are blocked more easily than unmyelinated nerves via the nodes of Ranvier and small nerves are blocked more easily than larger ones.

In general, the progression of anaesthesia is related to the myelination, diameter and velocity of conduction of the nerve fibers. The drug binds to the sodium channels intracellularly and depolarization is prevented by blocking the sodium influx into the nerve cells. Nerve conduction is blocked by interacting with voltage sensitive sodium channels on the cell membrane of sensory and motor nerves[20]. It also interferes with conduction and impulse transmission in other tissues.

PHARMACOKINETICS

The plasma concentration following therapeutic administration is determined by the dose and the route of administration of Levobupivacaine since absorption is dependent upon the tissue vascularity. The absorption of Levobupivacaine is biphasic after epidural administration. Small quantity of drug is absorbed rapidly into the circulation and remaining drug is absorbed slowly.

Doses up to 150 mg has shown mean Cmax levels up to 1.2 micrograms/mL [21]. The epidural absorption is affected by age as the fraction of drug absorbed decreases. In older age (aged > 70 years) there is shorter absorption phase compared with the younger (aged 18-44 years) patients. Lower

dose is recommended in older patients since they have an increased spread of analgesia by ~ 3 dermatomes.

The volume of distribution is 66.91 L. The pKa of Levobupivacaine is 8.1 and the half-life is 3.3h. The rate of clearance is 39.06 ± 13.29 L/h.

The main binding site for Levobupivacaine is alpha-1-glycoprotein [21]. Protein binding of Levobupivacaine is 97%. The percentage of drug that circulates free in the plasma is less than 3%. Unwanted side-effects and toxic manifestations can occur due to the free proportion of the drug acting on other tissues.

METABOLISM AND EXCRETION

Metabolism of Levobupivacaine is mediated by Cytochrome (CYP) CYP3A4 isoform and CYP1A2 isoform to Desbutyl Levobupivacaine and 3-hydroxy Levobupivacaine respectively which are inactive metabolites. 3-hydroxy Levobupivacaine is found to undergo further transformation to glucuronide and sulfate conjugates. These conjugates are then excreted in urine and feces.

THERAPEUTIC USES

Subarachnoid block:15 mg of Levobupivacaine, as intrathecal administration provides an adequate sensory and motor blockade lasting for approximately 6.5h [22]. Levobupivacaine produces a differential neuraxial

blockade at low concentrations with preservation of motor function which may be favorable for ambulatory surgery. Dose sparing effect of Levobupivacaine is achieved by addition of opioids.Less hemodynamic variations and increased quality of the block was seen during the peri-operative period.

Epidural anaesthesia: In thoracic epidural anaesthesia, administration of Levobupivacaine provides sensory block and stable hemodynamics in the intraoperative period as well as same duration of post-operative analgesia comparable to Bupivacaine after thoracic surgeries [(23).]

POST-OPERATIVE ANALGESIA:

EPIDURAL ANALGESIA:

In the post operative period, infusion of 15 mg/h of Levobupivacaine gives effective relief of pain[(24).] The concentration of Levobupivacaine determines the quality of analgesia.

WOUND INFILTRATION:

Infiltration of local anaesthetic along the incision line is used frequently to provide post-operative analgesia [(25).]

LABOR ANALGESIA

COMBINED SPINAL-EPIDURAL LABOR ANALGESIA

Combined spinal-epidural (CSE) is the widely used technique in obstetric patients to provide adequate analgesia. It provides effective and rapid onset analgesia with minimal risk of toxicity [26]. The minimum local analgesic dose administered intrathecally was 2.73-3.16mg for Levobupivacaine.

In CSE analgesia technique, intrathecal administration of Levobupivacaine and addition of Fentanyl to it prolongs the duration and increases the success rate of the sensory blockade. It also provides a local anaesthetic sparing effect with more effective analgesia and less motor blockade as compared with a double dose of each drug [27]. In addition of Epinephrine to a mixture of Levobupivacaine and opioid, the success rate of sensory blockade is increased, but the motor blockade is also increased.

EPIDURAL LABOR ANALGESIA

Because of less motor blockade and less toxicity as compared to Bupivacaine and a longer lasting analgesia Levobupivacaine is being favored in labor analgesia.Rather than the type of anaesthetics, the analgesic efficacy mainly depends on the concentration and atleast 0.1% is needed for satisfactory analgesia. With no significant influence on the mode of delivery, duration of labor, or neonatal outcome, Levobupivacaine confers adequate and safe labor analgesia [28].

OPHTHALMIC SURGERY

Levobupivacaine is used as a preferred local anaesthetic in various ocular blocks including peribulbar block for cataract surgery and retro bulbar block for vitreo-retinal surgery because of its low cardiovascular and neurological toxicity [29].

PEDIATRIC ANAESTHESIA

In pediatric anaesthesia, Levobupivacaine is being used increasingly for subarachnoid block, caudal block, epidural anesthesia and as a continuous epidural infusion for post-operative analgesia.

SUBARACHNOID BLOCK

For spinal anaesthesia, the dose of Levobupivacaine in neonates is slightly higher than for Bupivacaine or Ropivacaine. Dose that is appropriate for infant spinal anaesthesia is 1.2mg/kg of isobaric 0.5% Levobupivacaine [30].

CAUDAL BLOCK

The dose that is recommended for effective caudal anaesthesia has been reported to be 2.5 mg/kg of Levobupivacaine [31].

GERIATRIC ANESTHESIA

Elderly patients coming up for various surgeries such as transurethral resection of the prostate or bladder tumour, orthopaedic trauma or joint

replacement, cataract surgery, usually have some associated cardiac or pulmonary disease.

Levobupivacaine is considered to be a better local anaesthetic than Bupivacaine because of its safer pharmacological profile when used for subarachnoid block in the geriatric patients having associated co-morbid diseases and undergoing prostatic resections. Side-effects can be further reduced by addition of Fentanyl and also by decreasing the effective dose of Levobupivacaine for adequate analgesia [32].

PERIPHERAL NERVE BLOCK:

With the use of higher concentrations of Levobupivacaine (0.5-0.75%) the quality and duration of peripheral nerve block is improved . Levobupivacaine administered via a peripheral nerve block continuous catheter provides very good post-operative analgesia. It also decreases the post-operative systemic opioids requirements[33].

TOXICITY:

Toxicity that occurs is related to the unbound drug that is present in the plasma level and more likely due to an inadvertent intravenous injection. Central nervous system and cardiovascular system are primarily involved in the systemic toxic reactions. The amount of drug in the blood level required to produce central nervous system toxicity is less than that required to produce circulatory collapse [34].

CENTRAL NERVOUS SYSTEM TOXICITY:

Early symptoms of central nervous system toxicity are circumoral numbness, paraesthesia of the tongue, and dizziness.Sensory complaints include tinnitus and blurred vision. Excitatory signs such as restlessness, agitation, nervousness and paranoia often occurs earlier than signs of central nervous system depression such as slurred speech, drowsiness and unconsciousness.

The onset of tonic clonic seizures is heralded by muscle twitching and often followed by respiratory arrest.The selective blockade of inhibitory pathways are the reason for the occurrence of the excitatory reactions.

CARDIOVASCULAR SYSTEM TOXICITY:

There is a decrease in the rate of depolarization in the fast conducting tissue of purkinje fibres and the ventricular muscle. When compared to Lignocaine the rate of recovery of Levobupivacaine induced block is slower than that of Lignocaine. Signs such as sinus bradycardia, hypotension,atrioventricular heart block, idioventricular rhythms, and life threatening arrhythmias such as ventricular tachycardia, ventricular fibrillation and cardiac arrest occurs in case of extremely high concentration of the drug.

TREATMENT OF LEVOBUPIVACAINE TOXICITY:

Levobupivacaine has a safety margin of 1.3, which means that until the concentration rises by 30%, there are no toxic effects seen. The concentration

that is necessary to produce cardiac and neurotoxicity is higher for Levobupivacaine than for racemic Bupivacaine [35].

The presentations of Levobupivacaine toxicity were severe hypotension and bradycardia. The signs such as loss of consciousness, convulsions, hypotension and changes in QRS pattern of ECG occurs, after presumed intravenous injection during lumbar plexus block and signs such as loss of consciousness and convulsions occur after spinal, sciatic nerve and continuous lumbar plexus blocks. Treatment includes,

- Intubation, ventilator support, IV fluids, CPCR.
- 20% Intralipid (Lipid rescue)
- Administer 1.5ml/kg as initial bolus, the bolus can be repeated 1-2 times for persistent asystole. Start infusion of 0.25ml/kg/min for 30-45 mins; increase infusion rate up to 0.5ml/kg/min if hypotension is not responding.

SAFE DOSE OF LEVOBUPIVACAINE

The safe dose of Levobupivcaine is up to 3 mg/kg body weight.

CONTRAINDICATIONS

Levobupivacaine is contraindicated in patients with known hypersensitivity reactions to the drug or amino amide anaesthetics.

It is contraindicated in paracervical block in obstetrics since it is known to cause bradycardia and death of the fetus.

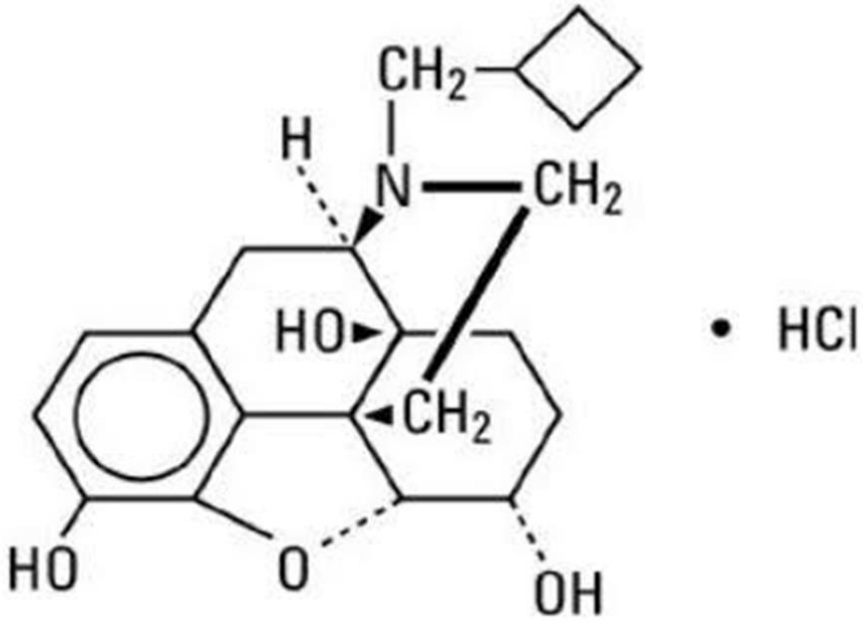
It is not used for intravenous regional anaesthesia (Bier block) because of risk of tourniquet failure and systemic absorption of the drug and cardiac arrest.

Levobupivacaine should be used with caution in patients with liver disease, epilepsy, impaired cardiovascular function and respiratory impairment.

PHARMACOLOGY OF NALBUPHINE

Nalbuphine (Nalbuphine hydrochloride) is a synthetic opioid agonist-antagonist analgesic. It belongs to the phenanthrene series. Opioid antagonist Naloxone and opioid analgesic Oxymorphone are chemically related to Nalbuphine hydrochloride. The chemical formula of Nalbuphine hydrochloride is 17-(cyclobutylmethyl)-4,5α-epoxymorphinan-3,6α,14-triol hydrochloride.

The molecular weight of Nalbuphine hydrochloride is 393.91.It is soluble in water, ethanol and insoluble in trichloromethane and ether. pKa of Nalbuphine hydrochloride is 8.71 and 9.96. The molecular formula of Nalbuphine hydrochloride is C21H27NO4.HCl. The structural formula is:



AVAILABILITY:

Nalbuphine is available in two concentrations, 10mg and 20mg of Nalbuphine hydrochloride per mL. The composition of Nalbuphine is 0.94% sodium citrate hydrous, 1.26% citric acid anhydrous, and 0.2% of a 9:1 mixture of methylparaben and propylparaben as preservatives; If necessary, with hydrochloric acid pH is adjusted to 3.5 to 3.7. The 10 mg/mL strength contains 0.2% sodium chloride.

Nalbuphine is also available in paraben-free formulation in two concentrations, 10 mg and 20 mg of Nalbuphine hydrochloride per ml in ampoules. One ml contains 0.94% sodium citrate hydrous and 1.26% citric acid anhydrous.

PHARMACOLOGY

Nalbuphine is a potent analgesic. The analgesic property of Nalbuphine on a milligram basis is critically equivalent to that of Morphine.Nalbuphine binds to mu, kappa, and delta but not to sigma receptors.It is a kappa agonist and partial mu antagonist [36].

After intravenous administration the onset of action is within 2 to 3 minutes. Following subcutaneous or intramuscular injection it is less than 15 minutes.

Nalbuphine has plasma half life of 3 to 6 hours.It has one-fourth opioid antagonist activity of Nalorphine and 10 times that of Pentazocine.Increase in dose greater than 30mg do not produce further respiratory depression and thus it exhibits a ceiling effect.

Nalbuphine has potent opioid antagonist activity by itself. Opioid-induced respiratory depression from the mu agonist analgesic is partially reversed or blocked by Nalbuphine when administered following or concurrent with mu agonist opioid analgesics such as Morphine, Oxymorphone, Fentanyl. In patients dependent on opioid drugs it may increase the withdrawal symptoms.

METABOLISM AND EXCRETION

Metabolism of Nalbuphine occurs in the liver to inactive glucuronide conjugates. Nalbuphine and its metabolites are excreted to a great extent in the feces. The elimination half life of nalbuphine is 3 to 6 hours.

INDICATIONS AND USAGE

1. Nalbuphine is indicated for the relief of moderate to severe pain.
2. In preoperative and postoperative analgesia it can also be used as a supplement to balanced anesthesia [37].

CONTRAINDICATIONS

1. Nalbuphine should not be administered to patients who are hypersensitive to the drug.
2. When Nalbuphine is administered during labour, severe fetal bradycardia, respiratory depression at birth, apnea, cyanosis and hypotonia can occur.
3. In the presence of head injury, intracranial lesions or a pre-existing increase in intracranial pressure the possible respiratory depressant effects and the ability of potent analgesics to elevate cerebrospinal fluid pressure (resulting from vasodilation following CO2 retention) may be markedly increased. So Nalbuphine should be administered with extreme caution in these circumstances and should be used only when essential.

INTERACTION WITH OTHER CENTRAL NERVOUS SYSTEM DEPRESSANTS

Concomitant administration of opioid analgesics, general anaesthetics, phenothiazines, tranquilizers, sedatives, hypnotics, or other CNS depressants including alcohol with Nalbuphine may exhibit an additive effect. The dose of one or both agents should be reduced when such combined therapy is used.

PRECAUTIONS

Impaired Respiration:

Nalbuphine induced respiratory depression can be reversed by Naloxone hydrochloride when indicated [(38).]

Impaired Renal or Hepatic Function:

Metabolism of Nalbuphine occurs in the liver and excretion occurs in the kidneys. In patients with renal or liver dysfunction, Nalbuphine should be used with caution and administered in reduced amounts.

Biliary Tract Surgery:

Nalbuphine causes spasm of the sphincter of Oddi, so it should be used with caution in patients about to undergo surgery of the biliary tract.

DOSAGE:

160mg/day is the maximum recommended human dose of Nalbuphine[(39).]

ADVERSE REACTIONS

The adverse reactions of Nalbuphine is as follows:

1. Sedation
2. Nausea and vomiting
3. Dizziness ,vertigo, head ache and dry mouth.
4. Nervousness, depression, restlessness, euphoria, floating, confusion, faintness, hallucinations, dysphoria, numbness and tingling.

OVERDOSAGE

In case of overdosage, an opiate antagonist such as Naloxone or Nalmefene is administered intravenously. It is a specific antidote.

Oxygen, intravenous fluids, vasopressors and other supportive measures should be used as indicated.

MATERIALS AND METHODS

SOURCE OF DATA:

Patients undergoing breast surgeries at Govt. Chengalpattu Medical College Hospital from November 2018 to April 2019 of six months duration were included in the study after obtaining written informed consent. Patients were assessed by applying inclusion and exclusion criteria.

SAMPLE SIZE: 60

STUDY

Effect of 0.125% of levobupivacaine versus 0.125% of levobupivacaine with nalbuphine as an adjuvant on thoracic paravertebral block to manage postoperative pain after breast surgeries.

DESCRIPTION:

Sample size was estimated to be 30 patients in each group . Sample size was calculated based on the pilot study.

STUDY DESIGN:

- Randomized controlled trial.

INCLUSION CRITERIA:

- Female patients.
- Women giving informed consent.

- ASA I, II and III patients posted for elective breast surgeries.
- Females of age group 18-60 years.

EXCLUSION CRITERIA

1. Women not giving consent
2. Women who are subjected to surgery on both sides or reconstruction of the breast.
3. Infection at the site of injection.
4. Anticoagulant use.
5. Coagulopathy.
6. Hypersensitivity to local anaesthetic agent.
7. Pregnant women.
8. Those with central neuropathy or those with renal or hepatic diseases.
9. Individuals with psychiatric disorders.
10. Overweight patients with a BMI > 30.
11. ASA IV patients.

EQUIPMENTS :

1. Sterile tray.
2. Sterile towel.
3. Sterile swabs.
4. Sponge holding forceps.

5. 10% of Povidone iodine solution.
6. 10 ml syringe.
7. 2ml syringe with 24 G needle.
8. 16-gauge Tuohy needle.
9. 5 ml glass syringe.
10. 0.25% of Levobupivacaine ampoule.
11. 10mg of Nalbuphine ampoule.

METHODOLOGY:

1. A total of 60 patients in the above mentioned inclusion criteria were selected. Patients were divided into two groups of 30 in each group. Patients selected were informed about the risks and benefits involved in performing the block. After getting informed consent patients who were willing to participate in the study were enrolled and analyzed.This study is a prospective, comparative study. Patients were evaluated preoperatively, examined and investigations done prior to the assessment.

2. Procedures were explained and informed written consent were obtained.The procedure was carried out in the operation theatre where facilities for resuscitation were available. Routine monitoring was done with ECG, Pulse Oximetry, NIBP, ETCO2.Intravenous cannulation done with 18G venflon and IV fluids started.Before block placement incremental doses of IV

midazolam(upto to a maximum dose of 0.06mg/kg) given to decrease anxiety and discomfort during the procedure.`

3. A group of 30 patients who received thoracic paravertebral block with 15cc of 0.125% of Levobupivacaine and followed by general anesthesia form Group A.

4. A group of 30 patients who received thoracic paravertebral block with 15cc of 0.125% of Levobupivacaine and 10mg of Nalbuphine followed by general anesthesia form Group B.

The patients were monitored meticulously throughout the surgery and post operatively by pulse oximetry, ECG, heart rate and noninvasive blood pressure for hemodynamic stability. Postoperatively pain was assessed and documented upto 48 hours.

Time to the first analgesic demand which is defined as time from completion of the paravertebral block injection till the time to the first analgesic demand was noted.

Incidence of postoperative nausea and vomiting were documented.Patient satisfaction was documented.Postoperative pain was assessed by Visual analog scale rating from 0 to 10. 0 indicates no pain, 10 indicates worst intolerable pain.VAS scores greater than 4 were treated with Tramadol 100mg IV and the time for need of first rescue analgesia was noted. Also the technique related

complications like hypotension,vascular puncture, pleural puncture, pneumothorax and Horner's syndrome were noted.

Data collected in the study was presented in a tabulated manner and the scoring of visual analogue scale, rescue medications,adverse effects and the associated complications were entered.

DATA ANALYSIS

Data analysis was performed using Microsoft Access and SPSS software version18. Two-way ANOVA test was used to compare quantitative parametric data. Benferroni post-hoc was used to test the significance between the two groups. Kruskal Wallis test was used to compare quantitative non parametric data. Chi square test was used to compare qualitative data .P value equal to or less than 0.05 was considered to be significant.

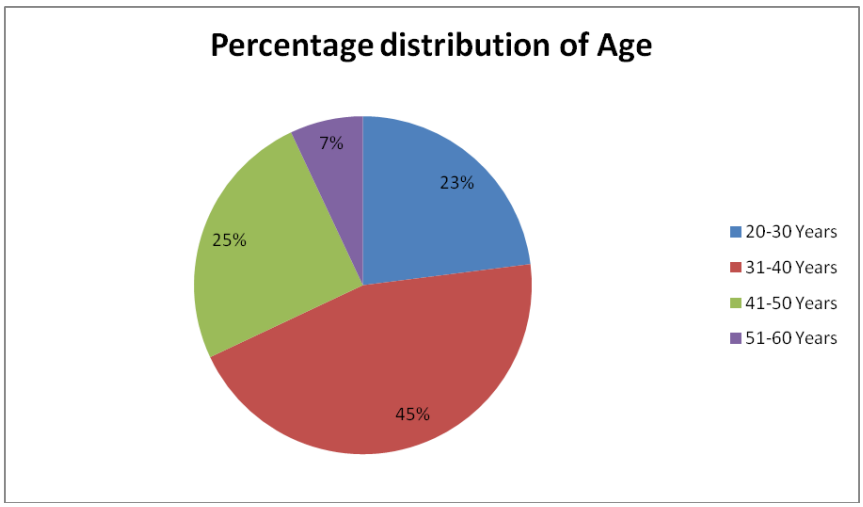
OBSERVATION AND RESULTS

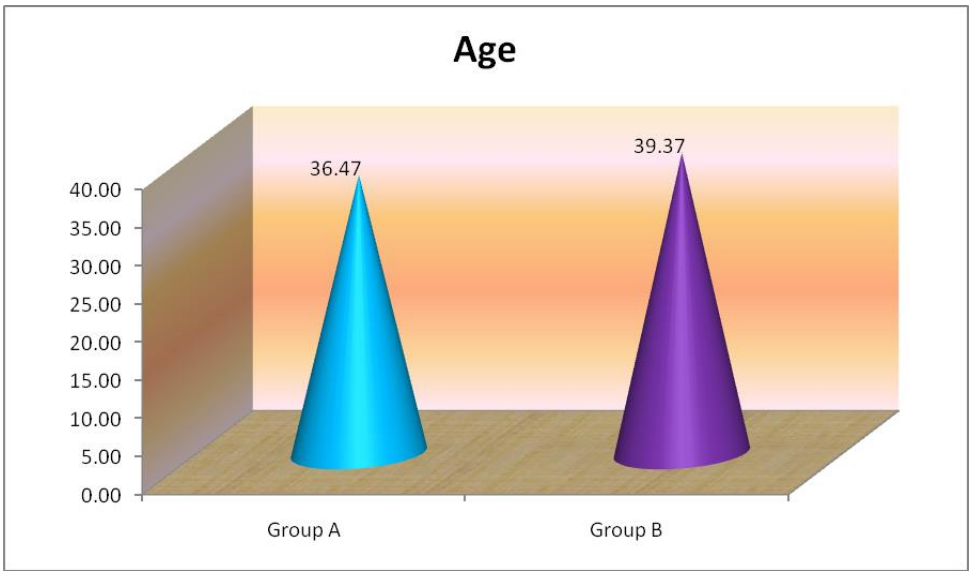
GROUPS:

Group	Intervention
Group A	Levobupivacaine only
Group B	Levobupivacaine and Nalbuphine

AGE DISTRIBUTION:

AGE GROUP	FREQUENCY	Percent
20-30 Years	14	23.3
31-40 Years	27	45.0
41-50 Years	15	25.0
51-60 Years	4	6.7
Total	60	100.0

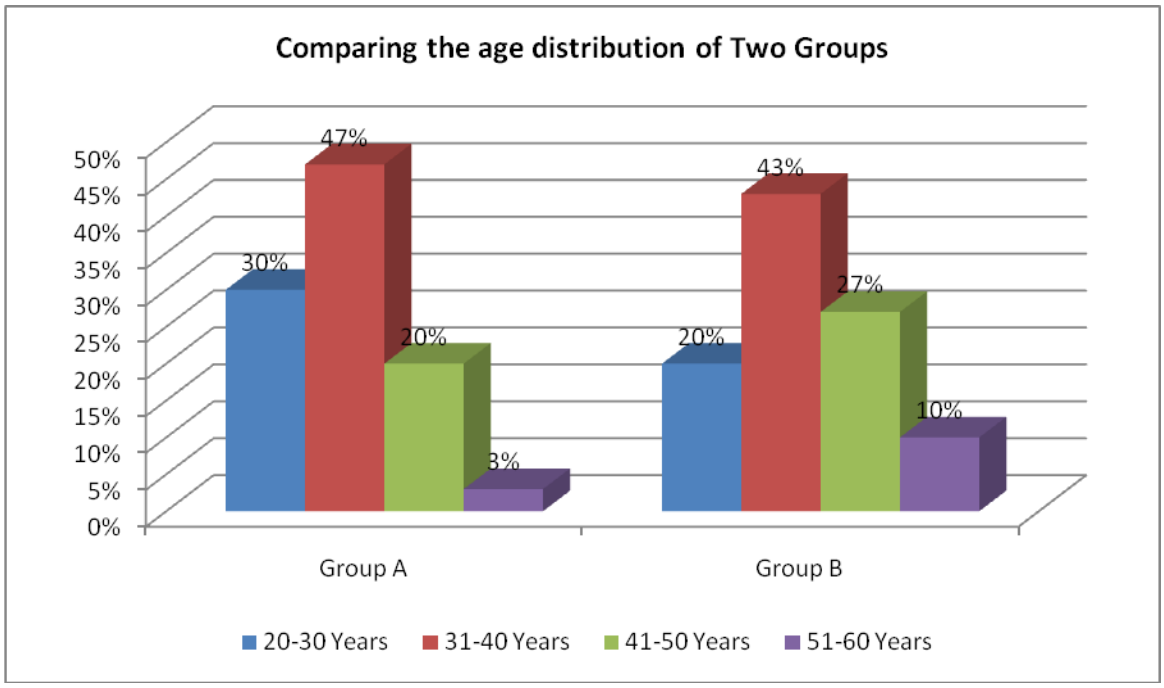




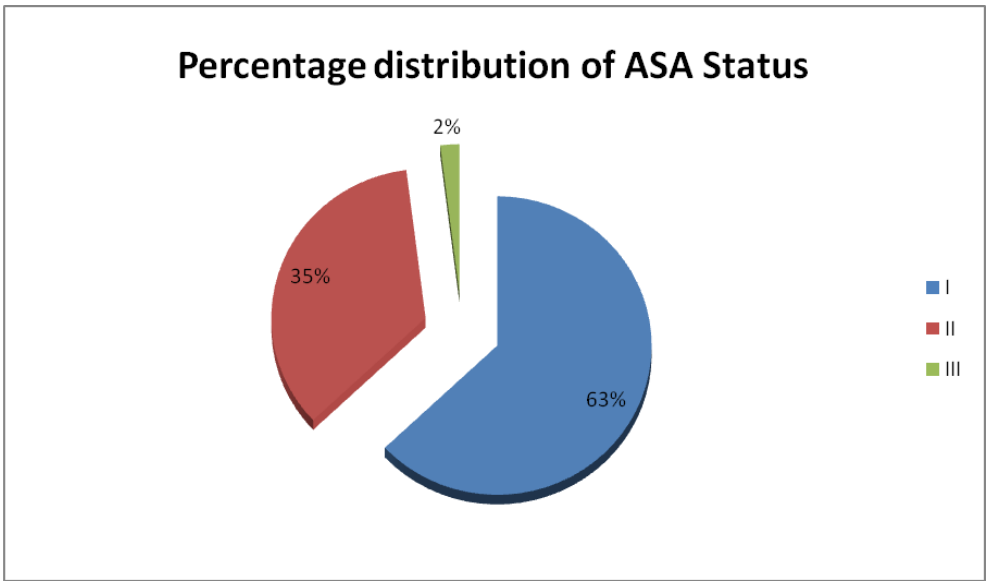
Majority of the group A patients belonged to 31-40 years age class interval (n=14, 46.7%) with a mean age of 36.467 years. In the group B patients, majority belonged to 31-40 years class interval (n=13, 43.3%) with a mean age of 39.367 years. The association between the intervention groups and age distribution is considered to be not statistically significant since $p > 0.05$ as per two way repeated measure ANOVA test.

			Group		Total
			Group A	Group B	
Age Group	20-30 Years	Count	9	6	15
		% within Group	30.0%	20.0%	25.0%
	31-40 Years	Count	14	13	27
		% within Group	46.7%	43.3%	45.0%
	41-50 Years	Count	6	8	14
		% within Group	20.0%	26.7%	23.3%
	51-60 Years	Count	1	3	4
		% within Group	3.3%	10.0%	6.7%
Total		Count	30	30	60
		% within Group	100.0%	100.0%	100.0%

Pearson Chi-Square=1.923 p=0.589



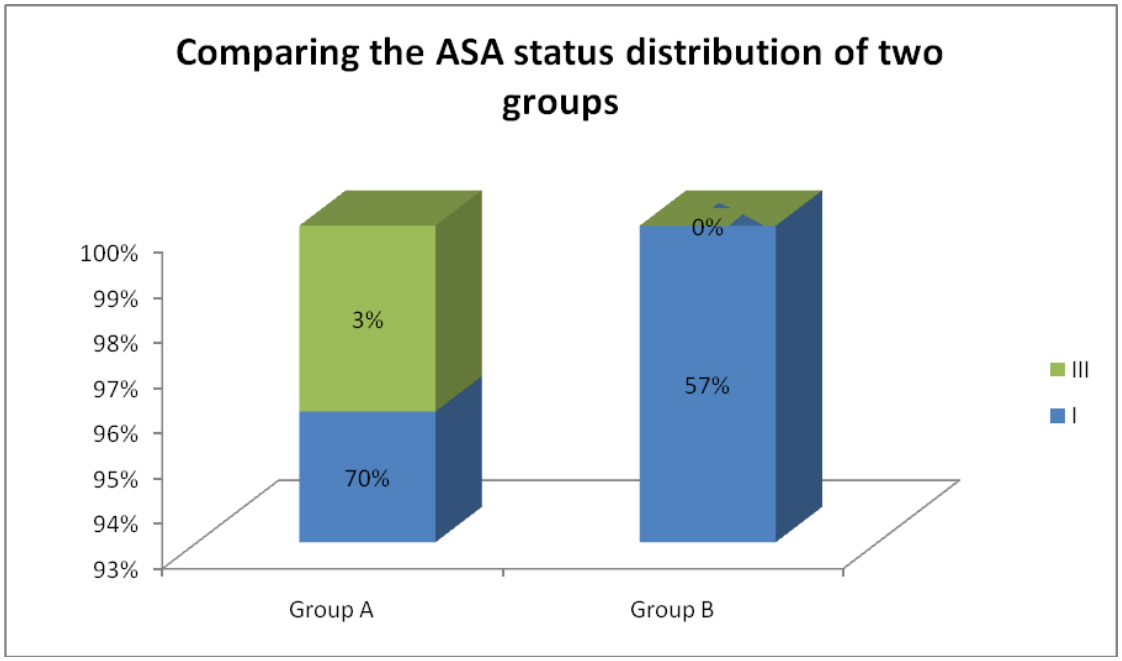
ASA PS STATUSASA Status	Frequency	Percent
I	38	63.3
II	21	35.0
III	1	1.7
Total	60	100.0



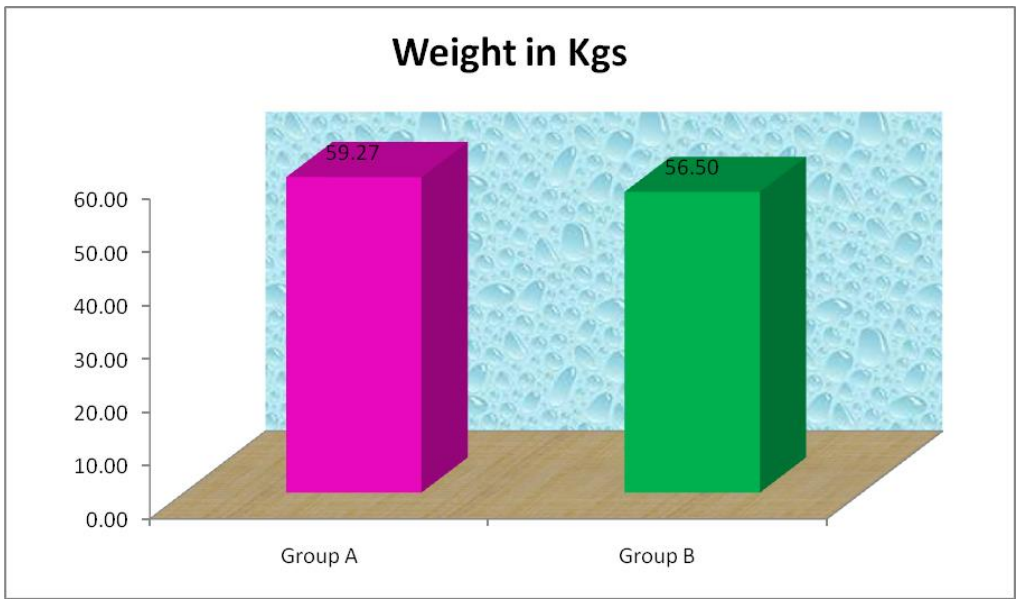
			Group		Total
			Group A	Group B	
ASA Status	I	Count	21	17	38
		% within Group	70.0%	56.7%	63.3%
	II	Count	8	13	21
		% within Group	26.7%	43.3%	35.0%
	III	Count	1	0	1
		% within Group	3.3%	0.0%	1.7%
Total		Count	30	30	60
		% within Group	100.0%	100.0%	100.0%

Pearson Chi-Square=2.612 p=0.271

Majority of the group A and B patients belonged to ASA I (n=21 and 17, 70% and 56.7% respectively). The association between the intervention groups and ASA PS Classification status is considered to be not statistically significant since $p > 0.05$ as per two way repeated measure ANOVA test.



WEIGHT DISTRIBUTION

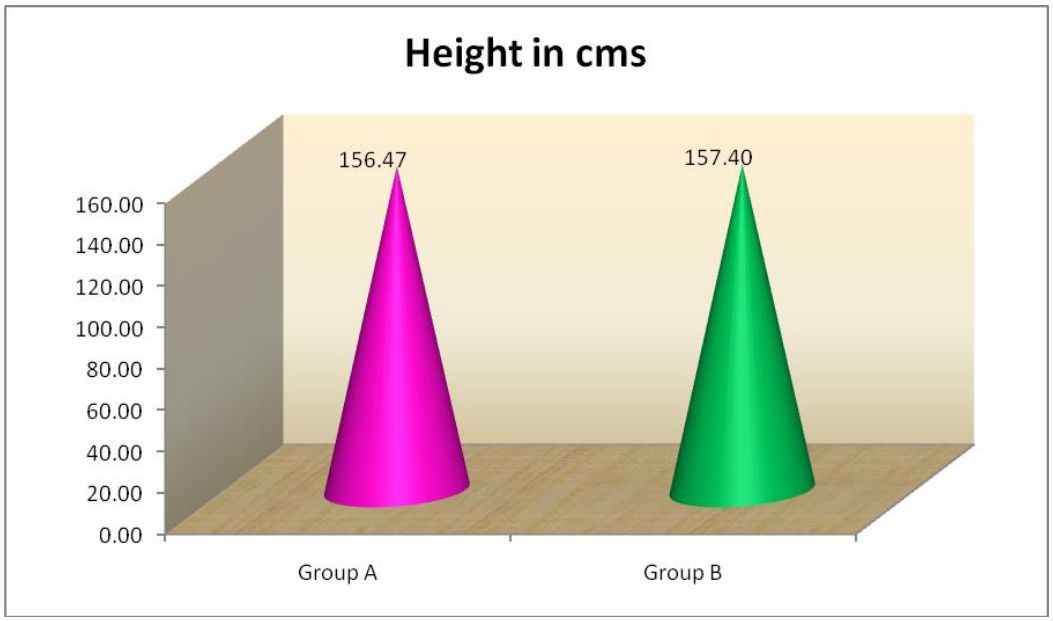


Majority of the group A patients belonged to 51-60 kgs weight class interval (n=19) with a mean weight of 59.267 kg. In the group B patients, majority belonged to 51-60 kgs weight class interval (n=21) with a mean weight of 56.50 kg. The association between the intervention groups and weight distribution is considered to be not statistically significant since $p > 0.05$ as per ANOVA test.

HEIGHT DISTRIBUTION

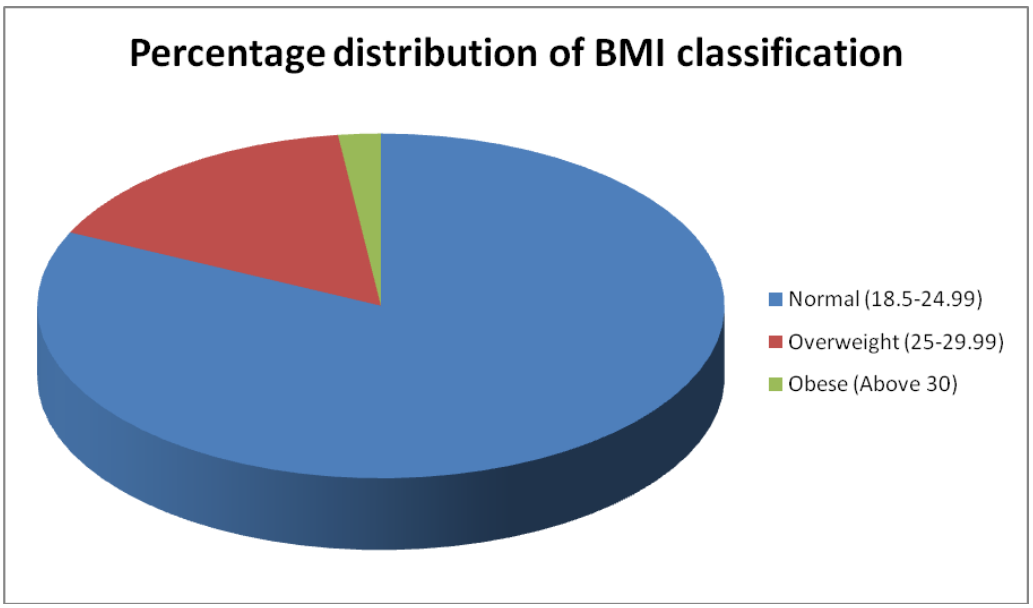
Majority of the group A patients belonged to 151-160 cms height class interval (n=18) with a mean height of 156.467 cms. In the group B patients, majority belonged to 151-160 cms height class interval (n=21) with a mean height of 157.400 cms. The association between the intervention groups and

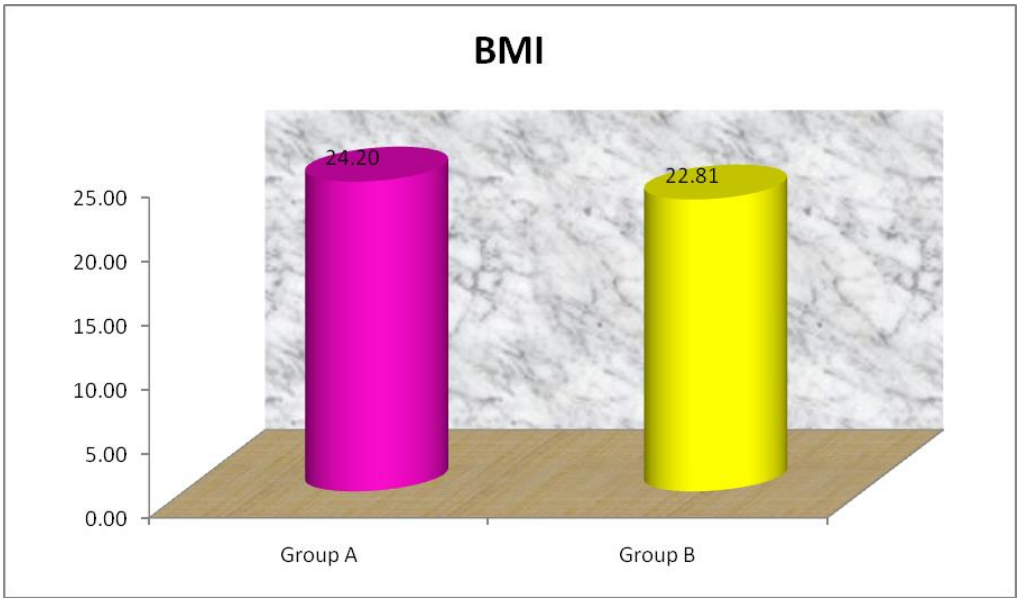
height distribution is considered to be not statistically significant since $p > 0.05$ as per ANOVA test.



BODY MASS INDEX

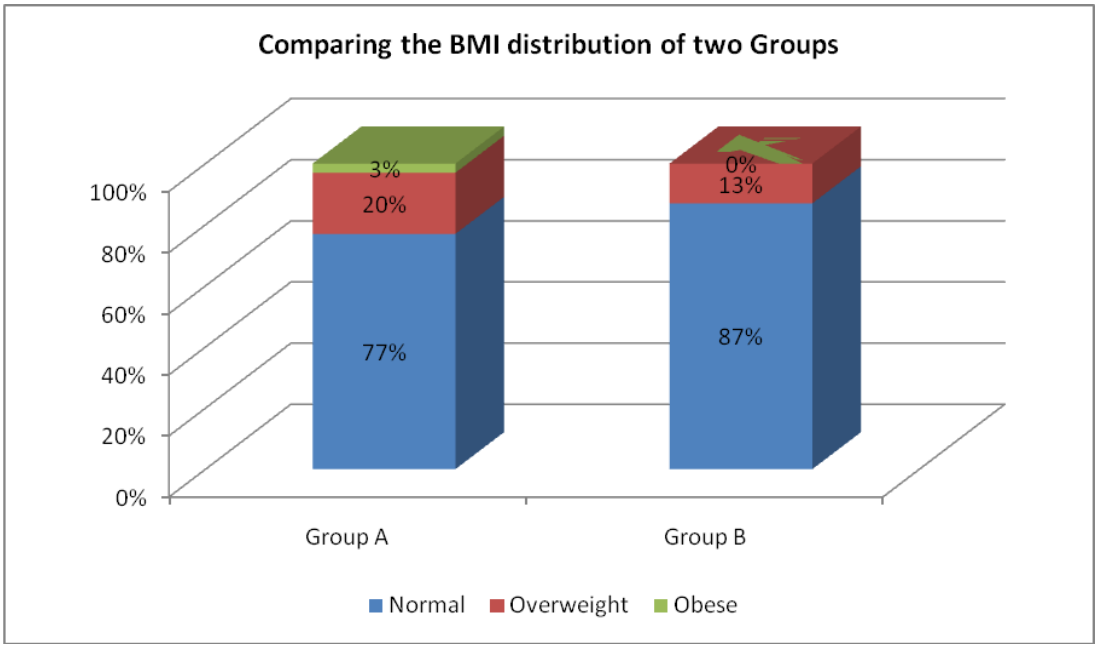
BMI	FREQUENCY	PERCENT
Normal (18.5-24.99)	49	81.7
Overweight (25-29.99)	10	16.7
Obese (Above 30)	1	1.7
Total	60	100.0


Percentage distribution of BMI classification
Normal (18.5-24.99)
Overweight (25-29.99)
Obese (Above 30)


BMI
24.20
22.81
25.00
20.00
15.00
10.00
5.00
0.00
Group A
Group B

					Total
			Group A	Group B	
BMI class	Normal (18.5-24.99)	Count	23	26	49
		% within Group	76.7%	86.7%	81.7%
	Overweight (25-29.99)	Count	6	4	10
		% within Group	20.0%	13.3%	16.7%
	Obese (Above 30)	Count	1	0	1
		% within Group	3.3%	0.0%	1.7%
Total		Count	30	30	60
		% within Group	100.0%	100.0%	100.0%

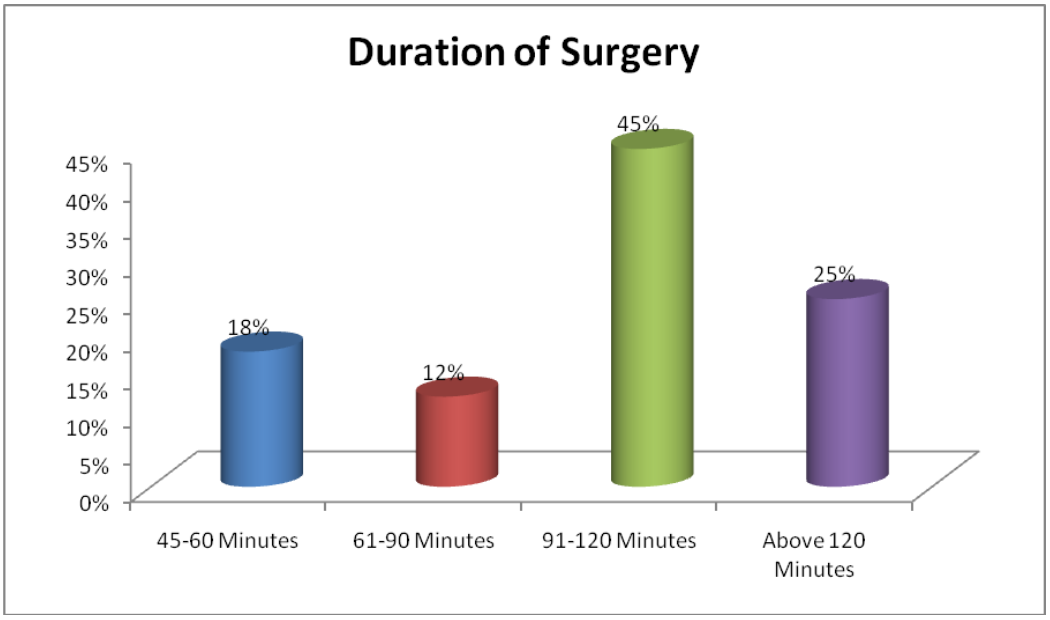
Pearson Chi-Square=1.584 p=0.453

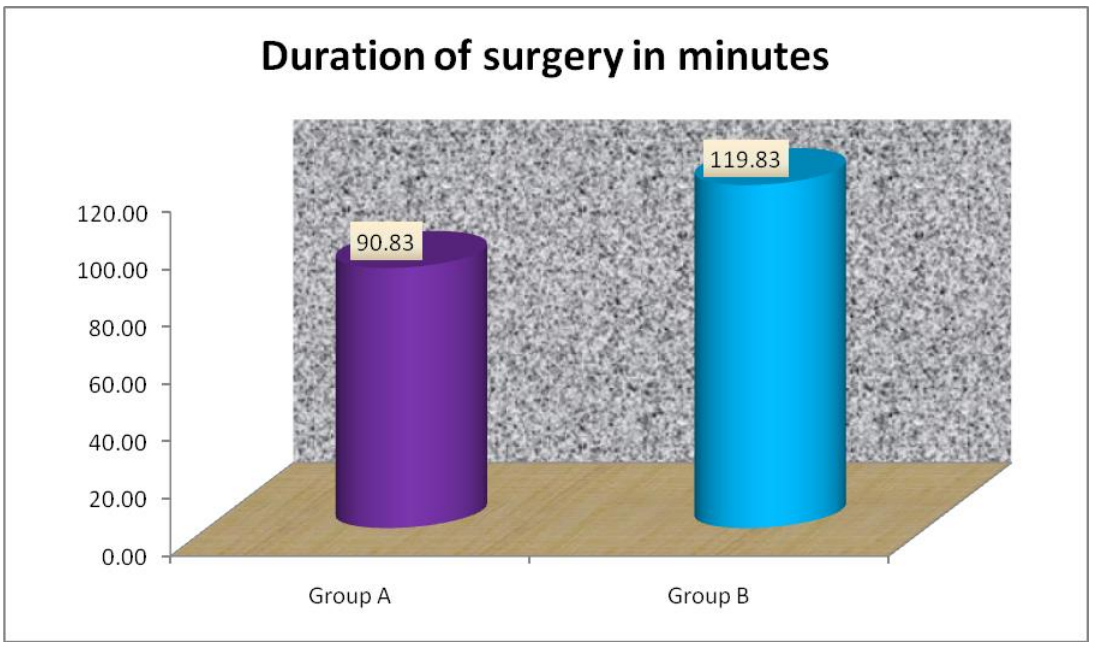


Majority of the group A patients belonged to normal BMI class interval (n=23, 76.7%) with a mean BMI of 24.200. In the group B patients, majority belonged to normal BMI class interval (n=26, 86.7%) with a mean BMI of 22.806. The association between the intervention groups and BMI distribution is considered to be not statistically significant since p > 0.05 as per two way repeated measure ANOVA test.

DURATION OF SURGERY

DURATION OF SURGERY	FREQUENCY	PERCENT
45-60 Minutes	11	18.3
61-90 Minutes	7	11.7
91-120 Minutes	27	45.0
Above 120 Minutes	15	25.0
Total	60	100.0

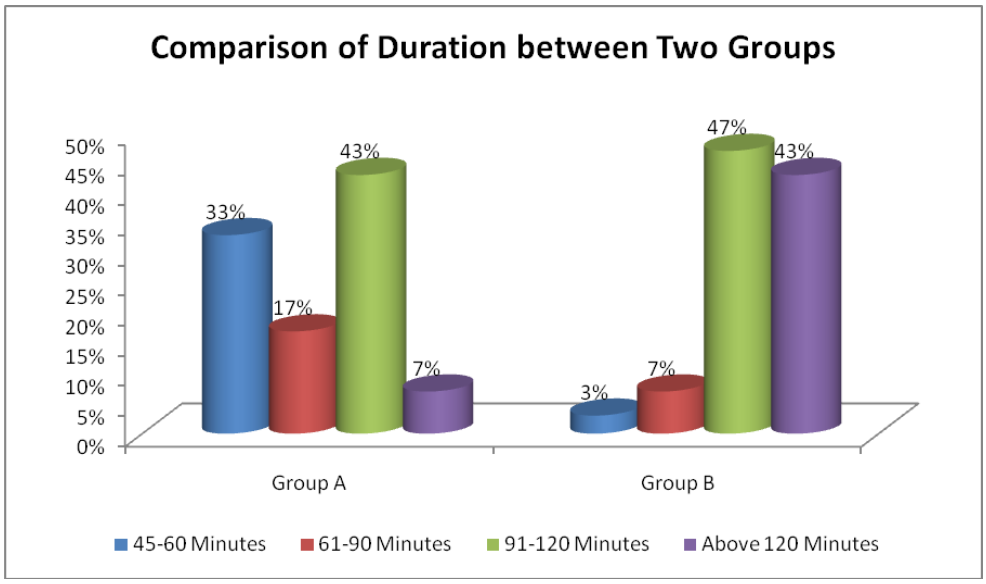




			Group		Total
			Group A	Group B	
Duration	45-60 Minutes	Count	10	1	11
		% within Group	33.3%	3.3%	18.3%
	61-90 Minutes	Count	5	2	7
		% within Group	16.7%	6.7%	11.7%
	91-120 Minutes	Count	13	14	27
		% within Group	43.3%	46.7%	45.0%
	Above 120 Minutes	Count	2	13	15
		% within Group	6.7%	43.3%	25.0%
Total		Count	30	30	60
		% within Group	100.0%	100.0%	100.0%

Pearson Chi-Square=16.753** p<0.001

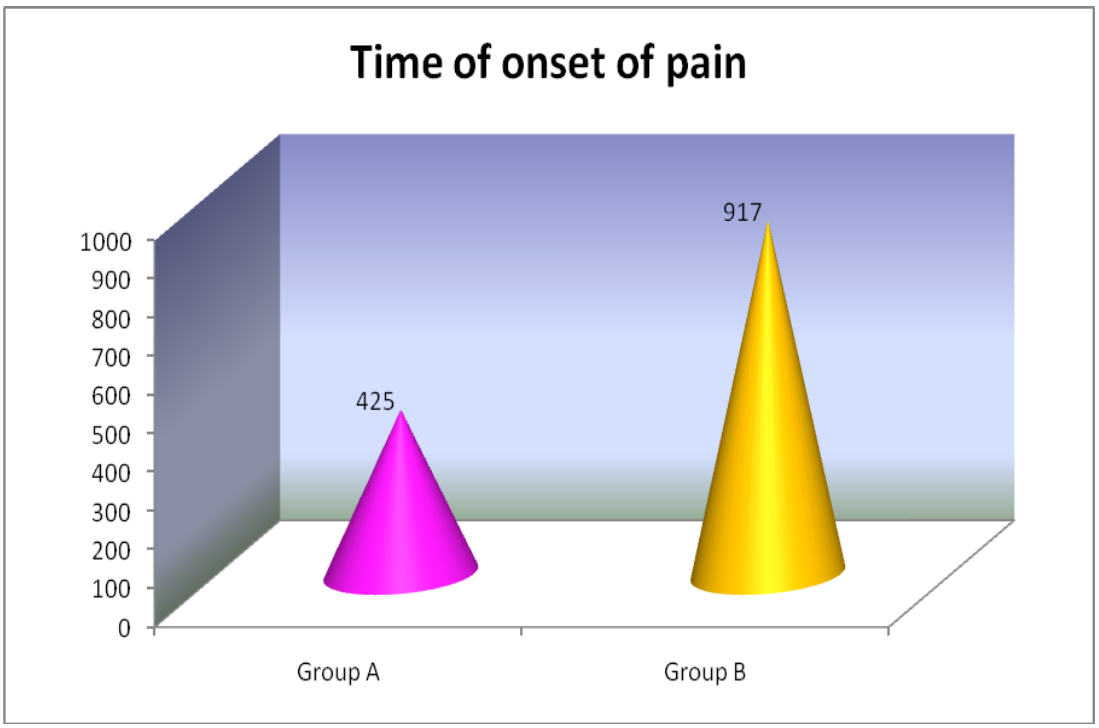
Majority of the group A patients belonged to 91-120 minutes duration of surgery class interval (n=13, 43.33%) with a mean duration of surgery of 90.833 minutes. In the group B patients, majority belonged to 91-120 minutes duration of surgery class interval (n=14, 46.7%) with a mean duration of surgery of 119.833 minutes. The association between the intervention groups and duration of surgery distribution is considered to be statistically significant since $p<0.05$ as per ANOVA test.



Independent t test						
	Group	N	Mean	Std. Deviation	Std. Error Mean	t value
Duration of surgery in minutes	Group A	30	90.8333	30.31681	5.53507	4.254**
	Group B	30	119.8333	21.79384	3.97899	
Time of onset of pain postoperatively (minutes)	Group A	30	425.3333	57.99723	10.58880	18.550**
	Group B	30	917.0000	133.08411	24.29772	

**p<0.001

TIME OF ONSET OF PAIN POSTOPERATIVELY



Majority of the group A patients belonged to 400-600 minutes, time of onset of pain postoperatively class interval (n=25) with a mean of 425.33 minutes. In the group B patients, majority belonged to 901-1200 minutes, time of onset of pain postoperatively class interval (n=26) with a mean of 917.0 minutes. The association between the intervention groups and time of onset of pain postoperatively is considered to be statistically significant since $p < 0.05$ as per two way repeated measure ANOVA test.

	Group	N	Mean	Std. Deviation	Std. Error Mean	t value	P value
AGE	Group A	30	36.467	8.123	1.483	1.375	0.174
	Group B	30	39.367	8.211	1.499		
Ht in cms	Group A	30	156.467	3.491	0.637	1.048	0.299
	Group B	30	157.400	3.410	0.623		
Wt in Kg	Group A	30	59.267	6.313	1.153	1.82	0.074
	Group B	30	56.500	5.425	0.990		
BMI in Kgm2	Group A	30	24.200	2.415	0.441	2.35	0.453
	Group B	30	22.806	2.174	0.397		
Duration of surgery in minutes	Group A	30	90.833	30.317	5.535	4.254**	p<0.001
	Group B	30	119.833	21.794	3.979		
Time of onset of pain postoperatively in minutes	Group A	30	425.333	57.997	10.589	18.55**	p<0.001
	Group B	30	917.000	133.084	24.298		

Comparison of VAS

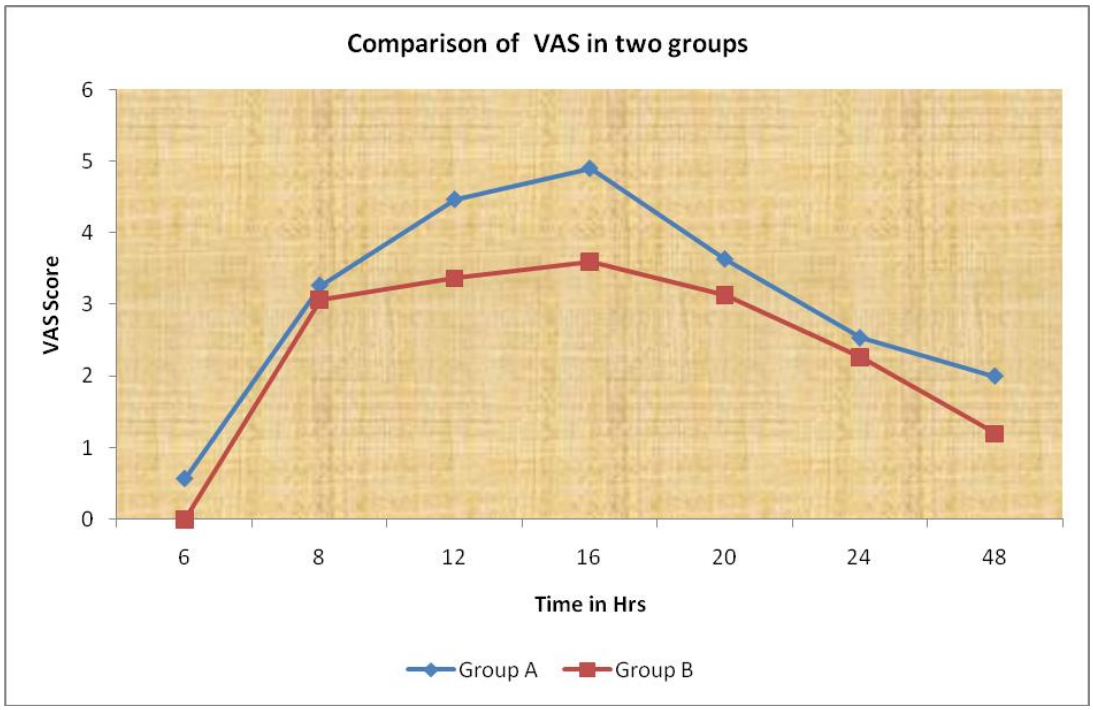
Descriptive Statistics				
	Group	Mean	Std. Deviation	N
6 Hrs	Group A	0.5667	1.30472	30
	Group B	0.0000	0.00000	30
	Total	0.2833	0.95831	60
8 Hrs	Group A	3.2667	1.14269	30
	Group B	3.0667	1.14269	30
	Total	3.1667	1.13745	60
12 Hrs	Group A	4.4667	0.81931	30
	Group B	3.3667	0.76489	30
	Total	3.9167	0.96184	60
16 Hrs	Group A	4.9000	1.68870	30
	Group B	3.6000	1.06997	30
	Total	4.2500	1.54728	60
20 Hrs	Group A	3.6333	1.44993	30
	Group B	3.1333	0.86037	30
	Total	3.3833	1.20861	60
24 Hrs	Group A	2.5333	1.10589	30
	Group B	2.2667	0.78492	30
	Total	2.4000	0.96023	60
48 Hrs	Group A	2.0000	1.20344	30
	Group B	1.2000	0.71438	30
	Total	1.6000	1.06086	60

Tests of Within-Subjects Effects					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	702.381	6	117.063	133.751**	0.000
Time * Group	15.324	6	2.554	2.918**	0.009
Error(Time)	304.581	348	0.875		

Note: There is difference in time and VAS score: Group B is better than Group A

4. Group * Time					
Measure: MEASURE 1					
Group	Time in Hrs	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Group A	6	0.567	0.168	0.229	0.904
	8	3.267	0.209	2.849	3.684
	12	4.467	0.145	4.177	4.756
	16	4.900	0.258	4.383	5.417
	20	3.633	0.218	3.198	4.069
	24	2.533	0.175	2.183	2.884
	48	2.000	0.181	1.638	2.362
Group B	6	0.000	0.168	-.337	0.337
	8	3.067	0.209	2.649	3.484
	12	3.367	0.145	3.077	3.656
	16	3.600	0.258	3.083	4.117
	20	3.133	0.218	2.698	3.569
	24	2.267	0.175	1.916	2.617
	48	1.200	0.181	0.838	1.562

At 6 hours post operatively group A and group B had a mean VAS score of 0.5667 and 0.000 respectively. At 8 hours post operatively group A and group B had a mean VAS score of 3.2667 and 3.0667 respectively. At 12 hours post operatively group A and group B had a mean VAS score of 4.4667 and 3.3667 respectively. At 16 hours post operatively group A and group B had a mean VAS score of 4.900 and 3.600 respectively. At 48 hours post operatively group A and group B had a mean VAS score of 2.000 and 1.200 respectively. The association between the intervention groups (group A Vs group B) and VAS score at 6, 8,12, 16 and 48 hours post operatively is considered to be statistically significant since $p < 0.05$ as per two way repeated measure ANOVA test.

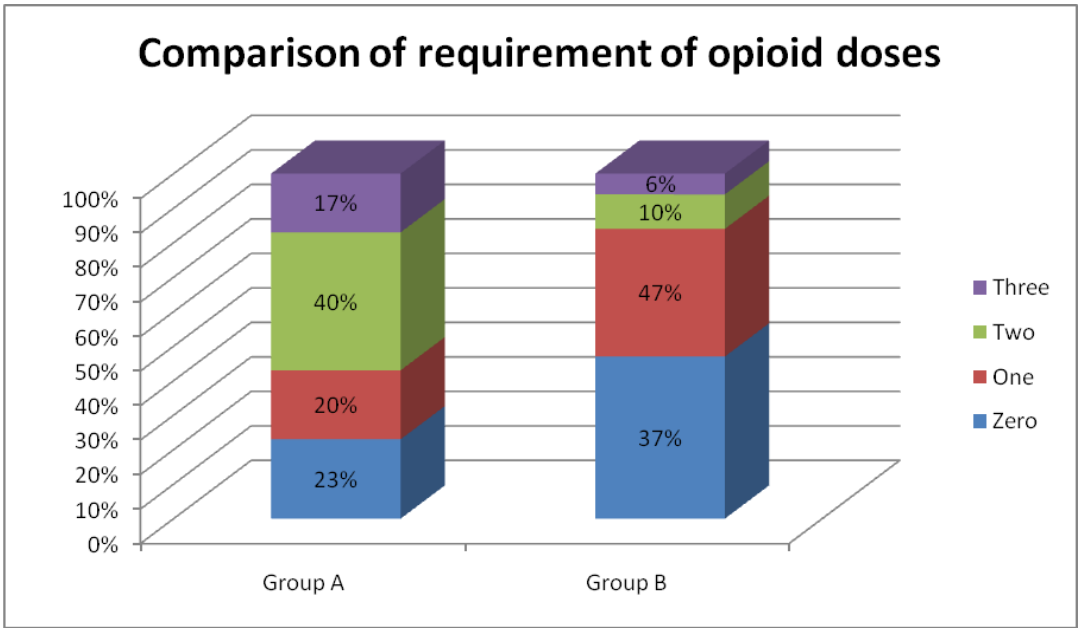


REQUIREMENT OF OPIOID DOSES

Requirement of opioid doses in 48 Hrs					
			Group		Total
			Group A	Group B	
Requirement of opioid **doses** in 48 Hrs	.00	Count	7	11	21
		% within Group	23.3%	6.7%	35.0%
	1.00	Count	6	14	17
		% within Group	20.0%	46.7%	28.3%
	2.00	Count	12	3	15
		% within Group	40.0%	10.0%	25.0%
	3.00	Count	5	2	7
		% within Group	16.7%	6.7%	11.7%
Total		Count	30	30	60
		% within Group	100.0%	100.0%	100.0%

Pearson Chi-Square=10.490* p=0.015

Majority of the group A patients required two doses of opioid in 48 hours (n=12, 40.0%). In the group B patients, majority required one dose of opioid in 48 hours (n=14, 46.7%).The association between the intervention groups (group A Vs group B) and number of doses of opioid required in 48 hours is considered to be statistically significant since $p < 0.05$ as per ANOVA test.



Comparison of PR

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
PR baseline	Group A	78.4667	7.31900	30
	Group B	74.7667	7.61887	30
	Total	76.6167	7.63820	60
30 M IOP PR	Group A	78.3333	5.03322	30
	Group B	76.8667	6.60059	30
	Total	77.6000	5.86631	60
1 HR IOP PR	Group A	77.9667	5.45504	30
	Group B	79.2000	4.36601	30
	Total	78.5833	4.93789	60
2 HR IOP PR	Group A	76.0000	5.55226	30
	Group B	75.8667	5.50694	30
	Total	75.9333	5.48300	60

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
0 HR POP PR	Group A	76.2333	5.33488	30
	Group B	76.3667	4.47586	30
	Total	76.3000	4.88269	60
30 M POP PR	Group A	76.3000	5.31848	30
	Group B	78.1000	5.32625	30
	Total	77.2000	5.35455	60
1 HR POP PR	Group A	76.3667	5.56766	30
	Group B	78.2000	5.42917	30
	Total	77.2833	5.52986	60
2 HR POP PR	Group A	74.7667	5.78156	30
	Group B	75.5000	4.73250	30
	Total	75.1333	5.25120	60
4 HR POP PR	Group A	79.0667	6.29139	30
	Group B	77.0667	6.03400	30
	Total	78.0667	6.19422	60
8 HR POP PR	Group A	77.6667	5.10127	30
	Group B	78.2333	5.92879	30
	Total	77.9500	5.49090	60
12 HR POP PR	Group A	77.1667	5.97745	30
	Group B	76.5333	5.32226	30
	Total	76.8500	5.62026	60
16 HR POP PR	Group A	75.8667	5.27671	30
	Group B	78.8000	5.19549	30
	Total	77.3333	5.39826	60

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
20 HR POP PR	Group A	76.9667	6.04856	30
	Group B	77.7333	5.80685	30
	Total	77.3500	5.89117	60
24 HR POP PR	Group A	75.6667	6.17187	30
	Group B	76.3667	5.31415	30
	Total	76.0167	5.72089	60
36 HR POP PR	Group A	76.5667	5.71558	30
	Group B	77.5000	5.16453	30
	Total	77.0333	5.42113	60
48 HR POP PR	Group A	77.4000	5.44312	30
	Group B	76.8667	5.27017	30
	Total	77.1333	5.31855	60

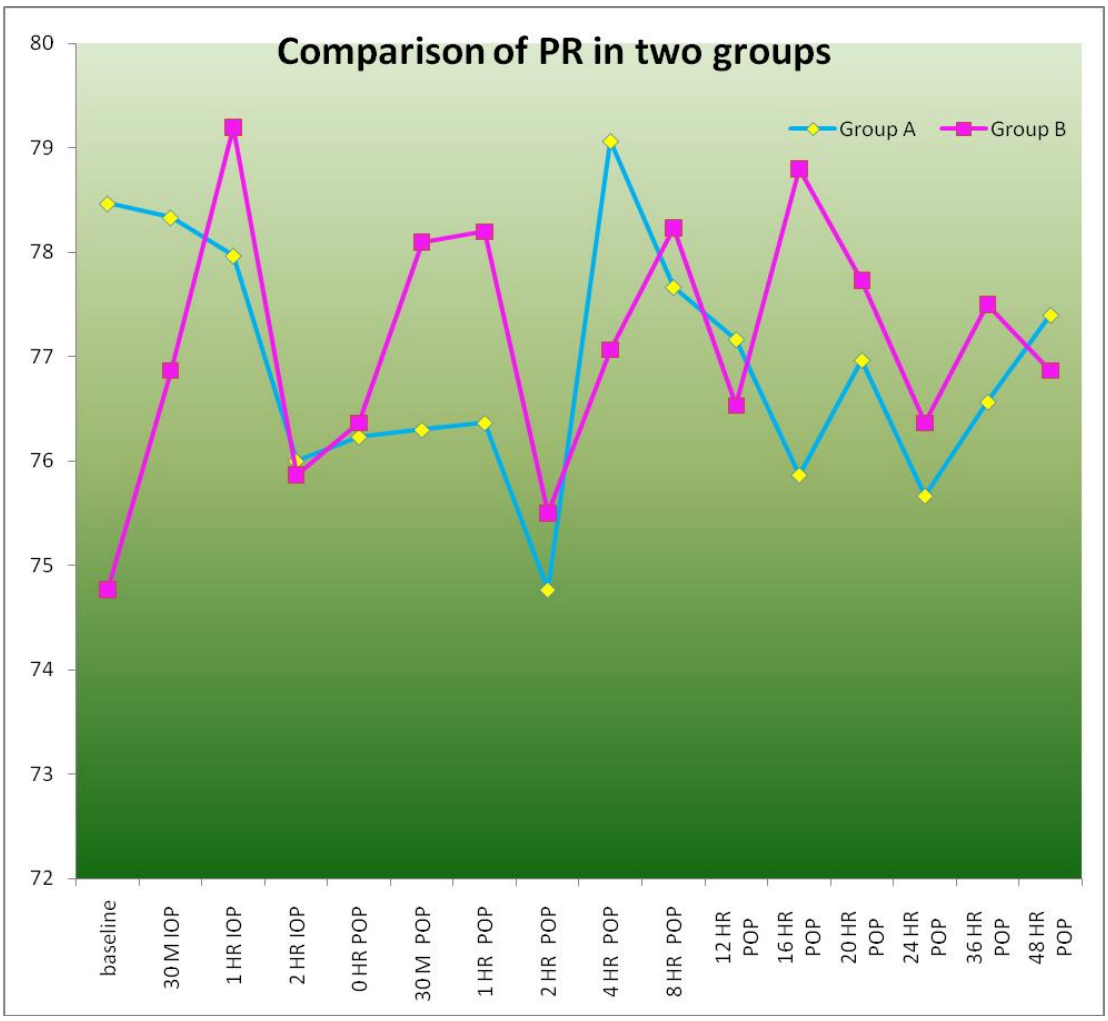
At baseline, group A and group B patients had a mean Pulse rate of 78.4667 and 74.7667 beats per minute respectively. At 48 hours, group A and group B patients had a mean Pulse rate of 77.4000 and 76.8667 beats per minute respectively. As per two way repeated measure ANOVA test the association between the intervention groups (group A Vs group B) and pulse rate from baseline to 48 hours postoperatively is considered to be not statistically significant since $p > 0.05$.

Tests of Within-Subjects Effects					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	691.166	15	46.078	1.431	0.126
Time * Group	592.049	15	39.470	1.225	0.246
Error(Time)	28022.098	870	32.209		

4. Group * Time					
Group	Time	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Group A	PR baseline	78.467	1.364	75.737	81.197
	30 M IOP PR	78.333	1.072	76.188	80.478
	1 HR IOP PR	77.967	0.902	76.161	79.772
	2 HR IOP PR	76.000	1.010	73.979	78.021
	0 HR POP PR	76.233	0.899	74.434	78.033
	30 M POP PR	76.300	0.972	74.355	78.245
	1 HR POP PR	76.367	1.004	74.357	78.376
	2 HR POP PR	74.767	0.965	72.836	76.697
	4 HR POP PR	79.067	1.125	76.814	81.319
	8 HR POP PR	77.667	1.010	75.645	79.688
	12 HR POP PR	77.167	1.033	75.098	79.235
	16 HR POP PR	75.867	0.956	73.953	77.780
	20 HR POP PR	76.967	1.082	74.800	79.133

	24 HR POP PR	75.667	1.051	73.562	77.771
	36 HR POP PR	76.567	0.994	74.576	78.557
	48 HR POP PR	77.400	0.978	75.442	79.358

Group B	PR baseline	74.767	1.364	72.037	77.497
	30 M IOP PR	76.867	1.072	74.722	79.012
	1 HR IOP PR	79.200	0.902	77.394	81.006
	2 HR IOP PR	75.867	1.010	73.846	77.888
	0 HR POP PR	76.367	0.899	74.567	78.166
	30 M POP PR	78.100	0.972	76.155	80.045
	1 HR POP PR	78.200	1.004	76.190	80.210
	2 HR POP PR	75.500	0.965	73.569	77.431
	4 HR POP PR	77.067	1.125	74.814	79.319
	8 HR POP PR	78.233	1.010	76.212	80.255
	12 HR POP PR	76.533	1.033	74.465	78.602
	16 HR POP PR	78.800	0.956	76.886	80.714
	20 HR POP PR	77.733	1.082	75.567	79.900
	24 HR POP PR	76.367	1.051	74.262	78.471
	36 HR POP PR	77.500	0.994	75.509	79.491
	48 HR POP PR	76.867	0.978	74.909	78.825



Comparison of MAP

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
MAP baseline	Group A	86.5333	8.18212	30
	Group B	84.1000	8.02732	30
	Total	85.3167	8.12924	60
30 M IOP MAP	Group A	85.8667	7.47286	30
	Group B	84.7333	7.34816	30
	Total	85.3000	7.36989	60

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
1 HR IOP MAP	Group A	83.4333	7.16641	30
	Group B	86.9333	5.72311	30
	Total	85.1833	6.66763	60
2 HR IOP MAP	Group A	82.5667	8.71259	30
	Group B	83.9333	7.95216	30
	Total	83.2500	8.29871	60
0 HR POP MAP	Group A	85.0333	7.23251	30
	Group B	84.4000	7.48608	30
	Total	84.7167	7.30473	60
30 M POP MAP	Group A	82.9667	6.64096	30
	Group B	84.0667	6.60686	30
	Total	83.5167	6.59093	60
1 HR POP MAP	Group A	84.7667	6.64718	30
	Group B	85.5333	7.65071	30
	Total	85.1500	7.11605	60
2 HR POP MAP	Group A	80.6000	6.57896	30
	Group B	84.2667	6.46440	30
	Total	82.4333	6.72553	60
4 HR POP MAP	Group A	83.3667	7.42077	30
	Group B	84.2000	7.20823	30
	Total	83.7833	7.26518	60
8 HR POP MAP	Group A	83.9333	7.94782	30
	Group B	82.3333	6.42910	30
	Total	83.1333	7.21220	60
12 HR POP MAP	Group A	85.2000	6.66644	30
	Group B	82.2333	7.51405	30
	Total	83.7167	7.19956	60
16 HR POP MAP	Group A	82.0667	7.41821	30
	Group B	81.1333	7.51428	30

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
	Total	81.6000	7.41780	60
20 HR POP MAP	Group A	85.2667	7.38560	30
	Group B	83.7000	7.05227	30
	Total	84.4833	7.20285	60
24 HR POP MAP	Group A	85.7000	7.38194	30
	Group B	85.8667	7.31429	30
	Total	85.7833	7.28614	60
36 HR POP MAP	Group A	81.6667	6.61416	30
	Group B	86.8000	7.32685	30
	Total	84.2333	7.38842	60
48 HR POP MAP	Group A	84.3667	7.64507	30
	Group B	81.4333	7.57347	30
	Total	82.9000	7.68820	60

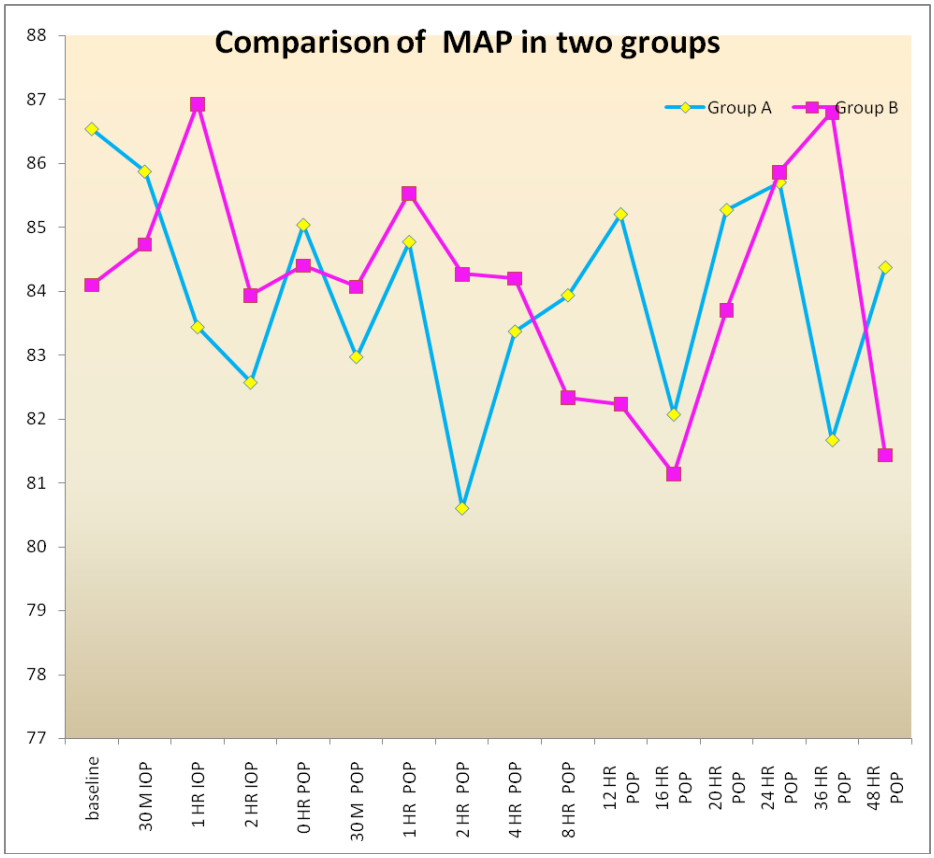
Tests of Within-Subjects Effects					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	1272.696	15	84.846	1.607	0.066
Time * Group	1304.863	15	86.991	1.648	0.056
Error(Time)	45933.067	870	52.797		

At baseline, group A and group B patients had a mean MAP of 86.5333 and 84.1000 mm Hg respectively. At 48 hours, group A and group B and patients had a mean MAP of 84.3667 and 81.4333 mm Hg respectively. The association

between the intervention groups (group A Vs group B) and MAP from baseline to 48 hours postoperatively is considered to be not statistically significant since p > 0.05 as per two way repeated measure ANOVA test.

4. Group * Time					
Group	**Time**	**Mean**	**Std. Error**	**95% Confidence Interval**	
				Lower Bound	**Upper Bound**
Group A	baseline	86.533	1.480	83.571	89.495
	30 M IOP	85.867	1.353	83.158	88.575
	1 HR IOP	83.433	1.184	81.063	85.803
	2 HR IOP	82.567	1.523	79.518	85.615
	0 HR POP	85.033	1.344	82.343	87.723
	30 M POP	82.967	1.209	80.546	85.387
	1 HR POP	84.767	1.308	82.148	87.386
	2 HR POP	80.600	1.191	78.216	82.984
	4 HR POP	83.367	1.336	80.693	86.040
	8 HR POP	83.933	1.320	81.292	86.575
	12 HR POP	85.200	1.297	82.604	87.796
	16 HR POP	82.067	1.363	79.338	84.795
	20 HR POP	85.267	1.318	82.628	87.906
	24 HR POP	85.700	1.342	83.015	88.385
	36 HR POP	81.667	1.274	79.116	84.217
	48 HR POP	84.367	1.389	81.586	87.148
Group B	baseline	84.100	1.480	81.138	87.062
	30 M IOP	84.733	1.353	82.025	87.442
	1 HR IOP	86.933	1.184	84.563	89.303
	2 HR IOP	83.933	1.523	80.885	86.982
	0 HR POP	84.400	1.344	81.710	87.090
	30 M POP	84.067	1.209	81.646	86.487
	1 HR POP	85.533	1.308	82.914	88.152

4. Group * Time					
Group	Time	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
	2 HR POP	84.267	1.191	81.883	86.650
	4 HR POP	84.200	1.336	81.527	86.873
	8 HR POP	82.333	1.320	79.692	84.975
	12 HR POP	82.233	1.297	79.637	84.829
	16 HR POP	81.133	1.363	78.405	83.862
	20 HR POP	83.700	1.318	81.061	86.339
	24 HR POP	85.867	1.342	83.181	88.552
	36 HR POP	86.800	1.274	84.249	89.351
	48 HR POP	81.433	1.389	78.652	84.214



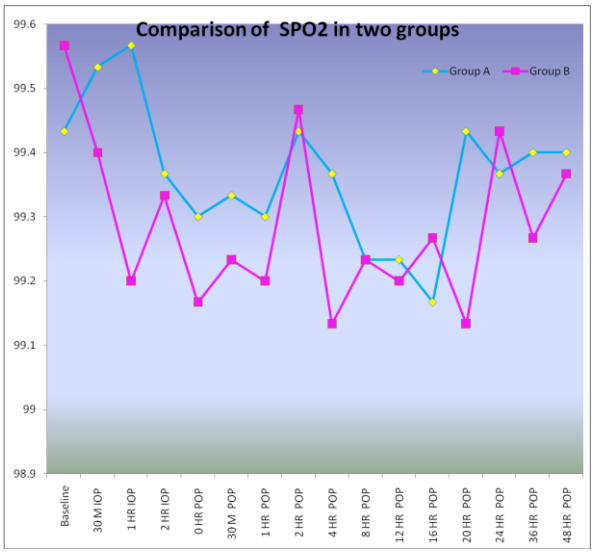
Comparison of peripheral capillary oxygen saturation

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
SPO2 baseline	Group A	99.4333	0.72793	30
	Group B	99.5667	0.62606	30
	Total	99.5000	0.67648	60
30 M IOP SPO2	Group A	99.5333	0.62881	30
	Group B	99.4000	0.56324	30
	Total	99.4667	0.59565	60
1 HR IOP SPO2	Group A	99.5667	0.62606	30
	Group B	99.2000	0.48423	30
	Total	99.3833	0.58488	60
2 HR IOP SPO2	Group A	99.3667	0.71840	30
	Group B	99.3333	0.60648	30
	Total	99.3500	0.65935	60
0 HR IOP SPO2	Group A	99.3000	0.74971	30
	Group B	99.1667	0.74664	30
	Total	99.2333	0.74485	60
30 M IOP SPO2	Group A	99.3333	0.71116	30
	Group B	99.2333	0.77385	30
	Total	99.2833	0.73857	60
1 HR IOP SPO2	Group A	99.3000	0.70221	30
	Group B	99.2000	0.71438	30
	Total	99.2500	0.70410	60
2 HR IOP SPO2	Group A	99.4333	0.97143	30
	Group B	99.4667	1.00801	30

Descriptive Statistics				
	Group	**Mean**	**Std. Deviation**	**N**
	Total	99.4500	0.98161	60
4 HR IOP SPO2	Group A	99.3667	0.49013	30
	Group B	99.1333	0.43417	30
	Total	99.2500	0.47389	60
8 HR IOP SPO2	Group A	99.2333	0.43018	30
	Group B	99.2333	0.50401	30
	Total	99.2333	0.46456	60
12 HR IOP SPO2	Group A	99.2333	0.43018	30
	Group B	99.2000	0.48423	30
	Total	99.2167	0.45442	60
16 HR IOP SPO2	Group A	99.1667	0.37905	30
	Group B	99.2667	0.44978	30
	Total	99.2167	0.41545	60
20 HR IOP SPO2	Group A	99.4333	0.72793	30
	Group B	99.1333	0.86037	30
	Total	99.2833	0.80447	60
24 HR IOP SPO2	Group A	99.3667	0.76489	30
	Group B	99.4333	0.62606	30
	Total	99.4000	0.69380	60
36 HR IOP SPO2	Group A	99.4000	0.72397	30
	Group B	99.2667	0.78492	30
	Total	99.3333	0.75165	60
48 HR IOP SPO2	Group A	99.4000	0.72397	30
	Group B	99.3667	0.66868	30
	Total	99.3833	0.69115	60

Tests of Within-Subjects Effects					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	8.062	15	0.537	1.502	0.098
Time * Group	4.329	15	0.289	0.806	0.671
Error(Time)	311.358	870	0.358		

At baseline, group A and group B patients had a mean SPO2 of 99.4333 and 99.5667 percentage respectively. At 48 hours, group A and group B patients had a mean SPO2 of 99.4000 and 99.3667 percentage respectively. As per two way repeated measure ANOVA test the association between the intervention groups (group A Vs group B) and SPO2 from baseline to 48 hours postoperatively is considered to be not statistically significant since $p > 0.05$.



4. Group * Time					
Group	**Time**	**Mean**	**Std. Error**	**95% Confidence Interval**	
				Lower Bound	**Upper Bound**
Group A	baseline	99.433	0.124	99.185	99.681
	30 M IOP	99.533	0.109	99.315	99.751
	1 HR IOP	99.567	0.102	99.362	99.771
	2 HR IOP	99.367	0.121	99.124	99.610
	0 HR POP	99.300	0.137	99.027	99.573
	30 M POP	99.333	0.136	99.062	99.605
	1 HR POP	99.300	0.129	99.041	99.559
	2 HR POP	99.433	0.181	99.072	99.795
	4 HR POP	99.367	0.085	99.197	99.536
	8 HR POP	99.233	0.086	99.062	99.405
	12 HR POP	99.233	0.084	99.066	99.401
	16 HR POP	99.167	0.076	99.015	99.319
	20 HR POP	99.433	0.145	99.142	99.725
	24 HR POP	99.367	0.128	99.111	99.622
	36 HR POP	99.400	0.138	99.124	99.676
	48 HR POP	99.400	0.127	99.145	99.655
Group B	baseline	99.567	0.124	99.319	99.815
	30 M IOP	99.400	0.109	99.182	99.618
	1 HR IOP	99.200	0.102	98.995	99.405
	2 HR IOP	99.333	0.121	99.090	99.576
	0 HR POP	99.167	0.137	98.893	99.440
	30 M POP	99.233	0.136	98.962	99.505
	1 HR POP	99.200	0.129	98.941	99.459
	2 HR POP	99.467	0.181	99.105	99.828
	4 HR POP	99.133	0.085	98.964	99.303
	8 HR POP	99.233	0.086	99.062	99.405

4. Group * Time					
Group	**Time**	**Mean**	**Std. Error**	**95% Confidence Interval**	
				Lower Bound	**Upper Bound**
	12 HR POP	99.200	0.084	99.033	99.367
	16 HR POP	99.267	0.076	99.115	99.419
	20 HR POP	99.133	0.145	98.842	99.425
	24 HR POP	99.433	0.128	99.178	99.689
	36 HR POP	99.267	0.138	98.991	99.543
	48 HR POP	99.367	0.127	99.112	99.621

DISCUSSION

Pain in the postoperative period is the distressing period for any patient and many drugs are being used for it with varying safety concerns. NSAIDS and Paracetemol are used in many patients but intensity of analgesia vary from patients to patients which may not be complete pain relief for those with minimal threshold. Opioids might provide better analgesia but leads to many complications particularly when large and cumulative doses are used which needs close hemodynamic and respiratory monitoring in the postoperative period.

Nalbuphine, a 14-hydroxymorphine derivative, is a potent analgesic with opioid receptor k agonist and μ antagonist properties.Nalbuphine maintains or augments μ- receptor based analgesia and modifies the μ-receptor side effects. Subduing of serotonin uptake in the neurons causes augmentation of the inhibitory pathways in the spinal cord for pain. Excitation on the central nervous system neurons by opioid receptors causes suppression of intracellular adenylyl cyclase,opening of potassium channels, and closure of the calcium channels. This results in hyperpolarization of the cell membrane potential and also suppression of action potential spread of ascending pain pathways.

This study is done to find out whether addition of Nalbuphine as an adjunct to Levobupivacaine in thoracic paravertebral block has real impact on the duration of postoperative pain relief which is the primary outcome measure

by comparing with Levobupivacaine alone in patient undergoing breast surgeries.

In our study, age group included was between 18-60 years and the mean age of Levobupivacaine only group is 36.467 years and Levobupivacaine and Nalbuphine group is 39.367 years. The association between the intervention groups and the age distribution is not statistically significant.

In the study conducted by Omar Mostafa et al, the age groups selected were between 18 to 78 years and the mean age in Bupivacaine and Nalbuphine group is 55.2 years and that of the control group is 55.8 years. In our study and also in Omar Mostafa et al study, age distribution and intervention groups is not statistically significant and they were standardised. Hence selection bias was excluded.

In our study, the mean weight of Levobupivacaine only group is 59.267 kgs and Levobupivacaine and Nalbuphine group is 56.500 kgs. The association between the intervention groups and the weight distribution is not statistically significant.

In the study conducted by Omar Mostafa et al, the mean weight in Bupivacaine and Nalbuphine group is 80.6 kgs and that of the control group is 80.3 kgs. There was no statistical significance difference between the groups in our study and Omar et al study and hence selection bias was excluded.

In our study, the mean height of Levobupivacaine only group is 156.467 cms and Levobupivacaine and Nalbuphine group is 157.400 cms. The association between the intervention groups and the height distribution is not statistically significant.

In the study conducted by Omar Mostafa et al, the mean height in Bupivacaine and Nalbuphine group is 169.5 cms and that of the control group is 169.9 cms. There was no statistical significant difference in height selection between groups in both studies and hence selection bias was excluded.

In our study, the mean BMI of Levobupivacaine only group is 24.200 and Levobupivacaine and Nalbuphine group is 22.806. The association between the intervention groups and the BMI distribution is not statistically significant.

In the study conducted by Omar Mostafa et al, the mean BMI in Bupivacaine and Nalbuphine group is 28.1 and that of the control group is 27.8. There was no statistical significant difference in BMI in both studies.

In our study, American society of Anaesthesiologist (ASA) physical status I, II and III were enrolled and there is no statistical significant difference in both the groups. In Omar et al study, ASA I to III physical status were included and they were standardised in all three groups.

In our study, the mean duration of surgery of Levobupivacaine only group is 90.833 minutes and Levobupivacaine and Nalbuphine group is 119.833

minutes. The association between the intervention groups and the duration of surgery is statistically significant since p<0.05.

In the study conducted by Omar Mostafa et al, the mean duration of surgery in Bupivacaine and Nalbuphine group is 80 minutes and that of the control group is 90 minutes. This difference is significant with a p-value of <0.05.

DURATION OF SENSORY BLOCKADE AND TIME TO THE FIRST ANALGESIC REQUEST:

In our study, the mean duration of sensory blockade in Levobupivacaine only group is 425.333 minutes and in Levobupivacaine and Nalbuphine group is 917.000 minutes. The mean sensory block duration time was significantly longer in Levobupivacaine and Nalbuphine group compared to Levobupivacaine only group by a mean difference of 491.667 minutes. This difference is significant with a p-value of <0.05 as per two way repeated measure ANOVA test.

In the study conducted by Omar et al, the mean duration of sensory blockade in Bupivacaine and Nalbuphine group is 508 minutes and that of the control group is 195 minutes .The difference between the two groups was significant with a p value<0.05.

Our study showed that addition of 1mLof Nalbuphine of 10mg to 15mL 0.125% of Levobupivacaine in Levobupivacaine and Nalbuphine group improved the quality of the block and thus improvement in the pain scores and time to the first

analgesic request was prolonged to 917.000 minutes with a statistical significance of P<0.05 compared to Levobupivacaine only group which was 425.333 minutes.

This was congruous with Gupta et al.,who studied the effect of adding Nalbuphine 10mg to 20mL 0.5% Bupivacaine in supraclavicular nerve block in upper arm surgery. Their results showed increased sensory and motor block time length. The postoperative analgesia time was 481.53 minutes in Nalbuphine group and 341.31 minutes in Bupivacaine only group with a statistical significant difference of P<0.05.

Also, our result was compatible with that of Abdelhaq et al. who used increased dose of Nalbuphine in supraclavicular block, showed better results, pointing that higher doses lead to improved quality of the block and increase in the length of analgesia in Nalbuphine group (835.18minutes) compared to the control group (708.14minutes) (P value<0.05).

Same results were also seen in study done by Chatrath et al. And also postoperative Tramadol consumptions were significantly lowered in Nalbuphine and Bupivacaine group (22.5 mg) than Bupivacaine only group (75mg) in the first 24hours, which was found in the study done by Mohamed et al., Mohta et al., and Das et al.

Our study showed that doses of opioid requirement was less in Levobupivacaine and Nalbuphine group with a maximum of one dose in 48 hrs

of postoperative period compared to two to three doses in Levobupivacaine only group. The difference is statistically significant with a p-value of <0.05 as per ANOVA test.

QUALITY OF ANALGESIA

The quality of analgesia in the postoperative period was assessed by visual analog scale.

In our study the VAS score was high at 6 to 8 hrs with a mean of 4.4667 in Levobupivacaine only group and the VAS score was high at 12 to 16 hrs with a mean of 3.3667 in Levobupivacaine and Nalbuphine group. The association between the intervention groups and the VAS score distribution is statistically significant. This indicates that the time of onset of pain in the postoperative period is prolonged in Levobupivacaine and Nalbuphine group compared to only Levobupivacaine group.

In our study there was no intraoperative or postoperative complications related to the drug and the technique which was described earlier.

CONCLUSION

1. Addition of Nalbuphine as an adjuvant to Levobupivacaine at thoracic paravertebral block in breast surgeries provide intense sensory blockade for more than 12 hrs in the postoperative period.

2. The requirement of number of doses of opioids postoperatively is reduced considerably on addition of Nalbuphine to Levobupivacaine.

3. Time to the first analgesic request was longer in Nalbuphine and Levobupivacaine group compared to Levobupivacaine only group in the postoperative period.

4. Adverse effects such as postoperative nausea and vomiting was significantly lower in Nalbuphine and Levobupivacaine group.

5. Complications like respiratory depression was significantly lower in Nalbuphine and Levobupivacaine group.

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ETHICAL COMMITTEE APPROVAL CERTIFICATE

INSTITUTIONAL ETHICAL COMMITTEE

Reg. No: ECR/774/INST/TN/2015

GOVT. CHENGALPATTU MEDICAL COLLEGE, CHENGALPATTU

Title of Work	:	Effect of 0.125% of levobupivacaine versus 0.125% of levobupivacaine with nalbuphine as an adjuvant on thoracic paravertebral block to manage postoperative pain after breast surgeries
Principal Investigator	:	Dr.P.Uvasri
Designation	:	II[nd] Year PG
Co-Investigators	:	Dr.R.Mala M.D.,D.A., Professor Department of Anaesthesiology Chengalpattu Medical College, Chengalpattu
Department	:	Anaesthesiology

The request for an approval From the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 09.08.2018 at the Medical Education Unit, Government Chengalpattu Medical College, Chengalpattu at 11.00 AM.

The Members of the committee, the Secretary and the Chairman are pleased to inform you that your proposed project mentioned above is approved.

You should inform the IEC in case of any changes in study procedure, site, investigator investigation or guide or any other changes.

1. You should not deviate from the area of work for which you applied for ethical clearance.
2. You should inform the IEC immediately, in case of any adverse events or serious adverse reactions.
3. You should abide to the rules and regulations of the institution(s).
4. You should complete the work within the specific period and if any extension is required, you should apply for permission again and do the work.
5. You should submit the summary of the work to the ethical committee on complete of work.

MEMBER SECRETARY,
IEC, CHENGALPATTU MEDICAL COLLEGE
CHENGALPATTU.

DEAN
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CHENGALPATTU.

PROFORMA

EFFECT OF 0.125% OF LEVOBUPIVACAINE VERSUS 0.125% OF LEVOBUPIVACAINE WITH NALBUPHINE AS AN ADJUVANT ON THORACIC PARAVERTEBRAL BLOCK TO MANAGE POSTOPERATIVE PAIN AFTER BREAST SURGERIES.

CASE NO: **DATE:**

NAME:_____ **AGE:**_____ **WEIGHT:**_____ **HEIGHT:**_____

IP NO: **DATE OF PROCEDURE:**

ADDRESS FOR COMMUNICATION: BMI: ASA Physical status:

CONTACT NO:

DIAGNOSIS:

CO-MORBID ILLNESS:

PREVIOUS SURGERY HISTORY:

DRUG HISTORY:

Group A : Thoracic paravertebral block with 15cc of 0.125% of Levobupivacaine and followed by general anesthesia

Group B : Thoracic paravertebral block with 15cc of 0.125% of Levobupivacaine and 10mg of Nalbuphine, followed by general anesthesia

INVESTIGATIONS: Hb: TC: Platelets:

Blood sugar: RFT: LFT:

Urine routine: ECG: CXR:

Electrolytes: HIV/ HBSAG/HCV: Blood Group:

Others:

VITALS: BP: PR: TEMP: SPO2: CVS: RS:

AIRWAY: SPINE: DENTITION:

NECK MOVEMENTS: OTHERS:

ANAESTHESIOLOGIST- Dr. **SURGEON**-Dr.

Premedication:

Position:

Space:

Technique:

Needle:

Level:

Drug given:

Following parameters are noted:

TIME	HR	SBP	DBP	MAP	SPO2
PREOP					
POST OP					
30 MIN					
1 hr					
2 hrs					
4 hrs					
8 hrs					
12 hrs					
16 hrs					
20 hrs					
24 hrs					
36 hrs					
48 hrs					

Rescue medications:

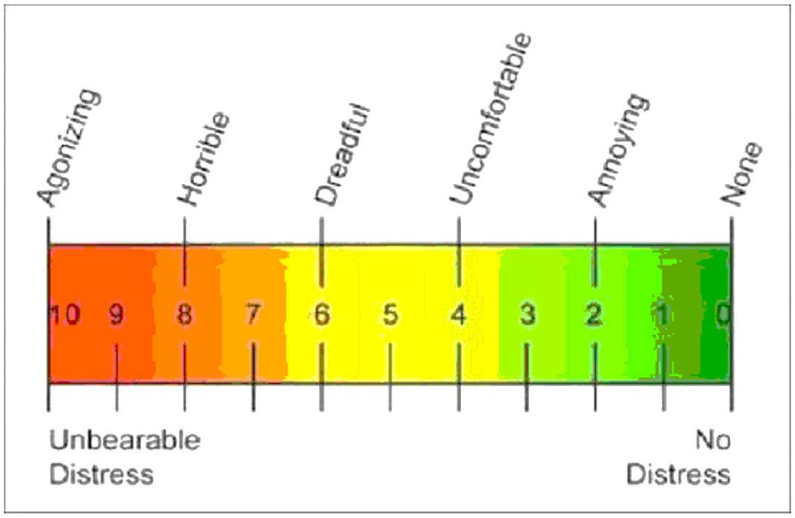
Side effects:

Post operative pain medication:

Pain assessment:

PREOP/POSTOP	VISUAL ANALOGUE SCALE
Before block	
Post op	
1 hr	
2 hrs	
4 hrs	
8 hrs	
12 hrs	
16 hrs	
20 hrs	
24 hrs	
36 hrs	
48 hrs	

VISUAL ANALOGUE SCALE



PATIENT FEED BACK:

SIGNATURE:

INFORMED CONSENT FORM

Name of the Participant :_____ Age_____Ipno_____Date_____

Documentation of the informed consent :

I _____have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in :Title of the Study :"**EFFECT OF 0.125% OF LEVOBUPIVACAINE VERSUS 0.125% OF LEVOBUPIVACAINE WITH NALBUPHINE AS AN ADJUVANT ON THORACIC PARAVERTEBRAL BLOCK TO MANAGE POSTOPERATIVE PAIN AFTER BREAST SURGERIES.**" I have read and understood this consent form and the information provided to me.

1. I have had the consent document explained to me.
2. I have been explained about the nature of the study.
3. I have been explained about my rights and responsibilities by the investigator.
4. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.
5. I have been advised about the risks associated with my participation in this study.*
6. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.*
7. I have not participated in any research study within the past _____month(s).*
8. I have not donated blood within the past _____months-
9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.*
10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.
11. I hereby give permission to the investigator to release the information obtained from me as a result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.
12. I have understand that my identity will be kept confidential if my data are publicly presented .
13. I have had my questions answered to my satisfaction.
14. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

Signature of attending doctor **Signature of the patient/guardian**

WITNESS:

1) **2.**

PATIENT CONSENT FORM

STUDY DETAIL:

"EFFECT OF 0.125% OF LEVOBUPIVACAINE VERSUS 0.125% OF LEVOBUPIVACAINE WITH NALBUPHINE AS AN ADJUVANT ON THORACIC PARAVERTEBRAL BLOCK TO MANAGE POSTOPERATIVE PAIN AFTER BREAST SURGERIES"

STUDY CENTRE:

GOVT. CHENGALPATTU MEDICAL COLLEGE AND HOSPITAL, CHENGALPATTU

PATIENT NAME:_____ **AGE:**_____ **IP NO**_____

I confirm that i have understood the purpose of procedure for the above study.

I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfactions.

I understand that my participation in the study is voluntary and that i am free to withdraw at anytime without giving any reasons, without my legal rights being affected.

I understand that investigator, regulatory authorities and ethics committee will not need my permission to look at my health record both in respect to the current study and any further research that may be conducted in relation to it, even ifi withdraw from the study, i understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

I agree to take part in the above study and to comply with the instructions given during the study and faithfully be cooperative with the study team and to immediately inform the study staff if i suffer from any deterioration in my health or wellbeing or any unexpected or unusual symptoms.

I hereby give consent to participate in this study.

I hereby give permission to undergo complete clinical examinations and diagnostic test.

Signature/ thumb impression: Signature of the investigator:

Patient name and address:

Place:

Date:

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு :

"பெண்களின் மார்பக அறுவைசிகிச்சைக்குப் பின் ஏற்படும் வலிக்கு 0.125% லீவோபுபிவாகெய்ன் மருந்து தனியாகவும் மற்றும் 0.125% லீவோபுபிவாகெய்ன் மருந்துடன் நால்பு.ப்பைன் என்ற மருந்தை சேர்த்தும் உள்ள கலவையை நெஞ்சுக்கூடு முதுகெலும்பின் பக்கத்தில் செலுத்துவதால் ஏற்படும் வலி நிவாரணம் மற்றும் பிற விளைவுகளை ஒப்பிடும் ஆய்வு"

ஆய்வு செய்யப்படும் இடம்:

பங்கு பெறுபவரின் பெயர்:

பங்கு பெறுபவரின் வயது: **பங்கு பெறுபவரின் எண் :**

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டுள்ளது. நான் இவ்வாய்வில் தன்னிச்சையாக பங்கேற்கின்றேன். எந்த காரணத்தினாலோ, எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்து மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர், என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவை இல்லை என அறிந்து கொள்கிறேன். இந்த ஆய்வின் மூலம் கிடைக்கும் தகவலையோ, முடிவையோ மருத்துவர் **பயன்படுத்திக் கொள்ள** சம்மதம்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக் கொள்கிறேன். இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் ஒத்துழைப்பு அளிப்பேன் **என்று உறுதியளிக்கிறேன்.**

பங்கேற்பவரின் கையொப்பம்: **சாட்சியாளரின் கையொப்பம்**

இடம்: **இடம்:**

தேதி: **தேதி :**

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்:

ஆய்வாளரின் கையொப்பம்:

இடம்: **தேதி:**

MASTER CHART

GROUP A (LEVOBUPIVACAINE ONLY)

S.NO	NAME	AGE	SEX	ASA Status	Wt in Kg	Ht in cms	BMI in Kg/m2	Duration of surgery (minutes)	Time of onset of pain postoperatively (minutes)	VISUAL ANALOG SCALE							Requirement of opioids in 48 Hrs
										6 Hrs	8 Hrs	12 Hrs	16 Hrs	20 Hrs	24 Hrs	48 Hrs	
1	**Anitha**	25	F	I	53	155	22.1	60	360	3	4	4	3	2	1	0	0
2	**Sangeetha**	37	F	II	70	161	27	45	480	0	3	4	4	3	1	0	1
3	**Gayathri**	34	F	I	69	158	27.6	90	420	0	3	4	5	4	3	1	2
4	**Janani**	30	F	I	58	160	22.7	60	540	0	4	4	3	2	0	0	0
5	**Karthiga**	38	F	I	62	149	27.9	120	300	3	4	5	6	4	3	2	2
6	**Lakshmi**	40	F	II	60	156	24.7	110	480	0	4	3	2	1	0	0	0
7	**Bakya**	28	F	I	55	153	23.5	60	360	4	5	6	5	6	4	2	3
8	**Fathima**	48	F	I	62	149	27.9	160	400	0	3	4	5	6	3	2	2
9	**Asha**	52	F	III	60	156	24.7	100	380	0	4	6	7	5	4	2	3
10	**Thilagam**	48	F	II	55	153	23.5	110	520	0	3	4	5	3	2	1	1
11	**Deepika**	32	F	I	49	158	19.6	60	480	0	0	4	3	2	2	1	0
12	**Sindhu**	24	F	I	60	159	23.7	45	400	0	3	5	7	4	3	2	3
13	**Jaya**	38	F	II	62	158	24.8	90	420	0	4	5	7	5	2	1	2
14	**Vijaya**	36	F	I	50	155	20.8	100	380	0	4	3	2	1	1	1	0
15	**Sudha**	42	F	I	52	158	20.8	60	440	0	3	5	7	5	3	2	3
16	**Ramya**	44	F	I	51	147	23.6	120	360	3	4	5	4	4	2	2	2
17	**Viji**	50	F	II	59	158	23.6	140	400	0	3	4	5	4	3	2	1
18	**Akila**	48	F	I	58	155	24.1	120	480	0	3	5	7	5	4	2	2
19	**Ilakiya**	36	F	I	61	157	24.7	110	460	0	4	5	4	5	3	2	2
20	**Devi**	26	F	I	55	155	22.89	60	380	0	3	5	7	3	4	2	2
21	**Kalaivani**	28	F	I	78	159	30.85	45	360	4	5	4	3	2	1	1	1
22	**Yamuna**	32	F	I	61	160	23.83	60	400	0	0	4	5	4	3	1	1
23	**Sumathi**	34	F	I	59	160	23.05	70	480	0	3	5	7	5	2	1	2
24	**Malathi**	27	F	I	63	156	25.89	90	520	0	3	5	5	4	3	2	2
25	**Lavanya**	32	F	I	61	157	24.75	100	420	0	4	5	3	2	1	1	1
26	**Vinodhini**	40	F	II	62	160	24.22	120	480	0	3	5	7	5	3	2	2
27	**Bharathi**	38	F	II	64	158	25.64	110	440	0	4	3	3	2	1	1	0
28	**Palaniammal**	47	F	II	49	155	20.4	120	380	0	4	5	7	0	4	2	3
29	**Kala**	26	F	I	61	159	24.13	90	460	0	0	3	4	2	1	1	0
30	**Pattamal**	34	F	I	59	160	23.05	100	380	0	3	5	5	4	3	2	2

HEMODYNAMIC PARAMETERS OF GROUP A

GROUP A (Levobupivacaine only)

S.NO	BASE LINE			INTRA-OP PULSE RATE			POST-OP PULSE RATE											
	PR	MAP	SPO2	30 M	1 HR	2 HR	0 HR	30 M	1 HR	2 HR	4 HR	8 HR	12 HR	16 HR	20 HR	24 HR	36 HR	48 HR
1	87	88	100	84	82	80	80	84	86	88	90	76	80	76	89	82	84	86
2	80	90	100	76	74	78	72	76	76	78	76	89	90	89	76	78	76	74
3	78	80	100	72	74	76	74	75	72	78	80	92	81	88	90	107	98	90
4	80	92	99	77	65	67	77	80	68	82	84	96	81	91	72	88	86	85
5	87	100	99	78	76	72	70	74	73	76	74	76	96	92	79	99	92	90
6	76	74	100	84	77	82	78	71	77	78	71	77	99	78	79	82	78	80
7	70	99	98	68	66	64	66	68	67	64	73	77	98	81	70	79	80	78
8	80	84	98	78	68	76	66	71	75	74	89	82	80	76	87	88	86	84
9	78	82	100	70	67	64	68	71	68	72	74	92	75	76	69	78	80	78
10	90	79	100	82	77	76	77	78	77	80	81	90	74	72	76	78	80	82
11	88	80	99	82	72	77	74	76	75	76	80	89	81	76	79	80	78	80
12	78	85	100	65	64	66	68	65	67	66	79	89	90	86	73	87	84	85
13	70	90	100	72	67	71	76	74	78	75	78	90	84	79	79	80	82	78
14	96	95	99	88	85	88	87	82	79	80	86	98	81	81	78	90	88	86
15	76	78	100	75	76	80	77	76	76	72	76	93	76	74	84	88	86	84
16	76	87	100	78	68	76	78	73	74	78	75	80	96	72	90	94	90	88
17	80	84	99	76	74	71	73	70	77	74	80	98	76	74	79	89	82	84
18	84	90	100	77	69	66	76	72	75	81	72	85	90	91	73	89	88	87
19	70	88	99	74	72	69	68	73	80	72	81	95	77	72	69	79	80	78
20	85	94	99	82	71	78	75	75	74	80	80	93	73	75	71	90	88	86
21	68	106	100	88	76	78	70	76	90	86	86	84	98	90	72	108	98	92
22	74	78	100	69	66	61	65	72	68	77	66	90	88	80	65	95	94	88
23	80	88	98	82	84	80	78	77	76	80	84	96	73	88	88	87	86	85
24	82	90	100	77	72	71	74	74	70	80	71	93	75	79	73	89	85	80
25	76	80	99	83	82	79	78	78	80	71	76	98	80	77	79	78	80	82
26	74	87	100	82	75	75	79	83	74	86	83	82	99	91	75	99	94	92
27	80	80	100	71	68	62	70	73	72	67	70	90	90	92	71	84	82	82
28	92	80	99	75	69	66	80	74	77	73	83	95	86	85	81	95	95	90
29	88	70	99	68	63	64	67	70	74	76	69	92	88	75	69	88	86	84
30	82	98	98	87	75	76	67	74	76	74	68	94	91	75	75	88	88	86

GROUP A (Levobupivacaine only) cont…

S.NO	INTRA-OP MAP			POST-OP MAP												INTRA-OP SPO2			POST-OP SPO2											
	30 M	1 HR	2 HR	0 HR	30 M	1 HR	2 HR	4 HR	8 HR	12 HR	16 HR	20 HR	24 HR	36 HR	48 HR	30 M	1 HR	2 HR	0 HR	30 M	1 HR	2 HR	4 HR	8 HR	12 HR	16 HR	20 HR	24 HR	36 HR	48 HR
1	82	80	82	78	76	74	76	89	85	78	78	80	78	76	74	100	100	100	100	100	99	99	98	100	98	99	100	100	99	100
2	87	83	84	82	80	78	76	78	89	78	82	78	82	80	84	100	100	100	99	99	99	100	100	99	99	98	100	100	100	99
3	78	76	76	74	76	76	78	90	88	90	91	88	93	90	89	100	100	99	99	99	99	100	100	99	100	99	100	98	99	100
4	88	84	80	78	80	78	82	78	92	90	88	86	84	83	82	99	100	99	99	99	99	99	100	99	99	98	99	99	100	99
5	97	95	88	84	87	82	80	84	98	102	92	88	82	80	78	100	99	99	98	99	99	99	98	98	98	98	99	98	99	100
6	73	78	76	77	74	75	76	74	85	90	82	84	88	86	87	99	99	98	98	98	98	99	99	98	99	97	99	98	99	100
7	92	90	89	87	89	82	80	98	84	87	83	80	82	80	84	99	99	99	99	99	98	99	99	98	98	97	98	98	98	99
8	85	82	84	82	79	78	80	82	96	85	78	80	82	80	82	100	100	100	99	98	99	99	100	100	100	100	100	100	99	100
9	78	76	74	78	76	74	76	78	90	87	90	78	80	78	82	99	98	99	100	98	99	97	98	99	98	99	98	99	99	100
10	73	73	74	75	72	73	76	80	95	88	84	82	86	88	78	100	100	100	100	99	100	100	100	99	98	98	99	99	100	99
11	78	76	74	78	76	75	78	80	86	96	82	78	82	78	82	99	99	99	99	98	99	98	98	98	99	99	99	99	100	99
12	80	78	74	78	80	80	79	78	96	94	90	87	89	87	85	99	100	100	99	100	99	99	98	98	98	99	99	98	99	100
13	86	82	79	78	80	82	80	82	94	84	90	88	89	84	82	100	100	100	100	99	99	98	99	98	99	98	98	99	100	99
14	83	82	84	86	82	84	86	87	94	89	84	86	82	80	78	100	100	99	99	98	98	99	100	99	98	98	99	100	100	99
15	76	74	76	77	76	78	76	77	88	86	86	88	90	88	86	100	100	100	99	99	98	98	99	99	98	98	99	100	99	100
16	80	78	80	80	79	78	79	80	75	90	78	76	80	78	76	99	99	99	98	99	98	99	98	98	98	99	99	99	99	100
17	83	78	76	78	80	76	78	76	87	84	80	78	80	76	78	99	99	99	99	98	99	98	98	99	99	98	99	99	99	100
18	88	78	82	84	81	77	78	78	75	88	83	79	81	80	84	100	100	100	100	100	100	99	99	98	99	98	99	98	100	99
19	85	81	80	83	84	78	79	80	96	86	86	84	86	84	88	100	100	100	100	100	100	100	100	100	99	100	100	99	100	99
20	88	84	83	86	84	82	83	88	96	86	87	85	77	78	80	100	100	100	99	100	100	100	98	100	98	100	100	99	99	99
21	100	99	194	96	94	96	94	96	98	99	94	98	102	99	98	98	98	98	98	99	98	98	99	99	98	99	99	98	99	100
22	76	74	77	76	74	76	72	77	88	75	78	77	78	80	82	99	100	99	100	100	100	99	99	98	98	99	98	99	100	98
23	83	82	78	84	80	78	78	80	98	94	86	78	84	82	84	99	99	100	100	100	100	100	100	100	99	99	100	100	99	100
24	88	87	85	87	86	84	86	78	97	92	88	89	88	86	84	100	100	100	99	99	99	98	100	100	99	99	100	100	99	100
25	76	77	85	81	80	84	85	86	98	88	87	90	91	88	86	100	100	100	99	98	99	98	99	99	98	98	100	100	100	99
26	82	78	82	83	79	80	83	79	80	97	79	91	78	80	76	100	100	100	100	98	98	99	99	100	100	100	99	99	99	99
27	77	78	76	80	82	84	80	86	98	87	85	84	80	78	82	98	99	98	98	99	98	99	99	99	98	97	98	98	100	99
28	76	77	78	82	84	86	84	86	97	85	84	78	78	82	80	100	100	100	100	100	99	98	98	100	100	99	99	99	100	100
29	72	78	80	82	78	82	86	82	84	96	86	84	80	78	76	100	99	99	98	98	100	100	98	98	99	98	99	100	99	99
30	101	98	94	96	93	90	94	92	102	99	96	89	90	88	86	100	100	98	100	99	99	100	100	99	98	99	100	100	99	100

GROUP B (LEVOBUPIVACAINE AND NALBUPHINE)

S.NO	NAME	AGE	SEX	ASA Status	Wt in Kg	Ht in cms	BMI in Kg/m2	Duration of surgery (minutes)	Time of onset of pain postoperatively (minutes)	VISUAL ANALOG SCALE							Requirement of opioids in 48 Hrs
										6 Hrs	8 Hrs	12 Hrs	16 Hrs	20 Hrs	24 Hrs	48 Hrs	
1	**Shanthi**	29	F	I	52	154	21.9	105	960	0	0	0	4	5	4	3	**1**
2	**Parvathy**	30	F	I	55	159	21.8	95	720	0	0	3	5	6	4	2	**1**
3	**Deivanai**	48	F	II	70	158	28.02	135	840	0	0	2	4	3	4	2	**0**
4	**Roja**	52	F	II	64	160	25	120	800	0	0	0	4	3	2	**2**	**0**
5	**Rajeshwari**	49	F	I	56	158	22.4	140	1100	0	0	0	0	4	3	**2**	**0**
6	**Varalakshmi**	39	F	I	48	155	20	60	760	0	0	4	5	4	4	3	**1**
7	**Lakshmi**	28	F	II	54	161	20.8	125	1200	0	0	0	0	4	5	3	**1**
8	**Priya**	36	F	I	54	158	21.6	100	900	0	0	0	4	6	5	4	**2**
9	**Rakshana**	48	F	I	52	160	20.3	120	1000	0	0	0	0	4	4	2	**0**
10	**Lokeshwari**	56	F	II	63	160	24.6	110	820	0	0	0	4	6	5	5	**3**
11	**Selvi**	50	F	I	48	157	19.5	130	780	0	0	3	5	6	5	**3**	**2**
12	**Sathya**	44	F	II	58	158	23.2	160	940	0	0	0	4	5	3	**2**	**0**
13	**Lalitha**	38	F	II	57	161	22	110	1100	0	0	0	0	4	5	**3**	**1**
14	**Shanthi**	42	F	I	59	160	23	140	1050	0	0	0	3	5	4	**2**	**1**
15	**Kalaiselvi**	40	F	II	58	160	22.7	120	760	0	0	4	4	3	2	**2**	**0**
16	**Alamelu**	28	F	I	62	149	27.9	90	920	0	0	0	4	2	2	**1**	**0**
17	**Nagavalli**	38	F	I	60	156	24.7	110	840	0	0	0	4	3	2	**2**	**0**
18	**Manonmani**	36	F	II	55	153	23.5	130	790	0	0	4	3	4	3	**2**	**0**
19	**Subalakshmi**	40	F	II	58	160	22.7	160	1000	0	0	0	4	5	5	**3**	**1**
20	**Rani**	28	F	I	49	158	19.6	120	800	0	0	3	4	4	3	**2**	**0**
21	**Pooja**	31	F	I	62	160	24.22	140	780	0	0	0	4	4	2	2	**0**
22	**Mohana**	36	F	II	60	159	23.7	110	920	0	0	0	4	6	5	**3**	**1**
23	**Ezhilvizhi**	40	F	I	58	162	22.1	145	1060	0	0	0	0	4	6	4	**2**
24	**Yasodha**	45	F	I	64	158	25.64	130	1100	0	0	0	0	4	7	5	**3**
25	**Raniammal**	38	F	I	49	155	20.4	145	1150	0	0	0	3	4	3	2	**0**
26	**Devi**	31	F	II	52	158	20.8	125	840	0	0	0	4	3	2	1	**0**
27	**Kayal**	29	F	I	50	155	20.8	100	780	0	0	3	5	6	4	3	**1**
28	**Latha**	36	F	II	51	147	23.6	90	960	0	0	0	4	5	3	**3**	**1**
29	**Archana**	42	F	I	59	158	23.6	120	860	0	0	0	4	3	4	**2**	**0**
30	**Chithra**	54	F	II	58	155	24.1	110	980	0	0	0	0	4	6	**3**	**1**

HEMODYNAMIC PARAMETERS OF GROUP B

GROUP B(Levobupivacaine with nalbuphine)

S.NO	BASELINE			INTRA-OP PULSE RATE			POST-OP PULSE RATE										
	PR	MAP	SPO2	30 M	1 HR	2 HR	0 HR	1 HR	2HR	4 HR	8 HR	12 HR	16 HR	20 HR	24 HR	36 HR	48 HR
1	89	97	100	82	85	80	83	75	78	66	67	69	75	78	98	99	84
2	76	90	100	73	76	71	70	67	68	70	67	66	76	98	96	88	84
3	78	76	100	80	81	85	77	65	84	71	66	75	89	73	76	78	70
4	69	72	100	68	76	69	74	67	70	68	78	80	98	96	92	84	88
5	76	88	100	68	66	74	82	73	88	66	84	66	78	96	90	86	81
6	68	70	99	69	77	80	82	76	77	76	72	82	73	74	98	92	80
7	80	98	99	76	79	73	81	76	71	72	68	70	88	92	96	88	86
8	77	93	100	74	79	67	73	65	68	69	73	78	100	98	96	82	88
9	72	88	100	68	69	73	76	72	68	70	76	74	88	90	88	86	82
10	60	78	100	62	68	72	70	68	70	66	68	72	89	90	88	84	86
11	73	90	99	76	88	80	78	76	78	74	73	70	74	87	92	88	86
12	80	100	99	82	79	85	82	78	76	74	76	79	94	92	90	86	84
13	88	78	100	86	82	75	76	74	71	76	70	69	70	86	88	82	80
14	67	80	99	65	68	63	62	64	66	64	62	66	71	84	82	80	81
15	81	76	99	82	76	84	78	74	70	76	72	75	86	89	88	85	87
16	75	87	100	85	80	82	75	76	70	68	69	74	88	90	82	84	80
17	62	90	98	60	63	61	62	60	62	64	66	64	86	82	80	78	75
18	70	81	99	72	69	68	68	64	69	66	65	63	87	81	75	86	82
19	71	78	100	72	65	66	67	68	67	70	68	71	82	87	83	80	84
20	68	80	100	81	78	70	71	74	70	72	72	74	79	88	81	67	63
21	83	81	100	80	82	85	76	74	70	68	66	64	90	84	86	81	79
22	80	78	99	82	68	70	71	65	69	70	67	67	87	83	65	69	77
23	64	74	100	62	74	71	73	70	69	66	65	62	81	85	83	69	72
24	81	86	100	78	88	72	71	66	69	64	63	73	68	86	82	64	63
25	78	88	98	72	78	61	64	65	67	70	68	66	87	71	74	79	80
26	70	96	99	68	66	61	62	64	62	67	68	67	62	64	88	84	72
27	68	90	100	72	78	64	62	64	65	66	61	64	66	83	79	75	67
28	84	82	100	85	80	87	79	71	77	67	68	70	89	84	70	79	82
29	71	80	100	68	70	72	67	64	61	64	65	66	62	89	71	77	81
30	68	78	100	72	68	75	72	70	65	64	68	66	87	76	74	70	75

GROUP B(Levobupivacaine with nalbuphine) cont…

S.NO	INTRA-OP MAP			POST-OP MAP										
	30 M	1 HR	2 HR	0 HR	1 HR	2 HR	4 HR	8 HR	12 HR	16 HR	20 HR	24 HR	36 HR	48 HR
1	80	75	74	76	77	75	77	74	70	70	73	88	80	76
2	76	74	71	73	76	74	73	75	72	75	83	79	77	72
3	70	72	70	72	74	71	75	72	71	84	80	83	77	74
4	70	71	72	73	71	72	74	73	74	80	77	77	72	73
5	78	74	72	74	72	76	77	77	77	70	83	82	85	78
6	72	73	74	76	74	72	74	70	72	75	72	85	76	74
7	80	78	73	76	74	76	78	78	77	85	80	74	85	77
8	80	76	74	74	76	72	76	73	76	84	80	78	82	80
9	74	72	73	74	73	72	74	76	77	82	76	74	71	77
10	70	72	74	76	79	74	76	74	76	86	80	74	76	72
11	78	76	73	74	72	76	74	72	73	72	84	82	84	76
12	88	84	82	80	82	84	86	82	82	89	84	80	77	82
13	70	72	73	71	70	72	76	74	71	74	83	76	80	72
14	74	72	72	74	75	77	75	73	76	73	80	78	76	82
15	73	74	70	73	74	76	74	78	76	87	82	78	82	74
16	79	74	76	75	74	72	74	77	80	88	85	76	80	84
17	78	76	78	74	76	74	76	72	80	89	84	75	85	73
18	70	72	71	71	73	71	74	75	74	84	80	77	74	72
19	74	72	73	72	71	77	75	76	77	78	83	75	77	76
20	75	71	74	76	72	74	73	76	75	78	85	80	78	81
21	71	70	72	73	72	74	73	77	76	85	81	73	75	72
22	74	71	72	74	76	77	74	76	74	82	77	74	78	74
23	70	71	74	73	75	72	74	77	78	83	80	74	77	72
24	78	74	72	74	73	72	74	77	74	73	84	80	82	78
25	75	72	73	74	75	74	76	74	77	85	79	72	74	75
26	82	80	77	76	75	76	78	77	75	78	86	75	80	83
27	83	80	77	75	78	74	73	74	77	84	77	75	72	74
28	78	76	74	77	74	75	73	75	73	83	77	82	78	81
29	73	72	71	72	74	72	71	74	76	74	84	80	79	77
30	75	70	72	74	76	72	71	74	85	83	80	78	81	77

S.NO	INTRA-OP SPO2			POST-OP SPO2										
	30 M	1 HR	2 HR	0 HR	1 HR	2 HR	4 HR	8 HR	12 HR	16 HR	20 HR	24 HR	36 HR	48 HR
1	99	99	100	99	100	99	99	100	99	98	100	99	99	100	100
2	100	100	99	100	99	100	99	100	99	99	100	99	100	99	100
3	99	99	100	99	100	99	100	100	100	99	100	99	99	100	100
4	99	99	100	100	99	99	99	99	100	99	100	99	100	100	99
5	100	100	99	99	100	99	100	99	100	99	100	99	99	99	100
6	99	99	99	99	98	99	97	98	98	99	99	99	98	98	100
7	99	99	100	98	98	99	100	99	99	97	98	98	99	99	99
8	100	99	100	98	98	97	98	99	100	99	97	99	97	98	99
9	100	99	99	98	98	98	100	99	98	97	99	97	99	99	98
10	99	99	100	99	98	99	99	98	99	98	98	99	98	99	99
11	99	100	99	99	98	99	99	99	100	99	97	98	97	99	100
12	99	99	100	99	99	100	99	99	98	99	98	98	98	98	99
13	99	100	99	100	100	99	99	98	99	97	98	98	99	99	100
14	99	100	100	99	100	99	99	100	99	99	99	100	99	100	99
15	100	99	99	98	99	100	100	99	98	98	99	100	100	99	99
16	100	99	99	98	99	99	98	99	99	100	99	99	100	100	99
17	99	99	98	99	98	99	98	99	99	99	98	100	99	99	100
18	100	99	99	98	98	99	99	98	98	99	99	100	100	100	100
19	99	99	100	99	99	100	99	100	99	99	100	99	100	100	99
20	100	99	99	100	99	99	99	99	100	100	100	99	99	99	100
21	100	99	99	99	100	99	100	99	99	98	98	99	100	99	100
22	99	100	99	100	99	99	99	98	99	98	99	99	100	100	100
23	100	99	100	99	100	99	100	99	100	99	100	99	100	99	99
24	99	100	99	98	100	99	100	99	100	99	99	99	99	100	100
25	99	99	100	99	98	97	98	98	98	99	99	98	99	98	99
26	99	98	99	99	97	99	99	98	99	98	98	97	98	99	98
27	100	99	100	99	99	99	97	98	99	98	99	97	99	98	99
28	100	99	99	98	99	98	99	99	99	98	99	99	98	97	98
29	100	99	99	100	100	99	100	99	98	99	99	98	99	98	100
30	99	100	100	99	100	100	99	99	100	99	100	100	99	100	99