"A PROSPECTIVE, RANDOMIZED COMPARATIVE STUDY EVALUATING THE ANALGESIC EFFICACY AND SAFETY PROFILE OF THORACIC EPIDURAL BLOCK VERSUS THORACIC PARAVERTEBRAL BLOCK USING A CONTINUOUS INFUSION OF BUPIVACAINE IN PATIENTS UNDERGOING ELECTIVE MAJOR BREAST SURGERY"

Dissertation submitted to

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in partial fulfilment for the award of the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X

INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE

MADRAS MEDICAL COLLEGE

CHENNAI- 600 003

APRIL 2015

CERTIFICATE

This is to certify that the dissertation entitled, **"A PROSPECTIVE, RANDOMIZED COMPARATIVE STUDY EVALUATING THE ANALGESIC EFFICACY AND SAFETY PROFILE OF THORACIC EPIDURAL BLOCK VERSUS THORACIC PARAVERTEBRAL BLOCK USING A CONTINUOUS INFUSION OF BUPIVACAINE IN PATIENTS UNDERGOING ELECTIVE MAJOR BREAST SURGERY"** submitted by Dr.V.S.YAMINI in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai., is a bonafide record of the work done by her in the INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE, Madras Medical College and government hospital, during the academic year 2012-2015.

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This is to certify that the dissertation entitled, **"A PROSPECTIVE, RANDOMIZED COMPARATIVE STUDY EVALUATING THE ANALGESIC EFFICACY AND SAFETY PROFILE OF THORACIC EPIDURAL BLOCK VERSUS THORACIC PARAVERTEBRAL BLOCK USING A CONTINUOUS INFUSION OF BUPIVACAINE IN PATIENTS UNDERGOING ELECTIVE MAJOR BREAST SURGERY"** submitted by Dr.V.S.YAMINI, in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai., is a bonafide record of the work done by her in the INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE, Madras Medical College and government hospital, during the academic year 2012-2015.

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DECLARATION

I hereby declare that the dissertation entitled **"A PROSPECTIVE, RANDOMIZED COMPARATIVE STUDY EVALUATING THE ANALGESIC EFFICACY AND SAFETY PROFILE OF THORACIC EPIDURAL BLOCK VERSUS THORACIC PARA VERTEBRAL BLOCK USING A CONTINUOUS INFUSION OF BUPIVACAINE IN PATIENTS UNDERGOING ELECTIVE MAJOR BREAST SURGERY"** has been prepared by me under the guidance of **PROF.Dr. B.KALA M.D., D.A.,** Director Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai and submitted to **The Tamilnadu Dr. MGR Medical University,** Guindy, Chennai – 32 in partial fulfilment of the regulations for the award of the degree of M.D.[Anaesthesiology], examination to be held in April 2015.

This study was conducted at Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai.

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

Date :

Place : Chennai

Dr.V.S.YAMINI

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ABSTRACT

"A PROSPECTIVE, RANDOMIZED COMPARATIVE STUDY EVALUATING THE ANALGESIC EFFICACY AND SAFETY PROFILE OF THORACIC EPIDURAL BLOCK VERSUS THORACIC PARAVERTEBRAL BLOCK USING A CONTINUOUS INFUSION OF BUPIVACAINE IN PATIENTS UNDERGOING ELECTIVE MAJOR BREAST SURGERY"

INTRODUCTION

Breast cancer frequently requires surgical intervention and hence causes pain both physically and psychologically. Inadequate pain management leads to several complications including acute pain, reduction in respiratory effort, impaired lung function and delay in hospital discharge. Hence multiple modalities have been tried for post operative pain relief in breast surgeries.

AIM

To compare the analgesic efficacy and safety profile of thoracic epidural and thoracic paravertebral block using a continuous infusion of bupivacaine in patients undergoing elective major breast surgery.

MATERIALS AND METHODS

60 patients were randomly allocated into either of the two groups.

GROUP P

Thirty patients in this group received 8ml of 0.25% bupivacaine as bolus through thoracic paravertebral block, after the completion of the surgical procedure followed by a continuous infusion of 0.1ml/kg/hr of 0.125 % bupivacaine for 48 hours.

GROUP E

Thirty patients in this group received 8ml of 0.25% bupivacaine as bolus through thoracic epidural block, after the completion of the surgical procedure followed by a continuous infusion of 0.1ml/kg/hr of 0.125 % bupivacaine for 48 hours.

OBSERVED PARAMETERS

The following parameters were compared between the two groups:

1. Post operative visual analogue score
2. Post operative hemodynamics
3. Incidence of complications
4. The need for rescue analgesics

RESULTS

On the course of study, the onset of analgesia, degree of analgesia measured by Visual Analogue Score provided by both the epidural and paravertebral groups was comparable. The failure rates in technique in both the groups were also comparable. The need for rescue analgesics were also comparable in both the groups. It was also found that the incidence of hypotension was more in patients belonging to the thoracic epidural group.

CONCLUSION

This study concludes that both thoracic epidural block and thoracic paravertebral block provide comparable post operative analgesia in patients undergoing elective major breast surgery but the haemodynamic stability was better maintained with thoracic paravertebral group compared to thoracic epidural group.

KEYWORDS

Post Operative Pain Relief, Thoracic epidural block, Thoracic paravertebral block.

INTRODUCTION

Breast cancer is perhaps one of the most common cancers in women that require frequent surgical intervention[1] and thereby causing pain both physically and psychologically. Nearly 40% of post operative breast surgery patients experience significant acute post operative pain reflecting inadequacy of conventional pain management[2]. Also, the incidence of chronic post operative pain in these patients is as high as 50% and inadequate analgesia is an independent risk factor[3]. Inadequate pain management leads not only to post operative discomfort but can also cause a reduction in respiratory effort, impaired lung function and eventually atelectasis , hypoxemia and pulmonary infection.

It was Corning who first performed epidural anaesthesia with cocaine[4]. But the first publication of Epidural anaesthesia which was a caudal approach was done by Jean Athanese Sicard and Fernand Cathelin in 1901. The lumbar approach to the epidural space was developed 20 years after the caudal approach. In 1921, Fidel Pages, who is called the father of modern epidural anaesthesia described the intraspinous approach to the epidural space. Archile Mario Dogliotti first described the modern technique of loss of resistance for identification of the epidural space and also the concept of lumbar segmental anaesthesia. Gutierrez, in 1932, described the hanging drop sign for identification of the epidural space.

In 1945, Tuohy needle was introduced which is being widely used now. Eugene Aburel placed a silk ureteral catheter in epidural space and used it for labour analgesia. However the first polyvinyl catheter with closed tip was introduced in 1962 which made continuous infusion much easier.

Thoracic epidural is considered to be a gold standard for pain relief in breast surgeries as it attenuates the surgical stress response and provides a favourable homeostatic milieu. However it does have its own complications like hypotension, bradycardia, urine retention, total spinal anaesthesia and in rare cases paraplegia.

So alternate techniques are looked upon as a part of multimodal approach to pain control which can give similar degree of analgesia but lesser side effects.

Paravertebral block was first performed by Hugo Selheim[5] of Leipzig in 1905 and was a popular technique for providing analgesia in the early part of the twentieth century. However its use came down over the years until a publication by Eason and Wyatt in 1979 which brought back its renaissance[6]. Without much physiologic derangement, this method produces unilateral analgesia as in breast surgery, renal surgery, inguinal hernia repair, cholecystectomy, thoracic surgery and appendicectomy. Its application has now been tried in the alleviation of

refractory angina pectoris, intractable pain of malignancy, post traumatic sympathetic dystrophies, and neuropathic pain.

Paravertebral block is referred to as safe, effective, technically simple with fewer side effects and is possibly regaining its importance for regional analgesia after breast surgeries.

With this background idea, this study was conceptualized to compare the analgesic efficacy and safety profile of thoracic epidural block with thoracic paravertebral block using a continuous infusion of bupivacaine in patients undergoing elective major breast surgery.

AIM OF THE STUDY

AIM:

To compare the analgesic efficacy and safety profile of thoracic epidural block and thoracic paravertebral block using a continuous infusion of bupivacaine in patients undergoing elective major breast surgery .

DESIGN OF STUDY:

Prospective, randomized, single blinded, case control study

OBSERVED PARAMETERS:

The following parameters were compared between the two groups:

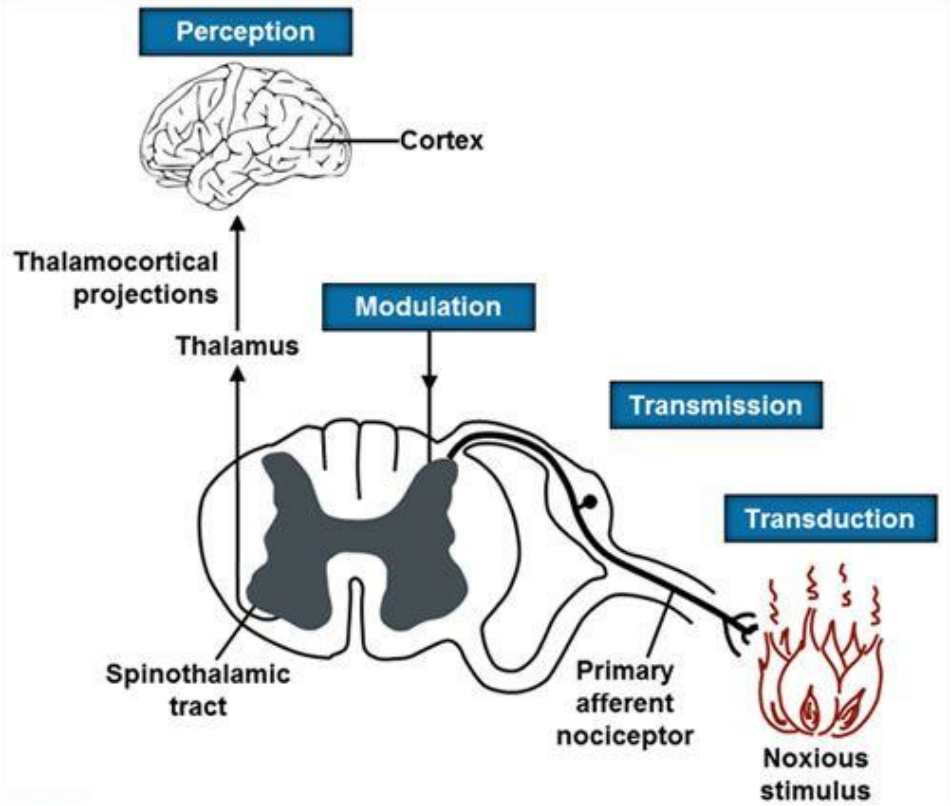
1. Post operative visual analogue score
2. Post operative hemodynamics
3. Incidence of complications
4. Need for rescue analgesic.

PHYSIOLOGY OF PAIN

Pain is an unpleasant sensory and emotional experience associated with an actual or potential tissue damage**.** And the process of nociception is a dynamic process with multiple points of activation and modulation. Persistent noxious stimulus may result in rapid neuronal sensitization and possibly chronic pain.

NEUROBIOLOGY OF PAIN

The experience of pain involves a series of processes namely—transduction, transmission, modulation, and perception[7]



- **Transduction**

Transduction is the process by which a noxious stimulus is converted to an electrical impulse in sensory nerve endings.

- **Transmission**

Transmission is the conduction of these peripheral electrical nerve impulses to the central nervous system.

- **Modulation**

Modulation is the process of altering pain transmission. Both inhibitory and excitatory mechanisms modulate pain impulse transmission both at the peripheral and central nervous system.

- **Perception**

Perception of pain occurs at the thalamus while the discrimination of pain occurs at the sensory cortex.

Surgery produces tissue injury and consequently there is release of inflammatory mediators such as bradykinin, prostaglandins, serotonin, histamine, cytokines, substance P, glutamate. These noxious stimuli are perceived by the peripheral nociceptors namely the myelinated Aδ and

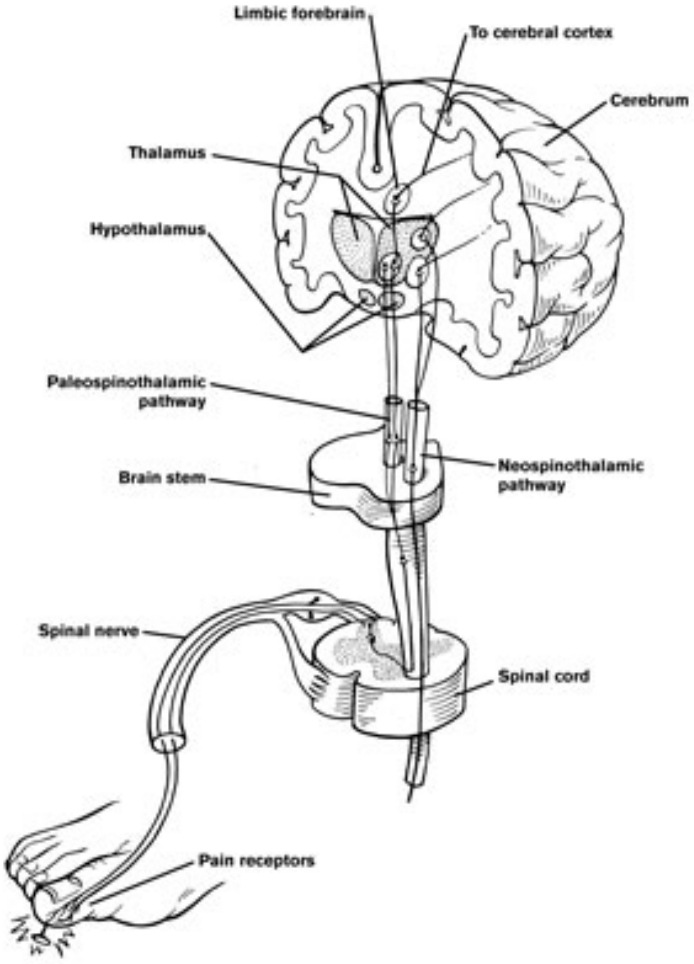
unmyelinated C nerve fibers which are free nerve ending receptors present in skin, muscles, joints, viscera, and vasculature. Electrical impulses are transduced ; propagation and transmission of action potential occurs via the opening and closing of sodium and potassium ion channels.

Afferent fibers from peripheral nociceptors terminate in the dorsal horn cells of the spinal cord through the dorsal root ganglion. Some impulses pass to the anterior and anterolateral horns to initiate segmental spinal reflex responses. Others are transmitted to higher centers through the spinothalamic tract. The neospinothalamic tract projects to the posterior portions of the thalamus and is related to spatial and temporal aspects of pain perception, whereas the paleospinothalamic tract projects to the medial thalamus and is responsible for initiation of unpleasant aspects of pain as well as autonomic nervous system responses to pain. Other pathways involved in cephalad transmission of pain impulses include spinocervical, spinoreticular and spinomesencephalic tract.

Inhibitory modulation on dorsal horn neurons is brought about by the descending pathways arising from the periaqueductal gray area and raphe magnus nucleus, thereby completely suppressing pain signals entering by ways of dorsal spinal roots. The neurotransmitters identified

in these inhibitory pathways are norepinephrine, serotonin and endogenous opioids.

PAIN PATHWAY



ACUTE EFFECTS OF POSTOPERATIVE PAIN[8]

- Suprasegmental reflex responses to pain result in increased catecholamine and catabolic hormone secretion (e.g., cortisol, adrenocorticotropic hormone, antidiuretic hormone, glucagon, aldosterone, renin, angiotensin II), and decreased secretion of anabolic hormones. The net effects include water and sodium retention, increased levels of blood glucose, free fatty acids, ketone bodies, and lactate.

- The negative nitrogen balance and protein catabolism may impede convalescence.

- Sympathetic activation may increase myocardial oxygen consumption, which may lead to the development of myocardial ischemia and infarction

- Nociceptors are activated after surgical trauma and may initiate several detrimental spinal reflex arcs. Postoperative respiratory function is markedly decreased, especially after upper abdominal and

thoracic surgery. Spinal reflex inhibition of phrenic nerve activity is an important component of this decreased postoperative pulmonary function.

- Activation of nociceptors may also initiate spinal reflex inhibition of gastrointestinal tract function and delay return of gastrointestinal motility. Hyperglycemia from the stress response may contribute to poor wound healing and thereby depression of immune function.

- The stress response may be an important factor in the postoperative development of hypercoagulability. Enhancement of coagulation (i.e., decreased levels of natural anticoagulants and increased levels of procoagulants), inhibition of fibrinolysis, and increased platelet reactivity and plasma viscosity.

CHRONIC EFFECTS

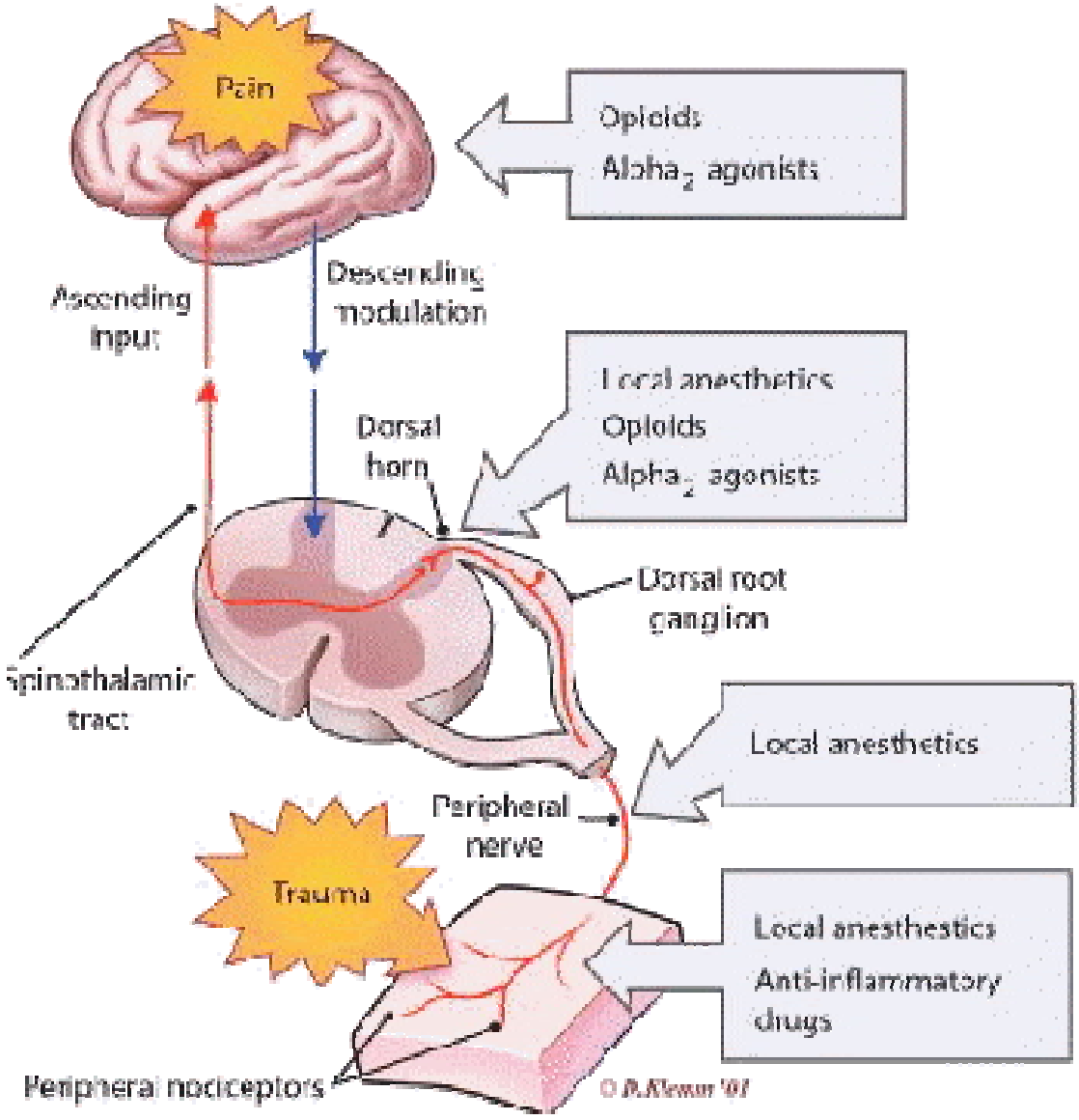
Poorly controlled acute post operative pain is major factor contributing to chronic post surgical pain.

PROVIDING POST OPERATIVE PAIN RELIEF

Hence the following are the target sites for post operative pain control

- Peripheral level – Local anaesthetics, peripheral nerve blocks, NSAIDs, Opioids
- Spinal cord level – Opioids , Alpha 2 agonists, Local anaesthetics.
- Cortical level – Opioids.

Providing Postoperative Pain Relief



BREAST SURGERY

The breast is a modified sweat gland. It lies in the subcutaneous layer of the anterior thoracic wall, anterior to the pectoralis major muscle. It extends vertically from the second to the sixth rib and horizontally, it extends from the lateral border of the sternum to the mid axillary line.

SENSORY INNERVATION OF THE BREAST

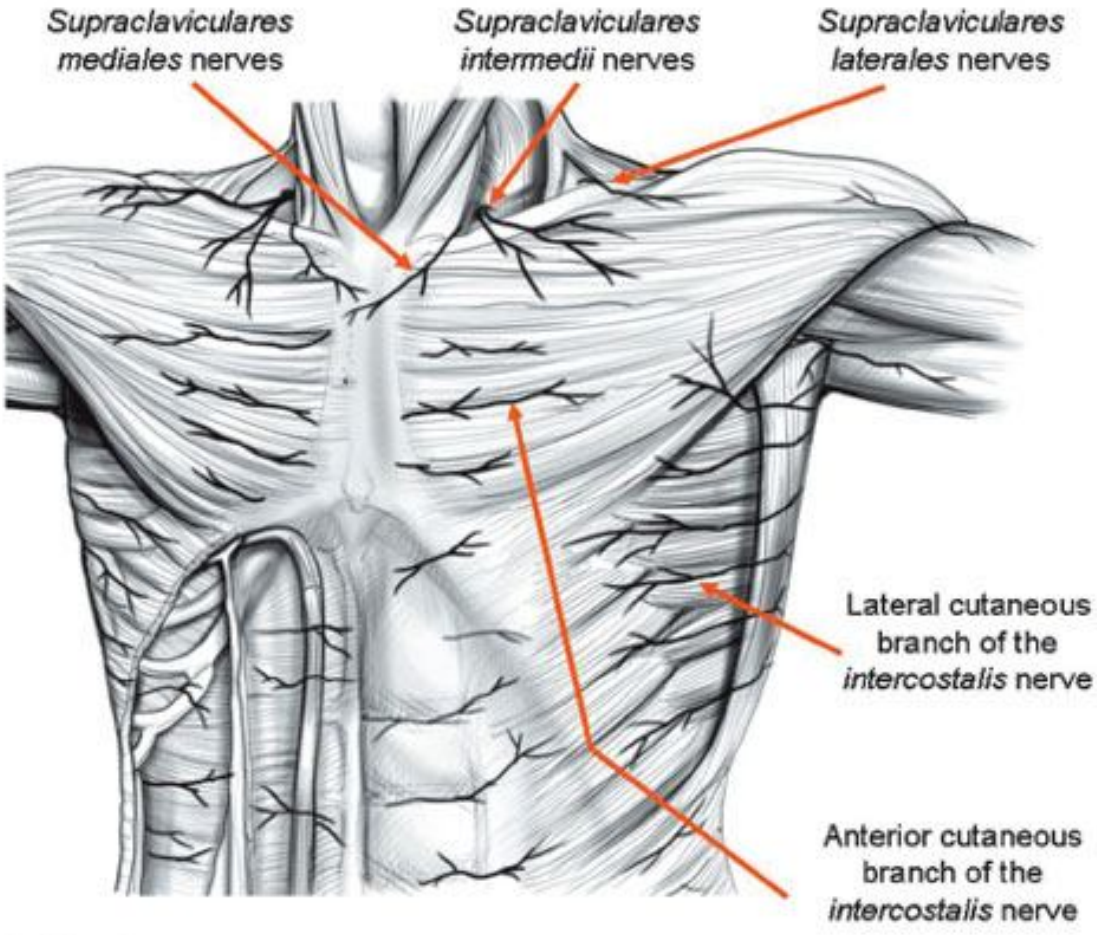
The human breast is supplied by medial, lateral and superior mammarii branches of nerves (Fig. 9). [9]

1. The medial branches are constituted by the anterior cutaneous branch of the intercostal nerves extending from the second to sixth spaces.
2. The lateral branches are constituted by the communicating branch and the anterior division of the lateral cutaneous branch of the intercostal nerves extending from third to sixth spaces. The lateral cutaneous branch of the second intercostal nerve, named the intercostobrachialis nerve runs to supply the base of the axilla and the superior medial face of the arm.

3. The superior branches supply the most cranial region of the breasts and constituted by the supraclaviculares mediales, intermedii and laterales nerves which are branches of the plexus cervicalis.

The mammary papilla is plentifully supplied by free and branched nerve ends.

SENSORY INNERVATION OF THE BREAST



Acute, severe pain after breast surgery is caused by resection, retraction , injury to intercostal nerves, abnormal abduction of the arm during axillary surgery and hematoma formation. Suboptimal pain management not only has major physiological but also psychological implications. Hence proper control of pain not only provides comfort to the patient but also facilitates deep breathing, effective expectoration and early ambulation.

PAIN RELIEF IN BREAST SURGERIES

- Thoracic epidural block
- Thoracic paravertebral block
- Intercostal Nerve block
- Pectoral Nerves Block
- Systemic opioids
- NSAIDs
- Patient controlled intravenous analgesia
- Patient controlled epidural analgesia

Regional techniques have received much attention because of less sedation and early ambulation. Of them, the thoracic epidural block is considered the gold standard technique for pain relief after breast surgery. Paravertebral block is a safe and good alternative to this gold standard technique.

EPIDURAL BLOCK

Epidural anaesthesia is a versatile technique with a unique feature of segmental neural deafferentation which in contrast to the uncontrolled level of blockade in spinal anaesthesia, blocks only the desired segments for analgesia. The analgesia can be extended in the post operative period using continuous catheters.

EPIDURAL SPACE

It is an elliptical space surrounding the dural sac extending from the foramen magnum to coccyx and communicating to the paravertebral space through the intervertebral foramina.

BOUNDARIES: [10]

The boundaries of the epidural space include:

Above **:** The foramen magnum where the periosteal and spinal layer of dura fuse together.

Below **:** The sacrococcygeal membrane

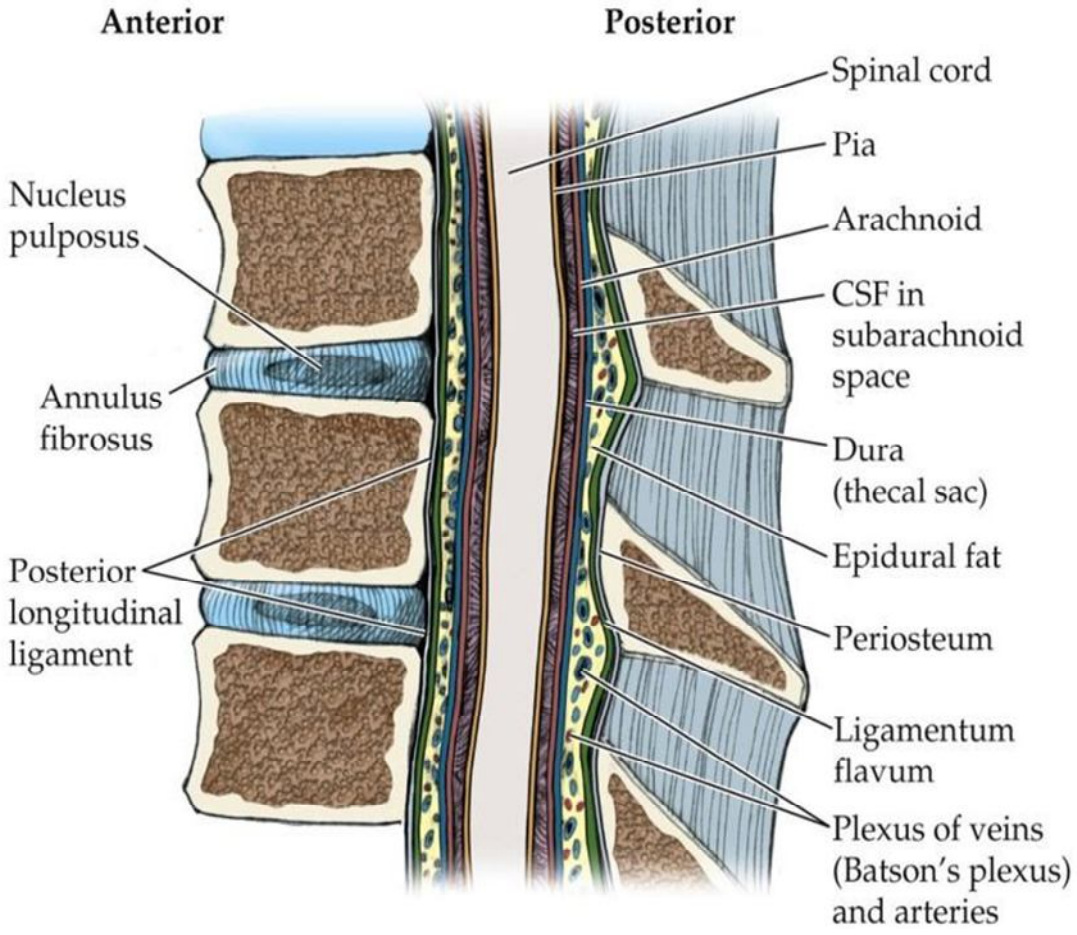
In front **:** The posterior longitudinal ligament

Posterior : Ligamentum flavum and the anterior surface of the vertebral laminae

Laterally : The pedicles of the vertebrae and the intervertebral foramina.

EPIDURAL SPACE

“



CONTENTS :

Epidural space contains loose areolar tissue, fat, spinal nerve roots , arteries, venous plexus and lymphatics. 31 pairs of spinal nerves exit the intervertebral foramina with their dural sleeves.

The epidural space is reached in the mid sagital plane by penetrating the following structures in the midline using an epidural needle :

- Skin and subcutaneous tissue
- Supraspinous ligament
- Interspinous ligament
- Ligamentum flavum

Thoracic epidural is unique in that the spinous processes of the vertebral column are oblique and especially between T4-T7 the tips of the spines usually overlie the next lower vertebra. The distance as measured to the epidural space from the skin is approximately:

i.	Cervical	1.0 to 1.5 mm
ii.	Upper thoracic	2.5 to 3.0 mm
iii.	Lower thoracic	4.0 to 5.0 mm
iv.	Lumbar	5.0 to 6.0 mm

SITES OF ACTION OF LOCAL ANAESTHETICS:[11]

1. On the nerves that traverse the epidural space

2. On the nerves that pass out through the intervertebral foramina

3. On the nerves in the subarachnoid space – by diffusion through the dura.

Predominant evidence shows that the actual site of action is in the region of the intervertebral foramina where the spinal nerves lose their protective dural sheaths.

FATE OF THE EPIDURAL AGENTS:

Bromage summarized the fate of epidurally introduced local anaesthetic agents.

1. Leakage through vascular absorption by the internal vertebral venous plexus

2. Leakage through the intervertebral foramina

3. Diffusion though the dural root sleeves

4. Diffusion through the dura mater

The dispersion of the epidural agent is up and down the space and also along the spinal nerve through the intervertebral foramina.

VOLUME CAPACITY OF EPIDURAL SPACE

Volume of solution required for an epidural anaesthetic depends upon the number of segments to be blocked and the site of injection. Approximately the volume of analgesic solution injected in millilitres per number of dermatomes blocked is as follows

- Cervical 1.5ml
- Thoracic 2 ml
- Lumbar 2.5 ml

FACTORS AFFECTING THE EXTENT OF EPIDURAL ANAESTHESIA

1. Volume of the solution
2. Selection of the appropriate interspace
3. Speed of injection of the drug
4. Age of the patient

5. Height of the patient

6. Position of the patient

7. Effect of gravity

8. Specific gravity of anaesthetic agent

DETECTION OF EPIDURAL SPACE

Several methods have been described to identify the epidural space using the loss of resistance felt when the ligamentum flavum is penetrated or the potential negative pressure that is present in the epidural space.

(A) NEGATIVE PRESSURE TECHNIQUES

The negative pressure present in the epidural space was originally described by Heldt and Moloney in 1928. This negative pressure is relative to the atmospheric pressure.

In the thoracic region, it varies from 1 to 3 cm H2O with an average of 2 cm H20. The techniques include:

1. Hanging drop sign

2. Odom's capillary tube method

3. Manometer technique

(B) DISAPPEARENCE OF RESISTANCE TECHNIQUES

1. Syringe technique

2. Balloon technique

3. Vertical tube of Dawkins

4. Brooke's device

PHYSIOLOGICAL EFFECTS OF EPIDURAL BLOCKADE[12]

The physiological effects of epidural blockade depend on the level of epidural blockade and on the number of spinal segments blocked.

CARDIOVASCULAR SYSTEM

The cardiovascular effects of thoracic block above T4 are a result of a high sympathetic block. Profound hypotension and bradycardia occur when the cardiac sympathetic fibers arising from T1 to T4 are blocked. Vasomotor tone is maintained by the sympathetic thoraco lumbar outflow arising from T5 to L1 innervating the vascular smooth muscle. Epidural anaesthesia causes blockade of these fibers bilaterally causing venodilation with venous pooling of blood and hence resulting in hypotension.

RESPIRATORY SYSTEM[13]

Epidural blockade even upto thoracic level have minimum effects on ventilation and oxygenation. Major alteration in pulmonary function is not seen even with abdominal or intercostal muscle paralysis by a high thoracic block.

GASTROINTESTINAL SYSTEM

Vagal action becomes unopposed due to blockade of sympathetic splanchnic fibers from T5 to L1 level, leading to increase in secretions, peristalsis and contracted gut.

RENAL SYSTEM

Urinary retention may occur till the block wears off. Renal function is maintained normally because the renal blood flow is usually maintained.

NEUROENDOCRINE RESPONSE

Epidural block decreases the stress response and maintains the homeostatic milieu by decreasing the release of stress hormones like adrenaline, noradrenaline and vasopressin.

COMPLICATIONS:

I. PHYSIOLOGICAL:

- Hypotension
- Bradycardia

II. TECHNICAL:

- Inadvertent dural puncture
- Inadvertent vascular puncture

III. COMPLICATIONS WITH CATHETERS:

- Misplacement
- Kinking or Curling
- Occlusion
- Knotting
- Shearing damage

IV. CLINICAL:

- Total subarachnoid block
- Severe hypotension
- Convulsions and neurological sequelae
- Reactions to local anaesthetic agents

V. V.MISCELLANEOUS:

- Hematoma
- Epidural abscess
- Meningitis
- Anterior spinal artery syndrome
- Arachnoiditis and transverse myelitis

CONTRAINDICATIONS :

ABSOLUTE :

- Patient’s refusal
- Coagulopathy or patient on anticoagulant drugs
- Hypovolemia
- Raised intracranial tension
- Local infection at the injection site

RELATIVE :

- Vertebral anomaly
- Preexisting motor or sensory neurological deficits
- Fixed cardiac output states

CONTINUOUS INFUSION EPIDURAL ANALGESIA

Infusion techniques in the epidural space as well as on the peripheral nerves are now commonly used for treatment of acute and chronic pain. Continuous epidural infusion offers certain therapeutic advantages over intermittent bolus injection.

- Wide variability in the duration of effective analgesia is avoided with continuous infusion compared to intermittent boluses.
- Continuous infusions provide ease of titration, particularly when shorter acting drugs are used.
- Intermittent bolus injection technique leads to tachyphylaxis with repeat boluses. In contrast, continuous infusion of the analgesic with the same dose actually increases the intensity of the block.

LIMITATIONS OF CONTINUOUS INFUSION EPIDURAL ANESTHESIA

Complications of continuous epidural anaesthesia include

- Accidental intrathecal administration of the analgesic drug
- Infection
- Epidural hematoma
- Respiratory depression.

To decrease the incidence of these complications, the following guidelines are advocated:

1. The use of appropriate concentrations of local anesthetics (e.g., bupivacaine, 0.0625% to 0.125%) prevents serious hypotension and facilitates diagnosis of subarachnoid catheter migration more readily by providing progressive levels of sensory blockade where none would have been expected.

2. Daily examination of catheter insertion sites, monitoring of temperature, and periodic check for neurologic signs of meningism are essential. If findings consistent with infection are present, the catheter should be removed and the patient should be treated appropriately.

3. Incidence of epidural hematoma is not significant if epidural catheters are placed at least 1 hour before heparinization.

PARAVERTEBRAL BLOCK

Paravertebral block is the technique in which placement of the local anaesthetic produces somatic block and sympathetic block unilaterally and this technique has enjoyed a comeback in the recent years as it is easy to perform with lesser complications and better hemodynamic stability.

ANATOMY OF THE THORACIC PARAVERTEBRAL SPACE

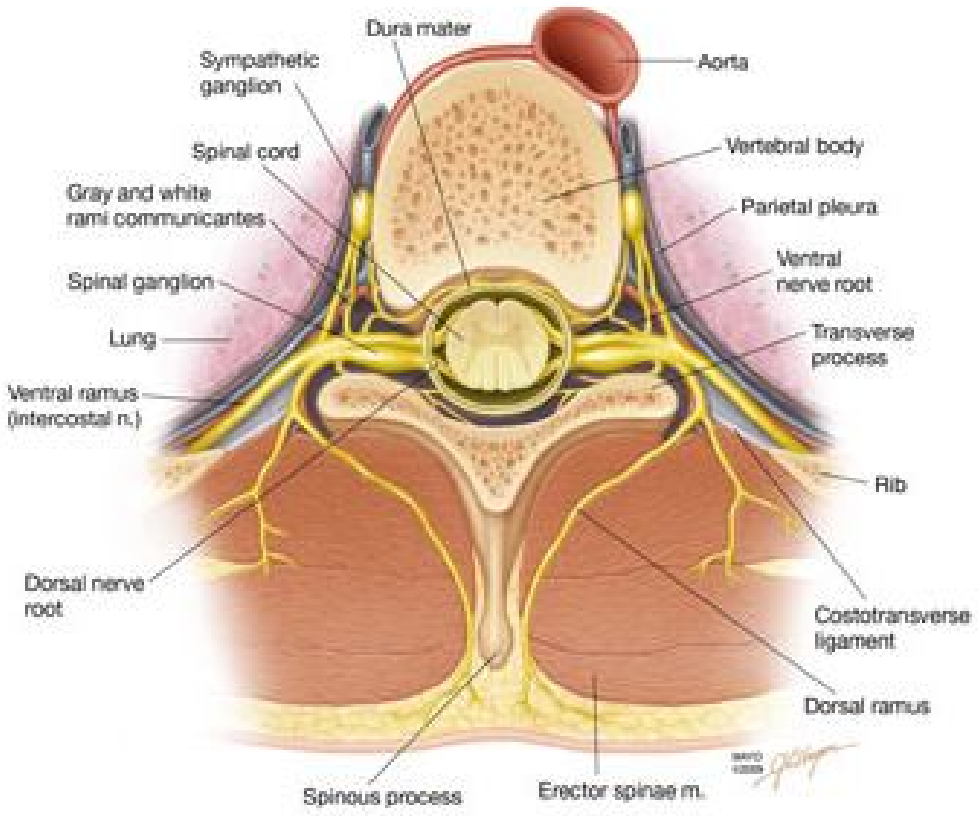
The thoracic paravertebral space extends from T1 cephalad and upto T12 caudally. Most paravertebral blocks are performed at the thoracic level since there is a direct communication between the adjacent levels in the thoracic region. Within this paravertebral space, the spinal root emerges from the intervertebral foramen and divides into dorsal and ventral rami. The sympathetic chain also lies in the same fascial plane, just anterior to the intercostal nerve and communicates with it via the rami communicantes. Hence, PVB produces unilateral sensory, motor and sympathetic blockade[14]. It is a wedge spaced space in all three dimensions lying on either side of the vertebral column with the following boundaries.

BOUNDARIES :

Medial wall : Vertebral bodies, Intervertebral discs and Intervertebral foraminae.

Anterolateral wall : Parietal pleura and the innermost intercostal membrane

Posterior wall : Superior costotransverse ligament, transverse processes of the thoracic vertebrae, Heads of the ribs.



COMMUNICATIONS :

Laterally : With the intercostal space

Medially : To the epidural space through the intervertebral foraminae

Above and below : With the ipsilateral paravertebral space

CONTENTS:

Paravertebral space contains the spinal nerves, the white and grey rami communicantes, the sympathetic chain, intercostals vessels and fatty tissues.

INDICATIONS FOR PARAVERTEBRAL BLOCK

(A) UNILATERAL SURGICAL PROCEDURES IN THORACO ABDOMINAL REGION

- Cholecystectomy
- Renal surgery
- Appendicectomy
- Inguinal hernia repair

- Breast surgeries
- Thoracic surgery

(B) RELIEF OF ACUTE PAIN

- Fracture ribs
- Liver capsule pain

TECHNIQUE OF PARAVERTEBRAL BLOCK

Preparation:

After obtaining informed consent, an IV access is secured, standard non invasive monitors are connected and full resuscitation facility is made available. Strict aseptic precautions are taken when preparing the patient for the paravertebral block.

POSITIONING:

When the patient is awake, the block can be performed by making the patient seated and flexing the neck and the back. When performed under general anaesthesia the patient is turned to lateral position and with the operated site uppermost.

PROCEDURE:

After choosing the desired level, the paravertebral space is identified using the 16G Tuohy needle by the loss of resistance technique. The epidural needle is introduced through the skin approximately 2- 3 cm lateral to the midline, corresponding to the cephalad end of the spinous process. The needle is advanced till it contacts the transverse process. This depth varies from 2-4 cm depending upon the individual. The needle is walked over the upper border of the transverse process. At this point, the loss of resistance syringe is attached to the epidural needle and further advancements are made in cranial angulations in small increments upto 1-1.5 cms and the paravertebral space is identified using the loss of resistance syringe until there is a loss of resistance or a subtle click is felt or sometimes even audible on penetration of the superior costotransverse ligament.

CATHETER INSERTION FOR CONTINUOUS ANALGESIA:

Catheterization in the paravertebral space requires slightly more force than that required to thread an epidural catheter. There is an increased risk of intercostal or epidural cannulation on deeper insertion.

MECHANISM OF SPREAD OF INJECTED DRUG:

Local anaesthetic injected in the paravertebral space extends not only in the craniocaudal direction, but it can also spread variably to prevertebral plane, intercostal space and even into the epidural space. In the paravertebral space, the spinal nerves are devoid of a fascial sheath, and hence they are exceptionally susceptible to the local anaesthetic agent. This explains the high quality of analgesia and prevention of chronic pain syndromes.

For continuous local anaesthetic infusions the recommended volume is 0.1 ml / kg/hr in adults and 0.2 ml/kg /hr for children.[15]

IDENTIFICATION OF PARAVERTEBRAL SPACE:

1. Loss of resistance technique
2. Contrast injection and identification with X-ray
    - Dye spreads over the superior and inferior necks of the ribs and along the vertebrae called “Linear streaming”
3. Pressure monitoring with transducer attached to Tuohys needle
    - Muscular plane shows an increase in pressure
    - Paravertebral space shows a decrease in pressure or an inversion of pressure wave form.
    - Pleural puncture shows a negative pressure both during inspiration and expiration.

SIDE EFFECTS AND COMPLICATIONS

Only a few have been observed

- Hypotension (4.6% cases)
- Pleural puncture
- Pneumothorax
- Vascular puncture
- Ipsilateral Horner syndrome
- Total spinal anaesthesia
- Pain at the skin puncture site

CONTRAINDICATIONS

ABSOLUTE

- Local sepsis
- Tumors at the level of injection in the paravertebral space
- Allergy to local anaesthetic drugs
- Patient refusal

RELATIVE

- Severe coagulopathy
- Severe respiratory disease
- Ipsilateral diaphragmatic paresis

ADVANTAGES OF PARAVERTEBRAL BLOCK

- Can be performed in an anticoagulated patient
- No risk of spinal hematoma
- Less risk of neurological complications compared to thoracic epidural block
- Significant hypotension is unusual since the sympathetic block is rarely bilateral.
- Unlike the other central neuraxial technique, urinary retention does not occur.

PHARMACOLOGY OF BUPIVACAINE

Bupivacaine is a widely used amide local anaesthetic drug. Local anaesthetics prevent or relieve pain by interrupting the nerve conduction. Their action is on the site of application and it rapidly reverses on diffusion from the site of action in the nerve.[7]

Bupivacaine (Marcaine, Sensorcaine), was first synthesized by A.F.Ekenstam in 1957. Clinically it was first used by Windenson and Techimo in 1963.

Bupivacaine has a long duration of action. And it also has a tendency to produce more sensory block than motor block. This has made bupivacaine a popular drug for providing prolonged analgesia in the postoperative period. Bupivacaine is being commonly used to provide effective analgesia with the use of indwelling catheters and continuous infusions.

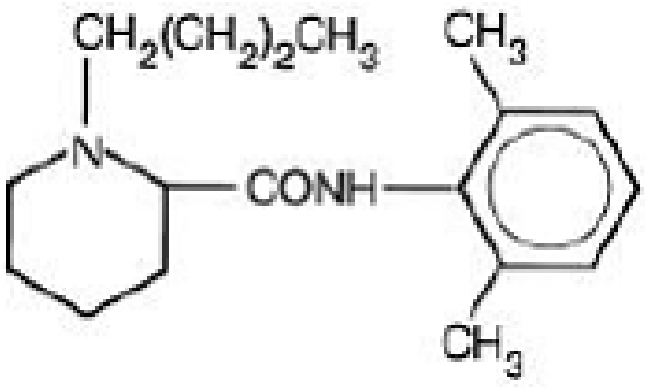
Bupivacaine is produced as a racemic mixture containing equal proportions of the ‘S’ and ‘R’ enantiomers. It is available as a hydrochloride salt for clinical use.

In general, small nerve fibers are more susceptible to the action of local anesthetics than the larger nerve fibers. Autonomic nerve fibers, small unmyelinated C fibers - mediating pain sensations and small myelinated A delta fibers - mediating pain and temperature sensations are very susceptible to the action of local anaesthetics.

IUPAC NAME OF BUPIVACAINE:

1-butyl-N-(2,6-dimethylphenyl) piperidine-2-carboxamide.

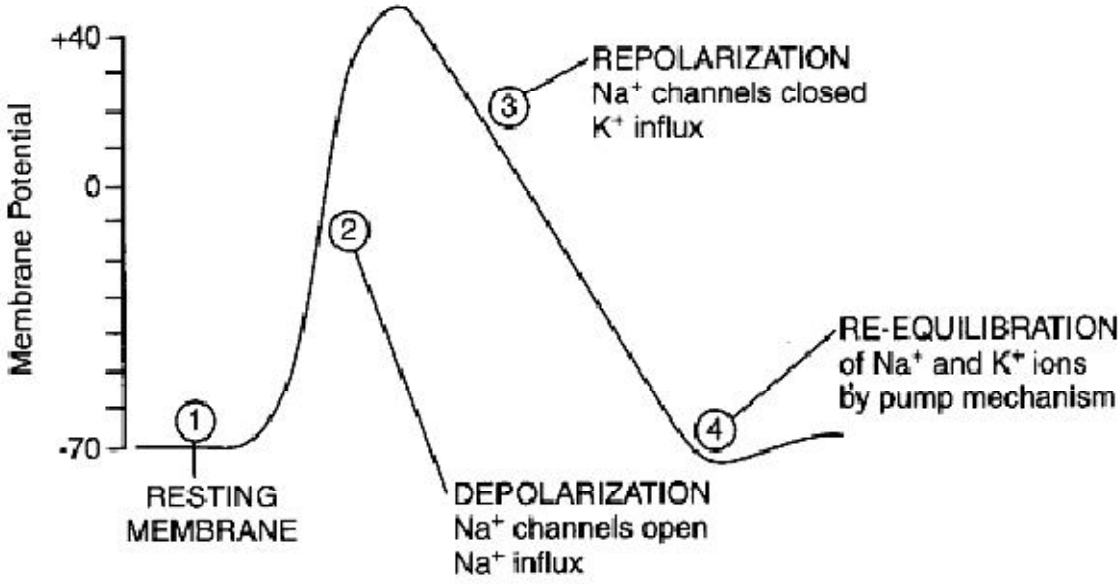
CHEMICAL STRUCTURE



The recommended routes of administration and the indicated Bupivacaine injection concentrations are:

- Local infiltration 0.25%
- Peripheral nerve block 0.25% and 0.5%
- Retrobulbar block 0.75%
- Sympathetic block 0.25%
- Epidural block 0.25%, 0.5% and 0.75%
- Paravertebral block 0.25%, 0.5%, and 0.75%
- Caudal 0.25% and 0.5%

MECHANISM OF ACTION OF LOCAL ANAESTHETIC:



The principal ions involved in generating the action potential in the nerve membranes are sodium and potassium. This ionic gradient for sodium and potassium is maintained by a sodium-potassium ion-translocating adenosine triphosphatase (ATPase) pump mechanism within the nerve. In the resting state, the nerve membrane is more permeable to potassium ions than to sodium ions and this results in an electrical potential of −60 to −70 mV across the nerve membrane.

Bupivacaine prevents the transmission of nerve impulses by inhibiting passage of sodium ions by binding to the alpha subunit of the ion selective channel which is in an inactivated – close state and stabilizes them. This prevents its conformation to rested close or activated open state. In inactivated closed state, the ion channel is not permeable to sodium and hence the propagation of action potential and conduction of nerve impulses cannot occur.

PHARMACOKINETICS

Absorption of bupivacaine depends on site of injection, dose and adjuvants used . The plasma concentration is determined by the rate of tissue distribution and rate of clearance. Bupivacaine is a weak base with pK value above the physiological pH. Hence metabolic acidosis leads to an increase in ionized fraction of drug and poor quality anaesthesia.

Bupivacaine binds to plasma protein alpha 1 acid glycoprotein. It undergoes aromatic hydroxylation, N de alkylation, amide hydrolysis and conjugation.

- Molecular Weight : 288
- pKa : 8.1
- Onset of action : 20-40 min
- Duration of action : 240- 480 min
- Protein binding : 95%
- Volume of distribution : 73 litres
- Clearance : 0.47l/min
- Elimination Half life : 210 min
- Toxic plasma concentration : More than 5 µg/ml.

SIDE EFFECTS:

1. Allergic reactions

2. Neurotoxicity

3. Cardiotoxicity - Bupivacaine is more depressant on cardiac contractility. Enhanced cardiotoxicity of bupivacaine is because of its action that it blocks cardiac Na+ channels rapidly during systole and also it dissociates much more slowly during diastole. So a significant fraction of Na+ channels remain blocked at the end of diastole. Thus, the block by bupivacaine is cumulative. This predisposes the patient to reentrant phenomena, leading to ventricular dysrhythmias,

4. Hepatotoxicity

REVIEW OF LITERATURE

Pain is now considered as the fifth vital sign and needs regular monitoring as suggested by the American Pain Society. An effective management of acute postoperative pain helps in avoiding the respiratory, cardiovascular, hemodynamic and metabolic complications thereby aiding in speedy recovery and early patient discharge.

1. **Vogt et al**[16] did a randomized study in postoperative pain management after thoracoscopic surgery with single injection thoracic paravertebral block. 40 patients were randomly allotted to two groups . The study group (n =20) received intravenous patient controlled analgesia with morphine and a single injection thoracic paravertebral block with 0.4 ml/kg of 0.375% bupivacaine and adrenaline 1:200000. The control group (n=20) received puncture at the back without any drug injection and intravenous patient controlled analgesia with morphine. The median Visual Analogue Score on coughing in the paravertebral group at half an hour and 24 hours after surgery was 31.0 (20.0 – 55.0) and 30.5 (17.5- 40.0) respectively, whereas that in the control group was 70.0 (30.0 -100.0) and 50.0 (25.0-75.0) respectively. Statistically

significant difference was observed in VAS in the entire observation period ($p < 0.05$).

No differences were found in the peak expiratory flow rate or the incidence of any other side effect between both the groups.

The study concluded that paravertebral block provides significant pain relief after thoracoscopic surgery compared to conventional patient controlled analgesia.

2. **Azad et al** [17] did a comparative study of post operative pain relief using continuous epidural with local anaesthetics and fentanyl versus patient controlled intravenous analgesia with piritramid in patients undergoing thoracotomy. In this study, 50 patients were included for randomized trial. 25 patients in the continuous epidural analgesia group (EA group) received an infusion of local anaesthetics (bupivacaine 0.125% or ropivacaine 0.2%) and fentanyl 4-5 micrograms/ml with a flow rate of 4-10 ml/hr for postoperative analgesia. The other group of 25 patients received intravenous patient controlled analgesia with piritramid (bolus 2.5 mg , lock out 15 minutes , maximum of 25 mg/hr, no background infusion).

Visual analogue score, at rest and on coughing , pulmonary function test were compared. Analgesia at rest and on coughing were significantly better in the EA group. EA group also showed significantly better pulmonary function test, better general condition and lower incidence of sedation and nausea. However the incidence of pruritus was more with the EA group than the patients with PCA. Duration of hospital stay was shorter with Epidural group, however this difference did not reach statistical significance. There was an incidence of one atelectasis in the EA group. No major complications related to EA or PCA were observed.

This study concluded that EA with local anaesthetics and fentanyl provided superior post operative pain relief compared to PCA with piritramid and also EA has lower incidence of sedation and nausea.

3. **Karmakar et al** [18] did a prospective non randomized case series study to evaluate the efficacy of a continuous thoracic paravertebral infusion of bupivacaine in patients with multiple unilateral fractured ribs for post operative pain management. Fifteen patients with multiple unilateral fractured ribs were taken up for the study and insertion of catheter in the thoracic paravertebral space was done . An initial injection of 0.3ml/kg of 0.5% bupivacaine (1.5mg/kg) with 1:200000

epinephrine was administered followed 30 minutes later with a continuous infusion of 0.25% bupivacaine at 0.1 to 0.2 ml/kg/hr for 4 days.

Significant improvement in pain scores (at rest , $p = 0.002$; during coughing , $p= 0.001$) , respiratory rate ($p<0.0001$) , PEFR ($p= 0.01$), FVC ($p=0.007$) , SaO2 ($p=0.04$) and O2 index ($p= 0.01$) were noticed 30 minutes after the initial injection which were sustained for 4 days when the thoracic paravertebral infusion was in use ($p<0.05$). PaCO2 did not change significantly after the initial injection. However it was significantly lower on day 4 than the post TPVB value ($p= 0.04$)

The study came to a conclusion that continuous infusion of bupivacaine in thoracic paravertebral space is an effective and simple method of providing continuous pain relief in patients with unilateral multiple fractured ribs. It also provided a sustained improvement in respiratory parameters and oxygenation.

4. **Mehta et al** [19] conducted a randomized prospective study to compare the quality of analgesia, hemodynamic stability, complications and respiratory parameters in patients undergoing elective robotic assisted

coronary artery bypass grafting (CABG) by using thoracic epidural technique versus thoracic paravertebral technique. 36 patients were included in the study and they received either thoracic epidural or thoracic paravertebral block.

The quality of analgesia was comparable in both the groups. No significant differences were seen with respect to arterial blood gases and hemodynamics . Pulmonary functions were better maintained in PVB group postoperatively. The study concluded that PVB is a safe and effective technique for post operative analgesia compared to TEA after robotic assisted CABG.

5. **Dhole et al** [20] did a prospective randomised comparative study for postoperative analgesia using continuous thoracic epidural analgesia (TEA) and paravertebral block (PVB) in patients undergoing minimally invasive coronary artery bypass (MIDCAB) surgery for quality of analgesia, hemodynamics, complications, respiratory efforts and compliance to chest physiotherapy.

No statistically significant difference was noted in visual analogue scores and the requirement of supplemental analgesia was similar in both the groups. In the TEA group, Cardiac index was significantly higher at 4 hours and 6 hours. Respiratory rates were lower in PVB group at 8, 10 and 12 hours. All other parameters were comparable. PVB is technically easier, safer than and as effective as TEA for post operative analgesia after MIDCAB surgery.

6. **Casati et al** [21] did a randomized , prospective study to compare the post operative analgesia in patients undergoing thoracotomy for lung resection surgery using continuous infusion of 0.2% Ropivacaine with either a thoracic epidural (group EPI, n = 21) or thoracic paravertebral (group PVB, n = 21) at an infusion rate of 5–10 mL h−1. The degree of pain at rest and during coughing as recorded by visual analogue score, haemodynamic variables and blood gas analysis were recorded every 12 hours for the first 48 hours. The visual analogue score was comparable in both the groups (p=0.29). Rescue morphine analgesia was required in four patients of group EPI (19%) and five patients of group PVB (23%) (P = 0.99). The PaO2/FiO2 ratio was significantly reduced in both groups from baseline values. Hypotension defined as

systolic arterial pressure decrease >30% of baseline was observed in four patients of group EPI only (19%) (P = 0.04).

Patient satisfaction with either technique is clinically comparable (p=0.65).

The study concluded that a continuous infusion of ropivacaine through thoracic paravertebral analgesia is as effective as thoracic epidural analgesia in post thoracotomy pain but paravertebral block is associated with lesser haemodynamic effects.

7. **Cheung et al** [22] did a prospective study to evaluate the efficacy of a right thoracic paravertebral block for anaesthesia and analgesia during percutaneous radiofrequency ablation (PRFA) of liver tumours. The study group consisted of 20 patients who received multiple injections of thoracic paravertebral block at T6 to T10 levels . Block was given thirty minutes before PRFA and pain was assessed using a numerical rating. Patients were also assessed for residual pain and analgesic consumption during the 24 hours after the intervention.

This study concluded that a right thoracic paravertebral block is a safe technique for anesthesia and analgesia in patients undergoing percutaneous radiofrequency ablation (PRFA) for liver tumours.

8. **Richardson et al** [23] did a prospective comparative study on patients undergoing thoracotomy by randomly allocating 100 patients into thoracic epidural group or thoracic paravertebral group. Preoperative bolus doses of bupivacaine followed by continuous infusion was given and the following parameters were observed : post operative analgesia, pulmonary function and stress responses .

The paravertebral group showed significantly lower visual analogue scores at rest and on coughing. The need for patient controlled morphine was also lesser in this group. The patients in this group also showed higher oxygen saturations and lesser post operative morbidity.

Stress response as measured by serum cortisol and glucose levels was significantly lower in the paravertebral group. Higher incidence of

side effects namely hypotension, nausea and vomiting was noticed in the epidural group.

The study hence concluded that paravertebral block was superior to epidural block using bupivacaine with this regimen.

9. **Gulbahar et al** [24] compared the effectiveness in relieving the pain caused by a thoracotomy incision by thoracic epidural blockade (TEB) and the paravertebral blockade (PVB) methods. Bolus dose of 5ml of 0.25% bupivacaine was given just prior to thoracic closure followed by infusion rate of 0.10 ml/kg/hr. (1 h lock interval and 2 ml bolus) through a patient-controlled elastomeric infusion pump.

The groups were compared according to the parameters such as analgesic efficacy (VAS), respiratory function tests (FEV1), peak expiratory flow rate (PEFR), Arterial blood gases, Stress response (serum cortisol and glucose levels), adverse effects, Need for additional analgesia, duration of catheter application procedure, mean hospital stay and postoperative follow-up. Regarding VAS scores, no significant differences were detected in the postoperative days 1—3 between the two groups ($p = 0.943$, $p = 0.896$, $p = 0.686$). There was also no significant difference between the groups in terms of additional morphine sulphate requirement, FEV1, PEFR, serum

cortisol and glucose levels. However the duration of catheterisation and adverse effects were significantly lower in the paravertebral group.

The study thus concluded that PVB catheterisation can be easily performed and preferred method over TEB which has a high incidence of adverse effects and complication rates.

10. **Moawad et al** [25] conducted the study to compare single dose paravertebral block (PVB) versus single dose epidural blockade (EP) for pain relief after renal surgery.

80 patients were randomly allotted into two groups and were subjected to either of the analgesic techniques. General anesthesia was induced for all patients. Postoperative pain was assessed over 24 h using Visual analog scale (VAS). Postoperative total pethidine consumption, respiratory complications , hemodynamics and blood gasometry were also recorded. EP group showed significant decrease in both heart rate and mean blood pressure at most of the operative periods when compared with PVB group. There was no significant

difference in total rescue analgesic consumption or postoperative VAS between the studied groups.

The study thus concluded that PVB provided greater hemodynamic stability than epidural analgesia in patients undergoing renal surgery and the study recommends the use of paravertebral block in patients with co existing circulatory disease.

11. **Davies et al** [26] did a systematic review and meta analysis of 10 randomised studies comparing epidural analgesia with paravertebral block in patients undergoing thoracic surgery. No significant difference in pain scores was noticed between the two groups. Pulmonary function was better with the paravertebral group. Other complications like urinary retention, nausea, vomiting , hypotension were more with the epidural group. Failure rate in technique was lower with the paravertebral group.

This review concluded that PVB and epidural analgesia provide comparable pain relief in patients undergoing thoracic surgery but PVB group has lesser side effect profile with respect to haemodynamic stability and pulmonary complications.

12. **Joshi et al** [27] did a systematic review of randomized trials evaluating regional techniques for post operative analgesia in **patients** undergoing thoracotomy. They evaluated thoracic epidural, thoracic paravertebral , intercostal and interpleural analgesic techniques and compared each other to systemic opioid analgesia in adult thoracotomy. Post operative pain relief , analgesic use and complications were analysed.

This review concluded that continuous paravertebral block was as effective as thoracic epidural analgesia with local anaesthetic but was associated with a reduced incidence of hypotension. Paravertebral block had reduced incidence of pulmonary complications. Continuous paravertebral block and thoracic epidural block were superior to intercostal block technique and although these were superior to systemic analgesia ; interpleural analgesia was inadequate.

13. **Santhosh et al** [28] compared epidural block with paravertebral block for post thoracotomy pain relief . It involved fifty patients who were divided into a group of 25 patients each and received 8 ml of 0.25%

bupivacaine either in **thoracic** epidural region or thoracic paravertebral region at the end of surgery.

No difference was observed between the two groups regarding the mean pain score. 50% patients in epidural group showed hypotension compared to 8% patients in paravertebral group. The technical failure rate was 20% in epidural group compared to 8% in paravertebral group. The study concluded that both thoracic epidural and thoracic paravertebral block provided effective post operative analgesia following thoracotomy.

However in paravertebral block the failure rate and complications were much less compared to thoracic epidural block.

MATERIALS AND METHODS

After approval of the study by our institutional ethics committee the study was conducted in 60 ASA Grade III patients undergoing major elective breast surgery namely modified radical mastectomy under general anaesthesia. The age of the patients ranged from 18 to 60 years , weight ranging from 35 to 65kgs and height ranging from 145 to 170 cm. All patients were thoroughly examined preoperatively.

Informed written consent was obtained from each patient after the procedure was fully explained in the patient's own language. Age, weight, height, side of surgery were noted in all patients. Vital parameters like pulse rate, blood pressure, spo2, respiratory rate were recorded in the assessment room. Baseline investigations like hemoglobin, blood sugar, blood urea, serum creatinine, platelet count, bleeding time, clotting time, chest X ray, ECG, were checked. Thorough examination of all the systems and airway assessment was done.

Patient's refusal, thoracic vertebral disease or deformity, local sepsis, coagulation disorders, neurological disorders, pre existing motor or sensory deficit, psychiatric disorders, cardiac failure, renal failure, patients allergic to local anaesthetics were excluded from the study. Visual analogue score was explained to the patients. The patients were

shown a 10cm long scale marked 0-10 on a blank paper and told that 0 represented “no pain” and 10 represented “worst possible pain”.

MATERIALS USED:

1. 16G 9cm Tuohy needle with Huebers tip,
2. 18G epidural catheter with filter,
3. Loss of resistance syringe,
4. 5ml syringe.
5. Continuous syringe infusion pump,
6. Local anaesthetics
    (a) 2% lignocaine with 1 in 200000 adrenaline.
    (b) 0.25% bupivacaine
    (c) 0.125% bupivacaine
7. Sterile drapes
8. Visual analogue scale

60 patients were randomly allocated into either of the two groups.

GROUP P:

Thirty patients in this group received 8ml of 0.25% bupivacaine as bolus through thoracic paravertebral block, after the completion of the surgical procedure followed by a continuous infusion of 0.1ml/kg/hr of 0.125 % bupivacaine for 48 hours.

GROUP E:

Thirty patients in this group received 8ml of 0.25% bupivacaine as bolus through thoracic epidural block, after the completion of the surgical procedure followed by a continuous infusion of 0.1ml/kg/hr of 0.125 % bupivacaine for 48 hours.

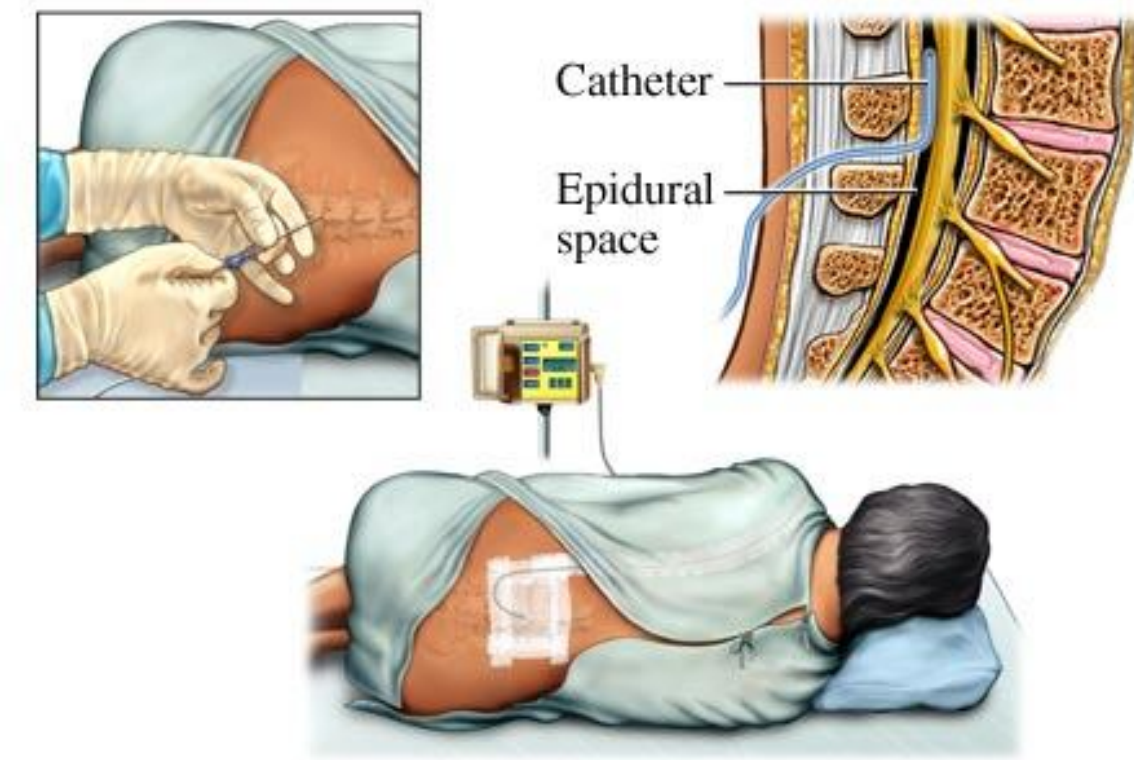
After shifting the patient to the operating room, ECG, pulse oximeter, Non invasive blood pressure monitors were connected and baseline readings were recorded.

Intravenous access was obtained with an 18 G intravenous cannula.

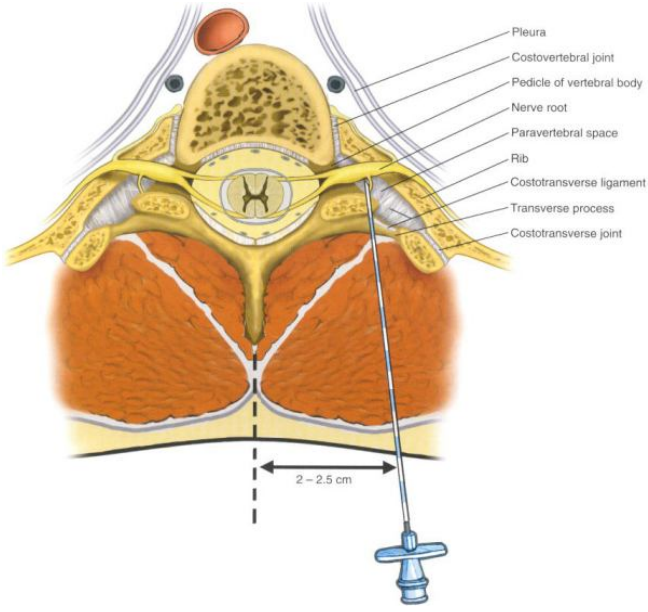
In Group E, before the start of surgery, the patient's back was prepared with povidone iodine, draped with sterile towels and under sterile aseptic precautions thoracic epidural block was performed at T6-T7 epidural space with 16G Tuohy needle by loss of resistance technique.

Epidural catheter was introduced 4cm cephalad so that the epidural tip was approximately at the level of T3.

If vascular or dural puncture was encountered during the attempt, the space above was chosen to give the block. A test dose of 3ml of 2% lignocaine with 1:200000 adrenaline was given through the epidural catheter to ascertain the correct placement of the catheter.



In group P, before the start of surgery, under strict aseptic precautions, thoracic paravertebral block was performed at T6-T7 paravertebral space with 16G Tuohy needle by loss of resistance technique. The epidural needle was introduced through the skin approximately 3 cm lateral to the midline and corresponding to the cephalad end of the spinous process. The needle was advanced till it contacted the transverse process and the needle was walked over it . At this point, the loss of resistance syringe was attached to the epidural needle and further advancements were made in small increments and the paravertebral space was identified using the loss of resistance technique. 4cm of the 18G epidural catheter was kept in the paravertebral space and directed cephalad . Test dose of 3ml of 2% lignocaine with 1:200000 adrenaline was given through the epidural catheter.



Inj.Glycopyrolate 0.2mg and inj.Fentanyl 2 µg/kg were given as premedication.

Preoxygenation was done.

Induction was done with inj. Thiopentone 5mg/kg.

After checking for good mask ventilation, muscle relaxation was aided with Inj.Vecuronium bromide 0.1mg/kg.

Intravenous lignocaine (Xylocard) was given 1.5mg/kg before intubation to attenuate the stress response.

Patients were intubated and secured with appropriate size cuffed endotracheal tube.

Bladder catheterization was done before the start of surgical procedure.

Anaesthesia was maintained with N2O and O2 in a ratio of 2:1 and 1 MAC of Sevoflurane.

Muscle relaxation was maintained with intra venous vecuronium and intra operative pain relief was managed with adequate doses of fentanyl.

Blood loss, hypotension or any other complication was managed appropriately intra operatively.

After the surgery was over, patients were turned supine and ventilation was assisted. Once adequate spontaneous respiratory attempts had come, the patients were reversed with Neostigmine 50µg/kg and Glycopyrolate 10 µg/kg. Patients were extubated after thorough oral suctioning.

At this time, the patient's pulse rate, Systolic blood pressure, Diastolic blood pressure were noted down and these values were taken as baseline values for subsequent hemodynamic measurements.

In group E, after ensuring the correct placement of the catheter, 8 ml of 0.25% bupivacaine was injected as thoracic epidural block and in group P, after ensuring the correct placement of the catheter, 8 ml of 0.25% bupivacaine was injected as paravertebral block.

Post operative Visual Analogue Score was noted every 10 min after giving the drug.

Procedure was considered a failure, if there was an unsatisfactory post operative analgesia with VAS score more than 4 during assessment at 20 min after giving the block. These patients were excluded from the study and were given inj.Pentazocine 0.6mg/kg for pain relief.

All the patients were shifted to post anaesthesia care unit for observation for next 48 hours. The patient's vitals were recorded every 10 min for first 1 hour and then every half an hour for 2 hours, then at 4hours, 6 hours, 8hours, 12hours , 24hours, 36hours and 48hours.

A continuous infusion of 0.125% Bupivacaine was started one hour after the bolus, using a syringe infusion pump.

Time to reach complete analgesia is defined as the time duration at which the patient's Visual Analogue Score becomes zero.

Rescue analgesia was given at any time when VAS more than 4. Inj. Pentazocine 0.6 mgkg-1 was given intravenously when the VAS exceeded 4.

Hypotension was defined as 20% fall in mean arterial pressure from the baseline.

Bradycardia was defined as pulse rate less than 50 beats / minute and was managed with Inj Atropine 0.6mg

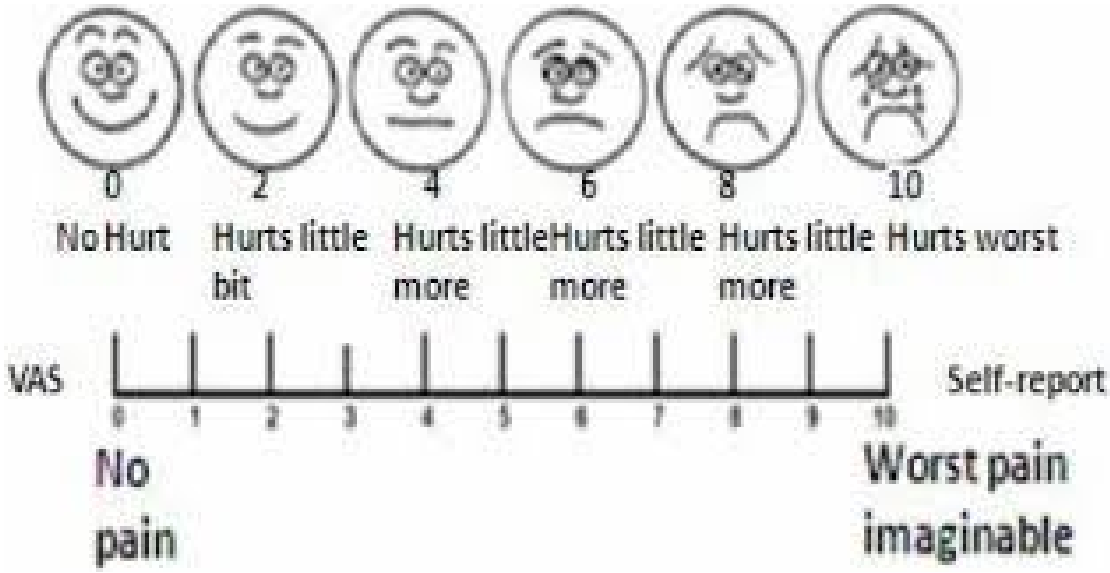
Bedside chest X ray was done to rule out pneumothorax.

Other complications like local anaesthetic toxicity were also noted.

VITAL SIGNS:

Pulse Rate, Systolic Blood Pressure, Diastolic Blood Pressure were recorded for observation.

VAS SCORE:



OBSERVATION & ANALYSIS

Prospective, randomized, single blinded (subject) controlled trial to compare the analgesic efficacy and safety profile of continuous infusion of bupivacaine through thoracic epidural block and thoracic paravertebral block in adult patients undergoing elective breast surgery. 60 patients were taken into the study group. 30 belonged to group P (Paravertebral block) and 30 belonged to group E (Epidural block).

Results were expressed as mean and standard deviation. All statistical analysis was carried out using SPSS for windows version 15.0. The t-test was used for comparison of quantitative variants. Qualitative variants were compared using the chi-squared test or fischer's exact test.

A p value of less than 0.05 was considered statistically significant.

TABLE : 1

DEMOGRAPHIC PROFILE – AGE

GROUP	N	MEAN	SD	P VALUE
P	29	43.45	6.801	0.249 **Not Significant**
E	30	45.57	7.152	

The age distribution in group E was from 34yrs to 58 yrs and in group P it was from 34yrs to 60 yrs. The mean age distribution in both the groups was similar .Both the groups are comparable in terms of age.

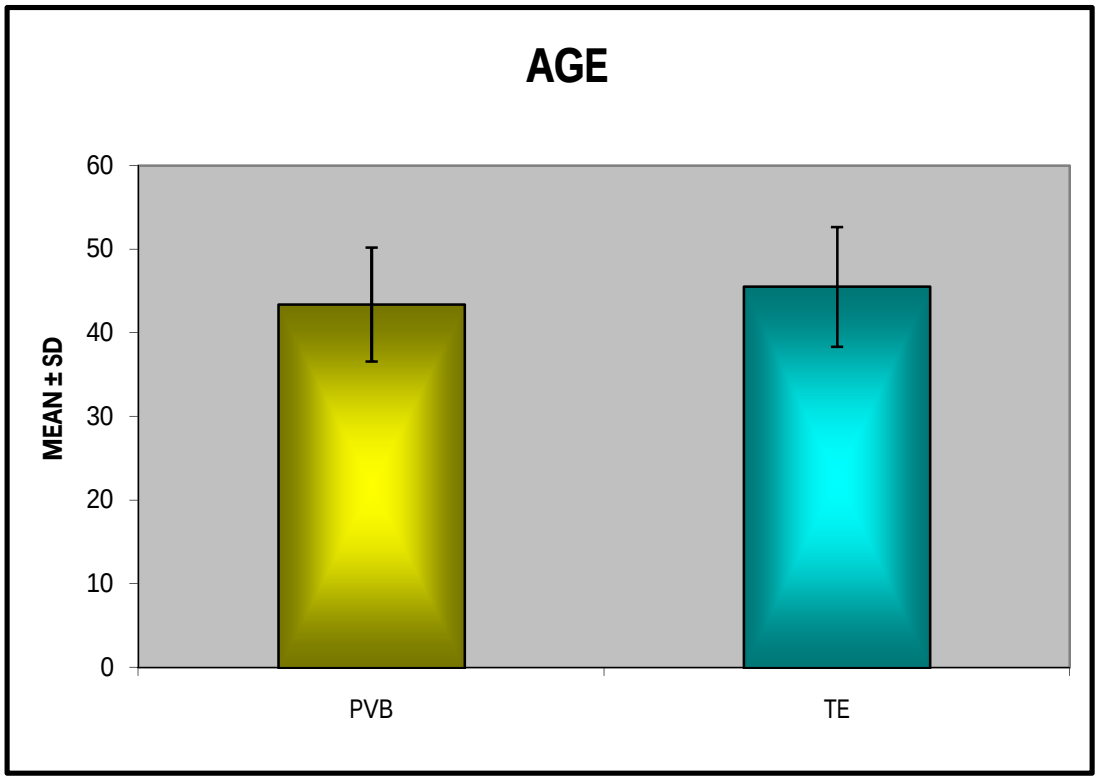


TABLE – 2

DEMOGRAPHIC PROFILE – BMI

GROUP	N	MEAN	SD	P VALUE
P	29	23.49	0.84	0.216 **Not significant**
E	30	23.79	1.00	

The mean BMI of group P is 23.49 and that of group E is 23.79. The p value is more than 0.05 and hence the data is not statistically significant and both the groups are comparable in terms of BMI.

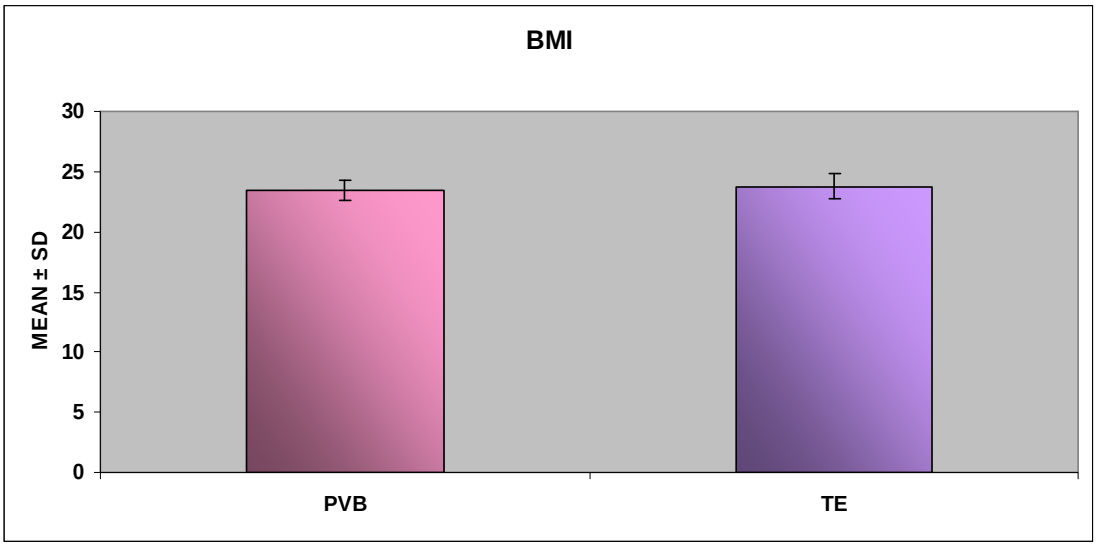


TABLE – 3

SIDE OF SURGERY

GROUP	P	E
R	16 (55.2%)	17 (56.7%)
L	13 (44.8%)	13 (43.3%)

13 epidural and 13 paravertebral blocks were performed on left side while 17 epidural and 16 paravertebral blocks were performed on right side. The p value is 0.908 which is not significant and both the groups are comparable.

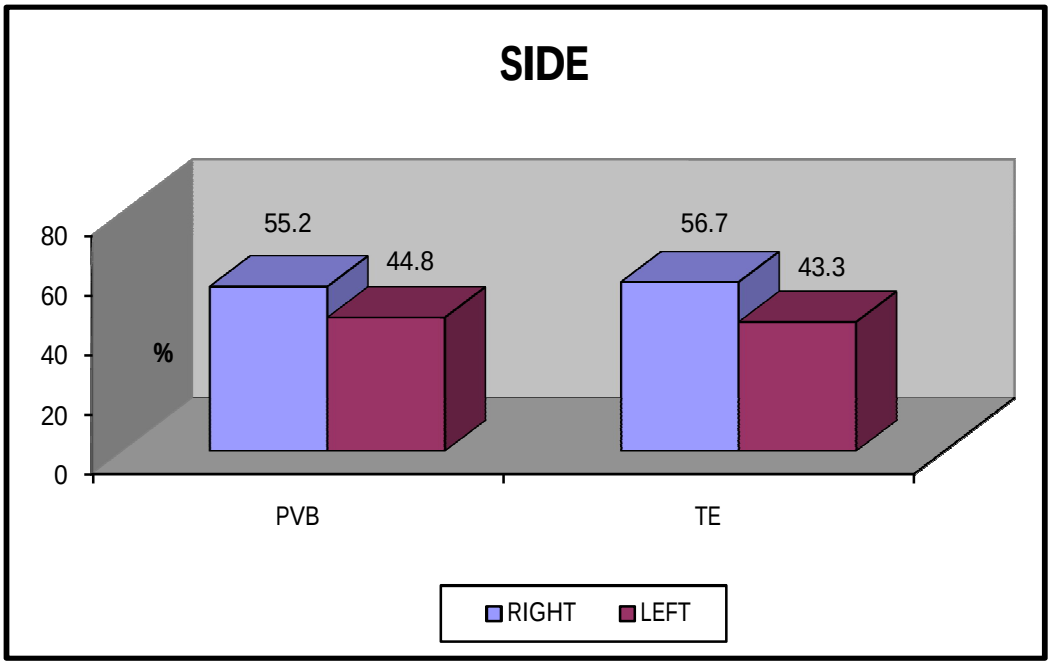


TABLE – 4

TIME TO REACH COMPLETE ANALGESIA (VAS = 0)

GROUP	N	MEAN	SD	P VALUE
P	29	42.62	3.499	0.427 **Not Significant**
E	30	43.63	5.881	

In group P, the mean time to reach pain score = 0 is 42.62 minutes compared to 43.63 minutes compared to group E. This data is not significant (p more than 0.05) by student's t test .

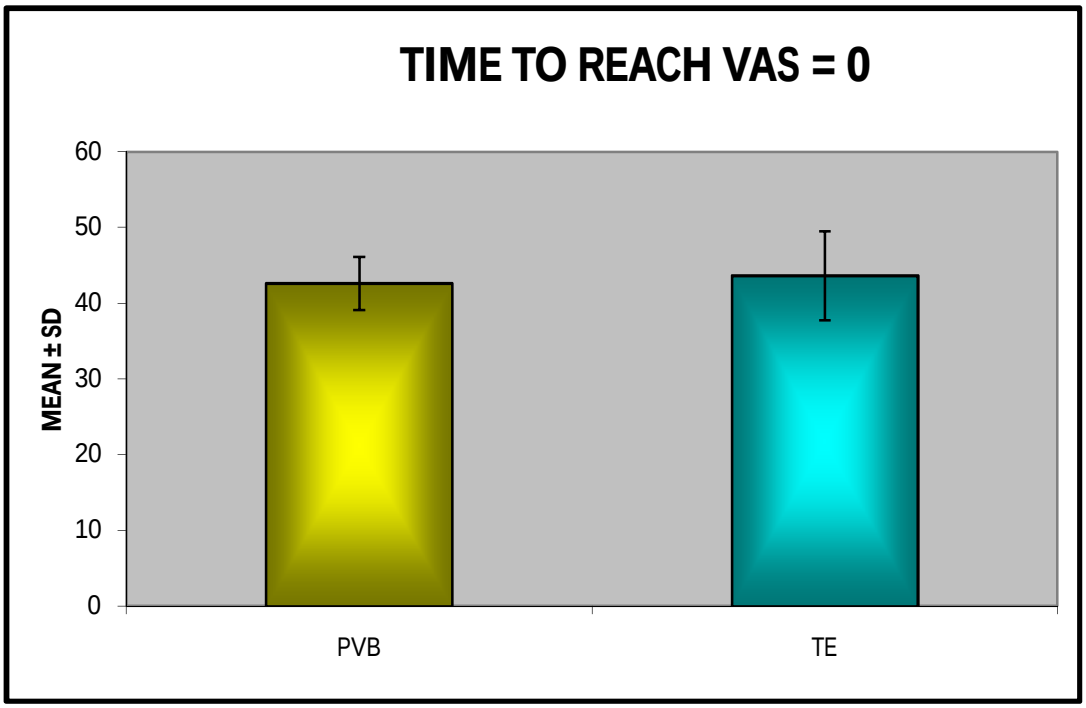


TABLE – 5

TECHNICAL FAILURE

	GROUP	NUMBER	YES	%	NO	%	P value
FAILURE	**P**	30	1	3.3%	29	96.7%	0.313 (Not significant)
	E	30	0	0%	30	100%	

The overall failure rate in group P was 3.3% (1 patient) and in group E it was 0% (No patients) with P value = 0.313 which was not statistically significant by Fisher's exact test.

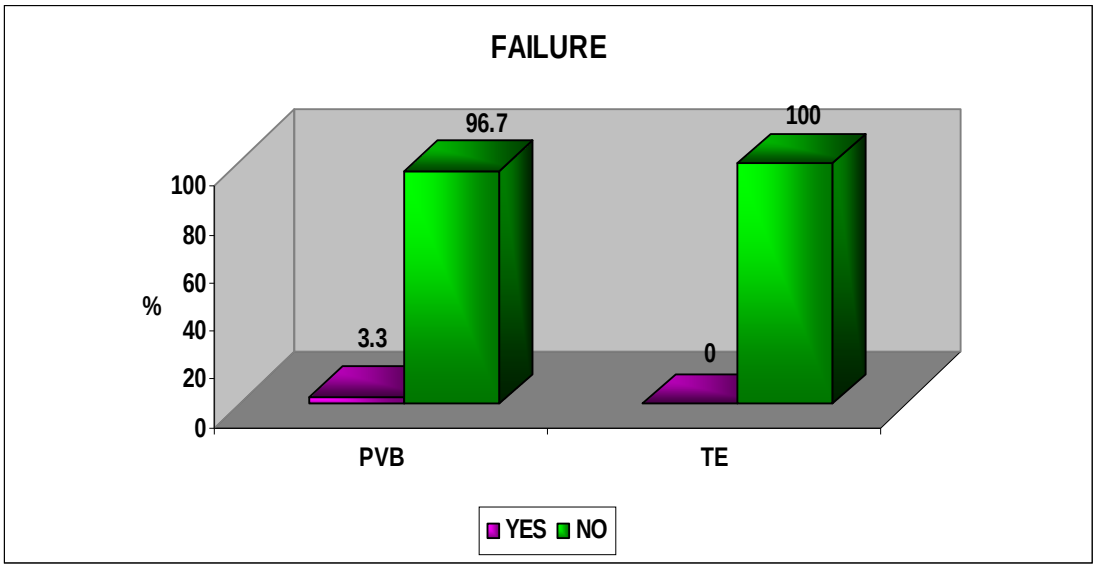


TABLE – 6

VISUAL ANALOGUE SCORE

	GROUP	N	Mean	S.D.	P.Value
VAS – 0M	Group P	29	5.03	1.017	0.050 Significant
	Group E	30	4.53	0.900	
VAS – 10M	Group P	29	4.14	0.516	0.000 Significant
	Group E	30	3.37	0.809	
VAS – 20M	Group P	29	3.45	0.910	0.001 Significant
	Group E	30	2.60	0.894	
VAS – 30M	Group P	29	2.00	0.000	p value cannot be calculated
	Group E	30	2.00	0.000	
VAS – 40M	Group P	29	1.38	0.942	0.624 Not Significant
	Group E	30	1.50	0.938	
VAS – 50M	Group P	29	0.00	0.000	0.083 Not Significant
	Group E	30	0.20	0.111	
VAS – 1 Hr.	Group P	29	0.24	0.435	0.620 Not Significant
	Group E	30	0.30	0.466	
VAS – 1.5 Hrs	Group P	29	0.90	0.310	0.966 Not Significant
	Group E	30	0.90	0.305	
VAS – 2 Hrs	Group P	29	0.97	0.186	0.981 Not Significant
	Group E	30	0.97	0.183	
VAS – 2.5 Hrs	Group P	29	0.97	0.186	0.087 Not Significant
	Group E	30	1.07	0.254	
VAS – 3 Hrs	Group P	29	1.07	0.458	0.760 Not Significant
	Group E	30	1.10	0.305	
VAS – 4 Hrs	Group P	29	1.31	0.541	0.616 Not Significant
	Group E	30	1.23	0.626	
VAS – 6 Hrs	Group P	29	1.69	0.541	0.224 Not Significant
	Group E	30	1.47	0.819	
VAS – 8 Hrs	Group P	29	1.90	0.618	0.172 Not Significant
	Group E	30	1.70	0.466	
VAS – 12 Hrs	Group P	29	2.03	0.680	0.797 Not Significant
	Group E	30	2.00	0.263	
VAS – 24 Hrs	Group P	29	2.17	0.602	0.380 Not Significant
	Group E	30	2.07	0.254	
VAS – 36 Hrs	Group P	29	2.83	0.602	0.179 Not Significant
	Group E	30	2.63	0.490	
VAS – 48 Hrs	Group P	29	2.86	0.581	0.754 Not Significant
	Group E	30	2.90	0.305	

The P values of visual analogue score are statistically significant till 20 min. after which they become statistically insignificant. This means that both epidural and paravertebral block are comparable in terms of visual analogue score.

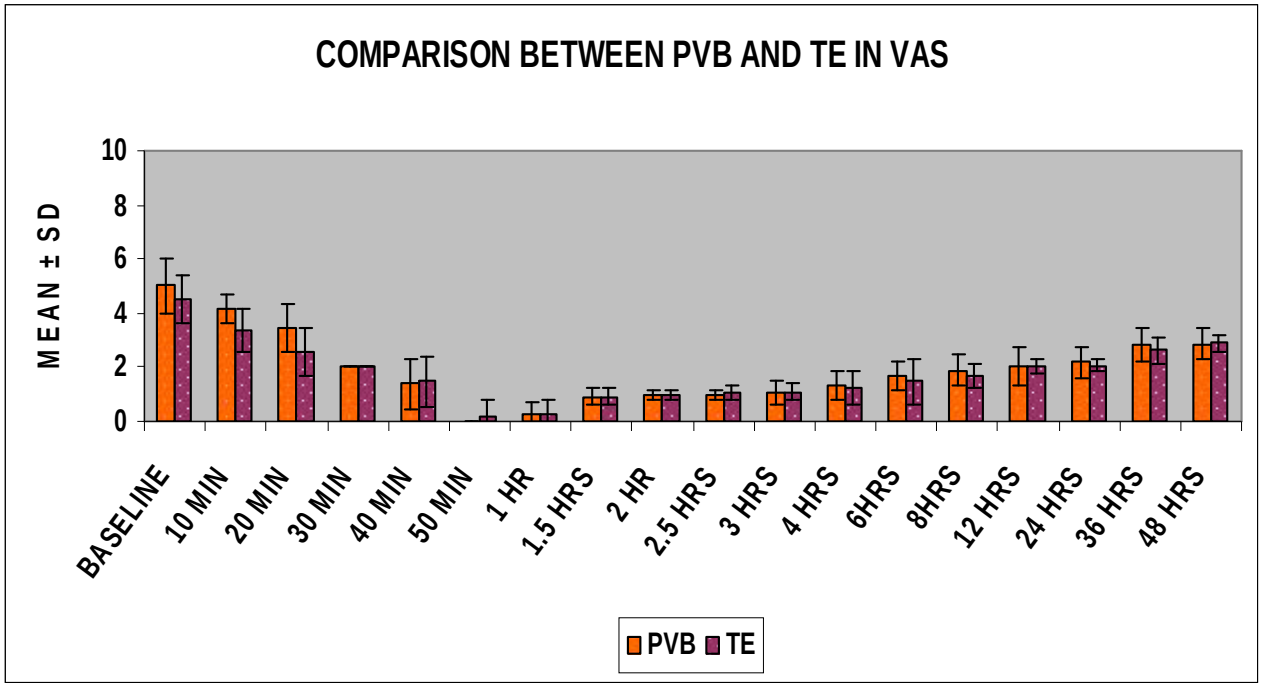


TABLE – 7

PULSE RATE

	GROUP	N	Mean	S.D.	P.Value
Baseline PR	Group P	29	77.97	7.297	0.766 Not Significant
	Group E	30	78.53	7.286	
PR – 10M	Group P	29	76.90	7.063	0.341 Not Significant
	Group E	30	78.67	7.102	
PR – 20M	Group P	29	77.07	7.583	0.804 Not Significant
	Group E	30	77.53	6.673	
PR – 30M	Group P	29	77.55	7.571	0.406 Not Significant
	Group E	30	76.00	6.654	
PR – 40M	Group P	29	77.48	7.074	0.864 Not Significant
	Group E	30	77.17	7.047	
PR – 50M	Group P	29	76.24	7.059	0.660 Not Significant
	Group E	30	77.07	7.287	
PR – 1 Hr.	Group P	29	76.17	6.420	0.401 Not Significant
	Group E	30	77.67	7.107	
PR – 1.5 Hrs	Group P	29	76.55	7.273	0.708 Not Significant
	Group E	30	77.27	7.296	
PR – 2 Hrs	Group P	29	76.41	7.023	0.459 Not Significant
	Group E	30	77.77	6.912	
PR – 2.5 Hrs	Group P	29	76.90	6.667	0.844 Not Significant
	Group E	30	76.57	6.151	
PR – 3 Hrs	Group P	29	77.41	6.593	0.881 Not Significant
	Group E	30	77.17	6.035	
PR – 4 Hrs	Group P	29	77.28	7.225	0.823 Not Significant
	Group E	30	77.68	6.082	
PR – 6 Hrs	Group P	29	77.55	7.462	0.933 Not Significant
	Group E	30	77.70	6.024	
PR – 8 Hrs	Group P	29	76.83	7.071	0.684 Not Significant
	Group E	30	77.50	5.488	
PR – 12 Hrs	Group P	29	77.28	6.670	0.705 Not Significant
	Group E	30	77.90	5.898	
PR – 24 Hrs	Group P	29	77.10	7.413	0.638 Not Significant
	Group E	30	77.93	6.000	
PR – 36 Hrs	Group P	29	77.21	8.011	0.902 Not Significant
	Group E	30	77.43	5.911	
PR – 48 Hrs	Group P	29	77.21	7.780	0.670 Not Significant
	Group E	30	77.97	5.744	

Both the groups are comparable in terms of pulse rate. The p value is more than 0.05 at all times and hence statistically insignificant.

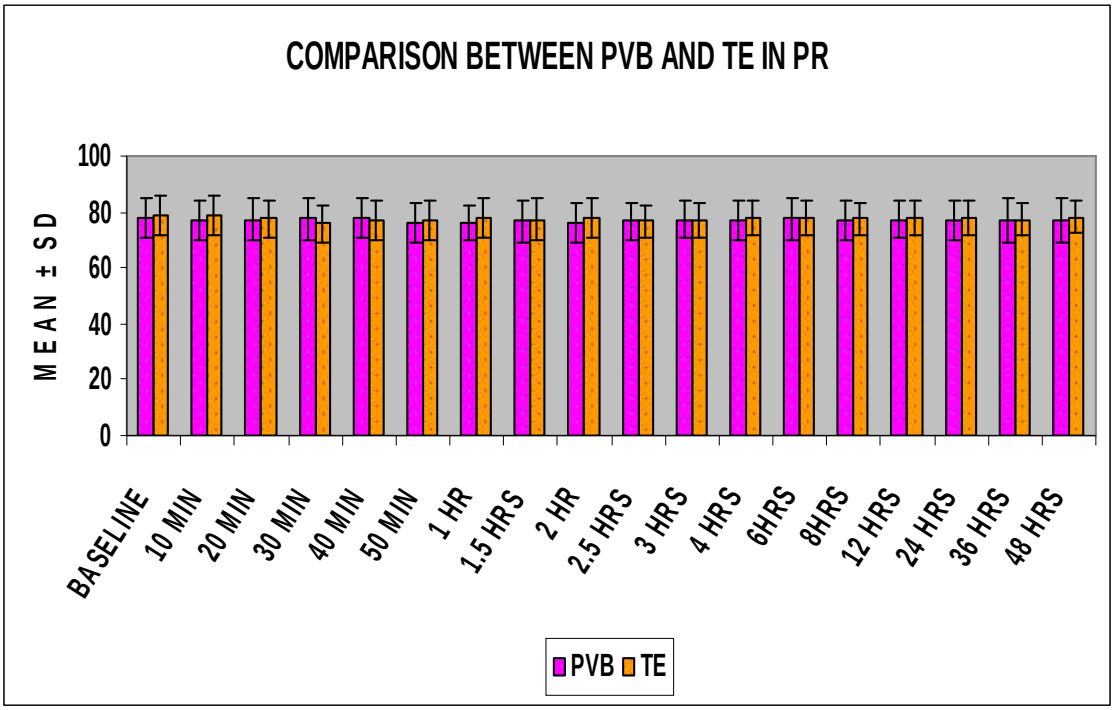


TABLE – 8

SYSTOLIC BLOOD PRESSURE

	GROUP	N	Mean	S.D.	P.Value
Baseline SBP	Group P	29	120.31	6.459	0.43 Not Significant
	Group E	30	121.77	7.555	
SBP – 10M	Group P	29	118.66	6.286	0.61 Not Significant
	Group E	30	117.73	7.497	
SBP – 20M	Group P	29	117.62	5.538	0.00 Significant
	Group E	30	110.87	6.252	
SBP – 30M	Group P	29	114.59	6.173	0.00 Significant
	Group E	30	100.23	6.537	
SBP – 40M	Group P	29	113.97	6.555	0.00 Significant
	Group E	30	104.23	6.947	
SBP – 50M	Group P	29	113.97	5.779	0.00 Significant
	Group E	30	107.57	6.719	
SBP – 1 Hr.	Group P	29	116.21	4.967	0.00 Significant
	Group E	30	110.37	6.419	
SBP – 1.5 Hrs	Group P	29	117.69	5.549	0.001 Significant
	Group E	30	111.77	7.089	
SBP – 2 Hrs	Group P	29	119.03	5.797	0.006 Significant
	Group E	30	114.23	7.060	
SBP – 2.5 Hrs	Group P	29	119.43	5.865	0.009 Significant
	Group E	30	115.13	6.350	
SBP – 3 Hrs	Group P	29	118.17	4.863	0.152 Not Significant
	Group E	30	116.07	6.170	
SBP – 4 Hrs	Group P	29	117.69	5.373	0.504 Not Significant
	Group E	30	116.63	6.615	
SBP – 6 Hrs	Group P	29	117.79	5.564	0.194 Not Significant
	Group E	30	115.63	6.960	
SBP – 8 Hrs	Group P	29	118.03	5.355	0.473 Not Significant
	Group E	30	116.80	7.559	
SBP – 12 Hrs	Group P	29	118.00	5.203	0.665 Not Significant
	Group E	30	117.27	7.492	
SBP – 24 Hrs	Group P	29	116.93	5.154	0.616 Not Significant
	Group E	30	117.77	7.347	
SBP – 36 Hrs	Group P	29	116.90	5.031	0.506 Not Significant
	Group E	30	118.07	8.021	
SBP – 48 Hrs	Group P	29	117.97	5.123	0.831 Not Significant
	Group E	30	118.33	7.765	

The difference in mean systolic blood pressure between the two groups at 20 min, 30 min, 40 min,50 min, 1 hr,1.5 hrs,2 hrs and 2.5 hrs was statistically significant. Hence there was a significant decrease in systolic blood pressure with epidural block compared to paravertebral block. Maximal decrease in systolic blood pressure was observed 30 min after the block.

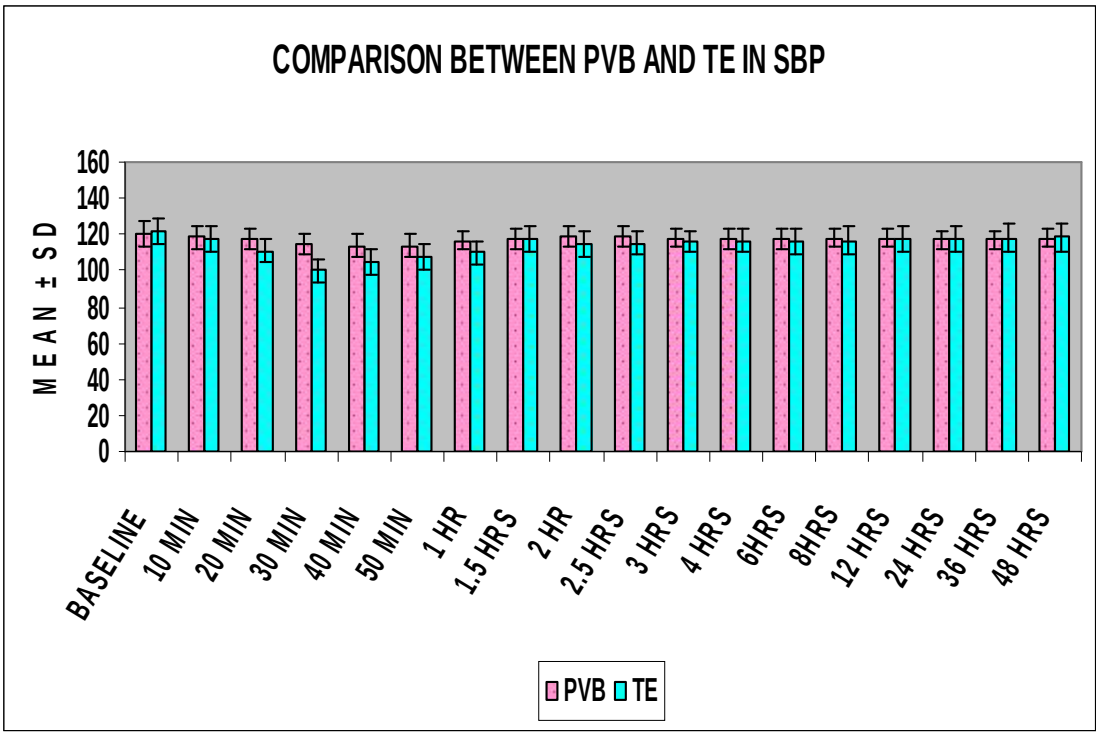


TABLE – 9

DIASTOLIC BLOOD PRESSURE

	GROUP	N	Mean	S.D.	P.Value
Baseline DBP	Group P	29	81.90	4.402	0.802 Not Significant
	Group E	30	82.20	4.809	
DBP – 10M	Group P	29	79.31	4.285	0.203 Not Significant
	Group E	30	77.73	5.078	
DBP – 20M	Group P	29	77.31	3.874	0.000 Significant
	Group E	30	72.43	5.224	
DBP – 30M	Group P	29	75.48	4.540	0.000 Significant
	Group E	30	63.90	5.074	
DBP – 40M	Group P	29	73.90	4.507	0.000 Significant
	Group E	30	65.80	5.635	
DBP – 50M	Group P	29	75.21	3.931	0.000 Significant
	Group E	30	68.87	5.164	
DBP – 1 Hr.	Group P	29	76.34	3.638	0.000 Significant
	Group E	30	70.00	4.962	
DBP – 1.5 Hrs	Group P	29	77.38	4.048	0.000 Significant
	Group E	30	71.57	4.703	
DBP – 2 Hrs	Group P	29	77.76	3.879	0.000 Significant
	Group E	30	72.53	4.337	
DBP – 2.5 Hrs	Group P	29	78.55	4.461	0.001 Significant
	Group E	30	74.20	4.745	
DBP – 3 Hrs	Group P	29	79.07	4.088	0.000 Significant
	Group E	30	74.67	4.619	
DBP – 4 Hrs	Group P	29	78.97	3.986	0.026 Significant
	Group E	30	76.13	5.406	
DBP – 6 Hrs	Group P	29	80.17	4.132	0.004 Significant
	Group E	30	77.63	5.075	
DBP – 8 Hrs	Group P	29	80.14	4.977	0.006 Significant
	Group E	30	76.50	4.740	
DBP – 12 Hrs	Group P	29	80.41	4.602	0.003 Significant
	Group E	30	76.73	4.578	
DBP – 24 Hrs	Group P	29	80.31	4.645	0.006 Significant
	Group E	30	76.87	4.569	
DBP – 36 Hrs	Group P	29	80.00	3.454	0.029 Significant
	Group E	30	77.60	4.643	
DBP – 48 Hrs	Group P	29	81.03	4.040	0.006 Significant
	Group E	30	77.90	4.389	

The difference in mean diastolic blood pressure between the two groups was statistically significant from 20 min and there after.

Hence there is a significant decrease in diastolic blood pressure with epidural block compared to paravertebral block. Maximum decrease in blood pressure was noted 30 min after the block.

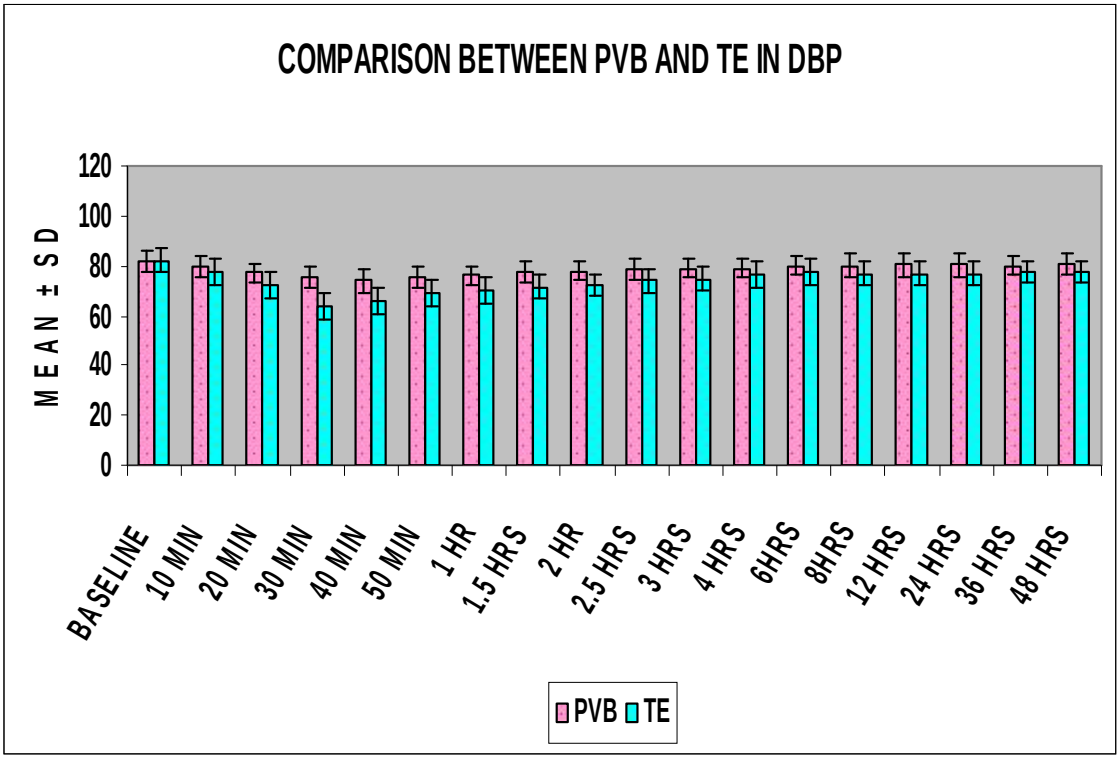


TABLE – 10

MEAN ARTERIAL PRESSURE

	GROUP	N	Mean	S.D.	P.Value
Baseline MAP	Group P	29	94.41	4.602	0.633 Not Significant
	Group E	30	95.00	4.771	
MAP – 10M	Group P	29	92.00	4.268	0.459 Not Significant
	Group E	30	91.10	4.971	
MAP – 20M	Group P	29	90.48	3.832	0.000 Significant
	Group E	30	85.00	4.210	
MAP – 30M	Group P	29	88.10	4.483	0.000 Significant
	Group E	30	75.67	4.229	
MAP – 40M	Group P	29	86.97	4.740	0.000 Significant
	Group E	30	78.17	5.528	
MAP – 50M	Group P	29	87.76	4.006	0.000 Significant
	Group E	30	81.57	4.539	
MAP – 1 Hr.	Group P	29	89.31	3.413	0.000 Significant
	Group E	30	83.20	4.619	
MAP – 1.5 Hrs	Group P	29	90.48	3.961	0.000 Significant
	Group E	30	84.53	4.485	
MAP – 2 Hrs	Group P	29	91.17	3.846	0.000 Significant
	Group E	30	86.07	4.127	
MAP – 2.5 Hrs	Group P	29	91.72	4.423	0.000 Significant
	Group E	30	87.43	4.264	
MAP – 3 Hrs	Group P	29	91.86	3.824	0.001 Significant
	Group E	30	88.10	4.302	
MAP – 4 Hrs	Group P	29	91.62	3.968	0.039 Significant
	Group E	30	89.20	4.795	
MAP – 6 Hrs	Group P	29	92.69	3.771	0.024 Significant
	Group E	30	90.10	4.751	
MAP – 8 Hrs	Group P	29	92.34	4.143	0.016 Significant
	Group E	30	89.57	4.439	
MAP – 12 Hrs	Group P	29	92.59	4.040	0.018 Significant
	Group E	30	89.97	4.181	
MAP – 24 Hrs	Group P	29	92.24	3.582	0.044 Significant
	Group E	30	90.23	3.910	
MAP – 36 Hrs	Group P	29	91.97	3.111	0.258 Significant
	Group E	30	90.83	4.371	
MAP – 48 Hrs	Group P	29	93.00	3.295	0.056 Significant
	Group E	30	91.13	4.006	

The difference in mean arterial pressure between the two groups was statistically significant from 20 min upto 24 hrs. Hence there is a significant fall in mean arterial pressure with epidural block when compared to paravertebral block. Maximal decrease in mean arterial pressure was observed 30 min after the block.

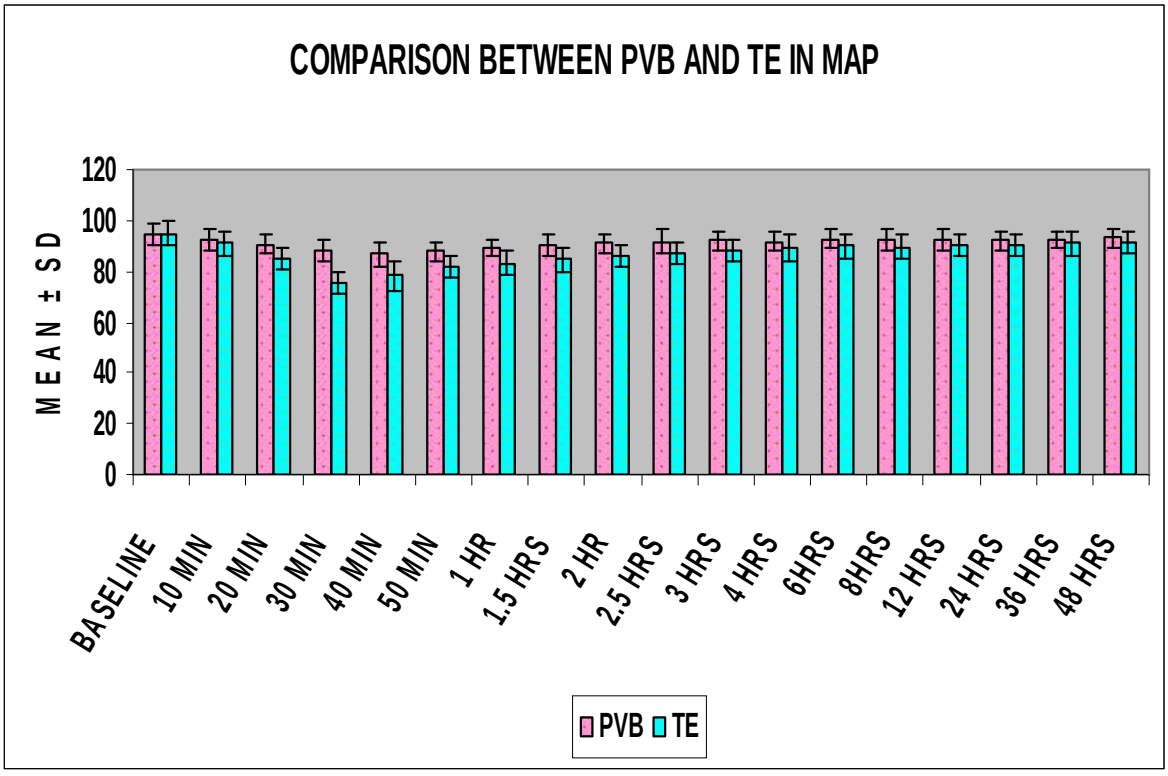


TABLE – 11

INCIDENCE OF HYPOTENSION

	Number	Yes		No	
P	29	1	3.4%	28	96.6%
E	30	21	70%	9	30%

21 patients of the 30 patients (70%) who received thoracic epidural had clinically significant hypotension. This in comparison to paravertebral only 1 out of 29 patients had hypotension (3.4%). The calculated P value is 0.000 which is statistically significant.

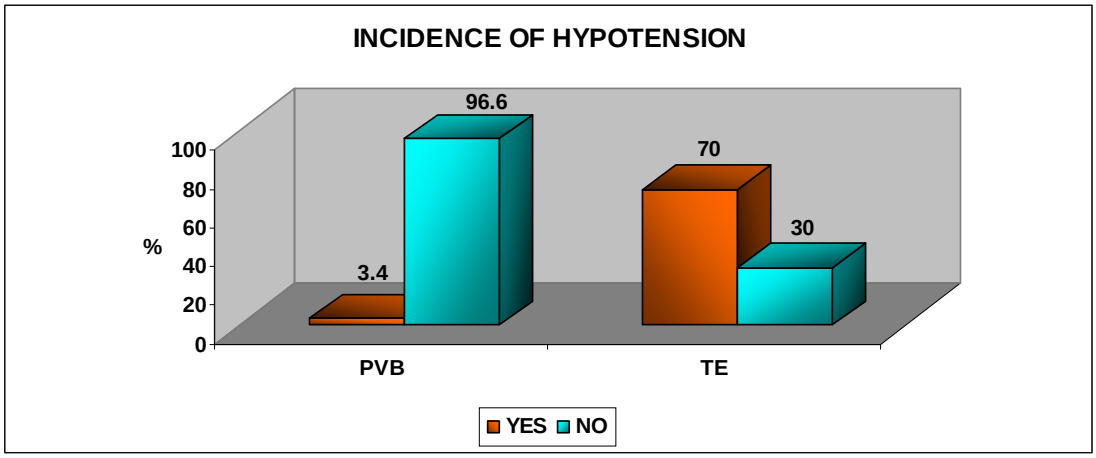
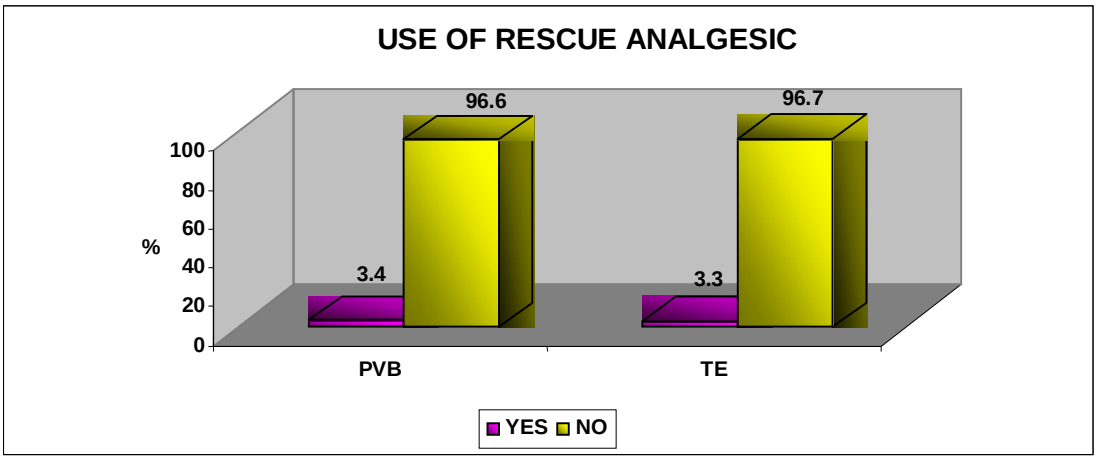


TABLE – 12

NEED FOR RESCUE ANALGESIC.

	Number	Yes		No	
P	29	1	3.4%	28	96.6%
E	30	1	3.3%	29	96.7%

1 out of the 30 patients (3.3%) who received thoracic epidural block and 1 out of 29 patients (3.4%) required rescue analgesic. The calculated P value is 0.981 which is not significant. Hence both the groups have similar requirement for rescue analgesic.



DISCUSSION

The aim of the study is to compare the analgesic efficacy and safety profile of thoracic epidural block with thoracic paravertebral block using a continuous infusion of bupivacaine for post operative pain relief in patients undergoing elective major breast surgery.

The effective bupivacaine concentration for post surgical pain relief was found to be 0.125% to 0.375% by Conacher I.D[29] et al and Ross I.D[30]. et al. Hence 0.25% bupivacaine was used for this study and followed by 0.125% bupivacaine for continuous infusion.

In our study the time taken to reach pain score of 0 in visual analogue score in group P (paravertebral block) is 42.62 ± 3.499 min and in group E (epidural block) is 43.63 ± 5.881 min which is not statistically significant. This signifies that the time required for onset of analgesia is almost the same for thoracic epidural and thoracic paravertebral block.

These results are similar to a study done by Santosh et al who noted that both epidural and paravertebral block provided comparable onset of analgesia.

In our study, there was no significant change with respect to pulse rate between both the groups. Similar results were obtained by P.J.Mathews[31] and Conacher et al in their studies.

Systolic Blood Pressure, Diastolic Blood Pressure, Mean arterial blood pressure were measured between the two groups. Statistically significant difference in systolic, diastolic and mean arterial pressure was noted between the two groups. Group E showed maximum reduction in systolic, diastolic and mean arterial blood pressure at about 30 minutes after the injection of local anaesthetic.

This result co relates with a similar study done by Santosh et al who noted that maximum blood pressure drop occurs in the epidural group 20 to 30 minutes after giving the bolus of bupivacaine.

In our study, the visual analogue scores in both the groups did not show any statistically significant difference showing a comparable degree of post operative analgesia in both the groups. This is similar to the study done by Mathews et al who also showed no significant difference in analgesia as compared by VAS recorded over a period of 24 hours, at different time intervals. Mehta et al [32] observed lower VAS score at 2,6,8,12 hours in the epidural group. But K.Pertunnen et al[33] observed good operative pain relief in both the epidural and paravertebral groups one hour after the surgery and found comparable segmental analgesia in both the groups upto 20 hours which is similar to our study.

The overall failure rate in group E was 0% and in group P it was 3.3%. Whereas Santosh et al reported the overall failure rate of 8% in paravertebral group and 20% in epidural group. Lonnquvist[34] in his study reported a failure rate of 10% on paravertebral group.

The incidence of hypotension in group E was 70% whereas that of group P was 3.44%. Santosh et al in their study noted an incidence of hypotension in 50% in epidural group and 8.6% in paravertebral group.

There was no incidence of bradycardia in both the epidural or paravertebral groups.

Hence both thoracic epidural and thoracic paravertebral blocks provide comparable analgesia after breast surgery but thoracic epidural block is associated with a higher incidence of hypotension because of bilateral sympathetic blockade whereas the incidence of hypotension is less in thoracic paravertebral block which usually causes only unilateral sympathetic blockade.

SUMMARY

We conducted a prospective, randomized , single blinded (patient) controlled trial in a group of 60 patients belonging to ASA III undergoing major elective breast surgery namely modified radical mastectomy to compare the analgesic efficacy and safety profile of thoracic epidural block with thoracic paravertebral block using a continuous infusion of bupivacaine. They were randomly assigned to undergo paravertebral block or epidural block for post operative pain relief. All the blocks were given by the same anaesthesiologist.

The aim of the study was to compare the post operative analgesia by visual analogue score, hemodynamic stability, side effects and need of rescue analgesics for thoracic epidural and thoracic paravertebral block in patients undergoing elective major breast surgery.

On the course of study, the onset of analgesia, degree of analgesia measured by Visual Analogue Score provided by both the epidural and paravertebral groups was comparable. The failure rate in technique in both the groups was also comparable. The need for rescue analgesics was also comparable in both the groups.

It was found that the incidence of hypotension was more in patients belonging to the thoracic epidural group which showed statistical significance.

There was no incidence bradycardia or any other complication in either groups.

CONCLUSION

This study concludes that both thoracic epidural block and thoracic paravertebral block provide comparable post operative analgesia in patients undergoing elective major breast surgery but the haemodynamic stability was better maintained with thoracic paravertebral group compared to thoracic epidural group.

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ETHICS COMMITTEE APPROVAL

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. Yamini. V.S.
Postgraduate MD (Anaesthesia),
Madras Medical College,
Chennai – 600 003.

Dear Dr. Yamini. V.S.

The Institutional Ethics Committee has considered your request and approved your study titled **"A Prospective randomized control study comparing the analgesic efficacy and safety profile of thoracic Epidural versus thoracic para vertebral block using continuous infusion of bupivacaine in elective breast surgeries" No. 33082014.**

The following members of Ethics Committee were present in the meeting held on 05.08.2014 conducted at Madras Medical College, Chennai-3.

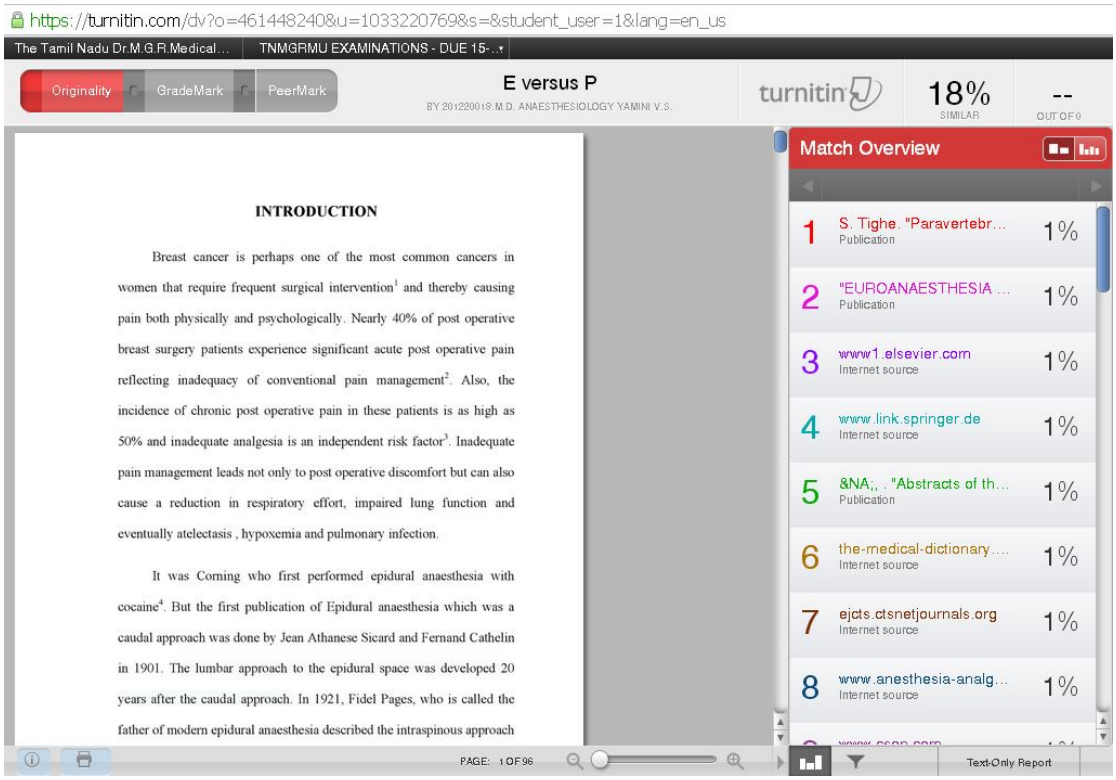
12. Dr.C.Rajendran, M.D.,	: Chairperson
13. Dr.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
14. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
15. Prof.R.Nandhini, M.D., Inst.of Pharmacol ogy, MMC	: Member
16. Dr.G.Muralidharan, Director Incharge, Inst.of Surgery	: Member
17. Prof.K.Ramadevi, Director i/c, Inst.of Biochemistry, MMC	: Member
18. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
19. Prof.Tito, M.D., Director i/c, Inst.of Internal Medicine, MMC	: Member
20. Thiru S.Rameshkumar, Administrative Officer	: Lay Person
21. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
22. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

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

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003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INTRODUCTION
Breast cancer is perhaps one of the most common cancers in women that require frequent surgical intervention[1] and thereby causing pain both physically and psychologically. Nearly 40% of post operative breast surgery patients experience significant acute post operative pain reflecting inadequacy of conventional pain management[2]. Also, the incidence of chronic post operative pain in these patients is as high as 50% and inadequate analgesia is an independent risk factor[3]. Inadequate pain management leads not only to post operative discomfort but can also cause a reduction in respiratory effort, impaired lung function and eventually atelectasis , hypoxemia and pulmonary infection.
It was Corning who first performed epidural anaesthesia with cocaine[4]. But the first publication of Epidural anaesthesia which was a caudal approach was done by Jean Athanese Sicard and Fernand Cathelin in 1901. The lumbar approach to the epidural space was developed 20 years after the caudal approach. In 1921, Fidel Pages, who is called the father of modern epidural anaesthesia described the intraspinous approach
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INTRODUCTION

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1

PATIENT CONSENT FORM

Study title: **"A Prospective, Randomized Comparative Study Evaluating the Analgesic Efficacy and Safety Profile of Thoracic Epidural Block Versus Thoracic Para Vertebral Block using a Continuous Infusion of Bupivacaine in Patients Undergoing Elective Major Breast Surgery".**

Study centre: INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE, MADRAS MEDICAL COLLEGE & RAJIV GANDHI GOVT GENERAL HOSPITAL, CHENNAI 600003.

Participant Name: Age: Sex: I.P.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 satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I 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.

Date: Signature / thumb impression of patient:

Place: Patient name:

Signature of the investigator:

Name of the investigator:

PROFORMA

"A PROSPECTIVE, RANDOMIZED COMPARATIVE STUDY EVALUATING THE ANALGESIC EFFICACY AND SAFETY PROFILE OF THORACIC EPIDURAL BLOCK VERSUS THORACIC PARAVERTEBRAL BLOCK USING A CONTINUOUS INFUSION OF BUPIVACAINE IN PATIENTS UNDERGOING ELECTIVE MAJOR BREAST SURGERY"

NAME: AGE: SEX: I.P.No:

DIAGNOSIS: SURGERY PLANNED:

PREOPERATIVE ASSESSMENT:

HISTORY:

CO-MORBID ILLNESS & TREATMENT DETAILS:

EFFORT TOLERANCE _____METS

H/O PREVIOUS SURGERY:

GENERAL EXAMINATION:

HEIGHT: WEIGHT: BMI:

ANAEMIA: JAUNDICE: SPINE:

PULSE: BP: CVS: RS:

INVESTIGATIONS:

Hb: BT: CT

BLOOD GROUPING & TYPING

BLOOD SUGAR: UREA: CREATININE

ECG: CXR:

EPIDURAL/PARAVERTEBRAL BLOCK:

SPACE	NEEDLE	SIZE	APPROACH	POSITION	DRUG

ANALGESIA BY V.A.S;

TIME TO REACH V.A.S. = 0

TIME	PR	SBP	DBP	MAP	VAS	SIDE EFFECTS
BASELINE						
10 MIN						
20 MIN						
30 MIN						
40 MIN						
50 MIN						
1 HR						
1.5 HRS						
2 HR						
2.5 HRS						
3 HRS						
4 HRS						
6HRS						
8HRS						
12 HRS						
24 HRS						
36 HRS						
48 HRS						

SIDE EFFECTS

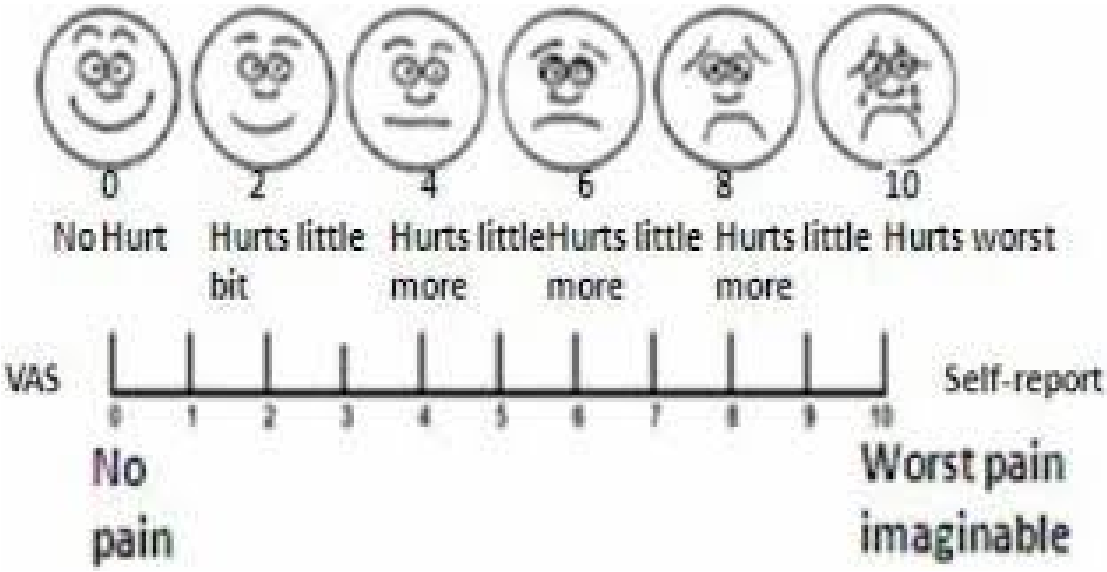
Side Effects	
Hypotension	
Bradycardia	
Need for rescue analgesia	

INJ. EPHEDRINE(6 mg iv bolus):

INJ. ATROPINE(0.6 mg iv bolus):

RESCUE ANALGESIA:

PAIN SCORE : (VISUAL ANALOGUE SCALE)



GROUP E										
S.No	**NAME**	**IP NO.**	**AGE**	**SIDE**	**WT**	**HT**	**BMI**	**ASA**	**FAILURE**	**TIME TO REACH VAS = 0**
1	MALLIGA	19544	40	R	52	153	22.21	3	NO	46
2	SABINA	18873	53	R	58	159	22.94	3	NO	42
3	KANNAMMAL	21816	52	R	65	162	24.77	3	NO	35
4	JAYANTHI	22965	38	L	55	158	22.03	3	NO	32
5	SHANTHI	23186	35	L	56	155	23.31	3	NO	37
6	NIRMALA	23745	45	L	63	158	25.24	3	NO	43
7	RATHINAMMAL	26565	45	L	65	162	24.77	3	NO	48
8	ESWARI	29636	36	L	54	153	23.07	3	NO	35
9	SATHYA	29099	33	L	59	157	23.94	3	NO	51
10	IGNESIUS	27233	57	R	61	162	23.24	3	NO	48
11	MURUGAMMAL	29023	49	L	62	160	24.22	3	NO	46
12	HAFIA	33215	39	R	57	155	23.73	3	NO	52
13	ANURADHA	42487	48	L	55	154	23.19	3	NO	39
14	LYDIA	32348	45	R	64	161	24.69	3	NO	43
15	NAGAMMAL	33723	58	R	63	161	24.3	3	NO	46
16	MANGAYARKARASI	31209	55	L	62	159	24.52	3	NO	47
17	MUTHALAGI	36941	34	R	58	157	23.53	3	NO	34
18	GANGALAKSHMI	36832	35	R	57	162	21.72	3	NO	43
19	USHA UNNI	32439	56	L	61	158	24.44	3	NO	46
20	MAMTHIA MANDAL	31368	45	R	59	161	22.76	3	NO	34
21	KAMALA	21265	40	R	58	155	24.14	3	NO	45
22	JAYANTHI	28189	45	R	63	159	24.92	3	NO	46
23	SARASU	37436	43	L	65	161	25.08	3	NO	53
24	MAHALAKSHMI	34629	47	L	62	157	25.15	3	NO	52
25	TAMILSELVI	33963	48	R	59	158	23.63	3	NO	45
26	YASODHA	22530	50	R	58	161	22.38	3	NO	47
27	DHANAM	40723	53	R	61	163	22.96	3	NO	51
28	CHINNAKANNU	41394	50	L	64	159	25.32	3	NO	42
29	SAROJA	52746	45	R	60	158	24.03	3	NO	38
30	KUMARI	50978	48	R	59	158	23.63	3	NO	43

GROUP E																		
S.No	**BASELINE PR**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	72	76	77	76	75	74	77	71	78	73	75	76	79	80	77	75	76	78
2	85	86	85	76	74	73	76	78	82	81	84	82	81	82	86	74	75	81
3	66	67	67	64	61	60	59	61	62	65	66	63	68	67	69	67	68	63
4	84	86	85	78	79	81	84	82	79	78	80	75	81	83	84	86	82	80
5	78	79	77	75	76	73	74	76	79	75	72	83	80	79	76	78	77	76
6	82	83	81	79	76	77	75	74	73	74	75	78	82	79	75	74	75	78
7	78	79	77	76	75	77	76	75	78	75	79	78	79	76	75	78	75	74
8	67	66	68	65	67	66	67	65	67	68	67	68	68	69	70	71	72	69
9	81	83	82	84	83	79	76	75	76	74	73	79	78	77	81	83	82	81
10	82	83	84	75	84	81	79	75	75	77	79	82	84	81	83	84	83	84
11	74	75	73	77	79	75	73	74	76	78	81	79	76	77	75	78	73	82
12	61	63	62	64	65	63	69	64	66	64	65	67	63	65	64	67	68	72
13	72	73	74	69	71	72	70	74	76	78	77	74	76	78	76	78	81	80
14	76	74	71	73	72	74	76	78	75	72	73	75	74	78	82	79	73	75
15	84	83	82	79	80	81	83	83	81	75	77	81	79	82	80	79	81	79
16	82	81	78	81	80	83	84	85	86	84	83	82	81	79	83	84	85	82
17	86	83	81	80	79	78	82	83	82	81	82	83	83	84	79	82	81	83
18	74	73	72	68	71	72	74	75	73	75	74	76	78	76	78	75	77	79
19	82	80	79	78	79	81	80	82	84	83	85	82	83	81	83	84	83	85
20	65	64	63	62	65	66	65	64	66	65	68	67	64	63	65	66	64	68
21	93	92	91	90	94	95	92	93	95	88	87	86	89	84	85	87	84	86
22	84	85	83	82	84	83	85	81	78	75	77	74	78	79	75	78	81	78
23	83	84	82	79	83	82	84	83	85	84	83	87	85	81	83	86	88	85
24	85	84	83	82	85	82	84	86	85	86	84	87	83	82	85	82	81	85
25	87	88	83	87	86	88	87	86	85	84	86	85	82	83	84	85	86	82
26	82	81	80	78	79	81	83	82	84	83	82	81	80	82	84	83	81	83
27	79	78	76	78	80	81	80	79	78	77	76	75	74	73	76	78	75	74
28	74	75	76	73	75	76	76	75	73	72	71	74	73	75	73	70	71	72
29	77	76	75	74	76	75	76	76	77	75	78	74	75	76	78	75	74	73
30	81	80	79	78	82	83	84	83	79	78	76	77	75	74	73	72	71	72

GROUP E																		
S.No	**BASELINE SBP**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	124	121	118	106	109	112	115	118	121	119	117	122	116	112	118	115	116	114
2	118	123	114	96	101	102	106	110	108	112	113	115	112	114	116	113	112	113
3	112	114	107	93	108	102	105	104	101	106	108	107	104	103	108	115	106	103
4	121	117	112	106	108	107	110	112	115	113	117	116	115	119	121	118	119	123
5	108	103	98	97	92	95	96	98	101	103	105	107	104	106	105	109	106	103
6	132	127	118	115	117	118	121	116	117	118	121	124	121	122	126	125	127	125
7	126	119	112	105	113	115	117	112	119	121	120	118	116	117	121	120	123	122
8	116	114	108	102	107	106	108	103	117	113	119	112	116	118	114	115	109	114
9	121	119	115	98	112	116	113	119	118	115	112	117	114	116	121	122	117	115
10	128	117	113	91	105	106	109	104	109	112	114	115	116	119	121	120	122	124
11	117	113	108	101	92	104	107	113	114	112	115	113	109	112	114	119	121	118
12	124	121	114	89	108	109	112	115	116	121	119	118	117	115	118	115	113	119
13	131	129	113	102	108	115	117	121	124	125	128	129	127	126	128	129	131	132
14	129	124	121	95	112	117	122	125	127	124	124	123	124	123	121	126	127	128
15	125	119	112	102	112	114	115	116	121	123	120	122	124	123	121	128	126	123
16	118	116	103	94	103	106	112	115	117	114	119	116	117	119	121	118	116	113
17	103	98	95	94	90	93	95	92	94	96	97	101	99	94	95	96	97	101
18	132	127	111	104	107	109	112	115	121	123	124	128	125	129	131	128	127	126
19	125	121	114	95	103	109	112	119	122	121	118	119	115	117	118	116	114	119
20	127	125	121	117	104	115	116	114	113	117	118	121	122	124	123	125	126	122
21	116	114	109	105	101	103	105	107	112	110	108	104	106	107	109	112	115	116
22	114	109	107	96	98	101	102	104	108	112	111	109	108	110	112	107	108	109
23	121	118	109	107	99	108	109	112	115	116	118	114	117	119	113	110	115	114
24	115	112	108	104	92	95	103	104	108	109	113	115	114	111	106	109	112	114
25	124	119	108	100	108	112	115	118	114	116	117	119	115	121	122	118	120	121
26	132	127	118	94	104	107	109	114	116	118	119	121	124	126	125	122	124	126
27	135	128	115	103	107	112	117	114	116	113	119	121	123	124	120	124	127	126
28	116	104	101	96	105	108	109	112	115	117	112	114	116	119	121	123	124	125
29	124	119	117	104	94	99	107	113	116	118	121	124	123	122	115	123	126	127
30	119	115	107	96	108	112	115	114	112	117	116	115	110	117	114	113	116	115

GROUP E																		
S.No	**BASELNE DBP**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	84	81	74	62	63	67	72	71	74	75	72	73	78	80	82	85	87	83
2	78	73	62	60	64	66	61	65	65	68	71	72	73	75	76	77	78	81
3	73	69	68	61	67	68	67	69	65	68	71	72	74	72	71	70	69	73
4	82	79	76	64	75	78	76	77	76	78	79	78	76	77	78	79	78	77
5	79	77	68	58	58	62	64	69	72	73	71	74	75	76	77	76	78	79
6	89	78	72	62	69	73	75	79	76	78	77	76	78	77	79	78	78	76
7	76	71	67	61	65	69	72	71	73	75	74	75	76	75	74	72	73	71
8	82	79	75	66	76	77	74	73	75	78	76	81	80	79	77	78	75	76
9	91	83	79	65	71	72	74	76	73	75	72	78	82	81	80	81	83	82
10	78	75	71	58	66	67	68	65	69	64	65	64	66	67	68	69	71	72
11	79	71	69	62	55	62	61	64	65	67	68	66	69	68	64	66	67	65
12	86	83	79	68	67	68	66	69	71	72	74	73	75	77	78	81	82	84
13	92	89	77	72	74	73	76	78	81	83	85	88	84	82	83	85	86	81
14	84	79	73	62	63	67	69	72	71	74	73	75	82	79	78	77	81	79
15	81	79	73	65	67	68	72	71	74	75	77	79	80	76	78	77	79	81
16	76	68	63	56	62	64	65	67	69	71	72	70	69	71	73	72	74	75
17	84	80	79	73	62	65	68	74	78	77	79	82	81	82	83	80	79	81
18	88	83	75	61	67	69	71	73	75	78	82	87	85	84	82	80	79	81
19	79	73	67	60	65	68	69	71	72	75	77	75	78	74	76	73	75	79
20	76	71	65	61	53	58	63	65	66	67	68	69	71	68	70	69	72	74
21	78	75	69	65	64	67	68	69	71	72	74	75	73	70	76	74	75	76
22	82	79	74	65	72	74	72	75	71	74	76	77	78	75	76	78	77	79
23	83	81	79	76	69	75	76	79	78	81	80	79	81	78	77	76	79	80
24	76	75	71	66	61	63	64	65	68	67	69	71	73	72	74	76	75	77
25	85	81	79	63	75	76	78	81	79	78	77	81	83	82	84	80	79	81
26	89	85	75	61	63	65	66	68	69	72	74	78	85	83	79	81	82	84
27	84	81	74	62	64	67	72	71	73	76	75	79	78	77	72	78	76	74
28	83	72	64	58	62	65	68	69	72	74	71	76	79	75	77	78	76	73
29	85	81	79	76	63	78	79	75	77	81	82	79	84	82	81	80	83	82
30	84	81	77	68	72	75	74	76	78	80	79	82	83	81	79	80	82	81

GROUP E																		
S.No	**BASELINE MAP**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	97	94	88	76	78	82	86	86	89	89	87	89	90	90	94	95	96	93
2	91	89	79	72	76	78	76	80	79	82	85	86	86	88	89	89	89	91
3	86	84	81	71	80	79	79	80	77	80	83	83	84	82	83	85	81	83
4	95	91	88	78	86	87	87	88	89	89	91	90	89	91	92	92	91	92
5	88	85	78	71	69	73	74	78	81	83	82	83	84	86	86	87	87	87
6	103	94	87	79	85	88	90	91	89	91	91	92	92	92	94	93	94	92
7	92	87	82	75	81	84	87	84	88	90	89	89	89	89	89	88	89	88
8	96	90	86	78	86	86	86	84	89	89	90	91	92	92	89	90	86	88
9	96	95	91	76	84	86	87	90	88	88	85	91	92	92	93	94	94	93
10	94	89	85	69	79	80	81	78	82	80	81	81	82	84	85	86	88	89
11	91	85	82	75	67	76	76	80	81	82	83	81	82	82	80	83	85	82
12	98	95	90	75	80	80	81	84	86	88	89	88	89	89	91	92	92	96
13	105	102	89	82	86	87	89	92	95	96	99	101	98	96	98	99	101	98
14	99	94	89	73	79	83	86	89	89	90	90	91	96	93	92	93	96	95
15	95	92	86	77	82	83	86	86	89	91	91	93	94	91	92	94	94	95
16	90	84	76	68	71	78	80	83	85	85	87	85	85	87	89	87	88	87
17	90	86	84	80	71	74	77	80	83	83	85	88	87	86	87	86	85	87
18	102	97	87	75	80	82	85	87	90	93	96	100	98	99	98	96	95	96
19	94	99	82	71	77	81	83	87	88	90	90	89	90	88	90	87	88	92
20	93	89	83	79	70	77	80	78	81	83	84	86	88	86	87	87	90	90
21	90	88	82	78	76	79	80	81	84	84	85	84	84	82	87	86	88	89
22	92	89	85	75	80	83	82	84	83	86	87	87	88	86	88	87	87	89
23	95	93	89	85	79	86	87	90	90	92	92	90	93	91	89	87	91	91
24	89	87	83	78	71	73	77	77	81	81	83	85	86	85	85	87	87	89
25	98	93	88	75	86	90	90	93	90	90	90	93	93	95	97	92	92	94
26	103	99	89	72	76	79	80	83	84	87	89	92	98	96	94	94	96	98
27	101	96	87	75	78	82	87	85	87	88	89	93	93	92	88	93	93	91
28	94	82	76	70	76	79	81	83	86	88	84	88	91	89	91	93	92	90
29	98	93	91	85	72	85	88	87	90	93	95	94	97	95	92	94	97	97
30	95	92	87	77	84	87	88	88	89	92	91	93	93	93	90	91	93	92

GROUP E																		
S.No	**VAS 0 MIN**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	4	2	2	2	2	0	1	1	1	1	1	2	2	2	2	2	2	2
2	4	3	2	2	2	0	1	1	1	2	1	1	1	2	2	2	3	3
3	4	3	3	2	0	0	1	1	1	1	1	1	1	2	2	2	2	3
4	6	2	2	2	0	0	1	1	1	1	1	2	2	2	2	2	3	3
5	4	3	2	2	0	0	1	1	1	1	1	1	1	2	2	2	2	3
6	6	3	2	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
7	4	4	2	2	2	0	0	1	1	1	1	1	1	1	2	2	2	2
8	4	2	2	2	0	0	0	1	1	1	1	1	1	1	2	2	2	3
9	6	4	2	2	2	0	0	1	1	1	1	1	1	1	1	2	2	3
10	4	3	2	2	2	0	0	1	1	1	1	1	1	1	2	2	2	2
11	4	3	3	2	3	0	0	1	1	1	1	1	2	2	2	2	3	3
12	6	4	2	2	2	0	0	1	1	1	2	1	2	1	2	2	3	3
13	4	3	2	2	0	0	1	1	1	1	1	1	2	2	2	2	3	3
14	4	2	2	2	2	0	0	1	1	1	1	1	1	2	2	2	3	3
15	4	4	2	2	2	0	0	1	1	1	1	1	1	1	2	2	3	3
16	4	4	2	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
17	4	4	4	2	0	0	1	1	1	1	1	1	1	2	2	2	3	3
18	6	4	4	2	2	0	0	1	1	2	2	4	5	2	2	2	3	3
19	4	4	4	2	2	0	0	1	1	1	1	1	1	2	2	2	3	3
20	6	4	4	2	0	0	1	1	1	1	2	2	2	2	3	3	3	3
21	4	4	4	2	2	0	0	1	1	1	1	1	1	1	2	2	2	3
22	6	4	4	2	2	0	0	1	1	1	1	2	2	2	2	3	3	3
23	4	4	4	2	2	2	0	0	1	1	1	1	2	2	2	2	3	3
24	4	2	2	2	2	2	0	0	0	1	1	1	1	1	2	2	2	3
25	6	4	2	2	2	0	0	1	1	1	1	1	1	2	2	2	3	3
26	4	4	2	2	2	0	0	1	1	1	1	1	1	2	2	2	3	3
27	4	4	4	2	2	2	0	0	1	1	1	1	1	2	2	2	3	3
28	4	4	2	2	2	0	0	1	1	1	1	1	1	1	2	2	2	3
29	4	4	2	2	0	0	1	1	1	1	1	1	1	2	2	2	3	3
30	4	2	2	2	2	0	0	1	1	1	1	1	1	2	2	2	2	3

GROUP P										
S.No	**NAME**	**IP NO.**	**AGE**	**SIDE**	**WT**	**HT**	**BMI**	**ASA**	**FAILURE**	**TIME TO REACH VAS = 0**
1	FATHIMA MARY	13223	40	L	62	163	23.34	3	NO	38
2	VIOLET	29887	40	L	58	154	24.46	3	NO	41
3	KOMALA	21365	44	R	54	149	24.32	3	NO	39
4	CHITRAMANI	34615	43	L	59	162	22.48	3	NO	43
5	SUNDARIBAI	28930	43	R	61	158	24.44	3	NO	46
6	MALA	32719	45	L	63	165	23.14	3	NO	44
7	SHANTHI	33104	40	R	57	158	22.83	3	NO	38
8	LATHA	34361	45	R	66	165	24.24	3	NO	37
9	MEENATCHI	45191	53	L	58	163	21.83	3	NO	42
10	MAHESWARI	40243	42	R	63	164	23.42	3	NO	46
11	LALITHA	34712	45	R	59	162	22.48	3	NO	45
12	SELVI	40395	38	R	56	158	22.43	3	NO	38
13	KANNI	35570	42	L	58	162	22.1	3	NO	44
14	DHANALAKSHMI	40793	48	R	57	158	22.83	3	NO	48
15	MUNIAMMAL	38987	40	L	59	161	22.76	3	NO	47
16	JULIE	41876	37	L	53	154	22.35	3	NO	39
17	JANSI RANI	42208	34	R	54	156	22.19	3	NO	38
18	KOKILA	44525	60	L	64	165	23.51	3	NO	45
19	SARASWATHI	44006	53	L	58	159	22.94	3	NO	46
20	CHINNAKULANDHAI	47637	49	R	59	162	22.48	3	NO	48
21	RIYANA BEGUM	52142	37	R	61	163	22.96	3	NO	47
22	PARIMALA	52781	51	L	57	158	22.83	3	NO	38
23	MAHARANI	51209	40	R	63	165	23.14	3	NO	42
24	ETHIAMMAL	47235	35	R	58	164	21.56	3	NO	45
25	KANCHANA	50561	60	L	56	158	22.43	3	NO	39
26	LAKSHMI	51656	43	R	64	165	23.51	3	NO	41
27	KAVITHA	43718	39	R	57	158	22.83	3	NO	44
28	GOWRI	43725	35	L	62	163	23.34	3	NO	43
29	KULLAMMAL	43990	39	R	59	160	23.05	3	NO	45
30	KANAGA	37759	52	L	56	153	23.92	3	YES	NIL

GROUP P																		
S.No	**BASELINE PR**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	73	72	75	74	78	74	73	71	69	73	74	71	74	76	75	72	77	72
2	62	64	68	65	71	69	67	63	65	64	67	66	64	63	67	63	65	62
3	84	86	87	85	83	81	82	86	84	83	86	87	85	82	81	83	80	85
4	83	82	85	81	84	83	82	86	86	85	87	89	86	84	85	87	89	84
5	79	75	73	75	71	72	74	76	78	76	77	79	74	76	75	78	76	75
6	72	73	71	74	75	72	74	76	75	74	76	73	72	71	76	78	69	73
7	74	72	71	75	77	75	73	74	74	75	73	72	71	76	77	75	72	74
8	81	79	76	75	77	78	79	72	74	76	78	75	78	74	77	76	75	72
9	79	75	76	77	74	73	71	72	73	75	72	74	76	73	75	72	71	74
10	69	68	67	66	65	63	68	69	65	67	64	65	66	63	64	65	62	64
11	66	65	64	67	68	62	61	60	62	64	67	66	65	63	64	63	64	62
12	73	71	73	75	72	76	77	72	72	71	74	75	73	74	72	73	74	76
13	85	84	85	86	88	82	84	85	82	81	84	83	87	85	86	84	88	85
14	87	85	84	83	86	87	84	88	86	87	85	91	87	86	88	89	85	84
15	73	72	74	71	75	73	77	75	74	76	78	74	76	77	72	74	76	75
16	91	92	93	94	89	85	83	86	85	87	84	86	89	85	84	86	91	90
17	84	82	84	85	81	83	86	82	84	86	85	81	84	83	82	79	82	83
18	75	77	74	76	73	71	72	78	76	77	74	73	75	78	74	76	75	72
19	88	86	85	87	84	83	81	82	85	82	83	85	86	84	86	85	87	84
20	84	81	84	85	88	86	87	83	83	85	86	87	85	86	84	86	89	91
21	74	76	78	75	77	72	73	76	73	75	76	72	75	74	76	78	75	77
22	82	79	81	80	76	77	75	76	78	76	78	79	81	78	79	80	78	79
23	78	76	74	75	71	74	73	72	75	73	78	76	77	74	76	75	78	79
24	65	63	61	62	65	64	67	68	65	67	66	68	64	67	69	63	65	68
25	86	84	87	86	85	88	81	83	85	84	86	82	84	83	86	85	86	87
26	80	78	76	79	78	76	77	81	78	79	75	76	78	76	77	78	76	75
27	77	76	75	78	79	76	75	74	77	76	75	78	76	74	75	78	76	77
28	84	83	82	87	88	84	83	85	82	84	83	85	87	88	86	84	85	86
29	73	74	72	71	69	72	70	69	71	72	74	73	74	75	73	71	73	74
30	81	79	81	83	86	88	86	87	89	87	89	91	92	89	87	88	87	86

GROUP P																		
S.No	**BASELINE SBP**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	123	121	118	109	117	116	114	119	117	118	115	116	118	114	121	122	119	118
2	127	126	124	115	122	121	123	124	125	122	121	123	125	127	126	128	124	126
3	121	120	119	107	116	118	117	115	119	118	117	116	118	121	120	117	118	116
4	115	116	117	114	110	112	113	111	115	114	116	115	114	115	117	116	117	114
5	117	115	114	113	112	115	117	116	118	114	113	114	116	115	117	112	115	116
6	125	123	121	119	118	117	119	120	122	124	121	119	116	122	116	121	114	118
7	104	103	102	99	98	103	105	102	101	104	105	103	108	104	105	106	107	103
8	113	111	110	112	108	113	114	115	113	112	116	113	115	114	117	118	112	110
9	123	124	123	121	119	118	121	120	117	122	121	120	122	125	119	121	122	124
10	124	121	122	118	117	116	119	121	120	123	122	118	116	120	115	119	117	119
11	118	117	116	115	114	112	115	116	118	116	117	116	115	114	116	118	114	118
12	116	114	115	109	108	110	112	114	113	112	116	115	118	119	114	115	113	116
13	124	122	121	120	119	118	117	121	122	124	121	123	125	124	119	120	122	121
14	118	115	117	116	115	107	112	113	116	119	118	117	118	115	114	109	110	116
15	117	115	114	112	109	108	113	117	121	124	118	121	115	113	117	113	119	114
16	125	121	118	115	118	119	121	124	126	125	116	118	121	124	120	116	115	117
17	127	125	121	119	117	122	125	126	128	131	125	124	121	120	118	117	119	124
18	119	117	118	115	112	109	114	116	119	121	117	115	116	118	122	116	109	121
19	126	125	123	121	119	118	121	123	124	120	122	125	124	119	121	122	124	125
20	131	129	127	126	125	126	125	124	126	125	125	124	129	125	127	125	126	124
21	122	121	119	118	117	115	116	120	121	119	121	120	118	119	122	118	119	121
22	125	123	120	119	117	121	122	123	125	127	126	125	124	122	124	119	121	120
23	128	126	124	121	119	116	118	122	127	125	124	124	126	125	127	123	124	125
24	115	114	113	112	109	106	113	115	117	118	116	112	115	114	113	111	117	115
25	103	102	104	98	95	103	105	106	108	107	106	105	104	107	105	106	108	110
26	124	122	121	119	118	116	117	121	120	119	116	115	114	117	121	120	116	114
27	119	117	115	112	109	108	114	113	115	121	116	117	115	118	115	114	113	117
28	123	121	119	117	118	114	117	122	120	118	121	122	121	119	117	115	121	120
29	117	115	116	112	110	108	111	114	119	121	119	118	109	114	117	114	115	119
30	125	123	125	128	131	142	141	138	144	145	143	144	146	143	142	146	142	141

GROUP P																		
S.No	**BASELNE DBP**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	83	81	79	72	75	78	76	74	72	78	79	81	78	79	82	81	80	83
2	81	79	77	75	76	75	78	77	79	81	76	78	77	80	79	78	82	84
3	79	75	72	69	71	73	74	77	75	75	74	76	75	73	78	72	81	83
4	78	74	73	71	67	72	75	76	77	74	78	79	81	80	79	83	84	83
5	81	78	75	74	72	75	76	76	79	73	74	75	78	76	77	79	82	83
6	82	79	76	75	74	76	74	75	77	78	76	75	78	74	75	78	79	83
7	76	75	72	71	68	72	74	76	75	72	75	72	74	78	75	83	80	79
8	84	81	79	75	72	74	73	76	77	79	81	82	78	83	80	79	81	82
9	86	83	78	75	76	78	77	75	79	81	82	80	83	88	85	87	82	85
10	85	84	81	72	74	75	78	81	83	79	82	81	84	83	81	79	80	78
11	79	76	78	75	71	68	72	73	74	75	77	76	78	75	74	78	79	81
12	82	79	76	77	75	76	78	79	81	80	81	79	78	81	80	79	81	83
13	85	84	82	81	80	78	81	83	82	85	84	83	85	86	87	89	79	84
14	87	85	82	87	83	79	82	81	83	85	86	84	86	89	87	85	82	86
15	84	81	80	78	79	82	81	83	80	81	84	83	85	86	87	83	85	82
16	89	87	84	82	81	82	80	84	83	85	86	83	84	86	87	88	85	86
17	78	77	74	72	71	73	72	74	75	77	76	75	74	73	75	74	73	72
18	75	74	72	70	68	73	71	72	74	75	76	75	74	76	77	73	78	79
19	91	87	84	83	80	79	82	81	83	85	84	86	85	84	89	90	86	87
20	89	86	83	81	79	78	82	84	81	83	85	88	84	87	86	83	85	83
21	83	79	78	77	75	76	74	78	79	80	82	79	84	83	81	80	76	77
22	84	81	79	78	76	79	81	82	78	83	81	82	84	87	86	84	82	85
23	82	78	76	75	74	75	76	78	79	81	80	79	75	78	82	77	76	78
24	76	75	77	74	71	68	73	72	75	78	77	78	75	79	81	80	76	74
25	72	69	68	67	64	65	68	67	69	67	70	72	75	73	76	78	79	81
26	81	79	77	76	75	79	75	78	73	76	78	81	79	76	77	78	75	76
27	78	76	74	71	68	73	76	74	71	72	75	77	74	78	76	73	75	78
28	82	79	78	76	74	75	77	79	81	80	78	76	78	75	74	78	75	72
29	83	79	78	80	74	75	78	79	81	80	76	75	76	78	79	80	82	83
30	80	76	75	73	72	75	76	73	76	78	74	77	76	75	78	79	81	83

GROUP P																		
S.No	**BASELINE MAP**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	96	94	92	84	89	90	88	89	87	91	91	92	91	90	95	94	93	94
2	95	91	92	88	91	90	93	92	94	94	91	93	93	95	94	94	96	98
3	93	90	87	81	86	88	88	89	89	89	88	89	89	89	92	87	93	94
4	90	88	87	85	81	85	87	87	89	87	90	91	92	91	91	94	95	93
5	93	90	88	87	85	88	89	89	92	86	87	88	90	89	90	90	93	94
6	97	93	91	89	88	89	89	90	92	93	91	89	88	90	88	92	90	94
7	85	84	82	80	78	82	85	84	83	82	85	82	86	86	85	90	89	87
8	93	91	89	87	84	87	86	89	89	90	92	92	90	93	92	92	91	91
9	98	96	93	90	90	91	91	90	91	94	95	93	96	100	96	98	95	98
10	98	96	94	87	88	88	91	94	95	93	95	93	94	95	92	92	92	91
11	92	89	90	88	85	82	86	87	88	88	90	89	90	88	88	91	90	93
12	93	90	89	87	86	87	89	90	91	90	92	91	91	93	91	91	91	94
13	98	95	95	94	93	91	93	95	95	98	97	96	98	98	97	99	93	96
14	97	95	93	96	93	88	92	91	94	95	96	95	96	97	96	93	91	96
15	95	92	91	89	89	90	91	94	93	95	96	95	95	95	97	93	96	92
16	101	98	95	93	93	94	93	97	97	98	96	94	96	98	98	97	95	96
17	94	93	90	87	86	89	89	91	92	95	92	91	89	88	89	89	88	89
18	89	88	87	85	82	85	85	86	89	90	89	88	88	90	92	87	88	93
19	102	99	97	95	93	92	95	95	96	96	96	99	98	95	99	100	98	99
20	103	100	97	96	94	94	96	98	96	97	98	100	99	99	99	97	98	96
21	96	93	93	90	89	88	88	92	93	93	95	92	95	95	94	92	90	91
22	97	95	92	91	89	93	94	95	93	97	96	96	97	98	98	95	95	96
23	97	94	92	90	89	88	90	92	95	95	94	95	92	93	97	92	92	93
24	89	88	89	86	83	80	86	86	89	91	90	89	88	90	91	90	89	87
25	82	80	80	77	74	77	80	80	82	80	82	83	84	84	85	87	88	90
26	95	93	91	90	89	91	89	92	88	90	90	92	90	89	91	92	88	88
27	91	89	87	84	78	84	88	87	85	88	88	90	87	91	89	86	87	91
28	95	93	91	89	88	88	90	93	94	92	92	91	92	89	88	90	90	88
29	94	91	90	90	86	86	89	90	93	93	90	89	87	90	91	91	93	95
30	95	91	91	91	91	97	97	94	98	100	97	99	99	97	99	101	101	102

GROUP P																		
S.No	**VAS 0 MIN**	**10 MIN**	**20 MIN**	**30 MIN**	**40 MIN**	**50 MIN**	**1 HR**	**1.5 HRS**	**2 HR**	**2.5 HRS**	**3 HRS**	**4 HRS**	**6HRS**	**8HRS**	**12 HRS**	**24 HRS**	**36 HRS**	**48 HRS**
1	6	4	4	2	0	0	1	1	1	1	3	2	2	2	2	3	3	3
2	4	4	4	2	2	0	0	1	1	1	1	1	1	2	2	2	3	3
3	6	6	4	2	2	0	0	1	1	1	1	1	1	2	2	2	3	3
4	4	4	4	2	2	0	0	1	1	1	1	1	2	2	2	3	3	3
5	6	4	4	2	2	0	0	1	1	1	1	2	2	2	2	2	3	3
6	4	4	4	2	0	0	0	1	1	1	1	2	2	4	5	3	2	2
7	6	4	4	2	0	0	1	1	1	1	1	2	2	2	2	3	3	3
8	4	4	2	2	2	0	0	1	1	1	1	1	2	2	2	3	3	3
9	6	4	4	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
10	4	4	4	2	0	0	1	1	1	1	1	2	2	2	2	2	3	3
11	6	6	4	2	0	0	1	1	1	1	1	1	2	2	2	2	3	3
12	6	4	4	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
13	4	4	2	2	2	0	0	1	1	1	1	1	2	2	2	3	3	3
14	4	4	4	2	2	0	0	1	1	1	1	1	1	1	2	2	3	3
15	6	4	4	2	2	0	0	0	1	1	1	1	1	2	2	2	3	3
16	6	4	2	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
17	6	4	4	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	4	4	2	2	0	0	1	1	1	1	1	2	2	2	2	2	3	3
19	4	4	4	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
20	6	4	4	2	2	0	0	1	1	1	1	1	1	1	2	2	2	3
21	4	4	4	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
22	6	4	4	2	2	0	0	0	1	1	1	1	1	1	2	2	3	3
23	4	4	2	2	2	0	0	1	1	1	2	2	2	2	2	2	3	3
24	6	4	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3	3
25	4	4	4	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
26	6	4	2	2	2	0	0	1	1	1	1	1	1	2	2	2	3	3
27	4	4	2	2	2	0	0	1	1	1	1	1	2	2	2	2	3	3
28	6	4	4	2	0	0	1	1	1	1	1	2	2	2	2	2	3	3
29	4	4	4	2	2	0	0	1	1	1	1	2	2	2	2	2	3	3
30	6	6	6	6	6	6	-	-	-	-	-	-	-	-	-	-	-	-