"EVALUATION OF THE EFFECT OF EPIDURAL VOLUME EXTENSION ON THE CHARACTERISTIC OF SUBARACHNOID BLOCKADE WITH LOW DOSE OF HYPERBARIC BUPIVACAINE FOR INFRAUMBILICAL SURGERIES- A ONE YEAR RANDOMIZED CLINICAL TRIAL"

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ABBREVIATIONS

ASA	-	American society of Anesthesiologists
BMI	-	Body mass index
CSEA	-	Combined spinal epidural anesthesia
CSF	-	Cerebrospinal fluid
CVS	-	Cardiovascular system
DBP	-	Diastolic blood pressure
EV	-	Epidural volume
EVE	-	Epidural volume extension
LA	-	Local anesthetic
LOR	-	Loss of resistance
LSCS	-	Lower segment caesarean section
MEV	-	Minimum epidural volume
NS	-	Normal saline
NIBP	-	Non invasive blood pressure
PACU	-	Post anesthesia care unit
PDPH	-	Post dural puncture headache
SAB	-	Sub arachnoid blockade
SAS	-	Sub arachnoid space
SBP	-	Systolic blood pressure
SD	-	Standard deviation

ABSTRACT

TITLE:

"EVALUATION OF THE EFFECT OF EPIDURAL VOLUME EXTENSION ON CHARACTERISTICS OF SUBARACHANOID BLOCKADE WITH LOW DOSE OF HYPERBARIC BUPIVACAINE FOR INFRAUMBILICAL SURGERIES": A ONE YEAR RANDOMISED CLINICAL TRIAL.

KEYWORDS:

Spinal anesthesia, epidural volume extension, low-dose hyperbaric bupivacaine, intrathecal injection, normal saline

BACKGROUND:

Subarachnoid block with 0.5% hyperbaric bupivacaine has been extensively used for infraumbilical surgeries. However, the associated hypotension restricts the dose which can be safely administered especially in patients with pre-existing cardiac conditions. Epidural volume extension is a technique which is postulated to increase the maximum sensory level achieved using low dose of local anesthetic in subarachnoid block without the associated hemodynamic instability normally expected. Hence this study

has been undertaken to assess the effect of epidural volume extension on characteristics of low dose subarachnoid block.

OBJECTIVE:

To determine the onset and duration of sensory blockade, maximum level of sensory block achieved and onset and duration of motor blockade in both groups, i.e., with and without epidural volume extension and to compare the intraoperative hemodynamic parameters between the two groups.

METHODOLOGY:

A total of 60 patients, ages 18 to 60, who were scheduled for elective infraumbilical surgeries were divided into two groups at random (A and B). Group A patients received spinal anesthesia, whereas Group B patients were given epidural volume extension along with spinal anesthesia. Between the two groups, data on the onset, maximum level, and two-segment regression of the sensory block, the onset and duration of the motor block, and the intraoperative hemodynamic parameters were recorded.

RESULTS:

Both groups' operative and demographic traits were similar. Mean sensory blockage onset time in Group A was 2.55 minutes, while it was 1.96 minutes in Group B ($p<0.05$). mean two-segment regression took 71.53 minutes for Group A and 86.47 minutes for Group B. In Group A, the highest level of sensory blockade was at T10, whereas in Group B, it was at T8. Mean motor blockage onset times for Groups A and B were 4.17 and 2.83 minutes, respectively. Motor blockade lasted an average of 141.13 minutes in Group B and 144.03 minutes in Group A ($p>0.05$). Between Group A and Group B, hemodynamic parameters were similar.

CONCLUSION:

Early onset of sensory and motor blockade, a high level of sensory blockade, and a shorter time for two segment regression occur when a low dose of intrathecal hyperbaric bupivacaine (10 mg) is combined with an epidural volume extension. Additionally, hemodynamic stability is preserved.

CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF GRAPHS

LIST OF PHOTOGRAPHS

INTRODUCTION

The advantages of regional anesthesia over general anesthesia are simplicity, avoidance of use of many anesthetic drugs and their metabolism and excretion, effective block with small dose of local anesthetic, economical, and safe technique.[1] One of the key benefits is the capacity to provide prolonged post-operative pain control that is superior to that offered by systemic opioids alone.[2]

Most patients undergoing infraumbilical especially lower extremity orthopaedic surgery are elderly, and many of them have other concurrent medical conditions. In order to maintain a safe and desired level of blockage and prevent excessive sympathectomy in these individuals, the right regional anesthetic approach must be used.[2]

The first description of combined spinal-epidural anesthesia dates back more than 35 years.[3] The modern conventional needle-through-needle procedure was first used in clinical settings in 1982.[4] A neuraxial approach called combined spinal-epidural anaesthesia is appropriate for caesarean sections, various urological and gynaecological procedures, and lower limb surgery amongst others. The spinal

component allows for rapid induction of anesthesia and the drugs delivered via an epidural catheter maintain analgesia during the postoperative period.[5]

A variation of combined spinal epidural anesthesia which has been recently proposed is ‘epidural volume extension’. Immediately following an intrathecal injection, 0.9% NS is injected into the epidural space.[6] Its goal is to rapidly increase the height of sensory blockade produced by the intrathecal drug deposition invoking the volume effect, in which the saline epidural injection contracts the theca, which causes CSF to be squeezed and subarachnoid local anesthetic to disseminate more cephalically. This impact here is distinct from the block enhancement cause by EVE with LA, as the block height is extended via saline injection by a mechanical volume effect and has no impact on how long a block lasts. Hence, it is proposed that a higher level can be achieved using a lower amount of intrathecal local anesthetic.[7]

OBJECTIVES

PRIMARY OJECTIVE:

To determine the onset and duration of sensory blockade, maximum level of sensory block achieved and onset and duration of motor blockade in both groups, i.e., with and without epidural volume extension.

SECONDARY OBJECTIVE:

To compare the intraoperative hemodynamic parameters between the two groups.

REVIEW OF LITERATURE

Takiguchi et al. established clinical and myelographic augmentation of sensory blockade in CSEA in 1997 using 5 mL and 10 mL normal saline administered post-intrathecal block, epidurally.[8]

Kim AR et al in 2005 tested the effect of CSE with EVE on c-section. This study showed that CSE with EVE offered appropriate anesthesia for a planned caesarean section while using just 70% of the bupivacaine dosage and facilitating lower limbs' quicker motor recovery, which reduces PACU stay.[9]

J M Vicente et al carried out a study in 2006 comparing the efficacy of spinal 0.5% Bupivacaine (H) with fentanyl vs 0.25% levobupivacaine with fentanyl and EVE with 6 ml of saline by means of an epidural catheter and concluded that utilizing low doses of levobupivacaine with an opiate in combination with EVE is a safe, effective technique that may allow the doses and motor block to be reduced when hyperbaric levobupivacaine is administered.[10]

Rajiv Singh Bhandari et al concluded in 2018 that low-dose intrathecal Bupivacaine (H) (10 mg) in combination with EVE (10 ml 0.9% NS) is linked to an early onset and heightened sensory block, a prolonged time for two segment regression, early commencement of motor blockade and reduced risk of hypotension owing to decreased intrathecal drug concentration.[11]

In 2012, Kaur et al performed a prospective, randomised, double-blind research on 105 individuals who were posted for elective caesarean section, wherein the participants were arranged themselves at random into three groups, each with 35 people. Intrathecally, Group A got 10 milligram of 0.5% Bupivacaine (H) and 25 microgram Fentanyl. Group B received 7 milligram of 0.5% Bupivacaine (H)and 25 microgram Fentanyl intrathecally. And, Group C received 7 milligram of 0.5% Bupivacaine (H) and 25 microgram Fentanyl intrathecally and 10 ml of NS in epidural space after five minutes of intrathecal drug administration. The authors concluded that the patients in the EVE group had considerably lower scores on the modified bromage scale. This resulted in a motor block that lasted noticeably less time.[12]

On the contrary, S Kucukguclu et al[13] in 2008 and Yamazaki et al[14] in 2000 concluded that, the baricity of the spinal anaesthetic solution employed does not alter the reinforcement of SAB by epidural injection of saline.

In 2011, Tyagi A et al executed a study contrasting the impact of patient's position while the block is being performed, on the findings of EVE and concluded that if application of EVE is intended to quickly extend the sensory block after intrathecal administration of hyperbaric bupivacaine, instead of siting, the CSE block should be executed in a lateral position to avoid restricted spread of LA to lumbar and sacral roots.[15]

In 2014, Tyagi A et al performed yet another study to evaluate the minimum volume of epidural saline administration on spinal anesthesia and concluded that the MEV of normal saline is 7.4 ml, and within five minutes of EVE, it has the potential to enhance sensory block by at least two dermatomal segments.[16]

Eileen lew et al carried out a prospective, randomized, double blind research in 2004 and concluded that CSEA with EVE provided adequate anesthesia for c-section and rapid motor recovery in the lower limbs is linked to a small bupivacaine dosage (55%). There is no substantial difference in the sensory or motor block onset whereas there was a noticeable difference in the regression of the sensory block to L1 among the two groups. They also discovered that there was no discernible change found in lowest SBP among the two groups. The rationale behind this was that in this trial, only 5 mg of Bupivacaine (H) was utilised, compared to 9 mg in the single shot spinal group also both the groups had the same sensory level.[17]

Atiharsh et al in 2012 examined the effectiveness and block characteristics of fentanyl and tramadol to reinforce SAB by EVE in lower abdominal surgeries and concluded that EVE has the ability to substantially raise block height, however, it appears to be confined only to the physical attribute of extra volume in epidural space and are independent of the agent used.[18]

Manoj Tripathi et al in 2015 also backed up the hypothesis. He came to the conclusion through his research that in a c-section, spinal block with EVE of 15 ml induces a rise in sensory block level. In compared to a single shot, the period to regression of sensory block to L1 is extended. 1.5 ml of plain (isobaric) bupivacaine with 15 ml of EVE is sufficient for c-section. As a result, the EVE approach is suggested for c-section, with the added benefit of a lower incidence of adverse effects.[19]

The lengthy duration of action of intrathecal bupivacaine might unduly prolong the time required to fulfil PACU release criteria for patients having brief obstetric procedures. In 2019, Mark F Powell et al conducted a randomized study where the control group received 10 milligram of 0.5% isobaric bupivacaine with 15 microgram of fentanyl into the intrathecal space. The EVE group had an intrathecal injection of 0.5% isobaric bupivacaine (5 milligram) and fentanyl (15 microgram) immediately followed by a 10 ml injection of NS for the EVE via the epidural needle and concluded that in patients having brief obstetric operations, the administration of low-dose isobaric bupivacaine in conjunction with 10 ml of

saline EVE enables for speedier motor recovery and time to fulfil PACU discharge requirements.[20]

In 2010, E Guash et al investigated the occurrence of maternal hypotension following spinal bupivacaine or levobupivacaine administration and the spread after epidural NS injection. They randomly assigned women due for caesarean section to one of four groups, each of which received 5 mg of 0.25% bupivacaine with or without saline EV; 5 mg of 0.25% levobupivacaine; or 6 mg of 0.3% levobupivacaine. In addition, each patient got 25 micrograms of fentanyl per 2 millilitres of local anesthetic. They observed that whereas the group given 5 mg of levobupivacaine had the lowest rate of hypotension, the requirement for rescue analgesia was higher. Because they offer a decent level of sensory blockage, doses of 5 mg and 6 mg may be sufficient for caesarean delivery.[21]

BASIC SCIENCES

ANATOMY

The epidural space is the most experimented cavity in human beings. It was first described by Corning[22] in 1901. The anatomical space between the duramater and the vertebral canal is called the epidural space. It was thought to be a real space while in reality it is merely a potential space. 24 individual vertebrae forms the vertebral column constituting 7 cervical, 12 thoracic, 5 lumbar while the fused vertebrae includes 5 sacral and 3 to 5 coccygeal bones remaining rudimentary. The epidural and the subarachnoid spaces are housed and protected by these vertebrae. The fusion of the membranes of the medulla spinalis and the duramater overlying the periosteum at the foramen magnum forms the upper boundary of the epidural space, whereas the sacrococcygeal membrane forms the lower limit. The bodies of vertebrae along with intervertebral discs and posterior longitudinal ligament binds the epidural space anteriorly while laterally it is encircled by the pedicles and intervertebral foramina.

EMBRYOLOGY

At the gestational age of 13 weeks, the connective tissues plug the epidural space and the posterior longitudinal ligament and the duramater are tethered. Three stages differentiate the evolvement of the epidural space inside the connective tissue at the 13th week subsequently. These are namely the primary epidural space formed in embryos measuring 16-31 mm crown rump length , reduction in the volume of the primary epidural space occurs when embryos measure about 35-55 mm crown rump length and formation of the secondary epidural space occurs at the embryological growth phase of 60-70mm crown rump length. The attachment of the vertebral body to the posterior longitudinal ligament lateral to the midline and to the dorsal margin of intervertebral disc occurs at the 15th week of embryonic life. At week 21, the binding between the duramater and posterior longitudinal ligament is ligament like at the vertebrae. At week 32, the superficial layer of posterior longitudinal ligament and the duramater are adherent. Groups of adipocytes begin to develop at the 39th week. The upper thoracic regions of the

spinal cord has the most roomy epidural space. The epidural space at the level of C7-T1 in adult measures 0.4 mm posteriorly, in the upper thoracic region it measures about 7.5 mm, calibration of 4.1mm at T11-T12 and in the lumbar region it is about 4-7mm. This space is much greater in volume when compared to the corresponding subarachnoid space at the same level. It takes about 0.3 ml of a local anaesthetic to block a spinal segment in the SAS while about 1.5-2 ml of local anaesthetic is required to produce an epidural block. The cervical, thoracic, lumbar and sacral spaces form the divisions of the epidural space. They are defined according to their margins. The membranes of medulla spinalis and dura mater lining the periosteum fuses from the foramen magnum till the lower border of vertebrae prominens to form the cervical epidural space. While from the lower boundary of C7 to the upper boundary of L1 constitutes the thoracic epidural space. The extension of the lumbar epidural space is from the lower border of L1 vertebra till the upper border of S1 vertebra. The upper margin of S1 to sacrococcygeal membrane demarks the sacral epidural space. The inbuilt negative pressure within the epidural space limits its demarcation. There are two theories

explaining this negative pressure. The Cone Theory states that the needle introduced into the epidural space depresses the dura, consequently creating a larger epidural space. It is thus considered an artefact caused by the indentation of the dura by the advancing needle. Telford and Holloway[23] demonstrated that epidural space pressures were always positive and negative pressures were only recorded when there is tenting of the dura with a relatively blunt needle. The Transmission Theory considers that the vacuum in the epidural space is caused by the transmission of the intrapleural negative pressure via the intervertebral foramina to the peridural space. This negative pressure is greatest at points of firm attachment and in the thoracic region. It is less in the lumbar region and least or absent in the sacral area. Gil et al.[24] ,2008 demonstrated that specifically in the thoracic epidural space, particularly in the sitting posture, there is development of more negative pressure than in the lateral recumbent position. This therefore clearly shows that when the hanging drop technique is used to identify the epidural space, sitting position defines the epidural space more distinctly.

The constituents of the epidural space

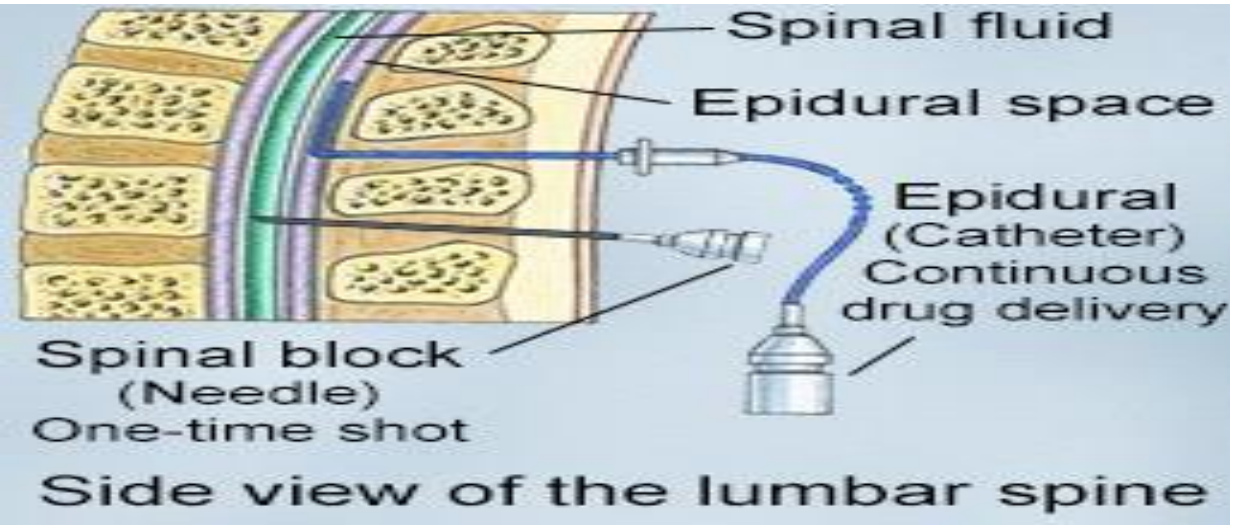
Semi-liquid fat, epidural arteries, loose areolar connective tissue, lymphatic channels, the nerve roots of the spinal cord, and a vast venous plexus are contained in the epidural space. Hogan,[25] 1998 proved that the contents of the epidural space are segregated by distinct zones where the vertebral canal comes in contact with the duramater and arranged in a circumferential series of compartments discontinuously.

Semi-liquid Fat

There has been numerous studies about the fat distribution in the epidural space. A study carried out by Reina et al.,[26] 2006 proved that there is a predictable pattern of distribution of epidural fat abundantly within the spinal canal. Adipocytes are also numerous in the duramater, sleeving the spinal nerve roots. There is no embedment of fat cells within the laminas of the dural sac which form the dura mater. The pulsatile movements of the dural sac is buffered by these adipocytes in the

extradural space which also serves to protect the neural elements. Thus this creation of a lipophilic reservoir facilitates smooth movements during flexion and extension of the spine allowing the dural sac to slide over the periosteum of the vertebrae. Reina et al.,[26] 2006 showed the continuous metameric pattern of arrangement of the epidural fat in human adults. The storehouse of fat in the dural sleeves could act as reservoir of drugs thus leads to greater effect on nerve roots compared to the drugs stored in epidural fat. This is due to the proportionately larger concentration of fat near the nerve roots, and their closer proximity. Reina et al.,[26] 2009 also highlighted that the pathologies altering the distribution or fat content changes the absorption or distribution of drugs administered in the epidural space.

FIGURE 1



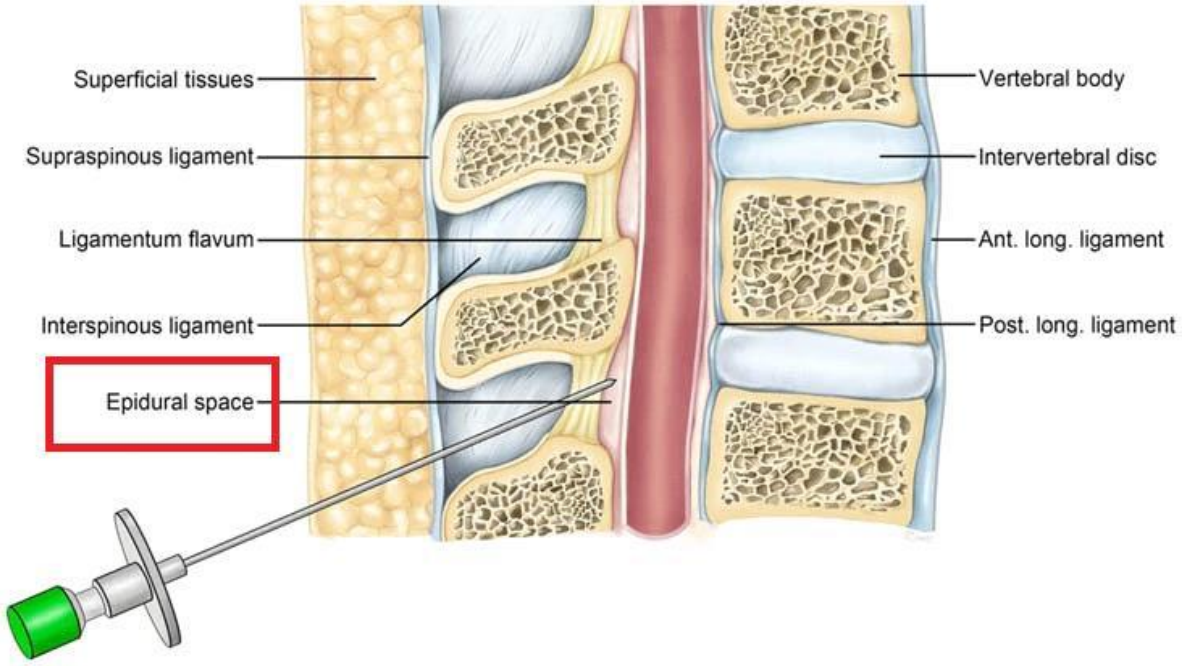


FIGURE 2: ANATOMY OF EPIDURAL SPACE

Applied Anatomy and Clinical Importance of the Epidural Space

The distribution of adipocytes is predominantly on the dorsal region of the space. It is connected via a vascular pedicle to the middle of the ligamentum flavum and arranged in triangular capsular shapes. This peculiarity of the adipocyte arrangement contributes to the resistance during epidural catheter insertion and for the pharmacokinetics of local anaesthetics and drugs injected into the space to act on the dorsal spinal nerve roots.

Lymphatic System

The lymphatic system contained within the epidural space act as scavengers by removing the foreign particles including microbes from the epidural and subarachnoid spaces. The dural roots mainly harbour the lymphatics.

The Valveless Vertebral venous plexus

Domisse,[27] 1975; Parkin and Harrison,[28] 1985; Brockstein et al.,[29] 1994 thoroughly studied the internal vertebral venous plexus and found them to be anchored within the epidural space. Mehl,[30] 1986 claimed that this plexus of veins caused tapping

of blood in the epidural needle. There are four longitudinal interconnecting vessels, two anterior and two posterior which contribute to the internal vertebral venous system. Williams et al.,[31] 1989 on the contrary showed that the external vertebral plexus is made up of anterior and posterior plexus of veins lying peripheral to the vertebrae. Being located anterior to the vertebral bodies the external vertebral venous system is related to the laminae, spinous processes, transverse processes and articular processes of the vertebrae respectively. The segmental veins of the neck, the intercostal, azygos and lumbar veins form the communicating channels of this system. Batson's vertebral venous plexus is formed by the network of periosteal veins of the vertebral column, along with the internal and external vertebral plexuses. (Domisse,[27] 1975). Being predominantly situated in the anterior and lateral portion of the epidural space, these veins unite with the azygous venous system finally. During conditions like ascites and pregnancy, increase in intrathoracic or intra-abdominal pressures is directly transmitted to this system as the entire system is valveless, leading to major congestion and enlargement of

vessels within the spinal canal. A sparse quantity of fat circumference the epidural venous plexus. A rich valveless venous plexus fills the anterior epidural space. The plexus makes important communications with the cerebral venous system namely, the sigmoid sinus, basilar veins, vertebral vein, occipital veins, and the azygous vein. The transmission of abdominal and thoracic cavity pressures to the epidural space is because of the linkage with the abdominal and thoracic venous system via the intervertebral foramina. The sacral venous plexus is formed by the connection of vertebral venous plexus with the iliac veins. There is an increased risk of bleeding while securing the epidural needle or catheter when there is distension of the venous plexus during advanced stages of pregnancy, obstruction of inferior vena cava or abdominal cavity malignancies.

Arteries of the epidural space

The branches of the ilio-lumbar arteries forms the vascular supply to the lumbar epidural region. Advancement of the epidural needle does not injure these arteries as they are found laterally.

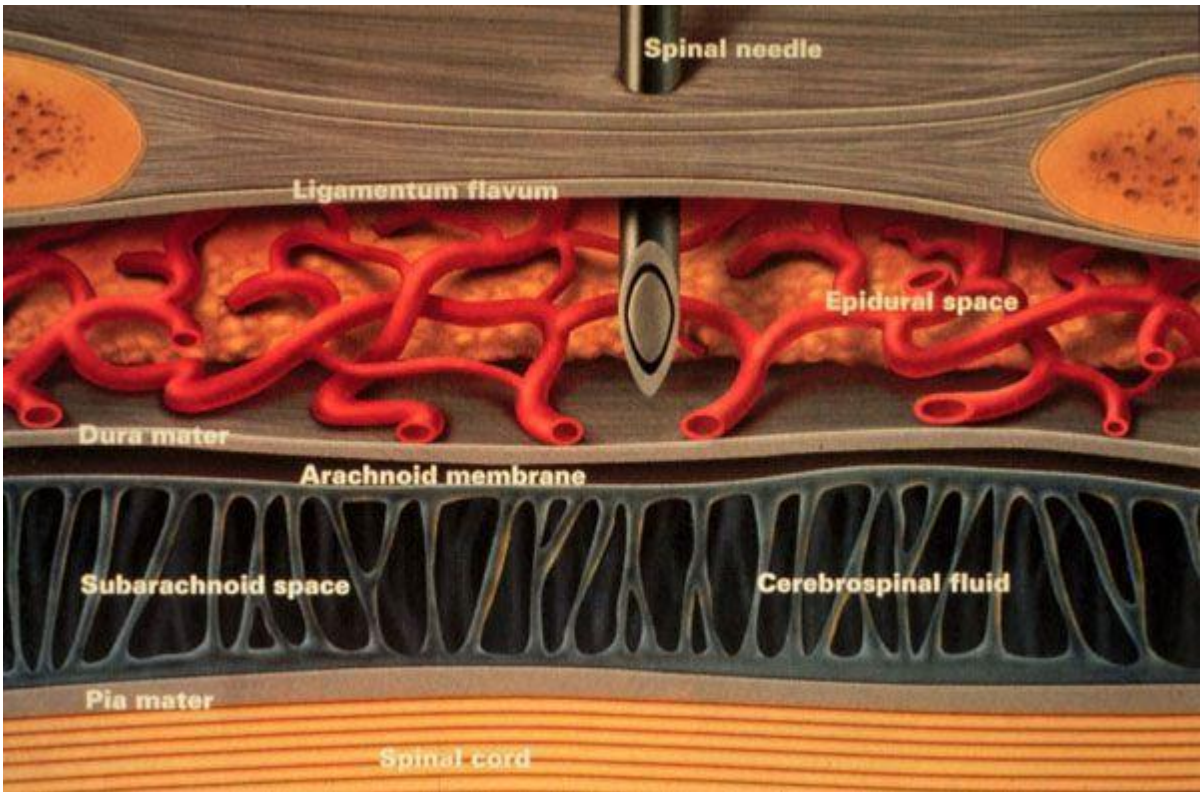


FIGURE 3: EPIDURAL SPACE AND ITS CONTENT

Identifying the extradural space

Identifying the epidural space is a demanding technique and as anaesthesiologists it is of crucial importance. The first demonstration of this space was made by Dogliotti,[32] 1933 about 83 years back. The functionality of the epidural analgesia depends upon the accuracy of detection of the epidural space. As the epidural needle is inserted in the midline, it pierces the skin, the subcutaneous tissue, the supraspinous, interspinous ligament and has to traverse the ligamentum flavum to reach the space. The depth of the epidural space is defined as the distance from overlying skin to the tip of the needle just penetrating into the epidural space (Lai et al.,[33] 2005). In obese patients the depth is difficult to identify.

To improve the probability of success rate in identification of the peridural space, Ravi et al.,[34] 2011 found out a correlation between the body mass index(BMI) and the depth of the epidural space This study showed that the depth of the epidural space increased significantly as the BMI increased. Based on linear regression analysis, the equation for depth of epidural space is Depth (mm) = a + b (BMI).

Where a = 17.7966 and b = 0.9777.

Identification of the epidural space

Negative pressure contributes to the most traditional method of spotting the epidural space. In order to minimize the associated complications, any technique identifying the epidural space should be simple, safe and reliable. Loss of resistance (LOR) is one of the most reliable technique in identifying the extradural space. In this method a glass or plastic syringe is filled with either air or saline or local anaesthetic and advanced from the skin by applying a continuous or intermittent pressure on the piston. The point where it becomes possible to inject through the syringe marks the loss of resistance. As the injection through the ligamentum flavum is not possible, this technique always works better. The syringe may contain air or saline. Since air has a greater compressibility than saline or local anaesthetic, the specifications of the technique are different whereas it carries the same principles. The identification of the epidural space with LOR to lidocaine or air plus lidocaine has minimal chance of puncturing the dura as compared to air alone and technique wise also it is potentially difficult. Evron et al.,[35] 2004 has stated that sequential use of air and lidocaine has no benefits over lidocaine alone.

The complications associated with this technique has been studied. Nay et al.,[36] 1993 proved that paraplegia could result from LOR to air, the development of pneumocephalus was highlighted by Nafiu & Bullough,[37] 2007. Okutomi & Hoka,[38] 1998 insisted the association between LOR to saline and the dilution of the injected local anaesthetic.

Hanging Drop Sign: A small drop of sterile distilled water is placed on the hub of the needle after it is introduced to the level of resistance indicating the beginning of the ligamentum flavum. When the needle is advanced through the yellow fibrous tissue, this drop will be sucked into the epidural space. This is called the “sign of the drop”.

Capillary Tube Method: Odom developed an improved method for detecting the epidural space where he devised a small capillary tube filled with sterile saline in which one or two bubbles of air were placed. These acted as a meniscus. As soon as the needle entered the epidural space, the saline was sucked in and the

air bubbles could be seen advancing into the space. Michel & Lawes,[39] 1991 devised a new technique called modified drip method to identify the epidural space. In this trial, an infusion of saline was filled in the tubing and attached to the hub of the epidural needle and the distal 40 cm was left full of air. In a majority of cases, precise identification of the extradural space was accomplished in a petty time. In contrast to the manual loss of resistance technique and hanging drop method, this study showed a clear edge.

Lin et al.,[40] 2002 observed a novel approach called as "membrane in syringe" with two distinct benefits. A syringe is divided into two halves by keeping a plastic membrane in the middle. The distal nozzle end of the plastic syringe is filled with saline. The other hollow cylindrical portion of the syringe is closed with the plunger. The air compartment is the space enclosed between the rubber plunger and the plastic membrane. First and foremost advantage of this technique is that air entrance is prohibited without hampering the feel of compressibility. Wrinkling of the plastic membrane and injection of saline

indicates the entrance into the epidural space is the second benefit of this technique. The Macintosh epidural balloon serves as a simple method in identifying the extradural space. A small balloon is filled with 2 to 3 ml of air and lodged on to a glass adapter attached to the epidural needle when it reaches the ligamentum flavum. The collapse of the balloon signifies the epidural space penetrance. Fyneface-Ogan & Mato,[41] 2008 weighed the identification characteristics of both epidural balloon and LOR technique and ascertained that the space could be more swiftly detected at the first attempt by the epidural balloon although the cost factor plays a role.

Samada et al.,[42] 2011 invented an optimal pressure producing loss of resistance device called the Epidrum for localising the epidural space. The operation of the device is at a high pressure set to be liberated into the extradural space, taking care not to cause premature leakage into the patient's tissues. An extremely thin diaphragm situated at the top of the Epidrum acts as the meniscus of a manometer

to create an optimal pressure. This facilitates the operator to identify the position of the needle tip with help of the diaphragm's signal.

Epidrum has the following advantages

• Shorter learning curve as the procedure is comparatively simple. When the trainee is performing the procedure the trainer can monitor the diaphragm signal.

• It is an effective, trustworthy and harmless procedure.

• Post dural puncture headache and the risk of epidural haematoma formation could be drastically prevented by using a smaller needle

• A visual endpoint is offered.

• False positive errors could be minimized by using an optimized, low and constant pressure

• Dural tap can be easily seen by the draining CSF

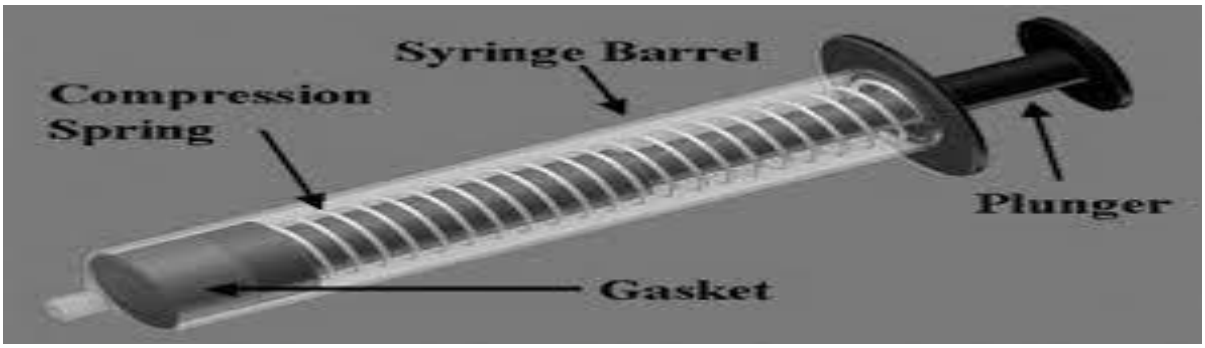


FIGURE 4: EPIDRUM

FIGURE 5: LOSS OF RESISTANCE SYRINGE AND ITS TECHNIQUE

HISTORY

• **Soresi** was the first person to perform Combined Spinal Epidural technique in 1937.

• **Cerelaru** used separate spaces for each component in 1979.

• **Brownridge** in 1981 advised the use of CSE in caesarean section.

• **Carrie** in 1984 described needle through needle technique.

• **Dr**. **Morgan** in 1993 introduced CSEA (combined spinal epidural analgesia) for labour – walking epidurals.

EQUIPMENTS REQUIRED:

EPIDURAL NEEDLE:

The Epidural needle most commonly used is 16G or 18G Tuohy needle with bent tip with 8 cm/10 cm long shaft. A radical improvement suggested by Huber resulted in bending the point and placing the bore opening on the side of the point. This is called Tuohy-Huber point needle with a blunt leading edge and a lateral opening at the tip. The Epidural catheter is 16G or 18G with single hole at the end

or closed end with side holes at multiple levels. A 0.2 micrometer filter at proximal end is to prevent contamination by bacteria and injection of particulate matter through the catheter. Other types of epidural needles are Crawford Point Needle and Hustead Needle.

SPINAL NEEDLE:

Quincke Babcock's needle 23G - 27G is most commonly used standard spinal needle. It has a small hub and a sharp point with a medium length cutting bevel. A stylet is fitted matching the bevelled tip to the cannula point. The hub is designed with a Luer-Lock connector. Other types are fine gauge needles (24G -27G) with a pencil point tip (Sprotte or Whitacre). The combined spinal epidural kit consists of 8cm Tuohy needle with 120 mm spinal needle or 10 cm Tuohy needle with 150 mm spinal needle. Optimum protrusion of spinal needle in the kit is 1.7 cm.

CSE TECHNIQUES:

• **SINGLE PASS :**

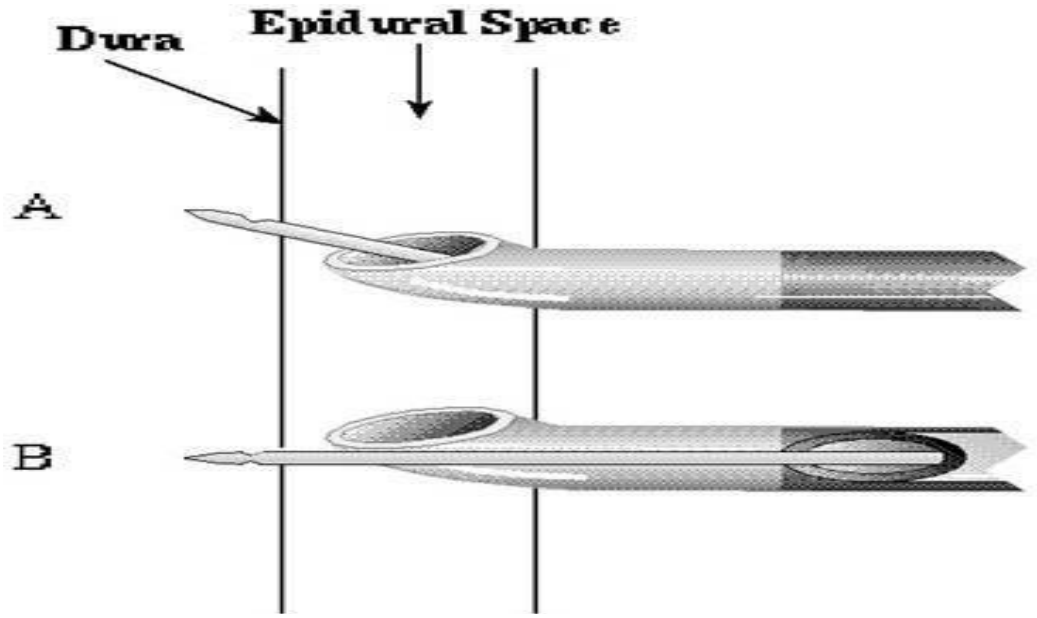
It was first described by **Soresi** in 1931. In this technique needle introduced into the epidural space injects some quantity of local anaesthetic and then advanced further into the subarachnoid cavity where subsequent dose of local anaesthetic is deposited. It is not used nowadays and there is no longevity of the block.

• **NEEDLE THROUGH NEEDLE:**

16 G or 18 G epidural needle is used to identify the epidural space. Spinal needle of size 24G to 27G is then introduced via the epidural needle, till dural piercement is felt. Spinal needle stylet is then removed. Cerebrospinal fluid needs to be visualized in the hub of the spinal needle. Injection of local anaesthetic agent is done. Spinal needle is taken out and about 3.5 cm of the epidural catheter is placed inside. Epidural catheter is secured with sterile tapes and used to prolong pain relief once the spinal anaesthesia wears off.

• **NEEDLE THROUGH NEEDLE (BACKEYE+) :**

Epidural needles, with back-eye on the curve, specially designed for allowing spinal needle introduction in a straight line, tip coming out through the back-eye, entering the subarachnoid space. The epidural catheter then travels along the curved part of the epidural needle and the tip is positioned cephalad.



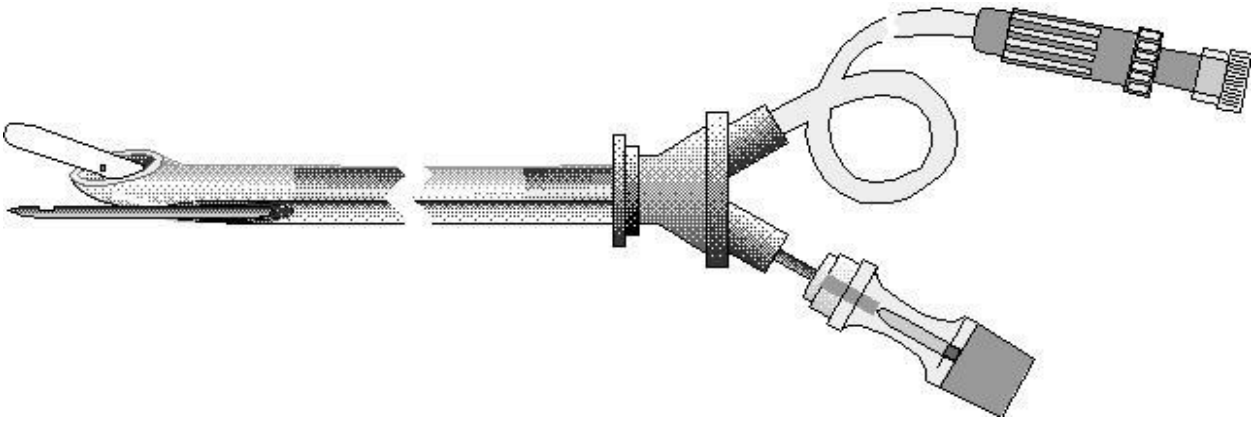


FIGURE 6: NEEDLE THROUGH NEEDLE TECHNIQUE

• **LOCKING NEEDLE THROUGH NEEDLE:**

It has locking device to stabilize the spinal needle with the epidural needle, after identifying the epidural space, which provides stability to the spinal needle.

• **SEPARATE NEEDLES THROUGH SEPARATE INTERSPACES:**

Epidural catheter and spinal needle are introduced separately at two different intervertebral spaces. Possibility of catheter injury by the spinal needle tip cannot be ruled out.

• **SEPARATE NEEDLES THROUGH SAME INTERSPACES :**

Epidural catheter is placed first followed by spinal needle insertion and then the subarachnoid drug administration. Provides good patient satisfaction.

• **COMBINED NEEDLE :**

This avoids the friction, supposed to occur while using needle through needle technique and separates the epidural and spinal components.

• **DUAL CATHETER TECHNIQUE :**

Spinal and epidural catheterization can be done separately. They have the possibility of catheter entanglement, cauda equina syndrome and accidental subarachnoid injection of high volume of drugs, mistaking spinal for epidural catheter that might result in total spinal anaesthesia.

SPINAL ANAESTHESIA ALONE

ADVANTAGES:

• Rapid onset

• High reliability than epidural

• Dose requirement reduced, prevents toxicity

• End point of needle placement is definite.

DISADVANTAGES:

• No options to extend the blockade.

• As dura is deliberately breached, the risk of postdural puncture headache is high.

EPIDURAL ANAESTHESIA ALONE

ADVANTAGES:

• Used widely

• Familiarity of the technique

• Epidural catheter allows top up doses to produce alteration or prolongation of the blockade

• Hypotension occurs slowly when compared to SAB.

• PDPH is uncommon, unless accidental dural puncture occurs.

DISADVANTAGES:

• Slow onset

• Sometimes asymmetrical or patchy

• Huge volume of local anaesthetic agents needed

• Certain spinal nerve roots could not be blocked.

COMBINED SPINAL EPIDURAL ANAESTHESIA CAN THUS PRODUCE…

• Rapid induction of anaesthesia

• The quality of pain relief is better

• Low dose of local anaesthesia required

• Epidural catheter can prolong and optimize spinal block

COMPLICATIONS OF CSE TECHNIQUE:

• Technically difficult

• Extensive blockade

This may be due to

• Bolus of epidural local anaesthetic agent may act on the spinal nerves.

• The epidural drugs may cross the dural membrane

• Accidental migration of catheter tip to the intrathecal cavity.

-Epidural bolus of anesthetic agent can extend the intrathecally administered drug, only while the subarachanoid blockade is developing (13 minutes)

• PDPH

• Meningitis

• Neurological sequalae is rare.

FIGURE 7: COMBINED SPINAL EPIDURAL KIT

RATIONALE BEHIND EPIDURAL VOLUME EXTENSION

Epidural volume extension (EVE) is an alteration of the CSE technique where normal saline is injected into the peridural space after subarachnoid injection of hyperbaric bupivacaine. This is aimed at rapidly increasing the sensory level obtained spinally by causing thecal compression to ascend the intrathecal drug.

EVE is a unique technique for regional anaesthesia which offers reliability and rapidity of spinal anaesthesia along with the flexibility of epidural anaesthesia. Desired degree of surgical anaesthesia is achieved with a small dose of local anaesthetic which prevents adverse hemodynamic effects seen with the conventional doses. It avoids the disadvantages of general anaesthesia in patients with high cardiac risk by avoiding the cardiodepressant drugs.

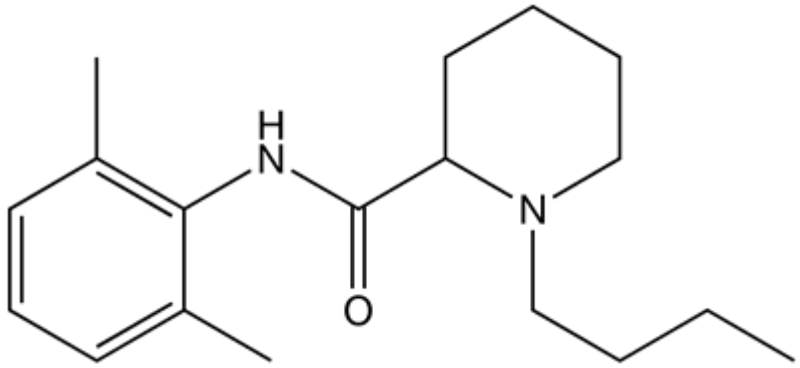
We could titrate the level of anaesthesia, vary the intensity of block, extend the duration of anaesthesia and also deliver postoperative analgesia. It provides early ambulation and is also cost effective. EVE is a novel technique which is increasingly being used nowadays for orthopaedic, gynaecological and urological

procedures thus commanding a unique place in the anaesthesiologist's armamentarium.

PHARMACOLOGY OF BUPIVACAINE

Bupivacaine is an amide local anaesthetic agent. It belongs to the homologous series of n-alkyl substituted pipecholyl xylidine group. It was first synthesized by **Ekenstam** in 1957 and was used clinically in 1963. It is produced for clinical use as a racemic mixture containing both 'S' and 'R' forms in equal proportion. It is supplied as a hydrochloride salt

CHEMICAL STRUCTURE:



1-butyl-n-(2, 6-dimethyl phenyl) -2-piperidine decarboxamide hydrochloride monohydrate.

PHYSIO – CHEMICAL PROFILE:

Molecular weight - 288

pKa - 8.1

Plasma protein binding - 95%

Partition coefficient - 28 (lipid solubility)

T ½ - 210 min

Clearance - 8.3 l/min

MECHANISM OF ACTION:

Like all the other local anaesthetics, it inhibits Na channels. It decreases or prevents large transient increase in permeability of the cell membranes to Na ions that follows depolarization of the membrane and thereby blocks the nerve conduction. It also reduces the permeability of the resting nerve membrane to potassium ions as well as sodium ions and hence has got a stabilising action on all excitable membranes.

EFFECTS:

1) Local – nerve blockade

2) Regional – pain, temperature, touch, motor power and vasomotor tone supplied by the nerves are blocked.

3) Systemic – effects due to systemic absorption or accidental intravenous administration.

It is 4 times more potent than lignocaine but the onset of action is slower. The duration of action is longer. Sensory block is more marked than the motor block.

SYSTEMIC EFFECTS:

Central Nervous System:

Can produce circumoral numbness, metallic taste, tinnitus, light headedness, dizziness, confusion, slurred speech, convulsions

Cardiovascular System:

Depresses automaticity and contractility of the heart and slows down the conduction of the cardiac action potential as there is prolongation of PR and QR intervals on ECG. Re-entrant phenomenon and ventricular arrhythmias may occur. All these results mostly from high lipid solubility. R-enantiomer is more toxic than S-enantiomer. Pregnancy increases cardiotoxic effects of bupivacaine

KINETICS:

• Rapidly absorbed from the site of injection

• Peak systemic concentration – 5 to 30 minutes after administration

• Duration of action – 360 to 720 minutes

• Metabolism in liver – dealkylation to pipecoloxylidine, aromatic hydroxylation

• Excretion – 5% by kidney as unchanged drug and rest as metabolites

PREPARATION:

• 0.25%, 0.5% solutions in 10, 20 ml vials, respectively

• 5mg/ml (0.5%) bupivacaine with 80 mg dextrose (to increase baricity) in 4 ml ampoules for subarachnoid injection (baricity – 1.0207)

USES:

• Central neuraxial blocks

• For local infiltration subcutaneously

• Peripheral nerve blockade

SIDE EFFECTS:

Bupivacaine exhibits selective cardiotoxicity. It is due to its lipophilicity and blockade of cardiac sodium channels. Accidental intravenous injection precipitates hypotension, cardiac dysrhythmias like sinus tachycardia, supraventricular tachycardia, atrioventricular heart block, ventricular tachycardia, premature ventricular contractions, wide QRS complexes and ST - T wave changes.

CONTRAINDICATIONS:

• Known hypersensitivity to amide local anaesthetics

• Intravenous regional anaesthesia (IVRA)

MATERIALS AND METHODS

Present study titled “Evaluation of the effect of epidural volume extension on characteristics of subarachnoid blockade with low dose of hyperbaric bupivacaine for infraumbilical surgeries” was done in “Department of Anesthesiology, KLE’s Dr. Prabharkar Kore Hospital, Belgaum during the period of January 2021 to March 2022”.

Date – source:

Patients aged 18-60 years, of either gender, belonging to American Society of Anesthesiologists (ASA) grade I and II, undergoing infra-umbilical surgery under spinal anaesthesia at KLES Prabhakar Kore Charitable Hospital, Nehru Nagar, Belgaum -10 during the period from January 2021 to March 2022.

Study type:

Randomized controlled trial conducted over a period of one year three months.

Duration of study:

Between a period of January 2021- March 2022- One year three months.

Inclusion Criteria:

- Patients belonging to ASA status I and II
- Age between 18 to 60 years.
- Patients undergoing elective infra-umbilical procedures under spinal anaesthesia.
- Provides consent.
- Patients with height between 150-170 cm.

Exclusion Criteria :

- Patients refusing regional anaesthesia.
- Patients who are unable to give consent.
- Patients with significant liver, kidney or CVS dysfunction.
- Patients with a history of LA allergy.
- Patients in whom spinal and epidural anaesthesia is contraindicated.
- Hemodynamically unstable patients.
- Patients belonging to ASA III or more.

Sample Size Calculation

The minimum sample size formula is

$$n = \frac{(z_\alpha + z_\beta)^2(s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

where z_α denotes the level of significance and z_β denotes the power of the test. For a 5% threshold of significance, z_α =1.96 and for an 80% power of the test, z_β =0.84.

REF: “Evaluation of the effect of epidural volume extension on characteristics of subarachnoid blockade with low dose of hyperbaric bupivacaine for infra-umbilical surgeries.”

$\bar{x}_1$ is the first group’s average (27.55) and $\bar{x}_2$ is the second group’s average (30.62).

s_1 denotes first group’s standard deviation (3.41) and s_2 denotes second group’s standard deviation (4.89).

The sample size achieved with these values is **60**.

There will be two groups of 30 people each.

Methodology:

After approval from the institutional ethics committee and consent from the patients for participating in the study, this randomized clinical trial study was conducted at Charitable Hospital and Medical Research Centre, Jawaharlal Nehru Medical College, Belagavi.

A total of 60 patients undergoing surgery under spinal anesthesia were included in the study.

After having met inclusion and exclusion criteria, patients were randomized based on computer generated randomization table into one of the two groups.

Group A: Patients undergoing elective infra-umbilical procedures under spinal anaesthesia.

Group B: Patients in whom epidural volume extension (EVE) is given along with spinal block.

A thorough pre-anesthetic evaluation will be done on the day before surgery. CBC, RBS, Serum Creatinine will be done for all patients. ECG and X-ray Chest will be done if age > 40 years. Airway assessment and spine examination will be done. On the day of surgery, intravenous access is secured using appropriate size iv cannula and iv fluids is started. Standard monitoring devices are attached before induction of anaesthesia, including NIBP, ECG and pulse oxymeter. With patients in sitting position and under sterile aseptic precaution the back is painted and draped. L3-L4 intervertebral space is identified and 2 ml (10 mg) of hyperbaric bupivacaine is injected through 23 G Quincke's spinal needle (Group A). In Group B patients, after initial sterile painting and draping of the back, first L2-L3 intervertebral space is identified and an 18 G Tuohy's epidural needle is inserted, and the epidural space is verified using the loss of resistance to air approach and epidural catheter is threaded and fixed with 4 cm catheter inside the epidural space. L3-L4 intervertebral space is then identified and 23 G Quincke's spinal needle is inserted and after establishing that CSF is flowing freely, 2 ml (10 mg) of hyperbaric bupivacaine is administered. After performing spinal block, patient is immediately made to lie down supine and 8 ml of 0.9% NS with no preservatives is introduced through the epidural catheter. Vitals are measured every 5 minutes for 1 hour, then every 15 minutes until the procedure is finished. Beginning of the sensory block, height of maximum sensory block, sensory block regression over two segments (min), onset and motor block duration and intraoperative hemodynamic variables will be recorded and compared among the two groups.

Motor block (in minutes) will be assessed using the Modified Bromage Scale.

0 = Capable of moving the hip, knee, and ankle

1 = The hip cannot be moved, although the knee and ankle may

2 = Hip and knee are immobile, however the ankle may move.

3 = Inability to move hip, knee, and ankle

Statistical Analysis :

The research compares two groups. Mean and standard deviation will be computed for continuous quantitative data. The intergroup continuous variables will be compared using appropriate statistical procedures such as the unpaired student t test. The student's paired t test will be used to compare two quantitative variables within a group. The median will be used to represent discrete variables. Discrete variables will be subjected to nonparametric tests. Rates, ratios, and percentages will be used to represent categorical data. The Chi-square test or Fisher's exact test will be used to assess the relationship between the result, clinical, and demographic factors. All tests will be considered significant if the p-value is less than 5% (0.05).

RESULTS

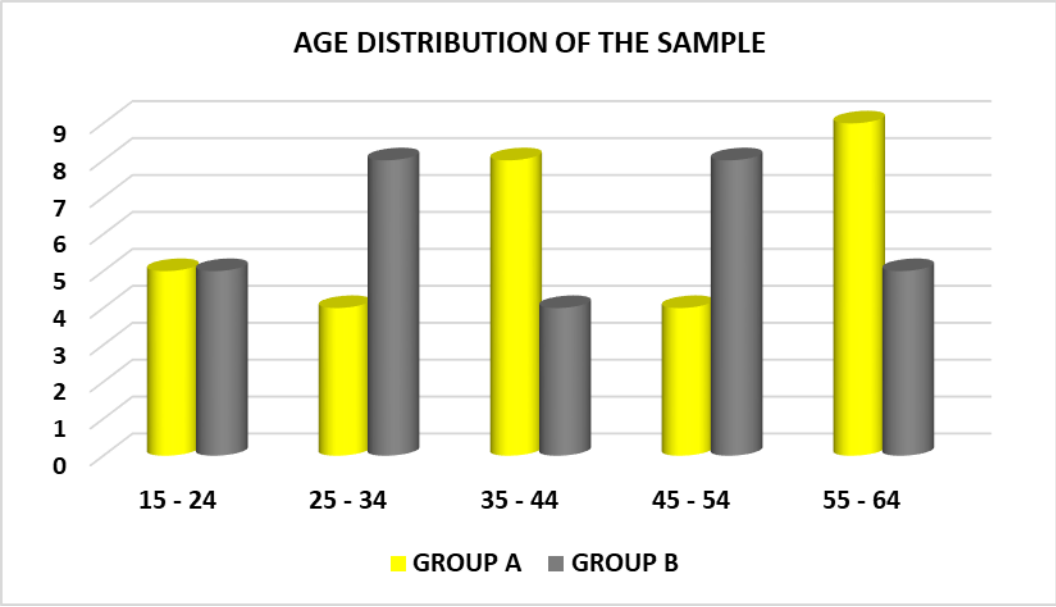
Study titled “Evaluation of the effect of EVE on characteristics of subarachnoid blockade with low dose of hyperbaric bupivacaine for infra-umbilical surgeries” was conducted in Department of Anesthesiology, Jawaharlal Nehru Medical College, KAHER, Belagavi from January 2021 to December 2021. 60 patients enrolled were randomly divided based on computer generalized randomization table into 2 groups of 30 each. This study has been done to note the onset and duration of the sensory block, maximum height of sensory block achieved and onset and duration of the motor blockage in both groups i.e., with and without epidural volume extension and to compare the intraoperative hemodynamic parameters between the two groups.

Tabulation of data was done, mean and standard deviation was calculated for all sets of data.

TABLE-1 AGE DISTRIBUTION:

Study group	Mean+/- SD (Age in years)	P value
A	41.87+/-14.10	0.5771
B	39.90+/-13.04	

In Group A, the average age was 41.87 years and in Group B the average age was 39.90 years. the P value was 0.5771, not significant statistically.

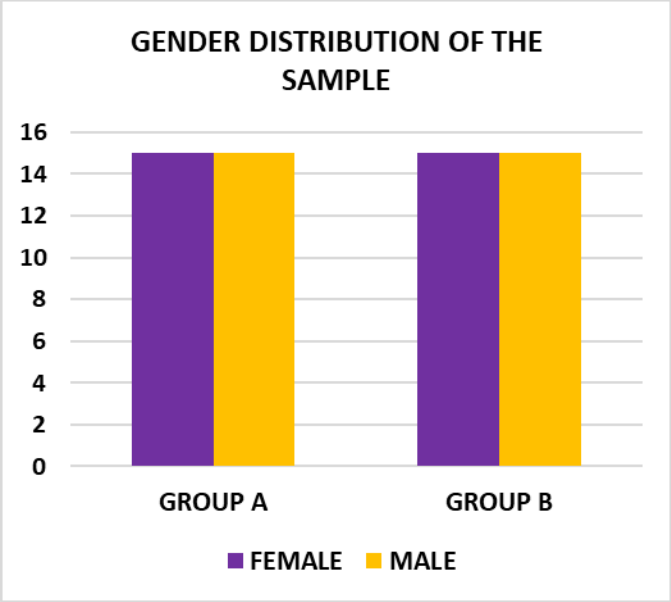


GRAPH -1

TABLE-2 SEX DISTRIBUTION

GENDER	Group A	Group B	P value
Female	15(50%)	11(50%)	0.5
Male	15(50%)	15(50%)	
Total	30	30	

15 females made up both Group A and B, and 15 men made up Group A and B. P-value for gender distribution (0.5) was not significant statistically.



GRAPH -2

TABLE -3 HEIGHT DISTRIBUTION

Study group	MEAN+/-SD (Height in cms)	P value
A	161.23+/-6.06	0.3443
B	159.77+/-5.85	

The mean height across the 2 groups were 161.23 cms and 159.77 cms in Gr A and B, respectively with a non significant P value (0.3443).

TABLE 4- COMPARISON OF ONSET OF SENSORY BLOCKADE (MINUTES) AMONG 2 GROUPS

Study group	Mean (minutes)	S.D.	P- value	Inference
A	2.55	1.07	0.0110	S
B	1.96	0.59		

Mean sensory block onset was 2.55 minutes in Group A and 1.96 minutes in Group B with a significant P value (0.0110).

TABLE 5 – COMPARISON OF TWO SEGMENT REGRESSION (MIN) BETWEEN 2 GROUPS

Study group	Mean (minutes)	S.D.	P value	Inference
A	71.53	12.42	<0.0001	HS
B	86.47	7.10		

In Groups A and B, the average two segment regression was 71.53 minutes and 86.47 minutes, respectively.. The P value (<0.0001) was highly significant.

TABLE 6 – MAXIMUM SENSORY BLOCKADE LEVEL ACHIEVED

	GROUP A		GROUP B	
MAXIMUM LEVEL ACHIEVED BY SENSORY BLOCK	**NUMBER**	**%**	**NUMBER**	**%**
T5	1	3.33	2	6.67
T6	1	3.33	9	30.00
T7	0	0.00	1	3.33
T8	7	23.33	11	36.67
T10	8	26.67	6	20.00
T11	2	6.67	0	0.00
T12	6	20.00	1	3.33
L1	5	16.67	0	0.00
TOTAL	30	100.00	30	100.00

8 participants in Group A has maximum sensory level achieved at T10 dermatome, 7 participants have at T8, 6 at T12, 5 at L1, 2 at T11, followed by 1 each at T5 and T6, respectively and none at T7. Whereas, in Group B, 11 participants show maximum sensory level achieved at T8, 9 at T6, 6 at T10, 2 at T5, 1 each at T7 and T12, respectively and none at T11 and L1.

TABLE 7 – COMPARISON OF ONSET (MINUTES) OF MOTOR BLOCKADE

Study Group	Mean (minutes)	S.D.	P value	Inference
A	4.17	2.23	0.0024	VS
B	2.83	0.63		

The mean onset of motor blockade was 4.17 minutes in Group A and 2.83 minutes in Group B. The P-value (0.0024) was statistically significant.

TABLE 8 – COMPARISON OF DURATION (MIN) OF MOTOR BLOCKADE

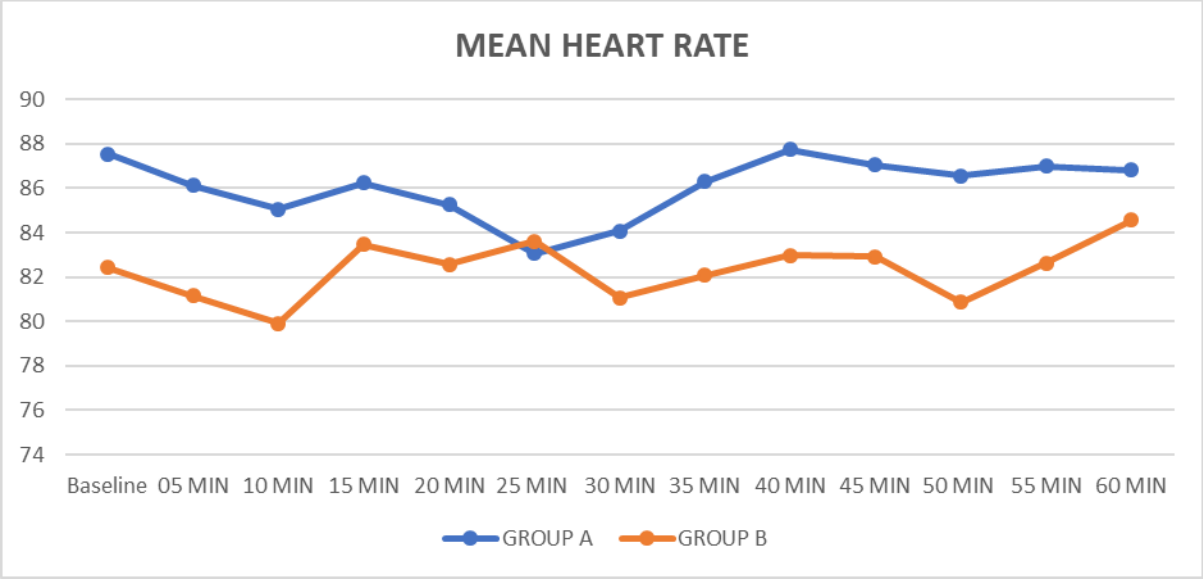
Study Group	Mean (minutes)	S.D.	P value	Inference
A	144.03	40.90	0.7368	NS
B	141.13	23.23		

The motor blockade's average duration in Group A was 144.03 minutes and in Group B was 141.13 minutes. The P-value (0.7368) was not significant.

TABLE 9 – COMPARISON OF HEART RATE BETWEEN GROUP A AND GROUP B

	HEART RATE					
	GROUP A		GROUP B			
TIME	MEAN	S.D.	MEAN	S.D.	p VALUE	INFERENCE
Baseline	87.54	10.63	82.43	10.22	0.0953	NS
05 MIN	86.12	11.64	81.17	9.84	0.0803	NS
10 MIN	85.07	11.41	79.90	10.32	0.0709	NS
15 MIN	86.23	8.18	83.47	10.98	0.2728	NS
20 MIN	85.27	9.40	82.57	10.41	0.2960	NS
25 MIN	83.07	9.24	83.60	9.76	0.8287	NS
30 MIN	84.07	8.37	81.07	17.59	0.4088	NS
35 MIN	86.31	7.81	82.07	11.20	0.1135	NS
40 MIN	87.74	12.05	82.96	11.93	0.1667	NS
45 MIN	87.05	10.37	82.92	12.80	0.2602	NS
50 MIN	86.56	7.32	80.86	11.65	0.0953	NS
55 MIN	87.00	6.19	82.64	12.30	0.2780	NS
60 MIN	86.83	5.88	84.57	6.19	0.5154	NS

The mean value of heart rate between Group A and B when compared were statistically insignificant with a p value > 0.05



GRAPH -3

TABLE 10 – COMPARISON OF SYSTOLIC BLOOD PRESSURE BETWEEN GROUP A AND B

	SYSTOLIC BLOOD PRESSURE					
	GROUP A		GROUP B			
TIME	MEAN	S.D.	MEAN	S.D.	p VALUE	INFERENCE
Baseline	127.41	17.92	123.41	11.86	0.2731	NS
05 MIN	126.33	17.04	121.03	12.52	0.1751	NS
10 MIN	117.63	15.69	113.77	13.23	0.3065	NS
15 MIN	111.73	12.42	110.43	11.46	0.6750	NS
20 MIN	108.93	13.29	107.17	11.33	0.5817	NS
25 MIN	108.13	13.41	105.23	10.51	0.3551	NS
30 MIN	106.21	13.25	105.37	12.27	0.8013	NS
35 MIN	107.19	11.43	104.97	11.95	0.4843	NS
40 MIN	109.82	11.43	107.89	13.05	0.5891	NS
45 MIN	109.89	11.61	107.46	11.15	0.4960	NS
50 MIN	112.67	14.65	107.24	12.07	0.2319	NS
55 MIN	114.83	9.58	109.29	9.04	0.1422	NS
60 MIN	114.17	8.95	110.00	9.50	0.0855	NS

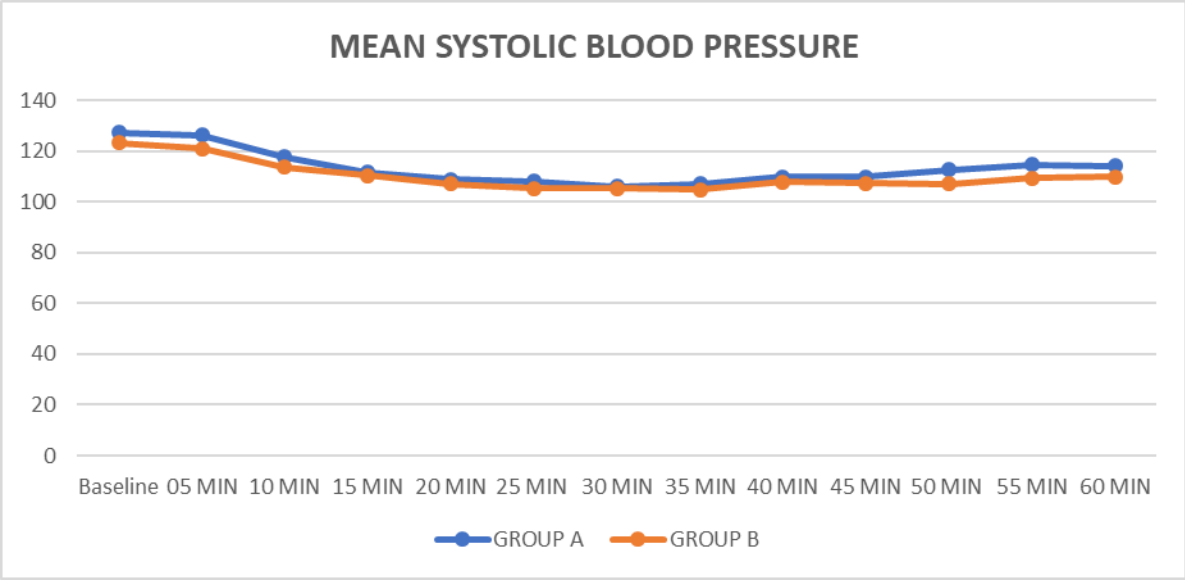
In the above table showing intergroup analysis between Group A and B, the mean systolic blood pressure throughout the intraoperative course when compared was statistically not significant.

TABLE 11- INTRA-GROUP COMPARISON OF SYSTOLIC BLOOD PRESSURE

	GROUP A			
TIME	**MEAN**	**S.D.**	**p VALUE**	**INFERENCE**
BASELINE	123.93	11.53	--	--
05 MIN	126.33	17.04	0.2629	NS
10 MIN	117.63	15.69	0.0411	S
15 MIN	111.73	12.42	0.0241	S
20 MIN	108.93	13.29	0.0171	S
25 MIN	108.13	13.41	0.0381	S
30 MIN	106.21	13.25	0.0251	S
35 MIN	107.19	11.43	0.0421	S
40 MIN	109.82	11.43	0.0061	S
45 MIN	109.89	11.61	0.0171	S
50 MIN	112.67	14.65	0.0480	S
55 MIN	114.83	9.58	0.0475	S
60 MIN	114.17	8.95	0.0328	S

	GROUP B			
TIME	**MEAN**	**S.D.**	**p VALUE**	**INFERENCE**
BASELINE	119.37	10.02	--	--
05 MIN	121.03	12.52	0.2858	NS
10 MIN	113.77	13.23	0.0351	S
15 MIN	110.43	11.46	0.0011	S
20 MIN	107.17	11.33	0.0471	S
25 MIN	105.23	10.51	0.0371	S
30 MIN	105.37	12.27	0.0251	S
35 MIN	104.97	11.95	0.0101	S
40 MIN	107.89	13.05	0.0463	S
45 MIN	107.46	11.15	0.0381	S
50 MIN	107.24	12.07	0.0283	S
55 MIN	109.29	9.04	0.0302	S
60 MIN	110.00	9.50	0.0315	S

The above tables showing intragroup analysis of SBP for Group A and B, fall in systolic blood pressure is significant after 10 min of induction till 60min intraoperatively in both the groups.



GRAPH -4

TABLE 12 – COMPARISON OF DIASTOLIC BLOOD PRESSURE BETWEEN GROUP A AND B

	DIASTOLIC BLOOD PRESSURE					
	GROUP A		GROUP B			
TIME	MEAN	S.D.	MEAN	S.D.	p VALUE	INFERENCE
Baseline	80.02	12.1	77.31	12.36	0.3771	NS
05 MIN	79.07	11.58	76.13	11.24	0.3236	NS
10 MIN	74.27	13.06	71.13	8.42	0.2739	NS
15 MIN	72.03	11.71	70.33	8.66	0.5252	NS
20 MIN	71.27	11.52	67.20	8.78	0.1294	NS
25 MIN	70.80	10.45	67.10	7.96	0.1282	NS
30 MIN	71.18	9.83	69.07	8.91	0.3944	NS
35 MIN	72.19	9.69	70.17	9.17	0.1042	NS
40 MIN	72.91	10.10	68.04	8.56	0.0739	NS
45 MIN	70.89	10.91	68.75	7.19	0.0879	NS
50 MIN	71.20	12.33	69.48	7.87	0.0821	NS
55 MIN	78.58	6.29	68.79	6.64	0.0608	NS
60 MIN	77.00	4.51	68.86	9.55	0.0639	NS

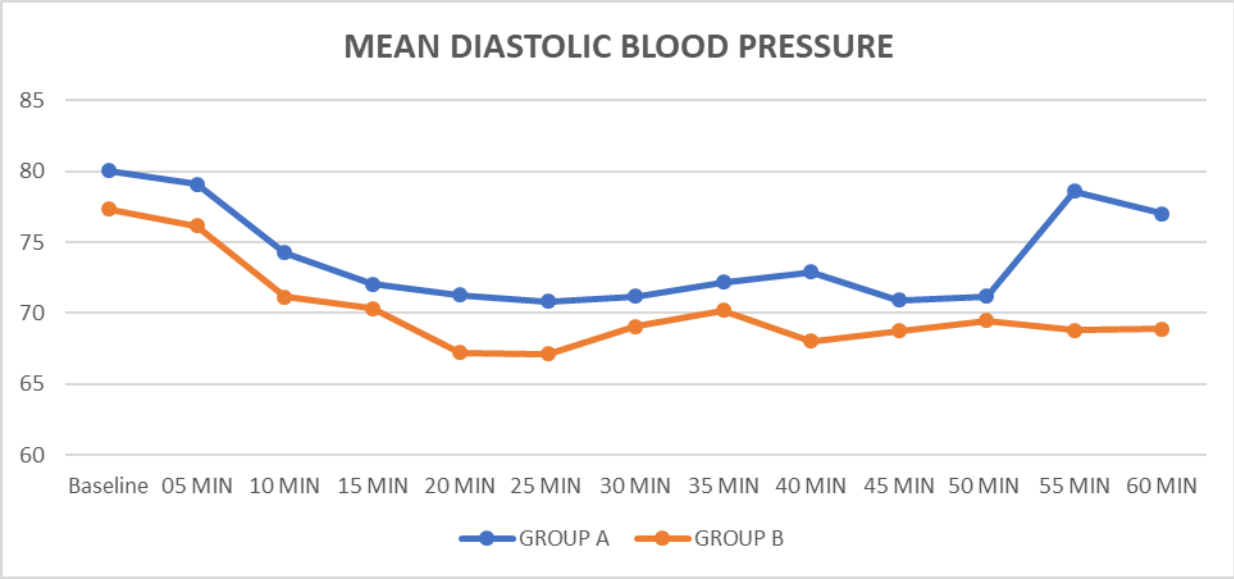
In the above table showing intergroup analysis between Group A and B, the comparison of mean diastolic blood pressure throughout the intraoperative course was proven to be statistically unreliable.

TABLE 13- INTRA-GROUP COMPARISON OF DIASTOLIC BLOOD PRESSURE

	GROUP A			
TIME	**MEAN**	**S.D.**	**p VALUE**	**INFERENCE**
BASELINE	77.97	7.58	--	--
05 MIN	79.07	11.58	0.3326	NS
10 MIN	74.27	13.06	0.0930	NS
15 MIN	72.03	11.71	0.0120	S
20 MIN	71.27	11.52	0.0052	S
25 MIN	70.80	10.45	0.0018	S
30 MIN	71.18	9.83	0.0025	S
35 MIN	72.19	9.69	0.0575	NS
40 MIN	72.91	10.10	0.0678	NS
45 MIN	70.89	10.91	0.2414	NS
50 MIN	71.20	12.33	0.2175	NS
55 MIN	78.58	6.29	0.3947	NS
60 MIN	77.00	4.51	0.0936	NS

	GROUP B			
TIME	**MEAN**	**S.D.**	**p VALUE**	**INFERENCE**
BASELINE	75.30	8.00	--	--
05 MIN	76.13	11.24	0.3710	NS
10 MIN	71.13	8.42	0.0571	NS
15 MIN	70.33	8.66	0.0123	S
20 MIN	67.20	8.78	0.0012	S
25 MIN	67.10	7.96	0.0012	S
30 MIN	69.07	8.91	0.0030	S
35 MIN	70.17	9.17	0.0615	NS
40 MIN	68.04	8.56	0.0677	NS
45 MIN	68.75	7.19	0.0742	NS
50 MIN	69.48	7.87	0.1987	NS
55 MIN	68.79	6.64	0.2140	NS
60 MIN	68.86	9.55	0.0681	NS

The above tables show intragroup analysis of DBP for Group A and B. Fall in diastolic blood pressure is significant after 15 minute of induction till 30minute intraoperatively in both the groups.

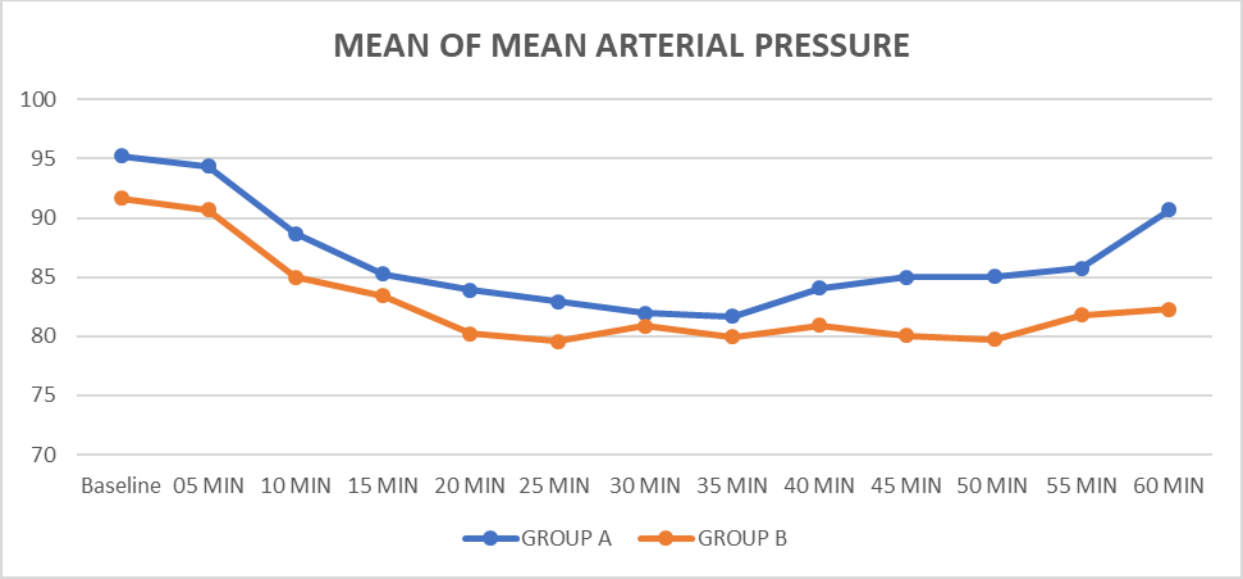


GRAPH -5

TABLE 14 – COMPARISON OF MEAN ARTERIAL PRESSURE AMONG 2 GROUPS

	MEAN ARTERIAL PRESSURE					
	GROUP A		GROUP B			
TIME	MEAN	S.D.	MEAN	S.D.	p VALUE	INFERENCE
Baseline	95.23	12.24	91.64	10.91	0.2792	NS
05 MIN	94.37	12.09	90.70	10.79	0.2203	NS
10 MIN	88.70	11.49	85.00	8.97	0.1696	NS
15 MIN	85.27	10.35	83.43	8.65	0.4596	NS
20 MIN	83.90	9.45	80.20	8.70	0.1201	NS
25 MIN	82.93	8.21	79.57	7.47	0.1022	NS
30 MIN	81.96	7.22	80.87	9.06	0.6136	NS
35 MIN	81.69	6.96	79.97	8.69	0.4365	NS
40 MIN	84.09	7.99	80.93	8.93	0.2023	NS
45 MIN	85.00	8.54	80.04	7.49	0.0525	NS
50 MIN	85.06+	10.61	79.71	8.17	0.0611	NS
55 MIN	85.75	6.22	81.79	6.72	0.0744	NS
60 MIN	90.67	3.93	82.29	8.92	0.0757	NS

In the above table showing intergroup analysis between Group A and B, the comparison of mean arterial pressure throughout the intraoperative course was found to be statistically insignificant.



GRAPH -6

TABLE 15- DURATION OF SURGERY

DURATION OF SURGERY					
GROUP A		GROUP B			
MEAN	S.D.	MEAN	S.D.	p VALUE	INFERENCE
47.33	11.80	44.00	11.33	0.2689	NS

In the above table, the mean duration of surgery for Group A was 47.33 minutes and Group B was 44 minutes with a p value of 0.2689- not significant.

OXYGEN SATURATION

SpO_2 was maintained in all patients with all patients maintaining SpO_2 between 97% - 100%

DISCUSSION

Epidural volume extension (EVE) technique is a unique regional anesthesia technique that provides the advantages of epidural anesthesia, as well as the reliability, density and speed of spinal anesthesia. In addition, the degree of sympathectomy associated with spinal anesthesia can be reduced. The degree of hemodynamic impairment is low as the dose of the drug used in the epidural volume extension technique is small, while avoiding the negative aspects of general anesthesia in patients at high risk of heart disease by averting the negative inotropic effect of anesthetic agents as well as the detrimental effect on venous return due to Positive pressure ventilation.[43]

This is a prospective randomized controlled trial where 60 individuals between 18 to 60 years who underwent non emergency infra-umbilical surgeries under SAB with and without EVE with normal saline were divided randomly into two groups. This study was done to note the onset and duration of sensory blockade, maximum level of sensory block achieved, the onset and duration of motor blockade and to compare the intraoperative hemodynamic parameters between the two study groups.

In comparison to SAB, EVE with normal saline following SAB using a low dose of local anesthetic in a CSE technique has been shown to provide a higher level of sensory blockade as well as rapid motor recovery.

The current study assessed the efficiency of EVE with normal saline immediately after low intrathecal dosage of hyperbaric bupivacaine in comparison to spinal anaesthesia alone.

After comparing the effects of different patient positions on the outcomes of EVE, Tyagi A et al[15] came to the conclusion that if EVE is being used to achieve a rapid extension of sensory block after intrathecal administration of heavy bupivacaine, the CSE block ought to be executed in a lateral position rather than a sitting position which was attributed to a restricted spread of LA to lumbar and sacral roots and inability to spread cephalad the caudally gathered intrathecal bupivacaine, thereby causing EVE to fail in sitting position. In our study, we made the patient lie down supine immediately after intrathecal bupivacaine administration and patient immediately received sterile saline within the epidural space allowing for a successful EVE as shown by a noticeably higher level of sensory block achieved.

Mardirosoff et al[44] demonstrated that in order for intrathecal injection with EVE to have effect, the patient should be placed in a supine position within five minutes after subarachnoid block. If epidural saline administration was delayed by 10 minutes, failure was common. It's ineffectiveness when carried out 20 minutes after intrathecal injection was demonstrated by Trautman et al.[45] Therefore, we made the patient lie down supine immediately after intrathecal bupivacaine administration and patient immediately received EVE to allow for a successful epidural volume extension.

The two groups in our research were comparable for all of the demographic factors (age, gender).

Gocke et al.[46] observed that an epidural injection of 8-10ml saline shortly after intrathecal bupivacaine administration increased the cephalad extent of the sensory block, indicating that the epidural volume effect may be responsible for the extension of sensory block. In our research, the amount of saline used for EVE was set at 8 ml, maximum sensory level achieved was T5 (2 patients) with maximum patients (11) achieving level of T8. In spinal anesthesia alone group maximum patients (8) achieved level of T10. From this we can safely draw the conclusion that EVE with normal saline of 8 ml is sufficient to produce higher sensory block than plain spinal alone.

Regression of the sensory block over two segments in Group B took noticeably longer than in Group A, on an average, by a difference of 14.94 minutes compared to Group A. The difference is substantial (p-value <0.05).

We can safely draw the conclusion from this study that using subarachnoid blockade in conjunction with an epidural volume extension results in anesthesia that works well and lasts a long time.

Salman et al[47] and Lew et al.[48] arrived to the conclusion that the group with EVE showed prompt development of sensory and motor block, heightening of the sensory block, and two-segment regression time extension, corroborating the findings of our study.

Kaur et al.,[12] demonstrated a faster recovery of the lower limb motor function following elective c-section using EVE with 10ml normal saline because of deliberate use of a small intrathecal dose of local anesthetic. The mean difference in motor blockage duration in our investigation was 2.9 minutes, which was statistically insignificant (p-value=0.7368).

According to Loubert et al.[49] and Beale et al.,[50] EVE was unable to increase the height of sensory block, which is in opposition to the results of our investigation.

Hemodynamic parameters did not differ significantly with regard to the two groups, highlighting the safety of the EVE technique. Howewer, intra-group

analysis showed there is a significant alteration in blood pressure among the two groups which can possibly limits the use of this technique in elderly with an already compromised cardiovascular system. Our study does not concur with the findings of the research conducted by Almeida CR et al[51] in 2022, that showed that under a low-dose spinal block of 5 mg levobupivacaine and 15 mcg fentanyl combined with saline EVE, hemodynamic instability can be limited which in turn can benefit high risk cardiac patients.

In this study we used 0.5% sensorcaine heavy for spinal anesthesia. Effect of EVE on low-dose spinal anesthesia with 0.5% levobupivacaine as well as isobaric bupivacaine can also be studied in the future.

Limitations of the study are that accidental migration of the epidural catheter into the intrathecal and intravascular space is possible. Also, this technique may not be feasible for emergency surgeries especially emergency LSCS.

CONCLUSION

It is possible to draw the conclusion that a low dose of intrathecal hyperbaric bupivacaine (10 mg) combined with an EVE (8 ml normal saline) causes early onset and prolonged duration of sensory block, early onset but similar duration of motor block with similar change in hemodynamic parameters as compared with subarachnoid block alone.

SUMMARY

The present study entitled "**EVALUATION OF THE EFFECT OF EVE ON CHARACTERISTICS OF SUBARACHNOID BLOCKADE WITH LOW DOSE OF HYPERBARIC BUPIVACAINE FOR INFRA-UMBILICAL SURGERIES: A ONE YEAR RANDOMIZED CLINICAL TRIAL**" was conducted at Charitable Hospital and Medical Research Centre, Jawaharlal Nehru Medical College, Belagavi.

After approval from the institutional ethics committee and consent from the patients and having met inclusion and exclusion criteria, a total of 60 patients of ASA I and II between age group 18-60 years undergoing surgery under spinal anesthesia were included in this study.

The aim of this study was to determine sensory blockade's onset and duration, maximum level of sensory block achieved and onset and duration of motor blockade in both groups, i.e., with and without EVE and to compare the intraoperative hemodynamic parameters between the two groups.

This study showed that a low dose of intrathecal hyperbaric bupivacaine (10 mg) combined with an EVE (8 ml normal saline) causes sensory and motor block to appear early, a significant sensory blockage and an expedited two segment regression while keeping the hemodynamic equilibrium.

There is a need for further studies in future involving a larger sample size to determine the effect of EVE on characteristics of SAB with low dose of heavy

bupivacaine for infra-umbilical surgeries and the effect of EVE on low-dose spinal anesthesia with 0.5% levobupivacaine as well as isobaric bupivacaine can also be studied.

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ANNEXURE I

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr. /Mrs. /Miss. _____ we are requesting you to enroll you in the study titled **"EVALUATION OF THE EFFECT OF EPIDURAL VOLUME EXTENSION ON CHARACTERISTICS OF SUBARACHNOID BLOCKADE WITH LOW DOSE OF HYPERBARIC BUPIVACAINE FOR INFRAUMBILICAL SURGERIES": A ONE YEAR RANDOMIZED CLINICAL TRAIL** conducted in the Department of Anesthesiology, J.N. Medical College, Belagavi under KAHER, Belagavi.

Respected Sir/Madam, we request you to participate in our study as you are eligible for it. During the study you will be asked some questions regarding your medical history and you are supposed to answer to the best of your knowledge.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N.Medical College. If you decide to participate you are free to withdraw at any time.

Purpose of the study: The purpose of research is to study the effect of epidural volume extension by normal saline on spinal blockade and its sensory, motor and hemodynamic characteristics with low dose of hyperbaric bupivacaine for infraumbilical surgeries.

Procedure Involved: If you agree to enroll in my study, I will ask you present, past and family history. Then you will be clinically examined in detail. You will be allotted into one of the two groups randomly using computer generated software. Group A will be anaesthetized using spinal block. Group B will get epidural volume extension by normal saline with spinal block.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll yourself in this study. Your decision will not change any health care services offered to you or your ward at K.L.E. S Hospital & MRC.

Risks:

There is almost no risk involved with spinal block with epidural volume extension.

Benefits: Epidural volume extension with normal saline in patients undergoing spinal anaesthesia extends the block height by a mechanical volume effect and increases the regression time thus prolonging the duration of action of block while maintaining hemodynamic stability due to decreased dose of intrathecal local anaesthetic.

Privacy and Confidentiality:

The only people to know that you are as research subject are you and members of the research team. No information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with your identity remaining confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES Hospital and MRC, Belagavi. There is no compensation or payment for such medical treatment by law. If you get injured you may contact **REG NO. BA0120017** at Department of Anesthesiology, J.N. Medical College.

Questions:

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact **REG NO. BA0120017**, Department of Anesthesiology, J.N. Medical College, Belagavi. If you have any queries about your rights as a study subject, you may call Dr. Harsha Hegde, Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number-0831-2473777, J.N. Medical College, Belagavi.

CONSENT STATEMENT TO PARTICIPATE IN RESEARCH STUDY

"EVALUATION OF THE EFFECT OF EPIDURAL VOLUME EXTENSION ON CHARACTERISTICS OF SUBARACHNOID BLOCKADE WITH LOW DOSE OF HYPERBARIC BUPIVACAINE FOR INFRAUMBILICAL SURGERIES": A ONE YEAR RANDOMIZED CLINICAL TRAIL.

I Mr./Mrs.---------- voluntarily agree for the participation as a subject for the study. By signing this consent form I am not giving up any of my legal right. I may withdraw from the study any time. I am signing the consent form after having read or been read to me in my vernacular language, including the risk and the benefits and having all my queries cleared.

Name of study patient:

Signature or the left thumb impression:

Name and signature of witness:

Name and signature of investigator:

Date: ---------- Place: ----------

ANNEXURE II – Ethical clearance

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 66 **Date: 25/01/2021**

To,
Reg. No. BA0120017
PG student in Anaesthesiology,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"EVALUATION OF THE EFFECT OF EPIDURAL VOLUME EXTENSION ON CHARACTERISTICS OF SUBARACHANOID BLOCKADE WITH LOW DOSE OF HYPERBARIC BUPIVACAINE FOR INFRAUMBILICAL SURGERIES" : A ONE YEAR RANDOMIZED CLINICAL TRIAL,** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Smita Sonoli)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Harsha Hegde)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

55

ANNEXURE III – PROFORMA

"EVALUATION OF THE EFFECT OF EPIDURAL VOLUME EXTENSION ON CHARACTERISTICS OF SUBARACHNOID BLOCKADE WITH LOW DOSE OF HYPERBARIC BUPIVACAINE FOR INFRAUMBILICAL SURGERIES": A ONE YEAR RANDOMIZED CLINICAL TRAIL.

Group allotted :

Name	:	Age	:
Gender	:	Weight	:
Height	:	Date of surgery	:
Address	:	Occupation	:

Pre examination evaluation

Past History

- HTN ☐ DM ☐ IHD ☐ Arrhythmia ☐ Valvular heart diseases ☐

- H/o previous surgery/(s) where airway difficulty was encountered. Yes ☐ No ☐

General physical examination

Weight (Kg)	:	Temperature (^{0}F)	:	Pallor	:
Cyanosis	:	Pedal edema	:	Clubbing	:
PR	:	BP	:	RR	:

Systemic examination:

RS : CNS :

CVS : GIT :

Preoperative physical status ASA Grade I ☐ II ☐

Airway assessment:

Spine:

Investigations:

Hb(gm/dl): TLC:

Platelet count: Renal profile:

ECG: CXR:

METHODOLOGY:

After obtaining the approval of ethical committee and written informed consent, a total of 60 patients undergoing surgery under spinal anesthesia will be included in the study.

After having met inclusion and exclusion criteria and having obtained informed consent, patients will be randomised based on computer generated randomization table into one of the two groups.

Group A: Patients undergoing elective infraumbilical surgery under spinal anaesthesia.

Group B: Patients in whom epidural volume extension is given along with spinal block.

A through pre-anesthetic evaluation will be done on the day before surgery.

On the day of surgery, intravenous access is secured using appropriate size iv cannula and iv fluids is started.

Standard monitoring devices are attached before induction of anesthesia, including non-invasive arterial blood pressure, heart rate, ECG and oxygen saturation.

with patients in sitting position and under sterile aseptic precaution the back of them is painted and draped. L3-L4 intervertebral space is identified and 2 ml (10 mg) of hyperbaric bupivacaine is introduced through 23 G Quincke's spinal needle (Group A).
In Group B patients, after initial sterile painting and draping of the back, first L2-L3 intervertebral space is identified and an epidural tap is performed using 18 G Tuohy's needle and 4 cm catheter is threaded in epidural space. After performing spinal block, patients are immediately made to lie down supine and 8 ml of preservative free 0.9% normal saline is introduced through the epidural catheter.

Vitals are measured every 5 min for 1 h and then every 15 min towards the end of surgery.

The onset and duration of sensory blockade, maximum level of sensory block achieved, onset and duration of motor block and intraoperative hemodynamic parameters are evaluated and compared between the two groups.

SENSORY BLOCK:

Onset of sensory blockade (minutes)	
Maximum level achieved	
Two-segment regression (minutes)	

MOTOR BLOCK:

Onset for motor blockade (minutes)	
Duration of motor blockade (minutes)	

VITALS (After giving spinal anaesthesia):

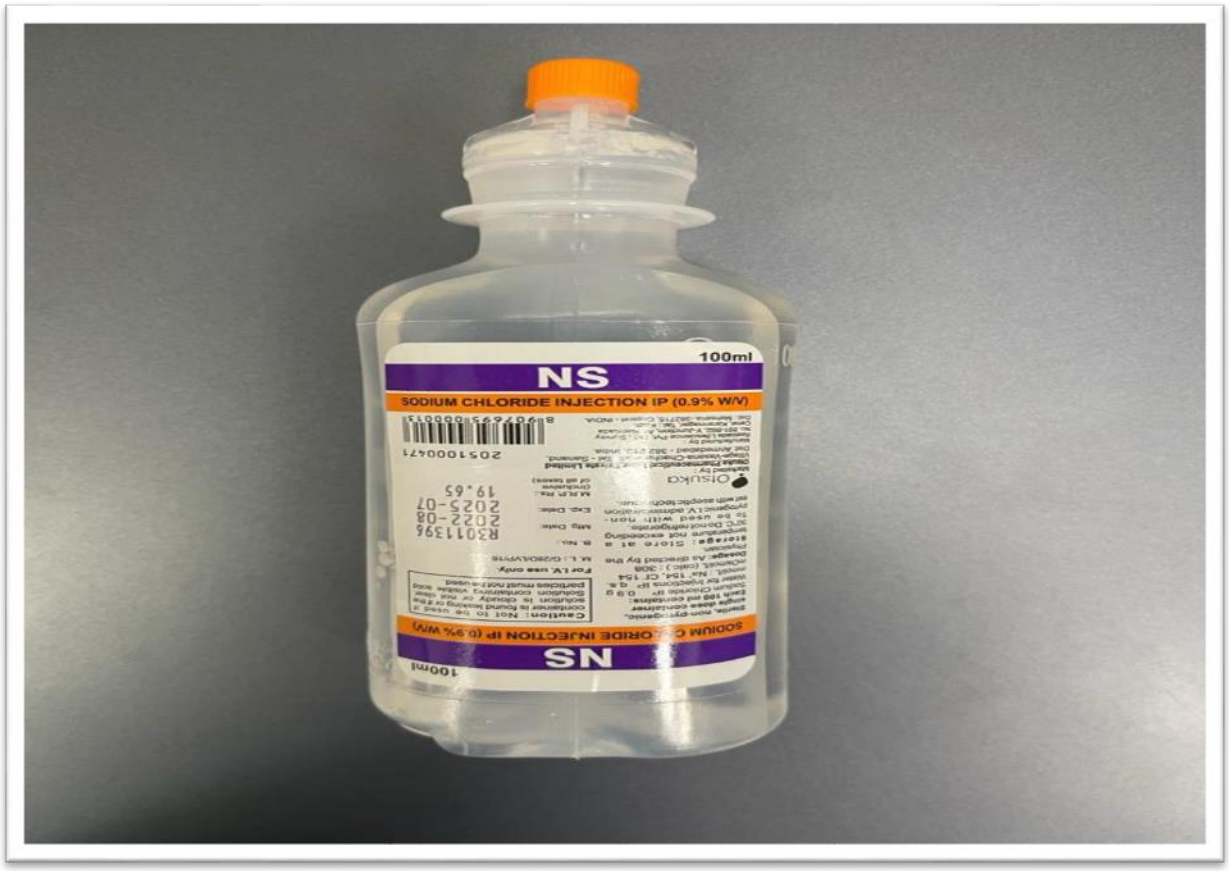
Time	BP	HR
5 minutes		
10 minutes		
15 minutes		
20 minutes		
25 minutes		
30 minutes		
35 minutes		
40 minutes		
45 minutes		
50 minutes		
60 minutes		

Subsequently, towards the end of the surgery vitals will be monitored every 15 minutes.

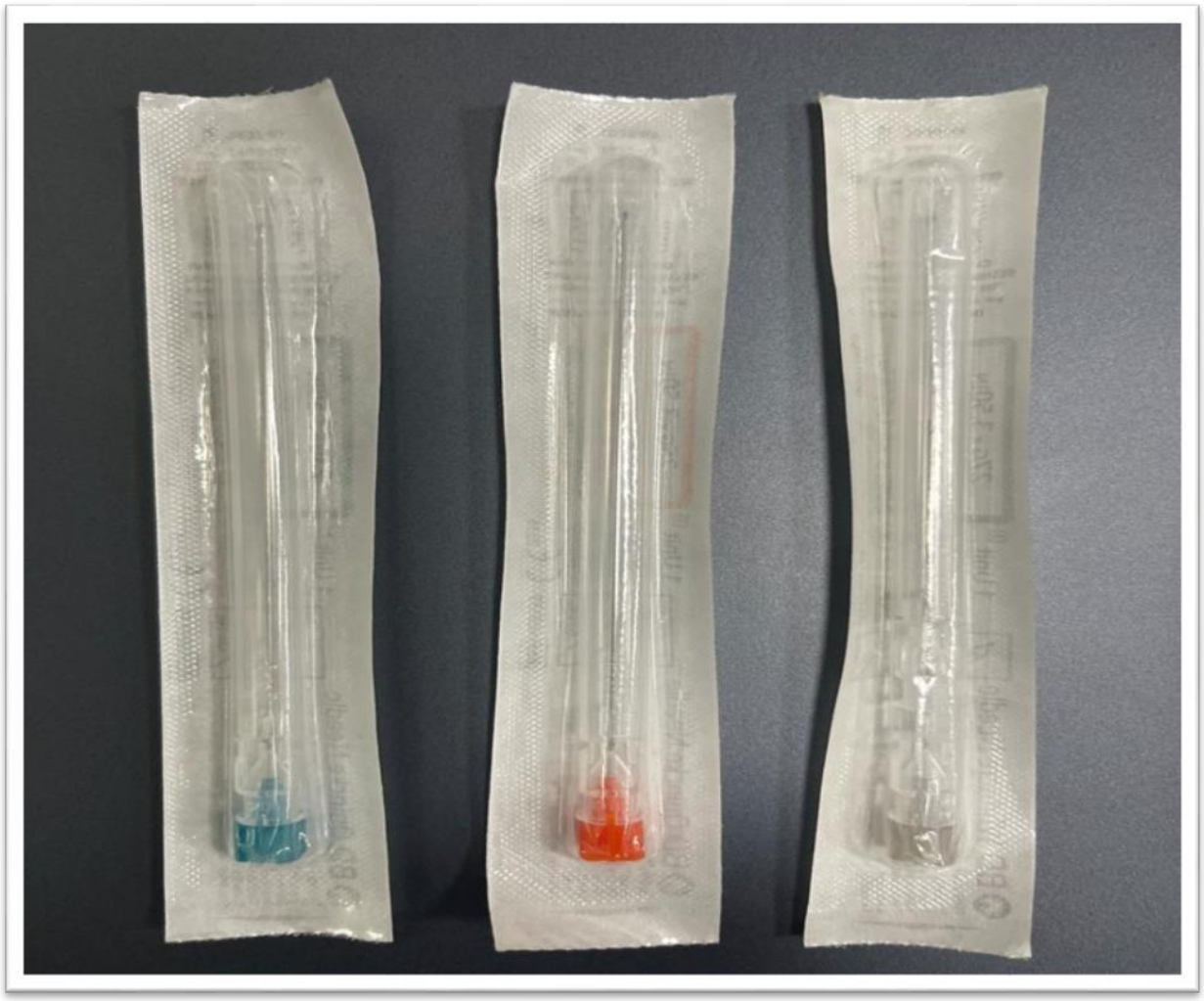
ANNEXURE IV

Photographs

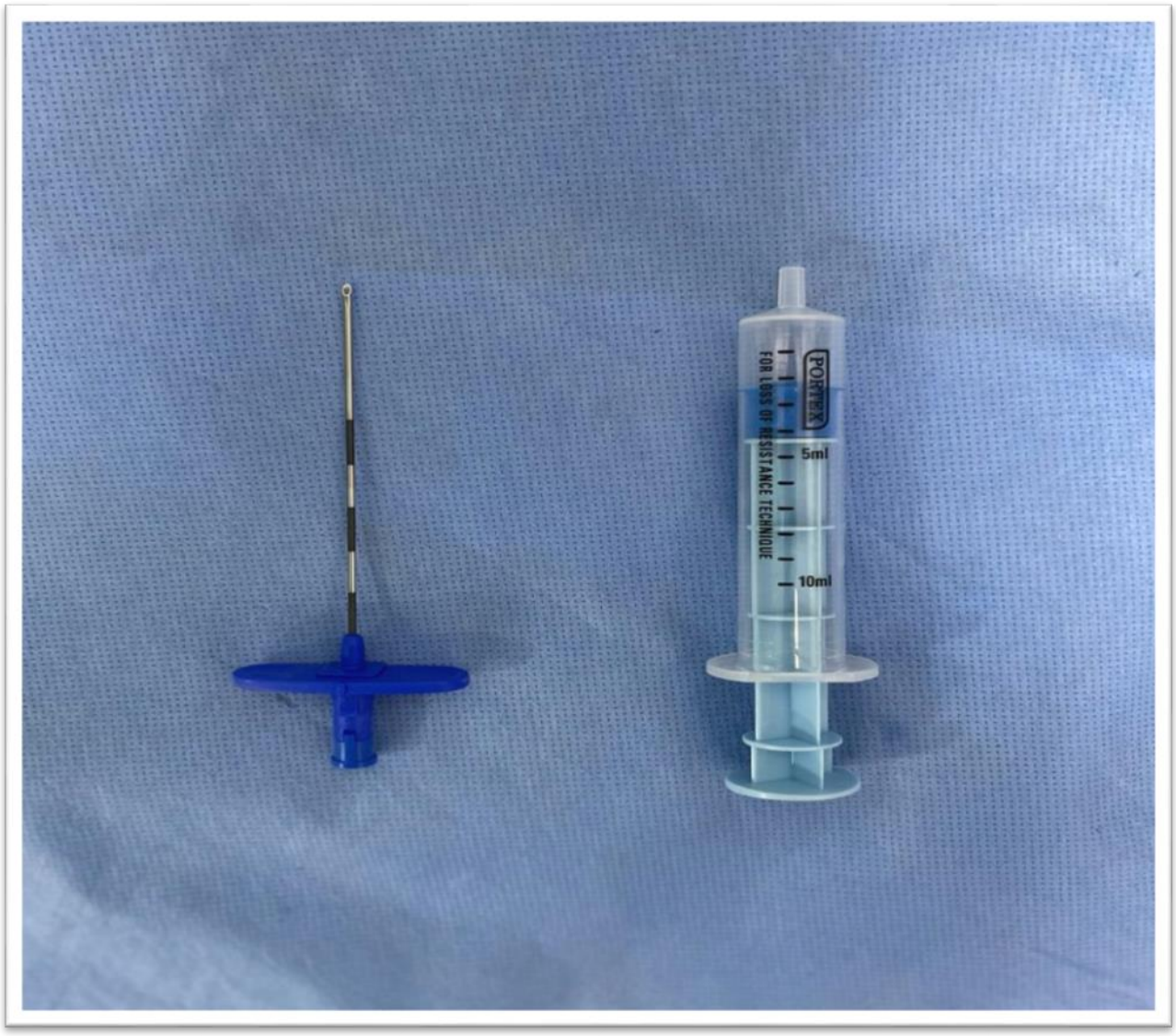
PHOTOGRAPH 1: HYPERBARIC 0.5% BUPIVACAINE AMPOULE



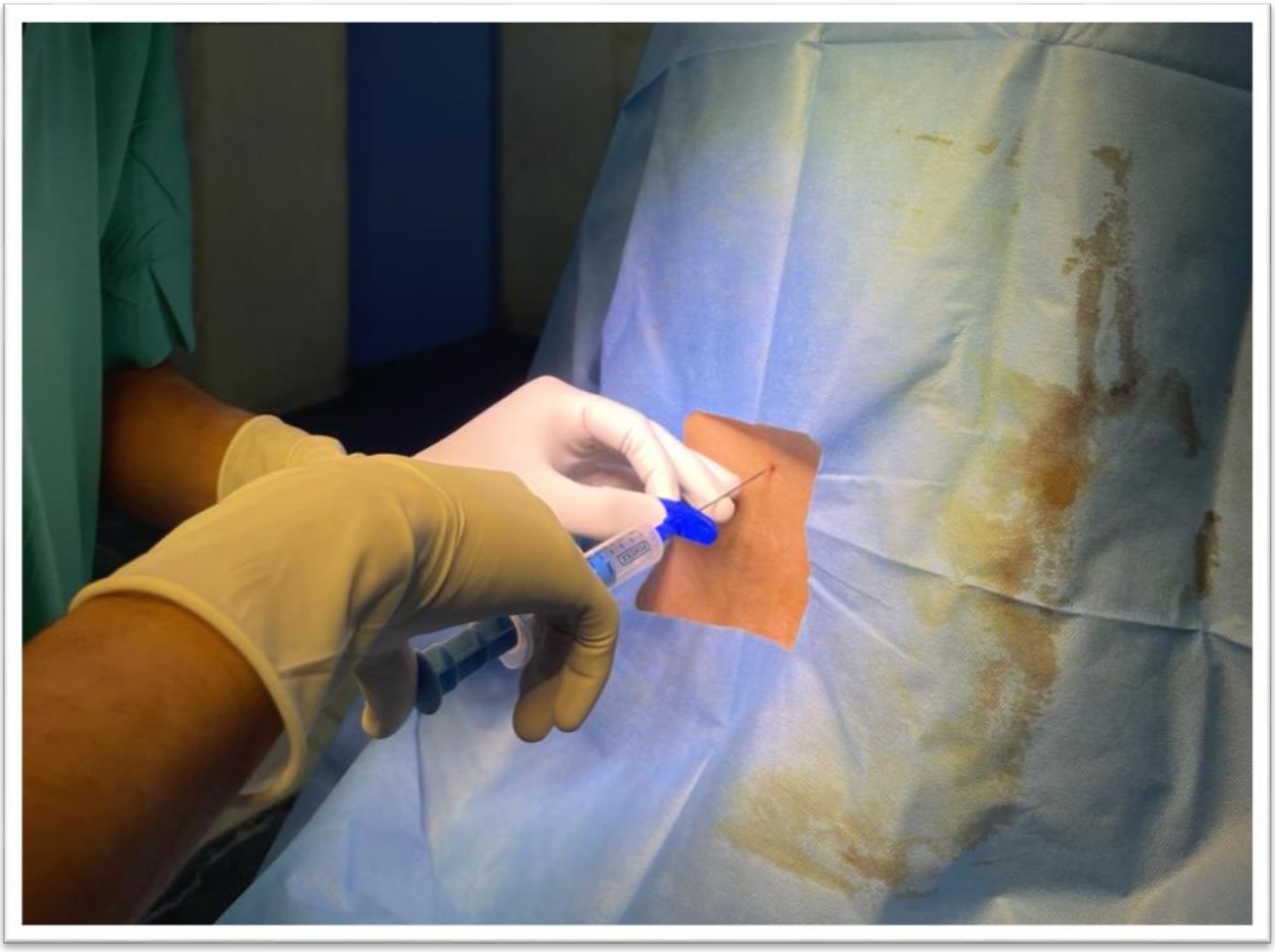
PHOTOGRAPH 2: NORMAL SALINE



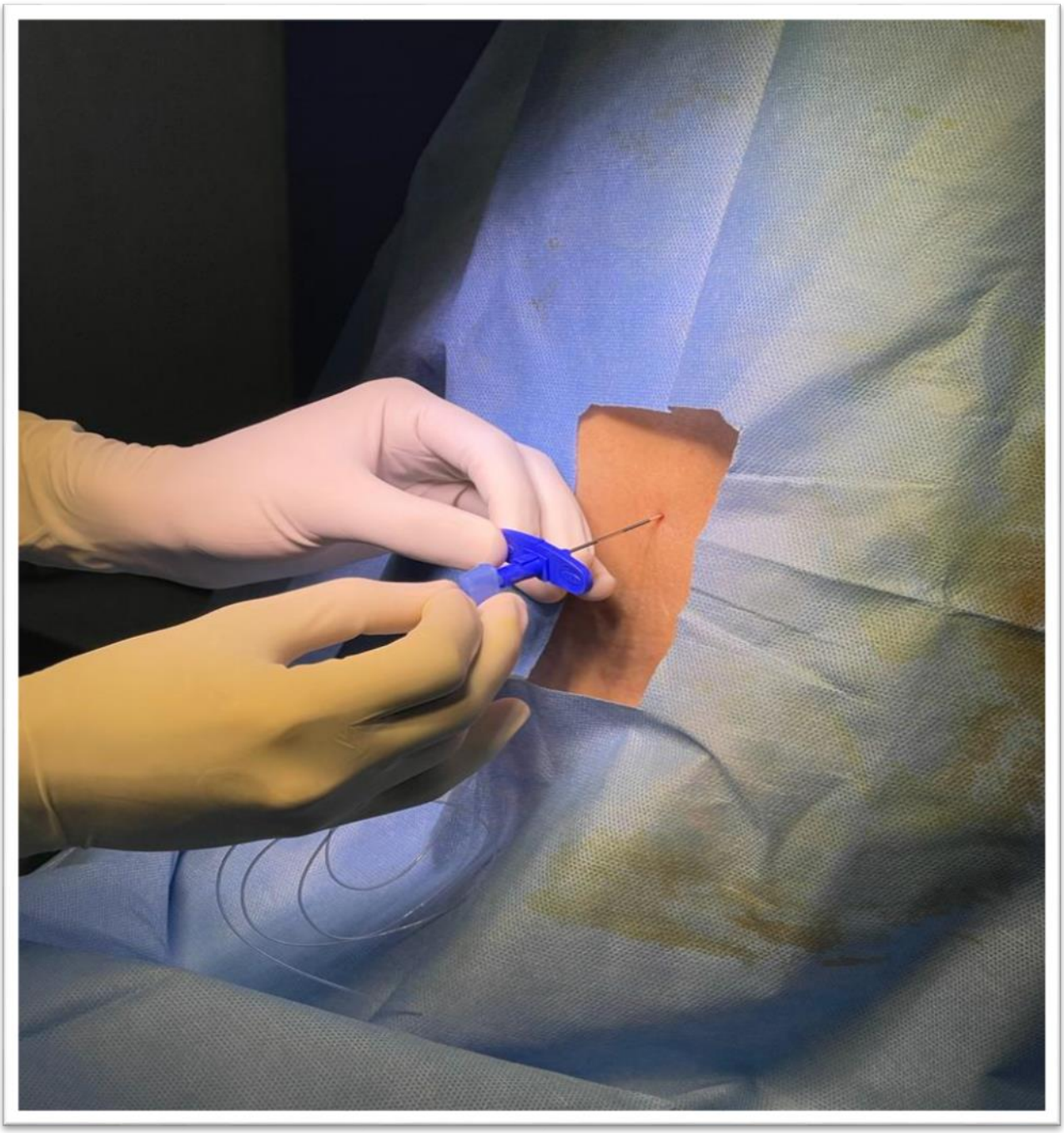
PHOTOGRAPH 3: SPINAL NEEDLES



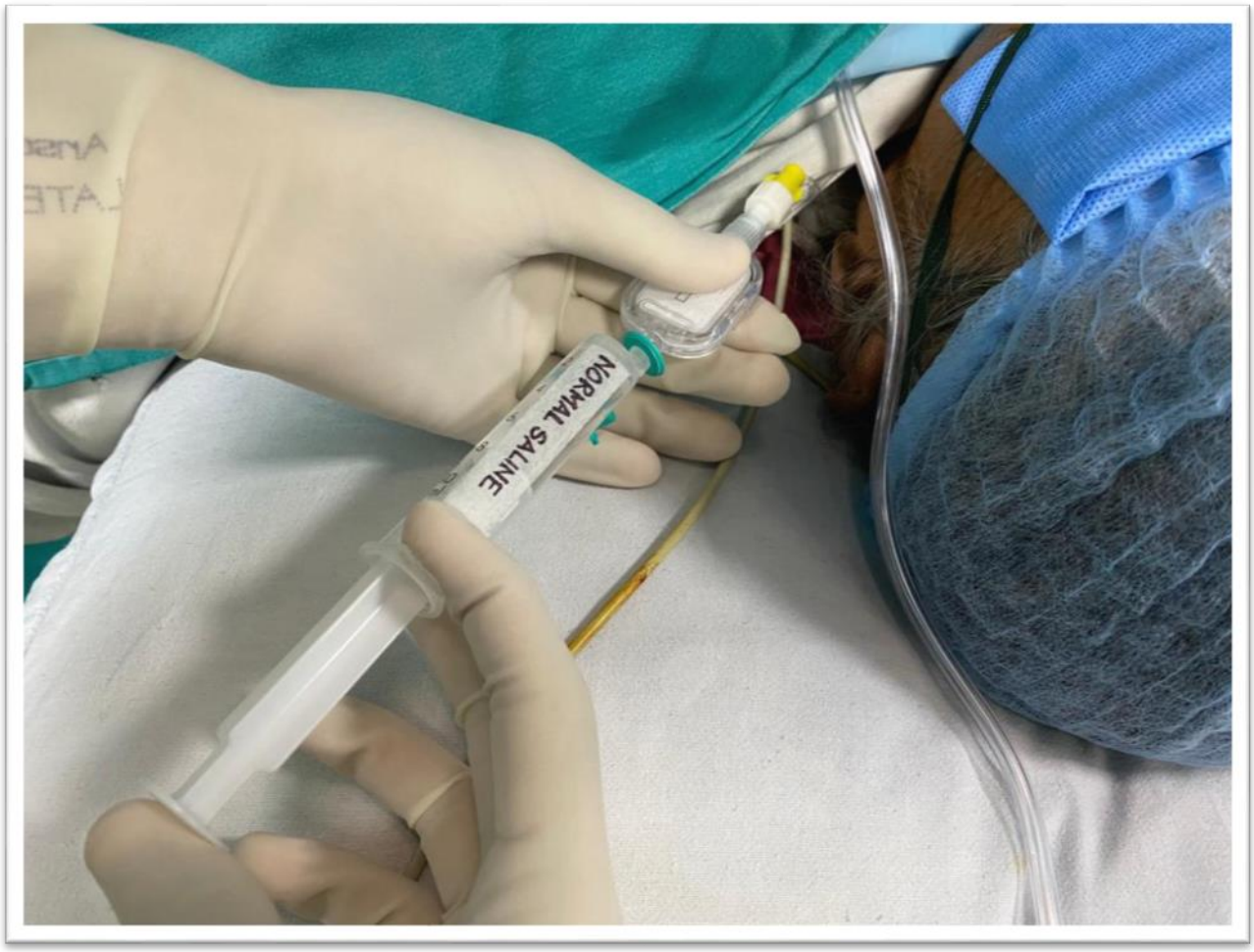
PHOTOGRAPH 4: TUOHY NEEDLE AND LOR SYRINGE



PHOTOGRAPH 5: LOSS OF RESISTANCE TO AIR TECHNIQUE



PHOTOGRAPH 6: THREADING OF EPIDURAL CATHETER INTO EPIDURAL SPACE



PHOTOGRAPH 7: EPIDURAL VOLUME EXTENSION WITH NORMAL SALINE

ANNEXURE V

Key to Master chart:

M : Male

F : Female

Kg : Kilogram

BP : Blood Pressure

ASA : American society of Anesthesiologists (Grades I – IV)

HR : Heart Rate

RR : Respiratory Rate

SBP : Systolic Blood Pressure

DBP : Diastolic Blood Pressure

GROUP A

				Baseline Data						sensory block			motar blockade		HEART RATE												
Sl no.	IP Number	Age	ASA	Height (cms)	Weight (Kgs)	HR (bpm)	SBP (mm Hg)	DBP (mm Hg)	Respiratory rate (BPM)	Onset of sensory blockade (min)	Maximum level achieved	Two-segment regression (min)	onset (min)	Duration (min)	05 MIN	10 MIN	15 MIN	20 MIN	25 MIN	30 MIN	35 MIN	40 MIN	45 MIN	50 MIN	55 MIN	60 MIN	75 MIN	90 MIN
1	1056035	60/F	2	152	68	92	132	78	13	2	T12	85	3.1	93	88	89	83	84	80	82	81	80	78	84				
2	1056254	22/F	1	160	70	74	126	74	12	5	T10	90	10	110	84	83	80	81	82	78	79	80	81	80				
3	1054156	36/M	1	153	76	80	120	72	12	2.7	T10	72	3	190	93	80	78	82	84	88	94	122						
4	1058528	41/M	1	160	66	74	110	70	12	2	T12	66	3	180	84	86	82	82	82	84	88	86	79	82	80			
5	1049198	28/F	1	167	68	72	120	80	14	1.5	T10	76	2.5	95	88	90	94	78	68	69	84	75						
6	1050095	58/F	2	161	94	75	130	80	15	2.5	L1	30	4	40	93	95	95	96	93	92	91	91	90	99	92	94		
7	1060002	55/M	1	168	75	88	130	70	14	2	T8	72	7	87	102	94	86	75	63	65	67	75	77	75				
8	1044406	57/F	2	170	55	76	110	87	16	3.1	T12	66	5	105	93	92	94	91	84	85	87	86						
9	1050805	35/M	1	159	63	78	134	82	14	2.8	T8	72	3.2	190	85	80	82	83	87	80	89	86	83	78	88	82		
10	1049984	32/F	2	164	52	73	128	77	15	5	T10	81	6	125	93	92	94	91	84	85	87	86	90	89	86			
11	1059277	35/F	1	166	50	89	119	72	14	1.5	T8	70	2.5	190	87	83	83	78	89	78	89	92	99					
12	1043713	51/M	2	157	68	77	130	88	15	4	T6	85	7	167	91	87	84	87	83	84	85	88	82	82	80	83	82	
13	1050834	60/M	2	156	92	89	130	89	18	0.5	T5	85	1	145	109	89	79	75	72	73	71							
14	1054974	43/M	2	150	76	87	134	82	16	1.6	T11	55	3	162	92	93	88	96	94	100	98	92	94	88	87	92		
15	1047222	43/F	1	163	50	78	110	72	15	2.5	T11	65	3.2	183	110	108	100	105	96	98	95	90	92	93	98			
16	1059439	45/M	1	168	82	70	123	87	16	2	L1	86	2.6	158	78	76	80	79	84	86	80	83	90					
17	1059204	44/F	1	169	55	73	123	76	15	1.9	T12	68	2.5	170	88	84	87	84	83	83	90	88	86	87	85			
18	1058948	51/M	1	154	80	89	113	69	17	2.5	T8	68	3.5	190	86	86	88	84	80	79	82	86	81	85	82	80		
19	1055500	65/F	2	170	68	80	110	60	15	2.3	T8	70	3.3	190	92	88	94	94	87	88	93	90	91	89	86			
20	1051954	20/F	1	161	48	88	110	80	16	1.5	T8	72	2	158	92	90	94	94	94	90	93	96						
21	1049297	40/M	2	152	78	87	130	70	15	2.1	T10	73	3.4	180	86	86	83	78	81	79	86	85	85	80	82			
22	1065294	60/M	1	168	84	78	114	82	17	2.2	L1	81	2.5	150	87	89	92	89	90	91	93							
23	1059765	30/F	2	163	76	87	120	70	16	3.1	T8	60	6	150	63	60	90	87	3	87	80	60	70					
24	1049542	60/F	2	157	89	87	136	87	18	2	T10	72	3.5	178	89	87	80	89	90	92	95	88	87	93	98	90		
25	1050460	46/M	2	153	86	90	128	79	17	2	T12	66	3	175	92	96	90	94	89	94	93							
26	1060350	21/F	1	163	52	60	100	70	16	2	T10	70	3.4	110	59	54	61	54	56	74	74	113	119	101				
27	1054883	58/M	2	170	77	89	117	78	16	3.5	L1	50	7	90	70	76	75	80	78	75								
28	1053745	57/F	1	159	68	93	148	90	18	5	L1	70	10	90	90	87	81	90	82	84								
29	1055053	28/F	1	163	45	100	133	78	17	3	T10	80	6	120	104	99	100	96	97	95								
30	1083035	21/M	1	161	71	120	150	90	15	2.7	T12	90	3	150	110	113	90	82	77									

SYSTOLIC BLOOD PRESSURE														DIASTOLIC BLOOD PRESSURE														MEAN ARTERIAL PRESSURE													
05 MIN	10 MIN	15 MIN	20 MIN	25 MIN	30 MIN	35 MIN	40 MIN	45 MIN	50 MIN	55 MIN	60 MIN	75 MIN	90 MIN	5 MIN	10 MIN	15 MIN	20 MIN	25 MIN	30 MIN	35 MIN	40 MIN	45 MIN	50 MIN	55 MIN	60 MIN	75 MIN	90 MIN	5 MIN	10 MIN	15 MIN	20 MIN	25 MIN	30 MIN	35 MIN	40 MIN	45 MIN	50 MIN	55 MIN	60 MIN	75 MIN	90 MIN
140	108	106	103	99	100	98	99	96	88					82	74	64	64	60	56	58	60	52	50					93	87	88	83	85	80	77	76	73	70				
120	116	110	104	96	100	99	95	101	96					70	66	62	56	53	53	55	53	56	58					96	94	90	93	89	83	80	78	79	76				
120	110	98	100	96	98	98	98							70	68	66	68	66	70	70	70							87	82	77	79	76	79	79	79						
130	124	110	100	110	98	100	98	100	100	105				85	80	76	74	76	80	74	76	80	74	76	79	82	80	100	95	87	83	87	86	83	83	86	88	88			
118	128	121	118	116	132	118	122							68	55	62	61	61	65	67	66							70	69	74	73	73	76	77	77						
127	115	117	129	131	124	120	117	112	112	110	120			81	78	74	74	79	79	77	76	76	78	73	78			86	84	92	88	90	88	82	88	85	86	77	89		
120	100	104	97	100	103	105								80	70	66	80	82	84	80								92	80	78	86	88	90	88							
131	127	132	135	126	133	133	129							86	92	90	93	85	90	89	86							100	98	94	96	92	102	100	100						
130	126	111	115	107	101	99	103	120	118	118	120			82	77	75	76	75	72	70	73	78	78	78	82			98	93	87	89	86	82	80	83	92	91	91	95		
140	136	133	131	127	132	135	126	133	133	129				99	98	89	86	92	90	93	85	90	89	86				110	105	95	100	98	94	96	92	102	100	100			
130	115	117	109	101	97	100	103	105						90	87	90	87	83	80	82	84	80						103	96	99	94	89	86	88	90	88					
167	150	130	123	121	131	116	126	124	126	131	140	150		75	72	70	71	67	69	71	60	68	64	74	76	80		106	98	97	82	80	81	89	67	80	73	96	98	100	
97	83	84	93	95	88	94								74	60	58	61	64	62	67								78	68	67	64	73	67	76							
130	130	110	98	96	100	98	100	100	105	110	120			90	88	84	78	74	76	78	80	80	83	85	90			103	102	93	85	81	84	85	87	87	90	93	100		
130	125	110	115	110	98	99	100	96	100	100				70	72	70	66	62	60	64	68	67	69	70				90	90	83	82	78	73	76	79	77	79	80			
140	133	115	100	115	105	110	110	115						90	87	83	76	78	73	77	77	80						107	102	94	84	90	84	88	88	92					
136	115	110	115	103	97	100	102	108	115	115				102	91	87	91	83	79	81	83	87	91	92				102	91	87	91	83	79	81	83	87	91	92			
130	119	107	99	94	93	97	100	102	110	107	115			89	85	81	76	72	73	76	76	80	78	80	82			103	96	90	84	79	80	83	84	87	89	89	93		
130	123	117	109	101	99	102	106	104	110	112				86	85	80	75	73	70	70	75	73	76	77				101	98	92	86	82	80	81	85	83	87	89			
112	107	103	100	105	99	106	110							82	77	78	73	76	77	80	78							92	87	86	82	86	84	89	89						
140	133	117	105	110	107	103	110	108	120	125				78	73	71	68	70	72	70	68	70	73	74				99	93	86	80	83	84	81	82	83	89	91			
104	96	100	99	95	101	96								56	53	53	55	53	56	58								93	89	83	80	78	79	76							
104	95	89	85	103	103	114	119	111						63	55	53	44	53	0	92	52	90						77	68	65	58	70	68	98	74	98					
130	130	123	117	111	108	110	111	108	112	116	118			89	85	83	78	72	68	71	71	67	70	78	80			103	100	96	91	85	81	84	84	81	84	91	93		
134	127	115	105	108	110	112								92	89	85	86	82	80	80	80							106	102	95	92	91	90	91							
99	100	97	97	97	98	125	132	135	145					60	59	58	57	57	65	79	87	91	97					73	73	71	70	70	76	94	102	106	113				
83	84	93	95	88	94									60	58	61	64	62	67									68	67	64	73	67	76						
147	116	122	115	116	125									74	52	51	58	62	57									112	85	67	88	72	83						
124	126	131	140	150										68	64	74	76	80										80	73	96	98	100							
147	132	120	117	117										81	78	67	66	72										103	96	85	83	87							

GROUP B

				Baseline Data						sensory block			motor blockade		HEART RATE													SYSTOLIC BLOOD PRESSURE												
Sl no.	IP Number	Age	ASA	Height (cms)	Weight (Kgs)	HR (bpm)	SBP (mm Hg)	DBP (mm Hg)	Respiratory rate (BPM)	Onset of sensory blockade (min)	Maximum level achieved	Time taken for regression (min)	onset (min)	Duration (min)	05 MIN	10 MIN	15 MIN	20 MIN	25 MIN	30 MIN	35 MIN	40 MIN	45 MIN	50 MIN	55 MIN	60 MIN	75 MIN	90 MIN	05 MIN	10 MIN	15 MIN	20 MIN	25 MIN	30 MIN	35 MIN	40 MIN	45 MIN	50 MIN	55 MIN	60 MIN	75 MIN	90 MIN
1	1081087	32/F	1	163	55	86	120	70	12	1.5	T6	100	2.3	115	102	92	90	91	93	94	92	91	93	80	81	81	80	74	132	129	116	118	116	135	135	133	129	127	124	121	124	122
2	1001236	29/M	1	158	65	70	130	76	12	1.5	T10	90	2.5	140	61	51	50	5249	57	53	52	52	57	54					108	101	115	114	113	113	110	117	106	105			
3	1056421	40/M	1	167	76	90	110	80	16	2	T8	96	3	150	99	94	90	81	81	81	82	80	76	78	67				123	88	113	111	113	112	108	105	110	110	111			
4	1080318	50/M	1	153	74	78	120	77	17	1	T6	90	2	105	79	76	78	74	63	63	62	62	54	55	54				133	120	122	116	119	123	122	136	125	122	121			
5	1086888	50/F	1	163	63	85	113	73	15	1	T5	88	2	90	72	65	110	73	70	63	60	61	65	66	71	75	68	63	150	140	133	119	113	110	113	115	116	119	102	121	136	130
6	1085563	60/M	2	159	73	89	130	72	16	1.1	T8	93	2.1	100	76	78	79	73	81	79	67	74	67	75					130	125	101	89	85	90	95	96	100	103				
7	1047999	60/M	1	155	72	78	110	70	15	1.8	T6	78	2.2	118	84	85	86	78	84	82	80	86							118	115	110	107	103	108	110	115						
8	1061642	29/M	1	168	70	66	110	65	14	2.3	T8	100	3.2	172	87	85	84	89	79	83	87	90	91	89	91				130	127	121	115	120	123	118	120	125	126	120			
9	1061372	31/F	1	151	69	83	116	71	17	2.5	T7	86	3	148	76	78	83	82	90	89	88	92	93	95	91				130	125	122	126	118	120	111	116	107	103	110			
10	1059930	58/M	1	158	81	75	114	77	15	1.9	T6	74	2.8	150	63	60	90	87	83	87	80	60	70	74	78				104	95	89	85	103	103	114	119	111	103	120			
11	1083113	24/F	1	162	75	85	113	65	15	2.1	T10	86	2.5	167	95	97	99	94	89	87	89	93	95	96	100				110	106	100	105	104	100	99	95	97	93	98			
12	1019582	41/F	1	163	73	89	120	72	15	1.4	T8	87	2.1	160	90	93	94	95	99	94	91	89	93						125	111	119	105	107	100	98	106	103					
13	1021428	22/F	1	166	45	72	105	63	16	1.1	T6	90	2.5	150	78	79	76	73	79	6	70								105	100	99	91	88	90	90							
14	1021300	23/F	1	157	47	79	111	70	15	1	T8	78	2	138	83	85	83	85	90	93	88	93	84						110	107	100	97	91	95	96	99	100					
15	1020540	48/F	2	153	83	89	132	85	16	2.1	T10	83	2.7	159	90	92	98	94	91	85	79	91	85	84					140	137	125	128	110	99	110	104	111	100				
16	1026987	50/M	2	158	89	89	130	90	16	2	T8	86	3.5	119	90	89	91	92	97	87	79	83							138	133	128	126	112	110	117	100						
17	1027544	55/F	2	163	63	74	113	73	18	2.6	T8	87	3	162	79	73	71	79	74	73	82	81	83	84					117	109	105	99	93	96	95	91	100	103				
18	1026983	26/F	1	168	52	70	103	65	15	2.1	T6	75	3.1	107	69	74	79	71	83	82	79								104	100	94	97	99	88	90							
19	1027492	38/M	1	150	72	82	119	78	15	2.5	T8	85	2.8	153	90	93	91	98	89	84	89	82	90	89	94	93			119	111	109	108	109	100	110	105	107	101	103	102		
20	1027542	32/F	1	160	58	68	110	70	16	1.4	T6	90	2.7	160	79	76	74	73	79	86	89	84	83	82					110	110	104	98	91	88	87	86	82	80				
21	1028295	21/M	1	158	64	78	107	69	13	2.5	T10	78	2.6	119	79	76	79	78	81	82	84	84	85	81	85	81			120	116	108	105	101	94	91	97	104	100	99	100		
22	1028450	51/F	2	170	69	85	133	93	16	1.8	T8	79	3	154	87	89	85	82	90	95	99	98	101	94					130	115	104	100	110	106	99	107	111	106				
23	1028576	63/M	1	151	79	78	126	81	14	2.8	T12	79	4	116	89	82	88	96	94	91	99	95	87	89					115	100	95	93	80	85	79	83	88	95				
24	1028706	50/F	2	167	85	89	143	92	16	2.7	T6	92	3.4	148	88	81	85	93	94	97	92	94							143	133	129	117	111	118	104	109						
25	1028612	53/M	1	161	78	87	123	86	15	2.1	T5	88	2.5	141	76	75	79	73	76	80	81	83	80						117	105	109	98	110	111	108	109	111					
26	1029562	33/F	1	163	75	79	126	76	17	1.8	T10	77	2.4	139	78	76	79	95	83	79									109	105	100	108	99	95								
27	1036341	37/F	1	167	64	76	109	70	16	2.3	T8	86	3	169	67	76	68	73	72	79	78	75	74	76	78	84			109	104	106	100	109	111	107	98	98	99	98	100		
28	1038421	35/F	1	153	58	85	129	75	15	3	T6	88	4.3	171	75	78	89	84	89	98	79	87	98	87	87	90			115	116	122	120	109	119	15	125	117	120	111	116		
29	1048455	31/M	1	155	72	69	126	72	17	2.2	T8	86	4.1	165	76	76	72	79	85	82	89	87	89	78	93				109	104	100	111	104	108	117	109	118	120	108			
30	1057475	50/F	2	153	75	80	130	83	15	2.8	T10	99	3.7	149	78	73	84	90	93	98	94	93	97	92	87	88			128	126	115	109	117	111	106	118	103	117	105	110		

DIASTOLIC BLOOD PRESSURE														MEAN ARTERIAL PRESSURE													
5 MIN	10 MIN	15 MIN	20 MIN	25 MIN	30 MIN	35 MIN	40 MIN	45 MIN	50 MIN	55 MIN	60 MIN	75 MIN	90 MIN	5 MIN	10 MIN	15 MIN	20 MIN	25 MIN	30 MIN	35 MIN	40 MIN	45 MIN	50 MIN	55 MIN	60 MIN	75 MIN	90 MIN
79	75	76	70	76	84	86	81	82	77	81	78	81	89	96	93	89	86	89	101	102	98	97	93	95	92	95	100
62	63	76	82	80	78	83	82	61	57					77	75	89	92	91	89	92	93	76	73	0			
64	71	63	66	69	67	61	62	62	64	70				83	76	79	81	83	82	76	76	78	79	83	0	0	0
110	75	70	63	67	72	75	69	66	69	69				117	90	87	80	84	89	90	91	85	86	86	0	0	0
94	84	82	72	67	64	61	66	74	79	62	75	57	80	112	102	99	87	82	79	78	82	88	92	75	90	83	96
78	75	70	69	68	67	70	65	63	61					95	91	80	75	73	74	78	75	75	75	0	0	0	0
80	75	73	71	69	70	72	74							92	88	85	83	80	82	84	87	0	0	0	0	0	0
70	67	67	64	66	65	62	65	66	63	67				90	87	85	81	84	84	80	83	85	84	84	0	0	0
90	87	85	84	81	78	74	73	76	77	78				103	99	97	98	93	92	86	87	86	85	88	0	0	0
63	55	53	54	50	73	76	79	80	77	76				76	68	65	64	67	83	88	92	90	85	90	0	0	0
70	67	66	65	70	71	68	69	70	65	64				83	80	77	78	81	80	78	77	79	74	75	0	0	0
78	71	69	67	68	71	70	69	66						93	84	85	79	81	80	79	81	78	0	0	0	0	0
70	71	69	66	63	67	70								81	80	79	74	71	74	76	0	0	0	0	0	0	0
70	65	68	66	61	73	62	63	64						83	79	78	76	71	80	73	75	76	0	0	0	0	0
87	81	70	74	74	72	71	73	73	71					104	99	88	92	86	81	84	83	85	80	0	0	0	0
89	81	83	83	76	71	64	65							105	98	98	97	88	84	81	76	0	0	0	0	0	0
76	72	70	68	69	78	69	63	64	62					89	84	81	78	77	84	77	72	76	75	0	0	0	0
65	60	58	50	55	51	55								78	73	70	65	69	63	66	0	0	0	0	0	0	0
68	60	55	56	51	56	52	53	59	60	59	53			85	77	73	73	70	70	71	70	75	73	73	69	0	0
67	60	68	55	57	50	52	57	51	53					81	76	80	69	68	62	63	66	61	62	0	0	0	0
68	61	63	57	55	49	52	53	59	60	59	58			85	79	78	73	70	64	65	67	74	73	72	72	0	0
94	88	84	79	74	70	60	65	64	58					106	97	90	86	86	82	73	79	79	74	0	0	0	0
65	67	61	56	65	61	66	57	65	62					81	78	72	68	70	69	70	65	72	73	0	0	0	0
87	81	89	79	70	81	84	89							105	98	102	91	83	93	90	95	0	0	0	0	0	0
68	67	61	59	58	63	67	63	61						84	79	77	72	75	79	80	78	77	0	0	0	0	0
75	72	69	64	69	70									86	83	79	78	79	78	0	0	0	0	0	0	0	0
78	72	76	69	76	69	72	71	62	61	69	70			88	82	86	79	87	83	83	80	74	73	78	80	0	0
76	78	72	68	69	81	79	74	72	78	67	73			89	90	88	85	82	93	57	91	87	92	81	87	0	0
73	68	71	69	71	76	73	69	73	71	69				85	80	80	83	82	86	87	82	88	87	82	0	0	0
70	65	73	71	69	74	71	68	69	71	73	75			89	85	87	83	85	86	82	84	80	86	83	86	0	0