"A STUDY TO TEST THE EFFICACY AND SAFETY OF PRE PROCEDURE ULTRASOUND GUIDED PARAMEDIAN TECHNIQUE AS COMPARED TO CONVENTIONAL LANDMARK GUIDED PARAMEDIAN TECHNIQUE IN ADMINISTERING SPINAL ANESTHESIA"

By

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In partial fulfilment of the requirements for the award of the degree of

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IN

ANAESTHESIOLOGY

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ABSTRACT

A STUDY TO TEST THE EFFICACY AND SAFETY OF PRE PROCEDURE ULTRASOUND GUIDED PARAMEDIAN TECHNIQUE AS COMPARED TO CONVENTIONAL LANDMARK GUIDED PARAMEDIAN TECHNIQUE IN ADMINISTERING SPINAL ANESTHESIA

Background and Aims:

Regional anaesthesia is a very widely used safe anaesthetic technique for elective as well emergency surgeries. It is given through different approaches, namely: 1. Midline; 2. Paramedian;
3. Taylor. Also it is practiced through the conventional landmark guided approach or the more modern ultrasound approach.

In the quest for a more efficacious way of practising spinal anaesthesia , here we compare both the conventional and USG guided methods and see for ourselves how the two hold up against each other through various parameters.

OBJECTIVES OF STUDY:

1. To compare the number of needle passes between the two groups
2. To compare the number of needle attempts between the two groups
3. To compare the first pass success rate and the first attempt success rate in both groups.
4. To compare the occurrence of blood in spinal needles between the two groups.

METHODS:

A randomized comparative study of one and a half years duration, based on ASA grade 1 and 2 types of patients undergoing lower limb, lower abdominal and pelvic surgeries of age groups 50 and above. The patients were randomized into two groups of 40 patients each either receiving paramedian spinal anaesthesia either

through landmark guided or through USG guided technique. Number of needle passes, needle attempts, first pass success rates, failures and complications were compared between both the groups.

RESULTS:

The mean number of passes is 2.6 in USG group v/s 3.7 in LM group [p value = 0.021], the mean number of attempts was 1.41 in LM group v/s 2.6 in USG group. The complications were 7.5% in USG group v/s 37.5% in LM group and the failure rates were 0% in USG group v/s 25% in LM group. Both the groups were comparable in respect to age, gender, height and weight criterias.

CONCLUSION:

USG guided group showed superior results but the availability of the USG machine is a huge deterrent. In places where its available, it is usually a better option. But it involves a specific skill set that takes time to master. Landmark guided paramedian technique is an easier method to master and doesn't require any expensive investment like an USG machine.

LIST OF ABBREVATIONS USED

US	:	Ultrasound
CSE	:	Combined Spinal Epidural
IV	:	Intravenous
RA	:	Regional Anaesthesia
GA	:	General Anaesthesia
LSCS	:	Lower Segment Caeserian Section
MRI	:	Magnetic Resonance Imaging
PS view	:	Paramedian Sagittal
PSO view	:	Paramedian Sagittal Oblique
ASA	:	American Society of Anaesthesiologists
CT	:	Computerised Tomography

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INTRODUCTION

Neuraxial anaesthesia (spinal and epidural anaesthesia) is one of the most regularly used regional anaesthesia techniques in modern anaesthesia. It's been widely utilised to make lower-limb, pelvic, and lower-abdominal surgery easier. Any innovation in clinical research aimed at improving the safety, efficiency, and efficacy of neuraxial procedures will have an impact on millios of patients.

When compared to general anaesthesia, neuraxial anaesthesia and analgesia has a number of advantages, including superior analgesia[1], lower overall morbidity and mortality. (up to 30% in all types of surgery and up to 11% in patients undergoing high-risk non-cardiac surgery)[2]–[4], reduction in postoperative respiratory complications[5], reduction in blood transfusion rate[6], reduction in postoperative paralytic ileus [7], and reduction in surgical site infection[8].

The approach for performing neuraxial anaesthesia (spinal and epidural) as a landmark guided technique hasn't altered much since it was first described.
Since 1900, numerous advances in needle design and pharmacology have been made in the field of neuraxial anaesthesia.

The practise of neuraxial anaesthesia has been substantially improved and augmented thanks to USG guidance. Ultrasound is only recently being used in neuraxial anaesthesia. USG as a means for neuraxial scanning was started as early as 1980 [9], it was not widely adopted until the early 2000s [10]–[16]. The presence of a spinal canal enclosed in bone and the intensity of the tissue in question (sub-arachnoid space and epidural space), both of which limit the utility of the ultrasound beam, make neuraxial ultrasound difficult. In comparison to superficially located peripheral nerve blocks, it is a more difficult talent to acquire. The causes of poor neuraxial ultrasonography images are still unknown.

Ultrasound can be used in a variety of ways to help with neuraxial block. It can be used as a pre-procedural evaluation to determine the underlying architecture of the spine, or it can be utilised to guide the administration of spinal or epidural anaesthetic in real time. The demand for wide bore needles and the technological problems involved with simultaneous ultrasound scanning and needle advancement limit the use of real-time ultrasound guiding [17].

Pre-procedure ultrasonography elicits interspinous level, midline, depth of the epidural and or sub-arachnoid space, angle of needle insertion and ideal needle point entry to aid in the performance of neuraxial block.

Its application increases neuraxial methods' precision and efficacy [18]. To improve the safety of neuraxial blocks, researchers employed neuraxial ultrasound to locate the interspinous gap. The amount of interspinous anaesthesia used to give spinal anaesthesia is a surrogate measure for probable spinal cord injury[19]. When compared to palpation, neuraxial ultrasound identifies interspinous space more precisely (up to 90% accuracy can be reached with training) [20] . It has a steep learning curve that could make its adoption difficult. Finally, the expense and time required to make routine ultrasound use more convenient, may be prohibitive.

The number of passes and attempts are utilised as indicators of the effectiveness of neuraxial block delivery. Multiple passes and attempts during neuraxial anaesthesia have been linked to an increased risk of post-dural-puncture headache, paraesthesia, and neuraxial hematoma [21–24]. In patients with complex surface anatomic landmarks, pre-procedural ultrasonography is suggested for spinal anaesthesia [25].

AIM AND OBJECTIVES

AIM

To compare the efficacy and safety of pre procedure ultrasound guided paramedian technique to traditional landmark guided paramedian technique in the administration of spinal anaesthesia.

OBJECTIVES

Primary Objective

1.To compare the number of needle passes between the two groups

2.To compare the number of needle attempts between the two groups

Secondary Objective

1.To compare the first pass success rate and the first attempt rate in both groups.

2.To compare the occurrence of blood in spinal needles between the two groups

3.To compare the incidence of radicular pain and paraesthesia in the two groups.

REVIEW OF LITERATURE

HISTORICAL ASPECT

James Leonard Corning , a neurologist in New York , provided the first spinal analgesia in 1885. H accidently perforated the dura mater while testing with cocaine on a dog's spinal.[26]

August Bier injected 3 ml of 0.5% cocaine solution into a 34 yr old worker on August 16,1898' in Kiel, which was the first intendd spinal anaesthetic for surgery in human.

Nicolae Racoviceanu, a surgeon of Romanian origin employed opiods for analgesia in interthecal space in 1901. He was the first to do so anfd he published his findings in Paris in 1901[27].

Bogin et al claimed to be the frst to employ neuraxial ultrasonography to study the structure of the vertebral column to help in lumbar puncture in 1971[28].

In 1978, **Porter and colleagues** used ultrasonography as a diagnostic tool to get an impression of the lumbar spine and figure out the width of the spinal canal[29].

Cork and colleagues were the first anaesthesiologists to use USG as a tool to find definitive landmarks with respect to epidural anaesthesia.

Grau and colleagues conducted a series of experiments between 2001 and 2004 that laid the groundwork for the therapeutic use of ultrasonography for central neuraxaial blockade[10]-[14].

Real time imaging for paramedian for insertion of a combination spinal epidural needle was described by Karmakar et all in 2009.In this case series , real time needle visualization was successful in 14 of the 15 patients[31].

The SonixGPS system, according to **Brinkman et all** in 2013 , May allow needle tip visibility down to the ligamnetum flavum.[32].

The Sonix GPS is a new needle tracking system that was recently approved in Canada for US guided needle interventions and shows current and projected needle tip position in real time.

REVIEW OF LITERATURE

The majority of equipment developments in neuraxial blocks were to make the visualization of the needle more prominent and easier . The procedure for performing a neuraxial block (spinal and epidural) with help of landmarks hasn't altered much since it was first described.

Multiple puncture and consequences such as pos dural puncture headache, epidural hematoma and neural damage are reduced when the epidural and sub arachnoid spaces are identified on the first attempt.

De Filho GR et al investigated the predictors of successful first neuraxial blocks. A total of 1481 individuals were enrolled in the study all of whom were given spinal or epidural anaesthetic. Age, geneder , height , weight , body habitus , anatomical landmarks (palpability of the spinous processes), spinal anatomy , patient placement , premedication ,needle type and guage, approach, spinal level of block and the amount of experience of the provider were all documented for each block. The subarachnoid and epidural areas were identified using free passage of CSF through a needle or loss of resistance to saline or air , respectively.

The success or failure of the first effort was the outcome variable (whether or not the needle was correctly located with one skin puncture and produed adequate surgical anaesthesia). The study found that the first attempt success rate was 61.51 percent .The quality of anatomical landmarks , the provider's level of experience and the suitability of patient positioning were all independent predictors. The study concluded that the chances of the patient's subarachnoid or epidural space location at the first attempt was influenced by the quality of the patient's subarachnoid or epidural space placement.[33]

When compared to a landmark based strategy , preprocedural usg has been found to improve the ease and efficacy of establishing anaesthesia. Preprocedural USG guided spinal anaesthesia has been studied extensively to determine its safety and efficacy. Rapid progress ha s been made to the point that standard preprocedural USG scanning is now suggested to reduce the danger of dural puncture in pregnant ptients conducted at or above the L2-L3 interspinous space[34]

Bogin I.N . et all colleagues investigated the use of two- dimensional echospondylography for lumbar puncture landmark determination (article in Russian language)[28]

Grau et al looked at 80 patients who had a LSCS and were given CSE. They were randomly assigned to either US guided (n=40) or control (n=40) group. An ultrasound scan was used to determine the best insertion level and to estimate the depth of the epidural space. A single skilled operator performed both US scan and the CSE. The US guided group had a higher success rate on the first needle pass than the control group (75% v/s 20%) p 0.001. [35]

Grau et al looked at 30 parturients who had LSCS and were given CSE. They were assigned to one of three groups (each with ten participiants) : a control group ; a group that received no treatment ; or a group that received treatment. A group that had the CSE performed using a real time , two operator , US guided freehand technique and a group that had the CSE conducted utilizing a preprocedural US scan with a linear transducer to determine optimal insertion point, trajectory and depth to epidural space. One patient in the control group had asymmetric block, but not in the other two group (not significant). One patient in the control group had patchy block, but not in the group (not significant). There was no difference between the groups in terms of intraoperative pain or patient satisfaction. The realtime US guided group had

a 100% success rate on the first needle pass, compared to 70% in the pre-procedural US group and 40% in the control group. ***[36].***

Chin and Chan et al looked at 50 patients who had total joint arthroplasty and were given spinal anaesthesia. To find the best needle entry position, an US scan was used. Using a midline technique, the same operatoer applied spinal anaesthesia at the designated interspace. The first needle insertion success rate was 84% (defined as a new skin puncture that did not include a change in needle trajectory without full withdrawal from the skin) (42 out of 50). The success percentage on thr first needle pass (defined as any forward needle advancement) was 52% (26 out of 50). ***[37]***

Furness et al looked at 49 people who had a lumbar spine X ray. One of the three anaesthesiologists used surface palpation of markers to identify the interspaces between L2 and L5. A radiologist used ultrasound to identify and mark these interspaces. The markers were then compared to a lumbar spine lateral radiograph. In 71% of cases, there was agreement between the US detected and radiograph indicated interspaces. Interspaces that have been clinically identified and those that have been identified by radiographs are in agreement in 30% of cases.The difference between US and radiograph identified interspaces was never more than one level, but the difference between clinically and radiograph identified interspaces was more than one level in as many as 27% of patients. ***[38]***

Watson et al looked at 17 patients who had their spines scanned with an MRI. A linear US transducer was used to identify and mark the L3-L4 interspace. This was found to be related to the L3-L4 space found on the MRI scan. In 76% of patients, there was agreement between the US detected and MRI identified interspace. In the other 24% individuals, the L3-L4 interspace was found at L2-L3 instead of the US identified L3-L4 interspace. ***[39]***

Locks et al studied 90 patints in whom the L3-L4 interface was detected and marked using the intercristal line by an operator with more than 5 years of expertise in obstetric anaesthesia. The L3-L4 interspace was identified using US scan. In 51% of cases , there was agreement. Clinically diagnosed interspace was 1 level lower in 3% of patients, 1 level higher in 40% of patients and 2 levels higher in 6% of patients when compared to the US identified interspace ***[40].***

Pysyk et al looked at 114 volunteers who underwent a US scan to find the interspace that corresponded to the intercristal line. It matched to L2-L3 in 13% of cases, L3-L4 in 73% of cases and L4-L5 in 14% of cases ***[41].***

Vallejo et al looked at 370 women who had a labour epidural. Randomized to either a US guided (n=189) or a control (n=181) group. A single anaesthesiologist with experience in ultrasound- guided epidurals performed the ultrasound scan. The operator doing the epidural was informed of the depth of the epidural space, the location of the midline and the probe angle. 15 first year residents performed all epidurals under the supervision of a blinded staff anesthesiologist. The rate of epidural failure was lower in the US guided group (1.6% v/s 5.5%) p value of 0.02 than in the control group. The USG guided group required fewer needle passes to achieve success than the control group (1 v/s 2) p value of 0.01. In both the PS oblique and transverse perspectives, there was a strong correlation between ultrasound estimated epidural space depth and actual needle insertion depth (r=0.91) ***[42]***

Tran et al looked at 19 patients who underwent LSCS and were given a CSE. An onscreen overlay and fixed needle guide were used in this feasibility study of a real time, single- operator, US- guided method. In 18 of 19 patients, the epidural space was successfully penetrated. A lengthier needle track and the inability to access

interspaces below L2-L3 were two drawbacks. [43].

Real time imaging for paramedian insertiom of a CSE needle was described by **Karmakar et al.** Real time needle visualization was successfully used in 14 of 15 patients in this case series. [31]

Chin and colleagues compared as to in how many times they could get CSF in first try and success rate of eliciting difficult anatomic surface landmarks in patients using a conventional surface landmark guided median technique (LM group) v/s a preprocedure US assisted median approach (US group) in a prospective randomised controlled trial. The first needle attempt success rate was (32 % v/s 65%) with a p value of 0.01 and the first needle pass success rate was (8% v/s 27 %) with a p value of 0.009 [44]

The first needle attempt success rate of patients aged 21 to 80 years was compared in a prospective randomized controlled trial study conductec by **Y C Lim and colleagues.** The success rate of the first needle effort was (64% v/s 52%) with a p value of 0.16, which was not statistically significant. [45]

The first effort success rate and needle manipulation rate of the traditional surface landmark guided median technique (LM group) and the pre-procedure US assisted paramedian approach were compared in a prospective randomized controlled trial study by **K. Srinivasan and colleagues** (USG group). The first needle attempt and first needle success rates were (60% v/s 84%) with a p value of 0.0075 and (40% v/s 28%) with a p value of 0.21, respectively, which were statistically insignificant. Both the groups had failure rate of 12% and 4 % respectively. Two patients in LM group had haemorrhagic taps but none in USG group. [46]

ANATOMY OF SPINE

Anatomy of the Spine in General

The spinal cord is the lower part of the central nervous system responsible for establishing contact between the brain and peripheral organs [57] . It occupuies the upper two thirds of the spinal canal which is composed of the vertebral bones and fibro- cartilaginous intervertebral discs. There are 7 cervical, 12 thoracic and 5 lumbar vertebrae. The sacrum is a fusion of 5 sacral vertebrae and there are small rudimentary coccygeal vertebrae. The spinal canal is convex anteriorly in the cervical and lumbar regions. The canal contains the spinal cord with its coverings of the meninges, fatty tissue and the Batsons venous plexus. The spinal cord is covered in CSF, of around 150ml, and corresponds with the changes in the weight and habius of the patient [58].

The extent of the spinal cord is from the Foramen magnum to the level of L1 in adults and L3 in children. The lower end is cone shaped and is called conus medullaris. The apex of the conus continues as filum terminalae [59]. Puncturing dura above this level is can damage the spinal cord. An important landmark is the Tuffier's Line. The pia mater, the innermost of the three meningeal layers, has lots of blood vessels and covers the spinal cord as well as the brain. The arachnoid membrane is a delicate, non- vascular membrane closely attached to the outermost layer i.e. the dura. The arachnoid is the principle blood-brain barrier [55].

The structures pierced by the spinal needle before reaching the CSF:

1. Skin
2. Subcutaneous fat
3. Supraspinous ligament
4. Interspinous ligament
5. Ligamentum flavum
6. Epidural space
7. Dura
8. Subarachnoid space containing the CSF

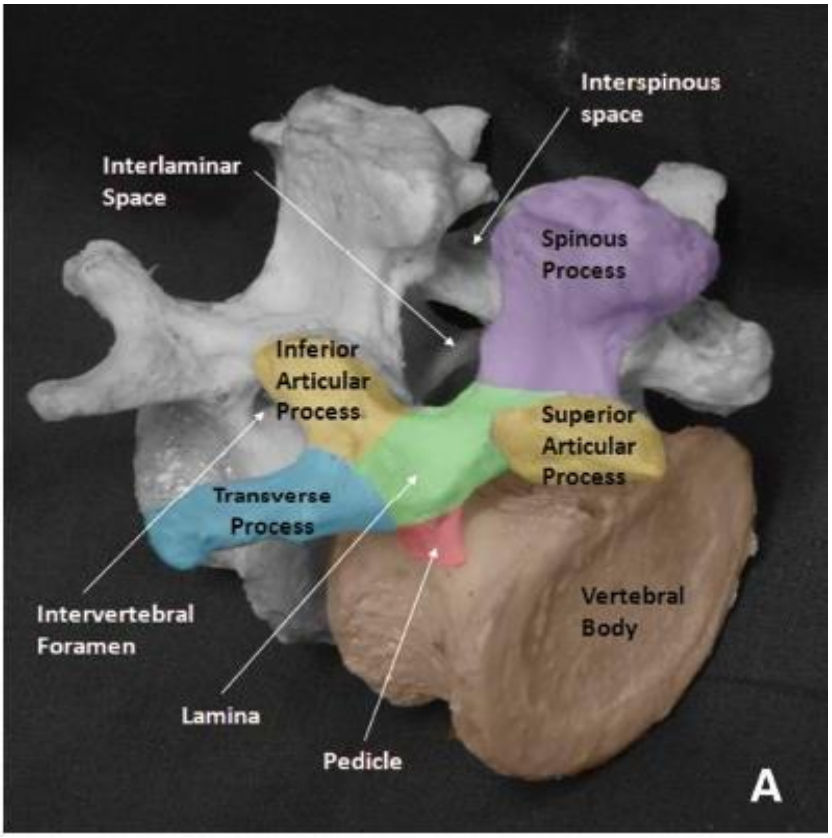


Fig1-Three quarter oblique view of adjacent lumbar vertebrae

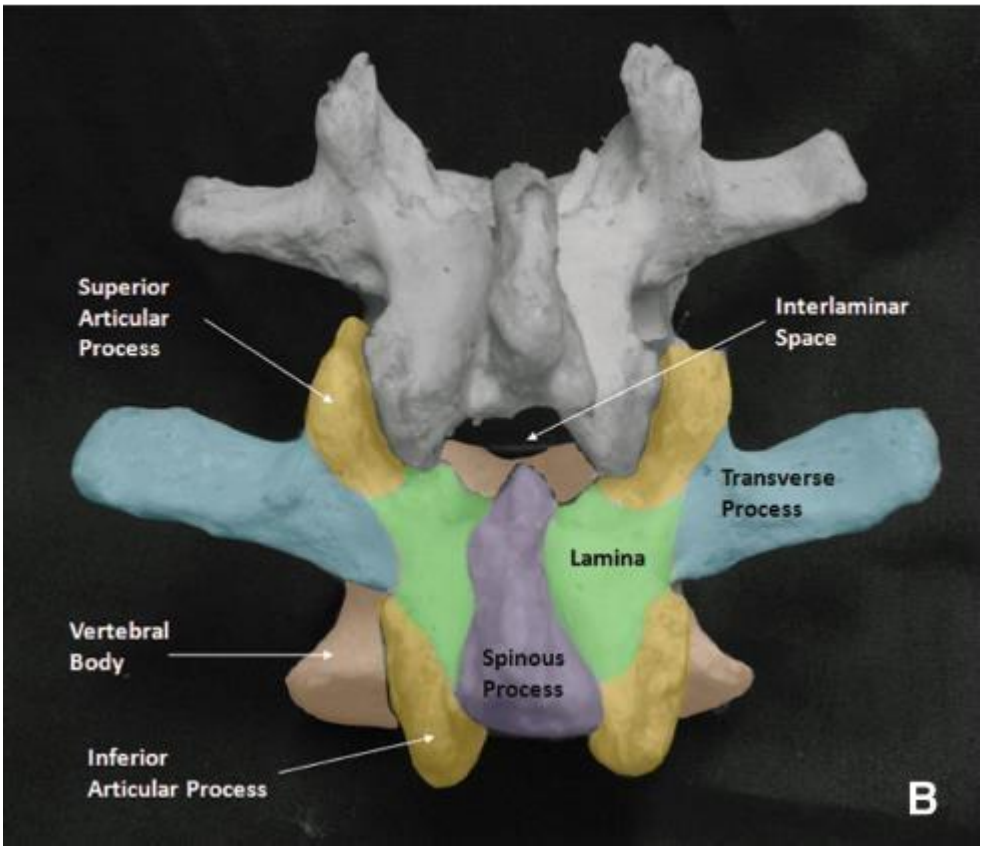


Fig 2-posterior view of adjacent lumbar vertebrae

The Lumbar Spine

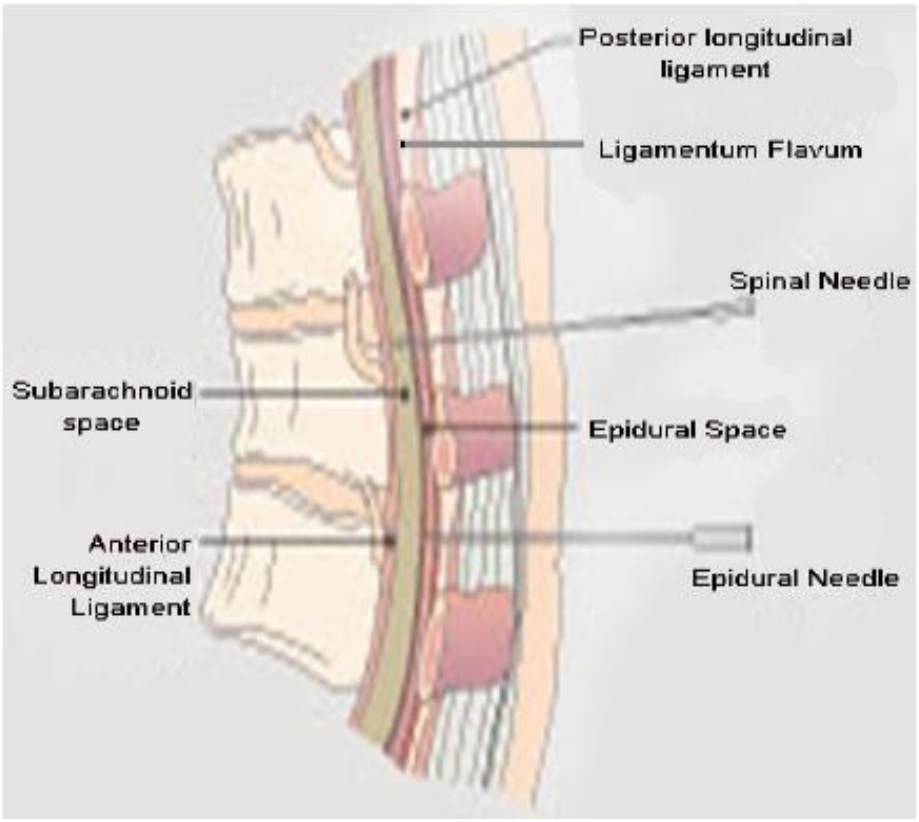


Fig 3 -Lumbar subarachnoid spaces

BASIC ULTRASOUND PHYSICS AND TECHNOLOGY [54]

The detection of sound a it is reflected by various tissue surfaces in the body is the basis of ultrasound technology.

The acoustic frequency of ultrasound waves ranges from 2 to 15 Mhz.When sound waves travel through a medium, they produce an echo when they come into contact with another medium.

When ultrasound scanners reach a tissue interface, they transmit sound waves that produce an echo within the body.

As a result of the varying acoustic impedances of human tissue or fluids, ultrasound images reflect shapes, including those of anatomical features.

Significant sound wave reflection occurs at the interfaces of substances with differing acoustic impedances, resulting in high contour definition between various tissues.

Fluids, in general, provide perfect sound transmission wit no echoes, resulting in a black image.

Sound waves are attenuated and dispersed by tissue, resulting in homogenous or heterogenous appearances.

The number of cycles per second is defined as frequency(Hz).

For surface structures, high frequency provides great spatial resolution but lesser penetration depth; for deeper structures, lower frequencies are necessary.

The best imaging frequencies for superficial tissue visualization are between 7.5 and 15 MHz.

For vast anatomical regions and deeper nerve structures, lower frequencies (2-7 MHz) may be employed.

The length of one cycle in one direction of wave propagation is defined as a

wavelength (mm).

The displacement of the wave per unit of time is described as velocity (m/s).

The velocity of ultrasonic waves is determined by the different acoustic impedences (densities) of tissue.

The square root of the wave energy is used to compute the amplitude.

The amplifier gain feature improves the signal to noise ratio by adjusting the strength of weak echoes.

The amplitude of an ultrasonic wave decreases with time as it travels through tissue, which is known as attenuation.

Time gain compensation (TGC) compensates for wave attenuations by boosting the signal's amplitude factor.

A transmitter, a transducer , a receiver and a display are the four major components of a portable or cart based ultrasound scanner (figure- 4).

The energy is sent to the transducer by the transmitter in brief bursts or pulses, with the rate of pulses emitted by the transducer being regulated by the transmitter.

The transducer, also known as a probe or scan head, converts the transmitter's electric energy into sonic puslses (sound waves).

The transducer also acts a receiver for reflected echoes, converting pressure variations into electric impulses.

Curved and linear transducers are the most often utilized transducers for regional anaesthesia.

Curved transducer covers a vast surface field of view while coupling to the contact (footing) area is reduced (fig 5).

The drawback is that the image has a non-linear line density, which makes it slightly more difficult for a beginner to understand.

The signals are amplified by the receiver.

Ultrasound signals can be shown in a variety of ways, including A-mode, which shows echo information as an amplitude signal; M-mode, which shows motion with respect to time; and B-mode, which shows brightness information and provides a body slice image.

B-mode display is used for the majority of images.

A grey scale (a scale from black to white with numerous shades of grey in between) is typically used with a variation in the display of brightness (or whiteness) to indicate reflected signals of changing amplitude.

The hyperintensity signals appear white (hyperechoic), while the lowest intensity signals seem dark (hypoechoic) or black (anechoic), with intermediate intensities appearing as shades of grey.[54]

Fig 4 - Cart based ultrasound scanner SONOSITE M-TURBO

Fig 5 – Curvilinear probe 2-5 MHz

SONOANATOMY OF SPINE

Since the profundity and restricted acoustic windows regularly forestall exact sight of the key anatomic structures, pattern recognition is critical in interpreting spinal somoanatomy.

Hard surfaces show hyperechoic (white) straight designs underneath thick acoustic shadowing (dark) that totally darkens any more profound highlights. Hyperechoic, connective tissue structures, like tendons and fascial films, are present, their acoustic impedance is lower than that of bone allows imaging of deeper tissues. The acoustic impedance of fat and fluid is extremely low, making them hypoehoic (dark).

Ultrasound imaging planes:

The ultrasound probe and beam can be oriented in three different ways(fig 6):

1. **Paramedian sagittal (PS),** when the beam is oriented beside the midline sagittal plane;
2. **Paramedian sagittal oblique (PSO)** when the beam is tilted and aimed towards the median sagittal plane;
3. **Transverse**, when the beam is oriented parallel to the transverse or horizontal plane.

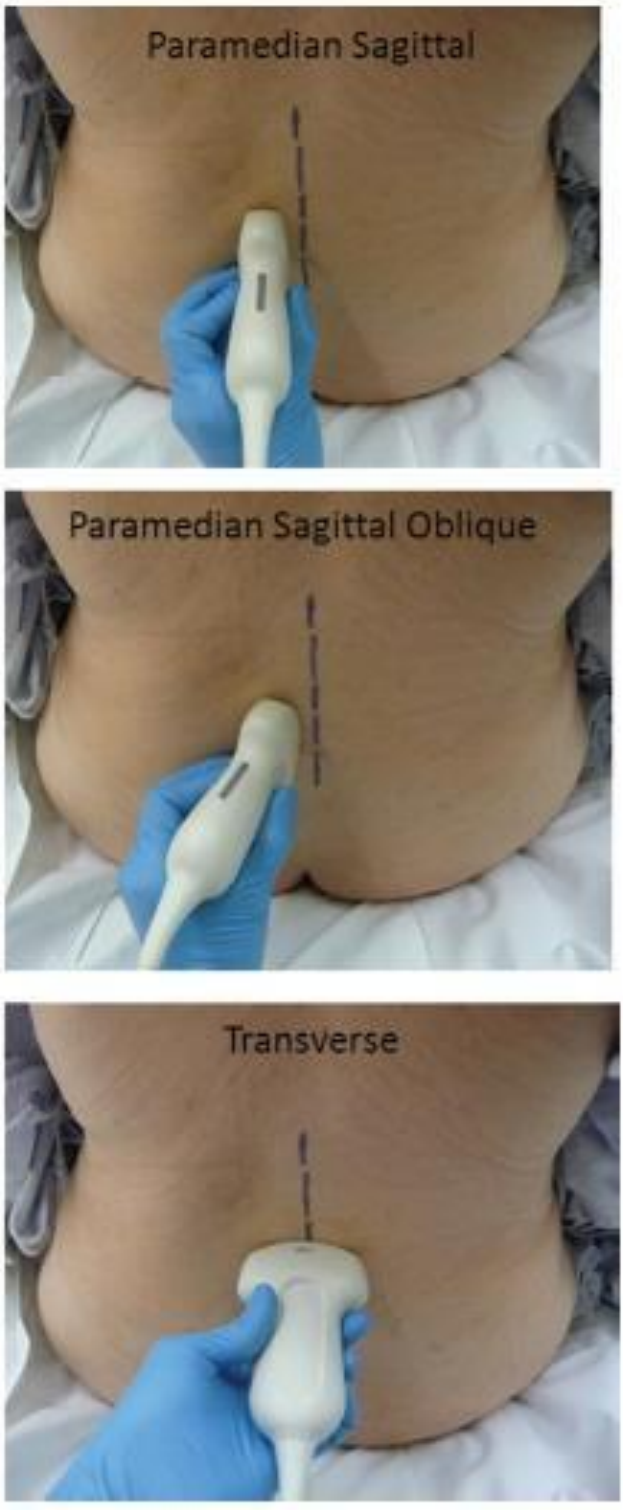


Fig 6-ultrasound probe orientations

A precise way to deal with checking works with both the course of example acknowledgement and the general presentation of ultrasound-directed neuraxial blockade.

There are five basic ultrasonographic views that may be obtained:

1. **Paramedian sagittal transverse process view:** To begin with the ultrasound probe is placed in a PS direction 3-4 cm horizontal to the midline and just above the sacrum's top limit. The cross over cycles of progressing lumbar vertebrae are depicted in this perspective. These appear as short hyperechoic curvilinear structues with articulated " **finger like**" acoustic shadowing underneath , giving them the look of the **trident sign** (addressed by the finger-like acoustic shadows of the cross over proceses). Between the acoustic shadows and profound to the cross over processes, the striated psoas is the important muscle to be seen (fig 7).
2. **Paramedian sagittal articular process view:** The probe is slid medially from the PS cross over process view until a steady hyperechoic line of "bumps" appears (fig 8). Each bump addresses the aspect joint between a prevalent and second rate articular course of progressive vertebrae in this PS articular interaction image. Both the predominant and second rate articular cycles are seen at a shallower depth than the cross over processes because they are in the coronal plane back to the cross over cycles.
3. **Parasagittal oblique view:** The test is adjusted from the PS articular cycle view to point the pillar in a parallel to average direction toward the middle sagittal plane. The lumbar vertebrae's inclining hyperechoic laminae form a "sawtooth" like shape in this view. The mediating holes are for the paramedian interlaminar spaces, via which the following structures (from

shallow to profound) can be imagined: ligamentum flavum, epidural space, posterior dura mater, intratechal space, foremost dura, posterior longitudinal ligament and back vertebral body (fig. 9). The posterior complex is a singular direct hyperehoic structure that includes the ligamentum flavum, epidural space and posterior dura. The ligamentum flavum and posterior dura may be detected as two hyperehoic lines separated by the hypoechoic fat-filled back epidural space with minor sliding and shifting developments of the test. In grown-ups, the anterior dura, posterior longitudinal tendon and posterior part of the vertebral body or intervertebral circle are all seen as a single direct hyperehoic structure (the anterior complex) and are never distinguished from one another.

4. **Transverse spinous process view:** The probe is turned 90 degrees into a cross over direction and fixed on the neuraxial midline once the assessment in the PS plane is completed. When the probe is over a spinous process, the tip of the process appears as a shallow hyperechoic line with acoustic shadowing beneath it. On one or both sides of the spinous process, the hyperechoic lamina is visible, but any remaining designs of interest are obscured by strong acoustic shadowing (fig 10).
5. **Transverse interlaminar view:** From the cross over spinous process view, sliding the probe in a cephalad or caudad direction adjusts the shaft to the interspinous and interlaminar space, giving a cross over interlaminar viewpoint on the material of the vertebral trench. Normally, the spinous process straight acoustic shadow given way to a less dull vertical line (the interspinous tendon outlined by the nesrby echogenic erector spinae muscles) and, deeper still, the two equal hyperechoic lines of the back and foremost

complex separated by the hypoechoic intrathecal space (fig 11). The transducer may need to be relocated cephalad to improve the picture of the vertebral channel, depending on the diameter of the interspinous space and the point at which the spinous cycles project.

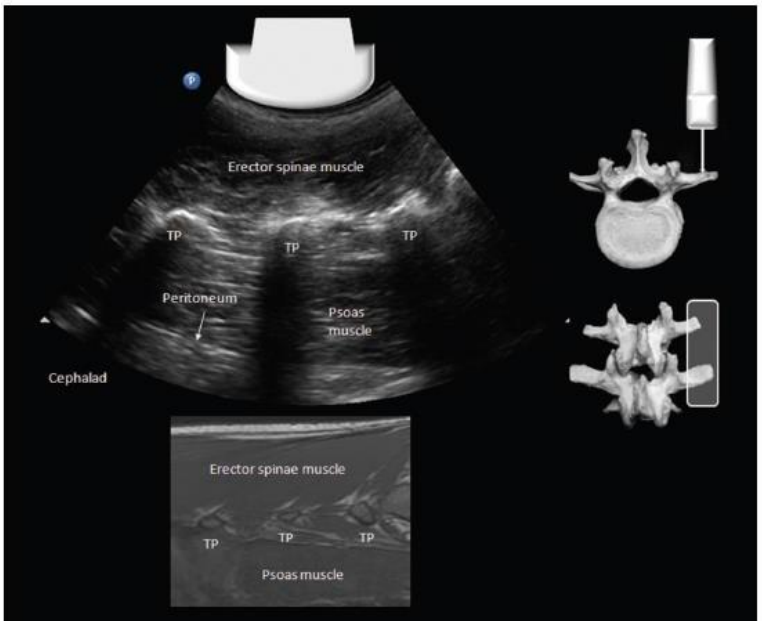


Fig 7-paramedian sagittal transverse process view of lumbar spine

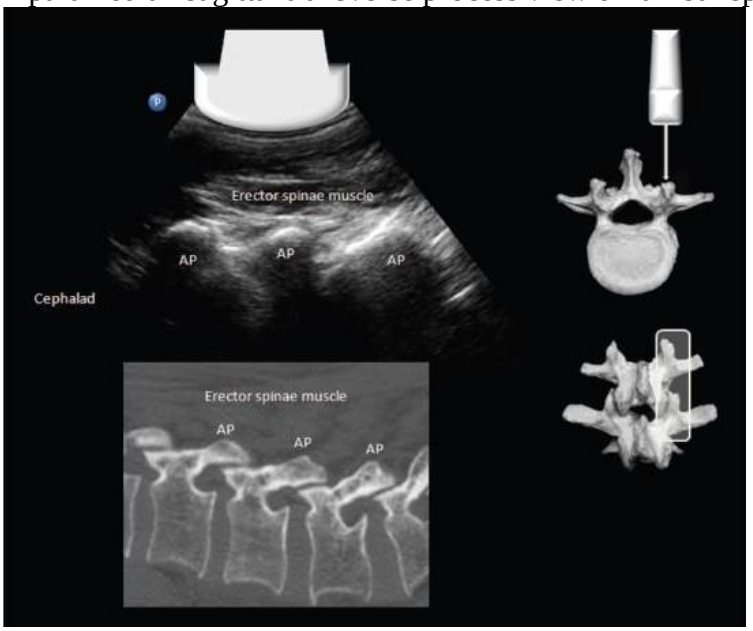


Fig 8-paramedian sagittal articular process view of lumbar spine

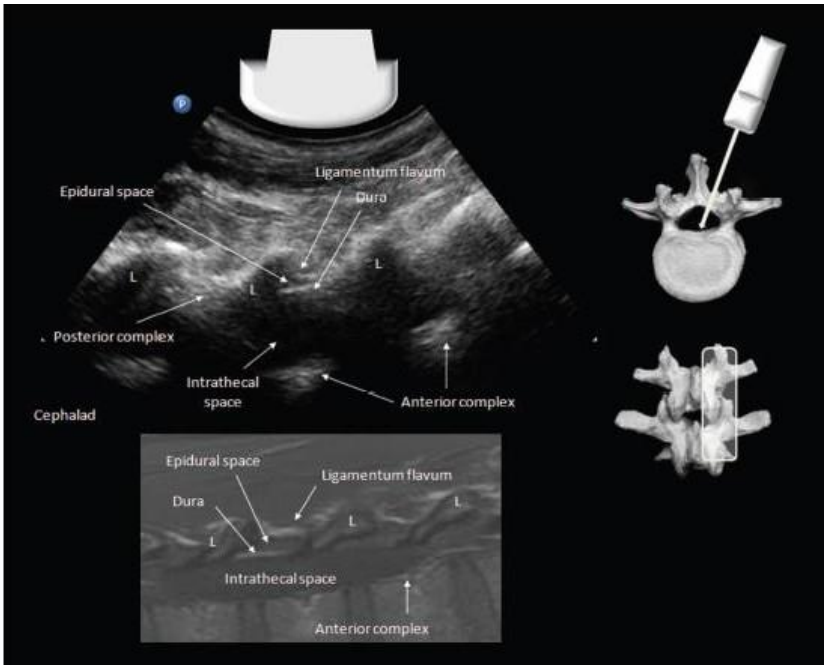


Fig 9-paramedian sagittal oblique view lumbar spine

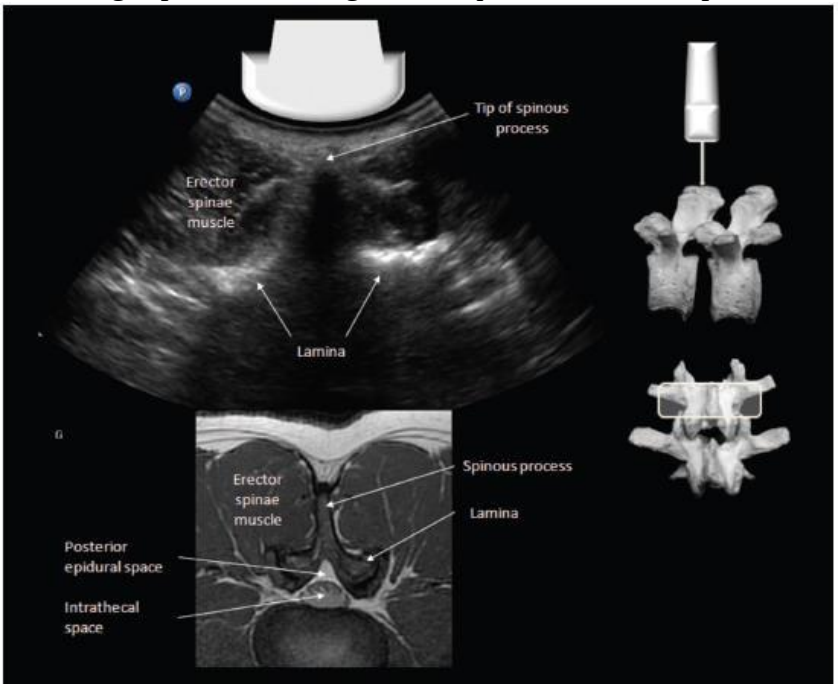


Fig 10- transverse spinous process view of lumbar spine

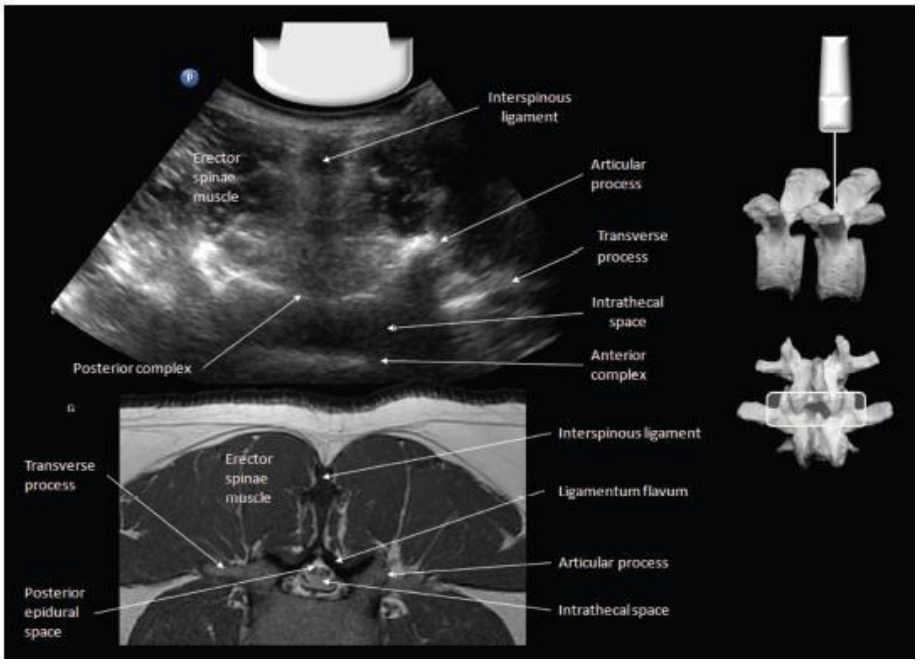


Fig 11-transverse interlaminar view of lumbar spine

APPROACHES TO SPINAL ANAESTHESIA *[56]*

Basically three approaches:

1. **Median approach**
2. **Paramedian approach**
3. **Taylor approach**

Median Approach:

The patient was seated on a level trolley with his feet propped up on a foot rest. He was given a cushion to cuddle and told to keep his back arched, with an assistant holding the patient to help with placement.

The anesthesiologist, who had been cleansed prior to the procedure and was wearing a mask and sterile gloves, maintained strict asepsis throughout the treatment .

Chlorhexidine at 2% was used to prepare the skin.

The introducer spinal needle was introduced at a modest cephalad angle of 10°to 15° through skin, subcutaneous tissue and supraspinous ligament to reach the substance of the interspinous ligament once the suitable area had been determined.

The introducer was held stable with the index and thumb, while the other hand stabilized the spinal needle to prevent it from changing position and going any deeper than the ideal length.

The needle was slowly advanced through the ligamentum and dura, with its bevel end in cephalad direction, until a change of resistance was found.

Often, upon passing through the barrier, there was a small “pop” or click sensation.

CSF developed at the needle hub after the stylet was removed.

The back of the other hand would steady the spinal needle against the patient’s spine and CSF starts freely flowing and filling the hub of the spinal needle, while the syringe carrying the drug is attached to the needle.

CSF was sucked freely into the syringe once more, and the anaesthetic dose was given at a rate of 0.2 ml/sec.

Midline approach was most routinely used for spinal anaesthesia.

Paramedian Approach

When the midline approach failed or was not viable due to anatomical variations, the paramedian method was adopted (calcified interspinous and supraspinous ligaments in elderly patients).

The anatomical limitation of the spinous process is avoided in the paramedian technique by putting the needle laterally, vessels may be encountered in this approach, resulting in haemorrhagic tap.

Patient placement is identical to that of the median method and stringent asepsis is identical to that of the median technique.

Chlorhexidine at 2% was used to prepare the skin.

We raised a skin wheal at 1cm lateral and distal to the corresponding spinous process once the proper space has been identified.

The spinal introducer and needle are then entered in a cephalomedial plane 10°to 15° off the sagittal plane; if the needle comes in contact with bone or there is a feeling of resistance, it is redirected slightly the bevel facing upwards.

If again resistance is felt, but this time at a depth where much more of the needle has gone inside, the needle is likely to be " walked up" the lamina, so the modest cephalad angulation is maintained.

The ligamentum flavum was the most common source of resistance.

A pop was often felt when a spinal needle went through the dura mater. Folowing the acquisition of CSF, the block is performed in the same manner as the midline approach.

Taylor Approach

Taylor JA was the first to describe it in 1940. It was essentially a lumbosacral puncture variation of traditional paramedian technique at the level of L5-S1.

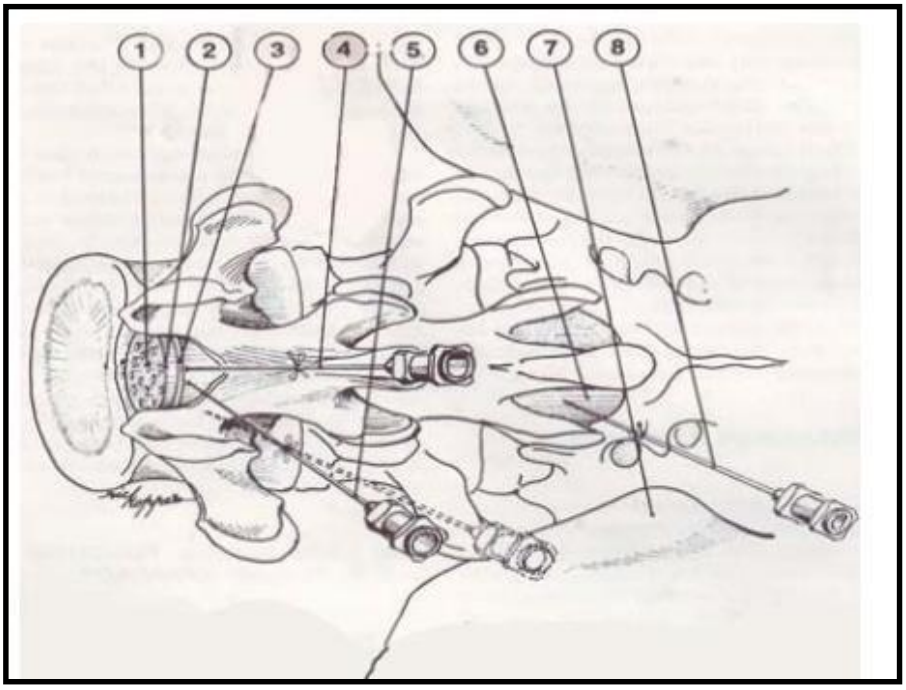


Fig 12-median and paramedian approach in lumbar region

The figure denotes:

1. Cauda equine
2. Dura mater
3. Ligamentum flavum
4. Median approach
5. Paramedian approach
6. Lumbosacral canal
7. Posterior superior iliac spine
8. Taylor’s approach

MATERIAL AND METHODS

PLACE OF STUDY

- This study was carried out in department of anesthesiology B.L.D.E.(DU)'S Shri B.M.Patil Medical College, Hospital and Research centre, Vijayapura.

STUDY DESIGN

- Randomised ComparitiveTrial
- Randomisation: Block randomisation with equal allocation

STUDY POPULATION

- Patients aged 50 years and above planned for elective lower abdomen, pelvic and lower limb surgeries under spinal anesthesia

INCLUSION CRITERIA

- All consented patients planned for elective lower abdomen, pelvic and lower limb surgeries under spinal anaesthesia
- Age 50 years and above
- ASA GRADE I AND II

EXCLUSION CRITERIA

- Patients with known allergy to local anaesthetic drug.
- Patients with coagulopathies
- Signs of infection at site of injection
- Patients with previous spinal surgeries
- Patients with chronic systemic disorders
- Patients with chronic hypertension
- Patient refusal
- Neurological disorder or deficit

STUDY TOOL

1. Consent form (Annexure -2)
2. Predesigned data collection format (Annexure-3)
3. Consort 2010 flow diagram (Annexure-4)

APPROVAL FROM INSTITUTIONAL ETHICAL COMMITTEE

- Approval from the institutional ethical committee was taken before initiation of the study and the study trial was registered with Clinical Trials Registry-India after ethical committee approval.

CONSENT

- The method of spinal anaesthesia was explained to the patients when they came to us for fitness of their respective operations .
- After informing them about the entire procedure with it's due risks, a consent was taken.

SAMPLE SIZE

- Sample size is calculated to test the following hypothesis: H0:μ1-μ2=0 against H1:μ1-μ2

STATISTICAL DATA:

80 patients (40 per group) are required to have a 90% chance of detecting, as significant at the 5% level, an increase in the easy grading of palpated landmarks from 23.5% in the LM group to 57% in the USG group. Calculation based on the formula: $n = f(\alpha/2, \beta) \times [p\,1 \times (100 - p\,1) + p\,2 \times (100 - p\,2)] / (p\,2 - p\,1)\,2$ where p1 and p2 are the percent success in the control and experimental group respectively

Sample size calculated was 40 in each arm

Note: Interquartile/2 is taken as an estimate of SD

SAMPLING TECHNIQUE

Patients were randomised using random number generating software

Group allocation was concealed by enclosing the codes in a sealed opaque envelope. Consort flow chart diagram of study is attached as **Annexure 3**

The patients was randomly divided in two groups.

- **LM group**: spinal anesthesia administration by conventional landmark guided median technique
- **USG group**: pre-procedure ultrasound guided paramedian technique .

Methodology

- In the operating room an intravenous access was taken.
- We attached different monitors like non-invasive blood pressure monitoring, oxygen saturation probe, electrtocardiogram leads to the patient to take the recordings.
- All patients were started with intravenous fluids like ringers lactate or sodium

chloride at the rate of 10ml/kg/hr

- They would sit with their backs arched forward and would keep their feet on a stool to prevent it from dangling.
- They would hug a pillow while bending forward and were requested to maintain that back posture with an assistant holding the patient to aid positioning.

In **LM group:**

- Sepsis prevention was given paramount importance and after ensuring the same, the suitable lumbar interspinous space was selected after palpation, We had the help of an imaginary line that joined the highest points of the iliac crest on both sides.
- The dura was puntured using a 25 gauge Quincke **(**3.5 inch/9 cm) spinal needle with the paramedian approach.
- The spinal needle was inserted at an angle of 10°-15° to the sagittal plane in an cephalomedial approach to the skin.
- The needle was pushed forward until there was a sudden give away feeling, that showed that we had entered the subarachnoid space. The cerebrospinal fluid started freely flowing and filling up the needle. That was taken as the confirmation for entry in the subarachnoid space.
- Once it was confirmed that we were in the right space, the spinal needle was held firmly between the thumb and the index finger while resting on the patients back and thus stabilizing the needle from changing its position.
- All procedures were supervised by an experienced anaesthesiologist.

In USG group (fig-13,14,15),patient positioned same as **LM group** under full aseptic technique gloves,gown,mask and sterile transducer cable sheath were

employed.

A standard curvilinear 2-5 MHz transducer attached to US device (sonosite-M Turbo) was applied to the patient's back lateral to midline.

The USG image was optimised by setting an appropriate scanning depth (6-10 cm), selecting a transducer frequency and adjusting the gain to obtain the best possible image.

The sacrum was identified first and then the probe was moved cephalad in the paramedian axis with a 10-15 degree tilt toward the midline.

The lumbar laminae L5 and interlaminar space between L5 and S1 was noted and probe was positioned with its midline point directly above the selected space.

The transducer was then rotated 45 degree towards the midline into an oblique paramedian sagittal view

Subsequent interspinous spaces was identified by counting the interlaminar spaces in a cranial direction.

The interspinous space at which the clearest image of the anterior complex (ligamentum flavum dura complex [LFD]) and posterior complex (posterior longitudinal ligament [PLL]) obtained was selected.

At the selected interspace, and with the probe positioned to obtain the clearest ultrasound image, a skin marker was used to mark the midpoint of the long border of the probe and the midpoints of the short borders of the probe.

The medial angulation of the probe was also noted to facilitate guiding the insertion of the spinal needle.

At the same horizontal level as the midpoint of the long border of the probe, the midpoint of the line drawn between the 2 short border midpoints of the probe was used as paramedian insertion point for the spinal needle

Ultrasound gel near the selected skin puncture site was carefully removed using sterile gauge prior to insertion.

In both groups, after 4 attempts were unsuccessful alternative method was used. For patients in group LM ,ultrasound was used or GA was used. For patients in group USG ,a conventional landmark paramedian approach technique was used or GA was used and these cases are considered as failures.

Data collection

- Demographic and anthropometric data including age, gender, height and weight were collected.
- The data was analysed by appropriate statistical tests

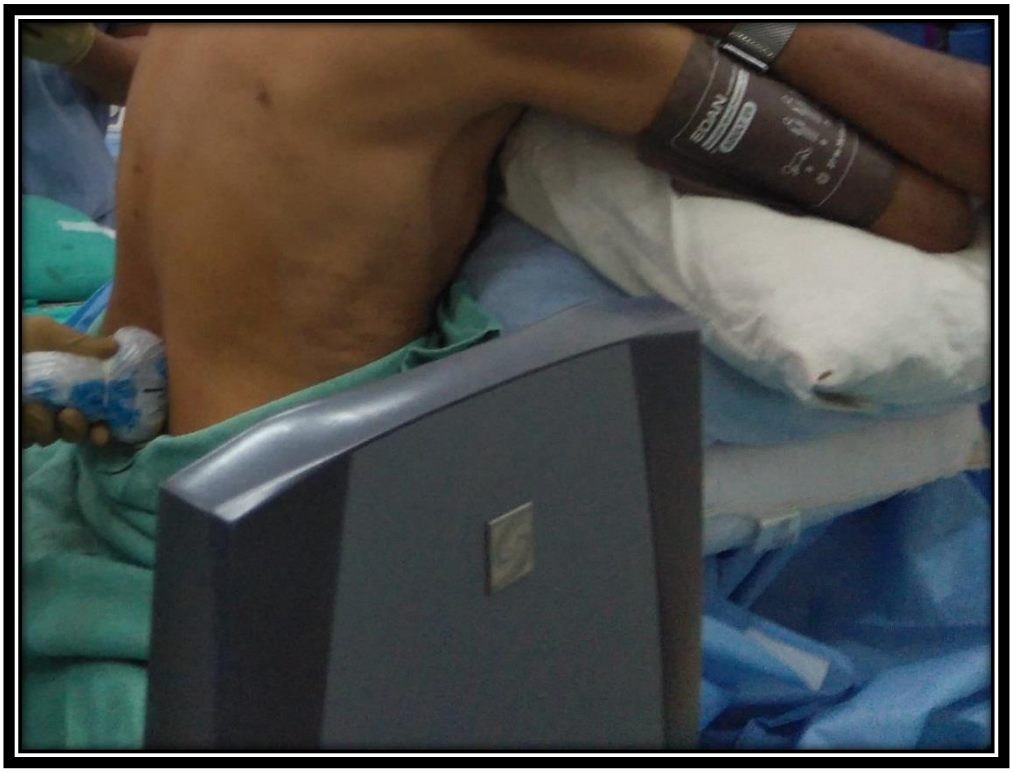


Fig-13 patient position and curvilinear probe placement during preprocedure US scanning

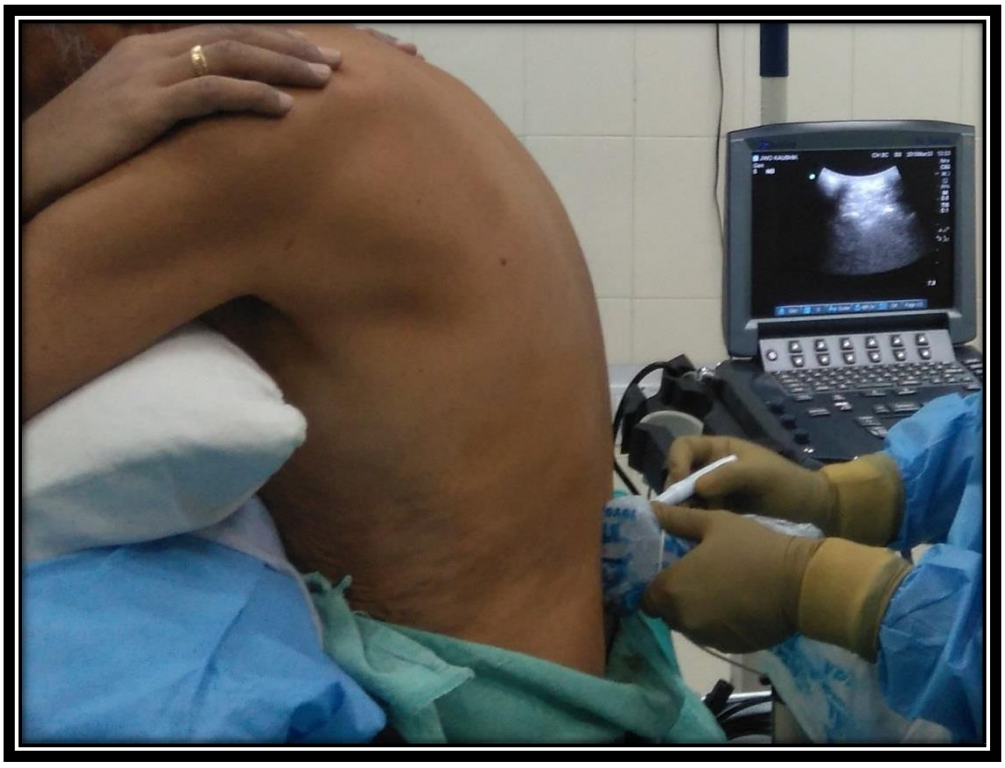


Fig- 14 probe positioned in PSO view and midpoint of long border of probe marked

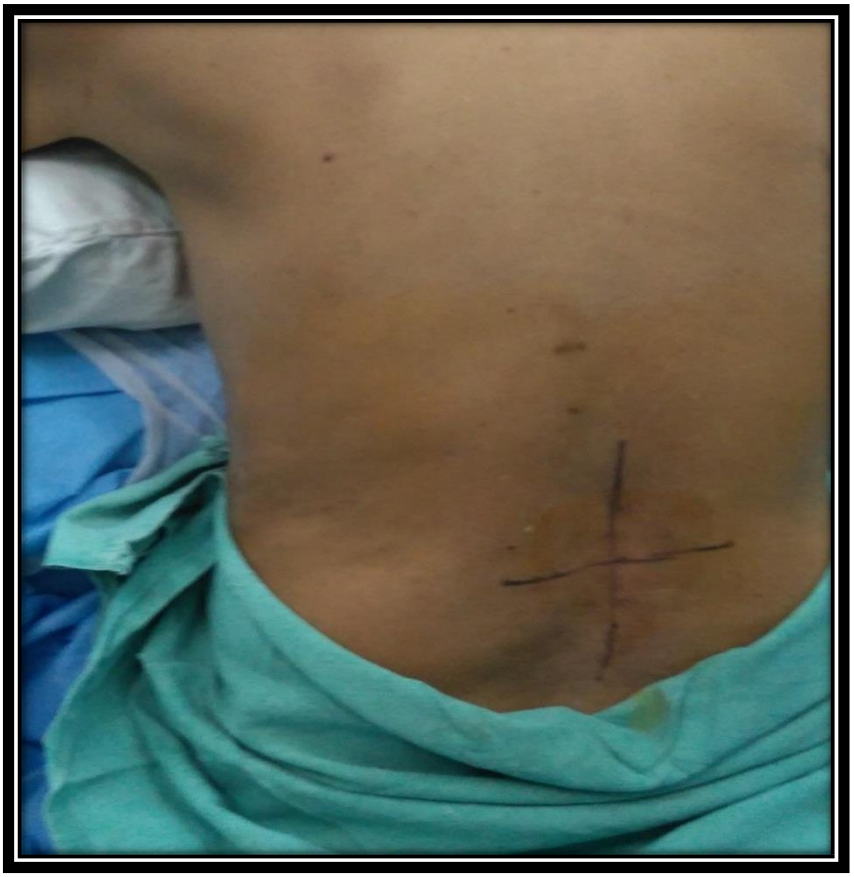


Fig-15 point of needle insertion at intersection point in paramedian approach

RESULTS

Statistical methods used

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean±standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square (χ^2) test was used for association between two categorical variables.

The formula for the chi-square statistic used in the chi square test is:

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

The subscript "c" are the degrees of freedom. "O" is observed value and E is expected value. C= (number of rows-1)*(number of columns-1)

The difference of the means of analysis variables between two independent groups was tested by unpaired t test.

The t statistic to test whether the means are different can be calculated as follows:

$$t = \frac{(\overline{x_1} - \overline{x_2}) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

where $\bar{x}_1$ = mean of sample 1

$\bar{x}_2$ = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

s_1^2 = variance of sample 1 = $\frac{\Sigma(x_1 - \bar{x}_1)^2}{n_1}$

s_2^2 = variance of sample 2 = $\frac{\Sigma(x_2 - \bar{x}_2)^2}{n_2}$

If the p-value was < 0.05, then the results were considered to be statistically

significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.23(IBM Statistics, Chicago, USA)and Microsoft office 2007.

Table 1 : Distribution of Age between Study Groups

Parameter	USG Group		LM Group		p value
	Mean	SD	Mean	SD	
Age(yrs)	59.3	9.30	62.5	6.20	0.625

Figure 1: Distribution of Age between Study Groups

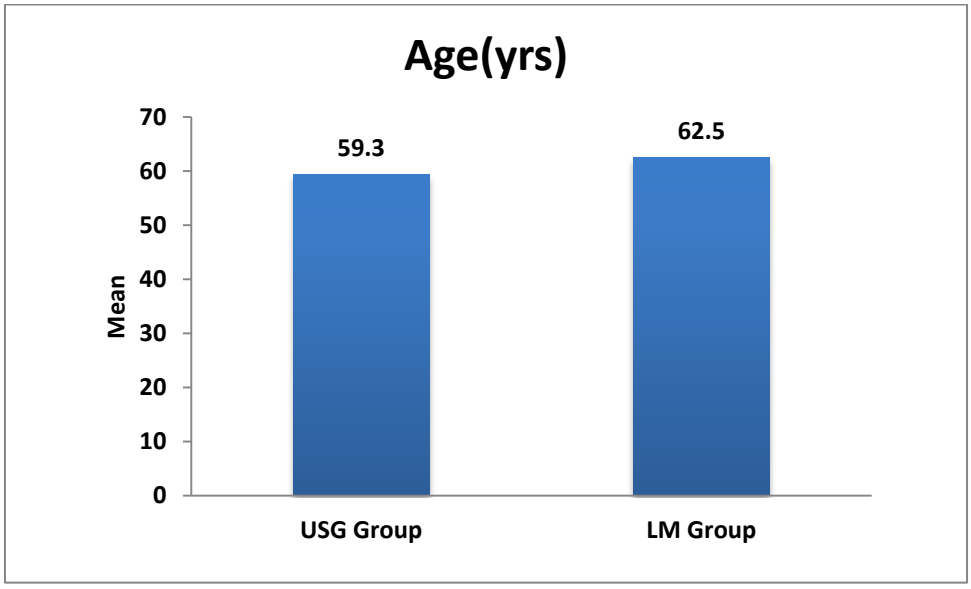


Table 2 : Distribution of Gender between Study Groups

Gender	USG Group		LM Group		p value
	N	%	N	%	
Male	33	82.5%	31	77.5%	0.567
Female	7	17.5%	9	22.5%	
Total	40	100.0%	40	100.0%	

Figure 2 : Distribution of Gender between Study Groups

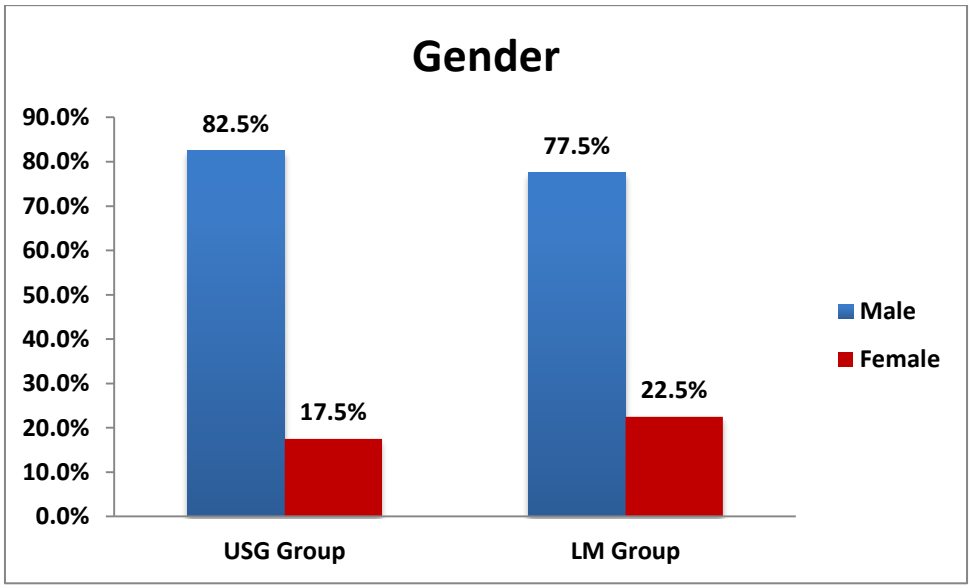


Table 3 : Distribution of ASA between Study Groups

ASA grade	USG Group		LM Group		p value
	N	%	N	%	
Grade I	18	45.0%	23	57.5%	0.008*
Grade II	22	55.0%	7	17.5%	
Total	40	100.0%	40	100.0%	

Note: p value* significant at 5% level of significance (p<0.05)

Figure 3 : Distribution of ASA between Study Groups

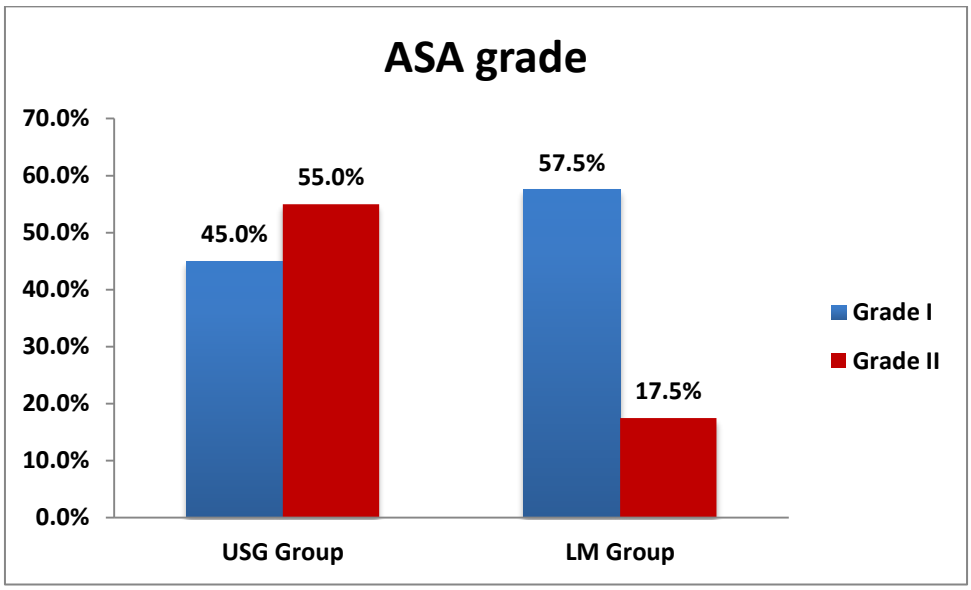


Table 4: Distribution of Weight between Study Groups

Parameter	USG Group		LM Group		p value
	Mean	SD	Mean	SD	
Weight	66.3	4.80	67.1	5.80	0.778

Figure 4 : Distribution of Weight between Study Groups

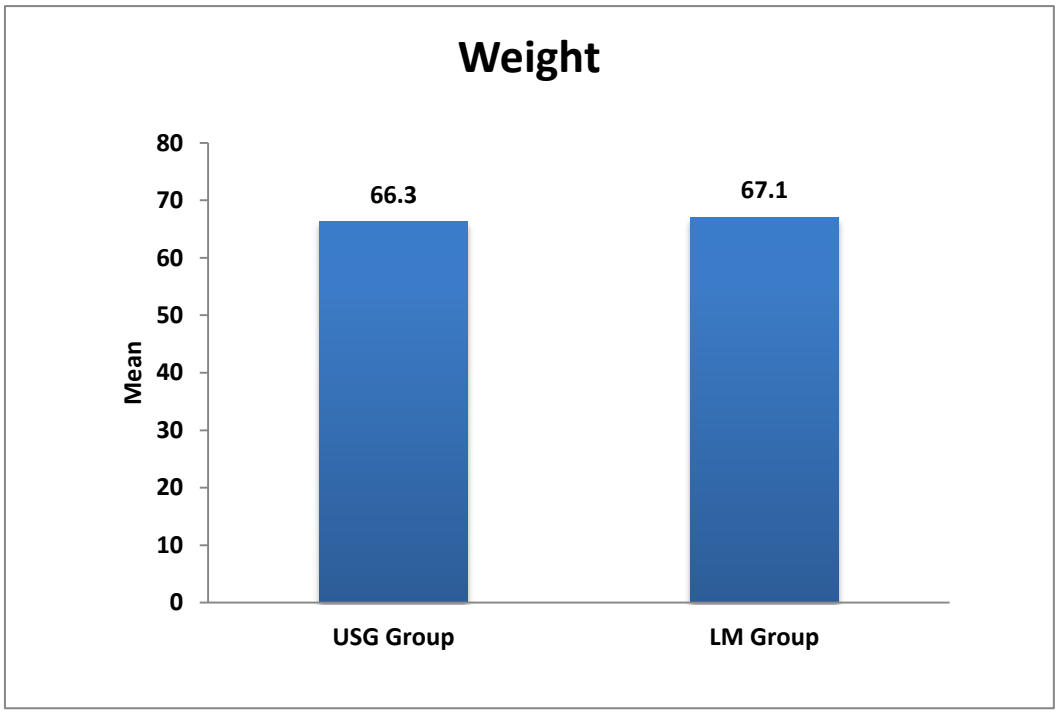


Table 5 : Distribution of Height between Study Groups

Parameter	USG Group		LM Group		p value
	Mean	SD	Mean	SD	
Height	159.3	6.90	160.8	5.60	0.251

Figure 5 : Distribution of Height between Study Groups

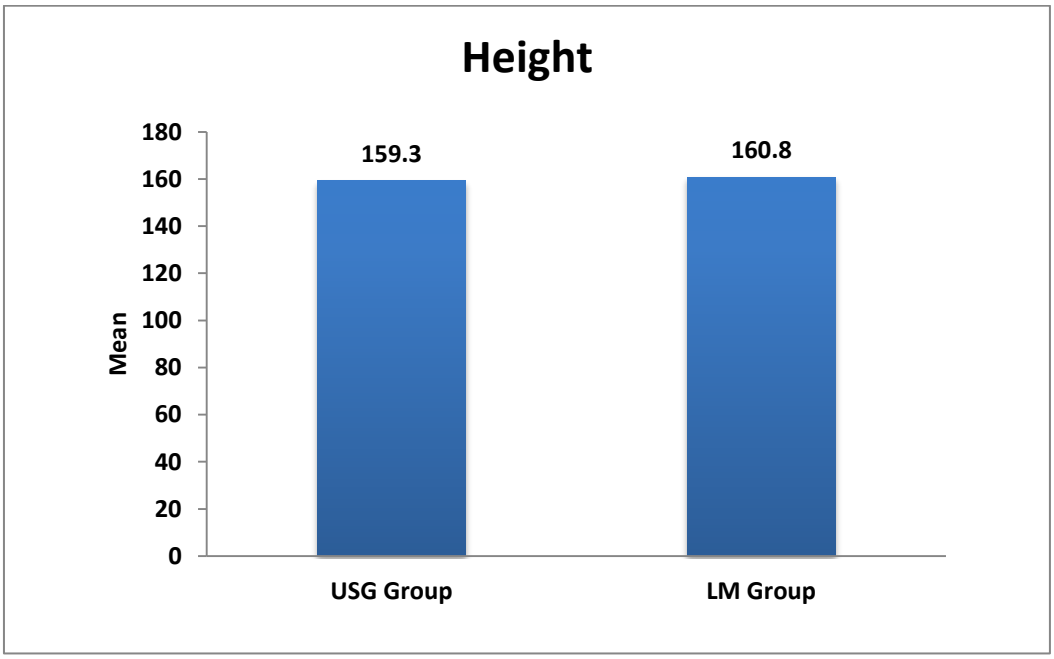


Table 6 : Distribution of No. of attempts between Study Groups

No. of attempts	USG Group		LM Group		p value
	N	%	N	%	
1	21	52.5%	10	25.0%	0.010*
2	15	37.5%	11	27.5%	
3	4	10.0%	8	20.0%	
4	0	0.0%	11	27.5%	
Total	40	100.0%	40	100.0%	

Note: p value* significant at 5% level of significance (p<0.05)

Figure 6 : Distribution of No. of attempts between Study Groups

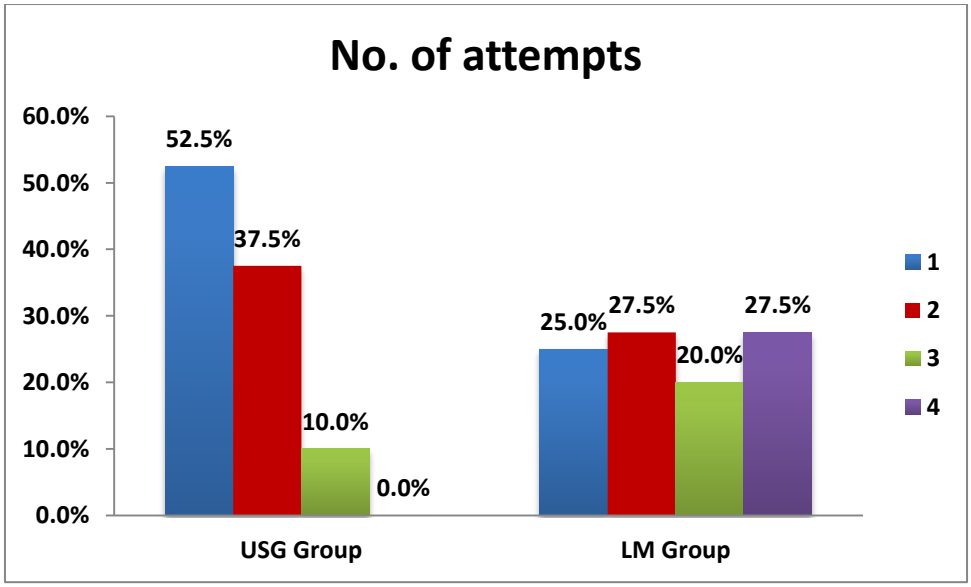


Table 7 : Distribution of Mean No. of attempts between Study Groups

Parameter	USG Group		LM Group		p value
	Mean	SD	Mean	SD	
No. of attempts	1.41	0.80	2.6	0.60	<0.001*

Note: p value* significant at 5% level of significance (p<0.05)

Figure 7 : Distribution of Mean No. of attempts between Study Groups

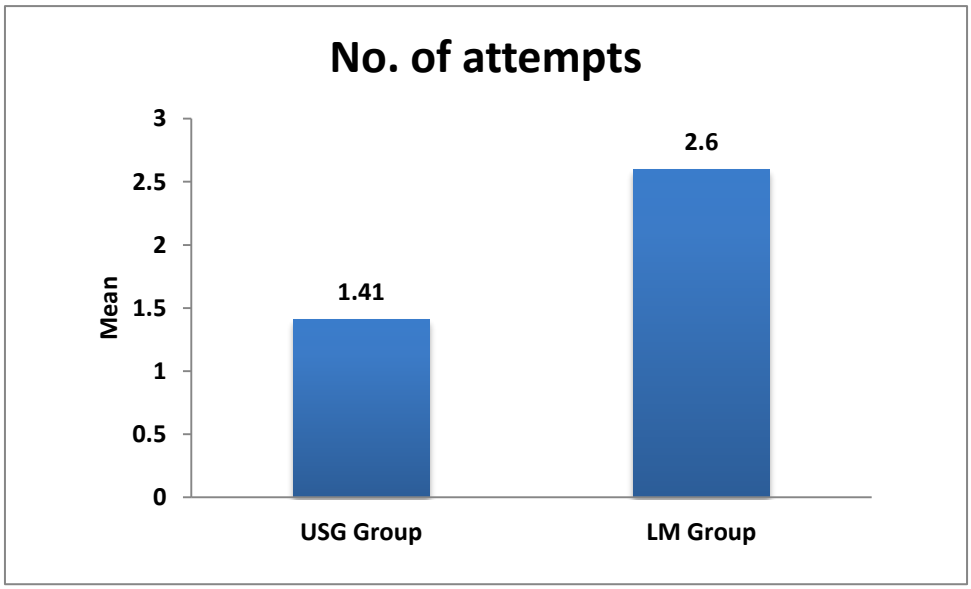


Table 8 : Distribution of No. of passes between Study Groups

No. of passes	USG Group		LM Group		p value
	N	%	N	%	
1	4	10.0%	5	12.5%	0.046*
2	12	30.0%	7	17.5%	
3	16	40.0%	15	37.5%	
4	6	15.0%	2	5.0%	
5	2	5.0%	11	27.5%	
Total	40	100.0%	40	100.0%	

Note: p value* significant at 5% level of significance (p<0.05)

Figure 8 : Distribution of No. of passes between Study Groups

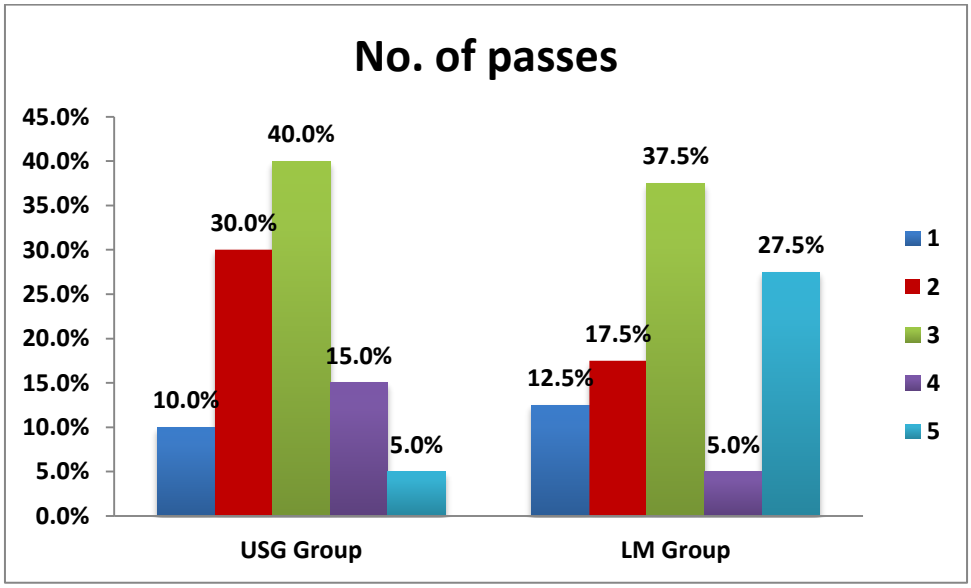


Table 9 : Distribution of Mean No. of passes between Study Groups

Parameter	USG Group		LM Group		p value
	Mean	SD	Mean	SD	
No. of passes	2.6	1.10	3.7	1.20	0.021*

Note: p value* significant at 5% level of significance (p<0.05)

Figure 9: Distribution of Mean No. of passes between Study Groups

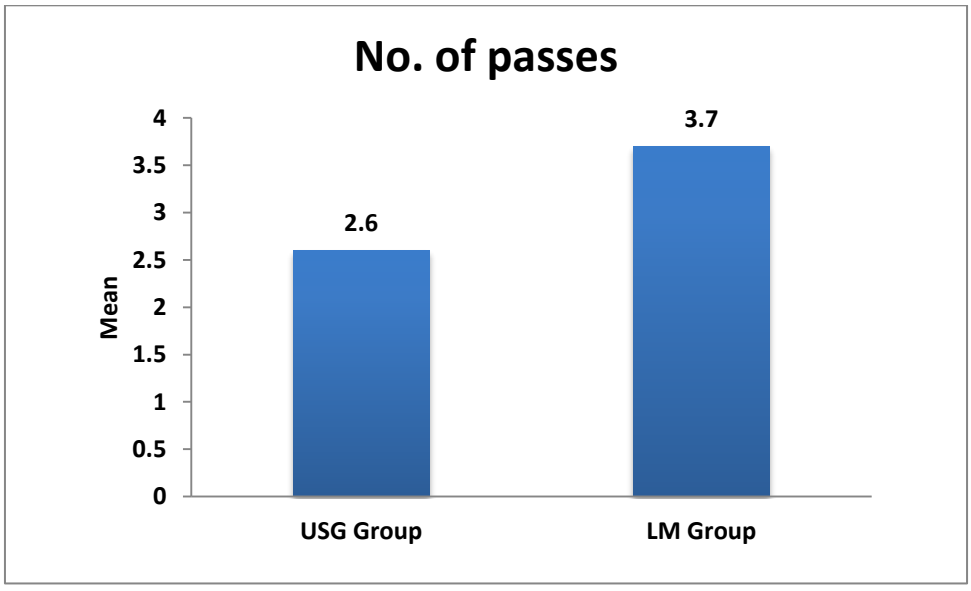


Table 10 : Distribution of Complications between Study Groups

Complications	USG Group		LM Group		p value
	N	%	N	%	
Blood in needle	3	7.5%	5	12.5%	0.020*
Failures	0	0.0%	10	25.0%	
Absent	37	92.5%	25	62.5%	
Total	40	100.0%	40	100.0%	

Note: p value* significant at 5% level of significance (p<0.05)

Figure 10: Distribution of Complications between Study Groups

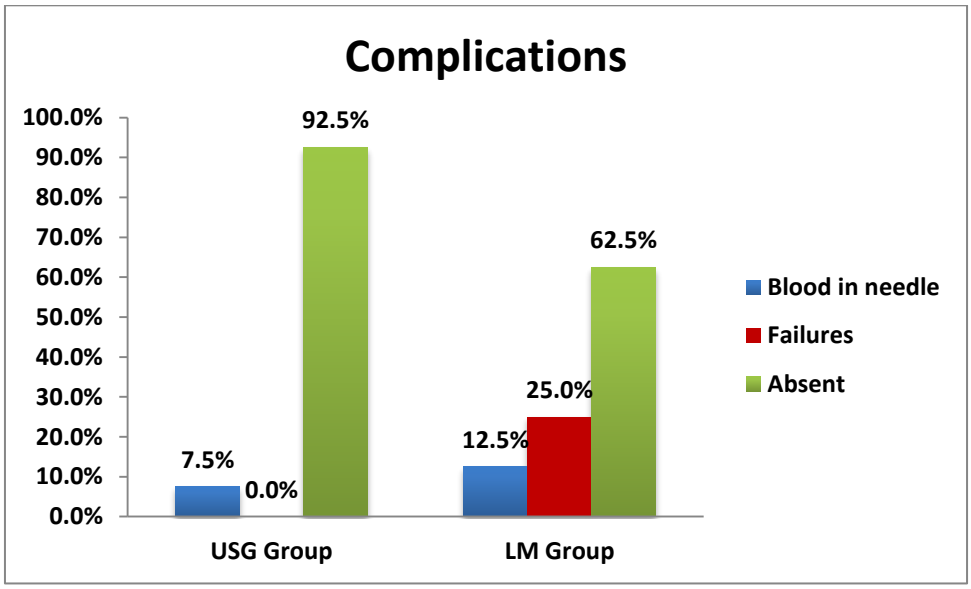
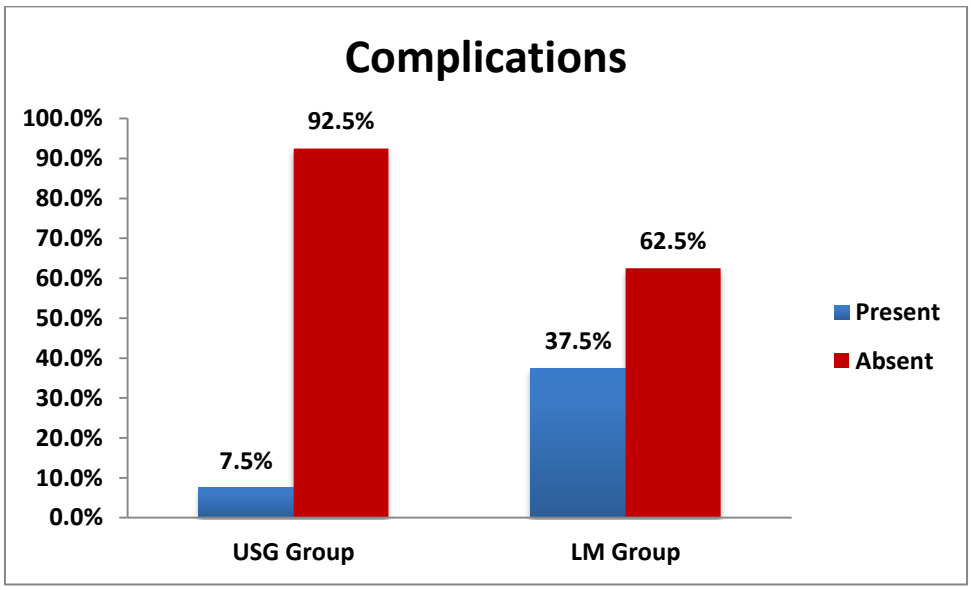


Table 11 : Distribution of Complications between Study Groups

Complications	USG Group		LM Group		p value
	N	%	N	%	
Present	3	7.5%	15	37.5%	0.001*
Absent	37	92.5%	25	62.5%	
Total	40	100.0%	40	100.0%	

Note: p value* significant at 5% level of significance (p<0.05)

Figure 11 : Distribution of Complications between Study Groups



DISCUSSION

The median or paramedian technique to spinal anaesthesia can be used.

The median method is most commonly used for spinal anaesthesia, although it may be challenging for senior individuals (age 50 and up, which was our study population) since they have calcified ligaments.

The calcification of the supraspinous and intraspinous ligaments makes passing thin guage spinal needles challenging.

In senior patients, the paramedian technique is a favourable alternative since it avoids the supraspinous and interspinous ligaments and instead targets the ligamentum flavum directly after going the paraspinal muscles.

Preprocedure USG imaging of thr spine reduces the technical difficulties one might face while giving spinal anaesthesia specially for people who have calcified ligaments or distorted anatomy.

By ensuring the correct space identification, it makes the procedure more safe and efficient , but there is insufficient evidence to support routine use of USG in all patients.

The quality of anatomical landmarks was found to be an independent predictor of performance in a study by **G de Filho colleagues** [35] . The other two predictors being:- A) The provider's level of skill in putting spinal or epidural anaesthesia with a single needle advancement and B) the suitability of patient positioning during the block placement.

Poor spinal architecture and a growing number of tries were also found to be independent predictors of difficulties after neuraxial block implantation.

Patints whose spine could easily be felt and tjose who can stretch their spine had a higher likelihood of first attempt success and ,as a result, fewer problems,

according to the study.

Grau and colleagues *[36]* compared the success percentage of the first needle pass in the control group and US guided group who had received CSE for LSCS.

The imitial pass success rate was 75% and 20% respectively, with a p value of 0.001.

Grau and colleagues *[35]* compared the success percentage of the first needle pass in three groups:

1. A comparision group
2. A group who has a pre-procedural ultrasound scan with a linear transducer.
3. A two-operator , real-time, USG freehand approach that earned CSE for LSCS.

The initial needle pass success rates were 100%, 70% and 40% respectively, with a p value of 0.03

Despite difficult to palpate landmarks in 38% of patients, **Chin and colleaugues** *[37]* prospective cohort study results demonstrated that by using a preprocedure USG assisted paramedian approach, the first time the needle was pricked and the first time needle crossed the ligamentum successfully, the rates were 84 % and 52% respectively. This fact is correlated by our study as well.

Between the control group and US aided group, **Vallejo and colleagues** *[42]* examined the number of needle passes for success and epidural failure rates.

With a p value of 0.01 and a p value of 0.02 respectively, the findings were (2% v/s 1%) and (5.5% v/s 1.6 %).

Chin and colleaugues *[17]* compared the first time the needle was pricked and the first time the needle crossed the ligamentum flavum successfully in cases of difficult anatomic surface landmarks patients using a conventional surface landmark guided

median technique (LM group) v/s a preprocedure US assisted median approach in a prospective randomized controlled trial (USG group).

The first time needle was pricked , the success rate was (32% v/s 65%) with a p value 0.001 and the first time ligamentum flavum was pierced, the success rate was (8 % v/s 27%) with a p value of 0.009.

The first time needle was pricked in patients aged 21 to 80 years was compared in a prospective randomized controlled trial study by **Y.C.Lim and colleagues** ***[45].***

The success rate of first needle effort was (64% v/s 52%) with a p value of 0.16 which was not statistically significant.

The first needle time needle was pricked and first time needle crossed the ligamentum flavum, success rate of the traditional surface landmark guided median technique (LM group) and the preprocedure USG assisted paramedian approach (USG group) were compared in a randomized controlled trial study by **K.Srinivasan and colleagues.**

The first time needle was pricked and first time ligamentum flavum was pierced, success rates were (60% v/s 84%) with a p value of 0.0075 and (40% v/s 28%) with a p value of 0.21 respectively, which were both statistically insignificant. Both groups had a failure rate of 12% and 4% ,respectively. Haemorrhagic tap was discovered in 2 patients in LM group and 0 patients in USG group.

In the present study, the first needle attempt and first needle success rates in conventional surface guided landmark guided paramedian technique (LM group) and the pre-procedure USG assisted paramedian approach (USG group) were evaluated in this study.The first needle attempt and first needle mean pass success rate were (1.41 v/s 2.6) with a p value of less than 0.001 and (2.6 v/s 3.7) in USG and LM respectively. Failure rate of 0% and 25% was observed in LM and USG groups

respectively. The rate of complications is 7.5% in USG group v/s 37.5% in LM group. 5 patients in LM group and 3 patients in USG group had haemorrhagic taps.

LIMITATIONS

There are a few drambacks in this study.

Firstly, the results reported in thi study were obtained by a novice (second year resident) under the supervision of an experienced anaesthesiologist, which may limit the reproducibility of the results. Furthermore, the learning curve has yet to be clearly defined, necessitating additional research.

Secondly, the procedure is hampered by the fact that needle insertion is not guided in real time by USG, but rather by skin markings created with USG's help.Most transducers in the United States currently lack marks indicating the midpoint. As a result , while marking a needle insertion point on the skin during a pre-procedure scan, there is a risk of error.

Thirdly, the participants in this study were aged patients who may have degenerative spinal illness with restricted interspinous and interlaminar gaps due to ossification of interspinous ligaments and hypertrophy of facet joints, respectively.
It may be physically difficult or impossible to guide an ultrasound beam or a needle into the spinal canal in such patients. When performing a US scan, there is a risk of tissue deformation, especially in the elderly, who have loose, mobile skin.

Fourthly, in a paramedian approach, skin marking doen not tell us the angle at which the needle needs to be pushed forward into the space. The probe is tilted both forwards and backwards, to provide an ideal image of interlaminar space and thus estimate this.

SUMMARY

The present study was conducted to compare the number of needle attempts and number of needle passes for successful dural puncture and first needle attempt and first needle pass success rate between group LM and group USG who underwent surgeries under spinal anaesthesia.

It also compares the incidence of complications like paraesthesia, haemorrhagic tap and failure in both groups.

The results for number of attempt in USG group was (mean +SD) 1.41+0.80 and LM group was 2.60+0.60. It was statistically significant.[$p<0.001$]

The results for number of passes in USG group was (mean +SD) 2.60+1.10 and LM group was 3.7+1.20. It was statistically significant.[$p=0.021$].

The first needle attempt success rate was 52.5% in group USG and 25% in group LM and first needle pass success rate was 10% in USG group v/s 12.5% in LM group.

The incidence of hemorrhagic tap in group USG was 3 out of 40 whereas in group LM it was 5 out of 40 cases. .Paresthesia was absent in both the groups.

In USG group no failures noted but in LM group 10 cases were noted and after maximum of five failure attempts alternative approach was used for successful dural puncture.

CONCLUSION

Pre-procedure US imaging in oldernpatients in the paramedian technique is possible and gives useful information, according to the findings of this study.

We thought it was an important skill to learn.

The study also found that imaging the spinal canal with ultrasound in the same patient category, where it was most beneficial, could be problematic.

Despite good US images of the spinal canal, there were a few occasions when technical difficulties arose.

As a result, more research into the learning curve of USG assisted central neuraxial blocking is needed.

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ANNEXURE – 1

IEC/NO-131/2019
22-11-2019

B.L.D.E. (DEEMED TO BE UNIVERSITY)
(Declared vide notification No. F.9-37/2007-U.3 (A) Dated. 29-2-2008 of the MHRD, Government of India under Section 3 of the UGC Act, 1956)
The Constituent College
SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The ethical committee of this college met on 13-11-2019 at 3-15 pm to scrutinize the synopsis of Postgraduate students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has been accorded Ethical Clearance

Title: A study to test the efficacy and safety of pre procedure ultrasound guided paramedian technique as compared to conventional landmark guided paramedian technique in administering spinal anesthesia

Name of PG student: Dr. Sankalpa Saha, Department of Anaesthesiology

Name of Guide/Co-investigator:, Dr. D G Talikoti, Professor, Department of Anaesthesiology

DR RAGHVENDRA KULKARNI
CHAIRMAN
Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College,BIJAPUR-586103

Following documents were placed before Ethical Committee for Scrutinization:

1. Copy of Synopsis / Research project
2. Copy of informed consent form
3. Any other relevant documents.

B.L.D.E.(Deemed to be University)
SHRI B.M.PATIL MEDICAL COLLEGE,VIJAYAPUR-586103

INSTITUTIONAL ETHICAL COMMITTEE

Date : 13-11-2019

1. Name of UG/PG Students/Researcher: Dr. Sankalpa Saha
2. Department : Anaesthesiology
3. Title : A Study To Test The Efficacy And Safety Of Pre Procedure Ultrasound Guided Paramedian Technique As Compared To Conventional Landmark Guided Paramedian Technique In Administering Spinal Anesthesia
4. Guide/Co-Guide/Principle Researcher: Dr. D G Talikoti, Professor
5. Date of Admission (PG Only) :

Observation :

- No ethical issues observed

I.E.C. Remarks : Ethical Clearance accorded/be Chairman after corrected revised version is submitted by stipulated time.

1. Any alternation in Synopsis protocol should be intimated to E.C. in writing for review & approval.
2. Any adverse effects to subject of the study should be intimated in writing to E.C.
3. If study is stopped or an included patient is out of study inform E.C. the same with reason.

Signature of the Committee Members :

1. Dr Raghavendra Kulkarni, Chairman
2. Dr Tejaswini Vallabha
3. Dr Akram Naikawadi
4. Dr P.B.Jaju
5. Dr Chandrashekhar Bhuyyar
6. Dr Pranesh Jahagirdar
7. Dr Manjunatha Aithala
8. Dr Satish Patil
9. Dr Mohammed Shannawaz

ANNEXURE – 2

SAMPLE INFORMED CONSENT FORM

B.L.D.E.(DEEMED TO BE UNIVERSITY)

SHRI B.M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA– 586103, KARNATAKA

TITLE OF THE PROJECT:

" A STUDY TO TEST THE EFFICACY AND SAFETY OF PRE PROCEDURE ULTRASOUND GUIDED PARAMEDIAN TECHNIQUE AS COMPARED TO CONVENTIONAL LANDMARK GUIDED PARAMEDIAN TECHNIQUE IN ADMINISTERING SPINAL ANESTHESIA"

PRINCIPAL INVESTIGATOR : **Dr. SANKALPA SAHA**

Department of Anaesthesiology

BLDE(Deemed to be University)

Shri.BM.Patil Medical College

Hospital & Research Centre,

Vijayapura–586103 Karnataka.

Email ID : sahasankalpa88@gmail.com

PG GUIDE : **Dr. D G TALIKOTI**

Professor,

Department of Anaesthesiology.

BLDE (Deemed to be University)

Shri B.M Patil Medical College Hospita

& Research Centre, Vijayapura–586103.

PURPOSE OF RESEARCH:

I have been informed that this study is **"A STUDY TO TEST THE EFFICACY AND SAFETY OF PRE PROCEDURE ULTRASOUND GUIDED PARAMEDIAN TECHNIQUE AS COMPARED TO CONVENTIONAL LANDMARK GUIDED PARAMEDIAN TECHNIQUE IN ADMINISTERING SPINAL ANESTHESIA"**

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

PROCEDURE:

I understand that I will be participating in the study **"A STUDY TO TEST THE EFFICACY AND SAFETY OF PRE PROCEDURE ULTRASOUND GUIDED PARAMEDIAN TECHNIQUE AS COMPARED TO CONVENTIONAL LANDMARK GUIDED PARAMEDIAN TECHNIQUE IN ADMINISTERING SPINAL ANESTHESIA"**

BENEFITS:

I understand that my wards participation in this study will help in finding out: **"A STUDY TO TEST THE EFFICACY AND SAFETY OF PRE PROCEDURE ULTRASOUND GUIDED PARAMEDIAN TECHNIQUE AS COMPARED TO CONVENTIONAL LANDMARK GUIDED PARAMEDIAN TECHNIQUE IN ADMINISTERING SPINAL ANESTHESIA"**

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. **Dr. SANKALPA SAHA** is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me.

And that a copy of this consent form will be given to me for keep for careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that **Dr. SANKALPA SAHA** will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly due to my participation in this study, such injury will be reported promptly,

then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date: **DR.SANKALPA SAHA**

(Investigator)

Patient's signature Witness to above signature

STUDY SUBJECT CONSENT STATEMENT:

I confirm that **Dr. SANKALPA SAHA** has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

(Participant)

Date

(Witness to above signature)

Date

ANNEXURE - 3

PROFORMA

STUDY: "A STUDY TO TEST THE EFFICACY AND SAFETY OF PREPROCEDURE ULTRASOUND GUIDED PARAMEDIAN TECHNIQUE AS COMPARED TO CONVENTIONAL LANDMARK GUIDED PARAMEDIAN TECHNIQUE IN ADMINISTERING SPINAL ANESTHESIA"

Name: Age: Sex:

Relationship:

IP Number:

Unit: Date of Admission: Date of Surgery:

Consent : Yes/No

Diagnosis :

Surgery :

ASA physical status : I / II

Height :

Weight :

BMI :

General Physical Examination :

Pulse rate :

BP:

CVS :

RS :

Any other significant findings :

Spinal column:-

Group assigned : LM ☐

USG ☐

Position :

Total number of needle passes -

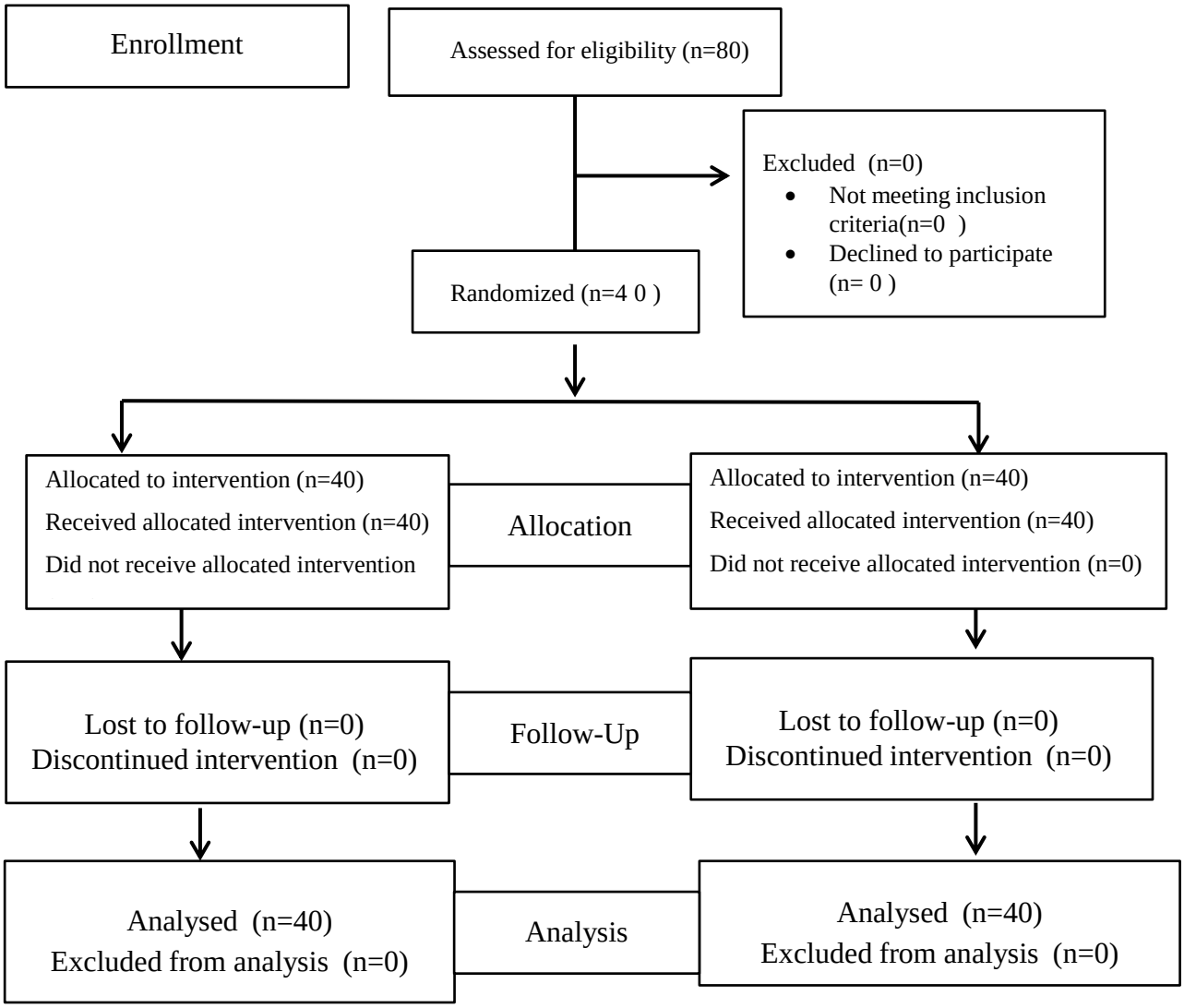
Total number of needle insertion attempts -

Incidence of radicular pain,paraesthesia -

Incidence of Periprocedural Pain-

ANNEXURE – 4

CONSORT 2010 Flow Diagram



ANNEXURE – 5

MASTER SHEET

LM GROUP

Sr.No	Age(yrs)	Sex	Weight(kg)	Height(cm)	ASA	Diagnosis	number of	number of passes	Complications
1	55	M	65	160	1	inguinal Hernia (lt)	2	2	Nil
2	51	M	54	155	1	fistula in Ano	1	2	Nil
3	62	M	82	174	2	Diabetic foot (rt)	2	3	Blood in needle
4	54	M	54	158	1	inguinal Hernia (lt)	1	1	Nil
5	51	M	58	156	2	Diabetic foot (rt)	2	2	Converted to GA
6	75	M	50	58	2	Gangrene foot (lt) Optd	1	2	Nil
7	60	M	70	160	2	Haemorrhoid	2	4	Nil
8	71	M	60	158	2	Inguinal Hernia (rt)	1	1	Converted to GA
9	50	M	65	162	2	inguinal Hernia (lt)	1	3	Nil
10	66	F	50	156	2	Uterovaginal prolapse	2	2	Nil
11	65	M	78	170	2	PIVD L4,5	2	3	Nil
12	51	M	65	166	1	Inguinal Hernia (rt)	1	1	Blood in needle
13	60	M	82	174	1	Hydrocele (lt)	1	2	Nil
14	55	M	50	155	1	Inguinal hernia B/L (lt>rt)	2	4	Nil
15	72	M	60	164	2	Haemorrhoid	1	3	Converted to GA
16	54	M	70	166	1	Hydrocele (rt)	2	4	Nil
17	70	M	59	160	2	Diabetic foot (lt)	1	2	Nil
18	65	M	78	170	2	LCS L4,5	2	2	Nil
19	70	F	58	152	2	Varicose veins B/L (lt>rt)	1	3	Converted to GA
20	70	M	53	158	2	Inguinal Hernia (lt)	1	1	Nil
21	78	M	60	156	2	Pyocele (lt)	1	2	Converted to GA
22	50	M	67	165	1	Hydrocele (lt)	2	3	Nil
23	51	M	61	158	1	Inguinal Hernia (lt)	1	2	Nil
24	65	M	70	166	2	Degloving injury leg (rt)	3	5	Blood in needle

25	56	M	68	160	1	Bimalleolar ankle fracture (lt)	1	2	Converted to GA
26	57	M	75	170	1	ACL tear knee (rt)	1	2	Nil
27	51	F	63	156	2	Distal ureteric calculus (lt)	1	1	Converted to GA
28	79	M	53	155	2	BPH for TURP	2	4	Nil
29	52	F	56	164	1	PIVD L4,5	3	3	Nil
30	53	M	72	174	1	PIVD L4,5	2	3	Converted to GA
31	72	M	64	152	2	Inguinal Hernia (rt)	1	3	Nil
32	50	M	84	158	1	Ureteric calculus (lt)	1	2	Nil
33	61	M	60	156	2	Fracture Tibia proximal (lt)	2	3	Nil
34	70	M	60	160	2	PAOD Lower limb (rt)	2	5	Blood in needle
35	58	M	60	162	1	fistula in Ano	1	3	Nil
36	50	F	48	150	2	Varicose veins (lt)	1	1	Nil
37	54	M	58	165	1	Inguinal Hernia (rt)	2	3	Converted to GA
38	52	F	68	160	1	Femur #	1	3	Nil
39	63	M	70	168	2	BPH For TURP	2	3	Blood in needle
40	68	M	78	170	2	ACL Tear Lt knee	4	5	Converted to GA

USG GROUP

Sr.No	Age(yrs)	Sex	Weight(kg)	Height(cm)	ASA	Diagnosis	number of attempts	number of passes	Complications
1	55	M	67	165	1	Varicose veins (lt)	2	3	Nil
2	63	M	65	160	2	Inguinal Hernia (rt)	4	5	NIl
3	51	F	71	164	1	Haemorrhoids	2	3	Nil
4	50	M	70	165	1	Fissure in ano	1	1	Nil
5	53	M	72	168	1	PIVD L4,5	3	2	Blood in needle
6	63	M	55	160	2	Inguinal Hernia (rt)	1	2	Nil
7	76	M	61	158	2	Inguinal Hernia (lt)	4	5	Nil
8	57	M	86	168	1	Lateral meniscus tear(lt)	2	5	Nil
9	53	F	65	156	2	Pilonidal Sinus	2	3	NIl
10	51	F	71	160	1	Haemorrhoids	3	4	Nil
11	67	M	57	158	2	Inguinal Hernia (rt)	1	3	Nil
12	54	M	66	160	1	Pilonidal Sinus	3	4	Nil
13	58	M	75	165	1	Incisional Hernia	2	3	Nil
14	54	M	80	168	1	Inguinal Hernia (rt)	3	3	Nil
15	59	M	51	156	2	Inguinal hernia (rt)	1	1	Nil
16	52	M	55	164	1	Varicose veins (lt)	2	3	Blood in needle
17	70	M	58	162	1	ACL Tear knee (rt)	2	3	Nil
18	55	F	50	156	1	Haemorrhoids	1	2	Nil
19	53	M	67	158	1	Varicose veins (lt)	4	5	
20	51	F	48	152	1	Incisional Hernia	1	1	Nil
21	63	M	56	160	2	PIVD L4,5	1	3	Nil
22	60	M	60	164	1	Inguinal Hernia(rt)	1	1	Nil
23	54	M	57	158	1	Pilonidal Sinus	1	2	Nil
24	51	M	55	160	2	Diabetic foot(lt)	3	4	Nil
25	69	M	54	166	2	Soft Tissue Swelling thigh(rt)	2	3	Nil
26	53	M	58	165	1	Ureteric calculus (rt)	1	3	Nil
27	61	M	60	162	2	Incisional Hernia	2	4	Blood in needle
28	57	M	57	156	2	BPH for TURP	3	3	Nil
29	55	M	60	164	1	Inguinal Hernia (rt)	1	1	Nil
30	63	F	50	154	1	Haemorrhoids	4	5	Nil

31	50	F	53	150	1	Ureteric calculus (rt)	4	5	Nil
32	52	M	63	166	1	Pilonidal Sinus	2	3	Nil
33	65	M	67	168	2	Fissure in ano	2	4	Nil
34	56	M	58	162	1	Inguinal Hernia (lt)	3	4	Nil
35	50	F	54	152	1	Ureteric calculus (rt)	1	1	Nil
36	57	M	65	168	1	PIVD L4,5	2	3	Nil
37	60	M	58	160	1	Inguinal hernia (lt)	4	5	Nil
38	60	M	80	165	1	BPH for TURP	2	3	Nil
39	69	F	70	158	2	Inguinal Hernia	1	3	Nil
40	62	M	65	1560	1	Femur #	1	3	Nil