TO COMPARE THE EFFECTIVENESS OF REAL-TIME ULTRASOUND GUIDED SPINAL ANAESTHESIA VERSUS PRE-PROCEDURAL ULTRASOUND GUIDED SPINAL ANAESTHESIA IN OBESE PARTURIENTS:

A RANDOMIZED CONTROL TRIAL

BY

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DISSERTATION SUBMITTED TO

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Under the guidance of

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"The practice of medicine is an art, not a trade, a calling, not a business. A calling in which your heart will be exercised equally with your head.” - William Osler

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ABBREVIATIONS

AG – Anatomically Guided

ASA – American Society of Anaesthesiologists

BMI – Body Mass Index

CI – Confidence Interval

CSF – Cerebrospinal Fluid

IQR – Interquartile Range

MAP – Mean Arterial Pressure

PPUS – Pre-Procedural Ultrasound

PUS – Pre-Procedural Ultrasound

RUS – Real-Time Ultrasound

US – Ultrasound

USG – Ultrasound-Guided

USRTG – Ultrasound Real-Time Guidance

VAS – Visual Analog Scale

ABSTRACT

BACKGROUND: Spinal anesthesia is the preferred technique for elective cesarean sections. However, standard landmark-guided approaches can be challenging in obese parturients due to difficulty in identifying anatomical landmarks, leading to multiple attempts and increased complication risks. Neuraxial ultrasound-guided (USG) techniques offer a promising solution by enhancing procedural accuracy and efficiency.

AIM: The Aim of our study is to compare the effectiveness of real-time ultrasound-guided (RUS) spinal anesthesia versus pre-procedural ultrasound-guided (PPUS) spinal anesthesia in obese parturients posted for elective cesarean sections.

METHODOLOGY: A total of 80 obese parturients (BMI >30 kg/m2, ASA II-III) who were scheduled for elective cesarean sections were randomized into two groups: Group PPUS and Group RUS. Primary outcomes included the number of attempts, needle passes, and time taken for successful dural puncture. Secondary outcomes included intervertebral space identification time, successful analgesia time, and hemodynamic stability. Statistical analysis was performed using SPSS v20, with $p<0.05$ considered significant.

RESULTS : The Group RUS demonstrated significantly fewer attempts (1.7±0.6 vs. 4.5±1.0, $p<0.05$) and needle passes (2.1±1.0 vs. 5.7±1.3, $p<0.05$) compared to the Group PPUS . The mean time for intervertebral space identification was shorter in the Group RUS (60.3±25.6 vs. 160.8±45.2 seconds, $p<0.05$), as was the time for successful lumbar puncture (93.6±30.0 vs. 249.2±63.3 seconds, $p<0.05$). Both groups achieved a 100% success rate in spinal anesthesia.

CONCLUSION : Both Group RUS and Group PPUS techniques are effective for spinal anesthesia in obese parturients. However, RUS was significantly better[i] technique in reducing the number of attempts, needle passes, and procedural time, making it a more efficient and precise.

Keywords: Spinal anesthesia, Obese parturients, Real-time ultrasonography, Pre-procedural ultrasound, Cesarean section.

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INTRODUCTION

Spinal anaesthesia is the preferred technique for elective cesarean sections, commonly performed using a "blind" approach guided by surface landmarks. However, identifying these landmarks can be challenging in obese parturients, often resulting in multiple attempts. Such repeated attempts are associated with increased risks of complications, including paraesthesia, spinal hematoma, and post-dural puncture headache. In obese parturients, the manual palpation technique becomes particularly difficult due to the obscured bony landmarks. Preprocedural neuraxial ultrasound-guided (USG) assessment offers a promising solution by improving spinal anaesthesia performance and reducing the number of attempts required in this high-risk population.

Obesity is becoming more common among pregnant women, with studies indicating maternal obesity rates ranging from 20% to 35% worldwide, which makes spinal anaesthesia in this population an escalating challenge. The pre-procedural neuraxial ultrasound technique has emerged as an effective method for performing spinal anaesthesia by accurately delineating spinal anatomy and facilitating successful needle insertion.[2,3] Routinely , the anatomical landmark-guided method has been used to locate the subarachnoid space however, this approach can be unreliable in patients with obesity, edema, or anatomical variations, often resulting in incorrect identification of lumbar interspaces. Multiple needle insertion attempts not only increase patient discomfort and stress but also increases the risk of neuronal damage. Neuraxial ultrasound blockade is a relatively recent advancement in regional anaesthesia as it addresses these challenges by providing a precise and reliable assessment of spinal anatomy. In pre-procedural USG- guided technique needle is inserted blindly after confirming the surface anatomical landmarks as compared to Real time USG (RUS) image accusation of the spinal needle which seems to be a more efficient and preferable option.

Real-time ultrasound (RUS) facilitates precise identification of the needle insertion site and trajectory for spinal anaesthesia. However, no studies have directly compared the efficacy of RUS-guided spinal anaesthesia with pre-procedural ultrasound (PPUS)-guided spinal anaesthesia in obese parturients. Ultrasound-guided techniques not only enhance procedural success but also play a crucial role in training environments, assisting novice anaesthesiologists in gaining proficiency in administering spinal anaesthesia.

Obese parturients face a heightened risk of complications during spinal anaesthesia because of anatomical alterations, excess adipose tissue, and difficulties in achieving proper positioning, highlighting the importance of adopting more effective methods such as RUS and PPUS. Our study aims to evaluate and compare these two modalities by assessing primary variables, including the number of attempts, needle passes, and time required for successful dural puncture. Secondary variables include the median time to identify the intervertebral space, achieve successful analgesia, and a complete lumbar puncture. A failed lumbar puncture will be defined as the absence of CSF fluid.

REVIEW OF LITERATURE

In a study conducted by Ansari T et al., (2014) they assessed US guided spinal anaesthesia in obstetrics. In this study, the average procedure time, number of skin punctures, and needle passes were comparable between the ultrasound guided technique and landmark technique. There was no statistically significant difference in the number of patients achieving successful spinal anaesthesia after a single puncture. These findings suggest that in patients with easily palpable spines, spinal anaesthesia performed by anaesthetists experienced in both ultrasound and landmark techniques does not significantly benefit from ultrasound in terms of success rates, procedure time, or number of attempts.[29]

Srinivasan K et al (2015) conducted a randomized single blinded study. They studied conventional landmark guided midline technique versus pre procedural ultrasound guided paramedian techniques in spinal anaesthesia in100 patients who underwent elective hip joint replacement surgeries. The study showed routine use of paramedian spinal anesthesia in the orthopedic patient population who underwent joint replacement surgery, guided by pre procedural ultrasound examination, significantly decreases the number of passes and attempts needed to enter the subarachnoid space.[30]

M. Creaney, et al (2016) conducted a randomised trial on Ultrasound to identify the lumbar space in female patients with difficult bony landmarks presenting who were posted for elective caesarean section under spinal anaesthesia with 20 parturients. The study showed that the use of ultrasonography to locate the needle insertion point reduced the number of needle passes in parturients with difficult lumbar spinous processes who underwent elective caesarean section under spinal anaesthesia. Its use did not prolong overall procedural time.[31]

In a study conducted by Chong SE et al., (2017) they assessed the Real-time US guided paramedian spinal anaesthesia to evaluate the success rate. Real-time ultrasound guidance enhances the effectiveness of paramedian spinal anaesthesia by increasing success rates, minimizing the number of attempts, improving single-pass success, and reducing the time required for dural puncture. Additional research is needed to confirm its value in high-risk populations, including obese and elderly patients.[3]

In a study conducted by Elsharkawy H et al., (2017) they assessed the real time US guided spinal anaesthesia in patients with anatomical difficulties. In this trial they involved 38 patients both in Ultrasound (US) and control groups and they achieved a 100% block success rate. There was no significant difference in the number of attempts between the groups ($P < 0.83$), while the US group demonstrated slightly longer time to block ($P < 0.0653$) and marginally higher patient satisfaction ($P < 0.09$). Anaesthesiologists rated the US-guided procedure, as more difficult than the control group ($\chi^2 = 10.85$, $P < 0.001$). These findings suggests that while real-time US guidance for spinal anaesthesia in challenging patients was associated with longer procedure times, fewer needle insertion attempts, and higher satisfaction, the differences were not statistically significant.[32]

Dhanger S, et al (2018) compared the use of landmarks to that of a pre-procedural ultrasonography assisted midline technique for locating the subarachnoid space in 100 parturients undergoing elective cesarean sections. The number of attempts needed to perform a lumbar puncture on a parturient was shown to be much lower when pre-procedural ultrasound was used instead of the standard landmark technique.[33]

In a study conducted by Narkhede HH et al., (2019) they assessed the anatomical landmark guided midline versus pre-procedural US guided midline technique for spinal anaesthesia. The ultrasound-guided (UG) group demonstrated a significantly higher rate of successful dural puncture on the first needle insertion attempt (90% vs. 50%, $P < 0.05$) compared to the anatomical-guided (AG) group. The mean number of needle passes was significantly lower in the

UG group (1.07 vs. 1.90, $P < 0.05$), and only 3.3% of UG patients required more than three midline attempts. Procedure time was notably shorter in the UG group (2.25 minutes vs. 4.35 minutes), while VAS scores for pain were comparable and not found to be statistically significant between groups. These findings underscore the value of preprocedural ultrasound imaging in facilitating central neuraxial blockade, particularly in elderly patients with challenging anatomical landmarks.[34]

In a study conducted by Park SK et al., (2019) they assessed the US assisted versus landmark guided paramedian spinal anaesthesia in elderly. The ultrasound-assisted paramedian technique significantly reduced the number of needle passes (median [IQR]: 1.0 [1.0–2.0] vs. 4.5 [2.0–7.0]) and achieved a higher first-pass success rate (65.0% vs. 17.5%; both *p* < 0.001) compared to the landmark-guided technique. Although the ultrasound approach required more time to establish landmarks (117.5 s [85.5–150.7 s] vs. 17.5 s [14.0–23.0 s]) and total procedure time (181.5 s [133.5–212.5 s] vs. 92.5 s [62.5–176.5 s]) it significantly shortened the time to administer spinal anaesthesia (39.5 s [31.5–71.3 s] vs. 77.0 s [45.8–136.5 s]; and $p < 0.001$). Additionally, the ultrasound group experienced lower procedural pain scores 3 [2–4] vs. 4 [4–6]; *P* = 0.009 and discomfort scores 2 [0–3] vs. 5 [2–6]; $p = 0.003$. These findings highlight the advantages of neuraxial ultrasonography in reducing needle manipulations, pain, and discomfort, making it a valuable tool for facilitating spinal anaesthesia in elderly patients.[35]

In a study conducted by Mengzhu L et al., (2019) they assessed the US assisted technology versus conventional landmark location method for spinal anaesthesia in obese patient undergoing caesarean section. The study highlights the benefits of pre procedural ultrasound examination in facilitating spinal anaesthesia for obese parturients (BMI 35–43 kg/m^2) in the lateral position. The pre procedural ultrasound group demonstrated a significantly higher first-attempt success rate, fewer cases requiring more than 10 needle passes, fewer puncture attempts, shorter procedure times (including needle site identification), and higher patient satisfaction scores compared to the landmark group. However, for patients with BMI 30–34.9 kg/m², there were no significant differences in first-attempt success rates or procedure times, except for longer needle site identification time in the ultrasound group. These findings suggest that ultrasound guidance is particularly advantageous for patients with higher BMI, enhancing procedural efficiency and success while improving patient experience.[36]

In a study conducted by Uyel Y et al., (2020) they assessed the pre procedural US versus landmark guided spinal anaesthesia. The study demonstrated that pre procedural ultrasonography significantly enhances the technical performance of spinal anaesthesia in elderly patients with challenging anatomy. The first-attempt success rate for accessing the subarachnoid space was notably higher in the ultrasound group (74.4% vs. 53.8%, $p = 0.008$). Patients in the ultrasound group also required fewer needle insertion attempts (median 1 vs. 2, $p = 0.038$) and redirections (median 2 vs. 3, $p = 0.028$) compared to the landmark-guided group. However, no significant differences were observed between the groups regarding total procedure time, pain scores, patient satisfaction, or complications.[37]

In a study conducted by Ravi PR et al., (2021) they assessed the real-time US guided spinal anaesthesia versus pre-procedural US guided spinal anaesthesia in obese patients. The Group RUS demonstrated significantly better outcomes compared to the PUS group, with a median number of attempts of 2 (IQR 1–2) versus 4 (IQR 2–4) ($P< 0.001$). Additionally, the Group RUS required fewer passes, less time to identify the space, and shorter time for successful lumbar puncture compared to the PUS group. Overall, the PUS group exhibited longer times and higher attempts for these procedures, highlighting the efficiency of the RUS approach.[38]

In a study conducted by Chen L et al., (2022) they assessed the Real time US guided versus US assisted spinal anaesthesia. The first-attempt success rate (80.7% vs. 52.6%; 95% CI for the difference, 11.6–44.6) and first-pass success rate (63.2% vs. 31.6%; 95% CI for the difference, 14.2–49) were significantly higher in the ultrasound-assisted spinal anaesthesia (USAS) group compared to the ultrasound real-time guidance (USRTG) group (both P = .001). The number of attempts (1 [1–1] vs. 1 [1–3]; P = .001) and median passes (1 vs. 3; P < .001) were significantly lower in the USAS group. The USRTG group demonstrated a shorter locating time 175 seconds vs. 315 seconds; p < .001 , but required a longer procedure time 488 seconds vs. 200 seconds [p < .001 and total time 694 seconds vs. 540 seconds; p = .036. Adverse reactions and complications were comparable between the groups. However, patient satisfaction scores were significantly higher in the USAS group, with more patients reporting high satisfaction (score of 3–5, P = .008). Anaesthesiologists rated the procedure in the USRTG group as "more difficult" (P = .008). In elderly patients with hip fractures, the USAS technique outperforms the USRTG approach due to its higher success rate, shorter procedure time, greater patient satisfaction, and less difficult for anaesthesiologists. Therefore, the USAS technique appears to be the more suitable option for this patient population.[39]

In a study conducted by Park SK et al., (2022) they assessed the US assisted spinal anaesthesia. The ultrasound-assisted paramedian approach demonstrated higher efficiency compared to the midline approach for spinal anaesthesia. The paramedian group required significantly fewer needle passes (median 1 [IQR 1–2] vs. 3 [2–6]; p < 0.001) and achieved higher first-pass and first-attempt success rates (58.9% vs. 21.4%; 91.1% vs. 53.6%; both p < 0.001). Additionally, the total procedure time was notably shorter in the paramedian group (113 [72.5–146.5] seconds vs. 196 [138–298.5] seconds; p< 0.001). Sonographic image quality was rated as good in 94.6% of paramedian sagittal oblique views compared to 54.5% of transverse median views. Importantly, there were no significant differences in the incidence of periprocedural complications between the two groups. These findings suggest that the paramedian approach is a more effective and efficient option for preprocedural ultrasound-guided spinal anesthesia.[40]

In a study conducted by Coviello A et al., (2023) they assessed the impact of US assisted method on success rate of spinal anaesthesia. In this study, 88 patients were assigned to the Landmark-guided spinal anaesthesia group (Group A) and 91 to the Ultrasound-Assisted spinal anaesthesia group (Group B). Results showed that in Group B, the number of attempts by trainees ($p < 0.005$), procedure time ($p < 0.001$), and patient discomfort ($p < 0.001$) were significantly reduced compared to Group A. These findings highlight that Ultrasound-Assisted single-shot spinal anaesthesia performed by novice trainees decreases the number of attempts, complication rates, procedural pain, overall patient discomfort and improving procedural outcomes.[41]

CLINICAL ANATOMY

SPINAL ANAESTHESIA

Spinal anesthesia involves injecting a local anesthetic into the subarachnoid space, temporarily interrupting nerve transmission. It is commonly preferred for cesarean sections, especially in elective procedures, because it reduces risks associated with general anaesthesia, such as aspiration, difficult airway management, and negative effects on the foetus.

HISTORY

The term "spinal anesthesia" was coined by Leonard Corning in 1885 during his experiments with cocaine to address neurological issues. His initial trials, beginning with a dog, resulted in temporary hind limb paralysis. Later, he administered the anesthesia to a human subject, initially with no effect, but successfully achieving numbness on a subsequent attempt. Corning's early work suggested the dog received spinal anesthesia, while the human likely received an epidural. August Bier introduced modern spinal anesthesia in 1899 when his assistant. Dr. Hildebrandt, underwent a lumbar puncture. Despite initial difficulties, they persisted, and within 23 minutes of injection, observed complete sensory and motor block.

However, it is not without its challenges, with maternal hypotension being the most common complication. The hypotension is caused by preganglionic sympathetic blockade, which induces vasodilation through spinal block-induced sympatholysis. As a result, the drop in systolic blood pressure can reduce uteroplacental perfusion, potentially compromising fetal oxygenation and leading to hypoxia and acidosis.[5]

Hypotension following cesarean delivery under spinal anaesthesia has been a focus of medical research for over 50 years. Various studies report its incidence to range widely, from 7.4% to 74.1%, highlighting the variability and prevalence of this complication in obstetric anesthesia.[6]

One of the most difficult difficulties in obstetric anaesthesia is determining the most efficient treatment plan to ensure haemodynamic stability during spinal anaesthesia for caesarean delivery.

ANATOMY

Performing spinal anaesthesia requires an in-depth understanding of three-dimensional spinal anatomy. The vertebral canal, which extends from the foramen magnum to the sacral hiatus, encases the spinal cord and nerve roots. It includes seven cervical, twelve thoracic, and five lumbar vertebrae, along with the sacrum and coccyx, which are fused false vertebrae. The adult spine has four curvatures that play a key role in the distribution of local anaesthetic within the subarachnoid space. Additionally, the bony structure of the vertebral canal can act as a barrier to spinal needle advancement during the procedure.

The vertebrae are held together by Intervertebral discs and series of overlapping ligaments namely.

- Anterior longitudinal ligament
- Posterior longitudinal ligament
- Ligamentum flavum
- Interspinous ligament
- Supraspinous ligament

There are certain typical palpable landmarks that may correspond to a specific level, such as the most prominent spinous process, which is commonly associated with the seventh cervical vertebra. The inferior angle of the scapula is commonly aligned with the seventh thoracic vertebra. The Tuffier line, which typically intersects the vertebral column at the L4-L5 intervertebral space, serves as the main landmark for needle placement during spinal anesthesia. A thorough understanding of the anatomy in this region is crucial for the successful administration of neuraxial block by the anesthetic provider.

The intervertebral canal consists of:

1. Roots of spinal nerves

2. Spinal membrane with the spinal cord and cerebrospinal fluid

3. Vessels, fat and areolar tissue

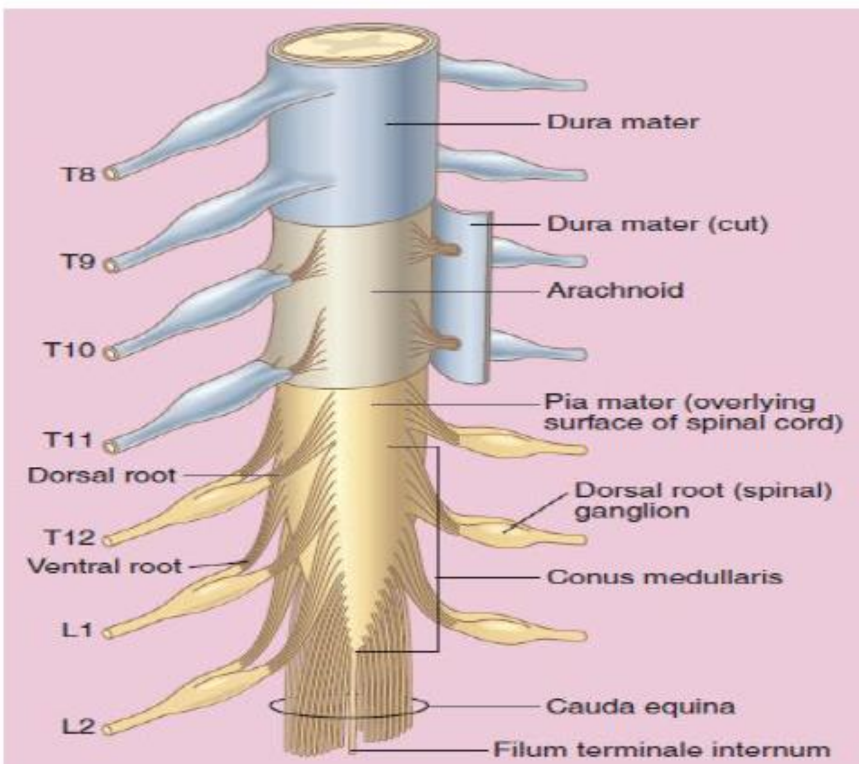


Figure 1: Coverings of spinal cord

The spinal cord begins at the medulla, at the upper border of the atlas, and extends down to the conus medullaris. Due to the differing growth rates of the vertebral canal and spinal cord, the cord ends much higher than the bony canal. In fetuses, the cord spans the full length of the canal, while in infants, it terminates at the upper border of L3, and in adults, at the lower border of L1. Below the conus, the nerve roots align parallel to the axis, forming a structure resembling a horse's tail, known as the cauda equina. The meninges, composed of three layers of connective tissue, surround and protect the spinal cord.

- Dura mater
- Arachnoid mater
- Pia mater

The dura mater is a strong, fibroelastic membrane that extends from the lower border of the second sacral vertebra to the upper margins of the foramen magnum. This protective dural layer is traversed by the spinal cord's anterior and posterior nerve roots. The arachnoid mater, a thin, translucent sheath that clings firmly to the dura's inner surface and provides impermeability, is located beneath it. The primary pharmacologic barrier that stops drugs from moving from the epidural to the subarachnoid space is the arachnoid mater.

The pia mater is a highly vascular layer that closely adheres to the spinal cord, extending fine septa into its structure. At its inferior end, the pia mater continues as the filum terminale, which passes through the distal end of the dural sac and attaches to the periosteum of the coccyx. The cerebrospinal fluid (CSF), produced by the choroid plexus in the lateral, third, and fourth ventricles, fills the subarachnoid space between the arachnoid mater and pia mater. This space contains the spinal nerve roots and the denticulate ligament. To avoid damaging the spinal cord, which terminates at the lower border of the first lumbar vertebra, lumbar punctures are typically performed below the second lumbar vertebra, specifically at the L3-L4 interspace.

Blood supply of spinal cord

Three longitudinal arterial channels supply the spinal cord

- One anterior spinal artery
- Two posterior spinal arteries

The vertebral arteries serve as the main blood supply to the spinal arteries, though their reach is limited to the cervical portion of the spinal cord. The posterior spinal arteries, which originate from the cranial vault, supply the dorsal (sensory) section of the spinal cord through extensive collateral anastomotic connections from the subclavian and intercostal arteries. As a result, this region of the spinal cord is largely protected from ischemic injury. Additionally, the spinal arteries are further supplied by radicular arteries that run alongside the roots of the spinal nerves.

A limited number of radicular arteries are notably larger, with the most significant being the arteria radicularis magna, also known as the artery of Adamkiewicz. This artery arises from the aorta in the lower thoracic or upper lumbar region and may supply blood to up to the lower two-thirds of the spinal cord. Injury to this artery can lead to anterior spinal artery syndrome. Additionally, there is no anastomosis between the anterior and posterior spinal arteries, meaning that thrombosis in either of these arteries can result in spinal cord infarction.

Venous drainage of the spinal cord is through six longitudinal venous channels.

- Unpaired anteromedian and posteromedian venous channels
- Two paired anterolateral and posterolateral channels.

The venous channels connect to form a plexus, which drains into segmental veins such as the vertebral veins, azygos veins, lumbar veins, and lateral sacral veins. These veins are visible in the lateral epidural region and ultimately drain into the azygos venous system.

Spinal nerves

Below the dorsal root ganglion, nerve roots combine to form 31 pairs of spinal nerves (8 cervical, 12 thoracic, 5 lumbar, 5 sacral, and 1 coccygeal). In a supine patient, sensory fibers located at the posterior aspect of the subarachnoid space are particularly susceptible to hyperbaric local anesthetic solutions, as they tend to lie dependent. The dura is thinned in this region, known as the dural sleeve, which facilitates the penetration of local anesthetics. The onset of spinal block occurs when local anesthetics block sodium ion conductance in this area. The skin area innervated by each spinal nerve is called a dermatome, and the afferent fibers from each dermatome are located more rostrally than their corresponding vertebral level, as the lower nerve roots descend before exiting the intervertebral foramen.

CSF is secreted at rate of 0.3 to 0.5 ml/min. The average volume ranges from 120 to 150 ml, 25 ml of which is in the cerebral subarachnoid space, 35 ml in the ventricles and spinal subarachnoid space contains about 75 ml.

CSF Pathways

Cerebrospinal fluid (CSF) flows from the lateral ventricles to the third ventricle through the Monro foramen, then to the fourth ventricle via the Sylvius aqueduct. From the fourth ventricle, CSF enters the subarachnoid space through the median foramen of Magendie and the lateral foramina of Luschka. The fourth ventricle serves as the sole functional connection between the cerebral ventricles and the subarachnoid space. CSF is then absorbed by the brain and spinal cord.

CSF Absorption

Cerebrospinal fluid (CSF) absorption occurs through two main processes: primarily through rapid drainage via the arachnoid villi and granulations into the superior sagittal sinus and its lateral lacunae, eventually entering the great dural sinuses, and secondarily through a slower escape into the true lymphatic vessels along a perineural route. On average, about 300-380 ml of CSF enters the venous circulation daily.

Lumbar Vertebrae

The vertebral body, pedicle, transverse process, superior and inferior articular processes, lamina, and spinous process are the several parts that make up the lumbar vertebra. The interspinous and interlaminar gaps are the areas that separate two neighbouring vertebrae. The bases of the inferior and superior articular processes, the laminae, and the spinous processes all define the interlaminar space. The spinal needle must pass through the interlaminar gap in order for the procedure to be successful.

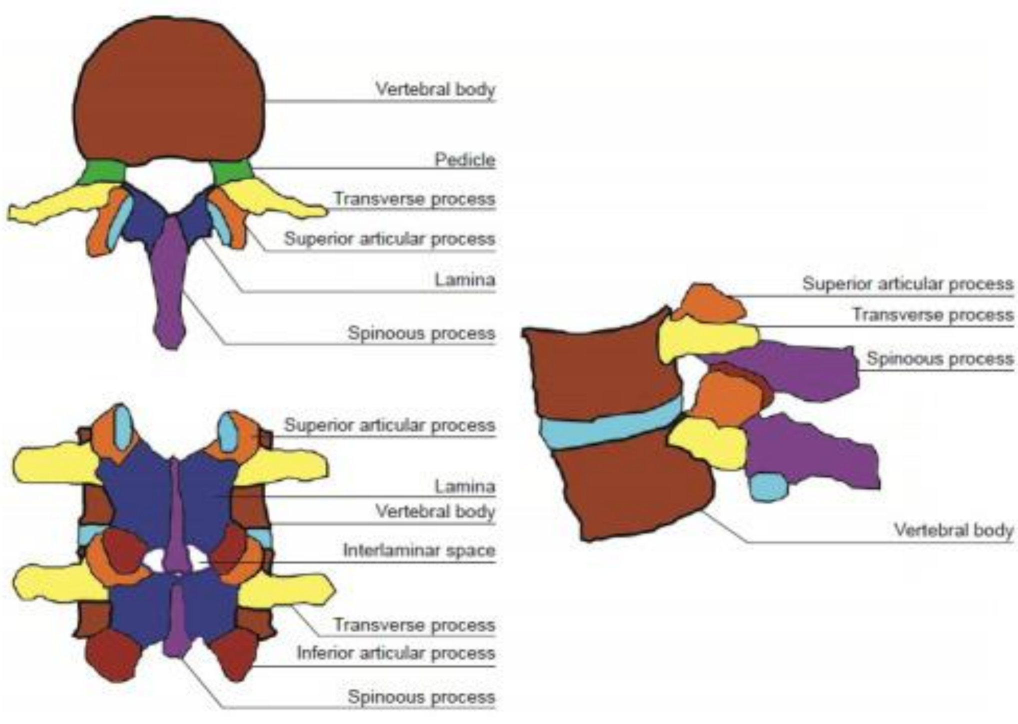


Figure 1: Anatomy of lumbar vertebrae[6]

Mechanism of action

When injected intrathecally local anesthetics primarily bind to the spinal nerve roots and peripheral spinal cord regions. Rostral spread occurs via arterial pulsations from the skull, with lesser amounts reaching the central spinal cord region. Blockade of efferent motor and autonomic transmission results from anterior nerve fiber blockage, while somatic and visceral impulses are blocked by posterior nerve fiber blockade.

Somatic blockade

Spinal anesthesia achieves dense sensory and motor block with minimal anesthetic dose and volume. Smaller sympathetic fibers are more susceptible to blockade compared to larger sensory and motor fibers. Factors influencing drug penetration and uptake include drug mass, concentration of drug in CSF, the contact surface area, content of lipid, vascular supply of the local tissue, and size of the nerve root .

Clinical progression of differential nerve block in order is –

1. Autonomic fibres – sympathetic blockade occurs at two to six segments higher than the sensory block
2. Sensory fibres – cold > warm > pinprick >pain >touch >pressure
3. Motor fibres – two to three segments below the sensory block is when the motor block happens.

Differential nerve block depends on the following factors :

- Fibre arrangement in the nerve bundle
- Fibre diameter
- Inherent nerve fiber activity
- Variability in agent spread,

- Effects on ion channels other than Na+
- The specific local anesthetic drug used.

Autonomic blockade:

Spinal anesthesia predominantly blocks sympathetic and to a lesser extent, parasympathetic efferent transmission. Thoracolumbar is the sympathetic outflow; craniosacral is the parasympathetic outflow. Nonetheless, the neuraxial anaesthesia has no effect on the vagus nerve.

PHYSIOLOGICAL EFFECTS

Cardiovascular system:

Physiological effects of the spinal anesthesia resemble those induced by a combination of alpha 1 and beta-adrenergic receptor actions. Activation of beta 2 receptors leads to vasodilation, causing peripheral blood pooling and reduced venous return. This reduction in venous return subsequently decreases cardiac output. Sympathetic blockade predominantly induces veno dilation due to the limited presence of smooth muscle in venules. The primary causes of hypotension following spinal anesthesia are decreased cardiac output and systemic vascular resistance. Bradycardia may occur due to reduced right atrial filling or involvement of cardioaccelerator fibers from T1 to T4.

In case of hypotension –

- Trendelenburg position and leg elevation
- Oxygen supplementation
- Crystalloids and colloids administration
- Vasopressors like ephedrine, phenylephrine
- Atropine for bradycardia

Respiratory effects:

In healthy patients, pulmonary function remains largely unchanged with neuraxial blockade. Spinal anesthesia at mid-thoracic levels (without affecting the phrenic nerve) results in minimal or no alteration in tidal volume, respiratory rate, minute ventilation, or arterial blood gases. Hemodynamic resuscitation can relieve apnea even in cases of complete spinal anesthesia, indicating that the reason may be brain stem hypoperfusion rather than phrenic nerve block. However, caution is warranted when using neuraxial blocks in patients with respiratory compromise, as paralysis of respiratory muscles can impair effective coughing and secretion clearance, particularly affecting expiratory muscles.

Gastrointestinal effects:

Spinal anesthesia induces sympathetic blockade, leading to increased parasympathetic activity and subsequent gastrointestinal hyperperistalsis. This may cause patients to experience nausea and vomiting. Hepatic blood flow decreases with reductions in mean arterial pressure resulting from any anesthesia technique.

Renal function effects:

Neuraxial blockade accompanies a decrease in renal blood flow, though the decline is not clinically significant. When perioperative urinary catheterization is unnecessary, it is advisable to use the smallest effective dose of short-acting drugs required for the surgical procedure and to limit intravenous fluid administration. Monitoring for urinary retention is essential postoperatively to prevent bladder distension following spinal anesthesia

Central nervous system effects:

In neuraxial blockade there is reduced coronary blood flow, increased cerebral vascular resistance which reduces cerebral perfusion. no significant changes observed.

Metabolic and endocrine effects:

Surgery induces a neuroendocrine response characterized by the release of various substances. Neuraxial blocks effectively attenuate this response by reducing catecholamine release, potentially decreasing perioperative arrhythmias and ischemic events.

MECHANISM OF DRUG SPREAD:

There are several factors which contribute to the level of blockade after a spinal anaesthesia. They are

Characteristics of the injected solution:

1. **Baricity:**

Baricity refers to the density of local anesthetic solution relative to the density of cerebrospinal fluid (CSF), which is approximately 1.00059 g/liter.

Solutions are classified based on their density:

- Hypobaric – density < 1
- Isobaric – density = 1
- Hyperbaric – density >1, Hyperbaric drug spread is more predictable hence it is made hyperbaric by adding dextrose.
- Gravity significantly influences the spread of hyper- and hypobaric solutions.

2. **Volume, dose and concentration:**

- These factors are interconnected, with dose being the most critical determinant of local anesthetic spread
- Volume * concentration = dose

3. **Addition of drugs**

- Vasoconstrictors – Vasoconstrictors prolong the duration of action by reducing systemic absorption, thereby enhancing the retention of the drug in the subarachnoid space

- Opioids – Opioids, when added to local anesthetics, exert a synergistic effect without affecting motor blockade.

Patient factors

- **Age** – Advancing age correlates with reduced conduction velocity, axonal degeneration, fewer nerve fibers, and diminished CSF volume. Consequently, elderly patients require lower doses as the block height increases.
- **Height** – Height influences anesthesia spread, especially in cases of extreme variation.
- **Weight** – BMI affects anesthesia distribution; obese patients may experience increased spread due to reduced volume of CSF.

Position

a) Lateral decubitus with universal flexion:

Patient should be positioned with their back parallel to the operating table (OT) table axis, thighs flexed upward, and neck forward (fetal position). Head high/head low positioning can be utilized to leverage the baricity of spinal local anesthetics.

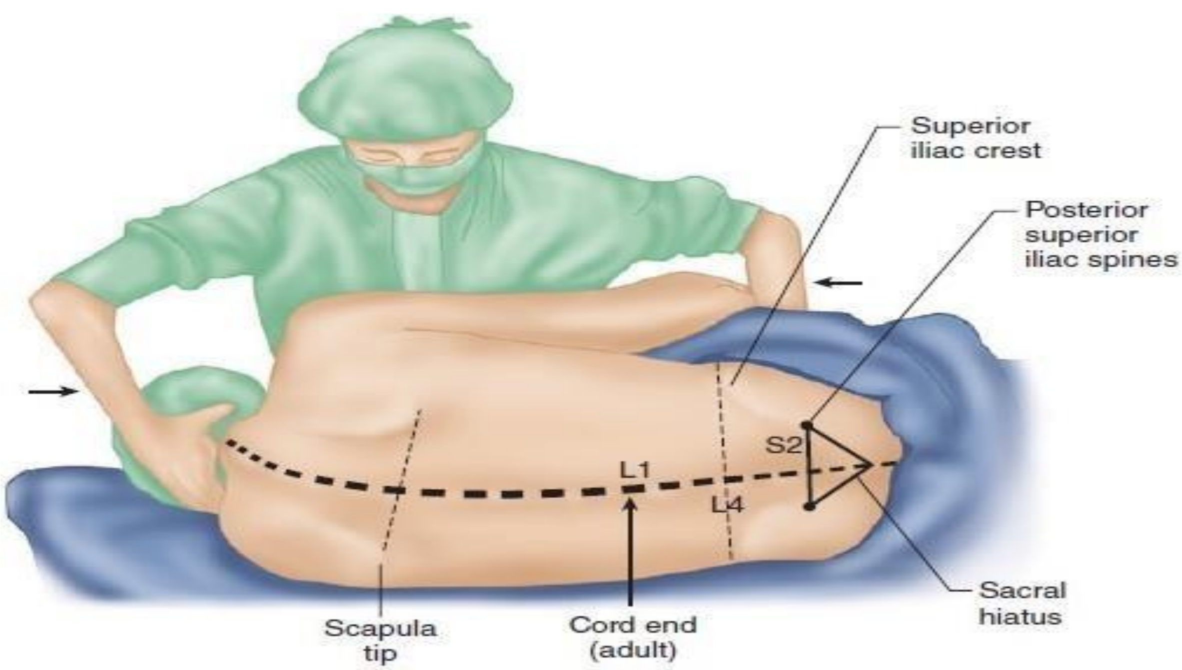


Figure 3: Lateral decubitus with universal flexion

b) Sitting position:

The patient sits upright, back parallel to the OT table axis, feet supported, head flexed, arms supporting a pillow over the chest, and arching their back (C-shaped position). This maximizes intervertebral space opening.

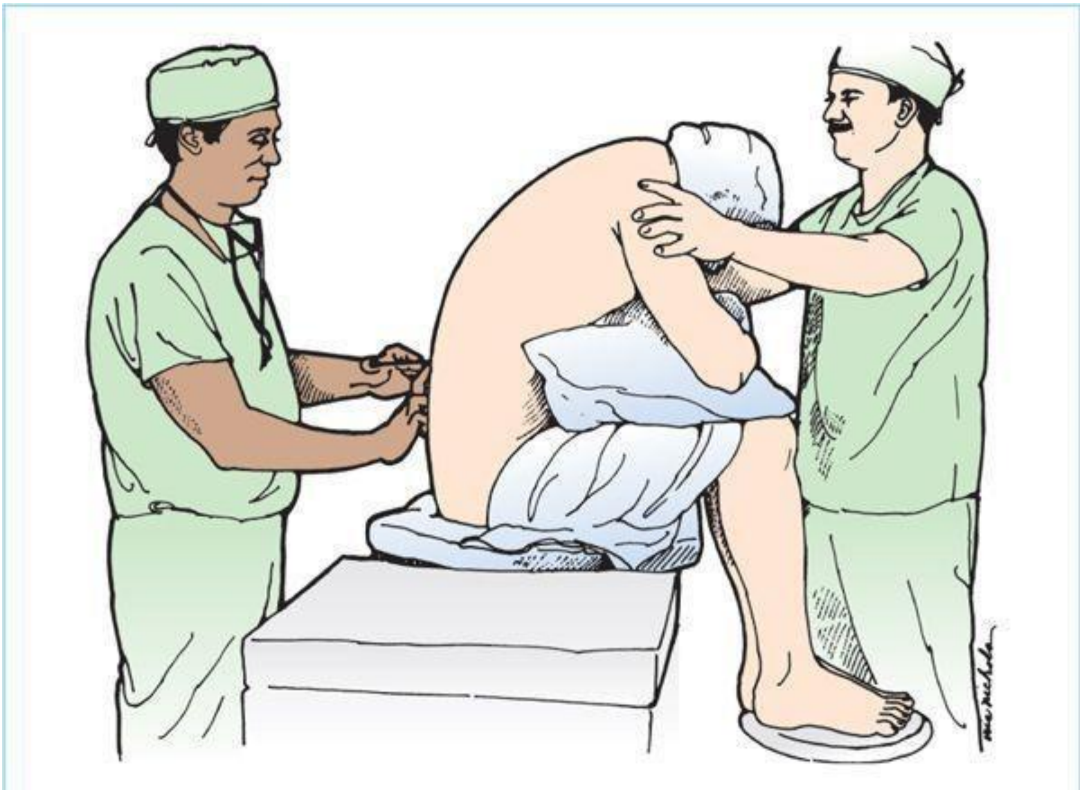


Figure 4: Sitting position for spinal anesthesia

c)Prone position:

The prone position is used when the patient will be in this position for the surgical procedure (rectal, perineal and lumbar procedures). Hypobaric local anaesthetics are administered. Patient positions self, lumbar lordosis has to be minimized, a paramedian approach is often used.

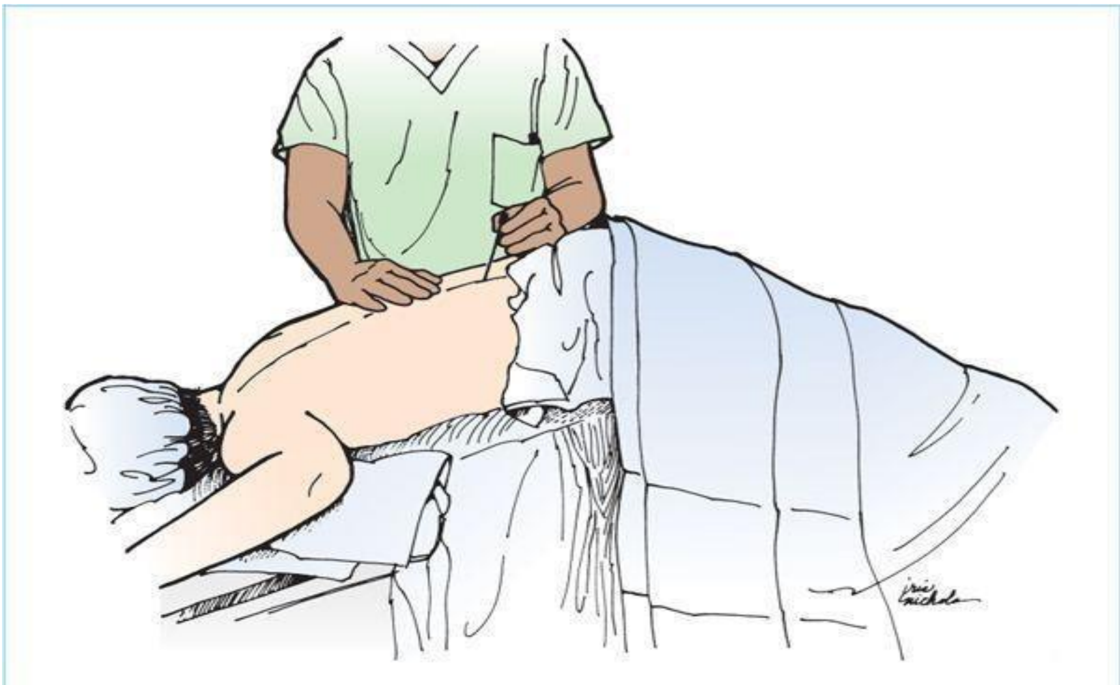


Figure 5: Prone position for spinal anesthesia

Procedure factors

1. **Patient position:**

The Trendelenburg and reverse Trendelenburg postion of the patient affect the spread of the local anesthetic drug and the degree of block.Whereas hypobaric solutions tend to ascend, hyperbaric solutions tend to settle downward.

2. **The injection level:**

A larger spread is obtained by injecting with the plain solutions at higher levels.

3 . **Type of needle:** Various spinal needles are available, which can be classified according to:

i. Size of the needle – Sizes are available from 18 to 30G. Large gauze spinal needles improves tactile sensation of needle placement, whereas complications related to CSF leaks and post dural puncture headache are less with finer needles.

ii. Shape of spinal needle tip –

1. Dura cutting needles
2. Dura splitting needles

Dura cutting needles

- These needles are bevelled tips with cutting edges
- Cuts longitudinally aligned dural fibres
- It causes more CSF loss and more likely to cause PDPH
- Examples: Quincke, Atraucan, Greene.

Dura splitting needles

- These are also called as pencil point tip needles.
- The aperture is on the side of the shaft and require more time to insert. Less amount of tissue coring and less likely to cause PDPH.
- Examples: Whitacre, Sprotte, Eldor

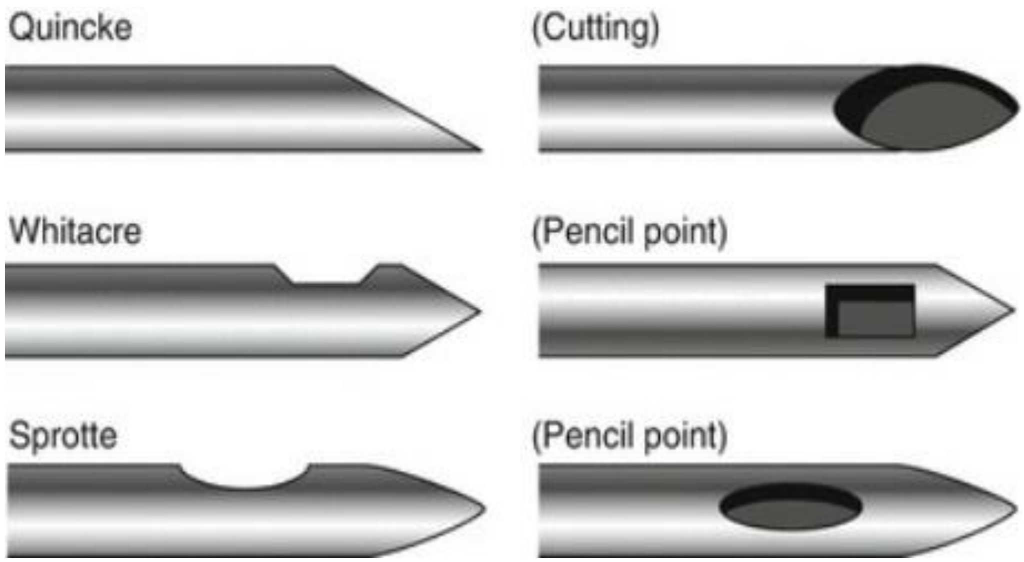


Figure 6 : Tip designs of different spinal needles

3. **Technique of injection of drug**

After the appearance of CSF in the needle hub, aspiration is done and local anesthetic is injected slowly. Sympathetic blockade is confirmed by assessing sensory and motor blockade. Rate of injection: Rapid injections result in marked diffusion, leading to higher levels of blocks.

4. **Characteristics of spinal fluid:**

Factors such as volume, density, and pressure of CSF play a role in anaesthesia spread.

Projection and puncture

After ensuring the patient is correctly positioned, it is crucial to follow strict aseptic precautions. Betadine solution is applied followed by surgical spirit , then wiped it off with dry gauze and covered the back with sterile drape , Tuffier's line is identified by a horizaontal line joining the highest border of both iliac crest corresponding to either the L4-L5 interspace or the L4 vertebral body. The subarachnoid space can be accessed in two ways:

Midline approach

- Advantages include an anatomically straightforward projection and a relatively avascular plane.

- The spinal needle is inserted midline, at a 15-20 degree cephalad angle, with the bevel parallel to the dura's longitudinal fibers, after local infiltration with 2% lignocaine.
- The dorsal to ventral structures that are punctured are the dura, supraspinous ligament, interspinous ligament, and skin.
- Upon passing through the ligamentum flavum and dura, there are noticeable pop. The needle is placed in the subarachnoid space following the second giveaway. Following placement confirmation via CSF aspiration, 0.2 ml/s of local anesthetic is given.

Para median approach

This approach avoids anatomical limitations imposed by the spinous process by placing the needle laterally.

Aim for the midline 1 cm below from the spinal needle, 10-15 degrees off the sagittal plane, in line with the mid space. As development proceeds, the dura gives way characteristically and CSF is acquired.

Contraindications of spinal anaesthesia:

Absolute

- Significant coagulopathy
- Localized sepsis
- Raised intracranial pressure
- Severe untreated hypovolemia
- Valvular heart diseases- fixed output lesions/stenotic lesions
- Septic shock
- Severe anemia
- Arachnoiditis, meningitis

Relative

- Neurological deficits and demyelinating diseases
- Spinal deformities
- Sepsis
- Thromboprophylaxis
- Inherited coagulopathy

Complications

Appropriate patient selection and care should be established to help obviate common complications associated with neuraxial anaesthesia. While many of the complications are of very low incidence, it's worth being aware of them. Severe complications are believed to be extremely rare, but the frequency is probably underestimated. Some common complications include the following:

Immediate Complications:

- **Hypotension:** A drop in blood pressure is a common and significant immediate complication due to sympathetic blockade, which can lead to vasodilation.
- **Nausea and Vomiting:** These are also frequent immediate side effects, potentially related to hypotension and the effects of the anaesthetic itself.
- **Failed or Uneven Block:** The anaesthetic may not provide adequate or complete sensory or motor blockade, requiring adjustments or alternative techniques.
- **Shivering:** This can occur due to the anaesthetic's effect on temperature regulation.
- **Bradycardia:** A slow heart rate can also occur as a result of the sympathetic blockade.
- **Urinary Retention:** Difficulty or inability to urinate can occur due to the anaesthetic's effect on bladder function.

Delayed Complications:

- **Post-Dural Puncture Headache (PDPH):** This is a common and potentially debilitating complication, typically occurring within 24-72 hours after the procedure. It is caused by leakage of cerebrospinal fluid (CSF) through the dural puncture site.
- **Neurological Complications:** While rare, serious neurological complications can include nerve damage, spinal cord ischemia, or cauda equina syndrome.
- **Spinal Hematoma:** Bleeding around the spinal cord can occur, potentially leading to nerve compression and neurological deficits.
- **Infection:** Although rare, infection of the spinal area can occur, potentially leading to meningitis or abscess formation.
- **Arachnoiditis:** Inflammation of the arachnoid membrane surrounding the spinal cord can cause pain and neurological symptoms.
- **Transient Neurological Syndrome:** This can manifest as pain, numbness, or weakness in the lower limbs and buttocks.
- **Backache:** Back pain can occur as a result of the procedure itself or as a complication

SONO ANATOMY OF LUMBAR VERTEBRAE

A curved-array probe is placed on the patient's back when they are sitting or in a lateral decubitus position with their lumbar spine flexed in order to acquire an ultrasonographic image of their spine. Sagittal, transverse, and diagonal views are the three main orientations in which the ultrasonic probe can be used. The probe's angle can be angled cephalad or caudad in the transverse plane or medially in the parasagittal plane to maximise imaging of target structures. The diagonal view can be used well for real-time ultrasound-guided neuraxial block, even if it is less frequently used for preprocedural ultrasound imaging.

Sagittal view of lumbar spine

Depending on the placement and angle of the probe, there are five main sagittal plane views that can be used to see the lumbar spine. Views of the sagittal transverse process, sagittal articular process, sagittal lamina, and sagittal spinous process can be acquired by moving the probe from a lateral position towards the neuronal axis midline. Furthermore, by tilting the probe medially from the sagittal lamina view or sagittal articular process view towards the midline, the parasagittal oblique view can be obtained. By clearly displaying the anterior complex (posterior longitudinal ligament, posterior surface of the vertebral body, and intervertebral disc) and posterior complex (ligamentum flavum–dura complex), this view is especially helpful for identifying the ideal intervertebral level for puncture. Additionally, it assists in choosing the intervertebral level with the highest interlaminar level.

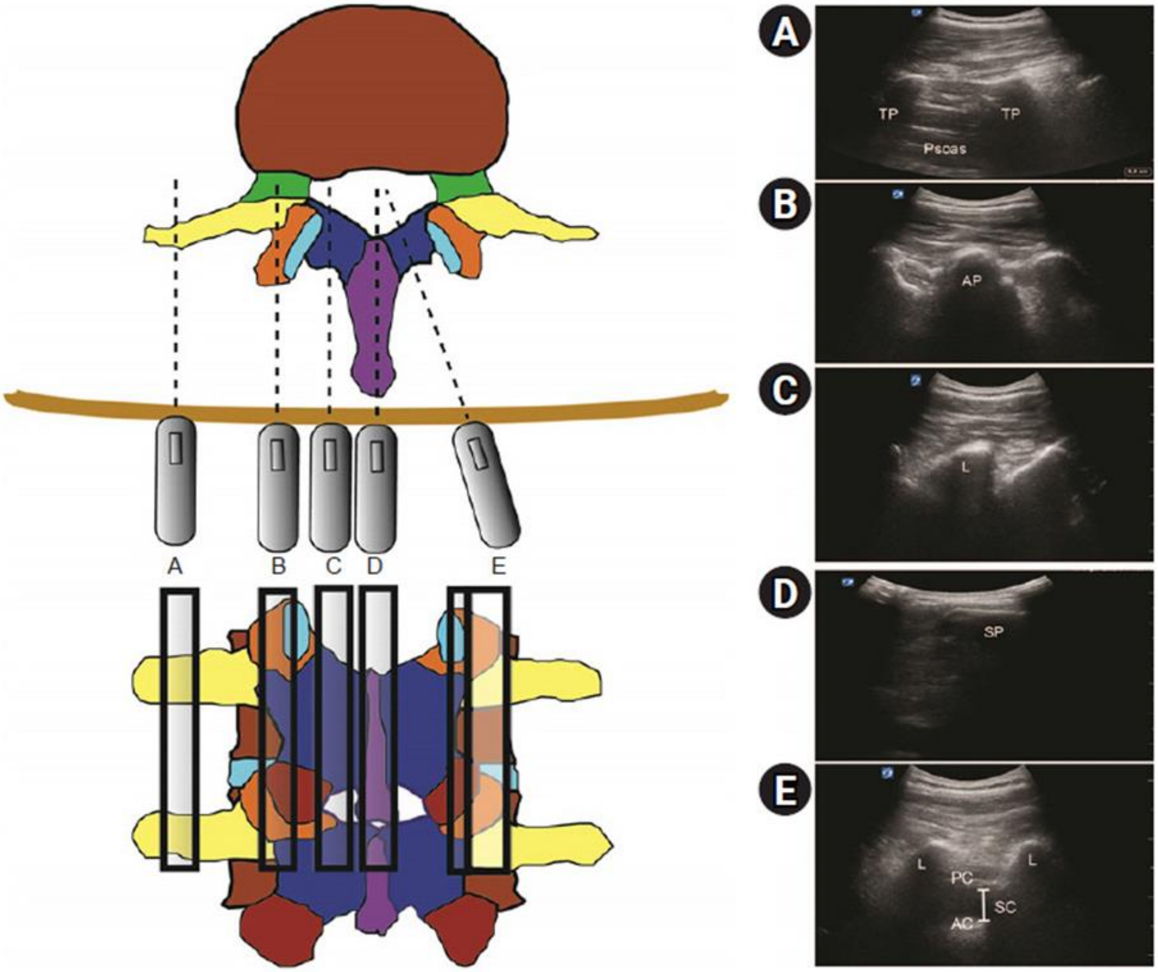


Figure 7: Sagittal view of lumbar spine[6]

Sagittal transverse process view (A), articular process view (B), lamina view (C), spinous process view (D), and parasagittal oblique view (E) are the several types of sagittal process views. PC stands for posterior complex, AC for anterior complex, L for lamina, SP for spinous process, TP for transverse process, AP for articular process, and SC for spinal canal (intrathecal space).

Transverse view of Lumbar spine

There are two common transverse perspectives for lumbar neuraxial block: transverse spinous process and transverse interlaminar. The transverse spinous process view, which shows the linked tips of the spinous processes, aids in locating the midline. The probe is slid cephalad or caudad from the transverse spinous process view to achieve the transverse interlaminar view. To see the dural sac between the anterior and posterior complexes clearly in this view, the probe may need to be slightly tilted cephalad or caudad.

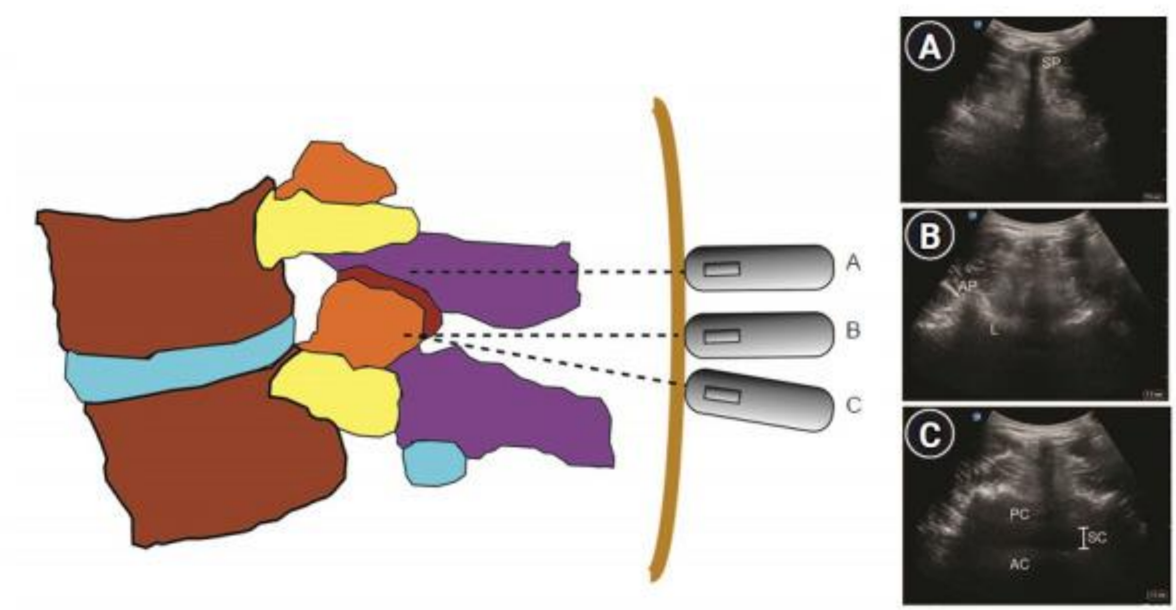


Figure 8: Transverse views of lumbar spine[6]

(A) Transverse spinous process view, (B) transverse interspinous process view, (C) tilted transverse interspinous process view. SP: spinous process, AP: articular process, L: lamina, PC: posterior complex, AC: anterior complex, SC: spinal canal (intrathecal space).

Diagonal view of lumbar spine

The diagonal view is achieved by rotating the ultrasound probe approximately 45 degrees from the sagittal articular process view, creating a blend of transverse and sagittal perspectives. In this view, the spinous process of the upper vertebral body, the interlaminar space, and the lamina of the lower vertebral body can be visualized. This view is particularly useful for performing real-time ultrasound-guided neuraxial block procedures.

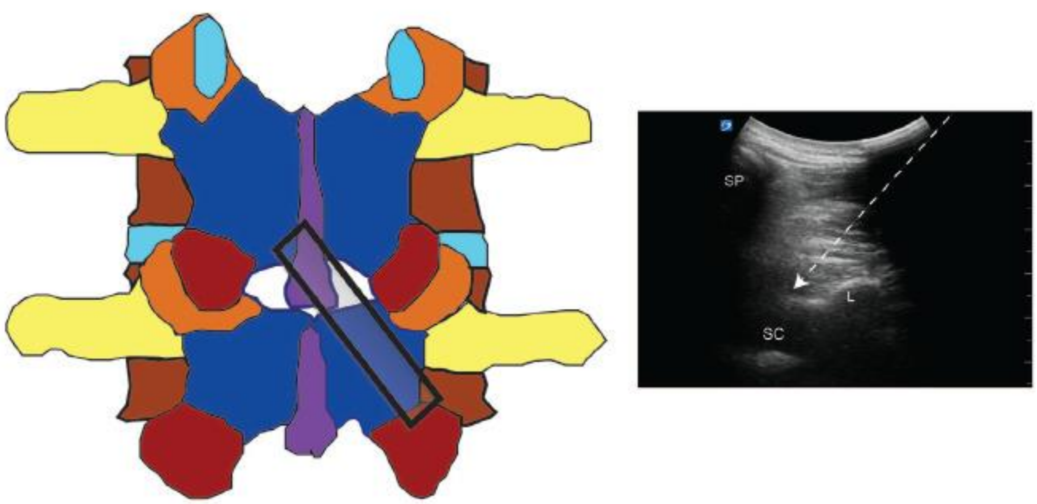


Figure 9: Diagonal view of the lumbar spine[6]

Ultrasound guided techniques for lumbar neuraxial blocks

Previous reviews have provided a detailed description of a methodical approach to adult lumbar neuraxial block guided by ultrasound[7]. Pre procedural ultrasound screening and real-time ultrasound guidance are the two basic applications of ultrasonography in lumbar neuraxial blocks. Usually, a low-frequency curved-array ultrasonic probe is used, such as one that operates between 2 and 5 MHz. Carefully adjusting the depth (often set to 7–10 cm), focus placement, and gain settings on the sonograph is necessary to maximise its quality. In order to reduce the danger of neurological problems such sticky arachnoiditis.[8,9]

Identification of space

1 **Confirmation of midline:** Place the ultrasound probe horizontally over the midline to obtain the transverse spinous process view, identifying the spinous processes as reference points.

2 **Locate the interlaminar space:** Determine the interlaminar space using either the transverse interlaminar view or the parasagittal oblique view, and then choose the best intervertebral level for neuraxial puncture based on these views.

3 **Find the trajectory and location of insertion of the needle**: Determine the ideal needle insertion position and angle using the transverse interlaminar view.
To see the intrathecal space clearly and identify the three-dimensional probe orientation wherein the anterior and posterior complexes are most clearly apparent, tilt the probe cephalad or caudad as required.

4 **Evaluate the depth of the needle insertion:** Measure the distance from the skin surface to the posterior complex to estimate the depth of needle insertion.

5 **Perform the neuraxial block:** Insert the needle at the predetermined insertion point and angle, guided by the information obtained from the ultrasound imaging.

Paramedian Approach Based on Bony Structures:

1. **Verify the neuraxial midline:** Use the transverse spinous process view to identify the midline based on the alignment of the spinous processes.

2. **Locate the interspinous space:** Use the transverse view to locate the interspinous space. To find the interlaminar space and choose the best intervertebral level for the neuraxial puncture, if at all possible, utilise the parasagittal oblique view.

3. **Determine the needle insertion point:** Mark the insertion site around 1 cm above to the lower spinous process and 1 cm lateral to the midline, or 1 cm below to the caudad tip of the upper spinous process and 1 cm lateral to the midline, once the midline, spinous process, and interlaminar space have been determined.

4. **Adjust needle angulation:** Insert the spinal needle with a slight medial angulation of 5–10 degrees and a cephalad tilt of 5–10 degrees, similar to the conventional paramedian approach.

This ultrasound-assisted approach relies on the identification of key bony structures, similar to the conventional paramedian method, but allows for greater precision through the use of ultrasound imaging. It is particularly beneficial for extremely obese patients or when ultrasound image quality is suboptimal, as it facilitates more accurate localization of the underlying bony landmarks.

Pre procedural Ultrasound-Assisted Paramedian Approach Based on the Parasagittal Oblique View

1. **Confirm the midline:** Start with the transverse spinous process view to identify the midline. Then, position the ultrasound probe longitudinally, 1–2 cm lateral to the midline, with a slight medial tilt.
2. **Identify the interlaminar space:** Use the parasagittal oblique view to locate the interlaminar space, selecting the intervertebral level with the largest visible interlaminar space.

3. **Optimize probe angle:** Determine the medial tilt of the probe in the sagittal plane that provides the clearest image of the interlaminar space. Slight cephalad or caudad angulation of the probe may be required in some cases.
4. **Estimate needle insertion depth:** Measure the distance from the skin to the posterior complex to approximate the depth of needle insertion.
5. **Perform the puncture:** Insert the needle at the predetermined insertion point, using the angle determined from the ultrasound view.

This paramedian approach, guided by the parasagittal oblique view, offers potential advantages over the midline approach that relies on the transverse interlaminar view. The parasagittal oblique view often provides superior visibility of the interlaminar space, particularly in elderly patients. Since the ultrasound beam and the needle trajectory align directly through the same pathway in this view, cephalad or caudad needle angulation is usually unnecessary. Instead, the approach involves only medial angulation, making it a more direct path to the intrathecal or epidural space through the interlaminar space.

Real-time US guided neuraxial block

Real-time ultrasound-guided (US-guided) neuraxial block is a promising and practical technique that can enhance the success of neuraxial anaesthesia, particularly in challenging cases.[10,11] However, its implementation can be difficult due to factors such as the large size of the probe, the small gauge of the needle, and the relatively deep location of the target structure. Several methods are available for performing real-time US-guided neuraxial block, including sagittal, transverse, and diagonal in-plane approaches.

We have performed the procedure based on the parasagittal oblique view and it has been shown to improve the first-attempt success rate compared to the traditional landmark-guided paramedian approach.[3] However, needle insertion from the non-dependent side may result in a "dry tap" due to the effects of gravity, even when the needle tip is correctly placed in the intrathecal space. A prospective observational study reported that the diagonal view-based real-time US-guided spinal anaesthesia was successfully performed in 97 out of 100 consecutive patients within a median of three needle passes.[2]

To facilitate the transverse in-plane paramedian approach, the probe application site can be slightly adjusted to create more space for the puncture and needle manipulation.[14] Additionally, the use of an electromagnetic needle tracking system can further aid in performing real-time US-guided spinal anaesthesia with greater precision.[13]

Patients with difficult anatomy (Obesity, Scoliosis etc)

Several studies have observed whether ultrasound (US) assistance improves the technical performance of neuraxial blockades in patients with challenging anatomy, such as moderate to severe obesity, lumbar scoliosis, ankylosing spondylitis, or a history of lumbar spine surgery. Chin et al., compared the first-attempt success rate of spinal anaesthesia with and without US assistance in these populations, finding that preprocedural US imaging facilitated spinal anaesthesia. Similar findings were reported in obstetric patients with difficult anatomical landmarks. Wang et al., demonstrated that ultrasound performed by a single experienced anaesthesiologist before neuraxial blockade significantly improved the first-attempt success rate.[14]

Ekinci et al., also showed that using preprocedural US imaging significantly reduced the number of skin punctures, while the total procedure time remained comparable to the conventional spinal anaesthesia technique.[15] The recent study in patients with documented lumbar scoliosis or a history of previous spinal surgery yielded similar results, indicating that the number of needle passes and puncture attempts was significantly lower in the US group compared to the control group, although the total procedure time was not significantly different between the two groups.[16]

Despite the additional time required for ultrasound, difficulties in identifying the midline or intervertebral space in patients with abnormal vertebral anatomy typically lead to increased procedural time with conventional palpation techniques, resulting in no overall difference in procedure time. Given the reduced number of needle manipulations and improved patient satisfaction, US neuraxial imaging should be considered for patients expected to have difficult neuraxial blockades.

Advantages of US guided Neuraxial block

Ultrasound (US) imaging provides critical clinical information for performing successful neuraxial blocks. It enables precise identification of the puncture level by revealing key details such as the widest interlaminar space, the depth from the skin to the dura, and the exact spinal level. Accurate localization of the intervertebral spaces and lumbar vertebral levels is essential for achieving effective neuraxial blockade. While many anaesthesiologists commonly rely on palpation to identify vertebral levels, studies consistently demonstrate that palpation is an unreliable method for this purpose.[17-20]

Pre procedural US imaging offers valuable anatomical insights, including the structure of intervertebral spaces and bony landmarks, while also identifying the optimal skin puncture point and needle insertion angle. These advantages enhance the ease and accuracy of performing neuraxial blockade.[1,21] US imaging can also predict the distance from the skin to the intrathecal space, facilitating dural puncture. Research shows a strong correlation between US-determined depths and actual needle depths.[22–25] However, clinicians should note that US-predicted depths may slightly underestimate the true distance due to tissue compression caused by the probe during image optimization.

Accurate identification of intervertebral levels via US imaging is also a significant safety consideration in neuraxial blockade. US more reliably determines intervertebral levels compared to palpation.[20] The conus medullaris typically terminates between T12 and L3[27] and unintended dural punctures above the L1-L2 interspace risk injury to this structure. While most studies on US-assisted neuraxial blockade assess safety as a secondary outcome[28] pre procedural US imaging may help avoid such complications, underscoring its importance in clinical practice.

AIMS AND OBJECTIVES

THE AIM OF OUR STUDY :

To compare the effectiveness of two modalities of spinal anaesthesia i.e., real-time ultrasound guided technique and pre-procedural Ultrasound-guided landmark technique in obese parturients.

OBJECTIVES:

Primary Objective:

Successful spinal anaesthesia with respect to

- Time for identifying the space
- Number of attempts (number of times the spinal needle will be withdrawn from skin and inserted)
- Number of needles passes (number of forwarding advancements of the spinal needle in a given interspinous space)
- Time taken for successful lumbar puncture and analgesia

Secondary Objective:

- Hemodynamic stability
- Complications of spinal anaesthesia

MATERIALS & METHODS

Study population: The study was done on obese parturients undergoing elective cesarean sections with ASA grade II and III.

Inclusion Criteria:

- Parturients who received elective cesarean delivery under spinal anaesthesia with BMI >30kg/m2
- ASA II-III scheduled for elective cesarean sections
- Age 18 to 35 years
- ≥37 weeks of gestation

Exclusion Criteria:

- Emergency C-section
- Contraindications for spinal anesthesia
- History of lumbar spinal diseases and lumbar surgery
- Uncontrolled hypertension , uncontrolled diabetes
- Epilepsy

Methodology:

Pre anaesthetic evaluation:

The Pre anaesthetic evaluation included the following:

History:

History of underlying medical illness, previous history of surgery, anaesthetic exposure, and hospitalization will be elicited.

Physical Examination:

- The general condition of the patient.
- Vital signs -heart rate, blood pressure, respiratory rate.
- BMI of the patient
- Detailed examination of the spine
- Examination of the respiratory system, cardiovascular system, and central nervous system.
- Airway assessment by Mallampati grading.
- The procedure of spinal anaesthesia was explained to the patient and patient attendees.

Investigations /Interventions

Routine investigations include CBC, FBS, ECG, Chest X-ray, HIV, HbsAg, Urine routine, HbA1c, UKB.

Materials used : The following materials are used in our study

1) Ultrasonography machine (Sono site M – turbo , USA) and a high frequency linear transducer with frequency 7-13Hz
2) A sterile spinal anaesthesia tray containing bowls, gauze and central hole towel
3) Sterile gloves
4) Echogenic 25G BD spinal needle

5) One 2ml syringe and one 5ml syringe

6) Betadine solution and spirit

7) 2% Lignocaine for local infiltration , Bupivacaine heavy (NEON laboratories), Buprinorphine as additive

8) Monitors – spo2 , NIBP , ECG

9) Sterile glove to drape the ultrasound probe

Fig 10: sterile spinal anaesthesia tray

Fig 11: Sono site M ultrasound machine

Procedure:

Pre anaesthetic evaluation was done in the ward. Patients were kept nill by mouth for more than 8hrs overnight fasting. Patients were selected for the study based on the inclusion and exclusion criteria. Patients were given detailed explanations of the procedures and informed consent was taken. Group RUS group participants received procedural USG guided paramedian spinal anaesthesia, and Group PPUS received pre-procedural USG guided paramedian spinal anaesthesia.

Basal vital parameters were recorded. Patients were monitored with oxygen saturation, NIBP and electrocardiogram.. The intravenous line was secured. The patient was positioned sitting on a level table resting with an assistant holding the patient to aid positioning. Under strict aseptic precautions, local infiltration of 2% lignocaine was given. The dural puncture was carried out at

L3-L4/L4-L5 level. In both the groups, a 25G Quincke's needle was used to inject about 2ml of hyperbaric bupivacaine 0.5% with adjuvant 60mcg of buprenorphine intrathecally.

Sterile conditions are maintained by placing a transparent sheet over the ultrasound machine and using the 2-5Mhz curvilinear probe. In the Group PPUS, Ultrasound was used to identify the L3-L4, L4-L5 interspinous space with the best image of the anterior complex (ligamentum flavum dura complex- LFD) and the posterior complex (posterior longitudinal ligament- PLL) being in the parasagittal oblique (PSO) view. At these selected interspaces, the probe was positioned to obtain a clear ultrasound image, after which, a skin marker was used to mark the mid-point along the long border of the probe, and the mid-points along the short borders of the probe. At the same horizontal level as the mid-point of the long border of the probe, the mid-point of the line drawn between the two short border midpoints of the probe was used as an insertion point for the insertion of the spinal needle. Using these points as guides, spinal anaesthesia was administered.

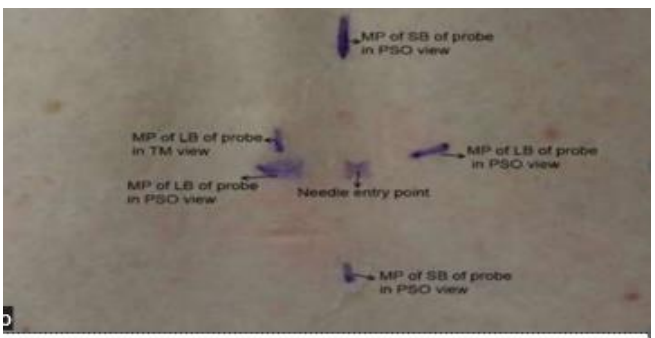


Fig 12: Needle insertion for a PPUS approach at the intersection point between the skin markings of the middle point (MP) of short border (SB) of probe in parasagittal oblique (PSO) view and MP of long border (long border) of probe

In the Group RUS ,real-time images in PSO view was used to locate the L3-L4, L4-L5, interspinous space, and visualize the needle into the spinal canal. The sacrum was the first structure to be identified, after which the probe was advanced cephalad with an angle of 20° tilted towards the midline. Then, the lumbar lamina was identified along with a target space between L3-L4 and L5-S1. The probe was then further rotated 25° towards the midline to achieve classical oblique parasagittal approach. In addition to facilitating the visualization of the lamina, intervertebral space, and posterior longitudinal ligament complex, this perspective also allows for the more ergonomic manipulation of the needle and probe simultaneously. In order to puncture the ligamentum flavum/dura complex, the needle was inserted into the interlaminar space gradually. This is the stage that we experience the “the typical giveaway feeling”.

Fig 13 : Technique of RUS probe

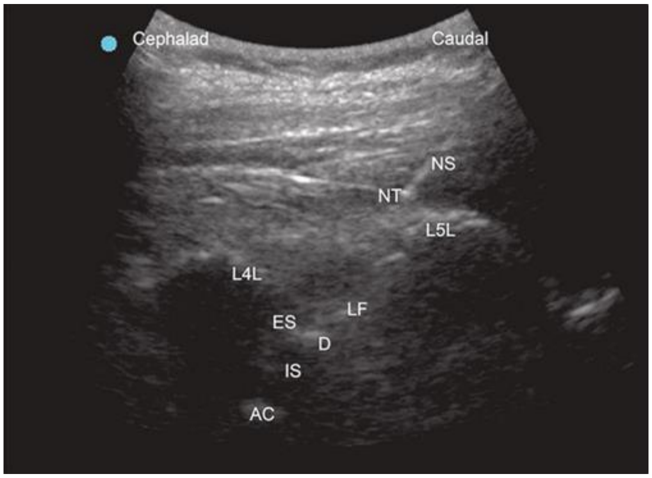


Fig 14 : US image showing spinal needle insertion (real-time) in the paramedian oblique view with needle directed towards the L4-L5 inter-laminar space. NS: needle shaft, NT: needle tip, L4L: L4 Lamina, L5L: L5 lamina: LF: ligamentum flavum, ES: epidural space; D: Dura,IS: intrathecal space, AC : anterior complex

This study evaluated the variables, and/or their mean of values, and determines whether they are statistically significant in order to "predict" the efficacy of two modalities of spinal anaesthesia in obese patients .The outcome variable were the number of attempts, passes, landmark identification time and lumbar puncture time (sec).

The patient's vital parameters were monitored throughout the procedure. Patients were assessed for the feeling of nausea, dizziness, vomiting and pruritis. Hypotension and bradycardia was treated as per standard protocol.

METHOD OF COLLECTION OF DATA:

Source of data : This study will be carried out in the Department of Anaesthesiology, B.L.D.E.U's Shri. B.M. Patil Medical College, Hospital and Research center, Vijayapura.

Study Design: A randomized control study

Study Period: from June 2023 to dec 2024

Present study included total of 80 patients with 40 patients in each group i.e

1. Group **RUS** (n=40) received Real time ultrasound guided spinal anaesthesia
2. Group **PPUS** (n=40) received Pre procedural ultrasound guided spinal anaesthesia

SAMPLE SIZE

The required minimum sample size is 40 per group (i.e. a total sample size of 80, assuming equal group sizes) to achieve a power of 90% and a level of significance of 5% (two sided), for detecting a true difference in means between two groups.

The anticipated Mean ±SD of pre-procedural USG guided group will be 78.35±58, and the real time USG guided group 38.19±28 resp.

(ref: https://journals.lww.com/ijaweb/fulltext/2021/05000/real_time_ultrasound_guided_spinal_anaesthesia_vs.2.aspx)

$$^{\text{ref}}N = 2\left[\frac{(Z_{\alpha}+z_{\beta})*S}{d}\right]^2$$

Z_{α} Level of significance=95%

Z_{β}--power of the study=90%

d=clinically significant difference between two parameters

SD= Common standard deviation

STATISTICAL ANALYSIS

The data obtained were entered into a Microsoft Excel sheet, and statistical analysis was performed using a statistical package for the social sciences (Version 20). Results were presented as Mean ±SD, Median and IQR, counts and percentages and diagrams. For normally distributed continuous variables between two groups were compared using the independent t test, for not normally distributed variables, Mann Whitney U test was used. Categorical variables between the two groups were compared using Chi-square test. A $p<0.05$ was considered statistically significant.

RESULTS

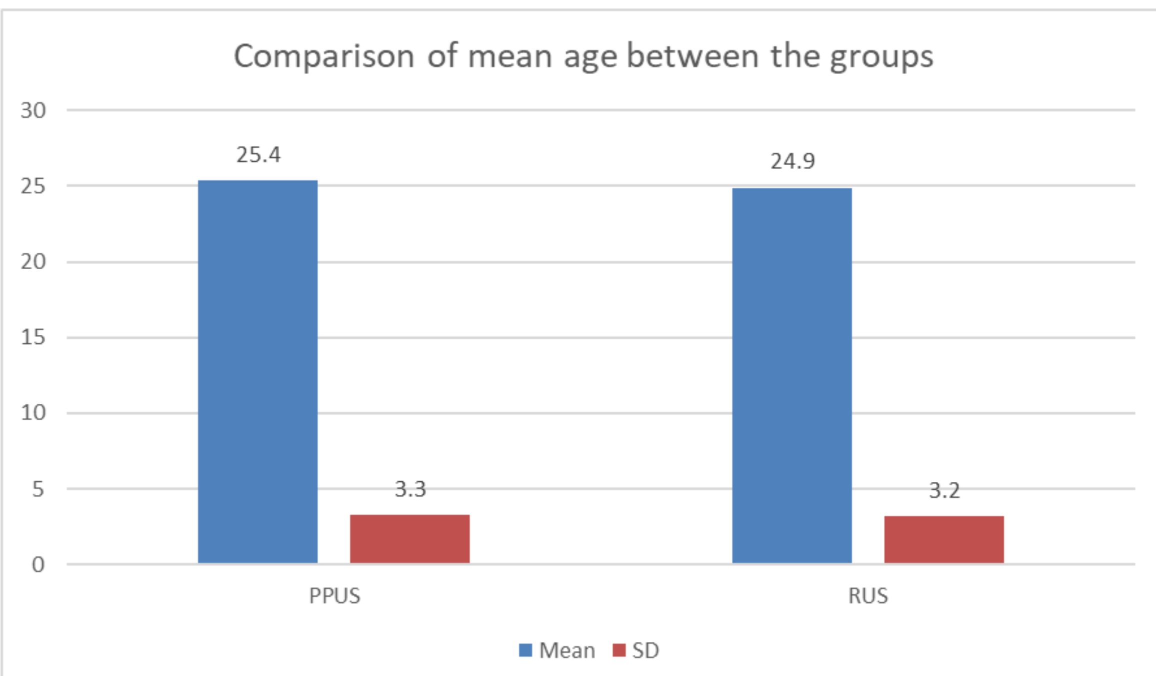
1.AGE

The mean age between the groups were comparable and found to be not statistically significant. The mean age in Group PPUS was 25.4yrs and Group RUS was 24.9yrs.($p>0.05$)

Table 1: Comparison of mean age between the groups

	Group PPUS		Group RUS		p-value
	Mean	SD	Mean	SD	
Age in years	25.4	3.3	24.9	3.2	0.473

Graph 1 : comparison of Mean age between the groups



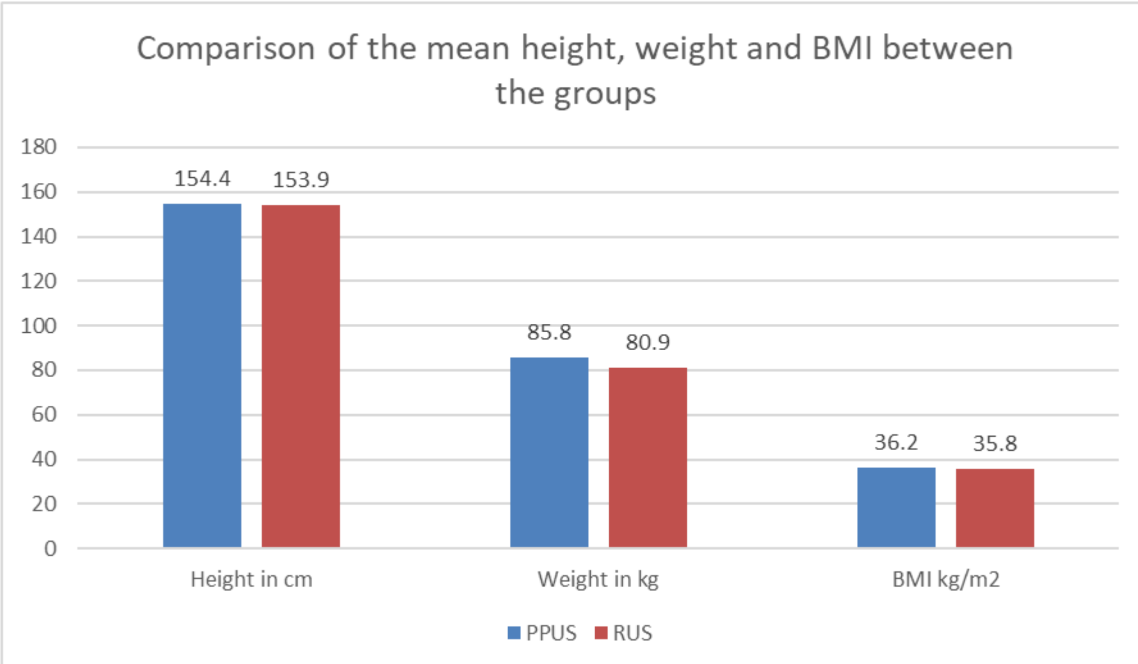
2.HIEGHT ,WIEGHT and BMI

The physical characters such was mean weight was found to be significantly higher in Group PPUS compared to Group RUS . However BMI and mean height was comparable between the groups and not statistically significant.

Table 2: Comparison of the mean height, weight and BMI between the groups

	Group PPUS		Group RUS		p-value
	Mean	SD	Mean	SD	
Height in cm	154.4	5.9	153.9	4.8	0.69
Weight in kg	85.8	6.4	80.9	4.6	0.01*
BMI kg/m^2	36.2	3.8	35.8	2.5	0.05*

Graph 2: Comparison of the mean height, weight and BMI between the groups



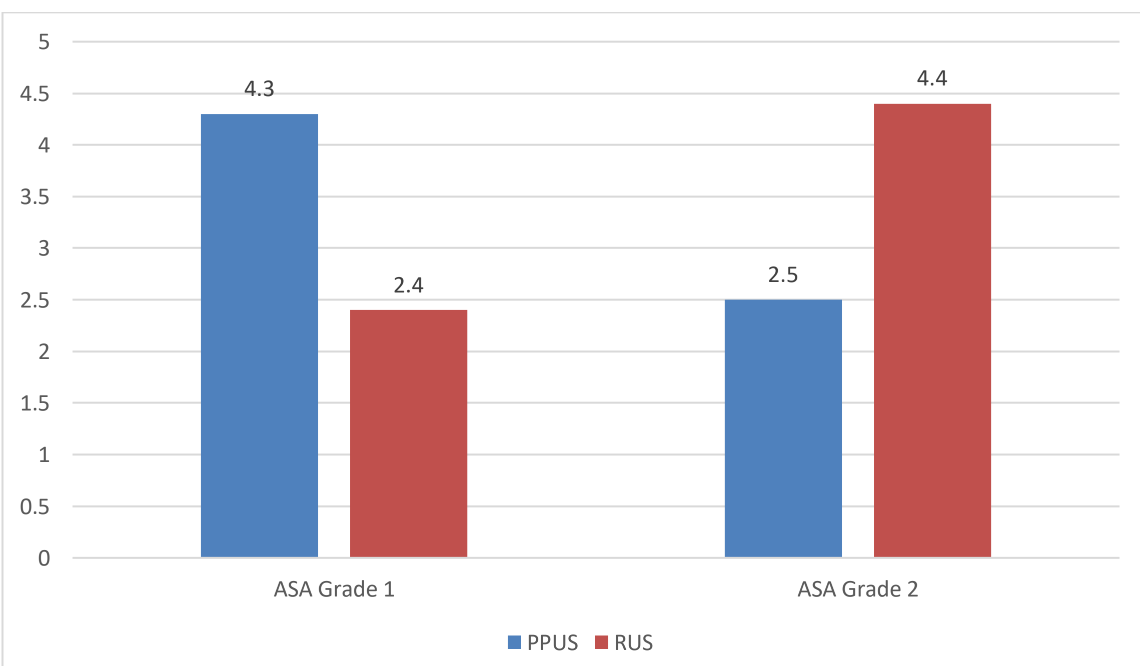
3.ASA grading

The ASA grade distribution was comparable between the groups and was not found to be statistically significant.

Table 3: Comparison of the ASA grade between the groups

		Group PPUS		Group RUS		Chi-square (p-value)
		n	%	N	%	
ASA Grade	I	36	90.0%	38	95.0%	1.2 (0.63)
	II	4	10.0%	2	5.0%	

Graph 3: Comparison of the ASA grade between the groups



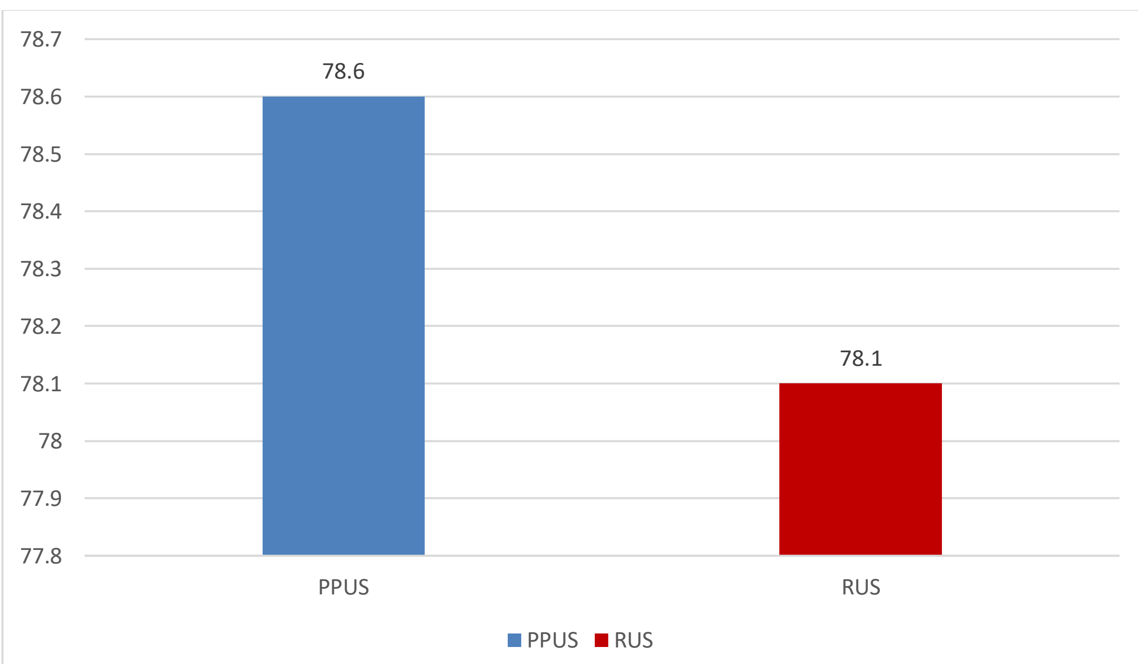
4.HEART RATE AND MEAN ARTERIAL PRESSURE (MAP)

The mean heart rate and MAP was comparable between the groups and was not statistically significant.

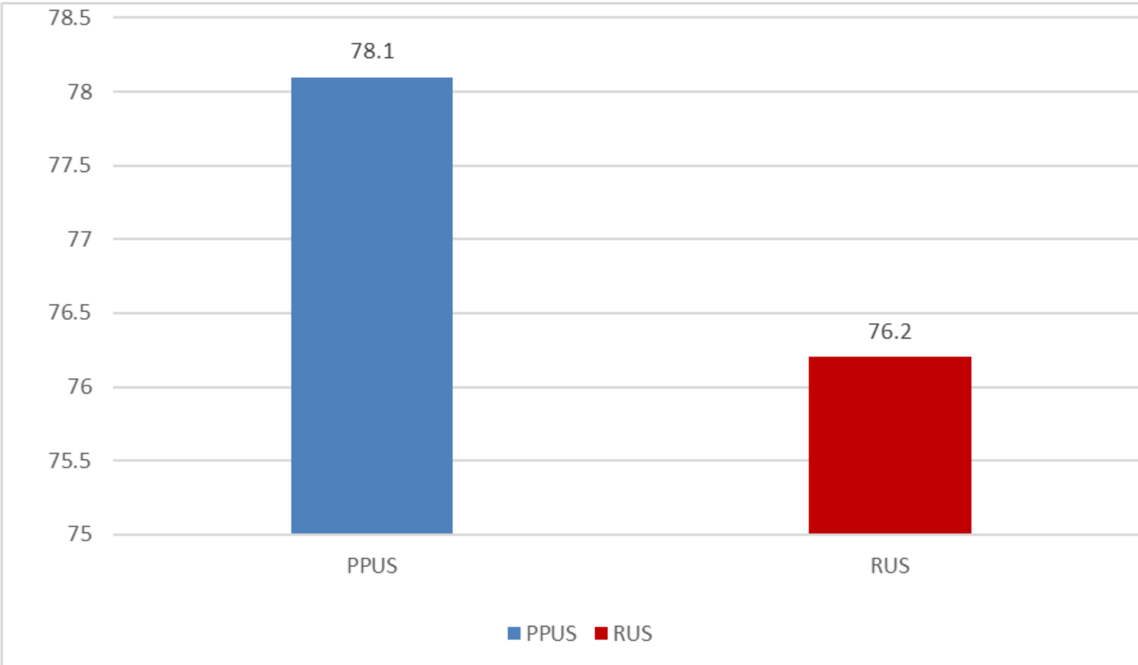
Table 4: Comparison of mean heart rate and MAP between groups

	Group PPUS		Group RUS		p-value
	Mean	SD	Mean	SD	
Mean HR bpm	78.6	9.2	78.1	7.0	0.78
MAP mmhg	78.1	8.0	76.2	6.6	0.24

Graph 4: Comparison of Mean heart rate between groups



Graph 5: comparison of Mean arterial pressure (MAP) between groups



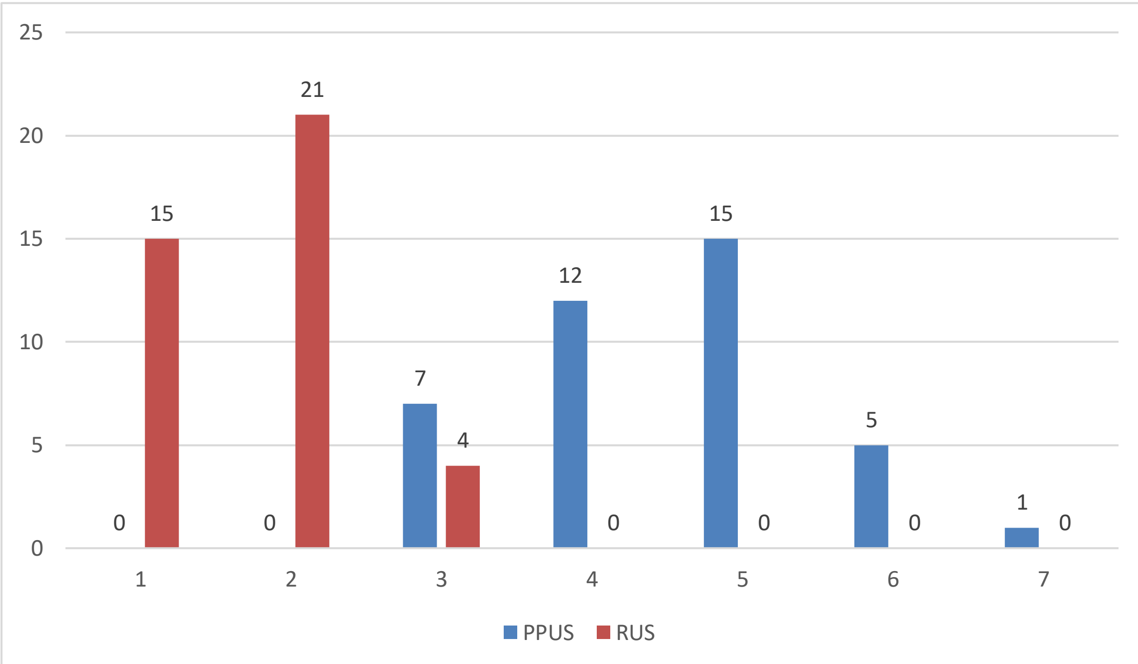
5.NUMBER OF ATTEMPTS

There are significantly less number of attempts in Group RUS compared to Group PPUS.($p<0.05$) Majority were with 1st and 2nd attempt in Group RUS compared to the 4th to 6th attempts in Group PPUS. Also, the mean number of attempts were significantly lower in Group RUS (1.7±0.6) compared to Group PPUS (4.5±1.0). ($p<0.05$)

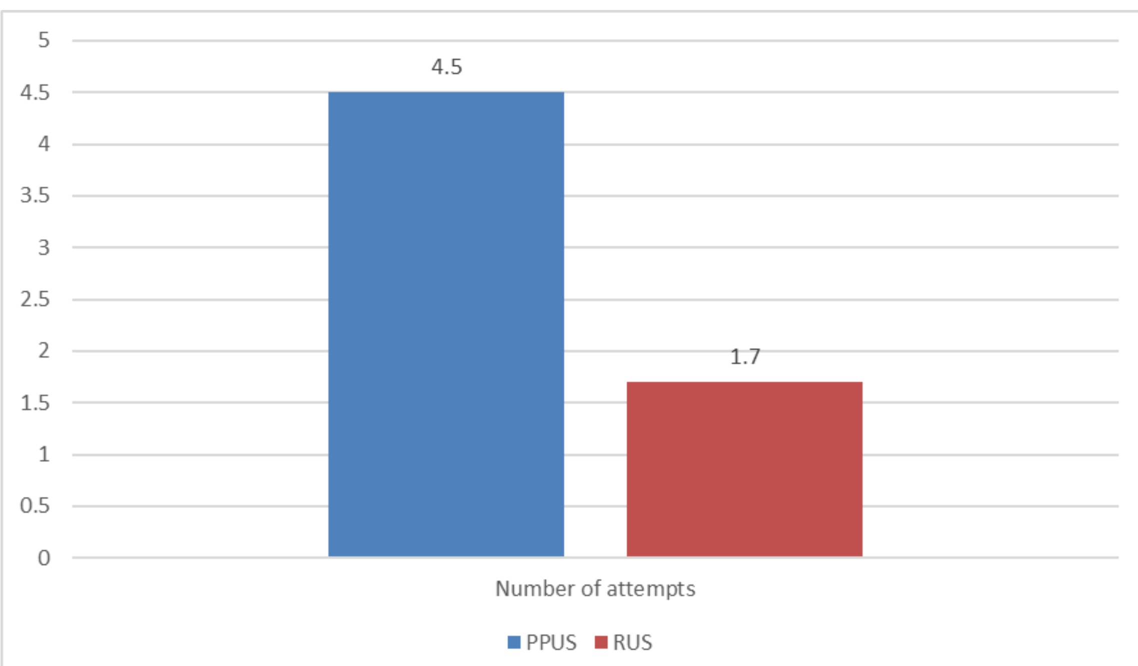
Table 5: Comparison of number of attempts between the groups

		Group PPUS n=40		Group RUS n=40		Chi-square (p-value)
		n	%	N	%	
Number of Attempts	1st attempt	0	0.0%	15	37.5%	69.818 (0.01)*
	2nd attempt	0	0.0%	21	52.5%	
	3rd attempt	7	17.5%	4	10.0%	
	4th attempt	12	30.0%	0	0.0%	
	5th attempt	15	37.5%	0	0.0%	
	6th attempt	5	12.5%	0	0.0%	
	7th attempt	1	2.5%	0	0.0%	
	Mean ± SD	4.5±1.0		1.7±0.6		0.01*

Graph 6: Comparison of number of attempts between the groups



Graph 7: Comparison of the mean number of attempts between the groups



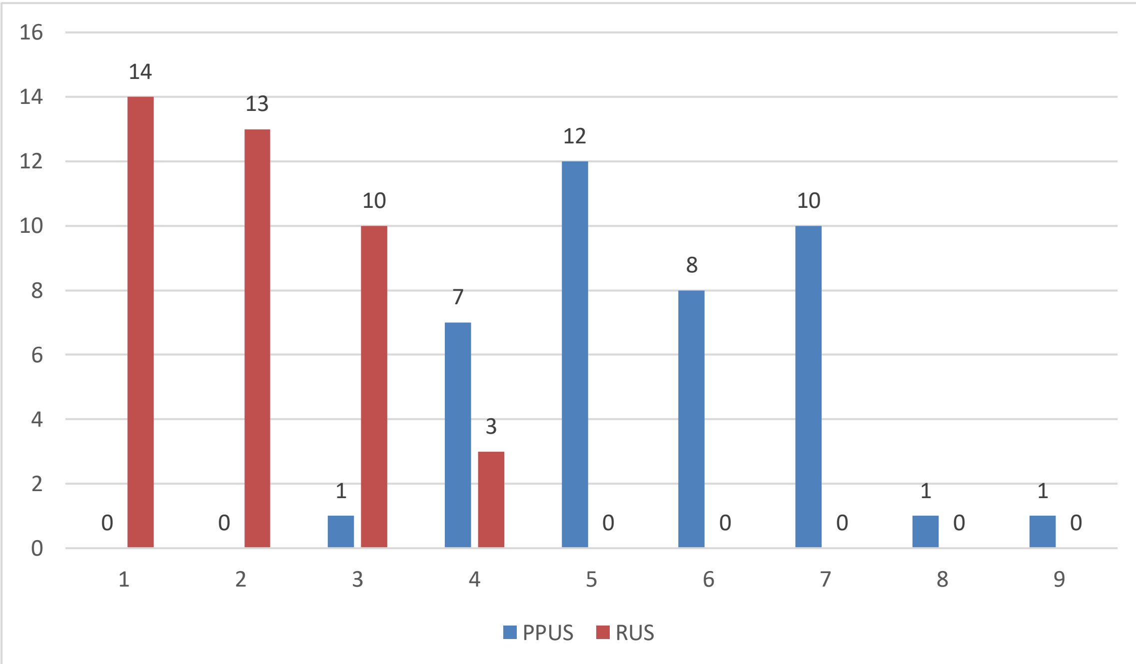
6.NUMBER OF NEEDLE PASSES

The number of needle passes was found to be significantly lower in Group RUS compared to Group PPUS.($p<0.05$) Majority of cases needed the 1-2 number of needle pass in Group RUS in comparison to the 4-7 number of needle pass in Group PPUS. Also, the mean number of needle pass were significantly lower in Group RUS (2.1±1.0) compared to Group PPUS (5.7±1.3).($p<0.05$)

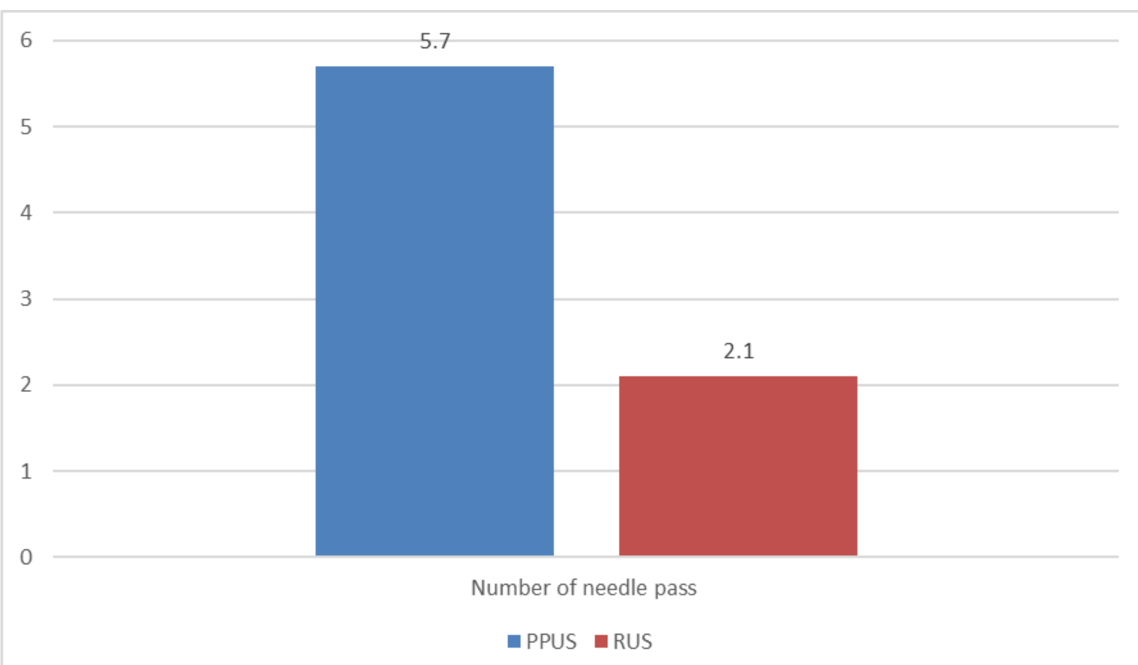
Table 6: Comparison of number of needle passes between the groups

		Group PPUS n=40		**Group RUS n=40**		**Chi-square (p-value)**
		n	%	N	%	
Number of needle passes	1st pass	0	0.0%	14	35.0%	67.96 (0.01)*
	2	0	0.0%	13	32.5%	
	3	1	2.5%	10	25.0%	
	4	7	17.5%	3	7.5%	
	5	12	30.0%	0	0.0%	
	6	8	20.0%	0	0.0%	
	7	10	25.0%	0	0.0%	
	8	1	2.5%	0	0.0%	
	9	1	2.5%	0	0.0%	
	Mean ± SD	5.7±1.3		2.1±1.0		0.01*

Graph 7: Comparison of number of needle passes between the groups



Graph 8: Comparison of the mean number of needle pass between the groups



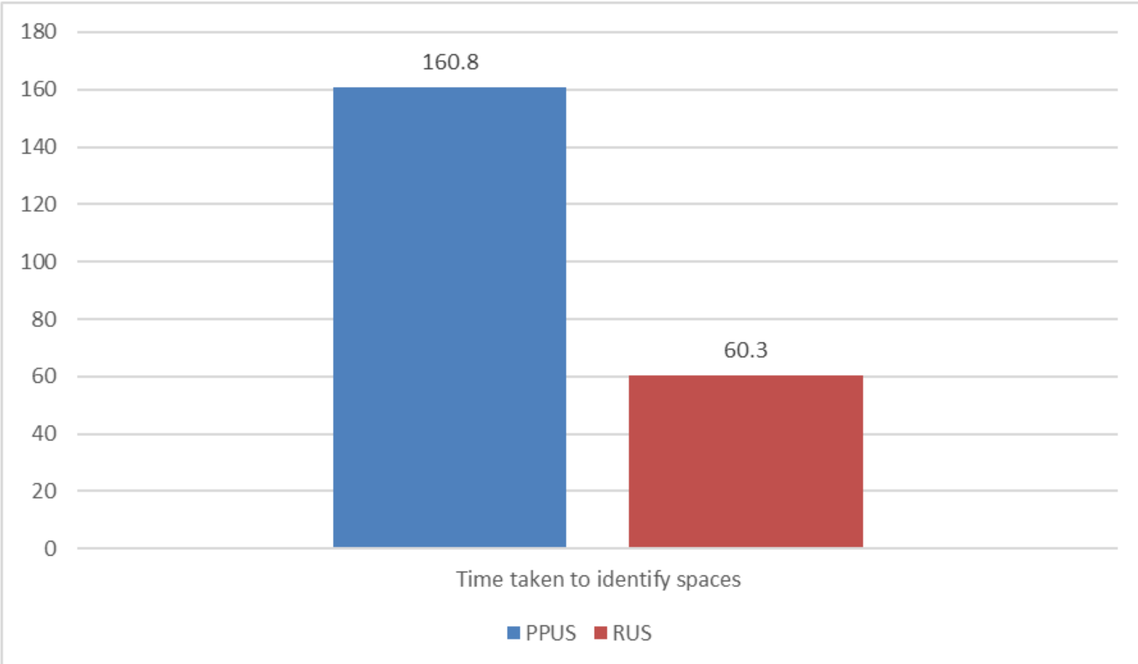
7.TIME TAKEN TO IDENTIFY SPACE , FOR SUCCESSFUL LUMBAR PUNCTURE AND SUCCESS RATE

There is significant longer duration of time taken to identify the spaces in Group PPUS (160.8±45.2) compared to Group RUS (60.3±25.6). similarly, there is significant longer duration of time taken for successful lumbar puncture in Group PPUS (249.2±63.3) compared to Group RUS (93.6±30.0). ($p<0.05$) Success rate was found to be similar 100 percent in both the groups.

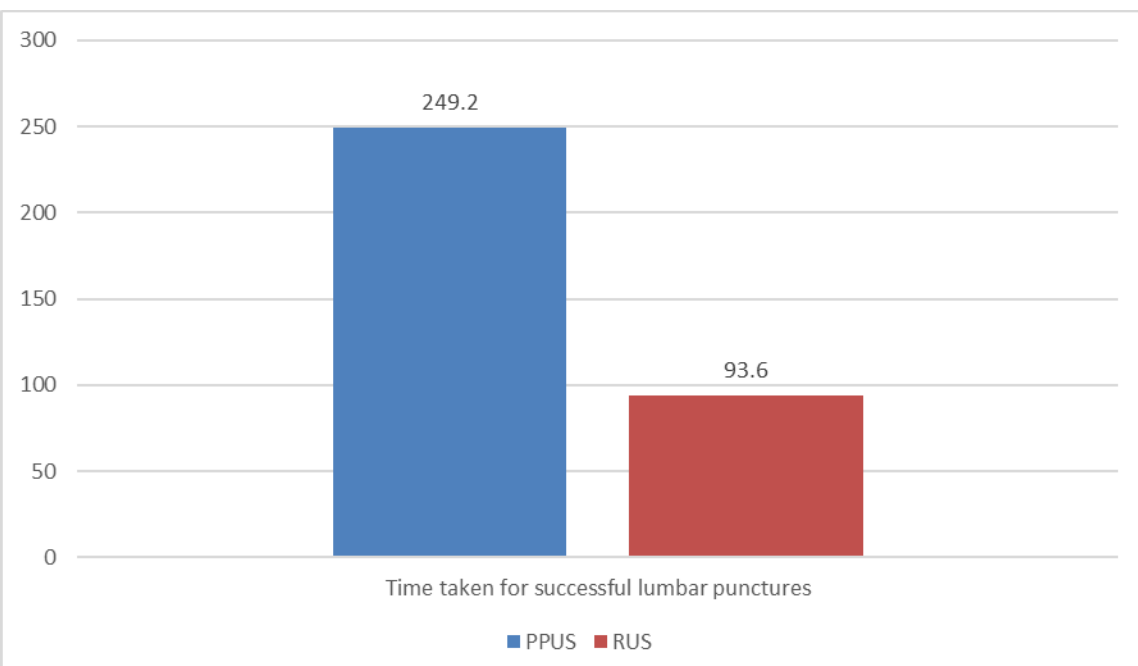
Table 7: Comparison of time taken to identify space, for successful lumbar puncture and success rate between the groups.

	Group PPUS		Group RUS		p-value
	Mean	SD	Mean	SD	
Time taken to identify spaces	160.8	45.2	60.3	25.6	0.01*
Time taken for successful lumbar punctures	249.2	63.3	93.6	30.0	0.01*
Success rate	100.0	.0	100.0	.0	-

Graph 9: Comparison of the mean Time taken to identify spaces between the groups



Graph 10: Comparison of the mean Time taken for successful lumbar punctures between the groups



DISCUSSION

Spinal anesthesia is the preferred anesthetic technique for cesarean sections due to its effectiveness, safety profile, and ability to provide rapid onset of sensory and motor blockade. However, its successful administration relies heavily on the precise identification of anatomical landmarks, which can be challenging in obese parturients. Excess adipose tissue, altered spinal anatomy, and difficulty in palpating bony landmarks increase the risk of multiple needle insertion attempts, leading to complications such as post-dural puncture headache, spinal hematoma, and neurological injury.

To overcome these challenges, ultrasound-guided techniques have gained prominence in neuraxial anesthesia. Ultrasound facilitates accurate localization of the spinal structures, optimizing the success of spinal anesthesia while minimizing complications. Two primary approaches have been adapted: pre-procedural ultrasound (PPUS) and real-time ultrasound (RUS) guidance. PPUS involves identifying the optimal puncture site before the procedure, marking it on the skin, and subsequently inserting the spinal needle based on these landmarks. In contrast, RUS involves continuous ultrasound visualization of the spinal needle in real time as it advances through the interlaminar space.

Given the growing prevalence of maternal obesity and the challenges it presents for spinal anesthesia, it is essential to determine which ultrasound technique offers greater efficacy, efficiency, and safety in this high-risk population. Our study aims to compare RUS and PPUS in terms of procedural success, number of attempts, needle passes, time taken for dural puncture, and overall feasibility in obese parturients undergoing elective cesarean section.

Present study included total of 80 patients with 40 patients in each group. The mean age between the group was comparable with no significant difference. The mean age in Group PPUS was 25.4yrs and Group RUS was 24.9yrs.($p>0.05$) The ASA grade distribution was found to be comparable between the groups, with no significant difference noted. The mean heart rate and MAP were found to be comparable between the groups.

Similar to present study Ravi PR et al., documented with comparable mean age of patients between the groups with mean age of 55.5yrs in PUS group and 58.5yrs in Group RUS , with no significant difference in gender distribution between the groups. [38]In similar study by Chen L et al., the mean age, gender distribution, ASA grades and physical characters such as height, weight and BMI were comparable between both the groups.[39]

There is significant less number of attempts in Group RUS compared to Group PPUS.($p<0.05$) majority were with 1st and 2nd attempt in Group RUS compared to the 4 to 6 attempts in Group PPUS. Similarly, the number of needle passes was found to be significantly lower in Group RUS compared to Group PPUS ($p<0.05$) Majority of cases needed the 1-2 number of needle pass in Group RUS in comparison to the 4-7 number of needle pass in Group PPUS.

In concordance to present study Ravi PR et al., documented with better outcomes in Group RUS compared to the PUS group with median number of attempts of 2 (IQR 1–2) versus 4 (IQR 2–4) ($P< 0.001$). Additionally, the Group RUS required fewer passes, less time to identify the space, and shorter time for successful lumbar puncture compared to the PUS group. Overall, the PUS group exhibited longer times and higher attempts for these procedures, highlighting the efficiency of the RUS approach. The success rate documented in their study was 98% in PUS group and 92.5% in Group RUS .[38]

In study by Park SK et al., the ultrasound assisted approach achieved a significant fewer needle pass, higher first pass and first attempt success rate.[40] Also in study by Chen L et al., documented number of attempts and median pass were significantly lower in ultrasound assisted spinal anaesthesia compared to the real time US guided anaesthesia. [39]

Another study by Uyel Y et al., the first-attempt success rate for accessing the subarachnoid space was notably higher in the ultrasound group (74.4% vs. 53.8%, $p = 0.008$). Patients in the ultrasound group also required fewer needle insertion attempts (median 1 vs. 2, $p = 0.038$) and redirections (median 2 vs. 3, $p = 0.028$) compared to the landmark-guided group. However, no significant differences were observed between the groups regarding total procedure time, pain scores, patient satisfaction, or complications.[37]

In similar, Mengzhu L et al., found that the ultrasound group demonstrated a significantly higher first-attempt success rate, fewer patients requiring more than 10 needle passes, fewer puncture attempts, shorter procedure times (including needle site identification), and higher patient satisfaction scores compared to the landmark group. However, for patients with BMI 30–34.9 kg/m^2, there were no significant differences in first-attempt success rates or procedure times, except for longer needle site identification time in the ultrasound group. These findings suggest that ultrasound guidance is particularly advantageous for patients with higher BMI, enhancing procedural efficiency and success while improving patient experience[36]

Also in study by Dhanger S et al., the number of attempts needed to perform a lumbar puncture on a pregnant patient was shown to be a much lower when pre-procedural ultrasound was used instead of the standard landmark technique is what the study found.[33]

There is significant longer duration of time taken to identify the spaces in Group PPUS (160.8±45.2) compared to Group RUS (60.3±25.6). similarly, there is significant longer duration of time taken for successful lumbar puncture in Group PPUS (249.2±63.3) compared to Group RUS (93.6±30.0). ($p<0.05$) Success rate was found to be similar 100 percent in both the groups.

Ravi PR et al., also documented with less time to identify the space, shorter time for successful lumbar puncture in Group RUS compared to PUS group. [38] Chen L et al., documented with significant shorter locating time in Group RUS , however there was significant longer procedure time and total time in Group RUS .[39]

In concordance to present study Narkhede HH et al., documented with the ultrasound-guided (UG) group demonstrated a significantly higher rate of successful dural puncture on the first needle insertion attempt (90% vs. 50%, $P < 0.05$) compared to the anatomical-guided (AG) group. The mean number of needle passes was significantly lower in the UG group (1.07 vs. 1.90, $P < 0.05$), and only 3.3% of UG patients required more than three midline attempts. Procedure time was notably shorter in the UG group (2.25 minutes vs. 4.35 minutes), while VAS scores for pain were comparable between groups. These findings underscore the value of preprocedural ultrasound imaging in facilitating central neuraxial blockade, particularly in elderly patients with challenging anatomical landmarks.[34]

From a clinical perspective, these findings support the growing adoption of real-time ultrasound guidance in obstetric anesthesia. While group PPUS remains a viable option, group RUS appears to offer significant advantages in terms of procedural ease and efficiency. Further research with larger sample sizes and multicenter trials could provide additional insights into optimizing neuraxial ultrasound techniques for high-risk obstetric populations.

ADVANTAGES OF ULTRASOUND GUIDED SPINAL ANAESTHESIA

1. **Training and Implementation in Clinical Practice:** Since real-time ultrasound guidance significantly reduces the time required to identify the intervertebral space and complete the lumbar puncture, anesthesiology departments should prioritize training anesthesiologists in this technique. Simulation-based training and hands-on workshops should be incorporated to improve proficiency, particularly for novice practitioners.
2. **Use of RUS for High-Risk and Difficult Cases:** In patients with high BMI, anatomical variations, or a history of difficult spinal anesthesia, RUS will be the preferred method. This will help in reducing multiple attempts and procedural time, thereby lowering the risk of post-dural puncture headache and other complications.
3. **Standardization of Ultrasound Protocols for Spinal Anesthesia:** Hospitals and anesthesia societies should consider developing standardized protocols for ultrasound-

guided spinal anesthesia, ensuring consistency in probe selection, patient positioning, and image interpretation. Establishing guidelines for RUS versus PPUS use in different patient populations can optimize outcomes.

4. **Further Research and Multicenter Trials:** While this study demonstrates the superiority of RUS in obese parturients, larger multicenter studies should be conducted to validate these findings. Future research should explore additional factors such as operator experience, patient satisfaction, and long-term outcomes associated with ultrasound-guided spinal anesthesia.
5. **Cost-Effectiveness and Resource Allocation:** Given the improved efficiency and procedural success of RUS, healthcare institutions should evaluate the cost-effectiveness of investing in ultrasound equipment and training. Integrating real-time ultrasound into routine anesthetic practice could lead to long-term benefits by reducing procedure-related complications and hospital stay durations.
6. **Patient Education and Shared Decision-Making:** Patients undergoing elective cesarean sections should be informed about the benefits of ultrasound-guided spinal anesthesia, particularly the advantages of RUS in reducing procedural difficulty. Engaging patients in shared decision-making can enhance their confidence and cooperation during the procedure.

By incorporating these steps, hospitals and anesthesia providers can improve the safety, efficacy, and overall experience of spinal anesthesia for obese parturients.

SUMMARY

- Present study included total of 80 patients with 40 patients in each group.
- The mean age between the group was comparable with no significant difference. The mean age in Group PPUS was 25.4yrs and Group RUS was 24.9yrs.($p>0.05$)
- The physical characters such was mean weight and BMI was found to be significantly higher in Group PPUS compared to Group RUS . However, the mean height was comparable between the groups.
- The ASA grade distribution was found to be comparable between the groups, with no significant difference noted.
- The mean heart rate and MAP were found to be comparable between the groups.
- There is significant less number of attempts in Group RUS compared to Group PPUS ($p<0.05$) majority were with 1st and 2nd attempt in Group RUS compared to the 4 to 6 attempts in Group PPUS. Also, the mean number of attempts were significantly lower in Group RUS (1.7 ± 0.6) compared to Group PPUS (4.5 ± 1.0). ($p<0.05$)
- Similarly, the number of needle passes was found to be significantly lower in Group RUS compared to Group PPUS ($p<0.05$) Majority of cases needed the 1-2 number of needle pass in Group RUS in comparison to the 4-7 number of needle pass in Group PPUS. Also, the mean number of needle pass were significantly lower in Group RUS (2.1 ± 1.0) compared to Group PPUS (5.7 ± 1.3) ($p<0.05$)
- There is significant longer duration of time taken to identify the spaces in Group PPUS (160.8 ± 45.2) compared to Group RUS (60.3 ± 25.6). similarly, there is significant longer duration of time taken for successful lumbar puncture in Group PPUS (249.2 ± 63.3)

compared to Group RUS (93.6±30.0). ($p<0.05$) Success rate was found to be similar 100 percent in both the groups.

CONCLUSION

We compared the effectiveness of real-time ultrasound (RUS) guided spinal anaesthesia versus pre-procedural ultrasound (PPUS) guided spinal anaesthesia in obese parturients. RUS guidance was significantly more efficient in terms of procedural ease , fewer attempts and needle passes to achieve successful spinal anaesthesia compared to group PPUS. We observed real-time ultrasound guidance enhances precision, minimizes procedural difficulty, and may improve patient comfort.

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BLDE (DU)/IEC/ 957/2023-24 10/4/2023

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this University met on **Saturday, 18th March, 2023 at 11.30 a.m. in the CAL Laboratory, Dept. of Pharmacology,** scrutinized the Synopsis/ Research Projects of Post Graduate Student / Under Graduate Student /Faculty members of this University /Ph.D. Student College from ethical clearance point of view. After scrutiny, the following original/ corrected and revised version synopsis of the thesis/ research projects has been accorded ethical clearance.

TITLE: "TO COMPARE THE EFFECTIVENESS OF REAL-TIME ULTRASOUND GUIDED SPINAL ANAESTESIA VERSUS PRE-PROCEDURAL ULTRASOUND GUIDED SPINAL ANAESTHESIA IN OBESE PARTURIENTS- A RANDOMIZED CONTROL TRIAL".

NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR: DR.SUMAN S. HIREMATH

NAME OF THE GUIDE: DR.PRATIBHA S.D., ASSOCIATE PROFESSOR, DEPT. OF ANAESTHESIOLOGY.

Dr. Santoshkumar Jeevangi
Chairperson
IEC, BLDE (DU),
VIJAYAPURA

Chairman,
Institutional Ethical Committee,
BLDE (Deemed to be University)
Vijayapura

Dr.Akram A. Naikwadi
Member Secretary
IEC, BLDE (DU),
VIJAYAPURA

MEMBER SECRETARY
Institutional Ethics Committee
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

Following documents were placed before Ethical Committee for Scrutinization.

- Copy of Synopsis/Research Projects
- Copy of inform consent form
- Any other relevant document

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.

BLDE (DU): Phone: +918352-262770, Fax: +918352-263303, Website: www.bldedu.ac.in, E-mail:office@bldedu.ac.in

College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldedu.ac.in

SAMPLE OF INFORMED CONSENT FORM:

BLDE (DEEMED TO BE UNIVERSITY), SHRI B.M.PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTER, VIJAYAPURA-586103, KARNATAKA

TITLE OF PROJECT: **TO COMPARE THE EFFECTIVENESS OF REAL-TIME ULTRASOUND GUIDED SPINAL ANAESTHESIA VERSUS PRE-PROCEDURAL ULTRASOUND GUIDED SPINAL ANAESTHESIA IN OBESE PARTURIENTS: A RANDOMIZED CONTROL TRIAL**

PRINCIPAL INVESTIGATOR: DR SUMAN HIREMATH
JUNIOR RESIDENT
Department of Anesthesiology
BLDE(DU), Shri B.M Patil Medical College Hospital
Vijayapura, Karnataka

PG GUIDE : DR PRATIBHA S D
MD -Anesthesiology
PROFESSOR (ADDITIONAL)- Department of Anesthesiology BLDE(DU), Shri B.M Patil Medical College Hospital
Vijayapura, Karnataka

PURPOSE OF RESEARCH:

I have been informed that in this study is to compare the effectiveness of Real time ultrasound guided spinal anaesthesia versus pre-procedural ultrasound guided spinal anaesthesia in obese parturients :

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

PROCEDURE:

I understand that I will be taking part in the study: TO COMPARE THE EFFECTIVENESS OF REAL-TIME ULTRASOUND GUIDED SPINAL ANAESTHESIA VERSUS PRE-PROCEDURAL ULTRASOUND GUIDED SPINAL ANAESTHESIA IN OBESE PARTURIENTS: A RANDOMIZED CONTROL TRIAL

RISKS AND DISCOMFORTS:

I understand that I/my ward participating in the study may experience some discomfort during the procedure, and I know that necessary measures will be taken to reduce them.

BENEFITS:

I understand that me/my ward participating in this study will help in finding out the TO COMPARE THE EFFECTIVENESS OF REAL-TIME ULTRASOUND GUIDED SPINAL ANAESTHESIA VERSUS PRE-PROCEDURAL ULTRASOUND GUIDED SPINAL ANAESTHESIA IN OBESE PARTURIENTS: A RANDOMIZED CONTROL TRIAL

CONFIDENTIALITY:

I understand that the medical information produced by this study will become a part of this hospitals records and will be subjected to the confidentiality and privacy regulations of this hospital. If the data is used for publication in the medical literature or for teaching purposes, 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 audio tapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time to Dr. Suman hiremath as she is available to answer my questions and 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 the study with someone 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 a careful reading.

REFUSAL OR WITHDRAWAL OR PARTICIPATION:

I understand that my participation is voluntary, and I may refuse to participate or 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. Suman hiremath can terminate my participation in this study at any time after he has explained the reason for doing so and has helped arrange for my continued care by my 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 my participation in this study, the such injury will be reported promptly and the medical treatment will be available to me/my ward, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving my legal rights. I have been explained about the purpose of this research, the procedure required and the possible risk and benefits to the best of my abilities and my language of understanding.

Date: Dr Suman hiremath

(Investigator)

Patient/Parent signature Witness

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. SUMAN HIREMATH 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 the language of my understanding.

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

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(Participant) (Date)

PROFORMA

STUDY: TO COMPARE THE EFFECTIVENESS OF REAL-TIME ULTRASOUND GUIDED SPINAL ANAESTHESIA VERSUS PRE-PROCEDURAL ULTRASOUND GUIDED SPINAL ANAESTHESIA IN OBESE PARTURIENTS: A RANDOMIZED CONTROL TRIAL

Patient Details

Name: Height: Diagnosis:

Age: Weight: Surgical procedure:

Sex: BMI:

Past history:

General physical examination:

Pallor Icterus Cyanosis Clubbing Edema

Lymphadenopathy Mallampatti Grading (I II III IV)

Vital parameters:

Pulse Blood pressure Respiratory rate Temperature

Systemic Examination:

CVS RS CNS PER ABDOMEN

Investigations:

Hb: TLC: Platelet count: Urine Routine:

HIV: HbsAg: HCV: HbA1c:

FBS: UKB Drug Therapy:(Insulin/Oral):

Parameters	Group -RUS	Group-PPUS
Number of attempts		
Number of needle passes		
Time taken to identify space(s)		
Time taken for successful lumbar puncture(s)		
Success rate		
Converted to GA		

MASTERCHART

SL No	Group	Name	Age in years	Height in cm	Weight in kg	BMI kg/m2	ASA Grade	MEAN HR bpm	MAP mmHg	Number of attempts	Number of needle passes	Time taken to identify space(s)	Time taken for successful lumbar puncture(s)	Success rate	Converted to GA
1	RUS	Jayashree	31	155	90	37.4	1	88	93	2	2	150	100	100	NO
2	RUS	Prema	26	150	80	35.5	1	84	90	2	2	45	120	100	No
3	RUS	Firdos	23	153	87	39.4	1	90	88	1	1	30	50	100	NO
4	RUS	Sheela	21	155	75	31.2	1	80	75	1	1	30	45	100	NO
5	RUS	Manjula	30	160	90	35.2	1	82	78	2	2	45	110	100	NO
6	RUS	Bhagyashree	23	150	80	35.6	1	74	70	2	2	60	75	100	NO
7	RUS	Sana	23	148	80	36.5	1	68	74	1	1	40	60	100	NO
8	RUS	Sunita	21	160	80	31.2	1	78	80	2	1	35	60	100	NO
9	RUS	Prerana	29	155	80	33.3	1	80	74	2	1	40	65	100	NO
10	RUS	Pavitra	23	156	78	32.1	1	84	70	2	2	80	120	100	NO
11	RUS	Basamma	26	160	80	31.3	1	64	68	1	1	40	60	100	NO
12	RUS	Priyanka	28	158	82	32.3	1	74	72	2	2	65	85	100	NO
13	RUS	Arpita	27	160	89	34.8	1	90	70	2	1	30	70	100	NO
14	RUS	Basamma H	23	155	75	31.2	1	90	74	1	1	15	20	100	NO
15	RUS	Akshata	24	158	80	32	1	92	78	2	3	75	80	100	NO
16	RUS	Soundarya	22	152	78	33.8	2	80	76	3	4	90	120	100	NO
17	RUS	Sunanda	24	145	75	35.7	1	68	70	2	1	80	110	100	NO
18	RUS	Priyanka M	22	156	78	32.1	1	84	70	2	2	80	120	100	NO
19	RUS	Ranjita	20	155	79	32.9	1	72	68	1	2	90	150	100	NO
20	RUS	Geetha	25	162	84	32	1	68	68	2	3	50	90	100	NO
21	RUS	Rashmi	26	156	84	34.5	1	88	72	1	2	65	100	100	NO
22	RUS	Rukmini	24	155	82	34.1	1	76	70	1	3	68	120	100	NO
23	RUS	Ruksana	24	150	78	34.7	1	80	72	3	4	45	100	100	NO
24	RUS	Mallawwa	28	148	76	34.7	2	74	70	2	3	55	130	100	NO
25	RUS	Tabassum	26	155	76	31.6	1	70	74	1	3	50	80	100	NO

26	RUS	Aishwarya	27	166	86	31.2	1	74	66	3	4	60	90	100	NO
27	RUS	Julie	25	154	78	32.9	1	80	78	2	2	80	100	100	NO
28	RUS	Janum b	32	150	80	35.5	1	80	80	1	1	30	60	100	NO
29	RUS	Monika	25	148	82	37.4	1	74	74	2	3	75	150	100	NO
30	RUS	Divya	31	150	89	39.6	1	72	80	1	1	50	70	100	NO
31	RUS	Yogeshwari	29	158	82	32.3	1	74	76	2	1	40	65	100	NO
32	RUS	Mehboob	23	156	82	33.7	1	78	84	2	3	70	100	100	NO
33	RUS	Veena	22	148	80	36.5	1	70	82	1	1	30	70	100	NO
34	RUS	Mayuri	20	146	82	38.5	1	80	82	3	3	70	100	100	NO
35	RUS	Sumitra	25	150	78	34.7	1	78	88	1	3	70	110	100	NO
36	RUS	Bhagyashree m	20	148	70	30.6	1	78	82	1	1	50	100	100	NO
37	RUS	Yallavva	23	154	78	32.9	1	80	84	2	2	90	150	100	NO
38	RUS	Bhavana	28	158	84	33.6	1	84	80	2	3	100	120	100	NO
39	RUS	Rekha	24	154	78	32.9	1	70	74	2	2	90	120	100	NO
40	RUS	Prema	22	150	89	39.6	1	72	74	1	2	55	100	100	NO
41	PPUS	Nazmin	23	155	75	31.2	1	78	88	3	6	120	260	100	NO
42	PPUS	Baslingamma	33	140	90	45.9	1	72	74	4	8	80	280	100	NO
43	PPUS	Nilofer	22	152	95	41.1	1	80	82	4	3	150	250	100	NO
44	PPUS	Mahadevi	26	155	90	39.5	1	82	82	4	4	180	220	100	NO
45	PPUS	Savitri	26	156	78	32.1	1	88	96	4	5	160	250	100	NO
46	PPUS	Ameena	29	155	80	33.3	1	80	90	3	6	90	180	100	NO
47	PPUS	Basamma	26	155	80	33.3	2	74	84	4	9	120	260	100	NO
48	PPUS	Bhagirathi	26	160	84	32.8	1	72	92	5	5	200	300	100	NO
49	PPUS	Sangeetha	24	150	78	34.7	1	68	70	4	6	220	300	100	NO
50	PPUS	Sneha	24	155	84	35	2	92	75	5	6	200	300	100	NO
51	PPUS	Jyoti	30	150	102	45.3	2	110	70	3	5	90	98	100	NO
52	PPUS	Surekha	30	150	84	36.4	1	96	74	5	7	120	150	100	NO
53	PPUS	Anita	28	165	90	33.1	1	80	68	6	6	210	340	100	NO
54	PPUS	Uma shri	25	148	80	36.5	1	70	66	5	5	200	280	100	NO

53	PPUS	Anita	28	165	90	33.1	1	80	68	6	6	210	340	100	NO
54	PPUS	Uma shri	25	148	80	36.5	1	70	66	5	5	200	280	100	NO
55	PPUS	Radhika	22	150	85	37.8	1	80	68	4	7	170	260	100	NO
56	PPUS	Sneha. D	23	162	88	33.1	1	68	70	6	7	250	350	100	NO
57	PPUS	Pooja	29	152	78	33.8	1	64	64	3	4	100	160	100	NO
58	PPUS	Savita	25	140	90	45.9	1	88	96	5	5	180	240	100	NO
59	PPUS	Harshita	23	155	90	39.5	1	74	84	6	7	240	360	100	NO
60	PPUS	Mamatha	22	142	85	42.2	1	78	72	5	7	180	250	100	NO
61	PPUS	Vidya	27	155	80	33.3	1	74	74	5	5	200	300	100	NO
62	PPUS	Shobha	34	155	78	32.5	1	88	70	5	6	180	250	100	NO
63	PPUS	Reshma. s	24	160	84	32.8	1	68	74	3	4	100	170	100	NO
64	PPUS	Radhika. m	27	148	85	38.8	1	80	78	4	5	180	250	100	NO
65	PPUS	Aishwarya. k	24	158	90	36.1	1	70	84	5	5	160	240	100	NO
66	PPUS	Savitha. s	24	150	90	40	1	68	78	4	6	180	300	100	NO
67	PPUS	Uma	22	154	88	37.1	1	80	76	7	7	240	320	100	NO
68	PPUS	Priya	20	160	94	36.7	2	72	70	5	5	200	250	100	NO
69	PPUS	Kaveri	22	155	84	35.4	1	74	70	5	7	120	160	100	NO
70	PPUS	Shailaja	24	156	84	34.5	1	72	74	3	4	140	200	100	NO
71	PPUS	Siddamma	30	152	78	33.8	1	80	86	4	4	100	180	100	NO
72	PPUS	Baby	28	160	100	39.1	1	80	84	5	5	180	220	100	NO
73	PPUS	Malashree	24	163	88	33.1	1	78	82	3	4	120	150	100	NO
74	PPUS	Manjula	28	165	90	33.1	1	74	84	5	7	110	250	100	NO
75	PPUS	Vani	29	162	94	35.8	1	80	82	4	4	150	250	100	NO
76	PPUS	Sangameshwari	22	150	84	36.4	1	96	74	5	7	120	150	100	NO
77	PPUS	Sowmya	25	160	94	36.7	1	88	78	6	7	150	300	100	NO
78	PPUS	Vandana	20	155	78	32.5	1	78	82	5	5	200	340	100	NO
79	PPUS	Preeti	22	155	80	33.3	1	74	80	4	5	180	280	100	NO
80	PPUS	Bhagya	24	156	84	34.5	1	74	80	6	6	160	320	100	NO

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