

**COMPARING THE EFFECT AND OUTCOMES BETWEEN GENERAL
ANAESTHESIA Vs. COMBINED EPIDURAL AND GENERAL ANAESTHESIA
IN ELECTIVE LUMBAR SPINE SURGERY: A RANDOMIZED CONTROL
STUDY**

BY

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Dissertation submitted to the
**B.L.D.E. (DEEMED TO BE UNIVERSITY)
SHRI B.M. PATIL MEDICAL COLLEGE
HOSPITAL AND RESEARCH CENTER
VIJAYAPURA, KARNATAKA**



In partial fulfillment of the requirements for the degree of
**DOCTOR OF MEDICINE
IN
ANAESTHESIOLOGY**

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DR. PRIYADHARSHINI.V

ABBREVIATIONS

CSE - Combined Spinal Epidural
 PACU – Post Anaesthesia Care Unit
 VAS – Visual Analog Scale
 EA – Epidural Anaesthesia
 SA – Spinal Anaesthesia
 GA – General Anaesthesia
 RA – Regional Anaesthesia
 BP – Blood Pressure
 SBP – Systolic Blood Pressure
 DBP – Diastolic Blood Pressure
 PONV – Postoperative Nause & Vomiting
 CRBD – Catheter Related Bladder Discomfort
 LOS – Length of Stay
 HR – Heart Rate
 MAP – Mean Arterial Pressure
 CEG / CEGA – Combined Epidural/General Anaesthesia
 LOR – Loss of Resistance
 HCL – Hydrochloride
 CNS – Central Nervous System
 GPCR – G-Protein Coupled Receptors
 AMP – Adenine Monophosphate
 BBB – Blood-Brain Barrier
 CSF – Cerebro Spinal Fluid
 ECG – Electrocardiogram
 ASA – American Society of Anaesthesiologists
 NIBP – Non-Invasive Blood Pressure
 BIS – Bispectral Index
 SpO₂ – Saturation of Peripheral Oxygen
 IV – Intravenous
 mins - minutes
 mg – milligram
 mcg – microgram
 ml – millilitre

ABSTRACT

Background:

The choice of anaesthesia technique in elective lumbar spine surgery significantly influences perioperative outcomes. While general anaesthesia (GA) remains the standard approach in Lumbar spine surgery, combined epidural and general anaesthesia (CEGA) has gained attention for its potential benefits. This study aims to compare the effects intraoperatively and postoperative outcomes of GA versus CEGA in patients undergoing elective lumbar spine surgery.

Methods:

A randomized controlled trial was conducted on sixty four patients scheduled for elective lumbar spine surgery for over one and half years. Participants were randomly assigned to receive either GA alone or CEGA. The parameters that were observed were intraoperative vitals, isoflurane requirement, total blood loss throughout the surgery and postoperative parameters such as vitals, pain scoring scale (VAS Score), the duration at which rescue analgesic was needed and the complications were noted.

Results:

Preliminary findings indicate that patients in the CEGA group experienced better intraoperative hemodynamic stability in comparison to GA group. The anaesthetic agents required and loss of blood during surgery was significantly reduced in CEGA group. While in postoperative period, the pain score and the duration of first rescue analgesic required were lower in the CEGA group and also complications post surgery were less encountered.

Conclusion:

The use of CEGA in elective lumbar spine surgery appears to offer significant advantages over GA alone, particularly in terms of intraoperative isoflurane use, blood loss and postoperative pain management. These findings suggest that CEGA may be a preferable anaesthetic technique for lumbar spine surgery. Further research with a larger sample size is recommended to validate these results.

Keywords: General anaesthesia, combined epidural and general anaesthesia, lumbar spine surgery, postoperative pain, fentanyl, Bupivacaine.

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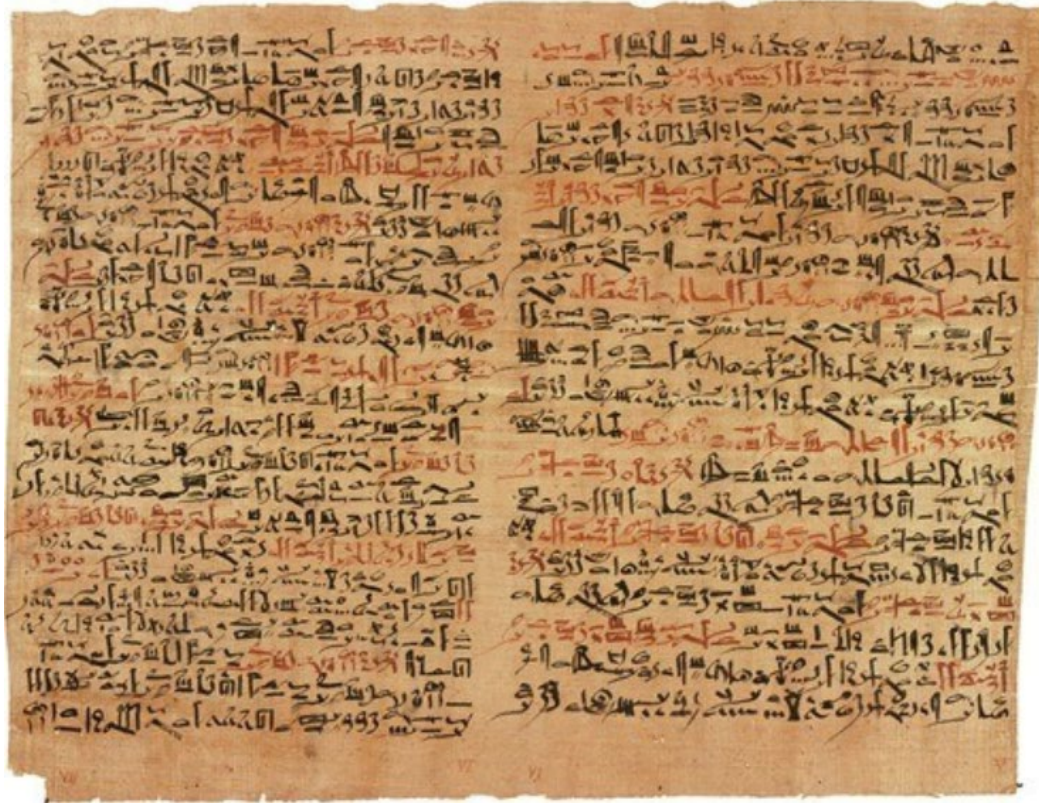
INTRODUCTION

HISTORY BEHIND LUMBAR SPINE SURGERY

Lumbar spinal disorders significantly contribute to morbidity and functional incapacitation. Worldwide, lumbar spine surgery is a crucial intervention, offering relief to many who suffer from lower back and lower extremity discomfort^[1].

Ancient spinal interventions are typically divided into four significant periods: the Egyptian and Babylonian , the Greek and early Byzantine, the Arabic , and the Medieval periods. The earliest written references to surgery are in the Edwin Smith Papyrus from the Egyptian and Babylonian periods, which dates back to after 1700 BC. This document details 48 cases of injuries related to the spine and cranium^[2].

Figure Number 1: Two plates of the Edwin Smith Surgical Papyrus.

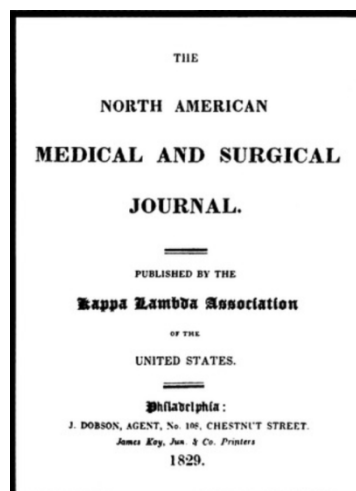


Some of the renowned works in the field of surgery were offered by the scientists from the Hellenistic era. Hippocrates, who later became known as the “Father of Spine Surgery,” made important innovations along with Gal of Pergamum. Between 750 AD and 120 AD, coined as the Arabic and Byzantine era, primarily focused on codifying and translating the works of scholars from the Greek and Roman eras.

Henry Cline carried out the first-ever Laminectomy at the level of the thorax in London in 1814, but that patient had passed unexpectedly three days later the procedure, which was explained by the extent of the serious injury suffered. In order to relieve pressure over the spinal cord and nerve outlets, portion of the body of vertebrae adjacent to the spinal cord was excised which was described as Laminectomy. There was no record of an ideal laminectomy procedure until 1828.

A patient who has suffered acute traumatic paraplegia following a fall from a horse was operated on in 1828 by Alban G. Smith, an unprolific surgeon from Danville, Kentucky. In addition to the patient surviving the laminectomy, Smith is credited with the patient's partial neurological recovery. The procedure and results of the surgery were reported in the North American Journal of Medicine and Surgery (1829) (*figure number 2*)^[3].

Figure Number 2: First ever Publication on the successful laminectomy as per the report by Smith

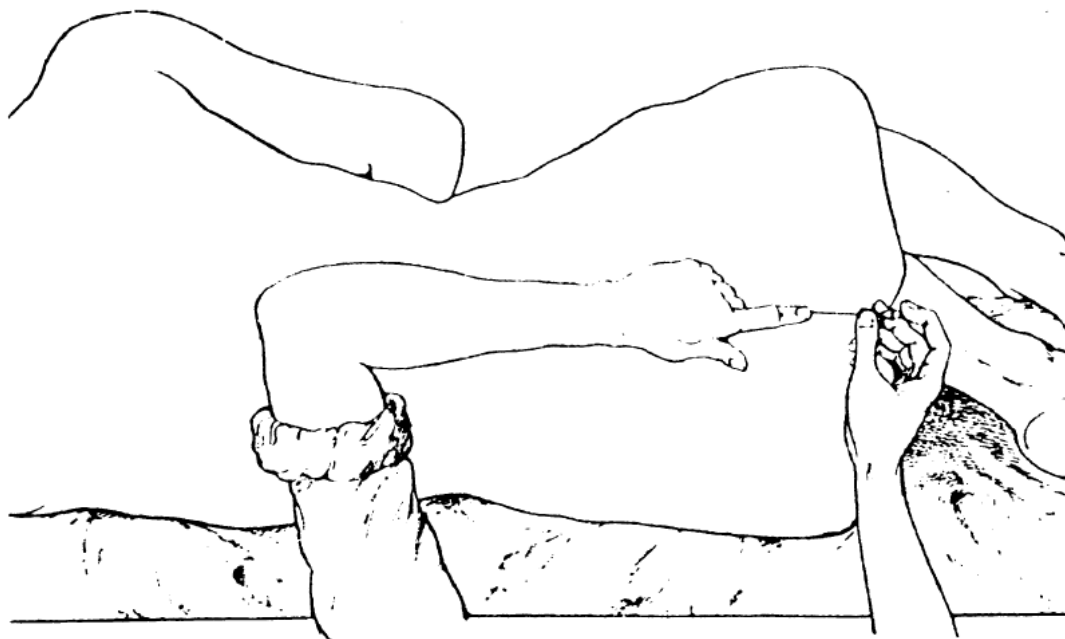


Some of the shortcomings during these surgeries in the early phase were the pain management, infection of the surgical site which later lead to septicemia and most often was fatal. Introduction of general anaesthetic agents (in the mid of 1840s) such as ether, cholorform and nitrous oxide as well as the adoption of the Listerian method (use of carbolic acid in the 1870s) mitigated the above said complications^[3].

HISTORY BEHIND EPIDURAL ANAESTHESIA^[4]

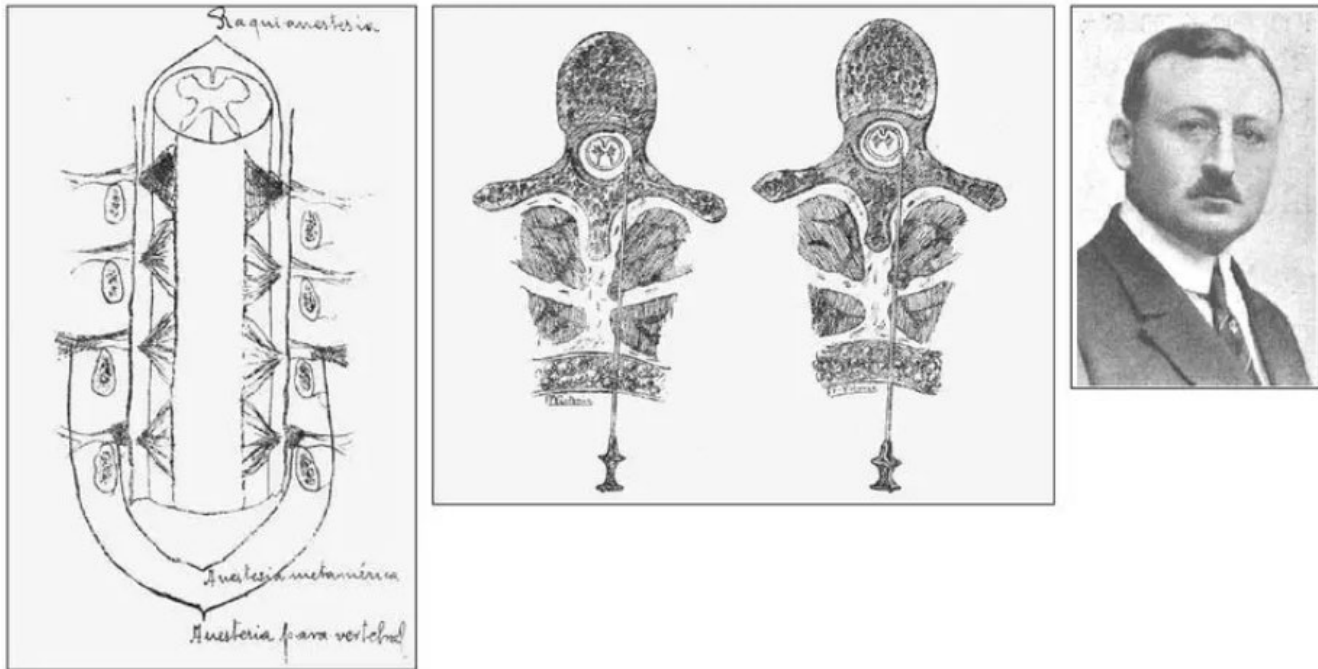
- In the New York Medical Journal, the concept of ‘spinal anesthesia and local medication (anaesthetization) of the spinal cord’ was articularised in October 1885 by a physician, James Leonhard Corning (1855–1923). For many years, his work has been considered the first spinal blockade, although there was no evidential proof that the drug was injected into the intrathecal space.
- A few made individual efforts to study the analgesic effect of administering local anesthetics in epidural space. One among them was Fernand Cathe’lin (1873–1929), who documented the outcomes following the blockade of the last sacrococcygeal nerves by an anesthetic agent in 1901. Cathe’lin had access through the sacral hiatus, unlike Corning, who had access via the lumbar.

Figure Number 3: Positioning for caudal anesthesia as suggested by Fernand Cathelin



- A Romanian surgeon brought about the root of the continuous epidural block (caudal), Eugen Bogdan Aburel (1899–1975). He explained the procedure and its analgesic effect post-delivery at meet held by the Obstetrics and Gynaecological Society of Paris in the year 1931, under the topic "L'Anesthe'sie locale continue' (prolonged) en obste'trique."
- Amid World War I, Fidel Page (1886-1923), a Spanish surgeon, documented his works on epidural anesthesia in a Spanish journal. He gained knowledge of epidural anesthesia through his involvement in war camps and shared experiences with German surgeons. His works could not be retrieved in any other journals, as his works were documented in Spanish.

Figure number 4: The documentation of work by Fidel Page^[8]



- Unaware of the works of Page, a surgery professor from the University of Modena, Italy, Achile Mario Dogliotti (1897-1966) published his works on lumbar epidural anesthesia. Late in 1931, he learned about Page's works on the same. Dogliotti began quoting Page's works worldwide in all his presentations and the articles published in Italy, the United States, the United Kingdom and Germany.
- The credit for the studies on locating the epidural space goes to Alberto Guiterrez. He was an Argentina-based anesthetist who became notable for developing the "hanging drop technique" in 1932. He derived his conclusions from the works of Jean Anthanase Sicard (1872-1929), a French neurologist. Sicard discovered spinal cord anomalies by administering contrast media. He described a "loss of resistance" when entering the epidural space, followed by a series of investigations to find the pressure in the epidural space. A Proof-based

study had already been established in 1928, which indicated that the pressure in the space was negative.

- The technique of neuraxial blockade was further modernized by the invention of Combined spinal-epidural anesthesia (CSE). Ryszard Rodzinski (1890-1948), a surgeon from Poland, was the pioneer in integrating the techniques of both spinal and epidural anesthesia.
- Rodzinski's technique has been in use since 1925. Nevertheless, almost 50 years later, Ioan Curelaru revolutionized the combined spinal-epidural anesthesia by passing a catheter through the epidural space at a particular lumbar level, after which spinal anesthesia was performed in the year 1979. Curelaru's demonstrations were published in a journal in Germany under the paper "Praktische Anaesthesie"^[4].

PURPOSE OF THE STUDY:

In the current era, advancements in surgical procedures involving the spine and spinal cord have significantly broadened the scope of treatment possibilities. With the rise in cases of long-term back problems and surgical advancements, a broad spectrum of conditions, ranging from single-level to complex multi-stage reconstruction, is now being effectively managed^[5].

It is widely agreed that various factors, such as the patient's condition, the surgical procedure, the choice of regional or general anesthesia, and the standard of perioperative care, collectively impact surgical outcomes^[6].

Given the advantages such as patient tolerance, a secured airway, enhanced surgical field exposure with muscle relaxants, early postoperative assessments and better management of intraoperative hemodynamic fluctuations, General anesthesia is commonly favored for spinal surgeries. Nevertheless, it carries its risks, particularly for elderly patients and those with cardiopulmonary conditions^[5].

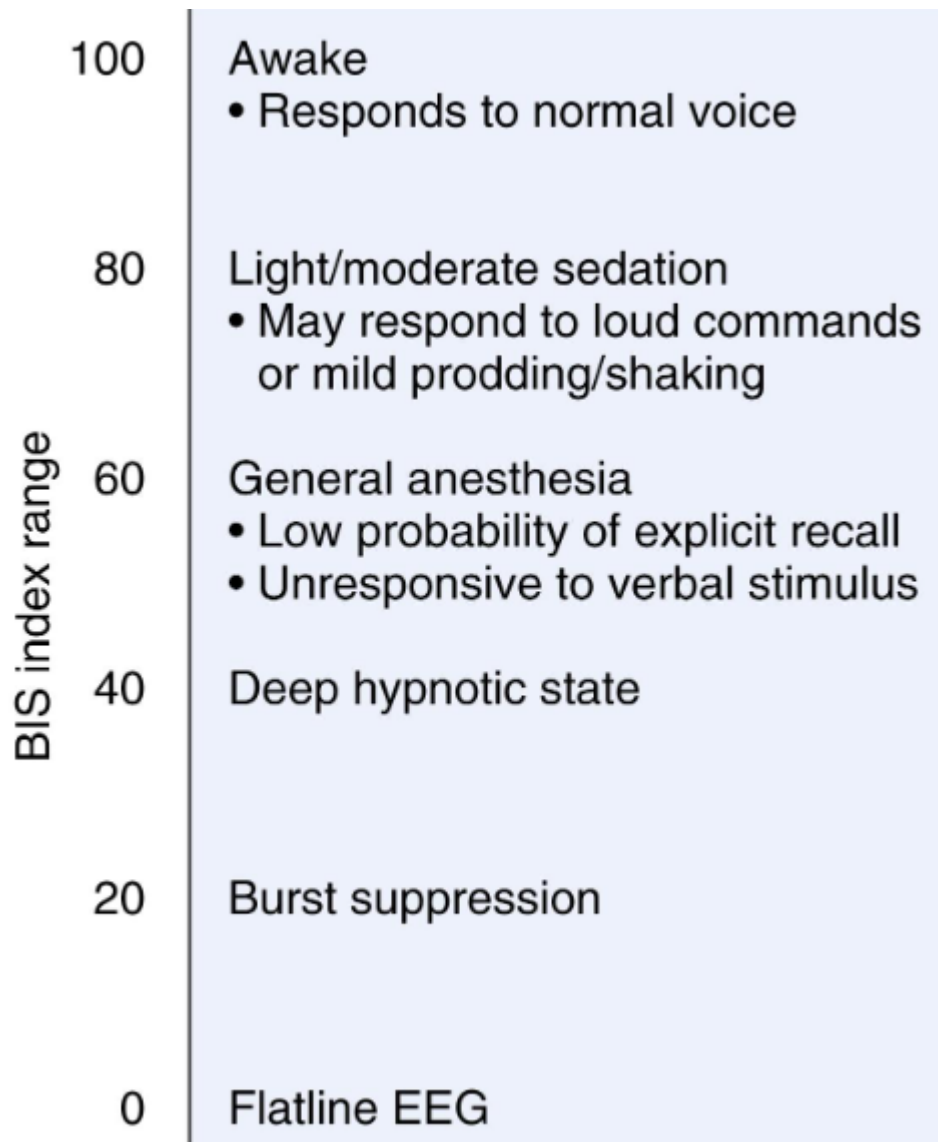
Epidural neuraxial anesthesia is more frequently utilized as an adjunct to general or spinal anesthesia for postoperative pain management. The strong sympathetic blockade achieved by intraoperative neuraxial anesthesia enhances blood flow to the lower extremities, decreases the risk of hypercoagulability, and reduces the workload on the heart. Perioperative epidural analgesia, which combines low-dose local anesthetics with opioids, offers distinct advantages, primarily in terms of enhanced pain relief and reduction or elimination of systemic opioid use. Therefore, perioperative neuraxial analgesia will likely enhance bowel movement, cause no respiratory complications, facilitate earlier mobilization, and ultimately reduce the risk of thrombosis^[6].

Hence, this study aims to co-relate the effects of general anesthesia and combined epidural/general anesthesia over the use of intraoperative anesthetic agents, analgesic requirement and other complications following the laminectomies and discectomy involving one or two-level spine disc surgery.

This study is to show that the outcomes seen in sole general anesthesia are overcome by the combined epidural/general anesthesia in the lumbar spine surgery^[7].

BISPECTRAL INDEX





AIMS AND OBJECTIVES OF THE STUDY

AIM:

To compare the effect and outcomes both intraoperatively and postoperatively following the sole general anaesthesia and combined epidural/general anesthesia in Lumbar spine disc surgeries.

OBJECTIVE :

PRIMARY OBJECTIVE:

To assess and show the efficacy of combined epidural and general anaesthesia over sole general anaesthesia in variables such as Mean arterial blood pressure, Heart rate, Blood loss and amount of anaesthetic agents used.

SECONDARY OBJECTIVE:

To assess the total analgesic rescues and the adverse effects postoperatively following general anaesthesia and combined epidural and general anaesthesia.

- To assess the vital parameters and compare the outcomes postoperatively.
- To assess the postoperative analgesic effect between both the groups.
- To assess the period of administration of the first rescue analgesic in both the groups and compare it.
- To evaluate the complications between both the groups.

REVIEW OF LITERATURE:

1. **Thepsoparn, Marvinet *al.* (2018)^[20]**. 22 patients who were planned for elective lumbar spine surgery were divided into two groups at random. Before receiving general anaesthesia with desflurane and cisatracurium, a single shot of epidural with 0.25% of bupivacaine in addition to 4 mg of morphine making a total volume of 10 mL was given to patients allotted in Group B (Block) .Group G (general) was given only general anesthesia, along with desflurane, cisatracurium, and any other systemic analgesics the attending anesthesiologist felt were necessary. At the post anesthesia care unit (PACU) and 24 hours after the procedure, the postoperative VAS score, opioid requirement, blood loss by the end of the surgery and postoperative complications was noted. At the PACU and after 24 hours, the fentanyl requirement was marked lower ($P < 0.05$) in group B (block). At PACU, the mean fentanyl dosage for groups B and G was 20 and 85 mcg, respectively. The mean fentanyl dose received by the patients at 24 hours was 386 g for group G and 80 g for group B. Both groups experienced comparable levels of pain as assessed by a numerical scale for rating the same, total blood loss, and complications. Compared to general anaesthesia alone, single-shot low-thoracic spinal anaesthesia offers superior pain management.

2. **Mohammad Azad Majediet *al.* (2019)^[21]** Based on inclusion and exclusion criteria, this clinical study was performed on over 80 patients having laparoscopic cholecystectomy with EA or GA. Blood pressure changes, SBP & DBP, heart rate, and saturation of oxygen in arterial blood were the intraoperative parameters that were monitored after the patients were divided into two groups of 40 at random.

Itching, chills, vertigo, and vomiting frequency in the two groups were noted. Use of the t-test and Chi-square tests was combined with descriptive analysis to complete the study. The findings revealed that at 4, 6, and 12 hours after anesthesia, the mean of the following parameters : SBP and DBP, heart rate, saturation of oxygen in arterial blood, and the frequency of PONV was noted to be statistically significant ($P = 0.05$) between the two groups, and it was higher in a group of GA. According to the study's findings, factors like SBP, DBP, and arterial blood oxygen saturation are significantly impacted by thoracic EA in individuals who have undergone laparoscopic cholecystectomy. Additionally, EA is the preferred strategy because it is less complicated than GA.

3. **Marvin Thepsoparnet *et al.* (2022)^[22]** In this study, patients received sole general anaesthesia (GA) and another group received combination of single-dose of epidural shot in the thoracic at a level between T11-L1, consists of 10ml 0.25% of Bupivacaine along with 4mg Morphine. In comparison to the GA group, the combined GA + EA group's length of stay was found to be considerably shorter (3.780.81 [meanstandard deviation] and 4.791.51 days, respectively; $p=.017$). Operating time, blood loss, 24-hour postoperative morphine consumption (mg), and numerical rating score (at rest) at the postanesthesia care unit were all substantially decreased in the epidural group. Combining epidural and/or G.A. treatment increased the likelihood that patients would report higher levels of patient satisfaction ($p=.008$). However, the group receiving Epidural shot found to have more significant frequency of hypotension during the (72.2% vs. 21.1%, $p=.003$). The two patient groups had similar rates of adverse events and surgical field rating ratings. In individuals having elective lumbar spine surgery, combined lower thoracic epidural and/or GA was linked to lower LOS.

4. **Khajavi *et al.* (2013)**^[7] undertook a study where comparison of the impact between the general and combined general/epidural anaesthesia on the outcomes both intraoperatively and postoperatively. Wherein a total of 80 patients were recruited for this study, with both groups exhibiting comparable demographic characteristics. Intraoperatively, the MAP and HR were significantly higher in the GA group compared to the CEG group. The mean intraoperative bleeding was markedly lower in the CEG group in comparison to the GA group ($P = 0.002$). The blood pressure was observed to be stable in group with CEG group compared to GA alone group. Additionally, the mean percentage of the anesthetic agent Isoflurane used during surgery was significantly lower in the CEG group than in the GA group (0.67 ± 0.15 vs. 1.23 ± 0.25 , $P < 0.001$). hence it was concluded that combined epidural with general anaesthesia has more advantages over sole general anaesthesia.

5. **Attari *et al.* (2011)**^[23] This study aimed to analyse the outcomes from both intraoperative and postoperative results from SA and GA in over 72 patients who were posted for lumbar disc surgeries. There was observed that the patients in the SA group lost significantly less blood than those in the GA group. Their blood pressure and heart rate were also more stable during surgery. Surgeons were more satisfied with the procedures in the SA group. Additionally, fewer patients in the SA group needed pain medication after surgery, and their pain levels were lower compared to the GA group. This study shows that neuraxial blockade is significantly more advantageous than GA in the aspect of pain management post surgery and reduced bleeding intraoperatively and also more stability in vitals and reduced complications.

6. **Demirel et al. (2003)**^[24] this study was conducted to prove the supremacy of epidural over general anaesthesia in lumbar spine surgeries. 2 groups were allocated with a total of 60 patients. the pulse rate and mean arterial pressure was found to be on the lower end in epidural group when compared to general anaesthesia group. The incidence of high BP was noted in GA group. Intraoperative bleed is lesser in EA group. Postoperative pain peaks early in the GA group. This study shows no change in duration of stay in hospital. Results showed EA has more advantage over GA in lumbar spine surgeries.

CLINICAL ANATOMY

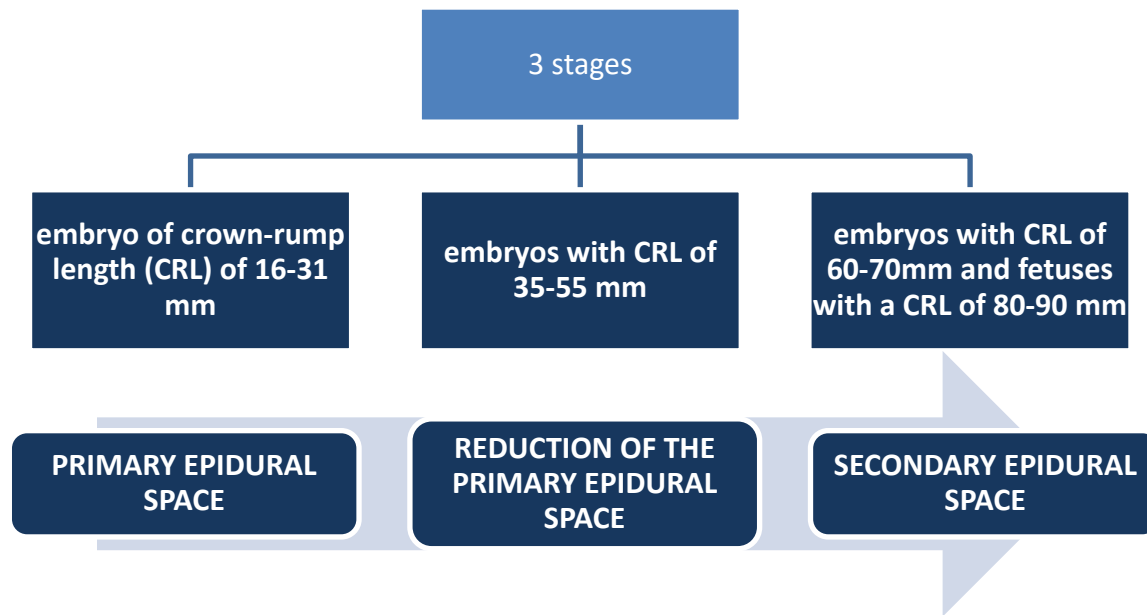
EPIDURAL SPACE

INTRODUCTION^[8]:

- Anatomically the space between the spinal canal & the sheath of dura was first identified by Corning JL in 1901. Depending on the anatomical location, it could be an actual space or merely a potential one.
- In order to describe the internal structure of the epidural space, a number of novel techniques were employed, such as examination by dissection, radiological imaging such as magnetic resonance imaging (MRI), computerised tomographic epidurography, dying techniques (epidural resin injections), and cryomicrotome sectioning of frozen cadavers, as cited in Hogan QH, 1991.
- The epidural space is argued for years as not a naturally open anatomical space, neither when living nor after death. According to Parkin & Harrison (1985), the space only becomes visible when the dura mater is intentionally separated from the spinal canal by injecting agents like contrast or local anaesthetic solutions.

EMBRYOLOGY OF EPIDURAL SPACE:

By the 13th week of embryonic development, the epidural space arises from the merged Dura mater and posterior longitudinal ligament. At the 13th week, the connective tissue in the epidural space evolves on stages of three as mentioned in Rodionov et al., 2010.



Research indicates that the primary epidural space is influenced majorly by the spinal cord and its dura mater, whereas the secondary epidural space is formed by the walls of the vertebral canal (cited in Rodionov et al., 2010). During this stage of embryonic development, the paramedian is connected to the posterior margin of the intervertebral disc and the vertebral body by the posterior longitudinal ligament (PLL). Once established, the anterior internal vertebral venous plexus runs both anterolaterally and anteromedially.

The posterior longitudinal ligament (PLL) connects the posterior margin of the intervertebral disc to the vertebral body next to the midline during this stage of embryonic development. Anterolaterally and anteromedially, the anterior internal vertebral venous plexus develops. The posterior longitudinal ligament continues to thicken and differentiate into deep and superficial layers by the fifteenth week. According to Hamid et al. (2002), at 21 weeks, the dura mater and posterior longitudinal ligament (PLL) seem to be connected like a ligament at the level of the vertebral body.

The dura mater is seen to be securely affixed to the posterior longitudinal ligament's (PLL) superficial layer by 32 weeks. Adipocyte clusters start to form by 39 weeks.

ANATOMY OF THE VERTEBRAL COLUMN:

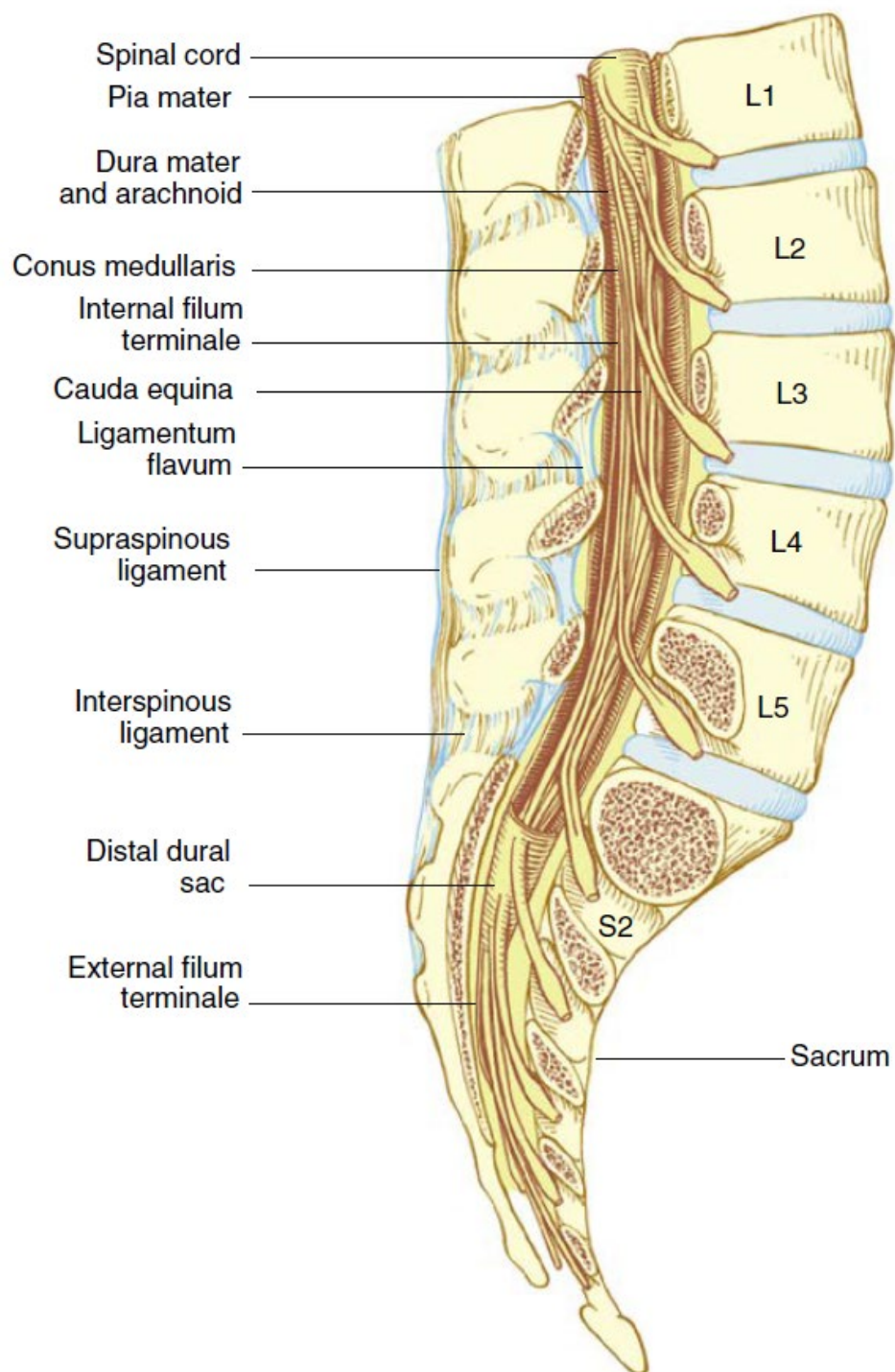
The vertebral column is composed of 24 different vertebrae, including seven cervical, twelve thoracic, and five lumbar vertebrae. The three to five coccygeal bones are still primitive even though they are linked, and the five sacral vertebrae are united. These vertebrae contain the subarachnoid and epidural compartments.

EPIDURAL SPACE – SPATIAL CHARACTERISTICS:

The upper thoracic levels have the most spacious epidural space. According to Nickalls and Kokri (1986), in adult, the epidural space measures approximately 0.4 mm at 7th cervical level till first thoracic level, 7.5 mm in the T1 till T10, 4.1 mm at the bottom thoracic levels (T11 to T12), and 4-7 mm in the lumbar region.

It takes about 1.5 – 2.0 ml of a local anesthetic to block a spinal segment in the epidural space while the volume (0.3 ml) is far less in the subarachnoid space for a similar block.

Figure number 5 : Spinal Cord Anatomy – the caudal end



SHAPE AND SIZE OF THE EPIDURAL SPACE:

Depends on the shape of lumbar vertebral canal and also on the dural sac's location and size present in it. Although epidural space is considered as a potential space, it could be 5mm deep.

TYPES OF EPIDURAL SPACE:

The epidural space is divided into four levels according to the corresponding vertebral canals: 1. Cervical epidural space

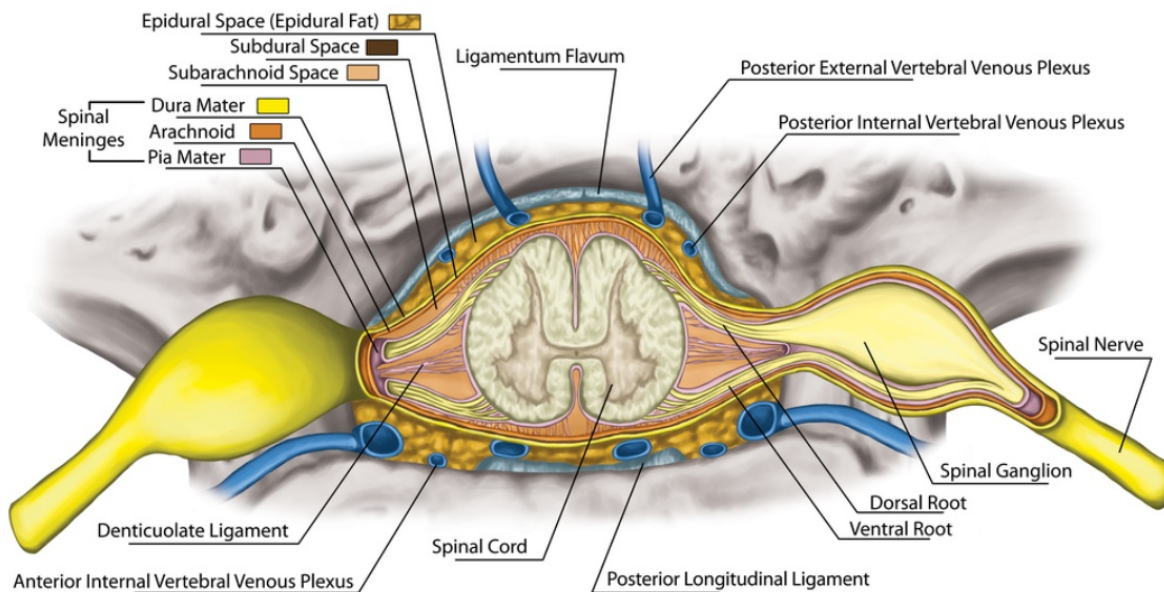
2. Thoracic epidural space

3. Lumbar epidural space

4. Sacral epidural space

- Cervical epidural space - upper border is located at the level of foramen magnum where there is adhered spinal with periosteal layer of the dura mater and the lower border is formed by the 7th cervical vertebrae.
- Thoracic epidural space - upper border begins from the lower edge of 7th cervical vertebrae till the upper edge of the 1st lumbar vertebrae.
- Lumbar epidural space - upper border begins from the lower edge of the 1st lumbar vertebrae ends with the upper margin of the S1 vertebrae.
- Sacral epidural space - contained from the upper border of S1 until the sacrococcygeal membrane ends.

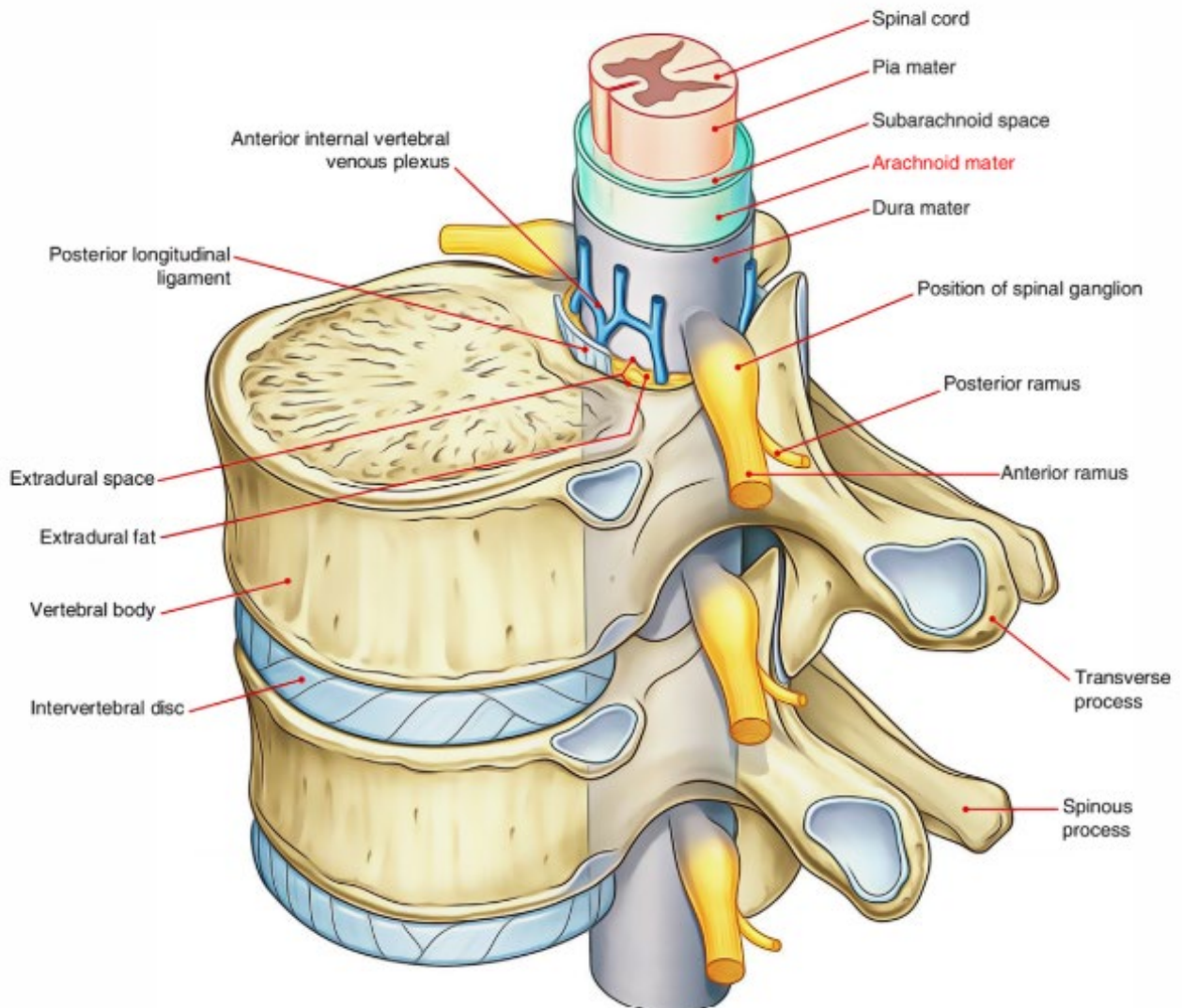
Figure number 6: Cross sectional view of vertebrae.



BOUNDARIES OF THE EPIDURAL SPACE:

- Superior border – at the level of the foramen magnum formed by fused spinal and periosteal layers of the dura mater.
- Inferior border – formed by the sacrococcygeal membrane.
- Anterior components – are posterior longitudinal ligament, body of the vertebrae and intervertebral discs.
- Laterally – lies the pedicles of the vertebra and the foraminae between the vertebrae
- Posteriorly – lies the ligamentum flavum, facet joints capsules and the laminae.

Figure number 7: The anterior, posterior and lateral relations to the spinal cord



PRESSURE WITHIN THE EPIDURAL SPACE:

The pressure is predominantly negative except at the level of the sacral region. The main factor responsible for this negative pressure is due to the advancement of the epidural needle which would lead to the initial bulge of the ligamentum flavum just before entering the epidural space. This bulge subsides immediately after puncturing the layer and on entering the epidural space.

The positivity of the negative pressure is determined according to the position of the vertebral canal. The normal pressure while entering the epidural space is inbetween -1 and -7 cm H₂O.

The location of the epidural space is confirmed by a technique of “Hanging drop method” which can be demonstrated when the epidural space has negative pressure. This predominantly is achieved by administering epidural anesthesia while the patient is sitting rather than in lateral position.

THE CONTENTS OF THE EPIDURAL SPACE:

The following are the contents of epidural space:

1. Fat of semi – liquid state
2. Lymphatic system
3. Arterial Vascular system
4. Loose areolar connective tissue
5. Nerve roots of the spinal cord
6. The plexuses of the venous system.

- **Fat:**

Plenty of fat is found inside the dura which surrounds the nerve roots arising from spinal cord. These epidural fat are not bound inside the laminae of dura. One of the main function of this fat is to safeguard the nerve root from the rhythmic pulsations of the dural sac. It also acts as a storage of lipid soluble drugs. It plays as an insulation from friction of dura over the spinal canal periosteal layer caused during flexion and also extension. Compared to drugs stored in epidural fat, those stored in dural sleeves

may have a stronger effect on nerve roots. The reason attributing to this is more fat in the nerve root sleeves than in the epidural space, and there is less space between the fat and the nerves in this region^[9].

- Lymphatic system:

The nerve roots are covered by dura where the lymphatics are abundantly found surrounding it. These are located in the epidural space and the main function of which is to locate and eliminate the microorganisms from the spaces such as subarachnoid and epidural.

- Vertebral venous system:

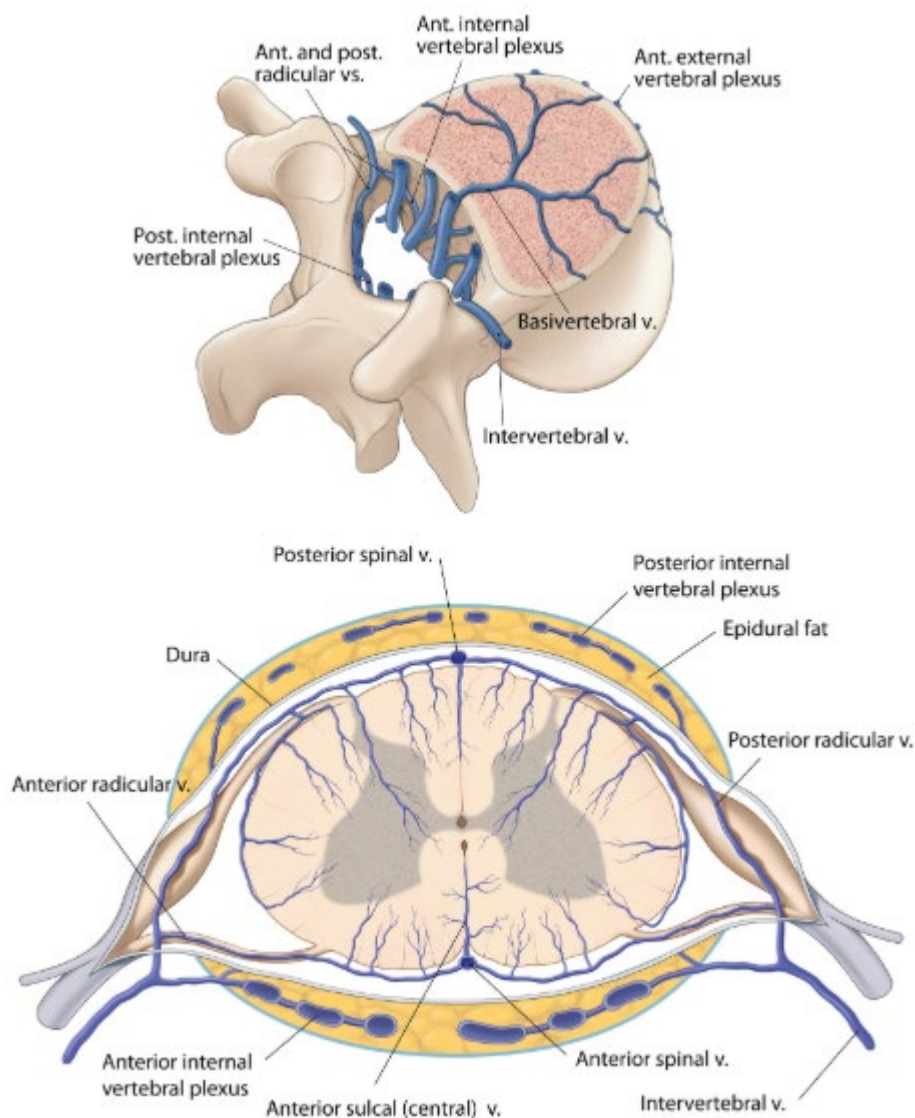
There are 2 major plexuses draining the vertebral structures: The internal venous plexus and the external venous plexus. There are 4 interlinked vertically running venous vessels arranged as 2 on anterior and 2 on posterior surface which forms the internal vertebral venous plexus. The both posterior and anterior plexuses make up the external venous plexus, which extends tangentially over the vertebrae.

The venous plexus of vertebrae is linked to the segmental veins of neck, azygos, venae lumborum and intercostal veins. The Batson plexus is formed by the combination of internal & external vertebral plexuses. Venous plexus of epidural space drains into the azygos venous system. Epidural space is prone for congestion because the batson plexus is a valveless venous system which on increased intraabdominal/ intrathoracic pressure leads to engorgement of the veins.

Batson plexus is a dense venous plexus located in anterior epidural space which consists of valveless veins. This plexus connects with the occipital vein, basilivertebral vein,

intracranial sigmoid, azygous system, and basilar venous sinuses. The abdominal and thoracic veins, which transmit pressure from the intrathoracic and intraabdominal regions to the epidural space, are linked to the plexus through the intervertebral foramina. The iliac veins are also communicate with the plexus via the sacral venous plexus. The risk of injury during needle or catheter insertion in the epidural area increases when the venous plexus becomes enlarged due to factors like intraabdominal tumors, advanced pregnancy, or obstruction of the inferior vena cava.

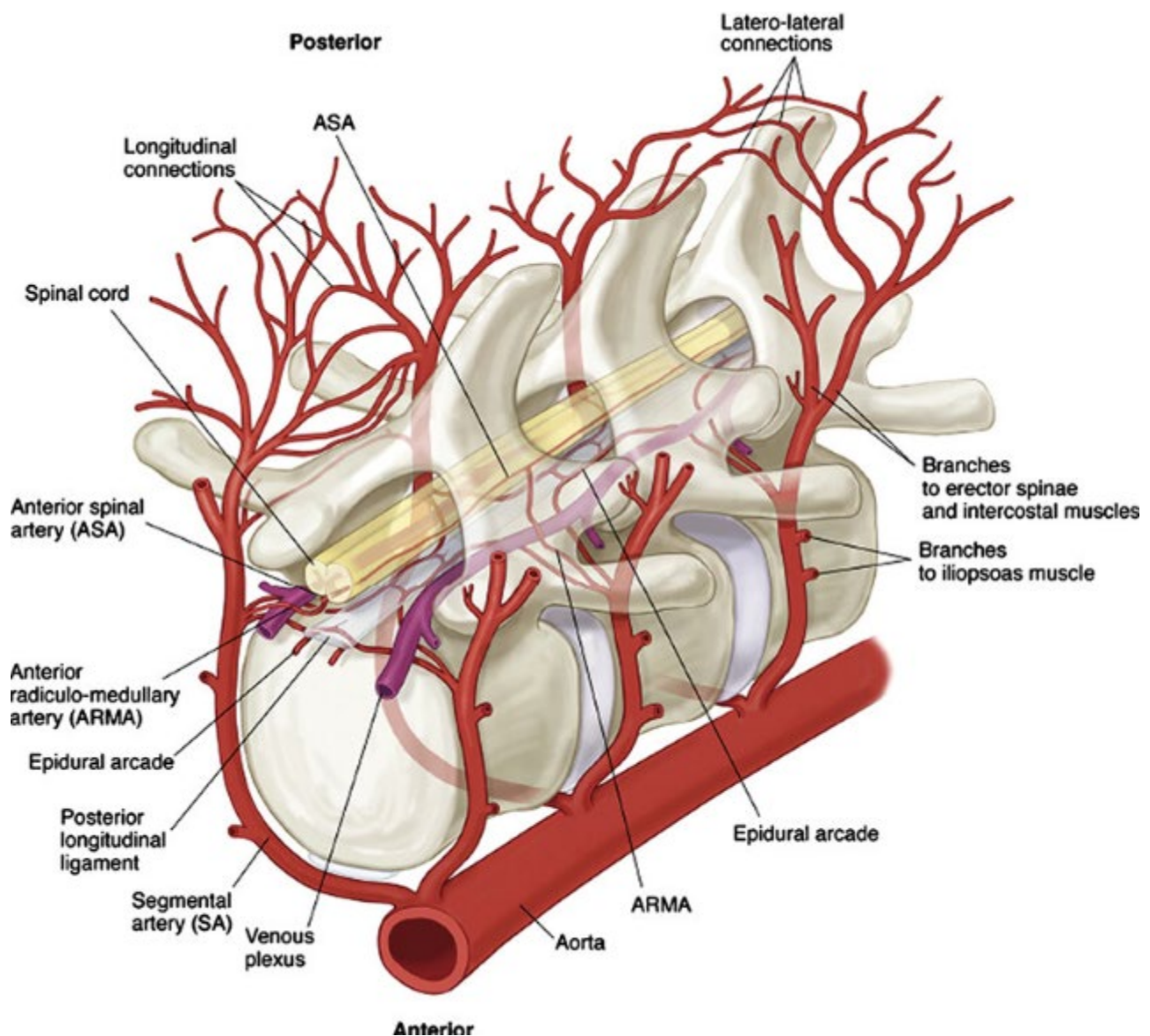
Figure number 8: Cross sectional of spinal cord showing the venous drainage.



- Epidural arterial system:

The lumbar epidural space receives arterial supply significantly from ilio-lumbar arteries. The advancement of the epidural needle cannot compromise the epidural arteries as they are situated in the lateral component of the space.

Figure number 9: Epidural arterial supply.



IDENTIFICATION OF THE EPIDURAL SPACE:

Identifying the epidural space is pivotal due to its technical complexity. The identification of this space was first illustrated around 78 years back by Dogliotti in 1933. The effectiveness of epidural analgesia relies on precise needle placement. When inserted at the midline, the epidural needle passes through the ligamentum flavum, supraspinous ligament, interspinous ligament, and subcutaneous tissue. As noted by Lai et al. (2005), the distance between the skin and the entry point of needle tip into the space defines how deep in the epidural space is located. Locating this space can be particularly challenging, especially in obese individuals, due to its depth.

HOW TO IDENTIFY THE SPACE?

Numerous methods have been developed to locate the epidural space. The negative pressure that exists when the epidural needle is put into the epidural space is the basis for most of these conventional methods for locating the epidural space. Methods to locate the epidural space should be easy & uncomplicated, functional, less-risky, and dependable in order to avoid the problems arising due to it.

The loss of resistance (LOR) is the technique that is most precise for detecting the epidural space. This approach involves using air, using saline, or using solutions such as anaesthetic agents (local). The syringe attached to the epidural needle in order to inject, sustained and rhythmic on-off pressure is applied to the piston of the syringe in the direction of the reservoir of the syringe, allowing smooth piston movement. This technique is effective because injecting into the dense ligamentum flavum is nearly impossible. The syringe may contain either saline or air.

The LOR technique is subjective and relies on manual interpretation, or the "feel" of a pressure change, making it prone to failure in 5% to 15% of cases, especially in

untrained hands. The long epidural needle may be obstructed by tissue or a blood clot, preventing consistent LOR detection. When air is used in the LOR method, complications such as headaches, nerve damage, and disrupted drug distribution can result in ineffective analgesia. While saline can help mitigate these issues, it does not provide the same tactile feedback as air. Alternative methods now exist for detecting changes in pressure or resistance, many of which use automated, pneumatic, or mechanically enhanced feedback systems. ^[10]

THE TUOHY NEEDLE – THE HISTORY AND ITS EVOLUTION^[11]

Esteemed anesthesiologist Edward B. Tuohy pursued his education at the Mayo Clinic. A passionate proponent of neuraxial blockade, he played a pivotal role in guiding others through his leadership as president of the American Society of Anesthesiologists and his involvement in early academic societies.

While Tuohy was aware of the initial clinical work on epidural blocks by Paget and Dogliotti, his main focus was on continuous spinal anaesthesia, and he first substituted Lemmon's flexible needle with a No. 4 silk catheter with a 15-gauge Barker needle (Fig. 10)^[11].

Huber, an innovative dentist from Seattle, is best known for inventing the hypodermic needle. Designed with a elongated, pointed, and bent tip, the needle aimed to reduce injection pain and prevent skin plugs from being deposited into deeper tissues. Despite the fact that, Huber originally created it for tissue and intravenous injections, Tuohy realised that its angled tip could aid in guiding spinal catheters. To enhance its functionality, Tuohy introduced a stylet to minimize the skin clogging.

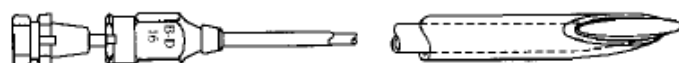
Figure number 10 : Various types of epidural needles through the history



15 ga Barker Spinal Needle 1907. First used by Touhy to thread a No. 4 ureteric silk catheter into the subarachnoid space (1944)



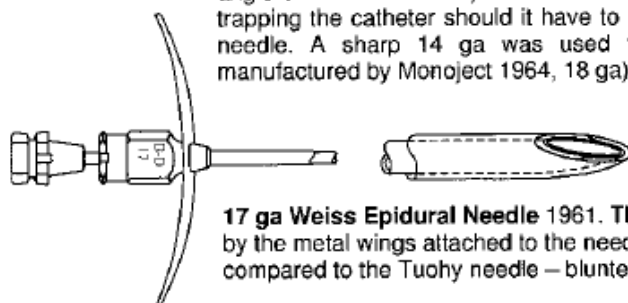
15 ga Huber Point Epidural Needle (Tuohy Needle) 1945. Tuohy can be credited with applying the Huber point (curved tip) design to the epidural needle and with adding a stylet. The needle tip was sharp as the intended application was continuous spinal anesthesia



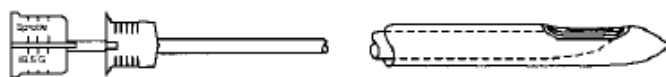
16 ga Tuohy-Flowers Needle 1950. Flowers dulled the sharp Tuohy needle tip and added a sharp stylet that would protrude past the needle tip to facilitate perforation of the skin. This design was prone to needle or stylet tip damage.



15 ga Hustead Epidural Needle 1954. (modified from the Tuohy needle) specified as a.) heel-to bevel distance < 27 mm b.) bevel angle of 12–15 ° and c.) a rounded heel to reduce the danger of trapping the catheter should it have to be withdrawn through the needle. A sharp 14 ga was used to break the skin. (first manufactured by Monoject 1964, 18 ga)



17 ga Weiss Epidural Needle 1961. This needle is characterized by the metal wings attached to the needle hub and the — compared to the Tuohy needle — blunted tip.

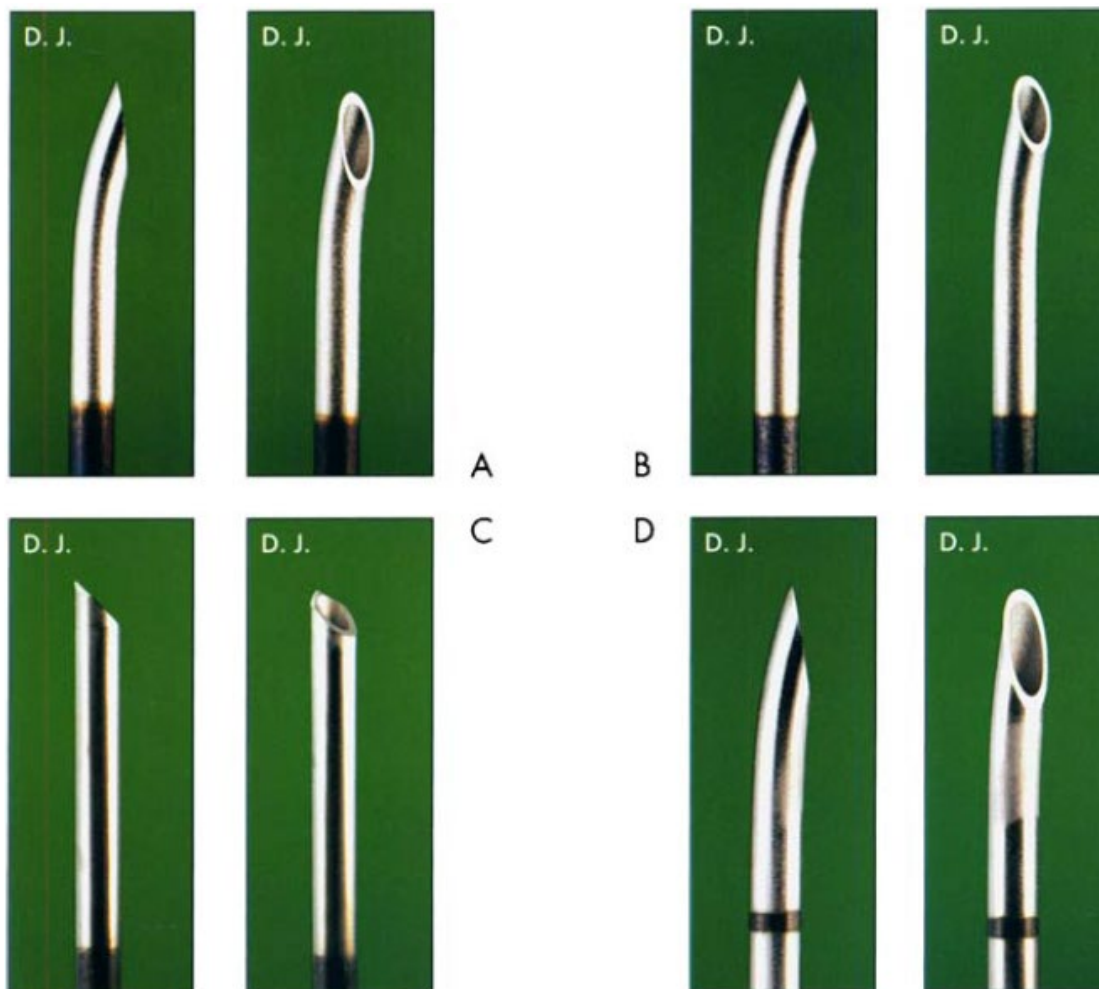


18.5 ga Special Sprotte Epidural Needle 1987. First "pencil-point" epidural needle to be used with a 23 ga epidural plastic catheter. Developed by Sprotte to minimize tissue trauma ("atraumatic needle")



16 ga Crawford Epidural Needle.

*Figure number 11: various types of now available needles for epidural anaesthesia.
A- Tuohy , B – Hustead , C - Crawford, D - Weiss*



PROCEDURE

SINGLE SHOT TECHNIQUE

POSITIONING OF THE PATIENT:

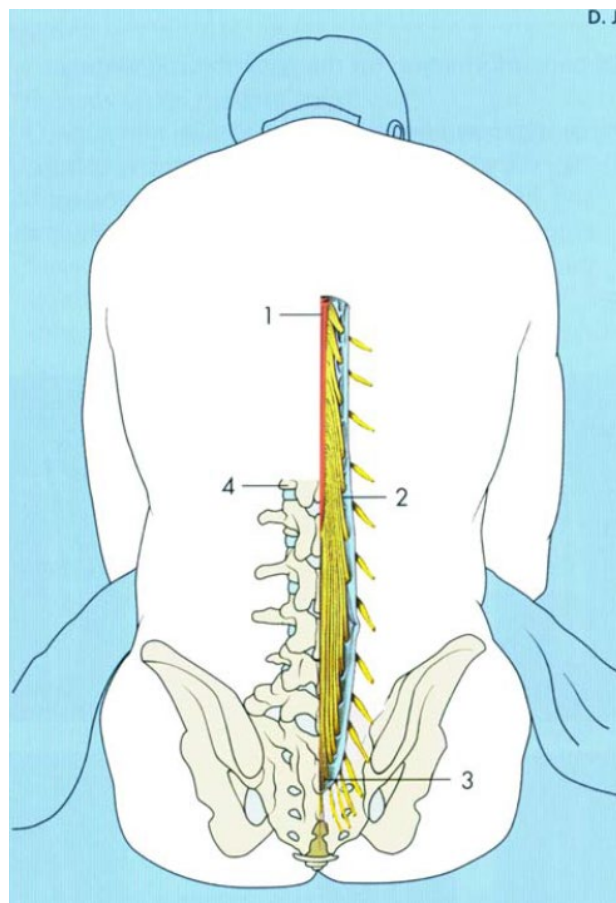
Proper patient positioning is essential for the successful administration and deposition of the local anesthetic agent. The main position in which epidural is given are lateral posture or in seated position. For proper visualization of the midline, it is important to minimize the lumbar lordosis.

Injection technique

Median approach – Landmarks:

The most commonly preferred location for epidural is between the L2-L3 space or L3-L4 space, since these lie once the conus medullaris ends. The centre of the spinous process is felt and the opted intervertebral space is located and marked. Often midline approach is chosen because the ligamentum flavum remains thicker here, a deep epidural space where the vasculature is minimal.

**Figure number 12 : Conus medullaris (lower edge of the first lumbar vertebra).
(1)Conus medullaris, (2) cauda equina, (3) dural sac, (4) L1 segment**



STEPS:

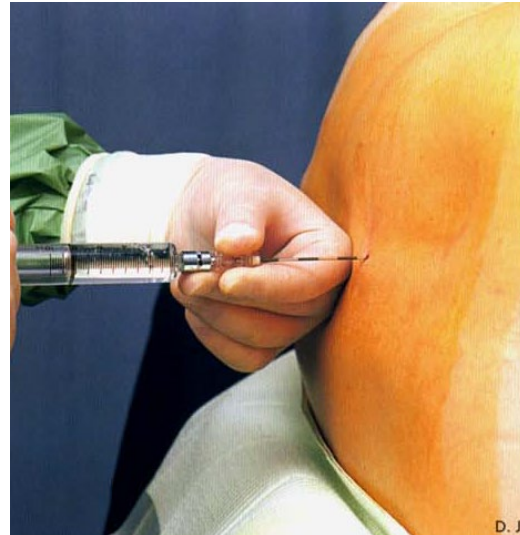
1. Skin is prepared by aseptic precautions by painting thoroughly and then is draped under sterile conditions.
2. Local anaesthetic is injected at the site of the epidural injection by administering 1-1.5ml of 2% lignocaine plain solution.
3. **Piercing the layers of the midline – ligaments of supraspinous and interspinous and then ligamentum flavum.** : 2nd and 3rd fingers of left hand positioned over the intervertebral space, right hand to hold the epidural needle. The needle is advanced and piercing the supraspinous ligament which is 1cm

thick. The bevel end is placed in such a way that it lies laterally and then it is moved further 2-3 cm till it touches interspinous ligament. In order to confirm the space, the trocar of the needle is removed and low-resistance syringe is connected.

Figure number 13(a): left image – skin painted and draped and administration of local anaesthetics, right image – marking of the epidural injection site.

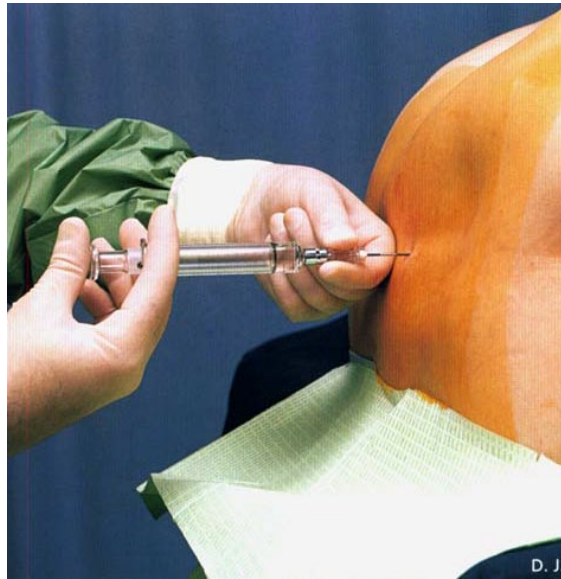


Figure number 13(b) : left image – insertion of the tuohy needle, right image – attachment of the LOR syringe



Once interspinous ligament is pierced through, the needle is moved in a slow manner millimeter-by-millimeter to accurately secure the needle.

Figure number 13(c) : identification of the epidural space by LOR technique



4. Entering the epidural space - For optimal stability, the left hand is positioned with its dorsum firmly against the patient's back, allowing the thumb and index finger to securely hold the needle. The needle is then advanced incrementally, millimeter by millimeter, while simultaneously exerting controlled resistance. Concurrently, the right thumb applies pressure to the syringe plunger. The detection of a loss of resistance signifies successful entry into the epidural space, facilitating the smooth administration of the syringe's contents. The identification of the epidural space is achieved through the loss-of-resistance technique.

VARIOUS TECHNIQUES TO IDENTIFY THE EPIDURAL SPACE:

Saline:

Once the needle is inserted through the interspinous ligament, the stylet is withdrawn and a low resistance syringe loaded with saline along with a tiny bubble of air (indicator) is connected to the hub of the needle. On passing through the ligamentum flavum, the air bubble gets squeezed on applying certain pressure. Once the needle enters the epidural space, the bubble resumes its initial size which indicates that the needle is in the epidural space.

Air:

This method is unsuitable for practitioners with limited experience or for cases expected to involve procedural complexities.

Benefit: Upon successfully accessing the epidural space, no fluid should be expelled from the needle. Consequently, any cerebrospinal fluid (CSF) that does appear can be more readily distinguished.

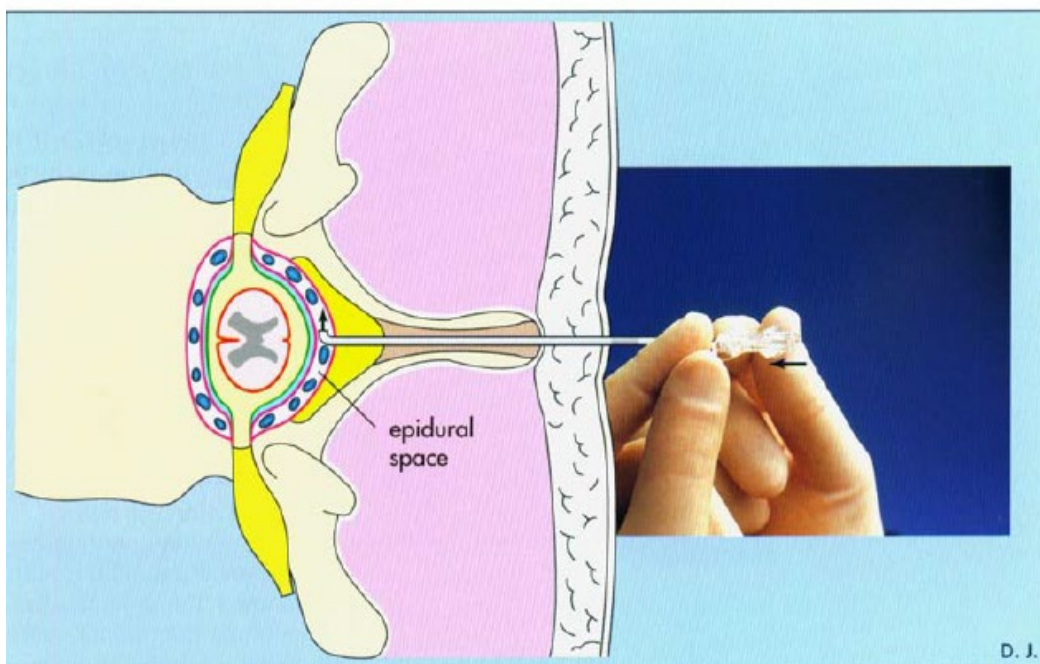
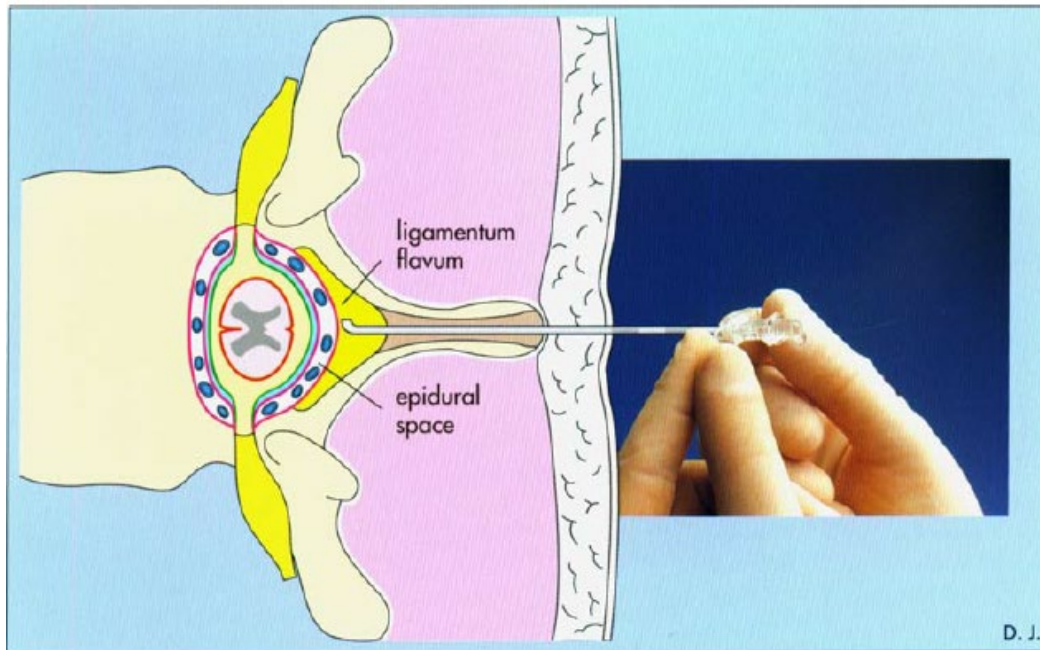
Drawbacks: The loss-of-resistance sensation is less distinct, and unlike the saline injection technique, the dura is not effectively displaced by the needle tip. There are high risks to develop pneumocephalus, air embolism, retroperitoneal air collection, compression of spinal cord/ nerve root from accumulation of air in the epidural space and may also lead to subcutaneous emphysema.

"Hanging Drop" Technique:

As the needle progresses to the interspinous ligament, a droplet of saline is administered into its hub. As the needle advances past the ligamentum flavum and into the epidural

region, the negative pressure usually created during inspiration drives the droplet inward, indicating correct positioning.

Figure number 14 : above image demonstrates the “Hanging drop” technique – the upper image – epidural needle lies in the ligamentum flavum hence the resistance will be felt. 2nd image – needle lies in the epidural space demonstrating the sucking of the drop into the space.



LOCAL ANAESTHETICS^[12]

- Pharmacological drugs with membrane-stabilizing qualities have been extensively employed in clinical practice since 1884, when ophthalmologist Carl Koller first recognised the local anaesthetic effects of cocaine.
- Significant developments in this category of pharmaceuticals encompass the creation of procaine in 1898, lidocaine in 1943, and bupivacaine in 1957.
- Moreover, substantial progress has been made in optimising dose protocols, especially when used in conjunction with other medications, including opioids and α_2 -adrenergic agonists.

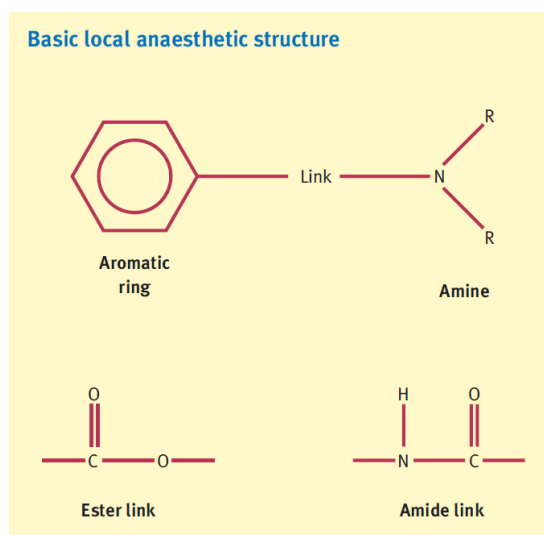
CHEMICAL STRUCTURE:

The basic chemical structure of local anaesthetics consists of a hydrophilic amine group, a connecting moiety, and a lipophilic aromatic ring; they are mainly categorised as tertiary amines (figure 15). Compounds are classified into two primary categories based on their chemical bonds: amides (-NH-CO-) and esters (-O-CO-).

Amide-based anaesthetics commonly used in clinical settings include lidocaine, prilocaine, (levo-)bupivacaine, and ropivacaine. Esters are the precursors of substances including amethocaine, procaine, cocaine, and chlorprocaine. In order to increase solubility and stability, anesthetics—which are classified as weak bases—are made for injection as efficient conjugate acidic hydrochloride salts (pH 3–6).



Figure number 15 : Chemical formula of local anaesthesia

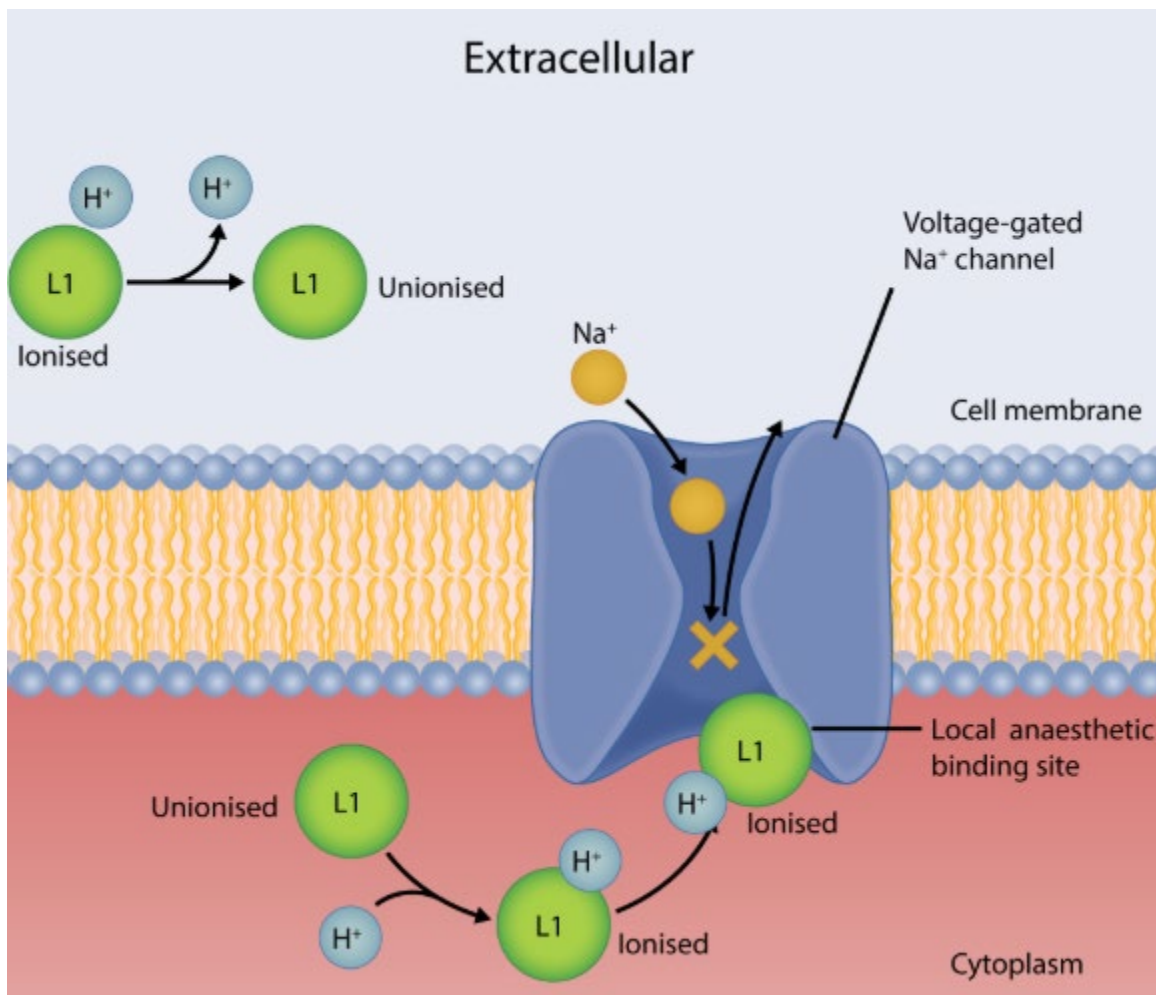


LOCAL ANAESTHETICS – HOW IT WORKS:

- Local anaesthetics work by preventing the propagation of axonal action potentials which results from stopping the inward sodium (Na^+) current at the sodium ionophore during depolarisation.
- Local anaesthetics function by blocking the inward sodium (Na^+) current at the sodium ionophore during depolarisation, which interferes with the propagation of axonal action potentials.
- The pharmacodynamic profile is intricate, as it modulates calcium, potassium, and G-protein-regulated ion channels, thus further affecting neuronal excitability.
- Local anaesthetics are most often found in an ionised acidic state (pH 3–6) when they are administered. The axolemma can be permeated by certain ionised compounds that dissolve in an alkaline perineural milieu (pH 7.4) and change into a lipid-soluble free base. The molecule re-ionizes into its active form upon entering the acidic axoplasm, which limits sodium conductance either intracellularly or by interaction with the lipid bilayer of the cell membrane. Anaesthetic activity is due to the ionised (ammonium) state's essentiality in

blocking sodium channels, although the non-ionized form is more effective at penetrating axons.

Figure number 16: mechanism of action of local anaesthetic.



When neurones are stimulated, sodium ion channels move through four states: resting, active, inactivated, and deactivated. This is because when the channels are stimulated, structural alterations take place.

The state-dependent blockade exhibits maximal efficacy in the active state, reduced efficacy in the inactivated state, and negligible effects in the deactivated or/ resting state. The efficacy of local anaesthetic blockade is markedly affected by the functional

condition of the ionophore. The anaesthetic can only cross the membrane in its non-ionized (free base) form when the sodium channel is closed, a characteristic of the deactivated or resting states. In contrast, stimulation of the nerve, and to a lesser degree its inactivation, allows for the opening of channels that facilitate the direct entry of the ionised anaesthetic into the nerve. Repeated activation or prolonged ionophore opening enhances frequency-dependent (or phasic) blockage by increasing the extracellular influx of the ionised form.

When a greater percentage of ionised molecules are present outside the membrane, particularly in response to stimulation, blocking starts more quickly. As a result, bupivacaine exhibits a more pronounced frequency-dependent block than lidocaine.

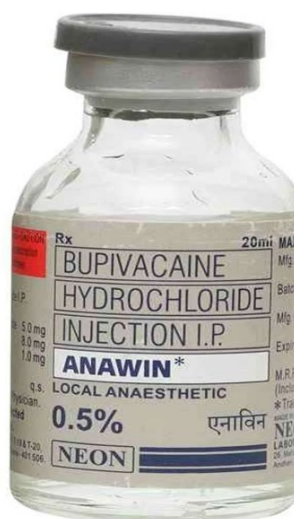
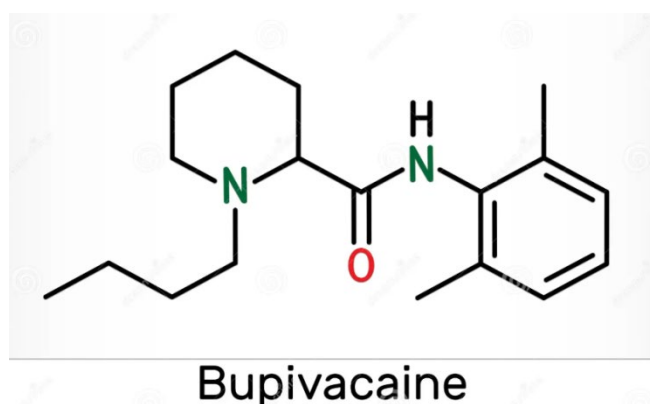
SPREAD OF LOCAL ANAESTHETICS IN EPIDURAL SPACE^[13]

Local anaesthetic solutions spread laterally, towards the head end, and towards the tail end when they are injected into the lumbar epidural region. There is little restriction on the drug's ability to diffuse through the intervertebral foramina. Therefore, a greater number of intervertebral foramina promote lateral leakage as the anaesthetic spreads over the lumbar and thoracic epidural region, requiring a larger amount of anaesthetic per blocked segment. Furthermore, the anterior sacrum's foramina, which are noticeably bigger than the intervertebral foramina, cause further drug loss as the anaesthetic agent passes through into the sacral epidural area. This increases the segmental dosage requirement even further. Consequently, an increased segmental dosage demand is correlated with a higher total dose injected into the epidural space, and a lower total dose decreases the segmental dose requirement.

BUPIVACAINE^[14,15,16,17,18]

Bupivacaine HCL, an amide-type local anaesthetic (1-butyl-2', 6' pipecoloxylidide hydrochloride)*, is recognised for its prolonged effects. The primary solution was formulated by Ekernstam in the year 1957 and manufactured at A. B. Bafors Laboratories (Molndel, Sweden). Since that time, it has been subjected to clinical investigations, and perceptions regarding this medication have transformed.

Figure number 17: (a) – structural formula of bupivacaine, (b) – Bupicavaine 0.5% (local) vial.



MECHANISM OF ACTION:

- The prevailing comprehension of the mechanism by which local anaesthetics function is that they impede the influx of sodium ions across the neuronal membrane, therefore preventing the activation of action potentials.
- Local anaesthetics are believed to modify the arrangement of phosphate groups by competitively binding to calcium channels situated in the outer lipid layer of the neuronal membrane.

- The impediment of the membrane's molecular transition from its dormant, sodium-impermeable state to its active, sodium-permeable state significantly obstructs the flow of sodium ions.
- Bupivacaine's significant affinity for brain structures is thought to enhance its prolonged duration of action.

INDICATIONS

Infiltration operations, peripheral nerve blocks, retrobulbar blocks, caudal blocks, and epidural blocks are among the procedures for which Bupivacaine hydrochloride injection is authorised to provide local or regional anaesthesia and analgesia.

Bupivacaine isotonic solutions should not be used for subarachnoid (spinal) blocks.

CONTRAINDICATIONS

- Individuals with a documented history of hypersensitivity to amide-type local anaesthetics or any components present in bupivacaine solutions are advised against the administration of Bupivacaine.
- Bupivacaine is contraindicated in instances of severe shock, heart block, or in the presence of infection or inflammation adjacent to the proposed injection site.
- Bupivacaine is to be avoided for intravenous regional anaesthesia (Bier Block).
- The administration of bupivacaine in the context of intravenous regional anaesthesia, commonly referred to as a Bier block, has been linked to documented instances of cardiac arrest and mortality.

Table No. 1 : Recommended concentrations and doses of Bupivacaine hydrochloride.

Recommended Concentrations and Doses of Bupivacaine Hydrochloride				
Type of Block	Conc.	Each Dose		Motor Block¹
		(mL)	(mg)	
Local infiltration	0.25% ⁴	up to max.	up to max.	—
Epidural	0.75% ^{2,4}	10-20	75-150	complete
	0.5% ⁴	10-20	50-100	moderate to complete
	0.25% ⁴	10-20	25-50	partial to moderate
Caudal	0.5% ⁴	15-30	75-150	moderate to complete
	0.25% ⁴	15-30	37.5-75	moderate
Peripheral nerves	0.5% ⁴	5 to max.	25 to max.	moderate to complete
	0.25% ⁴	5 to max.	12.5 to max.	moderate to complete
Retrobulbar ³	0.75% ⁴	2-4	15-30	complete
Sympathetic	0.25%	20-50	50-125	—
Dental ³	0.5%	1.8-3.6	9-18	—
	w/epi	per site	per site	
Epidural ³	0.5%	2-3	10-15	—
Test Dose	w/epi		(10-15 micrograms epinephrine)	

¹ With continuous (intermittent) techniques, repeat doses increase the degree of motor block. The first repeat dose of 0.5% may produce complete motor block. Intercostal nerve block with 0.25% may also produce complete motor block for intra-abdominal surgery.

² For single-use, not for intermittent epidural technique. Not for obstetrical anesthesia.

³ See **PRECAUTIONS**.

⁴ Solutions with or without epinephrine.

PHARMACOKINETICS:

- The total dosage, concentration of the medication, and the method of administration all influence the rate at which local anaesthetics are absorbed into the systemic circulation.
- The maximum concentration of bupivacaine in the bloodstream is attained within 30 to 45 minutes following its administration for caudal, epidural, or peripheral nerve block in human subjects. Within the subsequent 3 to 6 hours, these levels diminish to a point of insignificance.

- In humans, bupivacaine has a plasma elimination half-life of roughly 2.7 hours, with a range of 1.2 to 4.6 hours. The half-life in babies ranges from 6 to 22 hours, which is a significantly longer period than that in adults. In the older population, the half-life is prolonged.
- Binding of local anaesthetics are associated with plasma proteins levels. In contrast to the more hydrophilic substances, the highly lipophilic agents, such as bupivacaine, exhibit a significantly greater degree of protein binding. In individuals with optimal health, approximately 95% of bupivacaine is associated with proteins. An increased availability of the unbound drug will occur if there is a decrease in the concentration of plasma proteins.

VARIOUS FORMS OF DELIVERY OF THE DRUG:

Bupivacaine is sold at various concentrations: 0.25%, 0.5%, and 0.75%.

The administration of anaesthesia includes various techniques:

- Locally to anaesthetize used in the form of infiltration to inhibit pain from the local site of incision
- Regional nerve blocks for oral or small surgical and in orthopaedic procedures,
- Used in Spinal anaesthesia by injecting the drug into the cerebrospinal fluid for orthopaedic and abdominal surgeries as well as caesarean deliveries,
- To Block motor & sensory (as in spinal anesthesia) as well as just the sensory blockade needed for labor analgesia provided by epidural analgesia in obstetric field.
- In pediatric surgeries, where Bupivacaine can be administered in blocks at a causal level to provide anaesthesia as well as analgesia in surgeries below umbilicus.

SYSTEMIC EFFECTS:

Bupivacaine dosages cannot exceed 3 mg/kg. After absorption, systemic effects are produced. The dosage, injection site, volume, and physicochemical properties of the material all affect the rate and extent of absorption. Because it is lipophilic, bupivacaine has a higher potency and less systemic absorption.

Central nervous system:

- Bupivacaine can produce CNS toxicity through systemic absorption or direct intravascular injection due to its ability to pass the blood-brain barrier.
- Some of the negative effects that manifest in a dose-dependent manner include lightheadedness, tinnitus, circumoral numbness, tongue paraesthesia, seizures, unconsciousness, coma, respiratory arrest, and cardiovascular depression.
- Bupivacaine (3.5) exhibits a more favourable ratio of cardiovascular collapse (CC) to CNS toxicity (CC/CNS) than lidocaine (7.1).

Cardiovascular system:

- At elevated concentrations, bupivacaine diminishes myocardial contractility and conduction velocity, reduces the refractory period, and inhibits myocardial automaticity.
- The primary factors contributing to these effects are the direct obstruction of cardiac sodium channels and the suppression of the autonomic nervous system.
- Cardiac arrest may arise from conditions such as bradycardia, heart block, and hypotension.
- The challenges associated with resuscitation efforts are exacerbated by the significant protein binding of bupivacaine, especially in cases of hypoxaemia, respiratory acidosis, and during pregnancy.

Respiratory system:

The hypoxic drive is reduced by bupivacaine. Apnoea can be caused by depression of the medullary respiratory centre or paralysis of the phrenic or intercostal nerves.

Hematological system:

Bupivacaine decreases platelet aggregation, improves fibrinolysis, prevents thrombosis, and decreases coagulation. Patients who get epidural bupivacaine have fewer embolic occurrences.

ADVERSE EFFECTS:

When used at the right dosages, bupivacaine has comparatively little side effects. However, intravascular injections or high dosages may result in systemic toxicity.

Toxicity:**Central Nervous System:**

Initially characterised by CNS excitatory symptoms such as restlessness, agitation, and tonic-clonic convulsions, this is subsequently accompanied by CNS depressive symptoms including fatigue, unconsciousness, coma, and respiratory arrest. Additionally, one may experience circumoral numbness, paraesthesia, dizziness, tinnitus, and blurred vision.

Cardiovascular system:

Decreases BP, Atrioventricular block, arrhythmias especially ventricular and cardiac arrest.

Allergic reactions:

Not frequently observed. The main cause for such anaphylactic reactions is due to the presence of Methylparaben as the preservative.

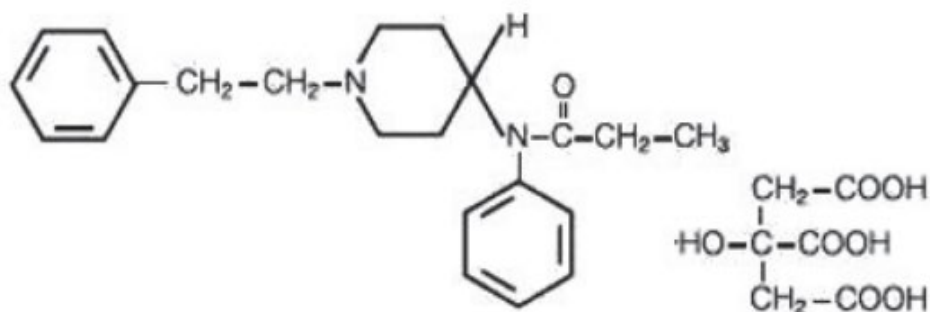
Musculoskeletal:

On Intramuscular administration of Bupivacaine it might lead to cystic degeneration, edema and necrosis. This makes Bupivacaine toxic to skeletal muscle and leads to breaking down of the same.

FENTANYL^[19]

Fentanyl is a potent opioid agonist. The formulation consists of fentanyl citrate, with one millilitre of the solution containing fifty micrograms of fentanyl. Sodium hydroxide is included into the solution to maintain its pH within the range of 4.0 to 7.5. The chemical structure of fentanyl citrate is N-(1-phenethyl-4-piperidyl) propionanilide citrate (1:1). The compound's formula is C₂₂H₂₈N₂O • C₆H₈O₇.

Figure number 18 : Structural formula of fentanyl



CLINICAL PHARMACOLOGY

Mechanism of Action:

The prime action of fentanyl is on Mu- opioid receptors located in the central nervous system. These receptors which are G-protein coupled receptors (GPCR). Fentanyl acts on these GPCR via two routes:

- By inhibiting Adenylyl Cyclase: the cyclic AMP production reduced leading to decreased excitation of neurons.

- Transformation of Ion channels: facilitates reduced calcium ion entry and in exchange potassium are pushed out which makes the neurons to be depolarized leading to block in the secretion of the neurotransmitters.

The above changes has an inhibitory action on the ascending pathway for pain, leading to reduction in the pain perception and response to painful stimuli.

Affinity:

Fentanyl has high affinity towards Mu-opioid receptor. This attributes to the analgesic effect and sedative property of the Fentanyl.

Pharmacodynamics:

Fentanyl can be used as the following:

- As an analgesic – in both acute and chronic pain.
- As a sedative
- Since it has a suppressive action on brainstem respiratory centres which in turn would lead to reduced respiratory rate.
- Gives an effect of feeling good because it activates the reward pathway.
- Constricts the pupils leading to miosis.

Pharmacokinetics:

Fentanyl is a highly lipid soluble chemical which facilitates crossing the blood-brain barrier. It has a quick onset of action. It undergoes hepatic metabolism using cytochrome P450 enzyme especially CYP3A4 which would lead to production of inactive metabolites which gets excreted through the kidneys.

As per a three-compartment model,

- Distribution time : 1.7 minutes
- Redistribution time : 13 minutes
- Terminal elimination half-life: 219 minutes

The total volume of distribution : 4 litres per Kg.

Typical side effects include:

- Respiratory depression which is dose-dependent.
- Reduced gastro-intestinal motility.
- Nausea & Vomiting due to stimulation of chemoreceptor zone.
- Bradycardia.
- Chest wall rigidity.

The above side effects of fentanyl should be kept in mind while being used for clinical purpose.

Usage:

- The analgesic efficacy of 100 mcg (0.1 mg) (2.0 mL) is about equivalent to that of 10 mg of morphine or 75 mg of meperidine.

Properties of Fentanyl:

- Sedation and analgesia constitute the primary therapeutic effects. The analgesic efficacy of opioid analgesics may be transient due to alterations in the ventilation of alveoli and respiratory rate. A high fentanyl dosage leads to a greater diminishment in exchange of gases. Apnoea may occur due to elevated doses.

The incidence of vomiting is found to be reduced in Fentanyl than in comparison to Morphine or/ Meperidine .

- The potency of analgesic property is attributed towards the property of Fentanyl to diffuse through the BBB. It takes 5 minutes for the distribution of the drug equally in plasma and CSF. This being the reason behind, more potent a drug in comparison to Morphine.
- Human skin wheal tests and histamine level assays show that fentanyl rarely causes clinically significant histamine release. According to recent human investigations, histamine gets secreted at concentrations up to 50 mcg/kg (0.05 mg/kg) (1 mL/kg) which is not clinically significant.
- Fentanyl has better hemodynamic stability and cardio-protective property. On increasing the dose of Fentanyl, the stress response is suppressed.

INDICATIONS

- Used in surgical procedures which are of lesser duration to reduce the pain intraoperatively.
- For Pain management in the post anaesthesia care unit.
- Used as an additive in General anesthesia and neuraxial blockade techniques.
- It is used in general anesthesia induction when certain complicated cases are posted such as Neurology cases, complex orthopaedics surgeries or in Cardio-thoracic vascular surgeries and in surgeries where patients with multiple underlying comorbidities are posted.

CONTRAINDICATIONS

Those patients who had previously developed some unacceptance in terms of anaphylactic reactions or some other side effects post administration.

MATERIALS AND METHODS

SOURCE OF DATA

This study will be carried out in the Department of Anesthesiology, BLDE (DU) Shri B M Patil Medical College, Hospital & Research center, Vijayapura

METHOD OF COLLECTION OF DATA:

Study Design: Randomized control study

Study Period: April 2023 to December 2024

Sample size:

In order to achieve a power of 99% for detecting a difference in proportions of -0.50 between the two groups (test - reference group) at a two-sided p-value of 0.05, the study would need a sample size of 32 for each group (i.e., a total sample size of 64, assuming equal group sizes). This is based on the assumption that 80% of the subjects in the reference population have the factor of interest.

- With the Anticipated Proportion of tachycardia group GA 80% in group C.E.G.

30% (ref)

resp., the study must be done with a sample size of 32 per group. (i.e., a total sample size

of 64 assuming equal group sizes), to achieve a power of 99% for detecting a difference in proportions between two groups at a two-sided p-value of 0.05.

Formula used

- $$n = \frac{(Z_{\alpha} + Z_{\beta})^2 2 p * q}{MD^2}$$

Where Z= Z statistic at a level of significance

MD= Anticipated difference between two proportions

P=Common Proportion

q= 100-p

Statistical Analysis

- The data obtained will be entered into a Microsoft Excel sheet, and a statistical package for the social sciences will be used to perform the statistical analysis (Version 20).
- Results will be presented as Mean±SD, counts and percentages and diagrams.
- Normally distributed continuous variables between two groups will be compared using the Independent t-test. For not normally distributed variables, the Mann-Whitney U test will be used.
- Repeated measures of the ANOVA/Friedman test will be used to compare results within the group with the post hoc test.
- Categorical variables between the two groups will be compared using the Chi-square test.
- .p<0.05 will be considered statistically significant. All statistical tests will be performed in two-tailed.

INCLUSION CRITERIA:

1. Age 18-65 years
2. ASA I and II
3. Diagnosed with lumbar spine disc disease involving one or two levels.

EXCLUSION CRITERIA

1. Patient's refusal consent for the epidural.
2. Systemic anticoagulation ailments.
3. Patients with septicemia.
4. Patients with local infection at the site of the epidural.

METHODOLOGY:

Pre-anesthetic evaluation:

- History: Medical History, Surgical history, Mode of anaesthesia used in previous surgery.
- Physical examination
- Vitals: Heart rate, Respiratory rate, temperature, height, and weight.
- Systemic examination: Respiratory system, Cardiovascular system, Central Nervous system.
- Assessment of Airway by Mallampatti grading and mouth opening.
- Investigations: Complete blood Hemogram, Viral serology, ECG.
- The patient will be taken consent for the procedure and to be part of the study.

Preoperatively:

Patients were randomly assigned to one of the two groups (32 patients each) through chit picking, with the assignments sealed in envelopes by an individual not involved in the study. The two groups being Group A, where only GA is administered and Group B, where combined Epidural with GA is chosen as the plan of anaesthesia. The sealed envelopes were opened by the chief anaesthesiologist just before the procedure. The data collector, the postoperative care unit nurses and patients were blinded to the assigned intervention.

After shifting the patient to O.T., the patient is connected with ASA standard monitors such as ECG, NIBP, and SpO₂. After random allocation by chit picking, the patient is allotted to Group A, i.e., Sole GA or Group B, i.e., Epidural with G.A.

Group B patients will be prepared for epidural under strict precautions, Epidural with Tuhoy's 18G with a single injection of 18ml of 0.25% Bupivacaine (45mg) + 25mcg of Fentanyl (2 ml) in 18 ml of distilled water administered either at the same or a level below the level of surgery in the sitting position.

All patients receiving G.A. will be given premedication with Glycopyrrolate (0.2mg), Ondansetron (4mg) and Midazolam (1mg) – IV then induced with Propofol (2-3 mg/kg), Fentanyl (2 mcg/kg) and muscle relaxation by Atracurium (0.5 mg/kg). Followed by intubation with appropriate size of Endotracheal tube. Maintenance of Anaesthesia will be achieved by combined effect of N₂O/O₂ and Isoflurane. The bispectral index score (BIS) of 40–60 will determine how much isoflurane to use. All patients will be operated on prone position. Throughout the procedure, the BIS indicator will be used to track the depth of anesthesia, oxygen saturation, heart rate, systolic and diastolic blood pressure, oxygen saturation, and heart rate (HR). The same surgeon will perform every surgery. The American Society of Anesthesiologists' (ASA) and the physical variables (age, sex, height and weight) would all be noted.

If in case, hypotension or bradycardia (HR 60 and MAP 65 mmHg) develops, atropine or ephedrine 5 mg IV will be administered. At the end of the surgery, the total blood loss is noted. As the patient starts having spontaneous breathing, reversal is achieved with Neostigmine (2.5mg) and glycopyrolate (0.5mg). When adequate efforts are made by the patient, extubation is carried out.

Intra-operative:

Following surgical incision:

1. Time will be noted (Time-0) and

Parameters:

- I. Heart rate(HR),
- II. Systolic blood pressure(SBP),
- III. Diastolic blood pressure(DBP),
- IV. Mean Arterial pressure(MAP)
- V. Oxygen saturation(SpO₂)

will be recorded at an interval of every 5 minutes (min) from Time-0 for the initial 30 min.

2. After that, at an interval of every 15min, the parameters will be recorded till the end of the surgery.
3. The depth of the anesthesia will be monitored using the BIS index throughout the surgery.
4. At the end of the surgery, the total blood loss is noted.

Postoperative:

1. After completing the surgery, the patient will be extubated upon fulfilling the extubation criteria and shifted to the post anesthesia care unit (PACU).
2. In PACU, pain scoring will be done using postoperative pain score, i.e., Visual Analogue Scale (VAS) score.

Interpretation:

1. Pain Assessment:

- Mild pain will be considered when the VAS score is between 1 and 3;
- Moderate pain when VAS Score is between 4 and 6
- Severe pain will be recorded when the VAS Score is > 7 .

2. Postoperative Rescue Analgesia:

The first dose of postoperative rescue analgesia will be given when a VAS score of <7 is recorded or on-demand by the patient (whichever is earlier) and repeated if required. Rescue analgesia used will be **Injection Diclofenac 75mg intramuscularly given** whenever needed.

RESULTS

In our study the collected data were represented in the master chart. Two groups (GROUP A and GROUP B) of 64 patients were randomly selected, with 32 individuals in each group undergoing elective lumbar spine operations.

- GROUP A received sole general anaesthesia as mentioned in the methodology.
- GROUP B received single shot of epidural anaesthesia with 0.125% Bupivacaine along with fentanyl in it followed by general anaesthesia.

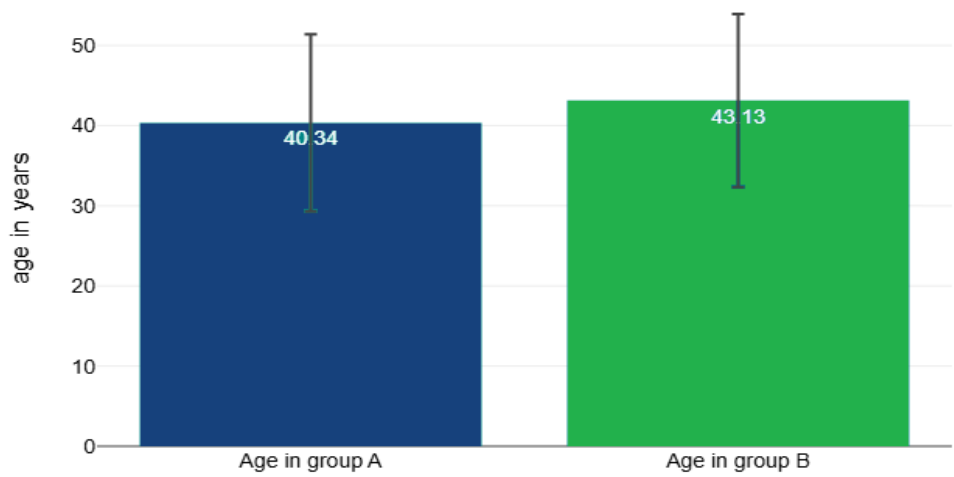
P-value which are less than 0.05 are considered statistically significant.

1. DISTRIBUTION OF AGE:

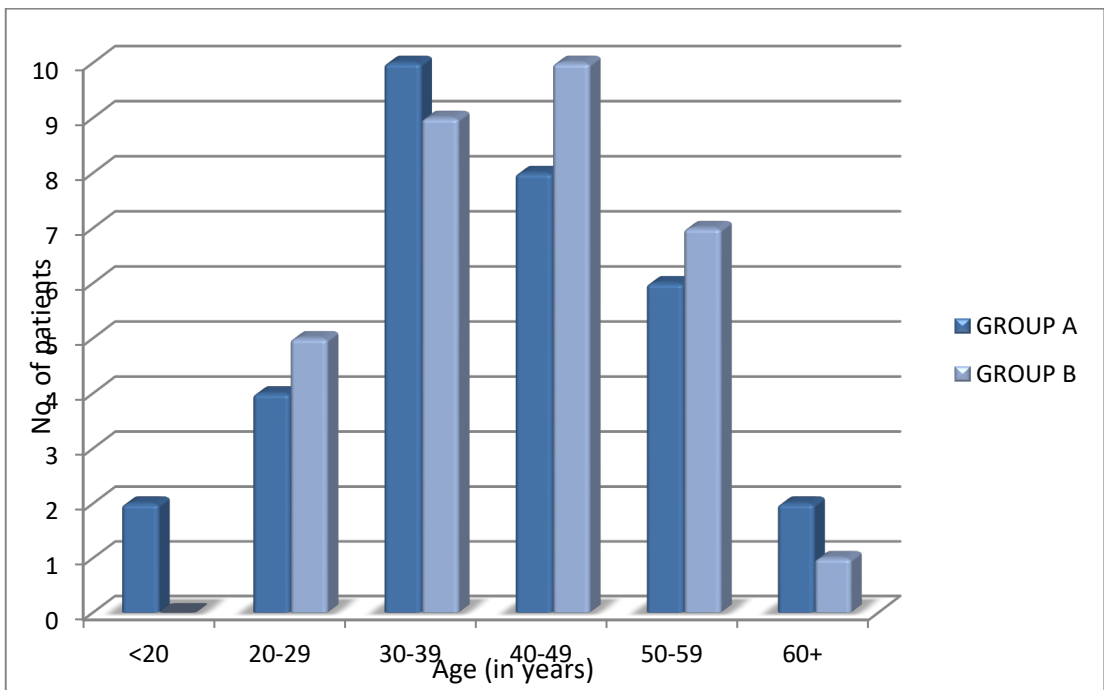
Table 2 : Distribution of age

AGE		NO. OF PATIENTS	%	CHI SQUARE TEST VALUE	P VALUE
GROUP A	<20	2	100	2.796	0.731
	20-29	4	44.4		
	30-39	10	52.6		
	40-49	8	44.4		
	50-59	6	46.2		
	60-65	2	66.7		
GROUP B	<20	0	0		
	20-29	5	55.6		
	30-39	9	47.4		
	40-49	10	55.6		
	50-59	7	53.8		
	60-65	1	33.3		
Statistically insignificant as P value is more than 0.05					

Graph 1(a): Mean distribution of age in each group.



Graph 1(b) : Distribution of patients in various age group range



- In our study, 2 patients were under 20 years of age, 9 patients were in the range of 20-29 years, 19 patients were in the range of 30-39 years, 18 patients were in the

range of 40-49 years, 13 patients were in the range of 50-59 years and 3 patients were in the 60-65 years of age.

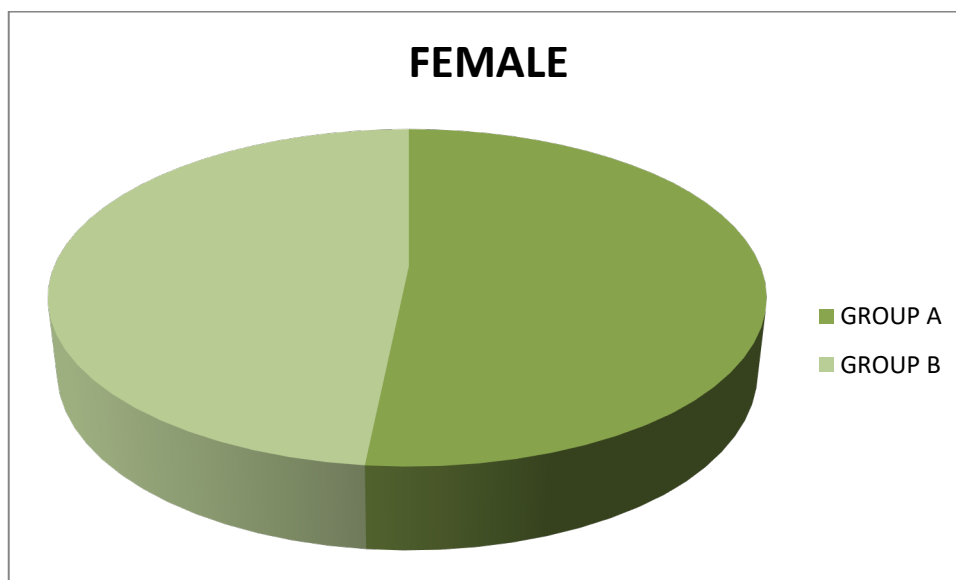
- Group A exhibits a greater proportion of patients in the <20 age category (100%) relative to Group B (0%). In the 20-29 age range, Group B surpasses Group A with a marginally higher percentage (55.6% versus 44.4%). For the 30-39 age range, Group A holds a superior percentage (52.6%) compared to Group B (47.4%). In the 40-49 and 50-59 age categories, Group B demonstrates a higher percentage (55.6% and 53.8%, respectively) than Group A (44.4% and 46.2%). In the 60-65 age group, Group A again shows a higher percentage (66.7%) in contrast to Group B (33.3%).
- In our study, the age wise distribution of the sample in the above two groups (GROUP A & GROUP B) are comparable with a P-value that is statistically insignificant.

2. COMPARISON OF GENDER:

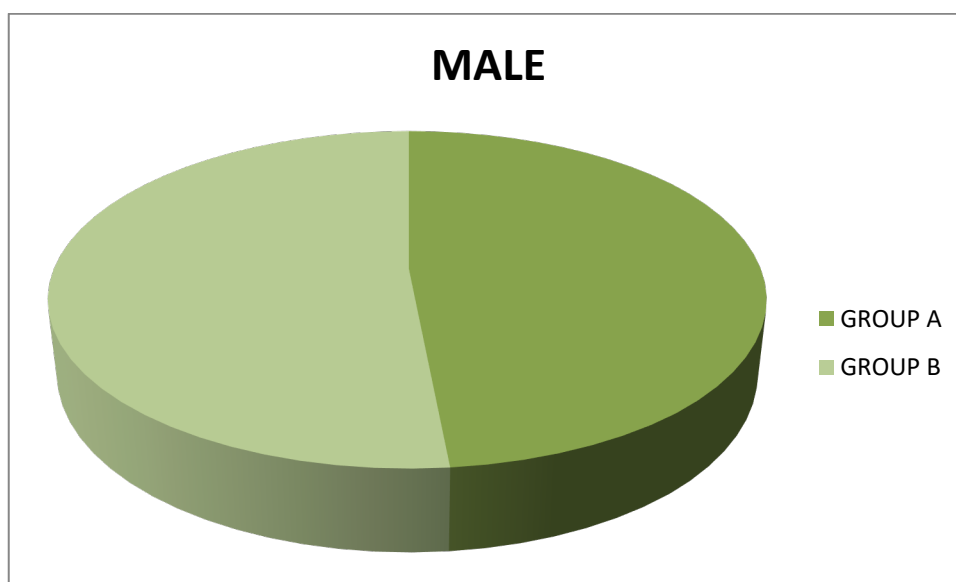
Table 3: Gender distribution in each group

GENDER		NO. OF PATIENTS	%	CHI – SQUARE	P- VALUE
GROUP A	F	16	51.6	0.063	0.802
	M	16	48.5		
GROUP B	F	15	48.4		
	M	17	51.5		
Statistically insignificant as P value is more than 0.05					

Graph 2(a): Comparison of female patient distribution in each groups



Graph 2(b): Comparison of female patient distribution in each groups



- The proportions of males and females in Groups A and B are similar, and the P-value is elevated (0.802), indicating that gender does not significantly influence group classification. The gender distribution is equitable between the two groups.

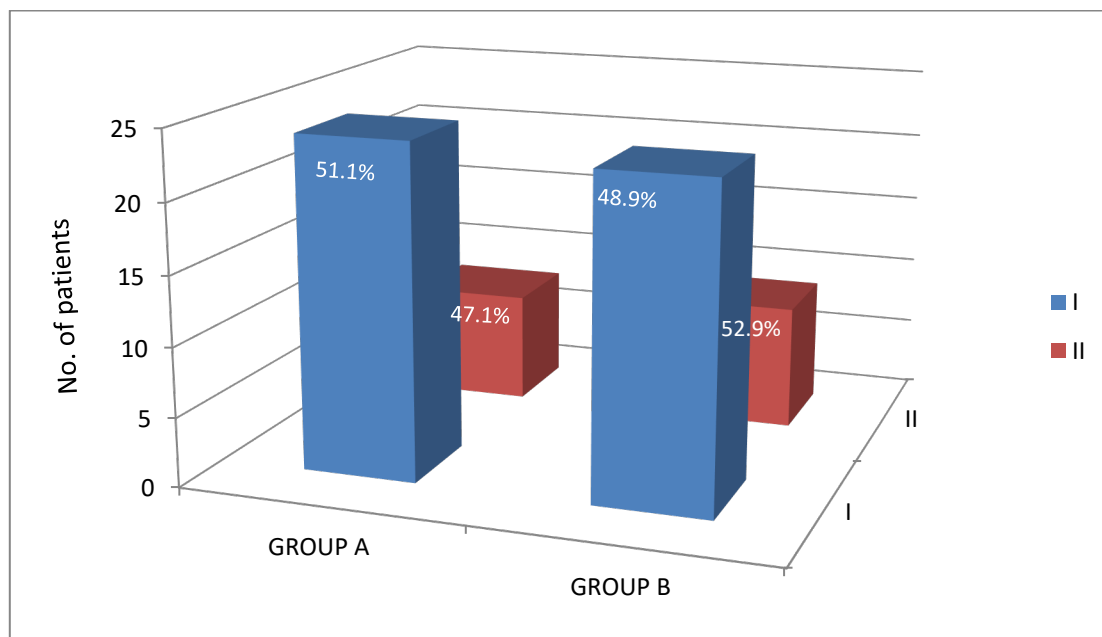
3. ASA GRADE:

Table 4 : ASA grade of patients assigned for the study

ASA GRADE		NO. OF PATIENTS	%	CHI-SQUARE	P-VALUE
GROUP A	I	24	51.1	0.080	0.777
	II	8	47.1		
GROUP B	I	23	48.9		
	II	9	52.9		
Statistically insignificant as P value is more than 0.05					

- The high P-value of 0.777 indicates that ASA grade does not significantly influence group classification.
- The distribution of ASA Grade I and II is approximately equal between Group A and Group B.

Graph 3: Distribution of patients according to ASA grade



INTRAOPERATIVE PARAMETERS:

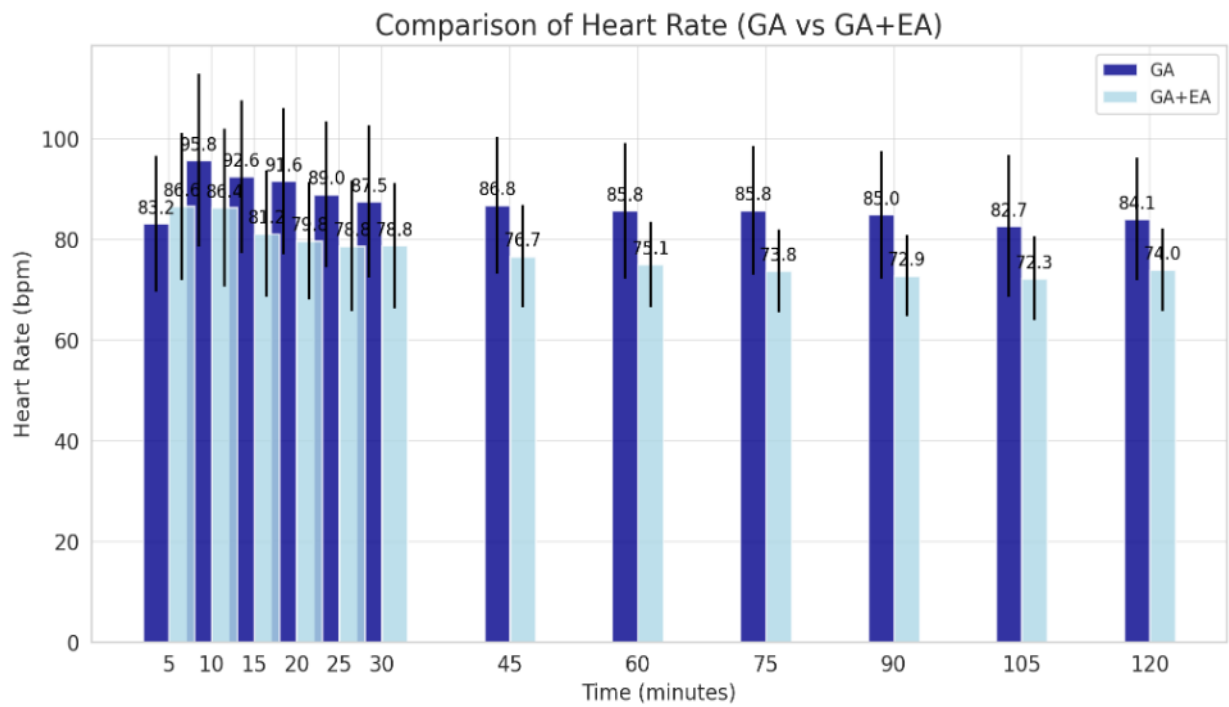
4. HEART RATE:

Table 5: Intraoperative heart rate comparison

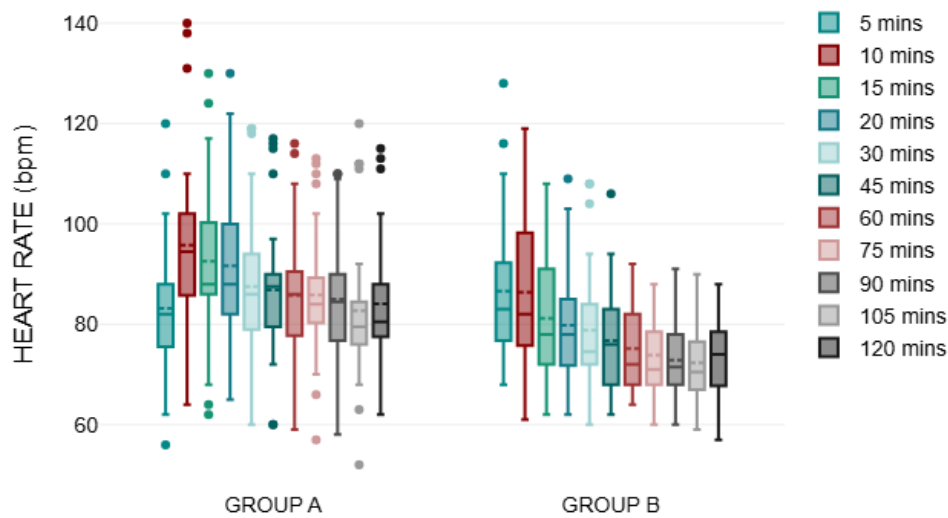
HEART RATE (bpm)	GA		GA+EA		Mann whitney test	Significant value
	Mean	Std. Deviation	Mean	Std. Deviation		
5 mins	83.19	13.441	86.63	14.606	462.500	0.506
10 mins	95.75	17.177	86.38	15.723	352.500	0.032*
15 mins	92.56	15.195	81.19	12.504	300.000	0.004*
20 mins	91.63	14.573	79.81	11.674	244.000	0.000*
25 mins	89.03	14.499	78.78	13.015	292.500	0.003*
30 mins	87.53	15.134	78.81	12.458	301.500	0.005*
45 mins	86.84	13.598	76.72	10.199	270.000	0.001*
60 mins	85.75	13.498	75.13	8.515	256.500	0.001*
75 mins	85.84	12.796	73.84	8.188	219.000	0.000*
90 mins	84.97	12.635	72.88	8.051	211.000	0.000*
105 mins	82.69	14.120	72.31	8.326	243.000	0.000*
120 mins	84.09	12.172	74.00	8.160	250.500	0.000*
*statistically significant as p-value is less than 0.05						

- Group B has significantly lower heart rate from 10 minutes to 120 minutes since intubation. The greatest difference has been observed in the range of 90-120 minutes, when compared between the groups A and B. Almost 10-12 bpm lesser in Group B compared to Group A.
- Hence, its been observed that Group A has a constant high heart rate over the entire time of surgery in comparison to Group B.

Graph 4(a): Bar diagram showing comparison of Intraoperative Heart rate



Graph 4(b): Box plot showing the Heart rate range in both the groups



- This explains that the epidural component, which blocks the sympathetic nervous system and also reduced the stress response, is the main element in controlling and keeping the heart rate stable throughout the surgery post-induction.
- The above values explain that patients receiving epidural shot have better hemodynamic stability.

5. SYSTOLIC BLOOD PRESSURE:

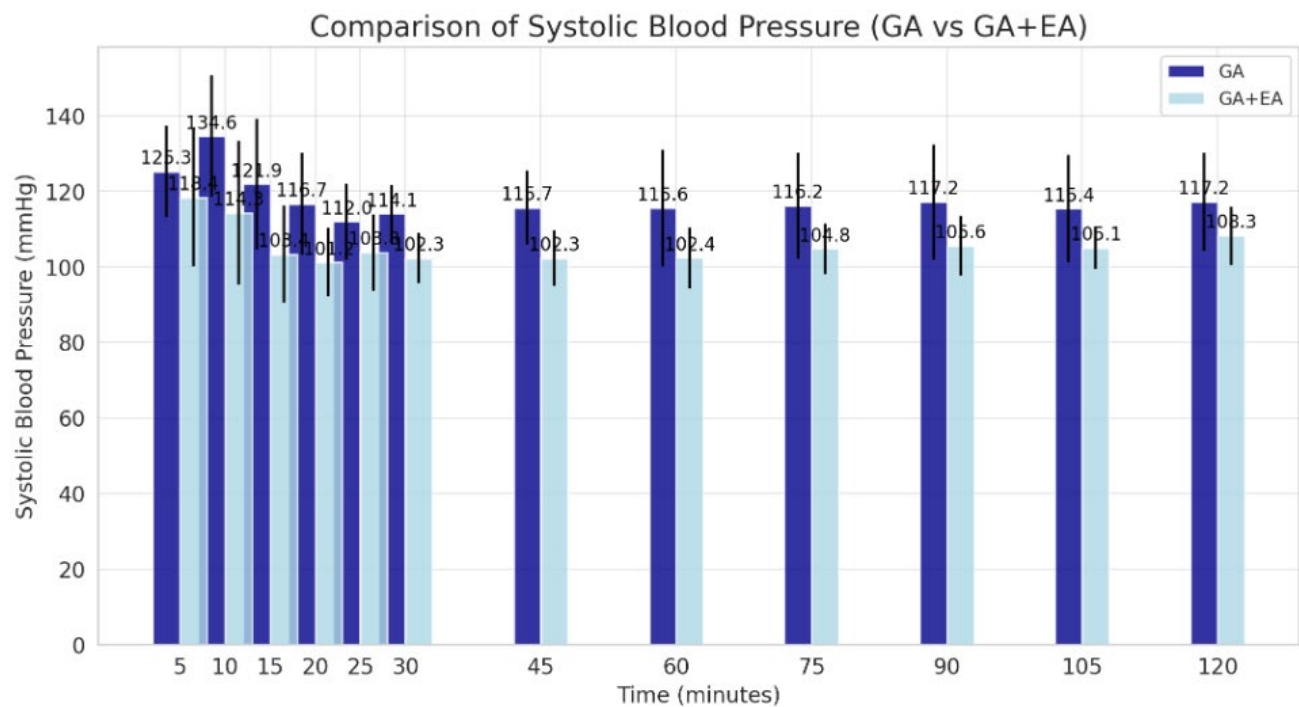
Table 6: Comparison of SBP between two groups (Group A Vs Group B)

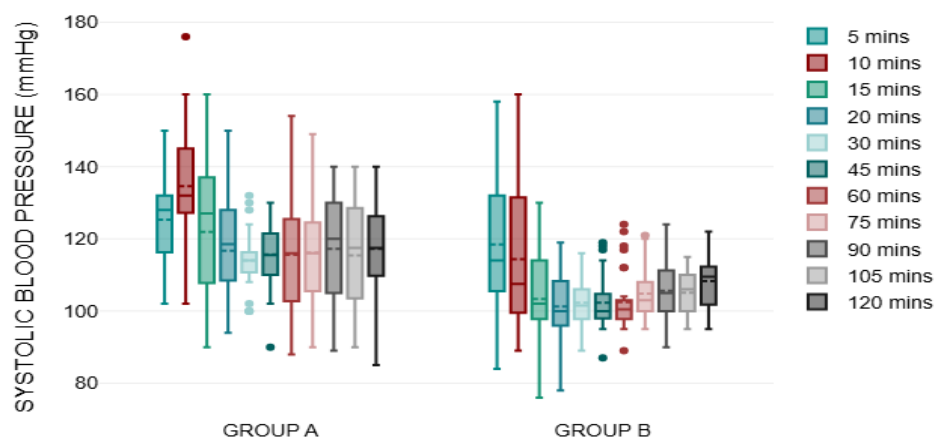
SYSTOLIC BLOOD PRESSURE (mmHg)	GA		GA+EA		Mann Whitney test	Significant value
	Mean	Std. Deviation	Mean	Std. Deviation		
5 mins	125.28	12.102	118.41	18.164	355.500	0.035*
10 mins	134.56	16.092	114.34	19.097	223.000	0.000*
15 mins	121.91	17.421	103.38	12.921	216.500	0.000*
20 mins	116.72	13.405	101.25	9.091	187.000	0.000*
25 mins	111.97	10.063	103.84	10.138	261.000	0.001*
30 mins	114.06	7.607	102.31	6.606	129.000	0.000*
45 mins	115.69	9.790	102.31	7.328	133.500	0.000*
60 mins	115.63	15.360	102.44	8.136	205.500	0.000*
75 mins	116.19	13.992	104.84	6.605	257.000	0.001*
90 mins	117.25	15.236	105.56	7.971	275.500	0.001*
105 mins	115.41	14.187	105.09	5.584	298.000	0.004*
120 mins	117.22	12.998	108.28	7.663	279.500	0.002*
*statistically significant as p-value is less than 0.05						

- The average SBP is seen to be constantly lower in Group B as compared to Group A at any given point after induction.

- The P-value according to the Mann-Whitney test shows significant difference (P-value <0.05) between the two Groups (A Vs B) at all the points. This suggests that in Group B there is a significant lesser SBP maintained throughout the surgery.
- However, at the 10 minutes post-induction, there is a significantly higher SBP observed in group A when compared to Group B (GA: 134.56 ± 16.09 vs. GA+EA: 114.34 ± 19.10).
- The trend in SBP from 10 minutes of induction onwards maintains constantly lower and stable in Group B.

Graph 5(a): Bar chart for comparison of Systolic blood pressure.



Graph 5(b): Box plot showing the distribution SBP entities in both the groups

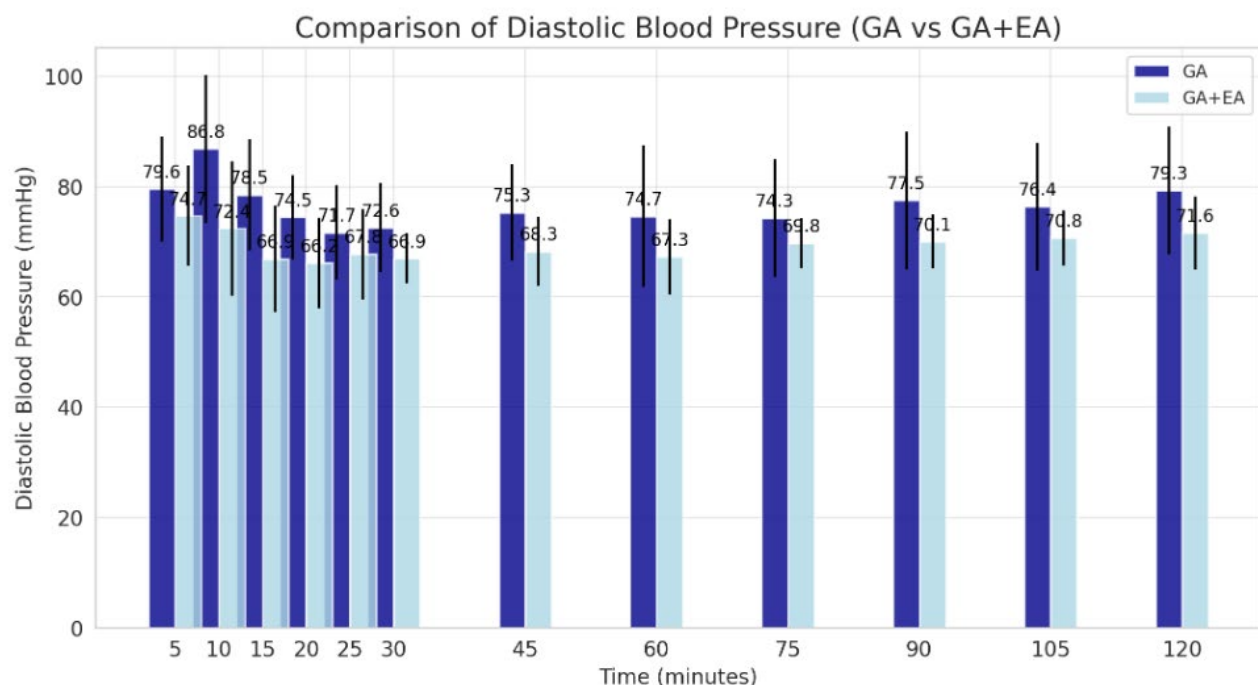
6. DIASTOLIC BLOOD PRESSURE:

Table 7: Comparison of Diastolic Blood pressure

DIASTOLIC BLOOD PRESSURE (mmHg)	GA		GA+EA		Mann Whitney test	P-value
	Mean	Std. Deviation	Mean	Std. Deviation		
5 mins	79.59	9.497	74.69	9.110	376.500	0.067
10 mins	86.84	13.323	72.41	12.160	178.000	0.000*
15 mins	78.53	10.039	66.91	9.610	209.500	0.000*
20 mins	74.47	7.624	66.16	8.211	241.000	0.000*
25 mins	71.69	8.623	67.81	8.213	383.000	0.083
30 mins	72.56	8.036	66.94	4.550	313.500	0.007*
45 mins	75.31	8.686	68.28	6.259	250.500	0.000*
60 mins	74.66	12.838	67.31	6.860	319.500	0.010*
75 mins	74.31	10.639	69.75	4.522	342.500	0.022*
90 mins	77.53	12.485	70.06	4.852	297.500	0.004*
105 mins	76.41	11.562	70.75	5.035	310.500	0.007*
120 mins	79.31	11.577	71.59	6.652	270.500	0.001*
*statistically significant as p-value is less than 0.05						

- In all the time points post-induction, the DBP is constantly lower in Group B when compared to Group A. This suggests that Epidural anaesthesia administration provides better hemodynamic stability as it blocks the sympathetic activity.
- The p-value is less than 0.05 at multiple time points which indicates that Group B patients had more stable and controlled intraoperative blood pressure compared to Group A.
- Hence this trend gives a conclusion of better cardiovascular stability and also reduced anaesthetic drug requirements.

Graph 6: Bar chart showing the comparison between both the groups



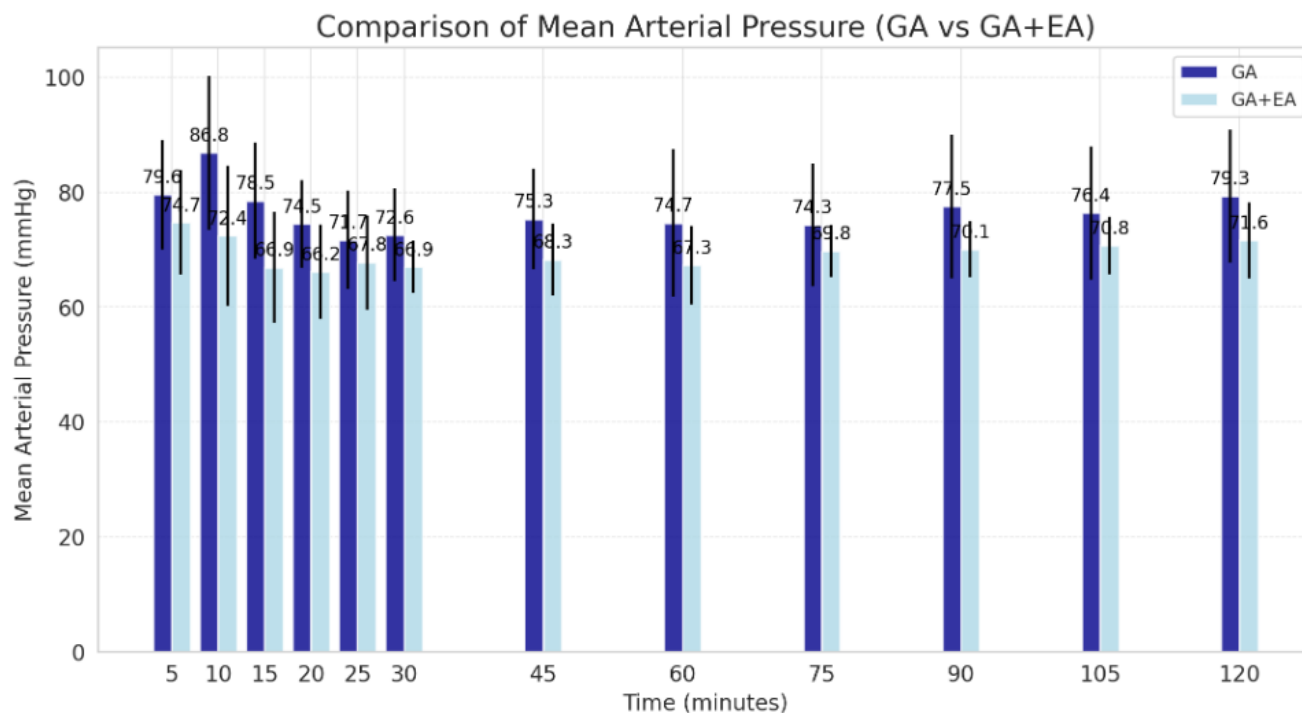
7. MEAN ARTERIAL PRESSURE:

Table 8: Comparison of Mean Arterial pressure

MEAN ARTERIAL PRESSURE (mmHg)	GA		GA+EA		Mann Whitney test	P-value
	Mean	Std. Deviation	Mean	Std. Deviation		
5 mins	79.59	9.497	74.69	9.110	376.500	0.067
10 mins	86.84	13.323	72.41	12.160	178.000	0.000*
15 mins	78.53	10.039	66.91	9.610	209.500	0.000*
20 mins	74.47	7.624	66.16	8.211	241.000	0.000*
25 mins	71.69	8.623	67.81	8.213	383.000	0.083
30 mins	72.56	8.036	66.94	4.550	313.500	0.007*
45 mins	75.31	8.686	68.28	6.259	250.500	0.000*
60 mins	74.66	12.838	67.31	6.860	319.500	0.010*
75 mins	74.31	10.639	69.75	4.522	342.500	0.022*
90 mins	77.53	12.485	70.06	4.852	297.500	0.004*
105 mins	76.41	11.562	70.75	5.035	310.500	0.007*
120 mins	79.31	11.577	71.59	6.652	270.500	0.001*
*statistically significant as p-value is less than 0.05						

- The effect of group B on MAP is more prominent 10 minutes post-induction and from then on through out the surgery.
- This suggests that epidural administration in addition to general anaesthesia provides better perfusion stability which is beneficial in lumbar spine surgeries.

Graph 7: Bar chart representing the comparison of Mean arterial pressure (MAP)

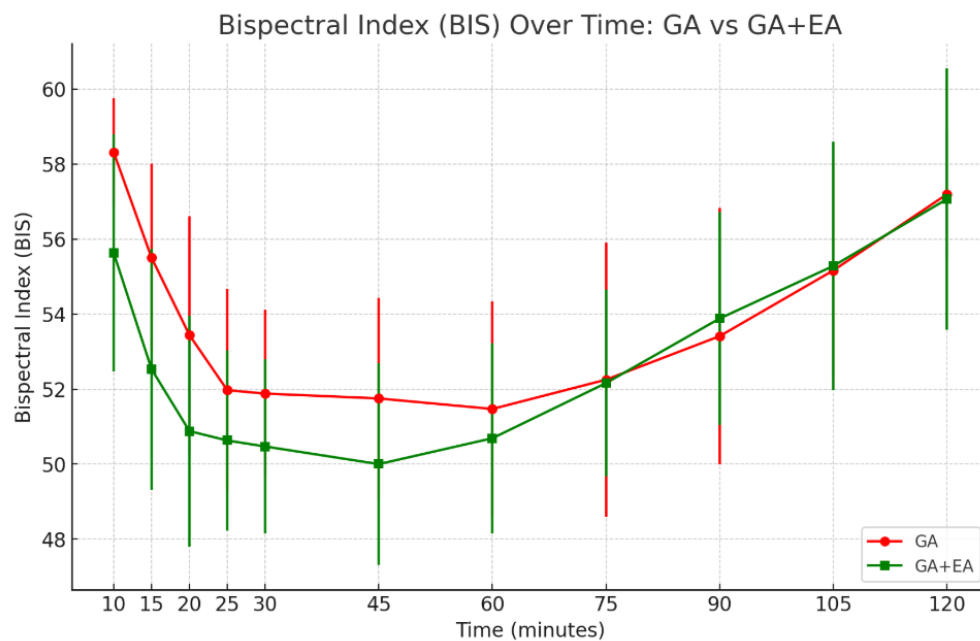


8. BISPECTRAL INDEX:

- The P-value is significant ($p\text{-value} < 0.05$) during the first 45 minutes into the surgery which suggests enhanced anaesthetic depth in the early duration of the surgery. This is due to the synergistic action of epidural anaesthesia.
- This early reduction in BIS potentially reduces the amount of drug used in maintaining general anaesthesia, eventually reducing the side effects from those drugs.
- However, 60 minutes post-induction, the BIS levels are comparable in both groups ($p\text{-value} > 0.05$) suggesting that the depth of anaesthesia is similar in both groups.

Table 9: Bispectral index of both Group A and Group B

BISPECTRAL INDEX	GA		GA+EA		Mann Whitney test	P-value
	Mean	Std. Deviation	Mean	Std. Deviation		
5 mins	-	-	-	-	-	-
10 mins	58.31	1.447	55.63	3.170	189.500	.000*
15 mins	55.50	2.514	52.53	3.213	218.500	.000*
20 mins	53.44	3.172	50.88	3.077	270.000	.001*
25 mins	51.97	2.694	50.63	2.406	356.500	.034*
30 mins	51.88	2.240	50.47	2.328	347.500	.025*
45 mins	51.75	2.688	50.00	2.688	334.500	.015*
60 mins	51.47	2.874	50.69	2.533	460.000	.478
75 mins	52.25	3.654	52.16	2.490	498.000	.850
90 mins	53.41	3.425	53.88	2.837	479.000	.655
105 mins	55.16	2.852	55.28	3.304	489.000	.755
120 mins	57.19	1.712	57.06	3.482	444.500	.358
*statistically significant as p-value is less than 0.05						

Graph 8: Bispectral index over time (GA vs GA+EA)

9. ISOFLURANE REQUIREMENT:

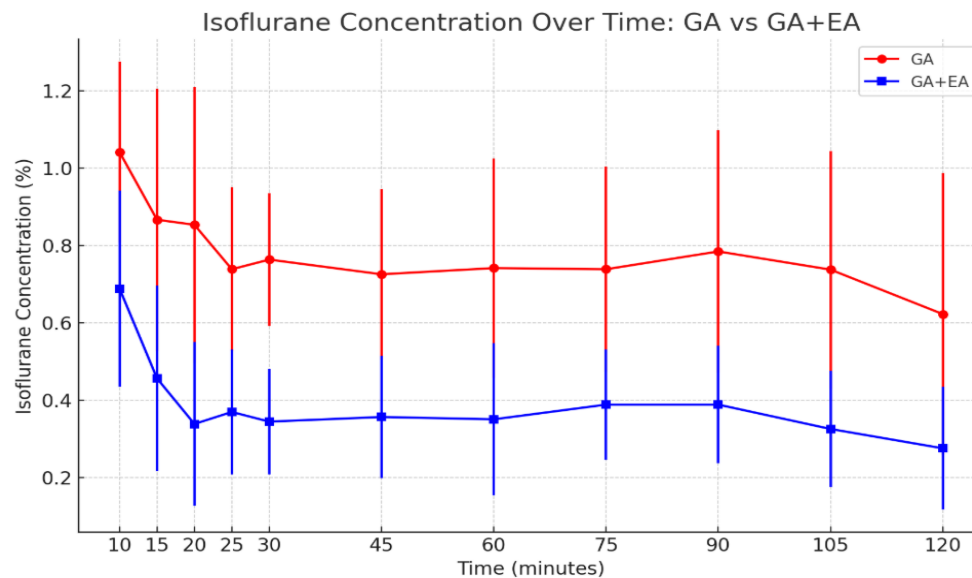
- The mean highest mean concentration in the Group A is found to be 1.041 at 10 minutes has gradually reduced over the time.
- In the Group B, the highest mean concentration was observed to be 0.688 at 10 minutes and it reduces over time after 10 minutes of post-induction.
- At 120 minutes, there was a significant difference in the isoflurane requirement. The concentration of isoflurane use fell significantly in Group B (0.275) when compared to Group A (0.622).

Table 10: Comparison of the isoflurane used in Group A & Group B

ISOFLURANE	GA		GA+EA		Mann Whitney test	P-value
	Mean	Std. Deviation	Mean	Std. Deviation		
5 mins	-	-	-	-	-	-
10 mins	1.041	.2340	.688	.2537	.2537	.000*
15 mins	.866	.3395	.456	.2395	.2395	.000*
20 mins	.853	.3565	.338	.2121	.2121	.000*
25 mins	.738	.2121	.369	.1615	.1615	.000*
30 mins	.763	.1718	.344	.1366	.1366	.000*
45 mins	.725	.2200	.356	.1585	.1585	.000*
60 mins	.741	.2838	.350	.1967	.1967	.000*
75 mins	.738	.2661	.388	.1431	.1431	.000*
90 mins	.784	.3133	.388	.1519	.1519	.000*
105 mins	.737	.3066	.325	.1503	.1503	.000*
120 mins	.622	.3643	.275	.1586	.1586	.000*
*statistically significant as p-value is less than 0.05						

- The p-value was observed to be significant throughout the surgery (p-value <0.05) suggesting that epidural anaesthesia provides an effective anaesthetic-sparing effect which reflects on the reduction in the isoflurane requirement.

Graph 9: Line graph showing the isoflurane usage in Group A vs. Group B



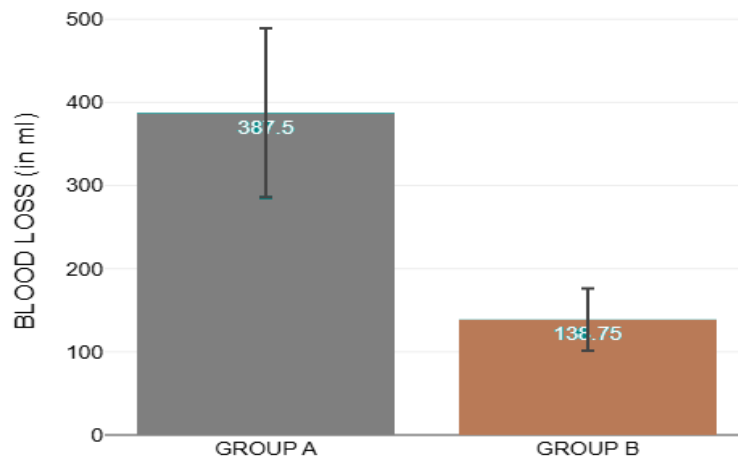
10. TOTAL AMOUNT OF BLOOD LOSS:

Table 11: Comparison of the total amount of blood loss in both groups

Total amount of blood loss (ml)					
GROUP - GA		GROUP – GA + EA		Mann Whitney test	P - value
Mean	Std. Deviation	Mean	Std. Deviation		
387.50	101.600	138.75	37.222	18.000	0.000*
*statistically significant as p-value is less than 0.05					

- The mean blood loss in Group A is 387.50 ± 101.60 ml and in Group B is 138.75 ± 37.22 ml, which is significantly lower.
- The p-value is 0.000, which is highly significant, suggesting a precise difference in blood loss between both the groups. This indicates that Epidural with GA group has a significant reduction in the blood loss compared to GA group.
- The reduction in the amount of blood loss in Group B suggests that there is better hemodynamic stability and reduced vasodilation associated with epidural anaesthesia which can lead to reduced need for transfusions, faster recovery and better patient outcomes as compared to Group A.

Graph 10: Bar graph showing Total blood loss in Group A vs. Group B



POSTOPERATIVE PARAMETERS

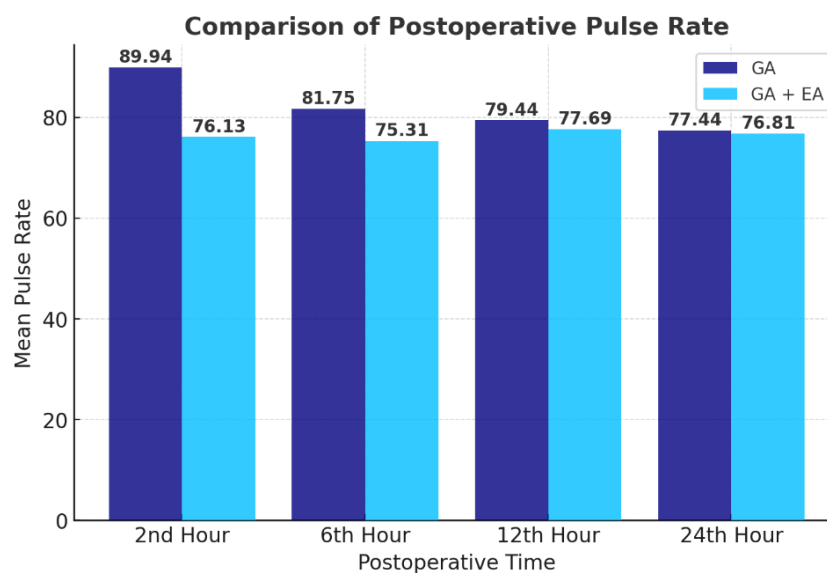
11. PULSE RATE:

Table 12: Comparison of postoperative pulse rate

PULSE RATE	GROUP – GA		GROUP – GA + EA		Mann Whitney Test	P-value
	Mean	Std. Deviation	Mean	Std. deviation		
2 nd hour	89.94	9.151	76.13	5.633	80.000	0.000*
6 th hour	81.75	8.451	75.31	5.625	293.500	0.003*
12 th hour	79.44	6.933	77.69	7.502	462.000	0.499
24 th hour	77.44	5.086	76.81	7.146	469.000	0.560
* statistically significant as p-value is less than 0.05						

- The P-value is less than 0.05 in the 2nd and 6th hour of postoperative period, indicating that there is a statistically significant difference suggesting that the epidural anaesthesia leads to a significantly lower pulse rate in the early postoperative period likely due to better pain and hemodynamic stability.

Graph 11: Bar chart of comparison of postoperative pulse rate



12. POSTOPERATIVE SBP, DBP & MAP:

Table 13: Comparison of Postoperative systolic blood pressure in both groups.

SBP (mmHg)	GROUP – GA		GROUP – GA + EA		Mann Whitney Test	P-value
	Mean	Std. Deviation	Mean	Std. deviation		
2 nd hour	130.53	7.247	113.91	6.497	63.000	0.000*
6 th hour	122.19	6.761	113.69	8.271	237.500	0.000*
12 th hour	120.06	8.088	114.69	9.209	347.500	0.023*
24 th hour	120.25	8.692	117.13	7.430	404.000	0.128
* statistically significant as p-value is less than 0.05						

Table 14: Comparison of Postoperative Diastolic blood pressure in both groups.

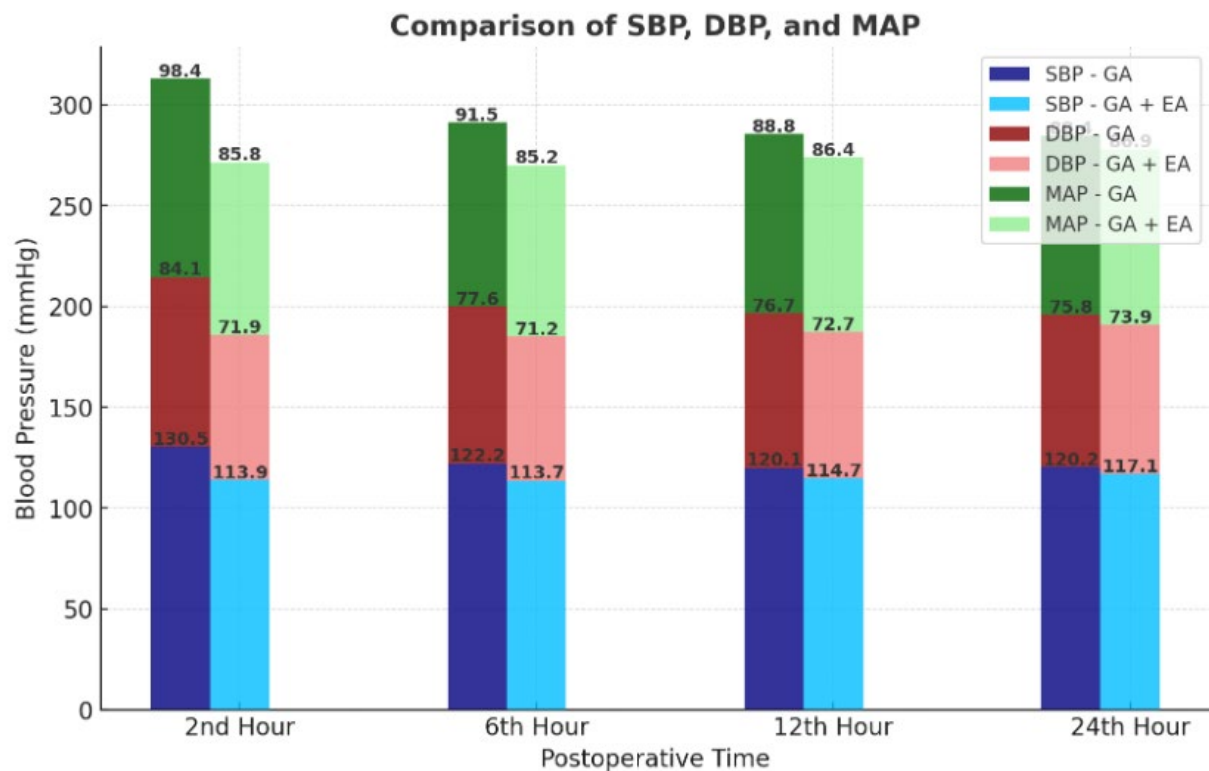
DBP (mmHg)	GROUP – GA		GROUP – GA + EA		Mann Whitney Test	P-value
	Mean	Std. Deviation	Mean	Std. deviation		
2 nd hour	84.09	7.420	71.94	4.697	82.000	0.000*
6 th hour	77.63	6.598	71.25	4.892	236.000	0.000*
12 th hour	76.69	7.100	72.69	4.993	357.500	0.026*
24 th hour	75.84	6.181	73.88	6.200	437.000	0.271
* statistically significant as p-value is less than 0.05						

Table 15: Comparison of Postoperative Mean arterial pressure in both groups.

MAP (mmHg)	GROUP – GA		GROUP – GA + EA		Mann Whitney Test	P-value
	Mean	Std. Deviation	Mean	Std. deviation		
2 nd hour	98.38	6.158	85.75	4.813	69.500	0.000*
6 th hour	91.47	5.814	85.19	5.158	227.500	0.000*
12 th hour	88.84	6.957	86.38	6.529	418.000	0.201
24 th hour	88.38	5.841	86.91	5.300	429.500	0.254
* statistically significant as p-value is less than 0.05						

- Group B results show significantly lowered SBP, DBP and MAP in the early postoperative period upto 12 hours. By the 24th hour, Blood pressure stabilizes between both groups.
- This suggests that the epidural anaesthesia provides hemodynamic stability in the immediate postoperative period.

Graph 12: Comparison of SBP, DBP and MAP among both the groups.



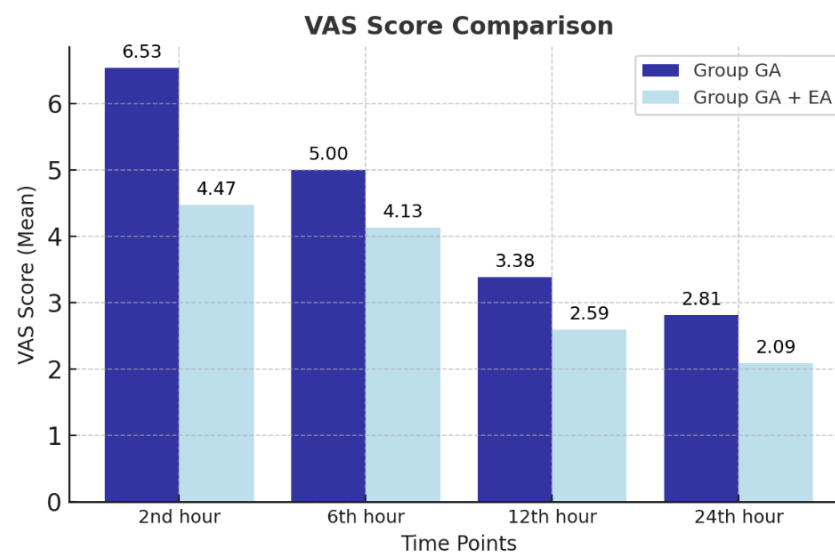
13. VAS SCORE:

Table 16: comparison of the VAS Score in Group A vs. Group B

VAS Score	GROUP – GA		GROUP – GA + EA		Mann Whitney Test	P-value
	Mean	Std. Deviation	Mean	Std. deviation		
2 nd hour	6.53	.621	4.47	.761	29.000	0.000*
6 th hour	5.00	.672	4.13	.833	225.000	0.000*
12 th hour	3.38	.492	2.59	.615	202.000	0.000*
24 th hour	2.81	.535	2.09	.296	173.000	0.000*
* statistically significant as p-value is less than 0.05						

- VAS Score when compared in both group, the p-value was found to be significantly lower at all the time points post-operatively.
- This suggests that the Epidural anaesthesia provides much better postoperative analgesic effect as compared to sole General anaesthesia, especially in the first 24 hours. Better pain control may lead to improved patient control, reduced opioid requirements and faster recovery.

Graph 13: Bar chart representing VAS Score comparison



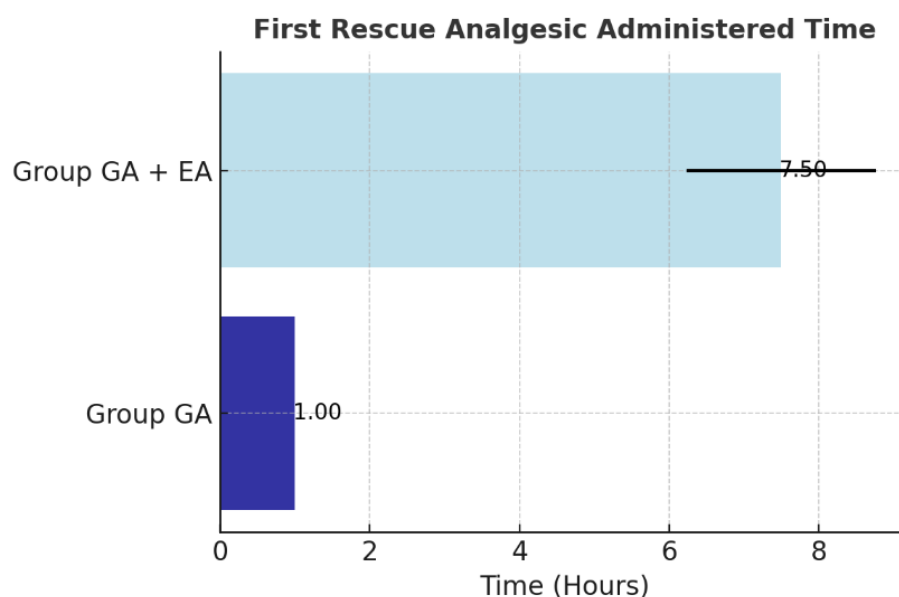
14. FIRST RESCUE ANALGESIC:

Table 17: First rescue analgesic administration in each group.

FIRST RESCUE ANALGESIC ADMINISTERED TIME					
GROUP - GA		GROUP – GA + EA		Mann Whitney test	P - value
Mean	Std. Deviation	Mean	Std. Deviation		
1.00	0.000	7.50	1.270	0.000	0.000*
*statistically significant as p-value is less than 0.05					

- The Mann-Whitney test resulted in a P-value of 0.000, indicated a statistically significant difference between the two groups ($p < 0.05$)
- Patients in the GA+EA group required significantly delayed administration of rescue analgesia compared to the GA group.
- This suggests that the addition of epidural analgesia provides prolonged pain relief, reducing the need for early rescue analgesia.

Graph 14: Bar chart – first rescue analgesic administered time



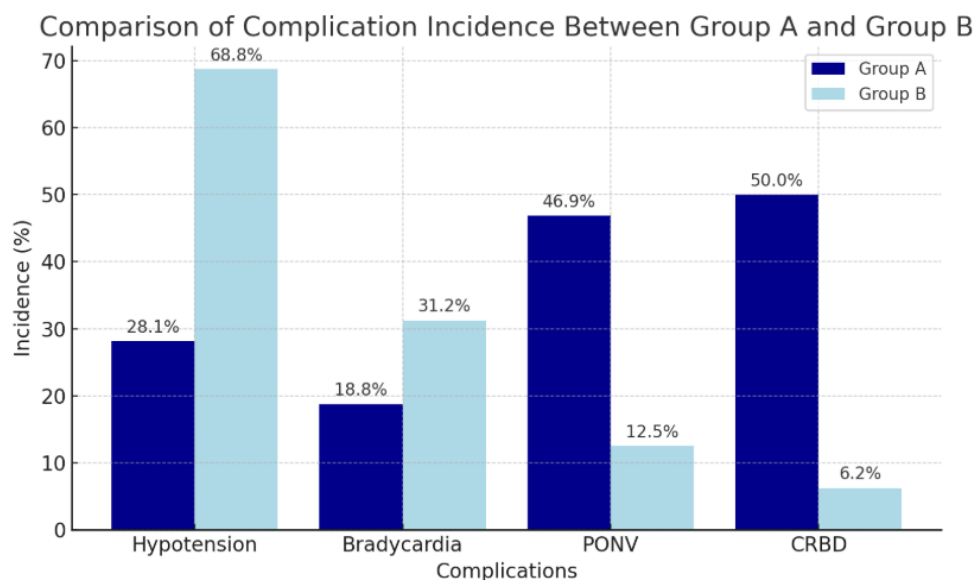
15. INTRAOPERATIVE/ POSTOPERATIVE COMPLICATIONS:

Table 18: Comparison of complications in both the groups

COMPLICATIONS	GROUP A (n=32)	GROUP B (n=32)	P - VALUE
Hypotension	9 (28.13%)	22 (68.75%)	0.002*
Bradycardia	6 (18.75%)	10 (31.25%)	0.387
PONV	15 (46.88%)	4 (12.5%)	0.005*
CRBD	16 (50.0%)	2 (6.25%)	0.000*
*statistically significant as p-value is less than 0.05			

- The results that were observed are that hypotension is significantly more common in patients receiving epidural along with general anesthesia, whereas PONV and CRBD are more frequent in those receiving GA alone. On the other hand, Bradycardia did not show a significant difference between the groups.
- Hence the choice of anesthetic technique should consider these potential complications to optimize patient outcomes.

Graph 15: Bar chart depicting various complications in both the groups



DISCUSSION

The lumbar spine surgeries usually necessitate for positioning the patient in prone position. Hence the conventional choice of anesthesia in such surgeries were general anesthesia, as it secures the airway and eliminates the awareness or movement of patient while in prone position undergoing surgery.

Although GA might be the primarily opted plan of anesthesia for many years now, some studies shows regional anaesthesia to be more advantageous^[30].

The reason for restricted use of regional anaesthesia is due limitations such as delayed assessment of nerve injuries postoperatively, masking the presence of hematoma post-surgery, and the anaesthetist become blamed for an untoward nerve injury occurred during surgery and also sole SA/EA are unsuitable for prolonged and complicated surgeries. Nonetheless, increasing proofs supports the preference of RA over GA for patients undergoing simple, relatively short lumbar spine surgeries^[25,26,27,28,29].

An ideal anaesthetic method should ensure quick onset as well as rapid recovery. Its necessary to maintain optimal intraoperative hemodynamic stability and if feasible, reduces the necessity for blood transfusions. Additionally, the anesthetic considerations for a surgery are to curtail the postoperative outcomes such as pain , analgesic use, nausea and vomiting, that facilitates early discharge from the PACU^[31,32].

This study is to throw evidence on the role of addition of epidural anesthesia along with general anesthesia (combined epidural/general anesthesia (CEG)) in

intraoperative hemodynamic stability which has effect on decreasing the blood loss. The administration of epidural local anaesthetics also showed reduction in the requirement of the inhalational anaesthetics used for the maintenance of general anesthesia during the lumbar spine surgery. The postoperative benefits that were established in this study are better patient outcomes by minimizing the pain, requirement of opioids and reduced adverse effects of general anaesthesia.

The present study aimed to compare the effects and outcomes of general anesthesia (GA) versus combined epidural and general anesthesia (GA+EA) in elective lumbar spine surgery. The results provide insights into the demographic distribution, intraoperative parameters and anesthetic requirements in both groups.

1. DEMOGRAPHIC CHARACTERISTICS:

The age and gender distribution between the two groups were statistically insignificant ($p > 0.05$), suggesting that the groups were comparable. The ASA classification also showed no significant difference ($p = 0.777$), confirming that the preoperative health status of patients in postoperative parameters were due to the anesthetic technique rather than baseline patient characteristics. This goes in hand with the study done by Attari et al (2011)^[23].

2. INTRAOPERATIVE HEMODYNAMICS:

The heart rate remained consistently lower in group B (GA+EA) compared to Group A (GA alone) from 10 minutes post-induction onwards, with statistically significant differences ($p\text{-value} < 0.05$). At 10 minutes, mean value of heart rate in Group A is 95.75 ± 17.177 and in Group B is 86.38 ± 15.723 and the $p\text{-value}$ is 0.032. The lower

heart rate in the Group B can be attributed to the sympathetic blockade provided by epidural anesthesia, which helps in maintaining hemodynamic stability and reducing stress responses during surgery. Similarly, Khajavi et al. (2013) observed that the mean intraoperative heart rate was notably higher in Group A compared to the Group B, with an increased incidence of bradycardia in the latter. This feature may be attributed to variations in the local anesthetic dosage used in their study^[7]. On the other hand, findings in Suryavanshi et al. (2016) showed no statistical significance in the HR between CEG group and GA group at all the time period in the initial first one hour of post-induction^[33].

Regarding the SBP and DBP were significantly lower in Group B at multiple time points post-induction ($p < 0.05$). The MAP was significantly lower in the Group B at multiple time intervals post-induction, indicating better perfusion stability with epidural anesthesia. This plays crucial role in attenuating hemodynamic fluctuations, reducing intraoperative stress response and improving cardiovascular stability. This leads to reduction in intraoperative complications and increased blood loss which are beneficial in lumbar spine surgeries. Previous studies have also noted that intraoperative MAP was significantly lower in the Group CEG group compared to the GA group (Pan et al., 2015; Tikuišis et al., 2009)^[34,35].

A significant reduction in isoflurane concentration was observed in the Group B at all time points ($p < 0.05$). This highlights the anesthetic-sparing effect of epidural anesthesia, which is clinically significant as it reduces exposure to volatile anesthetics, thereby minimizing potential side effects such as postoperative nausea, vomiting and delayed recovery. Similarly, Khajavi et al. (2013) and Pan et al. (2015) found that the isoflurane requirement was significantly lower in the CEG group,

reinforcing the advantages of epidural anesthesia in reducing overall anesthetic agent consumption^[7,34].

Casati, L., et al. (2002)^[36] in their study, sixty patients were randomly allotted into 6 groups to assess the requirement of intraoperative anesthetic (thiopental and isoflurane) by administering epidural bolus with 0.125% or 0.0625% along with fentanyl (2mcg/ml) before general anaesthesia induction posted for colon resection. The MAP and BIS were used as an index to maintain the depth of anaesthesia. It was concluded that there were significant reduction in the use of isoflurane by 35% similar results were observed in our study.

Our results were found to be matched with Matheson's study^[37] (1960), who reported significantly lower blood losses in patients who underwent lumbar laminectomies with epidural anesthesia. In another study conducted by Greenbarg et al.^[38] enrolled 80 patients who were scheduled for lumbar spine surgery administered epidural for one group and general anesthesia for another group, showed reduction in bleeding intraoperatively, less requirement of IV opioid use and decreased urinary retention with epidural anesthesia.

3. POSTOPERATIVE OBSERVATIONS:

In PACU and in the ward, for the first 24hours the patients enrolled in our study was followed up postoperatively to observe hemodynamic parameters such as SBP, DBP and MAP. Our study showed a significantly lower values in SBP & DBP upto the first 12 hours of postoperative period ($p < 0.05$) in Group B, suggesting that epidural anesthesia primarily provides hemodynamic benefits in the immediate postoperative

period. By 24 hours, there was in-significant variation among the two groups ($p = 0.128$ & $p = 0.271$: SBP & DBP respectively).

In our study, observed pain profile in the patients enrolled revealed that the VAS Score were significantly lower with the Group B than in the Group A for the first 24 hours post surgery. This is in accordance with Sale et al. (2016)^[39] whose finding concluded significantly reduced VAS score in CEG group than Group A especially upto first 6 hours of postoperative period.

The post-operative analgesic requirement in Group B was much delayed than in the Group A. The mean of the duration at which the analgesics were administered in both the groups were: Group A – 1 hour and Group B – 7.50 ± 1.270 hours in the postoperative period. This is attributed to the fentanyl additive administered in the epidural which in a similar study by Cherng et al. (2005)^[40] disclosed that fentanyl with ropivacaine in epidural route fastens the onset of action for both sensory and motor block.

The reduced postoperative analgesic requirement is attributed to various mechanisms. One of them is the blocking effect of epidural fentanyl on the sensitization of the afferent nociceptive pathway which leads to reduction in the pain scores^[41].

One of the important aspect of regional anesthesia is that it provides good postoperative analgesia associated with lesser incidence of PONV. This goes in hand with the some of the previous studies such as Jellish et al. (1996)^[30] and Demish et al. (2003)^[24].

LIMITATIONS:

The major drawbacks of our study are as follows:

- Limited sample size which reduces the statistical significance.
- Our study was restricted only to patients who are under ASA grade I or II
- The administration of epidural was difficult in obese patients and patients who had calcified spine.
- Accidental injury to ligamentum flavum during lumbar spine surgery can lead to complications that may affect the efficacy of epidurally administered drugs. Thus affecting the outcome of our study.

CONCLUSION

The combined epidural and general anesthesia provides superior intraoperative hemodynamic stability, lessens the blood loss which provides dry surgical field, reduces the anesthetic drug requirements and enhances the overall patients' safety during elective lumbar spine surgeries. Hence CEG technique proves to be an optimal plan of anesthesia for lumbar spine surgeries as it gives better satisfaction to the surgeon as well as the patient. Further studies with larger sample sizes and long-term postoperative outcomes can help reinforce these findings and guide future anesthetic protocols.

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SAMPLE INFORMED CONSENT FORM

B.L.D.E.(DU) SHRI B.M.PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTER,
VIJAYAPURA - 586103, KARNATAKA

TITLE OF THE PROJECT:

COMPARING THE EFFECT AND OUTCOMES BETWEEN GENERAL ANAESTHESIA Vs
COMBINED EPIDURAL AND GENERAL ANAESTHESIA IN ELECTIVE LUMBAR SPINE
SURGERY: A RANDOMIZED CONTROL STUDY.

PRINCIPAL INVESTIGATOR: Dr. PRIYADHARSHINI.V
Department of Anaesthesiology
BLDE (DU) Shri B M Patil Medical College &
Research Center, Sholapur Road Vijayapura-03
Email: priz1694@gmail.com

PG GUIDE: Dr. VIJAYKUMAR. T.K.
M.D., DA
Professor
Dept. of Anaesthesiology
BLDE (DU) Shri B M Patil Medical College &
Research Centre, Sholapur Road Vijayapura – 03.

PG CO-GUIDE: Dr. BASAVARAJ. T. BADADAL
M.B.B.S., M.S., M.Ch. (NEUROSURGERY)
Associate Professor
Dept. of General Surgery
BLDE (DU) Shri B M Patil Medical College &
Research Centre, Sholapur Road Vijayapura – 03.

PURPOSE OF THE STUDY:

I have been notified that this study is to compare the effects and outcomes between General anaesthesia and combined Epidural and General anaesthesia in elective Lumbar spine surgeries. I have been explained the reason for doing this study and 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: A prospective randomized study of comparison of the effects and outcomes between General anaesthesia and combined Epidural and General anaesthesia in elective Lumbar spine surgeries.

RISKS AND DISCOMFORTS:

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

BENEFITS:

I understand that my ward participating in this study will help in finding a prospective randomized study comparing the effects and outcomes between General anaesthesia and combined Epidural and General anaesthesia in elective Lumbar spine surgeries.

CONFIDENTIALITY:

I understand that this study's medical information will become a part of this hospital record and will be subjected to the confidentiality and privacy regulation of this hospital.

Suppose the data are used for publication in the medical literature or teaching purposes. In that case, no names will be used, and other identities such as photographs and audio and videotapes will be used only with my special written permission. I understand that I may see the picture and videotapes and hear audiotapes before giving consent.

REQUEST FOR MORE INFORMATION:

I understand that I may ask as many questions as possible about the study at any point in time. Dr. PRIYADHARSHINI.V is available to answer my questions or concerns. I know that I will be notified of any significantly novel findings revealed during the period of this study, which may influence my continued participation.

If during this study, or at a later period, I wish to discuss my involvement in or concerns regarding this study with a third party not directly involved, I am aware that the social worker of the hospital has been made available for me to talk to. And that a copy of this consent form will be given to me to keep for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my engagement in this clinical study is on a voluntary basis, and I may refuse participation or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or genuine care at this hospital.

I also understand Dr. PRIYADHARSHINI.V will terminate my participation in this study at any time after she 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 events of injury to me/my ward resulting directly due to my participation in this study, such harm will be reported promptly. Medical treatment would be available to me, but no further compensation will be available.

I understand that by me agreeing to participate in this study, I am not waiving my legal rights. I have explained in detail to _____ the purpose of this research, the procedures which are required and the possible risk and benefits, to the best of my ability in patients own language

DATE

(investigator)

Dr. PRIYADHARSHINI.V

PATIENT/PARENT SIGNATURE

Witness

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. PRIYADHARSHINI.V has explained the purpose of this research, the study procedure that I will undergo, and the possible discomforts and benefits that I may experience in my language.

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

(Participant)

(Date)

(Witness to above signature)

(Date)

SCHEME OF CASE TAKING (PROFORMA)

PATIENT DETAILS:

NAME	
AGE	
SEX	
HEIGHT	
WEIGHT	
WARD	
DIAGNOSIS	
PROCEDURE	
PAST HISTORY	

GENERAL PHYSICAL EXAMINATION:

PALLOR	ICTERUS	CYANOSIS	CLUBBING	EDEMA	LYMPHADENOPATHY

VITALS PARAMETERS:

PULSE	BLOOD PRESSURE	RESPIRATORY RATE	TEMPERATURE

SYSTEMIC EXAMINATION:

CVS :

RS :

P/A:

CNS :

AIRWAY ASSESSMENT:

Mallampatti Grade : **Spine:**

Mouth Opening :

ASA Grade : **Neck Movements:**

INVESTIGATIONS:

Hemoglobin	HIV
PCV	HbsAg
TC	HCV
Platelet Count	CXR
RBS	ECG
Sr. Creatinine	INR
Sr. Urea	
BT - CT-	

GROUP: A / B						
INTRAOPERATIVE PARAMETERS	Heart Rate (bpm)	Blood Pressure (mmHg)	Mean Arterial Pressure (mmHg)	SpO2 %	BIS	Isoflurane %
Time						
5 mins						
10 mins						
15 mins						
20 mins						
25 mins						
30 mins						
45 mins						
60 mins						
75 mins						
90 mins						
105 mins						
120 mins						

Total Amount of Blood loss:

POSTOPERATIVE PARAMETERS				
Time	Pulse Rate	Blood Pressure	Mean Arterial pressure	VAS Score
2nd hour				
6th hour				
12th hour				
24th hour				

Time of administration of first rescue analgesic:

Postoperative complications (if any):

BIO-DATA

CURRICULUM VITAE OF GUIDE:

Guide Name : Dr. Vijaykumar T Kalyanappagol

Date of Birth : 08/09/1964

Education : M.B.B.S. from M R Medical College Kalaburgi.
M D from Shri B.M. Patil Medical college, Vijayapura.
D A from J.N. Medical College Belgaum

Designation : Professor in Anesthesiology

Teaching : Total work experience 30 years
P.G. teaching for 22years
P.G. guide 13 years

Address : Plot No.43, Basaveshwar Nagar, Opposite BLDE Hospital,
Ashram Road, Vijayapura.

CURRICULUM VITAE OF CO-GUIDE

Co-Guide Name: Dr. Basavaraj. T. Badadal

Date of Birth: 14/02/1982

Education: M.B.B.S from BLDE (DU) Shri B M Patil Medical College
M.S. (General Surgery) from Coimbatore Medical College,
Coimbatore, The Tamil Nadu DR MGR Medical University,
Chennai, Tamil Nadu.
M.Ch. (Neurosurgery) from Nizam Institute of Medical
Sciences, Hyderabad

Designation: Associate Professor in Dept. of General Surgery

INVESTIGATOR'S BIODATA:

Name : Dr. Priyadharshini.V

Qualification : M.B.B.S. from Chengalpattu Medical College,
Chengalpattu,
The Tamil Nadu Dr MGR Medical College, Chennai,
Tamil Nadu

KMC Registration No.: 157550

Address : Department of Anaesthesiology
B.L.D.E. (Deemed to be University),
Shri B. M. Patil Medical College Hospital & Research center,
Vijayapura – 586103, Karnataka.

Contact No.: 9092149947

Email ID : priz1694@gmail.com

ETHICAL CLEARANCE



BLDE

(DEEMED TO BE UNIVERSITY)

Declared as Deemed to be University u/s 3 of UGC Act, 1956

Accredited with 'A' Grade by NAAC (Cycle-2)

The Constituent College

SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

BLDE (DU)/IEC/ 947/2023-24

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: "COMPARING THE EFFECT AND OUTCOMES BETWEEN GENERAL ANAESTHESIA Vs COMBINED EPIDURAL AND GENERAL ANAESTHESIA IN ELECTIVE LUMBAR SPINE SURGERY: A RANDOMISED CONTROL STUDY".

NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR: DR.PRIYADHARSHINI V.

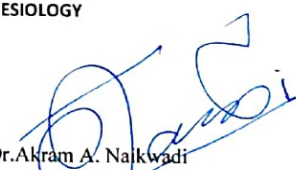
NAME OF THE GUIDE: DR.VIJAYKUMAR T.K., PROFESSOR, DEPT. OF ANAESTHESIOLOGY

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

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

Following documents were placed before Ethical Committee for Scrutinization.

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


Dr. Akram A. Nalkwadi
Member Secretary
IEC, BLDE (DU),
VIJAYAPURA
MEMBER SECRETARY
Institutional Ethics Committee
BLDE (Deemed to be University)
Vijayapura-586103, Karnataka

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

BLDE (DU): Phone: +918352-262770, Fax: +918352-263303, Website: www.bldeedu.ac.in, E-mail: office@bldeedu.ac.in
College: Phone: +918352-262770, Fax: +918352-263019, E-mail: bmpmc.principal@bldeedu.ac.in

Scanned with CamScanner

MASTER CHART – GROUP A

S.No.		NAME		AGE (yrs)		SEX (M/F)		HEIGHT (cms)		WEIGHT (kgs)		ASA GRADE		INTRAOPERATIVE PARAMETERS																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														
														HEART RATE (bpm)																SYSTOLIC BLOOD PRESSURE (mmHg)																DIASTOLIC BLOOD PRESSURE (mmHg)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																														
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GENERAL ANAESTHESIA GROUP - A group																																																										
S.No.	MEAN ARTERIAL PRESSURE (mmHg)												BISPECTRAL INDEX												ISOFLURANE												INTRAOPERATIVE PARAMETERS						amount of blood loss															
	5mins	10mins	15mins	20mins	25mins	30mins	45mins	60mins	75mins	90mins	105mins	120min	5mins	10mins	15mins	20mins	25mins	30mins	45mins	60mins	75mins	90mins	105min	120min	5mins	10mins	15mins	20mins	25mins	30mins	45mins	60mins	75mins	90mins	105min	120min																						
1	102	100	98	94	92	82	82	86	89	108	104	100	-	57	55	52	53	52	52	55	52	55	57	59	-	1	1	0.8	0.6	0.6	0.6	0.8	0.6	1	1	1	0.8	500																				
2	100	100	98	94	82	82	84	84	88	106	100	96	-	58	55	55	54	54	50	49	49	50	54	56	-	1.2	1	1	0.8	0.8	0.8	1	0.8	1	1	1	1.2	350																				
3	92	98	96	86	82	82	84	100	98	106	96	102	-	58	60	59	55	54	50	52	52	54	55	56	-	1	15	1	0.8	0.6	0.8	1	1	1	1	0.8	600																					
4	83	89	68	72	74	82	88	62	87	84	81	84	-	59	48	46	50	55	60	48	55	56	58	-	1	0.2	0	0.2	0.8	1	0	0.6	0.4	0.4	500																							
5	83	108	83	84	84	84	84	93	96	107	102	84	-	58	56	56	52	52	49	48	50	53	56	-	1	0.6	1	0.8	0.8	0.8	0.8	1	1	1	0.8	600																						
6	107	100	107	96	91	86	83	81	97	87	89	98	-	58	55	52	50	48	50	50	55	56	58	60	-	1.2	1	1	1	1	1	0.8	1.2	0.8	0.6	0.4	200																					
7	87	92	94	95	96	93	90	83	81	92	97	93	-	58	54	54	55	54	52	50	48	52	55	59	-	0.4	0.4	0.6	0.6	0.6	0.6	0.4	0.6	0.6	0.2	300																						
8	103	87	83	83	88	94	89	95	103	100	105	100	-	55	50	48	49	50	52	52	56	55	58	56	-	1	0.6	0.8	1	0.8	0.8	0.8	1	1	1	1	1	400																				
9	101	103	94	92	83	83	83	98	93	83	87	81	83	-	58	55	55	48	52	56	52	50	50	52	56	-	1	0.8	0.8	0.4	0.6	1.2	1	1	1	1	0.6	200																				
10	96	102	97	93	91	92	93	86	83	72	85	90	-	61	58	57	56	55	55	54	54	53	56	58	-	1	1	1	1	1	1	0.6	0.6	0.4	0.2	0.2	150																					
11	87	84	88	84	86	80	88	86	80	83	79	93	-	57	55	48	47	50	50	52	54	58	59	-	0.4	0.4	0.4	0.4	0.4	0.4	1	1	1	1	1	0.6	300																					
12	95	113	97	80	88	90	93	126	104	106	92	98	-	60	58	49	50	50	52	58	54	52	55	58	-	1.2	0.6	0.6	0.6	0.6	0.6	1.5	1	1	0.8	0.8	450																					
13	97	107	104	95	91	81	89	97	100	97	100	91	81	-	59	58	54	52	52	53	55	58	59	60	-	1.2	1	1	1	0.8	0.8	0.8	1	1	1	1	1	1	1	400																		
14	103	84	79	79	80	82	72	93	90	87	98	85	-	56	55	48	46	54	54	55	56	55	56	55	-	1	1	0.8	0.8	0.6	0.6	0.6	0.6	1	1	1	1	1	500																			
15	95	100	85	80	83	85	76	80	75	72	83	110	-	56	55	52	50	48	48	50	52	55	56	58	-	1	1.2	0.8	0.6	0.6	0.6	0.4	0.4	0.4	1	1	1	1	400																			
16	104	114	107	101	92	91	83	79	97	102	90	91	-	61	56	54	52	52	52	54	56	58	59	59	-	1	1	1	1	0.8	0.6	0.4	0.4	1	1	0.6	0.4	350																				
17	85	153	94	85	82	76	79	77	71	66	76	83	-	60	59	56	55	52	54	50	48	46	50	55	-	1.5	15	1	0.8	0.8	0.8	0.8	0.6	0.2	0.2	0.2	550																					
18	99	105	76	85	75	78	93	105	109	98	81	93	-	56	50	55	52	50	52	55	58	56	55	59	-	0.8	0.6	0.6	0.6	0.6	0.4	0.4	0.4	0.6	0.6	0.6	0.6	0.4	400																			
19	87	99	96	94	101	97	97	111	116	110	107	99	-	58	55	55	56	57	55	58	60	59	58	56	-	1	0.8	0.8	1	0.8	0.8	1	1	1	1	1	0.8	400																				
20	93	80	90	94	88	82	79	82	85	88	95	112	-	58	56	55	58	55	58	50	50	53	55	58	-	1	0.8	0.8	1	1	0.8	0.8	0.8	0.6	0.8	0.8	1.5	450																				
21	83	103	89	85	95	96	97	96	99	104	103	100	96	-	58	55	55	52	53	52	50	54	56	59	59	-	1	0.6	1	0.6	0.8	0.8	0.8	0.8	0.8	1	1	1	1	400																		
22	82	92	99	93	89	83	85	75	70	91	98	86	-	60	58	54	52	50	50	48	46	52	54	56	-	1.2	1	1	0.8	0.8	0.6	0.4	0.2	0.8	1	1	0.2	400																				
23	83	88	87	99	87	97	97	97	87	91	94	91	86	-	58	56	56	55	52	55	54	56	56	57	58	-	1	0.8	0.8	0.6	0.6	0.6	0.6	1	1	1	1	0.8	400																			
24	100	121	112	116	96	90	88	84	73	70	66	62	-	59	55	55	54	52	50	50	46	48	50	55	-	1	1	1.5	0.8	0.6	0.6	0.4	0.6	0.4	0.2	0.2	0.2	500																				
25	83	100	80	78	70	77	83	78	85	86	77	93	-	59	55	54	52	50	50	50	52	50	50	55	-	1	1	0.8	0.6	0.6	0.6	0.6	0.6	0.8	1	1	1	1	400																			
26	82	99	79	75	73	89	97	85	85	84	79	87	-	58	55	50	48	52	54	50	56	55	55	56	-	1	0.4	0	0.4	1	1	0.4	0.6	0.4	0.4	0.4	0.4	300																				
27	103	99	120	97	87	82	75	78	73	67	65	74	-	59	58	57	52	52	50	50	48	47	50	54	-	1	1.5	1.5	1	1	0.8	0.6	0.4	0.4	0.2	0.2	400																					
28	83	92	83	85	81	81	83	82	89	88	101	83	-	54	53	58	50	52	54	54	54	55	55	55	-	1	1	1.2	0.8	0.8	0.8	1	1	1.2	1.5	1	1	300																				
29	99	103	96	93	91	91	95	86	81	82	87	93	-	58	57	55	54	52	50	49	49	50	56	-	1	1	1	1	1	0.6	0.6	0.6	0.4	0.4	0.2	0.2	400																					
30	97	102	73	73	73	91	96	65	86	85	81	83	95	-	59	55	52	52	54	50	48	47	50	52	55	-	1.5	0.2	0.2	0.8	1	0.4	0.6	0.6	0.4	0.4	0.2	300																				
31	97	112	100	89	79	79	98	100	91	98	97	92	-	58	55	52	50	48	48	50	52	54	55	56	-	1.2	1.2	1	0.8	0.8	1	1	1	1	1	0.8	0.4	400																				
32	103	106	94	90	85	98	88	83	77	74	90	72	-	58	55	52	50	48	47	48	50	52	55	58	-	1.5	1	1	1	0.8	1	1	0.8	0.4	0.4	0.2	300																					

MASTER CHART – GROUP A (cont.)

POSTOPERATIVE PARAMETERS																				
PULSE RATE (bpm)				STOLIC BLOOD PRESSURE (mmHg)				STOLIC BLOOD PRESSURE (mmHg)				MEAN ARTERIAL PRESSURE (mmHg)				VAS score				1st
2nd hr	6th hr	12th hr	24th hr	2nd hr	6th hr	12th hr	24th hr	2nd hr	6th hr	12th hr	24th hr	2nd hr	6th hr	12th hr	24th hr	2nd hr	6th hr	12th hr	24th hr	RESCUE ANALGE
82	74	72	76	130	114	122	130	80	72	84	84	90	84	82	86	7	5	4	4	1
84	72	70	74	132	124	122	130	84	70	84	80	92	82	80	84	6	5	3	3	1
82	78	72	70	138	128	130	122	90	78	82	86	100	88	84	82	7	6	4	3	1
82	72	80	84	130	124	116	132	82	72	80	84	90	80	76	84	7	5	4	4	1
82	90	76	72	130	140	120	120	80	80	70	80	97	100	87	93	7	5	3	3	1
102	86	74	72	140	130	120	120	90	80	80	70	107	97	93	87	7	6	4	3	1
80	78	72	74	110	120	120	110	70	70	70	70	83	87	87	83	6	4	3	2	1
82	78	72	74	120	110	120	110	70	70	80	70	87	83	93	83	6	5	3	2	1
88	72	86	76	130	120	130	110	80	70	80	70	97	87	97	83	7	5	3	3	1
90	82	78	72	130	120	110	110	80	70	70	70	97	87	83	83	7	6	4	3	1
92	84	82	80	130	120	130	134	80	80	80	82	97	93	97	99	6	5	3	2	1
98	102	90	88	142	130	120	140	84	80	80	80	103	97	93	100	6	6	4	3	1
104	82	80	72	136	127	130	130	82	84	80	84	100	98	97	98	6	4	3	2	1
88	90	86	82	136	128	120	120	88	78	70	70	104	95	87	87	5	4	3	2	1
118	92	90	82	140	130	130	130	90	90	80	80	107	103	97	97	6	5	3	2	1
82	80	78	72	120	118	110	110	80	78	70	70	93	91	83	83	6	4	3	3	1
92	90	88	82	132	130	128	120	77	80	78	70	95	97	95	87	6	5	3	3	1
72	80	82	88	124	115	132	130	98	80	89	80	107	92	103	97	5	4	3	3	1
96	76	82	78	124	116	132	120	94	84	86	80	104	97	101	93	6	4	3	3	1
88	76	82	80	130	110	120	120	80	75	70	80	97	87	87	93	7	5	3	3	1
102	94	98	82	133	120	114	120	87	86	72	70	102	97	86	87	7	5	4	3	1
94	84	72	74	140	120	110	110	82	80	70	70	101	93	83	83	6	5	3	3	1
92	74	82	80	130	112	110	120	80	68	70	70	97	83	83	87	7	5	4	3	1
98	84	72	70	130	120	110	110	80	80	70	70	97	93	83	83	7	5	3	3	1
92	88	82	76	130	120	110	110	80	80	70	70	97	93	83	83	7	6	4	3	1
92	82	78	80	120	130	110	120	80	80	70	80	93	97	83	93	7	5	4	3	1
88	82	78	80	138	120	110	110	88	80	70	70	105	93	83	83	7	6	4	3	1
84	70	72	72	130	120	110	110	90	70	70	70	103	87	83	83	7	5	3	3	1
88	72	80	82	120	120	130	130	80	70	80	80	93	87	97	97	7	6	4	3	1
82	102	90	82	132	124	116	120	88	72	82	80	103	89	93	93	7	4	3	3	1
82	72	74	72	130	120	120	120	90	80	70	70	103	93	87	87	7	5	3	2	1
100	78	72	80	140	130	130	120	107	97	97	87	107	97	97	87	7	5	3	2	1

[illegible]

MASTER CHART – GROUP B (contn.)

Total amount of blood loss (ml)	POSTOPERATIVE PARAMETERS																				
	PULSE RATE (bpm)				SYSTOLIC BLOOD PRESSURE (mmHg)				DIASTOLIC BLOOD PRESSURE (mmHg)				MEAN ARTERIAL PRESSURE (mmHg)				VAS score				1st RESCUE
	2nd hr	6th hr	12th hr	24th hr	2nd hr	6th hr	12th hr	24th hr	2nd hr	6th hr	12th hr	24th hr	2nd hr	6th hr	12th hr	24th hr	2nd hr	6th hr	12th hr	24th hr	ANALGESIA
200	74	80	82	74	110	100	120	110	70	70	70	70	83	80	87	83	5	4	2	2	8
100	72	74	68	70	110	110	100	110	70	70	70	70	83	83	80	83	4	3	2	2	8
100	72	64	78	82	120	110	110	128	70	82	74	88	84	88	76	82	5	4	3	2	6
150	76	80	82	74	110	100	120	110	70	70	70	70	83	80	87	83	6	4	2	2	8
100	72	74	68	70	110	110	100	110	70	70	70	70	83	83	80	83	4	3	2	2	8
150	78	82	90	84	110	120	120	110	70	70	80	70	83	87	93	83	4	3	3	2	7
100	86	74	92	72	104	110	120	110	66	70	80	70	79	83	93	83	4	3	2	2	6
150	82	76	84	90	130	120	110	110	80	70	70	70	97	87	83	83	5	4	3	2	6
120	86	82	78	90	110	120	100	130	70	70	70	80	83	87	80	97	5	4	3	3	8
100	72	66	62	64	110	100	100	110	70	60	60	60	83	73	73	77	5	4	2	2	8
150	80	78	72	72	120	110	110	120	80	70	70	70	93	83	83	87	6	4	2	2	8
100	78	82	80	72	130	110	110	120	80	70	70	80	97	83	83	93	5	4	3	2	7
200	78	80	82	72	110	120	110	110	80	70	70	70	90	87	83	83	5	4	3	2	8
140	82	78	76	72	120	110	120	118	70	70	76	72	87	83	91	87	3	4	2	2	9
150	82	80	78	80	110	120	120	130	70	70	80	80	83	87	93	97	3	4	2	2	8
160	70	76	72	80	110	120	110	110	70	70	70	74	83	87	83	83	4	5	3	2	8
100	88	82	78	80	110	108	114	124	70	68	72	70	83	81	86	88	4	5	3	2	8
150	68	72	78	82	113	120	114	110	68	70	66	70	87	87	92	83	5	6	4	3	6
120	72	84	70	74	118	126	108	112	72	78	70	80	87	94	83	91	5	6	4	3	6
100	68	74	80	78	116	120	110	130	72	74	74	80	87	89	86	97	4	5	2	2	8
150	78	72	80	82	124	110	110	120	72	70	70	70	89	83	83	87	4	5	3	2	5
100	72	70	82	86	114	120	130	128	76	74	80	72	89	89	97	91	4	5	3	2	8
150	72	66	62	64	110	100	120	110	70	60	70	70	83	73	87	83	4	3	2	2	7
100	78	82	80	78	110	120	120	120	60	70	80	80	77	87	93	93	4	5	3	2	10
200	80	76	90	88	120	120	130	120	80	70	80	80	93	87	97	93	4	4	3	2	7
100	82	72	76	70	104	110	124	120	70	72	70	70	81	85	88	87	3	5	3	2	8

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