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**“COMPARISON OF LEVOBUPIVACAINE 0.25%  
AND ROPIVACAINE 0.25% FOR CAUDAL  
EPIDURAL ANAESTHESIA IN CHILDREN  
UNDERGOING INFRAUMBILICAL SURGERY”-  
A RANDOMISED CLINICAL TRIAL.”**

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**J. N. MEDICAL COLLEGE**

**BELAGAVI - 590010. KARNATAKA**

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**SEPTEMBER/OCTOBER 2025**

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With reference to the above, we wish to inform you that your proposed research project titled "COMPARISON OF LEVOBUPIVACAINE 0.25% AND ROPIVACAINE 0.25% FOR CAUDAL EPIDURAL ANAESTHESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERIES – RANDOMISED CLINICAL TRIAL", is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

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## LIST OF ABBREVIATIONS

ASA - American Society of Anaesthesiology.

mg - milligram.

Kg - kilogram.

BW - Body weight.

% - Percent/percentage.

NIBP – Non-invasive blood pressure.

ECG – Electrocardiogram.

Spo<sub>2</sub> – Oxygen saturation.

MAC – Minimum Alveolar Concentration

CSF – Cerebro spinal fluid.

O<sub>2</sub> – Oxygen.

N<sub>2</sub>O – Nitrous Oxide.

SBP – Systolic Blood Pressure.

DBP – Diastolic Blood pressure.

& - And

SD – Standard Deviation.

bpm – Beats per minute.

HR – Heart rate.

mmHg – millimeters of Mercury.

Yr – Years.

Inj. – Injection.

ml – milliliter.

mm – millimeter.

## ABSTRACT

**TITLE:** COMPARISON OF LEVOBUPIVACAINE 0.25% AND ROPIVACAINE 0.25% FOR CAUDAL EPIDURAL ANAESTHESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERIES -A RANDOMISED CLINICAL TRIAL.

**BACKGROUND AND AIMS:** Anaesthesia for paediatric patients is highly specialised because of the physiological, pharmacological, and psychological differences between children and adults. Regional anaesthesia techniques have become routine interventions in children and infants. Paediatric regional anaesthesia is an excellent technique for balanced intraoperative and postoperative analgesia.

Caudal epidural anaesthesia is a widely used regional anaesthesia technique that involves the administration of local anaesthetics into the caudal epidural space through the sacral hiatus. Caudal epidural anaesthesia is commonly practiced in paediatric anaesthesia and also done in adults for various surgical procedures, it also provides analgesia both intraoperatively and postoperatively for surgeries involving the lower abdomen, pelvis, perineum, lower limbs and reduces the usage of systemic opioids, minimises their side effects, such as respiratory depression, nausea, and vomiting. The aim of the study is to evaluate the efficacy and duration of analgesia of 0.25% Levobupivacaine and 0.25% Ropivacaine in paediatric patients undergoing infraumbilical surgeries under caudal epidural anaesthesia.

**STUDY DESIGN:** A RANDOMISED CLINICAL TRIAL.

**MATERIALS AND METHODS:** A total of 92 patients of either sex, ASA Grade 1,2 posted for elective infraumbilical surgeries were enrolled in the study and randomized in to two groups. Group L patients received 0.25% of levobupivacaine 1ml/kg and

Group R patients received 0.25% ropivacaine 1ml/kg. Caudal effectiveness score was assessed intraoperatively. Post operatively up to 2hrs Modified Hannallah pain score was used to assess the duration of analgesia and if any rescue analgesia used also recorded.

**RESULTS:** Levobupivacaine 0.25% provides prolonged duration of analgesia and compared to Ropivacaine 0.25% and efficacy is almost similar to ropivacaine for caudal epidural anaesthesia in paediatric patients underwent infraumbilical surgeries.

**CONCLUSION:** Both Levobupivacaine and Ropivacaine demonstrated similar effects on hemodynamic stability, respiratory function, and behavioural responses indicating a possible advantage in postoperative comfort. However, with comparison to Ropivacaine, Levobupivacaine provides a significant longer duration of analgesia, making it a more effective option for prolonged pain control.

**KEY WORDS:** Caudal epidural anaesthesia, Levobupivacaine, Ropivacaine, Infraumbilical surgeries, Postoperative analgesia.

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## **INTRODUCTION**

Paediatric anaesthesia requires a specialized approach due to the distinct psychological, physiological, and pharmacological differences between children and adults. In paediatric patients regional anaesthesia methods have become a standard practice, offering an effective method for both intraoperative and postoperative pain management. These techniques play a crucial role in achieving balanced analgesia while minimizing the need for systemic opioids.

One popular kind of regional anaesthesia is caudal epidural anaesthesia, which involves administering local anaesthetics through the sacral hiatus into the caudal epidural area. For many kinds of surgical procedures, caudal epidural anaesthesia is frequently used in both paediatric and adult anaesthesia. Additionally, it minimizes the use of systemic opioids and associated adverse effects, includes vomiting, respiratory depression, nausea, while providing analgesia both during and after surgery for surgeries involving the pelvis, lower abdomen, perineum, and lower limbs.

It is a useful adjuvant during general anaesthesia because it can lower the response of stress to surgery, reduce the requirement for intravenous & inhaled anaesthetics, promote a quick and simple recovery, and give sufficient postoperative pain relief instantaneously.

In 1901, caudal anaesthesia was first described by Jean-Anthanase Sicard, and Fernand Cathelin. Over time, it became a preferred technique, especially in paediatrics, due to its safety, ease of administration, and ability to provide effective pain relief.

Racemic Bupivacaine is a local anaesthetic drug extensively used by the caudal route especially in the children. However, early research indicates that Ropivacaine and Levobupivacaine may have a lower risk of systemic toxicity compared to other local anaesthetics, making them safer alternatives for regional anaesthesia.

Levobupivacaine is a levorotatory isomer of bupivacaine, which has a better safety margin for local anaesthetic systemic toxicity (LAST) and has been accepted for continuous infusion and for regional blocks which are in large volume. Different researches have assessed the effect of Levobupivacaine and in children for dosage up to 2.5 mg/kg/body weight; it was a more effective agent for caudal anaesthesia. It is known to have a rapid onset of surgical anaesthesia and is also found to be a stronger agent in post-operative analgesia in comparison with bupivacaine 0.25%.

Ropivacaine is a local anaesthetic that was recently approved for use and is less toxic to the heart and central nervous system and motor function interfaces was less than bupivacaine; these features of ropivacaine could be of great advantage in a paediatric population.

Research papers comparing the ropivacaine and levobupivacaine for caudal anaesthesia in paediatric patients were not found in the literature search.

Hence, we try to assess the effectiveness of 0.25% levobupivacaine and 0.25% ropivacaine in patients, particularly in paediatric age having caudal epidural anaesthesia for infra-umbilical procedures.

**AIMS AND OBJECTIVES**

This study primary objectives and aims are:

PRIMARY OBJECTIVE:

To assess the efficacy of 0.25 % ropivacaine and 0.25 % levobupivacaine in paediatric patients having caudal epidural anaesthesia for infraumbilical operations

SECONDARY OBJECTIVE:

To assess the,

1. Duration of postoperative analgesia.
2. Complications if any.

**REVIEW OF LITERATURE**

Caudal epidural anaesthesia is an extensively used regional anaesthesia method that involves the administration of local anaesthetics through the sacral hiatus into the caudal epidural area. 0.25% bupivacaine is commonly used for caudal epidural anaesthesia. However, much of the existing literature shows 0.25% bupivacaine is more effective for caudal anaesthesia but also has some toxic effects. So levobupivacaine and ropivacaine are relatively new local anaesthetic drugs to counter the issues of bupivacaine. Therefore, we aimed to address the effectiveness of ropivacaine and levobupivacaine for better analgesia and less toxicity to patients.

In this study, Sethi D examined the hundred parturient women who are undergoing an elective caesarean section and compared the characteristics of equal potential spinal anaesthetic drugs during spinal anaesthesia such as plain levobupivacaine of 0.5%, plain ropivacaine of 0.75% with hyperbaric bupivacaine of 0.5%. And this paper concludes that in elective caesarean deliveries where anaesthesia given through spinal block, the anaesthetic effect of the 10 mg or 15mg of the plain levobupivacaine and ropivacaine respective drugs gave comparable results with respect to the hyperbaric bupivacaine of 10 mg. [4]

In another study, a comparison was done by Khushboo Malav et al. between the two anaesthetic drugs such as ropivacaine and levobupivacaine on 100 patients who were undergone ankle surgeries for that sciatic nerve block was given & observed that prolonged duration of analgesia post operatively with the use of levobupivacaine of 0.5% rather than the ropivacaine of 0.5%. [5]

In this research, an analysis was carried out by Ajay Singh et al. between the anaesthetic drugs given during the inguinal hernia surgeries through spinal

anaesthesia. This clinical study shows significant results such as early mobilization in day care surgeries and less time of motor & sensory block while using levobupivacaine of 0.5% and also decreases the intra- operative hypotension incidence compared to the results which had been observed while hyperbaric racemic bupivacaine of 0.5% applied. [6]

In a comparative study which was conducted by Arpita Laha et al. on the children who are undergone infraumbilical surgeries through caudal analgesia with plain ropivacaine and a combination of ropivacaine with clonidine. And the researchers concluded that there was an improvement in the post operative analgesia with the combined doses of clonidine (2 mcg/kg) and ropivacaine of 0.2% rather than the plain ropivacaine of 0.2%. And observed that with the usage of mixed drug of ropivacaine clonidine shows significantly no change in post-operative sedation or motor block prolongation.[7]

In this study, the Neelam Dogra et al. conducted a trail on the paediatric patients who are undergoing inguinal hernia surgeries and applied caudal analgesia with a combination of tramadol, Levobupivacaine and each of them separately. They came to the conclusion that the combination of 0.125 percent levobupivacaine and 1.5 mg/kg tramadol provided a significant increased value than the independent supplements in the duration of postoperative analgesia. [8]

In this paper, Kopacz, Dan J.et al conducted a randomized trial on adults with age group of 18 to 80 years, for them anaesthesia was given through epidural while undergoing lower abdominal surgeries this trail was done to evaluate the extent, onset & duration of motor and sensory block with the two different drugs such as Levobupivacaine of 0.75% and racemic bupivacaine of 0.75%. However, the study results indicated that the equivalent score in the sensory and motor block, and

concluded that the both anaesthetics drugs were effective and tolerated in epidural anaesthesia. [9]

This research paper deals with the randomized study which was conducted by Pasquale DeNegri, M.D, Giorgio Ivani, M.D., et al on children with age group of 1 to 7 years who were undergone minor sub-umbilical surgeries and received the caudal anaesthesia with a three local anaesthetic drugs, and this study was intended to understand the difference in the motor block and post-operative analgesia. The different drugs such as 0.2% ropivacaine, 0.25% racemic bupivacaine and Levobupivacaine of 0.25% were used. During the first 24 hours post-operative analgesia was monitored by OPS score, if the score was 5, support dose of 10 to 15 mg/kg was administrated with paracetamol as part of rescue analgesia. This study concluded that there was a low occurrence of motor block for ropivacaine compared with the racemic bupivacaine during early post-operative period and observed a similar post-operative analgesia with the three anaesthetic drugs. [10]

In this study, the trail was conducted by Praveen P., Ramadevi R., and Pratheeba N on the children with the age of 1 to 10 years who were undergoing infra-umbilical surgeries, the patients received the anaesthesia through caudal block with levopubivacaine and ropivacaine of 0.25% each. With the motor power scale, motor blockade was assessed and with the help of modified Hannallah objective pain scale, pain was assessed regularly. If the score was greater than equal to 4, then as a rescue analgesia paracetamol suppositories 20 mg/kg were given. The results showed both analgesia post operatively and motor block incidence were comparable in both groups. [11]

A randomized study was conducted by P. Gautier et al. on caesarean sections patients while the anaesthesia through intrathecal and spinal epidural. The anaesthetic drugs

applied were ropivacaine of 12 mg, Levobupivacaine and bupivacaine of 8 mg respectively and all are combined with a 2.5 mg of sufentanil. Based on study results they concluded that when caesarean section was performed with combined mixture of bupivacaine and sufentanil, it was an adequate choice for spinal anaesthesia. And compared to the Levobupivacaine a higher success rate, prolonged motor block and analgesia duration were observed in bupivacaine. [12]

In this study, a two-stage trial was conducted by Ingelmo et al. on paediatric patients to compare the drug dosage response curves of ropivacaine and Levobupivacaine, applied through caudal. In the primary stage, 80 boys were received a random anaesthetic drug either of the two drugs. While in the 2nd phase, another thirty-two subjects were added to monitor the range of upper dosage response. This study indicated a similar efficacy in paediatric anaesthesia and no significant difference were observed between ropivacaine and Levobupivacaine. [13]

A study was done by A. Gentili, L. Pasini, et al on the young patients with an age group of 4 to 5 years, where they received the anaesthesia through caudal for sub-umbilical surgeries. This study showed the safety & effectiveness of the ropivacaine and levobupivacaine. However, the different cardiovascular performance profiles were observed. To avoid the high haemodynamic risk in children the findings of cardio circulatory of the both drugs should be re-considered before regional anaesthesia.[14]

In this study by Shashi Kumar Gupta, Vijay Kumar Nagpal, and Seema B paediatric patients with age of two to six years who were undergoing sub umbilical surgeries under general anaesthesia electively were observed. Based on the anaesthesia drug received through caudal are divided into two groups such as ropivacaine and levobupivacaine. Based on the results the researchers concluded that there was longer

duration of action with 0.25% of ropivacaine compared to Levobupivacaine of 0.25% and both the drugs showed similar results in terms of side effect profiles and post-operative analgesia. [15]

A randomized study was conducted by K. Chandran, R. Selvakumar, Sendhil Kumar Mohan, M. Suresh, and on children with age group of 3 to 8 years who are undergoing sub-umbilical surgeries following induction with general anaesthesia, patients received the random anaesthesia drug before surgery caudally with 0.25% bupivacaine or ropivacaine of 0.25%. This study concentrated on the comparison of duration of analgesia and sensory and motor block and quality in children. This study concluded that both the drugs provided similar observations in terms of analgesia duration and sensory recovery, and there was a less motor blockade with ropivacaine than bupivacaine and less intrinsic toxicity was observed in ropivacaine. The results were observed with Hannallah pain scale and motor power score. [16]

A randomized study was conducted by Ruchi Gupta, Jasveer Singh, Jagdeep Sharma, Anita Kumari, Lakshmi Mahajan, on the children up to 10 years of age who are undergoing infra-umbilical surgeries to observe the complications and efficacy of the three different drugs which are applied with same dosage of 0.25% ropivacaine, bupivacaine, and levobupivacaine through caudal block. A Hannallah pain score which was modified was used to evaluate the post-operative pain relief and caudal block effectiveness was evaluated by using caudal effectiveness score. This study results concluded that these three drugs were safe and effective in terms of stable intra-operative quality, haemodynamic profile and no significant complications were noted in the patients. [17]

## **BASIC SCIENCES**

### **Applied anatomy of caudal block [19-24]**

Caudal block is a type of neuraxial regional anaesthesia performed by injecting local anaesthetics into the caudal epidural space, which is the sacral extension of the epidural space, commonly used in paediatric anaesthesia and in some adults for pain management procedures.

As an anaesthesiologist should have an accurate and deep knowledge of the anatomy of sacrum and caudal space for safe and successful administration of caudal epidural anaesthesia in terms of spread of drug in caudal epidural space and level of block achieved.

The caudal anatomy involves the sacral region, including the caudal epidural space, sacral hiatus, and surrounding structures.

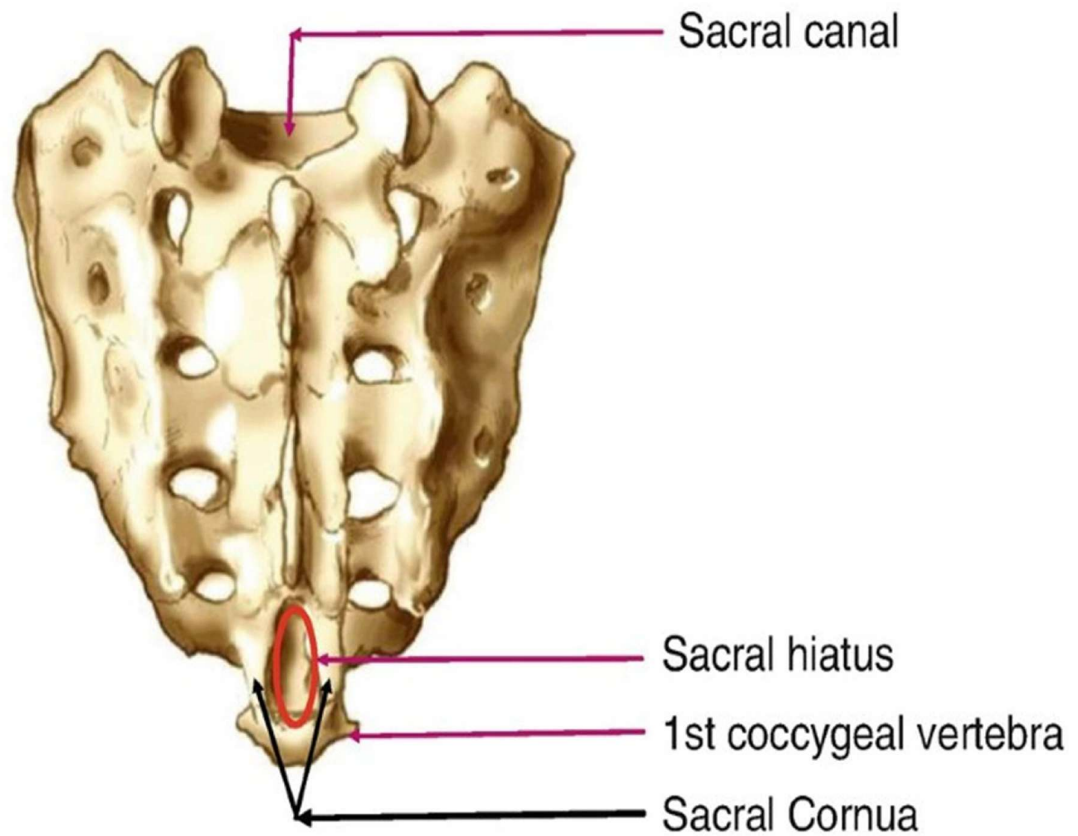
### **Embryology of the Sacrum**

- The sacrum forms from the fusion of five sacral vertebrae (S1–S5) by adulthood.
- The coccyx develops from four rudimentary coccygeal vertebrae, which may remain separate or partially fuse.
- The sacral canal is the continuation of the vertebral canal and contains sacral nerve roots, the filum terminale, and the epidural venous plexus.
- The sacral hiatus forms due to the failure of the S4 and S5 vertebral laminae to fuse, leaving an opening in the posterior sacrum.

## **Bony Landmarks**

- Sacral Hiatus:
  - Formed due to the incomplete fusion of the laminae of the S5 (and sometimes S4) vertebra.
  - Found at the lower end of the sacrum.
  - Bordered by the sacral cornua (bony prominences on either side of the hiatus).
  - Covered by the sacrococcygeal ligament (an extension of the ligamentum flavum).
- Sacral Cornua:
  - Located on both sides of the sacral hiatus.
  - Important for identifying the correct needle insertion point.
- Coccyx:
  - Located inferior to the sacral hiatus.
  - Provides a reference point for needle placement.

The spinal canal in neonates extends as far as L3 and reaches L1 position at one year of age. It is necessary to administer lumbar epidural or spinal anaesthetics at or below L3-L4 to reduce the incidence of spinal cord damage. The spinal canal in neonates extends as far as S3-S4 but usually regresses to the adult level of S1-S2 by one year of age.



The sacrum is a triangular shaped bone which is formed by the fusion of five vertebral segments. The anterior surface is smooth while posterior is rough. It articulates with fifth lumbar vertebra superiorly and with the coccyx inferiorly. Sacral crest is in the midline and is formed by the fusion of spinous processes. Foramina are formed by the fusion of transverse processes of sacral segments and are present on each side of midline. There are four such sacral foramina.

The sacral hiatus is a V-shaped or U-shaped notch resulting from the failure of fusion of lamina of fifth vertebral segment. It is covered by the sacrococcygeal ligament and unfused lamina on each side (laterally) form bony prominences known as sacral cornua.

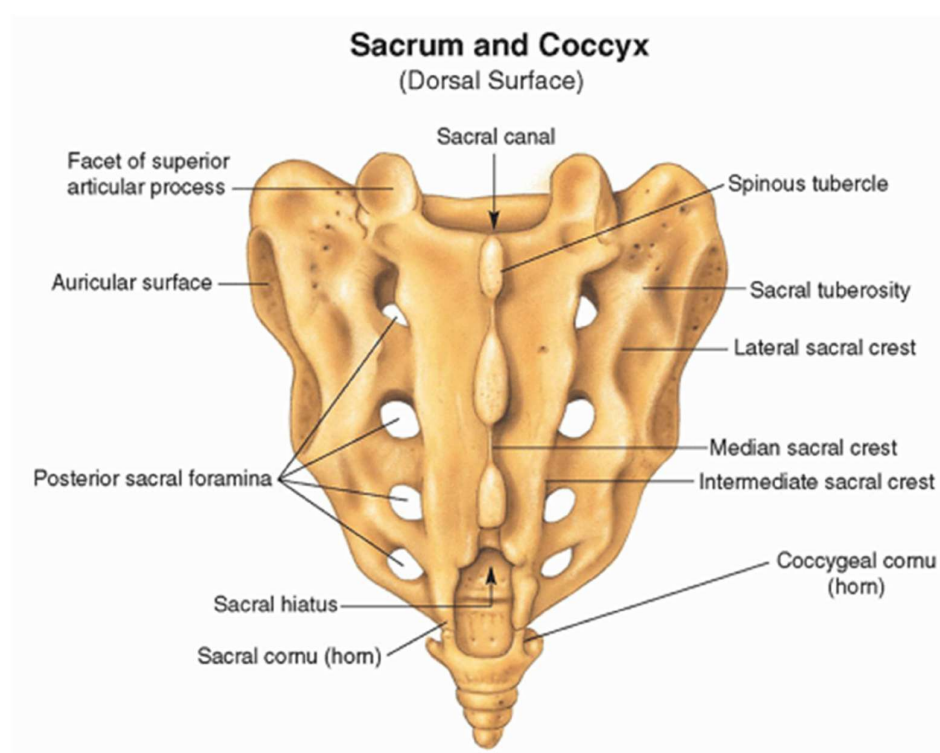


Fig 1: Dorsal surface of Sacrum and Coccyx

The anterior and posterior primary rami of S1-S5 segments and the coccygeal components exit from sacral canal through the anterior and posterior foramina of sacrum and laterally through the sacral hiatus as sacral and coccygeal nerves.

**Contents of sacral canal:**

- 1) The terminal part of the dural sac ending at S2.
- 2) The five sacral nerve roots and the coccygeal nerve which constitutes cauda equina.
- 3) The filum terminale.
- 4) The sacral epidural venous plexus
- 5) Epidural fat.

The capacity of the canal is about 12-65ml (mean -33ml)

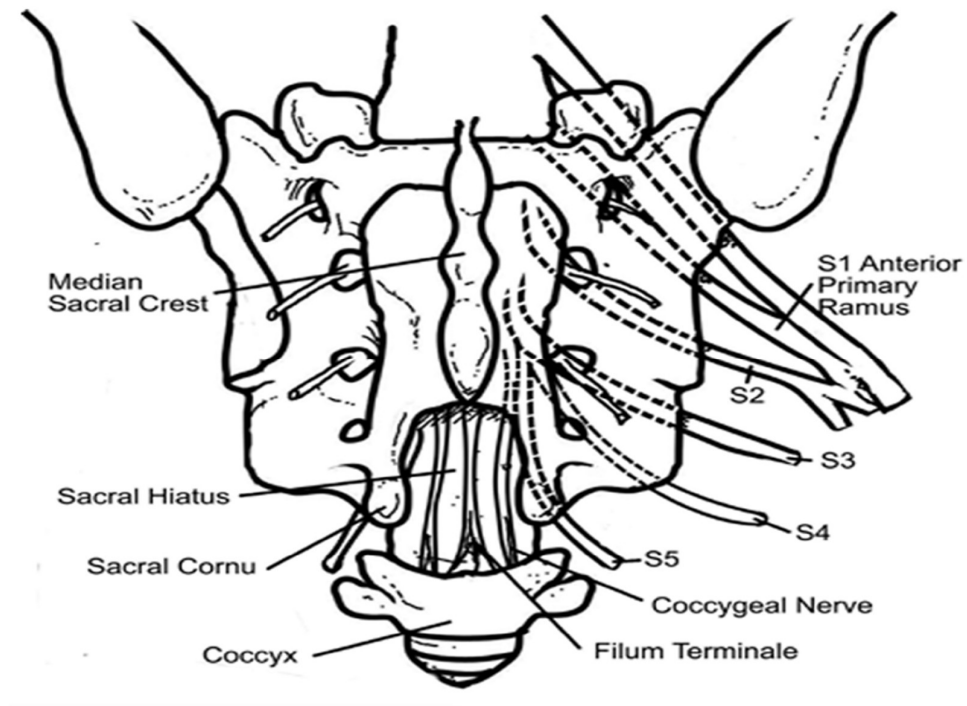


Fig 2: Contents of sacral canal

#### **Anatomical variations of the sacrum and sacral hiatus [25,26]**

The following anomalies were revealed during detailed anatomical studies done by Trotter-

1) In 40% of the population the dural sac was extending below the middle of the second sacral vertebra. In 42% of the population the distance between the apex of the hiatus and the dural sac was less than the mean of 47mm (this distance being important to avoid dural puncture)

2) In 47% of the population the apex of the hiatus was at a level superior to the lower third of the fourth sacral vertebra. In 25% of the population accessory apertures were present in the dorsal wall while agenesis of dorsal wall was seen in 2% of the population.

3) In 5% of the population the anteroposterior diameter of the canal at the apex of the hiatus was less than 2mm. 1-2% of the population showed blocks of the sacral canal lumen.

The hiatus showed wide variation in size and shape from the normal inverted U to longitudinal or horizontal slits. The sacral hiatus can be closed, asymmetrically open or widely open secondary to the anomalies in the pattern of fusion of laminae of sacral arches. The hiatus is absent in 7.7% of population.

### **Physiology of caudal block [27-29]**

A caudal block produces a limited sacral block with minimal physiological changes. Some degree of autonomic blockade is seen along with sensory and motor block of sacral roots. The sacral component of the craniosacral outflow is blocked leading to loss of the visceromotor function in the bladder and bowel distal to the splenic flexure of the colon. A limited degree of sympathetic block occurs as the sympathetic outflow from spinal cord ends at L1 level.

### **Onset of anaesthesia**

It occurs slowly, noted first on the buttocks. Loss of sensation proceeds over the buttocks and up the sacrum. This loss is usually seen after 5 minutes. The first modality of sensation to be lost is the pain, followed by touch and then temperature. Last to be affected are the motor fibres and some loss of function appears in 10 minutes.

Due to physiological differences children respond differently to local anaesthetics as compared to adults. These are immature hepatic system with decreased hepatic blood flow, reduced enzyme levels, and greater volume of distribution.

The contents of the epidural space are more gelatinous and less fibrous in children compared to adults. Epidural fat is fluidic in consistency and loosely packed till 7-8 years of age when it starts becoming denser. So it favours the spread of local anaesthetics as well as allowing easy passage of epidural catheters up to the thoracic level from caudal or lumbar approach.

The normal rise in adrenocorticotrophic hormone, antidiuretic hormone, cortisol, catecholamines, insulin and growth hormone levels associated with general anaesthesia and surgery are blocked by caudal anaesthesia in perioperative period.

### **Indications of caudal block**

Caudal block is indicated for the intraoperative and postoperative pain relief for infraumbilical surgeries like -

- 1) Herniorrhaphies, torsion of testis, orchidopexy,
- 2) Gastrointestinal surgeries (hirschsprung disease, anorectal malformations etc)
- 3) Urinary tract surgeries
- 4) Gynaecologic perineal procedure
- 5) Management of vasospastic diseases of lower extremities
- 6) Management of pelvic and extremity pain.

### **Contraindications of caudal block**

- 1) Active disease of Central nervous system
- 2) Infection at the site of caudal block

3) Malformation of lower spine and meninges

4) Coagulopathies and bleeding diathesis

**Technique of caudal block [27,28,30,32]**

Caudal block can be performed as a single shot or a continuous caudal by inserting a catheter. Most children will not accept this procedure while awake and hence needs to be sedated or anaesthetised prior to the administration of caudal block.

All necessary equipments required for general anaesthesia must be assembled and checked along with resuscitation equipment, monitors, and suction. Functional IV access has to be taken.

A short 22-25gauge needle with 45degree short bevel with or without stylet is recommended for caudal block.

Patient is positioned in the lateral decubitus or Sim's position. It can also be given in prone position.

Successful caudal block depends on the identification of following bony landmarks-

- 1) Posterior superior iliac spines
- 2) Sacral cornua
- 3) Sacral hiatus between the cornua

The two posterior superior iliac spines and the sacral hiatus form an equilateral triangle. Sacral hiatus can be palpated as a depression between the two sacral cornua.

The exact needle placement and spread of the injected drug increase the efficacy and safety of the regional block.

Sacral hiatus is then punctured using 22-23gauge short bevelled needle. The needle is inserted at an angle of 45-60° to the skin till the characteristic 'give or pop' is felt indicating piercing of sacrococcygeal ligament. The needle is then lowered to an angle of 15-20° and advanced 2-3mm further into the caudal space.

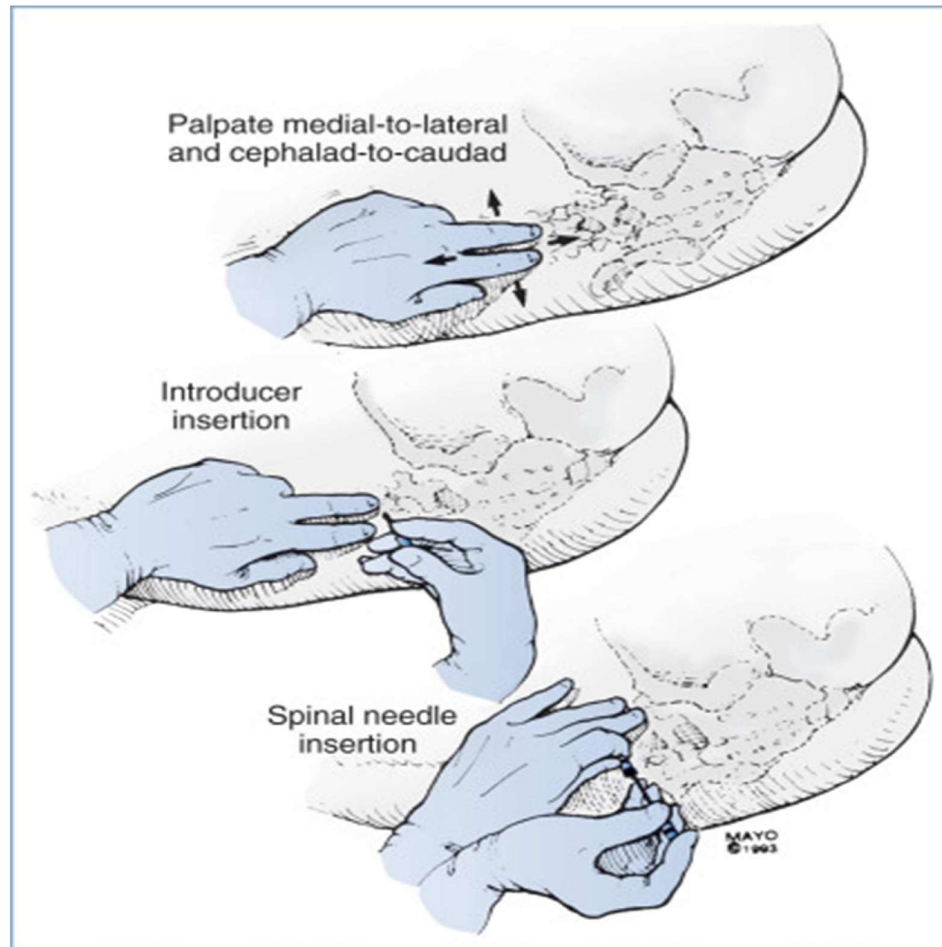


Fig 3: Technique of caudal epidural block and needle placement

**Signs of correct needle placement:**

- Feeling of definite pop on piercing the sacrococcygeal ligament.
- Negative aspiration of CSF, blood.

- No subcutaneous bulge or superficial crepitus after rapid injection of anaesthetic solution or air.
- No tissue resistance to injection.
- Whoosh test- In this test the stethoscope is placed over midline lower lumbar spine and the characteristic whoosh sound is heard on injection of 2-3 ml of air via the caudal needle.

### **Dosage calculation for caudal block**

#### **Armitage formula [31]**

- 0.5 ml/kg for lumbosacral block
- 1 ml/kg for thoraco-lumbar block
- 1.25 ml/kg for mid-thoracic block
- No local pain during injection of solution.

#### **Complications:**

- Inadvertent dural puncture (1.2%)
- Vascular puncture-0.5%
- Systemic toxicity
- Trauma of spinal cord and roots
- Partial or complete failure of block because of technical error or low dose volume of drugs
- Interosseous injection caused by piercing the thin layer of cortical bone of sacrum
- Infection (bacterial contamination leading to meningitis, encephalitis, abscess formation)

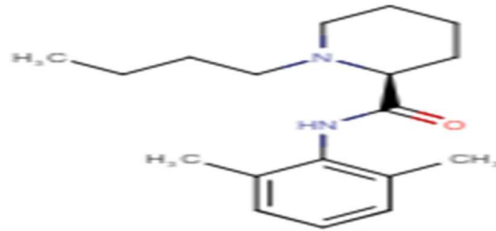
- Inappropriate level of block (lateralization of block, block level being too high or too low)
- Urinary retention due to blockade of S2-S4 sacral roots
- Others bleeding with haematoma formation, excessive motor blockade, injury to pelvic viscera, broken needles or catheter, hypotension.

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## Levobupivacaine [33]

Levobupivacaine is a long-acting local anaesthetic and an enantiomer of bupivacaine. While bupivacaine is widely used in surgery and obstetrics, it carries a risk of severe cardiotoxicity, making Levobupivacaine a safer alternative.

### Chemical structure:



### Pharmacokinetics:

#### 1. Absorption

- Route-dependent absorption: Faster from highly vascular sites (e.g., epidural, intercostal), slower from poorly perfused areas (e.g., subcutaneous).
- Onset of action:
  - Infiltration & Peripheral Nerve Blocks: 10–20 minutes.
  - Epidural: 15–30 minutes.
  - Spinal: Rapid (<5 minutes).
- Bioavailability: Not used orally due to extensive first-pass metabolism.

#### 2. Distribution

- Highly protein-bound (~97%), primarily to  $\alpha$ 1-acid glycoprotein, reducing free drug availability.

- Volume of distribution (Vd): 66–80 L, indicating good tissue penetration.
- Lipophilicity: Similar to bupivacaine but slightly lower CNS & cardiac toxicity.
- Placental transfer:
  - Minimal foetal exposure due to high protein binding.
  - Considered safer for obstetric use than racemic bupivacaine.

### 3. Metabolism

- Extensively metabolised in the liver via CYP3A4 and CYP1A2 enzymes.
- Major metabolic pathways:
  - N-dealkylation → Pipecolylxylidine (PPX) (inactive).
  - Hydroxylation → Minor inactive metabolites.
- No active metabolites, reducing toxicity risk.

### 4. Excretion

- Primary route: Renal excretion (mainly as metabolites).
- Unchanged drug in urine: <5%.
- Clearance: ~0.47 L/min (lower than ropivacaine).
- Elimination half-life:
  - Healthy adults: ~2.6–3.5 hours.
  - Neonates & Elderly: Prolonged due to reduced hepatic metabolism.

## 5. Special Considerations

### Hepatic Impairment

- Reduced metabolism → Prolonged elimination half-life & increased plasma levels.
- Dose adjustment is required in liver disease.

### Renal Impairment

- Minimal impact since metabolism is hepatic.
- No major dose adjustments are needed.

### Pregnancy & Placental Transfer

- Minimal foetal exposure due to high protein binding.
- Preferred for labour analgesia and caesarean sections due to lower foetal toxicity.

### **Mechanism of Action:**

- Blocks Voltage-Gated Sodium Channels:
  - Prevents Na<sup>+</sup> influx in nerve membranes.
  - Inhibits action potential generation, causing reversible sensory and motor blockade.
- Selective Sensory Blockade:
  - At lower concentrations, it preferentially blocks sensory fibres over motor fibres.

- Higher doses produce more profound motor blockades.
- Differential Nerve Sensitivity:
  - Smaller, myelinated fibres ( $A\delta$  and C fibres) are blocked first (pain & temperature).
  - Larger, unmyelinated fibres ( $A\beta$  and  $A\alpha$  fibres) are blocked later (touch, pressure, motor).

**Pharmacodynamics:**

Central Nervous System (CNS)

- Produces sensory and motor blockade, with a dose-dependent effect.
- Causes differential blockade (sensory > motor), making it useful for analgesia while preserving some motor function.

Cardiovascular System (CVS)

- Minimal vasodilation, leading to prolonged analgesic action.
- Lower affinity for cardiac sodium channels, making it less cardiotoxic than bupivacaine.

Respiratory System

- No direct depressant effect on respiration at therapeutic doses.
- Epidural and spinal blocks may impair intercostal muscle function if the spread is excessive.

Dosage for Caudal Epidural Anaesthesia

- Paediatric patients (typically 1-12 years old):
  - 0.2–0.5 mL/kg of 0.25% levobupivacaine (maximum recommended dose: 2.5 mg/kg).
  - Provides analgesia for 4–8 hours.
- Adults:
  - Typically, 15–30 mL of 0.25–0.5% levobupivacaine is used.
  - Adjust based on patient weight and surgical procedure.
  - The maximum dose should not exceed 150 mg in adults to minimise systemic toxicity.

#### **Levobupivacaine toxicity**

<b>System</b>	<b>Adverse Effects</b>
<b>CNS</b>	Dizziness, tinnitus, seizures, respiratory depression
<b>CVS</b>	Hypotension, bradycardia, conduction block, arrhythmias
<b>Respiratory</b>	Hypoventilation, apnea
<b>Allergic</b>	Rash, anaphylaxis (rare)
<b>Local Tissue</b>	Nerve injury, myotoxicity, pain
<b>Fetus (Obstetrics)</b>	Bradycardia, acidosis
<b>Metabolic</b>	Acidosis, hyperkalemia

#### **Immediate Actions (General Management)**

If toxicity is suspected, follow these steps immediately:

- Stop administration of levobupivacaine.

- Call for help & initiate resuscitation if needed.
- Ensure airway protection and adequate oxygenation.
- Maintain circulation and blood pressure.
- Monitor vital signs continuously (ECG, BP, SpO<sub>2</sub>).

## 2. Central Nervous System (CNS) Toxicity Management

Symptoms: Dizziness, tinnitus, confusion, seizures, respiratory depression

Treatment Approach:

Mild cases (e.g., dizziness, perioral numbness, agitation):

- Stop further drug administration.
- Provide 100% oxygen via face mask.
- Ensure adequate ventilation.

Seizures or severe agitation:

- Benzodiazepines (first-line):

o Midazolam (1–2 mg IV) OR Diazepam (5–10 mg IV).

- Propofol (small doses) can be used if seizures persist (in haemodynamically stable patients).
- Avoid high-dose propofol in patients with cardiovascular instability.

Respiratory depression or apnoea:

- Bag-mask ventilation or endotracheal intubation with mechanical ventilation if necessary.

### 3. Cardiovascular System (CVS) Toxicity Management

Symptoms: hypotension, bradycardia, arrhythmias, cardiac arrest

Treatment Approach:

Mild hypotension/bradycardia:

- IV fluids (crystalloids) to maintain BP.
- Atropine (0.5–1 mg IV) for severe bradycardia.

Severe cardiovascular collapse (arrhythmias, cardiac arrest):

- Initiate Advanced Cardiac Life Support (ACLS).
- CPR if cardiac arrest occurs.
- Avoid high doses of epinephrine (use small incremental doses, e.g., 10–100 mcg IV boluses).
- Consider vasopressors (e.g., norepinephrine, vasopressin) for refractory hypotension.
- Sodium bicarbonate (50 mEq IV) for metabolic acidosis if present.

### 4. Lipid Emulsion Therapy (Lipid Rescue)

Indication: Severe CNS and cardiovascular toxicity (e.g., seizures, arrhythmias, cardiac arrest)

Protocol for Lipid Rescue Therapy (Intralipid 20%):

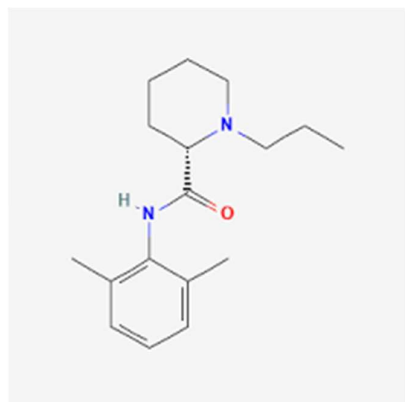
- Initial bolus: 1.5 mL/kg IV over 1 minute
- Continuous infusion: 0.25 mL/kg/min
- Repeat bolus if no response (up to 3 doses total).
- Increase infusion rate to 0.5 mL/kg/min if cardiovascular instability persists.
- Continue for 10–30 minutes or until recovery.

Lipid emulsion works by "binding" free levobupivacaine in the blood, reducing toxicity.

## Ropivacaine [34]

Ropivacaine is a long-acting amide-type local anesthetic widely used in regional anaesthesia and pain management. It was developed as a safer alternative to bupivacaine, with reduced cardiotoxicity and neurotoxicity while maintaining effective analgesic properties. Ropivacaine has a chiral structure, and it is marketed as the pure S-enantiomer, which is responsible for its improved safety profile.

### Chemical structure:



**Molecular Formula:** C<sub>17</sub>H<sub>26</sub>N<sub>2</sub>O

**Molecular Weight:** 274.40 g/mol

**IUPAC Name:** (S)-N-(2,6-dimethylphenyl)-1-propylpiperidine-2-carboxamide

### Structural Components:

Ropivacaine belongs to the amino amide class of local anaesthetics and has three key structural components:

- Aromatic Ring (Lipophilic Part)

The 2,6-dimethylphenyl group contributes to lipophilicity and enhances the anesthetic potency.

It helps in the penetration of nerve cell membranes.

#### Intermediate Amide Linkage

- Intermediate amide linkage

The amide (-CONH-) bond connects the aromatic ring to the tertiary amine.

This makes it metabolically more stable than ester-type local anesthetics (e.g., procaine).

The amide linkage also contributes to its long duration of action.

- Piperidine Ring (Hydrophilic Part)

The S-enantiomeric piperidine moiety improves selectivity and reduces cardiotoxicity compared to bupivacaine.

The tertiary amine (-NH group) determines the ionization and solubility properties.

#### 2D Chemical Structure of Ropivacaine

- Chirality and Enantiomerism

Ropivacaine is an S-enantiomer of 1-propyl-2',6'-pipecoloxylidide. Chirality plays a significant role in:

1. Reducing cardiac and CNS toxicity (as compared to the R-enantiomer in racemic mixtures like bupivacaine).
2. Providing selective sensory blockade while sparing motor function at lower concentrations.

The S-enantiomer binds less strongly to sodium channels in myocardial and central nervous system tissues, making ropivacaine safer than racemic local anaesthetics.

**Pharmacokinetics:**

1. Absorption

- Depends on the site of administration: Higher vascularity → Faster absorption.
- IV (fastest) > Intercostal > Epidural > Brachial plexus > Subcutaneous (slowest).
- Slower systemic absorption than bupivacaine due to lower lipophilicity.
- Peak plasma concentration (C max) depends on dose, concentration, and perfusion at the injection site.

2. Distribution

- Protein Binding: ~94% (mainly  $\alpha$ 1-acid glycoprotein).
- Volume of Distribution (Vd): 41–60 L
- Tissue Penetration:
  - Highly perfused organs (brain, heart, kidneys, and lungs) receive drugs first.
- Skeletal muscle acts as a reservoir.
- Crosses the placenta but is less toxic to the fetus than bupivacaine.

3. Metabolism

- Primarily in the liver by CYP1A2 and CYP3A4 enzymes.

- Major metabolite: 3-Hydroxy-ropivacaine (inactive, excreted in urine).
- Metabolism is slower in neonates and liver-impaired patients.

#### 4. Elimination

- Excretion: Mainly renal (86%) as metabolites.
- Half-life ( $T_{1/2}$ ):
- Epidural: 4.2 hours
- IV: 1.8 hours
- Neonates: Longer due to immature liver metabolism.
- Clearance: 8–13 L/h

### **MECHANISM OF ACTION**

#### Step 1: Penetration into the Nerve Membrane

Ropivacaine exists in two forms:

Non-ionized (lipophilic) → Crosses nerve membrane.

Ionized (hydrophilic) → Blocks sodium channels from inside.

The pKa of ropivacaine (8.1) means a portion remains non-ionized at physiological pH (7.4), allowing membrane penetration.

#### Step 2: Sodium Channel Blockade

Inside the axon, ropivacaine binds to intracellular voltage-gated  $\text{Na}^+$  channels in the inactivated state.

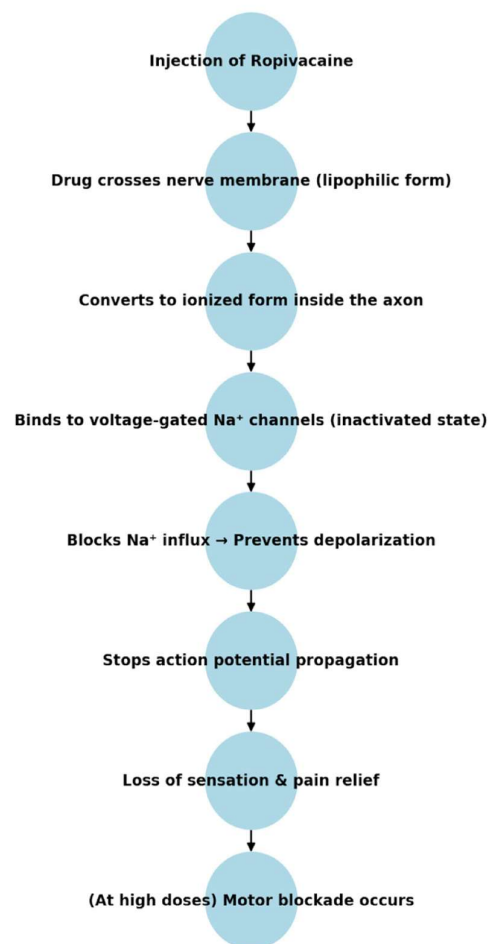
This prevents Na<sup>+</sup> influx, blocking depolarization and action potential propagation.

### Step 3: Inhibition of Nerve Signal Transmission

If Na<sup>+</sup> channels remain blocked, the nerve fails to reach threshold potential, stopping pain signals from reaching the brain.

Smaller, unmyelinated pain fibers (C fibers, A $\delta$  fibers) are blocked first, followed by larger motor fibers (A $\alpha$ ).

### Mechanism of Action of Ropivacaine



Selectivity & Differential Blockade

At low concentrations ( $\leq 0.2\%$ ) → Preferential sensory block (pain relief with minimal motor impairment).

At higher concentrations ( $\geq 0.5\%$ ) → Both sensory and motor blockade, making it useful for surgical anaesthesia.

## **MATERIALS AND METHODS**

The current study, titled "COMPARISON OF LEVOBUPIVACAINE 0.25% AND ROPIVACAINE 0.25% FOR CAUDAL EPIDURAL ANAESTHESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERIES" -A RANDOMISED CLINICAL TRIAL

The study, which was carried out at Dr. Prabhakar Kore Hospital and Medical Research Centre, KLE Society Belgaum for one year, focused on patients having elective infra umbilical surgeries and receiving a combination of intravenous sedation & caudal epidural anaesthesia. The study included both genders and children aged 1–11 who were classified as ASA grades 1 and 2.

Study type: Randomized clinical Trial.

The following were included in the criteria:

- Age; 1- 11 years
- ASA 1, 2
- Individuals receiving infraumbilical procedures.
- Consent from parents (willing to give informed consent for study participation).
- The surgery took less than an hour to complete.

The following were excluded criteria:

- Individuals with a local anaesthetic allergy.
- Individuals with irregular coagulation.
- Individuals having neurological deficiencies and anomalies of the spine.
- Patients who have an infection at the caudal block location.

Period of study: One year

Sample size for study: 92

Sample size calculation:

At 95% confidence interval 80% power  $n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (SD_1^2 + SD_2^2)}{(x_1 - x_2)^2}$   $n = 45.5 \cong 46$  per group Required sample size =  $46 * 2 = 92$

Where,  $Z_{1-\alpha/2} = 1.96$   $Z_{1-\beta} = 0$ .

$$SD_1 = 3.97, SD_2 = 5.89 \quad x_1 = 59.43 \quad x_2 = 56.47$$

Sampling Technique:

The primary goal of the study was to compare two groups. For the continuous quantitative variables, the mean and standard deviation were calculated. The intergroup continuous variables were evaluated using the unpaired student's t test and other suitable statistical techniques. Within a group, two quantitative parameters were compared using paired t tests.

The categorical data was represented using percentages, ratios, & rates. To find out the association between the outcome, clinical, and demographic characteristics, the chi square test or Fisher's exact test was utilized.

In addition to the aforementioned, appropriate tools such as regression, correlation, and ANOVA were employed based on the situation.

Discrete variables were expressed by the median.

Nonparametric testing was utilized to compare discrete variables. The comparison was shown utilizing the appropriate graphs.

For every test, a p-value of less than five percent (0.05) was considered significant.

**METHODOLOGY (Study Protocol):**

Ninety-two children between the ages of one and eleven who were posted for procedures electively under caudal epidural anaesthesia after receiving institutional review board approval were included in our study.

The day before surgery, a preoperative evaluation was conducted to find out if the patients fulfilled the requirements for inclusion and parental consent was obtained. Before the surgery, patients were given guidelines to observe the proper fasting period. Routine tests, including haemoglobin and platelet counts, were done.

The nil per mouth status had been confirmed on the day of the procedure, and the i v cannula was secured on the forearm

The subjects were splits into two groups using a computer-generated randomization table.

Group L: For caudal epidural anaesthesia, patients were given 1 milliliter per kilogram of body weight of 0.25% levobupivacaine.

Group R: For caudal epidural anaesthesia, patients were given 1 milliliter per kilogram of body weight of 0.25% ropivacaine.

Children were pre medicated with glycopyrrolate of 0.004 mg/kg BW and ketamine 1 mg/kg BW of ketamine to lessen the stress of parental separation. Following premedication, the patients were taken to the operating room where standard monitoring including non-invasive blood pressure (NIBP), Spo2, and an ECG were attached.

Patients were put in the left lateral position after being induced with isoflurane at 1 MAC. sacral hiatus and sacral cornua were felt. A 22gauge hypodermic needle was used to pierce the skin over the sacrococcygeal ligament. The needle was placed into

the skin surface at an angle of 45 to 60 degrees and progressed until the sacrococcygeal ligament was punctured, or felt. The needle was advanced two to three millimeters further into the sacral canal after being lowered to 20 - 30 degree angle with respect to the skin, a stethoscope was placed over the lower lumbar spine and two to three milliliters of air were injected (whoosh test), which verifies the caudal epidural space. The trial medication was given following negative aspirations for blood and CSF.

The study drug was given i.e;

Group L: For caudal epidural anaesthesia, patients were given 1 milliliter per kilogram of body weight of 0.25% levobupivacaine.

Group R: For caudal epidural anaesthesia, patients were given 1 milliliter per kilogram of body weight of 0.25% ropivacaine

Following the study drug injection, subjects were put in a supine position and kept in a deep state of anaesthesia using O<sub>2</sub>, N<sub>2</sub>O, and isoflurane while breathing on their own using the Jackson Rees circuit.

Before starting the surgical procedure, the caudal efficacy score was evaluated intraoperatively (Table 1).

Score	Definition
1	Able to reduce sevoflurane concentration, heart rate >20% of baseline, along with limb movements
2	Able to reduce sevoflurane concentration, heart rate >20% baseline, with no movements
3	Isoflurane concentration stopped, minimal or no change in heart rate, no movement on stimulation

Following confirmation of adequate caudal block, surgery was initiated, and hemodynamic parameters were taken for every five minutes until the surgery was completed by the end of surgery they received 100% oxygen for 5 minutes and the inhalational agents were stopped. After that, the patients were transferred to the post-anaesthesia care unit. The length of absolute analgesia in the ward and recovery room was measured at 15-minute intervals using a modified Hannallah pain score (Table 2). As an alternative, injectable paracetamol (10 mg /kg) was utilized as rescue analgesia.

<b>Observation</b>	<b>Criteria</b>	<b>Points</b>
Crying	No crying	0
	Crying responding to tender loving care	1
	Crying not responding to tender loving care	2
Movement	None	0
	Restless	1
	Thrashing	2
Agitation	Asleep/calm	0
	Mild	1
	Hysterical	2
Swallowing of secretion	Normal	0
	Uncomfortable	1
	Unable	2
Verbalization of pain	Asleep/states no pain	0
	Vague/can't localize	1
	Can localize pain	2

Following surgery, diastolic & systolic blood pressure, Spo2, breathing rate & heart rate were measured as hemodynamic parameters. Other complications were assessed, comprising fever, retching, vomiting, urine retention, bradycardia, and respiratory depression.

**RESULTS**

A total of 92 paediatric patients aged 01-11 years through the caudal epidural anaesthesia were evaluated and they were randomly allocated in to 2 groups based on computer generated random pattern.

Levobupivacaine (sample size (n)=46)

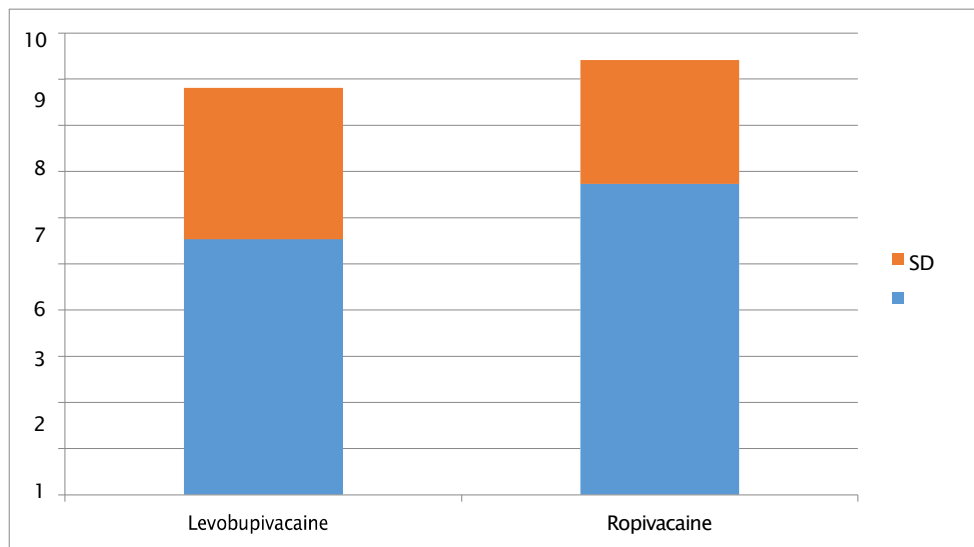
Ropivacaine (sample size (n) =46)

A Microsoft Excel spreadsheet was used to enter the data. After the analysis of data, the findings were tabulated as follows.

Table 3: Mean Age distribution (yrs)

GROUP	MEAN	SD	MIN	MAX	P VALUE
Levobupivacaine	5.54	3.27	01	12	0.055
Ropivacaine	6.74	2.61	02	12	

Graph 1: Mean Age (yrs)

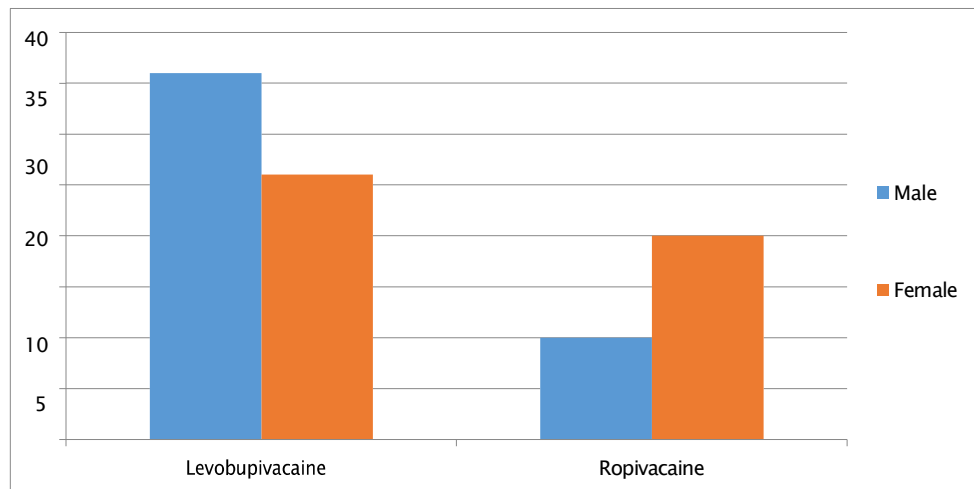


The mean age was  $5.54 \pm 3.27$  in Levobupivacaine group and  $6.74 \pm 2.61$  in Ropivacaine group. The two groups changes were statistically significant.

Table 4: Sex distribution

	Levobupivacaine		Ropivacaine		P Value
	Number	Percentage	Number	Percentage	
Male	36	78.2	26	56.5	0.2888
Female	10	21.8	20	43.5	
Total	46	100	46	100	

Graph 2: Sex distribution



There were 26 males and 10 females in the Ropivacaine group and 36 males and 10 females in the Levobupivacaine group in this study. The study found no statistical significance in this gender distribution.

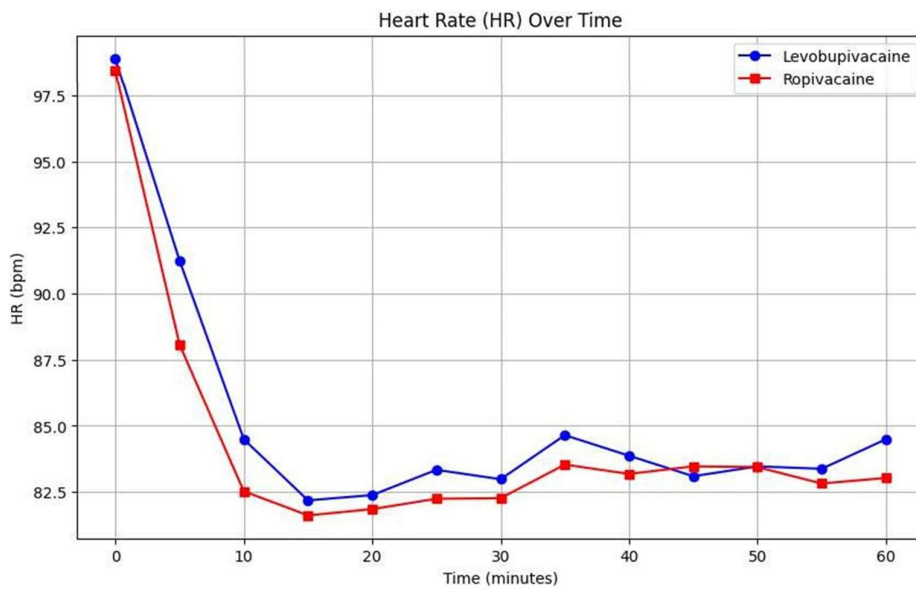
HAEMODYNAMIC PARAMETERS (MINUTES)

Table 5: Heart Rate

		Levobupivacaine Mean	Levobupivacaine SD	Ropivacaine Mean	Ropivacaine SD	P VALUE
HR(B pm)	BASELINE	98.911	13.673	98.435	12.488	0.596060330 3
	5 Min	91.244	10.674	88.065	9.0784	
	10 Min	84.489	10.796	82.522	9.0252	
	15 Min	82.178	8.6477	81.609	7.458	
	20 Min	82.378	9.4423	81.848	8.3745	
	25 Min	83.333	8.6313	82.239	7.0496	
	30 Min	82.978	7.5541	82.261	6.1552	
	35 Min	84.644	8.2319	83.533	8.1425	
	40 Min	83.867	8.1864	83.178	7.8053	
	45 Min	83.091	7.9957	83.465	6.6165	
	50 Min	83.465	7.6084	83.436	7.2176	
	55 Min	83.372	7.352	82.816	7.9248	
	60 Min	84.488	6.3096	83.026	6.3565	

At baseline, Levobupivacaine had a mean heart rate (HR) of 98.91 bpm (SD = 13.67), while Ropivacaine had a mean of 98.44 bpm (SD = 12.49). After 5 minutes, Levobupivacaine mean HR was 91.24 bpm (SD = 10.67) and Ropivacaine was 88.07 bpm (SD = 9.08). At the 10- minute mark, Levobupivacaine mean HR was 84.49 bpm (SD = 10.80), while Ropivacaine was 82.52 bpm (SD = 9.03). After 15 minutes, Levobupivacaine had a mean HR of 82.18 bpm (SD = 8.65), and Ropivacaine had a mean of 81.61 bpm (SD = 7.46). At 20 minutes, Levobupivacaine mean HR was 82.38 bpm (SD = 9.44), while Ropivacaine mean HR was 81.85 bpm (SD = 8.37).

Graph 3: Heart Rate



After 25 minutes, Levobupivacaine had a mean HR of 83.33 bpm (SD = 8.63), and Ropivacaine mean HR was 82.24 bpm (SD = 7.05). At 30 minutes, Levobupivacaine mean HR was 82.98 bpm (SD = 7.55), while Ropivacaine was 82.26 bpm (SD = 6.16). After 35 minutes, Levobupivacaine had a mean HR of 84.64 bpm (SD = 8.23), and Ropivacaine was 83.53 bpm (SD = 8.14). At 40 minutes, Levobupivacaine mean

HR was 83.87 bpm (SD = 8.19), while Ropivacaine was 83.18 bpm (SD = 7.81). After 45 minutes, Levobupivacaine had a mean HR of 83.09 bpm (SD = 7.99), and Ropivacaine had a mean of 83.47 bpm (SD = 6.62). At 50 minutes, Levobupivacaine mean HR was 83.47 bpm (SD = 7.61), while Ropivacaine was 83.44 bpm (SD = 7.22). After 55 minutes, Levobupivacaine had a mean HR of 83.37 bpm (SD = 7.35), and Ropivacaine mean HR was 82.82 bpm (SD = 7.92). Finally, at 60 minutes, Levobupivacaine mean HR was 84.49 bpm (SD = 6.31), while Ropivacaine mean HR was 83.03 bpm (SD = 6.36). Throughout the 60-minute period, the heart rates for both groups remained relatively close, with Levobupivacaine having slightly higher values at most time points, However, there were no significant variations between the groups

Table 6: Systolic blood pressure

		Levobupivacaine mean	Levobupivacaine SD	Ropivacaine Mean	Ropivacaine SD	P VALUE
SBP (Hg)	BASELINE	98.956	8.7944	100.83	6.9163	0.7480133 7
	5 Min	96.533	8.7521	96.413	7.0256	
	10 Min	95.289	7.0426	94.283	6.0614	
	15 Min	92.311	7.3234	93.326	6.7167	
	20 Min	92.25	8.3612	93.087	7.586	
	25 Min	91.867	8.7871	93.174	8.1084	
	30 Min	92.867	8.6913	91.87	7.8673	
	35 Min	92.933	8.3381	92.711	7.0955	
	40 Min	92.622	8.6092	93.889	7.5173	
	45 Min	91.773	7.0297	92.186	6.6306	
	50 Min	92.535	8.114	92.923	7.2779	
	55 Min	91.465	7.9282	91.5	8.1066	
	60 Min	92.744	7.609	92.763	7.0306	

At baseline, Levobupivacaine had a mean systolic blood pressure (SBP) of 98.96 mm Hg (S D = 8.79), while Ropivacaine had a mean of 100.83 mm Hg (S D = 6.92). At 5 minutes, Levobupivacaine recorded a mean SBP of 96.53 mmHg (SD = 8.75) compared to 96.41 mmHg (SD = 7.03) in Ropivacaine. By the 10-minute mark, Levobupivacaine mean SBP was 95.29 mmHg (SD = 7.04), while Ropivacaine was 94.28 mmHg (SD = 6.06). At 15 minutes, Levobupivacaine had a mean SBP of 92.31 mmHg (SD = 7.32) and Ropivacaine had 93.33 mmHg (SD = 6.72), with similar trends continuing through 20 minutes (92.25 mmHg vs. 93.09 mmHg) and 25 minutes (91.87 mmHg vs. 93.17 mmHg). After 30 minutes, Levobupivacaine had a mean SBP of 92.87 mmHg (SD = 8.69), while Ropivacaine recorded 91.87 mmHg (SD = 7.87). At 35 and 40 minutes, the SBP values for Levobupivacaine were 92.93 mmHg (SD = 8.34) and 92.62 mmHg (SD = 8.61), respectively, while Ropivacaine had 92.71 mmHg (SD = 7.10) and 93.89 mmHg (SD = 7.52). By 45 minutes, Levobupivacaine mean SBP was 91.77 mmHg (SD = 7.03) and Ropivacaine was 92.19 mmHg (SD = 6.63), followed by 92.54 mmHg (SD = 8.11) vs. 92.92 mmHg (SD = 7.28) at 50 minutes. At 55 minutes, Levobupivacaine recorded 91.47 mmHg (SD = 7.93) and Ropivacaine had 91.50 mmHg (SD = 8.11). Finally, at 60 minutes, Levobupivacaine mean SBP was 92.74 mmHg (SD = 7.61), and Ropivacaine was 92.76 mmHg (SD = 7.03). Overall, at no point in time were there significant variations in SBP between the two groups.

Graph 4: Systolic Blood Pressure

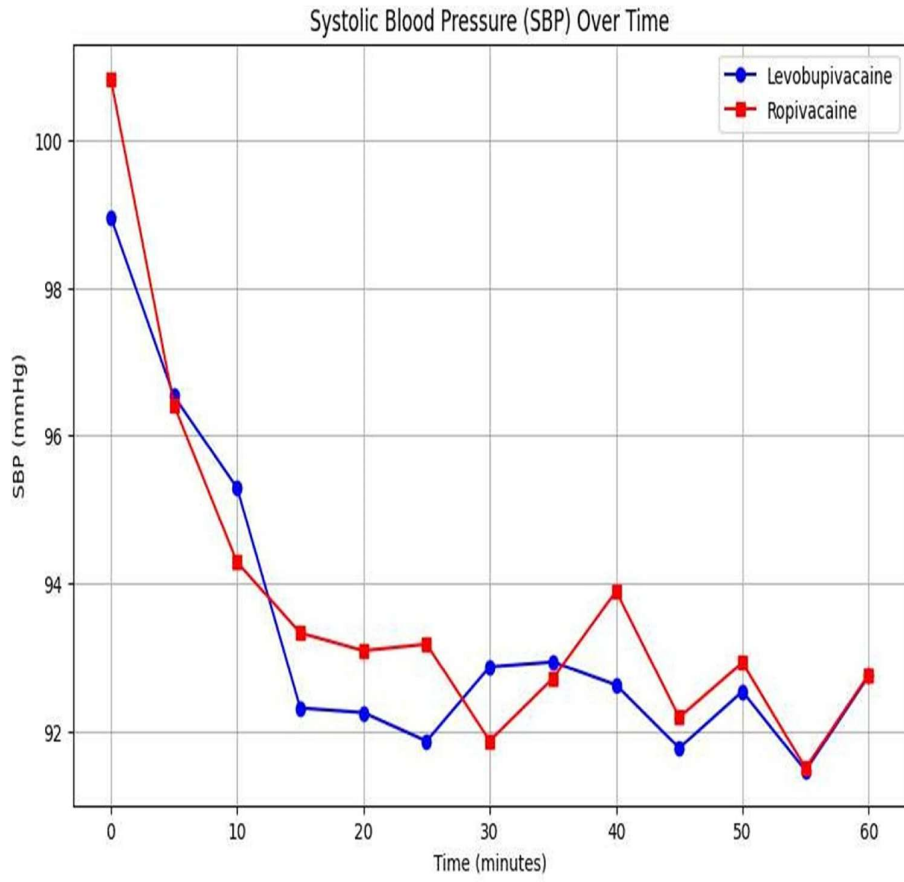
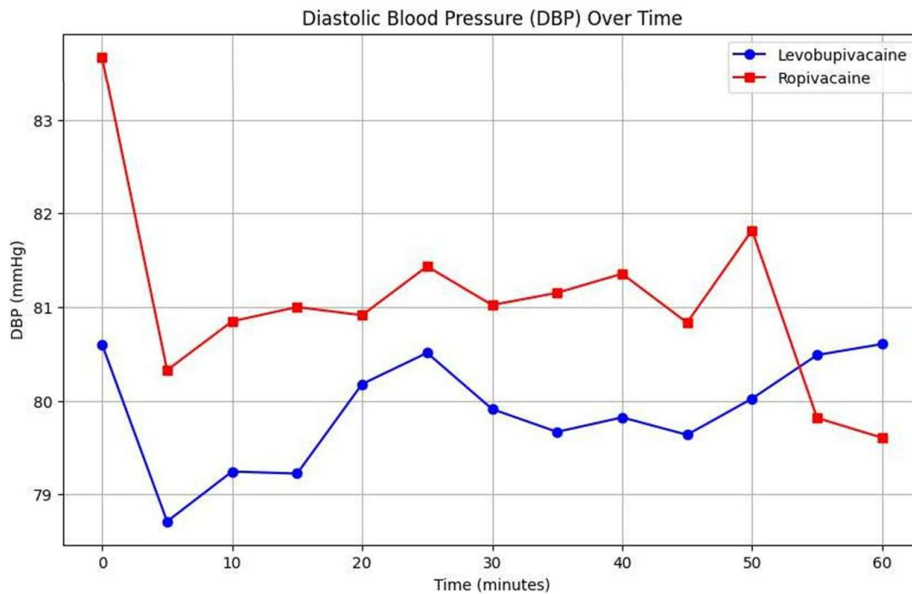


Table 7: Diastolic Blood Pressure

		Levobupivacaine Mean	Levobupivacaine SD	Ropivacaine Mean	Ropivacaine SD	P VALUE
DBP (mmHg)	BASELINE	80.6	6.2088	83.674	6.7923	0.00002403476 6
	5 Min	78.711	6.5004	80.326	6.2113	
	10 Min	79.244	6.0018	80.848	5.1982	
	15 Min	79.222	5.9556	81	6.3316	
	20 Min	80.178	5.9439	80.913	6.528	
	25 Min	80.511	6.2346	81.435	7.6729	
	30 Min	79.911	6.1966	81.022	6.3961	
	35 Min	79.667	5.9784	81.152	6.7757	
	40 Min	79.822	6.199	81.356	7.3952	
	45 Min	79.636	6.4435	80.833	7.0708	
	50 Min	80.023	6.1587	81.821	7.7489	
	55 Min	80.488	6.1472	79.816	7.3037	
	60 Min	80.605	6.1245	79.605	6.3311	

At baseline, Levobupivacaine had a mean diastolic blood pressure (DBP) of 80.60 mm Hg (S D = 6.21), while Ropivacaine had a higher mean of 83.67 mmHg (SD = 6.79). Over the 60- minute period, DBP values fluctuated but remained relatively stable within each group. At 5 minutes, Levobupivacaine recorded a mean DBP of 78.71 mmHg (SD = 6.50) compared to 80.33 mmHg (SD = 6.21) in Ropivacaine. By 10 minutes, Levobupivacaine mean DBP was 79.24 mmHg (SD = 6.00), while Ropivacaine was 80.85 mmHg (SD = 5.20). At 15 minutes, Levobupivacaine had a mean DBP of 79.22 mm Hg (S D = 5.96), while Ropivacaine had 81.00 mmHg (SD = 6.33). At the 20-minute mark, Levobupivacaine recorded a mean DBP of 80.18 mmHg (SD = 5.94) compared to 80.91 mmHg (SD = 6.53) in Ropivacaine.

Graph 5: Diastolic Blood Pressure



By 25 minutes, Levobupivacaine DBP was 80.51 mm Hg (S D = 6.23), and Ropivacaine was 81.44 mmHg (S D = 7.67). At 30 minutes, Levobupivacaine had a mean DBP of 79.91 mmHg (SD = 6.20), while Ropivacaine recorded 81.02 mmHg

(SD = 6.40). At 35 and 40 minutes, Levobupivacaine DBP values were 79.67 mmHg (SD = 5.98) and 79.82 mmHg (SD = 6.20), respectively, while Ropivacaine had 81.15 mmHg (SD = 6.78) and 81.36 mmHg (SD = 7.40). At 45 minutes, Levobupivacaine had a mean DBP of 79.64 mm Hg (SD = 6.40) compared to 81.15 mmHg (SD = 6.78) in Ropivacaine. Levobupivacaine had a mean SpO<sub>2</sub> of 98.68% (SD = 1.33) compared to 98.70% (SD = 1.30) in Ropivacaine. By 50 and 55 minutes, Levobupivacaine recorded SpO<sub>2</sub> values of 98.23% (SD = 1.52) and 98.58% (SD = 1.75), respectively, while Ropivacaine had 98.10% (SD = 1.52) and 98.50% (SD = 1.39). Finally, at 60 minutes, Levobupivacaine mean SpO<sub>2</sub> was 99.30% (SD = 1.05), while Ropivacaine was 99.24% (SD = 1.15). Throughout the observation period, SpO<sub>2</sub> levels remained high in both groups, with minimal fluctuations and no significant differences between them.

Modified Hannallah pain score (MHPS)

Table8: Blood Pressure (BP)

		Levobupivacaine Mean	Levobupivacaine SD	Ropivacaine Mean	Ropivacaine SD	p VALUE
BP	BASELINE	0	0	0	0	0.9022921897
	15Min	0	0	0.0217	0.1474	
	30Min	0	0	0	0	
	45 Min	0	0	0	0	
	60 Min	0	0	0	0	
	75 Min	0	0	0	0	
	90 Min	0	0	0.0217	0.1474	
	105 Min	0	0	0	0	
	120 Min	0	0	0	0	

At baseline, both Levobupivacaine and Ropivacaine had no recorded BP events (mean = 0, SD = 0). Throughout most of the observation period, BP events remained absent in both groups, except at 15 minutes and 90 minutes, where Ropivacaine recorded a mean BP event occurrence of 0.0217 (SD = 0.1474), while Levobupivacaine remained at 0. At all other time points (30, 45, 60, 75, 105, and 120 minutes), both groups consistently had no BP events (mean = 0, SD = 0). Overall, there was no meaningful variation in BP events between the groups, indicating minimal or no occurrence of such events during the study duration.

Graph 6: Blood Pressure (BP)

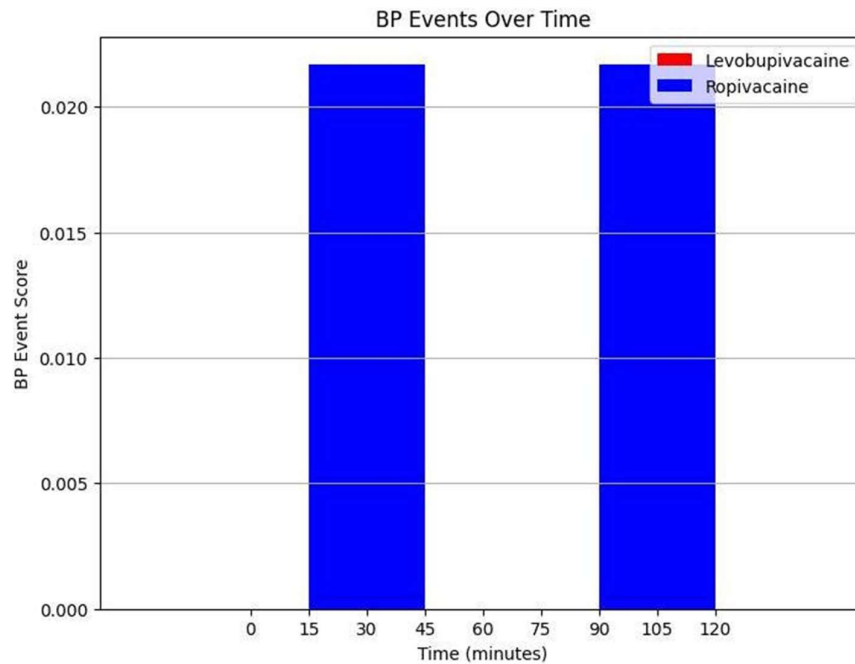
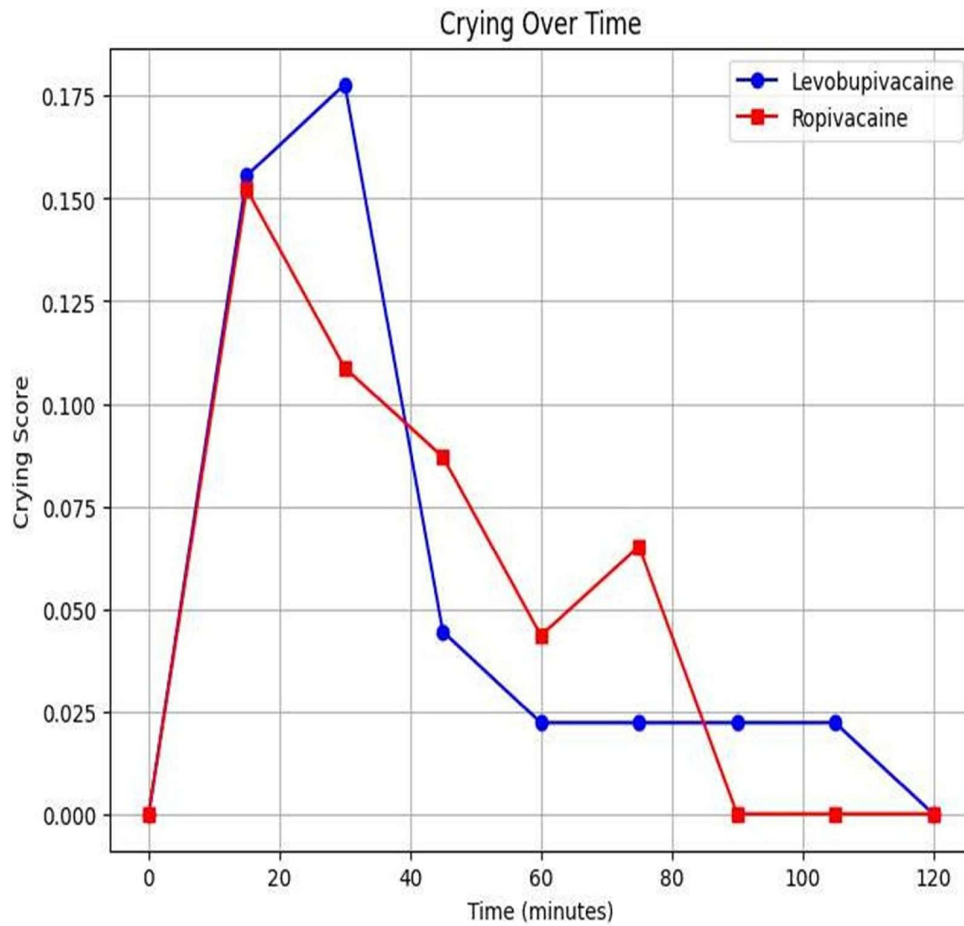


Table 9: CRYING

		Levobupivacaine Mean	Levobupivacaine SD	Ropivacaine Mean	Ropivacaine SD	P VALUE
CRYING	BASELINE	0	0	0	0	0.4342959883
	15Min	0.1556	0.3632	0.1522	0.3632	
	30Min	0.1778	0.3832	0.1087	0.3147	
	45Min	0.0444	0.2062	0.087	0.2849	
	60Min	0.0222	0.1474	0.0435	0.2062	
	75Min	0.0222	0.1474	0.0652	0.2496	
	90Min	0.0222	0.1474	0	0	
	105Min	0.0222	0.1474	0	0	
	120Min	0	0	0	0	

At baseline, both Levobupivacaine and Ropivacaine had no recorded crying events (mean = 0, SD = 0). Over time, crying events were observed in both groups but remained low throughout the study. At 15 minutes, Levobupivacaine had a mean crying occurrence of 0.1556 (SD = 0.3632), while Ropivacaine recorded a similar mean of 0.1522 (SD = 0.3632). By 30 minutes, Levobupivacaine mean increased slightly to 0.1778 (SD = 0.3832), whereas Ropivacaine mean was 0.1087 (SD = 0.3147).



Graph 7: Crying

At 45 minutes, crying events reduced in both groups, with Levobupivacaine at 0.0444 (SD = 0.2062) and Ropivacaine at 0.087 (SD = 0.2849). The trend continued at 60 minutes, where Levobupivacaine had a mean of 0.0222 (SD = 0.1474) and Ropivacaine had 0.0435 (SD = 0.2062). At 75 minutes, Levobupivacaine remained at 0.0222 (SD = 0.1474), while Ropivacaine recorded a slightly higher mean of 0.0652 (SD = 0.2496). By 90 and 105 minutes, crying events in Levobupivacaine remained unchanged at 0.0222 (SD = 0.1474), while Ropivacaine had no recorded crying events (mean = 0, SD = 0). Finally, at 120 minutes, both groups showed no crying events. Overall, while crying events occurred sporadically, they remained minimal, with no substantial differences between the two groups throughout the study.

Table 10: MOVEMENT

		Levobupivacaine Mean	Levobupivacaine SD	Ropivacaine Mean	Ropivacaine SD	P VALUE
MOVEMENT	BASELINE	0	0	0	0	0.7179550816
	15Min	0 .0444	0 .2062	0	0	
	30Min	0 .0222	0 .1474	0	0	
	45Min	0 .0222	0 .1474	0 .087	0 .2849	
	60Min	0.0667	0 .2496	0.0652	0 .2496	
	75Min	0 .0889	0 .2849	0 .087	0 .2849	
	90Min	0 .0667	0 .2496	0 .087	0 .2849	
	105Min	0 .0222	0 .1474	0 .0217	0 .1474	
	120Min	0	0	0 .0217	0 .1474	

At baseline, both Levobupivacaine and Ropivacaine had no recorded movement events (mean = 0, SD = 0). Movement events appeared sporadically over time. At 15 minutes, Levobupivacaine recorded a mean movement occurrence of 0.0444 (SD = 0.2062), while Ropivacaine had no recorded movements. By 30 minutes, Levobupivacaine mean decreased to 0.0222 (SD = 0.1474), while Ropivacaine remained at 0. At 45 minutes, Levobupivacaine mean stayed at 0.0222 (SD = 0.1474), whereas Ropivacaine showed a slight increase with a mean of 0.087 (SD = 0.2849). At 60 minutes, both groups exhibited similar movement= 0.2496). By 75 minutes, movement events slightly increased in both groups, with Levobupivacaine at 0.0889 (SD = 0.2849) and Ropivacaine at 0.087 (SD = 0.2849). At 90 minutes, Levobupivacaine recorded a mean of 0.0667 (SD = 0.2496), while Ropivacaine remained at 0.087 (SD = 0.2849). At 105 minutes, both groups showed minimal movement, with Levobupivacaine at 0.0222 (SD = 0.1474) and Ropivacaine at 0.0217 (SD = 0.1474). Finally, at 120 minutes, Levobupivacaine had no recorded movements, while Ropivacaine had a mean movement occurrence of 0.0217 (SD = 0.1474). Overall, movement events were minimal and sporadic, with no substantial differences between the two groups.

Graph 8: Movement

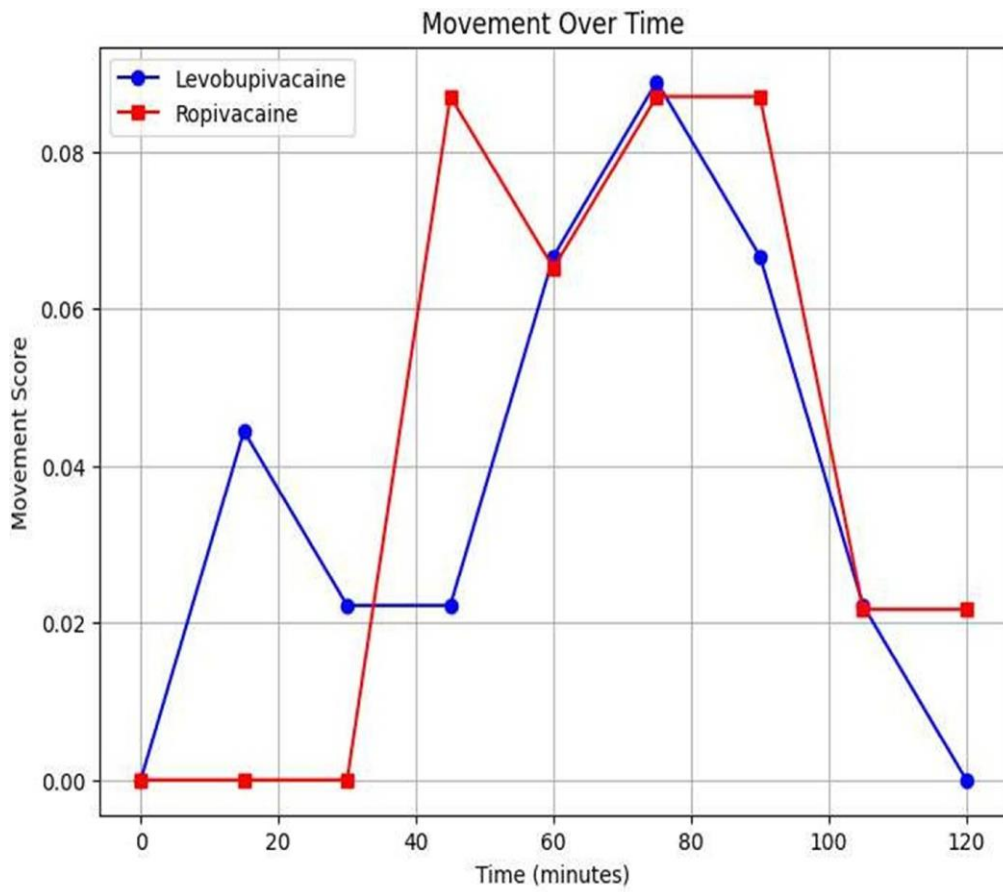


Table 11: AGITATION

		Levobupivacaine Mean	Levobupivacaine SD	Ropivacaine Mean	Ropivacaine SD	P VALUE
AGITATIO N	BAS ELIN E	0	0	0	0	0.61426141 6
	15Mi n	0	0	0	0	
	30Mi n	0.0222	0.1474	0.0435	0.2062	
	45Mi n	0	0	0.0217	0.1474	
	60Mi n	0.1111	0.3147	0.0217	0.1474	
	75Mi n	0.0667	0.2496	0.087	0.2849	
	90Mi n	0.0222	0.1474	0.0435	0.2062	
	105M in	0	0	0.0435	0.2062	
	120M in	0.0222	0.1474	0	0	

At baseline and 15 minutes, both Levobupivacaine and Ropivacaine had no recorded agitation events (mean = 0, SD = 0). At 30 minutes, Levobupivacaine recorded a mean agitation occurrence of 0.0222 (SD = 0.1474), while Ropivacaine had a slightly higher mean of 0.0435 (SD = 0.2062). At 45 minutes, Levobupivacaine had no agitation events, whereas Ropivacaine recorded a mean of 0.0217 (SD = 0.1474). By 60 minutes, Levobupivacaine had a notable increase in agitation events with a mean of 0.1111 (SD = 0.3147), while Ropivacaine remained lower at 0.0217 (SD = 0.1474). At 75 minutes, both groups had similar occurrences, with Levobupivacaine at 0.0667 (SD = 0.2496) and Ropivacaine at 0.087 (SD = 0.2849). At 90 minutes, Levobupivacaine had a mean of 0.0222 (SD = 0.1474), while Ropivacaine recorded 0.0435 (SD = 0.2062). At 105 minutes, Levobupivacaine had no agitation events, while Ropivacaine maintained a mean of 0.0435 (SD = 0.2062). Finally, at 120 minutes, Levobupivacaine recorded a mean agitation event occurrence of 0.0222 (SD = 0.1474), while Ropivacaine had none. Overall, agitation events were sporadic and minimal in both groups, with no major differences between them.

Graph 9: Agitation

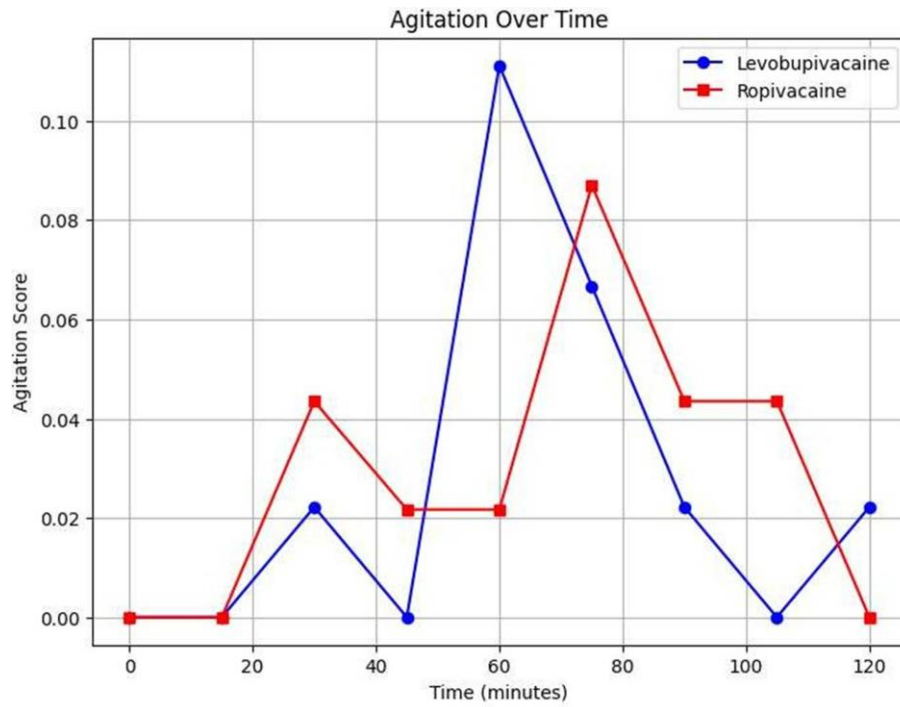
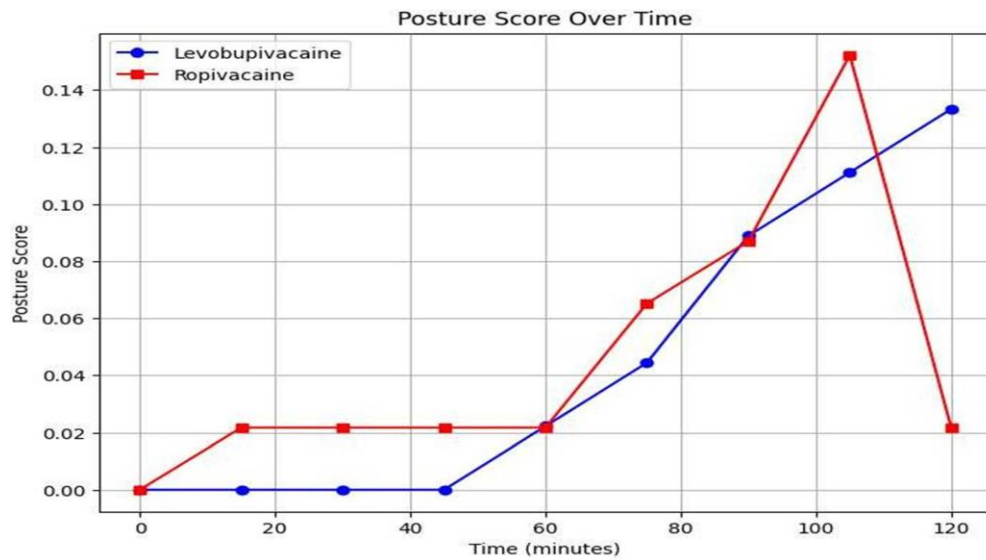


Table 10: Posture

		Levobupivacaine Mean	Levobupivacaine SD	Ropivacaine Mean	Ropivacaine SD	P VALUE
POSTURE	BASE LINE	0	0	0	0	0.6585646189
	15 Min	0	0	0.0217	0.1474	
	30 Min	0	0	0.0217	0.1474	
	45 Min	0	0	0.0217	0.1474	
	60 Min	0.0222	0.1474	0.0217	0.1474	
	75 Min	0.0444	0.2062	0.0652	0.2496	
	90 Min	0.0889	0.2849	0.087	0.2849	
	105 Min	0.1111	0.3147	0.1522	0.3632	
	120 Min	0.1333	0.3405	0.0217	0.1474	

At baseline, both Levobupivacaine and Ropivacaine had no recorded posture events (mean = 0, SD = 0). At 15, 30, and 45 minutes, Ropivacaine recorded a slight increase in posture events (mean = 0.0217, SD = 0.1474), while Levobupivacaine remained at 0. At 60 minutes, both groups had comparable posture event occurrences (Levobupivacaine: mean= 0.0222, S D = 0.1474; Ropivacaine: mean = 0.0217, S D= 0.1474). The frequency of posture events increased in both groups at later time points, with Levobupivacaine showing a steady rise from 75 minutes (mean = 0.0444, SD = 0.2062) to 120 minutes (mean = 0.1333, SD = 0.3405). Ropivacaine followed a similar trend, peaking at 105 minutes (mean = 0.1522, SD = 0.3632) before dropping at 120 minutes (mean = 0.0217, SD = 0.1474). Although slight variations were observed, posture event occurrences remained relatively low throughout the study duration.

Graph 10: Posture



		Levobupivacaine	Levobupivacaine	Ropivacaine	Ropivacaine	P value
		Mean	SD	Mean	SD	
Verbal ization of pain	BAS ELIN E	0	0	0	0	0.3616630 21
	15 Min	0	0	0	0	
	30 Min	0	0	0	0	
	45 Min	0	0	0	0	
	60 Min	0	0	0	0	
	75 Min	0	0	0	0	
	90 Min	0	0	0	0	
	105 Min	0	0	0	0	
	120 Min	0.0222	0.1474	0.0435	0.2062	

Table 13: Verbalisation of pain

At baseline, neither Levobupivacaine nor Ropivacaine reported any verbalization of pain (mean = 0, SD = 0). Throughout the observation period, there were no verbalization of pain recorded at 15, 30, 45, 60, 75, 90, and 105 minutes, with both groups maintaining a mean of 0 and SD of 0. However, at 120 minutes,

Levobupivacaine recorded a slight occurrence of pain complaints (mean = 0.0222, SD = 0.1474), while Ropivacaine had a slightly higher mean of 0.0435 (SD = 0.2062). Despite this minor variation, verbalization of pain were largely absent in both groups throughout the study duration.

Graph 11: Verbalization of pain

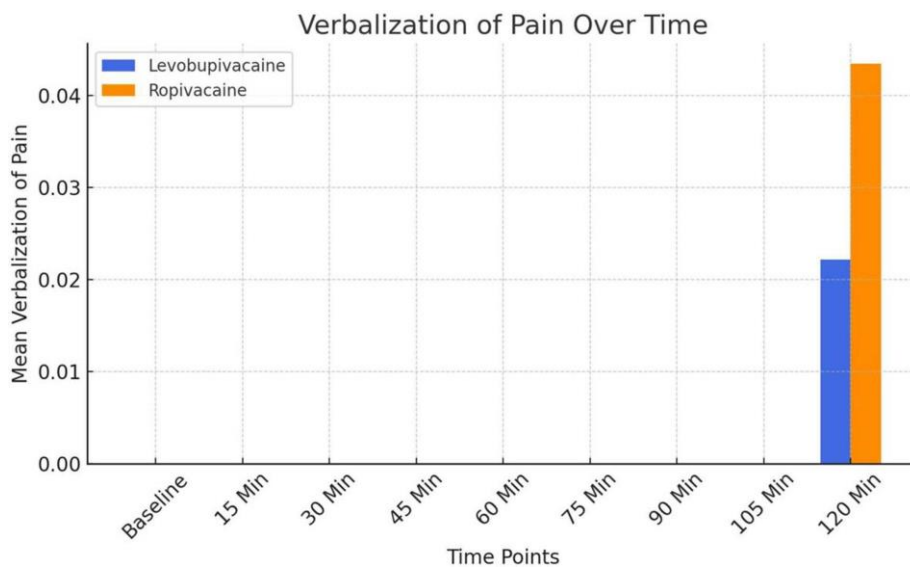
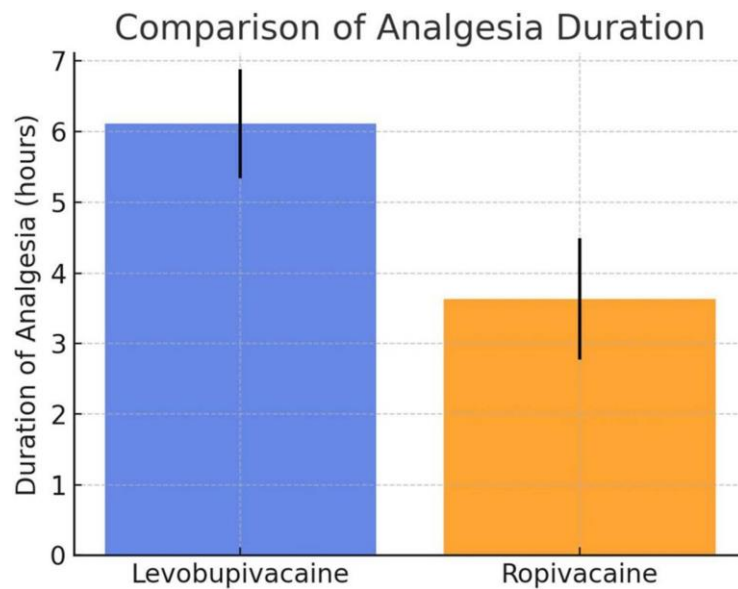


Table 12: ANALGESIA DURATION

	Analgesia duration		P Value
	Levobupivacaine	Ropivacaine	P < 0.0001
Mean	6.108695652	3.630434783	
SD	0.7667611788	0.8591648568	

The mean analgesia duration was significantly longer in the Levobupivacaine group (mean = 6.11 hours, SD = 0.77) compared to the Ropivacaine group (mean = 3.63 hours, SD = 0.86), with a highly significant difference (p < 0.0001). This indicates that Levobupivacaine provided a more prolonged analgesic effect compared to Ropivacaine.

Graph 12: Analgesia duration



## **DISCUSSION**

Regional anaesthesia is becoming very popular in paediatric individuals, even though general anaesthesia is most oftenly used technique. Adequate anaesthesia and appropriate postoperative pain management are provided by caudal anaesthesia both before and after surgery, regarded it as one of the commonly used regional blocks used in paediatric sub umbilical procedures. It is safe, dependable, simple to use, and not linked to any serious side effects.

A total of 92 participants took part in our study, and the participants had been divided up into two separate groups of 46.

The Ropivacaine groups mean age was 6.74 years with a standard deviation of 2.61, whereas the Levobupivacaine groups mean age was 5.54 years with a standard deviation of 3.27. Although the 2 groups were identical in terms of age, age had no bearing on the comparison of these medications.

Multiple physiological data was recorded at various time intervals between the levobupivacaine and ropivacaine groups such as heart rate, oxygen saturation (SpO<sub>2</sub>), diastolic blood pressure (DBP), and systolic blood pressure (SBP). Overall, there were no statistically significant differences in SBP, DBP, or SpO<sub>2</sub> levels between the ropivacaine and levobupivacaine groups, however there were minor variances in systolic blood pressure & heart rate at particular intervals between ropivacaine and levobupivacaine groups, suggesting that the two medications in this trial had comparable physiological effects.

The duration of analgesia is a key factor in the effectiveness of local anaesthetics used in caudal epidural anaesthesia. The extended analgesic duration reduces the need for supplemental pain relief, which may decrease opioid use and associated side effects.

Our study's findings suggest that both groups had little agitation, movement, crying or verbalization of pain, as we described in the results chapter. Rare instances of posture and blood pressure incidents occurred, so there was not a significant distinction between the two groups. It is a better option for prolonged pain relief because it persists for prolonged time for extra postoperative pain treatment.

Our findings line up with the results of other research studies, such as one by Khushboo Malav et al., evaluated the efficacy of ropivacaine 0.5% & levobupivacaine 0.5% for foot and ankle procedures shown that in sciatic nerve blocks, 0.5% Levobupivacaine considerably extends the postoperative analgesia duration more than ropivacaine 0.5%.

Another study conducted by Jagdeep Sharma and other researchers to evaluate the caudal effectiveness score and duration of analgesia of levobupivacaine 0.25 %, ropivacaine 0.25 %, and bupivacaine 0.25 %. Levobupivacaine and ropivacaine had similar durations of postoperative analgesia. Bupivacaine produced analgesia for a longer duration than ropivacaine and levobupivacaine. These two studies confirm our findings by demonstrating that levobupivacaine produces analgesia for a longer duration than ropivacaine.

Ajay Singh et al. carried out a study to assess the efficacy of hyperbaric racemic bupivacaine 0.5% versus plain levobupivacaine 0.5 % for spinal anaesthesia during inguinal hernia operations. The findings demonstrated that 0.5% levobupivacaine had a shorter duration of sensory & motor block and permitted earlier movement during daycare protocols. Compared to bupivacaine, this has been associated to a lower incidence of intraoperative hypotension. Pasquale DeNegri, M.D, Giorgio Ivani, M.D.et al. studied the effects of these three local anesthetics 1 mL /kilogram with either ropivacaine of 0.2%, racemic bupivacaine of 0.25%, or levobupivacaine of 0.2%

on postoperative analgesia or motor block in children aged one to seven. Their results demonstrated that when given caudally to children, bupivacaine 0.25%, levobupivacaine 0.25%, & ropivacaine 0.2% offered similar postoperative analgesia. In the early postoperative phase, ropivacaine had been associated to a lower rate of motor block than racemic bupivacaine.

## **CONCLUSION**

Both Levobupivacaine and Ropivacaine demonstrated similar effects on hemodynamic stability, respiratory function, and behavioural responses indicating a possible advantage in postoperative comfort. However, with comparison to Ropivacaine, Levobupivacaine provides a significant longer duration of analgesia, making it a more effective option for prolonged pain control. This finding aligns with other research findings which reported similar intraoperative quality and safety profiles but varying durations of analgesia for Ropivacaine.

Given its longer duration of analgesia and comparable safety profile, Levobupivacaine may be a preferable choice in paediatric caudal anaesthesia where prolonged pain relief is desired. In future study, with large number of samples and longer follow-ups may further strengthen these findings and assess additional factors such as recovery profiles, patient satisfaction, and the role of analgesic adjuncts in optimizing pain management strategies.

## **SUMMARY**

The current study titled “COMPARISON OF LEVOBUPIVACAINE 0.25% AND ROPIVACAINE 0.25% FOR CAUDAL EPISURAL ANAESTHESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERIES” -A RANDOMISED CLINICAL TRIAL was conducted among 92 ASA I and II patients aged between 1 to 11 years scheduled for elective infraumbilical surgeries under caudal epidural anaesthesia as per the inclusion and exclusion criteriae. The patients were randomly divided in two groups by computerised randomisation method, Group L received 0.25% levobupivacaine 1ml/kg and Group R received 0.25% ropivacaine 1ml/kg.

Following parameters were seen in present study -

- ❖ Haemodynamic – Heart rate, Blood pressure, Spo2.
- ❖ Intraoperatively – Caudal effectiveness score.
- ❖ Post operatively Modified Hannallah pain score up to 2hrs.
- ❖ Rescue analgesia used if required.

In present study the observations are as follows – Haemodynamic parameters (heart rate, blood pressure, and oxygen saturation), and postoperative pain management using Modified Hannallah Pain Score (MHPS). Results indicated that heart rate, systolic and diastolic blood pressure, and oxygen saturation remained comparable between both groups, with no statistically significant differences. Postoperative observations such as crying, movement, agitation, posture, and verbalisation of pain were minimal in both groups, showing no significant variations. However, the analgesic duration was significantly longer for Levobupivacaine (6.11 hours)

compared to Ropivacaine (3.63 hours) ( $p < 0.0001$ ), suggesting superior pain relief in the Levobupivacaine group.

Overall, the findings suggest that Levobupivacaine provides longer analgesia than Ropivacaine while maintaining similar safety profiles, making it a preferable choice for paediatric caudal anaesthesia.

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**ANNEXURE – I - INFORMED CONSENT FORM**

**"COMPARISON OF LEVOBUPIVACAINE 0.25% AND ROPIVACAINE 0.25% FOR CAUDAL EPIDURAL ANAESTHESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERY" - A RANDOMISED CLINICAL TRIAL.**

**INFORMED CONSENT FORM**

**Name of Student/Principal Investigator:** Dr. xxxx

**Name of Guide/Co-Investigators:** Dr. xxxx

**Objective:** To evaluate the effectiveness of 0.25% Levobupivacaine and 0.25% Ropivacaine in paediatric patients undergoing infraumbilical surgeries under caudal epidural anaesthesia.

**Introduction:** Anaesthesia for paediatric patients is highly specialized because of the physiological, pharmacological, and psychological differences between children and adults. Regional anaesthesia techniques have become routine interventions in children and infants. Paediatric regional anaesthesia is an excellent technique for balanced intraoperative and postoperative analgesia. The most frequently used technique is epidural block through a caudal approach.

It is a useful adjunct during general anaesthesia and for providing postoperative analgesia after genital, lower abdominal and lower limb operations. It can reduce the inhaled and intravenous anaesthetic requirement, attenuate the stress response to surgery, facilitate a rapid smooth recovery, and provide good immediate postoperative analgesia

Racemic Bupivacaine 0.25% is the most widely used local anaesthetic by the caudal route in paediatric patients. However, preliminary evidence suggests that Levobupivacaine and Ropivacaine may be associated with less systemic toxicity.

Levobupivacaine is a L-isomer of bupivacaine, which has a better margin of safety for local anaesthetic systemic toxicity and has been accepted for continuous infusion and large volume regional blocks. Various studies have evaluated the effect of Levobupivacaine and found it to be an effective agent for caudal anaesthesia in children up to a dose of 2.5mg/kg/body weight. It is known to have a rapid onset of surgical anaesthesia and is also found to be effective in postoperative analgesia in comparison with bupivacaine 0.25%.

Ropivacaine is a local anaesthetic, which is recently approved for use and is less toxic to the central nervous system and heart and interferes less with motor function than bupivacaine, these characteristics of Ropivacaine could beneficially be of great benefit in a paediatric population. Literature search did not reveal any study comparing Levobupivacaine and Ropivacaine for a caudal epidural anaesthesia in paediatric patients. Hence we make an attempt to evaluate the effectiveness of 0.25% Levobupivacaine and 0.25% Ropivacaine in paediatric patients undergoing infraumbilical surgeries under caudal epidural anaesthesia.

**Explanation of procedure:** If you agree to enroll in my study, I will ask you present, past, and family history. Then you will be clinically examined in detail. You will be allotted into one of the three groups randomly generated by computer-generated software.

Group L: Patients will receive 1ml/kg/body weight of 0.25% Levobupivacaine for caudal epidural anaesthesia

Group R: Patients will receive 1ml/kg/body weight of 0.25% Ropivacaine for caudal epidural anaesthesia

**Withdrawal from participation in the study:** Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

**Possible benefits of participating in the study:** You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

**Possible risks of participating in the study:** There are no risks involved in participating in this study.

**Privacy and confidentiality:** The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

**Financial incentives:** You will not receive any payment for participating in this study.

**Authorization for publication of aggregated data:** Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

**Questions:** In case you have any questions related to the study, in the future, or in case of study-related injury or illness, you can contact the following

If you have any questions or complaints with regard to your right as a study participant you may contact **Dr. Harsha Hegde**, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

**Legal rights:** By signing this consent form, we are not waiving any of your legal rights.

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**CONSENT STATEMENT**

I am making a voluntary decision to participate in the study

**"COMPARISON OF LEVOBUPIVACAINE 0.25% AND ROPIVACAINE 0.25% FOR CAUDAL EPIDURAL ANAESTHESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERY"- A RANDOMISED CLINICAL TRIAL.**

My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

**ANNEXURE - II PROFORMA**

**"COMPARISON OF LEVOBUPIVACAINE 0.25% AND ROPIVACAINE 0.25% FOR CAUDAL EPIDURAL ANAESTHESIA IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERIES"-A RANDOMISED CLINICAL TRIAL**

**GROUP ALLOTTED:**

**L**

**R**

Date of Examination:

IP NO:

Name:

Age:

Gender:

Weight:

Address:

Informant and relationship with the participant:

**PRE-ANAESTHETIC EVALUATION**

**Chief Complaints:**

**Past History:**

<b>Hypertension</b>		<b>Drug Therapy</b>	
<b>ICU admission</b>		<b>URTI</b>	
<b>Diabetes Mellitus</b>		<b>Valvular Heart Disease</b>	

<b>Asthma</b>			
<b>Tuberculosis</b>			
<b>Ischaemic Heart Disease</b>		<b>Previous Surgeries</b>	

**Family History:****General physical examination**

<b>Weight</b>		<b>Pallor</b>	
<b>Height</b>		<b>Icterus</b>	
<b>Temperature</b>		<b>Cyanosis</b>	
<b>Pulse</b>		<b>Clubbing</b>	
<b>Blood Pressure</b>			
<b>Respiratory Rate</b>			

**Systemic examination:**

<b>Respiratory System</b>		<b>CNS</b>	
<b>CVS</b>		<b>GIT</b>	

**Airway Assessment:**

Mouth Opening:

Teeth:

Jaw Movements:

Spine:

**Investigations:**

Hb%: Platelet Count:

TLC: INR:

FBS: Prothrombin time:

Serology:

**PREOPERATIVE PHYSICAL STATUS**

ASA Grade I II III IV V

**Diagnosis:**

**Proposed surgery:**

**DATA ANALYSIS:**

	Caudal effectiveness score
At 5 Min	
At 10 Min	
At 15 Min	
At 20 Min	

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**INTRAOPERATIVE PARAMETERES**

	<b>HR</b>	<b>SBP</b>	<b>DBP</b>	<b>SPO2</b>
Baseline				
At 5 Min				
At 10 Min				
At 15 Min				
At 20 Min				
At 25 Min				
At 30 Min				
At 35 Min				
At 40 Min				
At 45 Min				
At 50 Min				
At 55 Min				
At 60 Min				

<b>Parameters</b>	
Duration of postoperative Analgesia	
Complications (if any)	

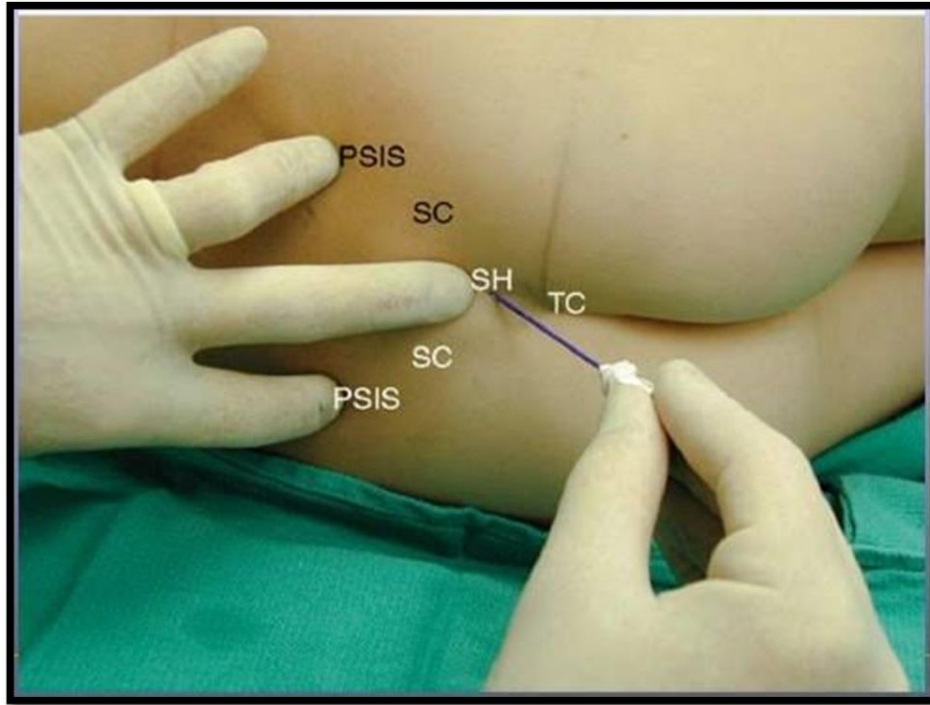
MODIFIED HANNALLAH PAIN SCORE (MHPS)

	<b>BP</b>	<b>Crying</b>	<b>Movement</b>	<b>Agitation</b>	<b>Posture</b>	<b>Verbalisation of pain</b>
Base Line						
At 15 Min						
At 30 Min						
At 45 Min						
At 60 Min						
At 75 Min						
At 90 Min						
At 105 Min						
At 120 Min						

Name of the Investigator:

Name of the Guide:

**ANNEXURE - III**  
**PHOTOGRAPHS**



**PHOTOGRAPHS 1: CAUDAL PROCEDURE**



**PHOTOGRAPHS 2: CAUDAL EPIDURAL TRAY**



**PHOTOGRAPHS 3: 0.25% LEVOBUPIVACAINE**

**ANNEXURE – IV**

**MASTER CHART**







