

**A COMPARATIVE STUDY OF 0.25%
BUPIVACAINE AND 0.25% ROPIVACAINE
THROUGH CAUDAL BLOCK FOR PAEDIATRIC
SUB-UMBILICAL SURGERIES**

Dissertation

Submitted in partial fulfilment of the regulation of

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BRANCH X ANAESTHESIOLOGY**



**STANLEY MEDICAL COLLEGE
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CERTIFICATE

This is to certify that the dissertation titled “**A Comparative Study of 0.25% Bupivacaine and 0.25% Ropivacaine through Caudal block for Paediatric Sub-Umbilical Surgeries**” is a bonafide original work done by **Dr. Sendhil Kumar Mohan** during May 2009-April 2011 in partial fulfillment of the requirements for M.D. (Anaesthesiology) Branch X Examination of the TamilNadu Dr.M.G.R. Medical University to be held in April 2011.

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DECLARATION

I **Dr. SENDHIL KUMAR MOHAN** solemnly declare that this dissertation, titled “**A COMPARATIVE STUDY OF 0.25% BUPIVACAINE AND 0.25% ROPIVACAINE THROUGH PAEDIATRIC CAUDAL BLOCK FOR SUB-UMBILICAL SURGERIES**” is a bonafide record of work done by me in the Department of Anesthesiology, Stanley Medical College and Hospital, Chennai under the guidance of **Prof. Dr.S.PONNAMBALA NAMASIVAYAM, M.D.,D.N.B.,D.A.**, Professor of Anesthesiology, Government Stanley Medical College & Hospital, Chennai- 600 001.

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I ntroduction

INTRODUCTION

The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”.¹ In children, even the definition of pain has been debated.² In fact, pain experienced by infants and children often goes unrecognized or even neglected.³ Research over the past two decades has provided incontrovertible evidence that not only do neonates experience pain but also that unrelieved pain has adverse long-term consequences, including harmful neuroendocrine responses, disrupted eating and sleep cycles, and increased pain perception during subsequent painful experiences.^{4,5,6}

Pain management is an essential component of care provided by paediatric anesthesiologists. Regional anaesthesia plays an important role in providing pain relief both in the intra-operative and post-operative periods in paediatrics. Caudal epidural anaesthesia is the most commonly practiced regional technique in children. The practice of placing a caudal block before incision in general anaesthesia results in reduced inhaled concentrations of volatile anaesthetics intraoperatively.⁷

Local anaesthetics are commonly used either alone or with additives through the caudal route but the motor block produced may be a cause of distress to children in the postoperative period.⁸

Bupivacaine is a long-acting amide local anaesthetic that has provided reliable anaesthesia and analgesia with differential motor-sensory blockade for more than 40 years.^{9,10} But, toxicity due to accidental intravascular or intrathecal injections of bupivacaine resulting in severe neurological, cardiovascular depression even leading to death prompted studies on the mechanism of the cardiotoxic effects of local anaesthetics and search for drugs with less cardiotoxicity.^{11,12} Bupivacaine is commercially available as racemic mixture of R- and S- enantiomers. It has been shown that block of the inactivated state of the cardiac sodium and potassium channels is stereoselective, with R-bupivacaine being more potent than S-bupivacaine.¹³

In response to the problem of increased cardiac toxicity of racemic mixtures of bupivacaine, single enantiomers were developed and Ropivacaine is the first local anaesthetic to be prepared as a pure S-enantiomer.¹⁴ Studies have shown that ropivacaine is less cardio and neurotoxic than bupivacaine.^{14,15,16} The sensory block provided by ropivacaine is similar to that produced by an equivalent dose of

bupivacaine in extradural and peripheral nerve block whereas the motor block produced by ropivacaine is slower in onset, less intense and shorter in duration than bupivacaine.¹⁴

These features combined with decreased cardiovascular and neurological toxicity make ropivacaine very useful in paediatric practice especially for day case surgery which is increasing in frequency. Hence, this study was undertaken to compare the effectiveness of ropivacaine with bupivacaine for caudal anaesthesia in children.

Aim of the Study

AIM OF THE STUDY

To compare 0.25% Ropivacaine and 0.25% Bupivacaine, given in a volume of 0.75ml/kg through a single Presurgical Caudal block in children aged 3-8 years undergoing sub-umbilical procedures in terms of the Quality and Duration of Analgesia, Motor and Sensory block.

Caudal anaesthesia

CAUDAL EPIDURAL ANALGESIA

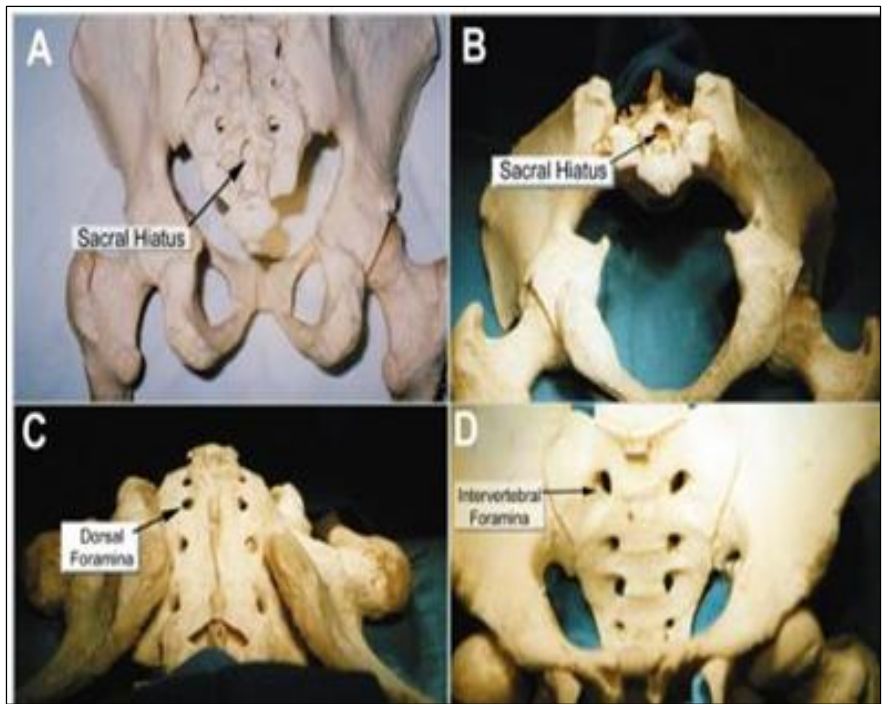
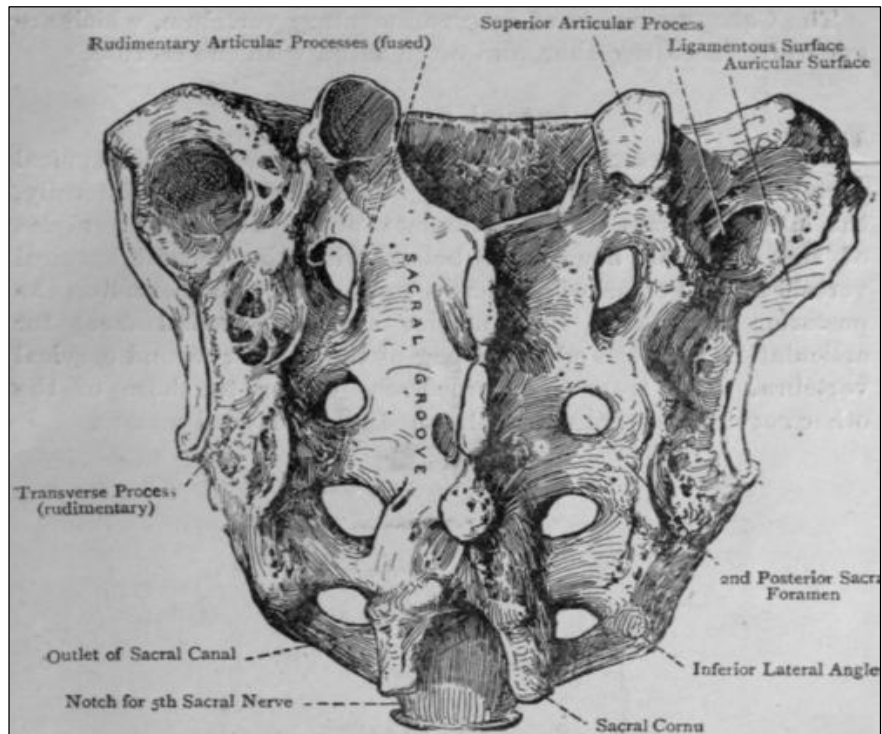
ANATOMY OF SACRUM^{17,18}

The Sacrum is formed by the gradual fusion of the lamina of the five sacral vertebrae. Variations of this fusion are common and are responsible for the failure rate of caudal epidural analgesia.

The sacrum is triangular in shape, the apex below articulates with the coccyx, while the base above has medial and lateral portions. The medial part represents the body of the 1st sacral vertebra and articulates with the corresponding surface of the body of the 5th lumbar vertebra. The lateral portions (alae) represent fused costal and transverse elements.

The anterior surface is concave and ridged at the sites of fusion between the five sacral vertebrae (Fig. 1). Lateral to the ridges are the large anterior sacral foramina through which the anterior primary rami of the first four sacral nerves pass. These are formed due to the fusion laterally of the transverse processes of the sacral embryologic segments. There are usually four such foramina, the fifth being absent. Local anaesthetic solution injected into the sacral epidural space pass freely through these foramina.

Fig.1. Anatomy of Sacrum



The posterior surface which is rough has greater interest for the anaesthesiologist. It is convex and in the midline runs a bony ridge, the median sacral crest with three or four rudimentary spinous processes.

The Sacral hiatus is a deficiency of posterior wall resulting from failure of fusion of the lamina of the fifth sacral vertebra that communicates with the sacral portion of the vertebral canal. This hiatus is triangular in shape with its apex at the spine of fourth sacral vertebra. In surface marking, it normally forms an approximately equilateral triangle with the two posterior superior iliac spines. There are bony prominences on the lateral margins of the space – the sacral cornua – which represent the inferior articular processes of the fifth sacral vertebra. The base of the hiatus is the superior surface of the coccyx. The posterior Sacrococcygeal ligament, a continuation of the ligamentum flavum, is attached to the bony margin and covers the hiatus. In some cases the apex of the hiatus is the third sacral spine, due to the absence of the third and fourth laminae, and occasionally the whole of the bony posterior wall is deficient. When the lamina of the fifth sacral vertebra is present, the hiatus may be very small with a diameter as narrow as 2mm making the introduction of a caudal needle almost impossible.

There are four pairs of posterior sacral foramina corresponding with the anterior ones. The sacral canal is triangular and is the continuation of the epidural space and the dural sac, which usually terminates at the lower border of the second sacral vertebra though occasionally it extends below this point. The caudal epidural space contains the sacral and coccygeal nerve roots and filum terminale and continuation of the epidural venous plexus. Fibrous bands may be present in the sacral epidural space dividing it into loculi which prevent the spread of local anesthetic solutions and may result in incomplete anaesthesia.

PHYSIOLOGICAL EFFECTS¹⁷

Local anaesthetic introduced into the epidural space blocks nerve conduction to an extent determined by concentration and volume of the drug injected, sensitivity of different fibre types and by the drug employed. Although all agents tend to block preganglionic B fibres more readily, followed by pain fibres, touch, proprioception and motor fibres in that order when injected epidurally, there is a difference in the selectivity for different sensory fibres. Smaller and unmyelinated C and A delta fibres are blocked earlier than the larger nerve fibres.

The effects of caudal block on the cardiovascular system are minimal except in cases of high caudal block. The blood pressure and heart rate do not decrease significantly. Respiration is usually not affected even in high block.

TECHNIQUE¹⁷

The sacral hiatus at the lower end of sacrum is extremely easy to identify in infants and young children. The Sacral hiatus is relatively more cephalad in infants and thus the distance between the sacral hiatus and the end of dural sac is relatively short.

The lateral position is most often employed to perform a caudal block in children. To identify the sacral hiatus, the tip of the coccyx should be first palpated with the left index finger applying firm pressure to identify the coccyx and then the finger gently from side to side proceeding in a cephalad direction. The first double bony protruberances encountered are the two cornua of sacrum that define the sacral hiatus. The cornua should be marked either mentally or with the skin marking pen. The sacral hiatus can also be identified by drawing an equilateral triangle with the line joining the two posterior superior iliac spines forming the base and the sacral hiatus forming the apex (Fig. 2).

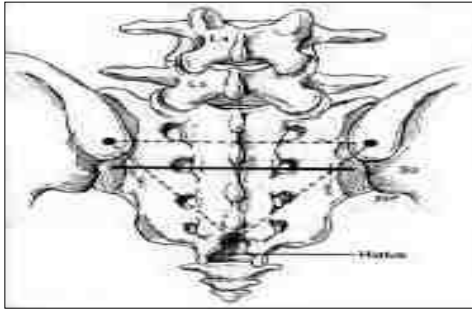
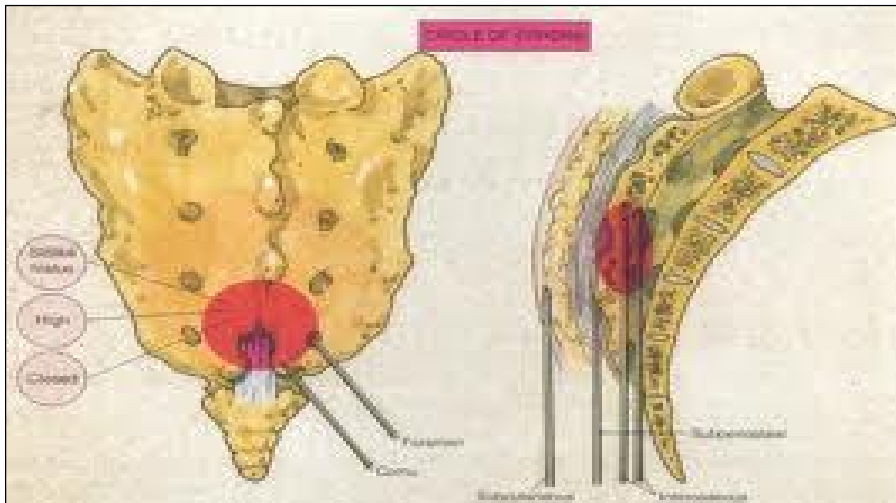
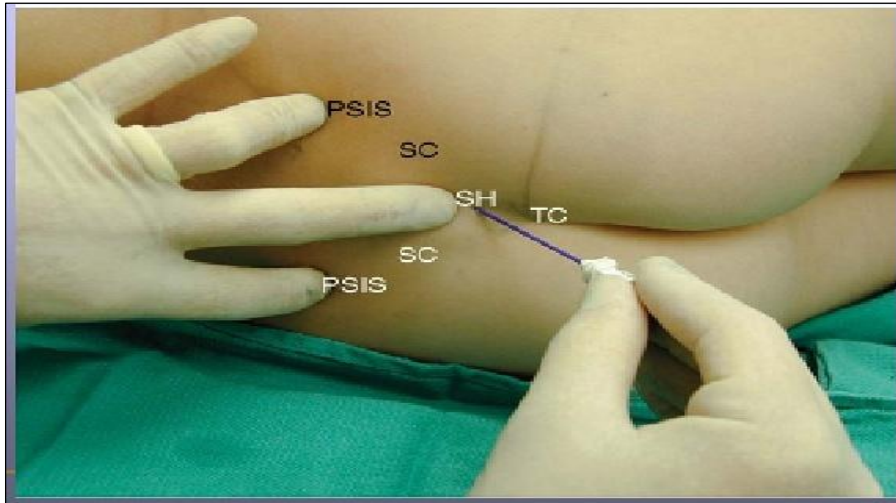


Fig.2. Surface Anatomy

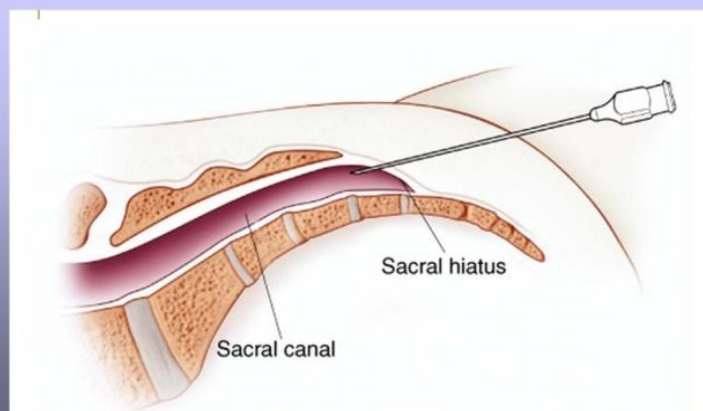
After careful skin preparation, the sacral hiatus is again identified using firm pressure by the left index finger. Strict aseptic precautions should be maintained. A short beveled 23 gauge needle, preferably Crawford needle, is placed in the midline in the notch between the sacral cornua at an angle of about 45° with the skin (first position) and directed cranial to penetrate the sacrococcygeal ligament, at which time contact is made with the anterior bony wall of the caudal canal(second position)(Fig.3). The needle is then depressed almost flush with the skin and then advanced into the sacral canal for 2 to 3 cm.

The advancement should not be higher than a line joining the posterior superior iliac spines (S2 vertebra) since the dural sac ends between the first and second sacral vertebrae in majority of patients and even lower in neonates and infants. Auscultation of sound over the caudal canal by injecting air (Oosh) or drug (Swoosh) can be done to confirm the presence of the needle in the caudal space. After negative aspiration for blood or cerebrospinal fluid, the appropriate amount of local anesthetic is injected and the child is placed in supine position.

Fig.3. Needle insertion



Lateral view of the caudal space and needle insertion.



CALCULATION OF VOLUME OF LOCAL ANAESTHETIC FOR CAUDAL ANAESTHESIA

1. Armitage formula :¹⁹

Sacral dermatomes – 0.5ml/kg,

Sacral and lumbar – 1ml/kg

Mid-thoracic – 1.25ml/kg

2. Spiegel formula:²⁰

For upper abdominal surgery, $V = 4 + D - 15/2$ where V is the volume of local anesthetic in milliliters and D is the distance between C7 and the sacral hiatus in centimeters.

3. Satayoshi formula:²¹

$V = D - 13$ Where V is the volume of local anesthetic in milliliters and D is the distance from C7 to the sacral hiatus in centimeters.

4. Schulte-Scheinberg and Rahlfs formula:²²

Volume in ml /spinal segment = $0.0558 + 0.09729(\text{age in years})$

5. Takasaki formula:²³

Volume in ml / spinal segment = $0.056 (\text{weight in kg}) - 0.002$

Physiology of Pain and its Assessment in Children

PHYSIOLOGY OF PAIN

Pain is a complex constellation of unpleasant sensory, perceptual and emotional experiences and certain associated autonomic, psychological, emotional, and behavioral responses. Untreated pain in children, as the result of vaccinations and blood draws, surgery, headaches or repeated painful procedures, can have long-term effects.²⁴

NEUROPHYSIOLOGY OF PAIN²⁵

A variety of chemical, thermal or mechanical insults can result in the sensation of pain. A mosaic of pain receptors or nociceptors in the body tissues ultimately project to pain centers in the brain. The somatosensory system is subserved by different groups of afferent fibers differentiated by their anatomy, rate of transmission and sensory modality transmitted. The afferent fibres that relay pain information to the dorsal horn of the spinal cord and then on to the brain include small-diameter C-fibres and thinly myelinated A-delta fibres.

The dorsal horn is organized into fairly discrete lamellae. The primary afferent first-order synapses (nociceptive-specific neurons) are located in layers 1, 2 and 5 of the dorsal horn. Signals are then relayed rostrally to the thalamus and the cortex. In addition, afferent impulses

are carried to the brainstem, limbic system, and hypothalamus to mediate many of the autonomic and affective component responses to noxious stimuli. Deeper in the dorsal horn are located wide dynamic range neurons (WDR) that appear to be important in the development of hyperalgesia or wind-up phenomenon. These neurons may be responsible for firing in pain syndromes that are not associated with obvious tissue-damage as well.

DEVELOPMENTAL NEUROBIOLOGY OF PAIN

Nociceptive pathways in the periphery, spinal cord, and brain develop in a series of stages through the second and third trimester in humans. By 26 weeks of postconceptual age there is sufficient maturation of peripheral and spinal afferent transmission for the late-gestation fetus or preterm neonate to respond to tissue injury or inflammation with withdrawal reflexes, autonomic arousal and hormonal-metabolic stress responses. There are also changes in responsiveness after injury or repetitive stimulation indicative of central sensitization.²⁶

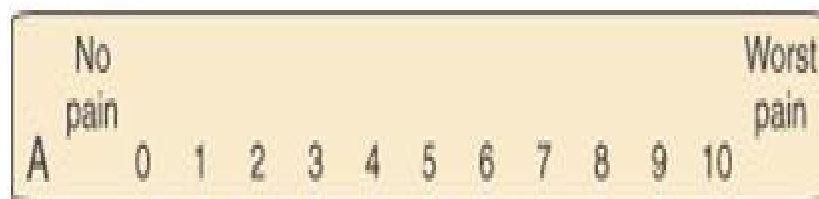
It is important to understand that pain due to surgical procedures not only results in an immediate nociceptive response but also results in

changes in the nociceptive activation pathways that lead to hypersensitivity, hyperalgesia and allodynia.^{27,28}

ASSESSMENT OF PAIN

SELF-REPORTING TECHNIQUES

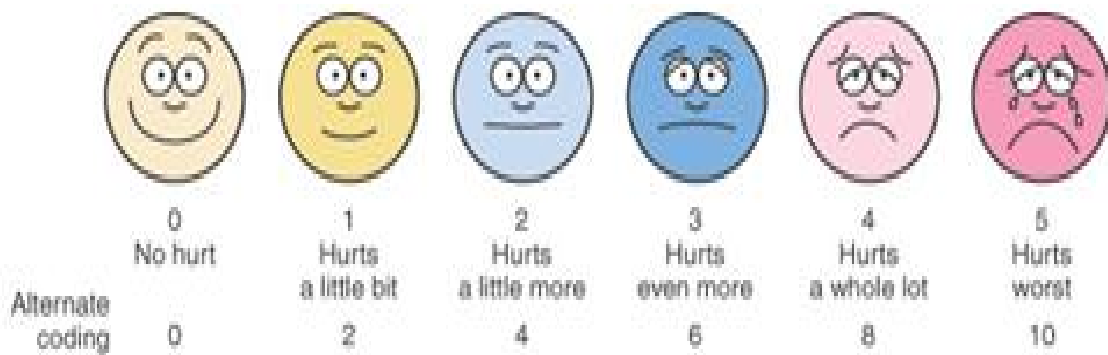
A. Visual analog pain scale (VAS):²⁹ It is often considered to be the gold standard for pain assessment. It is a 10cm horizontal line defined by “no pain” on the left end and “severe pain” on the right. It is used in older children and adolescents. The patient slides the cursor along the ruler until it reaches the level that represents the intensity of his pain. The other side of the ruler is graduated over 10mm and gives the investigator a numerical measure of pain. In children, the Verbal analog scale³⁰ (pain rated from 0- no pain to 10- most possible pain) may be more reliable.



B. Analogue Chromatic Continuous Scale (ACCS):³¹ The VAS has been modified for smaller children to equate pain intensity with colours in this scale. Instead of a line, the patient's side of the scale is a wide band of colour ranging from pink for no pain to dark red for

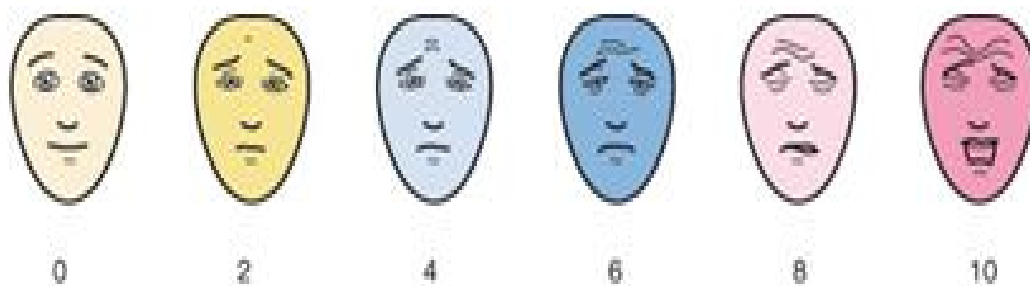
maximum pain, with increasing shades of red for intermediate degrees of pain.

C. FACES pain scale:³² It is useful in children of 3 years and above. This scale has cartoon drawings of faces from smiling to crying with tears. This has score from 0 -5 or 0 – 10.



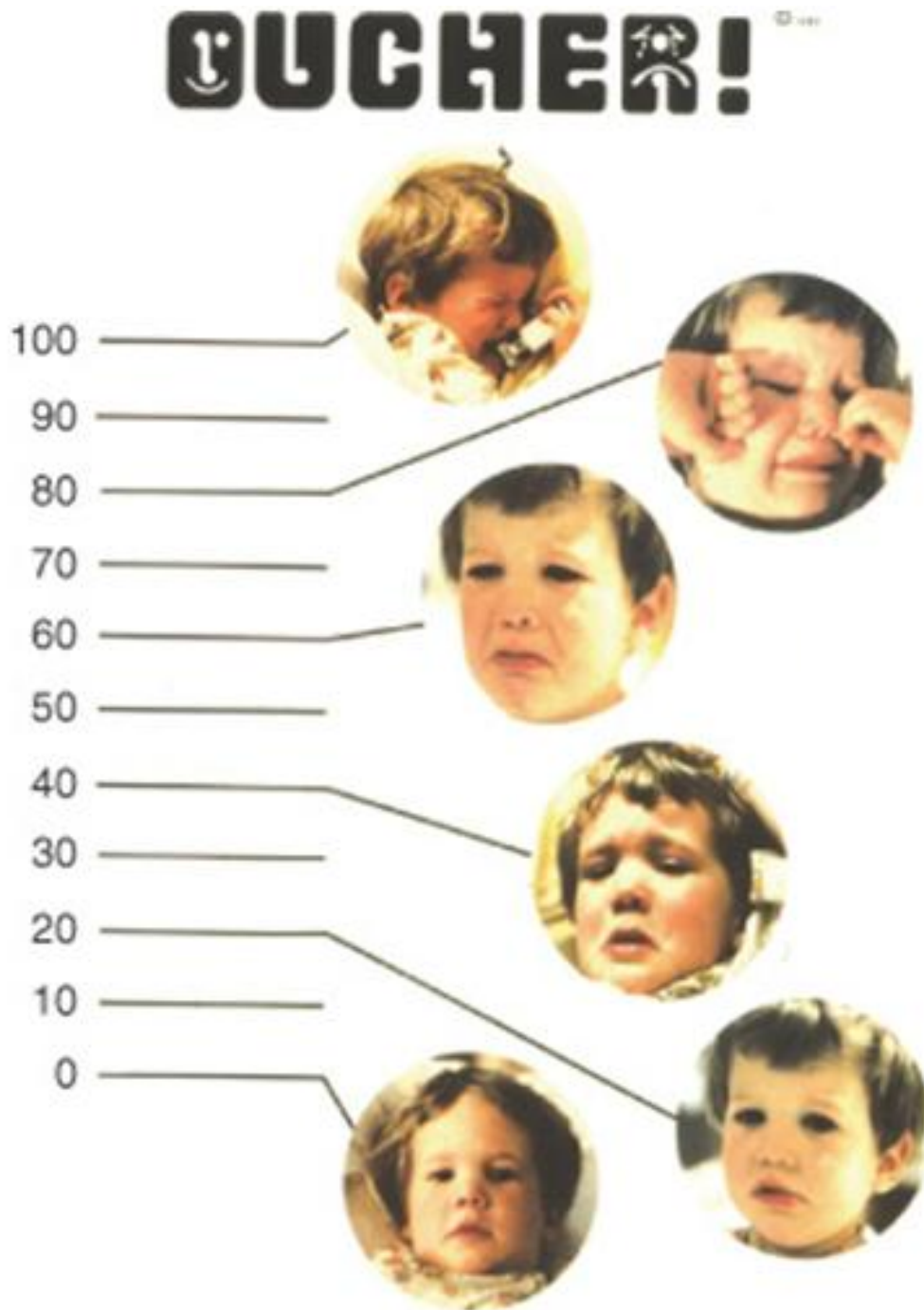
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D. Bieri – Modified Scale:^{33,34} This has Line drawings of faces from neutral to crying. This is mainly used for children more than 3 years old and has score from 0 -6 (original), 0 -5 or -10 (modified).



E. OUCHER Scale: (Beyer)³⁵ It is used in 3-12 years children.

This up and down scale has photographs of a child in six increasing degrees of pain scored from 0 for the comfortable and calm face to 100 for the upset crying face.



BEHAVIOURAL AND COMPOSITE PAIN ASSESSMENT SCALES

1. **Premature Infant Pain Profile (PIPP):**^{36,37} This is mainly used for Preterm and full-term neonates. Gestational age, behavioral state, heart rate, oxygen saturation, brow bulge, eye squeeze, nasolabial furrow are the parameters assessed in this scale. It has 0 – 21 scoring.
2. **Neonatal Infant Pain Scale (NIPS):**³⁸ This is based on facial expression, cry, breathing pattern, arms, legs, state of arousal. It is mainly used for Preterm and full-term infants. It has 0-10 score.
3. **CRIES:**³⁹ *Crying, O2 saturation, Increased vital signs (Heart rate, Blood pressure), Expression and Sleeplessness* are assessed in this scale. It is used in Full-term neonates and has a 0- 10 score.
4. **FLACC:**⁴⁰ This is mainly used in 2 months to 7 years old children. *Facial expression, Legs, Activity state, Crying, Consolability* are assessed in this scale. It has 0 -10 score.
5. **Children`s Hospital of Eastern Ontario Pain Scale (CHEOPS):**⁴¹ *Cry, Facial expression, verbalization, torso position, touch (affected area), Legs* are assessed in this scale. It is used in 1-7 year age group. It has 4-13 scoring system.

6. **COMFORT Score:**⁴² It is applicable for all ages. The indicators assessed are alertness, calmness/agitation, respiratory response, physical movements, heart rate, blood pressure, muscle tone, facial tension. It has 0 -40 score.
7. **Hannallah Objective Pain Scale:**⁴³ It is a sensitive and reliable tool in evaluating post-operative pain in children. It uses six parameters like Systolic blood pressure, Crying, Movement, Agitation, Posture and Verbalization of pain. It is scored from 0 – 12.

PHYSIOLOGICAL MEASURES

Observing changes in vital signs such as heart rate, blood pressure, respiration, oxygen saturation and sweating caused by pain remove the subjectivity of behavioral pain scoring methods, but these parameters may reflect changes for reasons other than pain and hence not often used.

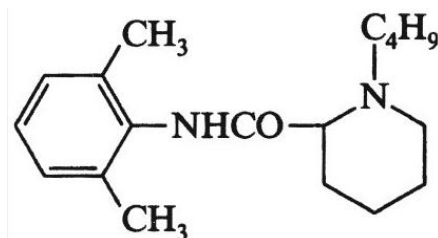
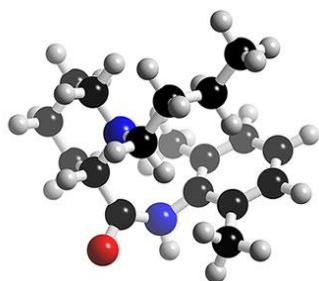
Pharmacology of Bupivacaine

PHARMACOLOGY OF BUPIVACAINE

HISTORY

It is an amide linked local anesthetic synthesized by B.A.F. Ekenstam in 1957 and introduced into clinical practice by Talivuo in 1963.

CHEMICAL STRUCTURE⁴⁴



An amino amide local anesthetic having a benzene ring (lipophilic) at one end linked by an amide group to a tertiary amine (hydrophilic) on the other end of the molecule. It belongs to the group of pipercoloxylidide local anaesthetics. All drugs in this group like mepivacaine, ropivacaine, levobupivacaine possess chirality due to the asymmetric carbon atom so that they may have optical isomers (enantiomers). The enantiomers may vary in their pharmacokinetics, pharmacodynamics and toxicity. Hence, administering a racemic drug mixture is, in reality, administration of two different drugs.⁴⁵ Bupivacaine is available as a racemic mixture with the S-enantiomer less toxic than the R form.

PHYSICOCHEMICAL PROPERTIES¹⁴

Molecular weight	288
pKa	8.1
Partition coefficient (N heptane/ buffer)	10
Potency	4
Protein binding in %	95
Fraction % non ionized at pH 7.4	17
Lipid solubility	28

MECHANISM OF ACTION

Local anaesthetics prevent transmission of nerve impulses (conduction blockade) by inhibiting passage of sodium ions through ion-selective sodium channels in nerve membranes.⁴⁶ They diffuse in their uncharged base form through neural sheaths and the axonal membrane to the internal surface of cell membrane sodium ion channels. Here, they combine with hydrogen ions to form a cationic species which enters the internal opening of the sodium ion channel and binds with the channel in the inactivated-closed state. This produces blockade of the sodium ion channel thereby decreasing sodium ion permeability and preventing depolarization of the cell membrane.

Binding affinities of local anaesthetics to the sodium ion channels are stereospecific thereby contributing to their differing potencies

among the enantiomers. In addition to sodium ion channels, local anaesthetics block voltage-dependent potassium channels but with lower affinity. Other additional actions may include blockade of voltage-dependent calcium ion channels (L-type most sensitive) and their action on G-protein coupled receptors.⁴⁷

Differential conduction blockade is illustrated by selective blockade of small C fibers and small- and medium-sized A fibers, with loss of pain and temperature and preservation of touch, proprioception and motor function at low concentrations of local anaesthetics.

PHARMACOKINETICS⁴⁴

The onset and duration of conduction blockade is related to the pKa, lipid solubility and extent of protein binding of the drug. A low pKa and high lipid solubility are associated with a long duration of action. (Table 1)

ABSORPTION

The absorption of bupivacaine from its site of injection into the systemic circulation is influenced by the site of injection and dosage and use of epinephrine but the ultimate plasma concentration is determined

by the rate of tissue distribution and the rate of clearance of the drug. Lipid solubility is important in the tissue redistribution as well as being a primary determinant of the drug potency with bupivacaine being highly lipid soluble and more potent. Protein binding will also influence its distribution and excretion that parallels the lipid solubility and is inversely related to its plasma concentration.

Table – Pharmacokinetics

Elimination half life	210 min
Volume of distribution (Vdss)	73 L
Clearance (l/min)	0.47
Toxic plasma concentration	>3 mics/ml

BIODEGRADATION AND ELIMINATION

Liver is the site of metabolism. Two major factors controlling the clearance of the amide linked local anesthetics are hepatic blood flow and hepatic function. The principal pathways are N-dealkylation, aromatic hydroxylation, amide hydrolysis and conjugation (ref). The mean total urinary excretion of bupivacaine and its dealkylation and hydroxylation metabolites account for >40% of the total anaesthetic dose. Alpha₁ acid glycoprotein is the most important plasma protein binding site of bupivacaine.

ADVERSE EFFECTS AND COMPLICATIONS

Systemic toxicity

This is due to an excess plasma concentration of the drug. Plasma concentrations are determined by the rate of drug entrance into the systemic circulation relative to their redistribution to inactive tissue sites and clearance by metabolism. The magnitude of the toxicity depends on dose administered, vascularity of the injection site, presence of epinephrine in the solution and the protein binding of bupivacaine.

Central Nervous System

Circumoral numbness is often an early symptom with restlessness, vertigo, tinnitus, and difficulty in focusing developing later. Further increases in the CNS concentration result in slurred speech and skeletal muscle twitching which signals the imminence of tonic-clonic seizures. Seizures are usually followed by CNS depression, which may be accompanied by hypotension and apnea. The typical plasma concentration of bupivacaine associated with seizures is 4.5-5.5 mic/ml. Hypoxia, Hypocarbica, hyperkalemia and acidosis can decrease the seizure threshold and increase CNS toxicity. The treatment includes

oxygenation, ventilation and benzodiazepine or barbiturates for termination of the seizures.

Cardiovascular system

The cardiovascular system is more resistant to the toxic effects of high plasma concentrations than is the CNS. Part of the cardiac toxicity that results from high plasma concentrations occurs because it also blocks the sodium channels in the heart and this block of the inactivated state of the cardiac sodium and potassium (hKv1.5) channels is stereospecific with R-bupivacaine, being more potent than S-bupivacaine¹³. The primary cardiac electrophysiologic effect of local anaesthetics is a decrease in the rate of depolarization in the fast conducting tissues of Purkinje fibers and ventricular muscle.⁴⁸ Action potential and the effective refractory period are also decreased by local anesthetics.

Accidental intravenous injection of bupivacaine may result in precipitous hypotension, cardiac dysrhythmias like Premature ventricular contractions, Supraventricular tachycardia, Atrioventricular heart block and Ventricular tachycardia that may be resistant to

conventional resuscitative measures. Cardiotoxic plasma concentrations are 8-10 mic/ml.⁴⁹

Moreover, bupivacaine depress the maximal depolarization rate of the cardiac action potential (V_{max}) by virtue of its ability to inhibit sodium ion influx via sodium channels. This V_{max} depression by bupivacaine is considerably more than lidocaine and ropivacaine.¹⁴ In addition, the rate of recovery from a use-dependent block is slower in bupivacaine-treated papillary muscles. Moreover, high blood levels of bupivacaine will prolong conduction time through various parts of the heart indicated by prolongation of PR interval and QRS complex. It also exerts dose-dependent negative inotropic action on cardiac muscle.

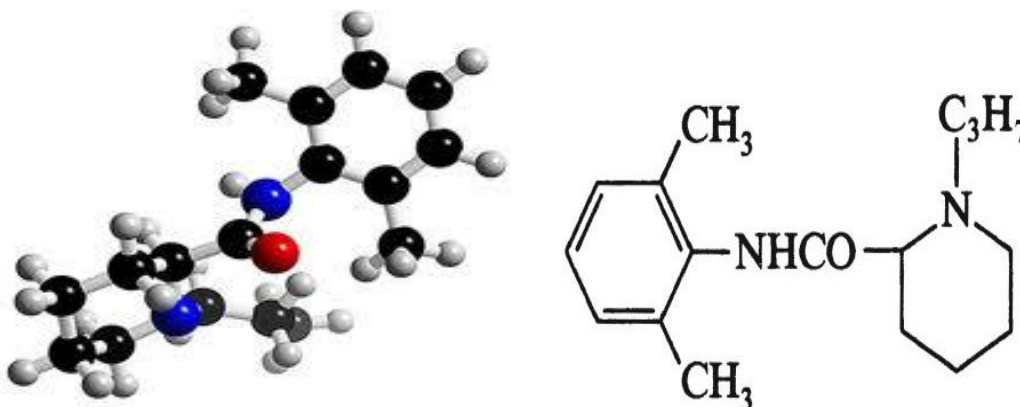
Pharmacology of Ropivacaine

PHARMACOLOGY OF ROPIVACAINE

GENERIC NAME Ropivacaine Hydrochloride injection

CHEMICAL STRUCTURE^{14,44}

It is a member of the amino amide class, of local anesthetics. It is chemically described as S-(-)-1-propyl-2',6'-pipercoloxylidide hydrochloride monohydrate. Ropivacaine belongs to pipercoloxylidide group of local anaesthetics with a propyl group attached to the piperidine nitrogen. However, it differs from other drugs in the group in that they are racemic preparations, while ropivacaine is the first drug to be available as a pure S-(-) enantiomer. The drug has the following structural formula:



PHYSICOCHEMICAL PROPERTIES

The drug substance is a white crystalline powder, with a chemical formula of $C_{17}H_{22}N_2O \cdot HCl \cdot H_2O$. The pKa of ropivacaine is approximately the same as bupivacaine (8.1) and is similar to that of mepivacaine (7.7). However, ropivacaine has an intermediate degree of lipid solubility compared to bupivacaine and mepivacaine determined by the N heptane/buffer partition coefficient.

Molecular weight (base)	274
pKa	8.1
Potency	4
Protein binding in %	94
Fraction % non ionized at pH7.4	17
Partition Coefficient (N heptane/buffer)	2.9

MECHANISM OF ACTION

Ropivacaine is a member of the amino amide class of local anesthetics and is supplied as the pure S-(-) enantiomer. Local anesthetics block the conduction of nerve impulses by blocking the sodium ion channels, thereby decreasing sodium ion conductance and preventing depolarization of the cell membrane.

PHARMACOKINETICS⁴⁴

Parameters	Value
Elimination (t _{1/2} in min)	108
Clearance (L/min)	0.44
V _{dss} (L)	59
Protein Binding (%)	94

ABSORPTION

The systemic absorption of ropivacaine after caudal injection is slow with peak plasma concentration being achieved much later than bupivacaine. This may be due to the intrinsic vasoconstrictor property of ropivacaine at low concentrations.

BIODEGRADATION AND METABOLISM⁴⁴

Ropivacaine is metabolized in liver into 2,6-pipecoloxylidide and 3-hydroxyropivacaine by cytochrome P-450 enzymes. Both metabolites have significantly less local anaesthetic potency than ropivacaine. About 1% is excreted unchanged in the urine. Its Clearance is higher than bupivacaine and elimination half-time shorter.¹⁴ The higher clearance may offer an advantage over bupivacaine in terms of systemic toxicity. It has a lipid solubility intermediate between lignocaine and bupivacaine and is highly bound to alpha₁-acid glycoprotein.

SYSTEMIC TOXICITY

Central Nervous System Toxicity

Ropivacaine produces similar spectrum of symptoms involving the central nervous system like bupivacaine but the duration of symptoms is shorter with the former. Moreover, studies have shown that higher doses and free plasma concentrations of ropivacaine were tolerated before symptoms were elicited.⁵⁰

Cardiovascular System Toxicity:

Cardiovascular effects are less pronounced with ropivacaine. The very slow reversal of Na⁺-channel blockade after a cardiac action potential, which is a hallmark of bupivacaine, is considerably faster with ropivacaine. In addition, the negative inotropic potency of ropivacaine on isolated cardiac tissue appears to be considerably less than that of bupivacaine.^{51,52} Studies in animals show that aggressive cardiac resuscitation after an intentional intravenous bolus in dogs leads to effective reversal of the toxic effects far more frequently with ropivacaine than with bupivacaine indicating that ropivacaine is less cardiotoxic.⁵³

The greater safety of ropivacaine than bupivacaine may be related both to the reduced toxicity of the single (S) - isomer and the difference between the propyl and butyl -N- piperidine substituent.⁵⁴

Review of Literature

REVIEW OF LITERATURE

Manjushree Ray et al (Indian J. Anaesth. 2003).⁵⁵ The authors compared 30 children aged 5-8 years who were scheduled for urogenital operations and received 0.75ml/kg of either 0.25% Bupivacaine or 0.25% Ropivacaine via caudal route after induction of general anaesthesia. They observed that the quality and duration of postoperative pain relief (398 ± 23 min in group A vs 405 ± 18 min in group B) as measured by Hannallah pain scale did not differ significantly between the two groups. The motor power score after two hours was 7.1 ± 0.9 and 9.3 ± 1.0 in group A and B respectively indicating quicker motor recovery in ropivacaine group. They concluded that caudal ropivacaine provided effective postoperative analgesia with less motor blockade when compared with bupivacaine.

Samia Khalil, M.D. et al (Anesthesiology 1999).⁵⁶ The authors studied 81 children of 1-10 years of age who were randomly allocated to receive caudal anaesthesia with ropivacaine or bupivacaine 0.25% 1ml/kg after induction of anaesthesia. They found that the quality and duration of pain relief measured by Hannallah pain scale did not differ between the two groups and noted that none of the study children had

complete motor power recovery (score 10) within 3 hours after placement of the caudal block. The reflex scores and Sensory block did not differ between the treatment groups. They also observed that there was no difference between the two groups in mean time to first micturition (254 ± 140 min for bupivacaine vs 321 ± 164 min for ropivacaine). They concluded that caudal ropivacaine provided reliable postoperative analgesia with similar motor and sensory effects, and similar time to first micturition compared to bupivacaine.

G.Ivani et al (British Journal of Anaesthesia 1998).⁵⁷ The authors, in double-blind, multi-centre study, randomly allocated 245 children aged 1-10 years undergoing elective minor surgery to receive a single caudal injection of 1ml/kg of either 0.25% Bupivacaine or 0.2% Ropivacaine after induction of light general anaesthesia. The mean onset time was similar for both the groups (10.4 ± 2.3 min group R vs 9.7 ± 2.2 min). The mean time to first analgesia was 233.2 min in the bupivacaine and 271 min in the ropivacaine group that was statistically insignificant. No motor block was seen in either group on awakening. They observed that low concentrations and large volumes are the key to obtaining differential block in children because of the small diameter of the A-delta and C-fibres and the small distance between the nodes of

Ranvier. They suggested that 0.2% ropivacaine 1ml/kg is equivalent to the same volume of 0.25% bupivacaine given through caudal route.

M.J. Da Conceicao et al (British Journal of Anaesthesia 1998).⁵⁸

The authors studied 60 children aged 3-6 years who received either 0.375% ropivacaine or 0.375% bupivacaine 1ml/kg by caudal route after induction of anaesthesia. They observed that ropivacaine group showed a shorter duration of motor block than the bupivacaine group ($P < 0.05$). There were no significant differences in Maunuksela pain scores in the postoperative period. They summarized that caudal ropivacaine appears to induce similar sensory block with shorter motor block to that of bupivacaine.

Giorgio Ivani MD et al (Paediatric Anaesthesia 1998).⁵⁹ The

authors examined 40 patients aged 1-9 years undergoing elective minor surgery who received caudal injection of either bupivacaine 0.25% 2mg/kg (group 1) or ropivacaine 0.2% 2mg/kg (group 2) after induction of general anaesthesia and maintained with isoflurane with spontaneous breathing. The mean onset of block was 12 ± 2 min for group 1 and 9 ± 1 min for group 2 ($P < 0.05$). The quality and duration of analgesia was superior in group 2 (520 min in group 2 vs 253 min in group 1) whereas there was no motor block at awakening in either group and no side

effects were noticed. They observed that 2mg/kg of 0.2% ropivacaine is sufficient to obtain a sensory block level of T7 that gave superior analgesia than bupivacaine.

Giorgio Ivani MD et al(Can. J. anesth. 1999).⁶⁰ In a prospective double blind study, the authors studied 28 infants aged 1-12 months undergoing elective major abdominal surgery who received after induction of general anaesthesia either 0.7ml/kg bupivacaine 0.25% (group B) or ropivacaine 0.2% (group R) via lumbar epidural block. The duration of analgesia was 491 ± 291 min (group R) and 456 ± 247 min (group B). They concluded that the similar onset and duration of 0.7ml/kg of 0.2% ropivacaine and 0.25% bupivacaine suggests that ropivacaine in children seemed to be more potent than bupivacaine and is safe and effective for pediatric regional anaesthesia.

G.Luz et al (Paediatric Anaesthesia 2000).⁶¹ The investigators compared the analgesic efficacy and degree of motor block induced by ropivacaine 0.1% (R0.1) and 0.2% (R0.2) with bupivacaine 0.2% (B0.2) after caudal anaesthesia in children. They observed that the duration of analgesia (median/range) was significantly shorter in group R0.1 (1.7/0.2-6h) than in group R0.2 (4.5/1.7-6h) or group B0.2 (4/1-6h) with a $P < 0.05$. They also observed that the motor block in the first 2 hours

postoperatively was significantly less for both ropivacaine groups compared with bupivacaine ($P < 0.05$). They concluded that 0.2% ropivacaine provides similar pain relief to 0.2% bupivacaine and less motor block than bupivacaine in the early postoperative period.

Christian Breschnan et al (Paediatric Anaesthesia 2005).⁶² The authors compared 182 children aged 1-7 years undergoing inguinal hernia repair or orchidopexy who received 0.2% concentration, 1 ml/kg of either levobupivacaine (group L) or ropivacaine (group R) or bupivacaine (group B) via caudal route. They found that the motor block was significantly less in group R and L than in group B with no significant difference in postoperative analgesia between them. They concluded that during the first 2 hours postoperatively, the degree of motor block was significantly less with ropivacaine and levobupivacaine than with bupivacaine.

G. Ivani MD et al (Pediatric Anesthesia 2005).⁶³ The authors compared 0.2% ropivacaine with 0.25% levobupivacaine in 60 children aged 1-7 years scheduled to undergo minor surgery when administered through caudal block after induction of anesthesia. The median onset time was 8 min and 7 min for the R and L groups respectively. The median time to first analgesic demand was 380 and 308 min in

ropivacaine and levobupivacaine groups, respectively. They concluded that 0.2% concentrations of ropivacaine or levobupivacaine are clinically very similar with regard to postoperative analgesia and postoperative motor blockade in children undergoing sub-umbilical surgery.

Pablo M. Ingelmo MD et al (Pediatric Anesthesia 2006).⁶⁴The authors investigated 90 children aged 1-7 years scheduled for inguinal hernia repair or orchidopexy under propofol anesthesia who received a caudal block with 1ml/kg of 0.2% bupivacaine, 0.2% ropivacaine or 0.2% levobupivacaine. They observed that the proportion of children with an effective caudal block during surgery was significantly higher in patients receiving levobupivacaine and bupivacaine compared with those receiving ropivacaine. But there were no significant differences between groups in the time from caudal injection to the first administration of analgesic medication (2 ± 0.7 h in bupivacaine group, 2 ± 0.4 h in levobupivacaine group, 2 ± 0.8 h in children receiving ropivacaine with $P=0.7$). They also observed that there were no statistical differences between groups on the incidence and intensity of residual motor blockade at wake up or 3h after the local anesthetic injection. They concluded that when combined with propofol anesthesia

without volatile anesthetics, 0.2% levobupivacaine and 0.2% bupivacaine are more effective during surgical stimulation than 0.2% ropivacaine for caudal use with no difference in the analgesic onset times, residual analgesia or residual motor blockade.

H. Wulf et al (Anaesthesia 2000).⁶⁵ The authors evaluated the pharmacokinetics of 1ml/kg 0.2% ropivacaine in 25 infants and toddlers after caudal epidural injection. Mean (S.D.) Peak Plasma concentrations of ropivacaine were 0.73(0.27) in infants and 0.49 (0.21) µg/ml in toddlers and there were no signs of local anaesthetic toxicity. They observed that maximum plasma concentrations occurred after a median (range) period of 60(15-90) min and 52.5 (30-120) min in infants and toddlers respectively. They concluded that from a pharmacokinetic point of view caudal blockade with 0.2% ropivacaine 1ml/kg can be regarded as a safe dose in children.

K.Knudsen et al (British Journal of Anaesthesia 1997).⁶⁶ The authors compared the incidence of CNS symptoms and changes in echocardiography and electrophysiology during i.v. infusions of ropivacaine, bupivacaine and placebo. Acute tolerance of i.v. infusion of 10mg/min was studied in a crossover, randomized, double-blind study in 12 volunteers previously acquainted with the CNS effects of lignocaine.

The maximum tolerated dose for CNS symptoms was higher after ropivacaine in nine of 12 subjects and higher after bupivacaine in three subjects. The maximum tolerated unbound arterial plasma concentration of bupivacaine was twice as high after ropivacaine. The time to disappearance of all symptoms was shorter after ropivacaine ($P < 0.05$). Bupivacaine increased QRS width during sinus rhythm compared with placebo and Ropivacaine. Bupivacaine also reduced both left ventricular systolic and diastolic function compared with placebo while ropivacaine reduced only systolic function.

Raafat S. Hannallah, M.D., et al (Anesthesiology 1987)⁴³ evaluated 44 children aged 1.5-12 years scheduled for ambulatory orchidopexy under caudal analgesia and ilioinguinal /iliohypogastric nerve blocks for postoperative analgesia using a scoring system that included Blood pressure, crying, movement, agitation, posture, complains of pain that were scored from 0-2.

Wolf AR et al (Anesthesiology 1988)⁶⁷ compared different concentrations of bupivacaine for caudal block in 114 children aged 6 months to 10 years undergoing elective surgeries like orchidopexy, hernia repair, urethroplasty and Circumcision. They selected a volume of 0.75ml/kg of bupivacaine for caudal block based on the calculation of

0.056ml/kg/segment for 13 spinal segments to be blocked and found that this volume provided adequate analgesia and similar duration of block for both superficial abdominal and genital surgeries in infants and children.

Pradipta Bhakta et al (Indian J. Anaesth. 2007).⁶⁸ The authors evaluated the efficacy of intranasal normal saline (group 1) and intranasal midazolam in doses of 0.2 (group 2) and 0.3 mg/kg (group 3) intranasally in 45 children aged 2-5 years, scheduled for minor elective surgery. A statistically significant change in the level of sedation was found at 5 minutes in group2 and at 10 min in group 3. They concluded that intranasal midazolam in a dose of 0.2mg/kg is an effective premedication for producing effective sedation and anxiolysis in paediatric patients without any untoward side effect.

Materials and Methods

MATERIALS AND METHODS

This was a Prospective Double blinded Randomized Comparative Study conducted in Government Stanley Hospital, Chennai from April 2010 to September 2010. After obtaining clearance from the Institutional Ethics Committee of the Stanley Medical College, Chennai-1, the study was explained in detail to the parents and written Informed Consent was obtained from them.

Sixty children satisfying the selection criteria were randomized by computer generated randomization table into two groups of thirty each – Group B and Group R. The randomization sequence was prepared in double-blinded cancelled manner. The study solution was prepared by a final year post-graduate student who was not associated with the study. The caudal block was performed by an assistant professor whereas the observations were done by the author. The study blinding was broken after the statistical analysis.

The children in group B received 0.75ml/kg of 0.25% Bupivacaine (0.5% solution diluted in equal volumes of distilled water) whereas those in group R received 0.75ml/kg of 0.25% Ropivacaine

(0.5% solution diluted in equal volumes of distilled water) through the caudal route.

CRITERIA FOR PATIENT SELECTION

The criteria for including the children in the study were:

- Age 3-8 years
- Male or Female
- ASA I or II physical status
- Elective lower abdominal or urologic surgeries like Herniotomy, Orchidopexy, Processus vaginalis sac ligation (PVSL), Circumcision and Urethroplasty

EXCLUSION CRITERIA

The children with the following problems were excluded from the study:

- Local infection in the Caudal region
- Pre-existing Neuromuscular disease
- Congenital anomaly of the lower back
- Mental retardation, Delayed development
- Bleeding diathesis

MATERIALS

The materials that were used for the study include

- 22G Hypodermic needle
- 0.25% Bupivacaine and 0.25% Ropivacaine
- Appropriate size intravenous canulae and I.V. fluids
- Drugs for General Anaesthesia
- Appropriate size Endotracheal tubes
- Other Airway equipments
- Paediatric Breathing Circuit
- Monitors, Working Suction
- All Emergency drugs

STUDY METHODS

The children were fasted for 6 hours for solids and 2 hours for clear liquids. All children were premedicated with Intranasal Midazolam 0.2mg/kg⁶⁸ 15-20 min before surgery. They were brought into the operation theatre and intravenous access was secured with appropriate size intravenous canula. Maintenance infusion was started with Isolyte-P (4-2-1 rule)⁶⁹ and Inj. Atropine 0.02mg/kg i.v. was given.

Standard Monitors like Pulse Oximeter, Blood pressure, ECG, Temperature probe, Precordial stethoscope were placed and baseline values recorded. Then the children were pre-oxygenated with 100%O₂ for 3 minutes and induced with Inj. Propofol 2.5mg/kg i.v. After administering Inj. Atracurium 0.5 mg/kg i.v., the children were mask ventilated with N₂O:O₂ (3:3) and 2% Sevoflurane mixture for 3 minutes. Under direct laryngoscopy with the appropriate size laryngoscope blade, orotracheal intubation was performed with the appropriate size endotracheal tube and the tube position confirmed by capnography and tube secured.

PROCEDURE

The children were then placed in left lateral position and under sterile aseptic precautions, a sterile 22G hypodermic needle was introduced in Caudal epidural space and after confirming the space, 0.75 ml/kg of either 0.25% Bupivacaine or 0.25% Ropivacaine was administered slowly. To detect and avoid an inadvertent intravascular or subarachnoid injection, the syringe was repeatedly aspirated and the local anaesthetic was injected in increments while watching vital signs and the ECG monitor. Then the patients were placed in supine position and anaesthesia was maintained with Nitrous Oxide and Oxygen

mixture (4:2), 1% Sevoflurane and top-up doses of Inj. Atracurium (0.1mg/kg). The incision was made 10 min after caudal block.

An independent blinded Observer (the author) recorded heart rate and Blood pressure, Oxygen saturation just before and after surgical incision and then every 5 min interval till the end of surgery. If the patient responded to the incision with a greater than 15% increase in Systolic Blood pressure or Heart rate, Inj. Fentanyl 1 µg/kg i.v. was administered. Significant bradycardia was defined as greater than 20 % decrease from baseline and significant hypotension requiring treatment was defined as more than 20% fall of Systolic blood pressure from baseline. At the end of the surgery, residual neuromuscular blockade was reversed with Inj. Neostigmine 0.05mg/kg i.v. and Inj. Atropine 0.02mg/kg i.v. and the child was extubated awake. The child was then shifted to the recovery room for Observation.

POST-OPERATIVE PERIOD

Post-operatively, apart from monitoring Pulse rate, Systolic Blood Pressure and oxygen saturation, the following parameters were assessed:

- A. Quality of Analgesia was assessed by Hannallah Objective Pain Scale⁴³ every 15 min for the first two hours and every 30 min for the next 8 hours.

Hannallah Objective Pain Scale (OPS)

No	Observation	Criteria	Points
1.	Systolic Blood pressure	+ 10% pre op > 20% pre op > 30% pre op	0 1 2
2.	Crying	no crying Crying responding to tender loving care Crying not responding to tender loving care	0 1 2
3.	Movement	none Restless Thrashing	0 1 2
4.	Agitation	asleep/calm Mild Hysterical	0 1 2
5.	Posture	no special posture Flexing legs and thighs Holding groin	0 1 2
6.	Verbalisation of Pain	asleep/states no pain Vague/Can't localize Can localize pain	0 1 2

B. The Time between the caudal block and administration of the first rescue analgesic drug was noted. Diclofenac rectal suppository 1mg/kg⁷⁰ was given as rescue analgesic when the pain score equals or exceeds 4.

C. Motor power was assessed by Motor power scale every 15 min for the first two hours and every 30 min for the next eight hours. The time of attaining full motor recovery (Score = 10) was noted.

Motor power scale

1.	Muscle Tone	Flaccid 0	Hypotonia 1	Normal 2
	Muscle Power(Flexion)	Unable	Partial	Normal
2.	Ankle	0	1	2
3.	Knee	0	1	2
4.	Thigh	0	1	2
5.	Ability to stand	0	1	2

D. Level of Sensory block was assessed by Pin-prick test every 15 min interval till the patients regained complete sensory recovery.

E. The time to first micturition and any adverse events or complications were noted.

STATISTICAL ANALYSIS

Data was expressed as mean \pm standard deviation. Quantitative analysis was compared with Independent sample student's t-test for continuous variables; Chi-square test with Yates correction was used for discrete variables like sex, types of surgery. When using the above statistical tests to compare the mean among the two groups, a p-value of less than or equal to 0.05 was taken as significant. All analyses were done using SPSS version 11.5 statistical software. All values were rounded off to a maximum of two decimals.

Observation and Results

OBSERVATIONS AND RESULTS

DEMOGRAPHIC VARIABLES

Age Distribution among Groups R and B

Of the 30 children in group R, 21 were between 3-5 years of age as against 23 children in group B with a minimum age of 3 years and a maximum of 8 years in both the groups. The mean age was similar, being around five in both groups, with no significant difference between them. (Table 1)

Table -1

Variable	Group R		Group B		P-value	S.E.D.	C.I. difference 95%	
	Mean	SD	Mean	SD			Lower	Upper
Age (years)	4.93	1.82	4.83	1.82	0.83*	0.47	-0.84	1.04
Weight (kg)	14.13	3.00	14.07	3.96	0.94*	0.91	-1.75	1.88
Height (cm)	111.73	5.79	111.63	6.43	0.95*	1.58	-3.06	3.26

* Not Significant : S.E.D. Standard Error of Difference C.I. Confidence Interval

Weight and Height Distribution among Groups R and B

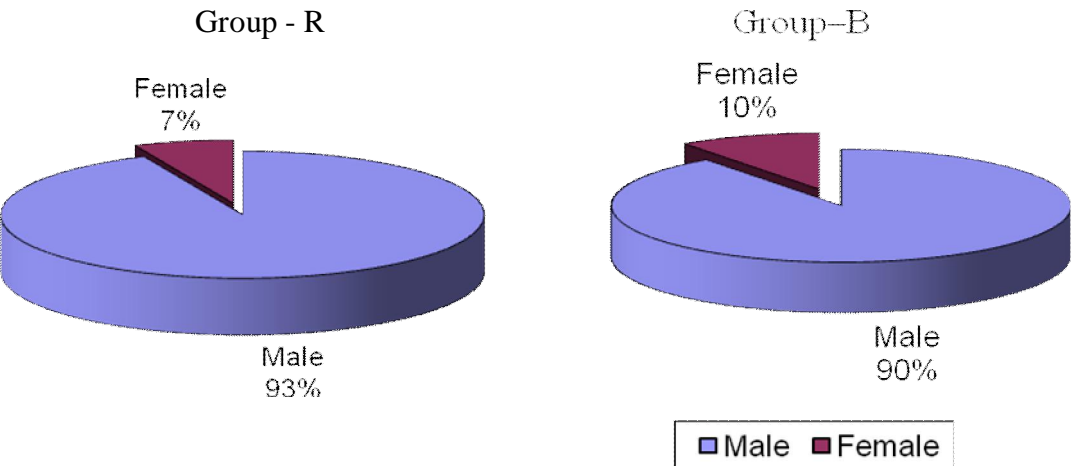
All children except two in group R and one in group B weighed less than 20 kg. The least weight in group R was 10 kg compared to 9 kg

in group B. The average weight in both the groups was around 14 kg with no significant difference.

In group R, 5 children were taller than 120 cm as against 3 in group B with shortest being 104cm and 103 cm respectively. The mean height was 111.73cm in group R and 111.63cm in group B, the difference being statistically not significant (Table 1).

Gender Distribution among Groups R and B

Among the 30 children in Group R, 28 were boys and 2 were girls whereas in Group B, 27 were boys and 3 were girls. There was no significant difference between two groups in terms of gender distribution.

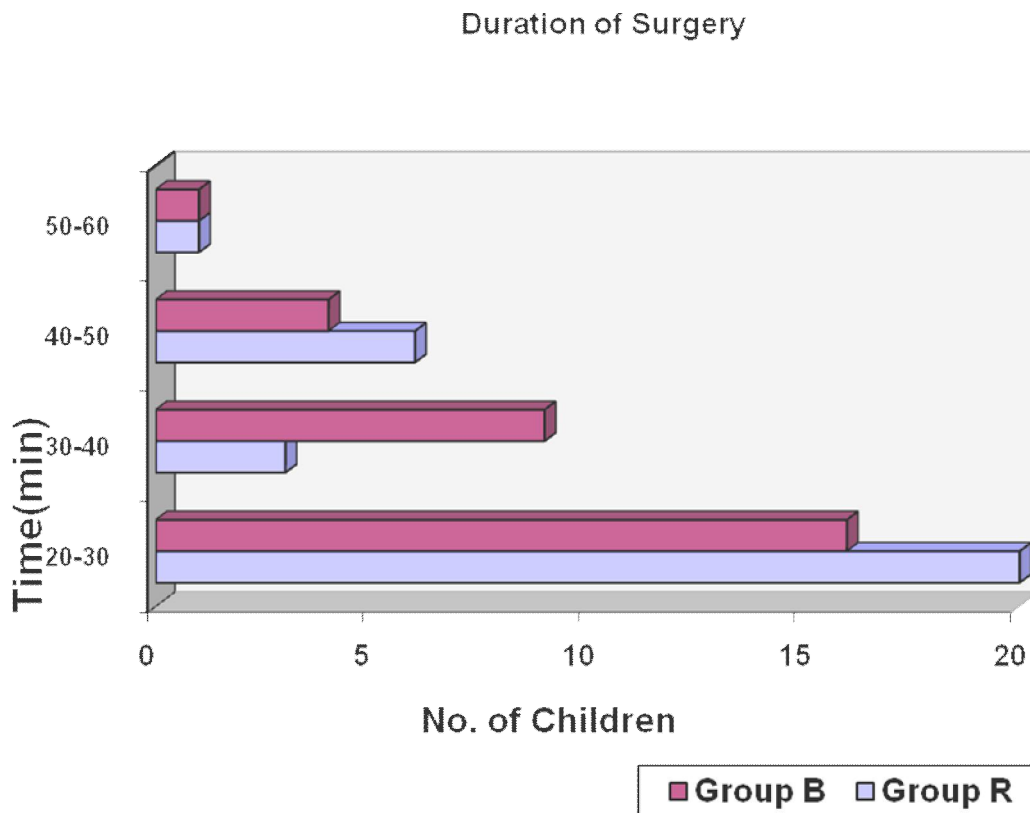


DURATION OF SURGERY

The shortest duration of surgery in both the groups was 20 min whereas the longest was 55 min in group R and 60 min in group B. The mean duration of surgery was 32.67 ± 10.06 min in group R and 32.83 ± 9.62 min in group B, the duration being comparable between the two groups.

Duration of surgery	Group R		Group B		P-value	S.E.D.	C.I. diff 95%	
	Mean	SD	Mean	SD			Lower	Upper
Time (min)	32.67	10.06	32.83	9.62	0.95*	2.54	-5.26	4.92

* Not Significant



TYPE OF SURGERY

Of the 60 children, 17 children in each group underwent surgeries involving thoraco-lumbar dermatomes that required a maximum level of T10 whereas the remaining 36 surgeries of both groups involved the sacral dermatomes. In group R, one case of hamartoma thigh and one case of rectal polyp were present in the others category compared to 1 case of anoplasty and 2 cases of foreign body granuloma in the lower limbs that were present in the group B.

Surgery	Group R		Group B		Total	
	N	%	N	%	N	%
PVSL	6	20.0	4	13.3	10	16.7
URETHROPLASTY	5	16.6	6	20.0	11	18.3
HERNIOTOMY	6	20.0	8	26.7	14	23.3
PVSL+CIRCUMCISION	3	10.0	2	06.7	05	08.3
CIRCUMCISION	6	20.0	4	13.3	10	16.7
ORCHIDOPEXY	2	06.7	3	10.0	05	08.3
Others	2	06.7	3	10.0	05	08.3
TOTAL	30	100	30	100	60	100

Chi-square 1.78 df=6 significant value =0.94 (Not Significant)

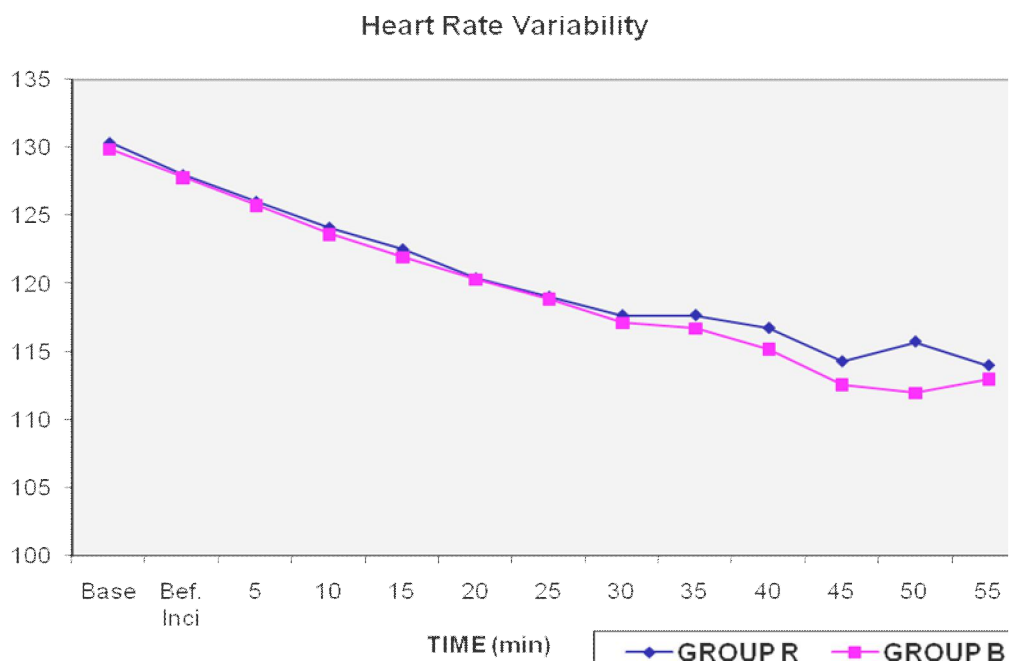
PVSL – Processus vaginalis sac ligation

There was no significant difference in the type of surgery between the two groups.

HEMODYNAMIC PARAMETERS

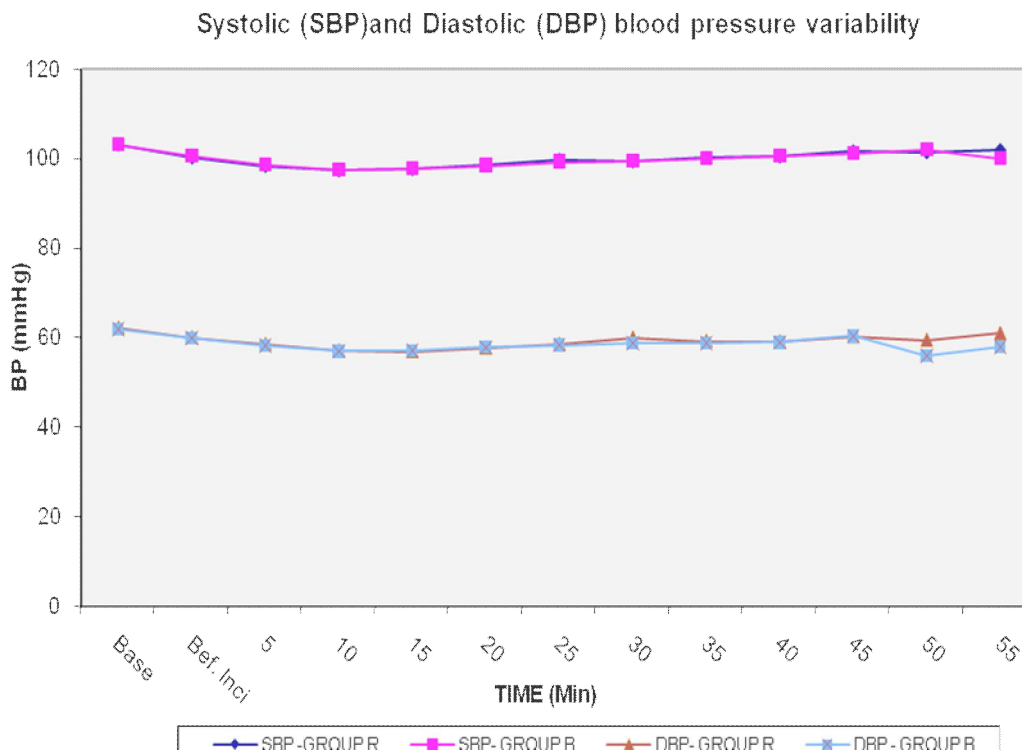
Heart rate

The mean baseline heart rate was 130.37 ± 5.86 min in group R compared to 129.87 ± 5.68 min in group B. The maximum heart rate before incision in group R was 138 beats/min as against 140 beats/min in group B where as that 5min after incision was 138 beats/min in both the groups with no significant difference in their means. The intra-operative heart rate at 5, 10, 15, 20, 25, 30 minutes were lower than the baseline but there was no significant bradycardia recorded in any of the children during the study. The mean heart rates at 5 min intervals up to the completion of surgery did not differ significantly between the two groups.



Blood pressure

The lowest baseline systolic blood pressure in both the groups was 98 mmHg whereas the corresponding diastolic blood pressure was 58mmHg in group R as against 56mmHg in group B with no difference in the means. Both the systolic and diastolic blood pressures decreased marginally during the intra-operative period but no patient had a fall greater than 20% from baseline values. But, both the mean systolic and diastolic blood pressures, before incision (100.33 ± 2.47 in group R vs 100.60 ± 2.69 in group B) and at 5 min intervals up to the completion of surgery did not differ between the two groups.



Oxygen saturation

There was no significant desaturation either in the intra-operative or postoperative periods in both the groups.

No adverse events were observed in any of the children during the study.

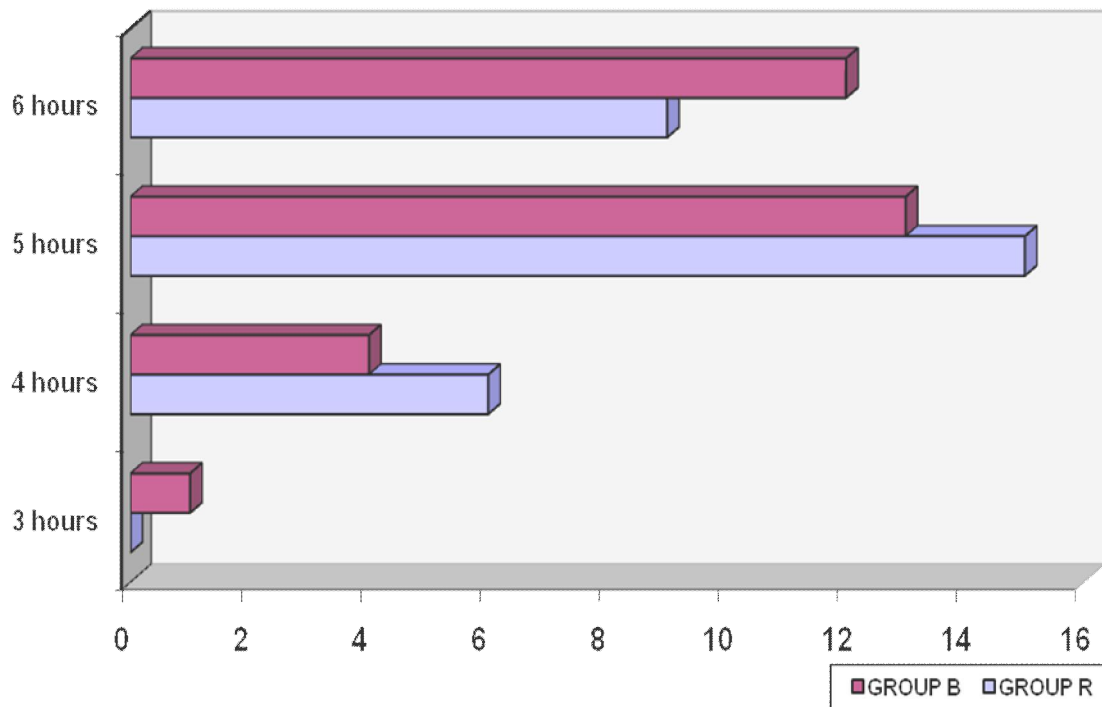
ANALGESIA

All the blocks were successful with none of the children responding to the skin incision with an increase in Heart rate or Systolic Blood pressure. There was no need for supplementation with Inj. Fentanyl intra-operatively.

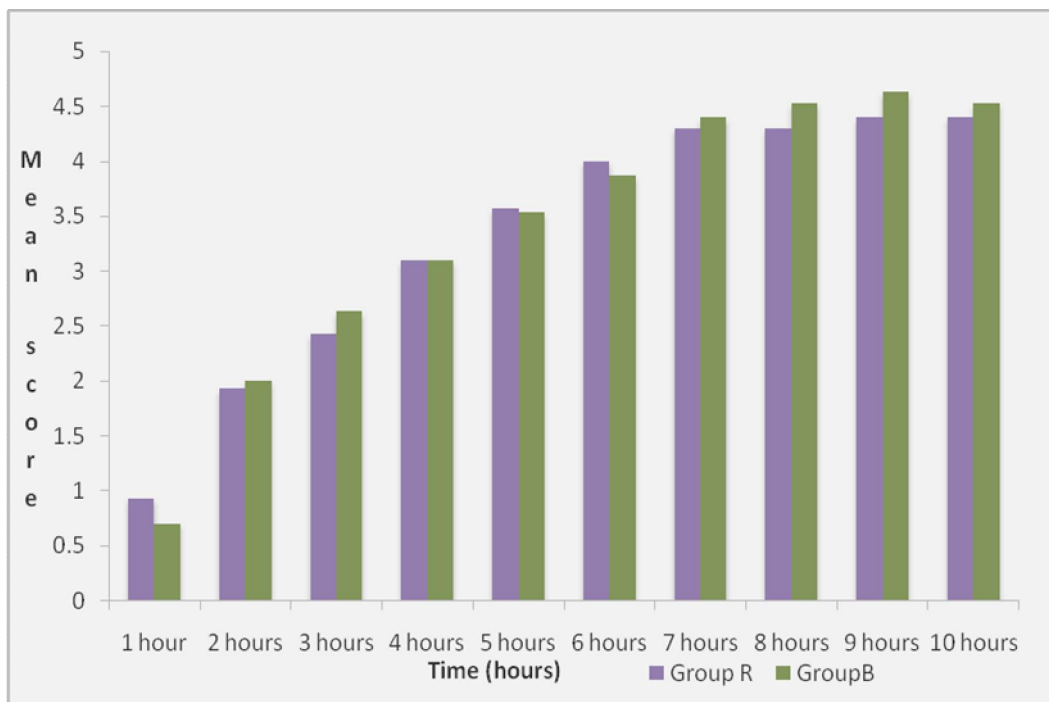
Only one child in group B was given diclofenac suppository at the end of 3 hours whereas none in group R required supplementary analgesia during the same time period. At the end of 4 hours, 6 Children in group R required diclofenac suppository whereas in group B, 5 children required rescue analgesia.

But by the end of 5 hours, only 18 children in group B had received diclofenac suppository in contrast to 21 children in group R though the difference was statistically insignificant. In group R only one child against three children in group B did not require supplemental pain relief within 6 hours. But, all children required rescue analgesia by the end of 7 hours.

NUMBER OF PATIENTS REQUIRING RESCUE ANALGESIA



HANNALLAH PAIN SCORE



Hannallah Objective Pain Score

Time	Group R		Group B		p-value
	N	Mean \pm SD	N	Mean \pm SD	
1 hour	30	0.93 \pm 0.25	30	0.70 \pm 0.65	0.08
2 hours	30	1.93 \pm 0.25	30	2.00 \pm 0.53	0.09
3 hours	30	2.43 \pm 0.50	30	2.63 \pm 0.67	0.48
4 hours	30	3.10 \pm 0.40	30	3.10 \pm 0.61	0.36
5 hours	30	3.57 \pm 0.57	30	3.53 \pm 0.82	0.83
6 hours	30	4.00 \pm 0.59	30	3.87 \pm 0.86	0.71
7 hours	30	4.30 \pm 0.54	30	4.40 \pm 0.81	0.46
8 hours	30	4.30 \pm 0.47	30	4.53 \pm 0.57	0.09
9 hours	30	4.40 \pm 0.50	30	4.63 \pm 0.62	0.11
10 hours	30	4.40 \pm 0.50	30	4.53 \pm 0.63	0.37

Post-operatively, the quality and duration of analgesia did not differ between the two groups. The Hannallah pain scores did not differ significantly at 0,1,2,3 hours post-operatively between the two groups. But the mean scores were slightly less in group R than in Group B after 6 hours, though they were statistically insignificant.

Time of first analgesia	Group R		Group B		P-value	S.E.D.	C.I. of diff. 95%	
	Mean	SD	Mean	SD			Lower	Upper
Time (min)	338.83	44.75	346.67	51.06	0.53*	12.39	-32.65	16.98

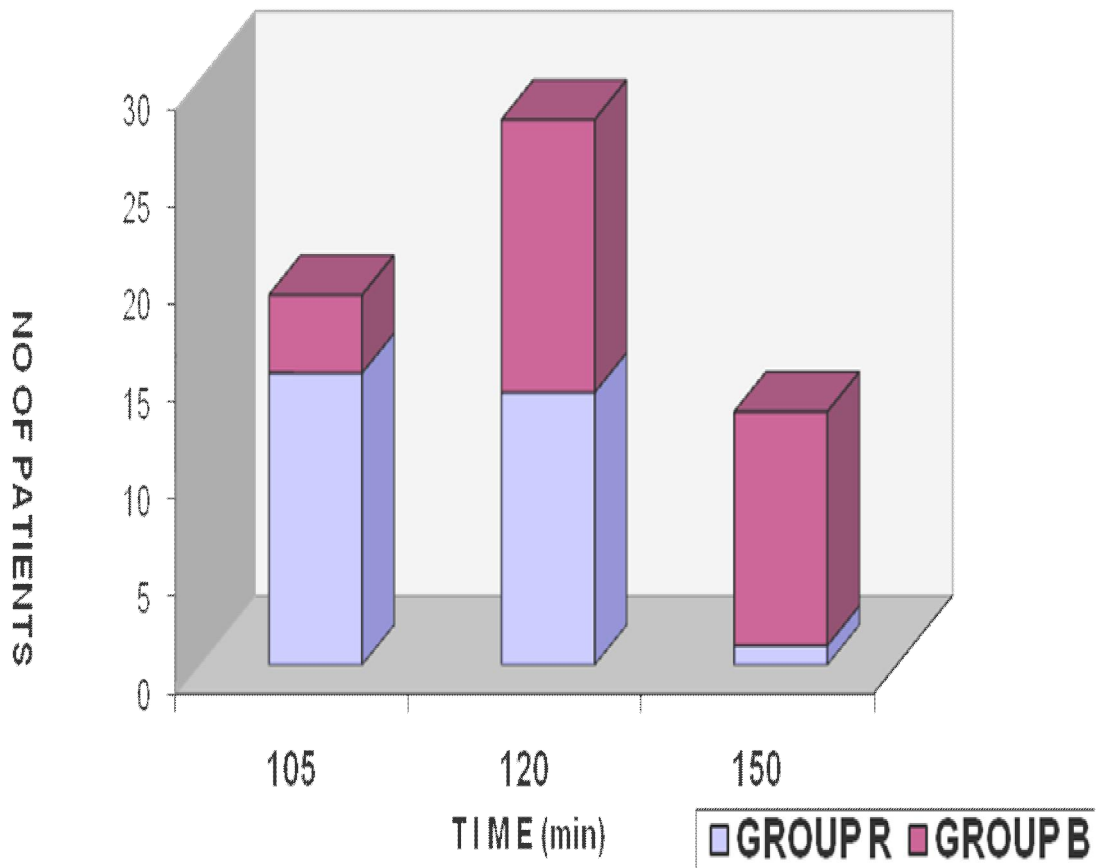
* Not significant

The mean time from caudal placement to the first administration of pain medication was 338.83 ± 44.75 min in group R and 346.67 ± 51.06 min in group B, the difference being statistically insignificant ($P=0.53$)

MOTOR POWER RECOVERY

15 children in group R had full motor power (score =10) at the end of 105 min after surgery whereas only 4 children had full motor power in group B. At the end of 120 min, only one out of the total 30 children in group R did not have full motor recovery whereas 12 out of the 30 children in group B were having mild motor weakness. All children had regained full motor power by the end of two and half hours in both the groups.

FULL MOTOR RECOVERY



Motor Power Score

Time	Group R		Group B		p-value
	N	Mean \pm SD	N	Mean \pm SD	
0 Minutes	30	2.33 \pm 0.48	30	2.03 \pm 0.18	0.003
30 Minutes	30	3.30 \pm 0.75	30	2.63 \pm 0.56	0.002
60 Minutes	30	5.03 \pm 0.85	30	4.13 \pm 1.01	0.001
90 Minutes	30	7.80 \pm 0.93	30	6.73 \pm 1.05	0.001
105 Minutes	30	9.17 \pm 0.95	30	8.20 \pm 0.85	0.001
120 Minutes	30	9.97 \pm 0.18	30	9.47 \pm 0.73	0.001
150 Minutes	30	10.00 \pm 0.00	30	10.00 \pm 0.00	-

Immediately after surgery, the mean motor score was 2.33 ± 0.48 in group R as against 2.03 ± 0.18 in group B. Although this was clinically not significant, it was statistically highly significant with a P value of 0.003. The mean scores at 30min and 1 hour after surgery were both clinically and statistically significant between the two groups with higher scores observed in ropivacaine group.

Variable (min)	Group R		Group B		P-value	S.E.D.	C.I. of diff 95%	
	Mean	SD	Mean	SD			Lower	Upper
Full Motor Recovery	113.50	10.18	128.50	17.48	0.001	3.69	-22.39	-7.61

The mean time for full motor recovery in group R was 113.50 ± 10.18 min compared to 128.50 ± 17.48 min in group B the difference being highly significant (P=0.001).

SENSORY RECOVERY

The sensory block (mean \pm s.d.) resolved completely by 77.50 ± 2.67 min in ropivacaine group and by 80.00 ± 7.19 min in bupivacaine group, the difference being statistically not significant (P=1.49).

Variable (min)	Group R		Group B		P-value	S.E.D.	C.I. of diff 95%	
	Mean	SD	Mean	SD			Lower	Upper
FULL SENSORY RECOVERY	77.50	2.67	80.00	7.19	1.49*	1.67	-5.82	0.85

*not significant

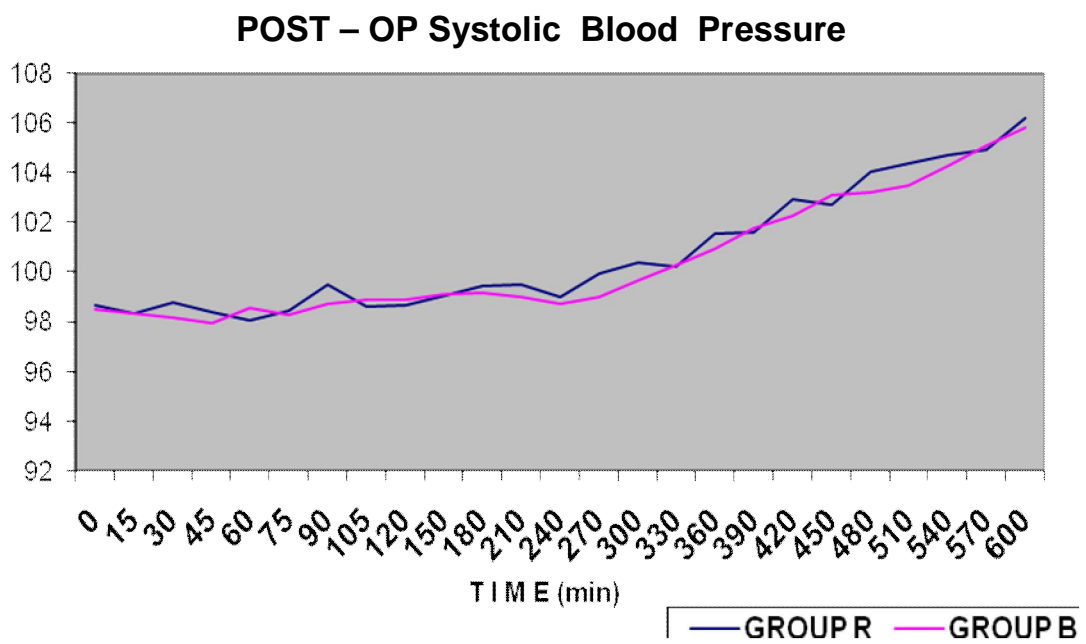
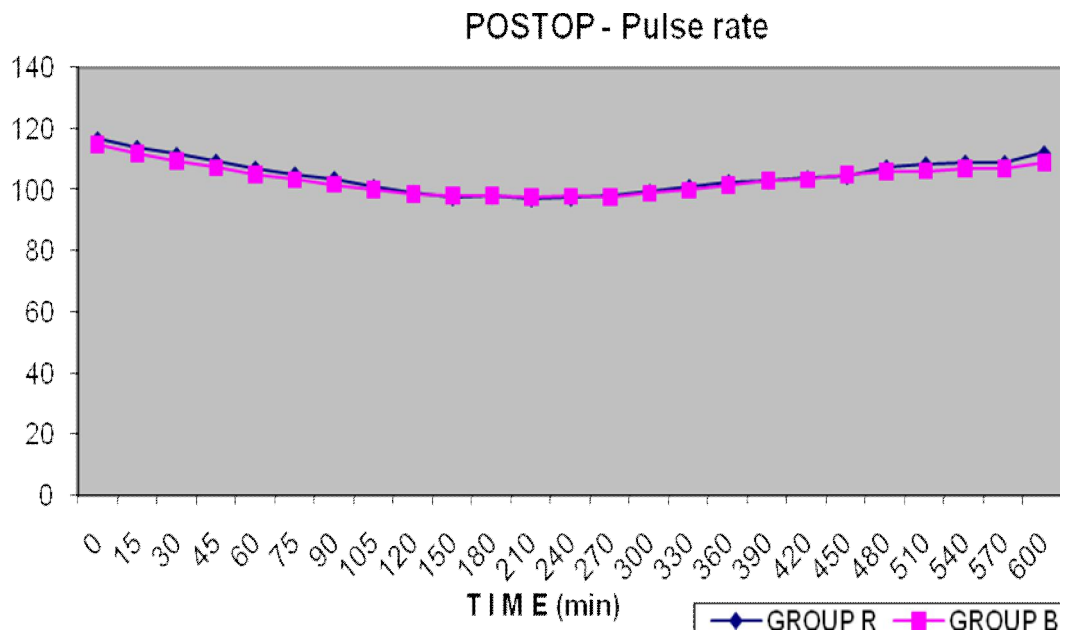
TIME TO FIRST MICTURITION

Of the 60 children, 6 in group R and 4 in group B were already catheterized for their urethroplasty surgeries. There was a delay of at least 6 hours in passing micturition in the remaining children. Among others, there was no difference in the time to first micturition between group R (326.88 ± 41.88 min) and B (330.00 ± 32.62 min). No child required catheterization postoperatively due to retention.

Variable (min)	Group-I		Group-II		P-value	S.E.D.	C.I. of diff 95%	
	Mean	SD	Mean	SD			Lower	Upper
Time to first Micturition	326.88	41.88	330.00	32.62	0.30*	10.57	-24.38	18.13

*not significant

Postoperatively, there were no adverse hemodynamic alterations without any significant difference in the Pulse rate, Blood pressure and the Oxygen saturation between the two groups.



Discussion

DISCUSSION

Our study showed that a single pre-surgical caudal injection of ropivacaine after induction of anaesthesia provided good quality analgesia of sufficient duration following lower abdominal and perineal surgeries.

The mean age in the two groups was comparable - around five years with a minimum of 3 years and a maximum of 8 years. The mean weight (around 14 kg) and height (around 112 cm) were also comparable in both the groups. All our study children were premedicated with intranasal midazolam 0.2mg/kg as suggested by Pradipta Bhakta et al.⁶⁸ Since the majority of the procedures were for inguinal hernia, hydrocele, orchidopexy and phimosis, the mean duration of surgery was short - around 32 min in both the study groups. All the children had stable hemodynamics intraoperatively. A marginal decrease in heart rate and blood pressure which was seen in our study could be explained by the fall in these parameters that is usually associated with induction of anaesthesia and a successful caudal block.

Ropivacaine has been used in different concentrations for caudal block with varying efficacy. Da Conceicao et al⁵⁸ used ropivacaine

0.375% for caudal block and found that it produces sufficient analgesia for lower abdominal surgery in children. But, Ivani et al^{57,59} in two different studies observed that 0.2% ropivacaine given through the caudal route in children is sufficient to provide sensory blockade for infra-umbilical surgeries. In our study, we used 0.25% ropivacaine that provided reliable and long duration analgesia. This finding is in conjunction with previous studies .^{55,56}

We included children who underwent surgeries involving lumbosacral (low) as well as lower thoracic (high) innervations but the number of low and high procedures did not differ between the two groups. Wolf et al⁶⁷ demonstrated that 0.75ml/kg of 0.25% or 0.125% bupivacaine with epinephrine caused adequate sensory blockade for high procedures involving 13 dermatomes in children. In our study, we used 0.75ml/kg volume for caudal injection that was adequate for both thoracolumbar as well as sacral surgeries. But, other studies^{19,56,59} have used 1ml/kg of local anaesthetic for thoracolumbar surgeries.

Many workers^{57,59} had observed that 1ml/kg of 0.2% ropivacaine and 0.25% bupivacaine by caudal block had similar onset and duration. They compared these concentrations in order to achieve equal volumes and to maintain blindness of the study. But, we used equal volumes of

0.25% concentration of both ropivacaine and bupivacaine, thereby achieving study blinding as done by Khalil et al⁵⁶ and others.⁵⁵

G.Ivani et al⁵⁹ found that the mean onset time of caudal 0.2% ropivacaine was 9 min with that of 12 min for 0.25% bupivacaine whereas another study⁵⁷ had observed that the mean onset time was 9.7 and 10.4 min respectively. Since our aim was not to compare the onset times, we used a fixed time of 10min after caudal block for incision for both the groups. In our study, this was found adequate for both ropivacaine and bupivacaine with no child requiring fentanyl supplementation.

T.L.Ala-Kokko et al⁵⁰ had evaluated that 1ml/kg of 0.2% ropivacaine (2mg/kg) and 0.2% bupivacaine (2mg/kg) given by caudal route in 30 children aged 2.3 to 8.7 years resulted in peak plasma concentrations of 1.22 µg/ml and 1.28 µg/ml respectively which is much less than the maximum tolerated venous concentrations of ropivacaine (2.2(0.8) and bupivacaine (2.1 +-1.2) in adult volunteers.¹⁵ They also observed that the time taken to achieve peak concentrations were significantly longer for ropivacaine than bupivacaine indicating slower absorption and tissue distribution of the former after caudal administration. This difference may be due to the intrinsic

vasoconstrictor effect of ropivacaine at low concentrations and higher lipid solubility of bupivacaine. In our study, we used 0.75ml/kg of 0.25% ropivacaine, i.e.1.875 mg/kg of ropivacaine that is much less than that used in the above study. This obviated the need for measuring plasma concentration in our study.

In our study, the mean time from caudal block to first dose of diclofenac administration was comparable for both the groups with the average being slightly less than 6 hours. A similar trial⁵⁶ using 0.25% bupivacaine or 0.25% ropivacaine showed that postoperative analgesia was required at a mean time of 11hours for both drugs whereas another study⁵⁸ using 0.375% bupivacaine or ropivacaine revealed that the mean time for first analgesia was around 5 hours in both drugs. On the contrary, Ivani et al⁵⁹ compared 0.2% ropivacaine with 0.25% bupivacaine and observed that first requirement of rescue analgesia was 253 and 520 min for bupivacaine and ropivacaine groups respectively($P<0.05$). But this finding was not replicated by other studies.^{55,56,57}

Our study showed that significant motor block was demonstrated in all our study children in the recovery room, with the ropivacaine group having a statistically significant greater motor power score than

bupivacaine group. This faster resolution of motor blockade in the ropivacaine group continued in the post-operative ward also. This is in conjunction with other studies⁵⁵ that recorded quicker motor recovery with 0.25% ropivacaine than 0.25% bupivacaine. Khalil et al⁵⁶ also found delayed motor recovery in both the groups and found that those who received 0.25% ropivacaine had slightly higher mean motor score at the end of 3 hours than those who had received 0.25% bupivacaine. Da Conceicao et al⁵⁸ used a higher concentration (0.375%) of ropivacaine and bupivacaine and observed that there was significant difference between ropivacaine and bupivacaine groups in motor block postoperatively with lesser blockade in the former. This quicker motor recovery in ropivacaine group may be due to its less lipid solubility as determined by the N-heptane/buffer partition coefficient of 2.9 as against that of 10 for bupivacaine.¹⁴ This low lipid solubility and high pKa (8.1) of ropivacaine causes blockade of A – delta and C fibers supplying pain and touch sensation to a greater extent than that of the A- α and A- β fibers supplying motor sensation.

Other workers^{55,56} had observed that there were no significant differences in the quality or duration of sensory blockade between equal doses and concentrations of bupivacaine and ropivacaine and reported

that sensory block resolved earlier than motor block. Our study also supported their views.

In our study, there was a delay in micturition of around five and half hours in both the groups with no significant difference between them. This was supported by others⁵⁶ who did not find any difference in the time to first micturition between ropivacaine and bupivacaine. This delay may be due to the blockade of the sacral fibres caused by caudal block that prevents voiding of urine.

Only one child in ropivacaine and 2 children in bupivacaine group had vomiting postoperatively that was treated with Inj. Ondansetron 0.01mg/kg i.v. This may be due to the effects of general anaesthetics.

Due to the smaller study group, we did not encounter any instance of intravenous or intraosseous injections that could have resulted in local anaesthetic toxicity, thereby conferring an added advantage for ropivacaine in terms of increased safety profile.

Our study and others^{56,57,59} have compared the effects of caudal ropivacaine and bupivacaine when administered along with volatile anaesthetics intraoperatively. Pablo M. Ingelmo et al⁶⁴ in their study observed that without the effects of volatile anaesthetics,

0.2% ropivacaine is less effective during surgical stimulation than 0.2% bupivacaine and 0.2% levobupivacaine when used for caudal block. They reasoned out this finding based on the observation that all volatile anaesthetics depress the spinal alpha-motor neuron activity and may potentiate caudal ropivacaine. But they too observed that there was no difference in the analgesic onset times or residual analgesia indicating ropivacaine is an effective local anaesthetic.

Summary

SUMMARY

Bupivacaine is the most frequently used local anaesthetic for caudal anaesthesia in children that provides reliable and long-lasting anaesthesia and analgesia. Ropivacaine provides pain relief similar to bupivacaine with less motor blockade and being a pure S-enantiomer is less cardiotoxic than the latter.

The aim of the study was to compare Caudal Ropivacaine 0.25% and caudal Bupivacaine 0.25% in terms of the quality and duration of analgesia, motor and sensory block for sub-umbilical surgeries.

In a double-blinded comparative study, 60 children aged 3-8 years of ASA I or II physical status were randomly allocated to receive a single presurgical caudal injection of 0.75ml/kg of either 0.25% Ropivacaine (Group R) or 0.25% Bupivacaine (Group B) after induction of general anaesthesia. Apart from monitoring the vital parameters, all children were assessed for postoperative analgesia by Hannallah pain scale and for motor blockade by Motor power score. The time for full sensory recovery was also observed.

The groups were comparable for age, sex, weight, height, vital signs, duration and type of surgery. The quality and duration of postoperative pain relief did not differ between the two groups (338.83 ± 44.75 min in group R Vs 346.67 ± 51.06 min in group B). The motor blockade was significantly less in ropivacaine group than in bupivacaine group with quicker motor recovery recorded in group R (113.50 ± 10.18 min) than group B (128.50 ± 17.48 min) with a $P < 0.001$. The time for full sensory recovery was similar for both the groups (77.50 ± 2.67 min in group R vs 80.00 ± 7.19 min in group B). Postoperative vitals were stable in all the children and the time to first micturition did not differ between the two groups (326.88 ± 41.88 min in R vs 330.00 ± 32.62 min in B). No adverse events occurred during the study.

Ropivacaine is a safe and effective local anaesthetic for paediatric caudal anaesthesia. Ropivacaine 0.25% 0.75ml/kg provided good quality and adequate duration of analgesia similar to bupivacaine in equal volumes and concentration when administered for caudal block for sub-umbilical surgeries. Ropivacaine produced significantly faster motor recovery than bupivacaine giving a distinct advantage over the latter by allowing the children to be discharged earlier.

Conclusion

CONCLUSION

In conclusion, Caudal Ropivacaine 0.25%, 0.75ml/kg provided reliable and long lasting analgesia similar to 0.75ml/kg of 0.25% Bupivacaine in children undergoing sub-umbilical surgeries. Ropivacaine caused less motor blockade than bupivacaine with similar time for sensory recovery. These along with the lower intrinsic toxicity of ropivacaine make it an effective and safe drug for day case surgery in paediatric patients.

Annexure

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CERTIFICATE FOR APPROVAL OF ETHICAL COMMITTEE

To

Dr.Sendhil Kumar Mohan, PG in MD(Anes)

Dear Dr.Sendhil Kumar Mohan, PG in MD(Anes)

The Institutional Ethics Committee reviewed and discussed your application for approval of the project entitled

"Comparison of Ropivacaine with Bupivacaine for Paediatric Caudal Block"

The following members of the ethics committee were present at the meeting held on 28.01.2018 at the Council Hall, Stanley Medical College, Chennai-1 at 10.00AM

Dr.C.B.Tharani, Director of Pharmacology,

Madras Medical College, Chennai-3 - Chairman of the Ethics Committee

Dr.S. Chitra, Vice-Principal,

Stanley Medical College, Chennai - 1- Member Secretary of the Ethics Committee

MEMBERS

Dr.Jayanthi

Prof.of Medical Gastroenterology

Dr.Madhavan

Prof.of Pharmacology

Dr.E.Dhandapani

Prof.of Medicine

Dr.Sujatha Sridharan

Prof.of Paediatrics

Thiru.Pachaiappan,

Junior Administrative Officer,

Thiru.A. Senthil Manoharan,

Advocate

We approve the project to be conducted in its presented form.

The Institutional Ethics Committee/Independent Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Chitra S

Member Secretary,

Ethics Committee

MEMBER SECRETARY
ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE
CHENNAI-600 001.

நோயாளி தகவல் தாள்

குழந்தைகளுக்கான காடல் ப்ளாக்கில் (Caudal Block) ரோபிவேகேய்ன் மற்றும் புபிவேகேய்ன் மயக்க மருந்துகளை ஒப்பிடும் ஆய்வு

நோயாளிகளுக்கான தகவல் :

ஆராய்ச்சியின் நோக்கமும், ஆதாயங்களும் :

உங்கள் குழந்தையை ஈடுபடுத்த திட்டமிடப்பட்டுள்ள இந்த மருத்துவ ஆராய்ச்சி ஆய்வானது, 0.25% ரோபிவேகேய்ன் அல்லது 0.25% புபிவேகேய்ன் மயக்க மருந்துகள் குழந்தையின் முதுகில் சிறு ஊசி மூலம் செலுத்தப்பட்டு அதனால் ஏற்படும் வ- நிவாரணம் போன்ற குறியீடுகளை ஒப்பிட்டுப் பார்ப்பதை நோக்கமாக கொண்டுள்ளதாகும். மருத்துவ விவரக் கையேட்டில் அறிவிக்கப்பட்டுள்ள ஆய்வுகளின் படி, ரோபிவேகேய்ன் மருந்து புபிவேகேய்ன் மருந்தைவிட குறைவான இருதய பாதிப்பையே ஏற்படுத்துகிறது. மேலும் இது குழந்தையை விரைவாக நடமாட வைக்க உதவுகிறது. இந்த மருந்து குழந்தைகளில் பாதுகாப்பானதாகவும் இருப்பதாக அறியப்படுகிறது. இம்மருந்தினால் உங்கள் குழந்தை பயனடைவார்கள் என எதிர்பார்க்கப்படுகிறது. இந்த ஆய்வின் மூலம் பெறப்படும் அறிவானது, இது போன்ற அறுவை சிகிச்சை செய்து கொள்ளும் மற்ற குழந்தைகளுக்கும் பயனுடையதாக அமையும்.

மாற்று மயக்க மருந்துகள்:

காடல் ப்ளாக்கில் ரோபிவேகேய்ன் மற்றும் புபிவேகேய்ன் மருந்துகள் அல்லாமல் -க்னோகேய்ன் போன்ற மருந்துகளும் உபயோகத்தில் உள்ளன. இது மேற்குறிப்பிட்டுள்ள இரண்டு மருந்துகளை விட குறைவான நேரமே வ- நிவாரணம் அளிக்கும்.

மாற்று மயக்க முறைகள் :

இது போன்ற தொப்புளுக்கு கீழே செய்யப்படும் அறுவை சிகிச்சைக்கு (குட-றக்கம், விரைநீர் கோர்த்துதல், விரை இறங்காமல் இருப்பது போன்றவற்றிக்கு அறுவை சிகிச்சை செய்வது) வெறும் முழு மயக்கமே முன்னால் கொடுக்கப்பட்டு வந்தது. இந்த முறையில் வ- நிவாரணிகளை இரத்த நாளத்தின் மூலமாக கொடுப்பதினால் ஏற்படக் கூடிய மூச்சு விடுவதில் சிரமம் மற்றும் போதிய வ- நிவாரணம் இல்லாதது போன்ற சிரமங்கள் உள்ளன.

உண்டாகக்கூடிய இடர்கள் :

அனைத்து மயக்க மருந்து மற்றும் மயக்க முறைகளுடன் இருப்பது போலவே இந்த முறையிலும் சில எதிர்பாரா இடர்கள் நடைபெறலாம். காடல் ப்ளாக் முறையில் மிக அரிதாக இந்த மயக்க மருந்துகள் இரத்ததிலலோ அல்லது எலும்புகளுக்குள்ளோ செலுத்தப்படுவதற்கான வாய்ப்பு உள்ளன. அப்படியாக நேரும் பட்சத்தில், அது இருதய பாதிப்பையும் ஏற்படுத்தலாம். இந்த மருந்துகளினால் ஒரு சில பேருக்கு அறுவைசிகிச்சைக்குப் பின் வாந்தி அல்லது சிறுநீர் கழிப்பதில் தாமதம் போன்ற சிறு பிரச்சனைகள் ஏற்பட வாய்ப்புள்ளது.

இந்த ஊறுகளை குறைக்கும் பொருட்டு மருத்துவரால் செய்யப்படும் பொருத்தமான கூர்ந்தாராய்வு சோதனைகள் மற்றும் முன்னெச்சரிக்கை நடவடிக்கைகளுடன் இந்த ஆய்வை வடிவமைக்க அக்கறை எடுத்துக் கொள்ளப்பட்டுள்ளது. ஆய்வு பொருப்பேற்றுள்ள மருத்துவர், இந்த ஆய்வு மருந்துகளுடன் தொடர்புடைய மற்ற அனைத்துப் பிற இடங்களைப் பற்றியும் உங்களுக்கு விளக்குவார்.

ஆய்வு நடைமுறைகள் :

இந்த ஆய்வில், உங்கள் குழந்தைக்கு அறுவை சிகிச்சைக்கு செல்லும் முன் தூக்கமருந்து கொடுத்து அறைக்கு எடுத்துச் சொல்லப்படுவார்கள். அங்கு இரத்த நாளத்தில் சிறு ஊசி மூலம் முழு மயக்கம் மற்றும் மூச்சுக் குழாயில் சிறு டியூப் (Endotracheal Tube) மூலம் செயற்கை சுவாசம் கொடுக்கப்படும். பிறகு உங்கள் குழந்தைகளின் முதுகில், சிறு ஊசி மூலம் ஆய்வின் மருந்துகள் (ரோபிவேகேய்ன் அல்லாத புபிவேகேய்ன்) செலுத்தப்பட்டு அறுவை சிகிச்சை செய்யப்படும். சிகிச்சைக்குப்பின் குழந்தையை மயக்கத்தில் இருந்து வெளியே கொண்டு வரப்பட்டு மூச்சுக் குழாயில் இருந்து டியூப் எடுக்கப்படும். அறுவை சிகிச்சைக்குப்பின் உங்கள் குழந்தையின் வ-, உணர்ச்சியின் அளவு மற்றும் தசைகளை இயக்கும் திறன் ஆகியவை பரிசோதிக்கப்படும். உங்கள் குழந்தைக்கு வ- ஏற்பட்டால் அதற்கான வ- நிவாரணி கொடுக்கப்பட்டு தொடர்ந்து உங்கள் குழந்தை மருத்துவரால் கண்காணிக்கப்படும்.

ஆய்வில் உங்கள் உரிமைகள் :

உங்கள் மருத்துவப் பதிவேடுகள் மிகவும் அந்தரங்கமாக வைத்துக் கொள்ளப்படும். இந்த ஆய்வின் முடிவுகள் அறிவியல் பத்திரிகைகளில் பிரசுரிக்கப்படலாம். ஆனால், பெயரை வெளியிடுவது மூலம் உங்கள் குழந்தை அடையாளம் காட்டப்படமாட்டார்கள். இந்த ஆய்வில் உங்கள் குழந்தையின் பங்கேற்பு தன்னிச்சையானது மற்றும் காரணங்கள் எதையும் கூறாமலேயே நீங்கள் இந்த ஆய்வி-ருந்து எந்த ஒரு நேரத்திலும் விலகிக் கொள்ளலாம். எப்படியிருந்தாலும் உங்கள் குழந்தைக்கு தகுந்த மயக்க மருந்து கொடுத்து அறுவை சிகிச்சை செய்யப்படும். இந்த ஆய்வில் ஏதேனும் பக்க விளைவுகள் ஏற்பட்டால் உங்கள் குழந்தைக்கு முழு சிகிச்சை மருத்துவ குழுவினரால் அளிக்கப்படும்.

நாள் :

பெற்றோர் கையொப்பம்/
இடது பெருவிரல் ரேகை

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

குழந்தைகளுக்கான காடல் ப்ளாக்கில் ரோபிவேகேயன் மற்றும் புபிவேகேயன் மயக்க மருந்துகளை ஒப்பிடும் ஆய்வு

ஆராய்ச்சி நிலையம் : அரசு ஸ்டான்- மருத்துவமனை,
சென்னை - 600 001.
பங்கு பெறும் குழந்தையின் பெயர் : வயது :
பங்கு பெறும் குழந்தையின் எண் : பா-எம் : ஆண் பெண்
பெற்றோர் பெயர்/ விலாசம் :

பெற்றோர் இதனை (✓) குறிக்கவும்.

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும். அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் என் குழந்தையை இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்க வைக்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் என் குழந்தையை இவ்வாய்வில் இருந்து விலக்கி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என் குழந்தையுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். என் குழந்தையை ஆய்வில் இருந்து விலக்கிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன்.

இந்த ஆய்வில் என் குழந்தையை ஈடுபடுத்த முழுமனதுடன் ஒப்புக் கொள்கிறேன். இந்த மயக்க மருந்துகள் மற்றும் மயக்க முறையினால் ஏற்படக் கூடிய பின் விளைவுகள் மற்றும் எதிர்பாராத விளைவுகள் பற்றி எனக்கு விளக்கமாக தெரிவிக்கப்பட்டது.

இந்த ஆய்வில் என் குழந்தைக்கு முழு மயக்கம் கொடுத்த பின் முதுகில் சிறு ஊசி மூலம் (காடல் ப்ளாக்) ரோபிவேகேயன் அல்லது புபிவேகேயன் மயக்க மருந்துகளை கொடுக்க சம்மதிக்கிறேன். மேலும், அறுவை சிகிச்சைக்குப் பின் குழந்தையின் வ-, உணர்ச்சியின் அளவு மற்றும் இடுப்பு, கால் தசையை இயக்கும் அளவு போன்ற அனைத்து விதமான பரிசோதனைகளையும் செய்து பார்க்க நான் முழுமனதுடன் சம்மதிக்கின்றேன்.

என் குழந்தையின் நலன் கருதியே இந்த ஆய்வு மேற்கொள்ளப்பட்டது என்று தெரிந்து இந்த ஆய்விற்கு ஒப்புளிக்கின்றேன்.

பெற்றோரின் கையொப்பம் இடம் தேதி

கட்டைவிரல் ரேகை (இந்த படிவம் படித்து காட்டப்பட்டு புரிந்து கைரேகை அளிக்கின்றேன்)
ஆய்வாளரின் கையொப்பம் இடம் தேதி
ஆய்வாளரின் பெயர்

PROFORMA

Date : Serial No.

Name :

Age/Sex : Weight : Ht : I.P. No. :

Diagnosis :

Surgery Planned :

ASA Status : Parental Consent :

Associated medical conditions : Last Oral intake :

Premedication : Intranasal Midazolam : Time :

Shifted to O.T. Time : I.V. access :

Monitors : Baseline : HR : B.P. : SpO2 :

Induction : Propofol Atracurium

Intubation : E.T.Size :

Caudal Block time :

Volume of the Local Anaesthetic:

Incision time :

Intra-op parameters :

Time 0 5 10 15 20 25 30 35 40 45 50 55 60

HR

BP

SpO2

Intra-op complications

PROFORMA (Contd.)

Extubation

Reversal : Neo Atropine

Recovery /Reflexes :

Duration of Surgery:

Post-OP :

1. Hannallah Pain Scale

0	15	30	45	60	75	90	105	120	150	180	210	240	270	300	330	360	390	420	450	480	510	540	570	600	

2. Motor Power Scale

0	15	30	45	60	75	90	105	120	150	180	210	240	270	300	330	360	390	420	450	480	510	540	570	600	

3. Vital Parameters

	0	15	30	45	60	75	90	105	120	150	180	210	240	270	300	330	360	390	420	450	480	510	540	570	600
PR																									
SBP																									
SP0 ₂																									

Time of First Analgesic drug administration :

Time of Full Motor recovery :

Time of Full Sensory recovery :

Time for first Micturition :

Anaesthesiologist's Signature

MASTER CHART - DEMOGRAPHIC - DATA

S. No	Group	AGE	SEX	Wt(Kg)	Ht (cm)	I.P. NO.	SURGERY	VOL.L.A.
1	B	3.5	M	12	106	61958	R PVSL	9
2	B	3	M	9	104	61644	L IH	6.75
3	B	3	M	10	103	61965	CIRCUM	7.5
4	R	8	M	23	122	61954	RECTAL POLYP	17.25
5	R	5	M	14	110	61963	R PVSL	10.5
6	B	3	M	10	105	61960	R PVSL WITH CIRCUM	7.5
7	B	3.5	M	11	106	62012	R ORCHIDOPEXY	8.25
8	R	5	M	13	114	62103	URETHROPLASTY	9.75
9	R	8	M	15	118	62099	LIH	11.25
10	B	5	M	11	112	62098	R PVSL	8.25
11	B	7	M	19	116	61964	CIRCUMCISION	14.25
12	B	3	M	9	104	62096	CIRCUM	6.75
13	R	5	M	13	115	62102	RPVSL	9.75
14	B	5	M	15	116	62101	LIH	11.25
15	R	6	M	16	116	62093	L PVSL	12
16	R	4	M	12	108	62155	URETHROPLASTY	9
17	R	3.5	M	12	106	62226	RPVSL,CIRCUM	9
18	B	3	M	10	106	62158	R PVSL WITH CIRCUMCISION	7.5
19	R	3	M	10	104	62160	CIRCUM	7.5
20	B	8	F	19	118	62157	BIL. HERNIOTOMY	14.25
21	B	5	M	14	115	62285	URETHROPLASTY	10.5
22	B	5	M	16	117	62219	RIH	12
23	B	8	M	20	120	62221	RIH	15
24	B	5	M	18	116	62291	RECTAL POLYP	13.5
25	B	3	M	11	104	62329	L PVSL	8.25
26	B	5	M	16	117	62340	R PVSL	12
27	R	4	M	13	105	62393	LIH	9.75
28	R	8	M	18	120	62059	R IH	13.5
29	B	8	M	19	122	62063	L ORCHIDOPEXY	14.25
30	R	3	M	11	104	62113	URETHROPLASTY	8.25
31	R	8	M	17	116	62115	R ORCHIDOPEXY	12.75
32	B	8	M	24	119	62116	MAGPI	18
33	R	3.5	F	14	114	62110	CLITOROPLASTY	10.5
34	B	3	M	10	102	62444	ANOPLASTY	7.5
35	R	3	M	12	110	62118	R PVSL	9
36	B	5	F	13	116	62443	RIH	9.75
37	B	5	M	14	118	62447	URETHROPLASTY	10.5
38	B	7	M	18	120	62456	RIH	13.5
39	B	4	M	13	110	62454	R ORCHIDOPEXY	9.75
40	R	4	M	12	113	62534	CIRCUM	9
41	B	3	M	12	105	62660	URETHROPLASTY	9
42	B	8	M	19	118	62450	URETHROPLASTY	14.25
43	R	3	M	13	108	62650	CIRCUM	9.75
44	B	4	M	14	108	62339	URETHROPLASTY	10.5
45	R	8	M	22	120	62702	L ORCHIDOPEXY	16.5
46	R	3	M	14	105	62652	CIRCUM	10.5
47	R	4	M	12	105	62709	R PVSL	9
48	R	5	M	13	108	62785	CIRCUM	9.75
49	B	3	M	9	103	62745	LIH	6.75
50	B	4	F	13	109	62832	HAMARTOMA	9.75
51	R	5	M	15	110	62786	RIH	11.25
52	R	3	M	12	106	62829	R PVSL WITH CIRCUM	9
53	R	6	M	15	120	62830	HYPOSPADIAS	11.25
54	B	5	M	14	114	62878	CIRCUMCISION	10.5
55	R	3.5	M	12	105	62875	R PVSL WITH CIRCUM	9
56	R	3	F	11	106	62781	RIH	8.25
57	R	6	M	15	118	62876	URETHROPLASTY	11.25
58	R	5	M	13	114	62874	R PVSL	9.75
59	R	4.5	M	14	112	62748	RIH	10.5
60	R	8	M	18	120	62880	CIRCUM	13.5

MASTER CHART-POST OPERATIVE ANALGESIC REQUIREMENT

S. No.	Group	T.F.A. (min)	T.M.R. (min)	T.S.R. (min)	T.F.M (min)
1	B	460	150	120	420
2	B	425	150	120	450
3	B	475	150	120	375
4	R	455	150	120	400
5	R	395	120	105	375
6	B	330	120	105	475
7	B	280	150	105	420
8	R	330	105	105	
9	R	315	105	105	480
10	B	310	120	105	450
11	B	330	120	105	475
12	B	255	105	105	510
13	R	380	120	105	495
14	B	275	105	105	450
15	R	360	105	105	425
16	R	335	105	105	
17	R	390	120	105	500
18	B	280	105	105	420
19	R	245	105	105	470
20	B	305	105	105	500
21	B	390	150	120	
22	B	370	120	120	375
23	B	330	120	105	420
24	B	340	120	105	450
25	B	360	150	120	480
26	B	365	150	105	420
27	R	290	105	105	390
28	R	375	120	105	420
29	B	355	120	105	450
30	R	370	120	120	
31	R	365	120	105	375
32	B	335	120	105	480
33	R	335	120	105	
34	B	400	150	120	435
35	R	310	105	105	400
36	B	335	120	105	490
37	B	310	120	105	420
38	B	380	150	120	440
39	B	385	150	105	435
40	R	305	105	105	400
41	B	315	120	105	
42	B	335	120	120	
43	R	340	120	105	360
44	B	305	105	105	
45	R	355	105	105	420
46	R	290	105	105	440
47	R	350	120	120	420
48	R	305	105	105	450
49	B	335	120	105	450
50	B	370	150	120	480
51	R	385	120	120	420
52	R	335	105	105	475
53	R	290	105	105	
54	B	360	120	105	490
55	R	355	120	105	520
56	R	255	105	105	475
57	R	355	120	105	
58	R	285	105	105	480
59	R	340	120	105	500
60	R	370	120	120	475

MASTER CHART - POST OPERATIVE PULSE RATE - TIME (MIN)

S. No.	Grp	0	30	60	90	120	150	180	240	300	360	420	480	540	600
1	B	120	116	110	106	100	102	98	104	98	99	103	107	109	110
2	B	120	115	106	102	98	96	97	97	98	103	103	107	107	109
3	B	118	114	110	107	103	102	101	97	98	103	105	106	107	110
4	R	118	115	112	108	102	100	100	100	104	109	113	120	118	122
5	R	116	116	112	108	103	100	99	96	99	104	104	106	105	112
6	B	117	112	109	105	102	101	100	97	96	100	103	107	108	112
7	B	118	113	110	107	104	102	100	97	98	103	104	108	110	110
8	R	110	110	106	100	97	96	97	97	99	103	107	118	118	120
9	R	116	110	106	102	98	96	96	96	100	105	105	106	110	114
10	B	112	107	104	101	97	98	99	98	97	102	106	108	109	112
11	B	110	106	103	100	97	95	94	98	99	103	102	107	107	110
12	B	120	116	113	108	105	102	100	97	98	104	103	107	107	108
13	R	114	110	106	108	103	101	100	97	97	102	102	108	112	116
14	B	118	112	106	103	98	95	96	97	98	99	101	105	106	106
15	R	115	110	108	108	102	99	97	96	100	104	104	112	114	120
16	R	116	112	106	102	97	95	97	95	98	102	101	98	106	105
17	R	114	110	108	107	102	100	98	97	101	105	105	104	108	110
18	B	122	116	112	108	104	102	101	100	99	99	103	105	107	108
19	R	128	120	116	110	105	103	101	97	102	104	104	122	118	115
20	B	112	107	103	100	98	96	98	97	97	101	100	101	102	106
21	B	112	107	103	99	96	98	96	97	98	100	101	104	106	107
22	B	113	108	103	100	98	96	98	99	98	101	99	104	106	105
23	B	113	108	104	102	98	96	98	97	100	103	107	108	107	108
24	B	117	112	108	104	101	99	97	96	101	105	106	105	109	114
25	B	126	117	110	104	100	106	103	101	105	110	108	108	107	110
26	B	112	105	101	98	98	99	101	96	101	101	103	107	107	108
27	R	120	112	104	100	96	95	97	97	97	101	99	104	102	106
28	R	112	108	102	101	96	96	95	97	99	99	103	101	99	104
29	B	114	108	105	101	97	98	96	97	101	105	104	107	108	108
30	R	116	110	106	102	97	95	97	94	98	102	101	103	103	108
31	R	108	104	100	101	96	94	96	95	97	99	102	104	105	106
32	B	111	105	101	97	96	95	97	98	99	102	101	105	107	108
33	R	120	114	108	100	96	95	96	96	96	100	99	103	102	105
34	B	117	110	105	101	97	98	96	98	99	99	104	105	106	110
35	R	120	114	110	105	100	98	99	99	99	101	104	103	107	108
36	B	122	116	110	106	102	100	98	99	100	101	103	104	105	109
37	B	108	103	100	98	95	97	96	97	101	100	104	108	110	112
38	B	112	108	104	100	96	94	97	97	100	101	105	106	105	108
39	B	110	103	99	96	95	96	98	99	103	98	103	107	105	106
40	R	122	115	112	104	99	97	99	96	100	100	100	107	108	110
41	B	113	109	104	101	97	96	98	99	98	99	104	106	107	110
42	B	101	96	93	97	98	96	99	98	99	102	103	107	104	104
43	R	120	115	112	107	102	100	98	98	102	99	99	102	106	108
44	B	118	113	108	104	99	100	97	98	99	103	105	106	106	110
45	R	110	104	98	97	95	93	95	96	99	100	104	105	106	110
46	R	124	119	115	110	105	103	102	101	100	103	107	108	112	115
47	R	115	110	106	105	101	99	100	102	102	106	107	113	113	117
48	R	116	112	107	103	98	97	99	100	99	103	103	107	111	115
49	B	122	117	112	107	104	102	100	97	98	103	104	105	108	112
50	B	112	106	102	98	97	96	98	98	99	100	104	105	109	108
51	R	116	110	105	103	99	97	99	98	98	102	103	107	109	112
52	R	122	116	110	106	101	100	101	100	101	104	106	105	110	115
53	R	106	101	97	94	96	95	97	98	100	105	106	110	109	112
54	B	107	102	97	95	95	98	99	98	95	102	103	107	108	109
55	R	112	106	100	99	95	93	95	96	99	103	105	109	112	114
56	R	122	117	113	110	104	102	100	101	100	105	109	113	113	118
57	R	114	105	98	97	94	95	95	96	97	102	104	108	109	113
58	R	120	116	110	104	97	95	97	96	101	102	101	108	112	114
59	R	120	115	110	105	99	97	99	99	100	100	104	105	109	110
60	R	118	112	108	103	98	98	98	95	97	103	104	104	105	107

MASTER CHART - POST-OPERATIVE SYSTOLIC BLOOD PRESSURE - TIME (MIN)

S. No.	Grp	0	30	60	90	120	150	180	240	300	360	420	480	540	600
1	B	100	100	100	100	100	98	102	98	102	102	102	102	104	104
2	B	98	98	98	98	98	96	100	96	98	100	100	100	104	104
3	B	98	98	98	98	100	98	96	100	100	100	104	106	104	104
4	R	100	100	98	100	100	102	100	100	102	106	102	102	104	102
5	R	102	100	100	104	102	104	102	100	104	102	104	108	104	108
6	B	96	96	96	96	96	98	94	94	98	102	98	98	102	102
7	B	98	98	98	98	98	96	100	96	100	102	98	102	102	102
8	R	98	98	98	102	100	98	100	98	102	102	106	108	104	106
9	R	100	100	98	98	100	100	102	98	98	102	102	106	106	106
10	B	98	98	98	98	94	96	98	98	98	100	100	100	104	102
11	B	98	94	98	98	98	100	98	98	98	102	102	98	102	106
12	B	96	96	96	96	100	98	96	100	100	100	100	104	104	106
13	R	98	100	100	100	100	98	100	100	98	102	106	106	108	106
14	B	98	96	100	100	100	102	100	96	100	100	104	104	104	104
15	R	100	100	100	100	100	98	100	98	100	100	104	108	104	106
16	R	100	100	96	100	100	102	100	102	106	104	106	106	106	106
17	R	98	94	98	98	96	98	96	100	98	100	100	102	102	106
18	B	98	98	98	98	98	100	98	98	102	102	104	102	106	104
19	R	100	100	98	102	98	100	98	102	98	98	102	102	106	106
20	B	98	98	98	102	102	100	98	102	98	102	106	106	104	104
21	B	98	98	98	98	98	96	100	96	100	100	100	102	102	104
22	B	98	98	98	98	98	100	98	98	100	100	100	104	104	108
23	B	100	100	100	100	100	102	104	104	104	104	104	104	104	108
24	B	100	100	104	102	102	100	102	102	98	102	102	106	104	106
25	B	98	98	98	94	98	96	98	98	98	98	102	102	102	104
26	B	100	96	100	100	104	102	100	104	100	104	104	104	104	108
27	R	98	102	98	100	100	98	100	100	104	102	106	106	106	108
28	R	98	98	98	98	98	100	98	98	100	100	104	104	104	106
29	B	98	98	98	98	98	100	98	98	98	98	102	102	102	106
30	R	98	98	98	102	98	100	102	98	102	98	102	102	106	106
31	R	98	102	98	102	102	100	104	100	104	102	102	106	106	108
32	B	100	100	102	98	98	100	102	102	102	102	106	108	108	108
33	R	98	98	98	98	96	98	100	98	98	100	98	98	98	102
34	B	98	98	94	98	98	96	98	98	98	102	102	102	102	106
35	R	102	102	98	102	98	100	102	100	98	100	100	102	106	104
36	B	98	98	98	98	98	100	98	98	98	102	102	102	106	104
37	B	100	100	98	102	98	100	102	98	102	98	102	104	106	106
38	B	98	98	98	102	100	102	98	102	98	102	106	106	106	110
39	B	100	100	100	100	100	102	100	100	100	104	104	104	108	108
40	R	98	98	98	98	98	96	98	98	102	98	102	102	102	106
41	B	98	98	98	102	98	96	100	96	100	96	100	100	104	108
42	B	100	100	100	96	100	102	100	100	100	100	102	106	106	106
43	R	98	98	94	98	94	98	96	96	98	102	102	98	102	104
44	B	98	98	98	98	98	96	98	98	98	102	102	104	102	106
45	R	98	98	102	98	102	98	100	98	102	102	102	106	106	108
46	R	98	98	98	94	98	96	98	98	98	102	106	110	106	110
47	R	100	100	100	100	98	100	98	98	100	100	104	104	104	108
48	R	98	98	98	98	100	98	100	96	98	100	100	100	104	108
49	B	98	98	98	98	98	96	98	98	98	98	102	102	102	106
50	B	98	98	98	98	98	100	98	98	102	102	102	104	108	110
51	R	98	100	100	100	96	98	100	100	96	100	100	104	108	106
52	R	96	96	96	100	96	98	100	96	102	106	104	106	108	110
53	R	98	98	98	98	100	98	96	98	100	100	104	102	102	106
54	B	100	100	100	100	100	104	102	98	102	102	106	108	108	110
55	R	100	98	98	98	98	96	98	100	100	104	100	104	104	106
56	R	96	96	96	100	96	100	98	102	98	102	104	100	104	104
57	R	100	100	96	100	100	102	102	102	102	106	106	106	106	108
58	R	98	98	98	98	96	98	100	96	102	102	102	104	106	106
59	R	98	98	98	98	98	100	98	102	98	102	102	104	104	104
60	R	98	98	98	102	102	100	98	98	104	102	106	106	106	106

KEY TO MASTER CHART

Grp	-	Group
R	-	Ropivacaine
B	-	Bupivacaine
M	-	Male
F	-	Female
Wt	-	Weight in kilograms
Ht	-	Height in centimeters
Vol. L.A.	-	Volume of local anaesthetic
L/R PVSL	-	Left/Right Processus Vaginalis Sac Ligation
LIH/RIH	-	Left/Right Inguinal Hernia
D.O.S.	-	Duration of Surgery
Base	-	Baseline
Bef. Inc.	-	Before Incision
T.F.A.	-	Time for First Analgesic drug administration
T.M.R.	-	Time for Full Motor Recovery
T.S.R.	-	Time for Full Sensory Recovery
T.F.M.	-	Time for first Micturition