"A PROSPECTIVE, RANDOMIZED DOUBLE BLINDED CONTROL STUDY COMPARING INJECTION BUPIVACAINE 0.25% AND INJECTION ROPIVACAINE 0.2% FOR CAUDAL ANALGESIA IN PAEDIATRIC PATIENTS UNDERGOING ELECTIVE LOWER ABDOMINAL SURGERIES"

Dissertation submitted to

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

In partial fulfillment for the award of the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X

INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE

MADRAS MEDICAL COLLEGE

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APRIL 2016

CERTIFICATE

This is to certify that the dissertation entitled, **"A PROSPECTIVE, RANDOMIZED DOUBLE BLINDED CONTROL STUDY COMPARING INJECTION BUPIVACAINE 0.25% AND INJECTION ROPIVACAINE 0.2% FOR CAUDAL ANALGESIA IN PAEDIATRIC PATIENTS UNDERGOING ELECTIVE LOWER ABDOMINAL SURGERIES"** submitted by **Dr. SILAMBARASAN . S**, in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamil Nadu Dr. M.G.R. Medical University, Chennai, is a bonafide record of the work done by him in the INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE, Madras Medical College and government hospital, during the academic year 2013-2016.

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CERTIFICATE BY THE GUIDE

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DECLARATION

I hereby, solemnly declare that this dissertation entitled **"A PROSPECTIVE, RANDOMIZED DOUBLE BLINDED CONTROL STUDY COMPARING INJECTION BUPIVACAINE 0.25% AND INJECTION ROPIVACAINE 0.2% FOR CAUDAL ANALGESIA IN PAEDIATRIC PATIENTS UNDERGOING ELECTIVE LOWER ABDOMINAL SURGERIES"** is a bonafide record of the work done by me in the Institute of Anaesthesiology and Critical Care, Madras Medical College and Government General Hospital, Chennai, during the period 2013 – 2016 under the guidance of **Prof. DR. N. KRISHNAN M.D., D.A.,** Professor of anaesthesiology, Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai – 3 and submitted to The **Tamil Nadu Dr. M.G.R. Medical University,** Guindy, Chennai – 32, in partial fulfilment for the requirements for the award of the degree of M.D. Anaesthesiology (Branch X), examinations to be held on April 2016.

I have not submitted this dissertation previously to any university for the award of degree or diploma.

Place: Chennai. **Dr . SILAMBARASAN.S**

Date:

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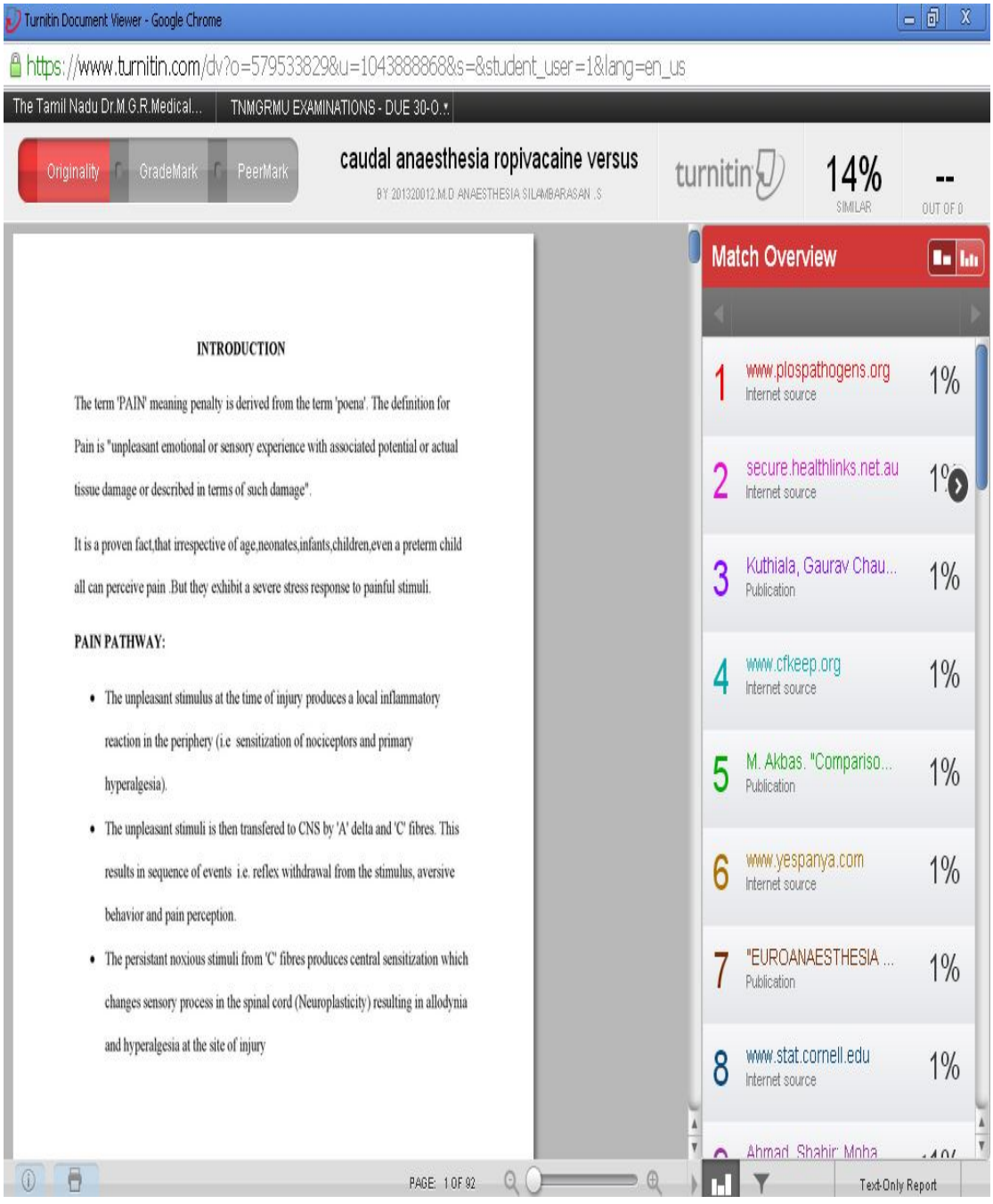
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INTRODUCTION
The term 'PAIN' meaning penalty is derived from the term 'poena'. The definition for Pain is "unpleasant emotional or sensory experience with associated potential or actual tissue damage or described in terms of such damage".
It is a proven fact,that irrespective of age,neonates,infants,children,even a preterm child all can perceive pain .But they exhibit a severe stress response to painful stimuli.
PAIN PATHWAY:
The unpleasant stimulus at the time of injury produces a local inflammatory reaction in the periphery (i.e sensitization of nociceptors and primary hyperalgesia).
The unpleasant stimuli is then transfered to CNS by 'A' delta and 'C' fibres. This results in sequence of events i.e. reflex withdrawal from the stimulus, aversive behavior and pain perception.
The persistant noxious stimuli from 'C' fibres produces central sensitization which changes sensory process in the spinal cord (Neuroplasticity) resulting in allodynia and hyperalgesia at the site of injury
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INTRODUCTION

PAIN PATHWAY:

CONTENTS

INTRODUCTION

The term 'PAIN' meaning penalty is derived from the term 'poena'. The definition for Pain is "unpleasant emotional or sensory experience with associated potential or actual tissue damage or described in terms of such damage[2]".

It is a proven fact, that irrespective of age, neonates, infants, children, even a preterm child all can perceive pain. But they exhibit a severe stress response to painful stimuli.

Pain Pathway

- The unpleasant stimulus at the time of injury produces a local inflammatory reaction in the periphery (i.e sensitization of nociceptors and primary hyperalgesia).
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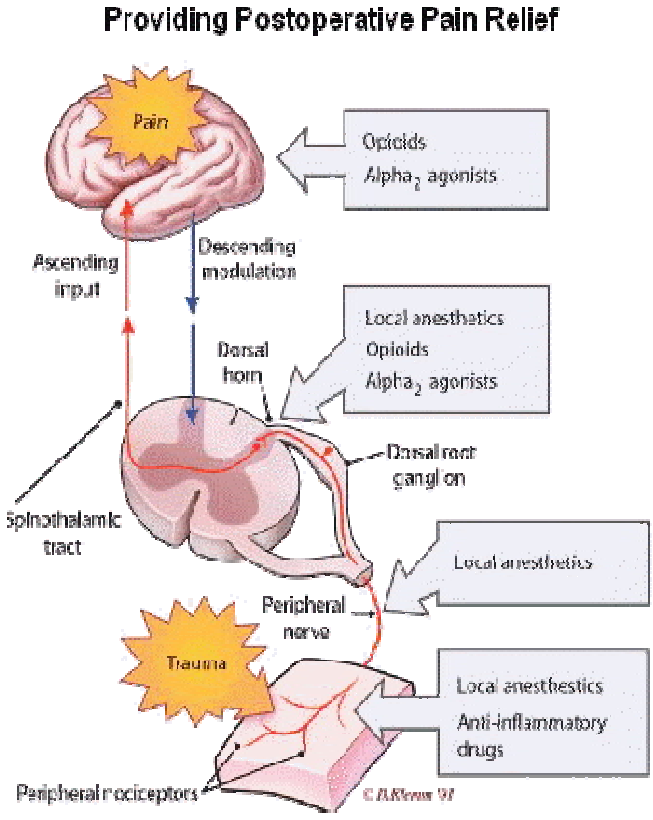


During early Neonatal period there are certain differences in the mechanism of pain response as follows:

- They have lower threshold for pain sensation(Higher pain threshold in adults) with exaggerated reflex responses.
- In the motor component of withdrawal reflex, there is less coordination i.e. involvement of whole body movements during withdrawal response.
- The receptive fields of sensory neurons are larger and highly overlapping which influences sensory localization and discrimination.

Though 'A' delta and 'C' fibres matures after birth but 'C' fibres mature later than 'A' delta; so in Neonates 'A' delta is responsible for central sensitization rather than 'C' fibre.

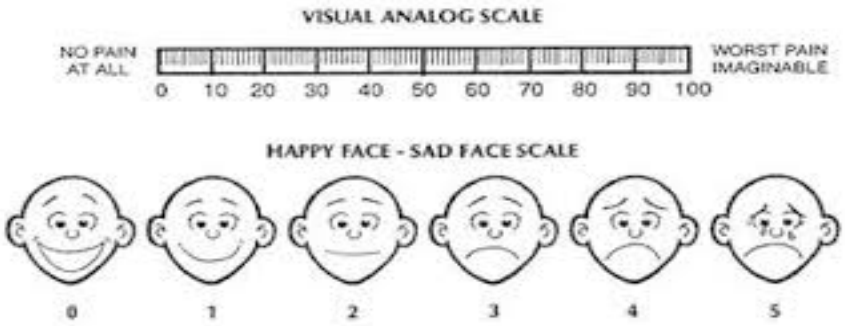
At birth the peripheral inflammatory response is under developed.

Pain Assessment In Children

The wide range of physiological and behavioral responses, cognitive abilities, psychological development from the period between the preterm neonate and adolescent causes huge problems for valid and reliable measurement[5].

1. Self report measures:

- **VAS**- Visual Analog Scale



- **FACES**

- **Manchester pain scale**

2.Observational behavioral measures:

- **FLACC** - Faces, Legs, Activity, Cry &Consolability
- **CHEOPS** - Children's Hospital of Eastern Ontario Pain Scale
- **CRIES** - Crying Requires increased oxygen administration Increased vital signs Expression Sleeplessness.
- **COMFORT**

- **Objective Pain score**

FLACC behavioral pain score: total score 0-10

Criteria	Score 0	Score 1	Score 2
Face	No particular expression or smile	Occasional grimace or frown withdrawn, uninterested.	Frequent to constant quivering chin clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Cry	No cry(awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth tense	Arched, rigid or jerking
Consolability	Context relaxed	Reassured by occasional touching, hugging or being talked to distractible	Difficult to console or comfort

Bromage Scale

Grade	Criteria	Degree of block
I	Free movement of legs and feet	Nil(0)
II	Just able to flex knees with free movement of feet	Partial(33%)
III	Unable to flex knees, but with free movement of feet	Almost complete(66%)
IV	Unable to move legs and feet	Complete(100%)

Drugs acting at various sites of pain pathway

- Peripheral site - Local anesthetics (Bupivacaine, Lignocaine), NSAIDS, Opioids
- Spinal cord - Opioids, alpha 2 agonists (Clonidine), Local anesthetics
- Cortical level- Opioids

Different combined modes of treatment are used for effective management of pain. Of these methods pain relief obtained by regional anesthesia is more efficient and it has several advantages they are:

1. Analgesia obtained by regional block decreases general anesthetic requirements, resulting in:

- Quick recovery
- Decreased incidence of Post operative nausea and vomiting.
- Lessens postop Opioid usage
- Early return of gastro intestinal function
- Early mobilization and discharge

2. Regional block avoids undesirable autonomic reflexes like

- Laryngospasm
- Cardiac dysrhythmias

3. Regional block provides good muscle relaxation

- Reduced use of muscle relaxant, decrease the risk of respiratory insufficiency

4.After major surgery immobilization of child is easier because of adequate pain relief and residual motor blockade.

5. Decreases intra and post operative bleeding

6. Reduces stress response

7. Greater cardiovascular stability

8. Fewer incidence of hypoxia

9. Less requirement of post operative ventilatory support

10. Children are free of hypotensive response from sympathectomy caused by

Local Anesthesia

11. Regional anaesthesia is preferred in children with the:

The past history of malignant hyperthermia and Bronchopulmonary dysplasia.

Anatomic & Physiologic factors influencing regional block in children	
Factors	**Anaesthetic Implications**
Lower termination of spinal cord (L3-4)	Epidural approaches above L3 to be avoided whenever applicable
Lower Projection of Dural sac (S3-4)	High risk of inadvertent penetration of the Dura mater
Delayed myelinization of nerve fibres	Intramural penetration of local anesthetics is easier Onset time shortened Diluted local anesthetic is effective as more concentrated anesthetic
Cartilaginous structure of bones and vertebrae	Danger of direct trauma Use short and short beveled needles
Changing axis of coccyx and absence of growth of sacral hiatus	Identification of sacral hiatus difficult above 6-8 years Increased failure rate of caudal anesthesia
Delayed ossification and growth of iliac crests	Tuffier's line passes over L5-S1 interspaces
Increased fluidity of epidural fat	Increased diffusion of local anesthetic up to 6-7 years of age with excellent caudal blockade
Loose attachment of sheaths and aponeurosis to underlying structures	Larger volume of LA for epidural blocks due to leakage along spinal nerve roots
Sympathetic immaturity, diminished autonomic adaptability of the heart,	Hemodynamic stability during neuraxial blocks Fluid preloading and use of vasoactive agents

smaller vascular bed in lower extremities	not needed.
Low plasma protein content(HSA and AAG)	Increased unbound free fraction of all local anesthetic: greater danger of systemic toxicity
High cardiac output and heart rate	Increased regional blood flow resulting in high systemic absorption of LA: shorter duration of action
Enzymatic immaturity	Slower metabolism of LA with risk of accumulation
Increased extracellular fluids	Increased distribution volume of LA with increased risk of accumulation after continuous infusion
Absorption from epidural space	The time (Tmax) to reach peak plasma concentration(Cmax) remains basically unchanged
Metabolism	Low plasma cholinesterase activity Decreased Cytochrome P450 activity Phase 2 reactions immature up to 3 years of age
Elimination half life	> 1yr: same as adults < 1yr: increased thus favoring accumulation wit repeated injections
Systemic toxicity	Thresholds of toxicity of the unbound form of LA: 0.3µg/ml for Bupivacaine

AIM OF STUDY

This study compares the efficacy of using caudal 0.25% Bupivacaine and 0.2% Ropivacaine for postoperative pain relief and motor blockade in children posted for elective Lower abdominal surgery and also assess intra operative haemodynamic vital parameters.

CAUDAL ANAESTHESIA

It is most commonly used regional anaesthesia technique in children though it is oldest.

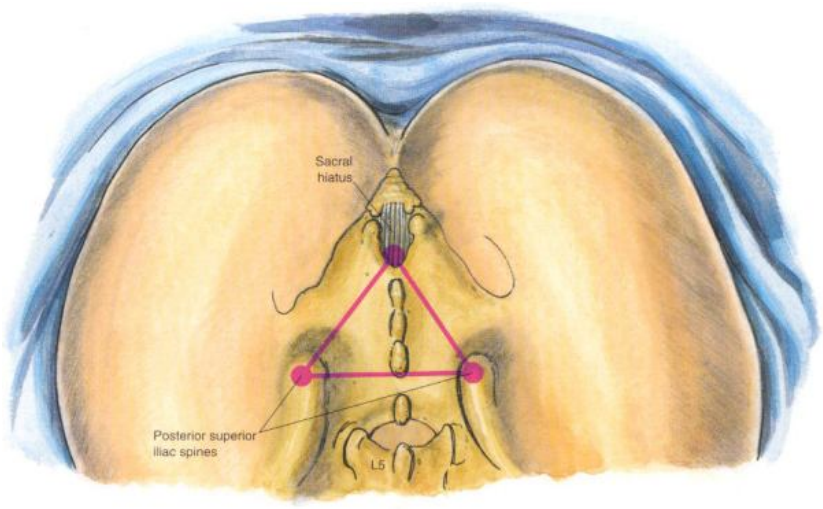
History

- This technique was first described by Cathelin and Sicard in the year 1907
- In the year 1909Steckel of Germany first used this technique.
- In the year 1923 Meeher and Bonar used this technique in Obstetrics and Gynecology.
- Continuous caudal technique was developed by Edwards and Hingson in the year 1942.

Anatomy Of Caudal Block

Caudal block is performed at the site of sacral hiatus through sacrococcygeal membrane.

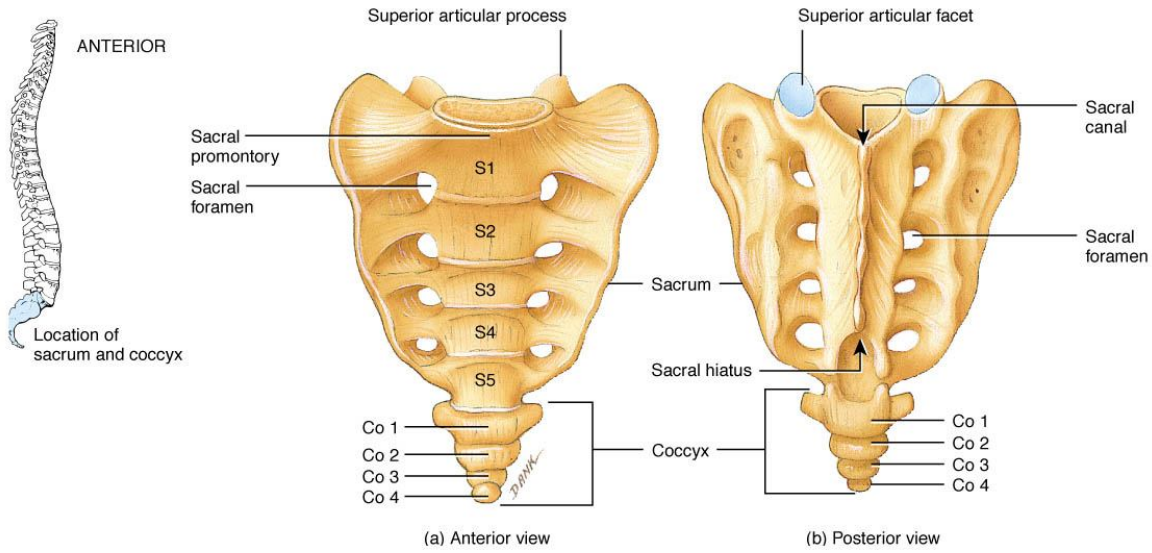
It is identified by equilateral triangle formed by sacral hiatus and posterior superior illiac spines[9].



SACRAL HIATUS:

Sacral hiatus is bony defect located at lower end of sacram just above sacrococcygeal junction and it is triangular in shape.

It is formed by non fusion of fifth sacral and ocassionally by fourth sacral vertebral arches .



It resembles inverted U or V shaped aperture bounded laterally by two palpable bony parts ,the sacral cornu and it is covered by sacrococcygeal membrane and above covered by skin and subcutaneous tissue.Sacral hiatus shows change in size and shape with increasing age.

Long axis of sacram and coccyx forms acute angle in neonates .Angle increases as age increases which closes sacral hiatus and thus makes caudal block difficult to perform at the age after 17years[22].

In neonate caudal space is filled with epidural fat which has spongy ,gelatinous appearance with discrete spaces between fat globules with very minimal connective tissue fibre so the local anaesthestics spread in rapid and uniform manner.

Epidural fats gets denser with fibrous strands after age of six to seven years so the spread of local anaesthestics is limited .

Like lumbar epidural space caudal space is highly vascularised with veins without valves so the inadvertent intravascular injection will cause systemic toxicity.

The important characteristics of caudal epidural space is that it communicates freely with perineuralspace. This favours good quality of block even with dilute local anaesthetic agents in large volumes.

Distance between skin and epidural space depends on age and weight of patient.

Mean distance between skin and epidural space in children aged two months to seven years is around 21mm.

Distance between sacral hiatus apex and dural sac between age group 10 months to 18 years is 30+/10.4.So 25mm length short beveled needle is enough to reach sacral space and thereby avoiding dural puncture[9].

Indications:

- Infraumblical surgeries such as urinary and lower GI tract surgeries .
- Below diaphragm surgeries especially in sacral and lumbar areas such as Orthopaedic surgeries involving lower limb and pelvic girdle.
- In ex-premature infants younger than 60 weeks postconceptional as pure single anaesthetic technique.

Contraindication

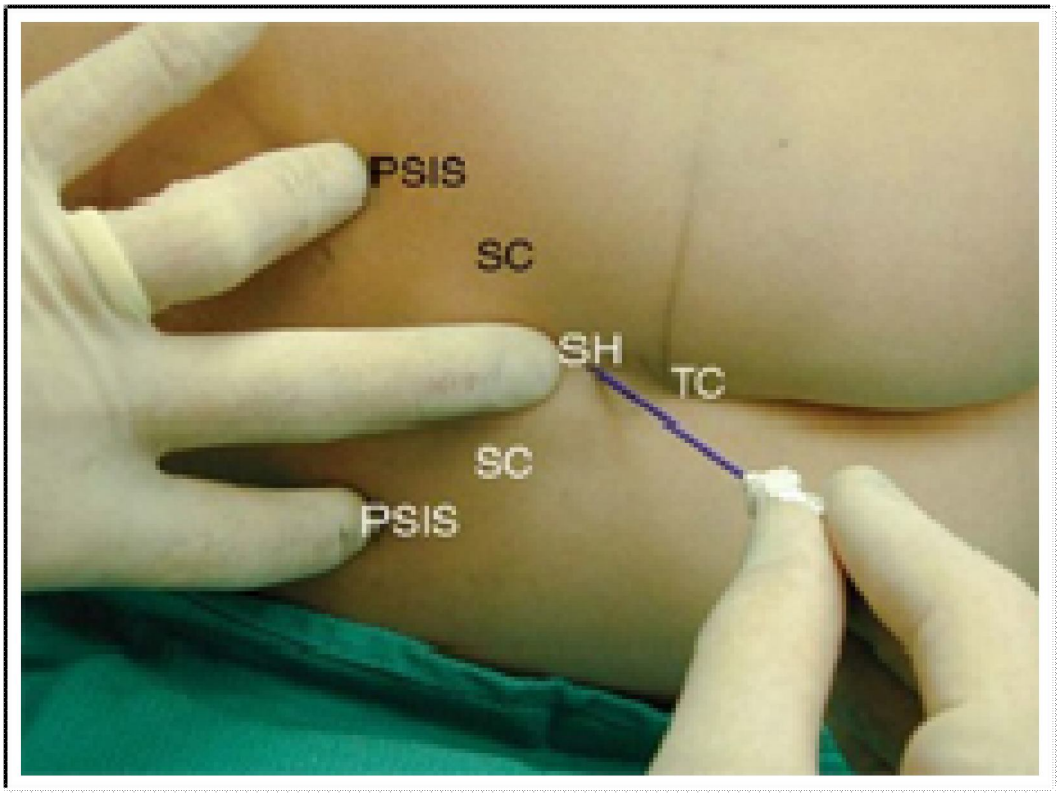
- Infection at the site of injection
- Bleeding disorders
- Sacral anomaly
- Raised ICT
- Patients with neuromuscular disease

Technique

Ready with all equipment including block tray,suction and resuscitation equipments.

Positioning

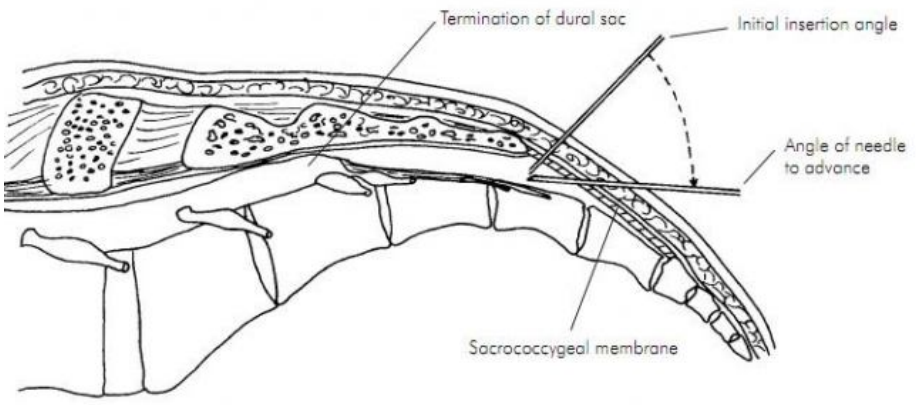
Preferred position is lateral sims position left side down for right handed persons with upper leg more flexed and lower leg slightly flexed at the hip so that upper leg lies over and above the lower leg and in contact with bed. This position separates the buttocks.



Other Position

Prone position with pillow under pelvis so that both legs are rotated and the toes of both feet are facing medially results in separation of buttocks.

Identify sacral hiatus by U or V shaped shallow depression .Then 22G short beveled needle is inserted at the apex of sacral hiatus with angle of 60 degree till distinct pop is felt due to penetration of sacrococcygeal ligament.



Apex of hiatus is selected because it is deepest part of canal so there is high chance for the entire bevel of needle to be in canal.

Needle with longer bevel may partially outside the canal or may traumatize a vessel or periostium as it is advanced further.

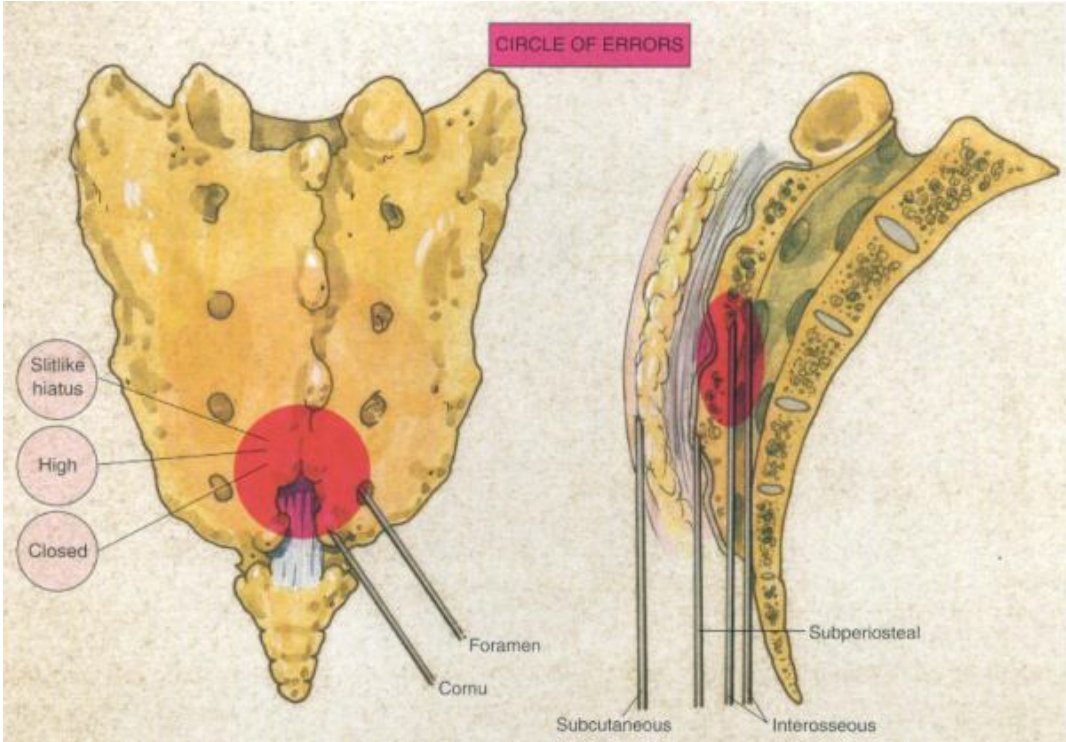
Needle is then angled towards skin so that needle lies approximately to the long axis of canal. Needle is then inserted further.

Stabilize the needle ,aspirate for blood and CSF and administer drug in small volumes after repeated aspiration.

During administration of drug monitor ECG for doubling in size of T wave or arrythmias as sign of intravascular injection.

Signs of Correct Needle Placement

- On aspiration there should be no CSF,air or blood.
- There should not be subcutaneous bulge or superficial crepitus after injection of 2 to 3ml of drugs.
- There should not be resistance to injection.
- On injection there should be no pain .
- By performing whoosh test-Inject 2-3ml of air and auscultate with stethoscope over lumbar region .
- This test is not in practice nowadays.
- If catheter is inserted it should enter the canal freely.



Drug Selection

Drug dosage for block depends on two factors:

1. Volume of local anaesthetics .

2. Volume of epidural space which changes with age.

Formula for dose calculation are

Armitage Formula

For all Sacral dermatome -0.5ml/kg

For Lumbar and Sacral dermatomes 1ml/kg

For Sacral, Lumbar and lower Thoracic dermatome -1.25ml/kg

Takasakis Formula

Volume (ml)=0.05ml/kg/dermatome to be blocked.

Of these two, Armitage formula remains most dependable.

Takasaki provides best approximated clinical result.

Level and density of block depends on volume and concentration of drug respectively[22].

Complications

- Inadvertent intravascular or intraosseous injection
- Dural puncture.
- Epidural hematoma due to vascular injury
- Neural injury
- Infection(Meningitis and epidural abscess)
- Retention of urine
- Failure of blocks(Complete or Partial)
- Infection in the subarachnoid or the epidural space results in worst sequences.
- Meningitis and epidural abscess are the most serious complication. The presentation of clinical science and symptoms are similar for both except fever, raised ESR and leucocytes count in epidural abscess. So

when a child presents with PUO with indwelling catheter, catheter should be removed immediately.

- Very rarely epidural hematoma can occur. Early diagnosis, immediate intervention and decompression results in good outcomes.
- Use of opioids very rarely results in urinary retention.

Failure rate is 3 to 5%.As age advances especially in children > 7 years failure rate also increases.

Continous Caudal Catheter Technique

Indicated in the case where prolonged analgesia is needed[22]

Procedure

Technique is same as of single shot technique but needle used is larger i.e Crawford needle or large i.v. Cannula.The merits of Crawford needle over to Tuohy Needle are bevel of Crawford needle lies in alignment with shaft of needle, so catheter exits the needle in line with Crawford but not in Tuohy , which is angulated. Catheter is threaded 2 to 3 cm or above depending upon the level of block needed. The tip of the needle should be at or near to the midpoint of dermatomes involved in surgical incision.

Continuous thoracic epidural analgesia can be obtained by threading the catheter from caudal space especially in children (< 6 years of age). There is a chance for kinking or lodging of catheter in the dural sleeve.

Correct position is confirmed by

- Ease of administration of drugs
- Negative aspirations
- By Imaging (Radiographic or USG Imaging)
- Stimulation of nerve via catheter
- ECG recording

The main demerits of this techniques is infection, so a double occlusive dressing is needed

PHARMACOLOGY OF BUPIVACAINE

Bupivacaine is an amide type Local anesthetic agent.

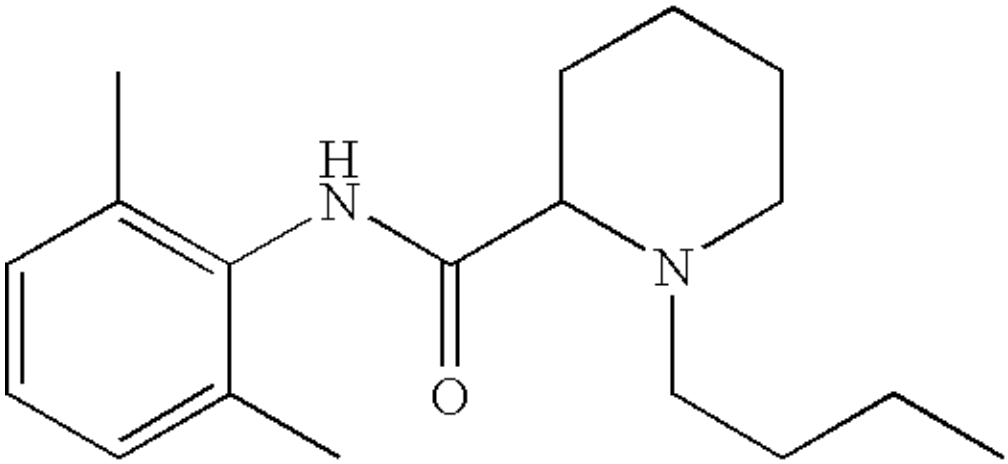
In the year 1957, Ekenstam first synthesized Bupivacaine and clinically first applied by Widmon and Telimo in the year 1963.

It belongs to the group n-alkyl substituted Pipecholylxylidines.

It is available as racemic mixture containing both S and R in equal proportion.

It is supplied as hydrochloride salt.

Chemical Structure



Bupivacaine

It has a butyl group attached on the piperidine nitrogen atom of the molecule.

It is most potent and long acting local anesthetic drug.

It is more lipid soluble, highly protein bound and greater intrinsic potency.

It crosses the placenta and blood brain barrier[24]

Physio-Chemical Profile

- Molecular weight is 228
- Molecular Formula is $C_{18}H_{29}CIN_20.H_2O$
- Chemical Name is 1-butyl-N-(2,6-dimethylphenyl)piperidine-2-carboxamide hydrochloride monohydrate.
- Pka-8.1
- Plasma protein binding capacity-95%
- Partition coefficient-28(lipid solubility)
- Plasma clearance - 8.3 l/min
- Elimination half life -210 min
- Elimination half life in neonates & young infants-480 to 720 min
- Umblical vein - maternal arterial concentration ratio-0.32[24]

Pharmacological Properties

Onset- moderate.

Potency- 4.

Duration-Long.

Mechanism of Action

Similar to all local anesthetics, It inhibits Na Channels. It transiently inhibits permeability of cell membranes to Na ions which cause depolarization of the membrane and thereby prevents nerve conduction. It inhibits permeability of resting nerve membrane of sodium as well as potassium ions and thus results in stabilizing action of all excitable membranes[8].

Pharmacokinetics

- Absorbed rapidly from the site of administration.
- Reaches peak systemic concentration after 5 to 30 min of administration.
- Plasma concentration of drugs depends on route of administration, dose , vascularity of injection site.
- Addition of vasoconstrictor like adrenaline prolongs duration of action and decreases rate of absorption.
- Duration of action-360 to 720 min.
- First pass dose dependent pulmonary extraction occurs.
- Metabolized in liver- enzymatic actions are dealkylation to pipecoloxylidine, aromatic hydroxylation.
- Excretion-only 5% as unchanged drug and remaining drug as metabolites.

- Intercoastal blocks gives highest peak plasma concentration(1-4 mg/L after 400 mg dose) while subcutaneous abdominal injection gives lowest plasma concentration.
- Epidural and major plexus block are intermediate concentration.
- In children, rapid absorption is seen with caudal block (1-1.5mg/L after dose of 3mg/kg)
- Highly protein bound (alpha1-acid glyco protein).

Preparations Available

0.25%,0.5% solutions in 10,20ml vials respectively.

0.5%(5mg/ml) Bupivacaine with 80mg Dextrose(hyper baric)in 4ml ampoules are available for intrathecal injection(baricity - 1.0207)

Maximal Dose

2.5mg/kg body weight and strength used is 0.25-0.75% with or without adrenaline. Adrenaline decreases absorption of drug, so reduces its toxicity and also causes mild intensification and modest prolongation of block[8].

Effects

Local anesthesia - for nerve blockade.

Regional-blocks pain ,temperature, touch, motor power and vasomotor tone .

Systemic effects- due to high peak plasma concentration(Accidental i.v administration or rapid systemic absorption)

It is more potent (4 times) than Lignocaine with longer duration of action.

It produces differential sensory/motor blockade.

ADVERSE EFFECTS:

Adverseeffect occurs when there is rapid absorption or inadvertent intravascular injection

Adverse reaction are due to high plasma levels of drug caused by excessive dosage, rapid absorption, delayed elimination, altered metabolism, intravascular injection, hypersensitivity, diminished tolerance of patient[24].

It affects mainly central nervous system and cardio vascular system.

Central Nervous System: Toxicity are

- Circumoral numbness, Metallic taste.
- Light headedness, dizziness, tinnitus.
- Confusion, slurred speech
- Convulsions.
- Cardio Vascular System: produces dose related toxicity
- Decrease automaticity and contractility of heart

On purkinje fibers and ventricular muscles, it reduces rapid phase of depolarization and hence results in prolonged PR and QT interval.

Re-entrant phenomenon and ventricular arrthymias can occur.

Slow rate of recovery from use dependent blockade (Na channels are blocked in fast in slow out manner). These effects are due to high lipid solubility.

S-enantiomer(Ropivacaine) is less toxic than R-enantiomer (Bupivacaine). Cardiotoxic effects of Bupivacaine enhances during pregnancy.

Allergic Reaction

Due to preservative added(Methyl paraben).

Treatment Of Toxicity

- It signs of toxicity appear, injection of drugs should be stopped immediately.
- If convulsion occurs, first maintain patent airway and ventilated with oxygen and maintain circulation.
- If convulsion persists start anticonvulsant medication such as ultra short acting barbiturate (eg. Thiopentone) or a benzodiazepine (eg. Diazepam) by IV.
- If ventricular fibrillation or cardiac arrest occurs, effective cardiovascular resuscitation treatment must be instituted

Uses

Used in local or regional anaesthesia as follows:

Surgical Anaesthesia

- Epidural block for surgery
- Peripheral nerve blockade

Analgesia

- In continuous epidural infusion are intermittent bolus epidural administration for analgesia in post operative pain or labor pain.
- Strength is 0.25% and 0.5 %

Contraindication

- Known hypersensitivity to amide type local anesthetics.
- Intravenous regional anesthesia(HighlyCardiotoxic),Obstetrical paracervical block and all I.V infusions.
- Infection at the sight of injection or presence of septicaemia
- In spinal and epidural anaesthesia for patient with uncorrected hypotension.

Recommended Dosage For Surgical Anaesthesia

- Lowest dose that results in effective anaesthesia should be used. In general surgical anaesthesiarequires higher dose and concentration than required for analgesia.
- Spread of anaesthesia is affected by volume of drug[24].

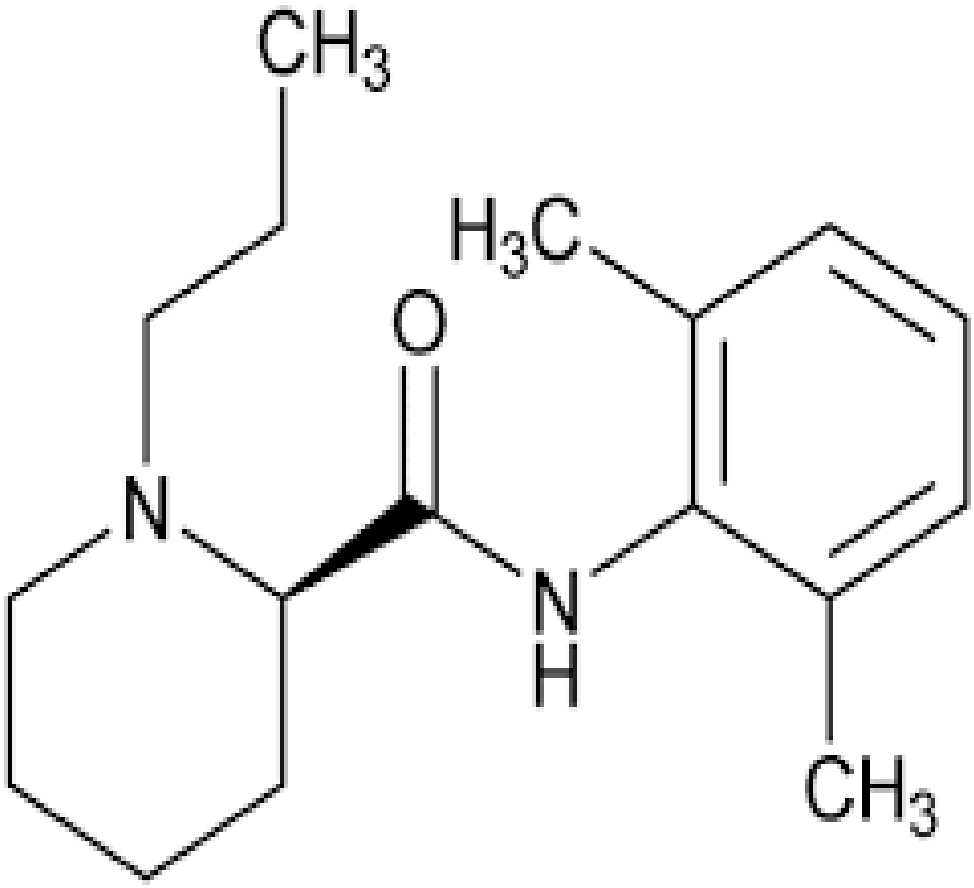
PHARMACOLOGY OF ROPIVACAINE

Ropivacaine is a long acting local anaesthetic agent of amide group. It is a pure S-enantiomer structurally similar to Bupivacaine (1-propyl-2,6-pipecoloxylidide). It is less Cardiotoxic and less motor blockade than Bupivacaine.

Physio-Chemical Characters

- It is a pure enantiomers of (S-) Sterioisomers.
- It possess levorotatory counterclockwise rotation.
- S- enantiomers of local anesthetic when compared to R+(dextroratoryclockswise rotation) possess different affinity for different ion channels of sodium, pottasium and calcium results in signifcant reduction in central nervous system and cardiac toxicity.
- Optically pure S- enantiomers of parent chiral molecule Propivacaine[24].

Chemical Structure



Molecular Weight	274
PKa	8.1
Partition co-efficient	2.9
Mean uptake ratio	1.8
Protein binding	94%

Mechanism of Actions

It acts by reversible inhibition of sodium ions influx and thereby blocks impulse conduction in nerve fibres.

Less lipophilic than Bubivacaine and so less likely to penetrate large myelinated motor fibers.

Selective action on pain transmitting Aδ and c fibres rather than Aβ which are responsible for motor actions.

Pharmacodynamics

Due to less lipophilic and streoselective properties Ropivacaine possess higher threshold for Cardiotoxicity and CNS toxicity.

CNS effects occur earlier than Cardiotoxic symptoms.

In CVS, it affects contractility, conduction time and QRS duration.

It possess platlet aggregation inhibition properties at concentrations of 3.75 and 1.88 mg/ml.

It has invitro antibacterial activity[8].

Pharmacokinetics

Plasma concentration depends on route of administration, total dose administered, haemodynamic and circulatory condition of the patient and vascularity of administration site.

When administered IV,pharmacokinetics were linear and dose proportional upto 80mg.

Mean Half life exhibits in two phase. Initial phase mean half life is 14 min followed by slower Phase mean half life of approximately 4.2 hrs.

It is 94% bound to plasma proteins(α1-acid gylco protein).

Metabolized extensively in the liver by cyp3A4.

It is excreted mainly by kidney accounting for 86% of excretion.

Though it crosses the placenta during caesarian section, The total plasma concentration in fetal circulation is very low.

Total plasma concentration raises during continuous epidural infusion[8].

Tolerability

It is well tolerated in adult and pediatric patient,irrespective of route of administration.

In Woman undergoing LSCS, tolerance to the fetus is good. Common side effects to fetus with Ropivacaine are neonatal to jaundice ,bradycardia.

In children, irrespective of route of administration , it is well tolerable between the age group 1 month to 15 years.

Clinical Application

Efficacy of Ropivacaine is compared with Bupivacaine and its isomers by various clinical studies.

1. Surgical Anaesthesia

Provide effective anesthesia when administered via epidural, spinal and peripheral nerve blocks.

Epidural Ropivacaine:

- Ropivacaine is mainly given via lumbar route and used for caesarean section, Gynecological procedures, various abdominal, orthopedic and vascular surgeries.
- Sensory and motor blockade and duration of analgesia produced by epidural Ropivacaine(Mean duration 1.7-4.2 hrs) is same as that of Bupivacaine(Mean duration 1.8-4.4hrs) but duration of motor blockade is less in Ropivacaine.
- It also providespost operative pain relief[8].

2. Intra Thecal Injection

For intra thecal administration, higher dose of Ropivacaine is needed. Hyperbaric solution of Ropivacaine faster onset and recovery from the block.

3. Peripheral Nerve Blocks

- Indicated in many orthopedic procedures.
- Ropivacaine 0.5% provides sensory and motor block (inter scalene,brachial axilary block)for hand and arm surgery.
- For femoral ,sciatic and combined femoral and sciatic block(Lower Limb surgeries),Ropivacaine 0.75% provides faster on set of actions.

4. Post Operative Pain Management

Epidural Ropivacaine is used for post operative pain relief in various surgical procedure(Eg. Upper and Lower abdominal surgeries , Lower Limb, orthopedic and gynecological surgeries).

5.Management Of Labour Pain:

- Used epidurally for providing labour analgesia.
- Dose:Ropivacaine (0.2%) 10 to 20 ml bolus with intermittent top up injections(20-30mg)/Continuous epuidural(6to10ml/hr).
- Additives like Fentanyl 2mcg/ml to 0.1% Ropivacaine significantly decreases Ropivacaine concentration and provide analgesic effect

similar to Ropivacaine 0.2%.Addition of Clonidine (α2 agonists) prolongs the duration of action of Ropivacaine.

6.**Chronic Pain Management**

Ropivacaine is used in the management of chronic lumbo sacral pain and as a palliative treatment for refractory migrane.

Drug interactions

Should be cautious when used with other local anaesthetics or agent with similar amide groups due to additive toxic effect.

Fluvoxamine(inhibitor of Cytochrome P4501A2)interact with Ropivacaine and increase the plasma level of Ropivacaine when used concurrently.

Also interact competitively with Imipramine and Theophylline which are metabolised by CYP1A2.

REVIEW LITERATURE

1. Da conceicaomj et al[6] conducted a study in 60 paediatric patient posted for surgery in age group of 3 -6 years. Method of study was double blind technique. 60 patients were divided into two groups, Group 1 and Group 2. Group 1 was given 0.375% Ropivacaine(1ml/kg) and Group 2 was given 0.375% Bupivacaine(1ml/kg) caudally. This study found that there is no difference in duration and quality of analgesia in two groups but motor blockade is less in Ropivacaine group.

2. G.Ivani et al[10] conducted a study in 245 patients in the age group of 1- 10 years for elective minor surgery. The type of study was randomized double blind technique. They divided the patient into two groups,Group B and Group R. Group B(n=123) was given 0.25%of Bupivacaine (1ml/kg) caudally and Group R (n=122) was given 0.2% of Ropivacaine(1ml/kg) caudally.HR ,NIBP and SPO2 were observed during procedure at specific time intervals post operative pain was observed by objective pain scale and motor block by four point Bromage scale. They found that sensory block produced by Ropivacaine and Bupivacaine were nearly equal but in Ropivacaine group motor blockade is less dense with shorter duration.

3. Khalil et al[15] conducted a study in 81 paediatric population posted for day care surgeries. Method of study was double blind clinical trial. They divided 81 population into two groups. One group was given 0.25% Bupivacaine(1ml per kg) caudally and other group was given Ropivacaine 0.2%(1ml per kg)

caudally. Baseline vital parameters before induction were noted. Postop pain and motor recovery were noted. This study showed that there were no significant difference in effect and duration of analgesia, motor and sensory effect or time of first micturition between two groups.

4. J.S Tan et al[26] conducted a study in Paediatric patient of 112 members belonged to age group of 5 to 12 years posted for elective circumcision. Method of study was randomized double blind technique. They were divided into 2 group. One group was given 0.25% Bupivacaine(0.5ml/kg) and 0.2% Ropivacaine(0.5ml/kg) caudally. This study results showed that there is no significant difference in haemodynamic parameters, sensory and motor blockade.

5. Manjushree ray et al[23] conducted a study in paediatric age group of 30 patient posted for Genito urinary operation between age group of 5 to 8 years. Patient were divided into two groups by randomized double blind technique. Group A(n=15) was given 0.25% Bupivacaine(0.75ml/kg)caudally and Group B was given 0.2% Ropivacaine (0.75%ml/kg)caudally. Baseline vital parameters and intra hemodynamics were noted. Postoperative pain measured using Hannallah pain scale and motor power by Motor power scale. This study found that there is no significant difference in duration of analgesia and hemodynamic parameter but motor recovery is good in Ropivacaine group.

6. Lacatelli et al[18] conducted a study in 99paediatric patient posted for Infraumblicalsurgeries . Study design was randomised double blinded

technique. They divided the 99 patient into three groups.Group1 ,Group2 and Group3 were given 0.25% Bupivacaine , 0.2% Ropivacaine and 0.2% of Levobupivacaine caudally. This study found that there is no significance difference in effect of analgesia in all the three groups but the duration is longer in group receiving Bupivacaine. Bupivacaine group had high residual motor blockade and prolonged duration of block than Ropivacaine and Levobupivacaine.

7. Breschan et al[3] conducted a study in paediatric age group of 182 children between the age 1 to 7 years posted for Lower abdominal surgeries. The study design was prospective randomized double blind technique. They were divided into 3 groups. Group L was given 0.2% Levobupivacaine (1ml/kg) , Group R was given Ropivacaine 0.2%(1ml/kg) and Group B was given 0.25% Bupivacaine (1ml/kg) caudally. This study results showed that motor blockade was significantly less after Ropivacaine and Levobupivacaine group while there is no statistical significance in duration of analgesia in all groups.

8. Tarlike P et al[27] conducted a study in 112 paediatric patient in the age group of 1-12 years posted for Lower abdominal and Urological procedure. Study design was double blinded retrospective randomised study. They divided the 112 paediatric patient into two groups,Group BF and Group RF. Group BF(n=70) was given Bupivacaine 0.25%(2mg/kg) plus injection Fentanyl 1µg/kg caudally and Group RF(n=42) was given Ropivacaine 0.2%(2mg/kg) plus injection Fentanyl 1µg/kg caudally. Intrahaemodynamics parameters were

observed. Postoperative pain and motor power were observed . This study found that there is no significance difference between two groups in duration of analgesia and haemodynamic parameters. But motor recovery less in Bupivacaine group.

9. S.S.Chipde et al[4] conducted a study in 50 pediatric patient in the age group of 1-10 undergoing Urogenital surgeries. The study type was prospective randomized double blinded control study.They divided 50 patients into two groups, Group 1 and Group 2. Group 1(n=25) was given 0.25% of bupivacaine (1ml/kg) caudally and Group2 (n=25) was given 0.25% of Ropivacaine caudally. Baseline HR, BP were recorded before induction of anaesthesia. Intraoperative haemodynamics was recorded at specific time interval. Post Operative pain was observered by five point observer scale and motor block by modified Bromage scale. They found that there is no difference in duration of analgesia between two groups and motor blockade was less in Ropivacaine group when compared to Bupivacaine group.HR and SBP recorded at specific time intervals doesn't show significant in their study.

10. Mukeshkumar et al[16] conducted a study in 60 paediatric population in the age group of 2-8 years posted for Infraumblical surgeries. The study design was prospective randomised double blinded technique. They divided the patient into 2 groups,Group A and Group B. Group A(n=30) was given Ropivacaine 0.2%(1ml/Kg) caudally and Group B(n=30) was given Bupivacaine 0.2%(n=30) caudally. Baseline vitals(HR,NIBP,SPO2) are recorded.

Intraoperative haemodynamics were recorded in specific intervals. Pain was observed in objective pain score and sedation was observed in school going children using sedation score and motor power by motor power scale. They found that there is no significance difference in duration of analgesia and haemodynamic parameters between 2 Groups. But motor recovery is good in Ropivacaine group.

MATERIALS AND METHODS

This study was prospective randomized double blinded study. This study was starting after getting approval of Institutional ethical committee and written informed consent of parents or guardian. Patients who satisfied inclusion criteria are divided into two groups- Group A and Group B.

Sample Size Calculation:

Sample size was determined based on

Study

Comparison of Ropivacaine and Bupivacaine with Fentanyl for caudal epidural in pediatric surgery

Authored by

Tarlika P Doctor et al in anesth Essays Res. 2013 May-Aug; 7(2): 212–215.

In this study duration of analgesia was prolonged in both group RF and BF. Time for first rescue analgesic for group RF (6.1 ± 1.1 hr) compared to group BF (5.6 ± 0.9 hr)with a difference of 16%.

Description

- The confidence level is estimated at 95%
- With a Z value of 1.96
- The confidence interval or margin of error is estimated at +/-10
- Assuming that 80 percent of the sample will have the specified attribute

p% =16 and q%=84

$$n = p\% \times q\% \times [z/e\%]^2$$

$$n = 16 \times 84 \times [1.96/10]^2$$

$$n = 51.63$$

Therefore 52 is the minimum sample size required for the study.

In our study 60 subjects were chosen (n=30 in Bupivacaine arm and n=30 in Ropivacaine arm)

Group A – 0.25% Bupivacaine(n=30)

Group B – 0.2% Ropivacaine(n=30)

Inclusion Criteria

- Age: 1 to 4 years
- ASA: 1& 2
- Surgery: Elective lower abdominal surgery

Exclusion Criteria

- Infection at the site of injection
- Patient with bleeding disorder
- Patient with Neuro muscular disease and mental retardation
- Lack of written informed consent
- Patient taken for emergency surgery

Materials Used

- Intravenous cannula (22G, 24G)
- Laryngoscope with appropriate size blade
- Pediatric stylet
- Endotracheal tubes /Laryngeal mask airway of corresponding size
- Drugs-Inj.Propofol, Sevoflurane,inj.Ketamine,Inj. Fentanyl, Normal Saline, Injection Atropine and other emergency drugs
- Monitors- ECG, NIBP,SPO2, Temperature monitoring
- 2ml, 5ml and 10ml syringe
- Bupivacaine 20ml via 0.5%
- Ropivacaine 20ml ampule 0.2%

METHODOLOGY

This study was performed at the department of Anesthesia, Institute of child Health and hospital for children. The aim of the study was comparison between Bupivacaine and Ropivacaine for caudal analgesia in pediatric patient undergoing Infraumblical surgeries.

Sixty children between the age group 1 to 4 years posted for elective Lower abdominal and Urogenital surgeries were randomly divided into two groups for study.

Patients were randomly allocated into two groups using computer generated number.

Anesthesiologist who was unaware of drug combination was involved in the administration of caudal block and observation of the patients involved in the study.

- Group A - receiving caudal epidural block of 1ml per kg of 0.25% Bupivacaine
- Group B - receiving caudal epidural block of 1ml per kg of 0.2% Ropivacaine

The age and weight of the child was noted. Preoperative fasting protocols should be strictly followed.

All patients posted for surgery were premedicated with oral Midazolam(0.5mg/kg) 30minutes before surgery.

The child was connected to monitors(NIBP, ECG, pulse oximeter, temperature and precordial stethoscope monitoring. Intravenous line was secured with 22G or 24G IV cannula into the vein on the dorsum of hand.

Patient was induced with Propofol 3mg per kg mixed with Xylocaine 2% 0.5 mg per kg and Ketamine 0.5mg per kg. Patient was maintained in spontaneous ventilation with 50%N20 & 50%O2 and Sevoflurane 1 to 2% using Jackson Rees circuit and appropriate size face mask.

After induction child was turned to left lateral position.

- Group A - Administered 1ml per kg of 0.25%Bupivacaine caudally.
- Group B - Administered 1ml per kg of 0.2% Ropivacaine caudally.

Intraoperatively IV fluids was given at the rate of 15-20mlperkg per hr using Ringer lactate.

Intraoperatively every five minutes Heart rate, blood pressure, respiratory rate, Spo2were noted. Surgery was started after 10mins.

Caudal block was regarded as failure if there is raise of heart rate or blood pressure > 20% of preincision value. If there was block failure, supplemented with injection Fentanyl 1mcg/kg iv for pain.

Child was monitored in the recovery room for 2 hours and then transferred to Postoperative ward.

Pain was assessed by using FLACC pain score, if the score is 3 or above give rescue analgesia injection Fentanyl 2mcg/kg iv for pain relief.

Motor blockade was assessed using Bromage score(Grade 1 to 4). Patient is considered as recovery from the motor blockade if the score is grade1.

The heart rate, NIBP and complications like vomiting and urinary retention are recorded post operatively. If the heart rate is < 60/min(Bradycardia) then treat it with injection Atropine.

Oral feeding was started after 2 hours. Before discharge all patients were examined for Neurological function clinically.

Primary Parameters noted include:

- FLACC pain score
- Duration of analgesia
- Bromage scale

Secondary Parameters include:

- Heart rate
- Systolic, Diastolic and mean blood pressure
- SPO2 .
- Any adverse effects

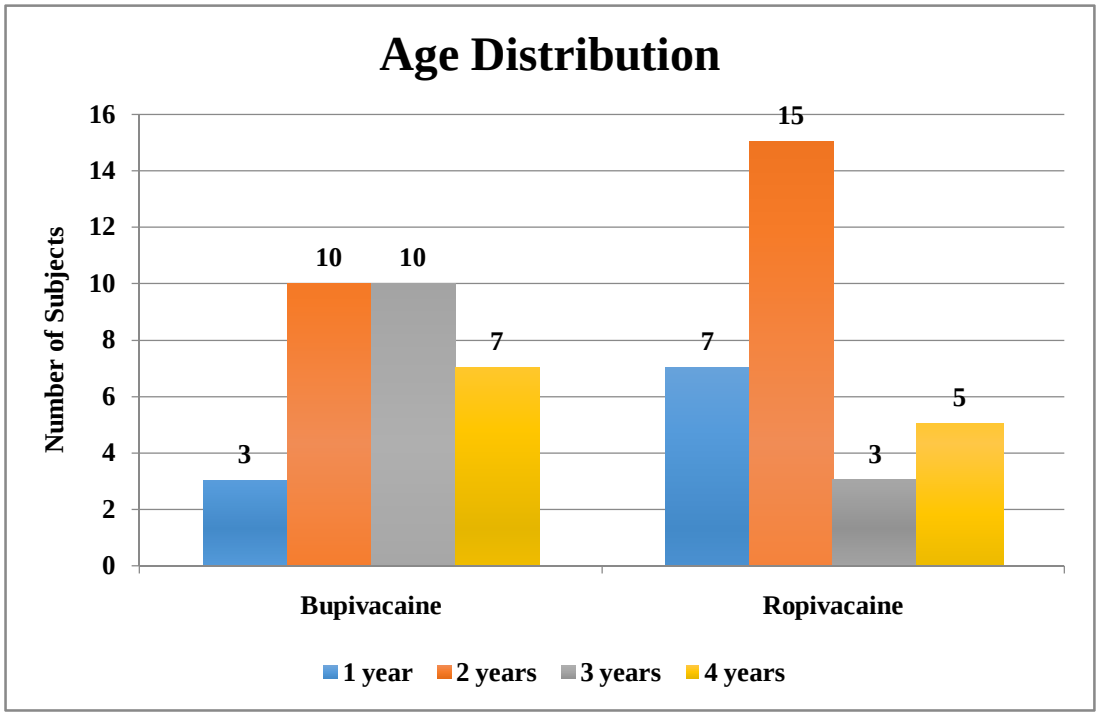
OBSERVATION AND RESULTS

All statistical analysis as carried out using SPSS for windows version 20.0.The results are expressed as mean and standard deviation. statistical analysis was carried out by student's t –test from parametric data like age ,weight, heart rate ,blood pressure. Then parametric data like type of surgery ,duration of surgery, post operative complications were analyzed using chi square test and fisher's exact test. A p value of <0.05 was considered as statistically significant.

Both the groups were comparable in terms of age, sex, weight and duration of surgery.

DATA ANALYSIS

AGE

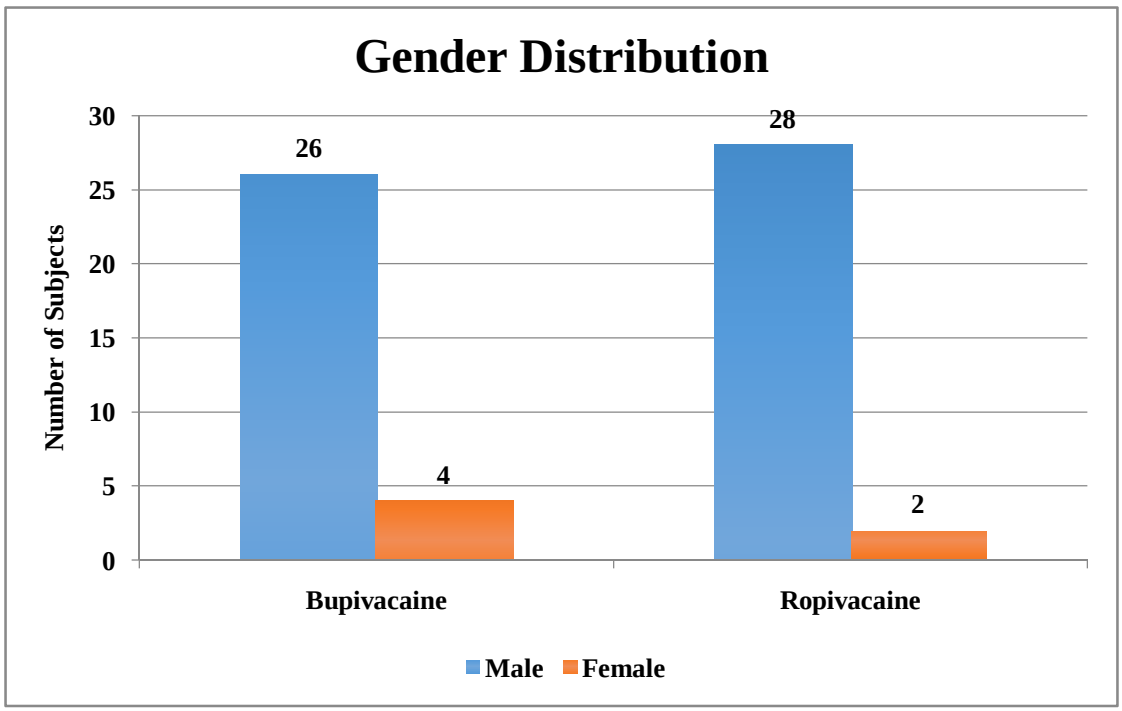


Age Distribution	Bupivacaine	%	Ropivacaine	%
1 year	3	10.00	7	23.33
2 years	10	33.33	15	50.00
3 years	10	33.33	3	10.00
4 years	7	23.33	5	16.67
Total	30	100	30	100

Age Distribution	Bupivacaine	Ropivacaine
N	30	30
Mean	2.70	2.20
SD	0.95	1.00
P value Unpaired t Test		0.0517

Majority of the Bupivacaine group patients belonged to the 2 years age class interval (n=10, 33.33%) with a mean age of 2.70 years. In the Ropivacaine group patients, majority belonged to the same age class interval (n=15, 50%) with a mean age of 2.20 years. The association between the intervention groups and age distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

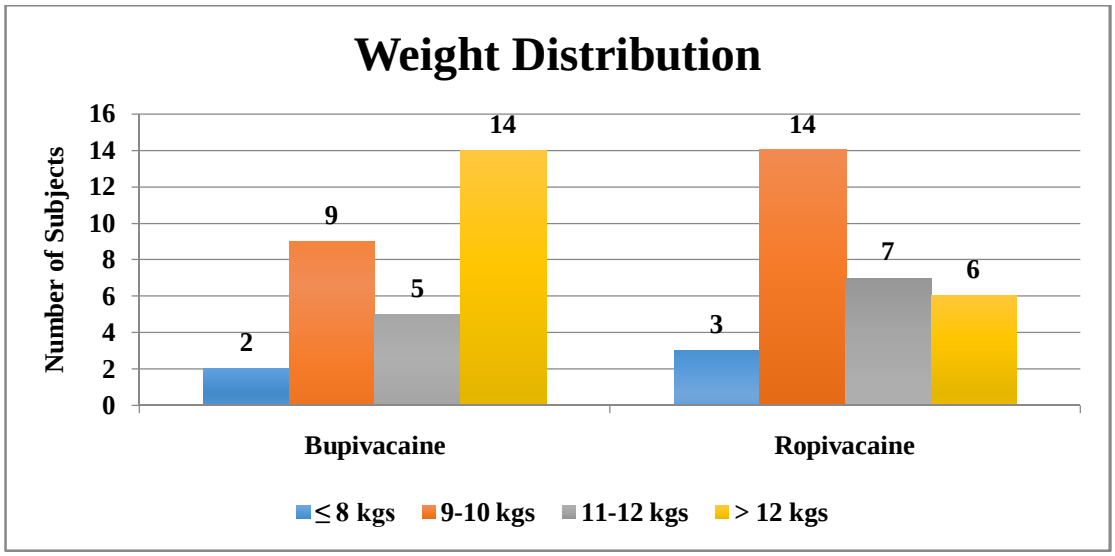
GENDER



Gender Distribution	Bupivacaine	%	Ropivacaine	%
Male	26	86.67	28	93.33
Female	4	13.33	2	6.67
Total	30	100	30	100
P value Fishers Exact Test			0.9089	

Majority of the Bupivacaine group patients belonged to the male gender class interval (n=26, 86,67%). In the Ropivacaine group patients, majority belonged to the same gender class interval (n=28, 93.33%). The association between the intervention groups and gender distribution is considered to be not statistically significant since $p > 0.05$ as per chi squared test

WEIGHT

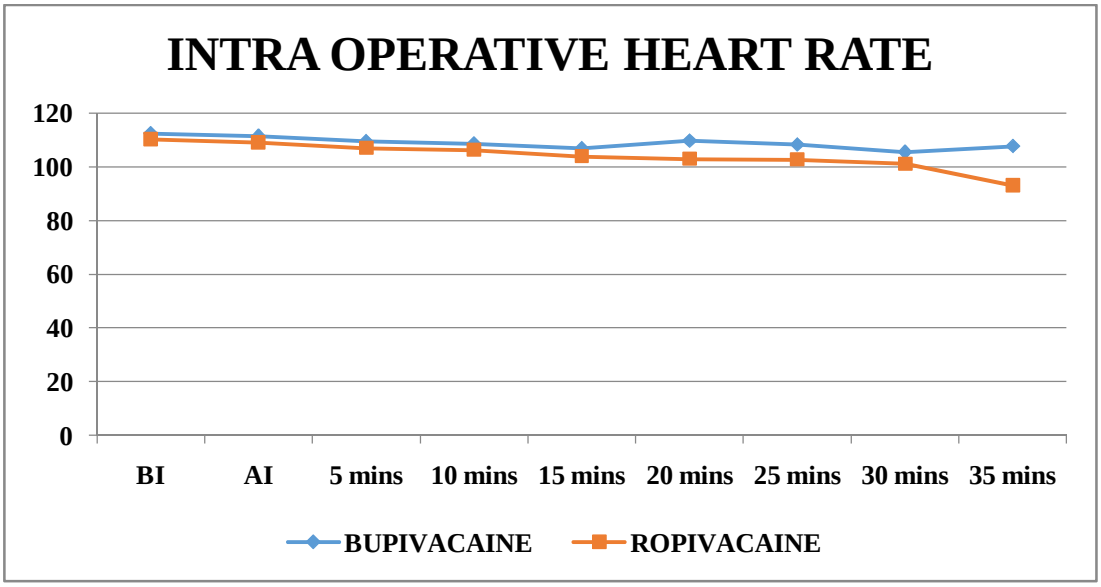


Weight Distribution	Bupivacaine	%	Ropivacaine	%
≤ 8 kgs	2	6.67	3	10.00
9-10 kgs	9	30.00	14	46.67
11-12 kgs	5	16.67	7	23.33
> 12 kgs	14	46.67	6	20.00
Total	30	100	30	100

Weight Distribution	Bupivacaine	Ropivacaine
N	30	30
Mean	11.83	10.87
SD	2.32	2.03
P value Unpaired t Test		0.0913

Majority of the Bupivacaine group patients belonged to the > 12 kgs weight class interval (n=14, 46.67%) with a mean weight of 11.83 kgs. In the Ropivacaine group patients, majority belonged to the 9-10 kgs weight class interval (n=14, 46.67%) with a mean weight of 10.87 kgs. The association between the intervention groups and weight distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

INTRA OPERATIVE HEART RATE

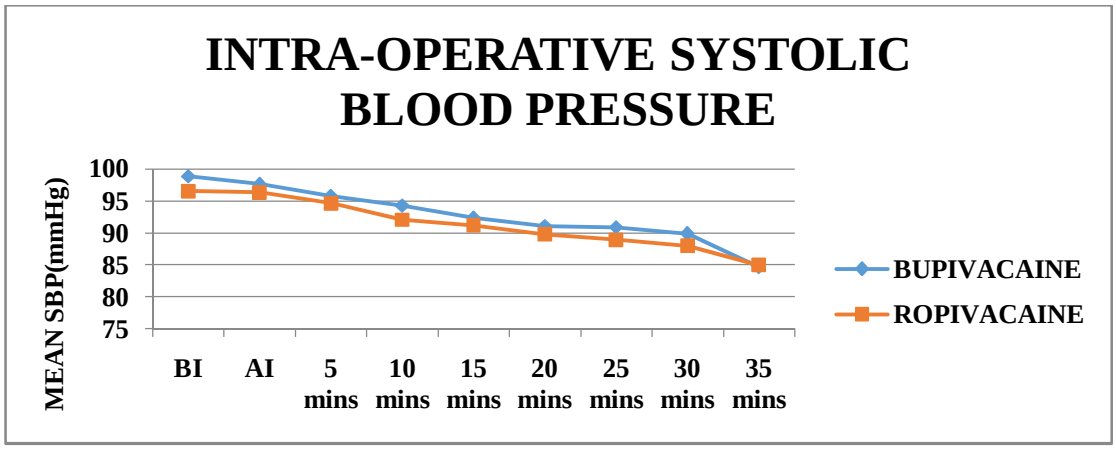


Intraoperative Heart Rate		BI	AI	5 mins	10 mins	15 mins	20 mins	25 mins	30 mins	35 mins
Bupivacaine	N	30	30	30	30	30	27	18	11	3
	Mean	112.37	111.37	109.40	108.53	106.80	109.67	108.22	105.45	107.67
	SD	16.01	15.15	14.95	14.57	14.10	13.45	13.92	13.69	13.80
Ropivacaine	N	30	30	30	30	30	27	17	5	1
	Mean	110.17	108.87	106.93	106.23	103.83	102.89	102.65	101.00	93.00
	SD	12.74	11.94	10.40	10.95	10.52	9.35	7.78	8.40	0.00
P value Unpaired t Test		0.1027	0.0676	0.0739	0.1326	0.1163	0.1127	0.1523	0.4399	1.0000

Results

By conventional criteria the association between the intervention groups and Intraoperative heart rate is considered to be statistically insignificant since $p < 0.05$ as per unpaired t test.

INTRAOPERATIVE SYSTOLIC BLOOD PRESSURE

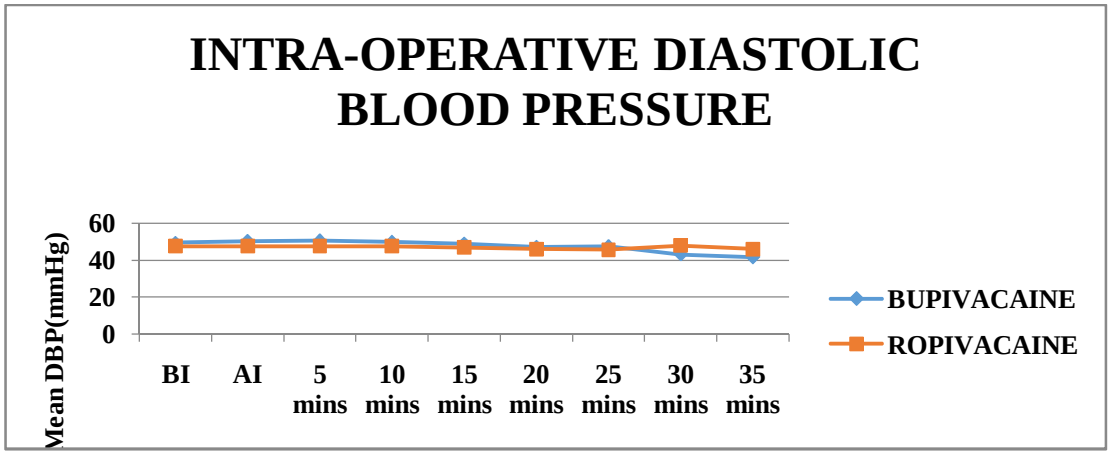


Intraoperative Systolic Blood Pressure		BI	AI	5 mins	10 mins	15 mins	20 mins	25 mins	30 mins	35 mins
Bupivacaine	N	30	30	30	30	30	27	18	11	3
	Mean	98.87	97.67	95.80	94.30	92.40	91.07	90.89	89.91	84.67
	SD	5.65	5.50	5.42	6.17	7.12	7.08	7.11	6.50	5.51
Ropivacaine	N	30	30	30	30	30	27	17	5	1
	Mean	96.53	96.33	94.60	92.07	91.20	89.81	88.94	88.00	85.00
	SD	4.58	5.69	4.98	5.04	4.69	6.40	6.41	7.68	0.00
P value Unpaired t Test		0.079	0.075	0.08	0.09	0.094	0.0743	0.0935	0.4868	1.0000

Results

Majority of the Bupivacaine group patients belonged had a mean Intraoperative systolic BP of 92.84 mmHg.. In the Ropivacaine group patients had a mean Intraoperative Systolic BP of 91.38mmHg. The association between the intervention groups and Intraoperative systolic BP is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

INTRAOPERATIVE DIASTOLIC BLOOD PRESSURE

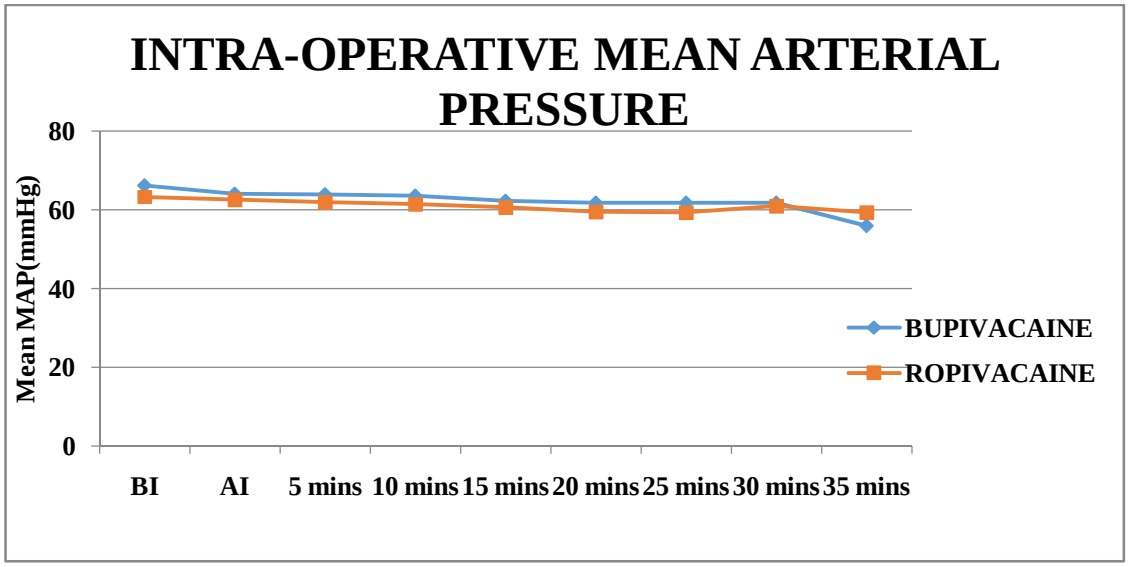


Intraoperative Diastolic Blood Pressure		BI	AI	5 mins	10 mins	15 mins	20 mins	25 mins	30 mins	35 mins
Bupivacaine	N	30	30	30	30	30	27	18	12	3
	Mean	49.37	50.27	50.53	49.80	48.90	47.19	47.39	43.17	41.67
	SD	5.05	5.37	4.67	6.06	5.12	5.98	5.56	4.84	1.53
Ropivacaine	N	30	30	30	30	30	27	17	5	1
	Mean	47.80	47.80	47.63	47.77	46.93	45.96	45.65	48.00	46.00
	SD	3.36	3.54	3.82	3.89	4.67	5.38	5.88	5.10	0.00
P value Unpaired t Test		0.09	0.08	0.07	0.1284	0.1256	0.4335	0.3754	0.1125	1.0000

Results

Majority of the Bupivacaine group patients belonged had a mean Diastolic BP of 47.58mmHg.. In the Ropivacaine group patients had a mean Diastolic BP of 47.06mmHg. The association between the intervention groups and Diastolic BP is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

INTRAOPERATIVE MEAN ARTERIAL PRESSURE

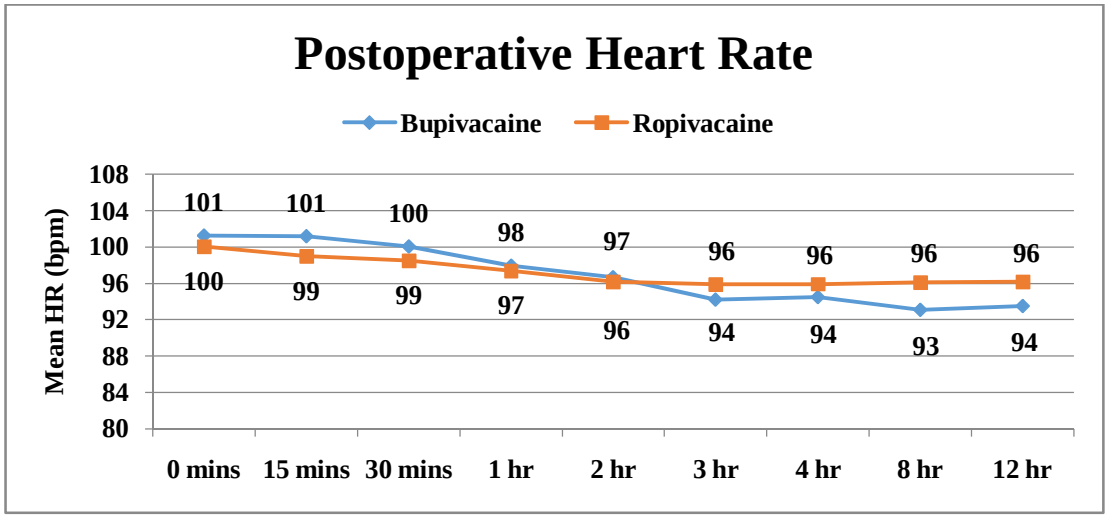


Intraoperative Mean Arterial Pressure		BI	AI	5 mins	10 mins	15 mins	20 mins	25 mins	30 mins	35 mins
Bupivacaine	N	30	30	30	30	30	27	18	12	3
	Mean	66.20	64.07	63.96	63.63	62.40	61.81	61.89	61.81	56.00
	SD	4.63	4.74	3.94	5.26	5.03	5.29	5.32	9.46	1.73
Ropivacaine	N	30	30	30	30	30	27	17	5	1
	Mean	63.38	62.64	61.96	61.53	60.69	59.58	59.41	61.00	59.33
	SD	3.09	3.25	2.93	3.41	3.90	4.64	5.34	5.14	0,00
P value Unpaired t Test		0.07	0.09	0.07	0.092	0.08	0.1048	0.1787	0.8248	1.0000

Results

Majority of the Bupivacaine group patients belonged had a mean MAP of 62.41 mmHg.. In the Ropivacaine group patients had a mean MAP of 61.05mmHg. The association between the intervention groups and MAP is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

POSTOPERATIVE HEART RATE

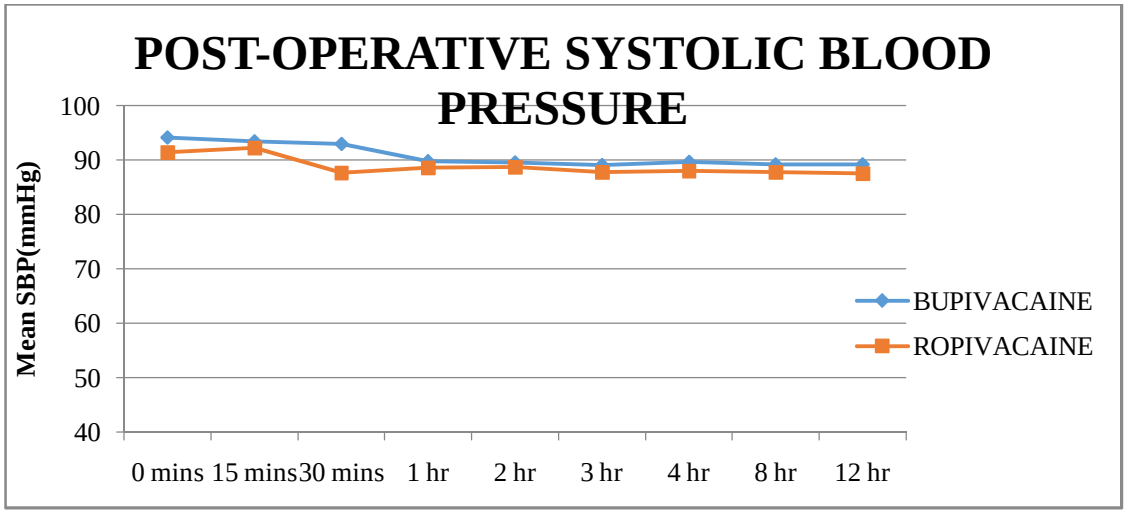


Postoperative Heart Rate		0 mins	15 mins	30 mins	1 hr	2 hr	3 hr	4 hr	8 hr	12 hr
Bupivacaine	N	30	30	30	30	30	30	30	30	30
	Mean	101.27	101.17	100.07	97.97	96.70	94.20	94.47	93.07	93.50
	SD	8.20	9.30	8.25	7.38	5.36	6.08	4.20	4.85	4.35
Ropivacaine	N	30	30	30	30	30	30	30	30	30
	Mean	100.07	98.97	98.50	97.37	96.17	95.87	95.93	96.13	96.17
	SD	4.46	3.40	3.19	4.02	4.15	3.25	2.91	3.58	3.23
P value Unpaired t Test		0.4851	0.2314	0.3380	0.6976	0.6684	0.1922	0.0821	0.0874	0.074

Results

Majority of the Bupivacaine group patients belonged had a mean Postoperative heart rate of 96.93bpm. In the Ropivacaine group patients had a mean Postoperative heart rate of 97.24bpm. The association between the intervention groups and Postoperative heart rate is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

POSTOPERATIVE SYSTOLIC BLOOD PRESSURE

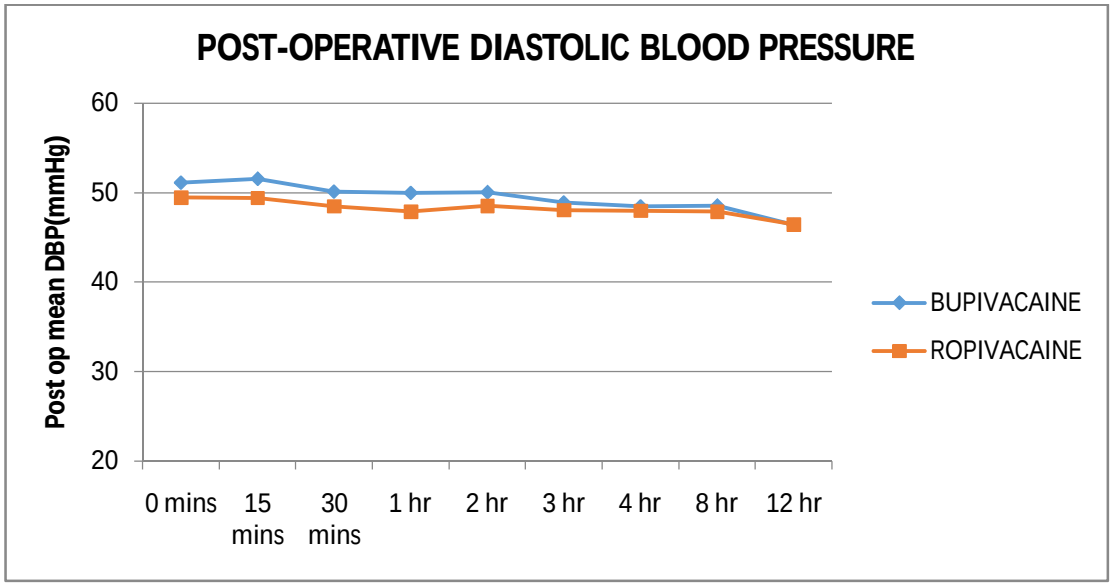


Postoperative Systolic Blood Pressure		0 mins	15 mins	30 mins	1 hr	2 hr	3 hr	4 hr	8 hr	12 hr
Bupivacaine	N	30	30	30	30	30	30	30	30	30
	Mean	94.07	93.40	93.00	89.73	89.50	89.01	89.70	89.13	89.13
	SD	5.57	4.84	5.17	5.92	5.30	5.14	5.65	5.76	7.30
Ropivacaine	N	30	30	30	30	30	30	30	30	30
	Mean	91.37	92.27	87.63	88.60	88.73	87.80	88.03	87.73	87.53
	SD	3.99	3.90	16.50	3.94	4.81	5.18	4.90	5.18	6.39
P value Unpaired t Test		0.1355	0.3224	0.0981	0.094	0.07	0.091	0.057	0.090	0.067

Results

Majority of the Bupivacaine group patients belonged had a mean Postoperative systolic BP of 90.74 mmHg.. In the Ropivacaine group patients had a mean Postoperative systolic BP of 88.85mmHg. The association between the intervention groups and Postoperative systolic BPis considered to be not statistically significant since $p > 0.05$ as per unpaired t test

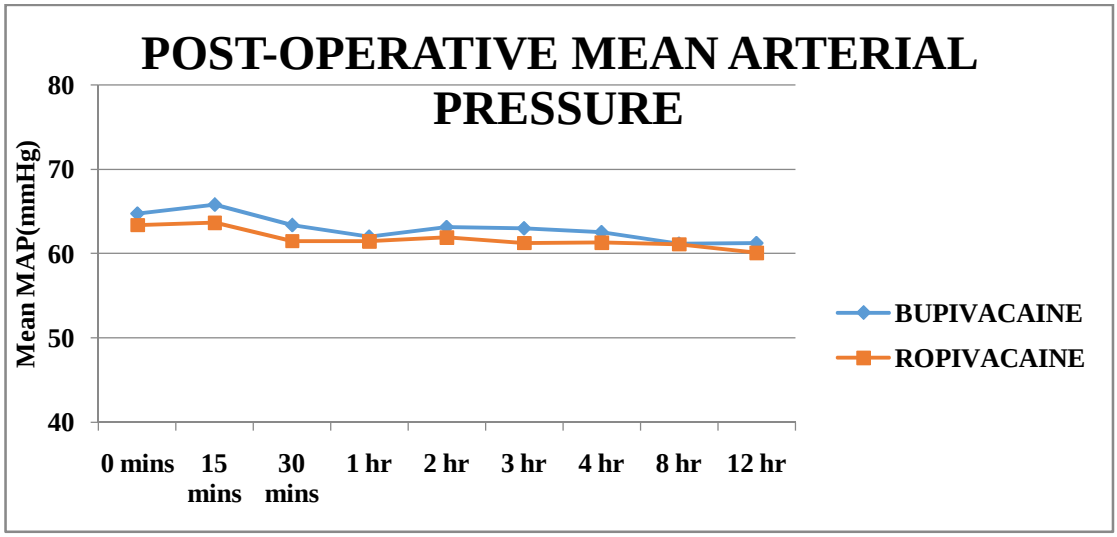
POSTOPERATIVE DIASTOLIC BLOOD PRESSURE



Postoperative Diastolic Blood Pressure		0 mins	15 mins	30 mins	1 hr	2 hr	3 hr	4 hr	8 hr	12 hr
Bupivacaine	N	30	30	30	30	30	30	30	30	30
	Mean	51.10	51.57	50.10	50.01	50.07	48.87	48.50	48.53	46.40
	SD	4.79	5.45	5.14	4.53	5.21	5.79	5.78	4.97	5.08
Ropivacaine	N	30	30	30	30	30	30	30	30	30
	Mean	49.47	49.43	48.50	47.90	48.53	48.07	48.00	47.87	46.47
	SD	4.44	3.13	2.47	3.82	3.98	5.00	4.40	4.44	4.46
P value Unpaired t Test		0.07	0.08	0.09	0.09	0.090	0.5691	0.7076	0.2775	0.9571

Results

Majority of the Bupivacaine group patients belonged had a mean Diastolic BP of 49.46mmHg.. In the Ropivacaine group patients had a mean Diastolic BP of 48.24mmHg. The association between the intervention groups and Postoperative Diastolic Bp is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

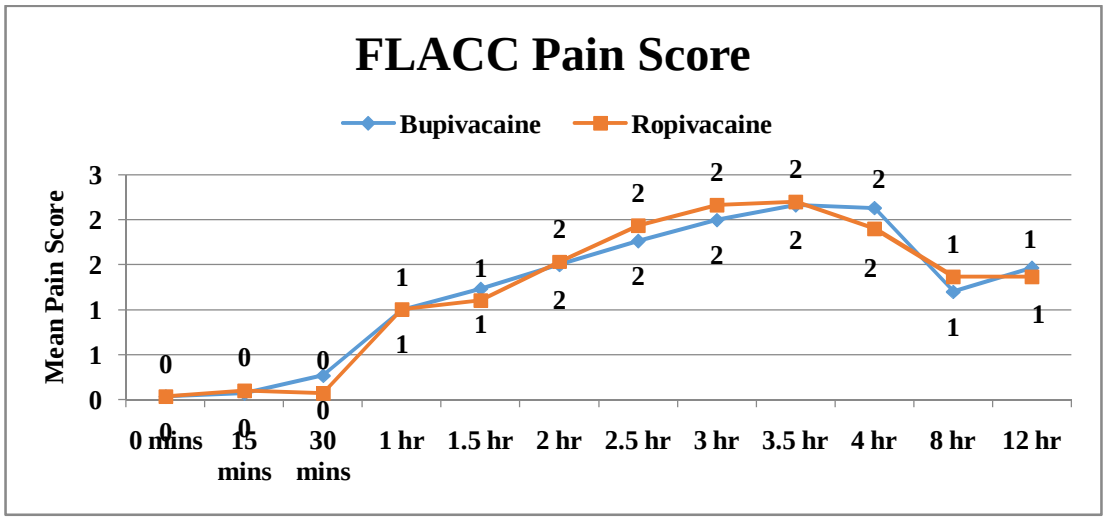


Postoperative Mean Arterial Pressure		0 mins	15 mins	30 mins	1 hr	2 hr	3 hr	4 hr	8 hr	12 hr
Bupivacaine	N	30	30	30	30	30	30	30	30	30
	Mean	64.76	65.84	63.40	62.04	63.21	63.04	62.57	61.17	61.31
	SD	4.22	4.44	4.31	4.10	3.99	4.62	4.51	3.42	4.79
Ropivacaine	N	30	30	30	30	30	30	30	30	30
	Mean	63.43	63.71	61.54	61.47	61.93	61.31	61.34	61.16	60.16
	SD	2.79	2.64	5.34	3.31	3.55	4.38	3.71	3.57	4.04
P value Unpaired t Test		0.07	0.0617	0.08	0.07	0.09	0.1413	0.2565	0.9219	0.3169

Results

Majority of the Bupivacaine group patients belonged had a mean MAP of 63.03 mmHg.. In the Ropivacaine group patients had a mean MAP of 61.78mmHg. The association between the intervention groups and MAP is considered to be not statistically significant since $p > 0.05$ as per unpaired t test

FLACC PAIN SCORE



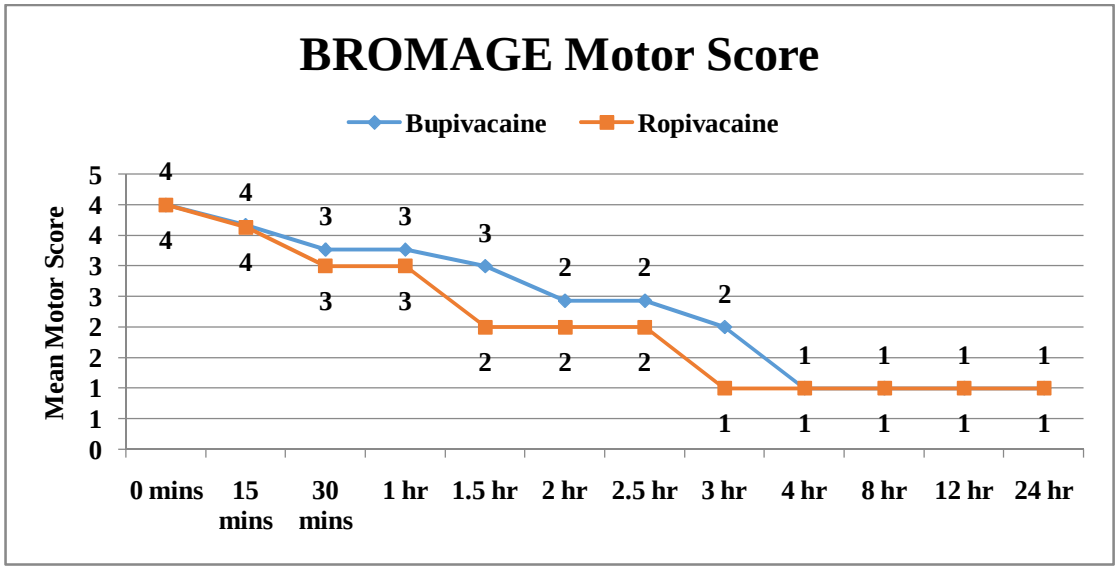
FLACC Pain Score		0 mins	15 mins	30 mins	1 hr	1.5 hr	2 hr
Bupivacaine	N	30	30	30	30	30	30
	Mean	0.03	0.07	0.27	1.00	1.23	1.50
	SD	0.18	0.37	0.64	0.00	0.43	0.51
Ropivacaine	N	30	30	30	30	30	30
	Mean	0.03	0.10	0.07	1.00	1.10	1.53
	SD	0.18	0.55	0.37	0.00	0.31	0.51
P value Unpaired t Test		1.0000	0.7826	0.1438	1.0000	0.1720	0.8003

FLACC Pain Score		2.5 hr	3 hr	3.5 hr	4 hr	8 hr	12 hr
Bupivacaine	N	30	30	30	30	30	30
	Mean	1.77	2.00	2.17	2.13	1.20	1.47
	SD	0.57	0.37	0.65	0.97	0.41	0.51
Ropivacaine	N	30	30	30	30	30	30
	Mean	1.93	2.17	2.20	1.90	1.37	1.37
	SD	0.37	0.53	0.76	0.84	0.49	0.49
P value Unpaired t Test		0.1827	0.1647	0.8557	0.3256	0.1574	0.4407

Results

By conventional criteria the association between the intervention groups and mean FLACC pain score postoperatively is considered to be statistically insignificant since $p > 0.05$ as per unpaired t test.

BROMAGE MOTOR SCORE



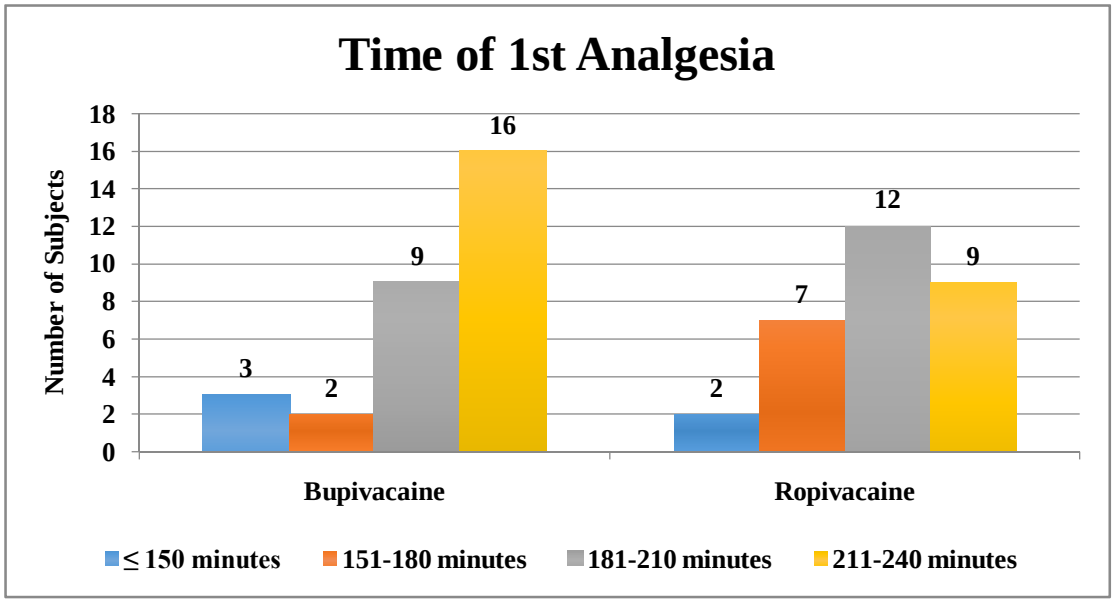
BROMAGE Motor Score		0 mins	15 mins	30 mins	1 hr	1.5 hr	2 hr
Bupivacaine	N	30	30	30	30	30	30
	Mean	4.00	3.67	3.27	3.27	3.00	2.43
	SD	0.00	0.48	0.45	0.45	0.00	0.50
Ropivacaine	N	30	30	30	30	30	30
	Mean	4.00	3.63	3.00	3.00	2.00	2.00
	SD	0.00	0.49	0.00	0.00	0.00	0.00
P value Unpaired t Test		0.0117	0.0007	0.0029	0.0029	1.0000	0.0001

BROMAGE Motor Score		2.5 hr	3 hr	4 hr	8 hr	12 hr	24 hr
Bupivacaine	N	30	30	30	30	30	30
	Mean	2.43	2.00	1.00	1.00	1.00	1.00
	SD	0.50	0.00	0.00	0.00	0.00	0.00
Ropivacaine	N	30	30	30	30	30	30
	Mean	2.00	1.00	1.00	1.00	1.00	1.00
	SD	0.00	0.00	0.00	0.00	0.00	0.00
P value Unpaired t Test		0.0001	1.0000	1.0000	1.0000	1.0000	1.0000

Results

By conventional criteria the association between the intervention groups and mean BROMAGE motor score between 0-1 hours and 2-2.5 hours postoperatively is considered to be statistically significant since $p < 0.05$ as per unpaired t test. In simple terms, in patients belonging to bupivicaine group, the mean BROMAGE motor score is increased to an average of 2.34 score points in comparison with patients belonging ropivicaine group in whom the mean BROMAGE motor score is an average of 2.05 score points

TIME OF 1ST ANALGESIA



Time of 1st Analgesia	Bupivacaine	%	Ropivacaine	%
≤ 150 minutes	3	10.00	2	6.67
151-180 minutes	2	6.67	7	23.33
181-210 minutes	9	30.00	12	40.00
211-240 minutes	16	53.33	9	30.00
Total	30	100	30	100

Time of 1st Analgesia	Bupivacaine	Ropivacaine
N	30	30
Mean	214.00	203.50
SD	43.68	43.45
P value Unpaired t Test		0.3544

Majority of the Bupivacaine group patients belonged to the 211-240 minutes time of 1st analgesia class interval (n=16, 53.33%) with a mean time of 214.00 minutes. In the Ropivacaine group patients, majority belonged to the 181-210 minutes time of 1st analgesia class interval (n=12, 40%) with a mean time of 203.50 minutes. The association between the intervention groups and time of 1st analgesia is considered be not statistically significant since $p > 0.05$ as per unpaired test.

DISCUSSION

Caudal block is one of the common technique used in paediatric age group for providing pain relief. It not only provides Intra and Post Operative Analgesia but also decrease the requirement of anaesthetic agent both Intraoperative and Post Operatively. It decrease the use of volatile anaesthetics and opioids. It provides post operative pain relief, early mobilization and discharge. It is indicated in Infra umblical surgeries like Hernia repair , lower limb surgery, procedures in sacral area of nerve distribution and orthopaedic pelvic girdle surgery.

AGE DISTRIBUTION

Two groups which received caudal Bupivacaine and Ropivacaine were compared with respect to age distribution.

Majority of the Bupivacaine group patients belonged to the 2 years age class interval (n=10, 33.33%) with a mean age of 2.70 years. In the Ropivacaine group patients, majority belonged to the same age class interval (n=15, 50%) with a mean age of 2.20 years. The association between the intervention groups and age distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test. This results were similar to study obtained by SS Chipde et al[4] (2014) and Manjushree ray et al[23] (2003)

GENDER DISTRIBUTION:

The two group which received Bupivacaine and Ropivacaine were compared with respect of gender distribution.

Majority of the Bupivacaine group patients belonged to the male gender class interval (n=26, 86,67%). In the Ropivacaine group patients, majority belonged to the same gender class interval (n=28, 93.33%). The association between the intervention groups and gender distribution is considered to be not statistically significant since $p > 0.05$ as per chi squared test. This result were similar to observation made by SS Chipde et al[4] (2014) and Manjushree ray et al[23] (2003)

WEIGHT DISTRIBUTION:

Here the two groups which received caudal Bupivacaine and Ropivacaine were compared with respect to weight distribution.

Majority of the Bupivacaine group patients belonged to the > 12 kgs weight class interval (n=14, 46.67%) with a mean weight of 11.83 kgs. In the Ropivacaine group patients, majority belonged to the 9-10 kgs weight class interval (n=14, 46.67%) with a mean weight of 10.87 kgs. The association between the intervention groups and weight distribution is considered to be not statistically significant since $p > 0.05$ as per unpaired t test. This results were

similar to observation obtained by SS Chipde et al[4] (2014) and Manjushree ray et al[23] (2003)

Intraoperative Haemodynamics

Here the two groups which received caudal Bupivacaine and Ropivacaine were compared with respect to Intraoperative haemodynamics.

Intraoperative haemodynamics like systolic blood pressure, diastolic blood pressure and mean arterial blood pressure were compared between two groups and found to be statistically insignificant as the p value is >0.05

My observation of statistical insignificant changes in intra operative hemodynamic were similar to the result of SS chipde et al[4] (2014) and Manjushree ray et al[23] (2003)

Postoperative Haemodynamics

Two groups which were given caudal Bupivacaine and Ropivacaine were compared with respect to Postoperative haemodynamics.

The association between two groups with respect to Postoperative heart rate, systolic BP, diastolic BP and MAP were found to be statistically insignificant with the p value >0.05.

My observation of statistical insignificant changes in intra operative hemodynamic were similar to the result of SS chipde et al[4] (2014) and Manjushree ray et al[23] (2003)

Flacc Pain Score

Two groups which were given caudal Bupivacaine and Ropivacaine were compared with respect to FLACC Pain score achieved at various time intervals(0hr, every hr for 12 hrs). The FLACC pain score of less than 4 were considered as effective analgesia.

The duration of Postoperative analgesia between two groups were not significant statistically. The mean duration of Postoperative analgesia in Bupivacaine group was 214 mins and for Ropivacaine group was 203.50mins which was not significant statistically. This result were similar to observation obtained by SS Chipde et al[4] (2014) and Manjushree ray et al[23] (2003)

Time for First Rescue Analgesia

Here the two groups which received caudal Bupivacaine and Ropivacaine were compared with respect to time for first rescue analgesia in minutes.

In Patients belonged to Bupivacaine group mean time for first rescue analgesia is 214mins(3.56hrs) and in Ropivacaine group mean time for first rescue analgesia is 203.50mins(3.39hrs) and it was statistically insignificant with p value of >0.05

This duration of analgesia in our study was less than that was observed by chipde et al that is 276.8 minutes for Bupivacaine group and 284.8 minutes for Ropivacaine group. But the difference between the both groups were statistically insignificant.

Motor Bromage Score

Here two groups which received caudal Bupivacaine and Ropivacaine were compared with respect to Bromage motor score recorded at various time intervals(0hr, every hour for 12 hr and at 24hrs). The total score is 4(Grade 1 to 4). Grade 1 is considered as full motor recovery and Grade 4 as complete motor recovery. Bupivacaine group had high motor score when compared to Ropivacaine group which significant statistically with p value of <0.05. So when compared to Bupivacaine, Ropivacaine had earlier motor recovery. So Ropivacaine can be used in condition requiring early mobilization and discharge after surgery such as Day Care surgeries. This result is in comparison with the study of SS Chipde et al[4] (2014) and Manjushree ray et al[23] (2003) while it doesn't comparable to the study of J.S tan et al[26] (2000)

JS.tan et al[26] (2000) In their study they compare the analgesic effect of caudal Bupivacaine and Ropivacaine for Postoperative pain relief in children posted for elective circumcision. This study showed that there is no significant difference in motor blockade for Bupivacaine and Ropivacaine group which is not similar to my study.

Problems due to prolonged complete motor blockade:

- Prolonged immobilization
- Increased hospital stay
- Increases the risk of nerve damage and skin injury
- Parent anxiety

Complications

There were no complication like

- Urinary retention
- Respiratory depression
- Bradycardia
- Hypotension
- Nausea and vomiting

SUMMARY

This study was conducted to compare the efficacy of caudal 0.25% Bupivacaine and caudal 0.2% Ropivacaine for post operative pain relief in patient posted for Lower abdominal surgeries.

The following observations were made:

- The duration of analgesia in caudal Bupivacaine group is (213.6mins) and caudal Ropivacaine group is (203.4mins)
- FLACC pain score for analgesic assessment were similar in both Bupivacaine and Ropivacaine group.
- Motor blockade between caudal Bupivacaine and Ropivacaine were statistically significant with more motor blockade with Bupivacaine
- Bromage score for motor recovery showed that the bupivacaine group had delayed recovery than ropivacaine group.
- Intra operative and Post operative heart rate, Systolic BP, diastolic BP and MAP were statistically insignificant between two groups.

CONCLUSION

From my study I conclude that administration of caudal 0.25% Bupivacaine and 0.2% Ropivacaine for children undergoing Lower abdominal surgery have similar effects on duration of analgesia but motor recovery is early in Ropivacaine. Hence Ropivacaine can be used for patient posted for day care surgery which will help in early discharge of the children.

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PROFORMA

Title:

"Comparison between Injection Bupivacaine 0.25%and Injection Ropivacaine 0.2% for caudal analgesia in paediatric patients"

DATE: ROLL NO:

NAME:

AGE: SEX:

IP NO:

DIAGNOSIS:

SURGICAL PROCEDURE DONE:

Ht: CVS:

HB:

Wt: RS:

IID - DENTITION -

PRE OP ASSESSMENT: ASSESSMENT NO:

HISTORY:

Any Co-morbid illness

H/O Documented Difficult Airway

H/O previous surgeries

INFORMED CONSENT IN TAMIL:

RANDOMIZATION DONE BY COMPUTER GENERATED NUMBER:

IV LINE

PREMEDICATION

MONITORS

BASELINE VITAL PARAMETERS

Heart Rate	
NIBP	
SPO2	
RR	

MEASURES OF STUDY OUTCOME:

	HR	SBP	DBP	MAP	RR	SPO2
PRE OP						
Before Induction						
After Induction						
Before caudal analgesia						
After caudal analgesia						
Intra Operatively every 5 minutes						

Post Operatively in PACU vital parameters, pain score and motor scores recorded as follows.

- Every 5 minutes for up to 30 minutes
- Every 10 minutes for next 30 minutes
- Then at every hour for 12 hour
- Then at every two hours till 24 hours

INFORMATION TO PARTICIPANTS

Investigator: Dr SILAMBARASAN S

Name of the Participant:

Title: "Comparison between Injection Bupivacaine 0.25%and Injection Ropivacaine 0.2% for caudal analgesia in paediatric patients."

You are invited to take part in this research study.We have got approval from the IEC.Your are asked to participate because you satisfy the eligibility criteria.We want to compare Analgesic efficacy of Bupivacaine and Ropivacaine in caudal analgesia.

What is the Purpose of the Research:

The following parameters are noted and used for comparison between the groups:

Motor and sensory block

Quality and duration of analgesia

Haemodynamics monitoring heart rate and blood pressure

The Study Design

Prospective, randomised, double blinded study.

Sample size was determined based on

Study

Comparison of Ropivacaine and Bupivacaine with Fentanyl for caudal epidural in pediatric surgery

Authored by

Tarlika P Doctor et al in Anesth Essays Res. 2013 May-Aug; 7(2): 212–215.

In this study duration of analgesia was prolonged in both group RF and BF. Time for first rescue analgesic for group RF (6.1 ± 1.1 hr) compared to group BF (5.6 ± 0.9 hr)with a difference of 16%.

Description:

- The confidence level is estimated at 95%
- With a Z value of 1.96
- The confidence interval or margin of error is estimated at +/-10
- Assuming that 80 percent of the sample will have the specified attribute

p% =16 and q%=84

$n = p\% \times q\% \times [z/e\%]^2$

$n= 16 \times 84 \times [1.96/10]^2$

$n= 51.63$

Therefore 52 is the minimum sample size required for the study.

In our study 60 subjects were chosen (n=30 in Bupivacaine arm and n=30 in Ropivacaine arm)

Group A – 0.25% Bupivacaine(n=30)

Group B – 0.2% Ropivacaine(n=30)

Benefits

It provides good perioperative and postoperative analgesia and reducing general anesthesia requirement and providing smooth pain free awakening.

As compared with Bupivacaine Ropivacaine provide early motor recovery and so early mobilisation of patient

Discomforts and risks

Accidental intravascular injection, Subarachnoid and rectal puncture, nerve injury.

This intervention has been shown to be well tolerated as shown by previous studies. And if you do not want to participate you will have alternative of setting the standard treatment and your safety is our prime concern.

Time :

Date :

Place :

Signature / Thumb Impression of Patient

Patient Name:

Signature of the Investigator : _____

Name of the Investigator : _____

PATIENT CONSENT FORM:

Study title:"Comparison between Injection Bupivacaine 0.25%and Injection Ropivacaine 0.2% for caudal analgesia in paediatric patients."

Study center:

INSTITUTE OF CHILD HEALTH AND HOSPITAL FOR CHILDREN,

MADRAS MEDICAL COLLEGE,

CHENNAI.

Participant Name: Age: Sex: I.P.No:

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety,advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

Time:

Date: Signature / thumb impression of patient

Place: Patient name:

Signature of the investigator:

Name of the investigator:

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

குழந்தைகளின் அறுவை சிகிச்சையின்போது முதுகு தண்டுவட வால்பகுதியின் ஊடாக 0.25% பூபிவேக்கெய்ன் மற்றும் 0.2% ரோப்பிவேக்கெய்ன் ஆகிய மருந்துகளை உட்செலுத்தி அதன் வலி நிவாரணத் திறனை ஒப்பீடு செய்தல்

ஆராய்ச்சியாளர் பெயர் : மரு.எஸ்.சிலம்பரசன்

பங்கேற்பாளர் பெயர் :

ஆராய்ச்சியின் நோக்கம்

குழந்தைகளின் அறுவை சிகிச்சையின்போது முதுகு தண்டுவட வால்பகுதியின் ஊடாக 0.25% பூபிவெக்கெய்ன் மற்றும் 0.2% ரோப்பிவேக்கெய்ன் ஆகிய மருந்துகளை உட்செலுத்தி அதன் பின்வரும் விளைவுகளை கண்காணித்து ஒப்பீடு செய்தல்.

1) உணர்ச்சியற்றல் திறன் மற்றும் அசைவில்லா திறன்.

2) வலி நிவாரணத்தின் தன்மை மற்றும் கால அளவு.

3) நாடித்துடிப்பு மற்றும் இரத்த அழுத்தத்தை கண்காணித்தல்.

ஆய்வுமுறை

ஆய்வில் பங்குபெறும் நோயாளிகள் இரண்டு குழுக்களாக பிரிக்கப்படுவர்

குழு-1 0.25% பூபிவேக்கெய்ன் 1 மி.லி/கி.கி என்ற அளவில் உட்செலுத்துதல்

குழு-2 0.2% ரோப்பிவேக்கெய்ன் 1மி.லி/கி.கி என்ற அளவில் உட்செலுத்துதல்

நன்மைகள்

அறுவை சிகிச்சை நடைபெறும்போதும் அதற்குப் பின்னரும் நல்ல வலி நிவாரணத் தன்மையை அளித்து, மற்ற மயக்க மருந்துகளின் தேவைகளை வெகுவாக குறைக்கின்றது. மேலும் அறுவை சிகிச்சை முடிந்து மயக்கம் தெளியும் வேளையில் வலி இல்லாமல் சீராக மயக்கத்திலிருந்து வெளிவர உதவி செய்கின்றது.

பூபிவேக்கெய்ன் உடன் ஒப்பிட்டால் ரோப்பிவேக்கெய்ன் மருந்து விரைவாக அசைவுறும் தன்மையை கொடுக்கின்றது. இதன் மூலம் அறுவை சிகிச்சைக்குப் பின்னர் நோயாளி விரைவில் எழுந்து நடமாட உதவி செய்கின்றது.

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராயச்சியின் தலைப்பு

குழந்தைகளின் அறுவை சிகிச்சையின்போது முதுகு தண்டுவட வால்பகுதியின் ஊடாக 0.25% பூபிவேக்கெய்ன் மற்றும் 0.2% ரோப்பிவேக்கெய்ன் ஆகிய மருந்துகளை உட்செலுத்தி அதன் வலி நிவாரணத் திறனை ஒப்பீடு செய்தல்

ஆய்வு நிலையம் : மயக்கவியல் துறை, சென்னை மருத்துவக் கல்லூரி சென்னை - 3.

பங்கு பெறுவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்குபெறுபவர் இதனை (✓) குறிக்கவும்

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

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

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

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் 'இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிகிறேன். ☐

பங்கேற்பவரின் பெற்றோர் கையொப்பம் ..... இடம்..... தேதி.....

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம்..... தேதி.....

ஆய்வாளரின் பெயர் .....

அசௌகரியங்கள் மற்றும் பக்கவிளைவுகள்

மருந்துக்கலவை எதிர்பாராதவிதமாக இரத்த நாளம் மற்றும் தண்டுவட உறைவழைப் பாதையின் ஊடாக செலுத்தப்படுதல் நரம்பு மற்றும் மலக்குடலில் ஊசி காயம் ஏற்படுத்த வாய்ப்புள்ளது.

இந்த முறையான ஆய்வு ஏற்கனவே பல இடங்களில் நடத்தப்பட்டு உள்ளது. மேலும் இதன் பாதுகாப்பு உறுதிசெய்யப்பட்டுள்ளது. நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விரும்பவில்லை என்றால் எப்போதும் உபயோகப்படுத்தப்படும் மருந்தே கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்கள் முக்கிய நோக்கமாகும்.

இந்த ஆய்வு சம்பந்தமான எல்லா புள்ளி விவரங்கள் மற்றும் நோயாளிகளின் விவரங்கள் ரகசியமாக வைக்கப்படும். இந்த ஆய்வு சம்பந்தப்பட்ட எல்லா பரிசோதனைகள், மருந்துகள் மற்றும் மருத்துவ சேவைகள் அனைத்தும் நோயாளிகளுக்கு இலவசமாக வழங்கப்படும்.

ஆய்வாளரின் பெயர் பங்குபெறுபவரின்பெற்றோர் பெயர்

ஆய்வாளரின் கையொப்பம் பங்குபெறுபவரின் பெற்றோர் கையொப்பம்

நாள் :
இடம் :

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.S.Silambarasan
Postgraduate M.D.(Anaesthesiology)
Madras Medical College
Chennai 600 003

Dear Dr.S.Silambarasan,

The Institutional Ethics Committee has considered your request and approved your study titled **"Comparison between Injection Bupivacaine 0.25% and Injection Ropivacaine 0.2% for caudal analgesia in paediatric patients" No.03082015.**

The following members of Ethics Committee were present in the meeting held on 04.08.2015 conducted at Madras Medical College, Chennai-3.

1. Prof.C.Rajendran, M.D.,	: Chairperson
2. Prof.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.Sudha Seshayyan, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.B.Vasanthi, M.D., Professor Pharmacology, MMC	: Member
5. Prof.A.Rajendran, M.S., Professor, Inst.of Surgery, MMC	: Member
6. Prof.Saraswathy, M.D., Director, Inst. Of Pathology, MMC	: Member
7. Prof.Srinivasagalu, Director, Inst.of Inter Med. MMC	: Member
8. Tmt. J.Rajalakshmi, J.A.O. MMC, Ch-3	: Lay Person
9. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
10. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

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

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

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

MASTER CHART

				GROUP A BUPIVACAINE					INTRA OP HEART RATE											
S.No	Name	Age	Sex	IP NO	Weight	DOS	BI	AI	5	10	15	20	25	30	35	40	45	50	55	1HR
1	bharkavi	3yrs	male	1053/15	12kgs	20	143	142	140	139	138	137								
2	gokunath	4yrs	male	1064/15	13kgs	25	125	123	124	123	120	124	120							
3	vetrivel	1yrs	male	1300/15	9kgs	15	135	136	135	137	136									
4	madeswaran	2yrs	male	1124/15	10kgs	25	120	123	124	122	125	122	120							
5	yogendran	3yrs	male	1136/15	14kgs	30	115	116	113	120	124	122	124	123						
6	maadesh	2yrs	male	1117/15	9kgs	25	140	139	141	134	126	130	125							
7	mohanakrishnan	4yrs	male	921/15	14kgs	20	123	122	124	123	125	121								
8	hariharan	4yrs	male	2164/15	15kgs	30	109	110	108	106	112	108	106	101						
9	mithran	3yrs	male	1057/15	12kgs	25	151	143	141	125	124	123	115							
10	tamilselvan	4yrs	male	1062/15	14kgs	15	102	103	105	101	106									
11	saitharun	1yrs	male	1057/15	8kgs	35	130	132	131	135	132	124	122	124	118					
12	praveen	3yrs	male	1097/15	13kgs	40	124	125	126	124	122	117	119	114	113	112				
13	akash	4yrs	male	940/15	15kgs	30	105	103	101	98	99	97	88	90						
14	rishi	3yrs	male	1028/15	13kgs	20	100	101	102	101	92	95								
15	sabarianand	3yrs	male	928/15	13kgs	25	97	99	98	95	96	95	90							
16	dharsan	2yrs	male	931/15	11kgs	20	112	115	104	105	110	101								
17	guruprasad	2yrs	male	1074/15	11kgs	30	109	104	105	102	100	98	94	92						
18	gunanidhi	2yrs	male	1063/15	10kgs	20	122	120	125	112	110	108								
19	chandru	3yrs	male	1185/15	15kgs	15	105	103	101	102	100									
20	karthik	2yrs	male	1314/15	10kgs	20	110	111	113	108	105	99								
21	perarasu	2yrs	male	1038/15	10kgs	25	124	125	120	123	110	111	107	105						
22	bhavatharini	1yrs	female	1192/15	9kgs	30	151	150	145	141	135	132	131	125						
23	ranjana	3yrs	female	1162/15	13kgs	25	120	119	114	120	113	109	105							
24	kamalesh	2yrs	male	984/15	11kgs	20	105	107	104	103	102	101								
25	dharsan	2yrs	male	1408/15	10kgs	20	113	116	115	111	109	105								
26	priya	3yrs	female	1087/15	14kgs	25	101	102	100	107	102	99	96							
27	surya	2yrs	male	2031/15	12kgs	30	112	109	106	105	100	101	97	99						
28	paramesh	4yrs	male	2012/15	15kgs	35	95	96	97	93	94	93	96	93	92					
29	radhika	3yrs	female	1052/15	13kgs	30	100	102	104	99	97	98	93	94						
30	kumar	4yrs	male	1179/15	15kgs	20	93	95	96	92	90	91								

POST OP HEART RATE											INTRA OP SYSTOLIC BP											INTRAOP DIASTOLIC BP											
0	15	30	1HR	2HR	3HR	4HR	8HR	12HR	BI	AI	5	10	15	20	25	30	35	40	45	50	55	1HR	BI	AI	5	10	15	20	25	30	35	40	45	50	55	1HR
112	113	109	105	102	95	99	97	100	101	100	97	98	96	97									63	57	56	45	47	48								
109	105	102	105	96	95	89	85	88	104	101	108	101	99	97	93								60	55	57	50	53	52	55							
114	121	104	101	103	98	99	100	97	96	97	93	87	88										55	56	55	53	47									
101	103	105	99	95	96	97	98	100	95	96	100	101	102	98	99								56	61	62	60	57	54	47							
99	97	100	98	95	87	88	86	90	105	109	102	99	100	98	102	88							62	58	59	63	60	58	57	54						
113	120	116	96	99	100	95	94	93	99	101	98	103	88	89	90								49	47	50	48	55	56	53							
115	116	104	102	100	101	98	92	96	108	105	100	101	98	97									57	55	54	49	56	53								
100	96	95	100	97	90	91	88	89	101	104	103	105	103	102	98	100							61	60	50	52	55	52	53	46						
109	106	105	102	98	94	101	105	98	105	100	98	97	101	105	98								56	57	58	62	49	48	53							
95	91	93	89	92	91	88	87	90	98	87	88	85	90										52	45	43	39	42									
112	114	115	109	110	113	105	102	101	95	96	90	96	95	85	87	77	79						60	56	55	49	47	40	42	46	43					
109	106	110	101	102	98	97	96	100	100	98	89	93	92	90	88	92	85	80					57	59	61	58	54	45	47	39	40	42				
90	88	87	85	92	84	92	87	86	105	103	101	103	101	94	93	92							62	61	57	55	53	48	46	43						
92	91	95	93	95	92	93	92	91	98	97	89	88	83	87									55	56	54	47	48	48								
90	100	96	93	92	95	93	91	93	100	90	92	87	88	77	79								50	52	50	49	47	38	39							
99	98	97	94	95	93	92	94	94	97	98	87	85	76	80									52	44	45	47	40	42								
92	91	93	90	87	88	94	92	93	101	99	94	95	94	85	86	88							55	53	54	56	50	53	52	47						
102	101	99	98	95	94	93	90	93	105	98	99	97	89	88									50	45	47	48	50	52		135						
101	100	98	99	95	90	92	89	86	104	101	100	98	90										56	53	52	47	48									
98	99	98	95	92	97	90	95	94	102	100	98	90	93	92									55	50	51	45	47	40								
100	101	96	100	99	96	97	95	97	96	98	94	90	89	92	90	93							50	60	55	53	46	49	42	41						
114	115	123	125	112	109	100	99	98	90	87	87	85	78	79	76	80							50	51	52	45	47	43	42	40						
102	103	101	98	99	92	98	96	98	100	92	96	95	97	94	87								55	47	48	46	43	42	40							
101	99	98	97	95	94	96	93	95	96	97	98	87	88	89									47	49	48	40	42	39								
104	98	101	102	97	92	93	95	89	86	89	91	92	87	88									45	46	48	42	39	37								
97	95	96	95	98	93	94	89	88	85	90	92	87	80	82	83								48	49	53	50	52	50	51							
96	97	95	94	93	95	92	93	95	90	92	91	90	95	92	97	92							55	54	52	45	47	48	46	44						
90	91	90	92	94	89	88	87	90	104	105	103	101	98	97	95	93	90						50	52	46	47	48	45	46	40	42					
89	88	90	92	93	87	98	94	93	98	97	96	95	97	98	95	94							47	48	49	47	45	40	42	43						
93	92	91	90	89	88	92	91	90	102	103	100	98	97	87									61	62	55	57	53	54								

								INTRAOP MAP						POST OP SYSTOLIC BP								
BI	AI	5	10	15	20	25	30	35	40	45	50	55	1HR	0	15	30	1HR	2HR	3HR	4HR	8HR	12HR
75.66666667	71.33333333	69.66666667	62.6666667	63.3333333	64.3333333									97	99	95	97	96	97	87	89	90
74.66666667	70.33333333	74	67	68.3333333	67	67.6666667								98	101	102	101	103	98	97	100	105
68.66666667	69.66666667	67.66666667	64.3333333	60.6666667										88	87	89	78	87	89	90	91	97
69	72.66666667	74.66666667	73.6666667	72	68.6666667	64.3333333								98	97	92	90	88	97	92	89	95
76.33333333	75	73.33333333	75	73.3333333	71.3333333	72	65.3333333							101	102	98	100	96	95	90	94	93
65.66666667	65	66	66.3333333	66	67	65.3333333								98	97	95	101	88	89	94	92	103
74	71.66666667	69.33333333	66.3333333	70	67.6666667									99	96	101	87	85	93	92	93	97
74.33333333	74.66666667	67.66666667	69.6666667	71	68.6666667	68	64							102	101	96	98	95	102	104	101	102
72.33333333	71.33333333	71.33333333	73.6666667	66.3333333	67	68								90	92	95	96	100	103	97	99	98
67.33333333	59	58	54.3333333	58										92	98	96	89	101	100	95	89	98
71.66666667	69.33333333	66.66666667	64.6666667	63	55	57	56.3333333	55						78	85	86	85	82	84	83	78	90
71.33333333	72	70.33333333	69.6666667	66.6666667	60	60.6666667	56.6666667	55	54.66					87	88	90	92	85	89	93	91	78
76.33333333	75	71.66666667	71	69	63.3333333	61.6666667	59.3333333							97	93	99	89	83	84	90	94	93
69.33333333	69.66666667	65.66666667	60.6666667	59.6666667	61									100	89	87	90	88	90	85	86	94
66.66666667	64.66666667	64	61.6666667	60.6666667	51	52.3333333								99	98	92	96	89	88	83	87	83
67	62	59	59.6666667	52	54.6666667									98	92	88	89	93	92	90	87	89
70.33333333	68.33333333	67.33333333	69	64.6666667	63.6666667	63.3333333	60.6666667							97	99	100	98	95	93	95	96	99
68.33333333	62.66666667	64.33333333	64.3333333	63	64		90							88	85	87	90	92	91	99	92	91
72	69	68	64	62										97	93	95	92	89	88	89	85	87
70.66666667	66.66666667	66.66666667	60	62.3333333	57.3333333									98	95	96	89	85	83	78	76	72
65.33333333	72.66666667	68	65.3333333	60.3333333	63.3333333	58	58.3333333							90	92	88	87	91	92	95	93	89
63.33333333	63	63.66666667	58.3333333	57.3333333	55	53.3333333	53.3333333							90	92	95	96	92	89	88	83	84
70	62	64	62.3333333	61	59.3333333	55.6666667								87	88	78	77	89	90	92	95	86
63.33333333	65	64.66666667	55.6666667	57.3333333	55.6666667									92	95	96	86	85	87	84	85	87
58.66666667	60.33333333	62.33333333	58.6666667	55	54									97	88	89	92	91	90	95	93	89
60.33333333	62.66666667	66	62.3333333	61.3333333	60.6666667	61.6666667								87	88	90	92	90	96	95	93	91
66.66666667	66.66666667	65	60	63	62.6666667	63	60							90	92	93	89	85	88	84	85	87
68	69.66666667	65	65	64.6666667	62.3333333	62.3333333	57.6666667	58						98	94	92	96	95	90	93	92	96
64	64.33333333	64.66666667	63	62.3333333	59.3333333	59.6666667	60							97	96	93	95	88	89	84	86	86
74.66666667	75.66666667	70	70.6666667	67.6666667	65									92	90	97	95	89	86	88	90	85

POST OP DIASTOLIC BP									POST OP MAP								
0	15	30	1HR	2HR	3HR	4HR	8HR	12HR	0	15	30	1HR	2HR	3HR	4HR	8HR	12HR
55	56	48	50	55	61	57	49	48	69	70.3333333	63.6666667	65.6666667	68.6666667	73	67	62.3333333	62
57	60	61	55	54	56	63	48	49	70.6666667	73.6666667	74.6666667	70.3333333	70.3333333	70	74.3333333	65.3333333	67.6666667
56	54	57	54	58	49	49	45	48	66.6666667	65	67.6666667	62	67.6666667	62.3333333	62.6666667	60.3333333	64.3333333
60	58	55	53	55	53	56	53	50	72.6666667	71	67.3333333	65.3333333	66	67.6666667	68	65	65
59	62	60	57	58	61	57	45	49	73	75.3333333	72.6666667	71.3333333	70.6666667	72.3333333	68	61.3333333	63.6666667
56	57	58	61	60	45	47	49	52	70	70.3333333	70.3333333	74.3333333	69.3333333	59.6666667	62.6666667	63.3333333	69
59	61	60	55	56	47	49	46	42	72.3333333	72.6666667	73.6666667	65.6666667	65.6666667	62.3333333	63.3333333	61.6666667	60.3333333
61	64	62	56	53	48	49	50	51	74.6666667	76.3333333	73.3333333	70	67	66	67.3333333	67	68
56	57	54	47	49	44	48	53	55	67.3333333	68.6666667	67.6666667	63.3333333	66	63.6666667	64.3333333	68.3333333	69.3333333
45	49	50	46	43	53	52	50	54	60.6666667	65.3333333	65.3333333	60.3333333	62.3333333	68.6666667	66.3333333	63	68.6666667
47	53	52	55	56	54	53	57	53	57.3333333	63.6666667	63.3333333	65	64.6666667	64	63	64	65.3333333
55	52	48	47	54	57	52	46	49	65.6666667	64	62	62	64.3333333	67.6666667	65.6666667	61	58.6666667
56	50	51	54	43	42	41	39	37	69.6666667	64.3333333	67	65.6666667	56.3333333	56	57.3333333	57.3333333	55.6666667
54	53	53	56	50	49	46	43	42	69.3333333	65	64.3333333	67.3333333	62.6666667	62.6666667	59	57.3333333	59.3333333
50	54	55	56	57	53	47	48	43	66.3333333	68.6666667	67.3333333	69.3333333	67.6666667	64.6666667	59	61	56.3333333
52	50	45	47	48	39	38	42	40	67.3333333	64	59.3333333	61	63	56.6666667	55.3333333	57	56.3333333
55	61	62	58	53	47	49	45	43	69	73.6666667	74.6666667	71.3333333	67	62.3333333	64.3333333	62	61.6666667
50	61	57	55	57	53	52	52	50	62.6666667	69	67	66.6666667	68.6666667	65.6666667	67.6666667	65.3333333	63.6666667
56	52	53	45	47	49	48	49	50	69.6666667	65.6666667	67	60.6666667	61	62	61.6666667	61	62.3333333
57	54	50	47	43	42	46	52	38	70.6666667	67.6666667	65.3333333	61	57	55.6666667	56.6666667	60	49.3333333
56	50	54	51	53	47	40	37	41	67.3333333	64	65.3333333	63	65.6666667	62	58.3333333	55.6666667	57
50	45	47	48	49	43	40	42	50	63.3333333	60.6666667	63	64	63.3333333	58.3333333	56	55.6666667	61.3333333
52	54	50	45	43	39	40	37	51	63.6666667	65.3333333	59.3333333	55.6666667	58.3333333	56	57.3333333	56.3333333	62.6666667
50	52	53	50	47	48	49	50	42	64	66.3333333	67.3333333	62	59.6666667	61	60.6666667	61.6666667	57
47	52	55	50	51	54	50	47	42	63.6666667	64	66.3333333	64	64.3333333	66	65	62.3333333	57.6666667
50	52	56	57	54	46	47	43	40	62.3333333	64	67.3333333	68.6666667	66	62.6666667	63	59.6666667	57
50	45	48	47	43	45	42	40	42	63.3333333	60.6666667	63	61	57	59.3333333	56	55	57
45	43	44	46	48	46	47	43	47	62.6666667	60	60	62.6666667	63.6666667	60.6666667	62.3333333	59.3333333	63.3333333
42	44	45	49	50	52	55	52	51	60.3333333	61.3333333	61	64.3333333	62.6666667	64.3333333	64.6666667	63.3333333	62.6666667
55	52	50	54	45	44	46	44	43	67.3333333	64.6666667	65.6666667	67.6666667	59.6666667	58	60	59.3333333	57

GROUP A BUPIVACAINE																									
	FLACC PAIN SCORE												BROMAGE SCORE(MOTOR SCORE)												
S.No	0	15	30	1HR	1.5HR	2HR	2.5HR	3HR	3.5HR	4HR	8HR	12HR	0	15	30	1HR	1.5HR	2HR	2.5HR	3HR	3.5HR	4HR	8HR	12HR	24 HR	TIME OF FIRST ANALGESIA (Min)
1	0	0	0	1	1	2	2	3	1	1	1	2	grade 4	grade4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	180
2	0	0	0	1	1	1	1	2	3	1	1	2	grade 4	grade 4	grade 3	grade 3	grade 3	grade2	grade2	grade2	grade2	grade 1	grade 1	grade 1	grade 1	210
3	0	0	0	1	1	2	1	2	2	3	1	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
4	0	0	1	1	2	2	3	1	1	2	2	2	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	150
5	0	0	1	1	2	2	2	2	3	1	1	2	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	210
6	0	0	1	1	2	2	2	2	2	3	1	1	grade 4	grade 3	grade3	grade 3	grade 3	grade 2	grade 2	grade 2	grade1	grade 1	grade 1	grade 1	grade 1	240
7	0	0	1	1	2	2	2	2	2	3	1	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
8	0	0	0	1	1	2	2	2	2	3	1	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
9	0	0	0	1	1	1	1	2	3	1	1	2	grade 4	grade 3	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	210
10	0	0	0	1	1	1	1	2	2	3	1	1	grade 4	grade 3	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
11	0	0	0	1	1	1	2	2	2	3	1	1	grade 4	grade 3	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
12	0	0	0	1	1	2	2	2	3	1	1	1	grade 4	grade 3	grade 3	grade3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	210
13	0	0	0	1	1	1	1	2	2	3	1	2	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade1	grade 1	grade 1	grade 1	grade 1	240
14	0	0	0	1	1	2	2	2	3	1	2	2	grade 4	grade 3	grade3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	210
15	0	0	0	1	1	1	2	2	2	3	1	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
16	0	0	0	1	1	1	2	2	2	3	2	2	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
17	0	0	0	1	1	1	1	2	3	1	1	2	grade 4	grade 3	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade1	grade 1	grade 1	grade 1	grade 1	210
18	0	0	0	1	1	1	1	2	2	3	1	1	grade 4	grade 3	grade 3	grade 3	grade3	grade2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
19	0	0	0	1	1	1	1	2	2	3	1	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
20	0	0	0	1	1	1	2	2	2	3	1	1	grade 4	grade 4	grade 3	grade3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
21	0	0	0	1	1	1	2	2	3	1	1	2	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade1	grade 1	grade 1	grade 1	grade 1	210
22	0	0	0	1	1	1	2	3	1	1	2	2	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	180
23	0	0	0	1	1	1	2	2	3	1	2	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	210
24	0	0	1	1	2	2	3	2	2	2	1	1	grade 4	grade 3	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	150
25	0	0	0	1	1	2	2	2	2	3	1	2	grade 4	grade 3	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
26	0	0	0	1	1	2	2	2	3	1	1	2	grade 4	grade 4	grade 3	grade 3	grade3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	210
27	0	0	0	1	2	2	2	2	2	3	1	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
28	0	0	0	1	2	2	2	2	2	3	1	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240
29	1	2	3	1	1	2	2	1	1	1	2	2	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	30
30	0	0	0	1	1	1	1	2	2	3	1	1	grade 4	grade 4	grade 3	grade 3	grade 3	grade 2	grade 2	grade 2	grade2	grade 1	grade 1	grade 1	grade 1	240

GROUP B ROPIVACAINE							INTRA HEART RATE														POST OP HEART RATE								
S.NO	Name	Age	Sex	IP NO	Weight	DOS	BI	AI	5	10	15	20	25	30	35	40	45	50	55	1HR	0	15	30	1HR	2HR	3HR	4HR	8HR	12HR
1	vinay	4yrs	male	1180/15	12kgs	25	130	123	120	125	130	121	112								106	105	102	100	98	97	96	94	92
2	sham	2yrs	male	1004/15	10kgs	25	114	115	116	114	111	107	103								104	100	98	99	97	94	92	102	100
3	**jeyanadhan**	**1yrs**	**male**	**1603/15**	**10kgs**	30	106	105	103	102	98	99	95	100							98	99	96	95	95	97	94	100	101
4	**niranjana**	**4yrs**	**male**	**1047/15**	**15kgs**	35	98	97	95	94	96	94	96	94	93						93	94	97	94	93	96	94	96	93
5	**perinbam**	**2yrs**	**male**	**1050/15**	**12kgs**	25	125	123	121	120	115	117	111								101	99	95	97	95	94	96	94	98
6	**mahesh**	**2yrs**	**male**	**1056/15**	**10kgs**	25	109	110	108	106	102	98	95								98	96	95	94	93	94	93	92	93
7	**dyash**	**1yrs**	**male**	**1319/15**	**8kgs**	20	103	102	100	98	95	96									97	95	100	89	90	92	92	93	94
8	**shawanth**	**2yrs**	**male**	**1180/15**	**12kgs**	15	115	109	105	102	101										100	98	99	95	96	91	98	97	96
9	**deeshak**	**4yrs**	**male**	**2130/15**	**14kgs**	30	98	99	100	101	112	113	112	115							105	104	103	105	102	103	101	104	102
10	**kishore**	**1yrs**	**male**	**1345/15**	**10kgs**	25	132	127	125	126	121	117	119								109	102	101	99	103	98	100	97	96
11	**harish**	**2yrs**	**male**	**2835/15**	**10kgs**	25	123	122	124	125	114	112	110								101	99	98	97	96	95	100	101	97
12	**nithish**	**2yrs**	**male**	**1190/15**	**11kgs**	20	112	113	114	120	106	101									98	96	100	101	89	94	92	98	99
13	**gajendran**	**2yrs**	**male**	**1183/15**	**10kgs**	20	104	102	102	100	98	99									100	99	98	97	95	94	99	95	96
14	**dhanush**	**2yrs**	**male**	**1087/15**	**10kgs**	25	99	98	100	101	87	89	90								98	100	101	102	98	96	98	97	97
15	**dharsan**	**2yrs**	**male**	**1146/15**	**9kgs**	20	86	87	89	90	85	86									90	96	95	99	98	100	95	97	93
16	**hemanth**	**1yrs**	**male**	**2142/15**	**10kgs**	25	100	101	99	97	93	101	102								104	102	103	100	104	99	98	99	101
17	**aakash**	**2yrs**	**male**	**2120/15**	**10kgs**	25	112	111	109	105	101	99	98								98	99	102	104	97	98	94	95	97
18	**abisek**	**1yrs**	**male**	**611/15**	**10kgs**	20	132	125	120	115	116	110									99	101	97	98	99	95	98	99	100
19	**kamalesh**	**2yrs**	**male**	**984/15**	**11kgs**	15	115	116	106	105	102										99	97	100	101	102	97	94	95	96
20	**ranjith**	**4yrs**	**male**	**1310/15**	**14kgs**	20	122	112	106	105	101	100									98	99	96	94	95	97	98	87	89
21	**raj**	**1yrs**	**male**	**1255/15**	**10kgs**	20	140	142	133	130	125	124									113	110	108	102	103	101	103	100	102
22	**navin prabhakar**	**3yrs**	**male**	39077	**10kgs**	30	109	103	104	105	106	101	102	101							103	99	98	100	101	102	98	96	96
23	**ramu**	**2yrs**	**male**	**876/15**	**11kgs**	20	113	120	111	105	102	104									100	102	97	99	90	95	95	96	98
24	**raghavi**	**3yrs**	**female**	**974/15**	**14kgs**	25	106	105	102	101	103	99	98								103	99	102	100	98	99	95	97	93
25	**arun**	**4yrs**	**male**	**2335/15**	**15kgs**	15	95	93	96	90	93										98	96	95	94	93	90	94	93	94
26	**stephen**	**3yrs**	**male**	**2173/15**	**13kgs**	30	101	98	99	95	96	97	97	95							97	96	95	94	95	96	93	94	96
27	**nithya**	**2yrs**	**female**	**1432/15**	**11kgs**	20	102	105	104	101	103	100									97	95	96	90	92	95	93	89	95
28	**tharun**	**1yrs**	**male**	**1012/15**	**7kgs**	25	99	100	97	112	108	102	104								98	99	96	90	95	94	97	94	95
29	**ragu**	**2yrs**	**male**	**1132/15**	**9kgs**	20	100	102	102	98	99	97									99	97	95	94	93	90	94	95	93
30	**amith**	**2yrs**	**male**	**1044/15**	**8kgs**	25	105	101	98	99	96	95	101								98	96	97	98	90	93	94	98	93

INTRA SYSTOLIC BP														INTRA OP DIASTOLIC BP											
BI	**AI**	**5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**	**45**	**50**	**55**	**1HR**	**BI**	**AI**	**5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**	**45**	**50**	**55**	**1HR**
101	102	95	92	90	94	86								50	52	47	48	42	40	45							
96	95	94	98	94	86	87								46	53	51	52	54	56	51							
97	95	94	86	85	84	86	78							52	53	46	47	43	42	39	43						
93	90	87	88	84	86	87	84	86						48	47	48	46	51	52	50	53	46					
98	99	95	97	97	96	98								46	48	51	52	55	53	54							
97	95	94	88	89	85	86								50	51	47	48	51	48	42							
98	89	85	88	86	84									46	50	52	54	52	48								
97	98	94	89	88										53	52	51	47	48									
102	107	103	98	95	102	101	99							52	46	47	48	50	54	52	51						
98	99	88	90	89	76	78								50	45	46	43	40	42	37							
88	89	90	87	85	86	87								52	46	42	41	46	39	38							
90	92	93	95	94	92									45	42	40	45	43	41								
88	89	94	93	95	93									46	50	52	51	50	48								
96	85	86	84	82	79	80								54	47	48	49	50	51	52							
98	86	88	85	87	89									47	50	51	48	49	47								
98	86	87	89	95	93	92								50	52	46	47	48	43	42							
86	85	82	81	80	78	79								49	50	53	37	39	38	37							
98	96	87	89	86	82									46	47	50	53	52	47								
100	101	87	90	88										45	48	50	51	46									
97	95	87	88	89	90									50	52	48	49	45	42								
98	87	88	84	85	76									52	43	41	47	43	40								
95	94	98	93	92	90	95	86							46	48	50	52	48	49	51	42						
90	93	85	86	88	89									45	42	46	50	52	54								
87	86	89	83	84	86	82								42	45	50	51	52	46	47							
95	93	92	87	88										40	42	43	45	40									
87	86	88	89	90	86	87	88							45	43	40	46	42	52	50	51						
95	93	97	96	93	94									46	50	52	51	50	40								
90	88	86	78	79	80	82								50	51	52	50	45	47	48							
89	87	86	85	82	80									45	44	46	43	42	40								
94	90	99	96	87	88	85								46	45	43	42	40	42	41							

							INTRAOP MAP							POST OP SYSTOLIC BP								
BI	AI	5	10	15	20	25	30	35	40	45	50	55	1HR	0	15	30	1HR	2HR	3HR	4HR	8HR	12HR
67	68.6666667	63	62.6666667	58	58	58.6666667								96	99	95	86	87	94	90	95	96
62.66666667	67	65.3333333	67.3333333	67.3333333	66	63								95	97	95	94	87	88	89	84	83
67	67	62	60	57	56	54.6666667	54.6666667							98	95	93	87	85	87	85	86	79
63	61.3333333	61	60	62	63.3333333	62.3333333	63.3333333	59.3333333						95	96	95	88	89	85	86	78	77
63.33333333	65	65.6666667	67	69	67.3333333	68.6666667								96	95	99	87	88	85	79	80	82
65.66666667	65.6666667	62.6666667	61.3333333	63.6666667	60.3333333	56.6666667								93	96	97	88	89	83	86	87	78
63.33333333	63	63	65.3333333	63.3333333	60									97	95	95	93	88	86	92	95	93
67.66666667	67.3333333	65.3333333	61	61.3333333										98	93	89	88	78	79	84	84	87
68.66666667	66.3333333	65.6666667	64.6666667	65	70	68.3333333	67							95	99	97	96	98	98	95	96	99
66	63	60	58.6666667	56.3333333	53.3333333	50.6666667								87	88	89	90	91	96	88	89	85
64	60.3333333	58	56.3333333	59	54.6666667	54.3333333								88	90	92	91	95	94	93	90	87
60	58.6666667	57.6666667	61.6666667	60	58									89	95	93	88	89	90	95	87	86
60	63	66	65	65	63									90	92	91	85	87	94	94	93	96
68	59.6666667	60.6666667	60.6666667	60.6666667	60.3333333	61.3333333								89	87	89	86	90	92	91	94	96
64	62	63.3333333	60.3333333	61.6666667	61									90	94	92	93	96	87	88	89	92
66	63.3333333	59.6666667	61	63.6666667	59.6666667	58.6666667								96	95	87	86	88	89	93	92	90
61.33333333	61.6666667	62.6666667	51.6666667	52.6666667	51.3333333	51								98	99	89	97	90	93	91	89	86
63.33333333	63.3333333	62.3333333	65	63.3333333	58.6666667									86	88	85	82	80	87	90	92	91
63.33333333	65.6666667	62.3333333	64	60										92	90	88	89	91	84	82	80	84
65.66666667	66.3333333	61	62	59.6666667	58									86	87	90	92	91	83	82	88	90
67.33333333	57.6666667	56.6666667	59.3333333	57	52									87	90	84	82	86	80	91	92	94
62.33333333	63.3333333	66	65.6666667	62.6666667	62.6666667	65.6666667	56.6666667							90	92	86	80	79	78	76	80	75
60	59	59	62	64	65.6666667									87	88	85	90	94	92	90	91	94
57	58.6666667	63	61.6666667	62.6666667	59.3333333	58.6666667								90	92	3	87	86	84	80	84	85
58.33333333	59	59.3333333	59	56										89	87	85	90	95	93	93	92	89
59	57.3333333	56	60.3333333	58	63.3333333	62.3333333	63.3333333							87	90	93	92	95	93	92	87	88
62.33333333	64.3333333	67	66	64.3333333	58									89	87	86	90	92	87	86	83	85
63.33333333	63.3333333	63.3333333	59.3333333	56.3333333	58	59.3333333								90	93	92	89	88	85	89	90	96
59.66666667	58.3333333	59.3333333	57	55.3333333	53.3333333									88	87	86	85	84	83	87	78	79
62	60	61.6666667	60	55.6666667	57.3333333	55.6666667								90	92	89	87	86	85	84	87	84

POST OP DIASTOLIC BP									POST OP MAP								
0	15	30	1HR	2HR	3HR	4HR	8HR	12HR	0	15	30	1HR	2HR	3HR	4HR	8HR	12HR
46	48	50	52	54	56	46	47	50	62.6666667	65	65	63.3333333	65	68.6666667	60.6666667	63	65.3333333
50	52	53	54	50	43	46	47	45	65	67	67	67.3333333	62.3333333	58	60.3333333	59.3333333	57.6666667
45	47	48	46	48	42	47	51	50	62.6666667	63	63	59.6666667	60.3333333	57	59.6666667	62.6666667	59.6666667
55	52	50	53	54	52	51	45	46	68.3333333	66.6666667	65	64.6666667	65.6666667	63	62.6666667	56	56.3333333
46	47	48	46	52	51	50	47	49	62.6666667	63	65	59.6666667	64	62.3333333	59.6666667	58	60
52	55	46	49	43	44	41	45	42	65.6666667	68.6666667	63	62	58.3333333	57	56	59	54
47	43	46	45	56	54	53	54	51	63.6666667	60.3333333	62.3333333	61	66.6666667	64.6666667	66	67.6666667	65
46	54	52	51	48	45	47	52	53	63.3333333	67	64.3333333	63.3333333	58	56.3333333	59.3333333	62.6666667	64.3333333
45	52	50	51	49	55	50	51	52	61.6666667	67.6666667	65.6666667	66	65.3333333	69.3333333	65	66	67.6666667
53	52	46	47	48	50	49	46	44	64.3333333	64	60.3333333	61.3333333	62.3333333	65.3333333	62	60.3333333	57.6666667
58	50	45	47	48	46	48	43	42	68	63.3333333	60.6666667	61.6666667	63.6666667	62	63	58.6666667	57
60	54	53	52	49	45	43	46	40	69.6666667	67.6666667	66.3333333	64	62.3333333	60	60.3333333	59.6666667	55.3333333
46	50	51	47	48	49	50	48	49	60.6666667	64	64.3333333	59.6666667	61	64	64.6666667	63	64.6666667
50	51	52	50	45	46	47	48	48	63	63	64.3333333	62	60	61.3333333	61.6666667	63.3333333	64
48	49	50	52	53	54	46	48	49	62	64	64	65.6666667	67.3333333	65	60	61.6666667	63.3333333
45	46	47	43	42	50	51	52	50	62	62.3333333	60.3333333	57.3333333	57.3333333	63	65	65.3333333	63.3333333
50	52	45	46	47	43	42	40	42	66	67.6666667	59.6666667	63	61.3333333	59.6666667	58.3333333	56.3333333	56.6666667
53	51	50	47	48	40	39	40	41	64	63.3333333	61.6666667	58.6666667	58.6666667	55.6666667	56	57.3333333	57.6666667
50	48	47	40	43	42	46	43	42	64	62	60.6666667	56.3333333	59	56	58	55.3333333	56
53	51	46	48	49	51	50	52	48	64	63	60.6666667	62.6666667	63	61.6666667	60.6666667	64	62
57	54	50	47	45	43	49	42	40	67	66	61.3333333	58.6666667	58.6666667	55.3333333	63	58.6666667	58
50	46	47	36	37	39	39	41	40	63.3333333	61.3333333	60	50.6666667	51	52	51.3333333	54	51.6666667
46	47	48	49	50	52	54	55	53	59.6666667	60.6666667	60.3333333	62.6666667	64.6666667	65.3333333	66	67	66.6666667
50	51	52	47	49	46	46	48	43	63.3333333	64.6666667	35.6666667	60.3333333	61.3333333	58.6666667	57.3333333	60	57
46	47	50	52	52	55	54	48	46	60.3333333	60.3333333	61.6666667	64.6666667	66.3333333	67.6666667	67	62.6666667	60.3333333
45	47	46	50	52	53	55	54	53	59	61.3333333	61.6666667	64	66.3333333	66.3333333	67.3333333	65	64.6666667
46	47	48	50	52	54	56	54	50	60.3333333	60.3333333	60.6666667	63.3333333	65.3333333	65	66	63.6666667	61.6666667
56	50	46	47	48	43	47	52	39	67.3333333	64.3333333	61.3333333	61	61.3333333	57	61	64.6666667	58
45	46	47	46	50	51	52	53	50	59.3333333	59.6666667	60	59	61.3333333	61.6666667	63.6666667	61.3333333	59.6666667
45	44	46	47	47	48	46	44	47	60	60	60.3333333	60.3333333	60	60.3333333	58.6666667	58.3333333	59.3333333

GROUP B ROPIVACAINE

	FLACC PAIN SCORE												BROMAGE SCORE(MOTOR SCORE)												TIME OF 1ST ANALGESIA IN MIN
S.No	0	15	30	1HR	1.5HR	2HR	2.5HR	3HR	3.5HR	4HR	8HR	12HR	0	15	30	1HR	1.5HR	2HR	2.5HR	3HR	3.5HR	4HR	8HR	12HR	24 HR	
1	0	0	0	1	2	2	2	2	3	2	2	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
2	0	0	0	1	1	1	2	2	2	3	1	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
3	0	0	0	1	1	1	2	2	3	2	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
4	0	0	0	1	2	2	3	1	1	2	2	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	150
5	0	0	0	1	1	2	2	2	2	3	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
6	0	0	0	1	2	2	2	2	3	1	1	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
7	0	0	0	1	1	2	2	2	2	3	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
8	0	0	0	1	1	1	1	2	3	1	1	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
9	0	0	0	1	1	1	2	2	2	3	1	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
10	0	0	0	1	1	1	2	2	3	1	1	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
11	0	0	0	1	1	1	2	2	2	3	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
12	0	0	0	1	1	1	2	2	2	3	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
13	0	0	0	1	1	1	2	3	1	2	2	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	180
14	0	0	0	1	1	1	2	3	1	1	2	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	180
15	0	0	0	1	1	1	2	3	1	1	2	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	180
16	0	0	0	1	1	2	2	2	3	1	2	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
17	0	0	0	1	1	2	2	2	2	3	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
18	0	0	0	1	1	1	2	2	2	3	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
19	0	0	0	1	1	1	2	2	3	2	2	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
20	0	0	0	1	1	2	2	2	3	1	1	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
21	0	0	0	1	1	2	2	3	2	2	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	180
22	0	0	0	1	1	2	2	2	3	2	2	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
23	0	0	0	1	1	2	2	3	2	1	1	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	180
24	0	0	0	1	1	2	1	2	3	1	1	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
25	1	3	2	1	1	2	1	1	1	2	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	15
26	0	0	0	1	1	2	2	2	2	3	2	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	240
27	0	0	0	1	1	2	2	3	1	1	2	2	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	180
28	0	0	0	1	1	1	2	2	3	1	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210
29	0	0	0	1	1	1	2	3	2	2	1	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	180
30	0	0	0	1	1	2	2	2	3	1	2	1	grade 4	grade4	grade3	grade 3	grade 2	grade 2	grade 2	grade 1	grade 1	grade 1	grade 1	grade 1	grade 1	210