

**A COMPARATIVE STUDY TO EVALUATE THE  
EFFICACY OF PARACETAMOL AS RECTAL  
SUPPOSITORY IN PAEDIATRIC PATIENTS  
UNDERGOING SUBUMBILICAL SURGERY WITH  
CAUDAL BUPIVACAINE**

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**M.D. DEGREE EXAMINATION**

**M.D. ANAESTHESIOLOGY—BRANCH X**

**CHENGALPATTU MEDICAL COLLEGE, CHENGALPATTU.**



**THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY**

**CHENNAI, TAMILNADU**

**MARCH 2010**

## **CERTIFICATE**

This is to certify that this dissertation titled **“A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF PARACETAMOL AS RECTAL SUPPOSITORY IN PAEDIATRIC PATIENTS UNDERGOING SUBUMBILICAL SURGERY WITH CAUDAL BUPIVACAINE”** has been prepared by Dr.K.R.Padmanabhan MBBS.,D.A., under my supervision in the Department of Anaesthesiology, Chengalpattu Medical College&Hospital, Chengalpattu during the academic period 2008-2010 and is being submitted to the Tamil Nadu DR.M.G.R. Medical University, Chennai in partial fulfillment of the University regulation for the award of the Degree of Doctor of Medicine(Branch-X MD Anaesthesiology) and his dissertation is a bonafide work.

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### **DECLARATION**

I, Dr. K.R.Padmanabhan solemnly declare that the  
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**“A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF  
PARACETAMOL AS RECTAL SUPPOSITORY IN PAEDIATRIC  
PATIENTS UNDERGOING SUBUMBILICAL SURGERY WITH  
CAUDAL BUPIVACAINE”** is a bonafide work done by me in  
the Department of Anaesthesiology, Chengalpattu Medical  
College & Hospital, Chengalpattu, under the able guidance  
of Prof.R.S.VIJAYALAKSHMI,M.D.D.A., Professor and HOD,  
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College, Chengalpattu, after getting approval from ethical  
committee.

Place: Chengalpattu.

Date:

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PROFORMA

MASTER CHART

# **INTRODUCTION**

## **INTRODUCTION**

The postoperative pain in pediatric patient is not adequately managed, though it causes morbidity and mortality at times. It is now accepted that pain should be anticipated, and safely and effectively controlled, in all children, whatever their age, maturity or severity of illness be<sup>1,2,9</sup>. Because of the multiplicity of mechanisms involved in post operative pain, a multimodal analgesia regimen, with a combination of opioid and non-opioid analgesic drugs is

often used to augment the analgesic efficacy and reduce the polypharmacy and its side effects<sup>3</sup>.

Peripheral tissue injury provokes both peripheral sensitization and central sensitization<sup>4,5</sup>. These changes contribute to the post-traumatic pain hypersensitivity state which manifests as an increase in the responsiveness to noxious stimuli and a decrease in the pain threshold, both at the site of injury and in the surrounding uninjured tissue<sup>4,5</sup>.

Single shot caudal epidural analgesia is a widely used regional technique for intra and postoperative pain relief during lower abdominal, inguinal and penoscrotal surgeries in paediatric patients<sup>6</sup>. It is technically simple, safe and reliable, and provides effective analgesia for surgery below the umbilicus. However, the analgesic effect of caudal bupivacaine lasts for 4-12 hours. Different additives are used to prolong the period of post operative analgesia<sup>7</sup>.

The use of caudal Morphine provides excellent analgesia with higher incidence of serious side effects like respiratory depression, nausea, vomiting and urinary retention<sup>7</sup>. Other combination such as ketamine, clonidine, tramadol and midazolam have also been used as adjuvant to bupivacaine for caudal analgesia. All of them provide

improved analgesia without any serious side effects. However, clonidine, ketamine, tramadol and midazolam do have potential risk of producing hypotension, behavioral changes, vomiting and sedation respectively <sup>8</sup>.

Paracetamol is a good analgesic. It has high therapeutic range and safe and easy to administer in children especially in the form of suppository. Rectal paracetamol is devoid of complications of non steroidal anti-inflammatory drugs, such as coagulopathy, nephropathy, gastropathy and bronchial asthma <sup>10, 11</sup>.

Studies have demonstrated that mechanical hyperalgesia surrounding the wound in post operative patients and experimentally, heat induced, secondary hyperalgesia share a common mechanism of central neuronal sensitization which contributes to post operative pain. Paracetamol by its central effect on the nociceptive process involving central sensitization provides excellent post operative analgesia <sup>12</sup>.

In my institution I choose to study the post operative analgesic effect of rectal paracetamol in addition to caudal bupivacaine in paediatric patients subjected to sub umbilical surgeries.

*AIM*

## **AIM**

To evaluate the efficacy and duration of post operative analgesia of paracetamol rectal suppository, in paediatric patients undergoing subumbilical surgeries.



# *PATHOPHYSIOLOGY*

## *OF*

### *POST OPERATIVE*

### *PAIN*

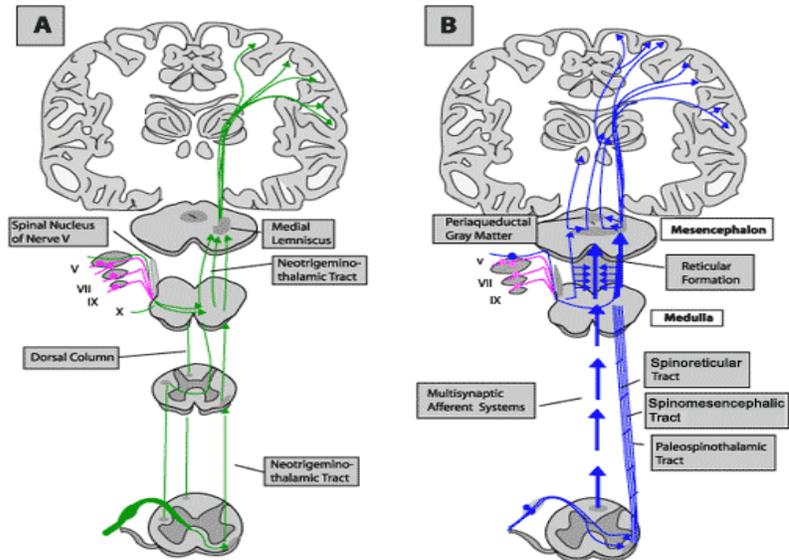
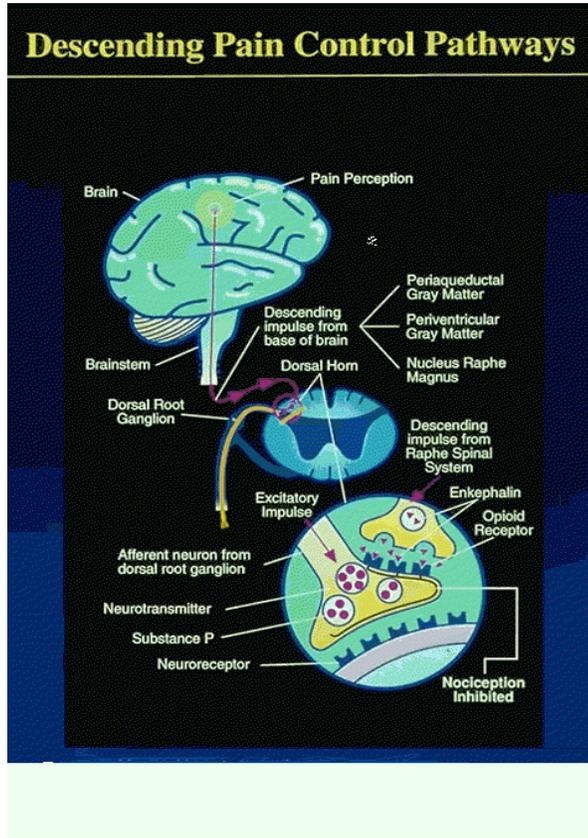
#### **PATHOPHYSIOLOGY OF**

#### **POSTOPERATIVE PAIN**

When surgical stimulus is applied to a part of the body, there is activation of peripheral nociception by the inflammatory mediators (peptide, lipid, neurotransmitters and neurotrophins). The stimulation of peripheral nociceptors, initiate transduction and transmission of nociceptive information to central nervous system and the process of neurogenic inflammation, leading to vasodilatation and plasma extravasations in the periphery.

The peripheral stimuli travel from the peripheral nociceptor to dorsal horn in the spinal cord. The impulses from spinal cord are transmitted to central nervous system through Spinothalamic and Spinoreticular tract causing suprasegmental and cortical response, which ultimately produces the perception of pain. The anterior and anterolateral spinal horns are also stimulated initiating segmental responses which may lead to increased skeletal muscle tone, inhibition of phrenic nerve or even decreased gastric motility.

# Pain Pathways



Continuous release of inflammatory mediators result in

- (1) Activation of dormant nociceptors
- (2) Decreased threshold for activation of nociceptors
- (3) Increased discharge rate with activation
- (4) Increased rate of basal (spontaneous) discharge
- (5) Intense stimulation may result in central sensitization and hyperexcitability

Experimental studies show that noxious stimuli can produce expression of new genes (which are the basis of neuronal sensitization) in the dorsal horn of spinal cord within an hour and these changes are sufficient to alter behavior within the same time frame. There are acute and chronic effects of surgical stimulus.

The perioperative period is associated with a variety of pathophysiological responses that may be initiated or maintained by nociceptive input, although these responses may have had a teleological purpose, the same response to the iatrogenic nature of modern surgery may be harmful. Uncontrolled perioperative pain may potentiate some of these perioperative pathophysiological changes and increase morbidity and mortality of the patients.

The nociceptive stimulation of the periphery leading to central sensitization results in neuroendocrine response,

which is a combination of peripheral and systemic response. This further leads to hypothalamo-pituitary-adrenocortical and sympathoadrenal response. Suprasegmental reflex response to pain results in increased sympathetic tone, increased catecholamine and catabolic hormone secretion, and decreased secretion of anabolic hormones. The extent of stress is influenced by many factors, including the type of anesthesia and intensity of surgical injury with the extent of stress response proportional to the degree of surgical trauma.

The effects of the above reflexes include,

- (1) Sodium and water retention,
- (2) Hyperglycemia,
- (3) Increased free fatty acids,
- (4) Increased ketone bodies,
- (5) Increased lactate levels,
- (6) Increased oxygen consumption,
- (7) Hypercoagulability, (DVT, vascular graft failure and myocardial ischemia)
- (8) Postoperative immune suppression ,
- (9) Increased myocardial oxygen consumption,
- (10) Delayed gastric motility,
- (11) Decrease in postoperative respiratory function in upper abdominal and thoracic surgery.

Uncontrolled pain may result in sympathetic nervous system activation, causing a variety of potentially harmful physiologic responses that may adversely influence the extent of morbidity and mortality of patients. Nociceptor activation may also result in several detrimental inhibitory spinal reflexes. Control of the

pathophysiologic process associated with acute postoperative pain may attenuate the stress response, sympathetic outflow, and inhibitory spinal reflexes and may lead to improvements in morbidity, mortality, and other nontraditional outcomes.

Surgical tissue injury is known to produce neuroplastic changes leading to spinal sensitization and the expression of stimulus-evoked hyperalgesia and allodynia. Poorly controlled acute postoperative pain may be an important factor in the development of pathologic long-term chronic pain .

Prevention of central sensitization and control of postoperative pain may decrease the incidence of chronic pain. In case of inflammatory pain there is release of inflammatory and pro-inflammatory cytokines from the cells that sensitize or stimulate free nerve endings, initiate the coagulation cascade, and activate immune system. The ensuing lowering of the activation of the receptors for pain at the site of injury results in the bombardment of the spinal cord with continuous noxious input via A-delta and c-fiber. Additionally, under the influence of intense inflammatory pain, A-alpha and A-beta fibers are induced to participate in the transmission of pain signals. This is significant, given that their input is not filtered in the spinal cord in the same way as

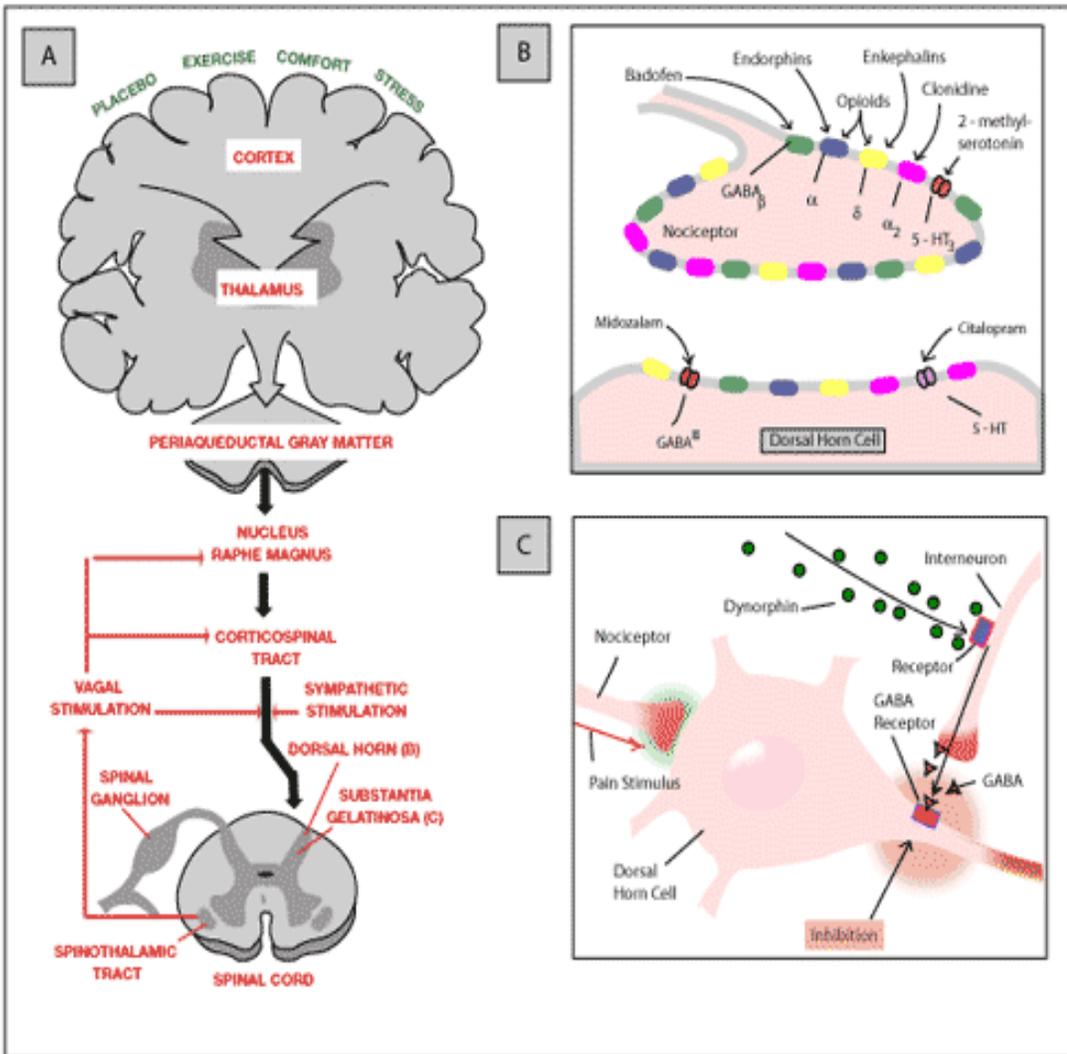
A-delta and c-fibers, nor can it be dampened or modified as effectively with classic analgesic medications such as opioids.

It is believed that the continuous nature of the input provokes changes in the chemical milieu in the spinal cord and triggers structural reorganization that raises the potential for establishing neuropathic pain. Thus, every time when there is enhanced noxious input, there is an induction of decreased central inhibition that would ordinarily modify the input and the subsequent Central nervous system response

13.

Caudal bupivacaine inhibits the input of noiceceptive stimulus Paracetamol , through its inhibition of prostaglandin synthesis in the central nervous system, prevents central sensitization component of Post operative pain.

### **Central & Peripheral sensitization**



***PHARMACOLOGY OF***

***BUPIVACAINE***

## PHARMACOLOGY OF BUPIVACAINE

Bupivacaine is an amino amide local anaesthetic with a pKa of 8.1 and maximum protein binding, potency, and lipid solubility, metabolized by microsomal enzymes in liver, but slowly metabolized than Xylocaine and Prilocaine. Maximum dose is 2-3 mg/kg body weight. Decrease in hepatic function and hepatic blood flow, can reduce metabolic clearance and predisposes to bupivacaine toxicity. Accidental intravascular injections, can cause blockage of cardiac sodium channels and hence predisposes to cardiac toxicity, such as

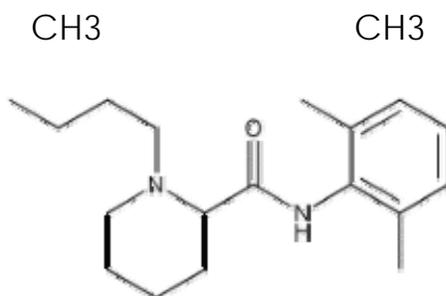
hypotension, dysrhythmias, atrioventricular block. But in paediatric age group accidental vascular injection, can easily be prevented by properly performed caudal epidural block with all precautions.

### Structure of Bupivacaine.

Formal Chemical Name (IUPAC)

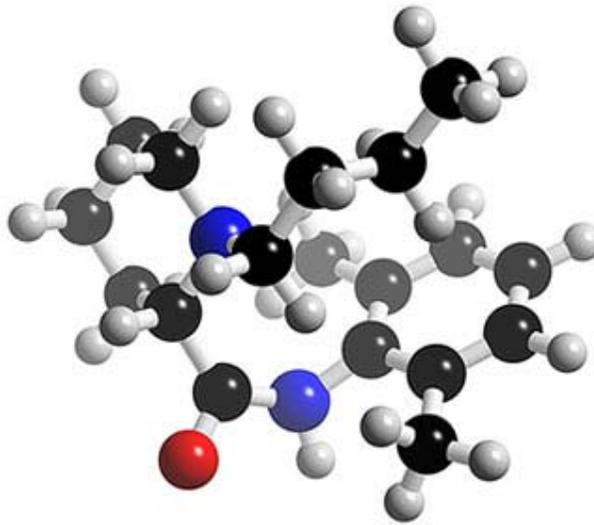
1-butyl-N-(2,6-dimethylphenyl)piperidine-2-carboxamide

C<sub>18</sub> H<sub>28</sub> N<sub>2</sub> O



CH<sub>3</sub>

### 3 dimensional Structure of bupivacaine



Systemic exposure to excessive quantities of bupivacaine mainly result in central nervous system (CNS) and cardiovascular effects. CNS effects usually occur at lower blood plasma concentrations and additional cardiovascular effects present at higher concentrations, though cardiovascular collapse may also occur with low concentrations.

CNS effects may include CNS excitation (nervousness, tingling around the mouth, tinnitus, tremor, dizziness, blurred vision, seizures) followed by depression (drowsiness, loss of consciousness, respiratory depression and apnea).

Cardiovascular effects include hypotension, bradycardia, arrhythmias, and/or cardiac arrest – some of which may be due to hypoxemia secondary to respiratory depression <sup>14</sup>.

*CAUDAL*

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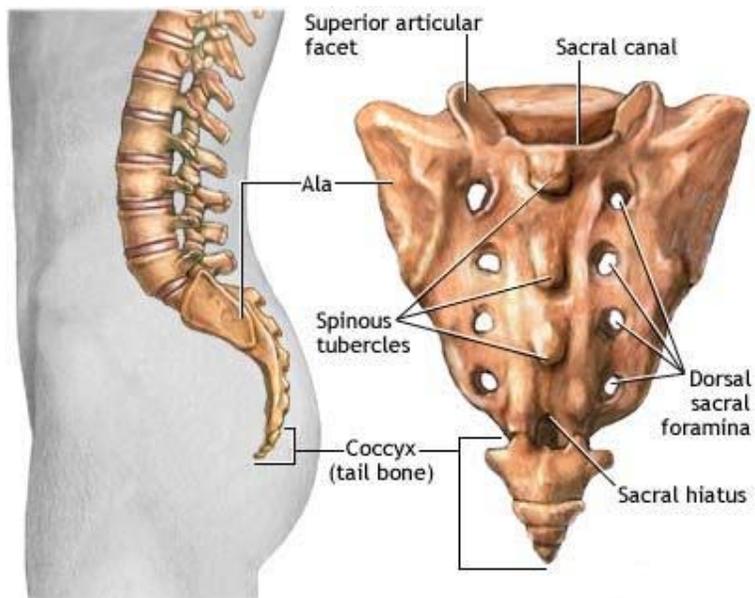
*EPIDURAL*

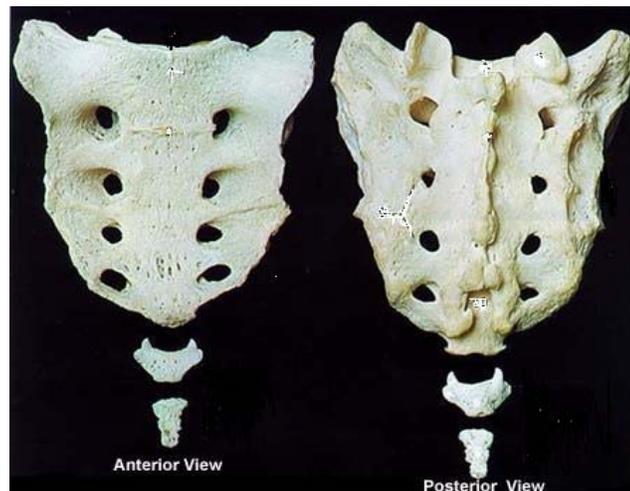
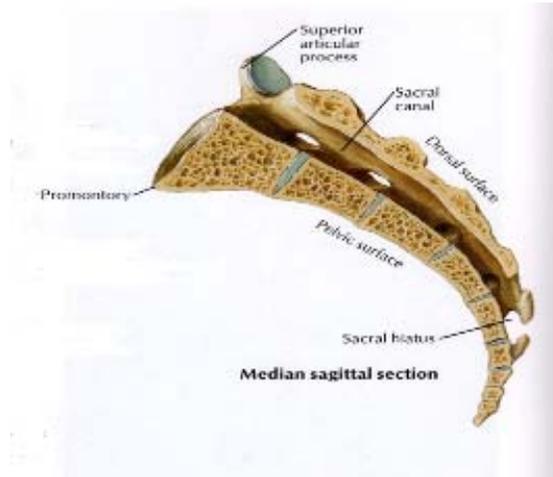
## CAUDAL EPIDURAL

Caudal anaesthesia has been used for many years and is the easiest and safest approach to the epidural space. When correctly performed there is little danger of either the spinal cord or dura being damaged.

### Anatomy

The caudal epidural space is the lowest portion of the epidural system and is entered through the sacral hiatus. The sacrum is a triangular bone that consists of the five fused sacral vertebrae (S1- S5). It articulates with the fifth lumbar vertebra and the coccyx.





### The sacral canal contains:

1. The terminal part of the dural sac, ending between S1 and S3.
2. The five sacral nerves and coccygeal nerves making up the cauda equina. The sacral epidural veins generally end at S4, but may extend throughout the canal. They are at risk from catheter or needle puncture.

3. The filum terminale - the final part of the spinal cord which does not contain nerves. This exits through the sacral hiatus and is attached to the back of the coccyx.

1. Epidural fat, the character of which changes from a loose texture in children to a more fibrous close-meshed texture in adults. It is this difference that gives rise to the predictability of caudal local anaesthetic spread in children and its unpredictability in adults. Local anaesthetic drugs injected into the extradural space may cause nerve blocks at three possible sites:(a) On the spinal nerves in the paravertebral space. This probably occurs only in young subjects.(b) On the spinal nerves intradurally. This is probably the essential site of blockade.(c) On the spinal cord.

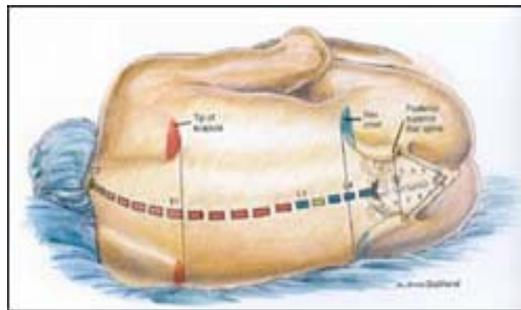
### **Contraindications**

- Infection at the site of the needle insertion.
- Coagulopathy or anti coagulation drugs .
- Pilonidal cyst
- Congenital abnormalities of the lower spine or meninges, because of the unclear or impalpable anatomy.

### **Technique.**

The procedure must be carried out with a strict aseptic technique. The skin should be thoroughly prepared and sterile gloves worn. Any infection in the caudal space is extremely serious.

### Adult caudal position



### Paediatric caudal position



There are three main approaches: the prone, the semi-prone, and the lateral. The choice depends on the preference of the anaesthetist and the degree of sedation of the patient.

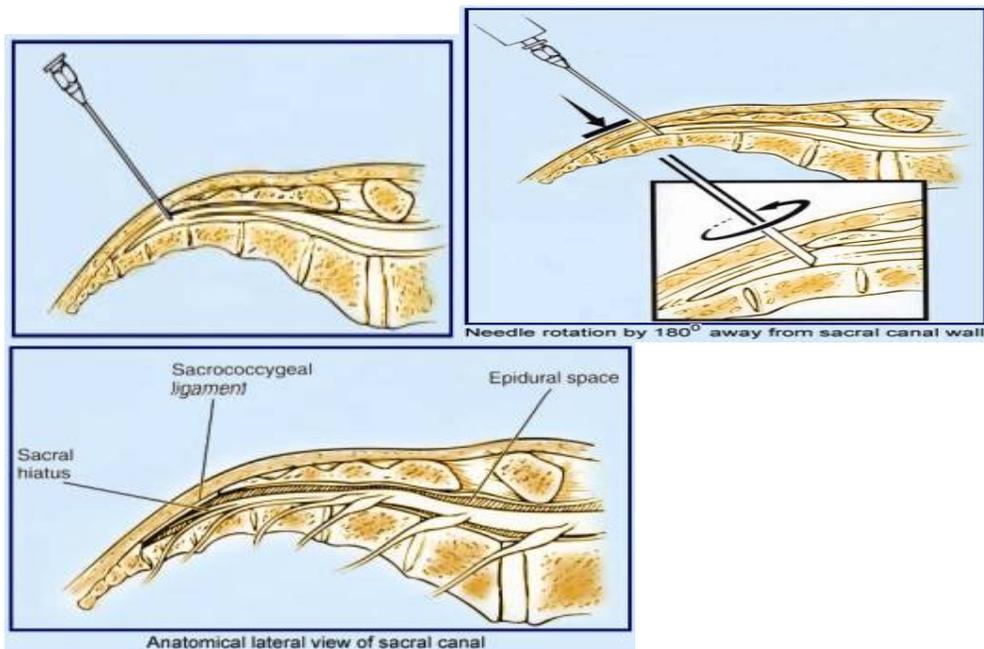
The prone position is often easiest in the adult, as fat tends to move away from the mid-line and landmarks are easier to find

The semi-prone position is preferred for the anaesthetised or heavily sedated patient as the control of airway is easier in this position, while still allowing reasonably easy access to the sacral hiatus. The lateral position is often used in children, as the landmarks are easier to find than in adults. Care should be taken to avoid over flexing the hips (as for lumbar epidurals) as this can make the landmarks more difficult to palpate.

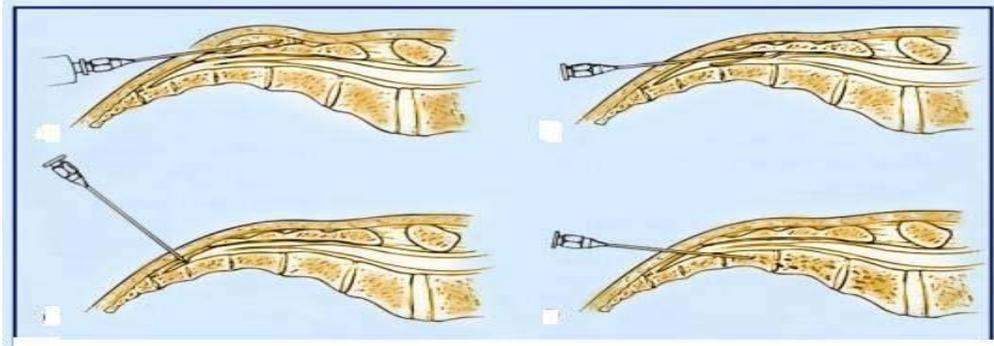
The landmarks are palpated. The sacral hiatus and the posterior superior iliac spines form an equilateral triangle pointing inferiorly.

The sacral hiatus can be located by first palpating the coccyx, and then sliding the palpating finger in a cephalad direction (towards the head) until a depression in the skin is felt. (In an adult the distance from the tip of the coccyx to the sacral hiatus is approximately the same as the distance from the tip of their index finger to their proximal inter phalangeal joint)!

### Caudal Epidural Technique & Anatomical relations



### Abnormal placements of needle during caudal block



As there can be a considerable degree of anatomical variation in this region confirmation of bony landmarks is the key to success. The needle can penetrate a number of different structures mimicking the feel of entering the sacral hiatus. It is important to establish the midline of the sacrum as considerable variability occurs in the prominence of the cornua, causing problems unless care is taken

Once the sacral hiatus is identified the area above is carefully cleaned with antiseptic solution, and a 22 gauge short bevelled cannula or needle is directed at about 45° to skin and inserted till a "click" is felt as the sacro-coccygeal ligament is pierced. The needle is then carefully directed in a cephalad direction at an angle approaching the long axis of the spinal canal.

The recommended maximum dose of Bupivacaine is 2 mg/kg with or without adrenaline or Lignocaine 4 mg/kg without adrenaline and 7 mg/kg with adrenaline. These dosages are the maximum for a correctly injected dose. If the drug is inadvertently injected intravenously even very small doses may be detrimental and cause serious toxicity.

Drugs that are commonly used include Lignocaine 1% and Bupivacaine 0.25%, although higher concentrations may be needed for muscle relaxation.

Drugs used for epidural injections should come from single use ampoules and be preservative free.

Various regimes have been produced to calculate the appropriate dose of local anaesthetic, the doses vary widely:

1. Armitage recommends bupivacaine 0.5ml/kg for a lumbosacral block, 1 ml/kg for a thoraco-lumber block, and 1.25 ml/kg for a mid thoracic block. He recommended the use of 0.25% bupivacaine for the block up to a maximum of 20 ml. For larger volumes he recommended adding one part of 0.9% NaCl to three parts local anaesthetic to produce a 0.19% mixture.
2. Scott calculates the dose from the child's age or weight). If the child is of average weight for its height both figures will be the same. If the child is overweight use the figure based on age to avoid the possibility of overdose.

Scott's lower doses are more likely to produce analgesia to the expected height, whereas Armitage will get anaesthesia. Dosages for adults are 20-30 ml for a block of the lower abdomen and 15-20 ml for a block of the lower limb and perineum <sup>15</sup>.

In my study I am using 0.25% of Bupivacaine 1ml/kg for all children undergoing sub umbilical surgeries for post operative analgesia.

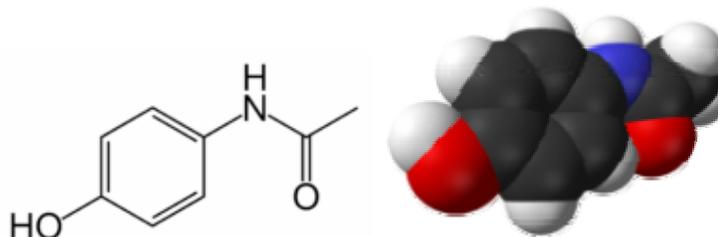


*PHARMACOLOGY*  
*OF*  
*PARACETAMOL*

## PHARMACOLOGY OF PARACETAMOL

Paracetamol is a N -acetyl -para-aminophenol derivative that exhibits analgesic and antipyretic activity. It does not possess anti-inflammatory activity.

*Structure of Paracetamol*



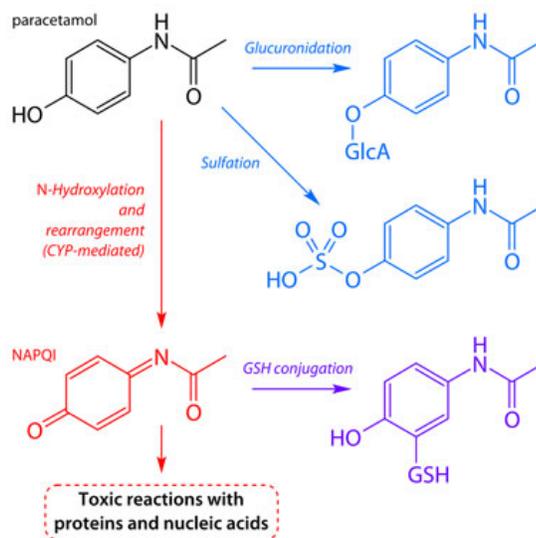
N -acetyl -para-aminophenol

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Following rectal administration peak plasma concentration occurs within 45 to 60 minutes. Paracetamol is distributed into most body tissues. Plasma protein binding is negligible at usual therapeutic doses but increases with increasing doses. The elimination half-life varies from 1 to 3 hours.

## Mechanism of action

Paracetamol may exert its analgesic effect via molecular targets distinct from COX. In the brain and spinal cord paracetamol is conjugated with arachidonic acid to form N- arachidonylphenolamine (AM 404). AM 404 is a known capsaicin receptor and the Cannabinoid CB 1 receptor system, both of which confer analgesia in the central nervous system. This pathway also account for the antipyretic effect of paracetamol and known to cause inhibition of prostaglandin synthesis in brain.

### *Metabolism of Paracetamol*



Paracetamol is metabolised extensively in the liver and excreted in the urine mainly as inactive glucuronide and sulfate conjugates. Less than 5% is excreted unchanged. The

metabolites of paracetamol include a minor hydroxylated intermediate which has hepatotoxic activity. This intermediate metabolite is detoxified by conjugation with glutathione, however, it can accumulate following paracetamol overdose (more than 150mg/kg or 10g total paracetamol ingested) and if left untreated can cause irreversible liver damage. Paracetamol is metabolised differently by premature infants, newborns, infants and young children compared to adults, the sulfate conjugate being predominant <sup>16</sup>.

#### *Adverse effects*

Side effects of paracetamol are rare and usually mild, although haematological reactions have been reported. Skin rashes and hypersensitivity reactions occur occasionally. Over dosage with paracetamol if left untreated can result in severe, sometimes fatal liver damage and very rarely, acute renal tubular necrosis <sup>17,18,19</sup>.

Paracetamol should be used with caution in patients with:

- impaired hepatic function
- impaired renal function

Rectal paracetamol suppository is easily available, can be easily administered and especially in children the rectal bioavailability is more when compared to adults 20, 21, 22 .

In my study 20 mg /kg paracetamol rectal suppository, along with caudal bupivacaine is used. It is available as 80 mg & 170 mg suppositories in the trade name of ANMOL & PANADOL .

### Rectal Paracetamol Suppository



Preservative free 0.5 % Bupivacaine vial & Ampoule



*ASSESSMENT OF  
POST  
OPERATIVE PAIN  
IN  
PAEDIATRIC  
PATIENTS*

## **ASSESSMENT OF POST OPERATIVE PAIN IN PAEDIATRIC PATIENTS.**

Pain is defined by the International Association for the Study of Pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It is now accepted that pain should be anticipated, safely and effectively controlled, in all children, whatever their age, maturity or severity of illness may be. Unfortunately the postoperative pain in pediatric patient is not adequately managed despite of it's cause for morbidity and even some reported mortality <sup>23</sup> .

Pain measurement in children is difficult, this has led to proliferation of a multiplicity of pain measurement scores for neonates, infants and children. Most scores try to assign a numerical value to one of these dimensions: namely cognitive, physiological, sensory, behavioral, and even facial expression.

The anaesthesiologist must be adequately trained and aware of the manifestations of acute pain in the various age groups and must be experienced in intervening safely, effectively and appropriately to control the pain. Assessing

pain in neonates and young children requires use of age appropriate scales. There is no empirical evidence demonstrating the superiority of one assessment tool over another, but research suggests that the same scale should be used within an institution .

In my study, **The FLACC Behavioral Scale for Postoperative Pain in YoungChildren** <sup>24</sup> is used for the assessment of post operative pain in paediatric patients undergoing subumbilical surgery.

FLACC: Face, Legs, Activity, Crying, Consolability scale has been validated from 2 months to 7 years. FLACC uses 0-10 scoring <sup>24</sup> .

<i>Parameter</i>	<b>Finding</b>	<b>Points</b>
<i>Face</i>	No particular expression or smile	<b>0</b>
	Occasional grimace or frown withdrawn disinterested	<b>1</b>
	Frequent to constant quivering chin clenched jaw	<b>2</b>
<b>Legs</b>	Normal position or relaxed	<b>0</b>
	Uneasy restless tense	<b>1</b>
	Kicking or legs drawn up	<b>2</b>
<b>Activity</b>	Lying quietly normal position moves easily	<b>0</b>

	Squirming shifting back and forth tense	1
	Arched rigid or jerking	2
<b>Cry</b>	No cry (awake or asleep)	0
	Moans or whimpers occasional complaints	1
	Crying steadily screams or sobs frequent complaints	2
<b>Consolability</b>	Content relaxed	0
	Reassured by occasional touching hugging or being talked to distractable	1
	Difficult to console or comfort	2

FLACC score = SUM(points for all 5 parameters)

**Interpretation:**

Minimum score : 0 ,      Maximum score : 10

The higher the score the more the behavior reflecting discomfort and pain. The rescue analgesic were given when the score is 4 and above.

REVIEW OF LITERATURE

Steve Golladay, Sue Hutter, Eric Koehn, Thurman Hunt, Rao Gutta et al 2003 <sup>25</sup> studied in 32 children undergoing paediatric peritonoscopy about post operative analgesic effects of rectal paracetamol 30 mg

/kg and caudal bupivacaine separately. The initial PACU score was  $4.1 \pm 3.1$  for rectal paracetamol and  $2.3 \pm 3.0$  for caudal bupivacaine block ( 0.6 ml 0.25 % )  $p=.03$ . 44% of rectal paracetamol group did not require any rescue analgesic dose, however they concluded that the caudal bupivacaine is more effective than rectal paracetamol alone. In my study I intended to study the efficacy of rectal paracetamol with caudal bupivacaine and comparing it with caudal bupivacaine alone group .

**Warth H, Astfalk W , Walz GU et al 1994** <sup>26</sup> study in 267 cases of paediatric inguinal herniorrhaphy & orchidopexy about the efficacy of rectal paracetamol 20mg/kg. Need for the rescue analgesics was significantly higher in orchidopexy group than the inguinal herniorrhaphy ( $p<.01$ ) and 75 % of inguinal herniorrhaphy patients did not require rescue analgesics. When rectal paracetamol at the dose of 20 mg /kg is equally effective than the higher doses more than 30 mg/kg. In my study I use only 20 mg/kg.

**Mummadi Sanjeeva Reddy, FFARCSI, and Pyati Srinivas, FFARCSI et al study 2002** <sup>27</sup> reported hepatotoxicity in a child,

when rectal paracetamol was used more than 175 mg/kg /day. The dose of rectal acetaminophen 175 mg/kg on the first day was larger than the suggested dosage i.e., 40 mg/kg followed by 20 mg/kg 6 hourly. But the hepatotoxicity was attributed to associated factors such as fever, fasting, and use of larger doses of thiopental and metronidazole, rather than the dose of rectal paracetamol alone. The authors referred to the Anderson et al. paper to justify this dose. This was the first reported case of therapeutic misadventure with rectal acetaminophen leading to hepatotoxicity.

**ARZU MERCAN MD, M. MURAT SAYIN MD, SIBEL SAYDAM MD et al 2006** <sup>28</sup> in their study have found that supplemental rectal paracetamol at the third hour of caudal blockade enhances the quality of postoperative analgesia better than its addition at the fourth hour in children undergoing inguinal surgery. In my study I administer rectal paracetamol immediately following caudal analgesia and the surgical procedure is started after 15 mins.

**Asma Khalid, Safia Zafar Siddiqui, Saeeda Haider and Sadqa Aftab LIII et al 2007** <sup>29</sup> 60 children, undergoing

inguinoscrotal surgeries, aged from 1 to 12 years, ASA 1 and 2, were included in the study. The patients were divided into two equal groups. The group receiving Bupivacaine with Tramadol was called 'group BT' and the group which received only Bupivacaine was labeled as 'group B'. Group BT was given 0.25%, 0.8 ml/kg Bupivacaine and Tramadol 2 mg/kg while the other group B was given 0.25%, 0.8 ml/kg Bupivacaine through caudal route. Mean duration of analgesia in **group B was 6.206 +/- 1.5 hours**. In my study instead of tramadol I use rectal paracetamol along with caudal bupivacaine, to avoid the possibility of delayed respiratory depression of opioids.

**AK Pan, A.rudra et al 2005**<sup>8</sup> studied in 100 children, undergoing unilateral inguinal herniotomy, about the post-operative analgesic effects of caudal bupivacaine 0.25% , 1 ml / kg (**B**), caudal bupivacaine with ketamine 0.5 mg/kg (**BK**), caudal bupivacaine with midazolam 50 ug/kg (**BM**) and caudal bupivacaine with ketamine 0.5 mg/kg and midazolam 50 ug/kg (**BKM**). The post operative analgesic effect of Group **BK**- 587 12± 5 mins, group **BM**-660 13± 0 mins, and group **BKM** - 1080 11± 0 mins In group **B**, where only caudal bupivacaine

administered, the post operative analgesic effect was **402± 16** mins.

**Jan Muhammed Sheik, Sikandar ali et al 2004**<sup>30</sup> studied in 176 boys aged 2-8 years, about the post operative analgesic effect and other post operative events, of single shot caudal epidural bupivacaine 0.25 % 0.75 ml /kg. Mean duration of analgesia was 10.43 hrs ± 34 mins. Mean first urine voiding time was 161.79 mins 83.2 mins. Post operative nausea and vomiting incidence was 7% and urine retention incidence was 1.4 %.

**Dipasri bhattacharya, Arnab Banerjee et al 2003**<sup>31</sup> compared the post operative analgesic effect of Rectal diclofenac ( n=50) 1 mg /kg with caudal bupivacaine ( n=50) 0.25 %, 1ml/kg in 100 children undergoing inguino scrotal surgeries. The post operative analgesic requirement on the day of surgery, was more in Rectal Diclofenac alone group. In my study I use rectal paracetamol along with caudal bupivacaine.

**Neeru gupta, renu Wakhloo et al 2008<sup>32</sup>** studied in sixty children, undergoing sub-umbilical surgeries, about the post operative analgesic effects of rectal diclofenac along with caudal bupivacaine. Group I received caudal bupivacaine 0.5 ml /kg 0.25%. Group II received rectal diclofenac 1mg/kg. Group III received caudal bupivacaine 0.5 ml/kg along with rectal diclofenac 1mg/kg. The mean post operative analgesic time was Group I - 8.2hrs  $1. \pm 3$  hrs,  
Group II -12.4  $\pm 3.4$  hrs and Group III - 13  $\pm 2.3$  hrs.

**Shahid Khan and mohammed Iqbal Menon et al 2006<sup>33</sup>** studied in sixty children of age 13-53 months, undergoing hypospadiasis repair, about the post operative analgesic effect of caudal bupivacaine with tramadol. Group A received caudal bupivacaine 0.25% 1ml /kg with tramadol 1mg/kg. Group B received only caudal bupivacaine 0.25% 1ml /kg. The mean duration of post operative analgesia in Group A was 10.4  $1. \pm 69$  hrs and in group B was 7.9 $\pm 3$  1.52 hours.

# ***METHODS***

# AND

# MATERIALS

## METHODS AND MATERIALS

The study was conducted in Chengalpattu Medical college Hospital during the period May 2009 - August 2009 .Sixty ASA I children were taken up for a Prospective randomized comparative double blind trial and were grouped into Group C (caudal bupivacaine) and Group S (caudal bupivacaine with paracetamol suppository).

### Inclusion Criteria

1. ASA I
2. Age 3- 8 years ( < 20 Kg ).
3. All subumbilical surgeries .

### Exclusion Criteria

1. Children with h/o allergic to local anaesthetics.
2. Undiagnosed diarrhea.
3. Coagulopathies.
4. Local sepsis.

5. Recent respiratory infection.
6. Abnormalities of sacrum ,vertebral column and spinal cord.
7. The Children with developmental delay.

After getting approval from the hospital ethical committee and informed consent from parents, 60 children undergoing sub umbilical surgeries, aged from 3 to 8 years weighing less than 20 Kg of either gender, ASA 1, were included in the study.

Randomization was done by draw of lots. Pre-operative evaluation included detailed history, clinical examination, investigations Hb, PCV,BT/CT, Blood grouping Rh typing & Urine alb/sugar were done. Any relevant specialist opinion and care were obtained.

Drawing of lots for randomization and preparation of study was done by a consultant who took no further part in the study . The rest of the study was conducted by me and an investigator who was blinded to the drug administered.

#### Procedure

Sixty children belong to ASA I category ,who were scheduled to undergo sub- umbilical Surgeries were randomized into two groups Group **C** and Group **S** . Parents were explained about the study and consent obtained. All the children were examined previous day of

surgery and pulse rate, blood pressure and respiratory rate were recorded.

**Fasting guide lines:**

- a] clear fluids upto 2 hours, milk
- b] semisolid upto 4 hours,
- c] formula foods upto 6 hours and
- d] solid foods upto 8 hours.

**Group C** - Control group with caudal bupivacaine 0.25 %  
1ml /kg.

**Group S** - Study group Rectal Paracetamol Suppository  
20mg/Kg with caudal Bupivacaine 0.25 % 1ml /kg.

**Premedication** ; Inj. Glycopyrrolate 10 ug/kg im 30 mins  
before Surgery.

**Monitoring** ; Parameters Monitered are

Heart Rate with Precordial stethoscope .

Pulse rate

ECG,

NIBP,

Surface temperature &

SpO<sub>2</sub> using multiparameter monitor

Surface temperature monitoring was done instead of nasopharyngeal and rectal temperature, because of face mask ventilation and use of cold suppository respectively.

**Induction & Maintenance**; Baseline parameters heart rate , pulse rate, respiratory rate, surface temperature, blood pressure and pulse oximetry were recorded after connecting to the monitor, and an intravenous line secured with 22 gauge venflon. After preoxygenation,

intravenous anaesthesia was induced with inj. Ketamine 2.5mg/kg, and inj.midazolam 0.05mg/kg iv and anaesthesia was maintained in spontaneous ventilation with 50% O<sub>2</sub> & 50% N<sub>2</sub>O with halothane 0.5%-1.0 % for first 15 mins and thereafter anaesthesia was maintained with 66.7% nitrous oxide and 33.3%oxygen, with out halothane using face mask and Jackson Ree's modification of Ayre,s T-piece circuit .

**Caudal Epidural** ; All the 60 children received caudal epidural 0.25% bupivacaine 1ml /kg in left lateral position under aseptic precautions.

Thirty Children under Group S received rectal paracetamol 20 mg/kg using lignocaine gelly in the same position , following caudal epidural.

Thirty children under Group C received only caudal epidural anaesthesia. Surgery was allowed to start after 15 mins. Postoperatively, immediately after surgery, patients were sent to recovery room and mother was allowed to be with the child, to give tender loving care and all the postoperative parameters were monitored in the recovery room. Children were given oral feeds after 2 hours of surgery .

**Parameters Monitored**

1. Pre induction HR, SpO<sub>2</sub>, RR, ECG, BP and Surface Temperature.
2. Post induction HR, SpO<sub>2</sub>, RR, ECG, BP and Surface Temperature
3. Intraoperatively continuous monitoring of HR, RR, ECG, SpO<sub>2</sub>, BP and Surface Temperature was done and recorded every 5 mins till the surgery is completed. Postoperatively, all the above parameters were monitored and recorded every 15 mins for first 2 hours and thereafter every 30 mins upto 10 hours. Blood pressure was not recorded after 2 hours as repeated inflation and deflation of BP cuff may interfere the pain assessment scale. The other parameters were monitored using pulse oximeter probe without much disturbing child.
4. Postoperatively assessment of pain was done using FLACC pain scale and the scoring monitored in all children postoperatively every 15 mins for first 2 hours and every 30 mins upto 10 hours and corresponding HR, RR, and Aldrete recovery score, were monitored at same time intervals. For study purpose the HR, RR, FLACC score & Aldrete recovery

score were specifically recorded at 2.30, 3.00, 3.30, 4.00, 4.30, 5.00, 5.30, 6.00, 6.30 & 7.00 hours and compared in both groups

5. According to **pain scoring, rescue analgesics** were given when pain score is more than three in FLACC pain scale, the time at which the rescue analgesic given is recorded and that was considered as the effective postoperative analgesic period.
6. Presence of nausea and vomiting noted down.

0- No post operative nausea and vomiting,

1- PONV that disappeared spontaneously with no need for treatment,

2-PONV that disappeared with treatment,

3-PONV that does not disappear despite medical treatment.

Modified Aldrete recovery score assessed in both groups

Parameter	Finding	Points
<b>Colour &amp; Oxygenation</b>	SpO <sub>2</sub> <90% on Oxygen	<b>0</b>
	SpO <sub>2</sub> >90% on Oxygen	<b>1</b>
	SpO <sub>2</sub> >90% on room air	<b>2</b>
<b>Respiration</b>	Apnea	<b>0</b>
	Dyspneic, shallow or limited breathing	<b>1</b>
	Breathes deeply coughs freely	<b>2</b>
<b>Circulation</b>	Blood pressure more than $\pm 50$ mm of Hg of normal	<b>0</b>

	Blood pressure $\pm$ 20-50 mm of Hg of normal	1
	Blood pressure $\pm$ 20 mm of Hg of normal	2
<b>Consciousness</b>	Not responsive	0
	Arousable on calling	1
	Fully awake	2
<b>Activity</b>	No Movement	0
	Moves two extremities	1
	Moves all extremities	2

8. Surface Temperature monitoring done both post operatively and any rise in temperature above 100<sup>0</sup> F is noted .
9. First Urine voiding time is noted post operatively

# ***OBSERVATION &***

## ***RESULTS***

### **OBSERVATION AND RESULTS**

The study constituted of sixty children undergoing sub-umbilical surgeries. They were evaluated for post operative pain score using FLACC scale rescue analgesic time, the modified aldrete recovery score, rise in temperature, post operative nausea and vomiting, first post

operative urine voiding time were compared between Group S (rectal paracetamol with caudal bupivacaine) and Group C (caudal bupivacaine alone).

The Mean Rescue Analgesic time in the Group S is  $353 \pm 6.0$  mins and in the control Group C is  $253 \pm 3.9$  mins, ( $p < 0.0001$ ,  $t$  value 13.9). There is significant increase in the post operative analgesia time and quality and there is less pain score in the study Group S when compared to the control Group C. The incidence of fever and post operative nausea and vomiting is higher in the control group C. Most of the children voided urine within 6-7 hours. There was no need for catheterization and no incidence of retention of urine in any of the children.

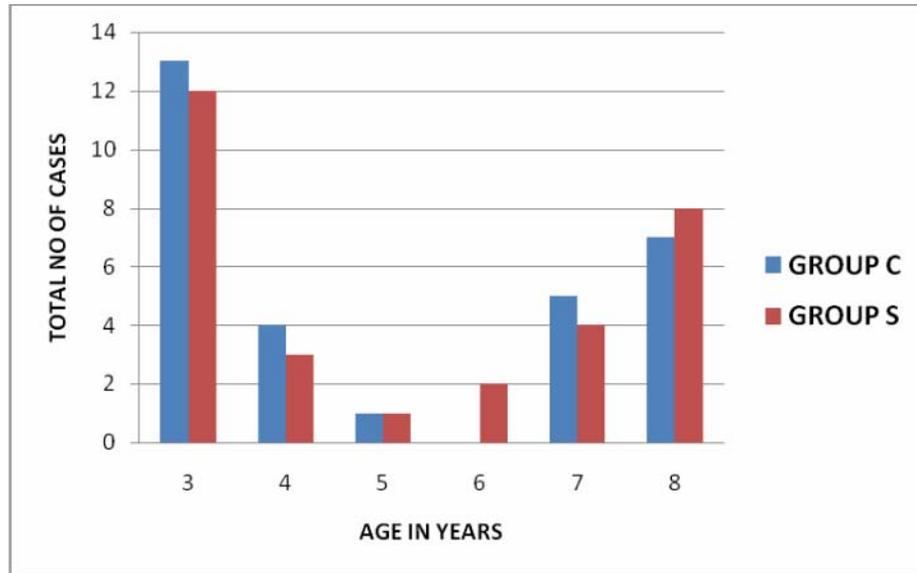
The variables age, weight, Pain scores, rescue analgesic time, heart rate, respiratory rate, the modified adrete recovery score and urine voiding time were analysed using Levene's test for equality of variances and t-test for equality of means. The distribution of sex and the incidence of fever and postoperative nausea and vomiting were analysed using Chi-square test.

#### **MEAN AGE IN BOTH GROUPS C & S**

The age groups in both the Group C & S were found to be statistically comparable by Independent samples test. The Mean  $\pm$  St d of Age in Study and Control groups are  **$5.2 \pm 2.2$  years** and  **$5.0 \pm 2.2$  years** respectively which is not statistically significant ( $t=0.36$ ,  $p>0.05$ ).

**DISTRIBUTION OF CASES IN DIFFERENT AGE GROUPS IN BOTH GROUPS**

**Age Distribution**

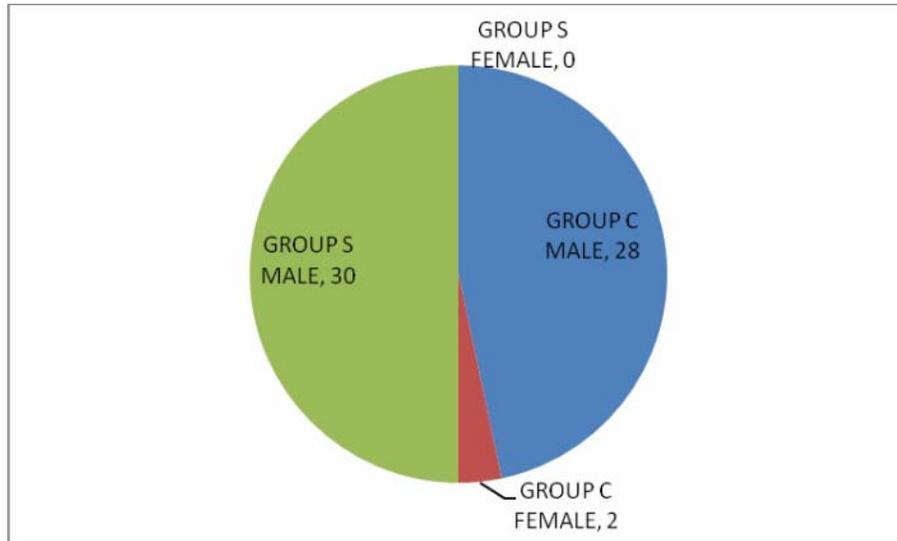


GROUPS	GROUP C	GROUP S	P Value
MEAN AGE	5.0 ± 2.2 Yrs	5.2 ± 2.2 Yrs	t=0.36, p>0.05

The distribution of cases in all ages in both groups C & S were statistically comparable.

**Comparison of Distribution of sex in Group C & S**

**Sex distribution in study and control groups**



SEX	Study	Control
Male	100.00%	93.30%
Female	0.00%	6.70%

### Mean Weight in both Rectal Paracetamol ( Group S) &

### Caudal Bupivacaine( Group C)

The weight distribution in both the Group C & S were found to be statistically comparable by Independent samples test. The rectal paracetamol group had mean weight of 15.7 +/- 3.3 kg and the caudal bupivacaine group had mean weight of 15.8 +/- 3.8 kg which is not statistically significant . The p value > 0.05 . It shows that the study and control groups are comparable before the intervention. The distribution of all cases in each weight groups in the rectal paracetamol and caudal

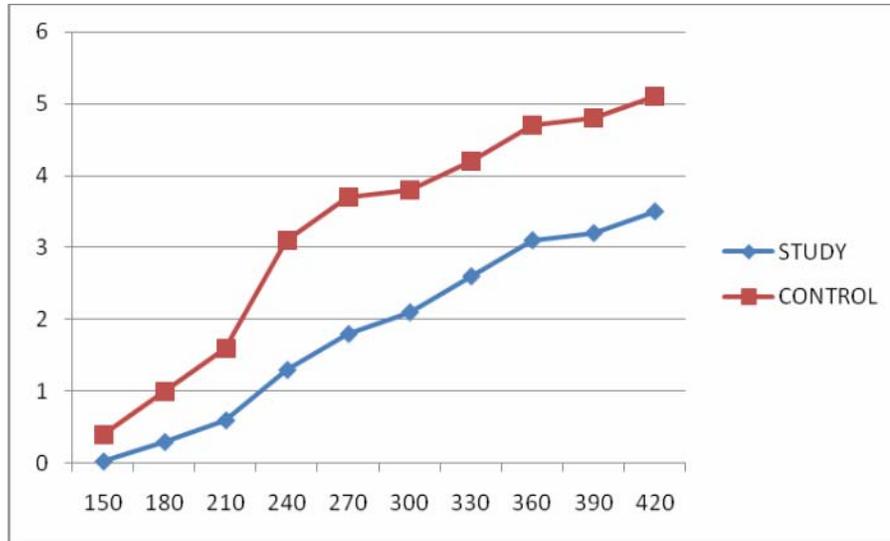
bupivacaine group is comparable and in all weight groups there is significant increase in rescue analgesic time in rectal paracetamol group.

	10-12 KG		13-15 KG		16-18 KG		19-20 KG	
	GROUP C	GROUP S						
NO.OF CASES	9	7	6	8	5	6	10	9
MEAN RESCUE ANALGESIA TIME (hrs )	4.30	5.47	4.25	5.45	4.06	5.55	4.06	6.10

**Comparison of FLACC Pain scores In both the Rectal Paracetamol Group S & Caudal Bupivacaine Group C**

Post operative pain was assessed in both groups C & S using FLACC pain scale and compared in both groups .

**FLACC PAIN SCORE AT DIFFERENT POST OPERATIVE TIME INTERVALS**



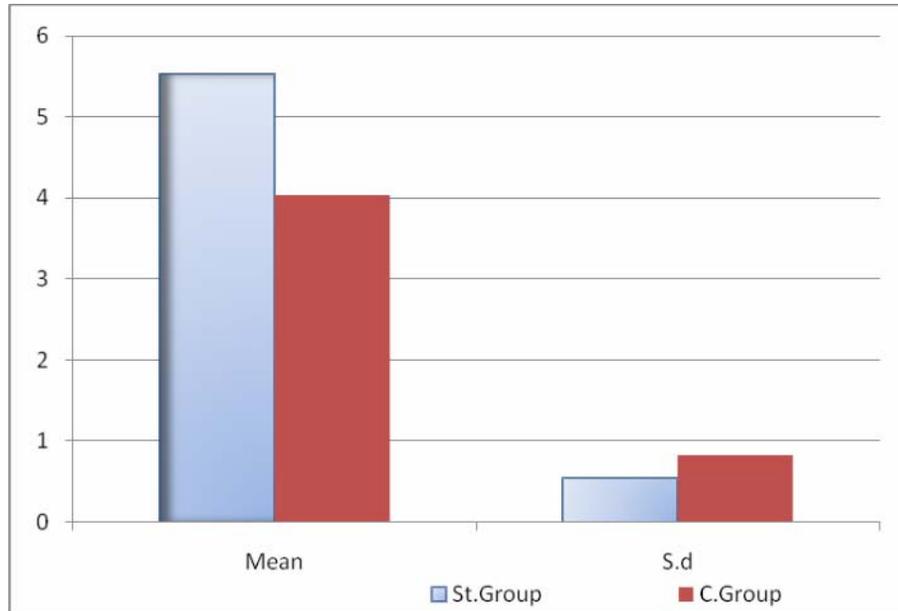
**Time in Mins**

Minimum pain score ; 0 , Maximum pain score ; 10

Five criterias **F**acial expression , **L**egs position, **A**ctivity, **C**ry and **C**onsolability were considered and each criteria was given 0,1,& 2 scores for absent , moderate and severe response to pain , respectively.

At all post operative intervals the pain score is significantly low in the study group S ( rectal paracetamol ) than in the control group C. The quality of post operative analgesia is better in the study Group S than in the control Group C. There are many other pain scoring scales like Modified observational pain score, CHEOPS pain score, Visual analog scale etc., but in my study FLACC score is more appropriate for age group 3-8 yrs.

**Mean & Standard deviation of Rescue Analgesic time in Hours  
in both Groups**



**MEAN ± STANDARD DEVIATION (MINIMUM, MAXIMUM) OF  
RESCUE ANALGESIC TIME in minutes ( R A Time)**

Time	Mean ± Std (Max, Min)	p value (t-value)
STUDY	353± 6.0 (300, 420)	<0.0001 (13.9)
CONTROL	253 ± 3.9 (210,285)	

There is a highly significant difference between the study group and control group on mean R.A.Time (t=13.9, p <0.0001).

## WEIGHT DISTRIBUTION AND RESCUE ANALGESIC TIME

	10-12 KG		13-15 KG		16-18 KG		19-20 KG	
	GROUP	GROUP	GROUP	GROUP	GROUP	GROUP	GROUP	GROUP
	C	S	C	S	C	S	C	S
NO.OF CASES	9	7	6	8	5	6	10	9
MEAN RESCUE ANALGESIA TIME (hrs )	4.30	5.47	4.25	5.45	4.06	5.55	4.06	6.10

The Rescue analgesic time is is prolonged in 10-12 kg group by 1 hour 17 mins, 13-15 kg group by 1 hour 20 mins in rectal paracetamol group when compared to control group.

The Rescue analgesic time is is prolonged in 16-18 kg group by 1 hour 49 mins, 18-20 kg group by 2 hour 4 mins in rectal paracetamol group when compared to control group.

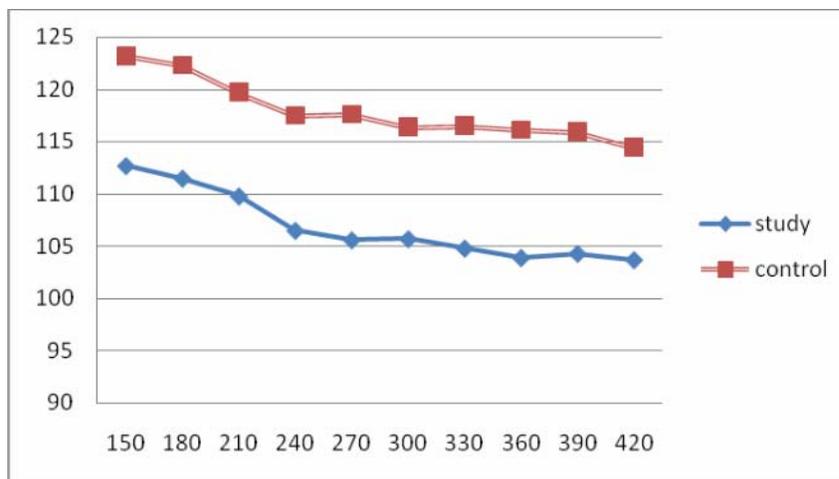
**Distribution of cases and Mean Rescue analgesic time and in both Rectal Paracetamol Group S and only Caudal bupivacaine Group C .**

	<b>GROUP C</b>			<b>GROUP S</b>	
	<b>Circumcision</b>	<b>Herniotomy</b>	<b>Rectal Polyp</b>	<b>Circumcision</b>	<b>Herniotomy</b>
<b>Total</b>	<b>14</b>	<b>13</b>	<b>3</b>	<b>20</b>	<b>10</b>
<b>Percentage</b>	<b>46.6%</b>	<b>43.3%</b>	<b>10.0%</b>	<b>63.3%</b>	<b>36.6%</b>
<b>Mean R.A.Time</b>	<b>4 hr 18 mins</b>	<b>4 hr 2 mins</b>	<b>4 hr 30 mins</b>	<b>6 hr 2mins</b>	<b>5 hr 42 mins</b>

The Mean rescue analgesic time is prolonged significantly in Group S (rectal paracetamol) both for circumcision and herniotomy when compared to control group C. The mean rescue analgesic time is prolonged 16 mins in group C & 20 mins in group S for circumcision cases when compared to herniotomy cases Rectal polyp belonged to control group and the mean rescue analgesic time is prolonged by 28 mins than herniotomy.

**Comparison of Heart rate and Respiratory rate at different post operative intervals in both Rectal paracetamol( group S) and Caudal bupivacaine ( Group C).**

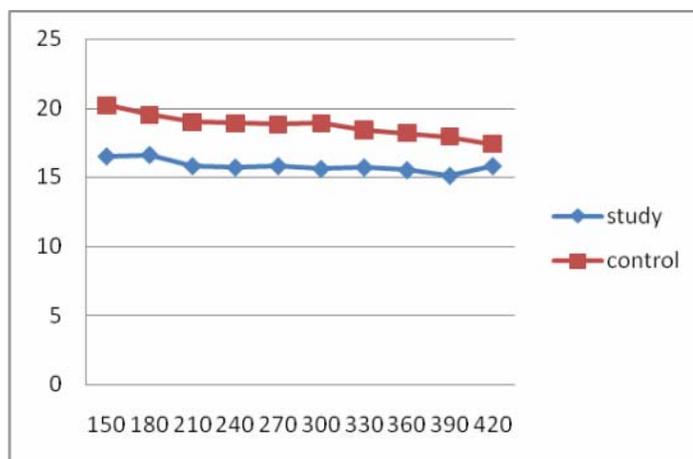
**DISTRIBUTION OF HR AT DIFFERENT INTERVAL OF TIME**



**Time in Mins**

Time in Mins	Group S	Group C
150	112.7	123.2
180	111.5	122.3
210	109.8	119.7
240	106.5	117.5
270	105.6	117.6
300	105.7	116.4
330	104.8	116.5
360	103.9	116.1
390	104.3	115.9
420	103.7	114.4

## DISTRIBUTION OF REPIRATORY RATE AT DIFFERENT INTERVAL OF TIME



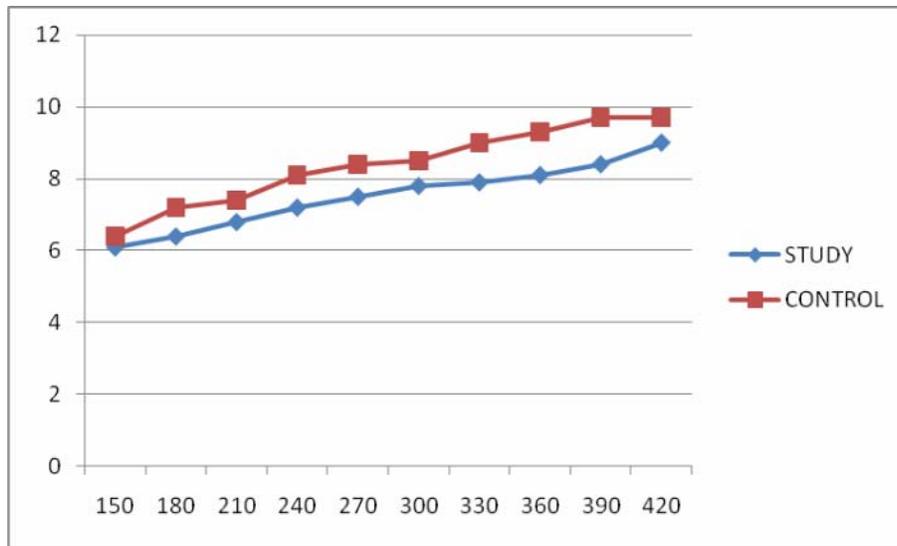
Time in mins

Time in Mins	Group S	Group C
150	16.5	20.2
180	16.6	19.5
210	15.8	19
240	15.7	18.9
270	15.8	18.8
300	15.6	18.9
330	15.7	18.4
360	15.5	18.2
390	15.1	17.9
420	15.8	17.4

There is significant difference in Heart rate and Respiratory Rate in both the Rectal paracetamol group S and Caudal bupivacaine group C. Both heart rate and respiratory rate is significantly low in rectal paracetamol group than the caudal bupivacaine group at all post operative time intervals which reflects

that the **quality of post operative analgesia is better in the rectal paracetamol group S.**

**ALDRETE RECOVERY SCORE AT DIFFERENT POST OPERATIVE TIME INTERVALS**



Time in mins

**At all time intervals the aldrete recovery score is higher but it is not statistically significant in the Control group C than the Rectal suppository group S**

Time in mins	Group S	Group C
150	6.1	6.4
180	6.4	7.2
210	6.8	7.4
240	7.2	8.1
270	7.5	8.4

300	7.8	8.5
330	7.9	9
360	8.1	9.3
390	8.4	9.7
420	9	9.7

**INCIDENCE OF POST OPERATIVE COMPLICATIONS IN  
BOTH GROUP C&S**

**POST OPERATIVE COMPLICATIONS**

Group	PONV	Rise in TEMPERATURE	FIRST URINE VOIDING TIME	SIGNIFICANCE FOR FIRST URINE VOIDING TIME
CONTROL	11	5	4.48 MIN	P < 0.05
STUDY	0	0	5.42 MIN	

The incidence of post operative nausea and vomiting and rise in temperature is significantly more in Control group than the Rectal paracetamol group.

First post operative Urine voiding time in study and control groups are  $5.42\pm 0.54$  and  $4.48\pm 0.36$  hours respectively which is statistically significant ( $t=4.48$ ,  $p < 0.0001$ ).

## **RESULTS**

1. The Comparison of Mean Rescue analgesic time in Rectal Paracetamol group **S** and the Caudal bupivacaine group **C**, were statistically significant at 2.30 , 3.00, 3.30, 4.30, 5.00, 5.30 , 6.00, 6.30 & 7.00 hrs of post operative time intervals and is significantly higher in rectal paracetamol **Group S** than the caudal bupivacaine only **Group C** .
2. The Comparison of Mean FLACC Pain score in both **Groups S & C** , were statistically significant at 2.30, 3.00, 3.30, 4.30, 5.00, 5.30 , 6.00, 6.30, & 7.00 hrs of post operative intervals and is significantly

lower in Rectal paracetamol group **S** than the caudal bupivacaine only group **C**.

3. The Comparison of Heart rate & Respiratory Rate in both **Groups S & C**, were statistically significant at 2.30, 3.00, 3.30, 4.30, 5.00, 5.30, 6.00, 6.30, & 7.00 hrs of post operative intervals and is significantly lower in the Rectal paracetamol group **S** than the caudal bupivacaine only group **C**.
4. The Aldrete recovery score is significantly lower in Rectal paracetamol group **S** than the caudal bupivacaine only group **C** **but it is not statistically significant.**
5. The incidence of PONV & Rise in temperature is significantly lower in the Rectal paracetamol group **S** than the caudal bupivacaine only group **C**.
6. The first urine voiding time post operatively is significantly prolonged in Rectal paracetamol group **S** than the Caudal bupivacaine only group **C**.



# **DISCUSSION**

## **DISCUSSION**

The present study was designed to evaluate the effectiveness of rectal paracetamol suppository along with caudal bupivacaine in paediatric sub umbilical surgeries. A total of sixty patients were randomized into two groups S & C of 30 each.

Group C received only caudal bupivacaine and group S received rectal paracetamol suppository 20 mg / kg along with caudal bupivacaine 0.25% 1ml /kg . Both the groups were monitored for FLACC pain scale.

Rescue analgesic time ,HR , RR, SpO<sub>2</sub>, Sedation score , Aldrete recovery score , Incidence of PONV, Rise in temperature, and First urine voiding time were also monitored.

The FLACC pain score is significantly low in the rectal paracetamol group S than the control group C indicating that the quality of postoperative analgesia is better in the rectal paracetamol group when compared to control group C where only caudal bupivacaine is used .

The mean rescue analgesic time in rectal paracetamol group S is significantly prolonged. Period of analgesia in Group S (353 mins  $\pm$  6.0 ) & Group C (253 mins  $\pm$  3.9) with P value < 0.0001 & t value 13.9.

According to **Bertolini A, Ferri.A et al** <sup>16</sup> it has been demonstrated that paracetamol may exert its analgesic effect via molecular targets distinct from COX. In the brain and spinal cord paracetamol is conjugated with arachidonic acid to form N- arachidonylphenolamine (AM 404). **AM 404** is a known capsaicin receptor and the **Cannabinoid CB 1** receptor system, both of which confer analgesia in the central nervous system. This pathway also account for the antipyretic effect of paracetamol and known to cause inhibition of prostaglandin synthesis in brain.

**Steve golladay, Sue hutter et al** <sup>25</sup> used either rectal paracetamol 30 mg /kg or caudal bupivacaine alone in 32 children undergoing peritonioscopy and found that 54 % children in the rectal paracetamol group did not require any further analgesia in 24 hours of post -op period. This confirms the effectiveness of post operative analgesia of paracetamol when used alone.

In our study the rectal paracetamol when combined with caudal bupivacaine as in group **S** , the quality and duration of post operative analgesia is enhanced . Caudal bupivacaine takes care of

immediate post operative pain relief and the rectal paracetamol take care of late post operative period . Paracetamol is known for its safety in paediatric patients . Following rectal administration of suppository the therapeutic levels of 10 ug /dl is achieved within 1-2 hours with a rectal bioavailability of 75-99%. In therapeutic doses the incidence of liver cell failure is only (1:5,00,000). The only other contra indication is, known hypersensitive reactions to Paracetamol, which is very rare.

**Neeru Gupta & Anjali Mehtha et al** <sup>31</sup>, found in their study that the duration of post operative analgesia with caudal

bupivacaine 0.25% only, was 8.2 hours and **AR Wolf, Hughes D, Wade A et al** <sup>36</sup> study revealed 7 hours of post operative analgesia.

In our study , the caudal bupivacaine group C had post operative analgesia upto 4hs 13 mins. This was lesser than the above study and this could be due to differences in surgery performed method of

assessing pain score, bupivacaine dose and volume, & calculation of analgesia time.

**FLACC** pain scale at all post operative intervals were lesser in Rectal paracetamol group **S** than the Caudal bupivacaine group **C**.

The mean & standard deviation of **FLACC score**. The **Rescue analgesic time** is is prolonged in 10-12 kg group by 1 hour 17 mins, 13-15 kg group by 1 hour 20 mins in rectal paracetamol group when compared to control group. The Rescue analgesic time is is prolonged in 16-18 kg group by 1 hour 49 mins, 18-20 kg group by 2 hour 4 mins in Rectal paracetamol **Group S** when compared to Control **Group C**.

In the older children under our study weighing **16-20 kg** had higher post operative analgesia in Rectal paracetamol **Group S** **35 -45** mins than the children weighing **10-15 kg** in the same group. This can be explained by the better pain tolerance in the older children and effectiveness of the reassurance by the parents according to **Goddard, pickup SE et al** <sup>35</sup>.

The Mean First Rescue analgesic time in our study is prolonged in both groups in children ,who underwent circumcision than the children with herniotomy. In **Group S** by **20 mins** & in **Group C** by **18 mins**. This is mainly because in our study we sare using 1ml/kg of 0.25% bupivacaine for caudal analgesia, whereas for a block upto **L1-L2** for circumcision , only 0.5 ml is required according to **Armitage** <sup>14</sup>.

At all post operative time intervals, there is **10- 11%** increase in the Heart rate, in the control group C, than the Rectal paracetamol group S in our study. According to study conducted by **Mauniksela Eeva et al** <sup>37</sup> there was 20% increase in heart rate. There is 20-25 % increase in respiratory rate in control group C than Group S which is consistent with the above **Maunksela Eeva et al** <sup>37</sup> study .

The Aldrete recovery score is comparatively higher in the caudal bupivacaine group C but not statistically significant and probably due to less analgesia, in this group the child feeling pain recovers faster.

The incidence of post operative nausea and vomiting is 33% in Group C & 0% in Group S, when compared to 7% of **Jan Muhammad Shaik & Sikander ali Mughal et al** <sup>30</sup> study, where 143 were given only caudal bupivacaine . The incidence of rise in temperature was 16.6 % in Group C and 0% in Group S.

In my study the mean first urine voiding time is significantly prolonged in Group S ( 5hr 42min ) than the Group C( 4hr 48min ) and P value is <0.05. according to **Jan Muhammad Shaik & Sikander ali Mughal et al**<sup>30</sup> study, the time to micturition following caudal bupivacaine is  $161.79 \pm 83.9$  mins and on an average the child passed urine in 6-8 hours. In my study there is no retention of urine and no need for catheterization in either groups

The lesser number of patients in the study and lack of follow up to evaluate complaints in subsequent post operative days, were few of the drawbacks in this study.

# **CONCLUSION**

## CONCLUSION

I conclude from the above study that the addition of paracetamol suppository to caudal bupivacaine enhances the quality and extends the duration of post operative analgesia better than the caudal bupivacaine alone in paediatric patients undergoing subumbilical surgeries , in fulfilling the criteria's mentioned in the aim of study.

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# *APPENDIX*

**APPENDIX**

**RECTAL PARACETAMOL STUDY - PROFORMA**

**Name:**

**Age:**

**Sex:**

**Height:**

**Weight:**

**ASA:**

**Clinical Diagnosis:**

**Surgery:**

**Group:**





## ABBREVIATIONS USED IN MASTER CHART

1.**Ht** - Height,

2.**Wt** - Weight,

3.**IP.No** – Inpatient Number,

4.**M**- Male,

5.**F** - Female,

6.**HR**- Heart Rate,

7.**RR** - Respiratory Rate,

8.**Aldrete**- Modified Aldrete recovery score,

9.**FLACC**- FLACC Behavioural Pain scale,

10.**Temp**- Temperature,

11.**PONV**- Postoperative Nausea & Vomiting,

12.**Urine Void Time**- First postoperative urine voiding time,

13.**Rescue Analges Time**- First Rescue Analgesic Time.

14. **Group C**- Control group where only caudal bupivacaine is used.

15.**Group S** - Study group where rectal paracetamol suppository in

addition to caudal bupivacaine is used.



*MASTER*

*CHART*

*GROUP C*

S.No.	Name& Surgery	Age	Sex	T.No.	HT cm	WT Kg	2.30 Hrs				3.00 Hrs				3.30 Hrs				4.00 Hrs				4.30 Hrs				5.00 Hrs				5.30 Hrs				6.00 Hrs				6.30 Hrs				7.00 Hrs				Temp	PON V	R.A Time	Urine void.time
							HR	RR	AL DR E	FLA CC	HR	RR	AL DR E	FLA CC	HR	RR	AL DR E	FLA CC	HR	RR	AL DR E	FLA CC	HR	RR	AL DR E	FLA CC	HR	RR	AL DR E	FLA CC	HR	RR	AL DR E	FLA CC	HR	RR	AL DR E	FLA CC	HR	RR	AL DR E	FLA CC								
C1	MOHANBABU CIRCUMCISION	4	M	8694	95	15	140	22	7	2	142	24	7	2	134	20	8	3	128	21	8	4	130	20	9	4	124	21	9	5	124	20	9	5	126	19	9	5	128	18	9	5	128	19	10	5	Normal	0	3.30	3.45
C2	THIRARTHY L)HERNIOTOMY	7	M	10369	116	20	120	24	7	1	116	22	7	1	114	20	8	1	114	20	9	3	116	20	9	3	118	20	9	4	120	20	9	4	122	20	9	4	122	20	10	4	120	22	10	5	Normal	0	3.40	4.30
C3	LOKESH LOGANATHAN REGAL POLYP	3	M	11297	90	12	108	22	6	0	114	18	7	1	114	18	7	1	114	18	8	3	112	18	8	4	112	18	9	3	108	20	9	4	106	22	9	4	104	20	10	4	104	24	10	5	Normal	1	4.30	5.00
C4	HEMANATHAN REGAL POLYP	3	M	11301	100	16	128	26	6	0	126	26	7	1	126	27	8	1	126	28	8	2	124	24	8	3	122	24	9	3	122	22	9	4	122	22	9	4	122	20	9	4	120	18	10	4	Normal	0	4.30	5.30
C5	ABID FARHAM CIRCUMCISION	3	M	1432	92	14	130	24	6	1	128	24	7	1	126	26	7	2	126	24	8	4	124	26	8	4	124	24	8	4	126	22	9	5	122	24	9	5	122	24	9	5	126	24	10	6	Normal	0	4.00	4.30
C6	AKASHKUMAR L) HERNIOTOMY	4	M	1452	100	15	104	26	6	1	102	24	6	2	102	22	7	2	100	22	8	4	98	22	8	4	98	20	8	4	98	22	9	4	96	22	9	5	94	20	9	5	94	20	10	6	Normal	1	3.45	4.00
C7	MAHESH L) HERNIOTOMY	4	M	12147	98	16	118	26	7	1	118	24	7	2	114	24	7	2	110	24	8	3	112	24	8	4	112	22	8	4	110	22	9	4	110	20	9	5	108	20	10	5	106	20	10	5	Normal	0	4.00	4.30
C8	AKASH L) HERNIOTOMY	7	M	1458	126	18	120	18	7	0	122	18	8	1	120	18	8	2	118	16	9	4	118	1	9	4	116	16	9	4	116	16	9	4	115	15	10	5	117	16	10	5	118	16	10	5	Normal	1	4.00	4.30
C9	SURESH BABU L) HERNIOTOMY	8	M	19629	124	20	126	18	7	1	128	16	7	1	120	16	8	2	118	16	9	4	118	16	9	5	116	16	9	5	115	15	9	6	117	15	10	7	114	14	10	7	114	14	10	7	Normal	0	3.45	4.00
C10	VEDAVARSHINI L) HERNIOTOMY	7	F	19641	126	20	120	22	7	0	118	22	7	1	122	18	8	1	116	18	8	2	114	20	9	3	114	20	9	3	114	20	9	3	114	18	9	4	114	18	10	4	114	17	10	5	Normal	1	4.30	5.00
C11	MANIKANDAN CIRCUMCISION	8	M	14783	126	20	104	18	6	0	102	16	7	1	98	16	7	2	98	14	8	3	102	16	8	3	104	16	9	4	105	18	9	4	106	1	10	4	104	16	10	5	98	14	10	5	Normal	0	4.30	6.00
C12	KARTHIK CIRCUMCISION	3	M	14745	96	12	126	18	7	0	124	16	7	1	124	16	8	2	118	18	8	3	118	17	9	4	118	16	9	4	120	16	10	4	122	16	10	5	122	16	10	5	110	14	10	5	Normal	1	4.30	5.30
C13	BHARATH CIRCUMCISION	3	M	14772	98	12	140	22	5	0	136	20	6	1	128	18	6	2	124	18	7	3	120	18	7	3	122	18	7	4	122	17	8	4	120	18	8	4	120	17	8	5	118	18	9	5	101°F	1	4.00	5.00
C14	RUSEETH L) HERNIOTOMY	4	M	16702	106	12	126	22	6	0	120	24	6	1	123	22	7	1	118	20	8	2	126	18	8	4	118	22	8	4	118	22	9	4	120	20	9	5	122	22	10	5	120	20	10	5	101°F	1	4.30	5.30
C15	ARUNACHALAM L) HERNIOTOMY	8	M	17630	120	20	124	14	6	0	124	14	6	0	122	15	7	1	124	14	8	3	126	15	8	3	124	18	8	3	122	14	9	4	120	14	9	4	120	15	10	4	118	14	10	5	Normal	0	4.00	5.00

S.No.	Name & surgery	Age	Sex	IP.No.	HT cm	WT Kg	2.30 Hrs				3.00 Hrs				3.30 Hrs				4.00 Hrs				4.30 Hrs				5.00 Hrs				5.30 Hrs				6.00 Hrs				6.30 Hrs				7.00 Hrs				Temp	PO NV	Urine Voiding TIME	RA Time
							HR	RR	AL DR E	FLA CC																																								
C16	NAVEEN CIRCUMCISION	3	M	19632	94	10	128	16	6	0	126	18	18	1	120	20	7	1	120	20	7	2	122	22	8	3	118	20	8	3	118	19	8	4	118	22	9	4	116	20	9	4	118	20	10	5	101°F	0	5.30	4.30
C17	VARUN RECTAL POLYP	5	M	18624	106	15	120	16	6	0	118	18	7	0	116	15	7	1	114	16	8	3	108	18	9	4	106	16	9	4	108	17	9	4	104	15	10	5	106	16	10	4	105	15	10	4	Normal	1	6.00	4.30
C18	ELANGO CIRCUMCISION	8	M	19633	122	20	120	20	6	0	120	18	7	1	118	18	7	2	116	18	8	4	116	18	8	4	114	18	8	4	114	19	9	4	114	18	9	5	112	16	10	5	114	14	10	5	Normal	0	5.00	4.30
C19	YOKESH RAJ CIRCUMCISION	3	M	19656	98	12	132	20	6	0	132	22	7	0	28	18	8	1	126	18	8	2	126	18	8	3	124	16	9	3	124	16	9	4	124	16	10	4	124	16	10	5	120	16	10	5	101°F	0	5.00	4.30
C20	ASHARAJ CIRCUMCISION	3	M	20696	92	11	128	16	6	0	126	18	6	1	120	20	7	1	120	20	7	2	122	22	8	3	118	20	8	3	118	19	8	4	118	22	9	4	116	20	9	4	118	20	10	5	Normal	0	5.45	4.45
C21	VINOTH CIRCUMCISION	8	M	20695	124	20	120	20	6	0	120	18	7	1	118	18	7	2	116	18	8	4	116	16	8	4	116	18	8	4	114	17	9	4	114	18	9	5	112	16	10	5	114	14	10	5	Normal	0	4.45	4.30
C22	SNEHA L1) HERNIOTOMY	7	M	21712	126	18	120	18	7	0	120	18	8	1	120	18	8	2	118	16	9	4	118	18	9	4	116	16	9	4	116	16	9	4	115	15	10	5	117	16	10	5	118	1	10	5	101°F	1	5.00	4.00
C23	DINESH CIRCUMCISION	8	M	22620	128	20	120	24	7	1	118	22	7	1	114	20	8	1	114	20	9	3	116	20	9	3	118	20	9	4	120	20	9	4	122	20	9	4	122	20	10	4	122	20	10	5	Normal	0	4.30	3.45
C24	VASANTH CIRCUMCISION	3	M	23506	98	12	126	18	7	0	124	16	7	1	124	16	8	2	118	18	8	3	118	17	9	4	118	16	9	4	120	16	10	4	122	16	10	5	122	16	10	5	110	14	10	5	Normal	1	5.15	4.30
C25	RAMESH CIRCUMCISION	3	M	23506	94	12	130	17	7	0	132	18	7	1	128	16	8	2	120	17	8	3	120	17	8	3	119	17	9	4	122	17	10	4	122	16	10	5	126	17	10	6	118	14	10	4	Normal	0	5.30	4.45
C26	KISHORE L1) HERNIOTOMY	3	M	23520	100	16	118	26	7	1	118	24	7	2	114	24	7	2	110	24	8	3	112	24	8	4	112	24	8	4	110	22	9	4	110	20	9	5	108	20	10	5	106	20	10	5	Normal	0	4.30	4.00
C27	GIRIDHARAN L1) HERNIOTOMY	3	M	29431	96	13	120	16	6	0	118	16	7	0	116	15	7	1	114	18	8	3	108	18	9	4	106	16	9	4	108	17	9	4	104	15	10	5	106	16	10	4	105	15	10	4	Normal	1	5.45	4.30
C28	MANOJ CIRCUMCISION	3	M	24438	98	14	130	24	6	1	128	24	7	1	126	26	7	2	26	24	8	4	124	26	8	4	124	24	8	4	126	22	9	4	122	24	9	5	122	24	9	5	126	24	10	6	Normal	0	4.30	4.00
C29	LOGANATHAN L1) HERNIOTOMY	7	M	24428	128	20	126	18	7	1	128	16	7	1	120	18	8	2	118	16	9	4	118	16	9	5	116	16	9	5	115	15	9	6	117	15	10	7	114	14	10	7	114	14	10	7	Normal	0	4.00	3.45
C30	KISHOREKUMAR L1) HERNIOTOMY	8	M	24413	124	20	124	14	6	0	124	14	6	0	122	15	7	1	124	14	8	3	126	15	8	3	126	18	8	3	122	14	9	4	120	14	9	4	120	15	10	4	118	14	10	5	Normal	0	5.00	4.00

*MASTER CHART*

*GROUP S*



S.No.	Name&Surgery	Age	Sex	T.No.	HT cm	WT Kg	2.30 Hrs				3.00 Hrs				3.30 Hrs				4.00 Hrs				4.30 Hrs				5.00 Hrs				5.30 Hrs				6.00 Hrs				6.30 Hrs				7.00 Hrs				Temp	PON V	URINE VOIDING TIME	RESCUE ANAL GESIC Time
							HR	RR	ALD RE	FLA CC																																								
S1	LOKESH CIRCUMCISION	3	M	7609	94	14	124	20	7	0	120	20	7	0	118	18	8	0	114	18	9	1	114	18	9	1	114	16	9	2	108	16	9	2	108	16	9	4	106	16	9	4	104	16	10	4	NORM	0 NIL	6.30	6.00
S2	VASANTH KUMAR CIRCUMCISION	3	M	7608	90	12	124	22	6	0	120	20	7	0	124	22	7	0	122	20	8	1	118	22	8	2	118	22	8	2	116	20	9	3	116	20	9	4	116	20	10	4	114	18	10	4	NORM	0	6.30	6.00
S3	SANJAY CIRCUMCISION	6	M	7819	120	16	118	24	6	0	116	22	7	0	112	22	8	1	108	20	8	1	106	22	8	2	106	22	9	2	106	20	9	3	108	22	9	4	108	18	10	4	108	16	10	4	NORM	0	6.30	6.00
S4	SAKTHIVEL CIRCUMCISION	3	M	9520	92	15	114	18	6	0	114	20	6	0	112	18	7	1	106	18	7	2	106	16	8	2	108	16	8	3	104	16	8	4	104	16	8	4	108	18	9	4	106	17	10	4	NORM	0	6.00	5.30
S5	VISHWA CIRCUMCISION	3	M	9522	94	14	123	22	7	0	121	21	7	0	116	18	8	0	114	16	9	1	114	16	9	2	114	15	9	2	108	16	9	2	108	16	9	4	106	14	9	4	104	15	10	4	NORM	0	7.00	6.00
S8	MUNUSWAMY CIRCUMCISION	8	M	10367	12	16	98	18	6	0	96	18	7	0	98	16	7	0	98	16	7	1	96	16	7	2	94	16	8	2	94	16	8	3	98	14	9	4	98	14	9	4	98	14	9	4	NORM	0	6.00	6.00
S7	DENISAM CIRCUMCISION	3	M	10364	98	118	140	16	6	0	142	16	6	0	140	16	7	1	136	16	7	1	134	16	7	2	134	18	8	2	128	18	8	2	126	16	8	3	120	16	9	4	120	16	9	4	NORM	0	6.00	6.00
S8	HARIKRISHNAN LJ HERMIOTOMY	4	M	10369	98	15	128	16	6	0	128	16	7	0	118	14	7	1	108	14	7	2	106	16	8	2	104	15	8	3	104	15	8	3	104	16	9	4	104	18	9	4	98	18	9	4	NORM	0	8.00	6.00
S9	NAVARASU CIRCUMCISION	5	M	14750	110	15	114	16	6	0	112	14	6	0	120	14	7	0	106	14	7	1	106	14	7	2	106	14	8	2	98	14	8	3	98	14	8	3	96	13	8	4	98	14	9	4	NORM	0	7.00	6.30
S10	TAMILSELVAN LJ HERMIOTOMY	8	M	14744	130	20	112	16	7	0	108	16	8	1	106	14	8	1	104	14	9	2	104	14	9	3	104	15	9	3	104	13	9	4	104	14	9	4	105	13	9	4	102	12	10	4	NORM	0	4.30	5.30
S11	DINESH KUMAR LJ HERMIOTOMY	4	M	14759	98	12	104	14	8	1	108	15	6	2	104	13	6	2	102	14	7	3	102	14	7	3	98	12	8	3	98	12	8	4	98	14	9	4	94	12	9	4	94	12	10	4	NORM	0	5.30	5.30
S12	DEPAK CIRCUMCISION	6	M	16688	103	13	116	15	6	0	114	14	6	0	113	14	7	0	112	14	7	1	114	12	7	2	118	14	7	2	118	14	8	3	108	14	8	3	108	14	8	3	107	14	9	4	NORM	0	5.00	5.30
S13	SATHISH CIRCUMCISION	3	M	16689	86	12	118	16	6	0	116	18	6	1	118	18	7	1	104	18	7	2	104	16	7	2	104	16	8	2	104	16	8	3	104	16	8	3	112	14	8	3	114	16	9	4	NORM	0	6.00	5.00
S14	THARUN CIRCUMCISION	7	M	16698	124	20	104	12	6	0	104	14	6	1	102	14	7	1	98	14	7	1	98	14	7	2	98	14	8	2	98	14	8	3	96	14	8	3	98	14	9	3	96	12	9	4	NORM	0	5.30	7.00
S15	SHIAM CIRCUMCISION	7	M	16697	118	16	114	14	6	0	113	14	6	0	112	16	7	0	112	16	7	1	108	18	8	1	106	18	8	2	106	18	8	2	106	16	8	3	106	16	9	4	106	16	9	4	NORM	0	5.30	6.00

S.No.	Name& Surgy	Age	Sex	T.No.	HT cm	WT Kg	2.30 Hrs				3.00 Hrs				3.30 Hrs				4.00 Hrs				4.30 Hrs				5.00 Hrs				5.30 Hrs				6.00 Hrs				6.30 Hrs				7.00 Hrs				URINE			
							HR	RR	ALD RE	FLA CC	Temp	PON V	VODING TIME	R.A .Time																																				
S16	TAMILARASAN L1) HERNIOTOMY	3	M	17641	102	12	108	20	6	0	106	20	6	1	108	20	6	1	112	18	7	1	116	18	7	2	118	18	7	2	120	18	7	2	118	18	8	2	116	18	8	3	114	18	9	3	NORMA L	0	4.30	5.30
S17	MANICKAM CIRCUMCISION	8	M	17364	130	20	92	13	6	0	92	13	6	0	90	13	6	0	92	14	6	1	90	14	7	1	92	13	7	1	90	14	7	1	90	14	7	2	90	13	7	2	88	13	8	2	NORMA L	0	5.00	6.30
S18	SARAVANAKUMAR CIRCUMCISION	3	M	18618	93	12	108	20	6	0	106	18	6	0	108	16	6	1	104	18	7	1	105	18	7	2	104	18	7	2	105	18	7	2	106	16	7	2	108	16	8	2	109	16	8	3	NORMA L	0	6.30	6.00
S19	DEENA CIRCUMCISION	8	M	18620	122	20	96	14	6	0	94	16	6	0	94	14	6	0	90	13	7	0	92	14	7	0	92	14	7	0	94	18	7	1	96	16	7	1	98	16	7	1	100	16	8	1	NORMA L	0	6.00	6.00
S20	KIRUBAKARAN R1) HERNIOTOMY	8	M	18121	124	20	106	14	6	0	104	14	6	0	98	14	6	0	96	14	6	1	96	13	7	1	94	13	7	2	92	14	7	2	90	14	7	2	90	14	7	2	90	13	8	2	NORMA L	0	4.30	5.30
S21	PRAJAN CIRCUMCISION	3	M	18631	96	10	120	18	6	0	120	16	6	0	116	14	6	0	120	14	7	1	110	14	7	1	110	14	7	1	118	14	7	1	108	14	7	2	108	13	8	2	108	14	8	3	NORMA L	0	5.00	6.30
S22	KARTHIK L1) HERNIOTOMY	8	M	19635	120	20	118	14	6	0	120	14	6	0	116	14	6	1	120	14	7	2	120	16	7	2	120	14	7	2	132	14	7	3	126	15	8	3	126	14	8	3	128	14	9	4	NORMA L	0	6.00	6.00
S23	HEMANDH CIRCUMCISION	3	M	20721	96	16	108	20	6	0	106	18	6	0	108	16	6	1	104	18	7	1	105	18	7	2	104	18	7	2	105	16	7	2	106	16	7	2	108	16	8	2	109	16	8	3	NORMA L	0	6.30	6.00
S24	JAGADEESH R1) HERNIOTOMY	8	M	20694	136	20	92	13	6	0	92	13	6	0	90	13	6	0	92	14	6	1	90	14	7	1	92	13	7	1	90	14	7	1	90	14	7	2	90	13	7	2	88	13	8	2	NORMA L	0	5.30	6.30
S25	MOHAMED OMER L1) HERNIOTOMY	7	M	21708	130	18	112	16	7	0	108	16	8	1	106	14	8	1	104	14	9	2	104	14	9	3	104	15	9	3	104	13	9	4	104	14	9	4	102	13	9	4	102	12	10	4	NORMA L	0	4.30	5.30
S26	ASHOK CIRCUMCISION	8	M	21716	134	20	104	12	6	0	104	14	6	1	102	14	7	1	98	14	7	1	98	14	7	2	98	14	8	2	98	14	8	3	96	14	8	3	98	14	9	3	96	12	9	4	NORMA L	0	5.30	7.00
S27	SASIKUMAR CIRCUMCISION	4	M	22661	120	16	128	16	6	0	128	16	7	0	118	14	7	1	108	14	7	2	106	16	8	2	104	15	8	3	104	15	8	3	104	16	9	4	104	18	9	4	98	16	9	4	NORMA L	0	7	6.00
S28	NISHANTH CIRCUMCISION	3	M	23510	96	13	118	16	6	0	116	18	6	1	118	18	7	1	104	18	7	2	104	16	7	2	104	16	8	2	104	16	8	3	104	16	8	3	112	14	8	3	116	16	9	4	NORMA L	0	6.00	5.00
S29	SHANTHAKUMAR R1) HERNIOTOMY	3	M	23514	98	15	114	18	6	0	114	20	6	0	112	18	7	1	106	18	7	2	106	16	8	2	108	16	8	3	104	16	8	4	104	16	8	4	108	18	9	4	106	17	10	4	NORMA L	0	6.00	5.30
S30	KARTHIK R1) HERNIOTOMY	7	M	24439	130	20	106	14	6	0	104	14	6	0	98	14	6	0	96	14	6	1	96	13	7	1	94	13	7	2	92	14	7	2	90	14	7	2	90	14	7	2	90	13	8	2	NORMA L	0	4.30	5.30

