A STUDY OF THE EFFICACY AND SAFETY OF CLONIDINE AS AN ADJUNCT TO BUPIVACAINE FOR CAUDAL ANALGESIA IN CHILDREN

Dissertation submitted for M.D. Degree Examination

BRANCH X - ANAESTHESIOLOGY

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MARCH – 2009.

CERTIFICATE

This is to certify that this dissertation entitled

"A study of the efficacy and safety of clonidine as an adjunct to bupivacaine for caudal analgesia in children"

is a bonafide record of the work done by Dr.N.Kamala Kannan under my supervision and guidance in the department of Anaesthesiology at Government Raja Mirasudhar Hospital of Thanjavur Medical College, Thanjavur during the period of his post graduate study from May 2007 to March 2009 for the partial fulfillment of M.D. (Branch X - Anaesthesiology) degree.

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INTRODUCTION

"Pain is a more terrible lord of mankind than even death itself" said nobel laureate ALBERT SCHWEIZER. Pain has become the fifth vital sign and is now a critical focus of the patient. The relief of pain has been the fundamental aspect of the practice of anaesthesiology. Proper management of pain remains one of the most important and pressing responsibilities of the anaesthesiologist.

There is increasing evidence that optimal pain management can impact outcome beyond the intraoperative period. Alleviation of postoperative pain may continue to improve clinical outcomes, hasten recovery, facilitate early mobilization and return to daily living. Children suffer pain in the same way as adults though they may be unable to describe the pain or their subjective experiences. Unfortunately, even when their pain is obvious, children frequently receive no treatment or inadequate treatment.

Pain is a perception that is far more complex than simple transmission of information along nerve pathways to the brain. It consists of a component of transmission of pain sensation, a component of processing and evaluation by higher centers of the brain and a component of reaction to sensation.

The response to pain in children consists of behaviour, psychological and social changes. The cognitive ability, child's trust of caregivers and previous painful experiences will influence this response. The manner in which the family reacts to the stress of a child's pain will also influence the response to pain.

Appropriate pain management is of great importance when dealing with children, because the way the child is treated may influence the way he or she deals with pain for the rest of his or her life. Untreated pain can lead to physiological complications, psychological distress and personality changes in developing children, family disruption and prolongation of hospital stay with resultant increased expenses. In addition social withdrawal, temper tantrums and autistic behaviour are also seen in these children.

Various pharmacological agents and analgesic delivery systems have been employed to avoid under treatment of pain in children. Many children will withdraw or deny their pain in an attempt to avoid yet another terrifying and painful experience, of the intramuscular injection. Genitourinary surgery is generally associated with considerable pain of long duration.

Caudal extradural block with bupivacaine ensures satisfactory analgesia in the initial postoperative period only. It becomes ineffective once the block wears off. Various methods have been devised to extend the duration of regional analgesia with local anesthetics like the placement of a catheter and using adjuvants like tramadol, ketamine, neostigmine and opioids. The placement of catheter carries the risk of infection and delayed mobilization.

The use of ketamine, opioids and neostigmine is limited because of potential side

effects like sedation, respiratory depression, nausea and vomiting.

The role of clonidine as an analgesic administered by extradural route is now well established in children. Coadministration of caudal clonidine in a dosage of 1μg|kg with 0.25% bupivacaine has been found to prolong analgesia without any adverse effects.

Extradural clonidine in a dose of 1 – 3μg|kg added with local anaesthetics intensifies the analgesia by approximately 50%. The sedative property of clonidine reduces the requirements of hypnotics and is often a desirable feature.

This study was conducted to assess the efficacy and safety of clonidine in low doses as an adjunct to bupivacaine for postoperative pain relief in paediatric patients.

LET US REMEMBER THE HIPPOCRATES OATH “DIVINE IS THE TASK TO RELIEVE PAIN”

II. AIM OF THE STUDY

To assess the efficacy of 1μ|kg of clonidine as a caudal adjunct to bupivacaine for postoperative pain relief in paediatric patients.

To assess the safety of clonidine, as a caudal adjunct to bupivacaine to increase the duration of analgesia.

III. ANATOMY OF THE CAUDAL EPIDURAL SPACE

SACRAL HIATUS

It is a bony defect, triangular in shape and situated at the lower end of the sacrum just above the sacrococcygeal junction. The hiatus results from non-fusion of the 5th sacral and at times 4th sacral vertebral arches. It appears as an inverted U or V; the large bony processes on each side are called the cornua. The sacral cornua are in fact the embryological remains of the inferior articular processes of the 5th sacral vertebrae. The hiatus is covered by the sacrococcygeal membrane formed by the superficial and deep fibers of sacrococcygeal ligaments and is attached laterally to sacral cornua.

The sacrococcygeal membrane is actually a continuation of ligamentum flavum. The sacrum is cartilaginous in neonates and infants**,** and its ossification is completed between 25 to 30 years of age. At increasing age, the sacrococcygeal angle increases, thus closing sacral hiatus and therefore making caudal anaesthetic more difficult. This is especially true after the age of 7 years**.**

SACRAL CANAL AND THE CAUDAL EPIDURAL SPACE

The sacral canal is a caudal extension of the spinal canal. The spinal canal contains the last spinal nerve roots, which forms the cauda equina and also the filum terminale that anchors spinal cord to coccyx and sacrococcygeal ligament. The dural sac projects upto S3 - S4 level at birth, reaching the adult level of S2 during second year of life.

The caudal epidural space in a neonate is filled with epidural fat, which has a gelatinous spongy appearance with distinct spaces between the fat globules and very few connective tissue fibers. This facilitates uniform and rapid spread of the local anaesthetic solutions. Between 6 to 7 years of age, the epidural fat gets denser and is surrounded by fibrous strands, thus reducing uniform spread of local anaesthetic solutions. The epidural space is richly vascularised and the veins are without valves; thus an inadvertent intravascular injection can lead to instantaneous systemic toxicity.

Caudal anaesthesia requires identification of the sacral hiatus. The sacrococcygeal ligament overlying the sacral hiatus lies between the sacral cornu. To facilitate locating the cornu, the posterior superior iliac spine should be located and by using the line between them as one side of an equilateral triangle, the location of sacral hiatus approximated. After the sacral hiatus is identified the index and middle finger of the palpating hand are placed on the sacral cornu, and the caudal needle is inserted at an angle of approximately 45 degree to the skin in relation to the coccyx. While advancing the needle, a decrease in resistance to needle insertion should be appreciated as the needle enters the caudal space. The needle is advanced until bone is contacted and then slightly withdrawn, and the needle is redirected rostrally at a 20 to 30 degree angle to the skin. During redirection of the needle and after a loss of resistance is encountered again, the needle is advanced approximately 2 to 3 mm into the caudal canal.

COMPLICATIONS OF CAUDAL ANAESTHESIA

Intravascular or intraosseous injection:-This may lead to grand mal seizure and cardio respiratory arrest.

Dural puncture: Extreme care must be taken to avoid this as a total spinal block will occur if a dose for a caudal block is injected into the subarachnoid space.

Perforation of the rectum: While simple needle puncture is not important, contamination of the needle is extremely dangerous if it is then inserted into the epidural space.

Sepsis: This should be very rare occurrence if strict aseptic procedures are followed

Urinary retention: This is not uncommon and temporary catheterization may be required

Subcutaneous injection: This should be obvious as the drug is injected

Hematoma:

Absent or patchy block:

IV. PHARMACOLOGY OF BUPIVACAINE

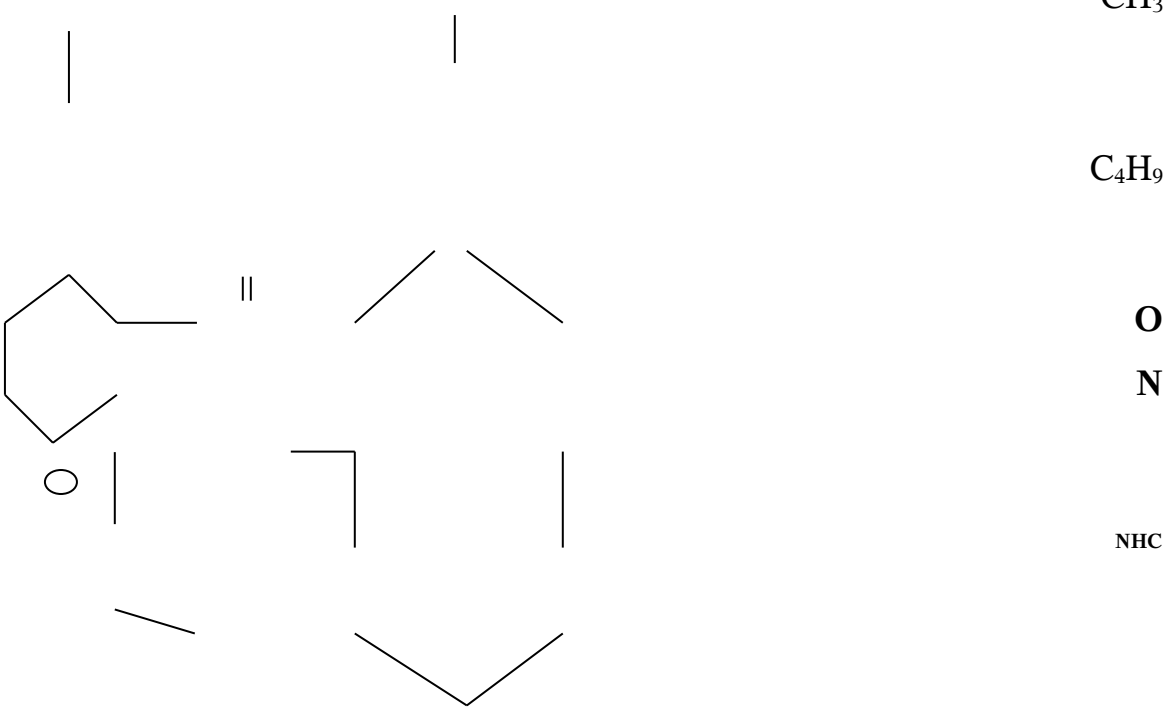
The pharmacology of local anaesthetics is generally the same in children as it is in adults. There are differences like

1. Increased volume of distribution
2. Decreased protein binding of local anaesthetics
3. Enzyme immaturity

Decreased protein binding of local anaesthetics and enzyme immaturity can lead to systemic toxicity of local anaesthetics with high protein affinity.

Caudal injections of bupivacaine are now routinely used in children undergoing lower abdominal and urogenital surgery to provide intraoperative and postoperative analgesia.

BUPIVACAINE



CH_3

It is an amide local anaesthetic characterized as pipecoloxylidides. Addition of a butyl group to the piperidine nitrogen of mepivacaine results in Bupivacaine. It is a chiral drug because of possession of asymmetric carbon atom.

It was first synthesized in Sweden by **EKENSTAM** and his colleagues in 1957 and used clinically by **L.J.TELIVUO** in 1963. Its molecular weight is 288.

MECHANISM OF ACTION

It prevents transmission of nerve impulses by inhibiting passage of sodium ions through ion selective sodium channels in nerve membranes. They do not alter the resting transmembrane potential or threshold potential.

PHARMACOKINETICS

It is a weak base that has pk value above physiologic pH. At pH 7.4 only 15% exists in nonionised form. Absorption depends on the site of injection, dosage and use of epinephrine. Lung is capable of extracting bupivacaine from circulation, which will limit concentration of drug that reaches systemic circulation. This first pass pulmonary extraction is dose dependent suggesting that it becomes saturated rapidly.

pk	:	8.1
Protein Binding	:	95%
Lipid solubility	:	28
Volume of distribution	:	73 litre
Clearance of drug from plasma	:	0.471 lit/min

Elimination half life	:	210 min (3.5 hours)
Onset time	:	5 -7 min
$t_{½}\alpha$	:	2.7 min
$t_{½}\beta$	:	28 min

METABOLISM

Slowest metabolism among amide local anaesthetics. It undergoes aromatic hydroxylation, N- dealkylation, amide hydrolysis and conjugation. Only the N-desbutyl bupivacaine has been measured in blood or urine after epidural or spinal anaesthesia. Alpha-1 acid glycoprotein is the most important protein-binding site of bupivacaine.

SIDE EFFECTS

Bupivacaine is more cardio toxic than equieffective doses of Lignocaine. This is manifested by severe ventricular arrhythmias and myocardial depression. Bupivacaine blocks cardiac Na+ channels rapidly during systole and dissociates more slowly during diastole, so that a significant fraction of Na+ channels remain blocked at the end of the diastole. Thus the block by Bupivacaine is cumulative and substantially greater.

CLINICAL USE

Onset of anaesthesia and duration of action are long. Its tendency to provide more sensory than motor block has made it popular for providing postoperative analgesia. Used for

- Infiltration anaesthesia
- Field block anaesthesia
- Nerve block anaesthesia
- Spinal anaesthesia
- Epidural anaesthesia

RECOMMENDED DOSE

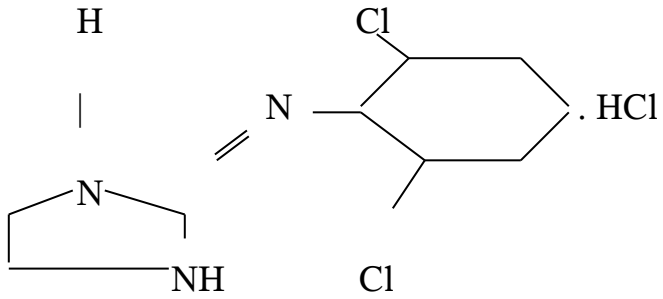
Bupivacaine without epinephrine – 2 mg/Kg

Bupivacaine with epinephrine – 3 mg/Kg

TOXIC PLASMA CONCENTRATION THRESHOLD

- 2 µg / ml

V. PHARMACOLOGY OF CLONIDINE HYDROCHLORIDE



N – (2,6 – dichlorophenyl) -4, 5 –dihydro – 1H – imidazol – z – amine.

Clonidine is a direct acting $\acute{\alpha}_2$ agonist prescribed historically as an antihypertensive agent. In addition to its antihypertensive effect, in recent studies, clonidine has been demonstrated to be an effective sedative and analgesic and to reduce the amount of anaesthetic agents required. Therefore, a reconsideration of possible new indications for clonidine in clinical anesthesiology seems to be justified.

MECHANISM OF ACTION

Clonidine is a selective partial $\acute{\alpha}_2$ – adrenergic agonist with a selectivity ratio of about 200: 1 in favour of $\acute{\alpha}_2$ receptors. It is lipid soluble and easily penetrates the blood brain barrier to reach the hypothalamus and medulla when injected epidurally. It stimulates the inhibitory $\acute{\alpha}_2$ – adrenergic receptors located on neurons in the superficial laminae of spinal cord and brainstem nuclei thereby reducing central neural transmission of pain impulses. Inhibition of substance – p release is believed to be involved in the

analgesic effect.

Some contribution to the analgesic effect of clonidine may be through release of acetylcholine in the neuraxial region. This enhances sensory and motor block of C and A ά fibres by local anaesthetics by increasing potassium conductance.

Sedation usually accompanies the use of clonidine through its actions on the locus ceruleus. Sedation after epidural clonidine likely reflects systemic absorption and vascular redistribution to higher centers.

Clonidine affects blood pressure in a complex fashion after neuraxial or systemic administration because of opposing actions at multiple sites. In the nucleus tractus solitarius and locus ceruleus of the brainstem, activation of postsynaptic $\acute{\alpha}_2$ – adrenergic receptors reduces sympathetic drive. It also activates non-adrenergic imidazoline – preferring binding sites in the lateral reticular nucleus, thereby producing hypotension and an anti-arrthymic action. In the periphery, its action on presynaptic $\acute{\alpha}_2$ – adrenoceptors at sympathetic terminals reduce the release of norepinephrine causing vasorelaxation and reduced chronotropic drive. The brainstem and peripheral effects of $\acute{\alpha}_2$ - adrenoceptor stimulation are counterbalanced by direct peripheral vasoconstriction through its action on α_1- adrenoceptors from circulating concentrations of clonidine. As a result, the dose – response for clonidine by neuraxial or systemic administration is U-shaped, with peripheral vasoconstriction from circulating drug concentrations at high

doses opposing central sympatholysis.

PHARMACOKINETICS

Clonidine is highly lipid soluble and hence rapidly absorbed after oral, intravenous and epidural administration. After epidural administration, clonidine is rapidly and extensively absorbed into the spinal CSF compartment, with concentration peaking 30 to 60 minutes after injection. There is a strong correlation between clonidine concentration in the CSF and analgesia after epidural clonidine administration. Epidurally administered clonidine readily partitions into plasma via the epidural veins and attains systemic concentrations (0.5 – 2 ng | ml) that are associated with a hypotensive effect mediated by the central nervous system. After intravenous administration it is readily distributed into extravascular sites including the central nervous system.

Molecular mass	230.093 gm / ml
Bioavailability	75 – 95%
Protein binding	20 – 40%
Volume of distribution	2.1 $\pm$ 0.4 L / Kg
Elimination T ½	9 $\pm$ 2 hrs
Onset time	26 $\pm$ 11 mins

METABOLISM

In the liver it undergoes hydroxylation to form major metabolite p-

hydroxyclonidine. Only 50% of the drug is metabolized in the liver and the remaining is excreted as unchanged drug in the urine. Plasma albumin is the most important protein binding site for clonidine varies between 20 – 40% in vitro.

SIDE EFFECTS

The most common side effects produced by clonidine are drowsiness, drymouth, bradycardia and hypotension. It also causes inhibition of orgasm in women. Rebound hypertension can occur after abrupt discontinuation of clonidine therapy (1.2 mg / day) as early as 8 hours and as late as 36 hours after the last dose. Rebound hypertension can usually be controlled by reinstituting clonidine therapy or by administering a vasodilating drug such as hydralazine or sodium nitroprusside.

CLINICAL USE

HYPERTENSION

Clonidine has been proved to be effective in treatment of patients with severe hypertension or renin dependent disease. The usual daily adult dose is 0.2 to 0.3 mg orally. Transdermal clonidine patch designed for weekly administration is useful for surgical patients who are unable to take oral medications.

ANALGESIA

Preservative free clonidine administered into the epidural or subarachnoid space produces dose dependent analgesia and unlike opioids, does not produce respiratory

depression, pruritus, delayed gastric emptying, nausea and vomiting. It prolongs the effects of both sensory and motor blockade.

PREANESTHETIC MEDICATION

Oral preanesthetic medication (3 to 5μg/kg) dose of clonidine (a) blunts reflex tachycardia associated with direct laryngoscopy for intubation of trachea (b) decreases intraoperative lability of blood pressure and heart rate. (c) decreases plasma catecholamine concentrations (d) dramatically decreases anaesthetic requirements for inhaled and injected drugs.

TREATMENT OF SHIVERING

Slow intravenous administration of clonidine 30μg stops shivering

ATTENUATION OF HEMODYNAMIC EFFECTS OF KETAMINE

Oral clonidine premedication 5 μg|kg administered 90 minutes before induction of anesthesia attenuates the blood pressure and heart rate increases that normally follow the administration of ketamine 1 mg | kg intravenously.

TREATMENT OF OPIOID WITHDRAWAL

Clonidine is effective in suppressing the signs and symptoms of withdrawal from opioids. Clonidine may be useful in attenuating the symptoms associated with cigarette smoking and nicotine withdrawal.

DOSAGE GUIDELINES: CLONIDINE DOSE

Intrathecal - 15 μg to 30 μg

Epidural - 1 μg | kg (or) 50 μg

30 μg | hr (for infusion)

Intravenous - 50 – 75 μg (or) 1μg | kg 15 minutes prior to induction for intubation response attenuation

150 – 300 μg (or) 3 μg / kg for hypertensive crisis

30 μg given slowly for shivering management.

VI. CALCULATION OF THE VOLUME OF LOCAL ANAESTHETIC FOR CAUDAL ANAESTHESIA

Many formulae based on weight, age and number of spinal segments to be blocked and the parameter 'D' (Distance from C7 to sacral Hiatus) have been used to determine the dose of local anaesthetic required.

SPIEGEL et al (6) described a formula to calculate the total volume of Bupivacaine (V) depending on the distance separating the sacral hiatus from the spinous process of the 7^{th} cervical vertebra as follows

$$V = 4 + (D-15)/2$$

V-Volume of local anaesthetic

D- Distance from C7 to sacral Hiatus

BROMAGE PR et al (23) proposed a formula to determine the volume of local anaesthetics to be injected into the caudal epidural space depending on the age of the patient and per spinal segment.

$V = 0.106 + (0.075 \text{ X Age in years})$

V-Volume of local anaesthestic per spinal segment

TAKASAKI M et al (24) suggested a calculation depending on the weight of the patient in kg.

V = 0.056 ml X Body weight (in kg) X number of spinal segments to be blocked.

SCHULTE – STEINBERG examined the statistical influence of age, weight and height on caudal dose requirements before puberty. He found that the pattern of spread was highly predictable in children. The relationship between age and dose requirements was strictly linear = 0.1 ml / segment / year of age.

V is volume in ml of 1% lignocaine or 0.25% bupivacaine.

In practice, however, it is easier to use the formula describes by **ARMITAGE EN et al (5)**

LUMBOSACRAL	0.5 ml/kg
THORACOLUMBAR	1 ml/Kg
MIDTHORACIC	1.25 ml/Kg

Of 0.25% bupivacaine.

MODIFIED ARMITAGE EN et al

Sacral	0.5 ml / kg
Thoracic (T_{10})	0.75 ml / Kg
Thoracic (T_6)	1 ml / Kg
Mid Thoracic (T_4)	1.25 ml / Kg

Of 0.25% bupivacaine.

Modified Armitage formula was used in this study. This formula is easy to use, reliable and safe in children.

VII. ASSESSMENT OF PAIN IN CHILDREN

Children present problems of assessment of pain when compared with adults because of their lower level of verbal fluency and the likelihood that varying development levels alter their understanding of questions or tests. Hence assessment of pain proved difficult in children. Assessment and management are interrelated. Unfortunately validated totally acceptable tools for measuring pain in children are not available. Various methods are available as per **Brown TCK. (25)**

1. Physiological measurements
2. Self report techniques
3. Behavioural assessment

PHYSIOLOGICAL MEASUREMENTS

Changes in pulse, blood pressure and respiration reflect autonomic arousal. Autonomic responses to pain and their measurement form an important aspect of certain pain scales. Metabolic changes cause release of catecholamine, growth hormone, glucagons, cortisol, aldosterone and beta-endorphins, which have been documented in infants and children following noxious stimulation. Only plasma cortisol has been shown to correlate with behavioural responses to noxious stimuli.

SELF REPORT TECHNIQUES

As described by **Manuksela et al, (6)** these are the best indicators of a child's subjective experience. Various methods have been used:

(a) VISUAL ANALOGUE SCALE (26)

The accepted method of measurement of pain in adults is acceptable and provides reproducible results in children down to an age of five years. VAS using a 10 cm length scale marked "no pain" at one to "worst pain possible" at the other end. The child is asked to identify a point on the scale, which corresponds to his pain. The point is measured from the left hand end and reported in mm from 0 to 100 or in cm from 0 to 10. A score of less than 4 is no pain, less than 6 implies tolerable pain and more than 6 means he needs medication.

(b) OUCHER SCALE (7)

It is a variant of the faces scale and is designed to measure pain intensity in children aged 3 to 12 years. The scale is displayed in a poster format. It consists of a vertical numerical scale (0 to 100) on the left and six photographs of children in varying degrees of pain positioned vertically to the right. This scale is based on mimic, vocalization and irritability.

Characteristics of increasing pain are:

(1) Distortion of face such as lowering of the brow, broadening of the nasal root, angular and squarish mouth, tightly closed eyes and tightening of the jaw.

(2) Vocalization, changing from sobbing or groaning to cry.

(C) WONG – BAKER FACES PAIN RATING SCALE (8)

It is recommended for persons of age three and more. It contains six different faces of expression varying from a happy to sad mood. The patient has to be explained that each face is for a person who feels happy because he has no pain (hurt) or sad because he has some or a lot of pain. Ask the patient to choose the face that best describes how he is feeling.

A similar scale was designed by **Daiva Bieri et al (9)** to assess pain in the Children's Hospital, University of Helsinki. This scale was based on mimic, vocalization, movements or rigidity of the limbs and the body, response to handling and irritability together with the measured cardioventilatory parameters.

BEHAVIOURAL ASSESSMENT

This method of assessment relies on observation of behaviour and is more useful in the pre-school age group of children. They score the behaviour, which represent the

reaction to pain and scores are allotted according to the degree of alteration of a particular behaviour .The behavioural score include vocal behaviour such as cry, scream, verbally expressed pain and anxiety and nonverbal behaviour such as muscle rigidity, torso movements, leg movements, facial expression.

(1) **THE PBRS:** Pain behaviours rating scale and Children's Hospital of Eastern Ontario pain scale - **CHEOPS (10)** are the two such scales. The observation in these scales can have an observer bias.

(2)**THE OBJECTIVE PAIN SCALE:** This measures pain as a physiological variable, blood pressure along with behavioral changes. This has been shown to be a sensitive and reliable tool in evaluating postoperative pain in children who are not able to verbally comment upon their pain experience. This takes into account the systolic blood pressure, cry and it's response to love and care, movement, agitation and verbal evaluation as described by **Hannallah RS. (28)**

Children's Hospital Eastern Ontario Pain Scale (CHEOPS)

(Recommended for children 1-7 years old) – A score greater than 4 indicates pain.

Item	Behavioral		Definition	Score
Cry	No cry Moaning Crying Scream	1 2 2 3	Child is not crying Child is moaning or quietly vocalizing silent cry. Child is crying, but the cry is gentle or	

			whimpering Child is in a full-lunged cry, sobbing; may be scored with complaint or without complaint.	
Facial	Composed Grimace Smiling	1 2 0	Neutral facial expression. Score only if definite negative facial expression. Score only if definite positive facial expression.	
Child verbal	None Other complaints Pain complaints Both Complaints Positive	1 1 2 2 0	Child not talking. Child complains, but not about pain, e.g., “I want to see mommy” of “I am thirsty”. Child complains about pain. Child complains about pain and about other things, eg., “It hurts; I want my mommy”. Child makes any positive statement or talks about others things without complaint.	
Torso	Neutral Shifting Tense Shivering Upright Restrained	1 2 2 2 2 2	Body (not limbs) is at rest; torso is inactive. Body is in motion in a shifting or serpentine fashion. Body is arched or rigid. Body is shuddering or shaking involuntarily. Child is in a vertical or upright position. Body is restrained.`	
Touch	Not touching Reach Touch Grab Restrained	1 2 2 2 2	Child is not touching or grabbing at wound. Child is reaching for but not touching wound. Child is gently touching wound or wound area. Child is grabbing vigorously at wound. Child’s arms are restrained.	
Legs	Neutral Squirm/Kicking Drawn up / tensed Standing Restrained	1 2 2 2 2	Legs may be in any position but are relaxed; includes gentle swimming or separate – like movements Definitive uneasy or restless movements in the legs and/or striking out with foot or feet. Legs tensed and/or pulled up tightly to body and kept there. Standing, crouching or kneeling. Child’s legs are being held down.	

FLACC Scale

Category	Scoring
No particular expression or smile	
Occasional grimace or frown, withdrawn, disinterested	
Frequent to constant quivering chin, clenched jaw	
Normal position or relaxed	
Uneasy, restless, tense	
Kicking, or legs drawn up	

Each of the five categories (F) Face; (L) Legs; (A) Activity; (C) Cry; (C) Consolability is scored from 0-2, which results in a total score between zero and ten.

TABLE -1: OBJECTIVE PAIN SCALE

TLC - TOUCH, LOVE AND CARE

VIII. MATERIALS AND METHODS

The study population consisted of 40 ASA I and ASA II children in the age group of 2 years to 8 years admitted to undergo elective lower abdominal general surgical procedures at our hospital.

Exclusion criteria consisted of local infection in the caudal region, bleeding diathesis, preexisting neurological (or) spinal diseases and congenital anomaly of the lower back. The study was approved by the institutional ethics committee.

A written consent was obtained from the parents after they were informed about the procedure to be performed, to give post operative analgesia for their children. The children were allocated randomly into two groups of 20 patients each. One group named group B received 0.75 ml/kg of 0.25% bupivacaine alone. Another group named group BC received 0.75ml/kg of 0.25% bupivacaine with 1microgram/kg clonidine.

All children were kept fasting for 6 hours. They were received by an anaesthesiologist inside the premedication room one hour before surgery. Preanaesthesia check up was done and the children were premedicated with syrup midazolam 0.5 mg/kg 45 minutes prior to the surgery.

After premedication, they were received by an anaesthesiologist inside the operation room for surgery. Baseline cardio respiratory parameters such as pulse rate, noninvasive blood pressure, electrocardiogram, respiratory rate and oxygen saturation(SpO_2) were recorded and monitored continuously every 5 minutes intraoperatively and thereafter every 30 minutes for next 12 hrs.

Patients were induced with increasing concentration of halothane (0.4-2%) with oxygen 30% and nitrous oxide 70% mixture using T – piece with Jackson Rees modification and facemask. Intravenous line was secured after achieving adequate depth of anaesthesia.

Intubation is facilitated with Inj.suxamethonium chloride 2mg/kg. Patients were intubated with an appropriate size uncuffed endotracheal tube orally. No opioids were used intraoperatively.

Under controlled ventilation, muscle relaxation was maintained with Inj.vecuronium 0.08mg/kg. Anaesthesia was maintained with halothane 0.5 – 1% and 70 % nitrous oxide in oxygen mixture.

After induction of anaesthesia, the patients were positioned in the left lateral position with hips and knees flexed.

Under strict aseptic precautions, a 22 G hypodermic needle was inserted in the sacral hiatus at 45 degree angle to the skin. Once the sacrococcygeal membrane was penetrated and loss of resistance obtained, the angle was changed and needle was directed up the canal for further 2 to 3 mm. The injection was made after gentle aspiration to rule out any intrathecal or intravascular placement. Group B received 0.25% bupivacaine alone. Another group BC received 0.25% bupivacaine with clonidine 1microgram/kg.

The dosage of local anaesthetic injected into the caudal space was calculated according to the MODIFIED ARMITAGE formula.

The surgical incision was made 10 minutes after administering the caudal block. Meanwhile the children were surgically prepared and draped.

Adequate caudal analgesia was defined as haemodynamic stability as indicated by absence of increase in heartrate and mean arterial pressure of more than 15% compared with baseline values obtained just before surgical incision.

If the mean arterial pressure increased by more than 15% of baseline value, analgesia was considered inadequate and rescue opioids like Inj.Fentanyl 2 microgram/kg was given. These patients were excluded from the study.

Intraoperative fluid management was taken care by using HOLIDAY AND SEGAR formula.

On completion of surgery, the residual effect of the muscle relaxant was reversed with Inj.neostigmine 50 microgram/kg and Inj.atropine 20 microgram/kg and patients were extubated when fully awake.

The recovery was assessed using MODIFIED ALDRETE SCORE (27) and children were shifted to the post operative ward, where monitoring of respiratory rate, oxygen saturation (SpO_2), pulse rate and blood pressure were continued. The quality of analgesia was assessed hourly, for the first 6 hours and then every 2 hours for the next 6 hours.

The intensity of pain was measured using the OBJECTIVE PAIN SCALE SCORE devised by HANNALLAH RS.(28). Each parameter was awarded a score of 0-2 accordingly. The sum total of the awarded score was taken at each time interval. A log was kept at the bedside for noting the occurrence of possible complications including hypotension, bradycardia and respiratory depression.

Patients were administered rescue analgesia with Syrup paracetamol 10mg/kg on evidence of pain (i.e) if the OBJECTIVE PAIN SCALE reached a value of 5. The duration of analgesia was calculated from the time of injection of the drug in the epidural space to the time when OPS reached 5.

Postoperative sedation score was done using RAMSAY SCALE every one hour for first 6 hours and then every 2 hours for the next 6 hours. Respiratory depression was defined as decrease of (SpO_2) less than 93% or a decrease in respiratory rate less than 10/min. Excessive sedation was defined as a RAMSAY SEDATION SCORE of V or VI

Caudal block and monitoring of scores for pain and sedation were performed by anaesthesiologists blinded to the study allocations.

TABLE –II MODIFIED ALDRETE'S SCORE

TABLE III: RAMSAY SEDATION SCORE

Six point sedation score was assigned as follows

SCORE	CLINICAL DESCRIPTION
I	**Anxious, Agitated**
II	**Cooperative, Oriented, Tranquil**
III	**Responds only to verbal commands**
IV	**Asleep with brisk response to light stimulation**
V	**Asleep with sluggish response to stimulation**
VI	**Asleep without response to stimulation**

IX. OBSERVATION AND ANALYSIS

Forty Patients posted for elective lower abdominal general surgical procedures who were admitted in the Department of Paediatric surgery, RAJA MIRASUDHAR HOSPITAL, THANJAVUR MEDICAL COLLEGE, of Physical status ASAI and II were taken up for the study.

They were randomly divided into two groups of 20 patients each to receive caudal block as mentioned below.

One group (group BC) received a mixture of 0.75ml / kg of 0.25% bupivacaine and 1microgram/kg clonidine, 20 minutes before surgery. Other group (group B) received 0.75ml / kg of 0.25% .bupivacaine alone 20 minutes before surgery. The patients were assessed by a blinded observer in the postoperative period.

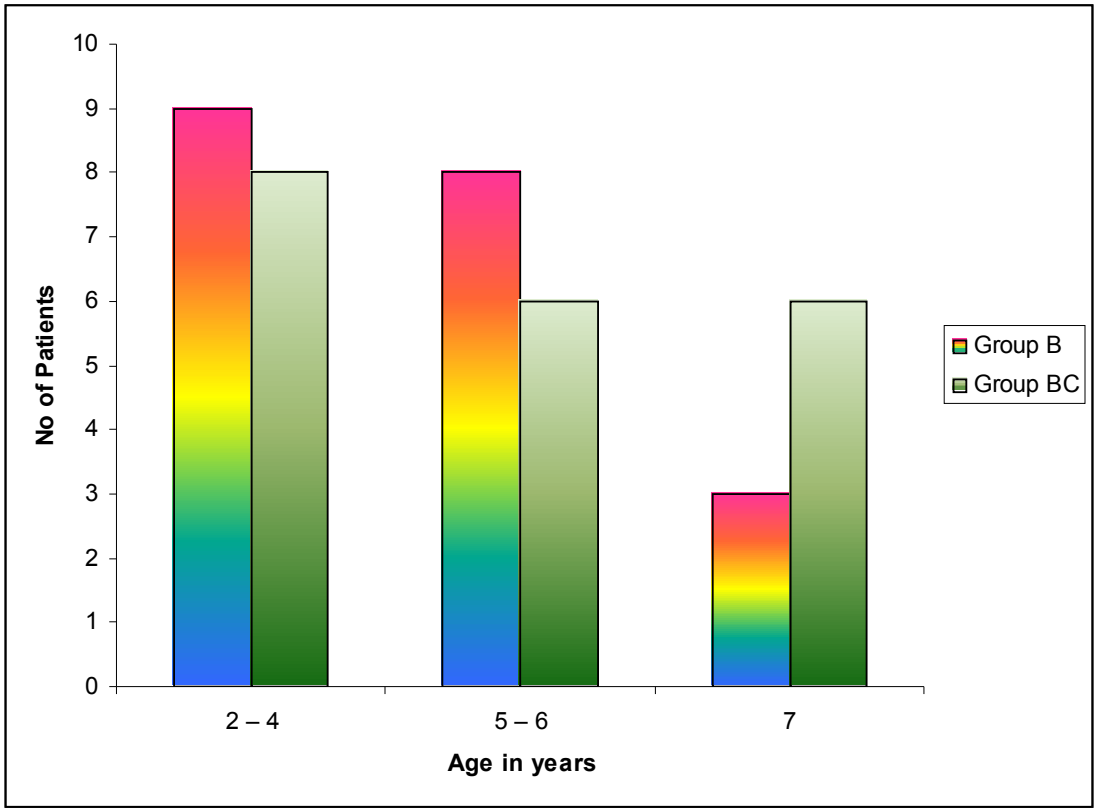
AGE AND SEX DISTRIBUTION

The age distribution in both groups ranged from 2-8 years as follows.

AGE IN YEARS	GROUP B		GROUP BC	
	MALE	FEMALE	MALE	FEMALE
2 – 4	6	3	6	2
5 – 6	5	3	4	2
7	2	1	4	2
	13	7	14	6

From this table it is clear that the number of children in 2 – 4 yrs, 5 – 6 yrs and 7 years interval are not much different between the two groups. This shows age was not a confounding factor.

AGE DISTRIBUTION



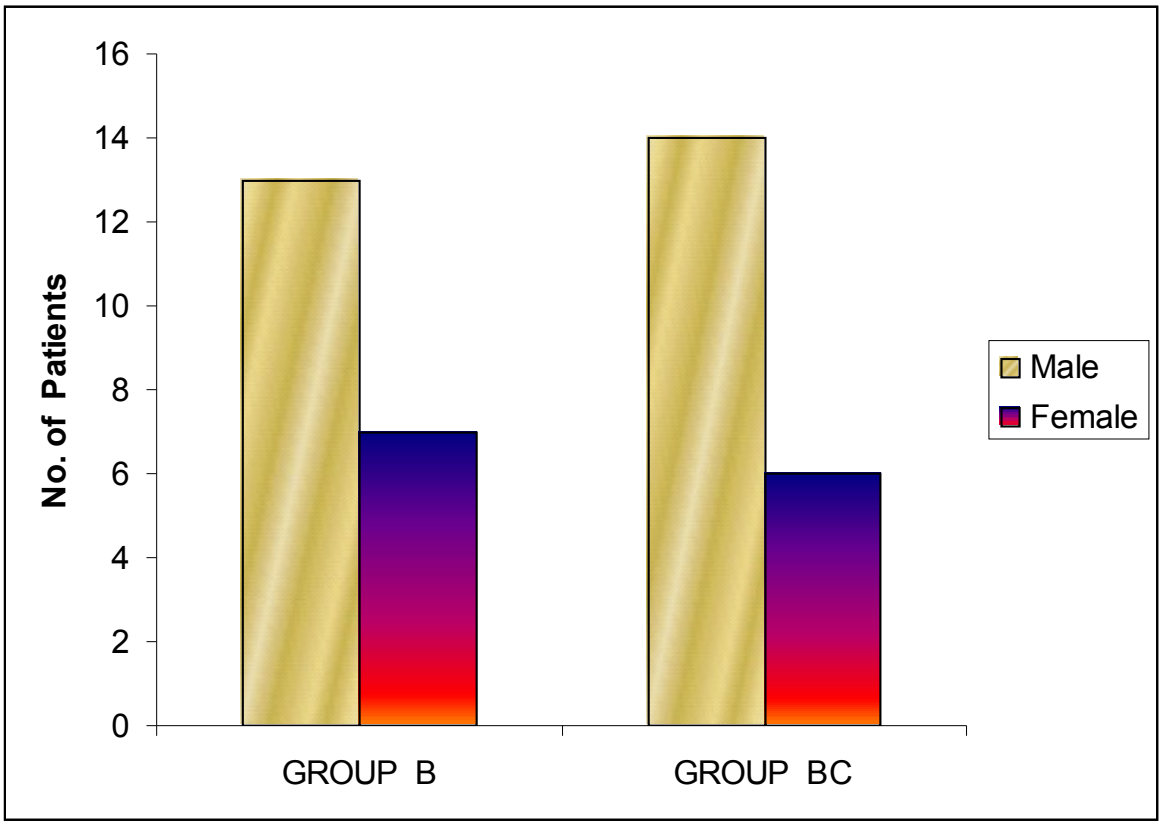
In this bar diagram, the horizontal axis represents age in years and vertical axis represents the number of patients. The age distributions in both groups are not much different.

Mean Age in years ± S.D	GROUP B	GROUP BC	P VALUE
	4.8 ± 1.44	5.15 ± 1.63	0.48

S.D (Standard deviation)

There was no statistically significant difference in age distribution (P > 0.05). Hence there is no bias in the age distribution.

DISTRIBUTION



In group B 65% are male and 35% are female and in group BC 70% are male and 30% are female. The sex distribution in both the group is also not much different. Hence there is no bias in the sex distribution.

WEIGHT DISTRIBUTION

Mean Wt in kgs $\pm$ S.D	GROUP B	GROUP BC	P VALUE
	22.1 $\pm$ 5.18	18 $\pm$ 5.41	0.46

S.D (Standard deviation)

There was no statistically significant difference in weight distribution ($P > 0.05$). Hence there is no bias in the weight distribution.

TYPES OF SURGICAL PROCEDURES

The various surgical procedures performed are shown below.

SURGICAL PROCEDURES	GROUP B	GROUP BC
Herniotomy	12	12
Pvsac ligation	5	4
Hypospadias	3	4
Total	20	20

From this table it is clear that the type of surgical procedures between the two groups is not much different. Hence there is no bias in the type of surgical procedures.

DURATION OF ANALGESIA

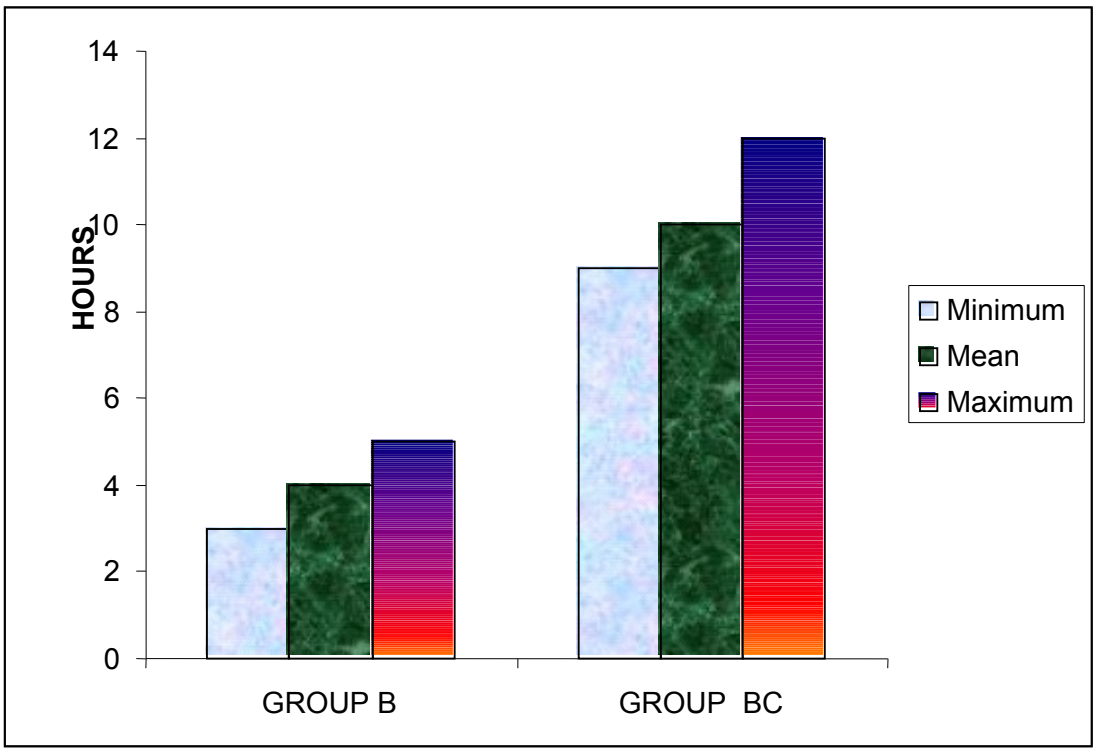
Duration of analgesia in group B (0.25% Bupivacaine) ranged from 3 to 5 hours with a mean duration of 4.3 hours. Duration of analgesia in group BC (0.25% Bupivacaine and 1microgram/kg clonidine) ranged from 9 to 12 hours with a mean duration of 10.2 hours.

DURATION OF ANALGESIA

Mean duration of	GROUP B	GROUP BC	P VALUE
Analgesia in hrs $\pm$ S.D	4.3 ± 0.73	10.2 ± 1.01	0.0001

S.D (Standard deviation)

DURATION OF ANALGESIA



The mean duration of analgesia in group BC is 10.2 hours, whereas in group B it is only about 4.3 hours. This means that group BC has got extended duration of analgesia when compared with group B. This duration of analgesia is also statistically significant as detected by using student 'T' test, by which the probability value is less than 0.05 ($P < 0.0001$). This P value means that it is highly significant.

MEAN HAEMODYNAMIC CHANGES

In both the groups there was no significant change in the heartrate from the base line value, both in the intraoperative and in the postoperative period ($P > 0.05$). Changes in the MAP (Mean arterial pressure) in the both groups did not show any marked deviation from the base line ($P > 0.05$).

Mean Haemodynamic changes

	Group B Mean heart rate / min	**Group BC Mean heart rate / min**	**P value**
Preoperative	112 ± 8	110 ± 8	0.42
During Intubation	123 ± 9	122 ± 8	0.63
Intra operative	108 ± 6	108 ± 10	0.88
Post operative	98 ± 5	102 ± 8	0.074

Mean Haemodynamic changes

	Group B Mean arterial pressure (mm Hg)	**Group BC Mean arterial pressure (mm Hg)**	**P value**
Preoperative	84 ± 3	83 ± 5	0.55
During Intubation	96 ± 4	95 ± 4	0.85
Intra operative	84 ± 4	84 ± 3	0.58
Post operative	77 ± 5	79 ± 2	0.067

SEDATION

Post operative sedation score was done using RAMSAY SCALE every one hour for first 6 hours and then every 2 hours for next 12 hours. At no time during the study period were the patients deeply sedated requiring Oxygen supplementation. Patients had a sedation score of III, IV as per Ramsay scale in the post operative period. Group BC had more number of patient with a sedation score of III and IV,as per RAMSAY scale, when compared to group B. In both the groups no patient had a sedation score of V or VI.

RAMSAY SEDATION SCORE

	GROUP B	**GROUP BC**
	Number of patients	
I	Nil	Nil
II	12	2
III	6	10
IV	2	8
V	Nil	Nil
VI	Nil	Nil

X. REVIEW OF LITERATURE

Caudal block is a simple and safe technique, which can be routinely adopted in children. This provides effective intraoperative and postoperative analgesia for almost all types of interventions on the lower part of the abdomen and the lowerlimbs, especially in neonates, infants and certain high risk children as per the experience of ARMITAGE EN (11) AND ARTHUR DS (12)

Caudal anaesthesia is usually but not always combined with a light general anaesthesia with Halothane followed by Isoflurane either at the beginning or, sometimes, at the end of surgical procedure. DALENS B, HASNAOUTA (13)

HANNALLAH RS (15) et al conducted a study in children in the age group of 18 months to 12 years scheduled for orchidopexy to evaluate the effectiveness of caudal analgesia and compared it with local nerve blocks. They found that both caudal as well as Ilioinguinal/Iliohypogastric nerve blocks administered following inhaled anaesthesia for orchidopexy are safe and equally effective in controlling post operative pain of children.

GUNTER (16) et al conducted a study on 122 children aged 1 to 8 years scheduled for out patient inguinal herniorhaphy who were randomized to receive, in a double blind fashion, caudal anaesthesia with bupivacaine in one of the six

concentrations (0.125%, 0.15%, 0.175%, 0.2% 0.25% and 0.5%).

After incision a programmed reduction in inspired halothane resulted, if tolerated by the subject. Although all concentrations were effective for combined general caudal anaesthesia in children, they concluded that 0.175% bupivacaine offers the best combination of effectiveness, rapid recovery and discharge for paediatric surgical outpatients without any motor blockade.

In another study by WOLF AR(17) et al on 114 infants and children of age 6 months to 10 years, undergoing elective superficial lower abdominal or genital surgery to find the optimum concentration of bupivacaine for caudal analgesia, concluded that 0.125% bupivacaine with 1 in 2,00,000 adrenaline provided equipotent analgesia and significantly less motor blockade than 0.25% bupivacaine.

LEE (18) et al conducted a randomized double blind study in children underging elective orthopaedic surgery and assessed the clinical value of combining clonidine with bupivacaine for caudal analgesia. Forty six children aged 1 – 10 years were randomly allocated into two groups to receive 0.25% bupivacaine 1 ml/kg alone and 0.25% bupivacaine – clonidine 2microgram/kg mixture. Bupivacaine – Clonidine mixture group required significantly less supplementary analgesia postoperatively. He concluded that the addition of clonidine 2microgram/kg to 0.25% bupivaccaine 1ml/kg

significantly prolonged the duration of caudal analgesia(9.8 hours) compared with that provided by bupivaccaine alone (5.2 hours).

KLIMSCHA (20) evaluated the analgesic efficacy and haemodynamic and respiratory safety of clonidine when added to bupivacaine for caudal blocks in 58 children aged 2 to 3 years coming for hernia repair. Patients were randomly given a caudal injection of 0.75ml/kg of either saline placebo(P group), bupivacaine 0.25% (B group), bupivacaine 0.25% plus epinephrine 1 in 2,00,000 (BE group), bupivacaine 0.25% plus clonidine 1 microgram/kg (BC 1 group) or bupivacaine 0.25% plus clonidine 2 microgram/kg (BC 2 group). The duration of analgesia was significantly longer in BC1 (6 Hours) and BC2 (6 hours). Bradycardia and respiratory depression were not observed. He concluded that clonidine 1 and 2microgram/kg can be safely added to bupivacaine caudal blockade in small children for ambulatory hernia repair to achieve an increased duration of analgesia.

DE KOCK (21) investigated the analgesic potency of epidural clonidine when used as an sole analgesic agent during and after major abdominal surgery in 56 young adult patients. He concluded that epidural clonidine produced dose dependent intraoperative and postoperative analgesia without major side effects.

EISANACH JC (22) et al conducted a randomized study in 280 patients of age 3

to 6 years for infraumbilical surgery at epidural clonidine doses 1-5microgram/kg with 0.125% bupivacaine 1 ml/kg. He concluded that addition of 1-3 microgram/kg clonidine to 0.125% bupivacaine epidurally doubles duration of post operative analgesia compared with bupivacaine alone(6.2hours) But in doses more than 3 microgram/kg clonidine there was haemodynamic depression.

JAMALI(19) et al conducted a randomized double – blind study in 45 paediatric patients aged 1 – 7 years presenting for subumbilical surgery and assessed the efficacy of clonidine as adjunct to bupivacaine for caudal analgesia. Patients were randomly allocated in to three groups of 15 each. one group received 1 ml/kg of 0.25% bupivacaine with epinephrine 1 in 2,00,000 (EG), another group received 1 ml/kg of 0.25% bupivacaine with clonidine 1 microgram/kg (CG) and last group 1 ml/kg of 0.25% bupivacaine alone.

The mean duration of analgesia was longer in the bupivacaine - clonidine mixture group (16hours). He concluded that the duration of postoperative analgesia with caudal bupivacaine was significantly increased by addition of clonidine 1 microgram/kg.

XI. DISCUSSION

The past decade has witnessed many advances in the understanding and treatment of pain in children. Recently regional blocks are being used for pain relief in children. Local anaesthetic agents have been routinely used for regional blocks in children. The use of adjuncts can effectively help in reduction of the dose and an increase in duration of the local anaesthetic agents.

This study was undertaken to assess the efficacy and safety of clonidine with bupivacaine in paediatric patients undergoing lower abdominal surgeries under caudal analgesia. KLIMSCHA.W et al carried out a similar study and concluded that clonidine 1microgram/kg and 2microgram/kg can be safely added to bupivacaine caudal blockade in small children for ambulatory hernia repair to achieve an increased duration of analgesia (median [range]) was (360 [270-360] minutes and 360 [355-360] minutes respectively). The major drawback of their study was the limited time of post operative assessment because of early discharge (6 hours.). In our study, the duration of post operative assessment was 12hours to assess the maximum duration of analgesia provided by clonidine and local anaesthetic combination.

In a study by JAMALI .S et al on the advantage of the use of clonidine in paediatric regional analgesia, the dose of bupivacaine used was 1ml/kg of 0.25%

bupivacaine and duration of analgesia was 16 hours. In the present study however, 0.75 ml/kg of 0.25% bupivacaine was used. The dose of clonidine used was 1microgram/kg and the duration of analgesia was 10.2 hours. This may be explained by the fact that the quality, level and duration of the caudal blockade is depends on the dose, volume and concentration of the injected drugs as per SILVANI, CAMPORESI, AGOSTNO, SALVO study (14). They compared the duration of post operative analgesia in children undergoing hypospadiasis repair when two different volumes and concentrations of fixed doses of ropivaccaine were used. They concluded that high volume low concentration regimen produces prolonged analgesia as compared to low volume high concentration regimen.

LEE .JJ et al in their study used clonidine in the doses of 2microgram/kg in children undergoing orthopaedic surgery and found significant prolongation of analgesia (9.8 hours) as compared to bupivacaine (5.2 hours). However, when compared to the present study, there is no added advantage of increasing the dose of clonidine to 2microgram/kg from 1microgram/kg, because there is no marked increase in the duration of analgesia in the two studies. In our study, the dose of clonidine used was 1microgram/kg with 0.75ml/kg of 0.25% bupivaccaine in children undergoing superficial infraumblical surgeries and the duration of analgesia was 10.2 hours. This may be due to the different type of surgical procedures in both the studies.In the LEE JJ et al study,the patient have undergone orthopedic surgery which requires more analgesia

when compared to superficial infra umbilical surgeries done in our study.

EISENACH et al found hypotension and bradycardia as the most common side effect with caudal clonidine in a dose dependant manner, the incidence being less with 1microgram/kg.This study confirms the finding of haemodynamic changes as shown by other workers. There was no significant decrease in heart rate, respiratory rate and blood pressure from the baseline with the use of clonidine in a dose of 1microgram/kg with bupivacaine in caudal epidural analgesia.

There was no significant sedation in the post operative period leading to respiratory depression. The sedation score was either IV or less as per RAMSAY SCALE in all patients. KLIMSCHA et al have shown in their study that the sedation score was lower in the group who were administered clonidine 1microgram/kg as compared to clonidine 2 microgram/kg.

LEE et al have also confirmed significantly longer sedation when clonidine 2 microgram/kg was used. At no time in this study, was there a decrease in respiratory rate and fall in oxygen saturation (SpO_2) requiring oxygen supplementation. The findings of the present study are consistent with the findings of JAMALI et al who found no significant sedation with clonidine in the doses of 1microgram/kg.

XII. SUMMARY

In a randomized double blind study, we have examined the analgesic efficacy of caudal bupivacaine alone or a mixture of bupivacaine – clonidine in forty children (ASA I,II) aged 2 to 8 years undergoing lower abdominal surgeries. They were randomly allocated into two groups (n-20) to receive a caudal injection of 0.25% bupivacaine alone or a mixture of 0.25% bupivacaine with 1 microgram/kg clonidine. Monitoring of scores for pain and sedation were performed by anaesthesiologists blinded to the study allocations. Time to the first analgesic administration (Syrup paracetamol) was longer ($p<0.05$) with mean duration of analgesia of 10.2 hours in the bupivacaine – clonidine group than in the bupivacaine only group (mean duration of 4.3 hours). In both the groups, there was no significant change in the heart rate and mean arterial pressure from the baseline value, both in the intraoperative and in the postoperative period ($p>0.05$). Though group BC (bupivacaine with clonidine) had significant sedation score as compared to group B (bupivacaine), at no time during the study period, were the patients deeply sedated requiring oxygen supplementation.

XIII.CONCLUSION

This study concludes that the addition of clonidine in the doses of 1microgram/kg to 0.75ml/kg of 0.25% bupivacaine for caudal blockade significantly prolongs the duration of analgesia in pediatric patients.

This dose is safe for use in pediatric patients without any additional risk.

XIV. BIBLIOGRAPHY

[1]. **BERNARD DALENS.** Regional anaesthesia in infants, children and adolescents 1995 - 1st edition – page 171.

[2]. **MCGOWN RG.** Caudal analgesia in children: Five hundred cases for procedure below the diaphragm. Anaesthesia 1982; 37: 808-819.

[3]. **BROADMAN LM, HANNALLAH RS, NORDEN DM** et al. "KIDDIE CAUDALS"; experiences with 1154 consecutive cases without complications. Anaesthesia Analgesia 1987; 66: s191.

[4] **SPIEGEL P.** caudal anesthesia in pediatric surgery: A preliminary report. Anaesthesia Analgesia 1962; 41:218-221.

[5] **ARMITAGE EN.** Regional anaesthesia in paediatrics. Clinical Anaesthesiology. 1985: 3;553-568.

[6] **BROWN TCK, FISK GC**. Authors. Textbook of anaesthesia for children with a section on intensive care. 2 nd edition. Oxford: Blackwell scientific publications, 1992.

[7] **BEYER JE, WELLS N :** The assessment of pain in children. Pediatric clinics in North America 1989 : 36 , 837.

[8] **WONG DL , BAKER CM :** Pain in children : Comparison of assessment scales. Paediatric Nursing 1988: 14, 9.

[9]. **DAIVA BEIRI, ROBERT A .REEVE, CHAMPION GD, LOUISE ADDICOAT, JOHN B. ZIEGLER**. Faces pain scale for self assessment of the severity of pain experienced by children. Pain 1990; 41:139-150.

[10] **MCGRATH PJ, JOHNSON G, GOODMAN JT, SCHILLENGER J, DUNN J, CHEPMEN J, CHEOPS.** A behavioural scale for rating postoperative pain experienced by children. Advances in pain research and therapy. Vol 9, Newyork Raven 1985; 395-402.

[11] **ARMITAGE EN.** Caudal Block in Children. Anaesthesia 1979; 34:396-398.

[12].**ARTHUR DS**. Caudal anaesthesia in infants and neonates. Anaesthesia 1980:35:1136-1137.

[13] **DALENS B, HASNAOUI A**. Caudal anaesthesia in paediatric surgery. Success rate and adverse effects in 750 consecutive patients. Anaesthesia Analgesia 1989;

68:83-89.

[14] **SILVANI,CAMPORESI,AGOSTINO,SALVO** evaluated quality and duration of caudal block against the volume of the local anaesthetic applied.Minerva anestesiol 2006 Jun 72(6):453-9

[15] **HANALLAH RS, BROADMAN LM, BELLMAN AB.** Comparison of caudal and Ilioinguinal /Iliohypogastric nerve blocks for control of post orchiopexy pain in pediatric ambulatory surgery. Anaesthesiology 1987; 66:832-834.

[16] **GUNTER , DUNN CM , BENNIE JB, PENTECOST LD, BOWER RJ, TERNBERG JL.** Optimum concentration of bupivacaine for combined caudal general anaesthesia. Anaesthesiology 1991:75;57-61.

[17] **WOLF AR, VALLEY RO, FEER OW.** Optimum concentration of bupivacaine for caudal analgesia. Anaesthesiology. 1988; 69:102-106

[18] **LEE JJ. RUBIN AP.** Comparison of Bupivacaine – clonidine mixture with plain Bupivacaine for caudal analgesia in children. Br.J. Anesthesia 1994 : 72(3) : 258 – 262.

[19] **JAMALI.S, MONIN.S, NEGON.C.** et al. Clonidine in paediatric caudal anesthesia. Anaesthesia Analgesia 1194 : 78(4) : 663 – 666.

[20] **KLIMSCHA.W, CHIAIRI.A** et al : The efficacy and safety of clonidine / Bupivacaine combination in caudal blockade for paediatric hernia repair.

[21] **DE KOCK.M, PALOPOULOU.A** et al. Epidural clonidine (or) Bupivacaine for intra and postop analgesia. Anaesthesia 1997 : 86 : 285 – 292.

[22] **EISANACH JC, DE KOCK M, KLIMSCHA W.** Alpha 2 adrenergic for regional anaesthesia ; a clinical review of clonidine (1984 – 85). Anaesthesia 1996 ; 85 : 665 – 674.

[23] **BROMAGE PR.** Aging and epidural dose requirements. British journal of anaesthesia 1969; 41 : 1016 – 1022.

[24] **RICE LJ, PUDIMAT MA, HANALLAH RS.**Timing of caudal block placement in relation to surgery does not affect duration of postoperative analgesia in paediatric ambulatory patients. Canadian Journal of Anaesthesia 1990:37:429-431.

[25] **BROWN TCK, FISK GC**. Authors. Textbook of anaesthesia for children with a section on intensive care. 2 nd edition. Oxford: Blackwell scientific publications, 1992.

[26] **AITKEN RCB :** A growing edge of measurement of feelings. Proc R soc Med 62: 989 – 993,1969.

[27] **ALDRETE JA** : The post anaesthesia recovery score . J clin anesth 7:89;1995.

[28] **HANALLAH RS.** Postoperative analgesia in the pediatric patient. Canadian Journal of Anaesthesia 1992; 39:649-654.

[29] **ARMANDO FORTUNA**. Caudal Anaesthesia . A simple and safe technique in paediatric surgery. British Journal Of Anaesthesia 1967; 39:165-170.

[30] **JENSEN BH** Caudal block for postoperative pain relief in children after genital operations. Acta anaesthesiologica scandinavica 1981;25:373-37.

XV.PROFORMA

NAME AGE SEX WT IPNO

ASA PHYSICAL STATUS:

HISTORY

PR BP CVS RS

OTHERS

INVESTIGATIONS

HB% TC DC

BLOOD GP&Rh typing OTHERS

DIAGNOSIS

SURGICAL PROCEDURE :

CAUDAL ADMINISTRATION

TIME

DRUG

VOLUME

SEDATION SCORE

ALDRETES SCORING

DURATION OF ANALGESIA

RESCUE ANALGESIC DRUG USED

COMPLICATIONS

- DROWSINESS
- HYPOTENSION
- BRADYCARDIA

XVI.MASTERCHARTS

GROUP B

No	Name	Age Yrs	Sex	Wt Kgs	Duration of analgesia Hrs
1.	Rajbabu	3	M	15	4
2.	Prasanth	3	M	16	4
3.	Viknesh	3	M	17	3
4.	Abirami	3	F	18	4
5.	Priyadarshini	3	F	17	5
6.	Chitra	4	F	21	4
7.	Ezhilarasan	4	M	25	3
8.	Omprakash	4	M	17	5
9.	Vishnu	4	M	12	5
10.	Muthukumar	5	M	24	4
11.	Jagadesh	5	M	26	4
12.	Praveen	5	M	23	5
13.	Valli	5	F	28	5
14.	Kamatchi	6	F	28	5
15.	Lakshmi	6	F	25	4
16.	Ajith	6	M	26	5
17.	Praveen	6	M	16	3
18.	Prakash	7	M	28	5
19.	Sanjay	7	M	25	5
20.	Nirmala	7	M	27	4
Total					86
Mean					4.3

GROUP BC

No	Name	Age Yrs	Sex	Wt Kgs	Duration of analgesia Hrs
1.	Prathap	3	M	15	10
2.	Vijay	3	M	10	12
3.	Srinivasan	3	M	11	11
4.	Abisek	3	M	14	10
5.	Surendar	3	M	10	10
6.	Senthikumar	4	M	13	9
7	Srimathy	4	F	13	10
8.	Abirami	4	F	20	12
9.	Mani	5	M	23	10
10.	Iswarya	5	F	15	11
11.	Prasad	6	M	18	10
12.	Manikandan	6	M	18	12
13.	Bhuvaneshwari	6	F	15	9
14.	Iniyan	6	M	18	9
15.	Chandru	7	M	25	9
16.	Kathiravan	7	M	24	9
17.	Parthiban	7	M	25	10
18.	Saran	7	M	25	10
19.	Saranya	7	F	25	9
20.	Archana	7	F	23	11
Total					204
Mean					10.2