"A COMPARISON OF EFFICACY OF ULTRASOUND GUIDED VERSUS TRADITIONAL APPROACH FOR CAUDAL EPIDURAL ANAESTHESIA IN PAEDIATRIC PATIENTS- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL.".

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ENDORSEMENT

This is to certify that the dissertation entitled **"A COMPARISON OF EFFICACY OF ULTRASOUND GUIDED VERSUS TRADITIONAL APPROACH FOR CAUDAL EPIDURAL ANAESTHESIA IN PAEDIATRIC PATIENTS"- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL''** is a bonafide research work done by **REG NO. BA0115001.**

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LIST OF ABBREVIATIONS USED

ASA	-	American Society of Anaesthesiologists
CNS	-	Central nervous system
CVS	-	Cardiovascular system
GA	-	General anaesthesia
RA	-	Regional anaesthesia
HR	-	Heart rate
bpm	-	Beats per minute
I.V.	-	Intravenous
LA	-	Local anaesthetic
kg	-	Kilogram
mg	-	Milligram
v/s	-	Versus
Min	-	Minutes
ml	-	Millilitre
NIBP	-	Non invasive blood pressure
O_2	-	Oxygen
S	-	Sacral
SD	-	Standard deviation
SpO_2	-	Peripheral saturation of oxygen
V_E	-	Minute ventilation
PSIS	-	Posterior Superior Iliac Spine
Hb	-	Haemoglobin

ABSTRACT

Background and objective:

Caudal anaesthesia is the most frequently performed regional anaesthetic technique in children. In the traditional method location of caudal epidural space is difficult and the puncture attempts needed are also more. Ultrasound can help to identify the caudal epidural space precisely, with lesser number of punctures and fewer complications. This randomized controlled trial was done to evaluate the efficacy of ultrasound guided versus traditional method of caudal block in paediatric age group.

Methods:

70 ASA I–II children undergoing elective infraumbilical surgeries under caudal epidural block were randomly allocated to one of the two groups – traditional method and whoosh test (group A) or ultrasound guided caudal block (group B). Success rate of block, puncture frequency, complications were analysed. A p value of < 0.05 was considered significant.

Results:

The success rate of block was similar between two groups (31of 35 children in group A vs 35 of 35 in group B, $p=0.12$). The first puncture success rate was higher in group B than in group A (33 of 35 vs 10 of 35 respectively $p<0.05$). Second attempt was required in 20 of 35 patients in Group A as compared to 2 of 35 patients in Group B. In group A, 5 patients required third attempt while none in Group B required more than two attempts. None of the complications like bloody puncture, dural puncture, subcutaneous bulging were noted in either group.

Conclusion:

Ultrasound can be used as an adjuvant tool in performing caudal epidural block as it provides real-time images in guiding the needle into the caudal epidural space with fewer complications and lesser number of punctures with higher success rate as compared to traditional method of caudal block and whoosh test.

Keywords – caudal, regional, traditional, whoosh, ultrasound, children

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INTRODUCTION

"Pain is inevitable, suffering is optional"

"Divine is the task to relieve pain''– Hippocrates

Caudal anaesthesia is the most frequently used regional anaesthetic technique in paediatric patients[1].Caudal epidural anaesthesia involves the injection of local anaesthetics into the epidural space through the sacral hiatus[2]. It serves as an important tool in controlling painand also for the anaesthetic management in children undergoing surgical procedures below the umbilicus[1].

Successful caudal blockade mainly depends upon the correct placement of needle in the caudal space[3].It benefits the patient by decreasing the intraoperative use of volatile anaesthetic agents and narcotics with less postoperative nausea and vomiting[1].

In the traditional caudal epidural technique, the needle is inserted at right angle to the skin surface until the sacrococcygeal ligament is pierced with the characteristic "give away'' or "pop".The needle is then lowered to 20-30 degree and advanced 2-3mm further into the sacral canal[4].

The risk of inadvertent dural or vascular puncture is more in paediatric age group as sacral hiatus is small and shallow in the conventional technique. To insert the needle correctly into the sacral canal with anatomic variationswill also be difficult sometimes[4].

The use of ultrasound in regional anaesthesia is being increasingly used in adult and paediatric patients recently[1]. Chances of bony ossification in children are less as compared to adults. Ultrasound imaging helps to delineate sacral and caudal anatomy. It also helps in guiding of caudal needle insertion and to visualize the caudal injectate[5]. Hence ultrasound serves as an important tool in caudal epidural blocks specially in children[1].

In the traditional method location of caudal epidural space is difficult and the number of punctures required are also more.Ultrasound helps in identifying the caudal epidural space accurately and with less number of punctures so will be beneficial in terms of accuracy and decrease in the incidence of complications.

The earlier studies done used ultrasound either to determine the optimal angle for needle insertion during caudal block or to visualise the cranial spread after caudal injectate but direct study comparing the efficacy of traditional method and ultrasound guided caudal block in children are lacking.

Hence we undertook the study to compare the success rate of block, puncture frequency and associated complications of ultrasound guided with traditional method for caudal epidural anaesthesia in paediatric patients aged 1-11 years.

OBJECTIVES

The objectives of the present study were:

Primary Objective: To compare the success rate of block and puncture frequency of ultrasound guided with traditional method for caudal epidural anaesthesia in paediatric patients aged 1-11 years.

Secondary objective: To study and evaluate associated complications of ultrasound guided with traditional method for caudal epidural anaesthesia in paediatric patients aged 1-11 years.

REVIEW OF LITERATURE

The history of epidural anaesthesia goes way back to 1901, when two French clinicians Jean. E. Sicard and Fernand Cathelin working independently injected cocaine through the sacral hiatus thus pioneering caudal epidural block. Sicard applied the technique purely for nonsurgical purpose of pain relief in patients with sciatica and tabes. However, Cathelin used the technique for surgical anaesthesia, considering it to be a safer alternative to spinal anaesthesia for inguinal hernia repair.[6]

The caudal block thus given was found to be adequate for perineal surgeries. In 1909 Stoeckel used caudal block in obstetrics whereas Lawen used in surgery. The next significant advance came when Hingson and Edwards adapted the continuous spinal analgesia technique of Lemmon to caudal method. They demonstrated that the level of spinal segment block through the caudal approach could be raised by increasing the volume of injected solution[7].

In 1943 Adams, Lundy and Seldon proposed the use of ureteral catheter for continuous caudal anaesthesia whereas continuous drop method was introduced by Bloch[7].

In the year 2012, a study was conducted by Zhonghua YX, Liu JZ, Wu XQ, Li R to compare ultrasound imaging and classic method of surface landmarks and whoosh test for identification of caudal epidural space. 102 American Society of Anesthesiologists (ASA) I–II pediatric patients aged from 1 month to 8 years scheduled for urologic or perineal surgery were included. Patients were randomly assigned into 2 groups- ultrasound group (n=52) and control group (n=50). Sacral cornua and sacral hiatus sites were determined by ultrasonic imaging or classic method of anatomical surface landmarks. Caudal puncture was made in the patients of both groups. After the caudal puncture was successful local anesthetic was injected slowly into caudal space. The positive reaction in caudal space was monitored simultaneously by ultrasound and classic swoosh test. In ultrasound and control groups, the number of puncture attempts was 1.10±0.30 vs 1.56±0.63.The duration of puncture (1.40±0.39)vs(3.23±1.23)min, the success rate at the first puncture attempt 90.4%vs 66% and the total puncture success rate 100%vs 92% respectively. After the injection of local anesthetic, the positive rate of sacral needle insertion of ultrasonography and whoosh test were 97.96%vs 62.24% respectively[8].

The results in ultrasound group were superior than those in control group or with classic test and the difference had statistical significance (P<0.01). Hence they concluded that Ultrasonic positioning and monitoring for pediatric caudal block was both scientific, reasonable and accurate. It is superior to traditional method and has clinical application values for caudal block in children[8].

Another study was conducted by Raghunathan, Schwartz D, Connelly NR in 2008 to determine the accuracy of needle placement in the caudal space in children by whoosh test and ultrasonography. It was a retrospective observational study of caudal injections administered to 83 pediatric patients (0–11 years) admitted for elective surgery over a 4 month time period. While injecting the local anesthetic, a standard stethoscope was placed over the lower lumbar spine to auscultate for the ‘swoosh’ test. An ultrasound machine was used for real-time visualization of caudal injectate. Each test performed during the caudal injection (swoosh, turbulence on 2D imaging, or color flow on Doppler imaging) was recorded as positive, negative or equivocal. Eighty out of 83 patients (96.4%) had a successful caudal block based on minimal or no perioperative narcotic use, minimal or no response to surgical stimulation, the presence of motor blockade and patient comfort in the PACU. Ultrasound was significantly superior to 'swoosh' for sensitivity (96.3% vs 57.5%), negative predictive (40% vs 5.6 value) % and likelihood ratio (2.89 vs 1.73). Specificity and positive predictive value were not different between 'swoosh' and ultrasound. Amongst the ultrasound tests, turbulence was more sensitive than color flow Doppler (95.0% vs 78.8%). Hence it was concluded that ultrasonography is superior to the 'swoosh' test as an objective confirmatory technique during caudal block placement in children and the presence or absence of turbulence during injection within the caudal space to be the best single indicator of caudal success[5].

Another study was done by Zhang YF, Wang LZ, Chang XY, Xiao XH in 2013 to compare caudal block by sacral hiatus injection under ultrasound guidance with traditional sacral canal injection. 140 ASA I–II children undergoing inguinal hernia repair were randomly assigned to one of the two groups (Group C or Group H, n = 70). 1 ml/ kg of 0.25% ropivacaine was injected after the needle was inserted into the sacral canal in Group C, or after the needle pierced the sacrococcygeal ligament under a transverse ultrasound view in Group H. Success rate of block, puncture frequency, complications, and durations of block were recorded. The success rate of block was similar between two groups (95.7% in Group C vs 92.8% in Group H, $P > 0.05$). The first puncture success rate was higher, and the durations of block were shorter in Group H than in Group C (92.8% vs 60% and 145±23s vs 164±31s, respectively $P<0.05$). Incidence of bloody puncture was 18.6% in Group C and 5.7% in Group H ($P<0.05$). Subcutaneous bulging occurred in six patients (7.1%) in Group C but none in Group H ($P<0.05$). Hence Sacral hiatus injection under ultrasound guidance provided a reliable caudal block for pediatric inguinal hernia repair with the advantages of easier performance and fewer complications compared with traditional sacral canal injection[4].

A study was conducted by Carl PC, Chen MD, Simon FT, Tang MD in 2004 to investigate the feasibility of using ultrasound as an image tool to locate the sacral hiatus accurately for caudal epidural injections. 70 patients (39 male and 31 female patients) with low back pain and sciatica were included. Sacral hiatus was located using soft tissue ultrasonography. Under ultrasound guidance a 21-gauge caudal epidural needle was inserted into the sacral hiatus and then into caudal epidural space. Proper needle placement was confirmed by fluoroscopy. In all the study patients, the sacral hiatus was located accurately by ultrasound. Also the caudal epidural needle was guided successfully to the caudal epidural space through the sacral hiatus. 100% accuracy was seen in placement of caudal epidural needle into the caudal epidural space under ultrasound guidance which was in turn confirmed by contrast dye fluoroscopy. Hence, they concluded that ultrasound is radiation free, easy to use, and provides real-time images in guiding the caudal epidural needle into the caudal epidural space. Ultrasound may therefore be used as an adjuvant tool in caudal needle placement[2].

Triffterer L et al (2012) conducted a study where Ultrasound assessment of cranial spread during caudal blockade in children in relation to the effect of the speed of injection of local anaesthetics. 50 ASAI–II infants and children aged upto 6yr weighingupto25kgundergoing subumbilical surgery were included. Caudal blockade was performed under ultrasound observation using ropivacaine 1 ml /kg 0.2% or 0.35% and an injection was given at either 0.25 ml s or 0.5 ml s, respectively. Local anaesthetic flow and the extent of cranial spread was possible in all the patients under ultrasound guidance. All caudal blocks were considered successful, and all surgical procedures could be completed without any indications of insufficient analgesia. No statistically significant difference was observed between the two injection speeds regarding the cranial spread of the local anaesthetic in the epidural space. The significant finding was that the speed of injection of the local anaesthetic does not affect its cranial spread during caudal blockade in infants and children. Therefore, the prediction of the cranial spread of the local anaesthetic, depending on the injection speed, is not possible using ultrasound guidance[9].

Another study conducted by Galante D. Gaur A. Ahmed A., Pedrotti D (2014) where comparison between manual palpation versus ultrasound method to identify the sacrococcygeal hiatus for caudal block in infants was done. 50 pediatric patients aged 0 to 1 years undergoing caudal anesthesia for genitourinary and abdominal surgery were recruited. The landmark palpation method was used for each patient to determine the sacrococcygeal hiatus and the sacral cornuas. Once the space was identified an ultrasound scanning over the sacral area was performed as a different method to identify the exact point at which the needle has to be inserted to perform the anesthetic block. The proportion of inaccurate measurements were compared and the inaccurate measurement was defined as the overcoming of 0.5 mm from the correct anatomical position of the center point of the sacral hiatus. 42% of measurements by the landmark palpation method were inaccurate by ≥ 0.7 mm respect to the exact point. 28% of measurements performed by ultrasound method were inaccurate by ≥ 0.5 mm. This observational study demonstrated that no significant differences were recorded using both the landmark palpation or ultrasound methods[10].

A study conducted by Mahshid N (2014) et al to use ultrasound as a screening tool for performing caudal epidural injections. Two hundred and forty patients (male = 100, female = 140) with low back pain and sciatica who were candidates for caudal epidural injection were enrolled. Linear array ultrasound transducer was used to get the ultrasound images of the sacral hiatus and bilateral cornua. The distance between bilateral cornua and the anterior and posterior wall of the sacrum were measured at the base (sacral hiatus). Under the ultrasound guidance, they defined the injection as successful if turbulence of medication fluid was observed in the sacral canal, but correct placement of the needle and injectant was confirmed on fluoroscopic view as the gold standard technique. The epidurogram showed that the injection was successful in 230 of the 240 patients (95.8%). In eight patients, the injection was not in the correct place in the sacral canal. The sacral hiatus was closed in two patients hence it was not identified by ultrasound which inturn was identified by fluoroscopy. The mean distance of the sacral hiatus was 4.7 ± 1.7 mm and the mean distance between bilateral cornua was 18.0 ± 2.8 mm. The mean duration of the procedure was 10.8 ± 6.8 minutes. No major complication was observed in the next month. In conclusion, ultrasound could be used as a safe, fast and reliable modality to observe the anatomical variation of the sacral hiatus and to perform caudal epidural injections[11].

L. Brenner et al conducted a study in 2011where the cranial spread of different volumes of caudally administered local anaesthetics in children were evaluated using ultrasound. Seventy-five children aged 1 month to 6 yr who underwent inguinal hernia repair or more distal surgery were included. They were randomized to receive a caudal block with 0.7, 1.0, or 1.3 ml/kg ropivacaine. Ultrasound was used to assess the cranial spread of the local anaesthetic within the spinal canal. The absolute cranial segmental level and the cranial level relative to the conus medullaris were determined. All the blocks performed were clinically successful. A significant correlation was found between the injected volume and the cranial level reached by the local anaesthetic as assessed by ultrasound. But the dermatomal difference in cranial spread in the volume range 0.7 – 1.3 ml/kg was negligible. This along with observed variability did not allow for any clinically useful prediction of cranial block level based on injected volume[12].

A study conducted by Abukawa Y et al in 2015 where ultrasound versus anatomical landmarks for caudal epidural anesthesia in pediatric patients was compared. Under general anesthesia they evaluated increase in the distance between the bilateral superolateral sacral crests as the child grows, whether an equilateral triangle could be formed between the apex of the sacral hiatus and the bilateral superolateral sacral crests, and whether ultrasound could confirm the expansion of the epidural space. 282 ASA I–II children were included. All children were placed in the lateral bent knee position under general anesthesia. Anaesthetist drew an equilateral triangle and measured the distance between the bilateral superolateral sacral crests along a line forming the base of the triangle. Later sacral hiatus was identified by ultrasound. Differences of the distance between the anatomical landmarks measured by the anesthetist and by ultrasound were assessed[13]. Superolateral sacral crests and sacral hiatus could not be palpated in 2 patients hence they were excluded. The base of the triangle proportionally increased in relation to age up to 10 years old, with a significant correlation between age and the length of the base (Spearman's r value=0.97). Below 7 years of age the triangle was not equilateral. The sacral hiatus was identified by ultrasound and expansion of the epidural space was confirmed in all patients. Hence they concluded that performing ultrasound is important though detection of the anatomical landmarks by palpation differed from identification by ultrasound in pediatric patients[13].

Another study conducted by Park JH et al in 2006 for determining the optimal angle for needle insertion during caudal block in children using ultrasound imaging. 130 children aged 2–84 months were included in the study. Children were positioned in lateral position after giving general anaesthesia and ultrasonography was performed at the sacral hiatus. The median [range] values for the intercornual, caudal space depth and the distance from skin to the posterior sacral bony surface were 17.0 [9.6–24] mm, 3.5 [1–8] mm and 21.0 [10–39] mm, respectively. No significant correlation was seen with the optimal angle and age, weight, height or body surface area. The median [range] calculated optimal angle for the needle was 21.0 [10–38]. Hence they concluded that the needle should be inserted at about 20 degree to the skin to avoid puncture of the bone and potential intra-osseous injection[3].

BASIC SCIENCES

Applied Anatomy of caudal block[14-19]

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

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

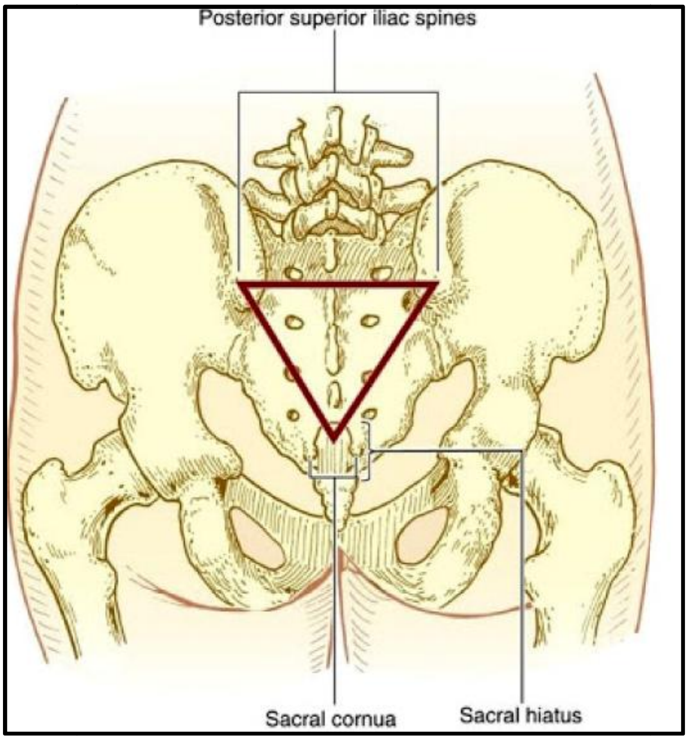


Fig 1- Landmarks of sacral hiatus

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

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

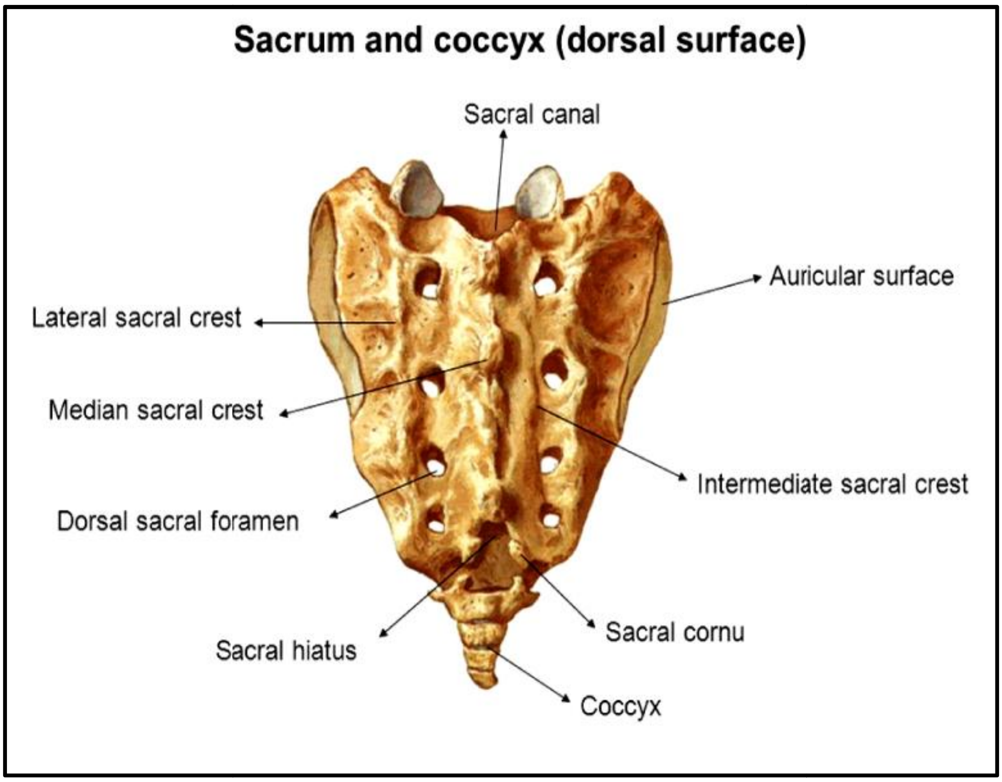


Fig 2 – Dorsal surface of Sacrum and Coccyx

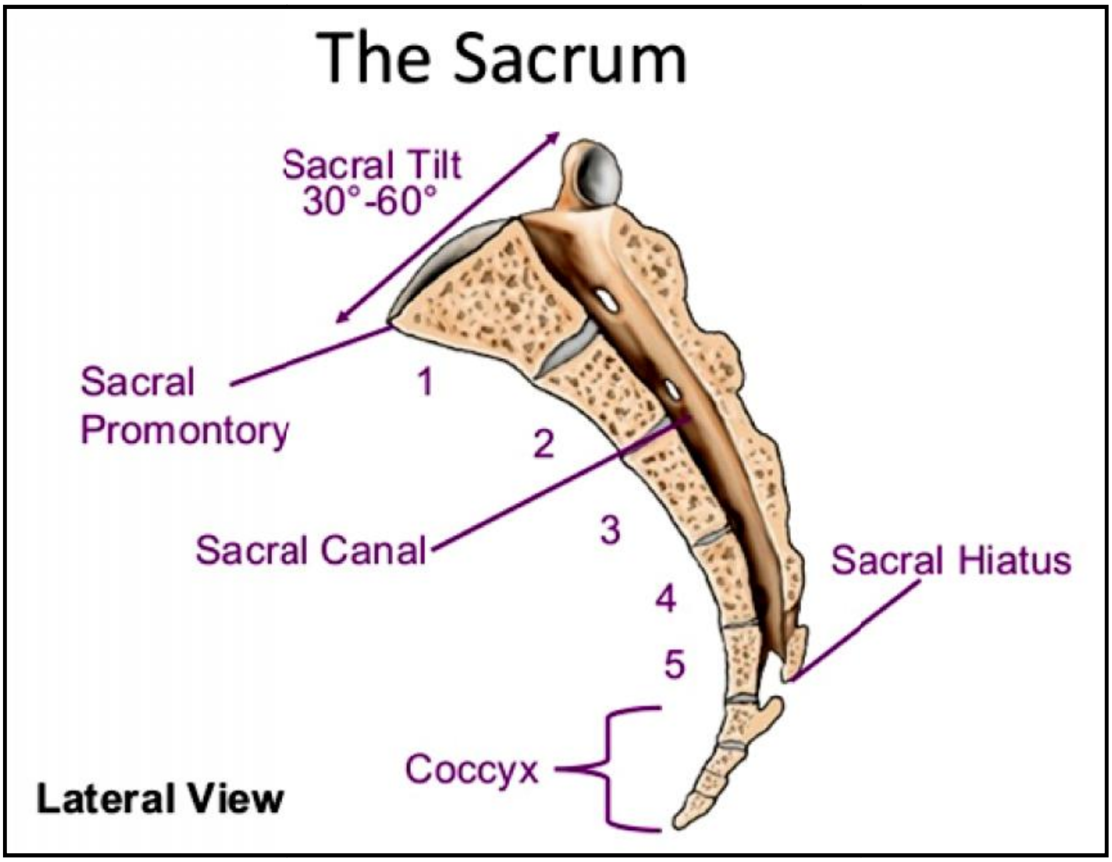


Fig 3 – Lateral View of Sacrum

The mean distance between the apex of the hiatus and the dural sac is 47mm. Mean distance from skin to anterior sacral wall is 21mm(10 to 39mm) between 2 months and 7 years of age. 25mm needles are long enough to reach the sacral epidural space and short enough to prevent inadvertent dural puncture in most of the patients.

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

Caudal Sonoanatomy[17, 20-22]

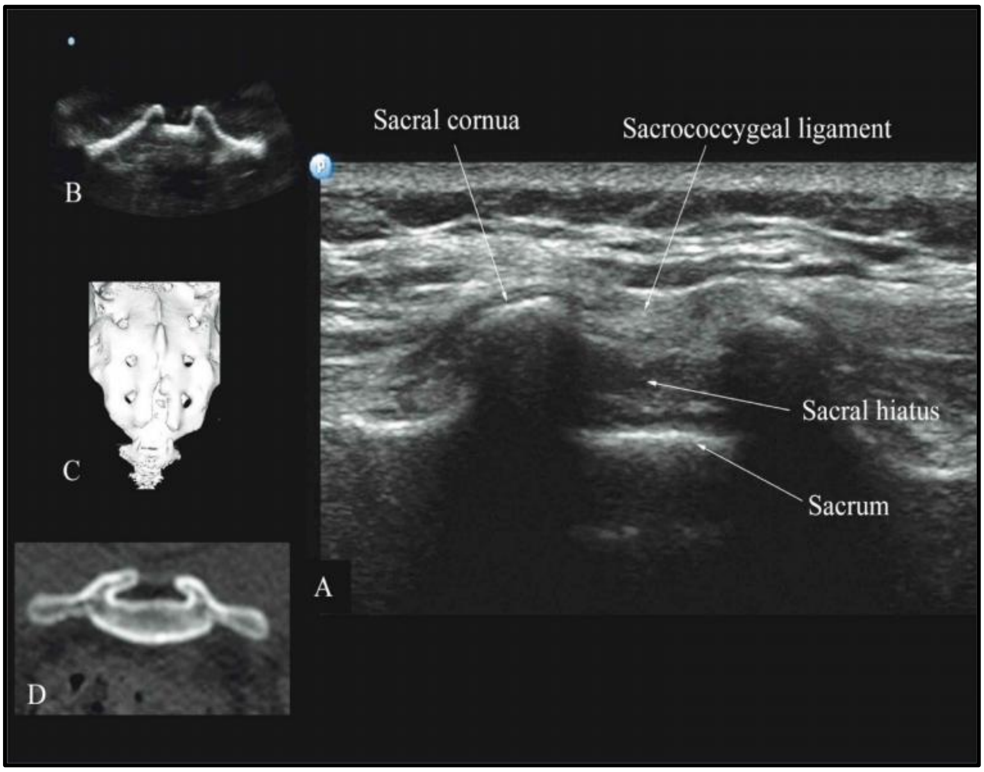
Visualisation of caudal space can be done in two views – transverse and longitudinal. A high frequency linear array transducer (13-6Hz) can be used for the scan.

Transverse view

At the sacral hiatus following structures can be visualised-

1) Two hyperechoic reversed U- shaped structures are the two bony prominences of sacral cornua.
2) Between the two cornua hyperechoic band like structure is the sacrococcygeal ligament. Posterior to the sacrococcygeal ligament is the base of the sacrum.
3) Caudal epidural space is the hypoechoic region observed between the sacrococcygeal ligament and the bony posterior surface of sacrum.

   The two sacral cornua and the posterior surface of sacrum produce a specific pattern on the ultrasonographic view known as '**Frog eye sign'** because of its resemblance to the eyes of the frog.



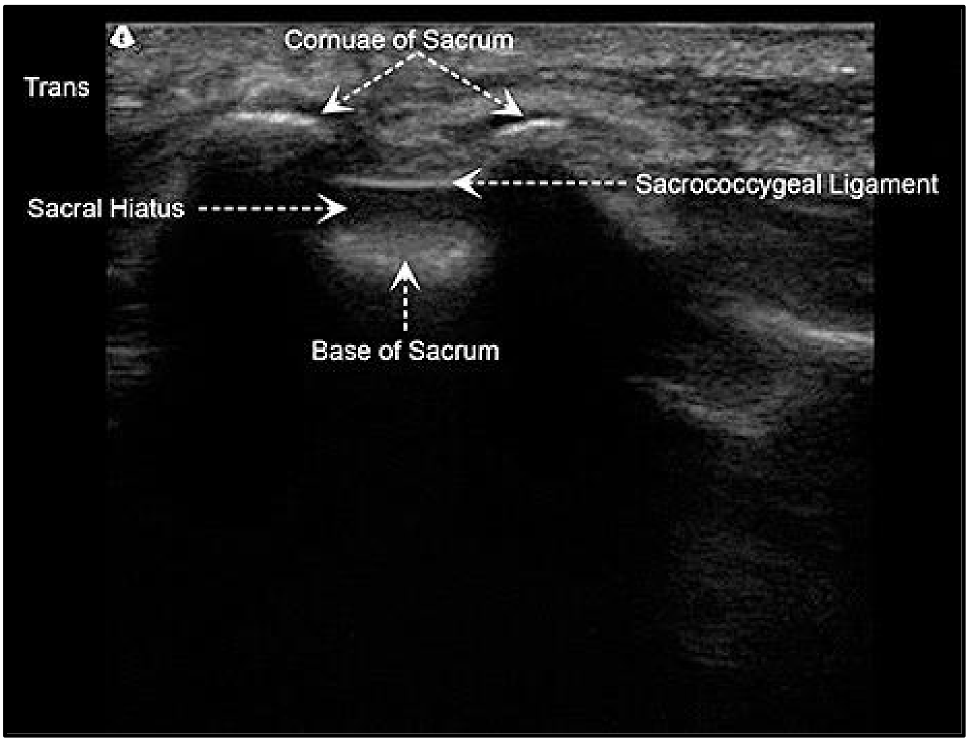


Fig 4 - Transverse view of caudal epidural space

Longitudinal scan

In the longitudinal axis it is possible to visualize the sacral vertebrae, filum terminale, and the termination of dural sac. The filum terminale is a cord like hyperechoic structure surrounded by hyperechoic nerve roots of cauda equina. It is difficult to differentiate filum terminale from the nerve roots because of their similar appearance (hyperechoic strands).

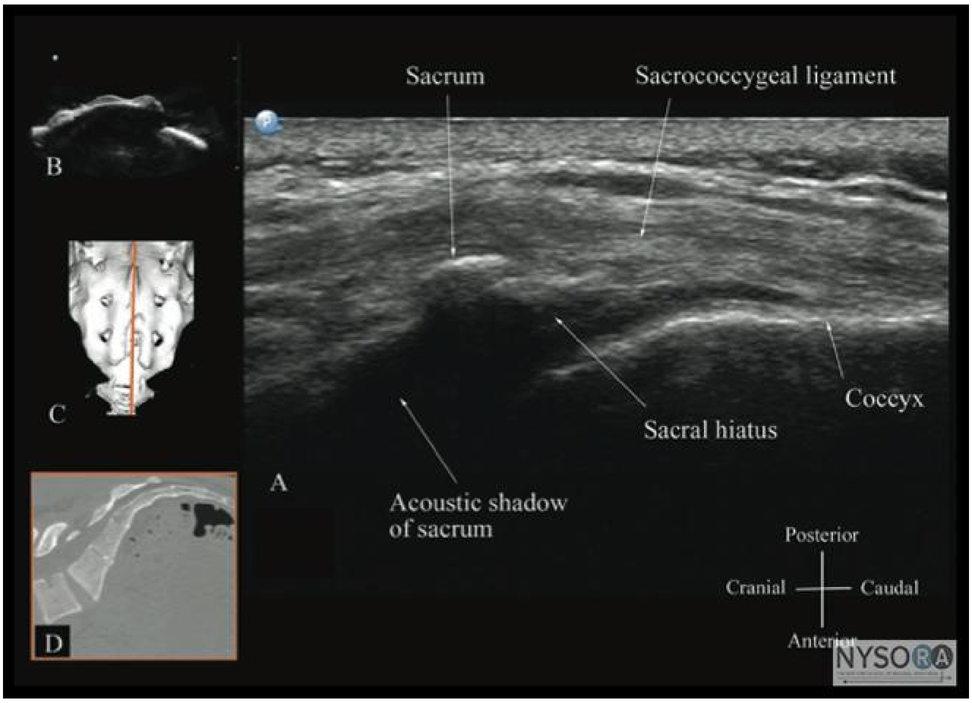


Fig 5 - Longitudinal view of caudal epidural space

Sacral canal and its contents

The sacral canal (caudal canal) is the continuation of the vertebral canal through the sacrum. It is curved and 3-4 inches long. Cross sectionally it is triangular in shape. Laterally it communicates with the anterior and posterior sacral foramina while inferiorly it ends as the sacral hiatus.

Contents –

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

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

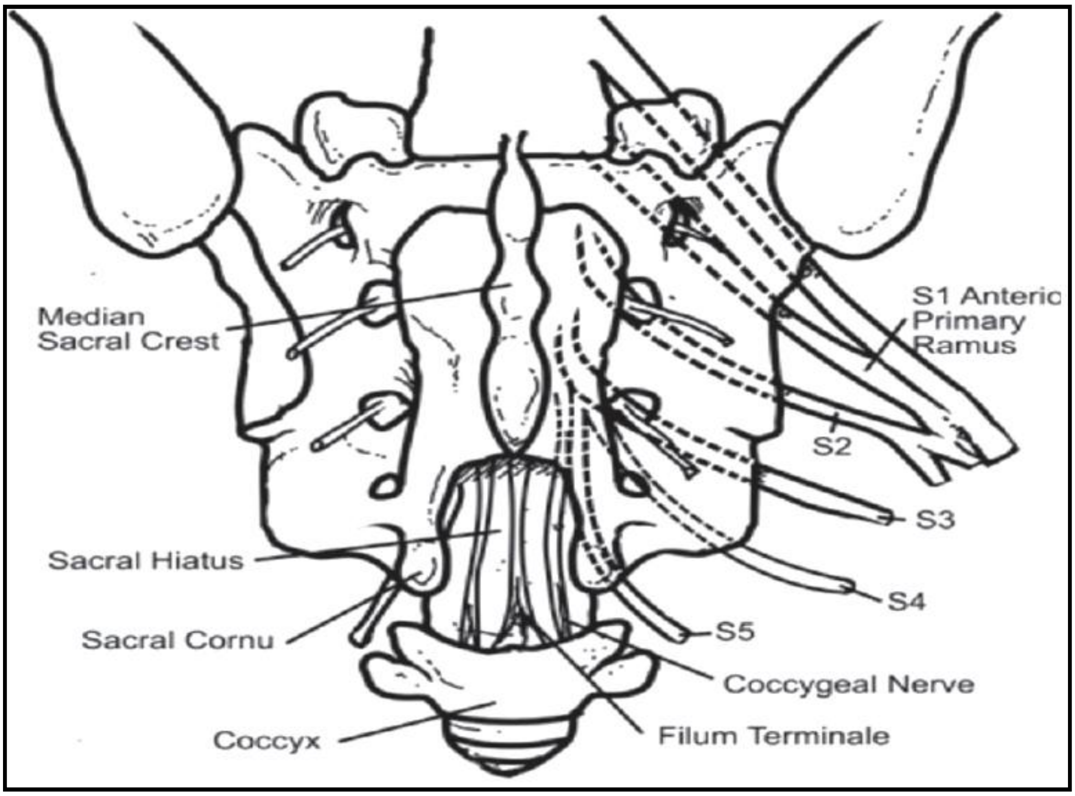


Fig 6- Contents of sacral canal

Anatomical variations of the sacrum and sacral hiatus[23,24]

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

1) In 40% of the population the dural sac was extending below the middle of the second sacral vertebra. In 42% of the population the distance between the apex of the hiatus and the dural sac was less than the mean of 47mm (this distance being important to avoid dural puncture)
2) In 47% of the population the apex of the hiatus was at a level superior to the lower third of the fourth sacral vertebra. In 25% of the population accessory apertures were present in the dorsal wall while agenesis of dorsal wall was seen in 2% of the population.
3) In 5% of the population the anteroposterior diameter of the canal at the apex of the hiatus was less than 2mm. 1-2% of the population showed blocks of the sacral canal lumen.

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

Physiology of caudal block[7,25,26]

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

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

Duration- after single injection of following drugs-

Drugs	Duration
Chlorprocaine2%	45 mins
Procaine 1.5%	1-1.5 hrs
Lidocaine 1.5%	1.25 – 2hrs
Mepivacaine 1.5%	2hrs
Bupivacaine 0.75%	5hrs

In children 0.25% bupivacaine is commonly used.

Effects -

Cardiovascular system – CVS changes are minimal. Fall in Blood pressure are not significant. Slowing of pulse is usually seen.

Effect on respiration – There is significant decrease in respiratory minute ventilation (V_E) and respiratory rate. Mean V_E decreases by 9% and respiratory rate by 16%. Tidal volume and Pa_{o2} remains unchanged. Impairment of resting ventilation is mainly because of afferent and efferent nerve blockade.

GIT – Gastrointestinal tone is increased.

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

The nerve diameter is smaller and has smaller amount of connective tissue compared to adults resulting in shorter onset time and shorter duration of blockade in children. As child grows older the nerve diameter increases with myelination along with more connective tissue in the endoneurium leading to longer onset time with prolonged duration of nerve block as in adults.

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

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

Indications of caudal block

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

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

Contraindications of caudal block

1) Active disease of Central nervous system
2) Infection at the site of caudal block
3) Malformation of lower spine and meninges
4) Coagulopathies and bleeding diathesis

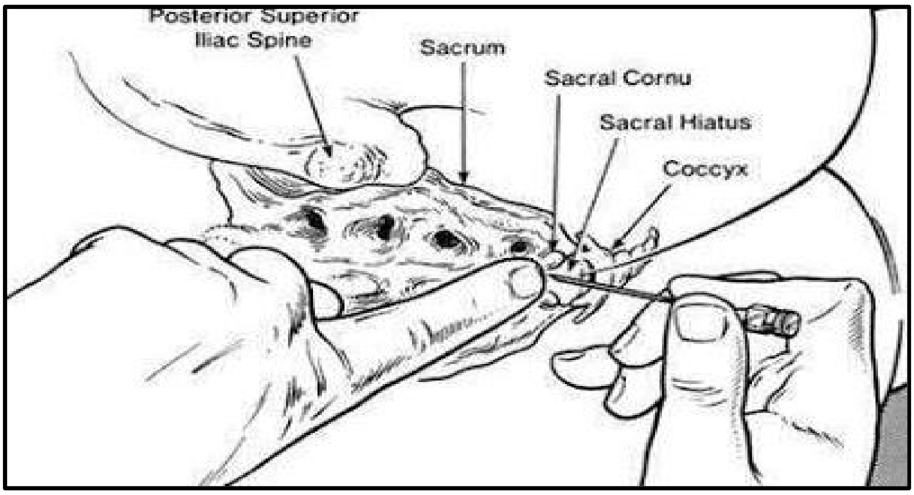
Technique of caudal block[14,25-27]

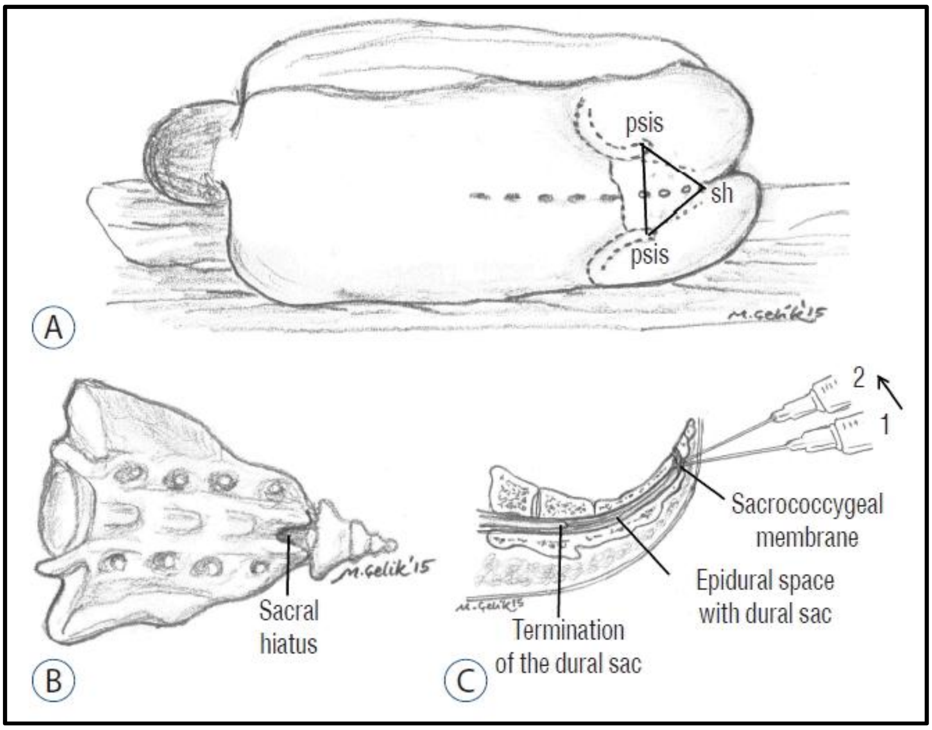
- Caudal block can be performed as a single shot or a continuous caudal by inserting a catheter. Most children will not accept this procedure while awake and hence needs to be sedated or anaesthetised prior to the administration of caudal block.
- All equipments necessary for general anaesthesia must be assembled and checked along with resuscitation equipment, monitors, and suction. Functional IV access has to be taken.
- A short 22- 25 gauge needle with 45 degree short bevel with or without stylet is recommended for caudal block.
- Patient is positioned in the lateral decubitus or Sim's position. It can also be given in prone position.
- Successful caudal block depends on the identification of following bony landmarks-
    1) Posterior superior iliac spines
    2) Sacral cornua
    3) Sacral hiatus between the cornua
- The two posterior superior iliac spines and the sacral hiatus form an equilateral triangle. Sacral hiatus can be palpated as a depression between the two sacral cornua. The exact needle placement and spread of the injected drug increase the efficacy and safety of the regional block.
- Sacral hiatus is then punctured using 22 -23 gauge short bevelled needle. The needle is inserted at an angle of 45-60^{o} to the skin till the characteristic 'give or pop' is felt indicating piercing of sacrococcygeal ligament. The needle is

then lowered to an angle of 15-20º and advanced 2-3mm further into the caudal space.

Signs of correct needle placement

- Feeling of definite pop on piercing the sacrococcygeal ligament.
- Negative aspiration of CSF, blood .
- No subcutaneous bulge or superficial crepitus after rapid injection of anaesthetic solution or air.
- No tissue resistance to injection.
- **Whoosh test –** In this test the stethoscope is placed over midline lowerlumbar spine and the characteristic whoosh sound is heard on injection of 2-3 ml of air via the caudal needle.
- No local pain during injection of solution.





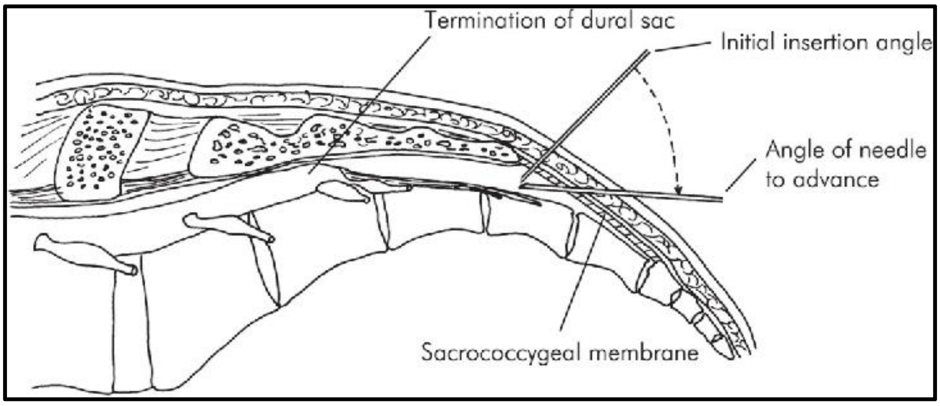


Fig 7 -Technique of caudal epidural block and the needle placement

Dosage calculation for caudal block

Armitage formula[28]

- 0.5 ml/kg for lumbosacral block
- 1 ml/kg for thoraco-lumbar block
- 1.25 ml/kg for mid-thoracic block

Complications

- Inadvertent dural puncture (1.2%)
- Vascular puncture – 0.5%
- Systemic toxicity
- Trauma of spinal cord and roots
- Partial or complete failure of block because of technical error or low dose/volume of drugs
- Interosseous injection caused by piercing the thin layer of cortical bone of sacrum
- Infection (bacterial contamination leading to meningitis, encephalitis, abcess formation)
- Inappropriate level of block (lateralization of block, block level being too high or too low)
- Urinary retention due to blockade of S2-S4 sacral roots
- Others – bleeding with haematoma formation, excessive motor blockade, injury to pelvic viscera, broken needles or catheter, hypotension

Pharmacology

Bupivacaine hydrochloride[28-30]

Bupivacaine hydrochloride belongs to amide group of local anaesthetics. It was synthesized by A F Ekanstam and colleagues in 1957.

Chemical name

1-n-butyl-1-D,L-piperidine-2-carboxylicacid-2,6 dimethylanilide hydrochloride

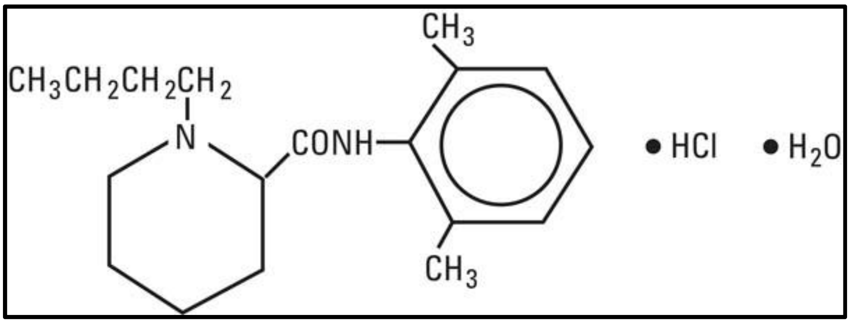


Fig 9-Chemical structure

Physicochemical properties

Molecular weight **–** 325g/mol (chloride salt), 288g/mol (base form)

pKa **–** 8.1

pH -5.4

Solubility **–** The base is sparingly soluble while the hydrochloride salt is readily soluble in water.

Stability **–**Bupivacaine hydrochloride is highly stable and has ability to withstand repeated autoclaving.

Specific gravity – 1.025 at 37ºC

Lipid solubility – Highly lipid soluble with a partition co-efficient of 28 and is 3-4 times more potent than lignocaine.

Protein binding – It is bound to alpha 1 acid glycoprotein with 95% protein binding.

Pharmacokinetics

The dose, site of injection, and presence of vasoconstrictor determine the absorption of bupivacaine. The rate of systemic absorption is proportional to the vascularity of the site of the injection (intercostal> caudal > epidural > brachial plexus > subcutaneous). Uptake of the drug into the fat is rapid as it is highly lipid soluble and it has also got vasodilatory effect.

It is metabolised in the liver by N-dealkylation primarily to pipecolyloxylidine. N-disbutyl and 4-hydroxy bupivacaine are also formed. CYP3A4 is the cytochrome involved in its metabolism which is immature in neonates and infants resulting in delayed clearance of the drug.

Excretion occurs through the kidneys. 10% of the drug is excreted unchanged in the urine within 24 hours whereas 5% is excreted in urine as pipecolyloxylidine.

Preparation

0.25% and 0.5% are the concentrations of bupivacaine hydrochloride solution used for peripheral blocks**.** The maximum dosage for epidural and caudal bolus injection is 3mg/kg for older children and 2mg/kg for neonates and infants.

Mechanism of action

The primary action of bupivacaine is on the cell membrane of the axon. Binding of the drug to the alpha subunit of the voltage gated sodium channels prevents the channel activation thus blocking sodium influx which is associated with membrane depolarisation. Impulse conduction is slowed down because of decrease in the rate of rise of action potential leading to the failure of propagation of impulse.

Membrane expansion theory – Drugs which donot form cations at physiological pH act by penetrating the axonal membrane. The membrane swells up and blocks sodium channels. As compared to the more specific drug receptor interaction this is the non specific action.

Pharmacodynamics

Cardiovascular system

Bupivacaine is cardiotoxic. It binds mainly to the myocardial proteins. The primary cardiac electrophysiologic effect is a decrease in the rapid phase of depolarisation in the purkinje fibres and ventricular muscle due to the decrease in availability of fast sodium channels in the cardiac membranes. The rapid phase of depolarisation by bupivacaine is greater compared to lignocaine whereas the rate of recovery of block is slower with bupivacaine.

Central nervous system

Bupivacaine shows biphasic effect on Central nervous system. The initial phase of CNS excitation mainly involves the selective blockade of inhibitory pathways in the cerebral cortex. As the dose increases there is depression of both inhibitory and facilitatory pathways leading to a generalised state of CNS depression.

Respiratory system

Excessive plasma levels of bupivacaine lead to medullary respiratory centre depression resulting in respiratory depression. It can also be caused by respiratory muscle paralysis as occurring in high blocks during subarachnoid anaesthesia.

Indications

Bupivacaine is used to produce local or regional anaesthesia or analgesia for surgeries in various concentrations of 0.25%, 0.5%, and 0.75%.

Dosage and administration

Bupivacaine hydrochloride produces complete sensory block while its action on motor function varies amongst the three concentrations in recommended doses.

0.25% - produces incomplete motor block when it is used for caudal or epidural or for peripheral nerve blocks.

0.5% - produces motor blockade with caudal, epidural or nerve blocks but the muscle relaxation could be inadequate for surgeries requiring complete muscle relaxation.

0.75% - produces complete motor block. It is used for epidural block in abdominal operations where complete muscle relaxation is needed. It can also be used for retrobulbar anaesthesia.

Toxicity[31]

Systemic toxic reactions are likely to occur when the safe limit of the drug is exceeded or due to accidental intravascular injection. Cardiovascular system is mainly involved. Allergic reactions to amide type of local anaesthetics are rarely seen. The toxic plasma concentration of bupivacaine is 4-5µg/ml.

The earliest signs of central nervous system toxicity are circumoral or tongue numbness, tinnitus, restlessness, light headedness, dizziness, confusion, small muscle twitches involving face and distal part of the extremities which can progress to generalised tonic-clonic seizures. In later stages it may progress to respiratory arrest.

The cardiotoxicity of bupivacaine varies from other local anaesthetics. The ratio of dose required for irreversible cardiovascular collapse and the dose necessary to produce central nervous system toxicity is lower for bupivacaine which is 3.7± 0.5. The cardiovascular manifestations of bupivacaine toxicity include syncope, arrhythmias, myocardial depression, hypotension, bradycardia. Cardiac resuscitation becomes more difficult following bupivacaine induced cardiovascular collapse. The cardiotoxicity of bupivacaine is potentiated by acidosis and hypoxia.

Treatment is mainly symptomatic. Management includes the following-

- Airway management with delivery of 100% oxygen.
- Endotracheal intubation and mechanical ventilation ,if necessary.
- Anticonvulsants like inj. Diazepam 0.1-0.2 mg/kg IV or inj. Thiopentone 2-3mg/kg.
- Cardiovascular stability is maintained with intravenous fluids and inotropic support with bolus and infusion of epinephrine.
- 20% intralipid – 1.5 ml/kg bolus followed by an infusion of 0.25 ml/kg/hr.

Introduction

Objectives

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Basic Sciences

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Discussion

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Conclusion

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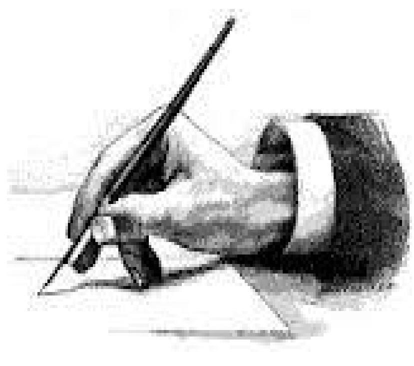


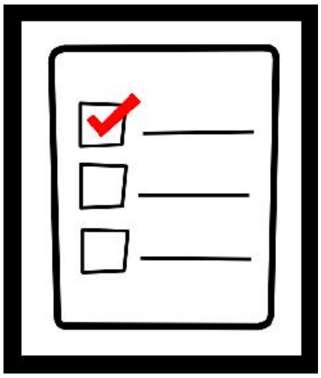
Annexure-I

Annexure-II

Annexure-III

Annexure-IV

Annexure-V



Annexure-VI

METHODOLOGY

The present study titled **"A COMPARISON OF EFFICACY OF ULTRASOUND GUIDED VERSUS TRADITIONAL APPROACH FOR CAUDAL EPIDURAL ANAESTHESIA IN PAEDIATRIC PATIENTS"- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL** was conducted in the Department of Anaesthesiology , KLE's Dr. Prabhakar Kore Charitable Hospital , Belagavi during the period of January 2016 to December 2016 .

Source of data

- Patients between the age group of 1-11 yrs belonging to ASA Grade I and II scheduled for elective lower abdominal surgeries under caudal epidural anaesthesia at K.L.E`S Dr. Prabhakar Kore Charitable Hospital , Nehru Nagar, Belagavi between January 2016 to December 2016 were included.

Study Design:

A one year randomised controlled trial.

Study Period:

One year from January 2016 to December 2016.

Selection criteria

Inclusion:

- ASA physical status I and II
- Age between 1 to 11 years.
- Patients undergoing elective lower abdominal surgeries.

- Parental consent.
- Duration of surgery less than 1 hour.

Exclusion:

- Patients allergic to local anaesthetics.
- Patients with coagulation abnormalities.
- Patients with spinal abnormalities and neurological deficits.
- Patients with infection at the site of caudal block.

Sample size:

Total sample size is 70 patients.

Caudal block using ultrasound.-35

Caudal block by traditional method and whoosh test.-35

Randomisation was achieved by computer generated randomisation chart.

Sample size calculation[4]: Using the results of previous study and taking first puncture success rate as parameter,

With type I error rate $\alpha = 0.05$ and

Type II error rate $\beta = 0.02$

Taking the level of significance at 5% (α=0.05), power of the test as 80% (β=0.2), we get $Z\alpha$=1.65 and $Z\beta$=0.84

With a power of 80% and using the formula-

Sample size $n = \frac{2(Z\alpha+Z\beta)^2 p(1-p)}{(p_0-p_1)^2}$

$n = \frac{2(1.96+0.84)^2(75)(25)}{(90-60)^2}$

n=33.3

n = number of samples

$Z\alpha$= 1.96

$Z\beta$= 0.84

P_0 = 90% (first puncture success rate with ultrasound)

P_1= 60% (first puncture success rate with traditional method)

For ease of calculations and sake of consistent result, sample size has been taken as 35. There are two groups of 35 each[4].

Methodology

After obtaining the approval of ethical committee and parental written informed consent, a total of 70 children undergoing elective lower abdominal surgeries under caudal epidural anaesthesia were included in the study.

After having met inclusion and exclusion criteria, patients were randomized based on computer generated randomization table into one of the two groups.

- Group A - Caudal block by traditional method and whoosh test.
- Group B – Caudal block using ultrasound.

A thorough pre-anaesthetic evaluation was done. Detailed medical and personal history was obtained. A detailed physical examination was done. Patients were advised fasting for 6 hours. Routine investigations such as Hb, platelet count were carried out.

In the preoperative holding area, all patients were premedicated with inj glycopyrrolate 0.01mg/kg and inj. ketamine 5mg/kg IM.

Inside the operation theatre, standard non – invasive monitors were attached and baseline HR, BP, SpO2 were recorded. Anaesthesia was induced with sevoflurane 2-4% in oxygen via facemask and peripheral venous access was taken.

Under strict aseptic precaution the following procedure was carried out:

Group A: The patient was put in left lateral position. Sacral cornua and hiatus was palpated. The skin over sacrococcygeal ligament was punctured using 22 gauge hypodermic needle. The needle was inserted at 45 – 60 degree angle to skin surface and advanced until a pop (piercing sacrococcygeal ligament) was felt. The needle was then lowered to 20-30 degree angle to the skin and advanced 2-3 mm further into the sacral canal. A stethoscope was placed over lower lumbar spine and 2-3 ml of air was injected (whoosh test) which confirmed caudal epidural space. After negative aspiration for blood and CSF, 1 ml/kg of 0.25% bupivacaine was injected and then the patient was turned supine.

Group B: The patient was put in left lateral position. In the transverse plane, sacral hiatus was first scanned at sacral cornua using a portable SonoSite ultrasound machine and a linear array transducer (13-6MHz) with a sterile sheath. The depth and gain settings were adjusted to obtain optimal image quality. Any abnormalities of sacrum and sacral hiatus were noted. In the longitudinal plane, the ultrasound image of hiatus was positioned in the middle of ultrasound screen. A 22 gauge needle was inserted at 45 – 60 degree angle to skin surface in an in-plane technique. Once the needle was visualized in the caudal space on the ultrasound imaging, 1 ml/kg of 0.25% bupivacaine was injected. It was confirmed by localized turbulence or dilatation of hiatus on ultrasound imaging. The patient was then turned supine.

After performing the block in both groups sevoflurane was switched off and sedation was maintained with inj. midazolam 0.05mg/kg and inj fentanyl 1microgram/kg along with O2 by face mask.

Motor movements were tested by pinprick method 10 min after LA injection and then skin incision was performed.

The following parameters were monitored:

A) **Successful block** - was defined as no motor or haemodynamic response as indicated by absence of increase in heart rate of 15% more than the baseline values obtained just before the incision.

Otherwise, the block was considered a failure, in which case standard endotracheal tube general anaesthesia was administered.

B) **Puncture frequenc**y – number of attempts made to identify caudal epidural space.

C) **Complications -** Any side effects which occured were duly documented.

D) **Vitals**: HR, BP and SpO_2 were monitored throughout the surgery at 10 minutes interval.

Statistical Analysis

The data was tabulated and master chart was prepared (AnnexureV). The categorical data was expressed as rates, ratios and percentages while continuous data was expressed as mean $\pm$ standard deviation. Student unpaired‘t‘ test was used to find significance of study parameters on continuous scale between the two groups. Chi - square test with Yate’s correction was used to find association between different classes of variables. A p – value < 0.05 was considered statistically significant.

RESULTS

This one year randomised clinical trial was conducted in the Department of Anaesthesiology, during the period of January 2016 to December 2016 at KLES Dr. PrabhakarKore Charitable Hospital, Belagavi attached to Jawaharlal Nehru Medical College, Belagavi.

A total of 70 children undergoing lower abdominal surgeries under caudal epidural block were randomly allocated into one of the following two groups based on a computer generated randomisation chart :

- Group A (n=35): Caudal block by traditional method and whoosh test.
- Group B (n=35): Caudal block using ultrasound.

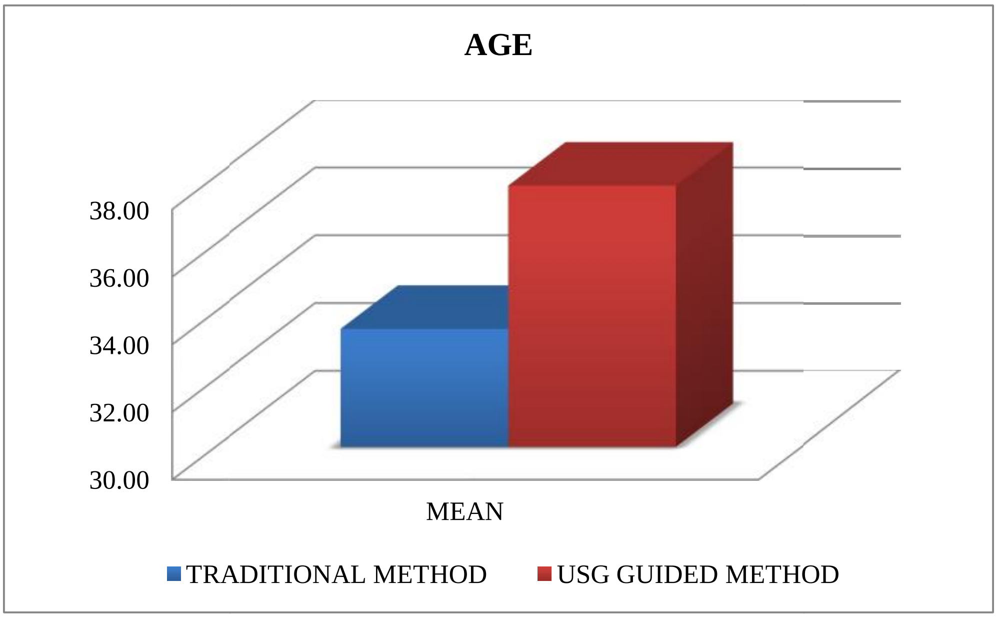
Data obtained were coded and analysed as below

.

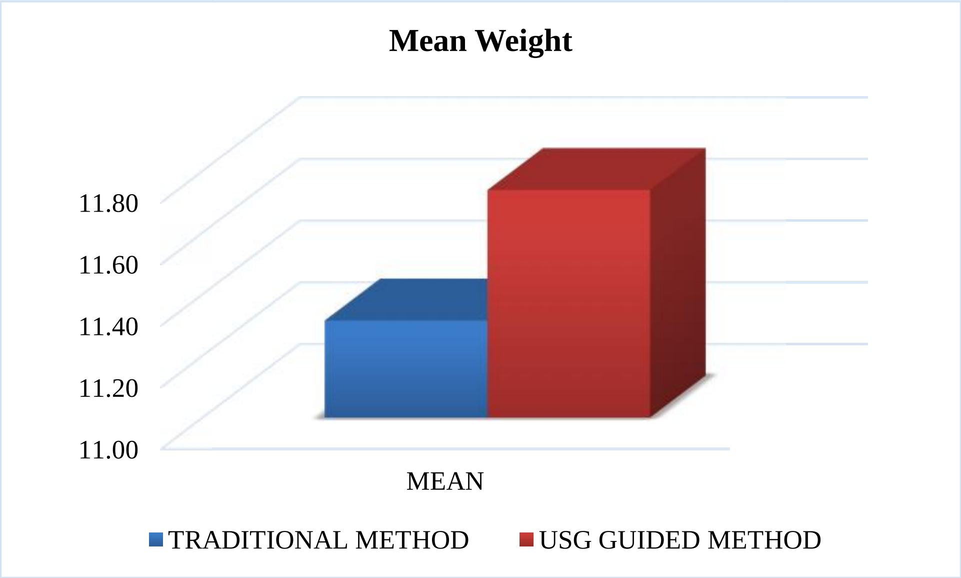
Table 1: Mean Age and Weight

	Group A		Group B		P value
	Mean	Standard Deviation	Mean	Standard Deviation	
Age (months)	33.49	22.61	37.71	23.63	0.44
Weight(kg)	11.31	3.97	11.74	3.48	0.63

Graph1: Mean Age (months)



Graph 2: Mean Weight (kg)



In the present study we found no statistically significant difference between group A and group B with regards to mean age (33.49±22.61 and 37.71±23.63 months respectively; p = 0.44), mean weight (11.31±3.97 and 11.74±3.48 kgs respectively; p = 0.63)

Table 2: Comparison of Gender Distribution

	Female	Male	Total
Traditional Method	3	32	35
USG Guided Method	7	28	35
Total	10	60	70

Graph 3: Gender Distribution

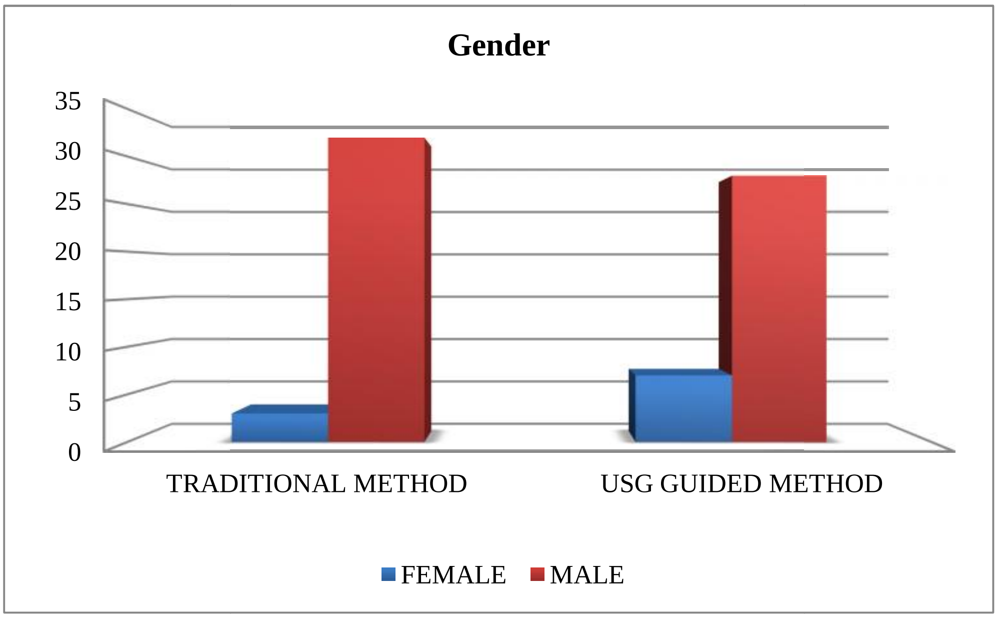
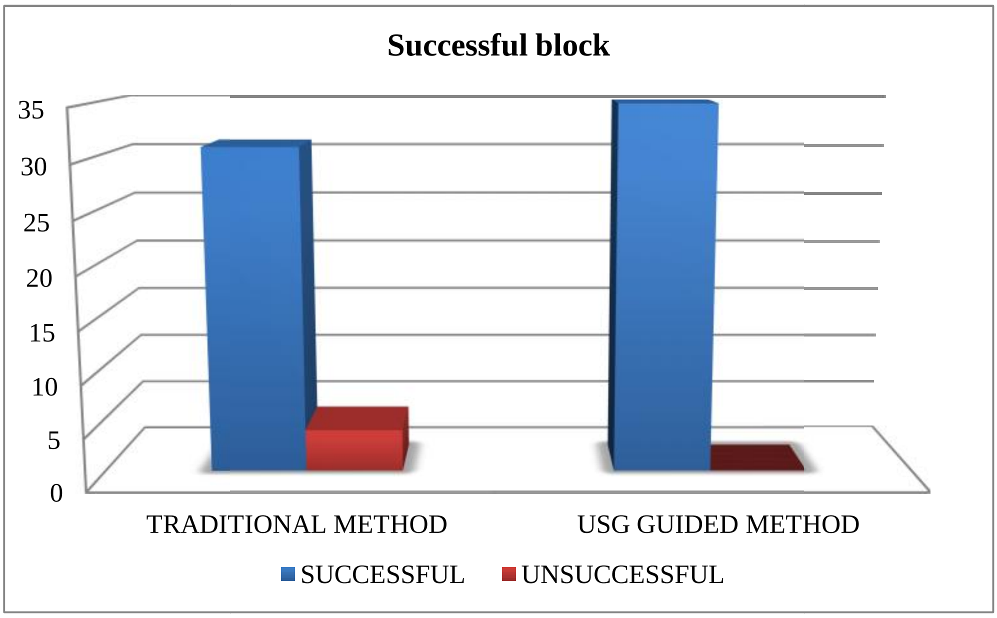


Table 3: Successful block (Also refer Graph 4)

	Successful	Unsuccessful	Total
Traditional method	31	4	35
USG guided method	35	0	35
Total	66	4	70

p value by Chi-square test with Yate's corection is 0.1224 (ns)

Graph 4: Successful block



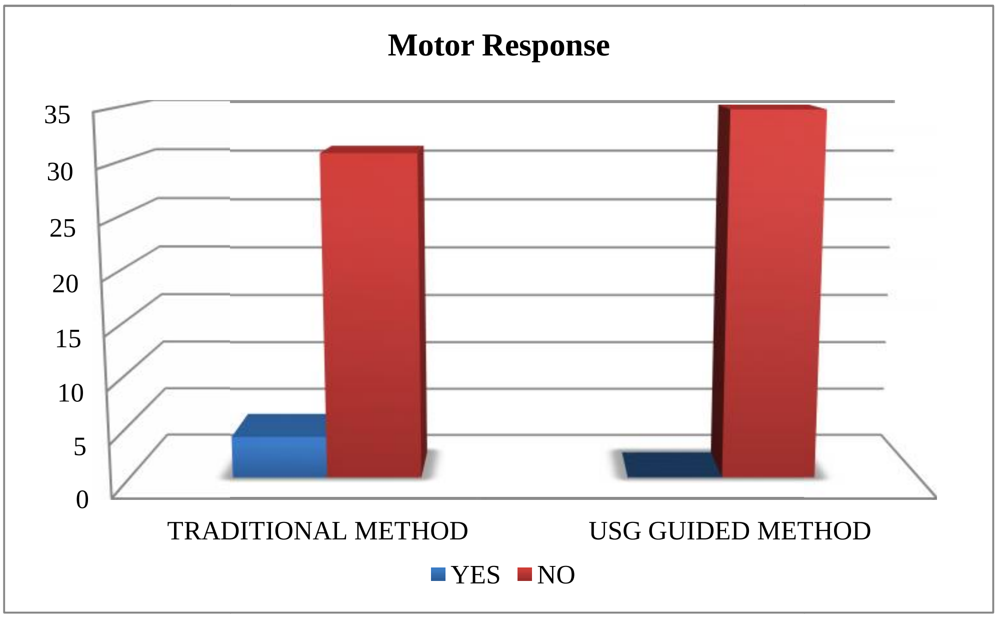
In our study, percentage of successful blocks were comparable in group A (31 of 35) and group B (35 of 35) and the difference was statistically nonsignificant(p= 0.12).

Table 4 : Motor response after block

	Yes	No	Total
Traditional method	4	31	35
USG guided method	0	35	35
Total	66	4	70

p value by Chi-square test with Yate's corection is 0.1224 (ns)

Graph 5: Motor response after block

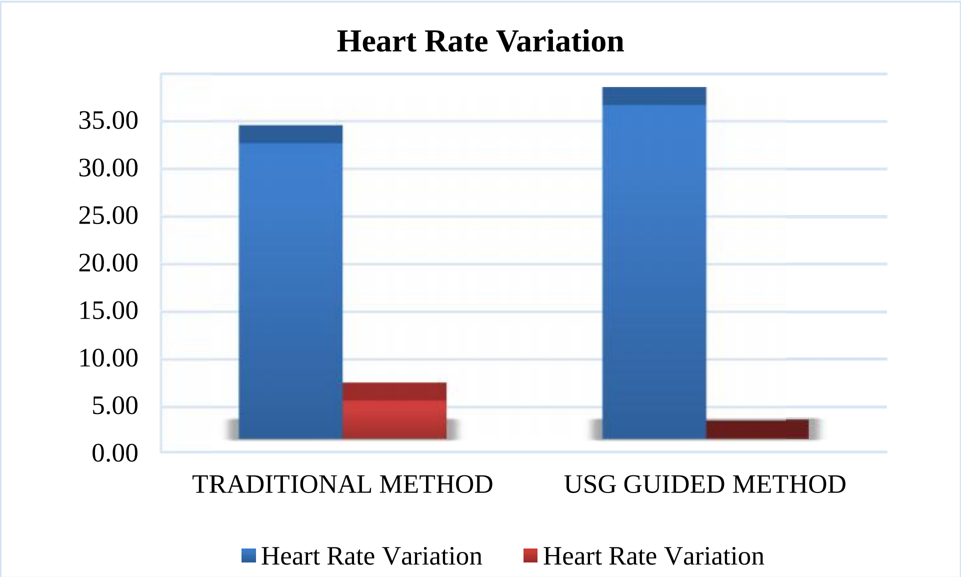


In the present study motor response after block was seen in only 4 patients in group A while none in group B and hence the difference was statistically nonsignificant (p < 0.122).

Table 5: Heart Rate Variation (increase) (Also refer graph 6)

	Heart Rate Variation (increase)	
	HR < 15%	HR>15%
Traditional method	31	4
USG guided method	35	0
Total	66	4

Graph 6: Heart Rate Variation (increase)



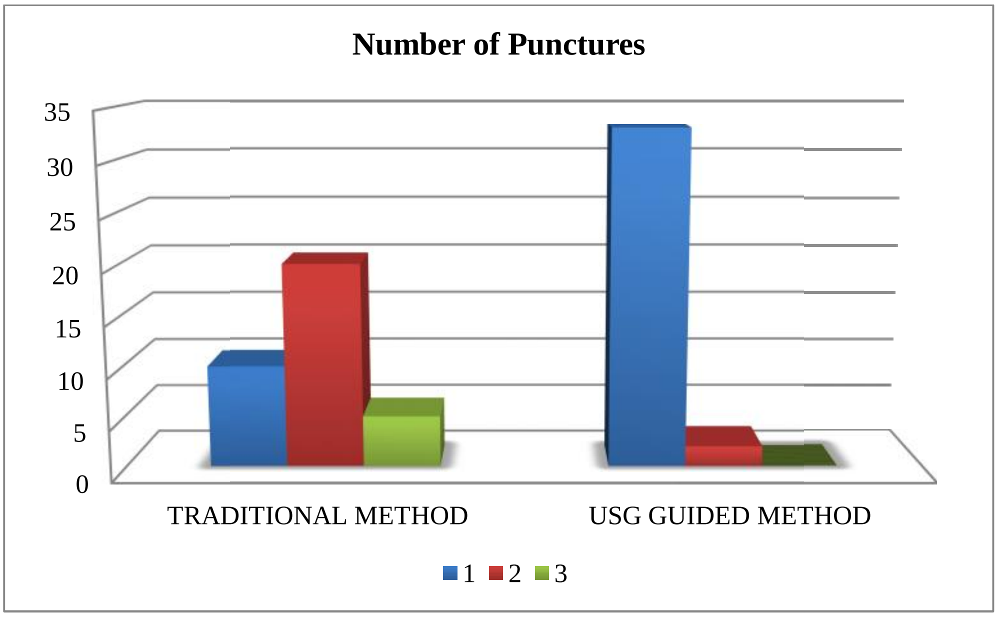
In the present study, only 4 patients in group A had increase in heart rate of >15% from baseline value while none in group B and was statistically nonsignificant ($p < 0.122$).

Table 6: Number of puncture attempts (Also refer graphs 7)

	1	2	3	Total
Traditional method	10	20	5	35
USG guided method	33	2	0	35
Total	43	22	5	70

p value by Chi-square test is <0.0001 (hs)

Graph 7: Number of Punctures



In the present study, the first puncture success rate was higher in Group B (33 of 35 patients) as compared to Group A (10 of 35 patients) and the difference was statistically significant (p value <0.0001). Second attempt was required in 20 of 35 patients in Group A as compared to 2 of 35 patients in Group B. In group A, 5 patients required third attempt while none in Group B required more than two attempts.

DISCUSSION

Regional anaesthesia (RA) has gained tremendous popularity in paediatric anaesthesia practice, either alone or in combination with general anaesthesia (GA). When used alone, RA avoids the potential harmful effects of GA such as airway complications, adverse effects of multiple drugs on the growing brain while providing adequate analgesia and optimal surgical conditions. RA with general anaesthesia helps to reduce the stress response, requirements for analgesics and muscle relaxants and aids in fast recovery. Since the analgesia can be continued after the surgery, post-operative complications are reduced by use of RA and early ambulation can be facilitated[32].

In smaller children, less than 7 years of age the caudal space is well differentiated and its location and landmarks remain consistent. It is formed by V-shaped or U-shaped notch called sacral hiatus which is covered by the sacrococcygeal ligament and two lateral bony prominences known as sacral cornua. The two posterior superior iliac spines and the sacral hiatus forming an equilateral triangle are the important landmarks for identification of caudal epidural space[14-19].Caudal block is thus one of the most commonly performed regional anaesthesia techniques in children for several lower abdominal and lower limb procedures. It reduces the requirement for general anaesthetic drugs, provides prolonged analgesia with minimal risk of respiratory depression while without significant risk of hemodynamic instability[33].

Traditionally, caudal block is performed by land mark technique using an epidural needle. The needle is blindly inserted at the sacral hiatus, directed cephalad at an angulation of 45 - 60^0 to the skin surface and the caudal space is located by feeling loss of resistance (piercing sacrococcygeal ligament). In this technique the path travelled by the needle after the skin puncture is not visible as well the distance between the various structures is variable. Further, sacrococcygeal ligament in children less than two years, is soft and loss of resistance may not be appreciable. Due to these reasons and being a blind technique, even in expert hands, landmark based traditional technique can be a potential source of serious complications and also can be a cause of failed or inadequate blockade. Dural puncture, bleeding into the epidural space and risk of infection are some of the major complications associated with repeated attempts at caudal puncture. This also will lead to discomfort of the patient and affects the parental satisfaction in children.

Introduction of ultrasonography (USG) in anaesthesia practice heralded a new era. Soon, its applications increased enormously and the benefits in regional anaesthesia were realized. . They include accurate identification of structures, ability to identify the path of the needle, ability to visualize the injectate being spread, reduced drug requirements, rapid onset of blockade, better success rate and reduced complications. In a preliminary observational study of 60 children, Steve et al demonstrated the usefulness of USG in delineating the caudal anatomy more accurately. Subsequently USG applications extended to paediatric regional anaesthesia as well, contributing to increased safety. Using ultrasound for central neuraxial interventional procedures (lumbar puncture) was first described by Bogin and Stulin in 1971. Identification of landmarks relevant to locate epidural anaesthesia using ultrasound was first reported by Cork and colleagues. Klocke and colleagues in 2003 were the first to describe ultrasound-guided caudal block[34]. Applying ultrasound increases the safety and efficacy of caudal epidural block in children[17, 35]. Specific to caudal block, USG is useful to delineate sacral and caudal anatomy, can be used as a guide to caudal needle insertion and also helps to visualize the caudal injectate[36].

The present one year randomized controlled study was undertaken at Department of Anaesthesiology, KLES Dr.Prabhakar Kore Charitable Hospital, Belagavi from January 2016 to December 2016. A total of 70 children undergoing infraumbilical surgeries under caudal epidural anaesthesia were randomly allocated into two groups using a computer generated randomization chart:

- Group A: received Caudal block by traditional method and whoosh test(n=35)
- Group B: received Caudal block using ultrasound (n=35)

In our study we found no statistically significant difference between group A and group B with regards to mean age (33.49±22.61 and 37.71±23.63 months respectively; p = 0.44), mean weight (11.31±3.97 and 11.74±3.48 kgs respectively; p = 0.63).

In our study puncture frequency was defined as number of attempts made to identify caudal epidural space. The first puncture success rate was higher in Group B (33 of 35 patients) as compared to Group A (10 of 35 patients) and the difference was statistically significant (p value <0.0001). Second attempt was required in 20 of 35 patients in Group A as compared to 2 of 35 patients in Group B. In group A, 5 patients required third attempt while none in Group B required more than two attempts. Higher first success rate is reflective of effectiveness of the approach or technique. In this case it reflects the usefulness of USG in locating the landmark accurately. Thus, it is obvious that use of USG guidance led to higher success rate in the Group B.

A study undertaken by Zhang YF, Wang LZ, Chang XY, Xiao XH (2013) to compare caudal block by sacral hiatus injection under ultrasound guidance with traditional sacral canal injection in 140 patients undergoing inguinal hernia repair. The first puncture success rate was higher in ultrasound group (Group H) than in traditional sacral canal group (Group C) ie 92.8% vs 60% respectively. Hence the findings of our study are similar to their study[4].

In another study done by Zhonghua YX, Liu JZ, Wu XQ, Li R (2012) comparing ultrasound imaging and classic method of surface landmarks and whoosh test in 102 ASA I-II paediatric patients undergoing urologic or perineal surgery under caudal epidural anaesthesia, the number of puncture attempts was 1.10±0.30 vs 1.56±0.63. Success rate at the first puncture attempt was 90.4% vs 66%in ultrasound group and classic method of surface landmarks and whoosh test respectively. Again, findings of our study confirm these findings of Zhonghua et al[8].

In our study, Successful block was defined as no motor or haemodynamic response as indicated by absence of increase in heart rate of 15% more than the baseline values obtained just before the incision. With this criteria, percentage of successful blocks were comparable in group A (31 of 35) and group B (35 of 35) and the difference was statistically nonsignificant ($p= 0.12$). Increase in heart rate of >15% from baseline value was seen in only 4 patients in group A while none in group B. However, this difference did not achieve statistical significance ($p<0.122$). Motor response after block was seen in only 4 patients in group A while none in group B and hence the difference was statistically nonsignificant ($p < 0.122$).

We recorded four failed caudal blocks – all of them were in traditional method of caudal block and whoosh test. In these patients, there were movements on testing by pin prick method 10 min after the administration of caudal block along with increase in heart rate of 15% more than the baseline value. Hence the block was judged to be inadequate and standard endotracheal tube general anaesthesia was administered as per study protocol.

Zhang YF, Wang LZ, Chang XY, Xiao XH in their study conducted in 2013, compared 140 patients undergoing inguinal hernia repair under caudal epidural anaesthesia, by dividing them in two groups: Group C and Group H. 1 ml/ kg of 0.25% ropivacaine was injected after the needle was inserted into the sacral canal in Group C, or after the needle pierced the sacrococcygeal ligament under a transverse ultrasound view in Group H. The success rate of block was similar between two groups (95.7% in Group C vs 92.8% in Group H, P > 0.05). Hence our study results are in agreement with theirs[4] (35 of 35 patients in USG group vs 31 of 35 patients in traditional method and whoosh test group).

In yet another study conducted by Zhonghua YX, Liu JZ, Wu XQ, Li R(2012) 102 ASA I and II pediatric patients aged from 1 month to 8 years scheduled for urologic or perineal surgery under caudal epidural anaesthesia were included. The positive rate of the sacral anesthesia needle insertion in ultrasound and control group were 97.96% and 62.24%, respectively, and the indexes were better than those of the traditional method (P <0.01). As this study used monitoring of the rate of sacral anaesthesia needle insertion in the caudal space to define as successful block without taking into account of motor response or heart rate variation (increase of >15% from baseline value) as done in our study, the results in ultrasound group were superior than those in classic test. Hence this could explain the difference (which is higher) in the success rate between this and our study[8].

Raghunathan, Schwartz D, Connelly NR in 2008 conducted retrospective observational study of caudal epidural injections on 83 pediatric patients (0–11 years) to determine the accuracy of caudal needle placement by swoosh test and ultrasonography. Eighty out of 83 patients (96.4%) had a successful caudal block as seen by minimal or no perioperative narcotic use, no response to surgical stimulation, presence of the motor blockade and patient comfortness in the PACU.'Swoosh' test was compared with transverse 2D imaging and color flow Doppler as a confirmatory test for caudal injections. Ultrasound was significantly superior to 'swoosh' for sensitivity (96.3% vs 57.5%), negative predictive (40% vs 5.6 value) % and likelihood ratio (2.89 vs 1.73). As this study used swoosh test instead of whoosh test the success rate of block is slightly different from our study[5].

In our study, complications like bloody puncture, dural puncture, subcutaneous bulging were also assessed. However none of these complications were noted in either group.

In a study conducted by Zhang YF, Wang LZ, Chang XY, Xiao XH (2013) the incidence of bloody puncture was 18.6% in sacral canal group (group C) and 5.7% in ultrasound group (group H) ($P<0.05$). Subcutaneous bulging occurred in six patients (7.1%) in Group C but none in Group H ($P<0.05$). This finding again showed the effectiveness of ultrasound in reducing the incidence of complications associated with caudal epidural block[4].

Hence ultrasound can be used as an adjuvant tool in performing caudal epidural block as it provides real-time images in guiding the needle into the caudal epidural space with fewer complications and lesser number of punctures and with almost 100% success rate as compared to traditional method of caudal block and whoosh test.

LIMITATIONS OF THE STUDY

1. The cranial spread of the local anaesthetic injected into the caudal space to determine the level of dermatomal block was not assessed which could have been done using ultrasound.
2. The duration of analgesia and the motor blockade of the lower extremities were not assessed in the postoperative period.

CONCLUSION

Our study showed that ultrasound guided caudal epidural block is a safe and reliable alternate to traditional technique as it provides real-time images in guiding the needle into the caudal epidural space and helps in visualizing the injectate. The most notable finding of our study was regarding the number of punctures needed to identify the caudal epidural space. The first puncture success rate was higher in ultrasound group as compared to traditional method of caudal block and whoosh test.

However, the overall success rate was similar in both groups. None of the complications like bloody puncture, dural puncture, subcutaneous bulging were noted in either group.

Ultrasound guidance being noninvasive, safe and providing real time images of sacral anatomy and caudal epidural space with high level of resolution, it can be used as an adjuvant tool in performing caudal epidural block in children undergoing elective lower abdominal surgeries.

SUMMARY

Caudal epidural block is the most frequently performed regional anaesthetic technique in paediatric patients undergoing infraumbilical surgeries. Traditionally performed by a land mark based technique, caudal block is usually considered as simple & safe procedure. It provides excellent analgesia during surgery as well as in postoperative period.

Introduction of ultrasonography into pediatric regional anesthesia is a significant development, Ultrasound guidance increases the safety and efficacy of caudal epidural block in children by delineation of sacral and caudal anatomy, guiding of caudal needle insertion and by visualization of the caudal injectate.

This one year randomised controlled trial was conducted in the Department of Anaesthesiology, KLES Dr.Prabhakar Kore Charitable Hospital Belagavi, during the period of January 2016 to December 2016. Total of 70 paediatric patients aged 1-11 years undergoing elective lower abdominal surgeries were randomly allocated to two groups namely, Group A (n= 35) which received Caudal block by traditional method and Whoosh test and Group B (n = 35) received Caudal block using ultrasound.

The success rate of block, puncture frequency and associated complications were studied. The hemodynamic parameters like heart rate, and oxygen saturation were continuously monitored.

Demographic parameters were comparable in both groups. In this study, the first puncture success rate was higher in Group B (33 of 35 patients) as compared to Group A (10 of 35 patients) and the difference was statistically significant (p value

<0.0001). Second attempt was required in 20 of 35 patients in Group A as compared to only 2 of 35 patients in Group B. In group A, 5 patients required third attempt while none in Group B required more than two attempts. Percentage of successful blocks were comparable in group A (31 of 35) and group B (35 of 35) and the difference was statistically nonsignificant ($p= 0.12$). Increase in heart rate of >15% from baseline value was seen in only 4 patients in group A while none in group B and this difference was statistically nonsignificant ($p < 0.122$). Motor response after block was comparable between group A and group B and was statistically nonsignificant ($p < 0.122$). Complications like bloody puncture, dural puncture, subcutaneous bulging were also assessed. None of these complications were noted in either group.

Overall, based on this study it may be concluded that ultrasound being non invasive, safe and providing real time images of sacral anatomy and caudal epidural space with high level of resolution and lesser number of punctures, it can be used as an adjuvant tool in performing caudal epidural block in children undergoing elective lower abdominal surgeries.

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ANNEXURE-I

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr/Mrs/Miss. ______________________________ we are requesting you to enrol your child in study titled **"A COMPARISON OF EFFICACY OF ULTRASOUND GUIDED VERSUS TRADITIONAL APPROACH FOR CAUDAL EPIDURAL ANAESTHESIA IN PAEDIATRIC PATIENTS"- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL.** J.N. Medical College, Belagavi under KLE University, Belagavi.

Respected Sir/Madam we request you to enrol your child to participate in our study as your child is eligible for participating in the study. During the study you will be asked some questions regarding your child's present complaint and you are supposed to answer to the best of your knowledge.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N.Medical College. If you decide not to participate you are free to withdraw at any time.

Purpose of the study:

The purpose of research is to compare the success rate of block, puncture frequency and complications of ultrasound guided versus traditional method for caudal epidural anaesthesia in paediatric patients.

Procedure Involved:

If you agree to enrol your child in my study, I will ask your child's present past and family history. Then your child will be clinically examined in detail and routine investigations like Hb, Platelet Count, will be done accordingly. Your child will be allotted into one of the two groups randomly using a computer generated software. One group will receive ultrasound guided caudal block and the other group will receive traditional method of caudal block.

Risks:

The risks like inadvertent dural or vascular puncture are minimal with the use of ultrasound guided caudal block compared to traditional method of caudal block.

Benefits:

It is found to be safe, easy to perform with fewer complications compared to traditional method of caudal block in paediatric patients.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enrol your child in this study. Your decision will not change present or future health care services offered to you at K.L.E. hospital.

Alternatives:

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality:

The only people to know that your child is a research subject are members of the research team. No information about your child or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results:

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your child's identity. Any information that is obtained in connection with this study and that can be identified with your child's identity remaining confidential.

Financial Incentives for participation:

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation:

In the event of injury related to the study, treatment will be made available through KLES' Hospital & MRC, Belagavi. There is no compensation or payment for such medical treatment by law.

Questions:

If you have any queries about your child's rights as a study subject, you may call Dr. Ganga Pilli, Professor, Department of Pathology and Chairman, J.N. Medical College Institutional Ethical Committee for Human Subjects Research, Phone number-9480275601, or extension 4052 at J.N. Medical College, Belagavi.

CONSENT FOR PARTICIPATION IN RESEARCH TRIAL.

"A COMPARISON OF EFFICACY OF ULTRASOUND GUIDED VERSUS TRADITIONAL APPROACH FOR CAUDAL EPIDURAL ANAESTHESIA IN PAEDIATRIC PATIENTS"- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL. I, Mr/Ms/Mrs ______________________________ voluntarily agree for the participation of my child as a subject of study. By signing this consent form I am not giving up any of my legal rights, I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : ____________________

Signature or the Left Thumb Print of parent : _____________________

Date:

Witness Name - ____________________ Signature:______________

Date:

Investigators Name: _________________ Signature:______________

Date:

Place : ______________

ANNEXURE II – PROFORMA

"A COMPARISON OF EFFICACY OF ULTRASOUND GUIDED VERSUS TRADITIONAL APPROACH FOR CAUDAL EPIDURAL ANAESTHESIA IN PAEDIATRIC PATIENTS"- A ONE YEAR HOSPITAL BASED RANDOMISED CONTROLLED TRIAL.

Name & Address of the patient: ____

Age of the Patient: _________________ IP. No. ___________________

Weight of Patient: _________________ Sex.

Anaesthesiologist: _________________ Surgeon:_________________

PREANAESTHETIC EVALUATION:

Chief Complaints:

Past History:

- History of Diabetes Mellitus/Hypertension/Asthma/Tuberculosis
- Drug Therapy:
- Previous Anaesthetic procedure/Previous surgeries:
- History of renal disease, hepatic disease and neurological diseases.

Family History

General Physical Examination:

Weight: Temperature: Pallor: Height

Cyanosis: Pedal Oedema: Clubbing:

Pulse : B.P: RR:

Airway Assessment:

Mouth Opening: Teeth:

Jaw Movements: MP Grading:

SYSTEMIC EXAMINATION:

Cardiovascular System:

Respiratory System:

Per Abdomen:

Central Nervous system:

Spine assessment:

INVESTIGATIONS:

Hb%: Platelet count:

Any Other:

ASA STATUS: Grade 1 / 2

Diagnosis:

Proposed Surgery:

Observations:

Readings will be recorded in the following manner:

Technique used: ____________________________.

Group: ____.

Time	Heart rate	Spo2

Time	Motor response after block

Successful block	puncture frequency

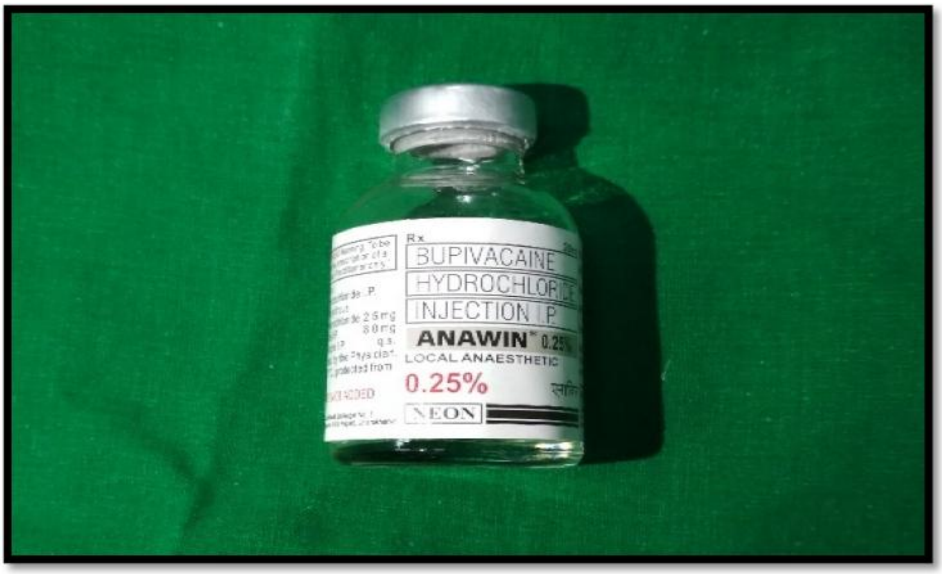
Successful block is defined as no motor or haemodynamic response as indicated by absence of increase in heart rate of 15% more than the baseline values obtained just before the incision.

Side Effects/ complications –

Signature of staff in charge:

ANNEXURE III: PHOTOGRAPHS

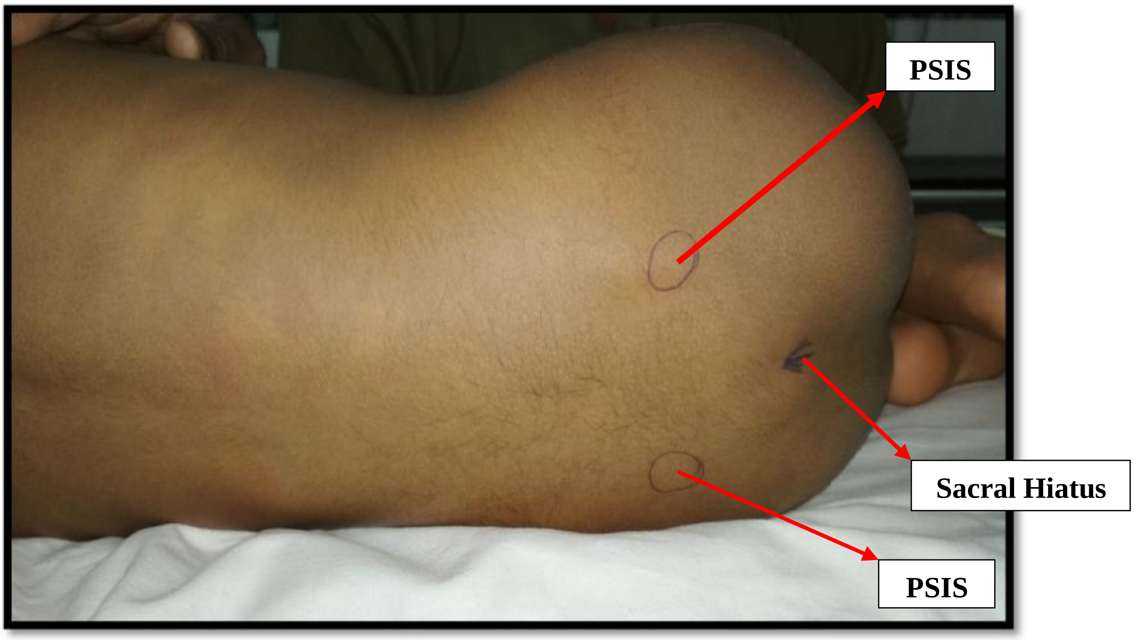
Photograph 1: 0.25% Bupivacaine Ampule



Photograph 2: Ultrasound Machine

Photograph 3: Caudal Epidural Tray

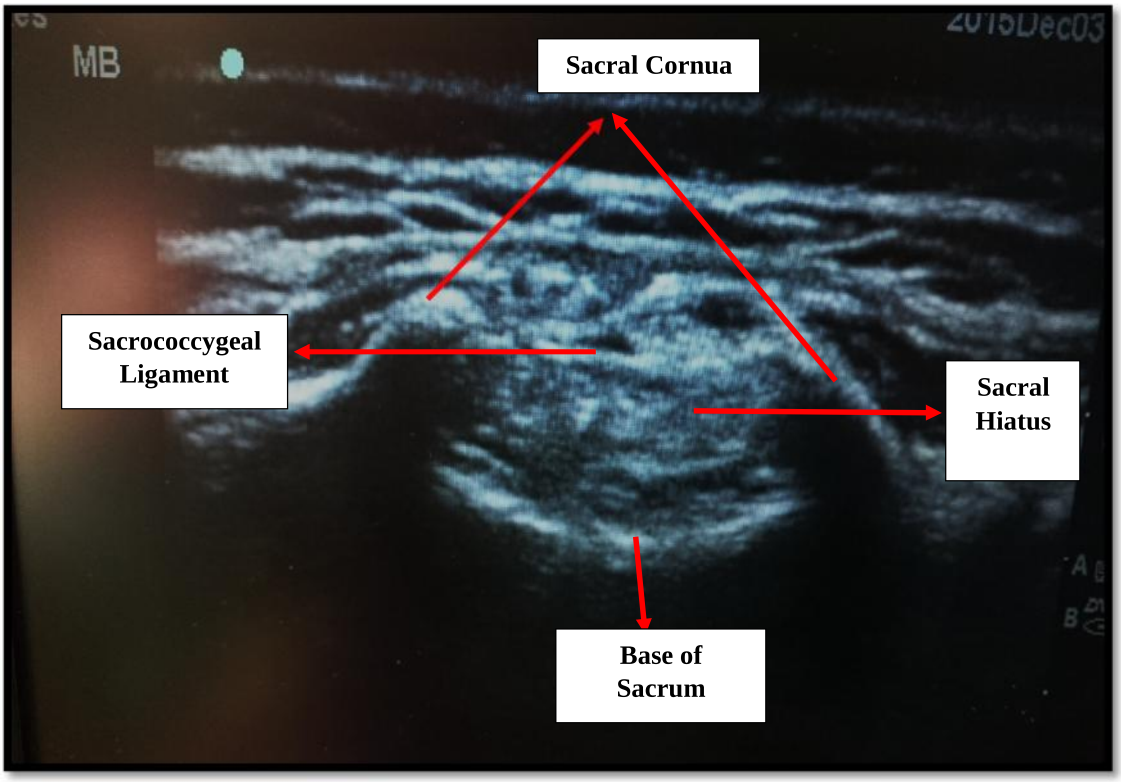
Photograph 4: Anatomical Landmarks of Caudal Epidural Block



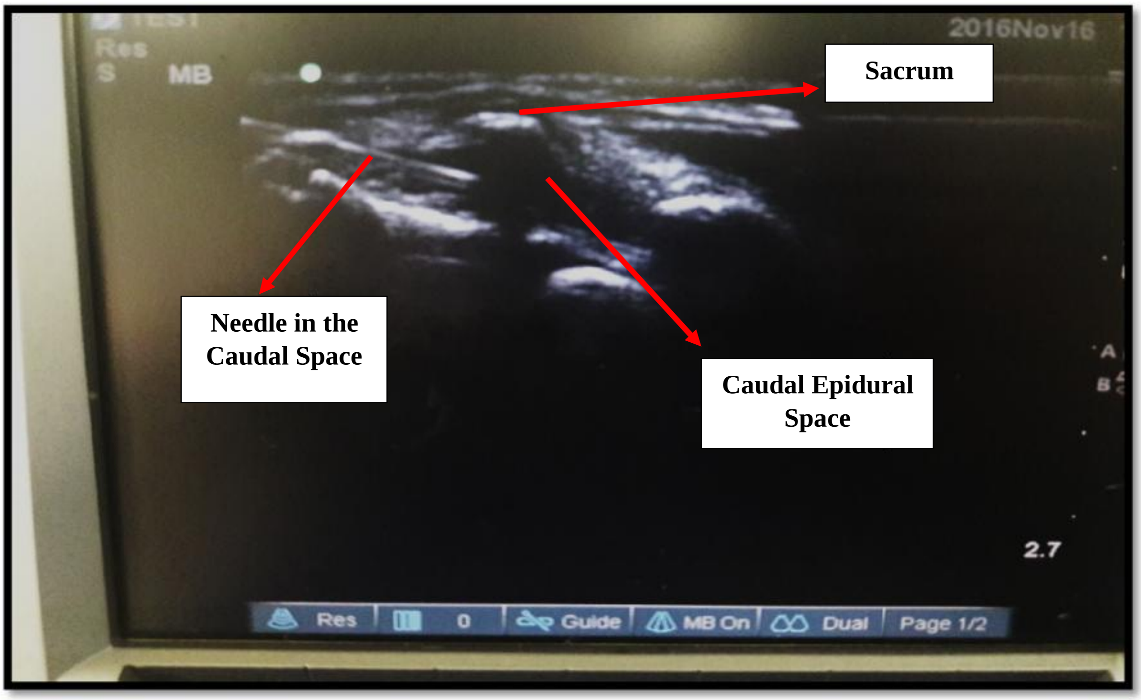
Photograph 5A: Procedure of Caudal Epidural (Traditional Method And Whoosh)

Photograph 5B: Injecting Drug in Caudal Epidural Space

Photograph 6A: USG Guided Caudal Epidural Block (Transverse View)



Photograph 6B: USG Guided Caudal Epidural Block (Longitudinal View)



ANNEXURE-IV - MASTER CHART

Traditional Method And Whoosh Test

Age (months)	IP no	weight(kg)gender		diagnosis	Surgery	Motor response after block	no of punctures	heart rate baseline	heart rate after 10min	outcome of block	complications
36	721657	10.1	M	right hydrocele	hydrocele repair	N	1	120	114	successful	nil
24	724228	11	M	phimosis	circumcision	N	2	130	124	successful	nil
12	724220	7	M	right hydrocele	hydrocele repair	N	2	140	128	successful	nil
24	723532	9	M	posterior urethral valve	cystoscopy	N	1	126	110	successful	nil
48	724478	11.7	M	hypospadias	urethroplasty	Y	2	110	130	unsuccessful	nil
36	725596	11	M	left hydrocele	hydrocele repair	N	3	120	112	successful	nil
18	726233	8.8	M	right inguinal hernia	right herniotomy	N	1	130	122	successful	nil
24	731475	10	M	phimosis	circumcision	N	1	136	122	successful	nil
48	732702	14	F	rectal polyp	excision	N	2	128	120	successful	nil
18	732749	9	M	right inguinal hernia	right herniotomy	N	2	126	120	successful	nil
48	734208	9.6	M	Phimosis	circumcision	N	2	120	114	successful	nil
60	735864	20.2	M	Phimosis	circumcision	N	1	104	98	successful	nil
72	735483	15.2	M	Phimosis	circumcision	N	2	96	90	successful	nil
72	735310	18.2	M	Phimosis	circumcision	Y	2	110	126	unsuccessful	nil
12	737901	10.4	M	posterior urethral valve with phimosis	cystoscopy with circumcision	N	3	130	122	successful	nil
12	738642	7.9	M	right undescended testis	right orchidopexy	N	2	146	134	successful	nil
12	738641	7.3	M	Phimosis	circumcision	N	1	140	130	successful	nil
36	740783	13	M	Phimosis	circumcision	N	2	150	142	successful	nil
48	742932	13	M	right inguinal hernia	right herniotomy	N	3	110	104	successful	nil
24	746143	11.4	M	hydronephrosis with stent insitu	stent removal	N	1	120	114	successful	nil
42	747087	12	M	Phimosis	circumcision	N	2	104	98	successful	nil
108	758346	20.4	F	left hernia	left herniotomy	N	2	96	90	successful	nil
36	760998	6.8	M	posterior urethral valve	cystoscopy	N	1	126	116	successful	nil
18	759367	7.2	M	hypospadias	urethroplasty	N	2	130	120	successful	nil
12	761417	6.9	M	left hernia	left herniotomy	N	2	130	122	successful	nil
20	761377	12.4	M	o/c/o open pyeloplasty	stent removal	N	1	134	126	successful	nil
18	760936	10.8	M	undescended testis	repair	N	3	138	124	successful	nil
24	762180	11	M	puj obstruction	cystoscopy	N	2	130	122	successful	nil
36	762758	10	M	Phimosis	circumcision	Y	2	120	138	unsuccessful	nil
12	764892	9	M	right inguinal hernia	right herniotomy	N	2	148	136	successful	nil
72	765004	22.2	F	bilateral inguinal hernia	bilateral hernia repair	N	3	102	94	successful	nil
18	765020	10	M	right inguinal hernia	right herniotomy	N	1	128	120	successful	nil
12	773462	5.8	M	hirschsprung's disease	rectal biopsy	N	2	156	142	successful	nil
12	770075	9.6	M	hypospadias	repair	Y	2	136	152	unsuccessful	nil
48	766819	14.1	M	undescended testis	orchidopexy	N	2	130	124	successful	nil

USG GUIDED METHOD											
Age (months)	**IP no**	**weight(kg)**	**gender**	**diagnosis**	**Surgery**	**Motor response after block**	**no of punctures**	**heart rate baseline**	**heart rate after 10min**	**outcome of block**	**complications**
36	724216	10.6	M	right inguinal hernia with phimosis	right herniotomy with circumcision	N	1	126	118	successful	nil
60	724215	14.7	M	Phimosis	circumcision	N	1	130	120	successful	nil
24	725150	10.8	M	hypospadias	urethroplasty	N	1	132	126	successful	nil
12	724085	6.5	F	ARM stage 1	repair	N	1	140	124	successful	nil
24	730928	11	F	right hernia	right herniotomy	N	1	118	110	successful	nil
60	730946	18.4	M	phimosis	circumcision	N	1	96	90	successful	nil
60	730955	17	M	right hydrocele with phimosis	hydrocele repair with circumcision	N	1	106	100	successful	nil
12	737785	10	M	left hydrocele	hydocele repair	N	1	136	130	successful	nil
36	738254	13.2	M	left undescended testis	herniotomy	N	1	116	110	successful	nil
48	731108	12.8	M	hypospadias	urethroplasty	N	1	120	112	successful	nil
24	736879	8.2	M	left hernia	left herniotomy	N	1	126	120	successful	nil
72	737017	20.1	M	right hernia	right herniotomy	N	1	100	96	successful	nil
24	746104	10	M	right hydrocele	hydrocele repair	N	2	124	118	successful	nil
24	746187	9.2	F	right inguinal hernia	right herniotomy	N	1	124	116	successful	nil
12	751314	8.9	M	right inguinal hernia	right herniotomy	N	1	144	132	successful	nil
18	750989	7	F	ARM	colostomy closure	N	1	154	140	successful	nil
12	772648	8.2	M	left hernia	left herniotomy	N	1	142	134	successful	nil
48	772632	11.7	M	right inguinal hernia	right herniotomy	N	1	114	108	successful	nil
48	735368	12.6	M	Phimosis	circumcision	N	1	106	98	successful	nil
18	772230	12	M	Phimosis	circumcision	N	1	126	120	successful	nil
36	772229	11.6	M	undescended testis	orchidopexy	N	1	120	114	successful	nil
24	773254	9.2	M	posterior urethral valve	cystoscopy	N	2	126	120	successful	nil
12	770444	9	F	ARM	colostomy closure	N	1	136	130	successful	nil
36	776251	11	M	Phimosis	circumcision	N	1	110	104	successful	nil
48	769344	13.6	M	ureterocele	cystoscopy	N	1	110	104	successful	nil
60	768254	15.6	M	right hydrocele	repair	N	1	102	96	successful	nil
60	770438	15.1	M	right inguinal hernia	right herniotomy	N	1	120	114	successful	nil
12	770428	9.3	M	right inguinal hernia with phimosis	right herniotomy with circumcision	N	1	140	132	successful	nil
24	770553	10.3	M	Phimosis	circumcision	N	1	128	120	successful	nil
96	777261	19	M	Phimosis	circumcision	N	1	98	92	successful	nil
36	776493	8.5	F	hirschsprung's disease	rectal biopsy	N	1	116	106	successful	nil
108	776412	17	M	rectal polyp	excision	N	1	92	86	successful	nil
24	777275	10.2	M	Phimosis	circumcision	N	1	136	124	successful	nil
48	777426	9.8	F	rectal polyp	excision	N	1	116	104	successful	nil
24	777698	8.7	M	Phimosis	circumcision	N	1	140	128	successful	nil

ANNEXURE V - KEY TO MASTER CHART

ASA	-	American Society of Anaesthesiologists
F	-	Female
M	-	Male
HR	-	Heart Rate (bpm)
min.	-	Minutes
kgs.	-	Kilograms
N	-	No
Y	-	Yes
Ns	-	Not significant
Hs	-	Highly significant

ANNEXURE – VI – ETHICAL CLEARANCE LETTER

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 369. **Date: 16/11/2015**

To,

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"A COMPARISON OF EFFICACY OF ULTRASOUND GUIDED VERSUS TRADITIONAL APPROACH FOR CAUDAL EPIDURAL ANAESTHESIA IN PAEDIATRIC PATIENTS – A ONE YEAR HOSPITAL BASED RANDOMIZED CONTROLLED TRIAL",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Ganga Pilli)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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