

**TITLE: RANDOMISED CONTROLLED TRIAL COMPARING CAUDAL
BLOCK ANALGESIA WITH CONVENTIONAL ANALGESICS
FOR POST OPERATIVE PAIN RELIEF IN CHILDREN AT
KENYATTA NATIONAL HOSPITAL NAIROBI, KENYA.**

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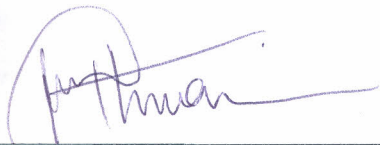
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DECLARATION

This dissertation is my own original work and has not, to my knowledge, been presented for any degree in any other University.



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SUMMARY

A prospective study was carried out at Kenyatta National Hospital over a period of three months (March to May 2001) comparing caudal block analgesia and conventional analgesics for post-operative pain relief, in two groups paediatric surgical patients undergoing genitourinary procedures. Both groups consisted of patients aged between one and twelve years. The aim of the study was to assess the efficacy of caudal block analgesia in providing post-operative pain relief and also to determine the incidence of side effects with caudal block analgesia.

The first group (conventional analgesics) consisted of forty patients, of which males were thirty two (80%) and females were eight (20%). The average age of children in this group was 4.45 ± 3.14 yrs and ranged from one year to twelve years. The average weight for children in this group was 14.83 ± 5.54 Kg(kilograms) and ranged from eight kilograms to twenty seven kilograms. Mean duration of analgesia was 50.31 ± 15.96 minutes and ranged from thirty minutes to seventy five minutes, while the mean duration of surgery was 33.50 ± 5.99 minutes and ranged from fourteen minutes to sixty five minutes.

The second group (caudal block analgesia) also consisted of forty inpatients, of which thirty three (82.5%) were males and females were seven (17.5%). The average age for children in this group was 5.17 ± 3.39 years and ranged from one year to twelve years and the average weight was 18.13 ± 6.67 kilograms and ranged from six and a half kilograms to thirty four kilograms. Average duration of analgesia in this group was 69.08 ± 41.61 minutes and ranged from twenty three minutes to two hundred and forty minutes, while the average duration of surgery was 52.89 ± 40.85 minutes and ranged from seventeen minutes to two hundred and twenty minutes.

Premedication was the same for all patients, being atropine 0.01 per kilogram body weight given intramuscularly. Induction was either inhalation with halothane (0-3%), nitrous oxide (50-70%) in oxygen or with intravenous sodium thiopentone 4-7 mg/kg body weight. Intubation was facilitated by suxamethonium at a dose of 1 mg/kg body weight intravenously. Immediately after intubation before any surgical stimulus analgesia was instituted. Group I received intravenous pethidine 1 mg/kg body weight while group II received caudal block with bupivacaine 0.25% according to the scheme suggested by Armitage.

The outcomes were assessed by the pain score of "modified" children's Hospital of Eastern Ontario Pain Score (mCHEOPS) from immediate post-operatively to 6 hours post-operatively. The study showed that there was no significant difference in pain scores from immediately post-operatively to 6 hours post-operatively in the two groups studied. The incidence of side effects with caudal block analgesia namely nausea, vomiting, delayed urination, delayed ambulation were also not statistically significant. There was a significant difference in the duration of anaesthesia and surgery between the two groups ($p < 0.05$). In this study pain requiring analgesia was defined as an mCHEOPs score of greater or equal to six (≥ 6).

INTRODUCTION

The last few years have seen serious attempts to improve post-operative pain. Post-operative pain differs from other types of pain in that, it is iatrogenic, usually transitory, with progressive improvement over a relatively short time course. The traditional management, of post-operative pain, namely that of prescribing a standard dose of intramuscular opioid on demand by nursing staff when patients threshold has been exceeded, leads to poor control of pain. The enormous variations in the extent of analgesic requirements depend upon many factors, for example, type of surgery, pharmaco-kinetic variability, and many others. A considerable effort has gone into developing new methods, such as patient controlled analgesia (PCA). The other main thrust has been better organization of delivery of analgesia through pain relief services (1-4).

A more appropriate development might be a switch to local analgesic techniques. Caudal block analgesia is one of the many local analgesic techniques used to provide post-operative analgesia in the early post-operative period (5,6,7).

Caudal block analgesia was introduced by Cathelin and Sicard (1872 – 1929) of Paris in 1901 but neither employed it for operations. It was used by Schlimpert in 1910 and in obstetrics by Stoeckel in 1909, who was the first to report painless vaginal delivery following injection of their discovered agent procaine, into the epidural space. Sacral extradural blocks in infants and children was first described in 1933.

Caudal block is a kind of epidural block technique, the needle being inserted through the sacral hiatus. The main indication for caudal block is to provide anaesthesia and analgesia for procedures or organs innervated through sacral nerves 2 to 5 and coccygeal nerves.

It's particular advantages not shared with alternative epidural techniques are:

- Minimal effects on innervation of the lower limbs, abdominal walls and blood vessels.
- Low risk of accidental dural puncture
- Minimal hypotension from spread of local analgesic solution to the thoracolumbar sympathetic outflow and therefore, suitable for all categories of high risk patients.

Previous reports have shown that randomized controlled trial carried out to compare caudal analgesia using bupivacaine for post-operative pain relief, produces good post-operative analgesia comparable to that produced by intramuscular analgesics (8,9,10,11,12). A single dose of caudal analgesic is a simple, safe and effective technique which has been particularly useful in children (13). Although several studies have confirmed the efficacy of caudal analgesia for post-operative pain relief, and that it is a technique practically applicable to children undergoing urologic procedures (14,15). Here at Kenyatta National Hospital (K.N.H) no studies have been done to compare the efficacy of caudal analgesia, especially in comparison with other conventional methods of post-operative pain relief.

The purpose of this study therefore, was to compare the efficacy of caudal analgesia versus conventional analgesics in providing post-operative pain relief and to document the incidences of side-effects with caudal analgesia.

AIMS AND OBJECTIVES

GENERAL

To compare the efficacy of caudal analgesia against conventional analgesia in providing post-operative pain relief and to document the incidences of side effects in the paediatric surgical population at Kenyatta National Hospital.

SPECIFIC

1. To compare the efficacy of caudal block analgesia against conventional analgesics in providing post-operative pain relief.
2. To assess the incidence of side effects with caudal block.

MATERIALS AND METHODS

STUDY DESIGN.

Prospective cohort study, where the sample population was paediatric surgical patients scheduled for elective surgery. Operations were urological procedures in the regions of the umbilicus and below.

STUDY SITE.

The study was carried out at Kenyatta National Hospital KNH, (a tertiary and referral hospital) in the paediatric surgical ward, and main theatre. The paediatric surgical ward is situated on level four of the tower block of KNH. It has a capacity of 60 beds. The paediatric surgical unit has four (4) elective surgical lists in a week, with an average of four to five patients in each list.

SAMPLE SIZE.

The formula to calculate sample size required relevant to my study was;

$$Z(1-\alpha) [P_1(1-P_1)+P_2(1-P_2)]/d^2$$

Where;

Z	=	Standard error of the mean corresponding to 95% confidence level (one tailed)
Z(1- α)	=	1.645
P ₁	=	Percentage of success (Caudal group)
P ₂	=	Percentage of success (Conventional analgesics)
d	=	Absolute precision.

The number of patients therefore, required using 5% level of significance with 95% power for caudal analgesia and 90% for conventional analgesics to within 10 points, a minimal sample of forty (40) patients per group is required.

PATIENT SELECTION.INCLUSION CRITERIA.

- i. American Society of Anaesthesiologists classification (ASA I-II)
- ii. In-patients with post-operative stay for a duration of ≥ 24 hours
- iii. Elective surgical cases (age 1-12 years)
- iv. Surgery from the umbilicus and below, namely genito-urinary procedures.

EXCLUSION CRITERIA.

- ASA \geq III
- Emergencies
- Day case surgeries (< 24 hours) post-operative hospital stay
- Allergy to the study drug.

PLAN OF THE STUDY.

Patients were identified as suitable for the study and were alternatively placed in either of the two groups:

GROUP I: Patients undergoing surgical urologic procedures under general anaesthesia using conventional techniques of pain relief.

GROUP II: Patients undergoing surgical urological procedures under general anaesthesia using caudal blocked for pain relief.

All patients under this study had a pre-anaesthetic review, when the paediatric surgical registrar made a theatre list. During the review, patient's general condition was assessed.

A written consent was taken. Basic investigations including haemoglobin and electrolytes were required and were checked at the time of pre-operative visit and made sure that they were recent and were within normal ranges. Also during the pre-operative visit, the patients were weighed and premedication prescribed and assurance given to both patient and parent. Patients were premedicated using atropine 0.01mg/kg and pethidine

1-1.5mg/kg intramuscularly, 30 minutes before induction of anaesthesia. The vital signs namely; pulse rate, blood pressure, respiratory rate and temperature were recorded in the ward and rechecked at the "receiving area" of main theatre. The patient was then wheeled into the operating theatre where he or she was placed to lie on the operating table. Monitoring equipments including electrocardiogram (E.C.G) electrodes, sphygmomanometer and temperature-recording strips were fixed and a record made. Relevant intravenous lines (I.V.) were also fixed. Fluid calculation, according to weight of the child and number of hours starved, was given appropriately. Anaesthesia was induced with

- Oxygen 3-4 litres/minute
- Nitrous 3-4 litres/minute
- Halothane 0-3%/minute.

For older children induction was facilitated by sodium thiopentone at a dose of 4-7mg/kg intravenously, after pre-oxygenation for three to five (3-5) minutes. In all patients intubation was facilitated by intravenous suxamethonium at a dose of 1mg/kg. Following intubation of the trachea, anaesthesia was maintained with halothane 0.5%-2% and 50-70% nitrous oxide in oxygen. Patients were given analgesia as per their grouping:

GROUP I: Patients in this group received pethidine at a dose of 1mg/kg intravenously as a form of intraoperative and post-operative analgesia.

GROUP II: Patients in this group received caudal block analgesia bupivacaine 0.25% according to the scheme suggested by Armitage (6)

At the termination of surgery, nitrous oxide and halothane were switched off. The patient was ventilated with 100% O₂. The pharynx was sucked and trachea extubated after return of protective reflexes. The patient was then given 100% O₂ by mask for another 2-5 minutes.

The patient was then handed over to the "recovery ward" staff. In recovery ward, routine observations of vital signs were made and a study chart representing the assessment of the patient's level of pain from none to severe was recorded. The same criteria and time interval for observations was followed for both methods of pain relief. For these observations, the method of pain scoring was an observational pain scoring system of the "modified children's Hospital of Eastern Ontario pain scale" (mCHEOPS). This has been developed to assess post-operative pain in children one year and older. It assigns a numeric score to aspects of behaviour which are associated with pain including posture, movement, language and crying. The mCHEOPS system is a valid and reliable method of assessing pain in children (16) and has been used by others in similar situation (17). The mCHEOPS assigns a score from 0 to 10. Additional data included incidence of vomiting, time to first urination and time to first ambulation.

The first readings were taken immediately, post-operatively in the "recovery ward" and hourly thereafter upto 6 hours post-operatively. The assessment of pain was done by a research assistant who had been trained in the use of pain scores but was blinded to the method of analgesia used. Records of nausea, vomiting, time to first urination and time

to first ambulation was also recorded.

In order not to interfere with ward management of post-operative pain relief, analgesia was instituted as per treatment chart ordered by the ward registrar. Pain scores of ≥ 6 were taken to mean as pain requiring analgesia. The statistical method employed in this study was Mann-Whitney U test was used to test for significant difference between the two test methods for continuous data and for categorical data, the chi-square statistic was used to test for differences between the two treatment methods.

RESULTS.

SEX.

A total of 80 patients were studied. Group I consisted of 40 patients of whom 32 were males (80%) and 8 were females (20%). Group II consisted also of 40 patients. 33 males (82.5%) and 7 females (17.5%).

ASA STATUS.

This was comparable with each group having 36 patients (90%) being ASA I and 4 patients (10%) in each group ASA II.

AGE.

Age distribution for the two groups was in the range of 1 year to 12 years, with a mean of 4.45 years \pm 3.14 in group I and mean of 5.17 years \pm 3.39 in group II.

WEIGHT.

Mean weight for group I was 14.83 kg \pm 5.44 and ranges were 8-27kg and the mean weight for group II was 18kg \pm 6.674, range 6.5-34 kg. This was statistically significant ($P < 0.05$).

DURATION OF ANAESTHESIA AND SURGERY.

Duration of both anaesthesia and surgery was longer for the caudal group than for conventional analgesia and was statistically significant ($P < 0.05$). Mean duration of

anaesthesia in the conventional group was 50.1 minutes \pm 15.96 range 30-75 minutes and for surgery 33.5 minutes \pm 14.99, range 14-65 minutes. While the mean duration for anaesthesia and surgery in the caudal group was 69.08 \pm 41.61 range 23-240 minutes and 52.89 \pm 40.85 range 17-220 minutes respectively.

The results for the two groups of patients for ASA status, sex, age, weight and duration of surgery and anaesthesia are shown in table 1.

Table 1:

Number of patients in each group with ASA status, sex, mean ages and weights, duration of surgery and anaesthesia.

		Conventional Analgesic group	Caudal group
Number of patients		40	40
ASA status	I	36 (90%)	36 (90%)
	II	4 (10%)	4 (10%)
Sex	Male	32 (80%)	33 (82.5%)
	Female	8 (20%)	7 (17.5%)
Age, years (Mean \pm S.D.)		4.45 \pm 3.14	5.17 \pm 3.39
Weight, kilogram (Mean \pm S.D)		14.83 \pm 5.54	18.13 \pm 6.67
Duration of anaesthesia(minutes) (Mean \pm S.D)		50.31 \pm 15.96	69.08 \pm 41.61
Duration os surgery (minutes) (Mean \pm S.D.)		33.50 \pm 5.99	52.89 \pm 40.89

PAIN SCORE

There was no significant difference in the analgesia produced by the two different methods as assessed immediately post-operatively by the observer. In the third hour post-operatively, 7/40 patients (17.5%) in the caudal group required to be given analgesics against none of the conventional analgesics. This was statistically significant. Four to six hours post-operatively there was no significant differences in the requirement of analgesia.

NAUSEA AND VOMITING.

There were no significant differences between the groups as regards to the occurrence of vomiting post-operatively. The incidence of vomiting in the first and second hours was not reported for both groups. At three hours post-operatively 1/40 (2.5%) of conventional analgesic group and 3/40 (7.5%) of caudal analgesic group were reported to have vomited. At four hours post-operatively 1/40 (2.5%) of the conventional analgesic group and 4/40 (10%) of the caudal analgesic group were reported to have vomited. At five hours post-operatively, only 1 patient (2.5%) in the caudal group was reported to have vomited, while at six hours post-operatively, only 1 patient (2.5%) of the conventional analgesic group was reported to have vomited. These differences were not statistically significant.

AMBULATION AND URINATION.

Most patients were able to void and were ambulatory within the first hour post-operatively.

DISCUSSION.

Most urogenital surgical procedures such as circumcision and correction of hypospadias cause much post-operative pain which in children may give rise to restlessness, agitation and crying. Feeling pain may cause the child to manipulate the operation site, narcotics are usually without satisfactory effect (18), whereas caudal block has been found to be a satisfactory method of pain relief in such cases (5,19,20,21,22). Caudal blocks using bupivacaine have been seen to provide pain relief for an average of four and a half hours in children (20).

In this study, we have found that both caudal bupivacaine and intravascular pethidine provide good analgesia. Randomized controlled trials done previously and shown that caudal bupivacaine produces good analgesia, were mainly compared to that of intramuscular analgesics. In one study, 40 boys aged between 2 years and 12 years selected for circumcision for surgical reasons in which caudal analgesia with bupivacaine 1.5mg/kg was compared with intramuscular morphine 0.15mg/kg, caudal analgesia was shown to be significantly better than morphine by means of a linear analogue scale, designed to quantify behaviour immediately after operation. The bupivacaine group was also shown to be superior in analgesia (9). The author showed caudal analgesia to be superior only in the first 30 minutes post-operatively.

May et al (11) in a definitive study of 44 otherwise healthy boys, age range 9 months to 9 years who underwent circumcision as day cases, analgesia was provided by either

bupivacaine (0.5ml/kg) by caudal injection or intramuscular buprenorphine 3 μ g/kg. They reported that both methods provided good analgesia, however in the first two hours post-operatively, caudal analgesia appeared superior in quality. This was not statistically significant. In the first 2 hours post-operatively, only one child in the caudal group required additional analgesia due to technical failure.

Bramwell (10) performed a clinical trial to compare the effects of intramuscular dihydrocodeine with caudal bupivacaine on post-operative pain and recovery in 181 children, who had undergone either circumcision, inguinal herniotomy or orchidopexy performed under general anaesthesia. The trial showed that different operations produced different patterns of pain and for ninety minutes following circumcision, there was significantly less pain with caudal analgesia but better pain relief could not be demonstrated following inguinal herniotomy and orchidopexy.

In another study (12) where analgesic effects of systemically administered diamorphine (0.07mg/kg) where, a small dose upto 0.5mg was given slowly intravenously during the early part of the operation and the remainder of the dose was given intramuscularly when surgery was completed. Caudal analgesia with 0.5% bupivacaine and caudal analgesia with 0.5% plain bupivacaine to which morphine sulphate was added (2mg added to 10mls of 0.5% bupivacaine), sixty boys undergoing circumcision were studied. Post-operative analgesia was assessed using the linear analogue scale. The time interval between operation and subsequent analgesic administration and the number of analgesic doses in

24 hours was compared. All three methods provided satisfactory results. The small dose of morphine used caudally did not produce prolonged analgesia.

Jensen (8) also did a study on twenty two children, to find out the effect and duration of the post-operatively applied caudal block, on post-operative pain relief after genital operations. His study was different as both groups were given caudal block analgesia, but one group was given bupivacaine and the other morphine (0.05mg/kg). He concluded that the duration of pain relief using caudal morphine was longer than caudal bupivacaine and was statistically significant.

In our study, there was no significant difference as regards to the low occurrence of post-operative nausea and vomiting. This compares well with (8,10). In contrast to other studies where though the frequency of vomiting was not significant between the groups but the frequency of vomiting was high (9,11,12). No other complications of either delayed ambulation and delayed micturition was reported in all the previous studies and this compares well with our study.

Reports have indicated that effective post-operative pain relief lasting 6-36 hours can be obtained in adults by the injection of 2-4mg of morphine into the epidural space (23,24,25). If such prolonged pain relief could be obtained in children after genital operations, the post-operative period might be quieter and uncomplicated.

CONCLUSIONS AND RECOMMENDATIONS.

- This study has shown that caudal blockade analgesia compares well with intravascular administration of pethidine in the provision of post-operative pain relief it can therefore be used to add to the wide range of available analgesics in our hospitals.
- The technique is easy to perform in children and because it results in a higher degree of pain relief than does intramuscularly administered opioids, it can be an alternative in cases where either caudal analgesia or intramuscular analgesia can be given.
- Current advances in anaesthesia have gone into researching not only with local analgesic bupivacaine, but new ones like ropivacaine, and also mixtures of local analgesics with opioids and therefore more research on caudal analgesia should be encouraged in our set up.

APPENDIX I (mCHEOPS).

Modified CHILDREN HOSPITAL OF EASTERN ONTARIO PAIN SCALE.

SCORE	0	1	2
CRY	NO CRY	CRYING	SCREAM
FACIAL	SMILING	COMPOSED	GRIMACE
VERBAL	POSITIVE	NONE OR OTHER COMPLAINT	PAIN COMPLAINT
TORSO	NEUTRAL	SHIFTING TENSE UPRIGHT	RESTRAINED
LEGS	NEUTRAL	KICK SQUIRM DRAWN UP	RESTRAINED

APPENDIX II DEMOGRAPHIC DATA

Name of patient

Age of patient years months

IP Number..... Ward

Sex

Diagnosis

ASA Status

Weight..... Kilograms

Operation

Premedication I/M Atropine..... mg

I/M Pethidine..... mg

PREOPERATIVE VITAL SIGNS.

HR...../min RR...../min BP..... mmHg S_aO₂

INDUCTION.

Inhalational: O₂ l/minN₂O l/min

Halothane l/min

Sodium thiopentonemg

Dose of suxamethonium.....mg

MAINTENANCE.

Nitrous oxide.....mg

Oxygen.....mg

Halothanemg

Duration of anaesthesia.....minutes

Duration of operation.....minutes

Blood loss.....mls

INTRAOPERATIVE MONITORING.

RR...../min PR...../min BP..... mmHg S_aO₂..... T.....°C

REVERSAL

PAIN SCORE VOMITING URINATION AMBULATION

- i. Immediately post-operative
- ii. 1 hour post operatively
- iii. 2 hours post operatively
- iv. 3 hours post operatively
- v. 4 hours post operatively
- vi. 5 hours post operatively
- vii. 6 hours post operatively

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