COMPARATIVE STUDY OF THE EFFECTIVENESS OF MORPHINE COMBINED WITH BUPIVACAINE VERSUS BUPIVACAINE ALONE FOR CAUDAL BLOCKS IN PAEDIATRIC PATIENTS UNDERGOING INFRAUMBILICAL SURGERIES AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

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I declare that this dissertation is my own original work and has not been submitted for a degree award in this or any other university. All resources contained herein have been duly acknowledged.

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DEDICATION

To my parents, Islam and Sabah Sherman, who have inspired and offered endless love and support.

To my husband Frederick and my son Keyaan for their moral support and encouragement throughout this time.

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OPERATIONAL DEFINITIONS

Emergence from anaesthesia: Defined as liberation of the patient from the state of anaesthesia.

General anaesthesia: Defined as a medically induced state of unconsciousness with loss of protective reflexes resulting from the administration of one or more general anaesthetic agents.

Induction of anaesthesia: Defined as administration of a drug or combination of drugs at the beginning of an anaesthetic that result in a state of general anaesthesia.

Paediatric patient: Referred to a child from 1 month up to 12 years of age.

Perioperative period: Defined as the time period describing the duration of a patient's surgical procedure. This refers to preoperative, intraoperative and postoperative period.

LIST OF ABREVIATIONS

AAGBI	Association of Anaesthetists of Great Britain and Ireland
ASA	American Society of Anaesthesiologist
FLACC	Face Legs Activity Cry Consolability
KNH	Kenyatta National Hospital
MAP	Mean Arterial Pressure
PACU	Post Anaesthesia Care Unit
SD	Standard Deviation

ABSTRACT

Background: Uncontrolled pain is often associated with increased incidence of postoperative nausea and delirium, prolonged Post Anaesthesia Care Unit (PACU) stay, delayed hospital discharge and delayed resumption of normal activities.(1) Caudal block is one of the most popular anaesthetic regional blocks performed in children worldwide. It provides efficient analgesia both intra- and postoperatively. Bupivacaine is commonly used for caudal block but its effects usually wear off early. Various additives such as morphine have been used to prolong the postoperative analgesic effects of caudal bupivacaine.

Objective: To compare perioperative analgesic effectiveness of bupivacaine combined with morphine and bupivacaine alone for caudal block.

Methodology: This was a comparative observational study that was carried out in paediatric ward, paediatric theatre and PACU. 122 patients aged between 2 months and 12 years were included. Of these, 61 patients received bupivacaine alone and 61 patients received bupivacaine-morphine for caudal block. Patients were monitored for 24 hours and duration of analgesia was noted.

Results: 90% of the patients in the bupivacaine-morphine group had analgesia for more than 24 hours and did not receive rescue analgesia. 95% of patients in the bupivacaine group required rescue analgesia within the first 8 hours of surgery. 0.1 % (n=6) developed pruritus and these were patients in the bupivacaine-morphine group. No other adverse effects were reported.

Conclusion: Caudal block using low dose morphine combined with bupivacaine had a prolonged analgesic effect compared to bupivacaine alone in paediatric patients undergoing infra-umbilical surgery at the KNH.

CHAPTER ONE: INTRODUCTION

The International Association for the Study of pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."(2)

Pain can have direct impact on health outcomes, and if uncontrolled may have diverse effects' on all areas of life. It is not only a sensory perception but has emotional, cognitive and behavioural components. If it is not adequately managed acutely, it might have long term negative effects on pain sensitivity, immune functioning, neurophysiology and attitudes.

In children, it is a subjective sensation which can only be experienced but not adequately expressed, because they depend on their parents for their wellbeing.(3)

Caudal block is one of the most popular regional blocks in children. It is easy and safe. A survey in the United Kingdom(in 2002) by J.C Sanders on paediatric regional anaesthesia, showed 202 of 210 (96%) paediatric anaesthetists used caudal anaesthesia and 123 paediatric anaesthetists used adjuvants with local anaesthetic. He concluded that caudal anaesthesia is widely used in paediatric patients. This technique is a useful adjunct during general anaesthesia and for providing post-operative analgesia.(4)

Different additives like ketamine, opioids, midazolam, clonidine and neostigmine have been used to increase the duration of action, since caudal bupivacaine block wears off early in the postoperative period and supplemental intravenous or intramuscular opiates are often needed.

Caudal epidural morphine has been shown to produce effective analgesia in paediatric patients and it is safe to use. In a study done by M.K Arora on "comparison of bupivacaine and morphine for relief of postoperative pain" concluded that mean duration of analgesia in the morphine group was 12-26 hours (median 20.8 +/- 3.4 hours) while in the bupivacaine group it was 5-12 hours. (5)

The main aim of this study was to compare the analgesic effectiveness of bupivacaine in combination with preservative free morphine versus bupivacaine alone in paediatric surgical patients undergoing infra-umbilical surgery.

CHAPTER TWO: LITERATURE REVIEW

Postoperative pain is defined as a condition of tissue injury together with muscle spasm after surgery. Persistent or uncontrolled pain is associated with increased incidence of nausea and delirium, prolonged post anaesthesia care unit (PACU) stay and delayed discharge. It may also delay resumption of activities. (1)Lack of appropriate analgesic management has significant impact on clinical outcomes. These include extended hospitalization, compromised prognosis, higher morbidity and mortality and the development of chronic pain as a result of neural plasticity.(6)

Goals of postoperative pain management are to relieve suffering, achieve early mobilization, reduce length of hospital stay and achieve patients' satisfaction.

Different modalities have been used in the treatment of post-operative pain. These include systemic analgesic (opioids and non-opioids) and regional analgesic techniques (neuraxial and peripheral).(2)

Systemic analgesics

Opioids: They are among the cornerstone options for the treatment of postoperative pain and are essential in the management of moderate to severe pain in both, medical and surgical patients.(7)

Examples of opioids include morphine, hydromorphone, fentanyl, sulfentanil, alfentanil, remifentanil and meperidine. They exert their effects on the u-receptors in the central nervous system. Side effects associated with systemic opioids are respiratory depression, sedation, gastrointestinal side effects, pruritus, urinary retention, bradycardia and muscle rigidity.

Nonopioids: These include non-steroidal anti-inflammatory drugs (NSAIDS), ketamine, tramadol and paracetamol.

Regional analgesic techniques

Neuraxial and peripheral regional techniques may be used for effective treatment of postoperative pain.

Neuraxial blocks include spinal, epidural and caudal blocks.

Analgesia provided by either neuraxial blockade or peripheral technique is noted to be superior to that with systemic opioids. Meta-analysis done by Brian M Block et al on efficacy of postoperative epidural analgesia, showed that epidural analgesia regardless of analgesic agent, location of catheter placement and type and time of pain assessment, provided better

postoperative analgesia compared with parenteral opioids. (8)Another meta-analysis done by Wu CL et al on efficacy of postoperative patient-controlled and continuous infusion epidural analgesia versus intravenous patient-controlled analgesia with opioids, concluded that, epidural analgesia provided superior postoperative analgesia overall compared intravenous patient-controlled analgesia.(9)

A Study done by Elliot J Krane et al on caudal morphine for postoperative analgesia in children, concluded that caudal preservative-free morphine provided analgesia for longer duration and without side effects than those seen with conventional parenteral morphine.(10)

Caudal block was first introduced by Cathelin in 1901 but was not used for any operations. In paediatric anaesthesia it was first used in 1933 by Meredith Campbell for cystoscopies.(11)

Caudal block is the most commonly used form of regional anaesthesia in children. It provides effective analgesia for both intraoperative and postoperative periods following a wide variety of lower abdominal and genitourinary surgical procedures. Examples of such procedures include urogenital, rectal, inguinal and lower extremity surgeries.(12)

It can be used as a sole anaesthetic method in adults, but in children it is combined with general anaesthesia.(12)

It offers excellent analgesia without the side effects of intravenous opioids e.g. nausea, vomiting, sedation and respiratory depression. (12)

Different additives have been used to increase the duration of action of local anaesthetics. Several studies have been done in this regard.

Dr Momanyi Kennedy et al in; "a prospective randomized control study comparing intraoperative and postoperative analgesic efficacy of clonidine with bupivacaine for caudal block in paediatric surgical procedures" demonstrated that addition of clonidine to bupivacaine prolongs the duration of analgesia to 8.03 hours compared to bupivacaine alone (5.18 hours).(13)

A study in Accra, Ghana in 2007 by Olubukola O Nafiu et al; "prospective randomized double blinded study to evaluate perioperative analgesic efficacy of caudal ketamine with or without bupivacaine in children undergoing lower abdominal surgery", showed that preservative free ketamine combined with bupivacaine prolonged analgesia for 14 hours compared to bupivacaine alone which lasted for only 4 hours.(14)

Dexamethasone has also been shown to increase the duration of action of local anaesthetics. Hong et al found that addition of dexamethasone to bupivacaine prolongs the duration of postoperative analgesia by 646 minutes compared to bupivacaine alone and decreases the incidence of postoperative nausea and vomiting in paediatric patients.(15)

"Comparison of caudal bupivacaine and morphine for relief of postoperative pain in children" by MK Arora et al, showed that low dose morphine combined with bupivacaine given caudally gave longer duration of analgesia of a mean of 20.8 +/- 3.4 hours in children undergoing urogenital, general surgical and orthopaedic procedures without significant side effects.(5)

2.1 Contraindications to Caudal Anaesthesia

Absolute contraindications to caudal anaesthesia include parental refusal and severe coagulation disorders which may either be constitutional, acquired or therapeutic.(2)
Other contraindications are severe infection such as septicaemia or meningitis, hydrocephaly and intracranial tumoral process, allergy to local anaesthetics, certain chemotherapies prone to induce subclinical neurologic lesions that can be acutely aggravated by a block procedure, uncorrected hypovolemia and cutaneous or subcutaneous lesions at the contemplated site of puncture.(2)

2.2 Complications of Caudal Anaesthesia

Dural Puncture: This occurs if the needle is advanced excessively into the subarachnoid space causing extensive spinal anaesthesia.(16)(17)(18)
Vascular Puncture: this can lead to intravascular injection and consequently LA systemic toxicity.(19)(20)
Partial or Complete Failure Block: this often occurs when the anaesthetist is not able to identify the anatomic landmarks and therefore is unable to insert the caudal needle into the epidural space.(18,19, (21) It frequently occurs in children with anomalies.
Rare complications of Caudal Anaesthesia: rectal puncture(22), unilateral block(23)and sacral osteomyelitis(24).

A one year prospective survey of the French language Society of Paediatric Anaesthesiologists on Epidemiology and morbidity of Regional Anaesthesia (ARPEF) in children established the safety of Regional Anaesthesia in children of all ages based on a large and representative series of paediatric anaesthetics. Data was collected from 85,412 anaesthetics (61,003 General Anaesthesia and 24,409 Regional Anaesthesia). Out of 24,409 regional anaesthesia given, 15,103 were Central Blocks. Caudal Blocks accounted for more than 60% of all cases of

Regional Anaesthesia. It was noted that complications were rare (25 incidents) and minor, and did not result in any sequelae or medico-legal action. (25)

2.3 Drugs used For Regional Anaesthesia

LOCAL ANAESTHETICS

Local anaesthetics provide anaesthesia and analgesia by blocking the transmission of pain sensation along the nerve fibres.(26)

Currently available, clinically useful agents are either Aminoesters or Aminoamides

Commonly used aminoesters include Procaine, Chloroprocaine, Tetracaine, and Cocaine. Aminoamides include Lidocaine, Mepivacaine, Prilocaine, Bupivacaine, Ropivacaine and Etidocaine.

Esters and amides differ in their chemical stability, locus of biotransformation and allergic potential. Amides are extremely stable while esters are unstable in solution.

Aminoesters are hydrolysed in plasma by cholinesterase enzymes while amides undergo enzymatic degradation in the liver.(2)

BUPIVACAINE

Bupivacaine has been the most commonly used agent for caudal block.(3) It is a long acting amide local anaesthetic agent with a structure similar to that of lidocaine except that the entire amine-containing group is butyl piperidine.(2)

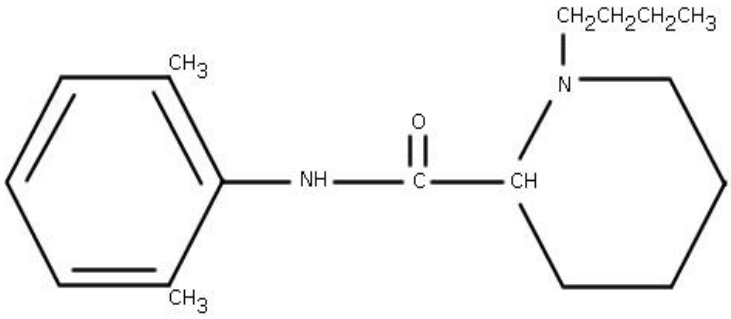

Figure 3: Structure of bupivacaine

Mechanism of action of bupivacaine is like other local anaesthetics. It blocks peripheral nerves by disrupting the transmission of action potential along the nerve fibres.(2)

Its long duration of action plus its tendency to provide more sensory than motor block has made it a popular drug for providing prolonged analgesia intra-operatively and post-operatively. It is used for nerve blocks with exception of intravenous regional anaesthesia. It is particularly suitable for continuous epidural analgesia in labour and is also of value for single shot epidural injections for surgery and spinal anaesthesia.(13).

2.4 Local anaesthetic toxicity

Local anaesthetic intoxication is a rare but catastrophic occurrence.

It can be divided into 3 categories:

Local toxicity.

Systemic toxicity.

Allergic reactions.

Local toxicity includes

Neurotoxicity, which can manifest as Transient neurological symptoms comprises of a syndrome of pain or dysthesia in the buttocks or legs after recovery from spinal anaesthesia or local anaesthetic myotoxicity.(26)

Systemic toxicity can either CNS or cardiovascular.

Central nervous toxicity: symptoms include circumoral paraesthesia, tinnitus, confusion, convulsions, and loss of consciousness, coma and respiratory depression.(26)

Cardiovascular toxicity is seen at a plasma concentration far greater than that for CNS toxicity. Symptoms include hypertension and tachycardia in the initial phase, myocardial depression, decreased cardiac output and hypotension in the intermediary phase and peripheral vasodilation, severe hypotension, sinus tachycardia, conduction defects and dysrhythmias in the terminal phase.(26)Among the potent long-acting agents, ropivacaine and levobupivacaine may have a safer cardiovascular toxicity profile than bupivacaine.(26).

Treatment of suspected systemic local anaesthetic toxicity is primarily supportive.

Administration of a local anaesthetic should cease immediately. Oxygenation and ventilation should be maintained and airway should be secured. Seizures should be controlled as it can increase the body’s metabolism and result in metabolic acidosis.

Mild myocardial depression and systemic vasodilation can be corrected with sympathomimetic agents. Pending cardiovascular collapse from severe cardiac dysrhythmias should prompt immediate cardiopulmonary resuscitation.(2)

Intravenous infusion of Lipid emulsion is used to hasten the return of normal cardiac function. The use of lipid infusions has been recommended by the Association of Anaesthetists of Great Britain and Ireland (AAGBI) in its guidelines for treating local anaesthetic toxicity a summary of which is presented in appendix 4

2.5 Opioids

The term opioid refers to all compounds related to opium.

They can be classified into:

Natural; which include morphine, codeine, papaverine and thebaine.

Semisynthetic; include heroin, dihydromorphone and thebaine derivatives (buprenorphine)

Synthetic; include morphinan series (butorphanol), diphenylpropylamine series (methadone), benzomorphan series (pentazocine), phenylpiperidine series (meperidine, fentanyl, sufentanil).

Opioids can be classified as agonists, partial agonists, mixed agonist-antagonists and antagonists on the basis of their interaction with opioid receptors.

Side effects of opioids include nausea and vomiting, urinary retention, constipation, pruritus, sedation and respiratory depression. (7)

2.6 Morphine Use in Caudal Anaesthesia

It is a naturally occurring opioid. Morphine produces its major effects in the CNS.

It mimics the effects of endogenous opioids by acting as an agonist at μ_1- and μ_2-opioid receptors throughout the body and is considered the standard agonist to which other μ-agonists are compared.

Morphine analgesia results from complex interactions at a number of discrete sites in the brain, spinal cord, and under certain conditions, peripheral tissues, and involves both μ_1 and μ_2 opioid effects.(27)

Routes of administration include intravenous, intramuscular, oral, subcutaneous, intrathecal and epidural.

Caudal epidural morphine has been shown to produce effective analgesia in paediatric patients. In a study done by Elliot J Krane on“ caudal morphine for postoperative analgesia: a comparison with caudal bupivacaine and intravenous morphine” concluded that caudal morphine provided 8-24 hours (median 12 hours) of analgesia in children without significantly

greater incidence of side effects than caudal bupivacaine (median 5 hours) or intravenous morphine (median 45 minutes).(10)

M.K Arora in; "comparison of bupivacaine and morphine for relief of postoperative pain" concluded that mean duration of analgesia in the morphine group was 12-26 hours (median 20.8 +/- 3.4 hours) while in the bupivacaine group it was 5-12 hrs.(5)

A prospective, randomized, double blinded study by Fernandes ML concluded that 20mcg/kg of morphine added to caudal bupivacaine 0.166% plus epinephrine 1:600,000 decreased the use of rescue analgesics in the postoperative period. Clonidine added to caudal bupivacaine provided no additional clinical benefit over bupivacaine alone. (32)

Side Effects of caudal morphine are dose dependant. Elliot J Krane in; "dose response of caudal morphine in children", compared the duration of action and frequency of side effects of 3 doses of caudal morphine in 32 children aged between 1.2-7.9 years, assigned randomly to receive 0.033mg/kg, 0.06mg/kg and 0.1mg/kg of preservative free morphine. They noted that duration of analgesia was longer in the 0.1mg/kg group than in the 0.033mg/kg and 0.06mg/kg but delayed respiratory depression occurred in one child in the 0.1mg/kg group. The authors recommended 0.033mg/kg of caudal morphine as an initial dose.(27)

Postoperative vomiting was also reported by Dostbil A et al in; "the effects of different doses of caudal morphine with levobupivacaine on postoperative vomiting and quality of analgesia after circumcision." They compared the effect of 3 different morphine doses, 7.5mcg/kg, 10mcg/kg and 15mcg/kg added to 0.125% levobupivacaine for caudal analgesia in 240 patients aged between 5-12 years. They noted that the incidence of postoperative vomiting was 5%, 12.5% and 17.5% respectively. In conclusion, because the incidence of vomiting was very low, the duration of postoperative analgesia was long and dose of 7.5mcg/kg caudal morphine was much lower than the doses previously reported to be associated with respiratory depression, the study supported the use of 7.5 mcg/kg caudal morphine added to 0.125% levobupivacaine.(28)

2.7 Study Justification

Pain is one of the most common, unpleasant and frightening symptoms associated with surgery.(1)Untreated acute postoperative pain leads to extended hospitalization, compromised

prognosis, higher morbidity and mortality and the development of chronic pain state as a result of neural plasticity.(6)

Caudal block is one of the most popular anaesthetic regional block performed in children worldwide.(4) It is simple, safe and does not require any complicated equipment. It provides efficient analgesia both intra-operatively and postoperatively.(9)Bupivacaine is commonly used for caudal block but its effects usually wear off early in the postoperative period. A study done by MK Arora showed that the duration of action of caudal bupivacaine ranged between 5-12 hours, while that of caudal morphine ranged from 12-26 hours. (5)

Similarly, Serlin S et al, in 1991 showed that single-dose caudal epidural morphine provided postoperative analgesia in children for 12-24 hours and was safe effective and easy to administer. 60 micrograms/kg of preservative-free morphine sulphate was administered caudally after induction of anaesthesia but before surgery began. (34)

Preservative free morphine used in combination with bupivacaine has been shown to prolong postoperative analgesia (5) and is safe to be used for caudal block. (22) .Although there are no studies on ethnic differences in response to caudal morphine, studies have been done on intravenous morphine and have shown that ethnicity is an important determinant. A study done by HH Zhou M.D, James R Sheller M.D, on "ethnic differences in response to morphine", compared pharmacokinetics and pharmacodynamics in eight Chinese and eight white healthy men after 0.15mg/kg of morphine intravenously. The clearance of morphine was noted to be higher in the Chinese men compared to that of the white men. It was also noted that morphine depresses the respiratory response to rebreathing carbon dioxide more in white men than in Chinese, resulting in a greater reduction in resting ventilation and resting end-tidal PCO2. Morphine-induced hypotension was much lower in the Chinese group than the white. However, it was noted that there was no inter-ethnic difference in the metabolism to normophine. This study shows that ethnicity is an important determinant of the disposition and effects of morphine. (33).

Alastair J.J Wood and Hong Hao Zhou in; "ethnic differences in drug disposition and responsiveness" concluded that for polymorphically metabolized drugs, interethnic differences may sometimes be explicable on the basis of an altered frequency of the different phenotypes in different ethnic groups.(29).

Various additives have been used to prolong the postoperative analgesic period in paediatric patients undergoing surgery. However there is scanty data for Africa in general and East Africa in particular on those various additives used.

This study aimed to determine whether addition of preservative free morphine to bupivacaine prolongs postoperative analgesia following caudal block in the African paediatric population and provide evidence for an Institutional protocol.

2.8 Study Objectives

2.8.1 Broad objective

To compare perioperative analgesic effectiveness of bupivacaine combined with morphine and bupivacaine alone for caudal block.

2.8.2 Specific objectives

1. To determine the post-operative analgesic effectiveness of bupivacaine combined with morphine for caudal block
2. To determine the post-operative analgesic effectiveness of bupivacaine alone for caudal block.

3. To evaluate the systemic side effects of bupivacaine combined with morphine.

2.9 Research Question

Does the addition of morphine to bupivacaine for caudal block prolong postoperative analgesic effect in paediatric patients undergoing infra-umbilical surgery?

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study design

A Comparative Observational Study

3.2 Study site

The study was carried out at Kenyatta National Hospital paediatric surgical ward (4A), paediatric theatre (theatre 12) and Post Anaesthesia Care unit (PACU).

KNH is the largest teaching and referral hospital in East and Central Africa with a bed capacity of one thousand eight hundred and fifty inpatient beds. It has twenty four operating theatres (16 specialized).

3.3 Study population

Paediatric patients who were scheduled for elective surgery at the Kenyatta National Hospital fulfilling the following criteria:

Inclusion criteria:

1. Paediatric patients scheduled for elective surgical procedures from the umbilicus and below.
2. Informed consent from the parents or guardian.
3. ASA class I & II paediatric patients.
4. Postoperative stay of more than 12 hours.

Exclusion criteria:

1. Emergency cases.
2. Neonates
3. ASA class III & IV patients
4. Day case surgeries
5. Allergies to local anaesthetics
6. Contraindication to caudal anaesthesia and
7. Patients whose parents/guardians have declined to give consent for the study.

3.4 Sample size calculation

Comparison of two proportions was used to calculate the sample size

$$n = \frac{[p_1(1-p_1) + p_2(1-p_2)]}{(p_1 - p_2)^2} \times c_{p,power}$$

Table 2

Commonly used values for $c_{p,power}$

	Power (%)			
P	50	80	90	95
0.05	3.8	7.9	10.5	13.0
0.01	6.6	11.7	14.9	17.8

Using the study by Parameswari et al (30) for comparison of proportions, p1 = 74%, p2 = 94%, and a power of 95% and Confidence interval of 99% ($C_{p.power}$ = 17.8)

$$n = \frac{[0.74(1-0.74)+0.94(1-0.94)}{(0.74-0.94)2} x\ 17.8 = 110.$$

Attrition of 10% allowed, sample size was 122, 61 patients in each arm.

3.5 Sampling method

Convenience sampling procedure was used to sample patients into two groups based on the drug that was used on the patients. The primary investigator recruited patients into the study consecutively in the process of undergoing the surgical procedures until the required sample size required in each group was achieved, that is 61 patients for each arm.

3.6 Sampling Procedure

The principal investigator reviewed the patients in the ward on the evening before the day of surgery. Patients were identified based on the inclusion and exclusion criteria. The nature of the study was explained to the patient's parent/guardian who was required to give an informed consent by signing a consent form.

Patients listed for surgery were assessed for eligibility and enrolled. Those not meeting the inclusion criteria and those refusing to participate were excluded. Patient's height, weight, blood pressure, pulse rate, oxygen saturation and temperature were taken by the principal investigator the day before surgery. The data was collected using a questionnaire (data collection tool) which was filled by the principal investigator or a trained research assistant**.**
Convenience sampling was used to recruit patients into the study until the required sample size was achieved.
The principal investigator did not make any decisions nor participated in the anaesthetic management of the patient. All the decisions on the management were made by the attending anaesthesiologist in charge of the list.

Upon arriving at the operating room, pre-induction vital signs were recorded. These included oxygen saturation, heart rate, blood pressure, respiratory rate and temperature. Induction of anaesthesia was performed as per the attending anaesthesiologist's discretion with either intravenous or inhalational anaesthetics. The attending anaesthesiologist in charge of the list decided on the drug to use for the caudal anaesthesia; whether bupivacaine alone, or bupivacaine with morphine. He/ she was expected to use the regime that he/ she was comfortable with. He/ she proceeded to administer caudal block as part of the routine practice. The anaesthesiologist also decided on which analgesic drug to use in case the caudal block was inadequate or had failed. Inadequate/ failed block was determined by an increase in heart rate and mean arterial pressure (MAP) of 20%- 25% within 15 minutes of skin incision.
Intraoperative vital signs were recorded every 5 minutes until the end of surgery by the principal investigator and a trained research assistant. Any analgesic drug given intra-operatively was recorded in the data collecting tool.

The principal investigator and the research assistant reviewed the patient's treatment needs for analgesia in the PACU and determined whether the block was effective or not.
Face, Legs, Activity, Cry, Consolability (FLACC)(31)scale was used to assess pain postoperatively in patients less than 7 years of age and Visual Analogue Scale (VAS) in patients above 7 years of age. If a patient scored more than 4, the attending anaesthesiologist was informed and treatment provided as per the anaesthesiologist's treatment plan. The time to first administration of analgesia was noted.
Sedation was assessed by the Pasero Opioid-induced Sedation Scale (POSS) (appendix 3)

Patients were monitored for adverse effects including sedation, urinary retention, pruritus and nausea and vomiting.

Follow up of patients was done for a period of 24 hours by either the principal investigator or the research assistants. Three research assistants were recruited and trained by the principal investigator on how to use the data collecting tool.

3.7 Data Analysis

The vital signs, pain score and duration of analgesia were analysed by use of means and standard deviation, and where applicable medians and interquartile ranges were calculated.

Survival analysis for the duration of analgesia was analysed suing a Kaplan –Meier.

Data was entered on MS Excel® spread sheet and analysis carried out on Stata 14® statistical software.

Data was presented as numbers (%) or mean ± SD and summarized using tables, Histograms and pie-charts as appropriate.

CHAPTER FOUR: RESULTS

In this study, we enrolled a total of 122 eligible paediatric patients slated for infraumbilical surgeries in KNH during the period of September 2017 to February 2018.

The bupivacaine group had 52 (85.2%) males while the bupivacaine-morphine group had 46 (75.4%), [Table 1]. The median age of the participants was 24 months with an interquartile range of 39 months.

The median weight was 11 kg with an interquartile range of 8.4 kg. Most of the participants studied were of normal weight (82) using the WHO z- score.

	Bupivacaine	**Bupivacaine + Morphine**	**Total**
Sex			
Male	52 (85.2)	46 (75.4)	98 (80.3)
Female	9 (14.8)	15 (24.6)	24 (19.7)
Age			
0 - 12 months	30 (49.2)	10 (16.4)	40 (32.8)
13 - 48 months	24 (39.3)	32 (52.5)	56 (45.9)
49 - 180 months	7 (11.5)	19 (31.1)	26 (21.3)
Weight			
Severely underweight	7 (11.5)	5 (8.2)	12 (9.8)
Underweight	5 (8.2)	9 (14.8)	14 (11.5)
Normal weight	42 (68.9)	40 (65.6)	82 (67.2)
Overweight	5 (8.2)	4 (6.6)	9 (7.4)
Obese	2 (3.3)	3 (4.9)	5 (4.1)

Table 1: Demographic Characteristics of Participants

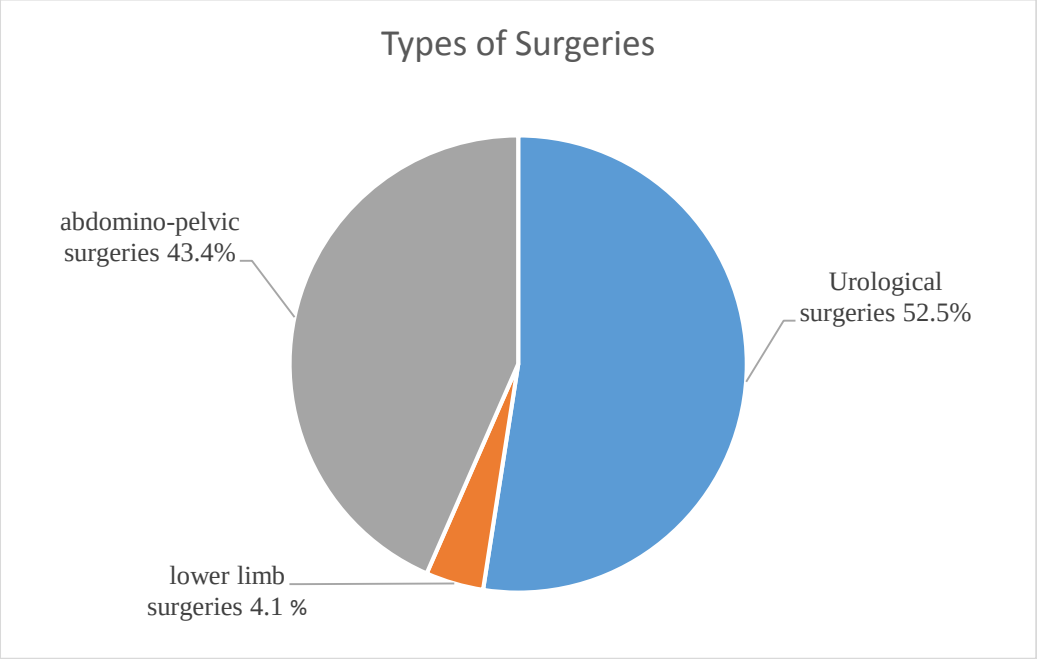

Figure 1: Types of Surgeries

Out of the 122 participants, 64 (52.5%) had urological, 53 (43.4%) abdomino-pelvic and 5 (4.1%) had lower limb surgeries. [Figure 1]

	Bupivacaine	**Bupivacaine + Morphine**	**Total**
Duration of surgery			
< 60 minutes	37 (60.7)	36 (59.0)	73 (59.8)
≥ 60 minutes	24 (39.3)	25 (41.0)	49 (40.2)

Table 2: Duration of Surgery

59.8% (73) of the surgeries took less than 60 minutes while the rest took more. [Table 2].

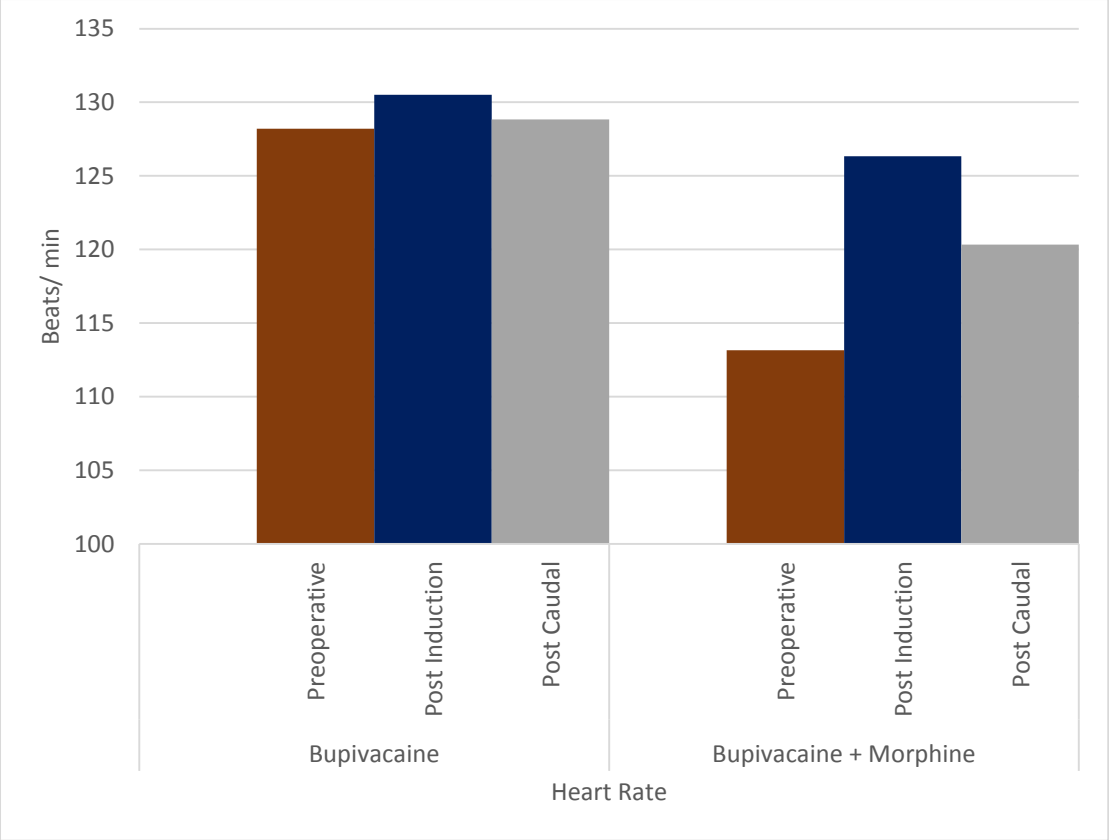

Figure 2: Mean heart rate

The mean preoperative heart rate was 121.21 beats/minute in the bupivacaine group and 113.16 beats/minute in the bupivacaine-morphine group. Mean post-induction heart rate was 130.51 beats/minutes in the bupivacaine group and 130.51 beats/minute in the bupivacaine-morphine group. The post-caudal heart rate was 128.84 beats/minute in the bupivacaine group and 120.34 beats/minute in the bupivacaine-morphine group [Figure 2]

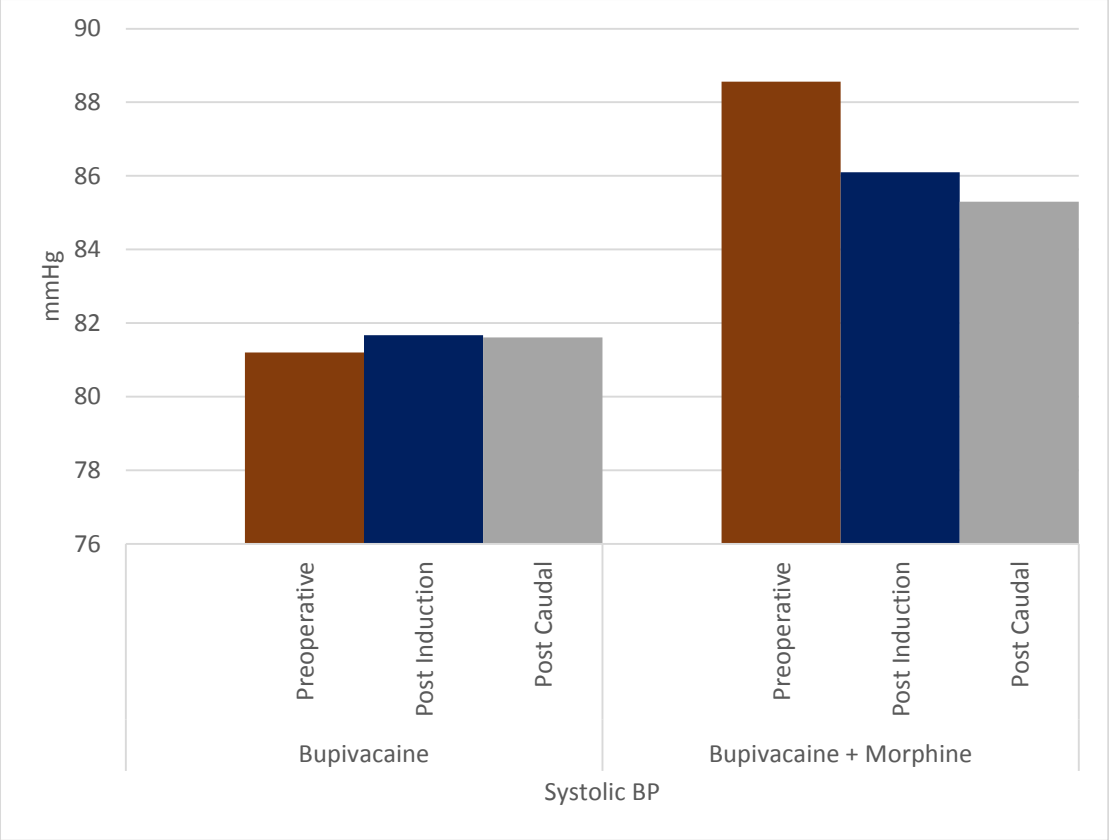

Figure 3: Mean systolic blood pressure

The mean preoperative systolic blood pressure was 81.20 mmHg in the bupivacaine group and 88.56 mmHg m the bupivacaine-morphine group. Post-induction systolic blood pressure was 81.67 mmHg in the bupivacaine group and 86.10 mmHg in the bupivacaine-morphine group. The mean post-caudal systolic blood pressure was 81.61 mmHg in the bupivacaine group and 85.30 mmHg in the bupivacaine-morphine group. [Figure 3]

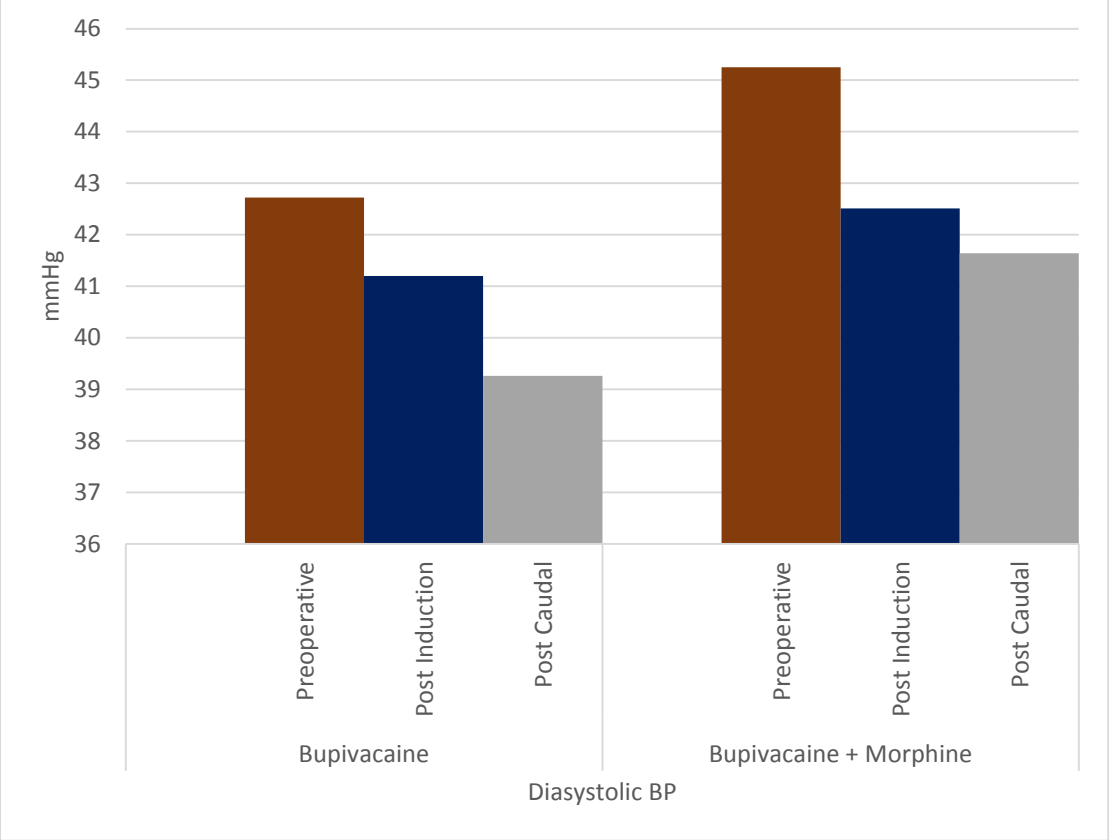

Figure 4: Mean diastolic blood pressure

The mean preoperative diastolic blood pressure was 42.72 mmHg in the bupivacaine group and 45.25mmHg in the bupivacaine-morphine. Post-induction diastolic blood pressure in the bupivacaine group was 41.20 mmHg and 42.51 mmHg in the bupivacaine-morphine group. Mean diastolic blood pressure in the bupivacaine group was 39.26 mmHg and 41.64 mmHg in the bupivacaine-morphine group. [Figure 4]

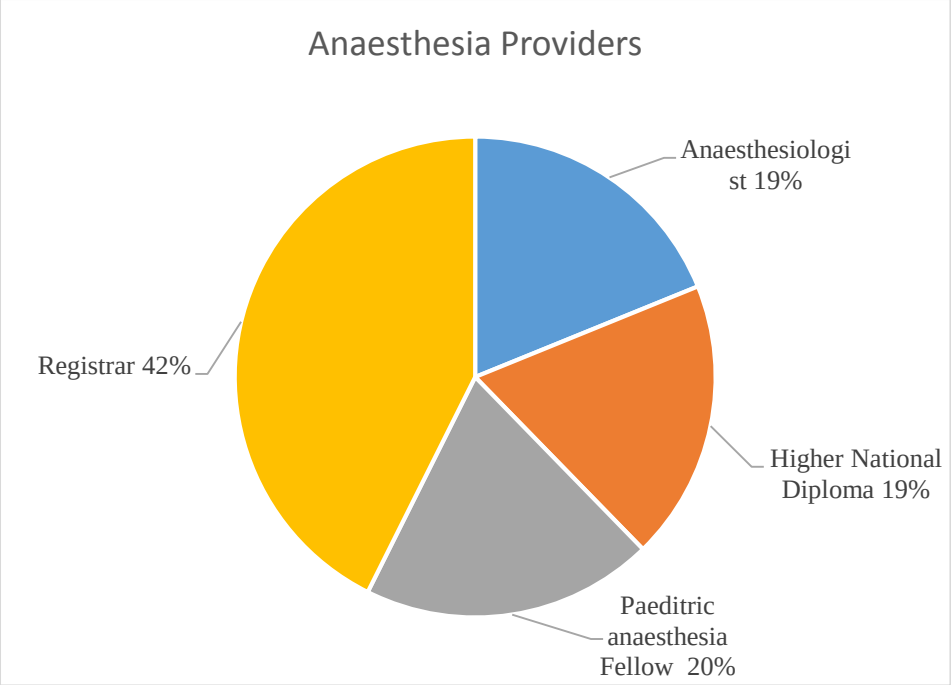

Figure 5: Anaesthesia Providers

Out of the 122 participants, 42% (52) of the caudal blocks were performed by Registrars while the attending anaesthesiologist performed 19% (23) and the other cadres of providers performed the rest. [Figure 5]

All patients received fentanyl and intravenous paracetamol. Caudal block was performed using 1ml/kg of 0.25% bupivacaine either alone or combined with 0.03 mg/kg of preservative-free morphine.

	Bupivacaine	**Bupivacaine + Morphine**	**Total**
Fentanyl	1		1
Fentanyl + Diclofenac		1	1
Ketamine	1		1
Morphine	4	3	7

Table 3: Rescue analgesia

6 participants in the bupivacaine group had failed caudal block and were given systemic analgesia and 4 of the participants in the bupivacaine-morphine group had failed caudal block that required intervention with a systemic opioid. [Tab 3]

Pain was assessed using either a FLACC scale for children below 7 years or a visual analogue scale for children above 7 years.

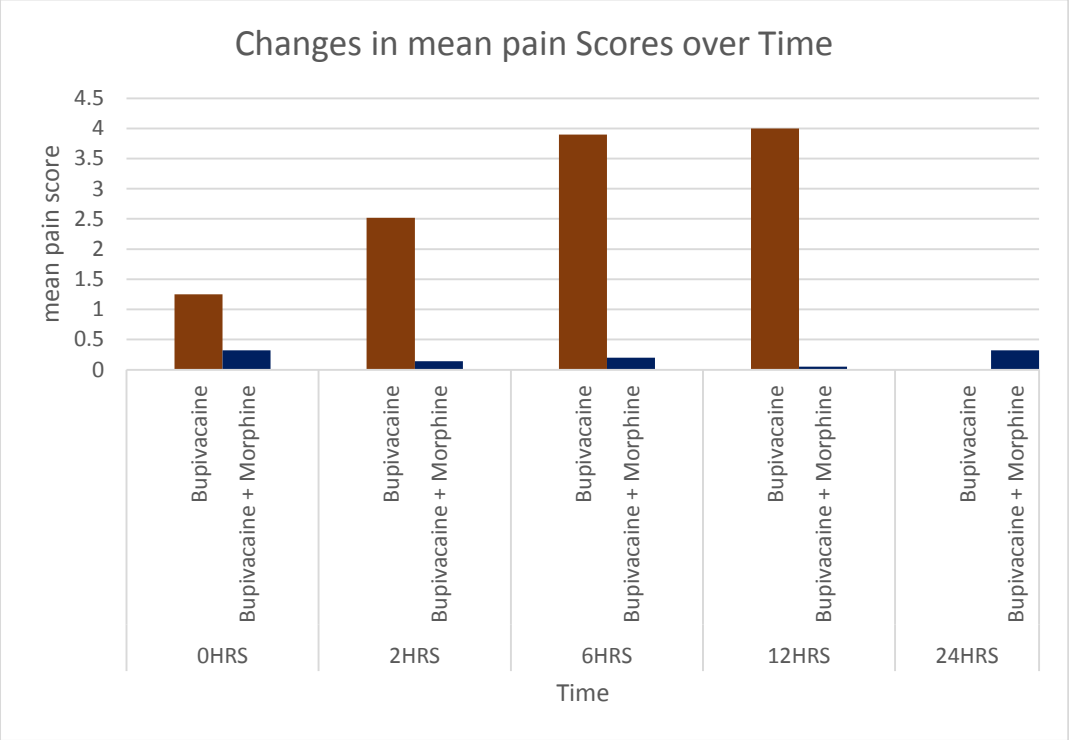

Figure 6: **Mean pain score versus time**

Mean pain score at 0 hours in the bupivacaine group was 1.25 (2.048) and 0.32 (1.105) in the bupivacaine-morphine group with a mean standard error of 0.146. At 2 hours, the bupivacaine group had a mean pain score of 2.52 (2.358) and bupivacaine-morphine group, 0.14 (0.401). The mean pain score at 6 hours in the bupivacaine group was 3.90 (1.934) and 0.2 (0.672) in the bupivacaine-morphine group. Bupivacaine group had a mean pain score of 4.00 (0.00) at 12 hours while bupivacaine-morphine group had 0.05 (0.297) with a mean standard error of 0.40. At 24 hours the mean pain score in the bupivacaine-morphine was 0.32 (1.193). Pain assessment in the bupivacaine group was not done as all the patients had received supplemental analgesia. [Figure 6]

Duration of analgesia in minutes	No. of Patients
0 – 120	1 (1.8)
121 – 240	13 (23.6)
241 – 360	22 (40.0)
361 – 480	16 (29.1)
481 - 600	3 (5.5)

Table 4: Bupivacaine Group

Duration of analgesia	No. of Patients
<24 hours	6 *
>24 hours	51

Table 5: Bupivacaine + Morphine Group

*lowest of 108 minutes, highest of 1245 minutes with median of 1036.50 minutes.

The mean duration of analgesia in the bupivacaine group was 313.15 minutes (SD=106.624) [Tab 4]. 51 participants in the bupivacaine combined with morphine group did not require analgesia within the 24-hour period [Tab 5]. 6 participants received analgesia within the 24-hour period with a median of 1036.50 minutes [Tab 5].

Kaplan-Meier Survival Analysis

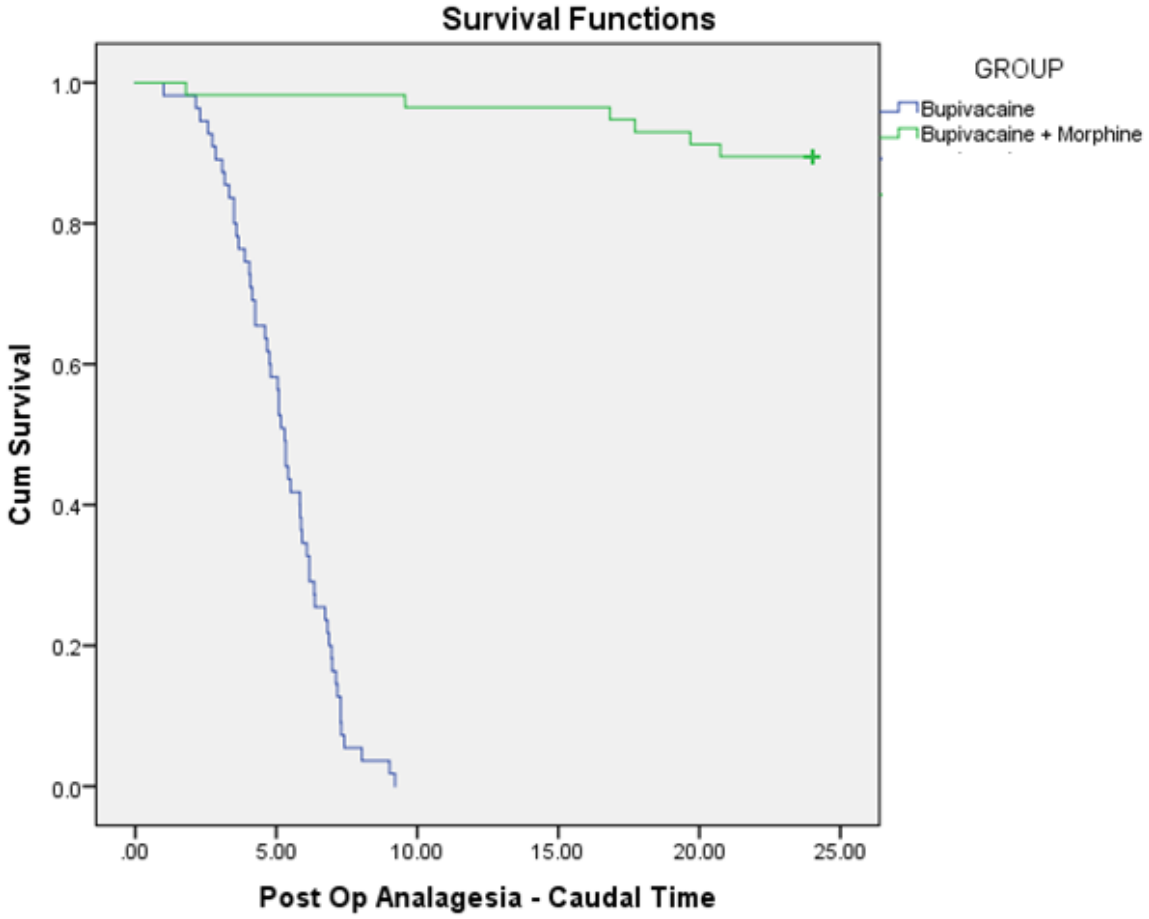

Figure 7: **Kaplan-Meier survival analysis**

SIDE EFFECTS

No serious side effect such as respiratory depression, apnoea or urinary retention was seen in any of the patients. 6 patients in the bupivacaine-morphine group developed pruritus; in 3 of them it was self-limiting, while in the other 3 interventions with chlorpheniramine was required.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATION

5.1 Discussion

Caudal block is the most commonly used form of regional anaesthesia in children. It provides effective analgesia for both intraoperative and postoperative periods. Bupivacaine is commonly used for caudal block but its effects usually wear off early in the postoperative period.

The main objective of this study was to compare perioperative analgesic effectiveness of bupivacaine combined with morphine and bupivacaine alone for caudal block in paediatric patients undergoing infraumbilical surgeries at KNH. The study was conducted in paediatric surgical ward, paediatric theatre and PACU.

The findings showed that addition of 0.03 mg/kg of preservative free morphine to 0.25% of plain bupivacaine offered a significantly longer duration of postoperative analgesia compared with that offered by bupivacaine alone (313 minutes). 55 patients required supplemental analgesia within the 24 hour period in the bupivacaine group whereas only 6 patients required supplemental analgesia within the 24 hour period in the bupivacaine- morphine group.

A study conducted by MK Arora (5) in 2004 with 0.25% bupivacaine and 0.25% bupivacaine combined with 0.03mg/kg of preservative free morphine showed that duration of analgesia in the bupivacaine-morphine group was 12-26 hours (median 20.8 +/- 3.4 hours). 28/40 patients required supplemental analgesics in the first 8 hours in the bupivacaine group whereas none in the bupivacaine-morphine group required analgesia during that time period. Only 2/40 patients required supplemental analgesic at 12 hours in the bupivacaine-morphine group. This did not compare with my study where 52/55 patients required supplemental analgesia in the first 8 hours in the bupivacaine group and 1 in the bupivacaine-morphine group was given supplemental analgesia in the first 8 hours.

Combination of caudal morphine and bupivacaine for relief of postoperative pain after orchidopexy in children has been reported by Wolf AR et al. (32) the bupivacaine- morphine group had better quality of analgesia and none of the patients required analgesia within the 20

hour period. This was similar to our study where 51/57 patients did not require analgesia within that period.

A comparison study between bupivacaine and morphine for postoperative pain relief in children after genital operations by Jensen BH et al (33) found that in children who received caudal morphine, the duration of analgesia was longer (1225 +/- 592 minutes) than that of bupivacaine alone (377 +/- 99 minutes). This was comparable to my study where the mean duration of bupivacaine alone was 313 minutes.

Study done by Elliot J Krane et al (27) on the dose response of caudal morphine in 32 children found that mean duration of analgesia in 0.033mg/kg, 0.067mg/kg and 0.1mg/kg of caudal morphine was 10 +/- 3.3 hours, 10.4 +/- 4.2 hours and 13.3 +/- 4.7 hours respectively. This compared with my study, where a dose of 0.03mg /kg preservative free morphine was used. 51/ 57 patients did not require supplemental analgesia within the 24 hour period.

There was no incidence of respiratory depression, apnoea, and urinary retention in the caudal bupivacaine-morphine group. 6 patients in the bupivacaine-morphine group developed pruritus; in 3 of them it was self-limiting, while in the other 3 intervention with chlorpheniramine was required. These findings compare well with similar ones by MK Arora el al (5) where no respiratory depression or apnoea was observed. 3 patients had nasal pruritus that was self-limiting and 3 had somnolence but responded well. There was no significant difference in the incidence of nausea, vomiting and urinary retention between the 2 groups. The results were also similar to the Mayhew JF et al (34) where 7.2% of the patients had pruritus, 13% had urinary retention and none had respiratory depression. Delayed respiratory depression occurred in 1 patient where 0.1mg/kg of caudal morphine was used as reported by Elliot J Krane et al (27).

5.2 Conclusion

1. This study demonstrated that caudal block using low dose morphine combined with bupivacaine is more potent than plain bupivacaine in providing intra-operative and post-operative analgesia.

2. Caudal bupivacaine alone also provided excellent analgesia in the early post-operative period but the effect wore off early, and supplemental analgesia was required.

3. No serious side effects were seen in any of the patients.

5.3 Recommendation

1. Randomized control trial to be done.
2. Follow up study of more than 24 hours would be useful.
3. The use of low dose preservative-free morphine combined with bupivacaine for caudal blocks in paediatric patients undergoing infraumbilical surgeries should be encouraged.

5.4 Study Limitation

1. The study was observational. There was lack of standardization on the choice of anaesthesia and medications given

2. Pain assessment in different age groups was challenging since 2 different pain scales were used for different age groups.

5.5 Data Protection

All data collected was kept locked and confidential at all times. Electronic forms of data shall be protected with confidential passwords at all times. Data was accessible to the investigator and data manager. Data was preserved until analysis, presentation and archival was done.

5.6 Ethical Considerations

Permission to conduct the study was sought from the Kenyatta National Hospital/ University of Nairobi –Ethics and Research Committee prior to commencement of the study.

Participants in the study were enrolled after the nature of the study had been explained to them and informed consent obtained.

Confidentiality was maintained at all stages of the study.

Study participants who declined inclusion and/or left the study at any point were allowed to do so without victimization or compromise to their management.

Any complications observed in any patients during the study was promptly and appropriately managed and reported to the Ethics and Research Committee.

No additional costs was incurred by the study participants.

Study findings were availed to the University of Nairobi and Kenyatta National Hospital.

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APPENDIX 1: CONSENT

Informed Consent

The principal investigator: Dr.Sultane Sherman

Institution: University of Nairobi

Sponsor: Self

Proposal:

A comparative study of the effectiveness of morphine combined with bupivacaine versus bupivacaine alone for caudal blocks in paediatric patients undergoing infra-umbilical surgeries at Kenyatta National Hospital.

Consent for Parent/Guardian

Written Explanation

My name is, Dr.Sultane Sherman and I am pursuing a post-graduate degree in Anaesthesia and Critical Care.

I am conducting a study to compare the effectiveness of morphine with bupivacaine and bupivacaine alone for caudal blocks in paediatric patients undergoing infra-umbilical surgeries. Pain is one of the most common, unpleasant and frightening symptoms associated with surgery. Persistent or uncontrolled pain **is** often associated with increased incidence of postoperative nausea and delirium, prolonged post anaesthesia care unit stay and delayed discharge. It may also delay resumption of normal activities.

Different additives have been used to prolong the duration of action of bupivacaine. Studies done have shown that morphine given in combination with bupivacaine can provide up to 20 hours of postoperative analgesia.

The study will go a long way in improving our management of postoperative pain. There is no monetary gain in participating in this study. The drugs used for the purpose of this study are catered for by the investigator and, therefore, there is no extra cost incurred in participating in this study

The study will involve placing the participants into two groups. One group will be given caudal morphine with bupivacaine. The other group will be given caudal bupivacaine alone.

The risks associated with participating in this study are rare. Since the drug used in the study is an opioid, it may cause deep sleep, respiratory depression, urinary retention, nausea and vomiting. These effect of the drug can be easily reversed with an antidote which is available. The doctors attending to your child are well equipped to managing these problems should any of them occur.

Your participation in this study is entirely voluntary. Whether you participate or not, all the services you receive in this hospital will remain unchanged. You will not be given any money or gifts to participate in this study. There may not be any benefit to you, but your participation will help us find an answer to the research question and, therefore, help us improve the management of our patients. If you change your mind, you can withdraw from participating at any time even if you had earlier agreed to participate.

Information collected about your child during the study will not be identified by your name but by a number known only to the researcher and will not be shared with or given to anyone.

If there is anything you are concerned about or is bothering you about the study please do not hesitate to ask me at any time. You can reach me on cell-phone number 0714788607.

This study will be conducted with the approval of KNH-UoN ERC. You can alsodirect any concerns or questions about this study to the KNH-UoN ERC, at Kenyatta National Hospital, P.O. BOX 20723, Nairobi, and Tel: 2726300-9.

Thank you.

Consent Form for Participants

I have read the foregoing information or it has been read to me. I have had the opportunity to ask questions about it and the questions I asked have been answered to my satisfaction. I consent voluntarily for my child/ward to participate in the study and I understand that I have the right to withdraw from the study at any time without in anyway affecting the medical care given to my patient.

Parent/Guardian name.....

Parent/Guardian signature..... Date.....

Researcher's signature..... Date.....

Statement by the researcher:

I confirm that the parent(s)/guardian was given an opportunity to ask questions about the study, and all the questions asked have been answered. I confirm the parent(s)/guardian has not been coerced to let their child participate in the study and the consent has been given freely and voluntarily.

Name:_____

Signature:_____

Date:_____

Maelezoyakibaliyamshiriki

MchunguziMkuu: Dr Sultane Sherman

Taasisi: Chuo kikuu cha Nairobi

Mfadhili: Binafsi

Pendekezo:

Utafiti wakulinganisha utendajikazi wa dawa inayoitwa morphine ikichanganywa na dawa inayoitwa bupivacaine ikilinganishwa na bupivacaine pekee katika upasuaje wa chini ya kitovu kwa watoto, zinazofanyika katika hospitali kuu ya Kenyatta.

Kibali cha mzazi/mlezi

Maelezo

Jina langu ni daktari Sultane Sherman. Mimi nina somea masomo ya udaktari ganzi (anaesthesia)

Nina fanya utafiti wakulinganisha utendajikazi wadawa inayoitwa morphine ikichanganywa na dawa inayoitwa bupivacaine ikilinganishwa na bupivacaine pekee katika upasuaje za chini yakitovu kwa watoto.

Uchungu na maumivu kutokana na upasuaji ni jambo la kawaida na ni la kuogopesha na si la kuridhisha kwa aliyefanyiwa upasuaje. Maumivu ambayo haijadhibitiwa au wa mdamrefu imehusishwa sana na kuchefuchefu nakuchanganyikiwa pamoja na mdawa kukaa hospitali kurefushwa nakuchelewa kutolewa hospitali. Pia inaweza kucheleweshe mgonjwa kuendelea na kazi zake za kawaida baadaya kutoka hospitali.

Utafiti tofauti zimefanywa kuweza kuongeza mda wa utendaji kazi wa dawa aina bupivacaine, na imesemakana kua kuchanganya bupivacaine na morphine inaipatia mda wa kazi hadi masaa 20 yakuzuia uchungu baadaya upasuaji.

Utafiti huu utasaidia pakubwa kuboresha utowaji huduma kwa wagonjwa katika kuzuia uchungu baada ya upasuaji. Dawa zinazo tumika katika utafiti huu zimelipiwa na mchunguzi kwahivo utafiti huu hauto kugharimu pesa zozote na pia hautopewa marupurupu yoyote.

Utafiti huu utafanywa kwa njia ya kuwagawanya wahusika katika vikundi viwili. Kikundi cha kwanza watapewa dawa ya bupivacaine iliochanganywa na morphine, na kikundi cha pili watapewa bupivacaine pekee yake.

Kujijumuisha katika huu utafiti hautokuletea madhara, na kama kutakuwa nayo ni madhara madogo na ambayo yanazuilika. Katika madhara ambayo wanaweza kutokea ni, inaweza

kusababisha usingizi mzito na kudidimia kwa kupumuwa, kukojoa kwa shida, kichefuchefunakutapika. Hizi athari ambazo zinaweza kutokea zina tibika na dawa ambayo inapatikana kwa urahisi. Madaktari ambao watahudumia motto wako wamejiandaa vyema kutatua shida kama hii pindiitapotokea.

Kushiriki kwako kwa utafiti huu ni kwahiari yako. Uamuzi wako kushiriki au kutoshiriki katikia utafiti huu hauto

Athiri matibabu yako kwa vyovyote vile. Hautopewa marupurupu yeyote lakin kushiriki kwako kwa huu utafiti utasaidia katika utafiti huu na kuboresha utoaji wahuduma ya afya kwa wagonjwa. Ukibaadilisha mawazo yako, unaweza kujitoa wakati wowote hata kama ulishakubali hapo mbeleni.

Mambo yote ambayo yatahusikana mtoto wako kama vile jina na ugonjwa wake hautojulikana na mtu mwengine naitabaki asiri.

Kama una maswali yeyote ama ungependa maelezo zaidi niulize wakati wowote.Unaweza kunipata kwa namba 0714788607.

Utafiti huu utafanywa kwa idhini ya bodi ya KNH-UoN ERC. Unaweza pia kupata maelezo zaidi ama kuuliza maswali kuhusu huu utafiti kutoka KNH-UoN ERC, Kenyatta National Hospital, S.L.P 20723, Nairobi. Nambaya simu 2726300-9

Asante sana.

Kibali cha mgonjwa

Nimesoma/nimesomewa maelezo ya utafiti.Nimepewa fursa ya kuuliza maswali na nimejibiwa kikamilifu. Nimekubali kwa hiari yangu motto wangu kushiriki katika utafiti huu. Nina elewa kwamba ninayo haki ya kujitoa kwa utafiti huu wakati wowote bila kupoteza hakI yangu ya matibabu.

Jina la mzazi/mlezi_____

Sahihiyamzazi/mlezi_____ tarehe_____

Sahihiyamchunguzi _____ tarehe _____

ASSENT FORM FOR CHILDREN AGED 8- 12 YEARS

Study Title: COMPARATIVE STUDY OF THE EFFECTIVENESS OF MORPHINE COMBINED WITH BUPIVACAINE VERSUS BUPIVACAINE ALONE IN CAUDAL BLOCKS DURING PAEDIATRIC INFRA-UMBILICAL SURGERY AT KENYATTA NATIONAL HOSPITAL.

My name is Dr.Sultane Sherman and I am doing a research on the above topic. A research study is a way to learn more about people. I am doing a study on how a drug called morphine when it is injected in your lower back can make you not to feel pain after your operation. You will be under anaesthesia hence you will feel no pain when this procedure is done. You do not have to be in this study if you do not want to be. This study will help anaesthesia providers to give better care to children who come to theatre for surgery. You will not be harmed during this study. When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

Sign your name here----------

Date……..

For further information you may contact:

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FOMU YA KIBALI KWA WATOTO WENYE UMRI WA MIAKI 8-12

Utafiti: UTAFITI WA KULINGANISHA UTENDAJI KAZI WA DAWA INAYOITWA MORPHINE IKICHANGANYWA NA DAWA INAYOITWA BUPIVACAINE IKILINGANISHWA NA BUPIVACAINE PEKEE KATIKA UPASUAJE KWA WATOTO, ZINAZO FANYIKA KATIKA HOSPITALI KUU YA KENYATTA.

Jina langu ni Dr.Sultane Sherman na nafanya huu utafiti. Utafiti ni njia ya kupata kuelewa zaidi kuhusu binadamu. Nafanya utafiti kuangazia vipi dawa inayoitwa morphine ikidungwa kwenye sehemu ya mgongo itaweza kukufanya usiweze kusikia maumivu baada ya upasuaji.Utakua katika hali ya ganzi kwahivo hautohisi uchungu wakati unapodungwa hii sindano. Sio lazima kushiriki katika huu utafiti kama hukuridhia. Utafiti huu utasaidia pa kubwa katika kuboresha utowaje huduma wa afya kwa watoto watakaofanyiwa upasuaji. Hautodhurika katika huu utafiti.Baada ya kumaliza huu utafiti, tutatayarisha ripoti kueleza matokeo ya huu utafiti.Jina lako halitotajwa katika hio ripoti, na hakuna atakaye jua kwamba ulishiriki katika huu utafiti. Unaweza kujiondosha katika utafiti huu wakati wowote hata kama ulikubali hapo mbeleni. Wazazi wako wanayo taarifa kuhusu utafiti huu.

Mimi, _____ ningependa kushiriki katika utafiti huu.

Sahihi yako_____

APPENDIX 4: DATA COLLECTION TOOL

1. BIODATA.

a. DATE …….

b. SERIAL NUMBER …….

c. INITIALS …….

d. AGE ……..**.....**years ……..months

e. SEX□ MALE□ FEMALE

f. WEIGHT ……kilograms

g. HEIGHT …….cm

h. DIAGNOSIS ……

i. OPERATION ……

j. ASA STATUS:

□ I

□ II

2. PRE-OPERATIVE VITAL SIGNS

BP: ……. mmHg P/R……..… SPO2: ….....

R/R: …… TEMP: ……

3. INDUCTION

TIME: …….... A.M/P.M

a. INHALATIONAL

□HALOTHANE/OXYGEN

□HALOTHANE/NITROUS OXIDE/OXYGEN

b. INTRAVENOUS

i) SEDATIVES

□PROPOFOL

□KETAMINE

□OTHERS

ii)MUSCLE RELAXANTS

□SUCCINYLCHOLINE

□ATRACURIUM

□OTHERS

c. CAUDAL BLOCK:

i)TIME:……A.M/P.M

□BUPIVACAINE

DOSE ……mls ……. %

□BUPIVACAINE PLUS MORPHINE

DOSE ……mls ……..%

ii)CAUDAL BLOCK CONDUCTED BY:

□ CONSULTANT ANAESTHESIOLOGIST

□ PAEDIATRIC ANAESTHESIA FELLOW

□ REGISTRAR

4. POST INTUBATION VITAL SIGNS:

BP: ……. mmHg P/R……..… SPO2: ….....

R/R: …… TEMP: ……

5. INTRAOPERATIVE

a. SURGERY

START TIME: ……

STOP TIME: ……

b. DRUGS USED INTRAOPERATIVE:

□ ODANSETRON

□ DEXAMETHASONE

□PARACETAMOL PER RECTAL

□ PARACETAMOL INTRAVENOUS

□ OTHERS

c. INTRAOPERATIVE RESCUE ANALGESIA:

□NONE

□FENYANYL

□ PETHIDINE

□TRAMADOL

□ MORPHINE

□ PARACETAMOL

d. MAINTENANCE OF ANAESTHESIA:

□HALOTHANE/NITROUS OXIDE/OXYGEN

□ISOFLURANE/NITROUS OXIDE/OXYGEN

□ PROPOFOL

□ KETAMINE

□ ATRACURIUM

□ OTHERS

e. REVERSAL

TIME: …….....**.....**A.M/P.M

f. DRUGS USED DURING REVERSAL:

□ NONE

□ ATROPINE

□ GLYCOPYROLATE

□ NEOSTIGMINE

INTRA-OPERATIVE MONITORING TABLE

TIME	**HEART RATE/MIN**	**BLOOD PRESSURE**	**SPO2**	**TEMP**	**RESP. RATE**

5. POST-OPERATIVE VITAL SIGNS

TIME	HEART RATE	BLOOD PRESSURE	SPO2	TEMP	RESP. RATE
IMMEDIATELY					
3 MIN					
6 MIN					
9 MIN					
12 MIN					
15 MIN					
20 MIN					
25 MIN					
30 MIN					
45 MIN					
60 MIN					
75 MIN					
90 MIN					
105 MIN					
120 MIN					

6. POST-OPERATIVE MONITORING

TIME	**PAIN SCORE**	**SEDATION**	**URINATION**	**PRURITUS**
IMMEDIATELY				
AFTER 10 MIN				
AFTER 20 MIN				
AFTER 30 MIN				
AFTER 1 HOUR				
AFTER 2 HOURS				
AFTER 3 HOURS				
AFTER 4 HOURS				
AFTER 5 HOURS				
AFTER 6 HOURS				
AFTER 12 HOURS				
AFTER 24 HOURS				

PARENT'S/PATIENT'S SATISFACTION:

□ YES

□ NO

7. RESCUE ANALGESIA

ANALGESIA	DOSE	TIME
MORPHINE		
PETHIDINE		
FENTANYL		
PARACETAMOL		
OTHERS		

APPENDIX 5: FLACC SCALE

(Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S, "The FLACC: A behavioural scale for scoring postoperative pain in young children. PediatrNurs 1997; 23:292-7)

CATEGORY		**SCORING**	
	0	**1**	**2**
FACE	NO PARTICULAR EXPRESSION OR SMILE	OCCASIONAL GRIMACE/FROWN/WITHDRAWN OR DISINTERESTED	FREQUENT OR CONSTANT QUIVERING OF THE CHIN/CLENCHED JAW
LEGS	NORMAL POSITION OR RELAXED	UNEASY, RESTLESS, TENSE	KICKING OR LEGS DRAWN UP
ACTIVITY	LYING QUIETLY, NORMAL POSITION, MOVES EASILY	SQUIMIRING, SHIFTING BACK AND FORTH, TENSE	ARCHED, RIGID OR JERKING
CRY	NO CRY	MOARNS OR WHIMPERS, OCCASIONAL COMPLAINTS	CRYING STEADILY, SCREAMS OR SOBS, FREQUENT COMPLAINT
CONSOLABILITY	CONTENT, RELAXED	REASURED BY OCCASIONAL TOUCHING, HUGGING OR BEING TALKED TO, DISTRACTABLE	DIFFICULT TO CONSOLE

0 = no pain

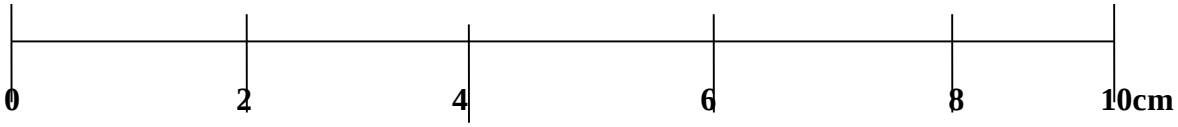
1-3= mild pain

4-7= moderate pain

8-10= severe pain

VISUAL ANALOGUE PAIN SCALE

(Myles PS, Troedel S, Boquest M, Reeves M: The Visual Analogue Pain Scale: Is it Linear or Non-linear? REGIONAL ANAESTHESIA AND PAIN MANAGEMENT: Anesth Anal 1999: 89: 1517)



A score of 4cm and above requires analgesic.

APPENDIX 6: PASERO OPIOID- INDUCED SEDATION SCALE

S	Easy to arouse.	Acceptable, no action necessary.
1	Awake and alert.	Acceptable, no action necessary.
2	Slightly drowsy, easily aroused.	Acceptable, no action necessary.
3	Frequently drowsy, arousable, drifts off to sleep during conversations.	Unacceptable, monitor respiratory status and sedation level until it is less than 3.
4	Somnolent, minimal or no response to verbal or physical stimulus.	Unacceptable, stop opioid and consider naloxone. Monitor respiratory status and sedation scale until it is less than 3.

APPENDIX 7: AAGBI SAFETY GUIDELINES
MANAGEMENT OF SEVERE LOCAL ANAESTHETIC TOXICITY (2010)

1. RECOGNITION	**Signs of severe toxicity:** . sudden alteration in mental status, severe agitation or loss of consciousness, with or without tonic-clonic convulsions. . cardiovascular collapse: sinus collapse, conduction blocks, asystole and ventricular tachyarrythmias may all occur . local anaesthetic toxicity may occur sometime after initial injection.
2. IMMEDIATE MANAGEMNET	. stop injecting the LA . call for help . maintain the airway and, if necessary, secure it with a tracheal tube. . give 100% oxygen and ensure adequate lung ventilation. . confirm or establish intravenous access . control seizures: give a benzodiazepine, thiopental or propofol in small incremental doses. . assess cardiovascular status throughout. . consider drawing blood for analysis, but do not delay definitive treatment to do this.

3. TREATMENT	**IN CIRCULATORY ARREST** . start CPR using standard protocols. . manage arrhythmias using the same protocols, recognizing that arrhythmias might be refractory to treatment . consider the use of cardiopulmonary bypass if available. **GIVE INTRAVENOUS LIPID EMULSION** **IMMEDIATELY** Give an initial intravenous bolus injection of 20% lipid emulsion **1.5mls/kg** over 1 min. and start an intravenous infusion of 20% lipid emulsion @ **15mls/kg/hr**	**WITHOUT CIRCULATORY ARREST** Use conventional therapy to treat: . hypotension . bradycardia . tachyarrhythmias **CONSIDER INTRAVENOUS LIPID EMULSION** **AFTER 5 MIN** Give a **maximum of2** repeat doses if: . cardiovascular stability has not been restored or . an adequate circulation deteriorates Leave 5 min between boluses. A **maximum of 3 boluses** can be given including the initial dose. AND Continue infusion at same rate but double the rate to **30mls/kg/hr** at any time after 5 min, if: . cardiovascular stability has not been restored or

	. Continue CPR throughout the treatment with lipid emulsion. . recovery from LA induced cardiac arrest may take＞1 hour. . propofol is not a suitable substitute for lipid emulsion. . lidocaine should not be used as an anti-arrhythmic therapy.	. an adequate circulation deteriorates Continue infusion until stable and adequate circulation has been restored or a maximum dose of lipid emulsion given.