UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

DEPARTMENT OF ANAESTHESIA AND INTENSIVE CARE

A COMPARATIVE STUDY OF DICLOFENAC AND WOUND INFILTRATION TO ADDITIONAL LANDMARK TECHNIQUE OF ILIO-INGUINAL/ ILIO-HYPOGASTRIC NERVE BLOCK FOR PAIN RELIEF IN CHILDREN UNDERGOING GROIN SURGERY- THE UNIVERSITY TEACHING HOSPITAL (UTH), LUSAKA, ZAMBIA.

By

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A dissertation submitted to the University of Zambia in partial fulfilment of the requirements for the award of the degree of Master of Medicine in Anaesthesia and Critical Care.

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DECLARATION

I **Dr Jane Chanda Kabwe** hereby declare that this dissertation represents my own work, and it has not previously been submitted either in whole or in part for a degree, diploma or other qualification at this or another University.

Signature.....Date.....

Candidate: Dr. Jane C. Kabwe

Signature.....Date.....

Supervisor: Dr Anthony Chisakuta

Signature.....Date.....

Co-Supervisor: Dr. Feruza Ismailova

CERTIFICATE OF APPROVAL

THIS DISSERTATION ENTITLED A COMPARATIVE STUDY OF DICLOFENAC AND WOUND INFILTRATION TO ADDITIONAL LANDMARK TECHNIQUE OF ILIO-INGUINAL/ ILIO-HYPOGASTRIC NERVE BLOCK FOR PAIN RELIEF IN CHILDREN UNDERGOING GROIN SURGERY- THE UNIVERSITY TEACHING HOSPITAL (UTH), LUSAKA, BY JANE KABWE HAS BEEN APPROVED AS PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE IN MASTER OF MEDICINE (ANAESTHESIA AND CRITICAL CARE) BY THE UNIVERSITY OF ZAMBIA, SCHOOL OF MEDICINE.

Head of Department:.....

Signature .....Date.....

Examiner I:.....

Signature.....

Examiner II:.....

Signature :.....

DEDICATION

To my beloved husband Jackson, my daughters Janice-Jendai and Jemina-Judy.

Without their love, patience and support, this could not have been possible.

ACKNOWLEDGEMENTS

First and foremost I want to thank the Almighty God that gave me the life and strength to carry out this research. It is my sincere gratitude to acknowledge the invaluable contribution and support of my supervisors, Dr A. Chisakuta and Dr F. Ismailova. Their guidance, advice, repeated corrections and revisions helped shape this project the way it is now. I also appreciate the contributions from the Department of Anaesthesia (UTH) and the University of Zambia (GPPF). I would like to thank Professor J. Kinnear, Dr D. Bould, Dr B. Andrews and Dr L. Bowen for their dedicated and timeless help. Finally, I am indebted to many colleagues and Sister T. Banda, who helped me collect data and Mr J. Banda for the analysis.

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ABBREVIATIONS

ASA	-	American Society of Anaesthesiologists classification
cm	-	centimetres
FLACC	-	Faces, Legs, Activity, Cry and Consolability
HR	-	Heart rate
IM	-	Intramuscular
MAP	-	Mean arterial pressure
mg/kg	-	milligram per kilogram
MMED	-	Master of Medicine
mls	-	millilitres
PG	-	post graduate
pKa	-	Dissociation constant
RR	-	Respiratory rate
UNZABREC	-	University of Zambia Biomedical Research Ethics Committee
UTH	-	University Teaching Hospital
WFSA	-	World Federation Societies of Anaesthesiologist
WHO	-	World Health Organisation

ABSTRACT

Background: Surgery in the groin region is commonly performed in paediatric patients at the University Teaching Hospital (UTH). Intramuscular (IM) Diclofenac and wound infiltration, with lignocaine, are the commonest analgesics administered intra-operatively.
The aim of this study was to determine whether an additional ilio-inguinal/ilio-hypogastric nerve block, done using the landmark technique, to IM diclofenac and wound infiltration with 1% lidocaine (with adrenaline 1:200,000), would improve post-operative analgesia in children undergoing groin surgery at the UTH.

Methods: This was a non-randomized intervention study of children (n=36) undergoing unilateral inguinal herniotomy, hydrocelectomy and orchidopexy operations at the UTH. The children were allocated to two groups: control group received IM diclofenac and wound infiltration, while intervention group received medication as in control group plus an ilio-inguinal/ilio-hypogastric nerve block performed by landmark technique. Intra-operative clinical observations and post-operative pain scores were analysed in the two groups of participants.

Results: 50% of the participants were under 60 months. Post-operatively, the pain scores measured at times 0 and 1 hour post operation were statistically non-significant in both groups (p values 0.181 and 0.355 respectively). Oral Paracetamol (15-20 mg/kg) was the only post-operative analgesic required by the patients in the study. At two minutes after skin incision the mean heart rate in the control group was 114/minute (p-value 0.023) while in the intervention group it was 108/minute (p-value 0.035). The mean respiratory rate at two minutes after skin incision in the control group was 31/minute (p-value 0.012) while in the intervention group it was 36/minute (p-value 0.019). When the baseline heart rate and respiratory rate were compared with the readings measured at the end of the operation, no statistically significant difference was noted in both groups (p-values 0.291 and 0.621; 0.792 and 0.32) respectively.

Conclusion: This study showed that that the addition of ilio-inguinal/ilio-hypogastric nerve block, done with the landmark technique, does not offer superior pain relief during the post-operative period in children undergoing unilateral groin surgery at UTH.

1.0 INTRODUCTION

In children surgical procedures that are carried out in the groin include: inguinal herniotomy, hydrocele repair (hydrocelectomy) and orchidopexy. These are commonly treated as day case operations but for these children to be discharged early, they must be provided with adequate analgesia in the post-operative period. Several techniques have been employed to provide post-operative pain relief including caudal block, wound infiltration and instillation of local anaesthetic into the wound at the end of surgery. It has been shown that ilio-inguinal nerve block with local anaesthetic is a useful technique in providing post-operative pain relief in this group of patients (Trotter et al 1995).

A study done in Birmingham on 120 children undergoing herniotomy concluded that, the ilio-inguinal nerve block is a simple, safe and effective technique for relief of pain after groin incision (Smith et al, 1982). This study hence shows that the use of ilio-inguinal nerve block is not a new phenomenon. However, there has been tremendous improvement in the way this nerve block is administered currently such as the use of ultrasound guided technique. When this technique is used in administering the nerve block, the accuracy is improved greatly because the local anaesthetic is administered near the anatomical location of the nerve.

Regional anaesthesia is a cornerstone of modern paediatric anaesthesia. Most of paediatric anaesthetists combine general and regional anaesthesia to provide superior and long lasting analgesia whilst the risk of respiratory depression that comes with opioids is avoided (Willschke et al, 2010).

Groin surgery is one of the common general paediatric operations performed at UTH. In the year 2012, a total number of 267 cases of groin operations were done, which included children aged one month to twelve years. On further analysis, some patients had multiple procedures which included bilateral inguinal hernias, umbilical hernia and circumcisions (unpublished data from Department of Anaesthesia audit).

At the UTH, for children undergoing groin surgery, post-operative pain management administered by the anaesthetist include IM diclofenac and wound infiltration with 1% lidocaine. Sometimes Ilio-inguinal/ilio-hypogastric nerve blocks and caudal block are

performed, but this is not a common practice. This is due to the non-availability of the drugs and special equipment needed to do blocks accurately.

Studies have shown that the use of ultrasound guidance during the conduct of ilio-inguinal/ilio-hypogastric nerve blocks, offers the advantage of direct visualization of the nerves and the adjacent anatomical structures (Willschke et al, 2005).

Even though there has been major progress in pain assessment and management, pain in the postoperative period has continued to be a clinical problem because the experience of pain has been reported as a common problem in clinical practice. Of the millions of children who undergo surgery every year, majority will experience significant pain in the hospital (Cummings et al, 1996).

In the management of pain, there is no single optimal method that can be used to achieve the best analgesia. Thus a multimodal approach is advised, as inadequately treated acute pain can lead to chronic pain later in life. Pain in children can be detrimental and leads to psychological stress to both the patient and parents (Holdcroft et al, 2005). Hence there is need to establish the prevailing peri-operative pain scores in this population and whether the nerve block done with the landmark technique offers any additional analgesia.

2.0 LITERATURE REVIEW

A) THE ILIO-INGUINAL NERVE BLOCK

Local anaesthetic drugs are a class of similar chemicals that reversibly block peripheral and central nerve pathways following regional administration (Butterworth et al, 1990). This prevention of nociception distinguishes regional anaesthesia, as a technique, from globally acting analgesic drugs, which affect the nociceptive pathway after the stimulus has occurred (Pinnock et al, 2000). Bupivacaine is a long acting local anaesthetic used widely in modern anaesthetic practice (Cox et al, 1998). The quality of analgesia which is produced is particularly suited to the early post-operative periods (Peck et al, 2008). Inguinal heniorrhaphy pain can be significant and difficult to treat without opioid analgesics. Blocking the ilio-inguinal and ilio-hypogastric nerves can provide good intra- and post-operative analgesia for most operations in the inguinal region (Ellis et al, 2004).
The classical approach uses a landmark technique which blocks the nerves immediately they separate into the different fascial layers (Willschke et al, 2005). The injection is made at a point 1 cm to 2 cm medial and 1 cm to 2 cm cephalad to the anterior superior iliac spine, using a short beveled needle, and is advanced perpendicular to the skin (Yarwood et al, 2010). However, the maximum safe dose for that child's weight (2 mg/kg) should not be exceeded.

This approach has a success rate of about 70%, with failure attributed to the local anaesthetic solution being placed more than one anatomical layer away from the nerves (Yarwood et al, 2010). A South African study investigating where local anaesthetic is actually placed without direct visualisation in 62 children scheduled for inguinal surgery, found a successful block attained in only 62% of cases (Weintraund et al, 2007). In an earlier study done also in South Africa in 100 children, the results showed that ultrasonographic visualization of the ilio-inguinal/ilio-hypogastric nerves was possible in all cases. It was also noted that the amount of local anaesthetic solution used in the ultrasound group was significantly lower than in the conventional 'landmark' group. The conclusion made was that ultrasound guidance of ilio-inguinal/ilio-hypogastric nerve blocks offers the advantage of direct visualization of the nerves and the adjacent anatomical structures (Willschke et al, 2005).

The superiority of the ilio-inguinal nerve block, over the caudal block, has also been shown. In Nepal, a study was conducted on 60 children undergoing herniotomy and it was concluded that 'simplified ilio-inguinal and ilio-hypogastric nerve block, in combination with small volume local anaesthetic wound infiltration with its longer mean duration of analgesia offers better safety margin to stat oral analgesics, than caudal block with local anaesthetic alone in children undergoing herniotomy' (Bhattarai et al, 2005). The above mentioned study is much more informative as it went into details such as duration of analgesia. This augment was also the conclusion made in an earlier study done were it was found that both ilio-inguinal nerve block and wound infiltration provide satisfactory analgesia whilst the complications of narcotics are avoided based on assessing pain intensity only (Reid, 1987). In a prospective randomised trial involving 41 children, the ilio-inguinal nerve block was compared with the seemingly effective alternative transversus abdominis plane block and it was concluded that, the ilio-inguinal nerve block provided more effective analgesia than the transversus abdominis plane block (Fredrickson et al, 2010).

B. POST-OPERATIVE PAIN IN CHILDREN

In a study done concerning post-operative pain in children, it was concluded that pain on the day of the operation predicted the occurrence of behavioural problems up to the 4th week, 2-4 weeks longer than the duration of pain itself. This finding emphasize the importance of effective prevention of post-operative pain as well as the importance of avoiding unpleasant experiences in all contacts children have with health care personnel (Kotiniemi et al, 1997).

Inadequately treated acute pain has been shown to be one of the causes of chronic pain later in life. Pain in paediatric patients is usually underestimated and hence under treated. Despite this recognition, inadequate prevention and relief of children's pain is still widespread (IASP, 2005).

Diclofenac is available in a parenteral, oral as well as rectal formulation. It inhibits the enzyme cyclooxygenase, thus preventing the formation of prostaglandins which sensitizes peripheral pain receptors to noxious stimuli (Peck et al, 2008). The paediatric dose is 1mg/kg three times a day for pain associated with minor surgery (BNF, 2011). In a study done in Ireland on 50 children undergoing orchidopexy, a single administration of rectal

diclofenac was found to be an effective method of significantly supplementing analgesia provided by the ilio-inguinal/ ilio-hypogastric nerve block (Mannion et al, 1994). When diclofenac was administered pre-operatively to paediatric patients in Texas, the incidence of restlessness and crying, as well as the post-operative opioid requirements, was less than in acetaminophen-treated patients (Paul et al, 2009).

The assessment of pain can be done both objectively and subjectively. In children, the pain score charts used are age dependent: for instance, the FLACC Pain Assessment Tool which incorporates five categories of pain behaviours: facial expression; leg movement; activity; cry; and consolability (Merkel et al, 1997). In a study done to determine its reliability and validity in eighty nine children aged two months to seven year, it was noted that the FLACC provides a simple framework for objectively quantifying pain behaviours in children who may not be able to verbalize the presence or severity of pain. The conclusion made was that the FLACC pain assessment tool is valid and reliable (Merkel et al, 1997).

3.0 STATEMENT OF THE PROBLEM AND JUSTIFICATION

3.1 STATEMENT OF THE PROBLEM

Inadequately treated acute pain has been shown to have a low risk for developing chronic pain later in life (Kristen et al, 2012).Unfortunately healthcare professionals underestimate post-operative pain in children (Hamers et al, 1998). Moderate to severe pain requires opioid analgesics as proposed by the World Health Organisation analgesic ladder (World Health Organization, 1998), which has also been adopted by the World Federation Societies of Anaesthetists.

However, in Zambia, anecdotal data at the UTH revealed firstly, fears (opiophobia), concerns and myths about opioid use. And secondly, very few nerve blocks are performed. Therefore, post-operative pain is not adequately managed currently and there is no follow up to actually quantify the pain scores in these children.

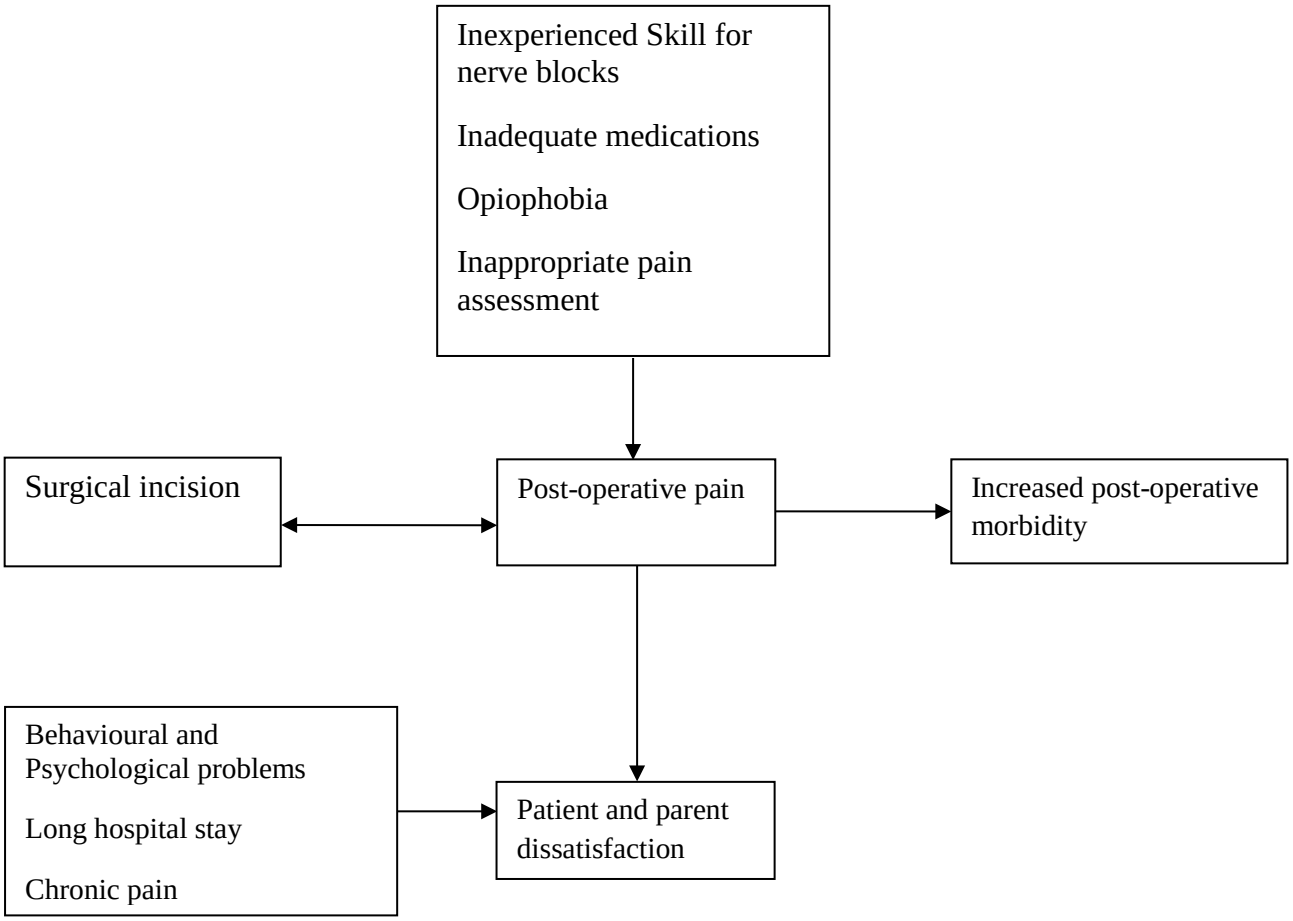
International pain management standards emphasize a multimodal approach; nerve blocks have been included in step four of the new adaptation of the analgesic ladder (Vargas-Schaffer, 2010). Thus nerve blocks are greatly encouraged especially in children to avoid the use of opioids. However without ultrasound guidance, the success rate is only about 60 to 70% due to placement of the drug in the wrong plane in relation to the nerve trunk.

3.2 STUDY JUSTIFICATION

During the conduct of the ilio-inguinal/ilio-hypogastric nerve block, there is no end point as seen in spinal anaesthesia or caudal blocks and its success heavily relies on the expertise of the individual performing the block in the absence of ultrasound guidance. Considering the high turnover of paediatric groin operations done at UTH, which is in a low resource setting, a study to determine whether the addition of a nerve block done using the landmark technique has additive analgesia is imperative. This study will establish whether the nerve blocks that are being done are actually useful or wasteful in this resource limited setting. It will also establish whether our usual care for pain management is adequate as opioids are not usually given in our setting.

During the literature review, only one study was found which compared nerve blocks given to two groups of participants, and rectal diclofenac being given to one of the participating groups (Mannion et al, 1994). Hence a study of this nature, which compares diclofenac in both groups to additional ilio-inguinal/ilio-hypogastric nerve block for pain relief, will give valuable data to help formulate local protocols for our setting.

3.3 CONCEPTUAL FRAMEWORK



→ Stands for "leads to", ⟷ stands for "may/may not lead to if adequately managed"

4.0 RESEARCH QUESTION

Does the addition of ilio-inguinal/ilio-hypogastric nerve block, done using the landmark technique, improve pain scores better than diclofenac and wound infiltration in children undergoing groin surgery in the immediate post-operative period at UTH?

5.0 HYPOTHESIS

5.1 NULL HYPOTHESIS

The ilio-inguinal/ilio-hypogastric nerve block, done using the landmark technique, in addition to the UTH usual care (IM diclofenac and local wound infiltration with 1% lidocaine), does not reduce immediate post-operative pain among children older than 2 years undergoing groin surgery when compared to UTH usual care alone.

5.2 ALTERNATE HYPOTHESIS

The ilio-inguinal/ilio-hypogastric nerve block, done using the landmark technique, in addition to the UTH usual care (IM diclofenac and local wound infiltration with 1% lidocaine), reduces immediate post-operative pain among children older than 2 years undergoing groin surgery when compared to UTH usual care alone.

6.0 OBJECTIVES

6.1 GENERAL OBJECTIVE:

- To determine whether ilio-inguinal/ilio-hypogastric nerve block done using the blind landmark technique would improve post-operative analgesia in children undergoing groin surgery at the UTH

6.2 SPECIFIC OBJECTIVES:

1. To compare the changes in intra-operative clinical observations (heart rate, respiratory rate and mean arterial pressure) of children receiving an additional ilio-inguinal/ilio-hypogastric nerve block to those not receiving the nerve block but usual UTH care.
2. To compare the severity of post-operative pain in children receiving an additional ilio-inguinal/ilio-hypogastric nerve block to those not receiving the nerve block but usual UTH care.
3. Quantify the post-operative analgesic consumption in children receiving an additional ilio-inguinal/ilio-hypogastric nerve block in comparison to those not receiving the nerve block but usual UTH care.

7.0 RESEARCH METHODS

Design: This was a non-randomised interventional study

Setting: The study was conducted in D-block paediatric theatre and D-block paediatric surgical ward of the UTH, Lusaka.

Study Population: Those that gave parental consent for study and fitted in the inclusion criteria of the study.

Inclusion Criteria: ASA I and II paediatric male children above 2 years of age and undergoing unilateral elective groin surgery, which included inguinal hernia repair, orchidopexy and hydrocelectomy.

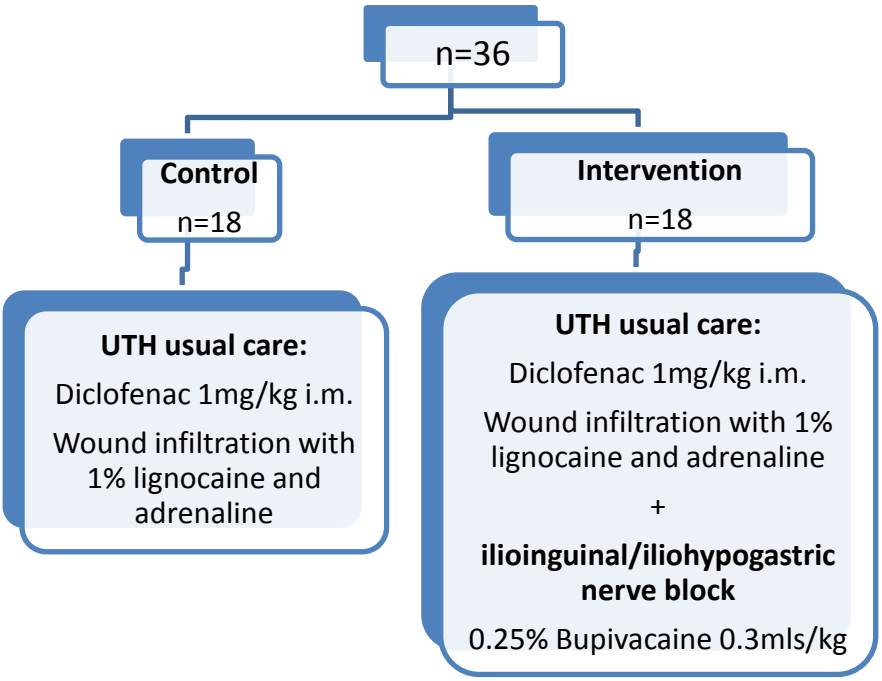
Exclusion Criteria: Refusal of consent for study; ASA III or IV; children less than 2 years old; Children undergoing bilateral groin surgery; children undergoing emergency groin surgery; and children having multiple procedures for example circumcision or umbilical hernia repair in addition to groin surgery.

Procedure: The usual pre-operative assessment was done on all eligible candidates and it was at this stage that informed parental consent was obtained. Following application of intra-operative monitoring, general anaesthesia was administered using oxygen and halothane.

There was a non-randomised systematic allocation of the two groups based on alternating weeks of the month. That is, week one and three of the month had control group participants whereas week two and four of the month had intervention group participants. The control group participants received the usual UTH care: Diclofenac intramuscularly (1mg/kg) after induction of anaesthesia and wound infiltration with 1% lidocaine with adrenaline 1:200,000 (7mg/kg) after the procedure. Whereas intervention group participants received the usual UTH care plus an addition ilio-inguinal/ilio-hypogastric nerve block with 0.25% plain bupivacaine at a dose of 0.3ml/ kg (following administration of the diclofenac) using the landmark technique (Willschke et al, 2005).

This systematic allocation of the groups was only known by the anaesthetist as to whether to give the block on not. The trained nurse in D-block, who carried out the observations, in the post-operative period was blinded as the data collection sheet was in two parts and the

nurse did not know which children received the block or not. The diagram below illustrates this.



Data collection: Data was collected by myself, Anaesthesia MMED students and a trained nurse (for the purpose of this study) in D-block theatre and ward. A Data Collection Protocol (Appendix), which had two separate parts, was used to capture all the necessary information pertaining to this study and was filled in by the data collectors (listed above) on each patient.

Outcomes: The severity of post-operative pain was the primary outcome measure and was scored using the FLACC pain scale (Appendix) on three occasions: immediately post-operatively when the patient was taken into recovery area (timed zero); at one hour; and at six hours. The secondary outcome measures were post-operative analgesic consumption and changes in intraoperative clinical observations

Sample Size: Calculated using Open Epi version 2.3. At 95% confidence interval and a power of 80%:

From literature, clinically significant difference in pain score is considered to be 10-20%, that is, a change in pain score of 1 to 2 (Powell C.V. et al, 2001). A change in pain score of 1.5 (15 %) was used.

Using the standard deviation in pain score of SD ± 1.5, statistical significance was taken as P< 0.05 (Jagannathan N. et al, 2009).

Sample size was calculated using mean difference and was found to be 18 in each group, giving a total of 36 participants.

Data Analysis:

Data collected was checked for completeness and accuracy at the end of every day of data collection. Data was backed up on soft copy, and hard copies of the whole dataset were kept safely under lock and key after entry.

Stata version 12 Software was used to analyse data as follows: Categorical variables such as age, type of operation and type of fluids given were presented as percentages in the two different groups of participants. Continuous variables such as weight were presented as the mean and standard deviation. The paired t-test was used to compare the changes in intra-operative means of clinical observations within the same group of participants, while the independent t-test was used for comparison of intra-operative means of clinical observations between the two different groups of participants. The Mann-Whitney U test was used to compare the pain scores between groups at times zero and one hour post-operatively. A result yielding a p value of less than 5 percent was considered to be statistically significant.

8.0 ETHICAL CONSIDERATION

Ethical approval was obtained from the University of Zambia Biomedical Research Ethics committee (Ref. No. 006-04-14). Permission from UTH to carry out a study in the institution was also given. Informed parental consent was obtained both for the procedure and study. This study did not disadvantage the participants or affect their management as they received the usual intra-operative standards for UTH. Patient confidentiality was observed at all times, participation, was voluntary and no patient was remunerated.

Just like any other clinical procedures done involving a patient, caution was taken to avoid any related complication that is: in advert intra-vascular injection of local anaesthetic solution by withdrawing and aspirating the syringe every time before infiltrating; perforation of small or large bowel puncture, by blunting the small gauged needle and not advancing beyond the loss of resistance. In this study there were no critical incidences encountered.

9.0 RESULTS

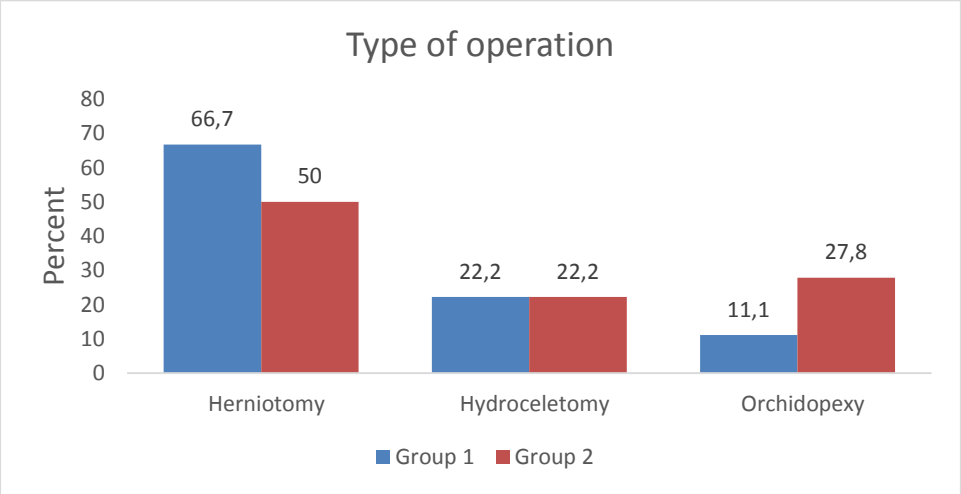
A total of 36 participants were recruited in this study, which was conducted in 2014 in the paediatric theatre and ward of the UTH, Lusaka, Zambia. Of these 18 participants received the usual UTH care i.e. Diclofenac IM and wound infiltration (Control group) intra-operatively. While the remaining 18 participants received in addition to the UTH care, the Ilio-inguinal/ilio-hypogastric nerve block (Intervention group). The results are presented below:

Table 1: Characteristics of categorical variables

Characteristic	**Control** n (%)	**Intervention** n (%)
Age		
≤60 Months	9 (50.0)	9 (50.0)
>60 Months	9 (50.0)	9 (50.0)
Type of Operation		
Herniotomy	12 (66.7)	9 (50.0)
Hydrocelectomy	4 (22.2)	4 (22.2)
Orchidopexy	2 (11.1)	5 (27.8)

In both groups of the study, half (18) the number of participants were aged above or below 60 months. Overall, there were more herniotomy operations done in both groups than the other operations.

Figure 1: Distribution of the types of operation



Types of operations in control group included herniotomy (66.7%), hydrocelectomy (22.2%), orchidopexy (11.1%) and in intervention group herniotomy (50%), hydrocelectomy (22.2%), and orchidopexy (27.8%).

Table 2: Characteristics of continuous variables

Characteristic	n	Mean	SD
Weight of Child			
Control	18	17.1	8.40
Intervention	18	19.1	5.58

The mean weight in the control group was 17.1 kg (standard deviation 8.40 kg), while the mean weight in intervention was 19.1 kg (standard deviation 5.58 kg).

Table 3: Mann-Whitney U test at 0 hour and 1 hour after operation

	N	Mean Rank	Mann-Whitney U	p
			119.5	0.181
Pain at 0 hour				
Control	18	20.86		
Intervention	18	16.14		
Pain 1 hour after operation			132.0	0.355
Control	18	16.83		
Intervention	18	20.17		

Figure 2: FLACC pain scores at 0 Hour

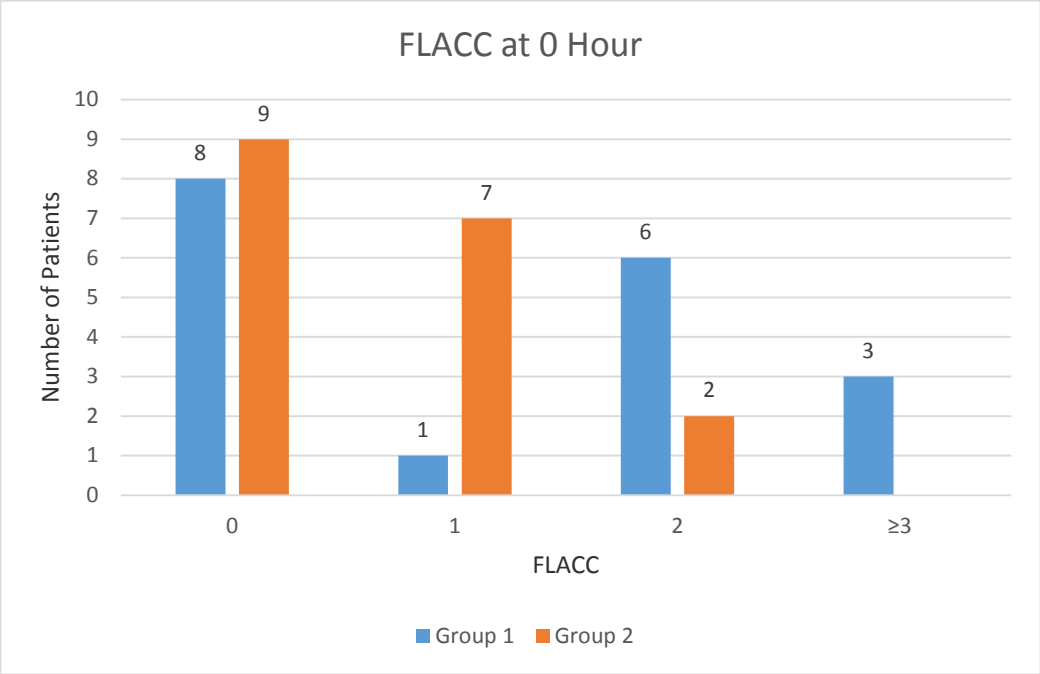


Figure 3: FLACC pain scores at 1 Hour

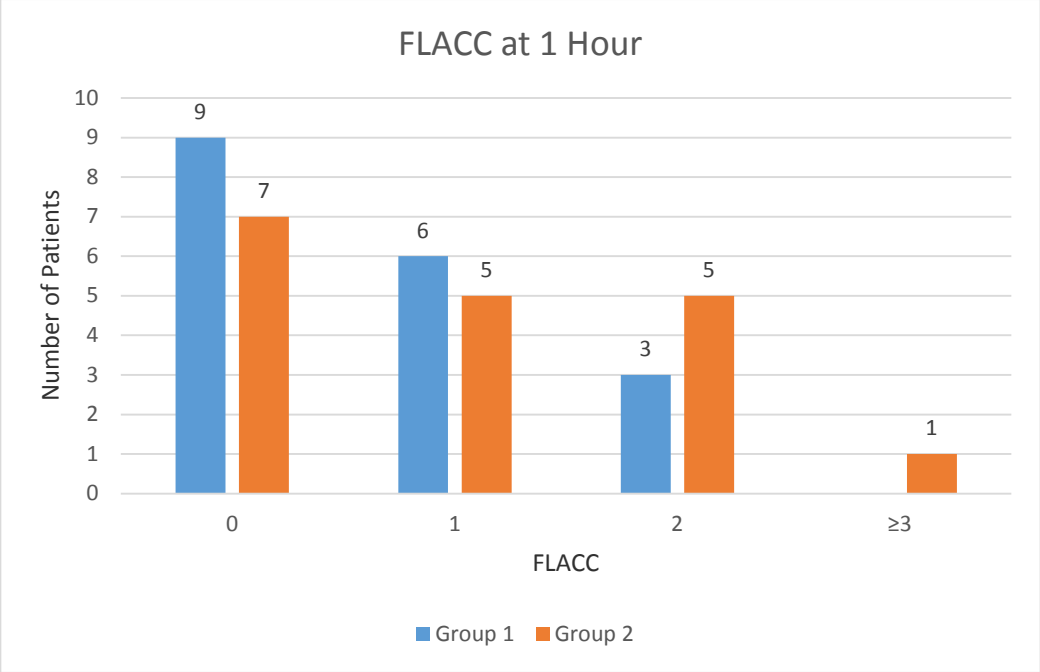


Table 4: Comparison of intra-operative clinical observations intra-group means (paired t-test) at baseline and two minutes after skin incision

	Control n=18				**Intervention n=18**			
	Mean	**SD**	**t**	**p**	**Mean**	**SD**	**t**	**p**
Heart rate			-2.504	0.023			-2.293	0.035
Baseline	107.2	20.5			100.9	16.9		
After two minutes	113.5	19.5			107.7	19.1		
Respiratory Rate			-2.820	0.012			-2.593	0.019
Baseline	27.1	7.7			31.9	9.5		
After two minutes	30.7	5.5			35.9	9.5		
Mean Arterial Pressure			-1.338	0.199			-2.284	0.036
Baseline	52.6	10.5			56.9	6.9		
After Two minutes	55.2	11.4			60.0	7.8		

Table 5: Comparison of intra-operative clinical observations intra-group means (paired t-test) at baseline and the end of operation

	Control n=18				**Intervention n=18**			
	Mean	**SD**	**t**	**p**	**Mean**	**SD**	**t**	**p**
Heart rate			-1.089	0.291			-0.504	0.621
Baseline	107.2	20.5			100.9	16.9		
At end of procedure	111.3	17.9			102.7	16.3		
Respiratory Rate			0.352	0.792			0.0.25	0.320
Baseline	27.1	7.7			31.9	9.5		
At end of procedure	26.7	7.1			30.5	6.1		
Mean Arterial Pressure			-0.618	0.545			-2.139	0.047
Baseline	52.6	10.5			56.9	6.9		
At end of procedure	54.1	11.5			61.3	8.9		

Figure 4: Trends of Mean Heart rate from baseline to the end of operation

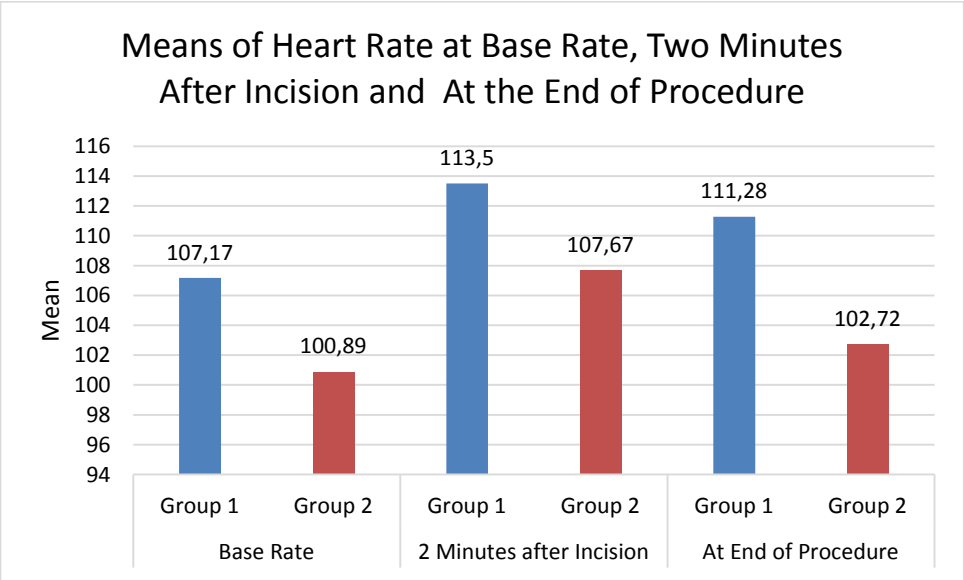


Figure 5: Trends of mean respiratory rate from baseline to end of operation

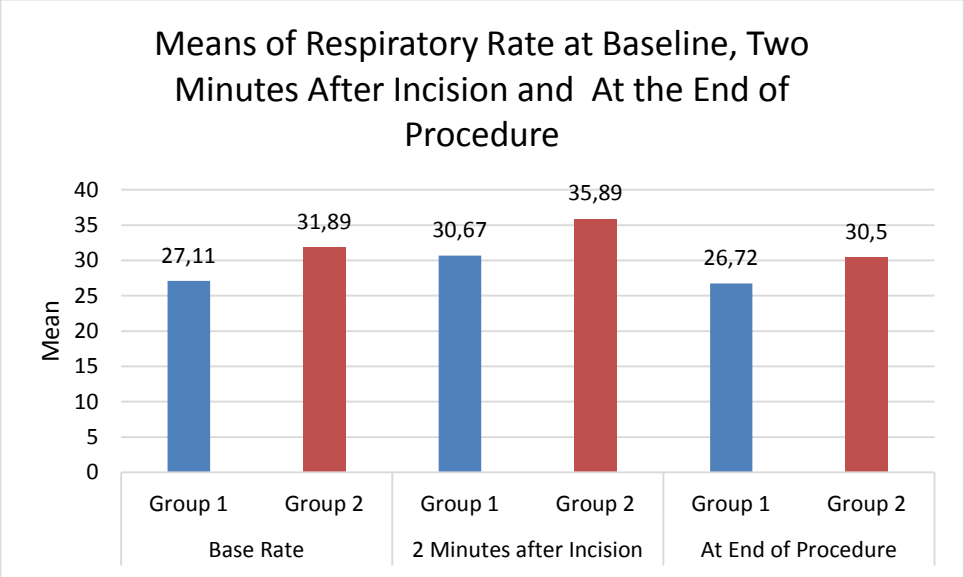


Figure 6: Trends of mean arterial pressure means from baseline to end of operation

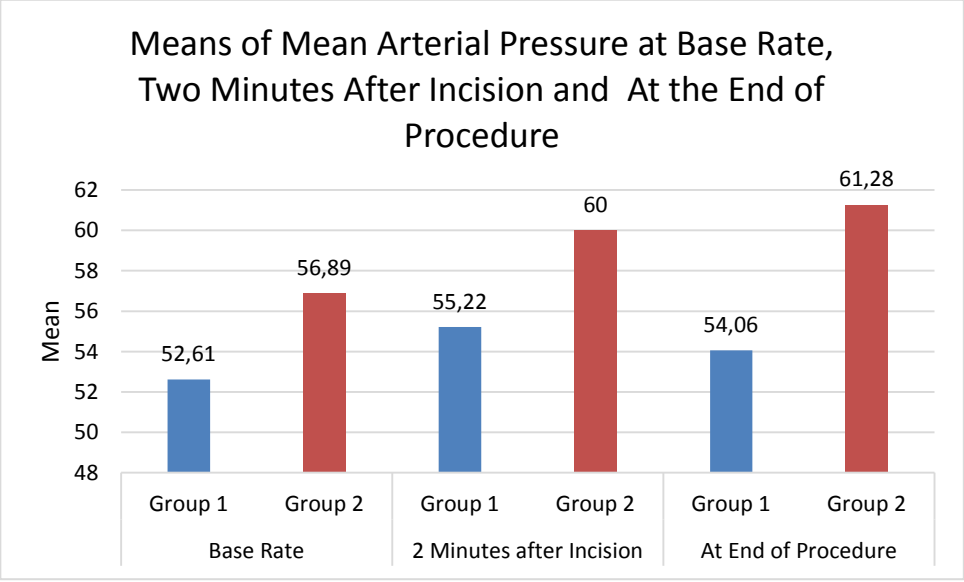


Table 6: Comparison of intra-operative clinical observations inter-group means (Independent t-test) at baseline between the two groups

	n	Mean	SD	t	p
Heart Rate at Baseline				1.003	0.323
Control	18	107.2	20.5		
Intervention	18	100.9	16.9		
Respiratory rate at Baseline				-1.660	0.107
Control	18	27.1	7.7		
Intervention	18	31.9	9.5		
Mean Arterial Pressure				-1.444	0.160
Control	18	52.6	10.5		
Intervention	18	56.9	6.9		

Table 7: Comparison of intra-operative clinical observations inter-group means (Independent t-test) two minutes after incision of skin between the two groups

	n	Mean	SD	t	p
Heart Rate at 2 minutes				0.907	0.371
Control	18	113.5	19.5		
Intervention	18	107.7	19.1		
Respiratory rate at 2 minutes				-2.024	0.053
Control	18	30.7	5.5		
Intervention	18	35.9	9.5		
Mean Arterial Pressure at 2 minutes				-1.470	0.152
Control	18	55.2	11.4		
Intervention	18	60.0	7.8		

Table 8: Comparison of intra-operative clinical observations inter-group means (Independent t-test) at the end of the operation between the two groups

	n	Mean	SD	t	p
Heart Rate at end of operation				1.500	0.143
Control	18	111.3	17.9		
Intervention	18	102.7	16.3		
Respiratory rate at end of operation				-1.712	0.096
Control	18	26.7	7.1		
Intervention	18	30.5	6.1		
Mean Arterial Pressure at end of operation				-2.123	0.042
Control	18	54.1	11.3		
Intervention	18	61.3	8.9		

Table 9: Comparison of means (Independent t-test) time difference (minutes): time difference between skin incision and diclofenac (A); time difference between last suture and diclofenac (B); time difference between Paracetamol time and last suture (C)

	n	Mean	SD	t	p
A				-0.100	0.041
Control	18	3.2	1.8		
Intervention	18	5.3	3.9		
B				-2.501	0.017
Control	18	26.7	12.3		
Intervention	18	37.3	13.3		
C				-0.388	0.701
Control	18	75.6	34.3		
Intervention	18	81.2	50.2		

The mean time taken between IM diclofenac administration and skin incision was 5.3 minutes (SD 3.9 minutes) in the intervention group and 3.2 minutes (SD 1.8 minutes) in the control group. The intervention group received their paracetamol later 81.2min (SD 50.2min) than the control group 75.6min (SD 34.3min).

10.0 DISCUSSION

Baseline characteristics were similar in both groups (Table 1); except for those who underwent orchidopexy were 27.8% in the intervention group and 11.1% in the control group. However, the numbers for the hydrocelectomy was same in both groups and herniotomy was the commonest type of operation performed.

Continuous variables were equally similar in both groups (Table 2) as the participants received the standardized intraoperative care and the halothane that was delivered was way above the minimum alveolar concentration in both groups being 2.0% (standard deviation 0.27). It was important to have the participant's halothane concentration above minimum alveolar concentration so as to avoid errors associated with the participants being in light plane of anaesthesia and hence affecting the intraoperative clinical observations.

In the immediate post-operative period (Zero hour), all 18 (100%) study participants in the intervention group had FLACC pain scale rating of 0 to 2, that is, relaxed and comfortable to mild discomfort, compared to 15 (83%) study participants in the control group. In this group, 3 (17%) of the study participants had FLACC pain scale rating of 3 or greater, that is, experienced more than mild discomfort. However, there was no statistical difference in the FLACC pain scale rating measured at zero and one hour after the end of the operation between the two groups. This implies that the addition of the ilio-inguinal / ilio-hypogastric nerve block, performed using the landmark technique, to the UTH usual care did reduce pain scores but was not superior to the UTH usual care alone because there was no statistically significant difference in the pain score ratings between the groups. It is important to note that in order for this study to be feasible, the senior Anaesthetic MMED students administered the ilio-inguinal/ilio-hypogastric nerve blocks. The success of the ilio-inguinal/ilio-hypogastric nerve block performed with the landmark technique relies heavily on the expertise of the individual performing the nerve block (Weintraud et al, 2008). It is possible that this might have impacted on the primary outcome measure of this study.

The participants were followed up to six hours, post-operatively, to assess their pain scores and analgesic consumption. For post-operative analgesia consumption, there was no difference in the two groups as every participant received oral paracetamol on the ward, as

prescribed on their drug charts. There was no additional analgesic medications administered. In this study the research nurse, who assessed the pain scores and analgesic consumption, was purely observing what was happening in the follow-up period and did not take part in the nursing duties on the ward. The attending ward nurses were responsible for administering the prescribed medication. Therefore, it is possible that since oral paracetamol was prescribed for all the study participants, they all received the same drug. It is also possible that they could have been perhaps some study participants who did not require the paracetamol and others that might have needed another type of analgesic medication. For this reason post-operative analgesic consumption, in this study, makes it not a good and valid indicator for assessing pain because it is affected by other confounders such as low nursing levels, availability of drugs, inadequate pain assessment and opiophobia.

In both groups, there was a statistically significant rise in heart rate and respiratory rate two minutes after skin incision compared with the baseline observations (Table 4). As is usual practice, in this study the surgeons were commencing to operate without giving the analgesic drugs time to work as evidenced by the mean time taken between diclofenac and skin incision as follows. The mean time that was taken between IM diclofenac administration and skin incision was 5.3 minutes (SD 3.9 minutes) in intervention group and 3.2 minutes (SD 1.8 minutes) in control group (Table 9). When diclofenac is administered orally, rectally, or intramuscularly, it is absorbed rapidly and reaches peak plasma concentrations in 10–30 minutes (Lee et al, 2015). The slow onset of action of the drugs used meant that by the time the skin incision was made in both groups, the participants had nociception. The mean maximum plasma concentration of bupivacaine for ilio-inguinal nerve block is 16-18 minutes for the different paediatric age groups (Smith et al, 1996).

As for the mean arterial pressure, the difference between baseline and two minutes after skin incision was not statistically significant in the control group (p-value 0.199). This cannot be adequately explained but a rise in heart rate and respiration mentioned above is significant enough to show nociception in the participants after skin incision making it clinically significant. In our setting, short acting opioids are not usually given for short procedures such as groin surgery. Hence the study design followed the usual pattern of

care. From this data is can be suggested that intramuscular diclofenac given early enough to children to avoid nociception associated with skin incision.

Comparing the means of the intraoperative clinical observations between the baseline and the end of the operation revealed no statistically significant difference in heart rate and respiratory rate in both groups (Table 5).This was in keeping with the fact that by then the drugs used in both groups had started working and there was no nociception as the difference between the baseline clinical observations and at the end of the operation was insignificant. More so both groups had received local wound infiltration with 1% lignocaine with adrenaline at the end of the surgery, which would have provided a level of additive analgesia to what was given earlier at the beginning before the skin incision. Though, the mean arterial pressure difference between baseline and end of the operation was higher in the intervention group, and had attained statistical significance (p-value 0.047). From this we cannot rule out the possibility of type 1 error as this study was single blinded and the anaesthetists that gave the block could have been bias and lowered the halothane concentration knowing for sure that the block had set in.

Overall comparison of the intra-operative clinical observation means between groups did not show any statistically significant difference in their baseline variables, two after skin incision and end of procedure (Tables 6-8 and figures 4-6). The importance of this comparison lies in the fact that it shows that at baseline, before the skin incision, the clinical observations were similar between groups. This helped in the matching of the clinical observations as it would have been difficult to have participants with the same baseline clinical observations to recruit in the study and follow up the trends intra operative.

However, it is prudent to acknowledge the study weakness of non-randomisation of the participants as the cost associated with the insurance of each and every participant was beyond the scope of the budget. Hence there is a possibility of systematic bias that would have occurred as participants on a particular list were having the same intervention.

10.1 CONCLUSION

In answering the research question, it can be concluded that the addition of the ilio-inguinal/ ilio-hypogastric nerve block done, using the landmark technique, does not improve pain scores better than diclofenac and wound infiltration in children undergoing groin surgery in the post-operative period. Both groups received paracetamol orally (15-20mg/kg) in their post-operative period and there was no need for additional analgesics.

For the intra-operative clinical observations, there was a significant increase in heart rate and respiratory rate at two minutes after skin incision in both groups. However, there was no statistically significant difference between the baseline and end of operation clinical observations in both groups.

In summary, this study showed that there is no difference in pain scores in children having an additional ilio-inguinal/ilio-hypogastric nerve block, done using the landmark technique, to those that received the UTH usual care (Diclofenac and wound infiltration).

10.2 RECOMMENDATIONS

1. Diclofenac is a good and effective analgesia in elective paediatric anaesthesia which should be used in the low income resource setting where availability of other drugs maybe a challenge. Intravenous diclofenac should be also considered as it has a shorter onset of action.
2. Future studies in this area to include ultrasound guided nerve blocks and caudal blocks which can be reliably performed with a landmark technique.

10.3 STUDY LIMITATIONS

- We currently have no monitoring of end tidal halothane levels at UTH; hence the pain scores at 0 hour could have been affected by the residual halothane still circulating in some participants.
- This study should have been a randomised controlled trial so that the possibility of systemic bias would have been eliminated as only the nurse carrying out the pain scores was blinded but the anaesthetists were not blinded.
- The study may not be a full representation of the general paediatric population as we only included those with only a unilateral skin incision.
- The nerve block was done by several senior MMed trainees and since its success heavily relies on expertise of the anaesthetist maybe in this study only one specific anaesthetist should have carried out all the nerve blocks for the study,
- We perhaps should have included three study groups in this study to have a wider range of comparison. Group 1 usual care, Group 2 ilio-ingunal/ilio-hypogastric nerve block and IM diclofenac, and Group 3 usual care plus ilio-inguinal/ilio-hypogastric nerve block.

11.0 REFERENCES

Allman, K., & Wilson, I. (Eds.). (2011). Oxford handbook of anaesthesia. Oxford university press.

Bhattarai BK, Rahman TR, Sah BP, Tuladhar UR: Analgesia after inguinal herniotomy in children: combination of simplified (single puncture) ilioinguinal and iliohypogastric nerve blocks and wound infiltration versus caudal block with 0.25% bupivacaine. Kathmandu Univ Med J (KUMJ). 2005 Jul-Sep; 3(3):208-11
BNF; BMJ group, Pharmaceutical press, 2011 ISBN 9780853699811

Butterworth, John F. ; Strichartz, Gary R. Molecular Mechanisms of Local Anesthesia: A Review Anesthesiology: April 1990 – Volume 72 – issue 4 ppg 711-734

Cox, C. R., Checketts, M. R., Mackenzie, N., Scott, N. B., & Bannister, J. (1998).

Comparison of S (-)-bupivacaine with racemic (RS)-bupivacaine in supraclavicular brachial plexus block. British journal of anaesthesia, 80(5), 594-598.

Cummings E.A., Reid G.J., Finley G.A. *et al* .Prevalence and Source of pain in paediatric in patients. *Pain* 1996; *68* : 25-31

Ellis H.: Anatomy for the Anaesthetist. Blackwell Publishing Massachusetts. 2004

Fredrickson MJ, Paine C, & Hamill J, (2010): Improved analgesia with the ilioinguinal block compared to the transversus abdominis plane block after pediatric inguinal surgery: a prospective randomized trial. Paediatric Anaesthesia, *20*(11), 1022–1027. doi:10.1111/j.1460-9592.2010.03432.x

Hammers J.P., Abu-Saad HH, van den Hout MA *et al.* Are children given sufficient pain relieving-medication post operatively? *J adv Nurs* 1998 ; *27*: 37-44

Holdcroft, A., & Jaggar, S. Core Topics in Pain. (A. Holdcroft & S. Jaggar, Eds.) (pp. 99–130). (2005). New York: Cambridge University press.

Jagannathan N, Sohn L, Sawardeker A *et al.* Unilateral groin surgery in children: will the addition of an ultrasound- guided ilioinguinal nerve block enhance the duration of analgesia of a single-shot caudal block? Paediaric Anaesthesia 2009 19: 892-898

Kotiniemi LH, Ryhänen PT, Moilanen IK. Behavioural changes in children following day case surgery. Anaesthesia. 1997 Oct; 52(10):970-6.

Kristensen AD, Ahlburg P, Lauridsen MC, Jensen TS, Nikolajsen L. Chronic pain after inguinal hernia repair in children. Br J Anaesth 2012;109:603-8. doi:10.1093/bja/aes250.

Lee, J. Y., Cho, J. H., Shin, M. C., Ohk, T. G., Lee, H. Y., & Park, C. W. (2015). Single intramuscular injection of diclofenac sodium in febrile pediatric patients. Indian Journal of Pharmacology, 47(3), 275–279

Mannion D, Armstrong C . Paediatric post orchidopexy analgesia- Effect of diclofenac combined with ilioinguinal/ iliohypogastric nerve block. Paediatric anaesthesia 1994 4: 327- 330

Merkel SI, Voepel-LewisT, ShayevitzJ.R, Malviya S.Voepel-Lewis T Pediatric Nursing[1997, 23(3):293-297]

Patel NB .Guide to Pain Management in Low-Resource Settings. International Association for the Study of Pain®. 2010. (9- 10)

Pain International Association For the Study of Pain® Volume XIII, No. 4 September 2005

Paul F. The role of non- opioid analgesic techniques in the management of post-operative pain. The New York school of regional anaesthesia. 2009

Peck E, Hill S. Pharmacology for anaesthesia and intensive care. Third edition. Cambridge University press. 2008

Pinnock C.A., Fischer H.B., Jones R.P. Peripheral Nerve Blockade. Third edition reprint. Churchill Livingstone- Harcourt publishers. 2000 (2-4)

Powell CV, Kelly AM, Williams A. Determining the minimum clinically significant difference in Visual Analogy pain score for children. Ann Emerg Med. 2001 Jan;37(1):28-31.

Reid MF, Harris R, Phillips PD, Barker I. Day-case herniotomy in Children. (1987). *42*, 658–661.

Smith BA, Jones SE. Analgesia after herniotomy in a Paediatric day unit. Br Med J (Clin Res Ed) 1982; 285:1466.1

Smith, T., Moratin, P., & Wulf, H. (1996). Smaller children have greater bupivacaine plasma concentrations after ilioinguinal block. British journal of anaesthesia, 76(3), 452-455.

Trotter C, Martin P, Youngson G, & Johnston G. A comparison of ilioinguinal/ iliohypogastric nerve block performed by anaesthetist or surgeon for post-operative analgesia following groin surgery in children. Paediatric Anaesthesia, (363–367)

Vargas-Schaffer, G. (2010). Is the WHO analgesic ladder still valid? Twenty-four years of experience. Canadian Family Physician, 56(6), 514-517

Weintraud, Marion MD; Marhofer, Peter MD; Bösenberg, Adrian MBChB, FFA (SA); Kapral, Stephan MD; Willschke, Harald MD; Felfernig, Michael MD; Kettner, Stephan MD :Ilioinguinal/Iliohypogastric Blocks in Children: Where Do We Administer the Local Anesthetic Without Direct Visualization? Anesthesia & Analgesia: January 2008 – volume 106 – Issue 1 – pp 89- 93.

Willschke H, Marhofer P, Machata , & Lönnqvist P. (2010): Current trends in paediatric regional anaesthesia. Anaesthesia, 65 Suppl 1(Suppl 1), 97–104. doi:10.1111/j.1365-2044.2010.06242.x.

Willschke H, Marhofer P, Bösenberg A, Johnston S, Wanzel O, Cox S, Sitzwohl C and Kapral S: Ultrasonography for ilioinguinal/iliohypogastric nerve blocks in children. Br. J. Anaesth. (August 2005) 95 (2): 226-230. doi: 10.1093/bja/aei157

World Health Organization (1998). Cancer pain relief and palliative care in children. Geneva: WHO. ISBN 978-92-4-154512-9.

Yarwood J. Nerves of the anterior abdominal abdominal wall: Continuing education in anaesthesia, critical care and pain. Volume 10 number 6, 2010.

12.0 APPENDICES

APPENDIX 1: THE FLACC PAIN SCALE

The FLACC Pain Scale

	SCORING		
CATEGORIES	**0**	**1**	**2**
FACE	No particular expression or smile	Occasional grimace or frown, withdrawn disinterested	Frequent to constant frown, clenched jaw, quivering chin,
LEGS	Normal position or relaxed.	Uneasy, restless, tense.	Kicking, or legs drawn up
ACTIVITY	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
CRY	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
CONSOLABILITY	Content, relaxed	Reassured by occasional touching, hugging or talking to, distractible	Difficulty to console or comfort

APPENDIX 2: DATA COLLECTION PROTOCOL PART ONE

A COMPARATIVE STUDY OF DICLOFENAC WITH WOUND INFILTRATION TO ADDITIONAL LANDMARK TECHNIQUE OF ILIO INGUINAL/ HYPOGASTRIC NERVE BLOCK FOR PAIN RELIEF IN CHILDREN UNDERGOING GROIN SURGERY- THE UNIVERSITY TEACHING HOSPITAL (UTH), LUSAKA, ZAMBIA.

Part One for the Anaesthetist:

1. PATIENT PARTICULARS

Date of operation……..

Name of operation…….

Age……...

Weight……..

ASA……

File #.....

2. ANAESTHETICS USED PLEASE TICK AND INDICATE AMOUNT:

2.1 Oxygen		
2.2 Halothane		
2.3 Atropine		
2.4 Ketamine		
2.5 Propofal		
2.6 Fluids		

3. ANALGESICS GIVEN AND TIME:

DRUG	YES(1)/ NO(2)	TIME
3.1 Diclofenac IM		
3.2 Local wound infiltration		
3.3Ilio-inguinal/ilio-hypogastric nerve block		

4. RECORD OF TIME

4.1 Induction of anaesthesia	
4.2 Surgical incision	
4.3 Surgical time up	
4.4 Recovery time	

5. VITALS AND TIMES

Vitals	Just before surgical stimuli (1)	2 minutes after skin incision (2)	End of procedure (3)
5.1 Heart rate			
5.2 Respiration rate			
5.3Blood Pressure(MAP)			

APPENDIX 3: DATA COLLECTION PROTOCOL PART TWO

A COMPARATIVE STUDY OF DICLOFENAC WITH WOUND INFILTRATION TO ADDITIONAL LANDMARK TECHNIQUE OF ILIO INGUINAL/ HYPOGASTRIC NERVE BLOCK FOR PAIN RELIEF IN CHILDREN UNDERGOING GROIN SURGERY- THE UNIVERSITY TEACHING HOSPITAL (UTH), LUSAKA, ZAMBIA.

Part Two for nurse to fill in:

6. PATIENT PARTICULARS

Date of operation……

Name of operation……

Age……..

File # ……

7. FLACC pain score chart given

7.1 At recovery	7.2 One hour After surgery	7.3 Six hours after surgery

8. OTHER ANALGESICS GIVEN POST OPERATIVELY

8.1 Drugs given and dosage	8.2 Frequency	8.3 Time given

If the child did not receive any analgesia give the reason(s) why: ……

…….

……

Date of Discharge…….

Time of discharge……..

APPENDIX 4: PATIENT INFORMATION SHEET-ENGLISH

A COMPARATIVE STUDY OF DICLOFENAC WITH WOUND INFILTRATION TO ADDITIONAL LANDMARK TECHNIQUE OF ILIO INGUINAL/ HYPOGASTRIC NERVE BLOCK FOR PAIN RELIEF IN CHILDREN UNDERGOING GROIN SURGERY-THE UNIVERSITY TEACHING HOSPITAL (UTH), LUSAKA, ZAMBIA.

Introduction

I, Jane Chanda Kabwe, a student of Master of Medicine (MMED) in Anaesthesia and Critical Care in the School of Medicine at the University of Zambia, hereby request your participation in the above mentioned study. This study is in partial fulfilment for the award of a Master of Medicine in Anaesthesia and Critical Care. Request is hereby made that you carefully read this document and ask me whatever you are not clear on. Kindly understand the purpose of the study and what is expected of you. Be informed also that participation in this study is absolutely voluntary. If you agree that your child can be enrolled in this study, you will be asked to sign the consent form in the presence of a witness.

The aim of the study

The main objective of this study is to determine whether ilio-inguinal/ilio-hypogastric nerve block, done using the blind landmark technique, in children undergoing groin surgery has good ‘pain killer’ effect at the University Teaching Hospital.

Procedure of the study

Only if you agree to participate in this study, shall we will obtain information from you (the parent/ guardian). There will be no recording of names in this study but the age, date of operation, name of operation and file number pertaining to your child which will be confidential. Depending on the week of the month, your child will either fall in group one or group two of this study. Those in group one will receive the usual UTH care (Diclofenac in the buttock and lignocaine in the wound). Those in group two will in addition to the UTH usual care receive the nerve block. All these shall be done in theatre after the child has been given medicine to ‘sleep’ as per protocol. Your child participating or not participating in this study will not be denied of the standard theatre monitoring and care.

Part one of the data will be collected by the anaesthetist in theatre whereas part two of the data will be collected by a trained nurse on the ward. On the ward the nurse will be using a pain scale to rate your child's pain score at one and six hours after the operation. The categories that will be assessed in this pain scale are: facial expressions, legs, activity, cry, and consolability. The nurse will also record other drugs given and the time.

Possible risks and discomforts

First and foremost, there will be no discomforts of needle pricks as all the drugs in this study will be given whilst your child is sleeping in theatre.

Just like any other clinical procedures done involving a patient, caution will be taken to avoid any related complication.

(i)In this study accidental injection of drugs in blood vessels will be avoided by counterchecking the syringe for blood every time before infiltrating the drug.

(ii) Perforation of small or large bowel punctures will be avoided by blunting the small needle so that it is not sharp and does not go beyond the space we want. In no way is this study an experiment in your child because world over nerve blocks are standard practices as part of pain management.

Benefits

There will be a qualified nurse that will trained specifically for this study that will be assigned to monitor your child. Your child participating in this study will benefit in that the nurse will actually be able to assess his pain score objectively using the above parameters indicated. Thirdly, in this study the nurse will be able to give your child the necessary pain killers appropriately when the assessment does indicate that there is a need for extra medication. Lastly but not the least, your child will be an ambassador for the data required for us to be able to formulate our own pain management protocols.

Confidentiality

All the information collected is strictly confidential. Data that will be collected, analysed, and reported on will not include the name of your child and therefore cannot be traced to him.

Consent

Your child's participation is absolutely voluntary therefore you are free to withdraw him from the study at any time for any reason without any consequences to you or him.

Am very grateful to you for considering your child's participation in this study. For any concerns and clarifications, please contact Dr Jane Chanda Kabwe or The University of Zambia Biomedical Research Ethics Committee (UNZABREC) on the following respective addresses:

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APPENDIX 5: PATIENT INFORMATION SHEET-NYANJA

MBIRI YA WODWALA

MAPUNZILO YAKUPALANISA DICLOFENAC NDI KULESA KUBABA MIZIPE YA M'CHIUNO YAMUTUPI YAWANA PAMENE ILESA KUPWETEKA- KU UTH, LUSAKA, ZAMBIA

CHIDZIWISO

Ine Jane Chanda Kabwe wophunzira za akatswili wa nkhwala mu kugoneka ndi kasamalidwe ka anthu wodwalisab mu sukulu la mankhala yapa University of Zambia. Nikupempani kutengako mbali muphunziro imene nachula iyi.

Phunziro imenei, mwachidule ndi kutsimikiza za photo ya ukatswili wa zamankhwala yo goneka ndiyolesa kubaba mizipe ya m'chiuno.

Pempho ndi yakuti werengani bwino- bwino pepala limene ndipo mundifunse pamene simunamvetsese bwino. Chode mvestesani cholinga cha mpunziro limeneli, ndipo cymene tiyembekeza kwa inu. Dziwani kuti kutengako mbali mu phunziro imenei ndi mosakakamisdwa, kuma kuzipeleka mwaulele. Ngati mwa bvomera kuti mwana wanu alembendwe mu phunzilo imenei, myyenera ku saina pepala imenei pamaso pa mboni.

CHOLINGA CHAPUNZIROYI

Cholinga cha punziroyi ndi kudziwa kuti kulesa kubaba kwa mizipe ya m'chiono mu Ana ang'ono kupitilira pasogolo muli Ana amene apelekedwa ku opaleshoni ya m'chiuno pa chipatala ca cikulu ca muno mu Lusaka (UTH)

MUNDANDA YA PHUNZIRO

Pokhapo mutabvomera kutengapo mbali mu phunziro yathu, tizalemba mbili yanu inu cifukwa ndimwe makolo kapena womsunga sikuzakhala ku lemba maina anu mu phunziro yathu koma tizhalemba zaka za mwana wanu tsiku la opaleshoni, cholingana ca opaleshioni nambala ya khadi ya mwana wanu ndiposo zonsezi tizasunga mwacisinsi. Kulingana ndimlungu wamumwezi, mwana wanu akhonza kunkhala mu gulu loyamba kapena gulu lachiwiri ya phunziro yathu. Onse aja amgulu loyamba azalandira thandizo kuchokera ku UTH, monga diclofenac ndikika mankhala muchilonda. Onse amgulu la chiwri naonse azalandila thandizo monga- diclofenac, ndi kuikidwa mankwala muchilonda ndiponso azalandira mankhwala yolesa kubaba mizipe ya m'chiuno zonsezi zizacitikira ku fyeta pambuyo pamugoneka.

Ngati mwana wanu azatengako mbali mu phunziro yathu kapena sazatengako mbali mu phunziro yathu bonse bali boyenenera kulandira thandizo ndiponso nakupelekedwa ku fyeta.

KUSAMVERA UKALI WAKALASIDWE KA NYELETI

Choyamba-yamba, sipazankhala cholesa kubaba akalasa nyeleti kulingana nkuti mankhwala yonse ya muphunziro yathu yazapatsidwa pamene mwana wanu atagonekedwa..

Monga mwanjira ilionse monhuza wodwala tizacita zotheka zili zonesa kuteteza odwala kuti asapeze bvoto. Mu phunziro yathu tizacita zotheka . Tizalasa nyeleti yathu ndipo tizadonsa kuona ngati kulibe migazi, ndipo pamene tipitiliza kulasa mankhwala yolesa kubaba kwa mizipe ya m'chiuno.

Chaciwiri kuboola kambo kang'ono na nyeleti ndioi tizatenga kanyeleti kang'ono ndi kukabuntisa kusogolo kwake.

Sitiyesera pa mwana wanu koma dziko lonse la pansi, kuvalika kwa mizipe ndiye njira imene bagwiritsa nchito kulesa kubaba.

KUYAMIKILA

Kuzankhala nasi anaphunzila kuyanganila ndiponso anayamikilanso mapunzilo musungila mwana wanu. Sono pamene mwana wanu atengako mbali mumaphunzilo amutundu aya azayamikila naye. Mwacisansopamene nasi ali kumuona azaziba banso zowawa mumwana pamene alikusebenzesa makina patupi pake. Mbali yacitatu nasi pamene azaziba zowawa azapeleka mankwala.; Ndiponso mwana wanu azankalanso pagulu pa wana anali ku onedwa mumapunzilo yoyamikila yolesa kuwawa mu mwana.

CHINSINSI

Mbiri yonse imene izalembedwa izakhala ya chinsinsi zones tizalemba, sitizaikapo dzina la mwana wanu, motero mwini wache sadza zi wika.

MBIRI

Kutengako mbali ko phunziro yathu mwana wanu ndi mwaufulukapena mwaulele, motero ndinu womasuka kuleka kapena kukana kutengako mbali muphunziro yathu nthawi ilionse pa cifukwa cilichonse mopanda zobvuta zili zonesa kwainu kapena kwa mwana wanu.

Ngati pali zimene simunamvetsetse kapena mulindi funso, chonde mungaonane ndi Dr. Jane Chanda Kabwe kapena a University of Zambia Biomedical Research Ethics Committee (UNZABREC) pa keyala iyi:

Dr Jane Chanda Kabwe

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APPENDIX 6: CONSENT FORM

CONSENT FORM

I, _____ hereby confirm that the nature of this clinical study has been sufficiently explained to me. I am aware that my personal details and of my child will be kept confidential and I understand that I may voluntarily, at any point, withdraw his participation without suffering any consequences. I have been given sufficient time to ask questions and seek clarifications, and of my own free will consent to participation in this research.

I have received a signed copy of this agreement

_____	_____	_____
Name of Participant (Print)	Participant (Signature or thumbprint)	Date

_____	_____	_____
Witness (Print Name)	Witness (Signature)	Date