Original Article

A Comparative Study of Diclofenac and Wound Infiltration to Additional Ilioinguinal/iliohypogastric Nerve Block With 0.25% Plain Bupivacaine for Pain Relief in Children Undergoing Groin Surgery – University Teaching Hospital (UTH), Lusaka

***Kabwe J. C.,[1] Chisakuta A.M.,[2] Ismailova F.[1]**

[1]University Teaching Hospitals, Adult Hospital, Department of Anaesthesia, Private Bag RWX1, Lusaka, Zambia.
[2]Beit Cure Hospital, Great North Road, PO Box 36961, Lusaka, Zambia.

ABSTRACT

Objective: 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. This study aimed at determining whether an additional ilioinguinal/iliohypogastric nerve block with 0.25% plain bupivacaine, done using the landmark technique,would improve post-operative analgesia in children undergoing groin surgery at the UTH when compared to IM diclofenac and wound infiltration with 1% lidocaine (with adrenaline 1:200,000).

Methods: A non-randomized intervention study of 36 children undergoing unilateral inguinal herniotomy, hydrocelectomy and orchidopexy was conducted at UTH. The children were allocated to two groups – Group 1 (control) received IM diclofenac and wound infiltration (UTH usual care), while Group 2 (intervention group) received medication as in control plus an ilioinguinal/ iliohypogastric nerve block performed by landmark technique.

The Mann-Whitney U test was used to compare the pain scores between the two groups and any result yielding a p-value of less than 5 percent was statistically significant.

Results: The operations done were unilateral inguinal herniotomy, hydrocelectomy and orchidopexy. Half of the participants were between 2-5years old and the other half between 5-7years. Post-operatively, the pain scores measured at times 0 and 1 hour were statistically non-significant in both groups (p-values 0.181 and 0.355 respectively). At the 6th hour post-operative, all of the participants had pain scores of 0. Oral Paracetamol (15 - 20 mg/kg) was the only post-operative analgesic received by the patients in the study.

Conclusion: This study showed that the addition of ilioinguinal/iliohypogastric 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.

***Corresponding Author:**
Jane Kabwe,
Email: janechandak@gmail.com

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Definition of Terms:

Landmark technique: Blind performance of a nerve block using well known identifiable landmarks to locate the area where a nerve lies.

Wound infiltration: Superficial injection of a local anaesthetic into the skin and subcutaneous tissue for pain relief.

UTH usual care: Perioperative analgesia administered to paediatrics in this case: Diclofenac intramuscularly and wound infiltration with lignocaine with adrenaline 1:200 000.

INTRODUCTION

Adequate analgesia in the peri-operative period for paediatric day case procedures such as groin surgery is essential. The ilioinguinal/iliohypogastric nerve block with local anaesthetic is a useful technique in providing post-operative pain relief in this group of patients.[1] The ilioinguinal/iliohypogastric nerve block is a simple, safe, and effective technique for relieving pain following groin incision.[1,2] 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, and these included children aged one month to twelve years. The peri-operative pain management, routinely administered by the anaesthetist, in this group of patients included IM diclofenac and wound infiltration with 1% lidocaine.

Several studies have shown that blocking the ilioinguinal and iliohypogastric nerves can provide good intra- and post-operative analgesia for most operations in the inguinal region.[1,3,4,5] A South African study of 62 children, described the actual placement of local anaesthetic agent without direct visualization of the nerves, and found that with the landmark technique, the local anaesthetic was inaccurately placed in more than three quarters of cases.[6] Hence the landmark technique has such a high failure rate without use of ultrasound guidance.

Diagram 1 shows the anatomical landmarks and relations including the placement of needle.[7]

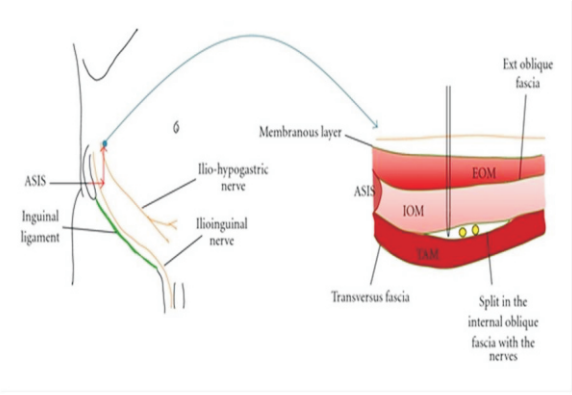

Diagram 1: Ilioinguinal and iliohypogastric nerves in relation to the landmark. EOM: external oblique muscle, IOM: internal oblique muscle and TAM: transversus abdominis muscle.[7]

Inadequately treated acute pain has been shown to have a low risk for developing chronic pain later in life.[8,9,10] However, literature shows that healthcare professionals underestimate post-operative pain in children.[11] Moderate to severe pain requires opioid analgesics as proposed by the World Health Organization's analgesic ladder[12], which has also been adopted by the World Federation Societies of Anesthetists.

However, in Zambia, anecdotal data at the UTH revealed: firstly fears (opiophobia), concerns and myths about opioid use in this group of patients; secondly, very few nerve blocks are performed, and they are done without ultrasound guidance. International pain management standards emphasize a multimodal approach, nerve blocks have been included in step four of the new adaptation of the analgesic ladder.[13] Thus nerve blocks are greatly encouraged especially in children to avoid the use of opioids.

Considering the high turnover of paediatric groin operations done at UTH, a low resource setting, this study determining whether the addition of a nerve block which is done using the landmark technique has additive analgesic effect is imperative. Moreover, it adds to literature in its novelty because after extensive literature search, only one study was found in which, both groups of participants had the

same nerves, as in the current study blocked, though rectal diclofenac was the comparator.[14] There is need to also establish whether our usual care for pain management is adequate as this is cardinal in formulating local protocols and policy making.

METHODS

A non-randomised single blinded interventional study was conducted involving 36 children between 2 - 7 years of age undergoing unilateral elective groin surgery. The sample size was calculated using Open Epi version 2.3. At 95% confidence interval and giving a power of 80%: clinically significant difference in pain score is 10 - 20%, that is, a change in pain score of 1 to 2.[15] We therefore used a change in pain score of 1.5 (15 %) in the current study. The standard deviation in pain score of SD ± 1.5, statistical significance was taken as $P< 0.05$.[16]

Those excluded from this study were ASA (American Society of Anaesthesiologists) III and IV patients, bilateral, multiple, and emergency groin surgeries. The participants were systematically allocated to either the control group (UTH usual care, which was IM Diclofenac, at a dose of 1ml/kg, and wound infiltration with 1% Lignocaine [with Adrenaline 1:200 000]) or the intervention group (UTH usual care plus an additional ilioinguinal/iliohypogastric nerve block with 0.25% plain bupivacaine at a dose of 0.3ml/kg). The expiry dates of all drugs used in this study were checked and ensured that they were not expired before use, and they were all stored at room temperature. The nerve blocks were done under general anaesthesia, which was induced and maintained with halothane and oxygen. The airway was secured, with patients spontaneously breathing, and minimum standard of monitoring applied prior to any performance of the nerve block. Experienced senior MMED Anaesthesia trainees conducted these blocks in this study. The landmark technique blocks the nerves immediately before they separate into the different fascial layers and the injection is made perpendicular to the skin 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.[1,4,5,7] The point of insertion in this study was approximated at 1.5cm ± 0.5 both medially and cephalad to the anterior superior iliac spine using a blunted size 23 gauge needle.

The primary outcome measure was severity of pain, which was scored by a blinded nurse, using the FLACC (Faces, Legs, Activity, Cry and Consolability) pain scale on three occasions: 0, 1 and 6 hours post-operatively. The nurse also observed the analgesics administered post operatively on the ward.

The independent t-test was used to compare the mean time taken between the administration of diclofenac and skin incision, and secondly between diclofenac administration and the knotting of the last suture at the end of the operation. The Mann-Whitney U test was used to compare the pain scores between the two groups. A result yielding a p-value of less than 5 percent at 95% confidence interval was statistically significant.

ETHICS APPROVAL

Ethical clearance to conduct this research was approved by the University of Zambia Biomedical Research Ethics committee (Ref. No. 006-04-14).

RESULTS

In both the control and intervention groups, half of participants were aged between 2-5 years and the other half between 5-7 years (Table 1). The break down for types of operations in control group was herniotomy 12, hydrocelectomy 4 and orchidopexy 2, while in the intervention group herniotomy 9, hydrocelectomy 4 and orchidopexy 5 (Table 1).

Table 1: Characteristics of categorical variables

Characteristic	Control N (%)	Intervention N (%)
Age		
2-5 years	9 (50.0)	9 (50.0)
5-7 years	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 the immediate post-operative period, which was time 0 in this study, out of the 36 enrolled, eight and nine of the study participants in the control and intervention groups, respectively, were pain free, while three in the control group had pain scores of 3 or greater and the remainder had a pain score of 1 or 2 in both groups (Figure 1).

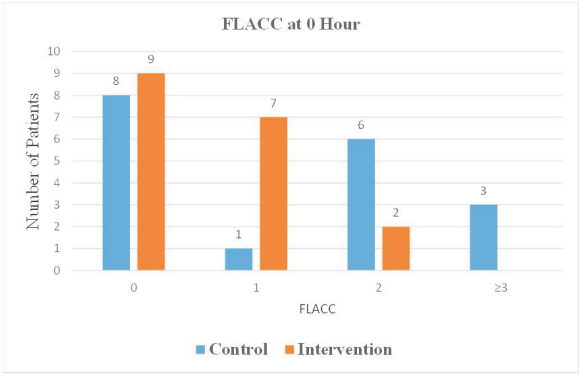

Figure 1: Pain scores at 0 hour in the control and intervention groups

The children were also assessed for pain at one-hour post operation and by this time they were fully awake from the effects of anaesthesia. We found that out of the 36 enrolled participants, nine and seven of those in the control and intervention groups, respectively, were pain free, that is had a pain score of zero (0). Those with pain scores of 1 and 2 were six and three, respectively, in the control group. Whereas in the intervention group, there was an equal number of participants with 1 and 2 pain scores each being five. There was one participant noted with a pain score of 3 or greater in this group (Figure 2).

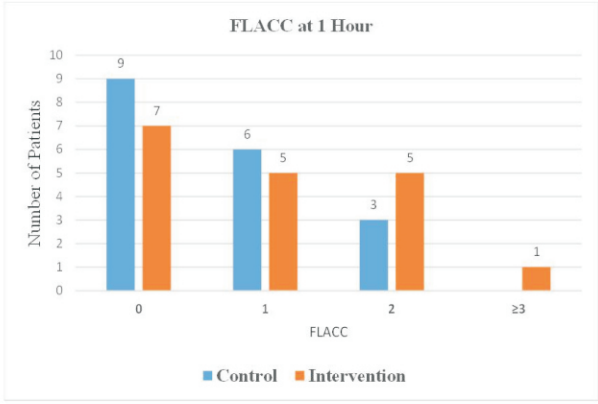

Figure 2: Pain scores at 1 hour in the control and intervention groups

We were also keen to find out the mean time taken between IM diclofenac administration and skin incision. The results were as follows: 3.2 minutes (SD 1.8 minutes) in the control group and 5.3 minutes (SD 3.9 minutes) in the intervention group, with a p-value of 0.041. Whereas the time difference between IM diclofenac administration and knotting of the last suture was 26.7 minutes (SD 12.3) and 37.3 minutes (SD 13.3) in the control and intervention groups, respectively, with p-value of 0.017 (Table 2).

Table 2: Comparison of means (Independent t-test) time difference (minutes): time differences between: skin incision and diclofenac (A); last suture knotting and diclofenac (B)

Characteristic	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		

The Mann-Whitney U test was used to analyse the significance of these different pain scores. It revealed that there was no statistically significant difference in the post-operative pain scores between the control and intervention groups at times 0 and 1

hour (p-values 0.181 and 0.355 respectively) (Table 3).

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

	N	Mean Rank	Mann-Whitney U	p
Pain at 0 hour			119.5	0.181
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		

The FLACC pain scores, which were rated at 6 hours post-operatively, showed that all study participantsin both groups, that is, 36 had 0 pain scores. Moreover, participants in both groups had received oral paracetamol (15-20mg/kg) as a post-operative analgesic as prescribed on the post-operative drug chart.

DISCUSSION

Even though this study has revealed that there is no statistically significant difference in pain scores between the control and intervention groups, it has enlightened the fact that children continue to have mild to moderate post-operative pain. In the immediate post-operative period (0 hour), 9 of study participants in the intervention group had FLACC pain scale rating greater than 0 compared to 10 of study participants in the control group.We would like to point out another important finding that at 0-hour post-operation, in the control group, 3 of the study participants had FLACC pain scale rating of 3 or greater, that is, experienced more than mild discomfort which was not seen in the intervention group. However, at 1-hour post operation when the children were fully awake from the effects of anaesthesia, the number of participants with post-operative pain greater than 0 increased to 11 in the intervention group of which one of them had a pain score of greater than 3. In the current study, we did not compare the pain scores to the type of operation done. Although all the three are groin surgeries with a unilateral incision, the technique and extent of operation differs. This might explain why we had a few participants with a pain score greater than 3. In a cohort study of 90 boys who had undergone either herniotomy or orchidopexy, it was noted that there were more children in the latter group that experienced moderate to severe pain in the first 48 hours than the former.[17]

The assessment of pain can be done both objectively and subjectively taking note that in children, the pain score charts used are also age dependent. In this study we used an objective pain assessment tool, that is, the FLACC Pain Assessment Tool which incorporates five categories of pain behaviours: facial expression; leg movement; activity; cry; and consolability. In an earlier study, it was validated in paediatric patients aged between two months of age to seven years and has been considered to be an efficient tool in providing a simplified framework for objectively quantifying pain behaviours in children who may not be able to verbalize the presence or severity of pain.[18]

In our protocol, 1ml/kg diclofenac intramuscularly was administered to participants in both groups as soon as the airway was secured. However, in the intervention group this was followed by blocking the ilioinguinal/iliohypogastric nerves with 0.25% plain bupivacaine, at a dose of 0.3ml/kg. This study has revealed that even though the time taken to actually perform the nerve block is short, it results in a significant difference in the time taken between IM diclofenac administration and skin incision, 3.2±1.8 (minutes) in the control group and 5.3±3.9 (minutes) in the intervention, with p-value of 0.041. Based on this study's findings that the mean time taken, in minutes, between IM diclofenac administration and knotting of last suture being 26.7±12.3 in the control group and 37.3±13.3 in the intervention group, with a p-value of 0.017, might have resulted in attaining higher plasma levels of diclofenac in the intervention group, and hence the lower pain scores. According to another earlier study, the administration of a single dose of rectal diclofenac, which was the comparator, was quite an

effective method of supplementing peri-operative analgesia to the ilioinguinal block as there were significant differences in pain scores and use of post-operative rescue analgesia when compared to the group that had received the ilioinguinal nerve block only.[14]

In the current study, the addition of the ilioinguinal/iliohypogastric nerve block, performed using the landmark technique, when compared 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 two groups. This is possible because without direct visualization of the nerve, a South African study found that the local anaesthetic, in most of the children, was wrongly placed in other surrounding structures and not around the nerves.[6] However, in an earlier study with similar settings involving 100 children, showed that ultrasonographic visualization of the ilioinguinal /iliohypogastric nerves was 100% possible.[4] The success of the ilioinguinal/ iliohypogastric nerve block performed with the landmark technique relies heavily on the expertise of the individual performing the nerve block.[6] It is possible that this might have impacted on the primary outcome measure of this study.

For post-operative analgesia consumption, there was no difference in the two groups as every participant received oral paracetamol, at a dose of 15-20mg/kg, on the ward as routinely prescribed on their drug charts. There were no additional analgesic medications administered. In our study, post operatively there was no intervention, apart from observations, made in the follow-up period. At UTH the usual post-operative analgesia for groin surgery is paracetamol thus, it is possible that since it was routinely prescribed for all the study participants, they all received paracetamol. We also cannot rule out the possibility 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, is not a good and valid indicator for assessing pain because other confounders affect it, such as low nursing staff levels, availability of drugs, inadequate pain assessment and opiophobia. Whereas in other studies it must be noted that post-operative analgesic requirement is a reliable outcome measure for the assessment of postoperative pain in paediatric patients.[1, 14, 16]

In addition, both groups had received local wound infiltration of 1% lignocaine with adrenaline 1:200 000 at the end of the surgery, which is the usual UTH care, and this would have provided a level of additive analgesia to that achieved earlier peri-operatively. From these findings, we cannot rule out the possibility of type 1 error as this study was a single blinded (the nurse only who carried out pain assessment) and not double blinded (anaesthetist). Double blinding would have ensured that the level of anaesthesia administered is not influenced by the knowledge of the nerve block. For this reason, this study should have been a randomized controlled double blinded trial to ensure such limitations are taken into consideration.

CONCLUSION

This study showed that there is no difference in pain scores in children having UTH usual care (IM diclofenac and wound infiltration with 1% lignocaine with 1:200 000 adrenaline) to those with an additional ilioinguinal/iliohypogastric nerve block with 0.25% plain bupivacaine, done with the landmark technique. Both groups received paracetamol orally (15 – 20 mg/kg) in their post-operative study period and there was no need for additional analgesics.

We recommend future studies in this area to include use of ultrasound-guided ilioinguinal/ iliohypogastric nerve blocks and caudal blocks which can be reliably performed with a landmark technique to minimize failure rates.

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