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Duration of Analgesic Free Period and Haemodynamic Stability Following Paediatric Herniotomy: A Comparison of Caudal Block Versus Pre-Incisional Field Block with Diclofenac Suppository

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Abstract

Paediatric herniotomy, a common surgical procedure in children, demands effective perioperative pain management to ensure patient comfort and minimise complications. Optimal pain control is crucial in paediatric populations due to their heightened sensitivity to pain and the potential long-term impact of poorly managed acute pain on their neurodevelopment. The choice between caudal block and field block with diclofenac remains a subject of debate. Factors such as the duration of analgesic-free periods and haemodynamic stability need to be assessed to guide clinical decisions. This study was conducted in the Jos University Teaching Hospital, Jos, Nigeria, among paediatric patients presenting for inguinal herniotomy. We conducted a randomised, single-blind controlled clinical trial where patients were recruited through the purposive sampling technique. Inclusion criteria included elective day cases, open unilateral inguinal herniotomies, and children aged 1–6 years with ASA physical classes I and II. One group of patients received 1 mL/kg of 0.25% plain bupivacaine caudally, while the other group of patients received pre-incisional field block with 1 mL/kg of 0.25% plain bupivacaine and

diclofenac suppository 1 mL/kg. duration of analgesic-free period and intraoperative haemodynamic parameters were assessed and documented. All the 58 enrolled patients were included in the final analysis, having completed the study. The study groups were comparable in all measured patient characteristics. The duration of analgesic free period was shorter in the caudal block group compared with the field block with diclofenac suppository group (282.86±18.43 minutes in the caudal block group and 291.03±16.33 minutes in the field block with diclofenac suppository group, p = 0.155). The heart rates, systolic blood pressures, diastolic blood pressures, and mean arterial pressures across both study groups were comparable from the start of surgery to the end of surgery. It can be concluded that both caudal block with 1 mL/kg of 0.25% plain bupivacaine and pre-incisional field block with 1 mL/kg of 0.25% plain bupivacaine plus 1 mL/kg of diclofenac suppository were comparable in providing effective post-herniotomy analgesia in the paediatric age group.

Keywords: Postoperative pain, Herniotomy, Caudal block, Field block, Bupivacaine, Diclofenac

INTRODUCTION

Paediatric herniotomy, a common surgical procedure in children, demands effective perioperative pain management to ensure patient comfort and minimise complications. Optimal pain control is crucial in paediatric populations due to their heightened sensitivity to pain and the potential long-term impact of poorly managed acute pain on their neurodevelopment (Sohn et al., 2012). Among various pain management techniques, regional anaesthesia, such as caudal epidural block, has demonstrated effectiveness in providing prolonged analgesia and haemodynamic stability (Wiegele et al., 2019).

Caudal block involves the administration of local anaesthetic into the caudal epidural space, offering reliable analgesia for lower abdominal and perineal surgeries (Shah & Suresh, 2013). Its benefits include decreased systemic opioid requirements and minimal sedation, but concerns remain about the potential for motor block and urinary retention (Suresh & Ecoffey, 2018). Alternatively, pre-incisional field blocks combined with diclofenac suppositories represent another approach to analgesia. Field blocks target somatic pain, while nonsteroidal anti-inflammatory drugs (NSAIDs) like diclofenac provide additional multimodal analgesia by addressing inflammation and reducing opioid requirements (Ziesenitz et al., 2022).

However, the choice between caudal block and field block with diclofenac remains a subject of debate. Factors such as the duration of analgesic-free periods, haemodynamic stability, and overall recovery profiles need to be assessed to guide clinical decisions (Zewdu et al., 2020). This study therefore sought to compare these techniques to determine their relative efficacy in paediatric herniotomy, considering both pain control and haemodynamic stability. The findings could contribute to evidence-based recommendations for paediatric pain management strategies, optimising outcomes for this vulnerable population (Berde & Sethna, 2020).

MATERIALS AND METHODS

This study was conducted in the Jos University Teaching Hospital, Jos, Nigeria, among paediatric patients coming for inguinal herniotomy. We conducted a randomised, single-blind controlled clinical trial in which patients were recruited through the purposive sampling technique and randomised into study groups A and B through balloting. Inclusion criteria included elective day case open unilateral inguinal herniotomy, children aged 1-6 years with ASA physical classes of I and II. Patients excluded from this study were those whose parents or guardians did not give consent, having allergy to any of the study drugs or history of bleeding diathesis, lumbosacral deformities, infection at site of caudal or inguinal injection, requiring greater than 20 mL of plain bupivacaine, asthmatics, or having anal deformities.

Group A received 1 mL/kg of 0.25% plain bupivacaine caudally, while group B received pre-incisional field block with 1 mL/kg of 0.25% plain bupivacaine and diclofenac suppository (1 mg/kg). The sample size for this study was estimated from the formula for experimental study design (Charan & Biswas, 2013), i.e., $n = (Z\beta + Z\alpha/2)^2 \text{ X } 2\sigma^2/E^2$, where a 95% confidence interval and 80% power of the study were considered, which corresponded to $Z\beta = 0.84$ and $Z\alpha/2 = 1.96$. The σ and E were assumed from a previous study (Kalu et al., 2022) to be 0.54 and 0.42, respectively. This gives a total sample size of 58 patients, with 29 patients in each study group assuming an attrition rate of 10%.

On the morning of the surgery, a preoperative assessment was done in the waiting area of the modular theatre to assess the patient's fitness for anaesthesia. Informed consent for caudal block, field block, and suppository insertion was then obtained following an explanation of the procedure to the understanding of the patient's caregiver. No

premedicants were given to the patients. Anaesthesia was induced using an incremental concentration of halothane (1–4%) in 100% oxygen via a tight-fitting face mask using the Jackson Rees breathing circuit. Maintenance of anaesthesia was done with 1–2% isoflurane in 100% oxygen, with the patients breathing spontaneously via a tight-fitting face mask with a Jackson Rees breathing circuit. The researcher conducted the caudal block in group A patients while the researcher, in collaboration with the surgeon, who was at least a senior registrar, administered the field block in group B patients.

For the patients in Group A, following the induction of anaesthesia, they were placed in the left lateral position with hip and knee flexed. The skin over the sacral region to the natal cleft was disinfected using providone iodine, and the sacral hiatus was identified employing palpation of both sacral cornua. A 22-guage short bevel needle was used for caudal puncture perpendicular to the skin surface and advanced 1 cm parallel to the skin after penetration of the sacrococcygeal membrane (evidence by loss of resistance and a feeling of a "give"). Subcutaneous emphysema was excluded by injection of 2 ml of air using an air-filled syringe into the caudal space. Aspiration was done to exclude subarachnoid or intravascular placement of the needle. Plain bupivacaine (1 ml/kg) of 0.25% up to a maximum of 20 ml was injected into the caudal space. The patients were then returned to the supine position for the surgery, which commenced 20 minutes after the caudal block. The success of the caudal block was predicted from the laxity of the anal sphincter secondary to the reduction in sphincter tone from the local anaesthetic block or turgidity of the penis in the male children.

For the patients in Group B, the field block was performed using a 21G hypodermic needle and the local anaesthetic agent (1 ml/kg of 0.25% plain bupivacaine) divided into four equal volumes. Four sites were infiltrated: 1-2 cm medial to the anterior superior iliac spine and to the external oblique aponeurosis, 1.5 cm above the midpoint of inguinal ligaments, the subcutaneous tissue from the pubic tubercle towards the umbilicus, and the subcutaneous tissue along the line of the skin incision. Rectal diclofenac (1 mg/kg) was inserted into the rectum with gloved fingers by the researcher. Surgery was then commenced 20 minutes after the field block.

At the end of these blocks, a research assistant was called into the operating room just before the start of surgery and was responsible for monitoring and recording the patient's physiological parameters at 10-minute intervals. The research assistant was also instructed

to note hypotension (>20% decrease in baseline systolic blood pressure) and excessive surgical bleeding (loss of more than 15% of estimated blood volume for age per bodyweight in kilograms). An intraoperative increase in the heart rate or blood pressure by more than 10% above the baseline after 15–20 minutes of either the caudal block or field block and diclofenac suppository was termed inadequate analgesia, and patients treated with intravenous acetaminophen 15 mg/kg body weight were withdrawn from the study.

After surgery, isoflurane was turned off. The oral cavity of the patients was suctioned, and the patients were moved to the Post-Anaesthesia Care Unit (PACU) when they were fully awake. They were continuously monitored in the PACU every 15 minutes for the 1st hour and subsequently 30 minutes for the next five (5) hours or until the patient required rescue analgesic. Whichever occurs earlier was considered the end of the observation for the patient. During this period, the research assistant blinded to the two treatment groups assessed the pain score using the objective pain scale on arrival in the PACU at 0 minutes, 15 minutes, 30 minutes, 45 minutes, and 60 minutes post-operatively and later at an interval of 30 minutes for the next 5 hours. A score of less than 4 was considered adequate pain control, while pain scores of 4 or greater were considered moderate to severe pain, and IV acetaminophen 15 mg/kg was given as supplemental/rescue analgesia.

Data was entered into and analysed by the Statistical Package for Social Sciences (SPSS version 23). Continuous variables, e.g., age, weight, height, and haemodynamic parameters, were reported as mean ± SD, while categorical variables like sex and ASA status were reported as numbers and percentages. The independent two-sample t-test and Chi square test were respectively the statistical tests that were used to analyse the continuous variables and categorical variables obtained from this study. A p-value of less than 0.05 was considered statistically significant.

Ethical clearance was obtained from the Jos University Teaching Hospital Research Ethics Committee before commencement of this study, and only patients whose parents or guardians gave verbal and written consent were recruited for this study.

RESULTS

All the 58 enrolled patients were included in the final analysis, having completed the study. Table 1 shows that the study participants had a mean age of 2.21±0.89 and 2.60±0.81 years in the caudal block and field block with diclofenac suppository groups, respectively. All

participants (100%) were males in both study groups. The study groups were comparable in all measured characteristics, as there was no significant statistical difference between them.

Table 1 Demographic and Surgical Characteristics of Study Participants

Characteristics	Caudal Block	Field Block*	T-test	p-value
Age, Mean±SD (yrs.)	2.21±0.89	2.60±0.81	0.531	0.469
Weight, Mean±SD (Kg)	13.11±2.06	13.21±2.47	1.222	0.274
Height, Mean±SD (m)	0.91±0.09	0.93±0.07	0.742	0.393
BMI, Mean±SD (Kg/m^2)	15.97±1.43	15.41±1.44	0.118	0.733
Gender (number/percent)				
Male	29(100)	29(100)	-	-
Female	0(0)	0(0)	-	-
ASA (number/percent)				
I	29(100)	29(100)	-	-
II	0(0)	0(0)	-	-
DOS**, Mean±SD (Mins)	32.06±4.12	31.03±3.10	1.0812	0.2847
DOA***, Mean±SD (Mins)	52.06±4.12	51.03±3.10	1.0812	0.2847

*Bupivacaine Field Block and Diclofenac Suppository, **Duration of Surgery, ***Duration of Anaesthesia

Table 2 shows that the duration of analgesic free period was shorter in the caudal block group compared with the field block with diclofenac suppository group (mean time to first analgesic requirement was 282.86±18.43 minutes in the caudal block group and 291.03±16.33 minutes in the field block with diclofenac suppository group). This difference was not statistically significant (p = 0.155).

Table 2 Duration of Analgesic Free Period

Study Groups	Time, Mean±SD (mins)	T-test	p-value
Caudal Block	282.86±18.43	2.126	0.155
Field Block*	291.03±16.33		

*Bupivacaine Field Block and Diclofenac Suppository

The mean intra-operative heart rate (figure 1) at the onset of surgery (0 minutes) was 122.86±8.15 beats/min in the caudal block group and 127.41±12.15 beats/min in the field block with rectal diclofenac group (p=0.145). The heart rates for both groups were noticed to be on the decline from 0 minutes to 40 minutes intra-operative period.

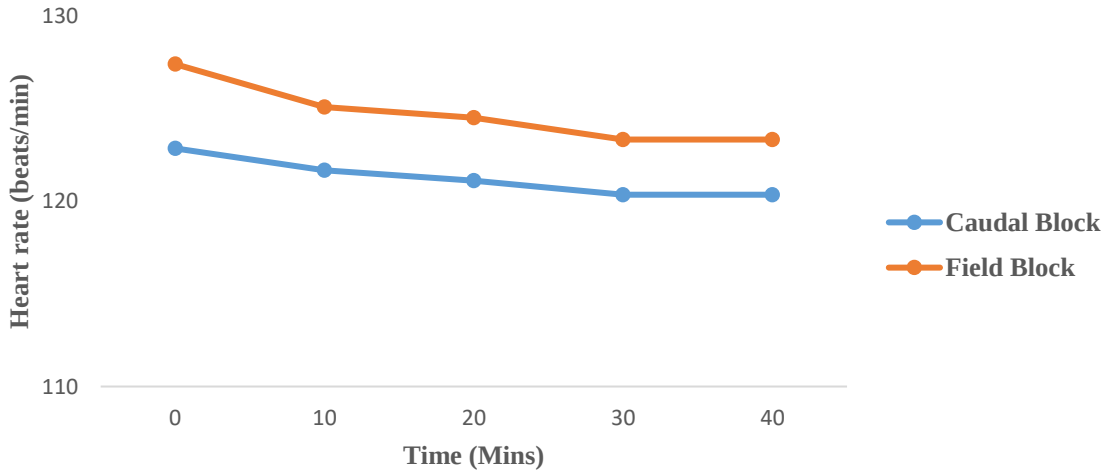

Figure 1: Mean Intra-operative Heart rates (bpm) at intervals in Study Groups (p = 0.145, 0.146, 0.089, 0.094 and 0.086 at 0 (start of surgery), 10th, 20th, 30th and 40th minutes respectively).

The mean systolic blood pressure (figure 2) between the study groups was observed to be generally on the downward trend from 0 to 40 minutes intra-operative period except for the slight elevation at 30 minutes for the caudal block group to 100.18±8.71 mmHg. This elevation was however not statistically significantly different from the field block with rectal diclofenac group (p=0.563). The difference in intra-operative systolic blood pressure in both groups was also not statistically significant in the entire intra-operative period.

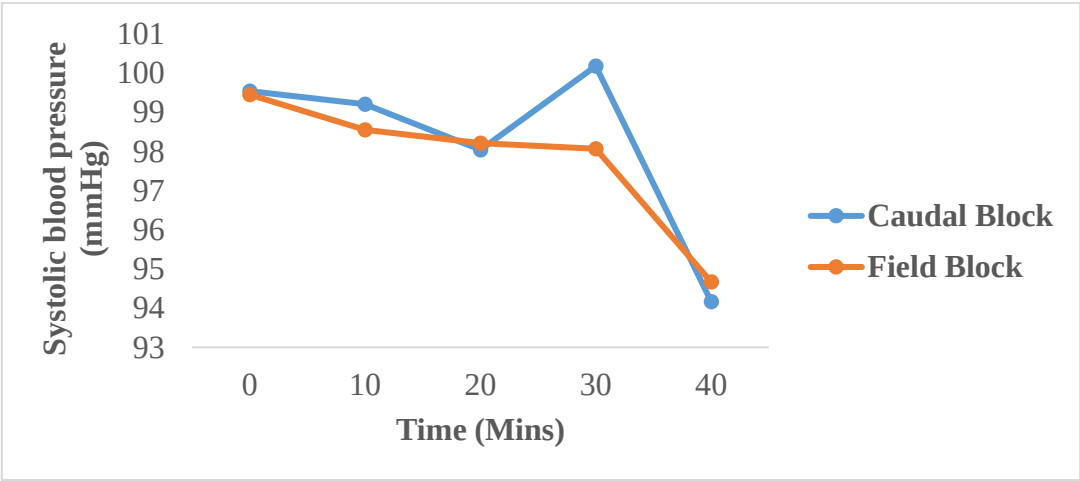

Figure 2: Mean Intra-operative Systolic blood pressure (mmHg) at Intervals in Study Groups (p = 0.637, 0.228, 0.338, 0.563 and 0.234 at 0 (start of surgery), 10th, 20th, 30th and 40th minutes respectively).

The mean intra-operative diastolic blood pressure (figure 3) at 0 minutes was 66.11±3.65 mmHg for the caudal block group and 63.96±7.36 mmHg for the field block with rectal diclofenac group (p=0.008). There was statistically significant difference in the intra-operative diastolic blood pressure for both study groups at all time intervals.

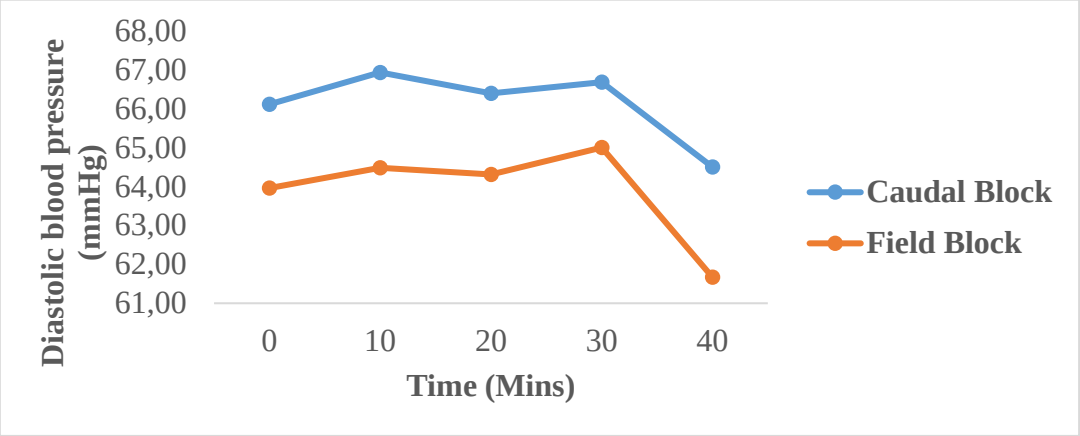

Figure 3: Mean Intra-operative Diastolic blood pressure (mmHg) at Intervals in Study Groups (p = 0.008, 0.001, 0.004, 0.001 and 0.035 at 0 (start of surgery), 10th, 20th, 30th and 40th minutes respectively).

The mean arterial pressure (figure 4) at 0 minutes intra-operative period was 77.21±4.25 and 75.86±7.15 for the caudal and field block with rectal diclofenac groups respectively with no significant statistical difference between them (p=0.057). Values of mean arterial pressure for both study groups were subsequently found to be statistically significant at 10-, 20-, 30- and 40-minutes intra-operative periods.

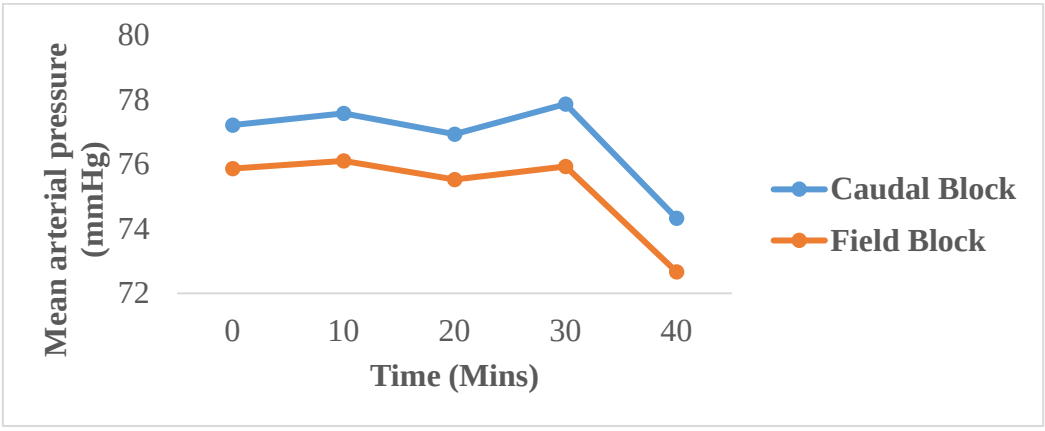

Figure 4: Mean Intra-operative Mean arterial pressure (mmHg) at Intervals in Study Groups (p = 0.057, 0.011, 0.011, 0.001 and 0.042 at 0 (start of surgery), 10th, 20th, 30th and 40th minutes respectively).

The mean intra-operative respiratory rates (figure 5) for both study groups were noticed to differ only slightly from each other at 0, 10-, 20-, 30-, and 40-minutes intra-operative periods. These differences were however all not statistically significant with the minimum and maximum respiratory rates being respectively 24.57±1.71 and 25.50±2.52 for the caudal block group and 24.00±2.00 and 24.76±1.35 for the field block with rectal diclofenac group.

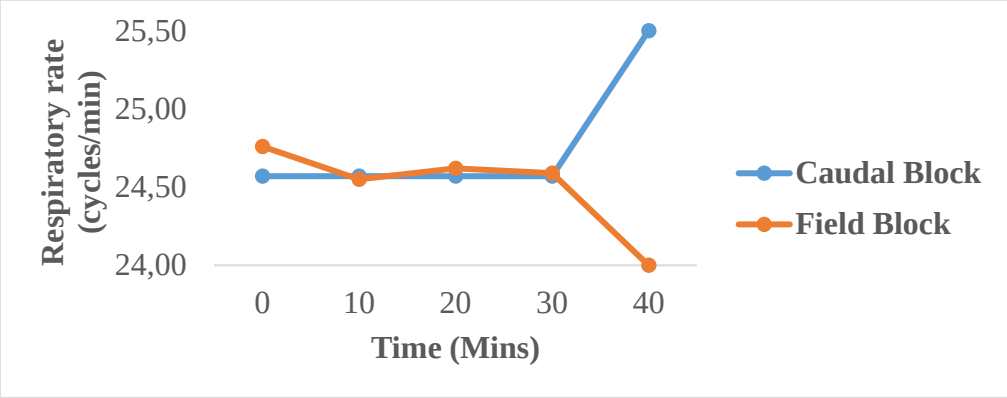

Figure 5: Mean Intra-operative Respiratory rate (cycles/min) at Intervals in Study Groups (p = 0.257, 0.053, 0.081, 0.054 and 0.707 at 0 (start of surgery), 10th, 20th, 30th and 40th minutes respectively).

The mean intra-operative arterial oxygen saturation (figure 6) was found to be only minimally different between both study groups. There was no significant statistical difference in the mean arterial oxygen saturation between the study groups with p values being respectively 0.061, 0.091, 0.071, 0.076 and 0.083 at 0, 10-, 20-, 30-, and 40-minutes intra-operative periods.

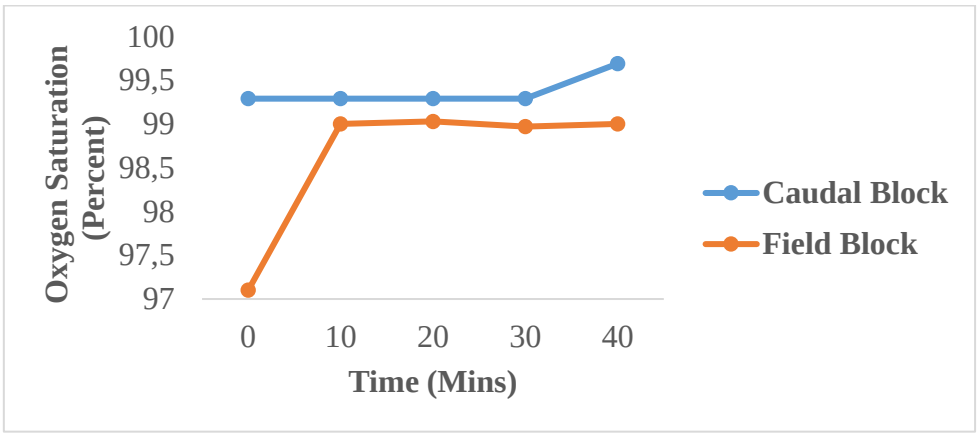

Figure 6: Intra-operative Oxygen Saturation (Percent) at Intervals in Study Groups (p = 0.061, 0.091, 0.071, 0.076 and 0.083 at 0 (start of surgery), 10th, 20th, 30th and 40th minutes respectively).

DISCUSSION

This study found that the duration of analgesic free period and the intra-operative haemodynamic changes were comparable between study groups. The duration of analgesic free period is usually indicative of the duration of post-operative analgesia. This study found it to be shorter in the caudal block group compared to the field block plus diclofenac suppository group however, the difference was not statistically significant (p=0.155). This finding could probably be due to the synergistic analgesia effect of the field block with rectal diclofenac which supposedly accounted for the longer duration of analgesia in the field block with rectal diclofenac suppository group.

Abdellatif et al. (2012) reported a similar finding to this index study. Their study was a prospective randomized controlled trial performed on children undergoing unilateral groin surgery. They compared ultrasound-guided ilioinguinal/iliohypogastric nerve blocks versus caudal block for post-operative analgesia over a 24 hours post-operative study period. The time to first requirement of analgesia in the study by Ravi et al. (2016) was also similar to that in this index study. They compared ultrasound guided nerve block versus caudal block for post-operative analgesia in children undergoing unilateral groin surgery over a 6 hours post-operative study period. A significant statistical difference in the mean time to first analgesic requirement was found in the study by Amminnikutty et al. (2016). They compared the analgesic effects of caudal block using 1ml/kg of 0.25% bupivacaine versus a combination of pre-incisional infiltration with 0.5ml/kg of 0.25% bupivacaine and diclofenac suppository 2mg/kg in the management of post-operative pain following inguinal herniotomy in children aged 4 – 8 years. The average time to first requirement of analgesia was 228.5 mins in the caudal block group and 331.0 mins in the bupivacaine infiltration with diclofenac suppository group, $p < 0.05$.

The addition of adjuvants in regional blocks is known to prolong the duration of analgesia. This was shown in the study by Varsha et al. (2021) Their study was a prospective randomised double-blind study to compare caudal epidural and ultrasound-guided ilioinguinal-iliohypogastric block for post-operative analgesia following paediatric inguinal hernia surgeries over a 24 hours post-operative study period. Forty-six children aged 1 – 10 years were randomised into two (2) groups. The mean time to first analgesic requirement was 808.3±453.1 mins in group 1 and 720.3±430.1 mins in group 2. This was not statistically significant ($p = 0.50$). This prolonged time to first requirement of analgesia in

their study can be attributed to the addition of dexmedetomidine in both the study groups as compared to only plain bupivacaine used in this index study. Kataria et al. (2019) in their study also reported similar prolonged duration of analgesia following the addition of dexmedetomidine in regional blocks. They compared caudal block and ilioinginal/iliohypogastrc block using combination of ropivacaine and dexmedetomidine with regard to efficacy, quality and duration of post-operative analgesia in children undergoing inguinal surgeries. Sixty-six children aged 3 – 12 years were randomly allocated into two (2) groups.

Intra-operative haemodynamic parameters often correlate with efficacy of analgesia. Most of the intra-operative haemodynamic changes in this index study were comparable in both study groups. It was found that the heart rates in both study groups followed a downward trend from the onset of surgery to end of surgery. This shows the effectiveness of both analgesic techniques in providing adequate intra-operative analgesia. The systolic blood pressures, diastolic blood pressures and mean arterial pressures across both study groups were comparable from the start of surgery to end of surgery. Ravi et al. (2016) found comparable intra-operative haemodynamic changes among the study groups like the findings in this index study. Their study was conducted among 60 children aged 3 – 12 years. They reported that the baseline and intraoperative haemodynamic changes between the two study groups were not statistically significant ($p > 0.05$). Kalu et al. (2022) in their prospective double blind randomised study noted that the difference in the intra-operative haemodynamic changes (heart rate, systolic blood pressure and diastolic blood pressure) between the two study groups were not statistically significant but comparable. HR; $p = 0.612$, SBP; $p = 0.237$ and DBP; $p = 0.521$. This finding is similar to this index study. The intra-operative haemodynamic parameters (heart rates, systolic blood pressures and diastolic blood pressures) were found to be comparable to the index study in another study (Seyedhejazi et al., 2014). They compared the analgesic effect of caudal and ilioinguinal-iliohypogstric nerve blockade using bupivacaine-clonidine in inguinal surgeries. Children aged 2 – 7 years were allocated randomly into two (2) groups. The systolic and diastolic blood pressures decreased during the surgery but the differences between the study groups were not statistically significant (SBP; $p = 0.176$ and DBP; $p = 0.111$). Heart rate changes between the two study groups were not significant ($p = 0.182$). This result is similar to this index study.

Another study with comparable intra-operative haemodynamic changes like this index study is the study by Somri and Colleagues (Somri et al., 2002). They compared the effect of ilioinguinal nerve block and caudal block on the plasma level of catecholamine in orchidopexy. Thirty children aged 1 – 8 years were allocated randomly into two (2) groups. Group 1 received ilioinguinal block with 0.5ml/kg of 0.25% bupivacaine while group 2 received caudal block with 1ml/kg of 0.25% bupivacaine. Plasma epinephrine and norepinephrine concentrations were measured at the time of induction of anaesthesia, at the end of surgery and in the postanaeshesia care unit. The heart rate, systolic blood pressure and diastolic blood pressure between the two study groups were not statistically significant (HR; p = 0.68, SBP; p = 0.76 and DBP; p = 0.72).

CONCLUSION

It can therefore be concluded that both caudal block with 1ml/kg of 0.25% plain bupivacaine and pre-incisional field block with 1ml/kg of 0.25% plain bupivacaine plus 1mg/kg of diclofenac suppository were comparable in providing effective post herniotomy analgesia in the paediatric age group.

Conflict of Interest

Authors declare no conflict of interest.

Acknowledgement

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