

# Postoperative Analgesia after Inguinal Herniotomy in Children; A Comparison of Combination of Intravenous Paracetamol and Rectal Diclofenac with Caudal Bupivacaine

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## Author's Contribution

<sup>1,3,4</sup>Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work, manuscript writing.

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## ABSTRACT

**Objective:** To compare the efficacy of intravenous paracetamol and rectal diclofenac combination with caudal block using 1ml/kg of 0.25% bupivacaine in the management of post-operative pain following paediatric inguinal herniotomy.

**Methodology:** This quasi-experimental study was conducted at the Department of Anesthesia, Holy Family Hospital, Rawalpindi, from February 2020 to August 2020. A total of 342 children aged 2-12 years requiring inguinal herniotomy were enrolled after satisfying the inclusion and exclusion criteria. Computer-generated random numbers were used to split the patients into two groups. Group A received intravenous paracetamol (30 mg/kg) and rectal diclofenac (1mg/kg). Group B received a caudal block using 1ml/kg of 0.25% Bupivacaine. Pain was assessed postoperatively in the PACU by modified Objective Pain Scale (OPS) every 15 minutes for the 1st hour and hourly up till 8 hours. Effective analgesia was defined as a modified OPS score of  $\leq 3$  for upto 8 hours after shifting to PACU. If at any time, the score was  $>3$  and the patient required a rescue analgesic, effective analgesia was not achieved.

**Results:** Effective analgesia was achieved in 82.46% of the patients (n=141) in Group-A versus 87.13% patients (n=149) in Group-B (p-value: 0.23).

**Conclusion:** There is no significant difference in the efficacy of analgesia in paracetamol/diclofenac combination group compared with caudal bupivacaine group.

**Keywords:** Caudal bupivacaine, Pediatric inguinal herniotomy, Rectal diclofenac.

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## Introduction

Pain is a common occurrence following pediatric surgery.<sup>1,2</sup> Despite evidence-based postoperative analgesia practice, moderate to severe pain is still experienced by upto 40% of hospitalized children.<sup>3,4</sup> Pediatric inguinal hernia repair is one of the most commonly performed pediatric surgery.<sup>5,6</sup> In a study conducted by Wilson C. et al., it was observed that 47% of inguinal hernia repair children were in moderate or severe pain on the day of surgery, which decreased over time lasting a median range of one day.<sup>1</sup>

Various regimen/techniques can be used to prevent postoperative pain after pediatric herniotomy. These regimen/techniques include the use of opioids such as fentanyl; use of NSAIDs such as ketorolac or diclofenac; use of regional anesthetic techniques such as caudal block or TAP block.<sup>6</sup> Multimodal approach to pediatric analgesia is supported by large amount of evidence based practice.<sup>2,7</sup>

Regional anesthesia via caudal epidural block with local anesthetic solution is the most favored technique to achieve adequate postoperative analgesia after pediatric

inguinal herniotomy.<sup>2,5-8</sup> In an Austrian study, 76.3% of all patients after receiving caudal block were recorded as being adequately pain & stress free and no further sedation was required during surgery.<sup>4</sup> But caudal block is also associated with a number of complications ranging from urinary retention, unintentional intrathecal, interosseous or intravascular injection to failure of block and has to be given under general anesthesia or sedation.<sup>5,6,8</sup>

An effective alternative to provide postoperative analgesia is with either paracetamol or oral/rectal diclofenac either alone or in combination which has shown promising results in various studies. Numerous studies showed the combination of NSAID with paracetamol to be more effective than NSAID or paracetamol alone in 85% and 64% of relevant studies, respectively.<sup>9</sup> In another study conducted by Riad et.al, compared to children who received each medication separately, those who received the rectal diclofenac-paracetamol combination reported less pain and required less morphine.<sup>10</sup>

Various studies have been conducted in the past comparing the efficacy of paracetamol or diclofenac alone with caudal bupivacaine showing greater postoperative analgesia in caudal block group but no study has been done to compare caudal block with combination of paracetamol and diclofenac. The principal aim of our study was to observe whether combination of paracetamol and diclofenac can be as efficacious as caudal bupivacaine in providing postoperative analgesia, which if found similar in efficacy can be used routinely in providing pediatric postoperative analgesia to avoid complications associated with caudal block.

## Methodology

This Quasi-experimental study was conducted at Department of Anesthesia, Holy Family Hospital, Rawalpindi from February 2020 to August 2020. The sample size was calculated using the WHO sample size calculator with a power of test of 90%, a level of significance of 5%, and expected population proportions of 76.3% in group A and 64% in group B, yielding 171 patients in each group. A total of 342 children, ASA class I or II, aged 2-12 years requiring inguinal herniotomy were enrolled after satisfying the inclusion and exclusion criteria. Patients with hepatic or renal disease, prior use of paracetamol or diclofenac in the last 24 hours, allergy to any of the three drugs (paracetamol, diclofenac,

bupivacaine), infection at site of caudal injection and history of bleeding diathesis were excluded from the study.

After clearance from hospital ethics board, formal informed consent was sought from the parents. Patients were recruited according to the aforementioned selection criteria. All patients were evaluated a day before procedure for pre-anesthesia assessment. Patients were prepared by fasting (6h for solid foods, 4 hours for semi-solid and 2 hour for clear fluids). Patients were randomly divided into two groups by computer-generated random numbers. Group A received intravenous paracetamol (30 mg/kg) and rectal diclofenac (1mg/kg). Group B received caudal block using 1ml/kg of 0.25% Bupivacaine. Premedication in the form of oral midazolam 0.1mg/kg was given. One parent was permitted to accompany the child into the pre-operative area to alleviate pre-operative apprehension. Upon arrival in the operating room, cardiac monitor was attached with ECG leads, NIBP, and pulse oximetry. Anesthesia was induced with 8% sevoflurane in 100% oxygen (6 L/min) through a facemask. After establishing a venous access, Nalbuphine (0.1 mg/kg IV) & Atracurium (0.5 mg/kg IV) was given.

Tracheal intubation was performed and anesthesia was maintained with 50% oxygen, 50% air and sevoflurane 2-3%. Interventional therapy was started after induction. Patients were blinded to group assignment. Intraoperative SBP, DBP and MAP was monitored every 5 min, while HR, heart rhythm, SaO<sub>2</sub>, peripheral temperature and end tidal carbon dioxide was monitored continuously. Bradycardia and hypotension was managed with intravenous atropine 0.02 mg/kg and phenylephrine 10mcg/kg respectively. Hypothermia was prevented in this study by giving warm intravenous fluids. The theater temperature was maintained at the range of 21–24 °C. At the end of surgery, inhalational anesthetics were discontinued. Neostigmine 0.05 mg/kg and glycopyrrolate 0.001 mg/kg was given. ETT was removed after return of sufficient spontaneous breathing, gag reflex, facial grimaces and purposeful motor movements. Patient was transferred to PACU once spontaneous breathing with airway patency without assistance was confirmed. One of the parents was allowed to stay in PACU.

In PACU patient was observed by a post graduate trainee, who was blinded to group allocation. Pain was assessed postoperatively in the PACU by modified Objective Pain Scale (OPS) every 15 minutes for the 1<sup>st</sup> hour and hourly

up till 8 hours. Effective analgesia was defined as a modified OPS score of  $\leq 3$  for upto 8 hours after shifting to PACU. If at any time, the score was  $>3$  and the patient required a rescue analgesic, effective analgesia was not achieved. At the score  $\geq 3$  rescue analgesic intravenous tramadol (1-2mg/kg) with intravenous dimenhydrinate (1.25mg/kg) was given. Time of requirement of first rescue analgesic was also noted.

Data was collected on a well-structured Performa and SPSS version 21.0 was utilized to analyze the data. Mean  $\pm$  S.D was calculated for quantitative variables like age, weight, height, and hospital stay in both study groups. Frequency & percentages were presented for qualitative variables like gender; efficacy in patients of both groups. p-value  $<0.05$  was considered statistically significant.

## Results

A total of 342 (171 in each group) fulfilling the selection criteria were enrolled in the study. Age distribution shows that 78.36 % (n=134) in Group A and 79.53 % (n=136) in Group-B were between 2-8 years of age whereas 21.64% (n=37) in Group A and 20.47% (n=35) in Group B were between 9-12 years of age. Mean  $\pm$  SD was calculated as 6.27 $\pm$ 2.34 years in Group-A and 6.13 $\pm$ 2.39 years in Group-B. (Table I)

**Table I: Demographic characteristics**

Parameter	Group-A (n=171)		Group-B (n=171)	
	N	%	N	%
<b>Age</b>				
2-8	134	78.36	136	79.53
9-12	37	21.64	35	20.47
Total	171	100	171	100
Mean age $\pm$ SD (in years)	6.27 $\pm$ 2.34		6.13 $\pm$ 2.39	
<b>Gender</b>				
Male	160	93.57	163	95.32
Female	11	6.43	8	4.68
Total	171	100	171	100

Gender distribution shows that 93.57 % (n=160) in Group A and 95.32 % (n=163) in Group B were male whereas 6.43% (n=11) in Group A and 4.68% (n=8) in Group B were females. (Table I). Mean hospital stay was calculated as 3.14 $\pm$ 1.27 days in Group A and 3.07 $\pm$ 1.10 days in Group-B. Mean BMI was calculated as 27.83 $\pm$ 2.32 in Group A and 27.93 $\pm$ 2.44 in Group B. Efficacy of analgesia was achieved in 82.46 % (n=141) of the patients in Group A and 87.13% (n=149) of the patients in Group B, p value was 0.23. (Table No II)

**Table II: Comparison of Efficacy in Both Groups (n=342)**

Efficacy	Group-A (n=171)		Group-B (n=171)	
	N	%	N	%
Yes	141	82.46	149	87.13
No	30	17.54	22	12.87
Total	171	100	171	100
<b>P value: 0.23</b>				

## Discussion

Postoperative pain can have several deleterious side effects such as restricting breathing, increasing myocardial oxygen consumption, impairing wound healing, and urinary retention.<sup>11</sup> Nowadays following systems based practice; pain management uses a multimodal approach. Multimodal analgesia is a concept that implies the concurrent use of a number of different analgesic drugs or methods to block multiple receptors in neuropathic and nociceptive pathways.<sup>12</sup> In order to achieve synergistic effects and reduce the negative effects of individual medications, psychological techniques, moderate analgesics like paracetamol, non-steroidal anti-inflammatory medicines (NSAIDs), opioids, and local and regional analgesia are frequently combined. Caudal block is commonly used in paediatric daycare surgery as a part of multimodal analgesic strategy. However, the main drawback after single-injection is the short block duration. Numerous studies have been conducted in the past comparing the efficacy of paracetamol or diclofenac alone with caudal bupivacaine showing greater postoperative analgesia in the caudal block group but no study has been done to compare caudal block with the combination of paracetamol and diclofenac. NSAIDs and paracetamol combination can have a synergistic effect owing to the differing mechanism of actions of both the drugs.

A study conducted by Riad et.al reported that in children who received each medication separately, those who received the rectal diclofenac-paracetamol combination reported less pain and required less morphine.<sup>10</sup> Rectal diclofenac is a helpful substitute for caudal bupivacaine and may have some benefits relative to caudal bupivacaine with regard to safety and simplicity of use for post-operative pain relief in children, according to a previous study by Ray et al<sup>13</sup> comparing the post-operative analgesic effect of rectal diclofenac with caudal levobupivacaine. Our findings are in line with this study

since there was no significant difference in the efficacy of analgesia achieved among the two groups.

Zewdu et al<sup>14</sup> reported that in the caudal-diclofenac group compared to the caudal alone and caudal-paracetamol groups, the pain score, the total amount of postoperative analgesics used, and the time it took to request the first analgesics were all significantly lower. The use of rectal route is efficient as it avoids first pass metabolism. This was reflected in the conclusion of the recent study by Patel et al<sup>15</sup> who concluded that compared to rectal diclofenac sodium suppository and rectal paracetamol suppository alone, Rectal Diclofenac-paracetamol combination suppository delivered safe, effective, and cost-efficient analgesia.

Sree et al<sup>16</sup> remarked that during the initial recovery period following infra umbilical procedures in infants and children, caudal block using injection Bupivacaine was superior to rectal diclofenac suppositories in terms of postoperative analgesia. However, no previous study has explored the combination of rectal diclofenac and Intravenous paracetamol in comparison with caudal bupivacaine. Our results show that this combination can be reliably used to provide effective post-operative analgesia similar to caudal block using bupivacaine. Similarly, a systematic review by Baird et al<sup>6</sup> found out that when comparing caudal blockade with alternate pain management techniques after pediatric inguinal herniotomy, there is no discernible difference in post-operative pain scores or rescue analgesia. Bupivacaine mainly has local anesthetic properties and has only weak anti-inflammatory properties. Therefore, patients complain of moderate to severe pain and require repeated doses of rescue medication as the local analgesic action gradually weans off. The incidence of side effects is also lower in the diclofenac group.

Nnaji et al<sup>17</sup> carried out a study on 90 children undergoing inguinal herniotomy to compare the efficacy of postoperative analgesia of caudal-bupivacaine and rectal diclofenac with caudal-bupivacaine and rectal-paracetamol. They concluded that caudal-bupivacaine and rectal-diclofenac combination offers prolonged postoperative analgesia and decreased pain scores compared to caudal-bupivacaine and rectal-paracetamol combination or caudal-bupivacaine alone.

The findings of our study are in agreement with the result of various studies described above, and the hypothesis of our study *"there is no difference in the efficacy in paracetamol/diclofenac combination group compared*

*with caudal bupivacaine group"* is justified. Patients having contraindications to caudal anaesthesia or in cases where performing caudal block is technically challenging can be considered for intravenous paracetamol and rectal diclofenac combination as the primary perioperative analgesic strategy. However, further multicenter, double blind randomized controlled trials are required to validate our results.

## Conclusion

There is no significant difference in the efficacy of analgesia in paracetamol/ diclofenac combination group compared with the caudal bupivacaine group. The combination of IV paracetamol and rectal diclofenac can be reliably used to provide effective analgesia in cases where caudal block cannot be performed either due to the presence of any contraindication or due to a lack of technical expertise.

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