

# Comparison of the Efficacy of Postoperative Diclofenac Suppository with Intramuscular Diclofenac in Children Undergoing Inguinal Hernia Surgery

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## ABSTRACT

**Objective:** To compare the analgesic effect of postoperative Diclofenac suppository with intramuscular Diclofenac in children undergoing inguinal hernia surgery.

**Patients and Methods:** This cross-sectional study was conducted at Paeds Surgery Department of Services Hospital Lahore, from August 2016 to March 2017. A total of 160 patients were included in the study and were divided into two groups, one receiving diclofenac suppository (Group DS) and the other group DI which received intramuscular diclofenac injection. Numerical variables like age and weight were analyzed statistically by taking their mean and standard deviation while the outcome variable like the severity of pain was categorized as no pain, mild, moderate and severe pain in frequency percentage at 0, 2 and 4 hours' interval.

**Results:** Total 160 patients were divided into 2 groups equally, 80 in each (DS & DI). There was no significant difference in the efficacy of diclofenac suppository and diclofenac intramuscular when calculated at 0, 2 and 4 hours' interval. When Chi-Square was applied to determine the association, it was observed that pain severity was significantly associated with age. However, the association of pain severity with weight and with time intervals in two groups was not statistically significant.

**Conclusion:** There was no significant difference between the postoperative analgesic effect of either suppository or intramuscular diclofenac but suppository route has an advantage over intramuscular in that it is easier and safer, less prone to injury, easy to administer and has a longer duration of action, especially preferable in pediatric patients.

**Keywords:** Children, Diclofenac Sodium, Inguinal Hernia, Intramuscular, Suppository.

### Author's Contribution

<sup>1</sup> Conception, synthesis, planning of research and manuscript writing

<sup>2</sup> Interpretation and discussion

<sup>3</sup> Data analysis, interpretation and manuscript writing, <sup>4,5</sup> Active participation in data collection

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## Introduction

The incidence of an inguinal hernia is almost 80,000 children in the world. It was found that the cumulative incidence of an inguinal hernia from birth to 15 years of age was 0.74% in females and 6.62% in males.<sup>1,2</sup> While in

the adult population almost all cases of sliding hernias are seen in men.<sup>3</sup> The processus vaginalis is an embryonic developmental outpouching of peritoneum attached to the testicle. When obliteration of the processus vaginalis fails

to occur, it results in an inguinal hernia. An inguinal hernia is an indication of elective herniotomy (in children) and herniorrhaphy (in adults), which prevents incarceration and subsequent strangulation. Multiple factors contributing to chronic pain include a scrotal hernia, hernia repair or emergency recurrent hernia repair. Postoperative pain may be less with laparoscopic procedures as compared to open procedures.<sup>4</sup> Pain caused by tension or compression may slowly diminish with time as a consequence of tissue reorganization.<sup>5</sup> The quality and duration of analgesia provided by morphine remain without comparison.<sup>6</sup> But due to the complications of opioids, in recent times, physicians have been paying attention to Non-steroidal anti-inflammatory drugs (NSAIDs) for pain control.<sup>7</sup> NSAID, Diclofenac, which reduces inflammation and relieves pain, is used to treat dental pain, muscle aches, and athletic injuries. It is frequently used to treat the swelling, stiffness, and pain related to arthritis.<sup>8</sup>

Perioperative analgesia in pediatrics herniotomies requires effective, safe and less invasive strategies. Local infiltration with Bupivacaine, caudal Bupivacaine, and rectal Diclofenac are widely used to alleviate the pain. Hernia repair is an outpatient procedure. Patients are usually a healthy and full-term child or infant. Diclofenac restrains prostaglandin synthesis by lessening cyclooxygenase activity, which sequentially, reduces the formation of prostaglandin precursors. Diclofenac suppository with local infiltration is an effective and less invasive alternative to caudal Bupivacaine for postoperative pain relief in pediatric hernia repair.

Different studies have been performed on the efficacy of analgesics for the postoperative pain of an inguinal hernia but there is lack of studies for effect of route of administration of diclofenac. This study was planned to compare intramuscular and suppository route of administration of diclofenac to see which of these is more effective.

## Patients and Methods

This study was conducted at Pediatric Surgery Department of Services Hospital Lahore, from August 2016 to March 2017. Children who presented for inguinal hernia repair were included in the study. The sample size was calculated using a reference from a previous study by

Saghar Samimi Sede et al.<sup>9</sup> For which confidence interval was taken as 95 %, and a total of 160 patients were included in the study. We collected 160 patients' data; authorization for the study protocol was obtained from the Hospital Ethical Committee and informed written permission was obtained from the parents of all children. The randomized control trial Non-probability sampling technique was used and patients were divided into two groups, one receiving diclofenac suppository (Group DS) and the other group DI receiving intramuscular diclofenac injection. Children from age 5-15 years, who were operated for an inguinal hernia were included in the study. Patients with a history of asthma, known allergy or contraindication for study drug, kidney or hepatic dysfunction, duration of surgery more than two hours or those who refused to give informed consent were excluded from the study. Standard patient monitoring involved measurement of blood pressure, pulse oximetry, electrocardiograph, inhalation agents and capnography. General anesthesia was administered by inhalation of sevoflurane in oxygen or intravenously with 2.5-3.5 mg/kg propofol. A laryngeal mask airway was inserted after induction of anesthesia. All patients were administered 50 µg/kg midazolam immediately after induction of anesthesia and 60% nitrous oxide, 40% oxygen, and sevoflurane during their operation. The sevoflurane concentration (2.0%) was regulated to achieve optimum intraoperative hemodynamic measurements. Intravenous fluids were administered in the operating room following standard guidelines (Ringer's lactate solution at maintenance rates). Postoperatively group DS received diclofenac suppository 2.5mg/kg and group DI received intramuscular diclofenac 2mg/kg. Patients were evaluated for severity of pain by a single autonomous observer 0, 2 and 4 hours after the return to the ward. The pain was evaluated using visual analogue score. The visual analogue scoring scale is a linear scale from 0-10 number, which shows the intensity of pain increases along with increasing number. According to this scale, no pain was labeled when VAS 0, mild pain when VAS 1-4, moderate pain when VAS 5-8 and severe pain when the patient had VAS 9-10.

For continuous variables, mean and SD were calculated. While categorical variables were analyzed as number and percentage. Chi-square test was applied to check effect

modification; independent sample t-test was applied to check the difference between the mean of both groups. p-value  $\leq 0.05$  was considered statistically significant.

## Results

Total 160 patients were included in the study and all were males. The mean age and weight of the patients were  $10.94 \pm 2.55$  years and  $31.04 \pm 10.45$  kg respectively (Table 1).

Characteristics	Mean	SD
Age (years)	10.94	2.55
Weight (kg)	31.04	10.45
Stratified Age (years)	Frequency	Percentage
5-10	71	44.4
11-15	89	55.6
Stratified Weight (kg)	Frequency	Percentage
12-25	60	37.5
26-48	100	62.5

When patients were stratified into different age and weight groups, it was noted that 55.6% (n=89) were aged from 11 to 15 years. Regarding weight, majority of the patients i.e. 62.5% (n=100) were between 26-48 kg (Table 1). The mean age, weight and pain severity of the patients' in-group DS and group DI have been mentioned in table 2.

Variables	DS Group (n=80) (Mean $\pm$ SD)	DI Group (n=80) (Mean $\pm$ SD)	p-value
Age (years)	$10.85 \pm 2.72$	$11.03 \pm 2.37$	0.583
Weight (kg)	$31.82 \pm 11.76$	$30.12 \pm 9.27$	0.598
Pain Severity	$1.89 \pm 1.03$	$2.00 \pm 1.006$	0.486

Statistical evaluation of these parameters revealed no significant difference between the two groups.

\		Pain Severity				p-value
		No	Mild	Moderate	Severe	
Stratified Age (years)	5-10	38	11	14	8	0.010
	11-15	32	35	13	9	
Stratified Weight (kg)	12-25	30	13	8	9	0.174
	26-48	40	33	19	8	

The severity of pain was notably associated with age (p-

value 0.010) but it was not considerably associated with weight (p-value 0.174) (Table 3). The main outcome variable of this study was pain severity. The mean severity of pain was  $1.89 \pm 1.03$  and  $2.00 \pm 1.006$  for the groups DS and DI respectively. It was observed that, in group DS, at 0-hour, the maximum number of patients 41.2% (n=33) were suffering from mild pain. While at 2 hours and at 4 hours' majority of patients 50% (n=40) and 62.5% (n=50) respectively had no pain (Table 4). It was noted that in group DI also, at 0 hour, 46.2% (n=37) had mild pain while at 2 hours and 4 hours' maximum number of patients 42.5% (n=34) and 53.7% (n=43) respectively had no pain (Table 5).

Group	Time	Levels of Pain	Frequency	Percentage
DS	0 Hour	No Pain	23	28.7
		Mild	33	41.2
		Moderate	15	18.7
		Severe	9	11.2
	2 Hours	No Pain	40	50.0
		Mild	18	22.5
		Moderate	10	12.5
		Severe	12	15
	4 Hours	No Pain	50	62.5
		Mild	15	18.7
		Moderate	9	11.2
		Severe	6	7.5

Group	Time	Levels of Pain	Frequency	Percentage
DI	0 Hour	No Pain	18	23.1
		Mild	37	46.2
		Moderate	21	26.2
		Severe	4	5
	2 Hours	No Pain	34	42.5
		Mild	21	26.2
		Moderate	9	11.2
		Severe	16	20
	4 Hours	No Pain	43	53.7
		Mild	14	17.5
		Moderate	17	21.2
		Severe	6	7.5

## Discussion

The results of our study revealed that there is almost no difference between the effectiveness of both suppository and intramuscular Diclofenac when given postoperatively. However, there is lower pain rating scale with suppository type of modality. Moreover, suppository route is safer, less prone to injury, easy to administer and has longer duration of action. Suppository route was introduced as a newer route to treat children in 21<sup>st</sup> century by Vincent Jannin et al.<sup>10</sup> This comprehensive meta-analysis compared the rectal and oral routes for reducing fever. And it was concluded by the comparison of these two routes and it may change the recommendations of American Academy of Pediatrics, whose recommendation was, so far, to refrain rectal administration to children.<sup>11</sup>

Diclofenac is used as an analgesic in pre- and post-operative pain management and illustrates excellent effectiveness by suppository administration alone, or in combination with other drugs.<sup>12</sup> Several studies have explored the use of paracetamol and Diclofenac in pediatric patients. Concurrent administration of Diclofenac in children receiving patient-controlled analgesia (PCA) morphine has a very considerable morphine-sparing effect, as demonstrated by Morton and O'Brien, although they were unable to explain any extra additive outcome of paracetamol.<sup>13</sup> Our study is concerned with postoperative use of Diclofenac via rectal and intramuscular route while most of the previous studies were concerned with preoperative administration of Diclofenac in children undergoing inguinal hernia. In a similar study by W Riad and A Moussa, preoperative Diclofenac suppository in combination with paracetamol was used which showed that its use spared the post-operative use of morphine.<sup>14</sup>

Sodium diclofenac is a non-steroidal anti-inflammatory drug, which shows analgesic effects in various conditions. A study suggests that sodium diclofenac presents the advantages that it could restrain prostaglandin biosynthesis by blocking the cyclo-oxygenase enzyme. By decreasing the production of prostaglandins, the feeling of pain may diminish in the peripheral nervous system; although a central anti-nociceptive effect has also been claimed for NSAIDs. Opioids are usually unable to remove the chemical mediators of pain and by using meperidine, the patients still have a vague feeling of pain.

Furthermore, sodium diclofenac does not result in respiratory depression or any other meperidine side effects such as vomiting, nausea, respiratory depression, itching, decreased gastrointestinal motility, tachycardia, physical dependency and hemodynamic instability. Sodium diclofenac similar to other NSAIDs has some gastrointestinal effects and there is a speculative risk of postoperative hemorrhage as it causes prolonged bleeding time and decreases platelet aggregation.<sup>15</sup>

In a preliminary study of the two-marketed formulations of Diclofenac, Intramuscular and suppository revealed that both preparations provided comparable analgesia but patients who received the suppository preparation were released earlier.<sup>16</sup> In another study, conducted to compare Intramuscular diclofenac with intravenous paracetamol in patients undergoing lower abdominal gynecological surgery, it was reported that IM diclofenac appears to be a superior post-operative analgesic as compared to intravenous paracetamol, with no added advantage of their combination over Intramuscular diclofenac, in terms of rescue analgesic requirements.<sup>17</sup> Diclofenac suppository is a superior choice for postoperative analgesia in pediatric patients going through tonsillectomy in comparison to bupivacaine infiltration as there were considerable variation in pain score ( $P < 0.05$ ) after two hours onwards postoperatively.<sup>18</sup> Another study, which compared the postoperative analgesic effect of suppository diclofenac with caudal bupivacaine suggested that suppository diclofenac although provides comparable analgesic effect postoperatively but immediate pain relief is difficult by the use of suppository diclofenac.<sup>19</sup> A study on comparison of efficacy of NSAIDs when given through different routes was performed which revealed that fastest and most effective analgesia was provided by intravascular route of administration. But other than that there was no significant difference in analgesic effect. In the same study it was shown that most side effects were through intramuscular and rectal routes i.e. discomfort at the site of injection (intramuscular route) and diarrhea, rectal irritation and non-retention of suppositories (rectal route).<sup>20</sup>

## Conclusion

There is no significant difference between the postoperative analgesic effect of either suppository or

intramuscular diclofenac but suppository route has an advantage over intramuscular in that it is easier, safer, less prone to injury, easy to administer and has longer duration of action, especially preferable in pediatric patients.

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