

# Comparison of Post-Operative Pain with Diclofenac Rectal Suppository vs Intravenous Tramadol in Patients Undergoing Inguinal Hernioplasty

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## ABSTRACT

**Background:** Pain is a highly intricate and distressing sensation that is subjective. There is uncertainty observed in the selection of optimal methods for intra and post-operative administration of analgesics for inguinal hernia repair surgery.

**Objective:** To compare the mean postoperative pain score in diclofenac rectal suppositories with intravenous tramadol in patients undergoing inguinal hernioplasty. **Study Design:** Randomized control trial. **Settings:** Department of Surgery, Allied Hospital, Faisalabad Pakistan. **Duration:** From November 25, 2022 to May 25, 2023. **Methods:** After approval of the ethical board, patients from OPD / emergency were enrolled. All the patients undergo inguinal hernioplasty under regional anesthesia. In group A, patients received diclofenac rectal suppository 100 mg, and in group B, patients received intravenous tramadol 100 mg. The visual analog scale was explained to the patients. Pain was assessed after the 2<sup>nd</sup>, 6<sup>th</sup>, and 12<sup>th</sup> hour of hernioplasty. All the information noted on proforma. **Results:** Comparison of the mean post-operative pain score shows  $3.67 \pm 0.48$  in Group A and  $2.40 \pm 0.50$  in Group B at 2 hours, p-value 0.000,  $3.64 \pm 0.49$  in Group A and  $3.43 \pm 0.50$  in Group B at 6<sup>th</sup> Hour, p-value was 0.605,  $3.30 \pm 0.47$  in Group A and  $4.0 \pm 0.79$  in Group B at 12<sup>th</sup> hour, p-value=0.000.

**Conclusion:** We concluded that diclofenac rectal suppository is significantly better than intravenous tramadol in patients undergoing inguinal hernioplasty in terms of mean postoperative pain score.

**Keywords:** Inguinal hernioplasty, Post-operative pain, Diclofenac rectal suppository, Intravenous tramadol.

## INTRODUCTION

Hernias are out-pouching of an organ through the body wall that normally contains it.<sup>1</sup> Inguinal hernias are the most common abdominal wall hernias, making up 75% of cases. The lifetime risk is 27% in males and boys, and 3% in females and girls. Surgery for inguinal hernia repair is a common procedure, accounting for 10-15% of surgeries worldwide. Mesh is used in hernia repair, which is a type of hernioplasty.<sup>2</sup>

It is a well-established fact that most patients undergoing surgical procedures experience acute postoperative pain. Pain is defined as an unpleasant emotional and sensory experience caused by actual or potential tissue damage, and it is imperative to address it adequately.

Inadequately relieved pain can cause severe distress to the patient, leading to physical and physiological function complications during the post-operative period. Moreover, if left untreated, it may lead to the development of chronic pain, which can result in negative psychological effects and have a significant economic impact on the patient's health. Therefore, it is crucial to manage pain effectively to prevent any adverse outcomes.<sup>6</sup>

Modalities of postoperative analgesia are systemic analgesic drugs which include opioids and non-opioids, and various regional analgesia techniques such as peripheral and neuraxial block.<sup>3</sup> Opioids are well-entrenched and most accepted analgesics in all age

groups, and Tramadol is a centrally acting opioid with a low affinity of opioid receptors. It acts on serotonergic and noradrenergic nociception, whereas its metabolite O-desmethyl tramadol acts on the  $\mu$ -opioid receptor. It inhibits serotonin and nor-epinephrine neuronal reuptake. Intravenous route of tramadol is used frequently.<sup>7</sup>

NSAIDs and COX-2 inhibitors are highly effective for postoperative pain relief, with diclofenac being particularly effective and potentially reducing peritoneal inflammation. Diclofenac suppositories have a rapid onset of action, with complete absorption within 4.5 hours and peak plasma concentration within 1-2 hours, sustained for up to 12 hours. The drug has a half-life of 1-2 hours in plasma, and 60% is eliminated through urine.<sup>8</sup>

Post operative pain score after 2<sup>nd</sup>, 6<sup>th</sup> and 12<sup>th</sup> hour of hernioplasty in diclofenac suppository were  $4.36 \pm 1.03$ ,  $3.84 \pm 1.17$  and  $3.12 \pm 1.01$ <sup>8</sup> and in intravenous tramadol,  $2.21 \pm 0.44$ ,  $4.99 \pm 0.92$  and  $5.67 \pm 0.44$  respectively.<sup>4</sup>

There is already a vast body of written material available on the topic of the management of people who are in need of after operation pain relief. In spite of the large range of treatment regimens that are utilized for post-operative pain management, there is still a discussion going on within the literature about the most effective analgesic drug and the most effective route of administration. It is essential, in accordance with an evidence-based approach to the treatment of patients, to investigate the analgesic drug that is most effective in reducing post-operative pain and the influence of the route of administration.

The findings of the research will be helpful in the treatment of post-operative pain after inguinal hernioplasty.

The objective of the study was to compare the mean post operative pain score in diclofenac rectal suppository with intravenous tramadol in patients undergoing inguinal hernioplasty.

## METHODS

This randomized control trial was conducted at Surgical unit 2, Allied Hospital, Faisalabad Pakistan. The duration of study was November 25, 2022 to May 25, 2023. By WHO sample size calculator it was 60 (30 in each group). Non-probability consecutive sampling technique was used.

Patients of age range from 18–60 years of both genders, patients undergoing inguinal hernioplasty for inguinal hernia (swelling in the right or left inguinal and scrotal areas. On examination, the swelling was reducible with positive cough impulse (increase in size of swelling with

coughing)) as per operational definition and ASA status I / II were included in the study.

Known allergy to tramadol or diclofenac, any physical or psychological condition that may affect pain response or ability to participate in the study, patients who require intensive care or ventilator support after their surgery, renal dysfunction, liver dysfunction and bleeding disorder were excluded from the study.

Patients who met the inclusion criteria and came through OPD/emergency were enrolled with informed consent after gaining approval from the hospital's ethics committee. All the patients undergo inguinal hernioplasty under regional anesthesia. Hernioplasty was performed by a senior surgeon. Patients were randomly divided into two groups. In group A, patients received diclofenac rectal suppository 100 mg, and in group B, patients received intravenous tramadol 100 mg.

The visual analog scale was explained to the patients. Pain was assessed after 2<sup>nd</sup>, 6<sup>th</sup> and 12<sup>th</sup> hour of hernioplasty. All the information was recorded on proforma.

The SPSS version 25 was used for data analysis. Descriptive statistics including mean and standard deviation of numerical values like age, BMI, and post-operative pain score. Frequency and percentage were calculated for all qualitative variables like gender, type of surgery, and ASA status. Post-operative pain score was compared by using an independent sample t-test between both groups. Effect modifiers like age, BMI, ASA status, type of surgery, and gender were controlled by stratification. Post-stratification independent sample t-test was applied. P-value  $\leq 0.05$  was considered significant.

## RESULTS

A total of 60 cases (30 in each group) fulfilling the selection criteria were enrolled to compare the mean postoperative pain score in diclofenac rectal suppository with intravenous tramadol in patients undergoing inguinal hernioplasty.

Age distribution shows that 24(80%) in Group A and 25(83.3%) in Group B were between 18-40 years of age whereas 6(20%) in Group A and 5(16%) in Group B were between 41-60 years of age, mean age in Group A was  $35.27 \pm 7.80$  years and in Group B  $33.53 \pm 7.70$  years.

Gender distribution shows that 23(76.7%) in Group A and 24(80%) in Group B were male whereas 7(23.3%) in Group A and 6(20%) in Group B were females.

ASA status of the patients shows that 8(26.7%) in Group A and 8(26.7%) in Group B had ASA-I whereas 22(73.3%) in Group A and 22(73.3%) in Group B had ASA II.

**Table 1: Descriptive statistics of ASA of the Patients**

ASA	Group A (n=30)		Group B (n=30)	
	No. of patients	%	No. of patients	%
I	8	26.7	8	26.7
II	22	73.3	22	73.3
<b>Total</b>	<b>30</b>	<b>100</b>	<b>30</b>	<b>100</b>

Descriptive statistics of the type of surgery of the patients show that 10(33.3%) in Group A and 11(36.7%) in Group B had elective surgery whereas 20(66.7%) in Group A and 19(63.3%) in Group B had an emergency cesarean section.

**Table 2: Descriptive statistics of the type of surgery**

Type of surgery	Group A (n=30)		Group B (n=30)	
	No. of patients	%	No. of patients	%
Elective	10	33.3	11	36.7
Emergency	20	66.7	19	63.3
<b>Total</b>	<b>30</b>	<b>100</b>	<b>30</b>	<b>100</b>

Comparison of the mean post-operative pain score in diclofenac rectal suppository with intravenous tramadol in patients undergoing inguinal hernioplasty shows  $3.67 \pm 0.48$  in Group A and  $2.40 \pm 0.50$  in Group B at 2 hours, p-value 0.000,  $3.64 \pm 0.49$  in Group A and  $3.43 \pm 0.50$  in Group B at 6<sup>th</sup> Hour, p-value was 0.605,  $3.30 \pm 0.47$  in Group A and  $4.0 \pm 0.79$  in Group B at 12<sup>th</sup> hour, p-value=0.000.

**Table 3: Comparison of the mean post- operative pain score in Group A & B(n=60)**

Pain score	Group A (n=30)		Group B (n=30)		P value
	Mean	SD	Mean	SD	
At 2 <sup>nd</sup> hour	3.67	0.48	2.40	0.50	0.000
At 6 <sup>th</sup> hour	3.64	0.49	3.43	0.50	0.605
At 12 <sup>th</sup> hour	3.30	0.47	4.0	0.79	0.000

**Table 4: Stratification according to age**

Age (years)	Pain score	Group A		Group B		P value
		Mean	SD	Mean	SD	
18-40	At 2 <sup>nd</sup> hour	3.63	0.49	2.40	0.50	0.00
	At 6 <sup>th</sup> hour	3.38	0.49	3.44	0.51	0.65
	At 12 <sup>th</sup> hour	3.29	0.46	4.04	0.73	0.000
41-60	At 2 <sup>nd</sup> hour	3.83	0.41	2.40	0.55	0.001
	At 6 <sup>th</sup> hour	3.33	0.52	3.40	0.55	0.840
	At 12 <sup>th</sup> hour	3.33	0.52	3.80	1.09	0.375

**Table 5: Stratification according to gender**

Gender	Pain score	Group A		Group B		P value
		Mean	SD	Mean	SD	
Male	At 2 <sup>nd</sup> hour	3.74	0.45	2.29	0.46	0.000
	At 6 <sup>th</sup> hour	3.39	0.46	3.50	0.51	0.465
	At 12 <sup>th</sup> hour	3.30	0.47	4.04	0.81	0.000
Female	At 2 <sup>nd</sup> hour	3.43	0.53	2.83	0.41	0.048
	At 6 <sup>th</sup> hour	3.29	0.49	3.17	0.41	0.64
	At 12 <sup>th</sup> hour	3.29	0.49	3.83	0.75	0.142

## DISCUSSION

Pain is unavoidable after surgical procedures, and the provision of acute pain relief management services during the perioperative period is considered to be one of the most important responsibilities of the perioperative team, particularly the anesthesiologist. Inguinal hernias are responsible for over 75% of all abdominal wall hernias across the globe, and surgery to correct inguinal hernias is one of the most frequent general surgeries, accounting for around 10-15% of all surgical operations.

It has been shown beyond a reasonable doubt that poor pain relief creates anguish for the patient, which in turn may adversely influence the patient's physical and physiological function, which can result in a variety of issues in the postoperative period. In addition, if the condition is not treated appropriately, it may result in the possible development of chronic pain, which may leave a patient with poor psychological impacts and can have an influence on the health care system.

Systemic analgesic medicines, which include opioids and non-opioids, as well as different regional analgesia approaches, such as peripheral and neuraxial block, are examples of modalities that may be used to treat postoperative pain. The rectal route is also one of them, and it is simpler and more tolerated by patients than the others.

There is already a vast body of written material available on the topic of the management of people who are in need of after operation pain relief. In spite of the large range of treatment regimens that are utilized for post-operative pain management, there is still a discussion going on within the literature about the most effective analgesic drug and the most effective route of administration. It is essential, in accordance with an evidence-based approach to the treatment of patients, to investigate the analgesic drug that is most effective in reducing post-operative pain and the influence of the route of administration.

In our study, age distribution of the patients was done, it shows that 24(80%) in Group A and 25(83.3%) in Group B were between 18-40 years of age whereas 6(20%) in Group A and 5(16.%) in Group B were between 41-60 years of age, mean age in Group A was  $35.27 \pm 7.80$  years and in Group B  $33.53 \pm 7.70$  years, 23(76.7%) in Group A and 24(80%) in Group B were male whereas 7(23.3%) in Group A and 6(20%) in Group B were females. Comparison of the mean post-operative pain score in diclofenac rectal suppository with intravenous tramadol in patients undergoing inguinal hernioplasty shows  $3.67 \pm 0.48$  in Group A and  $2.40 \pm 0.50$  in Group B at 2 hours, p-value 0.000,  $3.64 \pm 0.49$  in Group A and  $3.43 \pm 0.50$  in Group B at 6<sup>th</sup> Hour, p-value was 0.605,  $3.30 \pm 0.47$  in Group A and  $4.0 \pm 0.79$  in Group B at 12<sup>th</sup> hour, p-value=0.000.

Previous data reveals that postoperative pain scores after the 2<sup>nd</sup>, 6<sup>th</sup> and 12<sup>th</sup> hour of hernioplasty in diclofenac suppository were  $4.36 \pm 1.03$ ,  $3.84 \pm 1.17$  and  $3.12 \pm 1.01$ <sup>8</sup> and in intravenous tramadol,  $2.21 \pm 0.44$ ,  $4.99 \pm 0.92$  and  $5.67 \pm 0.44$  respectively.<sup>4</sup> The findings of our study are in agreement with previous data.

Jose B Cherayath *et al*<sup>9</sup> evaluated and differentiated the analgesic efficacy of tramadol via intravenous and rectal administration for inguinal hernia repair, they revealed that in the rectally administered tramadol, the analgesia duration is prolonged which further reduces the rescue analgesia requirement. Compared to intravenously administered tramadol, patient comfort is more in rectally administered tramadol as nausea and vomiting postoperatively is avoided, it was concluded that rectally administering tramadol is safer, easier, more reliable, non-invasive, more comfortable, and painless compared to intravenously administered tramadol. However, in our study, we administered diclofenac suppository.

Giorgi M *et al*<sup>10</sup> conducted a study in which based on mono and bi-compartmental models, plasma concentrations after rectal and intravenous administration were fitted respectively. After rectal administration, tramadol was detected from 5 minutes up to 10 hours, in lesser amounts than M5 and M2.

Because of this, using a tramadol rectal suppository as a postoperative painkiller in inguinal herniorrhaphy is a preferable option to administering tramadol via an intravenous line. The rectal route is simple, has a high level of acceptance, is very practical, and does not need any specialized expertise. There is significant absorption of the medicine when it is administered rectal,<sup>11</sup> although individual variances continue to exist. In addition, our research does have a few important caveats. To begin, our research only included two groups of participants in the study, and we did not have a third group of control patients or a group to serve as a comparison for the placebo. Also, the number of patients who participated in our study was rather low, which means that additional research including a substantial number of participants is required.<sup>12</sup>

## CONCLUSION

We found that diclofenac rectal suppository was significantly more effective than intravenous tramadol in reducing post-operative pain scores in patients undergoing inguinal hernioplasty.

## LIMITATIONS

It includes limited follow-up duration and may not capture long-term effects. The single-center design may limit generalizability.

## SUGGESTIONS / RECOMMENDATIONS

Future research should address these limitations for a comprehensive understanding of treatment outcomes

## CONFLICT OF INTEREST / DISCLOSURE

No conflicts of interest exist among the authors conducting the study.

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