

Comparison of Effectiveness between Diclofenac Suppositories and Injection Diclofenac in Abdominal Surgeries

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ABSTRACT

Objective: To compare the effectiveness of diclofenac suppositories and injection diclofenac in pain relief after abdominal surgeries.

Methodology: This quasi-experimental study was conducted at the West Surgical Ward, Mayo Hospital, Lahore from June 2022 to January 2023 after taking approval from ethical committee. Total 136 patients undergoing elective and emergency abdominal surgeries were enrolled in the study via non-probability convenience sampling technique. Informed written consent was taken from all the patients. The patients were divided into two groups (group A & B). Group A was given diclofenac suppositories and group B was given injection diclofenac via the intramuscular (I/M) route. The pain scores were recorded by using visual analogue scale (VAS) at 0, 8, 16, and 24 hours. The data was analyzed using Statistical Package for the Social Sciences (SPSS) version 26.

Results: There was a significant decrease in mean pain scores at 0, 8, 16, and 24 hours post-operatively in group A as compared to group B. The maximum difference in the means was observed at 16 hours post-operatively ($p < 0.001$). Only 15(11.1%) patients in group A required rescue analgesia, while more than half the patients in group B required rescue analgesia for effective pain relief ($p = 0.001$). The proportion of patients experiencing adverse effects of the drug in group A was significantly smaller (8.1%) as compared to group B (25.7%) ($p = 0.001$).

Conclusion: Rectal suppositories of diclofenac were significantly more effective for post-operative pain relief among patients undergoing abdominal surgeries as compared to diclofenac intramuscular injection.

Keywords: Pain. Post-operative. Visual Analog Scale. Analgesia. Diclofenac.

INTRODUCTION

Abdominal surgeries have a major role in the treatment of cases of non-traumatic acute abdominal pain. Appendicitis is the leading cause of acute abdominal pain, followed by cholecystitis and others.¹ The major complaint of surgical patients is the post-operative pain that occurs due to trauma to the tissues during surgery and activates pain pathways by the release of chemical mediators. Almost 22-67% patients experience moderate to severe pain during the first 24 hours after abdominal surgery as reported by various studies. The management of post-operative pain is the foremost challenge for surgeons as it is necessary for early mobilization and recovery as well as the psychological satisfaction of the patient.² Pain activates the sympathetic nervous system and renders the patient immobile. It also cripples the patient psychologically. All of this leads to more burden on the economy, hospitals, and healthcare

resources. In the modern era, post-operative pain relief is directed towards maximum comfort of the patient using safe and cost-effective analgesics.³

Diclofenac sodium belongs to the class of non-steroidal anti-inflammatory drugs (NSAIDs). They inhibit cyclooxygenase enzymes and prostaglandin synthesis. Diclofenac in particular inhibits both cyclooxygenase 1 and 2 enzymes as well as lipoxygenase and phospholipase A2. It is a potent analgesic for musculoskeletal and spasmodic pain.⁴ It has antipyretic effect and also helps in the reduction of inflammation.⁵

Diclofenac can be given orally as a tablet, through intramuscular injection or as a rectal suppository. Administration of the drug via the rectal route is easier and does not require a trained personnel as compared to the intramuscular route.⁶ Intramuscular administration should be done by following proper protocol & aseptic techniques, and failure to do so may result in localized infection or abscess formation.⁷ Administration of drug via the rectal route has the benefits of decreased first-pass metabolism, no gastric irritation, and higher local and systemic levels.⁸

Assessing the difference in pain relief and the need for rescue analgesia between diclofenac suppository and injectable diclofenac can guide clinicians in selecting the most effective and patient-friendly route of administration. This study aimed to compare the analgesic efficacy of diclofenac

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suppository versus injectable diclofenac in patients undergoing abdominal surgeries, to determine which route provides optimal post-operative pain control with reduced dependency on additional analgesics.

METHODOLOGY

This quasi-experimental study was conducted at the West Surgical Ward, Mayo Hospital, Lahore over a period of 8 months from June 2022 to January 2023 after taking approval from the ethical committee (Letter No. 233/RC/KEMU, 15-03-2021). A sample size of 136 participants was determined based on 80% power, 95% confidence interval, and the post-operative mean visual analog scale (VAS) pain scores for the diclofenac suppository and intramuscular injection groups reported as 3.88 ± 1.90 and 4.76 ± 1.75 , respectively.⁹ Patients were enrolled by using non-probability convenience sampling technique and were randomly divided into 2 groups of 68 each. Males and females, ≥ 18 years of age undergoing elective or emergency abdominal surgeries were included in the study. Patients with history of any previous abdominal surgery, NSAIDs contraindication (patients with gastritis, gastric or duodenal perforation), and patients on central nervous system (CNS) depressants or warfarin treatment were excluded.

Informed written consent was taken from all patients. The demographic data and body mass index (BMI) were recorded. Patients with BMI less 25 kg/m^2 were labeled as normal and those with $\geq 25 \text{ kg/m}^2$ were categorized as having deranged BMI. Group A was given diclofenac suppositories [Voltral suppository by DVAGO-100 mg twice daily (BD)] and group B was given intramuscular diclofenac [Injection Voren by DVAGO-75 mg or 1.5 mg/kg three times a day (TDS)]. If the pain was not relieved with diclofenac by either route, rescue analgesia was given in the form of injection nalbuphine via intravenous route at the dose of 10 mg.

Visual analog scale was used to measure pain at 0, 8, 16, and 24 hours post-operatively. Patients graded the severity of pain on VAS from 0 (no pain) to 10 (severe pain).⁹ The proportion of patients undergoing any adverse event (gastrointestinal tract discomfort, headache, itching) and requiring rescue analgesia were also recorded.

STATISTICAL ANALYSIS

Data entry and analysis was done by using Statistical Package for the Social Sciences (SPSS) version 26. Quantitative variables such as age, body mass index

(BMI), and VAS were presented as mean $\pm$ standard deviation (SD). Qualitative variables such as gender and adverse events were presented by frequency & percentages. The results for quantitative and qualitative variables were compared by using independent sample t-test and chi-square, respectively. A p-value < 0.05 was taken as significant.

RESULTS

The mean age of patients in group A and group B was 33.22 ± 9.58 years and 34.05 ± 10.70 years, respectively. The mean BMI of patients in group A was $25.71 \pm 2.35 \text{ kg/m}^2$ and the mean BMI of group B patients was $26.38 \pm 2.70 \text{ kg/m}^2$. Both groups didn't significantly differ in terms of age, gender, and BMI distribution ($p > 0.05$). In group A, only 15 (11.1%) patients needed rescue analgesia as compared to 39 (28.7%) patients in group B ($p = 0.001$). Also, 35 (25.7%) patients faced adverse events in group B as compared to group A, where only 11 (8.1%) patients suffered from adverse events ($p = 0.001$) (Table 1).

The patients receiving diclofenac suppositories showed significantly better pain relief compared to those who received Injection diclofenac via I/M route. Group A showed a reduction in mean pain scores at 0, 8, 16, and 24 hours post-operatively as compared to group B ($p < 0.001$) (Table 2). Pain reduction was greater in group A across all age categories. Participants aged 18-35 years had lower mean pain scores in group A (3.86 ± 0.89) compared to group B (4.13 ± 1.10) ($p = 0.028$). Similarly, in those aged ≥ 35 years, group A (3.75 ± 1.09) reported significantly less pain than group B (4.17 ± 1.27) ($p = 0.0043$). Both males and females in group A had significantly lower mean pain scores compared to their counterparts in group B ($p < 0.05$). The analgesic effect of group A treatment remained superior regardless of side effects. Among participants who experienced adverse effects, group A (3.75 ± 1.08) reported lower pain than group B (4.38 ± 1.16) ($p < 0.001$). The same pattern was observed in those without adverse effects ($p < 0.001$). Participants who required rescue analgesia had higher pain scores, but group A (3.85 ± 1.12) still showed significantly lower pain than group B (4.65 ± 1.30) ($p < 0.001$). Even among those not needing rescue analgesia, group A had better pain control ($p < 0.001$). When stratification was done for BMI, patients with normal & deranged BMI in group A had significantly lower mean pain score as compared to group B (p-value < 0.001) (Table 3).

Table 1: Demographic and Clinical Parameters of Groups A & B

Variables		Group A Diclofenac Suppositories (Frequency & Percentage)	Group B Injection Diclofenac (Frequency & Percentage)	Total	p-value
Age Groups (Years)	18 to <35	25(18.4%)	30(22.1%)	55(40.5%)	0.38
	≥35	43(31.6%)	38(27.9%)	81(59.5%)	
	Total	68(50%)	68(50%)	136(100%)	
Gender	Male	46(33.8%)	49(36.1%)	95(69.9%)	0.57
	Female	22(16.2%)	19(13.9%)	41(30.1%)	
	Total	68(50%)	68(50%)	136(100%)	
Adverse Events	Yes	11(8.1%)	35(25.7%)	46(33.8%)	0.001*
	No	57(41.9%)	33(24.3%)	90(66.2%)	
	Total	68(50%)	68(50%)	136(100%)	
Patients who Needed Rescue Analgesia	Yes	15(11.1%)	39(28.7%)	54(39.7%)	0.001*
	No	53(38.9%)	29(21.3%)	82(60.3%)	
	Total	68(50%)	68(50%)	136(100%)	

*Significant p-value

Table 2: Comparison of Post-Operative Mean Pain Scores between Study Groups

Time (Hours)	Group A (Mean Pain Scores)	Group B (Mean Pain Scores)	p value
0	4.94±0.96	5.67±0.79	<0.001*
8	4.4±0.99	5.25±1.09	<0.001*
16	3.95±0.89	5.06±1.53	<0.001*
24	3.75±1.09	4.69±1.05	<0.001*

*Significant p-value

Table 3: Comparison of Mean Post-Operative Pain Scores between Groups A & B regarding Demographic & Clinical Variables

Variables		Group A (Mean Pain Scores after 24 Hours (Mean±SD))	Group B (Mean Pain Scores after 24 Hours (Mean±SD))	p-value
Age Groups (Years)	18 to <35	3.86±0.89	4.13±1.1	0.028*
	≥35	3.75±1.09	4.17±1.27	0.004*
Gender	Male	3.7±1.07	4.16±1.07	0.0004*
	Female	3.88±1.16	4.46±1.08	<0.001*
Adverse Effects	Yes	3.75±1.08	4.38±1.16	<0.001*
	No	3.6±1.0	4.55±1.28	<0.001*
Rescue Analgesia	Yes	3.85±1.12	4.65±1.3	<0.001*
	No	3.58±1.1	4.49±1.32	<0.001*
BMI (kg/m ²)	Normal (18.5-24.9)	3.65±1.43	4.49±1.35	<0.001*
	Deranged (≥25)	3.86±0.51	4.62±1.1	<0.001*

*Significant p-value

DISCUSSION

The foremost challenge after a surgery is effective relief in pain with minimum possible side effects and cost-effectiveness.¹⁰ This study aimed to compare the effect of diclofenac suppositories and injection in the management and relief of pain after abdominal surgeries.

The mean age of patients in group A and group B was 33.22±9.58 years and 34.05±10.70 years, respectively. Pain reduction was significantly greater in group A in both age groups as compared to group B. Aleem et al. also reported that the mean age of patients who received diclofenac suppositories was 43.50±5.72 years and those who received diclofenac injections was 44.16±5.31 years. They reported

better pain control and relief with diclofenac suppositories; the most significant differences were recorded at 24 hours ($p=0.001$).¹¹ However, in our study, the most significant difference in score has been recorded at 16 hours, followed by 24 hours; this can be attributed to the difference in mean age of the populations in these studies.

In our study, 69.9% of the participants were males, whereas 30.1% were females. Pain reduction was significantly greater in group A across both gender categories as compared to group B. A previous study conducted in Faisalabad included approximately two-third males and one-third females. The study showed that diclofenac suppository was more effective at 12th hour ($p < 0.001$) as compared to 2nd and 6th hour in relief of post-operative pain.¹² A study conducted on pediatric patients with mean age of 6.05 ± 2.33 years for the relief of post-operative pain showed that patients who received diclofenac suppositories had lower pain scores ($p\text{-value}=0.03$) on VAS which corresponded to our study results.¹³ Another study was conducted to assess pain relief in the first 24 hours after cesarean section delivery. The study results showed better pain relief with diclofenac suppositories, similar to our study despite the fact that the sample population consisted of females only.¹⁴ Rab et al. included 72.45% males and showed effective pain relief with diclofenac suppositories after abdominal surgery.¹⁵ Another study compared the effects of the two forms of the drug in relief of the pain after vaginal delivery. The study showed that the patients who received diclofenac suppositories reported mild to moderate pain, while a few patients who received injection diclofenac reported severe pain as well, besides others who had mild to moderate pain ($p\text{-value}=0.002$ at 6 hours).¹⁶

In our study, the mean BMI of patients in group A & B was not significantly different. However, when stratification was done for BMI, patients with normal & deranged BMI in group A had significantly lower mean pain score as compared to group B ($p\text{-value} < 0.001$). A study conducted in Iran compared the effect of diclofenac suppositories with placebo group in relief of post-operative pain in patients undergoing laparoscopic cholecystectomy. Similar to our study, the placebo and diclofenac group did not significantly differ in terms of BMI distribution. The study showed significant reduction in mean pain scores on VAS of the patients who received diclofenac suppositories as compared to the other group ($p\text{-value} < 0.05$) but they did not reported the association of post-operative pain scores and BMI categories.¹⁷ Saeed et al. conducted a study on

females undergoing gynecological and obstetrical surgeries and reported that rectal diclofenac suppositories were effective for post-operative pain relief in patients with any BMI category.³

In our study, the results showed that mean pain on VAS was significantly lower for those who received diclofenac suppositories as compared to those who were given injection diclofenac at 0, 8, 16, and 24 hours ($p\text{-value} < 0.0001$). Altaf et al. compared the effectiveness of diclofenac suppositories versus injections in pain relief after perineal repair in primipara. Mean pain score on VAS in the suppositories group was 2.08 ± 0.96 and the score in the injection group was 5.92 ± 1.08 ($p\text{-value} < 0.0001$).¹⁸ A study compared rectal diclofenac suppository and transdermal diclofenac patch in the relief of pain after open cholecystectomy. The study concluded that the suppository form of the drug is more effective than transdermal patch ($p\text{-value} < 0.05$).¹⁹ These findings strongly support the results of our study. A study conducted in Nigeria compared rectal and intramuscular diclofenac for pain relief after abdominal surgery. The results showed significantly lower pain scores on VAS at 24 hours in the rectal suppository group. A statistically significant difference was found between the two groups ($p\text{-value} < 0.001$).²⁰ Elahabadi et al. conducted a study in Iran in which they compared diclofenac with acetaminophen suppositories in post-hemorrhoidectomy pain relief. Diclofenac suppositories had better analgesic effect and showed more satisfactory results.²¹ A study comparing oral and rectal diclofenac in pain relief after episiotomy and concluded that suppositories are far better in pain control. The mean pain score in the suppositories group was 2.93 as compared to 3.98 in the oral diclofenac group.²²

In our study, significant results showed that fewer (11.1%) patients in group A needed rescue analgesia as compared to 28.7% patients in group B. Hosny et al. conducted a study for relief of post-episiotomy pain and reported that only 1.1% patients ($p\text{-value}=0.01$) required rescue analgesia.²³ This was proportionately less as compared to our study and may be due to less extensive procedure and hence requiring lesser need for analgesia.

CONCLUSION

Rectal suppositories of diclofenac were significantly more effective for post-operative pain relief among patients undergoing abdominal surgeries as compared to diclofenac intramuscular injection. Diclofenac suppositories had shown significantly better pain relief as measured by VAS mean scores

at 0, 8, 16, and 24 hours. It was also observed that a smaller number of patients in the diclofenac suppositories group required rescue analgesia while more than half patients in the injection group demanded for rescue analgesia.

LIMITATIONS & RECOMMENDATIONS

The few limitations of this study included a single study setting and non-probability convenience sampling technique. Pain measurement by VAS introduced the risk of measurement bias since it is subjective and may vary from person to person. Multi-centered RCT with blinding should be done to further ascertain the results of this study. The groups should be further subdivided and matched for severity and type of abdominal surgery.

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Authors' Contributions:

M.A.U: Conceived the study, drafted the manuscript & coordinated data collection

F.L: Proofread the manuscript & ensured reference accuracy

F.M: Supervised the research & reviewed the manuscript

M.F: Performed statistical analysis & contributed to results interpretation

S.S.Z.J: Managed patient enrollment & clinical data verification

H.Z.A: Assisted in literature review & data organization

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