

# Comparison of Postoperative Outcome with Diclofenac Rectal Suppositories Versus Intramuscular Diclofenac in Patients Undergoing Laparoscopic Cholecystectomy

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## ABSTRACT

**Objective:** The aim of this study was to compare postoperative outcome with diclofenac rectal suppositories versus intramuscular diclofenac in patients undergoing laparoscopic cholecystectomy. **Study Design:** Randomized Controlled Trial. **Settings:** General surgery Department, Khawaja Muhammad Safdar Medical College Sialkot & Allied Hospital Faisalabad Pakistan. **Duration:** 2 year from May 2017 to April 2019. **Methodology:** After informed consent, 200 patients scheduled for laparoscopic cholecystectomy were randomized into two groups. Group-A got diclofenac sodium rectal suppository at time of induction of anesthesia and Group-B were given IM Diclofenac for postoperative pain relief. Assessment of pain was done using Visual Analogue Scale (VAS) by an observer which will be graded ruler ranging from 0-10 showing the minimal and maximum pain score respectively. The score was assessed post operatively at recovery time 6, 12 and 24 hours. Activity score was checked at 8, 12 & 24 hours postoperatively. Data was collected for pain & mobility through specially designed Performa. **Results:** Demographic characteristics, intraoperative and postoperative hemodynamics of the patients were similar between groups. Postoperative VAS were lower at all-time points in Group -A. Mean VAS was 6.41(SD 0.89), 4.03 (SD 0.92), 2.16 (SD 0.84) in group A as compared to 7.78 (SD 0.83), 5.86 (SD 0.92), 4.4 (SD 1.33) in group B after 6hr, 12 hr. & 24 hr. respectively. Mean activity score was 3.28 (SD 0.61), 1.8(SD 0.79), 1.1(SD 0.36) in group A and 4.35 (SD 0.63), 3.31 (SD 0.83), 2.85 (SD) in group B after 8 hr., 12 hr. and 24 hr. respectively. **Conclusion:** In patients undergoing laparoscopic cholecystectomy, application of diclofenac sodium rectal suppository at time of induction of anesthesia is more effective than IM diclofenac sodium and can be preferred in postoperative pain treatment.

**Keywords:** Diclofenac sodium, Laparoscopic cholecystectomy, Suppository, Postoperative pain, Activity.

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## INTRODUCTION

Laparoscopic cholecystectomy is commonly performed procedure for symptomatic gallstone disease.<sup>1</sup> Although laparoscopic cholecystectomy causes less pain and discomfort as does open cholecystectomy but still most of patients complain of postoperative pain at port site usually at epigastrium and umbilical port. The pain intensity is more severe in first few hours after surgery.<sup>2</sup> If pain is not managed properly it may have detrimental effects on cardiovascular system, central nervous system and respiratory system.<sup>3</sup> The goal of postoperative pain management is to reduce or eliminate the postoperative pain along with minimum side effects. Reduction in postoperative pain ultimately has many positive outcomes like early mobility, early oral intake, early discharge from hospital and ultimately ultimate early return to daily activities.<sup>4</sup>

Most common medication used for control of moderate pain postoperatively is NSAIDS. Opioids were drug of choice initially for postoperative pain but it has higher incidence of side effects like nausea, vomiting, respiratory depression and ileus. NSAIDS do not cause respiratory depression and ileus.<sup>5</sup>

NSAIDS are used by many routes as intramuscular, intravenous, oral, cutaneous patch and rectal routes

(suppositories). Suppository has many additional advantages than other routes. It decreases nausea, vomiting and gastritis caused most commonly by oral intake. Suppositories can be used in patients who are nil by mouth postoperatively. Rectal suppository has advantage over intramuscular route that first pass metabolism is avoided and also absorption of diclofenac is more with rectal route than with intramuscular route. Thus, rectal suppository represents simple and effective analgesia postoperatively in patients undergoing laparoscopic cholecystectomy.<sup>6</sup>

When NSAIDS are given intramuscularly their administration is painful and they usually require rescue analgesia in the form of opioids to control postoperative pain in patient who has undergone laparoscopic cholecystectomy.<sup>7</sup> Different studies conducted on patients of laparoscopic cholecystectomy have favored that Diclofenac suppository in 100 mg dose significantly decrease VAS score and reduce requirement of rescue analgesia.

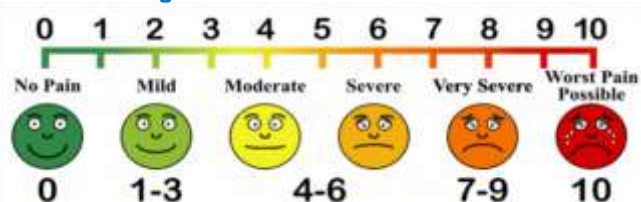
Rationale of current study is to check the effect of diclofenac rectal suppositories on postoperative outcome such as postoperative pain and mobility. Commonly intramuscular injection of NSAIDS is given to relieve postoperative pain in our

set up. This study will provide roadmap to use rectal suppositories as effective alternative to intramuscular diclofenac sodium injection in postoperative effective relief of pain ultimately leading to early return to home & activity.

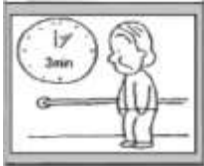
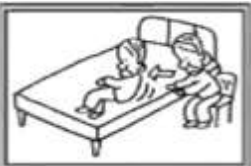



**Objectives:** The objective of the study is comparison of postoperative outcome with diclofenac rectal suppositories and intramuscular diclofenac in patients of laparoscopic cholecystectomy.

**Operational Definitions**

**1. Visual analogue scale:**



**2. Postoperative mobility:** It will be assessed at 8, 12 & 24 hour postoperatively with the help of following scale.

Score	Parameters
1	Maintain standing position without help for 3 min 
2	As transferring from sitting to bed, transferring oneself from & to sitting level 
3	Cannot transfer while sitting but maintain sitting position without assistance 
4	Does not maintain sitting position but change lying position 
5	Does not change lying position 

**METHODOLOGY**

**Study Design:** Randomized Controlled Trial.

**Settings:** General surgery Department, Khawaja Muhammad Safdar Medical College Sialkot & Allied Hospital Faisalabad Pakistan.

**Duration:** 2 years from May 2017 to April 2019.

**Sample Technique:** Non-probability purposive sampling.

**Sample Size:** Total 200 patients were included in this study (100 in each group)

**Inclusion Criteria:** Patient with symptomatic gallstone disease between age of 18 and 60 years.

**Exclusion Criteria:**

1. All known patients with history of upper abdominal surgery.
2. Patient with emphysematous cholecystitis.
3. Patient unfit for general anesthesia.
4. Patients who have comorbid conditions that may interfere with blood loss and pain assessment e.g. Blood dyscrasias, coagulation abnormalities, impaired cognition and limited mobility.

**Data Collection Procedure:** After the approval of the research proposal from the “Ethical Review Committee” as per inclusion and exclusion criteria all consecutive patients were taken who are admitted in Surgery Department of Khawaja Muhammad Safdar Medical College Sialkot & Faisalabad Medical University /Allied Hospital or present to Outdoor Patient Department of the Hospital. Informed consent was taken from all the patients for all investigations and the use of data for research purpose. Total 200 patients were selected for the study, who were randomly divided into two equal groups by using computer generated random number tables.

Group-A patients were given Diclofenac suppositories at the time of induction of anesthesia and Group-B were given IM Diclofenac for postoperative pain relief. Assessment of pain was done using Visual Analogue Scale (VAS) by an observer which will be graded ruler ranging from 0-10 showing the minimal and maximum pain score respectively. The score was assessed post operatively at recovery time 6, 12 and 24 hours. Activity score was checked at 8, 12 & 24 hours postoperatively. Data was collected for pain & mobility through specially designed Performa.

**Data Analysis Procedure:** All the data was analyzed using the SPSS v-19. Mean, range, median and standard deviation were calculated for all quantitative variables like age, Postoperative Activity Score and Post-operative Pain. Frequency and percentage were calculated by all qualitative variables like gender. Independent sample t-test was used to compare post-operative mobility and post-operative pain in both groups. Effect modifiers like age and gender were controlled by stratification. Post-stratification Independent sample t-test was applied. P-value < 0.05 was taken as significant.

**RESULTS**

**Table 1: Baseline Characteristics of Patients (Gender)**

	Frequency	Percent	Valid Percent	Cumulative Percent
<b>Male</b>	102	51.0	51.0	51.0
<b>Female</b>	98	49.0	49.0	100.0

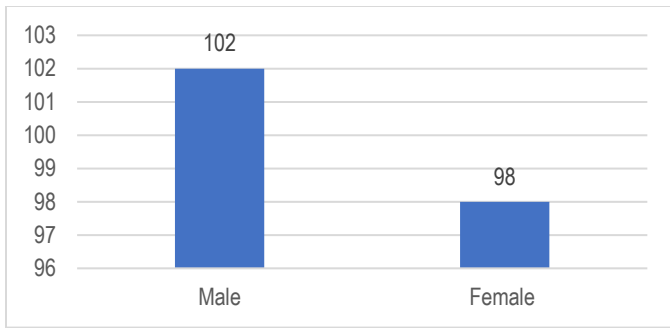


Figure 1: Sex Distribution

Table 2: Parameters of Group A

Parameter	Age	VAS 6hr.	VAS 12hr.	VAS 24hr.	AS 8hr.	As 12hr.	AS 24hr.
Number	100	100	100	100	100	100	100
Minimum	26-35	4	2	1	2	1	1
Maximum	>55	9	6	6	5	4	3
Mean	-	6.41	4.03	2.16	3.28	1.8	1.1
Standard deviation	-	0.889	0.915	0.838	0.604	0.79	0.362
Range	-	5	4	5	3	3	2
Median	-	6	4	2	3	2	1

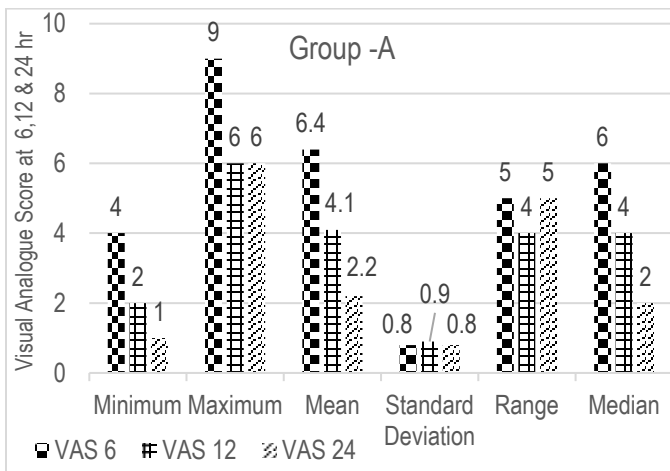


Figure 2: Visual analogue scale (VAS) score of group A

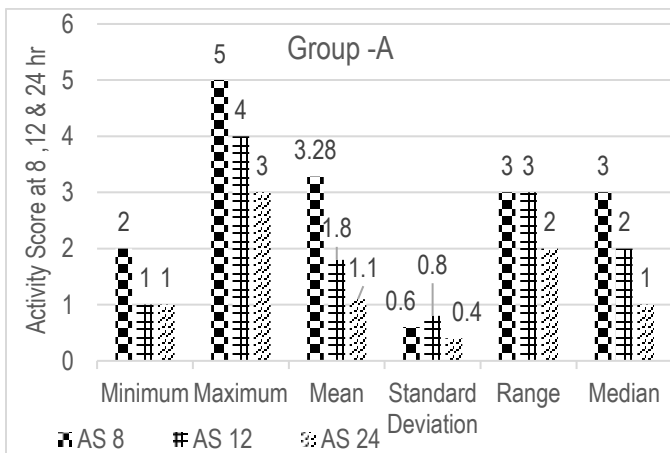


Figure 3: Activity Score (AS) of group A

Table 2: Parameters of Group B

S R #	Parameter	Age	VAS 6 hr.	VAS 12 hr.	VAS 24 hr.	AS 8 hr.	As 12 hr.	AS 24 hr.
1	Number	100	100	100	100	100	100	100
2	Minimum	26-35	6	4	2	3	1	1
3	Maximum	>55	9	7	6	5	5	4
4	Mean	-	7.78	5.86	4.4	4.35	3.31	2.85
5	Standard deviation	-	0.824	0.921	1.333	0.626	0.83	0.796
6	Range	-	3	3	4	2	4	3
7	Median	-	8	6	4	4	3	3

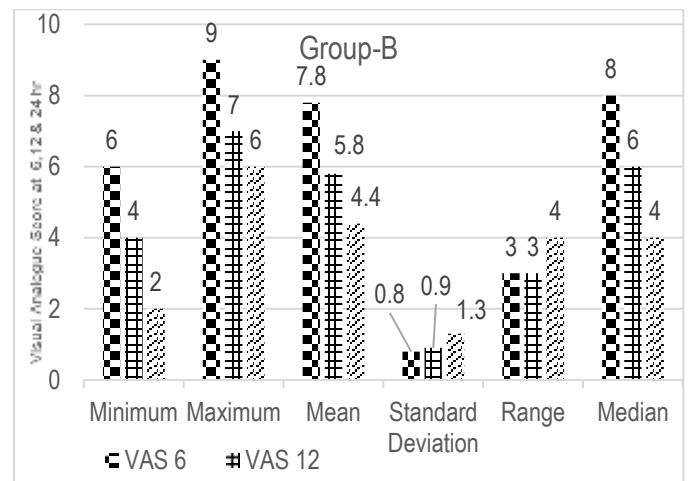


Figure 4: Visual analogue scale (VAS) score of group B

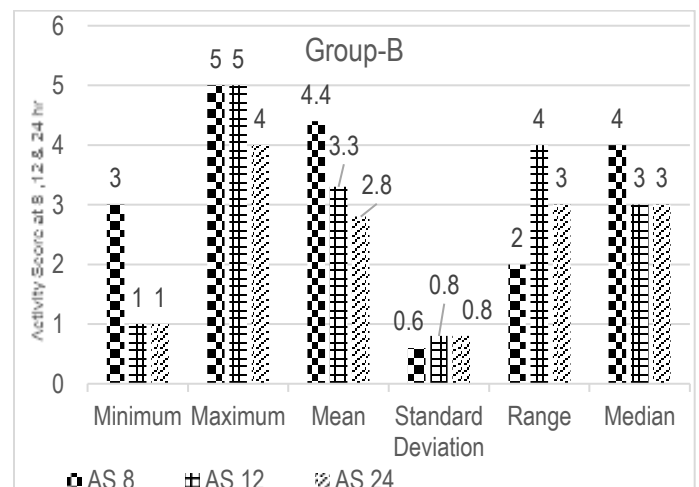


Figure 5: Activity score (AS) of group B

DISCUSSION

In this study, analgesic efficacies of suppositories and intramuscular forms of Diclofenac sodium following LC were compared. A significant decrease in post-operative VAS values was discovered in Group-A when compared with the Group-B. Post-operative pain peaks in the first hours and is controlled in

the following hours and gradually decreases in the 2nd-3rd post-operative days.

When diclofenac suppository is given at time of induction of anesthesia, it blocks noxious stimuli while acting as pre-emptive anesthesia and ultimately improves postoperative outcome. Use of diclofenac suppository is associated with sustained relief of pain for 2-3 hours after surgery. Several studies approve the use of rectal suppository in postoperative analgesia for various procedure. These studies reported significant reduction in postoperative and use of postoperative opioids.

Trans-rectal administration allows complete absorption and sustained release of medication forming rectal suppository as a potent analgesia. Transmission of pain signals evoked by tissue damage lead to sensitization of peripheral and central pain pathway. Mean pain score of in patients receiving rectal suppository is significantly lower than those receiving intramuscular diclofenac. The result is similar to Arab M. et Al (2013) who conducted diclofenac rectal suppository as simple & safe analgesic in Laparoscopic cholecystectomy<sup>9</sup>.

Patient with rectal suppositories used to move early and have good activity score as compared to group-B patient. This is best explained by effective pain control, better the pain control earlier the patient starts activity. The results of this study are very encouraging. It may be further studied.

## CONCLUSION

In patients undergoing laparoscopic cholecystectomy, application of diclofenac sodium rectal suppository at time of induction of anesthesia is more effective than IM diclofenac sodium and can be preferred in postoperative pain treatment.

## LIMITATIONS

Rectal suppositories are not used in patients having

- Hypersensitivity to the active substance or any of the excipients.
- History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy
- In patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other NSAID
- Proctitis

## SUGGESTIONS / RECOMMENDATIONS

We recommend use of rectal suppositories in every patient of laparoscopic cholecystectomy to have better outcome.

## CONFLICT OF INTEREST / DISCLOSURE

The authors declare that there is no conflict of interest to be declared.

## ACKNOWLEDGEMENTS

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## AUTHORSHIP CONTRIBUTION

Zafar Ali Choudry	Principal Investigator, Manuscript Writing
Muhammad Saleem Iqbal	Literature Review, Data Analysis, Tabulation
Munawer Nadeem	Data Collection
Salman Zafar	Data Collection, References Writing
Noor-ul-Huda	Tabulation of Results