

A Comparative Study of Pre-Operative Rectal Diclofenac Suppository and Intramuscular Diclofenac for Assessment of Post-Operative Pain in Patients Undergoing Laparoscopic Surgeries under General Anesthesia

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Abstract

Background: Post-operative pain management is a major concern despite many advances. Intramuscular diclofenac administration causes complications requiring an alternative route of administration. Rectal diclofenac suppositories are available and are proven to be safe for use. **Aims and objectives:** To compare the effectiveness of a pre-operative rectal diclofenac suppository (single dose) with intramuscular diclofenac (single dose) for postoperative pain among patients undergoing laparoscopic surgeries under general anesthesia.

Materials and Methods: Consented 77 patients undergoing elective laparoscopic surgeries, with American Society of Anaesthesiologists Grade I and II, age 18-70 years, and body mass index $\leq 30 \text{Kg/m}^2$ were divided into Group R (n=37, pre-operative rectal diclofenac suppository) and Group M (n=40, receiving pre-operative intramuscular diclofenac). Post-operative pain at 1 hour, 2 hours, 6 hours, 12 hours, and 24 hours, rescue narcotic analgesic requirement, post-operative hemodynamic fluctuations, and complications or adverse drug effects like mild rash, headache, and nausea within 24 hours postoperatively were assessed.

Results: Baseline characteristics were similar between the groups ($p > 0.05$). Mean pain scores were significantly lower in Group R compared to Group M at 1 hour (2.11 ± 0.311 vs. 2.90 ± 0.379 ; $p < 0.001$), 2 hours (2.29 ± 0.611 vs. 3.48 ± 0.640 ; $p < 0.001$), 6 hours (3.61 ± 0.547 vs. 4.65 ± 0.736 ; $p < 0.001$) 12 hours (3.04 ± 0.542 vs. 4.83 ± 1.062 ; $p < 0.001$) and 24 hours (2.87 ± 1.359 vs. 5.05 ± 0.714) respectively. The total dose of rescue narcotic analgesia was more in Group M (109.75 ± 15.440 mg) compared to Group R (59.86 ± 10.703 mg; $p < 0.001$).

Conclusion: Rectal diclofenac suppository provides better analgesia than intramuscular diclofenac in patients undergoing laparoscopic surgeries under general anesthesia.

Keywords: Rectal Route, General Anesthesia, Suppository, Laparoscopic Surgeries.

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Introduction

Post-operative pain is a major concern because it affects multiple systems and induces physiological, immunological, and psychological changes. Despite many advances in providing pain services, acute pain after surgery remains a severe cause of severe suffering that is often undermanaged despite our best efforts. [1]

Acute pain can be persistent; the tissue damage of surgery sets up pathophysiological processes in the peripheral and central nervous system that may produce chronicity. [2] The association between surgery, acute pain, and ongoing severe chronic pain are well defined. [3] There is therefore a pressing need for advances in the agents and techniques we can use to improve analgesia efficacy, and perhaps reduce the incidence of chronic suffering after surgery.

Pain management in the perioperative period has been traditionally based on opiates. Considering their side effects (respiratory depression, nausea, vomiting, and histamine release), new drugs, opiate-sparing drugs, and novel techniques were introduced for treatment. Non-opioids play an ever-increasing role in the treatment of postoperative pain. [4] [5]

Diclofenac is a commonly used analgesic, anti-inflammatory properties and exerts its action via prostaglandin synthesis by inhibiting cyclooxygenase-1 and cyclooxygenase-2 with relative equipotency. [6] Muscle damage, increasing bleeding risk and renal toxicity are the important noted adverse effects of intramuscular diclofenac administration, whereas giving diclofenac orally in nil per oral patient preoperatively increases the risk of gastrointestinal ulceration and bleeding. Therefore, a great need exists to find alternative routes of administration. Rectal diclofenac suppositories are available and are proven to be safe for use. [7]

Hence, in the present study, we tried to compare the efficacy and safety of intramuscular and rectal diclofenac in terms of pain score and amount of opioid analgesic required following lower abdominal surgery with or without the use of pre-operative rectal diclofenac suppository.

Materials and Methods

A present analytical cross-sectional study was performed on 77 patients undergoing elective laparoscopic surgeries in the Department of Anaesthesiology and Critical Care of Sri Aurobindo Institute of Medical Science and PG Institute, Indore, Madhya Pradesh, India, from April 2021 to September 2022.

All American Society of Anaesthesiologists (ASA) Grade I and II patients undergoing elective laparoscopic surgeries, aged between 18-70 years, and body mass index (BMI) ≤ 30 Kg/m² were included, whereas patients with any known malignancy – Identified in history, any positive history (might alter the pain threshold of the patient), ASA grade III or above (grading was done for the patients during pre-anesthetic evaluation), hepatitis B & C positive cases and pregnancy were excluded. Patients with a history of bleeding, mass, discharge, pain, or pruritus per anum suggestive of anorectal disease who were unfit for rectal diclofenac suppository and complicated laparoscopic surgeries like conversion to open procedure and prolonged duration of the procedure (more than 2 hours) were also excluded.

Patients were randomly divided into Group R (n=37; posted for laparoscopic surgeries under general anesthesia and receiving pre-operative single dose rectal diclofenac suppository) and Group M (n=40; posted for laparoscopic surgeries under general anesthesia receiving pre-operative single dose intramuscular diclofenac.

Patients were assessed and compared for post-operative pain at 1 hour, 2 hours, 6

hours, 12 hours, and 24 hours, rescue narcotic analgesic requirement, post-operative haemodynamic fluctuations, and complications or adverse drug effects like mild rash, headache, and nausea were recorded within 24 hours postoperatively.

Statistical Analysis

Data were recorded in the Microsoft Excel program, and statistical analysis was performed by the SPSS program for Windows, version 25 (SPSS, Chicago, Illinois). Continuous variables were presented as mean \pm SD, and categorical

variables were presented as absolute numbers and percentages. Data were checked for normality before statistical analysis. Descriptive analysis was performed to obtain the general characteristic of the study population. Categorical variables were analysed using the chi-square test or Fisher's exact test. Continuous variables were assessed using ANOVA or independent sample t-test. $P < 0.05$ was considered statistically significant.

Results

Table 1: Baseline characteristics of the study population

Characteristics	Intramuscular diclofenac		Rectal diclofenac suppository		P value*
	Mean	SD	Mean	SD	
Age; years	37.75	12.921	37.66	12.213	0.974
Sex; m/f	11 (27.5%)/29 (72.5%)		13 (34.2%)/25 (65.8%)		0.521
Weight; Kgs	54.93	7.346	57.50	7.613	0.269
Spo2;%	98.72	0.748	98.82	0.730	0.427
SBP; mmHg	123.25	6.558	124.74	7.618	0.358
DBP; mmHg	79.50	4.501	79.47	4.619	0.980
HR; beats/min	93.20	6.715	92.16	5.309	0.451
RR; / min	11.85	1.231	12.24	1.314	0.196

DBP: diastolic blood pressure; HR: heart rate; M: intramuscular diclofenac; R: rectal diclofenac suppository; RR: respiratory rate; SPO2: oxygen saturation; SBP: systolic blood pressure. * ANOVA

Table 2: Total dose of rescue narcotic analgesia (mg)

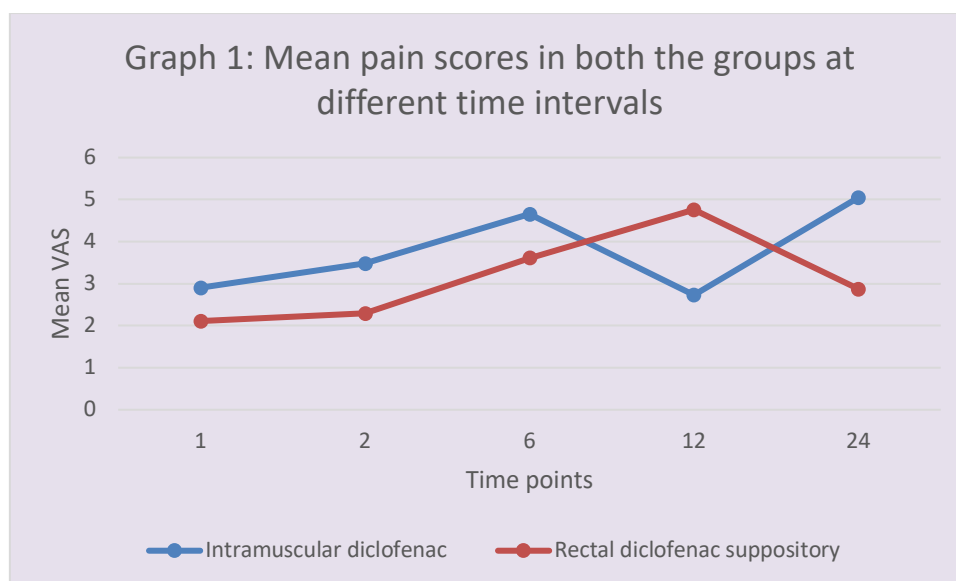
Group	N	Mean	Std. Deviation	P value*
Intramuscular diclofenac	40	109.75	15.440	<0.001
Rectal diclofenac suppository	37	59.86	10.703	

M: intramuscular diclofenac; R: rectal diclofenac suppository; *independent sample t-test

Table 3: Mean pain scores in both the groups at different time intervals

VAS	Group		P value*
	Intramuscular diclofenac	Rectal diclofenac suppository	
1	2.90 \pm 0.379	2.11 \pm 0.311	<0.001
2	3.48 \pm 0.640	2.29 \pm 0.611	<0.001
6	4.65 \pm 0.736	3.61 \pm 0.547	<0.001
12	4.83 \pm 1.062	3.04 \pm 0.542	<0.001
24	5.05 \pm 0.714	2.87 \pm 1.359	<0.001

* independent sample t-test



Discussion

Although laparoscopic surgeries have gained popularity due to a reduction in the pain caused by big incisions in typical open procedures, minimally invasive techniques are not painless. [8]

Postoperatively, narcotic analgesics are the most potent and effective painkillers; however, they are related to postoperative nausea and vomiting (PONV) and respiratory depression. Patient-controlled analgesia (PCA) lowers both of these side effects, but PCA pumps are unavailable in most facilities in low- and low-middle-income nations. [9, 10] According to a poll conducted by the global Surg® collaborative group in Kigali, Rwanda, Opioid analgesics are inaccessible to most patients in public hospitals in low middle income countries (LMICs) (expensive, drug control regulations, PCA pumps cost, or tedious hospital paperwork being a few factors). These adverse effects are not connected with diclofenac suppositories, which are widely available in most LMICs. [11]

In patients having laparoscopic surgeries, using a diclofenac suppository as a component of pain medicine during the perioperative period considerably reduces the need for opiate analgesia. Use of diclofenac suppository is associated with

persistent pain alleviation 2 to 3 hours following surgery when the efficacy of the local anaesthetic administered into the trocar sites has worn off. [12] This method has not been studied as a standard of care for patients undergoing laparoscopic treatment for gallstone disease. Where studies have indicated significant variations in the use of opioids as PCA between groups of patients receiving paracetamol or diclofenac group, the use of the Diclofenac group is advocated. [13]

Per rectal route of administration of diclofenac suppository excludes the reported adverse effects of muscle damage, increased risk of bleeding, and acute kidney injury (intramuscular route) or increased risk of gastrointestinal ulceration and bleeding (oral route), in addition to removing the first-pass effect. [6]

Several studies have demonstrated the efficacy of rectal diclofenac suppositories for post-operative analgesia in various surgical operations. The technique has been utilised effectively for cleft palate repair, ERCP, elective C-sections, herniotomy, and hemorrhoidectomy. 6 These investigations demonstrated a considerable reduction in the demand for opioid analgesics to treat immediate post-operative pain. At least two studies have shown that the opioid-sparing effect of

rectal diclofenac following complete abdominal hysterectomy or C-section reduces morphine consumption, improves post-operative analgesia, and decreases side effects such as drowsiness and nausea. [14,15] Dodd et al. showed that using rectal suppositories is a straightforward, effective, and safe strategy for lowering the pain women suffer following perineal damage within the first 24 hours after labour. [16]

Rectal administration of diclofenac is a safe and practical method that results in total absorption and prolonged release of medication to offer rapid onset and long-lasting post-operative analgesia. Sensitization of the peripheral and central pain pathways results from transmitting pain signals elicited by tissue injury. This study demonstrated the efficacy of pre-operative diclofenac rectal suppository for post-operative analgesia in laparoscopic surgeries. Patients taking pretreatment rectal diclofenac have considerably lower mean pain scores than the intramuscular diclofenac group. With the use of a diclofenac suppository, the incidence of requiring an opioid as a rescue analgesic and its dose is significantly reduced. Like Arab M. et al., who concluded that diclofenac rectal suppository is a simple and safe analgesic for laparoscopic surgeries [4], this study demonstrates that diclofenac rectal suppository is an effective and safe analgesic for laparoscopic surgeries.

The present study is not devoid of limitations. The study provides a straightforward comparison of a small population. However, the results are very encouraging, and a high-quality randomised controlled trial with a bigger sample size combined with the use of local anaesthetics may alter the standard of care for pain management in minimally invasive surgery. The study did not incorporate patient opinions regarding the new route of medicine administration. Acceptability of this rectal route may be an issue in some

cultures, particularly in low- and middle-income nations.

Conclusion

Rectal diclofenac suppository provides better analgesia than intramuscular diclofenac in patients undergoing laparoscopic surgeries under general anesthesia. However, there is a need for a large randomized clinical trial to provide more strength to present study results. We recommend using rectal diclofenac suppositories in patients undergoing laparoscopic surgeries under general anesthesia.

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