

Original Research Article

Prospective comparative study of use of diclofenac suppository (150 mg) and intramuscular diclofenac (75 mg) for pain management of patients in post-operative laparoscopic cholecystectomy

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ABSTRACT

Background: Laparoscopic cholecystectomy is a gold standard surgical procedure for treatment of gallstone disease. Early postoperative pain management will lead to early ambulation, early recovery. This study will help us to make a conclusion whether to use rectal suppositories of NSAIDS as effective alternative to intramuscular injection of NSAIDS for postoperative pain management and recovery of the patients in laparoscopic cholecystectomy. Rationale of this study is to check the effectiveness of Diclofenac rectal suppositories on postoperative patients for pain and morbidity.

Methods: Study was conducted in 50 patients. Diclofenac 150mg suppository (one and half) introduced per rectally at the time of induction of anaesthesia in 25 patients and in another group, 75 mg diclofenac injection given intramuscularly at the time of induction of anaesthesia in another 25 patients. Only single dose of diclofenac administered. For any pain complaints (VAS >3), a dose of intravenous paracetamol 1 gram was given SOS with minimum interval of 6 hours in both group. Readings was taken at an interval of 6, 12 and 24 hours postoperatively.

Results: There is significant reduction in postoperative pain in group A compare to group B according to VAS with significant p value (0.005 in 6 hours, <0.001 in 12 hours and <0.001 in 24 hours postoperatively). % of decrease in VAS is more in group A with p value 0.001 in 12 hours and 0.004 in 24 hours postoperatively.

Conclusions: In conclusion per rectal suppository of diclofenac for Laparoscopic cholecystectomy reduces pain in the initial postoperative period, it is easy to administer with no adverse effects and may become routine practice for this procedure. This simple, safe, inexpensive, effective form of diclofenac thus improve postoperative analgesia in hospital course. We advocate its use in all elective laparoscopic cholecystectomies.

Keywords: Diclofenac suppositories, Laparoscopic cholecystectomy, Post operative pain

INTRODUCTION

Laparoscopic cholecystectomy is a gold standard surgical procedure for treatment of gallstone disease.¹ LC is widely performed surgical procedure that achieves

superior outcomes in postoperative pain, recovery time, cosmetic issues, and morbidity. Though LC is associated with lesser postoperative pain than open cholecystectomy, but patients still experience some amount of pain. Basic post operative analgesia is still

based upon regional anaesthesia, Opioids, non-steroidal anti-inflammatory drugs (NSAIDS) and local anaesthetics. Use of multimodal or balanced analgesic techniques involving the use of small doses of Opioids in combination with non-opioids, for PO analgesia is a popular approach.

Pre-emptive analgesia strategies involve interventions at one or more sites along the pain pathway.² Postoperative pain can be divided into acute pain and chronic pain. Acute pain is experienced immediately after surgery (up to 7 days) and pain which lasts more than 3 months after the injury is considered to be chronic pain. Acute and chronic pain can arise from cutaneous, deep somatic or visceral structures. Early postoperative pain management will lead to early ambulation, early recovery and also it helps in decreased incidence of deep vein thrombosis. To reduce postoperative pain, laparoscopy has evolved over the laparotomy as it is less traumatic.³ Rectal NSAIDS suppositories can be used in patients' nil by mouth. For a number of drugs the extent of rectal absorption has been reported to exceed oral values, which may reflect partial avoidance of hepatic first-pass metabolism after rectal delivery.⁴

In patients undergoing laparoscopic cholecystectomy, application of diclofenac sodium suppository at the time of induction of anaesthesia is more effective than IM diclofenac sodium and can be preferred in postoperative pain treatment.⁵ Thus, rectal NSAIDS suppositories can be used for effective analgesia in post operative laparoscopic cholecystectomy.⁶ Rectal suppository of tramadol as well as diclofenac are effective for post-operative analgesia. Diclofenac is better alternative than tramadol as it is devoid of nausea and vomiting and have longer duration.⁷

This study aimed to compare postoperative pain by VAS score at 6, 12, 24 hours postoperatively in patients undergoing laparoscopic cholecystectomy receiving intramuscular diclofenac or diclofenac suppository. Secondary objectives were to compare per rectal diclofenac suppositories with intramuscular diclofenac in post operatively in patients undergoing laparoscopic cholecystectomy with regard to: 1) Return of intestinal peristaltic sound (at 6, 12, 24 hours postoperatively); 2) Post operative temperature (at 6, 12, 24 hours postoperatively) and 3) Duration of hospital stay (in days from admission to discharge).

METHODS

The study performed was a prospective, observational, clinical study. This study was conducted for a period of 8 months from October 2022 to June 2023. The source of data for study will be 50 patients. This study conducted at Mata Chanan Devi Hospital from OPD with patients admitted for elective laparoscopic cholecystectomy.

Inclusion criteria

Inclusion criteria were patients who underwent laparoscopic cholecystectomy surgery within the age group of 18-60 years and weighing more than 50 kg were included.

Exclusion criteria

Exclusion criteria were pregnant patients, patients on ventilator support; patients not willing to participate in the study; patients with pre existing renal disease or chronic liver disease where; NSAIDS were contraindicated; patients suffering from bronchial asthma; patients allergic to diclofenac; patients weighing less than 50 kg.

Materials

Diclofenac suppository (containing 150mg diclofenac sodium) Brand name: JUSTIN. One and half suppositories will be used. Only single dose of JUSTIN 150 mg is administered in 25 patients in one group. Injection Diclofenac (containing diclofenac sodium 75mg) Brand name: DYNAPAR. Single dose of intramuscular diclofenac is administered in 25 patients of another group. Digital thermometer for temperature measurements. Stethoscope for auscultation of intestinal peristaltic sound.

Methodology

Diclofenac 150mg suppository (one and half) will be introduced per rectally at the time of induction of anaesthesia in 25 patients and in another group, 75 mg Diclofenac injection will be given intramuscularly at the time of induction of anaesthesia in another 25 patients. Only single dose of diclofenac is administered. For any pain complaints (VAS >3), a dose of intravenous paracetamol 1 gram (inj. PARACIP) was given SOS with minimum interval of 6 hours in both group. Readings will be taken at an interval of 6, 12 and 24 hours postoperatively.

The parameters PAIN, IPS, temperature and duration of hospital stay were noted.

PAIN B visual analogue scale (at 6, 12, 24 hours postoperative).

IPS: Auscultation by stethoscope in all four quadrants of abdomen. (At 6, 12, 24 hours postoperative).

Temperature: By digital thermometer. (At 6, 12, 24 hours postoperative).

Duration of hospital stay: From day of admission to day of discharge.

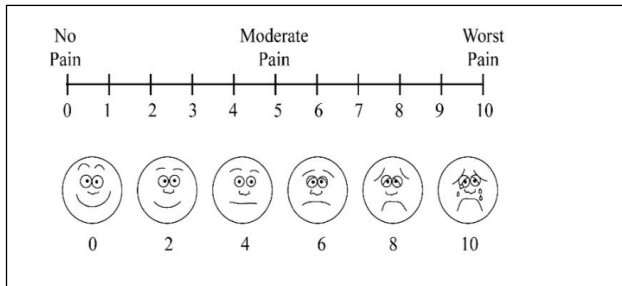


Figure 1: Pain score.

Outcomes

To predict whether per rectal suppositories of NSAIDS can be used as an alternative of intramuscular/intravenous NSAIDS in postoperative laparoscopic and perianal surgical patients.

Sample size calculations

The sample size was calculated to be FIFTY (50). Assuming $p < 0.05$ to be significant. The quantitative variables in both groups will be expressed as mean $\pm$ SD and compared using unpaired t-test between groups and paired t-test within each group at various follow-ups. 95% power is obtained. In group A, rectal 150mg single dose diclofenac suppository is used during induction of anaesthesia and in group B, 75mg intramuscular diclofenac injection is used during induction and readings are taken at 6,12,24 hours postoperative period in both groups.

Statistical method

Sample size has been taken as 50 patients. 25 patients divided into two groups. Group A who received single dose 150mg diclofenac rectal suppository and group B who received 75 mg intramuscular diclofenac single dose injection.

Formula used

Choudry et al reported the mean VAS score in Diclofenac sodium rectal suppository group to be 6.41 ± 0.889 , 4.03 ± 0.915 , 2.16 ± 0.838 at 6 hour, 12 hour and 24 hours respectively. At the same follow-ups, the Mean VAS score in IM diclofenac group were reported to be 7.78 ± 0.824 , 5.86 ± 0.921 , 4.4 ± 1.333 respectively. Assuming these as reference values, the minimum required sample size at 5% level of significance and 95% power is obtained as follows in Table 1.

Considering the number of such patients reporting to our hospital and also the period of study, we propose to take a sample of 25 patients per group for this study.

Table 1: Sample size calculation.

Follow-up	Suppository group	Intramuscular group	Sample size (N)
6 hours	6.41 ± 0.889	7.78 ± 0.824	10
12 hours	4.03 ± 0.915	5.86 ± 0.921	7
24 hours	2.16 ± 0.838	4.4 ± 1.333	6

The quantitative variables in both groups will be expressed as mean $\pm$ SD and compared using unpaired t-test between groups and paired t-test within each group at various follow-ups. The qualitative variables will be expressed as frequencies/percentages and compared using Chi-square test. A p-value < 0.05 will be considered statistically significant. IBM Statistical Package for Social sciences (SPSS) version 20.0 will be used for statistical analysis.

RESULTS

In the current study, 25 out of 50 patients were given diclofenac suppository and 25 out of 50 patients were given intramuscular diclofenac injection for pain control as seen from the Table 2.

Table 2: Case distribution.

Group	Number	Percentage
Suppository 150 mg	25	50
Injection 75 mg	25	50
Total	50	100

The Table 3 and chart shows the age distribution in the study groups. Among suppository group 20% were between 21-30 years, 28% were between 31-40 years, 20% were between 41-50 years, 32% were between 51-60 years.

Table 3: Age distribution.

Age (years)	Suppository 150 mg		Injection75 mg	
	N	%	N	%
21-30	5	20	2	8
31-40	7	28	7	28
41-50	5	20	7	28
51-60	8	32	9	36
Total	25	100	25	100
Mean±SD	41.88±11.24		44.48±9.58	
P value	0.192			

About 8 patients out of 25 were male and 17 patients out of 25 were females in diclofenac suppository group. 9 patients out of 25 were male and 16 patients out of 25 were females in intramuscular diclofenac group (Table 4).

Table 4: Sex distribution.

Gender	Suppository 150 mg		Injection 75 mg		P value
	N	Percent	N	Percent	
Male	8	32	9	36	0.383
Female	17	68	16	64	
Total	25	100	25	100	

The mean VAS score in diclofenac suppository group were 6.04 in 6 hours, 3.88 in 12 hours and 2.36 in 24 hours postoperatively. The mean VAS score in intramuscular diclofenac group were 6.52 in 6 hours, 4.72 in 12 hours and 2.96 in 24 hours postoperatively (Table 5).

Table 5: Post operative pain distribution in 2 groups at 6, 12, 24 hours.

Pain		6 hr	12 hr	24 hr
Suppository 150 mg	Mean	6.04	3.88	2.36
	±SD	±0.61	±0.73	±0.57
	P value (vs 6hr)	-	<0.001	<0.001
Injection 75 mg	Mean	6.52	4.72	2.96
	±SD	±0.65	±0.61	±0.61
	P value (vs 6hr)	-	<0.001	<0.001
P value (Supp vs Inj)		0.005	<0.001	<0.001

The mean percentage decrease in VAS score with respect to 6 hours were 35.66 in 12 hours and 61.03 in 24 hours in diclofenac suppository group. The mean percentage decrease in VAS score with respect to 6 hours were 27.52 in 12 hours and 54.69 in 24 hours (Table 6).

Table 6: Percent decrease in VAS score in two groups at 12, 24 hours.

Percent decrease in VAS score wrt 6hr		12 hr	24 hr
Suppository 150 mg	Mean	35.66	61.03
	±SD	±10.76	±8.53
Injection 75 mg	Mean	27.52	54.69
	±SD	±7.17	±7.78
P value		0.001	0.004

The peristaltic sound was present in all patients who received diclofenac suppository and intramuscular diclofenac in both the group (Table 7).

The mean post operative temperature were 98.02°F in 6 hours, 98.09°F in 12 hours and 98.13°F in 24 hours postoperatively in diclofenac suppository group. The mean post operative temperature were 97.86°F in 6 hours, 97.93°F in 12 hours and 97.99°F in 24 hours postoperatively in intramuscular diclofenac group (Table 8).

Table 7: IPS in two groups at 6, 12, 24 hours.

Intestinal peristaltic sound (IPS)	Suppository 150 mg		Injection 75 mg		P value
	N	%	N	%	
6hr	25	100	25	100	-
12hr	25	100	25	100	-
24hr	25	100	25	100	-

Table 8: Post operative temperature evaluation.

Temperature (°F)		6 hr	12 hr	24 hr
Suppository 150 mg	Mean	98.02	98.09	98.13
	±SD	±0.25	±0.23	±0.26
	P value (vs 6hr)	-	0.003	<0.001
Injection 75 mg	Mean	97.86	97.93	97.99
	±SD	±0.45	±0.42	±0.34
	P value (vs 6hr)	-	0.004	<0.001
P value (Supp vs Inj)		0.068	0.051	0.050

DISCUSSION

Freedom from pain should be a basic human right, limited only by our knowledge to achieve it.⁸ Experimental studies have demonstrated that tissue injury results in hyper excitability of dorsal horn neurons, and it has been suggested that similar alterations may play an important role in clinical pain states.⁹ Recent advances in the pathophysiology of pain have suggested that it is possible to prevent or to attenuate the neuronal hyper excitability that contributes to enhanced postoperative pain.¹⁰ Adequate pain relief postoperatively is important as it may reduce postoperative complications and encourage early ambulation of patient and decrease in length of hospital stay. The invention of newer generation of potent and safe pharmacological agents has opened up a lot of options and multimodal approach for providing adequate pain relief in postoperative patients. The choice of such an agent is guided by factors such as efficacy, convenience of administration, cost-effectiveness, safety profile. Post-operative pain is the main factor delaying discharge of patients undergoing day care procedure including laparoscopic procedures and hence adding to hospital cost. When researching for an optimum regime of pain relief in post-operative period, many groups of analgesics have been investigated for the post surgery analgesia depending on the route of administration. NSAIDS can have an analgesic effect lasting few hours. They have minimal sedative effects that can expedite the discharge of the patient. Local anaesthetic agents can have an opioid sparing effect. They reduce the nausea and vomiting, commonly encountered during general anaesthesia. In this way, they may be able to reach the criteria for early discharge from hospital. Early pain after LC is multifactorial. It is a combination of different pain mechanisms: parietal pain is caused by abdominal wall

penetration by trocar; visceral pain is due to dissection of gall bladder, traction on nerves and peritoneal inflammation are caused by raised intra-peritoneal pressure secondary to CO₂ insufflations. While referred pain in the shoulder tip is due to diaphragmatic irritation by residual CO₂.

In our study, the sample size was calculated to be 50. Assuming p value <0.05 to be significant. The quantitative variables in both groups will be expressed as mean±SD and compared using unpaired t-test between groups and paired t-test.

Within each group at various follow-ups. 95% power is obtained. n=25 in each group. Hence 25 patients were taken in each group.

In group A diclofenac suppository was used and in group B intramuscular diclofenac injection was used.

Efficacy compared with postoperative pain according to VAS score, intestinal peristaltic sound, postoperative temperature and postoperative hospital stay.

This study is conducted with diclofenac suppository of 150 mg single dose (Group A) vs intramuscular injection of diclofenac 75 mg over 50 patients to study postoperative analgesia.

In our study we observed that most of the patients who were operated for symptomatic cholelithiasis were aged between 51-60 years in Group A (32%) and in Group B (36%). Highest number of patients of cholelithiasis (59.6%) belongs to the middle age group of 41-60 years. The male to female ratio was 1:1.7 with female preponderance. According to study of Saxena et al.¹¹ The frequency of gallstones increases with age, escalating markedly after age 40 to become 4 to 10 times more likely in older individuals.¹² The reason for more incidence of cholelithiasis in middle age group may be due to increase in the rate of gall stone formation with increasing age. After 20 years of age, the rate of gallstone formation increases with each decade.¹³

There is significant reduction in postoperative pain in group A compare to group B according to VAS with significant p value (0.005 in 6 hours, <0.001 in 12 hours and <0.001 in 24 hours postoperatively). Use of diclofenac suppository as a constituent part of pain medication in the perioperative period significantly reduces need for opion analgesia in patients undergoing laparoscopic procedures. Use of diclofenac suppository has been associated with sustained relief of pain after 2 -3 hours after surgery when the effect of local anesthetist injected in the trocar sites wear off.¹⁴ Rectal suppository of diclofenac is suited for a preemptive approach of pain management and is efficient drug to reduce consumption of opioids in the postoperative period following laparoscopic cholecystectomy. Results showed statistically significant reduction in frequency and dosage

of rescue analgesia in diclofenac suppository group when compared to the control group ($p \leq 0.001$).¹⁵

Percentage of decrease in VAS is more in group A with p value 0.001 in 12 hours and 0.004 in 24 hours postoperatively. Significant difference in VAS pain score in diclofenac suppository group when compared to the control group was observed during zero, three, six, nine and 12 hour of post-operative observation.¹⁵

IPS was present in all patients underwent LC after 6,12 and 24 hour postoperatively in both groups. So, there is no significant change in IPS.

In this study there was no significant reduction in postoperative temperature and no significant reduction in postoperative hospital stay in both groups.

For any pain complaints (VAS>3), a dose of intravenous paracetamol 1 gram (inj. Paracip) was given SOS with minimum interval of 6 hours in both group.

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) with additional benefit of eliminating the first pass effect.¹⁴

Several studies have proven the effectiveness of rectal diclofenac suppositories in postoperative analgesia in various procedures are available. The modality has successfully been used in repair of cleft palate, ERCP, elective C-sections, herniotomy as well as hemorrhoidectomy.¹⁵⁻²¹

This study has several limitations. Pain is a subjective parameter and perception may vary from person to person. In our study, requirement of stretching of infraumbilical/supraumbilical port was not noted during gall bladder extraction. This factor may have had an impact on the postoperative pain score. Second, in this study we didn't assessed acute calculous cholecystitis patients, these are the patients who require more analgesia postoperatively and noted more pain scores, and this may have impact on postoperative pain scores and analgesia requirements. Third, the difficulty of surgery performed not assessed in this study. The assessment of this parameter seems to be confounded by factors like level of training and skill of the individual who performed it. This also means that, the operation time could have been lesser, if all procedures were performed by surgeons with similar skills in laparoscopy. Forth, we feel that fitness for discharge also could have been assessed at 6 hours following the surgery, as considerable number of patients had acceptable pain scores and were able to perform routine activity at 6 hours following surgery. Fifth, although most of the patients discharged by postoperative day 1, because of fear and financial reasons (insurance claims) were

discharged little later.

CONCLUSION

This study was undertaken to compare the postoperative analgesia and recovery following Laparoscopic cholecystectomy between the two groups. In this study, patients who received diclofenac suppository during Laparoscopic cholecystectomy, had better postoperative pain scores. Although there was no difference in time to resumption of normal activities (pre surgery work) between the two groups. In our study, had following advantages in postoperative outcome of the patient: safe, easy to administer, statistically significant pain reduction in initial postoperative period, non-invasive, simple and effective and economical to the patients, not associated with any complications, side effects as seen in the study, lower pain scores translated into increased patient functionality, Early ambulation (prevents DVT), special set of instruments are not required. In conclusion per rectal suppository of diclofenac for laparoscopic cholecystectomy reduces pain in the initial postoperative period, it is easy to administer with no adverse effects and may become routine practice for this procedure. This simple, safe, inexpensive, effective form of diclofenac thus improve postoperative analgesia in hospital course. We advocate its use in all elective laparoscopic cholecystectomies.

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