

## Efficacy of Tramadol V/s Diclofenac in Management of Post Laparoscopic Cholecystectomy Pain

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### Abstract

**Introduction:** Early post operative pain is the most common complain after elective laparoscopic cholecystectomy. The aim of this study is to determine the efficacy of intravenous tramadol compared to intravenous diclofenac for post operative pain relief.

**Materials and methods:** A randomized doubled blinded study with a cohort of 50 patients was carried out at Teerthankar Mahaveer Medical Hospital, Moradabad between August 2012 and September 2013. Intravenous tramadol 50 mg or intravenous diclofenac 75 mg were eight hourly given to randomly allocated groups after laparoscopic cholecystectomy by draw of chits. VAS score was taken at 4, 12, 20 and 28 hours. Data was analysed using SPSS version 16.

**Results:** A significant difference in VAS scores was found at 12 hour post operative ( $p= 0.0007$ ) with tramadol being more efficacious but having increased incidence of nausea and vomiting.

**Conclusion:** Tramadol an analgesic acting on opioid receptor appears to be more efficacious in providing pain relief post laparoscopic cholecystectomy over diclofenac.

**Key Words:** Laparoscopic Cholecystectomy, Tramadol, Diclofenac

### Introduction:

Pain is thought to be inadequately treated in one-half of all surgical procedures<sup>1</sup>. Early postoperative pain is the most common complaint after elective laparoscopic cholecystectomy<sup>2</sup>. Postoperative pain is the dominating complaint and the primary reason for prolonged convalescence after laparoscopic cholecystectomy<sup>3,4</sup>.

Tramadol is a synthetic analogue of codeine. It is an analgesic with a low affinity for opioid receptors. Its much of action is due to inhibition of the neuronal uptake of norepinephrine and serotonin at synapses in the descending inhibitory pain pathways. It was seen that the side effect profile of tramadol appears to be more acceptable to ambulatory surgical patients compared with the traditional opioids<sup>5</sup>.

The diclofenac is an inhibitor of key enzyme cyclo oxygenase, involved in the metabolism of arachidonic acid into various prostaglandin mediators of inflammation and pain<sup>6</sup>. Diclofenac is a phenyl acetic acid derivative belonging to the carboxylic acid class of NSAIDs. The present study was performed to compare the analgesic efficacy of intravenous tramadol versus diclofenac in preventing postoperative pain following laparoscopic cholecystectomy.

### Materials and Methods:

The study was conducted after approval by the Institutional Ethical Committee. Patients aged 18–60 years, scheduled for laparoscopic cholecystectomy and with ASA physical status I or

II, were eligible. Patients were excluded if they had any history of allergy to NSAIDs (non steroidal anti inflammatory drugs) or opioids, if they had a history of severe renal, hepatic, gastric or coagulative diseases, or if they had received analgesic drugs within 2 weeks before surgery. Patients were explained the use of visual analogue scale (VAS) to monitor post operative pain before surgery and written consent was obtained. Patients were blinded to the use of either of the two analgesics in post operative period.

Patients received premedication and anesthetic induction was done using standard anesthesia protocols. All patients included in the study received uniform pre operative and intra operative medication. Laparoscopy was performed after intra peritoneal insufflation of carbon dioxide and intra peritoneal pressure was maintained at 14 mmHg.

A total of fifty patients were recruited in the study between August 2012 to September 2013. Patients were randomly assigned to one of the study groups before surgery by drawing of chits. Hence two groups were formed, one was tramadol and the other diclofenac group. Post operative analgesia with either tramadol 50 mg or diclofenac 75 mg was prepared in identical syringes diluted with 2 ml normal saline by a single investigator. The analgesic was administered intravenously at 0, 8, 16, 24 hours post operative and pain score recorded at 4, 12, 20 and 28 hours by separate investigators who were blinded to the analgesic used. Additional dose of analgesia was given if VAS score was more than 30 or on demand. At the same time, patient sedation was assessed using a sedation scale (wide awake=0; mildly sleepy and responsive to verbal command=1; moderately sleepy and responsive to nociceptive stimulation=2, extremely sleepy and unrousable to nociceptive stimulation=3). The patients were asked about nausea and vomiting (yes or no).

Two efficacy variables, VAS score and demand for additional analgesia in the first twenty four hours following surgery were used to determine whether the two groups had significant difference with respect to post operative pain relief. Tolerability

was decided based on reporting nausea, vomiting or any other adverse reaction.

Data was analyzed using SPSS (Statistical Package for Social Sciences) version 16. P value was calculated by using Student's t test. A value of  $p < 0.05$  was considered to be statistically significant.

### Result:

A total of 52 patients in the period between August 2012 to September 2013 who were undergoing laparoscopic cholecystectomy were recruited in the study. 2 patients were later dropped out because of conversion to laparotomy. With random assignment two groups were formed, 'T' group of 25 patients who received intravenous tramadol and 'D' group of 25 patients who received intravenous diclofenac. The two groups 'T' and 'D' were matched with respect to age, weight and surgical time. The average age of subjects in group T was 44.12 years and in group D was 43.76 years. The average weight of patients in group T was 69.36 kg and in group D was 68.8 kg. An average of 79.92 minutes were taken for surgery in group T and 79.28 minutes in group D. The demographic data are compared and shown in (Table 1).

No significant difference was found in the sedation score between the two groups,  $p < 0.05$  (Table 2).

The mean pain score on visual analogue scale (VAS) in mm when measured from 0 mm to 100 mm was calculated for each group at 4, 12, 20 and 24 hours after surgery. At 4 hours post surgery the mean VAS score for group T was 20.56 mm as against D group mean of 22.96 mm ( $p = 0.014$ ). The difference in VAS score was found to be highly significant at 12 hours post surgery with  $p = 0.00071$ . At 12 hours mean VAS scores were found to be higher in both groups with score exceeding 30 for 2 patients in group D. Thereafter the VAS score were seen to be significantly declining in both groups and the analgesia was comparable in groups T and D with  $p$  being more than 0.05. (Chart 1).

More patients complained of nausea and vomiting in group T compared to group D. However the overall acceptability of tramadol as analgesia was more (Table 2).

**Table:-1 Demographic profile of patients included in the study.**

Variable	*Group T (n=25)	#Group D (n=25)
Mean age (years)	44.12	43.76
Mean weight (kg)	69.36	68.8
Male/Female	16/9	15/10
Mean surgical time (mins)	79.92	79.28
Mean anesthesia time (mins)	104.33	104.28

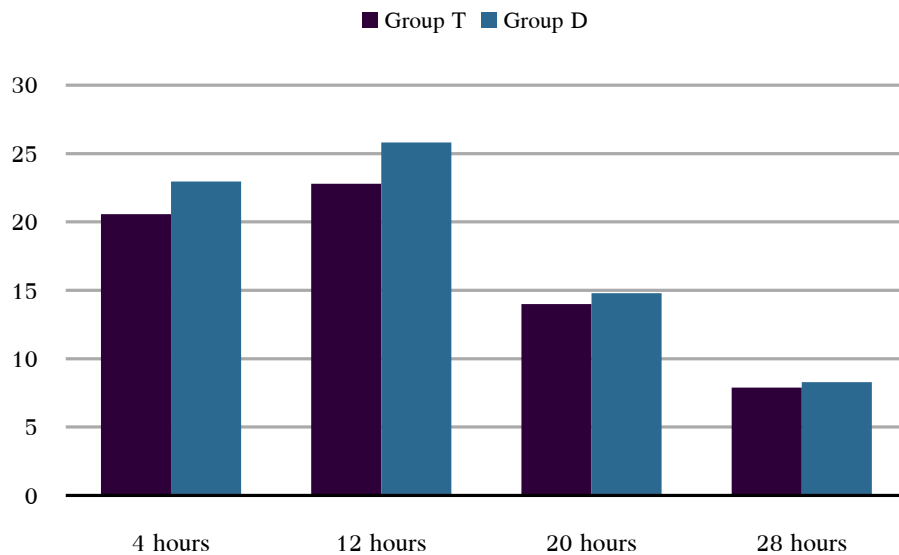
\*Group T: Group Receiving Intravenous Tramadol Post Operatively

#Group D: Group Receiving Intravenous Diclofenac Post Operatively

**Table 2:- Post operative sedation profile and reporting of nausea vomiting in the two groups:**

Variable	Group T (n=25)	Group D (n=25)
Sedation score 1 or 2	21	23
Sedation score 3	4	2
Nausea vomiting present	9	4

No significant difference was found in the sedation score among the two groups. More number of patients reported presence of nausea and vomiting after administering tramadol.



**Chart 1:** Pain scores on VAS. There is significant difference between the two scores at 12 hours with  $p=0.00071$ .  $P < 0.05$  for 4, 20 and 28 hours.

## Discussion:

Good postoperative analgesia is an important component of adequate and perioperative care. This is associated with improved outcome, improved patient satisfaction, reduction in perioperative stress, and coupled with a reduction in opioid consumption, fewer adverse side effects<sup>7,8</sup>. The present study suggests that tramadol reduces pain more effectively than diclofenac following elective laparoscopic cholecystectomy. Intravenous tramadol and intravenous diclofenac are both popular drugs for post operative pain relief following laparoscopic pain relief. The choice of one over the other was hitherto more dependent on the surgeon than clear cut evidence. To our knowledge we did not identify any study comparing the two analgesics tramadol and diclofenac for management of post laparoscopic cholecystectomy pain.

The greater efficacy of tramadol over diclofenac in managing post operative pain is found to be consistent with previous studies that show greater efficacy of opioid analgesics over NSAIDs<sup>9</sup>. In a study comparing tramadol with diclofenac in post cesarean patients it was found that the mean time to rescue dose of diclofenac was much shorter at 55 minutes compared to tramadol at 113 minutes<sup>10</sup>. In our study also we found that specially at 12 hours post surgery the patients in tramadol group reported lesser pain compared to diclofenac group. No patient in the tramadol group required additional dose of analgesia while three patients in diclofenac group had to be given an additional dose of analgesia as the VAS score exceeded 30 mm. In a study comparing diclofenac with tramadol in oral surgery it was however found that diclofenac was more effective with better tolerability profile<sup>11</sup>. Agarwal et al have

however suggested that oral preoperative single dose of pregabalin 150 mg is an effective method for reducing postoperative pain and fentanyl consumption in patients undergoing laparoscopic cholecystectomy. Boccara et al also in their study showed that the preoperative administration of ketoprofen was accompanied by a lower incidence of nausea and vomiting and better pain control following laparoscopic cholecystectomy<sup>12</sup>.

An interesting finding we noted was the increase of VAS scores at 12 hours after surgery compared to 4 hours after surgery. This increase may be attributed to the waning of anesthesia and intra operative analgesia.

A shortcoming in this study was that we did not have additional arms comparing the use of preemptive and preventive analgesia or a combination of drugs. Preemptive analgesia involves giving analgesia before surgery, with the aim of blocking the central sensitization of the nervous system as a result of the surgical incision and inflammatory damage<sup>13</sup>. Preventive analgesia, which may be confused with pre-emptive analgesia, is the commencement of analgesia before completion of surgery<sup>14</sup> or during the early post operative period<sup>15</sup>.

In a study comparing post cesarean analgesia it was found that the use of tramadol and diclofenac together may result in better relief of pain<sup>10</sup>. Therefore a study of such combination in post cholecystectomy may be the subject of future study.

### Conclusion:

In this study we found that even though intravenous tramadol may cause higher chance of nausea and vomiting it is better in relieving pain compared to intravenous diclofenac after laparoscopic cholecystectomy.

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