

## Original Research

### To compare the Diclofenac versus Different Paracetamol for Post-Operative Analgesia After Laparoscopic Cholecystectomy

Deepak Monga

Principal Specialist, Govt. Hospital, Sri Ganganagar, Rajasthan, India

#### ABSTRACT:

**Aim:** To compare the Diclofenac versus Different Paracetamol for Post-Operative Analgesia After Laparoscopic Cholecystectomy. **Methods:** This comparative study conducted in the Department of Anaesthesiology, 80 patients were included in the study. They were divided into two groups with 40 patients in each group. Group DP: Patients received Diclofenac with Paracetamol P (100 ml infusion) and Group DF: Patients received Diclofenac with Paracetamol PL (2 ml stat). Selected patients were from either sex, age group between 20 to 52 year, average weight, belonging to ASA grade I and II posted for laparoscopic cholecystectomy. **Results:** The demographic data showed that the mean age group was 37.1 years, weight was 60.19 kg, height was 161.5 cm and a sex ratio of female/ male=50/30 in either group. The mean duration of operation was  $32.1 \pm 7.9$  minutes and the mean duration of analgesia was  $111 \pm 19$  minutes. VAS taken for post-operative pain assessment was same in both the age groups over equal time interval without significant difference. The requirements of rescue analgesia were also same in both the groups. The patient satisfaction at 6 hour was assessed by taking verbal rating scale, which was same in both the age groups. **Conclusion:** On the basis of present study we concluded that both the group of patients have almost equal analgesic effect and patient satisfaction, when drugs were given as combination therapy in same dose.

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**Corresponding author:** Deepak Monga, Principal Specialist, Govt. Hospital, Sri Ganganagar, Rajasthan, India

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#### INTRODUCTION

Laparoscopic cholecystectomy is regarded as a daycare procedure that requires a shorter duration of hospital stay. Pain significantly reduces after laparoscopic cholecystectomy approach and it shorten the recovery period, therefore, reducing discharge time from 1 to 3 days to same day discharge with an earlier return to a normal life.<sup>1,2</sup> Studies have shown that laparoscopic surgery too causes postoperative pain in at least one-third of the patients and these patients have been seen taking more analgesics to alleviate pain.<sup>3</sup> The type of pain after laparoscopy differs from laparotomy which results mainly in parietal pain (abdominal wall), patients complain more of visceral pain after operative laparoscopy.<sup>4</sup> Different treatments have been proposed to relieve pain after laparoscopy. The choice of different drugs, the timing and route of their administration as well as the dosages are variable. Opioids and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are generally used for management of postoperative pain after

laparoscopic cholecystectomy. However, the clinical importance of infiltration of wounds with local anaesthetic agents, their intraperitoneal application, as well as the choice and dosages of these agents still remain controversial.<sup>5</sup>

Opioids remained the superior choice for severe pain; but their adverse effects demerit their wide use.<sup>6</sup> Opioids, like morphine, have associated respiratory depression, sedation, biliary spasm, decreased gastrointestinal motility, post-operative nausea and vomiting with confusion, in older patients.<sup>7</sup>

Paracetamol and diclofenac, the two non-opioid drugs selected in this study are preferred in post-operative pain reduction where the use of opioids are limited by their adverse effect.<sup>8</sup> Paracetamol is freely available as analgesic in hospital and community settings. In spite of extensive use, its efficacy as postoperative analgesic is still not fully elucidated. With the recent availability of intravenous solution of paracetamol there is increased interest in its use in the peri-operative setting. Paracetamol has been an effective

analgesic in the management of post-operative pain, unaided or as a combination with other analgesics.<sup>9,10</sup> Paracetamol is not linked with higher incidence of gastrointestinal, haematological, renal or the cardiovascular effects associated with non-steroidal anti-inflammatory drugs (NSAIDs), comprising that of selective cyclo-oxygenase-2 (COX-2) inhibitors.<sup>11</sup> Diclofenac a non-steroidal anti-inflammatory drug is administered to reduce inflammation and pain in postoperative period. It may be supplied as either the sodium or potassium salt.<sup>12</sup>

## MATERIAL AND METHODS

This comparative study conducted in the Department of Anaesthesiology, after taking the approval of the protocol review committee and institutional ethics committee. 80 patients were included in the study. They were divided into two groups with 40 patients in each group.

**Group DP:** Patients received Diclofenac with Paracetamol P (100 ml infusion)

**Group DF:** Patients received Diclofenac with Paracetamol PL (2 ml stat)

Selected patients were from either sex, age group between 20 to 52 year, average weight, belonging to ASA grade I and II posted for laparoscopic cholecystectomy. Patients with history of drug allergy, bleeding disorders<sup>13,14</sup>, asthma, gastro intestinal system bleeding, renal insufficiency, etc were excluded from the study.

Patient was taken into the pre-operative preparation room where intravenous (I.V) cannula was secured and 1 mg midazolam was given slow I.V. Then patient was shifted to the operation theatre and standard monitors ECG, NIBP and pulse oximeter were attached. All the patients were given injection 0.2 mg glycopyrolate I.V, 1 mg/kg body weight ondansetron I.V, 2 mg/kg fentanyl I.V as premedication. Induction was performed with 2 mcg/kg propofol I.V and after loss of consciousness 0.1 mg/kg vecuronium bromide I.V was given for muscle relaxation. Then patient was pre-oxygenated for 3 minutes and adequate size of I-gel was secured for ventilation. After confirming the proper placement of I-gel, anaesthesia was maintained with 1 litre of oxygen and 2 litres of nitrous oxide followed by propofol infusion. Stomach was decompressed with 10 Fr size of orogastric tube via side port of I-gel. Tidal volume and respiratory rate was adjusted to

maintain the EtCO<sub>2</sub> between 35-45 mm Hg. After 10 minutes of starting of surgery patients of DP group received 75 mg of diclofenac sodium aqueous I.V over a period of 10-15 minutes followed by paracetamol infusion (P) 15 mg/kg. DF group received diclofenac sodium I.V of same dose given over same period and paracetamol (PL) in same dose. After completion of surgery the muscle relaxant was reversed with injection neostigmine 0.05 mg/kg and glycopyrolate 0.01 mg/kg I.V. Once the patient gained full consciousness then shifted to post-operative care unit, where the patient was monitored for next 6 hours. The anaesthesiologist who was blinded for the study was asked to visit the patient at 30 minutes, 1 hour, 2 hour, 4 hour and 6 hour. He was also asked to keep the record of VAS score, any side effect like nausea, vomiting, headache, sedation, dizziness, rashes, neuralgia, myalgia, respiratory depression, hypotension or hypertension, bradycardia or tachycardia, shoulder pain, etc. Duration of analgesia was also recorded, starting from the time of administration of NSAIDs to perception of pain.<sup>15</sup> A four point verbal rating scale was used to assess the patient satisfaction following administration of analgesic drugs: Poor control, Fair control, Good control, Excellent control.

## STATISTICAL ANALYSIS

Statistical analysis was conducted using SPSS 24.0 software and comparisons among the groups were analyzed by using Chi-square test.

## RESULTS

The demographic data showed that the mean age group was 37.1 years, weight was 60.19 kg, height was 161.5 cm and a sex ratio of female/ male=50/30 in either group. The mean duration of operation was 32.1 ± 7.9 minutes and the mean duration of analgesia was 111 ± 19 minutes (Table 1). VAS taken for post-operative pain assessment was same in both the age groups over equal time interval without significant difference (Table 2). The requirements of rescue analgesia were also same in both the groups. The patient satisfaction at 6 hour was assessed by taking verbal rating scale, which was same in both the age groups (Table 3). There was no significant difference in incidence of side effect among both the groups (Table 4).

**Table 1: Demographic data of the patients**

Demographic data	Group DP	Group DF	P value
Age (in years)	37.2 ± 5.9	37.1 ± 6.1	>0.05
Sex (M/F)	50	30	>0.05
Weight (kg)	60.1 ± 10.5	59.8 ± 3.2	>0.05
Height (cm)	160.77 ± 11.36	161.78 ± 3.99	>0.05
Duration of Operation (in min)	32.11 ± 8.22	31.09 ± 11.25	>0.05
Duration of Analgesia (in min)	111.18 ± 7.88	111.21 ± 8.55	>0.05

**Table 2: VAS pain score of the patients**

Time	Group DP	Group DF	P value
30 min	4.35 ± 1.24	4.38 ± 1.39	>0.05
60 min	3.98 ± 1.26	3.99 ± 1.39	>0.05
120 min	3.54 ± 1.9	3.58 ± 1.28	>0.05
240 min	3.37 ± 1.6	3.78 ± 1.28	>0.05
6 hour	3.48 ± 1.90	3.50 ± 1.74	>0.05

**Table 3: Patient satisfaction at 6 hour of operation using Verbal Rating Scale**

Verbal rating scale	Group DP	Group DF	P value
Poor 1	2	2	>0.05
Fair 2	8	7	>0.05
Good 3	23	24	>0.05
Excellent 4	7	7	>0.05

**Table 4: Incidence of side effects**

Side effects	Group DP	Group DF	P value
Nausea and Vomiting	3	3	>0.05
Sedation	0	0	>0.05
Headache	3	2	>0.05
Restlessness	1	0	>0.05
Dizziness	1	1	>0.05
Rashes	0	0	>0.05

## DISCUSSION

Postoperative pain management is one of the most important and an ever challenging task for an anaesthesiologist. Postoperative pain is variable in duration, intensity and character and is the main factor delaying discharge of patients undergoing day-care procedures including laparoscopy and hence adding to the hospital cost. Pain after laparoscopic surgery may vary in quality and localization and is reported in several trials to be incisional, intra-abdominal, or referred (shoulder tip). The aetiology is complex, it could be due to damage to abdominal wall structures, visceral trauma, inflammation or peritoneal irritation because of carbon dioxide entrapment beneath the haemidiaphragms.<sup>16</sup>

The analgesics used for post-operative pain control are either opioids or NSAIDs or both. Diclofenac sodium is the most extensively used NSAID for this purpose. It has got analgesic, anti-inflammatory and antipyretic effect. It inhibits prostaglandin synthesis and somewhat COX-2 selective. Paracetamol is N-acetyl-Para amino-phenol diethyl amino acetic ester. It has got a good antipyretic effect and weak anti-inflammatory action. Paracetamol is available in two forms in market, as described in the introduction.

Beck et al. carried out a study among patients undergoing gynecological surgery involving vaginal and abdominal hysterectomies, in which they used paracetamol 20 mg/kg, 40 mg/kg alone and paracetamol 20 mg/kg single rectal dose in combination with diclofenac sodium 100 mg with a observational period of 24 hour after surgery, the result showed that combination of drugs had better pain management than paracetamol alone.<sup>17</sup> Breivik et al. carried out study in patients undergoing dental

surgery with impacted IIIrd molar tooth, he used diclofenac 100 mg, paracetamol 1000 mg alone and diclofenac 100 mg with paracetamol 1000 mg single rectal dose with 8 hours of observational period.<sup>18</sup> He observed that combination therapy has better pain control with 13-20% and 25-30% incidence of nausea and vomiting respectively. Matthews et al. used diclofenac 50 mg alone, diclofenac 50 mg with paracetamol 500 mg and used paracetamol 500 mg single oral dose before dental surgery for impacted IIIrd molar tooth with 12 hours observational period and found that pain intensity negative and no adverse effect.<sup>19</sup> Montgomery et al used paracetamol 1500 mg alone, diclofenac 100 mg alone and paracetamol 1500 mg in addition to diclofenac 100 mg single rectal dose given before surgery with 24 hours of observation following elective gynecological surgery. He found pain intensity to be positive and higher percentage of nausea and vomiting, which could be due to morphine used in higher doses.<sup>20</sup> Munishankar et al also found same result as Montgomery et al.<sup>21</sup> Riad et al carried out a study in children undergoing inguinal hernia surgery and they used diclofenac 1 mg/kg, paracetamol 40 mg/kg and a combination of diclofenac 1 mg/kg with paracetamol 40 mg/kg, in which all drugs were given rectally 1 hour before surgery. They found pain intensity to be lesser in combination of drug.<sup>22</sup> Siddik et al used placebo, diclofenac 100 mg rectally, paracetamol 2 gm I.V. and combination of paracetamol 3 gm I.V. 6 hourly with diclofenac 100 mg rectally 8 hourly for 24 hours following caesarean section operation. They found that pain was significantly lower in combination group and no difference in incidence of nausea and vomiting.<sup>23</sup> Hyllested et al. documented the analgesic

efficacy was better in combination than paracetamol alone in regards to pain score, rescue analgesia and pain relief.<sup>24</sup>

## CONCLUSION

On the basis of present study we concluded that both the group of patients have almost equal analgesic effect and patient satisfaction, when drugs were given as combination therapy in same dose

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