International Surgery Journal
Bijalwan A et al. Int Surg J. 2019 May;6(5):1716-1722
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: http://dx.doi.org/10.18203/2349-2902.isj20191896

Original Research Article

A comparative evaluation of analgesic effects of using intravenous paracetamol versus intravenous diclofenac post-operatively in laparoscopic cholecystectomy patients in SMIH, department of surgery, Dehradun

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Received: 13 February 2019
Revised: 13 March 2019
Accepted: 14 March 2019

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ABSTRACT

Background: Post-operative adequate analgesia plays an important role in early mobilization, short hospital stay and patient satisfaction in laparoscopic cholecystectomy. The use of opioids for providing postoperative analgesia has been marked by side effects like vomiting, nausea, sedation, respiratory distress, etc. hence, alternate drugs like paracetamol (PCM) and diclofenac are commonly used. In this study, we have compared the analgesic efficacy and any associated side effects of the two commonly used non-opioid NSAIDS namely paracetamol and diclofenac.
Methods: We compared 50 patients undergoing laparoscopic cholecystectomy in ASA I and II. They were randomly divided into two groups, Group A and Group B. Group A was administered intravenous PCM and Group B was administered injection diclofenac sodium. Postoperatively, these patients were assessed for pain, blood pressure, respiratory rate, and presence of any side effects like nausea, vomiting or any respiratory discomfort.
Results: The mean DBP, MAP and VAS score was significantly (p-value <0.05) in Group A as compared to Group B patients at 4, 8, 12 and 24 hours postoperatively. There was no statistically significant difference in mean SBP and O_2 saturation in both groups. The mean pulse rate was lower in Group A as compared to Group B at 8, 12 and 24 hours.
Conclusions: This study concluded that postoperative PCM infusion provided better analgesia for a prolonged period of time with minimal side effects.

Keywords: Lap cholecystectomy, Analgesia, Paracetamol, Diclofenac

INTRODUCTION

Laparoscopic cholecystectomy, first performed by Prof Dr Med Erich Mühe of Böblingen, Germany, on September 12, 1985, continues to be the gold standard in management of cholelithiasis.[1] It causes lesser postoperative pain, shorter hospital stay, and fewer complications.[2,3] However, inadequate analgesia in postoperative period mitigates all the aforementioned gains. The postoperative pain is somatic in nature at the incision site and visceral at the gall bladder bed. Stretching of diaphragm due to CO_2 infusion also contributes to the postoperative pain especially in right shoulder region.[4] Sometimes, pain may last for 24-72 hours leading to delay in hospital discharge of patients.[5] Postoperative pain additionally reduces patient well-being and satisfaction from surgery.[6,7] If not attended properly it could lead to a chronic pain condition.[8] Lack of adequate analgesia may cause reduced cough reflex, impaired breathing causing hypoventilation. Previously, opioid analgesics were used to relieve pain primarily, however, their usage was associated with several side

effects such as respiratory depression, sedation, biliary spasm, constipation, nausea and vomiting.[9,10] This necessitated the use of NSAIDS, which inhibit the cyclooxygenase pathway and decrease prostaglandin synthesis, thus breaking the vicious pain cycle.[9]

The use of Paracetamol and Diclofenac intravenously with opioids used only as rescue analgesia has reduced the dose of analgesia with minimal side effects while ensuring a better postoperative recovery.[11]

This study was conducted to compare the postoperative analgesic effects of paracetamol and diclofenac in laparoscopic cholecystectomy patients. The primary objective of this study was to compare visual analogue pain scores (VAS) of groups receiving paracetamol and diclofenac, to compare the proportion of patients requiring rescue analgesia in both groups within 24 hours of surgery. Postoperative vitals and side effects associated with analgesic usage were also compared in this study additionally.

METHODS

This study was conducted in department of General Surgery, Shri Guru ram Rai Institute of Medical and Health Sciences and associated Shri Mahant Indresh Hospital, Dehradun. Total of 50 patients undergoing for laparoscopic cholecystectomy were recruited for this study for a period of one year, from September 2017 to September 2018. The permission for conduct of this study was taken from Institutes Ethical Committee (IEC) and informed consent was taken from each study participants before enrollment in this study. The study participants were allocated randomly in two groups on the basis of analgesic they receive. The randomization was done by drawing one of the two labeled cards from sealed opaque envelope.

Inclusion criteria

Patients aged 18-64 years having American Society of Anesthesiologist (ASA) grade I and II willing to give consent were considered for this study.

Exclusion criteria

Patients aged below 18 years, ASA grade III and IV, patients with known allergy to NSAIDS, patients with renal or hepatic dysfunction like cholecystitis/ emphysema of gall bladder/acute pancreatitis/ pancreatitis after ERCP.

Intervention

After randomization of the patients in two groups (Group A and B), they were shifted to OT and all basic parameters were recorded including pulse rate, blood pressure, SPO_2 and RR. All the patients received similar premedication by the anesthetic.

Group A patients received injection paracetamol at rate of 15 mg/kg (maximum 1 gm) in 100 ml infusion and Group B patients received injection diclofenac at rate of 2mg/kg (maximum 75 mg) in 100 ml normal saline.

Both the drugs were administered approximately 15 minutes prior to completion of surgery. In Group A repeat dose of analgesia was given at 8 hourly interval and in Group B repeat dose was given at 12 hourly intervals.

All the parameters (PR, SBP, DBP, SPO_2 and RR) were recorded at 2, 4, 8, 12 and 24 hours postoperatively from both the groups. VAS score was recorded on the basis of visual analogue Wong Baker scale. Mild pain was categorized between 1-3 score, moderate pain between 4-6, and pain score >7 was categorized as severe. Rescue analgesia in form of I.V. tramadol 50 mg in 100 ml normal saline was administered for VAS score ≥7 or in patients complaining severe pain. Any complications like nausea, vomiting, etc were recorded in both the groups.

The data obtained was entered in SPSS version 23 software and analyzed. Independent t-test was used for comparing means of both groups and chi-square test was used to compare proportions of both groups. P-value <0.05 was considered significant.

RESULTS

Of all 50 patients, 41 (82%) were females reinforcing the well-known fact about increased prevalence of gall stones in females as compared to males. The mean (S.D.) age of males in group A was 39.58 (10.36) while that in group B was 39.62 (7.33). The mean (S.D.) age of females in group A was 39.77 (7.19) and in group B was 40.58 (8.64). The demographic variables were similar in both groups and p value was >0.05 in all the parameters (Table 1).

Table 1: Demographic variables of group A (paracetamol) and B (diclofenac).

Variables (n_1=n_2=25)		Group A (paracetamol)	Group B (diclofenac)	P value
Sex	M	4	5	NS
	F	21	20	NS
Age (in years)	M	39.58±10.36	39.62±7.33	NS
	F	39.77±7.19	40.58±8.64	NS

NS- Not significant (p>0.05).

Table 2: Comparison of Mean (S.D.) pulse rate of group A (paracetamol) and B (diclofenac).

Time interval (in hours)	Group A (paracetamol) Mean±SD	Group B (diclofenac) Mean±SD	P value
0	80.16±4.39	81.28±4.46	0.376 (NS)
2	84.72±6.73	80.40±4.51	0.010 (S)
4	81.48±6.65	80.32±5.68	0.488 (NS)
8	82.12±4.83	93.60±2.77	0.000 (S)
12	81.52±5.08	91.76±1.94	0.000 (S)
24	84.32±3.81	94.32±2.42	0.000 (S)

Table 3: Comparison of the mean (S.D.) systolic blood pressure (SBP) in group A (paracetamol) and B (diclofenac)

Time interval (in hours)	Group A (paracetamol) Mean±SD	Group B (diclofenac) Mean±SD	P value
0	123.20±12.15	127.20±8.90	0.191 (NS)
2	123.40±13.56	123.12±7.96	0.686 (NS)
4	122.00±12.58	124.40±9.60	0.452 (NS)
8	120.00±16.31	124.00±9.57	0.402 (NS)
12	120.80±12.88	123.60±9.07	0.379 (NS)
24	119.20±11.87	123.20±12.49	0.252 (NS)

Table 4: Comparison of mean (S.D.) diastolic blood pressure (DBP) in group A (Paracetamol) and B (Diclofenac).

Time interval (in hours)	Group A (paracetamol) Mean±SD	Group B (diclofenac) Mean±SD	P value
0	74.00±7.07	80.40±8.88	0.007 (S)
2	81.68±6.23	80.80±8.62	0.681 (NS)
4	74.80±7.14	82.40±8.30	0.001 (S)
8	73.20±9.00	83.60±9.52	0.000 (S)
12	74.80±6.53	80.00±10.00	0.034 (S)
24	75.60±8.69	81.20±6.00	0.011 (S)

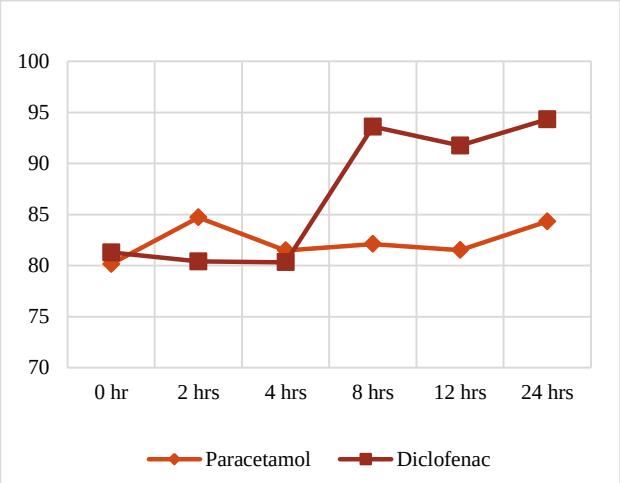

Figure 1: Line diagram showing comparison of mean pulse rate at different interval.

The line diagram of mean pulse rate depicts that pulse rate in this study was in physiological range (80-95), and the mean pulse rate in diclofenac group was higher after 4 hours postoperatively as compared to paracetamol group (Figure 1).

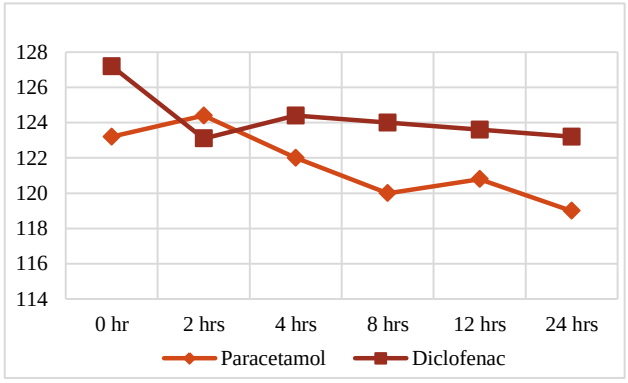

Figure 2: Line diagram showing comparison of mean SBP at different interval.

The postoperative pulse rate laid in a physiological range in both groups. At 2 hour, the mean (84.72) pulse rate in group A was significantly higher than that of group B (80.40). However, at 8, 12 and 24 hours postoperatively, the mean pulse rate of diclofenac group was higher significantly from paracetamol group ($p<0.05$). This reflected on the better and prolonged postoperative analgesia by paracetamol (Table 2).

The line diagram comparing mean SBP of diclofenac and paracetamol group showed that the mean systolic blood pressure in diclofenac group remained higher than that of paracetamol group except at 2 hours postoperative time interval (Figure 2).

In the initial postoperative period (up to 2 hours), the mean SBP of group 2 was higher (mean 127.2, S.D. 8.9) as compared to PCM group (mean 123.2, S.D. 12.15). At 2 hours, both were similar while after that at 4, 8, 12 and 24 hours, mean SBP of group A remained lower than that of group B. However, there was no statistically significant difference in SBP in both groups at any point ($p>0.05$). The mean systolic blood pressure remained within physiological range in both groups throughout the study duration (Table 3).

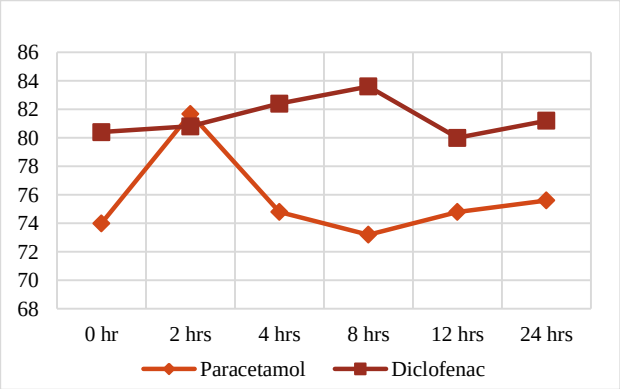

Figure 3: Line diagram showing comparison of mean dbp at different interval.

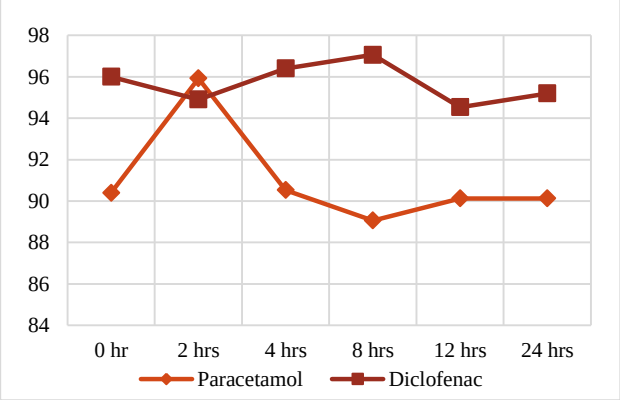

Figure 4: Line diagram showing comparison of mean MAP at different interval.

The line diagram showing trend of mean diastolic blood pressure in diclofenac and paracetamol groups depicts that mean DBP of diclofenac group remained higher than Paracetamol group except at 2 hours duration (Figure 3).

In this study, mean DBP was significantly higher in group B as compared to group A except at 2 hours ($p<0.05$). The mean DBP at 2 hours in group A (81.68) was higher than that of group B (80.8). The difference of mean DBP at 2 hours was statistically not significant with p-value of 0.68. The mean DBP ranged between 74 to 75.6 mm Hg in group A as compared to mean DBP range between 80.4 to 81.2 mm Hg in group B (Table 4).

The line diagram comparing mean MAP at different study intervals shows that mean MAP of group A was lower than that of group B throughout the study except at 2 hours postoperative time period. The mean MAP in group A ranged between 88-96 mm Hg and in group B ranged between 94-98 mm Hg (Figure 4).

In the current study, the mean MAP, similar to DBP, was lower in group A as compared to group B at all instances ($p<0.05$) except at 2 hours, where the MAP was higher in PCM group (95.92) than Diclofenac group (94.9). The MAP ranged from 90.4-90.13 in group A and 96 to 95.2 in group B. The difference in mean MAP between both groups was found statistically significant ($p<0.05$) at all time intervals except at 2 hours (Table 5).

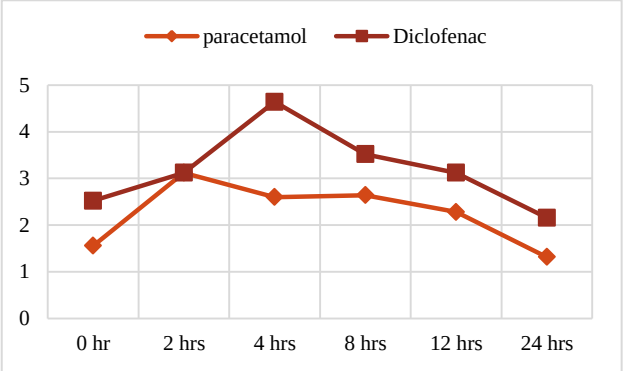

Figure 5: Line diagram showing comparison of mean VAS at different interval.

The line diagram showing changes in mean VAS of both groups at different time intervals depicts that mean VAS was higher in diclofenac group as compared to Paracetamol group except at 2 hours postoperative time period where both were equal. The mean VAS ranged between 1-3 in group A and 2-5 in group B (Figure 5).

The mean VAS score in group A was lower than mean VAS score in group B ($p<0.05$) in all instances except at 2 hours, were both mean VAS score were equal. This further illustrated the better patient comfort and pain control in group A (paracetamol) patients. The mean VAS was lowest at 24 hours postoperative time period with value of 1.32±0.50 in group A and 2.16±1.34 in group B (Table 6).

Further, 6 out of 25 patients (24%) in group B required rescue analgesia (Tramadol, 50 mg) as compared to only 2 out of 25 patients in group A.

In group B, 3 (12.1%) patients complained of vomiting and received Inj. Emset (4 mg) for that while none had such complaints in group A.

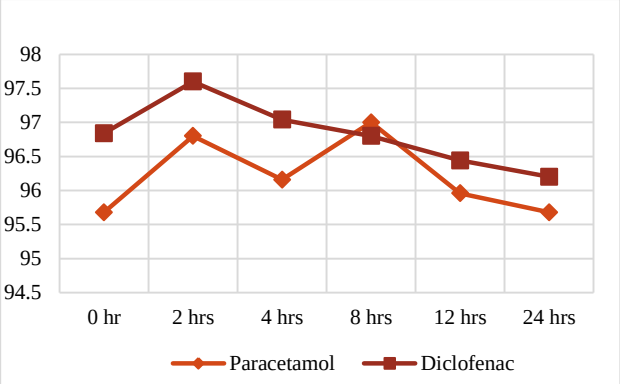

Figure 6: Line diagram showing comparison of mean VAS at different interval.

The mean O_2 saturation was within physiological range in both the groups throughout the study period. However, the O_2 saturation was higher in diclofenac group as compared to Paracetamol group at all time intervals except at 8 hours (Figure 6).

The mean O_2 saturation remained above 95.68 in both groups. The mean O_2 saturation in group A ranged between 95.68 to 97, while that in group B ranged between 96.2 to 97.6. There was no statistically significant difference in both groups at any point of study with regards to mean O_2 saturation ($p>0.05$) (Table 7).

Table 5: Comparison of mean (S.D.) mean arterial pressure (MAP) in group A (paracetamol) and B (diclofenac).

Time Interval (in hours)	Group A (paracetamol) Mean MAP±SD	Group B (diclofenac) Mean MAP±SD	P value
0	90.4±5.76	96±5.96	0.002 (S)
2	95.92±6.41	94.9±6.48	0.579 (NS)
4	90.53±6.97	96.4±6.46	0.004 (S)
8	89.06±7.39	97.06±6.75	0.000 (S)
12	90.13±5.69	94.53±6.39	0.016 (S)
24	90.13±5.29	95.2±6.4	0.006 (S)

Table 6: Comparison of mean (S.D.) VAS score in group A (paracetamol) and B (diclofenac).

Time Interval (in hours)	Group A (paracetamol) Mean±SD	Group B (diclofenac) Mean±SD	P value
0	1.56±1.26	2.52±1.29	0.011 (S)
2	3.12±1.25	3.12±0.93	1.00 (NS)
4	2.60±0.58	4.64±1.35	0.000 (S)
8	2.64±0.64	3.52±1.50	0.010 (S)
12	2.28±0.68	3.12±1.81	0.035 (S)
24	1.32±0.50	2.16±1.34	0.005 (S)

Table 7: Comparison of mean (S.D.) O_2 saturation in group A (paracetamol) and B (diclofenac).

Time Interval (in hours)	Group A (paracetamol) Mean±SD	Group B (diclofenac) Mean±SD	P value
0	95.68±2.78	96.84±1.50	0.074 (NS)
2	96.80±2.12	97.60±0.76	0.086 (NS)
4	96.16±2.01	97.04±2.79	0.208 (NS)
8	97.00±1.15	96.80±1.08	0.530 (NS)
12	95.96±1.74	96.44±1.04	0.245 (NS)
24	95.68±1.65	96.20±1.41	0.238 (NS)

DISCUSSION

The findings of this study broadly posed paracetamol as a better option for analgesia in laparoscopic cholecystectomy as compared to diclofenac especially in case of long-term analgesia (>4 hours) secondary to low mean DBP, MAP, PR and VAS score in Paracetamol group (group A) which was consistent with previous studies.

With reference to previous studies, our study was in contrast with those of Goel et al, who found significant variation in mean changes of pulse rate between the groups from 1-4 hours after surgery.[12] However, studies by Patel et al, Amin et al, Gohil et al, Paul et al did not

find any significant difference in both study groups. Also, Paul et al found initial rise of PR due to anxiety.[13-16]

In case of systolic blood pressure (SBP), it was found that mean of Paracetamol group was lower than that of diclofenac group in all studies.[12-14] Moreover, in study by Goel et al, difference of SBP was found in both groups after 4 hours of study.[12] Mean Diastolic blood pressure on the other hand, was found in Paracetamol group less than Diclofenac group but was not significant.[14,15]

In current study, mean DBP was found significantly less in Group A than Group B from 4 hours onwards. This may be due to better pain control in Paul et al did not found any significant difference in both groups except at 12 hours.[16] This can be attributed to inhibitory effect of Diclofenac on cyclooxygenase pathway preventing the conversion of arachidonic acid to PG and thromboxane.

Mean MAP in our study was significantly lower in PCM group at 4th hour onwards due to better pain control with PCM.

In our study we found the immediate post-operative recovery VAS score was comparable in both groups, but it became higher in diclofenac group 4th hour onwards. Mean VAS score was found significantly lower in Paracetamol group as compared to diclofenac group in all studies including this study.[12-15] Amin et al found higher VAS score in diclofenac group in initial 2 hours which increased afterwards.[14] Yoganarasimha et al, too observed lesser VAS score with PCM upto 5 hours while VAS score in diclofenac group peaked after 4 hours.[10]

Amin et al in their comparative study did not have any patients with complaints of postoperative nausea or vomiting as similar to findings of current study.[14] Paul et al attributed this to better pain control in PCM group as compared to diclofenac group.[16]

CONCLUSION

In our study we reached the conclusion that 1 gm of intravenous paracetamol given about 15 minutes prior to conclusion of surgery followed by 1 gm of intravenous paracetamol every 8 hourly, not only gives better and prolonged analgesia than diclofenac, as evidenced by low VAS score, but also with lesser complications like nausea and vomiting due to lesser or no requirement for rescue analgesia.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Bijalwan A, Singhal P, Altamash S. A comparative evaluation of analgesic effects of using intravenous paracetamol versus intravenous diclofenac post-operatively in laparoscopic cholecystectomy patients in SMIH, department of surgery, Dehradun. Int Surg J 2019;6:1716-22.