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Comparison of Analgesic Effect of Intravenous Paracetamol and Intravenous Diclofenac for Perioperative Analgesia in Laparoscopic Cholecystectomy

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Abstract:
Background*- Despite the minimal invasive nature laparoscopic surgery, postoperative pain in patients is substantial and limits an otherwise speedy recovery. Adequate analgesia is of the utmost importance for early ambulation and discharge reducing hospital stay. The use of opioid drugs for pain control during and after surgery is a common procedure in anaesthesia. However, their use is associated with side effects such as nausea, vomiting, sedation, and respiratory depression. Parecetamol and diclofenac the two non opioid drugs that are being used in perioperative period were selected to evaluate their relative efficacy.*
Methods*- The study was conducted in 50 patients aged between 18-65 years belonging to ASAI and II. The patients were randomly divided in two groups. Group A received paracetamol and Group B was administered diclofenac sodium. Both groups were assessed and general anaesthesia was given. Post operatively all patients were monitored for hemodynamic parameters, pain score and side effects.*
Results*- Profiles of hemodynamic changes were almost similar in both groups in respect of heart rate and blood pressure. However, paracetamol infusion provided hemodynamic stability both during and after surgery. Most of the patients in paracetamol group had VAS score < 7 for more the 5 hours after the surgery and provided an extended analgesia compared to diclofenac. No serious postoperative complication was observed in patients given paracetamol*
Conclusion*- Paracetamol infusion provides better and prolonged anaesthesia with low pain scores and lesser requirement for rescue analgesia compared to diclofenac. It also affects hemodynamic stability. No immediate postoperative complications were observed in patients who received paracetamol.*
Keywords: *Laparoscopic cholecystectomy,intravenous paracetamol, diclofenac sodium,*

I. Introduction

Since the introduction of Laparoscopic Cholecystectomy by Phillipe Mouret in 1987 [1] laparoscopy surgery is the most popular trend in recent days because of lower post operative morbidity including faster recovery time, shorter hospital stay, less pain and in some cases fewer complications [2,3] However, concern for the post operative pain remains the same. Despite the minimal invasive nature of this surgery, postoperative pain in patients undergoing laparoscopic surgery may be substantial and limit an otherwise speedy recovery. Post operative pain differs from patient to patient depending upon the site and nature of operation. Individual variations in response to pain are influenced by the genetic makeup, cultural background and gender [4].

Pain after laparoscopic cholecystectomy is usually acute in character that starts with the surgical trauma and ends with tissue healing [5, 6,7]. Although it is less intense than following open cholecystectomy, some patients still feel considerable discomfort during first 24-72 postoperative hours which can delay their discharge [8]. The origin of the pain after the surgery is multifactorial [9]. Pain arising from incision site being somatic pain whereas pain from the gall bladder bed being mainly visceral in nature and shoulder pain is mainly due to the residual CO_2 irritating the diaphragm.

Post operative pain not only affects the patients operative outcome, well being and satisfaction from medical care, but also may in some cases result in complications of serious nature [10,11]. In untreated cases it could lead to chronic postoperative pain after surgery [12]. . Fear and anxiety may aggravate post operative sufferings by causing rigid muscle contraction in an attempt to splint operative site [13] Lack of proper analgesia may cause the patients to hypo ventilate, thereby causing the reduction in vital capacity and other lung functions. It also affects cough reflexes.

Adequate analgesia is of utmost importance for early ambulation and discharge reducing hospital stay. The use of opioids for pain control during and after surgery is a common procedure in anaesthesia and a preferred choice for severe pain [14]. However, the use of these drugs is associated with side effects such as

nausea, vomiting, sedation, and respiratory depression [15]. Prescribed method of reducing and minimising side effects is concomitant administration of nonopioid analgesics [16]. Some of these are NSAIDS including diclofenac and paracetamol. Primary mechanism of these drugs is to inhibit the cyclooxygenase and prostaglandin synthesis which is considered to be important factor in the prevention of hypersensitivity and pain [14].

The use of IV paracetamol or IV diclofenac as analgesia, using an opioid as rescue analgesic only when needed, would reduce the amount of opioid used and ensure a comfortable postoperative recovery period. Parecetamol and diclofenac are the two non opioid drugs that are being used in perioperative period [17]. Paracetamol is one of the most ubiquitous drugs in hospitals and community settings. With the recent availability of an intravenous solution, its use is revitalised especially in the perioperative setting. Diclofenac is non steroidal anti inflammatory drug taken or applied to reduce inflammation and as an analgesic to reduce pain in certain conditions [18].

The study was thus conducted to compare the effects of paracetamol and diclofenac as peri operative analgesic in laparoscopic cholecystectomy. Main aim was to assess the postoperative visual analogue pain scores (VAS) and requirement of additional analgesic, despite administration of paracetamol or diclofenac in post operative period.

II. Materials And Methods

After obtaining approval of Ethics Committee of Government Medical College Srinagar, informed written consent was obtained from 50 patients aged between 18-65 years belonging to ASA class I and II scheduled for laparoscopic cholecystectomy. Patients having contraindication to paracetamol or to NSAIDs and patients on treatment with steroids, NSIADs or opioids before surgery were excluded. The patients were divided into two groups of 25 each irrespective of age and gender. Randomization was done by drawing one of two labelled cards (A&B) from a sealed opaque envelope.

In Group A IV paracetamol 1 mg/kg (maximum 1g in 100ml infusion) over 15-20 minutes, 30 min prior to the end of surgery was given. In group B IV diclofenac sodium 2mg/kg maximum 75 mg in 100 ml of normal saline 30 minutes prior to the end of surgery was administered.

Prior to the day of surgery all patients underwent pre anaesthesia check-up with routine and subjective investigation as per requirement. The patients were pre medicated and explained about the Visual Analogue Score (VAS).

After shifting to the operation theatre all standard monitoring equipments were connected and IV line secured. The baseline parameters like pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) , respiratory rate, oxygen saturation (spO_2) of all the patients were recorded. Patients were premedicated with inj pantoprazole 40 mg IV, inj dexamethasone 4 mg IV and inj tramadol1 mg/kg i v.

After preoxygenation anaesthesia was induced with inj propofol 2mg/kg i v. Intubation was achieved with inj vecuronium 0.1mg/kg iv. Anaesthesia was maintained with oxygen, nitrous oxide, isoflurane and vacuronium. The lungs were mechanically ventilated.Vital parameters including pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), and oxygen saturation were recorded at an interval of 5 minutes from time zero till the end of surgery. At the end of the surgery residual neumuscular blockade was reversed. The assessment of post operative pain in immediate postoperative period and further at 1h, 2h, 4h, 6h and 12 h was made. The changes in the pulse rate and respiratory rate at different time intervals were also recorded.

After extubation patients were transferred to PACU for assessment of postoperative pain. The patients were given rescue drug when the pain severity score was high and when they themselves complained of pain.

Side effects such as nausea, vomiting, respiratory depression, itching allergic reaction, stomach irritation, diarrhoea and constipation were cross examined and recorded. Post operative pain score was measured by using visual analogue scale (VAS) of 0 to 10, where 0 indicated no pain and 10 most severe pain after admittance to the recovery room. Post operative pain was observed at the interval of 15min, 1 h, 2h, 4h,6h and 12h. Pain scores were reported as pain at rest. Postoperatively Tramadol was given as rescue analgesic when VAS score was >7. Data were expressed as mean $\pm$SD and the statistical analysis was performed using a standard software package.

III. Results

The study was successfully conducted on all the 50 patients and there was no perioperative protocol deviation. The demographic data reveals that both groups are comparable in age, weight, sex and ASA grade (Table 1). There was no statistically significant difference in the duration of surgery. The surgery lasted for 47.83$\pm$ 5.56 min in Group A patients, it was 46.20 $\pm$7.07 in respect of Group B. There were 15 female patients in Group A and 14 in Group B suggesting that gall bladder stones are more prevalent in females than males.

Table 1 Comparison of various demographic parameters between two groups

Variable	Group A (n=25)	Group B (n= 25)	P value
Age (years)	46.93 ±8.31	48.44±6.34	> 0.05
Weight (Kg)	57.50 ±2.50	56.50± 2.60	> 0.05
ASA (I/II)	20/10	22/8	>0.05
Sex Male/Female	10/15	11/14	>0.05
Duration of Surgery	47.83 ± 5,56	46.20±7.07	> 0.05

The pain intensity score (Table 2, Fig 1,2) reveal that pain intensity score increased with hours. In paracetamol group peak was 6 hours after operation while in Group B patients the peak was reached 2 hours after operation. It is also observed that the lower VAS score in paracetamol group lasted for more than 5 hours and time to first request for rescue analgesia was longer for paracetamol as compared to diclofenac. Comparing the requirement of rescue analgesia to patients with pain score > 7 it is observed that number of patients who required rescue analgesia was 12 after 2 hours of surgery in Group B given diclofenac. However, the patients who had >7 pain score was comparatively less in group A. Only 8 patients administered paracetamol were given rescue analgesic and that too after 6 hours of surgery.

Table 2. Comparison of mean pain scores (VAS) between Group A and Group B

Time interval	n= 30		p value
	Group A (Paracetamol)	Group B (Diclofenac)	
0 h	1.57± 1.01	o.76 ± 0.75	0.005
1h	1.69 ± 0.76	1.87 ± 0.98	0.003
2h	1.77 ± 0.86	3.09 ± 0.85	0.511
4h	1.87 ±0.87	2.78 ± 1.98	0,001
6h	2.98 ± 1.15	2.43 ± 1.89	0.005
12h	1.31 ± 1.45	1.89 ± 1.13	0,301

Figure 1 Number of patients having VAS score > 7

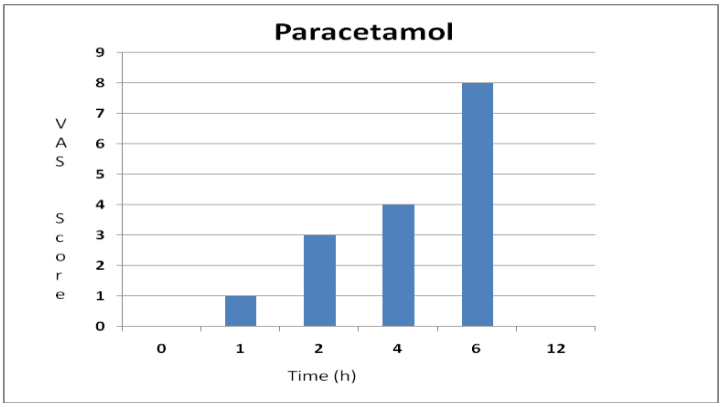
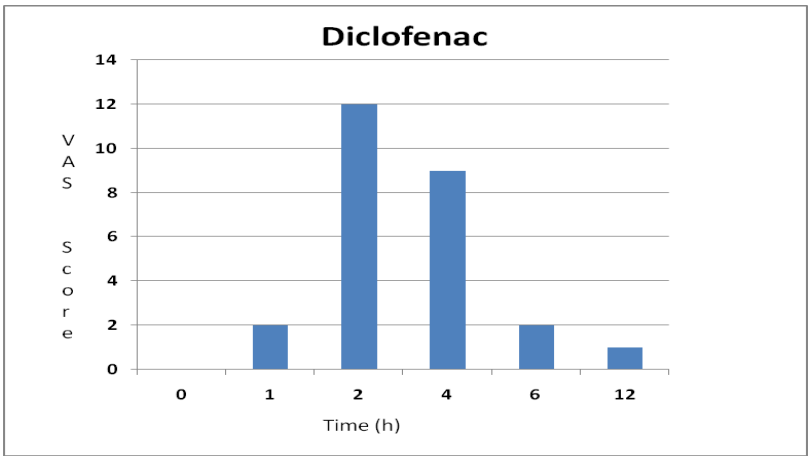


Fig 2. Number of patients having VAS Score > 7



While comparing the pulse rate it was observed that there is no significant variation in both the groups (Table 3).Pulse rate was in the increasing trend immediately after recovery from the anaesthesia which however, decreased at 4 hour interval. Mean changes of pulse rate at different intervals is insignificant. On observing the mean changes in the baseline values of vital parameters after 20 min of analgesic administration it was observed that there was a significant rise in the pulse rate from 82.267±7.55 to 85.75±6.54 in patients in Group B while it changed from 80.10±7.67 to 81.07±8.70 in Group A (paracetamol).

There was no significant variation in SBP and DBP, in both the groups. In group B mean values of SBP were 124.25±7.89 and 125.60±8.08 before administering analgesia and 20 min after respectively suggesting that there was no significant change. However, in group A, SBP dropped from 127.37±2.09 to 121.77±10.88. Similarly DBP increased from 80.00±6.49 to 82.47±6.58 in Group B while it decreased to 76.33±7.17 from pre analgesic value of 79.07±7.64 in patients under Group A. At the interval of 12 hour post operatively mean values of DBP were significantly higher in patients administered diclofenac.

In the present study increased respiratory rate from the base line was observed in both the groups. It was also observed that respiratory rates (RR) was higher throughout the post operative period in patients in Group B.

Table 3. Comparison of hemodynamic parameters

Time	HR (/min)		SBP (mmHg)		DBP (mmHg)		RR (/min)	
interval	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Pre anal.	8o.10±7.67	82.26±7.55	127.37±2.09	124.25±7.89	79.07±7.64	80.00±6.49	13.60±1.47	13.87±1.17
20 min	81.07±8.70	85.75±6.54	121.77±10.88	125.60±8.08	76.33±7.17	82.47±6.58	13.63±1.17	14.70±1.19
1 h	85.50±5.86	86.31±6.37	128.07±6.51	123.07±6.74	77.75±4.14	78.60±5.30	13.50±1.19	14.46±1.25
2 h	90.56±7.77	92.85±9.49	129.04±8.85	122.67±7.33	76.24±4.66	78.75±5.27	13.34±1.15	15.37±1.56
4 h	87.33±5.91	90.64±9.69	129.57±7.94	121.73±6.82	79.65±6.47	82.77±8.31	13.00±1.25	14.45 ±1.47
6 h	86.15±4.66	87.45±6.66	126.25±6.54	129.25±5.30	77.75±4.19.	81.77±6.47	13.77±1.19	15.60±1.27
12 h	87.33±4.15	90.86±6.27	127.27±4.78	130.67±5.67	76.24±4.27	83.67±5.71	13.37±1.24	14.25±1.45

During the post operative observations it was found that there was no serious complications requiring management like respiratory depression, itching, sedation observed in either group However, two patients complained of nausea and one was found vomiting amongst patients under group B.

IV. Discussion

One of the major benefits of laparoscopic technique compared with standard open surgery is the reduction of postoperative pain. Nevertheless, it is recognised that the skin and facial incisions through which laparoscopic trocars are inserted can still lead to significant degree of pain in post operative period [19]. Pain is a subjective sensation varying from person to person depending upon the psychomatic personality, age, nature of operation. Relief of pain is of paramount importance to the patients as it causes discomfort and also increases risk of pulmonary complications .The relief of postoperative pain helps in effective coughing and adequate ventilation. Number of pharmacological and non pharmacological approaches, are being used for the relief of post operative pain and investigations are still underway to find best method or pharmacological agent for post operative analgesia.

Effective analgesic therapy is an important component of post operative follow up. For this reason opioids are the most preferable analgesic agents during early post operative period after laparoscopy. However, opioids could cause some serious adverse effects such as over sedation, depression of respiration and gastrointestinal motility, nausea, and vomiting [20, 21]. To continue to improve the patient experience with laparoscopy and to minimize the opioid analgesia required after surgery some additive and synergic drugs such as local infiltration through incisional trocar sites, non steroids anti-inflammatory drugs (NSAID),paracetamol are used in pain management after laparoscopic surgery [22].

In this study analgesic efficacy of two drugs paracetamol and diclofenac sodium was compared with regard to their duration of action , degree of analgesia and side effects. The study was conducted in 50 patients belonging to ASA I and II to evaluate the effect of paracetamol and diclofenac infusion on hemodynamic response and the postoperative analgesia in the laparoscopic cholecycstectomy.

It is observed that the infusion of paracetamol at 1g dose has advantage in terms of post operative hemodynamic stability .The preoperative group A and B showed increase in pulse rate, after the administration of analgesic and after the recovery from anaesthesia. While there was no significant variation in pulse rate in the two groups it was almost equal to base line in Group A patients and higher in Group B. However, at 4 hour interval there was a mild decrease in the values of pulse rate suggesting that the initial increase in pulse rate is due to anxiety and not related to pain. Similar observations have also been advanced by Debashish Paul et al who while comparing the analgesic efficacy of paracetamol and diclofenac observed that there is no statistically

significant variation in pulse rate in both the groups [23]. Goel etal also recorded the same observations in their comparative studies on the analgesic effect of IV paracetamol and IV diclofenac sodium in patients undergoing various surgical procedures [13]. However, Debashesh etal found low pulse rate in patients administered diclofenac sodium [23].

In the present study no significant variation in SBP and DBP, was observed in both the groups. While no significant change in SBP was observed in Group B, 20 min after the administration of diclofenac, it dropped in patients given paracetamol with an increase touching base line values at 1 hour interval. It was also observed in the present study that DBP increased and registered a significantly high value from the base line at 12 hour interval in patients administered diclofenac. This may be because of predominant action of diclofenac to inhibit enzyme cyclooxygenase (C0X) which mediates the conversion of arachidonic acid to prostaglandins and thromboxanes [23].

The difference in respiratory rate amongst the groups is clinically insignificant. However, increased respiratory rate in the diclofenac group may be explained by lesser pain relief in the diclofenac group.

While comparing the pain scores high VAS score in the initial 2 hours postoperatively was recorded in paracetamol which was within the value of mild pain and there was no requirement of rescue analgesia. However VAS score was significantly higher in diclofenac group. Most of the patients in paracetamol group had VAS score < 7 for more than 5 hours after the surgery. Debashish Paul et al in their comparative study also observed analgesic effect of paracetamol effective up to more than 5 hours and high mean VAS score of patients administered diclofenac [23]. These findings are also corroborated by Goel et al while comparing the analgesic efficacy of paracetamol and diclofenac in patients undergoing laparoscopic cholecystectomy [13]. Yoganarasimha etal reported increase in pain intensity with hours with peak reaching at 6 hours after operation in patients administered paracetamol [15]. The authors also observed VAS score < 7 for more than 5 hours after surgery in most of the patients who received paracetamol against high number of patients with >7 mean pain score within first 3 hours after operation. Intravenous administration of paracetamol has already demonstrated its analgesic efficiency in patients with postoperative pain following gynaecologic surgery, hand surgery, spinal and orthopaedic surgeries [24, 25, 26].

The number of patients with > 7 VAS score was 12 at 2 hour interval in patients under Group B and required rescue analgesic earlier. However, the number of patients with > 7 VAS score was 8 at 6 hour interval and were administered rescue analgesia. This suggests that sufficient analgesic effectiveness was ensured in the post operative period in Group A patient's administered IV paracetamol. Yoganarsimha et al in their comparative studies also concluded that paracetamol infusion provides a better and prolonged analgesia to the surgical patients postoperatively as compared to diclofenac infusion [15]. It is believed that since intra operative delivery of paracetamol prevents central sensitization, its analgesic effect continues longer than its effect period [27]. Chandrasekharan et al suggested that analgesic effect of paracetamol is probably dependent on rate and amount of active drug reaching CNS where analgesic effect takes place. The authors further stated that selective inhibition of enzyme COX 3 in the brain and spinal cord explains the effectiveness of paracetamol in relieving pain and reducing fever without having unwanted systemic side effects [16].

In the present study it was observed that there was no postoperative complication in patients in Group A. However, 3 patients in Group B reported post operative complication with 2 suffering nausea and 1 was found vomiting. No case of urinary retention was observed in either group. In a related study Apfel etal concluded that properly tactically administered IV paracetamol reduces PONV, mainly mediated through superior pain control [28]. Arici etal found similar results with no significant side effects with IV paracetamol [29]. The findings in the present study are further corroborated by Debashish Paul et al who in their studies did not observe any side effects in patients using paracetamol infusion as post operative analgesia [23].

V. Conclusion

From the above study it can be concluded that paracetamol infusion provides better and prolonged analgesia with low pain scores and lesser requirement for rescue analgesia compared to diclofenac. It also affects hemodynamic stability. No immediate postoperative complications were observed in patients who received paracetamol.

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