International Journal of Medicine Research
ISSN: 2455-7404
www.medicinesjournal.com
Volume 3; Issue 1; January 2018; Page No. 45-49

Comparative evaluation of efficacy of intravenous paracetamol and intravenous diclofenac as post-operative analgesic in laparoscopic surgery

[1] Dr. Pratiti Gohil, [2] Dr. Gauri M Panjabi, [3] Dr. Bhumika Raval
[1] Assistant Professor, Department of Anesthesiology, Smt. Scl General Hospital, Ahmedabad, Gujarat, India
[2] Associate Professor, Department of Anesthesiology, Smt. Scl General Hospital, Ahmedabad, Gujarat, India
[3] 1st Year Resident, Department of Anesthesiology, Smt. Scl General Hospital, Ahmedabad, Gujarat, India

Abstract
Background: Although Laparoscopic surgery is a minimally invasive surgery, pain after the surgery is acute in character & patient feels discomfort during first 24 – 72 postoperative hours which can delay their discharge. So adequate analgesia is of the utmost importance for early ambulatory & speedy recovery. The use of opioids for pain is associated with side effects such as nausea, vomiting, sedation & respiratory depression. We planned our study to find out the best alternative to opioids for post-operative analgesia in patients undergoing Laparoscopic surgeries.
Method: The study was conducted in 60 patients aged between 18 – 65 years belonging to ASA I & II undergoing laparoscopic surgery were randomly divided into two groups. Group A received- Inj. Paracetamol @ 15 mg/kg (maximum 1g in 100 ml infusion) over 15-20 minutes 30 minutes before extubation. Group B received- Inj. Diclofenac sodium @ 2 mg/kg (maximum 75 mg) in 100 ml of Normal saline 30 minutes before extubation. Both groups were assessed & general anesthesia was given. A questionnaire was responded by patients & a chart was maintained for pain score in VAS & for side effects. Hemodynamic parameters were recorded.
Results: Hemodynamic changes were similar in both groups in respect of Heart rate & Blood pressure. However Paracetamol infusion provided better hemodynamic stability – both - during & after surgery. Most of the patients in Paracetamol group had VAS score <7 for more than 10 hours after surgery compared to diclofenac group. Patients who were administered Paracetamol infusion had better quality of analgesia & lesser side effects.

Keywords: laparoscopic surgeries, paracetamol, diclofenac sodium, vas score

Introduction

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 & in some cases fewer complications [2]. Despite the minimal invasive nature of this surgery, postoperative pain in patients undergoing laparoscopic surgery may be substantial & limit an otherwise speedy recovery [2].

Systemic opioid analgesics are regarded as whole standard in the treatment of severe postoperative pain. However, the use of these drugs is associated with side effects such as nausea, vomiting, sedation & respiratory depression [7]**.** It is therefore becoming increasingly common to administer NSAIDs (Diclonec) or paracetamol as adjunctive analgesics in order to reduce opioid related adverse effects & to improve quality of analgesia. Primary mechanism of NSAIDs is to inhibit the COX & prostaglandin synthesis which is considered to be important factor in prevention of hypersensitivity & pain [9]**.** Paracetamol infusion has been recently added to armentarium of anesthesiologist for postoperative anesthesia. Although widely used, its actions are not fully elucidated.

This study was conducted to compare the effects of paracetamol & diclofenac as a postoperative analgesic in laparoscopic surgeries. Main aim was to assess hemodynamic effects, duration of postoperative analgesia & side effects if any.

Materials & Methods

Informed written consent was obtained from 60 patients aged between 18-65 years belonging to ASA class I & II scheduled for laparoscopic surgeries. Patients having contraindication to paracetamol or NSAIDs & patients on treatment with steroids, NSAIDs or opioids before surgery & patients with altered renal function tests were excluded.

The patients were randomly allocated into two groups each irrespective of age & gender. Prior to the day of surgery, all patients underwent pre anesthesia check-up with routine & subjective investigations as per requirement. The patients were explained about the Visual Analogue Score (VAS). After shifting to the operation theatre, all standard monitoring equipments were connected & i.v. line secured. The baseline parameters pulse rate, systolic blood pressure, diastolic blood pressure, respiratory rate, oxygen saturation of all the patients was recorded.

Patients were pre medicated with Inj Emeset 4 mg i.v. & Inj Fentanyl 2 µg/kg i.v. After preoxygenation, anesthesia was induced with Inj. Thiopental sodium 5-7 mg/kg & Inj. Suxamethonium 1-2 mg/kg i.v. and intubated with appropriately sized cuffed endotracheal tube. Anesthesia was maintained with oxygen, nitrous oxide, and sevoflurane &

muscle relaxant. The lungs were mechanically ventilated. Vital parameters including pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP), end tidal CO2 (etCO2) & oxygen saturation (SpO2) were recorded at an interval of 5 minutes from time zero till the end of surgery. in Group A patients received Inj. Paracetamol @ 15 mg/kg (maximum 1g in 100 ml infusion) over 30 minutes prior to extubation and in group B, patients received Inj. Diclofenac sodium @ 2 mg/kg (maximum 75 mg) in 100 ml of NS over 30 minutes prior to extubation were given. At the end of surgery, residual neuromuscular blockade was reversed. Patient was monitored till completely recovered from general anesthesia. After extubation patients were transferred to PACU for assessment of pain without prescribing any analgesics in any form either from anesthesia or surgical side. The assessment of postoperative pain, pulse rate, SBP, DBP & respiratory rate in immediate postoperative period & further at 20 minutes, 2h, 4h, 6h, 8h, 10h & 12h were recorded. The patients were given rescue drug when the pain severity score was >7 & when they themselves complained of pain.

Side effects such as nausea, vomiting, respiratory depression, itching allergic reaction, Diarrhea, stomach irritation & constipation were cross examined & recorded.

Postoperative pain was measured by using Visual Analogue Score (VAS). For VAS score, Scale consisted of a 10 cm line anchored at one end by a label as “No pain” & at the other end by a label such as “the worst pain imaginable” or “pain as bad as can be”. The patients were simply asked to mark the line to indicate pain intensity in relation to 0 (no pain) to 10 (worst possible pain). The result was interpreted as distance in centimeter (cm) between 0 to the point marked by the patient.

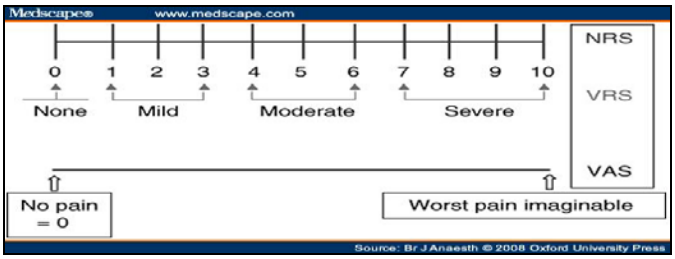

Fig 1

First dose of postoperative rescue analgesic was given on the basis of VAS score between >7 or on demand made by the patient (whichever was earlier) & repeated if required. Rescue analgesia was decided as Inj. Tramadol whenever required. Any complication or complain like nausea, vomiting, sedation, RR<10/minute or any other abnormal findings were recorded. Data were expressed as mean ± SD & the statistical analysis was performed using student’s t test and p value <0.05 was considered clinically significant.

Results

The study was conducted in 60 adult patients undergoing laparoscopic surgeries. The demographic data were comparable in age, weight, sex & ASA grade as shown in table 1 as shown below.

Table 1: Demographic Variables

Variables	Group A	Group B
Sex	M	16	12
	F	14	18
ASA	/	24	26
	,,	06	04
Age (in years)	31.03±9.70	30.9±7.99
Weight (in kg)	59.56±8.18	58.4±7.076

Table 2: Comparison of pulse rate at different time intervals

PULSE RATE	Group A	Group B	P-value
Pre analgesic	76±4.3	76±3.47	1.0
20 min	78.1±4.28	78.1±4.58	1.0
2hr	79±3.0919	79±4.211	0.2
4hr	78±3.361	84.3±3.97	<0.05 S
6hr	79.1±3.021	82.1±3.637	<0.05 S
8hr	80±2.892	80.1±6.898	0.94
10hr	82.6±2.852	80.1±7.941	0.11
12hr	84±3.102	80±9.58	<0.05 S

Pulse rate was in the increasing trend immediately after recovery from the anesthesia in both the groups. This initial increase in pulse rate was due to anxiety and not because of pain and is statistically insignificant. In group A, pulse rate increased at 10-12 hours, while in group B it was at 4-6 hours. This increase in pulse rate indicated the need of rescue analgesic.

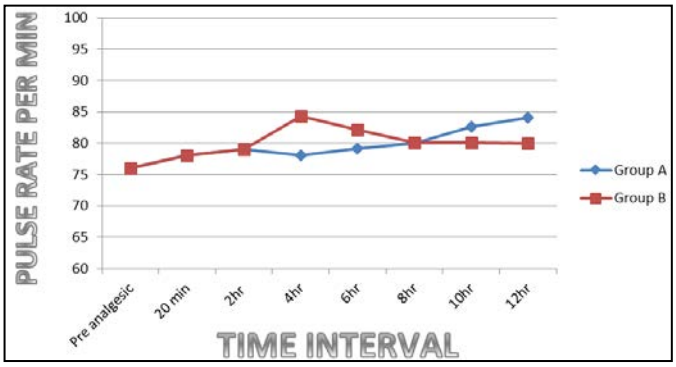

Fig 2: Comparison of pulse rate at different time intervals

Table 3: Comparison of SBP at different time intervals

SBP	GROUP A	GROUP B	P-value
Preanalgesic	122±3.47	122.2±4.52	0.84
20 min	125.5±1.24	129.8±.14.42	0.1
2hr	126±4.55	130±12.55	0.10
4hr	126.2±7.496	130.2±7.4	0.04 S
6hr	126.3±8.239	130.2±12.45	0.15
8hr	126.4±8.770	130.4±13.29	0.17
10hr	127.8±10.38	130.4±10.89	0.34
12hr	130.8±0.58	128±4.65	S

Mean SBP values are less in each time interval in group A (paracetamol) than group B (diclofenac). There was no significant variation in both the groups at different intervals up to 4 hours. The difference in mean values is statistically significant at 4 hours (126.2±7.496/130.2± 7.4) in Group A & B respectively. The mean SBP in Group A was 130.8±0.58 whereas 128±4.65 in Group B (p value) at 12 hours

postoperatively.

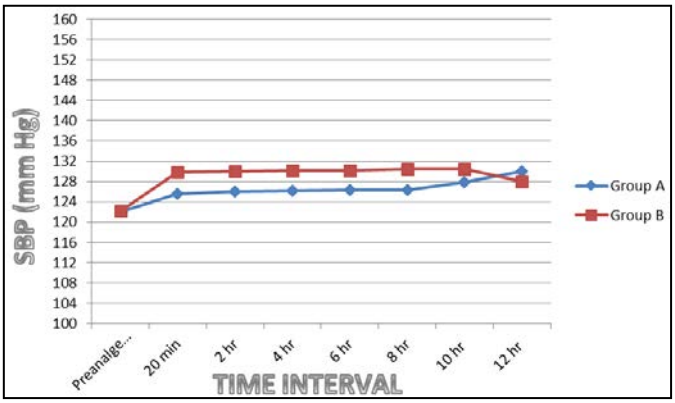

Fig 3: Comparison of systolic blood pressure at different time intervals

Table 4: Comparison of DBP at different time intervals

DBP	Group A	Group B	P-value
Preanalgesic	78±4.59	78.4±8.87	0.82
20 min	77.9±2.98	80.1±7.42	0.13
2hr	76.2±3.88	78.1±13.92	0.47
4hr	77.9±2.690	80±8.99	0.22
6hr	77.7±4.237	80.2±8.45	0.15
8hr	77.7±5.27	79.9±7.07	0.17
10hr	77±1.99	81.4±18.73	0.20
12hr	77.9±6.289	80.4±5.45	0.10

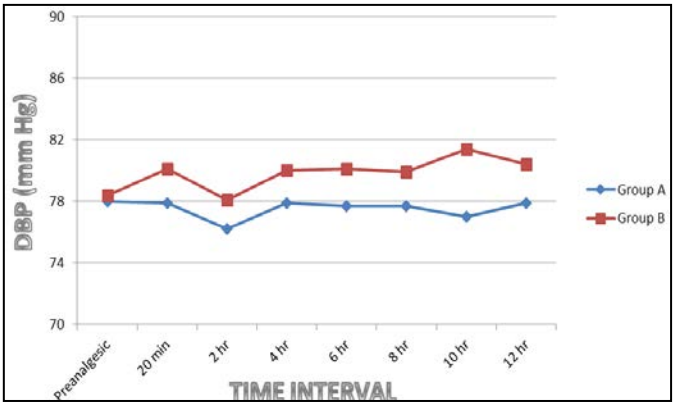

Fig 3: Comparison of diastolic blood pressure at different time intervals

Similarly DBP was less in each time interval in paracetamol group than diclofenac group but the difference was statistically not significant. In the present study increased respiratory rate from the baseline was observed in both the groups but were higher throughout the postoperative period in patients in Group B which was statistically not significant as shown in Table No.4.

Table 5: Comparison of RR at different time intervals

Respiratory Rate (RR)	Group A	Group B	P-value
Preanalgesic	13±4.37	13.2±5.29	0.87
20 min	13.6±0.95	14.4±2.57	0.11
2hr	13.5±1.106	14.3±2.933	0.167
4hr	13.54±1.044	14.5±3.9	0.19
6hr	13.5±2.956	14.45±1.44	0.11
8hr	13.5±2.12	14.32±5.68	0.46
10hr	13.6±1.67	13.9±0.92	0.3
12hr	13.7±1.514	14.1±0.9	0.21

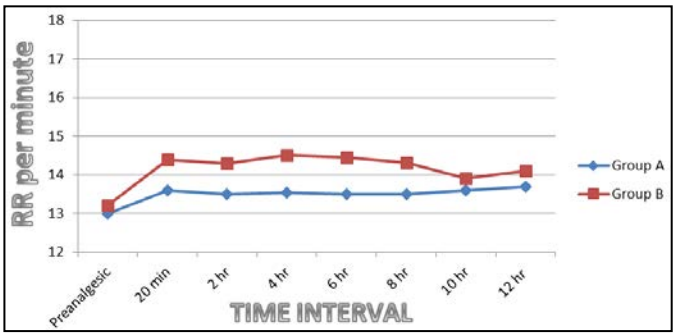

Fig 4: Comparison of respiratory rate at different time intervals

No serious complications like respiratory depression, itching or sedation were observed in either group.

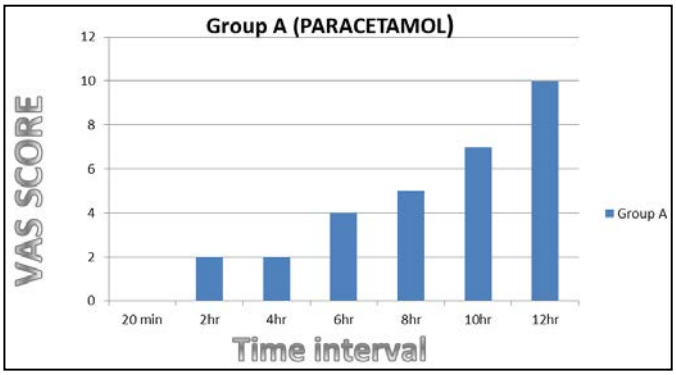

Fig 5: Comparison of VAS scores at different time intervals

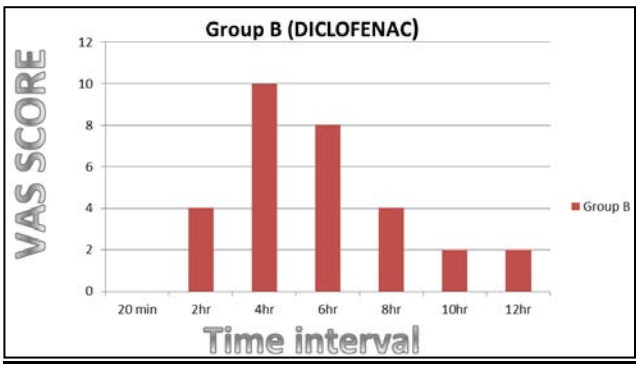

Fig 6: Comparison of VAS scores at different time intervals in Group B

In diclofenac group pain intensity increases with hour and made peak level in 4 hour after surgery as seen in figure. In group B 10 patients had vas score >7 at 4 hour after surgery while only 2 patients had in group A, indicating the need of rescue analgesic early in diclofenac group. At 12 hour after surgery, in group A 10 patients had VAS score >7 and rescue analgesic was given.

Discussion

Pain after laparoscopic surgery has three different components: incisional pain, visceral pain & shoulder pain (referred to visceral pain). Pain is often associated with autonomic, endocrine-metabolic, physiological & behavioral response [1]. Pain if inadequately relieved can result in various complications like atelectasis/ pneumonitis/ hypoxemia, deep vein thrombosis, delayed recovery of bowel function, myocardial ischemia & infarction, urinary retention & residual psychological trauma [1].To continue to improve the patient experience with laparoscopy & to minimize the opioid analgesia required after surgery some additive & synergistic drugs such as local infiltration through the incisional trocar sites, non-steroidal anti-inflammatory drugs (NSAID), paracetamol are used in pain management after laparoscopic surgery [2].

Paracetamol rapidly crosses the blood brain barrier, reaches a high concentration in the cerebrospinal fluid & has an anti-nociceptive effect mediated by CNS. This central effect has been regarded primarily as an indirect & reciprocal influence through cyclooxygenase enzyme inhibition & probably through serotoninergic system as well. Besides this central effect, it is accepted that paracetamol has a peripheral anti-inflammatory effect although this effect is limited[1]. In diclofenac sodium primary mechanism responsible for its anti-inflammatory, antipyretic, and analgesic action thought to be inhibition of cyclooxygenase (COX). It also appears to exhibit bacteriostatic activity by inhibiting DNA synthesis[2].

In this study analgesic efficacy of two drugs – paracetamol & diclofenac sodium was compared with regard to their duration of action, hemodynamic effects & side effects.

Our study shows increasing trend in pulse rate and SBP immediately after recovery from the anesthesia in both the groups. This initial increase was due to anxiety and not because of pain and is statistically insignificant. However in group A, pulse rate and SBP was increased at 10-12 hours, while in group B it was at 4-6 hours. This increase in pulse rate and SBP indicated wearing off effect of the drug during this period requiring rescue analgesic. No statistically significant difference was noted in DBP in both the groups. Respiratory rate was higher in diclofenac group compared to paracetamol but the difference was not statistically significant. Similar observations had also been observed by debashish paul *et al* [1]. Anka amin *et al* [2] also recorded the same observation in their comparative studies on post-operative analgesic effect of iv paracetamol and iv diclofenac in patient undergoing surgical procedures. It is observed that infusion of paracetamol at 1 gm. has advantage in terms of post-operative hemodynamic stability.

In this study, 42% of patients had VAS score >7 at 2- 4 hour postoperatively in diclofenac group probably due to wearing off the drug effect While 48% of patients in paracetamol group had VAS score was > 7 at 10-12 hour postoperatively. In both groups pain intensity increased with hours after surgery but peak level made at 4 hours in diclofenac group and 12 hours in paracetamol group. The time to first request for rescue analgesia after injection of study drug was approximately 3 times as long with paracetamol compared to diclofenac. Debashish paul [1] *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. These finding also corroborated by goel *et al* [3] while comparing analgesic efficacy of paracetamol and diclofenac in patients undergoing laparoscopic cholecystectomy. This shows paracetamol was more effective compared to diclofenac for postoperative analgesia.

No postoperative complication was noted in any group. In a related study Apfel etal[4] concluded that properly administered IV Paracetamol reduces PONV, mainly mediated through superior pain control. Arici *et al* [5] found similar results with no significant side effects with IV Paracetamol. The findings in the present study are further corroborated by Debashish Paul *et al* [1] who in their studies did not observe any side effects in patients using Paracetamol infusion as postoperative analgesia.

Conclusion

From the above study it can be concluded that paracetamol infusions provide better quality and prolonged analgesia with better hemodynamic stability compared to diclofenac in patients undergoing laparoscopic surgery.

References

1. Debashish Paul. *et al*, Comparative evaluation of efficacy of 4 Paracetamol & iv Diclofenac as postoperative analgesia in Laparoscopic Cholecystectomy. International Journal of biomedical research. 2015; 6(07):482-487.
2. Anka Amin. *et al*, Comparison of analgesic effect of iv Paracetamol & iv Diclofenac for perioperative analgesia in Laparoscopic Cholecystectomy. IOSR Journal of dental & medical sciences e-ISSN: 2279-0853.
3. Goel Pratyush. *et al*, Preemptive analgesia with iv Paracetamol & iv Diclofenac sodium in patients undergoing various surgical procedures: a comparative study Int J Biol Med Res. 2013; 4(3):3294-3300.
4. CC Apfel A. Tarun K. Souza J. Pergolizzi C, Hornuss. Intravenous acetaminophen reduces postoperative nausea & vomiting. A systemic review & meta-analysis, Pain. 2013; 154:677-89.
5. Arici S, Gurbet A, Turker B, Yavascaoglu S, Sahin. Preemptive analgesic effects of intravenous Paracetamol in total abdominal hysterectomy. 2009; 21:54-61.
6. Cakan Turkay MD, Inan Nurten MD, Culhaoglu Safiye MD. *et al.* Intravenous Paracetamol improves the quality of postoperative analgesia but does not decrease narcotic requirements. Journal of Neurosurgical Anesthesiology. 2008; 20(3):169-173.
7. Yoganarasimhan N, Ragavendra TR, Radha MK, Amitha S, Sridhar K. Comparison of Paracetamol infusion with diclofenac infusion for perioperative analgesia. Journal of medical & health sciences. 2012; 1(1):18-22.

8. Namrata Ranganath, Khushbu Goel, Sumitha C S, Arathi B H, Gowda VB, Rashmi Satheesh. A study of the analgesic efficacy of intravenous paracetamol versus intravenous diclofenac for the postoperative pain following modified radical mastectomy. International journal of recent trends in science & technology. 2016; 18(1):111-115.
9. Hurley RW. Acute post-operative pain. In RD miller, LJ Fleisher, JP Weiner-Kronish, W I Young (Ed) millers Anaesthesia 7th ed (USA: Ghurchil Livingstone 2010). 2763.