### Comparison Of Intravenous Paracetamol Versus Diclofenac Sodium As Preemptive Analgesia In Laparoscopic Surgeries

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### Abstract

**Aim and Objectives:** To assess and compare the effects of pre-emptive administration of intravenous Paracetamol and Diclofenac sodium in laparoscopic surgeries on post operative pain.

**Methodology:** In this Quasi experimental study, after approval from ethical committee and written informed consent taken from 90 patients of ASA physical status I,II and III of either sex scheduled to undergo elective laparoscopic surgeries under general anaesthesia were enrolled. Patients were randomly divided into one of the two groups of 45 patients each, patient received either Paracetamol (group P) or Diclofenac (Group D) 30 minutes before surgery. The degree of post operative pain was assessed using VAS at 0, 2, 4, 8, 12 and 24 hours post operatively. Results: The pain score at 0 hours were more than 4 in both the groups. Statistical analysis showed a significant difference between the 2 groups. Thereafter, the difference in pain scores in both Paracetamol group and Diclofenac group were not significant. Majority of the patients required rescue analgesia twice in the 24 hour period.

**Conclusion:** we conclude that either Paracetamol or Diclofenac administered alone pre-emptively is not sufficient to control post operative pain.

### Introduction

Pre-emptive analgesia is the treatment that is initiated before and is operational during the surgical procedure in order to reduce the physiological consequences of nociceptive transmission provoked by the procedure. Owing to this „protective“ effect on the nociceptive pathways, pre-emptive analgesia has the potential to be more effective than a similar analgesic treatment initiated after surgery. Consequently, immediate postoperative pain may be reduced and the development of chronic pain may be prevented. Uncontrolled post operative pain has delayed resumption of normal pulmonary function, restriction of mobility, nausea and vomiting, increase in systemic vascular resistance, cardiac functions and myocardial oxygen consumption through increase in catecholamines, induced by stress response. Adequacy of post operative pain control is one of the most important factors in determining for safe discharge of patient from hospital. It has a major influence on the patient’s ability to resume routine daily activities. Perioperative analgesia has traditionally been provided by opioids. However, extensive use of opioids is associated with a variety of perioperative side effects, such as ventilatory depression, drowsiness and sedation, post operative nausea and vomiting, pruritus, urinary retention, ileus, constipation and decreased patient satisfaction.
Pain in laparoscopic surgeries is due to trauma to abdominal wall and the visceral organ caused by the endoscope and the surgical instruments. Creation of pneumoperitoneum may be associated with tearing of blood vessels, traction on the nerves and release of inflammatory mediators, which causes somatic pain. The use of IV Paracetamol or IV Diclofenac as analgesia would reduce the amount of opioid used as rescue analgesia and ensure a comfortable postoperative recovery period. Paracetamol and Diclofenac are the two non opioid drugs that are being used in perioperative period. 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.

Methodology

Study Design: Quasi experimental study.

Sample size (including sample size calculation and justifications): $n = 2 \sigma^2 \left( Z_{1-\alpha/2} + Z_{1-\beta} \right)^2 d^2$ Level of significance $\alpha = 5\%$ power $(1- \beta) = 80\%$ clinical significant difference, $d=5$ $\sigma=11.9$ 90 healthy consenting patients (ASA 1 or ASA 2) divided in two groups Group P (Paracetamol) = 45 Group D (Diclofenac) = 45

Source of data/Sampling method Patients posted for laparoscopic surgeries in Yenepoya Medical College Hospital, Mangalore during the period of December 2016 to September 2018.

Sampling technique: Sampling done by closed envelop method.

Inclusion criteria: Patients undergoing elective laparoscopic surgeries lasting less than 3 hours, Patients of either gender between age of 18 and 65 years, ASA grade I, II, and III.

Exclusion criteria: ASA grade IV, and V, Patients with clinically significant cardiovascular, respiratory, hepatic, renal, neurologic, psychiatric, or metabolic disease, Patients with known allergy to either Paracetamol or Diclofenac Chronic analgesic therapy.

Materials and Methods: After ethical committee approval and informed consent, 90 patients belonging to “American society of Anaesthesiology” (ASA) grade I, II & III aged between 18 to 65 years, scheduled for elective laparoscopic surgeries were selected. Thorough preanesthetic evaluation and routine investigations were carried out before taking up the patient for surgery. An informed and written consent was taken from the patients enrolled for the study and patients were explained regarding Visual Analogue Scale. Then patients were divided into two groups chosen at random, using closed envelop method: Group P (Paracetamol): 45 patients. Group D (Diclofenac): 45 patients. Premedication: Tab Ranitidine 150 mg at night before surgery and 2 hours prior to induction. Tab Lorazepam 1 mg at night before surgery. 30 minutes before induction of anaesthesia, either 1 gram intravenous Paracetamol or 75mg of Diclofenac in 100 ml normal saline was administered based on randomization. On arrival to the operating room, routine monitoring was done of the following parameters: - Heart Rate - Non invasive blood pressure - Electrocardiogram - Oxy-haemoglobin saturation. A peripheral cannula was secured. Intravenous infusion of Ringer lactate was started. Intravenous Midazolam 1 mg and intravenous Fentanyl 1.5 mcg/kg was given. After preoxygenation with 100% oxygen for 3 minutes, patient was induced with intravenous Propofol 2 mg/kg and endotracheal intubation facilitated by Vecuronium 0.1 mg/kg. Anaesthesia was maintained with Isoflurane 1 MAC and Nitrous oxide in oxygen (70:30). At the
end of surgery, residual neuromuscular paralysis was antagonized with Neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg. After satisfactory recovery trachea was extubated and patient was shifted to post anaesthesia care unit. On arrival to the post operative unit (time 0), patient’s vitals - heart rate, blood pressure and Oxygen saturation was recorded. Postoperative pain was assessed by a blinded observer at time 0, 2, 4, 8, 12 and 24 hours post surgery using VAS score. Rescue analgesia with bolus doses of intravenous fentanyl (25 mcg) at VAS score more than or equal to 4 was given.

Results

The mean age of Group
P- 38.27 The mean age of
Group D-41.98
Mean age between both groups are comparable.
Laparoscopic appendicectomy was done in 16 patients. Laparoscopic cholecystectomy in 54 patients.

Diagnostic laparoscopy in 3 patients. Laparoscopic hernioplasty in 17 patients.

**Graph 2:** Gender distribution of both groups are comparable.

**Graph 3:** Distribution of Procedure
Pain scores in immediate post operative period were high in both the groups (>4).

Graph 4: Comparison of Pain score between the groups:

Pain scores in immediate post operative period were high in both the groups (>4).
Majority of the patients required rescue analgesia twice in 24 hour period. A small percentage of the patients required three times.

**Graph 5: Distribution of Rescue Analgesia between the groups**

Majority of the patients required rescue analgesia twice in 24 hour period. A small percentage of the patients required three times.
There was significant increase in heart rate in post operative period in both the groups.

Graph 6: Heart rate

Graph 7: SBP
Discussion

The study was undertaken to assess the efficacy of Paracetamol and Diclofenac sodium as a preemptive analgesic in laparoscopic surgeries. The pain score and requirement of rescue analgesia for both the groups were compared.

DEMOGRAPHIC DATA: The demographic data of both the groups were compared with respect to age and gender. It was not statistically significant. Laparoscopic appendicectomy was done in 16 patients, Laparoscopic cholecystectomy in 54 patients, Diagnostic laparoscopy in 3 patients and Laparoscopic hernioplasty in 17 patients.

VAS SCORE AND RESCUE ANALGESIA: It was observed that the visual analogue score for both groups were significantly higher (>4) at 0 hour postoperatively. The mean pain score was 5.80 in Paracetamol group and 5.62 in Diclofenac group. The difference between the two groups is statistically significant as p value is 0.032 (<0.05). Thereafter till 24 hours, the pain scores in both Paracetamol group and Diclofenac group were not statistically significant.

In a study conducted by Malaya Kumar et al, the VAS score was less in Diclofenac group in early postoperative period. Thereafter the efficacy of both the drugs was comparable. In a similar study conducted by Anirban Pal et al with Diclofenac and Paracetamol, concluded that there was statistically significant difference in pain score in Diclofenac group when compared to Paracetamol group. The requirement for rescue analgesia was comparatively less in Diclofenac group in first 24 hours. These studies are in accordance with our study in reducing pain score in early post operative period with preemptive use of intravenous Diclofenac sodium. After the initial hours there was no statistical significance in both the groups.
In a study conducted in 2015 by Karki A J et al concluded that intravenous Paracetamol provided better analgesia in the treatment of post operative pain compared to intravenous Diclofenac. Anka Amin et al conducted a similar study, which found Paracetamol infusion to provide effective and prolonged analgesia with low pain score and lesser requirement of rescue analgesia compared to Diclofenac. The results of these two above studies were not similar to our study.

RESCUE ANALGESIA: Majority of the patients required rescue analgesia twice in 24 hours (group P 37.8%, group D - 46.7%). A small percentage of patients required rescue analgesia three times (group P - 15.6%, group D - 13.3%). While in group P - 13.3% and group D - 13.3% did not require rescue analgesia. The requirement for rescue analgesia did not show any statistical significance. In a study conducted Anka Amin et al, the requirement of rescue analgesia was lesser in Paracetamol group compared to Diclofenac group. Sona Dave et al in their study concluded that the requirement of rescue analgesia in Diclofenac group was less compared to Paracetamol group. However in our study we did not observe any statistical significance in the requirement of rescue analgesia in both the groups. We evaluated the pain score and rescue analgesia requirement in various laparoscopic procedures. There was no statistically significant difference in pain score and need for rescue analgesia among patients undergoing laparoscopic cholecystectomy, laparoscopic appendicectomy, laparoscopic hernioplasty and diagnostic laparoscopy.

Hemodynamic Parameters: The pre-operative and post operative hemodynamic parameters like heart rate, systolic blood pressure, diastolic blood pressure and percentage saturation of oxygen were assessed. There was significant increase in heart rate in both the groups post operatively.

Systolic and diastolic blood pressure was raised in both the groups post operatively. There was no difference noted with percentage of oxygen saturation measured preoperatively and post operatively. When the above parameters were compared between the two groups postoperatively, there was no significant difference between the heart rate, diastolic blood pressure and percentage saturation of oxygen. However, we noticed statistically significant rise in systolic blood pressure in Diclofenac group. In a study, conducted by Malaya Kumar Patel et al. in Jan 2018, a comparative study of preemptive analgesic property of intravenous Paracetamol and Diclofenac sodium. The mean heart rate, blood pressure and respiratory rate were not statistically significant between Diclofenac group and Paracetamol group.

Conclusion

The following conclusions were arrived:

1. The pain score in immediate post operative period were high (>4) in both the groups. However there was statistically significant difference between Diclofenac and Paracetamol group. There after the difference in pain score in between the two groups were not significant.

2. Majority of the patients required rescue analgesia twice in the 24 hour period. A small percentage of patients required rescue analgesia three times, which indicates neither Diclofenac nor Paracetamol is sufficient enough to control post operative pain.
3. The pre-operative and post operative haemodynamic parameters like heart rate, systolic blood pressure, diastolic blood pressure and percentage saturation of oxygen were not significant.

4. In early post operative period there was statistically significant rise in systolic blood pressure in Diclofenac group. Therefore, we conclude that either Paracetamol or Diclofenac administered alone pre-emptively is not sufficient to control post operative pain.

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