Surgery Section

Comparative Evaluation of Different Parenteral Agents as Postoperative Analgesics among Patients of Lichtenstein Repair: A Prospective Observational Study

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ABSTRACT

Introduction: Hernia surgery is one of the most frequently done surgeries worldwide. It is of special concern since, the postoperative pain can be because of injury to the nerves apart from the skin incision. Different drugs are used as analgesics for the management of postoperative pain, but there are hardly any guidelines for their judicious use. Besides, these analgesics are not free from clinically significant adverse effects. Therefore, there is a need of developing some guideline/protocols for using analgesics postoperatively.

Aim: To compare the efficacy and safety of intravenous (i.v.) diclofenac bolus, i.v. paracetamol infusion, and i.v. tramadol as postoperative analgesics in cases of inguinal hernia undergoing Lichenstein repair (open hernioplasty).

Materials and Methods: A prospective observational study was conducted in the Department of General Surgery at a Tertiary Care Teaching and Training Institute, North India. The duration of the study was two months, from February 2021 to March 2021. A total of 57 patients were included in the study and grouped as per the primary analgesic used in them, out of which 18 belonged to group A (i.v. diclofenac bolus), 22 to group B (i.v. paracetamol infusion), and 17 to group C (i.v. tramadol). Visual Analogue

Scale (VAS) scores were assessed at 6 hours, 24 hours, and 48 hours, postoperatively. The type and frequency of additional analgesics used were noted. Any clinically significant adverse effects were also recorded. Analysis of Variance (ANOVA) and Chi-square tests were applied to analyse the continuous and categorical data respectively.

Results: The mean age of the study participants was 48 ± 16 years. The mean VAS scores at 6 hours were 3.6, 3.4, and 4.1 in the three groups, respectively. Whereas, at 24 hours and 48 hours, the scores were 3.5, 3.4, 3.4, and 2, 1.6, and 1.9, respectively. There was no statistically significant difference in the VAS scores. A total of 12 (66.67%) patients in group A, 18 (81.81%) in group B, and 16 (94.12%) in group C required additional analgesics but the difference was not statistically significant. Similarly, 5 (27.78%) patients in group A, 6 (27.27%) in group B, and 4 (23.53%) in group C suffered from adverse effects, but there was no statistically significant difference amongst them.

Conclusion: Intravenous diclofenac bolus, i.v. paracetamol infusion, and i.v. tramadol are equally efficacious and safe, when used as postoperative analgesics in cases of inguinal hernia undergoing Lichtenstein repair. But studies with larger sample size are required to draw any definite conclusion.

Keywords: Analgesics, Open hernioplasty, Postoperative pain, Skin incision

INTRODUCTION

The most important cause of apprehension related to any kind of surgery is postoperative pain. It is often a cause of significant stress to patients. Any surgical incision is likely to cause moderate to severe postoperative pain, if not dealt with adequately. Therefore, the role of adequate analgesia in the management of postoperative pain can't be overemphasised. Good analgesia can also reduce the deleterious effect on the immune system that surgery imposes [1]. Various parenteral analgesics having different modes of action are often required in the early postoperative period either alone or in combination [2]. Surgeons use these different analgesics as per their own preferences. There is no consensus regarding the type of analgesic to be used in a particular surgery, and neither there are any guidelines regarding the same. Besides, these analgesics are not free from clinically significant adverse effects. Therefore, there is a need of developing some guidelines/protocols for using analgesics postoperatively.

Hernia surgery is one of the most frequently done surgeries worldwide [3]. It is of special concern since, the postoperative pain can be because of injury to the nerves apart from the skin incision. Opioid analgesics are less preferred in comparison to non opioids {Non Steroidal Anti-Inflammatory Drugs (NSAIDS)/Acetaminophen} as the former has many undesirable adverse effects such as constipation, nausea and vomiting, respiratory depression, sedation etc., [4]. Diclofenac, paracetamol, and tramadol are the most used analgesics in postoperative period. Diclofenac is a non selective Cyclooxygenase (COX) inhibitor. It inhibits prostaglandin synthesis by inhibiting COX-1 and COX-2 enzymes [5]. Whereas, the in-vivo effects of paracetamol (acetaminophen) are similar to those of the selective COX-2 inhibitors [6]. Tramadol, a synthetic opioid of the aminocyclohexanol group, is a centrally acting analgesic having weak opioid agonist activity. It is usually well tolerated and the most common side effects are nausea and vomiting. In contrast to other opioids like morphine and pethidine, respiratory depression is less common during tramadol administration [7] and hence, it can be recommended for first-line management of postoperative pain. The choice amongst the above three drugs differs from Institution to Institution and also, from surgeon to surgeon. The route of administration of the drug also needs to be chosen, as there are several alternatives. In a systematic review published in 1998, they found that, the NSAIDs given by i.v. route had the fastest onset of action in managing patients of renal colic [8].

In a study conducted in China, the authors compared tramadol, morphine, and a combination of tramadol and morphine as

postoperative analgesics administered via the epidural route in patients undergoing abdominal surgeries for malignancies. They found that, the efficacy of tramadol was similar to morphine and the combination of the two. The frequency of nausea and vomiting was lower in the combination group [9]. In another study, the researchers compared bilateral Continuous Rectus Sheath Infusion (CSRB) versus Thoracic Epidural Infusion (TEA) in patients undergoing laparotomy by midline incisions [10]. They concluded that, CSRB is a safe, effective, and reliable means of postoperative analgesia with lower pain scores at several points of assessment as compared to TEA. Commonly, in surgical practice, parenteral (in the immediate postoperative period) or oral analgesics are prescribed for postsurgical pain relief in most surgeries, with or without epidural or other modes [2]. The i.v. paracetamol (acetaminophen) is a newer agent gaining worldwide popularity in acute postoperative pain relief [11].

Jebaraj B et al., performed a systematic review of eight prospective clinical trials and reached the conclusion that postoperative i.v. paracetamol reduced the need for opioids in cases of orthopaedic surgery [12]. In another systematic review of randomised controlled trials, Romsing J et al., found that, paracetamol administered by both rectal and parenteral routes produced clinically relevant analgesic effects in the postoperative period [13]. They also inferred that, concurrent use of paracetamol with NSAIDs was superior to paracetamol alone, but the same was not true when compared with NSAIDs alone. A study conducted by Rajkiran R et al., on patients, who underwent craniotomy for supratentorial tumours and found that, diclofenac was superior to paracetamol in terms of postoperative pain relief, the requirement of rescue analgesics and had no difference regarding adverse effects on the coagulation profile [14]. Shah UD et al., conducted a double-blinded randomised comparative study between paracetamol and diclofenac as postoperative analgesics in patients undergoing elective surgery under general anaesthesia [15]. They found that, both i.v. paracetamol and i.v. diclofenac were safe and effective analgesics without any major adverse effects. Traditionally, diclofenac has been used via the intramuscular route or as i.v. infusion for long. But in recent times, many studies have shown that, this drug can also be given as an i.v. bolus [16,17]. The i.v. bolus injection of diclofenac has been shown to be more effective in several studies as compared to i.v. infusion, which is complex to administer and more time consuming. In a study published in 2019, it was found that, diclofenac 75 mg/mL solution administered as an i.v. bolus was well tolerated had a faster onset of action, and a superior analgesic effect [16]. Similarly, a multicentre study conducted in India revealed that, i.v. bolus route of diclofenac 75 mg/mL solution was a better analgesic as compared to i.v. infusion (75 mg/3 mL) in terms of onset of action and pain and thrombophlebitis at the site of injection [17]. A Cochrane database systematic review published in 2018, the authors concluded that, there was insufficient data to assess whether i.v. diclofenac was associated with a different rate of complications (bleeding, renal dysfunction, cardiovascular events) as compared to other NSAIDs [18].

Because of the conflicting results of various studies and the varying preferences of different surgeons, this research was conducted with the aim to compare the efficacy and safety of i.v. diclofenac bolus, i.v. paracetamol infusion, and i.v. tramadol as postoperative analgesics in patients undergoing open hernioplasty in terms of postoperative pain, the need of additional analgesics and adverse effects.

MATERIALS AND METHODS

A prospective observational study was conducted in the Department of General Surgery at a Tertiary Care Teaching and Training Institute, North India. The duration of the study was two months, from February 2021 to March 2021. Institutional Ethics Committee (IEC) clearance was obtained (Reference no 2223/ RMLIMS/2020, IEC No 101/20). **Inclusion criteria:** Patients undergoing elective Lichenstein repair (open hernioplasty) for inguinal hernias were included in the study.

Exclusion criteria: Patients undergoing bilateral hernioplasty as bilateral incisions are likely to cause more pain and hence, can affect the analysis of results and patients with haepatic or renal insufficiency were excluded from the study.

Study Procedure

A total of 57 patients, fulfilling the inclusion criteria during the study period were included in the study, after being admitted for open hernioplasty. The Department had three different units (one of them being the author's unit) and each unit used a different primary analgesic as its protocol, therefore, patients admitted in different units were kept under different groups based on the primary analgesic:

- Group A (n=18)- 75 mg i.v. bolus diclofenac.
- Group B (n=22)- 1 g i.v. paracetamol infusion.
- Group C (n=17)- 100 mg i.v. tramadol.

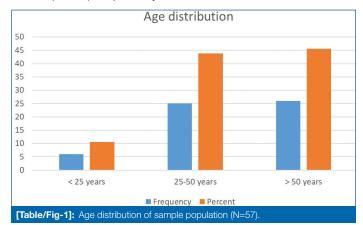
All patients were operated under spinal anaesthesia. Diclofenac was given at 12 hourly intervals (twice daily doses) whereas, paracetamol and tramadol were given at eight hourly doses (thrice daily doses) up to 48 hours postsurgery. VAS (by Hayes and Patterson) was used for assessing postoperative pain [19]. VAS scale is a 10-point scale having a 10 cm straight line with 0 (representing no pain) and 10 (representing worst possible pain) at its endpoints. Patients were asked to rate their pain on this scale and the scores were assessed. VAS scores (immediately after the surgery and then after 6, 24 & 48 hours of surgery), type of additional/supplemental analgesic, frequency of required additional/supplemental analgesic and adverse effects of the primary analgesic used were recorded.

STATISTICAL ANALYSIS

The R software with BlueSky statistics was used for statistical analysis. VAS scores were presented as mean scores whereas, adverse effects of the analgesics were depicted as percentage. The need of additional analgesics was presented as a percentage. Chi-square test was used for comparative analysis of categorical variables (need of additional analgesics and adverse effects of the analgesics) and the ANOVA test was used for comparison of continuous variables (VAS scores).

RESULTS

Out of the total 57 patients, 6 (10.5%) belonged to the age group <25 years, 25 (43.9%) belonged to age group 25-50 years whereas, 26 patients (45.6%) belonged to age group > 50 years [Table/Fig-1]. The mean age was 48 ± 16 years. All patients were males. A total of 4 (7%) of the patients were suffering from left direct hernia whereas, 19 (33.3%) were suffering from left indirect hernia. Similarly, the frequency of right-sided direct and indirect hernias were 5 (8.8%) and 29 (50.9%), respectively.



There was no statistically significant difference in the VAS scores in the three groups at different intervals [Table/Fig-2].

Time of administration (in hours post op)	Group A (n=18) Mean±SD	Group B (n=22) Mean±SD	Group C (n=17) Mean±SD	p-value		
6	3.4±1.0	3.6±1.3	4.1±1.1	0.21		
24	3.4±1.3	3.5±1.1	3.4±0.9	0.87		
48	1.6±0.5	2.0±0.8	1.9±0.7	0.213		
[Table/Fig-2]: Comparative analysis of VAS scores (One-way ANOVA used) (N=57).						

Diclofenac was associated with a maximum percentage (27.78%) of adverse effects as compared to 27.27% with paracetamol and 23.53% with tramadol [Table/Fig-3].

Parameter	Group A n (%)	Group B n (%)	Group C n (%)	χ²	p-value	
Frequency of adverse effects	5 (27.78)	6 (27.27)	4 (23.53)	0.45	0.84	
[Table/Fig-3]: Comparative analysis of adverse effects.						

In group A, paracetamol and tramadol were used as additional analgesics in six patients each. In group B, diclofenac and tramadol were given as additional analgesics in six and 12 patients, respectively. In group C, diclofenac and paracetamol were used as supplemental analgesics in 12 and four patients, respectively [Table/Fig-4].

Primary analgesic		Additional analgesic used			
used	NIL	Diclofenac	PCM	Tramadol	Total
Diclofenac (group A) n (%)	6 (33.3)	0	6 (33.3)	6 (33.3)	18
Paracetamol (group B) n (%)	4 (18.2)	6 (27.3)	0	12 (54.5)	22
Tramadol (group C) n (%)	1 (5.9)	12 (70.6)	4 (23.5)	0	17
Total n (%)	11 (19.3)	18 (31.6)	10 (17.5)	18 (31.6)	57

[Table/Fig-4]: Use of additional analgesics in different groups. NIL: No additional analgesic required

Group C required the additional analgesic for maximum number of times (94.12%) as compared to 81.81% in group B. Group A required the additional analgesic for a minimum number of times (66.67%). But this difference was not statistically significant [Table/Fig-5].

Primary analgesic used	Diclofenac (group A) n (%)	Paracetamol (group B) n (%)	Tramadol (group C) n (%)	Total n (%)	χ²	p- value	
Frequency of additional analgesic used	12 (66.67)	18 (81.81)	16 (94.12)	46 (80.70)	4.52	0.105	
[Table/Fig-5]: Comparative analysis of need of additional analgesic.							

DISCUSSION

In a randomised controlled trial published in 2006, the authors compared propacetamol (a prodrug of paracetamol) with diclofenac as postoperative analgesics in cases of orthopaedic surgery [20]. Propacetamol was given intravenously (infusion) in two divided doses of 2 gm, each of which was given five hours apart. Whereas, diclofenac was given as single dose of 75 mg intramuscularly. They concluded that, both drugs were effective when compared to placebo, but there was no statistically significant difference when they were compared against each other. Herein, the present study, two drugs were given by different routes. Moreover, one drug (propacetamol) was administered twice while the other one (diclofenac) was administered only once. In contrast, in the present study, all three drugs were given by i.v. route. Also, diclofenac was given in twice daily doses, and paracetamol and tramadol in thrice daily doses. In another randomised study conducted by Niemi L et al., they compared parenteral preparations of diclofenac with ketorolac and placebo (saline solution) [21]. All three drugs were given in two divided doses four hours apart. The first dose of each drug was given intravenously whereas, the second dose was given intramuscularly. They compared the need for rescue analgesic (which was oxycodone in the present study) and came to the conclusion that, the group that received diclofenac required significantly less number of rescue analgesic doses as compared to ketorolac and placebo. In the present study, side effects were similar in all three groups. The authors did not use placebo in the research. Instead, a comparison was done, among three different analgesics. Also, the routes of administration were similar each time. Aweke Z et al., did a comparative study among paracetamol (1 gm orally) and a combination of paracetamol and tramadol (100 mg intravenously) and paracetamol and diclofenac (75 mg intramuscularly) [22]. These drugs were given preemptively (60 minutes before surgery). The analgesic used during the postoperative period (tramadol) was according to the patient's needs. The patients selected were those, who underwent elective abdominal surgeries under general anaesthesia. They revealed that, the combination therapy required decreased doses of tramadol in the postoperative phase. Also, the time to the request of first analgesic was prolonged in the combination groups. The combination of paracetamol-tramadol was found to be superior to that of paracetamol-diclofenac. Contrary to this, the authors tested three different single-drug regimens. Besides, these were given as postoperative drugs and not preemptively in the present study.

Pal A et al., performed a comparative study in patients, who underwent lower abdominal gynaecological surgeries [23]. They compared diclofenac (75 mg intramuscularly) with paracetamol (1 gm intravenously) and combination of the above two drugs. All the regimes were given in eight hourly doses. They assessed the requirement of rescue analgesics and found that, diclofenac was more effective as compared to paracetamol and that the combination therapy had no added advantage over diclofenac alone. The authors used diclofenac as i.v. bolus injection in the present study and assessed VAS scores and adverse effects in addition to the requirement of rescue analgesics. In a study conducted in India and published in 2015, the authors compared diclofenac (75 mg) with tramadol (100 mg) in patients undergoing surgery for hernia and hydrocele [24]. Both the drugs were administered intramuscularly. They concluded that, diclofenac provided better analgesia than tramadol in the acute postoperative period. Also, tramadol required more frequent doses. The authors also compared diclofenac, tramadol and paracetamol in the present study, but found no statistically significant difference among the three drugs. In an another study published in 2021, the authors compared diclofenac with paracetamol in patients undergoing laparoscopic surgeries (both drugs were administered as i.v. infusion preemptively and then continued in the postoperatively) [25]. They reached the conclusion that, both i.v. diclofenac and i.v. paracetamol were equally effective as postoperative analgesics but paracetamol provided better analgesia for long duration. Also, paracetamol was associated with a lesser requirement of rescue opioid analgesic in comparison to diclofenac. In contrast to the present study, the authors used i.v. diclofenac bolus which has been found to be more effective than i.v. infusion in several other studies [14,15].

The authors chose hernia surgery (open hernioplasty) as a shortterm study (of two months duration) and this surgery is one of the most common surgeries performed electively. Barring a few, most of the studies conducted in this area, have suggested better efficacy of diclofenac as compared to paracetamol and tramadol. In the present study, the authors were unable to find any statistically significant difference between the three drugs. The reason can possibly be attributed to a shorter sample size.

Limitation(s)

The short duration of follow-up and small sample size were the major limitations.

CONCLUSION(S)

The i.v. diclofenac bolus, i.v. paracetamol infusion, and i.v. tramadol are equally efficacious and safe, when used as postoperative analgesics. But since, the present study was a short-term study with a limited sample size, studies with larger sample size are required to draw definite conclusions that can be applicable to the larger population and to formulate a guideline regarding postoperative pain management.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]

Plagiarism X-checker: Apr 05, 2023

• iThenticate Software: May 12, 2023 (8%)

Manual Googling: May 08, 2023

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AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: Apr 02, 2023 Date of Peer Review: Apr 20, 2023 Date of Acceptance: May 13, 2023 Date of Publishing: Sep 01, 2023

ETYMOLOGY: Author Origin

EMENDATIONS: 6