International Journal of Medical Anesthesiology

E-ISSN: 2664-3774
P-ISSN: 2664-3766
www.anesthesiologypaper.com
IJMA 2018; 1(1): 41-45
Received: 12-11-2018
Accepted: 15-12-2018

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A comparative study using injectable aceclofenac versus injectable diclofenac in postoperative analgesia

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DOI: https://doi.org/10.33545/26643766.2018.v1.i1a.306

Abstract
Optimal pain treatment is a requirement for early post-operative recovery, particularly in patients undergoing laparoscopic abdominal procedures, as these patients experience significant pain, which is most intense within the first 24 hours. Laparoscopic surgery is a principal technique for minimally invasive surgery of the abdomen, employed in procedures across multiple surgical disciplines. **Methods:** After receiving ethical committee certification and informal consent, 60 patients undergoing laparoscopic abdominal procedures between the ages of 25 and 55 were chosen for the study. 30 patients were randomly assigned to receive intramuscular injections of Aceclofenac, while the remaining 30 patients were treated with intramuscular injections of Diclofenac. The data obtained was analysed using the SPSS software version 18.0, and the analgesia data was equivalent in both groups in the postoperative period. The probability value (p-value) was used to establish the level of significance, with p0.05 being considered significant and p0.01 being considered severely unimportant.
Conclusion: The study concludes that Aceclofenac in injectable form is superior to Diclofenac in providing severe post-operative pain management in individuals with lower limb fractures. Additionally, it has a better tolerability profile. It has a lengthy half-life. As a result of the current investigation, we can fairly conclude that injection aceclofenac has a clear role in post-operative analgesia due to its extended duration of action (18-24 hours) and good anaesthetic quality.

Keywords: Pain, laparoscopic abdominal surgeries, injection aceclofenac, injection diclofenac

Introduction
In patients undergoing laparoscopic abdominal procedures, optimal pain treatment is a prerequisite for early postoperative recovery, as these patients experience significant pain, which is most intense within the first 24 hours after surgery. To today, a variety of treatment options are available, including opiates, multimodal therapy, and nonsteroidal anti-inflammatory medications (NSAIDs). The fact that NSAIDS are simple to administer and their effects can be easily monitored makes them a popular choice [1-5].
Aceclofenac is an effective and safe nonsteroidal anti-inflammatory drug (NSAID), with minimal renal, hepatic, and gastrointestinal (GI) adverse effects. When compared to diclofenac, aceclofenac is more widely used when administered orally, and it can be taken for up to four weeks without experiencing any negative side effects if taken correctly. Previously, aceclofenac was available as a parenteral formulation in the form of 1 mL ampoules containing 150 mg of the medication. The medicine was only meant for deep intragluteal and intramuscular injections and was not intended for subcutaneous administration. Because of the extreme agony that was induced by the intramuscular injection, the medicine was never widely utilised and received poor approval from both doctors and patients [6, 7].
The latest parenteral form of aceclofenac is an improved intramuscular version that has 150 mg of aceclofenac in 3 ml, with 50 mg in each ml. The injection is made into a stable lyophilized aqueous solution by adding additive urea and sodium citrate to the ampoule, reducing pain on intramuscular injection and permitting it to be delivered into the deltoid, which is advantageous. It is a sustained release injectable with increased efficacy, duration of action of 24 hours, and a superior tolerance profile [8, 9].
Regardless of type of operation, relief from pain is by far the most frequent indication for surgical intervention. The incidence of postoperative pain varies with the individual patients, but is largely governed by the site and nature of the operation. Pain after surgery is largely result of direct injury caused to the tissues, but may be further aggravated by associated reflex muscle spasm or visceral distension.

Its manifestation of autonomic, psychological and behavioural responses results in unpleasant sensory and emotional experience. It is of two characteristic types, a dull steady pain at rest or more severe stabbing pain associated with movement. Postoperative pain is self-limiting phenomenon, most intense during the first 24 hours and diminishes during the next 24 hours. Pain is minimal after 3-4 days following surgery. Postoperative pain is often associated with increased incidence of other unpleasant symptoms like nausea, vomiting, sweating and can be a cause of postoperative haemodynamic alterations [2].

Pain is subjective phenomenon. It is perceived only by the sufferer and the observer can only assess its magnitude from what the sufferer tells him. Management of postoperative pain has not been so easy since the study of postoperative pain itself has been a difficult process. The difficulty of measuring pain is one of the main problems in studying the subject.[4] Clinical measurements of pain control by a simple verbal scale or visual analogue score (VAS) is gaining popularity in routine postoperative care to monitor the analgesic efficacy and in determining postoperative pain management requirements.

Postoperative pain management has been done in two phases, one is preventive aspect and the other is the actual treatment of pain‘. The preventive phase can play a significant role by preoperatively preparing the patient psychologically explaining the surgical procedure and the probable intensity of pain. Pharmacological preparation by adequate pre-emptive treatment, premedication and by observance of accepted surgical principles and good anaesthesia coupled with proper postoperative care can minimize the amount of postoperative pain.

The newer parenteral aceclofenac is the nonsteroidal / non-narcotic agent with good analgesic potency [10]. Earlier 150mg/1ml non-aqueous injections were available, which were practically insoluble in water, painful on injection, with duration of action of 8 – 10 hours requiring further doses in a day. Recently 150 mg/3 ml stable lyophilized aqueous injection have been developed, minimizing the pain on injection. These are controlled released injections with improved efficacy and duration of action up to 18-24 hours. However, there has been no proper evaluation of this drug for the treatment of postoperative pain. The present study is undertaken to evaluate and compare the efficacy and duration of action of intramuscular injectable aceclofenac 150mg/3ml with intramuscular injectable diclofenac 75mg/3ml. The aim of the present study is ―comparison of injectable aceclofenac with injectable diclofenac in postoperative analgesia following laparoscopic abdominal surgeries‖ with respect to

1. A comparison of the duration of postoperative analgesic effects of aceclofenac and diclofenac injections.
2. Comparison of the relative efficacy of aceclofenac and diclofenac injections

The current study was conducted at Apollo Hospital Hyderabad to examine the relative efficacy of injection aceclofenac and injection diclofenac through intramuscular route for postoperative analgesia in patients undergoing laparoscopic abdominal procedures.

A randomized trial on 60 patients scheduled for laparoscopic abdominal procedures under general anesthesia was done after clearance from the Institutional Ethical Committee and written informed agreement from the patients. Patients between the ages of 25 and 55, of both sexes, with no systemic diseases were included in the study and divided into two equal groups of 30 patients each. Group I Aceclofenac, Group II Diclofenac.

Inclusion Criteria

1. ASA grade I and II
2. Age group: 25 to 55 years of either sex
3. Patients undergoing elective laparoscopic abdominal surgeries

1) Cholecystectomy
2) Appendectomy
3) Hysterectomy

Exclusion Criteria

1. Patients with history of hypersensitivity to NSAIDS
2. Peptic ulcer disease GI bleeding or other bleeding disorders.
3. Patients with abnormal liver or renal function tests
4. Patients on concomitant medication – Aspirin corticosteroids anticoagulants or antihistaminics
5. Any significant abnormality in preclinical trial screening
6. Patients with Motion sickness and migraine

All of the patients were evaluated clinically prior to surgery to rule out the presence of any medical conditions or a history of drug use.

The following examination was performed on all of the patients. X-ray chest, preoperative ECG, hemogram, blood chemistry, complete urine examination two groups of patients were chosen at random. Group for the evening before surgery Group I was told to take aceclofenac 100 mg tablet orally, while Group II was told to take diclofenac 50 mg tablet orally. All patients were given the same general anaesthesia technique, which included endotracheal intubation and controlled ventilation.

On the day of surgery, after transferring the patient to the preanaesthetic hold up section of the operating theatre, an 18G cannula was used to perform intravenous cannulation and connect the patient to a ringer lactate solution drip.

Glycopyrrolate 4 g/kg, ondansetron 15 g/kg, ranitidine 1 mg/kg, and fentanyl 2 g/kg were given slowly intravenously 20 minutes before induction.

Patient was connected to noninvasive blood pressure monitors, a pulse oximeter probe, and electrocardiographic leads as soon as they entered the operating room (limb leads.) PR, BP, and SPO2 were measured at the start of the experiment. Patients were induced with IV thiopentone sodium 5mg/kg after being preoxygenated for 3 minutes with 100% oxygen. Succinyl choline (2 mg/kg) was used to make intubation easier. After 60 seconds, the lungs were ventilated. A Macintosh laryngoscope blade was used to intubate the patient using an appropriate size oral cuffed, portex disposable endotracheal tube.

Following intubation, group 1 received an intramuscular injection of aceclofenac 150mg/3m1 in the deltoid region, while group II received an intramuscular injection of diclofenac 75mg/3m1 in the same area.

Anaesthesia was maintained with 0.08 mg/kg IV vecoronium bromide top-up doses and intermittent positive pressure ventilation with nitrous oxide and oxygen in a 66 percent: 33 percent ratio and 0.4 percent halothane using a circle absorber system connected to the Boyle's anaesthetic workstation. IV fluids were administered as needed, and

vital signs were kept track of. Neuromuscular blockade was reversed with IV neostigmine 60 mg/kg and IV glycopyrrolate 10 mg/kg at the conclusion of the surgery. The trachea was extubated and patients were transferred to the post-anaesthesia care unit after satisfying the extubation criterion (PACU). All patients received oxygen with a poly-mask in the postoperative period, and vital parameters such as pulse rate, blood pressure, and degree of analgesia as measured by a visual analogue score were recorded at 2, 4, 6-, 8-, 12-, and 24-hour intervals.

During the postoperative period, patients were monitored for any complications or side effects, and they were seen by a doctor. For eight hours, neither group received any rescue analgesia. After that, on-demand by the patient or when the visual analogue score was higher than 5 cm, group II received 8 hours of rescue analgesia in the form of injection diclofenac 75 mg/3m1. All data was compiled and statistically analyzed at the end of the study.

Statistical analysis

The data obtained were analyzed using SPSS software version 18.0. Appropriate statistical tests were used to determine the efficacy of drug.

Assessment of pain and pain scales

Pain is multidimensional, dynamic psychophysiological symptom determined not only by tissue injury but also by previous experience, personal beliefs, motivation & environment. There is no way to quantitative scientifically or mathematically the subjective experience of pain. An ideal pain measure should provide sensitive measurement free from bias, provide immediate information accurately and reliably, applicable in both clinical and research conditions [33].

Three frequently considered aspects of pain are:

1. Subjective (measured by self-report)
2. Behavioural (measured by observation and coding of behaviour)
3. Biological (measured by the sampling of physiological fluids and electrical potentials).

IASP emphasizes that pain is always subjective and self-report measures should be regarded as "Gold Standard.

Subjective pain assessment

Visual Analogue Scale

VAS is a simple and reliable measure of subjective pain (for adults and children above 8yrs). It consists of a 10cm horizontal or vertical line with two endpoints [34].

0 = No pain

10=Worst imaginable pain

It provides a numerical index of the severity of pain.

Results

Table 1: Age and per op PR and pre-op MAP of both groups

Parameter	Group I		Group II		t value	p-value
	Mean	SD	Mean	SD		
Age (yrs)	38.11	7.84	37.8	8.4	0.287	0.76
Pre OP PR (/min)	79.6	5.94	81.8	5.01	0.70	0.48
Pre OP MAP (mm of Hg)	88.2	6.32	87.8	5.61	0.41	0.65

The mean age in group I was 38.11 compared to group II where the manage was 37.8 there was no statistically significant difference in mean ages in either group ($p > 0.05$). The mean preoperative Pulse Rate (PR) in group I was 79.76compared to group II 81.8 ($p > 0.05$). The mean Preoperative Mean arterial Pressure (MAP) in group I was, 88.2 compared to group II at 87.8 ($p > 0.05$). There was no statistically significant difference, in the preoperative PR and MAP between the groups.

Table 2: Distribution of patients based on Gender

Gender	Groups I		Group II	
	No. of Patients	%	No. of Patients	%
Male	16	53.33	17	56.77
Female	14	46.67	13	43.33

In the present study male to female ratio was same in either groups.

Table 3: Type of surgery performed

Type of surgery	Group I		Group II	
	No. of patients	%	No. of patients	%
Cholecystectomy	15	40	14	40
Appendectomy	9	36	9	40
Hysterectomy	6	24	7	20

Group I & II included 30 patients each who underwent laparoscopic abdominal surgeries under general anesthesia. Group I included 15 patients of cholecystectomy 14 patients of appendicectomy and 9 patients of hysterectomy Group — II included 14 patients of Cholecystectomy 9 patients of appendectomy 7 patients of hysterectomy. There was no statistically significant difference in both Groups.

Table 4: Pulse rate (per min) comparison in two groups at different time interval postoperatively

Time interval	Group I		Group II		T value	P value
	Mean	SD	Mean	SD		
2 hours	78.21	6.9	81.7	5.49	1.34	0.14
4 hours	77.3	5.91	81.3	5.88	2.08	0.03
6 hours	78.5	5.75	86.4	4.24	5.45	<0.001
8 hours	78.9	5.43	88.6	3.76	7.7	<0.001
12 hours	81.5	5.09	81.6	5.40	0.39	
24 hours	83.4	6.11	81.9	5.35	0.41	0.67

Pulse rate was compared at different time interval, postoperatively it was observed that, mean pulse rate at 2 hours in group I was 78.21 /min compared to group II, 81.7/min there was no statistical difference in the mean pulse rates at 2 hours ($p>0.05$). Mean pulse rate at 4 hours was significantly lower in group I, 77.3 /min compared to group II, 81.3 /min ($p=0.04$). Mean pulse rate at 6 hours was significantly lower in group I, 78.5 /min compared to group II, 86.4/ min ($p<0.001$).Mean pulse rate at 8 hours was significantly lower in group I, 78.9 /min compared to group II, 88.6 /min ($p<0.001$). There was no statistical significance in the mean pulserates at 12 hours between group I, 81.5 /min and group II, 81.6, ($p >0.05$). There was no statistical significance in the mean pulse rates at 24 hours between group I, 83.7 / min arid group II, 81.9/min ($p >0.05$)

Table 5: MAP (in mm Hg) comparison in two groups at different time interval postoperative

Time interval	Group		Group		T value	P value
	mean	SD	Mean	SD		
2 hours	80.8	8.16	95.2	3.31	8.01	<0.001
4 hours	81.8	8.17	93.7	3.4	6.5	<0.001
6 hours	81.8	8.66	101.9	4.4	10.2	<0.001
8 hours	82.16	7.91	101.36	4.7	10.5	<0.001
12 hours	84.2	8.32	93.5	3.3	4.99	<0.001
24 hours	88.4	8.86	93.6	3.6	2.94	0.005

Mean arterial pressure was compared at different time interval postoperatively. It was observed that, mean arterial pressure at 2 hours was significantly higher in group II, 95.2 mm Hg compared to group I, 80.8 mm Hg (p<0.001). Mean arterial pressure at 4 hours was significantly higher in group II, 93.7 mm Hg compared to group I, 81.8 mm Hg (p<0.00l). Mean arterial pressure at 6 hours was significantly higher in group II, 101.9 mm Hg compared to group I, 81.8 mm Hg (p<0.001). Mean arterial pressure at 8 hours was significantly higher in group II, 101.36 mm Hg compared to group I, 82.16 mm Hg (p<0.00l). Mean arterial pressure at 12 hours was significantly higher in group II, 93.5mm Hg compared to group I, 84.2 mm Hg (p<0.001). Mean arterial pressure at 24 hours was significantly higher in group II, 93.6 mm Hg compared to group I, 88.4 mm Hg (p=0.005).

Table 6: VAS (pain score) comparison in two groups at different time interval postoperatively

Time interval	Group-I		Group- II		T value	P-value
	mean	SD	Mean	SD		
2 hours	0.81	0.5	1.9	0.35	2.6	<0.001
4 hours	0.95	0.2	2.8	0.21	7.9	<0.001
6 hours	1.8	0.4	2.89	1.8	10.21	<0.001
8 hours	1.5	0.7	4.2	1.6	22.98	<0.001
12 hours	1.78	0.6	3.9	0.8	8.56	<0.001
24 hours	3.51	0.5	4.1	1.1	2.82	0.008

Pain scoring at different time intervals postoperatively was measured using the VAS score. It was observed that the mean VAS score at 2 hr in group I was 0.81, significantly lower than group II, 1.0 (p=0.018). The mean VAS score at 4 hrs was significantly lower in group I, 0.95 compared to group II, 2.8 (p<0.001). The mean VAS score at 6 hrs. Was significantly lower in group I, 1.8 compared to group II, 2.89 (p<0.001). The mean VAS score at 8 hrs was significantly lower in group I, 1.5 compared to group II, 3.6 (p<0.001). The mean VAS score at 12 hrs was significantly lower in group I, 1.96 compared to group II, 3.9 (p<0.001). The mean VAS score at 24 hrs was significantly lower in group I, 3.52 compared to group II, 4.1 (p=0.008).

Discussion

The concern of postoperative pain can be addressed with a range of therapeutic options, including opiates, multimodal therapy, and nonsteroidal anti-inflammatory drugs (NSAIDs). Still, nonsteroidal anti-inflammatory drugs (NSAIDs) are a popular choice for postoperative pain analgesia because they are simple to administer, their effects can be easily monitored, and they do not suppress the cough reflex or breathing. It was decided to conduct this study in order to compare the relative efficacy and safety of intramuscular injection aceclofenac 150 mg/3 ml with intramuscular injection diclofenac 75 mg/3 ml in postoperative pain relief in patients undergoing laparoscopic abdominal surgeries.

Patients were divided into two groups of 30, with each group consisting of 30 patients. There was no statistical difference between the two groups in terms of age, gender, preoperative pulse rate and blood pressure recording, and there was no statistical difference in terms of preoperative pulse rate and blood pressure recording in Group I. After intubation, patients in Group II received intramuscular diclofenac 75mg/3ml after intubation. The patients who were chosen were between the ages of 20 and 55 years old. The mean age difference between the two groups was almost statistically insignificant. The ratio of males to females was the same in both groups. The difference between the average preoperative pulse rate and blood pressure was also statistically insignificant.

The first dose of medication was administered at the stroke of midnight. In addition to measuring the intensity of the pain, hemodynamic changes such as the heart rate and mean arterial blood pressure were measured at the same intervals as the pain measurements. Following the administration of study medications, the use of narcotic analgesics was prohibited for 8 hours.

Rescue analgesia injection diclofenac 75mg/3ml was given on the patient's request or if the VAS score was greater than 5cm on the pain scale.

In the past, aceclofenac was available in an injectable form for intramuscular administration in the form of 1 mL ampoules containing 150 mg of aceclofenac. The drug was only intended for deep intragluteal and intramuscular injections and was not intended for subcutaneous administration. Because of the severe pain that was caused by the intramuscular injection, the drug was never widely used and received poor approval from both doctors and patients.

There is currently no parenteral form of aceclofenac available; however, there is an improvised intramuscular version that contains 150 mg of aceclofenac in 3 mL, with each millilitre containing 50 mg of aceclofenac. Aqueous urea and sodium citrate are added to the ampoule to stabilise the solution and reduce pain during intramuscular injection. Additionally, the ampoule can be injected into the deltoid muscle, which is a significant advantage. It is a sustained release injection with improved efficacy, a duration of action of 18-24 hours, and a favourable tolerability profile. This is supported by Rajesh Kumar, Maheshwari, and Arpna Indurkhya's study of formulation and evaluation of aceclofenac injection made by mixed hydrotropic solubilization technique, which was published in the journal Pharmacotherapy [11].

The present study demonstrated that, when comparing Group I aceclofenac to Group II diclofenac at 2, 4, 6, 8, 12, and 24 hours, the mean pain scores by VAS showed significantly less pain scores in Group I aceclofenac. After 8

hours, all of the Group II patients were given injection diclofenac in 75mg/3ml as rescue analgesia if they requested it or had pain scores greater than 5cm, which can be explained by the pharmacokinetic properties of both drugs, respectively. When administered intravenously, aceclofenac takes 10 minutes to take effect, while diclofenac takes 20 minutes.

With the exception of diclofenac, which has a peak action of 2 hours, aceclofenac has a peak action of only 1 hour. The duration of action of injection aceclofenac is prolonged as a result of the controlled release of the drug.

At 2 hours, there was no statistically significant difference in pulse rate. By that time, both drugs have reached their peak levels of action. The mean pulse rate in Group I was significantly lower at the 4th, 6th, and 8th hours, indicating that the superior analgesia provided by injection aceclofenac was evident. There was no statistically significant difference in the mean pulse rate between Group I and Group II at 12 and 24 hours, which can be explained by the fact that rescue analgesia was administered to Group II after 8 hours. The mean arterial pressures in Group II were significantly higher than those in Group I, indicating that the injection aceclofenac provided excellent analgesia for up to 24 hours after administration.

In the current study, injection aceclofenac was found to be better tolerated. Patients treated with aceclofenac experienced only minor side effects, such as pain at the injection site, which were almost non-existent. According to the findings of this study, patients treated with injection aceclofenac 150mg/3ml experienced a greater overall percentage reduction in pain intensity, as well as a higher peak pain intensity difference score and a longer duration of action, than those treated with injection diclofenac 75mg/3ml, respectively.

Madhavi, *et al*. [12] concluded that aceclofenac is an effective and well tolerated drug in the treatment of osteoarthritis: a randomised double-blind comparative clinical trial versus diclofenac - an Indian experience. Aceclofenac is statistically superior to diclofenac in terms of compliance in the treatment of osteoarthritis, according to the study.

According to another study conducted by Dodhy *et al*. [13] titled “Comparison of efficacy of aceclofenac with diclofenac sodium for postoperative pain relief following laparoscopic cholecystectomy," aceclofenac in injectable form is superior to diclofenac in providing severe intensity postoperative pain relief in patients with lower limb fractures. Furthermore, it has a more favourable tolerability profile than the original. Because it has a long half-life, it is administered less frequently than other medications. As a result, aceclofenac is a more effective alternative to diclofenac in patients suffering from severe postoperative pain.

Conclusion

Predicated on the findings of the research, we conclude that long-acting NSAIDs such as injection aceclofenac 150 mg/3m1 have a specific role in postoperative analgesia for patients undergoing laparoscopic abdominal surgeries, due to their high quality of analgesia, sustained and prolonged duration of action (up to 18-24 hours), and minimal side effects on the kidneys and gastrointestinal tract (GIT).

Acknowledgment

The author is thankful to Department of Anesthesiology for providing all the facilities to carry out this work.

Conflict of Interest

None

Funding support

Nil

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