ORIGINAL ARTICLE

COMPARISON OF EFFICACY OF ACECLOFENAC WITH DICLOFENAC SODIUM FOR POSTOPERATIVE PAIN RELIEF FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY

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Received: August 3, 2018 Accepted: October 2, 2018

ABSTRACT

The object of the present study was to compare the efficacy of intramuscular injections of aceclofenac with diclofenac sodium for postoperative pain relief following laparoscopic cholecystectomy. The study was carried out in the Department of Anesthesiology, Combined Military Hospital, Quetta, Pakistan. A randomized clinical trial was performed over a period of six months from January to July, 2015. A total of 154 patients, age between 21–50 years, were enrolled and divided into two groups of 77 each. The mean age of patients in Group A and B was 36.1±6.8 and 36.1±7.1 years, respectively. The number of male and female patients in Group A were 52 (67.5%) and 25 (32.5%), respectively while in Group B the number was 50 (65.0%) and 27 (35.0%), respectively. The inclusion criterion of patients was based on the classification I and II of the American Society of Anesthesiologists (ASA). The patients of one group received IM injection of aceclofenac (150 mg) while the other group received IM injection of diclofenac sodium (75 mg), half an hour prior to extubation. The postoperative intensity of pain at 0.5, 1, 2, 4, 6, and 12 h was measured using visual analog scale (VAS). VAS value of >5 was considered as inadequate and an alternative analgesic (tramadol) was administered. A considerable decrease in postoperative VAS values was observed in Group A when compared with the patients of Group B (i.e. 61.0% vs 42.9%, p=0.023). Stratification with regard to age, gender, height, weight, and ASA status was performed. It has been observed that after laporoscopic cholecystectomy the relief in severe pain is better with IM injections of aceclofenac as compared to diclofenac sodium.

Keywords: Aceclofenac, diclofenac sodium, intramuscular injection, laparoscopic cholecystectomy, postoperative pain.

1. INTRODUCTION

Pain is an extraordinary complex sensation which is neither easy to describe nor quantify[1]. The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"[1]. Postoperative pain is usually a severe localized pain of varying intensity caused by increased prostaglandin synthesis[2]. Postoperative pain reaches to its maximum intensity within 3–5 h[2]. In more than fifty percent of the surgical patients, pain is not treated adequately[3].

The objective in managing postoperative pain is to reduce its intensity, enhanced recovery of the patient, and smooth the progress of usual activities of daily life[3]. As compared to open cholecystectomy, pain after laparoscopic cholecystectomy is less severe. However, a significant distress is often experienced by some patients[4]. Non steroidal anti-inflammatory drugs (NSAIDs) in parenteral form are a smart

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choice in managing postoperative pain[5]. These drugs are successful in treating an extensive range of postoperative pain with very less undesirable effects[6].

Aceclofenac is a phenyl acetic acid derivative and is chemically, 2-[2-[2-[(2, 6-dichloro phenyl) amino] phenyl [acetyl] oxyacetic acid. It has both anti-inflammatory and pain-relieving properties. It is a strong inhibitor of cyclooxygenase, which is responsible for the production of prostaglandins[7]. It is reported to have better therapeutic activity in parenteral form than diclofenac sodium injection in treating postoperative pain after fractures of lower limb[5]. Aceclofenac is known to have good tolerability profile, longer half-life, and lesser frequency for administration as compared to diclofenac[5]. The purpose of the present study is to compare and evaluate the postoperative analgesic effect of aceclofenac with diclofenac sodium in patients going through laparoscopic cholecystectomy.

2. METHOD

2.1. Study Design

The study has been carried out in the Department of Anesthesiology, Combined Military Hospital, Quetta, Pakistan. A randomized clinical trial has been carried out over a period of six months from January to July, 2015. A total of 154 patients were enrolled and divided randomly into two groups A and B, each containing 77 patients. All laparoscopic surgeries have been performed by a single surgeon.

2.2. Inclusion and Exclusion Criteria

The patients were informed about the aim of the study and a prior written consent was taken. Patients within the age group of 21–50 years fulfilling the classification I and II criteria of American Society of Anesthesiologists (ASA) were included in the study. Whereas patients with hypersensitivity to NSAIDs, co-morbid diseases like cardiac diseases, hepatic, or renal dysfunction, bleeding disorders, or with history of gastrointestinal bleeding were excluded from the study. Moreover, pregnant women or lactating mothers and patients who were reluctant to fulfill the protocol requirement were also excluded from the study.

2.3. Drug Administration

After the surgery, IM injections of aceclofenac (150 mg) and diclofenac sodium (75 mg) were given in the anterolateral portion of mid thigh to the patients of group A and B, respectively, half an hour prior to extubation.

2.4. Visual Analog Scale (VAS)

The intensity of postoperative pain in each patient has been measured at 0.5, 1, 2, 4, 6, and 12 h using VAS scale. VAS value of >5 was considered as inadequate and in such cases an alternate analgesic drug was given. IM injection of tramadol (2–3 mg/kg) was used as an alternate analgesic. The drugs used in the present study (aceclofenac and diclofenac sodium) are considered efficacious if patient did not need any alternate analgesic for 12 h after administration of those injections.

2.5. Data Analysis

All data has been analyzed using Statistical Package for Social Sciences (SPSS) version 17.0 (IBM, New York, USA). Standard deviation and mean was calculated for quantitative data. Percentages and frequencies were calculated for qualitative variables like efficacy and gender. Chi square test was performed for the comparison of group A with B, p value of ≤ 0.05 was considered as significant. Effect modifiers (age, gender, and ASA status) were controlled by stratification.

3. RESULTS AND DISCUSSION

Pain is an obnoxious and disturbing sensory feeling that is often associated with tissue damage. After surgical procedure, patients experience some sort of postoperative pain. This pain triggers stress response and certain biochemical reactions may take place[8]. Pain is the most important community health concern all over the world and represents a key medical, public, and financial dilemma[9]. Post surgery pain is usually a nociceptive pain. Surgical pain often results in hyperalgesia as well as peripheral and central sensitization. If this

condition is not treated, it will result in postoperative chronic pain[10]. Thus, managing pain especially postoperative pain is a matter of great concern for physicians and patients who are undergoing surgery. Patients frequently ask about the pain level they may feel after the surgery. Postoperative pain causes tachycardia and hyperventilation as well as decrease in alveolar ventilation. It may change to chronic pain, delay the wound healing and may lead to insomnia as well. All these factors affect patients' operative outcome, comfort, and contentment from medical care[11].

In the present study, patients enrolled in group A received aceclofenac injection (150 mg) whereas diclofenac sodium injection (75 mg) was administered to the patients of group B. The mean age of patients of group A was 36.1±6.8 years and for group B it was 36.1±7.1 years. In group A, 52 patients (67.5%) were male while the remaining 25 (32.5%) were female. Similarly in group B, 50 patients (65.0%) were male and 27 (35.0%) were female. The comparison of characteristics of patients between groups is shown in Table 1.

Mean weight of the patients is found to be 71.5±5.1 and 71.3±5.2 kg in groups A and B, respectively (Table 1). Mean height in group A and B are found to be 5.4±0.3 and 5.5±0.3 ft, respectively (Table 1). In group A, 33 patients (42.8%) and in group B 30 patients (39.0%) were fulfilling the ASA classification I status while the remaining were of classification II status (Table 1).

There are certain individual variations that exist in the pain intensity. They include genetic composition, cultural environment, gender and age[12]. Stratification with respect to age, gender, height, weight, and ASA status has been carried out and is presented in Table 2. The results indicate that all the studied variables are statistically significant.

Table 1. Comparison of the characteristics of patients between groups

Variables	Group A	Group B
Age (years)	36.1±6.8	36.1±7.1
Gender, n (%)		
Male	52 (67.5%)	50 (65.0%)
Female	25 (32.5%)	27 (35.0%)
Weight (kg)	71.5±5.1	71.3±5.2
Height (ft)	5.4±0.3	5.5±0.3
ASA (%)		
I	42.8	39
II	57.2	61

Table 2. Stratification with respect to age, gender, height, weight, and ASA status to drug efficacy

Variables	Drug Efficacy				*p* value
	Group A (n = 77) (Aceclofenac 150 mg)		Group B (n = 77) (Diclofenac sodium 75 mg)		
	Yes	No	Yes	No	
Age (years)					
21–30	4	11	7	10	0.388
31–40	30	12	16	22	0.008
41–50	13	7	10	12	0.203
Gender					
Male	37	15	21	29	0.002
Female	10	15	12	15	0.745
Height (ft)					
4.8–5.2	10	12	8	11	0.809
5.3–5.9	37	18	25	33	0.009
Weight (kg)					
60–70	13	16	8	23	0.122
71–80	34	14	25	21	0.098
ASA					
I	26	7	19	11	0.175
II	21	23	11	33	0.078

Currently, the practice of anesthesiology has been changed from intraoperative care to perioperative management. Pain management in the postoperative period is one of the most essential components of optimum postsurgical patient care[13]. Laparoscopic cholecystectomy is generally the first option in the cure of symptomatic gallbladder stone. Pain after the laparoscopic cholecystectomy is due to surgical handling, intraperitoneal CO_2 insufflation, intraabdominal pressure during surgery and irritation due to leakage of bile during surgery[14]. Pain is felt in epigastrium, radiating to shoulders and back, and most commonly in upper abdomen[15]. Postoperative pain is a significant factor that is responsible for increased morbidity and mortality and consequently the hospital stay is prolonged[16]. Preemptive analgesia can reduce the intensity and extent of pain and can also delay the onset of pain[17]. Non steroidal anti-inflammatory drugs (NSAIDs) are regularly used for this rationale. Nowadays laparoscopic cholecystectomy is considered as one of the ambulatory surgeries and is used to manage pain. However, still about 80% of the patients feel pain after surgery[18] and the intensity is maximum in the first hour[19]. It is reduced in the subsequent hours and slowly decreases in the second and third postoperative days[19].

In the present study, analgesic efficacies of aceclofenac (Group A) and diclofenac sodium (Group B) following laparoscopic cholecystectomy were compared (Table 3). A considerable decrease in postoperative VAS values has been observed in group A patients as compared to the patients of group B (61.0% vs 42.9%, p=0.023). These findings are comparable with the results of Sharma et al.[5], who used similar drugs to counter pain in patients with postoperative lower limb fractures. Their results also indicated that aceclofenac was superior to diclofenac in providing postoperative pain relief[5].

Table 3. Comparison of efficacy of aceclofenac with diclofenac sodium (n = 154)

Efficacy	Group A (n = 77) (Aceclofenac 150 mg)		Group B (n = 77) (Diclofenac sodium 75 mg)		Chi Square (*p* value)
	Number	%	Number	%	
Yes	47	61.0	33	42.9	5.10 (0.023)
No	30	39.0	44	57.1	
Total	77	100.0	77	100.0	

4. CONCLUSION

It is concluded that aceclofenac (150 mg) is better in pain management after laporoscopic cholecystectomy than diclofenac sodium (75 mg). Furthermore, aceclofenac established a good tolerability profile as compared to diclofenac sodium. Due to longer half-life, frequency of administration was also less thus resulting in better prognosis. The IM injection of aceclofenac is a good alternative to IM injections of diclofenac sodium for the management of postoperative pain.

FUNDING

None mentioned.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ETHICAL APPROVAL

The study was conducted after approval from the Ethics Committee of Combined Military Hospital, Quetta, Pakistan.

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