

# THE EFFECT OF COMBINATION OF DICLOFENAC SUPPOSITORY AND LIGNOCAINE CREAM ON POSTOPERATIVE PAIN AFTER ANAL SURGERY

By

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## ABSTRACT

**Background:** Anal surgery is associated with severe postoperative pain which is a source of such anxiety that some patients refuse the operation. Opiates and non-steroidal anti-inflammatory drugs have often been used to control pain.

**Objectives:** Evaluation of the effect of diclofenac suppository and lignocaine cream on postoperative pain after anal surgery.

**Paitents and Methods:** This study was a prospective randomized double blinded controlled study carried on 120 patients presenting with anal conditions (hemorrhoid, anal fissure or low perianal fistula), who underwent anal surgery. Patients were divided randomly into two equal groups. Group (A) was a control group, and group (B) received diclofenac suppository (100 mg) and topical lignocaine cream 5% (5 g) at the end of surgery. The mean VAS scores at 2, 4, 8, 12, and 24 hours after surgery were recorded.

**Results:** The pain reported by group (B) was statistically lower than that in control group (group A) in all intervals. Also, the incidence for administration of postoperative analgesic in group (B) was statistically lower than that in group (A).

**Conclusion:** Combination of diclofenac suppository and topical lignocaine cream significantly decreased the severity of postoperative pain after anal surgery, and decreased the requirement of post-operative analgesics.

**Key words:** Anal surgery, topical lignocaine, diclofenac suppository.

## INTRODUCTION

Commonly surgical anal conditions are hemorrhoids, anal fissure and perianal fistula. These conditions almost need surgical interference. Surgery is associated with severe postoperative pain which is a source of such anxiety that some patients refuse the operation. Opiates and non-steroidal anti-inflammatory drugs (NSAIDs) have often been used to control pain (*Ala et al., 2013*).

Opiates have important adverse effects including drowsiness, apnea, nausea, vomiting, respiratory depression, and ileus. NSAIDs are safer than opiates with the same effect on postoperative pain (*Lohsiriwat, 2012*).

Postoperative pain and delayed wound healing are the most annoying problems to the patients and the surgeons, pain may be explained by surgical wound in the sensitive perianal skin and anoderm and

the edema from inflammation around the wound (*Nienhuijs & de Hingh, 2010* and *Uzzaman & Siddiqui, 2011*). Various topical applications were used to reduce pain e.g. calcium channel blockers, local anesthetics, botulinum toxin, glyceryl trinitrate (GTN), metronidazole, opioids, sucralfate, one herbal cream mainly consist of Aloe vera (*Watson et al., 2016*). Consequently, the introduction of novel methods for the control of pain after anal surgery is required.

Local anesthetics considered as an important components of multimodal analgesic regimens for surgical wound and proved efficacy and tolerability when administered appropriately (*Golembiewski and Dasta, 2015*). Dicofenac sodium is a NSAID and has an analgesic and antipyretic effect.

The aim of our study was to evaluate the effect of diclofenac suppository and lignocaine cream on postoperative pain after anal surgery.

## PATIENTS AND METHODS

This study was a prospective randomized double blinded controlled study performed at the department of surgery, Al-Azhar university hospitals. It was carried on one hundred and twenty patients (69 males and 51 females) with the mean age  $38.7 \pm 3.8$  (range 17–67) years, presenting with anal conditions (hemorrhoid, anal fissure or low perianal fistula), who underwent anal surgery (hemorrhoidectomy, fissurectomy, or fistulotomy).

**Inclusion criteria:** Patients 17 years or older, have 3rd or 4th degree hemorrhoids, or those have chronic anal fissure or low perianal fistula.

**Exclusion criteria:** Patients with previous anal surgery, poorly controlled diabetes mellitus, severe anemia, hypoalbuminemia and liver or renal impairment.

All anal surgery (hemorrhoidectomy, fissurectomy, or fistulotomy) performed under spinal anesthesia. At the end of surgery, patients were divided randomly into two groups (A, B), 60 patients each group. Group (A) was a control group, and group (B) received diclofenac suppository (100 mg) and topical lignocaine cream 5% (5 gm) at the end of surgery.

All patients were admitted to surgical department of Al-Azhar University hospital and referred from outpatient clinics in the period between September 2015 and February 2018. The study was approved by the local ethics committee of surgery department. Informed consent was granted from all patients. All patients in our study underwent history taking, complete clinical examination and investigations.

Assessment of pain was based on a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (severest pain); 2, 4, 8, 12 and 24 hours after operation. Patients were given (Nalbuphine 4mg) intravenously if their VAS score was  $\geq 7$ . Pain scores, total nalbuphine consumption, patient's requests for administration of postoperative analgesics were recorded.

**Statistical analysis:**

Data were summarized by mean  $\pm$  standard deviation and categorical variables are expressed as percentage (%).

Univariate analyses were performed by Chi square, unpaired student's t-test. Results were considered significant if P values were less than 0.05.

**RESULTS**

The patient's characteristics including age, sex, types of anal surgery were recorded in the two groups (Table 1).

There were no significant differences between the two groups as regard baseline characteristics.

**Table (1): Base line patient's characteristics**

<b>Parameters \ Groups</b>	<b>Group A</b>	<b>Group B</b>	<b>Total</b>	<b>P- Value</b>
<b>No</b>	60	60	120	-
<b>Age (Years) Mean <math>\pm</math> SD</b>	38.9 $\pm$ 3.6	38.4 $\pm$ 4.3	38.7 $\pm$ 3.8	> 0.05
<b>Sex:</b>				
<b>Male</b>	31	38	79	> 0.05
<b>Female</b>	29	22	51	> 0.05
<b>Types of surgery:</b>				
<b>Hemorrhoidectomy</b>	25	23	48	> 0.05
<b>Fissurctomy</b>	23	24	47	> 0.05
<b>Fistulotomy</b>	12	13	25	> 0.05

Post-operatively: The mean VAS score at 2, 4, 8, 12, and 24 hours after surgery was recorded, it has been shown that the pain reported by group B (diclofenac

suppository and lignocaine cream) was statistically lower than that in control group (group A) in all intervals (Table 2).

**Table (2): Pain scores on a visual analogue scale (VAS) at different time points after surgery (mean  $\pm$  SD)**

<b>Parameters \ Groups</b>	<b>Group A</b>	<b>Group B</b>	<b>P-Value</b>
<b>VAS (after 2 hs)</b>	4.5 $\pm$ 1.8	1.6 $\pm$ 1.07	< 0.001
<b>VAS (after 4 hs)</b>	6.7 $\pm$ 2.5	4.6 $\pm$ 1.3	< 0.001
<b>VAS (after 8 hs)</b>	7.9 $\pm$ 1.02	5.8 $\pm$ 1.6	< 0.001
<b>VAS (after 12 hs)</b>	6.7 $\pm$ 0.8	5.5 $\pm$ 1.9	< 0.001
<b>VAS (after 24 hs)</b>	6.6 $\pm$ 1.4	5.3 $\pm$ 1.9	< 0.001

After 4 hours post-operatively, 11 patients (18.3%) of group B and 32 patients (53.3%) of group A required analgesic. Furthermore, 25 patients (41.6%) of group B and all patients (100%) of group A required analgesic at 8 hour post-operatively. After 12 hours, 35 patients (58.3%) of group B and 48 patients (80%) of group A required analgesics. After 24 hours, the

requirement of analgesics decreased in both groups, but still more significant in group A (Table 3). The incidence for administration of postoperative analgesic in group B was statistically lower than that in group A (P-value < 0.005). Also, the mean nalbuphine consumption dose in group B ( $6.3 \pm 3.5$  mg) was statistically lower than that in group A ( $16 \pm 6.8$  mg) with P-value < 0.001 (Table 3).

**Table (3): Incidence of post-operative analgesic dose requirement and consumption**

Parameters \ Groups	Group A. No (%)	Group B. No (%)	P-Value
After 2 hs	12 (20%)	0 (0%)	< 0.001
After 4 hs	32 (53.3%)	11 (18.3%)	< 0.001
After 8 hs	60 (100%)	25 (41.6%)	< 0.001
After 12 hs	48 (80%)	35 (58.3%)	0.01
After 24 hs	37 (61.6%)	22 (36.6%)	0.006
Nalbuphine consumption (mg)	$16 \pm 6.8$	$6.3 \pm 3.5$	< 0.001

## DISCUSSION

The severity of postoperative pain after anal surgery is a major problem. Multiple factors may be a cause of pain as patient's tolerance, type of anesthesia, type of post-operative analgesia, surgical technique and edema and tissue inflammation around the surgical wound all lead to more worsening of post-operative pain (Gupta *et al.*, 2008). It may delay discharge from hospital, recovery and return to work. Various invasive and noninvasive trails have been made to reduce pain after anal surgery (Shiau *et al.*, 2008).

Noninvasive methods suggested to control post-hemorrhoidectomy pain, including application of topical preparations such as botulinum toxin, nitrates (Watson *et al.*, 2016), and metronidazole do not seem to offer any

benefit in terms of rapid pain relief in the first 24 hours after open hemorrhoidectomy (Uzzaman and Siddiqui, 2011).

It has been shown that NSAIDs like diclofenac reduce postoperative pain by blocking cyclo-oxygenase (COX) enzyme and can be used as anesthetic drugs (Arab *et al.*, 2013).

Topical lignocaine cream (local anesthetic) and diclofenac suppository drugs had been investigated in this study to reduce the severity of postoperative pain.

Results of current study showed that; the pain reported by group B (diclofenac suppository and lignocaine cream) was statistically lower than that in control group (group A) in all intervals. Also, the incidence for administration of postoperative analgesic in group B was

statistically lower than that in group A. Also, the mean nalbuphine consumption dose in group B was statistically lower than that in group A.

In a study by (Shiau *et al.*, 2008), local anesthetic cream, EMLA cream (lidocaine 2.5% and prilocaine 2.5%) was used for post hemorrhoidectomy pain and showed a better pain control and patient satisfaction than control group.

(Rahimi *et al.*, 2012), in their study to evaluate the effect of EMLA cream and diclofenac suppository on post-operative pain, reported that EMLA showed better short-term pain control following hemorrhoidectomy, while more sustainable pain control was provided by diclofenac suppository.

(Alkhateep and Fareed, 2017), in their study on 150 patients, observed that pain intensity was significantly lower in local anesthetic cream group than placebo group at the 1st, 3rd and 7th days after anal surgery.

## CONCLUSION

Combination of diclofenac suppository and topical lignocaine cream is significantly lower the severity of postoperative pain after anal surgery and decrease the requirement of post-operative analgesics. Also increase the patient satisfaction.

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## تأثير توليفة لبوس ديكلوفاناك مع مرهم الليجنوكايين على الألم المصاحب للعمليات الشرجية

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**خلفية البحث :** تعتبر العمليات الشرجية من أكثر العمليات المصحوبة بالألم شديدة بعد إجراء العملية الجراحية مما يجعلها مصدرا للقلق والتوتر، مما يجعل الكثير من المرضى يرفضون عمل مثل هذه العمليات. و تعتبر العقاقير المخدرة والمسكنات الغير كورتيزونية من أكثر العقاقير المستخدمة للتحكم فى مثل هذه الآلام.

**الهدف من البحث:** تقييم تأثير توليفة لبوس ديكلوفاناك مع مرهم الليجنوكايين على الألم المصاحب للعمليات الشرجية.

**المرضى وطرق البحث:** أعدت هذه الدراسة على ١٢٠ مريضا كانوا يعانون من مشاكل شرجية مثل البواسير و الشرخ الشرجى أو الناسور الشرجى السفلى الذين تتراوح أعمارهم بين ١٧ و ٦٧ عام. وقد تم تقسيم المرضى عشوائيا إلى مجموعتين متساويتين: مجموعة (أ) لم يتم إعطاؤها شئ، مجموعة (ب) تم إعطائها لبوس ديكلوفاناك مع مرهم ليجنوكايين عند نهاية العملية الجراحية. وقد تم تسجيل شدة الألم بعد ٢، ٤، ٨، ١٢، ٢٤ ساعة بعد العملية.

**النتائج:** أثبتت النتائج إحصائيا أن شدة الألم كانت أقل بكثير فى مرضى المجموعة (ب) عنه فى مرضى المجموعة (أ). وبالتالي، كان معدل إعطاء المسكنات بعد العملية أقل بكثير بالنسبة لمرضى المجموعة (ب) عنه لمرضى المجموعة (أ).

**الاستنتاج:** إعطاء توليفة لبوس ديكلوفاناك مع مرهم الليجنوكايين عند نهاية العملية الجراحية الشرجية يؤدي إلى تقليل الألم بشكل كبير جدا وبالتالي يقلل معدل إعطاء المسكنات بعد العملية.