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Efficacy of Transdermal Diclofenac and Ketoprofen Patches for Postoperative Analgesia in Laparoscopic Surgeries: A Comparative Study

[1]Dr. Vinod C.N, Associate Professor, Department of Anaesthesiology and Critical Care, Kempegowda Institute of Medical Sciences, Bangalore

[2]Dr. Neelambika. Ragate, MD, Department of Anaesthesiology and Critical Care, Kempegowda Institute of Medical Sciences, Bangalore

Corresponding Author: Dr. Neelambika. Ragate, MD, Department of Anaesthesiology and Critical Care, Kempegowda Institute of Medical Sciences, Bangalore

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Abstract

Introduction: Pain relief after laparoscopic surgery is essential for enhancing recovery, ensuring patient satisfaction, and providing the ultimate benefit to patients. Several routes for the administration of analgesics during the postoperative period are available to anesthesiologists, including general anesthesia during the operation and various techniques for postoperative analgesia. The risk of and awareness about the side effects of nonsteroidal anti-inflammatory drugs (NSAIDs) have led to the development of preparations with an improved safety profile to limit systemic toxicity, such as ketoprofen and diclofenac transdermal patches.

Aim

- To determine the efficacy of transdermal patches for post-operative analgesia in patients undergoing laparoscopic surgeries.
- To estimate the duration of postoperative analgesia.
- To compare the time of need for rescue analgesia.
- To evaluate the side effects, if any in both groups.

Methodology

Study Place: This study was conducted in the Department of Anaesthesiology and Critical Care at Kempegowda Institute of Medical Sciences Hospital and Research Center, Bangalore.

Study Duration: May 2023- October 2023.

Study Design: A prospective comparative randomized study.

Sampling Method: Simple random sampling

Sample Size: 60 patients of either sex of age group 18-60 years posted for laparoscopic surgeries.

Result: The VAS score for pain intensity was recorded at 4 h after extraction. Any requirement of additional analgesia within the first 24 h and adverse effects due to patches were also recorded. Statistically significant difference was observed on comparing both the study groups. For diclofenac patch, the mean VAS score was 6.87 (1.43), whereas it was 5.37 (1.10) in case of ketoprofen patch.

Conclusion: Diclofenac and ketoprofen transdermal patches are helpful in relieving pain after laparoscopic surgeries. Patients with diclofenac patch required more additional analgesia as compared to that with ketoprofen patch. None of the drugs showed any adverse effects and were well tolerated by the patients.

Keywords: Laparoscopic surgeries, NSAIDS, Peritoneal irritation, Oral drugs

Introduction

Laparoscopic surgeries are considered relatively painless and are associated with early recovery and lesser duration of hospital stay, although they can cause severe pain, especially in the first 4 hours of the immediate post-operative period, attributed to the peritoneal irritation caused by the carbon dioxide insufflation pressures, bowel handling by the surgeons or irritation caused by the residual or retained blood. Transdermal drug delivery offers compelling opportunities to address the low bioavailability of many oral drugs, the pain and inconvenience of injections, and the limited controlled-release options of both. Non-steroidal anti-inflammatory drugs (NSAIDs) are one of the commonly used drugs for postoperative pain relief throughout the world as they require less monitoring and have fewer side effects. They are administered by oral, parenteral, inhalational and transdermal routes. The commonly used NSAIDS via transdermal route are Diclofenac and Ketoprofen. Here we conducted a study to determine the efficacy of the study drugs in post-operative analgesia.

Aims & Objectives

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Material and Method

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Sample Size Calculation

$$k = \frac{n_2}{n_1} = 1$$

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2/K)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$$n_1 = \frac{(1.3^2 + 1.3^2/1)(1.96 + 0.84)^2}{1^2}$$

$$n_1 = 27$$

$$n_2 = K * n_1 = 27$$

Total sample size: 27+27= 54~ 60

Δ = |μ2-μ1| = absolute difference between two means

σ1, σ2 = variance of mean #1 and #2

n1 = sample size for group #1

n2 = sample size for group #2

α = probability of type I error (usually 0.05)

β = probability of type II error (usually 0.2)

z = critical Z value for a given α or β

k = ratio of sample size for group #2 to group #1

Inclusion Criteria

- Patients aged between 18-60 years, of either sex.
- American Society of Anesthesiology (ASA) physical status 1 & 2.

Exclusion Criteria

- Subjects having history of heart block, bronchial asthma, bleeding disorders, taking anticoagulants, active peptic ulcer disease, skin diseases, liver and kidney disorders and drug/alcohol abuse.
- Pregnant and Lactating mothers.
- Subjects with hypersensitivity to the study medications.

Study Group and Methodology

- Subjects were administered general anaesthesia, following which application of either Diclofenac 100mg or Ketoprofen 30mg transdermal patch was done based on randomization done through computer generated randomization in 1:1 allocation. They were applied on non-hairy part of their back and surgery is carried out thereafter.
- Subject's pain was assessed post extubation by Visual Analog Scale (VAS 0-10) at 0h, 4h, 8h, 12h and 24h post-operative periods.
- At any point of time during the first 24h if subject complains of pain >2 on VAS score, Inj Tramadol 75mg IV was given as rescue analgesia and time of administration post-operatively was noted down. Dose was repeated if necessary.
- Subjects were also observed for any adverse events.
- Patient's and Investigator's global assessment of efficacy was done at 24h.

Result

Table 1: General Characteristics

Variable	Ketoprofen patch	Diclofenac patch	p-value
Age in years	45.83 ± 13.38	45.16 ± 12.06	0.99
Male : Female	8 : 22	9 : 21	0.99

The present study consisted of total of 60 patients, and all of them (100%) were evaluated in follow-up phase. Of these 60 patients, 43 (71.67%) were female, and 17 (28.33%) were male. Mean age of patients was 45.24± 13.38 years.

Table 2: VAS score

VAS score	Ketoprofen patch	Diclofenac patch	p-value
0 hour	0.16 ± 0.37	0.23 ± 0.43	0.61
4 hours	1.50 ± 0.63	2.03 ± 0.81	0.01
8 hours	1.37 ± 0.49	2.36 ± 0.61	0.01
12 hours	2.77 ± 0.86	3.93 ± 1.17	0.01
24 hours	5.37 ± 1.10	6.87 ± 1.43	0.01

The VAS score for pain intensity was recorded at 4 h after extraction of specimen in laparoscopic surgeries. Any requirement of additional analgesia within the first 24 h and adverse effects due to patches were also recorded. Statistically significant difference was observed on comparing both the study groups. For the diclofenac patch, the mean VAS score was 6.87 (1.43), whereas it was 5.37 (1.10) in the case of the ketoprofen patch.

Table 3: Rescue Analgesia Time

Rescue Analgesia Time	Ketoprofen patch	Diclofenac patch	p-value
	725.02 ± 122.67	435.37± 175.59	0.01

No major complication or adverse effects were observed in any of the groups. Three patients with ketoprofen

patch and two patients with diclofenac patch had mild fever following extraction.

Discussion

The transdermal route is one of the safest, non-invasive, and most innovative drug delivery systems that provide sustained drug delivery. It needs a single application a day and is convenient to use. Besides, it also offers other advantages such as self-administration, increased bioavailability, and easy termination of medication, leading to better patient compliance. In this, the drugs are delivered across the skin in the form of patches to have an effect on the tissues adjacent to the site of application or to have an impact after distribution through the circulatory system.[5]

Many studies show that the efficacy of transdermal patches is more than oral tablets. Talnia *et al*.[6] evaluated the effectiveness of transdermal diclofenac patch and compared it to oral diclofenac tablet as analgesic following extractions in orthodontic patients. He concluded that transdermal diclofenac has better efficacy in managing the postoperative mild-to-moderate intensity pain in premolar orthodontic extraction with lower adverse effects. The same results were reported by Funk *et al*.[7] and Krishna *et al*.[8] they concluded that diclofenac patches provide significantly better analgesia and have fewer side effects as compared to the tablets in the early postoperative period. Metry *et al*. showed the transdermal ketoprofen patch is an effective and safe method for relieving pain after venous cannulation.[9]

Hence, the present study compares two drugs belonging to NSAIDs given through this innovative method in postoperative extraction patients. In our study, we found that the ketoprofen patch offers better pain control as compared to the diclofenac patch as the mean visual analog was less when the ketoprofen patch had been used. The same results were observed by Bhargava *et al*.[10] in his study. The results of this study are also in accordance with Jadhav *et al*.[11] who compared the two patches after orthognathic surgery and Verma *et al*.[6] in which the patches were compared following lower limb orthopedic surgery.

Thus, our study shows that ketoprofen patch provided better analgesia than the diclofenac transdermal patch following laparoscopic surgeries.

Conclusion

Diclofenac and ketoprofen transdermal patches are helpful in relieving pain after laparoscopic surgeries. Patients with diclofenac patch required more additional analgesia as compared to that with ketoprofen patch. None of the drugs showed any adverse effects and were well tolerated by the patients.

A multi centric studies with a larger sample size are needed to evaluate the efficacy of these drugs in various surgical procedures to support it as a sole method to achieve analgesia postoperatively.

Ethical Issues

- Written informed consent will be taken from patients.
- Supervision by senior staff.
- The cost of the drug will be borne by the investigator.

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