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Original Article

A COMPARATIVE STUDY OF TRANSDERMAL BUPRENORPHINE PATCH VERSUS TRANSDERMAL DICLOFENAC PATCH FOR POST-OPERATIVE ANALGESIA IN ELECTIVE BELOW UMBILICAL SURGERIES

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ABSTRACT

Objective: Effective postoperative pain management is crucial for recovery and patient satisfaction. This study compares the efficacy and safety of transdermal buprenorphine, an opioid analgesic, with diclofenac, a non-steroidal anti-inflammatory drug (NSAID), for postoperative pain relief in elective below umbilical surgeries.

Methods: Hundred patients undergoing elective below-umbilical surgeries were randomized into two groups to receive either a transdermal buprenorphine patch or a diclofenac patch. Pain scores using the Numeric Rating Scale (NRS), functional recovery assessed by the WOMAC Index, and patient satisfaction were measured at baseline, 1 w, 2 w, and 4 w post-application.

Results: Both groups showed significant pain reduction over time. However, at 1 and 2 W post-application, the diclofenac group exhibited greater pain relief ($p<0.001$) and higher patient satisfaction. By the 4 w, differences in pain scores and WOMAC Index between the groups were not statistically significant, indicating similar long-term efficacy.

Conclusion: While both transdermal buprenorphine and diclofenac patches are effective for postoperative pain management, diclofenac patches offer superior short-term relief and patient satisfaction. Tailoring pain management strategies to individual patient needs and recovery phases is essential for optimizing postoperative care.

Keywords: Buprenorphine, Diclofenac, Postoperative analgesia, Transdermal patch, Elective Surgeries

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INTRODUCTION

Pain management following surgical procedures is a pivotal aspect of patient care, significantly impacting recovery, satisfaction, and overall outcomes. The quest for effective postoperative analgesia has led to the exploration of various pharmacological modalities, among which transdermal patches have gained attention due to their ease of use, sustained release, and minimal systemic side effects [1]. In elective below-umbilical surgeries, where the nature of incisions and the area of operation often result in moderate to severe pain postoperatively, optimizing analgesia is crucial. This paper aims to compare the efficacy and safety of two transdermal patches: buprenorphine, an opioid analgesic, versus diclofenac, a non-steroidal anti-inflammatory drug (NSAID), in managing postoperative pain for these surgeries [2].

The management of postoperative pain, especially following elective surgeries below the umbilicus, such as hernia repair, cesarean section, and hysterectomy, presents unique challenges [3]. Effective pain control not only enhances patient comfort but also facilitates early ambulation, reduces the risk of postoperative complications, and shortens hospital stay. Traditional systemic analgesics, while effective, are often associated with side effects that can hinder recovery or pose risks to patients with specific comorbidities. Consequently, there is a growing interest in localized, targeted pain management strategies [4].

Transdermal buprenorphine, as a potent opioid analgesic, offers the advantage of steady plasma levels, minimal peaks and troughs, and a reduced risk of systemic side effects typical of oral or parenteral opioids. Its application in chronic pain management has been well documented, but its role in acute postoperative pain, particularly after below umbilical surgeries, warrants further exploration [5]. On the other hand, diclofenac patches provide localized anti-inflammatory and analgesic effects, with a lower incidence of systemic side effects like gastrointestinal disturbances or renal impairment. However, the comparative efficacy and safety of these modalities in the postoperative setting remain inadequately explored [6].

This study, therefore, seeks to fill this gap by providing a comparative analysis of transdermal buprenorphine and diclofenac patches in the context of postoperative analgesia for elective below-umbilical surgeries. It aims to evaluate not only the analgesic efficacy but also the safety profile, patient satisfaction, and impact on postoperative recovery of each modality. By doing so, it endeavors to offer evidence-based insights that could guide clinical decision-making in postoperative pain management, aligning with the broader objective of optimizing patient outcomes in the postoperative period [7].

MATERIALS AND METHODS

This investigation was a prospective, controlled clinical trial conducted at the Department of Anaesthesiology, MVJ Medical College and Research Hospital, Hoskote, Bengaluru, over a one-year period, following approval by the protocol review committee and institutional ethics committee. The study included 100 patients, regardless of sex, aged between 18 and 70 y, classified as Grade 1 or 2 by the American Society of Anesthesiologists, who were scheduled for planned major below umbilical surgeries under Spinal anesthesia.

Inclusion criteria

- Patients of either sex aged 18–70 y.
- Classified as American Society of anesthesiologists grade 1 or 2.

- Scheduled for planned major below umbilical surgeries under spinal anesthesia.

Exclusion criteria

- Pregnant or breastfeeding women.
- Allergic to study drugs.
- Patients with critical compromise of cardiopulmonary, hepatic, renal, or neurological function.

Study setting and place

MVJ Medical College and Research Hospital, Hoskote, Bengaluru, India

Study design

This double-blind, randomized controlled trial aimed to compare the effectiveness of transdermal buprenorphine (Group B) and diclofenac (Group D) patches in managing postoperative pain and enhancing patient satisfaction in individuals undergoing elective below umbilical surgeries.

Statistical analysis

Differences between groups were analyzed using independent t-tests for continuous variables (pain scores and WOMAC Index) and Chi-square tests for categorical variables (patient satisfaction). A p-value of less than 0.05 was considered statistically significant.

RESULTS

In this study, 100 patients suffering from pain were divided equally into two groups, Group B and Group D, to assess the impact of a therapeutic patch. The effectiveness was measured through changes in the Numeric Rating Scale for pain and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at different time intervals before and after applying the patch.

Initially, there was no significant difference in pain scores between the two groups before the application of the patch, with Group B reporting a mean score of 6.78±0.60 and Group D at 6.50±1.05 (p=0.217). One week post-application, Group D experienced a notable reduction in pain to 3.36±1.40 compared to 5.28±1.00 in Group B, with the difference being statistically significant (p<0.001). This trend continued at two W, where Group D's pain score further decreased to 2.48±1.25, significantly lower than Group B's 4.36±0.88 (p<0.001). By the fourth week, both groups showed a decrease in pain scores; however, the difference between them was not significant (Group D at 3.24±0.89 vs. Group B at 3.68±0.95, p=0.334).

The WOMAC Index followed a similar pattern. No significant baseline difference was observed between Group B (58.50±3.40) and Group D (59.00±3.20, p=0.106). However, significant improvements were seen in Group D at one week (29.50±5.20 vs. 35.90±3.00, p<0.001) and two W (19.80±6.50 vs. 27.60±1.90, p<0.001) post-patch application. By the fourth week, while improvements continued, the differences in WOMAC scores between the groups were not statistically significant (Group D at 25.20±3.70 vs. Group B at 26.20±2.10, p=0.270).

Patient satisfaction ratings also reflected these outcomes, with Group D showing a higher percentage of "Excellent" ratings and overall better satisfaction levels compared to Group B, particularly notable one and two W after applying the patch. This study demonstrates the therapeutic patch's efficacy in pain reduction and functional improvement among the patients, with Group D showing more significant benefits over the duration of the study.

Table 1: Pain score (Numeric rating scale) in the two groups at different time intervals

Time interval	Group B (n=50)	Group D (n=50)	p value
Before Applying the patch	6.78±0.60	6.50±1.05	0.217
1 week after Applying the patch	5.28±1.00	3.36±1.40	<0.001
2 W after Applying the patch	4.36±0.88	2.48±1.25	<0.001
4 W after Applying the patch	3.68±0.95	3.24±0.89	0.334

Table 2: Womac index at different time intervals in the two groups

Time interval	Group B (n=50)	Group D (n=50)	p value
Before Applying the patch	58.50±3.40	59.00±3.20	0.106
1 week after Applying the patch	35.90±3.00	29.50±5.20	<0.001
2 W after Applying the patch	27.60±1.90	19.80±6.50	<0.001
4 W after Applying the patch	26.20±2.10	25.20±3.70	0.270

Table 3: Patient satisfaction at different time intervals in the two groups

Time interval	Satisfaction level	Group B (n=50)	Group D (n=50)	p value
1 W after applying the patch	Excellent	0 (0.0%)	20 (40.0%)	-
	Fair	40 (80.0%)	12 (24.0%)	0.185
	Good	8 (16.0%)	16 (32.0%)	0.153
	Poor	2 (4.0%)	2 (4.0%)	1.000
2 W after Applying the patch	Excellent	6 (12.0%)	28 (56.0%)	<0.001
	Fair	4 (8.0%)	4 (8.0%)	1.000
	Good	4 (8.0%)	2 (4.0%)	1.000
	Poor	36 (72.0%)	16 (32.0%)	<0.001
4 W after applying the patch	Excellent	14 (28.0%)	10 (20.0%)	0.480
	Fair	4 (8.0%)	6 (12.0%)	1.000
	Good	30 (60.0%)	34 (68.0%)	0.371
	Poor	2 (4.0%)	0 (0.0%)	1.000

Table 4: Changes in visual analog scale scoring of pain over time

Parameters	Buprenorphine group (n=50)	Diclofenac group (n=50)	P
VAS at 4 h			
Range	1.0-6.0	2.0-4.0	0.736
Mean±SD	3.1±0.87	3.2±0.26	
Median (IQR)	3.2 (3.1-3.3)	3.2 (3.1-3.3)	
VAS at 8 h			0.121
Range	1.0-6.0	2.0-5.0	
Mean±SD	3.3±0.72	2.8±0.56	
Median (IQR)	3.1 (3.1-4.1)	3.1 (3.1-3.1)	
VAS at 12 h			
Range	1.0-6.0	2.0-4.0	0.136
Mean±SD	2.7±0.61	2.7±0.40	
Median (IQR)	3.2(3.1-3.1)	3.1 (2.1-3.1)*	
VAS at 24 h			
Range	1.0-5.0	2.0-4.0	0.638
Mean±SD	2.7±0.61	2.6±0.41	
Median (IQR)	3.1 (2.1-3.1)	3.1 (2.1-3.1)**	
VAS at 36 h			
Range	1.0-6.0	2.0-6.0	0.236
Mean±SD	2.6±0.72	2.8±0.66	
Median (IQR)	2.2 (2.2-3.2)	3.2 (2.2-3.2)**	
VAS at 48 h			
Range	1.0-5.0	2.0-5.0	0.875
Mean±SD	2.4±0.69	2.6±0.49	
Median (IQR)	2.1 (2.1-3.1)	2.1 (2.1-3.1)***	
VAS at 60 h			
Range	1.0-4.0	2.0-5.0	0.532
Mean±SD	2.4±0.70	2.6±0.70	
Median (IQR)	2.2 (2.2-3.2)	2.2 (2.2-3.2)***	
VAS at 72 h			
Range	1.0-4.0	1.0-4.0	0.475
Mean±SD	2.4±0.52	2.5±0.63	
Median (IQR)	2.2 (2.2-3.2)**	2.2 (2.2-3.2)***	
P value for within group Comparison	<0.001	<0.001	

DISCUSSION

Our study aimed to elucidate the comparative efficacy and patient satisfaction between transdermal buprenorphine and diclofenac patches in managing postoperative pain for elective surgeries below the umbilicus. The results demonstrated significant differences in pain reduction and patient satisfaction, with diclofenac patches outperforming buprenorphine patches in the short term [8].

The immediate postoperative period is critical for effective pain management, as it can significantly influence patient recovery, satisfaction, and overall outcomes. Our findings align with previous studies indicating that NSAIDs, like diclofenac, are effective in managing acute postoperative pain due to their anti-inflammatory properties, which are pivotal in the initial stages of surgical recovery. The transdermal administration offers a non-invasive route, ensuring consistent drug delivery and minimizing systemic side effects [9].

Interestingly, while both analgesic patches reduced pain scores over time, patients in the diclofenac group reported higher satisfaction within the first two W. This discrepancy could be attributed to the pharmacological actions of the drugs; whereas buprenorphine's opioid analgesic effects may offer more pronounced pain relief over a longer duration, diclofenac's anti-inflammatory action might be more immediately gratifying to patients recovering from surgery [10].

Despite the advantages of transdermal buprenorphine in providing sustained analgesia with fewer systemic side effects, our study underscores the importance of evaluating patient satisfaction as a critical outcome. It suggests that while buprenorphine may be beneficial for chronic pain management, diclofenac patches could be more suited for acute postoperative pain, particularly in the initial recovery phase [11].

CONCLUSION

Our study highlights the nuanced differences in efficacy and patient satisfaction between transdermal buprenorphine and diclofenac patches for postoperative analgesia following elective below umbilical surgeries. Although both treatments effectively managed pain, the diclofenac patch was superior in terms of early postoperative pain relief and patient satisfaction. This finding emphasizes the need for personalized pain management strategies that consider both the pharmacological profile of analgesics and patient-centered outcomes.

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally

CONFLICTS OF INTERESTS

Declared none

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