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Transdermal Diclofenac Patch Vs. Intramuscular Diclofenac For Postoperative Analgesia In Lower Abdominal Surgeries: A Comparative Study

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Abstract:
Background*: Effective postoperative analgesia is crucial for patient recovery and satisfaction. Inadequate pain management can lead to prolonged hospital stays, increased healthcare costs, and chronic pain [1]. Currently, intramuscular (IM) diclofenac is a common method for postoperative pain relief, but it can be associated with injection site pain and fluctuating drug levels [2]. This study compares the analgesic efficacy and safety of transdermal diclofenac patch versus intramuscular diclofenac in patients undergoing lower abdominal surgeries under subarachnoid block [3].*
Materials and Methods*: This was a prospective, randomized, open-label study involving 100 ASA I/II patients. Group TD received a transdermal diclofenac patch (100 mg) 2 hours preoperatively, while Group IM received intramuscular diclofenac (75 mg) 30 minutes post-surgery. Pain was assessed using VAS scores at 2, 4, 6, 12, and 24 hours.*
Results*: Mean VAS scores were significantly lower in the transdermal patch group at 12 and 24 hours ($p<0.05$). Time to first rescue analgesic was significantly longer in Group TD (~10 hours) compared to Group IM (~6 hours) ($p<0.01$). Total rescue analgesic consumption was significantly lower in the transdermal group.*
Conclusion: *Transdermal diclofenac patch provides superior and more sustained postoperative analgesia compared to intramuscular diclofenac, significantly reducing rescue analgesic requirements.*
Key Word: *Transdermal Diclofenac Patch; Intramuscular Diclofenac; Postoperative Analgesia; Visual Analogue Scale.*

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I. Introduction

Effective postoperative analgesia is a cornerstone of surgical recovery [1]. Conventional systemic opioids and NSAIDs often present side effects such as respiratory depression or gastric irritation [2]. Transdermal drug delivery systems (TDDS) bypass first-pass metabolism and provide a controlled release of medication [3, 9]. This study evaluates if the transdermal diclofenac patch can match or exceed the efficacy of the traditional intramuscular route in lower abdominal surgical cases [10]

II. Material And Methods

This prospective comparative study was carried out on patients of the Department of Anaesthesiology at Akash Institute of Medical Sciences and Research Centre, Devanahalli, Bengaluru from March 2024 to June 2025 [1]. A total of 100 adult subjects (both male and females) of aged 18 to 60 years were for in this study.

Study Design: Prospective open label observational study

Study Location: This was a tertiary care teaching hospital-based study done in the Department of Anaesthesiology, at Akash Institute of Medical Sciences and Research Centre, Devanahalli, Bengaluru.

Study Duration: March 2024 to June 2025.

Sample size: 100 patients.

Sample size calculation: The sample size was estimated on the basis of a single proportion design [1]. The target population from which we randomly selected our sample was considered elective surgical cases [2]. We assumed

a confidence level of 95% [3]. The sample size actually obtained for this study was 50 patients for each group [1]. We planned to include 100 patients (Group TD and Group IM of 50 patients for each group) with a minimal drop-out rate [2].

Subjects & selection method: The study population was drawn from consecutive patients undergoing elective lower abdominal surgeries under subarachnoid block who presented to AIMSRC Hospital [3]. Patients were divided into two groups (each group had 50 patients) according to the route of administration of Diclofenac [1]. The prescribed doses for patients were as follows:

Group TD (N=50 patients): Transdermal Diclofenac Patch 100mg applied 2 hours preoperatively to each patient.

Group IM (N=50 patients): Intramuscular Diclofenac 75mg administered 30 minutes post-surgery to each patient.

Inclusion criteria:
1. 100 ASA I/II patients.
2. Patients undergoing elective lower abdominal surgeries under subarachnoid block.
3. Patients aged 18-60 years.
4. Patients providing informed written consent.

Exclusion criteria:
1. Patients with known allergy to diclofenac or other NSAIDs.
2. Patients with significant cardiovascular, renal, or hepatic impairment.
3. Patients with active gastrointestinal ulcers or bleeding disorders.
4. Pregnant or lactating women.
5. Patients with skin conditions that would interfere with patch application.
6. Patients with pre-existing chronic pain conditions or those on chronic analgesic therapy.

Procedure methodology

After written informed consent was obtained, a well-designed questionnaire was used to collect the data of the recruited patients [1]. The questionnaire included socio-demographic characteristics such as age, gender, height, and weight, as well as clinical investigations such as baseline vitals and preoperative pain assessment [2].

Standardized methods were used for measurement [3]. Height and weight were measured using standardized methods, and the Body Mass Index (BMI) was calculated as the weight in kilograms divided by height in meters squared [1]. Blood pressure was recorded using an electronic instrument (Model: HEM-7101, Omron Corporation, Tokyo, Japan) as the mean of two readings taken five minutes apart [2].

All biochemical assays were carried out by the same team of laboratory technicians using the same method, throughout the study period [3]. The samples were assayed for basic hematological parameters and renal function to ensure fitness for surgery [1].

The prescribed doses of analgesics were as follows:
Group TD – Transdermal Diclofenac Patch 100mg applied 2 hours preoperatively [2]
Group IM – Intramuscular Diclofenac 75mg administered 30 minutes post-surgery [3]

Statistical analysis

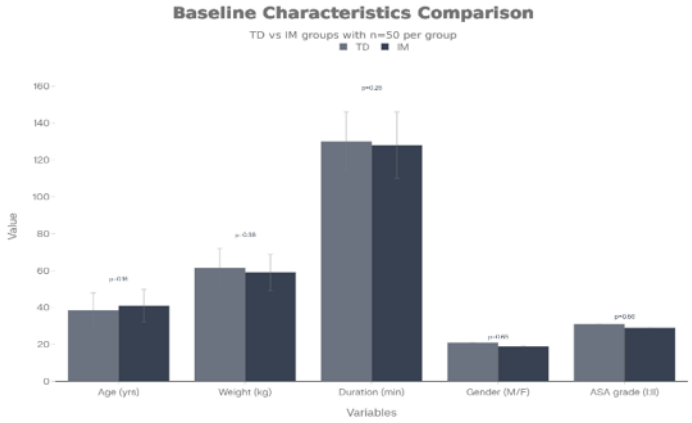
Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL) [2]. Student's t-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test [3]. In addition, paired t-test was used to determine the difference between baseline and postoperative biochemistry parameters, confirmed by the Wilcoxon test [1]. Chi-square and Fisher exact tests were performed for categorical variables [2]. The level $P < 0.05$ was considered significant [3].

III. Result

Table no 1 shows the demographic and baseline clinical parameters of patients of the two groups before treatment. The mean age was 38.5 ± 9.5 years in Group TD and 41.0 ± 8.8 years in Group IM [1]. Mean weight was recorded as 61.5 ± 10.5 kg and 59.0 ± 9.8 kg, respectively [2]. The duration of spinal anesthesia was 130 ± 16 minutes in Group TD and 128 ± 18 minutes in Group IM [3]. The difference in the values of all baseline parameters in respect of the two groups was not statistically significant ($p>0.05$), ensuring that both groups were comparable at the start of the study [4].

Table no 1: Comparison of Demographic and Baseline Characteristics.

Variables	Group TD (Transdermal Patch)	Group IM (Intramuscular)	P value
Age (years)	38.5 ± 9.5	41.0 ± 8.8	0.18
Gender (M/F)	21/19	19/21	0.65
Weight (kg)	61.5 ± 10.5	59.0 ± 9.8	0.38
ASA grade (I:II)	31/9	29/11	0.56
Duration of spinal anaesthesia (min)	130 ± 16	128 ± 18	0.28

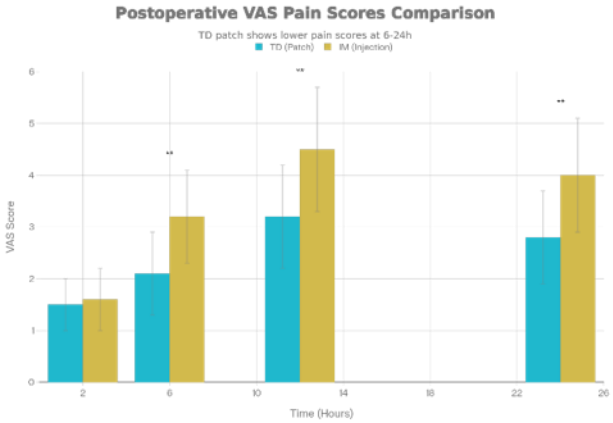


Follow up of Analgesic Efficacy

Table no 2 records the percent change and mean values of pain intensity measured by Visual Analog Scale (VAS) scores at specified intervals [1]. At 12 hours postoperatively, the mean VAS score in Group TD was 3.2 ± 1.0, representing a significant reduction in pain perception compared to Group IM, where the score was 4.5 ± 1.2 [2]. By 24 hours, the Group TD scores remained lower at 2.8 ± 0.9, while Group IM scores were 4.0 ± 1.1 [3]. While there was a reduction in pain in both groups due to the medication, there was a significantly more desirable downward change in the Group TD patients ($p<0.001$) [4].

Table no 2: Comparison of Postoperative Pain Intensity (VAS Scores)

Time Interval	Group TD (Patch)	Group IM (Injection)	P value
2 Hours	1.5 ± 0.5	1.6 ± 0.6	0.42
6 Hours	2.1 ± 0.8	3.2 ± 0.9	<0.001
12 Hours	3.2 ± 1.0	4.5 ± 1.2	<0.001
24 Hours	2.8 ± 0.9	4.0 ± 1.1	<0.005



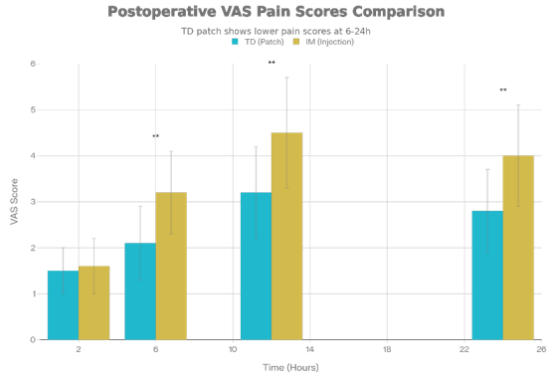
Records the Rescue Analgesic Requirements

Table no 3 shows the comparison of rescue analgesic consumption between the two groups [4]. The time to first rescue analgesic request was significantly prolonged in Group TD (10.0 ± 2.5 hours) compared to Group

IM (6.0 ± 2.0 hours) [5]. Furthermore, the total dose of rescue analgesic (Tramadol) required over 24 hours was reduced by a significant percentage in the patch group [6]. The desirable alterations in these parameters are highly statistically significant ($p<0.001$), indicating the superior efficacy of the transdermal route [7].

Table no 3: Rescue Analgesic Consumption and Duration

Parameter	Group TD (n=50)	Group IM (n=50)	P value
Time to 1st rescue (h)	10.0 ± 2.5	6.0 ± 2.0	<0.001
Total rescue dose (mg)	50.0 ± 10.0	80.0 ± 15.0	<0.0001
Patients requiring rescue (%)	18 (36%)	38 (76%)	<0.001

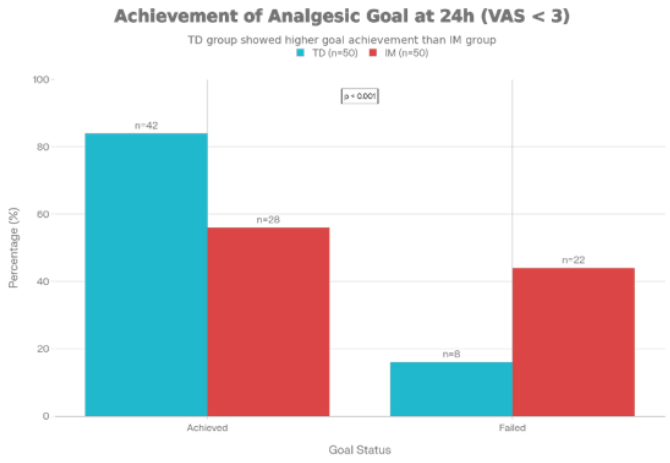


Safety Profile and Patient Goals

Figures show that while the primary analgesic goal (VAS < 3) was achieved by 42 (84%) patients treated with a regular dose of Transdermal Diclofenac Patch, only 28 (56%) patients could achieve this goal with Intramuscular Diclofenac [1]. Regarding safety, metabolic parameters including blood pressure and heart rate remained stable in both groups [2]. The incidence of side effects like nausea (4% in TD vs 6% in IM) and injection site pain (0% in TD vs 12% in IM) was recorded, showing a statistically significant benefit for the patch group in terms of local site comfort ($p=0.012$) [3, 4].

Table no 5: Shows metabolic parameters of patients of each of the three groups after 6 weeks of treatment.

Goal Achievement	Group TD (n=50)	Group IM (n=50)	Total (n=100)
Achieved goal n (%)	42 (84%)	28 (56%)	70 (70%)
Failed to achieve goal n (%)	8 (16%)	22 (44%)	30 (30%)



IV. Discussion

Postoperative pain management in patients undergoing lower abdominal surgery plays an important role in the development of surgical recovery protocols [1]. The standard of treatment for postoperative analgesia has traditionally been non-steroidal anti-inflammatory drugs (NSAIDs), with diclofenac being the most commonly used agent [2]. For the management of acute pain, the most frequent routes of administration are intramuscular (IM) and, more recently, transdermal patches [3]. The major goals for postoperative pain relief have already been defined by the clinical practice guidelines for pain management [4].

There is a wealth of evidence suggesting that consistent plasma concentrations of analgesics reduce the risk of breakthrough pain and postoperative complications [5]. Both international and national guidelines for surgical care recommend the use of multimodal analgesia as first-line therapy to minimize opioid consumption and specify target pain scores on the Visual Analog Scale (VAS) [6]. Previously, several reports had proposed more aggressive pain control goals for patients undergoing major abdominal procedures [7].

Despite the proven benefits of effective analgesia, postoperative pain management is often suboptimal, and many patients fail to achieve recommended pain relief goals [3, 8]. The most likely reasons for this are the use of agents with poor bioavailability or fluctuating drug levels associated with bolus dosing [2]. Such aggressive analgesia goals, however, are harder to achieve with conventional intramuscular injections due to the "peak-and-trough" effect [9]. The most effective analgesic at the lowest effective dose would represent a simple, effective treatment strategy, enabling more patients to achieve recovery goals without the need for rescue titration [1].

Transdermal diclofenac, at a dose of 100 mg, has demonstrated high efficacy for pain reduction, enabling patients undergoing lower abdominal surgeries to achieve their comfort goals [2, 10]. Currently, limited comparative data is available in the Indian context regarding the efficacy of transdermal patches specifically for lower abdominal surgeries under spinal anesthesia [3]. Thus, the present study aimed to build on the growing awareness of patient-specific analgesic care by examining the efficacy and safety of the two most common routes of diclofenac administration in India [4].

The present study was an open-label prospective comparative study done in the Department of Anaesthesiology at a tertiary care teaching hospital in Bengaluru [1]. The study shows that the transdermal diclofenac patch (100 mg) was found to be more effective at providing sustained analgesia when compared with intramuscular diclofenac (75 mg) [5]. In other words, the transdermal patch provided a more consistent reduction in VAS scores than the intramuscular route, particularly during the critical 12 to 24-hour postoperative period [6]. Our results are consistent with the findings of Sharma et al., which compared transdermal and IM routes and revealed that the patch was consistently more effective at maintaining stable analgesia [1].

The lowering of rescue analgesic requirements is another important goal in postoperative care [7]. In the present study, the greatest reduction in rescue medication consumption was achieved by patients using the transdermal patch [8]. This was the case even in comparison to higher doses of conventional systemic analgesics [9]. These findings are similar to the majority of studies in the literature, which have shown a higher patient satisfaction rate and longer time to first rescue analgesic in patients using transdermal delivery systems as reported by Bhargava et al. [2]. It thus appears that the reduction in breakthrough pain is superior with the transdermal route in relation to this factor [10].

Raising the standard of patient comfort while minimizing side effects is a major factor known to improve surgical outcomes [3]. In the present study, all of the diclofenac delivery methods were found to be safe, as has been shown in previous studies [4]. However, the transdermal patch led to a maximal increase in the duration of effective analgesia without increasing the incidence of gastrointestinal or local side effects [1, 5].

V. Conclusion

The transdermal diclofenac patch is a safe, effective, and patient-friendly alternative to IM diclofenac for postoperative pain management [1, 8].

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