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Original Research Article

Comparative evaluation of transdermal diclofenac patch versus oral diclofenac sodium for postoperative pain management following surgical extractions: A randomized single blinded clinical study

Sanya Gupta[1], Amit Gupta[1]*, Aviral Verma[1], Snehil Shrivastava[1], Aashi Jain[1]

[1]Dept. of Oral & Maxillofacial Surgery, ITS Dental College, Ghaziabad, Uttar Pradesh, India

Abstract

Background: Effective postoperative pain control is critical in oral surgery. Diclofenac sodium, a common NSAID, is available in various formulations, including oral and transdermal. This study compares the efficacy, tolerability, and adverse effects of transdermal versus oral diclofenac sodium in managing postoperative pain after surgical extractions.

Materials and Methods: A randomized clinical study was conducted on 40 patients undergoing surgical tooth extractions, divided into two groups (n=20 each). Group A received 200 mg transdermal diclofenac patches (once daily for 3 days), and Group B received 100 mg oral diclofenac tablets (twice daily for 3 days). Pain relief was evaluated using a 4-point pain relief score scale on postoperative days 1, 2, and 3. Tolerability, adverse effects, and patient comfort were also assessed.

Results: Group A showed significantly higher mean pain relief scores on all three days compared to Group B ($p<0.05$). Group A had fewer adverse effects, with 90% reporting no complications, compared to 50% in Group B ($p=0.0002$). Tolerability and patient comfort were significantly better in Group A ($p=0.019$ and $p=0.003$, respectively).

Conclusion: Transdermal diclofenac patches provide effective and well-tolerated postoperative pain relief with fewer side effects and better patient compliance than oral diclofenac. They present a viable alternative for postoperative analgesia in oral surgery.

Keywords: Diclofenac, Transdermal patch, Oral NSAIDs, Postoperative pain, Surgical extraction, Pain management.

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1. Introduction

Effective postoperative pain control is crucial in oral and maxillofacial surgery. It directly impacts patient recovery and satisfaction. Procedures such as the extraction of multiple teeth or impacted third molars often result in significant postoperative discomfort, necessitating appropriate analgesic strategies. Diclofenac sodium, a widely used NSAID offers potent analgesic and anti-inflammatory properties.[1]

Diclofenac works by blocking COX-1 and COX-2 enzymes, which are key to prostaglandin production—the main drivers of pain and inflammation. Unlike selective COX-2 inhibitors, it targets both enzymes, offering broad anti-inflammatory action. It also influences arachidonic acid metabolism, blocks thromboxane-prostanoid (TP) receptors, and interacts with the NO–cGMP pathway to enhance its effect.[2,3]

Diclofenac comes in several forms—Oral, Intravenous, Suppository, Transdermal patch, and Gel—each with different absorption and action profiles. Oral diclofenac is affected by first-pass liver metabolism, which lowers its bioavailability and can irritate the gut. Transdermal patches bypass the gastrointestinal system, offering steady release with fewer systemic side effects. Intravenous diclofenac acts quickly and is useful for acute pain but may cause more systemic reactions.[4]

*Corresponding author: Amit Gupta
Email: sanyagupta1312@gmail.com

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Though effective, long-term use of diclofenac can lead to notable side effects. Various studies have identified three main concerns: gastrointestinal complications, increased cardiovascular risk, and potential renal toxicity.[4]

To mitigate these issues, transdermal diclofenac patches have been developed, offering controlled drug release and potentially fewer systemic side effects.[5]

Transdermal drug delivery offers key advantages over oral routes by bypassing gastrointestinal tract and first-pass hepatic metabolism. This improves bioavailability, provides steady drug levels in the blood, ensures longer-lasting pain relief, and supports better patient compliance.[6] Various studies also indicate that transdermal diclofenac is as effective as oral diclofenac in managing postoperative dental pain, with patients reporting fewer gastrointestinal side effects, better overall tolerance and higher patient compliance.[7-10]

Transdermal patches are advanced, non-invasive systems that deliver drugs through the skin into the bloodstream over time. The design of a transdermal patch typically consists of multiple functional layers, each engineered to serve a specific role in drug storage, protection, adhesion, and delivery.[11]

The outermost layer, called the backing layer, is made of non-permeable materials like polyethylene or polyester. It shields the patch from moisture, air, and damage, prevents the drug from evaporating. Also, this layer provides structural support and integrity to the entire system.[11]

Just beneath the patch's backing is the drug layer, which varies by design. In a matrix-type patch, the drug is uniformly dispersed within a polymeric matrix (such as ethyl cellulose or hydroxypropyl methylcellulose). The drug is released by diffusion, migrating from the high-concentration zone within the matrix into the lower-concentration zone of the skin. In contrast, a reservoir-type patch includes a liquid or gel drug formulation enclosed within a compartment or reservoir, which is separated from the skin by a rate-controlling membrane. This semipermeable membrane governs the rate at which the drug diffuses out, ensuring a constant and predictable delivery over time.[11]

The adhesive layer sticks the patch to the skin and, in some designs, also holds the drug. The adhesives used must be skin-friendly, biocompatible, non-irritating, and capable of maintaining adhesion throughout the intended duration of use without causing discomfort or allergic reactions.[11]

The final layer is the release liner, which protects the adhesive layer and the drug content during storage. This liner, typically made from silicone-coated paper or film, is removed just before applying the patch to the skin.[11]

Once applied, the drug slowly passes through the skin's outer layer (stratum corneum) by passive diffusion, driven by the concentration difference between the patch and the blood vessels below. To be absorbed effectively, the drug needs to be both fat- and water-soluble to cross the skin barrier and move into deeper tissues. Factors like skin hydration, temperature, application site, and the drug's properties can affect rate and extent of absorption.[11]

According to previous studies, the site of application of the transdermal patch can influence the rate of skin absorption. Hairless areas such as the side of neck, trunk and upper arm typically show comparable absorption rates.[12]

This study aims to compare the effectiveness and safety of transdermal diclofenac patches versus oral diclofenac sodium for managing postoperative pain after surgical extractions. Key parameters such as pain relief intensity, patient comfort, drug tolerability, and the occurrence of any side effects were evaluated over a three-day period. By assessing both clinical and patient-centered outcomes, this research hopes to provide useful insights into optimizing pain control in oral and maxillofacial surgery — with a focus on safer, more comfortable, and more personalized care.

2. Materials and Methods

2.1. Study design and ethical considerations

This study was designed as a randomized, single blinded, parallel-group, comparative clinical trial conducted at the Department of Oral and Maxillofacial Surgery, I.T.S. Centre for Dental Studies and Research, Muradnagar, Ghaziabad. The trial duration spanned from July 2024 to March 2025. Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study. Written informed consent was obtained from all participants in accordance with the Declaration of Helsinki.

2.2. Participants

A total of 40 patients aged 18–60 years who required surgical extractions were enrolled. All participants were classified as American Society of Anesthesiologists (ASA) physical status I or II.

2.3. Inclusion criteria

1. Adults aged 18–60 years.
2. Patients requiring surgical extraction of teeth.
3. ASA grade I or II patients.

2.4. Exclusion criteria

1. Known allergy to diclofenac or other NSAIDs.
2. Presence of skin disorders.
3. History of alcohol abuse.
4. Pregnant or lactating women.

2.5. Sample size determination

A sample size of 40 patients (20 in each group) was determined based on feasibility within the study period and

available resources. This size was sufficient to perform preliminary comparative analysis between the two interventions.

2.6. Randomization and allocation

Eligible patients were randomly assigned into two groups (Group A and Group B) using simple random sampling. Allocation concealment was achieved using sealed opaque envelopes prepared by an independent staff member not involved in the trial execution.

1. Group A (n = 20): Received transdermal diclofenac sodium patch (200 mg). (**Figure 1**)
2. Group B (n = 20): Received oral diclofenac sodium tablets (100 mg, twice daily). (**Figure 2**)

2.6. Blinding

Due to the obvious differences in drug administration routes (patch vs. tablet), blinding of patients and surgeons was not feasible. However, outcome assessment was performed by an independent blinded observer to reduce detection bias.

2.7. Interventions

All surgical extractions were performed by the same surgeon under local anesthesia (2% lignocaine with 1:200,000 adrenaline) using standard techniques. Bone removal was done using Lindemann tungsten carbide bur No. 8 and carbide burs No. 701, 702, and 703 under copious saline irrigation. Wound closure was achieved using 3-0 black braided silk sutures with a simple interrupted technique. Sutures were removed on the 7th postoperative day.

2.8. Postoperative regimen

1. Group A: Applied a 200 mg transdermal diclofenac sodium patch (Nu Patch, Zydus-Cadilla) to the nape of the neck, replaced every 24 hours for 3 days.
2. Group B: Received 100 mg oral diclofenac sodium tablets twice daily for 3 days.

All patients were prescribed

1. Cap. Amoxicillin 500 mg + Potassium Clavulanate 125 mg (TDS for 3 days),
2. Tab. Ketorolac 10 mg as rescue analgesic,
3. Warm saline rinses 3–4 times/day starting 24 hours postoperatively.

2.9. Outcomes

Primary and secondary outcomes were assessed on postoperative days 1, 2, and 3 by an independent blinded observer:

1. Pain Relief: Measured using a 4-point pain relief score (0 = no pain, 4 = maximum pain).
2. Drug Tolerability: Rated by patients as Excellent, Good, Fair, or Poor.
3. Safety: Monitored through reported adverse effects (e.g., erythema, gastrointestinal discomfort, headaches).
4. Patient Comfort: Self-reported by patients based on convenience, ease of use, and satisfaction.

2.10. Statistical analysis

All data were analyzed using SPSS v21.0 and Epi Info v3.0. Continuous variables were expressed as mean ± standard deviation and compared using the Mann–Whitney U test. Categorical variables were compared using Fisher's exact test. A p-value of <0.05 was considered statistically significant.

Figure 1: Transdermal diclofenac patch

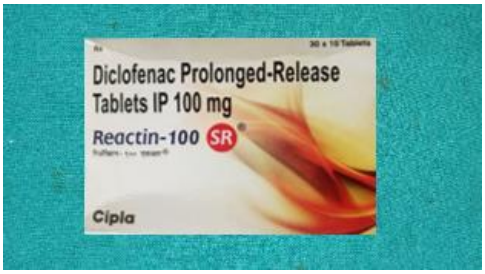

Figure 2: Oral diclofenac tablet

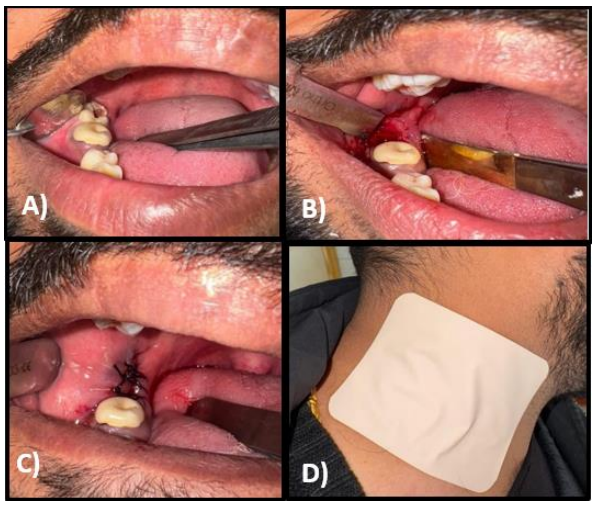

Figure 3: Group A, **a:** P re-operative intraoral view; **b:** Post-operative intraoral view; **c:** Primary closure using 3-0 BBS; **d:** Diclofenac patch placed

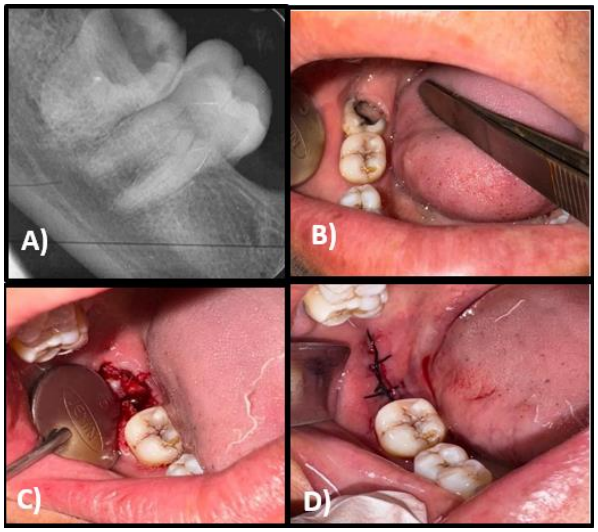

Figure 4: Group B, **a:** Pre-op IOPA; **b:** Pre-operative intraoral view; **c:** Post-operative intraoral view; **d:** Primary closure using 3-0 BBS

3. Results

A total of 40 patients who met the inclusion criteria were enrolled and randomly allocated into two groups (Group A and Group B), each comprising 20 participants. Group A received transdermal diclofenac sodium patches (200 mg, applied once daily for three days), whereas Group B received oral diclofenac sodium tablets (100 mg, administered twice daily for three days). All patients completed the study, and no dropouts were observed.

3.1. Demographic data

The baseline characteristics between the two groups were statistically comparable. There was no significant difference in the mean age or gender distribution ($p = 0.058$), minimizing potential confounding due to demographic disparities.

*3.2. Pain relief assessment (**Table 1**)*

Postoperative pain scores were evaluated by the blinded observer using a four-point pain relief scale on Days 1, 2, and 3. Group A (**Figure 3**) consistently demonstrated significantly better pain relief compared to Group B (**Figure 4**) across all time intervals. On Day 1, the mean pain score in Group A was 1.7 ± 1.13, significantly higher than Group B's 0.8 ± 0.7 ($p = 0.007$). On Day 2, Group A recorded a mean score of 2.85 ± 0.99, while Group B scored 2.15 ± 0.59 ($p = 0.012$). By Day 3, Group A maintained superior analgesia with a mean score of 3.65 ± 0.59, compared to 3.25 ± 0.55 in Group B ($p = 0.02$). These findings indicate sustained and statistically significant pain control in the transdermal group.

*3.3. Adverse effects (**Table 2**)*

The incidence of adverse effects was significantly lower in Group A. In the patch group, 90% of patients reported no side effects, while 10% experienced only mild local erythema at the application site. In contrast, 50% of participants in the oral diclofenac group reported no adverse effects, whereas 30% experienced gastrointestinal symptoms such as nausea and abdominal pain, and 20% reported headaches. The intergroup difference in adverse effect profiles was statistically significant ($p = 0.0002$), suggesting a superior safety profile for the transdermal route.

*3.4. Tolerability (**Table 3**)*

Patient-reported tolerability was also higher in Group A. A total of 90% of patients in the transdermal group rated their experience as excellent, while only 50% in the oral group gave a similar rating. In contrast, 40% of Group B participants described tolerability as fair or poor, compared to only 10% in Group A. This difference was statistically significant ($p = 0.019$), further supporting the higher acceptance of the transdermal formulation.

Table 1: Intergroup comparison of pain relief scores between group **A** and **B**.

Pain relief scores	Group A(n=20)	Group B(n=20)	Total	P value
On day 1				
Mean ± SD	1.7 ± 1.13	0.8 ± 0.7	1.25 ± 1.03	0.007§
Median(25th- 75th percentile)	2(0.75-2.25)	1(0-1)	1(0-2)	
Range	0-3	0-2	0-3	
On day 2				
Mean ± SD	2.85 ± 0.99	2.15 ± 0.59	2.5 ± 0.88	0.012§
Median (25th-75th percentile)	3(2-4)	2(2-2.25)	2(2-3)	
Range	1-4	1-3	1-4	
On day 3				
Mean ± SD	3.65 ± 0.59	3.25 ± 0.55	3.45 ± 0.6	0.02§
Median(25th-75th percentile)	4(3-4)	3(3-4)	3.5(3-4)	
Range	2-4	2-4	2-4	

§ Mann Whitney test

Table 2: Intergroup comparison of adverse effects between group A and B.

Adverse effects	Group A(n=20)	Group B(n=20)	Total	P value
Nil	18 (90%)	10 (50%)	28 (70%)	0.0002*
Gastrointestinal disturbances	0 (0%)	6 (30%)	6 (15%)	
Headache	0 (0%)	4 (20%)	4 (10%)	
Erythema	2 (10%)	0 (0%)	2 (5%)	
Total	20 (100%)	20 (100%)	40 (100%)	

Table 3: Intergroup comparison of tolerability between group **A** and **B**.

Tolerability	Group A(n=20)	Group B(n=20)	Total	P value
Excellent	18 (90%)	10 (50%)	28 (70%)	0.019*
Good	1 (5%)	2 (10%)	3 (7.50%)	
Fair	1 (5%)	3 (15%)	4 (10%)	
Poor	0 (0%)	5 (25%)	5 (12.50%)	
Total	20 (100%)	20 (100%)	40 (100%)	

Table 4: Intergroup comparison of patient comfort between group **A** and **B**.

Patient comfort	Group A(n=20)	Group B(n=20)	Total	P value
No	1 (5%)	10 (50%)	11 (27.50%)	
Yes	19 (95%)	10 (50%)	29 (72.50%)	
Total	20 (100%)	20 (100%)	40 (100%)	0.003*

*3.5. Patient comfort (**Table 4**)*

Subjective comfort levels were markedly greater in the transdermal group. A total of 95% of Group A patients expressed high satisfaction, highlighting ease of use, once-daily dosing, and the non-invasive mode of administration. In comparison, only 50% of Group B participants reported similar comfort. The difference in patient-reported comfort was statistically significant (p = 0.003).

4. Discussion

Managing post-operative pain continues to be a dynamic area of research, with newer formulations and treatment methods frequently emerging to replace outdated options. Pain following dental extractions presents a persistent challenge for both clinicians and patients due to the significant inflammatory response it elicits. Among the most widely used medications for controlling such pain are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Their effectiveness in managing postoperative dental discomfort is primarily attributed to their ability to inhibit the cyclooxygenase enzymes COX-1 and COX-2, which play a crucial role in the synthesis of prostaglandins.[4]

Oral administration of NSAIDs is often limited by the process of first-pass metabolism, which significantly reduces the drug's bioavailability before it enters systemic circulation. Moreover, oral NSAIDs are frequently associated with adverse effects, particularly gastrointestinal discomfort, which tends to worsen with higher dosages. To address these concerns, topical NSAID formulations have been developed as alternative delivery routes. These enable direct application to the site of pain, providing effective local relief while minimizing systemic exposure and related side effects. As a result, topical NSAIDs have become a valuable therapeutic option, combining efficacy with a lower risk of adverse reactions.[13]

Transdermal delivery systems represent a modern alternative to oral and other conventional methods of administering NSAIDs. In this approach, the medication is delivered through the skin via a patch and gradually absorbed into the bloodstream through the underlying capillaries. This controlled absorption provides a steady release of the drug, helping to maintain consistent plasma concentrations which is an important objective in effective therapeutic management.[13]

The analgesic efficacy, safety profile and tolerability of both oral and transdermal forms of diclofenac sodium were evaluated in patients undergoing surgical extractions. All subjects had a good periodontal status and were under ASA grade I and II.

In this study, diclofenac was used as analgesic, both in its oral and transdermal form, following the surgical extractions. It falls under the category NSAID, which exhibits anti-inflammatory, analgesic and anti-pyretic activity and has been routinely used as an analgesic following

surgical extractions. The two formulations of diclofenac used in this study were transdermal diclofenac patch 200mg, which is designed to stay at the site of application for 24 hours and oral diclofenac sodium 100mg tablets to be taken twice a day. The 50-sq. cm patch used in this study contains 200mg of Diclofenac Diethylamine as its active agent and allows for the sustained release of the drug.

Postoperative pain management plays a crucial role in ensuring optimal recovery and improving patient satisfaction following surgical interventions. Evaluation of pain is always subjective and can be evaluated in various scales. In this study, the pain relief score was used which had a rating of pain relief on a scale of 0 to 4. A higher score indicated a higher relief of pain. This a higher mean score indicated a better relief of pain.[1]

In the present study, at day 1,2 and 3, the frequency of pain relief score 4 was significantly more among the patch group (Group A) whereas scores 0,1,2,3 were significantly more among Tablet group (Group B). The mean pain relief score was significantly more among patch group (group A) indicating a significant amount of pain relief in this group. This result was in accordance with Nandavar et al (2016), where they concluded that in comparing post-operative pain relief following third molar extractions, transdermal diclofenac patch provided better pain relief.[14]

In multiple head-to-head comparisons such as those by Bachalli et al. (2009), Talnia et al. (2020), Wankhade and Mandlik (2020) transdermal diclofenac was shown to provide equal or better pain control than oral formulations, particularly in the first 24 hours post-surgery.[9,15,16]

In the present study, a significantly higher number of cases of group B reported adverse effects such as gastrointestinal irritations and headaches. Several clinical studies reinforce the safety advantage of transdermal diclofenac over its oral counterpart. Rajeswari et al. (2017) reported that only the oral group reported gastric discomfort, indicating a superior safety profile with the transdermal route. Similarly, Talnia et al. (2020), in a comparative study on premolar extractions, found no major adverse effects associated with the use of transdermal patches.

Wankhade and Mandlik (2020) also observed that patients using oral diclofenac postoperatively showed a higher incidence of gastrointestinal side effects compared to those using patches.[10,15,16]

Tolerability is a critical factor when selecting analgesic modalities for post-extraction pain management. In this study, excellent tolerability was reported to be significantly more by Patch group (group A) whereas good, fair and poor was reported to be significantly more by tablet group (group B) by the subject. This finding is in accordance with the study conducted by Bagga et al (2017) which concluded better tolerability with transdermal diclofenac patch.[17]

Patient comfort is an essential consideration in the selection of postoperative analgesic strategies, particularly in outpatient settings. Transdermal diclofenac patches have gained popularity not only for their pharmacologic efficacy but also for their contribution to enhanced patient comfort during recovery. In current study, the patient comfort was reported to be significantly higher in patch group (group A). Krishnan et al. (2015) similarly found patients expressed greater satisfaction with the transdermal patch, citing reduced dosing frequency and the absence of gastrointestinal discomfort as key factors contributing to a more comfortable postoperative experience. Even in comparative studies like Samal et al. (2021), where pain control efficacy was assessed across oral, intramuscular, and transdermal routes, patients rated the patch highest in terms of comfort and compliance, noting it as less disruptive to their routine and more tolerable overall.[14,18]

The outcomes of current study corroborates with previous studies evaluating the safety and analgesic efficacy of transdermal diclofenac patches for various surgical applications. Thus, a topical Diclofenac Diethyl-amine (200mg) transdermal patch is superior to the oral route in terms of efficacy, safety, patient compliance and tolerability and is considered as an effective alternative to conventional oral diclofenac treatment.

The transdermal diclofenac has the usual tendency to be subjected to absorption interferences due to the presence of anatomical barriers such as epidermis, dermis, and the underlying muscle tissue. The drug is usually retained or may undergo metabolism during its journey to the nearest vascular supply, hence, the amount of drug that reaches the circulation establishes a minimum plasma concentration. This low concentration hence leads to a lesser incidence of systemic adverse effects.[13]

5. Conclusion

The transdermal diclofenac patch is a safe, effective, and patient-friendly alternative to oral diclofenac sodium for managing postoperative pain following surgical dental extractions. It offers superior pain relief, reduced incidence of adverse effects, and better patient compliance.

Given its advantages in terms of tolerability, comfort, and sustained analgesic effect, transdermal diclofenac can be recommended, especially in patients prone to gastrointestinal intolerance or in those who prefer non-oral analgesic options.

6. Conflict of Interest

Authors have no competing interest to declare.

7. Source of Funding

None.

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