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Comparison of Oral Diclofenac & Transdermal Diclofenac Patch as a Post-Operative Analgesia in Orthodontic Patients Having Multiple Premolar Extractions: A Clinical Trial

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ABSTRACT:

Background: Aims: This study was conducted to evaluate and compare the analgesic efficacy of transdermal Diclofenac patches and oral Diclofenac tablets following orthodontic premolar extractions, and to assess any associated adverse effects.

Methods: A total of fifty young pre-orthodontic patients requiring bilateral extraction of maxillary and mandibular first premolars were enrolled in the study. Extractions were performed in two separate appointments. During the first visit, the right maxillary and mandibular first premolars were extracted, and patients were prescribed 50 mg oral Diclofenac sodium tablets to be taken three times daily for three consecutive days. At the second appointment, the contralateral (left side) premolars were extracted, and a 100 mg transdermal Diclofenac patch was applied once daily for the following three days. Pain intensity and pain relief were assessed on each of the three postoperative days using standardized 5-point Verbal Pain Intensity, Pain Relief Score Charts, Visual analogue scale (VAS) and Verbal response scale (VRS) three times in three consecutive days after 2 hours, 6 hours and 12 hours.

Results: Statistical analysis demonstrated a consistent increase in pain relief scores and a corresponding decrease in pain intensity scores, VAS scores and VRS over the three-day postoperative period for both oral Diclofenac tablets and the transdermal Diclofenac patch. Although both formulations provided effective analgesia, a greater number of patients expressed a preference for the transdermal patch, citing the convenience of once-daily application, better analgesia and a lower frequency of systemic side effects.

Conclusion: These findings suggest that the transdermal Diclofenac patch offers analgesic efficacy better than that of oral Diclofenac tablets. Additionally, the improved patient compliance associated with the patch indicates its potential utility as a routine option for managing postoperative pain following dental extractions.

INTRODUCTION

The premise of successful dental treatment extends beyond accurate operative techniques to encompass the prevention and management of post-operative complications. Among these, post-extraction pain continues to be a significant clinical concern. Dental practitioners are consistently challenged to identify analgesic modalities that not only provide effective and sustained pain relief but are also well-tolerated by

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patients, thereby improving compliance and promoting optimal recovery outcomes.

Non-steroidal anti-inflammatory drugs (NSAIDs) represent one of the most commonly utilized classes of analgesics for the management of post-extraction pain. Among them, diclofenac sodium is frequently prescribed due to its well-established anti-inflammatory and analgesic property[1,2,3].

When administered orally, approximately 50% of the absorbed dose of diclofenac becomes systemically available due to extensive first-pass hepatic metabolism. Moreover, the high plasma concentrations achieved via oral administration have been associated with an increased risk of adverse effects, particularly gastrointestinal disturbances[4,5,6,7]. In recent years, transdermal patches have emerged as innovative topical delivery systems for diclofenac and other NSAIDs. These systems offer the advantage of sustained drug release [, while significantly lowering plasma concentrations, thereby reducing the incidence of systemic adverse effects[8,9,10.]

The present study was conducted to compare and evaluate post-operative analgesia, adverse events, patient tolerability, and compliance associated with oral diclofenac sodium tablets versus diclofenac transdermal patches following multiple premolar extractions in patients undergoing orthodontic treatment. The bilateral extraction of maxillary and mandibular first premolars in young orthodontic patients provided an ideal clinical model for this comparison. The use of a crossover design, wherein identical surgical procedures were performed on two separate occasions in the same individuals, allowed each patient to serve as their own control, thereby minimizing inter-individual variability.

MATERIAL AND METHODS

This was prospective randomized interventional study conducted in tertiary care institute after obtaining institutional ethics committee approval. Study was conducted during period of June 2019 to December 2020. This study was conducted in accordance with Good Clinical Practice and in a manner to conform to the Helsinki Declaration of 1975, as revised in 2013 concerning human rights. Well-being and safety of patients were maintained during study. Sixty patients of either gender of age group 13-35years with healthy periodontal status without any systemic disease and willing to participate in study who require extraction of maxillary & mandibular premolars were divided into two groups (right and left side of jaw) on the basis of post-surgical treatment/management they received.

Patients refusing to give consent, allergic to local anaesthetic or NSAIDS, history of peptic ulcer, systemic diseases like bronchial asthma, epilepsy bleeding diathesis, pregnant and lactating mothers , patients not willing to give consent were excluded.

The first phase of the study involved the extraction of the right maxillary and mandibular first premolars in a single session. The procedure was carried out using a standardized set of instruments and equipment. Following the extractions, patients were prescribed 50 mg oral diclofenac sodium tablets, to be taken three times daily for three consecutive days, totalling ten tablets.

Patients were instructed to assess their pain intensity and the level of pain relief experienced over the postoperative period using a **Verbal Pain Intensity and Pain Relief Score Chart** This chart employed a 5-point scale, with scores ranging from 0 (no pain or no relief) to 4 (severe pain or complete relief), for each of the three postoperative days.

In addition to the prescribed diclofenac, patients were given **paracetamol 500 mg** tablets as rescue medication, to be consumed on an as-needed basis for additional pain relief. A total of nine paracetamol tablets were provided to each patient, with instructions to record their usage on the pain assessment chart. At the subsequent visit, patients were required to return any unused paracetamol tablets.

Postoperative Evaluation and Washout Period

After three days of medication administration, a one-day washout period was observed to allow for the complete clearance of the medications from the patient's system. On the following day, patients were recalled for evaluation, during which their verbal pain score charts were reviewed to assess the overall effectiveness of the oral diclofenac regimen.

Second Phase: Left Premolar Extraction and Transdermal Diclofenac Patch

In the second phase of the study, the left maxillary and mandibular first premolars were extracted, using the same standardized techniques. In contrast to the oral administration of diclofenac used in the first phase, a **100 mg transdermal diclofenac patch** ((Diclofenac Diethylamine 100 mg) was applied to the patients to evaluate its effectiveness in managing postoperative

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pain. The same verbal pain intensity and pain relief score charts were used to assess pain during this phase.

All premolar extractions were performed by a single operator, eliminating any potential bias related to operator differences. Additionally, since all premolars extracted from the same patient had similar periodontal conditions, any patient-related bias was also minimized.

Outcome Measures

Patient are asked to score the post-operative pain on Visual analogue scale (VAS), Verbal response scale (VRS), Pain intensity scale (PIS) and pain relief scale (PRS) three times in a three consecutive days after 2 hours, 6 hours and 12 hours.

The primary outcome measure was the comparison of pain intensity scores and pain relief scores between the two pain management approaches: oral diclofenac sodium (50 mg) and the transdermal diclofenac patch (100 mg). Secondary outcomes included the total number of paracetamol tablets consumed and patient-reported satisfaction with the pain management regimen.

Statistical Analysis: The results were interpreted as mean ± S.D. The data were statistically analysed with the SPSS 16.0 for Windows (SPSS Inc., Chicago, USA). Unpaired t test applied to find the statistical significant between groups. ANOVA (Post hoc) followed by Dunnet t test applied to find statistical significant between the groups. p value less than 0.05

RESULTS

Table 1:VAS score at different time intervals

Groups	**VAS score (MEAN±SD)**		
Day One	**2 hours**	**6 hours**	**12 hours**
Group I	4.88 ± 0.65	3.58 ± 0.60	2.56 ± 0.57
Group II	3.5 ± 0.50	2.5 ± 0.50	2.12 ± 0.68
P value	<0.0001	<0.0001	0.0007
Day Two	**2 hours**	**6 hours**	**12 hours**
Group I	3.2 ± 0.74	2.56 ± 0.60	2.22 ± 0.46
Group II	2.02 ± 0.61	1.5 ± 0.53	1.22 ± 0.50
P value	<0.0001	<0.0001	<0.0001
Day Three	**2 hours**	**6 hours**	**12 hours**
Group I	1.4 ± 0.52	0.6 ± 0.66	0.00 ± 0.00
Group II	0.56 ± 0.53	0.12 ± 0.32	0.00 ± 0.00
P value	<0.0001	<0.0001	

From above table, it can be seen that Visual Analog Scale (VAS) for pain shows mean score in group I (oral Diclofenac) was higher at all times compared to Group II (Transdermal Diclofenac Patch) at 2 hours, 6 hours and 12 hours on day 1, day 2 and day 3.(P value <0.0001)

Table 2: Mean VRS scores between the groups at different time periods

Groups	**VRS score (MEAN±SD)**		
Day One	**2 hours**	**6 hours**	**12 hours**
Group I	2.9 ± 0.3	2.58 ± 0.49	1.9 ± 0.41
Group II	2.54 ± 0.49	2 ± 0.34	1.4 ± 0.48
P value	<0.0001	<0.0001	<0.0001
Day Two	**2 hours**	**6 hours**	**12 hours**
Group I	1.88 ± 0.38	1.86 ± 0.34	1.42 ± 0.49
Group II	1.36 ± 0.48	1.12 ± 0.32	1.02 ± 0.14
P value	<0.0001	<0.0001	<0.0001
Day Three	**2 hours**	**6 hours**	**12 hours**

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Group I	1.1 ± 0.3	0.22 ± 0.41	0.00 ± 0.00
Group II	0.22 ± 0.41	0.08 ± 0.27	0.00 ± 0.00
P value	<0.0001	<0.0001	-

Verbal Response Scale (VRS) for pain shows mean score was statistically higher in group I (oral Diclofenac) compared to Group II (Transdermal Diclofenac Patch) at 2 hours, 6 hours and 12 hours on day 1, day 2 and day 3 .(P value <0.0001)

Table 3: Mean PIS scores between the groups at different time periods

Groups	**PIS score (MEAN±SD)**		
Day One	**2 hours**	**6 hours**	**12 hours**
Group I	2.92 ± 0.27	2.6 ± 0.48	1.94 ± 0.46
Group II	2.84 ± 0.36	1.92 ± 0.44	1.42 ± 0.49
P value	0.2117	<0.0001	<0.0001
Day Two	**2 hours**	**6 hours**	**12 hours**
Group I	1.96 ± 0.48	1.94 ± 0.46	1.44 ± 0.49
Group II	1.46 ± 0.49	1.06 ± 0.23	0.74 ± 0.43
P value	<0.0001	<0.0001	<0.0001
Day Three	**2 hours**	**6 hours**	**12 hours**
Group I	1.22 ± 0.41	0.58 ± 0.49	0.00 ± 0.00
Group II	0.32 ± 0.46	0.04 ± 0.19	0.00 ± 0.00
P value	<0.0001	<0.0001	-

Pain Intensity Scale (PIS) for pain shows mean score was higher in group I (oral Diclofenac) compared to Group II (Transdermal Diclofenac Patch) at 2 hours, 6 hours and 12 hours on day 1, day 2 and day 3 and this difference was statistically significant.(P value <0.0001)

Table 4: Mean PRS scores between the groups at different time periods

Groups	**PRS score (MEAN±SD)**		
Day One	**2 hours**	**6 hours**	**12 hours**
Group I	2.96 ± 0.19	2.58 ± 0.49	1.96 ± 0.44
Group II	2.84 ± 0.36	1.94 ± 0.42	1.46 ± 0.49
P value	0.0397	<0.0001	<0.0001
Day Two	**2 hours**	**6 hours**	**12 hours**
Group I	1.98 ± 0.46	1.82 ± 0.38	1.48 ± 0.49
Group II	1.46 ± 0.49	1.08 ± 0.27	0.82 ± 0.38
P value	<0.0001	<0.0001	<0.0001
Day Three	**2 hours**	**6 hours**	**12 hours**
Group I	1.16 ± 0.57	0.5 ± 0.5	0.00 ± 0.00
Group II	0.38. ± 0.48	0.00 ± 0.00	0.00 ± 0.00
P value	<0.0001	-	-

Pain Relief Scale (PRS) for pain shows mean score was more in group I (oral Diclofenac) compared to Group II (Transdermal Diclofenac Patch) at 2 hours, 6 hours and 12 hours on day 1, day 2 and day 3 and difference was statistically significant.(P value <0.0001)

None of the patients on oral diclofenac therapy or with diclofenac patch required paracetamol tablets for pain relief. Three patients consuming Oral diclofenac complained of burning and gastric acidity while none of

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the patients from transdermal patch group reported any adverse effects.

DISCUSSION

The management of postoperative pain continues to be a dynamic area of research, with newer formulations and treatment approaches frequently emerging to replace outdated methods. Pain following tooth extraction remains a persistent challenge for both dental practitioners and patients due to the significant inflammatory response it provokes[11].

Nonsteroidal anti-inflammatory drugs (NSAIDs) are among the most commonly used medications for managing dental postoperative pain. Their pain-relieving effects are primarily attributed to the inhibition of cyclooxygenase enzymes (COX-1 and COX-2), which play a central role in the production of prostaglandins, key mediators of inflammation and pain[12,13,14,15,16].

Despite their efficacy, orally administered NSAIDs are subject to first-pass metabolism, which can reduce the amount of active drug that reaches systemic circulation. Moreover, these medications are associated with several adverse effects, particularly gastrointestinal irritation, which tend to increase with higher doses.

To overcome these drawbacks, topical NSAID formulations have been introduced as alternative delivery systems. These provide targeted relief by delivering the drug directly to the affected site, enhancing local efficacy while minimizing systemic side effects. As a result, topical NSAIDs have gained recognition as effective and safer options for pain control in dental practice[17].

Transdermal delivery systems for NSAIDs represent a novel alternative to conventional oral or injectable administration methods. These systems deliver the medication through the skin, where it is gradually absorbed into the capillaries, ultimately reaching systemic circulation. This mode of delivery promotes a steady absorption rate, contributing to more consistent blood drug levels—often a desired therapeutic goal[18,19,20,21,22,23].

In this study, **Diclofenac** was selected as the analgesic agent and was administered in both oral and transdermal forms following multiple first premolar extractions in patients receiving orthodontic treatment. Diclofenac, a commonly used NSAID, possesses anti-inflammatory, analgesic, and antipyretic properties, making it a standard choice for managing post-extraction discomfort in dental procedures.

Two different formulations of Diclofenac were evaluated: a 50 mg oral tablet taken three times daily and a 100 mg transdermal patch. The transdermal patch, with a surface area of 50 square centimeters, delivers Diclofenac Diethylamine in a sustained-release manner over a 24-hour period at the application site.

The study assessed the pain-relieving effectiveness, safety, and patient tolerance of both formulations in individuals undergoing bilateral extraction of the maxillary and mandibular first premolars. Extractions were performed in two separate appointments: one side of the arch was treated during the initial visit, and the opposite side at the follow-up. This protocol enabled a direct comparison between the two drug delivery methods under nearly identical clinical circumstances. Oral Diclofenac was prescribed after the first extraction, while the transdermal patch was used following the second. All participants were within a similar age range, had healthy periodontal conditions, and underwent equivalent surgical procedures on both sides. This design allowed each patient to serve as their own control, minimizing inter-individual variability in pain perception and surgical trauma.

The once-daily 100 mg transdermal Diclofenac patch demonstrated comparable effectiveness to a daily dose of 150 mg oral Diclofenac in managing pain following dental extractions. These results align with observations by Krishna R *et al.*, who found that both oral and transdermal formulations of Diclofenac provided similar levels of pain relief in patients experiencing postoperative shoulder pain[24].

Bachalli *et al.*investigated the analgesic effectiveness of transdermal Diclofenac patches compared to oral Diclofenac following the surgical removal of impacted third molars. Pain levels were assessed at multiple intervals—2, 4, 8, 12, and 24 hours—across three consecutive postoperative days. On the first day after surgery, oral Diclofenac 100 mg showed statistically and clinically superior pain control compared to the transdermal patch[25]. However, by the second and third postoperative days, both forms of Diclofenac demonstrated similar efficacy in managing pain. These findings suggest that while transdermal Diclofenac may not provide as strong immediate postoperative relief as the oral form, it can serve as a viable alternative for

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managing later-stage postoperative discomfort in mandibular molar extractions. Additionally, Diclofenac—when administered at the lowest effective dose and for the shortest necessary duration—may be considered safe and well tolerated in patients with renal impairment[26,27,28].

Sanjay Talnia *et al.* observed that transdermal Diclofenac patches provided slightly better postoperative pain control than oral Diclofenac tablets in patients undergoing orthodontic premolar extractions. However, the difference was not statistically significant, as indicated by a Chi-square test ($P > 0.05$). The study concluded that transdermal patches effectively managed post-extraction pain with fewer systemic side effects. Nonetheless, their broader use may be restricted due to factors such as higher cost and limited availability[29].

In a related study, Chaitanya *et al.* found that transdermal Diclofenac patches were particularly effective in cases of mild to moderate pain, offering improved patient compliance and tolerability. While oral and intravenous Diclofenac provided greater pain relief in moderate to severe cases, the transdermal route remained advantageous in terms of ease of use and side effect profile[30].

Similarly, Samal *et al.* reported that transdermal Diclofenac serves as a promising option for managing mild to moderate postoperative pain following the surgical extraction of impacted third molars. Its efficacy, patient adherence, and favourable safety profile make it a compelling alternative to oral and injectable formulations. However, they emphasized the need for larger clinical trials to further evaluate its potential in various oral surgical procedures[31].

In the current study, patients who received the transdermal Diclofenac patch experienced a statistically and clinically significant reduction in postoperative pain, comparable to the pain relief achieved with oral Diclofenac tablets. Notably, between the first and second postoperative days, most of the of patients using the transdermal patch reported substantial pain relief, compared to 50% of those taking oral Diclofenac. This suggests a slightly higher early postoperative pain control with the transdermal formulation.

Tejasvi DV *et al.* found that oral administration of Diclofenac was associated with gastrointestinal (GI) side effects. In their study, transdermal Diclofenac patches (TDP) were applied at the test sites, while Diclofenac sodium was given orally at the control sites. The results indicated that TDP provided effective postoperative pain relief following root coverage procedures using subepithelial connective tissue grafts. Notably, unlike the oral route, the transdermal application did not lead to GI complications and was associated with improved pain tolerance[32].

In present study, none of the patients on oral diclofenac therapy or with diclofenac patch required paracetamol tablets for pain relief. Three patients consuming oral diclofenac complained of burning and gastric acidity while none of the patients from transdermal patch group reported any adverse effects

CONCLUSION

The transdermal Diclofenac patch has emerged as a promising option for managing mild to moderate pain following dental extractions. Its demonstrated analgesic effectiveness, combined with a lower incidence of systemic side effects, positions it as a valuable alternative to traditional oral NSAIDs. Pain management remains a critical concern in dental practice, impacting both patient comfort and clinical outcomes. With advancements in drug delivery systems and an expanding range of analgesics, the use of transdermal patches is likely to become more prevalent.

Compared to oral administration, the transdermal route represents one of the most innovative and effective developments in modern drug delivery. Transdermal drug delivery systems (TDDS) offer a non-invasive, patient-friendly, and reliable method for achieving systemic drug levels. However, to fully understand the therapeutic potential and limitations of transdermal Diclofenac, further research involving larger, long-term clinical trials is necessary.

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