



Comparison of Transdermal Diclofenac Patch with Oral Diclofenac Tablet in Control of Pain After Tooth Extraction

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Abstract

Background: Pain is an expected feature of the postoperative experience. If post-operative pain is not relieved, it can cause clinical and psychological changes that reduce quality of life.^[1] Nonsteroidal anti-inflammatory drugs (NSAIDs) are the most commonly used analgesic medications in dentistry. However, the toxicity of NSAIDs is now a major concern because to their widespread use.^[2] Analgesic medications can be taken by a variety of methods, including oral, parenteral, inhalation, and transdermal. Transdermal patches provide a consistent plasma concentration of the medicine without fluctuation and are more convenient than oral routes.^[3] The most commonly administered NASID is diclofenac. Which have anti-inflammatory, analgesic, and antipyretic properties.^[4] This study's aim was comparing the efficacy of transdermal diclofenac patch with oral diclofenac tablet in management of post extraction pain, swelling, trismus.

Material and Methods: Extraction procedures, including orthodontic, multiple tooth, and surgical third molar extractions, were performed on 100 participants in this experimental, randomized, split-mouth clinical study. The participants' ages ranged from 16 to 55, with 100 sites included in the study group (diclofenac transdermal patches group) and 100 sites included in the control group (oral diclofenac tablets group). Following surgery, patients were observed on a regular basis for up to 15 days.

Results: The pain measured by VAS score in the study group was significantly lower in comparison to the control group for orthodontic extractions and multiple extractions, whereas the VAS score for third molars was relatively higher in the study group. On the third postoperative day, the study group of 3rd molar extraction experienced significantly more swelling. There was no significant difference in mouth opening score between the study group and the control group from the third to the fifteenth post-operative day following 3rd molar extraction. The study group used more rescue drugs after third molar and numerous extractions than the control group. Gastric irritation was more common in the control group following 3rd molar and multiple extractions.

Conclusion: The transdermal diclofenac patch appears to be a potential analgesic strategy for the management of mild to moderate postoperative pain. It also reduces edema and facilitates mouth opening after tooth extraction, while preventing gastric discomfort.

Keywords: Diclofenac transdermal patches, oral Diclofenac tablets, Surgical 3rd molar extraction.

INTRODUCTION

Pain caused by tissue damage alters the somatosensory system, increasing the reactivity of both central and peripheral pain pathways. As a result, "prevention" or "pre-emption" of painful stimuli with analgesics is preferable to treatment.^[5] The notion of preemptive analgesia was developed in the early 1980s when experimental investigations demonstrated that central hypersensitization can be avoided by taking measures prior to the beginning of painful stimuli, hence lowering postoperative pain.^[2] To achieve optimal postoperative pain management, the patient's pain and suffering must be eliminated. Analgesic medications can be delivered orally, parenterally, inhaled, or transdermally.^[4]

Nonsteroidal anti-inflammatory medicines (NSAIDs) are the most popular pain relievers in dentistry. However, the toxicity of NSAIDs is a major concern today due to their widespread use.^[6] Diclofenac is the most often prescribed NSAID, with anti-inflammatory, analgesic, and antipyretic properties. When taken orally, only half of the absorbed dose of diclofenac is available in the systemic circulation after first-pass metabolism, and due to the high plasma concentration attained, oral diclofenac has the potential for significant adverse reactions, particularly in the gastrointestinal tract.^[7]

MATERIAL AND METHODS

This was an interventional study for comparing the efficacy of transdermal Diclofenac with oral Diclofenac in management of post-operative pain in bilateral extractions. This study was implemented as a randomized, in vivo study after clearance from the institutional ethical committee, on the 100 patients, selected on the basis of below mentioned inclusion criteria, presenting to the outpatient Department of Oral and Maxillofacial Surgery of College of Dental Sciences and Research Centre (CDS&RC), Ahmedabad from 2021 - 2024.

SELECTION CRITERIA

INCLUSION CRITERIA:

1. Patients in the age group of 16-55 years were be selected irrespective of sex, caste, religion and socio-economic status.
2. Bilateral orthodontic extractions.
3. Extraction of bilateral lower third molar with same angulation.
4. Multiple extractions.
5. Patients who agreed to follow the study protocol.

EXCLUSION CRITERIA:

1. Uncontrolled systemic diseases.
2. Patients with anti-coagulant therapy.
3. Patients allergic to Diclofenac or any NSAIDS
4. Patients under medication of NSAIDS or corticosteroids for any other illness.
5. Uncooperative patients not willing to commit to an appropriate post procedure follow-up.

DRUGS USED:

1. Antibiotic drug: Amoxicillin (cap. MOX 500mg)
2. Analgesic drug (NSAIDS):
Diclofenac sodium (Tab DAN 50 mg)
Paracetamol (Tab DOLO 500 mg)
Transdermal Diclofenac patch (DICLOPLAST 100 mg)
3. Antacid drug (Proton-Pump inhibitor): Ranitidine (Tab RANTAC 150mg)

ARMAMENTARIUM (FIGURE 1)

In this study, tooth extractions were carried out using either the trans-alveolar technique (bone guttering with a 702 straight fissure bur and high-speed rotary device—micromotor) or the intra-alveolar approach (elevators and forceps).



Figure 1.

- A. Armamentarium for extraction,
B. Diclofenac tablet & Transdermal diclofenac patch

METHODOLOGY

PRE-OPERATIVE PROCEDURES

A thorough patient history and consent form were documented. The procedure was thoroughly explained to the patient about the use of transdermal diclofenac patches as an alternative to oral diclofenac tablets. Maintaining aseptic precautions, armamentaria was prepared for the procedure. Those patients who were included in the control group were asked to take the preoperative Diclofenac sodium 50 mg tab one hour before the procedure, and those who were enrolled in the study group were instructed to apply the Diclofenac patch over their right upper arm two hours before the procedure.

INTRA-OPERATIVE PROCEDURES

Using the random method, the control group and study group sides were chosen. The control and study groups were separated by one week during the performance extraction process.

2% lignocaine hydrochloride was combined with adrenaline bitrate at a concentration of 1:80,000 to provide local anesthetic in both groups. Molt's No. 9 periosteal elevator was used to reflect a full-thickness mucoperiosteal flap, exposing the tooth and bone. Either the intra-alveolar (using extraction forceps and an elevator) or trans-alveolar (bone guttering with a 702 straight fissure bur at a rotary speed of 35,000 rotations per minute with copious saline irrigation) methods were used to extract the tooth. A Lucas curette was used to curette the periapical tissue or remnants of the tooth follicle that were connected to the socket. A bone file was used to smooth off sharp bony edges. To remove the debris, betadine and saline were used to fully debride the socket. After re-approximating the mirrored flap to its initial location, simple interrupted suturing with non-absorbable 3-0 black braided silk was used to establish primary closure.

POST-OPERATIVE PROCEDURE

After tooth extraction, control group patients received tablet diclofenac sodium 50 mg (DAN 50) for three days, whereas study group patients were instructed to change the patch every 24 hours for two days post-operatively.

For the control and study groups, capsule amoxicillin 500 mg (Mox 500) TDS was given for five days. Patients were also given tablet DOLO 500 mg and tablet RANTAC 150 mg as rescue medications if they experienced more pain or gastric irritation, respectively.

For a total of 72 hours after surgery, patients were given score sheets for pain metrics at intervals of two, six, and twelve hours. Take it on the third, seventh, and fifteenth days after surgery to check for edema and trismus. The number of paracetamol tablets required was then calculated after the participants stopped scoring if they need the DOLO 500 mg tablet for pain control.

The same surgeon carried out the extraction procedures at the research site on one side and the control site on the other.

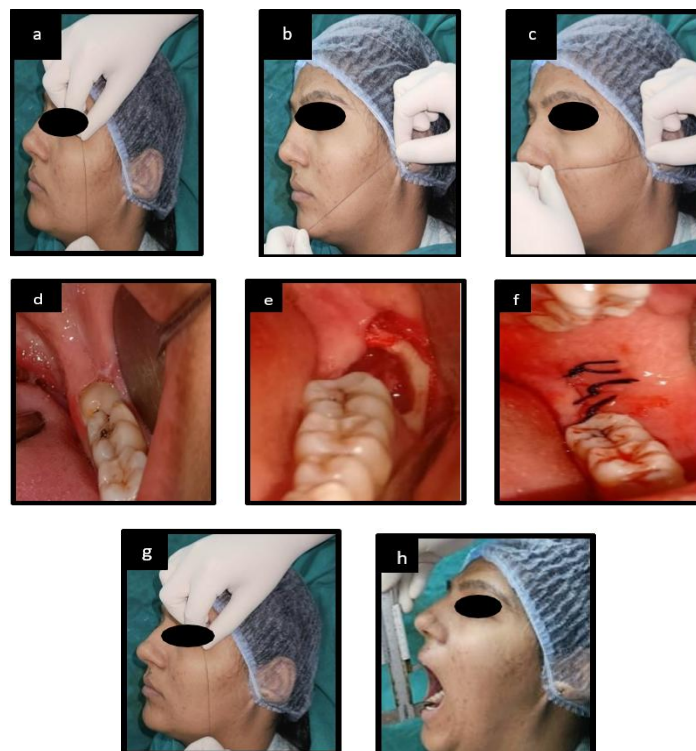


Figure 2. Control group. Pre operative facial measure from a-c: a) Outer canthus to angle of mouth, b) Tragus to soft tissue pogonion, c) Tragus to corner of mouth, d) Pre-operative site, e) Extraction socket, f) Simple interrupted suturing, 3rd post-operative day follow up g-h: g) Facial swelling measurement, h) Mouth opening

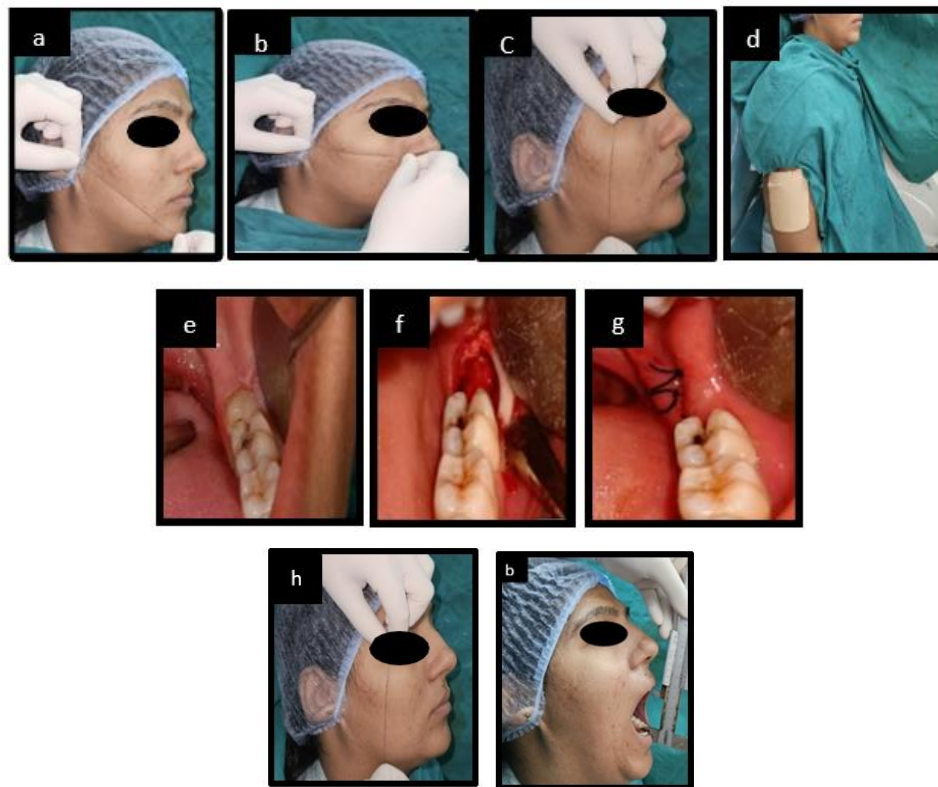


Figure 3. Study group. Pre-operative facial measure from a-c: a) Outer canthus to angle of mouth, b) Tragus to soft tissue pogonion, c) Tragus to corner of mouth, d) Transdermal patch application, e) Pre-operative site, f) Extraction socket, g) Simple interrupted suturing. 3rd day post-operative follow up h-i: h) Facial swelling measurement, i) Mouth opening

RESULTS

The Wilcoxon signed-rank test, which is the nonparametric equivalent of the student's paired t-test, and the student's paired t-test for the parametric approach were employed in the statistical study. Descriptive analysis was performed on the data to determine the mean and standard deviation of each variable. The 100 individuals who had their teeth out ranged in age from 16 to 55. Of these 100 cases, 52 were men and 48 were women. Each control and study group had 23 patients who had their third molar extracted, 31 patients who had multiple extractions, and 46 patients who had orthodontic extractions out of 200 operation sites.

PAIN (Visual analogue scale - VAS by Hayes and Patterson 1921) - The Visual Analog Scale (VAS) was used to subjectively measure post-operative pain in both groups at two, six, and twelve hours throughout the course of 72 hours after surgery.

Table 1: Pain VAS: Orthodontic extractions
ORTHODONTICEXTRACTIONS

DAY	PAIN	CONTROLSITE		STUDYSITE		P VALUE
		MEAN	SD	MEAN	SD	
DAY1	2HR	7.72	.958	4.91	1.170	<0.001**
	6HR	6.61	.881	4.89	1.178	<0.001**
	12HR	6.48	.863	3.80	.833	<0.001**
DAY2	2HR	6.07	.904	3.74	.953	<0.001**
	6HR	5.96	.665	3.28	1.047	<0.001**
	12HR	5.91	.412	2.59	1.002	<0.001**
DAY3	2HR	5.00	1.095	2.26	1.021	<0.001**
	6HR	4.78	1.114	2.17	1.235	<0.001**
	12HR	3.70	.726	1.67	.762	<0.001**

WilcoxonSignedRankTest:**p<0.001;Highlysignificant;*p<0.05;Significant p>0.05 ;Not significant

Table 2: Pain VAS: Multiple extractions
MULTIPLE EXTRACTIONS

DAY	PAIN	CONTROL SITE		STUDY SITE		P VALUE
		MEAN	SD	MEAN	SD	
DAY 1	2HR	7.68	.909	5.16	1.128	<0.001**
	6HR	6.45	.810	5.03	1.140	<0.001**
	12HR	6.03	.605	3.81	.601	<0.001**
DAY 2	2HR	5.94	.629	3.74	.682	<0.001**
	6HR	5.84	1.003	3.48	.851	<0.001**
	12HR	5.10	1.012	2.45	1.091	<0.001**
DAY 3	2HR	4.45	.961	2.42	.886	<0.001**
	6HR	4.42	1.177	2.06	.929	<0.001**
	12HR	3.81	.601	1.68	.653	<0.001**

Wilcoxon Signed Rank Test : **p<0.001; Highly significant;*p<0.05 ; Significant p>0.05 ; Not significant

Table 3: Pain VAS: Third molar
THIRD MOLAR

DAY	PAIN	CONTROL SITE		STUDY SITE		P VALUE
		MEAN	SD	MEAN	SD	
DAY 1	2HR	7.70	1.020	8.00	1.000	0.233
	6HR	6.65	1.027	7.35	.714	0.019*
	12HR	6.17	1.072	6.74	.964	0.029*
DAY 2	2HR	6.61	1.118	6.48	1.201	0.755
	6HR	5.91	1.164	5.86	0.625	0.443
	12HR	4.87	1.254	4.73	0.864	0.001*
DAY 3	2HR	4.78	.902	4.69	0.972	0.005*
	6HR	4.74	.915	4.65	1.112	0.561
	12HR	3.73	1.077	3.69	0.702	0.926

Wilcoxon Signed Rank Test : **p<0.001; Highly significant;*p<0.05 ; Significant p>0.05 ;Not significant

SWELLING (Gabka and Matsumura technique) - Both groups' preoperative face measures were recorded in order to provide a baseline for assessing postoperative edema. For both the control site and the research site, the average pre-operative facial measurement was 12.39 mm for patients for third molar extractions, 11.26 mm for patients for multiple extractions, and 11.68 mm for orthodontic tooth extractions. On the third, seventh, and fifteenth post-operative days, post-operative edema was noted in both groups.

Table 4: Swelling: Orthodontic extractions
ORTHODONTIC EXTRACTIONS

SWELLING	CONTROL SITE		STUDY SITE		P VALUE
	MEAN	SD	MEAN	SD	
PRE OP	11.68	1.028	11.68	1.0028	-
DAY 3	13.55	1.656	12.55	1.361	<0.001*
DAY 7	11.87	0.929	11.83	0.987	0.081
DAY 15	11.68	1.028	11.68	1.028	-

Student 't' test Paired : **p<0.001; Highly significant p<0.05 ; Significant p>0.05 ;Not significant

Table 5: Swelling: Multiple extractions
MULTIPLE EXTRACTIONS

SWELLING	CONTROL SITE		STUDY SITE		P VALUE
	MEAN	SD	MEAN	SD	
PRE OP	11.26	0.705	11.26	0.705	-
DAY 3	12.78	1.182	11.98	0.978	<0.001**
DAY 7	11.98	0.978	11.83	0.798	0.385
DAY 15	11.26	0.705	11.26	0.705	-

Student 't' test Paired : **p<0.001; Highly significant p<0.05 ; Significant p>0.05 ;Not significant

Table 6: Swelling: Third molar
THIRD MOLAR

SWELLING	CONTROL SITE		STUDY SITE		P VALUE
	MEAN	SD	MEAN	SD	
PRE OP	12.39	1.008	12.39	1.008	-
DAY 3	13.22	1.272	14.47	1.557	<0.001**
DAY 7	12.41	0.957	12.47	0.629	<0.001**
DAY 15	12.39	1.008	12.39	1.008	-

Student 't' test Paired : **p<0.001; Highly significant p<0.05 ; Significant p>0.05 ;Not significant

TRISMUS (Inter incisal distance) - In order to assess post-operative trismus, pre-operative mouth opening (interincisal distance) was measured in both groups. On both the control site and the study site, the average pre-operative facial measurement was 44.78 mm for the third molar, 44.29 mm for multiple extractions, and 45.48 mm for orthodontic extraction. On the third, seventh, and fifteenth post-operative days, trismus was observed in the control location.

Table 7: Trismus: Orthodontic extractions
ORTHODONTIC EXTRACTIONS

TRISMUS	CONTROL SITE		STUDY SITE		P VALUE
	MEAN	SD	MEAN	SD	
DAY 0	45.48	4.44	45.48	4.44	-
DAY 3	42.30	4.35	45.39	4.40	<0.001**
DAY 7	45.48	4.44	45.48	4.44	-
DAY 15	45.48	4.44	45.48	4.44	-

Student 't' test Paired : **p<0.001; Highly significant p<0.05 ; Significant p>0.05 ;Not significant

Table 8: Trismus: Multiple extractions
MULTIPLE EXTRACTIONS

TRISMUS	CONTROL SITE		STUDY SITE		P VALUE
	MEAN	SD	MEAN	SD	
DAY 0	44.29	4.26	44.29	4.26	-
DAY 3	34.13	6.04	39.84	4.25	<0.001**
DAY 7	39.58	4.35	42.87	4.68	0.001*
DAY 15	44.29	4.26	44.29	4.26	-

Student 't' test Paired : **p<0.001; Highly significant p<0.05 ; Significant p>0.05 ;Not significant

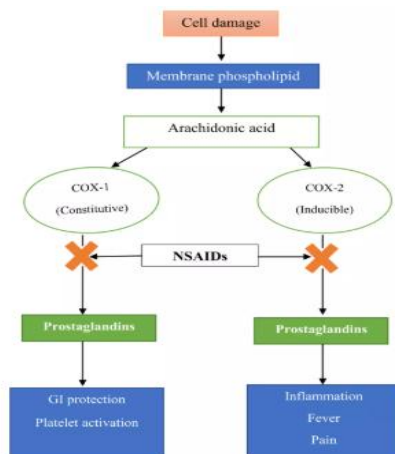
Table 9: Trismus: Third molar
THIRD MOLAR

TRISMUS	CONTROL SITE		STUDY SITE		P VALUE
	MEAN	SD	MEAN	SD	
DAY 0	44.78	4.166	44.78	4.166	-
DAY 3	34.26	4.41	33.22	5.846	0.043*
DAY 7	39.04	3.855	38.70	3.643	0.088
DAY 15	44.78	4.166	44.78	4.413	-

Student 't' test Paired : **p<0.001; Highly significant p<0.05 ; Significant p>0.05 ;Not significant

DISCUSSION

The field of research on managing postoperative pain is dynamic and ever-evolving. By preventing central sensitization, pre-emptive analgesia is a helpful method for managing postoperative pain.^[8] The availability and effectiveness of analgesics would determine the different ways in which they are administered. NSAIDs are one of the most popular drug classes because of their strong analgesic, anti-inflammatory, and antipyretic properties.

**Figure 4. NSAIDs mechanism of action**

The main mechanism by which NSAIDs were believed to have their potent anti-inflammatory effects was by inhibiting the synthesis of PGE₂, the main prostanoid produced during inflammation. According to the results of our study, patients who had orthodontic extractions and multiple tooth extractions at the study sites had much less postoperative edema on the third postoperative day than patients at the control locations. The edema decreased steadily between seven and fifteen days, and the rates of swelling reduction at the study and control locations did not differ significantly. The third molar surgical extraction patients' swelling significantly decreased on the third postoperative day after taking diclofenac tablets; however, following swelling reductions on the seventh and fifteenth postoperative days showed similar outcomes between the study and the control sites.

The bioavailability of transdermal diclofenac sodium was 1% higher than that of oral diclofenac. Nevertheless, the patch delivers long-term effectiveness and convenience by releasing the drug into the body gradually. Therefore, the requirement for rescue medications was only apparent in situations where Diclofenac patches were used. Two patients who had multiple extractions and five patients who underwent third molar surgery were found to require these additional paracetamol prescriptions.

Oral diclofenac was the NSAID that was prescribed the most frequently. Because of its first-pass metabolism, 50% of the oral dosage of diclofenac can enter the bloodstream. These drugs' high plasma concentration causes COX-1 inhibition, which reduces mucosal protection and causes undesirable side effects such as intestinal pain. Five patients who had their third molar extraction and two patients who received the diclofenac tablet following multiple extractions reported having stomach discomfort in this study. Patients who received the diclofenac patches did not report similar issues.

The analgesic effectiveness of oral diclofenac sodium versus diclofenac sodium transdermal patch in the treatment of postoperative pain after surgical extraction of impacted mandibular third molars was assessed subjectively in 2009 by

Bachali S et al. on 20 patients. The results of the statistical analysis and the clinical observation demonstrated that oral diclofenac sodium was marginally more effective than transdermal diclofenac sodium on the first postoperative day. On the second and third postoperative days, however, there was no clinical or statistical difference in the way either delivery method controlled pain.^[4]

The degree of postoperative analgesia, patient compliance, and frequency of adverse events were compared between oral and transdermal diclofenac tablets and patches in a 2013 study by Bhasker et al. on 20 patients who had bilateral orthodontic extractions. The findings of the study show that the transdermal diclofenac patch offers as strong analgesia as oral diclofenac tablets, with the added benefit of improved patient compliance and being suitable for routine post-extraction analgesia. They observed that two individuals using oral diclofenac tablets reported experiencing burning and stomach acidity. The transdermal patch did not cause any negative side effects.^[10]

Dastagir F et al. conducted a study in 2019 to evaluate the analgesic effectiveness of oral and transdermal diclofenac sodium patches in the treatment of postoperative pain, edema, and trismus after surgically extracting impacted mandibular third teeth. With a mean difference of 4.46 +/- 1.80 (SD) on day 2 and 0.26 +/- 0.70 (SD) on day 7, respectively, and statistically significant results of $p < 0.05$, the transdermal patch group significantly decreased the intensity of discomfort. With a mean difference of 14.21 +/- 1.08 (SD) on day 2 and 12.81 +/- 0.82 (SD) on day 7, with statistical significance values of $p < 0.05$, they observed that the transdermal patch group suffered from less severe swelling. On days two and seven, they observed that the transdermal patch group experienced a relatively lower degree of trismus than the oral diclofenac group, indicating that the diclofenac patch performed better than the diclofenac tablets.^[11]

Aimuwamwosa OD et al. conducted a study in 2020 to compare the effects of oral and transdermal routes of diclofenac administration on 68 patients having their third molars extracted. They found that the study group (transdermal diclofenac) experienced less severe trismus on day 7 postoperatively than the control group (oral diclofenac), and the results were statistically significant.^[12]

In 2020, Wankhede et al. conducted a study to compare the effectiveness of oral and transdermal diclofenac tablets in managing pain following surgical extraction of 40 patients' impacted mandibular third molars. Only one patient in the study needed an additional rescue medication following the diclofenac patch's use.^[13]

Additionally, Rajeshwari R et al. (2016) investigated the efficacy and safety of oral and transdermal diclofenac for the treatment of postoperative pain in patients with dental implants. The results showed that the diclofenac tablet and the transdermal patch had similar effects, since none of the 20 patients they looked at required rescue analgesics. When using the transdermal patches, none of the patients experienced any negative side effects, but three patients complained of mild burning and stomach irritation when taking the oral diclofenac.^[14]

CONCLUSION

By effectively reducing postoperative pain without adding to the patient's burden, transdermal patches can increase patient compliance. In addition to reducing edema and improving jaw opening after tooth extraction, the transdermal diclofenac patch appears to be a good analgesic method for the treatment of mild to moderate postoperative pain. It also avoids gastrointestinal discomfort. They work well as analgesics for those with a fear of ingesting drugs, people with mental disabilities, and people who were prone to gastritis.

STATEMENTS AND DECLARATIONS

- No funds, grants, or other support was received.
- The authors have no financial or proprietary interests in any material discussed in this article.
- This study was performed in line with the Nuremberg code of ethics. Approval was granted by the Ethics Committee of our institute.
- Informed consent was obtained from all individual participants included in the study
- Consent for participation was obtained from all the participants.
- Clinical trial number: Not applicable.

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