

Comparative Assessment of Efficacy, Tolerability and Adverse Events of Oral versus Transdermal Diclofenac Sodium in Managing Postoperative Pain of Surgical Extraction

¹Dr. Shobha Bharti, MDS, Senior Lecturer, Department of Conservative Dentistry and Endodontics, Buddha Institute of Dental Sciences and Hospital, Patna, Bihar.

²Dr. Alisha Singh, MDS, Assistant Professor, Department of Dentistry, ESIC Medical College and Hospital, Indore, Madhya Pradesh.

³Dr. Pavneet Kaur Soni, Post Graduate Student, Department of Periodontology and Implantology, Faculty of Dental Sciences, Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh.

Corresponding Author: Dr. Pavneet Kaur Soni, Post Graduate Student, Department of Periodontology and Implantology, Faculty of Dental Sciences, Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh.

Citation This Article: Dr. Shobha Bharti, Dr. Alisha Singh, Dr. Pavneet Kaur Soni, “Comparative Assessment of Efficacy, Tolerability and Adverse Events of Oral versus Transdermal Diclofenac Sodium in Managing Postoperative Pain of Surgical Extraction”, IJHDC – July – August – 2026, Volume. – 5, Issue – 4, P. No. 18 – 24.

Open Access Article: This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Efficacious control of the pain after procedure is vital during the oral surgical procedure. Diclofenac sodium is a commonly used NSAID used for pain control which is available in different formulations such as Transdermal and oral methods.

Aim: The present study was aimed to comparatively assess the efficacy, tolerability and adverse events of oral versus Transdermal diclofenac sodium in managing postoperative pain of surgical extraction.

Methods: The present study assessed 80 subjects that underwent surgical tooth extraction at the Institute within the defined study period and were divided

randomly into two groups of 40 subjects each where Group I subjects were given 200 mg transdermal diclofenac patches to be used once daily for 3 days and Group II subjects were given 100 mg oral diclofenac tablet twice daily for 3 days. Pain relief was assessed on a 4-point scale on postoperative day 1, 2, and 3. Patient comfort, adverse events, and tolerability was also assessed.

Results: The study results showed that significantly higher mean pain relief scores were seen in Group I on all three days compared to Group II subjects with $p < 0.05$. Fewer adverse events were seen in Group I with no complication in 90% subjects from Group I compared

50% subjects from Group II which was significant with $p=0.0001$. Patient comfort and tolerability was significantly better in Group I with p -values of 0.002 and 0.01 respectively.

Conclusion: The present study concludes that Transdermal patches of diclofenac provide well-tolerated and effective relief in the postoperative pain with few side-effects and better compliance in the subjects compared to subjects using the oral diclofenac. Hence, Transdermal diclofenac patches are a vital alternative to provide postoperative analgesia in oral surgery.

Keywords: Diclofenac, Oral NSAIDs, Postoperative Pain, Surgical Extraction, Transdermal Patch.

Introduction

Attaining the efficacious pain control is vital following the oral and maxillofacial surgical procedures as it has direct effect on the patient satisfaction and recovery. Various surgical procedures as extraction of impacted third molars or multiple teeth usually lead to significant postoperative discomfort which warrant the use of appropriate analgesic agents. Diclofenac sodium is one such widely used NSAID that provide potent anti-inflammatory and analgesic effect and works by blocking the COX-1 and COX-2 enzymes which are vital for production of prostaglandin. Prostaglandin is the main driver for inflammation and pain. In contrast to selective COX-2 inhibitors, it works on both the enzymes and provide broad anti-inflammatory action. It also interacts with the NO-cGMP pathway, blocks thromboxane - prostanoid (TP) receptors, and affects Arachidonic acid metabolism to enhance its effects.¹

Diclofenac is available in various forms including gel, Transdermal patch, suppositories, intravenous, and oral form with each form having different action and absorption profile. Oral diclofenac is influenced by first-

pass metabolism of liver that lower its bioavailability and have gut-irritation effects. Transdermal patches, another form of diclofenac, bypass the gastrointestinal system and has fewer side-effects and provide steady release. Intravenous diclofenac works quickly and is used in acute pain. However, it has more side-effects. Three main concerns of diclofenac use being renal toxicity, increased cardiovascular risk, and gastrointestinal complications. To eliminate these issues, Transdermal diclofenac patches have been advocated that provide lesser side-effects and controlled release of drug.²

Transdermal diclofenac patches have various advantages on oral route as bypass of first-pass hepatic metabolism and gastrointestinal tract which support better patient compliance, ensures longer-lasting pain relief, and provide steady drug levels in the blood.

Different studies from previous literature data indicate that Transdermal diclofenac is equally efficacious as oral diclofenac to manage the postoperative dental pain with subjects reporting few gastrointestinal effects, higher patient compliance, and better overall tolerance. Transdermal patches are non-invasive and advanced system that release drug into bloodstream directly over time.³

After application, drug is released slowly from outer layer of skin and then diffuse into bloodstream by difference in concentration of patch and the blood vessels. For effective absorption, factors as application site, temperature, and skin hydration matters.⁴

After assessing both patient-centred and clinical outcomes, the present study was aimed to comparatively assess the efficacy, tolerability and adverse events of oral versus Transdermal diclofenac sodium in managing postoperative pain of surgical extraction.

Materials and methods

The present randomized comparative clinical study was aimed to comparatively assess the efficacy, tolerability and adverse events of oral versus Transdermal diclofenac sodium in managing postoperative pain of surgical extraction. The study subjects were from Department of Dentistry of the Institute. Verbal and written informed consent were taken from all the subjects before study participation.

The present study assessed 80 subjects that underwent surgical tooth extraction at the Institute within the defined study period and were divided randomly into two groups of 40 subjects each where Group I subjects were given 200 mg Transdermal diclofenac patches to be used once daily for 3 days and Group II subjects were given 100 mg oral diclofenac tablet twice daily for 3 days. Pain relief was assessed on a 4-point scale on postoperative day 1, 2, and 3. Patient comfort, adverse events, and tolerability was also assessed.

The inclusion criteria for the study were subjects aged 18-60 years in ASA (American Society of Anesthesiologists) grade I or II, and requiring the surgical extraction of the teeth. The exclusion criteria for the study were subjects that were lactating or pregnant, had history of alcohol abuse, known allergy to any NSAID, or not willing to participate.

All the surgical extractions were done by a single surgeon expert in the field under local anesthesia as 2% lignocaine with 1:200,000 adrenaline utilizing the standard technique. Bone was removed using the carbide burs and under copious irrigation. The closure of the wound was done using the silk sutures using interrupted technique and sutures were removed after 7 days postoperative.

Postoperatively, Group I subjects were applied with 200 mg Transdermal diclofenac sodium patch at the nape of the neck which was replaced after 24 hours for 3 days and Group II subjects were given 100 mg oral diclofenac sodium tablets twice daily for 3 days. All the subjects were given Cap. Amoxicillin 500 mg + Potassium Clavulanate 125 mg (TDS for 3 days), Tab. Ketorolac 10 mg, and were advised warm saline rinses 3-4 times every day after 24 hours postoperative.

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

For statistical analysis, all the data were assessed using SPSS software version 26.0 (IBM Corp., Armonk, NY, USA) where continuous variables were presented as mean and standard deviation assessed using Mann Whitney U test and categorical variables were compared using the Fisher's exact test. The p-value of <0.05 was considered as statistically significant.

Results

The present randomized comparative clinical study was aimed to comparatively assess the efficacy, tolerability and adverse events of oral versus Transdermal diclofenac sodium in managing postoperative pain of surgical extraction. The present study assessed 80 subjects that underwent surgical tooth extraction at the Institute within the defined study period and were divided randomly into two groups of 40 subjects each where Group I subjects were given 200 mg Transdermal

diclofenac patches to be used once daily for 3 days and Group II subjects were given 100 mg oral diclofenac tablet twice daily for 3 days. Pain relief was assessed on a 4-point scale on postoperative day 1, 2, and 3. Patient comfort, adverse events, and tolerability was also assessed. The comparison of pain relief scores in the two groups of study subjects showed that pain relief scores were significantly higher in Group I compared to Group II with $p=0.006$. Similar higher scores were seen in Group I on day 2 and 3 with p -values of 0.01 and 0.01 (Table 1).

It was seen that for comparison of adverse events in two groups of study subjects, erythema was seen in 10% ($n=4$) subjects from Group I and 0 subjects from Group II. Headache was seen in no subject from Group I and 20% ($n=8$) subjects from Group II. Gastrointestinal disturbances were seen in 0 subject from Group I and 30% ($n=12$) subjects from Group II. No side effect was seen in 90% ($n=36$) subjects from Group I and 50% ($n=20$) subjects from Group II. The difference was highly statistically significant with the p -value of 0.0001 (Table 2).

The study results showed that for comparison of tolerability in two groups of study subjects, tolerability was excellent in 90% ($n=36$) subjects from Group I and 50% ($n=20$) subjects from Group II, good in 5% ($n=2$) subjects from Group I and 10% ($n=4$) subjects from Group II, fair in 5% ($n=2$) subjects from group I and 15% ($n=6$) subjects from Group II, and poor in 0 subjects from Group I and 25% ($n=10$) subjects from Group II. Tolerability was significantly better in Group I compared to Group II with $p=0.01$ (Table 3).

Concerning the comparison of patient comfort in two groups of study subjects, no was reported as the response in 5% ($n=2$) subjects from Group II compared to 50%

($n=20$) subjects from Group II. The response was yes in 95% ($n=38$) subjects from Group I and 50% ($n=20$) subjects from Group II. The patient comfort was significantly better in subjects from Group I compared to subjects from Group II with the p -value of 0.002 (Table 4).

Discussion

The present study assessed 80 subjects that underwent surgical tooth extraction at the Institute within the defined study period and were divided randomly into two groups of 40 subjects each where Group I subjects were given 200 mg Transdermal diclofenac patches to be used once daily for 3 days and Group II subjects were given 100 mg oral diclofenac tablet twice daily for 3 days. Pain relief was assessed on a 4-point scale on postoperative day 1, 2, and 3. Patient comfort, adverse events, and tolerability was also assessed.

The comparison of pain relief scores in the two groups of study subjects showed that pain relief scores were significantly higher in Group I compared to Group II with $p=0.006$. Similar higher scores were seen in Group I on day 2 and 3 with p -values of 0.01 and 0.01. These data were comparable to the previous studies of Gupta S et al⁵ in 2025 and Samal D et al⁶ in 2021 where data comparable to the present study were also reported by the authors.

The study results showed that for comparison of adverse events in two groups of study subjects, erythema was seen in 10% ($n=4$) subjects from Group I and 0 subjects from Group II. Headache was seen in no subject from Group I and 20% ($n=8$) subjects from Group II. Gastrointestinal disturbances were seen in 0 subject from Group I and 30% ($n=12$) subjects from Group II. No side effect was seen in 90% ($n=36$) subjects from Group I and 50% ($n=20$) subjects from Group II. The difference

was highly statistically significant with the p-value of 0.0001. These results were consistent with the findings of Bagga IK et al⁷ in 2017 and Wankhade P et al⁸ in 2020 where adverse effects with diclofenac oral and Transdermal reported by the authors were comparable to the results of the present study.

It was seen that for comparison of tolerability in two groups of study subjects, tolerability was excellent in 90% (n=36) subjects from Group I and 50% (n=20) subjects from Group II, good in 5% (n=2) subjects from Group I and 10% (n=4) subjects from Group II, fair in 5% (n=2) subjects from group I and 15% (n=6) subjects from Group II, and poor in 0 subjects from Group I and 25% (n=10) subjects from Group II. Tolerability was significantly better in Group I compared to Group II with p=0.01. These findings were in agreement with the results of Talnia S et al⁹ in 2020 and Nandavar A et al¹⁰ in 2016 where tolerability with diclofenac oral and Transdermal reported in present study was comparable to the results by the authors.

For the comparison of patient comfort in two groups of study subjects, no was reported as the response in 5% (n=2) subjects from Group II compared to 50% (n=20) subjects from Group II. The response was yes in 95% (n=38) subjects from Group I and 50% (n=20) subjects from Group II. The patient comfort was significantly better in subjects from Group I compared to subjects from Group II with the p-value of 0.002. These results correlated with the findings of Wong WF et al¹¹ in 2023 and Raja Rajeswari S et al¹² in 2017 where patient comfort reported by authors was comparable to the results from present study.

Conclusion

Considering its limitations, the present study concludes that Transdermal patches of diclofenac provide well-

tolerated and effective relief in the postoperative pain with few side-effects and better compliance in the subjects compared to subjects using the oral diclofenac. Hence, Transdermal diclofenac patches are a vital alternative to provide postoperative analgesia in oral surgery.

References

1. Gan TJ. Diclofenac: an update on its mechanism of action and safety profile. *Curr Med Res Opin.* 2010; 26:1715–31.
2. Durate ID, Lorenzetti BB, Ferreira SH. Peripheral analgesia and activation of the nitric oxide-cyclic GMP pathway. *Eur J Pharmacol.* 1990;186:289–93.
3. Selg E, Buccellati C, Andersson M, Rovati GE, Ezinga M, Sala A, et al. Antagonism of thromboxane receptors by diclofenac and lumiracoxib: Diclofenac and lumiracoxib as TP receptor antagonists. *Br J Pharmacol.* 2007;152:1185–95.
4. Bhaskar H, Kapoor P, Ragini. Comparison of Transdermal diclofenac patch with oral diclofenac as an analgesic modality following multiple premolar extractions in orthodontic patients: A cross over efficacy trial. *Contemp Clin Dent.* 2010;1:158–63.
5. Gupta S, Gupta A, Verma A, Shrivastava S, Jain A. Comparative evaluation of Transdermal diclofenac patch versus oral diclofenac sodium for postoperative pain management following surgical extractions: A randomized single blinded clinical study. *J Dent Spec.* 2025;13:226-232.
6. Samal D, Mishra N, Meher B, Kar IB, Kar R, Saipooja RH. Comparison of Safety, Efficacy, Patient Compliance and Cost Effectiveness of Transdermal, Oral and Intramuscular Diclofenac for Pain Control Following Oral Surgical Procedures. *J Maxillofac Oral Surg.* 2021;20:63–9.

7. Bagga IK, Jain P, Vijaykumar PA. Evaluation of efficacy, safety and tolerability of Transdermal diclofenac sodium patch for in the management of postoperative pain following surgical removal of impacted mandibular third molars. *Int J Current Res.* 2017;9:46168–73.
8. Wankhade P, Mandlik G. Clinical comparative study of diclofenac sodium Transdermal patch vs oral diclofenac sodium tablet as an analgesic and anti-inflammatory following removal of mandibular impacted third molars. *Int J Sci Res.* 2020;9:54-59.
9. Talnia S, Fry RR, Sharma A, Patidar DC, Goyal S, Gandhi G. Efficacy of Transdermal Diclofenac Patch as an Analgesic Following Premolar Extractions in Orthodontic Patients. *Ann Maxillofac Surg.* 2020;10:37-41.
10. Nandavar A, Lalitha RM, Prasad K, Kumar V, Singh D. Comparison of Transdermal diclofenac patch with oral diclofenac as an analgesic modality following removal of mandibular impacted third molars: A cross over efficacy trial. *Int J Pain.* 2016;7:01–12.
11. Wong WF, Ang KP, Sethi G, Looi CY. Recent advancement of medical patch for Transdermal drug delivery. *Medicina (Kaunas).* 2023;59:778.
12. Raja Rajeswari S, Gowda T, Kumar T, Mehta DS, Arya K. Analgesic efficacy and safety of Transdermal and oral diclofenac in postoperative pain management following dental implant placement. *Gen Dent.* 2017;65:69–74.

Legend Figure

Table 1: Comparison of pain relief scores in the two groups of study subjects

Sn.	Pain relief scores	Group I (n=40)	Group II (n=40)	Total	p-value
1	Day 1	1.5±1.11	0.6±0.5	1.23±1.01	0.006
2	Day 2	2.83±0.97	2.13±0.57	2.3±0.86	0.01
3	Day 3	3.63±0.57	3.23±0.53	3.43±0.4	0.01

Table 2: Comparison of adverse events in two groups of study subjects

Sn.	Adverse effects	Group I (n=40)		Group II (n=40)		Total		p-value
		n	%	n	%	n	%	
1.	Erythema	4	10	0	0	4	5	0.0001
2.	Headache	0	0	8	20	8	10	
3.	Gastrointestinal disturbances	0	0	12	30	12	15	
	None	36	90	20	50	56	70	
	Total	40	100	40	100	80	100	

Table 3: Comparison of tolerability in two groups of study subjects

Sn.	Tolerability	Group I (n=40)		Group II (n=40)		Total		p-value
		n	%	n	%	n	%	
1.	Excellent	36	90	20	50	56	70	0.01
2.	Good	2	5	4	10	6	7.50	
3.	Fair	2	5	6	15	8	10	
4.	Poor	0	0	10	25	10	12.50	
5.	Total	40	0	40	100	80	100	

Table 4: Comparison of patient comfort in two groups of study subjects

Sn.	Patient comfort	Group I (n=40)		Group II (n=40)		Total		p-value
		n	%	n	%	n	%	
1.	No	2	5	20	50	22	27.5	0.002
2.	Yes	38	95	20	50	58	72.5	
3.	Total	40	100	40	100	80	100	