ORIGINAL RESEARCH PAPER

Volume-7 | Issue-11 | November-2018 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

"COMPARATIVE EVALUATION OF ANALGESIC EFFICACY OF ORAL DICLOFENAC SODIUM AND TRANSDERMAL PATCH (NUPATCH®) AFTER PERIODONTAL FLAP SURGERY: A RANDOMIZED CROSS OVER CLINICAL TRIAL".

Dental Science

Chandrasekar B.M

Krishna Kripal* *Corresponding Author

Aiswarya Dileep

Kavita Chandrasekaran

Sushma Reddy Bhavanam

Manjunath S.M

ABSTRACT

AIMS AND OBJECTIVES: The aims and objectives of the present study was to compare and evaluate the analgesic efficacy of transdermal patch (NuPatch®) and oral diclofenac sodium during postoperative period in patient undergoing quadrant periodontal flap surgery and to compare and evaluate the patient compliance, tolerance, and adverse reaction following the use of NuPatch® and oral diclofenac sodium.

MATERIALS AND METHODS: A total of 60 quadrants were divided into groups based on inclusion and exclusion criterias as follows: Group I (30 quadrants): Diclofenac sodium 50 mg b.i.d will be given for three days in patients undergoing flap surgery in one quadrant. Group II (30 quadrants): NuPatch® 100 mg once daily will be given for three days to be applied on the deltoid region after flap surgery. Pain Intensity and pain relief were assessed postoperatively at two, six, and twelve hours on the same day and also on the 2nd and 3rd day using pain score chart consisting of Numerical Rating Scale and Visual Analog Scale by the respective patients.

RESULTS: The pain intensity and pain relief were found to be significantly reduced after first day in the group 2 compared to group 1. Adverse reaction like gastric irritation was found in group 1 with no adverse reaction in group 2.

CONCLUSION: The transdermal diclofenac patch seems to be a promising analgesic modality for the management of mild to moderate pain following periodontal flap surgeries, given the evidence of its established analgesic potency with a minimum incidence of systemic adverse effects.

KEYWORDS

Transdermal patch, diclofenac sodium, periodontal surgery, NuPatch

INTRODUCTION

Periodontal diseases are a group of inflammatory diseases causing alveolar bone loss and eventually leading to loss of teeth. Periodontal surgery is aimed to provide accessibility for proper removal of plaque and calculus and correction of bony irregularities occurring as a result of bone resorption.[1]

Successful periodontal treatment is not only based on correct surgical technique but also on the prevention and management of postoperative pain and complications.[2]

Pain is an unpleasant emotional experience usually initiated by noxious stimulus and transmitted over a specialized neural network to the CNS where it is interpreted as such.. Many factors mayinfluence postoperative pain intensity, such as the nature, duration, and extent of the surgery, and psychological aspects, such as stress and anxiety, over extension of the periodontal pack onto the soft tissue beyond the mucogingival junction or onto the frena and extensive and excessively prolonged exposure and dryness of bone also induce severe pain.[3]

The most widely used therapeutic class of analgesic compounds used to relieve post surgical pain are nonsteroidal anti-inflammatory drugs. One of the most commonly prescribed NSAID is diclofenac sodium, which causes anti-inflammatory, analgesic, and anti-pyretic activity.[4]

Oral Diclofenac:

Diclofenac sodium is a benzene-acetic acid derivative. Diclofenac sodium is available as delayed-release (enteric-coated) tablets for oral administration. The chemical name is 2 [(2,6-dichlorophenyl)amino] benzene acetic acid, monosodium salt.

Mechanism of action

Diclofenac sodium exerts its action via inhibition of prostaglandin synthesis by inhibiting cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2) with relative equipotency.

Transdermal patch:

Transdermal patches are associated with the following exclusive advantages viz, drugs which undergo extensive first pass metabolism, drugs with narrow therapeutic window, and drugs with short half life. eg fenatyl, nitroglyceriene etc.

To the best of our knowledge, there is no study done to compare and evaluate the analgesic efficacy of transdermal patch (NuPatch®) and oral diclofenac sodium during postoperative period in patients of South Indian population undergoing quadrant periodontal flap surgery.

Therefore, the present study was done to compare and evaluate analgesic efficacy of oral diclofenac sodium and transdermal patch (NuPatch®) after periodontal flap surgery in patients of South Indian population

The aims and objectives of the study :

To compare and evaluate the analgesic efficacy of transdermal patch (NuPatch®) and oral diclofenac sodium during postoperative period in patients of South Indian population undergoing quadrant periodontal flap surgery.

To compare and evaluate the patient compliance, tolerance, and adverse reaction following the use of NuPatch® and oral diclofenac sodium among patients of South Indian population.

METHODOLOGY

SOURCE OF DATA:

This study was done on patients who reported to Department of Periodontology, Rajarajeswari Dental College and Hospital, Mysore Road, Bangalore, who required quadrant wise periodontal flap surgery.

METHOD OF COLLECTION OF DATA:

The patients in the age group of 25-50 years having chronic periodontitis who required periodontal flap surgery for two quadrants and more were recruited for the study. A total of 60 surgical sites were divided into two groups as follows:

Group I (30 sites): Diclofenac sodium 50 mg b.i.d was given for three days in patients undergoing flap surgery in one quadrant.

Group II (30 sites): NuPatch® 100 mg once daily was given for three days to be applied on the deltoid region after flap surgery.

INCLUSION CRITERIA:
The patient who are diagnosed with chronic generalized periodontitis required periodontal flap surgery in any of the two quadrants and more are included in the study.

EXCLUSION CRITERIA:
1) The patients with history of systemic diseases.
2) The patients who are undergoing treatment with analgesics or corticosteroids during the trial period.
3) The patients with history or clinical evidence of allergy to diclofenac sodium oral or transdermal patch.
4) The patients who are suffering from peptic ulceration.
5) Pregnancy and lactating mothers.
6) Smokers and alcoholics.

SCREENING OF PATIENTS:
The quadrants which required periodontal flap surgery are confirmed through clinical examination and radiographic evaluation.

Pain Intensity and pain relief were assessed by the patient postoperatively at two, six, and twelve hours on the same day and also on the 2nd and 3rd day using pain score chart consisting of Numerical Rating Scale and Visual Analog Scale by the respective patients.

METHOD OF SAMPLE COLLECTION:
All subjects were explained the needs and objectives of the study. Only those subjects who agreed to participate in the study were included and written informed consent was obtained. The randomization of the study was carried out by using coin toss method.

After successful completion of phase I therapy, flap surgery was performed. Local anesthesia using lidocaine 2% and epinephrine 1:100000 were given prior to the surgical procedure.

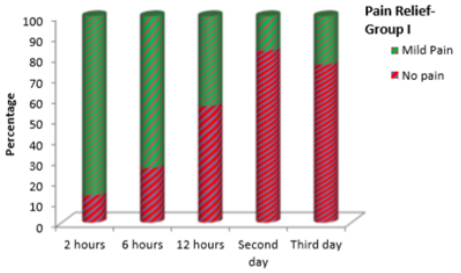
After the completion of each periodontal surgery for each quadrant, routine postoperative instructions were given to the patients along with the advice to take tablet diclofenac sodium 50 mg orally twice daily for three days; and NuPatch® 100 mg one patch per day for three days to be applied to the deltoid region. After each surgery, the subjects were asked to record and report the intensity and pain relief on the pain score chart postoperatively at two, six, and twelve hours and on 2nd and 3rd day which were provided to them. The patients were also advised to record and report the number of diclofenac sodium tablets or patches used and to return the remaining tablets/patches to the doctor on their next visit. The patients were recalled one week postoperatively for suture removal and pain score chart was evaluated. The rescue medication tablets taken, if any, were noted, and the patients were asked if they experienced any adverse effects such as gastric discomfort, nausea, vomiting, gastric acidity or burning sensation, dyspepsia, diarrhea, dizziness and pruritus. The patient's satisfaction with the surgery was assessed as well as their preference of oral diclofenac sodium or NuPatch®. The forms were collected for review on the day that the patients attended to remove the stitches after the second surgery.

RESULTS
In this randomized controlled clinical trial, we compared the analgesic efficacy, patient's compliance, tolerance, and adverse reaction following the use of NuPatch® and oral diclofenac sodium.

Table-1

Pain Relief	2 hours	6 hours	12 hours	Second day	Third day	% change
Group I (n=30)						
• No pain	4(13.3%)	8(26.7%)	17(56.7%)	25(83.3%)	23(76.7%)	63.4%
• Mild Pain	26(86.7%)	22(73.3%)	13(43.3%)	5(16.7%)	7(23.3%)	-63.4%
Group II (n=30)						
• No pain	1(3.3%)	11(36.7%)	22(73.3%)	30(100%)	30(100%)	96.7%
• Mild Pain	29(96.7%)	19(63.3%)	8(26.7%)	0(0%)	0(0%)	-96.7%
P value	0.353	0.405	0.176	0.052+	0.011*	-

Chi-Square test/Fisher Exact test

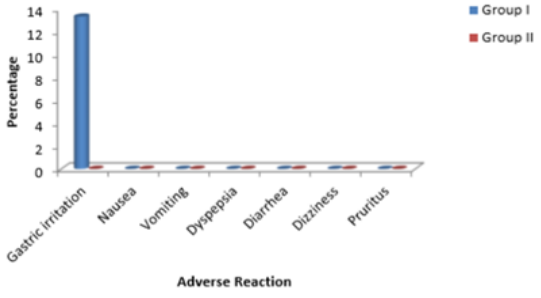


Graph-2

Table- 2

Adverse Reaction	Group I (n=30)	Group II (n=30)	Total (n=60)	P value
Gastric irritation	4(13.3%)	0(0%)	4(6.7%)	0.112
Nausea	0(0%)	0(0%)	0(0%)	1.000
Vomiting	0(0%)	0(0%)	0(0%)	1.000
Dyspepsia	0(0%)	0(0%)	0(0%)	1.000
Diarrhea	0(0%)	0(0%)	0(0%)	1.000
Dizziness	0(0%)	0(0%)	0(0%)	1.000
Pruritus	0(0%)	0(0%)	0(0%)	1.000

Fisher Exact test



Graph- 2

The comparative evaluation of pain relief at different time points was moderately statistically significant on third day with a p value of 0.011 as given in Table 1. The pain relief among the two groups was suggestively statistically significant on second day with a p value of 0.052 as given in Table 1. The pain relief among the two groups was not statistically significant at 2 hours, 6, hours, and 12 hours with a p value of 0.353, 0.405, and 0.176 as given in Table 1, Graph 1.

We found that the gastric irritation was 13.3% among group I patients and 0% in group II patients which is statistically significant with a p value of 0.112. Nausea, vomiting, dyspepsia, diarrhea, dizziness, and pruritus were found to be absent. Table 2, Graph 2

DISCUSSION
The choice of a pain model using open flap debridement surgery was because of its frequent use in periodontal practice, ease of recruiting patients, and the strong probability of a standardized surgical procedure.[5]

The efficacy of NSAIDs in reducing pain is based on their capacity to inhibit cyclo-oxygenases 1 and 2 (COX-1 and COX-2), key enzymes in prostaglandin (PG) biosynthesis.[6]

Transdermal systems for NSAIDs are an innovative delivery mechanism replacing oral and other traditional forms of drug administration.[7]

In our study, diclofenac sodium was used as analgesic, both in its oral and transdermal form, following periodontal flap surgery.

On analyzing the results obtained, we found viz the effect of analgesia, severity and intensity of pain are found to be very effective in both the groups. These findings are similar to those of Funk et al,[8] who reported

that when used in patients with postoperative shoulder pain, both oral and transdermal diclofenac showed similar analgesic efficacy.[9]

In the present study, patients using the transdermal patch reported a statistically and clinically significant reduction in pain scores, similar to those achieved with oral diclofenac sodium tablets.

In our study, on comparative evaluation of pain relief at different time points. The pain relief among the two groups was suggestively statistically significant on second day (p value of 0.052).[10]

In our study, in terms of safety, the transdermal patch was well tolerated and did not cause any local or systemic adverse effects whereas four patients on oral diclofenac therapy reported with gastric irritation.

CONCLUSION

Transdermal diclofenac therapy may have a role to play in postoperative pain, perhaps with an increased strength of the analgesic drug in the transdermal patch. The results of the study, both statistically and clinically showed that transdermal patch showed slightly better pain control in the first 24 hours when compared to the orally administered diclofenac sodium.

The adverse event like gastric irritation was found with oral administration of diclofenac sodium compared with transdermal patch. However, longer clinical trials with a larger sample need to be conducted before the real scope of the transdermal diclofenac patch can be clearly defined.

REFERENCES

1. Elkhatat EI, Elkhatat AE, Azzeghaiby SN, Tarakji B, Beshr K, Mossa H. Clinical and radiographic evaluation of periodontal intrabony defects by open flap surgery alone or in combination with Biocollagen® membrane: A randomized clinical trial. J Int Soc Prev Community Dent. 2015; 5(3): 190–198.
2. Steffens JP, Pochapski MT, Santos FA, and Pilatti GL. Efficacy of Anesthetic Agents to Delay Pain Onset After Periodontal Surgery. Anesth Prog. 2011; 58(2): 57–60.
3. Monheim's local anaesthesia and pain control in dental practice, 7th edition
4. Newman MG, Takei H, Klokkevold PR, Carranza FA. Carraanza's Clinical Periodontology 11th edition.
5. Hungund S, Thakkar R.Effect of pretreatment with ketorolac tromethamine on operative pain during periodontal surgery: A case-control study. J Indian Soc Periodontol. 2011 Jan;15(1):55-8.
6. Steffens JP, Santos FA, Sartori R, Pilatti GL. Preemptive dexamethasone and etoricoxib for pain and discomfort prevention after periodontal surgery: a double-masked, crossover, controlled clinical trial. J Periodontol. 2010;81:1153-1160.
7. Burian M, Tegeder I, Seegel M, Geisslinger G. Peripheral and central antihyperalgesic effects of Diclofenac in a model of human inflammatory pain. Clin Pharmacol Ther. 2003;74:113–20.
8. Funk L, Umaar R, Molajo A. Diclofenac patches for postoperative shoulder pain. Int J Shoulder Surg. 2008;2:47–8. applied Research. Vol. 10, No. 3, 2010.
9. Mazieres B. Topical Ketoprofen Patch. Drugs R D. 2005;6:337–44.
10. Tracy H. Breaking Barriers in Transdermal Drug Delivery. JAMA. 2005;293:2083.