

## The Effect of Diclofenac Mouthwash on Periodontal Postoperative Pain

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### ABSTRACT

**Background:** The need to relieve pain and inflammation after periodontal surgery and the side effects of systemic drugs and advantages of topical drugs, made us to evaluate the effect of Diclofenac mouthwash on periodontal postoperative pain.

**Methods:** In this double-blind, randomized clinical trial study 20 quadrants of 10 patients (n = 20) aged between 22-54 who also acted as their own controls, were treated using Modified Widman Flap procedure in two quadrants of the same jaw with one month interval between the operations.

After the operation in addition to ibuprofen 400 mg, one quadrant randomly received Diclofenac mouthwash (0/01%) for 30 seconds, 4 times a day (for a week) and for the contrary quadrant, ibuprofen and placebo mouthwash was given to be used in the same manner. The patients scored the number of ibuprofen consumption and their pain intensity based on VAS index in a questionnaire in days 1, 2, 3 and the first week after operation. The findings were analysed using two-way ANOVA, t-test and Wilcoxon. P-value less than 0.05 considered to be significant.

**Results:** There was a significant difference between the mean values of pain intensity of two quadrants in four periods (P = 0.031). But, there was no significant difference between the average ibuprofen consumption in two groups (P = 0.51). Postoperative satisfaction was not significantly different in two quadrants (P = 0.059). 60% of patients preferred Diclofenac mouthwash.

**Conclusion:** Diclofenac mouthwash was effective in reducing postoperative periodontal pain but it seems that it isn't enough to control postoperative pain on its own.

**Keywords:** Diclofenac, Mouthwash, Pain, Pain measurement.

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### Introduction

One of the problems in the scope of dentistry is postoperative complications; the most common ones are pain, bleeding, swelling and trismus. Precise assessment and control of these symptoms, especially pain, is very effective to gain patient's comfort.<sup>1</sup>

Pain is a series of unpleasant psycho-physiological experience that often begins with harmful provocations, and then is transferred to the CNS through nerve fibers.<sup>2</sup>

The pain after operation is increased by inflammation combined with primary repair. Use of non steroidal anti-inflammatory drugs (NSAIDs), to control the pain, is more effective than narcotics,

due to blocking the source of pain which in fact, is inflammation.<sup>3</sup>

One of the NSAIDs is Diclofenac, which reduces duration of pain.<sup>4</sup> Like other NSAIDs, Diclofenac inhibits the production of cyclooxygenase enzyme and prevents the arachidonic acid converting to other compounds such as prostaglandins. Analgesic effect of the drug is related to its peripheral anti-inflammatory effect and probably by weakening the pain threshold under the thalamus cortex, then the pain is decreased or interrupted.<sup>5</sup> At high drug concentrations in tissues, it seems that Diclofenac can act as sodium channel blocker which is mediated by topical analgesic.<sup>6</sup>

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According to systemic complications associated with the use of NSAIDs, it is preferred to relieve pain and inflammation by using topical medications.<sup>7</sup> The main benefit of topical application of a drug is the access to more concentration compared to the systemic use and minimizing side-effects. In addition, mucosal surface has usually rich source of blood that causes quick drug transfer in to systemic blood circulation and in most cases prevents the primary metabolism by liver.<sup>8</sup>

Oral rinse, oral suspension and rhombus tablets are the highest dosage forms of topical oral prescriptions.<sup>9</sup> Diclofenac mouthwash can be a good example in this field that by reducing the required dose of ibuprofen reduces its side effects.<sup>10</sup> Therefore, the aim of this study was to assess the effect of diclofenac mouthwash on periodontal postoperative pain.

### Materials and Methods

This study was conducted as an experimental, double-blind, randomized clinical trial. Twenty patients (5 males and 15 females) with the age range between 22 and 54 years, who required MWF (modified Widman flap) operation in two quadrants of their mouth (preferably maxilla) were selected.

The symmetry of two quadrants which required operation were confirmed through clinical examination and radiography and all operations were performed by a certain surgeon. After scaling and root planing and completing the phase I of treatment, the MWF procedure was performed. Each patient was given local anaesthesia using lidocaine 2% and epinephrine 1/80000 in tow operations. After the operation, no periodontal dressing (Co-Pack) was used and it was emphasised that the patients not to use any other drugs to control the pain but ibuprofen 400 mg every 6 hours and to continue to use it as required. Following the operation of one quadrant, in addition to ibuprofen, some patients randomly

received Diclofenac mouthwash to use 4 times a day for 30 seconds each time (for a week) and one month later, in the opposite quadrant which was used as control side, ibuprofen and placebo mouthwash was prescribed to be used in the same order. Patients were advised to use ibuprofen only in case of pain and to record the number of ibuprofen pills taken. Also, they were advised to record their pain scores based on VAS index that is from 0-10 in the questionnaires on the first, second and third days and a week after the operation. The patient's satisfaction with the operation was questioned as well as their preference of mouthwash after using both Diclofenac and placebo mouthwashes. The forms were collected for review on the day that the patients attended to remove the stitches. Average pain intensity and ibuprofen consumption were compared between the study and control quadrants. The patients were required to record their satisfaction of surgery of both quadrants in high, moderate and low levels.

The findings were evaluated and analysed using SPSS, the frequent two-way ANOVA, statistical t-test and Wilcoxon. P-value lesser than 0.05 considered to be significant.

### Results

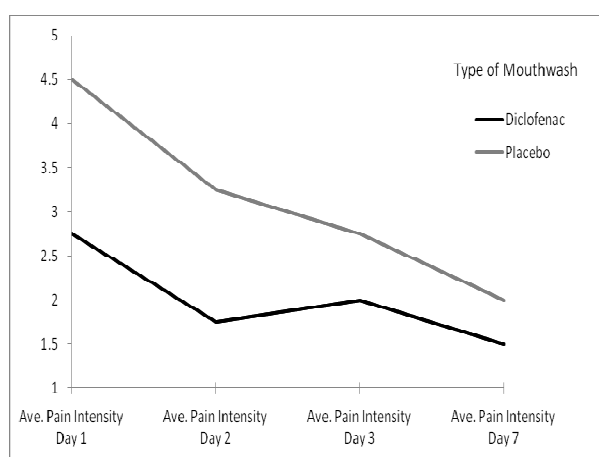
The average pain intensity and the number of ibuprofen pills taken in the first week after operation in both study and control quadrants are presented in Table 1.

The average values of post operative pain intensity in the study and control quadrants in four time periods are presented in Figure 1.

The moderate and high satisfaction rates in the diclofenac consumption were 20% and 80%, respectively. The moderate and high satisfaction rates in the placebo consumption were 45% and 55%, respectively. 60% of patients preferred the diclofenac mouthwash.

**Table 1.** Average pain intensity and number of ibuprofen consumption in both groups a week after operation.

	Diclofenac	Placebo	P-Value
Average Pain Intensity	1.96 ± 2.30	3.07 ± 2.41	0.029
Average Ibuprofen Consumption	3.95 ± 4.27	3.40 ± 3.41	0.51



**Figure 1.** Average pain intensity values in the study and control groups at four time periods after operation.

## Discussion

During this study, the effect of diclofenac mouthwash was assessed on periodontal postoperative pain and the findings indicated that the maximum intensity of pain in both groups was on the first day after the operation and it reached its lowest level on the seventh day. In evaluating the VAS index in four separated time periods after operation (the first, second, third and seventh days), the mean VAS in the study group was lower than that in the control group in each day. Although there was a significant difference on the second day, but no significant differences were observed on other days between the two groups (Figure 1). Mean VAS in study group was significantly lower than that of the control group which indicated the positive effects of Diclofenac mouthwash in reducing the pain. The results of our study were consistent with the results in Tramer and colleagues' study<sup>10</sup> and Weinstein's study.<sup>11</sup>

According to Weinstein<sup>11</sup> study which was conducted in 2001, the average pain intensity in Diclofenac mouthwash consumers was lower than placebo mouthwash consumers in the day of the operation and the day after the periodontal operation at 8 pm. Gingival indices including bleeding and color were significantly improved by Diclofenac mouthwash compared to placebo. According to this study, the diclofenac mouthwash presented a very well effect and safety in treating inflammation associated with oral or periodontal operation.<sup>11</sup>

Also, in the study conducted by Tramer and colleagues in 2001,<sup>10</sup> the periodontal postoperative pain was significantly reduced by using Diclofenac

mouthwash on the day after operation. After a week, the pain was reduced by more than 88%. Burning, redness and edema also showed similar behaviour.

Benefits of our study comparing to the above two studies included assessing pain severity in longer time periods; also, since the study and control groups in this study were the same, destructive impact factors decreased.

In the study conducted by Iraj<sup>4</sup> in 2005 the purpose was to evaluate the effects of 3% Diclofenac in 2.5% hyaluronan base versus 2.5% gel base alone on the pain, duration, and healing time of minor aphthous ulcers. The results showed that diclofenac gel is effective in reducing pain duration of the minor RAS although it is not effective in healing of it.<sup>4</sup>

According to the results obtained, diclofenac mouthwash was effective in reducing the periodontal postoperative pain but since in our study, the Ibuprofen painkiller was also taken, and to ensure that the pain relief was not entirely related to the effects of ibuprofen, repeated two-way ANOVA was performed considering time and group variables and the removal of Ibuprofen which similar results were obtained again. Therefore, Diclofenac mouthwash has relief effect on postoperative pain.

There was not any significant difference observed on the average Ibuprofen consumption between the two groups. This can be due to lack of patients' knowledge about the mouthwashes or the fear of coming pain that made them to take ibuprofen even before the postoperative pain starts. Another reason could be the inadequate impact of the mouthwash to control pain alone that made patients

to take ibuprofen. More detailed studies with larger sample numbers in this context are required.

Among the oral rinses, 60% of patients preferred the diclofenac mouthwash, which could be due to the relief effect of diclofenac mouthwash and the patients' pain palliation in the study group. Also, the satisfaction rate of operation was higher in the Diclofenac mouthwash consumption.

Basically, one of the effective factors in patient satisfaction of dental procedures is the amount of pain that the patient will suffer; therefore, the reason for higher satisfaction of operation in the study group might be due to experiencing less postoperative pain.

Topical application of diclofenac may make higher drug concentration in tissues that is higher than the drug density used systemically; so it is likely that other mechanisms are involved in analgesic effect of diclofenac. In high tissue concentration, it seems that diclofenac could act as sodium channel blockers which mediates the topical analgesia. Behavioural studies on rats suggest that similar concentration of diclofenac may open the sensitive potassium channels to ATP; however, the importance of this mechanism on the skin receptors is more than muscle receptors. Topical application of diclofenac makes the concentration of drug in tissue essentially higher than the concentration needed to inhibit the cyclooxygenase enzyme. Therefore, it is suggested that other mechanisms could also accompany the performance of topical medication.<sup>6</sup> It appears following the use of topical diclofenac, a collection of topical and environmental-systemic effects, causes more reduction in pain.

### Conclusion

It appears that, Diclofenac mouthwash was effective in reducing periodontal postoperative pain. Also, it seems that Diclofenac mouthwash alone is not sufficient to control the pain and should be associated with systemic use of other painkillers such as ibuprofen.

In the analyses by eliminating the effects of ibuprofen, diclofenac mouthwash acted effectively in relieving pain but more researches with a bigger sample size, without taking any other painkillers are required to accredit this result.

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### References

1. Griffin TJ, Cheung WS, Zavras AI, Damoulis PD. Postoperative complications following gingival augmentation procedures. *J Periodontol* 2006; 77(12): 2070-9.
2. Rafati Rahimzadeh M. Pain. 1<sup>st</sup> ed. Babol: Babol University of Medical Sciences Publications; 2001. p. 13, 14, 48, 51.
3. Wetherel J, Richards L, Sambrook P, Townsend G. Management of acute dental pain: a practical approach for primary health care providers. *Australian Prescriber* 2001; 24(6): 144-8.
4. Iraj F, Ghafgasi T, Eslami Samani M, Tashakori M, Siadat AH, Enshaieh S, et al. The efficacy of 3% diclofenac in 2.5% hyaluronan gel base for treatment of recurrent aphthous stomatitis (RAS): A double blind study. *Egyptian Dermatology Online Journal* 2005; 1(2): 4.
5. Trevor A, Katzung B, Masters S. Katzung ' pharmacology: Examination and Broad Review. 9<sup>th</sup> ed. New York: Mc Graw-Hill Medical; 1992. p. 157-160.
6. Dong XD, Svensson P, Cairns BE. The analgesic action of topical diclofenac may be mediated through peripheral NMDA receptor antagonism. *Pain* 2009; 147(1-3): 36-45.
7. Gage TW, Pickett FA. *Mosby's Dental Drug Reference*. 6<sup>th</sup> ed. USA: Mosby; 2003. p. 23, 352.
8. Motlekar NA, Youan BB. The quest for non-invasive delivery of bioactive macromolecules: a focus on heparins. *J Control Release* 2006; 113(2): 91-101.
9. Sveinsson SJ, Holbrook PW. Oral mucosa adhesive ointment containing liposomal corticosteroid. *International Journal of Pharmaceutics* 1993; 95(1-3): 105-9.
10. Tramer M, Bassetti C, Metzler C, Morgantini A. Efficacy and safety of mouthwash diclofenac in oral or periodontal surgery. *Minerva Stomatol* 2001; 50(9-10): 309-14.
11. Weinstein RL. Double blind placebo-controlled study on efficacy, acceptability and safety of mouthwash diclofenac in oral or periodontal postoperative period. *Minerva Stomatol* 2001; 50(9-10): 315-9.