Original Article

DOI: 10.7860/JCDR/2017/22165.9658

Dentistry Section

Effect of Diclofenac Mouthwash on Postoperative Pain after Periodontal Surgery

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ABSTRACT

Introduction: Non-Steroidal AntiInflammatory Drugs (NSAIDs) are widely used drugs for the management of pain. Oral administration of NSAIDs has various adverse events like gastrointestinal alterations - nausea, dyspepsia and gastrointestinal bleeding, hepatotoxicity and blood dyscrasias. As orally given NSAIDs are associated with systemic side effects, it is preferred to alleviate pain and inflammation using topical medication. Thus, recently the focus has been on the development of topical administration of NSAIDs in the form of gels, toothpastes and rinses.

Aim: To determine if diclofenac mouthwash, would be a better alternative to its systemic administration post surgery, in terms of patient acceptance and to minimize the adverse effects of orally administered drug.

Materials and Methods: The study was designed as a single blinded, randomized, controlled clinical trial. Thirty chronic periodontitis patients scheduled for full mouth flap surgeries were randomized to receive either Diclofenac Mouthwash (MW) or Diclofenac Tablets (TB), post surgery. The MW group patients (15) were advised to rinse undiluted 15 ml solution for 30 secs, twice daily for three days. TB group (15) was advised to take 50 mg tablet twice daily for three days. A 10 point Visual Analog Scale (VAS) and Wong Baker Facial Rating Scale (FRS) was recorded to measure the pain perception by the patients. Gingival status was assessed by the Modified Gingival Index (MGI) at Baseline and seventh day. Data pertaining to pain perception were analysed using repeated measures of ANOVA (Analysis of Variance) with post-hoc LSD test.

Results: Intra group comparisons showed a significant reduction in pain, post surgery. Inter group comparisons showed a significant reduction only in the MGI scores of MW group, when compared to TB group. Intergroup comparisons showed no significant reduction in pain scores between both the groups, stating that diclofenac mouthwash is as effective as oral administration.

Conclusion: Diclofenac mouthwash is a better alternative to the systemic administration post surgery, in terms of patient acceptance and to minimize the adverse effects of orally administrated drug.

Keywords: Facial rating scale, Non steroidal anti inflammatory drugs, Visual analog scale

INTRODUCTION

Pain is an unpleasant, sensory and emotional experience associated with tissue injury or infection, resulting in cellular damage [1]. Acute pain is described as sharp stabbing pain, while chronic pain is often dull aching and long standing [2,3]. The major cause for post operative pain is the spread of inflammation or swelling at the post operative site [4].

NSAIDs are widely used drugs for the management of pain. NSAIDs block the cyclo-oxygenase (COX) pathway, responsible for prostaglandin (PG) synthesis, thereby reducing pain. Due to the vasodilating action of PGs there is increased vascular permeability, with extravasation of fluids and white blood cells contributing to inflammation [5].

Oral administration of NSAIDs, have various adverse events like gastrointestinal alterations that includes nausea, dyspepsia and gastrointestinal bleeding. Topical NSAIDs are preferred, to relieve pain and inflammation, over systemic administration, minimizing the side effects [6]. Also, NSAIDs like flurbiprofen, ketorolac and diclofenac, show better penetrability into the gingival tissues due to their lipophilic nature. Thus, recently the focus has been increased on the development of topical administration of NSAIDs in the form of gels, toothpastes and rinses [7].

Diclofenac is a potent anti-inflammatory drug that is well suited for local use in the oral cavity. The drug results in decreased production of PGs hence, reduce inflammation or swelling and pain. It also reduces neutrophil production in vitro, reducing chemotaxis, superoxide and neutral protease production during inflammation [8,9].

It is hypothesized that diclofenac mouthwash would be a better alternative to its systemic administration, in terms of patient acceptance and to minimize the adverse effects of orally administered drug. Thus, the aim of present study was to determine and compare the efficacy of diclofenac mouthwash and its systemic formulation, in pain reduction after periodontal surgery.

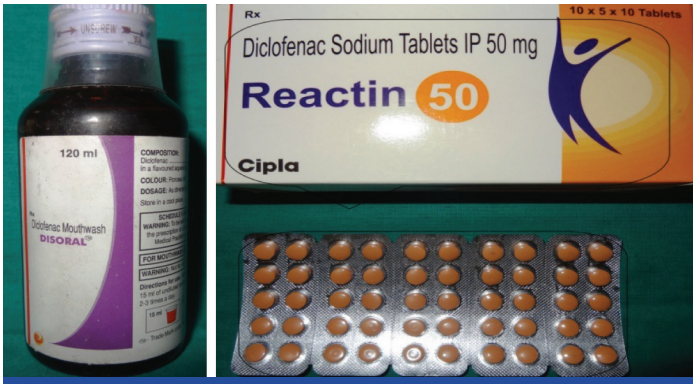
MATERIALS AND METHODS

The study was designed as a single blinded, randomized, controlled clinical trial. This clinical study was carried out in the Department of Periodontics, Sri Sai College of Dental Surgery, Vikarabad and FMS Dental Hospital, Hyderabad, Telangana, India from February 2013 to December 2013. Ethical clearance was obtained from the Institutional Ethics Committee of Sri Sai College of Dental Surgery, Vikarabad (370/sscds/IRB-E/OS/2013). Informed consent was obtained from the patients, prior to the study.

A total of 30 chronic periodontitis patients attending the dental hospital were selected for the study using purposive sampling technique. Systemically healthy patients with the age range of 25-45 years having a minimum of 16 teeth, with at least four posterior teeth having pocket depth of ≥ 5 mm in each quadrant were

included in the study. Patients with the history of intolerance or hypersensitivity to diclofenac, any systemic diseases or condition that affects the oral tissues, pregnant or lactating women, acute gingival or periodontal disease, patients on oral/systemic NSAIDs therapy for the last three months were excluded from the study.

Patients scheduled for full mouth flap surgeries were randomized to receive either TB or MW, post surgery. The study included Group 1- TB (tablet) group and Group 2- MW (mouthwash) group. 0.074% diclofenac mouthwash (Disoral) [Table/Fig-1] was prescribed to the MW group (15) patients and TB group patients (15) were advised to take 50 mg tablet (Reactin) [Table/Fig-2] postoperatively.



[Table/Fig-1]: Diclofenac mouthwash.
[Table/Fig-2]: Diclofenac tablets.

Procedure: To prevent the bias in pain perception, only maxillary quadrants were included in the study. In all the subjects, open flap debridement without regeneration, with modified flap operation by Kirkland was performed. Periodontal dressing was not placed as it might interfere with drug penetration into the gingival tissues. The MW group patients were advised to rinse undiluted 15 ml solution for 30 secs, twice daily for three days. TB group patients (15) were advised to take 50 mg tablet twice daily for three days. A 10 point VAS and Wong Baker FRS was given to the patients in a printed format. Patients were asked to record it themselves on the day of surgery based on their pain perception, in the evening (baseline) and twice daily (morning and evening) on the following seven days. Both VAS and FRS scores were recorded in the study, considering both the subjective and objective evaluation for pain perception. Gingival status was assessed by the MGI [10] at baseline and the seventh day. The investigator who evaluated all the parameters was blinded, ensuring single blindness of the study.

STATISTICAL ANALYSIS

Data pertaining to VAS scores and FRS scores, of baseline to second day were analysed using repeated measures of ANOVA (Analysis of Variance) with post-hoc LSD test. Intergroup comparisons were done with independent sample t-test. The level of significance was taken as $p<0.05$.

RESULTS

The data was collected for seven days. After the second day, the pain intensity was reduced to zero in almost all the patients; hence the analysis was limited to second day. Intra group comparisons in both the groups showed statistically significant reduction in the pain scores from baseline to the second day. Group 1 (TB) showing VAS of p-value= 0.01 and Group 2 (MW) showing p-value=0.008. [Table/Fig-3] Intergroup comparisons of VAS and FRS scores showed no significant differences between both the groups [Table/Fig-4].

DISCUSSION

In this study, diclofenac mouthwash was assessed for post periodontal surgery pain relief and also if it would be a better alternative to its systemic administration. Results indicated that

	Groups		Mean	SD	p-value	Post-hoc test
VAS	1 (TB)	BL	2.75	2.38	0.01*	BL>Day 2
		DAY 1 E	1.50	1.51		
		DAY 2 E	1.13	1.25		
	2 (MW)	BL	2.50	2.00	0.008 *	BL>Day 1,2
		DAY 1 E	2.00	1.69		
		DAY 2 E	1.50	1.20		
FRS	1 (TB)	BL	2.50	1.41	0.279	-
		DAY 1 E	1.25	1.04		
		DAY 2 E	1.25	1.49		
	2 (MW)	BL	2.75	1.83	0.017 *	BL>Day 2
		DAY 1 E	2.00	1.51		
		DAY 2 E	1.75	1.28		

[Table/Fig-3]: Intragroup comparisons of VAS and FRS scores.
Repeated measures of ANOVA (Analysis of Variance) with post-hoc test
VAS: Visual Analog Scale, FRS: Wong Baker Facial rating scale, E: Evening, BL: Baseline, TB: Tablet, MW: Mouthwash

			Group 1		Group 2		p- value
			Mean	SD	Mean	SD	
Scale	VAS	BL	2.75	2.38	2.50	2.00	0.7578
		DAY 1 E	1.50	1.51	2.00	1.69	0.4001
		DAY 2 E	1.13	1.25	1.50	1.20	0.4152
	FRS	BL	2.50	1.41	2.75	1.83	0.6783
		DAY 1 E	1.25	1.04	2.00	1.51	0.1244
		DAY 2 E	1.25	1.49	1.75	1.28	0.3327

[Table/Fig-4]: Intergroup comparisons of Group 1 (TB) and Group 2 (MW).
Independent sample t-test
VAS: Visual Analog Scale, FRS: Wong Baker Facial rating scale, E:Evening, TB: Tablet, MW: Mouthwash, BL: Baseline.

maximum amount of pain in both the groups was on the day of surgery that reached its lowest levels on day seven. The present study has clearly shown that 0.074% diclofenac mouthwash (Disoral) at a dose of 15 ml twice daily, is known to have significant local analgesic effects, and also the effects of diclofenac mouthwash was similar to that of systemic administration, which had been the major point in the study. This further improvise the patient acceptance and minimize the adverse effects of orally administered drug. The newer formulation of 0.074% diclofenac was known to be lipophilic in nature having better solubility and penetrability on contact with oral mucosa [11].

In an Indian study by Agarwal S et al., 0.074% diclofenac mouthwash (Disoral) was introduced and used to determine the local anti-inflammatory and analgesic effect on post periodontal surgery patients [12]. In their study, twenty periodontitis patients were randomized to receive either diclofenac mouthwash or placebo to rinse who were scheduled for full mouth flap surgery. This placebo controlled trial showed significant reduction in the pain scores by diclofenac mouthwash. The results of the present study were in accordance with previous studies conducted by Agarwal S et al, but they did not report the comparison between the systemic and the local administration of diclofenac [12].

In a study conducted by Yaghini J et al., the effect of diclofenac mouthwash on periodontal post operative pain was assessed [13]. Twenty quadrants of 10 patients were treated (as both test and control) with flap surgery, with one month interval between the flap surgeries. One of the two quadrants in each patient was assigned to the test group which was given a diclofenac mouthwash and the control group was given placebo mouthwash. Both the groups were simultaneously advised ibuprofen. They suggested that diclofenac mouthwash alone is not sufficient to control pain, even though it was effective in reducing periodontal postoperative pain. Also, the study could not attribute the analgesic effects to diclofenac mouthwash alone, as all the patients were given ibuprofen systemically.

In another study by Kostrica R et al., the efficacy of 0.074% diclofenac mouthwash in treating radiation induced mucositis of oral cavity was evaluated. In this placebo controlled trial [14], 77 subjects were asked to rinse thrice daily with 15 ml of solution for a minimum of two weeks up to a maximum of six weeks, showing favourable results with diclofenac mouthwash. Another double blind placebo controlled clinical trial confirmed the efficacy, acceptability and safety of 0.074% diclofenac mouthwash, post surgery [15].

The present study is in accordance with the multicenter trial wherein the efficacy of 0.074% diclofenac mouthwash was evaluated in 79 patients. All the parameters of inflammation i.e., pain, redness and oedema showed significant improvement, reporting that the mouthwash can be the choice in the treatment of inflammatory conditions following oral/periodontal surgery [16].

Serafini G et al., in their study compared the efficacy and tolerability of Diclofenac Epolamine (DHEP) mouthwash with diclofenac mouthwash (0.074%). They reported that DHEP is efficient to alleviate pain in the inflammatory conditions of the oral cavity [17].

There were few drawbacks of the present study firstly; 30 different patients of different age groups, with different pain perceptions were included in the study. Secondly, purposive sampling and smaller sample size are further limitations of the study.

CONCLUSION

The study highlights the safe and efficacious nature of diclofenac mouthwash in the treatment of oral/periodontal postoperative pain. It can be concluded that diclofenac mouthwash could be a better alternative to the systemic administration postsurgery, in terms of patient acceptance and to minimize the adverse effects of orally administered drug. Long term clinical trials and comparative studies with systemic administration, with a larger sample size is required to further accredit its usage in regular day to day practice. As diclofenac mouthwash is endowed by good efficacy and ease of use, it can be prescribed post periodontal flap surgery as an alternative to tablet form.

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FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Submission: **Jun 23, 2016**
Date of Peer Review: **Aug 01, 2016**
Date of Acceptance: **Dec 20, 2016**
Date of Publishing: **Apr 01, 2017**