Original Article

Efficacy of 0.074% Diclofenac Mouthwash In Pain Management of Recurrent Aphthous Ulcers

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Abstract

Aim and Objectives:

The aim of this study was to assess the analgesic effect of 0.074% diclofenac mouthwash in patients with aphthous ulcerations.

Materials and Methods:

The study was designed as a single-blind, placebo-controlled clinical trial. 60 patients with aphthous ulcerations were randomized to receive either diclofenac mouthwash or placebo and to rinse with 15 ml of solution thrice daily for a period of 7 days. Descriptive scale was used to assess pain. After the baseline measurement of pain was recorded on the first day of the patient's visit, spontaneous pain was recorded on the 3rd and 7th day of treatment.

Results:

Data obtained were fed to SPSS software version 17 and analyzed statistically using Descriptive analysis, Chi-square test and Paired sample T-test for group comparison. Spontaneous pain was significantly reduced by diclofenac mouthwash. P-value less than 0.05% was considered to be significant with a confidence interval of 95%. There was a significant difference between the mean values of pain intensity between case and placebo (P = 0.00).

Conclusions:

0.074% diclofenac mouthwash is an effective and acceptable product for symptomatic relief in all types of aphthous ulceration.

Keywords:

Aphthous ulcers, benzydamine hydrochloride mouthwash, diclofenac mouth wash, pain,

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Introduction

The oral mucosa is vulnerable to many lesions, one of the common being oral ulcerations. The thin nature of oral mucosa leads to formation of vesicles and bullae which break into ulcers in autoimmune conditions or may be substantially traumatized by sharp teeth, dentures or even hard food. These ulcers may then be secondarily infected by the oral micro flora followed by pain. According to International Association for the Study of Pain (IASP), pain is defined as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."[1] Managing pain is inherent to dental practice. The first objective of treating a patient in any case is alleviation of pain. Following establishment of a precise diagnosis and before initiating a definitive therapy, supportive measurement also plays an important role.

Recurrent aphthous ulcers are common painful mucosal conditions affecting the oral cavity. Despite their high prevalence, etiopathogenesis remains unclear.[2] These present as recurrent, multiple, small, round, or ovoid ulcers, with circumscribed margins, having yellow or gray floors and are surrounded by erythematous haloes, which may present first in childhood or adolescence.[2] Recurrent Aphthous Stomatitis (RAS) has been described under three different clinical variants as classified by Stanley in 1972, Major, Minor and Herpetiform apthous ulcers. There is no definitive curative treatment for RAS. Pain relief of minor lesions can be obtained with use of a topical anesthetic agent or topical diclofenac, an NSAIDS frequently used topically after eye surgery.[3] Treatment strategies must be directed towards providing symptomatic relief by reducing pain, increasing the duration of ulcer-free periods, and accelerating ulcer healing.[4,5] A study was carried out to determine the efficacy of 0.074% diclofenac mouthwash in alleviation of pain related to recurrent aphthous ulcerations.

Method

The study was carried out in the department of Oral Medicine and Radiology in Kantipur Dental College and Research Center, Basundhara Kathmandu from December 2010 to November 2012. This study was designed as a single-blind, placebo-controlled clinical trial. Convenient Sampling was taken for sample size determination. 60 patients with aphthous ulceration were selected randomly. Only patients with diagnosed cases of recurrent aphthous ulcers, who had atleast one episode of apthous ulceration in the past one year, that was severe enough to interfere with normal activities like eating, speaking etc. were included in the study. Exclusion criteria included patients with history of hypersensitivity to active substance diclofenac and benzydamine, pregnant/ lactating women, patients with no predisposing diseases and patients who had taken systemic NSAIDS therapy during the last 3 months of the study. Informed verbal consent was taken from each eligible participant. Willing participants were informed in detail by the investigators about the research project and its consequences. Privacy of the patients was ensured. The patients were randomly allocated in case and control/ placebo groups. Out of 60 patients, 30 were given diclofenac mouthwash (case group) and 30 were given benzydamine (placebo/control group) .The patients were blind to the type of mouthwash they were prescribed. They were instructed to use 15 ml mouthwash for 1 minute thrice daily. Descriptive rating scales (no pain=1, mild=2, moderate=3, severe pain=4) was used to measure the pain intensity. A baseline measurement of pain was performed on the first day of the patient's visit. Spontaneous pain was evaluated at the same time of the day on the 3rd day over telephonic conversation and on the 7th day of the patients visit. Data were fed to SPSS software version 17 and were analyzed statistically using descriptive analysis, Chi-square test and Paired sample T-test for group comparison. P-value less than 0.05% was considered to be significant with a confidence interval of 95%.

Result

Out of 60 patients, 24 were males and 36 were females (Table-1). All the patients completed the study. Most of the patients were aged between 21-30 years (Table -2). Minor aphthous ulcerations were seen in most of the patients, followed by major aphthous ulcerations and there were only two patients with herpetiform type of aphthous ulceration (Graph I). All the patients in case group found the product acceptable (Graph II). On the first day of the patient's visit to the hospital, most of the patients had moderate to severe pain (Graph

III). On the third day, 5 patients using diclofenac mouthwash reported of having no pain, 10 had mild pain and the rest had moderate pain whereas not a single patient in control group reported of complete pain relief on the third day and 4 patients still had severe pain (Graph IV). Likewise, on the 7th day, more patients in case group reported of having complete relief of pain compared to control group (Graph V). Spontaneous pain was significantly reduced by diclofenac mouthwash. There was a significant difference between the mean values of pain intensity between case and placebo (P = 0.00) {Table- 3}.

Table 1:Distribution of Gender

	Frequency(N)	Percentage (%)
Male	24	39.3
Female	36	59

Table 2: Distribution of Age

	Frequency(N)	Percentage (%)
15-20	17	27.9
21-30	35	58.4
<31	8	13.1

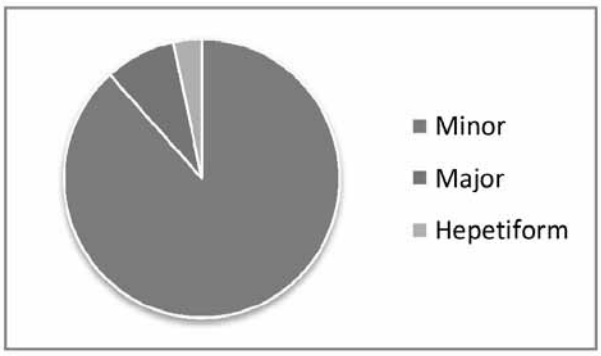
Table 3:Paired sample T test between placebo and control on 3rd and 7th day

	Mean*	Std Deviation	P value**
5th day	2.5333	.74712	.000
7th day	1.2000	.40338	.00

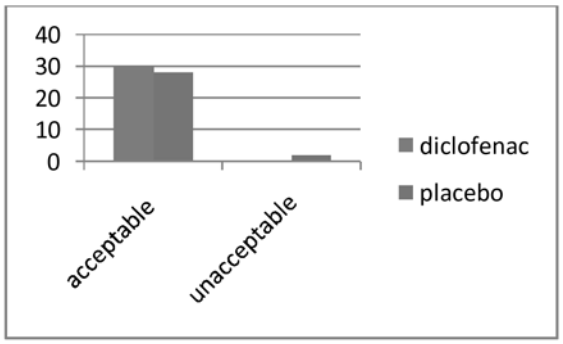
*Mean is in subscale (no pain=1, mild=2, moderate=3, severe pain=4)

**Statistically significant

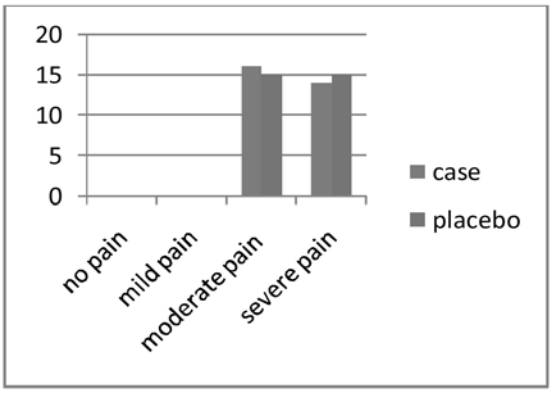
Graph I:Types of Aphthous Ulceration



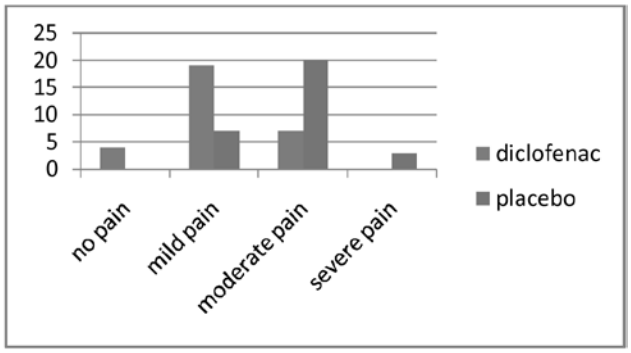
Graph II: Product acceptability



Graph III: Baseline measurement of Pain distribution on the first visit of the patient in OPD



Graph IV: Pain distribution on 3rd day following use of mouthwash in case and placebo



Discussion

Pain is an inevitable and unavoidable feeling that demands immediate therapy. Pain in dental therapy usually involves infiltration and systemic administration of NSAIDS. Clinical trials have shown that NSAIDS are effective in the management of any level of dental pain, whether mild, moderate or severe.[5] There are many side effects associated with systemic NSAIDS, the most common side effect being gastric irritability. Therefore it is preferred to treat the inflammatory condition of oral cavity with local formulations like mouthwash to prevent side effects of systemic NSAIDS.[6] In our study, pain decreased dramatically in most of patients by third day

following use of 0.074% diclofenac mouthwash which is consistent with the study carried out by Iraji F et al in 2005 .[7] Diclofenac is a powerful anti-inflammatory and analgesic drug that is well suited for local use in oral mucosal ulcerations as well as in periodontal and in postoperative period.[8,9,10,11] There are many advantages of diclofenac sodium over other counterparts like no staining on teeth, no damage to teeth enamel, no irritation to oral mucosa, no risk of fungal growth, no drying of salivary glands, no numbness and stinging feelings.[6] 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.[8] RAS is the most common cause of recurring oral ulcers and is essentially diagnosed by exclusion of other diseases. A detailed history and examination by a knowledgeable clinician should distinguish RAS from primary acute lesions such as viral stomatitis or from chronic multiple lesions such as pemphigoid, as well as from other possible causes of recurring ulcers, such as connective tissue disease, drug reactions, and dermatologic disorder.[1]

Use of antimicrobials, steroids, immunomodulators, topical analgesics, anti-inflammatory agents and physical therapy like laser ablation, chemical cauterization and low dense ultrasound are the various modalities proposed for management of aphthous ulcerations.[2,12] It was seen from this study that diclofenac mouthwash was more effective in reducing pain duration of the lesions in aphthous ulceration than compared to benzydamine mouth wash. Pain was drastically reduced in most of the patients using diclofenac mouthwash by seventh day. Few patients in placebo group found the product unacceptable and complained of stinging feeling. However, all the patients in the control group found the product tolerable and acceptable which was consistent with the study done by Agarwal S et al in 2010.[7] Thus 0.074% diclofenac mouthwash can be considered as an acceptable and highly effective adjunctive treatment for reducing pain in recurrent aphthous ulcers.

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References

1. Gleenberg S, Glick M .Burket's Oral Medicine ,Diagnosis and Treatment,10th edition Elsevier,2003:307-39.
2. Preeti L, Magesh K, Rajkumar K, Karthik R. Recurrent aphthous stomatitis.J Oral Maxillofac Pathol. 2011 Sep;15(3):252-6.
3. Saxen MA, Ambrosius WT, Rehemtula al-KF, Eckert GJ. Sustained relief of oral aphthous ulcer pain from topical diclofenac in hyaluronan: a randomized, double-blind clinical trial. Oral Surg Oral Med Oral Pathol Oral Radiol Endod1997;84:356–61.
4. Jurge S, Kuffer R, Scully C, Porter SR. Recurrent aphthous stomatitis. Oral Dis.2006;12:1–21.
5. Scully C, Porter S. Oral mucosal disease: Recurrent aphthous stomatitis. Br J Oral Maxillofac Surg. 2008;46:198–206.
6. Dionne RA, Berthold CW. Therapeutic uses of non-steroidal anti-inflammatory drugs in dentistry. Crit Rev Oral Biol Med 2001;12:315-30.
7. Iraji 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):1-6.
8. Agarwal S, Mathur S, Kothiwale S, Benjamin A. Efficacy and acceptability of 0.074% diclofenac-containing mouthwash after periodontal surgery: a clinical study. Indian J Dent Res. 2010 Jul-Sep;21(3):408-12.
9. 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.
10. 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.
11. Haas DA. An update on analgesics for the management of acute postoperative dental pain. J Can Dent Assoc 2002;68:476-82.
12. Barrons RW. Treatment strategies for recurrent oral aphthous ulcers. Am J Health Syst Pharm 2001; 58 (1): 41-50.