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THE EFFECTIVENESS OF COMBINATION OF BENZOXONIUM CHLORIDE & LIDOCAINE HYDROCHLORIDE FOR TREATING THE GINGIVITIS AND ULCERATION IN HUMAN

Rehab Faisal Ahmed*

ABSTRACT

The oropharyngeal cavity is exposed to a wide variety of germs. Gingivitis is the most inflammation affected the gum, To fight an infection, an effective and fast acting antiseptic is needed, the orofar lozenges is the drug used in this study which give to the patient with gingival inflammation who had attended the dental clinic in faullja city in Anbar city/ Iraq between the April to June 2010. This drug is effective in the treatment of gingivitis through its ability to inhibit the formation of dental plaque. The clinical trial done on 30 patients were submitted to a standardized evaluation protocol. The simplified bleeding index exhibited decline in the gum inflammation in the second week as compared with the first week treatment ($p < 0.01$) and the analysis referred there is significant differences between visits, also the ulcer healing occur in the third day after treatment that effective in reducing pain and decreasing healing time ($p < 0.05$).

Aims of the study: Evaluation of efficacy, safety, and acceptability of orofar drug.

KEY WORDS: Orofar lozenges, Gingivitis, Apthus ulcer.

INTRODUCTION

Orofar has two active substances, benzoxonium chloride and lidocaine hydrochloride. The Benzoxonium chloride has a bacterial activity in vitro against gram-positive and, to a lesser degree, gram-negative organisms. It also has fungicidal and antiviral activity against membrane viruses such as influenza, Para influenza and herpes hominies viruses. The cationic structure of benzoxonium chloride confers high surface activity

and hence good penetration while the lidocaine is a local anesthetic which relieves Pain caused by inflammation.

Several clinical trials have shown that Orofar is effective in the treatment of gingivitis through its ability to inhibit the formation of dental plaque which is the main etiology of gingivitis. The gingivitis is a reversible condition, & if treated, does not always progress to more sever periodontal disease, periodontitis which is a form

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of inflammatory diseases affecting the periodontium and lead to initiate destruction of the gingival tissues and periodontal attachment apparatus^(1, 2). Gingivitis is inflammation of the gingiva that does not result in clinical attachment loss whereas the Periodontitis is inflammation of the gingival and the adjacent attachment apparatus and is characterized by loss of connective tissue attachment and alveolar bone.⁽³⁾

The ulcer affects mucous membranes in the mouth and usually develops on the inner cheeks, gums, lips, and occasionally, the tongue. They may occur singly as aphthous stomatitis lesions or in groups as recurrent aphthous stomatitis (RAS). The sore is most painful during the first 3–4 days and the discomfort gradually diminishes and the sore heals in 10–14 days, usually without scarring.⁽⁴⁾ Before it becomes visible, the sore may produce a tingling or burning sensation and after 6–24 hours the ulcer appears as a round or ovoid and have inflammatory halos surrounded by a red area of inflammation.⁽⁵⁾

The hydrochloride, is a locally-acting with local anesthetic and analgesic properties providing both rapid and extended pain relief as well as a significant anti-inflammatory treatment for the painful inflammatory conditions of the mouth and throat.⁽⁶⁾

PATIENTS AND METHODS

Data for this study were retrieved from the patients with gum inflammation who had attended the dental clinic in faullja city in Anbar city/ Iraq between the Octobers to December 2010 to receive an orofar lozenge for treating gingivitis. Standard examination included history taking with intra-oral examination by periodontal probing, mirror & tooth percussion test were performed. A total of 30 female subjects were tested, all patients suffer from gingivitis with some patients have apthous ulcer.

The orofar tablet contains (1mg) benzoxonium chloride, (1mg) lidocaine hydrochloride and (1g) xylitol in an orange flavored base.

Procedure: the patient instruct to mouth rinse with water to get up from any food debris, removed the calculus by scaling methods, pocket curation after that give instruction the patient to put the lozenges in the oral cavity and allow to dissolve slowly in the mouth (used 1 each 6 hours), follow up the patients (1 week to 2 weeks). The gingival index system according to Loe & Siliness (1963), used to determine the occurrence of gingival inflammation at (4) surfaces of the teeth.

RESULT

The observational study by periodontal probe was performed on thirty patients from the dental clinic that association with gingivitis and some patients have apthous ulceration with gum inflammation. The mean age of the patients with gingivitis was(39,46), in figure (2) Oral health index yielded the following results: Gingival inflammatory response, evaluated by Loe and Silness rates, the simplified bleeding index exhibited decline in the gum inflammation in the second week as compared with the first week treatment ($p < 0.01$). ANOVA analysis referred there is significant differences during the follow up visits for each patient (table 1).

In figure (1) the total of 7 patients have a single, painful apthous ulcer with gingivitis (23%) and 23 patients have gingivitis only (77%) were treated with the orofar lozenge that releases active agents for pain

Reduction and rapid healing of ulcer in the third day after treatment were effective in reducing pain and decreasing healing time ($p < 0.05$) without adverse side effects. The efficacy of treatment with the tablet was documented, as well as patient satisfaction.

Table (1): Show significant differences between patients during three visits.

Gingival inflammation	ANOVA				
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	32760.800	2	16380.400	116.475	0.00
Within Groups	12235.200	87	140.634		
Total	44996.000	89			

Table (2): The mean differences and standard deviation for 3 groups of patients with gingival inflammation.

Gingival inflammation	Descriptives		
	N	Mean	Std. Deviation
Befor treatment	30	49.1333	16.9863
After treatment (1 week)	30	19.9333	11.1909
After treatment (2 week)	30	2.9333	2.8519
Total	90	24.0000	22.4850

*The mean differences is significant at 0.5 level

** (P < 0.01)

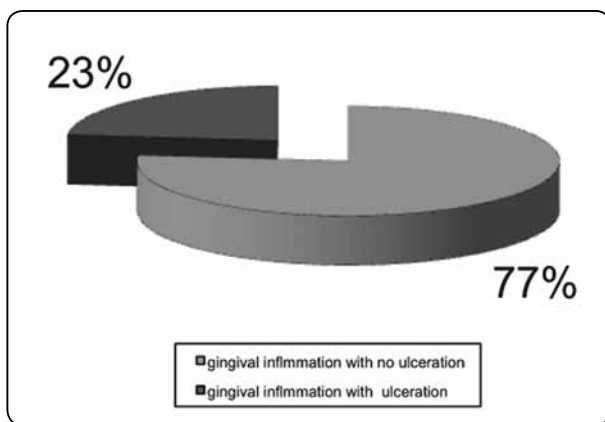


FIG. (1)

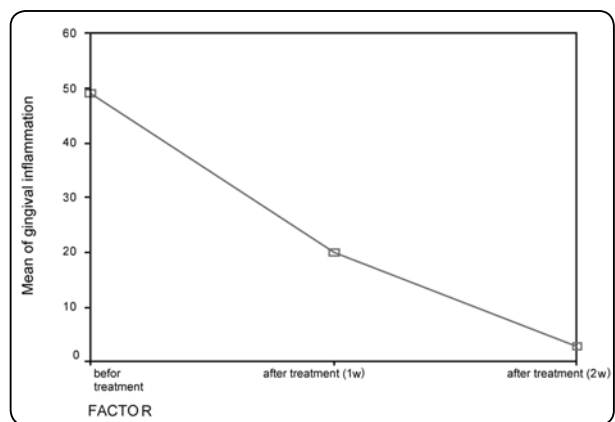


FIG. (2) Effect of orofar drug over Loe and Silness index (gingival index) of patients at three visits treatment. (**: p < 0.01) between the different visits (before treatment, after treatment 1 week, after treatment 2 week).



DISCUSSION

The present invention relates to a slowly erodible lozenge having pleasant organoleptic properties, which means that the user has a pleasant feeling in the mouth when sucking it due to the Xylitol contains which is a five carbon sugar alcohol that looks and tastes like sucrose, further benefits are that it is not metabolized by the cariogenic bacteria and that it has antibacterial properties⁽⁷⁾. When an active substance, especially a pharmaceutically active substance, is added to the composition, a buccal delivery system is obtained that releases the active substance slowly in a controlled manner. The active substance is Benzoxonium chloride (1mg) and Lidocaine hydrochloride (1mg), this substances effective against infection and which causes desensitization (anesthetic) so that is used for the treatment of inflammations and ulceration of the oral cavity⁽⁸⁾.

The Benzoxonium chloride is synthetic quaternary ammonium salt, surfactant, antiseptic, and anti-infective properties and it is used a topical antimicrobial agent in first aid antiseptics.⁽⁹⁾, whereas The hydrochloride, is a locally-acting nonsteroidal anti-inflammatory drug with local anesthetic and analgesic properties providing both rapid and extended pain relief as well as a significant anti-inflammatory treatment for the painful inflammatory conditions of the mouth . It

selectively binds to inflamed tissues (Prostaglandin synthetase inhibitor) and is virtually free of any adverse systemic effects. It may be used alone or as an adjunct to other therapy giving the possibility of increased therapeutic effect with little risk of interaction.⁽¹⁰⁾ This result in agreement with (Mersaco S.A.L, 2001).

Benzoxonium chloride exhibits a broad spectrum of microbiocidal activity against bacteria, fungi, and viruses, it is an allergen and several studies have cast doubt on its reputation for safety and it's still widely used in eyewashes, nasal sprays and mouthwashes⁽¹¹⁾, It is well known that dental plaque is composed of an aggregation of microorganisms deposited on the tooth surfaces and it is able to begin inflammatory changes in the gingival tissues and the mediators of the inflammatory response cause the changes in gingival tissues⁽¹²⁾, So that the mechanism of action of orofar is similar to the chlorohexidine by reducing dental plaque, oral bacteria and improve the inflamed tissue, ulceration healing and bad breath, further benefit the orofar is more effective than chlorohexidine due to the xylitol presentation which is a synergistic effect has been observed to enhance the efficacy⁽¹³⁾. Our result in agreement with (Decker EM, etal. 2008).

The orofar drug is well accepted by the patient due to the simplicity for using the drug with less undesirable side effect (only some patients suffer

from little nausea) in compare with other mouth wash such as chlorhexidine which cause stain on teeth especially on silicate and resin restoration for long period usage, also the prolonged used lead to alter taste sensation can be reversed by using chlorhexidine ⁽¹⁴⁾. But the study occur by Stuart B. Levy, who expressed that the over use of antiseptic and antibacterial agents might lead to an increase in dangerous, resistant strains of bacteria. The theory states that this could cause bacteria to evolve to the point where they are no longer harmed by antiseptics were differ in how easily bacteria are able to find genetic defenses against particular compounds. It can also be dose dependent and the resistance can occur at low doses but not at high; and resistance to one compound can sometimes increase resistance to others. ⁽¹⁵⁾

CONCLUSION

An orofar lozenge made from Benzoxonium chloride, lidocaine hydrochloride and Xylitol which highly effective for healing by killing both gram-positive and gram negative microbes and its inhibitory effect upon the formation of dental plaque due to its cationic structure, orofar has a high degree of surface activity which permits a strong penetrating effect.

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