Comparison of the Effects of Curcumin Mucoadhesive Paste and Local Corticosteroid on the Treatment of Erosive Oral Lichen Planus Lesions

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Abstract: Introduction: Lichen planus is a prevalent chronic mucocutaneous condition, whose exact pathogenesis has not been elucidated yet and its standard treatment at present involves the use of local corticosteroids. Curcumin is a colored material extracted from *Curcuma longa* plant species and is used as an appetizer and for medical purposes. It has anti-inflammatory, antioxidative and anti-cancerous properties. In the present study, the effect of mucoadhesive pastes containing curcumin and local corticosteroids was evaluated for the treatment of erosive lichen planus lesions.

Materials and methods: In this case–control study, 40 patients with oral lichen planus were evaluated. Twenty patients, as the cases, were given mucoadhesive pates containing curcumin and 20 patients, as the controls, were given local corticosteroids. The lesion sizes were recorded in the first session and during the follow-up sessions. Pain severities were measured and recorded using the visual analogue scale (VAS) on the first session and during the follow-up sessions. Data were analyzed with SPSS 19, using Student's t-test and Mann–Whitney test. Data are significant $P < 0.05$.

Results: The lesion sizes, pain severities and changes in classification of the lesions exhibited significant differences at different follow-up sessions (weeks 1, 2, 4, 8 and 12) in the two groups ($P < 0.05$). However, there were no significant differences between the group treated with curcumin and the group treated with local corticosteroids ($P > 0.05$).

Conclusion: Curcumin was effective in the treatment of oral lichen planus lesions and resulted in decreases in lesion sizes, pain and burning sensation severities and changes in classification of the lesions without any complications.

Keywords: Lichen planus■Oral■Curcumin■Anti-inflammatory agents

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INTRODUCTION

Lichen planus is a chronic mucocutaneous condition with an immune system origin. It involves the oral mucosa in 50% of the cases.[1] Lichen planus lesions can appear as keratotic lines and atrophic, erosive and bullous areas. Symptomatic cases require treatment and oral lichen planus is important for dentists from several aspects: 1) It is a chronic condition affecting the patient for several years; 2) It disturbs the patient by pain and burning sensation; 3) If left untreated, it might have a malignant potential; and 4) There is no definitive treatment available.[2] At present the usual treatment modality for lichen planus is the use of steroids, which is in fact a symptomatic treatment and does not lead to complete recovery from the lesions and the lessons recur immediately or after some time subsequent to the discontinuation of the treatment. Therefore, the patients have to use medications for a long time. In addition, such treatment cannot eliminate dysplasia and if dysplasia is present the whole lesion should be removed, which necessitates an extensive surgical procedure in many cases.[3] Use of steroids in the form of different medications, including orabase, has been considered the best treatment modality for lichen planus to date; however, use of steroids should be limited due to the complications of local and systemic steroids, including the potential to induce fungal infections, thinning of the mucosa, the possibility of systemic absorption, irritation of the digestive system and the increased risk for gastric hemorrhage.[4] Therefore, it seems it is necessary to carry out further studies with the use of other anti-inflammatory agents with no or limited side effects. Use of herbal medications has a long history in Iran and the medical use of plants is an age-old tradition in Iran.[5]

Curcumin is extracted from *Curcuma* plant and its anti-inflammatory effects have been shown. Curcumin has a long history as a major factor in medical science and still a number of its properties are used in medicine. Curcumin has been studied in chemistry as a preventive factor for oral cancers. Curcumin and its oily extract are inhibitors for a large number of disease processes due to their anti-inflammatory, antioxidative and antineoplastic properties.[6,7] In the present study the effect of mucoadhesive paste containing curcumin and local steroids on lichen planus lesions was evaluated. If this herbal medicine proves effective in controlling lichen planus, it can be considered an effective alternative treatment without complications to alleviate symptoms and accelerate healing of recurrent lichen planus lesions. In addition, if this herbal medicine proves effective, it can be used to treat other recurrent ulcers

in patients with Behçet's syndrome or oral ulcers in patients with inflammatory bowel conditions (Crohn disease and ulcerative colitis) or in the treatment of mucositis resulting from chemotherapy or radiotherapy in cancer patients, which result in modifications or even interruption of therapeutic regimens due to their severe nature in some cases.

In the present study, the effect of mucoadhesive pastes containing curcumin and local corticosteroids was evaluated for the treatment of erosive lichen planus lesions.

MATERIALS AND METHODS

This prospective clinical trial was performed in Department Of Oral Medicine at Zahedan, Iran, from May 2014 to October 2014, approved by the Ethics Committee of Zahedan University of Medical Sciences and registered at the Iranian Clinical Trials website under the code IRCT2014122020377. Inclusion criteria were biopsy-confirmed OLP in combination with a compatible clinical appearance. Atrophic-erosive lesions were limited to two sites of the oral cavity. Also, patients had received no current treatment with immunomodulatory agents. A one-week washout period was required prior to enrollment if patients were taking immunomodulatory agents.

Exclusion criteria were an inability to undergo oral biopsy for diagnosis, age younger than 18 years,[8] systemic diseases or malignancy, pregnancy, lesion/lesions with dysplasia, history of allergic reaction to corticosteroids or immunomodulatory drugs. Patients with lesions adjacent to an amalgam filling were also excluded from this study. All the patients signed informed consent forms after they received adequate explanations in relation to the necessity of treatment, the study procedures and the possible side effects in order to be included in the study and be followed for 3 months. The age, medical history, symptoms, the duration of affliction with the condition, the type, size and the location of the lesions and the history of mucocutaneous lesions were recorded in the data sheet of each patient. The subjects were matched in terms of age and gender and divided into two groups. The patients in the case group received the prepared mucoadhesive pastes to place on the ulcerated and atrophic areas three times a day after meals. The subjects were followed at 1-, 2-, 4-, 8- and 12-week intervals. In the control group, 20 subjects with oral lichen planus underwent treatment with a 0.1% betamethasone local steroid lotion three times daily and nystatin suspension, with the same follow-ups.

Preparation of mucoadhesive paste containing curcumin

All the procedures to prepare the mucoadhesive paste containing medications were carried out at the Faculty of Pharmaceutics, Tabriz University of Medical Sciences. The curcumin kit and all the necessary items were procured from the Sigma Company. The liquid paraffin and LDPE (low-density polyethylene) and HDPE (high-density polyethylene) were procured from Tabriz Petrochemical Company. First the oral paste containing curcumin extract was prepared and then mixed with a plasty base. The plasty base should be prepared at a ratio of 95% liquid paraffin and 15% polyethylene. To this end, two types of polyethylene were prepared. Two types of HDPE were procured from Tabriz Petrochemical Company. First the liquid paraffin was heated up to 120 °C-130 °C. After weighing the polyethylene, it was added to half of the liquid paraffin and the mix was agitated. After complete dissolution of polyethylene, the remainder of liquid paraffin was incorporated. An important consideration in this respect is the rate of cooling of the mix. A higher rate of cooling the paste will result in a more transparent paste, with a more orderly network and a more stable paste. To this end, two flat metallic containers were prepared. One of the containers was placed in ice water and the other one was placed on it. After the upper plate reached the same temperature as the ice water and complete dissolution of polyethylene in liquid paraffin, it was spread on the metallic plate in a thin layer so that it would cool rapidly. After the paste was formed, it was removed from the metallic plate with the use of a spatula. The procedures were repeated with both LD and HD polyethylene types. The best results were achieved with LD polyethylene.

To prepare the oral paste, pectin, gelatin and sodium carboxymethyl cellulose were mixed at a ratio of 1:1:1. After incorporation of curcumin extract to it, it was mixed with plasty base. In this context, first the gelatin was milled and then all the three materials, pectin, gelatin and sodium carboxymethyl cellulose, were passed through a 180-mm sieve. After they were accurately weighed, they were completely mixed in a mortar.

Before preparation of the mix, all these ingredients were stored at 60 °C for at least 16 h to dry up. Otherwise, due to the hygroscopic nature of the materials used in the formulation, the prepared paste will become hard within the tube after a few weeks. Then the plasty base was accurately weighed ad mixed in a mixer during incorporation of curcumin at 500 rpm. After making sure of homogeneous distribution, the colloidal components were added to the oral paste in a triturated form and mixed until a homogeneous mix was achieved. The paste was prepared in 66 formulations and evaluated in relation to release rates and physical properties. Then the best formulation was selected and placed in 10-g tubes.[6,7]

Table 1 presents the disease signs based on the classification presented by Thongprasom sign score for OLP.[9]

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