

An Evaluation of the Efficacy of Amlexanox and Triamcinolone Topical Paste in the Treatment of Recurrent Aphthous Stomatitis

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ABSTRACT

Introduction: Recurrent aphthous stomatitis (RAS) is a common condition of the mucosa of oral cavity characterized by recurrent attacks of small, round or oval, painful affecting 5-25% of the general population and rarely involves genital region. These lesions occur most commonly on the non-keratinized epithelium of oral cavity and ulcers heal within a period of 10-14 days with characteristic feature of pain causing difficulty on chewing, swallowing, and/or speaking. So, the purpose of present study was to evaluate the effectiveness of Amlexanox 5% and Triamcinolone 0.1% for the treatment of recurrent aphthous ulcers.

Material and Methods: This double-blinded randomized clinical study done in the Department of Oral Medicine And Radiology, Government dental college Srinagar includes 36 patients suffering from recurrent aphthous ulcers aged between 25 and 55 years old and, having minor aphthous ulcers not more than 48 hours old. Group-1 was administered with Triamcinolone 0.1% (Kenocort 0.1% oral paste, Abbott Laboratories Chicago USA), while the group-2 was administered with Amlexanox 5% (Lexanox 5% oral paste, macleods Pharmaceuticals India). The patients used these pastes four times daily for 7 days. The patients were followed at days 0, 3, 5 and 7 and scores were assessed using visual analog scale.

Results: The results showed that in both of the groups, there was reduction of pain and ulcer size significantly at subsequent follow up visits at 3rd, 5th and 7th days ($p < 0.01$). None of the patients reported with pain in both the groups on 7th day of treatment. No significant difference was noted between Triamcinolone and Amlexanox for their efficacy on pain relieving effect as well as on tingling in the present study.

Conclusion: This study showed that both Amlexanox and Triamcinolone are active treatment options for RAS with no statistically significant difference between Amlexanox and Triamcinolone with regards to pain, tingling and ulcer size reduction.

Keywords: Recurrent Aphthous Stomatitis, Triamcinolone, Amlexanox

INTRODUCTION

Recurrent aphthous stomatitis (RAS) is a common condition of the mucosa of oral cavity characterized by recurrent attacks of small, round or oval, painful ulcers that may be single or multiple covered by fibrin exudates.¹ RAS affects 5-25% of the general population and rarely involves genital region.² These lesions occur most commonly on the non-keratinized epithelium of oral cavity and ulcers heal within a period of 10-14 days.³ The etiology of RAS is unknown, however different factors have been shown to predispose RAS that include

nutritional deficiency, systemic diseases, immune disorders, stress, hormonal changes, genetic predisposition, and so on.⁴ The most characteristic of the aphthous ulcerations is pain causing difficulty on chewing, swallowing or speaking.⁵ Histologically, RAS is characterized by varying degrees of neutrophils and mononuclear cell infiltration of the lamina propria with inflammatory process playing an important role in the development of RAS.⁶

A number of different treatments have been used so far in RAS including steroids, analgesics, topical anesthetic agents, antiseptics and anti-inflammatory agents, sucralfate suspension, tetracycline suspension, silver nitrate cauterization, laser ablation, and traditional and home complementary remedies.⁷ Due to side effects following systemic use of some agents including steroids, the topical drug forms such as pastes are preferred.⁸ The aim of current therapeutic approaches should be to relieve pain, alleviate inflammation, decrease functional disability, promoting ulcer healing and reduction of the ulcer duration, frequency of recurrences and an increase in disease-free period.⁹ As such there is no definitive treatment for RAS. Some studies had been conducted on Amlexanox as a treatment for recurrent aphthous ulcers.

So, the purpose of present study was to evaluate the effectiveness of Amlexanox 5% and Triamcinolone 0.1% for the treatment of recurrent aphthous ulcers.

MATERIAL AND METHODS

This double-blinded randomized clinical study was done in the Department of Oral Medicine And Radiology, Government dental college Srinagar. The inclusion criteria include patients suffering from recurrent aphthous ulcers aged between 25 and 55 years old and, having minor aphthous ulcers not more than 48 hours old, not having taken any analgesic, antiseptic or corticosteroid therapy

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prior to the study. Exclusion criteria included patients with systemic diseases, smoking, pregnant or lactating patients, having undergone therapy for aphthous ulcers and denture wearers. Each patient had been informed about the treatment procedure and informed consent was obtained from them. Thirty six patients attending in our department were randomized into two groups equally. Group-1 was administered with Triamcinolone 0.1% (Kenocort 0.1% oral paste, Abbott Laboratories Chicago USA), while the group-2 was administered with Amlexanox 5% (Lexanox 5% oral paste, macleods Pharmaceuticals India). The patients used these pastes four times daily for 7 days. Patients were instructed about the application of drugs and asked not to use any other medications. The diagnosis of RAS was based on the clinical examination. The patients were evaluated by the severity of pain and tingling using a 10-point visual analog scale (VAS: 0-10; 0=no pain or tingling and 10=worst possible pain or tingling). The patients were followed at days 0, 3, 5 and 7 and scores were assessed. The lesion's greatest diameter was registered with measurements carried out by a ruler graded in millimeters.

STATISTICAL ANALYSIS

The data was collected and analyzed using SPSS version 16.8. Results were compared using t-test, Wilcoxon and ANOVA and statistically significant level was accepted at a p value < 0.05.

RESULTS

The subjects comprised of 18 male and 18 female with an average age 35.5 years. There was no side effects reported, that could restrict the progression of treatment by the patients and all participants finished the period of the study. The results showed that in both of the groups, there was reduction of pain and ulcer size significantly at subsequent follow up visits at 3rd, 5th and 7th days ($p < 0.05$). None of the patients reported with pain in both the groups on 7th day of treatment. No significant difference was noted between Triamcinolone and Amlexanox for their efficacy on pain relieving effect as well as on tingling in the present study. The size of the lesion was significantly decreased on follow up visits with no lesion present on 7th day of treatment.

DISCUSSION

RAS is a complicated condition with controversy regarding

the precise etiology that remains still unknown. It occurs with high frequency with worldwide distribution and wide age range of the affected people.¹⁰ This disease has a recurrent character and decreases the quality of life of the patients.¹¹ A number of treatments have been used for improving recurrent aphthous ulcers including both topical as well as systemic like corticosteroids, chlorhexidine, low intensity ultrasound, barrier techniques, laser and other medications like 5% amlexanox.¹² The purpose of this present study was to evaluate the effectiveness of Amlexanox 5% and Triamcinolone 0.1% in the treatment of recurrent aphthous ulcers.

The results showed that in both of the groups, there was reduction of pain and ulcer size significantly at subsequent follow up visits at 3rd, 5th and 7th days ($p < 0.05$). None of the patients reported with pain in both the groups on 7th day of treatment. No significant difference was noted between Triamcinolone and Amlexanox for their efficacy on pain relieving effect as well as on tingling in the present study.

Liu J et al. had reported Amlexanox significantly reducing the severity of pain in aphthous stomatitis.¹³ Khandwala A et al. stated that the patients treated with 5% Amlexanox have greater reduction in ulcer size and pain on days 3 to 5 when compared with vehicle-treated patients.¹⁴ Murray B et al. stated that 5% Amlexanox paste at the onset of prodromal symptoms in the treatment recurrent aphthous stomatitis can prevent progression to ulcer development and significantly reduces symptoms even if ulcers do develop.¹⁵

Currently, Amlexanox is the only clinically proven drug that has been approved by the US FDA for the treatment of aphthous ulcers.¹⁵ The exact mechanism of action is not well determined, however Amlexanox is having anti-allergic and anti-inflammatory properties that may be important in accelerating the healing process.¹⁶ As the side effects of systemic therapy is high, local drug therapy have been widely developed for the treatment of oral lesions. This may be an advantage for Amlexanox paste in the treatment of RAS with very low reported side effects. On the other hand, the long-term use of Triamcinolone may be associated with the development of local candidal infection.

CONCLUSION

In conclusion this study showed that both Amlexanox and Triamcinolone are active treatment options for RAS.

There was no statistically significant difference between Amlexanox and Triamcinolone for RAS treatment, regarding pain, tingling and ulcer size reduction.

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