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Original Research

Comparative evaluation of efficacy of topical 5% amlexanox oral paste and 0.1% triamcinolone acetonide oral paste in the treatment of oral ulcers

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ABSTRACT

Background: Recurrent aphthous stomatitis (RAS) is a common condition of the mucosa of oral cavity. The present study was aimed to compare efficacy of triamcinolone acetonide 0.1% and 5% amlexanox in management of recurrent aphthous stomatitis (RAS). **Materials & Methods:** The present study was conducted on 48 patients with history of recurrent aphthous stomatitis. Patients were divided into 2 groups of 24 each. Group I was prescribed topical application of 0.1% triamcinolone acetonide and group II was given topical application of 5% amlexanox. Both were to be applied on ulcers three times a day for 5 minutes. Patients were evaluated on 1st day, 4th day and 7th day for pain, size and erythema. **Results:** Group I had 10 males and 14 females and group II had 12 males and 12 females. The difference was non-significant ($P > 0.05$). The mean VAS score in group I on 1st day was 5.2, in group II was 6.4. on 4th day it was 3.2 in group I and 3.6 in group II. It was 1.4 in group I and 2.0 in group II on 7th day. The difference was significant ($P < 0.05$). The mean size of ulcer on 1st day was 4.3 mm and 4.8 mm in group I and group II respectively. It was 3.4 mm and 3.2 mm on 4th day in group I and group II respectively. It was 2.6 mm and 1.8 mm on 7th day in group I and group II respectively. The difference was non-significant ($P > 0.05$). On 1st day, there was severe erythema seen in both groups. on 7th day, it was mild in both groups. **Conclusion:** Both 5% amlexanox and 0.1% triamcinolone acetonide found to be effective in reducing size, erythema and pain in cases of aphthous ulcers.

Key words: Amlexanox, Pain, Triamcinolone acetonide

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INTRODUCTION

Oral 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. Aphthous Ulcers are canker sores which vary in size from 1-2 mm to 1 cm. They may occur alone or in groups anywhere on the mucous membranes in the mouth including the gums, tongue and throat.¹ RAS affects 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. Oral ulcerations, most often recurrent aphthous stomatitis (RAS), have plagued mankind since antiquity and perplexed clinicians since the beginnings of organized

medicines.² Of the three subtypes of RAS, RAS major (MaRAS), RAS herpetiform (He RAS), and RAS minor (MiRAS), the most common MiRAS accounts for 75%–85%. Aphthous ulcers first appear when a person is under physical or emotional stress, for example, trauma from dental procedures, aggressive tooth cleaning or accidentally biting your tongue or cheek, head colds, a deficiency in iron, folic acid, or vitamin B₁₂, menstrual periods and other hormonal changes, food allergies and sodium lauryl sulfate found in toothpaste may be causes.³ Amlexanox is a topical anti-inflammatory, antiallergic drug. It has been developed as a 5% topical oral paste for the treatment of patients with RAS. A topical steroid such as triamcinolone acetonide 0.1% is effective in cases of aphthous ulcers.⁴ The present study was aimed to compare

efficacy of triamcinolone acetonide 0.1% and 5% amlexanox in management of recurrent aphthous stomatitis (RAS).

MATERIALS & METHODS

The present study was conducted in the department of Oral Medicine & Radiology. It comprised of 48 patients with history of recurrent aphthous stomatitis minor with at least two previous episodes with healing within 7 days. All were informed regarding the study and written consent was obtained. Ethical clearance was taken prior to the study. Patient information such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 24 each. Group I was prescribed topical application of 0.1%

triamcinolone acetonide and groupie was given topical application of 5% amlexanox. Both were to be applied on ulcers three times a day for 5 minutes. Patients were evaluated on 1st day, 4th day and 7th day for pain, size and erythema. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table II, graph I shows that mean VAS score in group I on 1st day was 5.2, in group II was 6.4. on 4th day it was 3.2 in group I and 3.6 in group II. It was 1.4 in group I and 2.0 in group II on 7th day. The difference was significant (P< 0.05).

Graph I Assessment of pain (VAS) in both groups

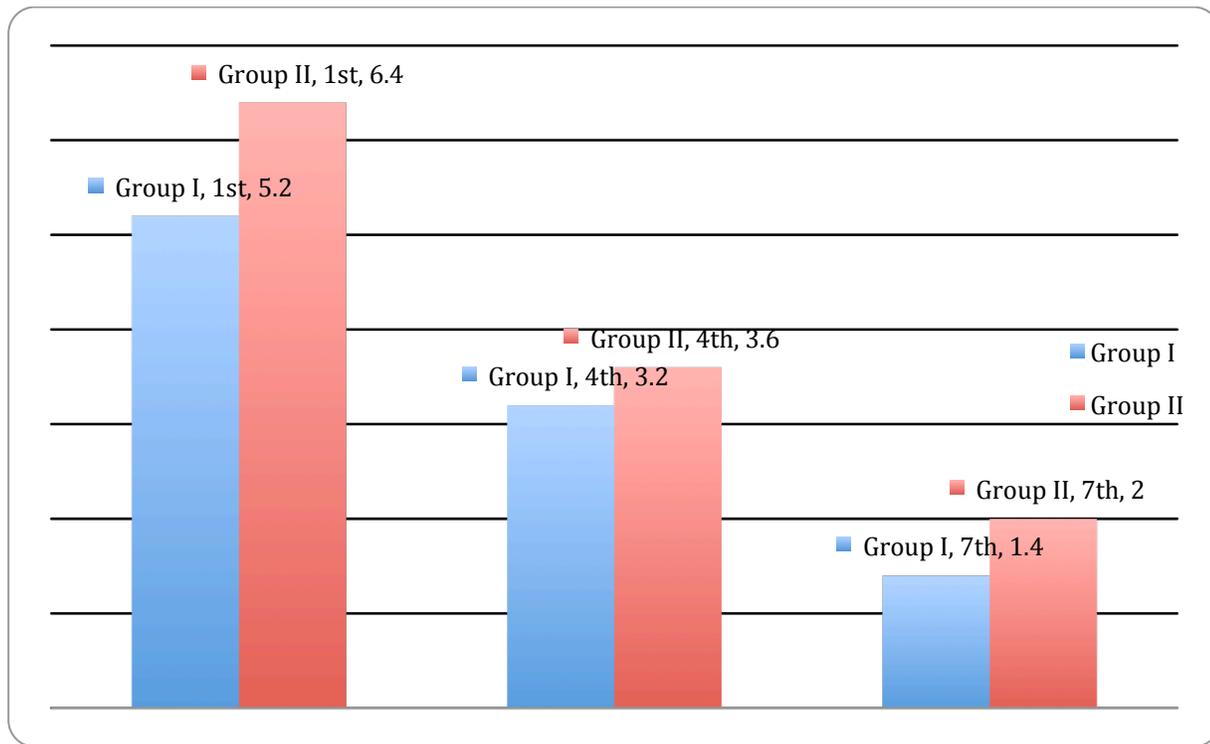


Table I Distribution of patients

Groups	Group I	Group II
Drug	0.1% triamcinolone acetonide	5% amlexanox
Males	10	12
Females	14	12

Table I shows that group I had 10 males and 14 females and group II had 12 males and 12 females. The difference was non-significant (P> 0.05).

Table II Assessment of pain (VAS) in both groups

Day	Group I	Group II	P value
1 st	5.2	6.4	0.04
4 th	3.2	3.6	0.01
7 th	1.4	2.0	0.02

Graph II shows that mean size of ulcer on 1st day was 4.3 mm and 4.8 mm in group I and group II respectively. It was 3.4 mm and 3.2 mm on 4th day in group I and group II respectively. It was 2.6 mm and 1.8 mm on 7th day in group I and group II respectively. The difference was non-significant (P> 0.05).

Graph II Assessment of size in both groups

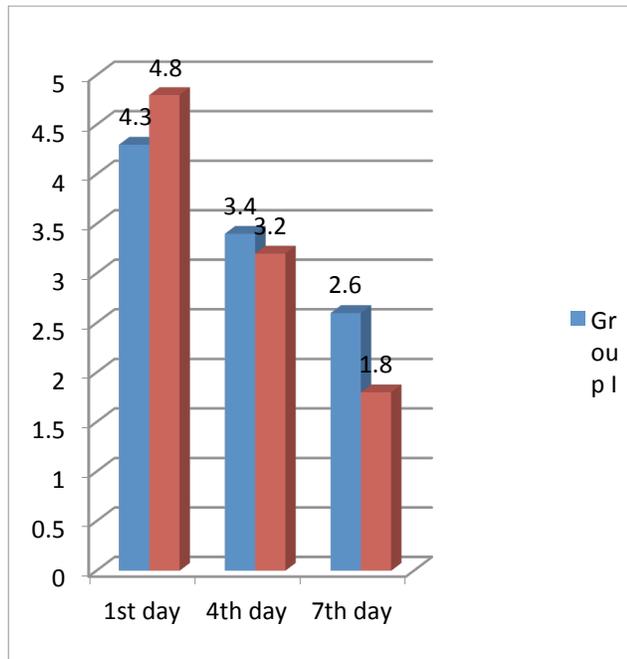


Table III Assessment of erythema in both groups

Day	Group I	Group II
1 st	Severe	Severe
4 th	Mild	Moderate
7 th	Mild	Mild

Table III shows that on 1st day, there was severe erythema seen in both groups. on 7th day, it was mild in both groups.

DISCUSSION

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. Definitive etiology is unknown, the diagnosis is entirely based on history and clinical criteria and no laboratory procedures exist to confirm the diagnosis. The comorbid factors strongly associated with RAS include trauma, genetic predisposition, allergy, T cell mediated immunological dysfunction, nutritional deficiency hormones, psychological stress, and infections ranging from viral to bacterial.⁶

In present study, group I was prescribed topical application of 0.1% triamcinolone acetonide and group II was given topical application of 5% amlexanox. Both were to be applied on ulcers three times a day for 5 minutes. We observed that mean VAS score in group I on 1st day was 5.2, in group II was 6.4. on 4th day it was 3.2 in group I and 3.6 in group II. It was 1.4 in group I and 2.0 in group II on 7th day. The difference was significant (P < 0.05).

Shrivastava et al⁷ found that ninety percent of controls when compared with 65% of the participants in the amlexanox group showed complete improvement of peri-ulcer erythema. Pain reduction was marked from the first to the fifth day. The control participants showed 90% reduction in pain in comparison to 70% in the amlexanox group. The mean ulcer size was shown to reduce from the first to fifth day in both groups. Completely healed ulcers were seen in 70% of the participants in the control group compared with 75% of the participants in the amlexanox group.

We found that mean size of ulcer on 1st day was 4.3 mm and 4.8 mm in group I and group II respectively. It was 3.4 mm and 3.2 mm on 4th day in group I and group II respectively. It was 2.6 mm and 1.8 mm on 7th day in group I and group II respectively. The difference was non-significant (P > 0.05).

Rodriguez et al⁸ found 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. 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.

We found that on 1st day, there was severe erythema seen in both groups. on 7th day, it was mild in both groups. Katti et al.⁹ 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. Robert et al¹⁰. had reported Amlexanox significantly reducing the severity of pain in aphthous stomatitis.

CONCLUSION

Both 5% amlexanox and 0.1% triamcinolone acetonide found to be effective in reducing size, erythema and pain in cases of aphthous ulcers.

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