

Comparative Effectiveness of Topical Triamcinolone in Orabase in Treating Recurrent Aphthous Stomatitis: A Comparative Study Between Diabetic and Non-Diabetic Patients

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Abstract

Background: Recurrent aphthous stomatitis (RAS), commonly referred as canker sores and is one of the most prevalent oral conditions affecting general and specific populations. It manifests as small, painful, round or ovoid ulcers with yellowish-white pseudomembranous center and erythematous margins primarily involving non-keratinized mucosa of the oral cavity.

Objectives: This study aimed to assess the clinical efficacy of topical triamcinolone in orabase for the management of recurrent aphthous stomatitis (RAS) in patients with type 2 diabetes mellitus compared with non-diabetic individuals.

Materials and Methods: A prospective comparative study was conducted on 130 patients clinically diagnosed with minor or major RAS, including 65 diabetic patients (cases) and 65 non-diabetic individuals (controls). All participants received topical triamcinolone acetonide in orabase, applied directly to the ulcer three times daily for seven days. Ulcer size was measured using a periodontal probe, pain intensity was assessed on a 0–10 Visual Analogue Scale (VAS), and healing duration (days to complete epithelialization) was recorded. Recurrence of ulcers was evaluated after a three-month follow-up. Data was analyzed using SPSS version 23.0, applying independent t-tests and chi-square tests, with $p < 0.05$ considered statistically significant.

Result: The mean age of participants was 36.7 ± 9.7 years, with a female predominance. Both groups showed significant improvement following treatment; however, diabetic patients demonstrated slower ulcer size reduction (0.9 ± 0.3 mm vs. 0.4 ± 0.2 mm, $p = 0.001$), higher mean VAS score at day 7 (1.4 ± 0.4 vs. 0.6 ± 0.5 , $p < 0.001$), and higher recurrence rate at three months (42% vs. 20%, $p = 0.01$) compared to non-diabetic individuals. Adverse effects were minimal.

Conclusions: Topical triamcinolone in orabase significantly improved ulcer healing, reduced pain, and minimized recurrence in both diabetic and non-diabetic RAS patients, though diabetic patients exhibited slower healing and higher recurrence rates.

Keywords: *Triamcinolone acetonide, Type 2 diabetes mellitus, Recurrent aphthous stomatitis, Pain assessment, Wound healing.*

Introduction

Recurrent aphthous stomatitis (RAS), commonly referred as canker sores and is one of the most prevalent oral conditions affecting general and specific populations. It manifests as small, painful, round or ovoid ulcers with yellowish-white pseudomembranous center and erythem-

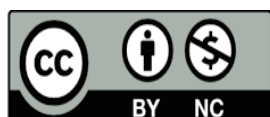
atous margins primarily involving non-keratinized mucosa of the oral cavity. The sites include buccal and labial mucosa, floor of the mouth and ventral surface of the tongue. RAS, being a benign and self-limiting in nature significantly affect the quality of life due to discomfort and pain during swallowing and speech and also has the potential to recur.^{1,2}

The global prevalence of RAS is ranging from 5% to 25%. The variations are based on geographic, socioeconomic and racial factors. The most commonly affected age of RAS is between 10-40 years and women are more dominant than men.^{3,4,5} The etiology of RAS remain unclear and elusive, multifactorial hypothesis involving genetic predisposition, immune dysregulation, stress, microbial imbalances, nutritional deficiencies, hormonal influences and systemic disease have been considered as the predisposing factors of RAS.^{4,6}

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Diabetes mellitus is a chronic metabolic disorder resulting from defect in insulin secretion, action or both and cause hyperglycemia. It has been found that diabetes mellitus affect oral health system that may result in higher incidence of dental caries, periodontal disease, fungal infections, delayed wound healing and salivary gland dysfunction. Diabetes mellitus results in hyperglycemia which alters the immune response and cytokine profiles that may exacerbate oral mucosal conditions such as RAS. The altered immune response results in delayed wound healing and impaired inflammatory response in diabetic patients that may affect the natural history and the clinical course of RAS and results in more severe symptoms and prolonged duration.^{3,7,8}

Triamcinolone is a medium potency corticosteroid with anti-inflammatory, immunosuppressive and anti-proliferative characteristics. The mechanism of action of triamcinolone is the inhibition of phospholipase A2, thereby preventing the pro-inflammatory mediators synthesis such as prostaglandins and leukotrienes. Moreover, it down-regulates the adhesion molecules and pro-inflammatory cytokines expression that results in resolution of inflammation and enhance epithelial regeneration.^{1,9}

The rationale of this case-control study that diabetic patients often present with more persistent and painful ulcers that are less responsive to standard therapeutic regimen. Moreover, triamcinolone which is applied locally is a corticosteroid that may behave differently in the context of diabetes mellitus which require focused investigation. This study helps in intending bridge this knowledge gap by evaluating and comparing the therapeutic outcomes of triamcinolone in diabetic and non-diabetic individuals with recurrent aphthous stomatitis.

Despite the widespread use of triamcinolone for managing RAS, limited evidence exist regarding the clinical effectiveness particularly in diabetic patients. Given the altered wound healing and immune response in diabetic patients, the therapeutic impact of triamcinolone in this population is necessary. Triamcinolone is widely used but their efficacy in diabetic patients is underexplored. Therefore, the aim of this study was to determine the clinical effectiveness of topical triamcinolone in orabase in managing recurrent aphthous stomatitis amongst type 2 diabetic patients and to compare the clinical outcomes with non-diabetic patients.

Material and Methods

This prospective, non-randomized comparative study was conducted in the Department of Oral and Maxillofacial Surgery, Lady Reading Hospital, Peshawar, from June 2023 to June 2024. Ethical approval was obtained from the Institutional Review Board before the commencement of the study (ERC no: **GU/Ethical Committ/2023/23**), and written informed consent was taken from all participants. A total of 130 patients with clinically diagnosed recurrent aphthous stomatitis (RAS) were enrolled according to the inclusion and

exclusion criteria. Participants were divided into two comparison groups based on diabetic status: Group A comprised 65 diabetic patients with RAS, while Group B included 65 non-diabetic patients with RAS. Diabetes mellitus was confirmed from recent medical records and HbA1c measurement, with values $\geq 6.5\%$ considered diagnostic.

RAS was defined as three or more episodes of clinically diagnosed aphthous ulcers per year. Healing duration was defined as the number of days from treatment initiation until complete epithelialization without pain. Pain intensity was measured using a 0–10 Visual Analogue Scale (VAS), and ulcer size was recorded as the largest diameter in millimeters using a periodontal probe. Patients aged 18–60 years with clinically confirmed RAS (minor or major) and at least three episodes per year were included. Group A consisted of type 2 diabetic patients for at least six months on stable medication with $\text{HbA1c} \leq 9\%$, whereas Group B included non-diabetic patients with no systemic illness and normal HbA1c levels. Patients with herpetiform ulcers, other oral mucosal diseases (such as pemphigus vulgaris or lichen planus), those using systemic corticosteroids or immunosuppressants, pregnant or lactating women, patients with uncontrolled diabetes ($\text{HbA1c} > 9\%$), a history of tuberculosis, recent drug use for RAS (within one month), uncontrolled hypertension, smoking, or known allergy to triamcinolone were excluded.

All participants received topical triamcinolone acetonide in orabase, applied directly to the ulcer three times daily after meals, and were instructed to avoid eating or drinking for at least 30 minutes after application. Treatment continued for one week with identical formulation and instructions for both groups. The primary outcome was the change in ulcer size from baseline to one week, while secondary outcomes included pain score, healing duration (in days), and recurrence rate at three months. Pain and ulcer size were recorded at baseline and after one week, while recurrence was assessed after three months. All clinical assessments were performed by two examiners who blinded to the diabetic status of the participants to minimize observer bias. The sample size was calculated using the WHO formula for comparison of two independent proportions, with $p_1 = 0.25$, $p_2 = 0.10$ (prevalence in diabetics) and $p_1 = 0.25$, $p_2 = 0.10$ (prevalence in non-diabetics), representing an absolute difference of 15%. With a two-sided α of 0.05 and 80% power, the required sample size was approximately 97 participants per group (total ≈ 194). Due to logistic constraints, 65 participants were included in each group (total $n = 130$), providing approximately 63.1% power to detect the same difference at a 5% significance level.

Data was analyzed using SPSS version 23.0. Continuous variables were expressed as mean $\pm$ standard deviation (SD) or median with interquartile range (IQR) depending on data distribution, while categori-

cal variables were presented as frequencies and percentages. Normality was assessed using the Shapiro–Wilk test. Categorical variables were analyzed using the chi-square test or Fisher’s exact test where applicable, and a p -value ≤ 0.05 was considered statistically significant.

Results

The overall mean age of participants was 36.7 ± 9.7 years, with 46.2% males and 53.8% females. A significant reduction in ulcer size was observed in both groups by day 7; however, diabetic patients demonstrated slower healing compared to non-diabetic individuals. The mean ulcer size on day 7 was 0.9 mm in diabetics and 0.4 mm in non-diabetics ($p = 0.001$). Similarly, pain scores (VAS) showed a significant reduction in both groups, yet remained higher among diabetic patients at day 7 (1.4 vs. 0.6, $p < 0.001$). The mean healing duration was significantly longer in the diabetic group (6.1 ± 1.3 days) compared to the non-diabetic group (4.9 ± 1.4 days, $p < 0.001$). At the 3-month follow-up, recurrence of RAS was observed in 42% of diabetic patients versus 20% of non-diabetic patients ($p = 0.01$).

Discussion

This study evaluates the clinical effectiveness of topical triamcinolone in the management of recurrent aphthous stomatitis amongst diabetic patients and non-diabetic patients. The findings of this study revealed that triamcinolone in orabase significantly reduced

ulcer size, severity of pain and healing duration in both groups with slightly delayed healing response from diabetic patients. The healing outcomes differ significantly due to underlying systemic factors in diabetic patient such impaired immunity and delayed wound repair. RAS is a recurring oral condition and attention must be paid to the disease’s pathogenesis, the therapeutic effects of medications and their side effects. Various treatment options exist for RAS be-

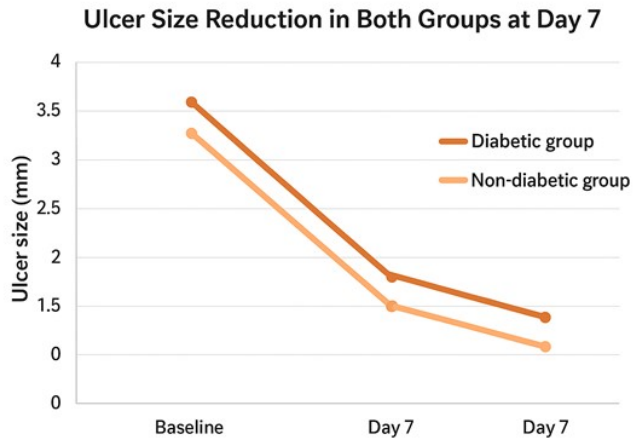


Figure 1: Comparison of ulcer size reduction between diabetic and non-diabetic patients at baseline and day 7. Both groups demonstrated a significant decrease in ulcer size by day 7; however, the diabetic group showed a slower rate of healing compared to the non-diabetic group.

Table 1 presents the detailed clinical outcomes at baseline and at day 7, while **Figure 1** illustrates the reduction in ulcer size in both groups at day 7.

Clinical Parameters		Diabetic group	Non-diabetic group	P value
Ulcer size (mm)	Baseline	3.5±0.49	3.3±0.57	0.001
	07 days	0.9±0.3	0.4±0.2	
VAS Score	Baseline	3.6±0.6	3.4±0.8	<0.001
	07 days	1.4±0.4	0.6±0.5	
Healing Duration (days)	Baseline			<0.001
	07 days	6.1±1.3	4.9±1.4	
Recurrence (3 months)		42 %	20%	0.01

cause the cause is unclear and most treatments are symptomatic treatment with no definitive cure available.¹ The delayed healing in diabetic patients in this study is in alignment with study of Fainsod-Levi et al¹⁰, in which they evaluate that hyperglycemia impairs neutrophil function and angiogenesis which are the two important processes in wound healing. Greenhalgh et al¹¹ demonstrate the diabetes mellitus disrupt normal inflammatory responses and prolong tissue damage and delayed epithelial regeneration. These research studies provide a valid reason for delayed wound healing in the diabetic patients.

The percentage of incidence is higher in females than males. There might be a higher prevalence of RAS in both children and adults among females.¹² The other research found that males were more common than females.⁹ This study showed that females outnumbered males.

Our study demonstrates that pain was reduced in diabetic and healthy patients and the pain was statistically significant. Mimura et al¹¹ showed reduction in pain after one week which is in consistence with our study. This study was in agreement with our study. In other study pain reduction was also seen but that was not statistically significant¹⁴ which opposes this study. The pain reduction in diabetic patients was slower than non-diabetic patients. According to Pop-Busui et al¹⁸ diabetic patients exhibit impaired nociceptive response which results in complicating the assessment of subjective symptoms like pain.

This research revealed a decrease in the size of ulcers and the findings of this study align with study conducted by Lynde et al.¹⁵ Meng et al¹⁶ established a criteria for ulcer size and demonstrate a reduction in size using various pastes.

The current research indicated that the length of time the ulcer altered its size was nearly identical in both diabetic and healthy individuals and was statistically significant. This differs from the findings of Mimura et al.¹³ Trinchieri et al¹⁷ revealed a strong reduction in size with shorter duration which is in agreement with this study.

The findings of this study indicate a higher recurrence rate of RAS among diabetic over a 3 months follow up period. This pattern corroborates the findings of Rohani, who in his study revealed increase frequency of RAS in diabetic individuals.¹⁹ The recurrence may be

poor glycemic control, immunosuppression and chronic low grade inflammation.

The strength of this study lies in its comparative design, which allowed for controlled evaluation of diabetic status affecting treatment response. The use of standardized ulcer size measurements and Vas scoring added to the objectivity of our findings. The three months follow up period provide an insight into the recurrence patterns that are often overlooked in short term trials.

The limitation of this study was small sample size, single centered design as well as the study type. Larger multi-centered studies would confirm the findings of this study in broader aspect. Stress factor have some rule in RAS^{4,6,7} which was not excluded in this study. Another limitation of this study is the subjective nature of the pain evaluation as depends on individual perceptions and may vary due to psychological or neurological factors. Future studies should explore adjunctive or alternative treatment options for RAS in diabetic patients. Tacrolimus, amlexanox and laser therapy have shown a promising results in recent trials.²⁰⁻²¹ Comparative evaluation these treatment modalities with triamcinolone and particularly in systemically compromised patients would offer a more valuable insights.

The implications of this study in the context would be that triamcinolone is effective for RAS in diabetics but the healing is delayed. Adjunctive antifungal may be required. Strict glycemic control and oral hygiene is mandatory. Routine follow up is necessary to avoid any recurrence. The findings of this study support the clinical utility of triamcinolone in managing RAS with careful monitoring is recommended in diabetic patients.

Conclusion

The findings of this study concluded that topical triamcinolone in orabase revealed a significant clinical impact on reducing ulcer size, pain and enhance healing in both diabetic and non-diabetic patients with RAS but diabetic patients showed a slower healing response compared to non-diabetic. Diabetes mellitus patients showed a higher recurrence rate of RAS after 3 months of follow up period than non-diabetic individuals.

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Author Contributions

1. **Mansoor Ahmad Miani:** Conception and design of study.
2. **Muhammad Shahid Khan Khattak:** Data collection and data analysis.
3. **Mahrukh Nisar:** Data collection and literature review.
4. **Riaz Khan:** literature review and Manuscript drafting.
5. **Irfan Khan:** Data analysis, interpretation, and literature review.
6. **Manzoor Khan:** Manuscript drafting, editing, and final approval of the manuscript.