Triamcinolone Acetonide, Amlexanox and Tacrolimus as topical application for oral erosive lichen planus: Clinical effectiveness and evaluation

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KEYWORDS
Amlexanox Paste, Triamcinolone Acetonide paste, Tacrolimus Paste, Oral Lichen Planus

ABSTRACT
Aim: Oral Lichen Planus (OLP), first described by Wilson E. in 1869, is a prevalent oral mucosal disease affecting the global population. The study evaluates and compares the clinical efficacy of various topical applications: Triamcinolone Acetonide 0.1% (TA1), Amlexanox 5% (TA2) and Tacrolimus 0.03% (TA3) in the treatment of OLP.
Materials and Methods: A study involving 90 patients aged 18-70 years enrolled in a randomized, single-blind, placebo-controlled clinical design enrolled them in three groups using three oral creams. Patients were monitored for allergic reactions and evaluated weekly for effectiveness and safety.
Results: Relative to baseline data, the acute sensation diminished by 31% after the first week, 57% after the second week, and 74% after the third week. The intra-group comparison of burning sensation scores was performed using the Wilcoxon matched-pairs signed rank test, a non-parametric statistical method. Compared to BL, there was a substantial decrease in burning sensation ($P<0.001$) during the first, second, and third weeks.
Conclusions: The research demonstrates that Amlexanox 5% oral paste, when used topically, markedly alleviates symptoms of OLP, diminishing the size of the erosive region and VAS scores within 28 days.

Introduction:

Inflammation of the oral mucosa, also known as a chronic mucocutaneous disorder affecting the stratified squamous epithelium, is the hallmark of OLP. The oral lesion is characterized by inflammatory tissue, open ulcers, and lacy patches that might be white or red in color. The 50s and 60s seem to be the worst years for women. Lesions within the mouth can be erosive, reticular, or atrophic.[1,2] Sites most typically affected include the labial mucosa, tongue, gums, vermillion border of lower lip, and posterior buccal mucosa. It is quite unusual for lesions to manifest on the palate, floor of the mouth, or upper lip.[3] Despite the rarity of malignant transformation, OLP has been associated with it.[4,6] The aetiology of the illnesses remained unknown, although the function of hepatitis C virus[7,8], psychological stress[9], herpes viruses type 1, HIV, HBV and HPV virus is seen. One possible cause of the condition is OLP. The role of immunological dysregulation, which includes T cells and macrophages, in the development of OLP is unclear.[10] Current study conducted to identify the clinical effectiveness of three different kind of drugs on OLP.

Material and Methods:
The study is conducted at Mithila Minority Dental College in Darbhanga, Bihar, India, involving patients aged 18-70 with oral pain and burning sensation. Patients were examined for blood cell count, hepatic and renal chemistry tests, and hypersensitivity tests for 0.1% TA1 paste, 5% TA2 paste, and 0.03% TA3 paste. Patients with severe systemic and oral diseases, history of topical treatment, lichenoid reactions, pregnancy and lactating mothers, and lichenoid reactions were excluded. The study used a prospective randomized, single-blind, placebo-controlled clinical design, and patients were divided into three groups involving three different oral applicants.

Group 1	**Group 2**	**Group 3**
N=30	N=30	N=30
Triamcinolone Acetonide	Amlexanox	Tacrolimus

Each patient was instructed to apply a small amount of the agent to the lesions twice a day, after each meal, for four weeks in a row. The first dose was observed, and the subjects were monitored for more than half an hour to detect adverse effects, such as allergies. For four weeks in a row, we tested the product's efficacy and safety. At the point when the erosive lesions had fully healed and the discomfort had subsided, the patients were instructed to stop taking the medicine and evaluated again.

Result: -
Post test: Dunn's Multiple Comparison Test

BL	P value
Group A vs Group B	>0.05 (NS)
Group A vs Group C	>0.05 (NS)
Group B vs Group C	>0.05 (NS)

-Significant (S), Non-significant (NS)

1st Week			P value
	Group A vs Group B	>0.05 (NS)	
	Group A vs Group C	>0.05 (NS)	
	Group B vs Group C	>0.05 (NS)	
Significant (S), Non-significant(NS)			
	2nd Week	P value	
	Group A vs Group B	>0.05 (NS)	
	Group A vs Group C	>0.05 (NS)	
	Group B vs Group C	<0.05 (S)	
	Significant (S), Non-si gnificant(NS)		
	3rd Week	P value	
	Group A vs Group B	<0.05 (S)	
	Group A vs Group C	>0.05 (NS)	
	Group B vs Group C	<0.001 (S)	
	Significant (S), Non-significant(NS)		

Discussion

OLP is a common oral mucosal disease characterized by plaquelike, erosive, atrophic, bullous, reticular, or papular lesions, often recalcitrant to medical management and highly symptomatic, predisposing to squamous cell carcinomas.[1] Topical corticosteroids are regarded as the primary therapeutic therapy for the management of OLP.[14] Traditional topical corticosteroids effectively treat OLP, as many patients require regular use of topical glucocorticoids to stabilize the chronic and recurrent condition.[1] Topical corticosteroids have short-term efficacy but negative effects like candidiasis, medication resistance, and mucocutaneous atrophy. Some people have allergies, limiting use. Immunosuppressive medications like cyclosporine and TA3 have mixed effectiveness but high costs, toxicity, and cancer risk.

TA2, an anti-inflammatory medication, is applied topically to suppress mast cell degranulation, reducing the production of TNF-α, histamine, and leukotrienes. These mediators increase vascular permeability, causing swelling and disrupting leukocyte function. A study found that TA2 treatment improved burning sensation and reduced erosive area in oral erosive OLP patients. The treatment also showed improvement in resolution of erythematous areas, with a significant improvement at the end of the third week.

The study, similar to Ji Fu et al's 7-day treatment, found significant reduction in erosive area and VAS scores in both topical TA2 and topical Dexamethasone groups without severe adverse reactions.[1] Previous studies have primarily examined the effectiveness of topical TA2 treatment in treating recurrent aphthous ulcers.[13] The study found topical TA2 safe and effective in all patients, with no irritation or sensitization, and normal gastrointestinal absorption, indicating its safe treatment.

OLP is an autoimmune condition, requiring corticosteroid therapy. Topical corticosteroids penetrate squamous epithelium, reduce T-cell activity, and inhibit cytokine gene transcription and inflammatory cell accumulation.[12] The study found that topical TA1 and TA3 significantly improved VAS scores by 60% and 74% on the 28th day, but relapses were common within 3-9 weeks of treatment cessation.

Javed A Qazi et al's study found TA3 ointment improved initial therapeutic response in 30 patients, but 12 experienced relapse within 6-8 weeks. Flare-ups in oral erosive OLP patients persist even after stopping TA3.

The study found significant improvement in clinical signs and symptoms after 28 days of treatment with topical TA1, TA2, and TA3 for oral erosive OLP, similar to a previous study by Ji Fu et al.[1]

Conclusion:

The research indicated that TA2 5% oral paste can markedly alleviate symptoms of OLP. It diminished the extent of the erosive region and VAS scores within 28 days. TA2 is well-tolerated and has no documented side effects or potential for sensitization, rendering it a valuable therapeutic option.

Declaration of Patient Consent:

All necessary patient consent documents have been received, as the authors attest. The patient or patients have provided their consent for the journal to publish their photos and other clinical data in this way. Although every attempt will be made to ensure the patient's confidentiality, they are aware that their names and initials will not be published.

Conflicts of interest:

There are no conflicts of Interest.

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