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EVALUATION OF EFFICACY OF TACROLIMUS AND TRIAMCINOLONE ACETONIDE OINTMENT IN THE MANAGEMENT OF SYMPTOMATIC ORAL LICHEN PLANUS: A COMPARATIVE STUDY

Tapaswini Bag*[1], Laxmikanth Chatra[2], Prashanth Shenai[3], Veena K M[3], Prasanna Kumar Rao[3], Rachana V Prabhu[4], Tashika Kushraj[5] and Shahul Hameed[6]

[1]Senior Lecturer, Dept of Oral Medicine And Radiology, College of Dental Science & Hospital, Devi Ahilya Bai Vishwavidyalaya University, Indore, Madhya Pradesh.
[2]Senior Professor and head, Department of Oral Medicine and Radiology, Yenepoya Dental College, Yenepoya University, Mangalore, Karnataka, India.
[3]Professor, Department of Oral Medicine and Radiology, Yenepoya Dental College, Yenepoya University, Mangalore, Karnataka, India.
[4]Associate Professor, Department of Oral Medicine and Radiology, Yenepoya Dental College, Yenepoya University, Mangalore, Karnataka, India.
[5]Reader, Department of Oral Medicine and Radiology, Yenepoya Dental College, Yenepoya University, Mangalore, Karnataka, India.
[6]Senior lecturer, Department of Oral Medicine and Radiology, Yenepoya Dental College, Yenepoya University, Mangalore, Karnataka, India.

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***Corresponding Author**
Dr. (Mrs.) Tapaswini Bag
Senior Lecturer, Dept of Oral Medicine And Radiology, College of Dental Science & Hospital, Devi Ahilya Bai Vishwavidyalaya University, Indore, Madhya Pradesh.

ABSTRACT

Introduction: Oral lichen planus (OLP) is a relatively common, chronic inflammatory condition and presumably autoimmune disease, which frequently present with burning sensation. Only symptomatic OLP requires treatment and efforts were made in a continued searching for novel therapies for symptomatic OLP. **Aim:** The study was aimed to compare the efficacy of treatment with topical tacrolimus with that of triamcinolone acetonide in orabase in subjects with symptomatic OLP. **Materials and Methods**: This prospective randomized comparative study, included 30 symptomatic OLP subjects, divided into two groups as group A and group B to recieve topical tacrolimus 0.03% ointment and triamcinolone acetonide 0.1% in orabase application respectively, twice daily for four consecutive weeks. Burning sensation using visual analogue scale (VAS) scale was recorded

at every visit. The data obtained was analyzed statistically by using Friedman & Man-Whitney test. **Results**: Subjects showed a higher (97%) reduction of burning sensation, erythematous area and size of the lesion in group A than in group B (77%). **Interpretation and conclusion**: Group A induced better therapeutic response than group B. No significant adverse effects were observed and no recurrence was noted during the treatment. Topical tacrolimus has been reported to be effective treatment for OLP, including those forms that had been recalcitrant to treatment. However, studies involving larger samples & longer period of treatment, follow-up are suggested in the future.

KEYWORDS: Oral lichen planus, Tacrolimus, Triamcinolone acetonide.

INTRODUCTION

Lichen planus is a relatively common disorder, estimated to affect 0.5% to 2.0% of the general population. It is a chronic, inflammatory disease that affects mucosal and cutaneous tissues. Oral lichen planus (OLP) occurs more frequently than the cutaneous form and tends to be more persistent. In contrast to cutaneous lichen planus, the oral form may persist for up to 25 years. Oral lesions may coexist with lesions of the genital mucous membranes or with lesions of cutaneous lichen planus. It affects women more often than men in a ratio 3:2.[1, 2] It rarely affected in adult and childhood. Clinical presentations of oral lichen planus include reticular, plaque-like, papular, erosive, atrophic, and bullous forms. The reticular form is the most common and asymptomatic, but the erosive, atrophic, and bullous forms are typically the most symptomatic with the complaints of severe burning sensation and pain, which can exacerbate by trauma and foods particularly hot, spicy or acidic. Most common sites include posterior buccal mucosa, tongue, gingiva, lip, floor of the mouth and palate.[3, 4] Corticosteroids are the class of drug most commonly used for the treatment of OLP. Triamcinolone acetonide, an intermediate acting steroid is the most widely available commercial preparation for the treatment of OLP. Recently, topical tacrolimus (0.03%-3%) a member of the immunosuppressive macrolide family was reported to be effective in the treatment of OLP.[5, 6] There are only few comparative studies between topical tacrolimus and triamcinolone acetonide in the management of OLP. Hence, a study has been undertaken to evaluate the relative efficacy of topical tacrolimus with that of triamcinolone acetonide in the management of OLP.

MATERIALS AND METHOD

This comparative study was carried out among the outpatients visiting department of Oral medicine and Radiology, Yenepoya Dental College and Hospital, Mangalore, after obtaining an ethical clearance from the ethical committee. The subjects in this study consisted of 30 symptomatic Oral lichen planus cases.Patients reporting to the OPD who were clinically & histopathological diagnosed cases of OLP and patients who were physically healthy, well oriented in time, space and as a person were included. Patients suffering from any systemic diseases, medically compromised patients, patients with a known allergy or contraindications to study medications,Lichen Planus patients already on a medication, histopathological examination with atypical or lichenoid dysplastic features were excluded in the study.

The following parameters were used in the establishment of diagnosis of oral lichen planus: A positive history of burning sensation on eating spicy food, emotional stress, changes in buccal mucosa, including the presence of diffuse papules, white plaque like area, bilateral Whikhame striae. Following armamentarium was used in the study: Mouth mirror, Explorers, Tweezers, Sphygmomanometer, Patient Performa, Patient consent form, Hospital Depression Anxiety Scale (HAD), twelve mega pixel digital cameras, Biopsy kit. 30 biopsy confirmed OLP patients were randomly divided into two groups Group A and Group B. Each consisting of 15 patients. Group A and Group B will be receiving drug "Tacrolimus" 0.03% and Triamcinolone Acetonide"0.1% ointment twice daily after food for two consecutive weeks. Oral prophylaxis was carried out in all patients before the treatment commenced. Efficacy of Tacrolimus and Triamcinolone acetonide ointment in OLP patients were evaluated by the following Criteria:

- Burning sensation was assessed by using Numeric rating scale (NRS) of 0 to 10, (where 0 is no burning sensation and 10 is worst possible burning sensation).
- Size of the lesion during the course of therapy – Clinical Evaluation(0 to 10, where 0 is constant,1 to 3 mild,4 to 6 moderate,7 to 9 severe and 10 is worst whether " increase" or "decrease" from 1st to 6th visit)
- Erythematous area will be assessed by its presence or absence indicated by the symbols present "+ "and absent "-"

All the cases were assessed on biweekly basis over a period of 3 months and followed up. Mann-Whitney and Friedman test for the comparision of Group-A and Group-B were used for statistical analysis.

RESULTS

The results of the present study showed, the age of collected sample size 30 OLP were divided equally into two groups, group A(tacrolimus)& group B(triamcinolone acetonide) out of which eleven patients [36.7%] below 40 years of age. Ten patients [33.3%] in the age group of 41-50 years. Nine patients [30.0%] above 50 years of age. There is no significant difference between age group pattern [p= 0.475 > 0.05] **[Table-1 & Graph-1]**.

Fifteen male patients [50%] in group A (tacrolimus) and fifteen female patients [50%] in group B (triamcinolone acetonide). There is no significant difference between the groups with respect to gender [p= 0.715 >0.05] **[Table-2 & Graph-2].**

Four different variant of OLP in both groups out of 30 patients actinic 1 [6.7%] ,annular [0%],erosive 8 [53.3%], reticular 6 [40%] in group A & actinic [0%], annular 1 [6.7%],erosive 5[33.3%], reticular 9[60%] in group B. There is no significant difference in variants of OLP in both groups [p=0.354 > 0.05]**[Table-3].**

In group A there is highly significant (Man Whitney test p=0.00<0.001), amount of decrease from pre-visit to 2nd visit was 55.56%,at 3rd visit 65.43%,at 4th visit 81.48%,5th visit 85.19%,and at 6th visit was 97.53% reduction. Similarly in group B from previsit to 2nd visit was 29.82%, at 3rd visit 49.12%, 4th visit 70.18%, 5th visit 80.70% and at 6th visit was 78.95% reduction.In other wards group A has significantly higher improvement in all the visits. The pretreatment mean burning sensation was 0.00 in group A & 0.00 in group B.There was not significant difference in mean from pre-visit to 1st visit in both the group(p=1.00>0.05). The improvement in burning sensation was stastically found to be significant (p<0.05) after 3rd visit, highly significant after 6th visit (p <0.01) between group A and group B. The average improvement in burning sensation difference in group A was 6.200, whereas in group B was 3.333 at the end of 6th visit. In other words group A has significantly higher improvement in all visits**. [Table-4 & Graph-3]**

When the evaluation of burning sensation was assessed among the 15 patients in group A ie tacrolimus group and 15 patients in group B ie triamcinolone acetonide group in the subsequent visits. The pre-treatment mean burning sensation was 6.33 in group A & 4.33 in group B. There was no significant difference in mean value from pre-visit to 1st visit in both the groups.The improvement in mean at the end of 6th visit was 0.13 in group A & 1.00 in group B.The improvement in burning sensation was stastically found to be significant after

2^{nd} visit, 3^{rd} ,4^{th} ,5^{th} visits & attained highly significant after treatment (Man Whitney test p= 0.000<0.001) in group A and group B**.[Table-5]**

When comparisons for size of the lesion was assessed among the 15 patients in tacrolimus group i c group A and 15 patients in group B ie triamcinolone acetonide group in the subsequent visits. In group A there is highly significant (Man Whitney test p= 0.000<0.001), amount of decrease from previsit to 2^{nd} visit was 55.56%,at 3^{rd} visit 65.43%,at 4^{th} visit 81.48%,5^{th} visit 85.19%,and at 6^{th} visit was 97.53% reduction. Similarly in group B from previsit to 2^{nd} visit was 29.82%, at 3^{rd} visit 49.12%, 4^{th} visit 70.18%, 5^{th} visit 80.70% and at 6^{th} visit was 78.95% reduction. In other wards group A has significantly higher improvement in all the visits compared to group B.

When comparisons for size of the lesion was assessed among the 15 patients in tacrolimus group i c group A and 15 patients in group B i c triamcinolone acetonide group in the subsequent visits. The pre-treatment mean size of the lesion was 0.00 in group A & group B was 0.00.There was no significant difference in mean value from pre-visit to 1^{st} visit (p=1.000>0.05). The improvement in size of the lesion as statistically found to be highly significant (p<0.05) after 2^{nd} visit. The mean difference in size of the lesion in group A was 5.267, whereas in group B was 3.000 at the end of 6^{th} visit. However the average improvement in size of the lesion was 97.83% in group A & 78.95% in group B at the end of 6^{th} visit**. [Table-6 & Graph-4]**

When the evaluation of size of the lesion was assessed among the 15 patients in group A ie tacrolimus group and 15 patients in group B ie triamcinolone acetonide group in the subsequent visits. The pre-treatment mean size of the lesion was 5.40 in group A & 3.80 in group B. There was no significant difference in mean value from pre-visit to 1^{st} visit in both the groups.The improvement in mean difference at the end of 6^{th} visit was 0.13 in group A & 0.80 in group B. The improvement in burning sensation was stastically found to be significant after 2^{nd} visit, 3^{rd} ,4^{th} ,5^{th} visits & attained highly significant after treatment (Man Whitney test p= 0.000<0.001) in group A and group B**.[Table-7]**

When comparisons for erythematous area was assessed among the 15 patients in tacrolimus group i c group A and 15 patients in group Bic triamcinolone acetonide group in the subsequent visits. The pre-treatment mean erythematous area was 0.00 in group A & group B was 0.00.There was no significant difference in mean value from previsit to 1^{st} visit

(p=1.000>0.05).The improvement in size of the lesion as stastically found to be highly significant (p=0.000<0.05) after 2nd visit. The mean difference in size of the lesion in group A was 3.000, whereas in group B was 2.200 at the end of 6th visit. In group A there is no reduction of erythematous area from previsit to 1st visit was 0.00% (Man Whitney test p=0.00>0.001), amount of reduction from previsit to 2nd visit was 37.78%, from previsit to 3rd visit was 33.33%, from previsit to 4th visit was 37.78%, previsit to 5th visit was 66.67% & at the end of 6th visit was 100%. Similarly in group B there were no reduction in erythematous area from previsit to 1st & 2nd visit (Man Whitney test p=0.00>0.001), amount of reduction from previsit to 3rd visit was 33.33%, previsit to 4th visit was 35.56%, previsit to 5th visit was 66.67% & at the end of 6th visit was 73.33% highly significant (p= 0.00<0.01). In other wards group A has significantly higher improvement in all the visits**. [Table-8 &Graph-5]**

When the evaluation of erythematous area was assessed among the 15 patients in group A ie tacrolimus group and 15 patients in group B ie triamcinolone acetonide group in the subsequent visits. The pre-treatment mean erythematous area was 3.00 in group A & 3.00 in group B. There was no significant difference in mean value from pre-visit to 1st visit in both the groups.The improvement in mean difference at the end of 6th visit was 0.00 in group A & 0.80 in group B.

The average improvement in group A there is highly significant (Friedman test value 87.454 ie p=0.00<0.01) amount of reduction in erythematous area from pre visit to end of 6th visit. Similarly group B showed highly significant (Friedman test value 89.014 ie p=0.00<0.01) amount of reduction in erythematous area from pre visit to end of 6th visit**. [Table-9]**

There is no significant difference between both the groups with respect to erythematous area except in the 2nd visit. At the end group A is showing better response than group B but statistically not significant.

OLP involvement in buccal mucosa changes occur after treatment in both group A (tacrolimus**)[Figure-1]** and group B(triamcinolone acetonide**)[Figure-2].** Showed higher reduction in burning sensation, size of the lesion and erythematous area in group A as compared to group B.

FIGURE LEGENDS

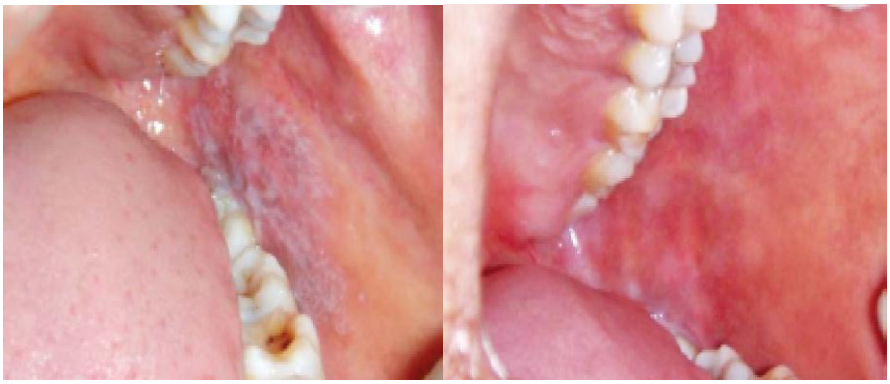

Figure - 1: Clinical changes pre and post treatment in Tacrolimus group (group A).

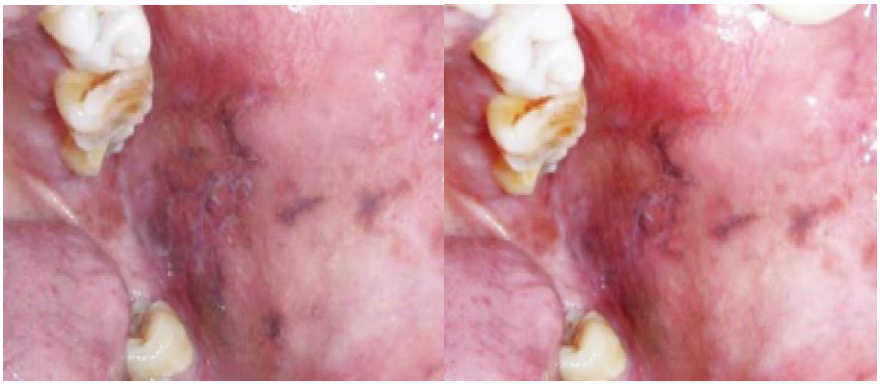

Figure - 2: Clinical changes pre and post treatment in Triamcinolone acetonide group (group B).

TABLE & GRAPH LEGENDS

Table-1 & Graph-1: Age group pattern in group A and group B.

		Group		
		Group A	Group B	Total
Age	40 and below	5	6	11
		33.3%	40.0%	36.7%
	41 - 50	4	6	10
		26.7%	40.0%	33.3%
	Above 50	6	3	9
		40.0%	20.0%	30.0%
Total		15	15	30
		100.0%	100.0%	100.0%

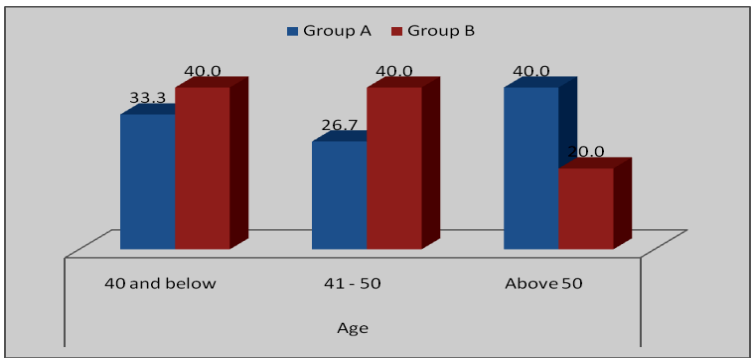

Table-2 & Graph-2: Evaluation of gender distribution in group A and group B.

		Group		
		Group A	Group B	Total
sex	F	8	7	15
		53.3%	46.7%	50.0%
	M	7	8	15
		46.7%	53.3%	50.0%
Total		15	15	30
		100.0%	100.0%	100.0%

X^2(Chi Square) =.133, p=.715, NS

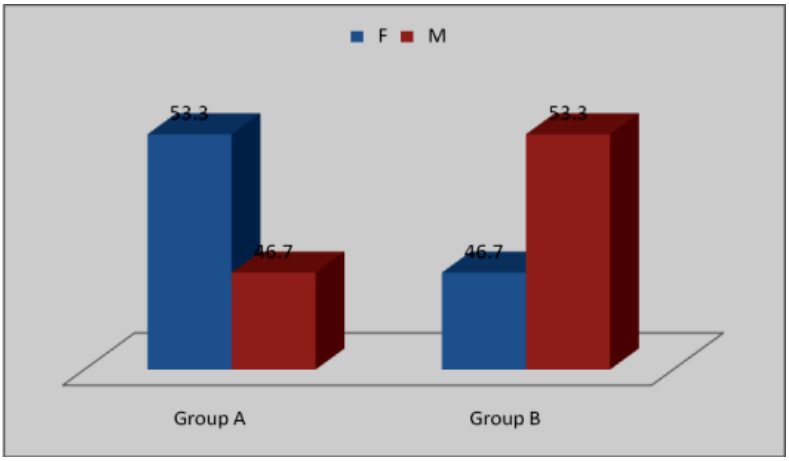

Table-3: Evaluation of sample distribution based on clinical diagnosis in group A and group B.

		Group		
		Group A	Group B	Total
Clinical variant OLP	ACTINIC	1	0	1
		6.7%	.0%	3.3%
	ANNULAR	0	1	1
		.0%	6.7%	3.3%
	EROSIVE	8	5	13
		53.3%	33.3%	43.3%
	RETICULAR	6	9	15
		40.0%	60.0%	50.0%
Total		15	15	30
		100.0%	100.0%	100.0%

Fishers exact test p=.354, NS = no significant.

Table-4 & Graph-3: Inter group comparison of efficacy of burning sensation between group A & group B.

Comparisons burning

:
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	Group	Mean Difference	Std. Error	change (%)	Mannwhitney test p value	
PREVISIT - @1STVISIT	Group A	.000	.000	.00	1.00	NS
	Group B	.000	.000	.00		
PREVISIT -@2NDVISIT	Group A	3.933	.492	62.11	.010	sig
	Group B	1.933	.483	44.62		
PREVISIT -@3RDVISIT	Group A	4.467	.496	70.53	.014	sig
	Group B	2.467	.542	56.92		
PREVISIT -@4THVISIT	Group A	5.333	.513	84.21	.010	sig
	Group B	3.333	.475	76.92		
PREVISIT -@5THVISIT	Group A	5.533	.496	87.37	.010	sig
	Group B	3.533	.487	81.54		
PREVISIT -@6THVISIT	Group A	6.200	.355	97.89	.000	HS
	Group B	3.333	.444	76.92		

sig: significant, NS: not significant, HS: highly significant

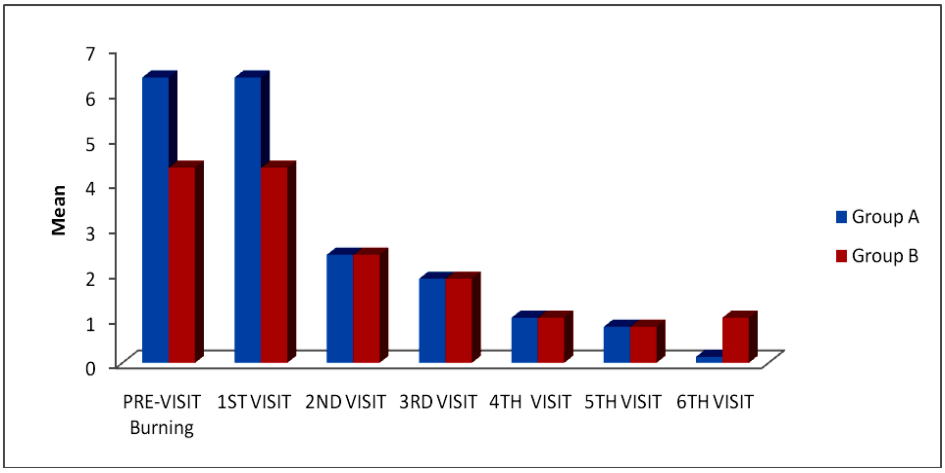

Table - 5: Evaluation of efficacy of burning sensation within group A & group B.

Group		N	Mean	Std. Deviation	Median	25th percentile	75th percentile	Freidman test value p value	
Group A	PRE-VISIT Burning	15	6.33	1.397	7.00	6.00	7.00	.000	HS
	1ST VISIT	15	6.33	1.397	7.00	6.00	7.00		
	2ND VISIT	15	2.40	1.298	2.00	2.00	3.00		
	3RD VISIT	15	1.87	1.246	1.00	1.00	2.00		
	4TH VISIT	15	1.00	1.000	1.00	.00	1.00		
	5TH VISIT	15	.80	.775	1.00	.00	1.00		
	6TH VISIT	15	.13	.352	.00	.00	.00		
Group B	PRE-VISIT Burning	15	4.33	1.676	5.00	3.00	6.00	.000	HS
	1ST VISIT	15	4.33	1.676	5.00	3.00	6.00		
	2ND VISIT	15	2.40	1.298	2.00	2.00	3.00		
	3RD VISIT	15	1.87	1.246	1.00	1.00	2.00		
	4TH VISIT	15	1.00	1.000	1.00	.00	1.00		
	5TH VISIT	15	.80	.775	1.00	.00	1.00		
	6TH VISIT	15	1.00	.655	1.00	1.00	1.00		

Table-6 & Graph-4: Inter group comparision of efficacy of size of the lesion between group A and group B.

Pairwise Comparisons size

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Group			Mean Difference (I-J)	Std. Error	change (%)	p	
Group A	PREVISIT	@1STVISIT	.000	.000	.00	1.000	NS
		@2NDVISIT	3.000	.402	55.56	.000	HS
		@3RDVISIT	3.533	.456	65.43	.000	HS
		@4THVISIT	4.400	.466	81.48	.000	HS
		@5THVISIT	4.600	.476	85.19	.000	HS
		@6THVISIT	5.267	.384	97.53	.000	HS
Group B	PREVISIT	@1STVISIT	.000	.000	.00	1.000	NS
		@2NDVISIT	1.133	.192	29.82	.001	HS
		@3RDVISIT	1.867	.236	49.12	.000	HS
		@4THVISIT	2.667	.287	70.18	.000	HS
		@5THVISIT	3.067	.300	80.70	.000	HS
		@6THVISIT	3.000	.338	78.95	.000	HS

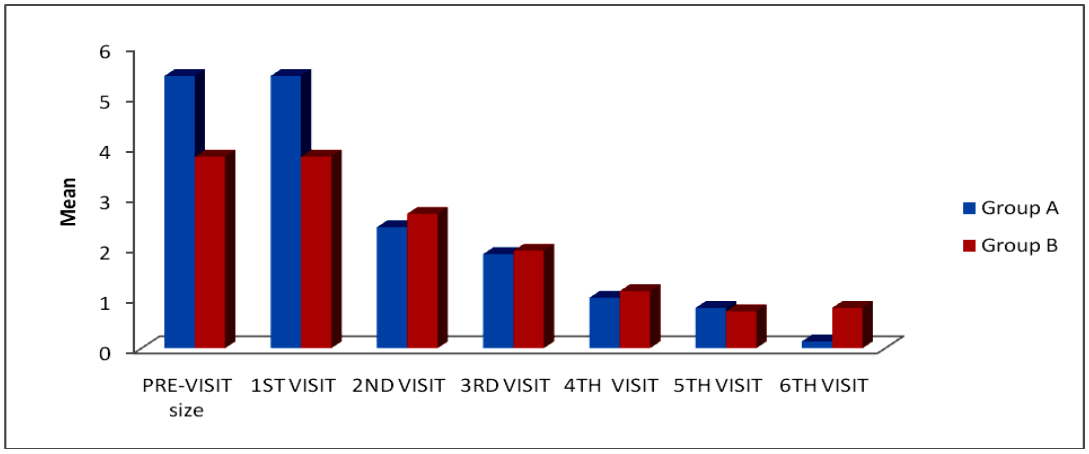

Table-7: Evaluation of efficacy of size of the lesion within group A and group B.

Group		N	Mean	Std. Deviation	Median	25th percentile	75th percentile	Friedman test p value	
Group A	PRE-VISIT size	15	5.40	1.298	5.00	4.00	7.00	.000	HS
	1ST VISIT	15	5.40	1.298	5.00	4.00	7.00		
	2ND VISIT	15	2.40	1.298	2.00	2.00	3.00		
	3RD VISIT	15	1.87	1.246	1.00	1.00	2.00		
	4TH VISIT	15	1.00	1.000	1.00	.00	1.00		
	5TH VISIT	15	.80	.775	1.00	.00	1.00		
	6TH VISIT	15	.13	.352	.00	.00	.00		
Group B	PRE-VISIT size	15	3.80	1.424	4.00	3.00	5.00	.000	HS
	1ST VISIT	15	3.80	1.424	4.00	3.00	5.00		
	2ND VISIT	15	2.67	1.589	2.00	2.00	3.00		
	3RD VISIT	15	1.93	1.335	1.00	1.00	2.00		
	4TH VISIT	15	1.13	1.125	1.00	.00	2.00		
	5TH VISIT	15	.73	.799	1.00	.00	1.00		
	6TH VISIT	15	.80	.414	1.00	1.00	1.00		

Table-8 & Graph-5: Inter group comparison of efficacy of erythematous area between group A & group B.

Pairwise Comparisons

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Group			Mean Difference	Std. Error	change (%)	p	
Group A	Previsit	@1stvisit	.000	.000	.00	1.000	NS
		@2ndvisit	1.133	.091	37.78	.000	HS
		@3rdvisit	1.000	.000	33.33	.000	HS
		@4thvisit	1.133	.091	37.78	.000	HS
		@5thvisit	2.000	.000	66.67	.000	HS
		@6thvisit	3.000	.000	100.00	.000	HS
Group B	Previsit	@1stvisit	.000	.000	.00	1.000	NS
		@2ndvisit	.000	.000	.00	1.000	NS
		@3rdvisit	1.000	.000	33.33	.000	HS
		@4thvisit	1.067	.067	35.56	.000	HS
		@5thvisit	2.000	.000	66.67	.000	HS
		@6thvisit	2.200	.107	73.33	.000	HS

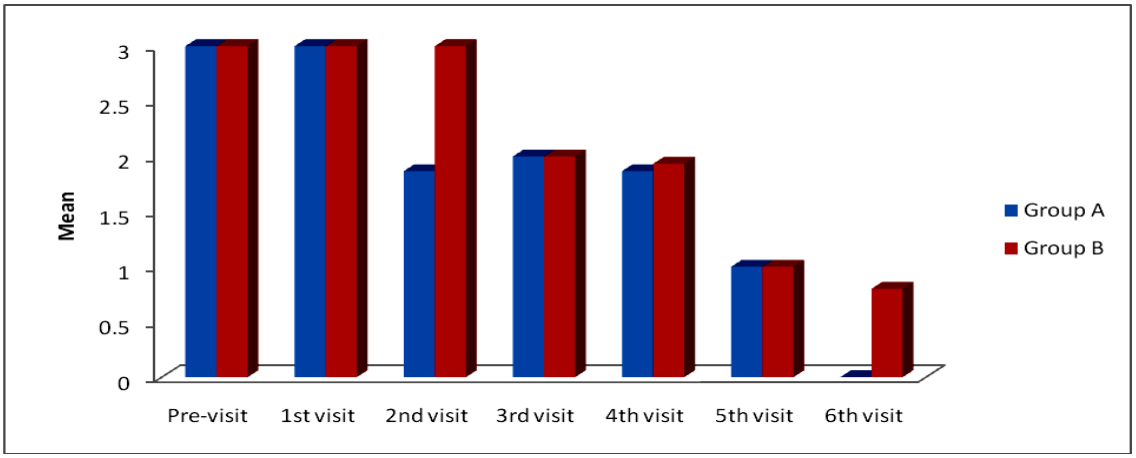

Table-9: Evaluation of efficacy of erythematous area within group A & group B.

Group		N	Mean	Std. Deviation	Median	25th percentile	75th percentile	Friedman test value	p value
Group A	Pre-visit	15	3.00	.000	3.00	3.00	3.00	87.454	.000
	1st visit	15	3.00	.000	3.00	3.00	3.00		HS
	2nd visit	15	1.87	.352	2.00	2.00	2.00		
	3rd visit	15	2.00	.000	2.00	2.00	2.00		
	4th visit	15	1.87	.352	2.00	2.00	2.00		
	5th visit	15	1.00	.000	1.00	1.00	1.00		
	6th visit	15	.00	.000	.00	.00	.00		
Group B	Pre-visit	15	3.00	.000	3.00	3.00	3.00	89.041	.000
	1st visit	15	3.00	.000	3.00	3.00	3.00		HS
	2nd visit	15	3.00	.000	3.00	3.00	3.00		
	3rd visit	15	2.00	.000	2.00	2.00	2.00		
	4th visit	15	1.93	.258	2.00	2.00	2.00		
	5th visit	15	1.00	.000	1.00	1.00	1.00		
	6th visit	15	.80	.414	1.00	1.00	1.00		

DISCUSSION

Lichen planus is a chronic inflammatory mucocutaneous disease that occurs in about 0.02 to 4% of general population affecting skin and mucosa. The lesion has a chronic clinical course with periods of exacerbation and remission with reports of lesions for up to 20 years. This study compared the safety and efficacy of topical tacrolimus ointment with triamcinolone acetonide ointment in patients suffering from OLP. The results indicate that both drugs are effective for the treatment of OLP.[7] This study shows that topical tacrolimus 0.03% ointment applied three times daily induced better therapeutic response than that of triamcinolone acetonide 0 .01% ointments. The positive aspect of the present study was that the included patients' responded well to topical tacrolimus. There are only few comparative studies between topical tacrolimus and triamcinolone acetonide in the management of OLP.

A prospective randomized study was conducted in 40 patients with the diagnosis of symptomatic OLP to compare the efficacy of topical tacrolimus ointment with triamcinolone acetonide ointment. In group I, 20 patients were treated with topical tacrolimus 0.1% ointment, applied 4 times a day for 6 weeks. In group II, 20 patients were treated with triamcinolone acetonide 0.1% ointment in the same way. The results showed that topical tacrolimus 0.1% ointment induced a better initial therapeutic response than triamcinolone acetonide 0.1% ointment. However, relapses occurred frequently within 3-9 weeks after the cessation of treatment.[8]

A study was conducted to compare the efficacy of adcortyl ointment (triamcinolone acetonide in orabase) with topical tacrolimus for the treatment of erosive oral lichen planus.60 patients with histopathologically confirmed oral lichen planus were enrolled in the study.The severity of lesions was scored from 0 to 5 . Patients were randomly given adcortyl (groupA) and topical tacrolimus ointment(groupB), asked to apply the medication on dried lesions 4 times a day. The lesions were evaluated after 4 weeks of treatment. Visual anlogue scale (VAS) was used to assess the severity of pain before and after treatment. The average score of lesions improved from 3.4 to 1.5 in patients who received adcortyl ointment and from 3.2 to 1.2 in patients who received tacrolimus ointment. The study concluded that topical tacrolimus is a safe and effective alternative therapy in the treatment of oral lichen planus.[9]

A randomized study conducted to compare the efficacy of topical tacrolimus ointment with that of triamcinolone acetonide ointment in subjects with symptomatic OLP, which included

30 symptomatic OLP subjects, divided into two groups as group A and group B received topical tacrolimus 0.03% ointment and triamcinolone acetonide 0.1% ointment application respectively,twice daily for four consecutive weeks.Burning sensation using Numeric rating scale (NRS),overall treatment response using Tel Aviv-Scan Francisco scale was recorded at every visit. Subjects in both the groups showed a significant reduction in burning sensation: however, it was higher (98%) in tacrolimuls group than in triamcinolone acetonide group (72%). The overall treatment response was significantly better in tacrolimus group.[10]

A randomized controlled study was conducted on 60 patients with symptomatic lesion of oral lichen planus. Study group comprised of 30 patients who received 0.1% tacrolimus in orabase therapy for 4 weeks. Control group comprised of 30 patients who received 0.1% triamcinolone acetonide in orabase therapy for 4 weeks. Study group shown clinical response ($p=0.002$) when compared to control group.[11]

A prospective randomized study was conducted in 30 patients with a confirmed diagnosis of symptomatic OLP out of (20 females and 10 males, 15 patients per treatment group) were treated with tacrolimus or triamcinolone acetonide for 4 weeks.Pain, burning sensation, severity and size of mucosal lesion were assessed. At the end of the treatment period, symptom scores were significantly lower in tacrolimus group than in triamcinolone group. The profile of mean lesion sizes did not differ significantly ($p>0.005$) between triamcinolone and tacrolimus groups but showed statistically significant improvement of the lesion sizes overall.[12]

A randomized-controlled trial was conducted to compare topical cyclosporin with triamcinolone acetonide for the treatment of oral lichen planus. Thirteen patients were randomly assigned to receive cyclosporin or triamcinolone acetonide 0.01% 3 times daily on the dried lesions after meals, for a period of 8 weeks.The results indicated that topical cyclosporin did not provide any beneficial effect, and was not effective than triamcinolone acetonide (0.1%) in the treatment of symptomatic oral lichen planus.[13]

A prospective randomized double study was conducted to compare treatment of topical tacrolimus and clobetasol in oral lichen planus. Tacrolimus 0.1% ointment was compared with corticosteroid clobetasol 0.05% of 30 patients (15 patients divided into 2 groups). In this study the profile of mean pain scores measured by VAS scores did not differ significantly

between the two groups.The present study showed that topical tacrolimus is more effective in reducing mean VAS scores than topical triamcinolone acetonide.[14,15]

A randomized controlled study was conducted on 60 patients with symptomatic lesion of OLP. Study group comprised of 30 pts who recieved topical tacrolimus 0.1% in orabase & 30 pts in control group who received topical triamcinolone acetonide 0.1% in orabase for 4 weeks. The result showed significant improvement of symptoms 96% in study group as compared to control group 90% & statistically significant (p= 0.002), improvement in erythematous area 74.4% & 45.1%. & statistically significant (p=0.002) & improvement in size of the lesion 93% & 53%, it was statistically significant (p=0.003) at the end of the treatment. No significant adverse effects were observed & no recurrence was noted during the treatment & follow up.Our study showed the reduction in mean score of BS from 1st visit to 6th visit ie 6.33 to 0.13 in group A & 4.33 to 1.00 in group B, statistically highly significant in both the groups(p=0.00). When there was comparision between two groups in every visit, the percentage of reduction in BS was 97.89% & 76.92 in group A & group B.[16]

CONCLUSION

In present study done on 30 clinically diagnosed & histopathologically confirmed oral lichen planus patients the following inferences were drawn: There was significant decrease in burning sensation,size of the lesion and erythematous area in patients with OLP when Tacrolimus 0.03% and Triamcinolone acetonide 0.1% ointment was used as treatment modality. Oral application of tacrolimus and triamcinolone acetonide ointment was well tolerated by Oral lichen planus patients without any side effects reported by the patients in this study. Larger number of patient's sample, with longer period of treatment follow-up, is required to draw further conclusion on the utility of spirulina in the treatment of Oral Lichen Planus.

CONFLICT OF INTEREST

We the authors of the manuscript titled "Evaluation of efficacy of Tacrolimus and Triamcinolone acetonide in the management of symptomatic oral lichen planus: A Comparative study" claims that there is no conflict of interest in the present research work.

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