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COMPARATIVE EVALUATION OF EFFICACY OF AYURVEDIC THERAPY WITH CONVENTIONAL PHARMACOLOGICAL THERAPY IN MANAGEMENT OF OSMF: RCT

Sudesh Kumar*., Nagaraju Kamarthi., Sangeeta Malik and Anshu Dwivedi

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ABSTRACT

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OSMF, Intraincisal Mouth Opening, Intralesional Injection, Aloevera, Curcumin, Corticosteroids

To compare and evaluate the efficacy of Ayurvedic treatment (Aloe Vera and turmeric) with conventional Pharmacological therapy (Intralesional injection of Dexamethasone and hyaluronidase), along with Physiotherapy in the management of Oral Submucous Fibrosis. Study group comprised of 60 patients who reported to the department of Oral Medicine and Radiology diagnosed with Oral Submucous Fibrosis. All the 60 patients were divided into two groups A (Ayurvedic Therapy) & B (Pharmacologic Therapy) randomly. Result showed that the improvement in interincisal opening between 1st to 12th week is more in group B (31.31%) then group A (22.55%) whereas burning sensation reduction is more in showed faster reduction in burning sensation and pharmacologic treatment showed faster increase in mouth opening.

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INTRODUCTION

Oral submucous fibrosis is "a chronic, insidious disease affecting any part of oral cavity and may extend to the pharynx and the oesophagus and may be preceded or associated with vesicle formation.¹ It is always associated with juxta-epithelial inflammation and followed by fibro elastic change of the lamina propria with epithelial atrophy leading to stiffness.²

It was first described by Schwartz in 1952.^{3,4,5,6} Numerous factors such as routine consumption of chili in food, areca nut chewing, nutritional deficiency, hereditary susceptibility, autoimmune and collagen disorders have been the etiologic factors concerned in the pathogenesis of this condition.^{7,8,9} The potentially malignant nature of this condition with a transformation rate of 3% to 7.6% has been mentioned in literature.^{10,11}

The prevalence of OSMF has increased over the past four decades from 0.03% to 6.42%. In 2002, the statistics of OSMF for India alone was 5 million people.^{1,12} The pathogenesis of the disease is not well-established, but the cause of OSMF is believed to be multifactorial. Various mechanisms were suggested for the etiopathogenesis of OSMF.^{13,14}

The treatment of patients with OSMF depends on the degree of clinical involvement. Treatment holds option of both nonsurgical and surgical approach. Non-surgical management includes multivitamin supplements including lycopene and range of medicines (e.g. intra-lesional injections of steroids, hyaluronidase, human placental extracts, chymotrypsin, pentoxyfilline and collagenase).

*Corresponding author: Sudesh Kumar

Also use of ayurvedic preparations of aloe vera, tulsi and turmeric has shown promising results.¹⁵ Surgical intervention includes cutting of fibrous bands, which is used in more extreme cases.⁹ Aloe vera It is a mannoprotein containing many amino acids called wound healing hormones.

Several studies have been successfully conducted on Aloe Vera as well as on turmeric. Curcumin (diferuloymethane) found in turmeric, a natural yellow pigment also exhibits anti-oxidant, antiinflammatory and anti-cancer properties. It was hypothesized that curcumin exerts anti-inflammatory activity by inhibiting a number of different molecules that participates in the process of inflammation. They also exhibit fibrinolytic property due to its ability to inhibit lipid peroxidation and check cellular proliferation, thereby reducing the rate of collagen synthesis.¹⁶

The literature supports the use of such several medical interventions. However, the numbers of reported randomized controlled trials are limited. Thus, this study is an effort to compare and evaluate the efficacy of Ayurvedic therapy [aloe vera & turmeric] with conventional pharmacological therapy [intralesional injection of dexamethasone and hyaluronidase] along with mouth opening exercises in the management of oral submucous fibrosis: a randomized controlled clinical study.

MATERIALS & METHODOLOGY

The study group comprised of 60 patients who reported to the department of Oral Medicine and Radiology diagnosed with OSMF. All the 60 patients were divided into two groups (A and B) randomly. Group A – Consisted of 30 patients who were given topical Aloe Vera gel (5mg/day) 3 times/day

(Krishna's herbal & Ayurvedic) and orally turmeric capsule (300mg) (Sanat products Ltd.) twice daily for 3 months along with mouth opening exercises. Group B -Consisted of 30 patients who were given intralesional injections of Dexamethasone (Dexra zenilabs ethica Ltd.) (4mg/ml) & Hyaluronidase (Hynidase shreya life science pvt. Ltd) (1500 IU) with insulin syringe weekly for 3 months along with mouth opening exercises. The duration of treatment was for three months. All the patients were evaluated for mouth opening (Inter-incisal distance in mm) & severity of burning sensation (VAS scale) at baseline (First visit), and at the end of 1st, 2nd and 3rd month of treatment. All the parameters were measured & recorded in every visit. Medication diary was provided to all patients for home follow up. All the results obtained were statistically analyzed.

OBSERVATION AND RESULTS

The mean age of subjects suffering from OSMF in group A is 33 years and in Group B is 29.57 years respectively. Total numbers of male were 87% and female 13% in Group A and total numbers of male were 90% and female 10% in Group B. (Table 1 Graph 1).

Table 1	l Age	and	Gender	Distribution	among	Group A	and A
				Group B			

	Grou (Ayury Thera	p A vedic upy)	Grou (Pharmac Thera	p B ological phy)
Mean Age		33		29.57
Standard Deviation				
(S.D.)		8.31		6.1
Maximum Age		50		45
Minimum Age		21		22
Median		32		28
Total No. of Study				
Patient		30		30
	n	%	n	%
Total No. of Male	26	87%	27	90%
Total No. of Female	4	13%	3	10%



Graph 1 Distribution of Study Subjects (Group A And Group B) In Mean, Standard Deviation Maximum Age, Minimum Age & Median.

The Mean Interincisal Opening in Group A & Group B at first visit was 27.20mm & 25.23mm respectively which increased at the end of 12th week of therapy, the Mean for the two groups being 33.33mm & 33.13mm. The difference in mean between Group A & B at 1st visit was 1.97mm and the difference in Mean decreased subsequently in the following

weeks, being the minimum after 9th week i.e. -0.13mm. (Table 2, Graph 2).



Graph 2 Comparisons of Mean Inter Incisal Distance (In Mm) Between 2 Groups At Different Time Interval.

Simultaneous comparison of Interincisal opening (in mm) among different time-points through ONE-WAY ANOVA for Group A shows F value is 49.171 which is greater than F crit value (1.744), and P value is 0.0001, whereas Simultaneous comparison of Interincisal opening (in mm) among different time-points through ONE-WAY ANOVA for Group B shows F value is 41.93 which is greater than F crit value (1.744) and p-value is 0.0001 shows a significant difference among successive time-points at .05 level of significance i.e. P<.05. (Table 3 & 4)

In 30 subjects the mean VAS Score decreased significantly i.e.7.90 to 0.00 for burning sensation in patients from Group A compared with VAS Score reduction in patient from Group B i.e. 8.33 to 0.33. In Group A the mean score for burning sensation is reduced from 7.90 to at the completion of 5 weeks of therapy. However Pharmacological therapy did not show much improvement after the same duration of therapy (i.e. after the completion of 5 weeks). (Table 5, Graph 3)



Graph 3 Comparison of mean VAS score between 2 Groups at different time interval

 Table 2 Mean, Standard Deviation & Standard Error Of Mean (S.E.M.) of Interincisal Opening (In Mm) For In Group A

 (Ayurvedic Therapy) and Group B (Pharmacological Therapy) and Difference B/W In Group A And Group B

	Group A (Ayurvedic Therapy)		Group B (Ph	Difference B/W					
Visit/Time -Points	Interincisal Opening (In Mm)			Interincisal Opening (In Mm)			Group A & Group B		
	MEAN	S.D.	S.E.M.	MEAN	S.D.	S.E.M.	MEAN	S.D.	S.E.M.
AT 1 VISIT (BASELINE)	27.20	1.81	.330	25.23	2.42	.441	1.97	3.00	.562
AFTER 1 st WEEK	27.33	1.75	.319	25.90	2.55	.465	1.43	3.28	.594
AFTER 2 nd WEEK	28.30	1.64	.300	26.77	2.37	.433	1.53	3.00	.548
AFTER 3rd WEEK	28.37	1.67	.305	27.57	2.33	.425	.80	3.00	.547
AFTER 4 th WEEK (1 MONTH)	29.23	1.70	.309	28.33	2.20	.402	.90	2.96	.541
AFTER 5 th WEEK	29.47	1.68	.306	29.20	2.23	.408	.27	3.00	.548
AFTER 6 th WEEK	30.23	1.68	.306	29.70	2.15	.393	.53	2.96	.539
AFTER 7 th WEEK	30.50	1.70	.310	30.47	2.24	.409	.03	3.05	.556
AFTER 8 th WEEK (2 MONTH)	31.23	1.68	.306	31.10	2.34	.427	.13	3.10	.566
AFTER 9 th WEEK	31.60	1.59	.290	31.93	2.23	.406	13	2.86	.522
AFTER 10 th WEEK	32.30	1.62	.296	32.30	2.26	.413	.00	2.89	.527
AFTER 11 st WEEK	32.67	1.52	.277	32.67	2.35	.430	.00	2.88	.525
AFTER 12 th WEEK (3 MONTH)	33.33	1.58	.289	33.13	2.18	.397	.20	2.68	.490

 Table 3 One-Way Anova – F Table for Simultaneous Comparsion Among Different Time-Points In Interincisal Opening (In Mm) For Group A (Ayurvedic Therapy)

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	1755.96	13	135.074	49.171	.0000*	1.744
Within Groups	1115.30	406	2.747		P<.05 (SIG.)	
Total	2871.26	419				

*shows a significant difference among successive time-points at .05 level of significance. i.e. P<.05

 Table 4 One-Way Anova – F Table for Simultaneous Comparsion Among Different Time-Points In Interincisal Opening (In Mm) For Group B (Pharmacological Therapy)

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	2860.10	13	220.01	41.93	.0000*	1.744
Within Groups	2130.50	406	5.25		P<.05 (SIG.)	
Total	4990.60	419				

*shows a significant difference among successive time-points at .05 level of significance. i.e. P<.05

 Table 5 Mean, Standard Deviation & Standard Error of Mean (S.E.M.) of Vas Score For Burning Sensation For Group A (Ayurvedic Therapy) And Group B (Pharmacological Theraphy) And Difference B/W Group A & Group B.

		Group A			Difference B/W Group A & Group B				
Visit/Time -Points	(Ayu	rvedic Thei	apy)	(Pharmacological Theraphy) (Vas Score For Burning Sensation)					
	(Vas Score l	For Burning	sensation)						
	MEAN	S.D.	S.E.M.	MEAN	S.D.	S.E.M.	MEAN	S.D.	S.E.M.
AT 1 VISIT	7.90	1.094	.200	8.33	.922	.168	.433	1.357	.248
(BASELINE)									
AFTER 1 st WEEK	5.90	1.213	.221	7.67	1.028	.188	1.767	1.547	.282
AFTER 2 nd WEEK	3.933	1.258	.230	6.70	.988	.180	2.767	1.591	.290
AFTER 3 rd WEEK	2.033	1.098	.201	6.00	1.114	.203	3.967	1.542	.281
AFTER 4 th WEEK (1 MONTH)	.533	.629	.115	4.97	1.245	.227	4.433	1.406	.257
AFTER 5 th WEEK	0.00	0.00	0.00	3.83	1.533	.280	3.833	1.533	.280
AFTER 6 th WEEK	0.00	0.00	0.00	2.87	1.697	.310	2.867	1.697	.310
AFTER 7 th WEEK	0.00	0.00	0.00	1.93	1.363	.249	1.933	1.363	.249
AFTER 8th WEEK	0.00	0.00	0.00	1.33	1.061	.194	1.333	1.061	.194
(2 MONTH)									
AFTER 9 th WEEK	0.00	0.00	0.00	.700	.837	.153	.700	.837	.153
AFTER 10 th WEEK	0.00	0.00	0.00	.233	.504	.092	.233	.504	.092
AFTER 11 st WEEK	0.00	0.00	0.00	.133	.434	.079	.133	.434	.079
AFTER 12th WEEK	0.00	0.00	0.00	.033	.183	.033	.033	.183	.033
(3 MONTH)									

 Table 6 One-Way Anova – F Table For Simultaneous Comparsion Among Different Time-Points In Vas Score For Burning Sensation For Group A (Ayurvedic Therapy)

Source Of Variation	SS	df	MS	F	P-value	F crit
Between groups	2630.25	13	202.33	484.06	.0000*	1.744
Within groups	169.7	406	0.42		P<.05 (SIG.)	
Total	2799.95	419				

*shows a significant difference among successive time-points at .05 level of significance. i.e. P<.05

Simultaneous comparison of VAS Score for burning sensation among different time-points through ONE-WAY ANOVA for Group A shows F value is 484.06 which is greater than F crit value (1.744), and p-value is 0.0001, whereas Simultaneous comparison of VAS Score for burning sensation among different time-points through ONE-WAY ANOVA for Group B shows F value is 255.988 which is greater than F crit value (1.744), and p-value is 0.0001 which shows a significant difference among successive time-points at .05 level of significance i.e. P<.05. (Table 6 & 7) Similarly in a study by Srivastava R, 860 patients were in the age range of 15–60 years, with a peak incidence in 30--40 years (34.88%), followed by 20–30 years (30.23%)²¹. Nigam also reported that the maximum number of OSMF cases found in their study was in the age group of 36--40 years²². Yadav *et al.* compared the Curcumin capsule (Turmix) with intralesional steroid injection in the treatment of OSMF and showed significant improvement in burning sensation in patients treated with curcumin tablets²³.

 Table 7 One-Way Anova – F Table For Simultaneous Comparsion Among Different Time-Points In Vas Score For Burning Sensation For Group B (Pharmacological Therapy)

Source of variation	SS	df	MS	F	P-value	F crit
Between groups	3588.76	13	276.059	255.988	.0000*	1.744
Within groups	437.83	406	1.078		P<.05 (SIG.)	
Total	4026.60	419				

*shows a significant difference among successive time-points at .05 level of significance. i.e. P<.05

 Table 8 Percentage % Improvement From 1st Visit To 12th Week In Group A (Ayurvedic Therapy) And Group B (Pharmacological Theraphy)

S.No.	Parameters	% Improvement From 1 ST Visit12 th week IN				
		Group a (Ayurvedic Therapy)	Group B (Pharmacological Theraphy)			
1 -	Interincisal Opening (In mm)	22.55%	31.31% ^(a)			
2	Vas Score For Burning Sensation	100 % ^(b)	99.60 %			
2	vas Score For Burning Schsation	100 /8	99.00 /0			

^(a) Interincisal Opening (In Mm) Is Better In Pharmacological Therapy While Vas Score For Burning Sensation Is Better In Ayurvedic Theraphy.^(b)

The improvement in interincisal opening between 1^{st} to 12^{th} week is more in group B (31.31%) then group A (22.55%) whereas burning sensation reduction is more in group A (100%) than group B (99.60%). (Table 8, graph 4)



Graph 8a Percentage (%) Improvement In Ayurvedic Therapy And Pharmacologic Therapy

DISCUSSION

Oral submucous fibrosis still remains a dilemma to the clinicians due to elusive pathogenesis and less well-defined classification systems. This disease is always associated with juxta-epithelial inflammation and followed by fibro-elastic change of the lamina propria with epithelial atrophy leading to stiffness¹⁷. The most common initial symptom is burning sensation of oral mucosa which is aggravated by spicy food. This is followed by blanching, stiffness of buccal mucosa and progressive reduced mouth opening¹⁸. Yang assessed the prevalence, gender distribution, age, income, and urbanization status of OSF patients in Taiwan and concluded that men had a significantly higher OSMF prevalence than women¹⁹. Sinor *et al.* in India found male predominance in OSMF cases²⁰.

Sudarshan R *et al* (2012) in his study found that Aloe vera group showed a better treatment response compared to the antioxidants group in reducing the burning sensation and improving mouth opening thereby enhancing the patients compliance²⁴. Similar study by Anuradha A *et al* (2017) showed that aloe vera can be an alternative, safe, and effective treatment regime in the management of oral submucous fibrosis²⁵. Our study is also in concurrence with the above studies and shows that VAS score for burning sensation was reduced in Ayurvedic treatment compared to Pharmacological group.

In 30 subjects the mean VAS Score decreased significantly i.e.7.90 to 0.00 for burning sensation in patients treated with Group A compared with VAS Score reduction in patient treated with Group B i.e. 8.33 to 0.33. In Group A the mean score for burning sensation is reduced from 7.90 to 0.00 at the completion of 5th week of therapy. However Pharmacological therapy showed less improvement in the mean score (8.33 to 3.83) after the same duration of therapy (i.e. after the completion of 5th week). This could be attributed to mechanism of action of Ayurvedic drugs. Curcumin inhibits the products of inflammation such as prostaglandin and leukotreines²⁶.

On the other hand, the polysaccharides contained in the gel of Aloe Vera leaves, induce the promotion of wound healing, and also have anti-inflammatory, immunomodulatory, and antioxidant properties. Further, sterols in the Aloe vera have strong ability to inhibit inflammation similar to the action of cortisone without any side effects²⁷. Anuradha A evaluated efficiency of Aloe vera in treatment of OSMF in 74 patients and found the clinical response to aloe vera was comparable to that of intralesional injections of hydrocortisone and hyaluronidase with antioxidant supplementation. This study concluded that aloe vera can be an alternative, safe, and effective treatment regime in the management of oral

submucous fibrosis. Long-term follow-up studies with larger sample size are recommended 24,25 . Our study also used combination of hyaluronidase (1500 IU) and dexamethasone (4 mg), weekly submucosal injections for 12 weeks. Like other studies, our study also shows significant improvement in inter incisional mouth opening in Group B using Intralesional injections. The mean interincisal opening in Group A & Group B at first visit was 27.20mm & 25.23mm respectively which increased at the end of 12th week of therapy, the mean for the two groups being 33.33mm & 33.13mm. The improvement in interincisal opening between 1^{st} to 12^{th} week is more in group B (31.31%) then group A (22.55%) whereas burning sensation reduction is more in group A (100%) than group B (99.60%) the drawback of intralesional injection of steroids is the local discomfort caused by injection. Although Group B showed better results as compared to group A, however the positive improvements encountered with Ayurvedic group were also quite encouraging and significant. In the present study Aloe Vera was found to be effective in reducing burning sensation and to a certain extent improvement in mouth opening in OSMF patients. Sudarshan R et al., found similar results that aloevera when compared with antioxidant, had a better response in oral submucous fibrosis (OSMF) patients in all the parameters assessed and in the entire clinicohistopathological stages particularly in those with mild stage clinically and early-stage Histopathological²⁴. Alam S et al., also conducted similar study in which they found that the group receiving aloe vera had a significant improvement (during treatment and follow up period) in most symptoms of OSMF like burning sensation, mouth opening, tongue protrusion, cheek flexibility compared with the non-aloe vera group²⁸. Thus, the findings in this study suggest a need for the further investigation on Aloevera & curcumin to have a fibrinolytic action in OSMF patients. Another limitation of our study was a less sample size. The bioavailability of curcumin is poor as curcumin is lipophilic compound so the maximum effectiveness of curcumin is not attained in the study group. Lack of Histopathological confirmation of the improvement at the end of the study is also a limitation observed in the present study. Thus our study highlights that Ayurveda therapy using aloe vera and turmeric shows promising results in treatment of OSMF. However, more high-quality, multi-centre randomized controlled trials with larger samples are needed to further assess the efficacy of these medicines in comparison to conventional pharmacological therapies.

CONCLUSION

The prevalence of OSMF was found to be more in males. Both Ayurvedic group and Pharmacological group showed marked increase in interincisal distance and reduction in burning sensation. Rate of increase in Inter-incisal distance was faster in Pharmacological group whereas rate of decrease in burning sensation in Ayurvedic treatment was faster. Comparing the two parameters mouth opening & the severity of burning sensation Conventional Pharmacologic therapy is more beneficial in improving the mouth opening in and Ayurvedic treatment benefits more in reducing the intensity of burning sensation. The clinical response to Aloe-vera & Turmix was comparable to intralesional injections of dexamethasone, hyaluronidase. No serious side effects were reported. Easy of availability, safety of use, cost effectiveness and non-invasiveness attributes of Aloe-vera & Turmix make it an alternative, effective choice of treatment regime in the

management of OSMF. Limitation is that lack of Histopathological confirmation of the improvement at the beginning and end of the study. Further studies involving a larger sample size with longer period of treatment follow up are recommended.

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