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THERAPEUTIC ULTRASOUND - A NEW RAY OF HOPE IN TREATMENT OF OSMF.

Dental Science

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ABSTRACT

The study aims to evaluate efficacy of drugs with jaw opening exercises in OSMF patients and comparing the same with addition of therapeutic ultrasound in stage II and stage III OSMF patients. 60 clinically diagnosed patients of OSMF were included having mouth opening 26mm-35mm (stage II) and 15mm-20mm (stage III) . Individual case history was recorded with details of habits and symptoms. Patients were divided into two groups of 30 patients each with institution of conventional method of treatment in Group I and ultrasound therapy in addition to conventional therapy in Group II.OSMF affects patients having positive history of betel nut chewing,young age and is more common in males. Significant relief in clinical symptoms and increased mouth opening during the course of treatment and quick relief was observed in Gr. II as compared to Gr. I patients treated by conservative therapy alone. Thus, Therapeutic Ultrasound' is a non-invasive treatment modality with no reported side effects and showing promising results making it sufficient to be used alone or along with conservative therapy as an alternative in the management of OSMF.

KEYWORDS

Osmf; M.m.o; Trismus.

INTRODUCTION:

OSMF is defined as a chronic insidious disease affecting any part of the oral mucosa and sometimes pharynx. Occasionally it is preceded and / or associated with vesicle formation and is always associated with juxtra epithelial inflammatory reaction followed by progressive hyalinization and fibro elastic changes in the lamina propria (sub epithelial fibrosis) with epithelial atrophy leading to stiffness of the oral mucosa and causing trismus and inability to eat.[1]

The etiology of OSMF is thought to be multifactorial that includes smoking, alcohol drinking, areca nut chewing, excessive consumption of chilies, spices, genetic predisposition etc.[2] But the recent evidences pointing mainly to betelnut chewing.

The major morbidity in OSMF patient is trismus and burning sensation in the oral cavity on consumption of hot and spicy food which is attributed to the inflammation of the oral tissues due to the presence of arecoline in arecanut [3,4]

The medical management of OSMF comprises of multivitamins, antioxidants, immunomodulatry drugs, topical or local injections of steroids, local injections of chymotrypsin, hyaluronidase, and placental extract. Surgical treatment comprises of excision of fibrous bands either by surgery or by laser and grafting by partial thickness skin flap, nasiolabial flap, buccal pad of fat or tongue flap [5,6,7,8,9,10]

Physiotherapy in the form of mouth stretching exercises has been found to be effective in quite number of patients as of today no ideal treatment has been identified. But with all these treatment modalities available including some invasive ones, the outcome is short lived.

'Therapeutic ultrasound' has been used in the treatment of keloids, burns, contractures etc. and has been successful because of its effect on the collagen fibers. It helps in making the collagen fibers more pliable and when used in OSMF patients it helps to improve the mouth opening as when used in combination with stretching exercises. [11,12,13]

So far antioxidants, topical steroids and physiotherapy (mouth stretching exercises) is used in treatment of OSMF with variable results. In the present study along with these conventional conservative methods therapeutic ultrasound is tried to evaluate the treatment outcome in term of reducing burning sensation and trismus in OSMF patients.

AIMS & OBJECTIVES:

The study aims to evaluate efficacy of drugs and jaw opening exercises in stage II & stage III OSMF patients – Group I and comparing the same with addition of therapeutic ultrasound – Group II.

MATERIALS & METHODS:

After obtaining prior permission from institutional ethics committee, an interventional study was carried out on 80 randomly selected patients of oral submucous fibrosis (OSMF). The study included 75 males and 5 females with age range of 18 – 41 years and having stage II (26mm-35mm mouth opening) and stage III (15mm-20mm mouth opening) of oral submucous fibrosis.

All the patients were strictly advised to discontinue the habit during the treatment and patients unable to do so were excluded from the study.

GROUP I:

Jaw opening exercises for 8 weeks, topical Triamcinolone acetonide for first15 days.(Fig I b) , antioxidants during the trial period. (Fig I c). Evaluation of mouth opening and other symptoms were done every week for 2 months.(Fig I a & I c)

Group II Same as group I with addition of Ultrasound therapy given daily for 7days in first and fifth week (total 15 cycles).

THE APPLICATION OF THE ULTRASOUND:

The treatment head was placed in contact with the cheeks using a coupling agent i.e. aquasonic gel and was slowly moved in a circular manner in relationship with the part while maintaining a perfect contact. Similar procedure was done on other side. Dosage: The treatment was given for 7 minutes and the intensity used was 0.7 Watts/cm^2. The treatment was given for 7 consecutive days followed by jaw opening exercises. The process was repeated again in second month for one week. (Fig I d)

JAW OPENING EXERCISES :

Compromising of Wide mouth opening, Lateral excursion of mandible, Protrusion of mandible and gradual mouth stretching.(Fig. II a,b,c & d)

Evaluations of the treatment outcome was made by: Measurement of Maximum Mouth Opening (M.M.O.) at the beginning, at the end of 1st week, 5th week, and 8th week by Vernier Caliper and also accessed by use of number of tongue blades at the designated time and

observations of symptom of burning sensation and ulceration observed throughout the study.

RESULTS:

The result and observation of the study is measured and interpreted as Group I and Group II consisting of 30 patients each (20 were excluded from initial 80 due to irregular visits), randomly divided into Stage II and Stage III OSMF of which in Group I, 19 (31.7%) patients were in stage II and 11 (18.3%) patients were in stage III and in Group II, 12 (20%) patients were in stage II and 18 (30%) patients were in stage III.

All the 60 patients in the present study gave a positive history of areca nut chewing in either the raw form 14 (23.3%), as a quid 1 (1.7%) or in a commercial preparation such as gutkha 38 (63.3%) .

Clinical symptom of burning sensation was present in 54 (90%), of which 29 (48.3%) were in stage II and 25 (41.7%) in stage III. This shows that in stage II burning sensation was slightly more. The history of ulceration was positive in 45(75%) of patients, of which 22(36.5%) were in stage II and 25(38.3%) were in stage III. This shows that at beginning the burning sensation was in 17(31.48%) patients in Stage II and 10(18.51%) in Stage III patients of Group I and 12(22.22%) patients in Stage II and 15(27.77%) in Stage III patients of Group II.

After the onset of treatment, it was observed that the burning sensation was reduced to zero in second week in all groups II patients (100%) as compared to group I in which it took 3-4weeks for 100% relief. (Table I).

Table I : Correlation between improvements in burning sensation in OSMF according to staging within Groups.

Burning Sensation	Stage II		Stage III		Total
	Group I	Group II	Group I	Group II	
At The Begning	17(31.48%)	12(22.22%)	10(18.51%)	15(27.77%)	54(100%)
At 1st week	15(27.77%)	9(16.6%)	8(14.81%)	13(24%)	40(74%)
At 2nd week	3(5%)	0	2(3%)	0	5(9%)
At 3rd week	1(1%)	0	1(1%)	0	2(3%)
At 4th week	0	0	0	0	0

In our study 23.3%,53.3% and 48.3% were the values obtained out of 100% (60) for Defective gustatory sensation, restricted tongue movements and speech defect respectively with higher values in stage III (13.3%,30% and 30%) as compared to stage II (10%,18.3%,23.3%) respectively.

When intra-group comparison was made with Wilcoxon Signed Ranks Test at beginning, at end of 1st week , 5th week and 8th week, the results obtained shows that there is increase in amount of mouth opening measurement in Group I(Table II) (Graph 1) and Group II(Table III) (Graph 2) patients at exit i.e 8th week compared to beginning. When comparison among the groups according to OSMF staging i.e Stage I and Stage II was done, it showed significant increase in mouth opening measurement in stage III of Group II patients. (Table IV) (Graph 3).

Table II: Comparison of maximum mouth opening among Group I patients. (at the beginning, at the end of 1st week, 5th week and 8th week of treatment). (Graph 1)

Maximum Mouth Opening	N	Mean	Std. Deviation	Minimum	Maximum
At the BEGNING	30	25.88	5.77	15.50	35.00
At 1st week	30	26.92	5.77	16.9	35.5
At 5th week	30	29.01	6.0	19	42
At 8th week	30	30.24	6.39	19.9	44.6

Multiple Comparison by Wilcoxon Signed Ranks Test

	1st week - BEGINNING	5th week - BEGINNING	8th week – BEGINNING
Z- value	-4.714)	-4.783	-4.784
P -value	0.000	0.000	0.000

P<0.000 very highly significant

Graph 1: Comparison of maximum mouth opening among Group I at the beginning, at the end of 1st week, 5th week and 8th week of treatment.

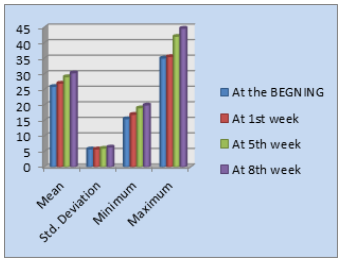


Table III : Comparison of maximum mouth opening among Group II patient (at the beginning, at the end of 1st week, 5th week and 8th week of treatment). (Graph2)

Maximum Mouth Opening	N	Mean	Std. Deviation	Minimum	Maximum
At the BEGNING	30	24.17	3.54	18.00	30.64
At 1st week	30	26.36	3.45	20.0	33.5
At 5th week	30	29.18	4.11	22	37
At 8th week	30	31.31	3.99	24.2	39.1

Multiple Comparison by Wilcoxon Signed Ranks Test

	1st week - BEGINNING	5th week - BEGINNING	8th week – BEGINNING
Z- value	-4.784	-4.783	-4.782
P –value	0.000	0.000	0.000

P<0.000 very highly significant

Graph 2: Comparison of maximum mouth opening among Group II at the beginning, at the end of 1st week, 5th week and 8th week of treatment.

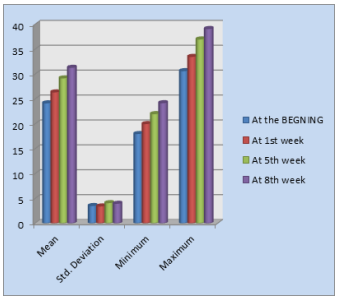
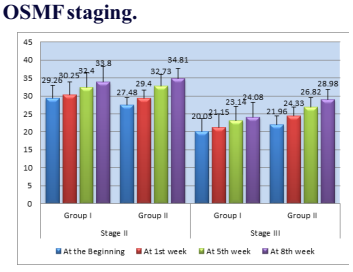


Table IV: Comparison of mouth opening with Group I and Group II.(at the beginning, at the end of 1st week, 5th week and 8th week of treatment) (Graph 3)

Maximum Mouth Opening	Groups		p- value
	Group I	Group II	
At the BEGNING	25.88± 5.77	24.17±3.54	0.147
At 1st week	26.92±5.77	26.36±3.45	0.689
At 5th week	29.01±6.0	29.18±4.11	0.829
At 8th week	30.24±6.39	31.31±3.99	0.419

P > 0.000 i.e not significant

Graph 3: Comparison of Mouth opening within study groups according to OSMF staging.



When mean difference was calculated between the mouth opening at beginning and that at exit between the Group I and Group II and was

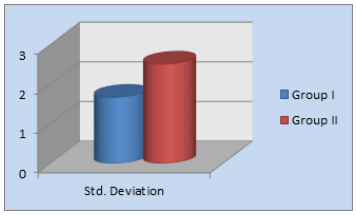
compared, the result obtained showed that there was highly significant increase in mouth opening measurement in Group II patients in stage III. (Table IV & V) (Graph 3 & 4).

Table V: Comparison of mouth opening within study groups according to OSMF staging.

Maximum Mouth Opening	Stage II		Stage III	
	Group I	Group II	Group I	Group II
At the BEGNING	29.26 ± 3.67	27.48±2.01	20.03±3.61	21.96±2.43
At 1st week	30.25±3.63	29.40±2.25	21.15±3.88	24.33±2.49
At 5th week	32.40±4.06	32.73±3.23	23.14±3.95	26.82±2.68
At 8th week	33.80±4.41	34.81±2.86	24.08±4.19	28.98±2.75

*p<0.05 significant

Graph 4 : Comparison of Mean difference among study groups at end of 8th week



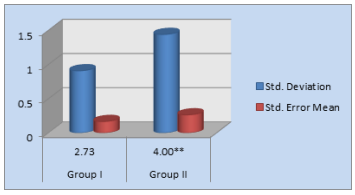
When comparison was done of the difference between the number of tongue blades at beginning and at exit i.e. 8th week used by patients for mouth stretching exercise and MO measurement, it was observed that in Group II the number of tongue blades increased rem arkably (p< 0.000). (Table VI)(Graph 5)

Table VI : Comparison of difference of number of tongue blades (used for MO measurement at beginning and at exit) with OSMF staging. (Graph 5)

GROUPS	N	Mean	Std. Deviation	Std. Error Mean
Group I	30	2.73	0.907	0.166
Group II	30	4.00**	1.438	0.263

**P<0.000 very highly significant

Graph 5: Comparison of difference of tongue blades (used for MO measurement at beginning and at exit) with OSMF staging.



DISCUSSION:

OSMF is characterized by trismus which is its major morbidity with addition of burning sensation and ulcerations. With the various modalities that have been used and tried so far, the success rate is limited and reversal of the trismus has been observed. Thus, 'Therapeutic ultrasound' which has shown promising results in treatment of scars, keloids and post burn contracture by decreasing the collagen formation and increasing its destruction, has been hypothesized in reduction of fibrosis in OSMF patients with its additive antinflammatory effect in treatment of burning sensa tion.[14,15,16,17]

In all 60 patients a positive history of areca nut chewing either in the raw form 14 (23.3%), as a quid 1 (1.7%) or in a commercial preparation such as gutkha 38 (63.3%) or combination of Betel nut + Gutkha+ Tobacco 1 (1.7%) was present in the present study, which according to the literature [4,18,19,20]was implicated to be a major causative agent for oral submucosal fibrosis. Some associated habits were also present along with betel nut in selected subjects, such as tobacco 4 (6.7%), cigarette smoking 15 (25%) and alcohol consumption in 25 (41.7%) of all 60 patients.

Vali Rajalalitha [21] has discussed that betel nuts contain an active alkaloid called arecoline, which stimulates fibroblasts to increase production of collagen by 150 %. OSMF remains active even after cessation of the chewing habit, suggesting that the components of the areca initiate OSMF and then it is the affect of gene expression in the fibroblasts, which then produce greater amounts of normal collagen. And thus, the first line of treatment being stoppage of its consumption before and after any therapy.[21]

After the onset of treatment , it was observed that the burning sens ation was reduced to zero in second week in all group II patients (100%) whereas, it took 3-4weeks for 100% relief in group I patient . Local application of corticosteroid was common factor in both group I and group II patients, however in addition group II patients received ultrasound indicating that therapeutic ultrasound played a positive role in healing of inflammation in OSMF as that of other ulcers reported in literature.[13,22]

On follow up, none of the patients reported ulceration during the period of study and on clinical examination, prompting the effectiveness of the therapy in both the groups, as also observed by *Jirge Vasanti*[22], Hayes PA[6] and Gupta Soma[3] in their studies and reported that, after administration of medicinal treatment (antioxidants and steroid).

Antioxidants are substances that interact with free radicals and prevent cellular damage serving as noninvasive treatment modality for OSMF. [3,9,19,22]Triamcinolone acetonide can be used for topical application with its anti-inflammatory action on burning sensation and ulcer formation.[4,19,20,23] In both Group I and Group II patients - the MO at baseline and at exit was found to be significant which is in accordance with previous studies that antioxidants and topical steroid play an important role in management of OSMF (p<0.05).

The intragroup comparison of MO at beginning, at end of 1st week, 5th week and 8th week in Group I patients was found to be highly significant statistically (p value < 0.000) and the similar results were obtained in intra group comparision of MO at the beginning and at the end of 1st week, 5th week and 8th week in Group II patients, which showed that there was improvement in MO measurement in OSMF patients irrespective of the interventions used in the period of two month i.e. 8 weeks.

However, when inter group comparison was made between Group I and Group II based on stage II and stage III patients, it was observed that the MO measurement in stage III was found to be statistically significant (28.98±2.75) (p < 0.05) at 8th week i.e. at exit (Table V).

Also on comparison of difference of MO at baseline (at beginning) and at exit (8th week) between Group I and Group II, statistically highly significant difference (p< 0.0000) in MO measurement was observed in Group II patients . This showed that the patients of early stage of OSMF can be successfully treated with conservative therapy i.e. antioxidants, topical steroid and jaw opening /stretching exercises, but if ultrasound is added in the therapy, results are excellent especially in patients with high grades of trismus as in stage III and significant reduction in burning sensation, which are the major morbidities in OSMF patients. This is attributed due to the property of ultrasonic waves to produce tissue heating at a deeper level than moist heat; this increase in local tissue temperature leads to increase in blood flow and removal of metabolic by products responsible for pain and may help decrease adhesions by disrupting collagen cross-linkage[24,25,26].

When comparison was done between the number of tongue blades used by patients at beginning and at exit i.e. 8th week for mouth stretching exercise ,it was observed that in Group II patients the number of tongue blades increased remarkably suggesting an additive effect of ultrasound in relieving trismus in OSMF patients[26].

Thus, 'Therapeutic ultrasound' can therefore be used as a treatment modality in OSMF patients which will play a substantial role in successful management or control of progression of this debilitating condition.

CONCLUSION:

'Therapeutic Ultrasound' with the property of collagen extensibility helps in reduction of the fibrosis in OSMF patients in addition to its anti-inflammatory effects on burning sensation and ulcer formation, giving a quicker recovery as compared to Group I . Also as it has no side effects, it can be tried in a larger sample size of patients with long term follow up to confirm its efficacy and accordingly frequency and

number of cycles can be altered in order to get superior results. Thus to conclude, in the present study Group II patients receiving 'Therapeutic Ultrasound' gave better results as compared to Group I receiving only conservative treatment consisting of systemic antioxidant, topical steroid and mouth stretching exercises, suggesting that 'Therapeutic Ultrasound' helps in increasing the MO , reducing burning sensation and ulcer formation in OSMF patients .

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CONFLICT OF INTEREST:

- There is 'NO Conflict of Interest'
- This article has not been submitted to any other journal for publication.
- There has been no funding for this study by any person or company.
- Before starting the clinical trial – informed consent has been taken from the patients.

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