



Comparative Evaluation of Lycopene and Therapeutic Ultrasound by Using Diagnostic Ultrasonography in the Management of Oral Submucous Fibrosis (OSMF): A Clinical Trial

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Abstract

Introduction: Oral Submucous Fibrosis is considered to be multifactorial with several treatment modalities available but only to provide symptomatic relief. The use of non-invasive biological techniques with minimal or no side effects is highly recommended in view of its premalignant nature.

Methodology: A total of 40 patients (20 in each group) who were clinically and histopathologically diagnosed as OSMF were included in the study. The patients were subjected to diagnostic ultrasonography to evaluate the masseter muscle and submucosal thickness. All the patients were then randomly divided into 2 equal groups where group I was given Lycopene therapy (8 mg twice a day for 3 months) and Group II was given therapeutic ultrasound in continuous mode at a frequency of 3 MHz and intensity of 1-1.25 W/cm² for 15

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minutes on each side of cheek (for consecutive 15 days). After that it was administered thrice in a week for next 15 days and then twice a week for next 1 month. All the patients were followed up at 7th day, 15th day, at 1 month and 3 months to evaluate all the parameters. After 3 months, post treatment Diagnostic USG was done to evaluate treatment outcome.

Results: There was a statistically significant difference observed among both the groups. There was significant reduction in burning sensation on VAS, ($p < 0.005$), increase in mouth opening and cheek flexibility ($p < 0.005$) in Therapeutic ultrasound group as compared to Lycopene group on 1 month and 3 months follow up visits.

Conclusion: Therapeutic ultrasound showed more improvement in improving signs and symptoms of OSMF as compared to Lycopene therapy.

Keywords

OSMF, Diagnostic Ultrasound; Anti-Oxidants; Physical Therapy; Therapeutic USG

Introduction

Oral Submucous Fibrosis (OSMF) is a chronic, insidious, progressive, scarring disease characterized by blanching, stiffness and fibrosis of the oral cavity [1]. The prevalence rate of this condition in Indian subcontinent is ranging between 0.2 to 1.2% [2].

The etiology of OSMF remains unclear and appears to be multifactorial [3]. The main aim in the management of OSMF is to relieve the symptoms like burning sensation as well as to improve the mouth opening apart from preventing its conversion to malignancy as the malignant potential rate is approximately 7-30% [4].

Also, since OSMF is known to be a condition with oxidative stress. Hence, strengthening the antioxidant system with supplements improves the signs and symptoms of OSMF significantly [5]. In our study, Lycopene is taken as one of the treatment options as it is extensively been studied in the treatment of OSMF since so many years. It is a powerful antioxidant and has a singlet-oxygen-quenching ability twice as high as that of beta-carotene and ten times higher than that of alpha-tocopherol [6].

Other than the various pharmacological treatment modalities available, the other Therapeutic option for relieving the symptoms of OSMF is physical therapy such as exercises, diathermy and therapeutic ultrasound. Literature suggests that during ultrasound therapy cell membrane permeability is increased leading to improved gas exchange which helps in the healing [7].

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Since it is a new therapeutic modality in the management of OSMF, there is paucity of literature evaluating the efficacy of therapeutic ultrasound in the management of OSMF. Multiple therapeutic regimes have come up for the treatment of OSMF but still a need for more efficient non-invasive, less expensive and biologically inert modality to manage such cases still continues.

Very few studies till now have been done to evaluate the efficacy of therapeutic ultrasound in management of OSMF. In view of this, the present study included Therapeutic ultrasound as another treatment modality in OSMF patients.

One of the most important aspect after a particular treatment is initiated in a patient is to assess the treatment outcome. Most of the studies have evaluated treatment outcome on the basis of clinical symptoms like reduction in burning sensation on VAS. In the present study we evaluated the treatment outcome by studying the changes on masseter muscle thickness and submucosal thickness using pre and post diagnostic ultrasonography. Studies have reported increase in the sub-mucosal thickness and masseter hypertrophy with advancing stage of OSMF [8]. Thus diagnostic ultrasound has been used as an investigating tool in this study to assess the severity of OSMF and also to evaluate the effectiveness of the management provided. Therefore, the main aim and objective of the study was to evaluate and compare the effectiveness of Lycopene and therapeutic ultrasound using clinical parameters and diagnostic ultrasonography.

Methodology

For this Randomized clinical trial, the patients were selected from the OPD of Department of Oral Medicine and Radiology. All the patients were explained about the study and a written informed consent was taken.

The patients were randomly allocated into two different groups i.e. one receiving Lycopene and the other group receiving Therapeutic ultrasound therapy. The institutional ethical committee clearance with ethical no. ITSCDSR/IEC/2018-21/OMR/01 has been obtained before starting the study.

The patients matching with the inclusion criteria and those who were clinically, ultrasonographically and histopathologically diagnosed and confirmed with the OSMF were included in the study.

Inclusion criteria:

- Burning sensation on intake of spicy foods
- Depapillation and blanching of oral mucosa
- Palpable fibrous bands and restricted mouth opening
- Shrunken uvula

Exclusion criteria:

- Fibrosis of oral mucosa leading to decreased mouth opening due to reasons other than OSMF such as anaemia, scleroderma, post radiation therapy, masseter muscle hypertrophy, temporo-mandibular joint disorders due to malocclusion, bruxism, impacted 3rd molar and other deleterious habits
- Patients with chronic illness, hypertension, pregnancy and any kind of allergy and medically compromised patients were excluded
- Patients who underwent treatment of OSMF previously were excluded
- Burning sensation on VAS was assessed with the grading of 0 to 10 in which 0 was counted as no burning sensation on VAS and 10 was counted as severe burning sensation. The maximum inter-incisal mouth opening was measured by using a measurement scale

Cheek flexibility and Tongue Protrusion was also checked by using a measurement scale. Prior to the treatment all the patients were subjected to diagnostic ultrasound for evaluation of sub mucosal and masseter muscle thickness and the baseline measurements were recorded.

Ultrasonographic images were evaluated by two observers with the patient lying in the supine position. The USG device that was used for the patients was LOGIQ C5 Premium (GE Health Care) with frequency of 6.0 MHz. Prior to USG for sub mucosal and master muscle thickness, the patients were asked to stretch the mucosa outside by placing the index finger on the buccal mucosa so as to equalize the empty space of the oral cavity. The transducer probe was kept in such a manner that no soft tissues were compressed as excessive pressure might lead to changes in the measurements of the thickness.

The mucosal lining was seen as a hyperechoic line and sub mucosa as hypoechoic band. This band of hypo echogenicity between the hyperechoic mucosa and muscle layer was measured as thickness of sub mucosa. After that, all the selected and histopathologically confirmed OSMF patients were counselled for habit cessation.

After diagnostic USG, patients were divided into 2 groups:

- Group 1: Patients were given Lycopene 16 mg dose in two divided doses for 3 months
- Group 2: Patients were subjected to Therapeutic ultrasound (Electroson- 709)

Saini R | Volume 3; Issue 1 (2022) | JDHOR-3(1)-043 | Research Article

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For group 1, the follow up was done at day 7, day 15th, 1 month and 3 months and all the parameters were recorded

For group 2, the patients were given therapeutic ultrasound for consecutive 15 days in which two days off was permissible and the follow up was done at day 7, day 15th, 1 month and 3 months. After 15th day, the patients were subjected to therapeutic ultrasound thrice a week for next 15 days and then twice a week for 1 month. All the patients of both the groups were instructed for mouth opening exercise for 10 minutes twice a day. All the parameters were recorded in the Performa on each follow up.

Results

Table-1 depicts the comparison of the burning sensation reduction, Mouth opening, Cheek flexibility and Tongue protrusion among both the groups at different intervals i.e. on Day 7, Day 15, 1 month and 3 months. The mean percentage improvement of burning on VAS was statistically significant at 7th day, 15th day, on 1 month and 3 months follow up whereas Mouth opening, Cheek flexibility and Tongue Protrusion in Group II was more at 1 month and 3 months follow up respectively after the treatment as compared to Group I [Fig. 1-6].

On comparing the mean difference in tongue protrusion, no statistically significant difference was found in both the groups on 1 and 3 months follow up.

Table 2 depicts- On pph comparing the mean difference in submucosal thickness, statistically significant difference was seen in both the groups at 3 months follow up.

On 3 months follow up, there was reduction in the mean submucosal mucosal thickness in group II as compared to group I from baseline to 3 months follow up with statistically significant difference.

And on comparing the mean difference in submucosal thickness from Day 1 to 3 months, the mean difference values in Lycopene (Group I) was less than Therapeutic ultrasound (Group II) which was statistically significant.

Table 3 depicts- On comparing the mean percentage change in masseter muscle thickness from baseline to 3 months follow up, the values for Lycopene were less than the Therapeutic ultrasound group with statistically significant difference.

Therefore, the mean masseter muscle thickness difference from baseline (Day 1) to 3 months was significantly more among therapeutic ultrasound (Group II) compared to Lycopene (Group I).

On comparing the mean difference in masseter muscle thickness, statistically significant difference was seen in both the groups at 3 months follow up.

On 3 months follow up, there was reduction in the mean masseter muscle thickness among both the groups in Lycopene group than the Therapeutic ultrasound group, with statistically significant difference.

On comparing the mean percentage change in masseter muscle thickness from baseline to 3 months follow up, the value for Lycopene was less than the therapeutic ultrasound with statistically significant difference. Therefore, the mean masseter muscle thickness difference from baseline (Day 1) to 3 months was significantly more among therapeutic ultrasound (Group II) compared to Lycopene (Group I)[Fig. 1-14] .

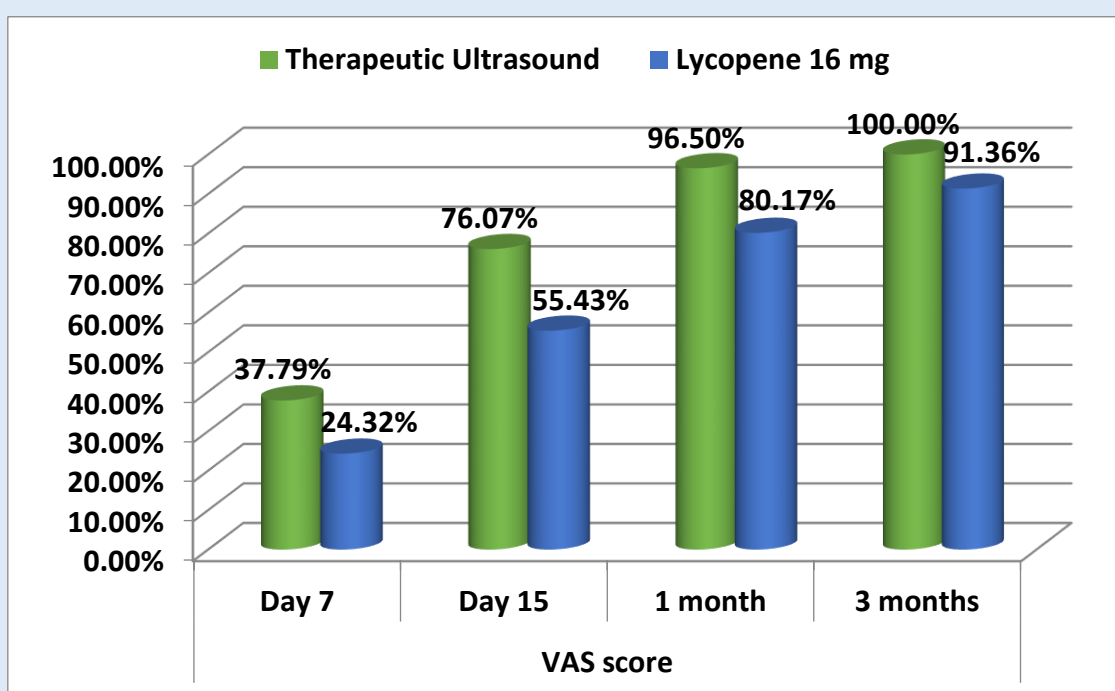


Figure 1: Bar graph depicting mean percentage reduction in burning sensation on VAS among both the groups (Lycopene and Therapeutic Ultrasound).

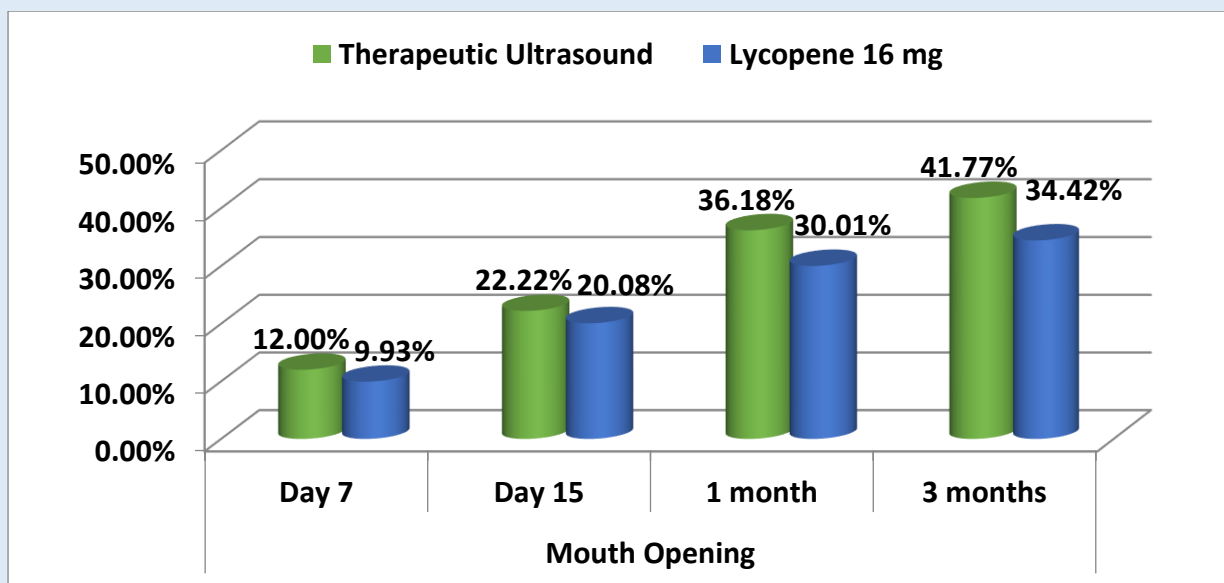


Figure 2: Bar graph depicting the mean percentage improvement in mouth opening among both the groups (Lycopene and Therapeutic Ultrasound).

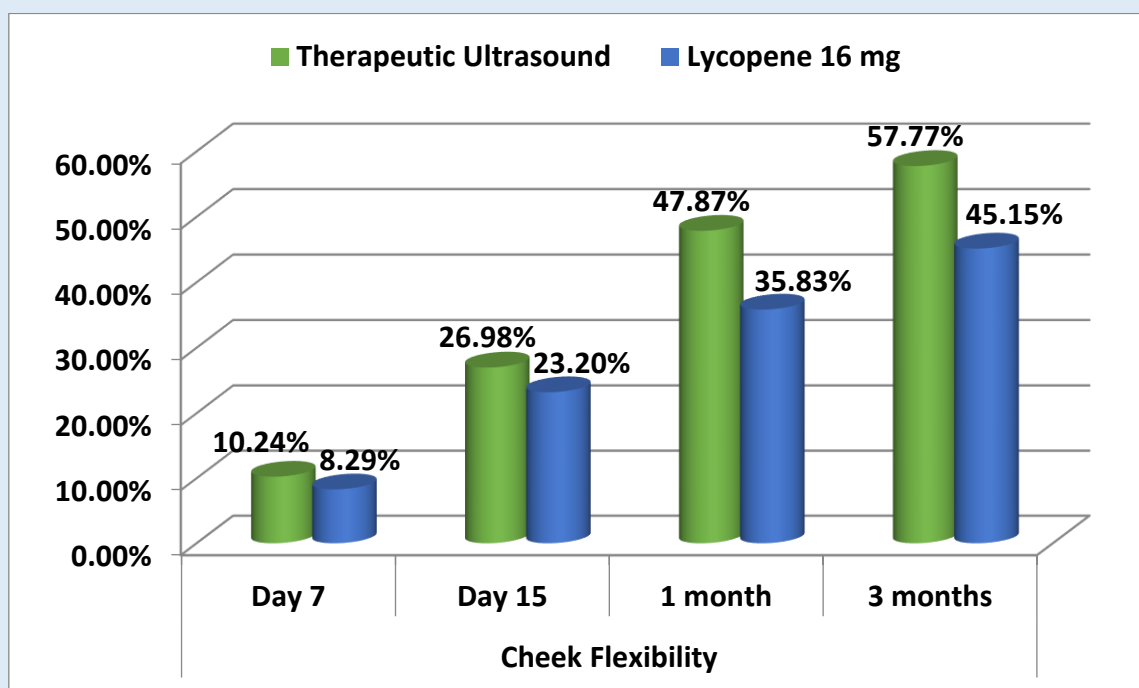


Figure 3: Bar graph depicting the mean percentage improvement of cheek flexibility among both the groups (Lycopene and Therapeutic Ultrasound).

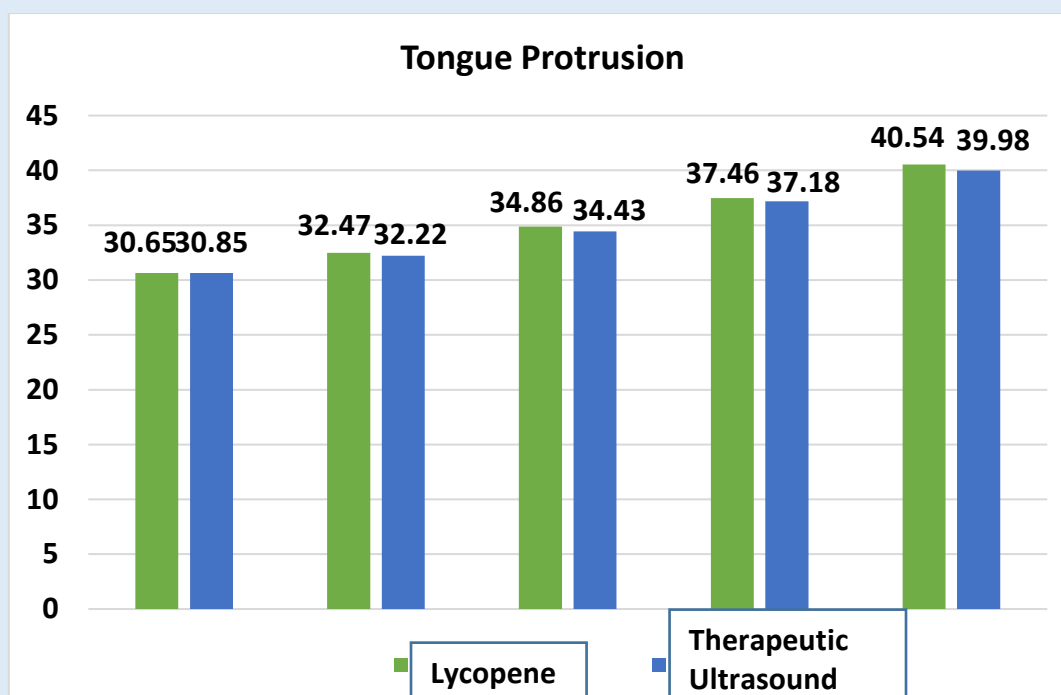


Figure 4: Bar graph depicting difference in tongue protrusion among both the groups (Lycopene and Therapeutic Ultrasound).

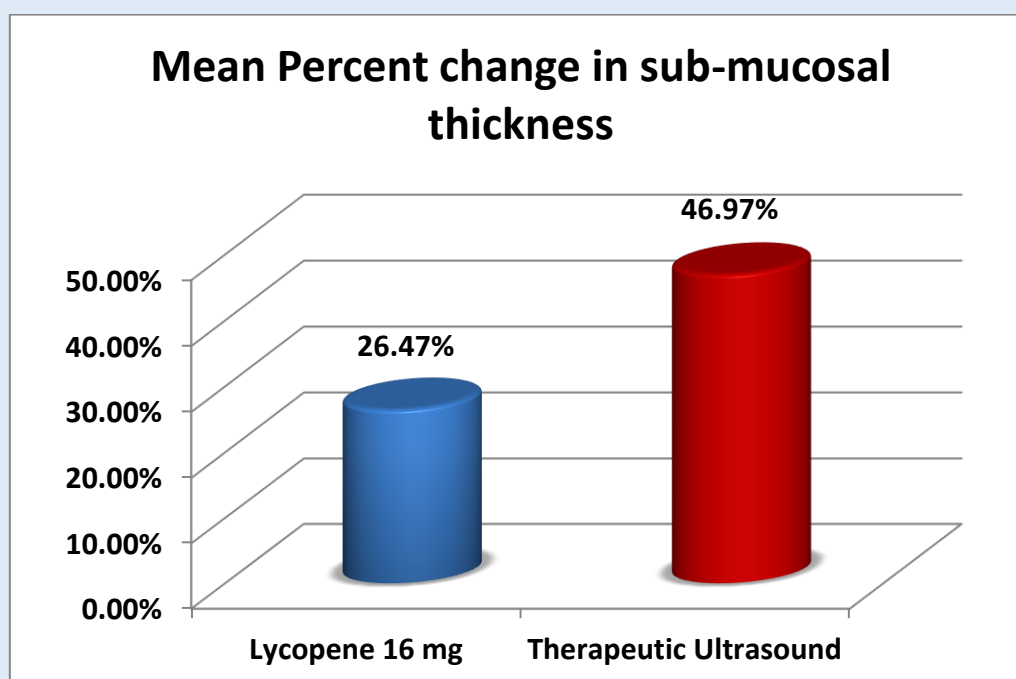


Figure 5: Bar graph depicting mean percentage change in sub-mucosal thickness after treatment on 3 months among both the groups (Lycopene and Therapeutic Ultrasound).

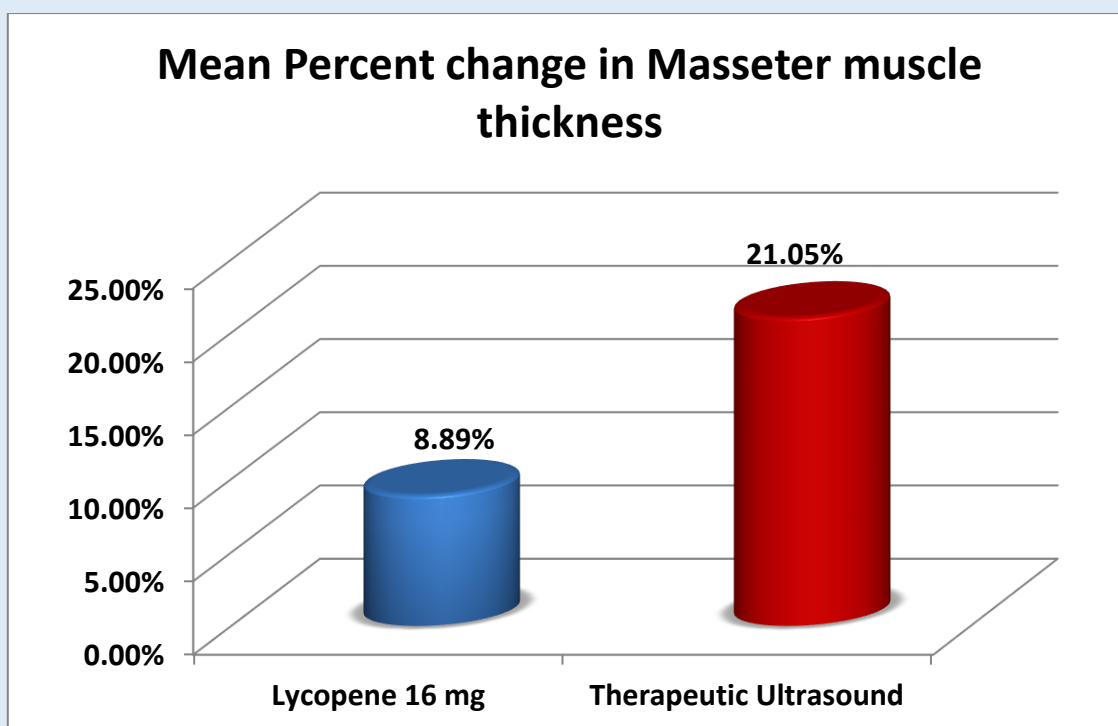


Figure 6: Bar graph depicting the mean percentage change in masseter muscle thickness after the treatment on 3 months follow up among both the groups (Lycopene and Therapeutic ultrasound).

	Lycopene 16 mg		Therapeutic Ultrasound		Mean Difference	t-test value	p-value
Burning on VAS							
VAS score	Mean	Std. Deviation	Mean	Std. Deviation			
Day 7	24.32%	5.72%	37.79%	10.85%	13.47%	4.913	0.001*
Day 15	55.43%	11.70%	76.07%	14.01%	20.64%	5.057	0.001*
1 month	80.17%	12.29%	96.50%	7.45%	16.33%	5.082	0.001*
3 months	91.36%	6.82%	100.00%	0.00%	8.64%	3.043	0.004*
Mouth Opening							
Day 7	9.93%	3.53%	12.00%	5.09%	2.07%	0.053	0.958
Day 15	20.08%	6.68%	22.22%	8.53%	2.14%	0.883	0.383
1 month	30.01%	9.98%	36.18%	10.37%	10.37%	3.363	0.019*
3 months	34.42%	10.99%	41.77%	11.20%	7.35%	3.385	0.023*

Saini R | Volume 3; Issue 1 (2022) | JDHOR-3(1)-043 | Research Article

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Cheek Flexibility							
Day 1	2.41	1.02	2.39	1.00	0.02	0.062	0.951
Day 7	2.65	1.02	2.58	1.02	0.06	0.201	0.842
Day 15	3.25	1.21	3.08	1.20	0.17	0.434	0.667
1 month	3.87	1.57	4.60	1.72	0.73	2.044	0.046*
3 months	4.94	2.77	5.88	2.91	0.94	2.156	0.042*
Tongue Protrusion							
Day 1	30.65	10.84	30.85	10.84	0.00	0.000	1.000
Day 7	32.47	10.88	32.22	10.83	0.25	0.074	0.941
Day 15	34.86	10.47	34.43	10.53	0.43	0.129	0.898
1 month	37.46	10.06	37.18	10.17	0.28	0.088	0.931
3 months	40.54	9.68	39.98	9.60	0.56	0.182	0.857
P value < 0.05 is considered as significant					* Significant difference		

Table 1: Comparison of mean of percentage reduction in burning sensation, mouth opening, cheek flexibility and tongue protrusion among two groups at different intervals.

	Lycopene		Therapeutic Ultrasound		Mean Difference	t-test value	p-value
Submucosal thickness	Mean	Std. Deviation	Mean	Std. Deviation			
Day 1	0.25	0.06	0.27	0.06	0.00	0.000	1.000
3 months	0.18	0.05	0.13	0.03	0.05	4.264	<0.001
Difference from day 1 to 3 months	0.06	0.02	0.12	0.04	-0.05	-5.513	<0.001
Percent change in sub-mucosal thickness							
Groups	Mean	Std. Deviation	Mean Difference	t-test value	p-value		
Lycopene	26.47%	7.99%	-20.50%	-8.377	0.000*		
Therapeutic Ultrasound	46.97%	7.48%					
P value < 0.05 is considered as significant * Significant difference							

Table 2: Comparison of mean difference and percentage change in submucosal thickness among two groups at different intervals.

Saini R | Volume 3; Issue 1 (2022) | JDHOR-3(1)-043 | Research Article

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	Lycopene		Therapeutic Ultrasound		Mean Difference	t-test value	p-value
	Mean	Std. Deviation	Mean	Std. Deviation			
Masseter muscle thickness							
Day 1	1.13	0.04	1.14	0.04	0.00	0.000	1.000
3 months	1.03	0.04	0.90	0.10	0.13	5.828	<0.001
Difference from day 1 to 3 months	0.10	0.02	0.24	0.08	-0.14	-7.644	<0.001
Percent change in Masseter muscle thickness							
Groups	Mean	Std. Deviation	Mean Difference	t-test value	p-value		
Lycopene	8.89%	2.14%	-12.16%	-7.188	0.000*		
Therapeutic Ultrasound	21.05%	7.26%					
P-value < 0.05 is considered as significant				* Significant difference			

Table 3: Comparison of mean difference and percent change in masseter muscle thickness among two groups at different intervals.

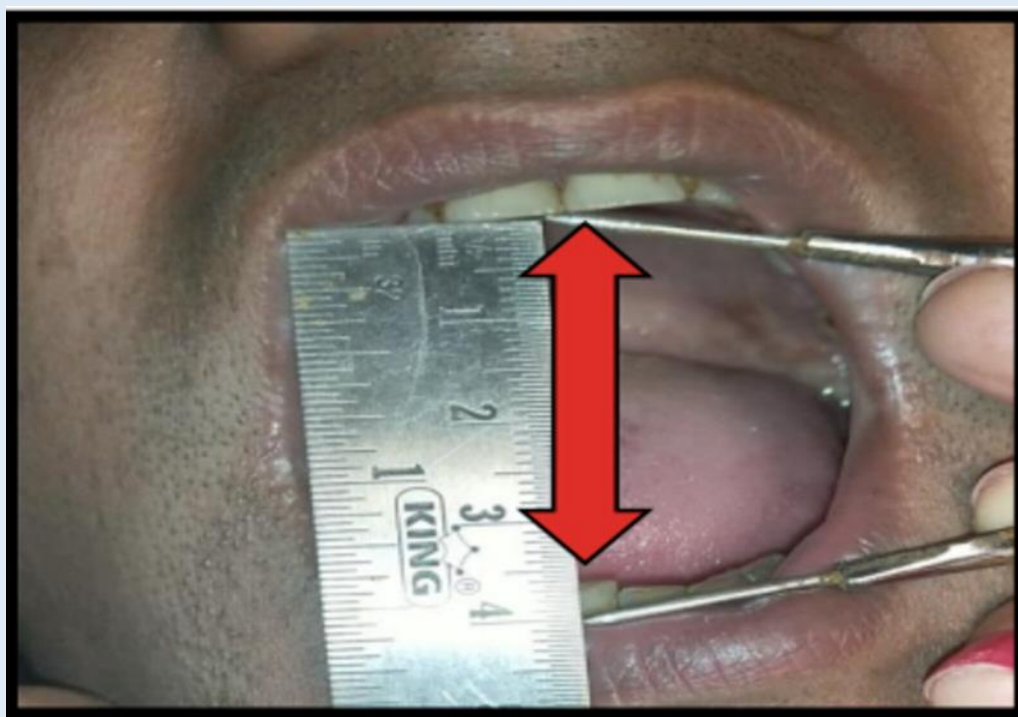


Figure 7: Pre lycopene therapy mouth opening.

Saini R | Volume 3; Issue 1 (2022) | JDHOR-3(1)-043 | Research Article

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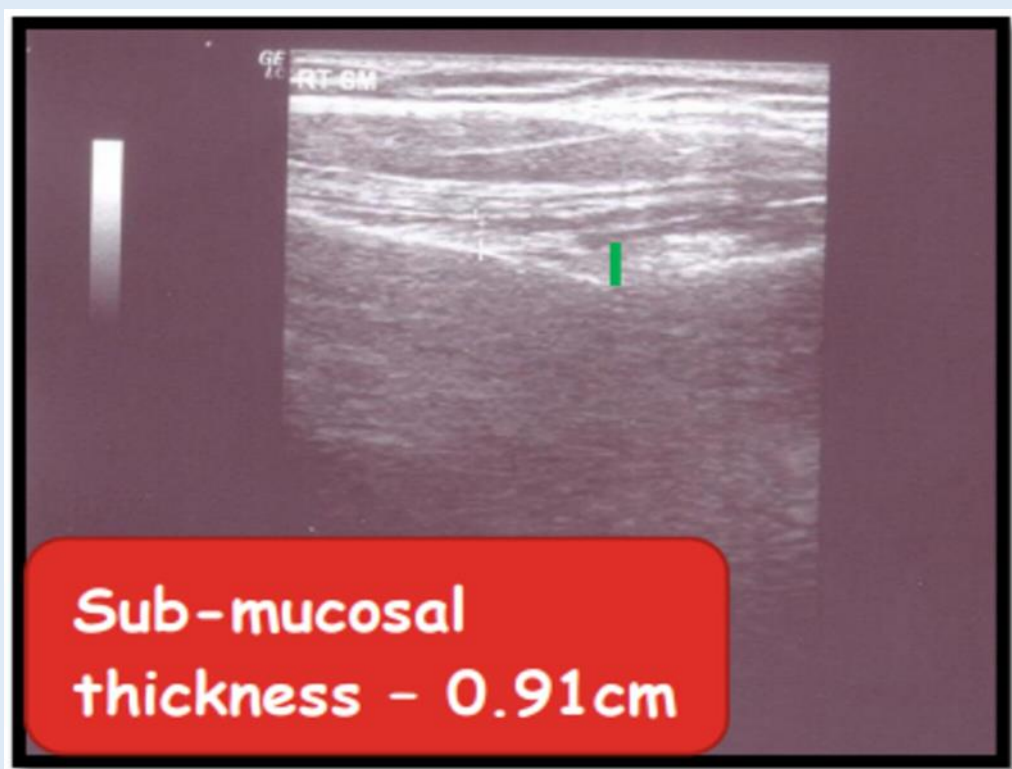


Figure 8: Pre lycopene therapy diagnostic ultrasound.

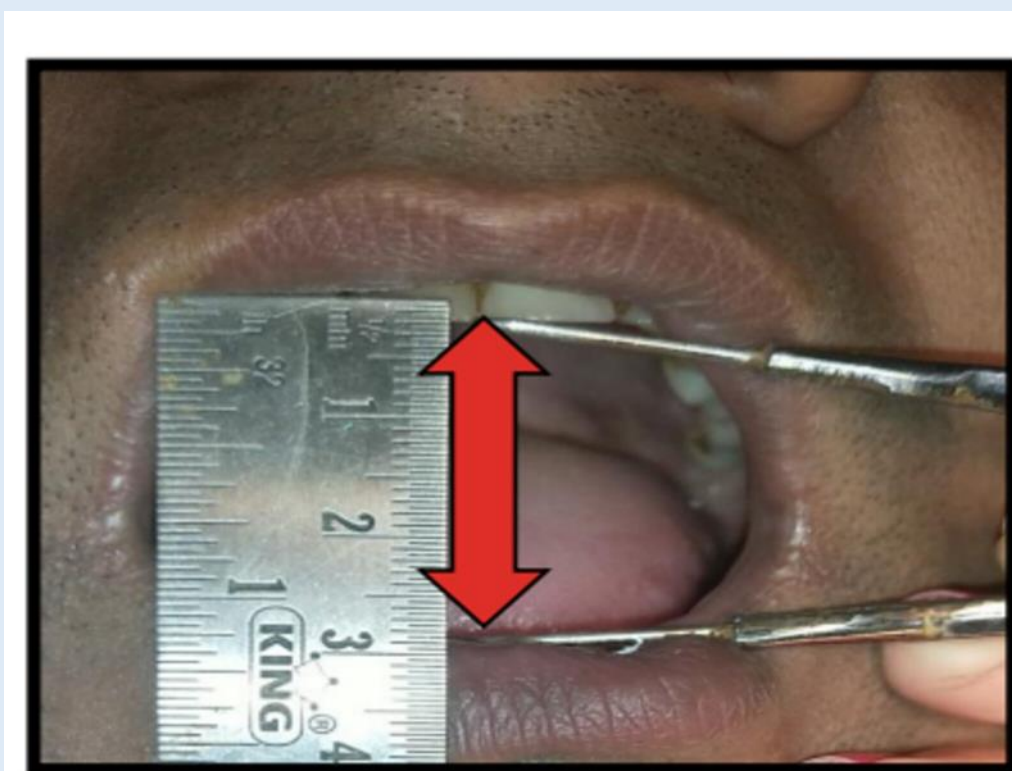


Figure 9: Post lycopene therapy mouth opening.

Saini R | Volume 3; Issue 1 (2022) | JDHOR-3(1)-043 | Research Article

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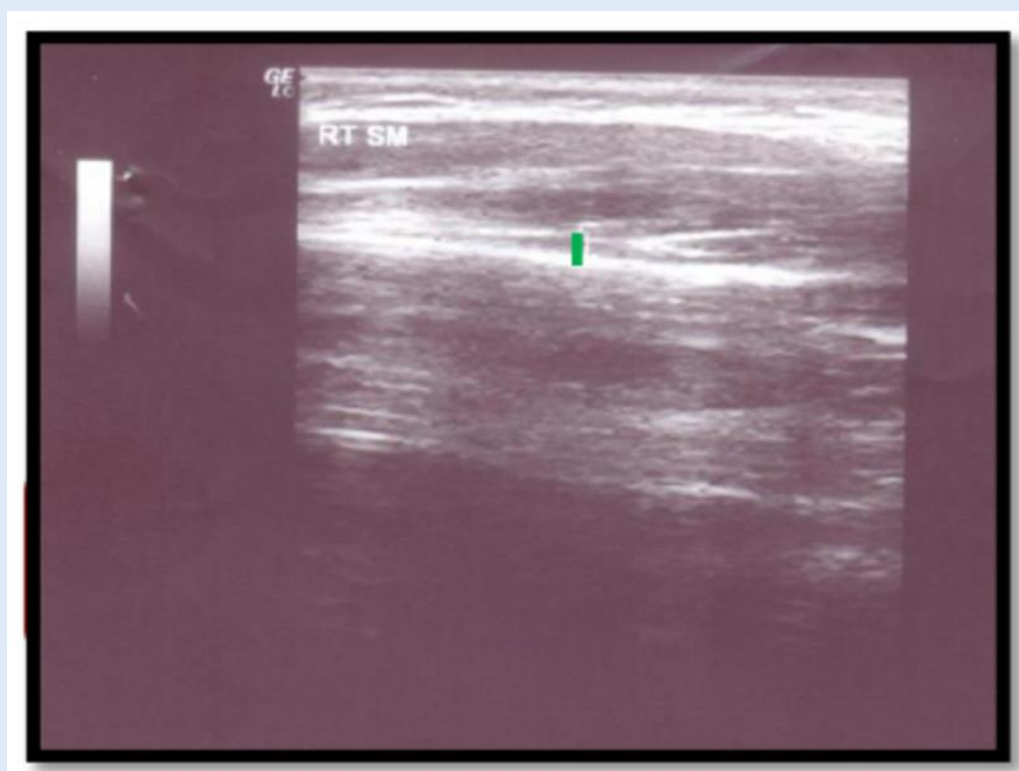


Figure 10: Post lycopene therapy diagnostic ultrasound.

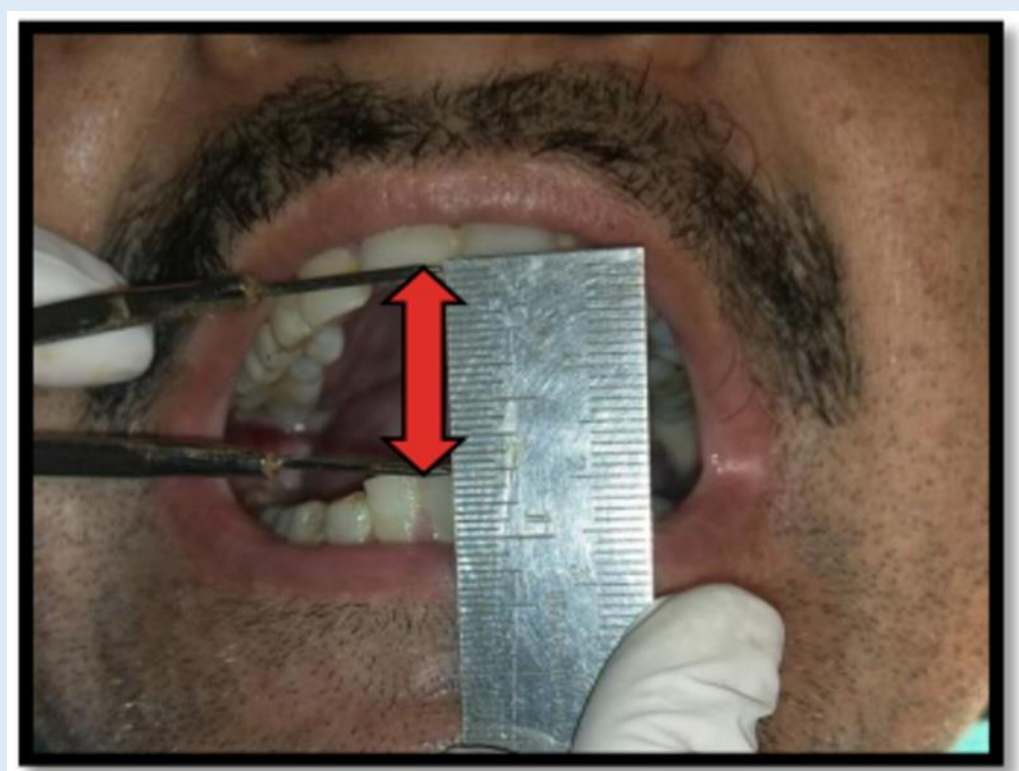


Figure 11: Pre therapeutic USG mouth opening.

Saini R | Volume 3; Issue 1 (2022) | JDHOR-3(1)-043 | Research Article

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Figure 12: Pre therapeutic USG diagnostic ultrasound.



Figure 13: Post therapeutic USG mouth opening.

Saini R | Volume 3; Issue 1 (2022) | JDHOR-3(1)-043 | Research Article

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Figure 14: Post therapeutic USG diagnostic ultrasound.

Discussion

In view of the multifactorial etiology of this debilitating condition, no significant non-invasive single treatment modality is available [9]. Therefore in this present study, we have compared Lycopene and Therapeutic ultrasound which are safe, convenient and simple modes of treatment of this chronic insidious condition.

Moreover there is paucity of literature on the use of Therapeutic ultrasound in management of OSMF patients and comparison of this therapeutic modality with Lycopene is also scarce. The treatment outcome was assessed by using diagnostic ultrasonography which is considered as a valuable tool in assessing the severity, extension, disease progression, and treatment outcome of the disease.

Therapeutic ultrasound is developing as a therapeutic modality of interest in the management of OSMF and according to a study done by Tyagi H, et al., it is a non-invasive and effective treatment modality used in the management of OSMF [10]. This therapeutic modality is considered to be an essential part to treat such patients as it works with various objectives by accelerating healing, increasing the extensibility of the collagen fibres, improving burning sensation and mobility, providing pain relief and reducing muscle spasm [10].

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Another proposed mechanism of US effect was an increase in tissue or muscle flexibility due to generation of heat which further leads to decrease in the stiffness of oral mucosa. The thermal effects of US results in enhancing the flexibility of collagenous fibrils by breaking the fibrous bands developed due to OSMF and consequently improves the elasticity of the oral musculature which ultimately leads to increase in the mouth opening [11].

The other treatment modality that has been assessed in this present study is Lycopene which has proven to be very effective in treating OSMF patients. According to Gupta S, et al., it is a carotenoid and also a natural pigment derived from plants which has both anti-carcinogenic and antioxidant properties. It acts by inhibiting abnormal fibroblast proliferation in OSMF and also regulates lymphocyte resistance to stress and suppresses inflammatory response [12].

In the present study, Therapeutic ultrasound was found to be more effective as compared to Lycopene in reducing burning sensation, improving mouth opening, cheek flexibility and other two parameters i.e. Sub-mucosal and masseter muscle thickness assessed by diagnostic ultrasonography. In accordance to present study, there were very few studies documented in the literature which have shown similar treatment outcomes using Therapeutic Ultrasound.

KPA Maneesha D, et al., and Tyagi H, et al., concluded that ultrasound therapy followed by jaw opening exercises can be an alternate mode of treatment for palliation in OSMF to improve burning sensation and mouth opening without any side effects [10,13]. In our study, both of these clinical parameters were seen to have improved more in Therapeutic ultrasound as compared to Lycopene with statistically significant difference. Dani V, et al., and KPA, et al., concluded that Therapeutic US and conventional jaw opening exercises prove more beneficial in improving mouth opening compared to only jaw opening exercises in OSMF [14,15].

Guduru H, et al., also compared intralesional injections of corticosteroids with Therapeutic ultrasound and concluded that Therapeutic ultrasound can be used as an adjuvant treatment in alleviating the signs and symptoms of patients of OSMF [16].

In the present study, Lycopene was the another treatment modality used in the management of OSMF, the results showed a positive outcome in relation to reduction in burning sensation, improvement in mouth opening, cheek flexibility and tongue protrusion from Day 15 till 3 months with significant values ($p < 0.05$).

Kumar A, et al., and Karemore T, et al., evaluated the efficacy of oral lycopene therapy and compared it with a placebo and stated that lycopene can and should be used in the initial management of OSMF as it improves burning sensation and mouth opening [17,18]. Selvam N, et al., and Goel S, et al., evaluated the efficacy of oral lycopene therapy in combination with conventional intralesional steroid therapy and stated that Lycopene in combination with

intralesional steroids and hyaluronidase, is highly efficacious in improving the mouth opening and reducing other symptoms in patients with Oral Submucous Fibrosis with no reported side effects [19,20]. Patil S, et al., and Gowda B, et al., compared the efficacy of two antioxidants, lycopene and aloe-vera and stated that lycopene can bring about significant clinical improvements in the symptoms like burning sensation, mouth opening and tongue protrusion when compared to aloe vera [21,22].

In the present study, reduction in burning sensation, improvement in mouth opening and cheek flexibility from Day 15 till 3 months with significant values ($p < 0.05$) were noted in Group 2 as compared to Group 1.

Very few articles have considered cheek flexibility and tongue protrusion as clinical parameters in their study. According to our study, when both of the treatment modalities i.e. Lycopene and Therapeutic ultrasound were compared cheek flexibility was seen to be more improved in Therapeutic ultrasound (Group II) as compared to Lycopene (Group I).

The other clinical parameter i.e. tongue protrusion showed more improvement in Lycopene group. The mean values of improvement in tongue protrusion were slightly more in Lycopene group as compared to Therapeutic Ultrasound. The reason attributed to this could be due to the systemic use of Lycopene drug which was administered for 3 months. The other reason for this could be since Therapeutic USG was not given intra-orally or over the surface of tongue hence it had less effect in improving tongue protrusion.

Conventionally, biopsy is considered as a gold standard for assessing the severity of oral potentially malignant disorders, but biopsy in OSMF is still controversial. Therefore, a newer innovative modality i.e. Diagnostic Ultrasonography has been included in this study.

Therefore to confirm the treatment outcome, Diagnostic Ultrasonography was carried out in both the groups pre and post treatment (3 months follow up) for evaluation of Sub-mucosal thickness and Masseter muscle thickness. There are few studies documented in the literature in which assessment of these two mentioned parameters i.e. Sub-mucosal thickness and Masseter muscle thickness have been done which is very helpful in assessing the treatment outcome [14].

In the present study, it was observed that the mean values of sub-mucosal thickness and masseter muscle thickness were reduced in the Therapeutic ultrasound group as compared to Lycopene at 3 months follow up which justifies the use of both the modalities in the management of OSMF patients.

Chakarvarty A, et al., evaluated the thickness of masseter muscle in OSMF patients and concluded that thickness of masseter muscle was found to be more in OSMF patients as

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compared to control group and also thickness was found to be more during contraction as compared to relaxation in both OSMF patients and normal individuals [23]. Iyenger A, et al., concluded that ultrasonographic examination of the echogenic pattern may help in understanding the nature of the disease process affecting the masseter muscle in various conditions [24].

As per best of our knowledge, there is not much studies that were conducted to assess the treatment outcome by using Diagnostic Ultrasonography. In the present study, Sub-mucosal thickness and masseter muscle thickness were assessed and noted to be decreased after the treatment at 3 months follow up in both the groups which suggests that better improvement was seen in Therapeutic ultrasound group when compared to Lycopene group. Similarly, the percentage change in sub-mucosal thickness and masseter muscle thickness after the treatment was seen to be more in Therapeutic ultrasound group as compared to Lycopene group which shows that Therapeutic ultrasound have been proven better as compared to Lycopene in improving the submucosal thickness and masseter muscle thickness [6].

Thus, apart from the different pharmacological treatments already used in OSMF patients, the other recent therapeutic option that can be considered for the management of this debilitating condition is Therapeutic Ultrasound. It helps in improving mouth opening and relief from burning sensation in a short period of time, which remains the major concern for these patients when they visit to an oral medicine specialist.

In the present study, clinical assessment as well as diagnostic ultrasonography justify efficacy of Therapeutic ultrasound as an adjunctive treatment modality for the management of OSMF patients. Till now we have not come across any study done which has compared Lycopene and Therapeutic ultrasound and assessed the treatment outcome by using Diagnostic Ultrasonography.

Conclusion

The results of present study concluded that therapeutic ultrasound could be highly effective treatment modality as compared to Lycopene in improving signs and symptoms of Oral Submucous Fibrosis.

Conflict of Interest

There are no conflicts of interest.

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