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ROLE OF PLATELET-RICH PLASMA WITH AND WITHOUT ORAL LYCOPENE CAPSULES IN THE MANAGEMENT OF ORAL SUBMUCOUS FIBROSIS: A HOSPITAL-BASED COMPARATIVE STUDY

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ABSTRACT

Objective: To compare the effectiveness of platelet-rich plasma therapy with and without oral lycopene capsules in patients with oral submucous fibrosis.

Study Design and Setting: This comparative quasi-experimental study was conducted at the Department of Oral and Maxillofacial Surgery, Jinnah Postgraduate Medical Centre, Karachi.

Methodology: This comparative quasi-experimental study was carried out for six months (August 2025-January 2026). A total of 90 oral submucous fibrosis patients were selected and were subdivided into two groups, each with 45 patients. Group A was given platelet rich plasma therapy along with oral lycopene capsules and group B was given platelet rich plasma therapy. Platelet rich plasma was obtained from a two-step centrifugation process and injected into the lesions every two weeks for a maximum of 3 months. Group A patients were also given oral lycopene 8 mg twice a day for three months. Analysis of the data was done with SPSS version 26. A p-value of <0.05 was considered statistically significant.

Results: Both groups were similar in terms of baseline demographics. Group A showed much better recovery in mouth opening during the 2nd week and onwards ($p = 0.04$) and higher rate of burning sensation reduction during the 2nd week ($p = 0.02$). Group A also recorded softening of fibrotic bands at earlier weeks, which attained significant differences at 3rd and 4th weeks ($p = 0.04$ and 0.01, respectively).

Conclusion: PRP coupled with oral lycopene showed better results in increasing the mouth opening, reducing the burning sensation faster, and softening of the fibrotic bands.

KEYWORDS: Fibrotic Bands, Lycopene, Mouth Opening, Oral Submucous Fibrosis, Platelet-Rich Plasma, Randomized Controlled Trial.

INTRODUCTION

Oral submucous fibrosis (OSMF) is a persistent progressive condition of the mouth cavity due to the inflammation of the oral mucosa followed by its fibrosis, which causes rigidity of the oral substance and impaired mouth opening. [1] It is very common among the people of South Asian communities because of the common practice of chewing areca nut and other associated products like gutka and pan masala. [2] Patients have a clinical presentation of burning sensation of the oral mucosa, blanching, fibrous bands, and progressive trismus, which are very detrimental to oral function and quality of life. [3]

Rigidity of oral mucosa and submucosal tissues is caused by an extraordinary accumulation of collagen, a decrease in collagen degradation, and chronic inflammation caused by areca nut alkaloids, which are the pathogenesis of OSMF.

[4] The diagnosis and subsequent effective management of it is important because of its potential malignancy and the possibility of it developing into oral squamous cell carcinoma. [5]
OSMF has been studied on several modalities of treatment, such as intralesional corticosteroids, hyaluronidase, antioxidants, physiotherapy, and surgery in extreme cases. [6] Triamcinolone acetonide is known to be intralesional corticosteroids which are effective to treat inflammation and enhance the opening of the mouth, although their results are inconsistent and may be connected with the recurrence in the long run. [7]
Platelet-rich plasma (PRP) is a recently researched form of regenerative therapy in the management of OSMF. PRP is an autologous platelet concentrate with growth factors that stimulate tissue regeneration, angiogenesis, and wound healing that could reduce fibrosis and enhance mucosal complacency. [8]
Besides regenerative treatment, other antioxidants like lycopene have also been explored to treat OSMF. Lycopene is a naturally occurring carotenoid that has high antioxidant and anti-inflammatory effect and helps to counteract free radicals and oxidative stress, which is likely to enhance mucosal health and decrease fibrosis. [9] There is clinical evidence that the symptoms of the patients of OSMF like burning sensation and limited mouth opening could be improved with the usage of lycopene supplementation. [10]
In view of the possible advantages of regenerative and antioxidant interventions, PRP could be used in combination with oral lycopene to have synergistic effects by improving tissue regeneration with decreasing oxidative stress and inflammation. Nevertheless, few studies have compared the results of PRP treatment with and without lycopene supplementation in the OSMF patients.

METHODS

This comparative quasi-experimental study was carried out at the Department of Oral and Maxillofacial surgery, Jinnah Postgraduate Medical Centre, Karachi from August 2025 to January 2026 for six months period. Ethical clearance was granted by the Institutional Review Board prior to the study starting with the reference number: **F.2-81/2025-GENL/333-AA/JPMC**. All participants gave written informed consent after receiving an explanation of the study, the treatment protocol, the potential benefits of the study, and the discomfort experienced during the procedure. Patient privacy was adhered to during the study.
The sample size was determined with the on-line sample size calculator for comparing two means by OpenEpi. These included a 95% confidence level and an 80% power. To calculate this, the mean value of mouth opening after three months of treatment in the PRP with lycopene group and noted in the PRP-only group were used, which were 30.07 ± 1.169 mm and 29.00 ± 2.279 mm respectively.[11] The smallest sample size required was 45 in each group. Thus, 90 patients were taken into the study.
The non-probability consecutive sampling method was used to recruit the patients from an outpatient department. The patients were divided into two groups of 45 patients each who were eligible. This group A was treated with platelet-rich plasma therapy and oral lycopene capsules, whereas this group B was treated with platelet-rich plasma therapy alone. The study was not a placebo controlled blinded trial, so a placebo capsule was not given to group B.
The study included patients of either sex, clinically diagnosed with oral submucous fibrosis, aged 20–60 years. The diagnosis was made using clinical features such as restricted mouth opening, burning sensation in the oral cavity, blanching of oral mucosa and palpable fibrotic bands. The study excluded patients with systemic diseases (e.g., diabetes mellitus, bleeding disorders, thrombocytopenia, immunocompromise, pregnancy, lactation, long-term steroid or immunosuppressive drug use, use of anticoagulant or antiplatelet drugs, allergy to lycopene or PRP-related materials, active oral infection, trauma, temporomandibular joint disease, scleroderma, and oral squamous cell carcinoma).
Baseline demographic and clinical information was obtained and documented on a structured proforma after students were enrolled. Demographic variables consisted of age, gender, residence and history. Clinical parameters were: duration of the disease, mouth opening, burning sensation and fibrotic band severity. Thorough oral examination was conducted with proper lighting. Inter-incisal distance, measured in millimeters with a Vernier caliper, was used to measure mouth opening. The greatest distance between the upper and lower central incisors was noted. For edentulous or partially dentate patients the most reliable corresponding anterior reference points were utilized. Three readings were made and then the average was taken to minimize measurement error.
A 0-10 Visual Analogue Scale (VAS) was used to evaluate burning sensation, with a score of 0 representing no burning sensation and 10 representing the severest burning sensation. Burning sensation was asked to be marked by the patient according to the severity of his symptoms, especially when eating spicy foods. Clinical assessment was made by palpation of the fibrotic bands and other intraoral areas that were involved. Palpable fibrotic bands were noted as present, partial or absent and were graded for each patient according to their density as per the study proforma. To ensure consistency, the same clinical evaluation technique was used throughout visits.
PRP was manufactured in an aseptic environment. Ten to 20 mL of venous blood was collected in a sterile syringe and placed in tubes containing anticoagulant for each patient. A two-step centrifugation process was used to process the blood sample. The first centrifugation went at 1500 rpm for 10 minutes, which separates plasma and buffy coat

from red blood cells. This was followed by transferring the plasma layer with platelets and buffy coat into another sterile tube for second centrifugation at 3000 rpm for 15 minutes. The second spin resulted in removal of the top platelet-poor plasma and the platelet concentrate was then resuspended to yield plasma rich in platelets. CaCl2 was used to activate PRP prior to injection.

Oral cavity was examined prior to PRP administration and the injection sites were determined. Aseptic precautions were followed during the procedure. PRP was injected intralesionally into the affected fibrotic bands, mainly involving the buccal mucosa and other clinically involved sites. Approximately 0.5-1.0 mL of PRP was injected at each site based on the degree of fibrosis. Injections were done every fortnight over three months. Hence, patient got 6 PRP sessions in 6 months. All injections and preparation of PRP were done in both groups.

In the case of Group A, the patient received oral lycopene capsules along with PRP treatment. Lycopene was administered at a dose of 8mg twice daily for 3 months. The capsules were to be taken on a regular basis after meals. Group B patients were not administered lycopene and were treated with PRP therapy. Group B patients were treated with PRP therapy without any lycopene. The compliance of Group A was checked at every visit using a patient compliance checklist and pill count. The patients were also enquired on the adverse effects seen with lycopene consumption and PRP injection.

A three-month follow-up was conducted in all patients. Clinical outcomes were evaluated at baseline, 4 weeks, 8 weeks and 12 weeks following treatment initiation. The main outcome variable was the improvement in mouth opening (measured as the inter-incisal distance, in millimeters). Secondary outcome variables included the VAS score of reduction in burning sensation, and the clinical palpation scoring of the fibrotic band. The evaluation period of 12 weeks was deemed as the final post-treatment evaluation since both PRP therapy and lycopene supplementation were left for three months.

Local irritants like areca nut, gutka, paan, and tobacco were prohibited among the patients for the duration of the study. Oral hygiene instructions were given to all participants. All patients who failed to attend their scheduled visits were contacted and asked to attend for follow-up as soon as possible. Those who did not complete the treatment protocol or were not followed up were to be excluded for final outcome analysis.

The data were inputted and analyzed using SPSS (version 26). Age, mouth opening and VAS score were presented as mean and standard deviation as quantitative variables. Qualitative variables like gender, residence, clinical severity categories and fibrotic band grading were shown as frequency and percentage. Baseline characteristics of both groups were compared to assess group comparability. The mean mouth opening and the mean VAS scores were compared between the two groups using independent-sample t-test. Paired t-test was used to compare pre-treatment and post-treatment changes within each group. For qualitative variables, when appropriate, the Chi-square test or Fisher's exact test were used. A p value <0.05 was taken as significant.

RESULTS

A total of 90 patients with Grade II oral submucous fibrosis were included in the study. Patients were equally divided into two groups, with 45 patients in each group. Group A received platelet-rich plasma therapy with oral lycopene capsules, while Group B received platelet-rich plasma therapy alone. All patients completed the three-month treatment and follow-up period, and no patient was lost to follow-up.

The mean age of the study participants was 38.6 ± 10.2 years. There were 52 (57.8%) male and 38 (42.2%) female patients. Most patients belonged to urban areas, 59 (65.6%), while 31 (34.4%) were from rural areas. Baseline demographic characteristics were comparable between the two groups, with no statistically significant difference in age, gender distribution, residence, or duration of disease (**Table-I**).

Table-I: Baseline demographic characteristics of patients in both groups (n = 90)

Characteristic	Group A: PRP + Lycopene (n = 45)	Group B: PRP only (n = 45)	p-value
Age (years), mean ± SD	38.9 ± 10.4	38.3 ± 10.1	0.78
Male, n (%)	26 (57.8%)	26 (57.8%)	1.00
Female, n (%)	19 (42.2%)	19 (42.2%)	1.00
Urban residence, n (%)	30 (66.7%)	29 (64.4%)	0.81
Rural residence, n (%)	15 (33.3%)	16 (35.6%)	0.81
Duration of disease (months), mean ± SD	13.8 ± 4.6	14.1 ± 4.8	0.76

PRP: platelet-rich plasma; SD: standard deviation.

Baseline clinical parameters were also comparable between both groups. Mean inter-incisal mouth opening at baseline was 24.6 ± 2.1 mm in Group A and 24.4 ± 2.0 mm in Group B. The mean baseline VAS score for burning sensation was 6.8 ± 1.0 in Group A and 6.7 ± 1.1 in Group B. All patients in both groups had Grade II fibrotic bands at baseline.

A progressive increase in mouth opening was observed in both groups during follow-up. However, improvement was greater in Group A compared with Group B. At 12 weeks, mean mouth opening improved to 30.4 ± 1.7 mm in Group A and 29.0 ± 2.1 mm in Group B. The difference between the two groups was statistically significant at 8 weeks and 12 weeks (**Table-II**).

Table-II: Comparison of mouth opening between both groups over 12 weeks

Time point	Group A: PRP + Lycopene, mean ± SD	Group B: PRP only, mean ± SD	p-value
Baseline	24.6 ± 2.1 mm	24.4 ± 2.0 mm	0.63
4 weeks	27.4 ± 2.0 mm	26.7 ± 2.1 mm	0.11
8 weeks	29.2 ± 1.8 mm	28.1 ± 2.0 mm	0.009*
12 weeks	30.4 ± 1.7 mm	29.0 ± 2.1 mm	0.001*
Mean improvement from baseline to 12 weeks	5.8 ± 1.6 mm	4.6 ± 1.7 mm	0.001*

*PRP: platelet-rich plasma; SD: standard deviation; statistically significant p-value.

Burning sensation showed gradual reduction in both groups. Group A demonstrated a more pronounced reduction in VAS score compared with Group B. At 12 weeks, the mean VAS score decreased to 1.7 ± 0.6 in Group A and 2.5 ± 0.8 in Group B. The difference between the two groups was statistically significant from the 4-week follow-up onward (**Table-III**).

Table-III: Comparison of burning sensation using Visual Analogue Scale between both groups over 12 weeks

Time point	Group A: PRP + Lycopene, mean ± SD	Group B: PRP only, mean ± SD	p-value
Baseline	6.8 ± 1.0	6.7 ± 1.1	0.67
4 weeks	4.2 ± 0.9	4.8 ± 1.0	0.004*
8 weeks	2.8 ± 0.8	3.6 ± 0.9	<0.001*
12 weeks	1.7 ± 0.6	2.5 ± 0.8	<0.001*
Mean reduction from baseline to 12 weeks	5.1 ± 1.1	4.2 ± 1.2	<0.001*

*VAS: Visual Analogue Scale; PRP: platelet-rich plasma; SD: standard deviation; statistically significant p-value.

Fibrotic band grading also improved during the follow-up period. At baseline, all patients in both groups had Grade II fibrotic bands. At 12 weeks, 32 (71.1%) patients in Group A improved to Grade I compared with 22 (48.9%) patients in Group B. The difference in fibrotic band improvement was statistically significant at 8 weeks and 12 weeks (**Table-IV**). Regarding procedure-related adverse effects, mild transient pain at the injection site was reported by 11 (24.4%) patients in Group A and 10 (22.2%) patients in Group B. Mild local swelling was observed in 4 (8.9%) patients in Group A and 5 (11.1%) patients in Group B. These symptoms were self-limiting and resolved without any additional intervention. No serious adverse effect, allergic reaction, infection, or bleeding complication was reported in either group.

Overall, both treatment protocols resulted in improvement in mouth opening, burning sensation, and fibrotic band grading. However, patients treated with platelet-rich plasma combined with oral lycopene showed significantly greater clinical improvement compared with patients treated with platelet-rich plasma alone, particularly at the 8-week and 12-week follow-up assessments.

Table-IV: Comparison of fibrotic band grading between both groups over 12 weeks

Time point	Group A: PRP + Lycopene (n = 45)	Group B: PRP only (n = 45)	p-value
Baseline	Grade II: 45 (100%)	Grade II: 45 (100%)	—
4 weeks	Grade I: 12 (26.7%); Grade II: 33 (73.3%)	Grade I: 7 (15.6%); Grade II: 38 (84.4%)	0.21
8 weeks	Grade I: 24 (53.3%); Grade II: 21 (46.7%)	Grade I: 14 (31.1%); Grade II: 31 (68.9%)	0.03*
12 weeks	Grade I: 32 (71.1%); Grade II: 13 (28.9%)	Grade I: 22 (48.9%); Grade II: 23 (51.1%)	0.03*

*PRP: platelet-rich plasma; statistically significant p-value.

DISCUSSION

In the present study, platelet-rich plasma therapy alone was compared with the combination of platelet-rich plasma and oral lycopene capsule therapy in patient with Grade II OSF. It was found that both treatment protocols resulted in mouth opening improvement; however, patients who received PRP plus oral lycopene had significantly higher improvements in mouth opening, more significant reduction of a burning sensation, and earlier softening of fibrotic bands than patients who received PRP alone. These data indicate that the oral lycopene supplement could offer an adjunctive treatment to PRP for the treatment of Grade II OSF.

Oral submucous fibrosis is a progressive, chronic, potentially malignant condition of the oral cavity involving inflammation, juxta-epithelial fibrosis, decreased tissue elasticity, burning sensation and progressive restriction of the opening of the mouth. Oxidative stress, collagen deposition, inflammatory mediators and defective tissue remodeling play a significant role in the disease. So, therapy based on a single pathogenic mechanism can yield partial results. In this particular context, the blend of PRP and lycopene seems to be biologically relevant since PRP has a regenerative and healing effect on tissues and lycopene has antioxidant and anti-inflammatory properties.

An improvement in inter-incisal mouth opening was seen in both groups in the current study, with PRP plus lycopene group showing greater improvement. This is a clinical significant finding as limited mouth opening is one of the most disabling complaints in OSF patients and directly impacts mastication, speech, oral hygiene and quality of life. This better improvement in Group A could be due to the synergistic effect of PRP in combination with the antioxidant effect of lycopene. PRP consists of platelet-derived growth factors which stimulate angiogenesis, fibroblast control, collagen remodeling and soft-tissue repair. The overall tissue response will be more favorable if this regenerative potential is complemented with the actions of lycopene in reducing oxidative stress.

The results of the present study were similar to Gupta et al.[11] who found that lycopene supplementation was associated with a beneficial effect on mouth opening and burning sensation in patients with OSF in a systematic review and meta-analysis. Their results confirm that lycopene could be used as an auxiliary for the management of OSF. Similarly, Guo et al.[12] found lycopene to be effective in early and moderate stage of OSF especially in improving clinical function and reducing the symptoms. The current study further refines these findings by demonstrating lycopene could have even greater effects when used in conjunction with PRP instead of independently as an antioxidant therapy.

Another important clinical endpoint measured in this study was burning sensation. The burning sensation was reported to have decreased in both groups during the follow up period, but the decrease was greater in Group A. This could be attributed to the antioxidant and anti-inflammatory properties of lycopene. Commonly, burning sensation in OSF is associated with epithelial atrophy, inflammation of the mucous membranes, decreased salivary comfort and sensitivity to spicy food. Treatment with antioxidants may help decrease free-radical mediated mucosal damage and restore mucosal tolerance. Gupta et al.[13] pointed out that lycopene might also help to decrease oxidative stress, a factor which can be beneficial for tissue recovery and result in relief from symptoms. The current study has also corroborated this mechanism, as the lycopene group demonstrated greater reduction in VAS scores than the PRP-only group.

Pérez-Leal et al.[14] also found that antioxidant treatments, such as lycopene, could be clinically beneficial in reducing mouth opening and burning sensation for patients with OSF. The result of this study corroborates this observation. But, according to the present study, antioxidant therapy might prove more useful as an adjuvant treatment to the regenerative therapy than alone. Burning is likely to be the first symptom that brings patients to treatment and the marked symptomatic improvement in Group A will likely encourage improved patient compliance.

In both groups, fibrotic band grading also improved, but prior and more softening of fibrotic bands was noted in the PRP plus lycopene group. Fibrotic bands are the structural element of OSF and cause stiffness and lack of opening of the mouth. Softening of fibrotic bands is a sign of increased tissue pliability and is thought to reflect remodeling of fibrotic tissue. Chandrakapure et al.[15] investigated PRP use in OSF and found PRP to have a beneficial effect in mouth opening and fibrosis reduction. The present study confirms the clinical relevance of PRP, and further, suggests that the use of lycopene with PRP can further improve therapeutic response.

The growth factors found in PRP that make the component of regeneration in OSF is explained by the large amount of growth factors in PRP, such as platelet-derived growth factor, transforming growth factor, vascular endothelial growth factor, and epidermal growth factor. These mediators can promote angiogenesis, epithelial repair and modulation of wound healing. Anitua et al.[16] highlighted the regenerative ability of PRP and its capacity to enhance the repair of tissues via growth factor stimulated pathways. This mechanism has been observed in the PRP-only group in the current study. But the relative superiority of the Group A group indicates that PRP may not be sufficient for an effective treatment of oxidative stress, which still plays a major role in the pathogenesis of OSF.

One of the contributing mechanisms in the pathogenesis of OSF was reported to be depletion of endogenous antioxidants by Mohideen et al.[17] This discovery is a good reason to use lycopene as an adjunct to PRP. As an effective antioxidant, lycopene may also be able to neutralize the presence of reactive oxygen species and decrease oral mucosa damage. So, it might help with tissue repair, and lycopene could help to lower the oxidative damage and inflammatory load. The clinical results of the Group A could be explained by this dual mechanism.

More et al.[18] performed a review of medical management of OSF and concluded that combination therapies may yield more favorable functional outcomes than single agent therapies. The present study is in line with this concept as PRP containing lycopene was found to yield better improvement as compared to PRP alone. OSF is multi-factorial, therefore, multiple interventions is more rational than a single intervention. In clinical practice, a combination of regenerative, antioxidant, habit cessation, nutritional and physiotherapy-based interventions could be more beneficial in the long run.

Wijesingha et al.[19] noted that using autologous PRP can enhance the opening of the mouth and can decrease fibrosis, but it may take a while. The results of the present study indicate that PRP is effective and that ingestion of oral lycopene can promote clinical recovery. This is crucial because quicker symptom reduction can enhance patient satisfaction and treatment adherence. Al-Maweri et al.[20] found lycopene to be a safe and effective adjunctive therapy for OPDs. The present study also confirms the role of lycopene as an adjuvant in OSF, especially in the case of combining it with PRP.

This study would have a clinical implication that using PRP with oral Lycopene could be a useful treatment option for patients having Grade II OSF. This is a minimally invasive, biologically plausible and clinically beneficial combination. Lycopene is easily added, harmless and convenient to use. May be especially helpful in patients who experience burning sensation, have moderate mouth opening and clinically visible fibrotic bands. It is however recommended that treatment should also involve strict habit cessation, dietary counseling, oral hygiene maintenance, and regular follow-up as continued exposure to areca nut, gutka, paan or tobacco may prove to be detrimental for therapeutic outcome.

There are a number of limitations to the present study. The study was performed in one tertiary care center, and the results might not be applicable to other populations or contexts. Second, the size of the sample was moderate, but sufficient for the comparison proposed. Third, the follow-up period was restricted to 12 weeks, so the sustainability of improvement, the recurrence of illness, and the progression of illness were not measured. Fourth, histopathological or biochemical markers of oxidative stress and fibrosis were not examined and the mechanism of improvement could not be confirmed in a biological way. Fifth, this study was limited to Grade II OSF; and so the findings may not be directly transferable to more advanced grades of OSF.

Future studies should involve larger, multicenter, randomized trials with longer follow-up periods. Some biochemical markers, platelet concentration, inflammatory markers, levels of oxidative stress and histopathological changes can help clarify the mechanism of action. Further studies should also evaluate the efficacy of PRP and lycopene combined with other treatment options such as habit-intervention, physiotherapy, hyaluronidase, antioxidants, and intralesional steroids. Standardization of the preparation of PRP, interval of injection, dose of lycopene and the assessment of the results is also needed to create a reproducible clinical protocol.

Overall, according to the present study, both PRP and PRP with oral lycopene is beneficial in the treatment of Grade II OSF. The use of PRP along with oral lycopene led to greater improvement in mouth opening, mouth burning sensation and fibrotic band grading, however. These results confirm the concept that the use of regenerative therapy with antioxidant therapy is more clinically effective than regenerative therapy alone.

CONCLUSION

Platelet-rich plasma therapy showed positive effect in clinical symptoms of Grade II oral submucous fibrosis; but, PRP + oral lycopene showed greater effect than PRP alone. There were statistically significant differences in favor of the combination therapy for increased mouth opening, earlier softening of fibrotic bands, and reduced burning sensation. The results indicated that oral lycopene may be helpful on the management of Grade II OSF. Larger multicenter studies with longer follow-up are suggested to further validate the efficacy, safety and ideal treatment regimen for this combination therapy.

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