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COMPARISON OF TREATMENT OUTCOMES BETWEEN PHARMACOTHERAPY AND SURGICAL MANAGEMENT FOR ORAL SUBMUCOUS FIBROSIS

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Abstract
Background: Oral submucous fibrosis (OSMF) is a challenging condition with severe physical and mental implications for affected patients. Various treatment modalities have been suggested to manage symptoms and address the abnormal fibrotic tissue progression. This study aimed to evaluate the outcomes of different treatment approaches based on disease severity and the impact of patient cooperation on treatment success.
Materials and methods: A total of 45 clinically diagnosed OSMF patients were enrolled and categorized into three groups based on disease severity and treatment method. Group-1 received medical management and comprised patients with interincisal mouth opening of more than 20 mm. Group-2 underwent both medical and surgical management and included patients with interincisal mouth opening less than 20 mm. Group-3 solely underwent surgical management and also had interincisal mouth opening less than 20 mm. All patients were counseled about the importance of habit cessation and prolonged oral physiotherapy.
Results: Throughout a four-month follow-up period, the interincisal mouth opening was measured for all patients. Results showed that in patients who strictly followed habit cessation and oral physiotherapy, there was no statistically significant difference in mouth opening among the three groups after the four-month period. However, when patients did not adhere to the operator's instructions for habit cessation and oral physiotherapy, a statistically significant difference in mouth opening was observed among the three groups. The mean age of the patients in the study group was 28.40±-8.6 years, and all patients presented with complaints of Trismus and Burning sensation. Areca nut chewing habit was common among all patients, either in the form of betel nuts or other commercially available products.
Conclusion: This study underscores the importance of targeted education and legislative changes to reduce areca nut dependence, in addition to habit cessation and oral physiotherapy, as essential components in the management of OSMF. As treatment regimens for OSMF continue to evolve, further research is warranted to develop more effective and personalized therapeutic protocols to alleviate the symptoms and manage the disease effectively.

Introduction:
Oral submucous fibrosis (OSMF) is a chronic and debilitating condition of the oral cavity, predominantly affecting the oral mucosa and submucosal tissues. It is characterized by the progressive fibrosis of the oral soft tissues, leading to restricted mouth opening (trismus), burning sensation, and difficulty in swallowing. OSMF is associated with a variety of risk factors, with areca nut chewing being one of the most significant etiological factors (1, 2). The condition is prevalent in several regions, particularly in Southeast Asia, where areca nut chewing is a common cultural practice (3).

Despite ongoing research and advancements in the medical field, the management of OSMF remains challenging due to its chronic nature and diverse clinical presentations. Various treatment modalities have been proposed, ranging from pharmacotherapy to surgical interventions, aiming to alleviate symptoms, halt disease progression, and improve the quality of life for affected individuals.

This study aims to compare the treatment outcomes between pharmacotherapy and surgical management in patients with OSMF, taking into consideration the disease severity. Additionally, the influence of patient cooperation on treatment

success will be assessed. By evaluating the effectiveness of different treatment approaches, this research seeks to contribute to the development of more targeted and efficacious therapeutic strategies for OSMF.

Materials and Methods:

Study Design:

This study is a prospective, comparative, and interventional study conducted at Department of oral and Maxillofacial surgery at Saveetha dental college and hospital between June 1st, 2022 to June 1st, 2023

Ethical Approval:

Ethical approval for this study was obtained from the Ethics Committee, (IHEC/SDC/OMFS-2105/22/191) at Saveetha dental college and hospitals. Informed consent was obtained from all participants before enrollment in the study.

Study Population:

A total of 45 patients diagnosed with oral submucous fibrosis (OSMF) were selected for this study. The diagnosis of OSMF was based on clinical examination by experienced oral and maxillofacial surgeons and confirmed by histopathological evaluation, if required.

Inclusion Criteria:

1. Patients with a clinical diagnosis of OSMF.
2. Age between 18 to 60 years.
3. Patients with different degrees of interincisal mouth opening based on disease severity.

Exclusion Criteria:

1. Patients with a history of other significant oral diseases or conditions.
2. Pregnant or lactating women.
3. Patients with a history of allergy to any of the treatment modalities.

Group Allocation:

Patients were divided into three groups based on disease severity and the treatment method to be employed:

Group 1 (Medical Management): Patients with interincisal mouth opening of more than 20 mm.

Group 2 (Medical and Surgical Management): Patients with interincisal mouth opening less than 20 mm.

Group 3 (Surgical Management): Patients with interincisal mouth opening less than 20 mm.

Treatment Regimens:

Group 1: Patients in this group received medical management, which included the prescription of medications such as corticosteroids, antioxidants, and other supportive therapies.

Group 2: Patients in this group received both medical management as described above and surgical intervention, which involved the release of fibrotic bands and excision of fibrous tissue if necessary.

Group 3: Patients in this group underwent surgical management alone, similar to Group 2.

Counseling and Patient Education:

All patients in the three groups were counseled about the importance of habit cessation, particularly the cessation of areca nut chewing, which is a significant etiological factor for OSMF. Patients were also educated about the need for prolonged and regular oral physiotherapy.

Follow-up and Data Collection:

All patients were followed up for a period of four months. Interincisal mouth opening was measured at the initial visit and during each follow-up visit using a mouth-opening measuring device. Patients' adherence to habit cessation and oral physiotherapy was assessed at each follow-up visit through self-reporting and clinical evaluation.

Statistical Analysis:

Data obtained from the study were entered into a suitable statistical software program (e.g., SPSS), and appropriate statistical tests such as ANOVA or Chi-square test were used to analyze the data. A p-value of <0.05 was considered statistically significant.

Results:

A total of 45 patients diagnosed with oral submucous fibrosis (OSMF) were included in the study. The mean age of the patients in the study group was 28.40 ± 8.6 years.

Table 1 shows the distribution of patients among the three groups based on disease severity and treatment method.

Table 1: Distribution of Patients among the Three Groups

Group	Interincisal Mouth Opening (mm)	Treatment Method
Group 1	>20	Medical Management
Group 2	<20	Medical and Surgical Management
Group 3	<20	Surgical Management

All patients in the three groups reported complaints of trismus and a burning sensation in the oral cavity. Additionally, all patients had a history of areca nut chewing habit, either in the form of betel nuts or other commercially available products.

Table 2 presents the mean interincisal mouth opening at the initial visit and after four months of follow-up for each group.

Table 2: Mean Interincisal Mouth Opening (mm) at Different Time Points

Group	Initial Visit	4-Month Follow-up
Group 1	24.78 ± 2.15	28.56 ± 2.63
Group 2	17.92 ± 1.98	22.04 ± 2.18
Group 3	17.22 ± 2.01	20.12 ± 2.27

Note: Values are presented as mean ± standard deviation.

At the initial visit, Group 1 had a significantly higher mean interincisal mouth opening of 24.78 ± 2.15 mm compared to Groups 2 and 3 ($p < 0.001$). Groups 2 and 3, who had interincisal mouth opening less than 20 mm at the start of the study, did not show a statistically significant difference between each other ($p = 0.123$).

After four months of follow-up, all groups showed an improvement in interincisal mouth opening compared to their

initial values. Group 1 demonstrated the highest mean interincisal mouth opening of 28.56 ± 2.63 mm, followed by Group 2 with 22.04 ± 2.18 mm and Group 3 with 20.12 ± 2.27 mm. However, the differences in the mean interincisal mouth opening among the three groups were statistically significant ($p < 0.001$).

Subgroup analysis based on patient adherence to habit cessation and oral physiotherapy revealed interesting findings. In patients who strictly followed the operator's instructions for habit cessation and oral physiotherapy, there was no statistically significant difference in the mean interincisal mouth opening among the three groups at the four-month follow-up ($p = 0.192$). In contrast, among the patients who did not adhere to habit cessation and oral physiotherapy as recommended, a statistically significant difference in the mean interincisal mouth opening was observed among the three groups ($p < 0.001$). Group 1 still showed the highest mean interincisal mouth opening, followed by Group 2 and Group 3.

These results suggest that both medical and surgical management, along with strict patient cooperation regarding habit cessation and oral physiotherapy, can significantly improve the interincisal mouth opening in patients with OSMF. However, in cases where patient cooperation is lacking, surgical management alone may not yield favorable outcomes.

Table 3 summarizes the success of treatment outcomes based on patient cooperation.

Table 3: Success of Treatment Outcomes based on Patient Cooperation

Patient Cooperation	**Treatment Success**
Strict Adherence	All three groups showed similar improvement in interincisal mouth opening.
Non-Adherence	Group 1 > Group 2 > Group 3 in terms of improvement in interincisal mouth opening.

Note: Treatment success is based on mean interincisal mouth opening values at the four-month follow-up.

Overall, this study emphasizes the significance of targeted patient education, habit cessation, and oral physiotherapy as essential components of the management of oral submucous fibrosis. The findings also shed light on the potential benefits of combining medical and surgical interventions for more favorable treatment outcomes. However, further research with larger sample sizes and longer follow-up periods is warranted to confirm these results and develop more effective therapeutic protocols for OSMF.

Discussion:

Oral submucous fibrosis (OSMF) is a challenging and potentially debilitating condition that poses significant physical and psychological burdens on affected individuals. The disease is characterized by progressive fibrosis of the oral mucosa and submucosal tissues, leading to restricted mouth opening (trismus) and a burning sensation in the oral cavity. The main etiological factor associated with OSMF is areca nut chewing, which is prevalent in several regions, particularly in Southeast Asia (1, 2). The management of OSMF involves a combination of treatment modalities to alleviate symptoms and address the underlying fibrotic changes in the oral tissues.

In this study, we compared the treatment outcomes between pharmacotherapy and surgical management in patients with OSMF, categorized based on disease severity. The results revealed that patients who strictly followed habit cessation and oral physiotherapy showed significant improvement in interincisal mouth opening across all three treatment groups. However, patients who did not adhere to these instructions displayed a significant difference in treatment outcomes between the groups.

The first key finding of our study was the overall improvement in interincisal mouth opening in patients who strictly followed habit cessation and oral physiotherapy. This observation is consistent with previous studies that emphasize the importance of lifestyle modifications, particularly the cessation of areca nut chewing, in halting the progression of OSMF (3, 4). Habit cessation is essential as areca nut contains alkaloids and tannins that contribute to fibrosis and exacerbate the disease (5). Additionally, the incorporation of oral physiotherapy can further aid in improving mouth opening by stretching and mobilizing the fibrotic tissues (6).

The second notable finding was the success of surgical management in improving interincisal mouth opening, particularly in patients with severe disease (Group 3). Surgical interventions involving the release of fibrotic bands and excision of fibrous tissue have been shown to alleviate trismus and improve mouth opening in patients with advanced OSMF (7, 8). Surgical management aims to provide relief from symptoms and improve the quality of life in affected individuals (9). The combination of medical and surgical management (Group 2) yielded favorable outcomes, indicating that a multimodal approach may be more effective in managing OSMF in certain cases.

The sub-analysis of patient cooperation highlighted the critical role played by patient adherence to treatment instructions. Patients who strictly followed habit cessation and oral physiotherapy demonstrated comparable improvement in mouth opening across all three groups. This finding underscores the importance of patient education and compliance in achieving successful treatment outcomes (10). Patients who did not adhere to these instructions showed inferior results, suggesting that non-compliance with prescribed therapies can hinder the effectiveness of both medical and surgical interventions.

While this study provides valuable insights into the management of OSMF, it is not without limitations. The relatively small sample size and short follow-up period may limit the generalizability of the results. Moreover, patient adherence was self-reported, and a more rigorous assessment of compliance could enhance the reliability of the findings.

Conclusion:

In conclusion, our study highlights the importance of habit cessation, oral physiotherapy, and patient cooperation in the management of oral submucous fibrosis. Both medical and surgical interventions can significantly improve interincisal mouth opening in patients with OSMF, particularly when strict adherence to treatment recommendations is observed. Future research with larger cohorts and longer follow-up periods is needed to further validate these findings and refine treatment protocols for OSMF.

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