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Oral Health Related Quality of Life in Oral Submucous Fibrosis Patients Using OHIP Tool: An Original Research

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***Abstract*---**The objective of the present study was to assess the oral-health-related quality of life (OHRQoL) of oral submucous fibrosis (OSMF) patients. A convenient sampling technique was used to recruit the clinically diagnosed patients of OSMF (n = 50). Based on the medical treatment, the patients were randomly divided into two study groups (group A and B). The group A patients received hyaluronidase (1500 IU) and Group B patients received submucosal intralesional injections of dexamethasone (2 mL; 4 gm/mL). Both the group A and B patients received respective medical therapy biweekly for a period of ten weeks. At the follow up visit (3 months), the impact of treatment

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on OHRQoL was assessed using the Oral Health Impact Profile-14(OHIP-14). Data were analyzed by a chi-square test for quantitative variables and an independent t-test for qualitative variables. The comparison of all clinical parameters before and after treatment was performed by a paired t-test. The results after treatment showed that there was a significant improvement in all domains of OHIP-14 except psychological disability. In addition, the OHRQoL of patients was significantly improved following the treatment.

***Keywords*---**oral cancer, oral health, oral submucous fibrosis, patients, quality life.

Introduction

Oral submucous fibrosis (OSMF) is a chronic, progressive and irreversible oral potentially malignant disorder that causes the blanching, stiffening and fibrosis of oral mucosa of different areas including lips, buccal mucosa, tongue, soft palate, and anterior pillar of the fauces.[1-4] The most characteristic feature of OSMF is the blanching (marble-like appearance) of buccal mucosa by impairing the local blood vessels. Epidemiological findings indicate that the OSMF is highly prevalent in Southeast Asian countries, particularly in the Indo-Pak sub-continent.[5-9] OSMF remains a great dental public health concern due to its significant transformation rate (7% to 13%) to oral cancers. The pathogenesis of the disease is believed to be multi-factorial. The possible causative factors of OSMF are deficiencies of essential vitamins, zinc, iron, and the presence of capsaicin present in chilies. Moreover, epidemiological studies have clearly documented that areca nut is the most common causative agent for developing OSMF.[10] The clinical presentation of OSMF depends on the disease stage and may include impaired mouth movement, marked rigidity, atrophy of muscle fiber, intolerance to eating hot and spicy food, inability to open mouth, burning sensation of oral cavity, recurrent oral ulceration, and reduced mobility of soft palate, which ultimately leads to further rigidity and disability in the mouth opening. The management of OSMF aims to cure the inability to open the mouth and the burning sensation that is caused by an intolerance to spicy food, inhibiting disease progression and decreasing the risks of the malignant transformation.[11-14] Evidence from the literature recommended that medical treatment included placental extracts, hyaluronidase, steroids,tissue remodeling by different methods, namely physiotherapy, exercises and splints to improve mouth opening. Furthermore, intralesional injections of various therapeutic agents, such as hyaluronidase (HD), dexamethasone (DM), triamcinolone have demonstrated promising outcomes in terms of pain reduction and improvement in mouth opening. Intralesional injections have demonstrated no or minimal adverse effects due to minimal systemic absorption.[15] Moreover, while treating OSMF patients, a variety of drug regimens have been employed, and each drug exhibited a different mechanism of action. This mechanism of action leads to a decrease in the proliferation of fibroblasts and deposition of collagen, consequently providing relief from symptoms. In addition, anti-inflammatory role of steroids is well-evident.[16] Hyaluronidase disintegrates and dissolves the fibrous bands, which provides relief from symptoms. It also causes the breakdown of hyaluronic acid, which eventually decreases the viscosity of the

intracellular substance.[17] Oral-health-related quality of life (OHRQoL) can be defined as an assessment of individuals regarding the oral health and how functional, psychological, social factors, pain, or discomfort affect the well-being of an individual. Considering that oral diseases commonly affect quality of life (QoL), OHRQoL is a useful research tool that has been frequently used by oral researchers.[18] Any ailment that can obtrude in the performance of routine dental tasks may also have detrimental consequence on general QoL. Therefore, after many analyses of the influence of oral diseases on different aspects of life, the concept of OHRQoL was developed. Quality of life may be disturbed due to oral diseases, which may affect the general well-being and everyday life activities of patients. However, the published literature contains studies that mainly emphasized the management of OSMF, with little emphasis on the improvement of QoL; these studied drugs have made great contributions to maintaining health. Drug therapy forms an inseparable part of OSMF management, which, apart from increasing mouth opening, and decreasing pain and a burning sensation, relieves patients of severe fibrotic changes which may ultimately improve the QoL of patients. Therefore, the aim of the present study was to evaluate the impact of the intralesional administration of HD and DM on patients' OHRQoL.[20]

Materials and Methods

This prospective study included the clinically diagnosed patients of OSMF. Patients were recruited using a convenient sampling technique (n = 50). The online calculator was used to calculate the sample size. The study that compared the sub-mucosal injections of HD and DM in patients with histo-pathologically confirmed OSMF was used to compute the sample. The study reported a mean reduction in pain, while opening mouth in the HD group was 1.98 0.69, compared to DM group (1.03 0.80); the sample size calculated at 95% confidence interval, considering power as 80%, which is a total of 50 patients, with 25 patients allocated to each group with a ratio of 1:1. To account for the non-response and loss to follow-up, the sample size was increased by 10%, thus the final sample size was 60. The inclusion criteria were patients with clinically diagnosed for OSMF, inter-incisal mouth opening (IIMO) between 15–35 mm, patients of either gender, patients over 18 years of age, patients not receiving any treatment for OSMF, patients agreeing to visit regularly for follow-up in accordance with the treatment protocol. The exclusion criteria were: patients with bleeding dyscrasias; patients with other causes of limited mouth opening (temporomandibular problems or pericoronitis, scleroderma, burns); patients with drug allergies or hypersensitivity to HD, DM or lignocaine; patients with any other mucosal disease (such as aphthous ulcers, leukoplakia, erythroplakia, oral squamous cell carcinoma) or skin lesions associated with oral lesions; pregnant and lactating women; patients with any systemic disease; and patients not willing to give up habits of chewing tobacco and betel nuts. A written informed consent was taken from the participants before the commencement of the study. Demographic information was recorded using the designed questionnaire. A detailed history of the disease and associated factors, such as habits and kind of areca nut used, were recorded of study groups (group A and B). The group A patients received hyaluronidase (1500 IU) and Group B patients received submucosal intralesional injections of dexamethasone (2 mL; 4 gm/mL). Both the group A and B patients received respective medical therapy biweekly for a period

of ten weeks. At the follow up visit (3 months), the impact of treatment on OHRQoL was assessed using the Oral Health Impact Profile-14(OHIP-14). Data were analyzed by a chi-square test for quantitative variables and an independent t-test for qualitative variables. The comparison of all clinical parameters before and after treatment was performed by a paired t-test. The results after treatment showed that there was a significant improvement in all domains of OHIP-14 ($p = 0.001$) except psychological disability ($p = 0.243$). In addition, the OHRQoL of patients was significantly improved following the treatment. Follow up of 3 months was recorded. The OHRQoL was measured by a shorter version of Oral Health Impact Profile-14 (OHIP-14). Briefly, the OHIP-questionnaire comprised 10 items and covered 5 domains: functional limitations, physical disability, psychological disability, physical pain, psychological discomfort, social disability, and handicap. A 5-point scale (0 for never to 4 for very often) was used to calculate the score for each item. The total score of OHIP-14 is in the range of 0 to 56. The data of all patients were recorded in the questionnaire before the commencement of treatment and after three months of treatment. Data was analysed statistically and were recorded on a questionnaire and analyzed using SPSS version-16. The qualitative variables (such as gender, age categories, kind of chewing habit and status of quality of life before and after treatment) were highlighted as frequency and percentage, whereas the quantitative variable (i.e., age) was presented as mean SD. Demographic characteristics, including age groups, gender, and kind of chewing habits, were compared between the two groups using chi-square statistics. The p-value < 0.05 was considered significant.

Results

There were no participants who reported any complications or adverse effects associated with the intralesional administration of the drug. Both groups showed a statistically insignificant difference with respect to deleterious habits inferential statistics, the p-value < 0.05 was considered significant.

Table 1
Both groups showed a statistically insignificant

SUBJECT	INTRALESIONAL	QUANTITY	
GROUP A	HYALURONIDASE	1500 IU	P<0.05
GROUP B	DEXAMETHASONE	2 Ml	

Discussion

The present study evaluated the effects of the localized delivery of DM and HD on the OHRQoL of patients suffering from OSMF.[21] The intralesional injections were administered to attain a high concentration at the local site of action, with minimal systemic absorption. An intralesional administration route was selected. In addition, it plays a significant role in comforting the patient by relieving symptoms. Many treatment modalities, such as medical, surgical and physiotherapy treatments, have been advocated to overcome the symptoms of OSMF patients.[22] In the present study, the proportion of males (50%) is equal to females (50%). Males use smokeless tobacco products more often than females; therefore, OMSF is more prevalent in males, and this is reflected in the present

study. When considering the habit of chewing areca nut, most of the study participants reported a history of using chewed gutka (43.8%).[23] In our study, all patients had a habit of chewing at least one smokeless tobacco product, and the consumption of such products was identified as the major etiological factor. The age of the majority of OSMF patients was 30–60 years. However, some previous studies reported those in their 30s as the most common age group.[24] It may be attributed to the fact that the consumption of smokeless tobacco between 20–30 years of age was comparatively low due to the restricted sale of such agents, or the appearance of symptoms was delayed until the age of 30 years due to active body immunity.[25-28] Comparing the QoL before and after 3 months of treatment, most of the subjects showed improvements followed by functional limitation. There was improvement in the physical pain. The QoL of patients improved after treatment. The paired mean differences showed significant improvements overall except psychological disability. This clearly shows that OHRQoL was impaired. The QoL of these patients was significantly improved following the treatment. When comparing the mean domains treated with DM and HD, all of the domains showed statistically insignificant results, indicating no difference between either drug on QoL, which suggests that both drugs are equally effective in terms of QoL.[29-30] There are certain limitations of the present study: only clinical methods were applied during the clinical dental examination, a biopsy was not performed and it was time-consuming procedure and may cause potential psychological trauma to patients. The limited sample size and loss to follow up may influence the study, and psychometric properties of the scale may vary in a larger subset of population.[31-35]

Conclusions

There was a significant improvement after treatment in all domains of OHIP-14, except psychological disability. In addition, the OHRQoL of these patients was significantly improved following the treatment. The intralesional administration of HD and DM was equally efficient in reducing the pain and intensity in oral submucous fibrosis patients.

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