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COMPARISON OF INTRALESIONAL HYDROCORTISONE AND HYALURONIDASE INJECTION TO SURGICAL REPAIR IN MANGING THE ORAL SUBMUCOUS FIBROSIS: A PROSPECTIVE CLINICAL STUDY

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ABSTRACT

Background: Oral submucous fibrosis (OSMF) is one of the most frequent premalignant illnesses with a high chance of developing into cancer. OSMF, which has a mean prevalence of 13% and a range of 0-4% depending on the geographic area, is frequently observed in India and is linked to the chewing of betel quid.

Aim: The goal of the current study was to evaluate and compare the efficacy of two treatment modalities for OSMF of varying degrees in order to evaluate symptoms and improvements in mouth opening. Additionally, the study evaluated the effectiveness and improvement in mouth opening of Z-plasty surgery vs intralesional hyaluronidase with Dexamethasone.

Methods: A total of 88 OSMF individuals with a range of grades were involved in the study. The age range of the study participants was 20-40 years, with a mean age of 27.6±4.68 years. The subjects were split into two groups: Group I received intralesional injections of Hyaluronidase and Dexamethasone, topical Triamcinolone Acetonide 0.1%, Placentrex, iron, and nutritional supplements; Group II received nasolabial flap repair and Z-plasty. Pallor, mouth opening, painful ulcerations, burning sensation, and oral mucosal blanching were measured and compared at preoperative assessment and at the one- and three-month postoperative follow-up.

Result: Patients with OSMF showed a considerable recovery after receiving both systemic and local therapy, which included iron and nutritional supplements along with injections of dexamethasone, hyaluronidase, and topical triamcinolone acetonide 0.1%.

Conclusion: The current study comes to the conclusion that both surgical and conservative management therapies are effective in lessening the severity and grading of OSMF. Additionally, student counseling to break bad habits can lower the occurrence of OSMF.

Keywords: oral submucous fibrosis (OSMF), premalignant state, injections intralesionally, burning sensation, hyaluronidase.

INTRODUCTION

Although oral submucous fibrosis has been known as a clinical entity in humans since ancient times, it was first identified in 1952 when Schwartz reported a fibrotic disorder in five Indian women's oral cavities that remained

unexplained.1, 2 Depending on the geographic locations evaluated, the prevalence of OSMF varies from 0-4%; the estimated mean prevalence is 13%.2. With a prevalence of.36% Ernakulum in Kerala, 0.4% in the Andhra Pradesh district of Srikakulam, 0.16% in the Gujarati city of Bhavnagar, 007% in Bihar, and 0.03% in Maharashtra, OSMF is more common in South India. Chewing betel nuts, drinking alcohol, chewing tobacco, chilling (capsicum), and pan and pan masala are the local etiologic variables linked to the condition.[3,4] With a strong likelihood of developing into a malignant lesion, OSMF is a complicated, long-lasting oral premalignant lesion. Juxta-epithelial inflammation and increasing submucosal tissue fibrosis are its defining features.5

Recurrent stomatitis, ulceration, and a burning feeling in the oral cavity are typical symptoms of OSMF. Hypersalivation, dry mouth, xerostomia, impaired gustatory perception, and/or intraoral petechiae are other typical symptoms that are linked. Additionally, in subjects with OSMF-induced eustachian tube blockage and extension to the pharynx, there is a decrease in hearing capacity and ear pain.Six The mucosa exhibits palpable fibrotic bands and is initially leathery. But in the advanced stage, mucosal resilience is lost, leaving the mucosa pale and hard. OSMF begins in the back of the mouth and spreads outward.7

According to Gupta et al.'s 1992 description, the clinical grading of OSMF is as follows:

• Grade I: Oral mucosa blanching alone, absent other symptoms.

• Grade II: The presence of oral ulcers, vesicles, burning and blanching sensations, and dry mouth.

• Grade III: Blanching and burning sensation, mouth dryness, vesicles or ulcers limiting mouth opening, and palpable bands throughout the mouth without involvement of the tongue.

• Grade IV: The presence of burning and blanching sensations, vesicles, or ulcers in the mouth, together with palpable bands and restricted mouth opening that involve the tongue.

• Grade V: All grade IV characteristics linked to persistent ulcer and cancer with histological confirmation.
• Grave VI: carcinoma identified by histopathology

Surgery or medication are the two methods used to treat OSMF. Intralesional injections of hydrocortisone and hyaluronidase, topical triamcinolone acetonide, antioxidants, systemic vitamins, placental extract, and, most recently, oral cow milk consumption are all part of the medical treatment. The nasopharynx and esophagus are other visceral organs that may be implicated, and they may be linked to a range of systemic diseases involving numerous organs.9. Z-plasty is a plastic surgery procedure that enhances function and appearance in OSMF patients without leaving scars behind. It is one surgical method used to treat OSMF.

Z-plasty involves making a Z-shaped incision, reflecting triangle flaps on two places that are opposed to each other, and then transposing the flaps. Less blood flow, wound tension, flap necrosis, wound infection, and hematoma are among the few related problems. Both medical and surgical approaches to managing OSMF have benefits and drawbacks.10 Nevertheless, there isn't much information in the literature about how the two compare. In order to compare and evaluate the effectiveness of the two treatment approaches in controlling OSMF at different stages and grading in relation to related signs, symptoms, and mouth opening, the current study was carried out.

MATERIALS AND METHODS

The goal of the current prospective clinical study was to evaluate the efficacy of two alternative treatment approaches for OSMF of varying grades in order to compare their effects on symptoms, signs, and mouth opening improvement. Additionally, the study evaluated the effectiveness and improvement in mouth opening of Z-plasty surgery vs intralesional hyaluronidase with Dexamethasone. The participants with reduced mouth opening due to OSMF who visited the Institute's Otorhinolaryngology Outpatient Department made up the study population. In all, 88 patients with various degrees of OSMF were included in the research.
The age range of the study participants was 20-40 years, with a mean age of 27.6±4.68 years. All subjects gave their informed consent after being fully told about the study's design. After being finally included, the subjects were split into two groups: Group I received intralesional injections of Hyaluronidase and Dexamethasone, topical Triamcinolone Acetonide 0.1%, Placentrex, iron, and nutritional supplements; Group II received nasolabial flap repair and Z-plasty.

At the first visit after inclusion, a thorough history including demographics such as address, occupation, sex, and age was documented for every subject from both groups.

Urine and standard blood work were then conducted, together with a general and cardiovascular examination, to determine the presence of endomyocardial fibrosis. The results were documented using structured proforma.

Pallor, mouth opening, painful ulcerations, burning sensation, and oral mucosal blanching were measured and compared at preoperative assessment and at the one- and three-month postoperative follow-up. Using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA for result formulation, the gathered data were statistically evaluated. The data were presented as a mean, standard deviation, percentage, and number. At $p<0.05$, the significance threshold was maintained.

RESULTS

The goal of the current prospective clinical study was to evaluate the efficacy of two alternative treatment approaches for OSMF of varying grades in order to compare their effects on symptoms, signs, and mouth opening improvement. Additionally, the study evaluated the effectiveness and improvement in mouth opening of Z-plasty surgery vs intralesional hyaluronidase with Dexamethasone. A total of 88 OSMF subjects of all genders and varying grades were enrolled in the study. The age range of the study participants was 20-40 years, with a mean age of 27.6±4.68 years. Following final inclusion, the subjects were split into two groups: Group I included 64 subjects, and Group II included 24 subjects who had undergone Z-plasty surgery.

Table 1 describes the distribution of study participants by gender. With Grade I OSMF, Group I included 17 girls and 21 males, for a total of 43.18% (n=38) subjects; in Grade II, the number of subjects was 29.54% (n=26), with 9 females and 17 males. Within Group II, 27.27% (n=24) of the individuals had Grade III OSMF, with 10 females and 14 men. Table 2 presents an interpretation of the postoperative findings at one month for the research individuals.

Pallor was observed in 7 participants with Grade I OSMF and 9 subjects with Grade II OSMF in Group I, while 13 subjects in Group II and Grade III OSMF showed it. Oral mucosal blanching was observed in 12 patients with Grade III OSMF in Group II and in 9 and 11 subjects with Grade I and Grade II OSMF in Group I. In Group I, there were 8 and 13 patients with Grade I and Grade II OSMF, respectively, and 15 subjects with Grade III OSMF who also had painful ulcers.

In Group I, the limited mouth opening was measured at 31.4 mm for Grade I and 26.8 mm for Grade II OSMF individuals, and 38.8 mm for Group II Grade III OSMF participants. Regarding pallor, oral mucosal blanching, painful ulcers, burning sensation, and mouth opening, all of these changes were statistically significant ($p=0.003$, 0.001, 0.01, 0.05, and 0.003, respectively) in two groups. These results were also evaluated three months after treatment in the current investigation. Seven subjects (3 in Grade I and 4 in Grade II subjects) in the non-surgical intervention group and seven in the surgical intervention group both had pallor.

At $p = 0.005$, this was statistically significant. A statistically significant ($p=0.002$) oral mucosal blanching was observed in 4, 7, and 7 patients with Grade I, II, and III OSMF, respectively. In 3, 5, and 6 patients, painful ulcers with Grade I, II, and III OSMF were observed at 3 months. Additionally, this had statistical significance ($p=0.003$).

Between Group I and II, as well as in Grade I, II, and III OSMF with 8, 7, and 8 individuals, respectively, the burning sensation was likewise statistically significant ($p=0.01$). In OSMF patients in Grade I, II, and III, the mouth opening was 37.4, 32.8, and 40.6, respectively. Table 3 indicates that this was statistically significant ($p=0.001$).

DISCUSSION

The goal of the current prospective clinical study was to evaluate the efficacy of two alternative treatment approaches for OSMF of varying grades in order to compare their effects on symptoms, signs, and mouth opening improvement. Additionally, the study evaluated the effectiveness and improvement in mouth opening of Z-plasty surgery vs intralesional hyaluronidase with Dexamethasone. A total of 88 OSMF subjects of all genders and varying grades were enrolled in the study. The age range of the study participants was 20-40 years, with a mean age of 27.6±4.68 years. Following final inclusion, the subjects were split into two groups: Group I included 64 subjects, and Group II included 24 subjects who had undergone Z-plasty surgery.

With Grade I OSMF, Group I included 17 girls and 21 males, for a total of 43.18% (n=38) subjects; in Grade II, the number of subjects was 29.54% (n=26), with 9 females and 17 males. Within Group II, 27.27% (n=24) of the individuals had Grade III OSMF, with 10 females and 14 men. The study's demographics aligned with those of studies conducted by Mithani S.K et al. (2007) and Hove C et al. (2001) that evaluated people with similar characteristics.

Pallor was observed in Group I in 7 individuals with Grade I OSMF and 9 subjects with Grade II OSMF, while it was observed in 13 subjects in Group II and Grade III OSMF, according to postoperative findings in the study participants at one month. Oral mucosal blanching was observed in 12 patients with Grade III OSMF in Group II

and in 9 and 11 subjects with Grade I and Grade II OSMF in Group I. In Group I, there were 8 and 13 patients with Grade I and Grade II OSMF, respectively, and 15 subjects with Grade III OSMF who also had painful ulcers.

In Group I, the limited mouth opening was measured at 31.4 mm for Grade I and 26.8 mm for Grade II OSMF individuals, and 38.8 mm for Group II Grade III OSMF participants. Regarding pallor, oral mucosal blanching, painful ulcers, burning sensation, and mouth opening, all of these changes were statistically significant (p=0.003, 0.001, 0.01, 0.05, and 0.003, respectively) in two groups. These findings were consistent with those of Nair U et al.(2004) and Reddy V et al.(2011), who observed similar mouth opening and other findings to those of the current study.

These results were also evaluated three months after treatment in the current investigation.

Seven subjects (3 in Grade I and 4 in Grade II subjects) in the non-surgical intervention group and seven in the surgical intervention group both had pallor. At p = 0.005, this was statistically significant. A statistically significant (p=0.002) oral mucosal blanching was observed in 4, 7, and 7 patients with Grade I, II, and III OSMF, respectively. In 3, 5, and 6 patients, painful ulcers with Grade I, II, and III OSMF were observed at 3 months. Additionally, this had statistical significance (p=0.003). Between Group I and II, as well as in Grade I, II, and III OSMF with 8, 7, and 8 individuals, respectively, the burning sensation was likewise statistically significant (p=0.01).

In Grade I, II, and III OSMF subjects, the mouth opening was 37.4, 32.8, and 40.6, respectively. At p=0.001, this was statistically significant. These findings aligned with the research conducted by Hazarey V.K et al. (2015) and Balaji S.M. (2016), which also found similar findings in terms of mouth opening, ulcerations, pallor, and oral mucosal blanching.

CONCLUSION

Within its limitations, the present study concludes that surgical as well as conservative management therapy helps in reducing the intensity and grading of OSMF. Also, counseling to break habits in students can decrease OSMF prevalence. However, the present study had few limitations including a smaller sample size, geographical area biases, shorter monitoring period, and single-institution nature. Hence, further longitudinal studies with a larger sample size and longer monitoring period are required to reach a definitive conclusion.

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TABLES

S. No	Study Group	OSMF Grade	Females	Males	Total
1.	**Group I**	I	17	21	38 (43.18)
2.		II	9	17	26 (29.54)
3.	**Group II**	III	10	14	24 (27.27)
4.	**Total**		36 (40.90)	52 (59.09)	88

Table 1: Demographic characteristics of the study subjects

S. No	Symptoms	Group I		Group II	p-value
		Grade I	Grade II	Grade III	
1.	**Pallor**	7	9	13	0.003
2.	**Oral Mucosal Blanching**	9	11	12	0.001
3.	**Painful Ulcers**	8	13	17	0.01
4.	**Burning sensation**	13	11	15	0.05
5.	**Mouth opening (Limited) in mm**	31.4	26.8	38.8	0.003

Table 2: Assessment of the postoperative symptoms in the study subjects after 1 month

S. No	Symptoms	Group I		Group II	p-value
		Grade I	Grade II	Grade III	
1.	**Pallor**	3	4	7	0.005
2.	**Oral Mucosal Blanching**	4	7	7	0.002
3.	**Painful Ulcers**	3	5	6	0.003
4.	**Burning sensation**	8	7	8	0.01
5.	**Mouth opening (Limited) in mm**	37.4	32.8	40.6	0.001

Table 3: Assessment of the postoperative symptoms in the study subjects after 3 months