INTRALESIONAL INJECTIONS IN OSMF- A CLINICAL RESEARCH

Original Article

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Background: Oral submucous fibrosis (OSMF) is a chronic insidious collagen-related disorder associated with betel quid chewing and characterized by progressive hyalinization of the submucosa. It is a well-recognized potentially malignant condition of the oral and oropharyngeal mucosa with initial inflammation followed by progressive fibrosis of the underlying connective tissues. Its treatment is not yet fully standardized, although one of the medical treatment is intralesional injections of steroids or placental extract (Placentrax).

Aims and Objectives: The objective of the study was to evaluate the efficacy of intralesional injections of Placentrax in various stages of OSMF.

Study Design: The study sample consisted of 8 OSMF patients with various clinical stages of Jani YY and Dudhia BB's staging system.

Materials & Methods: Patients received 2 ml of intralesional Placentrax injection, weekly intervals of 5 weeks. Treatment outcome was evaluated on the basis of improvement in trismus and reduction in burning sensation.

Results: Improvements were found in trismus and burning sensation.

Conclusion: Intralesional placental extract acts as a biogenic stimulant, it is cost-effective and improves the condition with minimal side-effects.

INTRODUCTION:

OSMF is insidious chronic debilitating disease affecting any part of the oral cavity and sometimes the pharynx. Although occasionally preceded by and/or associated with vesicle formation., it is always associated with juxta epithelial inflammatory reaction followed by a fibro-elastic changes of the lamina propria with epithelial atrophy leading to stiffness of the oral mucosa and causing trismus and inability to eat.[4,9,15,21] The most common etiology considered for causation of OSMF is "arecoline" which is a constituent of areca nut.[1,4,6,12,19,25] In the early cases of OSMF, oral mucosa becomes blanched and slightly opaque. Fibrosis of mucosa occurs in the late cases of OSMF; leading to stiffness & progression of fibrosis leads to difficulty in opening the mouth.[6,29]

The main goal of the treatment of OSMF is to reduce trismus, blanching/fibrosis and burning sensation.[1,2,3] Several therapeutic and surgical methods have been tried in the treatment of OSMF.[14,16,17,23,28] One of the important therapeutic modalities is intralesional injection therapy of placental extract.[4,5,9,18,24,30] The injection placentrex is an aqueous extort of human placenta containing nucleotides, enzymes, peptides/proteins, small organic components like amino acids, nucleotides, polydeoxyribonucleotides (PDRNs), carbohydrates and trace amount of lipids mostly bound to proteins steroids and vitamins. It acts by "biogenic stimulation".[5,27]

The aqueous extract of placenta acts as follows:

1. Hasten cellular metabolism
2. Aids in the assimilation of exudates
3. Stimulates regenerative development
4. Increases physiological purpose of organs
5. Produces noteworthy enhancement of wound healing
6. Has an anti-inflammatory consequence.[7]

Review Of Literature:

The use of Placetal extract is mainly due to the method of "tissue therapy" introduced by Filatov in 1933 and later in 1953.[7]

Sur and Bis was showed that it is a necessary biogenic stimulator. It stimulates pituitary adrenal cortex and regulates metabolism of tissue. It also increases vascularity of tissue.[7]

Materials and Methods:

The study sample consisted of 08 randomly selected patients coming to the Oral Medicine and Radiology department of the institute.

The patients who were habitual of eating spicy food and/or chewing areca nut/tobacco in addition

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to having examined for two or more of the following signs and symptoms suggestive of OSMF were included in the study:

- Burning sensation and difficulty in eating hot and spicy food
- Reduced mouth opening
- Presence of blanching and fibrosis.

The clinical staging was done by evaluating the clinical findings as per the criteria of Jani YY and Dudhia BB's staging system, which depends upon the severity of clinical features.

After clinical examination and staging, a punch biopsy was taken from the buccal mucosa, and the tissue was sent to the department of Oral Pathology of the institute for detailed histopathological examination.

Histological grading was done by the Oral Pathology department as per the criteria of Khanna and Andrade grading system, which depends upon the involvement of epithelium (keratinization and thickness) as well as connective tissue (hyalinization, fibrous tissue, fibroblasts, blood vessels, and inflammatory cells). Epithelial atypia in form of mild to severe dysplasia was summarized according to the criteria by Krammer.

Figure 1: Instruments used for punch biopsy

Figure 2: Method of Punch biopsy from left buccal mucosa

2ml of intralesional placentrax were given on both buccal mucosa at different sites.

According to the presence of blanching/fibrosis, injections were given first at the occlusal level of upper teeth and then followed by at middle occlusal level and occlusal level of lower teeth in all patients at different sittings.

Figure 3: Instruments used for intralesional placentrax injections

Figure 4: Application of intralesion placentrax in left buccal mucosa

RESULTS

The selected patients included 06 males, 02 females (n=08). Among all the youngest patient was male 27 years and eldest patient was female 50 years .In the present study, 2 cases were of stage II, 3 cases were of stage III and 3 cases were of stage IV.

Among 8 cases, 4 were showing mild dysplasia and 4 were showing moderate dysplasia histopathologically.

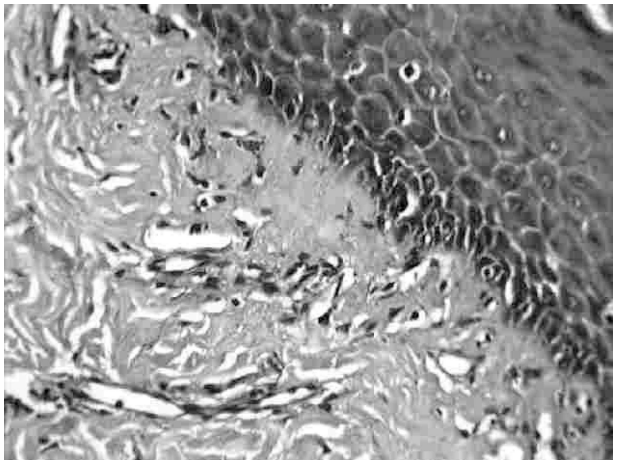


Figure 6: Mild Dysplasia

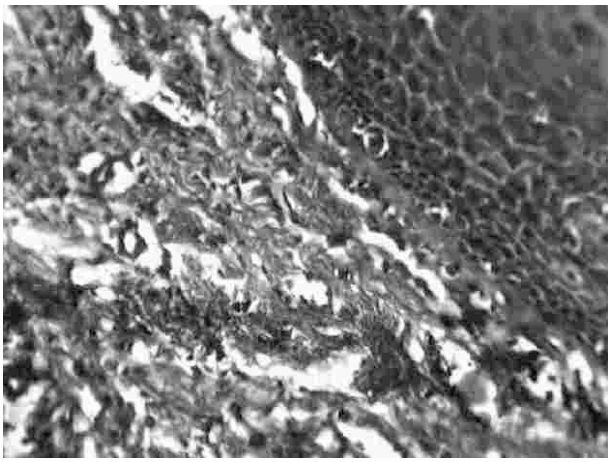
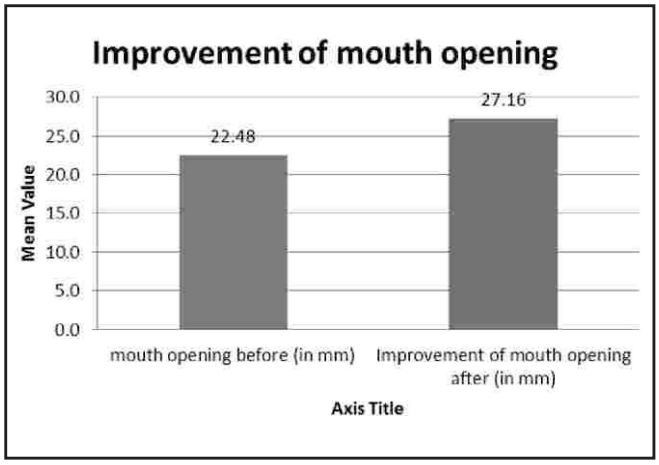


Figure 6: Moderate Dysplasia

Mouth opening (in mm)	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	P Value
Pre Treatment	22.48	8	7.65	2.704	4.69	0.001
Post Treatment	27.16	8	9.15	3.233		

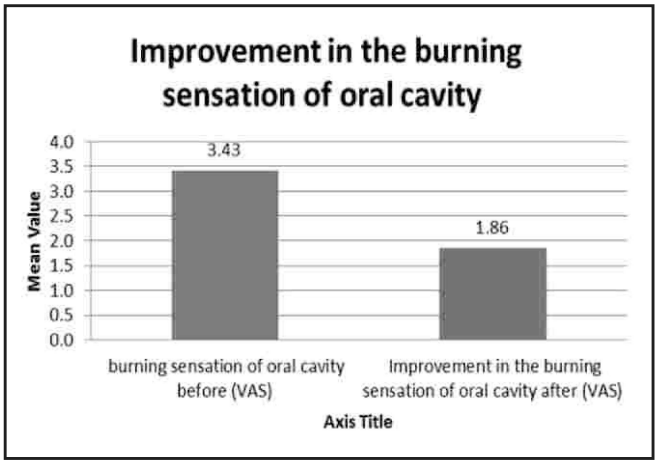
All the 8 patients were having different mouth opening at the time of diagnosis. It was recorded using vernier caliper to measure IID (inter-incisal distance). The significant improvement was seen in mouth opening after the treatment in all patients. (Table 1, Graph 1)



Graph 1: Improvement of mouth opening

Figure 7: Pre-op mouth opening

Figure 8: Post-op mouth opening



Graph 2: Improvement in burning sensation

Severity of burning sensation was measured by VAS(visual analog scale) and it was significantly improved after treatment. (Table 2, Graph 2)

Burning Sensation (VAS)	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	P Value
Pre Treatment	3.43	7	0.79	0.297	-1.57	.000
Post Treatment	1.86	7	0.38	0.143		

DISCUSSION

OSMF is a chronic debilitating condition with a high risk of malignant transformation.[5,6,9,12,20,26] It is a chronic disease and differs in symptoms and severity at every stage. Many surgical and therapeutic treatments have been tried for the cure of OSMF.[9,14,16,17,23,28] Intra-lesional injections of placental extract is one of the modalities and have shown relief from the symptoms and improvement in the mouth opening in patients with OSMF. [1,3,5]

In the present study, increase in mouth opening and reduction in burning sensation were considered as two basic parameters to evaluate the efficacy of Placental extract in the treatment of OSMF.

In all cases, statistically significant improvement was observed in mouth opening and burning sensation with the use of placental extract indicating the efficacy of this regimen in the treatment of OSMF.

Singh et al. and Shah et al., conducted a similar study to evaluate effectiveness of placental extract injections in the treatment of OSMF and favorable treatment outcomes were noted.[1,5]

Placental extract contains growth factors and anti-inflammatory agents and also antiplatelet activity. The action of placental extract is essentially biogenic stimulation and use is based on the tissue therapy method.[1,3,5,7] According to theory when animal and vegetable tissues are severed from the parent body and exposed to unfavorable conditions, but not mortal to their existence, undergo biogenic readjustment leading to development of substance in the state of their survival to ensure their vitality biogenic stimulators. Such tissues or their extract when implanted or injected into the body after resistance of pathogenic factors stimulates metabolic or regenerative process thereby favoring recovery.[3]

CONCLUSION

OSMF is a chronic insidious disease associated with areca nut chewing.[1,4,6,19,20,25]

It is a premalignant condition with a very high rate of malignant transformation, and hence its early diagnosis and treatment is mandatory.[5,6,9,12,20]

Intralesional placental extract is effective in treating OSMF[1,5] and present study is showing significant improvement in OSMF in all parameters of burning sensation and mouth opening.

Intralesional placental extract acts as a biogenic stimulant, it is cost-effective and improves the condition with minimal side-effects.[7]

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