

A Comparative Study of Hyaluronidase and Placental Extract in OSMF Cases: A Clinical Study

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ABSTRACT

Background: OSMF is a potentially malignant disease of the oral cavity associated with areca nut chewing. The present study compared Hyaluronidase and Placental extract in OSMF cases.

Materials & Methods: The present study was conducted on 60 patients of OSMF confirmed clinically and histopathologically. Patients were divided into 2 groups of 30 each. Group I patients were prescribed placental extract (2ml) + dexamethasone (4mg/ml) and group II were prescribed hyaluronidase (1500 IU) + dexamethasone (4mg/ml). The mouth opening was measured with Vernier's calliper.

Results: The mean pre- treatment mouth opening in group I was 25.2 mm and in group II was 26.2 mm. Post treatment mouth opening in group I was 26.2 mm and in group II was 32.8 mm. The difference was significant ($P < 0.05$). The mean pre- treatment burning sensation in group I was 6.52 and in group II was 6.24 mm. Post treatment burning sensation in group I was 1.82 and in group II was 1.20. The difference was significant ($P < 0.05$).

Conclusion: Authors found that both drugs were found to be equally effective in management of OSMF cases.

Keywords: Placental extract, Hyaluronidase, OSMF.

INTRODUCTION

OSMF is a potentially malignant disease of the oral cavity associated with areca nut chewing. It is considered as a disorder of collagen metabolism and is characterized by increased production and decreased degradation of collagen fibers. It is a chronic debilitating condition with high rate of morbidity as it causes progressive inability to open the mouth, resulting in difficulty in eating and thereby causing nutritional deficiencies.¹

The symptoms and subjective signs observed are burning sensation exacerbated by spicy or acidic foods, pain often referred to temporal region, increased or decreased salivation, reduced mouth opening, difficulty with mastication, difficulty with

phonation and deglutition, vesiculation or ulceration of oral mucosa.²

The main goal of the treatment of OSMF is to reduce trismus and burning sensation. One of the important therapeutic modalities is intralesional injection therapy. The most commonly used intralesional agents are placental extract, corticosteroids and hyaluronidase. The mechanism of action and therapeutic efficacy vary from one drug to another and their combinations used.³ Hyaluronidase by breaking down hyaluronic acid (the ground substance in connective tissue) lowers the viscosity of intercellular cement substance. Better results were observed with respect to trismus and fibrosis.⁴ Placental extract contains

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growth factors and anti-inflammatory agents and also has antiplatelet activity. It has biogenic stimulator action and is used on the basis of tissue therapy method. It stimulates metabolism, increases the vascularity and promotes regeneration and recovery of the tissue, upon implantation into the body.⁵ The present study compared Hyaluronidase and Placental extract in OSMF cases.

MATERIAL & METHODS

The present study consisted of 60 patients of OSMF confirmed clinically and histopathologically. The permission of the study was obtained from institutional ethical committee. All patients were informed regarding the study and their consent was obtained.

General data such as name, age, gender etc. was recorded. A thorough oral examination was performed by single examiner. Patients were divided into 2 groups of 30 each. Group I patients were prescribed placental extract (2ml) + dexamethasone (4mg/ml) and group II were prescribed hyaluronidase (1500 IU) + dexamethasone (4mg/ml). The mouth opening was measured with Vernier's calliper. Burning sensation was recorded using VAS scale. Patients were recalled after 1 month. Pre-treatment and post treatment values of burning sensation and mouth opening was recorded. Adverse effects were also recorded. Results were tabulated and subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table 1: Distribution of patients.

Groups	Group I	Group II
Drug	Placental extract (2ml) + dexamethasone (4mg/ml)	Hyaluronidase (1500 IU) + dexamethasone
Male	20	18
Female	10	12

Table I shows that group I patients were prescribed placental extract (2ml) + dexamethasone (4mg/ml) and group II were prescribed hyaluronidase (1500 IU) + dexamethasone (4mg/ml). Group I had 20

males and 10 females and group II had 18 males and 12 females.

Table 2: Assessment of mouth opening (mm) in both groups.

Groups	Pre treatment	Post treatment	P value
Group I	25.2	31.5	0.01
Group II	26.2	32.8	0.01

Table II, graph I shows that mean pre- treatment mouth opening in group I was 25.2 mm and in group II was 26.2 mm. Post treatment mouth opening in group I was 31.5 mm and in group II was 32.8 mm. The difference was significant ($P < 0.05$).

Graph I Assessment of mouth opening (mm) in both groups

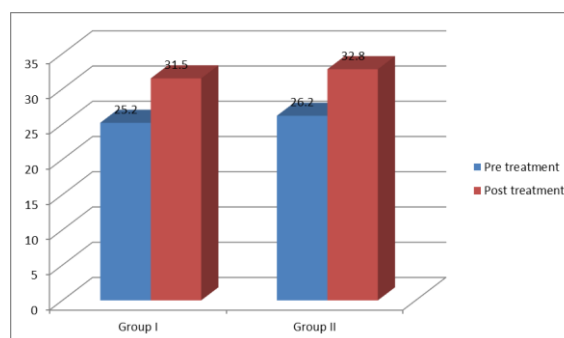
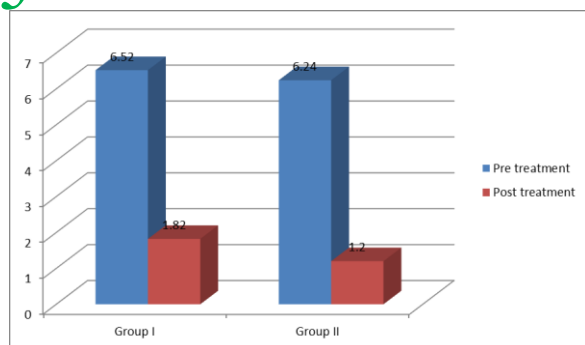


Table 3: Assessment of burning sensation (VAS) in both groups.

Groups	Pre treatment	Post treatment	P value
Group I	6.52	1.82	0.01
Group II	6.24	1.20	0.01

Table III, graph II shows that mean pre- treatment burning sensation in group I was 6.52 and in group II was 6.24 mm. Post treatment burning sensation in group I was 1.82 and in group II was 1.20. The difference was significant ($P < 0.05$).

Graph II: Assessment of burning sensation (VAS) in both groups.



DISCUSSION

OSMF is a precancerous condition and reports suggest that it is present since the time of Sushruta reported by Schwartz in 1962 and by Joshi in 1953; who described its singleton among the Indians. Many trials have been conducted but as such no definitive treatment is currently available.⁶ However, improvement can be obtained passably by intralesional injection of cortisone and hyaluronidase. It was observed that patients receiving hyaluronidase alone showed a quicker improvement in the burning sensation and painful ulceration produced by the effects of local by-products, although combination of dexamethasone and hyaluronidase gave better long-term results than other regimens.⁷ However, the addition of dexamethasone has its own advantages and contraindications and a slight improvement in the overall result observed in the combination group justifies the addition of dexamethasone to hyaluronidase.⁸ The present study compared Hyaluronidase and Placental extract in OSMF cases.

In present study we recruited 60 patients which were divided into 2 groups. Group I patients were prescribed placental extract (2ml) + dexamethasone (4mg/ml) and group II were prescribed hyaluronidase (1500 IU) + dexamethasone (4mg/ml). Group I had 20 males and 10 females and group II had 18 males and 12 females. Shah et al⁹ in their study included records of the 25 patients diagnosed with OSMF. They were divided into two study groups based on the treatment regimens, as Group A (placental extract + dexamethasone) and Group B (hyaluronidase + dexamethasone). In Group A and Group B, the average increase in mouth opening from baseline record to 8th week of treatment was 3.53 ± 1.26 mm and 3.65 ± 1.42 mm respectively and average decrease in burning sensation, noted by VAS scale, was 5.13 ± 1.13 and

4.90 ± 1.29 respectively. The pre- and post-treatment differences were found to be statistically significant for both the groups ($p < 0.001$) and for both the treatment outcomes. When the average difference of the treatment outcomes was compared between the two study groups, no statistically significant difference was noted ($p > 0.05$).

We found that mean pre- treatment mouth opening in group I was 25.2 mm and in group II was 26.2 mm. Post treatment mouth opening in group I was 26.2 mm and in group II was 32.8 mm. James et al¹⁰ included a total of 28 patients diagnosed with OSMF. They were treated by administering an intralesional injection of dexamethasone 1.5 ml, hyaluronidase 1500 IU with 0.5 ml lignocaine HCL injected intralesionally biweekly for 4 weeks. Improvement in the patient's mouth opening with a net gain of 6 ± 2 mm (92%), the range being 4-8 mm. Definite reduction in burning sensation, painful ulceration and blanching of oral mucosa and patient followed up for an average of 9 months.

We observed that mean pre- treatment burning sensation in group I was 6.52 and in group II was 6.24 mm. Post treatment burning sensation in group I was 1.82 and in group II was 1.20. Selvam et al¹¹ compared effectiveness of lycopene and antioxidants in combination with intralesional steroid and hyaluronidase injections. Result demonstrated favorable treatment outcomes in terms of mouth opening and burning sensation.

A study by Borle and Borle¹² postulated that treatment following intralesional injections of various drugs leads to aggravated fibrosis and pronounced trismus. The resultant worsening of this condition with submucosal injections are attributable to repeated needle stick injury to the soft tissues at multiple sites, clinical irritation from drugs being injected, and to the progressive nature of the disease. The same outcome has been observed with some surgical methods employed to treat OSMF. Conservative line of treatment like topical steroids, vitamins, antioxidants, physiotherapy would give expected symptomatic relief of pain and burning sensation.

The limitation of the study is small sample size.

CONCLUSION

Authors found that both drugs were found to be equally effective in management of OSMF cases.

CONFLICTS OF INTEREST

The authors declare they have no potential conflict of interests regarding this article.

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