

## Original Research

### Efficacy of intralesional dexamethasone and hyaluronidase therapy with and without ultrasound therapy in the management of OSMF patients

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#### ABSTRACT:

**Background:** The present study was conducted to compare efficacy of intralesional dexamethasone and hyaluronidase therapy with and without ultrasound therapy in the management of OSMF patients. **Materials & Methods:** Group I patients were prescribed given intralesional infiltration of dexamethasone + hyaluronidase and group II patients were prescribed intralesional infiltration of dexamethasone+ hyaluronidase + ultrasound therapy. Each group had 18 patients. **Results:** In group I, pre- treatment mouth opening was 1.4 cm and in group II was 1.6 cm. Post-treatment mouth opening in group I was 2.8 and 3.9 in group II. The difference in both groups was significant ( $P < 0.05$ ). The mean VAS pre- treatment in group I was 8.2 and in group II was 8.4. The mean VAS post- treatment in group I was 5.6 and in group II was 3.2. The difference was significant ( $P < 0.05$ ). **Conclusion:** Authors found that combination therapy of intralesional infiltration of dexamethasone+ hyaluronidase + ultrasound therapy found to be effective as compared to dexamethasone+ hyaluronidase alone in management of cases of OSMF.

**Key words:** Dexamethasone, Hyaluronidase, OSMF.

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#### INTRODUCTION

Oral Submucous Fibrosis (OSF) is a chronic condition almost exclusively occurring among Indians and to a lesser extent in the other Asiatic people. However, with the increase in immigration of people from the Indian subcontinent, dental professionals in many developed countries will encounter this disease in the near future.<sup>1</sup> A wide range of treatment including drug management, surgical therapy, and physiotherapy have been attempted till date, with varying degrees of benefit, but none have been able to cure this disease.<sup>2</sup> This is mainly due to the fact that the etiology of the disease is not fully understood and the disease is progressive in nature. Instead of continuing the limited available modes of therapy, the idiopathic nature of this condition indicates new avenues for its management.<sup>3</sup>

Several studies were done to study the effect of various drugs and physical therapies in the

management of OSMF.<sup>4</sup> However, physical therapy such as ultrasound therapy, which was found to have therapeutic benefit in musculoskeletal disorders such as fibromyalgia, acute periarticular inflammatory conditions, and osteoarthritis, has been less explored in OSMF.<sup>5</sup> Ultrasonic waves penetrate the skin to cause vibrations in tendons and soft tissues, providing gentle deep tissue heating that decreases pain and inflammation to speed healing in OSMF patients.<sup>6</sup> The present study was conducted to compare efficacy of intralesional dexamethasone and hyaluronidase therapy with and without ultrasound therapy in the management of OSMF patients.

#### MATERIALS & METHODS

The present study comprised of 36 patients of OSMF of both genders. Ethical clearance was obtained before starting the study. All were informed regarding the study and their written consent was obtained.

Patient information such as name, age, gender etc. was recorded. Patients were randomly divided into 2 groups of 18 each. Group I patients were prescribed given intralesional infiltration of 2 ml dexamethasone (4 mg/ml) + hyaluronidase 1500 IU dissolved in 0.5 ml of 2% lignocaine twice a week for 8 weeks and group II patients were prescribed intralesional

infiltration of 2 ml dexamethasone (4 mg/ml) + hyaluronidase 1500 IU dissolved in 0.5 ml of 2% lignocaine twice a week for 8 weeks and ultrasound therapy for 15 days. Burning sensation, and mouth opening was recorded. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

**RESULTS**

**Table I Distribution of patients**

| Groups | Group I                       | Group II  |
|--------|-------------------------------|---|
| Drug   | Dexamethasone + hyaluronidase | dexamethasone+ hyaluronidase + ultrasound therapy |
| Number | 18                            | 18  |

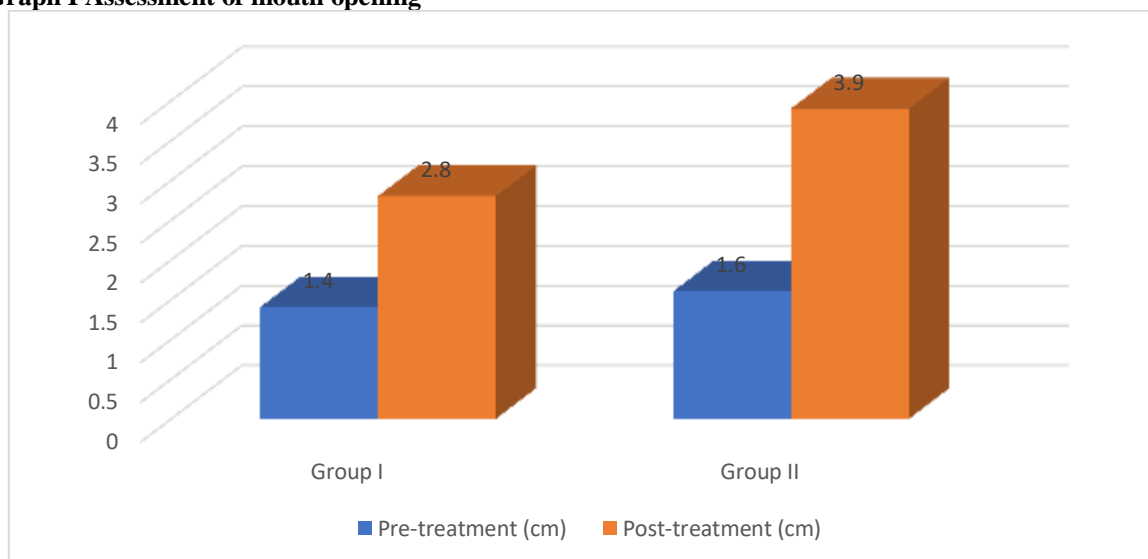
Table I shows that group I patients were prescribed given intralesional infiltration of dexamethasone + hyaluronidase and group II patients were prescribed intralesional infiltration of dexamethasone+ hyaluronidase + ultrasound therapy. Each group had 18 patients.

**Table II Assessment of mouth opening**

| Groups   | Pre-treatment (cm) | Post-treatment (cm) | P value |
|----------|--------------------|---------------------|---------|
| Group I  | 1.4                | 2.8                 | 0.02    |
| Group II | 1.6                | 3.9                 | 0.001   |

Table II shows that in group I, pre- treatment mouth opening was 1.4 cm and in group II was 1.6 cm. Post-treatment mouth opening in group I was 2.8 and 3.9 in group II. The difference in both groups was significant (P< 0.05).

**Graph I Assessment of mouth opening**

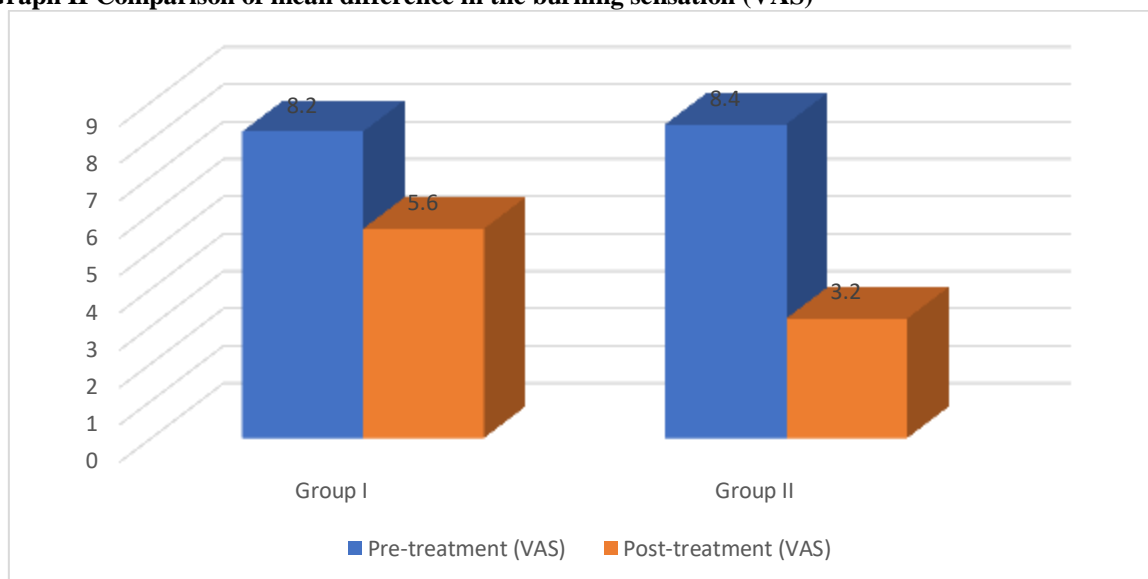


**Table III Comparison of mean difference in the burning sensation (VAS)**

| Groups   | Pre-treatment (VAS) | Post-treatment (VAS) | P value |
|----------|---------------------|----------------------|---------|
| Group I  | 8.2                 | 5.6                  | 0.04    |
| Group II | 8.4                 | 3.2                  | 0.001   |

Table III, graph II shows that mean VAS pre- treatment in group I was 8.2 and in group II was 8.4. The mean VAS post- treatment in group I was 5.6 and in group II was 3.2. The difference was significant (P< 0.05).

**Graph II Comparison of mean difference in the burning sensation (VAS)**



**DISCUSSION**

OSMF is a morbid, crippling, and a premalignant condition of the oral mucosa associated with the areca nut chewing habit.<sup>7</sup> It is commonplace in various Indian states to use pan quid with tobacco and lime. Several medical and surgical approaches have been tried for the management of OSF over the decades. The results are not predictable with some therapies and none has been consistently successful.<sup>8</sup> OSMF is a chronic disease of insidious onset with the deposition of fibrous tissue in the submucosal layer of the pharynx, palate, fauces, cheek, lips, and esophagus.<sup>9</sup> Global estimates of OSMF show confinement among Indians and Southeast Asians, with the overall prevalence rate in India ranging from 0.2% to 0.5%. The etiology of OSMF is considered multifactorial. The habit of areca nut chewing is the common etiological factor of OSMF in the Indian subcontinent.<sup>10</sup> The present study was conducted to compare efficacy of intralesional dexamethasone and hyaluronidase therapy with and without ultrasound therapy in the management of OSMF patients.

In present study, group I patients were prescribed given intralesional infiltration of dexamethasone + hyaluronidase and group II patients were prescribed intralesional infiltration of dexamethasone+ hyaluronidase + ultrasound therapy. Each group had 18 patients. Guduru et al<sup>11</sup> compared the clinical efficacy of intralesional infiltration of 2 ml dexamethasone (4 mg/ml) + hyaluronidase 1500 IU, ultrasound therapy in combination with intralesional infiltration and only ultrasound therapy, in reducing the signs and symptoms in patients with OSMF. A total sample of 33 participants grouped into Group A (intralesional infiltration of 2 ml dexamethasone 4 mg/ml + hyaluronidase 1500 IU dissolved in 0.5 ml of 2% lignocaine twice a week for 8 weeks), Group B (a combination treatment of intralesional infiltration twice a week for 8 weeks and ultrasound therapy for

15 days), and Group C (only ultrasound therapy for 15 days). Statistical analysis revealed that there was a significant difference in M.M.O in Group A ( $1.3 \pm 0.48$ ), Group B ( $2.55 \pm 0.75$ ), and Group C ( $1.65 \pm 1.20$ ) and also VAS score of  $42\% \pm 0.10$ ,  $41\% \pm 0.13$ , and  $15\% \pm 0.05$ , respectively, after treatment.

We found that in group I, pre- treatment mouth opening was 1.4 cm and in group II was 1.6 cm. Post-treatment mouth opening in group I was 2.8 and 3.9 in group II. We found that mean VAS pre- treatment in group I was 8.2 and in group II was 8.4. The mean VAS post- treatment in group I was 5.6 and in group II was 3.2.

Krishnamoorthy et al<sup>12</sup> studied the effects of colchicine in the management of oral submucous fibrosis. Fifty OSF patients were divided randomly into two groups and treated for 12 weeks. Group 1- Patients were administered tablet colchicine orally, 0.5 mg twice daily and 0.5 ml intralesional injection Hyaluronidase 1,500 IU into each buccal mucosa once a week. Group 2- Patients were administered 0.5 ml intralesional injection Hyaluronidase 1,500 IU and 0.5 ml intralesional injection Hydrocortisone acetate 25 mg/ml in each buccal mucosa once a week alternatively. Thirty-three percent in group 1 got relief from burning sensation in the second week. Inter group comparisons of increase in mouth opening and reduction in histological parameters indicated that group 1 patients responded better than group 2. These encouraging results should prompt further clinical trials with colchicine alone on a larger sample size to broaden the therapeutic usefulness of the drug in the management of OSF.

The limitation of the study is small sample size and short follow up.

**CONCLUSION**

Authors found that combination therapy of intralesional infiltration of dexamethasone+

hyaluronidase + ultrasound therapy found to be effective as compared to dexamethasone+ hyaluronidase alone in management of cases of OSMF.

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