ORIGINAL ARTICLE

Therapeutic Effects of Customized ORA Heal Mouthwash on Oral Lichen Planus Patients Reporting at Oral Medicine Clinic at Tertiary Care Hospital

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ABSTRACT

Objective: To determine the therapeutic effects of Customized Ora Heal mouthwash on oral lichen planus patients reporting at oral medicine clinic at tertiary care hospital.

Study Design: Descriptive Cross-sectional study

Place and Duration of Study: Department of Oral Medicine, from June-Dec 2022.

Methodology: This is a descriptive cross-sectional study in which a survey based on the visual analog scale (VAS) was planned and conducted on sixty patients reported to oral medicine department of Dental Hospital reporting with Lichen Planus. **Results:** The study included sixty participants, of which 31 (51.6%) were male and 29 (48.3%) female reporting at Oral medicine department of Dental hospital. The mean age of participants was 45.15. Pre-VAS of participants shows a mean score of 5.033 (moderate pain). After a follow-up of 2 weeks interval, post-VAS of participants shows a mean score of 2.231 (mild pain).

Conclusion: The study shows a decreasing trend in pain intensity of the participants using Ora Heal mouthwash based on pre VAS and post VAS score.

Keywords: Lichen Planus; Ora Heal; Mouthwash; Corticosteroids; VAS score; Pathogenesis; Autoimmune disorder; Mucocutaneous

INTRODUCTION

Oral Lichen planus (OLP) is considered a chronic inflammatory immune-mediated mucocutaneus disease of idiopathic etiology and affects various organs including oral cavity ⁽¹⁾ presents frequently in the elderly patients and affects women more than men in a ratio of 1.4:1 ^(1,2,13). Within the oral cavity, the tongue, buccal mucosa, and gingiva are commonly affected sites, but others are rarely involved ^(4,14). Clinically seen as reticular, papular, erosive, plaque, atrophic, or bullous forms, most commonly reticular and erosive/atrophic forms ^(4,5,10,14). This condition can cause severe side effects, including and significant oral pain and bleeding ulcers in the mouth. As a result, it is very painful and interrupts the daily routine of patients e.g. (drinking, eating, and talking) ^(6,7).

Corticosteroids have become the mainstay of treatment for OLP; however, other pharmacological modalities such as calcineurin inhibitors, retinoids, dapsone, anthocyanins ^{(3,10),} hydroxychloroquine, mycophenolate mofetil, and enoxaparin have contributed significantly to the treatment of this disease. ^(3,14,15,16). Non-pharmacological modalities comprise of Laser therapy, Puva therapy and photodynamic therapy. A variety of mouth washes are prescribed for the treatment of OLP. The major ingredients of these are Triamcinolone Acetonide, dexamethasone, nystatin, and lignocaine.

The use of mouthwash has been advocated in several case studies and its use promises or guarantees to be basic, compelling, effective, and safe for some time. Certainly, magic mouthwash consists of a variety of constituents which provide a synergistic effect to the treatment of OLP ⁽¹¹⁾. Very less literature is present to address the efficacy of magic mouthwash and thus further research is needed to address this issue. The presence of OLP in gingival tissue complicates oral hygiene procedures and their efficiency, it also adversely affects periodontal health for several reasons. Plaque control and consistent oral hygiene are fundamental to the treatment of all oral mucosal disorders. ^(10,13). No therapy for OLP is completely curative; symptomatic patient care is usually palliative.

Even after numerous mouth washes helped to recover patient of OLP but they somehow show no improvement prevention of caries and teeth sensitivity. It is important to improve oral health as well in such patients because the disease itself hampers the hygiene of the oral cavity. Therefore, this research will enable us to check the therapeutic effect of Ora Heal mouth wash to overcome these symptoms as well. The effect will be checked keeping in mind the pre and post VAS score. Many scales are present to assess the pain levels, but the Numeric Rating Scale (NRS-11) is a validated tool consisted of an 11-point scale for the patient for persistent self-reporting of pain. The Rating for Pain Level are as follow:

0 indicates No Pain

 $1{-}3$ Indicates Mild Pain (nagging, annoying, interfering little with ADLs)

4-6 Indicates Moderate Pain (interferes significantly with ADLs)

7–10 Indicates Severe Pain (disabling; unable to perform ADLs)

The visual analog scale or visual analog scale (VAS) is a psychometric reaction scale used in surveys to assess the degrees of pain. It is a measure of subjective traits or attitudes that cannot be measured specifically. When responding to the VAS items, respondents indicate their level of agreement with the statement by indicating their position along the solid line between the two endpoints. This continuous (or "analog") aspect of scales distinguishes them from other discrete scales such as the Likert scale. There's prove that visual analog scales have way better metrological properties than other discrete scales, so a more extensive run of measurable strategies can be connected to its estimations. Visual analog scale can be compared to other linear scales such as the Likert scale and the Borg scale. Although the sensitivity and reproducibility of the results are typically quite comparable, but VAS may occasionally perform better than other scales.

Objective: To compare therapeutic effects of Customized Ora heal Mouthwash on Oral Lichen planus patients via Pre and Post VAS scores.

METHODOLOGY

This is a descriptive cross-sectional study in which a survey was planned and conducted for a period of six months from June 2022 to December 2022 in Oral Medicine Department of Hospital. Ethical approval was obtained from the Institutional Review Board (IRB-978).

Sample size was calculated based on inclusion/exclusion criteria. Inclusion Criteria; Age(30-60 years), presentation <6

months, mild to moderate LP cases VAS(2-6), both genders, LP with or without Xerostomia Cases, any co-morbidity.

Exclusion Criteria; Patient with negative compliance, presentation> 6 months, severe LP cases Vas>6, Psychiatric Illness, any adjunct treatment, Liver Dysfunction.

The therapeutic effects of Ora Heal mouthwash was observed during the clinical evaluation of patients' using visual analog scale (VAS) for 14 days having 1:1 ratio (water: mouthwash). After 14 days, the patients were called for follow up to check the response of the Ora Heal mouth wash. The data was collected, transcribed, anonymized, and analyzed. The variables were expressed through mean and standard deviation.

The data analysis was completed through Statistical package for social sciences or SPSS 25.0 version. The usual descriptive data were produced in the form of continuous variables only through mean and standard deviation. Normality of the data was assessed through Kolmogorov smirnov.

Pre and Post VAS scores were compared and calculated through Paired T test. And the P value of less than 0.05 is considered significant.

RESULTS

The total number of participants in this study included 31 (51.6%) males and 29 (48.3%) females. The respondents were selected from outdoor patients of Oral Medicine Department. They were given a consent form along with the questionnaire to assess their pain levels. According to the results of the study, the pre and post visual analog scores (VAS) of participants have shown significant difference, showing a decrease in post VAS scores. The data about the effect of Customized Ora Heal mouthwash samples is shown in table 1 respectively.

Table 1: Distribution of participants based on Pre VAS and post VAS score:

Participants	Mean	Ν	Standard deviation	Standard Error
Pre VAS	5.033	60	1.153	0.2106*
Post VAS	2.216	60	1.717	0.3136*

*Mean (standard deviation) * Result shows Likert score

The table shows a decreasing trend in pain intensity of the participants based on pre VAS and post VAS scores.

The Statistics of table 1 shows 2 parameters, i.e., Pre-VAS score and post-VAS scores of 60 patients. According to our inclusion criteria, the age limit is set at 30-60 years and VAS score ranges from 0-6 (up to moderate pain level). All parameters show patients corresponding to the Ora Heal mouthwash. This mouthwash has resulted in great improvement and recovery in the patients. Moreover, this mouthwash has not only shown great results in curing lichen planus condition but has also act as an adjunct to the treatment of carious state in such patients as well.

DISCUSSION

There are numerous etiologic variables, including stress, immunologic diseases, genetics, and HCV infection, that may have a significant impact on the pathogenesis of oral lichen planus, a chronic mucocutaneous infection with an idiopathic etiology. (2,3) Patients report to the oral medicine department of dental hospital with usual complains of burning sensation, sensitivity to acidic and spicy foods, bleeding gums and ulceration, characteristic of lichen planus (6). Even though the erosive type of lichen planus is less common than the reticular form, we should pay closer attention to it because of its aggressive clinical symptoms. Despite the use of numerous medicines, including magic mouthwash and corticosteroids, retinoids, cyclosporine, dapsone, and others with different side effects, there is still no known cure found for lichen planus. (1, 10, 11, 12)

This research sought to ascertain the impact of Customized Ora Heal mouthwash on Lichen planus patients. The sample consisted of secret ingredients such as fluoride, numbing agents, an antifungal medication, and a topical steroid to reduce inflammation etc. The participants were given instructions on the use of the prescribed sample as it is only suitable for swishing orally before spitting it out, ingesting of the mouthwash was not recommended.

According to the results of the present study, a decreasing trend in pain intensity of the participants based on pre VAS and post VAS scores was found which signifies that Customized Ora Heal shows significant change in pre and post VAS scores of participants. Other treatment modalities were recommended if symptoms for OLP are severe even after using the prescribed mouthwash. Follow-up is required, including oversight of medication use, monitoring of side effects, and recurrent checks for potential malignant change ⁽¹⁷⁾.

CONCLUSION

The findings of this preliminary research indicate that using this customized mouthwash to treat oral lichen planus could be a safe and broad treatment option. However, a bigger population should be investigated to determine the therapeutic efficacy of this mouth wash along with occurrence of local adverse effects, such as secondary candidiasis in the oral cavity, which frequently occurs with a long-term use of topical corticosteroids.

Ethical Approval: Ethical approval of this study was obtained from Hospital.

Conflict of Interest: The authors have no conflicts of interest in this study.

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