RESEARCH PAPER

A Randomized, Double-Blind, Active Controlled, Parallel-Group, Clinical Study to Evaluate the Efficacy and Safety of Poly Herb Gel in Treatment of Clinically Diagnosed Grade 2 Oral Sub Mucous Fibrosis

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ABSTRACT

Context: Oral Submucous Fibrosis (OSMF) is a chronic, progressive, potentially malignant disorder of the oral cavity. Conventional management includes intralesional corticosteroid therapy; however, adjunctive therapies with herbal extracts and anti-inflammatory properties may enhance therapeutic outcomes.

Aims: To evaluate the efficacy of Polyherb Gel as an adjunct to standard care and to assess salivary malondialdehyde (MDA), sialic acid, and lactate dehydrogenase (LDH) levels as diagnostic and prognostic biomarkers in patients with Grade 2 OSMF.

Settings and Design: A randomized, double-blind, active-controlled, parallel-group clinical study conducted in patients clinically diagnosed with Grade 2 OSMF.

Methods and Material: Sixty patients with OSMF were randomly allocated into two groups. Group A received standard treatment along with Polyherb Gel, while Group B received standard treatment with placebo gel. Clinical parameters including mouth opening, burning sensation, mucosal blanching, and pain scores were assessed. Salivary levels of MDA, sialic acid, and LDH were estimated at baseline and post-treatment.

Statistical analysis used: Statistical analysis was performed using appropriate parametric and non-parametric tests. A p-value <0.05 was considered statistically significant.

Results: Patients in Group A showed a statistically significant reduction in salivary MDA, sialic acid, and LDH levels compared to the control group. Significant clinical improvement in mouth opening, burning sensation, mucosal blanching, and pain scores was also observed. No adverse effects were reported.

Conclusions: Polyherb Gel is a safe, non-invasive, and effective adjunctive therapy that provides significant biochemical and clinical benefits in the management of early-stage OSMF

Keywords: OSMF; Polyherb Gel; Salivary Biomarkers; Oxidative Stress

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INTRODUCTION

Oral Submucous Fibrosis (OSMF) is a chronic, progressive Oral Potentially Malignant Disorder (OPMD) predominantly associated with areca nut chewing[1,2]. In 1966, Pindborg defined OSMF as an insidious chronic disease affecting the oral cavity and occasionally the pharynx, characterized by juxta-epithelial inflammation followed by fibro-elastic changes of the lamina propria, epithelial atrophy, mucosal stiffness, trismus, and difficulty in eating [3].

OSMF is one of the most common OPMD in India, with prevalence rates of 1.2–4.6% in females and 0.2–2.3% in males. The risk of malignant transformation ranges from 1.9% to 9% among individuals aged 20–60 years.[4]

Saliva is an easily accessible biological fluid that reflects molecular alterations in oral tissues and serves as a valuable non-invasive tool for early detection and monitoring of OPMDs.[5] Elevated salivary levels of malondialdehyde (MDA), sialic acid, and lactate dehydrogenase (LDH) indicate lipid peroxidation, oxidative stress, and epithelial damage, and can act as prognostic markers for free-radical–induced cellular injury [6,7,8,9].

Current management of OSMF includes intralesional corticosteroids, hyaluronidase, antioxidants, physiotherapy, and surgery in advanced cases[10],[11]; However, these treatments are often invasive, expensive, require multiple clinical visits, and show variable efficacy, especially in early stages. Intralesional therapies may be painful and associated with side effects, while antioxidants require prolonged use with inconsistent outcomes.[12]

Managing grade 2 OSMF is very important and crucial as it could undergo malignant transformation, and there is no definitive therapy available highlighting a significant therapeutic gap. Polyherb formulations possessing anti-inflammatory, antioxidant, and wound-healing properties offer a safer and cost-effective adjunctive approach. Such formulations are particularly beneficial for patients from rural or economically weaker backgrounds due to improved compliance and reduced need for invasive procedures.[13,14]

Therefore, the present study aims to fulfil this therapeutic gap by clinically validating a non-invasive polyherbal gel as an adjuvant therapy for early-stage OSMF, potentially improving treatment outcomes and quality of life.

AIM:

The aim of the study is to evaluate the efficacy of poly herb gel with standard of care and to compare salivary biomarkers MDA, Sialic acid, LDH level as a reliable diagnostic and prognostic indicator in the Management of grade 2 OSMF.

OBJECTIVES:

- To examine and assess the oral findings in study groups with grade 2 OSMF before and after treatment using poly herb gel 2gm along with standard of care.
- To estimate salivary MDA, sialic acid, LDH levels before and after treatment in study groups and control group with grade 2 OSMF.
- To evaluate and compare the therapeutic efficacy of poly herb gel between study groups and the control group with grade 2 OSMF.
- To correlate changes in the salivary biomarkers level before and after treatment with poly herb gel in study groups and control group with grade 2 OSMF.

SUBJECTS AND METHODS:

It is a prospective, double-blind, randomized, placebo-controlled, parallel-group study conducted in the Department of Oral Medicine and Radiology, M R Ambedkar Dental College and Hospital, Bangalore after obtaining institutional ethics committee approval and informed consent from all participants. The study was prospectively registered with the Clinical Trials Registry of India in accordance with ICMR guidelines and was conducted in compliance with the Declaration of Helsinki (Edinburgh, 2000) and ICH–Good Clinical Practice guidelines.

A total of 60 patients, aged between 18–60 years falling under Grade 2 of OSMF as per the grading system provided by Kerr et al., were enrolled.

Participants selected after fulfilling criteria were randomly allocated into two groups using a computer-generated randomization list:

Group A (Study Group, n = 30): Received 2 g of polyherbal gel applied topically to the buccal mucosa twice daily for 12 weeks, along with standard of care comprising intralesional corticosteroid (2 ml dexamethasone 4 mg/ml) and hyaluronidase (1500 IU) administered weekly for 8 weeks.

Group B (Control Group, n = 30): Received a water-based placebo gel applied topically twice daily for 12 weeks, along with the standard of care.

Inclusion Criteria:

- Adults aged 18–60 years with clinically diagnosed Grade 2 OSMF
- No underlying comorbidities
- Willing to quit betel quid/areca nut/gutkha habits
- Committed to regular follow-ups, able to provide informed consent and comply with the study procedures.

Exclusion Criteria:

- Contraindicated / allergic to steroids or on systemic steroids
- Other mucosal disorders mimicking OSMF
- Prior treatment for OSMF
- Hypersensitivity to hyaluronidase or herbal drugs
- Grade 1, 3 or 4 OSMF
- Pregnant or lactating women
- Advanced disease with premalignant/malignant changes

The investigational herbal gel was sourced and provided by Natureorama Private Limited.

Selected polyherbal formulations as our investigational drug contains:

• Picrasma Quassioides[15]

• Carum Carvi[16]

• Piper Nigrum

• Caesalpinia bonduc [17,18]

• Withania Somnifera[19]

• Myristica Fragrans [20]

• Nigella Sativa [21]

• Ocimum Sanctum

• Mimosops Elengi

• Acacia Catechu [22]

• Cuminum Cyminium

• Boerhavia Diffusa

The present poly herb gel consists of the constituents which have Anti- inflammatory, Antioxidant, Immunomodulatory, Antibacterial and Anti-mutagenic action which suppressing tumour necrosis factor (TNF), enhance immunity and metabolic functions which is safer and also cost effective.

The collection of salivary samples is simple, non-invasive and cost-effective which provide critical insights into inflammation, oxidative stress, and tissue damage within the oral cavity.

Salivary samples are collected before the initiation of treatment and after completion of treatment.

In both group A and group B 5 ml of saliva were collected two hours after breakfast. Participants were instructed to rinse their mouths with distilled water to eliminate food particles. Using the spitting method unstimulated saliva was expectorated into a sterile plastic container. The containers were labelled and transported in an ice pack container at 2^{o} – 8^{0}C to the laboratory and centrifuged at 1000 × g at 2-8°C for 15 minutes and stored at-20°C or -80°C. The supernatant collected were estimated for salivary MDA, Sialic acid and LDH levels.

Safety & Efficacy end points were assessed;

- Change in the intra incisal distance (mouth opening)
- Change in the fibrous bands clinically
- Change in the burning sensation of oral mucosa
- Change in the swallowing
- Change in the improvement of speech
- Change in blanching of mucosa
- Change in evaluation of salivary Biomarkers

Clinical outcomes were assessed on day 30, 60, and 90 however salivary biomarkers were assessed pre and post treatment.

Safety end-points i.e Adverse events monitored on days of assessment as volunteered by the patient.

Statistical analysis was performed using SPSS software version 24.0 (IBM Corp., Armonk, NY, USA). Data were expressed as mean ± standard deviation (SD). Intragroup comparisons between pre- and post-treatment values were performed using the paired t-test, while intergroup comparisons were analyzed using appropriate parametric or non-parametric tests. A p-value < 0.05 was considered statistically significant.

RESULTS:

Sixty patients with clinically diagnosed Grade 2 Oral Submucous Fibrosis completed the study. Clinical parameters were evaluated at baseline and at follow-up visits, while salivary biomarkers were assessed at baseline and after 90 days of treatment

Clinical Parameters

Patients in Group A demonstrated a statistically significant reduction in burning sensation, pain scores, and blanching of oral mucosa by Visit 4, with complete resolution of burning sensation and mouth opening difficulty in all participants. Oral health–related quality of life scores and clinical grading of OSMF also improved significantly in Group A. In contrast, Group B showed minimal or no improvement across clinical parameters (Table 1).

Table 1. Posttreatment efficacy of Poly Herb Gel on clinical parameters in patients with Oral Submucous Fibrosis

Parameter	**Group A (n = 30)**			**Group B (n = 30)**		
	Pretreatment	Posttreatment	P*	Pretreatment	Posttreatment	P*
VAS score for burning sensation	2.64 ± 0.78	0.00 ± 0.00	<0.0001	2.52 ± 0.69	1.48 ± 0.62	<0.0001
Difficulty in mouth opening (% patients)	71.4%	0%	<0.0001	100%	Persistent	NS

Blanching of mucosa (score)	0.93 ± 0.25	0.54 ± 0.18	<0.0001	2.00 ± 0.00	1.93 ± 0.26	NS
Pain (VAS score)	2.64 ± 0.72	1.71 ± 0.61	<0.0001	2.44 ± 0.66	2.52 ± 0.63	NS
Oral health–related quality of life (OHRQoL) score	34.96 ± 5.21	27.86 ± 4.73	<0.0001	35.37 ± 5.08	35.12 ± 5.11	NS
Clinical grading of OSMF	1.64 ± 0.51	1.46 ± 0.51	<0.0001	1.48 ± 0.51	1.48 ± 0.51	NS

Salivary Biomarkers

Group A showed a significant reduction in salivary malondialdehyde, sialic acid, and lactate dehydrogenase levels at the end of the study compared to baseline. The magnitude of reduction was significantly greater in Group A than in Group B, indicating superior biochemical improvement with Poly Herb Gel therapy (Table 2).

Table 2. Posttreatment efficacy of Poly Herb Gel on salivary biomarkers in patients with Oral Submucous Fibrosis

Parameter	**Group A (n = 30)**			**Group B (n = 30)**		
	Pretreatment	Posttreatment	P*	Pretreatment	Posttreatment	P*
Malondialdehyde (MDA) (nmol/mL)	0.30 ± 0.02	0.24 ± 0.03	<0.0001	0.29 ± 0.03	0.28 ± 0.03	0.0133
Sialic acid (mg/dL)	33.25 ± 5.25	26.11 ± 4.36	<0.0001	30.52 ± 3.71	29.59 ± 4.33	0.0044
Lactate dehydrogenase (LDH) (U/L)	278.43 ± 27.02	243.19 ± 29.69	0.0006	264.26 ± 34.87	254.76 ± 34.08	NS

NS – Not significant; VAS – Visual Analog Scale.

No adverse events or treatment-related mucosal reactions were reported during the study period.

DISCUSSION:

Oral submucous fibrosis (OSMF) is a chronic, progressive oral potentially malignant disorder characterized by excessive submucosal collagen deposition, fibrosis, epithelial atrophy, and functional limitation of oral opening, leading to burning sensation and marked impairment in quality of life.[23,24]

In the present randomized clinical study, adjunctive use of Poly Herb Gel with standard care resulted in significantly greater clinical improvement compared to standard care alone, particularly in terms of reduction of burning sensation and pain. Burning sensation in OSMF has been linked to mucosal inflammation and epithelial atrophy caused by chronic areca nut exposure and reactive oxygen species (ROS)–mediated damage.[6]

Improvement in mucosal blanching and clinical grading in the Poly Herb Gel group suggests a favorable influence on early disease progression, as blanching is indicative of compromised vascularity and fibrotic changes within the lamina propria. These findings may reflect modulatory effects of the herbal constituents on fibrotic activity, potentially through regulation of collagen synthesis and remodelling pathways.

Enhancement in oral health–related quality of life observed with adjunctive therapy underscores its functional and psychosocial benefits for patients suffering from a chronic debilitating condition like OSMF.

Salivary biomarkers were included to provide objective biochemical evidence of therapeutic effect. Salivary malondialdehyde (MDA), a well established marker of lipid peroxidation and oxidative stress, was significantly reduced in the Poly Herb Gel group. Elevated salivary MDA levels have been documented in OSMF and correlate positively with disease stage and histopathological grade, reflecting heightened oxidative stress in the disorder.[6,25]

Salivary sialic acid, a marker associated with chronic inflammation, epithelial turnover, and risk of malignant transformation, also demonstrated a significant decrease with adjunctive therapy. Elevated levels of sialic acid have been observed in OSMF and other oral potentially malignant disorders, signifying altered glycoprotein metabolism and inflammatory activity.[26]

Lactate dehydrogenase (LDH), an intracellular enzyme released during cellular injury, showed significant reduction in the Poly Herb Gel group. Elevated salivary

and serum LDH levels are well documented in OSMF patients compared with healthy controls, indicating increased epithelial damage and cell turnover associated with disease activity.[25]

The consistently superior improvements observed in the Poly Herb Gel group across clinical parameters, salivary biomarkers, and quality of life measures support its therapeutic advantage as an adjunctive treatment in early stage OSMF. Importantly, no adverse effects or mucosal ulcerations were noted during the study, highlighting the safety and tolerability of the topical polyherbal formulation.

Herbal and antioxidant therapies have been increasingly investigated in OSMF management. Clinical trials and systematic reviews have shown positive outcomes with agents such as aloe vera, curcumin, lycopene, and other plant bioactives in improving symptoms and reducing oxidative stress in OSMF, although heterogeneity in study designs and outcomes limits direct comparisons.[27]

Limitations of this study include a relatively short follow up duration (12 weeks) and a modest sample size, which may not fully capture long term disease modification or relapse. Future research should incorporate extended follow up, larger cohorts, histopathological evaluation, and molecular biomarker assessments to further elucidate the antifibrotic and chemopreventive potential of Poly Herb Gel.

Within these limitations, the present study provides clinical and biochemical evidence supporting the efficacy and safety of Poly Herb Gel as an adjunctive therapeutic option in early stage OSMF.

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