

RESEARCH ARTICLE

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Comparing the Therapeutic Efficacy of Curcuma Caesia Roxb Over Curcuma Longa in Managing Oral Submucous Fibrosis: A Non-Randomized Clinical Trial

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Abstract

Objective: To determine and compare the therapeutic efficacy of Curcuma caesia Roxb over Curcuma Longa in managing Oral Submucous Fibrosis (OSMF). **Materials and Methods:** A clinical trial was conducted on 51 patients diagnosed with oral submucous fibrosis, who were equally divided into two groups. The first group received a treatment of powdered Curcuma caesia Roxb mixed with honey in an equal ratio. In contrast, the second group received powdered Curcuma longa mixed with honey in a similar ratio. Both groups were instructed to apply the mixture thrice daily for three months. Additionally, a control group received a placebo, and all patients were advised to continue physiotherapeutic mouth-opening exercises for three months. The parameters evaluated included burning sensation, cheek flexibility, mouth opening, and tongue protrusion. **Results:** Statistically significant results were observed after 3 months ($P < 0.001$). Group A showed more symptomatic improvement than Group B. Group A experienced a significant reduction in burning sensation and increased mouth opening, while Group B showed significant improvement in cheek flexibility. The mean percentage increase in mouth opening was significantly greater in Group A compared to Group B, but VAS scores for burning sensation did not show marked differences. P-value was statistically significant in both cases to show promising results. **Conclusion:** The study shows that Group A patients had reduced burning sensation, improved tongue protrusion, and increased mouth opening, while Group B had slightly better cheek flexibility. Curcuma caesia roxb improved clinical parameters like burning, tongue flexibility, and mouth opening. The study concludes that combination therapy can manage complex conditions like Oral Submucous Fibrosis effectively. Larger-scale studies with bigger sample sizes are recommended.

Keywords: antioxidant- black turmeric- Curcuma caesia Roxb- oral submucous fibrosis- yellow turmeric

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Introduction

Oral Submucous Fibrosis (OSMF) is an insidious, chronic condition affecting the buccal mucosa, vermillion border, and even soft palate & faucial pillars [1]. They are often considered one of the most common yet least understood and not wholly cured mucosal conditions. The Indian subcontinent is affected by this pathology on a vast and widespread level. Extending its inclusion from the northeastern zone of India towards the southern horizon, many people are suffering from this debilitating oral condition. Being multifaceted, it is impossible to cure a disease with a single ingredient or drug. Depending on the cause of the pathology, it becomes easy to manipulate and modify the treatment regimen accordingly to improve the prognosis.

Introducing Ayurveda-based studies in our modern

research context has been a boon for incurable pathologies. For decades, herbal products like Aloe vera, turmeric, Amla, Tulsi, honey, giloy, etc., have all been consumed regularly by us as these products show promising results against fighting such pathologies and create an innate immunity in our body against worldly pathogens. Turmeric(haldi) has always been an excellent antioxidant, antiseptic, and anti-aging product that many of our ancestors used. Not only this, but it also shows many promising properties like antimutagenic, cytotoxic, antifungal, and anti-inflammatory properties. These properties are due to curcumin in turmeric, which uplifts and strengthens the body's immune system.

A wide variety of turmeric is grown in different parts of India; out of them, Rhizomes of Curcuma caesia Roxb, commonly known as Black turmeric or Kali haldi, is the richest source of curcumin with the curcumin

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content of curcumin (2.82%), ar-curcumin (14.84%) [2, 3]. Comparing this with its most common counterpart, yellow turmeric or *Curcuma Longa*, the curcumin content is about (3-5%) [4-6]. Turmeric spice is widely accepted as a healing product and has several medicinal properties. However, despite its rich curcumin content, black turmeric's therapeutic efficacy and productivity remain less explored than yellow turmeric's. This paper emphasizes the effect of using black turmeric powder and compares it with yellow turmeric powder in patients suffering from oral submucous fibrosis [7].

Materials and Methods

This study was conducted in the Department of Oral Medicine and Radiology at a private institution from April 2023 to June 2023. Approval for the study was obtained from the institutional ethical committee (IHEC/SDC/PhD/OMED-1617/21/235). Patients diagnosed with OSMF (Stage 2 & Stage 3) according to the criteria set by More et al. [8] were enrolled in the study. Exclusion criteria included pregnant women, lactating mothers, patients with conditions such as diabetes mellitus, hypothyroidism, hypertension, renal disorders, cardiac disorders, etc., patients with known hypersensitivity to any drugs, those who had undergone treatment for oral submucous fibrosis, and patients with a history of other oral premalignant lesions or conditions. Fifty-one patients consented in writing and agreed to regular follow-up visits and were included in the study. A pilot study was performed to determine the sample size, and based on this, the final number of samples was established. The sample size was calculated using G Power software, with an Fx number set to 1.3. The demographic distribution consisted of 12 males and 5 females in Group A, 10 males and 7 females in Group B, and 14 males and 3 females in the Control group, with ages ranging from 25 to 70 years. All patients received informed consent, and the complete procedures were explained, although not all ingredients used were disclosed to the patients. A thorough clinical examination was conducted, and an independent examiner measured and recorded specific parameters. Biopsy specimens were collected from each patient and sent for histopathological analysis to confirm the presence of OSMF. Four clinical parameters related to OSMF were selected to evaluate and compare improvements in each patient before and after treatment.

1. Burning scale- Based on the Visual analog scale (VAS), each patient's grading of the burning sensation in the oral cavity was recorded and checked after every visit.

2. Mouth opening scale Interincisal distance was measured to determine each patient's maximum possible mouth size and evaluated pre- and post-treatment.

3. The Cheek flexibility scale (CF) was measured according to the procedures explained & described by Bailoor and Nagesh (Patil and Maheshwari, [9]).

4. Tongue protrusion was assessed from the mesio-incisal angle of the maxillary central incisor to the anterior portion of the tongue when maximally extended with the mouth wide open (Ramesh and Saba, [10]).

The patients were divided into two groups equally, with

each group having 17 patients with an unequal male-to-female ratio (Group A, Group B, and the Control Group). Group A patients were given a combination of Black turmeric powder and honey in an equal ratio of 1:1. Pure Black turmeric rhizomes were grown, dried, and crushed into a fine powder mixture. Before the trial, an initial in vitro study was performed on oral fibroblast cells to check for black turmeric's efficacy, cytotoxic potential, and antioxidant and anti-inflammatory properties (Figure 1, Supplementary Graphs 1- 3). Two grams of black turmeric powder were mixed with two milliliters of honey with the help of a measuring spoon. The mixture was mixed thoroughly and applied bilaterally and uniformly on the buccal mucosa and other areas affected by the patient. This mixture must be used thrice daily and continue for three months. Regular follow-ups are carried out after 15 days, at one-month, two-month, and three-month intervals, to check for the treatment progress.

Group B patients were provided with a mixture of yellow turmeric and honey, mixed in the same equal ratio of 1:1. Organically grown rhizomes of yellow turmeric are processed into powder form to make a fine powder. An in vitro study was done on oral fibroblastic cells to check for yellow turmeric's cytotoxic potential and antioxidant and anti-inflammatory properties at the preliminary level (Figure 2, Graphs 2, 4). The exact quantity of two gm powder was mixed with two ml of honey and applied by the patient in the affected areas orally thrice a day for three months, followed by fixed schedules of 15 days, one month, two months, and three months of follow-ups. (Figure 2) Both groups were compared with control groups to standardize the study results broadly. Control Group patients were provided with placebo therapy, and physiotherapeutic exercises were advised to the patients till completion of 3 months. Pre- and post-treatment clinical changes are calculated systematically.

Statistical analysis

Statistical analysis was done using SPSS 25 (Statistical

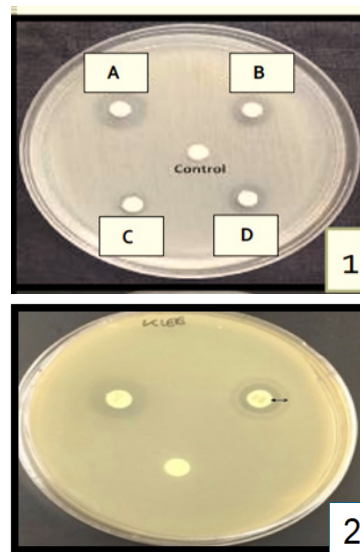


Figure 1. Antimicrobial Activity of *Curcuma Caesia* Roxb Extracts against *S. aureus* & compared with Antibiotic.

Package for Social Science by International Business Machines Corporation) to evaluate the study for statistical significance. After performing clinical procedures, the data was collected and tabulated correctly to understand and assess the efficacy results for each group. A paired t-test was conducted to evaluate the efficacy of the drugs at the individual level at an interval of baseline, one-month, two-month, and three-month duration.

Results

Group A, which included both test and control subjects, was assessed separately from the baseline to the end of the three months for burning mouth sensation. The sensation varied from 6.33 at baseline to 1.19 after the third month. Mouth opening measurements ranged from 2.75 (baseline) to 4.98 (end of third month), cheek flexibility ranged from 0.12 to 0.85, and tongue protrusion ranged from 3.01 to 4.08.

Similarly, Group B data demonstrated that burning mouth sensation varied from 6.13 at baseline to 2.89 after the third month. Mouth opening measurements ranged from 2.72 (baseline) to 4.18 (end of third month), cheek flexibility ranged from 0.13 to 1.55, and tongue protrusion ranged from 3.11 to 3.98. These metrics were evaluated using paired t-tests to analyze and quantify the clinical pre- and post-treatment changes for all four subjective findings.

The P value for the comparison of burning sensation and mouth opening between test Group A and the control group was determined to be 0.003 and 0.001, respectively, indicating statistical significance. Furthermore, for test Group B compared to the control group, cheek flexibility exhibited a statistically significant P value of 0.004.

Both results are statistically significant and well-documented (Table 1). Pre-treatment burning sensation and mouth opening were substantially reduced in test Group A, while cheek flexibility showed a notable, statistically significant improvement in test Group B after the three months. Comparative evaluations of parameters for Groups A and B are presented in Tables 1 and 2. The

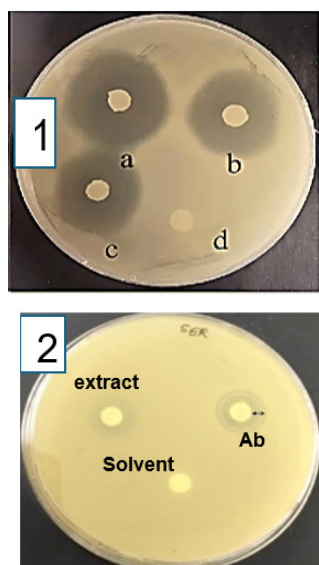


Figure 2. Antimicrobial Activity of Curcuma Longa Extract against *S. aureus* & Compared with Antibiotic

Table 2. Comparison of Mean Value of Parameters between Study Group B & Control Group at Different Time Intervals.

Variables	At Baseline			After one month			After two months			After three months		
	Group B	Control group	P value	Group B	Control Group	P value	Group B	Control group	P value	Group B	Control Group	P Value
Burning Sensation	6.13+/-1.34	6.54+/-1.34	0.7	4.8+/-1.01	6.38+/-0.57	0.9	3.23+/-0.62	6.21+/-1.39	0.2	2.89+/-0.51	6.17+/-1.05	0.4
Mouth Opening	2.72+/-0.42	2.69+/-0.73	0.1	3.39+/-0.47	2.77+/-0.6	0.05	4.05+/-0.53	2.89+/-0.69	0.11	4.18+/-0.49	2.95+/-0.56	0.21
Cheek Flexibility	0.13+/-0.04	0.23+/-0.05	0.3	0.41+/-0.08	0.28+/-0.13	0.02*	0.94+/-0.09	0.31+/-0.13	0.003*	1.55+/-0.03	0.35+/-0.11	0.004*
Tongue Protrusion	3.11+/-0.62	2.77+/-0.53	0.03*	3.88+/-0.71	2.79+/-0.43	0.7	3.65+/-0.54	2.84+/-0.63	0.04	3.98+/-0.62	2.89+/-0.32	0.2

Values in Cm.

Table 1. Comparison of Mean Value of Parameters between Study Group A and Control Group at Different Time Intervals

Variables	At Baseline			After one month			After two months			After three months		
	Group A	Control group	P value	Group A	Control Group	P value	Group A	Control group	P value	Group A	Control Group	P Value
Burning Sensation	6.33+/-1.34	6.54+/-1.34	0.7	3.8+/-1.01	6.38+/-0.57	0.03*	2.3+/-0.62	6.21+/-1.39	0.2	1.19+/-0.51	6.17+/-1.05	0.003*
Mouth Opening	2.71+/-0.42	2.69+/-0.73	0.1	3.49+/-0.47	2.77+/-0.6	0.06	4.55+/-0.53	2.89+/-0.69	0.1	4.98+/-0.49	2.95+/-0.56	0.31
Cheek Flexibility	0.12+/-0.04	0.23+/-0.05	0.3	0.21+/-0.08	0.28+/-0.13	0.02*	0.44+/-0.09	0.31+/-0.13	0.003*	0.85+/-0.03	0.35+/-0.11	0.4
Tongue Protrusion	3.01+/-0.62	2.77+/-0.53	0.03*	2.98+/-0.71	2.79+/-0.43	0.5	3.85+/-0.54	2.84+/-0.63	0.04	4.08+/-0.62	2.89+/-0.32	0.02*

Values in Cm.

Table 3. Composition of Curcuma Caesia Roxib and Curcuma Longa

Rhizome	Component	Percentage
C. caesia Roxib (Kerala variety)	δ -linalool	20.42%
C. caesia Roxib (Kerala variety)	δ -camphor	18.88%
C. caesia Roxib (Kerala variety)	ocimene	15.66%
C. caesia Roxib (Kerala variety)	1-arcurcumene	14.84%
C. caesia Roxib (Kerala variety)	zingiberol	12.60%
C. caesia Roxib (Kerala variety)	1,8-cineole	9.06%
C. caesia Roxib (Kerala variety)	δ -borneol	7%
C. caesia Roxib (Kerala variety)	1,8-cineole	30.40%
C. caesia Roxib (Kerala variety)	camphor	10.80%
C. caesia Roxib (Kerala variety)	curzerene	8.80%
C. caesia Roxib (Kerala variety)	curzerenone	5.80%
C. Longa (North-eastern variety)	zingiberene	25%
C. Longa (North-eastern variety)	cineole	1%
C. Longa (North-eastern variety)	sesquiterpenes	53%
C. Longa (North-eastern variety)	borneol	0.50%
C. Longa (North-eastern variety)	curcumin	3-6%
C. Longa (North-eastern variety)	curcumin I (diferuloylmethane)	94%
C. Longa (North-eastern variety)	curcumin II (demethoxycurcumin)	6%
C. Longa (North-eastern variety)	curcumin III (bis-demethoxycurcumin)	0.30%

(The reason behind its yellow color)



Figure 3. Showing Buccal Mucosal Blanching in Oral Submucous Fibrosis Patient

mean percentage reduction of VAS scores for burning sensation is absent, while the mean percentage increase in mouth opening shows statistically significant results for Group A patients relative to Group B results. Conversely, there is a considerable improvement in cheek flexibility for Group B patients compared to Group A, with statistically significant results. Similar metrics for tongue protrusion are observed in both Groups A and B. Thus, it can be concluded that both Test Groups A and B effectively manage Oral Submucous Fibrosis patients and deliver promising results, with the efficacy of Group A being slightly higher than that of Group B.

Discussion

Both black and yellow turmeric exhibit antiseptic

and anti-inflammatory properties by inhibiting the NF κ B activation mechanism at the cellular level. Curcumin in turmeric restricts the phosphorylation process, which results in the degradation of IB α . This causes NF- κ B to remain bound with I κ B α in the cell's cytoplasm, preventing it from entering the nucleus and participating in the transcription process. Research by Hastak et al. demonstrated the efficacy of turmeric extract, turmeric oil, and oleoresin, showing that all patients experienced varying degrees of clinical improvement in burning sensation due to the essential oils in the curcumin matrix. Major difference between the composition of Curcuma caesia roxb and Curcuma longa [11-13].(Table 3).

Das et al. [8] reported findings that align with our research, noting that patients in Groups I and II (curcumin capsules and curcumin oil) exhibited a statistically significant reduction in burning sensation and an increase in mouth opening, respectively, which is consistent with our results [14-16]. Our study provides a preliminary comparative analysis of black turmeric and yellow turmeric test groups for oral submucous fibrosis patients. The group treated with black turmeric demonstrated excellent results in reducing burning sensations and improving mouth opening. In contrast, Group B, treated with yellow turmeric, showed significant improvement in cheek flexibility [17-19]. The tongue protrusion for both groups remained almost the same, with a slightly higher tendency observed in group A. Black turmeric, a rich source of curcumin-rich phytonutrients and essential oils, is comparatively less explored [20]. To date, the yellow turmeric variety has primarily been focused on and used for therapeutic procedures. Yellow turmeric is commonly used in culinary practices as a spice in dishes such as curry and beverages like golden milk. It is also known for its

medicinal properties, which include soothing sore throats and promoting overall well-being [21].

Black turmeric's potent antioxidant properties help combat oxidative stress and free radical damage. Additionally, it supports digestive health, boosts the immune system, and may relieve inflammation. Black turmeric contains compounds such as tannins, elemene, and bornyl acetate, which offer various health benefits, including anti-inflammatory, anti-cancer, and antimicrobial properties [22, 23]. This paper emphasizes the positive outcomes of black turmeric on the submucosal level and presents promising results for mucosal and submucosal pathologies. The findings suggest that black turmeric could potentially be more effective than yellow turmeric when used under different variables and subjected to further investigation.

Conclusion- Turmeric has been used in Ayurveda, Unani, tribal, and Siddha natural therapy systems since old time. Clinical surveys show that a broad spectrum of pharmacogenetic properties is present in this potent drug. The activities of turmeric are either in powder or extracts, with limited or no side effects. Many products containing turmeric or a mixture of this drug have been launched in the Indian market for decades. This paper sheds light on the potency of curcumin content in different subspecies from *Curcuma* subgroups to be effective against various areas of pathogenicity. Yet, it has not been administered on a more significant level in study groups. Burning sensation in OSMF patients was reduced, and Mouth Opening was vastly improved by black turmeric extract. On the other hand, yellow turmeric extract showed promising results for cheek Flexibility. Extensive work has been reported on this herb. More studies should be conducted on this herb in different ratios and combinations to understand the level of antioxidant potential of the drug against many existing pathologies.

Author Contribution Statement

Dr Ankita Bohra- Manuscript writing, data synthesis, and technical modifications. Dr T.N. Uma Maheswari-Discussion writing and data collection. Dr Aditya Harsh-Sample size collection and estimation.

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Approval

The study was approved by the Scientific Ethical Committee of Saveetha Institute of Medical and Technical University. IHEC/SDC/PhD/OMED-1617/21/235.

Conflict of Interests

The authors do not show any conflicts of interest in the study.

Limitations of the study

We need more original research on the mass population and more neural networks to be included for more accurate and authentic outcomes.

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