



Efficacy of the holy basil in the treatment of oral submucous fibrosis: a systematic review and meta-analysis

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Abstract

INTRODUCTION. The review aimed to evaluate the therapeutic efficacy of holy basil (*ocimum sanctum*) in managing oral submucous fibrosis (OSMF), focusing on its impact on clinical symptoms such as burning sensation, mouth opening, tongue protrusion, cheek flexibility, blanching, and fibrosis.

MATERIALS AND METHODS. A comprehensive search was conducted across PubMed-Medline, Scopus, Embase, Cochrane Library and Google Scholar from the earliest available date upto 5th April, 2025. Studies included were randomized controlled trials (RCTs) and observational studies involving patients diagnosed with OSMF, assessing the efficacy of holy basil in any formulation (such as extract or oil) on clinical symptoms. Both Two reviewers independently performed data extraction and quality assessment using the Cochrane RoB 2.0 and ROBINS-I tools. Where appropriate, a metaanalysis (MA) was performed, where summarized raw mean (MRAW) standardized mean differences (SMDs) were calculated.

RESULTS. A total of 7 studies met the inclusion criteria, comprising 5 observational and 2 experimental studies conducted in India between 2017 and 2023. The MA demonstrated significant improvements in maximal mouth opening with MRAW = 36.14 mm; 95% confidence interval [CI]: 22.3–49.98) and reduction in burning sensation (SMD = 2.6; 95% CI: 1.94–3.25) in patients receiving holy basil-based treatments. Substantial heterogeneity was noted for mouth opening outcomes ($I^2 = 96\%$), whereas the results for burning sensation were relatively consistent across studies ($I^2 < 50\%$). Secondary outcomes, such as cheek flexibility, were reported in only one study, restricting broader generalization.

CONCLUSIONS. The findings suggest that Holy Basil, administered in various formulations, shows promising potential in improving key clinical symptoms such as maximal mouth opening, burning sensation, and tongue protrusion.

Keywords: oral submucous fibrosis, *ocimum sanctum*, anti-inflammatory agents, herbal, phytotherapy

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Эффективность туласи в лечении орального субмукозного фиброза: систематический обзор и мета-анализ

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Резюме

ВВЕДЕНИЕ. Целью обзора было оценить терапевтическую эффективность святого базилика (*Ocimum sanctum*) в лечении орального субмукозного фиброза (OSMF), с акцентом на его влияние на клинические симптомы, включая ощущение жжения, открывание рта, выдвижение языка, подвижность щек, бледность слизистой и фиброз.

МАТЕРИАЛЫ И МЕТОДЫ. Была проведена всесторонняя поисковая стратегия в базах PubMed-Medline, Scopus, Embase, Cochrane Library и Google Scholar с самого раннего доступного периода до 5 апреля 2025 г. Включались рандомизированные контролируемые испытания (РКИ) и наблюдательные исследования с пациентами, диагностированными с OSMF, оценивающие эффективность святого базилика в любой форме (экстракт, масло и т.д.) на клинические симптомы. Два независимых рецензента проводили сбор данных и оценку качества исследований с использованием инструментов Cochrane RoB 2.0 и ROBINS-I. При возможности проводился мета-анализ (МА), где рассчитывались суммарные сырье средние значения (MRAW) и стандартизованные разности средних (SMD).

РЕЗУЛЬТАТЫ. Всего 7 исследований соответствовали критериям включения: 5 наблюдательных и 2 экспериментальных исследования, проведенных в Индии в период с 2017 по 2023 гг. Мета-анализ показал значительное улучшение максимального открывания рта (MRAW = 36,14 мм; 95% ДИ: 22,3–49,98) и снижение ощущения жжения (SMD = 2,6; 95% ДИ: 1,94–3,25) у пациентов, получавших лечение на основе святого базилика. Для показателей открывания рта отмечалась значительная гетерогенность ($I^2 = 96\%$), тогда как результаты по ощущению жжения были относительно согласованы между исследованиями ($I^2 < 50\%$). Второстепенные исходы, такие как подвижность щек, были представлены только в одном исследовании, что ограничивает возможность широкой генерализации.

ВЫВОДЫ. Полученные данные свидетельствуют о том, что святой базилик в различных формах применения обладает перспективным потенциалом для улучшения ключевых клинических симптомов, таких как максимальное открывание рта, ощущение жжения и выдвижение языка.

Ключевые слова: оральный субмукозный фиброз, *ocimum sanctum*, противовоспалительные средства, травяные препараты, фитотерапия

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INTRODUCTION

Oral submucous fibrosis (OSMF) is a chronic, morbid disease characterized by its insidious onset and potential for malignant transformation. The World Health Organization (WHO) estimates that approximately 3–10% of OSMF patients may eventually progress to develop oral cancer [1]. This alarming statistic underscores the need for effective management strategies.

The pathogenesis of OSMF is complex, involving multiple factors, including genetic predisposition, en-

vironmental factors, and chronic inflammation [2]. Current treatment options, including surgical interventions and pharmacological therapies, have shown limited success and are often associated with significant side effects [3; 4]. Furthermore, many surgical approaches have been fruitful in treating moderate to severe cases, but have a major drawback of being invasive procedures with outcomes heavily dependent on patient compliance to follow oral physiotherapy post-surgery. Consequently, post-surgical relapses are common in

OSMF patients [5; 6]. On the other hand, drug therapy primarily focuses on alleviating symptoms, but has its own set of limitations [7; 8].

The limitations of current treatment options have led researchers to explore alternative therapies, including herbal extracts [2; 9; 10]. Various clinical studies have been conducted, revealing significant potential of herbal extracts in treating OSMF, owing to their antioxidant and anti-inflammatory properties, along with added advantages of minimal side effects and cost-effectiveness [11–13]. As OSMF is mainly seen in Indian and South-East Asian populations, primarily in individuals with lower socio-economic status, affordability of herbal medicines has further intrigued researchers [14–17]. Several herbal extracts, including lycopene, curcumin, aloe vera, salvia miltiorrhiza, and spirulina, have been studied for their potential roles in treating OSMF [8; 18–23]. However, heterogeneous scientific evidence, varying herbal formulations, and unproven long-term efficacy have led to the continuation of the quest for the most suitable treatment.

Tulsi or the Holy Basil (HoB), widely known as the “Queen of herbs” or “Elixir of life”, has gained traction in recent years [24; 25]. This HoB is known for its wide array of medicinal benefits, including anti-inflammatory, anti-pyretic, analgesic, antioxidant, immune modulation, anticarcinogenic, anticoagulant, and antidiabetic properties [26; 27]. These spectrum of properties of HoB prompted researchers to conduct numerous trials assessing its therapeutic efficacy in comparison with other interventions in the management of OSMF [28–32]. However, these trials have provided inconsistent results, and therefore, there seems to be a conflict regarding the effectiveness of HoB in treating OSMF. The potential HoB portrays in treating a complex disease like OSMF, owing to its remarkable medicinal properties, makes it stand out from other herbal extracts studied in the past. Therefore, to address the existing knowledge gap, a systematic review is necessary to synthesize and evaluate the available data on HoB’s efficacy in treating OSMF. The findings of this review aim to evaluate the role of HoB in alleviating the clinical symptoms of OSMF and to support the development of future trials, treatment guidelines, and policies, thereby assisting clinicians in translating research evidence into improved patient care.

Table 1. Definitions for key terminologies
Таблица 1. Определения ключевых терминов

Terms	Definition
Oral submucous Fibrosis (OSMF)	Defined by WHO Collaborating Centre for Oral Cancer in 2020 as “A chronic, insidious disease that affects the oral mucosa, initially resulting in loss of fibroelasticity of the lamina propria and as the disease advances, results in fibrosis of the lamina propria and the submucosa of the oral cavity along with epithelial atrophy”
Phytotherapy	Defined by WHO as “the medical discipline that allows the correct use, for preventive or curative purposes, of medicinal plants and their derivatives (phytotherapics or phytomedicaments), in relation to the pharmacological properties of their chemical constituents”
Herbal Medicine	Defined by National Cancer Institute (NIH) as “A type of medicine that uses roots, stems, leaves, flowers, or seeds of plants to improve health, prevent disease, and treat illness”
Efficacy	Defined by Boyd et al. 2014 as “the ability of an intervention to produce the desired beneficial effect”
Severity of OSMF	Described by Siddiqui et. al 2021 as “The severity of Oral Submucous Fibrosis (OSMF) is assessed by evaluating the extent of fibrosis, limited mouth opening, and associated symptoms like burning sensation and difficulty eating, with more advanced stages showing significant stiffness and trismus”

MATERIALS AND METHODS

A pre-defined protocol for this review was registered in the PROSPERO database (PROSPERO ID: CRD420251004886). This review abided with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) guidelines as depicted in Supplementary Table 1.

Eligibility criteria

PICOS (P – population, I – intervention, C – Comparator, O – Outcome, S – Study) framework comprised of:

Population [P] – Patients with OSMF;

Intervention [I] – Tulsi extract, oil (*occimum sanctum* or *tenuiflorum* or HoB);

Comparators [C] – may or may not be included;

Outcome [O] – changes in the clinical symptoms;

Study Design [S] – randomized controlled trials (RCT’s) and observational studies.

Scientific literature was excluded from this review if it had incomplete data, lacked full-text availability, presented non-comparable outcomes, involved malignant lesions, or was classified as a review article, pilot study, case report, or case series.

Information Sources and Search Strategy

A thorough scientific literature search was conducted via several databases: PubMed-Medline, Scopus, Embase, Cochrane Library and Google Scholar from the inception up to 5th April, 2025. Search key words used for this review included Medical Subject Headings terms (MeSH), keywords, other free-text terms, truncations. These keywords were coupled with boolean operators (AND, OR) to search for specific articles.

Detailed search strategy used for PubMed-Medline included – (“holy basil leaf extract”[Supplementary Concept] OR “holy basil leaf extract”[All Fields] OR (“basil extract”[Supplementary Concept] OR “basil extract”[All Fields]) OR (“*ocimum sanctum*”[MeSH Terms] OR (“*ocimum*”[All Fields] AND “sanctum”[All Fields]) OR “*ocimum sanctum*”[All Fields]) OR (“holy basil leaf extract”[Supplementary Concept] OR “holy basil leaf extract”[All Fields] OR “*tulsi*”[All Fields])) AND (“oral submucous fibrosis”[MeSH Terms] OR (“oral”[All Fields] AND “submucous”[All Fields] AND “fibrosis”[All Fields]) OR “oral submucous fibrosis”[All Fields]).

Table 2. Study characteristics of the included studies**Таблица 2.** Характеристики включённых в исследование работ

Study ID	Region	Objective	Study type	Trial Design	Trial Duration	Study setting	Age of participants	Overall sample size	Intervention	Control	Outcomes measured		Intervention duration	Confound-ing variable effects
											Primary	Secondary		
Madhulatha et al. 2017 [39]	Telangana, India	To evaluate the efficacy of Tulasi in the treatment of OSMF	Prospective observational study	Non- Randomized Controlled trial	2 months	Department of Oral medicine and Radiology, Dental College and Hospital	Range: 20–50 years	20	Tulsi paste (500 gm)	–	Mouth opening, Burning sensation	–	Twice daily	Cessation of Habit
Virani et al. 2018 [40]	Maharashtra, India	Assessment of utility of Tulsi and Turmeric in treatment of oral submucous fibrosis	Prospective observational study	Non- Randomized Controlled trial	3 months	Department of Oral medicine and Radiology, Dental College and Hospital	Range: 18–48 years	30	Tulsi + Turmeric gel	–	Mouth opening, Burning sensation	–	Five times daily	Other concurrent treatment
Khabiya et al. 2019 [41]	Maharashtra, India	To evaluate the efficacy of tulsi and curcumin in management of oral submucous fibrosis when used along with conventional oral antioxidant therapy	Prospective observational study	Non- Randomized Controlled trial	3 months	Department of Oral and Maxillofacial Surgery, Dental College and Hospital	Not mentioned	124	Oral antioxidant therapy + 1 gm turmeric powder + 1 gm Tulsi powder	Oral antioxidant therapy	Mouth opening, Burning sensation	–	Four to five times daily	Standardization of dose
Rizvi et al. 2019 [42]	Uttar Pradesh, India	To compare the efficacy of curcumin and tulsi gels in OSMF	Experimental study	Randomized Controlled trial	6 months	Department of Pharmacology, Medical College and Hospital	Mean age: 40.4 years	60	5 mg tulsi + 5 mg triamcinolone acetonide	5 mg of curcumin and 5 mg triamcinolone acetonide	Mouth opening, Burning sensation, tongue protrusion	–	Twice daily	Severity of OSMF
Biswas et al. 2022 [44]	Karnataka, India	To assess and compare the efficacy of topical Tulsi paste in the reduction of burning sensation and improvement in mouth opening among the patients with Groups A, B and C OSMF (Lai DR classification)	Prospective observational study	Non- Randomized Controlled trial	3 months	Department of Oral medicine and Radiology, Dental College and Hospital	Range: 18 and above	60	60 gm of tulsi paste	–	Mouth opening, Burning sensation	–	Twice daily	
Dalai et al. 2023 [45]	Odisha, India	To assess the effectiveness of tulsi and aloe vera in the treatment of oral submucous fibrosis (OSMF)	Prospective observational study	Non- Randomized Controlled trial	4 months	Department of Public Health Dentistry, Dental College and Hospital	Range: 20–55 years	30	1 gm tulsi powder + glycerin	1 gm aloe vera + glycerin	Mouth opening, Burning sensation	–	Two to three times daily	
Thomas et al. 2023 [43]	Karnataka, India	To compare the efficacy of Ocimum Sanctum (Tulsi) with Oxitard in the treatment of clinically diagnosed OSMF patients	Experimental study	Randomized Controlled trial	3 months	Department of Oral medicine and Radiology, Dental College and Hospital	Range: 20–60 years	90	Tulsi tablets 500 mg	Oxitard tablets	Mouth opening, Burning sensation, tongue protrusion	Cheek flexibility	Twice daily	

The search strategy keywords were modified appropriately for different databases as depicted in the Supplementary Table 2.

Selection Process

All studies identified through the search strategy were independently and blindly assessed by two authors (HS and PK), following an initial title screening that excluded irrelevant studies. Subsequently, abstracts of all the relevant articles were screened based on the established inclusion criteria. This preliminary screening was conducted using Rayyan, an online systematic review software. Consequently, full text of all the probably eligible studies underwent further screening based on the inclusion criteria. The study selection process was depicted via the PRISMA flow diagram which included number of studies identified, screened, eligibility assessment, studies involved in the final review, as well as reasons for exclusion at each stage.

Data Collection

The two independent reviewers (HS and PK) further extracted data from the included studies comprehensively and documented it in a tabular form. The table included study characteristics such as authors, year of publication, sample size, patient demographics, intervention, form of administration, follow-up and key outcome measures. Disagreements at any stage between the two reviewers were resolved through discussion and consensus with a third reviewer.

Data Items

Definitions of certain key terminologies used in the present review have been presented in the Table 1 [1; 33–36].

Outcome Measurements

The present systematic review (SR) was designed to address the research question by investigating the therapeutic efficacy of the HoB in managing OSMF, with a specific focus on its effect on the clinical symptoms. The primary outcomes of interest were threefold: firstly, the reduction in burning sensation (BS), as measured using the visual analogue scale (VAS); secondly, the increase in maximum mouth opening (MO), quantified by the inter-incisal distance in millimetres; and thirdly, improvement in tongue protrusion, assessed by measuring the movement beyond the incisor tips in millimetres. In addition to these primary outcomes, the review also explored few secondary outcomes, including improvements in cheek flexibility, as well as reductions in blanching and fibrosis.

Quality assessment

The quality assessment for this review was performed independently by two reviewers using the respective standard quality evaluation method and was corroborated by the third reviewer. RCTs were assessed using the Cochrane risk of Bias 2.0 (RoB 2.0) [37] tool, meanwhile the non-randomized studies were assessed employing the ROBINS-I tool [38]. In both the tools the risk of bias was assessed within the RCTs and non-randomized studies, where different domains were categorized into “low risk” [ROBINS-I, RoB2.0], “some concerns” [RoB 2.0], “moderate” [ROBINS-I] and “high risk” [ROBINS-I, RoB2.0].

Data Synthesis and Analysis

All the data were summarized in a tabular form in excel worksheets, which included the evaluation of various primary outcomes i.e., burning sensation (BS), mouth opening (MO), tongue protrusion (TP) and secondary outcomes like cheek flexibility, blanching, fibrosis and clinical staging. Studies were categorized into two groups: Group 1 evaluated maximal mouth opening (MO) and burning sensation (BS) in RCTs ($n = 2$), while Group 2 assessed the same outcomes in observational studies. Primary outcome variables from each study were combined for continuous data using a random effects model. The values and results of each study were represented separately. The basis of MA was the difference in means and SD of dentifrice on MO and BS. The data for the primary outcome was presented in the form of summarized raw mean (MRAW) as standardized mean differences (SMD) (95% confidence interval [CI]). Heterogeneity was tested by Chi-square test and I² statistic. A Chi-squared test resulting in $p < 0.1$ was considered to indicate significant statistical heterogeneity. The analysis was performed using software (Review Manager, version 4.2 for Windows, The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark).

RESULTS

Study Selection

The initial database search yielded 126 studies, of which 47 were identified as duplicates and subsequently removed. The remaining 79 studies underwent primary screening, during which 69 were excluded based on title and abstract evaluation. The remaining 10 studies were assessed for full-text to determine their eligibility based on the inclusion criteria. Following this assessment, three studies were excluded due to unsuitable study design or outcome measures. Ultimately, seven studies met the inclusion criteria and were included in this SR for comprehensive analysis.

Study Characteristics

In the seven studies [36–42] that were published from the year 2017 to 2023, five were observational and two were experimental studies. These studies were conducted in different regions of India; including Uttar Pradesh ($n = 1$), Odisha ($n = 1$), Telangana ($n = 1$), Maharashtra ($n = 2$), Karnataka ($n = 2$) with varying sample sizes ranging from 20 to 124. Four studies had a comparative analysis in assessing the efficacy of tulsi with various other interventions involving only antioxidant therapy, curcumin, aloe vera and OxitardTM tablets. Majority of the studies ($n = 4$) used a formulation with only Tulsi as the active ingredient, however, three studies used tulsi in combination with turmeric ($n = 2$) and triamcinolone acetonide ($n = 1$). Various formulations including paste, gel or tablet forms were employed to dispense the interventional agent (Tulsi). The majority of the studies focused on primary outcomes, primarily assessing maximal MO and BS, followed by tongue protrusion. Only one study [43] evaluated cheek flexibility in addition to the other primary outcomes.

Intervention Characteristics

Table 3 shows the intervention and control characteristics of the studies included in this review. MO, BS, and post-treatment value were extracted for the included studies. Studies utilized interventions with varied formulations, including gel, paste and powder forms.

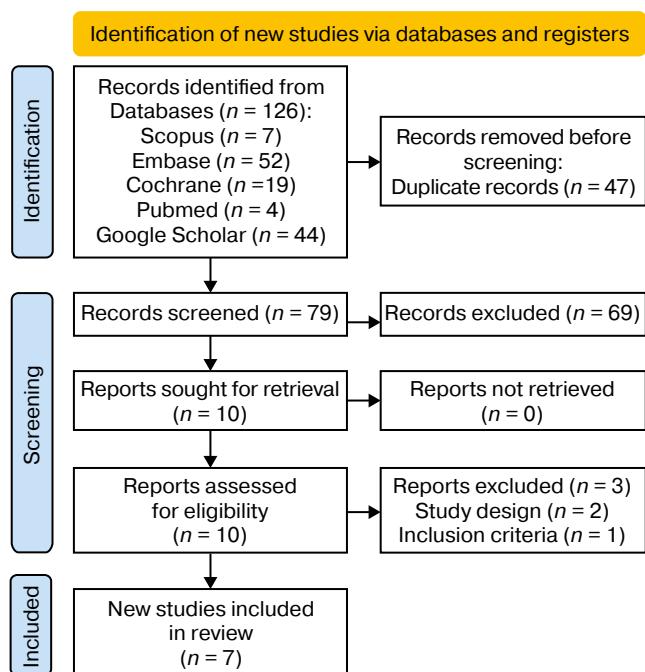


Fig. 1. Depicts PRISMA flow chart showing the study selection process

Рис. 1. Схема PRISMA, отражающая процесс отбора исследований

META ANALYSIS

Maximal Mouth opening (Group I)

All together 2 studies were analysed in Group I analysis, with a total of 60 subjects. As per the analysis performed using random effects model with inverse variance method, the summarized raw means (MRAW) was 36.14 with a 95% confidence interval (CI) of 22.3–49.98. A significant heterogeneity was observed ($p < 0.01$), pointing to inconsistent effects in magnitude and/or direction. The I^2 value denotes that 96% of the variability among studies arose from heterogeneity rather than random chance.

Maximal Mouth opening (Group II)

Group II analysis included two studies, each comprising 60 participants in both the experimental and control cohorts. There was no statistically significant difference seen between the two groups. The pooled SMD was 6.14, with a 95% CI ranging from -72.61 to 84.89. However, substantial heterogeneity was observed ($p < 0.01$), indicating considerable variability in effect size and/or direction across studies. The I^2 value of 99% suggests that nearly all variability is due to heterogeneity rather than random chance.

Burning Sensation (Group I)

All together 2 studies were analyzed in Group I analysis, with a total of 60 subjects. As per the analysis performed using random effects model with inverse variance method, the MRAW was 2.6 with a 95% confidence interval of 1.94–3.25. No significant heterogeneity was observed, suggesting that the effect sizes across studies were consistent in both magnitude and direction.

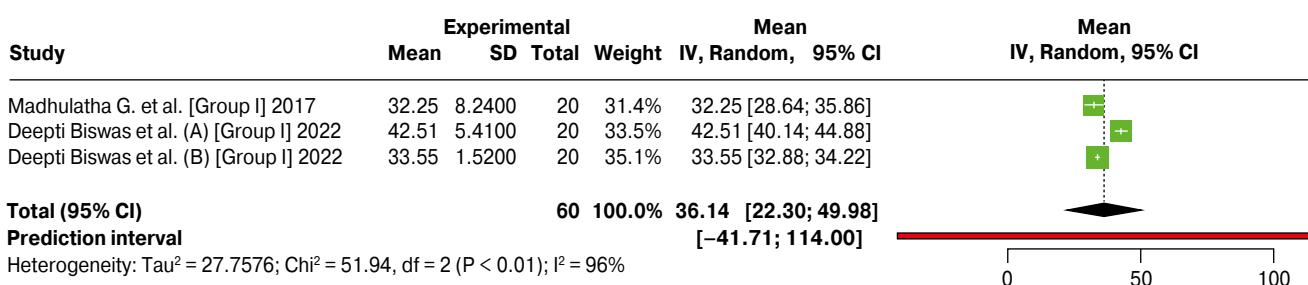


Fig. 2. Pooled estimate of maximal mouth opening in subjects of group I

Рис. 2. Объединенная оценка максимального открывания рта у участников группы I

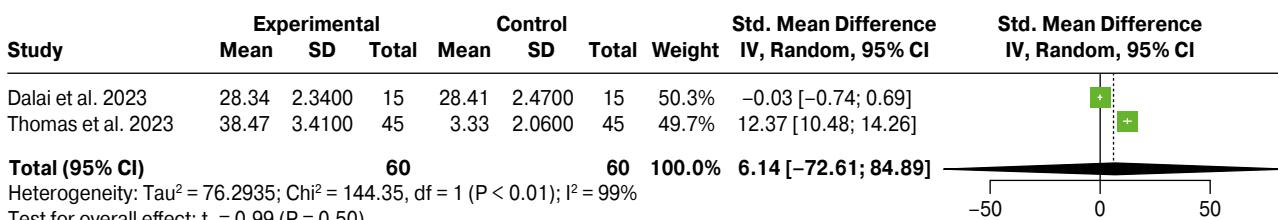


Fig. 3. Pooled estimate of maximal mouth opening in participants of group II

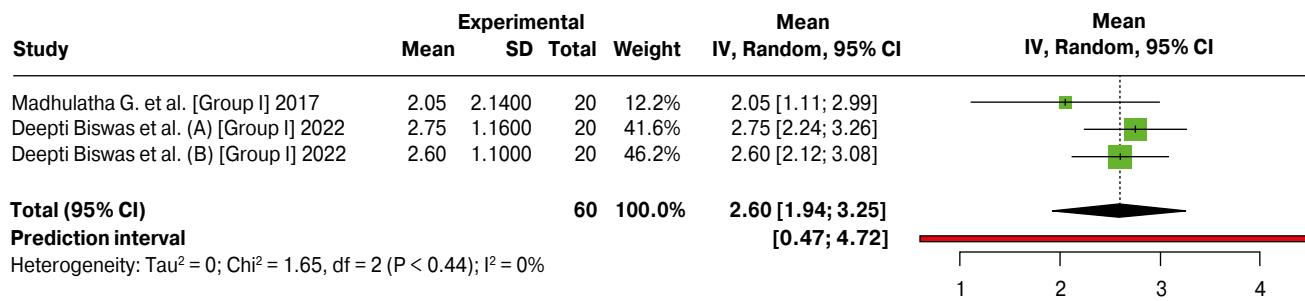
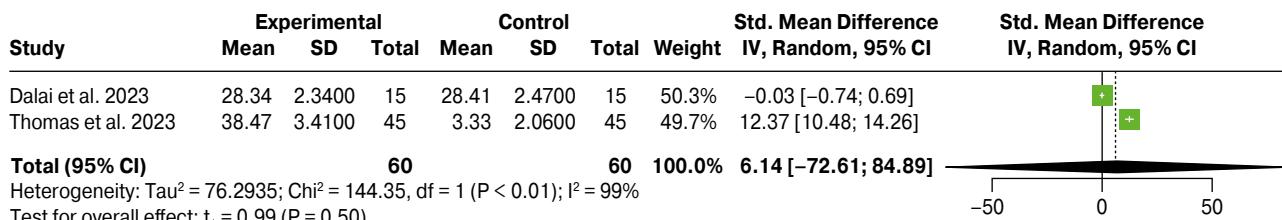
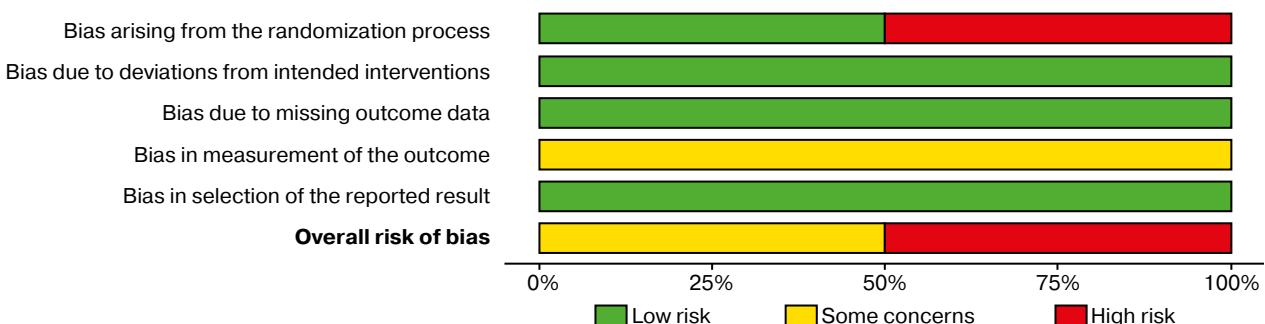
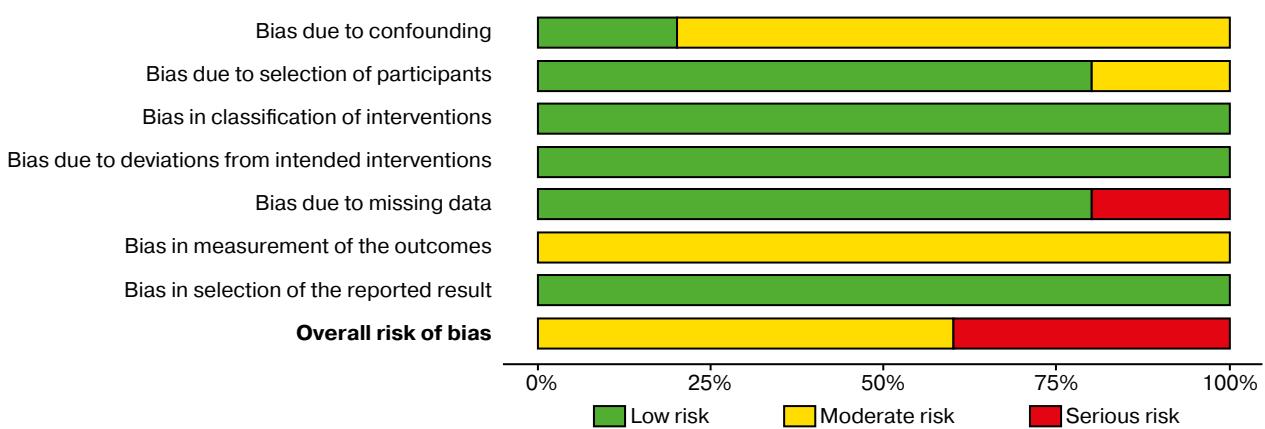
Рис. 3. Объединенная оценка максимального открывания рта у участников группы II

Table 3. Characteristics of intervention and control group**Таблица 3.** Характеристики группы вмешательства и контрольной группы

Study ID	Age of participants	Intervention characteristics					Control group				
		Type	Number of participants	Mean (SD)	Duration	p-value	Type	Number of participants	Mean (SD)	Duration	p-value
Madhulatha et al. 2017 [39]	Range: 20–50 years	Tulsi paste (500 gm)	20	MO (Post) – 32.25±8.24 BS (Post) – 2.05±2.14	Twice daily	MO=< 0.05 (S) BS=< 0.05 (S)	–	–	–	–	–
Virani et al. 2018 [40]	Range: 18–48 years	Tulsi + Turmeric gel	30	MO (Post) – 23.66±6.45 BS (Post) – 0.20±0.76	Five times daily	MO=< 0.05 (S) BS=< 0.05 (S)	–	–	–	–	–
Khabiya et al. 2019 [41]	Not mentioned	Oral antioxidant therapy + 1 gm turmeric powder + 1 gm Tulsi powder	62	MO (Post) – 33.30±3.16 BS (Post) – 3.10±1.29	Four to five times daily	MO=> 0.05 (NS) BS=> 0.05 (NS)	Oral antioxidant therapy	62	MO (Post) – 34.00±2.62 BS (Post) – 4.00±1.25	Four to five times daily	MO=> 0.05 (NS) BS=> 0.05 (NS)
Rizvi et al. 2019 [42]	Mean age: 40.4 years	5mg tulsi + 5mg triamcinolone acetone-nide	30	MO (Post) – 28.2±4.43 BS (Post) – 2.9±0.923 TP (Post) – 27.4±4.8	Twice daily	MO=> 0.05 (NS) BS=< 0.05 (S) TP=< 0.05 (S)	5 mg of curcumin + 5 mg triamcinolone acetone-nide	30	MO (Post) – 28.9±3.58 BS (Post) – 2±1.08 TP (Post) – 27.8±3.63	Twice daily	MO=< 0.05 (S) BS=< 0.05 (S) TP=< 0.05 (S)
Biswas et al. 2022 [44]	Range: 18 and above	60 gm of tulsi paste	60	Group A: MO (Post) – 42.51±5.41 BS (Post) – 2.75±1.16 Group B: MO (Post) – 33.55±1.52 BS (Post) – 2.60±1.10 Group C: MO (Post) – 26.05±2.27 BS (Post) – 2.75±0.91	Twice daily	MO=< 0.05 (S) BS=< 0.05 (S)	–	–	–	–	–
Dalai et al. 2023 [45]	Range: 20–55 years	1 gm tulsi powder + glycerin	15	MO (Post) – 28.34±2.34 BS (Post) – 2.32±1.28	Two to three times daily	MO=> 0.05 (NS) BS=> 0.05 (NS)	1gm aloe vera + glycerin	15	MO (Post) – 28.41±2.47 BS (Post) – 2.40±1.32	Two to three times daily	MO=> 0.05 (NS) BS=> 0.05 (NS)
Thomas et al. 2023 [43]	Range: 20–60 years	Tulsi tablets 500 mg	45	MO (Post) – 38.47±3.41 BS (Post) – 1.77±1.41 TP (Post) – 39.19±5.17 CF (Post) – 22.93±3.69	Twice daily	MO=< 0.05 (S) BS=< 0.05 (S) TP=< 0.05 (S) CF=< 0.05 (S)	Oxitard tablets	45	MO (Post) – 41.58±4.98 BS (Post) – 3.33±2.06 TP (Post) – 42.40±4.82 CF (Post) – 26.00±4.11	Twice daily	MO=< 0.05 (S) BS=< 0.05 (S) TP=< 0.05 (S) CF=< 0.05 (S)

Note: MO: Mouth opening; BS: Burning sensation. p values less than 0.05 are considered statistically significant (denoted as "(S)") and those greater than 0.05 are not statistically significant (denoted as "(NS)")

Примечание: MO: Открывание рта; BS: Ощущение жжения. Значения p меньше 0,05 считаются статистически значимыми (обозначены как «(S)»), а значения больше 0,05 – статистически незначимыми (обозначены как «(NS)»).

**Fig. 4.** Pooled estimate of burning sensation in subjects of group I**Рис. 4.** Объединенная оценка ощущения жжения у участников группы I**Fig. 5.** Pooled estimate of burning sensation in subjects of group II**Рис. 5.** Объединенная оценка ощущения жжения у участников группы II**Fig. 6.** Shows the graph for risk of bias among RCTs included in this review**Рис. 6.** График, показывающий риск систематической ошибки среди РКИ, включенных в данный обзор**Fig. 7.** Shows the graph for risk of bias among non-RCTs included in this review**Рис. 7.** График, показывающий риск систематической ошибки среди исследований без РКИ, включенных в данный обзор

Burning Sensation (Group II)

In total, two studies were included in the Group II analysis, comprising 60 participants each in the experimental and control cohorts. The results showed no statistically significant difference between the two groups, with a pooled SMD of 6.14 and a 95% confidence interval ranging from -72.61 to 84.89. The test for overall effect yielded an insignificant result. However, significant heterogeneity was detected ($p < 0.01$), indicating considerable variability in the magnitude and/or direction of effects across studies. The I^2 value of 99% suggests that this variability is largely due to heterogeneity rather than random variation.

Quality Assessment

Risk of bias in RCTs

The analysis of both the RCTs found that, one study [42] portrayed high risk of bias owing to incomplete documentation of the randomization process, lack of assignment and blinding process details. The other RCT [43] mentioned the details of randomization process (lottery method), as well as allocation of the participants was concealed.

Risk of Bias in Non-RCTs

The risk of bias was rated as high in two studies – Biswas et al. [44] and Dalai et al. [45] compared to the three non-RCTs. This higher bias was attributed to inadequate control of confounding factors, incomplete data reporting, and deviations from the pre-specified treatment protocols. All non-RCTs were rated as having some concerns, primarily because none of the studies clearly reported whether any deviations occurred from the planned treatment regimen.

DISCUSSION

The objective of the present systematic review was to assess the efficacy of the HoB in improving the clinical symptoms in patients with OSMF by analyzing clinical. Findings from the seven studies demonstrated mixed effects of HoB on the clinical symptoms associated with OSMF. Some [39; 40; 43; 44] showed promising potential for HoB in alleviating the clinical symptoms, primarily with respect to MO and BS, while others [41; 42; 45] reported insignificant effects. Therefore, the limited number of studies and the heterogeneity among them necessitate a meticulous understanding of these results.

Out of 126 initially screened studies, seven fulfilled the inclusion criteria, comprising two randomized controlled trials (RCTs) and five observational studies. The interventions utilized HoB either in its pure form [39; 43–45] or in combination with other agents such as curcumin [40; 41] or triamcinolone acetonide [42]. While these combinations may enhance therapeutic efficacy through synergistic mechanisms, they also introduce confounding effects, making it challenging to isolate HoB's specific contribution. Conversely, studies that used HoB in its pure form dispensed it in various formulations- ranging from paste to tablet and different dosage, which may have impacted its bioavail-

ability and therapeutic effect. Thomas et al. [43] administered 500mg of HoB tablets and observed promising results in improving the clinical symptoms such as MO, BS, TP (tongue protusion) and CF (cheek flexibility). This could be attributed to the systemic effects HoB, as OSMF – previously classified under premalignant condition – affects the generalized state of the body. Systemic administration of HoB might exert more potent medicinal effects compared to topical application.

On the other hand, Dalai et al., Biswas et al., Madhulatha et al. [39; 44; 45] dispensed HoB in paste form at doses of 1 gm, 60 gm, 500 gm, respectively. Among these studies, one [45] reported insignificant results, while the other two [39; 44] found significant outcomes. These findings highlight the importance of a comparator group and appropriate dosage for topical administration to achieve favorable results. Dalai et al. [45] used a considerably lower dose compared to the other two studies [39; 44], which may have reduced the effectiveness of HoB. Additionally, the absence of a comparator group in the latter two studies might have introduced bias in achieving the desired outcomes.

Of the seven included studies, four studies [39; 42–44] employed standard twice-daily application of the intervention. Three studies [39; 43; 44] demonstrated significant reductions in clinical symptoms, while one study [42] showed significant results with respect to reduction in BS but not in reduction in MO. significant improvement in BS but not MO. This discrepancy could be attributed to the lower dosage in combination therapy used by Rizvi D et al. study [42], which combined HoB with triamcinolone acetonide and used a significantly lower dose of HoB (5 mg) compared to the other three studies (500 g, 60 g, and 500 g) [39; 43; 44].

In contrast, three studies [40; 41; 45] prescribed more frequent applications—more than twice daily. Among these, only one study [40], which provided clear instructions for five daily applications, yielded statistically significant results. However, this study used a combination therapy (HoB combined with turmeric), which may have contributed to the positive outcome and introduced bias regarding attribution of benefits. The other two studies [41; 45], which vaguely prescribed ranges such as four to five times or two to three times daily, reported insignificant results. The negative outcomes could be attributed to unclear instructions regarding application frequency.

The meta-analysis focused on MO and BS as primary outcomes due to their reliability and reproducibility in assessing OSMF severity. Only studies that employed pure forms of HoB were included; thus, four out of seven studies were analyzed. The meta-analysis revealed that HoB showed potential in improving these clinical symptoms among OSMF patients. Specifically, summarized raw means indicated a positive effect with a mean difference of 36.14 and a 95% confidence interval ranging from 22.3 to 49.98. Despite these promising results, significant heterogeneity was noted among the studies ($I^2 = 96\%$), suggesting that variability was primarily due to differences in study designs and interventions rather than random chance.

The reduction in BS appeared more consistent across studies compared to MO outcomes. Virani et al. study [40] which used Tulsi-turmeric gel, demonstrated the most substantial improvement in BS scores – indicating a potential synergistic effect between these agents. However, other studies reported less pronounced or statistically insignificant changes compared to control therapies. This variability underscores the need for standardized formulations and protocols to better assess Tulsi's efficacy.

Several factors may account for the observed variability in outcomes: herbal compounds often suffer from poor lipid solubility and low systemic absorption – limiting their efficacy *in vivo* despite promising *in vitro* activity; curcumin's inclusion may have enhanced bioavailability through its known absorption-enhancing properties [46; 47]; combining Tulsi with agents like curcumin or triamcinolone may amplify anti-inflammatory effects while complicating attribution of therapeutic benefits; variability in disease severity, duration, and patient demographics likely influenced treatment responses; differences in application methods (e.g., topical vs oral), dosages, and treatment durations further contributed to inconsistent outcomes.

This systematic review's strengths include a thorough search strategy, stringent adherence to eligibility criteria, objective appraisal methods, and analytical techniques such as meta-analysis. However, certain limitations exist: variability in study designs complicates definitive conclusions about HoB's efficacy; methodological flaws such as improper randomization processes and inadequate blinding may introduce biases; significant heterogeneity among measured outcomes limits the overall validity of meta-analysis findings.

Future research should address these gaps by conducting large-scale RCTs with robust randomiza-

tion procedures and adequate sample sizes; developing uniform formulations of Tulsi-based therapies with clearly defined dosages; evaluating sustained efficacy over extended treatment durations; investigating pharmacokinetics and pharmacodynamics to optimize bioavailability; assessing additive or synergistic benefits when combining Tulsi with other agents like curcumin or triamcinolone while controlling confounding variables; incorporating additional clinically relevant endpoints such as quality-of-life assessments alongside MO and BS.

While the findings suggest that Tulsi may offer some symptomatic relief, particularly for BS, its role as a standalone treatment for OSMF remains inconclusive. The observed benefits are insufficient to recommend Tulsi as a monotherapy or primary intervention without further validation through high-quality research. To the best of our knowledge, this is the first review which serves as both a synthesis of current knowledge and a roadmap for future research aimed at unlocking the full therapeutic potential of Holy Basil in managing OSMF effectively.

CONCLUSION

The findings suggest that Holy Basil, administered in various formulations, shows promising potential in improving key clinical symptoms such as maximal mouth opening, burning sensation, and tongue protrusion. However, significant heterogeneity among studies and limitations in study design, sample size, and outcome reporting warrant cautious interpretation of the results. While the available evidence supports the therapeutic potential of Holy Basil, especially when systemically administered, further high-quality randomized controlled trials with standardized formulations and dosages are essential to validate its efficacy and guide clinical practice.

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ВКЛАД АВТОРОВ

А. Джетхлия – существенный вклад в разработку концепции или дизайна статьи; подготовка рукописи или ее критическая доработка с учетом важного интеллектуального содержания.

Х.К. Сохи – существенный вклад в разработку концепции или дизайна статьи; подготовка рукописи или ее критическая доработка с учетом важного интеллектуального содержания.

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П.К. Гонугунтла Камма – подготовка рукописи или ее критическая доработка с учетом важного интеллектуального содержания; одобрение версии для публикации.

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Ф.А. Насьям – подготовка рукописи или ее критическая доработка с учетом важного интеллектуального содержания; одобрение версии для публикации.

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Р.С. Маккад – подготовка рукописи или ее критическая доработка с учетом важного интеллектуального содержания; одобрение версии для публикации.