

Comparative Analysis Of Therapeutic Interventions For Burning Mouth Syndrome: An Umbrella Review And Meta-Analysis

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ABSTRACT

Background: Burning Mouth Syndrome (BMS) is a chronic idiopathic orofacial pain disorder characterized by persistent burning of the oral mucosa without identifiable clinical or laboratory abnormalities. Its multifactorial aetiology has given rise to a wide spectrum of therapeutic interventions and numerous systematic reviews with inconsistent conclusions.

Objectives: To synthesize and critically appraise evidence from existing systematic reviews and meta-analyses evaluating the effectiveness of pharmacological and non-pharmacological therapeutic interventions in BMS.

Methods: A systematic search of PubMed, Scopus, Cochrane, and Google Scholar (2000–2024) was conducted. Eleven systematic reviews were included. Methodological quality was assessed using AMSTAR-2 and certainty of evidence using the GRADE framework. Meta-analysis was performed using RevMan with a random-effects model.

Results: Pooled risk ratio for short-term outcomes was 4.44 (95% CI: 2.52–7.84; $p < 0.05$). Standardized mean differences were –1.26 (short-term) and –0.93 (long-term). Overall certainty of evidence was rated LOW due to high risk of bias across included reviews.

Conclusion: No single intervention demonstrates uniformly superior efficacy for BMS. A multimodal, individualized therapeutic approach is recommended. Standardized, long-term randomized controlled trials are urgently needed.....

Keywords: Burning mouth syndrome, Therapeutic interventions, Therapy....

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INTRODUCTION

Burning Mouth Syndrome (BMS) is defined as a chronic intraoral burning or dysesthetic sensation recurring daily for more than two hours per day for more than three months, without clinically evident causative lesions and with a normal appearance of the oral mucosa [1].

BMS predominantly affects postmenopausal women, with prevalence rates ranging from 0.7% to 15% in the general population [2]. The condition is frequently accompanied by dysgeusia, xerostomia, and significant psychosocial burden [3].

The pathophysiology of BMS remains incompletely understood, involving peripheral small-fiber neuropathy of the trigeminal system, central pain dysregulation, hormonal alterations particularly the decline of neuroprotective steroids at menopause and psychological comorbidities including anxiety and depression [4,5,6].

The expanding body of research on BMS therapeutics has produced numerous systematic reviews evaluating

pharmacological agents (clonazepam, alpha-lipoic acid [ALA], antidepressants), non-pharmacological approaches (cognitive behavioural therapy [CBT], low-level laser therapy [LLLT], acupuncture, and capsaicin) [7], with inconsistent and often conflicting conclusions. These discrepancies arise from variability in diagnostic criteria, outcome measures, study populations, and follow-up durations.

An umbrella review - a synthesis of existing systematic reviews and meta-analyses - is warranted to provide a high-level, comprehensive appraisal of the available evidence. This approach facilitates direct comparison of therapeutic options, identifies methodological gaps, and supports evidence-based clinical decision-making in BMS management.

PATHOPHYSIOLOGY

Peripheral Mechanisms

Neurophysiological evidence implicates the trigeminal system prominently in primary BMS. Blink reflex studies have identified focal trigeminal neuropathy in approximately 20% of patients^[8] Thermal quantitative sensory testing reveals somatosensory small-fiber pathology, including hypofunction of A δ cool afferents and relative preservation of C-fiber function, resulting in disinhibition of polymodal C-fiber nociceptors and characteristic burning pain^[9].

Immunohistochemical studies of tongue mucosal biopsies demonstrate upregulation of nerve growth factor (NGF), transient receptor potential vanilloid 1 (TRPV1) channels, and P2X3 receptors in sub-epithelial nerve fibers — molecular correlates of peripheral sensitization and neuropathic pain^[8,9].

Central Mechanisms

Functional MRI studies confirm decreased brain activation notably in the thalamus, patterns consistent with other neuropathic pain disorders^[8]. Positron emission tomography (PET) studies have demonstrated reduced striatal dopaminergic tone in primary BMS patients, suggesting dysfunction in central pain modulation and reward pathways^[6].

A proposed hypothesis identifies four converging conditions triggering BMS: chronic anxiety or post-traumatic stress; hormonal changes of menopause reducing neuroprotective steroids; exposure to neurotoxic agents; and genetic susceptibility. This model explains the female predominance, the psychosocial comorbidity, the strictly oral symptom distribution, and the peripheral and central neuropathic signs^[5,6].

METHODOLOGY

Search Strategy and Study Selection

A systematic bibliographic search was conducted in PubMed, Scopus, Cochrane, and Google Scholar from 2000 to 2024 using the keywords: 'burning mouth syndrome', 'therapeutic interventions', 'BMS', and 'therapy'.

The protocol of this umbrella review was prospectively registered in PROSPERO (CRD420251058913) and ethical clearance was obtained from the Institutional Ethics Committee (MADC/IEC/II/90/2025)

PICO Framework

The research question was structured using the PICO framework as detailed in Table 1.

Table 1: PICO Framework for Study Eligibility

PICO Component	Details
Population	Adults ≥ 18 years with primary or secondary BMS; no restrictions on sex or ethnicity; diagnosis based on accepted clinical criteria
Intervention	Pharmacological -Clonazepam, ALA, antidepressants, non-pharmacological- CBT, and physical interventions- LLLT, acupuncture, capsaicin
Comparator	Placebo, no treatment, or other active interventions
Outcomes	Primary: Pain intensity (VAS, NRS); Secondary: Quality of life, adverse effects, patient satisfaction

ALA: Alpha-lipoic acid; CBT: Cognitive Behavioural Therapy; LLLT: Low-Level Laser Therapy; VAS: Visual Analogue Scale; NRS: Numeric Rating Scale

Research Question

“What is the relative effectiveness and safety of various therapeutic interventions for managing Burning Mouth Syndrome, and to evaluate patient responses across treatment modalities?”

Eligibility Criteria

Inclusion criteria: Systematic reviews of therapeutic outcomes in adults (≥ 18 years) diagnosed with BMS using current criteria; pharmacological and non-pharmacological interventions; peer-reviewed English-language publications.

Exclusion criteria: Studies on oral burning not diagnosed as BMS; case reports, RCTs, observational studies; in vitro or animal studies; pediatric patients; non-therapeutic or diagnostic-only research.

Data Extraction and Quality Assessment

Data were extracted independently by two reviewers (10+ and 20+ years of experience) using a standardized Microsoft Excel form. Methodological quality was assessed using AMSTAR-2. Certainty of evidence was graded using

the GRADE framework, evaluating five downgrading domains (risk of bias, inconsistency, imprecision, indirectness, and publication bias) and three upgrading domains (large effect size, dose-response relationship, and minimal residual confounders).

Statistical Analysis

Meta-analysis was performed using RevMan software with a random-effects model (inverse variance method). Heterogeneity was evaluated using the I^2 statistic (fixed-effects for $I^2 < 50\%$; random-effects for $I^2 > 50\%$). Effect sizes were expressed as Risk Ratio (RR) and Standardized Mean Difference (SMD) with 95% confidence intervals. Short-term (< 3 months) and long-term (> 3 months) outcomes were analyzed separately.

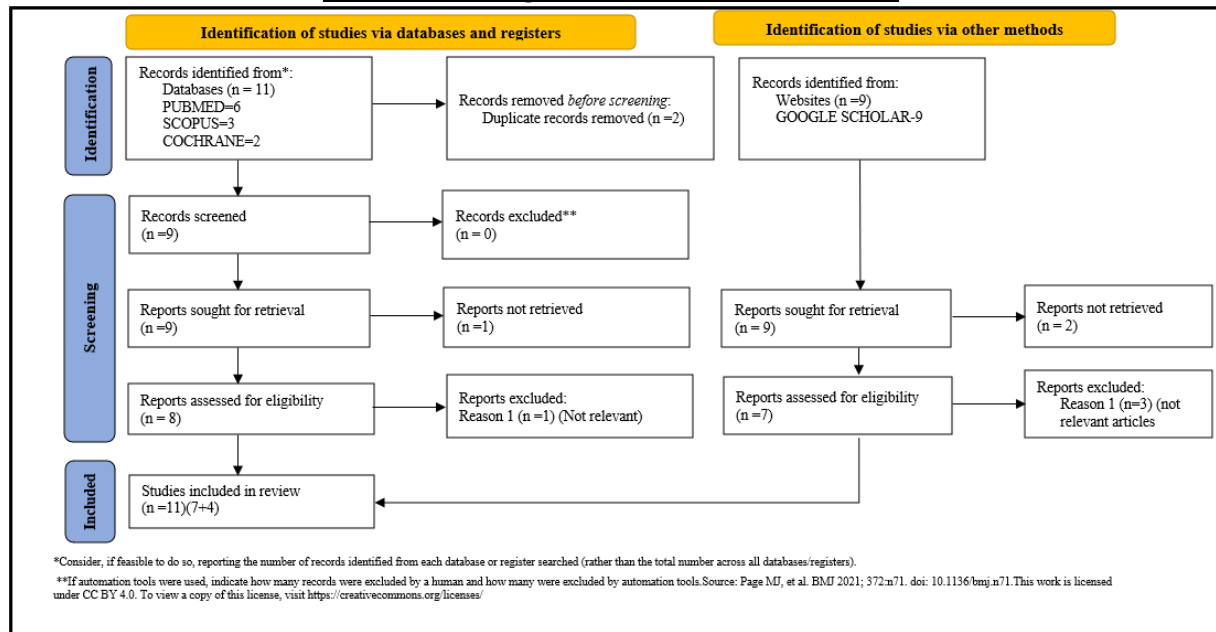
Protocol

The study selection process is illustrated using the PRISMA 2020 flowchart, a total of 20 records were identified, 2 duplicates were removed, and after screening and eligibility assessment, 11 systematic reviews were included (PRISMA 2020 flowchart (FLOWCHART 1)). This process ensures

transparency and reproducibility in study selection

FLOWCHART 1: PRISMA CHART

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources



Included Studies: Study Characteristics and Intervention Outcomes
Eleven systematic reviews were included, as summarized in Table 2. Of these, four conducted quantitative meta-analysis: Tan HL et al. (2022),¹² McMillan R et al. (2016),¹⁷

Camolesi GCV et al. (2022),¹⁸ and Zakrzewska JM et al. (2012).¹⁵ The review by Zakrzewska JM et al. (2012) was excluded from pooled meta-analysis as it included only a single primary study.

Table 2: Summary of Study Characteristics and Intervention Outcomes

S.No	Author, Country & Year	Design	Intervention	Population	Outcome	Key Findings
1	Zakrzewska J & Buchanan JA, UK (2016) ¹⁰	SR	Capsaicin, Clonazepam, ALA	Adults with BMS	VAS, symptom relief	Limited evidence; results inconclusive due to heterogeneity
2	Kisely S et al., Australia (2015) ¹¹	SR	Capsaicin, Clonazepam, ALA, Psychotherapy	Adults with BMS	Pain scores, QoL	Clonazepam and ALA show modest short-term benefit; significant placebo effect noted
3	Tan HL et al., UK (2022) ¹²	SR & MA	ALA, Clonazepam, CBT, LLLT	Adults with BMS	VAS pain scores	Multimodal therapy combining pharmacological and non-pharmacological approaches most effective

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4	Cabras M et al., Italy (2019) ¹³	SR	ALA, Clonazepam, Capsaicin, Antidepressants	Adults with BMS	Pain relief, symptom improvement	ALA and clonazepam beneficial; CBT, relaxation, and LLLT improve pain and QoL
5	Ślebioda Z et al., Poland (2014) ¹⁴	SR	Topical and systemic pharmacological agents	Adults with BMS	Pain reduction	Variability in treatment response; individualized therapy recommended
6	Zakrzewska JM et al., UK (2012) ¹⁵	SR & MA	Pharmacological therapies	Adults with BMS	VAS	Meta-analysis limited to one study; evidence insufficient
7	Kuten-Shorrer M et al., USA (2014) ¹⁶	SR	Neuropathic pain medications	Adults with BMS	Pain intensity	Neuropathic mechanism suggested; therapeutic evidence limited
8	McMillan R et al., London (2016) ¹⁷	SR & MA	ALA, Clonazepam	Adults with BMS	VAS, symptom improvement	Significant short- and long-term pain reduction with pharmacological therapy
9	Camolesi GCV et al., Brazil (2022) ¹⁸	SR & MA	Photobiomodulation / LLLT	Adults with BMS	VAS pain scores	Photobiomodulation significantly reduced pain; high heterogeneity in short term
10	de Matos ALP et al., UK (2021) ¹⁹	SR	Low-intensity laser therapy (LLLT)	Adults with BMS	Pain intensity, QoL	Consistent pain reduction in primary BMS; heterogeneity of protocols noted
11	Farag AM et al., UK (2022) ²⁰	SR	Pharmacological and alternative therapies	Adults with BMS	Pain relief	Variable efficacy of systemic interventions; evidence supports individualized treatment

SR: Systematic Review; MA: Meta-Analysis; ALA: Alpha-lipoic acid; CBT: Cognitive Behavioural Therapy; LLLT: Low-Level Laser Therapy; QoL: Quality of Life; VAS: Visual Analogue Scale

Methodological Quality (AMSTAR-2)

No review achieved a high AMSTAR-2 quality rating. TABLE 3. Reviews by Tan HL et al., Cabras M et al., Zakrzewska JM et al., McMillan R et al., Camolesi GCV et al., de Matos ALP et al., and Farag AM et al. were rated as moderate quality. Reviews by Zakrzewska J & Buchanan

JA, Kisely S et al., Ślebioda Z et al., and Kuten-Shorrer M et al. were classified as low or critically low quality. Common domains of weakness included absence of a priori protocol registration, inadequate duplicate study selection, failure to report excluded studies with justification, and omission of publication bias assessment.

TABLE 3: AMSTAR-2 RISK OF BIAS CHECKLIST

AMSTAR 2 Item	Zakrzewska J, Buchanan JA	Kisely S et al.	Tan HL et al.	Cabras M et al.	Ślebioda Z et al.	Zakrzewska JM et al.	Kuten-Shorrer M et al.	McMillan R et al.	Camolesi GCV et al.	de Matos ALP et al.	Farag AM et al.
1. PICO in research questions	●	●	●	●	●	●	●	●	●	●	●
2. Protocol established	●	●	●	●	●	●	●	●	●	●	●
3. Study design selection explained	●	●	●	●	●	●	●	●	●	●	●
4. Comprehensive literature search	●	●	●	●	●	●	●	●	●	●	●
5. Study selection in duplicate	●	●	●	●	●	●	●	●	●	●	●
6. Data extraction in duplicate	●	●	●	●	●	●	●	●	●	●	●
7. List of excluded studies	●	●	●	●	●	●	●	●	●	●	●
8. Studies described in detail	●	●	●	●	●	●	●	●	●	●	●
9. Risk of bias assessed	●	●	●	●	●	●	●	●	●	●	●
10. Funding sources reported	●	●	●	●	●	●	●	●	●	●	●
11. Appropriate meta-analysis methods	●	●	●	●	●	●	●	●	●	●	●
12. RoB impact in meta-analysis	●	●	●	●	●	●	●	●	●	●	●
13. RoB in interpretation	●	●	●	●	●	●	●	●	●	●	●
14. Heterogeneity explained	●	●	●	●	●	●	●	●	●	●	●
15. Publication bias investigated	●	●	●	●	●	●	●	●	●	●	●
16. Conflicts of interest reported	●	●	●	●	●	●	●	●	●	●	●
Overall Quality	●	●	●	●	●	●	●	●	●	●	●

● Yes / Low risk ● Partial / Some concerns ● No / High risk ○ Not reported

RESULTS

GRADE Certainty of Evidence

The GRADE assessment ^[30] is summarized in Table 4. Despite a moderate upgrading signal from effect size

(for ALA, benzodiazepines, and photobiomodulation), the high risk of bias across all included reviews necessitated a one-level downgrade. Overall certainty of evidence is rated LOW

Table 4: GRADE Certainty of Evidence Assessment

Domain	Assessment	Direction
Risk of Bias	At least one high-risk domain in all included SRs	↓ Downgrade
Inconsistency	No significant heterogeneity across included studies	No change
Imprecision	Significant pain reduction demonstrated with pharmacological treatments	No change
Indirectness	Direct outcome assessments used (VAS, NRS)	No change
Publication Bias	Low likelihood of selective positive reporting	No change
Effect Size	Moderate effect for ALA, benzodiazepam, and photobiomodulation	↑ Upgrade
Overall Certainty	Low — driven by high risk of bias across included reviews	LOW

Quantitative Synthesis (Meta-Analysis)

Short-term outcomes — Risk Ratio (RR): Pooling data from Tan HL et al. (2022) and McMillan R et al. (2016), the summarized RR was 4.44 (95% CI: 2.52–7.84; p<0.05),

indicating that active treatment reduces the risk of pain approximately 4.44 times more than placebo or control. No significant heterogeneity was detected.

Short-term outcomes — Standardized Mean Difference (SMD): Pooling Tan HL et al. (2022), McMillan R et al. (2016), and Camolesi GCV et al. (2022), the SMD was -1.26 (95% CI: -2.17 to -0.35 ; $p < 0.05$), indicating active treatment reduces VAS pain scores by 1.26 units more than control at < 3 months. Significant heterogeneity was detected ($I^2 = 98\%$; $p < 0.01$), reflecting variability in intervention types and protocols.

Long-term outcomes — SMD: The pooled SMD for follow-up > 3 months was -0.93 (95% CI: -2.17 to -0.35 ; $p < 0.05$), with no significant heterogeneity. This sustained effect suggests pharmacological and photobiomodulation therapies confer durable, though modest, benefits beyond the acute phase.

DISCUSSION

This umbrella review synthesizes evidence from 11 systematic reviews to provide a comprehensive appraisal of BMS therapeutics. Consistent with prior literature, no single intervention demonstrates uniformly superior efficacy^[7,8]. The modest and variable therapeutic outcomes reflect the biological heterogeneity of BMS — a condition involving overlapping peripheral neuropathic, central neurogenic, hormonal, and psychosocial mechanisms that vary between individuals.

Pharmacological Interventions

Pereira et al in (2022), Shim et al (2023) suggested that Topical clonazepam (0.5 mg lozenge, 2–3 times daily) has emerged as one of the most frequently evaluated treatments, likely acting through GABAergic modulation of neuropathic pain.^[21] Short-term symptom relief is consistently reported; however, concerns regarding dependency, sedation, and systemic absorption limit long-term use^[22].

Tan et al. (2022) and McMillan et al. (2016) in their systematic reviews reported that Alpha-lipoic acid (600 mg/day), an antioxidant with neuroprotective properties, has demonstrated modest improvement in pain intensity and burning sensation across multiple reviews^[12,17]. Discrepancies across studies are attributable to differences in dosage, treatment duration, and patient selection — factors that also amplify placebo effects commonly observed in chronic pain conditions.²³

Kutten-Shorrer et al. (2017) reported that Antidepressants and anticonvulsants (SSRIs, TCAs, gabapentinoids) are prescribed based on the neuropathic pain model but show limited high-quality evidence supporting routine use^[16]. Their benefits may be greater in patients with comorbid anxiety or depressive symptoms, underscoring the need for individualized treatment planning.

Non-Pharmacological Interventions

Feller et al (2017) stated that Cognitive behavioural therapy (CBT) demonstrates beneficial effects on pain perception, coping strategies, and quality of life by targeting the psychosomatic and central sensitization dimensions of BMS^[24]. Although CBT does not directly eliminate burning symptoms, its role in reducing pain-related distress and improving functional outcomes is clinically significant.

According to Nguyen et al. (2025), Low-level laser therapy / photobiomodulation (630–980 nm; 2–5 J/cm²; 2–3 sessions/week for 4–6 weeks) shows significant reductions in pain scores compared to sham treatments^[18,19]. Proposed mechanisms include modulation of nerve conduction, reduction of neurogenic inflammation, and enhancement of local microcirculation. Heterogeneity in laser parameters, however, limits definitive conclusions. Petruzzi et al in 2004, in his study with 23 patients proposed that Capsaicin (0.025% cream/rinse, 1–2 daily) acts via desensitization of TRPV1 receptors on C-type sensory nerve fibers, showing short-term benefits^[25]. Patient tolerability remains a concern. Acupuncture, while offering analgesic effects through endogenous opioid release, is limited by small sample sizes and methodological weaknesses in the current evidence base.

Evidence-Based Management Protocol

Based on the synthesized evidence, a stepwise clinical guideline is proposed:

Primary BMS - First-line: ALA (600 mg/day orally; for 60–120 days); topical clonazepam (0.5 mg lozenge, 2–3×/day); LLLT (630–980 nm; 2–5 J/cm²; 2–3 sessions/week for 4–6 weeks).

Primary BMS - Second-line: Topical capsaicin (0.025%, 1–2 daily); low-dose amitriptyline (10–25 mg), particularly for patients with comorbid anxiety or depression.

Secondary BMS: Address the underlying cause — nutritional deficiency, endocrine disturbance, medication-induced effects, or oral candidiasis — before initiating symptomatic pharmacotherapy.

LIMITATIONS

This umbrella review acknowledges several limitations that temper the interpretation of its findings.

Many included reviews showed high risk of bias, particularly in randomization, allocation concealment, and blinding.

Selective reporting and incomplete data reduced transparency in several studies.

Considerable heterogeneity in diagnostic criteria, intervention protocols, and outcome measures limited meaningful data pooling and contributed to high I^2 values.

Most studies had short follow-up durations, limiting assessment of long-term efficacy and relapse rates.

Future studies should focus on well-designed randomized controlled trials using standardized diagnostic criteria (ICHD-3/IASP), uniform outcome measures, and longer follow-up periods

CONCLUSION

Burning Mouth Syndrome (BMS) is a complex chronic orofacial pain disorder with no definitive cure. This umbrella review showed that active treatments provide better short-term symptom relief than placebo, although the overall certainty of evidence remains low due to high risk of bias. No single therapy achieves complete symptom resolution.

A multimodal, individualized approach combining pharmacological and non-pharmacological therapies

appears most effective. Early diagnosis, patient education, and empathetic counselling remain essential for improving treatment adherence and quality of life.

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