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Efficacy of Chamomile in the Prevention of Chemotherapy-Induced Oral Mucositis: A Systematic Review

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KEYWORDS

Chamomile

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ABSTRACT:

Introduction: Chemotherapy-induced oral mucositis (CIOM) is a common and dose-limiting complication of systemic anticancer therapy characterized by epithelial injury, inflammatory ulceration, oxidative stress, and significant pain. Increasing interest has focused on phytotherapeutic agents capable of modulating inflammatory and oxidative pathways involved in mucosal damage. *Matricaria chamomilla* L. (chamomile), rich in flavonoids, terpenoids, and α-bisabolol derivatives, demonstrates anti-inflammatory and antioxidant properties that may offer mucosal protection.

Methods:

Randomized controlled clinical trials assessing chamomile interventions for CIOM were identified through extensive electronic database searches conducted in PubMed, ProQuest, and Google Scholar. Studies published from January 2016 to April 2022.were screened. Outcomes assessed included mucositis incidence, severity grading, pain scores, and adverse events. Risk of bias was evaluated using the Cochrane RoB 2 tool.

Results:

Four randomized controlled clinical trials comprising 165 participants fulfilled the inclusion criteria. Chamomile was administered as cryotherapy infusion, mouthwash, or topical gel. Across studies, chamomile demonstrated a statistically significant reduction in mucositis severity and pain intensity compared with control interventions. No serious treatment-related adverse effects were reported.

Conclusions:

Chamomile-based interventions demonstrated favourable symptomatic improvement in CIOM, particularly in reducing mucosal severity and pain, with an acceptable safety profile. However, differences in formulations and study designs, along with small sample sizes, limit the strength of evidence, highlighting the need for larger, well-designed randomized trials to confirm definitive clinical efficacy.

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1. Introduction

Oral mucositis (OM) is a frequent and clinically relevant complication associated with chemotherapy. It manifests as erythema, mucosal inflammation, ulcer formation, and functional disturbance within the oral cavity. These changes often interfere with essential activities such as eating, drinking, and speaking, significantly affecting patient comfort and nutritional status [(1)]. In more severe presentations, OM may predispose individuals to secondary infections and necessitate chemotherapy dose modification or temporary discontinuation, thereby potentially compromising overall treatment effectiveness and quality of life. Certain cytotoxic agents, particularly 5-fluorouracil (5-FU), are strongly associated with mucosal injury, and a substantial proportion of patients exposed to these regimens develop clinically significant lesions [(2)]. Current epidemiological evidence suggests that chemotherapy-induced oral mucositis (CIOM) occurs in approximately 40–55% of patients receiving conventional cytotoxic therapy, with many experiencing moderate to severe disease (grade ≥2) [(1)]. Despite its high prevalence and clinical burden, preventive options remain suboptimal. Standard supportive approaches, including saline rinses, sodium bicarbonate solutions, and antiseptic mouthwashes such as chlorhexidine, have demonstrated limited and inconsistent benefit. Systematic reviews indicate that chlorhexidine does not significantly reduce the incidence or severity of OM and may be associated with adverse effects such as altered taste sensation and tooth discolouration, which can limit adherence [(3)]. These findings highlight the need for interventions that address the underlying biological mechanisms driving mucosal injury rather than relying entirely on symptomatic management. The development of CIOM involves a multifactorial biological process initiated by chemotherapy-induced epithelial DNA damage. This primary injury is amplified by excessive production of reactive oxygen species (ROS), which play a central role in propagating tissue damage. Elevated ROS levels activate redox-sensitive transcription factors, notably nuclear factor-kappa B (NF-κB), resulting in increased expression of pro-inflammatory cytokines including tumor necrosis factor-α (TNF-α), interleukin-1β (IL-1β), and interleukin-6(IL-6) [(6)]. The subsequent inflammatory cascade promotes cyclooxygenase-2 (COX-2) upregulation, enhances prostaglandin synthesis, and accelerates epithelial apoptosis, ultimately leading to ulcerative breakdown of the mucosal barrier. Targeting oxidative stress and inflammatory signaling pathways, therefore, represents a rational therapeutic strategy for mitigating the progression of mucosal injury.

Chamomile (*Matricaria chamomilla L.)* is a traditional medicinal plant widely recognized for its anti-inflammatory and antioxidant properties. Its pharmacologically active constituents include terpene alcohols, chamazulene, α-bisabolol derivatives, and flavonoids such as apigenin. These compounds possess free-radical-scavenging capacity and have demonstrated modulatory effects on inflammatory mediators implicated in oxidative tissue damage [(4)]. The combined antioxidant and anti-inflammatory actions of chamomile provide a mechanistic basis for investigating its potential role in reducing chemotherapy-induced mucosal toxicity. In recent years, chamomile-based preparations, including mouthwashes, topical gels, and infusion-based cryotherapy, have been explored as preventive interventions for CIOM [(5)]. Although individual randomized trials report reductions in mucositis severity and associated pain, variability in formulation, dosage, and methodological design has resulted in heterogeneous findings. Given the substantial clinical impact of CIOM and the biological rationale supporting chamomile's therapeutic potential, a comprehensive evaluation of randomized clinical evidence is necessary. Accordingly, the present systematic review aims to critically assess the efficacy and safety of chamomile-based interventions in the prevention of chemotherapy-induced oral mucositis.

2. Methods

Focused question and protocol registration

This review was performed in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria and the Participants, Intervention, Comparator, and Outcomes (PICO) framework. The study protocol was prospectively registered with PROSPERO under the registration number CRD420251167945. The research question investigated was: How effective and safe is chamomile in preventing and reducing chemotherapy-induced oral mucositis?

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The PICO criteria applied were:

Population (P) - Human participants (children or adults) underwent chemotherapy

Intervention (I) – Topical chamomile (mouthwash, gel, cryotherapy, infusion, oral cryotherapy)

Comparator (C) - Placebo, standard care, other mouthwashes

Outcome (O) - Incidence, severity, and pain of oral mucositis; safety and tolerability

Study design (S) - Randomized and non-randomized clinical trials

Eligibility Criteria

Inclusion criteria:

1. Studies evaluating topical chamomile preparations (mouthwash, gel, infusion, or extract) for the prevention of chemotherapy-induced oral mucositis, either alone or compared with placebo, standard care, or other preventive agents.
2. Randomized or non-randomized clinical trials conducted in human participants undergoing chemotherapy.
3. Studies reporting clinical outcomes, including incidence, severity, or pain associated with oral mucositis, assessed using validated grading scales.
4. All articles published only in English.

Exclusion criteria:

1. Studies not published in English, case reports, case series, review articles, monographs, retrospective studies, short communications, letters to the editor, commentaries, and animal studies were excluded.
2. Studies involving patients with systemic illnesses, pregnant or breastfeeding women, individuals receiving radiotherapy alone, and individuals with known chamomile allergy.

Search strategy:

A comprehensive literature search was conducted across Medline (via PubMed), ProQuest, and Google Scholar databases. The search used a combination of keywords such as ("chamomile"[MeSH Terms] OR “Matricaria chamomilla" OR "Matricaria recutita" OR "German chamomile") AND ("mucositis"[MeSH Terms] OR "oral mucositis" OR stomatitis OR "oral stomatitis”) AND ("antineoplastic agents"[MeSH Terms] OR chemotherapy OR antineoplastic OR "cancer therapy" OR "anticancer treatment”) AND ("prevention and control" OR prevention OR prophylaxis). Two investigators independently reviewed irrelevant studies based on titles and abstracts. Studies meeting the inclusion criteria underwent a second evaluation and were relabeled accordingly. A third reviewer resolved any disagreements**.**

Data collection process

Data were obtained through the use of a specifically designed extraction form that captured key study details, including the study title, author information, study period, year of publication, research design and setting, study population, use of randomization where applicable, details of the intervention and comparator, participant characteristics (age and sex), inclusion and exclusion parameters, along with the timing of outcome assessments, and reported primary and secondary outcomes along with any associated remarks. The systematic literature search included studies published from January 2016 to April 2022.

Quality assessment

The quality of the included randomized controlled clinical trials (RCTs) was independently evaluated by two reviewers using the Cochrane Risk of Bias 2 (RoB2) tool. Five domains were evaluated: outcome measurement, selection of reported results, missing outcome data, bias from randomization methods, and changes from planned treatments. Each study earned a rating of high risk, mild concerns, or low risk. A third expert stepped in to settle disputes.

Results

Literature search and study selection

The study selection process followed the PRISMA framework. An initial search retrieved 201 records from various databases, including the first 100 articles obtained. After eliminating duplicate entries and

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screening titles, 18 studies were considered for full-text evaluation. Fourteen studies were excluded, as five were review papers and nine did not focus on chemotherapy-induced oral mucositis. Consequently, four studies met the inclusion criteria and were included in the systematic review. (Figure 1)

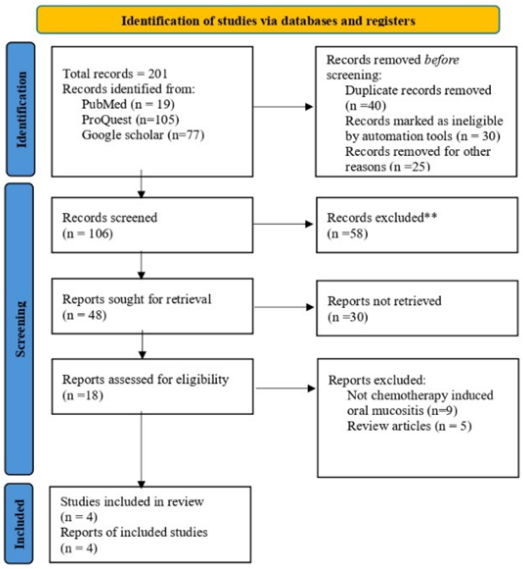

Figure 1: The Prisma flowchart.

General characteristics of the studies:

The four included RCTs involved a total of 165 participants. Two studies were conducted in Egypt, one study in Iran, and one study in Brazil. All the included studies subjects age ranged from 8 to 11 years, indicating predominantly pediatric populations, and an equal gender distribution was present. (Table - 1) and (Table 2)

Formulation – Intervention and control groups:

Essa DY et al. (2022) evaluated chamomile ice chips prepared by dissolving 10 g of chamomile in 400 mL of water, administered for 70 minutes during chemotherapy. [17] Elhadad A et al. (2020) assessed a 3% chamomile gel, applied three times daily from the initiation of chemotherapy and continued throughout the treatment period. [13] Diniz Ros Reis et al. (2016) consisted of 20 mL of chamomile mouthwash, administered thrice daily, starting a day prior chemotherapy and maintained for 14 days. [10] Pourdeghatkar F et al. (2017) one study, utilized 2.5% chamomile infusion ice chips, kept in the mouth for a minimum of 30 minutes during chemotherapy [12].

Clinical parameters:

Across the included studies, oral mucositis was assessed using standardized clinical measures. Essa DY et al. (2022) employed the ChIMES scale on days 8, 15, and 21. In contrast, the Elhadad A et al. (2020), Diniz Ros Reis et al. (2016), and Pourdeghatkar F et al. (2017) studies utilised the WHO oral mucositis grading system at various time points, including weeks 1–3 or days 7 and 14. Pain intensity was evaluated using either a 7-day Numerical Rating Scale (NRS) or a 10-point NRS. Additional secondary parameters reported included mucositis incidence, time to onset, requirement for supportive therapy, and tolerability of interventions.

Table 1: Characteristics of the studies included.

Author	Study year	Study design	Study Aim/ Objective	Sample size	Age (in years) and Gender	Study group
Dina Y. Essa et al (Egypt) [17]	2022	RCT	To evaluate whether chamomile oral cryotherapy prevents oral mucositis in pediatric cancer patients undergoing chemotherapy.	20	Control – 15.4 Intervention – 13 M – 10 F - 10	**Control group:** Plain ice-chip cryotherapy was used. **Intervention group:** Chamomile ice-chip cryotherapy was used.

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Mahmoud Ahmed Elhadad et al (Egypt) [13]	2020	RCT	To clinically examine how effective the topical chamomile oral gel is in preventing chemotherapy-induced oral mucositis.	45	Control – 9.86 Intervention - 10.75 M – 21 F - 24	**Control Group:** A placebo or standard oral care was used. **Intervention group:** Chamomile topical gel was used three times a day.
Fatemeh Pourdeghatkar et al (Iran) [12]	2017	RCT	To compare the effects of a topical mouth rinse and chamomile mouthwash on preventing oral mucositis caused by chemotherapy in children with cancer.	62	Control – 9.7 Intervention – 9.9 M – 35 F - 27	**Control Group:** Topical mouth rinse was used. **Intervention group:** Chamomile mouthwash is used three times a day.
Paula Elaine Diniz dos Reis et al (Brazil) [10]	2016	RCT	To compare cryotherapy made with only water to cryotherapy made with chamomile infusion for preventing and reducing the severity of oral mucositis in patients receiving 5-fluorouracil and leucovorin.	38	Control – 9.5 Intervention – 8.1 Gender not mentioned	**Control Group:** Cryotherapy with plain water **Intervention group:** Cryotherapy with chamomile ice chips was used.

Table 2: Characteristics of the studies included.

Author	**Study year**	**Study design**	**Formulation of chamomile and duration**	**Primary outcome**	**Secondary outcome**	**Results**	**Adverse effects**
Dina Y. Essa et al (Egypt) [17]	2022	RCT	Chamomile ice chips were given for 70 minutes during chemotherapy.	ChIMES scores were taken on days of 8, 15, and 21.	OM was assessed with the WHO scale on days of 8, 15, and 21.	On day 15, 80% of controls had grade 2 mucositis, versus none in the chamomile group.	None
Mahmoud Ahmed Elhadad et al (Egypt) [13]	2020	RCT	3% chamomile gel was applied thrice daily throughout chemotherapy.	OM was scored with the WHO scale during 1–3 weeks.	Pain was measured using the 7-day NRS.	Pain increased more over time in the conventional group, with no significant group difference.	None

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Fatemeh Pourdeghatkar et al (Iran) [12]	2017	RCT	Patients used 20 mL of chamomile mouthwash three times daily for 14 days.	WHO grading assessed OM incidence and severity on 7th and 14th day.	Pain, OM onset, supportive therapy, and intervention tolerability were recorded.	On day 14, mucositis severity was lower in the chamomile group than in controls.	None
Paula Elaine Diniz dos Reis et al (Brazil) [10]	2016	RCT	Patients used 2.5% chamomile ice chips during chemotherapy, with reviews on days of 8, 15, and 22. .	The occurrence of oral mucositis was recorded (yes or no).	Mucositis severity was assessed using the WHO scale, and pain was rated on a 10-point NRS.	Oral mucositis occurred in 50% of controls versus 30% of the chamomile group.	None

Outcome measures:

A study by Essa DY et al. (2022) reported that chamomile oral cryotherapy was associated with a significant decrease in both occurrence and intensity of chemotherapy-induced oral mucositis compared with plain cryotherapy. In the study group, Assessment of mucositis severity using the WHO scale revealed that no patients in the chamomile group experienced mucositis beyond grade 2, and lower pain scores were reported, with no adverse effects or toxicity identified [17].

A study by Pourdeghatkar F et al. (2017) observed that chamomile mouthwash significantly reduced the severity of oral mucositis at 14 days following chemotherapy compared with a topical mouth rinse. No significant difference was observed at day 7; however, chamomile demonstrated superior mucosal protection over time, with good tolerability and no reported adverse effects [12].

A study by Diniz dos Reis et al. (2016) demonstrated a lower incidence of oral mucositis and reduced mouth pain among patients receiving chamomile infusion

cryotherapy compared with water-based cryotherapy. Patients in the chamomile group did not develop WHO grade 2 or higher mucositis or ulcerations, and the intervention was well tolerated without chamomile-related toxicity [10].

A study by Elhadad A et al. (2020) reported that Topical chamomile 3% gel reduced the severity of mucositis and pain scores compared to controls. It enhanced healing, minimised tissue damage, and was well-tolerated without toxicity differences [13].

Most of the included studies demonstrated that chamomile showed effectiveness in reducing the risk of chemotherapy-induced oral mucositis. Chamomile-based interventions, including oral cryotherapy, mouthwash, and topical gel formulations, were associated with reductions in mucositis severity and pain scores compared with control interventions. No treatment-related adverse effects or toxicity were reported.

Quality Assessment:

Assessment of the methodological quality of the four included studies was conducted with the Cochrane Risk of Bias 2 (RoB 2) tool. The methodological quality of the included randomized controlled trials was evaluated across all relevant domains. Of the four RCTs assessed, one study demonstrated a low risk of bias across all domains, two studies raised some concerns, and one study was determined to carry a high risk of bias, primarily due to concerns about outcome measurement and selective reporting. Overall, the included studies were of acceptable methodological quality, and their findings can be considered reliable. (Figure 2)

It also indicated generally acceptable methodological quality among the included studies. Most studies (75%)

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were low risk for randomization, and all (100%) were low risk for deviations from the intended interventions and for completeness of outcome data. Outcome measurement showed more variability, with 50% low risk, 25% some concerns, and 25% high risk. For selective reporting, 75% had some concerns, and 25% were low risk. Overall, 25% of studies were low risk, 50% had some concerns, and 25% were high risk, highlighting the need for cautious interpretation in certain domains. (Figure 3)

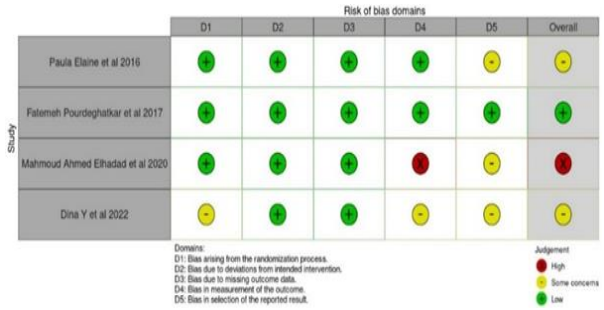

Figure 2. Risk of Bias summary (RoB 2).

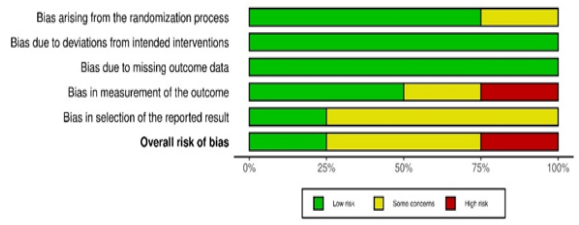

Figure 3. Risk of Bias graph (RoB 2).

Discussion:

Chemotherapy-induced oral mucositis (CIOM) is a frequent and debilitating complication of anticancer therapy, manifesting as erythema, ulceration, inflammation, and severe pain. These lesions can impair oral intake, speech, and oral hygiene, significantly affecting patient's quality of life, and occasionally necessitating dose reduction or interruption of chemotherapy [1]. Despite advances in supportive care, preventive strategies remain inconsistent and often depend on the specific chemotherapy regimen, highlighting the need for safe and effective adjunctive interventions. [3,7] Phytotherapeutic agents with antioxidant and anti-inflammatory properties have attracted increasing attention, and Chamomile (*Matricaria recutita L.*) has emerged as a promising candidate. Its bioactive flavonoids, including apigenin and luteolin, and sesquiterpenes such as α-bisabolol and chamazulene, are known to modulate inflammatory pathways, scavenge reactive oxygen species (ROS), and provide cytoprotective effects [8,14]. Apigenin inhibits NF-κB activation, reducing pro-inflammatory cytokine production, while α-bisabolol supports epithelial integrity and exhibits anti-ulcer activity. These mechanistic attributes provide a strong rationale for investigating Chamomile as a preventive and therapeutic agent for CIOM. The clinical benefits of Chamomile have now been explored across multiple randomized controlled trials using different formulations and delivery methods, revealing a consistent trend toward reduced mucositis severity and pain.

A study by Essa et al. first demonstrated that Chamomile ice-chip cryotherapy in pediatric cancer patients could markedly reduce the incidence of mucositis. Children receiving Chamomile ice during chemotherapy experienced no grade 2 mucositis by day 15, whereas 80% of controls reached this severity. The intervention was well-tolerated with no reported adverse effects, highlighting its potential as a safe and practical prophylactic measure [17]

A study by Elhadad A et al. investigated a 3% Chamomile topical gel applied three times daily in patients undergoing chemotherapy. Unlike the control group, whose pain increased over the three-week study period, patients receiving the gel maintained stable discomfort levels. This study emphasized that topical Chamomile can both prevent severe mucositis and stabilize patient-reported pain, complementing the protective effects observed with cryotherapy [13]

A study by Pourdeghatkar et al. evaluated the preventive impact of Chamomile mouthwash in pediatric oncology patients. By rinsing with 20 mL of Chamomile mouthwash three times daily for two weeks, patients experienced lower mucositis severity, delayed lesion onset, and decreased need for supportive care compared with standard rinses. These findings reinforced the versatility of Chamomile in multiple formulations, suggesting that consistent exposure of the oral mucosa to its bioactive compounds can enhance both prevention and early mitigation of mucositis [12]

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A study by Diniz dos Reis et al. evaluated Chamomile ice-chip cryotherapy in patients receiving 5-fluorouracil and leucovorin. Mucositis incidence and pain were tracked over three weeks. The Chamomile group showed a lower incidence of mucositis (30% versus 50% in controls) and had reduced pain scores, with no adverse events. Along with pediatric studies, these results suggest that Chamomile's protective effects are consistent across different age groups and chemotherapy regimens, further supporting its potential as a widely used preventive strategy (10).

The observed clinical benefits are biologically plausible. Chemotherapy generates ROS, which activate NF-κB and trigger pro-inflammatory cytokines such as TNF-α, IL-1β, and IL-6. This cascade enhances COX-2 expression, prostaglandin synthesis, and epithelial apoptosis, culminating in mucosal ulceration [(6)]. Chamomile's flavonoids and sesquiterpenes mitigate these pathways, scavenging ROS and reducing epithelial injury, thereby facilitating mucosal recovery.Formulation and mode of delivery appear to influence therapeutic outcomes. Cryotherapy reduces blood flow to the oral mucosa, limiting exposure to cytotoxic agents, and demonstrates enhanced effects when combined with Chamomile infusion [(10,17)]. Topical gels provide prolonged mucosal contact and improved bioavailability, while mouthwash efficacy may vary depending on extract concentration, duration, and standardization [(12,13)]. These differences underscore the importance of optimizing formulation for maximum clinical benefit.

Safety remains a crucial consideration in oncology populations. Across all studies, Chamomile interventions were well-tolerated, with no serious adverse events reported [(13,17)]. Nonetheless, variability in phytochemical composition, potential modulation of cytochrome P450 enzymes by flavonoids, and rare hypersensitivity reactions require attention in clinical practice [(18,19)]. Standardized formulations and careful monitoring are essential to ensure reproducible and safe outcomes. While the results are encouraging, limitations exist. The included trials had modest sample sizes, short follow-up periods, and heterogeneity in chemotherapy regimens, mucositis grading scales, and Chamomile formulations, precluding quantitative meta-analysis. Despite these constraints, all studies consistently showed reduced mucositis severity and pain, demonstrating Chamomile's promise as a safe and effective preventive intervention.

Conclusion:

Chemotherapy-related oral mucositis remains a major clinical challenge that can interfere with cancer therapy and diminish patient well-being. Existing evidence indicates that chamomile-based interventions may help to alleviate mucosal inflammation and pain, potentially through antioxidant and anti-inflammatory mechanisms.

However, variability in the preparation procedures and the limited availability of long-term safety evidence require the findings to be interpreted with caution. High-quality, multicentre clinical trials using standardized formulations and comprehensive safety monitoring are necessary to confirm therapeutic value and clarify associated risks. With stronger evidence, chamomile could be considered a supportive adjunct in oncology care.

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