Research Square

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Coconut oil/xylitol mouthrinse versus chlorhexidine and placebo for common oral mucosal lesions: a double-blind randomized controlled trial

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Abstract

Background

Natural-source mouthrinses are proposed as alternatives to chlorhexidine (CHX), but their effect on common oral mucosal lesions (COL) is poorly documented. We compared a coconut oil/xylitol rinse with CHX and a placebo rinse on clinical manifestations and patient-reported symptoms of COL.

Methods

In this single-centre, double-blind, parallel-group randomized controlled trial, 120 adults with glossodynia/pyrosis, recurrent aphthous stomatitis, herpes palate, xerostomia or oral lichen planus were randomized 1:1:1 (n = 40 per group) to gargle 20 mL of a coconut oil/xylitol rinse, 0.2% CHX or a mint-flavoured hydro-based placebo for 30 s twice daily for three weeks. The primary outcome was the presence of clinical manifestations of COL at follow-up; the secondary outcome was the presence of patient-reported symptoms. Adjusted logistic regression estimated odds ratios (OR) with 95% confidence intervals (CI).

Results

Mean age was 43.4 years and 59.2% of participants were women. Among participants with COL at baseline, manifestations had resolved in 77.8% (21/27) of the test group, 67.7% (21/31) of the CHX group and 51.4% (18/35) of the placebo group. After adjustment, the odds of persistent COL were higher with placebo than with the test rinse (OR 4.26, 95% CI 1.01–17.97; p = 0.048), whereas CHX did not differ significantly from the test rinse (OR 2.02, 95% CI 0.44–9.25) or from placebo (OR 2.10, 95% CI 0.60–7.35). Symptoms had resolved in 72.5% (29/40), 47.5% (19/40) and 25.0% (10/40) of the test, CHX and placebo groups, respectively. The odds of persistent symptoms were higher with placebo than with the test rinse (OR 10.57, 95% CI 2.81–39.79; p < 0.0001) and than with CHX (OR 3.77, 95% CI 1.10–12.97; p = 0.03); CHX and the test rinse did not differ significantly (OR 2.80, 95% CI 0.82–9.49).

Conclusions

The coconut oil/xylitol rinse was associated with fewer persistent lesions and symptoms than placebo and did not differ significantly from CHX, although confidence intervals were wide. Larger multicentre trials are needed to confirm these findings.

Trial registration: ClinicalTrials.gov ID NCT07175090

Background

The oral cavity has a peculiar anatomical and immunological milieu and is commonly affected by inflammatory conditions [1]. These include a diverse group of disorders, stemming from a range of causes, including infections, autoimmune or purely inflammatory forms [2]. Inflammatory disorders of

the oral mucosa are described often as common oral lesions [3–6]. Common superficial oral lesions can include [7] herpes palate, recurrent aphthous stomatitis, xerostomia, lichen planus, glossodynia and pyrosis.

Palatal herpes shows up as painful sores on the palate. The ulcers usually appear on the palatal mucosa, around the first molars. The lesions start as blisters that quickly turn into small, superficial ulcers about the size of a pinpoint and grouped together in clusters. These ulcers are often linear, running from front to back. The pain is sharp as soon as the lesions appear, making eating and drinking difficult [5]. Stomatitis aphthous can appear alone or secondary to numerous distinct disease processes [8]. Oral aphthosis is a painful inflammatory process of the oral mucosa. This condition is common, with prevalence rates ranging from 5% to 60% in different series. The goal of any treatment should be to alleviate pain, reduce the duration of ulcers, and prevent recurrence [9]. Oral herpes is an infection caused by HSV- type 1 [10]. Xerostomia, or dry mouth, is which has been associated with oral/teeth disease and can compromise food intake, nutritional status, and quality of life (QoL). is mainly caused by the intake of medications, chronic disorders like Sjögren's syndrome, and head and neck radiation [11]. The prevalence of xerostomia among old adults seems to be approximately 24%,indicating a considerable burden in this population [12]. Oral lichen planus is a relatively common T-cell mediated inflammatory disease with potential malignant transformation. It may present itself with pain and oral lesions such as ulcers and Wickhams striae [13]. In a review, worldwide prevalence of oral lichen seems to be 1.01% [14]. Glossodynia means pain of the tongue that can be induced by inflammation or ulcers [15]. This condition is characterized by a painful sensation in the tongue with oral symptom such burning mouth sensation [16]. The prevalence in US from a large Hospital-based database study was estimated to be 4% in adults. Gastroesophageal reflux disease (GERD) is a clinical condition in which stomach contents leak backward into the oesophagus [17]. It affects millions of people worldwide and has a detrimental effect on quality of life. The oral and maxillofacial as pyrosis manifestations of GERD may include dental erosion, xerostomia, mucositis, aphthous like ulcerations, sour taste, burning mouth [18].

We chose common oral lesions that are with challenging management and with infectious aetiology (herpes) and non-infectious aetiology (aphthosis, pyrosis or glossodynia and lichen plan) [5].

In recent years, mouthwashes have gained increasing attention from researchers, healthcare providers and the media, and similarly, the number of mouthwash products available over the counter (OTC) has continued to grow [19]. Concerns over synthetic chemicals in conventional mouthwashes have led to a rise in natural and herbal formulations exhibiting antimicrobial and anti-inflammatory properties [20]. Current commercial oral rinse offer is dominated by chemotherapeutic agents such fluoride and, essential oils and chlorhexidine (CHX) [21]. Being the gold standard of oral mouthwash, CHX is also associated with several undesirable side-effects including tooth-staining, taste alteration, calculus formation and oral mucosa desquamation/irritation [22]. Menthol as the most derived compound, are the main active ingredient [23] for anti-inflammatory and antibacterial effects [24]. On the market of mouthwashes, there are more rinses antibacterial than rinses anti-inflammatory [25]. In general, along

with a common belief about the effectiveness of most of the current chemical mouthwashes, most of the formulations may have side effects [26].

Our study design wants to expand the study of Lopez et al. 2025 [27] on anti-inflammatory evidence of coconut oil mouthwash compared to Chlorhexidine and placebo mouthwashes. Our intervention testing a xylitol/coconut oil new rinse is based on not-pulling daily regimen identical for the three groups, constituted of gargling for thirty seconds twice a day for three weeks. Pre/post inflammation will be assessed on presence/absence of clinical manifestations and on participant's symptoms. To our knowledge, this is the first time that five common oral lesions of oral medicine will be under an anti-inflammatory regrouped evaluation and exposed to a complete natural source mouthwash.

Methods

Study design:

Single-centre, double-blinded prospective randomized controlled trial evaluated the clinical effectiveness of coconut oil/xylitol, 0.2% CHX and placebo mouthwashes as anti-inflammatory agent on five parameters of oral medicine. The study adhered to the updated CONSORT 2025 guideline for reporting trials [28].

Trial registration:

Study Details | NCT07175090 | Evaluation of Coconut Oil Mouth Rinse on Periodontal Parameters | ClinicalTrials.gov

Ethics approval:

The study protocol, approved by the Ethical Health Committee of Pristina University under number - 312/3, March 3rd, 2024. All participants provided written informed consent prior to enrollment. Design was realized at the Periodontology and Oral Medicine department of the dental faculty of Pristina, Kosovo, between March 2025 and February 2026, prioritizing participant safety and protocol validity. The study was conducted in accordance with the Declaration of Helsinki.

Eligibility criteria:

Inclusion criteria: Adult (over 18 years) participants diagnosed with one of the five common oral lesions selected - herpes palate, xerostomia, recurrent aphthous stomatitis, lichen planus, glossodynia and pyrosis – based on unique collector expertise as academic specialist in periodontology and oral medicine. Participant possessing at least 16 natural teeth and capable of understanding and signing informed consent and follow study instructions.

Exclusion criteria: Individuals treated with antibiotics in the preceding 4 weeks or currently undergoing antibiotic therapy, regular consumers of xylitol, coconut, or coconut derivatives or CHX, pregnant and

breastfeeding individuals, patients with allergies to coconut, coconut-derived products and CHX, those with uncontrolled systemic diseases or current use of medications such as anti-inflammatory, antibacterial, hydrocortisone, corticosteroid, phenytoin, cyclosporine, immunosuppressant or anticoagulants, and those with history of chemotherapy or radiotherapy to the head and neck area.

Study variables:

Primary dependent variables: Common oral lesions (COL) presence at post-treatment follow up as the primary dependent variable. *Secondary dependent variable*: COL residual symptoms at post-treatment follow up as the secondary dependent variable.

Independent variables of interest was treatment group, and COL presence or symptoms at pre-treatment as a covariate, to adjust for possible differences at pre-treatment of COL between the groups.

Independent variables: A) Treatment group as the independent variable of interest. B) and COL presence at pre-treatment or symptoms as a covariate. Other independent variables are regrouped or specific conditions listed in the study: herpes palate, xerostomia, recurrent aphthous stomatitis, lichen planus and glossodynia and pyrosis.

Intervention:

Procedures of diagnosis of parameters oral manifestations and subjective symptoms have been guided by evidence-based from European authorities [29–32] (Table 1).

Table 1. Oral manifestations and subjective symptoms recorded for each condition

Pathology	Oral manifestations	Subjective symptoms
Herpes palati	Inflammation of the oral mucosa, Vesicles, Erosions, Ulcers, secondary infections	Temperature, Pain, Numbness, Sore throat, Dry mouth
Stomatitis aphthosa	Recurrent minor canker sores, major canker sores	Burning, Itching, Pain
Glossodynia et pyrosis	Tongue coating, tongue atrophy	Burning, Itching, Pain, Dry mouth
Xerostomia	Oral epithelial atrophy, glossed tongue	Dry mouth, Speech impediment, Eating impediment, Taste disturbance
Lichen planus oris	Lichenoid erosions, ulcers, plaques, mucosal erythema	Itching, Pain, Dry mouth speech impediment

Baseline (T1): Diagnostic procedures for determining the presence/absence of any oral lesions among the study selection (five parameters of oral medicine) based on clinical judgment [33] according to their

clinical appearance or manifestation, site and associated symptoms, by the blinded collector specialist in Periodontology and Oral Medicine. The project lasted 12 months (started March 2025): Approximately 180 approached subjects were needed to generate our sample size (120). Subjective symptoms of participants related to their clinical manifestations were captured by their anamnesis and interview, both verified by the same clinical collector. All participants, independent to their group allocations, received to same 500 mL opaque bottle of rinse (participants were blinded for rinse appropriation) and instruction about their three-week of rinse exposure They were asked to gargle twice a day (morning and night routine) for 30 seconds with about an average amount per use of 20 mL [34] for three weeks. A demonstration by study assistant of their first gargling experience have been conducted after each group allocation.

Three weeks after baseline (T2): Presence/absence of clinical detected manifestation of herpes palate, xerostomia, recurrent aphthous stomatitis, lichen planus and glossodynia and pyrosis have been reviewed for all recruited participants. The subjective symptoms of participants after rinse exposures have been collected. Both collections was conducted by the same blinded expert.

Standardization/Training

Prior the study, the study assistant 1 involved in the study were supervised and trained by the expert collector. She was already active at the site of the study: emphasizing standardization of the recruitment, appropriate bottle attribution and rinse instructions referring to the study protocol adherence. At T1, participants were asked to bring back empty their bottle of rinse at T2, to put emphasis on a steady implication in the follow-up. Another study assistant 2 was trained by the external (Canada) scientific consultant to prepare the project. Assistant 2 received from Spain LAB, the first opaque bottles of test and placebo groups. She received also privately purchased CHX bottles and transferred them in opaque bottles provided by Spain LAB. This assistant 2, gathered and classified the bottle by specific contain. After her confirmation, the international consultant applied the random computed list and gave instructions to put A, B or C on specific bottles. By this method, only assistant 2 and international consultant, both not involved in the study, knew the group attributions. Both assistant 1 and collector were blinded.

Preparation of the rinses:

Coconut oil/xylitol mouth rinse and hydro-based placebo rinse were manufactured by Boniquet International Dental LAB (Barcelona, Spain) with mint flavor. Since, all bottles were opaque, all participants and collectors were blinded and had no idea of the taste (flavor) and contain of the other bottles. CHX glutamate 0.2% bottles commonly used in mouthwash research [35], were provided privately in this case, assistant of research, used opaque bottles to transfer the CHX liquid prior the study.

Sample size:

The sample size was calculated based on a one-way ANOVA comparing mean outcome of study evaluating the effects of Coconut Oil as a novel approach to managing radiation-induced oral lesion such xerostomia [34]: The calculations carried out indicate that a minimum of 34 patients per group to run logistic regression model to reach 80% power with two-sided alpha = 0.05, yielding a required sample of 120 participants. This sample was necessary to ensure statistical reliability and avoid overlooking significant results. Since this study includes three groups, additionally, anticipating a dropout rate of 15%, the sample size was increased to 40 patients per group.

Statistical analysis:

Demographic and clinical characteristics of the study participants are summarized using frequency counts and percentages for categorical variables and means with standard deviations (SDs) for continuous variables.

A binary outcome representing the presence or absence of common oral lesions (COL) was defined as follows: presence (codes 2, 3, or 4) and absence (code 1). To descriptively summarize changes in COL status between pre-treatment and post-treatment follow-up, transition tables were constructed by treatment group. Participants were classified into one of four transition categories: present at both assessments (Present/Present), present at pre-treatment and absent at follow-up (Present/Absent), absent at pre-treatment and present at follow-up (Absent/Present), or absent at both assessments (Absent/Absent). A logistic regression model was fitted with COL status at post-treatment follow-up as the dependent variable. The primary independent variable was treatment group, and COL status at pre-treatment was included as a covariate to adjust for potential baseline differences between groups. Age, sex, and baseline condition were also included as covariates [36].

A second binary outcome representing the presence or absence of COL symptoms was defined as follows: presence (codes 2, 3, or 4) and absence (code 1). A logistic regression model was fitted with COL symptom status at post-treatment follow-up as the dependent variable and treatment group as the primary independent variable. Baseline symptom status was not included as a covariate because all participants reported symptoms at pre-treatment, resulting in no variability in this variable. Age, sex, and baseline condition were included as covariates [36].

For all logistic regression models, treatment effects are reported as adjusted odds ratios (ORs) with corresponding 95% confidence intervals (95% CIs). All hypothesis tests were two-sided and conducted at a significance level of 0.05. Model diagnostics were assessed using simulation-based residuals generated with the *DHARMa* package in R [37]. Visual inspection of diagnostic plots and formal residual tests did not indicate any important violations of model assumptions. To improve clinical interpretability, the final analysis focused on a binary outcome representing lesion presence versus absence and used logistic regression.

Randomization and group allocation:

Participants were randomly assigned to one of three groups in a 1:1:1 ratio using block randomization sequence (block size of 3) performed by computed list to ensure balanced sample size. Opaque 500 mL marked containers for measuring rinse volume were giving to participants who was unaware of their specific contents and bottles by so, were also blinded to data collector.

All 120 participants were directed to gargle rinse vigorously with 20 mL of the allocated mouthwash included in the daily morning/evening oral hygiene routine for three weeks:

- **Group 1 (CO/Xyl Group)**: Coconut oil/xylitol gargle 30 seconds twice a day
- **Group 2 (CHX Group)**: 0.2% CHX solution gargle 30 seconds twice a day
- **Group 3 (Placebo Group)**: Mint flavour hydro-based, gargle 30 seconds twice a day

Results

Table 2. Characteristics of study subjects (N=120)

Variable	**All subjects**		**Treatment**	
		Placebo n=40	Test n=40	CHX n=40
Age (years), mean (SD)	43.4 (17.7)	41.9 (18.5)	47.6 (18.9)	40.8 (15.1)
Gender, n (%)				
Female	71 (59.2)	22 (55.0)	22 (55.0)	27 (67.5)
Male	49 (40.8)	18 (45.0)	18 (45.0)	13 (32.5)

SD, standard deviation; Test, coconut oil/xylitol rinse; CHX, 0.2% chlorhexidine.

The study included adults on average aged of 43.4 years with 18% more female participants. The random allocation balanced adequately the demographic data distribution between groups (Table 2).

Table 3. Conditions of study subjects (N=120)

Condition	All subjects	Treatment		
		Placebo	Test	CHX
Glossodynia & Pyrosis	47 (39.2)	16 (40.0)	14 (35.0)	17 (42.5)
Aphthous stomatitis	39 (32.5)	13 (32.5)	12 (30.0)	14 (35.0)
Herpes palate	15 (12.5)	6 (15.0)	5 (12.5)	4 (10.0)
Xerostomia	11 (9.2)	2 (5.0)	5 (12.5)	4 (10.0)
Lichen Planus	8 (6.7)	3 (7.5)	4 (10.0)	1 (2.5)

Data presented as n (%). Test, coconut oil/xylitol rinse; CHX, 0.2% chlorhexidine.

The study included five different oral medicine conditions. The Glossodynia/Pyrosis and aphtous stomatitis oral lesions represent 72% of all conditions. Herpes palate, xerostomia and lichen plan reach respectively, 15, 11 and 8 participants. Random group allocation allowed homogenous inter-treatment condition distribution (Table 3).

Table 4. Pretest-Posttest transitions of COL status by treatment

Treatment	Presence/Presence	Presence/Absence	Absence/Presence	Absence/Absence
Placebo	17	18	1	4
Test	6	21	0	13
CHX	10	21	0	9

COL, common oral lesions. Presence/Absence denotes COL status at pre-treatment/post-treatment follow-up. Test, coconut oil/xylitol rinse; CHX, 0.2% chlorhexidine.

Table 4 presents the pre-post transition counts for COL status by treatment group. Among participants with COL present at pre-treatment, resolution of COL by follow-up was observed in 51.4% (18/35) of the placebo group, 77.8% (21/27) of the Test group, and 67.7% (21/31) of the CHX group. Persistence of COL was most frequent in the placebo group. New occurrences of COL among participants without COL at pre-treatment were uncommon, with only one case observed in the placebo group.

Table 5. Results of logistic regression analysis. Outcome: Presence of post-treatment COL*.

Comparison	OR	95%CI	*p* value
Placebo vs Test	4.26	1.01, 17.97	**0.048**
CHX vs Test	2.02	0.44, 9.25	0.52
Placebo vs CHX	2.10	0.60, 7.35	0.34

*Adjusted for pre-treatment oral manifestation, pre-treatment condition, age, sex. Abbreviations: CHX, chlorhexidine; CI, confidence interval; COL, common oral lesions; OR, odds ratio; Test, coconut oil/xylitol rinse.

Results of the logistic regression model show that after adjusting for presence of COL at baseline, sex, age and condition at baseline, the odds of presence of COL at post-test are significantly higher for placebo than for test. The odds of presence of COL at post-test are also higher for CHX as compared to test and for placebo as compared to CHX. However, these differences were not statistically significant (Table 5).

At follow-up, COL symptoms had resolved in 29 of 40 participants (72.5%) in the test group, 19 of 40 (47.5%) in the CHX group and 10 of 40 (25.0%) in the placebo group (Figure 1). After adjustment for condition, age and sex, the odds of persistent symptoms were higher with placebo than with the test rinse (OR 10.57, 95% CI 2.81–39.79; p < 0.0001) and than with CHX (OR 3.77, 95% CI 1.10–12.97; p = 0.03), whereas CHX and the test rinse did not differ significantly (OR 2.80, 95% CI 0.82–9.49; p = 0.12) (Table 6).

Table 6. Results of Logistic regression analysis. Outcome: Presence of post-treatment symptoms*.

Comparison	OR	95%CI	p
Placebo vs Test	10.57	2.81, 39.79	<0.0001
CHX vs Test	2.80	0.82, 9.49	0.12
Placebo vs CHX	3.77	1.10, 12.97	0.03

*Adjusted for pre-treatment condition, age, sex. Abbreviations: CHX, chlorhexidine; CI, confidence interval; COL, common oral lesions; OR, odds ratio; Test, coconut oil/xylitol rinse.

Discussion

This clinical trial of 120 adults evaluated the comparative effectiveness of coconut oil/xylitol, CHX and Placebo mouthwashes with potent anti-inflammatory agent, in managing some common oral lesions after three-week of exposition. Earlier studies tested coconut oil mouthwash using pulling oil long method and different inter-group methods of rinse's exposure. The study assessed clinical conditions of oral medicine such as herpes palate, xerostomia, recurrent aphthous stomatitis, lichen planus, and glossodynia/pyrosis along with objective and subjective inflammatory indicators using short gargling (30 seconds) for all three groups. Chlorhexidine mouthwash, widely regarded as the gold standard in oral therapy, served as active control for comparison. Since some previous oral conditions can heal by themselves within our follow up, a placebo served as passive control. The results demonstrated that tested mouthwash with coconut oil/xylitol using, twice a day and 30 seconds of gargling was better than chlorhexidine and placebo in improving participant's symptoms and clinical lesion manifestations.

To our knowledge, this is the first study using natural source mouthwash with complete anti-inflammatory orientation based on easy daily regimen for common oral regrouped lesions (COL). Tested xylitol/coconut oil rinse performed better than CHX and Placebo mouthwashes on primary outcome defined as presence or absence of clinical manifestations of regrouped oral lesions. The pre/post difference of all condition resolutions were 45% for Xylitol/Coconut oil group, 36% for CHX and 28% for placebo. This inter-group differences reached statistical signification between test and placebo (0.009) but not (0.09) between test and CHX. For secondary outcome, defined as presence or absence of participant symptoms, the tested rinse performed significantly better than other two. The T1/T2 difference was similar between placebo and CHX (23%) although the tested group had 48% of improvement. These group differences were strongly significant (0.001).

The two potent anti-inflammatory active ingredients of tested rinse are xylitol and coconut oil. Even if xylitol has been observed [38] to have anti-inflammatory effects in reducing gingival inflammation associated with periodontal disease, we did not find any study of specific xylitol mouthwash impacting on oral inflammation or lesions. Xylitol ingredient in mouthwash seems to be combined with other agents to optimize the antibacterial effect [39, 40]. In reviews, all referring coconut oil mouthwashes targeting oral inflammation used oil pulling method exposure [41, 42]. Traditional oil pulling with coconut oil is often hindered by several limitations, including its high viscosity, greasy texture, and the prolonged rinsing time required to achieve therapeutic efficacy [43].

Studies [27, 44, 45] seem indicate that coconut oil in mouthwash may confer anti-inflammatory benefits related to the direct action on pro-inflammatory cytokines by lauric acid being approximately 50% of all coconut oil medium-chain fatty acid [46]. The mechanism of xerostomia relief from coconut oil may be related to its ability to “coat” the mouth, forming a barrier to keep mucosal surfaces moist [34]. Coconut oil pulling has been proposed as a natural remedy for xerostomia due to its emollient properties and its ability to form a protective lipid film over mucosal surfaces, thereby reducing moisture loss. Recent study suggest that coconut oil-based rinses may enhance oral moisture and improve subjective comfort, particularly in individuals with salivary gland dysfunction or those undergoing post-radiation therapy [34].

In a pilot case series [34] of two weeks, almost half (41.4%) of participants were found with xerostomia benefit in the use of coconut oil. In our study and the COL symptoms, 72% of test group were found with improvements. Lopez et al. [27] compared coconut oil daily rinsing with oil pulling method (ten minutes/day) to CHX (one minute/day) and Placebo (one minute/day) 30 participants diagnosed with periodontitis. They found coconut oil treatment significantly modulates the oral microbiome, promoting a shift toward a healthier microbial profile, while also reducing key inflammatory markers. In our study, we assessed COL clinical manifestations and participant’s symptoms after test rinse exposition in three weeks with promising results equivalent and better than CHX. Soodsakorn et al. [47] used the same three groups as previous stud but with 51 adults aged over 60 years old assessing burning sensation, oral mucosal alterations, changes in oral *Candida* and bacterial counts, and user satisfaction. All participants were asked to gargle twice a day, for five minutes for coconut oil and for 30 seconds for CHX and Placebo. They concluded Clinically, FCoMW may be especially relevant for elderly denture

wearers at risk of Candida-associated stomatitis, patients with mucosal sensitivity who cannot tolerate chemical antiseptics, individuals with xerostomia requiring emollient support, and immunocompromised populations who require a safe preventive or antifungal mouthwash that avoids the adverse effects associated with CHX. This study under an easier daily regimen, showed similar promising benefits on burning sensation and mucositis. Monica et al. [44] had the objectives of evaluating the efficacy of coconut oil (VCO) pulling in reducing the microbial load and inflammatory mediators responsible for chronic periodontitis, in comparison to chlorhexidine (CHX) mouthwash and distilled water. They used thirty patients diagnosed with chronic periodontitis. Coconut oil pulling demonstrated a significant reduction in microbial and inflammatory markers in patients with chronic periodontitis, showing similar efficacy to CHX mouthwash. Some previous studies reported that CHX reduces oral tissue inflammation: this effect may predominantly stem from decreasing bacterial load rather than directly targeting proteins or peptide [48].

This study seems to confirm the anti-inflammatory capacity of coconut oil in mouthwash to help individuals with any COL described in our design.

The strengths of the study are first, the respect of CONSORT standards of RCT by random allocation, double blinded attribution and collection, standardization of detective method, simple interpretation (yes/no) of outcomes, three groups exposed to the same regimen and follow up. The number of participants of this study, seems [27, 47, 49] to be the highest one in comparable designs. The follow up of three weeks is a bit longer than the average reported in a review [41] of 42 studies lasting between 7 and 14 days. The daily regimen for all groups, was simple and feasible in concrete oral hygiene routine. Coconut oil/xylitol mouthwash reduces COL clinical and subjective impacts without the adverse effects associated with CHX as other studies pulling method found [49]. There is no data to suggest appreciable adverse effects of coconut oil as a lubricant [34].

This study has several limitations such the single-center design of collection with restricted to adults as convenient sample attending to a university department, may limit the generalizability of the findings. This academic department on day-to-day basis, has a higher frequency of burning mouth and aphthous stomatitis conditions than others COL. We couldn’t get the balanced of conditions to have a better interpretation of anti-inflammatory effect. Also, the study regrouped these fives conditions as COL: the choice of another grouping of conditions with less or different (inflammatory cause vs infective cause) oral lesions could have be more relevant for scientific purposes. Finally, the study was powered using an ANOVA-based sample size calculation for the original ordinal outcome. The final analysis focused on a clinically meaningful binary outcome (lesion presence versus absence) and used logistic regression. Although this approach improved clinical interpretability, dichotomization of the original ordinal outcome may have resulted in some loss of information relative to the analysis of the original scale”.

Presently, there are emerging new potent natural anti-inflammatory agents using mouthwash as vehicle [50]. A study [51] suggest that melatonin mouthwash is effective in preventing chemotherapy-induced mucositis. A six-week regimen of melatonin mouthwash significantly reduces the severity and duration

of mucositis, as well as the associated pain intensity. To the best of our knowledge, this study represents the first randomized clinical trial to investigate with a facilitating daily regimen followed for three weeks, the effects of coconut oil and xylitol mouthwash on oral regrouped common lesions clinical manifestations and participant's symptoms. These findings suggest that a natural source solution can help in oral inflammatory and infective challenges instead of options with chemical, invasive and side effects.

Future research should expand on these results by examining addition of effect on periodontal bacteria. Also, next scientific evidences to develop should include multi-center design with diversity of individual relevant predisposition such immune-compromised. Additionally, a long-term clinical studies have the potential to assess the durability of protection in regards to clinical re-appearance of some conditions.

Conclusions

The results of this RCT indicate that coconut oil and xylitol mouthwash may offer a clinically meaningful alternative to CHX in nonsurgical oral lesion therapy, achieving better clinical improvements in oral lesion parameters while minimizing side effect that often limit long-term CHX use. Its favorable tolerability and impact on patient-reported outcomes further supports its potential for integration into daily oral hygiene routines.

Abbreviations

CHX, chlorhexidine; CI, confidence interval; COL, common oral lesions; CONSORT, Consolidated Standards of Reporting Trials; GERD, gastroesophageal reflux disease; OR, odds ratio; QoL, quality of life; SD, standard deviation.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Ethical Health Committee of Pristina University (number 312/3, 3 March 2024). All participants provided written informed consent prior to enrollment. The study was conducted in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests. The test and placebo rinses, manufactured by Boniquet International Dental LAB, were donated by the same company, and the CHX was supplied privately by the authors

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Authors' contributions

KM designed the study, served as assistant 2, analysed the data and wrote the manuscript. SD-I served as assistant 1, and analysed the data, EM participated in the review of the manuscript. All authors read and approved the final manuscript.

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Figures

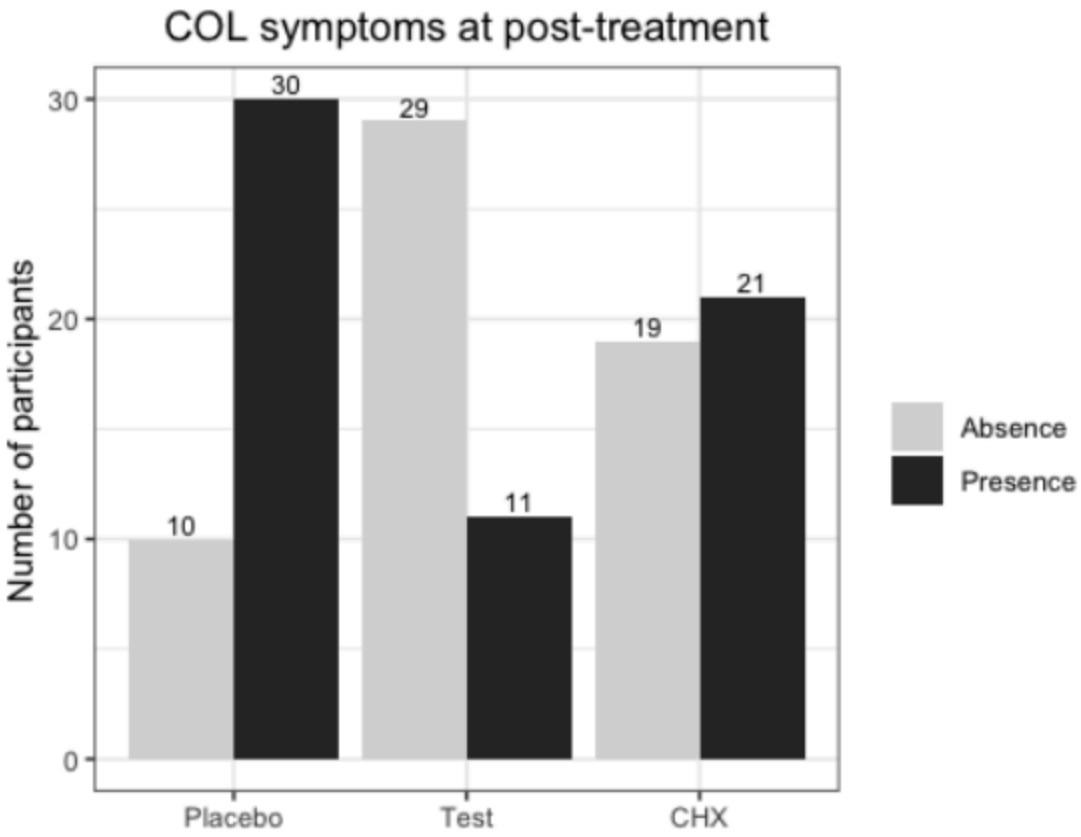

Figure 1

Distribution of COL symptom status at post-treatment follow-up by treatment group. All participants reported COL symptoms at baseline. Absence of symptoms at follow-up indicates symptom resolution,

whereas presence of symptoms indicates persistent symptoms.