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PILOT CLINICAL STUDY OF ESSENTIAL OIL OROPHARYNGEAL SPRAY OF *CYMBOPOGON GIGANTEUS* FOR OUTPATIENT ACUTE SORE THROAT IN BENIN

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ABSTRACT: Sore throat is acute inflammation of the pharynx and/or palatine tonsils, usually caused by an infection (viral or bacterial) and which frequently leads to the inappropriate use of antibiotics. In the context of antimicrobial resistance, herbal medicines, which contain multiple bioactive compounds, may offer alternatives. Hence, this study was conducted to evaluate the clinical efficacy and tolerability of a *Cymbopogon giganteus* Chiov (Poaceae) essential-oil oropharyngeal spray previously characterized for *in-vitro* and *in-vivo* antimicrobial activity. A single-arm phase 2 clinical trial was conducted at the Suru-Léré University Hospital Center, on adults aged 18 to 65 years with physician-diagnosed uncomplicated sore throat. Participants received the oropharyngeal spray for 7 days on an outpatient basis. Clinical efficacy was assessed using the main specific clinical signs observed on days 3 and 7 with a pre-established score. A total of 39 patients were enrolled. Rapid and substantial symptom reduction was observed by day 3 and maintained on day 7, yielding a final clinical success rate of 94.4%. Adverse events were limited to mild, transient hypersalivation (n=4) and dry throat (n=2), with no serious adverse events reported. This preliminary trial suggests that an oropharyngeal spray containing *Cymbopogon giganteus* Chiov (Poaceae) essential oil provides rapid and sustained symptom relief in acute sore throat with a favorable safety profile. Despite methodological limitations, these findings offer valuable proof-of-concept evidence and support the need for larger randomized controlled trials.

INTRODUCTION: Sore throat is an acute inflammation of the pharyngeal tonsils, typically presenting with a sore throat, dysphagia, fever, and headache.

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While most cases are of viral origin, caused by rhinoviruses, respiratory syncytial virus, adenoviruses, or influenza viruses, bacterial pathogens such as *Streptococcus pyogenes* (group A β-haemolytic streptococcus), as well as group C and G *streptococci*, *Fusobacterium nucleatum*, *Haemophilus influenzae*, and *Branhamella catarrhalis*, may also be involved [1]. Conventional treatment includes analgesics (paracetamol) or non-steroidal anti-inflammatory drugs (ibuprofen, diclofenac), local anesthetics (lidocaine), and antiseptics such as chlorhexidine.

Whatever the origin, antibiotics are commonly used without any confirmation of bacterial etiology, contributing to the growing issue of antimicrobial resistance.

In this context, phytotherapy represents a promising alternative. According to the World Health Organization (WHO) nearly 80% of the population in low-income countries relies on traditional medicine for primary healthcare [2]. Among the remedies used, essential oils, complex mixtures of volatile compounds, have shown antimicrobial potential. Traditionally administered via topical, oral (e.g., mouthwash), or inhalation routes, their clinical use remains limited due to insufficient toxicological and pharmacological data, particularly regarding chemical variability and contraindications in specific conditions (e.g., pregnancy, epilepsy, hypertension). In view of these considerations, *C. giganteus* constitutes a relevant case study with well-documented ethnopharmacological uses that could lead to further pharmacological and toxicological studies. Traditionally used in West Africa for febrile illnesses, respiratory conditions, and throat infections, *C. giganteus* has a long history of use. Indeed, it has been used traditionally since the 1900s for several conditions such as yellow fever, malaria, and tonsillitis [3]. In Togo, an infusion of the leafy stems is recommended for oral use for mental illness and conditions. In Cameroon, the dried and powdered roots are used in nasal inhalation to treat headaches and malaria. Bronchopulmonary Recently, a mixture of boiled water extracts of *C. giganteus* has been shown to have a powerful effect against chloroquine-resistant *Plasmodium*.

As for the essential oil of *Cymbopogon giganteus* (EOCG), previous study has demonstrated *in-vitro* antimicrobial activity against key pathogens involved in bacterial in acute sore throat. Then according to Toukourou *et al.,* 2020, EOCG exhibits a minimum inhibitory concentration (MIC) of 0.125% v/v against *Streptococcus pyogenes* and *Streptococcus pneumoniae*, and 0.25% v/v against *Haemophilus influenzae*, bacterial pathogens commonly implicated in bacterial pharyngotonsillitis [4]. EOCG is also effective *in-vivo* in infected mouse models and shows no acute or subacute oral toxicity in preclinical studies [4, 5]. In addition, an oropharyngeal spray based on EOCG 0.5% v/v, previously formulated at the Drug Research and Development (CRDM PharmaLab) Center of Cotonou, has shown a good profile, quality and stability [6]. Based on these preliminary data, the aim of our study is to conduct a clinical trial to confirm the efficacy and safety of a 0.5% v/v oropharyngeal spray containing EOCG in adult patients with acute sore throat, thereby strengthening the scientific evidence supporting its medical use in the treatment of a sore throat.

MATERIALS AND METHODS:

Drug Preparation: The investigational product named Phyto CG is anoropharyngeal spray based on 0.5% v/v essential oil of *Cymbopogon giganteus*. The composition of this product is virgin olive oil, purified water, Tween 60 (Merck®, Germany), Span 60 (Fagron®, France), essential oil of *Cymbopogon giganteus,* prepared extemporaneously as described in a previous study of CRDM Pharmalab [6], batches 001, 002, and 003 were used for the clinical study.

Methods:

Study Design: This study was designed as a single-arm open-label, prospective phase 2 clinical trial to evaluate the efficacy and tolerance of an oropharyngeal spray based EOCG for the treatment of a sore throat. The study was conducted at the Suru-Léré University Hospital Center,

Ethical Considerations: The clinical trial was reviewed and approved by the Ethics Committee of the Institute of Applied Biomedical Sciences under number 157 on 12/22/2022. It has been registered in the BMC clinical trial database ISRCTN registry under number ISRCTN10896729. Prior to enrollment, all participants received adequate information on the study's rationale, objectives, and procedures and subsequently provided written informed consent

Study Subjects: This open-label, outpatient study enrolled adults aged 18–65 years diagnosed by a physician. Diagnosis was based on seven predefined clinical signs inspired by Centor and McIsaac scores (slightly modified) [7, 8]. Oropharyngeal pain, fever, oropharyngeal erythema, oropharyngeal exudate, tonsillar hypertrophy, lymphoid follicles on the posterior pharyngeal wall, and cervical lymphadenopathy.

These signs were recorded on standardized case-report forms at baseline and at each subsequent visit. Efficacy treatment assessment was quantified using a per-sign clinical score to track change over time **Table 1.** Eligible participants provided written informed consent. Non-inclusion criteria were ongoing standard therapy for acute sore throat, known hypersensitivity to any component of the investigational product, age <18 or >65 years, pregnancy, and respiratory disorders. Exclusion during follow-up occurred if consent was withdrawn or non-protocol treatments were used. Sampling was consecutive and exhaustive over the study period, recruiting all eligible patients. The minimum required sample size followed Gehan's phase II guidance (α=5%, power=90%), yielding ≥29 participants; allowing for 20% of attrition, the target enrollment during the study period was 36 [9].

TABLE 1: CLINICAL SIGNS WITH DIFFERENT GRADES ASSIGNED

Clinical signs	Grades				
	0	**1**	**2**	**3**	**4**
Oropharyngeal pain (NRS 0–10)	0	1–2	3–4	5–6	7–10
Fever (Temperature)	<38°C	≥38°C and <40°C	≥40°C	NA	NA
Oropharyngeal erythema	Absent	Moderate	Intense	NA	NA
Oropharyngeal / tonsillar exudates	Absent	Moderate	Abundant	NA	NA
Tonsillar hypertrophy (enlarged tonsils)	Absent	Moderate	Intense	NA	NA
Lymphoid follicles (posterior pharyngeal wall)	Absent	Present	NA	NA	NA
Cervical lymphadenopathy (tender anterior nodes)	Absent	Present	NA	NA	NA

NA: Not applicable. Total score: sum of grades (min 0 – max 14): pain 0–4, fever 0–2, erythema 0–2, exudates 0–2, hypertrophy 0–2, follicles 0–1, lymphadenopathy 0–1.

Interventions and Outcome Measurement: At enrollment (Day 0), participants underwent a baseline medical examination, completed case-report forms, and received ourooropharyngeal spray after training for the correct use. Two oropharyngeal sprays, four times daily (do not exceed 10 sprays/day), for 7 days with 1 g of paracetamol taken morning, noon and evening for 48 hours then if pain. Tolerance was assessed immediately after the first dose via a structured questionnaire and at least 1-hour on-site observation, followed by remote checks by phone calls at 6 and 12 hours, then at 24, 36, and 48 hours post-enrollment. Participants were re-evaluated at the hospital on Day 3 by the physician. Those who showed improvement, which is defined as the resolution of at least 3 out of 7 predefined clinical signs of a sore throat, continued the treatment, whereas non-responders were switched to the standard protocol for treating sore throats standard therapeutic regimen used in Benin. Adverse events were recorded at every contact; serious events triggered immediate management and notification to the ethics committee within 48 hours. Daily calls after Day 3 captured symptoms and tolerability. The final visit on Day 7 included product retrieval and completion of study documentation. Data were collected on prespecified forms and analyzed using R software version 4.3.1. and GraphPad Prism version 6. They were expressed as mean ± standard deviation. Means were compared using the paired Student t-test. The significance threshold for differences was set at 5%.

RESULTS:

Age Distribution of Study Participants: At inclusion, the mean age of participants was 36.21 years, with a median of 40 years **Fig. 1.** The gender distribution was balanced across age groups, with no marked predominance of either sex.

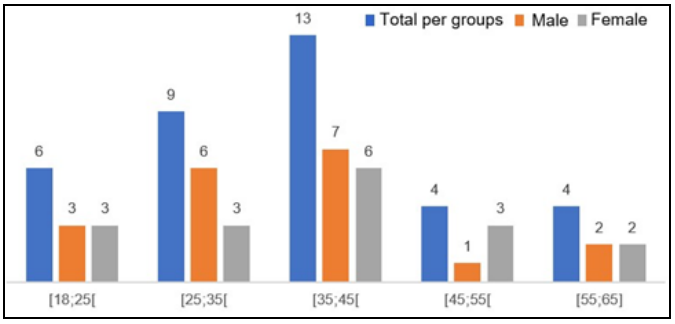

FIG. 1: GENDER DISTRIBUTION ACROSS AGE GROUPS

Screening and Enrollment of Study Participants: Between February 6 and March 31, 2023, a total of 313 patients were seen in consultation at the Department of Otorhinolaryngology (ENT) of CHUZ–Suru-Léré. Among them, 47 met the eligibility criteria. Of

these, 39 were enrolled and provided written informed consent. Eight eligible patients were not included: five were under 18 years old, one was over 65, and two were already on antibiotic therapy at the time of consultation **Fig. 2**. All participants were managed on an outpatient basis.

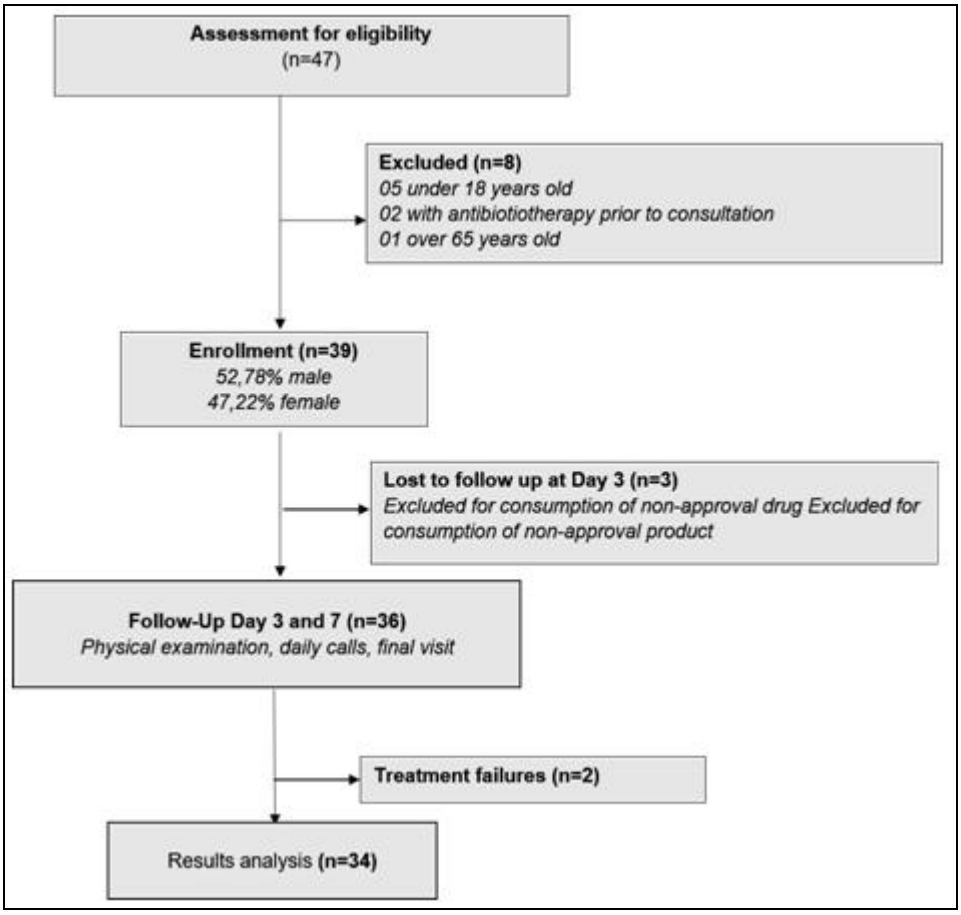

FIG. 2: FLOWCHART OF THE STUDY PROCEDURES

Distribution of signs at baseline (Day 0): The mean total symptom score at baseline was 5.56 (range: 3 to 9), with most participants presenting at least five of the seven clinical signs **Table 2.**

TABLE 2: DISTRIBUTION OF SIGNS AT BASELINE

Clinical signs at baseline (Day 0)	Patient	
	n	%
Oropharyngeal pain	39	100
Fever	14	35.9
Oropharyngeal erythema	38	97.4
Oropharyngeal exudates	4	10.3
Tonsillar hypertrophy	14	35.9
Cervical lymphadenopathy	2	5.1
Lymphoid follicles on posterior pharyngeal wall	23	59.0

Day 3 Reassessment (n = 39): Three participants were withdrawn for using non-protocol treatments (1 took antibiotics, 2 used herbal remedies out of habit), two were classified as treatment failures and were switched to standard care (amoxicillin + clavulanic acid), while the remaining 34 showed clinical improvement (26 at the visit and 8 by phone) with a 67.63% reduction in symptom scores observed ($p<0.05$).

4 participants reported transient hypersalivation, and 2 reported dry throat. All of these effects resolved spontaneously with an intake of potable water one hour after spraying administration. No other adverse events were reported.

Final Outcomes on Day 7 (n = 34): All participants who completed the investigational treatment showed complete resolution of symptoms, with no clinical signs of acute sore throat remaining. Reduction of clinical score reached 100% ($p < 0.05$) **Fig. 3**. That corresponding to a clinical success rate of 94.44% considering the 36 patients who received the treatment.

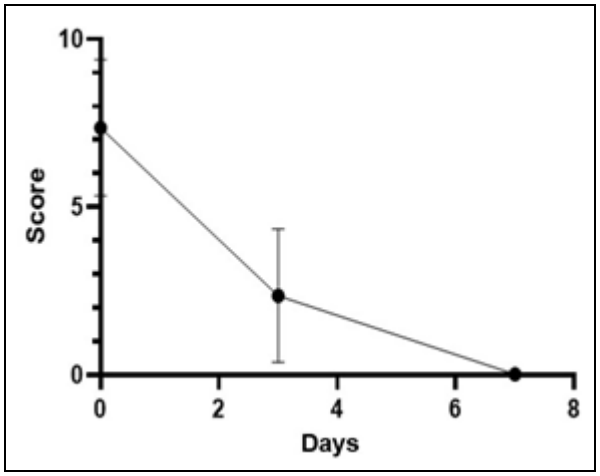

FIG. 3: EVOLUTION OF THE PARTICIPANT'S TOTAL MEAN CLINICAL SCORE DURING TREATMENT

DISCUSSION: Previous studies have demonstrated the antibacterial activity of *Cymbopogon giganteus* essential oil against several pathogens, including *Streptococcus pyogenes*, a leading cause of pharyngotonsillitis [4]. To translate these findings into clinical use, we evaluated in a single-arm phase II trial, an oropharyngeal spray developed on the basis of EOCG. Such trials are appropriate for new substances, allowing preliminary evaluation of clinical benefit and safety before proceeding to larger phase III studies.

Unlike many herbal medicine studies that prematurely attempt phase III designs, we chose phase II to avoid the risk of investing considerable resources into a potentially ineffective treatment. A relevant example is a randomized placebo-controlled trial on a spray containing five aromatic plants for upper respiratory tract infections, which failed to demonstrate clear efficacy [10]. Our approach was therefore to establish proof-of-concept through an exploratory phase II design.

To monitor disease evolution, we employed a composite clinical score based on seven signs of a sore throat (fever, oropharyngeal pain, cough, tonsillar hypertrophy, exudate, adenopathy, and lymphoid follicles). This score incorporates the five criteria of the Centor and McIsaac scores [7, 8] thus ensuring consistency with validated tools.

Rapid and substantial symptom reduction was observed between baseline and day 3, sustained on day 7 with a final clinical success rate of 94.44%. These outcomes are comparable to previous Chinese studies of herbal sprays, which reported success rates of 95–97% [11, 12, 13]. They are also comparable to prior randomized trials of *Echinacea/Sage* [14] and *Salvia officinalis* L. (Lamiaceae) sprays [15], both of which demonstrated >90% efficacy in acute pharyngitis. Notably, our results appear superior to those typically achieved with antibiotics such as penicillin or cefaclor (~87% efficacy) in uncomplicated sore throat [16]. This suggests that EOCG-based oropharyngeal spray may provide superior symptom relief while potentially reducing antibiotic use.

The failure rate in our study was low (5.6%) and may reflect infections caused by pathogens outside the antimicrobial spectrum of EOCG, although this hypothesis could not be tested due to the absence of microbiological confirmation.

In our trial, adverse events were limited to transient hypersalivation (n=4) and dry throat (n=2), all mild, self-limiting, and manageable with hydration; no serious adverse events occurred. This safety profile is consistent with randomized controlled trials of herbal oropharyngeal sprays for acute pharyngitis. For instance, an *Echinacea/Sage* spray reported only mild transient events such as burning or dryness, with no serious outcomes [14]. A placebo-controlled trial of *Salvia officinalis* L. (Lamiaceae) spray similarly observed only minor effects, such as mild throat dryness or burning [15]. More recently, a randomized controlled trial of *Andrographis paniculata* (Burm.f.) Nees (Acanthaceae) spray reported no adverse events at all [17]. Collectively, these data support that an EOCG-based oropharyngeal spray is well tolerated**,** with a safety profile comparable to other phytotherapeutic options for acute pharyngitis.

This study has limitations. Clinical assessments between days 0–3 and days 3–7 relied partly on self-reports from participants followed on an outpatient basis, introducing potential bias. In addition, paracetamol was prescribed for pain relief, precluding a direct evaluation of the analgesic properties of EOCG. Finally, the absence of bacteriological confirmation limits interpretation regarding pathogen-specific efficacy. Lack of blinding, small sample size, and a single-arm design can also introduce bias. Indeed, the distinctive sensory characteristics of plant-derived

products (taste, odor, color, texture) make the design of credible placebos particularly challenging [18]. Despite these limitations common in early-phase clinical investigations of phytotherapeutics, similar exploratory studies have advanced the field by providing valuable proof-of-concept evidence [19-20]. Our findings of rapid and sustained symptom reduction with an excellent safety profile provide valuable preliminary evidence that supports the rationale for larger randomized controlled trials of EOCG-based oropharyngeal spray."

CONCLUSION: This preliminary phase 2 trial demonstrates that an oropharyngeal spray formulated with essential oil of *Cymbopogon giganteus* provides rapid and sustained symptom relief in acute sore throat, achieving a clinical success rate of 94.4% with an excellent safety profile. Adverse events were limited, mild, and self-resolving, underscoring the favorable tolerability of the intervention. While methodological constraints, including small sample size, single-arm design, and lack of blinding limit generalizability, the findings are consistent with prior exploratory studies of phytotherapeutic sprays and provide valuable proof-of-concept evidence. These results justify the conduct of larger randomized controlled trials to confirm efficacy, establish comparative effectiveness against standard therapies, and further explore the potential of our oropharyngeal spray based on EOCG as safe and effective alternatives to antibiotics in the management of uncomplicated sore throat.

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CONFLICTS OF INTEREST: The authors declare no conflicts of interest.

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