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ORIGINAL ARTICLE

Oral essential oil therapy for managing patients with acute pharyngotonsillitis in primary care setting: a real-world experience

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ABSTRACT

BACKGROUND: Acute pharyngotonsillitis (APT) is a common medical condition, usually caused by a viral infection. Nevertheless, inappropriate antibiotic use is widespread. Oral essential oil therapy (OEOT) may be valuable in managing mild-moderate diseases, including APT. The present study aimed to evaluate the efficacy and safety of OA in managing patients with APT in a primary care setting.
METHODS: The study included 97 APT patients followed by primary care doctors. Oleobiotic Salud Respiratoria (manufactured by Pranarom International S.A.) containing five essential oils (oregano, cinnamon, lemon, eucalyptus, and pine) was used at two dosages and compared with oral Penicillin V. Patients were stratified into three groups accordingly. Treatments lasted five days. Sore throat, general conditions, and body temperature were assessed daily for ten days. The satisfaction of patients and doctors was also considered. Safety considered adverse events.
RESULTS: The two dosages of OEOT and antibiotics significantly (P<0.001) improved symptoms and reduced body temperature. Most patients and doctors were satisfied. There was no significant difference among the groups. All treatments were well tolerated.
CONCLUSIONS: The present study showed that a five-day oral essential oil therapy course with the product Oleobiotic Salud Respiratoria could be a valuable and safe option for managing patients with APT.

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KEY WORDS: Volatile oils; Anti-bacterial agents; Tonsillitis; Primary health care.

Introduction

Acute pharyngotonsillitis (APT) is a common infectious disease characterized by sore throat and frequent dysphagia.[1] Acute pharyngotonsillitis is mainly of viral origin, as viruses may cause it in 70-95% of cases, depending on the age.[2] However, bacterial APT should be promptly diagnosed as it may be a systemic disease with possible relevant sequelae, mainly in childhood.[3] Etiological diagnosis may be performed using clinical criteria or rapid swab tests.[4, 5] In this regard, the Centor/McIsaac scores assessment is a reliable tool to diagnose APT and is usable also for telemedicine.[6] Telemedicine is a fruitful option to manage patients with mild-moderate symptoms.[7] Acute pharyngotonsillitis is one of the most frequent reasons for consulting primary care doctors and antibiotic prescriptions.[8, 9] However, an-

tibiotic prescription is appropriate only for bacterial APT, mainly concerning Group A Streptococcus.[10]

Namely, different guidelines recommended management strategies.[11, 12] In particular, careful attention requires antibiotic stewardship.[13] A recent Cochrane review concluded that the balance between modest symptom reduction and the potential hazards of antimicrobial resistance must be recognized.[14] Another Cochrane review established that delayed antibiotics may be an acceptable compromise instead of immediate prescribing to significantly reduce unnecessary antibiotic use for RTIs while maintaining patient safety and satisfaction levels.[15] As a result, telemedicine can guarantee a high adherence to best practice guidelines and low antibiotic prescription.[16]

On the other hand, the practical management of APT in primary care settings does not always allow for strict adherence to guidelines, and even the use of telemedicine sometimes does not allow for a reliable diagnosis. Therefore, antibiotic prescriptions still remain an empirically used therapeutic option.

As a result, it may be advantageous to use complementary therapies in patients with non-severe symptoms and a low suspicion of bacterial APT. Oral essential oil therapy (OEOT) may be a valuable option in managing patients with APT.

Oral essential oil therapy uses concentrated essential oils extracted from herbs, flowers, and other plant parts to treat various diseases.[17] It is well-known that OEOT is a popular complementary therapy.[18] Oral essential oil therapy has been recognized as beneficial for managing some symptoms, including pain, nausea, vomiting, preoperative anxiety, well-being, anxiety, depression, stress, and insomnia.[19] Recently, it has been envisaged that essential oils and related isolated compounds could be useful to mitigate symptoms associated with COVID-19, obviously as complementary treatment.[20]

Based on this background, the present study aimed to investigate the possible role of oral essential oil therapy in managing patients with APT in a primary care setting, using telemedicine.

Materials and methods

Study design

This observational study conformed to the Helsinki Declaration. The study was conducted in Spain and performed as a retrospective and anonymous collection of clinical data. Thus, there the local rules do not require formal ethics approval.

The present experience involved seven Spanish general practitioners in the primary care setting. They are located in four provinces: four in Madrid, one in Granada, one in Malaga, and one in Cadiz. These doctors retrospectively collected anonymous clinical data of their patients managed in autumn-spring 2023/24 to intercept patients with APT.

Recruited subjects were observed throughout the study through medical visits (at baseline and at the end) and telemedicine (Whatsapp, SMS, or e-mail).

The inclusion criteria were adulthood, clinical diagnosis of APT without an etiological determination, and ability to understand the study's methodology and to sign an informed consent.

The exclusion criteria were pregnancy, lactation, fever (such as >38 °C), any antibiotic treatment in the 30 days preceding the start of therapy, a serious illness that could interfere with the interpretation of the study results, allergy or intolerance to oral Penicillin V or the components of the OEOT product.

Patients could be treated using three different therapeutic options. Group A took oral Penicillin V 500 mg/bid for 10 days. Group B took oral Oleobiotic Salud Respiratoria manufactured by Pranarom International S.A. at the recommended dosage, such as one capsule 3 times daily, with meals, for 5 days. Group C took oral Oleobiotic Salud Respiratoria at double dosages, such as two capsules 3 times daily, with meals, for 5 days.

The daily dose (*i.e.*, three capsules) of Oleobiotic Salud Respiratoria (Respiratory Health) contains essential oils of common oreganon (Origanum vulgare - 135 mg), eucalyptus (Eucalyptus sp. - 120 mg), cinnamon from China (Cinnamomum cassia - 90 mg), Scots pine (Pinus sylvestris - 60 mg), and lemon peel (Citrus limon - 45 mg).

Telemedicine was initiated autonomously by the patient at the same time as the start of therapy. The patient, via WhatsApp, SMS, or e-mail, monitored their clinical condition by sending simple self-assessment parameters, such as the visual analog scale (VAS) for sore throat intensity (0 = no symptoms, 10 = the most intense symptom) and overall status perception (0 = high discomfort, 10 = full wellness), and body temperature measurement (axillary) in °C. Clinical data were assessed daily from the onset of treatment (D0) to the tenth day (D10).

Statistical analysis

The primary outcome was to demonstrate the efficacy of Oleobiotic Salud Respiratoria in improving clinical conditions. The secondary outcomes included the time of improvement and symptom duration, comparison of the

two dosages of Oleobiotic Salud Respiratoria, tolerability evaluation, satisfaction grade of patients and doctors, and evaluation of antibiotic avoidance.

The statistical analysis was done using the IBM-SPSS Statistics version 28 computer application. The statistical techniques and tests included a descriptive analysis of qualitative variables with frequency tables and percentages. Contingency tables were used to cross-reference these variables. Means of their arithmetic mean values described the quantitative variables. To contrast the significance of the means of the same sample of subjects (repeated measures/related samples), the non-parametric tests Friedman and Wilcoxon were used. McNemar's Test was used to test for changes in repeated measures of categorical variables. In all these inferential statistical tests, significance is considered when $P<0.05$.

Results

The present experience included data on 97 patients, 30 (31%) belonging to Group A, 33 (34%) to Group B, and 34 (35%) to Group C. So, the inter-group consistency was homogenous.

Sore throat

Figure 1 shows the overtime evolution of the perception of sore throat intensity in the three groups. All groups showed a progressive reduction of symptom severity over time. There were significant ($P<0.001$) variations after three, five, and ten days. A significant improvement occurred in all groups at each time. In particular, 100% of patients of Group A, 88% of Group B, and 91% of Group C experienced an improvement already after three days.

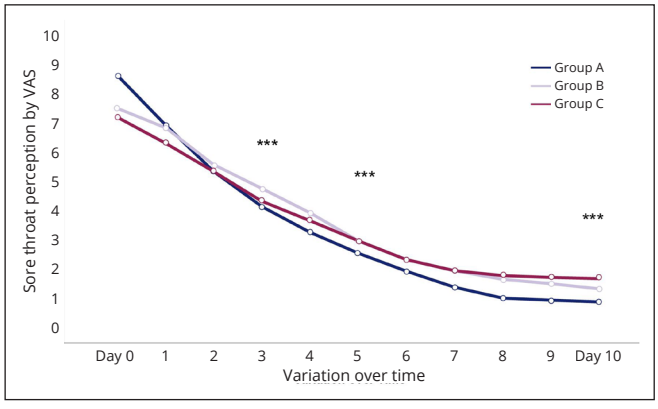

Figure 1.—Variations over time of the sore throat perception assessed by VAS in the three groups.

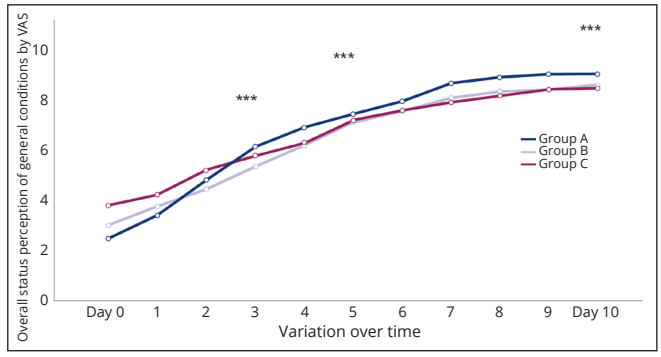

Figure 2.—Variations over time of the general conditions' perception assessed by VAS in the three groups.

Overall status perception of general conditions

Figure 2 shows the evolution of overall status perception over time in the three groups. All groups showed a progressive reduction of symptom severity over time. The change was significant in all groups already after three days ($P<0.001$). In particular, 100% of patients of Group A, 91% of Group B, and 82% of Group C experienced an improvement already after three days.

Body temperature

Figure 3 shows the overtime evolution of the body temperature in the three groups. All groups showed a progressive and significant reduction of body temperature over time. Notably, most of the patients did not have fever (body temperature >37.5 °C) at baseline.

Safety

Ten patients reported adverse reactions: four in Group A (one patient reported weakness, one diarrhea, one diarrhea

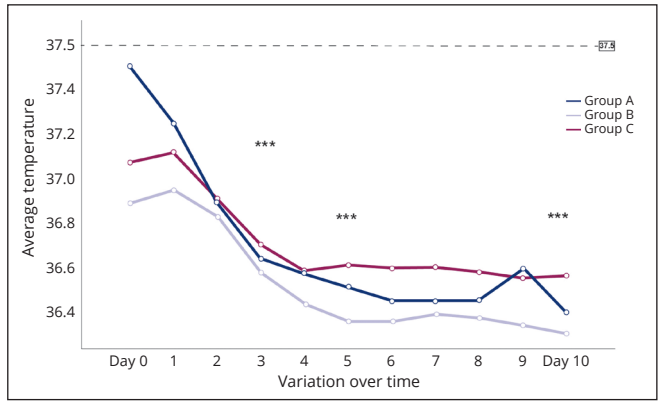

Figure 3.—Variations over time of body temperature (°C) in the three groups.

and dyspepsia, and one nausea), two in Group B (one patient reported dysphagia and one epigastric pain), and four in Group C (two patients reported dyspepsia, one nausea, and one gastric reflux). All events were mild and self-resolving.

Patient satisfaction

Figure 4 shows the distributions of satisfaction grades in the three groups. Most patients were satisfied with the treatment. Only some patients (15.2% in Group B and 11.8% in Group C) were partially satisfied. Consistently, 89.1% of Group B and C patients reported that they would resume OEOT to manage another episode.

Doctor evaluation

Figure 5 shows the distribution of satisfaction grades for the three different treatments. Most doctors were satisfied with the three treatments. However, some patients' outcomes in all groups were reported to be slightly satisfactory.

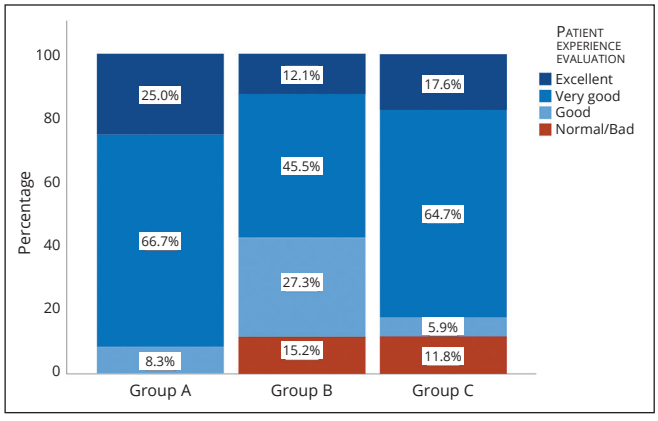

Figure 4.—Patient's evaluation of the treatment.

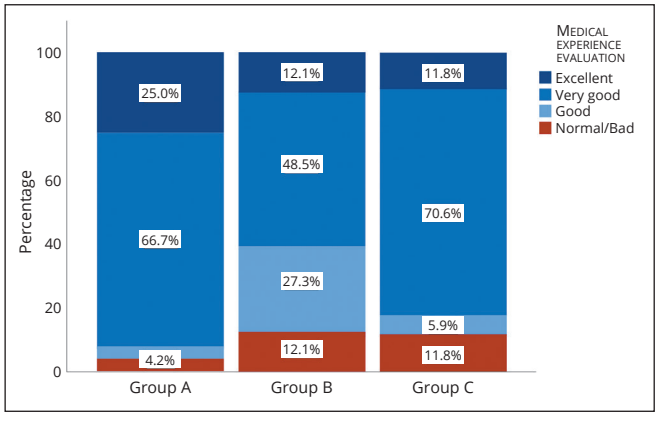

Figure 5.—Doctor's evaluation of the treatment.

Antibiotic avoidance

Doctors believed that 87.9% of patients in Group B and 85.3% in Group C had avoided antibiotics.

Discussion

Acute pharyngotonsillitis commonly affects adults and overall children. Although most cases recognize a viral cause, the empirical use of antibiotics remains a common practice, though often inappropriate. In addition to being ineffective, incongruous antibiotic use may lead to the risk of adverse events and the development of bacterial resistance. For this reason, the use of alternative therapies to mitigate symptoms and avoid the use of antibiotics may be an attractive option. In this regard, OEOT may be a possible alternative.

Oral essential oil therapy can boast a tradition of use dating back as far as ancient Egypt, pre-Columbian people, and India for a thousand years. However, the history of OEOT begins in more recent times, more precisely, around the 1920s, thanks to the work of the French chemist René Maurice Gattefossé. However, it had to wait a few more years before this alternative medicine was considered a discipline. The breakthrough came in 1964, thanks to the work of French physician Jean Valnet, who – with his book 'Aromathérapie' – laid the foundations for the discipline known today asOEOT.[21]

Oral essential oil therapy may be used to manage respiratory conditions using the inhaled or oral route.

Oleobiotic Salud Respiratoria is available as oral capsules. It is a multi-component food supplement scheduled for a five-day treatment. As it contains essential oils of Origanum vulgare, Eucalyptus sp., Cinnamomum cassia, Pinus sylvestris, and Citrus limon, it may be a valuable candidate for managing patients with APT.

The present study provided some relevant results. A five-day course of Oleobiotic Salud Respiratoria significantly reduced sore throat perception, improved cenesthesia, and reduced body temperature. Interestingly, the double dosage displayed superimposable effects compared with standard dosage. In addition, Oleobiotic Salud Respiratoria provided similar effects to a 10-day antibiotic course. In other words, OEOT exerted similar outcomes to antibiotics at half-time. These beneficial results were consistent with a good satisfaction rate by patients and doctors, which was also confirmed by a good tolerability profile. Finally, doctors considered that Oleobiotic Salud Respiratoria could avoid antibiotic therapy in most patients.

These positive effects depend on the active ingredients contained in the product in the form of essential oils. Essential oil is a volatile organic substance characterized by high concentration and hydrophobic volatility.[22] The source of essential oil may derive from any part of plant materials, including roots, fruits, wood, herbs, bark, twigs, leaves, seeds, buds, rhizomes, peels, flowers, or the entire plant.[23] As these plants possess curative properties, they are defined as medicinal plants. In particular, plants generating essential oils of commercial importance are named essential oil plants.[24] About 17,500 plants belong to this group, including different species, such as Zingiberaceae, Poaceae, Apiaceae, Umbelliferae, Asteraceae, Lamiaceae, Rutaceae, Compositae, Lauraceae, Cupressaceae, Acoraceae, Rosaceae, Oleaceae, Myristricaceae, Myrtaceae, etc.[25]

Steam distillation is the most widely used process for extracting essential oils from plants. It takes place in three steps: vaporization, cooling, and separation. Plants are arranged in layers on several grids inside the still, and water vapor is passed through them to extract the essential oil. A refrigerated coil condenses the water and drops it into a container. The essential oils contained, being lighter than water, remain on the surface and can thus be collected.

A quality essential oil should be 100% natural (not denatured with synthetic molecules, chemical emulsifiers, or mineral oils), pure (free of other nearby essential oils, vegetable oils, alcohol, turpentine, etc.), and whole (not amputated, not bleached, not de-diffused, not rectified, not over-oxidized, not peroxidized).

Essential oils used in scientific OEOT should meet strict quality criteria, such as certified botanical species and geographical origin, such as cultivation method, botanical stage of development, and extraction method.

Essential oils in plants have diverse functions: they moderate the plant's response to external stimuli, defend against herbivores and pathogenic microorganisms, represent communication signals between plants, and attract pollinating insects. For example, the oily exudates that appear when the trunk of a tree is injured prevent sap loss and act as a protective seal against pests and pathogenic organisms.

Essential oils have a very complex chemical composition and can contain many substances, including phenols, terpenes, aldehydes, ketones, ethers, epoxides, etc. Each essential oil, therefore, is characterized by a primary component that often confers a specific effect on the oil itself. The variability of the essential oil's composition is related to the time of harvesting the plant (not only the season but also the different times of day), the environment in which the plant is cultivated, and the various methods of extracting the essential oil. The composition is defined thanks to a specific technique: gas chromatography, which qualitatively and quantitatively identifies the different components contained in the essential oil. Also, it determines the effectiveness and degree of toxicity.

Essential oils are widely used for their antioxidant, anti-inflammatory, antimicrobial, antiviral, antifungal, antiparasitic, and immunostimulant activities.[26] Therefore, the ingredients of Oleobiotic Salud Respiratoria, such as essential oils of Origanum vulgare, Eucalyptus sp., Cinnamomum cassia, Pinus sylvestris, and Citrus limon, may exert beneficial activities.

In particular, Origanum vulgare and Citrus limon may block the cellular entry of viruses, including SARS-CoV-2.[27] Similarly, Eucalyptus essential oil may inhibit cell infection by coronaviruses.[28] Interestingly, Eucalyptus essential oils exert antibacterial activity against multidrug-resistant bacteria, *e.g.*, Staphylococcus aureus.[29] Namely, Eucalyptus essential oils have a relevant antimicrobial activity against many bacteria, fungi, and viruses.[30] In addition, Eucalyptus essential oils display anti-inflammatory activity. It has to be underlined that every infection is always associated with a reactive inflammatory response.[31]

Some clinical trials demonstrated that essential oils of Citrus limon may benefit patients with acute viral respiratory infections.[32]

Also, the essential oil of Origanum vulgare has been defined as a bioprotective agent because it exerts antibacterial, antioxidant, and chemoprotective activities.[33] Moreover, Origanum vulgare has antiseptic and antispasmodic effects.[34]

Cinnamomum cassia is an evergreen tree native to southern China. It was initially employed to treat digestive complaints, including dyspepsia, cramps, and meteorism.[35] Recently, a study demonstrated its antimicrobial activity.[36]

Finally, Pinus sylvestris may have anti-inflammatory and anti-hyperreactive effects and bactericidal and anti-film properties.[37, 38]

Based on this evidence, the observed findings may be due to the positive effects exerted by the five essential oils. Patients experienced rapid relief of sore throat, general condition improvement, and body temperature reduction.

Limitations of the study

However, this study had some limitations, including the open design, the lack of a placebo control, and the absence

of a biomarker assessment. On the other hand, this study was conducted in a real-world setting, such as primary care clinics. Therefore, the results could be generalizable to clinical practice.

Conclusions

The present study showed that a five-day course of oral essential oral therapy with Oleobiotic Salud Respiratoria could be a valuable and safe option in managing patients with APT.

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Conflicts of interest
The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions
Both authors contributed to the study's conception and design. Attilio Varricchio performed material preparation, data collection, and analysis. Giorgio Ciprandi wrote the first draft of the manuscript, which all authors commented on. All authors read and approved the final version of the manuscript.

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