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Local Application of Combined Drugs of Natural Essential Oils for the Prevention of Acute Pharyngitis

Diāna Katoviča[1*], Marks Ronis[2], Beāte Rundāne[3]

[1]Pauls Stradins Clinical University Hospital, Riga, Latvia
[2]Children's Clinical University Hospital, Riga, Latvia
[3]Faculty of Medicine, Rīga Stradiņš University, Riga, Latvia
Email: *diana.katovica@gmail.com

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Abstract

Objective: Viral pharyngitis, commonly known as a sore throat, is a widespread condition affecting people of all ages globally. This study aimed to assess the effectiveness of a medical device containing the combined drugs of natural essential oils (CDNEO) formulation in managing throat pain in patients with acute viral pharyngitis. With the growing resistance to traditional antibacterial treatments, essential oils have attracted interest for their potential analgesic, anti-inflammatory, and antibacterial properties. **Results:** The study involved 81 patients randomly divided into two groups: those taking a medical device containing combined drugs of natural essential oils (CDNEO) and those taking a placebo. A questionnaire was used to assess throat pain among the participants, with 45 receiving the CDNEO and 36 the placebo. The CDNEO group experienced a significant reduction in throat pain, with the average VAS score decreasing from 5.36 to 1.09, compared to the placebo group, which saw a decrease from 4.97 to 2.19. This difference, with $p < 0.001$, indicates statistical significance. Additionally, fewer patients in the CDNEO group required NSAIDs, highlighting significant differences in pain management and recovery times. **Conclusion:** By using a double-blind research method, it was possible to evaluate the effectiveness of the oils more objectively, since there was also a control placebo group. The study shows that CDNEO significantly reduces throat pain and decreases the need for additional pain relief medication in patients with acute viral pharyngitis. The findings suggest that natural essential oils could serve as an alternative treatment for pharyngitis, particularly in efforts to minimize NSAID use and combat antibiotic resistance.

Keywords

Sore Throat, Essential Oils, NSAID, Acute Viral Pharyngitis, Natural Treatment

1. Introduction

Pharyngitis is the inflammation of the mucous membranes of the oropharynx, commonly due to an infection, either viral or bacterial. Less common causes include allergies, trauma, cancer, reflux, and certain toxins [1]. Characterized by throat inflammation and irritation, viral pharyngitis can result from various viruses, such as the rhinovirus (15% - 20%), adenovirus (6%), coronavirus (>5%), herpes simplex virus (4%), influenza virus (2%), and the Epstein-Barr virus (<1%) [2] [3]. Although often a temporary discomfort, viral pharyngitis can disrupt daily activities and significantly reduce one's quality of life.

There are several methods to alleviate the symptoms of a common sore throat. Since it is viral, antibiotics are ineffective. Treatment centers on symptomatic relief, including systemic oral analgesics, topical therapies, and environmental measures for pain relief in adults with acute pharyngitis [4].

In the medical field, there is significant interest in topical treatments like essential oils (EOs) for their antibacterial properties, especially crucial in combating widespread bacterial resistance [5]. Notably, studies have shown the effectiveness of essential oils in aromatherapy for relieving sore throats, highlighting their therapeutic potential [6].

Much of the existing literature focuses on the properties of essential oils from individual plants. Notably, peppermint oil (*Mentha piperita*) is recognized for its antibacterial, antifungal, and antioxidant effects [7]. Similarly, tea tree oil (*Melaleuca alternifolia*) is valued for its anti-inflammatory properties [8] [9], while cinnamon oil (*Cinnamomum osmophloeum*) is recognized for its ability to inhibit interleukin synthesis, indicating potential anti-inflammatory benefits [10]. Calendula oil (*Calendula officinalis*) is commonly used for its antiseptic properties, especially for inflamed mucous membranes of the mouth and pharynx [11].

Considering the analgesic, anti-inflammatory, and antibacterial properties of essential oil preparations, this study aimed to determine the effectiveness of combined natural essential oil drugs (CDNEO) in reducing throat pain and improving quality of life in patients with acute viral pharyngitis.

The hypotheses for this study were as follows:

(H1) Combined drugs of natural essential oils are effective in reducing throat pain in patients with acute viral pharyngitis.

2. Materials and Methods

This randomized, prospective clinical study used a double-blind method and was carried out in three general practitioner (GP) practices in Daugavpils, Latvia, over

13 months (January 2023 - February 2024). The research followed ethical principles, receiving approval (number 2-PĒK-4/438/2023) from the ethics committee. It was conducted with informed consent from participants, who participated voluntarily and whose personal data was kept strictly confidential.

To investigate the medicinal properties of combined natural essential oil preparations (CDNEO), a partnership was established with the Latvian pharmaceutical company SIA Solepharm. This collaboration involved the voluntary and free provision of a sample of an oil medical device (Olefar) and a placebo to support the research.

Composition of the medical device includes sea buckthorn oil, calendula oil, peppermint oil, tea tree oil, and cinnamon oil. CDNEO and placebo were provided in identical glass vials labeled with sample numbers ranging from 1 to 130. Sodium chloride 0.9% saline was used as the placebo. Throughout the study, only the Latvian pharmaceutical company (SIA "Solepharm") had access to the contents of each sample. To minimize bias, doctors and researchers were unaware of the contents, and the samples were delivered in two unlabeled boxes with the vials premixed.

The doctor removes a sample from the selected box (No. 1 or No. 2), labeled only with the number on the consent form. At the time of administration, the patient is unaware of whether they received CDNEO or a placebo. After enrolling the necessary number of patients, the Latvian pharmaceutical company, SIA "Solepharm," disclosed the identity of each numbered sample—CDNEO or placebo.

2.1. Data Collection

Patients were selected from three general practitioners' (GPs) practices. Those who visited the GP for acute throat pain and were diagnosed with viral pharyngitis were invited to participate in the study.

Study inclusion criteria:

1) Patient consents to participate.

2) Age 18 and older.

3) Diagnosis of acute viral pharyngitis.

4) Random assignment to one of 130 samples.

5) Patient begins using the sample on the first treatment day, applying it three times daily with three puffs in the throat for a minimum of seven days.

Exclusion Criteria:

1) Patient's refusal to participate in the study.

2) Incorrect use of the medical device by the patient.

3) Hypersensitivity or allergy to any ingredients in the natural oil preparation.

Initial pain assessment was conducted using a Visual Analogue Scale (VAS) before using a medical device. Patients reported their pain level during GP inspection on a scale where 0 represents no pain and 10 represents the most severe pain possible. Age and gender data were collected from the patients' medical records. On the seventh day of treatment, researchers contacted the patients to rate their

pain on a 10-point scale, inquire about any additional analgesic therapy used, the day they resumed a normal diet without pain, and the duration and frequency of medical device use.

2.2. Statistical Analysis

The patient survey results were recorded in MS Excel. The statistical methods used included descriptive statistics and nonparametric tests: Pearson's Chi-Square tests and Mann-Whitney U test. For tables larger than 2 × 2 with a small sample (more than 20.0% of cells have an expected count of less than 5), the Fisher Exact Probability test was used. The analysis set the significance level at a p-value of less than 0.05, with a 95.0% confidence interval. Data analysis was conducted using IBM SPSS Statistics 29.0 (Statistical Package of Social Sciences).

3. Results

Of the 101 patients in the study, 20 (19.8%) did not meet the inclusion criteria because they used combined natural essential oil preparations (CDNEO) less than three times a day and for fewer than seven days, leading to their exclusion from further study.

The number of patients who met all selection criteria was 81, with 42 (51.9%) being women and 39 (48.1%) men. The average age of the patients was 44.47 years, with the youngest being 18 and the oldest 91 years old. Among the participants, 45 (55.56%) were included in the CDNEO group and 36 (44.44%) in the placebo group. (Table 1)

Table 1. Characteristics of patients who participated in the study (N = 81).

	N	%
Gender		
Women	42	51.9
Men	39	48.1
Age		
Minimum	18 year	
Maximum	91 year	
Average	44.5 year	
Group		
Olefar natural essential oil spray	45	55.6
Placebo	36	44.4

One of the questions asked was whether the oil spray benefited patients. Of those, 33 (73.3%) patients from the combined natural essential oil (CDNEO) group reported that the product was helpful, while 12 (26.7%) patients noted no benefit from the CDNEO. In the placebo group, 8 (22.2%) patients believed the preparation helped them, while 28 (77.8%) reported it did not. There were statistically significant differences between the product type and its perceived effectiveness ($p < 0.001$). (Figure 1)

We used a visual analogue scale (VAS) to measure pain intensity. A review article demonstrated moderate evidence of a moderate association (r = 0.48 to 0.54) between the VAS and the Neck Disability Index [12]. VAS provides reliable results. In both groups, the pain before using the preparation was similar: the average score for the combined natural essential oil (CDNEO) group was 5.36, and for the placebo group, it was 4.97 (pain from 0 to 10 points). There were no statistically significant differences between the two groups before treatment (p = 0.470). However, after using the preparation three times daily for at least 7 days, pain decreased in both groups. The noted average pain level in the CDNEO group was 1.09, compared to 2.19 in the placebo group. There are statistically significant differences between the type of product and the extent to which it reduced pain (p < 0.001). CDNEO was more effective than a placebo in reducing pain levels. (**Figure 2**)

There is a statistically significant difference in the frequency of non-steroidal anti-inflammatory drug (NSAID) usage between the two study groups (p = 0.002). In the combined natural essential oil (CDNEO) group, only 8 (17.8%) patients used additional pain relief medications, while 37 (82.2%) did not. However, in the placebo group, 19 (52.8%) patients required NSAIDs, while 17 (47.2%) reported not using them. (**Figure 3**)

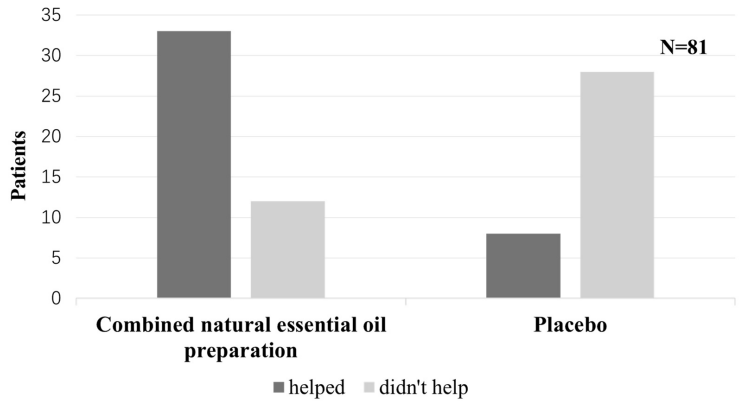

Figure 1. Subjective feelings of patients after taking drug.

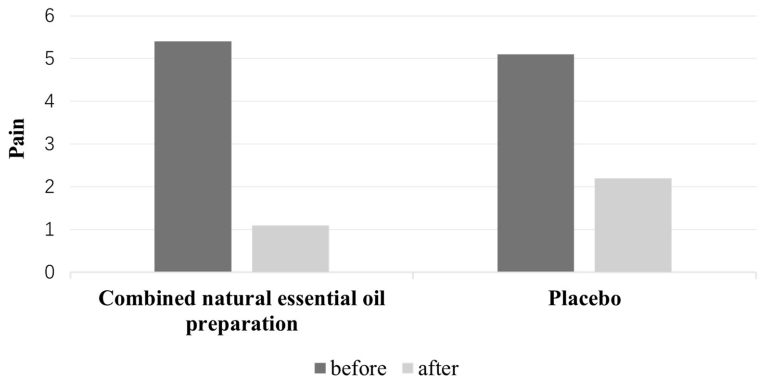

Figure 2. Pain before and after using the test drug.

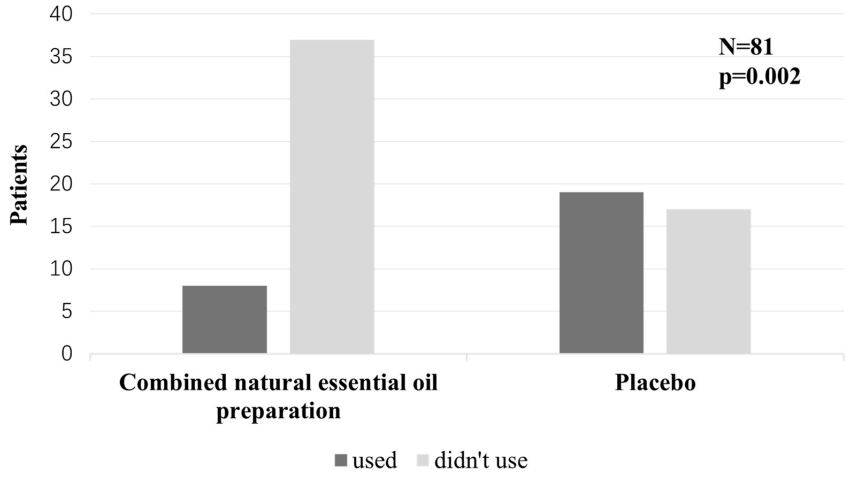

Figure 3. Use of pain relief medication in addition to the test drug.

There is a statistically significant difference between the two study groups in terms of when patients resumed their normal eating habits ($p = 0.03$). In the combined natural essential oil (CDNEO) group, the average day patients started their usual meals was 2.31, compared to 2.83 in the placebo group. Thus, the CDNEO group resumed their normal eating slightly earlier than the placebo group.

4. Discussion

The results indicate a statistically significant difference between the two study groups, showing that the local application of combined natural essential oils not only alleviates pain, improving quality of life and facilitating the resumption of daily activities, but also reduces the need for additional analgesic medications. This is particularly important considering the concerns about the overuse and side effects of NSAIDs. The composition of the combined natural essential oils includes sea buckthorn, calendula, cinnamon, tea tree, and peppermint, which possess analgesic, anti-inflammatory, and antibacterial properties that may reduce bacterial co-infection.

The study's success hinges on patient compliance and the acceptability of the treatment regimen. The simple application method, such as a throat spray, likely contributed to high compliance rates, making it a practical option for everyday use. Additionally, natural remedies are often viewed as safer by patients, enhancing their acceptability and willingness to adhere to the treatment protocol.

Considering economic aspects, the use of combined natural essential oils could offer a cost-effective alternative to conventional pharmaceuticals, especially in regions with limited healthcare access or where prescription medications are prohibitively expensive.

The positive outcomes of this study could influence public health policies, particularly in managing common viral infections like pharyngitis. Integrating natural essential oil preparations into national health guidelines could reduce antibiotic reliance, especially in treating conditions where antibiotics are ineffective,

such as viral infections. This approach could also help mitigate the global issue of antibiotic resistance.

Limitations and Future Research

The study's limitations include its small sample size, short treatment duration, and the use of 0.9% sodium chloride saline as a placebo. The saline's moisturizing effect on the oral mucosa could partially relieve pain in acute pharyngitis. Additionally, the tested sample's specific herbal taste may have psychologically led patients to believe in its effectiveness, potentially contributing to better results.

The study did not specify the cause of the patient's acute pharyngitis. Identifying the cause could further evaluate the effectiveness of the study medication depending on the cause of pharyngitis.

Future studies should aim to replicate these findings in larger populations and over extended periods. Additionally, exploring the biochemical mechanisms behind the analgesic and anti-inflammatory effects of essential oils could offer deeper insights into their therapeutic potential. While this study provides preliminary evidence supporting the efficacy of combining natural essential oils, further research should explore the effects of long-term use on safety and conduct detailed biochemical studies on essential oils.

5. Conclusion

Using a double-blind research method allowed for a more objective evaluation of the oils' effectiveness, as the study also included a control placebo group. The promising results underscore the potential of essential oil-based therapies in managing pharyngitis and other inflammatory conditions. As the healthcare landscape evolves towards more personalized and sustainable practices, natural remedies like combined essential oils could play a crucial role in shaping future therapeutic strategies. This shift towards integrating evidence-based natural treatments could significantly impact patient outcomes and overall public health.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Appendix

Questionnaire: Local use of a preparation of a combination of natural herbs for the prevention of acute throat pain

Patient tel.nr. _____

Preparation Nr. _____

Gender_____

Age_____

1. How do you rate the pain in the throat before you started using the preparation? On a pain scale from 0 to 10

0 (no pain) 1 2 3 4 5 6 7 8 10 (intolerable pain)

2. How do you rate the pain in the throat when eating before starting to use the preparation?:

1 2 3 4 5 6 7 8 9 10

3. Did you use painkillers?: YES NO Comment_____

4. If the previous answer was YES, how often? Comment _____

5. On which day after starting the use of the preparation did you resume daily diet?:

1 2 3 4 5 6 7 8 9 10

6. How do you rate the pain now? On a pain scale from 0 to 10

(no pain) 1 2 3 4 5 6 7 8 10 (intolerable pain)

7. Pain in general?

Worse than expected As expected Better than expected

8. How long have you been using the preparation? <7 days> 7 days Other_____

9. How many times a day did you use the preparation? 1 2 3 Other_____

10. Is the preparation helping you? YES NO

11. Did you like the taste of the preparation? YES NO