Treatment of dandruff with 5% tea tree oil shampoo

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Background: Dandruff appears to be related to the yeast *Pityrosporum ovale*. Tea tree oil has antifungal properties with activity against *P ovale* and may be useful in the treatment of dandruff.

Objective: We conducted a randomized, single-blind, parallel-group study to investigate the efficacy and tolerability of 5% tea tree oil and placebo in patients with mild to moderate dandruff.

Methods: One hundred twenty-six male and female patients, aged 14 years and older, were randomly assigned to receive either 5% tea tree oil shampoo or placebo, which was used daily for 4 weeks. The dandruff was scored on a quadrant-area-severity scale and by patient self-assessment scores of scaliness, itchiness, and greasiness.

Results: The 5% tea tree oil shampoo group showed a 41% improvement in the quadrant-area-severity score compared with 11% in the placebo group ($P < .001$). Statistically significant improvements were also observed in the total area of involvement score, the total severity score, and the itchiness and greasiness components of the patients' self-assessments. The scaliness component of patient self-assessment improved but was not statistically significant. There were no adverse effects.

Conclusion: Five percent tea tree oil appears to effective and well tolerated in the treatment of dandruff. (J Am Acad Dermatol 2002;47:852-5.)

Dandruff is characterized by white to whitish yellow, dry, loose scaling and mild pruritus of the scalp, and some would argue that it is a mild form of seborrheic dermatitis. The yeast *Pityrosporum ovale* is thought to be the causative agent of dandruff,[1,2] and this is supported by studies showing that anti-*Pityrosporum* agents such as zinc pyrithione, selenium sulfide,[3] ketoconazole,[4] and terbinafine[2] are effective in treating dandruff. Tea tree oil is active against a range of microorganisms, including *P ovale*[5] and thus may also be effective in treating dandruff.

Tea tree oil (*Melaleuca* oil) is an essential oil extracted primarily from the leaves of *Melaleuca alternifolia*, a shrub-like tree native to Australia. Tea tree oil has been used as a natural remedy for a variety of skin complaints for many years. During World War I, it was included in the first-aid kits of Australian troops to treat burns, bites, and infections. Tea tree oil has been used in the treatment of tinea pedis,[6] onychomycosis,[7] trichomonal vaginitis,[8] and acne.[9]

Tea tree oil is a complex mixture of hydrocarbons and terpenes, consisting of almost 100 substances, although the antimicrobial activity appears to be related to the major component, terpinen-4-ol.[10] The minimum inhibitory concentration for *P ovale* is 0.25% vol/vol.[5]

There is increasing demand for natural therapies, and tea tree oil is a popular choice. The aim of this study was to assess the effectiveness and tolerability of 5% tea tree oil shampoo compared with placebo in the treatment of mild to moderate dandruff.

PATIENTS AND METHODS

The Central Sydney Area Health Service Ethics Committee approved the study. All patients freely volunteered to participate, and informed consent was obtained. One hundred twenty-six male and female patients aged 14 years or older were recruited by local advertising. After a 2-week washout period during which Johnson's Baby Shampoo

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Table I. Demographic features of the 5% tea tree oil and placebo groups

	5% Tea tree oil group (n = 63)	Placebo group (n = 62)
Mean age (y)	39	42
Male (No. [%])	39 (62)	31 (49)
Total area score (mean ± SD)	13.0 ± 2.59	13.9 ± 2.35
Total severity score (mean ± SD)	6.9 ± 2.04	7.0 ± 1.92
Whole scalp lesion score (mean ± SD)	91.0 ± 38.0	99.9 ± 35.3
Scaliness (mm) (mean ± SD)	48.9 ± 19.5	53.6 ± 21.9
Itchiness (mm) (mean ± SD)	43.5 ± 21.3	49.1 ± 24.7
Greasiness (mm) (mean ± SD)	43.1 ± 26.7	31.8 ± 24.7

Scaliness, itchiness, and greasiness were recorded by patients along a 100-mm linear analogue scale, with the two extremes being "none" (0) and "worst ever" (100 mm).
Scores are expressed as mean ± standard deviation.

(Johnson and Johnson) was used daily, the patients were randomly assigned to receive either 5% tea tree oil shampoo or the vehicle shampoo as a placebo. Patients were asked to wash their hair daily, leaving the shampoo in for 3 minutes before rinsing, and were free to use a conditioner. Patients were reevaluated after 2 and 4 weeks and did not wash their hair on the day of examination.

Dandruff was assessed by the whole scalp lesion score.[11] The scalp was divided into quadrants, and for each quadrant, the area of involvement and severity were assessed. The area of involvement was measured on a scale of 1 to 5 in which a score of 1 meant less than 10% involvement, and a score of 5, more than 70% involvement. Severity was measured by a scale of 0 to 3 in which a score of 0 indicated normal skin, and a score of 3, marked erythema with thick confluent plates of yellowish white scales. The whole scalp score was then obtained by multiplying the total area of involvement score by the total severity score. For inclusion in the study, patients were required to have a whole scalp lesion score between 50 and 200, which had not changed by more than 50 after the washout period. Subjective assessments of scaliness of the scalp, itchiness, and greasiness were made on a 10-cm linear analogue scale, with the two extremes being "none" (0) and "worst ever" (10 cm).

This study was single-blinded because the distinctive odor of tea tree oil could identify it to those patients familiar with tea tree oil, although this information was not volunteered to patients. Blinding of the investigator was aided by not applying the shampoo on assessment days (to prevent the odor of the shampoo from identifying the patient group) and by avoiding discussions with patients regarding their shampoo. The data were recorded at baseline and 2 and 4 weeks later. Both the whole scalp lesion score and the patient self-assessment were determined without referring to previous measurements.

Patients excluded from the study included those with severe dandruff (whole scalp lesion score >200) or unstable dandruff (a change in the whole scalp lesion score >50 after the washout period), seborrheic dermatitis affecting the face and trunk, psoriasis, diabetes mellitus, immunosuppression, chronic disease not stabilized by medication, concurrent anticoagulation or systemic corticosteroid therapy, or a history of hypersensitivity to tea tree oil.

A standard deviation of 40% for the whole scalp lesion score was assumed, on the basis of previous work by this department (unpublished data), and it was determined that a sample size of 63 patients per treatment group would be required to have a power of 80% to detect a difference of 20% in the mean percentage change in the whole scalp lesion score with a 2-sided α level of .05. The intention-to-treat population was used, which comprised all patients who were randomly assigned to treatment, used study medication at least once, and had data recorded after baseline evaluation. Analysis of variance was used to compare the means.

RESULTS

One hundred twenty-six patients were enrolled in the study, and 63 were randomly assigned to each of the treatment arms. One patient, assigned to the placebo group, did not have data recorded after baseline evaluation so was not included in the intention-to-treat analysis. Five patients did not complete the study according to the protocol, but because data were recorded after baseline evaluation, were included in the intention-to-treat analysis; 3 patients violated the visit window criteria at one or more visits, one used the study medication on alternate days, and one used a prohibited medication (warfarin).

Demographic data for the study groups are shown in Table I. The only characteristic that was

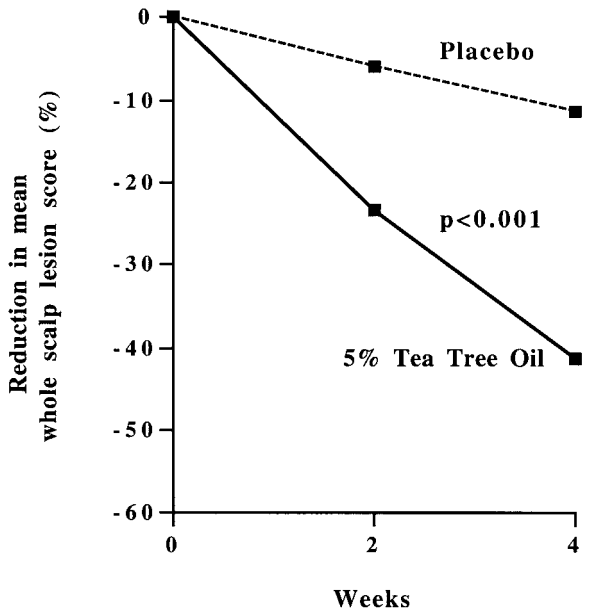

Fig 1. Percentage reduction in mean whole scalp lesion score.

noticeably different between treatment groups was the mean score for greasiness of scalp in the patients' self-assessments, which was higher (43.1) in the 5% tea tree oil group than in the placebo group (31.8). The groups were otherwise matched for sex, age, race, medical history, total area score, total severity score, whole scalp lesion score, and patient self-assessment of scaliness and pruritus.

Statistically significant improvements were observed in the whole scalp lesion score, total area of involvement score, the total severity score, and the itchiness and greasiness components of the patients' self-assessment in the 5% tea tree oil group compared with the placebo group (Fig 1). The scaling of the scalp component of patient self-assessment improved but was not statistically significant.

In 63 patients shampooing daily with 5% tea tree oil shampoo, the whole scalp lesion score fell from an average of 91.0 at baseline to 71.5 after 2 weeks and 53.0 after 4 weeks, a 41.2% drop in the mean score. For 62 patients using the placebo shampoo, the whole scalp lesion score was 99.7 at baseline, 93.0 after 2 weeks, and 88.2 after 4 weeks, an 11.2% reduction. The difference between the mean percentage change, −30.0, was statistically significant, with 95% confidence intervals being −44.2 and −15.9 and a *P* value of less than .001. Although the mean score was significantly reduced in the 5% tea tree oil group compared with the placebo group, only one patient in each group was completely free of dandruff at the end of the 4-week treatment period.

The total area of involvement score and total severity score were both significantly improved in the tea tree oil group. The total area score improved by 28.3% in the tea tree oil group compared with 12.5% in the placebo group ($P < .001$). The total severity score fell by 23.4% in the tea tree oil group compared with 2.8% in the placebo group ($P = .001$).

The patient self-assessment score of itchiness improved by 23.0% in the tea tree oil group compared with 12.1% in the placebo group ($P = .031$). The greasiness score improved by 25.9% in the tea tree oil group compared with 8.2% in the placebo group ($P = .001$). Scaliness improved by 25.6% in the tea tree oil group compared with 16.9% in the placebo group, but this difference did not reach significance ($P = .066$).

Tolerance of the topical applications was excellent, with no serious adverse events recorded and fewer events recorded in the tea tree oil group than in the placebo group. In the tea tree oil group, 3 (5%) patients reported adverse events, namely, mild stinging in the eyes, mild burning of the scalp while shampooing the hair, and mild itching of the scalp. In the placebo group, 8 patients (13%) reported adverse events, which included pruritus (n = 3), conjunctivitis (n = 1) and urticaria (n = 1); events considered not related were back pain, headache, and neck pain (n = 3). No adverse events were considered significant.

DISCUSSION

Shuster's review[1] of the etiology of dandruff provided strong arguments for an infective cause, namely *P ovale*, and a number of studies have demonstrated that anti-*Pityrosporum* agents such as selenium sulfide, nystatin, and ketoconazole are effective in treating dandruff.

We have demonstrated, in a randomized, single-blind study of 126 patients with mild to moderate dandruff, that 5% tea tree oil shampoo, when used daily for 4 weeks, reduces the whole scalp lesion score by over 40%, compared with an 11% reduction for placebo.

The whole scalp lesion score has been used by others to assess dandruff. Faergemann,[11] in a double-blind, placebo-controlled study of 36 patients, used 2% ketoconazole shampoo twice weekly for 4 weeks and found that the whole scalp lesion score fell from a mean of 25 to 3 compared with 27 to 19 in the placebo group. Faergemann et al[2] used terbinafine 1% solution once daily for 4 weeks in 20 patients with seborrheic dermatitis of the scalp. The whole scalp lesion score fell from a mean of 21 to 6. We have studied patients with a higher whole scalp

lesion score (50-200) at baseline and shown 5% tea tree oil shampoo to be similarly effective in reducing whole scalp lesion score as ketoconazole 2% and terbinafine 1% solution.

It is recognized that the treatment of dandruff with antifungal agents requires prolonged application because of the high rate of recurrence.[12,13] This study involved treatment with 5% tea tree oil shampoo daily for 4 weeks, and although there was an improvement in patient self-assessment scores and the whole scalp lesion score, only one patient actually achieved a complete response, as did one patient in the placebo group. Thus, it appears that 5% tea tree shampoo would require ongoing application for control of dandruff.

There were no significant adverse effects related to the tea tree oil shampoo. In fact, more adverse events were recorded in the placebo group than in the tea tree oil group. The adverse effects were mild and did not affect the patients' compliance with the treatment.

There is strong demand for natural therapies, and this is increasing. Tea tree oil has been a popular choice for many years and is now marketed in a variety of preparations for several indications, including shampoo for dandruff. We have shown that 5% tea tree oil shampoo is effective in reducing dandruff and is well tolerated.

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