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File: ■ Australian Eucalyptus (*Eucalyptus globulus*, Myrtaceae)
■ Lemon-scent Tea Tree (*Leptospermum petersonii*, Myrtaceae)
■ Head Lice

HC 041731-568

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RE: Clinical Efficacy of Australian Eucalyptus and Lemon-scent Tea Tree Essential Oils for Head Lice Treatment

Greive KA, Barnes TM. The efficacy of Australian essential oils for the treatment of head lice infestation in children: a randomised controlled trial. *Australas J Dermatol*. March 7, 2017; [epub ahead of print]. doi: 10.1111/ajd.12626.

Head lice infestation, most often seen in children aged 3 to 14 years, causes itching and discomfort, as well as parental anxiety, embarrassment, and school absences. The use of treatments containing neurotoxins has caused safety concerns and has led to resistant lice populations. Alternative treatments have been developed for improved efficacy and concerns about the use of neurotoxins. These authors conducted a multicenter, randomized, parallel-group trial to compare the safety and efficacy of head lice treatments of Australian eucalyptus (*Eucalyptus globulus*, Myrtaceae) oil and lemon-scent tea tree (*Leptospermum petersonii*, Myrtaceae) oil (EO/LP) with a neurotoxic mousse containing pyrethrins and piperonyl butoxide (P/PB) in children (trial 1). In trial 2, a single-blind, open trial, the authors studied the efficacy of the EO/LP solution in killing head lice after a single application. Skin irritancy and sensitivity tests were conducted in both adults and children, and the efficacy of EO/LP solution in killing live lice and louse eggs was tested in vitro.

Conducted in Queensland, Australia, the study included male and female schoolchildren up to grade 7 who had live head lice in their hair or on their scalp upon visual inspection and dry-combing with a head lice comb.

The EO/LP treatment used was MOOV Head Lice Solution (Ego Pharmaceuticals Pty Ltd; Braeside, Victoria, Australia), which contained 11% per weight eucalyptus oil and 1% per weight lemon-scent tea tree oil. The P/PB treatment was Banlice® Mousse (Pfizer Consumer Healthcare Group; West Ryde, New South Wales, Australia), which contained 1.65 mg/g pyrethrins and 16.5 mg/g piperonyl butoxide.

The EO/LP solution was applied 3 times – on days 0, 7, and 14. Although the P/PB mousse manufacturer recommended only 1 treatment, the mousse was applied twice – on days 0 and 7 – as recommended by the Therapeutic Goods Administration of

Australia. The technicians applying the treatments were not blinded because of the physical and smell differences between the treatments; however, the assessment technicians, subjects, and parents did not know which treatment was being used.

The intention-to-treat (ITT) population, which included all randomly assigned subjects before treatment, was used to determine the safety and efficacy. Subjects included in the per-protocol (PP) population were those who completed all treatments of the EO/LP solution or the P/PB mousse. Subjects' siblings who had lice were treated in the same manner as the subjects and were enrolled in the trial. Siblings with no head lice but with evidence of recent infestation underwent wet-combing. Any adverse effects were recorded at each study visit.

Of the 97 subjects in the ITT population, 76 met the requirements for the PP analysis. Subjects did not meet the PP requirements for the following reasons: 1 did not receive the required dose, 3 used alternative head lice treatments during the trial, 15 failed to comply with sibling control criteria, 1 failed to appear on day 21, and 1 withdrew due to an adverse event. Of the PP population, 40 received the EO/LP solution and 36 received the P/PB mousse.

Analysis of the PP population revealed a significant between-group difference in cure rate at 7 days, with 83% of the EO/LP group cured compared with 36% of the P/PB group ($P<0.0001$). On day 1, no significant differences were seen in cure rate between the 2 groups. In the ITT subjects, at day 7, 71% in the EO/LP group were cured compared with 33% in the P/PB group ($P=0.0002$). No significant between-group difference in cure rate was observed on day 1.

Of the 97 subjects who received at least 1 treatment, 21 adverse effects were reported in 13 subjects; the 18 adverse effects reported in the EO/LP group included transient mild to moderate sensations such as itchiness, stinging, or burning lasting no more than 5 minutes and requiring no treatment. The 3 adverse effects in the P/PB group included 1 crawling and 2 stinging sensations.

In trial 2, on day 0, 11 subjects with live lice received treatment with the EO/LP solution. The authors report that after the single EO/LP application, the 1,418 head lice collected were considered dead as they were wet-combed out of the hair. Upon examination 30 minutes after combing, all lice were confirmed dead.

For the skin irritation and sensitivity study, a patch containing the EO/LP solution was applied to the skin of the back for 24 hours every Monday, Wednesday, and Friday for 3 consecutive weeks. Then, 10 to 14 days afterwards, 1 challenge or retest dose was applied to a previously unexposed test site and assessed 24 and 48 hours later. Fifty-three of the 56 adult subjects enrolled in this study completed it; 3 withdrew for reasons unrelated to the study protocol. The authors report that no erythema, edema, or adverse effects were observed.

For the pediatric testing for skin irritation or sensitivity, 20 children aged 6 months to 4 years were examined on the scalp, face, and neck, and then the EO/LP solution was applied on days 0, 7, and 14. The subjects were evaluated after each application and again 24 hours after the last application. The authors report that no test-related irritation was observed, and no safety-related comments were made by any subjects or their parents.

In testing the in vitro efficacy of the EO/LP solution, the authors observed that no louse eggs hatched for 10 days after a 10-second immersion in the solution. Following immersion in the control (purified water) treatment, 24% of the eggs hatched after 7 days, 76% after 8 days, 92% after 9 days, and 92% after 10 days. Other findings revealed that 60 minutes after a 10-minute exposure to the EO/LP solution, 100% of the body lice were moribund or dead; all the body lice immersed in water were alive. The authors conclude that compared with the water treatment, the EO/LP solution was 100% effective in killing lice ($P<0.0001$).

The authors attribute the treatment failures seen in 7 of the 40 subjects in the EO/LP group in trial 1 to the fact that some lice or some eggs survived any 1 of the 3 treatments or that re-infestation occurred. After observing the results of the in vitro studies revealing "that the EO/LP solution is 100% ovicidal after only a 10-s immersion, it is more likely that the treatment failures are due to re-infestation," they write.

The authors conclude that "the EO/LP solution contains a proprietary combination of essential oils that has been shown to be safe and effective in eliminating head lice in Australia," and because the solution is both volatile and quickly effective, "it is unlikely to cause the development of head lice resistance in the community."

Both of the authors (KA Greive and TM Barnes) are employed by Ego Pharmaceuticals, the sponsor of the study and manufacturer of MOOV Head Lice Solution.

—Shari Henson

Referenced article can be accessed at http://onlinelibrary.wiley.com/doi/10.1111/ajd.12626/epdf.