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RESEARCH LETTER

Novel Topical Treatment for Dandruff & Dry Scalp Through Sustained Balance in Skin Microbiome

Alexander Xiao
Christopher Warren
Waheeda Samady
Lucy Bilaver

Northwestern University Feinberg School of Medicine, Center for Food Allergy and Asthma Research, Chicago, IL, USA

There is a growing body of evidence that atopic skin disease may be due to disturbed microbial composition on the skin.[1] This dysbiosis has been observed in infants with eczema, with certain bacteria such as the Staphylococcal species playing an important role in the process.[2–4] In recent years, treatments for these conditions by altering the skin microbiome have been attempted with some success. One study found that intervention with topically applied *R. mucosa* was associated with decreased disease severity and *S. aureus* burden.[5] However, treatment with emollients, probiotic supplementation or "natural" remedies like tea tree oils have had limited evidence of efficacy.[1]

Given this role the microbiome plays in atopic disease, our team has developed a novel, topical ointment primarily consisting of probiotics, honey, turmeric and B12 aimed at restoring a healthy skin microbiome. To examine its efficacy, we have completed the preliminary phases of a clinical trial. Our study was conducted as an Investigational New Drug with the FDA with approval from our Institutional IRB. Inclusion criteria were adults 18 and older with dry scalp and dandruff symptoms as determined by a trained research physician. Patients diagnosed with other scalp diseases such as psoriasis, tinea capitis, and pediculosis capitis, used systemic steroid or oral antibiotics in the past two months or had an allergy to any of the preparation components were excluded. Thirty-five adults (55% female, 40% White, 50% Asian, 5% Black, 5% Multiracial) with dry scalp were recruited and followed for this 2-week study. Participant median age was 26; IQR=8 years, range=20–78. The initial study visit consisted of a scalp exam and scalp photographs by a trained research physician to confirm that each participant had a dry scalp condition. At this time participants completed an intake survey including assessment of the participant demographics as well as the standardized assessments of scalp condition history and current symptoms described below.

The scalp exam, photographs and intake survey provided the basis for our initial evaluation of disease and symptom severity through the Investigator Global Assessment (IGA), Total Severity Score (TSS) and Scalpdex. The IGA is a 5-point validated instrument that rates overall disease severity according to the following categories: 0 = clear, 1 = almost clear, 2 = mild disease, 3 = moderate disease, 4 = severe disease. The TSS represents the sum of erythema, scaling, and pruritus severity scores of the scalp disease. A minimum TSS score is 0 (none) and the maximum TSS score is 9 (severe). Scalpdex is a validated 23-item quality-of-life questionnaire that is completed by participants to measure their subjective improvement with treatment.

Correspondence: Alexander Xiao
Email Alexander.xiao@northwestern.edu

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Participants were instructed to liberally apply the topical preparation to their scalp once daily for 14 days, leave in place for at least 7 minutes, and rinse in the shower. Participants returned after 14 days of treatment for an in-person follow up including a physician scalp assessment, end photograph and exit survey. At that point, the IGA, TSS and Scalpdex were again determined.

Results from paired *t*-tests with one-sided p-values found that after 2 weeks of treatment, overall disease severity by IGA decreased from 2.1 at baseline to 1.1 at the end of the trial ($t(34_{df})=8.15$; $p<0.001$). Additionally, mean TSS scores fell from 3.5 at baseline to 1.8 at the conclusion ($t(34_{df})=$ $p<0.001$). Overall Scalpdex decreased from 46.0 to 39.5 ($t(33_{df})=3.4$; $p=0.001$, reflecting significant reductions in the subjective quality of life burden associated with the scalp condition (Table 1). Notably, significant decreases were observed for all three TSS subscales ($p_{erythema}<0.001$; $p_{scaling}<0.001$; $p_{pruritis}<0.001$) as well as all three Scalpdex subscales ($p_{symptoms}=0.001$; $p_{emotion}<0.001$; $p_{functioning}=0.04$) (Tables 1 and 2). Additionally, the intervention was well-tolerated, without adverse effects or complaints reported by any study participants.

Overall, our preliminary data found that use of a novel, topical dry scalp product clinically reduced the symptoms and disease severity of dry scalp conditions, improved patient-reported quality of life within all assessed domains, and had no adverse effects in adults. These results are promising and build upon our understanding of how treatments targeting the skin microbiome can improve atopic disease outcomes. Future randomized controlled trials will shed further light upon the safety and efficacy of this novel product and help identify the populations most likely to benefit.

Table 1 IGA, TSS and Scalpdex Scores Before and After Intervention

	Baseline Mean(SD)	After Intervention Mean(SD)	P value
IGA Score	2.1 (0.6)	1.1 (0.8)	<0.001
TSS Score	3.5 (1.4)	1.8 (1.0)	<0.001
Erythema	1.8 (0.7)	1.3 (0.5)	<0.001
Scaling	2.4 (0.7)	1.8 (0.6)	<0.001
Pruritis	2.4 (0.7)	1.7 (0.6)	<0.001
Scalpdex Score	46.0 (13.4)	39.5 (10.3)	<0.001

Table 2 Scalpdex Score Subscales Before and After Intervention

	Baseline Mean(SD)	After Intervention Mean(SD)	P value
Symptom severity	46.5 (15.3)	39.0 (10.5)	<0.001
Emotional impact	48.6 (14.8)	40.9 (11.3)	<0.001
Functional impact	37.9 (13.6)	34.5 (11.1)	0.04

Data Sharing Statement

Upon publication of study findings deidentified data presented in the manuscript and data collection instruments will be made available to interested parties by request. Validated tools used for assessment may also be shared. Data will be retained for 10 years.

Please contact Christopher M. Warren, christopher.warren@northwestern.edu for data requests.

Ethical Considerations

The protocol for this study was approved by the Institutional Review Board of Northwestern University and complies with the Declaration of Helsinki. Written informed consent was obtained from all participants. Clinical trial registration number: NCT03830177.

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Disclosure

Dr Christopher Warren reports personal fees from Alladapt, outside the submitted work. The authors report no other conflicts of interest in this work.

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