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3% Kanuka oil cream compared to 1% hydrocortisone cream in treatment of mild atopic dermatitis

Abstract

Introduction: Atopic dermatitis is a common, relapsing chronic inflammatory skin condition. Pruritus is a frequent complaint of patients with atopic dermatitis which can impair quality of life. The aim of this study is to evaluate the use of Kānuka Oil 3% cream as a treatment option for this diseased population.

Methods: A randomized, double-blinded study was performed with 40 patients split into two treatment groups with the application of either kānuka oil 3% cream or hydrocortisone 1% cream. ISGA and WI-NRS assessments were performed at baseline, week 2, and Day 28.

Results: Kānuka Oil 3% cream showed statistically significant improvement in ISGA scores compared to hydrocortisone 1% cream (p=0.0082) at day 28. Worst Itch Numerical Rating Scale (WI-NRS) scores exhibited kanuka oil 3% cream showing greater improvement in itch reduction compared to hydrocortisone 1% cream by day 6. No adverse effects were reported by patients in either arm of the study.

Conclusion: Kānuka oil 3% cream offers a novel therapeutic option for patients with mild atopic dermatitis. The improvement in itch has the potential to improve the quality of life of patients inflicted with atopic dermatitis.

Keywords: atopic dermatitis, kanuka oil 3% cream, pruritus, hydrocortisone cream

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Introduction

Atopic Dermatitis is a common inflammatory skin disease that affects tens of millions of adults and children in the United States alone.[1] A global burden of disease survey found that atopic dermatitis was ranked second in terms of disability-adjusted life-years when compared to other common skin conditions.[2] It has been estimated that the direct and indirect costs of atopic dermatitis in the United States alone are over $5 billion dollars on an annual basis.[3]

This chronic skin condition is frequently accompanied by pruritus and can lead to psychosocial issues for many patients with consequent impaired quality of life.[4] The itch-scratch cycle seen in patients with atopic dermatitis can impair skin barrier function, making patients susceptible to infection. Based on the severity of the disease, there are many treatment options available to patients, ranging from over-the-counter moisturizers to corticosteroids to phototherapy to immunosuppressant's to novel biological treatments.[5] Poor treatment adherence is an important factor in many cases of treatment failure, and this is often due to a negative patient perception of the side effects of topical corticosteroids.[6]

Given the significant economic burden and prevalence of atopic dermatitis, it is important to explore novel treatment options for this condition. In particular, novel non-steroidal options may be viewed more favorably by patients and caregivers, and lead to improved patient compliance and treatment outcomes.

The use of natural products and complementary and alternative medicine (CAM) is increasing for many common chronic medical conditions and is common among patients with atopic dermatitis. However, there is little evidence of efficacy or safety from the few clinical trials which have assessed CAM therapies for this condition.[7]

Kānuka oil 3% cream is an over-the-counter treatment that is made by extracting the oil from the leaves and twigs of the kānuka tree (kunzea ericoides).[8] The tree is endemic to New Zealand and has been used as a remedy by Māori, the indigenous people of New Zealand.[8] The oil consists of many terpene, flavonoid, and lipid components, particularly α-pinene and p-cymene.[9,10] It has been shown to have anti-bacterial, anti-inflammatory, and moisturizing properties, all of which could potentially have therapeutic effects for patients with atopic dermatitis.[10] In particular, kānuka oil has been shown to significantly decrease the production of tumor necrosis factor-α (TNF-α), which itself has been shown to be involved in the development of eczematous lesions and skin itching.[11,12] The physiochemical properties of kānuka oil imply the potential use of kanuka oil as a non-steroidal treatment of inflammatory dermatoses such as atopic dermatitis.[13]

The underlying mechanism of action of kānuka oil, as well as results from a previous study, imply the potential use of kānuka oil in the treatment of inflammatory dermatoses such as atopic dermatitis.[9]

This study aimed to assess the efficacy and safety of kānuka oil 3% cream in the management of mild atopic dermatitis compared to hydrocortisone 1% cream over 28 days.

Methods

This was a 4-week, single-center, randomized, double-blind study that consisted of the application of kānuka oil 3% cream versus hydrocortisone 1% cream. Participants were randomized to apply either kānuka oil 3% cream or hydrocortisone 1% cream to affected areas of atopic dermatitis twice a day. Key inclusion criteria included age greater than 12 years, diagnosis of atopic dermatitis for longer than 2 years, investigator's static global assessment score of either 2 or 3, and initial worst itch numerical rating scale (WI-NRS) for itch

greater than 4. The key exclusion criteria included the use of topical or systemic corticosteroids within 28 days of entering the study, the use of any other non-emollient therapy within 28 days of entering the study, nursing, and pregnancy. During the study, patients were prohibited from using any systemic atopic dermatitis therapies as well as topical prescription and over-the-counter products. Patients were assessed at baseline, week two, and Day 28. The endpoint of the study was a comparison of ISGA and NRS scores. Data between the two groups was analyzed using a two-sample t-test to determine differences in efficacy between the ISGA among the two groups.

Key study measures included in the analysis are described below:

Investigator Static Global Assessment (ISGA) is a physician-assessed outcome where overall severity of disease is measured on a scale from 0 (clear) to 6 (very severe).[7] When evaluating the disease, physicians give a single global assessment rating based on physical exam findings including the presence of induration, erythema, and oozing.

The Worst Itch Numerical Rating Scale (WI-NRS) for itch assesses respondents answering one question about itch on a daily basis using a diary.[8] It is based on a scale of zero for no itch to ten for severe itch. With this scale, a 4-point improvement from baseline is considered a clinically meaningful response.

Results

A total of 40 patients were included in the analysis, with 20 patients assigned to each of the two groups (Table 1). All enrolled subjects successfully completed the study. The gender distribution was equivalent between the two groups, with 55% women and 45% men. The mean age for the hydrocortisone 1% cream group was 17.9 years of age while the mean age for the Kanuka oil 3% cream group was 18.1 years. All patients who initially enrolled in the study completed with no reports of adverse events.

Table 1 Statistical analysis

Statistics	Hydrocortisone 1% N = 20	Kanuka oil N = 20
Age (years) n	20	20
Mean (SD)	17.9 (4.64)	18.1 (5.67)
Median	16.5	16
Q1, Q3	15.0, 19.5	14.0, 22.0
Min, Max	13, 31	13, 34
CV%	26	31.3
Sex, n (%)		
Female	11 (55.0)	11 (55.0)
Male	9 (45.0)	9 (45.0)

CI, confidence interval; %CV, coefficient of variation; Q1, Q3, lower and upper quartiles; SD, standard deviation

In analyzing the ISGA scores, statistical significance (p-value=0.0082) was achieved on Day 28, with the kānuka oil 3% cream showing superior ISGA results compared to the 1% hydrocortisone cream. The mean change was approaching statistical significance by day 14 between the two groups as reflected in the mean change from baseline in the ISGA score (Table 2, Figure 1).

Table 2 Statistical significance

Visit statistics	Hydrocortisone 1% N = 20	Kānuka oil N = 20
Baseline		
Mean (95% CI)	2.40 (2.16, 2.64)	2.15 (1.98, 2.32)
Mean Diff. Kānuka oil vs Hydrocortisone 1% (95% CI)		-0.25 (-0.53, 0.03)
p-value [1]		0.0802
At Week 2		
Mean (95% CI)	1.80 (1.51, 2.09)	1.25 (0.95, 1.55)
Mean Diff. Kānuka oil vs Hydrocortisone 1% (95% CI)		-0.55 (-0.95, -0.15)
p-value [1]		0.0086
Change from Baseline at Week 2		
Mean (95% CI)	-0.60 (-0.84, -0.36)	-0.90 (-1.20, -0.60)
Mean Diff. Kānuka oil vs Hydrocortisone 1% (95% CI)		-0.30 (-0.67, 0.07)
p-value [1]		0.1077
On Day 28		
Mean (95% CI)	1.85 (1.41, 2.29)	1.05 (0.69, 1.41)
Mean Diff. Kānuka oil vs Hydrocortisone 1% (95% CI)		-0.80 (-1.34, -0.26)
p-value [1]		0.0051
Change from Baseline on Day 28		
Mean (95% CI)	-0.55 (-0.87, -0.23)	-1.10 (-1.36, -0.84)
Mean Diff. Kānuka oil vs Hydrocortisone 1% (95% CI)		-0.55 (-0.95, -0.15)
p-value [1]		0.0082

CI, confidence interval; Diff., difference. [1] p-value is calculated for Kanuka Oil vs Hydrocortisone 1% based on two-sample independent t-test.

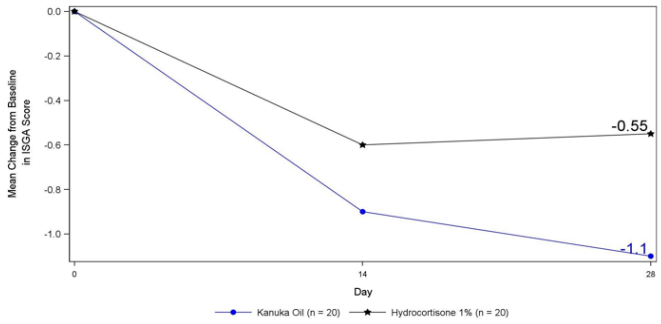

Figure 1 Mean change from baseline in the ISGA score.

In analyzing the NRS scores between kānuka oil 3% cream versus hydrocortisone 1% cream, the difference in itch reduction was noted around day 6, with kānuka oil showing continuous superior results compared to hydrocortisone cream 1% until the conclusion of the study at day 28 (Figure 2).

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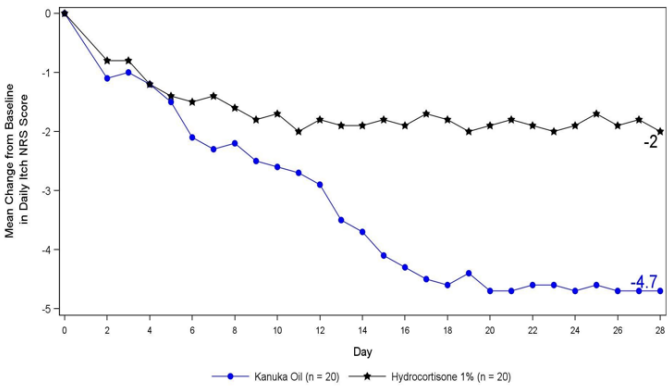

Figure 2 Mean change from baseline in the NRS score.

Discussion

This randomized controlled study in patients with mild atopic dermatitis found kānuka oil 3% cream to be a safe and effective therapeutic option. kānuka oil 3% cream showed statistically significant improvement in ISGA compared to hydrocortisone 1% cream in the treatment of patients with mild atopic dermatitis. In addition, starting on day 6, kānuka oil 3% cream showed a larger decrease in itch reduction than hydrocortisone 1% cream. No issues of tolerability or adverse events were reported with kānuka oil 3% cream.

Kānuka oil is a novel over-the-counter product that appears to be well tolerated in patients. It is all-natural and renewable in its production as it is found by distilling leaves and twigs from the kānuka tree (Kunzea ericoides), which is endemic to New Zealand. The therapeutic promise of this oil was originally recognized by the Māori, the indigenous people of New Zealand. The Māori have used the exudate of the kānuka tree as a treatment for inflammatory conditions, as part of a traditional healing system.[5] The oil consists of many terpene, flavanoid and lipid components, particularly α-pinene and p-cymene.[9,10] It has been shown to have anti-bacterial, anti-inflammatory, and moisturizing properties, all of which could potentially have therapeutic effects for patients with eczema.[10] In particular, kānuka oil has been shown to significantly decrease the production of tumor necrosis factor-α (TNF-α), which has been shown to be involved in the development of eczematous lesions and skin itching.[11,12]

This study builds on the findings of the only other study of kānuka oil cream in patients with atopic dermatitis.[9] This was a single-blind, parallel-group, randomised, vehicle-controlled trial, undertaken in community pharmacies in New Zealand. 80 adults with self-reported moderate-to-severe eczema were enrolled and the primary outcome measure was the Patient Orientated Eczema Measure (POEM), a self-reported scoring tool. Subjects were randomised to 3% kānuka oil cream or vehicle control, applied topically, twice daily, for six weeks. In this study, the mean POEM score (SD) improved between baseline and week six for the kānuka oil group, from 18·4 (4·4) to 6·8 (5·5). This improvement, compared to the control group, was clinically and statistically significant and the improvement in POEM score of the kānuka oil group of a mean of 11.6 was far greater than the minimum clinically important difference (MCID) of the POEM score of 3.4.[14–16]

Pruritus is a significant issue facing patients with atopic dermatitis. In this study, kanuka oil 3% cream was more effective than hydrocortisone 1% cream in relieving symptoms associated with itch. The greater efficacy associated with kānuka oil 3% cream in improving itch was seen by day 6, and continued to the completion of the study at day 28.

As the study has a small sample size, further work should be performed to investigate the potential role of Kānuka oil 3% cream in the treatment of mild atopic dermatitis. Moreover, given the significant improvement of itch in patients receiving kānuka oil 3% cream, more studies should be undertaken to see if this cream would be beneficial to patients experiencing itch from other dermatoses. Strengths of the study include the use of a physician-assessed outcome and the use of an active control to mimic results in real-world practice, as opposed to a placebo or vehicle control.

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None.

Conflict of interests

None.

Ethics statement

This study was approved by the Univo Institutional Review Board (IRB # 2024-SP035).

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