A topical *kanuka* honey formulation is an effective treatment for rosacea

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Introduction

Rosacea is an incurable chronic inflammatory skin condition for which novel therapies are needed as current treatments have limited efficacy. Honey is a potential topical treatment for rosacea as it has antimicrobial, anti-inflammatory properties and skin healing effects[1-2]. A recent pilot study has demonstrated that topical 90% medical-grade *kanuka* honey and 10% glycerine (Honevo, HoneyLab, New Zealand) is an acceptable and potentially effective treatment for rosacea[3].

The aim of this study was to investigate the efficacy of topical 90% medical-grade *kanuka* honey and 10% glycerine as a treatment for rosacea.

Methods

A parallel group randomised controlled trial with assessor blinding. 137 adults aged ≥16 with a baseline blinded Investigator Global Assessment of Rosacea Severity Score (IGA-RSS) of facial rosacea of ≥2 were recruited. Participants were randomised to Honevo or control (Cetomacrogol) which was applied twice daily for 30-60 minutes per application, for eight weeks. The primary outcome measure was the proportion of subjects who had a ≥2 improvement in the IGA-RSS at week 8.

IGA-RSS score

Numerical Score	Definition	Description
0	Clear	Almost no Rosacea (i.e. no papules and/or pustules); no or residual erythema; mild to moderate degree of telangiectasia may be present
1	Minimal	Rare papules and/or pustules; residual to mild erythema; mild to moderate degree of telangiectasia may be present
2	Mild	Few papules and/or pustules; mild erythema; mild to moderate degree of telangiectasia may be present
3	Mild to moderate	Distinct number of papules and/or pustules; mild to moderate erythema; mild to moderate degree of telangiectasia may be present
4	Moderate	Pronounced number of papules and/or pustules; moderate erythema; mild to moderate degree of telangiectasia may be present
5	Moderate to Severe	Many papules and/or pustules, occasionally with large inflamed lesions; moderate erythema; moderate degree of telangiectasia may be present
6	Severe	Numerous papules and/or pustules, occasionally with confluent areas of inflamed lesions; moderate to severe erythema; moderate to severe degree of telangiectasia may be present

Results - Participants

69 subjects were randomised to control and 68 to Honevo. Participants were predominantly aged 50-70, and had had rosacea for a mean of 15 years.

	Honevo N (%) N=68	Control N (%) N=69
Female	32 (47.1)	36 (52.2)
History of oral antibiotics	13 (19.1)	13 (18.8)
History of topical therapy	24 (35.3)	20 (29.0)
History of topical steroid	6 (8.8)	6 (8.7)
European	64 (94.1)	68 (98.6)
Maori	4 (5.9)	0 (0)
Asian	0 (0)	1 (1.5)

Primary outcome

24/68 (34.3%) in the Honevo group and 12/69 (17.4%) in the control group had a ≥2 improvement in IGA-RSS at week 8 compared to baseline (relative risk 2.03 (95% CI 1.11 to 3.72), P=0.020). The corresponding odds ratio was 2.59 (1.17 to 5.74).

Secondary outcomes

For Honevo vs. control group respectively:

- 7/68 (10.3%) withdrawals (3 for worsening rosacea) vs. 15/69 (21.7%) withdrawals (8 for worsening rosacea).
- Change in IGA-RSS at week 2 minus baseline was -1 (Hodges-Lehman estimate, 95% CI -1 to 0, P=0.03), and at week 8 minus baseline was -1 (Hodges-Lehman estimate, 95% CI -1 to 0, P=0.005).
- Number of applications per day was similar (mean (SD) 1.84 (0.23) vs. 1.86 (0.20), difference: -0.02 (95% CI -0.10 to 0.05), P=0.55).
- 31 vs. 37 adverse events reported, all of which were minor.
- In a post hoc analysis, the proportion with IGA-RSS of 0 at week 8 (i.e. full resolution) was 9/68 (13.2%) vs. 2/69 (2.9%), relative risk 4.6 (95% CI 1.0 to 20.4, P=0.031).

Discussion

While acknowledging the different primary outcome variables, in placebo controlled studies of topical metronidazole the relative risk (RR) of improvement with the physician's global evaluation was 1.95 (95% CI 1.5 to 2.6), and in placebo controlled studies of azelaic cream the RR of participant-assessed improvement was 1.52 (95% CI 1.3 to 1.8). By comparison, the RR of IGA-RSS improvement with Honevo was 2.0 (95%CI 1.1 to 3.7) and in the post hoc analysis the RR of resolution was 4.6 (95% CI 1.0 to 20.4).

The participants could not be blinded due to the appearance and smell of Honevo, but the primary outcome measure was assessed by an investigator who was blinded to treatment.

A 2 point reduction in IGA-RSS represents a clinically meaningful improvement, for example a change from 'severe' to 'moderate', or from 'moderate' to 'mild' rosacea severity.

Conclusion

This randomised controlled trial demonstrated that topical 90% medical-grade *kanuka* honey and 10% glycerine (Honevo) is an effective and well tolerated treatment for rosacea. About one third of participants had a clinically significant improvement in the IGA-RSS after 8 weeks of Honevo treatment, two-fold greater than that observed with the control treatment.

References

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