



Manuka Honey v Hydrogel to deslough venous leg ulcers-

A prospective, open label, multicentre randomised controlled trial.

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Background

0.12-2% of the population suffer from leg ulceration of which 70-80% are due to venous disease. 50% of all ulcers heal following 12 weeks of compression therapy, however, 50% reoccur within 3 months. To date, dressings applied in conjunction with compression have not improved healing outcomes beyond the 50% level. Yet, the condition of the wound bed in those ulcers that heal versus those that do not is unknown. The presence of slough in the wound bed potentially delays healing, provides a nidus for infection and impedes epithelial edge advancement.

The literature reports an increased interest in the use of honey in wound management. - Based on RCTs in acute wounds, non-controlled studies, case series and *in vitro* research honey reduces inflammation, has antibacterial properties, cleanses the wound bed and promotes wound healing. - However, RCTs to determine the efficacy of Manuka Honey in chronic wounds are lacking. - RCTs to determine the efficacy of Manuka Honey to deslough venous ulcers and the impact of such desloughing on healing of venous leg ulcers have not been conducted.

Method of outcome assessment

Weekly measurement of wound area. Weekly assessment of % of wound covered in slough. Exudate levels assessed on a 4 point scale. Pain scores recorded using visual analogue scale. Surface wound swabs taken at baseline and end of week 4. Follow-up review to determine if wounds had healed or not at week 12.

Results

108 patients were recruited over 34 months. 24% (n= 26) of patients withdrew. ITT analysis was conducted. At week 4 the mean percentage reduction in slough between groups was just outside of statistical significance (p=0.054). The mean wound area covered in slough reduced from 85% to 29% in honey group and 78% to 43% in the gel group (p=0.065). The difference in wound size between groups at week 4 was not significant (p=0.162). For all wounds a slough reduction of =50% had a higher probability of healing at 12 weeks (p=0.029). At week 12, honey treated wounds had a RR of 1.38 for healing compared to control (p 0.037). Healing rate at 12 weeks was higher in honey group when adjusted for Margolis index (OR 3.1, p 0.025).

Inclusion/exclusion criteria

Inclusion: •Persons with venous ulcers diagnosed on clinical examination having an ABPI of > 0.8. Having > 50% wound surface area covered in slough. Non-infected wounds less than 100cm². Able to provide written consent. Exclusion: •Persons taking antibiotics or steroid therapy for any reason. Wounds larger than 100cm². Clinically infected wounds. Persons allergic to honey dressings. Those unable to provide written informed consent. Persons < 18 years.

Primary Outcomes

To determine the ability of Manuka Honey (Woundcare 18+) to deslough venous leg ulcers in comparison to a standard agent (IntraSite Gel). To compare the percentage reduction in wound size after 4 weeks in both treatment groups. To compare the numbers healed after 12 weeks in both groups. Secondary Outcome measures To determine the effects on healing outcomes at week 12 when wounds are desloughed. To determine healing outcomes after 12 weeks for each group based on Margolis index at baseline.

Study design

Open label, prospective, multicentre, RCT. A priori calculation determined 156 wounds required. Ethical approval was granted. 4 acute hospitals, 4 community hospitals and 2 community leg ulcer clinics were included. Randomisation was via remote telephone. Allocated treatment was applied for 4 weeks with follow up review at week 8 and week 12. Treatment regimes (except honey or gel) was standardised between groups. All patients received compression therapy. Statistical analysis was on Intention to Treat (ITT) basis.

Margolis Index:

1 point if wound size > 5cm²
1 point if wound duration > 6 months. Score can be used to predict healing of venous ulcers at 24 weeks. Higher score = poorer prognosis.

Margolis et al(2000)Which venous ulcers will heal with amb-compression bandages? American Journal of Medicine 109(1), 15-19.

Conclusions

Manuka honey in the form of WoundCare 18+ reduced the percentage of slough in the wound bed by 67% after 4 weeks. A slough reduction of ≥ 50% had a higher probability of healing after 12 weeks (RR3.3, p 0.029). 39% of all wounds had healed at 12 weeks indicating for the first time healing rates of venous ulcers when slough is the predominant tissue in the wound bed. Manuka honey should be regarded as treatment option in modern wound management.

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