Honey-impregnated dressings and usual care did not differ for healing venous leg ulcers

QUESTION

Is honey effective for the management of venous leg ulcers?

METHODS

Design: randomised controlled trial (Honey as Adjuvant Leg Ulcer Therapy [HALT] trial).

Allocation: concealed.

Blinding: blinded (outcome assessor).

Follow-up period: 12 weeks.

Setting: 4 community-based district nursing services in Auckland, South Auckland, Waikato, and Christchurch, New Zealand.

Patients: 368 patients (mean age 68 y, 51% women) who had venous ulcers or mixed venous and arterial ulcers and could tolerate compression. Exclusion criteria were history of diabetes, rheumatoid arthritis or peripheral arterial disease, allergy to calcium alginate or manuka honey, and current honey treatment.

Intervention: calcium alginate dressings impregnated with manuka honey (n = 187) or usual care (a range of dressings) (n = 181). All patients received compression bandaging. Honey dressings were changed when compression bandaging was changed.

Outcomes: included complete healing at 12 weeks (defined as complete epithelialisation of ulcer with no scab), time to healing, change in ulcer area, health-related quality of life (Short Form 36 [SF-36] health survey, Charing Cross Venous Ulcer Questionnaire [CXVUQ], and EuroQol 5D [EQ-5D]), infections, and adverse events. The study had 90% power to detect a 30% relative increase in proportion of healed ulcers in the honey-treated group (55% to 71%) at 12 weeks.

Patient-follow up: 98%.

MAIN RESULTS

The honey-treated and usual care groups did not differ for complete healing (table), time to healing (mean difference [MD] –1.8 d, 95% CI −7.7 to 4.1), reduction in ulcer area (MD 8.6%, CI −4.7 to 24), SF-36 scores on physical (MD 1.1, CI −0.8 to 3.0) or mental (MD 0.7, CI −1.1 to 2.4) subscales, overall CXVUQ score (MD −1.6, CI −4.2 to 0.9), EQ-5D visual analogue scale (MD 1.6, CI −1.5 to 4.7), or infections (table). More patients in the honey-treated group reported ⩾1 adverse event and ulcer pain than in the usual care group (table).

CONCLUSION

Honey-impregnated dressings and usual care did not differ for healing venous leg ulcers.

Honey-impregnated dressings *v* usual care for venous leg ulcers*

Outcomes at 12 weeks	Honey	Usual care	RBI (95% CI)	NNT
Complete healing	56%	50%	12% (−8 to 36)	Not significant
			RRR (CI)	
Infections	17%	22%	23% (−17 to 49)	Not significant
			RRI (CI)	**NNH (CI)**
⩾1 adverse event†	59%	46%	30% (10 to 60)	8 (4 to 22)
Ulcer pain†	25%	10%	150% (50 to 320)	7 (4 to 21)

*Abbreviations defined in glossary. RBI, RRR, NNT, and CI calculated from data in article.
†RRI, NNT, and CI calculated from control event rate and relative risk in article.

ABSTRACTED FROM

Jull A, Walker N, Parag V, *et al*. Randomized clinical trial of honey-impregnated dressings for venous leg ulcers. *Br J Surg* 2008;**95**:175–82.

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► **Clinical impact ratings:** Wound care 6/7

COMMENTARY

Compression therapy is the mainstay of treatment for venous leg ulceration.[1] No evidence exists that dressings influence the rate of ulcer healing,[2] and the Royal College of Nursing[3] recommends the use of simple low-adherence dressings in combination with compression therapy. The trial by Jull *et al* evaluated the safety and effectiveness of honey dressings for venous ulcers. This is one of the largest leg ulcer studies and has several strengths. Patients were allocated to treatment groups by telephone randomisation, thereby eliminating selection bias. In addition, honey dressings were compared with usual care, and because usual care was adapted to meet specific wound or patient needs, the comparison between treatments was fair. Blinded outcome assessment was achieved with photographic evaluation of wound healing by an individual who was unaware of patient group assignments. The results showed that honey dressings did not improve venous ulcer healing at 12 weeks. Although these findings are in congruence with previous findings, several points should be considered when appraising their clinical importance. The sample size calculation was based on detecting a 30% relative increase in the proportion of healed ulcers in the intervention group at 12 weeks, which was derived from honey trials in patients with burns. However, Jull *et al* argued that one cannot extrapolate findings from acute wounds to chronic wounds. Almost 50% of uncomplicated venous leg ulcers will heal after 12 weeks.[4] The 50% that remain are the most challenging, and thus, it is difficult to justify the expectation that a topical treatment will improve healing rates from 55% to 71%. Jull *et al* reported that ulcer pain was greater in the honey group, yet it is unclear how or when this was assessed. Clinically, no new evidence exists to show that topical dressings help heal to ulcers more quickly, reiterating the importance of compression therapy as the gold standard of treatment.

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