



Best evidence topic

Medical grade honey in the management of chronic venous leg ulcers

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ABSTRACT

A best evidence topic in vascular surgery was written according to a structured protocol. The question addressed was: In patients with chronic venous leg ulcers (CVLU), does the use of medical grade honey as compared to standard wound therapy improve clinical outcomes?

A total of 299 papers were identified using the search protocol described, of which five represented the best evidence available to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated.

Two randomised controlled trials arrived at contradictory conclusions: one showing better outcomes for CVLU healing with use of honey over standard wound therapy and the other showing equivalent outcomes but more adverse effects. A third randomised controlled trial showed a non-significant reduction in bacterial colonisation of CVLU with honey compared to standard therapy. Two further studies – a prospective cohort study and a case series – supported the use of honey, but these were of lower grade evidence and had numerous methodological faults.

Therefore, the clinical bottom line is that there is no conclusive evidence that honey improves outcome in patients with CVLU, and until more robust trials are conducted, its benefit should be considered unproven.

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1. Introduction

A best evidence topic in vascular surgery was constructed according to a structured protocol, as described by the International Journal of Surgery [1].

2. Clinical scenario

A patient on your vascular ward has a chronic venous leg ulcer that is not healing with traditional compression bandage therapy. You are keen to try an alternative treatment and you have heard honey impregnated dressings can be of benefit, although you are unaware of evidence supporting this therapy, so you opt to consult the literature.

3. Three-part question

In [patients with chronic venous leg ulcers], does the use of

[medical grade honey] as compared to [standard wound therapy] improve [clinical outcomes]?

4. Search strategy

Search strategy using Medline from 1946 to August 2014 using the PubMed interface: (manuka OR medi*) AND (honey) AND (wound OR ulce* OR dressing OR venous OR vascular OR surgery OR treatment OR healing OR non-healing OR "non healing").ti.ab. The search was duplicate filtered. Reference lists of key articles were also searched for more references.

5. Search results

A total of 299 papers were found using the reported PubMed search. False positives, case reports and review articles were removed outright and both authors screened the remaining abstracts. Included studies investigated the use of medical grade honey (Manuka or otherwise) to improve outcomes compared to the non-use of honey (referred to hereon in as 'standard wound therapy'). Five articles represented the best evidence of answer the clinical question. We identified three randomised controlled trials

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Table 1
Best evidence papers.

Author, date, country and study type (level of evidence)	Patient group	Outcomes	Key results	Comment
Jull et al. [3] 2008 Br. J. Surg. New Zealand Randomised controlled trial (Level 2 evidence)	368 patients with CVLU treated with MGH or SWT MGH <i>n</i> = 187 SWT <i>n</i> = 181	Percentage healed at 12 weeks (MGH vs. SWT) Reduction in ulcer size (MGH vs. SWT) Mean time to heal (days) (MGH vs. SWT) Incidence of infection (MGH vs. SWT) One or more adverse event (MGH vs. SWT)	55.6% vs. 49.7%, <i>p</i> = 0.258 74.1% vs. 65.5%, <i>p</i> = 0.186 63.5 vs. 65.3, <i>p</i> = 0.553 17.1% vs. 22.1%, <i>p</i> = 0.228 59.3% vs. 46.4%, RR 1.3, 95% CI 1.1–1.6, <i>p</i> = 0.013	This open-label, multicentre RCT was the most methodologically robust of the five papers. This trial concluded that there is no considerable benefit in adding MGH to usual wound care, with negligible differences in three of the four clinical outcomes. Furthermore, the study in fact reported that honey was more expensive and that there was a significantly increased rate of 'one or more adverse events' associated with honey use, primarily pain. However, it is not clear how severe or long lasting the pain was. This otherwise rigorous study was limited by non-standardisation of compression dressings (this was left to nurse choice) and the non-blinding of the nurses involved with wound care, thus potentially introducing measurement bias.
Gethin et al. [4] 2009 J. Wound Care Ireland Randomised controlled trial (Level 2 evidence)	108 patients with CVLU treated with MGH or SWT MGH <i>n</i> = 54 SWT <i>n</i> = 54	Percentage healed at 12 weeks (MGH vs. SWT) Reduction in ulcer size at 12 weeks (MGH vs. SWT) Desloughing efficacy at four weeks (MGH vs. SWT) Adverse effects (MGH vs. SWT) Withdrawal from therapy (MGH vs. SWT)	44% vs. 33%, <i>p</i> = 0.03 34% vs. 13%, <i>p</i> < 0.001 Not significant, <i>p</i> = 0.367 0% vs. 0% 0% vs. 0%	This open-label, multicentre RCT showed healing outcomes were improved when MGH was added to wound therapy, but that MGH did not provide superior desloughing efficacy as compared to SWT. This trial compared two specific treatment strategies, but was limited by that fact that the authors failed to accrue the predetermined number of participants; had more patients been recruited, then further clinical benefits may have been demonstrated.
Gethin et al. [5] 2008 J. Clin. Nurs. Ireland Randomised controlled trial (Level 2 evidence)	108 patients with CVLU treated with MGH or SWT MGH <i>n</i> = 54 SWT <i>n</i> = 54	MRSA prevalence by week four (MGH vs. SWT) <i>P. aeruginosa</i> prevalence by week four (MGH vs. SWT)	30.0% vs. 83.3% (not significant, <i>p</i> > 0.05) 66.7% vs. 50.0% (not significant, <i>p</i> > 0.05)	This RCT illustrates the superior efficacy of MGH at eliminating MRSA from CVLUs when compared to SWT (although statistical significance was not achieved). The converse was true for <i>P. aeruginosa</i> . The main weakness of this trial is the small number of patients with these bacteria – larger trials of MRSA positive patients are warranted and until such time the results of this study should be interpreted with caution. Again, investigators were not blinded, but the authors explained the rationale behind this: MGH unmistakably stains wounds orange.
Dunford et al. [6] 2004 J. Wound Care United Kingdom Non-randomised cohort study (Level 3 evidence)	40 patients with CVLU treated with MGH MGH <i>n</i> = 40	Reduction in ulcer size (MGH; decrease vs. increase) Pain after 12 weeks (MGH; decrease vs. increase) Odour after 12 weeks (MGH; decrease vs. increase) Overall satisfaction (MGH; decrease vs. increase)	100% vs. 0% 50% vs. 27.5% 52.5% vs. 7.5% 17.5% vs. 82.5%	This prospective study showed that MGH was acceptable to most patients and generally improved self-rated clinical outcomes. However, a minority (27.5%) of patients reported increased pain with MGH. The value of this study is reduced by the use of subjective rather than objective criteria for a number of outcomes. Wound area, an example of objective criteria, was not tabulated effectively. An obvious weakness of this study was the lack of control group.
Schumacher [7] 2004 J Wound Care United Kingdom Case series (Level 4 evidence)	Six patients with CVLU treated with MGH MGH <i>n</i> = 6	Mean time to heal (days) (MGH) Complications (MGH)	22 (range: 4–54) None	This study suggests MGH dressings are associated with good outcomes. However it is greatly limited by its small number of highly selected patients and lack of control group for comparison. The authors compared their results with those of other previously published studies, however important methodological differences mean that such comparisons are of highly limited value.

CVLU = chronic venous leg ulcer, MGH = medical grade honey, MRSA = Methicillin-resistant *Staphylococcus aureus*, *P. aeruginosa* = *Pseudomonas aeruginosa*, RCT = randomised controlled trial, SWT = standard wound therapy.

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