A pragmatic randomised controlled trial of granulated sugar dressing in the management of sloughy necrotic exuding wounds.

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Background literature

- Hersage et al (1980) reported 99.2% cure using simple granulated sugar in 120 patients.
- Treatment of infection by wound dressing with honey & molasses dates back to ancient Egyptians.
De Feo et al (2003) compared granulated sugar with wound debridement on 25 patients with severe recurrent staphyloccocal mediastinitis. Total cure was noted on patients using granulated sugar.

Mpande & colleagues (2007) compared granulated sugar & honey on exuding wounds - not much difference
Infected open wounds are inherently painful, malodorous & disabling for pts

Impose significant burden to hospital & community health services

The National health burden is around £2.3-£3.1 billion per year (Posnett & Fanks 2007)
The aim of this study was to determine the effectiveness of granulated sugar therapy compared with standard autolytic debridement dressings in sloughy, necrotic or exudating wounds.
Methods

- A pragmatic multicentre open RCT with equal randomisation
- Site: three centres in the United Kingdom from June 2010 to June 2013.
Methods continued

- Participants were recruited from the vascular surgery wards and leg ulcer clinics of two acute NHS hospitals and one community NHS hospitals including patients receiving home treatments.
- Randomisation was stratified by wound size and type (chronic or acute).
<table>
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<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<td>Wounds were between 5 cm² and 40 cm² in area, with at least 25% of the wound</td>
<td>Patients who had arterial brachial pulse index (ABPI) less than 0.6, pregnant</td>
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<td>covered in by slough or exuding necrotic tissue.</td>
<td>patients and patients whose wounds had necrotic eschar were excluded.</td>
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<td>Ankle Brachial Pressure Index (ABPI) of greater than 0.6</td>
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<td>Diabetic and non-diabetic patients were included.</td>
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In the intervention group, wounds and the surrounding area were cleaned and dabbed dry with sterile gauze.

Yellow paraffin or ordinary Vaseline was then applied around the wound area to hold excess sugar.

The wound was dusted with granulated sugar until fully covered with no visible open area (approximately 1 to 2 mm thickness of granulated sugar).
A dressing pad was applied over the sugar and secured with surgical tape and bandage.

Dressings were changed everyday or every other day or as decided by the nurse.
Control group

- Dressing procedure followed a similar process to that explained above, except that participants received debridement agents (Alginate/Sorbsan Ribbon; Hydrofibre/Aquacel or Actisorb Silver), rather than sugar.
- Frequency - mainly every other day or after three days.
In both arms, patients with leg ulcers had adjuvant treatment with compression bandage in addition to their assigned wound care products.

Those with pressure ulcers were treated with appropriate pressure relieving methods.
Methods continued

- Intervention and control treatments were applied in the debridement phase: this ended either when debridement occurred or when treatment was stopped before debridement (withdrawal from the trial).
Methods continued

- Following debridement (as determined by the treating nurse) all participants received appropriate available trust formulary non-debriding dressings decided by the treating nurse.
Primary outcome

- The rate of wound debridement at four weeks, as determined using the TELER indicator system.
- Wounds scores of 0 to 5, with 0 indicating a deep necrotic offensive, infected wound, down to bone and 5 unbroken healthy skin.
Primary outcome

- We classified wounds with scores between 3 and 5 as debrided.
- Clinical evaluation and comments of doctors and nurses during ward rounds was utilised.
Secondary outcomes

- Wounds assessed at four weeks and included: reduction in wound area ($cm^2$), wound exudate leakage and wound appearance, pain, odour, percentage of slough and health related of quality of life.

- Wound area was measured weekly by the attending nurse using flexible wound dressing tape supplied with the dressing pack.
Wound photographs

- Wounds were photographed by a trained nurse or lead researcher using a simple digital camera as part of baseline data.
- Further photographs were taken weekly and on the day the wound was agreed to have been debrided.
Method of Application

Aliquotes containing 15g & 30g sugar

Sugar in place ready to be secured by appropriate dressings

Sugar secured in place

M.D. Murandu
Nurses also reported any potential adverse events, categorising them as:
- serious (death, life threatening event, admission to hospital in case of outpatient and home treatment),
- persistent or significant disability or incapacity) or non-serious (infection and deterioration of wound).
Ethical issues

- Medicine & Health Regulatory Authority (MHRA) approval obtained June 2008.
- Local Ethical Approval & Trust Approval obtained
- Each patient gave informed consent to take part and have their wound photographed
The original sample size calculation was based on time to debridement and powered on a proportional hazards survival analysis model.

The median times to debridement were assumed to be 11 days in the sugar treatment group, based on the information from a feasibility study and 21 days in the standard treatment group.
Sample size

- To have an 80% power to detect this difference at 5% alpha required 54 participants in each group. It was therefore planned to randomise 108 participants.

Sample size

Sample size

- Gethin G. Seamus C. Manuka honey vs hydrogel – a prospective, open label, multicentre, randomised controlled trial to compare desloughing efficacy and healing outcomes in venous ulcers. Journal of Clinical Nursing 2008; 18: 466-474
Results

- Forty one participants were randomised, 22 to sugar and 19 to standard dressings. Median age was 66 years (IQ range: 60-77) and 14 (64% were male).
- At baseline, wound characteristics, co-morbidities and wound types were similar in the two groups.
Results

- After four weeks 19 (86%) participants in the sugar group achieved debridement compared to 6 (32%) in the standard care group (Fisher’s exact test: p<0.001).
The sugar group also showed statistically significantly greater improvements in Health Related Quality of Life (30 points on visual analogue scale), wound area (8.9 cm²), percentage covered with slough (63%), exudate appearance, pain interfering with daily activities and pain disturbing sleep.
Discussion

- After four weeks exudating necrotic or sloughy wounds treated with sugar dressing were nearly three times more likely to be debrided than those treated with standard dressings.

- Reported was reduction in wound pain and an associated improvement in quality of life with no apparent adverse effects.
Discussion

- **Strengths**
- Stratification of wounds by size and aetiology.
- Carried out in more than one centre
- Allocation was concealed using a central telephone randomisation service and outcomes were assessed independently.
Discussion

- Limitations / weaknesses
- The small size of the study
- The relatively short period of follow up
- Non-blinded assessment of outcome
- The change in method of analysis from time to event to proportion debrided at four weeks.
Discussion

- Despite increasing the number of research sites included and extending the recruitment period the sample study did not recruit enough participants.
- Funding limitations prevented follow up for longer than four weeks.
Sugar dressings are more effective than standard dressings at achieving debridement in patients with exudating necrotic or sloughy wounds.
References

- 21:24; 57-66
References cont.

- Grocott P. Assessment of fungating malignant wounds. J Wound Care 1995; 4(7); 333-36.
- Gethin G. Seamus C. Manuka honey vs hydrogel – a prospective, open label, multicentre, randomised controlled trial to compare desloughing efficacy and healing outcomes in venous ulcers. Journal of Clinical Nursing 2008; 18: 466-474