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Clarification of statements made about results of the HALT trial

Statements that have been made about the results of the HALT trial on honey carried out on honey dressings on venous leg ulcers (e.g. "Treating venous leg ulcers with honey dressings unlikely to help healing") give the impression that the results were negative. The reality is that the results were inconclusive, not negative. Honey gave better results than the standard treatment:

- Comparing the participants in the honey-treated group with those in the usual care group there was a 5.9% absolute increase in healing achieved at 12 weeks
- The mean reduction from baseline ulcer area was 9.6% better in the honey-treated group compared with that in the usual care group
- There were 23% fewer episodes of infection in the honey-treated group compared with those in the usual care group

However, statistical analysis showed that these differences could have been due to chance so it cannot be concluded with certainty that honey gave better results. With the number of participants in the trial it would have required a 30% difference in the rate of healing to be achieved for the difference to be statistically significant. To get statistical significance with a smaller difference would have required a larger sample size (e.g. for a 10% difference 1,030 participants would be required), which would have greatly increased the costs of the trial.

Many other trials conducted on honey as a wound dressing have found larger increases in the rate of healing, but in these trials there was not a second treatment used in conjunction with the honey that would have made the wounds heal quickly anyway. The HALT trial was designed to test if honey gave improvement in the rate of healing when used along with compression bandaging for treatment of leg ulcers. (HALT = Honey as an Adjuvant in Leg ulcer Therapy.) Other clinical trials conducted on leg ulcers have shown that the dressings used make no difference: only pressure bandaging has been found to be effective. Since all participants in the HALT trial got pressure bandaging, the ulcers would in most cases be expected to heal, leaving little scope for improvement due to honey showing up as statistically significant.

Venous leg ulcers remain non-healing because of the stagnation of blood-flow. Using compression bandaging prevents this stagnation and thus removes this impediment to healing. With non-healing wounds other than venous ulcers healing cannot be achieved with pressure bandaging because the

impediments to healing are different (e.g. infection of the wound, or diabetes). It is on these that honey will give rapid healing when no other treatment is working. In some cases with venous ulcers, compression does not give healing because there are other impediments to healing as well as the stagnation of the blood-flow. Case studies have shown honey to be effective on these, and on cases where pressure bandaging could not be used on venous ulcers. The participants in the HALT trial were routine cases of leg ulcers.

Although the statements published about the findings of the HALT trial give the impression that there is no proven advantage in using honey dressings on leg ulcers, this is only in respect of the healing rates achieved. An important point that has not been made is that specialist knowledge is required to choose a conventional dressing appropriate for the state of the ulcer, but honey dressings can be used on any ulcer at any stage. Use of a conventional dressing that is not appropriate for the state of the ulcer can hinder healing or cause complications, but this cannot happen when honey dressings are used.

The statements published also give the impression that treatment with honey dressings was more expensive than with usual care, and that honey dressings gave more adverse events. The reality is that the HALT trial found:

- The average costs of treatment with honey per participant were 5.8% lower in the honey-treated group with those in the usual care group if also taken into account is the cost of six participants needing to be hospitalised, for a total of 40 days, in the usual care group compared with only three participants needing to be hospitalised, for a total of 10 days, in the honey-treated group
- The only statistically difference between the two groups in adverse events was in respect of pain. But although 47 participants in the honey-treated group reported one or more episodes of pain as an adverse event (compared with 18 in the group with the usual dressings), only four participants gave pain as the rationale for withdrawing from treatment, suggesting the pain is short-lived and/or tolerable.

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