INAHTA Briefs

Issue 2011/039

Title **Venus III: A Randomized Controlled Trial of Therapeutic Ultrasound in the Management of Venous Leg Ulcers**

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Reference Volume 15.13. ISSN 1366-5278. www.hta.ac.uk/project/1451.asp

Aim

To compare the clinical and cost effectiveness of low-dose ultrasound delivered in conjunction with standard care against standard care alone in treating hard-to-heal venous ulcers.

Conclusions and results

Regarding the median time to complete ulcer healing of all ulcers, we found a small, and statistically not significant, difference in favor of standard care (median 328 days, 95% confidence interval [CI] 235 days, inestimable) compared to ultrasound (median 365 days, 95% CI 224 days, inestimable). The groups did not differ in the proportion of patients with ulcers healed at 12 months (72/168 in ultrasound vs 78/169 standard care), nor in the change of ulcer size at 4 weeks. No evidence indicated a difference in recurrence of healed ulcers. The two groups did not differ in HRQoL (measured using the Short Form questionnaire-12 items). More adverse events were associated with ultrasound than with standard care. Ultrasound therapy as an adjuvant to standard care was found not to be cost effective when compared to standard care. The mean cost of ultrasound was 197.88 pounds sterling (GBP) (bias-corrected 95% CI – GBP 35.19 to GBP 420.32) higher than standard care per participant per year. We found a significant relationship between ulcer healing and area and duration at baseline. In addition, centers with high recruitment rates had the highest healing rates. Low-dose ultrasound, delivered weekly during dressing changes, added to the package of current best practice (dressings, compression therapy) did not increase ulcer healing rates, affect quality of life (QoL), or reduce recurrence. It was associated with higher costs and more adverse events. We found no evidence that adding low-dose ultrasound to standard care for hard-to-heal ulcers aids healing, improves QoL, or reduces recurrence. It increases costs and adverse events. The relationship between ulcer healing rates and patient recruitment is worthy of further study.

Recommendations

See Executive Summary link www.hta.ac.uk/project/1451.asp.

Methods

Design: A multicenter, pragmatic, parallel, two-armed randomized controlled trial with an economic evaluation. Allocation was concealed, treating nurses and patients were aware of allocation, and outcome assessment was by treating-nurse report confirmed by blinded review of photographs at healing and 7 days later. Setting: Community nurse services; community leg ulcer clinics; hospital outpatient leg ulcer clinics, among both urban and rural settings in England, Scotland, Northern Ireland, and Ireland. Participants: Patients were eligible to participate in the trial if they presented with a venous leg ulcer of >6 months' duration or >5 cm^2 and an ankle-brachial pressure index of ≥0.8. Interventions: Participants in the intervention group received low-dose ultrasound (0.5 W/ cm^2) delivered at 1 MHz, pulsed pattern of 1:4, applied to periulcer skin weekly for up to 12 weeks alongside standard care. Standard care consisted of low-adherent dressings and compression therapy, renewed as recommended by the patient's nurse and modified if required to reflect changes in ulcer and skin condition.

Further research/reviews required

We identified large variation in healing rates by trial centers, with centers recruiting more patients to the trial having higher healing rates. We controlled for ulcer area and duration; hence, it is unlikely that the difference in healing rates could be attributed to these prognostic factors being distributed differently across sites (ie, larger/old ulcers in one site). The relationship between ulcer healing rates and patient recruitment is worthy of further study.

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