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Therapeutic ultrasound for venous leg ulcers

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Review

Intervention

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Abstract

English

Background

Venous leg ulcers are a type of chronic, recurring, complex wound that is more common in people aged over 65 years. Venous ulcers pose a significant burden to patients and healthcare systems. While compression therapy (such as bandages or stockings) is an effective first-line treatment, ultrasound may have a role to play in healing venous ulcers.

Objectives

To determine whether venous leg ulcers treated with ultrasound heal more quickly than those not treated with ultrasound.

Search methods

We searched the Cochrane Wounds Specialised Register (searched 19 September 2016); the Cochrane Central Register of Controlled Trials (CENTRAL; the Cochrane Library 2016, Issue 8); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations, MEDLINE Daily and Epub Ahead of Print) (1946 to 19 September 2016); Ovid Embase (1974 to 19 September 2016); and EBSCO CINAHL Plus (1937 to 19 September 2016). We also searched three clinical trials registries and the references of included studies and relevant systematic reviews. There were no restrictions based on language, date of publication or study setting.

Selection criteria

Randomised controlled trials (RCTs) that compared ultrasound with no ultrasound. Eligible non-ultrasound comparator treatments included usual care, sham ultrasound and alternative leg ulcer treatments.

Data collection and analysis

Two authors independently assessed the search results and selected eligible studies. Details from included studies were summarised using a data extraction sheet, and double-checked. We attempted to contact trial authors for missing data.

Main results

Eleven trials are included in this update; 10 of these we judged to be at an unclear or high risk of bias. The trials were clinically heterogeneous with differences in duration of follow-up, and ultrasound regimens. Nine trials evaluated high frequency ultrasound; seven studies provided data for ulcers healed and two provided data on change in ulcer size only. Two trials evaluated low frequency ultrasound and both reported ulcers healed data.

It is uncertain whether high frequency ultrasound affects the proportion of ulcers healed compared with no ultrasound at any of the time points evaluated: at seven to eight weeks (RR 1.21, 95% CI 0.86 to 1.71; 6 trials, 678 participants; low quality evidence - downgraded once for risk of bias and once for imprecision); at 12 weeks (RR 1.26, 95% CI 0.92 to 1.73; 3 trials, 489 participants; moderate quality evidence - downgraded once for imprecision); and at 12 months (RR 0.93, 95% CI 0.73 to 1.18; 1 trial, 337 participants; low quality evidence - downgraded once for unclear risk of bias and once for imprecision).

One trial (92 participants) reported that a greater percentage reduction in ulcer area was achieved at four weeks with high-frequency ultrasound, while another (73 participants) reported no clear difference in change in ulcer size at seven weeks. We downgraded the level of this evidence to very low, mainly for risk of bias (typically lack of blinded outcome assessment and attrition) and imprecision.

Data from one trial (337 participants) suggest that high frequency ultrasound may increase the risk of non-serious adverse events (RR 1.29, 95% CI 1.02 to 1.64; moderate

quality evidence - downgraded once for imprecision) and serious adverse events (RR 1.21, 95% CI 0.78 to 1.89; moderate quality evidence downgraded once for imprecision).

It is uncertain whether low frequency ultrasound affects venous ulcer healing at eight and 12 weeks (RR 3.91, 95% CI 0.47 to 32.85; 2 trials, 61 participants; very low quality evidence (downgraded for risk of bias and imprecision)).

High-frequency ultrasound probably makes little or no difference to quality of life (moderate quality evidence, downgraded for imprecision). The outcomes of adverse effects, quality of life and cost were not reported for low-frequency ultrasound treatment.

Authors' conclusions

It is uncertain whether therapeutic ultrasound (either high or low frequency) improves the healing of venous leg ulcers. We rated most of the evidence as low or very low quality due to risk of bias and imprecision.

Plain language summary

English

Can ultrasound therapy help to heal venous (varicose) leg ulcers and/or improve symptoms?

What are venous leg ulcers, and who is at risk?

Venous leg ulcers are common wounds caused by damage or blockages in leg veins. This leads to pooling of blood and increased pressure in these veins. Eventually these changes can damage the skin and underlying tissue and form a long-lasting wound, or ulcer. These ulcers can be painful and leak fluid. They can also become infected. People at risk of developing venous leg ulcers include the elderly and those with mobility problems. They can be distressing for patients and costly to healthcare systems.

Why use ultrasound to treat leg ulcers?

Treatments for venous leg ulcers include compression bandages, which improve blood-flow in the legs, wound dressings, and medication such as antibiotics. Ultrasound therapy is sometimes used as an additional intervention, especially for difficult, long-standing ulcers. Sound waves are passed through the skin causing the tissue underneath to vibrate. The mechanisms by which ultrasound waves interact with healing tissues are not fully understood; they may have a positive or negative impact on the blood flow around the ulcers. We wanted to discover whether using ultrasound therapy can improve the healing of leg ulcers.

What we found?

In September 2016 we searched for randomised controlled trials (RCTs) that investigated whether ultrasound helps to heal or improves the symptoms of venous leg ulcers. We found 11 trials involving a total of 969 participants. The average (mean) age of participants ranged from 59 years to 70 years. The proportion of female participants ranged from 55% to 79%. Eight studies compared ultrasound with use of no ultrasound for venous leg ulcers and the other three compared ultrasound with sham ultrasound. Seven out of the eleven studies were at high risk of bias and we could not assess the potential bias in three studies due to poor reporting. One study was at low risk of bias.

The trials were all different, for example in their duration of follow-up (three weeks to 12 months), and the strength of the ultrasound waves used (high or low frequency ultrasound). It is not clear from this evidence whether ultrasound (high or low frequency) increases the healing of venous leg ulcers. The results of one study (337 participants) suggest that high-frequency ultrasound may be associated with more adverse events such as pain and skin redness (moderate quality evidence). The two studies that evaluated low-frequency ultrasound did not report whether participants experienced side effects. It is also uncertain whether either high- or low-frequency ultrasound affects participants' quality of life.

Quality of the evidence

Most of the studies we found did not have many participants, had short follow-up times and had weaknesses of study design that meant they were quite likely to give a misleading result. We consider the available evidence to be low quality due to these risks of bias.

This plain language summary is up to date as of September 2016.

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