Adding topical pale sulfonated shale oil to compression therapy and moist wound care reduced venous leg ulcer size but had no effect on complete wound healing after 20 weeks

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_Evid. Based Nurs._ 2006;9;86-
doi:10.1136/ebn.9.3.86

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Does topical application of pale sulfonated shale oil (PSSO) in addition to usual care with compression therapy and standard moist wound care improve healing of venous leg ulcers?

METHODS

- Design: randomised controlled trial.
- Allocation: (concealed) *
- Blinding: blinded (patients, healthcare providers, data collectors, and outcome assessors). *
- Follow up period: to the end of the 20 week treatment period.
- Setting: 13 outpatient wound clinics in Germany and Slovakia.
- Patients: 119 patients >18 years of age (mean age 69 y, 67% women) who had leg ulcers >=3 cm² caused by chronic venous insufficiency. Exclusion criteria were severe cardiac, respiratory, gastrointestinal, liver, or renal disease; malignancy; signs of wound infection; and pregnancy or lactation.
- Intervention: 10% Leukichtan PSSO gel (Ichthyol-Gesellschaft, Germany) (n = 62) or placebo gel (n = 57). Both gels were applied daily as a 2–2.5 mm thick layer directly onto the wound surface and covered by a non-adherent gauze dressing (Jelonet, Smith & Nephew Medical, Germany). Compression therapy was applied using short stretch elastic bandages.
- Outcomes: included ulcer area, relative reduction in ulcer area, complete healing (ie, complete epithelialisation), pain scores (10 cm visual analogue scale, 0 = no pain to 10 = maximum pain), and adverse events.
- Patient follow up: 85% of patients completed the trial (100% were included in the intention to treat analysis).

*Information provided by author.

MAIN RESULTS

At 20 weeks, patients in the PSSO group had smaller ulcers (6.2 v 10.8 cm², p<0.001) than the usual care group and greater relative reductions in ulcer area (72% v 19% reduction, p<0.001). The groups did not differ for patients with complete healing of ulcers (34% v 23% (relative benefit increase 49%, 95% CI –16 to 169)*), pain scores (1.8 v 2.6), or adverse events (12% v 11%).

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Source of funding: no external funding.

CONCLUSION

The addition of pale sulfonated shale oil gel to compression therapy and standard moist wound care in patients with venous leg ulcers resulted in smaller ulcers and greater relative reductions in ulcer size but had no effect on complete healing of ulcers after 20 weeks of treatment.

*Calculated from data in original article.

Commentary

The mainstay of treating venous leg ulcers is compression therapy, and there is no clear evidence that wound dressings or topical agents increase healing.¹ The trial by Beckert et al compared a vehicle gel with pale sulfonated shale oil—as opposed to the dark preparation, ichthammol, which has been used in leg ulcer care for many years. The trial population had larger ulcers than has been reported in many trials (ie, mean 13 cm²) but otherwise reflects patients with leg ulceration seen by many nurses. Importantly, investigators used a centralised randomisation service to conceal allocation and minimised performance bias by using a vehicle (placebo) gel so that clinicians treated the 2 groups alike.

All patients had short-stretch compression bandages and simple dressings throughout the trial, which is standard care in many settings. Interestingly, the gel and bandages were reapplied daily, in contrast to the weekly dressing changes that are standard in many countries. This suggests that carers or patients may have applied the bandages, which would differ from many countries in which dressing application is a nursing role. The frequency of application is important because application more than once per week is not standard practice in some countries; moreover, daily dressings may not be cost effective. The possibility also exists that compression bandages applied by patients or carers may not be as effective as professionally applied compression. The low healing rate in this trial (29% at 20 wks) may be related to the area of ulceration, as suggested by the authors, and/or the level of compression.

Key findings are that at 20 weeks, no differences were found in the number of ulcers healed, but overall, ulcers in the PSSO group were smaller. Pain levels and adverse events did not differ between groups. It is unclear whether patients benefit from reductions in ulcer area if the ulcer does not progress to healing. Area of ulceration may predict ulcer healing, but this trial offers weak evidence that PSSO accelerates ulcer healing. A larger trial with longer follow up is needed to determine whether PSSO heals more ulcers more quickly than usual care. It is of note that ulcers in the PSSO group were slightly larger and had been open for slightly longer than those in the control group, and this could have disadvantaged the PSSO group. This difference is likely a result of chance given the small sample size.

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