Pale sulphonated shale oil reduces the size of venous ulcers

Research question Does pale sulphonated shale oil help to heal venous ulcers?

Answer Possibly. Pale shale oil helps to reduce the surface area of ulcers compared with compression alone but may not increase the chance of cure.

Why did the authors do the study? Pale sulphonated shale oil is an established treatment for inflammatory skin conditions such as psoriasis and eczema. Experiments in vitro and in vivo suggest the oil may have beneficial effects on wound healing. These authors wanted to test it formally as a topical treatment for venous ulcers. Venous ulcers are common and notoriously hard to treat.

What did they do? 119 German and Slovakian patients took part in a randomised controlled trial comparing compression therapy alone with compression therapy plus pale shale oil for venous ulcers. All participants had ulcers caused by chronic venous insufficiency with a surface area of at least 3 cm². They were treated for 20 weeks with standard compression therapy plus a gel containing 10% pale sulphonated shale oil or standard compression therapy plus the vehicle (gel) only. The manufacturers of the active gel sponsored the trial, which was only single blind. The researchers who measured the surface area of the ulcers using photoplanimetry were unaware of treatment allocation.

After 20 weeks, the authors looked for differences between the groups in the size of the ulcers (relative reduction in surface area) and healing (complete epithelialisation). All analyses were intention to treat. The groups were comparable at baseline, except that patients allocated shale oil were heavier than those allocated the vehicle only.

What did they find? Venous ulcers treated with shale oil were 72% smaller at the end of the trial, shrinking from a mean of 15 cm² to a mean of 6.2 cm². Control ulcers shrank from a mean of 11.4 cm² to a mean of 10.8 cm² ($P = 0.0005$ for comparison with active treatment). A significant difference between the groups appeared after about six weeks' treatment and persisted until the end of the trial. Venous ulcers treated with the shale oil were also more likely to granulate and to heal completely than control ulcers, although the difference was not significant (21/62 (34%) completely healed *v* 13/57 (23%) in the control group, $P = 0.177$). Two patients in each group developed eczema and pruritis.

What does it mean? The patients in this study had large, chronic venous ulcers with an average surface area of 26 cm² and 17 cm² in the treatment and control groups respectively. Such ulcers can seriously affect patients' quality of life, so this study is encouraging. The authors were disappointed that the shale oil had no significant effect on the chance of complete healing. But healing rates were relatively low overall, and the trial relatively small and brief. Shale oil has anti-inflammatory and antibacterial properties, making an effect on wound healing biologically plausible. The treatment seemed safe in this trial but both the risks and benefits will need to be confirmed.

Beckert S. Efficacy of topical pale sulfonated shale oil in the treatment of venous leg ulcers: a randomized controlled, multicenter study. *J Vasc Surg* 2006;43:94-100

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Editor's choice

Living dangerously

Making life safer encourages us to live more dangerously. That's the message (well known to risk analysts) of the article by Michael Cassell and colleagues in this week's *BMJ* (p 605). Risk compensation has been seen with sunscreens (encouraging more time in the sun) and seatbelts (bad driving), and is now a growing problem among people at risk of HIV. This "horse trading" in risk is most frighteningly illustrated by reports of people relying on pre-exposure or post-exposure use of antiretrovirals to protect them from infection.

Unless we link prevention with initiatives to change behaviour, as has been done successfully in Uganda and elsewhere, drug resistant HIV will continue to spread, say Cassell et al. Efforts to contain drug resistance include intensive laboratory monitoring of antiretroviral treatment. But this is beyond the means of health systems in developing countries—the very places where prolonging the usefulness of cheaper first line drugs is most critical. Serena Koenig and colleagues argue that this lack of resource for monitoring antiretroviral treatment should not delay us making the drugs more widely available (p 602). Instead they recommend focusing efforts on meticulous adherence to treatment, which has been shown to be the most important factor in delaying drug resistance.

Can public-private collaboration help? Puneet Dewan and colleagues conclude that it has been effective in improving control of tuberculosis in India (p 574). But Angus Wallace (p 614) is deeply troubled by what he sees happening with private provision in the NHS. He gives a measured account, recognising some of the benefits of this "much needed development" but then describing a catalogue of problems: inadequate supervision of junior surgeons in independent sector treatment centres (ISTCs); lack of training opportunities in routine surgical procedures in the NHS; the artificial divide between the two, aimed to prevent NHS surgeons working in ISTCs—all pushed through for political reasons. The news this week of the departure of Nigel Crisp, the chief executive of the NHS (p 565), must raise questions about the current direction and speed of travel of the NHS reforms.

Meanwhile, some things to divert you on bmj.com. There's learning, laughter, and inspiration from this year's TED (technology, entertainment, design) conference in Monterey, California. The world's "thought leaders" gathered to explore the future we will create, and Tony Delamothe was there to hear and report back (<http://bmj.com/cgi/content/full/332/7540/DC1>). You can also now see which content is freely available online (research articles) and should find it easier to get to articles published "online first" (ahead of print)—currently virtually all our research articles. Finally, we have listed of all of you who served as peer reviewers for us in 2005 (<http://bmj.com/advice/reviewers.shtml>). This is one way to thank you for undertaking what must often seem like a thankless task, but without which the *BMJ* could not survive.

Fiona Godlee *editor* (fgodlee@bmj.com)