3 layer paste bandages were more effective than 4 layer bandages for healing venous leg ulcers

Meyer FJ, McGuinness CL, Lagattolla NR, *et al.* Randomized clinical trial of three-layer paste and four-layer bandages for venous leg ulcers. *Br J Surg* 2003;**90**:934–40.

Q Are 3 layer paste bandages as effective as 4 layer bandages for healing of venous leg ulcers?

METHODS

Design: randomised controlled trial.

Allocation: {concealed}*.

Blinding: unblinded.

Follow up period: 1 year.

Setting: a hospital leg ulcer outpatient clinic in London, UK.

Patients: 133 patients (56% men) with venous leg ulcers. Exclusion criteria: arterial disease, diabetes mellitus, rheumatoid arthritis or systemic lupus erythematosus, positive sickle cell test, HIV infection, ulcer area <0.25 cm² or >100 cm², known sensitivity to paste, or ulcer not of venous aetiology.

Interventions: 3 layer paste bandages (a Steripaste® hypoallergenic paste bandage, a Setopress® compression bandage, and a Tubigrip® bandage to hold everything in place) (n=64) or 4 layer bandages (Velband® orthopaedic wool, a crepe bandage, an Elset® compression bandage, and a Coban® bandage to secure preceding layers) (n=69). Fully trained ulcer clinic nurses applied the bandages. Patients were initially seen weekly in clinic, which was extended to fortnightly if the ulcer was healing well. Randomisation was stratified by ulcer size (small ≥0.25 but ≤2.5 cm², medium >2.5 but ≤25 cm², and large >25 but ≤100 cm²).

Outcomes: time to total ulcer healing, complete ulcer healing (restoration of entirely unbroken skin integrity with no purulent discharge after removal of scabs), and time to apply bandages.

Patient follow up: 84%.

*Information provided by author.

MAIN RESULTS

The 3 layer paste group had a shorter median time to healing than the 4 layer group (12 v 16 wks, $p = 0.04$ for log rank test), although the difference in healing rates occurred only after >20 weeks. At 1 year, more patients in the 3 layer paste group had healed ulcers (one

sided $p = 0.031$). Over the course of the study, 3 layer paste bandages took less time to apply than 4 layer bandages (mean 4.6 v 5.5 min, $p = 0.008$).

CONCLUSION

3 layer paste bandages were more effective than 4 layer bandages for healing venous leg ulcers, and healed ulcers more quickly than 4 layer bandages after 20 weeks of treatment.

Commentary

Although we know that compression heals venous ulcers, there is insufficient evidence to recommend a specific high compression system.¹ Meyer *et al* compared 2 high compression, multilayered bandage systems over 12 months. They applied the bandages using a technique to increase ankle pressure: bandages started above the ankle, then encompassed the foot, before proceeding up the leg to the knee.² This is one of few studies to have a sufficient follow up period. The sample appears to be representative of patients with venous ulcers, despite recruiting from a hospital clinic.

Meyer *et al* tried to reduce bias by stratifying randomisation by ulcer area, confirming healing using a third party, doing an intention to treat analysis, and having 2 statisticians independently analyse the data. They also analysed healing by life table, showing not only *how many* ulcers healed, but also *how quickly*. Reporting the proportion of ulcers healed at any point can be misleading (eg, Meyer *et al* found no difference until 20 wks). We now know that stratification should be by both ulcer area and duration, but this evidence was unavailable when this trial started.³ Stratifying by ulcer duration is unlikely to have changed the results because ulcers in the 3 layer group were of longer duration (mean 20 v 15 mo). Meyer *et al* reported no relation between ulcer duration and healing, but their study lacked power to detect such an association (ie, it was too small).

The key message from this study is that high compression bandaging by trained clinic nurses using a 3 layer paste system healed ulcers more quickly than a 4 layer system. However, it is not clear if nurses were more experienced with a 3 layer system before the trial. Given the learning curve associated with bandage application,⁴ an established high compression system may appear to be more effective than a newly introduced system even if no real difference exists in healing rates.

Given the relatively modest size of this trial, these results alone should not influence practitioners to stop using a 4 layer system. Practitioners who are currently using either a 3 layer paste or a 4 layer bandage system, and have acceptable healing rates, should continue with that system.

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2 Dale J, Callam M, Ruckley CV. How efficient is a compression bandage? *Nurs Times* 1983;**79**:49–51.

3 Margolis DJ, Berlin JA, Strom BL. Which venous leg ulcers will heal with limb compression bandages? *Am J Med* 2000;**109**:15–9.

4 Nelson EA, Ruckley CV, Barbenel JC. Improvements in bandaging technique following training. *J Wound Care* 1995;**4**:181–4.

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