Superficial venous surgery plus compression reduced ulcer recurrence in chronic venous leg ulceration


In patients with chronic venous leg ulceration, is superficial venous surgery plus compression more effective than compression alone for improving healing and reducing recurrence of ulcers?

METHODS

Design: randomised controlled trial.
Allocation: concealed.
Blinding: unblinded.
Follow up period: median follow up was 14 months (range 10–23 mo), comprising time from randomisation to healing (for patients with open ulcers) and from healing to recurrence or 12 months.
Setting: 3 leg ulcer clinics in Gloucestershire and north Bristol, UK.

Patients: 500 patients (38% women) who had open venous ulceration (68% of patients) or recently healed (≤0.6 m) venous ulceration (32% of patients) between the knee and malleoli for >4 weeks, ankle brachial pressure index >0.85, and superficial venous reflux alone or mixed superficial and deep venous reflux on duplex imaging. Exclusion criteria included occluded deep veins and inability to give informed consent.

Intervention: surgery plus compression (surgery group, n = 242) or compression alone (n = 258). In both groups, compression comprised weekly multilayer compression bandaging of open ulcers until the ulcer healed. Patients with healed ulcers (both at randomisation and during follow up) were provided with Class 2 elastic stockings.

Outcomes: 24 week ulcer healing rates (among 341 patients with open ulcers) and 12 month ulcer recurrence rates (among 428 patients with healed ulcers).

Patient follow up: 92% (analysis of relevant healing and recurrence rates was by intention to treat).

MAIN RESULTS

The 12 month ulcer recurrence rate was lower in the surgery group than in the compression alone group (table). The groups did not differ for 24 week ulcer healing rates (65% vs 65%, p = 0.85).

CONCLUSION

In patients with chronic venous leg ulceration, venous surgery plus compression was more effective than compression alone for reducing 12 month ulcer recurrence rates.

Leg ulcers affect between 1.5–3.0 per 1000 people in the general population, and most are associated with venous disease. Furthermore, good evidence shows that multilayer, high compression bandaging is effective for promoting venous ulcer healing. However, compression therapy provides only a temporary solution and does not address the underlying problem of incompetent or non-functioning venous valves. Therefore, ulcer recurrence rates are high.

The study by Barwell et al provides evidence that simple venous surgery may prevent venous ulcer recurrence. However, patients in this study were followed up for only 12 months, and longer term data are required. Similarly, surgery may be cost effective because leg ulcers are extremely costly to healthcare systems and patients alike; this hypothesis remains to be tested.

This study will be of particular interest to nurses in primary care, who are either in a position to refer patients for specialist vascular assessment or seek referrals on behalf of patients. Specialist vascular services with Duplex scanning facilities are necessary to implement these findings, and their availability varies widely. Such detailed assessment of potentially eligible patients is important because the study found no significant effect of surgery on recurrence for the subgroup of patients with mixed superficial and total deep vein reflux, and these patients should not be offered surgery. Results of this study, the only randomised controlled trial of surgery for venous leg ulcers, are exciting, and we await longer term follow up data with interest.

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Superficial venous surgery plus compression (surgery) v compression alone in chronic venous leg ulceration*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Surgery</th>
<th>Compression alone</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 month recurrence rates</td>
<td>12%</td>
<td>28%</td>
<td>60% (40 to 73)</td>
<td>6 (5 to 9)</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary; RRR, NNT, and CI calculated from hazard ratio in article.
†NNT refers to number of legs needed to treat.