Clinical prediction guide

A simple model based on wound size and duration predicted healing of venous leg ulcers at 24 weeks


QUESTION: Can a simple prediction rule be derived to identify patients in whom venous leg ulcers will heal within 24 weeks using limb compression bandages?

Design
2 cohort studies—1 for derivation and 1 for validation of the prediction model.

Settings
Derivation was done in a retrospective cohort from a cutaneous ulcer centre in a university hospital in Philadelphia, Pennsylvania, USA. Validation was done in >20 US clinical sites.

Patients
260 patients (mean age 66 y, 61% women, 62% white) were in the derivation cohort, and 219 patients (mean age 62 y, 51% women, 70% white) were in the validation cohort. Inclusion criteria for the derivation set were venous leg ulcer in the area from the mid calf to 1 inch below the malleolus, past or current history of lower leg oedema that had improved with leg elevation, and other venous diseases. Exclusion criteria were ischaemic leg, life expectancy <24 weeks, recent use of immunosuppressive agents, or history of cutaneous vasculitis or neutrophilic dermatoses. 1 wound per person was randomly chosen for study. Multilayered compression bandages were used and changed weekly. Patients who did not complete the assigned treatment were considered to have ulcers that were not healed.

Description of prediction guide
Prognostic factors used in the derivation of the guide were: ulcer area that is >5 cm² and ulcer duration that is >6 months. Other factors such as undermined wound margin, history of ulcer debridement, >50% of wound covered with fibrin, lipodermatosclerosis, and history of ulcer services were not included in the model. This was considered necessary because of the difficulty of measuring these factors and the relative lack of importance of these factors in determining healing.

Main outcome measure
Healed wounds within 24 weeks using the definition of the Wound Healing Society.

Main results
By 24 weeks, ulcers had healed in 65% of patients in the derivation cohort and in 56% of patients in the validation cohort. The table provides percentages of wounds healed for scores of 0, 1, and 2. This model correctly discriminated between ulcers that healed and did not heal within 24 weeks 87% of the time (area under the receiver operating characteristic curve 0.87, 95% CI 0.83 to 0.91).

Conclusion
A simple prediction rule using wound area and duration identified venous leg ulcers that were healed within 24 weeks using limb compression bandages.

Prediction of percentage of venous leg ulcers healed by 24 weeks in derivation and validation cohorts

<table>
<thead>
<tr>
<th>Score</th>
<th>Derivation cohort (95% CI)</th>
<th>Validation cohort (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>93% (87 to 97)</td>
<td>95% (75 to 99)</td>
</tr>
<tr>
<td>1</td>
<td>85% (54 to 76)</td>
<td>73% (62 to 83)</td>
</tr>
<tr>
<td>2</td>
<td>13% (6 to 24)</td>
<td>37% (28 to 45)</td>
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*1 point if a wound is >5 cm² and 1 point if a wound is >6 months old.

COMMENTARY

Although venous leg ulcers occur in up to 1% of the elderly population, there is limited evidence on prognostic factors that influence healing time.1 Margolis et al have developed a simple rule for predicting which venous leg ulcers are likely to heal within 24 weeks of treatment using limb compression bandages and suggest that identification of “hard to heal” ulcers could guide referral to specialist services.

The participants were all from the US and were treated with compression. The findings may differ in other settings.

The results are relevant to nurses caring for patients with leg ulcers, managing leg ulcer services, and researching leg ulcer interventions. The findings allow nurses to provide patients with information on the likelihood that their ulcers will heal within 24 weeks merely on the basis of ulcer duration and size. The study shows that ulcers of ≤6 months duration and ≤5 cm² in area that are treated with compression are highly likely to heal within 24 weeks. Conversely, ulcers of >6 months duration and >5 cm² in area are unlikely to heal within 24 weeks. Complex measurement techniques are unnecessary to ascertain whether an ulcer area is >5 cm², as the authors also show that ulcer length multiplied by ulcer width is an adequate measure of area.

The prediction rule applies to individual ulcers rather than individual people (who may have numerous ulcers). This means that the results might not help to predict whether a patient will be ulcer free in 24 weeks, which is likely to be the most important outcome for patients. Using this approach, those likely to have protracted healing times can be identified and may benefit from the use of other treatments in addition to compression, such as pentoxifylline.2

Ulcer duration and area are key characteristics that should be evenly distributed between treatment groups in randomised trials. Future trials should use strategies such as stratified randomisation to ensure that this happens, and researchers should report the distribution of these variables between groups at baseline.

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Clinical prediction guide EBN Volume 4 January 2001 27