Validation of venous leg ulcer guidelines in the United States and United Kingdom

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of multidisciplinary guidelines for the diagnosis and treatment of venous leg ulcers in both the UK and USA. The process used to develop such guidelines began with a consensus statement based on a literature review, development of algorithms, and a draft guideline for peer review, which resulted in a final guideline.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who were diagnosed and treated for venous leg ulcer disease. Patients were excluded from the study if they were referred to a specialised wound clinic for consultation during the course of the treatment.

Setting
The setting was primary care. The economic study was carried out in the UK and the USA.

Dates to which data relate
The study was undertaken in two different timeframes, before and after April 1997, the date at which distribution of the venous ulcer guidelines began. The duration of the time periods before and after April 1997 was not reported. The price year was not stated.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
In the prospective part of the study, the costing was undertaken prospectively on the same patient sample as that used in the effectiveness study. In the retrospective part of the study, the costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
The sample size seems to have been determined in the planning phase of the study, but no power calculations appear to have been performed. For the retrospective patient selection, the nurses at each site identified patients diagnosed and treated for venous leg ulcers. In the USA, 40 charts were randomly selected from a requested total of 150 patient charts.
In the UK, each surgery was asked to produce 20 records, of which 5 to 6 were randomly selected. Patients for the prospective phase were enrolled if the diagnosis after the nursing assessment was that of a venous leg ulcer.

A total of 160 patients were enrolled in the study. Of these, 80 (40 from the USA and 40 from the UK) were reviewed retrospectively and 80 (40 from the USA and 40 from the UK) prospectively. For the retrospective patients, the median age was 78 years for the UK sample and 71 years for the US sample. The proportions of women were 86% (UK) and 55% (USA), respectively. For the prospective patients, the median age was 77 years for the UK sample and 74 years for the USA sample. The proportions of women were 68% (UK) and 43% (USA), respectively.

**Study design**
This was a comparative study with historical controls. The study was multi-centred and was carried out in both the UK and the USA. The authors did not explicitly state the number of sites. The authors also failed to state the duration of follow-up, although it would appear to have been for one year or less. No loss to follow-up was reported.

**Analysis of effectiveness**
Patients hospitalised, lost to follow-up, or denied treatment were censored. The health outcomes used in the analysis were:

- compliance for ankle-brachial index, compression usage and tracing at first visit;
- the number of visits,
- the healing rates, and
- ulcer size.

Retrospective data were collected using forms that included age, gender, referring diagnosis, date of first visit, ankle-brachial index value, dressings or compressions used, ulcer measurement, and exit date. Prospective data were collected using the Diagnostic and Treatment Algorithm forms, which incorporated questions on predisposing conditions, clinical criteria for venous leg ulcers versus arterial leg ulcers, ankle-brachial index, and contributing non-venous causes. The prospective forms also included questions on underlying conditions, infection, granulating bed, applying appropriate dressing, use of compression, skin management, teaching, and follow-up or maintenance. No appropriate statistical techniques were used to show comparability between the two groups. However, it would appear that the retrospective group had a slightly higher median age than the prospective group and a significantly higher proportion of women.

**Effectiveness results**
In the retrospective group, ankle-brachial index was performed on 36% of the UK patients and 8% of the US patients. This increased to 93% (UK) and 96% (USA), respectively, for prospective patients.

In the retrospective group, compression was used in 55% of UK the patients and 27% of the US patients. This increased to 100% for all UK and US prospective patients.

A significant decrease was noted in the time to healing, (p<0.001), and the number of visits in the US population.

The results for time to healing, ankle-brachial index and compression were also reported for two sub-groups of healing time (less than 12 week and greater than 12 weeks).

The median ulcer size for UK patients with healing times of less than 12 weeks was 1.3 x 1.5 cm² for retrospective patients and 1.5 x 1.5 cm² for prospective patients. The corresponding sizes for US patients were 1.2 x 1.0 cm² (retrospective) and 1.2 x 1.1 cm² (prospective), respectively.

The median ulcer size for UK patients with healing times of greater than 12 weeks was 2.4 x 2.0 cm² for retrospective patients and 1.2 x 1.1 cm² for prospective patients. The corresponding sizes for US patients were 3.0 x 2.5 cm².
(retrospective) and 2.0 x 1.0 cm$^2$ (prospective), respectively.

The healing rates in both the USA and the UK increased following guideline implementation.

The healing rates for ulcers healing in less than 12 weeks were, in the prospective group, 70% in the USA and 65% in the UK. These rates were 23% (USA) and 40% (UK), respectively, in the retrospective group.

The healing rates for ulcers healing in more than 12 weeks were, in the prospective group, 14% in the USA and 30% in the UK. These rates were 18% (USA) and 43% (UK), respectively, in the retrospective group.

The healing rates for ulcers healing in less than one year were, in the prospective group, 84% in the USA and 95% in the UK. These rates were 40% (USA) and 83% (UK), respectively, in the retrospective group.

When wound size was not controlled, the UK prospective patients were more than twice as likely to heal than the retrospective patients, (relative risk, RR=2.1, p<0.01). In the USA, prospective patients were more than six times more likely to heal than the retrospective patients, (RR=6.5, p<0.0001).

Controlling for wound size resulted in a RR of 1.31 for UK prospective patients, although this finding was not statistically significant, (p>0.1). By contrast, in the USA, prospective patients were more than eight times more likely to heal than the retrospective patients, (RR=8.19, p<0.001).

**Clinical conclusions**
Guidelines for the diagnosis and treatment of venous leg ulcers resulted in better treatment care, faster healing rates, and lower time to healing and number of visits.

**Modelling**
A Cox proportional hazards model was used to estimate the time to healing. The authors found this model helpful because it dealt with censored data and allowed the impact of explanatory variables, such as wound size, to be considered.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the economic analysis. Thus, this study has been classified as a cost-consequences analysis.

**Direct costs**
The costs and the quantities were reported separately. The only direct costs included in the analysis were those relating to the number of visits by the nurses. This involved a mean classification of position, and an hourly rate of 9.75 per visit in the UK and $25.00 per visit in the USA. The authors did not report the price year or the sources of the costs.

**Statistical analysis of costs**
The costs were treated stochastically. The particular statistical tests used were not stated, but a 0.05 level of significance was used.

**Indirect Costs**
No indirect costs were included in the analysis.

**Currency**
UK pounds sterling (UK £) and US dollars ($).
Sensitivity analysis
No sensitivity analyses were performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
In the UK, the median cost for patients with ulcers healing in less than 12 months decreased from 136 to 38 after the introduction of the guidelines. In those with healing times of more than 12 weeks, the median cost decreased from 341 to 190.

In the USA, the median cost for patients with ulcers healing in less than 12 months decreased from $825 to $113 after the introduction of the guidelines. In those with healing times of over 12 weeks, the median cost decreased from $1,400 to $300.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The Oxfordshire Guideline for Venous Leg Ulcers and the Guideline for Diagnosis and Treatment of Venous Leg Ulcers developed at the University of Pennsylvania had been validated and shown to provide cost-effective, higher quality care than usual care. The authors therefore concluded that these guidelines should be considered standards of care for venous leg ulcer disease.

CRD COMMENTARY - Selection of comparators
No explicit justification for the comparator used (i.e. no guidelines) was provided. This seems reasonable given that the objective of the study was to ascertain the impact of the guidelines. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a comparative study with historical controls. This was appropriate for the study question, as the authors intended to assess the impact of multidisciplinary guidelines by comparing the before and after outcomes. The study sample was representative of the study population. The patient groups were compared, but the results of any appropriate statistical tests of significance were not reported. Thus, it is impossible to state whether the groups were shown to be comparable at analysis in terms of their age, gender and/or prognostic features. This will hamper the internal validity of the study. However, the authors satisfactorily controlled for wound size in the summary RR.

The authors conducted appropriate statistical tests of significance, but the p-values were often not reported. The corresponding p-values were, however, provided for the summary findings (i.e. RR of healing). The authors failed to consider potential confounding factors, intrinsic to many before and after studies. Factors such as improving medical trends over time, better health care management, and learning effects, could all have come into play, and may explain some of the differences found in the authors' results. The use of internal and external controls would have been a good means of minimising the potential for such bias.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.
Validity of estimate of costs
The authors failed to report the perspective adopted in the analysis. The only costs included in this analysis were those incurred by nurse visits. The costs and the quantities were reported separately, which will enhance the generalisability to other settings. For retrospective patients, the total costs calculated by the authors were not the same as what they should have been, according to the methods employed by the authors. For example, for 9 retrospective UK patients with ulcers healing in less than 12 weeks, who were visited by nurses (at 9.75 per visit), the total costs would have been 87.75, not the 136 reported by the authors. It is unclear if these differences were due to the inclusion of some unaccounted for costs, or mishandling of the data. This casts doubts on the results. Further, the costs of producing and distributing the guidelines was not considered. The p-values were not always reported, in this case only differences in total costs between US prospective and retrospective patients, but this adds to the poor reliability of the authors’ costing results. The price year was not stated, thus hampering any possible reflationary exercises.

Other issues
The authors made no comparisons with other studies, because prior studies had concentrated on the healing rates and cost-effectiveness of dressings used or treatment facilities for venous leg ulcers, which makes it difficult to separate the effect of the guideline from treatment protocols. The issue of generalisability was addressed by comparing the impact that the guidelines had in the US and the UK. The authors appear to have presented their results selectively, especially for the costs, and also by not reporting appropriate p-values for all results. The authors’ conclusions reflected the scope of the analysis. The authors did not report any further limitations.

Implications of the study
The authors stated that there now exists a standard of care that has been validated and should be used when evaluating products or other diagnostic treatment protocols. This should result in better interpretation of research data.

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None stated.

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Other publications of related interest

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