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 larval debridement therapy in the treatment of venous ulcers was studied. The sterile larvae of Lucilia sericata, produced by the Biosurgical Research unit in the Princess of Wales Hospital, Bridgend (Wales), were 2 to 3 mm in size and were covered by a containment dressing (Granuflex, ConvaTec Ltd.). The larvae and dressing were left for a maximum of 72 hours, and were removed or replaced if required. Larval debridement therapy was compared with hydrogel dressings. In the strategy, a standard hydrogel dressing (Intrasite gel; Smith & Nephew Medical Ltd.) was left for 72 hours and covered with a secondary dressing (Melolin, Smith & Nephew Medical Ltd.; or Telfa, Kendall Company).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients diagnosed as having a sloughy venous leg ulcer. Patients with evidence of arterial insufficiency, or who had undergone prior failed therapy, were excluded.

Setting
The setting was either a hospital or the community (since treatment could be administered in either of these settings). The economic study was carried out in Whitehaven, Cumbria, UK.

Dates to which data relate
The authors did not report the dates to which the effectiveness and the resource use data related. The price year was not given.

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

Link between effectiveness and cost data
The costing was carried out on the same study sample as that used for the effectiveness analysis. It appears to have been performed prospectively.

Study sample
No power calculations were performed in the planning phase of the study. Twelve consecutive patients referred to the
hospital where the study was performed, who were diagnosed as having a sloughy venous ulcer and who met the inclusion criteria and required debridement, were considered for the effectiveness analysis. These were randomised to one of the two study groups, six to larval therapy and six to hydrogel dressings. The patients in the larval therapy group had a mean age of 58 years (range: 48 - 72) and 2 were male. The patients in the hydrogel dressing group had a mean age of 54 years (range: 40 - 75) and 3 were male. The authors did not report any evidence that the study sample was representative of the study population.

Study design
This was a randomised, controlled trial that was performed at a single centre. The patients were followed up until debridement occurred, or for a maximum of one month. There were no losses to follow-up. Neither the assessment of the outcomes, nor the patients, was blinded to the treatment assigned.

Analysis of effectiveness
The basis for the effectiveness analysis was intention to treat. The primary health outcome assessed was the number of patients that achieved debridement (i.e. when the percentage of the surface area of slough was less than 5%). Although the authors reported that the groups were comparable at analysis, they were actually of similar age. The patients in the larval therapy group presented a lower male:female ratio than patients in the control group, and bigger values for ulcer size, proportion of ulcer covered by slough, and ulcer duration.

Effectiveness results
It appears that all patients in the larval therapy group achieved debridement, while only two patients in the control group were de-sloughed within the study period.

Clinical conclusions
Larval therapy seems to have been more effective than the hydrogel dressing in terms of achieving debridement.

Measure of benefits used in the economic analysis
No summary measure of benefit was used. The costs and effects were left disaggregated and the study was, in effect, a cost-consequences analysis.

Direct costs
The direct costs considered in the economic evaluation were those of the hospital. These included the costs of nursing time and the dressings associated with each of the treatments (i.e. hydrogel, sterile dressing packs, absorbent cotton gauze, crepe bandaging, Granuflex, nylon mesh, and larvae). Some of the resources used and all of the unit costs were reported separately. The dates to which the costing and the price year related, and the source of the unit costs, were not given. Therefore, it could not be inferred whether the estimation of the costs was based on actual data or a guess. Discounting was not performed, but it was not necessary since the period considered for the economic evaluation was very short (i.e. one month). The costs reported were the total costs and the median cost per patient.

Statistical analysis of costs
Some median values for the resources used and the costs were reported. Statistical analyses, to compare resource use and costs, were performed using the non-parametric Mann-Whitney U-test.

Indirect Costs
No indirect costs were estimated.
Currency
UK pounds sterling (GBP).

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
The total costs associated with larval therapy were 492, versus 1,054 for hydrogels. The median costs per patient were significantly lower for patients treated with larval therapy (78.64) than for those treated with the hydrogel dressing (136.23), (p<0.05).

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

Authors’ conclusions
Larval debridement would appear to be more cost-effective than standard hydrogel for the debridement of sloughy venous ulcers.

CRD COMMENTARY - Selection of comparators
The hydrogel dressing therapy was chosen as the comparator because it was current practice in the authors’ setting. You should consider which health technology is the most widely used for the treatment of venous ulcers in your own setting.

Validity of estimate of measure of effectiveness
Although a randomised, controlled study was performed, the fact that only 12 patients comprised the total study sample limits the results obtained. No statistical differences in baseline characteristics between the study groups appear to have been detected, although it has to be highlighted that the study lacked power because of the small sample size. Moreover, and for the same reason, it does not seem plausible that the study sample was representative of the study population. Although the authors stated that they had analysed the time required to de-slough, this was not reported in the results of the effectiveness analysis. In addition, recurrences, which are a relevant outcome in this kind of interventions, were not analysed. This might have been due to the short follow-up period considered at analysis. Further, the authors reported that the study might be subject to bias since the primary outcome used was subjective (depended on the assessment of the health professional) and the nurse who assessed the outcomes was not blinded. Therefore, the effectiveness analysis presented some relevant limitations that reduced the internal and external validity of the study findings.

Validity of estimate of measure of benefit
The only primary outcome assessed in the effectiveness analysis could be interpreted as the measure of benefit of the economic evaluation. However, other summary measures of benefit could have been used, such as healing rates, or the quality of life of patients under each one of the treatments. The latter may have allowed comparisons of the results with those from other interventions.

Validity of estimate of costs
The perspective adopted was not stated, although it appears to have been that of the hospital. The authors reported that some relevant costs (i.e. costs of travel and in-hospital stays) were not included. The authors acknowledged that,
considering inpatient costs, the total cost of hydrogel dressing therapy is likely to represent a many-fold increase in comparison with larval therapy. Hence, this omission is unlikely to have affected the authors' conclusion. An estimation of the indirect costs would have been required if a societal perspective was to be adopted. Most of the resource quantities were reported separately from the unit costs, which will enhance the generalisability of the authors' results. Since the costs were incurred during less than 2 years, they were appropriately not discounted. The dates to which the cost data and the price year related were not reported, nor were the sources used to obtain the unit costs. These facts may limit the validity of the cost results.

Other issues
The authors did not compare the study findings with those obtained by other studies. The issue of the generalisability of the results to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors did not report any additional limitations other than those that have been reported already.

Implications of the study
The study presented several caveats (reported already) that limited the validity of both the effectiveness and the cost analyses. The authors recommended further research, in the form of a larger study, to confirm the results obtained here and to demonstrate whether larval therapy should be established as a standard debridement agent in venous ulcers.

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Other publications of related interest

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