Clinical outcomes and cost-effectiveness of an externally applied electroceutical device in managing venous leg ulcers in clinical practice in the UK

• **Objective:** To estimate the cost-effectiveness of treating patients with a venous leg ulcer (VLU) with an externally applied electroceutical (EAE) device, plus dressings and compression bandaging or continuing with their previous care plan, from the perspective of the National Health Service (NHS) in the UK.
• **Method:** This was a prospective, single-arm, non-blinded, clinical and economic evaluation of EAE therapy performed in 2013/14. Patients' VLUs were treated with six active units of EAE therapy (each unit for two days) plus dressings and compression bandaging over a period of 12 days. Afterwards, patients were managed with a combination of dressings and bandages. Each patient acted as their own control so that clinical outcomes, resource use and costs associated with the wound over 12 months before the start of EAE therapy were retrospectively compared with the first 12 months after the start of treatment. The relative cost-effectiveness of EAE therapy was estimated at 2013/14 prices.
• **Results:** Within 12 months of starting EAE therapy 77% of all wounds healed and the other 23% improved. This difference in effectiveness between the 12-months period before and after EAE therapy was estimated to yield a 12% improvement in health gain of 0.09 QALYs ($p<0.01$), a 34% reduction in the requirement for nurse visits (from a mean 50.7 to 33.3 visits per patient) and a 26% reduction in the number of dressings. This resulted in an 11% reduction in the NHS cost of VLU management over 12 months after the start of treatment when compared with the previous 12 months (from £1,981 to £1,754 per patient). Hence, use of EAE therapy was found to be a dominant treatment (i.e. improved outcome for less cost).
• **Conclusion:** Within the study's limitations, use of the EAE device potentially affords the NHS a cost-effective treatment for managing VLUs when compared with patients remaining on their previous care plan.
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Accel-Heal; electroceutical therapy; compression; cost-effectiveness; economic evaluation; venous leg ulcer; UK

The concept of using an external electric current to promote healing of chronic wounds was first introduced more than 40 years ago.[1] Devices used to deliver this therapy commonly vary in voltage, current settings, application time, polarity, number of electrodes used, as well as the types of wounds to which they are applied. The use of continuous direct current of between 200–800 µA has been shown to improve ulcer healing[2–7] and over the past 35 years numerous studies have demonstrated statistically significant improvement in wound healing following the application of electrical stimulation.[8,9] In addition, electrical stimulation has been shown to improve wound perfusion and reduce pain.[4,7,10]

Electroceuticals broadly encompass all bioelectric medicine that employs electrical stimulation to affect and modify body functions.[11] The use of electroceuticals in the treatment of venous leg ulcers (VLUs) involves the transfer of an electrical current to the skin surface adjacent to the wound edge via two skin surface electrodes. The net effect is a flow of ions through the wound tissue. One such externally applied electroceutical device (EAE) is Accel-Heal. This is a certified Class IIA medical device which has been approved under the Medical Devices Directive 93/42/EEC. Accel-Heal delivers a proprietary sequence of electrical current at a micro-current level designed to augment soft-tissue healing particularly in dermal tissue. In 2011 this device was

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evaluated in a cohort of 22 patients with a non-healing VLU.[12] In this study the device resulted in an improvement in granulation in 95% of patients and 38% of wounds healed. Patients' mean pain score was reduced by 70% and exudate levels declined by 52%.[12] Additionally, the device resulted in a 6% increase in health gain of 0.017 quality-adjusted life years (QALYs) over 5 months and reduced the NHS cost of managing the VLUs by 15%, due in part to a 27% reduction in the requirement for nurse visits, over the first 5 months after the start of treatment.

The aim of this present study was to perform a clinical evaluation to estimate clinical outcomes, resource implications, cost impact and cost-effectiveness of EAE therapy in the management of VLUs in clinical practice in the UK, from the perspective of the National Health Service (NHS).

Methods

Study design

This was a prospective, single-arm, non-blinded, clinical and economic evaluation of EAE therapy in the management of VLUs in 2013–14. Each patient acted as their own control so that clinical outcomes, resource use and costs associated with the wound over 12 months before the start of EAE therapy were retrospectively compared with the first 12 months after the start of treatment.

Recruitment of centres

Nurses working in tissue viability clinics across the UK were contacted via newsletters and at wound care conferences and invited to participate in the evaluation. Those nurses who agreed to participate were self-selecting. A total of 13 nurses based at 11 centres agreed to participate in the study. Of these, six centres were community-based clinics and the other five were hospital outpatient clinics.

Study population

Patients were sequentially selected by nurses as they visited their clinic, following assessment and discussion. Patients were then asked to provide informed consent to participate.

To be eligible for inclusion into the study, patients had to be ≥18 years of age and have a VLU that had an ankle brachial pressure index (ABPI) ≥0.8 and ≤1.3. Patients were excluded from the study if they refused consent, or were moribund, or had other types of wounds or cancer or any pathology that could compromise response to treatment, or were pregnant.

Venous leg ulcer management

During the study, patients were treated with 6 active units of EAE therapy (each unit for 2 days) plus dressings and compression bandaging over a period of 12 days. Afterwards, patients were managed with a combination of dressings and bandages. The frequency of dressing change and type of dressing and compression used was based on individual assessed need and local protocol. All patients were assessed over a period of 12 months or up to healing if that occurred sooner following the start of EAE therapy. At the end of the study, patients' case report forms were sent to the authors for analysis.

Study variables

Information was prospectively recorded over a period of 12 months from the start of EAE therapy and included age, gender, wound durtaion, wound sizes (measured using a ruler), pain scores (measured using a clinician administered 10cm horizontal visual analogue scale), exudate levels (measured by visual inspection and classified as low, medium or heavy), clinician visits and use of dressings, bandages and topical treatments. This information was retrospectively compared with clinical outcomes and resource use documented in the patients' case records over the 12 months before the start of therapy.

Statistical analyses

Patients' outcomes and resource use were quantified over 12 months before and after the start of EAE therapy. Differences in patients' outcomes and resource use between the periods before and after the start of EAE therapy were tested for statistical significance using a Wilcoxon signed-rank test.

Logistic regression was used to investigate relationships between baseline variables and clinical outcomes. Multiple linear regression was also used to assess the impact of patients' baseline variables on resource use and clinical outcomes. All statistical analyses were performed using IBM SPSS Statistics (version 22.0; IBM).

Health-related quality of life

Utility scores express patient preferences for specific health states on a scale ranging from 0, representing death, to 1, representing perfect health. These scores provide the weights to estimate health-related quality of life (HRQoL) in terms of the number of quality-adjusted life years (QALYs) gained by an intervention or service. HRQoL was not collected in the evaluation. Hence, utility scores for VLUs,[13] previously obtained from the general public across the UK using standard gamble methodology, were assigned in a blinded manner (to eliminate potential bias) to each individual patient in the data set according to the health state of their wound at the end of each month in the study period. This enabled an estimation of patients' expected health status in terms of the number of QALYs over a period of 12 months before and after the start of EAE therapy.

Health economic modeling

A computer-based decision model was constructed depicting the treatment pathways and associated management of the wounds in the data set. The model spans the 12-months period before and after the start of EAE therapy.

Unit costs at 2013/14 prices[14–16] were assigned to the estimates of health-care resource use in the model to determine the NHS cost of managing patients over 12 months before and after the start of EAE therapy. Differences between the two periods were considered to be attributable to treatment with EAE therapy.

Cost-effectiveness analyses

The cost-effectiveness of managing patients with EAE therapy compared with continuing with their previous care plan was calculated as the difference between the expected cost of the two strategies over 12 months, divided by the difference between the expected number of QALYs between the two strategies over the same period. Hence, the cost-effectiveness of EAE therapy was expressed as the incremental cost per QALY gained. If the EAE therapy resulted in more QALYs for less cost it was considered to be the dominant (cost-effective) treatment.

Sensitivity analyses

To assess uncertainty, bootstrapping was undertaken to estimate the distribution of costs and QALYs. This involved generating 5,000 subsets of the data from each group on the basis of random sampling and replacing the data once sampled. Use of these subsets enabled the construction of a cost-effectiveness acceptability curve showing the probability of EAE therapy being cost-effective at different cost per QALY thresholds. Additionally, deterministic sensitivity analyses were performed on all of the model's inputs to identify how the relative cost-effectiveness of EAE therapy would change by varying the value of different parameters in the model.

Results

Patients' characteristics

The study population comprised a sample of 28 patients with one VLU and 1 patient with two VLUs who were being managed either in the community or at a hospital outpatient clinic. Patients' mean age was 66.0 years, 62% were male, the mean size of their VLU was 8.7cm^2 and the mean duration of their wound before the start of EAE therapy was 2.2 years. However, 23% of patients had a wound for ≤3 months before the start of EAE therapy. The patients' characteristics are summarised in Table 1.

Table 1. Patients' characteristics in the data set at study start

Number of wounds in sample	30
Mean age per patient (years)	66.0 (95% CI: 59.7; 72.3)
Male:female (%)	62:38
Mean body mass index per patient (kg/m^2)	28.4 (95% CI: 25.7; 31.0)
Diabetic (%)	3
Ambulatory (%)	97
Drank alcohol (%)	76
Mean wound area at baseline per patient (cm^2)	8.7 (95% CI: 4.9; 12.5)
Mean wound duration per patient (years)	2.2 (95% CI: 0.8; 3.6)
Wounds ≤3 months old at baseline (%)	23
Wounds 4–12 months old at baseline (%)	27
Wounds >12 months old at baseline (%)	50

Patient management and outcomes

Within 12 months after starting EAE therapy, 77% of all wounds had healed and the other 23% had improved. However, wounds larger than 12cm^2 failed to heal. So too did wounds older than 33 months. The mean area of wounds at the start of treatment that went on to heal was 5.2cm^2 compared with 20.1cm^2 for wounds that did not heal. Additionally, the mean age of wounds that healed was significantly less than that of wounds that did not heal (1.0 versus 6.1 years; $p<0.01$). The mean time to healing was 2.5 months.

The difference in effectiveness between the 12 months period before and after EAE therapy was estimated to yield a 12% improvement in health gain of 0.09 QALYs ($p<0.01$). The outcomes at 12 months after the start of EAE therapy are summarised in Table 2.

The rate of wound area reduction for patients who healed and those who remained unhealed is shown in Fig 1. The graph shows the beneficial effect of the EAE device on wound reduction, since the area of the unhealed wounds decreased by 42% over the study period.

Fig 1. Wound area reduction of venous leg ulcers (VLUs)

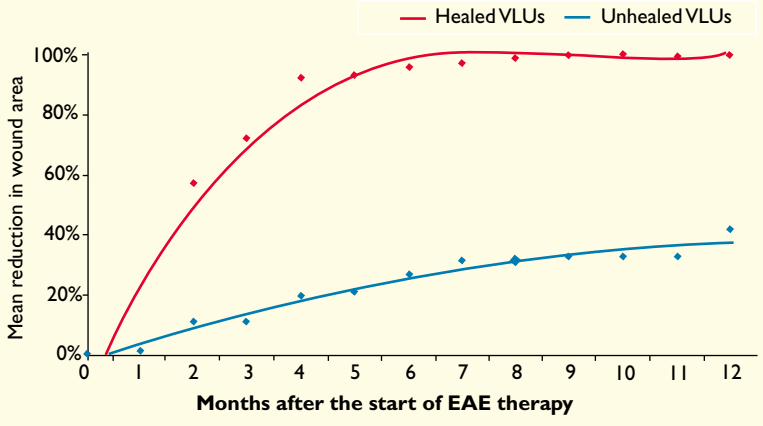


Table 2. Patients' outcomes

	Before the start of EAE therapy	At 12 months after the start of EAE therapy	p-value
VLUs that healed (%)	-	77	-
Reduction in wound size (%)	-	69	-
Mean wound area per wound (cm^2)	8.7 (95% CI: 4.9; 12.5)	2.7 (95% CI: 0.3; 5.2)	<0.001
Mean time to wound healing per wound (months)	-	2.5 (95% CI: 1.4; 3.6)	-
Mean pain score per patient	3.6 (95% CI: 2.4; 4.8)	0.63 (95% CI: 0.0; 1.3)	<0.001
Wounds with no exudate (%)	0	77	<0.001
Wounds with light exudate (%)	43	13	<0.001
Wounds with medium exudate (%)	37	10	<0.001
Wounds with heavy exudate (%)	20	0	<0.001
Mean number of QALYs per patient	0.74 (95% CI: 0.69; 0.79)	0.83 (95% CI: 0.78; 0.88)	0.01

95% confidence intervals in parenthesises; CI – confidence interval; VLU – venous leg ulcer; EAE – externally applied electrocuetical; QALYs – quality adjusted life years

Regression analysis found that wound area at 12 months was 0.73cm^2 larger for each additional month of wound duration (p = 0.001). Additionally, the % reduction in wound area at 12 months was 60% less for each additional month of wound duration (p=0.001). Pain scores of non-ambulatory patients at 12 months were 0.39 higher than that of ambulatory patients (p=0.001). Additionally, pain scores were 0.73 higher for each additional cm^2 of wound area at baseline (p=0.001). Logistic regression showed that wound duration was an independent risk factor for healing (odds ratio of 0.90; p=0.02) and the presence of exudate (odds ratio of 1.11; p=0.02).

Health-care resource use

Patients were predominantly managed by practice nurses (Table 3). Use of EAE therapy instead of patients continuing with their previous care plan is expected to lead to a 34% reduction in the requirement for nurse visits (from a mean 50.7 to 33.3 visits per patient) over the first 12 months after the start of treatment (Fig 2), thereby potentially releasing 17 nurse visits per patient for alternative use within the system. In addition, use of EAE therapy is expected to lead to a 26% reduction in the number of dressings (from 197 to 146) over the first 12 months after the start of treatment.

Health-care cost of patient management

By managing patients with 6 units of EAE therapy at an acquisition cost of £40 per unit (Table 4), the mean cost of health-care resource use over 12 months after the start of treatment was reduced by 11% compared with the previous 12 months (from £1,981 to £1,754 per patient). However, the mean cost of health-care resource use over 12 months before the start of treatment ranged from £1,196 for a wound that healed to £4,559 for an unhealed wound. The mean cost of managing wounds that healed was reduced by 35% to £779 per patient over 12 months after the start of treatment. The corresponding cost for the unhealed wounds increased by 9% to £4,959 per patient.

Nurse visits were the primary cost driver in both treatment groups, accounting for 77% and 61% of the NHS cost of patient management in the 12-months period before and after the start of EAE therapy, respectively. Electroceutical therapy accounted for 14% of the total health-care cost of

Table 3. Mean amount of health-care resource use per patient

	Over 12 months before the start of EAE therapy	Over 12 months after the start of EAE therapy	p-value
Health-care resource use			
Community nurse visits	8.9 (95% CI: 0.0; 21.0)	8.7 (95% CI: 0.0; 20.7)	ns
Practice nurse visits	29.8 (95% CI: 15.6; 43.9)	12.0 (95% CI: 0.5; 23.5)	<0.001
Tissue viability nurse visits	12.0 (95% CI: 7.5; 16.5)	12.6 (95% CI: 7.9; 17.4)	ns
Dressings and bandages			
Dressings	197.0 (95% CI: 0.0; 429.1)	146.1 (95% CI: 0.0; 333.8)	0.01
Compression bandages	33.6 (95% CI: 17.1; 50.1)	26.9 (95% CI: 12.5; 41.3)	ns
Non-compression bandages	32.7 (95% CI: 0.0; 80.4)	30.2 (95% CI: 0.0; 77.4)	ns

95% confidence intervals in parenthesises; CI – confidence interval; VLU – venous leg ulcer; EAE – externally applied electrocuetical; QALY's – quality adjusted life years; ns – not significant

Table 4. Mean NHS cost of health-care resource use per patient at 2013/14 prices

	Over 12 months before the start of EAE therapy		Over 12 months after the start of EAE therapy	
Community nurse visits	£294.80	(15%)	£286.00	(16%)
Practice nurse visits	£788.82	(40%)	£323.30	(18%)
Specialist nurse visits	£444.00	(22%)	£474.83	(27%)
Dressings	£214.27	(11%)	£251.55	(14%)
Compression bandages	£171.59	(9%)	£131.50	(7%)
Non-compression bandages	£33.28	(2%)	£29.79	(2%)
Topical applications	£34.23	(2%)	£16.90	(1%)
Electroceutical therapy	£0.00	(0%)	£240.00	(14%)
TOTAL	£1,980.99	(100%)	£1,753.87	(100%)

% of total expected cost is in parenthesis;
EAE – externally applied electrocuetical

managing patients over the 12 months after the start of treatment. Bandages, dressings and emollients accounted for the remainder of the health-care costs in both groups (Table 4).

Cost-effectiveness analyses

Managing patients with EAE therapy instead of continuing with their previous care plan is expected to lead to a £227 reduction in NHS costs, 77% of wounds being healed and a health gain of 0.09 QALYs at 12 months after the start of treatment. Hence, EAE therapy was found to be a dominant treatment (since the incremental cost per QALY gained was −£2,522) and potentially affords the NHS a cost-effective treatment for VLUs, although this was dependent on the duration of the wound (Table 5).

Sensitivity analyses

Bootstrapping (Fig 2) was performed to identify the distribution in the incremental costs and QALYs for the alternative treatment strategies (EAE therapy or continuation with a previous care plan). A cost-effectiveness acceptability curve was generated from the bootstrapped subsets (Fig 3), which demonstrated that, at a cost-effectiveness threshold of £20,000 per QALY, up to 99% of a cohort is expected to be treated cost-effectively by EAE therapy compared to continuation on a previous care plan.

Deterministic sensitivity analyses were performed on all the model's inputs, but only the main findings have been presented (Table 6). These analyses found the relative cost-effectiveness of EAE therapy to be sensitive to:

- Probability of healing
- Number of nurse visits
- Amount of bandages and dressings
- Utility values

The relative cost-effectiveness of EAE therapy was not sensitive to any of the other parameters studied.

Discussion

This study aimed to determine the clinical outcomes and relative cost-effectiveness of using the EAE device, Accel-Heal, in the treatment of VLUs in clinical practice in the UK, based on real world evidence. Accordingly, eligible patients were sequentially selected by nurses working in tissue viability as they visited the clinic and offered treatment with the device if they fulfilled the admission criteria. The advantage of this approach is that the patient pathways and associated resource use are based on actual clinical practice rather than trial protocol–driven resource use. However, this naturalistic approach does have its limitations. The nurses were self-selected, patients were not randomised to a treatment and there was no prospective comparator group. Additionally, the sample of wounds comprised a mix of acute and chronic VLUs. Hence, there may be confounding issues surrounding the nurse's decision to treat with the EAE device and the patient's willingness to accept the clinician's preferred treatment.

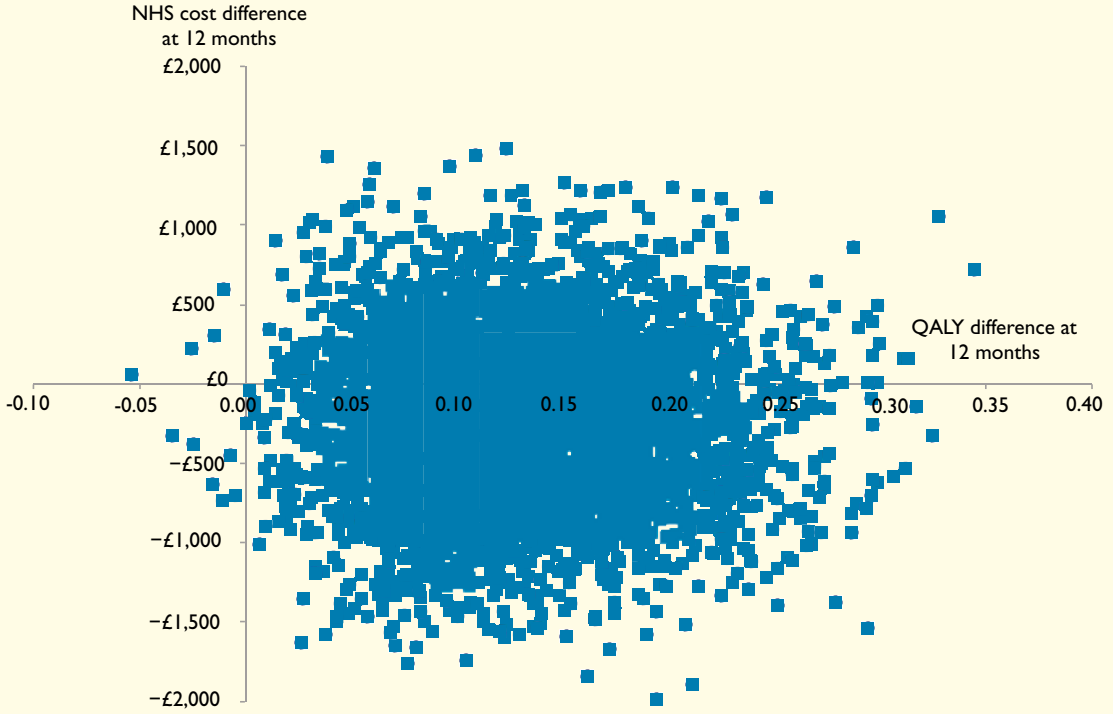
All patients in the clinical evaluation were assessed up to 12 months following the start of EAE therapy. Consequently, this analysis does not consider the

Table 5. Clinical effectiveness and cost-effectiveness of EAE therapy stratified by age of wound

Age of wound (months)	Wounds healed (%)	Incremental cost per QALY gained
<3	100	−£10,657
3–5	100	−£7,743
6–8	100	−£3,086
9–12	100	£2,076
>12	53	£10,538

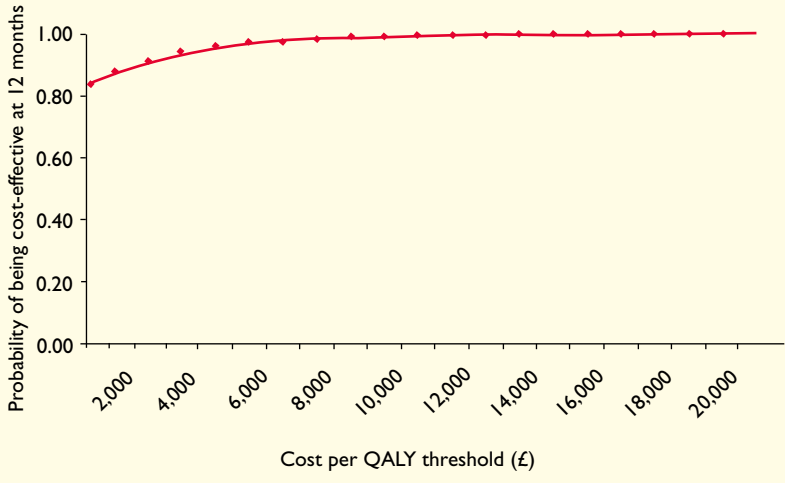
EAE – externally applied electrocuetical; QALY's – quality adjusted life years

Fig 2. Scatterplot of the incremental cost-effectiveness of EAE therapy compared with a previous care plan (5,000 bootstrapped samples).



potential impact of the wounds that remained unhealed beyond that period. The primary measure of efficacy in the evaluation was wound size, which was used as a proxy to determine whether a patient's wound was improving, remaining unchanged or getting worse. However, wound area measurements or percentage changes in ulcer size are only superficial measurements of healing as they fail to take wound depth into account. Moreover, pain was a considerable problem, and a major concern when treating patients. Thus, the fact that EAE therapy significantly reduced pain in these patients is noteworthy. Patients' exudate levels were also reduced following EAE therapy, which may correlate with improved healing and is reflected in the reduction in the number of nurse visits.

Fig 3. Probability of being cost-effective at different cost per QALY thresholds



The results, however, may be confounded by certain other limitations. Patients may have received more intensive treatment than they otherwise might have received had they not been participating in this study. Hence, this study's findings may not be indicative of those observed in actual clinical practice. The probabilities of outcomes and resource use have been extrapolated from a small cohort of predominantly ambulatory patients residing in their own home and managed at 11 centres in England. Hence, they may not be representative of patients from across the whole UK or indicative of hospitalised patients or those residing in nursing homes. Moreover, due to the nature of the study design and lack of a prospective comparator, the analysis may not be

Table 6. Deterministic sensitivity analyses

Scenario	Base case value	Range in the incremental cost per QALY gained with EAE therapy versus patients' previous care plan
Probability of being healed with EAE therapy ranges from 0.35 to 0.90	0.77	Ranges from £20,900 to −£3,500
QALY difference between before and after EAE therapy ranges between 0.03 and 0.19	0.09	Ranges from -£7,600 to −£1,200
Proportional change in the number of practice nurse visits ranges from 0.7 to 1.3	1	Ranges from −£1,000 to −£4,100
Proportional change in the number of community nurse visits ranges from 0.7 to 1.3	1	Ranges from −£2,500 to −£2,600
Proportional change in the number of specialist nurse visits ranges from 0.7 to 1.3	1	Ranges from −£2,600 to −£2,400
Proportional change in the amount of compression bandages ranges from 0.7 to 1.3	1	Ranges from −£2,800 to -£2,300
Proportional change in the amount of dressings ranges from 0.7 to 1.3	1	Ranges from −£3,000 to −£2,100
The utility value for a VLU ranges from 0.032 to 0.064	0.053	Ranges from −£1,100 to −£7,600
The utility value for an improving VLU ranges from 0.037 to 0.079	0.061	Ranges from −£4,300 to −£2,000

EAE – externally applied electrocuetical; QALYs – quality adjusted life years; VLU – venous leg ulcer

predictive of the incremental differences in clinical outcomes and resource use that will be seen in clinical practice when EAE therapy becomes routinely available. In addition, the analysis incorporated published utilities for VLUs[13] which the authors derived from members of the general public across the UK, and which included subjects with a VLU.[13] The utility scores of respondents who had a VLU were not significantly different from those respondents who did not have a wound.[13]

The model only considered direct health-care costs borne by payers (the NHS) and not those borne by patients. It incorporated resource use estimates and utility values for the 'average patient' and does not take into account such factors as age, duration of wound, wound area, suitability of patients to receive EAE therapy and level of clinicians' skills. The analysis was unable to consider the impact of other factors that may affect the results, such as comorbidities, and severity and pathology of underlying disease. Moreover, the economic analysis is based upon a small uncontrolled study and such small studies often overestimate the effect of wound interventions.[17]

Despite these limitations, the analysis shows that use of EAE therapy potentially affords the NHS a cost-effective (dominant) treatment for managing VLUs when compared to leaving patients on their previous care plan. It is expected to lead to a 11% cost reduction, a healing rate of 0.77 and a 12% improvement in health gain over 12 months when compared with leaving patients on their previous care plan. The costs were not reduced by >12% even though EAE was only administered for 12 days and many of the VLUs healed within the first few months of treatment because the cost of managing unhealed wounds increased after EAE therapy.

The number of nurse visits observed in this study are consistent with the findings from other studies.[18,19] Moreover, use of EAE therapy plus dressings and compression bandaging compared to continuing with a patient's previous care plan is expected to lead to a 34% decrease in the number of nurse visits over the first 12 months after the start of treatment, thereby potentially releasing 17 nurse visits per patient. Hence, EAE therapy's acquisition cost is offset by a reduction in the requirement for nurse visits, leading to a release of NHS resources for use elsewhere in the system, thereby generating an increase in NHS efficiency.

The efficacy of this particular device, in terms of healing, would appear to be restricted by the age of the wound before the start of treatment and wound area. In this evaluation, VLUs with a duration of >33 months did not heal and neither did VLUs with an area of >12cm^2. However, the area of the unhealed wounds had decreased by 42% over the 12 months study period. What is unknown is whether these wounds would go on to heal if they were re-treated with the EAE device for another 12 days. By way of

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comparison, in our previous study with this device among patients with a non-healing VLU of >6 months duration, wounds with a mean duration of >28 months did not heal and neither did wounds with a mean area of >12cm^2.[12] In that study, the device was estimated to heal 38% of VLUs within 5 months after starting EAE therapy compared with patients' previous care plan. This finding was comparable with that from a previous study in which the authors evaluated the cost-effectiveness of an electrical stimulation device, Posifect, in the treatment of chronic non-healing VLUs of >6 months duration.[13] The findings are also consistent with those from other studies in both VLUs[18,19,20] and diabetic foot ulcers.[19,20,21]

Conclusion

In conclusion, within the model's limitations, the cost-effectiveness of treating VLUs with EAE therapy relative to continuing with patients' prior care is dependent on healing rates, wound duration and size of wound. Generation of a robust clinical data set is a prerequisite for a more definitive estimation of the cost-effectiveness of this device. ■

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