Economic evaluation of compression therapy in venous leg ulcer randomised controlled trials: A systematic review

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Abstract

Objectives: To review literature and examine the type of economic evaluation conducted alongside compression therapy randomised controlled trials (RCTs) that reported VLU healing outcomes.

Design: We examined types of economic analyses included in compression RCTs, and investigated how economic evaluation methods were utilised and reported alongside RCTs. A systematic review was undertaken on the basis of pre-specified criteria for the assessment of the RCTs for inclusion. The databases searched included: The Cochrane library, MEDLINE, CINAHL, EMBASE, PUBMED, EBM Reviews.

Main outcome measures: Two review authors independently assessed the risk of bias of each included trial against key criteria: random sequence generation; allocation concealment; blinding of participants, personnel and outcomes; incomplete outcome data; selective outcome reporting; and other sources of bias, in accordance with methods recommended by the Cochrane Collaboration.

Results: We reviewed 85 abstracts, excluded 72 that did not fulfil the protocol inclusion criteria. Thirteen full text articles were reviewed, of which five studies met the inclusion criteria and were included in this review. We found little consistency in reporting between studies; in three studies compression treatments description were unclear. All included studies reported direct costs that showed incremental clinical benefit but only study one reported the difference in costs.

Conclusion: Future compression RCTs would benefit from standardised protocol for inclusion of economic evaluation alongside RCTs in wound management to ensure clinical and economic outcomes are measured and reported.

Introduction

Chronic venous leg ulceration is a common and important wound management problem, which causes significant morbidity and is associated with considerable cost to individuals and health services[1]. It is important to assess the economic impact of various approaches to wound management in tandem with clinical effectiveness alongside randomised controlled trials (RCTs) and the absence of such studies has recently been noted[2]. The aim of this article was to review the current literature and examine the type of economic evaluation conducted alongside compression therapy RCTs that reported venous leg ulcer (VLU) healing outcomes. We examined the types of economic analyses included in VLU RCTs and how economic evaluation methods were reported.

Venous ulcers account for 70–90% of ulcers found in the lower limb[3]. Most of the direct cost of treatment is associated with the supply of dressings including multi-layer/multi-component bandages and community nurse visits[4]. The high prevalence of venous ulcers also has a significant socio-economic impact in terms of medical care, days off work and reduced quality of life[5-7]. The UK National Health Service reported that venous ulcers caused the loss of two million working days per year and the direct costs of chronic wounds were between £2 and £3 billion annually. In the United States, chronic wounds affect 6.5 million patients[8]. A recent European overview of the future impact on costs in wound management reported that the rapidly changing demography will increase costs by €23 billion over the next 10 years[9]. The incidence and prevalence of VLUs in Australia is also on the rise due to an ageing population and the impact of obesity and diabetes[10]. The cost and resource implication of VLU management will cause considerable strain on the health system in the future.

It is known that compression therapy increases VLU healing rates compared with no compression and according to a recent Cochrane review multilayered systems are more effective than single-layered systems, but there are no clear differences in the effectiveness of different types of high compression[11]. The research evidence supporting current compression treatment is inadequate. Many studies of compression bandaging have small sample sizes and the quality of research in the area is poor and the review suggested more good-quality RCTs[12] are needed. Coupled with this is a lack of adequate reporting of healing outcome measures and of resource utilisation[2]. This gap in evidence may lead to inferior clinical practice while the lack of economic evaluation in studies leaves a vacuum to inform policy decision-makers. The European Wound Management Outcome Group has recently reported on recommendations to improve the quality of evidence in wound management including different approaches to how costs and benefits of different compression bandages are to be compared[2].

The treatment of venous ulcers

Compression is the mainstay treatment for venous ulcers[11]. It increases ulcer-healing rates compared with no compression[13] and multi-layered compression bandage systems have been found to be more effective than single-layered systems but there are no clear differences in the effectiveness of different types of high compression[14]. The type of dressing applied beneath compression has not been shown to effect venous ulcer healing[15].

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Economic evaluations

An economic evaluation compares the cost and consequences of two or more alternative interventions[16]. In contrast with cost of illness or burden of disease studies, which generally limit consideration of the economic burden of a disease or intervention, economic evaluations consider both the cost of the intervention and the benefits acquired. These are used to inform patients, clinicians, and policy/decision makers about cost-effectiveness of interventions and may form an aid to the decision-making process of how to best spend scarce health care resources.

Another key element in an economic analysis is determining which primary and/or secondary outcome data should be incorporated to determine the benefit of the intervention in question. In wound management this may include primary outcome measures such as cases successfully healed, or other clinical indicators including, but not limited to, number of venous leg ulcers avoided, pain-free days, change in healing rates and percentage in reduction healing rates[17]. Whichever outcome is chosen it needs to be clinically relevant to the patient in order to assist in the determination of the value of treatment in clinical practice.

Methods

A citation review was undertaken on the basis of pre-specified criteria for the assessment of the RCTs for inclusion. The criteria for including studies in this review were as follows:

- *Types of studies*: All published and unpublished RCTs comparing compression bandages.
- *Types of participants*: Adult patients with a venous ulcer as outlined in RCT definition.
- *Types of intervention*: Compression bandages – single, multilayer, elastic and inelastic.
- *Types of economic evaluation*: Cost minimisation analysis, cost-effectiveness, cost utility, cost benefit evaluations alongside RCTs.

Search methods for identification of studies

Using the following search strategy we identified those 'Types of studies' that included RCTs of venous leg ulcer

healing and compression therapy treatment provided these studies included economic perspectives.

Electronic searches

The databases searched included: *The Cochrane library*, MEDLINE, CINAHL, EMBASE, PUBMED, EBM Reviews. The database searches for relevant articles were undertaken on 12 March 2010. The following search strategy was utilised for each database listed:

*venous ulcer$.mp. or *Varicose Ulcer; compression.mp. ; bandage.mp. or *Bandages); Leg/ or *Bandages/ or elastic bandage.mp.); Quality of Life"/ or *Aged/ or health related quality of life.mp. or Health Status; Quality adjusted life year$.mp. or *Quality-Adjusted Life Years; QALY$.mp. or *Quality-Adjusted Life Years; Quality of Life"/ or *Patient Satisfaction/ or *Health Status Indicators/ or health preference$.mp. or *"Wounds and Injuries"/ or *Health Status; cua.mp. (24); cost effectiveness.mp. ; Economics, Medical/ or *Economics/ or *Quality-Adjusted Life Years/ or economic evaluation$.mp. or *Health Care Costs/ or *"Costs and Cost Analysis*

*Health Status Indicators/ or *"Quality of Life"/ or utility scale$.mp. or *Quality-Adjusted Life Years; Quality of Life"/ or utility preferences.mp. or *Health Status Indicators; Quality of Life"/ or utility weights.mp. or *Health Status Indicators.*

Searching other resources

Reference lists of all the trials identified were checked by the above methods. Current clinical trials registries were also reviewed. All trials (published or unpublished) were considered. Only studies in English were considered.

Figure 1. Search strategy flow chart.

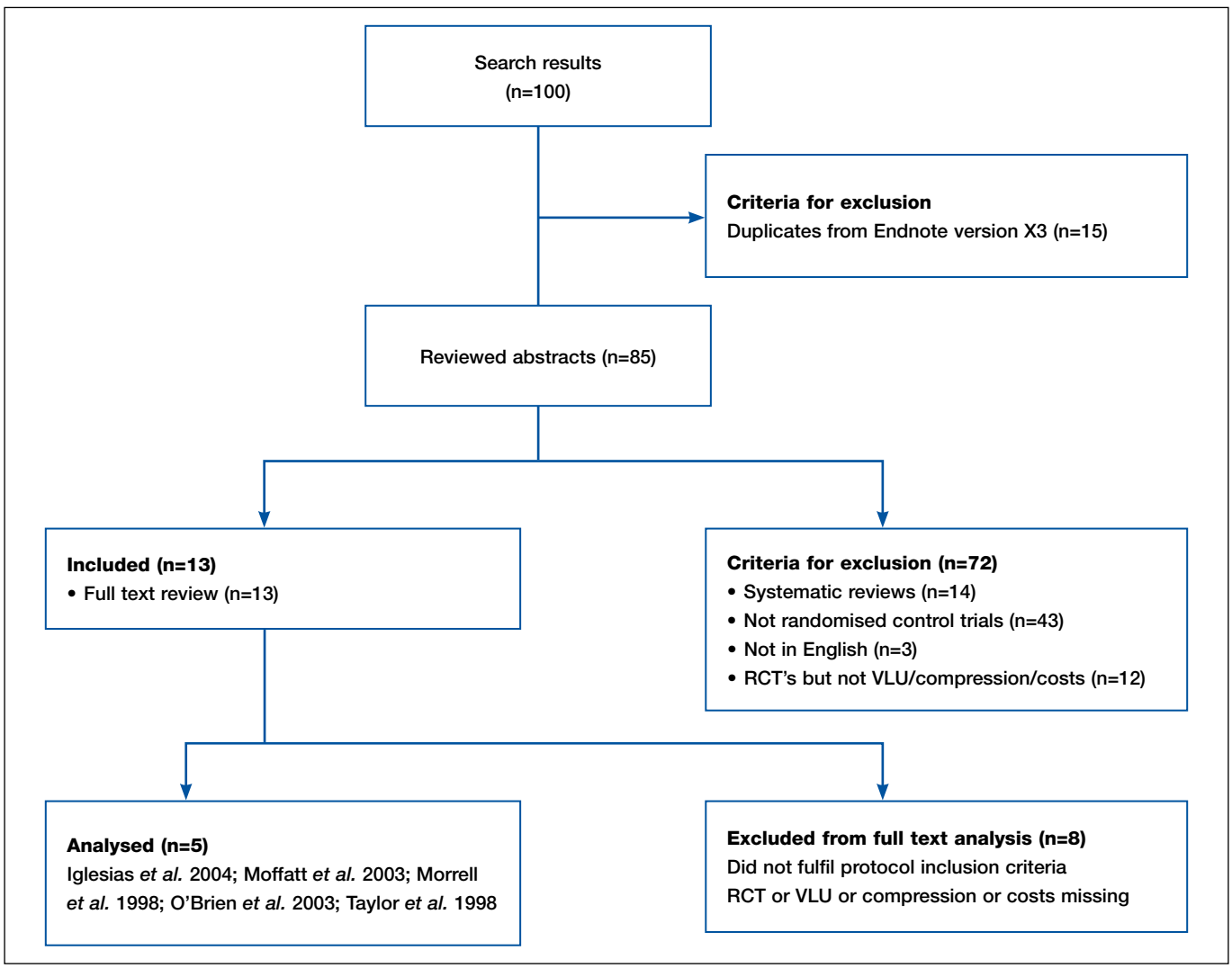

Table 1, Characteristics of included studies,

Author [country]	Interventions	Objective	Outcomes	Sample size number analysed setting/s	Clear NTP criterion†						Results/comments
					1	2	3	4	5	6	
Iglesias *et al.*[20] [United Kingdom]	Four layer compression versus short stretch compression bandage	To compare the clinical and cost-effectiveness of two different bandages for the healing of venous ulcers.	Primary endpoint Time to complete healing of all ulcers on the reference leg. Secondary outcomes Proportion of ulcers healed at 12 and 24 weeks. Withdrawals Adverse Events EuroQol5D, SF-12, Hyland leg and foot ulcer questionnaire Economic data	Sample size determined *a priori* 988 screened 601 excluded 387 randomised 1 LTF *Community, district nurse-led services; community leg ulcer clinics; hospital leg ulcer clinics with community outreach*	yes	yes	no	no	yes	yes	Cost utility analysis performed on patient level data. Time horizon one year. 4LB is associated with greater health benefit and lower costs but the differences were not statistically significant.
O'Brien *et al.*[21] [Ireland]	Four layer compression bandage versus usual care (not described)	Not clear. Aim stated study will compare the cost-effectiveness of four-layer compression bandaging for venous ulcers with that of other dressing treatments possible that compression bandaging not used.	Primary endpoint Time to heal the leg ulcer. Secondary Outcomes Resource use	Sample size determined *a priori* Number screened not reported 200 randomised 3 withdrawals/LTF *Patient home; local health centres; hospital*	no	no	no	no	no	no	Description of "other treatments" or "usual care" unclear. Unclear if one group was treated with compression therapy and the control group was treated with dressing and no compression. In this situation we would expect the findings to be in favour of the 4LB intervention.
Moffatt *et al.*[22] [United Kingdom]	Compare a four-layer with a two-layer bandage system in the management of chronic venous ulceration	Time to complete closure of ulcerated limb up to 24 weeks from trial entry.	Primary endpoint Time to complete closure of ulcer up to 24 weeks from trial entry. Secondary outcomes – treatment discontinuation. Adverse events	Sample size determined *a priori* Number screened not reported 112 randomised 38 withdrawals/LTF *Community leg ulcer clinics*	no	yes	no	no	no	yes	There is no significant difference in the rate of ulcer closure or the time to ulcer closure for patients managed with 4LB or 2LB. No evidence that either bandage is superior over 24-week follow-up. 4LB has lower cost.

Table 1 (continued). Characteristics of included studies.

Author [country]	Interventions	Objective	Outcomes	Sample size number analysed setting/s	Clear NTP criterion†						Results/comments
					1	2	3	4	5	6	
Morrell *et al.*[23] [United Kingdom]	To establish the relative cost-effectiveness of community leg ulcer clinics that use four layer compression bandaging versus usual care provided by district nurses	Time to ulcer healing. Patient health status. Recurrence of ulcers. Secondary aspects Personal costs	Primary endpoint Time to complete healing within 12-month follow-up period. Secondary end points Time to first recurrence of healed ulcer. Number of weeks the patients were free from ulcers Health status. Including: SF-36 EQ-5D McGill short form pain questionnaire Frenchay activities Index Resource utilisation	Sample size determined *a priori* 328 screened 233 randomised 40 withdrawals/LTF *Community-based research clinics*	no	no	no	no	no	yes	Community leg ulcer clinic costs compared to district nursing costs. Not bandage cost *per se*.
Taylor *et al.*[24] [United Kingdom]	Comparison of healing rates and therapy costs for conventional and four-layer high compression bandaging treatments of venous leg ulcers	To compare healing rates and associated treatment costs of four layer high compression bandage and conventional management over 12 week treatment period.	Significance of difference between the numbers of ulcers healed and associated treatment costs.	No sample size determined Number screened not reported 36 consecutive pts randomised 6 withdrawals/LTF *Hospital-based leg ulcer service and community*	no	no	no	no	no	no	Authors conclude that it is more efficacious and economical for nurse specialists to treat patients with venous ulcers with four layer compression bandaging when compared to district nurses who carry out standard treatments.

Abbreviations: ITT, intention to treat; LTF, lost to follow-up

1 adequate description of generation of allocation sequences.

2 treatment allocation concealed and described.

3 adequate participant blinding.

4 adequate outcome assessor blinding.

5 consistent follow-up schedule.

6 intention to treat analysis.

§ Statistical significance not reported

Data collection and analysis

Selection of studies

Two authors (CW, ZA) assessed the titles and abstracts of all studies identified by the initial search and excluded any clearly irrelevant studies. We obtained full versions of articles if, from this initial assessment, they potentially matched to the inclusion criteria. The review authors independently assessed full paper copies of reports of potentially eligible studies using the inclusion criteria. The reviewers resolved any disagreements on inclusion by consensus and if this failed, by arbitration by a third reviewer (KMK).

Data extraction and management

Details of studies were extracted and summarised using a data extraction sheet. If data were missing from reports, or clarification was needed, attempts were made to contact the authors to obtain missing information. Data from studies published in duplicate were included only once. Data extraction was undertaken independently by CW and ZA. Any discrepancy was resolved by discussion.

Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias of each included trial, against key criteria: random sequence generation; allocation concealment; blinding of participants, personnel and outcomes; incomplete outcome data; selective outcome reporting; and other sources of bias, in accordance with methods recommended by the Cochrane Collaboration[18] and CHEC (Consensus Health Economic Criteria) list[19].

As outlined in the flow chart (Figure 1) we reviewed 85 abstracts and excluded 72 that did not fulfil the protocol inclusion criteria. Thirteen articles were chosen for full text review, of which eight were excluded from analysis due to not fulfilling the inclusion criteria. The characteristics of five studies included in this review are described on Table 1.

Results

The five included studies were based in the United Kingdom. The settings were diverse including district nurse-led services, community leg ulcer clinics, hospital leg ulcer clinics, patient homes, local health centres and community-based research clinics. All included studies were RCTs. Only one study[20] described the allocation sequence and concealment adequately. No studies reported adequate participant blinding or clear outcome assessor blinding. Only one study[20] reported a consistent follow-up schedule of participants. Three studies[20,22,23] reported intention to treat (ITT) analysis.

The authors generally reported clinical effectiveness and some form of economic analysis. Only one study (Moffat *et al.*)[22] did not report a statistically significant difference for the primary outcome at study end. The studies presented a variety of outcomes. The primary outcome that was reported by all studies was time to healing. Though it was not clearly stated by all studies, it seemed that resource use was captured during the trials.

Clinical outcomes

The clinical effectiveness results of the five RCTs reviewed are outline in Table 1. Iglesias *et al.*[20] conducted a trial in the context of a specialised wound clinic and reported that four-layer bandaging (4LB) bandages were associated with greater health benefit, but the differences from healing outcomes were not statistically significant. Adjusted analysis using Cox proportional hazards model suggested a statistical significant treatment effect in favour of 4LB – hazard ratio for healing 0.72 (95% CI 0.57 to 0.91).

Moffatt *et al.*[22] reported a statistically significant difference between the two treatment arms after 12 weeks, with 40 out of 57 (70%) patients randomised to the 4LB with follow-up achieving ulcer closure compared with 30 out of 52 (58%) on the two-layer bandage (2LB), odds ratio = 4.23 (95% CI 1.29 to 13.86), p=0.02. By study end (24 weeks), 50 out of 57 (88%) patients randomised to the 4LB system with follow-up achieved ulcer closure (complete epithelialisation) compared with 40 out of 52 (77%) in the 2LB, hazard ratio =1.18 (95% CI 0.69 to 2.02), p=0.55.

The remaining three study reviews were unclear in their description of compression therapy treatments compared. O'Brien *et al.*[25] compared 4LB with "usual care" although "usual care" was not defined. It was unclear if one group was treated with compression and the control group was treated with dressings and no compression. The Kaplan-Meier estimate of the healing rate at three months was 54% with 4LB and 34% in usual system of care (control group). The authors report that the 4LB group healed ulcer earlier (p=0.006).

The Morrell *et al.*[23] study compared community leg ulcer clinics to district nursing care in costs rather than comparing compression bandage types. The study found that the

unadjusted healing rate in the intervention group compared with control was 1.45 (95% CI 1.04 to 2.03 (p=0.03). Taylor *et al.*[24] compared 4LB with district nurse 'conventional' treatments and found a higher proportion of patient in group A (12, 75%) had ulcers completely healed by the end of the trial when compared with those in group B (3, 21%) (p=0.003). The median healing time for group A was 55 days compared with 84 days for group B.

Outcomes used in the economic analyses

In the majority of studies, "time to healing" was the primary outcome measured. Morell *et al.*[23] and Iglesias *et al.*[20] measured various quality of life measurements as part of their secondary outcomes. Iglesias *et al.*[20] used EQ-5D data that was captured in order to derive quality adjusted life years (QALYs) for patients in the clinical trial and reported there was no statistically significant difference in the QALYs after the first year. Individuals in the 4LB group had, on average, a better quality of life than those in the short-stretch bandaging (SSB) group; the annual difference in QALYs was –0·02 (95% CI 0·08 to 0·04). In terms of the estimated mean time to healing over a year this was also not statistically significantly better. Morell *et al.*[23] utilised weeks free from ulcers as the outcome in their economic analysis. They found no difference in the SF-36 or the EuroQol and did not calculate QALYs for the economic analysis. Moffat *et al.*[22] did not report an incremental clinical benefit as there was no difference in the primary outcome examined between the two treatments. O'Brien *et al.*[21] did not identify a clinical outcome that would be utilised in the economic analysis. In the study by Taylor *et al.*[24], they indicate the use of the number of ulcers healed as the clinical outcome.

Costs

All studies indicated that resource utilisation and sometimes costs were captured during the clinical study, at various time periods. As shown in Table 3, all of the included studies reported direct costs. Costs included wound preparation (such as saline), ulcer applications (such as hydrocolloid dressings), skin applications (such as steroid cream), securing agents (such as gauze padding), bandages, nursing time, home visits, administration, GP services and hospital services. Where the perspective considered was that of the society, other costs such as travel and mileage costs were also considered, though other indirect costs such as productivity

Table 2. Evaluation of studies.

Study	Type of costs/ perspective	Type of economic evaluation undertaken	Outcome measure	Change in primary outcome	Confidence interval (CI) and P value	Outcome utilised in the economic evaluation	Change in costs	Outcome of economic analysis
Iglesias *et al.* 2004	Direct costs/ government perspective (UK NHS and Personal social Service)	Cost-effectiveness/ cost utility	Time to complete healing of all ulcers on the reference leg	Mean healing time for ulcers treated with four layer bandages was 10.9 days less than for ulcers treated with SSBs.	Adjusted analysis using Cox proportional hazards model suggested a statistical significant treatment effect in favour of 4LB – hazard ratio for healing 0.72 (95% CI: 0.57-.091)	Ulcer-free days (based on mean time to healing over 12 months) and QALYs (based on EQ-5D)	4L bandage mean cost £227.32 (95%CI £16.53–£448.30) less per patient per year than SSB	Difference in time to heal (days) 10.9 (–6.8,29.1). Difference in QALYs –0.02 (–0.08, 0.04) There were no statistically significant difference in QALYs or time to heal (days) between the two treatment groups.
O'Brien *et al.* 2003	Direct costs/ health board	Cost-effectiveness	Time to ulcer healing	Healing rate.	4L were 1.8 times more likely to heal by 3 months than those in control group (Control group not described adequately). 95% CI 1.2–2.9. The rate of healing throughout the 3 months was significantly better using four-layer bandaging (P = 0·006, log rank test).	None identified	Relatively small cost difference between the two groups Reduction in the median cost per leg healed with 4LB (€210 versus €234; p=0.040).	Difference in cost between groups reported only: Median cost per leg healed for 4LB (p=0.04)
Moffatt *et al.* 2003	Direct costs/ government perspective	No statement on type of economic evaluation only cost analysis. How the cost were derived was not stated in method only on the result section	Time to complete closure of ulcerated limb up to 24 weeks from trial entry	Based on ITT no evidence of difference between groups in either proportion closed at 24 weeks or in mean time to ulcer closure 4L group 50/57 healed 2LB group 40/52 healed. Eight (14%) on 4LB withdrew from their randomised bandage treatment compared with 30 (56%) on 2LB. Forty-seven (81%) of patients had closure on 4LB by study discontinuation, compared with 24 (44%) on 2LB (p<0.001).	At 12 weeks: Odds ratio=4.23,95% CI 1.29–13.36, p=0.02 At 24 weeks: hazard ratio for complete closure 1.18 (0.62–2.02), p=0.55	As there was no difference in clinical outcome this was not examined.	Despite the higher cost of 4LB the cost per week was higher in the 2LB group due to more frequent visits. Over 24-week treatment 2LB was expected to cost $61.50 (£41) more per patient for same clinical outcome	As there was no difference in clinical outcome a cost-effectiveness analysis was not conducted. The authors conducted a cost-analysis that included the direct costs of treatment.

Table 2. Evaluation of studies.

Study	Type of costs/ perspective	Type of economic evaluation undertaken	Outcome measure	Change in primary outcome	Confidence interval (CI) and P value	Outcome utilised in the economic evaluation	Change in costs	Outcome of economic analysis
Morrell *et al.* 1998	Direct costs/ government (NHS) perspective	Cost-effectiveness	Time to complete ulcer healing	Healing more evident in clinic group when compared with control group (p=0.03).	Crude healing rate in intervention group compared with control was 1.45 (95% CI 1.04–2.03.	Weeks free from ulcers	Mean annual treatment costs were £804.03 for clinic costs and £681 for the control – a difference of £122.99 (£1.56–£234.84). Mean total NHS costs were £878.06 per year for clinic group and £859.34 for the control (p=0.80).	CEA ICER: £2.46 (– £31.94 to £99.12) per ulcer-free week
Taylor *et al.* 1998	Direct costs/ government perspective	Not stated	Compare healing rates and associated treatment costs of 4LB (Group A) and conventional management (Group B) over 12-week treatment period.	4LB had higher rate of healing. Weekly treatment costs for 4LB group was less than conventional therapy (p=0.042).	A higher proportion of patient in group A (12, 75%) had their ulcers completely healed by the end of the trial when compared with those in group B (3, 21%) (p=0.003). The median healing time for group A was 55 days compared with greater than 84 days for group B.	Number of ulcers healed	Mean difference in weekly cost = £6.45, 95%CI= £1.22-11.68; p=0.042 Mean difference in whole trial cost=£113.51, 95%CI=£29.71–197.31; p=0.016	Treatment costs

Table 3. Summary of incremental costs.

Study	Type of costs/perspective	Change in costs
Iglesias *et al.* 2004	Direct costs/government perspective (UK NHS and Personal social Service)	4LB mean cost £227.32 (95%CI £16.53–£448.30) less per patient per year than SSB
O'Brien *et al.* 2003	Direct costs/health board	Reduction in the median cost per leg healed with 4LB (€210 versus €234; p=0.040).
Moffatt *et al.* 2003	Direct costs/government perspective	Over 24-week treatment 2LB was expected to cost $61.50 (£41) more per patient for same clinical outcome
Morrell *et al.* 1998	Direct costs/government (NHS) perspective	Mean annual treatment costs were £804.03 for clinic costs and £681 for control group, a difference of £122.99 (£1.56–£234.84).
Taylor *et al.* 1998	Direct costs/government perspective	Mean difference in whole trial cost=£113.51, 95% CI=£29.71-197.31; p=0.016

losses were not considered. Three out of the five studies reviewed reported cost from government perspective; O'Brien *et al.*[25] reported health board perspective, while only one study[20] reported costs from direct and societal perspective. All studies reported differences in treatment costs between the two bandage methods. Therefore, the authors were able to calculate difference between the costs of ulcer treatments.

Iglesias *et al.*[20] conducted a trial measured direct costs from a direct and social perspective. The cost of treating one ulcer was estimated to be £1,298–£1,526 per year based on 2001 costing. The authors also reported 4LB was associated with a lower cost than the SSB (4LB mean cost £227.32 (95%CI £16.53 to £448.30) less per patient per year than SSB).

Moffatt *et al.*[22] reported a higher mean cost of treatment in the 2LB compares with the 4LB system arm over 24 weeks ($1374 [£916] vs $1314 [£876] respectively) was explained by the increased mean number of bandage changes with the 2LB system (1.5 vs 1.1 per week). The authors reported 4LB advantages over the 2LB in terms of reduced withdrawal from treatment, fewer adverse incidents and lower treatment costs. O'Brien *et al.*[21] reported no reduction in the median cost per leg healed with the 4LB group (€210 versus €234; p=0.040) and the difference was very small in absolute terms[23].

Economic evaluation

Taylor *et al.*[24] reported costs per group with a reduction in the median cost per leg healed with 4LB (€210 versus €234; p=0.040).

Moffat *et al.*[22] found there was no significant difference in the rate of ulcer closure or the time to ulcer closure for patients managed with 4LB or 2LB and there was no evidence that either bandage was superior over the 24-week follow-up period. They conducted a cost analysis and calculated that over the 24-week treatment period, the 2LB cost $61.50 (£41) more per patient for the same clinical outcome.

Morrel *et al.*[23] conducted a cost-effectiveness analysis and found that the incremental cost-effectiveness ratio (ICER) was £2.46 (-£31.94 to £99.12) per ulcer free week. One-way sensitivity analysis was undertaken to investigate the effect that different assumptions might have on mean costs. Changes in assumptions relating to treatment costs and overheads in the control group did not significantly affect the magnitude of costs.

Iglesias *et al.*[20] conducted both cost-effectiveness (incremental time to healing; utilising unadjusted data) and a cost-utility analysis. They also conducted a sensitivity analysis across three scenarios and calculated a cost-effectiveness probabilistic analysis. When the confidence intervals were considered, neither outcome was statistically different between the groups. Iglesias *et al.*[20] conducted a trial that measured direct costs from a direct and social perspective. The cost of treating one ulcer was estimated to be £1,298 to £1,526 per year based on 2001 costing. The study reported that base case analysis demonstrated 4LB was associated with an improved health benefit, the 4LB group had a better quality of life than those in the SSB with an annual difference in QALYs reported as 0.02 (95% CI –0.08 to 0.04).

Discussion

The value of an economic evaluation lies in assisting decision makers who need to make informed choices. Economic evaluation takes into account both the benefit and costs of an intervention and provides an aid to funding decisions. An economic evaluation involves a specific comparison of the cost and consequences of at least two alternatives. The comparator should preferably be either that most commonly

utilised or the best current practice[2]. Ideally an economic evaluation should be more concerned with effectiveness [does it work in clinical practice?] than with efficacy [can it work in a defined population?]. When benefits are derived from RCTs, then what is utilised are efficacy outcomes. When assessing economic evaluations in wound care studies, it is important to identify the following criteria: the type of analysis conducted, the perspective of analysis; measure of benefit, estimating cost; type of cost, dealing with uncertainty; time horizon, and discounting (if the follow-up exceeds more than one year)[26].

Given the diversity of the studies and the reporting of the costs, it is difficult to draw any conclusions regarding the incremental costs across all studies. Usually the main outcome of interest in cost-effectiveness and cost-utility analyses is the ICER. The ICER shows the additional cost required in achieving an extra unit of outcome, and this would be useful to decision makers. For example, the incremental cost of improved healing rates of one compression bandage compared to another is a useful measure on which to base a clinical decision.

Though the studies reviewed were well conducted there may have been missed opportunities in the presentation of the evidence. The calculation of an ICER would have been a useful measure to decision makers, as economically what happens at the margin is most important. The incremental cost of improved healing rates of one compression bandage compared to another would have been a useful measure on which to base a clinical decision but only when considering technical efficiency questions. The use of other more generic outcome measures such as QALYs would allow the assessment of cost-effectiveness and value for money compared with treatments and interventions in other clinical contexts.

Conclusion

This review evaluated all available RCTs, examining the clinical effectiveness of different types of compression bandaging therapies that had undertaken an economic evaluation as part of their investigation, and reported and assessed these outcomes. Given the diversity of studies reviewed, we would recommend some consideration be given to the use of CHEC guidelines to ensure uniform and transparent reporting of economic evaluation alongside

RCTs. Clearer outcome measure reporting in RCTs and economic evaluations may facilitate improved best practice decision making by clinicians and health policy makers.

Abbreviations

4LB	Four-layer bandage
2LB	Two-layer bandage
CI	Confidence interval
ICER	Incremental cost-effectiveness ratio
QALYs	Quality adjusted life years
RCT	Randomised controlled trial
VLU	Venous leg ulcer

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