Clinical outcomes and cost-effectiveness of three alternative compression systems used in the management of venous leg ulcers

• **Objective:** To assess clinical outcomes and cost-effectiveness of using a two-layer cohesive compression bandage (TLCCB; Coban 2) compared with a two-layer compression system (TLCS; Ktwo) and a four-layer compression system (FLCS; Profore) in treating venous leg ulcers (VLUs) in clinical practice in the UK, from the perspective of the National Health Service (NHS).

• **Method:** This was a retrospective analysis of the case records of VLU patients, randomly extracted from The Health Improvement Network (THIN) database (a nationally representative database of clinical practice among patients registered with general practitioners in the UK), who were treated with either TLCCB (n=250), TLCS (n=250) or FLCS (n=175). Clinical outcomes and health-care resource use (and costs) over six months after starting treatment with each compression system were estimated. Differences in outcomes and resource use between treatments were adjusted for differences in baseline covariates.

• **Results:** Patients' mean age was 75 years old and 57% were female. The mean time with a VLU was 6–7 months and the mean initial wound size was 77–85cm^2. The overall VLU healing rate, irrespective of bandage type, was 44% over the six months' study period. In the TLCCB group, 51% of wounds had healed by six months compared with 40% (p=0.03) and 28% (p=0.001) in the TLCS and FLCS groups, respectively. The mean time to healing was 2.5 months. Patients in the TLCCB group experienced better health-related quality of life (HRQoL) over six months (0.374 quality-adjusted life years (QALYs) per patient), compared with the TLCS (0.368 QALYs per patient) and FLCS (0.353 QALYs per patient). The mean six-monthly NHS management cost was £2,413, £2,707 and £2,648 per patient in the TLCCB, TLCS and FLCS groups, respectively.

• **Conclusion:** Despite the systems studied reporting similar compression levels when tested in controlled studies, real-world evidence demonstrates that initiating treatment with TLCCB, compared with the other two compression systems, affords a more cost-effective use of NHS-funded resources in clinical practice, since it resulted in an increased healing rate, better HRQoL and a reduction in NHS management cost. The evidence also highlighted the lack of continuity between clinicians managing a wound, the inconsistent nature of the administered treatments and the lack of specialist involvement, all of which may impact on healing.

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Coban 2; compression; cost-effectiveness; economic evaluation; KTwo; Profore; venous leg ulcer; UK

Increasing bandage component stiffness has been proposed to improve the effectiveness of compression systems increasing venous ejection fraction in ambulant patients.[1] In clinical practice, the optimum care is determined by consideration of a number of factors, including the severity of the wound and the height and limb size of the patient.

There are many different compression bandages available, and they vary greatly in their ability to provide sustained compression over a prolonged period, owing to differences in their structure and content of elastomeric yarns.[2] Other factors, in addition to nurses' skills, such as limb circumference and shape, also affect the pressure produced beneath a compression bandage.[2] The relative efficacy of these various systems on ulcer healing is summarised in a systematic review of 4,321 randomised controlled trial participants.[2] One of the conclusions from the review was that multicomponent systems were more efficacious than single-component systems, and those with elastic bandages were more efficacious than inelastic systems. However, there were no clear differences in the efficacy of different types of high compression.[2] A more recent publication reported that in three separate studies the healing rate of non-healing venous leg ulcers (VLUs) of >3 months' duration never treated with

J.F. Guest,[1,2] PhD, Director of Catalyst, Visiting Professor of Health Economics; **A. Gerrish**,[1] RGN, BSc, Research Nurse; **N. Ayoub**,[1] BA, Researcher Assistant; **K. Vowden**,[3] MSc, RN, Nurse Consultant; **P. Vowden**,[3] MD, FRCS, Consultant Vascular Surgeon, Professor of Wound Healing Research 1 Catalyst Health Economics Consultants,

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Northwood, Middlesex, UK
2 Faculty of Life Sciences and Medicine, King's College, London, UK;
3 Bradford Teaching Hospitals NHS Foundation Trust and University of Bradford, UK.

Email: Julian Guest <julian.guest@catalyst-health.com

compression bandaging was double that of VLUs treated with compression.[3] Additionally, the healing rate among VLUs managed with short-stretch compression bandage was 22% higher than among those managed with multi-layer compression.[3] These compression systems have been demonstrated to produce similar compression levels when studied in controlled situations.

The aim of this present study was to use real-world evidence to assess the clinical outcomes and cost-effectiveness of using Coban 2, a two-layer cohesive compression bandage (TLCCB) compared with Ktwo, a two-layer compression system (TLCS) and Profore, a four-layer compression system (FLCS) in treating VLUs in clinical practice in the UK, from the perspective of the National Health Service (NHS).

TLCCB contains an inner latex-free foam sheet with a cohesive backing on the foam side to the skin. The outer layer is a short-stretch cohesive bandage that is applied over the inner layer to provide compression. The cohesive backing on the inner layer has adhesive properties that enable it to attach to the outer layer, so that the two layers interlock to create an inelastic bandage system.

TLCS consists of inelastic short-stretch bandage wadding that is designed to be in contact with the skin. This is attached to an outer elastic, long-stretch, cohesive bandage, which provides the required therapeutic pressure necessary to maintain improved blood flow.

FLCS is a multi-layer compression bandaging system that consists of a knitted viscose primary dressing as a wound contact layer; a roll of absorbent padding formed from viscose fibres; a woven 'crepe'-type bandage used to hold the absorbent padding in place; a lightweight Class 3a elastic compression bandage; and a Class 3b cohesive bandage that also acts as a retaining layer. The compression produced by this bandage system is the sum of the individual pressures produced by each of the three extensible bandages. Hence, limbs of different sizes require different proportions of the four components to achieve clinically effective levels of compression. The clinical evidence supporting these three compression systems has been reported elsewhere.[2,4–9]

Method

The Health Improvement Network database

The Health Improvement Network (THIN) database (Cegedim, London, UK) contains computerised information on >9 million anonymised patients entered by GPs from 500 practices across the UK. General practices across the UK using Vision Practice Management Software are invited to participate in the database and are self-selecting. The patient data within THIN have been shown to be representative of the UK population in terms of demographics and disease distribution.[10] Read codes are a coded thesaurus of clinical terms that are used by clinicians in the UK to record patient findings and procedures in health and social care information technology systems.[11] They have been in use in the NHS since 1985[11] and have been used to code specific diagnoses in the THIN database. A drug dictionary based on data from the Multilex classification has been used to code drugs in the database. Successive updates of patients' records to the database include any subsequent changes made by GPs. The computerised information in the THIN database includes patients' demographics, details of GP consultations, specialist referrals, nurse and other clinician visits, hospital admissions, diagnostic and therapeutic procedures, laboratory tests and prescriptions issued by GPs that are directly generated by the practice's information technology system. Hence, the information contained in the THIN database reflects real clinical practice, as it is based on patient records. Moreover, GPs are the gatekeepers to health care in the UK and patients' entire medical history is theoretically stored in their primary care record.

Study design

This was a retrospective cohort analysis of the case records of VLU patients randomly extracted from the THIN database who were treated with TLCCB, TLCS or FLCS.

Study population

The study population comprised a randomised sample of patients in the THIN database who were treated with TLCCB. The following criteria were used to randomly select the TLCCB-treated patients from the database:

- >18 years old or over
- Had a read code for a VLU
- Received TLCCB at any time for their VLU
- Had never received treatment with FLCS or TLCS before the start of treatment with TLCCB
- Had at least six months' continuous medical history in their case record from the first mention of TLCCB, unless they died.

The TLCCB-treated patients were matched with two randomly selected cohorts of FLCS-treated and TLCS-treated patients according to:

- Age (±5 years). Patients were >18 years old or over
- Gender (however this criteria was relaxed in order to fulfil the other criteria)
- Being managed at the same general practice
- Date of diagnosis of their VLU (±5 years)
- Year of treatment (±5 years)
- Received either FLCS or TLCS at any time
- Had never received treatment with one of the study's comparators before the start of treatment with FLCS or TLCS
- Had at least six months' continuous medical history in their case record from the first mention of FLCS or TLCS unless they died.

Ethics approval

Ethics approval to use patients' records from the THIN database for this study was obtained from the Research Ethics Committee that appraises studies using the THIN database.

Study variables

Information was systematically extracted from the patients' records for a period of six months from the start of treatment and included age, sex, length of wound and wound size (estimated to be 80% of the size of the primary contact dressing), wound-related health-care resource use, prescribed medication and clinical outcomes.

It was assumed that if a patient received a bandage or dressing on a specific date, but a clinician visit was not documented in their record, the patient had been seen outside of the general practice by a community nurse. Patients' outcomes and resource use were quantified for each group.

Statistical analysis

Differences between the groups were tested for statistical significance using a Kruskal-Wallis test or Chi-Square test. Analysis of covariance (ANCOVA) enabled differences in patients' outcomes and resource use between treatments to be adjusted for any heterogeneity in the following covariates: age, sex, date of starting treatment, length of wound and wound size at baseline. 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 Corporation).

Health economic modelling

A decision model was constructed using MS Excel depicting the patient pathways and associated management of patients in each of the three groups. The model was populated with transition probabilities, health-care resource use and clinical outcomes extracted from the THIN dataset. Non-wound-related resource use was excluded from the model. The model spans a period of six months from the start of treatment with each of the compression systems.

Since the timeframe was relatively short, and recurring events (in terms of patients moving into different health states) were relatively static, a decision-tree model was considered the most appropriate model to answer this study's objectives.

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 THIN database. Hence, utility scores for VLUs,[12] 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 dataset, 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 at six months from the start of treatment with one of the three compression systems.

Model outputs

The primary measure of clinical outcome was patients' health status in terms of the number of QALYs at six months. Secondary measures were a range of outcomes that included healing rate, wound size reduction and time to healing. By assignment of unit resource costs at 2012/2013 prices[13–15] to the resource use estimates within the model, the health-care cost of managing patients in each group over six months from the start dates was estimated.

Cost-effectiveness analyses

The relative cost-effectiveness of the three compression bandages was calculated as the difference between the expected costs of two groups divided by the difference in the number of QALYs between the same two groups and expressed as the incremental cost per QALY gained. If one of the compression bandages generated more QALYs for less cost it was considered to be the dominant (cost-effective) formula.

Sensitivity analyses

To assess uncertainty, bootstrapping was undertaken to estimate the distribution of expected costs, QALYs and incremental cost-effectiveness ratios. This involved generating 10,000 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 the alternative compression systems 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 the alternative treatments would change by varying the different parameters in the model.

Results

Patient characteristics

Patients treated with each compression system (n=500 per group) were obtained from the THIN database in accordance with the inclusion/exclusion criteria and matching criteria. Of these, 250 randomly selected patients in the TLCCB group were successfully

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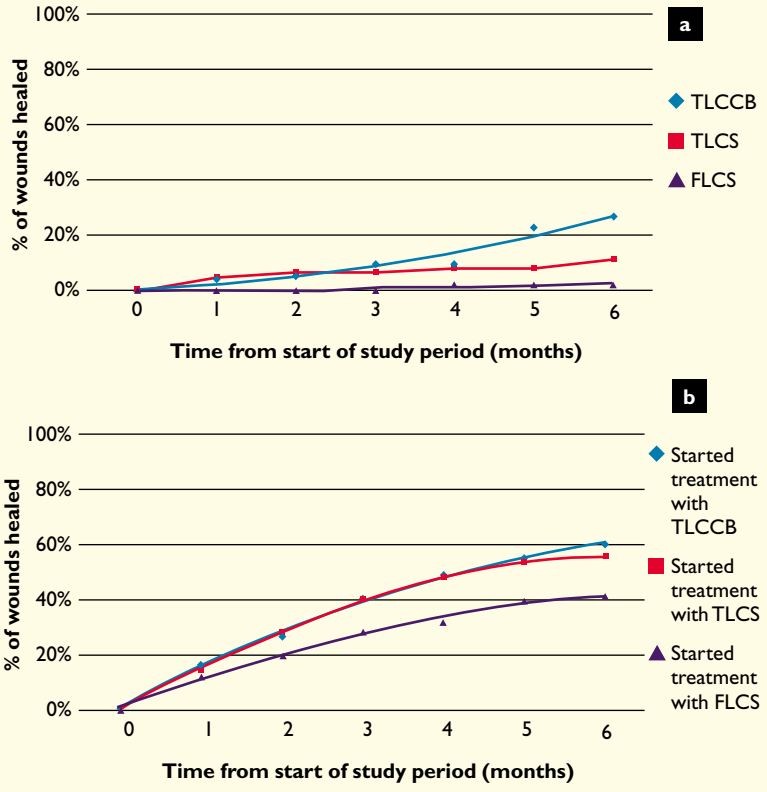
Fig 1. Healing rates among patients who remain on their initial compression (a), healing rates among patients who switched from their initial compression (b)



TLCCB – two-layer cohesive compression bandage; TLCS – two-layer compression system; FLCS – four-layer compression system

matched with 250 patients in the TLCS group, but with only 175 patients in the FLCS group. This is because 65% (n=325) of the 500 FLCS-treated patients who were randomly extracted from the THIN database received inappropriate compression (only absorbent padding and light conforming bandage).

There were no significant differences in patients' age, gender, age of patients' wound, initial wound size and the percentage of new wounds between the three groups (Table 1).

Patient management and outcomes

Between 73% and 79% of patients switched from their initial to another compression system after a mean of 1.2 months of treatment (Table 2). In some cases, this included switching to one of the study's other comparators. The healing rate for all patients was 44%, irrespective of bandage type. Overall, 51% of wounds in the TLCCB group healed by six months compared to 40% (p=0.03) and 28% (p=0.001) in the TLCS and FLCS groups, respectively. Also, patients in the TLCCB group experienced better HRQoL compared with the other two groups (Table 2). However, the mean time to healing was the same in all three groups (Table 2).

Healing rates for patients who continued to use their initial compression for the whole study period and those who switched to another compression system are shown in Figures 1a and 1b. Among those who continued to use their initial compression for the whole study period, significantly more VLUs in the TLCCB group healed by six months (26%) compared with the other two groups (TLCS (11%) and FLCS (2%); p<0.02) (Table 2).

Logistic regression showed that a patient's age (odds ratio 1.02; p<0.05), age of their wound (odds ratio 0.96; p<0.001) and size of their wound at the start of treatment (odds ratio 0.98; p<0.05) were independent predictors of healing. Additionally, a patient's wound size at the start of treatment was an independent predictor of reduced healing during the first month of treatment (odds ratio 0.97; p<0.001). Moreover, a patient's age (odds ratio 1.02; p<0.03) and the age of their wound (odds ratio 0.97; p<0.005) were independent predictors of switching from their initial compression. A patient's age was also an independent risk factor for dying during the study period (odds ratio 1.09; p<0.02).

Health-care resource use

There were no significant differences in health-care resource use between the three groups (Table 3). Patients were predominantly managed by practice nurses and community nurses; fewer than 0.1% of patients were seen by a tissue viability nurse. Of all the patients analysed, 53% were seen by a GP for their VLU and 4% were referred to a hospital physician in an outpatient clinic. On average, dressings were changed every 2 days in month one, decreasing to every 4–5 days by month six of the study period.

Table 1. Patients' characteristics in the dataset, at study start

	TLCCB	TLCS	FLCS
Cohort size	250	250	175
Mean age per patient (years)	74.7 ± 0.9	74.5 ± 0.9	76.9 ± 1.0
Female (%)	53%	62%	55%
New wounds (%)	38%	42%	38%
Mean age of wound per patient (months)	6.9 ± 12.4	6.1±12.6	6.7 ± 11.5
Mean initial wound size per patient (cm^2)	77.6 ± 1.7	77.0 ± 1.7	85.2 ± 2.1

TLCCB – two-layer cohesive compression bandage; TLCS – two-layer compression system; FLCS – four-layer compression system

Linear regression showed that for each additional year of age at baseline, patients had 0.2 fewer practice nurse visits (p=0.001). Linear regression also showed that for each additional cm^2 of wound area at baseline, the patients in the dataset incurred:

- 0.2 more community nurse visits (p=0.03)
- 0.4 more compression bandages (p=0.001)
- 1.2 more dressings (p=0.001)
- 0.3 more bandages (p<0.02)
- 0.5% less reduction in wound size (p= 0.002)
- Additional NHS management cost of £11 (p=0.001).

Moreover, for each additional month of having a wound at baseline, patients incurred:

- 0.5 more compression bandages (p=0.001)
- 1.6 more dressings (p=0.001)
- 0.8 more bandages (p=0.001)
- 1% less reduction in wound size (p=0.006)
- Additional NHS management cost of £20 (p=0.001).

Health-care cost of patient management

The six-monthly NHS cost of managing patients in each group is summarised in Table 4. The six-monthly NHS cost of managing a VLU with TLCCB was £2,412 ± 119 per patient, which was 11% and 9% lower than the cost of managing patients in the TLCS group (£2,707 ± 119 per patient) and FLCS group (£2,648 ± 144 per patient).

Community nurse visits were the primary cost drivers in all groups, accounting for 61–64% of the six-monthly NHS cost. Practice nurse appointments were the secondary cost driver, accounting for up to a further 12% of costs. Dressings and compression bandages each accounted for up to a further 10% of costs, while GP consults and hospital outpatient visits also accounted for up to a further 10% of costs.

Cost-effectiveness analyses

Use of TLCCB resulted in a lower six-monthly NHS cost and more QALYs than the other two compression systems. Hence, starting treatment with TLCCB was found to be the dominant strategy. Starting treatment with TLCS instead of FLCS resulted in an NHS cost increase of £58 per patient and a gain of 0.015 QALYs per patient. Hence, the cost per QALY gained from using TLCS instead of FLCS was £3,892.

The cost per QALY gained with TLCCB compared with both the other treatments was less than the National Institute for Health and Care Excellence's (NICE) recommended threshold of £20,000. Similarly, the cost per QALY gained with TLCS compared to FLCS was less than £20,000. Hence, these analyses suggest that TLCCB is the preferred treatment, followed by TLCS and FLCS, in that order.

Sensitivity analyses

Bootstrapping was performed to identify the distribution in the incremental costs and QALYs at six months for the three alternative compression systems (Fig 2),

Table 2. Patients' outcomes at six months

	TLCCB	TLCS	FLCS
Continue to use the compression bandage for the full study	21%	25%	27%
Mean time on the study compression bandage before switching per patient (in months)	1.3 ± 0.1	1.2 ± 0.1	1.2 ± 0.2
Patients in each group whose VLU healed* (%)	51%	40%	28%
Patients whose VLU healed while using their initial compression bandage for the six months' study period** (%)	26%	11%	2%
Patients whose VLU healed after switching from their initial compression bandage *** (%)	60%	56%	41%
Reduction in wound size (%)	60%	58%	57%
Mean time to wound healing per patient (months)	2.5±0.2	2.4±0.2	2.5±0.3
Mean number of QALYs per patient ****	0.374 ± 0.004	0.368 ± 0.004	0.353 ± 0.005
Patients who died during the study period (%)	2%	1%	4%

TLCCB – two-layer cohesive compression bandage; TLCS – two-layer compression system; FLCS – four layer compression system; VLU – venous leg ulcer

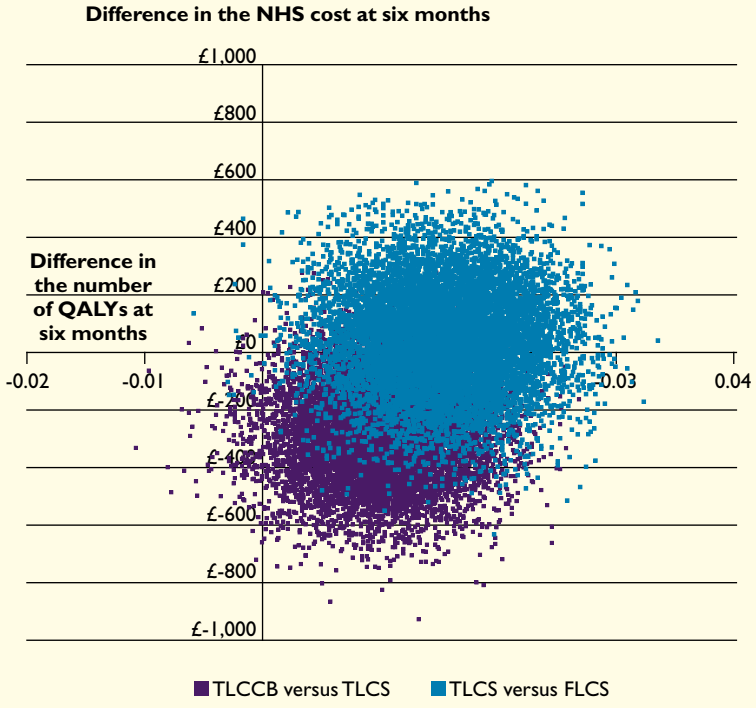
*TLCCB vs TLCS: p=0.03; TLCCB vs FLCS: p=0.001; TLCS vs FLCS: p< 0.05; **TLCCB vs TLCS and FLCS: p<0.02; ***TLCCB and TLCS vs FLCS: p=0.01; ****TLCCB vs FLCS: p=0.001; TLCS vs FLCS: p< 0.02

Table 3. Mean amount of health-care resource use per patient, over the six months study period

Health-care resource use	TLCCB	TLCS	FLCS
Community nurse visits	51.6 ± 4.6	54.7 ± 4.6	57.8 ± 5.5
Practice nurse visits	7.5 ± 1.2	12.5 ± 1.2	9.9 ± 1.4
Tissue viability nurse visits	0.03 ± 0.01	0.01 ± 0.01	0.03 ± 0.02
GP consults	2.4 ± 0.3	1.6 ± 0.3	2.5 ± 0.4
Hospital outpatient visits	0.5 ± 0.1	0.3 ± 0.1	0.7 ± 0.2
Diagnostic tests	0.30 ± 0.1	0.31 ± 0.1	0.18 ± 0.1
Hospital admissions	0.08 ± 0.02	0.03 ± 0.02	0.05 ± 0.02
Accident & emergency admissions	0.12 ± 0.03	0.09 ± 0.03	0.14 ± 0.04
Dressings and bandages			
Dressings	106.6 ± 8.0	96.2 ± 8.0	125.4 ± 9.8
Compression bandages	51.9 ± 3.4	59.8 ± 3.5	56.1 ± 5.2
Other bandages	37.5 ± 4.7	21.0 ± 4.7	69.8 ± 5.7
Prescribed medication			
Prescriptions for topical treatments	0.60 ± 0.1	0.09 ± 0.1	0.47 ± 0.1
Prescriptions for analgesics and NSAIDs	126.0 ± 11.3	130.0 ± 11.5	143.0 ± 17.6

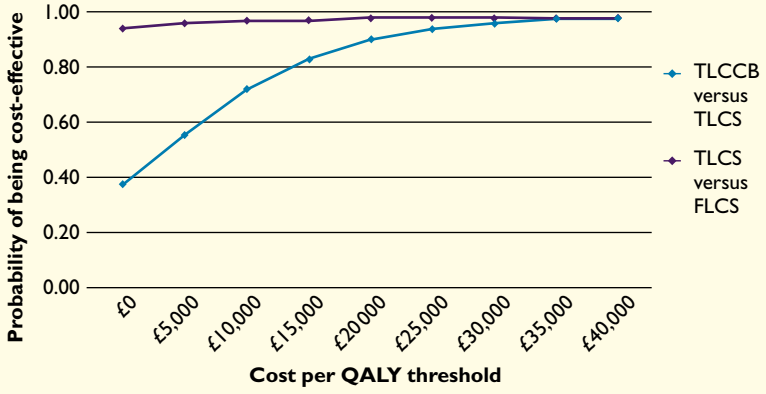
TLCCB – two-layer cohesive compression bandage; TLCS – two-layer compression system; FLCS – four-layer compression system; NSAIDs – nonsteroidal anti-inflammatory drugs

Fig 2. Scatterplot of the incremental cost-effectiveness of TLCCB versus TLCS and TLCS versus FLCS (10,000 bootstrapped samples)



TLCCB – two-layer cohesive compression bandage; TLCS – two-layer compression system; FLCS – four-layer compression system; QALY's – qualilty-adjusted life years

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



TLCCB – two-layer cohesive compression bandage; TLCS – two-layer compression system; FLCS – four-layer compression system

Discussion

This comparative study aimed to determine the clinical outcomes and relative cost-effectiveness of using TLCCB, TLCS and FLCS in the treatment of VLUs in clinical practice in the UK, based on real-world evidence. Accordingly, a random sample of patients in the THIN database who had a VLU diagnosis and were treated with TLCCB was compared with matched TLCS-treated and FLCS-treated patients. Patients in the data set had to have a clinical history for at least six months, unless they died, in order to exclude patients who had moved or changed their general practice. The advantage of using the THIN database 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. Patients were not randomised to the treatment they received. Hence, there would have been differences between the groups, resulting in the clinician's decision to treat with one of the three compression bandages and the patient's willingness to accept the clinician's preferred treatment. For example, the additional absorptive padding incorporated into FLCS may have favoured the use of this compression system in patients with more complex highly exudating wounds. Additionally, the VLUs in the FLCS group were larger, although the difference was not statistically significant, and this may suggest a degree of selection bias. Every attempt was made to account for these differences and to overcome the non-randomised study design. Differences in patients' outcomes and resource use between treatments were adjusted for any heterogeneity in age, gender, date of starting treatment, duration of wound and wound size at baseline. Moreover, 675 patients have been included in the analysis, which should have been a sufficiently large sample to allow for relevant baseline differences to be apparent. Nevertheless, there will have been some differences that have not been accounted for.

For patients to be included in the data set, they had to have been prescribed either TLCCB, TLCS or FLCS as their initial treatment during the study period and be matched on the basis of age, gender, the same general practice, date of VLU diagnosis and year of treatment. Wound severity was not included as a matching criteria, since this was not documented in the patients' records. All the patients in this data set had a VLU diagnosis and they were predominantly managed in the community by community nurses and practice nurses. Furthermore 53% of all patients were seen by a GP for their VLU during the study period and only 4% were referred to a hospital physician in an outpatient clinic. The THIN dataset in this study covers the period from 2009 to 2013, so this is a reflection of how most patients with VLUs were managed in the community in the UK at that time. Our study does not address the question of who should diagnose and manage VLUs or how it should be done, or the more complex question of integrated care pathways.

After adjustment for baseline differences, this study estimated that over the first six months after starting

treatment with TLCCB, the healing rate increased by 28% and 82% when compared with TLCS and FLCS respectively. However, the extent to which the higher healing rates observed in patients who switched from their initial compression bandage could be ascribed to the initial compression system is unknown. Nevertheless, these healing rates and the other outcomes are the consequences of the decision to initially treat with either TLCCB, TLCS or FLCS. Moreover, those patients who continued with their initial compression system throughout the study period showed significant differences in healing, with more than twice as many wounds recorded as being healed with TLCCB than with TLCS and FLCS. Moreover, patients in the TLCCB group experienced a better HRQoL; and they cost the NHS 9–11% less to manage than the patients in the other two groups. The question as to why healing increased so substantially after switching compression systems cannot be answered from this study and should be the subject of further research.

VLU healing rates at one month in the TLCCB and FLCS groups were consistent with those previously reported.[16] However, the healing rates at other time points among patients in the TLCS and FLCS groups were lower than those seen in several phase III studies.[7,8,17–19] This difference, together with the differences in healing rates between the three groups (Fig 1), reflects clinical differences between alternative compression systems that are experienced by patients in clinical practice. They also highlight the variance between healing rates reported in clinical trials and those observed in clinical practice, possibly reflecting the narrow admission criteria of clinical trials compared with the cohort of patients who receive treatment in clinical practice.

These differences may also highlight some of the practical problems associated with wound care in the community and the lack of skills required to both select and apply appropriate compression therapy. Patients in our dataset rarely saw the same nurse at successive visits. Hence, a lack of continuity of care and the practical difficulties experienced by non-specialist nurses in the community in achieving the correct levels of compression, as well as the lack of specialist involvement, may contribute to the poorer outcomes seen in clinical practice rather than controlled trials. Patients' compliance with compression bandaging may also be a contributory factor to these differences. Hence, this real-world evidence highlights the importance of training non-specialist nurses in the correct management of VLUs and the application of compression systems in order to overcome some of the problems encountered in clinical practice and to achieve better health outcomes than those currently being observed.

We have previously reported that nursing time is a cost driver in the management of VLUs[20,21] and the six-monthly cost of patient management is concordant with our previous studies on the cost of managing VLUs in clinical practice.[20,21]

Table 4. Mean NHS cost (at 2012/13 prices) of health-care resource use per patient over the six months study period

	TLCCB	TLCS	FLCS
Community nurse visits	£1505.10 (62%)	£1734.20 (64%)	£1626.90 (61%)
Compression bandages	£227.73 (9%)	£272.25 (10%)	£204.85 (8%)
Dressings	£206.54 (9%)	£197.08 (7%)	£260.10 (10%)
Practice nurse appointments	£195.00 (8%)	£325.00 (12%)	£257.40 (10%)
GP consults	£97.46 (4%)	£66.54 (2%)	£100.61 (4%)
Hospital outpatient appointments	£71.95 (3%)	£39.90 (1%)	£91.77 (3%)
Other bandages	£36.51 (2%)	£15.74 (1%)	£45.52 (2%)
Consumable	£17.59 (1%)	£12.90 (<1%)	£11.15 (<1%)
Diagnostic tests	£15.56 (1%)	£15.48 (1%)	£8.40 (<1%)
Accident and emergency admissions	£13.69 (1%)	£9.86 (<1%)	£16.59 (1%)
Prescribed drugs	£11.14 (<1%)	£13.02 (<1%)	£15.22 (1%)
Hospital admissions	£9.32 (<1%)	£3.68 (<1%)	£5.98 (<1%)
Topical treatments (emollients and other skin care products)	£2.79 (<1%)	£0.43 (<1%)	£2.17 (<1%)
Tissue viability nurse visits	£1.57 (<1%)	£0.49 (<1%)	£1.57 (<1%)
TOTAL	£2411.93	£2706.58	£2648.21

TLCCB – two-layer cohesive compression bandage; TLCS – two-layer compression system; FLCS – four-layer compression system

Limitations

This study has a number of other limitations. The results were censored at six months and excluded the costs and consequences of managing patients beyond this period. The THIN database may have under-recorded use of some health-care resources outside the GP's surgery, such as some home visits made by clinicians, community nurse visits, outpatient visits, attendance at accident and emergency departments and hospital admissions, if not documented in the GP records. The analysis excluded hospital-based prescribing, but this should have minimal impact on the results, since most prescribing is undertaken by GPs and some nurses in the community. The analysis only considered the cost of NHS resource use for the 'average patient' and no attempt was made to stratify resource use and costs according to gender, comorbidities, suitability of patients for different treatments, other disease-related factors and level of clinician's skills. Also excluded were the costs incurred by patients and indirect costs incurred by society as a result of patients taking time off work. However patients' mean age was >65 years, so it is unlikely that many were in employment.

Table 5. Sensitivity analyses

Scenario	Range in the cost per QALY gained with TLCCB versus TLCS	Range in the cost per QALY gained with TLCS versus FLCS
Probability of healing in all three groups ranges from 0.5 below to 1.5 above the base case value	Ranges from -£103,200 to -£30,800	Ranges from £11,000 to £1,500
Number of community nurse visits ranges from 50% below and above the base case value	Ranges from -£29,800 to -£68,000	Ranges from £314 to £7,500
Number of practice nurse visits ranges from 50% below and above the base case value	Ranges from -£38,100 to -£59,800	Ranges from £1,600 to £6,100
Number of GP consults ranges from 50% below and above the base case value	Ranges from -£51,500 to -£46,400	Ranges from £5,000 to £2,800
Number of hospital outpatient visits ranges from 50% below and above the base case value	Ranges from -£51,600 to -£46 300	Ranges from £5,600 to £2,200
Number of compression bandages ranges from 50% below and above the base case value	Ranges from -£45,200 to -£52,700	Ranges from £1,600 to £6,100
Number of dressings ranges from 50% below and above the base case value	Ranges from -£49,700 to -£48,200	Ranges from £6,000 to £1,800

This evaluation provided an estimate of the clinical outcomes, resource implications, and associated costs attributable to managing VLU patients in clinical practice. While the study results are compelling, the analyses of clinical outcomes were based on clinicians' entries into their patients' records and inevitably subject to a certain amount of imprecision and lack of detail. Moreover, the computerised information in the THIN database is collected by GPs for clinical care purposes and not for research. Prescriptions issued by GPs and nurses are recorded in the database, but it does not specify whether the prescriptions were dispensed or patient compliance with the product. Nevertheless, it is the authors' opinion that the THIN database affords one of the best sources of real-world evidence for clinical practice in the UK. To inform this opinion, this study's findings could provide the framework for an observational study comparing the use of TLCCB, TLCS and FLCS in the management of VLU patients in clinical practice to prospectively measure a range of clinical outcomes and HRQoL in combination with cost-effectiveness metrics.

Conclusion

Within the limitations of the dataset, real-world evidence demonstrates that starting treatment with TLCCB, compared to the other two compression systems, affords a more cost-effective use of NHS-funded resources since it resulted in an increased healing rate, better HRQoL and a reduction in NHS management cost. The evidence also highlighted the lack of continuity between clinicians managing a wound, the inconsistent nature of the administered treatments and the lack of specialist involvement, all of which may impact on healing. Clinicians managing wounds and those recommending compression products for use by community nurses may wish to consider the results of this study when making treatment recommendations. ■

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