Cost-effectiveness of two reduced pressure compression systems in treating newly diagnosed venous leg ulcers

Objective: To assess the clinical outcomes and cost-effectiveness of using two different reduced pressure compression systems in treating newly diagnosed venous leg ulcers (VLUs) in clinical practice, from the perspective of the UK's National Health Service (NHS).
Methods: This was a modelling study based on a retrospective cohort analysis of the case records of patients with a newly diagnosed VLU, randomly extracted from The Health Improvement Network (THIN) database, who were initially treated with a two-layer cohesive compression bandage (TLCCB Lite; Coban 2 Lite, 3M, US) or a two-layer compression system (TLCS Reduced; Ktwo Reduced, Urgo, France). No significant differences were detected between the groups. Nevertheless, analysis of covariance (ANCOVA) was performed to enable differences in patients' outcomes between the groups to be adjusted for any heterogeneity in baseline covariates. Clinical outcomes and cost-effectiveness of the alternative compression systems were estimated over 12 months after starting treatment.
Results: Time from wound onset to starting compression was a mean of two months. The probability of healing at 12 months was 0.59 in the TLCCB Lite group and 0.53 in the TLCS Reduced group. Patients in the TLCCB Lite group experienced a marginally better health-related quality of life (HRQoL) of 0.02 quality-adjusted life years (QALYs) per patient compared to those in the TLCS Reduced group. The 12-month NHS wound management cost was £3883 per patient treated with TLCCB Lite and £4235 per patient treated with TLCS Reduced. When the analysis was repeated without ANCOVA, the findings from the base case analysis remained unchanged (i.e., use of TLCCB Lite improved outcomes at lower cost).
Conclusion: Within the study's limitations, treating newly diagnosed VLUs with TLCCB Lite instead of TLCS Reduced potentially affords a cost-effective use of NHS-funded resources in clinical practice, since it is expected to result in an increased healing rate, better HRQoL and a lower NHS wound management cost.
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Coban 2 Lite • compression • cost-effectiveness • Ktwo Reduced • UK • venous leg ulcer • VLU • wound • wound care • wound healing

The prevalence of venous leg ulcers (VLUs) in adults over 18 years of age in the UK was estimated to be 1 per 100 individuals in 2017/18,[1] and they remain a major cause of morbidity and decreased health-related quality of life (HRQoL).[2]

The underlying pathophysiology of venous leg ulceration is assumed to be chronic venous insufficiency arising from venous hypertension.[3] Venous hypertension increases capillary permeability, resulting in tissue oedema and several biochemical and physiological effects that may lead to the formation of VLUs.[4] These same mechanisms may also hinder tissue repair.

Compression therapy is now generally accepted as the mainstay of treatment for promoting the healing of VLUs. By producing a graduated pressure in the lower limb to improve venous return, compression therapy can slow down or reverse the mechanisms resulting in chronic venous insufficiency.[5,6]

Compression therapy has been shown to be extremely beneficial in promoting VLU healing in both clinical trials[7] and clinical practice.[8,9] A two-layer cohesive compression bandage system (TLCCB; Coban 2, 3M, US) and a two-layer compression system (TLCS; Ktwo, Urgo, France) both provide high strength compression (35–40mmHg) and have been reported to be suitable for treating the majority of patients with an ankle–brachial pressure index (ABPI) of ≥0.8.[10,11] Some patients with painful VLUs are unable to tolerate high strength compression. Additionally, high strength compression may be contraindicated in patients with a mixed-aetiology leg ulcer or in those who have an ABPI of 0.5–0.8.[12] The TLCCB Lite (3M, US)[10,13] and TLCS Reduced (Urgo, France)[11] compression systems provide reduced pressure (25–30mmHg), making them safe and more suitable options for patients who are less tolerant of high strength compression therapy or for those for whom high pressure is contraindicated.

Notwithstanding this, there have been no head-to-head trials comparing TLCCB Lite with TLCS Reduced and no comparative observational studies. Hence, their effectiveness in clinical practice is largely unknown, nor is their relative cost-effectiveness. Hence, the aim of the present study was to compare the clinical outcomes and

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costs of using TLCCB Lite with TLCS Reduced to treat newly-diagnosed VLUs in clinical practice, from the perspective of the UK's National Health Service (NHS).

Method

Study design

This was a modelling study based on a retrospective cohort analysis of the case records of patients with a newly-diagnosed VLU initially managed with TLCCB Lite or TLCS Reduced, who were randomly extracted from The Health Improvement Network (THIN) database.

Ethical approval

Ethical 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 (Reference number 22SRC015).

The Health Improvement Network (THIN) database

The THIN database contains electronic records on >11 million anonymised patients entered by GPs from >560 general practices across the UK. The patient composition within the THIN database has been shown to be representative of the UK population in terms of demographics and disease distribution[14] and the database theoretically contains patients' entire medical history. Specific details about the THIN database have been previously described.[15]

(THIN is a registered trademark of Cegedim SA in the UK and other countries. IQVIA Medical Research Data (IMRD) incorporates data from THIN, a Cegedim Database. Reference made to THIN is intended to be descriptive of the data asset licensed by IQVIA.)

Study population

The study population was randomly selected from a sample of >2400 patients in the THIN database according to the following criteria:

- ≥18 years of age
- Had a Read code for a VLU between 1 October 2016 and 31 December 2019
- Received TLCCB Lite or TLCS Reduced as the first compression system for their VLU
- Had at least 12 months' continuous medical history in their case record from the first mention of their VLU, unless they healed.

Every patient in this cohort was assigned a random number. A representative sample of 250 TLCCB Lite-treated patients was then generated by random selection of the random numbers of the whole cohort using a uniform distribution. The TLCCB-treated patients were matched with a randomly selected cohort of TLCS Reduced treated patients according to age at the start of treatment (±5 years), sex, and date of the start of treatment with their compression bandage (±2.5 years), by identifying every patient in the THIN data set who matched these criteria. A representative sample of 250 patients who were treated with TLCS Reduced was then generated by random selection of this cohort. No statistically significant differences were found between the different matched THIN cohorts when tested with either a Mann–Whitney U-test or Chi-squared test.

Power calculations showed that a sample size of 250 patients per group would be sufficiently large to detect at least a 15% improvement in healing with 90% power and a type I (alpha) error of 0.05 between the groups.

Study variables and statistical analyses

Information was systematically extracted from the patients' records over a period of 12 months from the start of compression and included age, sex, clinical outcomes, wound-related healthcare resource use and prescribed dressings, compression and medication. It was assumed that if a patient received a dressing or bandage 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 district nurse.

Analysis of covariance (ANCOVA) was performed to enable differences in patients' outcomes between groups to be adjusted for any heterogeneity in age, sex, year the VLU started, time to the start of compression and comorbidities. Covariates that had a p-value ≥0.05 were excluded from the ANCOVA model.

Kaplan–Meier analysis found that the healing distribution between the two groups did not reach significance at the 0.05 level (Log Rank (Mantel-Cox): p=0.092) (Fig 1). The monthly rates of wound healing, improvement, remaining static and infection over 12 months in these cohorts were used to estimate the transition probabilities with which to populate an economic model (Table 1).

Logistic regression was used to investigate whether any of the baseline variables were independent predictors of any of the clinical outcomes.

All statistical analyses were performed using IBM SPSS Statistics version 23.0 (IBM Corp., US).

Health economic modelling

An Excel-based (Microsoft Corp., US) Markov model was constructed to estimate the costs and consequences of the decision by a clinician to initially manage a newly-diagnosed VLU with TLCCB Lite or TLCS Reduced (Fig 2). VLUs enter the model and are initially managed with either compression system. They then transition to one of two health states (i.e., static ulcer (an ulcer that remains unchanged) or improved ulcer (followed by healed ulcer)). The ulcers can either remain in their current health state or move to one of the other states and transition monthly for a total of 12 months. In addition to transition probabilities, the model was populated with clinical outcomes and healthcare resource use estimates derived from the patients' case records.

The health states were mutually exclusive and so each VLU represented in the model could be in only one of the health states at any given time during the 12-month time horizon of the model.

Healthcare resource use

Healthcare resource use associated with managing the VLUs, that was documented in the patients' case records, was quantified. The amounts varied according to whether a VLU was static, improving, infected or healed. Each health state in the model was populated with the corresponding amount of healthcare resources. This enabled healthcare resource use over 12 months from the start of compression to be estimated.

Utilities

HRQoL was not recorded in the THIN database. Hence, published utility scores for VLUs,[16] as previously reported,[15] were assigned to each health state in the model. This enabled patients' HRQoL in terms of the number of quality-adjusted life years (QALYs) at 12 months from starting compression to be estimated.

Unit costs

NHS unit resource costs at 2020/21 prices,[17–19] as previously reported,[15] were applied to the healthcare resources populating each health state in the model. This enabled an estimation of the total NHS cost of resource use attributable to managing a VLU over 12 months from starting compression.

Model outputs

The primary measure of effectiveness was patients' health status in terms of the number of QALYs at 12 months. The secondary measure was the probability of healing by 12 months from the time patients entered the model.

The total NHS cost of VLU management over 12 months from the time patients entered the model was estimated at 2020/21 prices.

Cost-effectiveness analyses

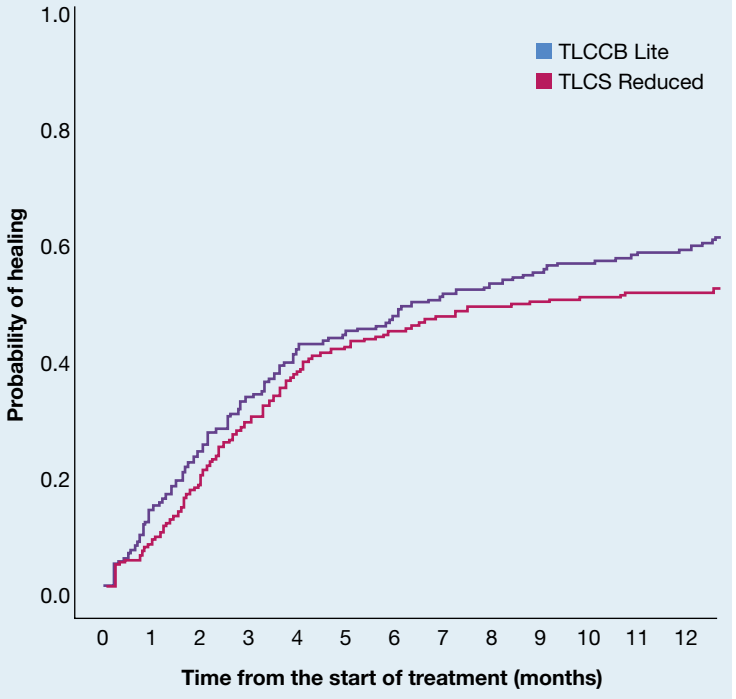
The relative cost-effectiveness of the alternative compression systems was calculated as the difference between the total VLU management costs of the two treatment groups divided by the difference in the number of QALYs between the two groups and expressed as the incremental cost per QALY gained. If one of the compression systems generated more QALYs for lower cost it was considered to be the dominant (cost-effective) intervention.

Sensitivity analyses

Probabilistic sensitivity analysis was undertaken to assess uncertainty within the model. This involved generating 10,000 iterations of the model by simultaneously varying the different inputs. To estimate the random values of the inputs, the standard error was assumed to be 20% around the mean values, but 10% around the utility scores (bounded by 0 and 1.0), and relevant distributions were assigned to the deterministic values (beta distributions for probabilities and utilities, and gamma distributions for resource use and costs), enabling the distribution of costs and QALYs to be estimated. This analysis enabled an estimation of the probability of the two compression systems being cost-effective at different cost per QALY thresholds.

Deterministic sensitivity analyses were also performed to assess the effect of independently varying the values of individual parameters within the model by 20% above and below the base case values, and varying the utility scores simultaneously by up to 10% above and below the base case values. These analyses identified how the relative cost-effectiveness of the alternative treatments change when varying individual parameters in the model. Deterministic sensitivity analysis also assessed the impact that the ANCOVA had on the relative cost-effectiveness of the two compression systems.

Fig 1. Kaplan–Meier analysis. The difference between the healing distribution of the two groups was p=0.092



Results

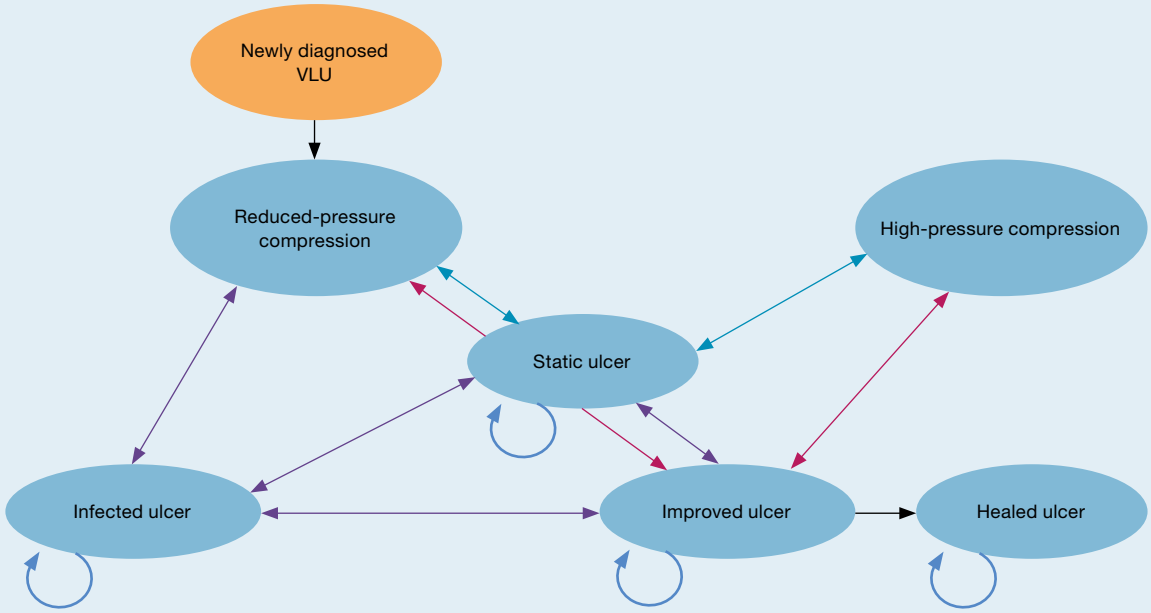
Patient characteristics

There were no significant differences in patients' age, sex, body mass index, comorbidities, smoking status, and time from wound onset to starting compression between the two groups (Table 2). The time from wound onset to starting compression was a mean of 2 months in both groups, which is consistent with current guidelines.

Patient management and outcomes

Outputs from the model indicated that the probability of healing by 12 months was 0.59 in the TLCCB Lite group and 0.53 in the TLCS Reduced group (Table 3).

Fig 2. Markov model. VLU—venous leg ulcer



Hence, treatment with TLCCB Lite is expected to increase the probability of healing by at least 10%. The time to healing was comparable in both groups (Table 3). These findings are reflected in the QALY analysis, which estimated that patients in the TLCCB Lite group experienced a marginally better (2%) HRQoL than those in the TLCS Reduced group (Table 3).

Logistic regression found that sex and age impacted on non-healing:

- Male (odds ratio (OR): 0.573; 95% CI: 0.393–0.836); p=0.004)
- Age (OR: 0.981; 95% CI: 0.967–0.996) p=0.012).

Logistic regression also found that smoking was an independent risk factor for developing an infected VLU (OR: 2.353; 95% CI: 1.476–3.750; p<0.001). Additionally, patients who had undergone debridement were 2.5-times more likely to have had an infected VLU.

Healthcare resource use

Patients' leg ulcers were predominantly managed by district nurses and to a lesser extent by practice nurses. Due to the higher healing rate in the TLCCB Lite group, the mean amount of healthcare resource use attributable to managing VLUs in this group was less than that used

Table 1. Monthly transition probabilities in the Markov model

	TLCCB Lite				TLCS Reduced			
Month	Static	Improved	Healed	Infected	Static	Improved	Healed	Infected
0	1.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00
1	0.37	0.12	0.28	0.23	0.49	0.09	0.16	0.26
2	0.40	0.12	0.33	0.15	0.46	0.12	0.31	0.11
3	0.36	0.09	0.42	0.13	0.39	0.08	0.38	0.15
4	0.34	0.09	0.46	0.11	0.40	0.02	0.46	0.12
5	0.34	0.08	0.47	0.11	0.42	0.03	0.46	0.09
6	0.35	0.06	0.50	0.09	0.42	0.03	0.48	0.07
7	0.36	0.04	0.53	0.07	0.42	0.03	0.50	0.05
8	0.38	0.03	0.54	0.05	0.42	0.03	0.50	0.05
9	0.36	0.03	0.55	0.06	0.40	0.03	0.51	0.06
10	0.34	0.03	0.57	0.06	0.40	0.02	0.52	0.06
11	0.35	0.03	0.58	0.04	0.40	0.02	0.53	0.05
12	0.37	0.02	0.59	0.02	0.43	0.02	0.53	0.02

Fig 3. Scatterplot of the incremental cost-effectiveness of TLCCB Lite compared with TLCS Reduced following 10,000 iterations of the model. NHS—UK National Health Service; QALY—quality-adjusted life year

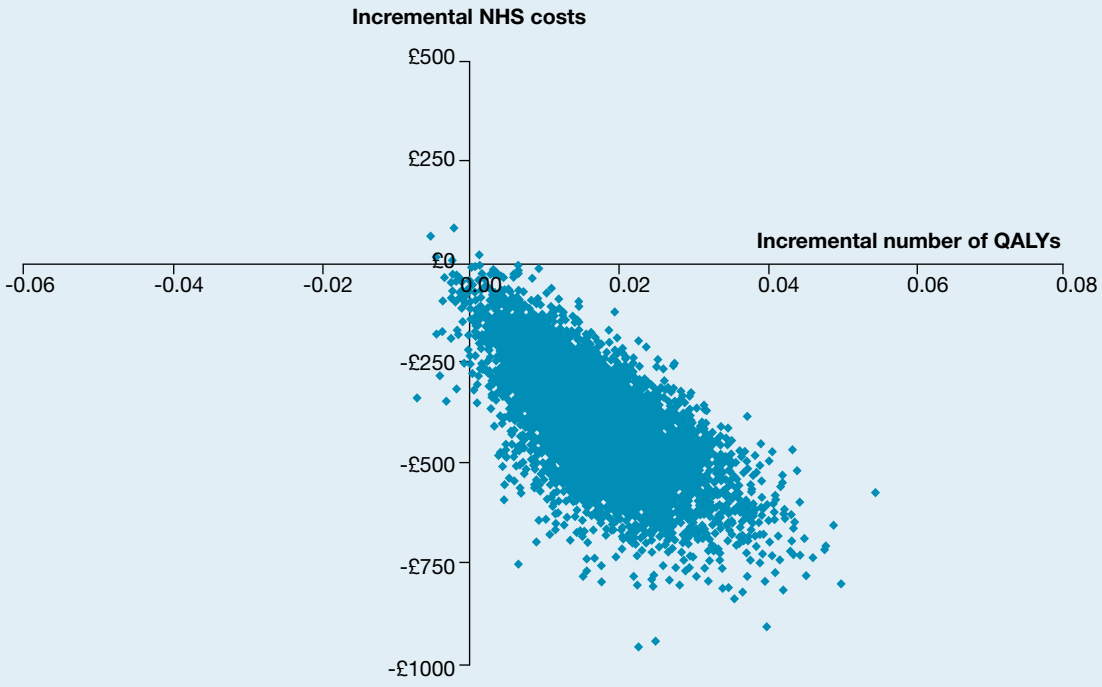


Fig 4. Tornado analysis showing the influence of increasing or decreasing key variables by up to 20% on the incremental cost per quality-adjusted life year (QALY) gained

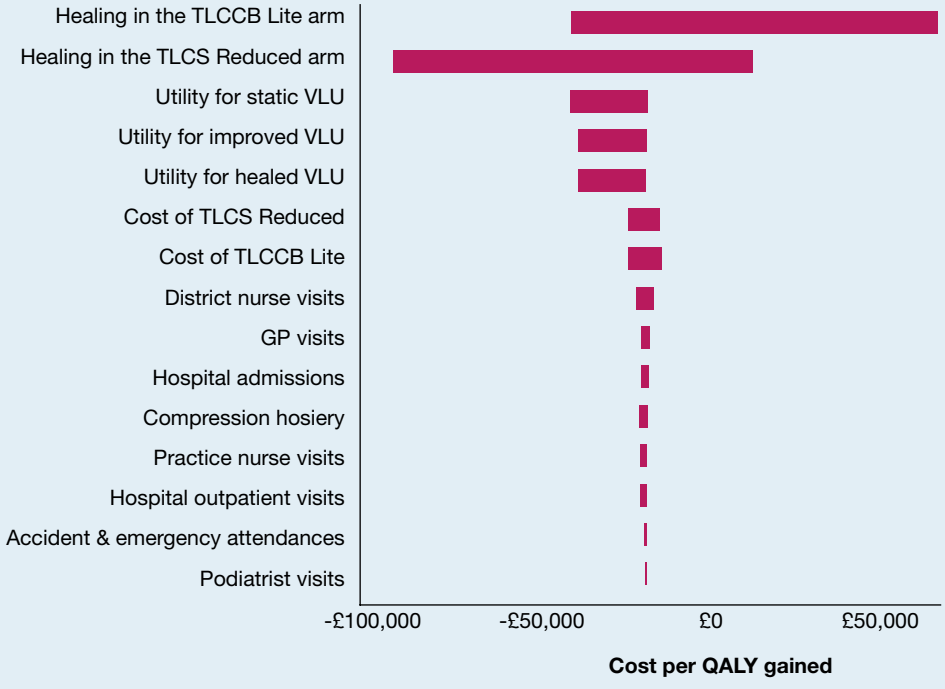


Table 2. Characteristics of the patients in the model

	TLCCB Lite	TLCS Reduced
Patient age, mean±standard deviation, years	76.0±14.2	78.6±11.6
Percentage female	54	57
Body mass index, mean±standard deviation (kg/m^2)	27.0±6.3	26.7±5.9
Percentage smokers	23	17
Percentage non-smokers	63	71
Percentage with unknown smoking status	14	12
Percentage with cardiovascular symptoms	32	34
Percentage with respiratory symptoms	29	23
Percentage with endocrinological symptoms	29	36
Percentage with gastrointestinal symptoms	15	18
Percentage with neurological symptoms	15	16
Percentage with ophthalmological symptoms	13	23
Percentage with genito-urinary symptoms	11	12
Percentage with musculoskeletal symptoms	11	9
Percentage with dermatological symptoms	10	23
Percentage with cancer	9	15
Percentage with cardiovascular symptoms	32	34
Percentage who had an ankle–brachial pressure index reported in their record	14	17
Time from wound onset to the start of compression, mean±standard deviation, months	1.8±1.7	1.8±1.6

to manage the VLUs treated with TLCS Reduced (Table 4). Fewer than 20% of all the patients had a Doppler ABPI recorded in their records (Table 2) and 20% of patients in both groups had undergone a mean of two documented debridement procedures. Additionally, 14% and 11% of patients in the TLCCB Lite and TLCS Reduced group, respectively, switched from their initial compression bandage to another compression system.

Table 3. Health outcomes

	TLCCB Lite	TLCS Reduced
Probability of the VLU being healed at 12 months	0.59	0.53
Probability of the VLU having improved at 12 months	0.02	0.02
Probability of the VLU being static at 12 months	0.37	0.43
Probability of the VLU being infected at 12 months	0.02	0.02
Probability of the VLU having been infected over the 12 months	0.51	0.58
Mean time to VLU healing (months)	3.63	3.50
Mean number of QALYs per patient at 12 months	0.85	0.83

VLU—venous leg ulcer; QALY—quality-adjusted life year

Healthcare cost of patient management

The total cost of leg ulcer management over the 12 months was estimated to be £3883 per VLU in the TLCCB Lite group, which was 8% lower than the cost of managing leg ulcers in the TLCS Reduced group (£4235 per VLU) (Table 5). The primary cost driver was district nurse visits, which accounted for up to 48% of the cost of managing VLUs in both groups. Compression bandaging and hosiery accounted for up to a further 18% of the total NHS cost of wound management in both groups (Table 5).

Cost-effectiveness analyses

Compared with TLCS Reduced, use of TLCCB Lite resulted in a £352 reduction in the 12-month NHS wound management cost and 0.02 more QALYs. Hence, starting treatment with TLCCB Lite was found to be the dominant (cost-effective) strategy.

Sensitivity analyses

Probabilistic sensitivity analysis highlighted the distribution in the incremental costs and QALYs at 12 months between both strategies (Fig 3). The graph indicated that the majority of samples were located in the bottom right-hand (dominant) quadrant. Outputs from the analysis showed that at a cost-effectiveness threshold of £20,000 per QALY, up to 82% of a cohort is expected to be treated cost-effectively with TLCCB Lite compared with TLCS Reduced.

Deterministic sensitivity analyses, in the form of a tornado diagram, were performed on all the model's inputs, but only the main findings have been presented (Fig 4). These analyses showed that the relative cost-effectiveness of the two compression systems was very sensitive to changes in healing rates. If the healing rate decreased by 10% in the TLCCB Lite group or increased by 10% in the TLCS Reduced group, then TLCS Reduced would become the cost-effective treatment. TLCCB Lite remained the cost-effective treatment for plausible changes in all the other parameters.

When the analyses were repeated without ANCOVA, outputs from the model indicated that the probability of healing by 12 months was 0.58 in the TLCCB Lite group and 0.54 in the TLCS Reduced group. This led to 0.845 QALYs per patient in the TLCCB Lite group and 0.825 QALYs per patient in the TLCS Reduced group. The resulting total cost of leg ulcer management over the 12 months was estimated to be £3983 per VLU in the TLCCB Lite group and £4232 per VLU in the TLCS Reduced group. Hence, the absence of ANCOVA reproduced the findings from the base case analysis, i.e., that starting treatment with TLCCB Lite is potentially the more cost-effective strategy, since it is expected to lead to better outcomes for less cost.

Discussion

This study would appear to be the first comparison between alternative reduced strength compression systems. All the patients in this study had a VLU which

was initially managed with reduced pressure compression, predominantly by district and practice nurses. The healing rates and healthcare resource use associated with managing these VLUs with reduced strength compression systems were comparable to those seen with VLUs managed with high pressure compression systems.[1,8,20–26] Additionally, the 12-month cost of patient management was concordant with our previous studies on the cost of managing VLUs in clinical practice.[1,8,20–26]

This economic analysis indicated the potential differences in both clinical effectiveness and VLU management costs between patients managed with TLCCB Lite and TLCS Reduced. The differences were based on a comparison of matched patients randomly extracted from the THIN database who had their newly diagnosed VLU initially treated with one of these two compression systems in clinical practice in the UK. Analysis of the THIN data set found that after 12 months from starting compression, at least 10% more wounds healed in the TLCCB Lite group. While the difference in the healing distribution between the two groups did not reach statistical significance at the 0.05 level, it may be of clinical importance to patients. Additionally, patients in the TLCCB Lite group are expected to experience a better HRQoL and their wound management cost is expected to be 8% less than that to manage VLUs in the TLCS Reduced group. Hence, TLCCB Lite was considered to be cost-effective compared with TLCS Reduced.

The differences in healing rates and wound management costs may also be of importance to the health services. The cost of managing an unhealed VLU has been estimated at being 3–4 times more than that of managing a wound that heals.[1] The VLUs that remained unhealed at 12 months in this study will have become hard-to-heal wounds, and there is an accumulating pool of patients with such leg ulcers.[1,21,22] VLU management remains challenging for all health services, with an estimated 330,000 new VLUs and 230,000 hard-to-heal VLUs in the UK in 2017/18.[1] Hence, any intervention that improves outcomes for lower cost has the potential to reduce the ever-increasing burden that VLUs impose on the UK's NHS.[1]

Results from a recent audit across six diverse community provider sites in England found unwarranted variation in compression usage across all the audit sites and at all locations within the audit sites, with the greatest use seen in community leg ulcer clinics and lowest usage in the home.[27] Additionally, compression usage decreased with patient age.[27] The audit also found a lack of confidence among clinicians about applying optimal compression to lower limb wounds, with clinicians stating that the reason for using reduced compression or no compression was based on their clinical judgement that high compression was not required.[27]

While the audit indicated an increased use of reduced or light compression in clinical practice,[27] the findings

Table 4. Mean amounts of healthcare resource use per venous leg ulcer (VLU) over 12 months from the start of compression

	TLCCB Lite	TLCS Reduced
District nurse visits	33.7	36.7
Practice nurse visits	9.8	10.7
GP visits	6.1	6.6
Analgesic prescriptions	0.8	0.6
Hospital outpatient visits	0.5	0.6
Podiatrist visits	0.3	0.4
Antibiotic prescriptions	0.2	0.2
Hospital admissions	0.2	0.2
Accident & emergency attendances	0.1	0.1
Compression bandages	42.9	47.0
Compression hosiery	15.0	17.0
Dressings	40.9	46.4

Table 5. Mean costs of healthcare resource use per venous leg ulcer (VLU) over 12 months from the start of compression (percentage of total cost in parentheses)

	TLCCB Lite		TLCS Reduced	
District nurse visits	£1855.97	(48)	£2017.75	(48)
GP visits	£475.00	(12)	£517.68	(12)
Compression bandages	£411.00	(11)	£428.88	(10)
Hospital admissions	£375.00	(10)	£420.00	(10)
Compression hosiery	£267.77	(7)	£303.36	(7)
Practice nurse visits	£215.78	(6)	£235.00	(6)
Dressings	£128.66	(3)	£144.50	(3)
Hospital outpatient visits	£121.00	(3)	£133.00	(3)
Accident and emergency attendances	£17.00	(<1)	£19.00	(<1)
Podiatrist visits	£8.63	(<1)	£9.81	(<1)
Prescribed drugs	£7.29	(<1)	£5.63	(<1)
Total	£3883.10	(100)	£4234.61	(100)

Reflective questions

- What criteria do you consider when deciding on whether to apply reduced strength or high strength compression?
- Is your use of reduced strength compression increasing? If so, why?
- Do you think you achieve the requisite level of pressure necessary for each patient to achieve an optimal outcome? If not, why not?

from our study indicate that VLU healing rates among patients who received a reduced pressure compression system were not too dissimilar to those seen in our recent study comparing the use of high pressure TLCCB with TLCS in clinical practice[15] (even though the patients who received a reduced compression system were around 10 years older than those in the high pressure compression study[15]). Furthermore, the healing rates in this study were comparable to those seen in several other studies using high strength compression systems.[28–32] The differences observed between the two groups in our study, and the inevitable differences between different VLU studies, may reflect the practical challenges experienced by non-specialist nurses in the community in achieving the correct levels of compression and the lack of skills and confidence required to both select and apply appropriate compression therapy.[1,20–22,27] For example, <20% of all the patients in our data set appeared to have undergone a Doppler ABPI measurement, contrary to national guidance,[33,34] raising the question of how accurate was the VLU diagnosis? Nevertheless, all the patients in the THIN data set had a VLU diagnosis documented in their case record and they were managed with reduced strength compression as if they had a VLU. Hence, the importance of training non-specialist nurses in diagnosis and the correct management of VLUs and the appropriate application of compression systems cannot be overstated. With this in mind, the NHS states on their website that application of a compression bandage to a VLU is a skilled procedure and should only be performed by trained healthcare staff.[35]

Up to 15% of patients in our THIN data set were switched from their initial reduced strength compression system to high pressure compression a mean of 2–3 months after starting treatment. Consequently, a minority of patients would not have been receiving their initial compression system at the end of the study and thus may not have been healed by that compression system. Nevertheless, economic analysis considers the costs and consequences of the initial decision. Hence, this study's results are a consequence of the initial decision to treat with TLCCB Lite or TLCS Reduced and are reflected in the costs, healing rates and QALYs for each group.

Limitations

The advantages and disadvantages of using patients' records in the THIN database for economic evaluations in wound care have been discussed elsewhere.[15] In summary, the advantage of using the THIN database is that the patient pathways and associated resource use are based on real-world evidence and reflect clinical practice. However, there may have been differences between the groups, resulting in the clinician's decision to treat with one of the two compression systems and the patient's willingness to accept the clinician's preferred treatment. Consequently, the possibility that undetected differences exist between the matched cohorts cannot be excluded, which may contribute to the different healing rates. However, this should have been addressed, to some extent, by the ANCOVA. The analyses were based on clinicians' entries into their patients' records and inevitably subject to a certain amount of imprecision and lack of detail. Consequently, wound size, wound severity and exudate levels were not included in the matching criteria, since they were not fully documented in the patients' records. Despite these limitations, 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. This view is supported by the publication of over 1945 research articles in peer reviewed journals that use this database as the source of their underpinning evidence.[36]

The analysis only considered NHS resource use and associated costs for the 'average patient' since there were insufficient data to assess the relative cost-effectiveness of the compression systems in particular subgroups. The study results were truncated at 12 months and excluded the costs and consequences of managing unhealed ulcers beyond this period. Patients' costs and indirect societal costs as a result of absenteeism from work were also excluded from the analysis. However, patients' mean age was >70 years, so it is unlikely that many were in employment.

The analysis was unable to consider the impact of other factors that may have affected the results, such as severity of underlying venous disease. The analysis was also unable to consider any intangible benefits that patients may have experienced following use of the different compression systems, irrespective of whether their wound healed. It should also be borne in mind that the analysis was unable to consider the level of a clinician's skills in administering each of the compression systems and was unable to discern the challenges clinicians may have had in applying compression.

Conclusion

In conclusion, within this study's limitations, starting treatment of newly-diagnosed VLUs with TLCCB Lite instead of TLCS Reduced potentially affords a cost-effective use of NHS-funded resources, since it is expected to result in an increased healing rate, better HRQoL and a reduction in NHS leg ulcer management cost. **JWC**

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