A systematic review of compression therapy for venous leg ulcers

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Authors' objectives
To determine the relative effectiveness of compression therapies used in the treatment of venous leg ulcers.

Searching
Eight major databases were searched including EMBASE, MEDLINE and CINAHL with no restriction on date or country of origin. Core journals (not stated) and conference proceedings were handsearched and additional studies were located by searching the bibliographies of retrieved articles. Searches were limited to English language articles or those that provided a sufficiently detailed English language summary.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs). RCTs using processes transparent before assignment e.g. open list of random numbers, case record, day of the week, surname etc. were included and subjected to subgroup analysis. Studies with less than 50 participants were included but assessed for significant heterogeneity.

Specific interventions included in the review
Compression treatments for leg ulcers including compression bandages (e.g. class I, II and III, multilayer, single layer, elastic and non-elastic), hosiery (e.g. different makes of below knee compression stocking), and intermittent pneumatic compression (e.g. Unna's Boot).

Participants included in the review
Patients with venous ulcers. Trials where the venous disease had not been established by vascular assessment were excluded if significant heterogeneity was found. Patients with mixed ulcer aetiology disease were excluded.

Outcomes assessed in the review
The following outcomes were included: complete ulcer healing, time to complete ulcer healing, recurrence rates (at 12 months), complications and morbidity (e.g. pain, necrosis, amputation, skin damage and discomfort), compliance with treatment, patient satisfaction and quality of life, and costs. Healing rates were not considered as a valid outcome measure.

How were decisions on the relevance of primary studies made?
Two reviewers assessed studies for inclusion. Disagreements were adjudicated by a third reviewer.

Assessment of study quality
Criteria were based on the CONSORT statement (see Other Publications of Related Interest no.1) and the Cochrane Collaboration checklists (see Other Publications of Related Interest no.2). The following were included: method of randomisation, degree of blinding, comparability of groups, intention to treat analysis, completeness of follow-up, blinding and objectivity of outcome assessment, appropriateness and completeness of the statistical analysis of results including sensitivity analysis. The authors do not state how the papers were assessed for validity, or how many of the reviewers performed the validity assessment.

Data extraction
Data was extracted independently by two reviewers. Data were extracted with regards to: study details, participant details, interventions, baseline comparability, results, drop-outs and additional comments.
Methods of synthesis
How were the studies combined?
Where sufficient studies were available without significant heterogeneity data were pooled using the DerSimonian and Laird random-effects model. Odds ratios (ORs) and 95% confidence intervals (CIs) were reported. Losses to follow-up were assumed to be failures of treatment. Studies were also described in a narrative.

How were differences between studies investigated?
Heterogeneity was assessed using the Cochran Q statistic and by carrying sensitivity analyses.

Results of the review
Eight RCTs involving 750 participants were included.

Due to heterogeneity and the small number of studies fulfilling the inclusion criteria meta-analysis was limited and the following comparison were made in terms of the number of ulcers healed:

Unna's Boot versus other therapies (3 studies):

There was no statistically significant difference between Unna's Boot compared with other therapies (OR=2.598, \( p=0.16 \)), this was unaffected by excluding trials from the analysis. Cochran Q \( p=0.22 \).

Pneumatic compression (2 studies):

Pooled OR=8.45 (95% CI: 0.627, 113.91, \( p=0.11 \)). Cochran Q \( p=0.32 \).

Compression versus no compression (2 studies):

Only one study was identified and this showed no clear statistically significant benefit (OR=2.0, \( p=0.12 \), 95% CI: 0.73, 5.47).

Multi-layer versus single layer compression bandages (1 study):

One study showed that multi-layer compression bandages were associated with a greater number of ulcers healed than single layer bandages (OR=3.481, \( p=0.002 \), 95% CI: 1.6, 7.6).

Elastic versus non-elastic bandages (1 study):

One trial showed that the odds of healing were greater with elastic bandages when compared with non-elastic bandages (OR=2.95, \( p<0.001 \), 95% CI: 1.2, 7.14).

Data concerning the other outcomes were simply listed in data tables and in a descriptive narrative and not synthesised as such.

Quality of the studies:

Quality of the studies were very mixed with the majority of trials being of relatively short duration (between 4 weeks and 18 months, median duration 12 weeks) and small sample size. In addition, little consideration was given in the published articles to a priori sample size and power calculations. Only two studies described their method of randomisation. None of the studies explicitly stated that assessors were blinded on the treatment allocation.

Cost information

Only one study reported cost data. The cost for hydroactive dressing (duaDerm; Convatec) was $14.24 (+/-1.63) and the cost for Unna's Boot was $11.76 (+/- 0.59), \( p=0.06 \).
Authors' conclusions
This systematic review shows that there is a statistically clear benefit from elastic and multi-layer systems in terms of the number of ulcers healed. However, there is only one trial within each comparison and so the results cannot be said to be conclusive.

CRD commentary
This review is based on clear inclusion criteria and searches a number of databases. However, details of the search strategy were not provided and studies were limited to those published in English or with English abstracts. This may result in the omission of relevant data. Publication bias is also an issue as no specific attempts were made to locate unpublished data. All of the studies were quality assessed prior to synthesis using a validated scale, however, the number of individuals involved in assessing study quality was not stated. Heterogeneity was also assessed using the Q statistic before studies were pooled where appropriate using a random-effects model. However, with only eight studies included in the review pooling was limited. The remaining outcomes and studies were described in tables and descriptively in the text, with little attempt to synthesise data for outcomes other than number of ulcers healed. The findings of the review would appear to be supported by the data presented however, in view of the comments listed caution is appropriate.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors state 'there is a clear need for more large, high quality trials, to confirm the benefits of compression therapy. Within these trials there needs to be more emphasis placed on economic and quality of life data to try and ascertain the cost-effectiveness and utility of the treatment options available'.

Bibliographic details

PubMedID
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Other publications of related interest

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.