

Compression for preventing recurrence of venous ulcers (Review)

Nelson EA, Bell-Syer SEM, Cullum NA, Webster J



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[Intervention Review]

Compression for preventing recurrence of venous ulcers

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ABSTRACT

Background

Up to 1% of adults will suffer from leg ulceration at some time. The majority of leg ulcers are venous in origin and are caused by high pressure in the veins due to blockage or weakness of the valves in the veins of the leg. Prevention and treatment of venous ulcers is aimed at reducing the pressure either by removing / repairing the veins, or by applying compression bandages / stockings to reduce the pressure in the veins.

The vast majority of venous ulcers are healed using compression bandages. Once healed they often recur and so it is customary to continue applying compression in the form of bandages, tights, stockings or socks in order to prevent recurrence. Compression bandages or hosiery (tights, stockings, socks) are often applied for ulcer prevention.

Objectives

To assess the effects of compression hosiery (socks, stockings, tights) or bandages in preventing the recurrence of venous ulcers.

To determine whether there is an optimum pressure/type of compression to prevent recurrence of venous ulcers.

Search methods

Searches of 19 databases including the Cochrane Wounds Group trials register and the Cochrane Controlled Trials Register, hand-searching of journals, conference proceedings, and bibliographies up to June 2000.

Selection criteria

Randomised controlled trials evaluating compression bandages or hosiery for prevention of venous leg ulcers.

Data collection and analysis

Data extraction and assessment of study quality were undertaken by two reviewers independently.

Main results

No trials compared recurrence rates with and without compression.

One trial (300 patients) compared high (UK Class 3) compression hosiery with moderate (UK Class 2) compression hosiery. A intention to treat analysis found no significant reduction in recurrence at five years follow up associated with high compression hosiery compared

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with moderate compression hosiery (relative risk of recurrence 0.82, 95% confidence interval 0.61 to 1.12). This analysis would tend to underestimate the effectiveness of the high compression hosiery because a significant proportion of people changed from high compression to medium compression hosiery. Compliance rates were significantly higher with medium compression than with high compression hosiery.

One trial (166 patients) found no statistically significant difference in recurrence between two types of medium (UK Class 2) compression hosiery (relative risk of recurrence with Medi was 0.74, 95% confidence interval 0.45 to 1.2).

Both trials reported that not wearing compression hosiery was strongly associated with ulcer recurrence and this is circumstantial evidence that compression reduces ulcer recurrence.

No trials were found which evaluated compression bandages for preventing ulcer recurrence.

Authors' conclusions

No trials compared compression with vs no compression for prevention of ulcer recurrence. Not wearing compression was associated with recurrence in both studies identified in this review. This is circumstantial evidence of the benefit of compression in reducing recurrence.

Recurrence rates may be lower in high compression hosiery than in medium compression hosiery and therefore patients should be offered the strongest compression with which they can comply.

Further trials are needed to determine the effectiveness of hosiery prescribed in other settings, i.e. in the UK community, in countries other than the UK.

PLAIN LANGUAGE SUMMARY

Compression hosiery (stockings) for preventing venous leg ulcers returning

Venous leg ulcers (open sores) can be caused by a blockage or breakdown in the veins of the legs. Compression, using bandages or hosiery (stockings), can help heal most of these ulcers, and might be able to prevent ulcers returning. However, the review found no trials comparing compression with no use of compression. There is some evidence that people wearing high rather than moderate compression are less likely to get a new ulcer. There is some evidence that people are more likely to continue wearing hosiery with moderate rather than high compression. There is some evidence that compression hosiery might prevent ulcers, but the evidence is not strong.

BACKGROUND

Venous ulceration is a chronic recurring condition. Callam found that 45% of ulcer patients in a Scottish study had open leg ulcers for more than 10 years (Callam 1985). There is a considerable cost to the patient in terms of prescription charges (dressings, drugs and bandages), increased laundry bills due to discharge from the ulcer, time off work attending nurse/doctor consultations, and pain, isolation and distress (Charles 1995). The treatment of leg ulceration is extremely costly to the health service (the UK NHS was estimated to have spent £300 million in 1992), mainly in terms of nursing time (Bosanquet 1992).

Around 1% of adults in industrialised countries are affected by leg ulceration at some time in their life (Baker 1991). Around three quarters of leg ulcers are caused by changes in the blood flow in the veins of the legs. These changes are caused by blockage (occlusion) and / or weakness in the valves of the veins (venous incompetence) (Callam 1985). The resulting ulcers are known as venous, stasis or varicose ulcers.

Occlusion and/or incompetence of the veins in the legs leads to increased pressure in the veins (venous hypertension). This can sometimes be seen as distended, tortuous (varicose) veins. In-

creased pressure in the veins may cause varicose eczema, oedema in the lower leg, and deposition of scar tissue (fibrin) and iron pigments in the skin. This may lead to breakdown of the skin, or can delay healing if the leg is injured.

Both treatment of venous ulcers and prevention of recurrence aims to reduce the pressure in the veins. This can be accomplished by surgical removal of superficial and/or perforating veins or blocking any incompetent veins by injecting an irritant solution (sclerotherapy) or by applying compression to reduce the pressure. Not all patients are suitable for, or agree to venous surgery. Surgery on the deep veins is experimental, unevaluated and not widely practised.

Until recently the main aim of venous ulcer care has been to heal the ulcer. The use of high compression bandaging has increased ulcer healing rates and the use of these bandages is widespread (Cullum 2000). Increased success in treating venous ulcers has meant that more patients are at risk of ulcer recurrence. Twelve month recurrence rates range between 26-69% (Monk 1982; Vowden 1997; Moffatt 1995).

There are many ways of applying compression, e.g. bandages, compression stockings or combinations of bandages and/or stockings. The interpretation of comparisons between compression systems is complicated by the lack of internationally agreed standards.

In the UK, stockings are classified according to the amount of force required to stretch them and hence the level of compression they can apply to a limb (Table 1). Even in the UK it appears that different specifications apply to hosiery supplied through hospitals and via community pharmacists. In addition, different classification systems are used in other countries.

OBJECTIVES

To assess the effects of compression hosiery (socks, stockings, tights) in preventing recurrence of venous leg ulcers; and specifically

to answer the following questions:

1. to what extent does compression (bandages or hosiery) prevent the recurrence of venous ulceration?
2. if compression prevents the recurrence of venous ulceration, what is the optimal level of compression?

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials which compare:

1. Compression versus no compression
2. Different strengths of compression
3. Different lengths of compression hosiery (below knee versus above knee / thigh length)
4. Compression bandages versus compression hosiery
5. Different types of compression hosiery
6. Different types of compression regimens (e.g. long stretch, short stretch, single layer)

There was no restriction on publication status, date or language.

Types of participants

People with healed venous leg ulcers. We will accept the trialists' inclusion criteria for venous leg ulcers.

Types of interventions

Compression bandages or hosiery (tights, stockings or socks). Studies of intermittent pneumatic compression devices are not included in this review as they are being considered in another Cochrane review (Mani 2000).

Types of outcome measures

The primary outcome measure is incidence of ulceration (break in the skin) anywhere on the treated leg, irrespective of cause.

Secondary outcome measures are:

- Duration of episodes of re-ulceration
- Proportion of follow up period for which the patient is ulcer free
- Incidence of ulceration on the other leg (also referred to as the contralateral leg)
- Patient compliance and comfort
- Cost of treatment
- Quality of life

Search methods for identification of studies

We searched the following databases using keywords: 'leg, ulcer, bandage, stocking, compression, prevention':-

MEDLINE (1966 to 1997); CINAHL (1982 to 1999); EMBASE (1980 to 1999), the Cochrane Wounds Group trials register (August 2000) and the Cochrane Controlled Trials Register (2000 issue 2). In addition hand searches of conference proceedings and wound care journals were undertaken.

Experts in wound care and companies that produce compression stockings/bandages were contacted to enquire about unpublished, ongoing and recently published trials.

Citations within obtained reviews and papers were scrutinised to identify additional studies.

Data collection and analysis

Titles and abstracts of all studies identified by the search process were assessed by one reviewer with respect to their relevance and design, according to the selection criteria. Full versions of articles were obtained if, from this initial assessment, they satisfied the selection criteria. Those rejected were checked by another reviewer. Full papers were checked to identify those that fit the inclusion criteria. This was repeated independently by another reviewer to verify.

Details of the studies were extracted and summarised using a pre-specified data extraction sheet. Missing data was minimised by contacting the authors. Studies that were published in duplicate were included only once. Data extraction was undertaken by one reviewer and checked for accuracy by a second.

Each study was appraised using a standard checklist to assess the validity of the methods used and data was collected from each study on:

- method of randomisation
- allocation concealment
- use of clear inclusion and exclusion criteria
- baseline comparability of treatment groups for important variables (e.g. extent of venous incompetence)
 - blinded outcome assessment
 - use of intention to treat analysis
 - extent of loss to follow up.

The method of synthesising the studies depended upon the quality, design and heterogeneity of the studies identified. We summarised dichotomous variables (e.g. proportion of people with recurrent ulcers) using either odds ratios or relative risk. Odds ratios were used where event rates were less than 30%. Where synthesis was inappropriate we undertook a narrative overview.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Three trials were identified and two met the inclusion criteria. The two included trials are described in full in the Characteristics of Included Studies Table. One trial compared the effectiveness of moderate (UK Class 2) and high (UK Class 3) compression hosiery in conjunction with a hospital based clinic ([Harper 1996](#)). One trial compared the effectiveness of two types of moderate (UK Class 2) compression stockings in community leg ulcer clinics ([Franks 1995](#)). One trial was excluded because the outcome used was not ulcer incidence ([Lewis 1976](#)).

Risk of bias in included studies

Details of the quality of each individual study are included in the Table of Included Studies. True randomisation with allocation concealment (i.e. the person recruiting the patient into the trial was unaware of which group they would be recruited to) was attempted in the trial by Harper but the person randomising patient was occasionally informed of the allocation of subsequent patients by the remote randomisation office. This may have influenced the recruitment to the trial. Franks et al used an open computer generated randomisation list and therefore allocation was not concealed.

Blinded outcome assessment was not reported in either trial. Harper defined a recurrence as a break in the skin of the leg persisting for at least six weeks (outcome assessor was not blinded). Franks did not define re-ulceration.

Baseline comparability was unclear in the trial by Harper (results are only published as an abstract). In the trial by Franks, patients allocated the Class 2 Medi sock had a median ulcer duration of 5.7 months compared to a median of 2.0 months in the Scholl group. This may reflect a greater severity of ulcer disease in the Medi group, and did not appear to be adjusted for in the analysis. Other baseline characteristics, such as a history of deep vein thrombosis and mobility were comparable.

Both trials were planned after calculation of an appropriate sample size.

Effects of interventions

Three trials were identified, of which two met the review criteria. There was no disagreement between reviewers in selection of included/excluded studies.

HOW THE RESULTS ARE PRESENTED AND WHAT THE TERMS MEAN

Results of dichotomous variables are presented as odds ratios (OR), or relative risk (RR) with 95% confidence intervals (CI). Odds ratios have been used where event rates are low (i.e. a recurrence rate of less than 30%). Relative risk has been used when event rates are greater than 30%. This is because odds ratios would give an inflated impression of the magnitude of effect ([Deeks 1998](#)) when event rates are high.

Relative risk of recurrence is the ulcer recurrence rate in the experimental group divided by the ulcer recurrence rate in the control group and indicates the likelihood of an ulcer recurring with an experimental stocking compared with a control treatment. By definition - the risk of an ulcer recurring in the control group is 1, so the relative risk reduction associated with using the experimental stocking is 1-RR. The relative risk indicates the relative benefit of a therapy but not the actual benefit, i.e. it does not take into account the number of people who would have had an ulcer recurrence anyway. The absolute risk reduction (ARR) can be calculated by subtracting the recurrence rate in the experimental group from the

recurrence rate in the control group. The ARR tells us how much the decrease in recurrence is due to the stocking, and its inverse is the number needed to treat, or NNT. Thus a recurrence rate of 50% with a control treatment, decreased to 30% with an experimental stocking translates into an ARR of $50\% - 30\% = 20\%$ ($0.5 - 0.3 = 0.2$). The NNT is the inverse of 20% (or 0.2) and this is 5. In other words 5 patients would need to receive the experimental stocking to prevent one additional leg ulcer.

The results are presented with reference to the original questions posed by the review:

1. To what extent does the application of compression bandages or hosiery to legs at risk of venous ulceration prevent recurrence?

We identified no studies that compared ulcer incidence in people with and without compression.

However both Harper and Franks report that not wearing compression hosiery was associated with high recurrence rates and this is indirect evidence that compression prevents ulcer incidence. In the Franks trial there was a non-significant trend for recurrence rates to be higher in partially and non-compliant patients (10/25 and 1/4) compared with compliant patients (43/136). Franks also reported that 11 out of 17 people who were excluded from the trial as they were unable to wear compression recurred (64%) compared with 58/171 who wore compression (34%). This meant that the relative risk of recurring without compression was 2.58, 95% confidence interval 1.33 to 5.01. In the Harper trial the recurrence rate in non-compliers was 32% compared to 19% in compliers (after 3 to 5 years follow-up).

2. If compression prevents recurrence, what is the optimal level of compression?

One trial (Harper 1996) with 300 patients followed up every 4 months for 5 years, compared ulcer recurrence rates in patients allocated to moderate (UK Class 2) or high (UK Class 3) compression hosiery. The interim results, after between 3 and 5 years follow up, reported a significantly lower recurrence rate in the high compression group compared to the moderate compression group (32% vs 23%). Median time to recurrence was not reported and this may be an important outcome for patients. However once all patients had been followed up for 5 years no statistically significant difference in recurrence rates were seen (39% vs 32%). This equates to a relative risk of recurrence of 0.82 (95% CI 0.61 to 1.12) at 5 years and this is shown in Analysis 2.1.

Fewer patients changed the grade of compression hose in the moderate compression group than the high compression group and whilst higher grades of compression may be more effective, fewer people comply. Relative risk of changing grade of hosiery from Class 3 was 1.41 (95% CI 1.04 to 1.91). This is shown in Analysis 2.2.

Franks compared two brands of moderate strength stockings (UK Class 2) and found no statistically significant difference in ulcer recurrence rate (Analysis 5.1).

DISCUSSION

Non systematic reviews of the literature invariably state that compression hosiery reduces the recurrence of venous leg ulcers (Capeheart 1996). There is no evidence that compression prevents the recurrence of venous ulcers. However, this may represent lack of evidence of benefit rather than evidence of lack of benefit. The use of compression after venous ulcer healing is widespread and it now appears unlikely that a trial could be undertaken with a control group receiving no compression. There is circumstantial evidence that people who fail to comply with compression hosiery have higher recurrence rates than those who do comply but this finding is less robust evidence of effectiveness than direct comparisons within randomised controlled trials.

The trials by Harper and Franks were conducted in different settings, hospital (Harper 1996) and community (Franks 1995). Different hosiery specifications operate in hospital and community supplied hosiery, with hospital hosiery exerting higher compression, and this may account for the lower annual recurrence rates in the hospital study (39% in 60 months compared with 32% in 18 months). Another explanation for the difference in recurrence rates may be that the Harper study defined a recurrence as a break in the skin lasting for 6 weeks. Franks does not describe their definition of recurrence but a shorter qualifying time would tend to inflate their recurrence rates in comparison.

The two trials were both conducted in the United Kingdom and used stockings which are approved for used by the UK Drug Tariff. It is unclear whether these results could be extrapolated to other countries where standards for stockings are different.

Given the prevalence of venous disease and the relatively large number of trials of compression for the treatment of ulceration (Cullum 2000) it is disappointing that only two trials appear to have been undertaken. Additional trials may have been carried out but are unpublished and their impact on these results is unknown. Prospective registration of trials would reduce any potential publication bias.

AUTHORS' CONCLUSIONS

Implications for practice

There is no evidence that high compression hosiery is more effective than moderate compression in the prevention of ulcer re-

currence. Compliance is lower in people wearing high compression stockings and patients should be prescribed the highest grade stocking they are able to wear.

Implications for research

- Trials should be large enough to detect clinically important differences in recurrence
- Trialists should define ulcer recurrence clearly as there may be small skin breaks due to varicose eczema that can be confused with a true ulcer recurrence
- A complete and thorough description of concurrent treatments including surgery, exercise advice and drug therapies should be given in trial reports
- Assessment of outcomes should be blind to treatment
- Survival rate analysis methods should be adopted for all studies that assess ulcer recurrence

- Studies to determine the biological mechanism involved in ulcer healing are needed. A better understanding of the healing process will lead to the development of validated outcome measures

- Economic evaluations should be conducted in future trials.

ACKNOWLEDGEMENTS

We would like to thank the following people who commented on the protocol and review for relevance, clarity and methodology:

Anne-Marie Bagnall, Malcolm Brewster, Marie Debbahi, Mark Fenton, Jacqui Fletcher, Peter Johnston, June Jones, Andrew Jull, David Margolis, Steve Thomas, Penny Whiting.

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Harper 1996 *{published and unpublished data}*

Harper DR, Nelson EA, Gibson B, Brown D, Ruckley CV. A prospective, controlled, randomized trial of class 2 and class 3 elastic compression in the prevention of venous ulceration. Proceedings of the 5th European Conference on Advances in Wound Management. London: Macmillan Magazines, 1996:55.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Franks 1995

Methods	RCT
Participants	Of 188 patients with newly healed venous leg ulcers, 166 could apply a compression sock. These were randomised. Patients allocated to Medi hosiery had longer pre-healing ulcer duration (5.7 months vs 2.0 months) than people in Scholl. Trial setting was a community leg ulcer service.
Interventions	1. Below knee (Medi) UK Class 2. 2. Below knee (Scholl) UK Class 2.
Outcomes	Recurred at 18 months 1. 21% 2. 34% (no significant difference) The actual number of recurrences for each group is not provided. All types of skin irritation 1. 23/92 (25%) 2. 26/74 (35%) (no significant difference) Could not apply hosiery 1. 12/92 (13%) 2. 13/74 (18%) Could not remove hosiery 1. 11/92 (12%) 2. 11/74 (15%)
Notes	An a priori sample size calculation was based on estimates of rate of reactions to stockings (20% vs 40%). Outcome assessment - unclear if blinded.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Harper 1996

Methods	RCT
Participants	300 people with recently healed venous leg ulcers. Trial setting was a hospital leg ulcer clinic
Interventions	1. UK Class 2 compression hosiery (moderate compression) 2. UK Class 3 compression hosiery (high compression) Each patient was measured for hosiery by an orthotist. Patients had a check up and resupply of hosiery every 4 months. Telephone hot-line to leg ulcer clinic in case of problems
Outcomes	Incidence of major recurrence (defined as a skin break for a minimum of 6 weeks) at 60 months 1. 59/151 (39%) 2. 48/149 (32%)

Harper 1996 (Continued)

	no significant difference (Cox proportional hazards model)	
Notes	An a priori sample size calculation was reported. Outcome assessment - not blinded. Intention to treat analysis.	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

RCT - randomised controlled trial

The Franks trial was supported by Medi UK Ltd. The Harper trial was supported by the Scottish Office, Medi UK Ltd. and Jobst Ltd.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Lewis 1976	Outcome was not ulcer recurrence

Characteristics of ongoing studies [ordered by study ID]**Vandongen**

Trial name or title	
Methods	
Participants	Patients whose venous leg ulcer had healed
Interventions	compression stockings (Venosan 2003) versus no compression stockings
Outcomes	1. Recurrence of ulceration 2. area of lipodermatosclerosis
Starting date	
Contact information	M C Stacey, Dept of Surgery, University of Western Australia, Fremantle Hospital, Western Australia 6160, Australia. Tel +61 89431 2500 fax +61 89431 2623 email: mstacey@cyllene.uwa.edu.au

Vandongen (Continued)

Notes	2 years follow-up
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DATA AND ANALYSES

Comparison 1. Compression hosiery versus no compression hosiery (Intention to treat)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of recurrence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 2. Class 3 compression hosiery (exptl) versus class 2 compression hosiery (control)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of recurrence at 5 years follow up	1	300	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.61, 1.12]
2 Change in grade of hosiery	1	300	Risk Ratio (M-H, Fixed, 95% CI)	1.41 [1.04, 1.91]

Comparison 3. Below knee compression hosiery versus thigh length compression hosiery

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of recurrence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 4. Compression hosiery versus compression bandages

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of recurrence	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 5. Comparison between different brands of compression hosiery (class 2)

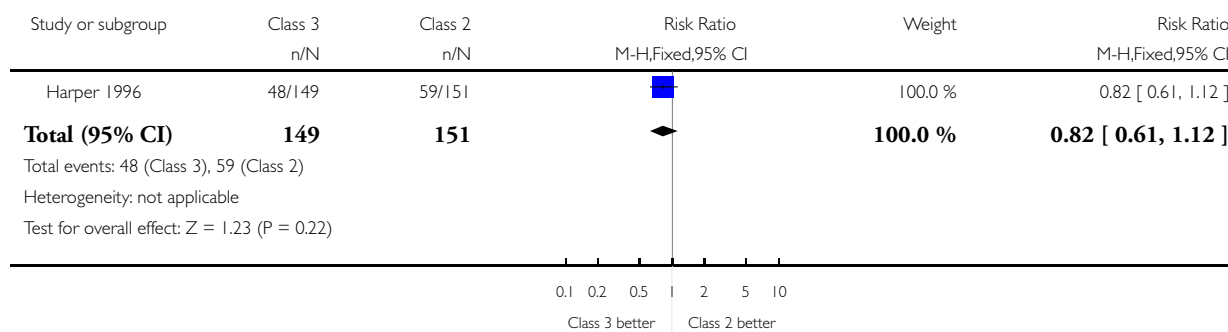
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Incidence of recurrence	1	166	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.45, 1.20]

Analysis 2.1. Comparison 2 Class 3 compression hosiery (exptl) versus class 2 compression hosiery (control), Outcome 1 Incidence of recurrence at 5 years follow up.

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Comparison: 2 Class 3 compression hosiery (exptl) versus class 2 compression hosiery (control)

Outcome: 1 Incidence of recurrence at 5 years follow up

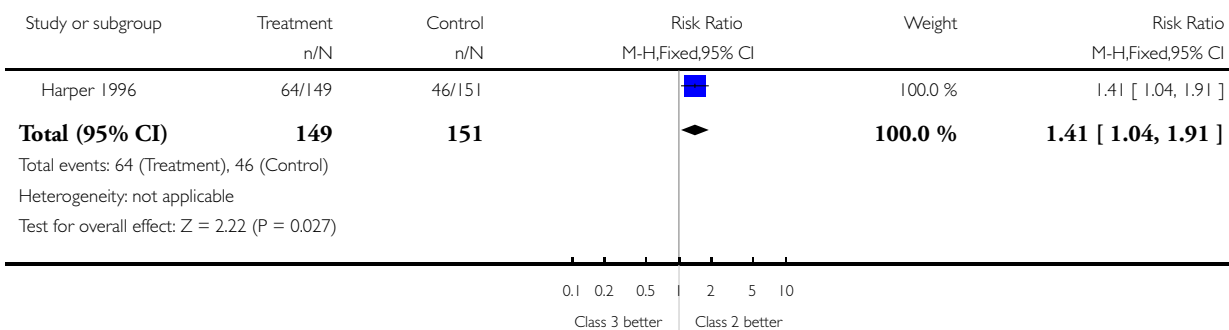


Analysis 2.2. Comparison 2 Class 3 compression hosiery (exptl) versus class 2 compression hosiery (control), Outcome 2 Change in grade of hosiery.

Review: Compression for preventing recurrence of venous ulcers

Comparison: 2 Class 3 compression hosiery (exptl) versus class 2 compression hosiery (control)

Outcome: 2 Change in grade of hosiery

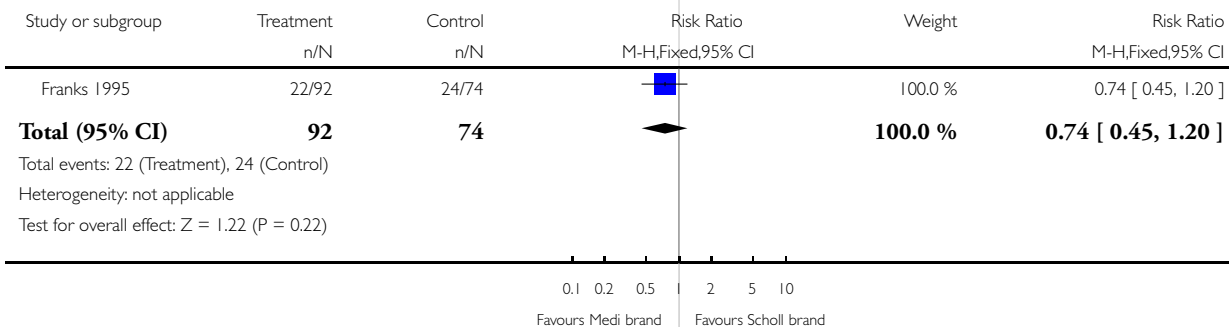


Analysis 5.1. Comparison 5 Comparison between different brands of compression hosiery (class 2), Outcome 1 Incidence of recurrence.

Review: Compression for preventing recurrence of venous ulcers

Comparison: 5 Comparison between different brands of compression hosiery (class 2)

Outcome: 1 Incidence of recurrence



ADDITIONAL TABLES

Table 1. Classification of compression stockings (UK)

Class	Descriptor	Ankle pressure	Indication
Class 1	light support	14-17 mmHg	Used to treat varicose veins
Class 2	medium support	18-24 mmHg	Used to treat severe chronic hypertension and severe varicose veins, and to prevent venous leg ulcers
Class 3	strong support	25-35 mmHg	Used to treat more severe varicosities, and to prevent venous leg ulcers

WHAT'S NEW

Last assessed as up-to-date: 22 August 2000.

Date	Event	Description
20 January 2010	Amended	Contact details updated.

HISTORY

Protocol first published: Issue 3, 2000

Review first published: Issue 4, 2000

Date	Event	Description
18 June 2008	Amended	Converted to new review format.
23 August 2000	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

EAN drafted the protocol; checked the literature search results against inclusion criteria; made initial decisions about inclusion; extracted data; undertook quality assessment and initial analysis; drafted the review.

SBS checked inclusion decisions; checked data extraction and quality assessment.

NC supervised the review; edited the protocol and review.

DECLARATIONS OF INTEREST

E Andrea Nelson was a trialist ([Harper 1996](#))

SOURCES OF SUPPORT

Internal sources

- Centre for Evidence Based Nursing, UK.
- Department of Health Studies, University of York, UK.

External sources

- NHS Health Technology Assessment Programme, England, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Bandages; Randomized Controlled Trials as Topic; Recurrence [prevention & control]; Risk; Varicose Ulcer [*prevention & control]

MeSH check words

Adult; Humans