Controversial aspects concerning practical compression therapy for leg ulcers: stockings or bandages

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S. O´Meara et al: Compression for venous leg ulcers. Cochrane Review 2012 Nov 14;11:CD000265.

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- Compression increases ulcer healing rates compared with no compression.
- Multi-component systems are more effective than single-component systems.
- Multi-component systems containing an elastic bandage appear to be more effective than those composed mainly of inelastic constituents.
- Two-component bandage systems appear to perform as well as the 4LB.
- Patients receiving the 4LB heal faster than those allocated the SSB.
- More patients heal on high-compression stocking systems than with the SSB.
  - High-compression stockings are associated with better healing outcomes than SSB at two to four months: RR 1.62 (95% CI 1.26 to 2.10), estimate from four pooled RCTs.
- Further data are required before the difference between high-compression stockings and the 4LB can be established.

Dolibog P, Franek A, Taradaj J, et al. A randomized, controlled clinical pilot study comparing three types of compression therapy to treat venous leg ulcers in patients with superficial and/or segmental deep venous reflux. *Ostomy/wound management*. 2013; 59: 22-30.

- Prospective, clinical pilot study
- 70 patients with unilateral VLUs
- Randomized to compression therapy by either
  - intermittent pneumatic compression (ICI), 60 mmHg at ankle, 60 min 1X / day
  - MCS Ulcer kit 30 – 40 mmHg
  - 2 layer short-stretch CB, 30-35 mm Hg (superficial reflux), 35 – 40 mmHg (superficial and deep reflux) Kikuheme measurement
- Treatment duration 15 days
- All patients received saline-soaked gauze dressings with micronised purified flavonoid fraction (Daflon 500 mg) once daily.
- Wound size reduction and percentage of wounds healed were significantly higher in groups receiving IPC or stockings than in groups using short-stretch bandages

Finlayson KJ, Courtney MD, Gibb MA, O'Brien JA, Parker CN and Edwards HE. The effectiveness of a four-layer compression bandage system in comparison with Class 3 compression hosiery on healing and quality of life in patients with venous leg ulcers: a randomised controlled trial. *International wound journal*. 2014; 11: 21-27.

- Randomised controlled trial
- Comparison of the effectiveness of a four-layer compression bandage system and Class 3 compression hosiery on healing and quality of life (QL) in patients with venous leg ulcers.
- 103 participants treated for 24 weeks.
- After 24 weeks
  - 86% of the four-layer bandage group and
  - 77% of the hosiery group were healed ($P = 0{\cdot}24$).
- Median time to healing
  - bandage group was 10 weeks
  - hosiery group 14 weeks ($P = 0{\cdot}018$)
- No differences in QL or pain measures
- Systems were equally effective in healing patients by 24 weeks; however, a four-layer system may produce a more rapid response.

Ashby RL, Gabe R, Ali S, et al. Clinical and cost-effectiveness of compression hosiery versus compression bandages in treatment of venous leg ulcers (Venous leg Ulcer Study IV, VenUS IV): a randomised controlled trial. *Lancet*. 2014; 383: 871-879.

- 457 patients presenting with VLUs of median areas 4.1 cm^2 and 3.7 cm^2
- Randomized to either
  - two-layer ulcer MCS (ulcer kit) or
  - four-layer bandage treatment
- Maximum follow-up: 12 months
- Median time to ulcer healing was
  - 99 days (95% CI 84–126) in the hosiery group
  - 98 days (95% CI 85–112) in the bandage group
- The ulcer healing rate was similar
  - 70.9% hosiery
  - 70.4% bandage

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	Hosiery group (n=230)	Bandage group (n=224)	Overall (n=454)
Male participants	117 (51%)	113 (50%)	230 (51%)
Age (years)	68·3 (15·1)	68·9 (13·8)	68·6 (14·5)
BMI (kg/m²)	30·9 (7·9)	31·2 (8·0)	31·0 (8·0)
Missing	3 (1%)	3 (1%)	6 (1%)
Mobility			
Walks freely	139 (61%)	150 (67%)	289 (64%)
Walks with difficulty	89 (39%)	71 (32%)	160 (35%)
Immobile	1 (<1%)	3 (1%)	4 (1%)
Ulcer characteristics			
Ulcer area (cm²)	4·1 (1·6–8·7)	3·7 (1·6–8·2)	3·9 (1·6–8·7)
Missing	1 (<1%)	0	1 (<1%)
Ulcer duration (months)	4·0 (3·0–12·0)	4·0 (2·0–9·0)	4·0 (2·0–11·0)
Missing	1 (<1%)	2 (1%)	3 (1%)
Time since first ulcer (months)	36·0 (4·0–120·0)	36·0 (4·5–120·0)	36·0 (4·0–120·0)
Missing	3 (1%)	4 (2%)	7 (2%)
Total ulcers on reference leg	1·0 (1·0–2·0)	1·0 (1·0–2·0)	1·0 (1·0–2·0)

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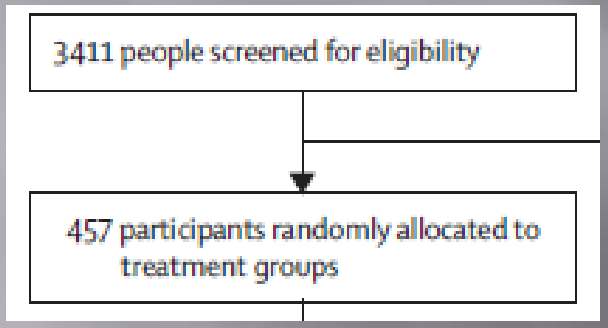
Only 457 of 3411 patients where included



One reason for exclusion

1713 not eligible for treatment with compression (not relevant study population)
- 464 were unable or unwilling to tolerate high compression
- 458 had an ABPI <0·80 (taken within the last 3 months)
- 183 had wound exudate levels that were too high for the use of compression hosiery
- 102 had gross leg oedema
- 282 had a leg ulcer of non-venous cause
- 20 had an ABPI >1·20 and in nurses' clinical judgment should not receive high compression
- 94 had an ulcer that had healed or was close to healing
- 33 had an ulcer that was not in the gaiter region
- 45 could not provide ABPI measurement
- 32 could not tolerate or apply trial treatments

Not all patients where eligible to compression stockings (ulcer kit) !

Patients who could not be treated by compression hoisery:
183 had wound exudate levels too high for hoisery
102 had gross led oedema

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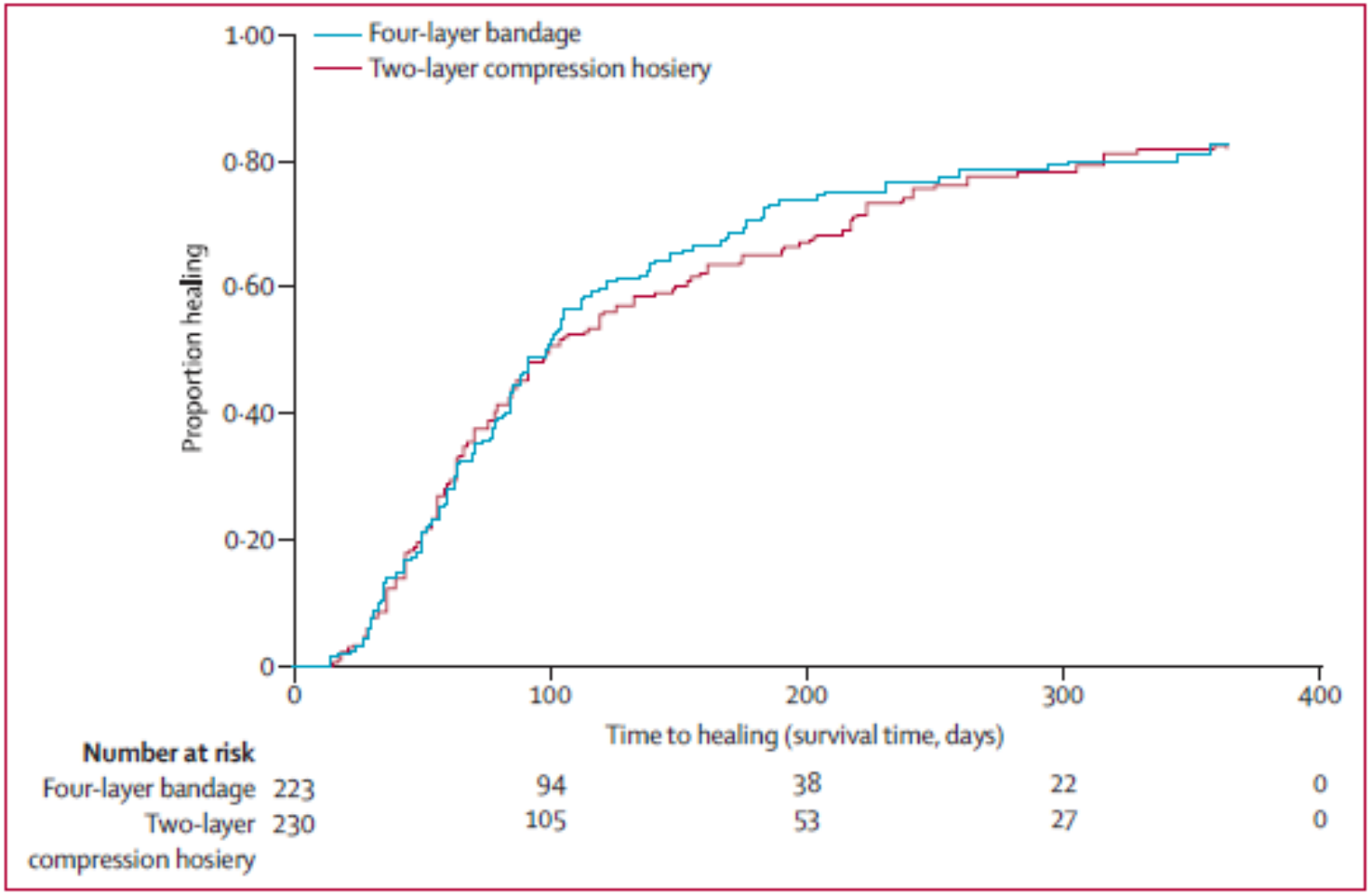

Figure 2: **Kaplan-Meier plot of time to healing (masked) by treatment group**

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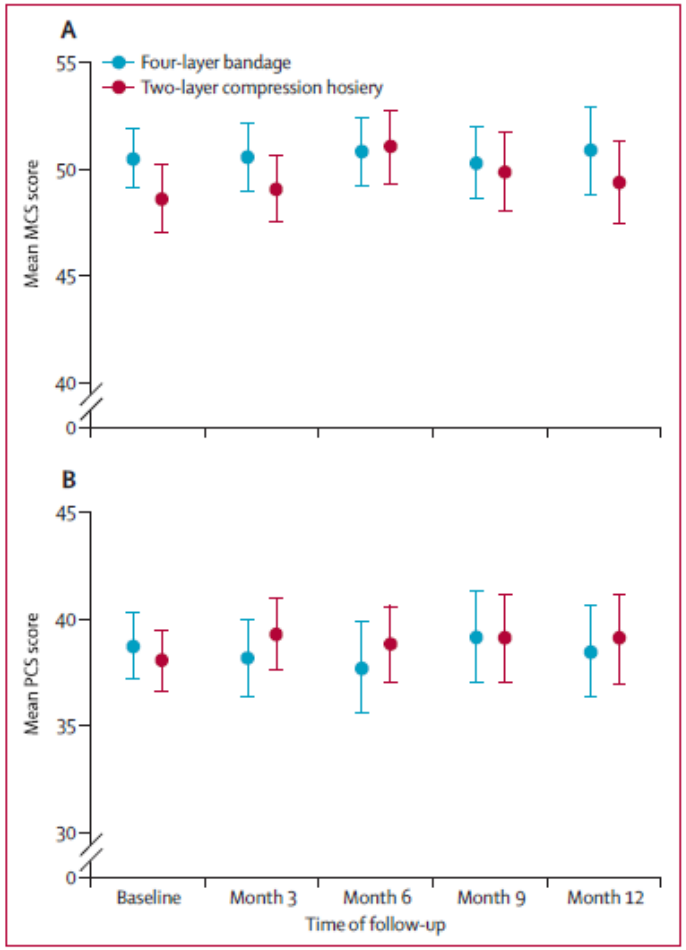

***Figure 3*: SF-12 mental component summary and physical component scores over time according to treatment group (mean and 95% CI)**
Error bars are 95% CIs. MCS=mental component summary. PCS=physical component summary.

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	Mean annual cost, £ (95% CI)†	Mean quality-adjusted life-years (95% CI)†
Hosiery group	1492·9 (1187·3 to 1954·3)	0·685 (0·665 to 0·716)
Bandage group	1795·3 (1559·7 to 2185·0)	0·651 (0·619 to 0·682)
Difference between groups	–302·4 (–697·6 to 96·2)	0·034 (–0·001 to 0·078)

£1=US$1·62. *Adjusted for ulcer duration (logarithmic), ulcer area (logarithmic), participant mobility, and centre. Participant mobility was defined as dichotomous variable (ie, walk freely *vs* walk with difficulty or immobile). Centre has been adjusted for by a multilevel model, with centre used as a random effect. †95% CIs are bias corrected.

Table 4: **Adjusted* annual costs and quality-adjusted life-years**

Summary

- Based on the current literature, the healing rates of VLUs are comparable between ulcer MCS (ulcer kit) and compression bandage (CB) systems in eligible patients.
- MCS may be more cost-effective compared to CB
- Reasons why MCS may not be choosen:
  - Circumferential ulcers / huge ulcer size
  - Untypical locations (e.g. Foot)
  - High amount of exsudate
  - Gross edema

Thank you very much for listening