

EFFECTIVENESS AND TOLERANCE OF AN ULCER COMPRESSION STOCKING FOR THE TREATMENT OF VENOUS LEG ULCERS COMPARED WITH A LOWER-LEG COMPRESSION BANDAGE

Jünger M, Wollina U, Kohnen R et al., Curr Med Res Opin 2004; 20(10): 1613–1624

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STUDY OBJECTIVE

Investigation of the effectiveness of the VenoTrain ulcertec compression stocking compared with phlebological compression bandages with regard to the healing rates of venous ulcers.

STUDY DESIGN

Prospective, multi-center, open, randomized, actively controlled study covering 16 phlebological outpatient clinics in Germany and the Netherlands as well as German practices specializing in phlebological treatment.

PATIENTS AND METHODS

134 patients with venous leg ulcers were randomized. Criteria for exclusion included being confined to bed, clinical indications of an infection of the ulcer, insulin-dependent diabetes mellitus, obesity, etc. 121 patients were included in the primary effectiveness analysis (ITT population).

The compression stocking and compression bandage were worn for at least eight hours each day, with an observation period of twelve weeks.

The primary objective was the healing rate after twelve weeks and the secondary objective covered the time it took for the ulcer to heal, the change in the size of the ulcer (measured in two dimensions), experiences of applying the compression process and patient compliance.

VenoTrain® ulcertec 39

10 mmHg 23–27 mmHg
Liner Overstocking

- Compression strength 34–39 mmHg
- Non-problematic venous ulcer of the leg with good tendency to heal
- Light liner for patients who can only tolerate little compression at night

VenoTrain® ulcertec 46

18 mmHg 23–27 mmHg
Liner Overstocking

- Compression strength 40–46 mmHg
- Treatment-resistant ulcers
- Ulcers with a poor tendency to heal
- Given tolerance and a good level of acceptance of compression

RESULTS

The study revealed that the compression stockings, with a healing rate of 47.5%, were significantly superior to the compression bandages, at 31.7% ($p = 0.0129$ [CI 95% for differences: 4.3% to 28.5%]). The average time it took for ulcers to heal was 46 days in both groups. The compression stockings took less time to put on than the compression bandages: 5.4 minutes (SD 5.4) for the VenoTrain ulcercertec and 8.5 minutes (SD 6.5) for the bandage ($p = 0.0001$).

The exploratory evaluation of the assessment by the nursing staff revealed further clear benefits of using the compression stockings, such as improved compression effect, less damage, and greater patient satisfaction.

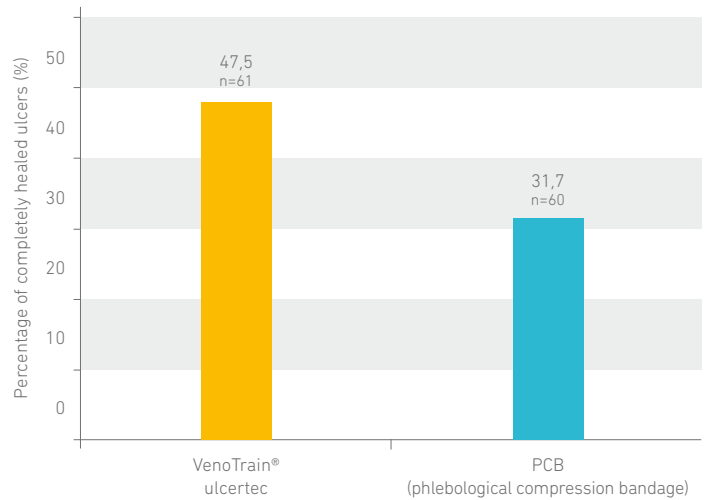
The exploratory evaluation using the patient questionnaire reinforced the superiority of the compression stockings in terms of constriction, freedom of movement and mobility, sweating, and itchy legs. Patients in the VenoTrain ulcercertec group also tended to experience less pain.

CONCLUSION

The VenoTrain ulcercertec set of compression stockings proved itself significantly superior to conventional phlebological compression bandages:

- Significantly improved healing rates
- Increased wearing comfort and ease of handling
- Greater acceptance among nursing staff and patients
- Increased compliance

Comparison of response rates for completely healed ulcers (ITT population)



* $p = 0,0129$