

Progressive versus conventional elastic stockings in patients presenting with mild venous insufficiency: a randomised clinical trial

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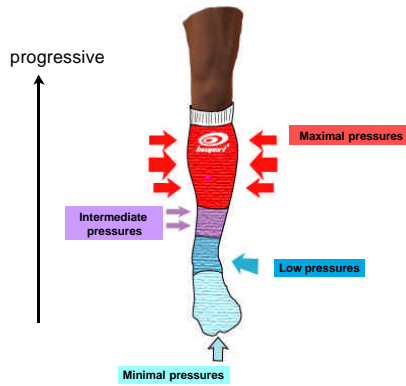


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Introduction

- Elastic stockings (ES) are recommended in venous insufficiency, for the prevention of thrombosis in the post-operative period [Wells et al. *Arch Intern Med* 1994, 154: 67-72] OR after an episode of venous thrombosis [Brandjes et al. *Lancet* 1997, 349: 759-62 ; Ginsberg et al. *Arch Intern Med* 2001, 161: 2105-9].
- Conventional ES: degressive compression from ankles to calf
- New concept of ES : progressive compression from ankles to calf (Figure 1), in order to optimise the comfort and convenience with at least the same efficacy of the degressive ones.
- Efficacy of the progressive ES already assessed in athletes after physical efforts in terms of venous return [Couzan et al. *Int Angiol* 2000, 19(suppl): 41]

Figure 1: concept of progressive ES



Aim of the study

- To assess the efficacy and convenience of the new elastic stockings, BVSPORT® in comparison to conventional ones in patients presenting with mild venous insufficiency.

Material and Methods (1)

Experimental design

- multicentre randomised double-blind clinical trial
- conventional stockings (class 2)
- progressive stockings
- centralised randomisation
- non-inferiority trial

Study population

- inclusion criteria:
 - mild venous insufficiency, i.e. class 1 in Porter's classification (corresponding to C0 or C1 in the CEAP or Hawaii classification)
 - indication of elastic compression by knee stockings
- exclusion criteria:
 - post-thrombotic syndrome
 - peripheral arterial disease
 - dermatological disease
 - renal or nephrotic or cardiac insufficiency

Material and Methods (2)

Treatments

- conventional ES: 20 mmHg at the ankle level
14 mmHg at the calf level
- progressive ES (BVSPORT®)
5 mmHg at the ankle level
20 mmHg at the calf level

Clinical outcomes

- main outcome : efficacy in terms of leg heaviness judged by the patient
- convenience in terms of comfort
- compliance: visual analog scale (VAS)
- evaluation after 15 days of ES wearing

Statistical analysis

- sample size assessment: 120 patients needed to demonstrate non-inferiority of the progressive ES (success rate = 80% in both group, $\alpha = 5\%$, $\beta = 10\%$, non-inferiority margin $\Delta = 18\%$)
- analysis: Blackwelder test, Fisher exact test and Student t test

Description of the study population

Inclusions

- 130 patients included from May 2003 to March 2004 suffering from venous insufficiency for 1 month up to 46 yrs.
- comparability at inclusion:

	Conventional ES (66 pts)	Progressive ES (64 pts)
Female gender	70%	67%
Age, yrs	43 ± 12	42 ± 13
Weight, kg	65 ± 11	65 ± 13
Ankle circumference, cm	22 ± 1.8	22 ± 1.6
Calf circumference, cm	36 ± 3.0	36 ± 3.0
APA or NSAID	1.5%	3.1%

Follow-up

- 3 clinical visits not performed: two patients lost from sight, one cancer discovery (patient no longer interested in the trial)..

Results

	Conventional ES (66 pts)	Progressive ES (64 pts)	Statistics
Main outcome: disappearance or major improvement of the leg heaviness	62.5%	73.0%	$D = -10.5\% [-26.7 ; 5.6] \ll \Delta$ $P < 0.001^*$
Stockings easily or very easily slipped on	56.2%	95.2%	$P < 0.0001$
No or light discomfort	59.4%	93.6%	$P < 0.0001$
Compliance: VAS between 0 (ES never worn) to 10 (ES worn every day)	8.0 ± 2.5	9.0 ± 1.9	$P = 0.016$

* Non-inferiority p value

Discussion

- Progressive ES : best comfort and convenience → improvement of compliance
- First randomised trial assessing elastic stockings in venous insufficiency
- Progressive ES should be assessed in combination with medical treatment in the prevention of post-operative venous thrombo-embolic events and in the treatment of thrombo-embolic disease.

Study participants (France)

Investigators

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Data management and analysis

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Sponsor

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