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


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Introduction

- 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]

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
- 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

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:

<table>
<thead>
<tr>
<th>Conventional ES (66 pts)</th>
<th>Progressive ES (64 pts)</th>
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</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>70%</td>
</tr>
<tr>
<td>Age, yrs</td>
<td>43 ± 12</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>65 ± 11</td>
</tr>
<tr>
<td>Ankle circumference, cm</td>
<td>22 ± 1.8</td>
</tr>
<tr>
<td>Calf circumference, cm</td>
<td>36 ± 3.0</td>
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<tr>
<td>APA or NSAID</td>
<td>1.5%</td>
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</tbody>
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Follow-up

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

Study participants (France)

Investigators

Dr Brisot, Clapiers
Drs Bucci and Diamand, Grenoble
Dr Coupe, Montpellier
Dr Couzan, Saint-Etienne
Dr Daussin, Strasbourg
Drs Gachel and Lebrun, Voiron
Dr Gris, Montbrison
Dr Jurus, Lyon
Dr Mollard, Chambery
Dr Polverelli, Roanne
Dr Prüfer, La Motte Servolex
Dr Riom, Grenoble
Dr Soulier-Sotto, Montpellier
Dr Spini, Pont de Beauvoisin
Dr Stinemann, Saverne

Data management and analysis

Thrombosis Research Group: C Assante, P Mismetti, H Décosus

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.

Sponsor

BVSport
16 cours d’Herbevoye
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[http://www.bvsport.com]