

## A Sample Study for a Phlebotrope: The EIVE Study

The clinical procession of insufficient venous functions of the lower extremities, a frequent complaint in daily phlebology, is well known in the medical field:

- Sluggishness
- Heaviness
- Tiredness
- Itchiness
- Legs without rest
- Nocturnal cramps
- An impression of “swelling” in the extremities

In varying degrees this symptomatology appears difficult to objectively appreciate based on this one study (6) and to render a delicate therapeutic evaluation of a phlebotrope. Also, paraclinical examinations are deceiving in the following domain:

- A capillaroscope carries no reliable element
- The Doppler allows some to recognize the hemodynamic value of the veins both deep and superficial, the backward surges, the incontinent perforations...thus eliminating a trial of post phlebitis patients and varicose patients but still not constituting an appreciative therapeutic criteria.
- The diverse techniques of plethysmographs, partial oxygen pressure, are unsatisfactory and give varying results.

Only the double blind appeared insufficient by reason of the number of outside factors interfering in the analysis:

- Climactic
- Seasonal
- Personal (heating, profession, life style, associated treatments...)

The lawmaker didn't make a mistake having decreed four strict requirements full obtaining full recognition of a veinotrope:

Following a pre-trial done previously (8), five symptoms were retained by several angiologists as evaluation criteria (figure Z) as insufficient venous functions:

- One principal criterion: Heaviness (or comparable impression of a sort in the distal segment of the lower limbs, a sort of sluggishness) quantified by the patient from zero to five depending upon the intensity.
- 4 annex criteria:
  - Itchiness counting as zero or one.
  - Nocturnal cramps (zero or one).

- Legs without rest (zero or one).
- Subjective oedema, described as an impression that the volume of the foot has increased as well as the ankle and the calves counted from zero to two:
  - 0 if absent
  - 1 if the sensation of the “swollen foot” appears in the second half of the day
  - 2 if felt earlier.

The total score for each patient could vary from zero to eight, going higher as the functional symptomatology became richer.

The experiment was conducted in five consultations:

During the first the doctor:

- Conducted a rigorous clinical examination eliminating those subjects exhibiting venous insufficiency through saphenous ostial incontinence (internal or external).
- By also eliminating those patients exhibiting an evolved nonsystematic varicose and those having a previous history of vein problems or scleriotherapy.
- By keeping those subjects who didn't exhibit a deep flow after a velocimetric examination by the systematic Doppler effect.
- Inscribe and totals on a grid the numbers from the interrogation including the clinical symptoms given. Then with the agreement of the patient he is chosen for the pre-experiment; given a placebo (unknown by the patient) for four weeks.
- The second consultation (considered as Day 0): If the patient is not sensitive to the placebo and has been following the protocol correctly he is chosen by lottery as which treatment he will take, that which is the placebo unknown to the patient for 12 weeks with two intermediate consultations: One at Day 28 and the fourth at Day 56.
- Finally, at the 12<sup>th</sup> week of the treatment there is a fifth consultation takes place at the end of the experiment (Day 84) with an analysis of the results.

At each consultation the doctor:

- Established a new score
- Noted the meteorological conditions of the day
- Assured himself of the stability of the risk factors:
  - Time of consultation
  - Time spent in the waiting room
  - Hours of orthostatism individual and professional

In order to avoid all possible seasonal variations the selection period was short (3 months) took place in the spring and the actual experiment took place through the summer into the early autumn.

The quality control of the study