INTRODUCTION: The aim of my study has been to evaluate the efficacy of a new method of compression sclerotherapy of GSV, with sclerosing agents in different physical forms, utilizing a combined compression system: Therapeutic and Hemodynamic. I have defined Therapeutic Compression the one applied to reduce only the caliber of the vein; Hemodynamic compression is the one capable of interrupting veno-venous shunts, and it protects the varicose veins, related to saphenous reflux, from the hemodynamic overload. This method allows the sclerosed vein, averting from recanalization (caused by reflux), to regular scarring.

MATERIALS and METHODS 255 Sapheno-femoral junctions (S/FJ's) - C2-6, Ep, As2 ± p, Pr - with a diameter of 5 to 18 mm (measured 3 cm below the junction) have been sclerosed utilizing the following method.

A) THE METHOD

1st Session: sclerotherapy of the trunk of GSV at the thigh I. With the patient standing, the Saphenous trunk and all the visible varicose veins are marked (with black ink).

II. Hemodynamic compression of the S/F junction is performed utilizing a device called Safeguard® (TM, Datascope), with the patient standing (Fig.1). This particular device consists of an adhesive medication with an inflatable and echo-transparent balloon, commonly used to achieve hemostasis after invasive vascular procedures (Fig.1a). The inflation of the balloon, done with a syringe and gel (Fig.1b), is Duplex-guided up to the interruption of the sapheno-femoral reflux (Fig.1c), selectively occluding the Saphenous Vein with no effect on the femoral vessels (Fig.1d) [1]. Deflate the Safeguard®.
III. The veins are emptied by placing the patient in Trendelenburg position (Fig.2a); after the Safeguard® is inflated, with air (same volume as the one used for interruption of the reflux with the gel) (Fig.2b).

IV. With the patient standing, the varicose veins, that have been deflated with the interruption of the reflux (by inflating the Safeguard®), are remarked with red ink (Fig.2c). V. The Safeguard® is deflated after applying a short-elastic bandage to the foot at the knee (Fig.3a). VI. Puncture of the saphenous trunk at the thigh (with or without echoguide), with 18 G needle (short catheter): according to Sigg’s technique « open needle » (patient standing, needle not connected to a syringe)[2], or to Sica’s technique “closed needle” (patient supine in semiupright position, needle connected to syringe with an extension) (Fig.3b) [3]. VII. Patient in Trendelenburg position and injection, in the saphenous trunk, of a 4-6% iodate solution in 180 cases (Group L) and of Polidocanol-foam 2% in 75 cases (Group F) (Fig.4a), followed by double compression (Fig.4b):

• Hemodynamic Compression: the Safeguard® is inflated with air (same volume used for the interruption of the reflux)

• Therapeutic Compression: eccentric positive rolls on the trunk of the GSV at the thigh and concentric bandage (foam bandage + removable short-elastic bandage) [4]

2nd Session (after one day*): sclerotherapy of the varicose veins submitted to reflux (Fig.5)

I. Only the varicose veins reduced by the inflation of the Safeguard®, marked in red during the test of interruption of the reflux, are sclerosed (see point 1-IV)

II. Application of removable short-elastic bandage and of eccentric positive compressions (rolls) over the treated veins

Control (after 3 days*): clinical and echo-Doppler check of the sapheno-femoral reflux (long reflux)

I. All eccentric positive compressions are removed (Safeguard® included, if reflux isn’t present)

II. Removable short elastic bandage is applied

3rd Session (after 15 days*): sclerotherapy of the remaining varicose veins, marked in black, not related to the long reflux (Fig.6).

I. Search for the leak points of short reflux (perforating veins)
II. Hemodynamic Compression: Safeguard® (12 cm) applied on the perforating vein to verify the interruption of the reflux (same procedure as discussed in point II-III-IV of 1st session)

III. Sclerotherapy of the varicose veins related to the short reflux

IV. Therapeutic Compression: removable short-elastic bandage and rolls over the treated veins [4]

Control (after 21 days*) : clinical and echo-Doppler check of the short reflux.

I. All eccentric and concentric compressions are removed

II. A class II o III A-G stocking to be worn for 30 days

Note - (*) Starting from 1st Session

B) THE MATERIALS: (in addition to the standard sclerotherapy tools)

I. Tilting table capable of Trendelenburg position

II. Cotton lint tampons 1,5 cm in thick and 2 cm in diameter for varicose veins

III. Cotton rolls with hard core:

• 4 cm thick and 9 cm long, (for the GSV trunk);

• 2 cm thick and 4 cm long (for the SSV trunk);

• 2-3 cm thick hemispheric shaped – for the muscular perforators, and half-moon shaped for the retro-tibial perforators.

IV. Safeguard® TM (Datascope)12 and 24 cm (balloons of different diameters)

V. Short-elastic bandages of 35% elongation, lifted at night.

RESULTS The evaluation of results has been done at 6, 8, 12 months with clinical and duplex criteria:

18 (10%) recurrences were instrumentally detected in the group L and 6 (8%) in the group F; 10 (5.5%) were clinically detected in the group L and 4 (5.3%) in the group F.

The major complications (arterial injection, severe allergic reaction and deep venous thrombosis) weren’t observed after Hemodynamic Compression Sclerotherapy (HCS: my method).
The $\chi^2$ test has demonstrated a statistically not significant difference of incidence of the Clinical (p: 0.81) and Duplex (p: 0.87) recurrencies between group L and M.

The incidence of Clinical and Duplex recurrencies, in the group L has been compared to the one of all my cases (23% of failures at instrumental level, and 12% at clinical level), observed in the course of a 15 years follow-up of 1500 cases of incontinent S/FJ, treated with the technique of Sigg [5]. The $\chi^2$ test has demonstrated a statistically significant difference at clinical level (p: 0.0141; odds ratio: 6.03), as well as instrumental (p: 0.0001; odds ratio: 0.37), in favor of my proposed method.

The incidence of Duplex recurrencies, in the group F has been compared to the one of experience of M. Sica (359 cases of incontinent S/FJ, treated with the foam-sclerotherapy) [3]. The $\chi^2$ test has demonstrated a statistically significant difference (p: 0.0314; odds ratio: 0.39), in favor of my proposed method (Tab. I).

**DISCUSSION**

Hemodynamic Compression significantly reduces the incidence of Clinical and Duplex Recurrences after GSV sclerotherapy with liquid or foam agents. In fact the application of Safeguard® protects:

- the lower underlying varicose veins from the hemodynamic overload of the veno-venous shunt; this allows them to undergo a normal process of scarring;

- the saphenous trunk from the long reflux, making it easily compressed by the bandage [6]; • the femoral vein from the possible progression of thrombus through the S/F junction. The leg bandage that blocks the superficial venous return from the distal veins, and the “compression crossectomy” afforded by the Safeguard®, bottle up the sclerosing agent in the saphenous trunk at the thigh. Furthermore, the saphenous trunk is completely emptying with the leg elevation in Trendelenburg position, after the puncture. This results in an important reduction of the size of the vessel, thus allowing the use of a smaller quantity of sclerosing foam and a regular distribution of it [7, 8]. The foam completely fills the lumen of the vein, from distal to proximal, without floating in blood as it would happen if injected in the supine position [9, 10].

For the sclerosis to be effective [11, 12], the veno-venous shunt to the varicose veins must be interrupted. This can be accomplished only with complete block (using the Safeguard®) at the leak point, which is easier to find, rather than at the multiple re-entry points (end points)[13]. This starting point corresponds at the S/F junction, or at the highest perforator (in instances of residual varicose
veins after sclerosing of the saphenous territory). In my experience with sclerosing of perforators [14], I have noted that such device can be substituted by particular tampons with hard core (see Materials point 3) [5].

CONCLUSIONS My method can be used with every technique of sclerosing injections, with every pharmacological agent in liquid or foam form. It is therefore far from being a new sclerosing technique and only represents a new STRATEGY (HCS Hemodynamic Compression Sclerotherapy). Although it may appear as a complex procedure, it surely offers the advantage of allowing the complete treatment of varicose veins of GSV in only three sessions.

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SUMMARY

AIM: The aim of my study has been to evaluate the efficacy of a new method of compression sclerotherapy of GSV, with sclerosing agents in different physical forms.

MATERIALS and METHODS: 255 lower extremities with primary varicose veins, with a long reflux of the GSV (C2-6, Ep, As2 ± p, Pr), have been submitted to sclerotherapy applying the following method: injection of the trunk of the GSV, according to Sigg's technique; echoguided compression of sapheno-femoral junction (done by an inflatable balloon called Safeguard); immediate eccentric positive compression on the trunk of the GSV; and short elastic bandage. RESULTS: The results have shown that applying this method of sclerotherapy the failure rate decreases.

CONCLUSIONS: The use of Safeguard interrupts reflux to the lower veins, and these can so be well sclerosed and compressed with short elastic bandage. My method can be used with every pharmacological agent in liquid or foam form.
FIGURES

Fig 1) 1st Session: interruption of saphenous reflux with echoguided compression of S/FJ. Femoral Vein/Artery (v/aF) and Sphenous vein (vS): before (C) and after (D) the inflation of balloon (P).

Fig 2) 1st Session: A) the varicose veins have been deflated with the Trendelenburg’s position of the leg B); the Safeguard is inflated; C) patient standing, only the varicose veins, that have been deflated, are remarked (red arrows).

Fig 3) 1st Session: A application of short-elastic bandage to the foot at the knee, the Safeguard is deflated to empty the saphenous trunk; B Puncture of full vein, according to Sigg or Sica’s technique.

Fig 4) 1st Session: A) injection of sclerosing agent (liquid or foam) in Trendelenburg position (Safeguard deflated); B) inflation of the Safeguard and Therapeutic Compression (eccentric and concentric).

Fig 5) 2nd Session: The suppression of the saphenous long reflux, made with the Sfeguard, deflates both the trunk of the GSV and the lower underlying varicose veins, that can be well compressed with bandage and rolls.

Fig 6) 3rd Session: A) The search of the leak points of short reflux. B) Safeguard applied on the perforating vein (black circle) to verify the interruption of it reflux. Sclerotherapy of the varicose veins related to the short reflux.

Tab I: Absence of statistically significant difference between the two groups (L and F) treated with the same technique (HCS); duplex failure rate is shown with the red colour, and clinical failure rate is shown with the yellow colour.