A new strategy in sclerotherapy of varicose veins

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AIM: *The aim of our study was to evaluate the efficacy of a new method of compression sclerotherapy of GSV and SSV.*
MATERIALS AND METHODS: *345 lower extremities with primary varicose veins, with a long reflux of the GSV (C2-6; Ep; As 2, 3; ± p; Pr), have been submitted to sclerotherapy applying the following method: injection of foam (Polidocanol 2%), or liquid sclerosant (iodate solution 4-6% or Polodocanol 3%) in the trunk of the GSV; echoguided compression of sapheno-femoral junction (performed using an inflatable device, the 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, independently to physical form of sclerosing agent.*
CONCLUSIONS: *The use of Safeguard® interrupts reflux to the lower veins, and these can so be well sclerosed and compressed with short elastic bandage.*

KEY WORDS: Long compression, Foam, Saphenous vein Sclerotherapy varicose veins

Introduction

The purpose of this paper is to present a new method of sclerotherapy of the Great Saphenous Veins (GSV) utilizing a combined compression system: Therapeutic and Hemodynamic. We 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 paper aims to demonstrate that our method allows the sclerosed vein, averting from recanalization (caused by reflux), to regular scarring.

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Materials and Methods

I. OUR TECHNIQUE IS MADE UP BY 3 SEQUENTIAL SESSIONS OF SCLEROTHERAPY.

1ST SESSION: *Scleroterapy of the trunk of GSV at the thigh*

A) With the patient standing, the Saphenous trunk and all the visible varicose veins are marked (with black ink).
B) Hemodynamic compression of the S/F junction is performed utilizing a device called Safeguard® (TM, Datascope), with the patient standing. This particular device consists of an adhesive medication with an inflatable and echo-transparent balloon, commonly used to achieve hemostasis after invasive vascular procedures The inflation of the balloon, done with a syringe and gel, is Duplex-guided up to the interruption of the saphenofemoral reflux, selectively occluding the Saphenous Vein with no effect on the femoral vessels [1].
At this point we can deflate Safeguard®.
C) Veins are emptied by placing the patient in Trendelenburg position; after the Safeguard® is inflated, with air (same volume as the one used for interruption of the reflux with the gel. In all cases the interruption

of reflux has been obtained using 28 cc of gel (average value ± 3)
D) With the patient standing, varicose veins, that have been deflated with the interruption of the reflux (by inflating Safeguard®), are remarked with red ink.
E) Safeguard® is deflated after applying a short-elastic bandage to the foot at the knee. The patient's position is not significant at this stage.
F) Technique of Puncture
a) with patient standing, the trunk of the GSV at thigh level is located by ultrasound (short axis projection);
b) only the 18G needle (1,2mm ∅) is inserted (without the syringe attached) to observe spontaneous blood outflow; a nurse is needed to help collect the blood in a basin.
This maneuver is useful for confirming that the needle is correctly positioned in the lumen of the vein [2]. Ultrasound can only guide the needle towards the venous trunk, but it cannot ensure that the tip of the needle is correctly positioned.
The patient lies down on the specially designed bed (see Materials-section III, Point i); the leg is raised about 35° with the foot placed on the footrest.
G) Technique of injection. With the leg in this position (which can also be replicated with the patient in the Trendelenburg position on a standard bed), the saphenous trunk is emptied and its diameter narrowed [1]. The needle is carefully connected to the syringe to inject 1cc of the liquid or foam sclerosing agent. This step generally needs to be repeated approximately 4 or 5 times to sclerose the saphenous trunk of a thigh. Steps F) and G) are performed in rapid succession, during the same session. Using a glass syringe (not plastic), if the piston encounters resistance and fails to slide smoothly, it means that the tip of the needle has slipped out of the vein.
Volume of injection:
– foam is injected until his echo-guided visualization at the S/FJ;
– or it can be injected about 0.7 cc ±0.3 of liquid agent, each 7-8 cm of venous trunk, (average of 5 injections are necessary for the sclerosis of a whole trunk of GSV). The injected volume has never exceeded 10 cc of sclerosing agent in foam or liquid form, per session.
The Sclerosing foam has been generated, according to Tessari method, with two disposable plastic syringes, with the outlets connected by a three-way-tap or a two-way-connector [3]. One syringe contains the liquid sclerosing solution, and the other contains air (liquid-to-air ratio is 1:4). Pumping (forward and backward) the contents of both syringes causes a turbulent flow that generates foam.
H) Compression:
Hemodynamic Compression: Safeguard® is inflated with air (same volume used to interrupt 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].

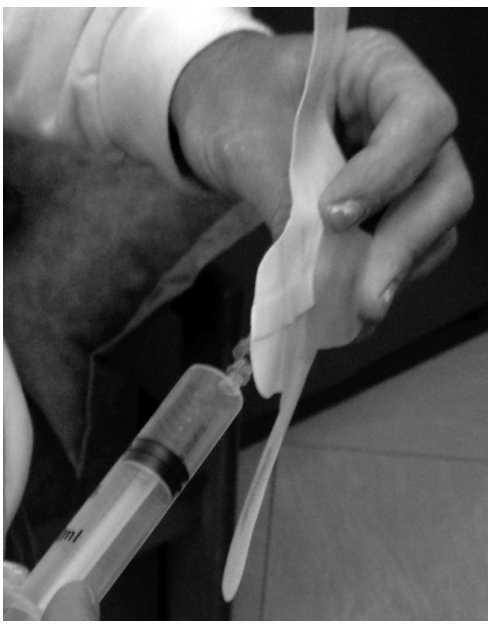

Fig. 1

2ND SESSION (after one day*): *scleroterapy of the varicose veins related to reflux*
A) 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 points A-B-C-D of 1st Session). The puncture technique is identical to the one described in point F/b of 1st Session (open needle). The injection technique is also identical to the one described above in point G) of first Session, with the leg raised in the Trendelenburg position and the vein emptied.
B) Application of removable short-elastic bandage and of eccentric positive compressions (rolls) over the treated veins.
Control (after 3 days*): clinical and echo-Doppler evaluation of the sapheno-femoral refiux (long reflux).
A) All eccentric positive compressions are removed (Safeguard® included, if reflux is not present).
B) 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.*

A) Points of short reflux are to be find out (perforating veins).
B) Hemodynamic Compression: Safeguard® (12 cm) applied on the perforating vein to verify the interruption of the reflux (same procedure as discussed in point B-C-D of 1st session).
C) Sclerotherapy of the varicose veins related to the short reflux.
D) Therapeutic Compression: removable short-elastic bandage and rolls over the treated veins [4].

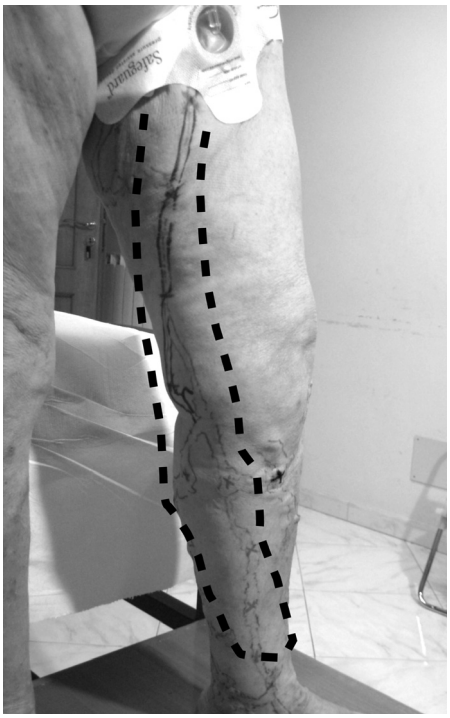

Fig. 2

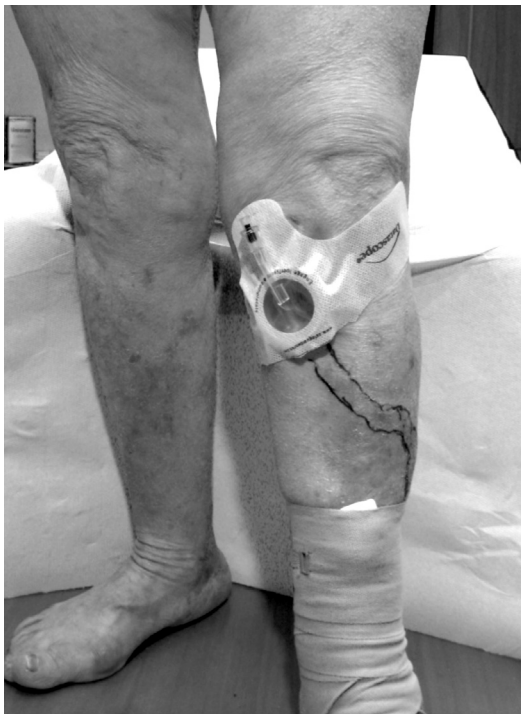

Fig. 3

CONTROL (after 21 days*): *clinical and echo-Doppler check of the short reflux.*
A) All eccentric and concentric compressions are removed.
B) A II or III class A-G stocking to be worn for 30 days.

Note - (*) Starting from 1st Session

II. UTILIZED MATERIALS: (in addition to the standard sclerotherapy tools)

The requested tool to perform HCS are listed below: a specially designed bed enables the patient to move quickly from standing to supine. The bed is comprised of two parts: a standard phlebology stool for observing the patient standing, and a gynecologic bed where the patient can sit and easily lie down and placing the foot in the special footrest attached to the instrument trolley. A tilting table capable of Trendelenburg position should be also available, as alternative.
Cotton lint tampons 1,5 cm in thick and 2 cm in diameter for varicose veins.
Safeguard® TM (Datascope)12 and 24 cm (balloons of different diameters).
Short-elastic bandages of 35% elongation, left during night.
Hard-cored cotton rolls of different dimensions, such as:
– 4 cm thick and 9 cm long, (for the GSV trunk);
– 2 cm thick and 4cm long (for the SSV trunk);
– 2-3 cm thick hemispheric shaped – for the muscular perforators, and half-moon shaped for the retro-tibial perforators.

III. CLINICAL SERIES STUDY

345 sapheno-femoral junctions (S/FJ's) - C2-6; Ep; As 2, 3 ± p; Pr - with a diameter of 5 to 18 mm (mean 9.2; standard deviation 3.4; median 7.8; mode 6,8), measured 3 cm below the junction, have been submitted to HCS utilizing: Polidocanol-Liquid 3% in 85 cases (Group A), of Polidocanol-foam 2% (performed according to Tessari's technique) in 80 cases (Group B) and of iodate solution 4-6% in 180 cases (Group C).
The exclusion criteria were: intolerance to the application of the Safeguard® and the impossibility to achieve interruption of reflux with the inflation of this device. In all cases it has been obtained the interruption of reflux using 28 cc of gel (average value ± 3).
The major complications (arterial injection, severe allergic reaction and deep venous thrombosis) were not observed after Hemodynamic Compression Sclerotherapy.

Results

The evaluation of results (success and failures) has been done at 6, 8, 12 months with clinical and duplex criteria.
Failure (recurrence) has to be considered the non-obtainment of well-defined objective Duplex-signs, and clinically the reappearance of varicose veins (>50% of initial condition).
Duplex-signs can be summarized as follows: morphological modifications (B-Mode), changes in the structure of

the wall like thickening or fragmentation; alterations of the venous lumen like echogenic densification and reduction of the caliber, up to the transformation into a cord; this last one would be synonymous of ideal sclerosing reaction. The most important finding has been the non-compressibility of the vessel. Hemodynamic modifications (Doppler) spread from a lack of flow (ideal sclerosing reaction) to a disappearing reflux. The last finding was equivalent to a restored valvular function after reduction of the caliber. If this reduction was insufficient, reflux was persisting.

7 (8.2%) recurrences were instrumentally detected in the group A; 6 (7.5%) in the group B; and 18 (10%)in the group C (table I).

4 (4.7%) were clinically detected in the group A; 4 (5%) in the group B and 10 (5.5%) in the group C.

The major complications (arterial injection, severe allergic reaction and deep venous thrombosis) were not observed after Hemodynamic Compression Sclerotherapy (HCS strategy).

The incidence of Clinical and Duplex recurrences, in the group C has been compared to the one of Control Group (1500 cases of incontinent S/FJ with a diameter of 9 mm -average value): 23% of failures at instrumental level, and 12% at clinical level, in the course of a 15 years follow-up, observed in our precedent experience. The patients of Control Group and Group C have been sclerosed in one session, with iodate solution 4-6% and immediate therapeutic compression; but only in the treatment of group C, has been also associated the hemodynamic compression (Safeguard) [5]. The χ^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 Group C. Therefore the hemodynamic compression improves the results of sclerotherapy, performed with the same technique with a sclerosing agent in the same chemical and physical form.

Assessing the comparability of different groups is an issue facing many researchers and evaluators in a variety of settings. However, the application of the Safeguard, removing previously the S/F reflux, standardizes the hemodynamic conditions of all patients. Furthermore the diameter of the saphenous termination was homogeneous in all cases treated with HCS method (Group A mean 9 mm; standard deviation 3,2; median 7.8; mode 6.8; Group B mean 8,9 mm; standard deviation 6,3; median 7; mode 6,8; Group C mean 9,4 mm; standard deviation 3.4; median 7.9; mode 6,8). Both of these conditions (hemodynamic and anatomic) make the three groups statistically comparable.

Comparison between group A and B: same technique and sclerosing agent in same chemical, but in different physical form. The χ^2 test shows not significant difference in recurrences incidence, between the results of sclerotherapy, with liquid Polidocanol and the one with Polidocanol foam (p 0.86; χ^2 0.03; odds ratio 1.11).

Comparison between group A and C: same technique and sclerosing agent in same physical form (liquid), but in different chemical form (detergent versus dehydrating agents). The χ^2 test shows not significant difference in recurrences incidence between the results of sclerotherapy with Polidocanol and the one with iodate solution (p 0.81; χ^2 0,05 odds ratio 0.90).

The Chi-Square Tests for Crosstabulation Tables (contingency tables) has demonstrated (at echodoppler level) not significant difference in recurrences incidence (p: 0.778) between all three groups (A, B and C) simultaneously considered (tab II, III). This analysis confirms the statistical evaluations to point b), and shows a lack of relation between the results of HCS method and different form of sclerosing agents.

Discussion

Hemodynamic Compression significantly reduces the incidence of Clinical and Duplex Recurrences after GSV sclerotherapy with liquid or foam agents. In fact, with Hemodynamic Compression Sclerotherapy, are not detectable the effectiveness differences between different sclerosants, related to Chemical properties (detergent and dehydrating agents) and to Physical properties (liquid and foam agents).

The application of Safeguard® protects:

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

– endothelium of saphenous trunk from "wash out effect" of long reflux [6], prolonging the contact time of sclerosing drug with the endothelium (the liquid form is equivalent in potency to foam, because the increase in this contact time is more important, in efficacy, than intravenous dilution of sclerosing agent);

– saphenous trunk from the long reflux, making it easily compressed by the bandage [7].

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 (the emptying of the venous lumen is easily verified by the interruption of spontaneous bleeding through the needle, not connected to the syringe). 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 [8,9]. 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 [10,11].

For the sclerosis to be effective [12,13], the veno-venous shunt to the varicose veins must be interrupted. Franceschi has demonstrated the importance of this

shunt, in the pathophysiology of varicose veins [14]. 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)[14]. This starting point corresponds at the S/F junction [15], or at the highest perforator (in instances of residual varicose veins after sclerosing of the saphenous territory). In our experience, with sclerosing of perforators [14]. I have noted that such device can be substituted by particular tampoons with hard core (see Materials-section III) [5].

Conclusions

Our method can be used with every technique of sclerosing injections, with every pharmacological agent in liquid or foam form. The liquid sclerosant showed, in this work, an efficacy equivalent to that one in foam form. The Polidocanol 3%, in liquid form, is currently the sclerosant of first choice in our sclerotherapy of the saphenous trunks. HCS (Hemodynamic Compression Sclerotherapy) is therefore far from being a new sclerosing technique and only represents a new strategy.
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.

Riassunto

OBIETTIVO: L'obiettivo del lavoro è stato quello di valutare l'efficacia di una nuova strategia nella scleroterapia dei tronchi safenici.
MATERIALI E METODI: Trecentoquarantacinque arti varicosi, con reflussi lunghi di VGS, sono stati sottoposti a scleroterapia col seguente metodo. Iniezione del tronco safenico di coscia di Polidiconalo in forma liquida al 3% in 85 casi (Gruppo A), di Polidocanolo in forma di schiuma al 2% in 80 casi (Gruppo B) e di soluzione iodata al 4-6% in 180 casi (Gruppo C). Essa è seguita da compressione immediata della vena con tamponi e bendaggio cortoelastico, associata a compressione emodinamica, consistente nell'interruzione del reflusso di crosse, ottenuta con l'applicazione di una medicazione (Safeguard) in corrispondenza della giunzione safeno-femorale, e dotata di palloncino gonfiabile sotto controllo ecografico per controllare l'efficacia nell'interruzione selettiva del reflusso.
RISULTATI: L'adozione di questa strategia (detta HCS Hemodinamic Compression Sclerotherapy) ha ridotto il tasso di recidive delle VGS sclerosate con soluzione iodata. Inoltre alcuna differenza significativa era rilevata nel tasso di recidive fra i tre Gruppi.
CONCLUSIONI: L'applicazione del Safeguard, in corrispondenza della giunzione safeno-femorale, migliora i risultati della scleroterapia, indipendentemente dall'uso di sclerosanti liquidi o in forma di schiuma, grazie all'interruzione del reflusso di crosse nelle vene sottostanti, consentendone così l'efficace compressione da parte del bendaggio ed evitando che il wash out da reflusso destabilizzi il consolidamento della sclerosi.

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