Foam-glue syringe: a novel combined echo-guided endovascular treatment

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Abstract

The "mixed" or "combined" method of treatment aims to use surgery and sclerosis only to the best of their respective aptitudes and at the same time to take advantage of the functional restoration capabilities of the residual varicosities. The aim of combining the two techniques was to allow one technique to partially or totally annul the limitations or defects of the other. Bassi said: "the advantages of the mixed method are numerous, important, and varied". Physiopathological advantages first of all, limiting stripping to the proximal vein tract allows for avoiding unnecessary venous sacrifice, as it has been demonstrated that the distal segment of the internal saphenous vein is not insufficient in the most advanced cases sclerotherapy, for its part, is greatly facilitated by the preliminary suppression of ostial reflux, so that the process of fibrous transformation of the injected varices takes place in the best possible way. In this way, Bassi argued for the necessity of combining surgery and sclerotherapy, limiting the former to the closure of the leakage points or so-called compartment jumps and the latter to the cleaning of the limb of all residual varicosities after the closure of the leakage points. This principle later became the basis of the Conservatrice Hemodynamique de I'Insuffisancie Veineuse en Ambulatoire (CHIVA) method/philosophy wonderfully described by Claude Franceschi that will lead us all to perform our treatments on the guidance of a meticulous hemodynamic examination, and in respect of the venous hemodynamic of the lower limbs.

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Introduction

I would like to begin this introduction by describing what Bassi called the "mixed method". The "mixed" or "combined" method of treatment aims to use surgery and sclerosis only to the best of their respective aptitudes and at the same time to take advantage of the functional restoration capabilities of the residual varicosities. The aim of combining the two techniques was to allow one technique to partially or totally annul the limitations or defects of the other.[1,2]

Bassi said: "the advantages of the mixed method are numerous, important, and varied". Physiopathological advantages first of all, limiting stripping to the proximal vein tract allows for avoiding unnecessary venous sacrifice, as it has been demonstrated that the distal segment of the internal saphenous vein is not insufficient in the most advanced cases sclerotherapy, for its part, is greatly facilitated by the preliminary suppression of ostial reflux, so that the process of fibrous transformation of the injected varices takes place in the best possible way.[1,2] In this way, Bassi argued for the necessity of combining surgery and sclerotherapy, limiting the former to the closure of the leakage points or so-called compartment jumps and the latter to the cleaning of the limb of all residual varicosities after the closure of the leakage points. This principle later became the basis of the Conservatrice Hemodynamique de I'Insuffisancie Veineuse en Ambulatoire (CHIVA) method/philosophy[3] wonderfully described by Claude Franceschi that will lead us all to perform our treatments on the guidance of a meticulous hemodynamic examination, and in respect of the venous hemodynamic of the lower limbs.

Nowadays, the application of the mixed method can be found in the techniques known as MechanOChemical Ablation (MOCA) and the latest Sclero Foam Assisted Laser Treatment (SFALT), which uses the combination of laser and sclerofoam. Based on these premises, we fully agree on the need for conservative hemodynamic phlebological therapy for varicose veins of the lower limbs with the characteristics of: i) invasiveness reduced to a minimum; ii) no use of operating theatres; iii) ultrasound control of the therapeutic act; iv) easy repeatability and correctability; v) perfect compliance with CHIVA hemodynamic standards.

I had the idea of building a device "syringe for successive injection of substances" with which it is possible to replace the series of ligatures proposed by Franceschi with this device, which combines the advantages of sclerofoam and glue with an extremely simple act, without the use of the operating room, without anesthesia, and with a simple act under ultrasound guidance. It is therefore possible to perform all the CHIVA manoeuvres listed above for a haemodynamic conservative therapy of the superficial venous system (interruption of the leakage points and frag-

mentation of the haematic column).[4] The synergy between two well-known and established therapeutic methodologies lies in the symbiosis of the two techniques, one correcting the limitations and errors of the other in an easy and practical outpatient therapeutic procedure. CHIVA is a strategy and not a technique. So, advanced technology may permit to perform CHIVA with more sophisticated and less invasive techniques.[5,6] Let us now list the merits and limitations of each technique performed individually and the advantages of symbiosis (Table 1). The symbiosis between the two procedures only creates advantages because: i) the echogenicity of the foam allows an act as precise and safe as a phlebography; ii) the aspiration of blood into the syringe does not create polymerization of the glue as this is only injected after the foam; iii) the spasm that the foam generates eliminates the need for compression after glue injection; iv) no need for anaesthetist nor operating room.

The above allows us to treat the leakage points, the so-called compartment jumps, and the splitting of the varicose blood column in accordance with the CHIVA rules written by Franceschi with a simple, easy, and ambulatory act.

Materials and Methods

The preparation of the sclerosing foam needs no further explanation, I will, however, summarise some key steps:

Two 5 mL syringes with little or no silicone are used, joined together by a three-way tap with, in my modus operandi, a 2-micron filter in between, which allows the foam to be homogeneous; in the first syringe, 1 mL of drug (3% sodium tetradecyl sulphate or 3% polyethoxydodecane) is sucked in; in the second syringe, 4/5 mL of air or biocompatible gas CO_2+O_2 or air alone is sucked in; about 20 passes are made between one syringe and the other, and the foam is ready to be injected.[7-12]

The cyanacrylate glue is drawn into a second 2 mL syringe. Some glues are very viscous and, therefore, require a needle no smaller than G21 to be injected. Syringes and needles can be pre-washed with glucosate solution, if necessary, for some glues.[13] There is currently an Italian glue composed by N-Butyl 2 Cyanoacrylate (NBCA) monomer plus Methacryloxy-Sulpholane Monomer (MS) that does not need this procedure as it has a density similar to water.[14] After having used the various types of glue offered by the American and Turkish markets (Cases 1-3), with the various limitations that the products had excessive viscosity, delayed polymerization, the need to pre-wash needles and syringes with the glucose solution, I started using an Italian glue (Case 4) NBCA+MS. It is a very fluid product, not need pre-washed with glucosate solution, it is well distributed inside the vessel, polymerizes rapidly in the release zone and therefore can be used in small quantities. Once the foam has been prepared with the 5 mL Foam Glue Syringe, the 2 mL syringe pre-filled with the glue to be used, and its G21 needle, 16 mm short, is inserted into the syringe's perforated plunger (*Supplementary Figure 1, Supplementary Figure 2*).

Under ultrasound guidance, the perforant or the compartment jump to be treated is identified, the chosen foam is injected, and immediately, the spasm is observed with the complete gluing of the vein itself; at this point, the glue syringe is advanced into the foam-glue syringe so that the needle of the 2 mL syringe pierces the rubbery diaphragm of the first syringe. You can then inject the glue at the precise point where you want the closure of the compartment to jump with the certainty that since the vein walls are firmly clamped on themselves for a period of 15/20 minutes, you will have a perfect bonding of the walls themselves without any need for external compression (*Supplementary Figure 3*).

Clinical cases

V. R., male, 65 years old

2008; left internal saphenous vein varicophlebitis, the haemocoagulative genetics check showed hyperhomocysteinemia (MTHFR heterozygosity), in the same year, the left internal saphenous vein was deconnected from the femoral to the saphenous vein, subsequently due to the appearance of scotomas after sclerotherapy with foam, patency of the foramen ovale was diagnosed. On December 17th, 2020, a check-up showed marked incontinence of Boyd's perforant on the left. It is, therefore, decided to proceed with joint foam-glue therapy at the same time (*Supplementary Figure 4*). With the Foam-Glue Syringe, 5 mL of foam Sodium Tetradecyl Sulfate 3% is injected, followed by 0,5 mL of glue (n-BCA-polymer). The patient was monitored for 2 years and half from the start of the foam-glue treatment. The follow-up highlighted the elimination of the reflux in Boyd's perforator (*Supplementary Figure 5*).

F. M. T., female, 65 years old

In 1990, the patient underwent a left internal safenectomy, with multiple varicectomies and ligation of the left gluteal perforant. On December 7th, 2020, during the Echo Color Doppler (ECD) examination, a perforant incontinence of the left thigh of gluteal origin was found, above the scar from a previous ligation (*Supplementary Figure 6*). With the Foam-Glue Syringe, 5 mL of foam Sodium Tetradecyl Sulfate 3% is injected, followed by 0,5 mL of glue (n-BCA-polymer). The patient was monitored for 2 years and half from the start of the foam-glue treatment. The follow-up highlighted the elimination of the reflux in gluteal perforant (*Supplementary Figure 7*).

Table 1. Limits and advantages of glue and foam during the single treatment.

Glue		Foam	
Limits	Advantages	Limits	Advantages
Complex use of the device now in use	Perfect closure of the treated segment	Foam dislocation due to spasm effect	Extreme ease and versatility of use
Immediate polymerization of the glue on contact with the blood	Rapid stabilisation of the treatment	Neutralisation of the effect	High echogenicity, which allows the treatment to be controlled like a phlebography
Need compression to bring the venous walls closer together (difficult for compression of muscle perforant)	Only one treatment for that area		Production of a long and power spasm leading to venous wall collapsing
	No anaesthesia No operating room		No anaesthesia No operating room

F. M. T., female, 65 years old (the same patient of Case 2, but in a different reflux point)

In 1990, the patient underwent a left internal safenectomy, with multiple varicectomies and ligation of the left gluteal perforant. On February 26th, 2021, during the ECD examination, a perforant incontinence of the left thigh of Thiery or perforating popliteal fossa was found (*Supplementary Figure 8*). With the Foam-Glue Syringe, 5 mL of foam Sodium Tetradecyl Sulfate 3% is injected, followed by 0,5 mL of glue (n-BCA-polymer). The patient was monitored for 2 years from the start of the foam-glue treatment. The follow-up highlighted the elimination of the reflux in Thiery's perforant (*Supplementary Figure 9*).

C. R., male, 39 years old

For 2 years, the patient has been reporting that he has a post-trauma varicose vein. The ECD examination reveals a reflux of the atypical postero-lateral perforant of the left thigh (*Supplementary Figure 10*). With the Foam-Glue Syringe, 5 mL of foam Sodium Tetradecyl Sulfate 3% is injected, followed by 0,3 mL of glue (NBCA + MS). The patient was monitored for 2 years from the start of the foam-glue treatment. The follow-up highlighted the elimination of the reflux in the perforant vein (*Supplementary Figure 11*).

Conclusions

We used the novel technique mainly on non-terminal perforators, which are very challenging both by using open surgery and endovascular techniques. Our preliminary results seem to suggest that this novel technique could also be applied to classic GSV, SSV varicose veins, and maybe this could merit a clinical trial. However, it is mandatory to respect the CHIVA indication for the treatment of the SFJ or just of the N2-N3 escape points.[15,16] These first data from clinical cases are encouraging. After more than two years of follow-up, no adverse events and/or allergies were found. The venous symptomatology and the reflux were eliminated with a simple treatment. A new revolution in the field of phlebology was born with this method. The combination of these two methods creates a synergy that allows the phlebologist, under echo guidance, to treat any venous pathology in a simple way and with a precise act and in line with the concept of a hemodynamic conservative phlebology of the superficial venous system.

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Online supplementary material:

Supplementary Figure 1. Foam-Glue Syringe.
Supplementary Figure 2. Foam glue syringe system ready for treatment.
Supplementary Figure 3. Foam glue syringe system echo-guide injection.
Supplementary Figure 4. A) haemodynamic cartography by Echo Color Doppler (ECD). In red, the incontinent perforant vein. B) leg area to be treated. C) reflux of Boyd's perforant vein to the ECD investigation.
Supplementary Figure 5. Follow up case 1. A) no reflux by Echo Color Doppler (ECD) in Boyd's perforant at 1 month. B) at 3 months no reflux. C) check at 6 months, no reflux. D) check at 12 months, no reflux. E) after 30 months, no reflux in Boyd's perforant.
Supplementary Figure 6. A) haemodynamic cartography by Echo Color Doppler (ECD). In red, the incontinent perforant vein. B) leg area to be treated. C) reflux of perforant vein to the ECD investigation.
Supplementary Figure 7. Follow up case 2. A) no reflux by ECD in gluteal perforant at 1 month. B) check at 6 months, no reflux. C) check at 12 months, no reflux. D) After 30 months, no reflux in gluteal perforant.
Supplementary Figure 8. A) haemodynamic cartography by Echo Color Doppler (ECD). In red, the incontinent perforant vein. B) leg area to be treated. C) reflux of perforant vein to the ECD investigation.
Supplementary Figure 9. Follow up case 3. A) no reflux by ECD in gluteal perforant at 1 month. B) check at 6 months, no reflux. C) check at 12 months, no reflux. D) after 24 months, no reflux in Thiery's perforant.
Supplementary Figure 10. A) haemodynamic cartography by Ecocolordoppler (ECD). In red, the incontinent perforant vein. B) leg area to be treated. C) reflux of perforant vein to the ECD investigation.
Supplementary Figure 11. Follow up case 4. A) foam-glue coaxial injection site. Note the hyperechogenicity on B-mode analysis. B) check at 6 months, no reflux. C) check at 12 months, no reflux. D) after 24 months, no reflux in atypical postero-lateral perforant vein.