

ELOQUENCE OF SYMBOLS

Varicose vein surgery in third millennium: only one option or more options?

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In this occasion we touch a taboo: which is the best and safest treatment for chronic venous disease (CVD) with varicose veins (VVs)? Glauco Bassi's "Le varici degli arti inferiori," published 60 years ago, is noteworthy; Raymond Tournay defined it "phlebologist's bible." The text is still today considered of fundamental importance in the field, containing the advances in phlebological knowledge that would be later fully developed.¹ The surgical intervention knowledges from medicine history are very numerous² but Bassi had then considered what should have been preferable on the basis of completely modern hemodynamic conceptions for the time (Figure 1), advising against other techniques that had to be abandoned for various reasons: irrational, relapsing, invasive, unesthetic (analyzing others already completely abandoned). Nowadays, it can be said that the panorama of more options in VVs surgery is even broader, creating a conflict with a hypothetical choice of techniques considered "priorities" by the most recent EBM Criteria (at the basis of restrictive guidelines), often motivated by economic principles (now subjected to significant methodological and substantial criticisms).³ During the 14th great UIP World Congress that was held in Rome in 2001, the opening of the Phlebological Third Millennium (dramatically affected by the news about the terrorist attacks against the Twin Towers in New York), the first clinical experiences with the endovenous thermal ablation (EVTA) of VVs in two technical modalities were presented: the endovenous LASER ablation (EVLA) and the endovenous radiofrequency ablation (RFA). It will be useful here to recall how previous UIP Congresses witnessed the birth of other different options: during the 12nd UIP Congress, that was held in London in 1995, subfascial

endoscopic perforator vein surgery (SEPS) was presented to replace the open techniques and it became instantly popular because of the minimally invasive nature of the procedure, even if then quickly abandoned in favor of other solutions. However, before, during the 10th UIP

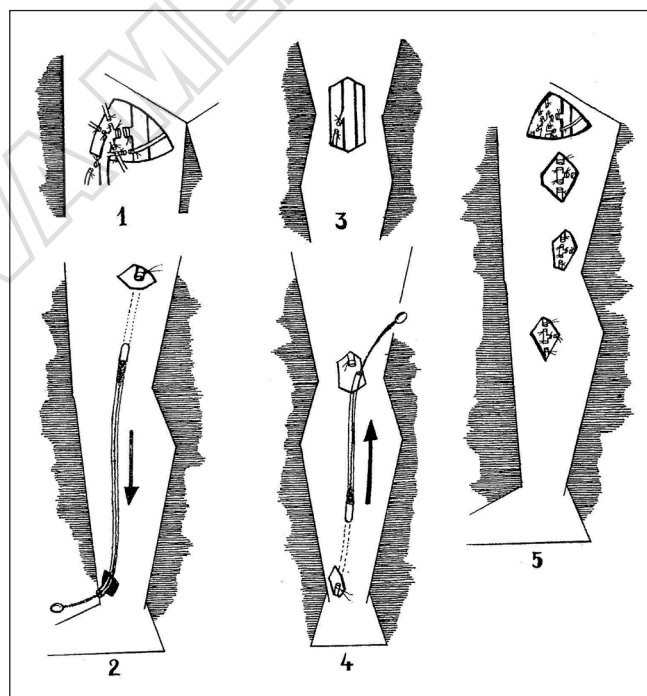


Figure 1.—The original drawing from Bassi's book regarding the substantially unchanged concept on treatment options for patients with symptomatic GSV (2) or SSV (4) incompetence with or without phlebectomies and CVD requiring treatment of incompetent perforating veins, when division or ligation or endovenous ablation should be considered (5).

World Congress of Strasbourg in 1989 one of the most original conceptions on the subject of study and therapeutic perspective of CVD (and not only of unaesthetic VVs disease, after being considered in CEAP Classification one sign and symptom of the CVD) was presented, defined with the French acronym CHIVA, for *cure conservative et hemodynamique de l'insuffisance veineuse en ambulatoire* (conservative and hemodynamic treatment of venous insufficiency in the office). This is a saphenous-sparing therapeutic approach based on hemodynamic concepts proposed by Claude Franceschi in 1988. The rationale behind this hemodynamic approach for the treatment of the disease is that increased transmural pressure (TMP) is responsible for progression of the signs and symptoms of CVD. TMP is elevated in superficial venous disease because of the higher hydrodynamic pressure caused by absence of orthodynamic pressure fractionating and presence of closed shunts. The CHIVA strategy aims to restore near-normal physiological flow with no destruction or ablation of the veins involved, and uses ligatures targeted to interrupt escape points and fractionate hydrostatic pressure. The number and position of these ligatures depend on duplex scan findings and every operation is tailored to each patient's reflux pattern. The great (GSV) and small (SSV) saphenous veins are left in place and are available in the future for bypass surgery and to channel the flow of varicose recurrence, if this occurs. In patients with chronic limb-threatening ischemia who had an adequate single segment of saphenous vein for conduit and were considered to be suitable candidates for both endovascular intervention and surgical bypass, initial bypass surgery was associated with a lower incidence of major adverse limb events or death than initial endovascular intervention.⁴ Now, we know the good results of CHIVA in comparison with old and new techniques, and CHIVA seemed to have superior clinical benefits on long-term efficacy for treating VVs.⁵ It is noteworthy a meta-analysis by Guo *et al.*, arrived from China, emerging nation also in the vascular field. Despite this point of view, in many countries, the surgery of GSV with high ligation and stripping (HLS) remains the most performed. This is the case of Italy, as recorded in the last national guidelines of 2016.⁶ Regarding the more tested EVTAs, they both enjoy a good evaluation, and even today, when compared, they are without any difference. In the treatment of CVD, the role of two EVTA (EVLA 1470-nm with Tulip-Tip™ fiber [Tulip Aesthetic, San Diego, CA, USA] and RFA ClosureFast™ [Medtronic, Dunlin, Ireland]), using a non-inferiority design for occlusion

rate (primary outcome) and postoperative side-effects (secondary outcome) in a single-blind, two-arm parallel RCT, was set up comparing the efficacy of EVLA and RFA. EVLA proved to be non-inferior to RFA ($P=0.15$) and thus at least efficacious when considering GSV occlusion rates at one year follow-up. Treatment of the GSV resulted in equal occlusion rates at one year of follow-up, with comparable side-effect profiles. No between-group differences in quality of life were shown.⁷ Last of endovenous ablation cyanoacrylate closure (CAC) is a minimally invasive surgery to treat incompetent saphenous veins. A study aimed to investigate the incidence, the risk factors for, and the management of thrombus extension after CAC, with the patients received therapeutic rivaroxaban or dabigatran, which resolved the thrombus within 2-4 weeks. No deep vein thrombosis or symptomatic pulmonary embolism was found, even if found not to be a rare complication after CAC. All patients should be informed of the risk of thrombosis prior to treatment.⁸ The role of sclerotherapy in the treatment of CVD of the lower limbs has been revolutionized by the introduction of ultrasound guided foam sclerotherapy (UGFS). Since then, the practice of saphenous UGFS has greatly increased, and in some guidelines is now considered even more appropriate than surgical treatment by stripping.⁹ However, currently available clinical trial evidence suggests that UGFS, EVLA and RFA are at least as effective as surgery in the treatment of GSV VVs. Due to large incompatibilities between trials and different time point measurements for outcomes, in 2014 the evidence was lacking in robustness. Further randomized trials were needed, with the aim to report and analyze results in a congruent manner to facilitate future meta-analysis.¹⁰ In a Cochrane review, six RCTs were included with 1160 participants, with a follow up of 1.5-10 years. Three RCTs compared CHIVA with HLS, two with EVTA (one RFA, one EVLA). The conclusion was that, based on this small number of trials, the CHIVA method may make little or no difference to the recurrence of VVs compared with HLS, RFA, or EVLA. It was acknowledged that results were imprecise because of the small number of events and high risk of bias. To date, no RCTs are available comparing CHIVA with non-thermal non-tumescent techniques.¹¹ Finally, what is new in the European Society for Vascular Surgery 2022 Guidelines, compared with the 2015 guidelines? Compared with this version of the guidelines on the management of CVD, the global structure of the document has been modified considerably to make it more practical and user friendly. A more recent

investigation into the cost effectiveness of interventional treatment for VVs in the UK National Health Service similarly concluded that interventional treatment for VVs is cost effective, with EVTA being the most cost effective for those patients for whom it is suitable.¹² Another review suggested that surgery and the minimally invasive techniques are similar in terms of efficacy or safety, so the relative cost of the treatments becomes one of the deciding factors.¹³ However, the investigators noted that high quality RCT evidence is required. Therefore, it is obvious that the above findings may not be applicable to all patients worldwide, as cost effectiveness largely depends on the local resources and healthcare situation. The correct question that Bassi already asked himself is: “How can I be treated for varicose veins and related superficial venous disease?” For many years, surgical “stripping” of the damaged superficial veins was the classical method to treat VVs and related problems. However, in the last 20 years, newer alternative methods have been developed to close the vein by using local heat or another method that can interact with the vein wall. These advances have been helped by the widespread availability of ultrasound, which is not only used for diagnosis but also to guide superficial venous treatment. The most common heat treatments make use of “EVLA” or “RFA,” where a special fiber is carefully inserted into the vein and, after injection of anesthetic, the fiber is used to heat and close the vein from inside. Most patients recover without any problem and can swiftly resume their normal activities. In recent years, more alternative methods to close the saphenous vein have been developed. These techniques do not use heat and hence no anesthetic needs to be injected to numb the vein. Instead of heat, mechanical and chemical irritation of the vein wall leads to closure of the vein, or the vein is closed with surgical glue. Other techniques, known for many years, have also been optimized. For instance, injection of a diseased vein with a chemical solution, traditionally called sclerotherapy, has been converted into “foam sclerotherapy,” where white foam, made by mixing the sclerosant solution with air, is injected into the vein. Whereas the availability of all these “minimally invasive” treatment methods for VVs may be a real benefit for patients, treatment choice has become very complicated. Therefore, it is important for the treating physician to discuss the pros and cons of different potential treatments with their patient. It should be a shared decision between the patient and the treating physician, to decide which treatment is likely to be the most appropriate for each individual.¹⁴ As VVs are never

exactly the same between one patient and the other, a “patient tailored” treatment approach is needed. Selection of surgical or sclerotherapeutic intervention should be guided by physician skill/experience and patient choice. The vascular physician should master all the possible treatment solutions, and then from case to case apply what he considers the best he can do.

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