Distal outpatients hemodynamic treatment of chronic venous insufficiency of the lower limbs: a new proposal.

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Distal outpatients hemodynamic treatment of chronic venous insufficiency of the lower limbs: a new proposal.

The etiology of the venous insufficiency of the lower limbs is related to the increase of the district pressure. This occurs in case of pressure overload of the afferent compartment with a progressive increase of the gradient until the reversal of the flow direction. Varicose veins would be the effect and not the cause of the pressure overload which must always be researched in the efferent (draining) compartment. The gradient inversion in a compartment causes a reflux circuit (venous shunt) only if - in addition to the escape point - one re-entry point is also active,
The closure of the escape point does not solve the etiological moment of the district pressure overload. It is therefore a symptomatic treatment that cannot reduce the potential of the system to cause recurrences. During walking, reflux will cause Transmural Pressure Peaks (PPT): in diastole if the reflux is systolic; in systole if the reflux is diastolic; in diastole and in systole if the reflux is diastolic-systolic. On this basis, it has been proposed CHIVA 2 distal outpatient treatment without CHIVA 1 with interesting haemodynamic effects. In the subcutaneous area by the pressure overload block it improves compartment drainage, reduces the peak of trans-mural pressure and the caliber of the varicose veins. In the intrafascial district: reduces peak and trans-mural walking pressure; does not change the drainage of the reflux; can restore an antegrade flow.

KEY WORDS: Hemodyamic venous treatment, Vricose veins, Venous Hemodynamic Map (VHM)

Background

Modern phlebology would have been born at the end of the eighties, following some brilliant intuitions of french hemodynamist, Claude Franceschi (Calenzana, Haute Corse, 1942).
With the advent of the Echo-Doppler - and later, of the Echo-color-Doppler - it has been possible to study the ultrasound anatomy and the hemodynamics of the venous system.
Starting from this new knowledge Claude Franceschi, in 1988, proposed the CHIVA, acronym for "*Cure Hémodynamique de l'Insuffisance Veineuse en Ambulatoire*" (Hemodynamic Treatment of Venous Insufficiency in Outpatient): a type of intervention whose main objective is to preserve the "*patrimoine veineux*", the main outflow veins of the lower limbs.
The technique presupposes an accurate Eco-color-Doppler study of the venous system of the lower limbs with the creation of an anatomical-functional cartography: the Venous Hemodynamic Map (VHM) whose information can allow transforming an ablative therapeutic procedure into a hemodynamic correction [1].
In this way it is possible to "repair" the veins, since we know how they work.
In those years there was emphatic talk of the "*Révolution Française*" for the treatment of varicose veins: in reality, the turning point was in the conservative hemodynamic therapeutic approach but, above all, in the diagnostic approach. This was absolutely innovative, since before then, no one had represented - on a paper scheme - both anatomy and hemodynamics of the veins.

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The venous hemodynamic study with ultrasound has now become the "gold standard" of diagnostics in Phlebology and can be considered the basis - not only of the CHIVA treatment - but of every therapeutic strategy.
Some "grade A" papers compare stripping with CHIVA, demonstrating the superiority of conservative hemodynamic treatment (refer). Since there are no other prospective randomized trials, no one is scientifically authorized to argue otherwise [2].
Any specialist who proposes ablative therapy (stripping, phlebectomies) or occlusive (laser, radiofrequency, sclero-mousse) should be required to explain the patient that there is an alternative possibility to "save" the venous heritage.
Saving a saphenous vein for residual venous drainage and (when possible) for any future by-passes, may be an appropriate choice. The results of this type of surgery would be even better - at the moment - than many ablative or occlusive treatments.
In 1992, vicarious flows from obstructed functional discharge of the lower limbs were described. They have been given the name "activations". These could be an indicator of surgical risk, thus enriching the cognitive heritage of Venous Hemodynamics [2].
In 2001 and 2003 the manuals of "Anatomic and Hemodynamic Terminology in Phlebology" and "The Venous Hemodynamic Map (MEV)" were published, laying the foundations of a new language (terminology, scheme and symbolism) and creating a consultation tool for the processing of the MEV. For the first time, the Phlebologist has an exclusive cultural heritage.
The types of reflux are then determined, which, like the vicarious flows, will condition the phlebological therapeutic indications.
In 2001 the School of Hemodynamic Phlebology was born, focused on the enhancement of the Venous Hemodynamic Map (VHM). The school is activated in the form of a high specialization course, at the Department of Cardio-Vascular and Respiratory Sciences (Prof. Francesco Fedele, University 'La Sapienza' of Rome).
The point of arrival of this first phase can be considered the "Consensus Conference" on hemodynamics organized on the occasion of the world phlebology congress in Rio de Janeiro (October 2005) in which - in addition to the coding of some hemodynamic terms - the venous hemodynamics as an essential cultural heritage for any doctor who wants to deal with venous pathology.
In 2008, the Phlebology Study Group of the Italian Society of Cardiology (SIC) promoted the first basic course in teleconference with other universities on hemodynamic phlebology in Cardiology.
Since ancient times, the figure of the phlebologist has always been very indeterminate, and this is evident from the extremely heterogeneous composition of the numerous phlebology societies, where angiologists, dermatologists, general and vascular surgeons, general practitioner, radiologists, cardiologists and sclerotherapists have always been represented.
Another paradoxical aspect is that - for a non-specialist branch and therefore not recognized from academic and healthcare institutions - there are a particularly large number of societies, associations and scientific groups.
How is it possible to become a phlebologist from all these specialists, coming from such different branches of Medicine?
The answer is (as the history of medicine teaches us) a branch becomes specialist when it possesses an absolutely exclusive and unique body of knowledge. For example, the cardiologist was "*ab initio*" differentiated from the internist by his ability to perform and interpret an electrocardiogram.
Finally a new era begins for Phlebology: a specialist can be called phlebologist if he is able to create and interpret a Venous Hemodynamic Map (VHM). This definition allows the entry of various medical specialist in the field of Phlebology and therefore we will have the phlebo-cardiologist, the phlebo-dermatologist, the phlebo-angiologist, the phlebo-vascular surgeon, the plebo-cardio-surgeon, the phlebo-general surgeon ... all sharing a common basic knowledge that is: venous hemodynamics.
The VHM represents today the indispensable prerequisite characterizing the activity of the phlebologist: it allows him to master (with the specificity that belongs to him) the choice of any therapeutic strategy, be it surgical, pharmacological or physical [3,4].

Distal outpatient hemodynamic treatments (DOHT)

Hemodynamic principles of the method

Any movement of blood - in whatever direction it occurs - is conditioned by the development of a gradient.
The gradient is a heritage of forces and is an expression of the energy of the system. Energy, from a physical point of view, cannot be measured: in fact there is no unit of measurement for energy. There is a unit of measurement for work, i.e. the ability to do a job.
From a physical point of view, energy is the ability to do work and the unit of measurement of work indirectly gives the unit of measurement of energy. Energy is an entity that indicates any kind of force.
Force is the only cause or action capable of varying the speed of displacement of a mass (m).
Forces are applied in straight lines or vectors.
Resistance is any cause capable of reducing the speed of movement of a mass or of opposing this speed.
Pressure is a force applied to a surface. Pressure manifests itself in different ways according to the types of application and transmission of forces.

In liquids and gases the type of transmission is different from that of solids. The force is exerted in every point of the volume with the same value. Pressure is the force applied per unit of volume and is equal to the sum of the forces aligned on the same vertical (height h) regardless of the mass. In practice, two tubes filled with liquid, of the same height h, but of different sections, have a different weight but the same pressure.
All points in a liquid that are at the same height (level) experience the same pressure per unit area. This pressure increases proportionally with the height of the liquid which divides these points from the surface. We call hydrostatic pressure (Phs) the pressures that depend on the force of gravity and static pressure (Ps) those pressures that, in motionless liquids, depend on forces other than gravity.
The blood flow does not depend directly on the pressures, but on the results of the applied forces. Pressures are only one way of expressing the applied forces. In the form of kinetic energy it is expressed in work, i.e. the force multiplied by the displacement.
Potential energy is defined when it indicates the work that would result from it, if the forces present were released. According to the law of conservation of energy: energy is never lost, but is transformed, while retaining its value. These premises of fluid dynamics applied to the venous system lead us to consider the following expressions of physics which are the starting points in the elaboration of distal outpatient hemodynamic treatments (Figs. 1, 2).

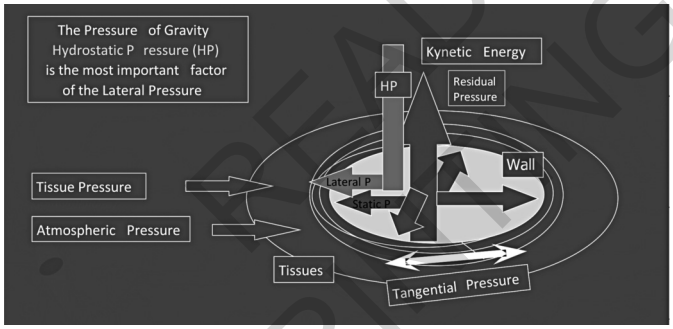

Fig. 1: Pressures which cause the venous insufficiency.

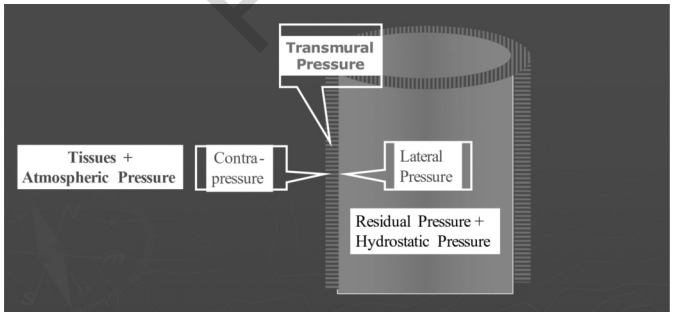

Fig. 2: Pressures involved in Transmural Pressure.

In the case of continent valves, the hydrostatic pressure is fractionated by the closure of these due to the variations in the pressure gradient along the venous axis during the phases of walking (Fig. 3).
In the case of valvular incontinence and reflux of the venous axis, the hydrostatic pressure is interrupted by the annulment of the pressure gradient at the level of the perforators returning to the venous shunt during the phases of walking [1].
The *Transmural Pressure Peaks* (PPT) are the main cause of the dilation of varicose veins as a contributing cause we will have the turbulence caused, during walking, by the increase of the flow velocity (Reynolds number) which occurs on the sections of the vessel that are effluent or with a vicarious circulation [2,4] (Fig. 4).
During walking there will therefore be Transmural Pressure Peaks (PPT):
– in diastole if the reflux is systolic
– in systole if the reflux is diastolic
– in diastole and in systole if the reflux is systolic-diastolic (Figs. 5, 6).
There are four compartments of the venous system of the lower limbs (Fig. 7):
– Cutaneous
– Subcutaneous
– Intrafascial
– Subfascial

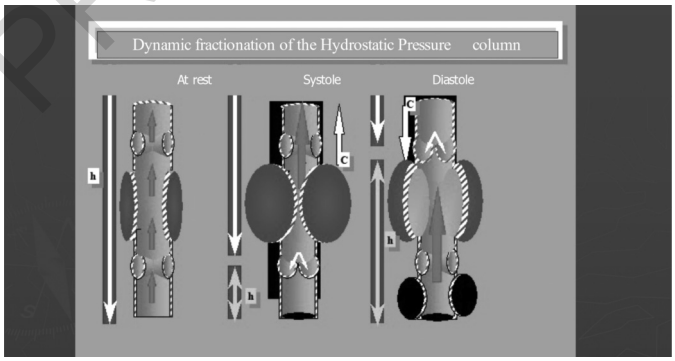

Fig. 3: Effect of continent valves on the hydrostatic pressure during the phases of walking (from C. Franceschi).

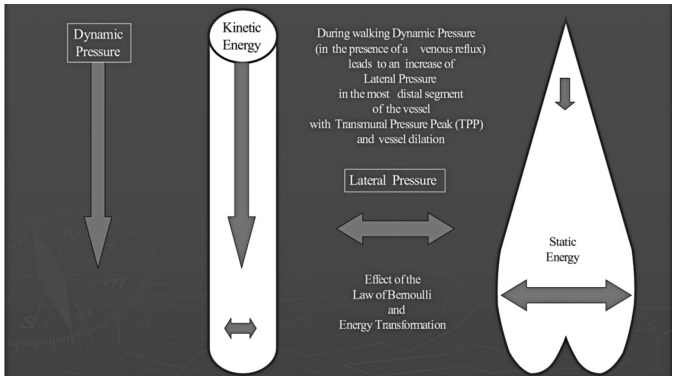

Fig. 4: The effect of Transmural Pressure Peak on vein wall.

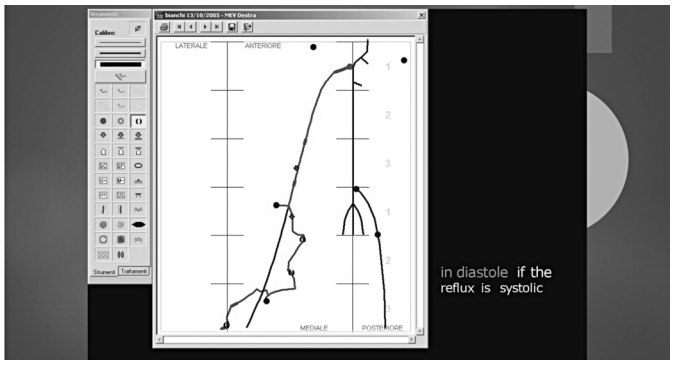

Fig. 5: Effect of Diastolic walking fase on Transmural Pressure Peak.

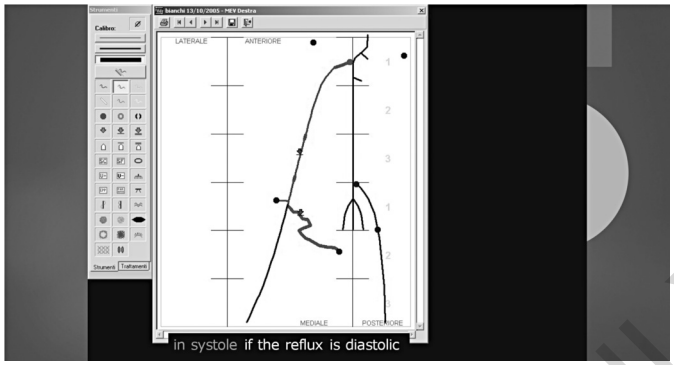

Fig. 6: Effect of Systolic walking fase on Transmural Pressure Peak.

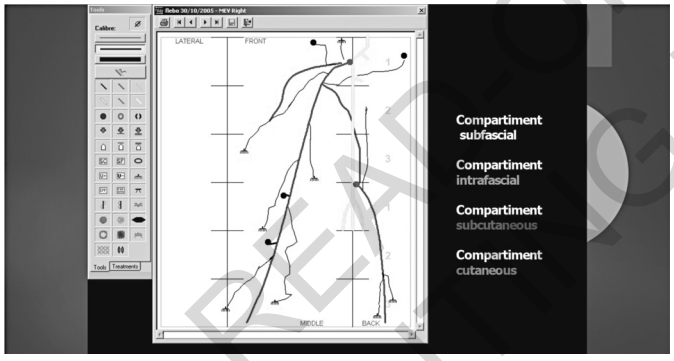

Fig. 7: Venous compartiments.

Usually the cutaneous compartment is afferent to the subcutaneous one which afferent in the intrafascial and the latter in the subfascial. The skin compartment can grasp (drain) directly into the subfascial etc. The venous system of the lower limbs is divided into:
– Superficial system (cutaneous, subcutaneous and intrafascial compartments);
– Connection system (perforant vein system);
– Deep system (subfascial compartment).
In 1992, we hypothesize that the etiology of venous insufficiency was an increase in the district pressure of a compartment with inversion of the gradient and pressure overload of the afferent compartment [4].
On the basis of this hypothesis, varicose veins are the

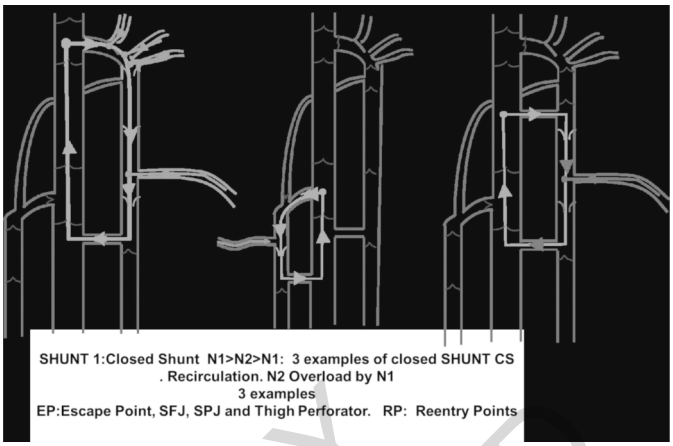

Fig. 8: Venous shunts (from C. Franceschi).

effect and not the cause of this pressure overload which must always be sought in the efferent (draining) compartment.
The inversion of the compartment gradient determines the creation of a reflux circuit (venous shunt) only if, in addition to the escape point, a return point is also active, with the development of a pressure and flow overload in the circuit itself (Fig. 8).
In the CVI of the lower limbs there are frequently several interconnected wastewater circuits both in the same compartment and between different compartments (Fig 9).
Interruption of the circuit at any point stops the gradient and the pressure overload and improves compartment drainage.
Reflux is when the blood comes back to the starting point bi-directional flow (instrumental Doppler report).
We can have two types:
Direct reflux: when the blood comes back to the starting point through the same axis.
Indirect reflux: when the blood comes back to the starting point (closed shunt) through an other way. In 1996 we identified three types of reflux: systolic, diastolic and systolic-diastolic.
The EPP Test is done by raising the patient into the tip of just one foot (Tip Toe Test) the operator analyses the variations in the flow speed that take place during elevation and the return to the starting position, of the subject, in the distal third of the thigh of the Great Saphenous Vein (GSV) (Fig. 9).
The EPP test allowed us to classify the reflux in three hemodynamic Types:
– systolic;
– diastolic;
– systo-diastolic.
Only with dynamic maneuvers it is possible to differentiate the types of reflux (Fig. 10). Our results: the diastolic reflux is correlated to less serious clinical cases (CEAP, C2/C3); the systolic, and the systo-diastolic reflux are correlated to more serious clinical cases (CEAP, C3/C4/C5).

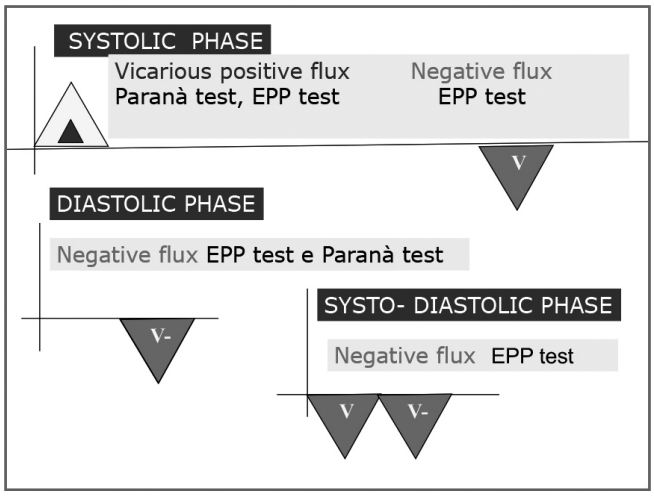

Fig. 9: The Doppler systolic, diastolic and systo-diastolic reflux.

Diastolic reflux can be assimilated to the historical brief saphenous reflux, while systolic and systodiastolic reflux to the long one, which are notoriously linked to different conditions of clinical severity, as we have also noted.

The closure of the escape point

1. does not resolve the etiological moment of the district pressure overload;
2. the district hypertension of the deep compartment remains active and leads to recurrences in a more or less short time depending on the degree of pressure in force at that point;
3. the incidence of such recurrences ranges from 20 to 80% according to average statistics in the literature [5,7,12];
4. The interruption of the leak point, which determines the hypertension of the intrafascial reflux circuit (saphene, etc.), has proved to be ineffective [5,6], in fact the results of such a strategy, implemented in the last 100 years, demonstrate the entity of the recurrences and this due to the impossibility:
- of a correct diagnosis of the cause of district hypertension of the deep subfascial compartment;
- of its elimination.

Distal outpatient hemodynamic surgery

Fundamental and indispensable cornerstone of classic varicose vein surgery (still today, after more than one hundred years of operations) is that the internal saphenous vein at the cross is tied flush to the femoral vein, after having interrupted all the accessory veins flowing into it and that it is removed (Safenectomy or Stripping of the saphenous vein).
This has become an axiom, to the point that when the outpatient hemodynamic Conservative Treatment of Varices CHIVA (1) was proposed in 1988, there was a violent reaction of rejection by the whole surgical world just because it was proposed to leave *in situ* and not remove the saphenous although, with this method, it was in practice correctly tied close to the femoral.
Now that, like never before, the new methods of endovenous treatment Laser EVLT or with Radio frequency RF, Sclero mousse impose, for obvious technical reasons, that the saphenous cross is left open; Those same people who were previously indignant if the cross hadn't been closed with the hamstring level, today, not only are they no longer indignant, on the contrary they argue that such a procedure is correct, on a haemodynamic level? We have already forgotten what can be considered an equivalent experimental model from the fifties?
When was an identical method on the hemodynamic level used in a very widespread way and had disastrous results in terms of recurrences?
We are referring to the low ligation of the internal saphenous vein (Trendelenburg surgery) which gave work for the following fifty years to vascular surgeons, who had to close the crosses left open [23].
The premises for being able to make therapeutic choices in the presence of a condition of varicosity of the lower limbs today are increasingly based on the knowledge of venous hemodynamics and on the accurate study of the venous system in static and orthodynamic conditions.
From the most recent studies of venous hemodynamics in about 10/45% the points of reflux, in the CVI course of the lower limbs, are extra saphenous [17]; and recurrences after conservative and ablative therapy are respectively about 18 and 35% [7], this means that it is indispensable:
1. perform a correct VHM of the lower limbs, before deciding on any surgical, endovenous laser or sclerotherapy treatment strategy;
2. reconsider on the level of current hemodynamic knowledge, of modern Phlebology, the surgical techniques that have been adopted up to now given the high incidence of recurrences reported in the literature from 20 to 80% [5-7,12].
3. Promote new therapeutic methods which, even if not free from post-operative relapses, are at least:
– at low surgical risk;
– with low anesthetic risk;
– at low risk of major complications;
– with equal (if not) minor risk of recurrences;
– with only distal recurrences, therefore easily reoperable with the same minimally invasive technique [13,16]. For almost 10 years, therefore, a hemodynamic approach has begun to be followed, taking into account the specificities of the case and the failures of a stubbornly aggressive treatment at the proximal level of IVC of the lower limbs [16,18]. Therefore, DOHT was born.
Below the description of its principles and application techniques.

General principles for a DOHT

1. Blockage of the reflux circuit of the subcutaneous compartment (accessories, branches R3 or R4 of the Franceschi's classification) at the points of confluence in the intrafascial system (saphenous, Giacomini's vein, accessory anterior saphenous of the thigh).
2. Non-closure of the reflux circuit of the intrafascial compartment at the points of confluence in the deep circle.

Hemodynamic principles of DOHT

1. Preservation of the superficial intrafascial venous axes;
2. Preservation of saphenous crosses and proximal escape points;
3. Fractionation of the hydrostatic pressure column;
4. Deconnection of distal venous shunts;
5. Transformation of a systolic reflux into diastolic;
6. Transformation of a diastolic reflux into a reflux with re-entry on saphenous perforant;
7. Compliance with drainage piercing units;
8. Respect for vicarious circles (activations);
9. Implementation of a stable drainage system.

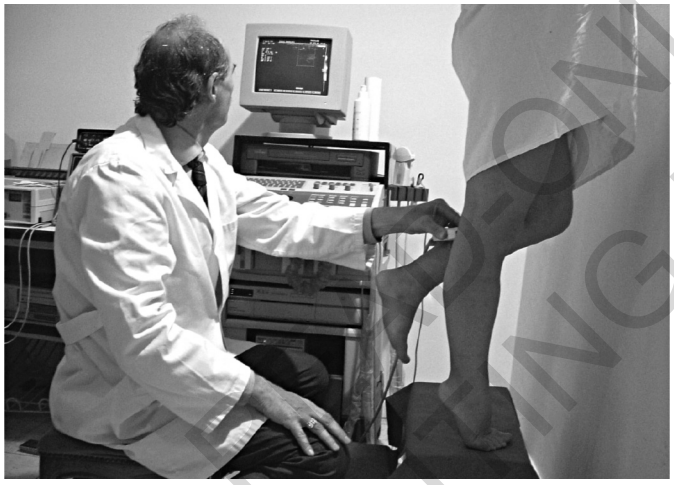

Fig. 10: The ultrasound assessment during EPP test.

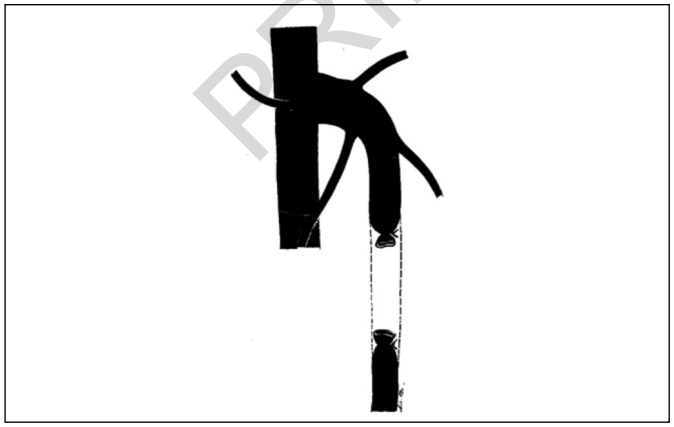

Fig. 11: Trendelenburg intervention.

Techniques that can be used for the execution of a DOHT.

1. Minimally-Invasive surgery, according to Muller [13];
2. EndoVenous Laser Treatment (EVLT) [16];
3. Hemodinamic Treatment with RadioFrequencies;
4. Hemodynamic treatment with sclerotherapy.

Hemodynamic Effects of DOHT

In the *subcutaneous district*:
– blocks pressure overload;
– improves compartmental drainage;
– reduces trans-mural peak and pressure;
– reduces the size of varicose veins.

In the *intrafascial district*:
– reduces trans-mural peak and pressure;
– does not vary the drainage of the reflux circuit, if present;
– can restore an anterograde flow (Fig. 11).
In 45% of DOHT cases the saphenous valve (immediately upstream of the interruption) can become incontinent and allow good drainage of the internal saphenous at three years up to 92% of cases [8] (Fig. 12).

DOHT restores a continence of the refluxing saphenous axis in 42% of cases [11,12] and creates the same hemodynamic conditions as EVLT without destroying the internal saphenous vein and with less risk of thrombosis and further complications.
At 3 years, only 8% of saphenous trunks remain continent [8]. In case of DOHT it is possible to have the appearance at one year of a neo-vein (visible in 5% of cases and not visible in 10%) that recreate the previous hemodynamic situation (Fig. 13).

At 3 years, about 30% distal relapses are reported [8].
The method proposed in summary consists of:

–in blocking the escape points, from saphenous or intrafascial branches, in subcutaneous accessory branches, visible or not;
– in blocking the escape points that flow directly from the deep system into subcutaneous branches;
– in compliance with drainage perforations;
– in respect of vicarious circles (activations).

Hemodynamic aim.

The main purpose is to block venous hypertension at a more proximal level (mid-proximal of the leg or higher, at the level of the thigh) to preserve the skin area of the distal third of the leg which is the one most at risk of major dermo-hypodermic complications of CVI (Fig. 13).

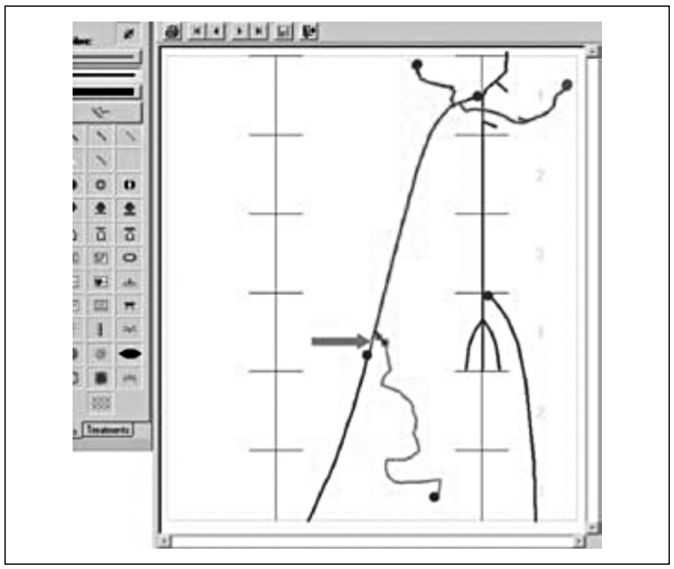

Fig. 12: Drainage in distal perforator after deconnection.

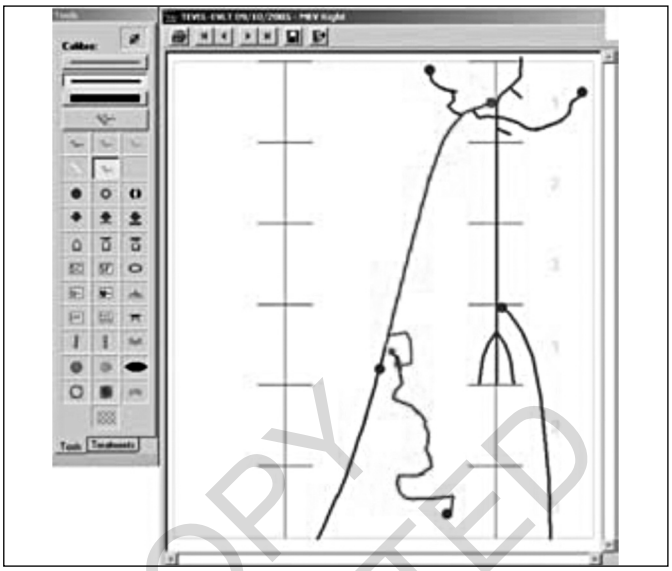

Fig. 13: Recourrence after deconnection.

Final considerations

There are excellent clinical results both for reduction of up to 75% of the volume of the accessories both for the segmental removal of the same if too superficial, voluminous or if too visible in the presence of scarce subcutaneous.
The trophic condition of the skin, dermal and hypodermic of distal leg improves considerably. The blockade of venous hypertension at a more proximal level prevents the evolution of the process and therefore of its clinical side effects. Currently the case history is still insufficient, as well as few years follow up.
However, the short-term results are satisfactory: both clinical and hemodynamic. In a few years, with a more important series, it will be possible to establish whether this hemodynamic treatment can become of first choice at least in selected patients.

Riassunto

Nel caso di eccessivo aumento pressorio del compartimento drenante profondo si ha l'inversione della direzione del flusso in quello superficiale. Per cui le vene varicose sarebbero l'effetto e non la causa di questo sovraccarico pressorio. L'inversione del gradiente pressorio in un compartimento provoca un circuito di reflusso (shunt venoso) solo se oltre al punto di fuga è attivo anche un punto di rientro. La chiusura del punto di fuga non risolve il momento eziologico del sovraccarico pressorio distrettuale. È quindi un trattamento sintomatico che non può ridurre il potenziale del sistema di causare recidive. Esistono tre tipi di reflusso: sistolico, diastolico e sistolico-diastolico. Su questa base è stato proposto il trattamento ambulatoriale emodinamico distale CHIVA 2 senza CHIVA 1 per trasformare i reflussi sistolici e sisto-diastolici in reflussi diastolici con l'obiettivo trasformare dei reflussi lunghi in brevi per prevenire le lesioni cutanee

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