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Reflux Elimination Without any Ablation or Disconnection of the Saphenous Vein. A Haemodynamic Model for Venous Surgery†

P. Zamboni*, C. Cisno, F. Marchetti, D. Quaglio, P. Mazza and A. Liboni

Department of Surgery and Vascular Laboratory, University of Ferrara, Italy

Objectives: *to investigate the possibility of the haemodynamic suppression of reflux in the greater saphenous vein (GSV) without any high ligation and/or stripping procedure.*
Design: *prospective study; single group of patients.*
Materials: *forty patients affected by primary chronic venous insufficiency of all clinical classes, with demonstrated duplex incompetence both of the sapheno–femoral junction (SFJ) and the GSV trunk, with the re-entry perforator located on a GSV tributary. The re-entry point was defined as the perforator, whose finger compression of the superficial vein above its opening eliminates reflux in the GSV.*
Methods: *air–plethysmographic parameters as well as duplex scanning were performed both preoperatively, and one, and six months later, respectively. Operation consisted in flush ligation and division from the GSV of the tributary containing the re-entry perforating vein.*
Results: *duplex investigation demonstrated both a forward flow and reflux disappearance in the GSV in 100% and 85% of the cases after 1 and 6 months, respectively. All air–plethysmographic parameters, with the exception of Ejection Fraction, improved significantly: Venous Volume changed from 150 ml $\pm$ 9 to 114 ml $\pm$ 7 ($p<0.0001$), Venous Filling Index from 4.9 ml/s 0.5 to 2.3 $\pm$ 0.2 ($p<0.0001$), and Residual Volume Fraction from 42 ml $\pm$ 3 to 30 $\pm$ 2 ($p<0.0001$).*
Conclusions: *this study demonstrates that reflux in the GSV system is supported by a gradient of pressure between the anatomical point of reflux and the point of re-entry in the deep veins. Disconnection of the flow to the re-entry perforator without high ligation of the sapheno–femoral junction suppresses GSV reflux.*

Key Words: Duplex scanning; Reflux; Venous haemodynamics; Saphenous vein; Venous insufficiency; Varicose veins surgery.

Introduction

Reflux is the main haemodynamic change detectable by means of ultrasound in venous segments of patients affected by primary chronic venous insufficiency (CVI). Standards define it as a retrograde flow longer than 0.5 s detected, at the release of manual or pneumatic cuff calf compression, in a venous segment by means of duplex in the standing and/or in the reverse Trendelenburg posture (Fig. 1 left). Reflux can be elicited also under Valsalva manoeuvre. Such a haemodynamic change is widely considered to be due to valve incompetence.[1–3]

We suppose that reflux is also determined by a gradient of pressure after exercise between the point of reflux and the point of re-entry in the deep veins through a perforator. In fact, during muscular systole the valves are open and the blood flows forward (Fig. 2a). When muscular relaxation occurs, the valves are closed in the competent deep venous system, creating a fragmentation of the hydrostatic column, whereas in the superficial system the valves are incompetent (Fig. 2b). The phenomenon determines hydrostatic columns of different heights between the superficial and the deep veins, leading to a gradient of pressure that promotes reflux (Fig. 2c).

Elimination of such gradient suppresses reflux. This can be easily observed by the means of duplex scanning in each vascular laboratory (Fig. 1 right).[4]

In support of this observation, previous reports describe the possibility of reflux elimination as an haemodynamic consequence of surgical procedure performed in other venous segments, without any direct action on the insufficient venous segment.[4–6] Based on these findings, we carried out a study in order to investigate both the clinical and the haemodynamic consequences of the surgical elimination of the gradient, obtainable by flush ligation and division from

* Please address all correspondence to: P. Zamboni, Department of Surgery, University of Ferrara, 44100 Ferrara (Italy).
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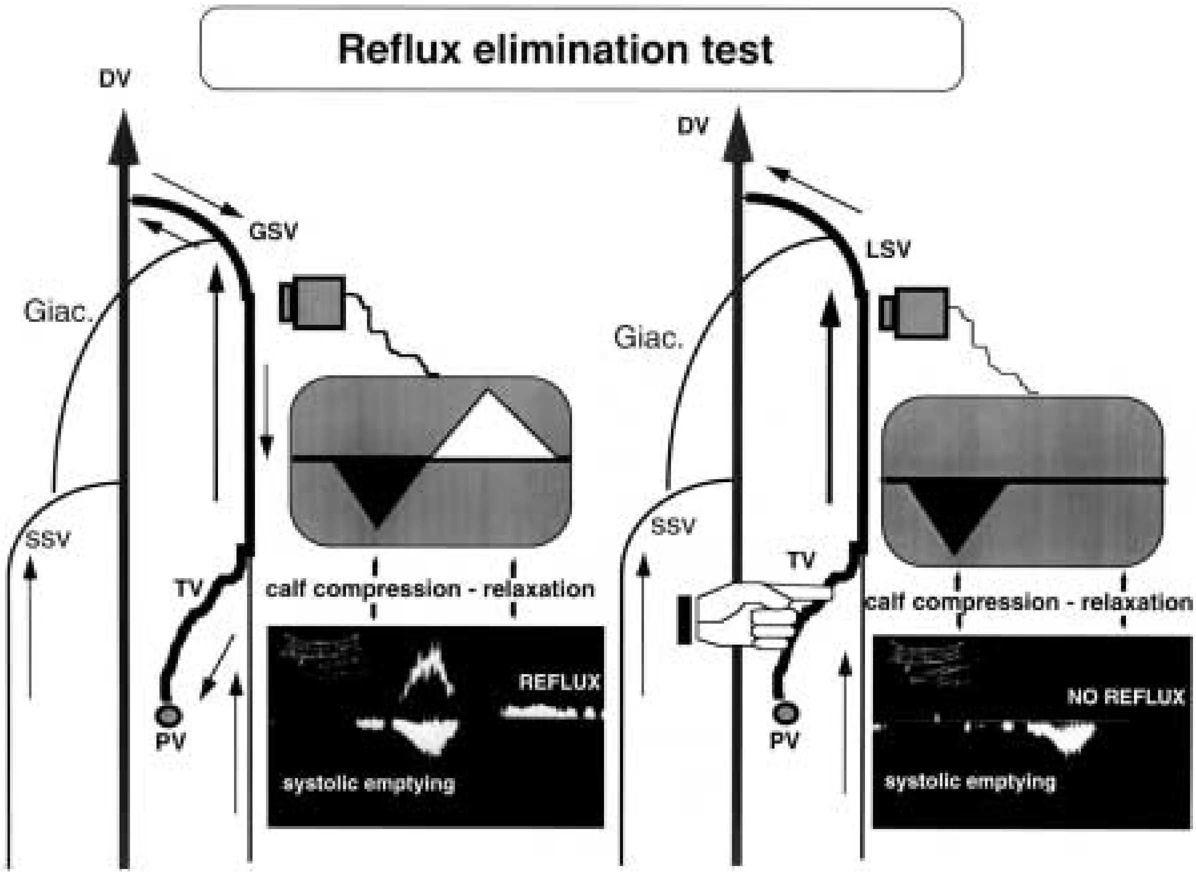


Fig. 1. Left: The Doppler signal in the case of a typical GSV insufficiency – is characterised by a biphasic waveform: the first negative wave, activated in the standing position by squeezing the calf muscle pump, illustrates the forward drainage of the saphenous system during muscular systole; the second positive wave illustrates retrograde flow inside the saphenous trunk in muscular diastole. Right: When the re-entry perforating vein of an incompetent greater saphenous vein is located on a superficial tributary, finger compression above the opening of the perforator determines the disappearance of the reflux signal in the saphenous vein. Legend: DV: deep venous system; GSV: greater saphenous vein; TV: superficial tributary; PV: re-entry perforating vein; Giac.: Giacomini vein; SSV: short saphenous vein.

the greater saphenous vein (GSV) of the tributary containing the re-entry perforating vein.

Materials and Methods

Patient selection

Seventy-five limbs in 57 consecutive patients (37 female, 20 male, mean age 56 years) who were referred to our vascular laboratory for CVI due to primary venous incompetence had their diagnosis confirmed by clinical and duplex scanning examination. We selected 40 limbs in 40 patients (26 female, 14 male mean age 52 years) with demonstrated duplex incompetence both of the sapheno–femoral junction (SFJ) and the main GSV trunk with one or more re-entry perforators located on tributary veins.[4,7] In addition, they satisfied the condition, at duplex investigation, of a patent and competent deep venous system as well as of a competent short saphenous vein.

Methods for duplex scanning

Patients underwent duplex examination (Ansaldo AU 5 Harmonic, 7.5–10 MHz probe, Genoa, Italy) in the standing position with the following procedure.

The ultrasonographic image of the so-called "saphenous eye", clearly demonstrable in the transverse duplex access of the internal surface of both the thigh and leg, was used for identification of the GSV.[4,8–11] The image is due to the duplication of the superficial fascia around the black circle of the saphenous vein and allows recognition and differentiation of such vessel from other superficial veins with the same anatomic distribution.

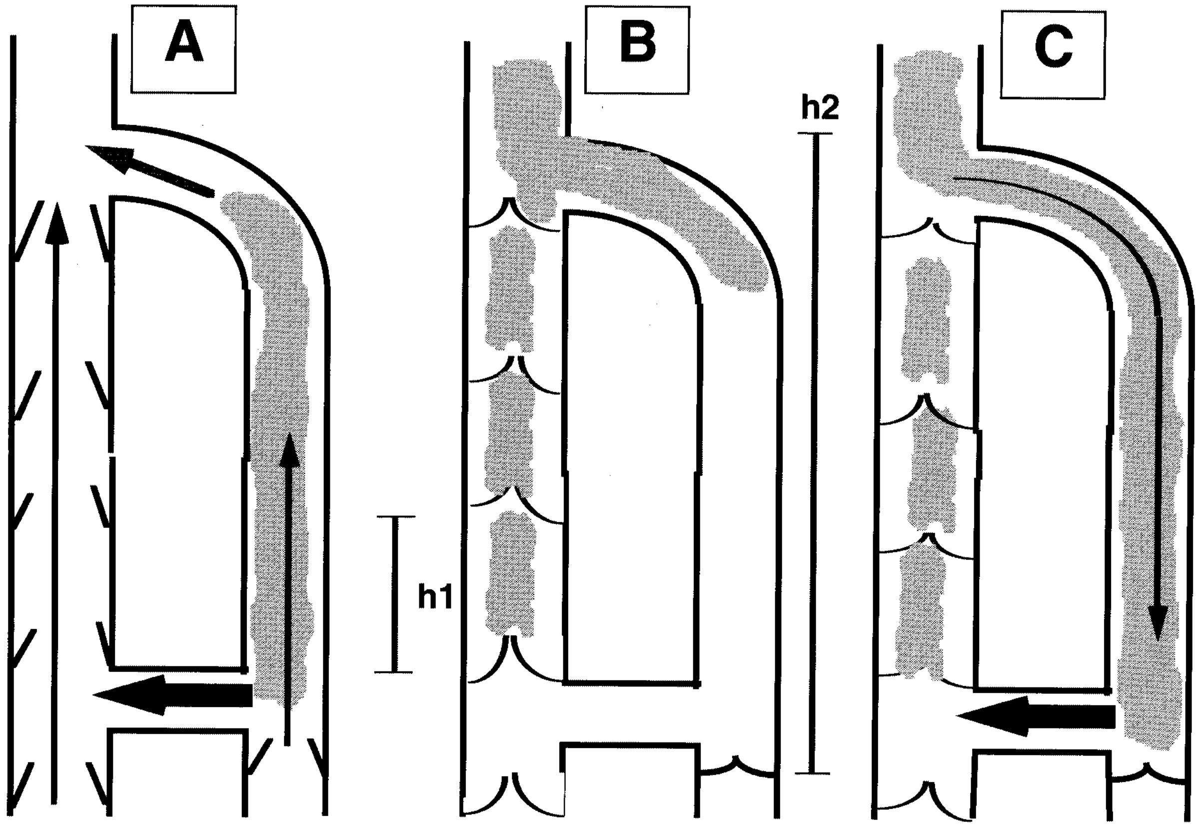


Fig. 2. During muscular contraction, A, valves are open and a forward flow is detectable. B, when muscular relaxation occurs valves are closed in the competent deep system permitting a fragmentation of the hydrostatic column, whereas in the superficial veins valves incompetence determines the formation of a higher hydrostatic column. C, hydrostatic columns of different heights creates the necessary gradient for the development of reflux.

Doppler sample volume was placed at an angle of 45° at the sapheno–femoral junction. Since the majority of the insufficient varicose veins are in turn collateral branches of a tributary of the main saphenous trunk. Doppler sample volume was also placed at different levels along the GSV, and at the origin of every ultrasonic visible tributary of the GSV. Reflux was detected as a reverse flow for longer than 0.5 s after manual squeezing. In addition, we detected the position of each ultrasonic visible perforating vein with the opening either on the main saphenous vein trunk or on an insufficient tributary; we tested the modification of the reflux signal on the saphenous vein after finger compression of the superficial vein above the opening of the perforator. When such manoeuvre of exclusion of the perforating vein abolished and/or reduced the reflux signal in GSV we considered such perforator the re-entry perforating vein or one of the re-entry perforating veins, respectively (Fig. 2).[4] In contrast, patients in which we documented the persistence of reflux under the manoeuvre of finger occlusion were excluded from the study. Figure 3 shows in detail the haemodynamic models found out in our patient population and their relative distribution.

CEAP classification

The selected patients were also classified in accord with the CEAP classification criteria.[3,12] The clinical class, C, ranged from C2 to C6 (25 with simple varicose veins (C2), 7 with oedema (C3), 4 with lipodermatosclerosis and/or other skin changes (C4), 2 with healed (C5) and 2 with active ulcer (C6), size 2 × 1.7 cm and 3.1 × 1.2 cm, respectively; all the selected patients presented with classic symptoms of CVI, of different severity. The aetiology was, obviously, primary. The anatomical distribution of cases was in the GSV above the knee in 6 cases, above and below the knee in 34 cases, in other superficial veins in 40 cases, perforators were found to be incompetent at the thigh in 6 cases and at the leg in 36.

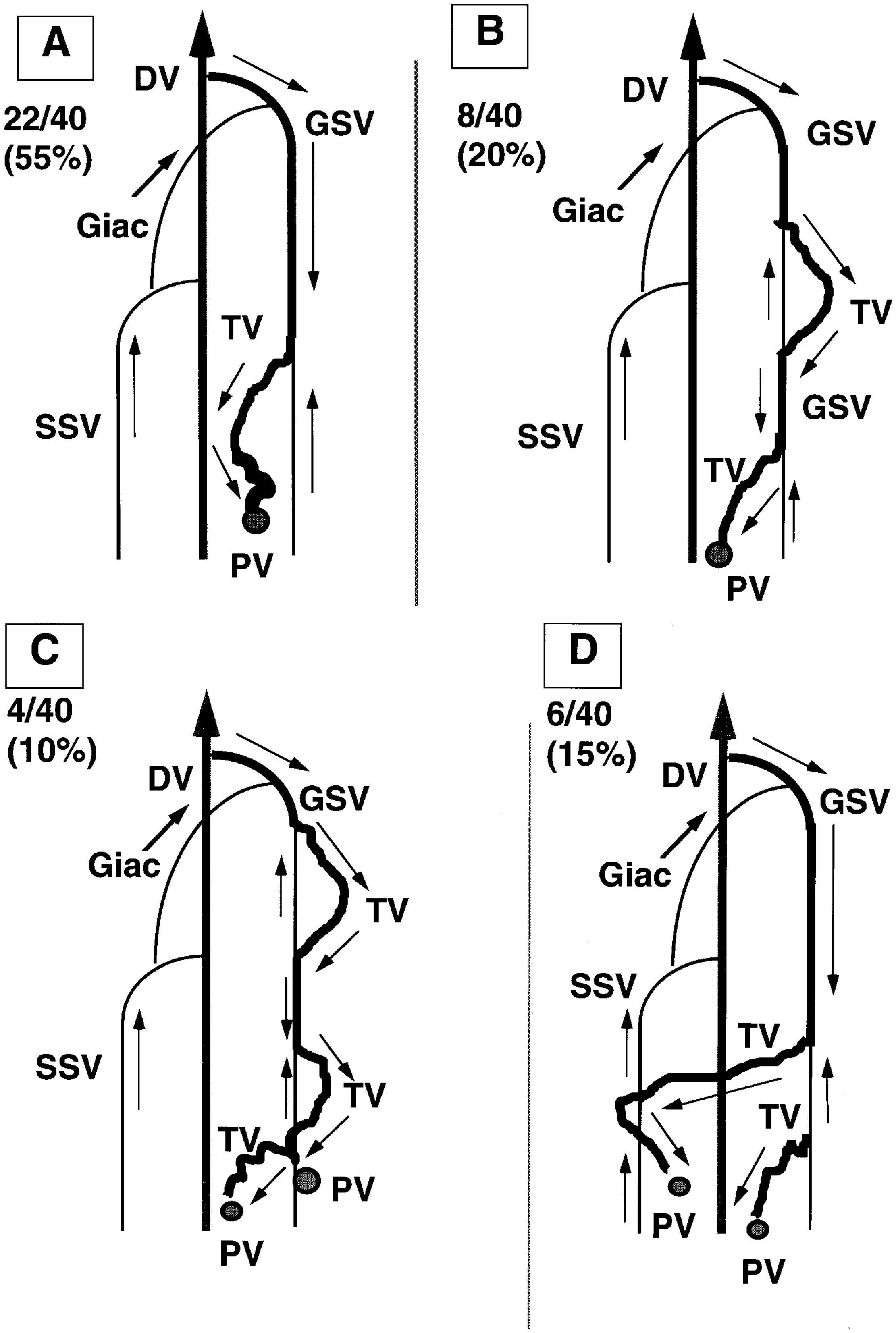


Fig. 3a, b, c, d, e. Haemodynamic patterns found out in the selected patients population and their distribution among cases. Operations consisted in flush ligation and division from the GSV of each insufficient tributary. Varicose tributaries were proximally or totally avulsed.

Finally the pathophysiology was due to reflux in all cases. The following algorithm describes the selected patients C2–6, EP, As2–3–5, p17–18, Pr.

Clinical assessment of the results

The assessment was performed by an independent assessor who had not been involved in previous surgical decision making and operative procedure (PM, Research Fellow in Surgery) according to the following criteria previously proposed in Literature.[13–15])

Objective assessment
class A: no visible and palpable varicose veins;
class B: a few visible and palpable varicose veins with diameter <5 mm;
class C: remaining or newly formed varicose veins with diameter >5 mm;
class D: insufficient main trunks and perforator.

In addition, functional and cosmetic results were self-assessed by the patients, at the time of the last examination in Hospital, using a simple analogue scale well explained by PM to the patients themselves.

Subjective assessment
class A: no inconvenience;
class B: slight functional or cosmetic imperfection, but satisfaction with the result;
class C: appreciable functional or cosmetic failure; improvement but dissatisfaction with the result;
class D: unaltered or increased inconvenience.

Venous function assessment

The selected patients underwent to air-plethysmography preoperatively, and 1 and 6 months postoperatively (APG) (ACI Medical, Sun Valley, CA, U.S.A.) at the same hour and temperature condition (between 8 am and 10 am, temperature 23°).[16,17]

Pre-operative duplex mapping

A preoperative skin map was obtained by duplex in order to identify the point where the superficial tributary had to be interrupted.[4] This point corresponds to the origin of each insufficient tributary vein from the GSV.

Operations

All operations were performed under local anaesthesia, and consisted of the disconnection of the origin of one or more tributary veins containing the "re-entry" perforating veins from the main trunk of the GSV. It is mandatory to perform a technically perfect flush ligation on the GSV trunk in order to firmly transform the refluent GSV into a GSV with a forward flow during muscular contraction, but no Doppler-detectable reverse flow during muscular relaxation. The dilated tributary veins were avulsed through multiple mini-incision technique, proximally, sparing the segments immediately above the re-entry perforating veins opening, or totally.

Patients were discharged 1–3 h after surgery with elastic stockings exerting 20–30 mmHg of pressure at the ankle.

Statistical analysis

All the data were expressed as mean $\pm$ SE of the mean giving the maximum and minimum 95% confidence intervals (CI max and min). Difference between preoperative and postoperative APG parameters were tested for significance using one-way analysis of variance (ANOVA). p values lower than 0.05 were considered to be significant.

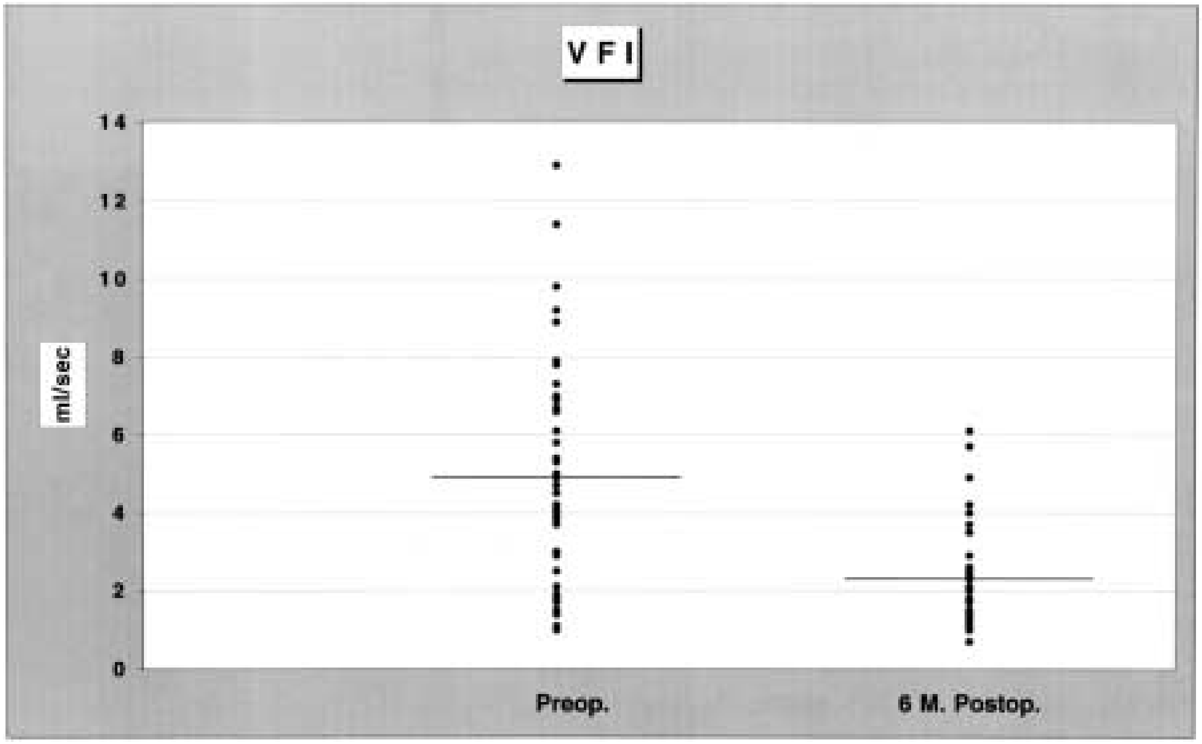
Results

Clinical assessment of the results

Objective and subjective assessment of the surgical results through the records of the independent assessor are showed in Table 1.

Table 1. Clinical assessment six months after surgery. Objective evaluation was made by an independent assessor, and subjective by the patients at their own controls. For the adopted criteria see text.

Assessment of clinical results	
Subjective evaluation	
Class A	35 (88%)
Class B	5 (12%)
Class C	0
Class D	0
Objective evaluation	
Class A	35 (88%)
Class B	5 (12%)
Class C	0
Class D	0



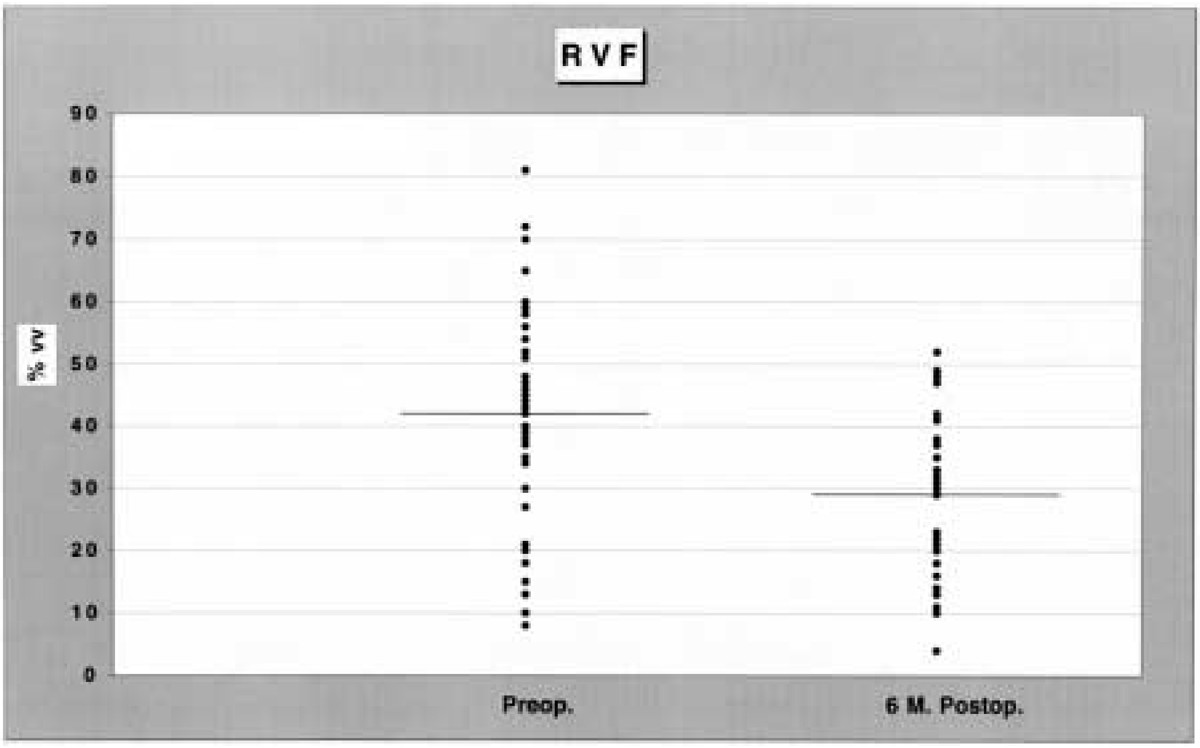


Fig. 4a and b. VFI and RVF improvement assessed, respectively, by means of APG 6 months after the surgical procedure.

Moreover, active ulcers healed in 18th and 23rd postoperative day, respectively. Both active and healed ulcers did not recur during the follow-up.

Post-operative duplex

In all cases, after 1 month from the operation, duplex investigation demonstrated a GSV with a forward flow during muscular contraction, but no reflux during muscular relaxation. Neither insufficient tributary vein nor perforating vein along the GSV were found.

After 6 months 34 patients maintained such a result. In contrast, six patients (15%) presented with an asymptomatic reflux in the GSV; 4 patients were originally C2, 1 C3, 1 C4.

In these 6 patients, at duplex scanning, the main difference, as compared to the pre-operative examination was the presence of a re-entry perforating vein on the main GSV trunk. No insufficient tributary vein were found in all cases.

Venous function assessment

All air–plethysmographic parameters, with the exception of Ejection Fraction (EF), significantly improved: Venous Volume (VV) changed from 150 ml $\pm$ 9 (95% CI min 133, max 167) to 119 $\pm$ 6 (95% CI min 107, max 133) and 114 ml $\pm$ 7 (95% CI min 100, max 128) after 1 and 6 months, respectively ($p<0.0001$);

Venous Filling Index (VFI) from 5 ml/s $\pm$ 0.5 (95% CI min 4, max 5.9) to 2 $\pm$ 0.2 (95% CI min 2, max 2.7) both after 1 and 6 months, respectively ($p<0.0001$);

Residual Volume Fraction (RVF) from 42 ml $\pm$ 3 (95% CI min 36, max 47) to 30 $\pm$ 2 (95% CI min 26, max 34) and 30 $\pm$ 2 (95% CI min 26, max 34) after 1 and 6 months, respectively ($p<0.0001$).

In the graphics of Figures 4a and 4b the improvement of VFI and RVF 6 months after the procedure is well apparent.

Discussion

In the case of a venous segment with incompetent valves, the hydrostatic column is capable of reaching sufficient height in order to create a gradient (Fig. 2). This physical element can produce a diastolic retrograde flow at high velocity representing the reflux detectable by Doppler/duplex instruments.[1–3] The outlet, i.e. the connecting vein between the venous segment, that is the site of a diastolic retrograde flow, and the designated receiving vessel, constitutes the re-entry in a retrograde flow system.

The concept of re-entry includes not only the strictly anatomical aspect of connection between superficial and deep veins, represented in our study by a perforating vein, but it is also necessary to include the haemodynamic aspect, which is the existence of a re-entry gradient.

It is clear that development of a gradient between two vessels presupposes that one of the two, the vessel designated to receive the retrograde flow, has lower pressure values on account of the segmentation of the hydrostatic column by the functional valves (Fig. 2).

If in fact this is not the case, no hydrostatic columns of different heights can be formed and consequently the creation of a gradient is impossible. When muscular relaxation occurs valves are closed in the competent deep system permitting a fragmentation of the hydrostatic column; simultaneously, in the superficial veins valve incompetence determines a reverse flow (Fig. 2).

The main finding of this study is the demonstration that reflux exists only when is supported by a gradient between two points of the vein system. Digital as well as surgical exclusion of the re-entry perforating vein/veins determined reflux disappearance in all cases. On the contrary, duplex evidence of reflux reappearance always occurred with the development of a new re-entry perforating vein: thus, there was no reflux without a re-entry gradient, despite the presence of incompetent valves.

In other words, once retrograde flow has been initiated by the re-entry gradient, the resultant drop in pressure promotes development of a gradient between the refluxing vessel and the vessel supplying the retrograde flow.

The concept of gradient elimination for the hemodynamic correction of the reflux is easily reproducible in each vascular lab. by means of duplex and the finger compression test showed in Fig. 1 and has been confirmed, in the present study, by its own surgical application.

(a) Reflux in the GSV is firmly suppressed by the disconnection of the tributary vein containing the re-entry perforating vein, just eliminating the gradient between the reflux point (i.e. the SFJ) and the re-entry point in the deep veins.
(b) Reflux doesn't exist more until the reappearance of the gradient. Reflux did recur in 15% of the patients in which a re-entry perforating vein newly developed, this time with the opening on the main GSV trunk.
(c) Reflux elimination achieved by the elimination of

the gradient determines significant improvement in venous function, as assessed by means of APG.

This could also explain the absence of symptomatology of the patients in which reflux did recur. Infact, despite the recurrence, the procedure improved significantly calf muscular pump function, expressed by RVF assessment (Fig. 4b).

APG parameters cannot be considered as an absolute measurement of venous function, and in some studies fails to correlate with clinical class, duplex findings and ambulatory venous pressure measurements.[19,20] However, it provides, non-invasively, useful parameters that in combination with clinical and duplex findings seems to confirm, in the present study, the achievement of the aims of the procedure. Particularly, the VFI recovery measured within 6 weeks after venous surgery for CVI appears to be predictive of a good clinical outcome.[21] In the present study, VFI improvement persists also at the 6 months postoperative control (Fig. 4a).

The short term follow-up does not permit us to be conclusive regarding the stability of the results and the proposed technique. At present, it can be considered more the promising surgical application of an haemodynamic model rather than an established new surgical procedure. Surgical elimination of reflux by gradient elimination appears to be a minimally invasive technique, known in Europe with the French acronym of C.H.I.V.A. 2;[4,22] in addition, as compared to flush ligation characterised by a reverse flow, it allows recovery of the physiologic cephalic flow.[4,14,15,22,24,25]

Regarding the applicability of the technique, patients selection was done only on the basis of the haemodynamic presentation. In our survey of 1378 limbs in 794 patients (unpublished data) affected by GSV and SFJ insufficiency, 744 extremities (54%) showed the haemodynamic pattern characterised by the re-entry Perforating Vein/Veins located on a Tributary Vein (Fig. 2).[4,7,15,22]

When such an haemodynamic condition is satisfied the procedure can be considered without any limitation of clinical class. We think possible limitations to verify in further studies are the presence of a varicose and/or of a very dilated GSV trunk (>12 mm). In the former case, sparing surgery is probably of little value, and, in the latter, the possibility of GSV postoperative thrombosis has been reported.[9,22]

Moreover, we believe that this haemodynamic principle could be surgically applied to other clinical situations. Recently, primary superficial venous reflux combined with deep venous reflux has been demonstrated to have 22% of prevalence;[23] in such cases some reports describe the elimination of femoral reflux after stripping procedure:[5,6] this important clinical observation could be even interpreted as the suppression of a re-entry gradient, with the anatomic pathway represented in this case by the SFJ. In such cases, Labropoulos[23] demonstrated a significantly higher peak velocity of reflux in the insufficient GSV as compared to the parallel, communicating and insufficient femoral vein.

In accord to the Bernoulli law, this determines a significant drop in pressure in the superficial veins as compared to the deep veins, proving indirectly the presence of a gradient of pressure between the two communicating segments during muscular diastole. Stripping and/or high ligation would eliminate the gradient, and correct the reflux in the femoral vein.

Longer follow-up as well the development of preoperative tests are warranted in order to investigate the role the haemodynamic correction of reflux in venous surgery.Finally, as far as the procedure described in the present study is concerned, we think that a long-term prospective study versus traditional stripping procedure, including pre and postoperative quality of life assessment and cost-analysis, is warranted.

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Legend for Fig. 3: no illustration supplied for Fig. 3e.