Laser-assisted strategy for reflux abolition in a modified CHIVA approach

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Abstract

The aim of this study was to assess feasibility and efficacy of an endovenous laser (EL) assisted saphenous-sparing strategy in chronic venous disease (CVD). Fourteen CVD patients (C2,3,4s Ep As Pr1,2,3) underwent a sapheno-femoral junction (SFJ) treatment by EL just from below the superficial epigastric vein downward for a limited tract, together with a flush ligation of the incompetent tributaries of the great saphenous vein (GSV) along the leg. The following GSV parameters were assessed 15 cm below the SFJ: reflux time, caliber, peak systolic velocity (PSV), end diastolic velocity (EDV), resistance index (RI). Venous clinical severity score and the Clinical, Etiological, Anatomical, and Pathophysiological (CEAP) classification clinical classes were assessed. At 1 year follow up 3 cases were considered failures because of a GSV thrombosis, even if they presented a GSV recanalization with a laminar flow within at the 2 years follow-up. Eleven procedures succeeded because neither minor nor major peri-procedural complications were reported, apart 2 cases of self-healing bruising. In these last 11 cases the procedure led to a GSV reflux suppression (from 3.1±0.4 s to a retrograde laminar draining flow), to a GSV caliber reduction (from 9.4±0.5 to 3.1±0.2 cm, P<0.001), to a PSV reduction (from 50.2±4.6 to 18.4±3.5 cm/s, P<0.001), to a RI reduction (from 0.9±0.2 to 0.51±0.2, P<0.005) and to an oscillatory flow suppression (EDV from –8.9±1.6 to 6.2±2.3 cm/s, P<0.001). Both CEAP and venous clinical severity score improved from 3 to 1 (P<0.001) and from 7±2 to 2±1 (P<0.05), respectively. The GSV flow reappeared below the shrunk tract draining into the re-entry perforator. Sapheno-femoral reflux suppression can be obtained by just a GSV segmental closure. An almost 80% of success rate of the present investigation paves the way for an even wider diffusion of endovenous techniques, moreover erasing the surgical requirements for those who would like to perform a saphenous-sparing strategy. In this way new devices could be used inside equally innovative strategies.

Introduction

In the last decade, endovenous techniques (ET) have been offering us more powerful and precise devices for the great saphenous vein (GSV) ablation.[1] However this technology advancement has not been followed by an equivalent strategy innovation.

Whatever brand new tool is used, whenever ablating the GSV, the strategy choice is the GSV abolition, as in the surgical stripping.

The most recent reviews point out a possible better pain control and post-operative quality of life following the ET, but at the same time provide overlapping outcomes in reflux suppression whenever making a comparison with the surgical GSV ablation.[2]

Conversely, through the years, CHIVA saphenous sparing surgical techniques have demonstrated their efficacy as an alternative strategy option to deliver an improved outcome.[3] It is possible to postulate that a not only technically but also strategically less aggressive approach could reduce the recurrence risk.[4,5]

In 2013 we reported the first two patients in which we successfully implied this new alternative approach to combine the laser-based mini-invasiveness together with the saphenous-sparing efficacy.[6] In these patients the incompetent sapheno-femoral junction (SFJ) was treated by an endovenous laser (EL) aiming for the obliteration of only the proximal segment to induce the closure from below the superficial epigastric vein (SEV) downward for a maximum of 10 cm of GSV. In this way the rest of the distal GSV segment remains patent/intact to allow the draining reversely toward a re-entry perforator located distally on the same GSV.[6] Aim of the present study is to answering those hemodynamics questions that were raised based on our preliminary experience.

Materials and Methods

This study included 14 chronic venous disease (CVD) cases (M/F: 1/1) (C2,3,4s Ep As Pr1,2,3). Two patients were C2, 10 were C3, 2 C4. The mean pre-operative venous clinical severity score (VCSS) was 7±2.[7]

All the patients presented incompetent tributaries of the GSV together with a SFJ reflux at the femoral side of the terminal valve, both at the Valsalva and calf muscle compression/relaxation maneuver.[8] In all the cases the re-entry perforator was on the GSV.

According to the saphenous-sparing terminology all the cases were type I+N3 shunts.[9,10]

All the patients underwent an echo-color-Doppler assessment and pre-operative mapping on the same procedural day, eliciting the flow both by active dorsiflexion (Wunstorf maneuver) and manual compression/relaxation maneuvers (Figure 1).

The following GSV parameters were assessed 15 cm below the SFJ: reflux time, diameter, peak systolic velocity (PSV), end diastolic velocity (lowest detectable velocity at the end of the muscular diastole) (EDV) and resistance index (RI). PSV represents the highest velocity assessed during the muscular systole. EDV is the lowest velocity value at the end of the diastolic phase.[11-15] RI is the ratio among the difference of PSV and EDV divided by the PSV according to the formula (PSV-EDV)/PSV.[11,13]

The same parameters were assessed at 1-week, 1-6-12-month follow-ups, together with a Clinical, Etiological, Anatomical, and Pathophysiological (CEAP) classification and VCSS. (Table 1)

Data were calculated as mean±standard deviation. The results were compared by using Student's *t*-test or Mann-Whithney as appropriate. Statistical significance was defined as P<0.05.

Operative procedure

All the patients underwent a flush ligation of the incompetent GSV tributaries along the leg.

The SFJ was treated by an EL segmental closure according to the following protocol: percutaneous GSV access at the distal third of the thigh with the patient in a reverse-Trendelenburg position, insertion of a 600 m radial fiber (1470 nm, 6W).

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A tumescent anesthesia (lidocaine 2% 5 cc + sodium bicarbonate 5 cc + saline solution 10 cc) was administered perivenously by a 25 G needle, under echo-color-Doppler (ECD) guidance, just along the segmental GSV tract to be shrunk below the SEV. The EL was then activated, shrinking the GSV at 200 J/cm for the first cm and at 100 J/cm for the following tract. An above-knee 20 mmHg elastic stocking compression was prescribed to all the patients for three days and nights, then just during the daytime for the following three weeks. All the patients gave their informed consent.

Results

Mean follow-up was 1 year.

Three cases were considered the failures because of a thrombosis that developed distally to the shrunk segment of GSV. Nevertheless in these three cases, at the 2 years follow up, at the ECD scanning the thrombosis disappeared resulting in a significantly reduced GSVs (from 9.8±0.3 mm to 2.8±0.2 mm), inhabited by a laminar flow draining retrogradely into the re-entry perforator.

At the 1 year follow up the remaining eleven procedures were considered successful with neither minor nor major peri-procedural complications except 2 cases of mild bruising that rapidly resolved spontaneously.

In these last 11 cases the procedure led to a GSV reflux suppression, to a GSV caliber reduction (from 9.4±0.5 to 3.1±0.2 mm, $P<0.001$), to a PSV reduction (from 50.2±4.6 to 18.4±3.5 cm/s, $P<0.001$), to a RI reduction (from 0.9±0.2 to 0.5±0.2, $P<0.005$) and to a oscillatory flow suppression (EDV from 8.9±1.6 to 6.2±.3 cm/s, $P<0.001$)(inversion of the end diastolic value from negative to positive, thus from refluxing bidirectional to laminar monodirectional flow).

Both CEAP and VCSS improved from 3 to 1 ($P<0.001$) and from 7±2 to 2±1 ($P<0.05$), respectively (Table 1). The shrunk GSV segment was 6.8±1.7 cm long and always distal to the SEV.

The GSV flow reappeared below the shrunk tract as a laminar reverse drainage directed toward the re-entry perforator focused on the same GSV.

The total energy delivery recorded the following parameters: laser on-time 111±45 s, total joules delivered: 671±67 J.

The average tumescence volume was 69.2±8.3 cc.

At 1-year follow-up a single recurrence was reported in the flush ligated GSV tributaries, without clinical complaints and only ECD detectable.

The remaining ten cases demonstrated a laminar drainage toward the same GSV tributary re-entry perforator.

GSV reflux was abolished in all the eleven cases.

Discussion

The constantly increasing demand for mini-invasiveness in saphenous refluxes treatment is surely pushing the phlebology world toward ET.[16,17] In the last decade, ablative surgery has assisted to its progressive replacement by the foam sclerotherapy, radiofrequency, and endovenous lasers.[18] Despite some analysis biases coming out from a not totally homogeneous study population, reliable reviews suggest ET to be as effective as the surgery in the treatment of saphenous vein refluxes.[2,19]

Moreover, ET has been considered not only as efficacious as stripping in the reflux suppression, but also able to provide a faster and less painful post-operative course.[20-22] Following the randomized controlled trials and network meta-analysis pointing out the endovenous performances, up to now, in technically suitable cases, the international guidelines favor ablative ET over open surgery with a Grade 1 B evidence.[23]

The same literature confirms that technological advancement through the last decade has offered a better chance of improved treatment in terms of mini-invasiveness of the procedure and post-operative quality of life. But at the same time it states that the successful rate in reflux suppression hasn't been changed significantly from the old surgical ablative procedure time.[20-22]

On the contrary, CHIVA saphenous-sparing varicose vein strategy have produced long-term efficacy data through the years, claiming both better long term outcomes and competitiveness with the surgical ablative option.[24-41] On this basis, we thought to explore the feasibility and outcome of a brand new strategy combining the laser mini-invasiveness together with the

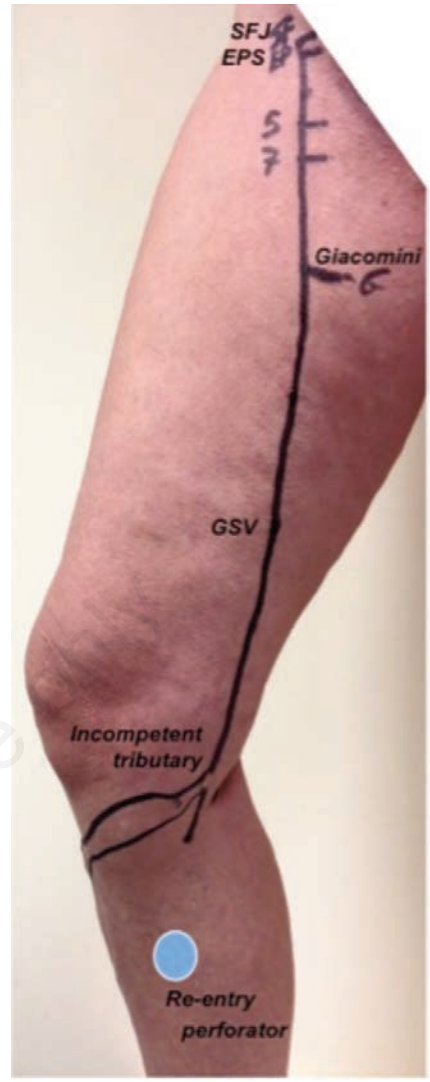

Figure 1. Preoperative assessment: all the patients underwent to a pre-operative echo-color-Doppler assessment and mapping on the same procedural day. GSV, great saphenous vein; SFJ, sapheno-femoral junction; EPS, external superficial epigastric vein.

Table 1. Hemodynamic parameters assessment: pre-operative (PRE-OP) and 1-year follow-up post-operative (POST-OP) great saphenous vein hemodynamic parameters assessment at 15 cm from the sapheno-femoral junction (SFJ) (P<0.05).

Hemodynamics parameters (15 cm below the SFJ)	PRE-OP	POST-OP
RT (s)	3.1±0.4	Retrograde laminar draining flow
Diam (mm)	9.4±0.5	3.1±0.2
PSV (cm/s)	50.2±4.6	18.4±3.5
EDV (cm/s)	–8.9±1.6	6.2±2.3
RI	0.9±0.2	0.51±0.2
CEAP	3	1
VCSS	7±2	2±1

RT, reflux time; PSV, peak systolic velocity; EDV, end diastolic velocity; RI, resistance index; CEAP, Clinical, Etiological, Anatomical, and Pathophysiological classification; VCSS, venous clinical severity score.

saphenous-sparing long-term efficacy.

As we published previously, two cases of SFJ refluxes were treated successfully with a saphenous-sparing principle delivering a segmental GSV closure below the SEV downward for a 10 cm and 7 cm long tract, respectively, to maintain physiological retrograde drainage through a well preserved GSV segment.[6] The present investigation follows these two cases to answer some of the many hemodynamic questions which were raised through the previous publication.

First of all, the SFJ incompetence treatment was achievable by just an only segmental closure which created a not refluxing but rather reversed flow, draining the preserved GSV trunk toward a previously selected re-entry perforator (Figure 2A and B). The presence of a re-entry perforator on the GSV (around 40% of reflux patterns)[10] is mandatory for the procedure. Alternatively, a significant stasis occurs leading to the thrombotic risk.

The oscillatory flow suppression is testified by the EDV post-operative inversion, thus characterizing a laminar flow that according to the recent literature leads to an anti-inflammatory endothelial phenotype.[42]

The post-operative GSV laminar flow significantly (Figure 3A) differs from the pre-operative reflux (Figure 3B). Pre-operative a multi-directional flow can be detected, together with a high PSV and an inverted EDV (Figure 3A). After the SFJ EV closure the pressure gradient is suppressed, in favor of drainage of the GSV blood into the re-entry perforator, so leading to the assessment of a monodirectional and slow flow in which the EDV presents the same PSV direction (Figure 3B).

The amount of shrunk centimeters does not look like to be the parameter that really matters for the maintenance of a draining GSV, rather it is the flow coming from the GSV tributaries distal to the shrunk tract. The failure that occurred in 3 out of 14 cases (21.4%) was associated to a GSV thrombosis that developed distally to the shrunk tract. This fact led us to reason about the main factors to take into account whenever planning an EL assisted-hemodynamic correction of the saphenous system. For example, the Giacomini vein was not detected in these 3 unsuccessful cases in contrast to the other 11 successful cases. Together with the re-entry perforators hemodynamics, this vein features could represent a fundamental data to be verified before performing this new hemodynamic procedure. Indeed, the role of Giacomini vein in lower limbs for venous drainage have drawn increasing attention lately (Figure 4A and B).[42-48]

Moreover, the GSV recanalization at 2 years

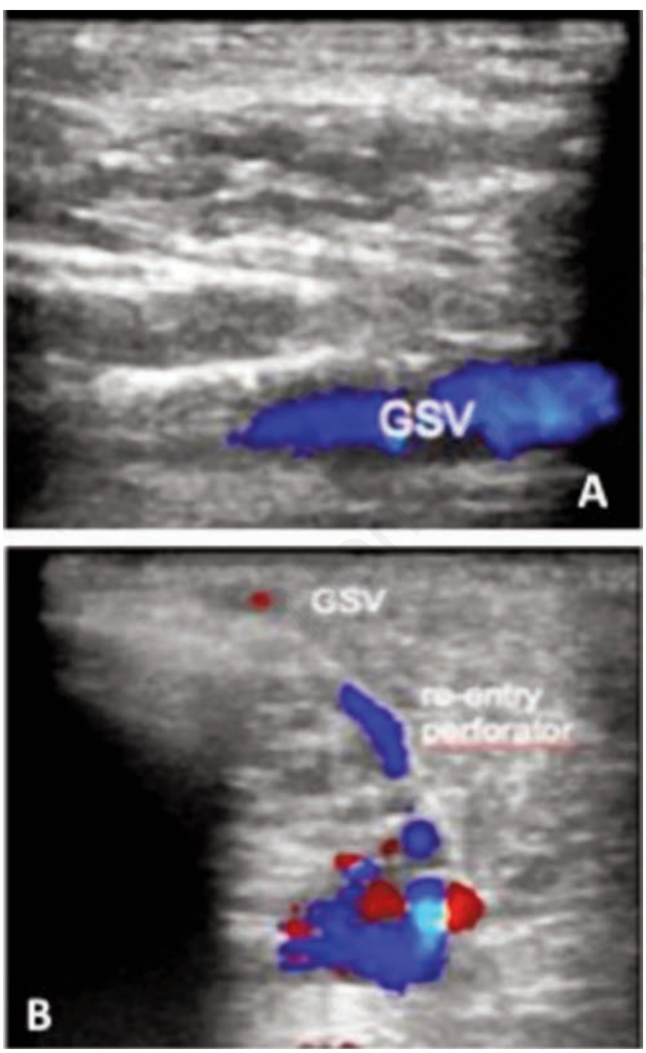

Figure 2. Post-operative flow: preserved great saphenous vein (GSV) (A) trunk presenting a laminar flow from below the shrunk tract downward toward its re-entry perforator (B).

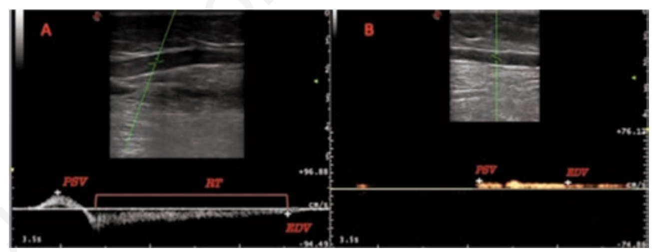

Figure 3. Pre and post-operative flow changes: (A) Pre-operatively, the great saphenous vein (GSV) reflux is characterized by a high peak systolic velocity (PSV), an inverted end diastolic velocity (EDV) and an evident turbulence. (B) Post-operatively, the EDV presents the same PSV direction and the flow decreases its mean velocity, being drained into the re-entry perforator. RT, reflux time.

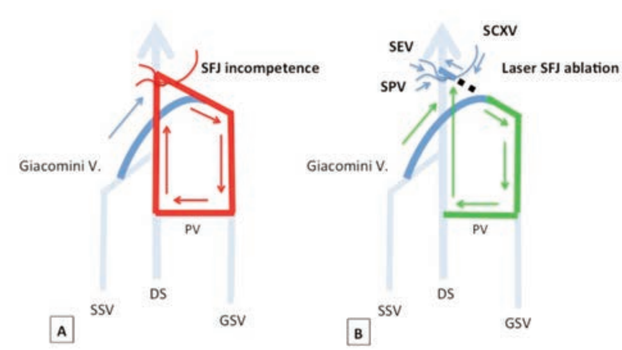

Figure 4. Giacomini vein: pre- (A) and post-operative (B) flow patterns. (A) pre-operatively a closed circuit (red line) is formed starting by the sapheno-femoral junction (SFJ) incompetent leaking point. A reflux is present into the great saphenous vein (GSV) until the confluence with a perforating vein (PV) which drains into the deep system (DS). At the following muscular systo-diastolic push the blood will go back into the incompetent SFJ. Giacomini vein (GV) presents a competent flow. (B) After laser assisted segmental SFJ ablation the closed circuit is interrupted, leading to a laminar monodirectional flow into the spared GSV and draining the same GSV into the PV (green line). SCXV, superficial circumflex vein; SEV, superficial epigastric vein; SPV, superficial pudendal vein.

in these three cases of post-operative thrombosis, together with the resolution of the pre-operative reflux and the vein caliber reduction, offer a preliminary data for future hemodynamics investigations. Whenever compared to a traditional surgical saphenous-sparing option, the herein presented technique is surely less cost-effective for the need of the laser device and fiber acquisition. Nevertheless a deeper cost-analysis is recommended to analyzing the indirect income derived by the greater numbers of procedures performed daily because of the faster procedural time coming from the endovenous rather than surgical act.

Certainly, this new hemodynamic approach mandates further investigations and the herein reported successful outcome (79.6%) will contribute on better understanding for this hemodynamic approach as well as new implication of the mini-invasive technology into the CVD field.[49,50]

Another topic of further research is the percentage of candidates to the strategy. Considering that in CVD almost half of the sapheno-femoral junctions are competent and that a re-entry perforator must be found on the GSV in order to apply this strategy, future investigations should be addressed to determine the effective role of the GSV tributaries along the leg in maintaining a draining flow.

The availability of a saphenous sparing option also for not surgical operators could lead to an increasing interest toward advanced hemodynamics, so rising also the interest toward advanced scanning in phlebology.

This could lead both to an age of not only new devices but also of innovative strategies and to a collective better understanding of the intricate venous drainage pathophysiology.

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