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Clinical Features of Minimal Invasive Venous Surgery: Indications and Advantages of Sclero-Foam Assisted Laser Therapy

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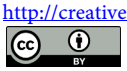

Abstract

In the modern day care, several minimal invasive approaches, both thermal and non-thermal, have been proposed for the surgery of varicose venous disease. Early diagnosis and subsequent surgical treatment may prevent complications onset and block the natural history of chronic venous disease. Nevertheless, the choice of surgical strategy must rely on the specific anatomic and clinical features of each patient. Hybrid procedures, that combine more endovascular and surgical techniques, may represent useful options to overcome some conventional limits and avoid performing the classical open venous surgery. Therefore, our efforts must aim to obtain an optimal functional outcome, in accordance with longer saphenous vein obliteration at mid-long term, in the respect of a minimal invasive surgery and the best possible cosmetic impact. This brief report will focus on the use of sclero-foam assisted laser therapy as chosen hybrid option, showing the technical modality and underlining the benefits, especially in particular subsets of patients affected from saphenous vein incompetence.

Keywords

Sclerofoam Therapy, Endovenous Laser Ablation, Varicose Vein Disease

1. Introduction

Over last decades, endovascular venous surgery (EVS) has increasingly displaced the classical open venous surgery for the treatment of saphenous vein insufficiency in accordance with the development and involvement of thermal and non-thermal ablative techniques [1]. Benefits of endovascular ablations are well-known in terms of clinical implications with a faster recovery of patients undergoing this kind of

surgery [2]. Nowadays dealing with the management of varicose vein disease, our efforts should also aim at a hybrid surgery that may combine more techniques, endovascular and surgical, thereby performing several procedures into the same intervention. Hereafter, we will describe the use and benefits of Sclero-Foam Assisted Laser Therapy (SFALT), hybrid technique mixing endovenous laser ablation with sclero-foam therapy.

2. Methods

In the last six months, we have identified a subset of twenty-five patients (8 males, 17 females with an overall mean age of 44 ± 9 years old), characterized from a very superficial saphenous vein or in presence of important dilatations (also with caliber > 1.4 cm), multifocal too. Most of the patients belong to C3 - C6 classes of CEAP classification, only five patients C2 CEAP showed a very superficial anatomic course.

Informed consent was given and signed from all patients before the procedure and our institutional review board analyzed the project in accordance to ethical approval.

The selection of the patients suitable for SFALT was made according to the following inclusion and exclusion criteria:

3. Inclusion Criteria

- Aged between 30 and 65 years.
- Multifocal dilatations of great saphenous vein (also with caliber ≥ 1.4 cm).
- Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification: C2 - C6.
- A reflux time of the GSV greater than 0.5 seconds.
- Too superficial subcutaneous course of great saphenous vein.

4. Exclusion Criteria

- Excess of tortuosity of great saphenous vein at the thigh segment.
- Pelvic venous varices history.
- Known history of coagulopathy.

This patient's setting underwent SFALT procedure at our Vascular Surgery Unit.

First of all, we performed a simple locoregional femoral anesthesia, therefore under ultrasound guidance we have inserted a laser fiber (Biolitec ELVeS® Radial® 2 ring fiber with 6Fr introducer, performing an endovenous laser ablation with a 1470 nm diode laser system) into the greater saphenous vein by percutaneous modality at the third superior of the leg and we gave small amounts of tumescent anesthesia along the saphenous course only in selected venous segments (superficial or dilatated). The choice of a locoregional anesthesia, because of easy reproducibility and absent rate of complications, was a challenging strategy in the attempt of reducing tumescent injections as far as possible.

So after having heated a 1 cm-starting venous segment at 200 J/cm (only in two

patients a sapheno-femoral junction surgical ligature, always under local anesthesia, was necessary because of venous diameters about 2 cm) or, in alternative, also after a synchronous compression ultrasonography of sapheno-femoral junction, we injected via the same percutaneous introducer an amount of 5 - 7 cc sclero-foam, maintaining the laser tip stucked into the vein (Figure 1). Foam preparation protocol included 3 cc of Polidocanol 2% solution mixed with 4 cc of air with the aim of obtaining the final scleromousse to inject directly into vein after transferring the mixture between two syringes for a total of 6 - 8 back-and-forth passes. Shrinkage related to endothelial spasm allowed a major susceptibility of dilated venous tracts to the action of endovenous laser, something very important in case of superficial saphenous vein where we were able to reduce the power (4 - 5 Watt) and the total amount of transmitted light energy. Only in two cases, patients underwent concomitant anterior accessory saphenous vein ablation because of its incompetence, so to avoid the risk of recurrence of recidive varices. Once completed the ablation procedure, elastic bandages were applied upon medications and were maintained throughout the day and the night for one week; then an above-knee 18 - 21 mmHg elastic stocking compression was prescribed to all the patients during the daytime for the following months.

All the patients were discharged at home after few hours from the end of the procedure, with a subsequent faster return to normal daily activities. A daily surgery could be carried out in outpatient settings, too.

A regular anti-thrombotic prophylaxis was given to patients administering a single dose/day of low weight molecular heparin for two weeks.

Figure 1. Once inserted the tip laser fiber, an amount of 5 - 7 cc of sclero-foam was injected through the same laser introducer after having heated a 1 cm-starting venous segment at 200 J/cm or, more easily, via a synchronous compression ultrasonography of sapheno-femoral junction.

5. Results

In all procedures, we observed no complications with an optimal cosmetic impact, that is something very useful, especially in younger patients. Paresthesia and dyscromia or other skin damages were not found neither major complications as thrombotic events occurred. Moreover, ultrasonographic follow-up at three months after surgery showed no recanalization signs (venous occlusion rate of 100%), with a greater saphenous vein shrinker than pre-operative diameters. In supine, at the mid-thigh the great saphenous vein caliber decreased from a baseline mean value of 0.8 ± 0.6 cm to a post-operative value of 0.5 ± 0.2 cm at 3-months follow-up**.** In addition, the mean preoperative Venous Clinical Severity Scores (VCSS) were 9.3 ± 2.2 decreasing to 7.6 ± 2. Most of sapheno-dependent varices were not more detectable at clinical follow-up, nevertheless, residual ones were simply closed through further injections of sclerosing agents. This *staging concept* allows to reduce surgical incisions, even if smaller, necessary for phlebectomies because we observed a shrinkage or disappearance of varices once removed the pathological saphenous reflux.

6. Discussion

Chronic venous disease (CVD) is nowadays a significant entity in terms of worldwide prevalence and incidence, lowering the overall quality of life of affected patients. Therefore, early diagnosis and a correct clinical evaluation with subsequent surgical treatment may prevent complications occurrence and block the natural history of varicose disease following functional classes progression according to CEAP classification. Exploring different options, over the last decades, thermal ablation by laser fiber or radiofrequency has been commonly considered as first-line modern treatments of lower extremity varicose veins [3]. Nevertheless, ultrasound guided foam sclerotherapy (UGFS) represents another tool for treating saphenous vein and tributaries incompetence and may be considered a viable strategy, especially in case of recidive varices.

The ideal of a surgery "*without cuts*" or minimally invasive must anyway allow the achievement of an optimal functional outcome, in the respect of a vein obliteration at mid-long term. Speaking of surgical skin port and wounds, "*Need for surgery*" should be the new dogma in the planning of a surgical procedure of a patient affected from CVD. Otherwise, this kind of venous surgery is often aimed at young women, so that also the cosmetic impact has to play a key role. Too large vessel diameters [4] or particularly superficial courses of saphenous veins may represent potential adverse factors to a correct implementation of an EVS. Hence, a careful vein analysis through a duplex ultrasound scan before the surgery will study venous reflux pattern, the anatomy and diameters of saphenous vein at various levels, addressing us to choose the best strategy tailored to each patient.

There is no single option suitable for all interventions, regarding both thermal and non-thermal, tumescent and non-tumescent approaches; there is the right intervention according to the specific clinical and anatomic features of the patient. Performing hybrid procedures, such as a SFALT, means to combine more endo-

vascular techniques, so that we may overcome some conventional technical limits avoiding classical open venous surgery, taking advantage of benefits of both techniques (endovenous laser ablation and sclero-foam therapy) [5].

Some currents of thought [6] advocate tumescent anesthesia-free approaches delivering the lowest energy through particular technological devices using lower temperatures, in order to minimize perivenous ecchymosis and hematoma. On the other hand, in cases of multifocal large dilatations, tumescent anesthesia, even in small amount, improves venous parietal contact surfaces ready to be heated from laser fiber of radiofrequency through the reduction of the venous diameter, whilst in the same way, too much superficial veins can be moved away from skin.

Shrinkage effect represents a kind of chemical pre-conditioning, induced from the intravenous injection of sclero-foam, able to prepare the vein to accept the ablation action of laser fiber with better final outcomes; moreover, the shrinkage plug, created heating a 1 cm-starting cranial venous segment at 200 J/cm, optimizes the local effect of the foam within the so-called "saphenous eye".

Although recent American and European guidelines favor endovenous laser therapy (as current NICE varicose vein guidance and 2023 Society for Vascular Surgery/American Venous Forum/American Vein and Lymphatic Society), and more widely the thermal ablations, also for larger venous diameters [7], use of higher energy/power settings and longer duration of delivery in these circumstances oppose the concept of performing a soft surgery increasing the incidence of skin injuries/dyscromia.

That's why reducing power of delivered energy becomes mandatory, especially in the case of too much superficial course of saphenous vein.

In order to minimize treatment failure as the onset of early vasal recanalization and in the respect of a soft, scarless surgery, SFALT is a challenging treatment modality in some special subsets of patients.

Moreover, post-procedural compression stockings play a crucial role in the view of optimizing venous occlusion rate and reducing natural swelling related to reactive inflammation status beyond pain management after surgery [8].

In alternative to SFALT, Radiofrequency Sclero-Foam (RFA-S) approach is another minimal invasive modality in which the saphenous vein heated from RFA action is further sealed with concomitant sclero-foam injection showing interesting outcomes in terms of safety and feasibility [9].

Therefore, both SFALT and RFA-S realize an example of thermochemical ablation and theoretically are considered comparable and sometimes interchanged options of treatment; my clinical insight is that our efforts should aim at identifying a patient profile who would receive better one procedure instead of another one with related therapeutical implications.

So *quid agam*? By studying differences between more patient subtypes that undergo SFALT and RFA-S, by comparing anatomic and functional variables in terms of venous occlusion rates, venous diameters and post-procedural complications, we might highlight the patient profile more suitable to SFALT or RFA-S leading

the most appropriate decision about the surgical strategy. Early and preliminary evaluations seem to suggest that SFALT is more applicable than RFA-S in case of superficial saphenous vein because of ability of reducing the power of delivered energy; further and discriminating analysis will be necessary in case of multifocal venous dilatations.

7. Conclusion

SFALT represents a safe and feasible hybrid option, easily reproducible, in order to overcome some conventional limitations to EVS, such as in cases of major caliber or too much superficial course of venous vessels, showing good functional results at short and mid-term and no complications [10]. Moreover, minor amount of perivascular tumescent infiltration, only in selected venous tracts, was necessary with clear benefit in terms of post-operative pain or ecchymosis/hematoma onset [11].

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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