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Great saphenous vein reflux treatment in patients with femoral valve incompetence, the Excluded Saphenous Vein Technique (ESVT): a pilot study

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Abstract. – OBJECTIVE: To describe and evaluate feasibility and efficacy of a saphenous ablation technique performed in patients with varicose veins (VVs), great saphenous vein (GSV) incompetence, and proximal femoral valve incompetence: the Excluded Saphenous Vein Technique (ESVT).

PATIENTS AND METHODS: Patients with primary great saphenous and proximal femoral valve incompetence underwent ESVT. This technique is composed of selective crossectomy, GSV ligation next to the thigh incompetent tributary vein, and saphenous vein sclerosing performed from the proximal zone. Demographic, clinical and instrumental data were collected. CEAP classification was used to describe VVs severity. The primary outcome was perioperative complications. Secondary outcomes were 30-days, 6-months and 1-years GSV occlusion rate, and VVs recurrence rate.

RESULTS: During a ten months period, 104 patients were analyzed. Among these, 82 patients underwent ESVT (59 female, age 50 ± 21 years), eighty C2 and two C5, according to CEAP classification. The average length of GSV treated was 23 ± 9 cm. No intraoperative complications occurred. A 1-year follow-up analysis revealed no partial or complete saphenous recanalization, deep venous thrombosis, pulmonary embolism. No VVs recurrence was detected during the follow-up period among the entire population.

CONCLUSIONS: ESVT seems to be a safe and effective treatment for primary saphenous reflux and proximal femoral valve incompetence. Further studies are needed to assess long-term results.

Key Words:
Venous insufficiency, Varicose veins, Vein valves, Great saphenous vein, Sclerotherapy, ESVT.

Introduction

In the general population, the prevalence of varicose veins (VVs) of the lower limbs is about 20-25%[1,2]. In the last decades, several treatments have been proposed to abolish great (GSV) or small (SSV) saphenous vein incompetence. Generally, the most important invasive venous treatments currently available are surgery and endovenous ablation procedures. Among the endovenous ablation procedures, non-tumescent non-thermal (NTNT) techniques increase the mini-invasiveness with non-inferior results compared to others tumescent or surgical procedure[3,4]. However, these new endovenous techniques, as endovenous radiofrequency (RFA), laser ablation (EVLA), cyanoacrylate injection (NBCA) or ultrasound-guided foam sclerotherapy (UGFS), reported questionable results in patients with incompetence of deep venous system and large GSV diameter. In particular, the deep femoral valve (DFV) incompetence just above the sapheno-femoral junction (SFJ) leads to an increased venous pressure on the ablated GSV segment, promoting its postoperative recanalization. In these patients, surgical correction with high ligation plus GSV stripping (HL+S) should be recommended, if no other deep valves dysfunctions are present. In order to maintain a surgical disconnection between femoral vein and GSV and to minimize GSV traumatism deriving from stripping, the Excluded Saphenous Vein Technique (ESVT) may be an available and safe alternative.

The aim of this study is to present a technical note about ESVT, along with its rationale and operative steps. Furthermore, to present a retro-

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spective analysis of patients with GSV and DFV incompetence and large GSV diameters, treated with ESVT.

Patients and Methods

Study Population and Inclusion Criteria

Patients with VVs of the lower limbs and DFV incompetence were enrolled in this study from January 1, 2017 to October 30, 2017 at General and Oncology Surgery Department, Andrea Tortora Hospital, Pagani (SA). Inclusion criteria were the following: age 18-80, Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) class C2-C6, GSV incompetence, DFV incompetence, GSV diameter > 10 mm; exclusion criteria were the following: pregnancy, lactation period, previous lower limbs or venous surgery, history of deep (DVT) or superficial (SVT) venous thrombosis, patients with a history of hypersensitivity to any component of the agent used for UGFS. Superficial and deep reflux CDUS evaluation were assessed according to the European Society for Vascular Surgery (ESVS) and Italian Society for Vascular Investigation (SIDV-GIUV) guidelines recommendations[5,6]. According to these guidelines, a GSV reflux > 0.5 seconds was considered significant, as a reflux > 1 second in the deep venous system. We have also considered a high volumetric flow rate through SFJ and GSV as a parameter for patients' enrollment. Saphenofemoral junction (SFJ) diameter was measured in a transversal view, as GSV diameter, which was measured at the middle third of the thigh.

The ESVT Technique

In the ESVT technique, surgery and ultrasound-guided foam sclerotherapy (UGFS) are combined to obtain selective crossectomy, thigh incompetent tributary vein ligation, treatment of the excluded GSV and VVs treatment (Figure 1). In particular, several procedural steps are followed, as described below:

A. The typical pattern is represented by an incompetent GSV (R2), with an incompetent tributary (R3) connected with a re-entry perforating vein (P) (shunt type III, according to CHIVA classification)[7]. First of all, infiltration with 4-5 cc of local anesthetic (Mepivacaine 2%) is performed in the inguinal region.

B. Selective crossectomy, sparing SFJ collaterals, according to Genovese and collaborators, is performed[8]. With color Doppler ultrasound (CDUS) scan guidance and under local anesthesia, thigh GSV ligation at the level of R3 is also obtained. Also, concomitant Giacomini vein is ligated, if present.

C. With SFJ, thigh GSV and R3 ligation, the incompetent GSV segment results now excluded. At this time, phlebectomies of non-saphenous VVs are performed.

D. After Trendelenburg position achievement, a tip-fenestrated 40 centimeters catheter (Nelaton Porges Neoplex Fr/Ch 10/3.3 mm)

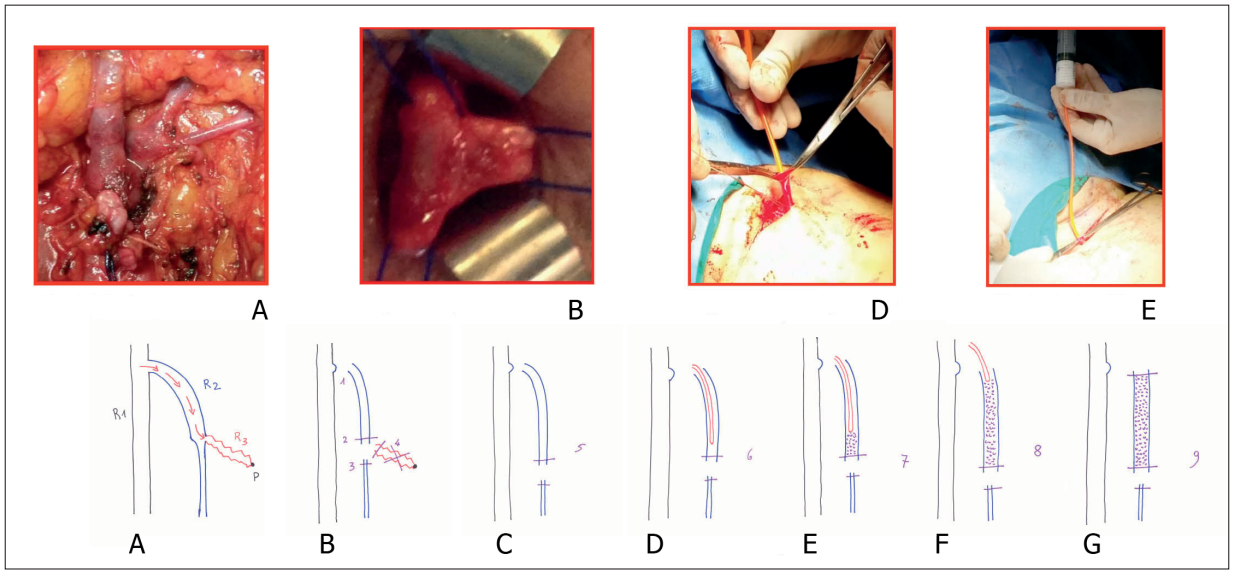

Figure 1. ESVT technique. ***A-C,*** Selective crossectomy. ***D-F,*** Ultrasound-guided foam sclerotherapy

is introduced into the proximal GSV, and advanced until the distal ligature. Aspiration with a 10cc syringe connected to the catheter is performed, in order to empty GSV.

E. Foam injection into the GSV. The foam is prepared according to the Tessari method, mixing 2 cc of a sclerosing agent (Atossisclerol 3%) with 8 cc of O_2 100% gas in silicon free syringes (20 cc) through a three-way valve.

F-G. Continuous catheter pull-back for the entire GSV excluded segment and GSV ligation, after catheter removal.

A manual compression is done along the treated GSV segment for 1 minute. Skin closure is obtained with an intradermic suture at the groin and Steristrip (3M Healthcare, St. Paul, MN, USA) for phlebectomy incision. After the procedure, a 23 mmHg elastic stockings (Struva® 23, Medi GmbH & Co, Bayreuth, Germany) is applied for 10 days, until the first follow-up examination.

Patients are discharged during the same day of the procedure. Low molecular weight heparin (0.4 mL per day) for 20 days and antibiotic therapy for 5 days (intramuscular Ceftriaxone, 1 g per day) are administered to each patient after the discharge.

Follow-up and Endpoints

A 10-day, 30-day and 6-month follow up with clinical and CDUS examination were performed in all patients. At 1-year, clinical and CDUS examination were performed by well-trained operators from three different vascular centers; they were blinded to the findings of each others' examinations. During CDUS investigation, GSV occlusion rate and VVs recurrence rate were analyzed.

The primary outcome was ESVT perioperative complications rate. Secondary outcomes were 30-days, 6-months and 1-years GSV occlusion rate, and VVs recurrence rate.

The study was performed in agreement with the Declaration of Helsinki and subsequent amendments. Written informed consent was obtained from all subjects. The study was approved by the local Ethics Committee.

Results

During the study period, 104 patients were initially enrolled. Among these, 22 patients were excluded because they did not fit into the inclusion criteria (19 with DFV competence, 2 with a history of DVT and 1 for previous endovenous GSV ablation). Finally, 82 patients (23 men and 59 women [ratio 2.6]) underwent ESVT. The average age was 50 ± 21 (IQR 27-69) and the right lower limb was affected in 40 (71.4%) cases. The average GSV diameter was 12 ± 2 mm. Average SFJ diameter was 17 ± 6 mm. In most cases, ESVT was performed in C2 patients (80/82, 97.5%), but also C5 patients (2/82, 2.5%) were treated. The whole population underwent ESVT as described above. No intraprocedural complications occurred. No SVT, DVT or EP cases occurred during the follow-up.

All patients completed a 1-year follow-up period after ESVT.

After 10 days, a CDUS examination revealed: stable sclerosing agent in the residual GSV in the entire treated segment and a not compressible, hyperechoic GSV aspect. No refluxing GSV was detected. Results were similar during the 30-day, 6-month and 1-year follow-up visits, with no documented SVT cases. Furthermore, no VVs recurrence was detected.

It is worthwhile to mention that all the ultrasonographers observed the same findings at 1-year with regard to the above findings.

Discussion

In recent years, venous procedures for saphenous vein incompetence and VVs were radically changed. The advent of tumescent and non-tumescent endovenous techniques, and their widespread use, led to a reduction in invasiveness, postoperative pain and a faster return to work activities[9]. Furthermore, these techniques have proven safe and effective, with non-inferiority in terms of VVs recurrence or GSV occlusion rate, compared to surgery[10]. Showing no remarkable immediate complications during varicose vein surgery, they could prevent long-term injury of untreated chronic venous disease[11,12]. Although very promising in treating saphenous reflux, endovenous procedures have some anatomical or hemodynamical drawbacks. Regarding anatomical contraindications, is not recommended to perform tumescent or non-tumescent procedures, as RFA, EVLA or NBCA, in case of tortuous or large diameter saphenous vein. Furthermore, if the distance between saphenous axis and skin is less than 0.5 cm, the risk of burns is augmented[13]. Regarding hemodynamic principles that could contraindicate endovenous procedure, the deep refluxing blo-

od column deriving from a DFV incompetence may provoke a huge reflux gradient in the incompetent SFJ and GSV, with an augmentation of the hydrostatic column. The absence or incompetence of DFV affects about 20-25% of patients with varicose veins, as mentioned by Cappelli et al[14]. In this paper, the Authors demonstrated a strict correlation between a GSV ≥ 8 mm and DFV incompetence/absence (sensibility 98.6%, specificity 80.4%, positive predictive value 88.2%, negative predictive value 97.4%, diagnostic accuracy 91.3%). Furthermore, it is already known that this condition may create a potential source of recanalization and activation of collateral circuit after non-endovenous procedures, as described by Gianesini et al[15]. After endovenous procedures, the persistent iliac blood column "beating" against a patent SFJ and an occluded GSV, increase even more these pathological conditions. Finally, the majority of these conditions may contraindicate also the use of UGFS, if performed by cannulating the GSV in its distal part.

With this report, we present our positive clinical case series with a technique used in case of DFV incompetence and large SFJ and GSV diameters. No perioperative and 1-year follow-up complication were described in a population of 82 patients. We prefer the ESVT in these patients because it combines GSV endovenous ablation without its traumatic removal and without contraindications of endovenous techniques. In particular, selective crossectomy, performed as the first ESVT step, stops the refluxing column deriving from deep venous system; the GSV ligation next to the main refluxing thigh tributary vein avoids the subsequent diffusion of the sclerosing agent at high concentrations (3%) through leg tributaries, minimizing any postoperative superficial venous thrombosis (SVT) in this collateral circulation; the use of catheter and foam, maximize the contact between venous wall and sclerosing agent, with an improvement in postoperative results, as demonstrated by other Authors[16,17].

Another important advantage of ESVT is the use of local anesthesia, without any anesthesiologist assistance. HL+S can be performed under local anesthesia, but it is recommended a light sedation during stripping, or a tumescent anesthesia along the GSV course, in order to avoid intraoperative pain and discomfort. In case of ESVT no other type of anesthesia is used, a part of local anesthesia at the SFJ, GSV ligation, and phlebectomy sites. Patients are hospitalized in a day-surgery regimen in all the cases.

Finally, ESVT technique is cost-effective because it involves only the use of a sclerosing agent, a simple catheter and crossectomy surgical instruments set. No need of endovenous devices and an anesthesiologist are required. The day-surgery regimen, in which ESVT should be proposed, minimizes hospitalization costs.

This pilot study does have some limitations, such as the small number of patients included and the short follow-up. On the other hand, the strengths are the high rates of adherence at the follow-up and the uniformity of findings found in examinations at 1-year by well-trained ultrasonographers from different vascular centers.

Conclusions

We observed that ESVT seems to be a valid, safe, inexpensive and effective technique in case of primary saphenous reflux and proximal femoral valve incompetence. Further studies are needed to assess long-term results and comparison with other venous procedures.

Conflict of Interest

The Authors declare that they have no conflict of interest.

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