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Ann Ital Chir, 2020 91, 1: 61-64
pii: S0003469X20030262
free reading: www.annitalchir.com

Luciano Izzo*, Federico Pugliese*, Gorizio Pieretti°, Sara Izzo*, Paolo Izzo*
With collaboration of: Gaetano Florio***, Mauro Del Papa***, Daniela Messineo**

*Department of Surgery "Pietro Valdoni", Policlinico "Umberto I", "Sapienza" University, Rome, Italy

**Department of Radiological Sciences, Oncology and Pathology, "Sapienza" University, Rome, Italy

***L.P. Delfino Hospital, Department of General Surgery, Colferro, Rome, Italy

°Multidisciplinary Department of Medical-Surgical and Dental Specialties, Plastic Surgery Unit, Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy

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AIM: The traditional surgical treatment for lower limb primary varicosity has been for a long time high ligation of sapheno-femoral junction and stripping of great saphenous vein. Surgery, however, has been frustrated by postoperative pains and discomfort and recurrences so that it has been challenged by minimally invasive endovenous techniques such as laser treatment and radiofrequency ablation. The aim of the article is to assess the feasibility, in a day hospital setting, of a combined approach to greater saphenous vein reflux: high ligation of sapheno-femoral junction and thermal treatment of the great saphenous vein.

METHODS: A retrospective analysis on 95 patients treated with high ligation and thermal ablation at our institution from January 2009 to July 2017 was performed, assessing duration of surgery, post-operative pain and analgesics requirements, early complications and resumption of activities.

RESULTS: Two patients (2.74%), in the laser group experienced skin burns in the course of the GSV. Moderate ecchymosis, by laser fibre-induced perforation of the vein wall, were observed in another two patients (2.74%). Four limbs (5.48%) in the EVLT group developed transient paraesthesias. Analgesic requirement on POD 3 was nil for RFA group; conversely half of the EVLT patients did take analgesics, either 2 or 3 tabs were required. On POD 7, the patients of RFA group continued to not ask for any analgesics, but the same half of the patients in EVLT group still needed 1-2 tabs to carry out their normal activities smoothly. On POD 15, no patient did require analgesics.

Resumption of routine activities was earlier for RFA group patients than for those in the EVLT group. The RFA group resumed their activities within 3 days, whereas EVLT group in 8-9 days. High ligation of the SFJ didn't add too much time or morbidities.

CONCLUSION: Catheter delivery of thermal energies for saphenous ablation, even when combined with high ligation of saphenous femoral arc, demonstrated to be minimally invasive, easy to learn and easy to perform in day hospital setting, with early return to normal activity. EVLT achieved similar results to RFA and both techniques were considered equally effective and safe; the results we obtained were not statistically significant but RFA showed less pain, ecchymosis and haematomas, as well as provided better short-term quality of life.

KEY WORDS: Day Hospital setting, Endovenous laser treatment, High ligation ablation of the saphenous vein, Radiofrequency ablation

Pervenuto in Redazione Gennaio 2019. Accettato per la pubblicazione Aprile 2019

Correspondence to: Prof. Luciano Izzo, Dipartimento di Chirurgia "P. Valdoni", "Sapienza" Università degli Studi di Roma, Via G. Tomasi di Lampedusa 9, 00144, Rome, Italy (e-mail: luciano.izzo@uniroma1.it)

Introduction

Lower limb varicose veins (LLVV) are very common^[1,10] and greater saphenous vein (GSV) reflux is the most common cause^{2,3}.

Most people experience symptoms of heaviness and itching at the end of the day, pain, discomfort, oedema and muscle cramps, although the clinical presentation ranges from simple cosmetic concerns like telangiectases or appearance of dilated veins to severe venous ulcers, lipodermatosclerosis and bleeding.

Treatments include conservative options and surgical procedures.

Considering the pathophysiology of chronic venous insufficiency (CVI), the only lasting and effective treatment is eliminate the venous reflux and ligation of the sapheno-femoral arc and stripping of the GSV used to be recognised as the choice treatment.

Surgery, however, has been frustrated by postoperative pains and discomfort, bruising and hyperpigmentation, lymphoceles and hematomas, inesthetic scars, and, in a 20-60% rate of incidence, recurrence^{4,9}; in light of these findings, less invasive treatment modalities were introduced.

In 1999, Bonè⁷ reported on delivery of endoluminal laser energy; since then, a method for treating the entire incompetent GSV segment has been described. Endovenous Laser Therapy (EVLT) allows delivery of laser energy directly into the blood vessel lumen with the goal of causing a non thrombotic vein occlusion by heating the vein wall, necessary to cause collagen contraction and denudation of the endothelium resulting in vascular wall thickening with eventual fibrosis of the vein. In 2000, Goldman⁸ published the first report on the treatment of varicose veins by radiofrequency ablation (RFA). The heat is generated by radio waves, a type of electromagnetic radiation surrounding an active electrode. This heat causes collagen shrinkage, denudation of endothelium and obliteration of the venous lumen. Other more recent studies followed^{9,11,12}.

This paper focuses on primary varicose veins (leaving aside those that are obviously secondary to deep vein lesions as post-thrombotic syndrome, primary deep venous insufficiency, deep venous obstruction or to congenital or acquired arteriovenous shuntings) reporting on an initial experience with high ligation of sapheno-femoral arc combined with thermal treatment, in a day hospital setting.

Methods

A retrospective review was made on 95 patients treated for LLVV from January 2009 to July 2017; 73 women and 22 men: 37 underwent ESVL (30 women) and 58 underwent RF (43 women) at Colleferro District Hospital, Rome, Italy. The patient population were similar in age, clinical, etiological, anatomical classification and comorbidities.

Thermal ablation was combined with a surgical approach for high ligation of the sapheno-femoral arc, in a day hospital setting.

A thorough history was taken and physical evaluation, including duplex scan, was performed on the limbs of these patients; study inclusion criteria included LLVV caused by GSV junction incompetence with GSV reflux; exclusion criteria were non palpable pedal pulses, post-thrombotic syndrome, primary deep venous insufficiency, deep venous obstruction, pregnancy and extremely tortuous GSV that would not had allowed an easy passage of either the Laser or RFA catheter.

Before treatment, lower extremity varicosities were marked in standing position.

Postoperative assessment involved duration of surgery, post-operative pain and analgesics requirements, early complications and resumption of activities.

TECHNIQUE

All patients, submitted to surgery in an operating room, were placed in supine position; 47 were administered perivenous tumescent anaesthesia (50 ml of 2% lidocaine and 1 ml of epinephrine [1:1000] diluted in 1 L of normal saline) along the entire course of GSV (13 in EVLT group and 34 in RFA group); 48 were administered epidural, upon the choice either of the patients or of the surgeon.

After surgical exposure of the sapheno-femoral junction (SFJ) to perform ligation of GSV near its ending and after thorough ligation and excision of all tributaries and ligation of the large perforating veins marked, the GSV was assessed nearby the malleolus by making a small venous cutdown. Patients were then placed in Trendelenburg position and the fibre was inserted at this point and passed upwards to below the point of ligation of GSV.

In the Laser group, the instrumentation employed consisted of a diode laser with an operative frequency of 980 nm and a 600 µm laser fiber (ELVES™ Biolitec AG, Italy). While pressing the pedal of the equipment, the fibre was pulled, according to its white spacing markers, while a 9W energy was applied. Treatment progress was assessed by probing the tract with the laser fibre.

In the RFA group the instrumentation employed was an RFG2 Plus Generator™ (VNUS medical Technologies, San Jose, CA). During energy emission, automatically adjusted by generator between 15 to 40 W for reaching and maintaining 120°C during 20-s cycles, the catheter was withdrawn every 6.5 cm, according to its white spacing markers, which indicated the pullback distance for each of the two treatment cycles we provided. The average procedure time in EVLT group was 75 minutes, with the majority of patients being operated on in 60-90 minutes, while in the RFA group, the average time required was 65 minutes with the maximum number of patients operated on in 50-80 minutes.

The stab incisions were closed with a subcuticular suture.

Compression bandages were applied to the operated limb from below up-wards at the end of the operation.

Postoperatively, endovenous infusion of 500 ml of normal saline with 60 mg of Ketorolac trimetamine and 80 mg of Pantoprazole was administered, at an infusion rate of 50 ml per hour.

No deep venous thrombosis prophylaxis was given.

Results

Patients walked after 5 hours and were discharged 8 hours after surgery, with their compression bandaging, to be left in place for 24 hours. Later on, it was replaced by class II elastic compression, for 15 days.

Subjects returned to the hospital on post operative day (POD) ^{3,7,15}.

Two patients (2.74%), in the laser group experienced skin burns in the course of the GSV. Moderate ecchymosis, by laser fibre-induced perforation of the vein wall, were observed in another two patients (2.74%). Four limbs (5.48%) in the EVLT group developed transient paraesthesias.

Analgesic requirement (Paracetamol 1000 mg) on POD 3 was nil for RFA group; conversely half of the EVLT patients did take analgesics, either 2 or 3 tabs were required. On POD 7, the patients of RFA group continued to not ask for any analgesics, but the same half of the patients in EVLT group still needed 1-2 tabs to carry out their normal activities smoothly. On POD 15, no patient did require analgesics.

Skin burns and ecchymosis disappeared as well as paraesthesias.

Resumption of routine activities was earlier for RFA group patients than for those in the EVLT group. The RFA group resumed their activities within 3 days, whereas EVLT group in 8-9 days.

Discussion

Primary varicose veins are a common problem in western countries ⁷. The most common site for reflux is the GSV ^{2,3}. The standard treatment for this reflux was surgical stripping of the vein from the groin to the ankle with high ligation of the SFJ. Its main disadvantage is postoperative pain and discomfort, bruising and hyperpigmentation, lymphoceles and hematomas, inesthetic scars and a 20-60% rate of incidence of recurrence ⁴.

Constant search for therapy cosmetically more acceptable and with less morbidity has resulted in minimally invasive endovenous treatments. RFA, which uses a catheter to direct radiofrequency energy from a dedicated generator and EVLT, which employs a laser fibre and generator to produce focused heat, are among these.

In this study, a comparison between EVLT and RFA, combined with high ligation of sapheno-femoral junction,

was made, analysing some parameters as duration of surgery, post-operative pain and analgesics requirements, early complications and resumption of activities. The average procedure time in EVLT group was 75 minutes, with the majority of patients being operated on in 60-90 minutes, while in the RFA group, the average time required was 65 minutes with the maximum number of patients operated on in 50-80 minutes. This slight difference in the procedure time can be explained by the difficulties we, technically, experienced more in introducing the laser fibre than the radiofrequency one; besides, the fact that we had, at the beginning of our experience, 2 laser fibre-induced perforations of the vein wall made us more cautious.

All patients were assessed for pain on POD 3, POD 7 and POD 15. When the patients were asked about pain in the postoperative period, it was found that the patients in the RFA group had minimal pain in the initial 2-3 day period, which reduced to nil within the next few days, but the patients who underwent EVLT had moderate pain in the first 7 days, which reduced to minimal within the next few days.

Early complications were skin burns in two patients in the EVLT group. This was observed at the beginning of our experience in two patients who denied local anaesthesia consent. We did not experience any more skin burns after applying cold moist gauze along the route of the vein in patients who were treated with EVLT in spinal anaesthesia.

No skin burns were detected in RFA group. Four patients in EVLT group complained of paraesthesia around the ankle postoperatively. Paraesthesia slowly reduced and disappeared in these cases.

The resumption of activities occurred earlier in the RFA group as compared to 8-9 days for patients in the EVLT group. This may be explained by the more pain experienced by this group of patients.

Complications such as skin burns are rare and they are likely to result for the high temperature used. The fact that such skin burns were not found in the patients who underwent perivenous infiltration suggests that tumescent anaesthesia means protection for the skin and surrounding structures against heat and should be considered the first choice, but, cold moist gauze along the course of the vein during the EVLT seems to be sufficient to avoid this minimal and transient adverse event. We continue to perform high ligation of the SFJ even in not stripping the vein. It's our opinion that this procedure doesn't add too much time or morbidities and may be useful to prevent, although a benign condition, heat-induced thrombosis (that we did not experience) and, above all, the first cause of recurrence in treatment of LLVV, that is inappropriate or incomplete ligation of SFJ in conventional surgery and inadequate delivery of energy to target vein in EVLT and RFA ⁸.

In conclusion, even in this very limited study, catheter delivery of thermal energies for saphenous ablation, even

if combined to high ligation of sapheno-femoral arc, demonstrates to be minimally invasive, easy to learn and easy to perform in day hospital setting, with early return to normal activity.

EVLTA achieves similar results to RFA and both techniques should be considered equally effective and safe; the results we obtained are not statistically significant but RFA seems to show less pain, ecchymosis and haematomas, as well as to provide better short-term quality of life.

Riassunto

Il trattamento chirurgico tradizionale per le varici primitive degli arti inferiori è stato per lungo tempo la legatura prossimale della giunzione safeno-femorale e lo stripping della grande vena safena. Questo trattamento è spesso complicato da dolore postoperatorio, disagio del paziente e dalle recidive. Scopo del nostro studio è valutare la fattibilità, in un contesto di day hospital, di un approccio combinato mini-invasivo di legatura prossimale della giunzione safeno-femorale con il trattamento termico della vena grande safena.

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