Varicose veins: new trends in treatment in a Vascular Surgery Unit

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Daniela P. Mazzaccaro*, Silvia Stegher*, Maria Teresa Occhiuto*, Lorenzo Muzzarelli */**, Giovanni Malacrida*, Giovanni Nano*/**

**First Unit of Vascular Surgery, IRCCS Policlinico San Donato, San Donato Milanese, Milano, Italy*
***University of Milan, Milan, Italy*

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AIM: Less invasive techniques such as foam sclerotherapy, endovenous laser or radiofrequency ablation have recently been introduced as a valid alternative to surgery for the treatment of varicose veins (VVs). We retrospectively reviewed our experience in the treatment of VVs with particular attention to how our therapeutic approach has changed over the last years.
MATERIAL OF *STUDY: Data of all patients consecutively treated from September 1st 2013 to July 31st 2015 for both primitive and recurrent VVs were retrospectively collected and analyzed. Statistical analysis was performed using the software JMP 5.1.2 (SAS Institute).*
RESULTS: *A total of 409 legs in 378 patients were treated. The percentage of stripping of the great saphenous veins (GSV) for primary VVs has decreased over the years (67% in 2013 vs 15.2% in 2015), differently from what happened to the percentage of RFA of the GSV (14.3% vs. 31.5% respectively in 2013 and in 2015) and to the percentage of legs treated with the A.S.V.A.L. technique (8.7% vs. 31.5% respectively in 2013 and in 2015). Likewise, in 2013 most procedures were performed using spinal anesthesia (77.5%), while in 2015 the most used anesthetic techniques were both the local anesthesia and the local anesthesia with conscious sedation (35.9% and 29.3% respectively). Postoperative course was uneventful in all cases but seven (1.7%). At follow-up (median 16.9 months, IQR 7.5-22.6 months), neither major adverse events nor deaths were recorded.*
CONCLUSIONS: *During the years of our experience, we observed a trend towards a less invasive approach for the treatment of VVs, with safe and effective results.*

KEY WORDS: Ablation Radiofrequency, Stripping, Varicose veins

Introduction

Chronic venous insufficiency (CVI) is the most common disease affecting the vascular system in the adult population[1]. A large amount of patients comes to the attention of the surgeon for the presence of varicose veins (VV). For almost 100 years surgery of the saphenous vein, by stripping it, has been the gold standard [2]. Recently, new less invasive treatments have caused a paradigm shift in the treatment of varicose veins. Foam sclerotherapy, endovenous laser or radiofrequency ablation have the advantage of less pain after the procedure, fewer complications, and a quicker return to work and normal activities with a lower need for either general or spinal anaesthesia and improved patients' quality of life [1].
We retrospectively reviewed the experience in the treatment of VV in our Operative Unit of Vascular Surgery with particular attention to how our therapeutic approach has changed over the last years.

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Correspondence to: Daniela P. Mazzaccaro, MD, Unit of Vascular Surgery, IRCCS Policlinico San Donato, Piazza Malan 1, 20097 San Donato Milanese (MI), Italy (E-mail: danymazzak83@libero.it; daniela.mazzaccaro@gmail.com)

Materials and Methods

Data of all patients consecutively treated from September 1st 2013 to July 31st 2015 for both primitive and recurrent varicose veins in our Operative Unit of Vascular Surgery were retrospectively collected and analyzed. It's a point of interest to underline that our Operative Unit performs majorly Vascular Surgery of the arterial district. However, in the last ten years, surgery of the VV has ever been performed with particular attention to newer techniques. The period of our analysis has been chosen to avoid bias due to learning curve of new treatments. In fact in our Operative Unit the systematic use of endovenous radiofrequency ablation (RFA) of the great saphenous vein (GSV) has been undertaken since 2013. Over the years, the surgical indications have changed. If possible, the GSV is preserved and varicose veins are treated using the A.S.V.A.L. technique (Ablation Sélective des Varices sous Anesthésie Locale, selective ablation of varicose veins under local anesthesia).

Each patient the very day of the procedure undergoes a careful preoperative ultrasound mapping of deep and superficial vascular system and an analysis of varicose tributaries in the upright position, with particular attention to the points of venous overload and drainage, the diameter of the incontinent saphenous vein. If the patient is to undergo endovenous ablation the GSV is studied to define the depth of the vein itself in relation to the skin surface and its rectilinear or sinuous course. Meanwhile, every vein is marked on the skin and a particular mark is posed in the region where the vein itself can be easily accessed.

If the GSV cannot be preserved because of a severe incompetence (defined as reflux which lasts more than 0.5 sec at duplex scan [3]), it is preferably treated by RFA. The stripping is reserved to cases in which the RFA is contraindicated, such as GSV diameter ≥ 1.5 cm, active superficial phlebitis [3], significant tortuosity of the GSV, distance from the skin < 5 mm [4] presence of a double GSVs both of them responsible for varicose veins (Fig. 1). During the collection of data, particular attention was paid to the type of operation, the anesthetic techniques and the length of hospital stay, with analysis of how each trend has changed over those two years.

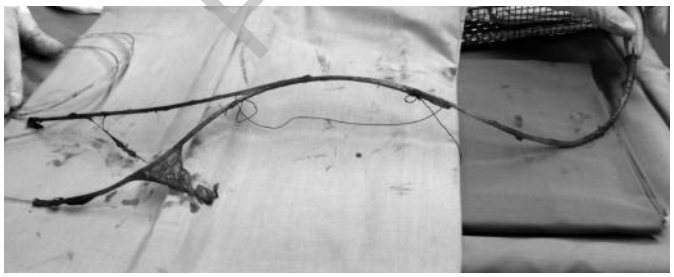

Fig. 1: Intraoperative image of stripping of a double GSV both of them sustaining VV at the level of the thigh.

RFA Technique Protocol

The RFA technique is used for the treatment of GSV alone and it has a standardized application protocol [5]. In the Operatory Room, the patient is placed in Trendelenburg position, and the GSV previously mapped is accessed generally with either a surgical cutdown or via percutaneous approach at the level of the knee using ultrasonography guidance. Once venous access is obtained, the RFA catheter is advanced with the assistance of ultrasonography till 1-2 cm above the saphenofemoral junction (SFJ), immediately inferior to the origin of superficial epigastric vein. A tumescent anesthesia using 1% lidocaine, bicarbonate and cold saline solution is injected along the vein within the saphenous sheath achieving a vein depth of at least 1 cm from the skin and a shrinkage of the vein itself on the catheter. The temperature of the probe is automatically set by the device at 120°C. The catheter is then withdrawn along the vein at interval of 7 cm every 20 seconds. After catheter withdrawal has been completed, ultrasonography is performed to confirm patency of the common femoral vein and superficial epigastric vein, and the successful closure of the vein. If necessary, the procedure is completed with phlebectomies under local anesthesia. At the end of the procedure, an elastic stock (30-40 mmHg) is applied to the treated leg and the patient is suggested to wear it at least one month in orthostatic position. The patient is usually discharged two hours after the procedure, if either a local or a local and sedation anesthesia is performed and he can resume normal activities immediately. At discharge, a follow-up ultrasonography is performed to confirm procedural success and the absence of clot extension into the femoral vein.

Surgery

Surgery of the GSV is almost ever performed as stripping at the level of the knee in association with phlebectomies. Stripping is usually performed in a retrograde fashion with the invagination technique.

Surgery of the small saphenous vein (SSV) is carried out with an incision at the level of the popliteal fossa where the vein is still superficial before entering the deep venous system. Similar to surgery of the GSV, SSV if necessary is stripped in a retrograde fashion with the invagination technique.

Both GSV and SSV surgery is completed with selective phlebectomies.

Phlebectomies alone with the A.S.V.A.L. technique are the treatment of choice when the saphenous trunk is not yet diseased considering either hemodynamic reflux or diameter. Surgical incisions for the phlebectomies are as small as possible (1-3 mm) and so performed with the distal part of a Nr. 11 blade. Muller's hook allows the aesthetic and efficient removal of all types of VVs

according to the technique invented by Dr. Robert Müller [6].
In case of important incompetence of SFJ causing VVs from the groin, with good diameter and no reflux of all the GSV we usually perform a sapheno-femoral crossectomy and A.S.V.A.L.
Considering our experience with recurrent VVs (REVAS)[7], surgery is carried out through a lateral approach with flush SFJ ligation as described in Li intervention.
In order to optimize the number of cut-downs and obtain the best cosmetic result, the site of the surgical incisions is mapped on the skin via ultrasound considering the region where the VV can be accessed as easily as possible and successfully.
Each patient after surgery is suggested to wear an elastic stock of 22-30 mmHg for a month at least in orthostatic position.

Anesthetic Techniques

The choice of the appropriate anesthetic technique depends on the type of treatment of VVs and on the extension of themselves.
Stripping is usually performed using either a spinal or a general anesthesia, according to the indication given by the anesthesiologist and the preference and compliance of each patient.
On the other side, both RFA and A.S.V.A.L. are performed using local anesthesia with or without a conscious sedation, whenever possible.
Intraoperative antibiotic prophylaxis is not routinely performed neither for surgical nor for endovenous procedures, except in case of history of recurrent infections, CEAP C6 clinical presentation and history of diabetes.
In our Operative Unit, each patient is routinely discharged on Low Molecular Weight Heparin (LMWH, 100 IU/kg daily) for 14 days if a procedure is conducted on a saphenous axis or in case of surgery for recurrent VVs requiring redo surgery on the groin or at the calf. Patients undergoing phlebectomies are usually not discharged on LMWH. Exceptions in both groups are individually discussed according to internal guidelines [8,9].

Statistical Analysis

Given the nature of the study, statistical analysis was performed in a descriptive manner using the software JMP 5.1.2 (SAS Institute). Categorical data are presented as number and percentage. Continuous data are expressed as median and interquartile range (IQR).

Results

From September 2013 to July 2015, a total of 409 legs in 378 patients were treated for CVI (clinical presentation in class C2-6 according to CEAP classification).
Among them, 296 were women (78.3%). The median age was 54 years (IQR 46-67).
As described in Table I, the percentage of stripping of the GSV has decreased over the years (67% in 2013 vs 15.2% in 2015), differently from what happened to the percentage of RFA of the GSV (14.3% vs. 31.5% respectively in 2013 and in 2015). Also the percentage of legs treated with the A.S.V.A.L. technique has increased from 2013 till now (8.7% vs. 31.5% respectively in 2013 and in 2015).
Likewise, in 2013 most procedures were performed using spinal anesthesia (77.5%), while in 2015 both the local anesthesia and the local anesthesia with conscious sedation were most used (35.9% and 29.3% respectively) (Fig. 2). Also in case of unsuccessful attempt of RFA of the GSV requiring surgical conversion to stripping, the procedure was performed using local anesthesia and adding conscious sedation during stripping manoeuvre, without any problems.
Stripping of the GSV was performed at the proximal third of the leg (high ligature) in all but thirteen cases, in which the GSV was totally removed at the level of the ankle. Regarding the RFA of the GSV, in the first

Table I - *Details about type of procedures performed for the treatment of varicose veins.*

	09/2013 – 12/2013 N=129	01/2014 – 12/2014 N=188	01/2015 – 07/2015 N=92
Stripping of the GSV	67%	30.3%	15.2%
Stripping of the SSV	1.4%	7.9%	3.3%
A.S.V.A.L. for primary varicose veins	8.7%	22.8%	31.5%
A.S.V.A.L. for recurrent varicose veins	3.6%	9.2%	13.1%
RFA of the GSV	14.3%	22.9%	31.5%
SFJ ligation	4.3%	3.2%	1.1%
Redo surgery (both SFJ and SPJ)	0.7%	3.7%	4.3%

Legend: GSV = great saphenous vein;SSV = small saphenous vein; ASVAL = Ablation Sélective des Varices sous Anesthésie Locale; RFA = RadioFrequency Ablation; SFJ = sapheno-femoral junction; SPJ = sapheno-popliteal junction

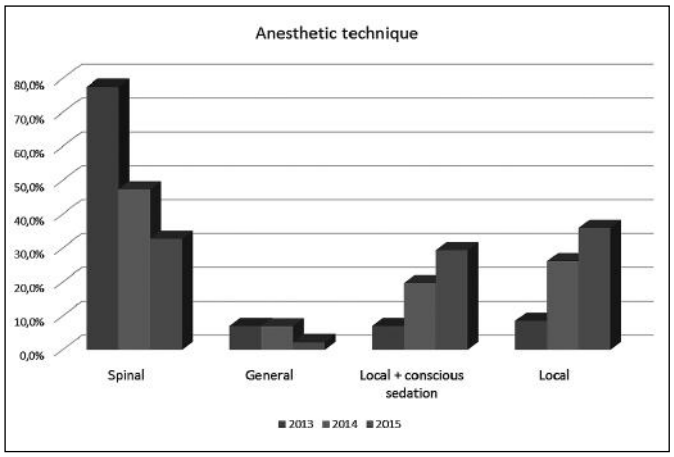

Fig. 2: Trend of the anesthetic technique for treatment of vein pathologies. Note the massive decrease in the use of invasive spinal and general anesthesia in favor of local anesthesia with or without conscious sedation.

period of our experience a little cut-down was usually performed to access the GSV at the level of the knee. Thereafter, a percutaneous access was performed whenever possible (none of the RFA of the GSV performed in 2013, 17.4% in 2014 and 33% in 2015). Conversion to surgical cutdown was reserved in case of spasm of the vein consequent to excessive manipulation of the vein itself with the needle.

RFA of the GSV was completed in 81 out of 87 cases (93.1%), as a surgical conversion was needed in 6 cases in which the RFA catheter could not be advanced through the GSV. In three of these patients, the stripping was performed using the local anesthesia with conscious sedation without any problems. In one case only, conversion to general anesthesia was needed for the patient's anxiety and discomfort despite sedation. In the remaining two cases, spinal anesthesia had already been chosen for the RFA procedure.

In two out these 6 cases, the surgical conversion was due to accidental perforation of the GSV at the tight level without any possibility to gain the lumen. In fact, even in the surgical option, a double stripper was needed in both antegrade and retrograde fashion. In three cases, we had probably underestimated the tortuosity of the vein previously mapped at the preoperative duplex scan, which however resulted to be excessive during the procedure, making it impossible to advance for the RFA catheter. In the last case, the GSV resulted to have a segmentary fibrosis at middle tight, where the vein itself was in a deep position and that was not correctly recognized during the preoperative duplex scan.

Treatment of CVI of the small saphenous vein (SSP) included sapheno-popliteal junction (SPJ) ligation in all cases and a stripping of the proximal segment of the SPP in 9 out of 11 cases (81.8%). We have had no experience of RFA of the SSP till now. Nevertheless, no neurological impairment was recorded after surgery.

Recurrent varicose veins after surgery were treated with either phlebectomies or surgical re-exploration of the SFJ or SPJ as appropriate (Table I).

Postoperative course was uneventful in all cases but seven (1.7%). In fact, a patient presented a thigh erysipelas three days after RFA procedure. She was successfully treated with local medicaments, oral antibiotics and non-steroidal anti-inflammatory drugs. One patient on post-operative day 1 presented an incomplete occlusion of the GSV after RFA at duplex scan, however with a reduction of the mean diameter of the vein and no more reflux at distal compression. Two patients were recognized to have a groin infection three-four days after GSV stripping. They were treated with antimicrobial therapy and no wound dehiscence was recorded thereafter. In the remaining three cases, large hematomas following two GSV stripping and one REVAS respectively occurred, which however spontaneously resolved using only elastic stocks.

The patients were discharged in the same day of the procedure when a local anesthesia with or without conscious sedation was performed. When either a spinal or a general anesthesia was performed, the patient was discharged on the following day.

At follow-up (median 16.9 months, IQR 7.5-22.6 months), neither major adverse events nor deaths were recorded. All patients who had undergone a RFA of the GSV had a successful occlusion of the vein itself at follow-up duplex scan. No recurrence was noted after surgery.

Discussion

The introduction of new less invasive approaches for CVI and varicose veins has caused a paradigm shift of treatment, in an attempt to improve patients' quality of life, to shorten either in-hospital stay and postoperative course, obtaining a quicker return to work and normal activities [1].

The advent of intravenous endoablation has in fact resulted in a dramatic decrease in the number of the stripping operations performed. Newer methods (non-thermal non-surgical), such as techniques that combine sclerotherapy with me+chanical disruption of the vein endothelium, are also emerging.

Both endothermal ablation and foam sclerotherapy were initially adopted without adequate evidence, driven by the enthusiastic pursuit of innovation and less invasive methods of treatment.

However good results with the use of radiofrequency endovenous ablation have been reported since 2008 by Pisano and Coll., who reported about 107 C2 CEAP patients who were successfully treated with immediate improvement of clinical symptoms and an optimal 5-year follow-up [10].

Recently, important trials and reviews have provided evidence recommending a sequential approach for the treatment of any patient with VVs, ranking endothermal ablation as the first method of choice, followed by foam sclerotherapy. Surgery is considered if both endothermal ablation and foam sclerotherapy are unsuitable [11,12].
This particular trend toward a less invasive approach was recorded in our experience too. Our results suggested an increase in number of endovenous radiofrequency ablation and of phlebectomies which were performed between 2013 and 2015, with a parallel decrease in the number of saphenous vein stripping procedures. When GSV stripping was performed, the preferred method was the high ligation rather than the total stripping at the ankle, in order to minimize the accidental risk of saphenous nerve injury. In some of latest cases, in the presence of functioning femoral and saphenous terminal valves, sparing of the superficial epigastric vein was also performed when possible, with a selective-haemodynamic sapheno-femoral junction ligation, as described by Genovese and Coll. [13].
This change in treatment also resulted in a lower need for either general or spinal anesthesia, with an increase in the number of procedures that could be performed under local anesthesia with or without conscious sedation. In the general management of perioperative care, this means no need for overnight in-hospital stay, with a greater comfort for the patient. Moreover he retains a better physical and emotional perception of the procedure. He also has a quicker recovery of the motility of the lower limbs and a quicker return to daily activities. Even in case of unsuccessful attempt of RFA of the GSV and need of immediate conversion to surgery, in our experience a well conducted local anesthesia with conscious sedation was enough to allow the surgical procedure, reducing patient's discomfort due to the eventual conversion to general anesthesia.
From the surgical point of view, our results suggested that the duplex scan has a central role in the definition of the pathology and of the appropriate treatment, with the basic idea to preserve the saphenous vein whenever possible, by making an extensive use of the A.S.V.A.L. technique [14]. The solution is pretty: the A.S.V.A.L. technique aims to eliminate only collateral varicose tributaries, if they are considered the origin of the disease. According to the A.S.V.A.L. technique, the mere fact of removing diseased varicose veins allows the saphenous vein to fully recover its function. As described by Pittaluga and Coll. [14], this treatment can be performed safely in a large group of patients with good midterm results, thanks to a proper exclusion of cases with advanced chronic venous disorder.
The patients are however preoperatively informed that every treatment is never definitive for the varicose disease itself but it has only the aim to resolve the VVs and their symptoms. A careful secondary prevention and follow-up visits are therefore suggested over the years.
Foam sclerotherapy is not yet routinely used as a primary therapy for saphenous axis in our Operative Unit. However, there is evidence in favor of ultrasound-guided foam sclerotherapy (UGFS), which was described as the simplest, quickest and cheapest method for varicose vein treatment. According to Krnić [15], it yielded satisfactory functional and cosmetic results with acceptable side effects, particularly at long term.
Moreover, Ebner H and Coll. [16] recently reported that in Italy perioperative sclerotherapy is widely used, mainly in the form of postoperative adjuvant sclerotherapy, but it is also used intraoperatively as sclerosurgery, with a reduced invasiveness of varicose vein surgery.
Despite all the publications in the literature, there is no firm evidence that one method of treating VVs is universally the best [17]. Currently available clinical trial evidence suggests that UGFS, endovenous laser therapy (EVLT) and RFA are at least as effective as surgery in the treatment of great saphenous varicose veins [3].
However, the general trend for the treatment of VVs is towards an improvement of patients' comfort with a global reduction of the invasiveness of the surgical act and of the risk of postoperative complications, keeping a good technical success with a full patients' satisfaction. Certainly, the retrospective and descriptive nature of our study represent also its main limit.

Conclusion

During the years of our experience, we observed a trend towards a less invasive approach for the treatment of varicose veins. In particular for primary varicose veins involving the GSV, the number of stripping has reduced over the years in favor of an increased number of A.S.V.A.L. procedures, when feasible, and RFA. This change in the modality treatment reflected a shift in the anesthetic technique also, with an increased number of either local or local with conscious sedation anesthesia rather than either a spinal or a general anesthesia.

Riassunto

La recente introduzione di tecniche meno invasive in alternativa al tradizionale stripping safenico ha rivoluzionato il trattamento delle vene varicose (VV), soprattutto nelle Unità Operative a prevalente indirizzo flebologico, ove la scleroterapia con mousse, il laser o la termoablazione con radiofrequenza (RFA) vengono applicate sempre più frequentemente con parallela riduzione del ricorso alle tecniche di chirurgia open. Nella nostra Unità Operativa Complessa di Chirurgia Vascolare, la patologia venosa viene affrontata da sempre, parallelamente a quella arteriosa; in particolare dal 2013, superata la prima fase di apprendimento, anche nella nostra Unità Operativa è stato introdotto l'uso sistematico della RFA

per il trattamento dell'incontinenza della vena grande safena (VGS). Abbiamo dunque retrospettivamente esaminato la nostra esperienza nel trattamento delle VV con particolare analisi del modo in cui il nostro approccio terapeutico è cambiato nel corso degli ultimi anni.
I dati di tutti i pazienti trattati consecutivamente dal 1 settembre 2013 al 31 Luglio 2015 per VV essenziali e recidive sono stati pertanto retrospettivamente raccolti e analizzati. L'analisi statistica è stata effettuata utilizzando il software JMP 5.1.2 (SAS Institute). Sono state trattate in totale 409 gambe in 378 pazienti. La percentuale di stripping della VGS per VV essenziali è diminuita nel corso degli anni (67% nel 2013 contro il 15.2% nel 2015), a differenza di quello che è successo alla percentuale della RFA della VGS (14.3% vs. 31.5% rispettivamente nel 2013 e nel 2015) e alla percentuale di gambe trattate con la tecnica ASVAL (8.7% vs 31.5%, rispettivamente, nel 2013 e nel 2015). Analogamente, nel 2013 la maggior parte delle procedure è stata eseguita utilizzando l'anestesia spinale (77.5%), mentre nel 2015 le tecniche anestesiologiche più utilizzate sono state l'anestesia locale e l'anestesia locale con sedazione (rispettivamente 35.9% e 29.3%). Il decorso postoperatorio è stato regolare in tutti i casi tranne sette (1.7%). Al follow-up (mediana 16.9 mesi, IQR 7.5-22.6 mesi) non sono stati registrati eventi avversi maggiori né decessi. Durante gli anni della nostra esperienza, abbiamo osservato una tendenza verso un approccio meno invasivo per il trattamento di VV, con risultati sicuri ed efficaci.

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