

Doppler ultrasound in the evaluation of recurrence after endovenous laser ablation of the great saphenous vein

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Abstract. Introduction. Recurrent varicose veins (RVV) are a common complication after varicose vein treatment, regardless of the applied therapeutic method. The aim of the present study was to establish the role of Doppler ultrasound (DUS) in the assessment of RVV in patients treated with endovenous laser ablation (EVLA) of the great saphenous vein varices (GSV), as compared to conventional surgical treatment. Material and method. Patients with conventional surgical treatment, interruption of the saphenofemoral junction (crossectomy), saphenectomy (stripping of the great saphenous vein), or/and phlebectomies were eligible for inclusion in the study. Also, patients with endovenous laser treatment performed on the GSV, too, under ultrasound guidance, were eligible. RVV were assessed in both groups, 2 years postoperatively, by DUS examination. Results. One hundred and thirty-eight patients with RVV were included in the study. Seventy four patients had conventional surgical intervention (group 1) for varicose veins and sixty-four had laser endovenous intervention (group 2). Ultrasound-detected varicose recurrence was present in all of the patients in our study, but only 16.66% was concomitantly present the clinical recurrence (clinically manifest). The differences in postoperative results between the two treatment methods during our study were not statistically significant. Conclusions. DUS is the golden standard in the diagnosis of RVV consecutive to interventions on the superficial venous system. Because ultrasound detected reflux is not always accompanied by clinically manifest symptomatology in RVV, careful and periodic ultrasound monitoring of the patients with chronic venous disease is necessary.

Key Words: recurrent varicose veins, ultrasound detected recurrence, clinical recurrence.

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Introduction

Varicose veins are given by chronic venous insufficiency and are associated with progressive impairments and comorbidities such as venous ulceration in stage C5 and C6 (CEAP – Clinical-Etiology-Anatomy-Pathophysiology classification from C2 (varicose veins without skin changes) to C6 (active venous ulcer) (Eklöf et al 2004; Darvall et al 2012), as well as with high cost of treatment. Furthermore, the quality of life of patients with varicose veins decreases with the increase of clinical grade (is inversely proportionally correlated with the clinical stage at admission in hospital (Gloviczki et al 2011 and Moore et al 2013). The prevalence of chronic venous insufficiency is higher in females (<1% to 40%) compared with males (<1% to 17%) with a similar pattern of prevalence of varicose veins (females:males = <1% to 73%:2% to 56%) (Carradice et al 2011). The main risk factors for varicose veins as reported in the specialty literature are family history, age, gender, previous

deep venous thrombosis, obesity, occupations (job) associated with orthostasis, and congenital conditions such as Klippel Trenaunay Syndrome (Beebe-Dimmer et al 2005; Kohno et al 2014; Wittens et al 2015). Similar risk factors for varicose veins has been reported in Romanian population, with higher frequency in females, overweight or obese patients, family history, and prolonged standing/sitting (Bahk et al 2012). In most of the cases the females are more affected by varicose veins (Moraru 2017), but in some populations, such as in Indian population for example, the pathology seems to be more frequent in males (Wrona et al 2015; Mirji et al 2011).

Different treatment options are available and directly linked with CEAP classification. Compression stockings, lifestyle changes such weight loss, leg elevation after prolonged orthostatism and oral medication are the most frequently used conservative measures. Conventional surgical methods, such as crossectomy (interruption of the saphenofemoral or saphenopopliteal

junction), saphenous vein stripping or phlebectomy, as well as minimally-invasive methods (such as foam sclerotherapy, endovenous laser ablation (EVLA) or radiofrequency ablation) represent other treatment options (Nitin *et al* 2016).

Recurrent varicose veins (RVV) are a common evolution (complication) after varicose vein treatment, regardless of the applied treatment method and can be radiologically, ultrasonographically or clinically assessed. RVV treatment is complex, though, and usually more difficult than the initial treatments since is accompanied by a lower level of patient's satisfaction (Hamdan 2012). Ultrasound is known to be the reference (golden) standard in the evaluation of the morphology and hemodynamics of the lower limb veins (Theivacumar *et al* 2009). The recurrence is reported to occur in 10-30% of cases after endovenous ablation (radiofrequency or laser therapy) and less frequent for stripping and excision (10-20%) (van Groenendael *et al* 2009). The comparison of EVLA with conventional surgery revealed fewer wound infections or paresthesia and less recurrences at 25 weeks (19% vs. 29%) for the conventional surgery (Groenendael *et al* 2009) with no significant differences at 2 years follow-up (Paravastu *et al* 2016). However, the quality of life reported in regards of recurrence after EVLA compared with conventional surgery are moderate to low quality (Avram *et al* 2003). Few data regarding this subject exists in literature concerning the Romanian population. Evidences depend largely upon the therapeutic strategy applied in case of recurrence (Avram *et al* 2003), for example occurrence of complications after conventional surgery consists of lipodermatosclerosis 467/1066, 26.92%, as the mostly frequent related complication, closely followed by varicophlebitis - 24.11% (Mironiuc *et al* 2010). Following these regards, the aim of our study was to evaluate the two-year ultrasonographic recurrence of varicose veins in a Romanian sample of subjects comparing endovenous laser ablation treatment with conventional surgical method.

Material and method

Study protocol

The study was conducted on patients, who addressed themselves at County Clinical Emergency Hospital of Cluj-Napoca, for two-year follow-up after a previous endovenous laser ablation (EVLA) or conventional surgery (CVS) of lower limb varicose veins, since 2014 until 2017. There were included in the study 138 adult subjects with ultrasonographic recurrence of varicose veins, diagnosed with stage C2-C6 lower limb venous insufficiency. Patients who did not agree to participate, pregnant or lactation women, subjects with other surgical intervention in the inguinal region or deep venous thrombosis did not meet the inclusion criteria and, therefore, were excluded from the study. The study was conducted according to the principles of the Declaration of Helsinki and was approved by the university ethical committee. All subjects included in the study signed an informed consent.

The Doppler ultrasound was performed with a Mindray Color Doppler Ultrasound (DC-6; MA-08102247) system using a 7L4A linear probe (5.0/7.5/10.0 MHz) by the same examiner on all subjects. Initial examination was done in module B, the anatomical details were assessed followed by the Doppler examination when the dynamic characteristics were evaluated. The great saphenous vein (GSV), the anterior accessory saphenous

vein (ASV) and the short saphenous vein (SSV) were evaluated, both morphologically and dynamically, searching for the presence of reflux. Diameter measured 3 cm above/below (proximally/distally) ? from the saphenofemoral junction and from the saphenopopliteal junction, were considered normal if the values were up to 3 mm. The diameter of the perforator veins, the vast majority of which were located on the medial region of the thigh and calf, were also measured and tested for reflux, through observation of the inflow and outflow at the fascia level. Both limbs were ultrasonographically evaluated and the hemodynamic changes, assessed by color Doppler ultrasound were noted after Valsalva maneuver or calf and thigh compression. The reflux more than 0.5s in the saphenous or higher than 0.35s in the perforator veins was considered significant (Wittens *et al* 2015). The GSV residual stump remained after crosssectomy or recanalization of the GSV after EVLA were efficiently evaluated during the Doppler ultrasound examination. The presence of recanalization of the GSV post crosssectomy through residual tributary, like the inferior epigastric vein, the superficial circumflex iliac vein or the external pudendal vein, was identified and differentiated from the neovascularization in the same area. The ultrasound evaluation was performed on two stages, at admission and at two year follow-up after conventional or endovenous treatment.

Statistical analysis

Qualitative data were summarized as absolute and relative frequencies. Quantitative variables were summarized with median and interquartile range if proved not to follow the normal distribution (Shapiro Wilk test). Chi-square test (with or without corrections) or Fisher exact tests were used to test the association on qualitative data. Mann-Whitney test was used to compare quantitative data on the group with conventional surgical intervention and respectively laser intervention, with 95% confidence interval (Jäntschi *et al* 2010). Statistical analysis was done with Statistica software (StatSoft, USA, v.8) and the tests were considered statistically significant if p-value was less than 0.05.

Results

Studied groups

Two thousand six hundred and eighty subjects referred to our clinic for two-years follow-up after treatment of varicose veins, among these, 138 presented ultrasonographically recurrence and were included in the study. Sixty-four patients were previously treated with EVLA and seventy-four underwent conventional surgical treatment. The main demographic and clinical characteristics of the patients included in the study are presented in Table 1.

Comparing the two groups of interest, most of the patients in the EVLA group presented symptomatic varicose veins (without trophic lesions) (77%), while 23% were in stages C4-C6. In the CVS group, 60% of subjects were in the early stages, C2 and C3 and the remaining 40% were in the more advanced stages, C4-C6. The distribution of subjects with different CEAP class diagnosis proved significantly different between the two groups ($p=0.0349$).

Table 1. Demographic and clinical characteristics of RVV patients

Characteristic	EVLA (n=64)	CVS (n=74)	Stat (p-value)
Age, years ^a	52 (41.5-61.25)	55 (43-65)	0.65 (0.5)
Gender ^b			
Female	52 (81.25)	58 (83.78)	0.15 (0.6)
Male	12 (18.75)	16 (16.22)	
Z-stat (p-value)	-12.81 (<0.0001)	-15.77 (<0.0001)	
Background / Environment ^b			
Rural	23 (35.94)	24 (32.43)	0.62 (0.4)
Urban	41 (64.06)	50 (67.57)	
Z-stat (p-value)	4.69 (<0.0001)	6.46 (<0.0001)	
Body mass index, kg/m ² ^a	27.5 (23.75-30)	28 (25-31)	1.31 (0.1)
Orthostatic activities, yes ^c	22 (34.38)	71 (95.95)	56.43 (<0.0001)
Stage of disease ^b			
C2	21 (28.38)	17 (26.56)	6.51 (0.08)
C3	36 (48.65)	21 (32.81)	
C4	14 (18.92)	24 (37.50)	
C5/6	3 (4.05)	2 (3.13)	
Clinical recurrence, yes ^b	10 (15.63)	13 (17.56)	4.51 (0.06)

EVLA = endovenous laser ablation; CVS = conventional surgery

a: median (Q1-Q3), in which Q=quartile; Mann-Whitney test

b: n (%), in which n=absolute frequency; Chi-Square test

c: n (%), Chi-Square Yates corrected

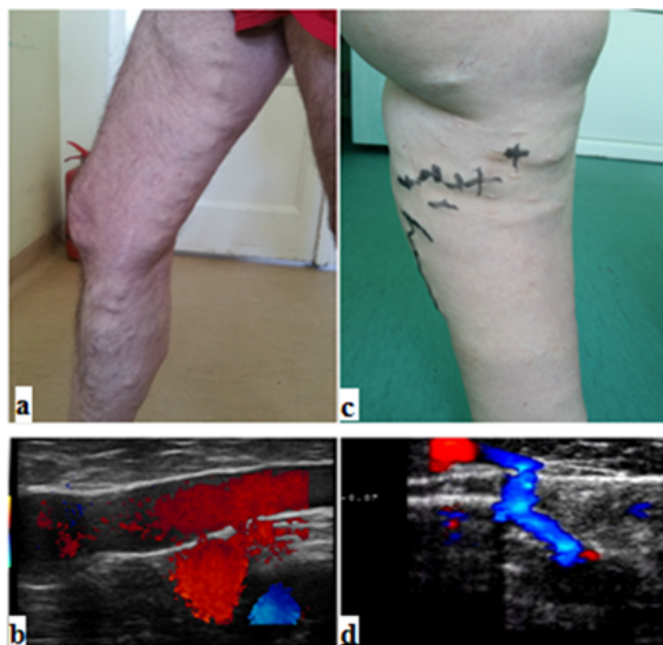


Fig. 1. RVV two years after varicose veins treatment. a), b): Clinical and ultrasound appearance of a completely recanalized GSV after EVLA; c), d): RVV due to the incompetent perforator vein in the left calf after surgical treatment.

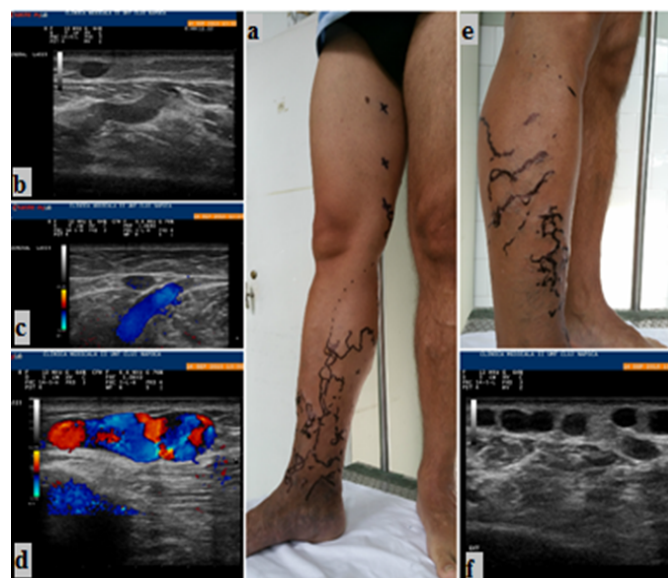


Fig. 2. RVV 2 years follow-up, after surgical treatment for right lower limb varicose veins. Male patient, 51 years old with RVV after CVS a): in orthostatism with mapping of the recurrent varicose veins; b),c): ultrasound and Doppler results, highlighting the incompetent thigh perforator vein; d): ASV with reflux; e),f): clinical and ultrasound images, highlighting the unsystematized varicose packages present on the outer anterior region of the right calf.

Table 2. Doppler examination: results by group and comparison between groups

Characteristic	EVLA (n=64)	CVS (n=74)	p-value
SFJ reflux ^a	10 (15.63)	10 (13.51)	0.913
GSV reflux/Total recanalization ^b	9 (14.06)	9 (12.16)	0.935
GSV Reflux/Partial recanalization ^b	6 (9.38)	7 (9.46)	0.100
GSV Reflux/Recanalization via SFJ collateral veins ^b	11 (17.19)	8 (10.81)	0.403
GSV Reflux/Recanalization via perforator veins ^a	11 (17.19)	12 (16.22)	0.879
Total ASV reflux ^b	3 (4.69)	5 (6.76)	0.886
Partial ASV reflux ^b	3 (4.69)	4 (5.41)	0.100
Incompetent thigh perforator veins ^b	7 (10.94)	7 (9.46)	0.992
Incompetent calf perforator veins ^b	10 (15.63)	9 (12.16)	0.755
Neovascularization ^b	4 (6.25)	9 (12.16)	0.373
Saphenopopliteal junction reflux ^b	5 (7.81)	8 (10.81)	0.763
SSV reflux ^b	4 (6.25)	5 (6.76)	0.100
GSV diameter (mm) ^c	8.05 (6-9)	7.15 (5.925-9)	0.098

EVLA = endovenous laser ablation; CVS = conventional surgery

a: n (%), where n=absolute frequency; Chi-Square test with or without correction

b: n (%), where n=absolute frequency; Fisher exact test

c: median (Q1-Q3), where Q=quartile; Mann-Whitney test

The results of the Doppler examination in the studied groups

The recurrence on GSV after EVLA involves the partial or total recanalization of the GSV (see Fig. 1), observed in our sample of subjects on 57.82% patients (95%CI [45.337-70.288]). In the CVS group, 36 patients (48%) presented recurrence on the GSV as a consequence of the partial or total stripping previously applied and the GSV reflux was emphasized by the Valsalva maneuver or through compression (reflux in the saphenofemoral junction, in incompetent perforator veins or in the affluent veins of the SFJ) (Fig. 2,3).

No significant differences were observed in regards of Doppler characteristics when EVLA group was compared with CVS group ($p>0.05$, Table 2).

The incompetent calf perforator veins were located on the inner region of the calf and were not responsible for the occurrence of the incompetent SSV, in the patients with ultrasound detected recurrences. Thus, the 9 patients (4 in EVLA and 5 in CVS) with ultrasound changes recorded in the SSV resulted as a consequence of the reflux in the saphenofemoral junction observed in 13 patients (5 in EVLA and 8 in CVS).

Clinical recurrence was detected in 16.66% (23 patients, 95%CI [23.462-48.413]) of the total investigated subjects. The clinical recurrences were slightly less frequent in ELVA group (15.62%, 95%CI [7.837-26.538]) compared with CVS group (17.56%, 95%CI [9.478-28.36]).

The surgical treatment, consisting of crossectomy, saphenectomy and phlebectomies were involved in a significantly higher proportion of cases in the CVS group. In the group of EVLA patients, the following minimally invasive methods were preferred: ultrasound-guided foam sclerotherapy, liquid sclerotherapy or laser treatment. Almost 65% of the RVV patients benefitted from one of these treatment methods, while the rest of them were administered phlebotonics, locally or systemically



Fig. 3. RVV at two-years follow-up after conventional surgery, left lower limb. a) patient in orthostatic position with ASV clinically visible; b),c): reflux in the SFJ and in the inferior epigastric vein.

and received elastic compression therapy, alongside measures to reduce risk factors (diet, physical exercise).

Discussions

It was possible to correctly assess RVV by using DUS in our study. The Doppler examination, which was performed with accuracy and thoroughness, proved to be useful in the examination and treatment of RVV patients both after conventional surgical

treatment and after endovenous laser treatment. The demographic data of the patients of the two studied groups showed significant differences in terms of prevalence of female patients, the proneness to overweight and prolonged orthostatism.

Age, gender, obesity, and extensive orthostatism are acknowledged as basic risk factors in the occurrence of RVV (Rass et al 2015). Although RVV occurs 2 to 3.5 times more frequently (Geier et al 2009), there are certain authors, such as Theivacumar et al, who report a RVV recurrence rate two times greater in male patients (Theivacumar et al 2009).

Studies conducted in order to appreciate the influence of the BMI on the occurrence and evolution of RVV incriminate obesity (Rabe et al 2006) and morbid obesity, but also overweight (BMI \geq 25) (Wittens et al 2015), not only as risk factors in ultrasound-detected varicose recurrence, but also in clinical recurrence. The proportion of cases in clinically advanced stages C4-C6 in the case of surgically treated patients is two times greater as compared to the data in the literature (Rass et al 2015). This is explained by the fact that the initial surgical treatment too was applied in advanced stages of the disease, and so the trophic disorders did not have time or efficient conditions to remit inside this 2-year interval.

The DUS assessment, which is an inexpensive, portable and reproducible method, provided us with data both on the anatomy and physiology of the superficial and deep venous systems (Bush et al 2014).

The reflux in the saphenofemoral junction is an important element, which lies at the origin of RVV. It is a consequence of the insufficiency, incompetence of the axial veins or their tributaries. The reason why a fundamental principle in the treatment of varicose disease is the interruption of the reflux areas, mening crosssectomy with the ligation of the GSV tributaries (Brake et al. 2013).

In our study, in the case of patients with ultrasound recurrences, the reflux in the saphenofemoral junction was more frequently encountered in the case of EVLA patients (15.63%) as compared to those who underwent surgical treatment, but lower than the values reported in the literature. Rasmussen et al revealed reflux in 18% of the EVLA-treated patients and in 10% of the surgically treated patients, while Disselhoff et al detected reflux in 22% of EVLA patients and in 28% of the surgically treated patients (Disselhoff et al 2011; Rasmussen et al 2013).

Among patients with SFJ reflux, only 85% have reflux in the GSV (Theivacumar et al 2007), fact also confirmed by the results of our study. ASV reflux also plays an important role in RVV; some authors recommend first intention ablation, even under the conditions in which the ASV is competent (Rasmussen et al 2010).

The thigh and calf perforator veins contribute to the occurrence of RVV, especially in surgically treated patients, as do the collateral veins of the GSV arch that remained unligated. Both can contribute to GSV recanalization. Bush et al identified the incompetent perforator veins, with a reflux of over 0.35 s, in 77% of the RVV patients (Bush et al 2014), which is superior to the values we obtained.

Neovascularization was noticed more frequently in the inguinal area in patients treated surgically than it was in EVLA patients, probably as a consequence of tissue trauma, with a subsequent release of angiogenic factors. Because in the absence of

a histological examination the assessment of neovascularization by ultrasound methods has a sensitivity of 42%, a specificity of 85.7%, and a predictive value of 60% (Geier et al 2009), we are reluctant to make any further assessments.

In the case of RVV, the ultrasound-detected recurrence was present even in the absence of any clinical recurrence. This aspect has been proven by clinical studies conducted for this purpose, which demonstrated an ultrasound-detected recurrence in proportion of 64% after 5 years, alongside a clinical recurrence rate of 4% (Chapman-Smith et al 2009; Labropoulos et al 2007). A possible limitation of our study could be the 2-year observation period, which could be extended to up to 5 years, with the observation and monitoring of the same parameters or by collecting new ones, such as: the number of vessels, their diameter, and reflux velocity, correlated with the severity of the disease. As a vascular examination method, the continuous Doppler could also have been available, but it does not provide morphological information on the superficial venous (Wittens et al 2015). Doppler ultrasound, on the other hand, being based on a combination of ultrasound imaging and pulsed Doppler wave, to which further color flow images may be added, is useful in the appreciation, from an anatomical and hemodynamic point of view, of the veins of the lower limb, and even of valvular incompetence (Molnar et al 2019). Being a highly reproducible method, it is the main method currently recommended in the examination of varicose veins, plethysmography, photoplethysmography, or phlebography being reserved for exceptional cases (Wittens et al 2015).

Despite the progress that has been made and despite an increase in the availability of the pre- and postoperative assessment of varicose patients, the recurrence rate after conventional surgical treatment continues to remain high (Theivacumar et al 2013). However, after the endovenous laser method, which has been used for more than 10 years in the treatment of varices and in whose case an ablation success rate of 79% is reported at 66.1 months (Seung Je Go et al 2016), there are but few systematic long-term recurrence assessment studies (Rasmussen et al 2013). Because ultrasound-detected reflux is not always accompanied by clinical symptomatology in RVV, new causes should be identified, for which a careful and periodic ultrasound monitoring of the patient with chronic venous disease would be necessary (Theivacumar et al 2007).

Conclusions

DUS is the golden standard in the diagnosis of RVV consecutive to interventions on the superficial venous system. Because ultrasound detected reflux is not always accompanied by clinically manifest symptomatology in RVV, careful and periodic ultrasound monitoring of the patients with chronic venous disease may be helpful in the early detection and prophylaxis of recurrence.

List of Abbreviations

ASV-anterior accessory saphenous vein, BMI-body mass index, CEAP-Clinical, Etiology, Anatomy, Pathophysiology, CVS-conventional surgery, DUS-Doppler ultrasound, EVLA-endovenous laser ablation, GSV-great saphenous vein, RVV-Recurrent varicose veins, SFJ-saphenofemoral junction, SSV-short saphenous vein.

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