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Catarina Maria Vieira Brazão

Recurrence of Varicose Veins After Surgery

Recorrência de Varizes Após Cirurgia

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Catarina Maria Vieira Brazão

Recurrence of Varicose Veins After Surgery

Recorrência de Varizes Após Cirurgia

Mestrado Integrado em Medicina

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Doutora Ana Filipa Campos Jácome

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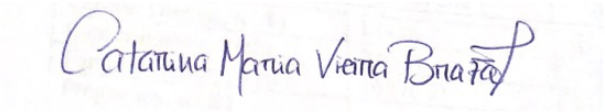
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DESIGNAÇÃO DA ÁREA DO PROJECTO

Cirurgia Vascular

TÍTULO DISSERTAÇÃO/~~MONOGRAFIA~~ (riscar o que não interessa)

Recurrence of Varicose Veins After Surgery

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ASSINALE APENAS UMA DAS OPÇÕES:

É AUTORIZADA A REPRODUÇÃO INTEGRAL DESTE TRABALHO APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	☐
É AUTORIZADA A REPRODUÇÃO PARCIAL DESTE TRABALHO (INDICAR, CASO TAL SEJA NECESSÁRIO, Nº MÁXIMO DE PÁGINAS, ILUSTRAÇÕES, GRÁFICOS, ETC.) APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	☐
DE ACORDO COM A LEGISLAÇÃO EM VIGOR, (INDICAR, CASO TAL SEJA NECESSÁRIO, Nº MÁXIMO DE PÁGINAS, ILUSTRAÇÕES, GRÁFICOS, ETC.) NÃO É PERMITIDA A REPRODUÇÃO DE QUALQUER PARTE DESTE TRABALHO.	☒

Faculdade de Medicina da Universidade do Porto, 23/03/2022

Assinatura conforme cartão de identificação: Catarina Maria Vieira Brazão

Recurrence of Varicose Veins After Surgery

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Article Highlights

Type of research: retrospective cohort study.

Key Findings: In 328 patients with chronic venous disease submitted to varicose veins surgery showed that male gender, absence of osteoarticular pathology and absence of superficial vein thrombosis history were associated with CEAP improvement, at 5 years. Secondary intervention due to REVAS was 1.6±0.7 at 3 years and 4.1±1.1% at 5 years.

Take Home Message: Clinical-reported outcomes at 5 years after surgery are somehow unsatisfactory, even if the secondary intervention due to REVAS was only 4.1% at 5 years.

Table of Contents Summary

Male gender, absence of osteoarticular pathology and absence of superficial vein thrombosis history were associated with CEAP improvement at 5 years after VVS in this retrospective cohort study of 328 patients. Clinical-reported outcomes after surgery were unsatisfactory, however secondary intervention due to REVAS was only 4.1% at 5 years.

Abstract

Introduction: Recurrent varicose veins after surgery (REVAS) are a common and costly problem of the available treatments and the etiology of these recurrences is still poorly understood. Our aim is to analyze patient's characteristics that could significantly contribute for REVAS.

Methods: This was an observational, retrospective cohort study, that included consecutive patients who underwent VVS in a tertiary hospital in 2016. Patients were excluded if they did not have a preoperative lower limb venous Doppler-ultrasound report or if did not have phone contact available.

All included patients answered to a questionnaire about demographics, comorbidities, life-style habits, and the current venous disease status. Surgery type and Doppler-ultrasound details were extracted from the clinical registries. Primary outcomes were symptomatic improvement, CEAP improvement and rate of secondary intervention due to REVAS at 5 years after surgery. Secondary outcome was to compare patients submitted to primary versus redo VVS in a case-control design.

Results: From a total of 1115 patients that underwent VVS in 2016, 328 were included in the study. The majority of patients were women (74%) with a mean and standard deviation age of 49±11 years.

Symptomatic improvement 5 years after surgery was referred by 89 patients (27.1%). Symptomatic improvement occurred more frequently in patients undergoing the first VVS (30.6%) comparing to those undergoing redo VVS (18.5%), P=0.026. CEAP improvement 5 years after surgery was reported in 162 patients (49.4%). Male gender (34.0% versus 18.2%; P=0.002), absence of osteoarticular pathology (95.1% versus 88.6%; P=0.032), absence of superficial vein thrombosis history (79.6% vs 68.7%;

P=0.024) were associated with CEAP improvement. Rate of secondary intervention due to REVAS was 4.1±1.1% at 5 years. Ninety-two patients (28%) from the whole sample had redo VVS. Patients undergoing redo VVS were more often treated with foam venous injection compared to patients that had their first VVS (3.3% vs 0%; P=0.02). Furthermore, patients undergoing redo VVS were older (48.3 vs. 58.6 years; P=0.01), had more often a history of superficial vein thrombosis (19.6% vs. 42.2%; P<0.01) and of deep vein thrombosis (1.7% vs 6.5%; P<0.023).

Conclusion: At 5 years, symptomatic and CEAP improvement after VVS is low, particularly for women, in patients with osteoarticular pathology or history of superficial vein thrombosis and after redo VVS. Further studies considering lifestyle risk factor and comorbidities as a cause for varicose veins recurrence are of major importance to better discuss with the patients the risks and benefits of a VVS.

Keywords: Venous Insufficiency; Varicose Veins; Veins; Recurrence; Risk factors

Introduction

Chronic Venous Disease (CVD) is a prevalent and conditioning disease with physical and psychological effects that involves seeking for treatment.[1-5] Older patients are more frequently affected.[2]

The prevalence of this disease has been increasing, especially in populations from developed countries in which it is becoming one of the most resource consuming pathologies.[4, 5] The prevalence of CVD may differ according to risk factors such as age, gender, obesity, number of pregnancies, episodes of venous thrombosis, physical activity, previous leg injury, family history, and ethnicity.[4, 5] Prolonged sitting or standing are also environmental factors that can contribute for CVD since the pumping of the calf muscle is ineffective due to prolonged leg immobility.[5]

Symptoms such as tiredness, heaviness, itching of the skin, nocturnal cramps and aching of the legs are signs that patients should seek for venous treatment, since it might impact their quality of life (QoL).[2]

In order to standardize the specific clinical signs of chronic venous disease, a Clinical, Etiological, Anatomical, and Pathophysiological (CEAP) classification system that ranges from C0 to C6 has emerged. According to the Clinical classification, C0 patients have no visible or palpable signs of venous disease. C1 patients could present telangiectasiae or reticular veins; C2 exhibit visible varicose veins; C3 patients presents edema; C4 could manifest with pigmentation and/or eczema (C4a) or lipodermatoscloresis and/or atrofie blanche (C4b); C5 patients exhibits healed venous ulcer and C6 presents active venous ulcer.[3]

After many years of studies, the inability to totally prevent the recurrence of varicose veins remains.[6] The recurrence rate of varicose veins can reach 80%[7] and

there are some possible causes for REVAS (REcurrence of varicose Veins After Surgery). Perrin and collaborators reported that the main source of recurrence of VVs were the incompetent perforator veins (75%).[8] Moreover, pelvic/abdominal causes, neovascularization, tactical and technical failure, or a moisture of them could be considered.[8]

The main purpose of this study was to address symptomatic improvement, CEAP improvement and rate of secondary intervention due to REVAS in a cohort of patients submitted to VVS (Varicose Vein Surgery) 5 years after surgery. We also compared patients submitted to primary versus redo VVS in a case-control design fashion.

Methods

Ethics statement

The study was approved by the local ethics committee of Faculdade de Medicina da Universidade do Porto/ São João Hospital Centre and respects the Declaration of Helsinki.

Study design

This study was performed in accordance with the STROBE guidelines for observational studies. This is retrospective cohort study that included patients undergoing elective varicose veins surgery, from January 2016 to December 2016 at a tertiary referral and university hospital. Patients were identified by diagnostic and procedural codes (ICD 9: 4549 [diagnosis] and 3859 [procedure]). Inclusion criteria were adult patients submitted to a VVS because of CVD during 2016. Patients that did not have registry of any phone contact in their clinical records or if they did not have any preoperative lower limb venous Doppler-ultrasound report were excluded. Likewise, those who did not provide consent to participate or the ones that did not answer the phone call after three attempts were also excluded. Patient's clinical information regarding venous Doppler-ultrasound reports, phone contact and surgery report were consulted in the clinical registries (Sclinic®). Patients that accepted to participate, answered to a detailed questionnaire about demographics, comorbidities, lifestyle habits and current venous disease status.

Definitions

Body Mass Index (BMI) was obtained by body mass divided by the square of body height (kg/m^2). Hypertension was considered if patient refer values above 140mmHg as

systolic blood pressure and 90mmHg as diastolic blood pressure or if anti-hypertension therapy. Diabetes Mellitus was defined as fast glucose above 126mg/dL or hypoglycemic therapy. Dyslipidemia was considered in patients with total cholesterol above 200 mg/dL or with statin therapy. Chronic renal insufficiency if patient is followed by nephrology because of renal failure, if did dialysis or if had kidney transplant. Osteoarticular pathology was considered in patients with osteoporosis, osteoarthritis or rheumatoid arthritis. Cardiac disease was defined as angina, previous myocardial infarction and arrythmias. Familiar history of VVs was only taken into account the 1st degree relatives.

Anatomic extension of the CVD was classified has: (a) involvement of one saphenous vein (including accessory saphenous veins) in one of the limbs or in both; (b) involvement of two saphenous veins (including accessory saphenous veins) in one of the limbs or in both; (c) involvement of more than two saphenous veins (including accessory saphenous veins) in one of the limbs or in both; and (d) solely involvement of incompetent tributary veins or perfurant veins.

Surgeries performed in patients with VVs included open surgery, radiofrequency and foam sclerotherapy. We divided surgeries in open surgery group and endovascular group (that includes patients treated by radiofrequency and patients treated with foam). In open surgery, in case of saphenous veins incompetence, an incision is done in the groin or in the popliteal fossa, with saphenopopliteal or saphenofemoral junction ligation and then the main vein is removed using a pin stripper by stripping. Any remaining incompetent venous tributaries are removed via tiny nicks in the skin. The groin wound is closed using dissolvable sutures. Radiofrequency is a technique that is used to treat saphenous veins. Saphenous vein is cannulated at the lowest point of reflux. A thin catheter is introduced inside the vein and a radiofrequency energy is delivered, generating temperatures of 120°C, destroying the vein. To facilitate the process, tumescent

anesthesia and external compression is used to compress externally the vein and to collapse it. Any remaining incompetent venous tributaries are removed via tiny nicks in the skin. Foam sclerotherapy consists in a non-surgical, ultrasound-guided and minimally invasive technique. Before injection of the foam, the patient is placed in trendelenburg position. A sclerosant (polidocanol) is injected into the incompetent vein and the progression of foam in followed with ultrasound to ensure a complete filling and subsequent spasm of the vein.

Outcomes

Patients were classified by CEAP Classification from C1 to C6 after being inquired specifically about the presence of the following manifestations of CVD: telangiectasia, reticular veins, varicose veins, edema, pigmentation and/or eczema, lipodermatosclerosis and/or atrofie blanche, healed venous ulcer or active venous ulcer.

Patients were considered symptomatic if they had tiredness, pain, “heavy legs”, itching or edema.

Secondary intervention was defined as any intervention due to REVAS after a period of 4 months after the surgery performed in 2016. Surgeries performed during the first 4 months after the index surgery were considered a second stage of the first intervention.

Statistical analysis

Statistical analyses were performed using IBM SPSS version 23 software (IBM Inc., Chicago, II, USA). A p value $< .05$ was considered statistically significant. Continuous variables were expressed as mean ± standard deviation when normally

distributed, otherwise as median and interquartile range. Data were assessed for normality with histogram. Categorical variables were expressed as percentages. Survival was evaluated using Kaplan-Meier curves.

Results

Patients' characteristics

A total of 1115 patients were submitted to varicose veins surgery in 2016 in a tertiary center due to chronic venous disease. Of these, only 328 patients met the inclusion criteria of these study (Figure 1). Most of the included patients were women (73.8%) and the mean and standard deviation age was 49.1 ± 11.2 years.

Three hundred and ten patients (94.5%) were symptomatic preoperatively and, considering CEAP classification, the majority of patients presented CEAP C2 (116 patients, 35.4%), CEAP C3 was referred by 82 patients (25.0%), 116 patients (35.4%) presented CEAP C2, 59 patients (18.0%) presented CEAP C4, 10 patients (3.0%) presented CEAP C5 and other 10 patients (30%).

One hundred and thirty-six patients (41.6%) had involvement of one saphenous vein in one or both limbs, 119 patients (36.4%) involvement of two saphenous vein in one or both limbs, 17 patients (5.2%) had involvement of more than two saphenous vein in one or both limbs and the remaining 55 patients (16.8%) had involvement of incompetent venous tributaries only.

The majority of the patients were submitted to VVS by open approach (91.8%) and the remaining patients underwent endovascular procedures (7.3% radiofrequency and 0.9% steam).

Symptomatic status

Comparing preoperative and the status of symptoms at the time of the phone call, 89 patients (27.1%) referred an improvement in their symptoms, 232 patients (70.7%) are in a similar status and 7 patients (2.1%) referred that were actually worst.

Patients undergoing primary VVS had more often improvement of their symptoms than patients undergoing redo VVS (30.6% versus 18.5%; P=0.026) (Table I).

CEAP status

Regarding CEAP variation, 162 (49.4%) patients reported CEAP improvement, 145 (44.2%) patients remain similar and 21 (6.4%) were worst in a median 5 years of follow-up.

Comparing between patients with CEAP improvement versus patients without CEAP improvement, male gender (P=0.002) was a predictor of CEAP improvement. Presence of osteoarticular pathology (P=0.032) and also superficial vein thrombosis history (P=0.024) were associated without CEAP improvement (Table II).

Secondary intervention due to REVAS

Median follow-up time was 5.00 ± 0.98 years. Twenty secondary interventions were realized during follow-up. Four procedures were realized in the first 4 months and the remaining 16 surgeries afterwards (Figure 2). Secondary intervention due to REVAS was 100% at 1 year, 1.6±0.7 at 3 years and 4.1±1.1% at 5 years.

Comparison between patients undergoing primary vs redo VVS

From the whole set of patients submitted to VVS in 2016, ninety-two patients (28.0%) had a redo VVS.

Patients undergoing redo VVS were older than patients undergoing primary VVS (48.3±11.7 years versus 48.3±11.7 years; P=0.010). Patients that had redo VVS had more often history of superficial (P<0.01) and deep (P=0.023) vein thrombosis.

Patients submitted VVS in which solely perforators and/or tributaries were treated a significative higher rate of redo VVS was found (P<0.01). Any statistically significative

difference was found between open surgery and endovascular techniques (radiofrequency and foam). However, patients treated with foam venous injection had more redo VVS comparing with the other techniques (3.3% vs 0%; P=0.02) (Table III).

Discussion

This study shows that symptomatic and CEAP improvement at 5 years following VVS is low, particularly in women, in patients with history of superficial vein thrombosis and after redo VVS. Despite this, only 4.9% of the patients underwent a new VVS after the index procedure. Patients that underwent redo VVS tend to be older, with previous history of superficial and deep thrombosis, despite the more frequent reported use of compression stockings.

One of the most intriguing factors of our study was that, despite de unsatisfactory outcomes reported during the phone questionnaire, only 4.9% of patients underwent a secondary intervention due to REVAS. In the medical literature, patient-centered care is more and more prominent. [9-11] The main difficulty in achieving this endeavor is the fact that there is no established tool that adequately reports and reflects patient perspectives and values. To identify outcomes of key importance to patients is to enable shared patient-clinician decision making, which appears to be desired by most vascular surgery patients but all too often not offered. [12] Another reason for this mismatch, might be the lack of a more sensitive measure to detect venous recurrence such as a Doppler ultrasound evaluation. Patients with worsening of their symptoms and of their CEAP classification might not have yet received adequate medical assessment and, at least part of them, might be in need of a secondary intervention due to REVAS. This hypothesis is further emphasized by the fact that no planned follow up is provided after surgery in the hospital where the surgery took place. Local practice and high case load dictate that the general care practician is most often the heath professional that will continue to observe the patient in the mid-long run, requiring a new vascular surgery appointment as deemed necessary.

Despite this mismatch, the identified risk factors should deserve our attention to better discuss with the patients the risks and benefits of a VVS.

In our study, female gender was a risk factor for unsatisfactory outcomes after VVS. Also, patients undergoing redo VVS were older than those having primary VVS. The importance of these demographic variables were documented before. A significative relation between older age and varicose veins was already referred by Clark et al[13] in their cross-sectional population study in the United Kingdom. A higher risk to venous disease in women is also frequently referred, comparing with men.[13, 14]

The occurrence of superficial and/or deep venous thrombosis were also associated with worse outcomes after surgery and had increased prevalence in patients submitted to redo versus primary VVS. Patients with varicose veins tends to have a higher risk of thromboembolic events, [15, 16] being the prevalence of superficial vein thrombosis in patients with varicose veins between 4% to 59%.[17, 18] These events needs medical evaluation, mostly specifically by vascular surgeons, that probably will notify varicose veins early and thus submitted these patients to venous ultrasound and then for surgery, if applicable.

We also verified an association between the presence of osteoarticular pathology and the lack of CEAP improvement. Patients with osteoarticular pathology might have leg complaints that can be attributed to other causes such as arthrosis or osteoporosis, beyond CVD symptoms.[19] It is possible that higher scores in symptoms that we attributed to CVD were instead explained because of osteoarticular pathology.

The low rates of symptomatic and CEAP improvement in the mid-term after VVS was disregard of the treatment modality used. Nevertheless, this finding deserves further confirmation as the use of endovascular procedures was relatively low in our study. Contrarily, Lawaetz et al. showed in their study that there was significant difference in

the incidence of varicose veins recurrence between high ligation/stripping and radiofrequency group. Significantly more patients in the high ligation/stripping developed recanalization in the great saphenous vein. The low number of endovascular interventions in our sample limited our potential results. [20]

The use of compression stockings seems to be an efficient conservative way to manage CVD.[21, 22] In our study, the use of compression stocking was not associated with improved symptoms or improved CEAP classification after VVS and this might be a situation in which inverse causality is present. Patients with a regular use of compression stocking probably have more symptoms of venous disease and so, the compression stockings are useful in reduce these symptoms. Patients that never used compression stockings are probably patients that did not have symptoms of venous disease after VVS and as such they were did not maintain it use.

This study has some limitations. We might have lack of external validation because we don't know the characteristics of patient that underwent VVS in 2016 but were not included in the study. Phone questionnaire was used to inquire about CEAP. CEAP classification requires physical exam that was replaced by a questionnaire about each dermatological alteration contemplated in the classification. Validated questionnaires for venous QoL assessment were not used because our protocol was primarily designed to identify demographics, comorbidities and life-style habits associated with secondary intervention due to REVAS. Furthermore, because of its retrospective nature, the application of QoL questionnaires to address the changes in QoL after surgery would be biased by recall bias. Despite this, it is also possible that our patient reported outcomes (PROMs) such as symptoms and CEAP improvement might also have some degree of recall bias, that would explain the mismatch between the clinical

outcomes and the rates of secondary intervention. This could be addressed through further studies of prospective nature.

Conclusion

This retrospective cohort study was designed to address outcomes after VVS, particularly the need for secondary intervention due to REVAS. Clinical-reported outcomes after surgery are somehow unsatisfactory, even if the secondary intervention due to REVAS was only 4.1% at 5 years.

More studies of prospective nature are fundamentally needed to consider lifestyle risk factor and comorbidities as a cause for varicose veins recurrence with the intention of discussing with the patients the risks and benefits of a VVS.

Disclosure:

It is declared that there is no financial interests in this research

References

1. Raffetto, J.D. and F. Mannello, *Pathophysiology of chronic venous disease.* Int Angiol, 2014. **33**(3): p. 212-21.
2. Davies, A.H., *The Seriousness of Chronic Venous Disease: A Review of Real-World Evidence.* Adv Ther, 2019. **36**(Suppl 1): p. 5-12.
3. Mansilha, A. and J. Sousa, *Pathophysiological Mechanisms of Chronic Venous Disease and Implications for Venoactive Drug Therapy.* Int J Mol Sci, 2018. **19**(6).
4. Wittens, C., et al., *Editor's Choice - Management of Chronic Venous Disease: Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS).* Eur J Vasc Endovasc Surg, 2015. **49**(6): p. 678-737.
5. Eberhardt, R.T. and J.D. Raffetto, *Chronic venous insufficiency.* Circulation, 2014. **130**(4): p. 333-46.
6. van Rij, A.M., et al., *Neovascularization and recurrent varicose veins: more histologic and ultrasound evidence.* J Vasc Surg, 2004. **40**(2): p. 296-302.
7. Gianesini, S., et al., *Femoral vein valve incompetence as a risk factor for junctional recurrence.* Phlebology, 2018. **33**(3): p. 206-212.
8. Perrin, M.R., N. Labropoulos, and L.R. Leon, Jr., *Presentation of the patient with recurrent varices after surgery (REVAS).* J Vasc Surg, 2006. **43**(2): p. 327-34; discussion 334.
9. Powell, J.T. and A. Wanhainen, *One Step Forward, Two Steps Backward?* Eur J Vasc Endovasc Surg, 2021. **62**(4): p. 642.

10. Peeters, G., et al., *Do patients have a say? A narrative review of the development of patient-reported outcome measures used in elective procedures for coronary revascularisation.* Qual Life Res, 2018. **27**(5): p. 1369-1380.
11. Wiering, B., D. de Boer, and D. Delnoij, *Patient involvement in the development of patient-reported outcome measures: a scoping review.* Health Expect, 2017. **20**(1): p. 11-23.
12. Santema, T.B., et al., *Shared Decision Making in Vascular Surgery: An Exploratory Study.* Eur J Vasc Endovasc Surg, 2016. **51**(4): p. 587-93.
13. Clark, A., I. Harvey, and F.G. Fowkes, *Epidemiology and risk factors for varicose veins among older people: cross-sectional population study in the UK.* Phlebology, 2010. **25**(5): p. 236-40.
14. Ebrahimi, H., F. Amanpour, and N. Bolbol Haghighi, *Prevalence and risk factors of varicose veins among female hairdressers: a cross sectional study in north-east of Iran.* J Res Health Sci, 2015. **15**(2): p. 119-23.
15. De Maeseneer, M.G., et al., *Editor's Choice - European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs.* Eur J Vasc Endovasc Surg, 2022. **63**(2): p. 184-267.
16. Müller-Bühl, U., et al., *Varicose veins are a risk factor for deep venous thrombosis in general practice patients.* Vasa, 2012. **41**(5): p. 360-5.
17. Leon, L., et al., *Clinical significance of superficial vein thrombosis.* Eur J Vasc Endovasc Surg, 2005. **29**(1): p. 10-7.
18. Karathanos, C., et al., *Recurrence of superficial vein thrombosis in patients with varicose veins.* Phlebology, 2016. **31**(7): p. 489-95.

19. Zolotukhin, I.A., et al., *Prevalence and Risk Factors for Chronic Venous Disease in the General Russian Population.* Eur J Vasc Endovasc Surg, 2017. **54**(6): p. 752-758.
20. Lawaetz, M., et al., *Comparison of endovenous ablation techniques, foam sclerotherapy and surgical stripping for great saphenous varicose veins. Extended 5-year follow-up of a RCT.* Int Angiol, 2017. **36**(3): p. 281-288.
21. Benigni, J.P., et al., *Efficacy of Class 1 elastic compression stockings in the early stages of chronic venous disease. A comparative study.* Int Angiol, 2003. **22**(4): p. 383-92.
22. Kakkos, S.K., et al., *Acute Effects of Graduated Elastic Compression Stockings in Patients with Symptomatic Varicose Veins: A Randomised Double Blind Placebo Controlled Trial.* Eur J Vasc Endovasc Surg, 2018. **55**(1): p. 118-125.

Table I: Characteristics of patients with and without improvement of their symptoms, 5 years following varicose vein surgery.

Patient's characteristics	**Total (N=328)**	**Symptomatic improvement (N=89)**	**Lack of symptomatic improvement (n=239)**	***P value***
Gender (female)	242 (73.8)	53 (59.6)	189 (79.4)	**<0.01**
Age (years)	49.18±11.23	49.11±11.08	49.21±11.31	0.944
Body mass index (kg/m^2)	26.40±4.13	25.85±3.85	26.61±4.21	0.125
Hypertension	98 (29.9)	32 (36.0)	66 (27.6)	0.142
Diabetes Mellitus	24 (7.3)	7 (7.9)	17 (7.1)	0.816
Dyslipidemia	81 (24.7)	25 (28.1)	56 (23.4)	0.384
Chronic kidney disease	2 (0.6)	0 (0.0)	2 (0.8)	0.387
Osteoarticular pathology	27 (8.2)	8 (9.0)	19 (7.9)	0.761
Cardiac Disease (a)	11 (3.4)	3 (3.4)	8 (3.3)	0.992
Familiar History of CVD	248 (75.6)	64 (71.9)	184 (77.0)	0.341
Pregnancies (number)				**0.048**
0	16 (4.9)	2 (3.7)	14 (7.3)	
1	76 (23.2)	12 (22.2)	64 (33.2)	
2	109 (33.2)	33 (61.1)	76 (39.4)	
3	29 (8.8)	6 (11.1)	23 (11.9)	
>=4	17 (5.2)	1 (1.9)	16 (8.3)	
Physical Exercise	196 (59.8)	57 (64.0)	139 (58.2)	0.334

Smoking				0.147
Actual smoker	62 (18.9)	23 (25.8)	39 (16.3)	
Ex-smoker	49 (14.9)	12 (13.5)	37 (15.5)	
Never smoked	217 (66.2)	54 (60.7)	163 (68.2)	
Redo varicose veins surgery	92 (28.0)	17 (19.1)	75 (31.5)	**0.026**
Superficial Vein Thrombosis	85 (25.9)	17 (19.1)	68 (28.5)	0.086
Superficial vein thrombosis (number)				**0.026**
One episode	307 (93.6)	72 (80.9)	163 (68.5)	
Multiple episodes	92 (28.0)	17 (19.1)	75 (31.5)	
Deep Vein Thrombosis	10 (3.0)	2 (2.2)	8 (3.3)	0.606
Number of deep vein thrombosis				0.490
One episode	7 (2.1)	1 (50.0)	6 (75.0)	
Multiple episodes	3 (0.91)	1 (50.0)	2 (25.0)	
Use of anticoagulation	9 (2.7)	2 (2.2)	7 (2.9)	0.737
Use of hormonotherapy				0.387
Actual user	159 (48.5)	37 (68.5)	122 (64.2)	
Prior user	59 (18.0)	14 (25.9)	45 (23.7)	
Never used	26 (7.9)	3 (5.6)	23 (12.1)	
Diary standing hours				0.603
<3 hours	36 (11.0)	8 (9.0)	28 (11.7)	
3 to 6 hours	101 (30.8)	29 (32.6)	72 (30.1)	
7 to 9 hours	126 (38.4)	31 (34.8)	95 (39.7)	
10 to 12 hours	65 (19.8)	21 (23.6)	44 (18.4)	

Diary sitting hours				0.504
<3 hours	186 (56.7)	48 (53.9)	138 (57.7)	
3 to 6 hours	104 (31.7)	27 (30.3)	77 (32.2)	
7 to 9 hours	31 (9.5)	12 (13.5)	19 (7.9)	
10 to 12 hours	7 (2.1)	2 (2.2)	5 (2.1)	
Use of Compression Stockings				0.633
Almost everyday	71 (21.6)	17 (19.1)	54 (22.6)	
Sometimes	42 (	10 (11.2)	32 (13.4)	
Never		62 (69.7)	153 (64.0)	
Anatomic extension of CVD (b)				0.775
One saphenous vein	137 (41.8)	39 (43.8)	98 (41.0)	
Two saphenous veins	119 (36.3)	31 (34.8)	88 (36.8)	
More than two saphenous veins	17 (5.2)	6 (6.7)	11 (4.6)	
Solely perforators and/or tributaries	55 (16.7)	13 (14.6)	42 (17.6)	
Type of surgery				0.293
Open	301 (91.8)	84 (94.4)	217 (90.8)	
Endovascular	27 (8.2)	5 (5.6)	22 (9.2)	

Legend: Categoric variables are expressed as number (percentage) and continuous variables as mean ± standard deviation. (a) Cardiac disease was considered in cases with angina and arrythmias. (b) Anatomic extension of CVD was classified as: involvement of one saphenous vein (including accessory saphenous veins) in one of the limbs or in both; involvement of two saphenous veins (including accessory saphenous veins) in one of the

limbs or in both; involvement of more than two saphenous veins (including accessory saphenous veins) in one of the limbs or in both; and solely involvement of incompetent tributary veins or perforators veins. CVD – Chronic venous disease

Table II. Characteristics of patients with and without CEAP improvement, 5 years following varicose vein surgery.

Patient's characteristics	**CEAP improvement (N=162)**	**Lack of CEAP improvement (n=166)**	***P value***
Gender (female)	107 (66.0)	135 (81.8)	**0.002**
Age (years)	49.14±11.75	49.22±10.74	0.948
Body mass index (kg/m^2)	26.37±3.96	26.43±4.30	0.895
Hypertension	48 (29.6)	50 (30.1)	0.923
Diabetes Mellitus	13 (8.0)	11 (6.6)	0.627
Dyslipidemia	44 (27.2)	37 (22.3)	0.306
Chronic kidney disease	1 (0.6)	1 (0.6)	0.986
Osteoarticular pathology	8 (4.9)	19 (11.4)	**0.032**
Cardiac Disease (a)	6 (3.7)	5 (3.0)	0.728
Familiar History of CVD	117 (72.2)	131 (78.9)	0.158
Pregnancies (number)			0.369
0	4 (3.7)	12 (8.6)	
1	33 (30.6)	43 (30.9)	
2	48 (44.4)	61 (43.9)	
3	17 (15.7)	12 (8.6)	
>=4	6 (5.5)	11 (7.9)	
Physical Exercise	103 (63.6)	93 (56.0)	0.163
Smoking			0.258
Actual smoker	62 (18.9)	30 (18.1)	

Ex-smoker	49 (14.9)	20 (12.0	
Never smoked	101 (62.3)	116 (69.9)	
Redo varicose veins surgery	43 (26.5)	49 (29.7)	0.526
Superficial Vein Thrombosis	33 (20.4)	52 (31.3)	**0.024**
Superficial vein thrombosis (number)			0.328
One episode	18 (54.5)	32 (61.5)	
Multiple episodes	17 (45.5)	20 (48.5)	
Deep Vein Thrombosis	3 (1.9)	7 (4.2)	0.213
Number of deep vein thrombosis			0.399
One episode	3 (100)	4 (57.1)	
Multiple episodes	0	3 (41.9)	
Use of anticoagulation	4 (2.5)	5 (3.0)	0.763
Use of hormonotherapy			0.505
Actual user	67 (62.0)	92 (67.6)	
Prior user	30 (27.8)	29 (21.3)	
Never used	11 (10.2)	15 (11.0)	
Diary standing hours			0.711
<3 hours	16 (9.9)	20 (12.0)	
3 to 6 hours	49 (30.2)	52 (31.3)	
7 to 9 hours	67 (41.4)	59 (35.5)	
10 to 12 hours	30 (18.5)	35 (21.1)	
Diary sitting hours			0.731

<3 hours	92 (56.8)	94 (56.6)	
3 to 6 hours	52 (32.1)	52 (31.3)	
7 to 9 hours	16 (9.9)	15 (9.0)	
10 to 12 hours	2 (1.2)	5 (3.0)	
Use of Compression Stockings			0.121
Almost everyday	30 (18.5)	41 (24.7)	
Sometimes	17 (10.5)	25 (15.1)	
Never	115 (71.0)	100 (60.2)	
Anatomic extension of CVD (b)			0.406
One saphenous vein	68 (42.0)	69 (41.6)	
Two saphenous veins	60 (37.0)	59 (35.5)	
More than two saphenous veins	11 (6.8)	6 (3.6)	
Solely perforators and/or tributaries	23 (14.2)	32 (19.3)	
Type of surgery			0.082
Open	153 (94.4)	148 (89.2)	
Endovascular	9 (5.6)	18 (10.8)	

Legend: Categoric variables are expressed as number (percentage) and continuous variables as mean ± standard deviation. (a) Cardiac disease was considered in cases with angina and arrythmias. (b) Anatomic extension of CVD was classified as: involvement of one saphenous vein (including accessory saphenous veins) in one of the limbs or in both; involvement of two saphenous veins (including accessory saphenous veins) in one of the

limbs or in both; involvement of more than two saphenous veins (including accessory saphenous veins) in one of the limbs or in both; and solely involvement of incompetent tributary veins or perforators veins. CVD – Chronic venous disease

Table III. Comparison between patients undergoing first varicose veins surgery (VVS) in 2016 versus those having redo VVS due to recurrence of varicose veins.

Patient's characteristics	**Primary VVS (N= 236)**	**Redo VVS (N= 92)**	***P value***
Gender (female)	164 (69.5)	77 (84.6)	0.106
Age (years)	48.3±11.7	58.6±9.6	**0.010**
Body mass index (kg/m^2)	26.26±3.91	26.73±4.65	0.353
Hypertension	71 (30.1)	27 (29.3)	0.878
Diabetes Mellitus	17 (7.2)	7 (7.6)	0.907
Dyslipidemia	56 (23.7)	25 (27.2)	0.529
Chronic kidney disease	2 (0.9)	0	0.375
Osteoarticular pathology	16 (6.8)	11 (12.0)	0.128
Cardiac Disease (a)	7 (3.0)	4 (4.3)	0.537
Familiar History of CVD	174 (73.7)	73 (79.3%)	0.316
Pregnancy number			0.127
0	13 (7.8)	3 (3.8)	
1	54 (32.5)	22 (27.5)	
2	63 (38.0)	45 (56.3)	
3	23 (13.9)	6 (7.5)	
4	11 (6.6)	3 (3.8)	
5	2 (1.2)	1 (1.3)	
Physical Exercise	141 (60.0)	55 (59.8)	0.971
Smoking			0.093
Actual smoker	46 (19.6)	16 (17.4)	

Ex-smoke	41 (17.4)	8 (8.7)	
Never smoked	148 (63.0)	68 (73.9)	
Superficial Vein Thrombosis	46 (19.6)	39 (42.4)	**<0.010**
Number of superficial vein thrombosis			**0.003**
1	31 (67.4)	19 (48.7)	
2	13 (28.3)	6 (15.4)	
3	1 (2.2)	6 (15.4)	
4	1 (2.2)	8 (20.5)	
Deep Vein Thrombosis	4 (1.7)	6 (6.5)	**0.023**
Number of deep vein thrombosis			0.679
1	3 (75.0)	4 (66.7)	
2	1 (25.0)	1 (16.7)	
3	0 (0.0)	1 (16.7)	
Use of anticoagulation	4 (1.7)	5 (5.4)	0.064
Use of hormonotherapy			0.262
Actual user	102 (62.6)	57 (71.3)	
Ex-User	44 (27.0)	14 (17.5)	
Never used	17 (10.4)	9 (11.3)	
Diary standing hours			0.655
<3 hours	29 (12.3)	7 (7.6)	
3 to 6 hours	70 (29.8)	30 (32.6)	
7 to 9 hours	89 (37.9)	37 (40.2)	

10 to 12 hours	47 (20.0)	18 (19.6)	
Diary sitting hours			0.243
<3 hours	128 (54.5)	58 (63.0)	
3 to 6 hours	77 (32.8)	27 (29.3)	
7 to 9 hours	23 (9.8)	7 (7.6)	
10 to 12 hours	7 (3.0)	0	
Use of Compression Stockings			**0.044**
Almost everyday	47 (20.0)	24 (26.1)	
Sometimes	25 (10.6)	17 (18.5)	
Never	163 (69.4)	51 (55.4)	
Anatomic extension of CVD (b)			**<0.01**
One saphenous vein	102 (43.4)	34 (37.0)	
Two saphenous veins	97 (41.3)	22 (23.9)	
More than two saphenous veins	12 (5.1)	5 (5.4)	
Solely perforators and/or tributaries	24 (10.2)	31 (33.7)	
Type of surgery			0.531
Open	217 (92.3)	83 (90.2)	
Endovascular	18 (7.7)	9 (9.8)	

Legend: Categoric variables are expressed as number (percentage) and continuous variables as mean ± standard deviation. (a) Cardiac disease was considered in cases with angina and arrythmias. (b) Anatomic extension of CVD was classified as: involvement of one saphenous vein (including accessory saphenous veins) in one of the limbs or in both;

involvement of two saphenous veins (including accessory saphenous veins) in one of the limbs or in both; involvement of more than two saphenous veins (including accessory saphenous veins) in one of the limbs or in both; and solely involvement of incompetent tributary veins or perforators veins. CVD – Chronic venous disease; VVS – Varicose veins surgery

Figures

Figure 1. Flow diagram demonstrating patients selection.

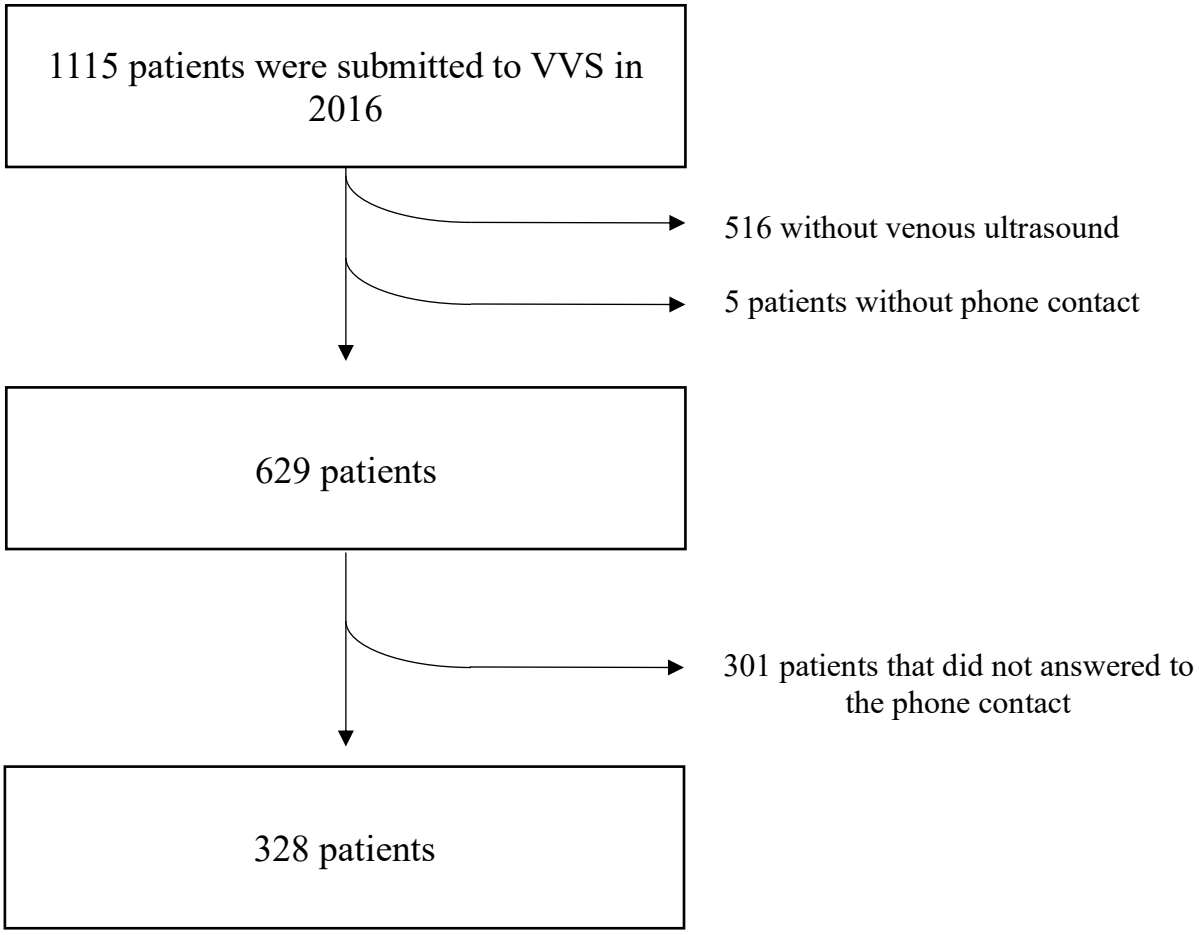
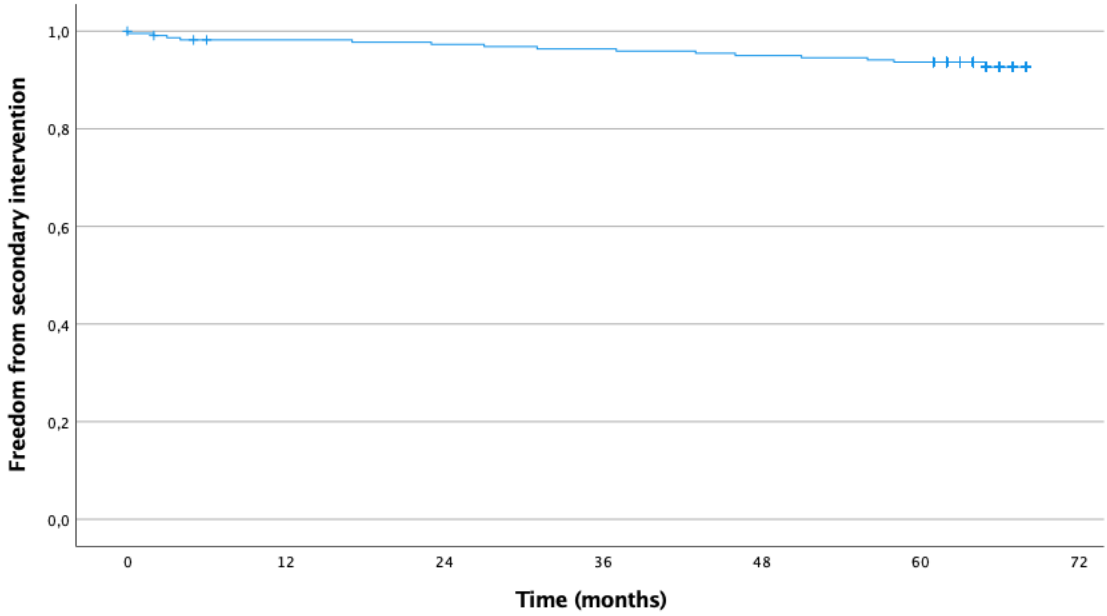


Figure 2: Kaplan-Meier curve of freedom from secondary intervention



Number at risk	222	216	214	212	209	206
Estimates (%)	99.6	98.2	97.3	96.4	95.0	93.7
Standard error (%)	0.4	0.9	1.1	1.3	1.5	1.6

Agradecimentos

Um agradecimento especial à Doutora Marina Felicidade Dias Neto por ter aceite ser a minha orientadora de Tese e, por apesar de estar longe, ter tido sempre ampla disponibilidade para esclarecer tudo o que precisasse. Agradeço também pela amabilidade que sempre teve comigo e pelo esforço que desenvolveu para que este trabalho fosse concretizado.

Gostaria de agradecer também à minha co-orientadora Doutora Ana Filipa Campos Jácome, pelo seu papel fulcral desde o início ao fim na realização deste trabalho e, por me ter acompanhado e ajudado sempre.

Um obrigado aos meus amigos que me acompanharam e ajudaram ao longo destes 6 anos de curso.

Por fim, deixo uma palavra de agradecimento aos meus pais e irmã pelo seu apoio incondicional. Demonstraram desde sempre interesse ao longo do meu percurso académico e fazem questão de estar sempre presentes nos momentos mais importantes da minha vida.

SÃO JOÃO

U.PORTO
FMUP FACULDADE DE MEDICINA
UNIVERSIDADE DO PORTO

Declaração

Para os devidos efeitos se declara que a Dra. Ana Filipa Campos Jácome submeteu para avaliação da Comissão de Ética do Centro Hospitalar Universitário de São João / Faculdade de Medicina da Universidade do Porto o protocolo 'Recorrence of Varicose Veins after Surgery - REVAS PORTO Study', e que o mesmo foi aprovado pela CE em 16 de fevereiro de 2022. Para os devidos efeitos se declara que Catarina Maria Vieira Brazão faz parte da equipa de investigação.

Porto e Centro Hospitalar Universitário de São João, 23 de março de 2022

O Secretário da Comissão de Ética

Pedro Brito

The STROCSS 2021 Guideline		
Item no.	**Item description**	**Page**
TITLE		
1	**Title** • The word cohort or cross-sectional or case-control is included* • Temporal design of study is stated (e.g. retrospective or prospective) • The focus of the research study is mentioned (e.g. population, setting, disease, exposure/intervention, outcome etc.) *STROCSS 2021 guidelines apply to cohort studies as well as other observational studies (e.g. cross-sectional, case-control etc.)	1
ABSTRACT		
2a	**Introduction** – briefly describe: • Background • Scientific rationale for this study • Aims and objectives	3
2b	**Methods** - briefly describe: • Type of study design (e.g. cohort, case-control, cross-sectional etc.) • Other key elements of study design (e.g. retro-/prospective, single/multi-centred etc.) • Patient populations and/or groups, including control group, if applicable • Exposure/interventions (e.g. type, operators, recipients, timeframes etc.) • Outcome measures – state primary and secondary outcome(s)	3
2c	**Results** - briefly describe: • Summary data with qualitative descriptions and statistical relevance, where appropriate	3-4
2d	**Conclusion** - briefly describe: • Key conclusions • Implications for clinical practice • Need for and direction of future research	4
INTRODUCTION		
3	**Introduction** – comprehensively describe: • Relevant background and scientific rationale for study with reference to key literature • Research question and hypotheses, where appropriate • Aims and objectives	5-6
METHODS		
4a	**Registration** • In accordance with the Declaration of Helsinki*, state the research registration number and where it was registered, with a hyperlink to the registry entry (this can be obtained from ResearchRegistry.com, ClinicalTrials.gov, ISRCTN etc.) • All retrospective studies should be registered before submission; it should be stated that the research was retrospectively registered ** "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject"*	7
4b	**Ethical approval** • Reason(s) why ethical approval was needed • Name of body giving ethical approval and approval number • Where ethical approval wasn't necessary, reason(s) are provided	7

4c	**Protocol** • Give details of protocol (*a priori* or otherwise) including how to access it (e.g. web address, protocol registration number etc.) • If published in a journal, cite and provide full reference	7
4d	**Patient and public involvement in research** • Declare any patient and public involvement in research • State the stages of the research process where patients and the public were involved (e.g. patient recruitment, defining research outcomes, dissemination of results etc.) and describe the extent to which they were involved.	7
5a	**Study design** • State type of study design used (e.g. cohort, cross-sectional, case-control etc.) • Describe other key elements of study design (e.g. retro-/prospective, single/multi-centred etc.)	7
5b	**Setting and timeframe of research** – comprehensively describe: • Geographical location • Nature of institution (e.g. primary/secondary/tertiary care setting, district general hospital/teaching hospital, public/private, low-resource setting etc.) • Dates (e.g. recruitment, exposure, follow-up, data collection etc.)	7
5c	**Study groups** • Total number of participants • Number of groups • Detail exposure/intervention allocated to each group • Number of participants in each group	7
5d	**Subgroup analysis** – comprehensively describe: • Planned subgroup analyses • Methods used to examine subgroups and their interactions	9
6a	**Participants** – comprehensively describe: • Inclusion and exclusion criteria with clear definitions • Sources of recruitment (e.g. physician referral, study website, social media, posters etc.) • Length, frequency and methods of follow-up (e.g. mail, telephone etc.)	7
6b	**Recruitment** – comprehensively describe: • Methods of recruitment to each patient group (e.g. all at once, in batches, continuously till desired sample size is reached etc.) • Any monetary incentivisation of patients for recruitment and retention should be declared; clarify the nature of any incentives provided • Nature of informed consent (e.g. written, verbal etc.) • Period of recruitment	7
6c	**Sample size** – comprehensively describe: • Analysis to determine optimal sample size for study accounting for population/effect size • Power calculations, where appropriate • Margin of error calculation	NA
METHODS - INTERVENTION AND CONSIDERATIONS		
7a	**Pre-intervention considerations** – comprehensively describe: • Preoperative patient optimisation (e.g. weight loss, smoking cessation, glycaemic control etc.) • Pre-intervention treatment (e.g. medication review, bowel preparation, correcting hypothermia/-volemia/-tension, mitigating bleeding risk, ICU care etc.)	8

7b	**Intervention** – comprehensively describe: • Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological etc.) • Aim of intervention (preventative/therapeutic) • Concurrent treatments (e.g. antibiotics, analgesia, anti-emetics, VTE prophylaxis etc.) • Manufacturer and model details, where applicable	7-9
7c	**Intra-intervention considerations** – comprehensively describe: • Details pertaining to administration of intervention (e.g. anaesthetic, positioning, location, preparation, equipment needed, devices, sutures, operative techniques, operative time etc.) • Details of pharmacological therapies used, including formulation, dosages, routes, and durations • Figures and other media are used to illustrate	NA
7d	**Operator details** – comprehensively describe: • Requirement for additional training • Learning curve for technique • Relevant training, specialisation and operator's experience (e.g. average number of the relevant procedures performed annually)	NA
7e	**Quality control** – comprehensively describe: • Measures taken to reduce inter-operator variability • Measures taken to ensure consistency in other aspects of intervention delivery • Measures taken to ensure quality in intervention delivery	NA
7f	**Post-intervention considerations** – comprehensively describe: • Post-operative instructions (e.g. avoid heavy lifting) and care • Follow-up measures • Future surveillance requirements (e.g. blood tests, imaging etc.)	NA
8	**Outcomes** – comprehensively describe: • Primary outcomes, including validation, where applicable • Secondary outcomes, where appropriate • Definition of outcomes • If any validated outcome measurement tools are used, give full reference • Follow-up period for outcome assessment, divided by group	9
9	**Statistics** – comprehensively describe: • Statistical tests and statistical package(s)/software used • Confounders and their control, if known • Analysis approach (e.g. intention to treat/per protocol) • Any sub-group analyses • Level of statistical significance	10
RESULTS		
10a	**Participants** – comprehensively describe: • Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons). Use figure to illustrate. • Population demographics (e.g. age, gender, relevant socioeconomic features, prognostic features etc.) • Any significant numerical differences should be highlighted	11
10b	**Participant comparison** • Include table comparing baseline characteristics of cohort groups • Give differences, with statistical relevance • Describe any group matching, with methods	11
10c	**Intervention** – comprehensively describe:	11

	• Degree of novelty of intervention • Learning required for interventions • Any changes to interventions, with rationale and diagram, if appropriate	
11a	**Outcomes** – comprehensively describe: • Clinician-assessed and patient-reported outcomes for each group • Relevant photographs and imaging are desirable • Any confounding factors and state which ones are adjusted	9
11b	**Tolerance** – comprehensively describe: • Assessment of tolerability of exposure/intervention • Cross-over with explanation • Loss to follow-up (fraction and percentage), with reasons	NA
11c	**Complications** – comprehensively describe: • Adverse events and classify according to Clavien-Dindo classification* • Timing of adverse events • Mitigation for adverse events (e.g. blood transfusion, wound care, revision surgery etc.) *Dindo D, Demartines N, Clavien P-A. Classification of Surgical Complications. A New Proposal with Evaluation in a Cohort of 6336 Patients and Results of a Survey. Ann Surg. 2004; 240(2): 205-213	NA
12	**Key results** – comprehensively describe: • Key results with relevant raw data • Statistical analyses with significance • Include table showing research findings and statistical analyses with significance	11-13
DISCUSSION		
13	**Discussion** – comprehensively describe: • Conclusions and rationale • Reference to relevant literature • Implications for clinical practice • Comparison to current gold standard of care • Relevant hypothesis generation	14
14	**Strengths and limitations** – comprehensively describe: • Strengths of the study • Weaknesses and limitations of the study and potential impact on results and their interpretation • Assessment and management of bias • Deviations from protocol, with reasons	16-17
15	**Relevance and implications** – comprehensively describe: • Relevance of findings and potential implications for clinical practice • Need for and direction of future research, with optimal study designs mentioned	16-17
CONCLUSION		
16	**Conclusions** • Summarise key conclusions • Outline key directions for future research	18
DECLARATIONS		
17a	**Conflicts of interest** • Conflicts of interest, if any, are described	19
17b	**Funding** • Sources of funding (e.g. grant details), if any, are clearly stated • Role of funder	NA

17c	**Contributorship** • Acknowledge patient and public involvement in research; report the extent of involvement of each contributor	NA

Table 2: The full revised STROCSS 2021 checklist

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3-4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-9
Bias	9	Describe any efforts to address potential sources of bias	16
Study size	10	Explain how the study size was arrived at	NA
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	NA
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	10
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	11 Figure1.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	11-12 Tables I, II, III
Outcome data	15*	Report numbers of outcome events or summary measures over time	11-13

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	11-13
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Tables I,II,II
Discussion			
Key results	18	Summarise key results with reference to study objectives	14-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	18
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	NA

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

No. Item

1.A) “This was an observational, retrospective cohort study”

B) “All included patients answered to a questionnaire about demographics, comorbidities, life-style habits, and the current venous disease status. (…) Further studies considering lifestyle risk factor and comorbidities as a cause for varicose veins recurrence are of major importance to better discuss with the patients the risks and benefits of a VVS.

2. “The prevalence of this disease has been increasing, especially in populations from developed countries (…) Prolonged sitting or standing are also environmental factors that can contribute for CVD since the pumping of the calf muscle is ineffective due to prolonged leg immobility.”

3. “The main purpose of this study was to address symptomatic improvement, CEAP improvement and rate of secondary intervention due to REVAS in a cohort of patients submitted to VVS, 5 years after surgery. We also compared patients submitted to primary versus redo VVS in a case-control design fashion.”

4. “This is retrospective cohort study that included patients undergoing elective varicose veins surgery, from January 2016 to December 2016 at a tertiary referral and university hospital. Patients were identified by diagnostic and procedural codes (ICD 9: 4549 [diagnosis] and 3859 [procedure])”

5. “included patients undergoing elective varicose veins surgery, from January 2016 to December 2016 at a tertiary referral and university hospital. Patients were identified by diagnostic and procedural codes (ICD 9: 4549 [diagnosis] and 3859 [procedure]).”

6.A) “Inclusion criteria were adult patients submitted to a VVS because of CVD during 2016(…)Patients that accepted to participate, answered to a detailed questionnaire about demographics, comorbidities, lifestyle habits and current venous disease status. “

B) NA. A matched study was not made.

7. “Patients were classified by CEAP Classification from C1 to C6(…) Surgeries performed during the first 4 months after the index surgery were considered a second stage of the first intervention.”

8. “Body Mass Index (BMI) was obtained by body mass divided by the square of body height (kg/m^2) (…) A sclerosant (polidocanol) is injected into the incompetent vein and the progression of foam in followed with ultrasound to ensure a complete filling and subsequent spasm of the vein.”

9. “Furthermore, because of its retrospective nature, the application of QoL questionnaires to address the changes in QoL after surgery would be biased by recal bias.”

10. NA. The patients included were submitted to VVS at Centro Hospitalar de São João- Porto from January to December of 2016.

11. NA. Quantitative variables were not used.

12.A)” Statistical analyses were performed using IBM SPSS version 23 software (IBM Inc., Chicago, II, USA (…) Categorical variables were expressed as percentages. Survival was evaluated using Kaplan-Meier curves.”

B) “Statistical analyses were performed using IBM SPSS version 23 software (IBM Inc., Chicago, II, USA).”

C) NA. There was no missing data.

D) NA. The patients clinical status could be assessed.

E) NA. It was not realized.

13. A)” A total of 1115 patients were submitted to varicose veins surgery in 2016 in a tertiary center due to chronic venous disease. Of these, only 328 patients met the inclusion criteria of these study (Figure 1). Most of the included patients were women (73.8%) and the mean and standard deviation age was 49.1 ± 11.2 years.

B) Figure 1.

C) Figure 1.

14.A) Table I, II, II

B) NA, because consecutive patients who underwent VVS were included, and those with exclusion criteria were excluded.

C) “Median follow-up time was 5.00 ± 0.98 years.”

15. “Three hundred and ten patients (94.5%) (…) However, patients treated with foam venous injection had more redo VVS comparing with the other techniques (3.3% vs 0%; P=0.02).”

16. A)“Three hundred and ten patients (94.5%) (…) However, patients treated with foam venous injection had more redo VVS comparing with the other techniques (3.3% vs 0%; P=0.02).”

B) NA. No continuous variables were categorized.

C) NA. No continuous variables were categorized.

17. Tables I,II,II

18. “In the medical literature, patient-centered care is more and more prominent.(…) To identify outcomes of key importance to patients is to enable shared patient-clinician decision making, which appears to be desired by most vascular surgery patients but all too often not offered.

19. “This study has some limitations.(…) to identify demographics, comorbidities and life-style habits associated with secondary intervention due to REVAS.”

20. “This retrospective cohort study was designed to address outcomes after VVS, particularly the need for secondary intervention due to REVAS(…) More studies of prospective nature are fundamentally needed to consider lifestyle risk factor and comorbidities as a cause for varicose veins recurrence with the intention of discussing with the patients the risks and benefits of a VVS.”

21. NA. No funds were required.

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Journal of
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J Vasc Surg 2016;3:23-35

Reporting standards for adverse events after medical device use in the peripheral vascular system.
J Vasc Surg 2013;58:776-86

Venous severity scoring: An adjunct to venous outcome assessment.
J Vasc Surg 2000;31:1307-12

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Full details are available at http://www.consort-statement.org/. This article provides a checklist of the items that should be included in the report of the methods, results and discussion and the suggested details of a flow diagram that provides information on patient flow through the study. See Reporting Standards.

Standards have been published that provide guidelines for reporting meta-analyses of the randomized controlled studies: See Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of randomized controlled trials: the QUORUM statement. Lancet 1999;354:1896-900.

Reporting standards have been published that provide guidelines for observational studies: See Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis of Observational Studies in Epidemiology [MOOSE] group. JAMA 2000;283:2008-12.

Preparing Your Manuscript File. The manuscript file for most submissions includes a title page, article highlights, table of contents summary, abstract, manuscript body and references. Detailed instructions for how to format the manuscript file are described below. Tables, figures, forms and supplemental materials are submitted as separate files and should not be embedded in the manuscript file. Please see the Article Type for specific word limits and requirements.

TITLE PAGE. A complete title page is required for all submissions and must appear at the beginning of the manuscript file. The title page must include:

Manuscript Title. Must be concise and accurately reflect the content of the manuscript. Must be declarative, stating the topic and results when possible, rather than posing a question. Correct formatting will aid researchers in locating your article on *Medline* once it has been published. Please make sure that your title:

IS NOT in the form of a question.
DOES NOT include "The First..." since these statements can not always be verified.
DOES NOT include a colon or any other punctuation to make it two parts.
DOES NOT Restate the article type: i.e. Experimental Research, Clinical Research, etc.,
****UNLESS** it is a Systematic Review, Meta-analysis, Clinical Practice Guidelines, Reporting Standards or a Randomized Controlled Trial.
DOES NOT State the type of statistical analysis, i.e. Multivariable Analysis.
DOES NOT include the names of the authors, your institution, or the number of patients.

Authors. Complete author names, degrees, corresponding institutions, departments, and divisions, in the order that they should appear in the final printed article

Corresponding Author(s). Please include the name(s), mailing address, phone number and email address for the **corresponding author** and **post-publication corresponding author** on the title page. See section on Corresponding Authors for more information.

Presentation Information (if applicable). Example: This study was presented in the plenary International Forum at the 2014 Vascular Annual Meeting of the Society for Vascular Surgery, Boston, Mass, June 5-7, 2014.

***Sponsoring Societies.** The author will also have the opportunity to indicate whether the manuscript was presented at a sponsoring society's annual meeting in the submission module. Doing so will allow the Editorial Office to report to the society about manuscript submission and acceptance rates, link the paper with a related society discussion, and add a society banner to the final published paper.

Keywords. Authors may use any five terms they choose to help readers identify this work. They may use the U.S. National Library of Medicine's MeSH Tools for Finding Keywords to generate these keywords.

TABLE OF CONTENTS SUMMARY AND ARTICLE HIGHLIGHTS. Authors of Clinical and Experimental Research submissions are required to include article highlights and a summary for the table of contents in the manuscript file. It must appear just before the abstract and be formatted using this template or it will not be accepted for review.

ABSTRACT. An abstract is required for all manuscripts except Venous Images, Letters to the Editor, Invited Commentaries, Editorials, and Presidential Addresses. Tables, figures, reference citations, and trademarked names should not appear in the abstract. Because many readers only have access to the abstract, it is essential that it contain numerical results and not simply summary conclusions.

Unstructured: Evidence Summaries, Practice Management, and Vascular and Endovascular Technique manuscripts require short, unstructured abstracts. Include the abstract after the title page in the manuscript file. Though an unstructured abstract does not have section headings, it must describe what is unique and important about the paper, the primary concerns of the patient(s), the important clinical findings, and the main diagnoses and interventions in a clear and organized manner. The final sentence of the abstract should describe the outcomes and the "take-away" lesson.

Structured: Experimental Research, Clinical Research, Education Corner and Review articles must include a structured abstract after the title page in the manuscript file. The abstract must clearly state the main factual points of the article. The abstract should be informative, not descriptive. Detailed results should be included in the abstract because many readers only have access to abstracts and not the entire article. A structured abstract will include combinations of the following headings that apply and are informative, as described in detail in previous publications:

Objective: including a precise statement of the exact question(s) addressed by the study and, if appropriate, the hypothesis
Methods: the basic study design and setting (i.e., community referral center, ambulatory or hospitalized patients), the patient/subject selection method and number, eligibility criteria, proportion withdrawn, and the exact treatment or

interventions
Results: main outcome measure(s), the main results should be stated with statistical significance
Conclusions: only conclusions supported by the study and their clinical application may be stated

Haynes RB, Mulrow CD, Huth EJ, Altman DG, Gardiner MJ. More informative abstracts revisited. *Ann Intern Med* 1990;113:69-76

Ad Hoc Working Group for Critical Appraisal of the Medical Literature. A proposal for more informative abstracts of clinical articles. *Ann Intern Med* 1987;106:598-604

MANUSCRIPT BODY. The usual sections for a full experimental or clinical research manuscript include Introduction, Methods, Results, Discussion, and Conclusion. Subheadings may be useful in the Methods and Results sections to help clarify the content in longer papers. Methods must be described in sufficient detail to allow others to reproduce the work. For established methods, appropriate references and a brief description are sufficient; but for new methods, appropriate details are required.

Please do not include statements that claim that this is the first time a procedure has been performed, reported, etc., as these claims are difficult to verify and may not be accurate.

If the description of the method is very long, the techniques should be summarized and referenced, and the details provided as an appendix that will be published on the internet but not in print. For human studies, the following details are generally important: eligibility (inclusion and exclusion criteria), randomization methods, blinding methods, total consecutive patients enrolled, and number of exclusions or drop outs and reasons.

REFERENCES. References should be cited consecutively in the text by superscript Arabic numbers in the order in which they are first mentioned in the text, a table, or a figure. References should not be cited alphabetically. The format for references is described in detail in "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (http://www.icmje.org/icmje-recommendations.pdf).

Articles in Press. References to articles in press must include authors' names, title of article, and name of journal. Include the online publication date if it is available.

Personal Communications and Unpublished Data are not to be Cited as References. Instead, indicate these sources in the text at the appropriate place and include the individual's preferred given name, initials, surname, title, city, and year of communication. A note of approval from the source for the statement should be appended to the manuscript.

Authors. If there are six or fewer authors, list all; if seven or more, list only the first six, then et al.

Format for Journal Articles: Josa M, Khuri SF, Braunwald NS, VanCisin MF, Spencer MP, Evans DA, et al. Delayed sternal closure: an improved method of dealing with complications after cardiopulmonary bypass. *J Thorac Cardiovasc Surg*1986;91:598-603.

Format for Books: Berger HJ, Zaret BL, Cohen LS. Cardiovascular nuclear medicine. In: Goldberger E, editor. *Textbook of clinical cardiology.* 1st ed. St Louis: CV Mosby; 1982. p. 326-45

Data References: Cite underlying or relevant datasets in your manuscript by citing them in your text and including a data reference in your Reference List. Data references should include the following elements: author name(s), dataset title, data repository, version (where available), year, and global persistent identifier. Add [dataset] immediately before the reference so we can properly identify it as a data reference. This identifier will not appear in your published article.

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should be certain that all references use the standard abbreviated journal names according to *Index Medicus.* This is imperative to ensure linking of references in the online version of the *Journal*. References that do not use the standard abbreviated journal names will not link.

Formatting Other Submission Files

ILLUSTRATIONS (FIGURES, CHARTS, GRAPHS). Limit illustrations to those that amplify, but do not duplicate the text. A reasonable number of line or halftone illustrations will be reproduced. You may not submit more than the maximum number of figures permitted for the selected article type. Please review the instructions for the specific article type before proceeding. Operative and pathology photographs should be in color. Figures and charts may be black and white unless sufficiently complex to require color. Original drawings or graphs should be prepared by computer software or by a professional artist. Inclusion of color illustrations is at the discretion of the Editor and fees apply.

For our staff to evaluate the quality of your images, each one must be submitted electronically via the Editorial Manager system as separate TIFF, JPEG, or EPS files. Submissions that include figures that are embedded in the text of the manuscript, or that include figures that are compiled in one file, will be returned to you for correction.

Each image must have a minimum resolution of 300 DPI at 3 inches wide. If an image includes text, it must be a minimum of 10-point font.

Cite each figure and figure panel in the manuscript text, including images that are intended to be “online-only” appendices. Number your figures consecutively in Arabic numerals according to the order that they are cited in the manuscript. (Example: Figure 1A, Figure 1B, Figure 2, Supplemental Figure 1, Supplemental Figure 2).

If a TIFF, JPEG or EPS image you uploaded appears very small in the submission PDF, it may be that the file contains a large area of white space surrounding the image. Please be sure to crop out the white space so that the reviewers can read your figures from the PDF.

Figures may be submitted as Microsoft Word or PowerPoint files if the image is sharp, all text is legible, and the figure spans at least 4 inches within the document.

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Life table graphs. Life-table graphs or survival curves should be presented as series of declining horizontal steps. When the standard error of the patency rate estimate is >10%, the curve should be truncated or else should be represented with a dotted line as a means of indicating lack of reliability of the estimate. An alternative way to present the data is to use 95% Confidence Intervals, adding vertical lines to the survival curve at relevant time-points. In addition, there should be an "n" for each group at the relevant time points along the x-axis. For point estimates at a particular time point, using Kaplan-Meier analysis with later events censored is preferable to using chi-square, which does not account for censoring. Because life table graphs are preferred for in-text inclusion, data tables should be submitted only for the online version of the manuscript if the authors desire to provide this level of detail. Differences between curves should be calculated using the log-rank test.

3D radiological data. You can enrich your online article by providing 3D radiological data in DICOM format. Radiological data will be visualized for readers using the interactive viewer embedded within your article, and will enable them to: browse through available radiological datasets; explore radiological data as 2D series, 2D orthogonal MPR, 3D volume rendering and 3D MIP; zoom, rotate and pan 3D reconstructions; cut through the volume; change opacity and threshold level; and download the data. Multiple datasets can be submitted. Each dataset will have to be zipped and uploaded to the online submission system via the '3D radiological data' submission category. The recommended size of a single uncompressed dataset is 200 MB or less. Please provide a short informative

description for each dataset by filling in the 'Description' field when uploading each ZIP file. Note: all datasets will be available for download from the online article on ScienceDirect. So please ensure that all DICOM files are **anonymized** prior to submission. For more information see: https://www.elsevier.com/books-and-journals/content-innovation/3d-radiological-data#instructions

FIGURE LEGENDS. Legends must be numbered, double spaced and uploaded as a separate Word document. Indicate original magnification and stain for photomicrographs.

VIDEOS. Videos that add to the understanding of the text are encouraged. All videos should be in MP4 format. The preferred codec is H264. Please do not submit videos that exceed 150 MB. Authors will be asked to resubmit modified files if necessary. Editing and formatting video is the author's responsibility. As with all other manuscript files, videos must be the original unpublished work of the authors. By submitting video files, the authors grant the Journal permission to publish the files in full or in part in the *Journal of Vascular Surgery: Venous and Lymphatic Disorders* in all formats and media now known or hereafter developed.

Author Summaries. Authors of Clinical, Experimental Research, and Review articles are encouraged to submit a 5-minute video summary of their manuscript.

Video Demonstrations: Authors should consider adding narration or explanatory captioning to video demonstrations of new techniques and procedures.

Editor Summary Videos: The Editor highlights select articles from each issue of *JVS-VL* in an Editor Summary Video which appears on YouTube and JVSVENOUS.ORG.

TABLES. Tables should enhance, not duplicate, the text. Results should not be summarized in a table; use a graph instead. Number your tables consecutively in Roman numerals according to the order of citation in the text. All tables must be cited, including tables intended to be supplemental “online-only”. Example: (Table I, Table II, Supplemental Table I, Supplemental Table II.) Supplemental tables are counted in the table limit for each article type. Tables must be created in a Microsoft Word using 12 pt. Times New Roman font. Tables must be uploaded together in one Word document, with each table starting on a new page and including a legend for each table. Tables may not be embedded in manuscript document. **Manuscripts with tables that do not meet these requirements will be returned to the author.**

Supplemental Tables. The Editors expect that the authors will only submit tables that are essential to the manuscript; however, tables that are not required to understand the manuscript, but that explain the work in greater detail, should be online-only. For example, a table summarizing the articles used in a meta-analysis should be online-only. Also, patient risk factors can frequently be included as an online table.

Abbreviations used in the tables should be explained in a footnote; however, abbreviations that have been defined in the body of the text do not need to be spelled out or explained in the table. If a table or any data therein have been previously published, a footnote in the table must give full credit to the original source, and the original *Publisher's* permission to reproduce the table must be provided.

Revised Submissions. Revised submissions must include all of the files required for a new submission, (updated manuscript file without editing marks, figures, tables, etc.) plus a redline manuscript and a completed reviewer response form.

REDLINE MANUSCRIPT. A redline manuscript is required for all revised submissions and must meet all of the formatting requirements of the non-redlined manuscript. The redline manuscript must include the abstract and title page. The redline manuscript must be created using "Track Changes" in Microsoft Word and must show every change that has been made in the revision. Manually highlighting, underlining or otherwise indicating the changes made is not enough. Once all the changes are shown, the redline must be saved as a PDF. This will ensure that the author will be able to cite the correct page and line numbers in the Reviewer Response form . Detailed instructions about how to create a redline document may be found here.

Requirements for Specific Submission Types

Submission Type	Abstract Structure	Abstract (Words)	Body (Words)	Figures and/or Tables	References	Special Rules
Clinical Research	Structured	250-400	3500	6 print +4 Online Only	50	Requires 10 or more Patients
Editorial	None	None	1000	0	10	Be sure to submit an original title.
Education Corner	Structured	250-400	3500	5 print +5 Online Only	30	None
Evidence Summary	Unstructured	150	1500	5 print +5 Online Only	50	None
Experimental Research	Structured	250-400	4500	6 print +4 Online Only	50	Most Experimental Research manuscripts will be accepted for JVS Vascular Science.
Invited Commentary	None	None	500	0	10	Be sure to submit an original title.
Innovative Technique	Unstructured	100	1200	4	10	
Letter to the Editor	None	None	350	1	10	None
Practice Management	Unstructured	150-200	3000	5 print +5 Online Only	30	None
Review Article	Structured	250-400	3500-5000	5 print +5 Online Only	75-125	Authors should include the type of review in the title of the manuscript, without making it two parts.
Special Article	None	Editor will determine upon invitation.				
Venous Image	None	None	350	4	5	Descriptions of images must be included in the text, since figure legends will not be published. Patients must consent to publication

Article Type Descriptions

Clinical Research Articles involve human clinical information, descriptions of patient populations, clinical applicability results and conclusions and must include 10 or more patients. Clinical Research includes:

Randomized Controlled Trials. Any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Authors must be sure to provide the clinical trial registration number and include a statement in the methods regarding Institutional Review Board approval and patient consent.

Observational Studies. Any study that observes individuals or measures outcomes without attempting to affect the outcome. Cohort, Case Control and Cross-sectional are types of observational study designs. Authors must state whether their study is retrospective or prospective and include the study dates and number of patients. Authors must

be sure to include a statement in the methods regarding Institutional Review Board approval and patient consent. If formal IRB approval was waived, a statement to express this must be included in the methods. The authors should also disclose whether identifiable private information was reviewed for the study, or the process for deidentifying private information.

Cohort. Prospective cohort studies follow one or more patient populations that are free of the outcome of interest for a predetermined period. Individuals who develop the outcome during the study period are compared with those who did not so to investigate the causes of disease, suggesting links between risk factors and health outcomes. The authors must describe the cohort(s), report the length of follow-up, and state which independent variables and outcomes were measured and how. The number of individuals unavailable for follow-up and whether they differed from those with complete follow-up should be included. For retrospective cohort studies, the authors describe if/how investigators were blinded when formulating the hypothesis and determining the dependent and independent variables.

Case-Control. Retrospective study comparing those who have an outcome or event (cases), and those who have not (controls). The source of cases and controls must be described as well as inclusion and exclusion criteria.

Cross-sectional. Study that analyzes data collected from a population, or a representative subset, at a specific point in time.

EDITORIALS. The Editors may solicit an Editorial on an important manuscript or topic to emphasize or explain the significance and relevance of the work to a venous disease specialty audience or to present different views to assist the readers in deciding on the application of the results and conclusions. The editorial should be objective and authoritative and should not exceed 1000 words in length. Even though Editorials are solicited, there is no prior commitment to publish them.

EDUCATION CORNER. Manuscripts for this section will be both invited papers as well as unsolicited submissions from authors with an interest in the training and education of vein and lymphatic specialists. The goal of this section is to discuss issues in the current training and education in venous and lymphatic disease, including patient-specific education, continuing education, as well as national and international workforce issues.

EVIDENCE SUMMARY. Articles in this section summarize the available evidence on a practice issue related to venous and lymphatic disease management. There is a 1500-word limit of the published evidence, often in tabular form, relating to the subject. The goal of this section is to give the readers a focused discussion which will positively influence their practice.

EXPERIMENTAL RESEARCH ARTICLES do not include human clinical information but may include those studies in which only group samples of human blood or tissue are used and the results/conclusions are research oriented. Occasionally, Experimental Research articles will be considered for publication in the *JVS-VL*; however, most Experimental Research manuscripts will be considered for publication in the JVS – Vascular Science.

Clinical Relevance Paragraph. For Experimental Research articles, the *Journal* requires a 100-word paragraph that describes the clinical relevance of the paper as it relates to its current or future clinical application. This paragraph will be printed immediately below the conclusion section of the abstract of the article but will not be included in the abstract that is available on *Medline*. The purpose of this section is to encourage clinicians to read this work and to help them understand its significance.

INVITED COMMENTARY. Upon acceptance of a manuscript, the Editor may request an expert commentary to accompany the published article. Authors who are invited to submit a commentary are asked to help explain how the study fits into the literature and whether it has implications for clinical practice. Authors should provide a unique title for their commentary. Authors should not repeat data or results from the article, since the commentary and article will be published together. However, the first reference must be to the article the commentary is about. Proper citation of the related article improves the online discoverability of the commentary. Authors may cite a few additional references if necessary, but the commentary is intended to be a discussion of the current article, not a literature review. Invited

authors should also be mindful that the authors of the related article will not be asked for a rebuttal. Please be tactful and professional when making critical comments.

LETTERS TO THE EDITOR/RESPONSES. Readers are encouraged to submit letters to the Editor regarding recently published *JVS-VL* articles. The title of a letter should express the main question or opinion of the authors. Letters should address the Editor, not the author, and include the original article as the first reference. Letters should not exceed 350 words and ten references. One illustration or table may be included if it amplifies a recent *JVS-VL* article by extending or clarifying the original manuscript content, or by presenting an opposing interpretation of the results or conclusions. Letters may also be used to submit brief original observations or opinions, although authors may not submit case reports in letter format. The authors of the original article may be provided with an opportunity to respond in a Letter to the Editor. If the authors respond in a timely fashion, both the Letter to the Editor and the authors' response will be published together.

PRACTICE MANAGEMENT. Manuscripts for this section will be both invited and unsolicited papers focusing primarily on issues of interest to the practicing specialist, including office management issues, vascular laboratory management, sociopolitical topics, recruitment, and reimbursement issues. Topics should be of interest to both academic and nonacademic practitioners.

REVIEW ARTICLES. There are several categories of review article. Authors should include the type of review in the title of the manuscript. Please do not use any punctuation in the title. Each type of review has a specific goal and audience. Review Articles may be solicited by the Editors directly or in response to suggestions by authors and will be evaluated as independent submissions and subject to peer review. Illustrations, tables, and graphs are encouraged in all review articles.

Narrative Review. Traditional narrative reviews are mainly descriptive and do not involve a systematic search of the literature. They focus on a subset of studies, based on availability and an author's selection. These reviews are often not comprehensive.

Systematic Review. Systematic reviews involve a comprehensive search strategy, reducing bias by analyzing all relevant studies on a topic; The Cochrane Collaboration (www.cochrane.org) is an example of an organization that produces systematic reviews. The PRISMA statement and checklist is recommended for an evidence-based minimum set of items for reporting in systematic reviews. The Institute of Medicine also produced standards for systematic reviews "Finding What Works in Health Care Standards for Systematic Reviews."

Meta-analysis. A meta-analysis is a type of systematic review that combines either qualitative or quantitative data from multiple studies, using a statistical approach, to increase power and resolve uncertainty. Meta-analyses of comparative studies usually include randomized control trials, but evidence from well conducted observational studies can also be included in some meta-analyses. The PRISMA statement and checklist is recommended for an evidence-based minimum set of items for reporting in meta-analysis (http://www.prisma-statement.org)

Systematic review and meta-analysis. Systematic review and meta-analysis are often combined, or may be combined in a single document and are highly encouraged.

SPECIAL ARTICLE: This carefully selected group of articles includes Historical Vignettes, legal issues, ethical issues, personal reflections, opinion writings and other important topics that do not fit into a defined submission category. Special Articles must be important to the readers of *JVS-VL*. They can be invited articles or unsolicited submissions.

INNOVATIVE TECHNIQUE. Manuscripts for this section will be either invited papers from recognized experts or unsolicited manuscripts. These articles are practical and well-illustrated descriptions and technical tips for new or established operative and/or endovenous procedures. Authors are encouraged to submit a narrated video with the publication. summarizing the advantages and disadvantages of the procedure.

VENOUS IMAGES. Submissions accepted for this section present interesting venous and lymphatic images and associated short educational summaries in a focused, report format. Illustrations and text must be confined to one

printed page (350 words max, four illustrations or fewer: one for the cover and three that must fit in the right-hand column). Venous Images may be featured on the cover of the *JVS-VL*. Please indicate which image should appear on the Journal cover in the in-text figure citation. The Editor may not select an image from your accepted manuscript for the cover; however, it is required that you designate one image as the cover image before submission. Previously, published images will not be considered for this section. Descriptions of images must be included in the text, since figure legends will not be published, and only key references should be provided (with a limit of five). Images must be of professional quality and meet the basic requirements for resolution specified in **Illustrations (figures, charts, graphs).**

Cover Image Format: Color illustrations are preferred for the cover. Cover images must not include arrows, or any other added graphics and, whenever possible, text should be cropped out. Appropriate images include radiographs, pathology, anatomy, operative findings, and other relevant clinical pictures. The images should illustrate features of venous and lymphatic disease, including technical approaches. Venous images should possess both scientific and artistic merit.

Consent. The patient must agree to publish their case details and images before the author may submit their manuscript. A statement regarding this consent must be included in the text of the manuscript. The author is responsible for obtaining written consent for publication and archiving that file. To protect the patient(s') privacy, the author SHOULD NOT submit the consent form to the Editorial Office. If a standard publication consent form is not available, this form may be used: **Download.**

Other Types of Publications

Presidential Addresses. A Presidential Address from a meeting of the Society of Vascular Surgery and affiliated societies will be published after editorial review, which may provide suggested improvements. Authors submitting Presidential Addresses must also submit a completed Application for Publication.

Reporting Standards, Practice Guidelines, and Appropriate Use Criteria. These three types of documents are developed under the auspices of the Society for Vascular Surgery and/or American Venous Forum and will be published after review by the Document Oversight Committee and approval by the Board of Directors of the Society for Vascular Surgery.

Debates. Manuscripts for this section will be invited papers describing a point/counterpoint debate between two recognized experts in the field, concerning a controversial clinical issue. These debates will be introduced by a brief case vignette. Each expert will submit a defense of their position, as well as a response to their opponent's argument. These manuscripts may be accompanied by an invited expert commentary.

Obituaries. The Journal will publish obituaries for individuals who have been Editor-in-Chief or Senior Editor, Founders, or recipients of the American Venous Forum Founder's Award.

Leaders in Venous Surgery. This new section will highlight the leaders of venous disease management, with a concise one-page review of the leader's career, as well as a photograph and a video. Manuscripts are accepted from a committee of the Society for Vascular Surgery who has videotaped interviews with most of these pioneers.

Society Discussions The discussions of papers presented at the Society for Vascular Surgery's Vascular Annual Meeting and at some of the meetings of the affiliated societies will be published with the manuscripts if they are submitted in a timely fashion; however, these discussions are subject to Editorial review and only those that enhance the text or present alternative views will be published.

Fees

Color Image Fee: If your manuscript is selected for publication in the *JVS-VL,* you will be charged a fee for the color images included in your paper. The color image charge is 650.00 USD for the first color image and 150.00 USD for each additional color image. Unless your figures are sufficiently complex to merit color, please submit charts and

graphs in black and white. There are no other mandatory submission or publication fees for this Journal.

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After Manuscript Acceptance

Role of the Publisher

Pre-Proof. The pre-proof is a fully citable version of the manuscript prior to proofreading and formatting by the Publisher. Pre-proofs allow the fastest possible publication and are indexed by Medline. These articles can be cited using the date of access and their unique DOI (Digital Object Identifier) number. Additional changes in the article may be needed and these will be included in the final version. The pre-proof for most article types will appear online approximately 6 weeks after acceptance.

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Print Publication. The article will appear in print once it is selected by the Editor for an issue. Print publication can be expected in 3-6 months from acceptance.

Publication Accessibility. The authors have the option to publish their research in a subscription or open-access format. Fees for open-access are collected by the *Publisher* and will have no bearing on the peer review or acceptance process. The open-access publication fee for the *Journal of Vascular Surgery: Venous and Lymphatic Disorders* is US $3300, excluding taxes. Learn more about Elsevier's pricing policy: http://www.elsevier.com/openaccesspricing

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SEQUENCE OF PUBLICATION. In general, manuscripts are published in the order they are received, providing that the Journal receives revisions in a timely fashion. Under unusual circumstances, a paper may be assigned priority for early publication if, in the view of the Editors, it contains important new information that should be brought to the attention of the readers immediately.

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