Great saphenous vein diameter does not correlate with worsening quality of life scores in patients with great saphenous vein incompetence

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Objective: **Previous studies have correlated increasing great saphenous vein (GSV) diameter with increasing CEAP clinical classification. Some insurance carriers are currently using specific GSV diameters to determine coverage for treatment of axial venous insufficiency. The aim of this study was to investigate the correlation of patient quality of life (QOL) measures with GSV diameters in varicose vein patients with GSV reflux.**

Methods: **Data were collected from the records of 91 patients prospectively enrolled in two varicose vein trials. The patients had symptomatic varicose veins with saphenofemoral junction and proximal GSV reflux. Maximum GSV diameter was measured on duplex ultrasound imaging, with the patient standing, within 5 cm of the saphenofemoral junction. Chronic Venous Insufficiency Questionnaire 2 (CIVIQ-2; Servier, Neuilly-sur-Seine, France), Venous Insufficiency Epidemiological and Economic Study (VEINES) Symptom (Sym) and QOL assessments, and the Venous Clinical Severity Score (VCSS) assessment were completed before treatment of GSV insufficiency. Demographic information, patient weight, height, and body mass index were collected. Correlations between pairs of data were done using Pearson product-moment and Spearman correlation coefficients.**

Results: **The 91 study patients (19 men, 72 women) were a mean age of 45 years (range, 18-65 years). The mean GSV diameter was 6.7 mm (range, 2.2-14.1 mm). The mean VCSS score was 7.8 (range, 3-12). There was a weak correlation between increasing GSV diameter and VCSS ($r = 0.23$; $P = .03$) and no correlation between GSV diameter and the CIVIQ-2 score ($r = 0.01$), VEINES-QOL ($r = -0.07$), and VEINES-Sym ($r = -0.1$).**

Conclusions: **GSV diameter is a poor surrogate marker for assessing the effect of varicose veins on a patient's QOL; thus, using GSV diameter as a sole criterion for determining medical necessity for the treatment of GSV reflux is inappropriate. Further correlations between QOL measures and duplex-derived objective findings are warranted. (J Vasc Surg 2012;56: 1634-41.)**

Currently, several insurance carriers in the United States have restricted coverage of venous ablation procedures to patients in whom the saphenous vein diameter reaches a specific duplex-derived size.[1,2] These measurements do not differ by patient sex, age, or body size. United Healthcare, for example, requires that the diameters of the great saphenous vein (GSV) and the small saphenous vein (SSV) must each measure at least 5.5 mm to qualify for coverage. The goal of these restrictions, presumably, is to provide an objective measure to divide patients with a medical necessity for treatment of GSV reflux from those in whom treatment is for cosmetic purposes or in whom the effect of varicose veins on their activities of daily living (ADLs) and quality of life (QOL) is not significant.

Previous studies have found that worsening CEAP clinical class correlates with increasing saphenous trunk diameters.[3-5] The Chronic Venous Insufficiency Questionnaire 2 (CIVIQ-2; Servier, Neuilly-sur-Seine, France)[6] and the Venous Insufficiency Epidemiologic and Economic Study (VEINES) Quality of Life/Symptom (QOL/Sym) questionnaires[7] are venous-specific patient-derived assessments that have been used as tools to assess baseline QOL and evaluate outcomes of clinical trials.[8] These QOL instruments have been validated in multiple patient populations.[6,7,9,10] The VEINES study group showed that increasing CEAP clinical class was associated with decreasing patient QOL.[11] The validity of extrapolating data from these studies to use vein diameter as a surrogate marker for effect on QOL has not been established.

The primary objective of this study was to determine if the diameter of the GSV correlates with patient-derived rather than physician-derived measurements of disease severity. Secondary objectives included correlation of patient morphologic measurements (height, weight, and body mass index [BMI]) with Venous Clinical Severity Scores (VCSS) and QOL scores, and correlation of QOL scores with each other and with the physician-derived VCSS.

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METHODS

An Institutional Review Board approved the experimental protocols of the trials reported in this study and informed consent forms. All participants gave informed consent.

Patients. The data for this study were obtained from two clinical trials sponsored by BTG International Ltd (London, UK). The purpose of the first trial was to compare a proprietary polidocanol endovenous microfoam vs placebo in the treatment of GSV or anterior accessory saphenous vein (AASV) incompetence conducted at four clinical sites in the United States.[12] The second trial compared QOL measurements, VCSS, and photography of the affected limb in patients before and after treatment with radiofreqency ablation (RFA) or endovenous laser treatment (EVLT) of the GSV or the AASV. The data from the second trial used in this study were from one clinical site (the first author's) because this was the only site that had data available for GSV measurements. From both data sets, we examined only the data from patients with GSV incompetence (excluding the patients with incompetence of the AASV alone). Data were contributed by 75 individuals in the first trial and by 16 in the second trial. GSV diameters were available on all 91 patients, and reflux times were available in 82 patients.

To be eligible for the trials, patients had to be between the ages of 18 and 65 years, have symptomatic varicose veins without active ulcers (CEAP clinical class C_{3-5} for the first trial and C_{2-5} for the second trial), and have reflux >0.5 seconds at the saphenofemoral junction (SFJ) and proximal GSV while standing. Exclusion criteria included venous ulceration, arterial insufficiency, obesity preventing compression of the treated limb, pregnancy, and breastfeeding. Patients with concomitant deep venous insufficiency (with exception of deep venous insufficiency limited to the segment of the common femoral vein adjacent to the incompetent SFJ) were excluded from the two trials.

Data collected. GSV diameters and reflux times were measured by registered vascular technologists with the patient standing. The GSV diameter used was the widest diameter of the GSV within 5 cm of the SFJ, measured to 0.1 mm. The reflux time was recorded in this same location to 0.1 second after manual calf compression.

To qualify as a study site, each vascular laboratory submitted a dossier of duplex scans and interpretations to an outside reviewer for adequacy. After this review, GSV diameters in each patient were collected one time at entry into the study by a single prequalified registered vascular technologist (intraobserver and interobserver variability was not performed as part of the study). Each patient completed the CIVIQ-2, VEINES-Sym, and VEINES-QOL questionnaires, and physicians completed VCSS before treatment.

Statistical analysis. Patient demographics, morphometric data, GSV diameter and reflux time data, VCSS scores, and the QOL scores were collected in an Excel database (Microsoft, Redmond, Wash) and underwent descriptive analysis. Distribution of QOL scores was normalized to allow analysis between data pairs using Pearson product-moment correlation coefficients (transforming the scores to parametric data). Spearman correlation coefficients were also determined, and the results from this analysis were virtually identical to the evaluation using Pearson correlation coefficients, with the exception of the data pairs of VCSS vs GSV diameter. For that data pair, Spearman correlation coefficients (ρ) were calculated, and for the sample size of 91 pairs of data, correlations were considered strong at a negative or positive r = 0.5 to 1.0, moderate at r = 0.3 to 0.49, weak at r = 0.1 to 0.29, and absent at r <±0.1. Statistical significance of r was determined using a critical values table for the Pearson and Spearman correlation coefficients.

Table I. Patient characteristics

Variable	*No. or mean (range)*
Sex	
Male	19
Female	72
Age, years	45 (18-65)
Height, cm	168 (135-203)
Weight, kg	77.9 (48.6-114.3)
BMI, kg/m^2	27.4 (17.8-41.7)
GSV diameter, mm	6.7 (2.2-14.1)

BMI, Body mass index; *GSV,* great saphenous vein.

RESULTS

Demographic, morphometric, and GSV diameter characteristics of the patient population are reported in Table I. The population was fairly typical for patients with varicose veins: 79% were women, and the mean age was 45 years. Eighty-seven of the patients were white, two were Asian, one was Hispanic, and one was African-American. There was a wide range of heights, weights, and BMIs represented, ranging from patients who would be considered underweight (BMI, 18 kg/m^2) to the grossly obese (BMI, 42 kg/m^2). GSV diameters varied widely, from 2.2 to 14.1 mm, with a mean diameter of 6.7 mm (standard deviation [SD], 2.4 mm). According to CEAP clinical class, six patients (6.6%) were C_2, 75 (82.4%) were C_3, eight (8.8%) were C_4, and two (2.2%) were C_5. Reflux times were a mean of 5 seconds (SD, 2 seconds; range, 0.6-15 seconds). One patient had a GSV with a reflux time of <1 second.

Table II summarizes the VCSS and QOL scores for the patient population. The physician-derived VCSS was fairly low, with a mean score of 6.4, showing that this population has relatively mild to moderate venous disease from a physician's perspective. Pearson product-moment correlation coefficient analysis was performed to assess the correlation between the VCSS and the QOL measures (Table III). A moderate, statistically significant correlation existed between the VCSS and the CIVIQ-2, VEINES-Sym, and VEINES-QOL scores. A strong correlation was present among the three QOL measures.

Table II. Venous Clinical Severity Score (*VCSS*) and quality of life (*QOL*) scores

Assessment	*Mean (range)*
VCSS	6.4 (3-12)
CIVIQ-2	42.5 (20-85)
VEINES	
Symptoms	40.5 (12-60)
QOL	82.7 (35-118)

CIVIQ-2, Chronic Venous Insufficiency Questionnaire-2; *VEINES,* Venous Insufficiency Epidemiological and Economic Study.

Table III. Pearson coefficient correlations (*r* values) between Venous Clinical Severity Score (*VCSS*) and quality of life (*QOL*) measures

Variable	*VCSS*	*CIVIQ-2*	*VEINES-Sym*	*VEINES-QOL*
VCSS	1	0.43	−0.37	−0.44
CIVIQ-2		1	−0.83	0.90
VEINES-Sym			1	0.96
VEINES-QOL				1

CIVIQ-2, Chronic Venous Insufficiency Questionnaire 2; *Sym,* symptoms; *VEINES,* Venous Insufficiency Epidemiological and Economic Study.
$P < .01$ for all correlations.

Table IV. Correlations (*r* values) between great saphenous vein (*GSV*) diameter and reflux time, and assessments of disease and quality of life

Assessment	*GSV diameter (n = 91)*	*Reflux time (n = 82)*
VCSS[a]	0.23[b]	−0.05
CIVIQ-2[c]	0.01	−0.01
VEINES-Sym[c]	−0.10	0.00
VEINES-QOL[c]	−0.07	−0.02

CIVIQ-2, Chronic Venous Insufficiency Questionnaire 2; *VCSS,* Venous Clinical Severity Score; *VEINES-Sym/QOL,* Venous Insufficiency Epidemiological and Economic Study-Symptoms/Quality of Life.
[a]Spearman correlation.
[b]$P = .02$, all other *P* values insignificant.
[c]Pearson correlation.

Correlation analyses between GSV diameter, reflux time, VCSS, and QOL measurements are reported in Table IV. This analysis showed a weak correlation between GSV diameter and VCSS and a very weak and statistically insignificant correlation between GSV diameter and VEINES-Sym scores. No correlation existed between GSV diameter, CIVIQ-2, and VEINES-QOL scores or between reflux time, VCSS, and any of the QOL scores. The analysis comparing GSV diameter to the physician-derived and patient-derived measures is shown in Figs 1 to 4, which show scatterplots of GSV diameter, VCSS, VEINES-SYM, VEINES-QOL, and CIVIQ-2 scores with best-fit lines.

Table V reports correlation analyses of patient height, weight, and BMI with GSV diameter and reflux time. This analysis showed a weak but statistically significant correlation between increasing weight and BMI with GSV diameter but no correlation between patient height and GSV diameter. There was a trend toward statistical significance in a weak inverse correlation between height and reflux time, and BMI and reflux time.

DISCUSSION

A population-based study conducted by Kaplan et al[13] in 2003 estimated that approximately 24% of adults have varicose veins and that significant association exists between disease severity and patient QOL. Extrapolating these data to the current population of the United States,[14] approximately 74 million adult Americans have varicose veins. The prevalence and severity of superficial venous insufficiency increases with age,[13,15] and as the United States population grows and ages, the number of patients with varicose veins is expected to increase. Studies have shown that treatment of varicose veins not only improves patient QOL[8] but is also more cost-effective than conservative management.[16] On the basis of a comprehensive review of current literature, clinical practice guidelines recently published by a joint committee of the Society for Vascular Surgery and the American Venous Forum have recommended endovenous thermal ablation (RFA or EVLT) over conservative management or open surgery in symptomatic patients (CEAP $\geq C_2$) with GSV incompetence.[17]

Procedures performed in the United States to treat incompetence of the GSV have steadily increased since the U.S. Food and Drug Administration approved RFA in 1999 and EVLT in 2002. The 153,000 RFA procedures, 211,000 EVLTs, and 16,000 vein strippings were performed in 2010. From 2007 to 2013, the number of EVLTs is projected to increase by 14.5%, RFA by 15.3%, and stripping will fall by 16%.[18] Decreased postoperative pain, avoidance of general anesthesia, and quicker return to normal activities offered by these new technologies have indisputably made treatment of venous incompetence more attractive to patients.[19-22]

Ablation procedures performed in the outpatient setting are less expensive than vein stripping performed in the hospital[23,24]; however, the increase in total venous procedures being performed has certainly caught the attention of insurance payers. Although improvements in QOL, a decrease in days off from work and in disability in patients treated for varicose veins are beneficial to society and cost-effective in the long-term, the increase in procedures in the short term is an unwelcome additional demand on health insurance companies.

Undoubtedly in response to the increase in ablation procedures, insurers have placed restrictions on the coverage of treatment for varicose veins. Most insurance carriers in our region require a trial of "conservative management," usually consisting of requiring patients to wear compression stockings for a specified period of weeks or months, and often requiring a chronic need for analgesics, and documentation on impact of ADLs, de-

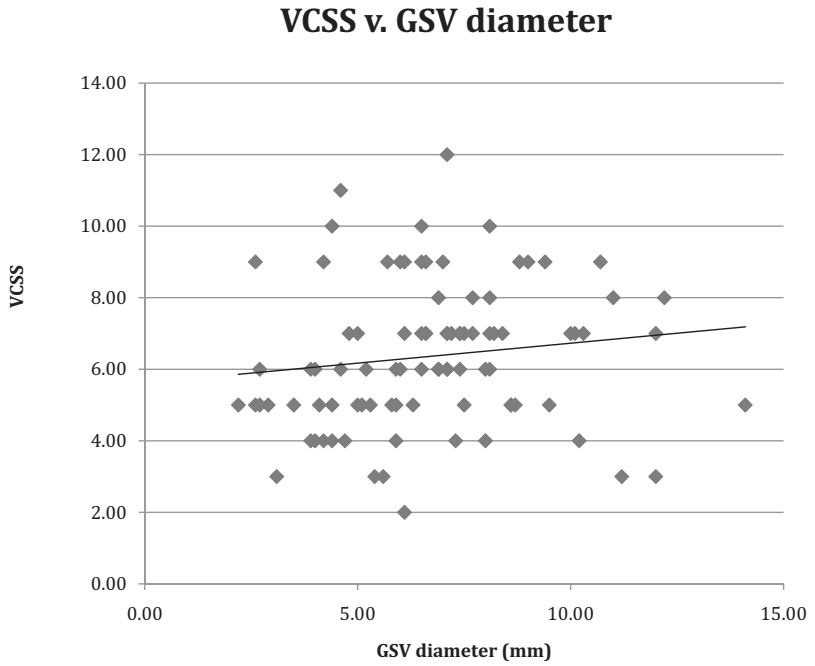

Fig 1. Scatterplot shows comparison of great saphenous vein (*GSV*) diameter and Venous Clinical Severity Score (*VCSS*).

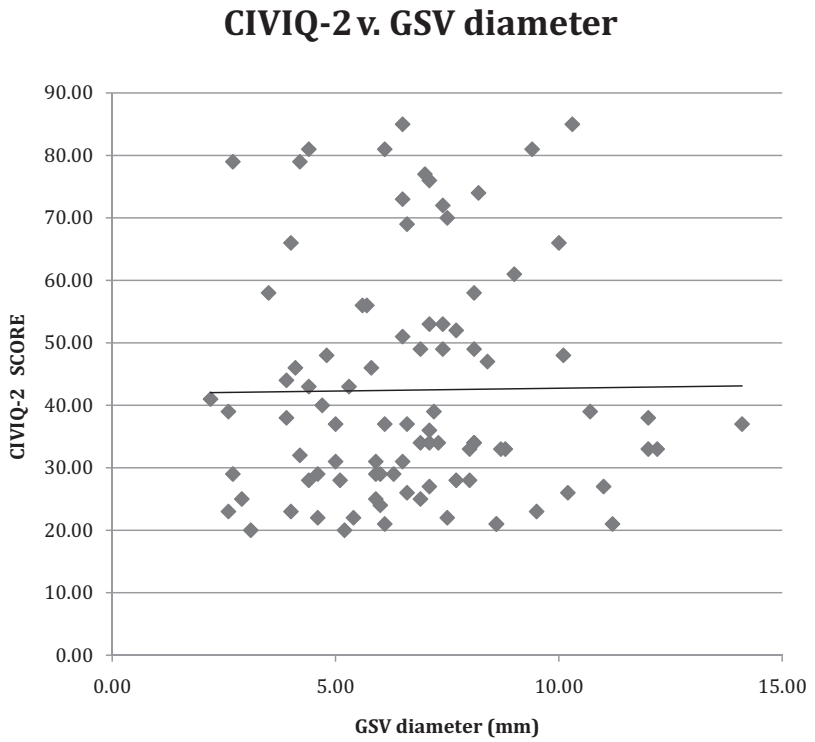

Fig 2. Scatterplot shows comparison of great saphenous vein (*GSV*) diameter and Chronic Venous Insufficiency Questionnaire 2 (*CIVIQ-2*) score.

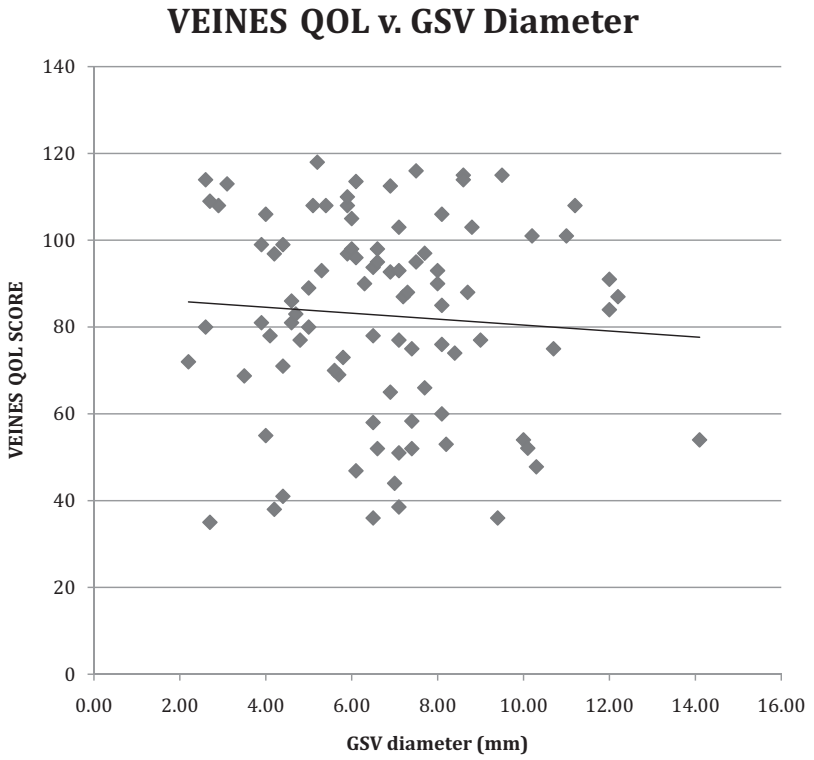

Fig 3. Scatterplot shows comparison of great saphenous vein (*GSV*) diameter and Venous Insufficiency Epidemiological and Economic Study Quality of Life (*VEINES-QOL*) assessment.

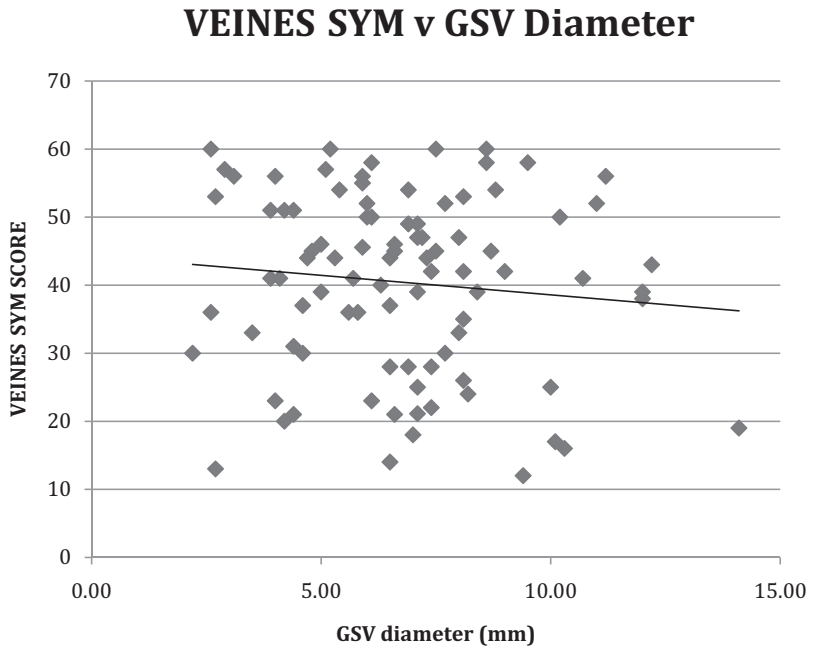

Fig 4. Scatterplot shows comparison of great saphenous vein (*GSV*) diameter and Venous Insufficiency Epidemiological and Economic Study Symptoms (*VEINES-SYM*) assessment.

Table V. Pearson coefficient correlations (*r* values) between great saphenous vein (*GSV*) diameter, reflux time, patient weight, height, and body mass index (*BMI*)

Variable	*GSV diameter (n = 91)*	*Reflux time (n = 82)*
Weight	0.26[a]	−0.04
Height	0.07	−0.19[b]
BMI	0.25[a]	−0.21[b]

[a] $P = .02$.
[b] $P < .10$.

spite the paucity of evidence that such conservative management is beneficial.[17]

More recently, insurance companies have begun placing restrictions on coverage of varicose vein treatment based not solely on physicians' determinations of medical necessity and on patient-reported symptoms and effect on ADLs but on specific duplex-derived measurements, including vein diameters. Ostensibly, GSV diameter is being used as a surrogate marker to indicate disease and to differentiate patients with "medical necessity" for vein treatment from those in whom the treatment is for cosmetic reasons. The effect of venous insufficiency on patient QOL lacks a readily definable objective surrogate marker such as exists for arterial insufficiency (eg, walking distance). The ultimate goal of any venous therapy should be to improve patient QOL, not to improve findings on anatomic and hemodynamic assessments. The use of surrogate markers to define successful end points for vein therapy has been criticized,[15] and our results would argue that the use of such markers to segregate patient populations into groups that should or should not be covered for vein treatment should be questioned as well.

The diameter of the GSV has never been used as a criterion to define venous reflux.[17,25] Authors studying the use of GSV diameter as a marker for hemodynamic impairment have had mixed results. Navarro et al[4] in 2002 studied 82 patients and concluded that a GSV diameter of ≤5.5 mm had a 78% specificity and a 87% sensitivity in predicting absence of "pathologic reflux." In 2008, Musli et al[26] studied 182 patients and concluded that the sensitivity (69.7%) and specificity (64.6%) of GSV diameter in predicting "hemodynamically significant reflux" was poor. GSV diameter can vary with patient positioning, Valsalva maneuvers, and BMI.[27] Although other authors have shown a correlation between CEAP clinical class and GSV diameter,[3-5] CEAP clinical class and patient QOL,[28,29] and CEAP clinical class and VCSS,[30] there are no published data directly correlating GSV diameter with patient QOL.

Our data show that in the described patient population, GSV diameter has only a weak association with VCSS and nonexistent correlation with patient QOL scores. QOL scores have an excellent correlation with each other and a moderate correlation with VCSS. These data support the recent publication by Shepherd et al,[8] who investigated the correlation between venous disease-specific QOL measurements with hemodynamic and anatomic assessments. The QOL assessment tools that they studied were the Aberdeen Varicose Vein Questionnaire (AVVQ) and the Specific Quality-of-life and Outcome Response Venous (SQOR-V) questionnaire. The authors concluded that the QOL measures correlated well with each other, had a weak but statistically significant correlation with VCSS, and poor correlation with anatomic reflux (Venous Segmental Disease Score and venous refill times).[8] The Shepherd et al data, as well as our findings, demonstrate that the assessment of the effect of superficial venous insufficiency on patient QOL cannot be simply assessed with surrogate anatomic or hemodynamic markers. Although previous works do correlate increasing GSV diameter with increasing CEAP clinical class, this correlation does not extend to patient perceptions of the effect of their venous disease on their life. As such, basing coverage for vein treatment on something as simple as GSV diameter is at best arbitrary.

QOL was measured in these patients many times during their evaluation and treatment, but only once in the "untreated" state at the entry of study. The QOL measurements at study entry were the only values used in this report. Multiple QOL measurements in the same patient before treatment would be more meaningful by adding strength to our findings. We would argue, however, that this study more closely mimics what happens in real clinical practice. The physician generally does not see the patient at multiple visits before recommending vein treatment. Patients are referred for evaluation, are seen, and then usually undergo a duplex evaluation. Multiple duplex evaluations to validate GSV diameter and multiple visits or patient contacts to assess the effect on QOL would be impractical and not reimbursed. The impetus for this report was the policy of a number of payers to limit treatment of GSV insufficiency to patients in whom the GSV diameter met a specific threshold. This report correlates a single assessment of GSV diameter with a patient-derived QOL measurement at a single time point, as is done in clinical practice.

This study has several limitations. GSV diameter, as measured by duplex scanning, can have interobserver and intraobserver variability and can also vary depending on time of day, patient positioning, and room temperature. Every effort was made to standardize patient positioning, room temperature, and scanning technique for GSV measurements; however, the scan was performed only once for each patient, and the time of day was not controlled.

Another limitation of this study is that this patient population had predominantly mild to moderate clinical venous insufficiency (CEAP clinical class C_{2-3} disease). Both trials specifically excluded patients at CEAP C_1 and C_6 and one trial excluded C_2 patients. As such, this cohort may not well characterize a typical practitioner's population of patients with varicose veins because patients with more

severe disease ($C_{4,5,6}$) and more mild disease (C_2) are both under-represented. It is possible that there is an association between GSV diameter and patient QOL in a patient population with more severe clinical disease (CEAP C_{4-6}). Further investigation in a patient population more heavily represented by patients with higher CEAP clinical classes is warranted.

CONCLUSIONS

GSV diameter is a poor surrogate marker for assessing the effect of varicose veins on a patient's QOL; thus, it is inappropriate to use GSV diameter as a sole criterion for determining medical necessity for the treatment of GSV reflux. Further correlations between QOL measures and duplex-derived objective findings are warranted.

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AUTHOR CONTRIBUTIONS

Conception and design: KG, DW
Analysis and interpretation: KG, DW, MM
Data collection: KG
Writing the article: KG
Critical revision of the article: KG, DW, MM
Final approval of the article: KG, DW, MM
Statistical analysis: KG, MM
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REFERENCES

1. United Healthcare. Coverage determination guideline. Ablative procedures for venous insufficiency and varicose veins; 2010. Available at: https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Veins_CD.pdf. Accessed January 4, 2012.
2. Cigna. Medical coverage policy. Varicose vein treatment effective 5/15/2011. Available at: http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0234_coveragepositioncriteria_varicose_vein_treatments.pdf. Accessed January 4, 2012.
3. Labropoulos N, Kokkosis AA, Spentzouris G, Gasparis AP, Tassiopoulos AK. The distribution and significance of varicosities in the saphenous trunks. J Vasc Surg 2010;51:96-103.
4. Navarro TP, Delis KT, Ribeiro AP. Clinical and hemodynamic significance of the greater saphenous vein diameter in chronic venous insufficiency. Arch Surg 2002;137:1233-7.
5. Barros MV, Labropoulos N, Ribeiro AL, Okawa RY, Machado FS. Clinical significance of ostial great saphenous vein reflux. Eur J Vasc Endovasc Surg 2006;31:320-4.
6. Launois R, Reboul-Marty J, Henry B. Construction and validation of a quality of life questionnaire in chronic lower limb venous insufficiency (CIVIQ). Qual Life Res 1996;5:539-54.
7. Lamping DL, Schroter S, Kurz X, Kahn SR, Abenhaim L. Evaluation of outcomes in chronic venous disorders of the leg: development of a scientifically rigorous, patient-reported measure of symptoms and quality of life. J Vasc Surg 2003;37:410-9.
8. Shepherd AC, Gohel MS, Lim CS, Davies AH. A study to compare disease-specific quality of life with clinical anatomical and hemodynamic assessments in patients with varicose veins. J Vasc Surg 2011;53:374-82.
9. Lozano FS, Launois R, Reflux Assessment and Quality of Life Improvement with Micronized Flavonoids (RELIEF) Spanish group. Quality of life (Spain and France): validation of the chronic venous insufficiency questionnaire (CIVIQ). Methods Find Exp Clin Pharmacol 2002;24:425-9.
10. Launois R, Mansilha A, Jantet G. International psychometric validation of the chronic venous disease quality of life questionnaire (CIVIQ-20). Eur J Vasc Endovasc Surg 2010;40:783-9.
11. Kahn SR, M'lan CE, Lamping DL, Kurz X, Bérard A, Abenhaim LA, et al. Relationship between clinical classification of chronic venous disease and patient-reported quality of life: results from an international cohort study. J Vasc Surg 2004;39:823-8.
12. Clinicaltrials.gov. Randomized, single blind, placebo controlled, to evaluate efficacy and safety of polidocanol endovenous microfoam for treatment of symptomatic, visible varicose veins with SFJ incompetence (pilot); 2009. Available at: http://www.clinicaltrials.gov/ct2/show/NCT00758420?term=Varisolve&rank=3. Accessed January 4, 2012.
13. Kaplan RM, Criqui MH, Denenberg JO, Bergan J, Fronek A. Quality of life in patients with chronic venous disease: San Diego population study. J Vasc Surg 2003;37:1047-53.
14. U.S. Census Bureau. U.S. Census Bureau Announces 2010 Census Population Counts – Apportionment Counts Delivered to President; 2010. Available at: http://2010.census.gov/news/releases/operations/cb10-cn93.html. Accessed January 4, 2012.
15. Carpentier PH, Maricq HR, Biro C, Ponçot-Makinen CO, Franco A. Prevalence, risk factors, and clinical patterns of chronic venous disorders of lower limbs: a population-based study in France. J Vasc Surg 2004;40:650-9.
16. Michaels J, Campbell W, Brazier J, Macintyre J, Palfreyman S, Ratcliffe J, et al. Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). Health Technol Assess 2006;10:1-196.
17. Gloviczki P, Comerota A, Dalsing M, Eklof B, Gillespie D, Gloviczki M, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the society for vascular surgery and the American venous forum. J Vasc Surg 2011;53:2S-48S.
18. Millenium Research Group. US market for varicose vein treatment devices; 2009. Report: RPUS:11VR09. Available at: http://www.mrg.net. Accessed January 4, 2012.
19. Helmy ElKaffas K, ElKashef O, ElBaz W. Great saphenous vein radiofrequency ablation versus standard stripping in the management of primary varicose veins-a randomized clinical trial. Angiology 2011;62:49-54.
20. Subramonia S, Lees T. Randomized clinical trial of radiofrequency ablation or conventional high ligation and stripping for great saphenous varicose veins. Br J Surg 2010;97:328-36.
21. Carradice D, Mekako AI, Mazari FA, Samuel N, Hatfield J, Chetter IC. Randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins. Br J Surg 2011;98:501-10.
22. Kalteis M, Berger I, Messie-Werndl S, Pistrich R, Schimetta W, Pölz W, et al. High ligation combined with stripping and endovenous laser ablation of the great saphenous vein: early results of a randomized controlled study. J Vasc Surg 2008;47:822-9.
23. Eidson JL, Atkins MD, Bohannon WT, Marrocco CJ, Buckley CJ, Bush RL. Economic and outcomes-based analysis of the care of symptomatic varicose veins. J Surg Res 2011;168:5-8.
24. Gohel MS, Epstein DM, Davies AH. Cost-effectiveness of traditional and endovenous treatments for varicose veins. Br J Surg 2010;97:1815-23.
25. Labropoulos N, Tiongson J, Pryor L, Tassiopoulos AK, Kang SS, Ashraf Mansour M, et al. Definition of venous reflux in lower-extremity veins. J Vasc Surg 2003;38:793-8.
26. Musil D, Herman J, Mazuch J. Width of the great saphenous vein lumen in the groin and occurrence of significant reflux in the saphenofemoral junction. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub 2008;152:267-70.

27. Jeanneret C, Labs KH, Aschwanden M, Bollinger A, Hoffman U, Jäger K. Physiological reflux and venous diameter change in the proximal lower limb veins during a standard Valsalva manoeuvre. Eur J Vasc Endovasc Surg 1999;17:398-403.
28. Enden T, Garratt AM, Kløw NE, Sandset PM. Assessing burden of illness following acute deep vein thrombosis: data quality, reliability and validity of the Norwegian version of VEINES-QOL/Sym, a disease-specific questionnaire. Scand J Caring Sci 2009;23:369-74.
29. Carradice D, Mazari FA, Samuel N, Allgar V, Hatfield J, Chetter IC. Modelling the effect of venous disease on quality of life. Br J Surg 2011;98:1089-98.
30. Kakkos SK, Rivera MA, Matsagas MI, Lazarides MK, Robless P, Belcaro G, et al. Validation of the new venous severity scoring system in varicose vein surgery. J Vasc Surg 2003;38:224-8.

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