Venous Clinical Severity Score has a suboptimal ability to detect improvement after iliac vein stenting across three years of follow-up

Halbert Bai, MPH, Jason B. Storch, BA, Jenny Chen, BA, *and* Windsor Ting, MD, *New York, NY*

ABSTRACT

Objective: Venous Clinical Severity Score (VCSS) is currently the gold standard for measuring the severity of chronic venous disease, especially in patients with chronic proximal venous outflow obstruction (PVOO) secondary to non-thrombotic iliac vein lesions. Change in VCSS composite scores is often used to quantitatively measure the degree of clinical improvement after venous interventions. This study sought to assess the discriminative ability, sensitivity, and specificity of change in VCSS composites for detecting clinical improvement after iliac venous stenting.

Methods: A registry of 433 patients who underwent iliofemoral vein stenting for chronic PVOO from August 2011 to June 2021 was retrospectively analyzed. These 433 patients had follow-up exceeding 1 year after the index procedure. Change in VCSS composite and clinical assessment scores (CAS) were used to quantify improvement after venous interventions. CAS is an assessment by the operating surgeon based on patient self-reporting to assess the degree of improvement at each clinic visit compared with before the index procedure longitudinally across the treatment course of a patient. Patients are rated as worse (−1), no change (0), mildly improved (+1), significantly improved (+2), and asymptomatic/complete resolution (+3) at every follow-up visit as compared with their disease severity prior to the procedure based on patient self-report. This study defined improvement as CAS >0 and no improvement as CAS ≤0. VCSS was then compared with CAS. Receiver operative characteristic curve and area under the curve (AUC) were used to evaluate change in VCSS composite for its ability to discriminate between improvement and no improvement after intervention at each year of follow-up.

Results: Change in VCSS was a suboptimal measure for discriminating clinical improvement (1-year AUC, 0.764; 2-year AUC, 0.753; 3-year AUC, 0.715). Across all three time points, a change in VCSS threshold of +2.5 maximized the sensitivity and specificity of the instrument to detect clinical improvement. At 1 year, change in VCSS at this threshold was able to detect clinical improvement at a sensitivity of 74.9% and specificity of 70.0%. At 2 years, VCSS change had a sensitivity of 70.7% and specificity of 66.7%. At 3 years of follow-up, VCSS change had a sensitivity of 76.2% and specificity of 58.1%.

Conclusions: Across 3 years, change in VCSS exhibited a suboptimal ability to detect clinical improvement in patients undergoing iliac vein stenting for chronic PVOO with considerable sensitivity but variable specificity at a threshold of 2.5. (J Vasc Surg Venous Lymphat Disord 2023;11:754-60.)

Keywords: Venous clinical severity score; Chronic venous disease; Iliac vein stenting; Iliac vein compression; Epidemiology; Diagnostic accuracy

Chronic venous disease (CVD) affects over 25 million adults in the United States.[1,2] A clinical tool that accurately discriminates venous disease severity before and after intervention is critical to evaluation and treatment of CVD. Currently, the Venous Clinical Severity Score (VCSS) is the most widely used standard for measuring and comparing venous disease severity and outcomes after venous interventions for both superficial and deep venous diseases.[3] It quantifies the clinical symptoms of venous disease using 10 clinical parameters, with each parameter scored from 0 to 3, for a total possible score of 30. Similar to the static CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classification, VCSS is a physician-generated measurement tool that assesses nine clinical symptoms of CVD including pain, pigmentation, inflammation, induration, venous edema, varicose veins, size of active ulcers, number of active ulcers, and duration of active ulcers, as well as compression therapy adherence.[4,5]

VCSS was developed by an ad hoc committee of the American Venous Forum in 2000 by Rutherford et al and subsequently revised by Vasquez et al in 2010.[5,6] The components of VCSS were selected to give greater

From the Division of Vascular Surgery, Department of Surgery, Icahn School of Medicine at Mount Sinai.

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Correspondence: Windsor Ting, MD, Division of Vascular Surgery, Icahn School of Medicine at Mount Sinai, 1425 Madison Ave, New York, NY 10029 (e-mail: Windsor.ting@mountsinai.org).

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weight to the most severe symptoms and sequelae of CVD that would be most likely to exhibit change in response to therapy.[7] Previous studies have highlighted the responsiveness of VCSS in grading subtle changes in the severity of CVD in a limited context. The ability for VCSS to detect clinical improvement after intervention has only been validated in the context of superficial venous disease.[8-10] Nonetheless, VCSS has now been widely used to measure changes in clinical signs and symptoms after interventions for deep venous diseases as well such as for non-thrombotic iliac vein lesions (NIVLs) and post-thrombotic syndrome.[11] To our knowledge, there has been no studies demonstrating the diagnostic accuracy, sensitivity, and specificity of VCSS in detecting clinical improvement after deep venous interventions. The aim of this study was to compare VCSS with a binary physician-generated measure of clinical improvement after iliac vein stenting across 3 years of follow-up.

METHODS

A registry of 433 patients who underwent iliofemoral vein stenting for chronic proximal venous outflow obstruction (PVOO) from NIVLs between August 2011 and June 2021 were retrospectively analyzed. Each patient in this cohort had follow-up 1 year after the initial stent placement. All cases were performed at a large tertiary hospital in New York City by a single surgeon. Research Electronic Data Capture (REDCap) electronic platform hosted at the Mount Sinai Health System was used to securely collect, manage, and store patient information.[12,13] Our Institutional Review Board waived individual informed consent because of the retrospective nature of this study (study no. STUDY-15-00,506: Sinai Vein Stent Registry; approval no. GCO 14-1497-0001-03-PD).

Change in VCSS composite scores and clinical assessment scores (CAS) were the two physician-generated measures for assessing clinical improvement employed in this study. CAS is a previously described measure that distills clinical improvement in leg symptoms into four simplified categories.[14-16] Each patient is rated worse (−1), no change (0), mildly improved (+1), significantly improved (+2), and complete resolution of venous symptoms (+3) at every follow-up as compared with their disease severity prior to the procedure. The operating surgeon determined the degree of clinical improvement based on patient self-report and physical examination at each clinic visit compared with before the index procedure, and this was documented in the patient's chart at each follow-up visit for data collection in this study. VCSS components were also recorded during each patient visit. This study measured symptoms on the symptomatic leg(s). Both CAS and VCSS were recorded ipsilaterally for the impacted leg(s). If both legs were affected, the leg with the most severe VCSS components and worst CAS were recorded for the study. The patient's symptom severity as well as the presence of iliac vein stenosis of greater than 50% compared with an adjacent normal vein segment on intravascular ultrasound were both considered prior to iliac vein stenting. This study sought to address the extent of agreement between change in VCSS composite scores and a reference standard to elucidate the ability for change in VCSS to detect clinical improvement after iliac vein intervention. Because VCSS is the current "gold standard," we sought to compare change in VCSS with a binary scale reflecting the presence of clinical improvement. Hence, this study defined clinical improvement as CAS >0 and no improvement as CAS ≤ 0. VCSS was then compared with this binary CAS standard.

Descriptive statistics were employed to define the demographic characteristics of this cohort. Receiver operating characteristic (ROC) curves and area under the ROC curves (AUC) were used to evaluate VCSS for its ability to discriminate between improvement and no improvement after intervention at each year of follow-up across 3 years. Sensitivity and specificity of change in VCSS composite scores for detecting clinical improvement were also calculated. All statistical analyses were performed using R (R Core Team, Vienna, Austria).

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective registry
- **Key Findings:** Across 3 years of follow-up, changes in composite Venous Clinical Severity Scores (VCSS) exhibited suboptimal ability to discriminate clinical improvement from no clinical improvement (1-year area under the curve [AUC], 0.764; 2-year AUC, 0.753; 3-year AUC, 0.715). Compared with a binary clinical standard, changes in VCSS composites had a suboptimal ability to detect clinical improvement with a sensitivity at each year of follow-up exceeding 70% at a change in VCSS threshold of +2.5 (1-year, 74.9%; 2-year, 70.7%; 3-year, 76.2%). However, the specificity of VCSS decreased across these 3 years at this threshold (1-year, 70.0%; 2-year, 66.7%; 3-year, 58.1%). A change in VCSS value of +2.5 maximized both sensitivity and specificity of the instrument for detecting clinical improvement.
- **Take Home Message:** Changes in VCSS composite scores show a suboptimal ability to detect clinical improvement after venous intervention across years of follow-up. A change in VCSS composite of +2.5 should be considered as the minimum threshold for demonstrating clinical improvement across years of follow-up.

Table I. Demographics, comorbidities, perioperative, and long-term outcomes of patients who received iliac vein stenting

Characteristic	
Total no. of patients	433
Age, years	61.5±12.6
Female gender	264 (61.1)
BMI, kg/m^2	26.7±5.8
History of DVT	69 (15.9)
Previous venous intervention	177 (43.8)
Previous venous stent	11 (2.7)
Diabetes	87 (20.1)
Hypertension	217 (50.1)
CAD	52 (12.8)
History of smoking	91 (21.0)
History of cancer	37 (8.9)
Ethnicity	
Asian	315 (76.1)
Black	31 (7.5)
Hispanic	31 (7.5)
White	37 (8.9)
Complications within 30 days	11 (2.5)
Number of stents	2.2±1.0
CEAP class	3.4±1.0
CEAP class	
C0	3 (0.7)
C2	28 (6.5)
C3	249 (57.5)
C4	107 (24.7)
C5	15 (3.5)
C6	31 (7.2)
Preoperative VCSS	
VCSS composite	10.3±4.0
Pain	
None	47 (10.9)
Mild	88 (20.3)
Moderate	220 (50.8)
Severe	78 (18.0)
Varicose veins	
None	159 (36.7)
Mild	57 (13.2)
Moderate	176 (40.6)
Severe	41 (9.5)
Venous edema	
None	18 (4.2)
Mild	29 (6.7)
Moderate	188 (43.4)
Severe	198 (45.7)
Pigmentation	
None	76 (17.6)
Mild	183 (42.3)
Moderate	146 (33.7)
Severe	28 (6.5)
Inflammation	
None	156 (36.0)
Mild	156 (36.0)
Moderate	90 (20.8)
Severe	31 (7.2)
Induration	
None	156 (36.0)
Mild	156 (36.0)
Moderate	91 (21.0)
Severe	30 (6.9)
Number of active ulcers	
0	399 (92.1)
1	22 (5.1)
2	6 (1.4)
≥3	6 (1.4)
Ulcer duration	
Not applicable	398 (91.9)
<3 months	7 (1.6)
3 months to 1 year	15 (3.5)
>1 year	13 (3.0)
Active ulcer size, cm	
Not applicable	400 (92.4)
<2	12 (2.8)
2-6	16 (3.7)
>6	5 (1.2)
Compression therapy	
Not used	145 (33.5)
Intermittent use of stockings	101 (23.3)
Wears stockings most days	78 (18.0)
Full compliance	109 (25.2)
Perioperative details	
Intraoperative DVT	129 (29.8)
Unilateral stent placement	172 (39.7)
Long-term outcomes	
Follow-up, days	1053.4±645.8
Reintervention requiring venography	82 (20.2)
Postoperative endovenous laser ablation	162 (39.9)
Number of reinterventions	2.0±1.3
Improvement in VCSS composite	
1-year	4.9±4.3
2-year	6.8±5.1
3-year	8.1±4.9

BMI, Body mass index; *CAD*, coronary artery disease; *CEAP*, Clinical-Etiology-Anatomy-Pathophysiology; *DVT*, deep venous thrombosis; *SD*, standard deviation; *VCSS*, Venous Clinical Severity Score.
Data are presented as number (%) or mean ± standard deviation.

RESULTS

The cohort of 433 patients was mostly female (61.1%) and Asian (76.1%), with a mean (± standard deviation) age of 61.5 ±12.6 years (Table I). Many patients had comorbidities, including diabetes (20.1%), hypertension (50.1%), coronary artery disease (12.8%), a history of smoking (21.0%), and cancer (8.9%). The mean (± standard deviation) of follow-up time was 2.89 ±1.77 years with follow-up of 64.2% at 2 years and 41.1% at 3 years in this cohort (Supplementary Table, online only). This cohort was drawn from a registry of patients (n = 840) receiving iliac vein stenting from NIVLs (Supplementary Table, online only). Across 3 years of follow-up, both the sensitivity and specificity were maximized at a change in VCSS composite threshold of +2.5. Change in VCSS at this optimized threshold was able to detect clinical improvement at a sensitivity of 74.9% and specificity of 70.0%. AUC of VCSS compared with binary CAS at 1-year was 0.764 with a 95% confidence interval (CI) of 0.686-0.841. At 2 years, VCSS change had a sensitivity of 70.7% and specificity of 66.7% at the optimized threshold. AUC at 2-year follow-up was 0.753 with a 95% CI of 0.678-0.827. At 3 years, VCSS change had a sensitivity of 76.2% and specificity of 58.1% at the +2.5 threshold (Table II). AUC at 3-year follow-up was 0.715 with a 95% CI of 0.614-0.815 (Fig).

DISCUSSION

We sought to determine the diagnostic accuracy of change in VCSS composite scores in detecting clinical improvement among patients with PVOO caused by NIVLs across years of follow-up. Prior work has demonstrated that VCSS has excellent validity[17,18] and reliability,[17] but to our knowledge, the only studies specifically examining its responsiveness to change have been conducted on patients undergoing treatment for superficial venous disease.[9-11] Many research studies and clinical trials have employed VCSS as the instrument for measuring clinical improvement after interventions for both superficial and deep venous diseases, but few, if any, have examined its validity in detecting clinical improvement compared with another clinical standard. The present study compared change in VCSS composites with a binary physician-generated assessment based on patient self-report and physical examination of whether the patient did indeed exhibit clinical improvement after iliac vein stenting for the treatment of PVOO.

As expected, change in VCSS composite accurately detects improvement after intervention at an AUC exceeding 70% across years of follow-up. We found the optimized threshold that maximizes sensitivity and specificity for detecting clinical improvement to be a change in VCSS composite score of +2.5. To our knowledge, this is the first study to identify and report a threshold necessary for detecting clinical improvement. The consistency of this threshold across 3 years of follow-up suggests that meeting this threshold is necessary for the instrument to detect clinical improvement. Future clinical trials of devices and therapeutics for the treatment of CVD should consider meeting at least a change in VCSS composite of +2.5 to demonstrate efficacy of the intervention longitudinally. That is, this study found that across 3 years of follow-up, improvement in VCSS composite of 2.5 points was associated with detectable clinical improvement in lower extremity symptoms when the patient presented to the operating surgeon. The present study also confirms the suspicions of some authors that VCSS is susceptible to false-positives.[3] The specificity of change in VCSS was variable and decreased across years of follow-up. This is likely due to comorbidities of patients over time that interfere with the accuracy of change in VCSS to detect clinical improvement. The longitudinal decrease in specificity may also reflect recurrence or the natural history of CVD progression. Nonetheless, the attenuated specificity across years of follow-up suggests that VCSS may require revision to better capture salient clinical outcomes after iliac vein stenting.

VCSS was primarily developed as a dynamic, physician-generated measure for assessing salient clinical signs and symptoms of superficial venous disease.[4,5,19] Components of VCSS such as visible varicosities, pigmentation, and induration are targeted at symptoms of varicose veins. Nonetheless, VCSS has now been widely adopted for measuring improvement after venous interventions for deep venous disease. Although some signs of CVD are shared between deep and superficial venous diseases, many signs and symptoms more prevalent in deep venous disease, including deep venous thrombosis, venous claudication, and pelvic discomfort, are not captured in VCSS.[19] The present study demonstrated that change in VCSS has suboptimal ability to detect clinical improvement after iliac venous stenting for PVOO. Future research should aim to refine VCSS to better capture the severity of deep venous disease. Including more clinical components relevant to the deep venous disease and potentially eliminating less clinically salient components could increase the sensitivity and specificity of the instrument for detecting clinical improvement on the ipsilateral limb.

Study limitations. This study was subject to several limitations. Binary CAS was used as the diagnostic measure of clinical improvement with which change in VCSS composite scores was compared. Similar to VCSS, CAS is a physician-generated measure of clinical improvement in symptoms that compares patient presentation at follow-up with before the index intervention.[14-16,20] Unlike VCSS, however, CAS is based on self-reported symptomatic improvement in CVD by patients combined with findings from physical exam. If the patient reported no lower extremity edema, but venous edema was present on physical exam, the physician deferred to

Table II. Threshold values for change in Venous Clinical Severity Score (*VCSS*) composite to detect clinical improvement

Change in VCSS composite	Sensitivity, %	Specificity, %
1-year follow-up		
−4.5	99.7	0.0
−3.5	99.2	4.0
−2.5	98.7	10.0
−1.5	97.7	20.0
−0.5	95.8	28.0
0.5	90.3	36.0
1.5	84.6	58.0
2.5	**74.9**	**70.0**
3.5	61.9	78.0
4.5	53.8	84.0
5.5	42.8	88.0
6.5	33.4	88.0
7.5	25.6	92.0
8.5	19.6	92.0
9.5	13.6	94.0
10.5	9.7	94.0
11.5	7.3	96.0
12.5	4.7	96.0
13.5	3.4	96.0
14.5	1.8	98.0
15.5	1.3	100.0
17.0	1.0	100.0
18.5	0.8	100.0
21.5	0.5	100.0
25.5	0.3	100.0
2-year follow-up		
−5.5	99.6	2.8
−3.5	98.3	5.6
−2.5	98.3	8.3
−1.5	97.1	16.7
−0.5	93.4	22.2
0.5	87.2	38.9
1.5	81.4	50.0
2.5	**70.7**	**66.7**
3.5	60.7	66.7
4.5	52.5	83.3
5.5	40.5	94.4
6.5	27.7	100.0
7.5	19.4	100.0
8.5	12.8	100.0
9.5	9.9	100.0
10.5	7.4	100.0
11.5	5.0	100.0
12.5	2.1	100.0
13.5	1.7	100.0
15.5	0.8	100.0
18.5	0.4	100.0
3-year follow-up		
−5.5	99.3	0.0
−4.5	98.6	3.2
−3.5	98.0	3.2
−2.5	98.0	6.5
−1.5	95.9	16.1
−0.5	92.5	19.4
0.5	90.5	32.3
1.5	83.7	45.2
2.5	**76.2**	**58.1**
3.5	63.3	71.0
4.5	49.0	74.2
5.5	38.8	87.1
6.5	32.7	90.3
7.5	24.5	93.5
8.5	21.1	93.5
9.5	10.2	96.8
10.5	7.5	100.0
11.5	6.8	100.0
12.5	2.7	100.0
13.5	2.0	1.0
14.5	1.4	1.0
17.0	0.7	1.0

Bold values indicate the threshold values that maximize both sensitivity and specificity of detecting clinical improvement.

the finding seen on physical exam. As with any self-report measure, biases can interfere with its precision and generalizability. Notwithstanding this limitation, the consistent optimal change in VCSS threshold of +2.5 strongly suggests that, despite potential inter-subject variability in reporting of CAS, there is likely a universal threshold at which patients with CVD report symptomatic improvement across 3 years of follow-up. Secondly, although the sample size was large, the study was performed at a single institution with a single, highly experienced surgeon, which may limit the generalizability of our findings. This study also examined patients with follow-up exceeding 1 year. Patients with longer-term follow-up could have a distinct disease course and face a heavier burden of CVD. However, this limitation further highlights the change in VCSS threshold of +2.5 necessary for therapeutics and interventions to demonstrate long-term efficacy. VCSS includes two components, namely pain and compression therapy compliance, that are self-reported by patients. Lastly, future studies should seek to characterize which of the 10 components of VCSS are most predictive of changes and long-term outcomes following iliac vein stenting.

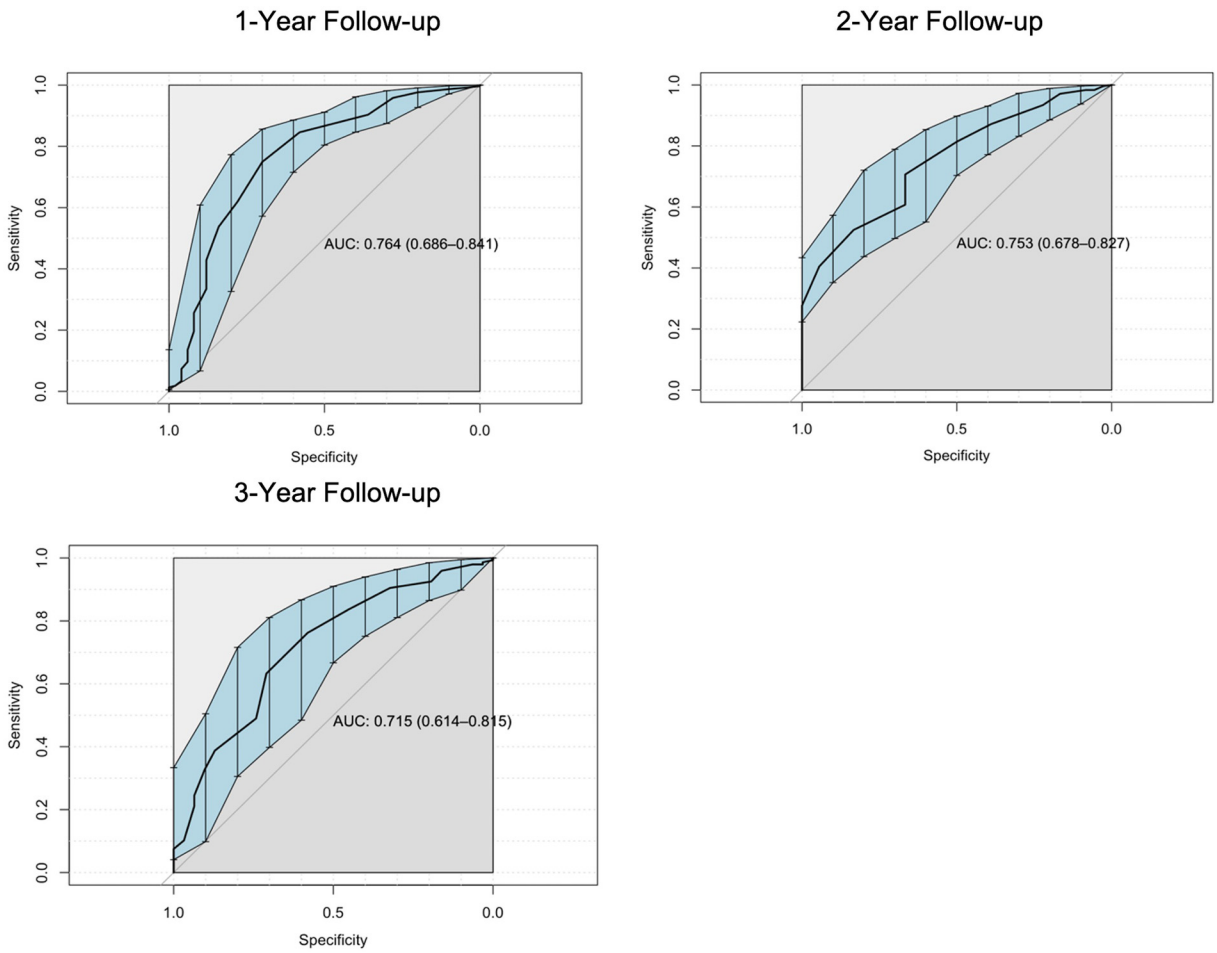

Fig. Improvement in composite Venous Clinical Severity Score (VCSS) receiver operative characteristic curves (ROC) and area under the ROC curves (*AUC*) for discriminating clinical improvement (95% confidence interval [CI] of the AUC).

CONCLUSIONS

Change in VCSS shows suboptimal ability to detect clinical improvement in response to iliac vein stenting for the treatment of PVOO from NIVLs at an AUC exceeding 70%. At an optimized threshold of +2.5, change in VCSS demonstrates sensitivity exceeding 70% and variable specificity ranging from 58.1% to 70.0% at detecting clinical improvement. Future research should aim to potentially revise VCSS to include more salient clinical signs and symptoms of deep venous disease to increase the validity and responsiveness of the instrument.

AUTHOR CONTRIBUTIONS

Conception and design: HB, WT
Analysis and interpretation: HB, JS, JC, WT
Data collection: HB, WT
Writing the article: HB, WT
Critical revision of the article: HB, JS, JC, WT
Final approval of the article: HB, JS, JC, WT
Statistical analysis: HB, WT
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Additional material for this article may be found online at www.jvsvenous.org.

Supplementary Table (online only). Number of patients who returned for follow-up at each yearly interval across 3 years

Year of follow-up	No.	Proportion of the original registry, %
1	433	51.5
2	278	33.1
3	178	21.2