From the American Venous Forum

Validation of Venous Clinical Severity Score (VCSS) with other venous severity assessment tools from the American Venous Forum, National Venous Screening Program

Marc A. Passman, MD,[a] Robert B. McLafferty, MD,[b] Michelle F. Lentz, MAS,[c] Shardul B. Nagre, MBBS, MS, MPH,[a] Mark D. Iafrati, MD,[d] W. Todd Bohannon, MD,[e] Colleen M. Moore, MD,[b] Jennifer A. Heller, MD,[f] Joseph R. Schneider, MD,[g] Joann M. Lohr, MD,[h] and **Joseph A. Caprini, MD,[i]** *Birmingham, Ala; Springfield, Ill; Baltimore, Md; Boston, Mass; Temple, Tex; Winfield, Ill; Cincinnati, Ohio; and Skokie, Ill*

Background: **Several standard venous assessment tools have been used as independent determinants of venous disease severity, but correlation between these instruments as a global venous screening tool has not been tested. The scope of this study is to assess the validity of Venous Clinical Severity Scoring (VCSS) and its integration with other venous assessment tools as a global venous screening instrument.**

Methods: **The American Venous Forum (AVF), National Venous Screening Program (NVSP) data registry from 2007 to 2009 was queried for participants with complete datasets, including CEAP clinical staging, VCSS, modified Chronic Venous Insufficiency Quality of Life (CIVIQ) assessment, and venous ultrasound results. Statistical correlation trends were analyzed using Spearman's rank coefficient as related to VCSS.**

Results: **Five thousand eight hundred fourteen limbs in 2,907 participants were screened and included CEAP clinical stage C0: 26%; C1: 33%; C2: 24%; C3: 9%; C4: 7%; C5: 0.5%; C6: 0.2% (mean, 1.41 ± 1.22). VCSS mean score distribution (range, 0-3) for the entire cohort included: pain 1.01 ± 0.80, varicose veins 0.61 ± 0.84, edema 0.61 ± 0.81, pigmentation 0.15 ± 0.47, inflammation 0.07 ± 0.33, induration 0.04 ± 0.27, ulcer number 0.004 ± 0.081, ulcer size 0.007 ± 0.112, ulcer duration 0.007 ± 0.134, and compression 0.30 ± 0.81. Overall correlation between CEAP and VCSS was moderately strong ($r_s = 0.49$; $P < .0001$), with highest correlation for attributes reflecting more advanced disease, including varicose vein ($r_s = 0.51$; $P < .0001$), pigmentation ($r_s = 0.39$; $P < .0001$), inflammation ($r_s = 0.28$; $P < .0001$), induration ($r_s = 0.22$; $P < .0001$), and edema ($r_s = 0.21$; $P < .0001$). Based on the modified CIVIQ assessment, overall mean score for each general category included: Quality of Life (QoL)-Pain 6.04 ± 3.12 (range, 3-15), QoL-Functional 9.90 ± 5.32 (range, 5-25), and QoL-Social 5.41 ± 3.09 (range, 3-15). Overall correlation between CIVIQ and VCSS was moderately strong ($r_s = 0.43$; $P < .0001$), with the highest correlation noted for pain ($r_s = 0.55$; $P < .0001$) and edema ($r_s = 0.30$; $P < .0001$). Based on screening venous ultrasound results, 38.1% of limbs had reflux and 1.5% obstruction in the femoral, saphenous, or popliteal vein segments. Correlation between overall venous ultrasound findings (reflux + obstruction) and VCSS was slightly positive ($r_s = 0.23$; $P < .0001$) but was highest for varicose vein ($r_s = 0.32$; $P < .0001$) and showed no correlation to swelling ($r_s = 0.06$; $P < .0001$) and pain ($r_s = 0.003$; $P = .7947$).**

Conclusions: **While there is correlation between VCSS, CEAP, modified CIVIQ, and venous ultrasound findings, subgroup analysis indicates that this correlation is driven by different components of VCSS compared with the other venous assessment tools. This observation may reflect that VCSS has more global application in determining overall severity of venous disease, while at the same time highlighting the strengths of the other venous assessment tools. (J Vasc Surg 2011;54:2S-9S.)**

From the Section of Vascular Surgery and Endovascular Therapy, University of Alabama at Birmingham, Birmingham[a]; Division of Vascular Surgery, Southern Illinois University School of Medicine, Springfield[b]; Baltimore[c]; Department of Surgery, Tufts University School of Medicine, Boston[d]; Scott & White Memorial Hospital & Clinic, Temple[e]; Department of Surgery, Johns Hopkins University School of Medicine, Baltimore[f]; Vascular and Interventional Program, Central DuPage Hospital, Winfield[g]; Good Samaritan Hospital, Cincinnati[h]; and North Shore University Health System, Skokie.[i]

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Reprint requests: Marc A. Passman, MD, Section of Vascular Surgery and Endovascular Therapy, University of Alabama at Birmingham, BDB 503, 1530 3rd Avenue S., Birmingham, Ala 35294-0012 (e-mail: marc.passman@ccc.uab.edu).

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Venous outcomes assessment tools have been used to evaluate the severity of venous disease and provide standardized evaluation of treatment effectiveness. While the CEAP classification system for chronic venous disease is useful to classify stages of venous disease, enabling patient comparison among different centers and studies, its components have been recognized to be relatively static and insufficient for determining changes in venous disease severity.[1,2] In an effort to improve standardized outcome assessment of venous disease with gradable elements that can change in response to treatment, in 2000, the American Venous Forum (AVF), Ad Hoc Committee on Venous Outcomes Assessment, proposed the Venous Clinical Severity Score (VCSS).[3] The VCSS system includes 10 clinical descriptors (pain, varicose veins, venous edema, skin pigmentation, inflammation, induration, number of active ulcers, duration of active ulceration, size of ulcer, and compressive therapy use), scored from 0 to 3 (total possible score, 30) that may be used to assess changes in response to therapy. While VCSS has been shown to have minimal intraobserver and interobserver variability,[4] validation with objective venous parameters has been reserved to only a few studies with limited sample size.[5,6] Despite lack of extended validation, there has been general acceptance and wide dissemination of VCSS for clinical and research purposes.[7-14]

With the creation of the AVF, the National Venous Screening Program (NVSP) in 2005, and its expansion in 2007,[15,16] several standard venous assessment tools were incorporated into the screening process as independent determinants of venous disease severity, but correlation between these instruments as a global venous screening tool has not been tested. The scope of this study is to assess the validity of VCSS and its integration with other venous assessment tools as a global venous screening instrument.

METHODS

Screening program. Since its inception in 2005, the AVF NVSP has had the mission of increasing awareness of acute and chronic venous disease through *education* on venous thromboembolism (VTE) and chronic venous insufficiency; *identification* of those at risk for VTE, the presence of venous obstruction or reflux, and the presence of chronic venous insufficiency; and *empowerment* of participants to inform others about the risk or presence of venous disease. Oversight of the NVSP is provided by the NVSP committee of the AVF (chairman, M.P.) under the direction of the AVF Executive Committee and leadership, NVSP administrative coordinator (M.L., RF Associates, Baltimore, MD), and Administrare, Inc. (Salem, MA). Nationwide site recruitment and participation in the NVSP during the study period was sought through medical societies interested in venous disease: the AVF, the Society for Vascular Surgery, and the American College of Phlebology. A training NVSP toolkit and all related screening and educational material was provided to interested sites through unrestricted educational grants from Juzo Corporation (Cleveland, OH) and Sanofi-Aventis (Bridgewater, NJ).

The NVSP screening process has been described and validated elsewhere.[15,16] Briefly, participants completed a self-administered demographic questionnaire and VTE risk assessment,[17] underwent a focused lower extremity examination, and were graded according to CEAP classification.[1,2] In 2007, VCSS[3] and abbreviated Chronic Venous Insufficiency Quality of Life (CIVIQ)[18,19] assessments were added to the screening process. An abbreviated venous duplex ultrasound examination for venous reflux and obstruction by vascular technicians at each site was performed on all participants. Venous duplex ultrasound screening focused on common femoral vein, saphenofemoral junction, and above-knee popliteal venous segments. With participants in the supine position and the head of the bed elevated to 30 degrees, a Valsalva maneuver was performed at each vein location with manual compression using B-mode to evaluate for obstruction, defined as inability to completely oppose vein walls, or reflux, defined as reversal of flow >0.5 seconds. An exit interview with the participant was performed by a health care provider at each site to review the venous screening findings. Participants received free venous disease educational brochures and a venous report card with direction to share the report with their primary care provider. All screening sites were requested to return collected data points without participant identifiers to NVSP administrative coordinator (M.L.) with data entry into the NSVP quality assurance registry (Access; Microsoft Corp., Seattle, WA).

Study design. The NVSP registry was queried for all participants with complete screening datasets from 2007 to 2009 for inclusion in the analysis. Inclusion in the study required complete participant data sets, including collected demographic data, clinical information, VTE risk assessment, CEAP, VCSS, abbreviated CIVIQ, and venous ultrasound findings. The VTE risk assessment, modified from VTE risk scoring system reported by Caprini et al,[17] evaluated participants' risk of developing VTE if placed into a high-risk situation (such as surgical procedure, major injury or other hospitalizations, malignancy, or prolonged immobility). Point scores based on the severity of individual VTE risk factors were assigned and totaled for a final VTE risk score and then categorized as low risk (0-1 point), moderate risk (2 points), high risk (3-4 points), and very high risk (>5 points). Clinical CEAP classification was determined by direct physical inspection of lower extremities by providers at each site (C0: No visible or palpable signs of venous disease; C1: Telangiectasies or reticular veins; C2: Varicose veins; C3: Edema; C4: Changes in skin and subcutaneous tissue; C5: Healed venous ulcer; C6: Active venous ulcer).[1,2] VCSS was determined based on current published reporting standards with scores for each attribute (0-3 points) and total score determined (Table I), from data collected on subjective questionnaire and direct physical assessment provider on site.[3] The abbreviated CIVIQ questionnaire ranked symptoms experienced during the preceding 4 weeks prior to screening according to a Likert scale of

Table I. Venous Clinical Severity Scoring system used by NVSP

Attribute	*Absent (0)*	*Mild (1)*	*Moderate (2)*	*Severe (3)*
Pain	None	Occasional	Daily	Daily with meds
Varicose veins	None	Few	Multiple	Extensive
Venous edema	None	Evening only	Afternoon	Morning
Skin pigmentation	None	Limited, old	Diffuse, more recent	Wider, recent
Inflammation	None	Mild cellulitis	Moderate cellulitis	Severe
Induration	None	Focal <5 cm	<1/3 gaiter	>1/3 gaiter
No. of active ulcers	None	1	2	>2
Active ulcer size	None	<2 cm	2-6 cm	>6 cm
Ulcer duration	None	<3 months	3-12 months	>1 year
Compression	None	Intermittent	Most days	Fully compliant

NVSP, National Venous Screening Program.

1 to 5 (1 - no pain/not bothered at all; 5 - intense pain/impossible to do). For data analysis, the 11 questions used in abbreviated CIVIQ were categorized as follows: pain (four questions), physical functioning (four questions), and social activities (three questions). Venous ultrasound findings of reflux or obstruction in the common femoral vein, saphenofemoral junction, or popliteal vein were stratified for descriptive purposes, but were combined either as presence or absence in the statistical analysis.

Statistics. Statistical analyses were performed using SAS v9.1 (SAS Institute Inc., Cary, NC) with statistical assistance provided through the Division of Vascular Surgery and Endovascular Therapy, Department of Surgery, University of Alabama at Birmingham (S.N.). Analysis was separated as participant or limb based when appropriate. Descriptive statistics were used for VTE risk factors, CEAP classification, VCSS, CIVIQ, and presence/absence of venous reflux and obstruction. Correlation trends as related to VCSS were determined using Spearman's rank coefficient (ordinal variables, nonparametric). When testing VCSS score for each limb against other limb based tests (CEAP, venous ultrasound), analysis was based on each limb. When testing VCSS against participant-based tests (VTE risk score, CIVIQ) analysis was performed both based on total number of limbs versus participants and based on random sampling of one limb per participant. Correlation was rated as follows: Very Weak/Negligible: $r_s = 0.0$ to 0.2; Weak/Low: $r_s = 0.2$ to 0.4; Moderate: $r_s = 0.4$ to 0.7; Strong/High: $r_s = 0.7$ to 0.9; Very Strong: $r_s = 0.9$ to 1.0.

RESULTS

Over the 2-year period, complete data sets were available for analysis on 5,814 limbs screened in 2,907 participants. Mean age was 58.9 ± 13.3 years, with a gender distribution of female (n = 2180; 75%) and male (n = 727; 25%). Mean body mass index was 29.2 ± 7.3. Race distribution included Caucasian (n = 2326; 80%), African-American (n = 233; 8%), Hispanic (n = 87; 3%), Asian (n = 84; 3%), and other (n = 177; 6%). Pre-existing medical factors included: hypertension (n = 988; 34%); diabetes mellitus (n = 291; 10%); congestive heart failure (n = 57; 2%); tobacco history: nonsmoker (n = 1742; 60%), past smoker (n = 960; 33%), current smoker (n = 205; 7%); and pertinent medications: aspirin (n = 638; 22%), clopidogrel (n = 57; 2%), other antiplatelet medication (n = 30; 1%), and warfarin (n = 118; 4%).

Table II. Correlation between VCSS parameters and mean clinical CEAP score (n = 5814 limbs)

VCSS	*CEAP score (r_s)*
Pain	0.12 ($P < .0001$)
Varicose vein	0.51 ($P < .0001$)
Edema	0.21 ($P < .0001$)
Pigmentation	0.38 ($P < .0001$)
Inflammation	0.27 ($P < .0001$)
Induration	0.21 ($P < .0001$)
Ulcer number	0.07 ($P < .0001$)
Ulcer size	0.05 ($P < .0001$)
Ulcer duration	0.08 ($P < .0001$)
Compression	0.18 ($P < .0001$)

VCSS, Venous Clinical Severity Score.
Spearman correlation: medium gray = moderate correlation; light gray = weak/low correlation; white = very weak/negligible correlation.

Mean total VCSS score (n = 5814 limbs) was 2.83 ± 0.47. VCSS mean score distribution for each category (range, 0-3) was pain 1.01 ± 0.80; varicose veins 0.61 ± 0.84; edema 0.61 ± 0.81; pigmentation 0.15 ± 0.47; inflammation 0.07 ± 0.33; induration 0.04 ± 0.27; ulcer number 0.004 ± 0.081; ulcer size 0.007 ± 0.112; ulcer duration 0.007 ± 0.134; and compression 0.30 ± 0.81.

Mean clinical CEAP clinical classification (n = 5814 limbs) was 1.4 ± 1.2, with CEAP clinical classification distribution: C0: 26%; C1: 33%; C2: 24%; C3: 9%; C4: 7%; C5: 0.5%; and C6: 0.2%. Overall correlation between CEAP and VCSS was moderate ($r_s = 0.49$; $P < .0001$), with highest correlation for VCSS attributes reflecting more advanced disease, including varicose vein ($r_s = 0.51$; $P < .0001$) and pigmentation ($r_s = 0.39$; $P < .0001$); low correlation for inflammation ($r_s = 0.28$; $P < .0001$), induration ($r_s = 0.22$; $P < .0001$), and edema ($r_s = 0.21$; $P < .0001$; Table II).

VTE risk assessment scoring for each participant question (n = 2907; Table III) is noted for prior deep vein thrombosis/pulmonary embolism (DVT/PE) in 7.9% and family history of DVT/PE in 19.1%. Mean total VTE risk

Table III. VTE risk assessment profile based on subjective questionnaire and point scoring system for participants undergoing venous screening (n = 2907)

VTE Risk Assessment Questions	*Points*	*N (%)*
1. Have you ever had a blood clot in your legs or lungs?	3	230 (7.9%)
2. Do you have a family history of blood clots in the veins?	3	558 (19.1%)
3. Do you currently or have you ever had swollen legs?	1	716 (24.6%)
4. Do you have visible varicose veins other than spider veins?	1	2139 (73.6%)
5. Do you have ileitis, Crohn's disease, or inflammatory bowel disease?	1	176 (6.1%)
6. Do you have serious lung disease or emphysema?	1	113 (3.9%)
7. Within the last month, have you had more than 3 days of continuous bed rest attributable to injury or illness?	1	85 (2.9%)
8. Within the last month, have you had a pelvic fracture or a plaster leg cast?	1	17 (0.6%)
9. Have you had a stroke, heart attack, or heart failure?	1	201 (6.9%)
10. Have you had major surgery lasting over an hour in the last month?	1	32 (1.1%)
11. Do you have or have you had a malignant disease (cancer)?	1	293 (10.1%)
12. Do you weigh over 250 pounds?	1	164 (5.6%)
13. Age between 40-59 years?	1	1241 (42.7%)
14. Age between 60-69 years?	2	752 (25.9%)
15. Age equal to or greater than 70 years?	3	649 (22.3%)
Women only		
16. Do you take birth control pills or estrogen (hormone) replacement therapy?	1	252 (8.7%)
17. Are you pregnant or have you given birth within the last month?	1	14 (0.5%)

VTE, Venous thromboembolism.

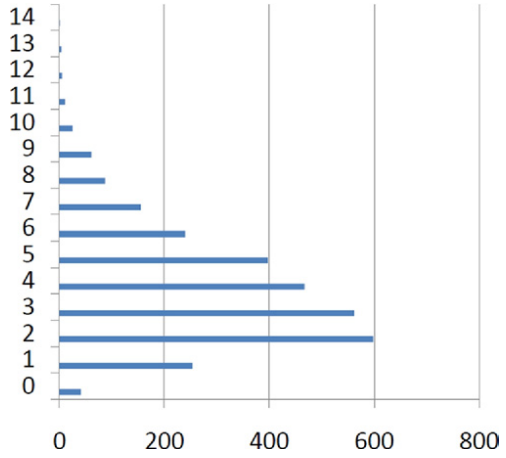

Fig. VTE risk assessment score distribution (y axis) for NVSP participants (x axis; n = 2907).

Table IV. Correlation between VCSS parameters (n = 5814 limbs) and mean total VTE risk assessment score (n = 2907 participants)

VCSS	*VTE Risk Assessment (r_s)*
Pain	0.17 ($P < .0001$)
Varicose vein	0.20 ($P < .0001$)
Edema	0.24 ($P < .0001$)
Pigmentation	0.18 ($P < .0001$)
Inflammation	0.13 ($P < .0001$)
Induration	0.11 ($P < .0001$)
Ulcer number	0.04 ($P < .0001$)
Ulcer size	0.04 ($P < .0001$)
Ulcer duration	0.03 ($P < .0001$)
Compression	0.18 ($P < .0001$)

VCSS, Venous clinical severity score; *VTE,* venous thromboembolism. Spearman correlation: light gray = weak/low correlation; white = very weak/negligible correlation.

score was 3.8 ± 2.2. VTE risk assessment score distribution for participants (anticipated risk estimate if placed in a high-risk situation for DVT/PE) was Low Risk (0-1 point) 11%; Moderate Risk (2 points) 21%; High Risk (3-4 points) 35%; Very High Risk (>5 points) 33% (Fig). Overall correlation between VTE risk assessment and VCSS for all limbs was low ($r_s = 0.34$; $P < .0001$) with weak/negligible correlation for most VCSS parameters (Table IV). There was no difference noted in correlation tables between VCSS and VTE risk assessment score comparing VCSS for all limbs and random sampling of VCSS based on one limb per participant.

Based on the modified CIVIQ assessment, overall mean score for each participant (n = 2907) as per general category included: Quality of Life (QoL)-Pain 6.04 ± 3.12 (range, 3-15), QoL-Functional 9.90 ± 5.32 (range, 5-25), and QoL-Social 5.41 ± 3.09 (range, 3-15). Overall correlation between CIVIQ and VCSS for all limbs was moderately strong ($r_s = 0.43$; $P < .0001$), with highest correlation noted for pain ($r_s = 0.55$; $P < .0001$) and edema ($r_s = 0.30$; $P < .0001$; Table V). There was no difference noted in correlation tables between VCSS and CIVIQ comparing VCSS for all limbs and random sampling of VCSS based on one limb per participant.

Based on screening venous ultrasound results, 38.1% of limbs had Reflux and 1.5% Obstruction in at least one of the segments imaged. Distribution of venous ultrasound results for all segments showed: Reflux – 18.6% femoral, 28.6% saphenous, 9.3% popliteal vein; Obstruction −0.4% femoral, 0.4% saphenous, 0.6% popliteal. Correlation between overall venous ultrasound findings (Reflux + Obstruction) and VCSS was low ($r_s = 0.23$; $P < .0001$) but was highest for varicose vein ($r_s = 0.32$; $P < .0001$; Table VI).

DISCUSSION

Methods for reporting venous outcomes have been in existence for many years, with more recent emphasis on physician-generated assessment tools that can be used to follow clinically defined end points and changes over time. While several venous outcome assessment tools exist, there

Table V. Correlation between VCSS parameters (n = 5814 limbs) and mean total CIVIQ score, QoL-Pain, QoL-Functional, and QoL-Social (n = 2901 participants)

VCSS	*Total CIVIQ score (r_s)*	*QoL – Pain (r_s)*	*QoL – Functional (r_s)*	*QoL – Social (r_s)*
Pain	0.55 ($P < .0001$)	0.58 ($P < .0001$)	0.50 ($P < .0001$)	0.42 ($P < .0001$)
Varicose vein	0.09 ($P < .0001$)	0.07 ($P < .0001$)	0.08 ($P < .0001$)	0.07 ($P < .0001$)
Edema	0.30 ($P < .0001$)	0.25 ($P < .0001$)	0.29 ($P < .0001$)	0.24 ($P < .0001$)
Pigmentation	0.06 ($P < .0001$)	0.04 ($P < .0001$)	0.06 ($P < .0001$)	0.05 ($P < .0001$)
Inflammation	0.06 ($P < .0001$)	0.04 ($P < .0001$)	0.06 ($P < .0001$)	0.06 ($P < .0001$)
Induration	0.06 ($P < .0001$)	0.04 ($P < .0001$)	0.06 ($P < .0001$)	0.04 ($P < .0001$)
Ulcer number	0.02 ($P < .0001$)	0.03 ($P < .0001$)	0.014 ($P < .0001$)	−0.002 ($P < .0001$)
Ulcer size	0.02 ($P < .0001$)	0.04 ($P < .0001$)	0.002 ($P < .0001$)	−0.004 ($P < .0001$)
Ulcer duration	0.007 ($P < .0001$)	0.0016 ($P < .0001$)	0.004 ($P < .0001$)	0.006 ($P < .0001$)
Compression	0.14 ($P < .0001$)	0.12 ($P < .0001$)	0.13 ($P < .0001$)	0.13 ($P < .0001$)

CIVIQ, Chronic Venous Insufficiency Quality of Life; *QoL*, quality of life; *VCSS*, Venous Clinical Severity Score.
Spearman correlation: medium gray = moderate correlation; light gray = weak/low correlation; white = very weak/negligible correlation.

Table VI. Correlation between VCSS parameters and positive venous ultrasound results (reflux + obstruction; n = 5814 limbs)

VCSS	*Venous ultrasound finding (r_s)*
Pain	0.03 ($P < .7947$)
Varicose vein	0.31 ($P < .0001$)
Edema	0.06 ($P < .0001$)
Pigmentation	0.19 ($P < .0001$)
Inflammation	0.16 ($P < .0001$)
Induration	0.10 ($P < .0001$)
Ulcer number	0.05 ($P < .0001$)
Ulcer size	0.05 ($P < .0011$)
Ulcer duration	0.04 ($P < .0004$)
Compression	0.12 ($P < .0001$)

VCSS, Venous Clinical Severity Score.
Spearman correlation: light gray = weak/low correlation; white = very weak/negligible correlation.

is no universally accepted system. In part, this reflects different emphasis within each scoring system from relatively static elements in clinical CEAP; to subjective parameters in venous quality-of-life disease-specific instruments such as CIVIQ used in this study or others such as the Venous Insufficiency Epidemiological and Economic Study,[20] the Aberdeen Varicose Vein Questionnaire,[21,22] and the Charing Cross Venous Ulceration Questionnaire;[23] to serial venous severity assessment tools such as Venous Severity Scoring (VSS), which includes Venous Disability Score (VDS), Venous Segmental Disease Score (VSDS), and VCSS.[3] Use of venous disease severity scoring should allow patient groups with similar degrees of severity to be compared in regard to outcome over time and following different therapies. Of the different venous severity assessment tools available, VCSS has been shown to parallel the severity of venous disease reliably and is the focus of this study.

While there has been general acceptance and wide dissemination of VCSS for clinical and research purposes, validation has been limited to only a few studies. Meissner et al,[4] in a validation study of VCSS involving 128 limbs in 64 consecutive patients with known chronic venous disease that were scored by separate observers at time zero and again within 28 days, found that there was no significant difference in intraobserver variability, and while interobserver reliability was good, there were differences noted in interobserver pain scores, skin pigmentation, and inflammation, leading to recommendation for refinements of the VCSS for better reliability in these categories. Gillet et al,[7] in 2894 patients with ultrasound confirmed chronic venous insufficiency involving the deep venous system, used CEAP classification to assess the severity of venous disease and correlate with VCSS, VSDS, and VDS. A significant increase in VCSS and VSDS ($P < .0001$) paralleled CEAP clinical class, with VDS higher in the C3 and C6 classes although not reaching significance because of small sample size, a significant link between the pain in VCSS and VDS ($P < .0001$), and significant increase in VCSS according to the presence of incompetent perforator vein ($P < .05$) and/or reflux in the deep femoral vein ($P < .05$). In an observational study, including 45 patients who underwent superficial venous surgery in 48 legs with primary varicose veins, Kakkos et al[6] showed that venous severity scores were significantly higher in limbs with advanced venous disease, demonstrating correlation with anatomic extent and that VCSS was better for measuring changes in response to superficial venous surgery than CEAP clinical class, leading to the conclusion that venous severity scoring systems should be used in clinical studies to quantify venous outcome. Ricci et al[5] evaluated VCSS against abnormalities found on venous ultrasound scans in a large kindred cohort of 210 patients with hypercoagulable state. VCSS showed good association with venous ultrasound abnormalities. Interestingly, when VCSS was zero, there was a high likelihood that the patient did not have venous disease. Although VCSS was devised to quantify the severity of chronic venous disease, evidence supported VCSS as a useful venous screening tool. While the use of the VCSS as an independent screening instrument was suggested, additional validation would be required.

While the validity of VCSS independently or in conjunction with other venous severity assessment tools has been supported by several other studies, integration of VCSS with other venous assessment tools as a global venous screening instrument has not been widely tested. The AVF, NVSP data set offers a large population sample of participants screened for venous disease using these various venous severity assessment tools. Several standard venous assessment tools, including VTE risk assessment, CEAP, clinical examination, and venous ultrasound were incorporated initially into NVSP in 2005, with expanded parameters in 2007, including VCSS and CIVIQ. With a large data set accrued over 2 years of 5814 limbs in 2907 screened participants, there is a unique opportunity to compare venous outcome assessment parameters for correlation with VCSS. Similar to several of the studies cited above, there was overall parallel correlation between VCSS and clinical CEAP (moderate; $r_s = 0.49$; $P < .0001$) in this study. Much of this correlation with clinical CEAP was driven by attributes reflecting more advanced disease, including varicose vein ($r_s = 0.51$; $P < .0001$) and pigmentation ($r_s = 0.39$; $P < .0001$) and lesser correlation with inflammation ($r_s = 0.28$; $P < .0001$), induration ($r_s = 0.22$; $P < .0001$), and edema ($r_s = 0.21$; $P < .0001$). Given that these areas of correlation represent overlapping aspects of both VCSS and clinical CEAP, some relationship between severity as reflected in each scoring system is predictable. While correlation between VCSS and clinical CEAP was overall moderate, any disparity may be more reflective of the difference between clinical CEAP, which is dependent on consecutive ordinal variables of increasing severity, and VCSS, which stratifies severity of each attribute and may be more accurate in determining severity distribution. Similarly, this overlapping trend may also explain the observed overall moderately strong correlation between VCSS and modified CIVIQ ($r_s = 0.43$; $P < .0001$), with highest correlation noted for pain ($r_s = 0.55$; $P < .0001$) and edema ($r_s = 0.30$; $P < .0001$), both of which are well represented in both VCSS and modified CIVIQ.

In contrast to Ricci et al,[5] in this study, correlation between overall venous ultrasound findings and VCSS was low ($r_s = 0.23$; $P < .0001$) and again was highest for varicose vein ($r_s = 0.32$; $P < .0001$). Much of this disparity may reflect differences in venous ultrasound screening techniques used in this study compared with other more comprehensive ultrasound used in other studies. Venous ultrasound used in NVSP was intended to be a rapid screening technique focusing on identification of obvious obstruction or reflux in just three locations: common femoral vein, saphenofemoral junction, and above-knee popliteal venous segments. While venous duplex ultrasound examination used in NVSP had been previously validated as a screening tool,[15,16] as an objective screening parameter performed in a just few minutes directed at identifying obvious disease in most common locations with provocative maneuvers limited to Valsalva only, there may be missed venous reflux or obstruction that would have otherwise been detected on a more comprehensive ultrasound examination.

While there is general overall correlation between VCSS and the other venous parameters used in NVSP that trends parallel to severity of venous disease, the strength of this correlation may be influenced by factors reflective of the screening process and variability among sites. Although the NVSP standardizes the screening approach with the infrastructure of the program, forms, and educational material provided to each site in the NVSP tool kit, there may still be variability in implementation of the program between sites. While guidelines are provided to each site on how to perform screening evaluation, for the subjective components collected from participants, there may be some differences in understanding the questions asked on the demographic questionnaire; for the objective components collected by each site's providers, there may be variable understanding of the venous physical examination findings; for objective venous ultrasound testing, although precise instructions are provided to each site on the focused screening venous ultrasound technique used in NVSP, there may be differences in interpretation of venous ultrasound testing at each site. While there may have been some variability within the individual sites in the sample used for this dataset, these sites were self-selected to participate in NVSP and are not a random representation of all vascular surgery practices. Clinicians at these sites who volunteered to participate may have a higher level of venous disease expertise and pre-existing comfort with venous screening instruments. Furthermore, inclusion of only participants with complete datasets for analysis in this study may also reflect sites that followed the screening protocols more closely, thereby providing better quality of data with less variance for analysis than those sites providing incomplete datasets. Because validity and reliability are both confounded in this study, the different correlations between VCSS scores and various other measures may be difficult to interpret since some may have higher and others may have lower reliability indexes. Statistically, this may mean the actual validity of VCSS is higher than stated here or, in contrast because of a higher correlation bias than may have been present in a more random sampling, it may actually represent an upper limit on estimate of correlation. However, the problem also remains that there could be correlations of zero within each treatment site, but because treatment sites differ on mean scores, the VCSS, CEAP, and CIVIQ scores would appear to be correlated when examined across sites.

Variability in strength of correlation seen in this study between VCSS and other venous outcome assessment tools may also be statistically affected by differences in the emphasis of the individual venous scoring instruments used in NVSP. While clinical CEAP is a tool for categorizing severity of lower limb venous disease based on objective clinical findings at a single point in time, VCSS was designed to assess changes in venous disease

over time with some components subjectively determined by the patient and assessed by the provider. Similarly, VTE risk scoring and CIVIQ incorporate some variable subjective and objective assessment, while venous ultrasound is solely an objective focused screening test. With variable scaling of subjective and objective interpretation built into each scoring system, there may be variable penetration into the observed results thereby affecting degree of correlation.

In addition, VCSS is a limb-based scoring system, and while some participants may have the same VCSS score for both limbs, others may have different scores for each limb. While this is less of a factor when comparing VCSS with other limb-based tests (ie, CEAP and venous ultrasound), it can be problematic when analyzing tests based on participant factors (ie, VTE risk assessment and CIVIQ), especially when there is a difference between limbs and it is not known which limb drives the participant-based score. Although one would assume that the worse leg has more impact than the better leg on the participant-based scores (CIVIQ and VTE risk assessment), these tests do not differentiate which limb is driving the patient-based score. Analysis was performed in this study both combining all limb VCSS scores and as a random single-limb sampling. Although only the combined results are reported, there was essentially no difference noted in correlation tables between VCSS and VTE risk assessment/CIVIQ scores comparing the combined-limb analysis and random sampling of VCSS based on one limb per participant. Based on the assumptions noted above, the validity of the statistical analysis performed is qualified and can be interpreted appropriately in the context of the observed trends. While VCSS has been recognized to be a valid outcomes assessment tool, which is further supported by this study applying VCSS with other venous outcome systems as a global screening instrument, there are some shortcomings within VCSS that make universal applicability difficult and may limit its use as a global screening instrument. Recommended revisions of VCSS have focused on simplifying some of the confusing elements within VCSS while maintaining sensitivity in stratifying the spectrum of venous disease.[4,6] With recent AVF update of VCSS, the goal is keeping core structure of the current version of VCSS intact, but refining necessary elements to enhance the ability of the VCSS to be used as an evidence-based outcome measure while allowing ongoing clinical trials using the VCSS to continue with only minor adjustments.[24,25] Based on the observations in this study, future planned validation of revised VCSS should factor in the correlation of VCSS with other venous assessment tools both for trained providers and for more general applicability as a global venous screening instrument.

The intention of this study was not to prove the validity of VCSS as an independent tool, but to show that it works in conjunction with the other venous outcome tools as part of the global screening instrument used in AVF-NVSP. Despite some variability in the NVSP screening data set, overall VCSS still correlated reasonably well with the other venous scoring systems used in NVSP. While there is correlation in NVSP between VCSS, CEAP, modified CIVIQ and venous ultrasound findings, subgroup analysis indicates that this correlation is driven by different components of VCSS compared with the other venous assessment tools. This observation may reflect that VCSS has more global application in determining overall severity of venous disease, while at the same time highlighting the overlapping strengths of the other venous assessment tools. In conclusion, this study supports the validity of VCSS and its integration with other venous assessment tools as a global venous screening instrument.

AUTHOR CONTRIBUTIONS

Conception and design: MP, RM, ML, MI, WB, CM, JH, JS, JL, JC
Analysis and interpretation: MP
Data collection: MP, ML
Writing the article: MP
Critical revision of the article: MP, RM, ML, SN, MI, WB, CM, JH, JS, JL, JC
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