The Center for Vein Restoration Study on presenting symptoms, treatment modalities, and outcomes in Medicare-eligible patients with chronic venous disorders

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ABSTRACT

Background: Chronic venous disorders (CVDs) have been estimated to affect up to 20 million Americans. Despite this huge prevalence, the signs, symptoms, and treatment outcomes in patients 65 years of age and older are not well defined. Our goal was to determine the presentation and treatment outcomes in elderly patients compared with a cohort of patients younger than 65 years.

Methods: From January 2015 to December 2016, we retrospectively reviewed prospectively collected data from 38,750 patients with CVD from the Center for Vein Restoration's electronic medical record (NextGen Healthcare Information Systems, Irvine, Calif). We divided patients into two groups; group A patients were younger than 65 years, and group B patients were 65 years of age or older. Medical and surgical history, presenting symptoms, treatment modalities, and revised Venous Clinical Severity Score before and after intervention were evaluated. A multivariate logistic regression analysis was performed to determine the predictive value of presenting and associated symptoms. Groups A and B were subdivided by Clinical, Etiology, Anatomy, and Pathophysiology class for subgroup analysis. Data were analyzed with GraphPad Prism (GraphPad Software Inc, La Jolla, Calif) or SAS version 9.4 statistical software package (SAS Institute, Cary, NC).

Results: There were 27,536 patients in group A and 11,214 in group B. Women constituted 78% of all patients. Group B demonstrated a higher incidence of chronic diseases compared with group A ($P \leq .003$). As initial presenting symptoms, pain, heaviness, fatigue, and aching were more common in group A than in group B (61% vs 55%, 30% vs 27%, 27% vs 24%, and 17% vs 12%, respectively; $P \leq .001$). Swelling, skin discoloration, and venous ulceration were more common in group B than in group A (29% vs 23%, 12% vs 6%, and 5% vs 2%; $P \leq .001$). Ablations were more commonly performed in group B patients with C4 to C6 disease ($P \leq .004$). The revised Venous Clinical Severity Scores before and 1 month after intervention were similar between groups. Treatment improvement was statistically significant in both groups ($P \leq .001$). Multivariate logistic regression analysis indicated that varices, bleeding, swelling, skin changes, venous ulceration, aching, heaviness, pain, fatigue, cramping, and restless legs were associated with the presence of CVD ($P \leq .001$).

Conclusions: Medicare beneficiaries presented with more chronic diseases and more severe disease. Initial and associated symptoms were highly associated with the presence of CVD. Despite requiring more interventions than patients younger than 65 years, Medicare beneficiaries demonstrated the same degree of clinical improvement. Medicare should not develop coverage policy decisions that prevent access to therapies that alleviate CVD-induced symptoms. (J Vasc Surg: Venous and Lym Dis 2018;6:13-24.)

Based on numerous and recent epidemiologic data, the prevalence of chronic venous disorders (CVDs) globally and in Western countries is enormous.[1-5] Since the development of the Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification, several epidemiologic investigations have reported the prevalence of CVD based on disease classification. Currently, the reported prevalence of varicose veins (C2 disease) ranges between 20% and 64%.[1] Five percent of the general population has C3 to C6 disease, with a 1% to 2% prevalence of C5 and C6 disease.[1] The enormous prevalence of the disease places an economic burden on health care delivery systems, forcing the development of resource allocation policies. Compounding the problem is a lack of large-scale U.S.-specific population data on the sensitivity and specificity of presenting symptoms that correlate with the presence of disease, efficacy of various treatment modalities, and whether treatment outcomes vary in a Medicare-eligible population compared with non-Medicare beneficiaries. In a time when health care resources are scarce, commercial and governmental payers need an evidence basis to determine how funds will be allocated. Lacking "gold standard" randomized controlled trials that include all interventions in all CVD patients, some basis for allocation decisions must be developed that has a level of evidence with high internal and external validity.

The purpose of this investigation was to determine the types of presenting symptoms observed, treatment

From the Center for Vein Restoration.

Author conflict of interest: none.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

https://doi.org/10.1016/j.jvsv.2017.08.018

modalities offered, and outcomes in patients treated for CVD based on CEAP classification, age, and revised Venous Clinical Severity Score (rVCSS).[6,7] We also wanted to focus our attention on CVD patients seeking care in the United States to provide third-party payers with generalizable evidence-based data. Current data indicate that CVD is more prevalent in the elderly and that the prevalence increases as a factor of age.[8] It is our hope that these data can be used to characterize the presenting signs and symptoms as well as treatment outcomes in Medicare beneficiaries and help third-party payers develop coverage policy decisions for allocation of health care resources.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected data
- **Take Home Message:** Analysis of data of 38,750 patients with chronic venous disorders revealed that Medicare beneficiaries presented with more advanced venous disease. Despite requiring more interventions than patients <65 years of age, Medicare beneficiaries demonstrated the same degree of clinical improvement at 1 month after therapy.
- **Recommendation:** The authors suggest that Medicare should not develop coverage policy decisions that prevent access to therapies that alleviate chronic venous disorder-induced symptoms.

METHODS

The Center for Vein Restoration (CVR) is a physician-run outpatient health care delivery organization that focuses on the diagnosis and management of patients with CVDs. Established in 2004, the center is composed of 69 centers in 10 states throughout the United States: Alabama (n = 1), Connecticut (n = 8), Indiana (n = 5), Maryland (n = 19), Michigan (n = 5), Ohio (n = 2), Pennsylvania (n = 2), New Jersey (n = 11), New York (n = 4), and Virginia (n = 12). The patients in this study are therefore representative of the diverse population of patients seeking medical care in the United States.

From January 2015 to December 2016, we retrospectively reviewed prospectively collected data from our Office of the National Coordinator for Health Information Technology-certified electronic medical record (NextGen Healthcare Information Systems, Irvine, Calif) at the CVR. Institutional Review Board approval for the investigation was obtained (IntegReview Institutional Review Board, Austin, Texas). Informed consent was not required. During that 2-year period, 38,750 patients were evaluated for the presence and possible treatment of CVD. Primary care providers referred 85% of patients to a CVR vein specialist for an evaluation of the patient's lower extremity symptoms. The remaining 15% of patients sought evaluation through a combination of screening events, community outreach programs, and direct to consumer marketing.

We divided patients into two groups; group A patients were younger than 65 years, and group B patients were 65 years of age or older. Medical and surgical histories, presenting symptoms, treatment modalities, and initial and post-treatment rVCSS results were analyzed and compared between groups. The rVCSS is a validated, physician-reported outcome tool used to measure the severity of venous disease.[7] It is a dynamic, quantitative assessment that is sensitive to treatment outcomes and designed to supplement the CEAP classification, which is descriptive and qualitative in nature.[6] Groups A and B were stratified by CEAP clinical classes for subgroup analyses of treatment outcomes. In patients with bilateral limb disease, the highest CEAP class was used to categorize patients. The initial rVCSS was obtained at presentation. As with the CEAP designation, the highest rVCSS was used as the patient's initial score. The post-treatment rVCSS was obtained 1 month after completion of a treatment plan. A treatment plan could consist of a combination of any of the following: a 3-month compression trial followed by an intervention; an axial great or small saphenous vein thermal ablation (laser or radiofrequency); an additional accessory or saphenous tributary ablation; ambulatory microstab phlebectomies; and ultrasound-guided foam sclerotherapy. Our primary analysis focused on patients who had ablations with or without adjunctive procedures. We also performed a subset analysis of patients based on the types of treatments to determine whether treatment paradigm affected the post-treatment rVCSS. Demographic data, presenting symptoms, and treatment outcomes were analyzed using GraphPad Prism (GraphPad Software Inc, La Jolla, CA) statistical analysis software. Demographic data and the incidence of presenting symptoms were analyzed with contingency tables and χ^2 analyses. Treatment outcomes and intervention rates were analyzed with a paired *t*-test. A multivariate logistic regression analysis of presenting and associated symptoms for their association with the presence of CVD was performed with SAS version 9.4 statistical software package (SAS Institute, Cary, NC).

RESULTS

Data for 38,750 patients were extracted and analyzed from the NextGen Healthcare Information Systems database. Table I demonstrates the demographic data by gender and age group. There were 27,536 patients in group A and 11,214 Medicare beneficiaries in group B. Bilateral disease was observed in 6320 patients (16% of total cohort or 46% of all patients treated). Women constituted 78% of the entire cohort. Medical comorbidities were greater in group B ($P \leq .0001$), except for

Table I. Demographic data

	2015	2016	Total
Age, years			
<65	11,252	16,284	27,536
≥65	4409	6805	11,214
Sex			
Female	12,204	17,980	30,184
Male	3450	5100	8550

	Group A (patients <65 years), No. (%)	Group B (patients ≥65 years), No. (%)	*P* value
Medical history			
HTN	8146 (30)	833 (64)	≤.0001
Diabetes	3582 (13)	2822 (25)	≤.0001
Asthma	2075 (8)	833 (7)	≤.74
Hypercholesterolemia	1994 (17)	1850 (16)	≤.0001
Cancer	975 (4)	1324 (12)	≤.0001
COPD	395 (1)	583 (5)	≤.0001
Stroke	230 (1)	309 (3)	≤.0001
DVT	82 (0.30)	47 (0.42)	≤.06
PAD	22 (0.08)	34 (0.03)	≤.0001
CAD	14 (0.05)	14 (0.12)	≤.02
Hypercoagulable	0 (0)	0 (0)	≥.99
Surgical history			
Gynecologic	5253 (19)	830 (7)	≤.0001
Orthopedic	1119 (4)	806 (7)	≤.0001
Previous vein procedure	128 (0.46)	5 (0.04)	≤.0001
Surgery, none	6516 (24)	1409 (13)	≤.0001
Presenting symptoms			
Aching	4714 (17)	1485 (13)	≤.0001
Bleeding	417 (2)	210 (2)	≤.01
Cramping	6718 (24)	2803 (25)	≤.21
Fatigue	7348 (27)	2736 (24)	≤.0001
Heaviness	8315 (30)	3005 (27)	≤.0001
Pain	16,907 (61)	6159 (55)	≤.0001
Restless legs	2843 (10)	1097 (10)	≤.11
Skin changes	1539 (6)	1290 (12)	≤.0001
Spider veins	4625 (17)	1367 (12)	≤.0001
Swelling	6284 (23)	3300 (29)	≤.0001
Thrombosis	1189 (4)	304 (3)	≤.0001
Ulcer	576 (2)	542 (5)	≤.0001
Varicosities	1607 (6)	567 (5)	≤.002
Associated symptoms			
Burning	2063 (7)	624 (6)	≤.0001
Dermatitis	171 (1)	137 (1)	≤.0001
Edema or swelling	11,872 (43)	6155 (55)	≤.0001
Hyperpigmentation	1159 (4)	925 (8)	≤.0001
Itching	1950 (7)	542 (5)	≤.0001
Pelvic symptoms	199 (1)	22 (0)	≤.0001
Skin ulceration	332 (1)	130 (1)	≤.718
Superficial thrombophlebitis	206 (1)	84 (1)	≥.99
Tingling	1027 (4)	316 (3)	≤.0001

CAD, Coronary artery disease; *COPD,* chronic obstructive pulmonary disease; *DVT,* deep venous thrombosis; *HTN,* hypertension; *PAD,* peripheral arterial disease.
Medical histories were significantly different between groups except for asthma, DVT, and hypercoagulable states. Group B demonstrated a higher incidence of disease compared with group A. Group A had more gynecologic procedures and group B had more orthopedic procedures. The prevalence of initial presenting symptoms between groups was significantly different except for restless legs and cramping. Similarly, associated symptoms differed except for the presence of tingling, superficial thrombophlebitis, and venous ulceration.

asthma, deep venous thrombosis, and hypercoagulable disorders, for which no differences were observed.

Gynecologic surgical procedures were greater in group A, and orthopedic surgical procedures were greater in group B ($P \leq .0001$). Group A had a higher incidence of all types of surgery (87% vs 75%; $P \leq .0001$).

Presenting symptoms. As an initial presenting symptom, pain, heaviness, fatigue, and aching were the most commonly recorded symptoms in both groups A and B (Figs 1 and 2).

Subgroup analyses indicated that pain, heaviness, fatigue, and aching were more common in group A than in group B (61% vs 55%, 30% vs 27%, 27% vs 24%, and 17% vs 12%, respectively; $P \leq .0001$; Table I). Swelling, skin discoloration, and venous ulceration were more common in group B than in group A (29% vs 23%, 12% vs 6%, and 5% vs 2%; $P \leq .0001$). There were no differences in the incidence of cramping and restless legs. Secondary associated symptoms of swelling (43% vs 55%) and hyperpigmentation (4% vs 8%) were more commonly reported in group B patients ($P \leq .0001$).

Recommendation rates. Of the entire cohort, an intervention was recommended for 48% of patients to address their CVD, and 35% proceeded with a treatment plan. When stratified by age and CEAP class, group A C2 patients were more likely to have an intervention compared with group B (35%-19%). There was no difference in intervention rates in CEAP C3 patients. Interventions were more common in group B CEAP C4, C5, and C6 patients (21% vs 35%, 2% vs 3%, and 3% vs 6%, respectively; Fig 3). Fig 4 demonstrates the intervention rates for the entire cohort by CEAP classification.

Intervention types. The types of interventions offered patients were thermal ablations (laser or radiofrequency) of axial great or small saphenous veins, ablations of additional accessory or saphenous tributaries, ambulatory

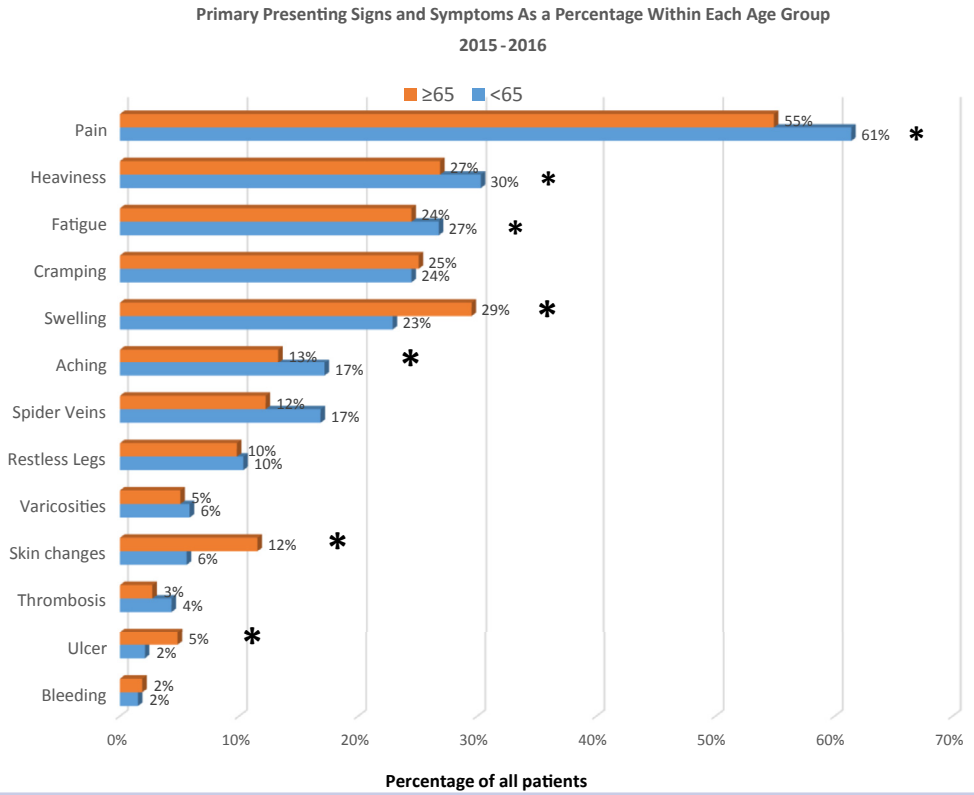

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Fig 1. Prevalence of initial presenting symptoms in symptomatic patients with chronic venous disorder (CVD). All differences as identified by *asterisks* were statistically significant.

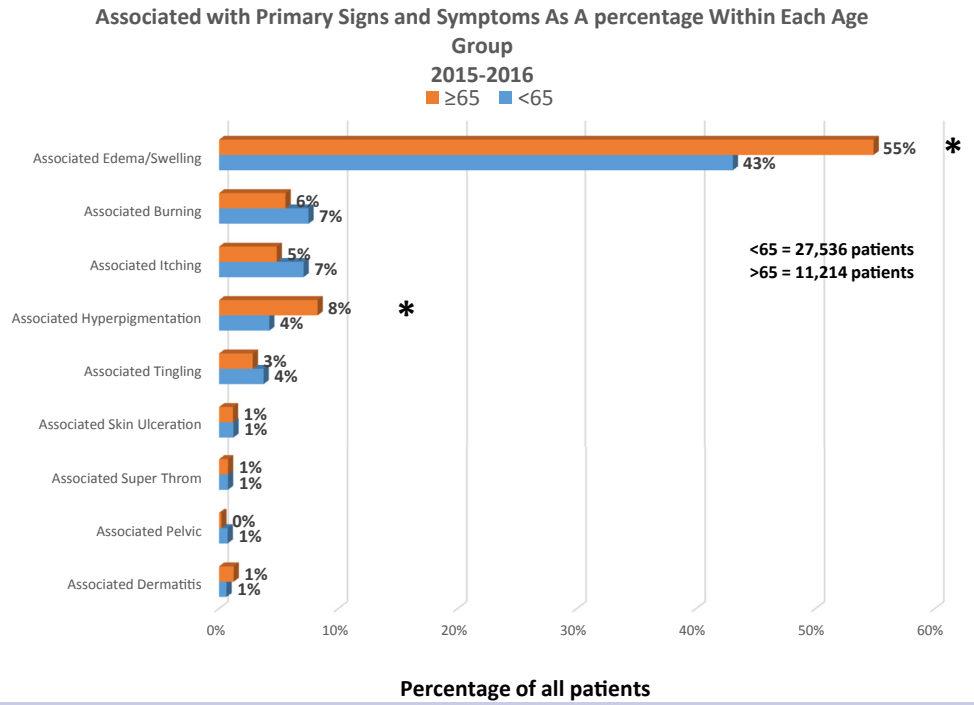

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Fig 2. Prevalence of symptoms associated with primary presenting symptoms in symptomatic patients with chronic venous disorder (CVD). All differences as identified by *asterisks* were statistically significant.

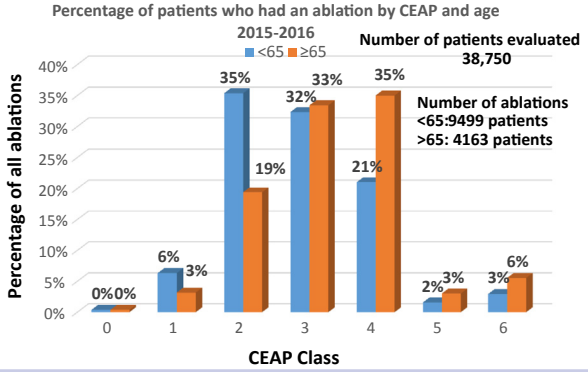

Fig 3. Interventions stratified by Clinical, Etiology, Anatomy, and Pathophysiology (*CEAP*) classification. Interventions were more common in group A C2 patients, similar in C3 patients, and more common in C4 to C6 group B patients.

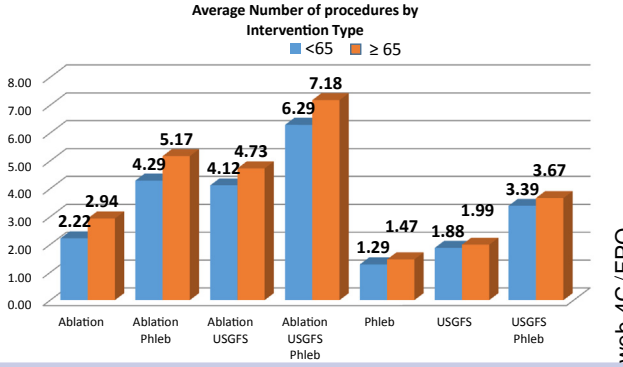

Fig 5. Average number and types of interventions based on age. Overall, group B patients tended to require more interventions than group A patients, suggesting more severe disease in group B. *Phleb,* Phlebectomy; *USGFS,* ultrasound-guided foam sclerotherapy.

microstab phlebectomies, and ultrasound-guided foam sclerotherapy. Fig 5 demonstrates the average number of procedures performed in each patient by intervention type. Patients older than 65 years had more interventions performed per patient. A subgroup analysis of intervention types indicated that the average number of ablations was greater in group B CEAP C2 to C6 patients ($P \leq .004$). The average numbers of phlebectomies and ultrasound-guided foam sclerotherapy sessions were similar between groups except for CEAP C2 group B patients (Figs 6-8; $P \leq .003$). Of the 38,750 patients, 47,620 procedures were performed. There were 23,341 procedures performed in the right limb and 24,066 in the left limb, with 213 procedures in undocumented limbs. Bilateral disease was observed in 6320 patients (16% of total cohort or 46% of all patients treated). On average, there were 1.7 ablations per limb performed. There were 13,442 ablations performed in 7816 right limbs and 14,004 ablations performed in 8077 left limbs. Bilateral ablations were performed in 5536 patients (40% of all treated patients).

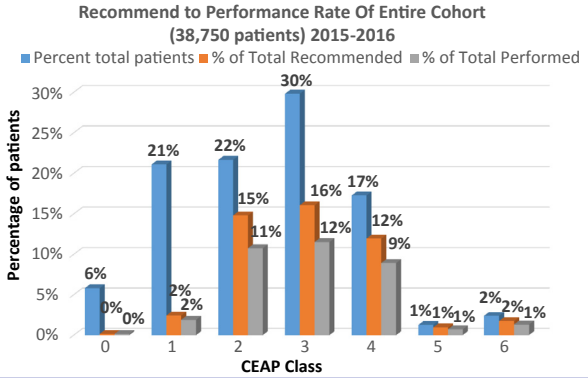

Fig 4. Intervention rate of entire cohort stratified by Clinical, Etiology, Anatomy, and Pathophysiology (*CEAP*) class.

Treatment outcome assessment. Regardless of intervention type, both groups demonstrated an improvement in symptoms based on comparison of initial and 1-month post-treatment rVCSSs ($P \leq .0001$; Figs 9 and 10). The percentage change in rVCSS was not associated with CEAP class or age. The rVCSSs before and after intervention differed only for initial rVCSS CEAP C6 patients. Group A had a higher rVCSS compared with group B ($P \leq .01$). At the time of this analysis, not all patients had completed their treatment plans, and therefore 1-month follow-up evaluations were not available for all patients. Of the entire cohort, 1-month rVCSS data were available for 75% (7166/9499) of patients in group A and 79% (3286/4163) of patients in group B. These patients were evaluated for the assessment of treatment efficacy. Table II indicates the number of patients and the types of interventions performed in patients with a 1-month follow-up evaluation.

Association of symptoms and the presence of CVD. To determine whether initial and associated signs and symptoms were associated with the presence of CVD,

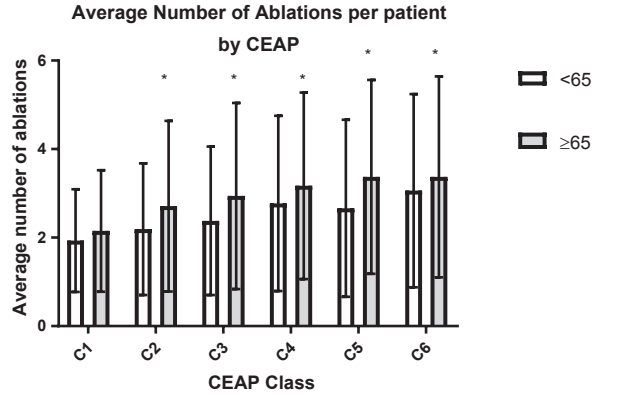

Fig 6. Group B C2 to C5 patients required more ablations compared with group A ($P \leq .004$). Noted differences as identified by *asterisks* were statistically significant. *CEAP,* Clinical, Etiology, Anatomy, and Pathophysiology.

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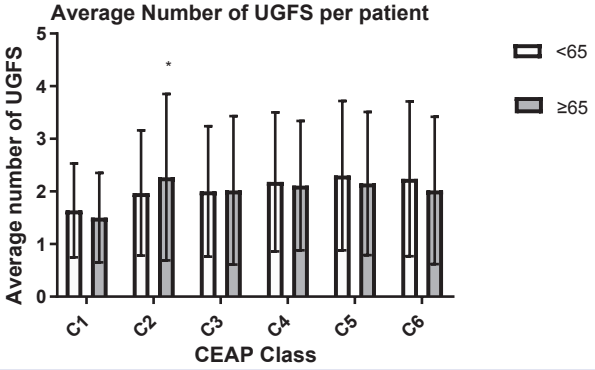


Fig 7. Group B C2 patients required more ultrasound-guided foam sclerotherapy (*UGFS*) sessions compared with group A ($P \leq .0001$). Noted differences as identified by *asterisks* were statistically significant. *CEAP,* Clinical, Etiology, Anatomy, and Pathophysiology.

a multivariate logistic regression analysis was performed (Table III). CEAP class C0 patients were used as control patients for the comparative analysis. As an initial presenting symptom, spider veins were not predictive of CVD in either group. Similarly, superficial thrombophlebitis in group B was not predictive of the presence of CVD. For associated symptoms reported in conjunction with the primary presenting symptoms, pelvic symptoms, burning, and tingling were not associated with CVD in either group. Surprisingly, in group B, the presence of CVD was not predicted in patients who indicated that their leg wound was not their primary reason for presentation and reported an associated "venous ulcer." This observation suggests that there may be other causes of leg wounds in elderly patients and that patients do not relate these wounds to their venous disease. All remaining initial and associated symptoms had odds ratios >1 and five symptoms had an odds ratio of 3 or higher ($P \leq .003$). Initial signs or symptoms of varicosities, venous ulceration, skin changes, bleeding, and swelling were highly associated with the presence of CVD (Table III; $P \leq .001$). Aching, heaviness, pain, and limb fatigue all had an odds ratio >1.5 (Table III; $P \leq .02$-$.001$).

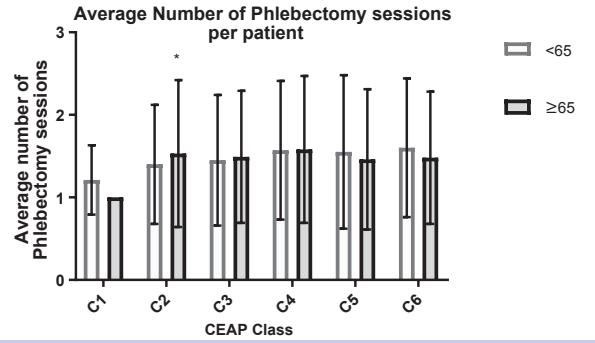


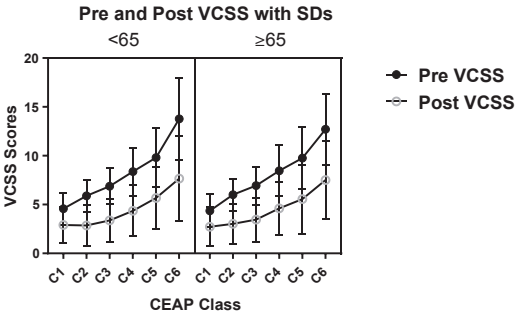
Fig 8. Group B C2 patients required more phlebectomy sessions compared with group A ($P \leq .0007$). Noted differences as identified by *asterisks* were statistically significant. *CEAP,* Clinical, Etiology, Anatomy, and Pathophysiology.

DISCUSSION

The current investigation analyzed 38,750 patients from 10 of the 50 states in the United States for the presence or absence of CVD, types of symptoms, and treatment outcomes. Of the entire cohort, 11,214 (29%) patients were Medicare beneficiaries. To our knowledge, this investigation represents the largest U.S.-based study of Medicare and non-Medicare beneficiaries suffering from CVD. Our investigation is unique in that in addition to analyzing the presenting symptoms and types of treatments, we analyzed rVCSS results on the basis of initial presentation and 1-month post-treatment scores and stratified patients according to their CEAP classification.

Numerous epidemiologic investigations of the incidence and prevalence of CVD in the Western world and globally have been published during the past 50 years, and modern studies have stratified data on the basis of the CEAP classification.[1-5,9] All these investigations have demonstrated a relationship between age, gender, and obesity and the severity of CVD that correlates with CEAP classification.[2,3,9-11] In addition, several investigations have reported on the presenting symptoms of CVD patients and whether these symptoms correlate with the presence of CVD and disease severity.[12] However, no studies have specifically focused on Medicare beneficiaries and possible differences in presentation, treatment modalities, and outcomes.

Several population-based investigations of the incidence, prevalence, and presenting symptoms of CVD have been reported. The majority are based in countries with national health care systems and therefore may not be representative of a U.S. population. The Edinburgh Vein Study evaluated a general population of 1566 patients aged 18 to 64 years.[13] It assessed the prevalence of CVD, the presence of reflux, and whether the symptoms of heaviness/tension and a feeling of swelling, aching, restless legs, cramps, itching, and tingling were associated with CVD. The investigators reported that isolated superficial reflux correlated with the presence of heaviness/tension and itching in women but not in men. Combined deep and superficial reflux was associated with a feeling of swelling, cramps, and itching in men and aching and cramps in women. The prevalence of CVD correlated with increasing age and worsening disease severity, as did the reported symptoms of heaviness/tension and a feeling of swelling, aching, and itching.[4,10] The investigators did not stratify patients according to CEAP class. The French vein study reviewed 2000 patients of all ages and demonstrated an increased prevalence and incidence of disease severity of CVD with increasing age.[2] Specifically, trophic skin changes and venous ulceration increased with each decile of age.



	Pre VCSS <65		Post VCSS <65		Pre VCSS >65		Post VCSS >65	
	VCSS	SD	VCSS	SD	VCSS	SD	VCSS	SD
C1	4.57	1.65	2.9	1.88	4.36	1.69	2.73	2.01
C2	5.89	1.64	2.86	2.06	6.01	1.62	3.03	2.07
C3	6.87	1.83	3.37	2.2	6.94	1.95	3.45	2.24
C4	8.38	2.45	4.36	2.59	8.46	2.6	4.6	2.72
C5	9.81	2.99	5.68	3.21	9.75	3.19	5.55	3.52
C6	13.78	4.22	7.65	4.32	12.71	3.62	7.51	3.99

Fig 9. Initial and 1-month post-treatment revised Venous Clinical Severity Score (rVCSS) demonstrating correlation of disease severity with Clinical, Etiology, Anatomy, and Pathophysiology (*CEAP*) classification. Differences between scores before (*Pre VCSS*) and after (*Post VCSS*) intervention for both groups were significant ($P \leq .001$). *SD,* Standard deviation.

These findings were similar to ours. The Bonn Vein Study I and II reported on the incidence, prevalence, and disease progression rates associated with CVD.[12] The studies investigated a general population of 3072 patients ranging from 18 to 79 years of age. They reported that 35.3% of patients demonstrated pathologic reflux and increased disease severity correlated with age and gender. In the Bonn Vein Study II, the investigators

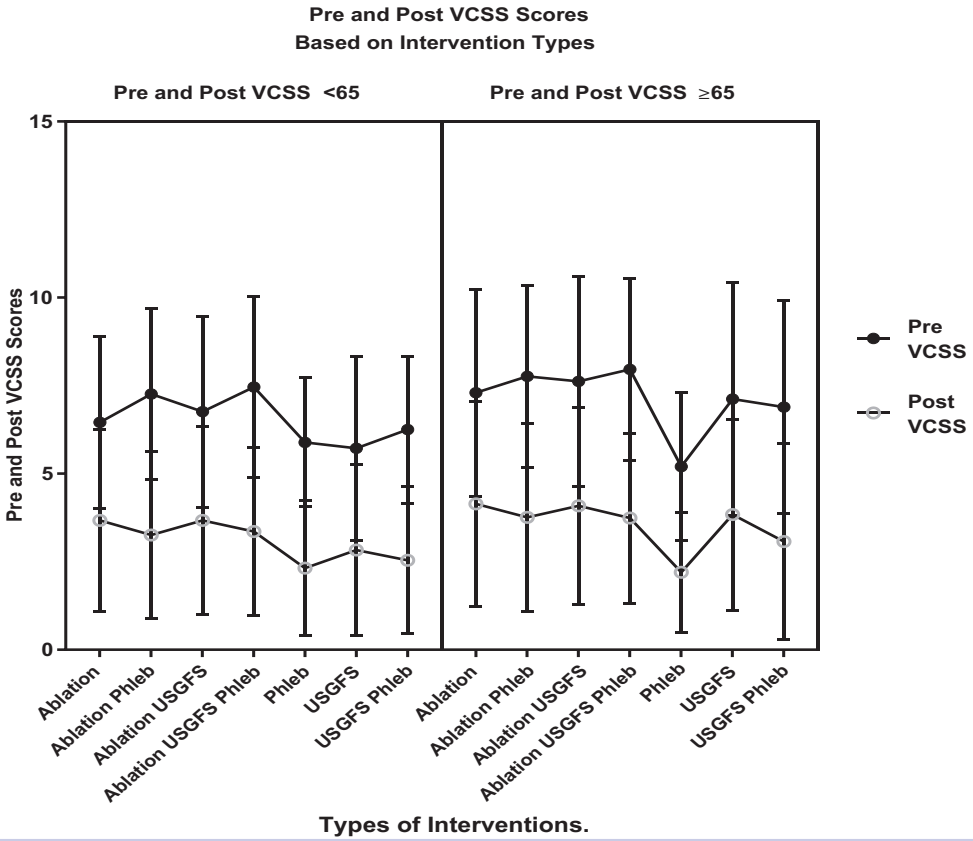


Fig 10. Initial and 1-month post-treatment revised Venous Clinical Severity Score (rVCSS) based on types of interventions. Differences between scores before (*Pre VCSS*) and after (*Post VCSS*) intervention were significant ($P \leq .001$). *Phleb,* Phlebectomy; *USGFS,* ultrasound-guided foam sclerotherapy.

Table II. Number and types of intervention by age group of patients who completed a treatment plan and returned for a 1-month follow-up evaluation

		VCSS before intervention		VCSS after intervention	
	No. of patients	Average	SD	Average	SD
>65 years					
Ablation	997	7.08	2.98	4.14	2.93
Ablation and phlebectomy	447	7.69	2.61	3.77	2.65
Ablation and USGFS	1050	7.55	2.89	4.11	2.76
Ablation, USGFS, and phlebectomy	792	7.96	2.64	3.77	2.44
Phlebectomy	0	0.00	0.00	0.00	0.00
Total >65 years	3286	7.52	2.84	3.99	2.73
<65 years					
Ablation	2026	6.31	2.50	3.66	2.55
Ablation and phlebectomy	1322	7.21	2.52	3.29	2.38
Ablation and USGFS	1834	6.76	2.75	3.70	2.71
Ablation, USGFS, and phlebectomy	1980	7.43	2.57	3.36	2.36
Phlebectomy	4	5.25	2.75	3.50	2.38
Total <65 years	7166	6.90	2.62	3.52	2.52
Grand total	10,453	7.10	2.71	3.67	2.59

SD, Standard deviation; *USGFS*, ultrasound-guided foam sclerotherapy; *VCSS*, Venous Clinical Severity Score.

reported that during 5 years, 32% of C2 patients with saphenous vein reflux progressed to either C3 or C4 disease. Gender, age, body mass index, and presence of swelling were risk factors for disease progression.[9] Age, gender, and obesity are the most important risk factors for the development of CVD. The French vein study, Edinburgh Vein Study, San Diego Population Study, Olmsted County vein study, and Bonn Vein Study I and II all reported that CVD correlated with increasing age.[2-5,9] The French vein study demonstrated a linear correlation with age and worsening CVD based on CEAP classification.[2] The San Diego Population Study reported a significant odds ratio of 2.4 for varicose veins and up to 4.85 for CVD in older patients.[3]

There is great controversy about CVD-related symptoms and whether these symptoms are predictive of the presence of CVD. In 2015, the Bonn Vein Study I investigators performed a multivariate logistic regression analysis on the following symptoms from Bonn Vein Study I patients: heaviness, tightness, swelling, pain after standing or sitting, pain while walking, muscle cramps, itching, and restless legs. As with the previous studies, symptom prevalence increased with age, with the highest prevalence observed in patients 70 to 79 years old (73.9%).[9] C2 to C6 patients demonstrated a significant association with heaviness, tightness, swelling, and itching, whereas pain on walking and muscle cramps were more prevalent in C3 to C6 and C3 to C4 patients, respectively. Restless legs demonstrated no association with CVD. Body mass index >25 kg/m^2 was associated with pain after standing or sitting and while walking.[9] In women, pain was associated with previous pregnancies, and a feeling of heaviness correlated with a history of three pregnancies or more.[9] In the current investigation, we observed that pain, heaviness, fatigue, and aching were the most common symptoms observed in all patients. However, subgroup analysis indicated that pain, heaviness, fatigue, and aching were more common in group A than in group B. Swelling, skin discoloration, and venous ulceration were more common in group B compared with group A. Secondary associated symptoms of swelling and hyperpigmentation were more common in group B, whereas burning and itching were more common in group A.

The specificity of venous-related signs and symptoms for predicting the presence of symptomatic CVD is currently controversial. Van der Velden reported similar symptoms in patients with hip and knee arthroses, spinal disk herniation, and peripheral arterial disease.[14] To address this question, we performed a multivariate logistic regression analysis of initial and associated presenting symptoms. We determined that as an initial presenting symptom, spider veins in both groups and superficial thrombophlebitis in Medicare patients were not associated with CVD. Similarly, associated symptoms of burning, tingling, and pelvic symptoms were not associated with CVD in either group. All remaining symptoms had odds ratios >1 and five symptoms had an odds ratio of 3 or higher. Varicosities, venous ulceration, skin changes, bleeding, and swelling were highly associated with CVD ($P \leq .001$). Aching, heaviness, pain, and limb fatigue all had an odds ratio >1.5 ($P \leq .02$-$.001$). These signs

Table III. Multivariate logistic regression analysis demonstrating ability of initial and associated symptoms to identify an association between symptoms and the presence of chronic venous disorder (CVD)

	Group A (<65 years)			
Variable	**Probability (χ^2)**	**Odds ratio**	**Lower CL**	**Upper CL**
Initial symptoms				
Varicosities	<.0001	22.548	16.703	30.44
Ulcer	<.0001	8.061	5.05	12.869
Bleeding	<.0001	5.613	3.715	8.482
Skin change	<.0001	5.015	4.009	6.273
Swelling	<.0001	4.238	3.892	4.614
Pain	<.0001	1.739	1.631	1.853
Heaviness	<.0001	1.663	1.537	1.8
Fatigue	<.0001	1.658	1.526	1.802
Aching	<.0001	1.608	1.474	1.753
Superficial thrombophlebitis	<.0001	1.521	1.286	1.798
Restless legs	.0002	1.233	1.104	1.376
Cramping	<.0001	1.196	1.11	1.287
Spider veins	[a]	0.476	0.439	0.516
Associated symptoms				
Hyperpigmentation	<.0001	6.723	5.111	8.844
Dermatitis	.0007	5.137	1.995	13.226
Skin ulcer	<.0001	3.746	2.381	5.894
Superficial thrombophlebitis	<.0001	2.761	1.661	4.59
Edema	<.0001	2.515	2.318	2.729
Itching	<.0001	1.504	1.319	1.715
Burning	.8357	1.012	0.901	1.138
Tingling	[a]	0.748	0.643	0.87
Pelvic symptoms	[a]	0.447	0.31	0.645
	Group B (≥65 years)			
Variable	**Probability (χ^2)**	**Odds ratio**	**Lower CL**	**Upper CL**
Initial symptoms				
Varicosities	<.0001	30.272	14.254	64.287
Bleeding	<.0001	7.353	3.387	15.961
Swelling	<.0001	5.478	4.727	6.349
Skin change	<.0001	4.818	3.606	6.438
Ulcer	<.0001	3.853	2.581	5.752
Aching	<.0001	1.783	1.508	2.108
Heaviness	<.0001	1.727	1.48	2.015
Pain	<.0001	1.672	1.502	1.861
Fatigue	<.0001	1.508	1.287	1.768
Superficial thrombophlebitis	.1195	1.364	0.923	2.017
Cramping	<.0001	1.305	1.149	1.482
Restless legs	.0281	1.257	1.025	1.541
Spider veins	>.05	0.61	0.519	0.716
Associated symptoms				
Dermatitis	.0036	5.826	1.778	19.093
Hyperpigmentation	<.0001	4.74	3.445	6.521
Edema	<.0001	3.328	2.899	3.821
Superficial thrombophlebitis	.043	2.521	1.03	6.171
Itching	.0067	1.499	1.119	2.008

(Continued on next page)

Table III. Continued.

Variable	Group B (≥65 years)			
	Probability (χ^2)	Odds ratio	Lower CL	Upper CL
Skin ulcer	>.05	0.916	0.448	1.872
Burning	>.05	0.861	0.692	1.071
Tingling	>.05	0.836	0.624	1.121
Pelvic symptoms	>.05	0.682	0.207	2.25

CL, Confidence limit.
All symptoms were associated with CVD in both groups except for tingling and pelvic symptoms in group B and only superficial thrombophlebitis in group A.
[a]Negative association.

and symptoms by themselves were highly associated with CVD. A combination of any of these signs and symptoms provides a multiplier effect, further increasing the likelihood for CVD.

As stated before, 85% of patients were referred by a primary care physician and 15% were self-referrals. After a complete evaluation, we noted that 52% of patients were not candidates for a venous intervention. Twenty-seven percent were C0 or C1. The remaining 25% had minor evidence of CVD or demonstrated other causes of their leg symptoms, such as lumbar disk herniation or arthritis. This observation emphasizes the need for a complete history, physical examination, and venous duplex ultrasound scan. For the diagnosis of CVD to be made, the history, physical examination, and venous duplex ultrasound examination must all confirm the diagnosis. As part of the history, the rVCSS and venous-specific quality of life assessment tool must be obtained at the initial assessment and on completion of any treatment plan to confirm the effectiveness of therapy. A patient-reported venous-specific quality of life assessment tool should be used as an additional adjunctive measure of treatment effectiveness but more important to determine the benefit of treatment based on the patient's perspective. The CVR investigators have added the 20-item Chronic Venous Insufficiency Questionnaire quality of life assessment tool as part of the patient's initial evaluation. We started using the tool in late 2016 and therefore did not include this information in the current analysis.

In this investigation, we demonstrated that disease severity, as documented by initial rVCSS, correlated with CEAP classification in both groups A and B. In a validation study of the rVCSS, Meissner et al reported that rVCSS of ≤3 was considered absence of disease, 4 to 7 was considered mild to moderate disease, and ≥8 was evidence of severe disease.[15] Our investigation demonstrated that at initial evaluation, patients with C2 and C3 disease demonstrated mild to moderate disease and that patients with C4 to C6 demonstrated severe disease. On completion of a full treatment plan, 1-month rVCSSs indicated that patients with C2 and C3 disease demonstrated absent or mild disease and C4 to C6 patients now had mild to moderate disease. These differences were clinically and statistically significant. To achieve these results, CVD patients required numerous interventions (Fig 5). On average, patients required 7.1 procedures to complete their treatment plan. The most common combination of intervention was one or more ablations, ambulatory microstab phlebectomies, and ultrasound-guided foam sclerotherapy. Group B C2 to C6 patients required more interventions than group A patients, suggesting more extensive and severe disease in elderly patients. A similar number of phlebectomy and ultrasound-guided foam sclerotherapy sessions were observed in both groups except for group B C2 patients, who had more sessions.

In July 2016, the Centers for Medicare and Medicaid Services' Medicare Evidence Development and Coverage Advisory Committee members met to determine whether the scientific evidence underpinning the benefit and risk of existing lower extremity chronic venous disease interventions that aim to improve health outcomes in the Medicare population supports a recommendation for allocating resources for venous interventions (J. Hilo, National Center for Health Research, July 21, 2016). Clinical outcomes of interest to the Medicare program include the following: reduction in pain; reduction in edema; improvement in functional capacity; improvement in quality of life; avoidance of acute and chronic venous thromboembolism; avoidance of chronic thromboembolic pulmonary hypertension; avoidance of initial venous skin ulceration and recurrent ulceration; improvement in wound healing; reduction in all-cause mortality; and avoidance of repeated interventions and harms from the interventions (Medicare Evidence Development and Coverage Advisory Committee, July 20, 2016).

This investigation reports on 11,214 Medicare beneficiaries from 10 states and addresses several areas of concern to the Centers for Medicare and Medicaid Services. The data in this investigation highlight major differences in presenting symptoms, medical comorbidities, and disease severity in Medicare and non-Medicare beneficiaries. Medicare beneficiaries have a higher incidence of comorbidities; present more often with skin changes, ulceration, pain, and swelling as the primary and

associated complaints; have a higher prevalence of CEAP C4 to C6 disease; have higher initial symptom severity as evidenced by higher initial rVCSS; and require more interventions to achieve a similar level of symptom improvement as non-Medicare beneficiaries. In short, they are sicker with more disease, and the data strongly suggest their quality of life may have been more adversely affected by their CVD compared with non-Medicare beneficiaries. Currently, Novitas, a local Medicare carrier, is considering a local coverage policy decision that would restrict access for CVD care to Medicare beneficiaries with C4b or C6 disease alone. These data strongly indicate that Medicare beneficiaries suffer from C2 to C6 disease. In addition, the presenting signs and symptoms are highly associated with the presence of CVD as demonstrated by our multivariate logistic regression analysis. Restricting access to care would adversely affect a patient's quality of life and require patients to suffer needlessly when effective therapies are not made available to them. It is our hope that this investigation will provide further evidence that CVD interventions benefit Medicare beneficiaries. Furthermore, failure to provide treatment at earlier levels of severity (C2 and C3) may have an impact on the number of patients who go on to require more invasive treatment as they develop more significant disease. These data strongly support continued resource allocation for the entire spectrum of CVDs in Medicare beneficiaries.

Limitations. The limitations of this investigation are that it is a retrospective analysis of prospectively collected data and that we did not present quality of life data. A patient-reported outcome metric that correlated with the rVCSS data would have further enhanced the strength of the treatment effect observed with the rVCSS. Furthermore, we presented only 1-month follow-up data. Continued improvement or decrement in rVCSS may be observed at further time points. The primary analysis focused on patients who underwent ablations. The majority of patients had adjunctive procedures like phlebectomies and ultrasound-guided foam sclerotherapy. To what degree the ablation or adjunctive procedures affected post-treatment rVCSS could not be determined. Finally, although CEAP class and rVCSS were collected by affected limbs, all outcome data, including data for patients with bilateral disease, were analyzed by individual patients and not by limbs. In patients with bilateral disease, the highest of the two CEAP classes and the highest of the two rVCSSs were used for analysis of treatment effect. Similarly, symptoms were coded by patients, independent of unilateral or bilateral disease.

CONCLUSIONS

Despite these limitations, this investigation demonstrates specific differences in Medicare beneficiaries compared with a cohort of patients younger than 65 years with CVD. Medicare beneficiaries have a higher prevalence of comorbidities. They exhibit the same signs and symptoms as non-Medicare patients do, with a higher incidence of swelling, venous stasis skin changes, and venous ulceration. In addition, CVD signs and symptoms are highly associated with the presence of CVD. Based on rVCSS, Medicare beneficiaries have higher disease severity requiring more interventions for correction of disease. Despite this observation, they achieve the same degree of symptom relief on completion of a treatment plan. Medicare and its local carriers should therefore not restrict reimbursement for CVD therapies, given the severity of disease present in this population of patients and the effectiveness of current treatments.

AUTHOR CONTRIBUTIONS

Conception and design: PP, SL, KN
Analysis and interpretation: PP, RV
Data collection: SL, RV
Writing the article: PP
Critical revision of the article: PP, SL, KN, RV
Final approval of the article: PP, SL, KN, RV
Statistical analysis: PP, RV
Obtained funding: Not applicable
Overall responsibility: PP

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Submitted Apr 21, 2017; accepted Aug 18, 2017.