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

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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