From the American Venous Forum

Age is not a barrier to good outcomes after varicose vein procedures

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ABSTRACT

Background: The Vascular Quality Initiative (VQI) Varicose Vein Registry (VVR) represents a patient-centered database launched in January 2015. Previous work describing overall trends and outcomes of varicose vein procedures across the United States demonstrates a benefit from these procedures. The existing gaps in evidence to support current and future Medicare coverage of varicose vein procedures necessitate further description of clinical outcomes in patients ≥65 years old compared with the population <65 years old.

Methods: This study analyzed prospectively captured anatomic, procedural, and outcome data for all patients in a national cohort of all VQI VVR-participating centers. The VQI VVR database was queried for all patients undergoing varicose vein procedures between January 2015 and July 2016. Preprocedural and postprocedural Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification, Venous Clinical Severity Score (VCSS), and patient-reported outcomes (PROs) were compared between patients <65 years and ≥65 years old. Univariate descriptive statistics of demographic and procedural data were performed. Student *t*-tests were then performed on change in CEAP classification, VCSS score, and PROs (heaviness, achiness, throbbing, swelling, itching, appearance, and impact on work) for each group.

Results: There were 4841 varicose vein procedures performed from January 2015 to May 2016. There were 3441 procedures performed in 2691 patients (3631 limbs) in the group <65 years old and 1400 procedures performed in 1068 patients (1467 limbs) in the group ≥65 years old. Truncal veins alone were the most common veins treated in both groups. The majority of patients were white and female in both groups. Most of the demographic characteristics were clinically similar (although statistically different) in both groups with the exception of a higher body mass index in the group <65 years old and a history of bilateral varicose vein treatment, and anticoagulation was more common among patients ≥65 years old. Patients in both groups experienced statistically significant improvement in VCSS, PROs, and CEAP class. There was no difference in overall complications between age groups.

Conclusions: All patients demonstrated an associated improvement in both clinical outcomes (CEAP class, VCSS) and PROs. There was no significant difference in the improvement in CEAP class and VCSS between patients younger and older than 65 years, although the younger population reported greater improvement in PROs. Given these findings, patients older than 65 years appear to benefit from varicose vein procedures and should not be denied interventions on their varicose veins and venous insufficiency on the basis of their age only. (J Vasc Surg: Venous and Lym Dis 2017;5:647-57.)

Varicose veins are estimated to affect up to 30% of Americans in the United States, and up to 10% of those patients develop skin changes.[1-5] Whereas varicose veins are common, they are often overlooked by providers because of an underappreciation of the associated morbidity. Nonetheless, venous disease is associated with significant functional limitations and decreased health-related quality of life.[6] Despite national Society for Vascular Surgery/American Venous Forum guidelines on treatment recommendation for varicose veins, there is currently a wide variation of interventions for varicose veins.[7] The Vascular Quality Initiative (VQI) Varicose Vein Registry (VVR) was developed with an incentive to query patient outcomes of various venous procedures and to facilitate the physician's decision-making in developing a treatment strategy with patients for optimal vein care.

Initial data from the VQI VVR suggest that despite the wide variation in clinical practice and physician preference, there is consistent benefit to varicose vein procedures.[7] Overall, patients experience improved Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) class, Venous Clinical Severity Score (VCSS), and patient-reported outcomes

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(PROs), suggesting these procedures to be an important tool for providers in the treatment of varicose veins.[7-9] However, there is a paucity of data describing age-related benefit to varicose vein procedures despite overwhelming evidence to suggest that the prevalence of varicose veins increases with age.[3,4]

Presently, Medicare reimburses varicose vein procedures only after a period of conservative management.[10] The appropriateness of this requirement is currently a topic of significant debate, as this is contrary to Society for Vascular Surgery/American Venous Forum evidence-based guidelines (1B), which recommend against compression therapy as primary treatment of symptomatic varicose veins.[1] The potential exists that Medicare-aged patients will not be covered at all. This issue was recently discussed at a Medicare Evidence Development and Coverage Advisory Committee meeting.[10,11] To better inform these decisions, it is imperative to explore the outcomes of varicose vein procedures in older patients. Our objective was to investigate clinical outcomes based on age, comparing those ≥65 years with those <65 years, in regard to CEAP class, VCSS, PROs, and overall complication rates. Our hypothesis was that patients ≥65 years of age benefit to the same extent as patients <65 years old in clinical outcomes without higher complication rates.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective review of prospectively collected data of the Vascular Quality Initiative (VQI) Varicose Vein Registry (VVR)
- **Take Home Message:** Procedures for varicose veins in 1068 patients ≥65 years of age resulted in similar improvement in Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) class and Venous Clinical Severity Score (VCSS) as in 2691 younger patients. Younger patients had more improvement in patient-reported outcomes.
- **Recommendation:** The authors recommend that Medicare beneficiaries should not be denied vein procedures on the basis of age alone.

METHODS

Data source and data capture. The VQI VVR is one of the 12 registries under the umbrella of the VQI. This registry started in January 2015 and currently has 24 participating centers within 13 regions across 46 states and Ontario. This registry includes all superficial varicose vein procedures for ≥C2 disease and excludes the treatment of deep veins, veins treated for trauma, and superficial veins in patients with C0-C1 disease. Once a center agrees to participate, every consecutive superficial varicose vein procedure is captured. Either the physician who performs the procedure or a designated trained individual for that center completes the data entry. Each data entry has a preoperative assessment; procedure-related assessment that includes the assessment of systemic complications as well as whether a patient requires hospitalization after the procedure; and postprocedural follow-up at two time points, early (0-3 months) and late (>3 months). The follow-up then determines whether the patient is either discharged or returns to clinic for an additional evaluation of other varicose vein procedures.

The preoperative assessment includes the recording of a preprocedure CEAP class, VCSS, and PROs. At this time, if a preoperative ultrasound study is performed, this is also recorded. After the preoperative assessment, the patient proceeds to the operating or procedure room for the varicose vein procedure. During the isolated varicose vein procedure, a patient can have up to six veins treated in either one or both limbs. Procedures performed on each vein are recorded as either ablation or surgery. We define ablation as "minimally invasive" procedures and include radiofrequency ablation, laser ablation, mechanochemical ablation, chemical ablation (by way of sclerosing agents), and embolic adhesive. Within the VQI VVR, surgery is defined as high ligation and stripping, stripping, stab phlebectomy, Trivex phlebectomy (LeMaitre Vascular, Burlington, Mass), open ligation, and endoscopic ligation. During the periprocedural period, systemic complications are assessed and include mild or severe allergic reactions, migraine, visual disturbance, cough/chest tightness, systemic infection, pulmonary embolism, transient ischemic attack, stroke, and death. Of note, systemic complications are not assessed again at any point in the follow-up period. Finally, the patient is then seen in clinic for follow-up at two time points, early (0-3 months) and late (>3 months), during which time postprocedure CEAP class, VCSS, and PROs are assessed (Fig 1). The postprocedure CEAP class, VCSS, and PROs scores that are captured in the VQI VVR data set are the values recorded at the most recent follow-up.

Procedure selection. The use of the VQI VVR was granted after submission and approval of the scientific protocol through the national VQI application process and through a local standard Institutional Review Board approval. All patient information was deidentified and did not require informed consent. Once access was granted, the data set of all procedures in the VQI VVR from January 2015 to August 2016 was made available. On initial review of the database, we found 46 procedures from 2014. Given that these were likely "back logged" as the VVR VQI was initiated in January 2015, we excluded these procedures. We also excluded all procedures that occurred after May 2016 and did not have an early follow-up documented. This exclusion avoided case capture appearing to be missing follow-up, when in reality insufficient time had passed to allow early follow up (0-3 months) after the procedure (Fig 2).