Supplementary Methods – Appendix A

Data Source and Study Design

We used a prospective, longitudinal cohort derived from 223 centers subscribed to the Vascular Quality Initiative (VQI) registry linked with Medicare claims outcome data using the Vascular Implant Surveillance and Interventional Outcomes Network (VISION) platform housed at Cornell University.[1] Demographic, clinical, and procedural variables were prospectively abstracted from medical records in this national registry by trained data collectors. VQI records were linked to Medicare claims data using a direct (social security number) and indirect (facility identifier and state, patient date of birth, sex, procedure date, and zip code) linkage. The linkage algorithm has been extensively evaluated, with a documented 93% successful matching rate and higher than 99% accuracy.[2,3]

The inclusion criteria were 1) patients undergoing a PVI between January 1, 2017 and December 31, 2018; 2) the index procedure, in the case of multiple PVIs; 3) age ≥65 years; 4) patients with CLTI or claudication (Non-CLTI); and 5) who underwent a procedure that was not aborted. The exclusion criteria were: 1) patients with acute limb ischemia; 2) patients without Medicare fee-for-service coverage; 3) patients treated at centers with missingness rates greater than the upper limit (third quartile + 1.5 × interquartile); 4) unidentified center or provider; 5) patients with missing laterality major amputation information; and 6) patients ≥ 1 missing data among the variables used for model adjustment.

Patients with CLTI were defined as patients with rest pain (Rutherford 4) or tissue loss (Rutherford 5-6), while non-CLTI was defined as patients with claudication (Rutherford 1-3) but no rest pain or tissue loss.

Approval for the study was granted by the Institutional Review Boards of Yale University and Weill Cornell Medicine.

Outcomes

The major amputation outcome was derived from Medicare claims files and defined using Current Procedural Terminology codes 27590 to 27592 (amputation, thigh), 27880 to 27882 (amputation leg), and 28805 (amputation foot). All-cause mortality was derived from the Centers for Medicare and Medicaid Services vital status files. Medicare claims data have been shown to have a high sensitivity and specificity for mortality (>99.9%) and procedural claims (>90%).[4] Patients were followed until the 1st major amputation event, until 2 years after the index procedure, until December 31, 2019, or until death, whichever occurred first. Patients were classified in 3 categories according to their status observed at the end of the follow-up: major amputation, death without major amputation or alive without major amputation (i.e., event-free).

Statistical Methods

For both the CLTI and non-CLTI cohort, patient and procedural baseline characteristics were described and compared by age groups and by status (alive without major amputation, underwent major amputation, or died without major amputation) at the end of the follow-up. Categorical variables were summarized as counts with percentages, and continuous variables as means with standard deviations and medians with interquartile ranges. Baseline characteristics were compared using Chi-square or Fisher's exact test for categorical variables, and ANOVA or Kruskal–Wallis's test by ranks for continuous variables. Statistical significance was determined using a p-value threshold of less than 0.05, and all tests were two-tailed. Standardized differences

were calculated to assess the effect size of baseline characteristics between patients ≥75 vs. <75 years old, with an absolute value below 0.10 or 0.20 considered negligible or small, respectively.[5]

Supplemental References:

1.   Tsougranis G, Eldrup-Jorgensen J, Bertges D, et al. The Vascular Implant Surveillance and Interventional Outcomes (VISION) Coordinated Registry Network: An effort to advance evidence evaluation for vascular devices. *J Vasc Surg* 2020; 72: 2153-2160. 20200520. DOI: 10.1016/j.jvs.2020.04.507.
2.   Mao J, Moore KO, Columbo JA, et al. Validation of an indirect linkage algorithm to combine registry data with Medicare claims. *J Vasc Surg* 2022; 76: 266-271 e262. 2022/02/20. DOI: 10.1016/j.jvs.2022.01.132.
3.   Columbo JA, Kang R, Trooboff SW, et al. Validating Publicly Available Crosswalks for Translating ICD-9 to ICD-10 Diagnosis Codes for Cardiovascular Outcomes Research. *Circ Cardiovasc Qual Outcomes* 2018; 11: e004782. 2018/10/26. DOI: 10.1161/CIRCOUTCOMES.118.004782.
4.   Butala NM, Strom JB, Faridi KF, et al. Validation of Administrative Claims to Ascertain Outcomes in Pivotal Trials of Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv* 2020; 13: 1777-1785. 20200715. DOI: 10.1016/j.jcin.2020.03.049.
5.   Austin PC. Using the Standardized Difference to Compare the Prevalence of a Binary Variable Between Two Groups in Observational Research. *Communications in Statistics - Simulation and Computation* 2009; 38: 1228-1234. DOI: 10.1080/03610910902859574.