Proposed Assessment of Trends in Disparities in PAD Outcomes
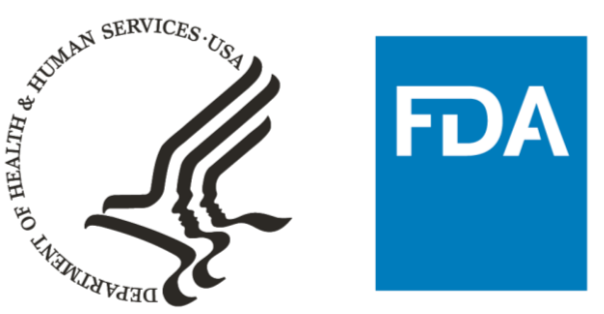
Osman Yogurtcu[1], Olamide Alabi[2], Misti Malone[3], Artur Belov[1], Orestis Panagiotou[3], Danica Marinac-Dabic[3], Gregory Pappas[1]

1. CBER/OBPV, 2. Emory School of Medicine, Atlanta 3. CDRH

Symposium Theme: Solutions for Public Health: Uniting Scientific Computing, Enterprise IT, and Innovative Technologies.

Abstract

➢ Is there a relationship between racial and socioeconomic status and outcomes for patients undergoing revascularization for peripheral artery disease (PAD) and can these changes be linked to interventions targeting health equity?

➢ We are using a Coordinated Registry Network (CRN) to answer the question.

Despite decades of knowledge about racial and socioeconomic disparities in peripheral artery disease (PAD) treatment and outcomes, it remains unclear whether these disparities are improving, worsening, or stable over time. This multistakeholder study investigates racial, ethnic, and socioeconomic disparities in PAD treatment and outcomes over time. As a coordinated registry network (CRN), the Vascular Quality Initiative (VQI)-VISION offers comprehensive data, including pre-operative risk factors, intraoperative details, post-operative outcomes, and one-year follow-up data, making it a valuable resource for research and quality improvement initiatives. Leveraging data from VQI-VISION, we examine trends in disparities, identify contributing social determinants of health, and assess progress made in addressing these disparities. More specifically, by analyzing the databases, we identify patients with symptomatic PAD. We examine the impact of race/ethnicity and socioeconomic status (SES) on major amputation risk after PAD diagnosis, adjusting for various patient characteristics and comorbidities. We assess adjusted hazard ratios for amputation risk using a Cox proportional hazards model. Our subgroup analyses explore temporal trends and disparities in amputation risk. We have finalized the study protocol, and the analysis of the database is ongoing. The results of this research have the potential to guide the development of targeted interventions and contribute to national monitoring of vascular health outcomes, aligning with the goals of the Department of Health and Human Services Healthy People 2030 initiative.

Introduction

Racial and ethnic disparities in vascular surgery outcomes are well-documented, with some groups experiencing poorer results. This issue is complex and multifactorial, involving both medical and socioeconomic factors.[1] Studies highlight disparities in peripheral artery disease (PAD), where Black and Hispanic patients often present with advanced disease and face poorer outcomes, despite adjusting for other factors. Neighborhood deprivation, limited healthcare access, and implicit bias contribute to these disparities.[2] Real-world evidence (RWE), generated from real-world data (RWD), offers a way to address healthcare disparities, quality of care, and the safety and efficacy of medical products. Coordinated registry networks (CRNs) efficiently curate and link RWD, offering a powerful model for generating RWE. The Society for Vascular Surgery's VQI and VISION initiatives demonstrate how scientific computing, and digital transformation can improve vascular healthcare quality (Figure 1). These initiatives use advanced data analytics to provide valuable insights into procedure outcomes, device performance, and safety concerns, ultimately leading to improved patient care.[3]

Materials and methods

- The **VQI** dataset, a national prospective quality registry, has been leveraged to capture high-quality outcomes data for over 1,000,000 vascular procedures performed across 1,000 subscribing sites in the United States, Canada, Puerto Rico, and Singapore. The data collection process relies on standardized, competency-based training for local abstractors, who extract data from patients' electronic health records (EHRs) and enter it into the data collection platform. To ensure data accuracy, interrater reliability checks are performed quarterly. The dataset includes amputation information abstracted from operative notes, mortality data derived from discharge summaries, and one-year follow-up data collected from EHRs within a 9–21-month post-procedure window. For patients with fee-for-service Medicare, the VQI has been linked with Medicare claims outcomes data using a validated matching algorithm, achieving high sensitivity and specificity.

- The **VISION**, housed at Weill Cornell Medicine, integrates the VQI with Medicare claims data, enabling the analysis of process outcomes variables such as medication adherence, tobacco cessation interventions, and pre-procedural assessments like ankle-brachial index (ABI) or angiography. By leveraging this integrated dataset, researchers can investigate the relationships between these process outcomes and patient outcomes, ultimately informing quality improvement initiatives and digital transformation in healthcare.

Our study is a retrospective observational cohort study leveraging data from the VQI and VISION (2012-2019) to track changes in outcome disparities for PAD patients across race, ethnicity, and place over time. Leveraging data from the INFRA, SUPRA, PVI, and AMP registries, we will focus on patients over 18 years old, representing all races and ethnicities. Our analysis will examine how treatment center participation in a quality improvement (QI) program, race/ethnicity, and socioeconomic indicators (such as insurance type, median income, and area deprivation index) influence disparities over time. We will assess key outcome measures, including process metrics (e.g., time from diagnosis to revascularization, rates of pre-procedural angiography) and clinical endpoints (e.g., major amputation, target limb reintervention, mortality). Also, we will analyze process variables, such as medications, tobacco cessation, and pre-procedural assessments, as both independent outcome measures and control variables to account for their potential influence on clinical outcomes. Race/ethnic-specific rates of subgroups will be further summarized using a disparity index. The Index of Disparity (ID) is a simple summary measure of disparity across population groups: where groups may be defined in terms of 'race/ethnicity, education, gender and/or income.[4,5]

OBJECTIVES	ENDPOINTS
Primary	
To analyze temporal trends in racial, ethnic, and socioeconomic disparities in post-operative major amputation risks for patients undergoing PAD revascularization procedures, namely, lower extremity infrainguinal bypass surgery, peripheral vascular intervention, and lower extremity suprainguinal bypass surgery.	Major amputation at 1 year.
Secondary	
To analyze temporal trends in racial, ethnic, and socioeconomic disparities in post-operative outcomes for patients undergoing peripheral artery disease (PAD) revascularization procedures, namely, lower extremity infrainguinal bypass surgery, peripheral vascular intervention, and lower extremity suprainguinal bypass surgery.	At 1 year, the following will be measured: • Major Adverse Limb Event (MALE) rate • Reintervention rate • Readmission rate • Length of hospital stay • Mortality rate
Tertiary/Exploratory	
To analyze temporal trends in the use of VQI-guided process interventions (medications, tobacco cessation, ABI/angiography) before PAD revascularization procedures, and to determine if racial, ethnic, or socioeconomic disparities exist in both intervention utilization within the VQI registry. This analysis aims to investigate whether these factors contribute to observed disparities in patient outcomes.	Process measures demonstrating successful implementation of clinical guidelines, including adherence to medication regimens, tobacco cessation interventions, and pre-procedural assessments (ABI or angiography) within one year after their vascular procedure.

To provide robust insights, we will adjust for potential confounders, including disease severity, comorbidities (e.g., diabetes, renal disease), and hospital/surgeon characteristics. We will also examine the impact of residential-level socioeconomic status, standard demographics (e.g., gender, age, US geographies), and the volume of surgeries at the location of care. Ultimately, this study will provide a comprehensive understanding of disparities in perioperative care for vascular surgery patients, including amputation rates, reintervention rates, readmission rates, length of hospital stay, post-operative complications, mortality rates, and adherence to process measures such as appropriate medications and smoking cessation interventions. For our VISION analysis, patients will be excluded if they cannot be linked to a Medicare fee-for-service database.

Results and discussion

- At the end of 2023, we started preparing an application for the VQI's National Research Advisory Committee (RAC) and we started bringing together a group of experts interested in PAD research and health equity. The group is composed of experts from FDA and from external scientists, statisticians, and physicians.

- In February 2024, the project was approved by the VQI RAC with ID number 5464. In March 2024, we started monthly meetings with our multistakeholder study group. Between March and August 2024, we have developed our study protocol and fulfilled our IRB requirements.

- In August 2024, we submitted our VISION research memorandum, which will allow us to work closely with the VISION in-house analysts to perform analyses on the dataset. We plan to wrap up our analysis and finish writing a manuscript based on the results in the first quarter of 2025.
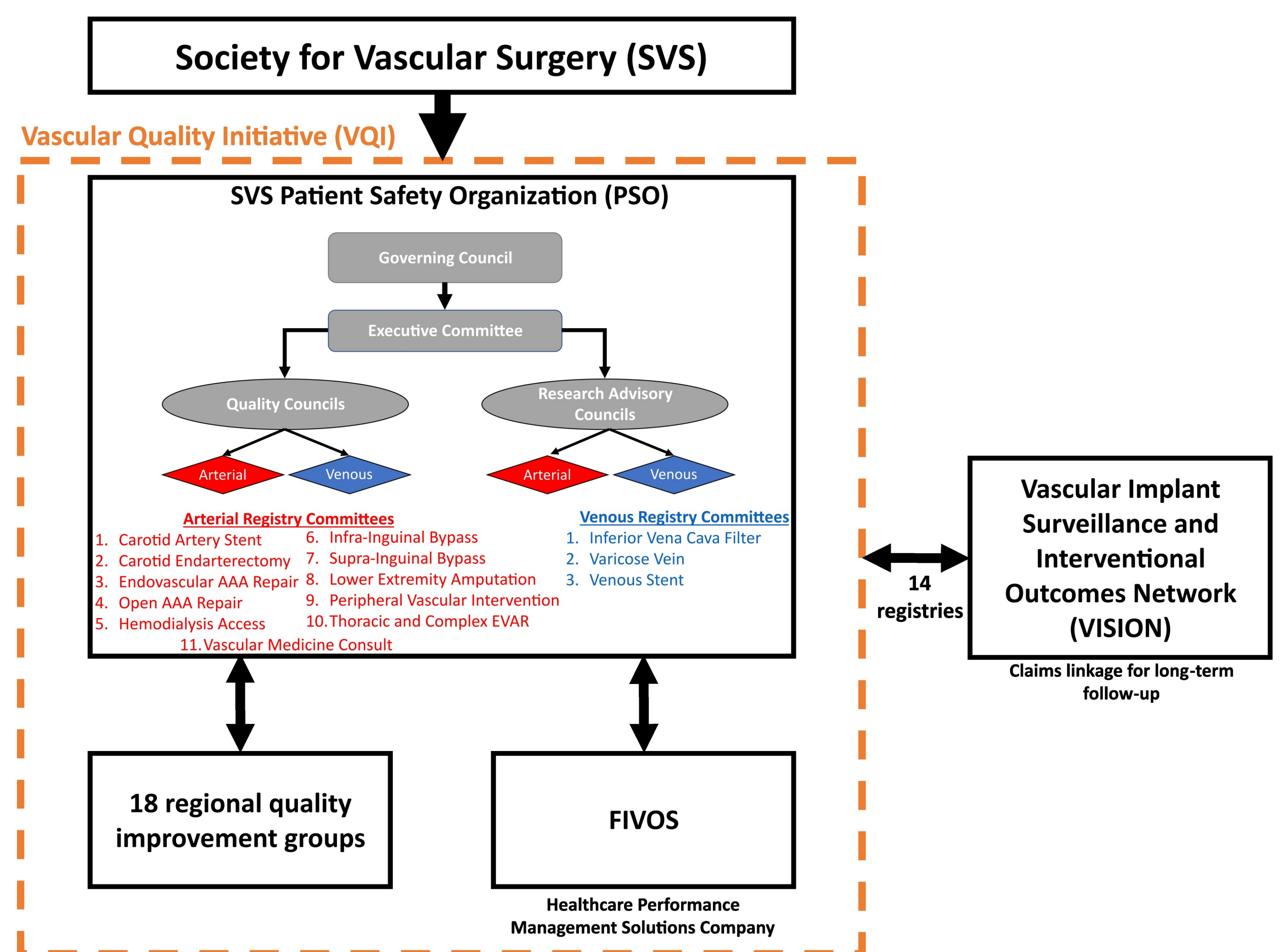

Figure 1. Structure of the VQI/VISION CRN. VQI is a collaboration of the SVS PSO, 18 regional quality improvement groups organized under the SVS PSO, and FIVOS (a healthcare performance management solutions company), its commercial technology partner. VQI functions as a CRN, collecting and analyzing data voluntarily reported by healthcare providers to help improve patient safety and healthcare quality. The SVS VQI Vascular Implant Surveillance and Interventional Outcomes Network (VISION) is an independent university-based project that links Medicare claims data to the registry.

Conclusion

Our analyses are still ongoing. However, the results of this research have the potential to guide the development of targeted interventions and contribute to the national monitoring of vascular health outcomes, aligning with the goals of the Department of Health and Human Services Healthy People 2030 initiative.

- The study's findings may reveal that racial, ethnic, and socioeconomic disparities in PAD outcomes persist over time, highlighting the need for continued efforts to address these disparities. Additionally, the analysis may show changes in disparities over time, such as improvements or worsening of outcomes for certain groups, which could inform strategies for addressing disparities and monitoring progress.

- The study may also identify specific social determinants of health that contribute to disparities in PAD outcomes, such as access to healthcare, education, or socioeconomic status, which could inform targeted interventions to address these underlying factors.

- Furthermore, the study may assess the effectiveness of existing interventions aimed at reducing disparities in PAD outcomes and identify areas for improvement.

- Ultimately, the results of the study could inform policy and practice changes aimed at reducing disparities in PAD outcomes, such as changes to healthcare access, reimbursement policies, or clinical guidelines, and contribute to the national monitoring of vascular health outcomes.

Acknowledgements and Disclaimer

References

1. Barshes NR, Minc SD. Healthcare disparities in vascular surgery: A critical review. Journal of vascular surgery. 2021;74(2):6S-14S.
2. Arya S, Binney Z, Khakharia A, et al. Race and socioeconomic status independently affect risk of major amputation in peripheral artery disease. Journal of the American Heart Association. 2018;7(2):e007425.
3. Cronenwett JL, Kraiss LW, Cambria RP. The society for vascular surgery vascular quality initiative. Journal of vascular surgery. 2012;55(5):1529-1537.
4. Pearcy JN, Keppel KG. A summary measure of health disparity. Public health reports. 2002.
5. Singh, Gopal K., et al. "State and Metropolitan Area Disparities in Long COVID-19 and Related Symptoms among US Adults, June-October 2022." International Journal of Translational Medical Research and Public Health 7.2 (2023): 1-14.