

EDITORIAL COMMENT

A “Win-Win” for Peripheral Vascular Intervention*

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The physicians, hospitals, and particularly the sponsors of “Safety of Contemporary Percutaneous Peripheral Arterial Interventions in the Elderly: Insights from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium Peripheral Vascular Intervention Registry” are to be congratulated for their innovative, forward-looking efforts to improve the quality of care for lower-extremity peripheral vascular disease (LE-PVD) patients in Michigan (1). Their report is based upon a large “real world” sample of heterogeneous patients treated in 18 hospitals (i.e., university-based, governmental, large multispecialty systems, and community hospitals) by a variety of physician specialists practicing peripheral vascular intervention (PVI). The primary outcome, which confirms the safety of PVI in elderly patients, will inform the national LE-PVD quality of care debate and impact future guideline documents.

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To analyze the risk of PVI associated with age, the authors segregated 7,769 consecutive LE-PVD patients into 3 age groups: 1) <70 years (52%); 2) 70 to 79 years (30%); and 3) ≥80 years (18%). Approximately two-thirds of the patients had chronic limb ischemia (claudication), with the remainder treated for critical limb ischemia (rest pain or limb salvage). Elderly patients were quite different from the younger groups, according to the demographic data shown in Table 1 in Plaisance et al. (1), with overrepresentation of several important comorbidities (female sex, low body weight, hypertension, heart failure, cerebrovascular disease, and anemia). The younger groups had a higher percentage with tobacco abuse, diabetes, hyperlipidemia, pulmonary disease, and dialysis. These “real world” differences are a major strength of this large registry data-

base, because they include patients often excluded from LE-PVD randomized trials of devices and drugs.

The data show that, as LE-PVD patients get older, they develop more advanced atherosclerotic lesions that require more complex PVI procedures. Percutaneous, nonsurgical treatment of increasingly complex LE-PVD was associated with a slightly lower success rate and more vascular access complications than was seen in the younger groups. The lower success rate might have been related to the unbalanced excess of 2 procedure variables: 1) more complex below-knee revascularization procedures were performed in elderly patients; and 2) more antegrade femoral access procedures were performed in elderly patients. In contrast to the retrograde femoral access technique, antegrade common femoral artery access is a more challenging technique that requires additional training and skill and does not allow the use of vascular closure devices. The more difficult antegrade access is preferred/required for complex below-knee interventions that were more commonly performed in elderly patients. The excess of these adverse variables in elderly patients and their potential linkage (one is associated with the other) makes risk adjustment and direct comparisons among the age groups more difficult than for a controlled study.

The major finding of this report, however, was that PVI in elderly patients (age ≥80 years) was not independently associated with an excess of major adverse cardiovascular events, contrast induced nephropathy, transfusion, or amputation (1). The data support a trend in clinical practice of adopting an “endovascular-first” approach to patients with LE-PVD requiring revascularization. As the authors point out, selecting PVI as the initial revascularization procedure avoids the greater morbidity and mortality of open surgical procedures and rarely, if ever, precludes a later attempt at surgery if necessary. Based upon what now seems to have been an incorrect perception of increased procedure risk, elderly patients with LE-PVD should not be denied PVI that might improve their quality of life by reducing pain and improving their ability to ambulate and exercise.

This report also raises a separate issue related to national efforts at improving overall quality of care by encouraging appropriate use and improving patient outcomes. The Blue Cross Blue Shield of Michigan Cardiovascular Consortium Peripheral Vascular Intervention (BMC2 PVI) Registry is a unique collaboration to evaluate evidence-based disease management in support of improving quality of care and patient outcomes. The stakeholders in this venture are a private insurer (Blue Cross Blue Shield of Michigan), a consortium of 18 Michigan hospitals (Online Appendix A in Plaisance et al.) (1), and clinician investigators who agreed to collaborate in this effort. The project was funded with laudable foresight by an unrestricted grant from Blue Cross Blue Shield of Michigan. The goal of the BMC2 PVI registry was to demonstrate that health outcomes in vascular patients could be improved by systematically collecting,

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analyzing, and reporting real-world patient data. The registry data can be used to provide feedback that can result in improvement in resource use. One obvious example in this dataset is the disparity in the use of statins among elderly PVI patients. It is now accepted that statin therapy is beneficial and cost-effective in elderly patients (2). The next step will be for the consortium to provide feedback and education to effect a change in prescribing statins to elderly patients.

A major issue for any large registry is controlling the quality and reliability of the data collected. The BMC2 PVI registry went to some lengths to ensure good data quality with a multistep review process, data checks at several stages, and a twice yearly on-site audit. The authors appropriately acknowledge the limitations of analyzing heterogeneous, self-reported, observational data without adjudication of outcomes. The lack of control groups makes performing some comparison analyses difficult. For example, there will be a strong selection bias among patients receiving open surgery compared with PVI that will limit any comparison of these populations. These groups might be so different with regard to comorbidities that post hoc risk adjustment will be very difficult if not impossible to perform.

The best part of this story is that a partnership that includes a major healthcare insurer, physicians, and hospitals resulted in the collection, analysis, and publication of valuable data representing the quality of health care for LE-PVD patients. It is important to reassure providers that PVI procedures should not be withheld from very elderly

patients for fear of increased procedure risk. This report provides a benchmark for PVI outcomes and encourages the adoption of continuous quality improvement initiatives across the BMC2 system. Finally, and most importantly, the BMC2 PVI registry is an excellent model for a “win-win” strategy for all stakeholders involved in the care of patients with vascular disease. Kudos to the doctors, hospital administrators, and the leadership of Blue Cross Blue Shield of Michigan for figuring out how to collaboratively align their incentives in the best interests of their patients.

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