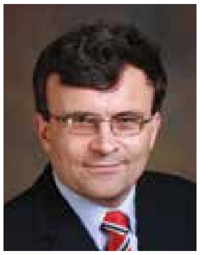

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CRITICAL LIMB ISCHEMIA: REPORTING OUTCOMES AND QUALITY

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Abstract

The impetus to pursue quality in limb salvage is high in the current economic environment. This has been spurred on by the diffusion of multiple technologies, the lack of well-defined cost-effectiveness benchmarks, and the paucity of process and structure benchmarks. Furthermore, no national database exists to capture current activity and trends, and lead structure and process changes that could analyze outcomes and improve standards in peripheral interventions for limb salvage. This manuscript examines the challenges in measuring outcomes and quality in limb salvage and explores the components necessary for ensuring quality in limb salvage interventions.

Introduction

The Institute of Medicine's report on patient safety has focused a significant spotlight on the role of quality in medicine.[1] Each component of the medical infrastructure — government, payers, hospital administration, professional organizations, physicians, nurses, and ancillary staff — is now working to define, report, certify, and reward quality. Coordination in these domains remains fragmented, and each is searching for and establishing its own benchmarks. Integration at all levels remains a significant challenge, and there is increasing competition for the same resources.

Significant variation exists in the intensity of vascular care provided to patients in the year before major amputation. Mean time to vascular surgery consultation for pedal tissue loss and rest pain is 73 days and 27 days, respectively. In some regions, patients receive intensive care, whereas far less vascular care is provided in other regions. African American patients with peripheral arterial disease (PAD) undergo amputation at two to four times the rate of Caucasian patients, and African American patients are more likely to be female and of a lower socioeconomic status. They are also much less likely than Caucasians to undergo attempts at limb salvage prior to amputation. Although there has been an absolute increase in the number of revascularization procedures for chronic limb ischemia, with a clear shift toward endovascular therapy, the amputation rates for these patients have not changed. However, the shift to endovascular interventions has increased the number of secondary procedures required to maintain limb-salvage rates equivalent to those of the pre-endovascular era. Endovascular interventions are now performed more often than bypass surgery for the treatment of lower extremity critical limb ischemia (CLI). These changes far exceed simple substitution. Between 1996 and 2006, more than three additional endovascular interventions were performed for every one procedure declined in lower extremity bypass surgery.[2] During this same time period, major lower extremity amputation rates fell by more than 25%.[2] According to the Nationwide Inpatient Sample (NIS),[3] endovascular interventions have altered the treatment paradigm for lower limb ischemia with an increase in costs and procedures. It is unclear if this represents an increase in the number of patients or the number of treatments per patient. Although mortality is slightly lower with endovascular therapy for all indications, amputation rates for limb-threat patients appear higher, as does the average cost. Longitudinal studies are necessary to determine the appropriateness of percutaneous transluminal angioplasty (PTA) in both claudication and limb-threat patients. The mortality benefit with PTA may ultimately be lost and average costs elevated if multiple interventions are performed on the same patients.

Peripheral interventions for limb salvage have traditionally been judged on their mortality, morbidity, and anatomic outcomes. Recently, however, the emphasis has shifted to patient-centered outcomes and retained functionality. In addition, the rapid diffusion of multiple technologies to more providers has altered the status quo and produced a flux in the quality baseline of peripheral interventions for limb salvage. While outcomes related to specific procedures or conditions are continually reported, structure and process indicators are scarcely evaluated in peripheral interventions. A recent analysis of the reporting of quality in peripheral interventions extracted 57 prospective articles from 859 eligible reports.[4] Structure as an indicator of quality of care was described in 19 reports, process in 7 reports, and outcome in 31 reports. Most studies based on structural measures considered the introduction of a clinical pathway or a registration system. Reports based on process measures showed promising results. Outcome as a clinical indicator mainly focused on identifying risk factors for morbidity, mortality, or failure of treatment. Many studies in peripheral interventions have used outcomes as the indicator of quality of care, but a shift towards process measures should be considered in the future.

Current Quality Measures

Mortality and Morbidity

The two areas most frequently tracked and reported for endovascular interventions are mortality at 30 or 90 days from the date of the procedure or in-hospital mortality during the same admission.

Anatomic

Traditionally, peripheral interventions have reported the anatomic results of revascularization in critical limb ischemia. Patency, the time a graft or intervention remains open, has three levels: 1) primary, in which the graft or lesion remains open without occlusion or re-intervention; 2) assisted primary, in which the graft or lesion remains open due to an intervention on the graft or lesion or its inflow or outflow tract to maintain patency; and 3) secondary, in which the graft or lesion remains open as a result of an intervention on the graft or lesion when it has become occluded. Target lesion revascularization is defined as any repeat revascularization procedure (percutaneous or surgical) of the original target lesion site.

Functional

Prevention of major limb loss was considered the successful parameter in patients with CLI, and major limb loss was considered a marker of poor quality in interventions for claudication. In the last decade, there has been increased emphasis on functional outcomes in critical limb ischemia, which include amputation-free survival (AFS), ambulation, and social independence. "Patency" and "limb salvage" are not automatically valid parameters when the functional outcome of treatment for CLI is assessed. In a small number of patients, the functional result is not favorable despite the anatomical patency and limb salvage. The considerable investment of human/financial resources needed to treat these patients is often questioned. A recent report, which drew from a candidate list of 1351 studies, found 19 reports (3 model-based, 12 cost-consequence, and 4 cost-analyses) suitable for review of cost effectiveness in lower-extremity interventions. Unfortunately, because of the small numbers, claudication and CLI studies were analyzed together. The authors found a trend favoring initial cost savings with endovascular therapy. Whether this benefit can be sustained over time is unknown. There was a noted lack of standardized patient-centric outcomes, longitudinal data, and reintervention data. The existing lower-extremity arterial revascularization economic literature is inadequate for drawing cost-efficacy conclusions and cannot inform guidelines for open versus endovascular treatment.[5]

Quality of life questionnaires give valuable information on the functional outcome of any treatment for critical ischemia. The problem with the generic tools in one particular subgroup of patients is the reliability and validity of the tests. The first disease-specific test in CLI is the King's College Vascular Quality of Life (VascuQoL) Questionnaire, which is recommended for patients with critical lower limb ischemia. It is very useful for scientific reporting and can retrospectively identify a particular group of patients in whom the technical success of the treatment did not result in improved quality of life. In general practice, use of the questionnaire can decrease the subjectivity factor when assessing the status of a patient with newly diagnosed or previously treated critical ischemia.[6]

Objective Performance Goals

Recently, the Society for Vascular Surgery's CLI Performance Goals Work Group developed a set of suggested objective performance goals (OPG) for evaluating treatments in CLI based on evidence from historical control studies. The primary efficacy endpoint was defined as perioperative (30-day) death or any major adverse limb event (amputation or major reintervention) occurring within 1 year. Results of open surgery controls demonstrated freedom from the primary endpoint in 76.9% (95% confidence interval [CI] 74.0–79.9%) of patients at 1 year, with AFS of 76.5% (95% CI 73.7–79.5%).[7] An additional 3% noninferiority margin was suggested in generating OPG for catheter-based therapies. Defined clinical (age >80 years and tissue loss) and anatomic (infrapopliteal anatomy or lack of good quality saphenous vein) risk subgroups provided significantly different point estimates and OPG threshold values.[7] A major adverse cardiovascular event (MACE) was defined as a myocardial infarction, stroke, or death (any cause). A major adverse limb event (MALE) was defined as an above-ankle amputation of the index limb or major reintervention, e.g., a new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis). Amputation-free survival was defined as survival without an above-ankle amputation of the index limb or death.

National Measures

National agencies also participate in quality assurance and benchmarking for limb salvage. The Medicare Physician Quality Reporting System and the Surgical Care Improvement Project programs track process measures related to antibiotic usage, deep venous thrombosis, and central-line infections and currently provide additional reimbursement for compliance. University Health Consortium provides procedure-specific data on length of stay, cost, and adverse outcomes to sites and ranks them accordingly. The National Surgical Quality Improvement Program, administered through the U.S. Department of Veterans Affairs and the American College of Surgeons, does track vascular procedures with generic outcomes. Health Grades and Leapfrog both track available data from the Centers for Medicare and Medicaid Services and payers, and they rank hospitals according to outcomes cost and specific quality and process measures for major vascular procedures. *U.S. News and World Report* publishes rankings in cardiac care and is widely held as a benchmark in cardiovascular care but does not track or rank peripheral vascular interventions.

Practice Guidelines and Reporting Standards

The Society for Vascular Surgery, the European Society of Vascular Surgery, the Society of Interventional Radiology, the American College of Cardiology, and the American Heart Association individually and in collaboration have begun to publish original and updated guidelines and reporting standards for peripheral vascular interventions. These guidelines and standards highlight best practices and expected results of practice that will allow benchmarking of quality reports.

Clinical Pathways

Clinical pathways are defined as complex interventions consisting of a number of components based on the best available evidence and guidelines for specific conditions.[8] A clinical pathway defines the sequencing and timing of health interventions and should be developed through the collaborative effort of physicians, nurses, pharmacists, and other associated health professionals Clinical pathways aim to minimize delays and maximize resource utilization and quality of care. They are also referred to as "integrated care pathways," "critical pathways," "care plans," "care paths," "care maps," and "care protocols." A study by Calligaro et al. gave one group of patients access to vascular critical pathways with a dedicated vascular patient care unit, outpatient preoperative arteriography, and anesthesiology-cardiology evaluations.[9] Length-of-stay goals were reduced to 1 day for extra-cranial, 5 days for aortic, and 2 to 5 days for lower-extremity surgery. Within this strategy, same-day admissions significantly increased (80% vs. 6.2%; P <0.0001), and average length of stay significantly decreased (3.8 vs. 8.8 days; P <0.0001) in those on a clinical pathway and those who were not. There were no significant differences in terms of the overall mortality and morbidity rates, in cardiac, pulmonary, or neurologic complications, or in readmission within 30 days. Annual hospital cost savings totaled $1,267,445.[9] The authors' search identified 30 studies, 24 of which were trials with a before-after design. Four trials had only an intervention group, one was a nonrandomized controlled trial, and one was a randomized controlled trial. Study sizes ranged from 6 to 1,200 patients, with the mean number of patients being 119 in the treatment group and 120 in the comparison group (where existent).

Clinical pathway implementation in surgery has manifold advantages. They improve objective and subjective quality of care, decrease hospital costs, increase staff satisfaction, and are valuable tools for training. Their effect seems to be most pronounced for high-volume or particularly complex treatments.[10]

Risk Stratification

Patients with CLI have significant atherosclerotic disease and as such are at a significant risk of myocardial infarction, arrhythmia, stroke, and death. The risk of death and nonfatal myocardial infarction can be accurately predicted by the Revised Goldman Cardiac Risk Index (RCRI) in patients undergoing vascular surgery. However, this risk is not reduced in any high-risk subset of the RCRI with preoperative coronary artery revascularization.[11] The PREVENT III (PIII) critical limb ischemia risk score is a simple published tool that can be used for estimating amputation-free survival in CLI patients considered for infrainguinal bypass.[12]

Recently, data from the Vascular Study Group of New England (VSGNE) has raised a concern that the RCRI will underestimate cardiac complications by 1.7- to 7.4-fold based on actual event rates of 2.6%, 6.7%, 11.6%, and 18.4% for patients with 0, 1, 2, and ≥3 risk factors, respectively.[13] In multivariate analysis of the VSGNE cohort, independent predictors of adverse cardiac events were increasing age (odds ratio [OR] 1.7–2.8), smoking (1.3), insulin-dependent diabetes (1.4), coronary artery disease (1.4), congestive heart failure (1.9), abnormal cardiac stress test (1.2), long-term beta-blocker therapy (1.4), chronic obstructive pulmonary disease (1.6), and creatinine ≥1.8 mg/dL (1.7). The VSGNE Cardiac Risk Index more accurately predicts in-hospital cardiac events after vascular surgery and represents an important tool for clinical decision-making.[13] For long-term prediction, the VSGNE group has shown that six preoperative patient characteristics are associated with a higher risk of death in multivariate analysis: CHF (hazard ratio [HR] 1.3, 95% CI 1.0–1.8), diabetes (HR 1.5, 95% CI 1.1–2.1), CLI (HR 1.7, 95% CI 1.3–2.4), lack of single-segment saphenous vein (HR 1.9, 95% CI 1.5–2/5), age over 80 (HR 2.0, 95% CI 1.5–2.7), dialysis dependence (HR 2.7, 95% CI 1.9–3.6), and emergent nature of the procedure (HR 3.4, 95% CI 1.7–6.8).[14] While patients with no risk factors had 1-year death rates that were less than 5%, patients with three or more risk factors had a 28% chance of dying before 1 year postoperatively. In the prospective and multicenter registry COhorte des Patients ARTériopathes (COPART), compliance with evidence-based medicine and pharmacological treatment was suboptimal in patients admitted for symptomatic claudication and critical ischemia.[15] However, it is important to note that statin use is associated with improved survival in CLI patients 1 year after surgical revascularization.[16]

Predictive Models of Outcomes

Using the best available evidence-based outcomes data, a group in Greenville, South Carolina[17] designed a standardization tool, the Lower Extremity Grading System (LEGS) score, that consistently assigns limbs to a specific treatment on the basis of presentation. Outcomes measured at 6 months included arterial reconstruction patency, limb salvage, survival, and maintenance of ambulatory status and independent living status. Limbs treated according to this standardization tool resulted in better outcomes compared with limbs treated contrary to the algorithm. These data suggest that routine use of an appropriately validated treatment standardization algorithm is capable of improving overall results for invasive treatment of lower extremity PAD.

The American Society of Anesthesiology (ASA) classification remains the most widely used risk-stratification system, and most patients undergoing revascularization procedures are classified as ASA III. One study has subdivided ASA III patients into two subgroups, ASA IIIA and ASA IIIB, simply based on their preoperative functional capacity measured in metabolic equivalents (METS) of <4 or ≥4.[18] Increasing age, albumin level, prevalence of CAD, diabetes mellitus, cerebrovascular disease, renal insufficiency (creatinine >1.5 mg/dL), CLI, and length of stay were significantly higher in ASA IIIB versus IIIA patients. Significantly more myocardial infarctions and deaths occurred in IIIB patients than in IIIA. The overall survival rate was significantly better in ASA IIIA than in ASA IIIB patients. A univariate Cox proportional model identified CAD, diabetes mellitus, COPD, renal insufficiency, hypercholesterolemia, presence of CLI, and preoperative albumin level of <3 g/dL or ≥3 g/dL as being significantly associated with survival. Multivariate analysis showed that being ASA IIIA or IIIB is an independent predictor of survival after adjusting for age, CAD, hyperlipidemia, COPD, and preoperative albumin levels.

Current State

From 1998 to 2003, there has been a progressive decrease in the national per capita rate of amputations: 13.2% overall and 21.2% for major amputations (P <.0001). Nationally and regionally, mortality has only slightly declined. For lower-extremity revascularization, after a sharp increase to 100,000 open procedures during the 1980s, the volume has remained constant for 10 years and began to decline in 1998, reaching 70,000 cases in 2003. In contrast, since 1996, endovascular interventions have increased 40%. Mortality between 1998–2003 remained virtually stable at 1.5% to 2% for endovascular procedures and 3% to 4% for open procedures.[19] Examination of the Nationwide Inpatient Sample has demonstrated that PTA has altered the treatment paradigm for lower limb ischemia, with an increase in costs and procedures.[20] Patients who underwent PTA were more often women (PTA: 46%, peripheral bypass graft (BPG): 42%, aortofemoral bypass (ABF): 45.2%; P <.01). Average costs for PTA increased over 60% between 2001–2007 for treatment of claudication ($8,670 to $14,084) and limb threat ($13,903 to $23,196). For BPG, average costs increased 36% for both claudication ($9,322–$12,681) and limb threat ($16,795–$22,910). In-hospital mortality was similar for PTA and BPG groups for claudication (0.1% vs. 0.2%; P =.04) and limb threat (2.1% vs. 2.6%; P <.01). In-hospital amputation rates were significantly higher for patients who had PTA (7%) versus BPG (3.9%, OR 1.67 [1.49–1.85]; P <.01). It remains unclear if this represents an increase in patients or in number of treatments per patient. Although mortality is slightly lower with PTA for all indications, amputation rates for limb-threatened patients appear higher, as does the average cost.

Data from state databases suggest that compared to vascular surgeons, cardiologists are more likely to treat patients with claudication than those with rest pain or gangrene/ulceration and often use significantly greater hospital resources. However, high practitioner volume, regardless of specialty, was associated with lower hospital resource utilization.[21] Hospital and surgeon volume, as a surrogate marker for quality, has been directly correlated with lower morbidity and mortality as well as differences in perioperative complications after multiple vascular procedures. A certificate of added qualification in General Vascular Surgery has also been shown to improve outcomes in patients undergoing vascular procedures.[22]

While endovascular procedures were found to have lower mortality rates overall, a greater number of safety events occur due primarily to bleeding complications in women and the elderly. In a study by Vogel et al., patient safety indicators were associated with advanced age, females, blacks, congestive heart failure, renal failure, hospital teaching status, and larger hospitals.[23] Patient safety indicator occurrence was associated with increased cost ($28,387 vs. $13,278; P <0.0001). Adverse events added significant cost and

Figure 1. Southern Vascular Outcomes Network (SoVONet). Map of region served by the SoVONet branch of the SVS Vascular Quality Initiative®.

• University of Arkansas, Little Rock, AR
• Baylor Heart & Vascular Hospital, Dallas, TX
• Hill Country Memorial Hospital, Fredericksburg, TX
• Memorial Hermann Southwest Hospital, Houston, TX
• The Methodist Hospital System, Houston, TX
• Christus St. John Hospital, Nassau Bay, TX
• Peripheral Vascular Associates, San Antonio, TX
• University of Texas Health Science Center San Antonio, San Antonio, TX
• University of Texas Medical Branch, Galveston, TX*
• Scott & White Hospital, Temple, TX*
• Ochsner Health System, New Orleans, LA*

**Network affiliation in progress.*

Table 1. Participating Institutions: Southern Vascular Outcomes Network (SoVONet).

occurred more frequently in teaching and large hospitals. Future organizational analysis may improve safety and reduce cost.

Vascular Quality Initiative

The Society for Vascular Surgery (SVS) launched the Vascular Quality Initiative® (VQI) in 2011 to improve the quality, safety, effectiveness, and cost of vascular healthcare by collecting and exchanging information.[24] The VQI combines the concepts of regional quality improvement developed in New England with the intention of becoming a robust national vascular database and leader in quality improvement in limb salvage. The New England registry is a validated regional data registry within a quality improvement initiative that has been associated with improved preoperative medication use and has helped define real-world practice and potential practice improvements.

SoVONet

The Methodist Hospital has as its motto "Leading Medicine." Vascular Surgery at Methodist is the lead and founding center for VQI in the Southern United States. The Southern Vascular Outcomes Network (SoVONet) represents the states of Texas, Arkansas, Louisiana, and Oklahoma and is centered on the academic medical centers in each of the major cities in the region that in turn are coordinating with local large private groups and community hospitals to increase participation (Figure 1, Table 1). Data is collected prospectively using a team approach where elements are entered by dedicated personnel, clinic staff, surgeons and residents through a web portal. SoVONet meets twice a year, in November and March, to discuss network progress, report findings, and coordinate research and quality assurance efforts.

The VQI provides a potential vehicle for future public and pay-for-performance reporting and has the potential to improve patient outcomes.[25] It uses the structure of a Patient Safety Organization (PSO) to ensure a focus on quality improvement and to provide the necessary safeguards for data confidentiality. The SVS PSO was listed by the Agency for Healthcare Research and Quality in February 2011. The SVS PSO collects data related to commonly performed major vascular procedures. These include carotid endarterectomy, carotid artery stenting, infrainguinal bypass, suprainguinal bypass, open infrarenal abdominal aortic aneurysm (AAA) repair, endovascular infrarenal AAA repair, thoracic endovascular aortic repair including branch/fenestrated AAA repair, peripheral vascular intervention of aortoiliac and lower-extremity arterial disease, and hemodialysis access.

Participants in VQI must commit to entering data for all consecutive procedures performed and submit billing data periodically to allow an audit that confirms complete entry of all procedures. Follow-up information is collected at 1 year for all procedures, an element unique to VQI, and at additional times for selected procedures that may require interval or longer follow-up. Analysis of aggregated data within the SVS PSO is directed by the PSO quality committee and performed by PSO staff. This includes the development of risk-adjustment algorithms to allow fair comparisons of hospitals or physicians, adjusted for potentially important differences in patient characteristics. Based on these analyses, the quality committee develops and disseminates information to improve patient safety, such as recommendations, protocols, or information regarding best practices. The SVS PSO is permitted to publish data that are nonidentifiable in terms of patient, physician, or hospital, allowing other regional quality groups to obtain data for specific regional quality analyses or research projects. It is also possible for multiple regional groups or centers to pool nonidentifiable data for analysis, projects that are approved and coordinated by the SVS PSO quality committee.

Proponents have long recognized the potential value of collaborative registries to answer clinical questions and provide benchmarking for quality improvement or assurance. While their value is significant, so are the logistical issues associated with data collection, auditing data accuracy, ensuring confidentiality, obtaining patient consent, and funding such efforts. In vascular surgery, one of the earliest registries is the Swedvasc effort, which has been in place since 1987. Subsequently, several other European vascular registries were organized and more recently integrated as Vascunet, under the auspices of the European Society for Vascular Surgery.[26] The United Kingdom UK Audit of Vascular Surgical Services and Australasian Vascular Audit (Australia and New Zealand)[27] have been organized in the UK and in Australia and New Zealand to function as quality assurance registries.

Conclusion

Quality is critical to patient safety, cost effectiveness, and a stronger health system. With the rise in limb salvage procedures, the infusion of expensive and complex technologies, and increasingly elderly and compromised patients, a robust quality reporting system that examines established benchmarks is a prerequisite for ensuring effective limb salvage interventions.

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