Validation of the Society for Vascular Surgery's Objective Performance Goals for critical limb ischemia in everyday vascular surgery practice

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Background: **To develop standardized metrics for expected outcomes in lower extremity revascularization for critical limb ischemia (CLI), the Society for Vascular Surgery (SVS) has developed objective performance goals (OPGs) based on aggregate data from randomized trials of lower extremity bypass (LEB). It remains unknown, however, if these targets can be achieved in everyday vascular surgery practice.**

Methods: **We applied SVS OPG criteria to 1039 patients undergoing 1039 LEB operations for CLI with autogenous vein (excluding patients on dialysis) within the Vascular Study Group of New England (VSGNE). Each of the individual OPGs was calculated within the VSGNE dataset, along with its surrounding 95% confidence intervals (CIs) and compared to published SVS OPGs using χ^2 comparisons and survival analysis.**

Results: **Across most risk strata, patients in the VSGNE and SVS OPG cohorts were similar (clinical high-risk [age >80 years and tissue loss]: 15.3% VSGNE; 16.2% SVS OPG; $P = .58$; anatomic high risk [infrapopliteal target artery]: 57.8% VSGNE; 60.2% SVS OPG; $P = .32$). However, the proportion of VSGNE patients designated as conduit high-risk (lack of single-segment great saphenous vein) was lower (10.2% VSGNE; 26.9% SVS OPG;$P < .001$). The primary safety endpoint, major adverse limb events (MALE) at 30 days, was lower in the VSGNE cohort (3.2%; 95% CI, 2.3-4.6) than the SVS OPG cohort (6.2%; 95% CI, 4.2-8.1; $P = .05$). The primary efficacy OPG endpoint, freedom from any MALE or postoperative death within the first year (MALE + postoperative death [POD]), was similar between VSGNE and SVS OPG cohorts (77%; 95% CI, 74%-80%) SVS OPG, 74% (95% CI, 71%-77%) VSGNE, $P = .58$). In the remaining safety and efficacy OPGs, the VSGNE cohort met or exceeded the benchmarks established by the SVS OPG cohort.**

Conclusion: **Community and academic centers in everyday vascular surgery practice can meet OPGs derived from centers of excellence in LEB. Quality improvement initiatives, as well as clinical trials, should incorporate OPGs in their outcome measures to facilitate communication and comparison of risk-adjusted outcomes in the treatment of CLI. (J Vasc Surg 2011;54:100-8.)**

Over 12 million patients in the United States have peripheral arterial disease (PAD),[1-4] and recent studies estimate that nearly 1 million have the most severe form of PAD, critical limb ischemia (CLI).[5] Surgical revascularization, while an effective treatment for CLI,[6] is associated with significant morbidity and mortality,[7-10] thus making less invasive treatment strategies desirable. Accordingly, endovascular interventions have emerged as an alternative to surgical arterial reconstruction.[1,11] However, while many have sought to compare these new and competing endovascular interventions to surgical bypass,[12-14] methodologic challenges exist in designing and executing these studies, and differences in patient characteristics and prohibitive costs have made randomized trials and other high-quality studies difficult to design and perform.[15]

Therefore, in order to establish objective benchmarks for comparison of safety and efficacy in lower extremity revascularization, the Society for Vascular Surgery (SVS) recently developed objective performance goals (OPGs) for the treatment of CLI[16,17] (Table I). These standards were derived from the surgical results of randomized controlled trials of several different treatments for CLI and offer a benchmark for nonrandomized evaluation of new treatments for lower extremity PAD, using the results from lower extremity bypass (LEB) as a comparator.

It remains unknown, however, if SVS OPGs accurately reflect everyday vascular surgery practice. The SVS OPGs were derived from carefully controlled studies using highly selected patients undergoing surgery in centers of excellence, where outcomes were recorded within closely monitored, independently adjudicated clinical trials. Whether the trials and results that the SVS OPGs were derived upon

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Table I. Definition of objective performance goals from the Society for Vascular Surgery Objective Performance Goals Working Group

Safety OPGs at 30 days
MALE (amputation or major reintervention[a])
MACE (MI, stroke or death)
Above-ankle amputation
Efficacy OPGs at 1 year
Freedom from MALE or POD
Limb salvage
Survival
AFS
Freedom from RAS
Freedom from RAO

AFS, Amputation-free survival; *MACE,* major adverse cardiac event; *MALE,* major adverse limb event; *MI,* myocardial infarction; *OPGs,* objective performance goals; *POD,* postoperative death; *RAO,* reintervention or amputation; *RAS,* reintervention, amputation, or restenosis; *VSGNE,* Vascular Study Group of New England.

[a]Major reintervention: placement of new bypass graft, use of thrombectomy or thrombolysis, or major surgical revision such as a jump or interposition graft. NB: In the VSGNE cohort, this also includes surgical patch angioplasty.

are broadly representative of real-world community and academic vascular surgery practice is unclear.

To determine if SVS OPGs accurately represent outcomes found in the everyday practice of vascular surgery, we studied patients undergoing LEB in the Vascular Study Group of New England (VSGNE), a regional quality improvement group. We applied the SVS OPGs to patients in the VSGNE, to discern if these targets could be reliably obtained by surgeons practicing in a variety of settings.

METHODS

Derivation of objective performance goals. The SVS OPGs were derived in recent work by Conte et al[16] and Geraghty et al[17]; the details of this derivation have been published previously. In brief, the SVS OPGs were calculated using independently adjudicated, line-item data from the surgical bypass arms of five multicenter randomized trials for CLI.[12,18-21] The SVS designated these OPGs as safety and efficacy measures as outlined in Table I. CLI was defined as ischemic rest pain or tissue loss, as well as compromised hemodynamics (ankle pressure <50, toe pressure <30, transcutaneous oxygen tension [$TcPO_2$] <30). To standardize the effect of bypass conduit, only those patients with an autogenous vein available for bypass conduit were included. Furthermore, congruent with the definitions listed in the OPG cohort, patients with end-stage renal disease on dialysis were eliminated from the analysis, given the disproportionately poor outcomes achieved in these patients.

Construction of Vascular Study Group of New England Cohort

Subjects. Patients undergoing LEB in hospitals participating in the VSGNE between 2003 and 2009 (2899 bypass procedures; (Appendix A, online only) were used to form the cohort for this analysis. Further details on this registry, derived from a broad spectrum of 15 community and academic centers across New England, have been published previously,[22] and others are available at http://www.vsgne.org.

To construct a cohort of patients with characteristics similar to those patients used to derive SVS OPGs, we included only patients who underwent open infrainguinal bypass procedures for CLI, and eliminated all patients with claudication (n = 609; 21% of the total). Additionally, we eliminated patients who underwent bypass with prosthetic conduit (n = 564; 20% of the total), and those patients with end-stage renal disease (n = 181; 6% of the total). We limited this analysis to patients with occlusive disease and eliminated all patients undergoing LEB for aneurysmal disease (n = 203; 7% of the total). Inflow arteries for bypass procedures could be iliac, femoral, or popliteal. Bypass target arteries could be above-knee or below-knee, popliteal, tibial, or pedal. Patients with concomitant endovascular procedures (such as an iliac stent done at the time of bypass surgery) were included in the analysis as well. Patients in whom long-term follow-up was unavailable were also excluded (n = 93; 3% of the total). Even though the laterality of procedures is recorded within the VSGNE, both before surgery and during follow-up, only the first limb operated on per patient was entered in the analysis to avoid confounding secondary to within-patient dependence. This occurred in 74 patients (3% of the total). Last, we eliminated any patient who was enrolled in the Project or Ex-Vivo vein graft Engineering via Transfection III (PREVENT III) trial or any other cohort represented in the SVS OPG dataset. This occurred in 24 patients across two centers (<1% of the total), and these patients were, therefore, eliminated from the analyses. Therefore, our cohort consisted of 1039 patients who underwent 1039 LEB procedures. Follow-up times varied from 1 month to 35 months, with a median of 12.8 months (SD of 5.2 months).

Definitions and outcome measures. Our unit of analysis was the patient, given that only one procedure per patient was analyzed. Patients were evaluated for preexisting medical comorbidities, and these data were prospectively entered into our registry by specifically trained surgeons, nurses, or clinical data abstractors. Over 70 clinical and demographic variables were collected on each patient.[22,23] Validation analyses to ensure complete submission of data were performed using hospital discharge abstracts. Furthermore, we used the Social Security Death Index to ensure that all deaths had been recorded in our dataset. Demographic data and the incidence of patient-level comorbidities are outlined in Table II.

Our main outcome measures were the OPGs themselves, recorded at 30 days for the safety OPGs, and 1 year for the efficacy OPGs (Table I). In univariate analyses, we compared the OPGs from the SVS data to those results derived from procedures performed within the VSGNE, using χ^2 for categorical variables (the safety measures studied at 30 days). We examined the efficacy outcomes at 1

Table II. Patient characteristics in the Vascular Study Group of New England and objective performance goal cohorts

	VSGNE cohort (n = 1039)		*SVS OPG cohort (n = 838)*		
Variable	*Number with characteristic*	*Proportion*	*Number with characteristic*	*Proportion*	P *value*
Female gender	334	32.2%	282	33.7%	.31
African American	7	0.7%	116	13.8%	.001
Age over 65	681	65.5%	570	68.0%	.42
Age over 80	212	20.4%	161	19.2%	.59
Hypertension	897	86.3%	640	76.4%	.02
Diabetes (all diabetics)	598	57.5%	477	56.9%	.74
Statin	566	54.3%	339	49.1%	.016[a]
Previous ipsilateral leg surgical interventions	149	14.3%	100	11.9%	.1
Previous ipsilateral leg surgical/endovascular intervention	302	29.0%	136	16.2%	.001
Ulcer/gangrene (not rest pain)	681	65.5%	618	73.7%	.02
Clinical high risk	159	15.3%	136	16.2%	.58
Anatomic high risk	600	57.8%	505	60.3%	.32
Conduit high risk	106	10.2%	163	26.9%	.001[b]

CLI, Critical limb ischemia; *OPG,* objective performance goal; *SVS,* Society for Vascular Surgery; *VSGNE,* Vascular Study Group of New England.
[a]Calculated out of 690 patients; statin use unavailable in remainder.
[b]Calculated out of 605 patients; conduit size unavailable in remainder.

Table III. Safety and efficacy objective performance goals: Results from the Society for Vascular Surgery objective performance goal cohort and the Vascular Study Group of New England

	SVS OPG cohort (mean, 95% CI)	*VSGNE (mean, 95% CI)*	P *value (SVS-OPG vs VSGNE)*	*OPG for endovascular procedures*
Safety outcomes at 30 days				
MALE (amputation or major reintervention)	6.1% (4.6-7.9)	3.2% (2.3-4.6)	.05	<8%
MACE (MI, stroke or death)	6.2% (4.7-8.1)	4.2% (3.3-5.4)	.35	<8%
Above-ankle amputation	1.9% (1.1-3.1)	1.9% (1.2-2.9)	.71	<3%
Efficacy outcomes at 1 year				
Freedom from MALE or POD	76.9% (74.0-79.9)	74.1% (70.9-77.0)	.58	71%
Limb salvage	88.9% (86.7-91.1)	90.9% (86.1-92.8)	.33	84%
Survival	85.7% (83.3-88.1)	91.6% (88.0-93.5)	.10	80%
AFS	76.5% (73.7-79.5)	84.4% (79.0-86.2)	.15	71%
Freedom from RAS	46.5% (42.3-51.2)	67.3% (64.0-70.4)	.02	39%
Freedom from RAO	61.3% (58.0-64.9)	72.3% (69.1-75.3)	.03	55%

AFS, Amputation-free survival; *CI,* confidence interval; *MACE,* major adverse cardiac event; *MALE,* major adverse limb event; *OPG,* objective performance goal; *POD,* postoperative death; *RAO,* reintervention or amputation; *RAS,* reintervention, amputation, or graft stenosis; *SVS,* Society for Vascular Surgery; *VSGNE,* Vascular Study Group of New England.

year using log-rank comparisons between high-risk and low-risk strata within VSGNE analytical groups over a 1-year period, and compared survival data and its surrounding 95% confidence intervals (CIs) between OPG data and VSGNE datasets.

Risk adjustment: high-risk subgroups and population-specific objective performance goals. The SVS OPG investigators used regression models to identify key variables that were associated with poor outcomes at 1 year. They designated patients with several important characteristics to be "high-risk." These high-risk groups were designated as clinical high-risk (age over 80 and tissue loss), anatomic high-risk (infrapopliteal distal target), and conduit high-risk (absence of single-segment great saphenous vein greater than 3 mm in diameter). For these efficacy outcome measures, comparisons between high-risk and low-risk strata were made using log-rank tests at 1-year follow-up.

Further, we were then able to use these high-risk criterion and their associated beta coefficients from univariate regression models to calculate population-specific OPGs for the VSGNE cohort, based on each individual patient's high-risk criteria. An example of how the VSGNE population-specific OPG for major adverse limb events (MALE) + postoperative death (POD) OPG outcome is calculated is illustrated below.

MALE or death within 30 days
OPG = (73.8586%-0.0622* [% infrapopliteal distal target])
OPG = (72.9620%-0.1386* [% age ≥80])

Table IV. Calculation of VSGNE-specific OPGS

	Population-specific OPG						
Patient characteristic	*Proportion in VSGNE*	*MALE + POD OPG*	*MALE + POD result for this subgroup in VSG (mean, 95% CI)*	P *value between SVS OPG and VSGNE*	*Amputation-free survival OPG*	*Amputation-free survival result for this subgroup in VSG (mean, 95% CI)*	P *value between SVS OPG and VSGNE*
Infrapopliteal target	57.8%	73.8%	69.3% (65.1-74.0)	NS	72.3%	81.3% (77.4-84.7)	.04
Age >80	20.4%	72.9%	74.1% (66.8-80.3)	NS	74.0%	76.4% (69.2-82.1)	NS
Tissue loss	65.5%	70.8%	71.4% (67.5-75.0)	NS	78.8%	81.8% (78.3-84.9)	NS
High clinical risk	15.3%	72.8%	70.8% (62.3-77.8)	NS	73.8%	72.5% (63.9-79.3)	NS

	Population-specific OPG					
Patient characteristic	*Limb salvage OGP*	*Limb salvage result for this subgroup in VSG (mean, 95% CI)*	P *value between SVS OPG and VSGNE*	*Death OPG*	*Death result for this subgroup in VSG (mean, 95% CI)*	P *value between SVS OPG and VSGNE*
Infrapopliteal target	86.3%	88.0% (84.5-90.8)	NS	78.6%	91.7% (88.8-93.3)	.03
Age >80	84.1%	90.5% (84.5-94.3)	.05	83.9%	83.7% (77.1-83.5)	NS
Tissue loss	90.2%	90.0% (87.0-92.4)	NS	82.7%	90.2% (87.4-92.5)	.03
High clinical risk	84.4%	88.6% (81.0-90.4)	NS	83.6%	81.0% (72.9-86.8)	NS

CI, Confidence interval; *MALE,* major adverse limb event; *NS,* not significant; *OPG,* objective performance goal; *POD,* postoperative death; *SVS,* Society for Vascular Surgery; *VSG,* Vascular Study Group; *VSGNE,* Vascular Study Group of New England.

OPG = (70.8437%-0.0089* [% tissue loss])
OPG = (72.8532%-0.1575* [% clinical risk])

The coefficients used in the four remaining efficacy outcomes are shown in Appendix B (online only). Finally, to account for all of the patient-level covariates in the calculation of each individual OPG, all the covariates were entered into multivariate models derived to predict each efficacy OPG based on each patient's individual characteristics. The multivariate equations for each OPG are shown in Appendix B (online only). These multivariable models take into consideration the patient-specific variables of anatomic, clinical, and conduit risk in determining each patient's individual risk of meeting each of the OPGs. By aggregating patients across the cohort, we were then able to generate population-specific OPGs for the patients that comprised the VSGNE cohort. All analyses were performed using Microsoft Excel (Redmond, Wash) and Stata (College Station, Tex). The Institutional Review Board at Dartmouth Medical School reviewed and approved our study protocol.

RESULTS

Patient characteristics. The 1039 patients who underwent 1039 LEB procedures in the VSGNE cohort were most commonly men (66%), elderly (mean age of 73 years), and white (99%; Appendix C, online only; Table II). Nearly all patients had a history of either prior or current smoking (79%). Over half of the patients (58%) had a history of diabetes, 40% had coronary disease, and nearly one-third (30%) had a history of chronic obstructive pulmonary disease. The majority of patients with CLI presented with tissue loss (65%), as opposed to rest pain (35%). Further, while all patients had available autogenous conduit, 13% used alternative types of autogenous conduit such as composite vein (7%), arm vein (4%), or lesser saphenous vein (2%). Further details about the characteristics of the cohort used are available in Appendix C, online only, Table II.

Overall, while patients in the VSGNE cohort were similar to patients in the SVS OPG cohort, small but significant differences exist between the two groups (Table II). For example, patients in the VSGNE cohort were less likely to be African American (0.7% VSGNE; 13.8% SVS OPG; $P < .001$) and more likely to have hypertension (86.3% VSGNE; 76.4% SVS OPG; $P = .02$). VSGNE patients were also more likely to be on statins (54.3% VSGNE; 49.1% SVS OPG; $P = .016$) and to have undergone previous vascular interventions (29.0% VSGNE; 16.2% SVS OPG; $P < .001$), but fewer had tissue loss (65.5% VSGNE; 73.7% SVS OPG; $P = .02$) Overall, the proportion who were designated as clinically high-risk was slightly lower (15.3 VSGNE; 16.2% SVS OPG; $P = .58$), as was the proportion designated as anatomically high risk (57.8% VSGNE; 60.2% SVS OPG; $P = .48$). However, the proportion designated as conduit high-risk differed between datasets (10.20% VSGNE; 26.9% SVS OPG; $P < .001$). Some of this difference may be attributable to differences in definition of an acceptable saphenous vein. It is important to note that while the SVS cohort required the vein to be >3 mm in diameter, the VSGNE

cohort did not have size parameters on their definition; rather, the vein was simply categorized as "acceptable." The more stringent definition used in the SVS OPG cohort may have, therefore, contributed to the higher proportion of patients designated as "conduit high-risk" in the SVS OPG cohort.

Safety outcomes and suggested objective performance goals in the VSGNE. The three safety OPGs studied at 30 days after surgery were MALE (amputation or major reintervention), major adverse cardiovascular events (MACE; myocardial infarction, stroke, or death), and major above-ankle amputation. The main safety OPG, MALE at 30 days, occurred in 6.1% (95% CI, 4.6%-7.9%) of patients in the SVS derivation dataset. In our cohort, we found that the MALE rate was slightly lower (3.2%, 95% CI, 2.3%-4.6%; $P = .05$). The second safety OPG, major amputation rate before 30 days, was similar in both the SVS and VSGNE datasets (SVS = 1.9%; 95% CI, 1.1-3.1), VSGNE = 1.9 (95% CI, 1.2-2.9; $P = .71$). Finally, the third safety OPG, major adverse cardiac event rate, was also similar between the two groups, as shown in Table III (SVS = 6.2%; 95% CI, 4.7-8.1), VSGNE = 4.2 (95% CI, 3.3-5.4; $P = .35$).

Efficacy measures and suggested objective performance goals in the VSGNE. We compared the efficacy outcomes established by the SVS OPGs with those calculated in the VSGNE. We found that the VSGNE dataset met all the efficacy OPGs suggested by the SVS (Table III). For example, for the main efficacy OPG, freedom from MALE, or POD, results were very similar between the SVS OPG dataset and the VSGNE (77%; 95% CI, 74%-80%) SVS OPG, 74% (95% CI, 71%-77%) VSGNE, $P = .58$). This trend was similar for the remaining OPGs, including limb salvage, survival, and amputation-free survival rates (Table III). Freedom from reintervention or amputation within the first year continued to reflect the slightly lower rate of reinterventions in the VSGNE dataset within the first year.

Risk adjustment: high-risk subgroups and multivariable modeling to predict risk. Next, we studied outcomes within the three high-risk subgroups (anatomic, clinical, and conduit) defined by the SVS OPG working group (Table IV). Overall, we found that in the VSGNE, 15% of patients were defined as clinical high-risk, 58% of patients were anatomic high-risk, and 10% used bypass conduit designated as high-risk.

First, we studied if the variables that were important in delineating high-risk and low-risk populations in the SVS OPG cohort accomplished the same task in the VSGNE cohort. We found that these risk subgroups discriminated performance well (Fig 1). For example, across all three subgroups, using the MALE + POD efficacy OPG, patients in the lower risk category had significantly better outcomes at 1 year (log-rank $P = .01$). Findings were similar across the entire remaining efficacy OPGs (Appendix D, online only).

Second, we questioned if outcomes were similar across high-risk subpopulations. For example, the population-specific OPG for MALE + POD in the anatomic high-risk group is 74.0%. While the MALE + POD result in the VSGNE cohort was slightly lower at 69.3%, the 95% CIs around the VSGNE dataset (65.1-74.0) included the adjusted OPG. Therefore, the VSGNE dataset met the OPG for this measure. Across all of the high-risk subgroups, the VSGNE cohort met or exceeded the OPG, indicating that even in high-risk patient subgroups, OPGs represent an attainable benchmark in real-world practice.

But what if a patient is high-risk across more than one category? This same calculation can be undertaken, adjusting for all of the risk categories simultaneously, using the multivariate models described in Appendix B (online only). These multivariate models calculate population-specific OPGs, based on each of the four inputs used in the SVS OPG multivariate model (infrapopliteal anatomy, age over 80, tissue loss, and conduit). We found these population-specific "adjusted" OPGs were, on average, similar to the SVS OPGs—reflecting the relative similarities in the VSGNE and SVS patient populations.

As shown in Fig 2, the outcomes achieved in the VSGNE cohort generally met or exceeded the adjusted OPG for all of the efficacy endpoints. Any instances wherein differences occurred between the VSGNE (Vascular Study Group [VSG]) outcomes and OPGs benchmarks (such as survival) were small and not clinically significant, with two notable exceptions: reintervention, amputation, or graft stenosis (RAS) and reintervention or amputation (RAO). These differences in the RAS and RAO endpoints, where the VSGNE cohort had significantly fewer adverse events of reintervention, amputation, or graft stenosis, likely represent an underestimate of the occurrence of these endpoints in the VSGNE dataset, because not all patients in the VSGNE dataset underwent routine surveillance duplex at 1-year follow-up.

DISCUSSION

Patients and their physicians are faced with difficult choices when making treatment decisions for CLI. While traditional surgical bypass is established and effective, alternative endovascular therapies have emerged as a popular alternative, most likely because they avoid invasive therapies in this frail patient population.[11] However, trials comparing these two modalities have proven difficult to design and expensive to perform. Therefore, the SVS has designed OPGs as a mechanism to provide benchmarks by which the performance of endovascular interventions and other treatment modalities can be measured. As our study demonstrates, even though these benchmarks were derived using data from highly selected clinical trials, they seem to accurately reflect the outcomes achieved in real-world LEB.

The generalizability of SVS OPGs, across highly selected clinical trials as well as within everyday vascular surgery practice, suggests that these benchmarks are an accurate performance measurement tool in lower extremity revascularization for patients with CLI. Further, the strong correlation between the outcomes of clinical trials and

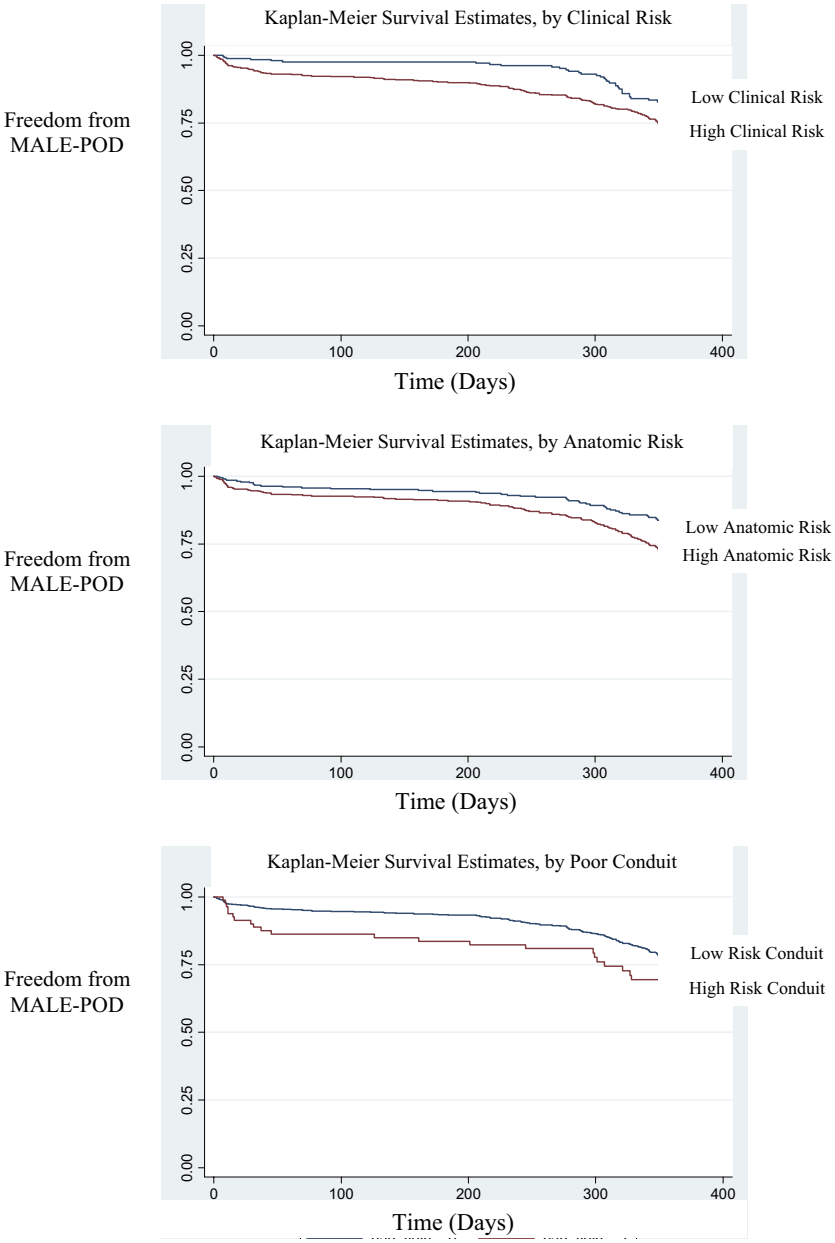

Fig 1. Major adverse limb events (*MALE*) and postoperative death (*POD*) at 1 year, in the high-risk and low-risk subgroups.

everyday practice suggests that, in the "real world," patients have widely available access to high-quality surgical lower extremity revascularization for CLI. Unlike early clinical trials of asymptomatic carotid endarterectomy,[24] wherein clinical trial results did not always translate into real-world outcomes, it seems that patients can be assured of similar outcomes regardless of the setting in which they undergo surgery.

This report adds to the growing evidence from clinical trials,[12,18-21] academic centers,[25,26] and regional collaboratives[8] that demonstrate that LEB is effective, reproducible, and broadly available. Therefore, policymakers and payers should ensure that endovascular interventions meet a similar benchmark. Many will argue that patients may accept shorter patency or higher reintervention rates for endovascular interventions, based on their less-invasive approach. This process occurred in the treatment of coronary artery disease.[27-30] While it is well known that patients will often "discount" a desired outcome based on a less morbid approach and shorter recovery,[31,32] the extent of this trade-off has yet to be defined. As less invasive procedures challenge traditional

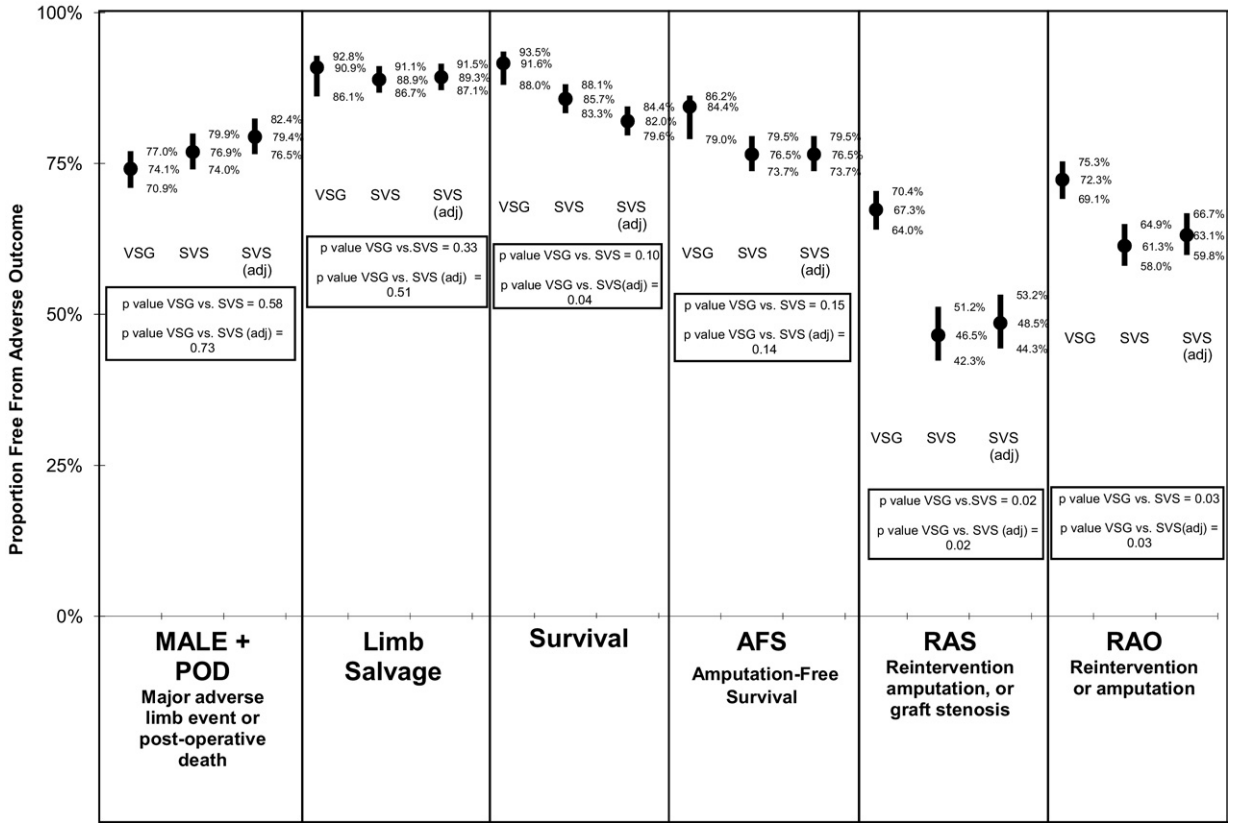

Fig 2. Proportion of patients remaining free from meeting each objective performance goal (OPG) within the Vascular Study Group of New England (*VSGNE*), within the Society for Vascular Surgery (*SVS*) OPG cohort, and within the VSGNE after adjustment for the proportion of patients with clinical, anatomic, and conduit high-risk criteria (SVS adj for VSG). *AFS*, Amputation-free survival; *MALE*, major adverse limb event; *POD*, postoperative death; *RAO*, reintervention or amputation; *RAS*, reintervention, amputation, or restenosis.

open surgery, it is likely that patients and providers will "vote with their feet" and choose the surgical procedure or endovascular intervention that they believe will provide the most effective treatment. However, the first step in determining treatment efficacy and effectiveness is to define the outcome measures, and our analysis demonstrates that the SVS OPGs represent plausible, achievable targets for patients with CLI.

Many will question why the SVS OPGs, which were primarily derived to determine endpoints for clinical trials, should matter to surgeons interested in quality improvement, such as those surgeons in the VSGNE. However, the essential components of any quality improvement effort, as outlined by Deming, usually involve a Plan/Do/Study/Act cycle.[33] In a Plan/Do/Study/Act cycle, a process is improved by planning how change will be implemented, implementing the change, studying the effect of change, and acting upon the results of these studies. We believe the SVS OPGs offer the advantage of standardization of outcomes during the "study" phase of these efforts. Many have documented wide variation in the assessment of efficacy in the study of lower extremity revascularization.[1,2,8,10] This problem limits effectiveness and generalizability, not only in clinical trials, but quality improvement efforts as well. By standardizing outcome assessment, OPGs can help to further efforts in the study of lower extremity revascularization, across both clinical trials of new devices as well as in structured quality improvement efforts.

Our study has several limitations. First, there are small differences between the definitions in the SVS OPG dataset and our VSGNE dataset. For example, reinterventions are categorized as catheter-based, surgical, or both in the VSGNE. However, a major/minor categorization scheme is used in the SVS OPG definition. Despite these disparities, the absolute differences in most of the efficacy endpoints between the two datasets were small (less than 5% at 1 year). Second, data within the VSGNE are self-reported by its participating centers and are not independently adjudicated, nor was duplex evaluation at 1 year mandated in our dataset. However, for two reasons, we believe our results accurately reflect outcomes with LEB in our region. First, participation in our regional quality improvement database is voluntary, and surgeons who freely allocate their time and effort are unlikely to purposefully contribute inaccurate

results. Second, in the majority of VSGNE centers, follow-up visits are coded by nursing or research personnel, limiting (to some extent) reporting bias, as compared to self-reporting by the operating surgeon. Third, our dataset is validated for inclusion and outcomes by comparing VSGNE outcomes with hospital billing data and the Social Security Death Index, as outlined in several prior reports.[8,23,34,35] Our third limitation centers around our measurement and definition of CLI in our cohort. In the SVS OPG cohort, hemodynamic criteria were used to support the diagnosis of CLI in the randomized trials. Extensive information was collected as line-item data to determine each patient's ankle pressure, toe pressure, or $TcPO_2$, with specific criteria required for inclusion (ankle pressure <50, toe pressure <30, $TcPO_2$ <30). In the VSGNE, hemodynamic criterion was available to confirm the diagnosis of CLI both before and after surgery in 47% of our patients with CLI. Within this group, the mean toe pressure was 0.2, and the mean ankle pressure was 0.38, lending credence to the diagnosis of CLI, at least in these patients. However, a sizeable portion of patients in our cohort do not have these variables routinely recorded, as our registry does not mandate practice patterns, and some surgeons in our dataset do not routinely measure ankle-brachial indexes at follow-up, especially in clinical settings where the significance is uncertain (such as a palpable graft pulse). However, realizing the value of these data in comparative research, more complete evaluation of hemodynamic data in patients with CLI remains an ongoing focus of our data collection improvement process. Fourth, while VSGNE outcome satisfied the SVS OPGs in our analyses, in some instances, this occurred only by using the 95% CI around the point estimate of the VSGNE outcome. For example, the SVS OPG freedom from MALE/POD outcome at 1 year was 77%, while this value in the VSGNE was only 74%, with a 95% CI that included 77%. Whether or not the SVS OPGs should be considered as a "hard target" and be considered unsatisfied if the actual point estimate is not reached, remains a question for future discussion. Fifth, given the observational nature of the VSGNE dataset, unmeasured confounders may have impacted our outcomes. However, the similarities between the results from the VSGNE dataset and the randomized trials from which the SVS OPGs were derived argue against any significant effect of any unmeasured confounders.

In summary, the development and broad implementation of the SVS OPGs in clinical trials, quality improvement efforts, and overall clinical assessment of lower extremity revascularization represents an achievable opportunity to advance the science of how vascular surgeons measure success or failure. However, looking forward, the current SVS OPGs represent the beginning of this effort, and expansion toward even more in-depth OPGs lies ahead. For example, the current SVS OPGs do not take into account quality of life, nor do they reflect the use of medical adjuncts such as antiplatelet agent or statin use. Given the focus of payers, providers, and policymakers on functional outcomes as well as evidence-based medicine, our future efforts will hope to shape new OPGs that will address the ability of vascular surgeons to design and achieve benchmarks in these critical areas.

CONCLUSIONS

The OPGs suggested by the SVS accurately represent broadly achievable targets in LEB surgery, irrespective of whether the procedure is performed within a clinical trial, an academic center, or in a community setting. Furthermore, in our region, LEB surgery performed in the context of a regional quality improvement registry demonstrates outcomes that are consistent with those found in multicenter randomized trials. Vascular surgeons interested in measuring the quality of treatment of patients with lower extremity PAD should use the SVS OPGs to study, report, and improve their outcomes.

AUTHOR CONTRIBUTIONS

Conception and design: PG, AS, MC, RP
Analysis and interpretation: PG, AS, MC, RP, JC
Data collection: PG, AS, MC, BN, JC, NH
Writing the article: PG, AS, RP
Critical revision of the article: PG, AS, RD, BN, NH, MC, RP, JC
Final approval of the article: PG, AS, RD, BN, NH, MC, RP, JC
Statistical analysis: PG, AS, BN, NH, MC
Obtained funding: PG, AS, MC, JC
Overall responsibility: PG

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Additional material for this article may be found online at www.jvascsurg.org.

Appendix A (online only)

Hospitals participating in the Vascular Study Group of New England

Catholic Medical Center, Manchester, NH
Central Maine Medical Center, Lewiston, Me
Concord Hospital, Concord, NH
Cottage Hospital, Woodsville, NH
Dartmouth–Hitchcock Medical Center, Lebanon, NH
Eastern Maine Medical Center, Bangor, Me
Fletcher Allen Health Care, Burlington, Vt
Lakes Regional General Hospital, Laconia, NH
Maine Medical Center, Portland, Me
Mercy Hospital, Portland, Me
UMass Memorial Medical Center, Worcester, Mass

Appendix B (online only)

Univariate calculation of OPGs

MALE+POD:
OPG = 73.8%−0.0622* (% infrapopliteal)
OPG = 72.9%−0.1386* (% age > = 80)
OPG = 70.8%−0.0089* (% tissue loss)
OPG = 72.8%−0.1575* (% clinical risk)

AFS:
OPG = 72.3%−0.0436* (% infrapopliteal)
OPG = 74.0%−0.2166* (% age > = 80)
OPG = 78.8%−0.1238* (% tissue loss)
OPG = 73.8%−0.2463* (% clinical risk)

Amputation:
OPG = 86.3%−0.053* (% infrapopliteal)
OPG = 84.1%−0.045* (% age > = 80)
OPG = 90.3%−0.096* (% tissue loss)
OPG = 84.4%−0.072* (% clinical risk)

Death:
OPG = 78.6%+0.014* (% infrapopliteal)
OPG = 83.9%−0.225* (% age > = 80)
OPG = 82.7%−0.042* (% tissue loss)
OPG = 83.6%−0.243* (% clinical risk)

RAS:
OPG = 78.6%+0.014* (% infrapopliteal)
OPG = 83.9%−0.225* (% age > = 80)
OPG = 82.7%−0.042* (% tissue loss)
OPG = 83.6%−0.243* (% clinical risk)

RAO:
OPG = 78.6%+0.014* (% infrapopliteal)
OPG = 83.9%−0.225* (% age > = 80)
OPG = 82.7%−0.042* (% tissue loss)
OPG = 83.6%−0.243* (% clinical risk)

Multivariate Calculation of OPGs

AFS OPG = 0.765870268 −0.001106445 (conduit high risk) +0.000223133 (popliteal outflow) −0.003513622 (clinical high risk)

MALE + POD OPG = 0.794055728 −0.001754896 (conduit high risk) −0.000703511 (popliteal outflow) −0.002245621 (clinical high risk)

DEATH OPG = 0.820355745 −0.00094661 (conduit high risk) +0.000843207 (popliteal outflow) −0.00349814 (clinical high risk)

AMPUTATION OPG = 0.893816479 −0.000848383 (conduit high risk) −0.000419496 (popliteal outflow) −0.001336974 (clinical high risk)

RAS OPG = 0.48667683 −0.003452089 (conduit high risk) +0.0000097161 (popliteal outflow) −0.002209077 (clinical high risk)

RAO OPG = 0.631924841 −0.003016539 (conduit high risk) −0.000301062 (popliteal outflow) −0.001228289 (clinical high risk)

AFS, Amputation-free survival; *OPG,* objective performance goal; *POD,* postoperative death; *RAO,* reintervention or amputation; *RAS,* reintervention, amputation, or graft stenosis.

Appendix C (online only). Patient characteristics in the VSGNE cohort

Variable	*VSGNE cohort (n = 1039)*
Male gender	68%
Right side	51%
Non-white race	2%
Not living home preoperatively	5%
Not independently ambulatory preoperatively	29%
Age	
<40	1%
40-50	5%
50-60	16%
60-70	26%
70-80	32%
80-90	18%
90-100	2%
Smoking (prior or current)	80%
COPD	29%
Diabetes (all diabetics)	58%
Non-insulin-dependent diabetics	21%
Insulin-dependent diabetics	37%
Coronary disease	36%
Congestive heart failure	21%
Rest pain	32%
Tissue loss	68%
Concomitant ipsilateral proximal angioplasty/stent	4%
Preoperative medication regimen	
Antiplatelet agent use	70%
Preoperative statin use	54%
Preoperative beta blocker use	
No beta blocker	16%
Perioperative beta blocker	24%
Chronic beta blocker	60%
Operative characteristics	
External iliac origin	1%
Common femoral origin	61%
Profunda origin	4%
Superficial femoral artery origin	22%
Above-knee popliteal origin	5%
Below-knee popliteal origin	8%
Superficial femoral artery recipient	1%
Above-knee popliteal recipient	10%
Below-knee popliteal recipient	31%
Tibio-peroneal trunk recipient	3%

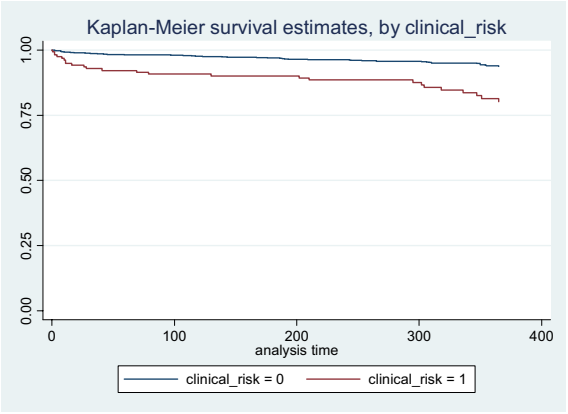
Appendix C (online only). Continued.

Variable	*VSGNE cohort (n = 1039)*
Anterior tibial recipient	14%
Posterior tibial recipient	15%
Peroneal recipient	10%
Posterior tibial artery at ankle recipient	6%
Dorsalis pedis recipient	8%
Tarsal recipient	2%
Anesthesia type	
General anesthesia	72%
Epidural	10%
Spinal	18%
Conduit	
In situ great saphenous vein	45%
Reversed great saphenous vein	28%
Nonreversed transposed great saphenous vein	15%
Lesser saphenous vein	1%
Cephalic/basilic vein	4%
Composite vein	7%
Completion study (duplex or arteriogram)	73%

VSGNE, Vascular Study Group of New England; *COPD,* chronic obstructive pulmonary disease.

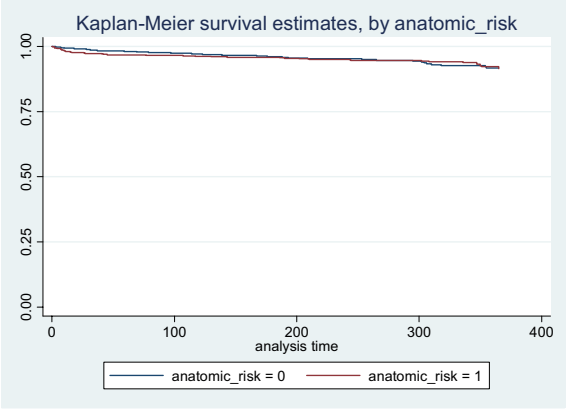
Appendix D (online only).

Death OPG: (all curves have SE <0.10.)

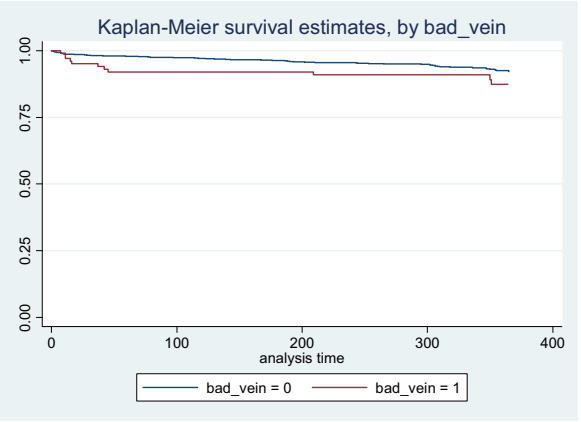


Log rank $P = .0001$.

OPG, Objective performance goal.

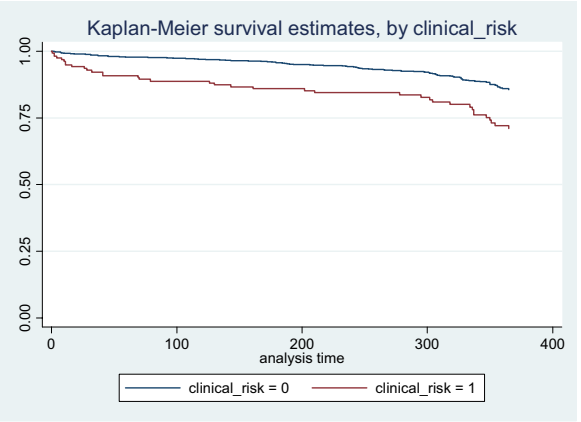


Log rank $P = .877$.

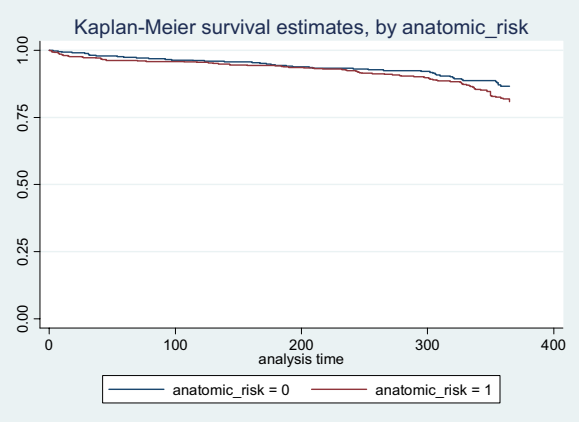


Log rank $P = .302$.

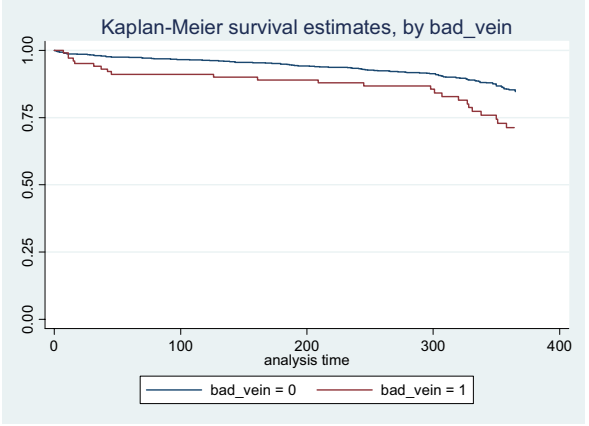
AFS OPG: (all curves have SE <0.10).



Log rank $P = .001$.

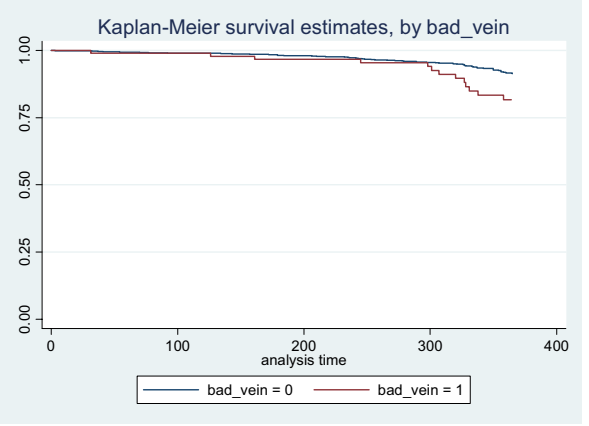


Log rank $P = .161$.



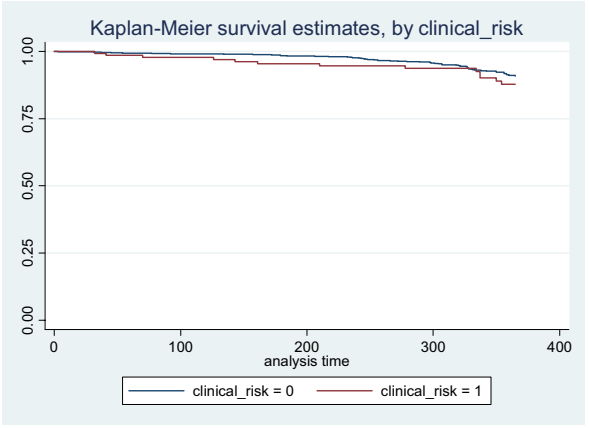
Log rank $P = .008$.

Amputation OPG: (all curves have SE <0.10).

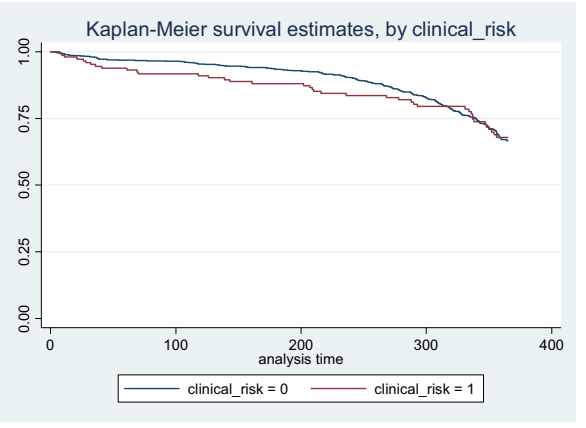


Log rank $P = .007$.

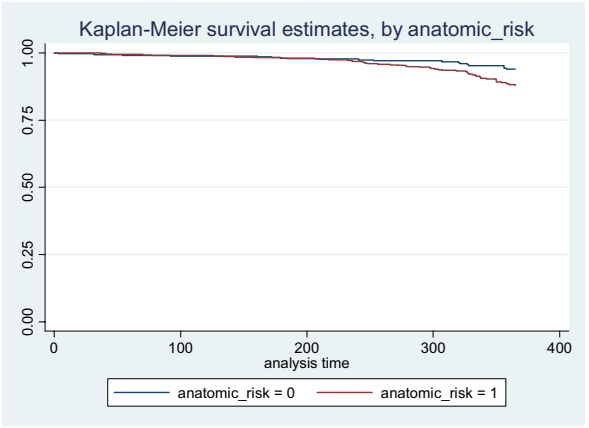
RAS OPG: (all curves have SE <0.10).



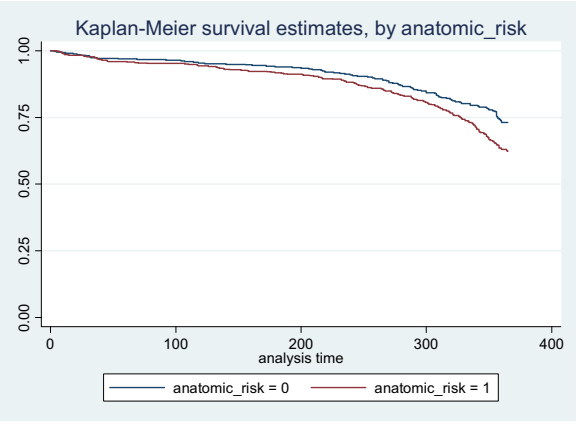
Log rank $P = .677$.



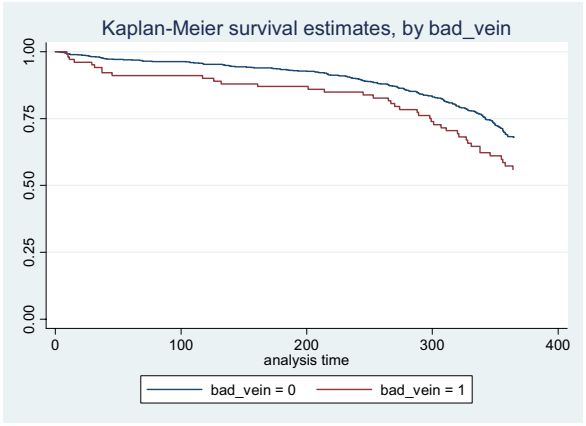
Log rank $P = .529$.



Log rank $P = .0185$.

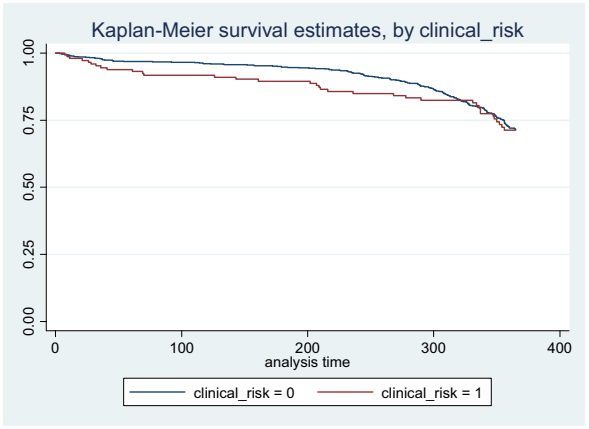


Log rank $P = .006$.

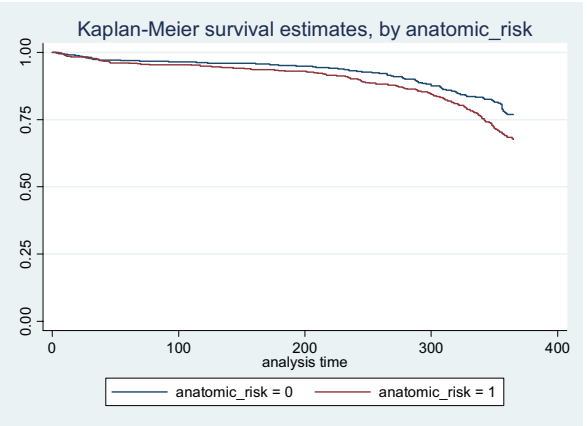


Log rank $P = .021$.

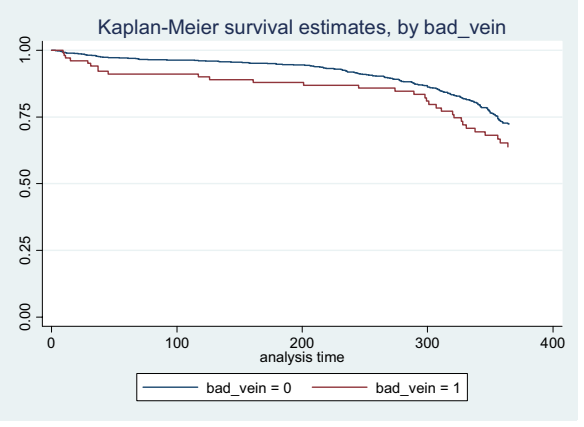
RAO OPG: (all curves have SE <0.10).



Log rank $P = .629$.



Log rank $P = .034$.



Log rank $P = .0173$.