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Peripheral Vascular Society Submission

Risk Factors for Early Failure After Peripheral Endovascular Intervention: Application of a Reliability Engineering Approach

Andrew J. Meltzer,[1] Ashley Graham,[1] Peter H. Connolly,[1] John K. Karwowski,[1] Harry L. Bush,[1] Peter I. Frazier,[2] and Darren B. Schneider,[1] New York and Ithaca, New York

Background: We apply an innovative and novel analytic approach, based on reliability engineering (RE) principles frequently used to characterize the behavior of manufactured products, to examine outcomes after peripheral endovascular intervention. We hypothesized that this would allow for improved prediction of outcome after peripheral endovascular intervention, specifically with regard to identification of risk factors for early failure.

Methods: Patients undergoing infrainguinal endovascular intervention for chronic lower-extremity ischemia from 2005 to 2010 were identified in a prospectively maintained database. The primary outcome of failure was defined as patency loss detected by duplex ultrasonography, with or without clinical failure. Analysis included univariate and multivariate Cox regression models, as well as RE-based analysis including product life-cycle models and Weibull failure plots. Early failures were distinguished using the RE principle of "basic rating life," and multivariate models identified independent risk factors for early failure.

Results: From 2005 to 2010, 434 primary endovascular peripheral interventions were performed for claudication (51.8%), rest pain (16.8%), or tissue loss (31.3%). Fifty-five percent of patients were aged $\geq$75 years; 57% were men. Failure was noted after 159 (36.6%) interventions during a mean follow-up of 18 months (range, 0–71 months). Using multivariate (Cox) regression analysis, rest pain and tissue loss were independent predictors of patency loss, with hazard ratios of 2.5 (95% confidence interval, 1.6–4.1; $P < 0.001$) and 3.2 (95% confidence interval, 2.0–5.2, $P < 0.001$), respectively. The distribution of failure times for both claudication and critical limb ischemia fit distinct Weibull plots, with different characteristics: interventions for claudication demonstrated an increasing failure rate ($\beta = 1.22$, $\theta = 13.46$, mean time to failure = 12.603 months, index of fit = 0.99037, $R^2 = 0.98084$), whereas interventions for critical limb ischemia demonstrated a decreasing failure rate, suggesting the predominance of early failures ($\beta = 0.7395$, $\theta = 6.8$, mean time to failure = 8.2, index of fit = 0.99391, $R^2 = 0.98786$). By 3.1 months, 10% of interventions failed. This point (90% reliability) was identified as the basic rating life. Using multivariate analysis of failure data, independent predictors of early failure (before 3.1 months) included tissue loss, long lesion length, chronic total occlusions, heart failure, and end-stage renal disease.

Conclusions: Application of a RE framework to the assessment of clinical outcomes after peripheral interventions is feasible, and potentially more informative than traditional techniques. Conceptualization of interventions as "products" permits application of product life-cycle models

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[1]Division of Vascular and Endovascular Surgery, Weill Cornell Medical College, New York-Presbyterian Hospital, New York, NY.

[2]Operations Research and Information Engineering, Cornell University College of Engineering, Ithaca, NY.

Correspondence to: Andrew J. Meltzer, MD, Division of Vascular and Endovascular Surgery, Weill Cornell Medical College, 525 East 68th Street, P-707, New York, NY 10065, USA; E-mail: ajm9007@med.cornell.edu

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that allow for empiric definition of "early failure" may facilitate comparative effectiveness analysis and enable the development of individualized surveillance programs after endovascular interventions.

INTRODUCTION

Despite widespread acceptance of endovascular intervention as a treatment option for peripheral arterial disease, the optimal role of catheter-based techniques remains ill-defined. Randomized trials that reflect ''real world'' disease and treatment options are sparse. Therefore, vascular specialists must select candidates for endovascular intervention (versus surgical bypass) on an individualized basis, after considering medical comorbidities and suitability for open surgery, as well as the likelihood of success using endovascular intervention.

Numerous studies have identified risk factors for poor outcome after endovascular intervention, including demographic factors, medical comorbidities, indication for intervention (i.e., critical limb ischemia [CLI] versus claudication), lesion characteristics, and procedural details.[1−10] In general, the analytical methods used in these reports follow guidelines outlined in reporting standards for surgical bypass (life-table comparisons, Kaplan—Meier survival analysis, and uni- and multivariate statistics using, e.g.,, the Cox proportional hazard model), with minimal modification in the endovascular era.[11−15] These methods are well accepted by vascular specialists and the life sciences community in general. However, these analytical methods may not represent the optimal approach with respect to informing our understanding of the risk factors for failure over time.

Our objective is to apply an innovative analytic approach, based on reliability engineering (RE) principles. RE is an engineering discipline that focuses on the study of reliability and failure of systems or manufactured products. The spectrum of RE methods is broad and includes failure mode and effect analysis, statistical analysis of failure data (''Weibull'' analysis), the development of product life-cycle models, and other techniques. RE-guided analyses are widely used by military analysts, engineers, and manufacturers to characterize the behavior of complex systems and manufactured products. Practically, these analytical methods are used to determine routine maintenance schedules, define consumer product warranty policies, and develop industrial standards for manufactured products ranging from ball bearings to microprocessors.

Here, we use an RE principle—based approach to examine outcomes after peripheral endovascular intervention. Our primary objective was to perform a ''proof of principle'' study to assess the utility of this approach to outcomes research in vascular surgery. We hypothesized that this analytical methodology would prove particularly effective in the identification of risk factors for early failure of endovascular therapy.

METHODS

Data Collection and Patient Selection

Patients undergoing endovascular intervention for chronic lower-extremity ischemia from 2005 to 2010 were identified in a prospectively maintained database. Indications for intervention included debilitating claudication (Rutherford class III) or CLI, defined as rest pain (Rutherford class IV) or tissue loss (Rutherford class V—VI). Patients with acute limb ischemia were excluded, as were those undergoing exclusively diagnostic studies. The study protocol was institutional review board approved.

Operative reports and angiograms were reviewed to determine lesion characteristics, procedural details, and runoff vessel status. Runoff was assigned a score of 0 to 3, representing tibial vessels with in-line flow to the foot in the treated limb. Comorbidities were defined in accordance with accepted standards, as previously reported.[9,11,12,16,17]

Procedural Technique

In general, percutaneous interventions included percutaneous transluminal angioplasty with or without adjunctive stenting. The majority of procedures were performed using local anesthesia, with intravenous sedation. Activated clotting time was maintained at >250 seconds after administration of intravenous heparin. 5- to 8-F sheaths were used. Lesions were crossed by either an intraluminal or subintimal technique using hydrophilic glidewires (0.035, 0.018, or 0.014 inch). Choice of treatment modality was at the discretion of the operating surgeon.

Balloon angioplasty was performed using appropriately sized noncompliant balloons, with inflation times ranging from 60 to 180 seconds at 6 to 15 atmospheres. Selective stenting in the femoropopliteal distribution was performed for residual stenosis >30% or presence of a flow-limiting dissection after angioplasty. Completion angiography, with evaluation of the distal runoff, was performed after all interventions. After the procedure, all patients were maintained on clopidogrel therapy (75 mg) for 30 days, after a loading dose immediately after the procedure (300 mg).

Follow-Up and End Points

Ankle−brachial indices and/or pulse volume recordings were obtained before interventions. Patients underwent scheduled follow-up at 1, 3, 6, and 12 months postoperatively and subsequently at annual intervals. ''Failure'' was defined as loss of patency based on duplex ultrasonographic assessment of systolic velocity ratio elevation >2.5 in the treated segment relative to the immediately proximal arterial segment, or evidence of complete occlusion. Patients were also determined to have failed in the setting of unimproved clinical symptoms or reduction in Ankle−brachial index or pulse volume recording. To permit accurate identification of failure time, interventions were deemed to have failed at the earliest evidence of clinical, hemodynamic, or duplex scan−detected failure in accordance with established guidelines.[11,12]

Statistical Analysis

Comparisons of patient demographics and lesion characteristics between groups (univariate analysis) were made using χ^2 analysis, t test, and Fisher exact test, as appropriate. Kaplan−Meier survival plots were generated to assess primary patency throughout follow-up and identify factors associated with reduced patency. Factors associated with reduced patency using univariate analysis ($P < 0.10$) were included in Cox proportional hazards models to identify independent predictors of patency loss.[14,15]

The distribution of failure times was plotted, and goodness of fit was assessed for candidate distributions (Weibull, exponential, normal, log normal, and gamma). For all analyses, the best-fit distribution was selected, and explanatory characteristics (including mean time to failure [MTTF]) were derived from curves fit to specific failure distributions.

To define ''early'' failures, the RE term of ''basic rating life'' was applied. This concept, denoted as ''L10,'' refers to the elapsed time or number of product cycles until a reliability of 90% (i.e., a 10% failure rate) is observed in a population.[18] Failures before L10 (i.e., the poorest performing 10% of interventions) were deemed ''early failures.''

Among failing interventions, risk factors for failure before L10 time were analyzed using univariate analysis, and predictors of failure ($P < 0.10$) were included in multivariate logistic regression models to identify independent predictors of early failure.

All analysis was performed using SPSS 19.0 (SPSS Inc., Chicago, IL) and Analysis of Reliability and Maintainability version 4.0 (REL v. 4.0, Waveland, Long Grove, IL).

RESULTS

From 2005 to 2010, 434 primary endovascular peripheral interventions were performed for claudication (51.8%), rest pain (16.8%), or tissue loss (31.3%). Fifty-five percent of patients were aged ≥75 years; 57% were men. Failure was noted after 159 (36.6%) interventions during a mean follow-up of 18 (0−71) months. Patient demographics, comorbidities, lesion characteristics, and treatment details are shown in Table I. Common comorbidities included diabetes (53.5%), chronic renal insufficiency (20.5%), and current smoking (13.1%). Chronic total occlusions were treated in 19% of the interventions, and long-segment disease (>20 cm) was treated in 15.7%. Mean length of femoropopliteal arteries treated was 187.3 ± 102.7 mm. The majority of patients had three- (40%) or two-vessel runoff (43.8%). Interventions confined to the femoropoliteal arteries comprised 81.8% of the cases; in 18.2%, tibial angioplasty was also performed. Stents were used in the majority (57.4%) of cases. All stents were used in the femoropoliteal arteries.

Factors associated with patency loss using univariate analysis ($P < 0.10$) included female sex, end-stage renal disease (ESRD), CLI, and angioplasty without stent placement. By multivariate analysis using the Cox proportional hazard model, rest pain and tissue loss were independent predictors of patency loss, with hazard ratios of 2.5 (95% confidence interval, 1.6−4.1; $P < 0.001$) and 3.2 (2.0−5.2, $P < 0.001$), respectively (Table II). Throughout follow-up, patients with CLI had reduced patency compared with those with claudication ($P < 0.001$; Fig. 1).

Analysis of failure time distribution data after all interventions revealed that the highest failure rate was observed in the early postintervention period. The failure rate subsequently decreased, only to increase again late in follow-up (Fig. 2). The

Table I. Univariate analysis of risk factors for failure

	Total (%) $n = 434$	Failure (%) $n = 159$	Early failure (%) $n = 47$	Failure *P* value	Early failure *P* value
Age >75 yr	240 (55.3)	83 (52.2)	24 (51.1)	0.21	0.32
Female	186 (42.9)	81 (50.9)	26 (55.3)	0.01	0.07
Diabetes	232 (53.5)	94 (59.1)	32 (68.1)	0.07	0.03
CRI	89 (20.5)	35 (22.0)	15 (31.9)	0.55	0.04
ESRD	43 (9.9)	21 (13.2)	14 (29.8)	0.08	<0.0001
CHF	44 (10.1)	18 (11.3)	13 (27.7)	0.54	<0.0001
Smoking	57 (13.1)	20 (12.6)	5 (10.6)	0.82	0.06
Claudication	225 (51.8)	61 (38.4)	9 (19.1)		
Rest pain	73 (16.8)	35 (22.0)	3 (6.4)	<0.0001	<0.0001
Tissue loss	136 (31.3)	63 (39.6)	35 (74.5)		
CTO	84 (19.4)	33 (20.8)	12 (25.5)	0.62	0.08
Length >20 cm	68 (15.7)	28 (17.6)	4 (8.5)	0.41	0.10
Runoff: 3	174 (40.0)	62 (39.0)	13 (27.7)		
Runoff: 2	190 (43.8)	77 (44.0)	17 (36.2)	0.36	0.56
Runoff: 1	70 (16.2)	20 (17.0)	17 (36.2)		
Tibial	79 (18.2)	33 (20.8)	16 (34.0)	0.31	0.005
Femoropopliteal only	355 (87.8)	126 (79.2)	31 (66.0)		
Stent	249 (57.4)	78 (49.1)	15 (31.9)	0.009	<0.0001
PTA only	185 (42.6)	81 (50.1)	32 (68.1)		

CRI, chronic renal insufficiency; ESRD, end-stage renal disease; CHF, congestive heart failure; CTO, chronic total occlusion; PTA; percutaneous transluminal angioplasty.

Table II. Multivariate analysis for patency loss (Cox proportional hazards model)

	B	SE	HR	95% CI for HR	*P* value
Rest pain	0.92	0.246	2.508	1.547−4.066	<0.001
Tissue loss	1.168	0.243	3.216	1.997−5.178	<0.001
Length >20 cm	0.032	0.234	1.033	0.652−1.635	0.891
CTO	0.344	0.214	1.41	0.927−2.146	0.108
CHF	0.552	0.289	1.737	0.986−3.06	0.056
ESRD	0.406	0.299	1.501	0.835−2.697	0.175
DM	0.231	0.213	1.26	0.83−1.912	0.278
Runoff: 2	0.211	0.254	1.235	0.751−2.032	0.406
Runoff: 1	−0.196	0.261	0.822	0.493−1.373	0.454
Male	−0.136	0.19	0.873	0.602−1.265	0.473
Smoker	0.194	0.287	1.214	0.692−2.129	0.499
Tibial treated	0.288	0.189	1.334	0.921−1.931	0.127

B, beta coefficient; SE, standard error; HR, hazard ratio; CI, confidence interval; DM, diabetes mellitus.

distribution of failure times for both claudication and CLI was fit to distinct Weibull distributions (Fig. 3). This is a standard technique to characterize the tendency of a population of products to fail over time in both a quantitative and qualitative manner.

The pattern of failure after interventions for claudication demonstrated an increasing failure rate, meaning that the failure rate increased over time. Actual parameters of the Weibull distribution were as follows: $\beta = 1.22$, $\theta = 13.46$, MTTF = 12.603 months (10.3−15.073), index of fit = 0.99037, $R^2 = 0.98084$ (Fig. 3A). The timing of failures after interventions for CLI demonstrated a decreasing failure rate, suggesting the predominance of early failures. Parameters for this distribution were as follows: $\beta = 0.7395$, $\theta = 6.8$, MTTF = 8.2 (6.252−9.51), index of fit = 0.99391, $R^2 = 0.98786$ (Fig. 3B).

In RE terms, the concept of basic rating life or L10 is a quantitative means of characterizing reliability in a population of products. This term essentially refers to the time until a 10% cumulative failure rate (90% reliability) is observed. In this series, actuarial patency was 90% at 3.1 months, defining this

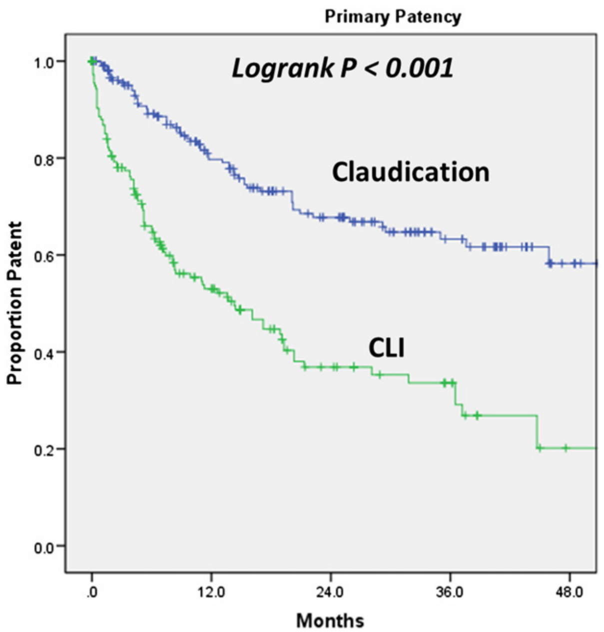

Fig. 1. Kaplan–Meier curves for primary patency over time based on indication for intervention.

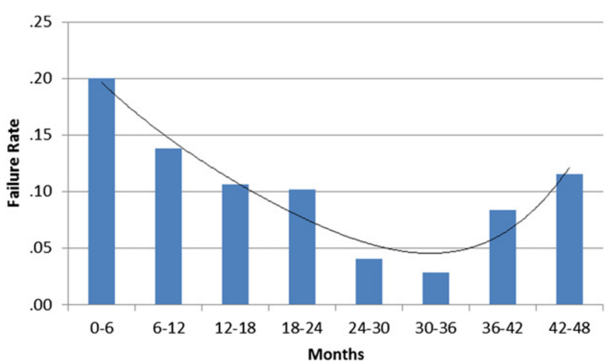

Fig. 2. Failure rate versus time plot suggests variation in the failure rate consistent with the ''bathtub curve'' model. Failure rate peaks within the first 6 months and subsequently decreases until late follow-up when failure rate increases again.

temporal cutoff as the basic rating life for endovascular intervention. Early failures, which accounted for 29.6% of all failures, were therefore defined as instances of patency loss before 3.1 months. Among patients with early failure, 19.1% presented with claudication, 6.4% presented with rest pain, and 74.5% presented with tissue loss (Rutherford class V). There were no amputations among those with claudication throughout follow-up. Among those with CLI and early failures, the majority of patients (94.5%) were those with Rutherford class V CLI. Factors associated ($P < 0.10$) with early failure on univariate analysis (Table I) included female sex, diabetes, renal insufficiency, ESRD, heart failure, current smoking, CLI, chronic total occlusions, long lesion length, tibial interventions, and angioplasty without adjunctive stenting. Using multivariate analysis of failure data, independent predictors of early failure included tissue loss, long lesion length, chronic occlusions, heart failure, and ESRD (Table III). Throughout follow-up, early failures were associated with statistically significant higher rates of endovascular reinterventions (48.9% vs. 19.5%, $P < 0.0001$), conversion to surgical bypass (44.6% vs. 4.9%, $P < 0.0001$), and major amputation (36.2% vs. 3.9%, $P < 0.0001$).

DISCUSSION

The constant introduction of novel endovascular devices and proliferation of clinical trials necessary for their regulatory approval, coupled with a concurrent focus on health care costs and use, have contributed to a unprecedented growth of clinical research in vascular surgery. Society-sponsored documents have advocated the adoption of objective performance goals and reporting standards for new technology; vascular surgeons have taken a serious interest in outcomes investigation and comparative effectiveness research. Despite this ''culture of innovation'' in vascular surgery, the analytical approach to clinical data has not evolved at a similar pace.

Current reporting standards suggest end points (e.g., ''technical success,'' ''early failure,'' ''midterm follow-up'') as well as guidelines for longitudinal outcomes reporting. Comparisons between groups are made using life-table analysis or Kaplan–Meier function; by convention, multivariate analysis is often performed using the Cox proportional hazard model.[11–13] Shortcomings of this widely accepted approach include statistical concerns related to the model assumptions, as well as the frequent disparity between statistical significance and clinical relevance.[11–13] An analysis using this ''traditional'' approach, relying on multivariate analysis using the Cox proportional hazards model to identify risk factors for patency loss, revealed only the indication for intervention (rest pain and tissue loss, relative to claudication) as independent predictors of patency loss (Table II). This finding is consistent with previous reports, and likely consistent with many vascular specialists' experiences.[1–8,19–22]

Beyond this traditional approach, we also evaluated outcomes of endovascular intervention for peripheral arterial disease using analysis guided by RE principles. RE is the study, evaluation, and life-cycle management of reliability: a product's ability

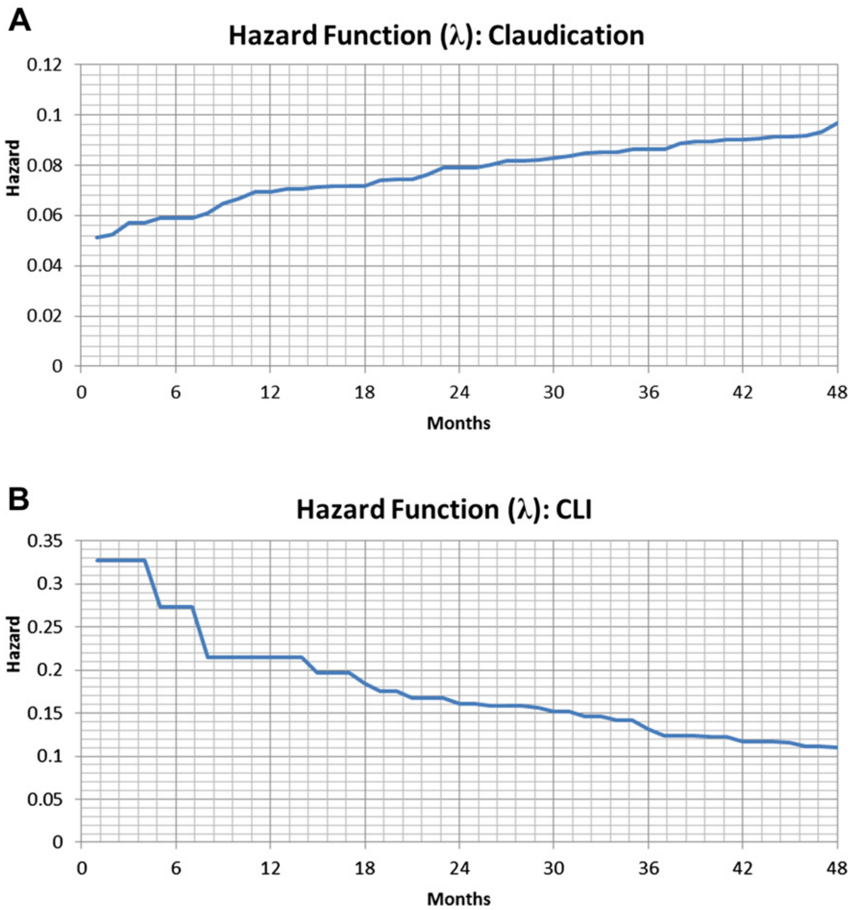

Fig. 3. Different hazard function plots based on indication for intervention (**A**). After interventions for claudication, the hazard function demonstrates an increasing failure rate, suggesting the predominance of ''burn-out'' failures, in contrast to the hazard function after interventions for critical limb ischemia (CLI), which follows a decreasing failure rate pattern, suggesting the predominance of early failures (**B**).

to perform required functions under stated conditions for a specified period.[16] RE principles are widely used to examine product reliability and failure in many fields, including manufacturing, engineering, and computer science. We hypothesized that the evaluation of peripheral interventions using an RE approach would provide additional clinically relevant insights and, in particular, would prove especially useful for objective assessment of the association between specific risk factors and early failure. Indeed, by applying RE analysis principles, we gained significant additional insights into the markedly different failure rates after endovascular intervention based on clinical indication for treatment, and we were further able to identify additional risk factors associated with early failure.

One focus of RE is the study of failure data. The failure rate of many products or systems, ranging from ball bearings to human life, can be described as following a ''bathtub distribution,'' so called because of its resemblance to a bathtub in cross section (Fig. 4).[16–18,23] In these plots of failure rate versus time, the failure rate is highest early in a product's life, during an ''infant mortality stage,'' when manufacturing defects become apparent. The failure rate then decreases to a low constant rate during a ''useful life'' stage, only to increase again during a ''burn-out'' period at the end of life. We have shown that the pattern of failure after peripheral interventions approximates this bathtub distribution, with differences in the distribution of failure rates and times based on indication for intervention (Figs. 2 and 3).

Potential benefits of an RE-based approach to failure data include the ability to gain more specific and clinically relevant information, such as the identification of the factors associated with an increased failure rate at any given time after

Table III. Multivariate analysis for early failure

	B	S.E.	OR	95% CI for OR	*P* value
Rest pain	−0.49	0.814	0.613	0.124−3.021	0.547
Tissue loss	1.894	0.76	6.648	1.497−29.513	0.013
Length >20 cm	1.489	0.752	4.434	1.015−19.365	0.048
CTO	1.453	0.625	4.275	1.256−14.552	0.02
CHF	2.714	0.841	15.091	2.901−78.513	0.001
ESRD	2.208	0.738	9.102	2.142−38.672	0.003
DM	−0.712	0.678	0.491	0.13−1.852	0.294
Runoff: 2	0.656	0.593	1.928	0.603−6.158	0.268
Runoff: 1	0.869	0.875	2.385	0.429−13.264	0.321
Male	0.209	0.596	1.232	0.383−3.965	0.726
Smoker	1.242	0.948	3.461	0.54−22.202	0.19
Tibial treated	0.519	0.517	1.68	0.61−4.625	0.315

OR, odds ratio.

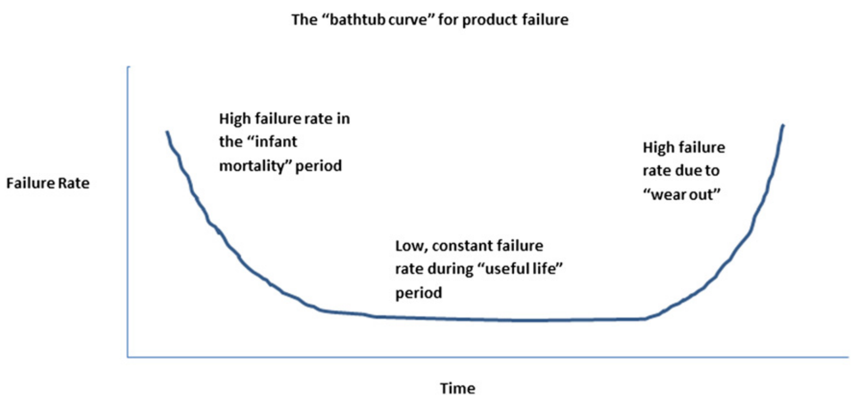

Fig. 4. The bathtub curve, a hypothetical plot of failure over time, may be applied to products and systems ranging from ball bearings to human life.

intervention. Furthermore, we identified an evidence-based cutoff for early failure based on the RE principle of basic rating life: by 3.1 months, 10% of all failures occurred. In RE terms, this concept of basic rating life is an index of product reliability.[18,23] Given the empirically defined threshold for the poorest performing interventions of basic rating life, also referred to as L10, a multivariate logistic regression identified the numerous factors independently associated with early failure: tissue loss, heart failure, chronic total occlusion, ESRD, and lesion length >20 cm. Although previous reports have identified these risk factors for patency loss over time, our analysis specifically demonstrates the significance of these risk factors in early failure, before 3.1 months. An additional benefit of this approach—as compared with the Cox regression performed on the same data—is its improved power and the ability to identify more independent risk factors for failure using a relatively small sample.

The RE-based analysis revealed that the timing of failure after interventions is markedly different based on indication for intervention, with a predominance of early failures (''infant mortalities'') after interventions for CLI in contrast to late failures, which are more likely after interventions for claudication. This suggests that the underlying mode of failure may differ depending on the indication. For example, because early failure rates are highest after interventions for CLI, this may indicate that thrombosis or technical factors may be common, in contrast to interventions for claudication, where late failures predominate, presumably related to restenosis and disease progression. The ability to characterize failure distributions, calculate MTTF, and estimate the probability of failure during specific time intervals, based on preoperative factors such as indication for intervention, lesion characteristics, revascularization technique, or comorbidities, is a potential strength of the RE-based approach that could be leveraged to develop individualized postintervention surveillance duplex scan schedules.

This study corroborates previous reports and clinical experience with respect to the accelerated patency loss observed after interventions for CLI versus claudication. However, to our knowledge, this is the first report to integrate RE principles into the analysis of vascular surgical outcomes. This approach allowed for the identification of an empirically defined cutoff for early failures as defined by RE principles. Redefining such benchmarks based on clinical data, rather than arbitrary time periods, has implications for outcomes reporting and comparative effectiveness research. Our attempt to specifically identify risk factors for failure before this cutoff may aid vascular specialists in patient selection for endovascular intervention. Patients with multiple risk factors for failed endovascular intervention before 3.1 months might be better served by surgical bypass.

The development of a ''product life cycle'' for endovascular interventions affirms the applicability of an RE approach to peripheral interventions. Our results suggest different life-cycle models based on disease severity. The pattern of failure for all interventions, when considered together, approximates the bathtub distribution; however, clearly, interventions for CLI are predisposed to early failure, whereas interventions for claudication tend to fail in a delayed manner. These findings underscore the differences in expected outcomes based on the severity of disease, and may be used to develop postintervention surveillance protocols that anticipate failure and allow for improved assisted patency rates.

Limitations of this study include its retrospective nature and limited follow-up. This initial study included patients representing a wide spectrum of disease, ranging from claudication to CLI with tissue loss, who underwent femoropopliteal intervention with or without concomitant tibial angioplasty. Therefore, we chose to define failure broadly to accurately estimate reliability across multiple failure modes. The quantitatively different failure distributions based on indication for intervention suggest that future efforts may be best served by considering these subgroups differently. Moreover, as this is a proof-of-concept application of engineering principles to clinical data, there is likely the possibility for refinement of the statistical approach in future studies.

Despite these limitations, we believe that our findings not only contribute to the mounting literature regarding the risk factors for patency loss after peripheral endovascular intervention but also demonstrate proof of principle that application of novel methods for outcome analysis after endovascular interventions using RE principles may provide important clinically relevant information. Future research efforts will include application of these principles for the development and validation of evidence-based individualized surveillance programs intended to better detect interventions at risk for failure in a time- and cost-sensitive manner, as well as for the development of specific RE-based models that characterize reliability and failure based on arterial disease burden and treatment modality.

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