Hospital Readmissions Following Endovascular Therapy for Critical Limb Ischemia: Associations With Wound Healing, Major Adverse Limb Events, and Mortality

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***Background*—**The significance of hospital readmission after endovascular therapy for critical limb ischemia (CLI) is not well established. We sought to investigate the incidence, timing, and causes of readmissions after endovascular therapy for CLI and whether readmission is associated with major adverse limb events (MALE) or mortality.

***Methods and Results*—**This was a retrospective study of 252 patients treated with endovascular therapy for CLI. During median follow-up of 381 days (interquartile range [IQR], 115–718), 140 (56%) were readmitted, with median time to readmission of 83 days (IQR, 33–190). Readmission within 30 days occurred in 14% of patients (n=35; 25% of readmissions). Most readmissions occurred between 30 and 180 days (n=67; 48% of readmissions). The most frequent reason for readmission was unhealed wounds (n=63; 45% of readmissions). Independent predictors of readmission by Cox proportional hazards analysis were unhealed wounds, presence of multiple wounds, age ≥70, female sex, hemodialysis, and history of heart failure ($P<0.05$ for each). By Kaplan–Meier analysis, readmission was greatest in patients with unhealed wounds, followed by patients who never had a wound, and lowest in patients whose wounds completely healed ($P<0.0001$ overall, and $P<0.01$ between groups). After multivariable adjustment, readmission remained an independent predictor of composite MALE (major amputation, bypass, or endarterectomy) or mortality (adjusted hazard ratio, 3.1; 95% CI, 1.5–6.5; $P=0.002$).

***Conclusions*—**Most readmissions occur 30 and 180 days after endovascular therapy for nonprocedural reasons. Unhealed wounds are an independent risk factor for readmission. Readmission is associated with increased MALE and mortality after endovascular therapy for CLI. **(*J Am Heart Assoc*. 2016;5:e003168 doi: 10.1161/JAHA.115.003168)**

Key Words: critical limb ischemia • major adverse limb events • mortality • peripheral artery disease • readmission • wound healing

Hospital readmissions identify patients at increased risk of adverse outcomes in many disease processes.[1] Avoiding 30-day readmissions has been adopted as a metric by the Centers for Medicare and Medicaid Services (CMS) by which quality of care is judged.[2] However, there are limited data on the causes of readmission for patients with critical limb ischemia (CLI) following endovascular therapy, and the temporal relationship between readmission and intervention beyond 30 days has not been adequately explored.[3,4] As such, the utility of using readmissions to gauge prognosis or quality of care in patients with CLI is not well established, and further study is needed before this practice is adopted.

Knowledge of the timing of readmission, specific reasons for readmission, predictors of readmission, and prognosis of patients readmitted may allow institutions to redirect resources to maximize preventive efforts and improve the safety, efficacy, and cost-effectiveness of treating patients with CLI. In addition, whereas major amputation or major adverse limb events (MALE) are frequently used as outcomes in studies of patients with CLI,[5] these endpoints do not capture readmission or the presence of persistent ulcers, both of which may significantly impact quality of life.

Given this, it is the aim of the current study to identify the frequency, time course, and causes of readmission after endovascular treatment of CLI. Furthermore, we focus on poor wound healing as a potential predictor of readmission, given that this has not been evaluated in previous studies. Finally, we aim to determine the

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significance of readmission by examining its association with MALE and mortality.

Methods

Study Population

Between November 1, 2011 and April 1, 2015, we conducted a retrospective analysis of patients with CLI treated with percutaneous revascularization at a tertiary care center. The inclusion criteria were the presence of CLI (as defined by American Heart Association/American College of Cardiology and TransAtlantic Inter-Society Consensus II guidelines)[6,7] and attempted endovascular therapy for CLI. There were no exclusion criteria. The study was approved by the institutional review board. All human subjects provided consent to participate in the study.

Data Collection

Baseline demographics, procedural characteristics, and details on occurrence and reasons for readmission were collected by review of the electronic medical record. Presence and characteristics of all wounds on the extremity of intervention were documented before the procedure and assessed on interval follow-up. Substantially all of the patients with wounds were followed in the institutional cardiovascular wound clinic. Wound characteristics and the date of complete wound healing were collected by the wound clinic and further determined by an experienced provider during chart review. All patients underwent assessment of their wound status for the duration of follow-up.

Study Endpoints

The study primary outcome was the first occurrence of hospital readmission after endovascular therapy for CLI. Each readmission was classified by the principle admitting diagnosis. The admitting diagnosis was abstracted from the chart by International Classification of Diseases, Ninth Revision, code and review of inpatient and outpatient notes. Cause of readmission was classified as wound related or nonwound related and by organ system (specific categories provided in Figures 1 and 2). Timing of readmission was determined and classified as ≤30 days after endovascular therapy, 30 to 180 days, and ≥180 days after endovascular therapy. Wound-related readmissions were defined as readmission attributed to the primary reason of poor wound healing, persistent wound-related pain, wound infection, or unplanned revascularization (surgical or endovascular). Readmissions for rest pain or intervention on nonindex extremity were classified as cardiovascular readmissions. Any readmission within 14 days of intervention attributed to a cardiovascular issue, cerebrovascular event, bleeding (including gastrointestinal), wound-related infectious disease, or acute kidney injury was considered procedure related and thus classified as a cardiovascular readmission.[8–10] Readmissions for gastrointestinal bleeding beyond 14 days were classified as a gastrointestinal cause. If a patient underwent a nonplanned procedure in the index extremity after the first procedure, this was considered a complication; however, if part of a multistaged planned procedure, outcomes were determined from the date of the last procedure. Only the first readmission for each patient was considered; repeat hospitalizations were not evaluated in this study.

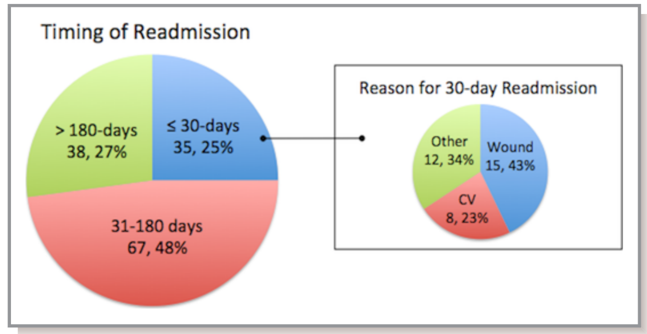

Figure 1. Timing of readmission and causes of 30-day readmission. Most readmissions occurred between 31 and 180 days (1–6 months), and only 25% of the total were within 30 days. Among those readmitted within 30 days, wound-related issues were the most common causes. CV indicates cardiovascular.

The study secondary outcome was a composite of MALE (defined as the first instance of major amputation, surgical endarterectomy, or surgical bypass to the index limb after the date of the endovascular procedure) and all-cause mortality. All-cause mortality was determined by the Social Security Death Index, Ohio Death Index, electronic medical record review, and telephone call in patients without recent follow-up.

Statistical Analysis

Continuous variables are presented as mean (SD) for parametric variables, median (interquartile range; IQR) for nonparametric variables and categorical variables as total number (percent) of patients. Continuous data were compared across baseline and procedural characteristics by Student *t* test for parametric variables or the Wilcoxon rank-sum test for nonparametric variables. Categorical variables were compared across groups by frequency distribution utilizing chi-square or Fisher exact tests.

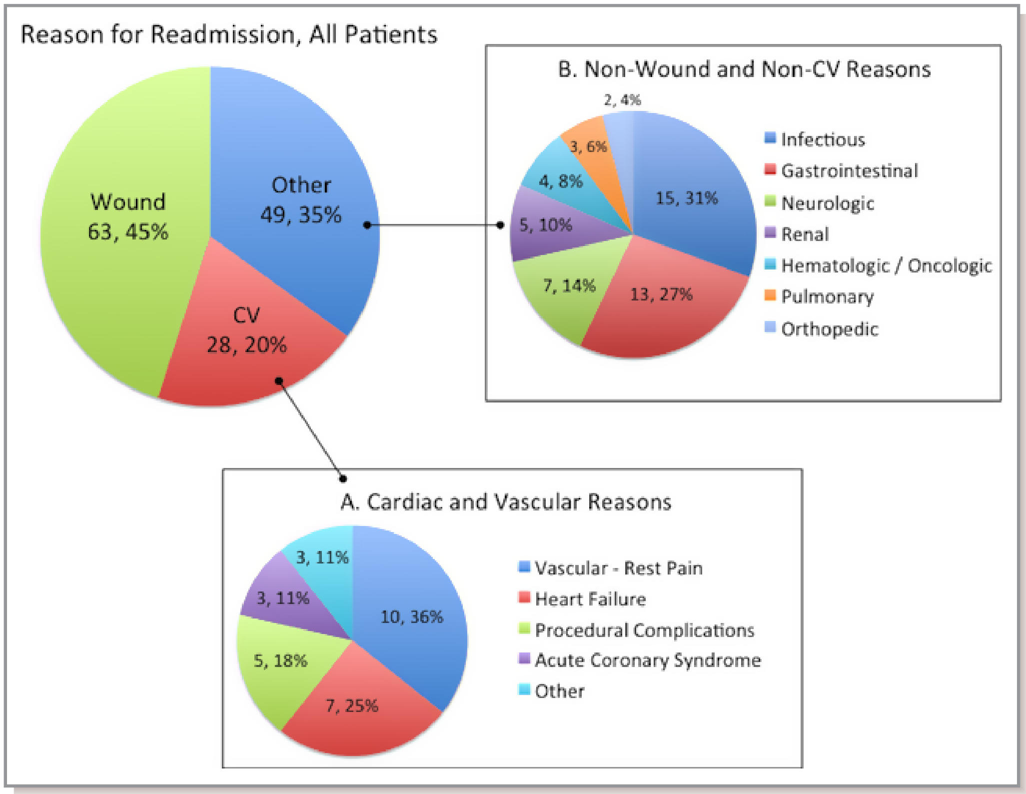

Figure 2. Frequency of various causes of readmission after endovascular therapy for CLI. Most patients were readmitted for wound-related issues. (A) Within the cardiovascular causes for readmission, limb rest pain and heart failure were the most common. (B) Among the nonwound, noncardiovacular reasons, infectious and gastrointestinal issues were most prevalent. CLI indicates critical limb ischemia; CV, cardiovascular.

Reasons and timing of readmission were determined by standard descriptive statistics. Predictors of readmission were determined by univariate Cox proportional hazards analysis. A separate Cox proportional hazards analysis was conducted treating wound healing as a time-dependent covariate. The final multivariable Cox proportional hazards model included all variables significant on a step-wise univariate screen utilizing $P<0.05$ as the entry criteria. Additional variables believed to be most clinically relevant from past studies were then added, following a 10 event to 1 variable ratio to avoid overfitting. Interaction between terms was tested and included in the final model, if significant. Each term in the Cox model satisfied the proportionality assumption, as did the overall model. Similar approaches were followed for covariate selection in the Cox proportional hazard model used to estimate MALE and mortality. Cumulative probabilities of readmission, MALE, and mortality were stratified across groups by the log-rank comparison utilizing the Kaplan–Meier method. Statistical significance for all comparisons was determined as $P<0.05$. All data analysis was performed with JMP Pro (version 11.1; SAS Institute Inc., Cary, NC) and R software (version 3.1.0; R Foundation for Statistical Computing, Vienna, Austria).

Results

Incidence and Causes of Readmission

During a median follow-up of 381 days (IQR, 114–723), 140 patients were readmitted (56% of all patients). Median time to readmission was 83 days (IQR, 31–195). Readmission within 30 days occurred in 35 patients (14% of all patients, 25% of readmissions; Figure 1). The most common causes of 30-day readmission were wound-related issues (43%), followed by noncardiovascular reasons (34%), and then cardiovascular causes (23%). Most readmissions occurred between 30 and 180 days (1–6 months) postintervention.

Wound-related issues were the most common cause of total readmissions (63 patients [45%]; Figure 2). Wounds were equally as likely to cause readmission within 30 days compared to other time periods. Illustrating this, wounds caused 43% of 30-day readmissions and 46% of readmissions after 30 days (P=0.844).

Cardiovascular causes were responsible for 19% of readmissions. Among the cardiovascular causes, 37% were attributed to worsening claudication or ischemic rest pain, either in the procedural or nonprocedural extremity (Figure 2A). In summation, CLI (persistent wounds or rest pain) was the cause of 52% of readmissions. There were 5 procedural complications (2% of total

Table 1. Clinical and Procedural Characteristics in the Study Population

	Not Readmitted (n=112)	Readmitted (n=140)	*P* Value
Baseline characteristics			
Age, y	68.9 (12.0)	69.2 (12.3)	0.82
Sex (female)	69 (62)	80 (57)	0.28
Body mass index, kg/m^2	27.9 (6.3)	28.8 (6.4)	0.52
Congestive heart failure	23 (21)	45 (32)	0.046*
Hypertension	100 (89)	125 (89)	1.00
Hyperlipidemia[†]	87 (78)	117 (84)	0.26
Smoking (current or past)	76 (68)	96 (69)	1.00
Diabetes mellitus			
Any (type 1 or 2)	67 (60)	106 (76)	0.009*
Insulin dependent	31 (28)	65 (46)	0.002*
Creatinine	1.5 (1.6)	2.1 (2.4)	0.02*
History of CAD	59 (53)	83 (59)	0.31
Medications[‡]			
Aspirin	99 (88)	114 (81)	0.16
$P2Y_{12}$ receptor inhibitor	89 (79)	88 (63)	0.005*
Statin	93 (83)	115 (82)	0.87
Noninvasive assessment			
Presence of wound	79 (71)	100 (71)	0.89
Rutherford class	4.9 (0.7)	5.0 (0.7)	0.27
Ankle-brachial index (ABI)[§]	0.61 (0.42)	0.71 (0.40)	0.07
Toe-brachial index (TBI)[§]	0.20 (0.27)	0.23 (0.27)	0.36
Location of intervention			0.57
Above the knee only	57 (51)	66 (47)	
Below the knee only	21 (19)	34 (24)	
Both above and below the knee	34 (30)	40 (29)	
Type of intervention			
PTA only	46 (41)	71 (51)	0.16
PTA+stent	48 (43)	50 (36)	0.30
PTA+atherectomy	19 (17)	25 (18)	0.87
Other (cutting balloon or laser)	16 (14)	22 (16)	0.86
Procedural outcomes			
No. of lesions treated	1.6 (0.8)	1.6 (0.8)	0.60
Change in ABI[§]	0.09 (0.44)	0.05 (0.43)	0.45
Procedural failure[‖]	10 (9)	14 (10)	0.83

CAD indicates coronary artery disease; PTA, percutaneous transluminal angioplasty.
*Significance at $P<0.05$.
[†]Any lipid-lowering agent or a low-density lipoprotein ≥130 mg/dL.
[‡]At time of endovascular therapy.
[§]After intervention; excludes noncompressible/nonobtainable values.
[‖]Defined as inability to restore perfusion to the target vessel; successful procedures must have had at least 1 vessel runoff to the affected extremity at the end of the case.

patients, 4% of readmissions), including 2 cardiac arrests, 1 acute limb ischemia event, 1 venous thromboembolism, and a transient ischemic attack. Among the noncardiovascular causes, the most common were infections not related to CLI (ie, urinary tract infections) and gastrointestinal reasons (ie, occult intestinal bleeding; Figure 2B).

Clinical and Procedural Characteristics by Readmission Status

Clinical and procedural characteristics were similar among patients not readmitted and those readmitted (Table 1). Of the few differences, patients readmitted were more likely to have a history of congestive heart failure, diabetes mellitus, and less likely to be on a $P2Y_{12}$ inhibitor before endovascular therapy ($P<0.05$ for all comparisons; Table 1). Additionally, average creatinine was higher among patients readmitted compared to those not readmitted (2.4 vs 1.6 mg/dL; $P=0.02$).

Predictors of Readmission

Associations between readmission, wound, clinical, and procedural characteristics were examined with Cox proportional hazards analysis (Table 2). After a multivariable adjustment for the 13 terms in Table 2, the independent predictors of readmission included wound status (overall, $P<0.0001$), presence of multiple wounds, age ≥70 years, female sex, hemodialysis use, and history of heart failure ($P<0.05$ for all comparisons).

A separate Cox proportional hazard analysis was conducted only in patients with wounds, treating wound healing as a time-dependent variable. In this analysis, time-dependent wound healing was significantly associated with a lower risk of readmission (hazard ratio [HR], 0.39; 95% CI, 0.22–0.68; $P=0.0009$).

Table 2. Multivariable Cox Proportional Hazards Analysis for Predictors of Readmission

Variable	Adjusted Hazard Ratio (95% CI)	*P* Value
Wound status		
Not healed vs healed	7.3 (4.3–12.9)	<0.0001*
No wound vs healed	3.7 (1.9–7.4)	<0.0001*
Not healed vs no wound	2.0 (1.1–3.5)	0.02*
Wound characteristics		
Multiple (≥2) wounds	1.8 (1.1–2.9)	0.02*
Gangrene or OM	0.8 (0.5–1.3)	0.31
Large wound area†	0.6 (0.4–1.1)	0.09
Clinical characteristics		
Age ≥70 years	1.7 (1.2–2.5)	0.003*
Sex (female)	1.5 (1.02–2.1)	0.04*
Diabetes, insulin dependent	1.4 (0.5–1.9)	0.08
Hemodialysis use	1.9 (1.02–3.4)	0.04*
Heart failure (history of)	1.9 (1.3–2.8)	0.002*
$P2Y_{12}$ inhibitor use	0.9 (0.6–1.3)	0.42
Aspirin use	0.6 (0.4–1.1)	0.08
Procedural characteristics		
Procedural failure	1.0 (0.5–1.9)	0.95
Stent placement	0.8 (0.5–1.1)	0.18

Multivariable model was adjusted for all of the terms in the table. OM indicates osteomyelitis.
*Significance at $P<0.05$.
†Large wound area denotes wound area in the top tertile (>2.38 cm^2). Results presented as hazard ratio (95% CI).

Readmission Stratified by Wound Status

Readmission occurred in 22 patients (37%) whose wounds healed, 40 patients (55%) of patients who never had a wound, and 78 patients (66%) with persistently unhealed wounds ($P=0.001$ between groups; Figure 3). On Kaplan–Meier analysis, the probability of readmission was greatest in patients with unhealed wounds, followed by patients without wounds, and lowest in patients with wounds that healed (log-rank $P<0.0001$; Figure 4).

Association Between Readmission, MALE, and Mortality

The total number of patients with either MALE or mortality was 66 (26%), of which 46 (18%) had MALE, and 30 (12%) died (10 patients with MALE also died and were thus counted once in the composite). The frequency of composite MALE or mortality was greater among patients readmitted compared to not readmitted (57 of 140 [41%] vs 9 of 112 [8%]; $P<0.0001$), as were MALE (41 of 140 [29%] vs 4 of 112 [4%]; $P<0.0001$) and mortality (24 of 140 [17%] vs 6 of 140 [5%]; $P=0.007$)

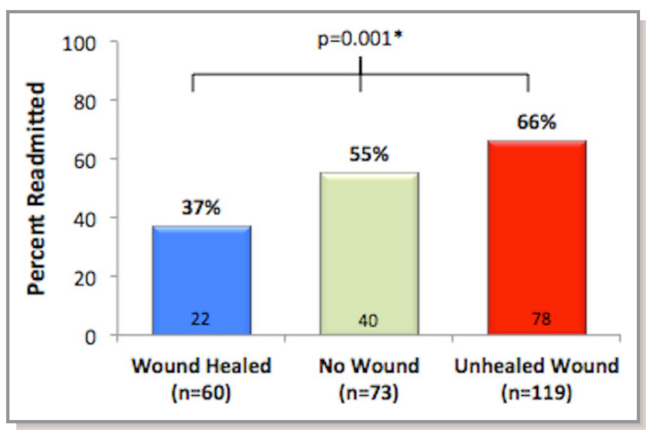

Figure 3. Prevalence of readmission based on wound status. Patients with unhealed wounds had the highest frequency of readmission during follow-up. Readmission was less frequent in patients who had a wound at the time of intervention but had wound healing than patients who never had a wound at all. *Statistical significance at $P<0.05$.

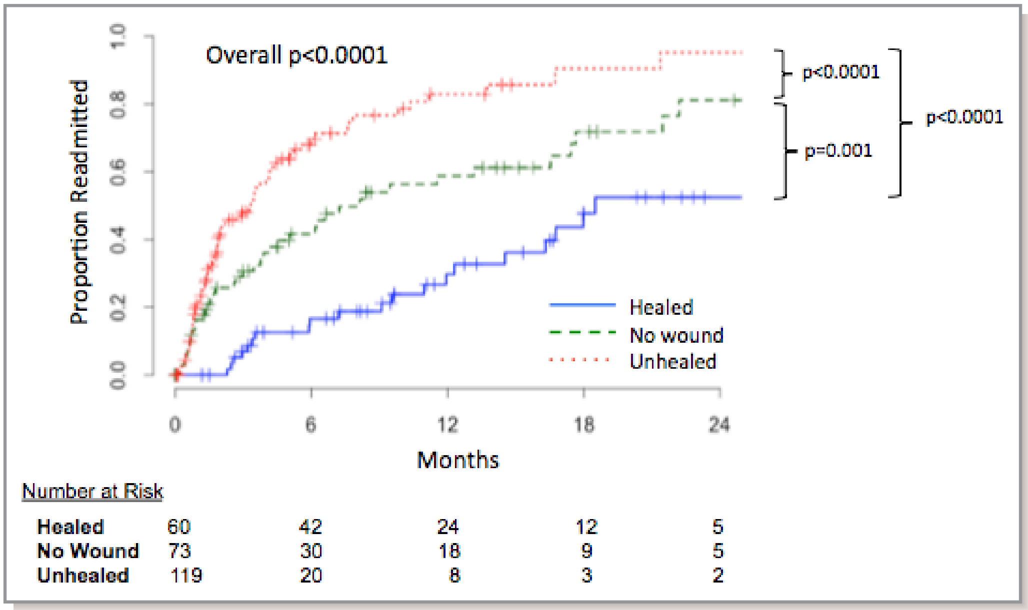

Figure 4. Kaplan–Meier analysis for the cumulative probability of readmission stratified by wound status. Probability of readmission was greatest in patients with unhealed wounds, followed by patients who never had a wound, and lowest in patients who had a wound at the time of intervention but had wound healing during follow-up.

when considered separately. By univariate Cox proportional hazards analysis, readmission was shown to be a risk factor for composite MALE or mortality (HR, 4.0; 95% CI, 2.0–8.1; P<0.0001). After multivariable adjustment (Table 3), readmission remained independently associated with composite MALE or mortality during follow-up (adjusted HR, 3.1; 95% CI, 1.5–6.5; P=0.002). Other independent predictors of MALE included presence of wound, creatinine ≥2.0, and age ≥70 years (P<0.05 for all; Table 3). By Kaplan–Meier analysis, the cumulative probability of MALE or mortality was greatest in patients readmitted during follow-up (P<0.0001; Figure 5).

Table 3. Multivariable Cox Proportional Hazards for MALE or Mortality

Variable	Adjusted Hazard Ratio (95% CI)	*P* Value
Readmission	3.1 (1.5–6.5)	0.002*
Presence of wound	2.2 (1.1–4.3)	0.02*
Creatinine ≥2.0	1.8 (1.04–3.2)	0.03*
Age ≥70 years	1.8 (1.1–2.9)	0.03*
Heart failure, history of	1.6 (0.99–2.7)	0.053
Diabetes mellitus, any	1.2 (0.6–2.3)	0.54

Multivariable adjustment performed for each of the variables above. MALE indicates major adverse limb events.
*Significance at P<0.05.

Discussion

In our study, we demonstrate that readmission is common in patients with CLI after endovascular therapy despite a high rate of procedural success, and that most readmissions are for chronic, wound-related issues. We show that ≈14% of patients are readmitted within 30 days postintervention (25% of readmissions), and that most readmissions occur between 30 and 180 days (1–6 months; 48% of readmissions). Furthermore, the majority of readmissions are attributed to nonprocedural reasons. To the best of our knowledge, ours is one of the first studies to quantify the prevalence of readmission beyond 30 days and to delineate the specific causes for readmission in this patient population and, as such, may help inform future decisions by CMS and policy makers. Readmission was independently associated with MALE and mortality, and importantly, wound healing was independently predictive of a lower risk of readmissions.

Our data suggest that the foremost effort should be placed on achieving wound healing as fast as possible in patients with CLI. We demonstrate that the presence of an unhealed wound is an independent risk factor for readmission after endovascular treatment of CLI, and this relationship remains significant even when subjecting wound healing to a more-stringent time-dependent analysis. Furthermore, we demonstrate that other independent risk factors for readmission include the presence of multiple wounds, age ≥70 years, female sex, hemodialysis, and a history of heart failure. With this knowledge, focused outpatient attention can be applied

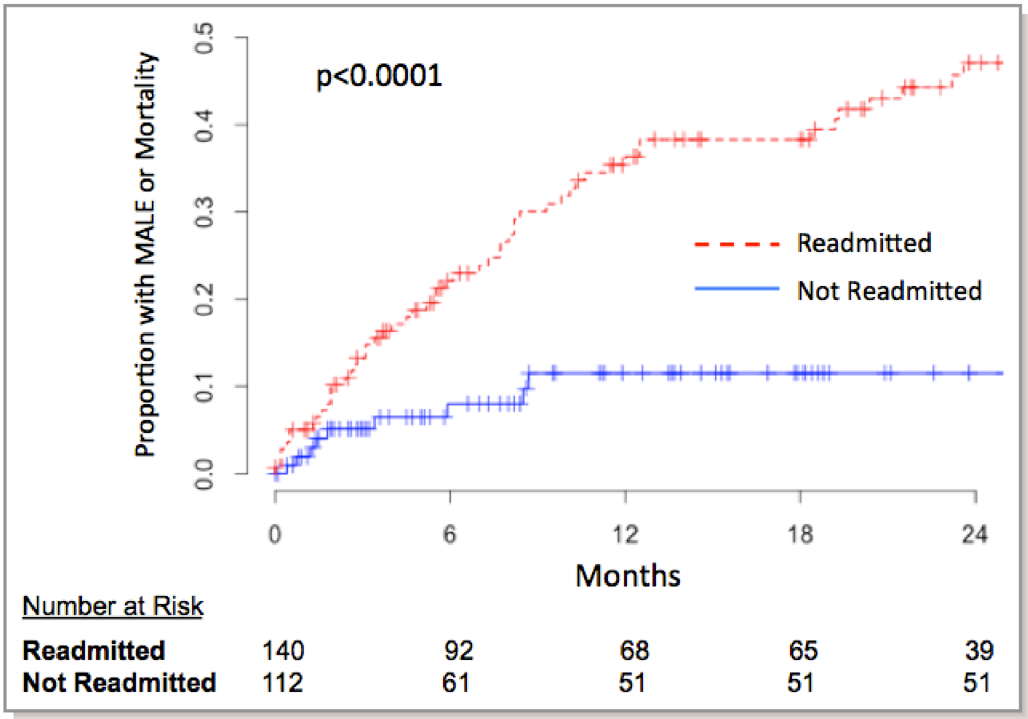

Figure 5. Kaplan–Meier analysis for the cumulative probability of MALE or mortality stratified by whether patients were readmitted. Probability of MALE or mortality was greater in patients readmitted compared to those not readmitted during follow-up. MALE indicates major adverse limb events.

to patients with CLI and these high-risk features in an effort to prevent readmissions and save health care expenditures.

In our institution, specialized wound care clinics and integrated home health care programs are made available to these patients. Despite this, 56% of patients were readmitted in our study, and it is possible that the rate is even higher in centers without a specialized wound care team. Focusing resources on wound healing and pain management may represent an opportunity to reduce readmissions and improve patient outcomes in this patient population.[11]

Most studies in the vascular field have used MALE and amputation-free survival as their primary endpoints. However, a focus on time to wound healing would be particularly relevant in the CLI patient population, given that this may help reduce readmission rates and improve pain management. Furthermore, even if amputation is eventually performed, a treatment may be considered successful if it speeds wound healing or delays amputation for as long as possible. The current study illustrates the importance of this, given that the largest reason for readmission was attributed to issues regarding chronic wound healing. Approaches that maximize wound healing and not just reduce amputation rates should be considered. Such techniques may include angiosome (or direct) revascularization[12,13] and aggressive outpatient wound care. Indeed, our data indicate that there is an unmet need for multidisciplinary management teams of wounds and comorbidities (such as diabetes, heart failure, and renal disease).[11,14,15] An ideal "wound team" may include a provider from infectious disease, diabetes management, podiatry, cardiology, and/or vascular surgery. The goal of this team should be to develop an individualized, realistic assessment of probability of wound healing, if antibiotics or additional medical therapies are needed to treat comorbidities and prevent readmission, determine which revascularization strategy would heal the wound as fast as possible, and subsequently define a personalized threshold for amputation if these strategies fail.

Importantly, though we demonstrate that there is an association between readmission, MALE, and mortality, our data do not suggest causation, nor that reducing readmissions would reduce MALE or mortality. We found that procedure-related reasons were an infrequent cause for readmissions, whether within 30 days or beyond. Our data suggest that patients who are readmitted represent a sicker population in need of personalized, intense medical intervention to prevent progression to MALE. Whereas 30-day readmissions after percutaneous coronary intervention have been embraced by the CMS as a measure of quality and a metric upon which reimbursement is based,[16] our data suggest that caution should be exercised when considering adopting a similar policy in patients with CLI, given that most readmissions are not within 30 days, most are not for procedural complications, and most are for noncardiovascular or chronic wound-related issues. If considering using readmission as a quality metric on which to base reimbursement, the specific cause of readmission should be carefully delineated. Penalizing operators for non-procedural-related readmissions may have a negative effect on quality of care, given that providers may select against doing procedures in patients with complicated medical comorbidities, while these are the patients that may benefit the most from intervention. The focus in this population should be on treating their underlying medical illnesses, improving outpatient wound care, and pain management rather than simply reducing readmissions.[10,17,18]

The current study also suggests that readmission may be used as a marker to identify sicker patients who are at elevated risk of MALE and mortality. Indeed, almost all MALE and mortality occurred in patients who were readmitted. Readmission occurred before MALE in the majority of patients and thus may serve as tool to identify high-risk patients on whom to focus preventative efforts. Furthermore, our results indicate that patients with CLI represent a population particularly prone to readmissions.[4,13] We found that among those readmitted, 25% were readmitted by 30 days, similar to the 30% rate reported in Vogel et al., and the 21% readmission rate reported by Han et al.[3,4] Different than these studies, however, we delineated the causes for readmissions, incorporated specific wound-related variables, and demonstrated that readmission is associated with MALE and mortality.

Our data also suggest that patients whose wounds heal are readmitted less often than those who never had a wound at all. Although reasons for this are unclear, rest pain is often caused by multilevel obstruction to arterial flow rather than discrete blockage (as is more commonly observed in patients with wounds).[19,20] Furthermore, the occurrence of wound healing suggests response to therapy and adequate tissue perfusion, which may infer better outcomes than patients with persistent rest pain.

This study has limitations. This was a single-center study and thus may not capture readmissions at other institutions and may underestimate readmission; however, nearly all patients were followed at our wound center and few were lost to follow-up. Second, we have only captured the first readmission in our cohort, and thus the number of readmissions per individual was not defined in this study. Third, all of the wounds in our study were classified ischemic in nature secondary to CLI, but some may have had a multifactorial etiology (ie, diabetes or venous insufficiency). This proportion was not quantified, may, in part, explain why certain wounds did not heal despite successful reperfusion, and why the incidence of MALE was high in this study despite revascularization. Furthermore, a minority of patients were followed beyond 12 months, and thus our results are less meaningful beyond this time point. Additionally, although we perform a multivariable adjustment, we cannot exclude bias from unmeasured confounders. Similarly, as a single-center study, results may not be generalizable to other centers.

Conclusion

Hospital readmissions are common following endovascular treatment of CLI. Most hospitalizations occur for wound-related reasons within 30 to 180 days (1–6 months) following the procedure. The presence of unhealed wound(s) independently predicts readmission, which, in turn, is independently associated with an increased risk of MALE or mortality during follow-up. Our findings support the use of readmission as a marker of increased risk of adverse outcomes after intervention for CLI. However, given that most readmissions are not for procedural complications, caution should be used when considering the use of readmission as a quality metric in this patient population, whether within the 30-day time frame or beyond. Though amputation-free survival is important, the highest efforts should be on achieving wound healing as quickly as possible in this patient population. In turn, this may reduce readmission rates, MALE, and mortality, thus lowering health care costs and improving outcomes in this patient population at high risk of adverse events.

Disclosures

None.

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Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *Circulation*. 2006;113:e463–e654.

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