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Authors
Ward, Robert
Dunn, Joie
Clavijo, Leonardo
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Outcomes of Critical Limb Ischemia in an Urban, Safety Net Hospital Population with High WIfI Amputation Scores

Robert Ward[1], **Joie Dunn**[2], **Leonardo Clavijo**[3], **David Shavelle**[3], **Vincent Rowe**[2], and **Karen Woo**[4]

[1]Department of Surgery, Keck School of Medicine, University of Southern California, Los Angeles, CA

[2]Division of Vascular Surgery and Endovascular Therapy, Department of Surgery, Keck School of Medicine, University of Southern California, Los Angeles, CA

[3]Division of Cardiovascular Medicine, Department of Medicine, University of Southern California, Los Angeles, CA

[4]Division of Vascular Surgery, Department of Surgery, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA

Abstract

Background—Patients presenting to a public hospital with critical limb ischemia (CLI) typically have advanced disease with significant comorbidities. The purpose of this study was to assess the influence of revascularization on 1-year amputation rate of CLI patients presenting to Los Angeles County USC Medical Center, classified according to the Society for Vascular Surgery Wound, Ischemia and foot Infection (WIfI).

Methods—A retrospective review of patients who presented to a public hospital with CLI from February 2010 to July 2014 was performed. Patients were classified according to the WIfI system. Only patients with complete data who survived at least 12 months after presentation were included.

Results—Ninety-three patients with 98 affected limbs were included. The mean age was 62.8 years. Eighty-two patients (84%) had hypertension and 71 (72%) had diabetes. Fifty (57.5%) limbs had Trans-Atlantic Inter-Society Consensus (TASC) C or D femoral–popliteal lesions and 82 (98%) had significant infrapopliteal disease. The majority had moderate or high WIfI amputation and revascularization scores. Eighty-four (86%) limbs underwent open, endovascular, or hybrid revascularization. Overall, one year major amputation (OYMA) rate was 26.5%. In limbs with high WIfI amputation score, the OYMA was 34.5%: 21.4% in those who were revascularized and 57% in those who were not. On univariable analysis, factors associated with increased risk of OYMA were nonrevascularization ($P = 0.005$), hyperlipidemia ($P = 0.06$), hemodialysis ($P = 0.005$), gangrene ($P = 0.02$), ulcer classification ($P = 0.05$), WIfI amputation score ($P = 0.026$),

Correspondence to: Karen Woo, MD, Division of Vascular Surgery, Department of Surgery, David Geffen School of Medicine, University of California, Los Angeles, 11301 Wilshire Boulevard, Mail Code 10H2, Los Angeles, CA 90073, USA; kwoo@mednet.ucla.edu.

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and WIfI wound grade ($P = 0.04$). On multivariable analysis, increasing WIfI amputation score (odds ratio [OR] 1.84, 95% confidence interval [CI] 1.0–3.39) was associated with increased risk of OYMA while revascularization (OR 0.24, 95% CI 0.07–0.80) was associated with decreased risk of OYMA.

Conclusions—The OYMA rates in this population were consistent with those predicted by the WIfI classification system. In this population, revascularization significantly reduced the risk of amputation. Comorbidities including diabetes mellitus and TASC classification did not moderate the association of WIfI amputation score with risk of 1-year major amputation.

INTRODUCTION

Critical limb ischemia (CLI) affects approximately 1% of the 8–10 million Americans who have peripheral arterial disease (PAD).[1,2] CLI is termed as such because it describes advanced stages of PAD, manifested clinically by rest pain, nonhealing ulcers, or tissue loss. Patients with CLI have high amputation rates with up to 25% major amputation at 1 year.[3] Traditionally, a diagnosis of CLI has been considered to be associated with limb loss unless revascularization was performed. However, several studies in which the only treatment for CLI was wound care have shown that approximately 50% of wounds can heal without revascularization.[4,5] The challenge in the clinical decision-making process is determining which patients will heal without revascularization and which patients will require revascularization.

In 2014, the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System (SVS Wound, Ischemia and foot Infection [WIfI]) was introduced.[6] The intention of this new classification system was to further stratify the CLI patient population to aide in determining which patients will require and benefit from revascularization. Based on scores for wound, ischemia, and infection severity, patients are assigned an estimated risk of amputation at 1 year and an estimated likelihood of benefit of, or requirement for, revascularization. The risk and the likelihood of benefit are categorized as very low, low, moderate, and high.

An early validation study of the SVS WIfI system found that there was no difference in amputation rates among limbs graded as high risk for amputation whether they were revascularized or not.[7] This suggests that certain patients who are categorized as high risk for amputation by the SVS WIfI system may not benefit from revascularization and that there may be factors associated with amputation that are not encompassed by the WIfI score. At Los Angeles County USC Medical Center, a large, urban safety net hospital, there is a large population of CLI patients who are treated aggressively by a limb salvage team. The purpose of this study was to assess the influence of revascularization on 1 year amputation rate of CLI patients presenting to Los Angeles County USC Medical Center, classified according to the SVS WIfI.

METHODS

A retrospective review of prospectively collected data for patients who presented to Los Angeles County USC Medical Center with CLI, defined as rest pain or tissue loss/

nonhealing ulcer, between February 2010 and June 2014 was performed. Patients who survived to 12 months and had follow-up data regarding limb status at 12 months were included. This study was approved by the institutional review board.

Data were obtained from a prospectively maintained database of all patients treated at Los Angeles County USC Medical Center for CLI. For this study, patient demographic data and comorbidities were abstracted. Each affected limb was treated as a unique entry. For patients with tissue loss, wound characteristics including ulceration descriptions and extent of gangrene, if any, were abstracted. Ankle–brachial indices (ABIs) and toe pressures were recorded. Signs and symptoms of infection including swelling, tenderness, warmth, purulent discharge, erythema, deep structure involvement, white blood cell count, heart rate, respiratory rate, and temperature were recorded. Angiographic lesions in the aortoiliac and femoro-popliteal distributions were classified using the Trans-Atlantic Inter-Society Consensus (TASC) classification guidelines. Revascularization procedures were recorded including the procedure type, anatomic location, and date. Amputations including the anatomical location and date were recorded. Each limb was retrospectively classified according to the SVS Lower Extremity Threatened Limb Classification System and given a score of 0–3 in regards to wound, infection, and ischemia. Based on those scores and the expert consensus put forth by Mills et al., limbs were then stratified by likely risk of major amputation at 1 year with medical therapy alone and the likely benefit of revascularization. Major amputation was defined as amputation at or above the level of the ankle. Minor amputation was defined as amputation distal to the level of the ankle.

The limb salvage team at Los Angeles County USC Medical Center comprised vascular surgeons, interventional cardiologists with training in vascular medicine, vascular surgery trainees, a vascular medicine trainee who has completed an internal medicine residency, a nurse practitioner, and a registered nurse. All CLI patients undergo noninvasive vascular laboratory evaluation with segmental pressures including ABI and toe pressure measurement and arterial duplex scanning. Endovascular interventions are performed by both surgeons and cardiologists and operative procedures are performed by surgeons. The decision to proceed with intervention and type of intervention is made in a multidisciplinary fashion based on clinical presentation, comorbidities, and degree of ischemia as measured by ABI and/or toe pressure. Patients receive optimal medical management by the cardiologists and the vascular medicine trainee. Wound care is performed by the surgeons, vascular surgery trainees, and the nurse practitioner.

Statistical analysis was performed using the Statistical Analysis System 9.3 (SAS Institute, Inc., Cary, NC). Summary results were presented as mean and standard deviation for continuous variables and as frequency (percent) for categorical variables. Two-group comparisons were assessed by the independent samples *t*-test or the Wilcoxon rank-sum test as appropriate of continuous variables and by chi-squared test or Fisher's exact test for categorical variables. All variables found to be significantly associated with risk of amputation on univariate analysis at a level of $P<0.1$ were entered into the multivariable analysis. To search for a final model, we used the stepwise selection.

RESULTS

A total of 211 patients were treated during the study period. Ninety-two patients with a total of 98 affected limbs met inclusion criteria. The excluded patients did not have at least 12-month follow-up and were unable to be contacted (*n* = 75) or had missing data points (*n* = 42) required to classify their limbs into the WIfI system. Additionally, there was one known mortality that occurred within 12 months of treatment.

Mean age was 62.8 (±11) years with 57% men. Eighty-two (84%) patients had hypertension, 71 (72%) had diabetes, 18 (18%) had coronary artery disease (defined as history of myocardial infarction or coronary artery revascularization), 38 (40%) had high cholesterol, 28 (29%) were current smokers, and 17 (17%) had chronic renal insufficiency. Sixty-nine patients had a measureable ABI, with a mean of 0.65 (standard deviation [SD] = 0.43). The remainder of the patients had noncompressible vessels and an unreliable ABI. Ninety patients had a toe pressure with a mean 22 (SD = 25). The remaining 2 patients did not have a viable toe for measurement of toe pressure. The number of limbs classified into each WIfI score is shown in Table I. There was no significant difference in the incidence of diabetes or hemodialysis dependence by WIfI amputation score (Table II). The majority of patients had high WIfI amputation scores and revascularization scores.

Twenty-six (27%) limbs suffered a major amputation within 1 year from presentation, while 72 (73%) remained major amputation free. Amputation rates increased with increasing WIfI amputation score (Fig. 1). Among each individual WIfI risk score, revascularization was associated with a lower risk of amputation compared with no revascularization, with a significantly lower rate of amputation among those with high amputation score who were revascularized compared with those who were not ($P = 0.039$) (Fig. 1). When moderate and high risk limbs were combined, those that were revascularized had a 1 year major amputation rate of 21% vs. 57% in those who were not revascularized ($P = 0.012$). Among patients with a high WIfI amputation score, who did not undergo revascularization and also did not suffer a major amputation (*n* = 5), 80% required a minor amputation procedure. There was no significant difference in the incidence of diabetes among those who underwent amputation versus those who did not (Table II). Among those who underwent revascularization and suffered amputation, the incidence of diabetes was 12/18 (66.7%) vs. 48/66 (72.7%) ($P = 0.61$) in those who underwent revascularization and did not require amputation. Among those who underwent revascularization and suffered amputation, the incidence of hemodialysis dependence was 4/18 (22.2%) vs. 1/66 (1.5%) ($P = 0.001$) in those who underwent revascularization and did not require amputation.

Open revascularization was performed in 37 patients (38%), endovascular revascularization in 34 patients (35%), and hybrid revascularization (combination of open and endovascular) in 13 patients (13%). No revascularization procedure was performed in 14 patients (14%). The 14 patients who did not undergo revascularization either refused intervention or were not offered intervention based on severity of comorbidities, poor functional status, and/or extent of tissue loss. The rates of amputation by revascularization type are shown in Figure 2.

On univariable analysis, factors associated with increased risk of 1 year major amputation were non-revascularization ($P = 0.005$), hyperlipidemia ($P = 0.06$), hemodialysis ($P = 0.005$), and increasing WIfI amputation score ($P = 0.026$). Diabetes mellitus, hypertension, coronary artery disease, smoking, TASC classification, and infrapopliteal disease were not significantly associated with risk of 1 year major amputation. On multivariable analysis, increasing WIfI amputation score (odds ratio [OR] 1.84, 95% confidence interval [CI] 1.0–3.39) was associated with increased risk of 1 year major amputation. Revascularization of any kind (OR 0.24, 95% CI 0.07–0.80) was associated with decreased risk of 1 year major amputation. In multivariable analysis, hemodialysis and hyperlipidemia were no longer statistically significant.

DISCUSSION

Although CLI has traditionally been considered an absolute indication for revascularization to prevent inevitable major limb amputation, ample evidence exists to suggest that not every patient with CLI will progress to major amputation in the absence of revascularization.[4,5] Distinguishing clinically between CLI patients who will benefit from revascularization to avoid major amputation and CLI patients who will not benefit from revascularization can be very challenging. Early classification systems of PAD such as the Fontaine and Rutherford classification systems contributed little to aiding in making this distinction.[8,9] Subsequently, the TASC guidelines were developed to classify the angiographic severity and extent of PAD.[3] The intention of the TASC guidelines was to address the rapid expansion of endovascular technology and provide guidance on whether endovascular or open surgical treatment was most appropriate. However, until recently, no formal guidelines existed that addressed the likelihood of amputation or the benefit of revascularization for an individual patient, a void which the WIfI classification hopes to fill.

The SVS WIfI classification was introduced in 2014[6] with the goal of better predicting amputation risk and accounting for the severity of wounds, ischemia, and foot infection, all of which are particularly relevant in diabetics that make up a large percentage of the CLI population. Patients with higher WIfI amputation scores have higher risks of amputation. An early validation study demonstrated that in patients with the highest WIfI amputation scores, there was no difference in amputation rates between patients who were revascularized and those who were not.[7] The aim of this study was to evaluate the influence of revascularization on CLI patients in a contemporary cohort of patients treated at a large, urban safety net hospital presenting with advanced disease and thus high WIfI scores.

In our cohort, the amputation rate increased with increasing WIfI amputation risk score, thus further validating the predictive nature of the WIfI classification. The WIfI classification does not predict the exact risk of amputation beyond categorization into very low, low, moderate, and high. Another recent series showed 1-year amputation-free survival to be 86% in WIfI stage 1 limbs, 83% in stage 2 limbs, 70% in stage 3 limbs, and 38% in stage 4 limbs.[10] The amputation rates in stage 1, 2, and 3 are comparable with those in our study; however, the amputation rate in stage 4 is much higher compared with our study.

The majority of patients in our study were in the highest WIfI amputation risk score category, indicating the advanced nature of their disease. In this category, revascularization significantly decreased the risk of amputation by 25%. This is in contrast to an earlier validation study, where revascularization only decreased the risk of amputation by 15%, which was not a statistically significant difference.[7] In our study, both the incidence of amputation in those who were revascularized and those who were not was lower than the previous validation study.[7] The patient population in the previous study had a significantly higher incidence of chronic kidney disease, dialysis dependence and diabetes, which may contribute to the difference in outcomes from our study.

Other authors have demonstrated that diabetes increases the risk of amputation.[10–12] This may be due to patients with diabetes having increased disease severity.[13] Despite this, our study did not demonstrate an association between diabetes and risk of amputation. Our study also demonstrated no significant correlation between the TASC classification of the lesion and risk of amputation. This is consistent with the intention of the TASC classification which is meant to direct selection of intervention type, open versus endovascular, as opposed to being a predictor of outcomes.[3]

Our study showed an association between hemodialysis and increased risk of amputation on univariate analysis. This is consistent with findings by other authors who have demonstrated that renal failure and dialysis dependence increase the risk of failure to achieve limb salvage despite a patent lower extremity bypass graft in the setting of CLI.[14–16] However, when dialysis dependence was included in a multivariable model with WIfI amputation score, dialysis dependence became nonsignificant. This may provide further validation of the predictive value of the WIfI classification system, suggesting that the scoring system itself accounts for the increased risk in amputation associated with dialysis dependence.

Among our cohort, amputation rates were highest across all WIfI scores for patients who underwent an endovascular procedure for revascularization compared with an open or hybrid technique. Interestingly, all patients who underwent a hybrid procedure remained major amputation free for the 1-year period. However, because our sample size within each procedure type is small, we do not believe that it is appropriate to make a correlation judgment between the technique and risk of amputation.

The primary limitations of our study is that it is a retrospective classification of patients into the WIfI system and the majority of patients in our study did not meet inclusion criteria, largely due to lack of necessary data and/or lack of follow-up. Poor compliance with follow-up is a well-described problem in the indigent, public hospital population.[17] The low mortality rate at 1 year may be due to a disproportionally high number of deaths in the 75 patients who were lost to follow-up. Every effort was made to contact the 75 patients who were lost to follow-up by calling them on multiple occasions. However, due to the nature of this population, those lost to follow-up did not have functional telephone numbers. Additionally, wound healing rates, an important outcome measure of revascularization, were not available in our database. Despite limited long-term follow-up, we believe that applying the WIfI classification to this population demonstrates its universal applicability as previous validation studies were not performed in patients in an urban, safety net hospital setting. The other advantage of this patient population is the advanced stages of disease and typically poorly controlled comorbidities, further validating the predictive value of the WIfI classification despite these potentially confounding factors.

CONCLUSIONS

The SVS WIfI amputation risk score correlates well with relative risk of amputation. The WIfI classification appears to account for the influence of comorbidities on the risk of amputation. Revascularization is beneficial in reducing the risk of amputation even in patients who present with high-risk WIfI amputation scores. Further work needs to be done to determine the exact risk of amputation associated with each amputation score as well as further stratification of patients who will benefit from a revascularization procedure versus those who will not.

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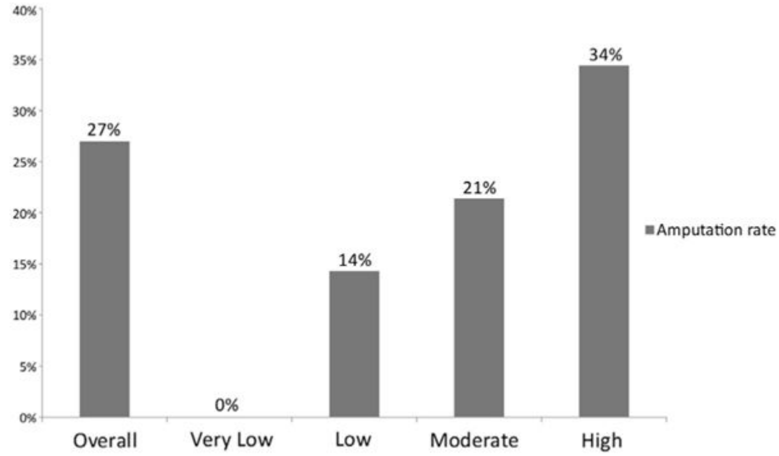

Fig. 1.

Amputation rates by WIfI amputation score.

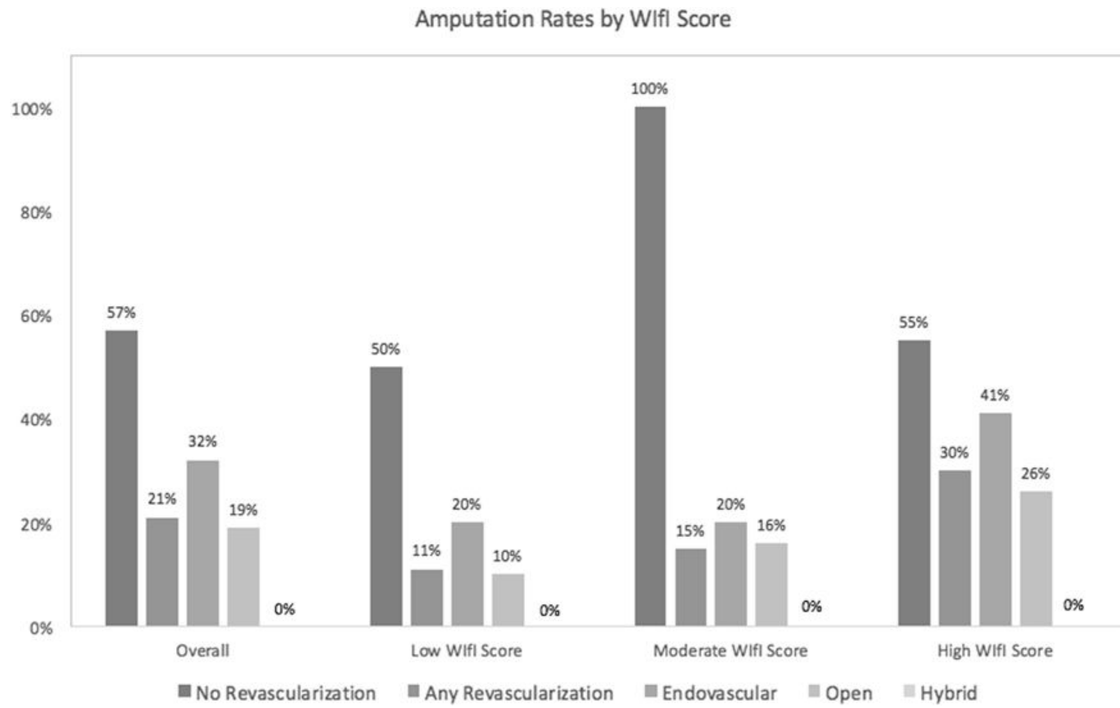

Fig. 2.
Amputation rates by WIfI amputation score and revascularization technique.

Table I

Distribution of WIfI amputation and revascularization scores

WIfI grades and scores	*n*(%)
Wound grade	
0	24 (24)
1	22 (22)
2	42 (43)
3	10 (10)
Ischemia grade	
0	6 (6)
1	8 (8)
2	17 (17)
3	67 (68)
Foot infection grade	
0	37 (38)
1	20 (20)
2	34 (35)
3	7 (7)
WIfI amputation score	
Very low	5 (5)
Low	21 (21)
Moderate	14 (14)
High	58 (59)
WIfI revascularization score	
Very low	9 (9)
Low	3 (3)
Moderate	20 (20)
High	66 (67)

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Table II

Distribution of diabetes and hemodialysis dependence by WIFI amputation score and 12-month major amputation status

Amputation score and status	Diabetes (%)	*P* value	Hemodialysis (%)	*P* value
WIFI amputation score				
Very low	4 (80)	0.07	0	0.3
Low	13 (61.9)		0	
Moderate	7 (50)		0	
High	47 (81)		5 (8.6)	
Twelve-month major amputation				
Yes	18 (69.2)	0.67	4 (15.4)	0.005
No	53 (73.6)		1 (1.4)	