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Prior Endovascular Intervention is Not Detrimental to Pedal Bypasses for Ischemic Wounds

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Abstract

Introduction—Endovascular strategies are often preferred for revascularization of ischemic foot wounds secondary to infrapopliteal disease due to the less invasive technique and faster recovery. Bypass is typically reserved for failures or lesions not amenable to balloon angioplasty. However, the effects of an endovascular-first approach on subsequent bypass grafts is largely unknown. This study evaluates the effects of prior tibial interventions on successive bypasses to pedal targets.

Methods—Patients who presented with ischemic tissue loss and tibial arterial occlusive disease to UPMC between 2006 and 2013 and underwent a surgical bypass to pedal arteries were included in this study. A retrospective chart review was conducted to obtain patient demographics, past medical history, extent of disease, prior tibial endovascular interventions, the treatment intervention, subsequent interventions, wound healing status, limb salvage, and patient survival. The primary outcome was primary patency of the pedal bypass graft.

Results—From 122 eligible patients, 27 had a prior endovascular tibial intervention (PTI) while 95 had no prior tibial intervention (nPTI) in the treatment of ischemic pedal wounds with mean follow-up of 24.5 and 20.5 months respectively ($P = 0.36$). The two groups were largely similar in terms of demographics, co-morbidities, wound size, and degree of ischemia. Runoff scores between the two groups were also comparable (5.0 ± 1.6 for PTI and 4.8 ± 1.9 for nPTI, $P = 0.59$). The plantar artery was a more common target vessel in the PTI group, while the posterior tibial artery was targeted more often in the nPTI group ($P = 0.04$). At 12 months, those with a prior tibial intervention exhibited a shorter primary patency (34.8% vs. 60.2%, $P = 0.04$). In a multivariate model, PTI was a significant risk factor for primary patency loss (HR 2.51, $P = 0.004$). Primary-assisted patency and secondary patency were similar between the two groups. Wound healing was improved in those patients who had a prior endovascular intervention with 63.8% healed at one

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year compared to only 34.8% of those without intervention ($P = 0.01$). Amputation-free survival was similar ($P = 0.68$), as was survival alone ($P = 0.50$).

Discussion—Despite a decrease in primary patency, pedal bypass was not otherwise negatively affected by a prior tibial intervention. Similar primary assisted patency, secondary patency, wound healing, and survival between the two patient populations indicate an endovascular-first approach is a feasible treatment strategy to achieve similar clinical outcomes in the management of ischemic foot wounds.

1. Introduction

Critical limb ischemia (CLI), the end stage of peripheral arterial disease (PAD), is a complex disease state characterized by poorer wound healing, increased risk of amputation, and increased mortality [1]. With mortality rates as high as 25% and amputation rates as high as 40% [2], early and effective revascularization procedures are critical. This is particularly challenging for CLI with tibial vessel involvement as both surgical and endovascular therapies are associated with poorer limb prognosis compared to more proximal disease [3]. The immediate goal of treatment in patients with CLI is wound healing and limb salvage, which historically has been accomplished through surgical bypass [4].

Improvements in endovascular technologies have provided an alternative treatment strategy that is less invasive yet maintains clinical effectiveness in terms of amputation and survival when compared to bypass surgery [5]. Specifically, endovascular interventions for infra-popliteal arterial disease have been shown to be equivalent to distal bypass in limb salvage and amputation-free survival, though patency rates are typically poorer [6, 7]. In cases where initial endovascular approaches fail, open surgical bypass is often successful in restoring adequate perfusion for limb salvage [8]. The effects of prior endovascular interventions on subsequent bypasses at the infra-popliteal level have not been well described. Therefore, this study's objective is to determine whether an endovascular-first approach has deleterious effects on the success of a subsequent inframalleolar bypass for ischemic wounds.

2. Material and Methods

2.1. Study Approval

This study was approved by the University of Pittsburgh Medical Center (UPMC) Institutional Review board. Patient consent was deemed unnecessary as the study constitutes a retrospective chart review.

2.2. Inclusion/Exclusion Criteria

The population included in this study were patients who presented to UPMC between 2006 and 2013 with ischemic tissue loss and tibial arterial occlusive disease and underwent a bypass to the pedal arteries (dorsalis pedis, distal posterior tibial, or plantar arteries). Eligible patients were required to have at least one follow-up appointment with documentation of the healing status of their wound. Patients were excluded if the index procedure was performed at an outside institution or if the wound on the treated limb could not be characterized or confirmed. Additionally, patients were also excluded if their wound

extended above the ankle or the affected limb had been treated with a prior bypass distal to the popliteal artery.

2.3. Data Collection

Eligible study participants were identified from a prospectively maintained list of patients who have undergone lower extremity bypasses. Additional patients were acquired by a search of the electronic medical record (EMR). All patients in the study had tibial occlusive disease; patients with concomitant disease more proximally were also included. Patients were dichotomized based upon whether they had undergone a prior tibial intervention (PTI) or no prior tibial intervention (nPTI) before the index bypass operation was performed.

Pertinent patient characteristics of those who met the inclusion criteria were obtained through a retrospective review of the EMR. These characteristics included patient demographics, past medical history, smoking history, and prior medications. Diagnoses of interest in the past medical history included coronary artery disease, heart failure, hypertension, hyperlipidemia, diabetes mellitus, hypercoagulable states, chronic obstructive pulmonary disease, lower extremity neuropathy, and cerebrovascular disease. Using the medical record, wounds were retrospectively categorized based on Wound, Ischemia, foot Infection (WIFI) criteria, which have been validated as a predictor of amputation risk and perceived benefit of revascularization [9]. Treatment characteristics such as timing, number of procedures, and initial complications were all considered. Distal outflow resistance was assessed by runoff scores as previously described in Society for Vascular Surgery reporting standards [10].

The primary outcome was primary graft patency, defined as freedom from any stenosis or intervention, as documented by subsequent inpatient or outpatient visits. Primary assisted and secondary patency, wound healing, major (above-ankle) amputation, major adverse limb events (MALE, defined as a composite of major amputation or major reintervention) [11], and mortality were studied as secondary outcomes.

2.4. Statistical Analysis

Data was compiled in Excel (Microsoft, Redmond, WA) and analyzed using Stata 15.0 (StataCorp, College Station, TX). Baseline characteristics were compared using Student's T-test or the Chi-squared test for continuous and categorical data, respectively. 30-day postoperative outcomes were compared in a similar fashion. Time-dependent outcomes (wound healing, amputation, mortality, and patency outcomes) were compared by survival analysis. Kaplan-Meier curves, stratified by treatment group, were used to depict differences, and the log-rank test was used to assess them. Cox proportional hazards models were utilized for identification of univariate and multivariate risk factors for the primary outcome. The final multivariate model was selected in a backward-stepwise fashion starting with significant or near-significant univariate risk factors. For all statistical tests, a P-value of <0.05 was considered to be statistically significant. For all Kaplan-Meier graphs, standard error was 10% at all points on all curves shown.

3. Results

3.1. Patient Population

We identified 130 patients who underwent pedal bypass during the study period. Of these, eight patients were excluded for having undergone a prior distal bypass. The remaining 122 patients met the eligibility criteria to participate in this study; 27 of these patients had a prior endovascular tibial intervention (PTI) while 95 did not (nPTI). The mean follow-up time was 20.5 months for the PTI group and 24.5 months for the nPTI group ($P = 0.36$).

3.2. Baseline Characteristics and Procedural Details

Demographic comparisons showed no statistically significant difference in age, gender or race between the PTI and nPTI groups (Table I). Additionally, past medical history was similar between the two groups except that PTI patients were more likely to be on warfarin therapy (37.0% vs. 16.8%, $P = 0.05$) and antiplatelet therapy (74.1% vs. 42.1%, $P = 0.03$).

Wound size and degree of ischemia were similar between the two comparison groups (Table II). No patients demonstrated systemic infections prior to the bypass procedure, but PTI patients were more likely to have moderate localized cellulitis or purulence pre-operatively (44.4% vs. 20.0%, $P = 0.03$). Runoff scores between the two patient groups were similar, indicating comparable pedal outflow resistance for the bypasses (Table II).

The most common inflow artery was the below knee popliteal artery (70%) and the frequency of use was similar between groups. In contrast, there was a statistically significant difference in target vessels between groups. More plantar artery targets were chosen as target vessels in the PTI group (25.9% vs. 9.5%) and more posterior tibial artery targets in the nPTI group (14.7% vs 3.7%, $P = 0.04$). The type of conduit was similar in both groups (Table III).

3.3. Wound Care

The wound care regimen was the same in all patients regardless of treatment performed. Wound care was coordinated in all patients by the vascular surgeon, who would evaluate wounds in the office at least on a biweekly basis and determine the optimal local wound care strategy alone or in conjunction with a podiatrist. Dressing changes and other aspects of wound care may have been provided by the patient or family members, visiting nurses, or staff at a skilled nursing facility as appropriate for each patient's individual needs.

3.4. Post-Operative Outcomes

30-day post-operative outcomes are detailed in Table IV and were generally similar. Mortality rates were low and similar between the PTI and nPTI groups (0% vs. 1.1%, $P = 1.00$), as were major amputation rates (0% vs. 1.1%, $P = 1.00$). There was no difference in the re-intervention rate in the immediate post-operative period (14.8% vs. 10.5%, $P = 0.51$). Hospital length of stay, discharge disposition, and ambulatory status were also similar between groups.

3.5. Long-Term Patency and Clinical Outcomes

Primary patency was significantly lower in the PTI group compared to the nPTI group ($P = 0.04$; Fig. IA). At one year, primary patency was 34.8% vs. 60.2% in the PTI and nPTI groups, respectively. Upon Cox regression analysis, PTI was found to be a predictor of loss of primary patency (HR 1.81, 95% CI 1.01–3.25, $P = 0.045$). Other significant or near-significant univariate predictors for loss of primary patency included CHF (HR 1.79, 95% CI 0.99–3.21, $P = 0.052$), history of CVA (HR 2.48, 95% CI 1.24–4.95, $P = 0.01$), current smoking (HR 2.12, 95% CI 1.08–4.13, $P = 0.03$), supragenicular inflow artery (HR 1.99, 95% CI 1.16–3.43, $P = 0.01$), and non-GSV conduit (HR 1.76, 95% CI 1.01–3.09, $P = 0.048$). A multivariate regression model was constructed using these predictors and is shown in Table V. Adjusting for these factors, prior tibial intervention was a significant risk factor for loss of primary patency (HR 2.51, 95% CI 1.34–4.72, $P = 0.004$). Of note, bypass target artery and runoff scores were investigated and did not contribute significantly to our multivariate model ($P = 0.97$ and $P = 0.28$, respectively, by a likelihood ratio test).

Primary assisted ($P = 0.58$; Fig. IB) and secondary patency ($P = 0.47$; Fig. IC) were similar between the two groups. At one year, primary assisted patency was 75.0% vs. 79.7% and secondary patency was 75.0% vs. 80.2%, respectively. PTI was not found to be a univariate risk factor for loss of primary assisted ($P = 0.63$) or secondary patency ($P = 0.52$). A multivariate model was constructed for each outcome with the same factors listed in Table V; in these models, PTI remained a non-significant predictor of loss of primary assisted ($P = 0.25$) or secondary patency ($P = 0.23$).

Wound healing rates were higher in the PTI group ($P = 0.01$; Fig. II). The rate of successful wound healing was 63.8% in the PTI group compared to 34.8% in the nPTI group at one year. Freedom from MALE was similar between groups ($P = 0.77$; Fig. IIIA) and was 79.6% vs. 77.0% at one year. Amputation-free survival was also similar (72.1% vs. 76.2%, $P = 0.68$; Fig. IIIB), as was survival alone (78.3% vs. 87.6%, $P = 0.50$; Fig. IIIC).

4. Discussion

This study served to determine the effects of prior endovascular interventions on subsequent inframalleolar bypasses with a pedal target for ischemic foot wounds. We found that, in our cohort, prior intervention did not significantly compromise wound healing, limb salvage, or mortality rates in patients with tibial arterial disease. There was, however, a notably decreased primary patency in the patients with a prior intervention. This may be linked to the need for more distal target arteries after a prior intervention. Though our analysis did not identify the target artery as a predictor of failure, we noted that 25.9% of the PTI patients underwent bypass to a plantar vessel compared to 9.5% of the nPTI patients. The use of a plantar vessel in lieu of the distal posterior tibial artery may be due to the compromise of the latter by the prior intervention. Studies on femoropopliteal interventions have shown a similar effect in necessitating the use of more distal bypass targets [12]. A more distal bypass often requires a longer, potentially more compromised conduit placed in an area of increased pressure with ambulation. This could in turn impact primary patency. Despite the large difference in primary patency between groups, primary assisted and secondary patency were

nearly identical, suggesting that a prior tibial intervention does not significantly impact the overall patency of a pedal bypass, albeit with a greater need for re-interventions.

A second explanation for our findings is that those who underwent prior tibial intervention had more significant, multi-level disease. However, we would expect that, based on our general practice, a heavier disease burden would predispose a patient to undergo a primary bypass operation rather than an endovascular intervention. Furthermore, a number of our findings indicate that our results are not a consequence of disease burden alone. We found no difference in the inflow artery used for the bypass, suggesting the degree of more proximal disease was similar. While a supragenicular inflow was found to be a risk factor for primary patency loss, PTI remained a risk factor after adjusting for the inflow effect. Runoff scores, a measure of the distal outflow, were similar between groups and not found to be a predictor in our model.

The rate of wound healing was significantly faster in the patients with PTI. While the reason for this observation is unclear, one would expect that the prior tibial angioplasty may have begun the wound healing process, resulting in a lower wound burden in these patients at the time of their bypass operation. The WIfI wound scores, however, were similar between the two groups. Another potential explanation for this difference in healing rates is that the PTI patients may have been receiving treatment for longer periods of time prior to their bypass procedure, thereby optimizing their co-morbidities to improve overall healing. Diabetes mellitus, renal impairment, and poor nutritional status are all known to impair wound healing and may have been better optimized in the PTI group at the time of the bypass [13]. Nevertheless, prior tibial intervention does not appear to have a detrimental effect on wound healing.

Aside from wound healing, we found no difference in the rate of any other clinical limb-related outcome. The similarities in major adverse limb events and amputation-free survival indicate that these patients, and the bypass grafts themselves, seem to be minimally affected by a prior tibial intervention. Our findings suggest that an endovascular-first approach is reasonable in patients with tissue loss and tibial artery occlusive disease and does not significantly impact the clinical success rate of a subsequent bypass operation.

The limitations of this study arise from its retrospective nature. There was likely inherent selection bias; in particular, patients not offered a prior endovascular intervention may have undergone a primary bypass operation due to a greater anatomic disease burden or a more severe wound. There may also have been some patients who no longer had suitable anatomy for a bypass after having a prior tibial intervention; these patients would not be included in our study. Additionally, the medical records detailing wound characteristics and size were largely non-uniform, often providing somewhat subjective documentation that made it more difficult to score wounds by WIfI criteria. Inconsistent patient follow-up also made it difficult to document exact time of wound healing. Finally, pedal bypass is a relatively infrequent procedure and a larger sample size would have allowed for more precise estimates and identification of risk factors for bypass failure after a prior intervention.

Despite these limitations, our study demonstrates that the secondary patency, wound healing, and limb salvage rates after a pedal bypass are not negatively affected by a prior endovascular tibial intervention. In many patients, an endovascular-first approach may be beneficial and does not preclude success with a subsequent distal bypass operation.

5. Conclusion

In patients with infrapopliteal arterial occlusive disease and ischemic foot wounds, endovascular tibial intervention is commonly used as a first-line treatment as it is less invasive and better tolerated than surgical bypass. This study demonstrates that, despite a decreased primary patency attributable to the need for more distal target vessels, prior endovascular tibial interventions do not significantly impact primary assisted or secondary patency, wound healing, or amputation rates in patients who underwent a subsequent inframalleolar bypass procedure. Endovascular tibial intervention is a lower-risk, reasonable treatment choice in these patients and only marginally affects the outcome of a subsequent pedal bypass.

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Fig. 1.

Kaplan-Meier curves showing patency outcomes stratified by treatment group. The three curves show primary (A), primary assisted (B), and secondary patency (C). PTI: prior tibial intervention; NoPTI: no prior tibial intervention.

Fig. 2. Kaplan-Meier curves showing wound healing rates stratified by treatment group. PTI: prior tibial intervention; NoPTI: no prior tibial intervention.

Fig. 3. Kaplan-Meier curves showing freedom from MALE (A), amputation-free survival (B), and overall survival (C), stratified by treatment group. PTI: prior tibial intervention; NoPTI: no prior tibial intervention.

Table I

Baseline characteristics, stratified by treatment group.

Factor	PTI N=27	No PTI N=95	P-Value
Demographics			
Age (mean)	72.0±9.9	69.8±9.8	0.425
Gender (% Male)	22 (81.5%)	72 (75.8%)	0.613
Ethnicity (% Minority)	5 (18.5%)	19 (20.0%)	1.000
Medical History			
Diabetes mellitus	22 (81.5%)	79 (83.2%)	0.781
Renal Insufficiency	8 (29.6%)	37 (38.9%)	0.499
End-Stage Renal Disease	4 (14.8%)	22 (23.2%)	0.433
Hypertension	21 (77.8%)	83 (87.4%)	0.351
Hyperlipidemia	17 (63.0%)	47 (49.5%)	0.308
Prior Myocardial Infarction	8 (29.6%)	32 (33.7%)	0.870
Coronary Artery Disease	19 (70.4%)	63 (66.3%)	0.870
Coronary Artery Bypass	5 (18.5%)	30 (31.6%)	0.232
Chronic Obstructive Pulm. Dis.	5 (18.5%)	7 (7.4%)	0.135
Cerebral Vascular Accident	4 (14.8%)	12 (12.6%)	0.752
Tobacco Smoking History	14 (51.9%)	45 (47.4%)	0.828
Warfarin Therapy	10 (37.0%)	16 (16.8)%	0.046
Statin Therapy	11 (40.7%)	48 (50.5%)	0.497
B-Blocker Therapy	14 (51.9%)	59 (62.1%)	0.461
Anti-Platelet Therapy	20 (74.1%)	40 (42.1%)	0.025

PTI: prior tibial intervention; nPTI: no prior tibial intervention.

Table II

Pre-operative wound characteristics scored by Wound, Ischemia, foot Infection (WIFI) classification system.

Factor	PTI N=27	No PTI N=95	P-Value
Wound Status			
No	0	0	0.759
Minor	5 (18.5%)	15 (15.8%)	
Major	18 (66.7%)	60 (63.2%)	
Extensive	4 (14.8%)	20 (21.1%)	
Ischemia			
Grade 0 (ABI 0.8, TP 60)	1 (3.7%)	8 (8.4%)	0.254
Grade 1 (ABI 0.6–0.79, TP 40–59)	7 (25.9%)	11 (11.6%)	
Grade 2 (ABI 0.4–0.59, TP 30–39)	1 (3.7%)	9 (9.5%)	
Grade 3 (ABI < 0.4, TP < 30)	11 (40.7%)	35 (36.8%)	
Existing Foot Infection			
No	10 (37.0%)	55 (57.9%)	0.034
Mild (< 2cm Cellulitis)	5 (18.5%)	21 (22.1%)	
Moderate (Cellulitis or Purulence)	12 (44.4%)	19 (20.0%)	
Extensive (Sepsis)	0	0	
Target Status			
Runoff Score	5.0 ± 1.6	4.8 ± 1.9	0.594

PTI: prior tibial intervention; nPTI: no prior tibial intervention. ABI: ankle-brachial index; TP: toe pressure.

Table III

Technical details of bypass operations.

Factor	PTI N=27	No PTI N=95	P-Value
Inflow Artery			
Above Knee	8 (29.7%)	25 (26.3%)	0.923
Below Knee	19 (70.3%)	70 (73.7%)	
Target Artery			
Dorsalis Pedal Artery	19 (70.3%)	72 (75.8%)	0.039
Posterior Tibial Artery	1 (3.7%)	14 (14.7%)	
Plantar Artery	7 (25.9%)	9 (9.5%)	
Conduit			
Great Saphenous Vein	24 (88.9%)	71 (74.7%)	0.517
Small Saphenous Vein	1 (3.7%)	3 (3.2%)	
Arm Vein	0	4 (4.2%)	
Spiced Vein	2 (7.4%)	16 (16.8%)	
Prosthetic Graft	0	1 (1.1%)	

PTI: prior tibial intervention; nPTI: no prior tibial intervention.

Table IV

30-day post-operative outcomes.

Factor	PTI	No PTI	P-value
Length of Stay (mean $\pm$ SD)	12.7 $\pm$ 6.0	10.2 $\pm$ 4.2	0.179
# Ambulatory	18 (66.7%)	74 (77.9%)	0.346
# Discharge Home	13 (48.1%)	33 (34.7%)	0.297
30-Day Complications			
Cardiac or Respiratory Arrest	1 (3.7%)	4 (4.2%)	1.000
Death	0	1 (1.1%)	1.000
Urinary Tract Infection	1 (3.7%)	10 (10.5%)	0.453
Deep Vein Thrombosis	0	0	1.000
Minor Amputations	6 (22.2%)	33 (34.7%)	0.319
Major Amputations	0	1 (1.1%)	1.000
Myocardial Infarction	1 (3.7%)	4 (4.2%)	1.000
Renal Failure	0	3 (3.2%)	1.000
Pneumonia	0	2 (2.1%)	1.000
Cerebral Vascular Accident	0	1 (1.1%)	1.000
Wound Complication	2 (7.4%)	16 (16.8%)	0.357
Second Procedure	4 (14.8%)	10 (10.5%)	0.509

PTI: prior tibial intervention; nPTI: no prior tibial intervention.

Table V

Univariate and multivariate predictors of loss of primary patency.

Factor	Univariate			Multivariate		
	HR	95% CI	P-Value	HR	95% CI	P-Value
PTI	1.81	1.01–3.25	0.045	2.51	1.34–4.72	0.004
CHF	1.79	0.99–3.21	0.052	1.87	1.01–3.48	0.048
CVA	2.48	1.24–4.95	0.01	2.40	1.16–4.99	0.02
Current Smoker	2.12	1.14–3.96	0.02	2.61	1.31–5.17	0.006
AK Inflow	1.99	1.16–3.43	0.01	1.71	0.97–3.00	0.06
Non-GSV	1.76	1.00–3.09	0.048	1.89	1.06–3.40	0.03

PTI: prior tibial intervention; CHF: congestive heart failure; CVA: cerebrovascular accident; AK: above-knee; GSV: great saphenous vein.