From the Society for Vascular Surgery

Outcomes of lower extremity revascularization among the hemodialysis-dependent

John M. Fallon, MD,[a] Philip P. Goodney, MD, MS,[a] David H. Stone, MD,[a] Virendra I. Patel, MD, MPH,[b] Brian W. Nolan, MD, MS,[a] Jeffrey A. Kalish, MD,[c] Yuanyuan Zhao, MS,[a] and Allen D. Hamdan, MD,[d] for the Vascular Study Group of New England, *Lebanon, NH; and Boston, Mass*

Objective: **Optimal patient selection for lower extremity revascularization remains a clinical challenge among the hemodialysis-dependent (HD). The purpose of this study was to examine contemporary real world open and endovascular outcomes of HD patients to better facilitate patient selection for intervention.**

Methods: **A regional multicenter registry was queried between 2003 and 2013 for HD patients (N = 689) undergoing open surgical bypass (n = 295) or endovascular intervention (n = 394) for lower extremity revascularization. Patient demographics and comorbidities were recorded. The primary outcome was overall survival. Secondary outcomes included graft patency, freedom from major adverse limb events, and amputation-free survival (AFS). Multivariate analysis was performed to identify independent risk factors for death and amputation.**

Results: **Among the 689 HD patients undergoing lower extremity revascularization, 66% were male, and 83% were white. Ninety percent of revascularizations were performed for critical limb ischemia and 8% for claudication. Overall survival at 1, 2, and 5 years survival remained low at 60%, 43%, and 21%, respectively. Overall 1- and 2-year AFS was 40% and 17%. Mortality accounted for the primary mode of failure for both open bypass (78%) and endovascular interventions (80%) at two years. Survival, AFS, and freedom from major adverse limb event outcomes did not differ significantly between revascularization techniques. At 2 years, endovascular patency was higher than open bypass (76% vs 26%; 95% confidence interval [CI], 0.28-0.71; $P = .02$). Multivariate analysis identified age ≥80 years (hazard ratio [HR], 1.9; 95% CI, 1.4-2.5; $P < .01$), indication of rest pain or tissue loss (HR, 1.8; 95% CI, 1.3-2.6; $P < .01$), preoperative wheelchair/bedridden status (HR, 1.5; 95% CI, 1.1-2.1; $P < .01$), coronary artery disease (HR, 1.5; 95% CI, 1.2-1.9; $P < .01$), and chronic obstructive pulmonary disease (HR, 1.4; 95% CI, 1.1-1.8; $P = .01$) as independent predictors of death. The presence of three or more risk factors resulted in predicted 1-year mortality of 64%.**

Conclusions: **Overall survival and AFS among HD patients remains poor, irrespective of revascularization strategy. Mortality remains the primary driver for these findings and justifies a prudent approach to patient selection. Focus for improved results should emphasize predictors of survival to better identify those most likely to benefit from revascularization. (J Vasc Surg 2015;62:1183-91.)**

Overall survival among hemodialysis-dependent (HD) patients undergoing lower extremity (LE) revascularization remains the crux for surgical decision making in this challenging patient population. Despite advances in surgical techniques, there has been little improvement in outcomes among these patients. In fact, 2-year overall survival rates following LE bypass in this population remain 23% to 52%.[1-6] With less than 25% of HD patients with a foot lesion alive at 5 years, the prognosis of a HD patient with peripheral artery disease (PAD) remains worse than most cancers.[7] Furthermore, PAD is a common and growing problem in HD patients. PAD has been shown to affect nearly one-third of patients on HD,[8] and, according to the U.S. Department of Health and Human Services, end-stage renal disease (ESRD) has increased by 600% over the past three decades. The advent and evolution of catheter-based therapies, however, may offer a less morbid therapeutic alternative for limb salvage in this patient population, though contemporary outcomes remain limited.

With an increasingly prevalent population of highly morbid HD patients with PAD, it is necessary to discern methods to optimize the delivery of LE revascularization. Interestingly, studies that demonstrated dismal survival reported satisfactory graft patency and limb salvage rates (60%-74% and 50%-85% at 2 years, respectively).[1-6] The contrast between poor survival and acceptable patency implies that many patients die from causes unrelated to

From the Division of Vascular Surgery, Dartmouth-Hitchcock Medical Center, Lebanon[a]; the Division of Vascular Surgery, The Massachusetts General Hospital,[b] the Division of Vascular Surgery, Boston University Medical Center,[c] and the Division of Vascular Surgery, Beth Israel Deaconess Medical Center,[d] Boston.

Author conflict of interest: none.

Presented at the 2014 Vascular Annual Meeting of the Society for Vascular Surgery, Boston, Mass, June 5-7, 2014.

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

Correspondence: John M. Fallon, MD, Department of Surgery, Dartmouth-Hitchcock Medical Center, One Medical Center Dr, Lebanon, NH 03756 (e-mail: john.m.fallon@hitchcock.org).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

http://dx.doi.org/10.1016/j.jvs.2015.06.203

Table I. Patient and procedural characteristics

Patient demographics	*Overall (N = 689)*	*Surgical open bypass (n = 295)*	*Endovascular (n = 394) 686 segments*	P *value*
Age, years				
<60	182 (26)	74 (25)	108 (27)	.35
60-69	210 (31)	84 (29)	126 (32)	
70-79	191 (28)	92 (31)	99 (25)	
>80	106 (15)	45 (15)	61 (16)	
Male gender	455 (66)	194 (66)	261 (66)	.90
Smoking				
Never	194 (28)	69 (23)	125 (32)	.05
Past	362 (53)	162 (55)	200 (51)	
Current	132 (19)	63 (21)	69 (18)	
CAD	342 (50)	158 (54)	184 (47)	.08
COPD	174 (25)	89 (30)	85 (22)	.01
CHF	296 (43)	130 (44)	166 (42)	.63
HTN	655 (95)	286 (97)	369 (94)	.05
DM				
None	135 (20)	60 (20)	75 (19)	.67
Any diabetes	554 (80)	235 (80)	319 (81)	
Ambulatory status				
Amb	379 (55)	159 (54)	220 (56)	.16
Amb w/ assistance	207 (30)	100 (34)	107 (27)	
Wheelchair	84 (12)	31 (11)	53 (14)	
Bedridden	17 (3)	5 (2)	12 (3)	
Living				
Home	618 (90)	271 (92)	347 (88)	.10
Nursing home/homeless	71 (10)	24 (8)	47 (12)	
Indication				
CLI (rest pain/tissue loss/acute ischemia)	617 (90)	276 (95)	341 (90)	.027
Claudication	52 (8)	15 (5)	37 (10)	
Procedure characteristics				
Urgency				
Elective	448 (65)	200 (68)	248 (63)	.41
Urgent	230 (33)	91 (31)	139 (35)	
Emergent	11 (1)	4 (1)	7 (2)	
At- or below-knee target	617 (63)	242 (82)	375 (55)	<.01
Above-knee target	363 (37)	52 (18)	311 (45)	<.01

Amb, Ambulatory; *CAD,* coronary artery disease; *CHF,* congestive heart failure; *CLI,* critical limb ischemia; *COPD,* chronic obstructive pulmonary disease; *DM,* diabetes mellitus; *HTN,* hypertension.
Data are presented as number (%).

their affected extremity. Thus, further work should focus on identifying HD patients with increased survival potential that can derive benefit from undergoing revascularization.

Therefore, the goal of this project was to conduct a contemporary, multicenter analysis of HD patients undergoing lower extremity revascularization. We queried patients within the Vascular Study Group of New England (VSGNE) to better understand relationships between revascularization, ESRD, and patient- and limb-related outcomes.

METHODS

Subjects and database. Data was collected using the VSGNE regional quality improvement registry. Included subjects were HD who underwent LE revascularization at or distal to the common iliac artery (n = 689) over the study interval (2003-2013). The overall group was stratified by revascularization technique: open surgical bypass (n = 295) and endovascular revascularization (n = 394). Patient demographics, comorbidities, and surgical characteristics were recorded. Indications for revascularization primarily included critical limb ischemia (rest pain, tissue loss, acute limb threatening ischemia) and a small subset of patients (<10%) with claudication. Aortic procedures were excluded.

Definitions. All included procedures were identified as the first revascularization noted for each patient. Although some patients ultimately underwent either open or catheter-based reintervention during the study period, clinical outcomes were associated with the index procedure.

Outcome measures. Patient demographics and surgical characteristics of the cohort were analyzed and stratified by revascularization technique. Analysis of short- and long-term outcomes were similarly examined by overall, surgical, and endovascular techniques. Follow-up reporting was done at 30 days, and 1, 2, and 5 years. The main outcome measure was overall survival. Secondary outcomes examined were patency, freedom from major adverse limb event (MALE), and amputation-free survival (AFS).