PAPER

Outcomes of Open Operation for Aortoiliac Occlusive Disease After Failed Endovascular Therapy

Rachel C. Danczyk, MD; Erica L. Mitchell, MD; Bryan D. Petersen, MD; James Edwards, MD; Timothy K. Liem, MD; Gregory J. Landry, MD; Gregory L. Moneta, MD

Objectives: To compare patient outcomes of primary open operation for aortoiliac occlusive disease (AIOD) with those of secondary open operations for failed endovascular therapy (ET) of AIOD.

Design: A retrospective cohort study was performed analyzing demographic characteristics, comorbidities, and outcomes.

Setting: Affiliated Veterans Affairs Hospital from January 1, 1998, through March 31, 2010.

Patients: Patients who underwent primary open operation for AIOD or secondary open operation for failed ET of AIOD.

Main Outcome Measures: Overall survival and limb salvage.

Results: Primary open operations (n = 153) were 67 aortobifemoral grafts (43.8%), 38 axillobifemoral grafts (24.8%), and 48 femoral-femoral grafts (31.4%). Secondary open operations (n = 35) were 28 aortobifemoral grafts (80.0%), 5 axillobifemoral grafts (14.3%), and 2 femoral-femoral grafts (5.7%). Mean (SD) 5-year survival was 48.2% (5.6%) and 66.8% (10.0%), respectively, for patients undergoing primary vs secondary open surgery for AIOD ($P = .01$). There were 7 amputations during a mean follow-up of 3 years, all in the primary open surgery group.

Conclusions: Despite a higher proportion of coronary artery disease and a 20% conversion of claudication to critical limb ischemia after failed ET for AIOD, survival was longer in patients undergoing secondary vs primary open surgery. Patients who underwent open surgery after failed ET for AIOD did not require amputation. Failed ET for AIOD does not lead to worse outcomes for patients undergoing open surgery for AIOD.

Arch Surg. 2012;147(9):841-845

ENDOVASCULAR THERAPY (ET) is the primary treatment for most patients with sufficiently symptomatic aortoiliac occlusive disease (AIOD). The current literature[1-5] supports this approach with patency rates of greater than 75% for ET of AIOD, including series partially composed of patients with advanced AIOD lesions (TransAtlantic Inter-Society Consensus class D). Primary operative management is, however, also reasonable treatment of advanced AIOD lesions.

See Invited Critique at end of article

Although frequently performed, primary ET of infrainguinal peripheral artery disease may limit and worsen surgical outcomes when ET has failed. The Bypass vs Angioplasty in Severe Ischaemia of the Leg trial showed that patients undergoing infrainguinal bypass after failed angioplasty have worse outcomes than those treated with bypass alone.[6] This finding was duplicated by the Vascular Study Group of New England[7]; however, it is not known whether surgical outcomes are worse after failed angioplasty and stenting of symptomatic AIOD compared with primary operative management for symptomatic AIOD. Given the outcomes literature available for those patients with infrainguinal peripheral artery disease undergoing ET, we hypothesized that patients who undergo open operation after failed ET for AIOD have worse survival and limb salvage rates than patients undergoing primary operative management of AIOD. This study therefore compared survival and limb salvage rates of patients undergoing primary open operations for symptomatic AIOD with those of patients undergoing secondary open operations for failed ET of symptomatic AIOD.

Author Affiliations: Division of Vascular Surgery (Drs Danczyk, Mitchell, Liem, Landry, and Moneta) and The Dotter Institute (Dr Petersen), Oregon Health & Science University, and Portland Veterans Affairs Medical Center (Drs Petersen and Edwards), Portland, Oregon.

Table 1. Clinical Characteristics of Patient Groups

Variable	Primary (n = 153)	Secondary (n = 35)	*P* Value[a]
Age, mean (SD), y	63.0 (9.6)	60.9 (6.2)	.24
Female sex, No. (%)	2 (1.3)	3 (8.6)	.05
Comorbidity, No. (%)			
CAD	72 (47.1)	25 (71.4)	.01
DM	39 (25.5)	10 (28.6)	.68
HTN	107 (69.9)	27 (77.1)	.54
HLD	69 (45.1)	22 (62.9)	.06
CRI	10 (6.5)	1 (2.9)	.69
HD	2 (1.3)	0	>.99
Tobacco history	136 (88.9)	34 (97.1)	.20
Medication, No. (%)			
Aspirin	74 (48.4)	32 (91.4)	<.01
Warfarin sodium	13 (8.5)	2 (5.7)	.74
Beta-blocker	51 (33.3)	16 (45.7)	.18
Clopidogrel bisulfate	4 (2.6)	5 (14.3)	.01
Statin	62 (40.5)	21 (60.0)	.04
Operation type, No. (%)			
Aortobifemoral	67 (43.8)	28 (80.0)	
Axillobifemoral	38 (24.8)	5 (14.3)	<.01
Femoral-femoral	48 (31.4)	2 (5.7)	
Indication, No. (%)			
Claudication	68 (44.4)	15 (42.9)	>.99
CLI	85 (55.6)	20 (57.1)	>.99
Rest pain	40 (26.1)	8 (22.9)	.83
Ulcer	21 (13.7)	4 (11.4)	>.99
Gangrene	11 (7.2)	0	.22
Acute ischemia	13 (8.5)	10 (28.6)	<.01

Abbreviations: CAD, coronary artery disease; CLI, critical limb ischemia; CRI, chronic renal insufficiency; DM, diabetes mellitus; HD, hemodialysis; HLD, hyperlipidemia; HTN, hypertension.

[a] By Pearson χ^2 test or Fisher exact test (when n < 10).

METHODS

PATIENTS

A total of 153 consecutive patients who underwent open surgical aortoiliac reconstruction for AIOD (aortobifemoral, axillobifemoral, or femoral-femoral bypass) from January 1, 1998, through March 31, 2010, at the Portland Veterans Affairs Medical Center were identified. These patients were included in the primary operation group.

Device implantation records were used to create a list of 35 patients who underwent operative reconstruction (aortobifemoral, axillobifemoral, or femoral-femoral bypass) for limb salvage after failed ET for AIOD from January 1, 1998, through March 31, 2010. These patients constituted the secondary operation group.

Demographic characteristics captured included sex and age. Comorbidities assessed were coronary artery disease, diabetes mellitus, hypertension, hyperlipidemia, chronic renal insufficiency (creatinine >1.5 mg/dL [to convert to micromoles per liter, multiply by 88.4]), end-stage renal disease requiring hemodialysis, and tobacco history. Patients were considered to have coronary artery disease if they had a history of myocardial infarction or a coronary artery bypass graft, or if it was listed in the medical history at initial presentation. Diabetes, hypertension, and hyperlipidemia were considered present if they were listed in the medical history at initial presentation. Patients with a positive tobacco history were either currently smoking at the time of initial presentation or had quit smoking within 10 years of initial presentation. Medications assessed included aspirin, warfarin sodium, beta-blockers, clopidogrel bisulfate, and any medication for the treatment of hypercholesterolemia. Indications for primary operations, such as claudication, rest pain, or tissue loss, were recorded in addition to ankle-brachial indices (ABIs). In the secondary operation group, indications for initial percutaneous treatment and aortoiliac reconstruction were recorded in addition to ABIs.

PROCEDURES

In the primary and secondary operation groups, the type of aortoiliac reconstruction performed was recorded (aortobifemoral, axillobifemoral, or femoral-femoral bypass). Major amputations (transtibial or transfemoral) performed at the time of either primary or secondary operation or during follow-up were also recorded.

FOLLOW-UP

Follow-up included ABI measurement and physical examination. Symptoms including intermittent claudication, rest pain, or tissue loss were recorded.

DATA ANALYSIS

Univariate analysis was performed using the Pearson χ^2 test or Fisher exact test (when n < 10) for categorical variables and the independent *t* test for continuous variables. Survival was calculated using the Kaplan-Meier method. The log-rank test (Mantel-Cox) was used to compare the survival between the primary and secondary operation groups. The survival for the type of operation that patients underwent was analyzed using log-rank pairwise comparisons with Bonferroni correction for more than 2 pairwise comparisons. Multivariate analysis of survival was performed using Cox regression modeling, and variables were entered into the model using the forced entry method. Cox regression analysis was performed specifically to identify risk factors that may affect mortality. Variables associated with outcomes after univariate analysis ($P < .05$) were included in the regression model. All statistical analyses were performed using SPSS, version 19 (SPSS, Inc). $P < .05$ was considered significant.

This study was approved by the institutional review board at the Portland Veterans Affairs Medical Center. Informed consent requirements were waived for this study.

RESULTS

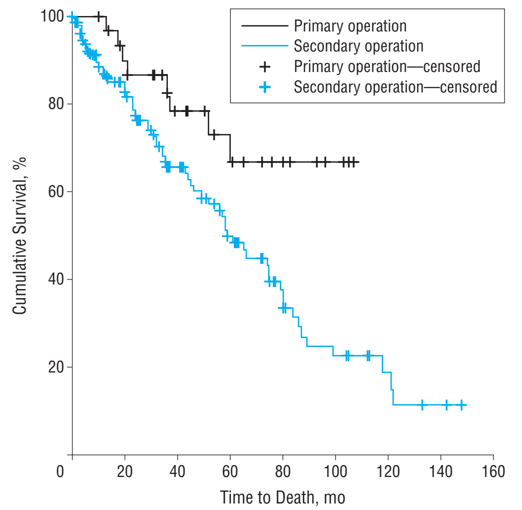
PATIENT CHARACTERISTICS

There were 153 patients treated with primary open operations and 35 patients undergoing operative reconstruction after failed ET for symptomatic AIOD (n=481). Clinical characteristics of patient groups are shown in **Table 1**.

PATIENT OUTCOMES

Ankle-Brachial Indices

The mean (SD) change in ABI postoperatively was 0.29 (0-0.60) for patients in the primary operation group and 0.27 (0-0.60) for those in the secondary operation group. There was no significant difference in ABI improvement between groups ($P = .77$).



Primary operation group

No. at risk	136	81	50	32	19	11	5	1
SE	0.01	0.03	0.05	0.06	0.06	0.06	0.06	0.05

Secondary operation group

No. at risk	32	26	17	12	7	3	0	0
SE	0.01	0.05	0.08	0.10	0.10	0.10	…	…

Figure 1. Comparison of overall survival in the primary and secondary operation groups. Survival was significantly longer in the secondary operation patient group compared with the primary operation group ($P = .01$; Kaplan-Meier method, log-rank test).

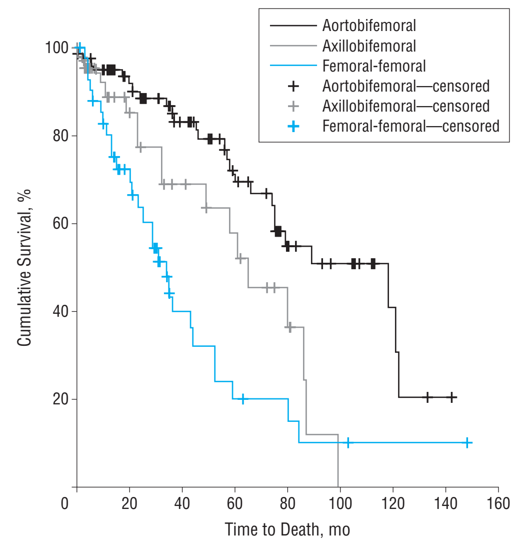
Clinical Outcomes

Of patients in the primary operation group, 26 (17.0%) were lost to follow-up, 65 (42.5%) died, and 7 (4.6%) required major amputations. Of patients in the secondary operation group, none were lost to follow-up, 9 (25.7%) died, and none required major amputations. Given the small number of patients undergoing amputation in this study, data analysis is not shown here.

More patients were lost to follow-up or required major amputation in the primary operation group compared with the secondary operation group; however, only the difference in number of patients lost to follow-up was significant ($P < .01$). Upon comparison of demographic characteristics, comorbidities, medications, types of operations, and indications for operations between patients who were or were not lost to follow-up, there was no significant difference.

The mean (SD) 2-year survival was 76.3% (4.1%) and 82.6% (7.1%), respectively, for patients undergoing primary vs secondary open surgery for AIOD. The mean (SD) 5-year survival was 48.2% (5.6%) and 66.8% (10.0%), respectively, for patients undergoing primary vs secondary open surgery for AIOD ($P = .01$) (**Figure 1**).

Survival was also compared on the basis of the type of aortoiliac reconstruction performed. The mean (SD) 2-year survival was 88.6% (3.8%) for patients who underwent aortobifemoral bypass operations, 60.5% (8.0%) for those with axillobifemoral operations, and 77.4% (7.7%) for those with femoral-femoral operations. The mean (SD) 5-year survival was 69.5% (6.5%) for patients who underwent aortobifemoral bypass operations, 20.0% (7.7%) for those with axillobifemoral operations, and 52.0% (10.8%) for those with femoral-femoral operations. The overall comparison of survival between the operation types was significantly different ($P < .01$) (**Figure 2**). The pairwise comparison of survival between operation types showed that survival after aortobifemoral bypass was longer than survival after femoral-femoral bypass, which was longer than survival after axillobifemoral bypass (all $P < .05$) (Figure 2).



Aortobifemoral group

No. at risk	81	59	43	29	16	11	0	0
SE	0.01	0.03	0.05	0.06	0.08	0.08	…	…

Axillobifemoral group

No. at risk	43	25	10	5	4	2	1	0
SE	0.00	0.07	0.09	0.08	0.07	0.06	0.06	…

Femoral-femoral group

No. at risk	44	23	14	10	0	0	0	0
SE	0.02	0.06	0.09	0.10	…	…	…	…

Figure 2. Comparison of overall survival according to type of operation performed ($P < .01$). Pairwise comparison showed survival of patients who underwent aortobifemoral bypass was longer than survival of those who underwent femoral-femoral bypass, which was longer than survival of those who underwent axillobifemoral bypass (all $P < .05$ after Bonferroni correction; Kaplan-Meier method, log-rank test).

The clinical characteristics of patients were compared between the 3 operation types. There were an increased number of patients with chronic renal insufficiency in the axillobifemoral group compared with the aortobifemoral and femoral-femoral groups (14.0% vs 3.2% and 4.0%, respectively; $P = .04$). More patients with critical limb ischemia (CLI) underwent either axillobifemoral or femoral-femoral bypass compared with patients with claudication (61.2% vs 35.1%; $P < .01$). No other significant differences in clinical characteristics were identified between the 3 operation types.

Univariate Analysis

Univariate analyses of demographic characteristics, comorbidities, medications, indications for operation, type of operation, and patient group (primary or secondary operation) were performed (**Table 2**). Variables asso-

Table 2. Univariate Analysis of Patients Who Died

Variable	Patients Who Died (n = 74)	*P* Value[a]
Age at operation, mean (SD), y	64.0 (10.0)	
Female sex, No. (%)	1 (1.4)	.65
Comorbidity, No. (%)		
CAD	43 (58.1)	.18
DM	27 (36.5)	.01
HTN	54 (73.0)	.74
HLD	31 (41.9)	.18
CRI	8 (10.8)	.03
HD	1 (1.4)	>.99
Tobacco history	66 (89.2)	.80
Medication, No. (%)		
Aspirin	40 (54.1)	.65
Warfarin sodium	10 (13.5)	.03
Beta-blocker	25 (33.8)	.76
Clopidogrel bisulfate	4 (5.4)	.74
Statin	27 (36.5)	.10
Indication, No. (%)		
CLI	45 (60.8)	.30
Rest pain	16 (21.6)	.39
Ulcer	14 (18.9)	.08
Gangrene	6 (8.1)	.35
Acute ischemia	11 (14.9)	.37
Operation type, No. (%)		
Aortobifemoral	28 (37.8)	<.01
Axillobifemoral	28 (37.8)	
Femoral-femoral	18 (24.3)	
Patient group, No. (%)		
Primary	65 (87.8)	.08
Secondary	9 (12.2)	

Abbreviations: See Table 1.
[a] By Pearson χ^2 test or Fisher exact test (when n < 10).

ciated with mortality included diabetes, chronic renal insufficiency, the use of warfarin, and either aortobifemoral or axillobifemoral operations (all $P < .05$). Indication for operation and patient group (either primary or secondary operation) was not associated with mortality (all $P > .05$) (Table 2).

Cox Regression Analysis

Diabetes, chronic renal insufficiency, and axillobifemoral bypass were associated with decreased survival with hazard ratios of 1.91, 2.87, and 3.14, respectively (all $P \leq .01$) (**Table 3**). Patients in the secondary operation group were associated with improved survival (hazard ratio, 0.43; $P = .03$).

Table 3. Multivariate Analysis to Identify Independent Predictors of Death in 74 Patients

Variable	Hazard Ratio (95% CI)	*P* Value[a]
Comorbidity		
DM	1.91 (1.16-3.13)	.01
CRI	2.87 (1.32-6.23)	<.01
Warfarin sodium	0.93 (0.44-1.98)	.85
Ulcer	1.15 (0.61-2.15)	.67
Operation type		
Aortobifemoral	1 [Reference]	
Axillobifemoral	3.14 (1.73-5.69)	<.01
Femoral-femoral	1.70 (0.89-3.23)	.11
Patient group		
Primary	1 [Reference]	
Secondary	0.43 (0.20-0.94)	.03

Abbreviations: CRI, chronic renal insufficiency; DM, diabetes mellitus.
[a] By Cox regression analysis.

COMMENT

Endovascular procedures for AIOD are clearly more durable than those for infrainguinal disease, but some endovascular interventions for AIOD do fail. Unlike failures of infrainguinal endovascular procedures, in which the consequences of such failures on subsequent open procedures have been at least somewhat examined,[6,7] there have been few data on the effect of failed ET for AIOD on the outcomes of an open operation performed for limb salvage.

This study focused on patient-centered outcomes of those undergoing aortoiliac reconstructions after failed ET for symptomatic AIOD. These outcomes were compared with those of patients undergoing primary operative treatment for symptomatic AIOD. Given the literature available for those patients with infrainguinal disease, we hypothesized that patients undergoing operative reconstruction after failed ET for symptomatic AIOD would have decreased survival and limb salvage rates compared with those undergoing primary open operation for symptomatic AIOD.

Our data, however, show that those patients undergoing operative reconstruction after failed ET for symptomatic AIOD had improved survival compared with patients who underwent primary open operation for symptomatic AIOD, whereas limb salvage rates were similar between the 2 patient groups. We found improved survival in the secondary operation group even though patients in the secondary operation group had an increased incidence of coronary artery disease compared with those undergoing primary open operation for AIOD.

Better survival in the secondary operation group may be a result of several factors. The patients were not randomized and those in the secondary operation group may be an overall more "robust" group, as indirectly indicated by the fact that 80.0% of the patients undergoing secondary operation were considered suitable candidates for an aortic-based procedure; this is a considerably higher proportion than among the patients who underwent primary open operations, where only 43.8% underwent an aortic procedure. This fact also reflects that, during the study, anatomically suitable patients were largely preferentially treated with stents independent of comorbidities.

More patients in the secondary operation group were taking aspirin, statins, and clopidogrel at the time of operation. All these medications appear to have a favorable effect on survival when used for secondary prevention in patients with symptomatic cardiovascular disease.[8-11] In fact, in the Clopidogrel versus Aspirin in Patients at Risk of Ischaemic Events study,[12] the survival benefit of clopidogrel compared with aspirin in patients with cardiovascular disease was largely driven by benefit in the patients with peripheral arterial disease, suggesting it is in the patients with symptomatic peripheral arterial disease where secondary prevention with medical management of atherosclerotic risk factors is most effective. Our study is also different from many series of interventions for AIOD[4,13-17] in that most patients were treated for CLI rather than claudication and such patients are more likely to have a greater overall burden of atherosclerosis with overall decreased life expectancy in both groups. Indeed, other series of interventions for AIOD appear to demonstrate improved survival compared with that found in our patients[13-17]; however, our patients were derived entirely from a Veterans Affairs hospital and 97.4% were men. The fact their 5-year mortality approached 50% may reflect their indication for intervention, with more than 50% of patients presenting with CLI, as well as a host of social, economic, burden of disease, and compliance issues perhaps more common to a population of patients derived entirely from a Veterans Affairs hospital. Therefore, although the data shown here cannot be directly extrapolated to all vascular surgery practices, the outcomes of our patients are likely no worse than the outcomes expected in a community-based practice.

Limb salvage rates were similar between the primary and secondary operation groups even though 20.3% of patients initially treated endovascularly for claudication symptoms presented with CLI at the time of the failure of their previous ET. Even given this concerning rate of conversion of claudication to CLI associated with failed ET of AIOD, and that more patients in the secondary operation group were treated for acute limb ischemia, there were only 7 major amputations in the entire series and all amputations were in the primary operation group. The small number of patients requiring amputation in this study limits our ability to make a meaningful comparison of limb salvage rates between the 2 patient groups. It does, however, seem reasonable to conclude that the need for major amputation in patients with symptomatic aortoiliac disease, even when many of the patients are treated for CLI, is rare and not dramatically affected by failure of previous ET for symptomatic AIOD.

Late survival is better in patients undergoing secondary vs primary open surgery for AIOD. Patients who undergo operative reconstruction after failed ET for symptomatic AIOD are not at increased risk for major amputation. Failure of ET for AIOD does not lead to worse outcomes in terms of survival or limb salvage for those patients who undergo subsequent open surgery for AIOD.

Accepted for Publication: April 27, 2012.
Correspondence: Erica L. Mitchell, MD, Division of Vascular Surgery, Oregon Health & Science University, 3181 Sam Jackson Park Rd SW, Mail Stop OP-11, Portland, OR 97239 (mitcheer@ohsu.edu).
Author Contributions: Drs Danczyk and Mitchell had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Mitchell, Edwards, Liem, Landry, and Moneta. *Acquisition of data:* Danczyk and Petersen. *Analysis and interpretation of data:* Danczyk, Liem, Landry, and Moneta. *Drafting of the manuscript:* Danczyk and Moneta. *Critical revision of the manuscript for important intellectual content:* Danczyk, Mitchell, Petersen, Edwards, Liem, Landry, and Moneta. *Statistical analysis:* Danczyk and Landry. *Administrative, technical, and material support:* Edwards and Moneta. *Study supervision:* Mitchell, Liem, and Moneta.
Financial Disclosure: None reported.
Previous Presentation: This paper was presented at the 83rd Annual Meeting of the Pacific Coast Surgical Association; February 19, 2012; Napa Valley, California, and is published after peer review and revision.
Additional Contributions: Sharon Kryger, BS, provided patient database support.

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