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Comparing patient outcomes between multiple ipsilateral iliac artery stents and isolated iliac artery stents

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Objective: Endovascular stents are accepted therapy for iliac artery stenoses and occlusions. Surgery is the recommended therapy for patients with severe iliac artery disease, including those with the combination of ipsilateral common iliac artery (CIA) and external iliac artery (EIA) stenoses/occlusions. This study compared patient outcomes, including late open conversion rates, for combined ipsilateral CIA and EIA stenting vs CIA or EIA stents alone.

Methods: Between 1998 and 2010, 588 patients underwent iliac artery stenting at two institutions. Patient comorbidities and outcomes were retrospectively reviewed, and analyses were performed using multivariate regression and Kaplan-Meier methods.

Results: There were 436 extremities with CIA stents, 195 with EIA stents, and 157 with CIA and EIA stents. The groups did not differ significantly in demographics, comorbidities, or treatment indications. During follow-up, 183 patients died, 95 underwent an endovascular reintervention, and 48 required late open conversion. For patients in the CIA or EIA stent group, the mean ± standard error survival was 5.3 ± 0.3 years, secondary endovascular intervention-free survival was 7.4 ± 0.6 years, late open conversion-free survival was 9.8 ± 0.4 years, and amputation-free survival was 7.6 ± 0.4 years. In the CIA and EIA stent group, survival was 6.1 ± 0.6 years, secondary endovascular intervention-free survival was 7.2 ± 0.6 years, late open conversion-free survival was 9.0 ± 1.1 years, and amputation-free survival was 8.4 ± 0.5 years. Survival, reintervention-free survival, late open conversion-free survival, and amputation-free survival were all similar between patient groups (all *P* > .05). CIA and EIA stenting in combination was not a predictor of death, reintervention, late open conversion, or amputation.

Conclusions: Outcomes are similar for patients with CIA or EIA stents and for those with combined ipsilateral CIA and EIA stents. Late open conversions for iliac artery stent failure are uncommon and not influenced by the location or extent of prior iliac artery stent placement. Endovascular therapy for aortoiliac disease should be extended to consider selected patients with ipsilateral CIA and EIA stenoses/occlusions. (J Vasc Surg 2012;55:1637-46.)

Endovascular therapy is the primary treatment of symptomatic aortoiliac occlusive disease (AIOD). With properly selected lesions, 70% to 79% primary patency at 5 years can be achieved with iliac artery percutaneous transluminal angioplasty and stenting (PTAS). Conversely, poor-quality run-off vessels, severity of ischemia, longer treated segments, diabetes, renal failure, tobacco use, and female sex have been associated with increased failure rates of endovascular treatment.[1-6]

Operative management of advanced AIOD lesions is currently recommended. Advanced AIOD lesions encompass a variety of aortoiliac disease patterns, some of which may actually be well treated with endovascular therapies. Treatment of selected advanced AIOD lesions with PTAS has resulted in primary patency rates of 69% to 85%.[7-9] Therefore, percutaneous treatment for some advanced AIOD lesions may be appropriate. One category of advanced AIOD includes combined common (CIA) and external iliac artery (EIA) disease, and many of these lesions are amenable to endovascular therapy.

An "endovascular first" approach for combined CIA and EIA lesions can be justified if patient-centered results are reasonable and failures do not lead to adverse patient outcomes such as death, limb loss, repeat endovascular interventions, or high rates of late open conversions for failed endovascular treatment. This study, therefore, evaluated patient outcomes for endovascular treatment of combined ipsilateral CIA and EIA disease. We compared these results to control patients with treatment limited to the CIA or EIA alone.

METHODS

This study was approved by the Institutional Review Board (IRB) at the Portland Department of Veterans Affairs (VA) Medical Center (PVAMC, IRB study No. 2452) and by the IRB at Oregon Health & Science University

(OHSU, IRB study No. 5248). Informed consent requirements were exempt from this study.

Patients. Device implantation records at the PVAMC and OHSU Hospital were used to create a list of 588 patients who underwent successful PTAS procedures for AIOD from January 1998 through March 2010. Patients whose procedures failed and those who had an iliac artery procedure as an adjunct to an aortic endograft were excluded.

Demographics captured included sex and age. Comorbidities assessed were coronary artery disease (CAD), diabetes mellitus (DM), hypertension, hyperlipidemia, history of tobacco use, end-stage renal disease requiring hemodialysis, and chronic renal insufficiency, defined as creatinine > 1.5 mg/dL. Patients were defined as having CAD if they had a history of myocardial infarction, coronary artery bypass grafting, or stenting. CAD, DM, hypertension, and hyperlipidemia were also considered to be comorbidities if they were listed in the medical history at the initial presentation. Patients with a positive tobacco history were either currently smoking at the time of initial presentation or had quit smoking ≤10 years of the initial presentation. Medications assessed included aspirin, warfarin, β-blockers, clopidogrel, and statins. Indications for PTAS, such as claudication, rest pain, or tissue loss, in addition to ankle-brachial indexes (ABIs) were also recorded.

Procedures. Procedural information collected with respect to initial PTAS included the location of stent placement and the diameters of stents placed in each artery. For the purposes of this study, patients were placed into the CIA or EIA stent group if stents were placed into the CIA or the EIA, but not both. Patients with stents placed in both the ipsilateral CIA and EIA were placed in the CIA and EIA stent group.

Self-expanding and balloon-expandable stents were used. Kissing stent placement was noted. Concomitant ipsilateral infrainguinal operations were also recorded and were defined as adjunct operations performed during the same hospitalization, including major amputations, minor amputations, common femoral artery reconstructions, profundaplasty, or lower extremity bypass.

During follow-up, secondary ipsilateral endovascular interventions after failed initial PTAS were recorded. Procedural information was collected as with the primary intervention. Concomitant operations performed in association with secondary endovascular procedures were also recorded. Late open conversions (aortobifemoral, axillobifemoral, femorofemoral) to treat iliac stent failure as well as ipsilateral concomitant procedures as defined above were recorded.

Complications in the immediate postprocedural period, after the initial PTAS, a secondary endovascular intervention, or a late open conversion, were assessed and included hematoma (local or retroperitoneal), arterial perforation (after PTAS), distal embolization, acute myocardial infarction, acute renal failure (creatinine increase ≥0.5 mg/dL), or unplanned postprocedure intensive care unit admission. Interventions for complications were also recorded.

Follow-up. Follow-up was annual and included ABI measurement and a physical examination. Information regarding claudication, rest pain, or tissue loss was also recorded.

Data analysis. Univariate analyses of variables were performed using the Pearson χ^2 test or the Fisher exact test (when n < 10) for categoric variables and independent t tests for continuous variables. Survival, secondary endovascular intervention-free survival, late open conversion-free survival, and amputation-free survival were calculated using the Kaplan-Meier method. The log-rank test (Mantel-Cox) was used to compare patient outcomes for patients treated with CIA or EIA stents and with those treated with CIA and EIA stents. Multivariate analyses of variables affecting patient outcomes were performed using Cox regression modeling. Variables were entered into the model using the forced entry method. All statistical analyses were performed using SPSS 19 software (IBM Corp, Somers, NY). Mean data are presented with the standard deviation. Values of $P < .05$ were considered significant.

RESULTS

Patient characteristics. Mean patient age at time of initial PTAS was 63.3 ± 9.9 years. There were 530 men (90.1%) and 58 women (9.9%), in whom 436 extremities were treated with CIA stents, 195 extremities were treated with EIA stents, and 157 extremities were treated with CIA and EIA stents. Comorbidities, medications, and indication for treatment at the time of PTAS for both patient groups are reported in Table I and in Supplementary Table I, *A* and *B* (online only). Most patients in both groups had CAD, hypertension, and a positive tobacco history. Most were taking aspirin before PTAS, and 52% reported claudication symptoms before PTAS (Table I).

Comparison of patients with CIA or EIA stents vs patients with CIA and EIA stents. Demographics, comorbidities, medications, and indications for initial PTAS of patients with CIA or EIA stents and patients with CIA and EIA stents in combination were compared (Table I). Patients treated with ipsilateral CIA and EIA stents were prescribed aspirin more frequently before PTAS than patients treated with CIA or EIA stents (73.8% vs 60.2%; $P < .01$). All other clinical characteristics were similar between the two groups (Table I).

Outcome for ankle-brachial index. Mean changes in ABI after primary PTAS, secondary endovascular intervention, and late open conversion are reported in Table II. There was no significant difference in ABI improvement when the CIA or EIA stent group was compared with the CIA and EIA stent group ($P > .05$ for all; Table II).

A total of 206 patients who presented with claudication before the initial PTAS had complete information regarding their symptoms at the time of follow-up. The mean ABI improvement for the 110 patients (53.3%) whose claudication symptoms resolved after PTAS was 0.18 ± 0.20, and the mean ABI change for the 96 patients (46.6%) with

Table I. Clinical characteristics of patient groups

Variables[a]	CIA or EIA stent (n = 447)	CIA and EIA stent (n = 141)	P
Age, years	63.6 ± 9.5	64.1 ± 10.4	.58
Female sex	50 (11.2)	8 (5.7)	.07
Comorbidities			
CAD	275 (61.5)	100 (70.9)	.05
DM	166 (37.1)	58 (41.1)	.43
Hypertension	359 (80.3)	117 (83.0)	.54
Hyperlipidemia	282 (63.1)	93 (66.0)	.55
CRI	60 (13.4)	13 (9.2)	.24
Hemodialysis	14 (3.1)	3 (2.1)	.77
Tobacco history	403 (90.2)	133 (94.3)	.17
Medications			
Aspirin	269 (60.2)	104 (73.8)	<.01[b]
Warfarin	35 (7.8)	9 (6.4)	.71
β-Blocker	232 (51.9)	76 (53.9)	.70
Clopidogrel	36 (8.1)	8 (5.7)	.46
Statin	258 (57.7	81 (57.4)	>.99
Indication			
Claudication	233 (52.1)	74 (52.5)	.92
CLI	206 (46.1)	67 (47.5)	.92
Rest pain	67 (15.0)	28 (19.9)	.24
Gangrene	37 (8.3)	11 (7.8)	>.99
Ulcer	60 (13.4)	18 (12.8)	.89
Acute ischemia	31 (6.9)	8 (5.7)	.70
Unknown	8 (<1.0)	0 (0.0)	>.99

CAD, Coronary artery disease; *CIA,* common iliac artery; *CLI,* critical limb ischemia; *CRI,* chronic renal insufficiency (creatinine >1.5 mg/dL); *DM,* diabetes mellitus; *EIA,* external iliac artery.

[a]Continuous data are expressed as the mean ± standard deviation; categoric data are expressed as number (%).

[b]Statistically significant (P < .05), χ² test/Fisher exact test.

persistent exercise-associated leg pain after PTAS was 0.07 ± 0.22 (P = .03). There was no association between the location of stents placed and resolution of claudication symptoms. Of those patients with CIA or EIA stents, 54.5% experienced resolution of their claudication symptoms and 45.5% continued to have exercise-associated leg pain after PTAS. In the CIA and EIA stent group, 50% experienced resolution of claudication while the remaining patients continued to have exercise-associated leg pain (P = .63).

Clinical outcomes. After PTAS in the CIA or EIA stent group, 95 patients (21.3%) were lost to follow-up, 141 (31.5%) died, 75 (16.8%) required secondary endovascular intervention, 36 (8.1%) required late open conversion for failed endovascular intervention, and 11 (2.5%) required major amputation (transtibial or transfemoral). After PTAS in the CIA and EIA stent group, 27 patients (19.1%) were lost to follow-up, 42 (29.8%) died, 20 (14.2%) required secondary endovascular intervention, 12 (8.5%) required late open conversion, and seven (4.9%) required major amputation. There were no significant differences in the number of patients who were lost to follow-up, died, required secondary endovascular intervention or late open conversion, or underwent amputation between the CIA or EIA stent patients and the CIA and EIA stent patients (P > .21 for all; Table III and Supplementary Table II, *A* and *B*, online only).

Of the 95 patients who required a secondary endovascular intervention, 49 reinterventions were performed to specifically address in-stent restenosis. There were 34 in-stent revisions in the CIA or EIA stent group and 15 in-stent revisions in the CIA and EIA stent group (P = .49).

Most patients who underwent late open conversion were treated with aortobifemoral bypass. Of the 36 patients in the CIA or EIA stent group who underwent late open conversion, 25 underwent aortobifemoral bypasses, three underwent axillobifemoral bypasses, and eight underwent femorofemoral bypasses. Of the 12 patients in the CIA and EIA stent group who underwent late open conversion, eight underwent aortobifemoral bypasses, three had axillobifemoral bypasses, and one underwent femorofemoral bypass. The data show that most of the bypasses performed in both groups were aortobifemoral bypasses (P = .02).

For patients in the CIA or EIA stent group, mean survival was 5.33 ± 0.3 years, secondary endovascular intervention-free survival was 7.44 ± 0.6 years, late open conversion-free survival was 9.88 ± 0.44 years, and amputation-free survival was 7.6 ± 0.4 years. For patients in the CIA and EIA stent group, mean survival was 6.1 ± 0.6 years, secondary endovascular intervention-free survival was 7.2 ± 0.6 years, late open conversion-free survival was 9.0 ± 1.1 years, and amputation-free survival was 8.4 ± 0.5 years. There was no difference in survival, secondary endovascular reintervention-free survival, late open conversion-free survival, or amputation-free survival between the CIA or EIA stent patients and CIA and EIA stent patients (Figs 1-3, data not shown for amputation-free survival).

Univariate analysis. Univariate analyses of demographic variables, comorbidities, medications, indications for primary intervention, and location of stent placement (CIA or EIA, CIA and EIA) were performed for all outcomes, including death, secondary endovascular intervention, late open conversion, and amputation (Table IV, amputation data not shown, and Supplementary Table III, *A* and *B*, online only). In addition, univariate analyses of stent diameter and the use of kissing stents were performed.

Variables associated with mortality included male sex, CAD, DM, hypertension, chronic renal insufficiency, hemodialysis, the use of warfarin, and critical limb ischemia (CLI) as an indication for intervention. Tobacco use was associated with death; however, 536 patients (91.1%) had a significant history of tobacco use. Location of stent placement was not associated with death.

The only variable associated with the need for secondary endovascular intervention was tobacco history: 93 patients (97.9%) had a positive tobacco history compared with two patients (2.1%) who were nonsmokers (P = .01).

Variables associated with late open conversion included male sex, hypertension, and acute ischemia (P <.05 for all). Seven patients (14.6%) undergoing late open conversion presented with acute ischemia compared with 41 (85.4%) who presented with claudication or CLI (P = .03). No other variables were associated with the need for late open conversion, including the location of stents placed at

Table II. Comparison of mean changes in ankle-brachial index (*ABI*) after revascularization procedure by group

| | CIA or EIA stent | | CIA and EIA stent | | |
Variable	Mean ΔABI	SD (95% CI)	Mean ΔABI	SD (95% CI)	P[a]
Primary PTAS	0.13	0.23 (0.11-0.15)	.17	0.23 (0.13-0.21)	.06
SEI	0.15	0.26 (0.11-0.20)	.14	0.22 (0.08-0.19)	.62
Late open conversion	0.21	0.33 (0.11-0.31)	.32	0.34 (0.16-0.48)	.23

CI, Confidence interval; *CIA,* common iliac artery; *EIA,* external iliac artery; *PTAS,* percutaneous transarterial angioplasty and stenting; *SD,* standard deviation; *SEI,* secondary endovascular intervention.
[a]Independent *t* test.

Table III. Clinical outcomes of common iliac artery (*CIA*) or external iliac artery (*EIA*) stent vs CIA and EIA stent groups

Outcome	CIA or EIA stent (n = 447) No. (%)	CIA and EIA stent (n = 141) No. (%)	P[a]
Lost to follow-up	95 (21.3)	27 (19.1)	.21
Death	141 (31.5)	42 (29.8)	.76
SEI	75 (16.8)	20 (14.2)	.51
Late open conversion	36 (8.1)	12 (8.5)	.86
Amputation	11 (2.5)	7 (4.9)	.25

SEI, Secondary endovascular intervention.
[a]χ^2 test, Fisher exact test.

initial PTAS. The only variable associated with the need for amputation was CLI as an indication for the procedure ($P < .01$, data not shown). Neither stent diameter nor the use of kissing stents was associated with death, the need for secondary endovascular intervention or late open conversion, or amputation ($P > .20$ for all, data not shown).

Cox regression analysis. Cox regression analysis was performed for clinical outcomes, including death, secondary endovascular intervention, and late open conversion. Cox regression analysis was not performed for amputation because only 18 patients required amputation. Variables significantly associated with outcomes ($P < .05$) after univariate analysis were included in the regression model (Table V and Supplementary Table IV, *A* and *B*, online only).

CAD and CLI were associated with decreased survival, with hazard ratios (HRs) of 1.84 and 1.91, respectively ($P < .01$ for all). Tobacco history was associated with increased survival (HR, 0.56; $P = .02$) and with decreased reintervention-free survival (HR, 5.15; $P = .03$). No variables were identified as independent predictors of the need for late open conversion ($P > .05$ for all).

Concomitant operations. At the time of the initial PTAS, 102 patients (17.3%) underwent a concomitant operation, including lower extremity bypass in 44, femoral artery reconstruction in 29, femorofemoral bypass in seven, and profundaplasty in eight. The remaining procedures included four digital amputations, two major amputations, and one superficial artery angioplasty.

After secondary endovascular intervention, 79 patients (83.2%) underwent a concomitant operation, including lower extremity bypass in 37, femoral artery reconstruction

in 25, femorofemoral bypass in 11, or profundaplasty in four.

At the time of late open conversion for failure of an aortoiliac catheter-based intervention, four patients (8.3%) underwent concomitant operations, comprising femoral artery reconstruction in two and lower extremity bypass in two.

For each of the clinical outcomes assessed, no difference was seen in the number of patients undergoing concomitant operations between the CIA or EIA stent group and the CIA and EIA stent group ($P > .23$ for all). In addition, a second analysis was performed excluding the 97 patients who underwent concomitant operations. The results of this secondary analysis did not change the results of the study (data not shown).

Complications. After PTAS, 46 (7.8%) complications were recorded. Hematoma accounted for 21 complications, with two of these retroperitoneal. Nine patients had an arterial dissection (seven EIA, two CIA), distal emboli occurred in five (one required embolectomy), three stayed overnight in the surgical intensive care unit, two patients had a rise in serum creatinine ≥0.5 mg/dL, one patient had acute myocardial infarction, one experienced congestive heart failure exacerbation, one had a pulmonary embolism, and one experienced a vasovagal episode. One patient died of a retroperitoneal hemorrhage associated with the initial PTAS.

After secondary endovascular intervention, eight (8.4%) complications were recorded. Hematoma accounted for two complications, distal emboli occurred in two, two had a rise in creatinine ≥0.5 mg/dL, one patient had an acute myocardial infarction, one patient had a stroke, and mesenteric ischemia in 1 patient required exploratory laparotomy with small bowel resection and an extended intensive care unit stay. No deaths were associated with secondary endovascular interventions.

No complications or deaths, as defined above, were associated with late open conversion.

For each of the above clinical outcomes, no difference was seen between the number of complications experienced by patients in the CIA or EIA stent group and the CIA and EIA stent group ($P > .34$ for all).

DISCUSSION

Endovascular intervention is accepted therapy for many patterns of symptomatic AIOD. Although operative management is recommended for advanced AIOD lesions,
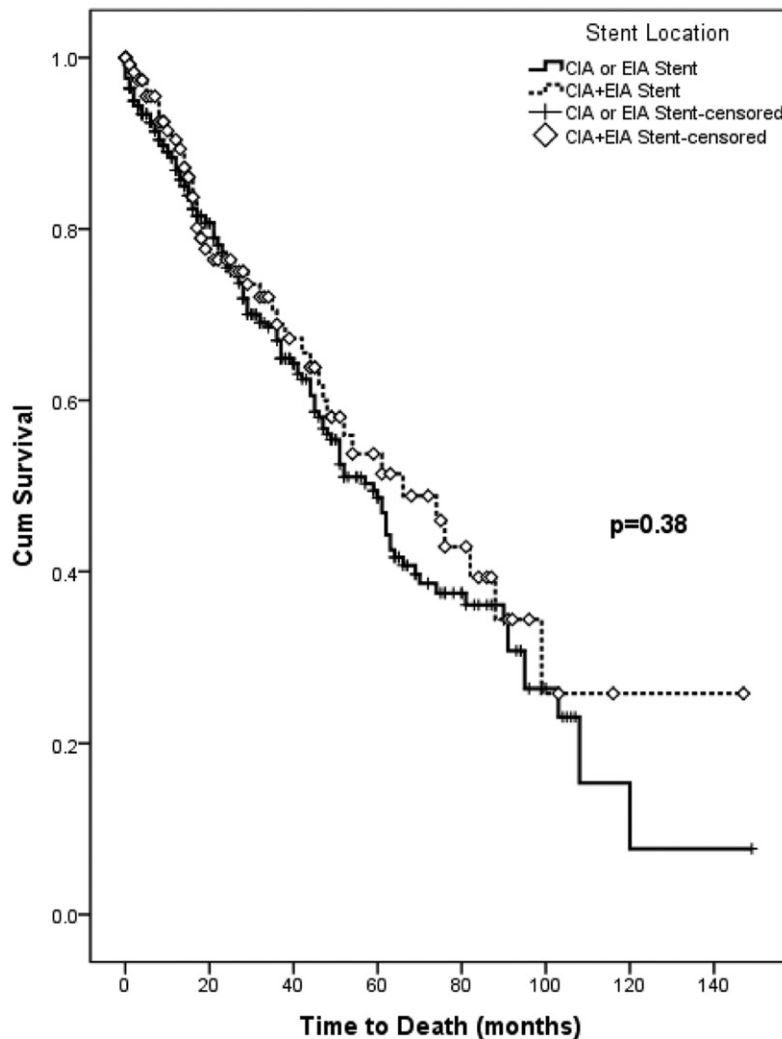
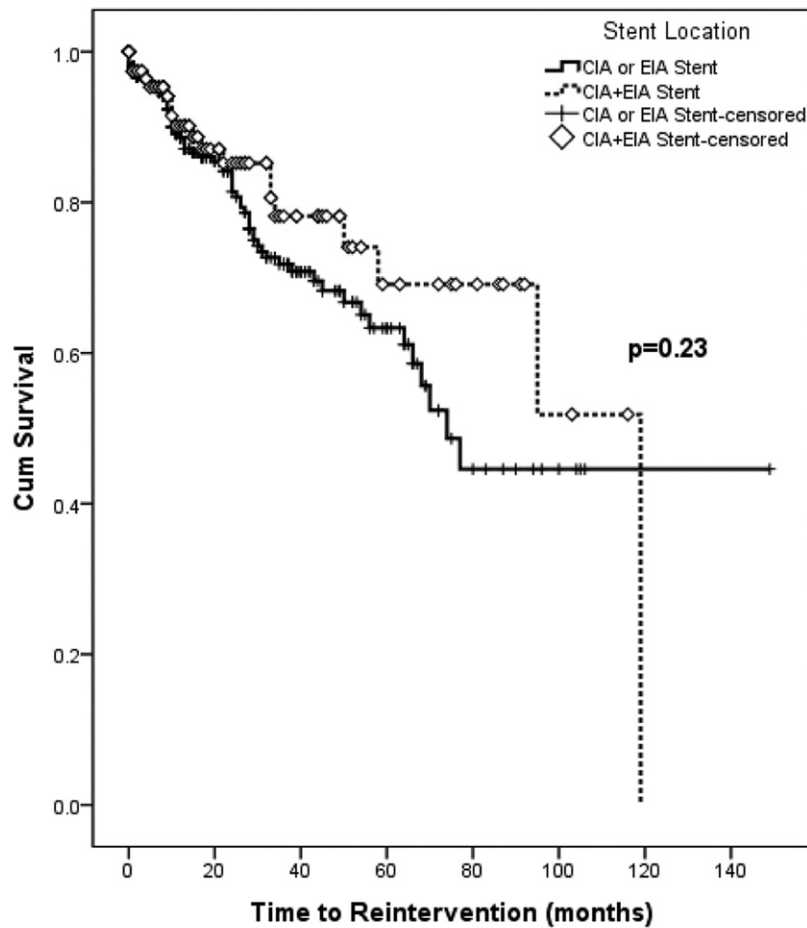| CIA or EIA Stent Group							
At risk	313	169	97	51	22	7	2	1
SE	0.02	0.03	0.04	0.04	0.05	0.06	0.07	0.07
CIA and EIA Stent Group							
At risk	102	54	35	20	10	2	1	0
SE	0.03	0.05	0.06	0.07	0.08	0.09	0.10	-

Fig 1. Kaplan-Meier analysis showed survival was similar between the common iliac artery (*CIA*) or external iliac artery (*EIA*) stent group and the CIA and EIA stent group (*P* = .38, log-rank test).

these lesions encompass many different patterns of disease, some of which are amenable to rather straightforward endovascular interventions.

Endovascular treatment of EIA lesions has also been questioned,[10-13] and by implication, treatment of a combination of ipsilateral EIA and CIA lesions may be associated with poorer results than treatment of isolated CIA or EIA lesions. However, few reports have focused on

results of endovascular treatment of ipsilateral CIA and EIA lesions.

This study focused on patient-centered outcomes of endovascular therapy of CIA and EIA occlusive lesions and not on patency. Although patency is important in the evaluation of new technologies, iliac artery stenting is clearly not new technology, and many of our VA patients were not monitored with serial imaging studies of the

CIA or EIA Stent Group

At risk	267	113	52	25	8	3	1	-
SE	0.02	0.04	0.04	0.06	0.07	0.07	0.07	-

CIA and EIA Stent Group

At risk	89	40	21	11	7	2	-	-
SE	0.03	0.05	0.05	0.08	0.16	0.22	-	-

Fig 2. Kaplan-Meier analysis showed reintervention-free survival was similar between the common iliac artery (*CIA*) or external iliac artery (*EIA*) stent group and the CIA and EIA stent group (*P* = .23, log-rank test).

treated vessels. We, therefore, chose to focus only on patient-oriented outcomes such as morbidity and need for further interventions. This approach, although not ideal, is in line with the recent orientation of the U.S. Food and Drug Administration, where patient-centered outcomes, such as need for reintervention and not patency, are considered the primary end points for evaluation of endovascular technology.[14]

Irrespective of patency, for an endovascular-first approach to a combination of CIA and EIA lesions to be reasonable there must, at a minimum, be acceptable initial outcomes of such procedures, a limited need for reintervention, and no

increased severity of the consequences of late failures. Our data, the largest series to date of endovascular treatment of combined treatment of CIA and EIA lesions,[15,16] therefore supports, from the patient perspective, combined endovascular treatment of selected ipsilateral CIA and EIA occlusive lesions. By analyzing patients with isolated EIA or CIA lesions as the control group, we found no differences in complications, improvement in ABI, survival, limb salvage, and need for time to reintervention or need for late open conversion in patients treated with catheter-based techniques for isolated CIA or EIA disease vs those treated for a combination of CIA and EIA disease.
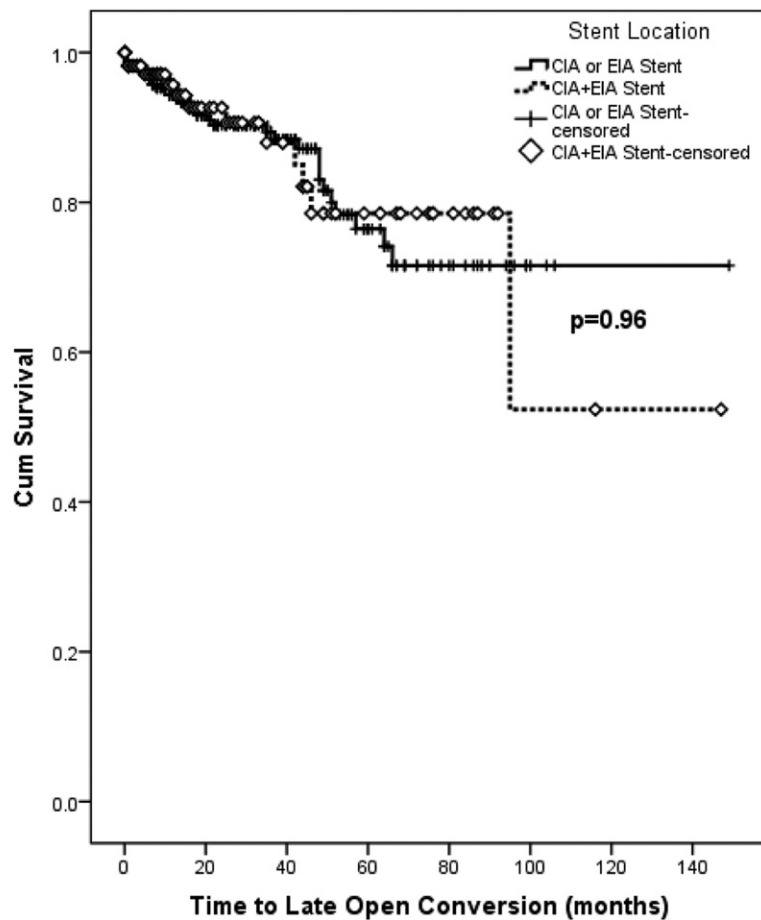
Fig 3. Kaplan-Meier analysis showed that late open conversion-free survival was similar between the common iliac artery (*CIA*) or external iliac artery (*EIA*) stent group and the CIA and EIA stent group (*P* = .96, log-rank test).

Our data for durability of combination treatment of ipsilateral EIA and CIA lesions is consistent with that reported by others for isolated EIA and isolated CIA occlusive lesions treated with endovascular techniques.[3,17] This justifies categorizing patients treated for isolated EIA and CIA arteries as the "control group" in evaluating combined treatment of ipsilateral CIA and EIA disease.

The combination of CIA and EIA stent placement is essentially a surrogate for length of diseased artery treated. The data here, therefore, may suggest the length of diseased artery treated endovascularly in the iliac artery position is less important than generally believed if stents are routinely used in the iliac arteries, as prior studies indicating increased length

of diseased segment treated portended poorer outcomes were based on selective rather than routine stenting.[13,18]

Failure of a prosthetic infrainguinal graft or an infrainguinal catheter-based procedure may lead to deterioration of the patient's prospects of subsequent operative intervention.[19,20] Our data with respect to AIOD, however, indicate late open conversion for failed PTAS of AIOD is infrequently required, and there seem to be no differences in the rate or types of subsequent open operative procedures required for failure of endovascular treatment of AIOD, regardless if the patient was initially treated for an isolated iliac lesion or a combination of ipsilateral CIA and EIA lesions.

Table IV. Univariate analysis of death, secondary endovascular intervention, and late open conversion

	Outcome					
	Death		SEI		Late open conversion	
Variables[a]	(n = 183)	P	(n = 95)	P	(n = 48)	P
Age at PTAS, years	66.9 ± 8.5		59.8 ± 8.1		57.2 ± 8.8	
Female sex	8 (4.4)	<.01[b]	12 (12.6)	.35	9 (18.8)	.04[b]
Comorbidities						
CAD	138 (75.4)	<.01[b]	61 (64.2)	>.99	31 (64.6)	>.99
DM	85 (46.4)	.03[b]	31 (32.6)	.25	12 (25.0)	.06
Hypertension	159 (86.9)	.02[b]	72 (75.8)	.20	32 (66.7)	.01[b]
Hyperlipidemia	113 (61.7)	.52	57 (60.0)	.42	29 (60.4)	.64
CRI	38 (20.8)	<.01[b]	6 (6.3)	.06	2 (4.2)	.11
Hemodialysis	11 (6.0)	.01[b]	1 (1.1)	.33	1 (2.1)	>.99
Tobacco history	159 (86.9)	.02[b]	93 (97.9)	.01[b]	44 (91.7)	>.99
Medication						
Aspirin	120 (65.6)	.52	55 (57.9)	.25	34 (70.8)	.35
Warfarin	20 (10.9)	.04[b]	3 (3.2)	.09	1 (2.1)	.25
β-Blocker	101 (55.2)	.37	49 (51.6)	.91	21 (43.8)	.23
Clopidogrel	11 (6.0)	.40	9 (9.5)	.40	2 (4.2)	.57
Statin	96 (52.5)	.09	55 (57.9)	>.99	26 (54.2)	.65
Indication						
CLI	114 (62.3)	<.01[b]	37 (38.9)	.42	19 (39.6)	.36
Acute ischemia	14 (7.7)	.59	6 (6.3)	>.99	7 (14.6)	.03[b]
Stent location						
CIA or EIA	141 (77.0)	.76	75 (78.9)	.51	36 (75.0)	.86
CIA and EIA	42 (23.0)		20 (21.1)		12 (25.0)	

CAD, Coronary artery disease; *CIA*, common iliac artery; *CLI*, critical limb ischemia; *CRI*, chronic renal insufficiency (creatinine >1.5 mg/dL); *DM*, diabetes mellitus; *EIA*, external iliac artery; *PTAS*, percutaneous transarterial angioplasty and stenting; *SEI*, secondary endovascular intervention.
[a]Continuous data are presented as mean ± standard deviation; categoric data as number (%).
[b]Statistically significant ($P < .05$), χ^2 test/Fisher exact test.

Table V. Cox regression of death, secondary endovascular intervention, and late open conversion

	Outcome					
	Death (n = 183)		SEI (n = 95)		Late open conversion (n = 48)	
Variable	HR (95% CI)	P	HR (95% CI)	P	HR (95% CI)	P
Female sex	0.59 (0.29-1.23	.16	1.61 (0.85-3.07)	.15	1.49 (0.67-3.33)	.33
Comorbidities						
CAD	1.84 (1.21-2.72)	<.01[a]	1.22 (0.74-2.01)	.43	1.98 (0.97-4.07)	.06
DM	1.29 (0.93-1.78)	.12	0.80 (0.50-1.30)	.37	0.55 (0.27-1.11)	.10
Hypertension	1.16 (0.70-1.92)	.58	0.86 (0.47-1.57)	.62	0.48 (0.22-1.06)	.07
Hyperlipidemia	1.01 (0.66-1.53)	.97	0.68 (0.37-1.23)	.20	0.87 (0.39-1.94)	.74
Tobacco history	0.56 (0.35-(0.90)	.02[a]	5.15 (1.18-22.48)	.03[a]	0.63 (0.21-1.86)	.40
Medication						
Aspirin	1.30 (0.93-1.82)	.13	0.73 (0.45-1.17)	.19	1.64 (0.81-3.32)	.17
β-Blocker	1.00 (0.71-1.40)	>.99	1.36 (0.83-2.21)	.22	1.22 (0.60-2.45)	.58
Statin	0.66 (0.44-0.99)	.05	1.18 (0.66-2.12)	.57	1.01 (0.46-2.18)	.99
Indication						
CLI	1.91 (1.38-2.64)	<.01[a]	1.38 (0.87-2.19)	.17	1.39 (0.74-2.63)	.31
Stent location						
CIA and EIA	0.80 (0.56-1.14)	.22	0.78 (0.45-1.34)	.37	1.06 (0.54-2.09)	.87

CAD, Coronary artery disease; *CI*, confidence interval; *CIA*, common iliac artery; *CLI*, critical limb ischemia; *DM*, diabetes mellitus; *EIA*, external iliac artery; *HR*, hazard ratio; *SEI*, secondary endovascular intervention.
[a]Statistically significant ($P < .05$), forced entry.

Furthermore, no postoperative complications occurred in patients in this series who underwent late open conversion for failed endovascular treatment of AIOD. This may partly reflect the small numbers of patients requiring late open conversion. In addition, the long time from the initial endovascular treatment to late open conversion, as well as compliance with follow-up, may select healthier patients with less aggressive atheroscle-

rosis who also have better medical management than the typical patient in a larger series of open operations for AIOD. In any case, however, patients undergoing late conversion in this series did well, indicating the patients were not likely harmed by their initial AIOD endovascular procedure with respect to a subsequent open procedure.

We do not believe these data can be used to justify a blanket approach to treatment of all combined ipsilateral CIA and EIA occlusive lesions. This was a retrospective study and patients were undoubtedly treated with some selection bias. We continue to believe open surgery for some patients with advanced AIOD is a very reasonable choice for better-risk patients. The potential selection of good-risk patients with more advanced lesions for open surgery could bias the data in terms of decreased survival for those treated with catheter-based techniques. Alternatively, there may be decreased need for reintervention after catheter-based treatment, because potentially, some patients with more advanced lesions that were felt would do poorly with a catheter-based procedure were advised to undergo open surgery.

Patients treated in this study were derived primarily from our affiliated VA hospital (PVAMC) and demonstrated 5-year mortality of 50% on a background of a high prevalence of tobacco abuse, and given the long time span of the study, less than universal use of adjunctive clopidogrel with stenting. Our results, therefore, may not be strictly extrapolated to a more community-based practice but are unlikely to be better than those achievable in a population of patients with less overall burden of disease. The results presented here, therefore, should be encouraging to competent endovascular practitioners in practices with varying populations of patients to perform combined ipsilateral CIA and EIA catheter-based procedures in selected patients with combined ipsilateral CIA and EIA occlusive disease.

CONCLUSIONS

Endovascular treatment of CIA occlusive disease or EIA occlusive disease or a combination of ipsilateral CIA and EIA occlusive disease results in similar patient-oriented outcomes. Open conversions for iliac artery stent failure are uncommon, occur late, and are not influenced by the location or extent of iliac artery stent placement. This study suggests that total endovascular management for selected patients with combined CIA and EIA disease is acceptable. Recommendations for therapy of AIOD should be modified to encourage endovascular therapy for selected patients with ipsilateral CIA and EIA stenoses or occlusions.

We thank Sharon Kryger for her assistance with the patient database creation and management that was vital to the completion of this work.

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DISCUSSION

Dr Mark R. Nehler (*Aurora, Colo*). Dr Danczyk and colleagues from Oregon Health & Science University present a comparison series of either multiple vs isolated endovascular treatment with stents in the iliac system. The procedural indications, demographics, and comorbidities are typical of the predominately Veterans Affairs population it represents. Of note, roughly 20% to 30% of the patients were not on either statins or antiplatelet therapy at the time of procedure, reflecting the 12-year time frame of the data set; both medications would be required as background therapy in clinical trials currently. Failure to cross the lesions was not included, making the results a bit better than reality and the loss to follow-up was high, at 20%, also reflecting the long duration of the study period.

Regardless of these study limitations, several points are undeniable: 15 to 25 percentage points of the lesions treated were TransAtlantic Inter-Society Consensus (TASC) D—more so in the multiple iliac stent group. There was no difference in the multiple vs isolated iliac stent group in secondary intervention and salvage operation over time, both a modest 15% and 8%, respectively. As such, this paper joins others that have demonstrated that a large number of TASC D iliac lesions can be treated successfully with an endovascular-first approach.

The TASC II guidelines were roundly criticized for the inclusion of many lesions in the C and D classes that could be approached endovascularly. Such is the risk of putting out lesion classification systems in a decade of such rapid improvements in endovascular techniques and widespread adoption of same. A proposed revised lesion scoring system would adjust all the lesions (aortoiliac, femoropopliteal, and a new tibial system) toward the endovascular side of the ledger, with only a few anatomic cases suggested as primary open surgery, with the vast majority of open revascularization to follow endovascular failure. This proposal has yet to be approved by all societies, as the actual data below the inguinal ligament is not as strong as in the iliacs.

As such the TASC lesion system is really most beneficial as a tool to compare anatomic arterial substrate and really corresponds to the T portion of the TNM classification system in oncology. It allows comparisons in registries, clinical trials, etc. Since the original system commented on open vs endovascular success likelihood, it has required revision over time as endovascular techniques and tools improved – and also the lesion classification has been contentious for the implications for clinical practice, which is really not the intent of the system per se.

As time goes by, many of the classic teaching regarding the limitations of endovascular approaches in the iliacs are fading. There are secondary procedures, but the actual number is not huge. There is device cost, but shorter hospital stays account for that, and it is cost-effective. Indeed, with the current bed crunch in most hospitals and patients in the emergency department waiting for beds, adding to the inpatient load with more open aortic procedures is hardly feasible.

The failure of iliac endovascular approaches also appears more favorable than open surgery. Infection is a rare event. As opposed to a graft limb occlusion, a failure of endovascular therapy in the iliacs appears less likely to embolize and lead to acute limb ischemia if the primary indication was claudication. Bowel obstruction, fistula, and incisional hernia are also not long-term complications.

I enjoyed the paper. It is well written and the analysis is very clear. To close, I have several questions for the authors:

First, my personal observations above aside, do the authors have an opinion regarding the outcome of endovascular failure after reviewing the records. Do patients who fail endovascular iliac intervention present with acute limb ischemia?

Dr Rachel C. Danczyk. Thank you for your thought-provoking comments and interesting question. First, we know that 20% of those patients presenting with claudication progress to critical limb ischemia (CLI) after endovascular failure. The number of patients with acute limb ischemia, specifically, in this group is quite small, with only eight patients presenting with acute ischemia after failure. The majority of patients who presented with progression to CLI experienced rest pain, followed by ulcers, and finally with acute ischemia.

Dr Nehler. Second, the number of patients with concomitant distal bypasses was not given in the results. Does having a distal revascularization dependent on revascularized inflow affect the approach to endovascular therapy in the aortoiliac segment proximally?

Dr Danczyk. At the time of initial percutaneous transluminal angioplasty and stenting (PTAS), 44 patients underwent lower extremity bypass operations. In general, the best operative approach is applied to each patient and if inflow can be established with aortoiliac artery stenting, even if a distal bypass is anticipated, then an endovascular approach to aortoiliac occlusive disease (AIOD) is pursued. Therefore, having a distal bypass dependent on revascularized inflow does not affect the approach to endovascular therapy in the aortoiliac artery segment.

Dr Nehler. Third, what if any role does surveillance have in these procedures?

Dr Danczyk. We do not currently have a surveillance protocol for iliac stent patients like we do for those with bypass grafts. In general, patients are followed with attention paid to clinical symptoms and ankle-brachial indexes (ABIs). Since iliac artery stents are not intervened upon prophylactically, we do not utilize a surveillance protocol.

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Supplementary Table I (online only). A, Clinical
characteristics of patient groups

Variable[a]	CIA or EIA stent (n = 368)	CIA and EIA stent (n = 123)	P
Age, years	62.9 ± 9.5	63.3 ± 10.6	.67
Female	34 (9.2)	8 (6.5)	.46
Comorbidities			
CAD	223 (60.6)	86 (69.9)	.07
DM	131 (35.6)	48 (39.0)	.52
Hypertension	294 (79.9)	103 (83.7)	.43
Hyperlipidemia	233 (63.3)	81 (65.9)	.67
CRI	36 (9.8)	12 (9.8)	>.99
Hemodialysis	9 (2.4)	3 (2.4)	>.99
Tobacco history	339 (92.1)	118 (95.9)	.22
Medications			
Aspirin	219 (59.5)	91 (74.0)	<.01[b]
Warfarin	22 (6.0)	6 (4.9)	.82
β-Blocker	189 (51.4)	65 (52.8)	.84
Clopidogrel	30 (8.2)	6 (4.9)	.32
Statin	219 (59.5)	70 (56.9)	.67
Indication			
Claudication	220 (59.8)	71 (57.7)	.75
CLI	148 (40.2)	52 (42.3)	.75
Rest pain	48 (13.0)	25 (20.3)	.06
Gangrene	19 (5.2)	5 (4.1)	.81
Ulcer	47 (12.8)	15 (12.2)	>.99
Acute ischemia	24 (6.5)	5 (4.1)	.38
Unknown	8 (<1.0)	0 (0.0)	>.99

CAD, Coronary artery disease; *CIA,* common iliac artery, *CLI,* critical limb
ischemia; *CRI,* chronic renal insufficiency (creatinine >1.5 mg/dL); *DM,*
diabetes mellitus; *EIA,* external iliac artery.

[a]Continuous data are expressed as mean ± standard deviation; categoric data
as number (%).

[b]Statistically significant ($P < .05$), χ^2 test/Fisher exact test.

Supplementary Table I (online only). B, Clinical characteristics of patient groups

Variable[a]	CIA Stents (n = 299)	EIA or CIA + EIA stents (n = 289)	P
Age, years	61.9 ± 9.1	64.1 ± 10.4	.01[b]
Female	37 (12.4)	21 (7.3)	.04[b]
Comorbidities			
CAD	181 (60.5)	194 (67.1)	.10[b]
DM	119 (39.8)	105 (36.3)	.40
Hypertension	235 (78.6)	241 (83.4)	.14
Hyperlipidemia	196 (65.6)	179 (61.9)	.39
CRI	45 (15.1)	28 (9.7)	.06
Hemodialysis	13 (4.3)	4 (1.4)	.05
Tobacco history	269 (90.0)	267 (92.4)	.31
Medications			
Aspirin	186 (62.2)	187 (64.7)	.55
Warfarin	16 (5.4)	28 (9.7)	.06
β-Blocker	154 (51.5)	154 (53.3)	.68
Clopidogrel	25 (8.4)	19 (6.6)	.44
Statin	184 (61.5)	155 (53.6)	.06
Indication			
Claudication	171 (58.8)	136 (47.1)	.01[b]
CLI	120 (41.2)	153 (52.9)	.01[b]
Rest pain	36 (12.4)	59 (20.4)	.01[b]
Gangrene	24 (8.2)	24 (8.3)	>.99
Ulcer	31 (10.7)	47 (16.3)	.05
Acute ischemia	20 (6.9)	19 (6.6)	>.99
Unknown	8 (2.6)	0 (0.0)	>.99

CAD, Coronary artery disease; *CIA,* common iliac artery; *CLI,* critical limb ischemia; *CRI,* chronic renal insufficiency (creatinine >1.5 mg/dL); *DM,* diabetes mellitus; *EIA,* external iliac artery.
[a]Continuous data expressed as mean ± standard deviation; categoric data as number (%).
[b]Statistically significant (*P* < .05), χ^2 test/Fisher exact test.

Supplementary Table II (online only). A, Clinical outcomes of common iliac artery (*CIA*) or external iliac artery (*EIA*) stent vs CIA and EIA stent groups

Outcome	CIA or EIA stent (n = 368) No (%)	CIA and EIA stent (n=123) No. (%)	P[a]
Lost to follow-up	66 (17.9)	24 (19.5)	.69
Death	110 (29.9)	35 (28.5)	.82
SEI	61 (16.6)	18 (14.6)	.67
Late open conversion	29 (7.9)	10 (8.1)	>.99
Amputation	8 (2.2)	7 (5.7)	.12

SEI, Secondary endovascular intervention.
[a]χ^2 test/Fisher exact test.

Supplementary Table II (online only). B, Clinical outcomes of common iliac artery (*CIA*) stents group vs external iliac artery (*EIA*) or CIA and EIA stents group

Outcome	CIA Stents (n = 299) No. (%)	EIA or CIA + EIA Stents (n = 289) No. (%)	P
Lost to follow-up	56 (18.7)	58 (20.1)	.75
Death	83 (27.8)	100 (34.6)	.08
SEI	57 (19.1)	38 (13.1)	.06
Late open conversion	26 (8.7)	22 (7.6)	.65
Amputation	7 (2.3)	11 (3.8)	.46

SEI, Secondary endovascular intervention.

Supplementary Table III (online only). A, Univariate analysis of death, secondary endovascular intervention, and late open conversion

Outcome[a]	Death		SEI		Late open conversion	
	(n = 143)	P	*(n = 78)*	P	*(n = 39)*	P
Age at PTAS, years	66.7 ± 8.6		60.0 ± 8.4		56.0 ± 8.2	
Female	4 (2.8)	<.01[b]	9 (11.4)	.38	7 (17.9)	.07
Comorbidities						
CAD	108 (74.5)	<.01[b]	50 (63.3)	>.99	25 (64.1)	>.99
DM	66 (45.5)	.01[b]	25 (31.6)	.37	10 (25.6)	.17
Hypertension	123 (84.8)	.17	63 (79.7)	.76	27 (69.2)	.09
Hyperlipemia	87 (60.0)	.26	47 (59.5)	.37	25 (64.1)	>.99
CRI	25 (17.2)	<.01[b]	5 (6.3)	.31	2 (5.1)	.41
Hemodialysis	7 (4.8)	.05	1 (1.3)	.70	1 (2.6)	>.99
Tobacco history	132 (91.0)	.25	78 (98.7)	.03[b]	37 (94.9)	>.99
Medication						
Aspirin	94 (64.8)	.68	43 (54.4)	.10	27 (69.2)	.49
Warfarin	12 (8.3)	.14	3 (3.8)	.60	0 (0.0)	.15
β-Blocker	79 (54.5)	.49	39 (49.4)	.71	18 (46.2)	.51
Clopidogrel	8 (5.5)	.35	6 (7.6)	>.99	2 (5.1)	.76
Statin	75 (51.7)	.04[b]	43 (54.4)	.39	22 (56.4)	.74
Indication						
CLI	84 (57.2)	<.01[b]	30 (38.0)	.62	13 (33.3)	.40
Acute ischemia	10 (6.9)	.54	5 (6.3)	.80	6 (15.4)	.02[b]
Stent location						
CIA or EIA	110 (75.9)	.82	61 (77.2)	.67	29 (74.4)	>.99
CIA and EIA	35 (24.1)		18 (22.8)		10 (25.6)	

CAD, Coronary artery disease; *CIA,* common iliac artery; *CLI,* critical limb ischemia; *CRI,* chronic renal insufficiency (creatinine >1.5 mg/dL); *DM,* diabetes mellitus; *EIA,* external iliac artery; *PTAS,* percutaneous transarterial angioplasty and stenting; *SEI,* secondary endovascular intervention.
[a]Continuous data are presented as mean ± standard deviation; categoric data are presented as number (%).
[b]Statistically significant ($P < .05$), χ^2 test/Fisher exact.

Supplementary Table III (online only). B, Univariate analysis of death, secondary endovascular intervention, and late open conversion

	Outcome					
	Death		SEI		Late open conversion	
Variable[a]	(n = 183)	P	(n = 95)	P	(n = 48)	P
Age at PTAS, years	66.9 ± 8.5		59.8 ± 8.1		57.2 ± 8.8	
Female	8 (4.4)	<.01[b]	12 (12.6)	.35	9 (18.8)	.04[b]
Comorbidities						
CAD	138 (75.4)	<.01[b]	61 (64.2)	>.99	31 (64.6)	>.99
DM	85 (46.4)	.03[b]	31 (32.6)	.25	12 (25.0)	.06
Hypertension	159 (86.9)	.02[b]	72 (75.8)	.20	32 (66.7)	.01[b]
Hyperlipidemia	113 (61.7)	.52	57 (60.0)	.42	29 (60.4)	.64
CRI	38 (20.8)	<.01[b]	6 (6.3)	.06	2 (4.2)	.11
Hemodialysis	11 (6.0)	.01[b]	1 (1.1)	.33	1 (2.1)	>.99
Tobacco history	159 (86.9)	.02[b]	93 (97.9)	.01[b]	44 (91.7)	>.99
Medication						
Aspirin	120 (65.6)	.52	55 (57.9)	.25	34 (70.8)	.35
Warfarin	20 (10.9)	.04[b]	3 (3.2)	.09	1 (2.1)	.25
β-Blocker	101 (55.2)	.37	49 (51.6)	.91	21 (43.8)	.23
Clopidogrel	11 (6.0)	.40	9 (9.5)	.40	2 (4.2)	.57
Statin	96 (52.5)	.09	55 (57.9)	>.99	26 (54.2)	.65
Indication						
CLI	114 (62.3)	<.01[b]	37 (38.9)	.42	19 (39.6)	.36
Acute ischemia	14 (7.7)	.59	6 (6.3)	>.99	7 (14.6)	.03[b]
Stent location						
CIA	83 (45.4)	.08	57 (60.0)	.06	26 (54.2)	.65
EIA or CIA + EIA	100 (54.6)		38 (40.0)		22 (45.8)	

CAD, Coronary artery disease; *CIA,* common iliac artery; *CLI,* critical limb ischemia; *CRI,* chronic renal insufficiency (creatinine >1.5 mg/dL); *DM,* diabetes mellitus; *EIA,* external iliac artery; *PTAS,* percutaneous transarterial angioplasty and stenting; *SEI,* secondary endovascular intervention.
[a]Continuous data are presented as mean ± standard deviation; categoric data as number (%).
[b]Statistically significant ($P < .05$), χ^2 test/Fisher exact test.

Supplementary Table IV (online only). A, Cox regression of death, secondary endovascular intervention, and late open conversion

	Outcome					
	Death (n = 143)		SEI (n = 78)		Late open conversion (n = 39)	
Variable	HR (95% CI)	P	HR (95% CI)	P	HR (95% CI)	P
Female	0.34 (0.12-0.93)	.04	1.60 (0.78-3.33)	.20	1.85 (0.77-4.47)	.17
Comorbidities						
CAD	1.85 (1.20-2.85)	<.01[a]	1.09 (0.66-1.79)	.75	1.47 (0.70-3.07)	.31
DM	1.29 (0.90-1.85)	.17	0.84 (0.50-1.39)	.49	0.65 (0.30-1.41)	.28
Hypertension	1.06 (0.61-1.84)	.85	0.78 (0.41-1.50)	.46	0.51 (0.21-1.22)	.13
Hyperlipidemia	0.94 (0.59-1.50)	.80	0.65 (0.35-1.22)	.18	0.90 (0.38-2.16)	.90
Tobacco history	0.40 (0.21-0.76)	.01[a]	7.63 (1.04-56.07)	.05	1.00 (0.23-4.40)	>.99
Medication						
Aspirin	1.31 (0.90-1.94)	.17	0.69 (0.41-1.14)	.14	1.47 (0.69-3.13)	.32
β-Blocker	1.18 (0.80-1.74)	.40	1.33 (0.78-2.28)	.29	1.04 (0.48-2.27)	.92
Statin	0.59 (0.37-0.93)	.02[a]	1.06 (0.57-1.97)	.85	1.15 (0.49-2.71)	.74
Indication						
CLI	2.27 (1.59-3.23)	<.01[a]	1.36 (0.83-2.24)	.22	1.24 (0.60-2.57)	.56
Stent location						
CIA and EIA	1.32 (0.88-1.98)	.19	1.39 (0.78-2.47)	.27	1.06 (0.50-2.26)	.87

CAD, Coronary artery disease; *CI,* confidence interval; *CIA,* common iliac artery; *CLI,* critical limb ischemia; *DM,* diabetes mellitus; *EIA,* external iliac artery; *HR,* hazard ratio; *SEI,* secondary endovascular intervention.
[a]Statistically significant ($P < .05$), forced entry.

Supplementary Table IV (online only). B, Cox regression of death, secondary endovascular intervention, and late open conversion

	Outcome					
	Death (n = 183)		*SEI (n = 95)*		*Late open conversion (n = 48)*	
Variable	*HR (95% CI)*	P	*HR (95% CI)*	P	*HR (95% CI)*	P
Female	0.35 (0.13-0.97)	.04[a]	1.58 (0.77-3.28)	.22	1.74 (0.71-4.25)	.23
Comorbidities						
CAD	1.87 (1.22-2.88)	<.01[a]	1.10 (0.66-1.82)	.72	1.56 (0.73-3.30)	.25
DM	1.26 (0.89-1.80)	.20	0.82 (0.49-1.36)	.44	0.65 (0.30-1.40)	.27
Hypertension	1.07 (0.61-1.86)	.82	0.78 (0.41-1.50)	.46	0.54 (0.22-1.29)	.16
Hyperlipidemia	0.92 (0.58-1.47)	.73	0.64 (0.34-1.20)	.16	0.84 (0.35-2.01)	.69
Tobacco history	0.39 (0.21-0.74)	<.01[a]	7.30 (0.99-53.70)	.05	0.92 (0.21-4.05)	.91
Medication						
Aspirin	1.24 (0.84-1.83)	.28	0.65 (0.40-1.07)	.09	1.47 (0.69-3.11)	.32
β-Blocker	1.23 (0.83-1.82)	.30	1.36 (0.79-2.32)	.27	0.99 (0.45-2.16)	.98
Statin	0.58 (0.36-0.91)	.02[a]	1.08 (0.58-2.02)	.81	1.23 (0.52-2.91)	.64
Indication						
CLI	2.23 (1.57-3.17)	<.01[a]	1.38 (0.84-2.27)	.20	1.26 (0.61-2.63)	.53
Stent location						
EIA or CIA + EIA	0.95 (0.68-1.33)	.77	0.88 (0.55-1.41)	.58	0.79 (0.40-1.57)	.50

CAD, Coronary artery disease; *CI,* confidence interval; *CIA,* common iliac artery; *CLI,* critical limb ischemia; *DM,* diabetes mellitus; *EIA,* external iliac artery; *HR,* hazard ratio; *SEI,* secondary endovascular intervention.

[a]Statistically significant ($P < .05$), forced entry.