

# Advanced Age and Disease Predict Lack of Symptomatic Improvement after Endovascular Iliac Treatment in Male Veterans

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**Background:** Endovascular angioplasty and stent placement is currently the most frequent treatment for iliac artery occlusive disease. However, despite a successful endovascular procedure, some patients do not experience symptomatic improvement and satisfaction with their care. This study seeks to identify patient-related factors associated with lack of symptomatic improvement after endovascular iliac artery treatment in male veterans.

**Methods:** Retrospective review of patients treated with endovascular methods for iliac artery occlusive disease between January 2008 and July 2012 at VA Connecticut Healthcare System. Symptomatic improvement on the first post-operative visit was evaluated, with bilateral treatments counted separately.

**Results:** Sixty-two patients had 91 iliac arteries treated with angioplasty and stent placement. Forty-seven (52 percent) legs had critical limb ischemia, and 77 (85 percent) had at least two-vessel distal runoff. Angiographic success was 100 percent. Patient-reported symptomatic improvement at the first post-operative visit was 55 percent (50/91). Lack of symptomatic improvement correlated with older age (OR 1.09 [1.03-1.17],  $p = 0.008$ ), presence of critical limb ischemia (OR 3.03 [1.09-8.65],  $p = 0.034$ ), and need for additional surgical intervention (OR 5.61 [1.65-17.36],  $p = 0.006$ ). Survival, primary and secondary patency, and freedom from restenosis were comparable between patients who reported symptomatic improvement and those who did not.

**Conclusions:** Despite angiographically successful revascularization, patients who are older or have critical limb ischemia who are treated with isolated endovascular iliac artery intervention are more likely to require additional interventions and less likely to experience symptomatic improvement. These patients may need more extensive infra-inguinal revascularization than isolated iliac angioplasty and stent placement, despite a preserved ankle-brachial index. Quality of life needs to be measured with formal instruments after iliac artery endovascular treatment, especially to determine long term outcomes.

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†Abbreviations: ABI, ankle-brachial index; CIA, common iliac artery; EIA, external iliac artery.

Keywords: peripheral artery disease, iliac artery, stenosis, stent, endovascular treatment, satisfaction, quality of life, critical limb ischemia

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## INTRODUCTION

Iliac artery occlusive disease is prevalent among elderly people, with up to 17 percent of men and 20 percent of women aged 55 and older having clinical evidence of disease [1]. Open surgical bypass has been the traditional treatment for iliac disease and provides excellent durability, but requires an invasive procedure with concomitant risk of perioperative complications [2]. Endovascular treatment has been described as a more minimally invasive alternative to open repair, with early studies showing the efficacy and long-term durability of percutaneous angioplasty and stenting as a first approach to iliac disease [3,4]. These pioneering results have been validated by large contemporary series [5,6]. Not surprisingly, indications now have expanded from simple stenoses to include advanced disease such as complex stenosis, as well as occlusions [7-9]. With 96 percent technical success, perioperative morbidity <10 percent and 96 percent 3-year and 85 percent 5-year patency endovascular techniques are now the most common first approach to treat iliac artery disease [6,10,11].

Despite the increased use of endovascular treatment for iliac artery disease, there is scant literature reporting patient satisfaction after these procedures [12]. Sullivan et al. reported that clinical improvement after iliac artery treatment was associated with disease severity as well as patient age [13]. Murphy et al. reported improved quality of life at 1 year following iliac stent placement for claudication [14]. The Dutch Iliac Stent Trial Study Group reported that despite successful endovascular revascularization improving quality of life, some patients do not benefit clinically and are not satisfied with their treatment [15]. We have observed that patients who do not report clinical improvement and satisfaction on the first post-operative visit are more likely to require additional surgical interventions. Therefore, we hypothesized that among patients who are expected to benefit from isolated endovascular iliac artery treatment, there is a subset of patients who will not be satisfied with their procedure. Since veterans have been demonstrated to form a group of patients with reduced self-reported quality of life and satisfaction with medical care [16], we examined this high risk group of patients to identify patient-associated factors that predict lack of symptomatic improvement and satisfaction after endovascular iliac artery treatment.

## MATERIAL AND METHODS

A retrospective review of all patients treated with endovascular methods for iliac artery occlusive disease between January 2008 and July 2012 by the Vascular Surgery service at the VA Connecticut Healthcare System (West Haven, Connecticut) was conducted. All patients treated with balloon angioplasty of the iliac arteries as a primary therapeutic procedure were included; primary stent placement was performed. When either both the common iliac and external iliac arteries in one patient

were treated or bilateral artery treatment was performed, each treated artery was counted separately, per Society for Vascular Surgery reporting standards [17]; however, patient mortality was based only on patients treated. Exclusion criteria included patients with aneurysmal disease and patients who underwent hybrid treatments during the same procedure (e.g., a concomitant open procedure at the same setting), as well as patients who planned to undergo staged subsequent procedures, including revascularization distal to the iliac arteries. Patients who had unexpected additional procedures to treat an immediate procedural complication were not excluded.

Angiographically determined areas of disease were categorized into mild (0-50 percent), moderate (51-79 percent), or severe (80-99 percent) stenoses or occluded (100 percent) based on the area of maximal disease, as commonly reported in our institution, based on local consensus of radiologists and vascular surgeons. Satisfaction with the procedure was defined as any qualitative subjective improvement in symptoms reported by the patient on the first post-operative visit, typically scheduled 2 weeks after the procedure. All patients were asked by a member of the surgical team whether their presenting symptoms had improved or not following the procedure; symptoms included intermittent claudication, rest pain, and wound healing. Symptomatic improvement was documented for left and right sides separately, if bilateral treatment was performed. The ankle-brachial index (ABI) was measured as the ratio of the systolic pressure at the ankle (highest of dorsalis pedis or posterior tibial arteries) to the highest of the left and right arm brachial systolic blood pressures; it is measured using a sphygmomanometer and a Doppler probe. The ABI change was measured at the first post-operative visit and was defined as the post-operative/pre-operative ABI. Distal runoff was evaluated as the number of tibial arteries patent on angiogram (<50 percent stenosis). Patients were followed after the procedure with physical examinations and duplex ultrasound at 6 months and then yearly thereafter, with abnormalities investigated with CT or conventional angiogram. Restenosis was considered present if >60 percent stenosis was present on the angiogram. Primary patency was defined as no evidence of occlusion within the target vascular lesion. Secondary patency was defined as patency in the target vascular lesion maintained by repeat intervention after restenosis or complete occlusion.

Variables were represented as mean  $\pm$  SEM or percentages. Categorical variables were compared with Chi-square analysis, and continuous variables were compared with the t-test or the median test. Kaplan-Meier analysis was used for primary patency, secondary patency, freedom from restenosis and survival analysis, with comparison of groups using the logrank and Breslow-Gehan-Wilcoxon tests. Multivariable logistic regression with backward elimination was used to determine the variables associated with post-procedural symptomatic improvement; initial variables included those variables that showed a correlation with symptomatic improvement ( $p < 0.10$ ) on univariable

**Table 1. Demographics of patients with endovascular iliac artery treatment.**

	Whole Group	Symptomatic Improvement	No Symptomatic Improvement	p
N (patients)	62	38 (61%)	24 (39%)	
N (arterial lesions)	91	50 (55%)	41 (45%)	
Age (years)	66.5 ± 0.8	65 ± 1	69 ± 1	0.0273*
Male gender	91 (100%)	50 (100%)	41 (100%)	
<b>Race</b>				0.2467
Caucasian	86 (95%)	46 (92.0%)	40 (97.6%)	
African American	5 (5%)	4 (8.0%)	1 (2.4%)	
SBP (mmHg)	142 ± 2	143 ± 3	141 ± 4	0.7739
DBP (mmHg)	71 ± 1	72 ± 2	69 ± 2	0.1127
Diabetes mellitus	42 (46%)	19 (38.0%)	23 (56.1%)	0.0849
Hypertension	76 (84%)	41 (82.0%)	35 (85.4%)	0.6668
Dyslipidemia	72 (79%)	39 (78.0%)	33 (80.5%)	0.7714
Smoking history	78 (86%)	39 (78.0%)	39 (95.1%)	0.0202*
History of myocardial infarction	40 (44%)	16 (32.0%)	24 (58.6%)	0.0112*
Chronic kidney disease	11 (12%)	3 (6.0%)	8 (19.5%)	0.0491*
Cerebrovascular disease	12 (13%)	3 (6.0%)	9 (22.0%)	0.0252*
<b>Symptoms</b>				<0.0001*
Claudication	44 (48%)	33 (66.0%)	11 (26.8%)	0.0002*
Critical limb ischemia	47 (52%)	17 (34.0%)	30 (73.2%)	0.0002*
Rest pain	20 (43%)	13 (26.0%)	7 (17.1%)	0.3062
Tissue loss	27 (57%)	4 (8.0%)	23 (56.1%)	<0.0001*
ABI pre-operative	0.61 ± 0.03	0.60 ± 0.03	0.63 ± 0.05	0.5367

SBP, systolic blood pressure; DBP, diastolic blood pressure; ABI, ankle-brachial index.

Categorical variables are represented as number (percentage). Continuous variables are represented as mean ± standard deviation.

analysis. All tests were 2-tailed with a type I error risk (alpha) equal to 0.05. JMP ® 9.0.0 software (SAS Institute, Cary, NC) was used for data analysis.

## RESULTS

Sixty-two patients had endovascular treatment of 91 iliac arteries to treat isolated iliac artery occlusive disease; patients frequently had bilateral treatment using both single and staged procedures. The demographic and risk factors of these patients are described in Table 1; notably, all patients were male with a mean age of 66.5 ± 0.8 years. As expected, patients frequently had a history of prior or current smoking (86 percent), hypertension (84 percent), dyslipidemia (79 percent), and severe cardiac disease (44 percent). Forty-eight percent of the patients presented with intermittent claudication and 52 percent with critical limb ischemia; of these patients, more than half presented with tissue loss. The average pre-operative ABI was 0.61 ± 0.03 (range 0.13-1.22).

Variables associated with the iliac artery treatment are shown in Table 2. Treatment was equally divided between the common iliac artery (CIA) and the external iliac artery (EIA). The degree of stenosis reported by the surgeon was moderate in 18 percent of patients and severe in 72 percent, with 10 percent having a total occlusion of the dis-

eased segment. All patients had stents placed, with a mean of 1.3 ± 0.1 stents placed on each side. The average length of iliac artery covered was 49 ± 3 mm. Angiographic success was 100 percent. Peri-procedural morbidity occurred in five cases (5 percent), and none of these were fatal. Two patients developed dissection, with one resulting in distal embolization and one causing thrombosis of the profunda femoral artery, which were both successfully treated using endovascular techniques. One case was complicated by femoral artery occlusion due to the closure device requiring open re-exploration and repair.

Short- and long-term outcomes are reported in Table 3. Thirty-day mortality occurred in two patients (3 percent); one patient died outside the hospital from unknown causes, and one patient with multiple comorbidities died of multi-organ system failure. Thirty-day morbidity included one stroke and one acute stent thrombosis that required thrombectomy and femoral-femoral bypass. All of these patients with 30-day complications were assessed after the procedure and included in the following results.

All patients returned for their first post-operative visit after a mean of 18 ± 1 days and were assessed for symptomatic improvement after the endovascular procedure. Patients reported an improvement in their symptoms and satisfaction with their procedure in 55 percent of cases (n = 50); however, there was no improvement or progression of

**Table 2. Procedural variables and peri-procedural outcomes of endovascular iliac artery endovascular treatment.**

	Whole Group	Symptomatic Improvement	No Symptomatic Improvement	p
<b>Iliac artery treatment location</b>				0.6201
Common iliac	47 (52%)	27 (54.0%)	20 (48.8%)	
External iliac	44 (48%)	23 (46.0%)	21 (51.2%)	
<b>Degree of stenosis</b>				0.1426
Moderate (50-79% stenosis)	16 (18%)	6 (12.0%)	10 (24.4%)	0.1224
Severe (80-99% stenosis)	66 (72%)	37 (74.0%)	29 (70.7%)	0.7282
Occlusion	9 (10%)	7 (14.0%)	2 (4.9%)	0.1470
Distal 2-vessel runoff	77 (85%)	40 (80.0%)	37 (90.2%)	0.1778
Number of stents used	1.3 ± 0.06	1.3 ± 0.09	1.3 ± 0.08	0.9166
Length of covered artery (mm) (mean ± SD)	49.2 ± 2.9	48.1 ± 3.6	50.5 ± 4.6	0.6860
Angiographic success	91 (100%)	53 (100%)	41 (100%)	
<b>Procedural morbidity</b>	5 (5.5%)	4 (8%)	1 (2.4%)	0.2467
Dissection	2 (2.2%)	2 (3.9%)	0 (0%)	
Distal embolization	1 (1.1%)	1 (2%)	0 (0%)	
Thrombosis of profunda femoral artery	1 (1.1%)	0 (0%)	1 (2.4%)	
Femoral artery occlusion due to closure device misplacement	1 (1.1%)	1 (2%)	0 (0%)	

Categorical variables are represented as number (percentage). Continuous variables are represented as mean ± standard deviation.

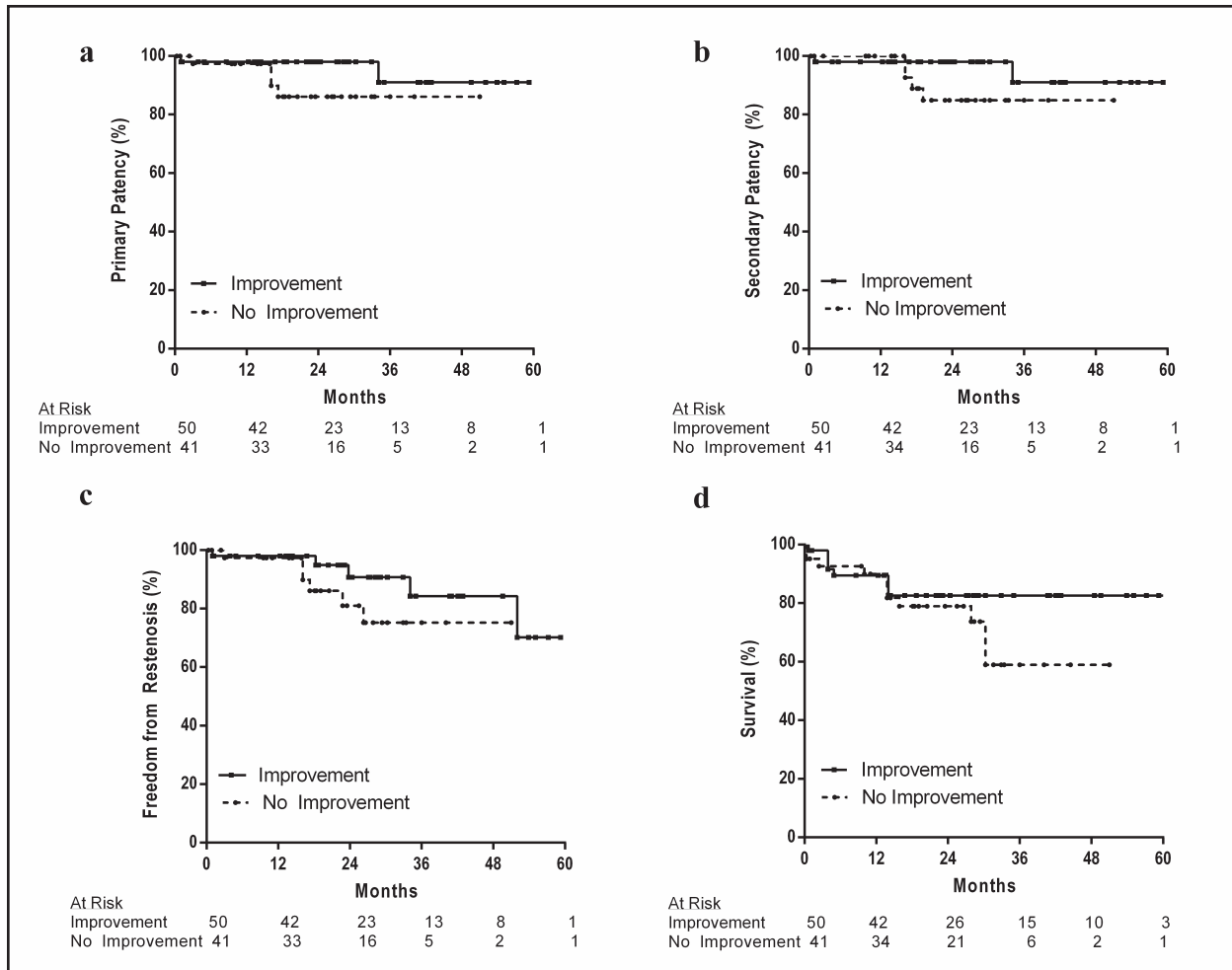
**Table 3. Short- and long-term outcomes after iliac artery endovascular treatment.**

	Whole Group	Symptomatic Improvement	No Symptomatic Improvement	p
Time to first post-operative visit (days)	17.8 ± 1.5	18.2 ± 2.1	17.4 ± 2.1	0.7749
<b>Pulse exam (first post-operative visit)</b>				0.3554
Absent	6 (7%)	2 (4.0%)	4 (10.3%)	
Dopplerable	60 (67%)	33 (66.0%)	27 (69.2%)	
Palpable	23 (26%)	15 (30.0%)	8 (20.5%)	
ABI post-operative	0.73 ± 0.04	0.75 ± 0.05	0.72 ± 0.05	0.6365
Change in ABI	0.13 ± 0.03	+0.2 ± 0.04	+0.06 ± 0.04	0.0224*
30-day mortality	2 (3.2%)	1 (2.6%)	1 (4.2%)	0.7390
30-day morbidity	2 (2.1%)	2 (4.0%)	0 (0%)	0.1953
30-day readmission	2 (3.3%)	1 (2.0%)	2 (4.9%)	0.4442
Follow-up time (months)	24.5 ± 1.6	26.5 ± 2.6	22.1 ± 1.8	0.1623
Restenosis (angiographically confirmed)	11 (12%)	5 (10.0%)	6 (14.6%)	0.4999
Mean time to restenosis (months)	21.0 ± 4.2	25.8 ± 8.5	16.9 ± 3.3	0.3693
Median time to restenosis (months)	18.3	23.8	16.7	0.3991
Additional intervention	31 (34%)	9 (18%)	22 (53.7%)	0.0004*
Mean time to intervention (months)	4.2 ± 1.3	4.8 ± 2	3.7 ± 1.7	0.6836
Late mortality	12 (19%)	5 (13.2%)	7 (29.2%)	0.1202

Categorical variables are represented as number (percentage). Continuous variables are represented as mean ± standard deviation.

their symptoms and lack of satisfaction in 45 percent of cases (n = 41; Table 1). Patients who did not report symptomatic improvement were older and more likely to have a history of smoking, myocardial infarction, chronic kidney disease, cerebrovascular disease, or critical limb ischemia (Table 1). Patients with critical limb ischemia were less

likely to report symptomatic improvement with isolated iliac intervention compared with patients who had claudication (p = 0.0002; Table 1). There were no significant differences in procedural variables between patients who were or were not symptomatically improved (Table 2). Although the post-operative ABI was comparable between the two



**Figure 1. Patency and survival of patients with or without symptomatic improvement after iliac artery endovascular treatment.** a) Primary patency (Logrank  $p = 0.17$ , Wilcoxon  $p = 0.20$ ); b) Secondary patency (Logrank  $p = 0.18$ , Wilcoxon  $p = 0.25$ ); c) Freedom from restenosis (Logrank  $p = 0.19$ , Wilcoxon  $p = 0.21$ ); d) Survival (Logrank  $p = 0.22$ , Wilcoxon  $p = 0.47$ ). The number at risk at each interval is listed below the x-axis.

groups, patients who reported no symptomatic improvement had less improvement in their post-operative ABI ( $+0.06 \pm 0.04$ ) compared to the improvement in patients who reported symptomatic improvement ( $+0.2 \pm 0.04$ ;  $p=0.02$ ; Table 3). During the mean follow-up time of  $24.5 \pm 1.6$  months (median 23.1 months, range 0.3 to 65.4 months), there was no difference in development in iliac artery restenosis between patients who were or were not symptomatically improved after the procedure ( $p = 0.4999$ ). However, patients who initially did not report symptomatic improvement were more likely to undergo additional intervention (54 percent versus 18 percent,  $p = 0.0004$ ; Table 3), with a mean time to subsequent intervention of  $4.2 \pm 1.3$  months. The most frequent subsequent interventions included an open infra-inguinal procedure (58 percent), minor amputation (24 percent), femoro-femoral bypass (12 percent), or major amputation (6 percent).

The 3-year survival rate of patients undergoing iliac artery endovascular treatment was 73 percent; at 3 years, primary and secondary patency rates were both 87 percent, and freedom from restenosis 79 percent in the overall cohort of

patients. There was no difference in primary or secondary patency, freedom from restenosis, or survival between patients who reported symptomatic improvement or not following treatment (Figure 1). A multivariable fit model was created to analyze factors that predicted symptomatic improvement after iliac artery endovascular treatment, including age, diabetes mellitus, history of smoking, history of myocardial infarction, chronic kidney disease, cerebrovascular disease, critical limb ischemia, and need for additional procedures (Tables 1-3). Using multivariable analysis, lack of symptomatic improvement after iliac artery treatment was only associated with older age ( $p = 0.008$ ), presence of critical limb ischemia ( $p = 0.034$ ), and need for additional surgical intervention ( $p = 0.006$ ) (Table 4).

## DISCUSSION

We report that 45 percent of male veterans undergoing angiographically documented successful endovascular treatment of iliac artery occlusive disease did not report improved symptoms after their treatment. Lack of symptomatic

**Table 4. Factors associated with lack of symptomatic improvement after iliac artery endovascular treatment.**

	Odds Ratio [95% CI]	P
Age	1.09 [1.03 – 1.17]	0.0082*
Critical limb ischemia	3.03 [1.09 – 8.65]	0.0340*
Additional surgical intervention	5.61 [1.65 - 17.36]	0.0059*

CI: confidence interval

improvement was associated with patients who were older and had critical limb ischemia prior to the procedure; these patients were also more likely to require additional intervention after the iliac endovascular procedure. These findings suggest that there is a subset of patients with increased burden of disease that will not be symptomatically improved with isolated iliac artery treatment despite a treatment plan that was thought to be appropriate for the patient's disease.

Few studies have looked at quality of life after percutaneous endovascular treatment of iliac artery disease. The Dutch Iliac Stent Trial Study Group reported that patients who underwent selective or primary iliac stenting reported a significant increase in all RAND 36-Item Health Survey items at 2 years, a superior quality of life compared to patients who were enrolled in exercise programs [15]. Late follow-up data from the same series showed that while this benefit was maintained, female sex and the presence of critical limb ischemia were predictive of iliac reintervention [18]. Murphy et al. reported markedly improved walking ability and health-related quality of life for patients with moderate to severe intermittent claudication following iliac artery stenting, but did not include patients with critical limb ischemia [14]. In our series, nearly half of our patients were not satisfied with the outcomes, claiming lack of symptomatic improvement, and almost half of this group required additional vascular interventions despite excellent patency rates; 3-year primary and secondary patency rates were 87 percent, comparable to other studies [5,11,19]. In addition, angiographically observed technical success was obtained in all patients, and 85 percent of the patients had at least two-vessel runoff. The majority of subsequent interventions treated infra-inguinal disease, suggesting that some distal disease was initially present but not thought to be severe enough to require treatment at the initial setting. However, nearly half of our patients presented with critical limb ischemia; patients with critical limb ischemia have reduced quality of life compared to patients with claudication [20-22], predisposing these patients to reduced satisfaction after the procedure (Table 1). Patients with critical limb ischemia typically have other advanced comorbid conditions, and thus, critical limb ischemia is likely a surrogate marker for advanced cardiovascular and other associated diseases (Table 4).

Despite pre-operative evaluation indicating peripheral arterial disease secondary to isolated iliac artery disease and excellent technical outcome, a substantial fraction of our patients did not have symptomatic improvement and accordingly were not satisfied with their treatment. Although

most of these unsatisfied patients presented with critical limb ischemia (Table 1), the average ABI of this group was 0.6, comparable to the group that was satisfied after the intervention. Not surprising, unsatisfied patients had minimal improvement in their ABI post-operatively (+0.06), correlating with the persistence of their symptoms. This suggests that these patients may be a subgroup of patients who received isolated iliac artery treatment, possibly because of their preserved ABI, but their high burden of disease may require therapy in addition to the iliac revascularization. The contemporary trend to measure patient satisfaction in many fields of medicine is spreading to management of vascular disease [23-26]. We believe that this study shows that lack of patient symptomatic improvement at the first post-procedural visit after iliac artery endovascular treatment reveals a subset of patients who will likely need additional treatment despite a successful endovascular procedure, and that early attention to potential additional treatment may increase symptomatic improvement and patient satisfaction with their vascular care.

Limitations of our study can be attributed to the retrospective analysis that precluded a prospective collection of data for validated quality of life surveys. Future studies using either general questionnaires such as the SF-36 and EuroQol or disease specific questionnaires such as the Vas-cuQol may allow improved discrimination between particular elements that affect quality of life after iliac intervention. However, despite the subjective nature of the main outcome, these findings correlated with objective data such as ABI improvement and reintervention (Table 3). While surveillance imaging data was available for most of our patients allowing the long-term determination of survival and patency, specific data regarding symptomatic improvement on subsequent follow-up visits was frequently lacking and thus assumption of asymptomatic status was not made. The modest size of our series and limitation to male veterans prohibit generalization of our findings to the general population of patients with vascular disease. Veterans have a greater number of comorbid conditions and reduced quality of life compared to civilians [16,27]. As such, studies in the non-veteran population, especially in patients with claudication, may show increased symptomatic improvement, increased quality of life, and satisfaction after endovascular iliac treatment.

In conclusion, we show that a high burden of peripheral artery disease, associated with advanced age and critical limb ischemia, predicts lack of immediate symptomatic improvement and, accordingly, lack of satis-

fection following isolated iliac artery endovascular intervention in male veterans. Lack of immediate symptomatic improvement is also associated with less improvement of ABI after the procedure and need for additional intervention. We believe that post-procedural self-reported symptomatic improvement is a reasonable surrogate marker for procedural success, at least until more specific measures are developed from validated studies. Quality of life needs to be measured with formal instruments after iliac artery endovascular treatment, especially to determine long-term outcomes. Our data also suggests that patients who present with advanced peripheral disease, despite preserved ABI, should be a subset of patients for whom additional revascularization procedures might be considered at the initial treatment episode, diminishing the need for reintervention. In particular, elderly patients with critical limb ischemia, who are appropriate candidates for treatment, should not be denied appropriately aggressive endovascular or open revascularization.

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