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Subintimal angioplasty of chronic total occlusion in iliac arteries: A safe and durable option

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Background: **Traditionally, aortobifemoral bypass has been the intervention of choice for iliac artery chronic total occlusions (CTOs). However, it is associated with significant morbidity and mortality, limiting its use in high-risk patients. To reduce procedural risk, subintimal angioplasty (SIA) for femoropopliteal CTO has been utilized by many, but few have extended this endovascular technique to treating iliac artery CTOs. We present our experience with 101 successful SIAs for iliac artery CTOs.**

Methods: **A retrospective review of consecutive patients with iliac artery CTOs treated with subintimal angioplasty from June 2000 to January 2009 was completed. Demographic and risk factor data were obtained, along with procedural data. Primary and secondary patency, survival, freedom from claudication, and limb salvage rates were determined by Kaplan-Meier survival analysis. Univariate and multivariate analyses were completed to identify factors adversely affecting primary patency.**

Results: **One hundred twenty patients underwent an attempted SIA of an iliac artery CTO, and 101 iliac artery CTOs were successfully treated, giving a technical success rate of 84%. Technical failure was due to the inability to re-enter the lumen in all cases. Indications for intervention were lifestyle-altering claudication in 64 patients (63%) and critical limb ischemia (CLI), in 37 (37%). Eighty-five patients underwent percutaneous SIA, while 11 patients underwent a combined SIA with surgical outflow procedure. Lesions were classified as TransAtlantic InterSociety Consensus (TASC) B, 39 (39%); TASC C, 27 (27%); and TASC D, 35 (35%). In 82 (81%) lesions, stents were deployed with an average of 1.2 (range, 0-3) stents utilized. A re-entry device was used in 14 (14%) lesions. Major complication rate was 3.0%, with a 30-day mortality rate of 1.0%. Primary and secondary patency rates at 1, 2, and 3 years were 86% and 94%, 76% and 92%, and 68% and 80%, respectively. Survival rate was 67% at 5 years, reflecting the poor health of this cohort. Limb salvage for CLI patients at 1 and 5 years was 97% and 95%, respectively. Freedom from claudication at 1 and 3 years was 89% and 73%. Univariate analysis identified hyperlipidemia, coronary artery disease, and prior surgical bypass in treated limb as factors for loss of primary patency; however, on multivariate analysis, no factors remained statistically significant.**

Conclusion: **This study demonstrates that SIA of iliac CTOs is feasible and can be performed safely and effectively, even in high-risk patients. Excellent patency and limb salvage rates can be achieved. In our experience, the safety and durability of SIA makes it an attractive first-line therapy for iliac artery occlusive disease. (J Vasc Surg 2011;53:367-73.)**

Therapeutic options for chronic total occlusions (CTOs) of iliac arteries have evolved during the past two decades. Although aortobifemoral bypass is still considered the gold standard for treatment of iliac artery CTOs, the procedure carries a mortality rate of 4.4% and a major complication rate of 12.1%.[1] As the population accumulates more comorbidities, fewer patients will be considered an acceptable risk for open revascularization.

As endovascular techniques have matured, these techniques have been applied to increasingly sicker patients. Kashyap published results for intraluminal endovascular interventions for aortoiliac occlusive disease with a primary patency rate of 74% at 3 years and a secondary patency of 95% at 3 years.[2] While the bulk of the literature details the use of intraluminal endovascular techniques for iliac stenoses, there has been a paucity of studies addressing iliac artery CTO. Most who have attempted crossing iliac artery CTOs in an intraluminal fashion have experience with inadvertently causing a subintimal dissection. The next logical question from this experience is: Can subintimal angioplasty (SIA) be used for treatment of iliac artery CTOs?

Developed in the United Kingdom in 1989, SIA has gained acceptance throughout Europe.[3] Theoretically, it circumvents the occluded lumen by creating a new channel within a subintimal plane. SIA can treat longer femoropopliteal artery occlusions than intraluminal angioplasty and is also considered to be safer than open surgery.[4] A meta-analysis of SIA revealed a technical success rate of 86%, with a 1-year primary patency rate of 56% and a limb salvage rate of 89%.[5] While this study analyzed 37 studies, only two of these included iliac artery interventions for a total of 79 patients. These results are similar to our published experience with infrainguinal SIA, with a 1-year primary patency of 45% and limb salvage rate of 88%.[6] This article also did not focus on iliac artery CTOs.

To date, there has not been a published series of iliac artery CTOs managed exclusively with SIA. Based on our

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experience with improved safety with SIA of femoropopliteal lesions, we hypothesized this technique could be applied to iliac artery CTOs to obtain a similar improvement in morbidity and mortality. It is the purpose of this study to determine the safety and durability of the technique in dealing with iliac artery CTOs.

METHODS

Patients. After approval of the Institutional Review Board, a retrospective review of patients who underwent SIA for an iliac artery CTO from June 2000 to January 2009 was performed. Patient hospital and clinic records along with angiograms were reviewed. Patient demographics, risk factors, indications for the procedure, procedural details, preoperative and postoperative vascular studies, and outcome data such as primary and secondary patencies, periprocedural complications, and mortality were collected in a database for analysis. Procedural details on secondary and tertiary interventions were also recorded. TransAtlantic InterSociety Consensus (TASC) II classification of treated lesions were determined intraoperatively or after review of angiographic studies under the direct supervision of the senior author or primary surgeon.[7]

Preoperative noninvasive evaluation. In general, ankle-brachial indices (ABIs) with waveform analysis were obtained to identify patients with aortoiliac occlusive disease. Those with studies consistent with such had aortoiliac duplex imaging to identify lesions and the presence of iliac artery aneurysms. The location of lesions determined optimal arterial access and iliac artery aneurysm was an absolute contraindication to SIA. Computed tomographic angiography (CTA) was not routinely utilized, except when screening for additional pathology.

Operative technique. Most SIA was performed in the angiographic suite, although those cases also requiring an immediate outflow procedure were completed in the operating room. The need for combined open surgery and SIA was determined by diagnostic angiogram. Patients with femoral lesions amendable to endarterectomy or those with need for immediate outflow revascularization were scheduled for a combined procedure.

Arterial access was obtained through femoral or brachial arteries. Not infrequently, bilateral simultaneous accesses were necessary. In most cases, a hydrophilic stiff or soft-tip 0.035-inch Glidewire (Terumo Medical Corporation, Somerset, NJ) was used in combination with an angled catheter such as the Glidecath (Terumo Medical Corporation) or Berenstein (AngioDynamics, Latham, NY). The catheter was used to engage the lesion and direct the wire into the subintimal plane. The Quick-Cross (Spectranetics Corporation, Colorado Springs, Colo) catheter was also used, mainly to give more columnar support for the wire in tight lesions.

Depending on the preferential dissection direction of the wire, SIA was performed in either an antegrade or retrograde direction. In a few cases, a 6-10 mm angioplasty balloon was used to create dissections in iliac arteries to facilitate subintimal dissection. Entry into the subintimal space was determined by the fluoroscopic behavior of the dissection wire and the significantly increased tactile resistance during dissection. If there were any questions of subintimal presence, a 1-2 mL injection of contrast was completed. As the subintimal space is not well vascularized, the dye remains in place when re-entry has not been achieved. In all cases, re-entry into the true lumen was verified angiographically prior to performing a balloon angioplasty. In difficult re-entry cases, re-entry devices such as the Outback (Cordis Corporation, Warren, NJ) and the Pioneer (Medtronic, Santa Rosa, Calif) were used.

After balloon angioplasty of the subintimal channel, selective stenting was utilized at the judgment of the surgeon based on criteria previously published in our infrainguinal SIA experience.[8] Type and number of stents used were also at the judgment of the individual surgeon. When bilateral common iliac artery lesions were treated, a kissing-balloon technique was utilized, otherwise, a unilateral balloon was utilized. Completion angiograms were performed in all cases. Due to concerns with rupture during SIA, an appropriately sized covered stent was available if extravasation was identified during the completion angiogram.

Anticoagulation was not routinely given preoperatively or postoperatively. Heparin was given routinely after placement of a working sheath and prior to dissection of lesions. Unless already on Plavix, newly stented patients were loaded on 300 mg and continued on 75 mg daily for 1 month. Double antiplatelet regimens were not routinely prescribed.

Definitions. Primary and secondary patencies were defined in compliance with the Society for Vascular Surgery® reporting standard for lower extremity ischemia.[9] These patencies were based on operative reports including secondary and tertiary procedures, both invasive and noninvasive vascular studies, and clinical status. Evidence of loss of patency included loss of pulses if present after the intervention, a duplex ultrasound study demonstrating occlusion or velocities >300 cm/s and having a lesion velocity to adjacent segment velocity ratio >3.5, angiographic evidence of $>50\%$ restenosis or reocclusion, or intraoperative evidence of occlusion. Technical success was defined as SIA with or without stenting demonstrating $<30\%$ residual stenosis and no flow-limiting lesion on completion angiogram. Symptomatic improvement was defined as subjective improvement in claudication symptoms in those patients with lifestyle-altering claudication.

Clinical-evaluation. Clinical follow-up was typically at 1 month, 6 months, 12 months, and then every 6 to 12 months thereafter. On follow-up, ABI with waveform analysis and aortoiliac duplex ultrasound studies were performed.

Statistics. Continuous data were expressed as mean standard deviation. $P < .05$ was considered to be statistically significant. Technical failures were not included in the statistical analysis as SIA had not been performed. Primary and secondary patencies, limb salvage, and freedom from claudication were analyzed by Kaplan-Meier survival analysis on an individual lesion basis. Survival was analyzed by

Table I. Patient risk factors and comorbidities in 96 successfully treated patients

Variable	*n (%)*
Hypertension	77 (80.2%)
Hypercholesterolemia	73 (76.0%)
Diabetes mellitus	38 (39.6%)
End-stage renal disease	13 (13.5%)
Coronary artery disease	55 (57.3%)
Previous smoker	31 (32.3%)
Current smoker	53 (55.2%)
Prior surgical bypass in treated limb	10 (10.4%)
Chronic obstructive pulmonary disease	11 (11.5%)
Obesity	35 (36.5%)

Kaplan-Meier survival analysis on an individual patient basis. Multivariate analysis was performed using Cox proportional hazard regression. SPSS 17.0 (SPSS, Chicago, Ill) was used for all statistical analysis.

RESULTS

Between June 2000 and January 2009, approximately 2000 patients underwent iliac artery angioplasty. Of these, 118 patients were identified as having undergone attempted SIA for iliac artery CTO. Two patients were excluded from analysis due to immediate lost to follow-up. The remaining 116 study patients were found to have a total of 121 iliac artery CTOs during angiography. The 15 vascular surgeons in this study obtained a technical success rate of 83.5% (101 iliac artery CTOs). Technical failure in 20 patients was due to inability to achieve re-entry into the true lumen. Reviewing the outcomes of these 20 patients revealed that 2 were lost to follow-up, 2 refused recommended surgical intervention and had no subsequent intervention, and 16 underwent surgical revascularization, consisting of iliofemoral endarterectomy, femoral-to-femoral bypass, and unilateral iliofemoral bypass.

The 96 patients undergoing successful iliac artery SIA had an average age of 63.8 ± 10.1 years old, with a male-to-female ratio of roughly 3:2 (55:41). Ethnicity of these patients was 62 (64.6%) Caucasian, 32 (33.0%) African American, 1 (1.0%) Hispanic, and 1 (1.0%) other ethnicity. The atherosclerotic risk factor profile for these patients is tabulated in Table I. This population demonstrated a marked prevalence of coronary artery disease (57.3%), diabetes (39.6%), and end-stage renal disease (13.5%). Other comorbidities tabulated included chronic obstructive pulmonary disease (11.5%) and obesity (36.5%). Additionally, prior vascular bypass operations had previously been performed in 10.4% of treated limbs.

Indications for iliac artery SIA were lifestyle-altering claudication, 64 (63.3%), and critical limb ischemia, consisting of 19 (18.8%) gangrene and 18 (17.8%) rest pain. Seventeen (16.8%) patients were considered to be at prohibitive risk for open surgery. This determination was based on preoperative evaluation of these patients' comorbidities and the surgeon's judgment. Eleven lesions were treated with a combined approach of SIA and surgical outflow operation, including common femoral artery endarterectomy with patch angioplasty or distal bypass. The remaining 90 lesions were treated with percutaneous SIA alone. These include five patients who also had contralateral iliac artery CTOs treated with SIA.

Table II. Distribution of 101 iliac artery chronic total occlusions

Vessels involved	*n (%)*
CIA	40 (39.6%)
Combined CIA and EIA	24 (23.8%)
Combined CIA, EIA, and SFA	5 (5.0%)
EIA	24 (23.8%)
Combined EIA and SFA	5 (5.0%)
Combined EIA, SFA, and popliteal artery	3 (3.0%)

CIA, Common iliac artery; *EIA,* external iliac artery; *SFA,* superficial femoral artery.

Table III. TASC II classification of 101 iliac artery chronic total occlusions

TASC II classification	*n*
B	39 (38.6%)
C	27 (26.7%)
D	35 (34.7%)

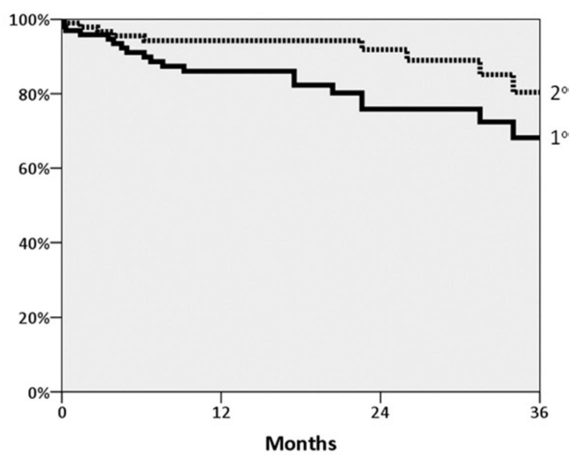
TASC, TransAtlantic InterSociety Consensus.

Arterial access was preferentially via the femoral arteries, 98 (97.0%), with only 3 (3.0%) brachial artery accesses. The details of vessel segments treated are listed in Table II, with their TASC II classifications listed in Table III. Crossing the CTO required an antegrade approach via a contralateral access in 52 (51.5%) lesions and a retrograde approach in 49 (48.5%). In treating bilateral common iliac artery occlusions, the kissing-balloon technique was utilized in 61 (60.4%) lesions, the remaining 40 (39.6%) had a unilateral balloon used. Some of these bilateral lesions were treated with combined intraluminal and subintimal techniques. Stents were deployed selectively in 82 (81.2%) lesions. A total of 119 stents were deployed, with a single stent in 49 (48.5%) lesions, 2 stents in 29 (28.7%) lesions, and 3 stents in 4 (4.0%) lesions. A re-entry device such as the Outback or Pioneer, was used in 14 (13.9%) lesions.

A 30-day procedural mortality rate of 1.0% (1) was achieved with a 30-day overall complication rate of 8.9% (9) occurred during this study and a major complication rate of 3.0% (3). These procedural complications are listed in Table IV. The majority of these complications did not require operative intervention. In one case, a presumed retroperitoneal bleed was explored, but no injury to the treated iliac artery was identified. The one death in this series occurred during a rupture of an external iliac artery. The injury was identified immediately after re-angioplasty of a partially deployed stent and was treated with a covered stent. While the patient remained hemodynamically stable throughout the remainder of his case, he went into cardiac arrest upon transfer to a stretcher. Despite regaining a

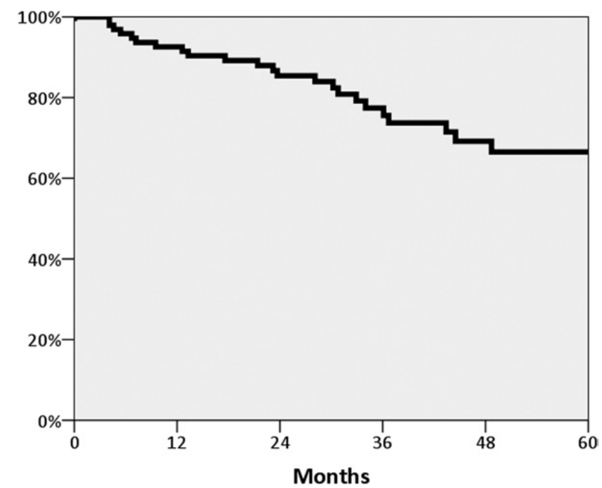
Table IV. Procedural complications during 101 subintimal angioplasties of iliac artery chronic total occlusions

Complication	*n*	*Outcomes*
Femoral pseudoaneurysm	2	Treated with ultrasound-directed thrombin injection
Groin hematoma	3	Managed by observation
Sheared sheath fragment	1	Sheath fragment removed with endovascular snare
Retroperitoneal hematoma	1	Underwent surgical exploration without identification of injury
Ruptured external iliac artery	2	Placement of covered stent during procedure in both cases, 1 death



Time (months)	0	12	24	36
Number at risk for primary procedure	100	59	33	16
Number at risk for secondary procedure	100	62	36	17

Fig 1. Primary and secondary patency of SIA of iliac artery chronic total occlusion (CTO). Primary and secondary patency at 36 months was 68% (SE, 7.1%) and 80% (SE, 7.0%).



Time (months)	0	12	24	36	48	60
Number at risk	95	84	64	42	27	17

Fig 2. Survival of treated iliac artery chronic total occlusion (CTO) cohort. Survival at 60 months was 66.5% (SE, 6.2%).

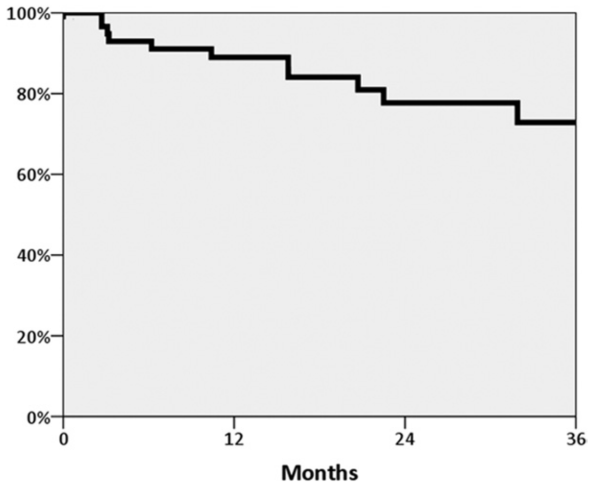
perfusing rhythm, he later expired of presumed cardiac etiology in the intensive care unit.

Average follow-up in this study was 20.4 ± 18.2 months. Baseline ABI for the treated limb was on average 0.52 ± 0.20. Mean postprocedure ABI for the treated limb was 0.76 ± 0.23. Mean last recorded ABI for treated limb was 0.81 ± 0.21, resulting in a mean lasting ABI improvement of 0.33 ± 0.26.

Primary and secondary patencies are presented in Fig 1. Primary and secondary patency rates at 1 year were 86.1% and 94.3%, at 2 years were 75.9% and 91.9%, and at 3 years were 68.2% and 80.4%. Examining the loss of primary patency, 15 failures were found on surveillance; however, only 10 patients proceeded with a secondary intervention, consisting of endovascular intervention (8 lesions), open thrombectomy (1 lesion), and subintimal channel relining with EVAR extension limb (1 lesion). Modalities detecting these failures were: angiography (3), duplex ultrasound (7), clinical examination (4), and CTA (1). Examining the tertiary procedures, the seven completed included femoral-to-femoral bypass (3), aortobifemoral bypasses (2), 1 aortoiliofemoral bypass (1), and aortoiliofemoral endarterectomy (1). In five of these lesions, loss of patency was detected by angiography (2) and duplex ultrasound (3). In one aortobifemoral bypass and the aortoiliofemoral bypass, these procedures were done for abdominal aortic pathology not loss of patency.

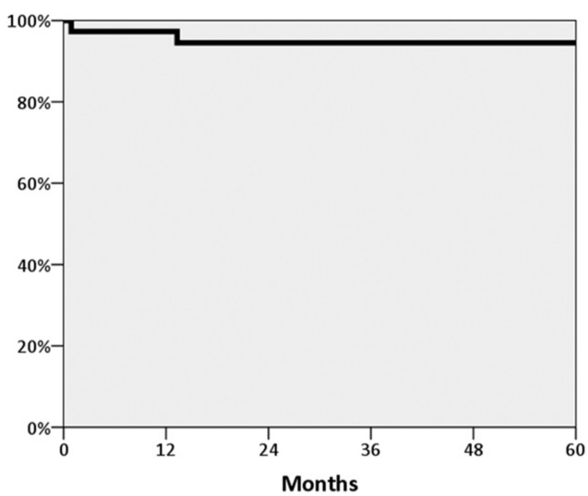
Survival is presented in Fig 2. Survival rate at 1, 3, and 5 years was 92.6%, 77.4%, and 66.5%, respectively. Freedom from claudication is presented in Fig 3. Symptomatic improvement was 89.0%, 77.8%, and 72.8%, respectively at 1, 2, and 3 years. Limb salvage in critical limb ischemia patients is presented in Fig 4. Limb salvage was 97.3% at 1 year and 94.5% at 5 years. Of the 19 patients with gangrene, 14 (73.7%) healed their wounds after intervention. Only two (5.4%) of the CLI patients required amputation, with one requiring amputation 1 month after intervention and the other after 13 months due to infrapopliteal occlusive disease.

The univariate analysis of factors for loss of primary patency (Table V), revealed hyperlipidemia, coronary artery disease, and prior surgical bypass in the treated limb to be statistically significant. However, on multivariate analysis, (Table VI) no factors continued to be statistically significant though hyperlipidemia, and coronary artery disease trended toward significance. The results were also analyzed with survival analysis using a log-rank test to compare primary patencies by TASC II classification, arterial segment involved, sex of patient, and combined procedure



Time (months)	0	12	24	36
Number at risk	63	42	24	13

Fig 3. Freedom from claudication. Freedom from claudication at 36 months was 73% (SE 7.7%).



Time (months)	0	12	24	36	48	60
Number at risk	37	35	28	17	12	9

Fig 4. Limb salvage in critical limb ischemia patients. Limb salvage at 60 months was 95% (SE, 3.8%).

Table V. Univariate analysis of variables for loss of primary patency in 101 subintimal angioplasties of iliac artery chronic total occlusions

Variable	*HR*	*95% CI*	P *value*
Male sex	1.31	0.70-2.44	.40
Age ≥ 70	1.01	0.53-1.95	.97
Age ≥ 80	1.55	0.61-3.94	.36
Obese	1.35	0.73-2.49	.34
Hypertension	0.58	0.29-1.15	.12
Hyperlipidemia	3.80	1.35-10.65	.01
Diabetes mellitus	1.09	0.59-2.00	.79
End-stage renal disease	1.22	0.51-2.89	.66
Coronary artery disease	2.28	1.17-4.46	.02
Ever smoked	1.07	0.58-1.98	.82
Actively smoking	0.92	0.59-1.41	.69
Chronic obstructive pulmonary disease	0.62	0.19-2.01	.43
Prior surgical bypass in treated limb	2.34	1.03-5.30	.04
Nonsurgical candidate	1.42	0.68-2.97	.35
Combined SIA and outflow procedure	1.79	0.76-4.26	.19
Unilateral balloon used	1.67	0.88-3.17	.12
Antegrade subintimal dissection	0.83	0.45-1.53	.55
Stents used	1.05	0.49-2.28	.90
Re-entry device used	1.00	0.42-2.37	1.00
Critical limb ischemia	1.16	0.62-2.14	.65
Common iliac artery (CIA) involved	0.76	0.40-1.42	.39
External iliac artery (EIA) involved	1.67	0.87-3.21	.13
Superficial femoral artery involved	0.91	0.36-2.31	.84
Popliteal involved	0.68	0.09-4.94	.70
Combined CIA and EIA lesion	1.26	0.67-2.39	.47
TASC B	1.26	0.69-2.33	.46
TASC C	1.30	0.68-2.50	.43
TASC D	0.60	0.30-1.20	.15

CI, Confidence interval; *HR,* hazard ratio; *TASC,* TransAtlantic InterSociety Consensus.

Table VI. Multivariate analysis of risk factors for loss of primary patency in 101 subintimal angioplasties of iliac artery chronic total occlusions

Variable	*HR*	*95% CI*	P *value*
Hyperlipidemia	2.78	0.97-8.03	.06
Coronary artery disease	1.97	0.97-3.99	.06
Prior bypass in treated limb	1.80	0.77-4.21	.17
Combined SIA and outflow procedure	1.26	0.51-3.12	.62
Unilateral balloon used	1.36	0.67-2.76	.40
External iliac artery involvement	1.59	0.78-3.23	.20

CI, Confidence interval; *HR,* hazard ratio; *SIA,* subintimal angioplasty.

status. All comparisons were not statistically significant, likely due to inadequate power in each subgroup.

DISCUSSION

The TASC II guidelines recommend open surgery for TASC D; however, multiple published series demonstrate that TASC D classified iliac artery CTO can be managed endovascularly.[2,7,10,11] Most of these series utilize intraluminal techniques to traverse the iliac obstruction, with a minority of lesions managed with SIA. In this study of iliac artery CTO managed exclusively with SIA, 34.7% of the lesions were graded TASC D. Although a technical success rate of 83.5% was seen in this study, the majority of these lesions were TASC C and D (61.4%), and all of these lesions were iliac artery CTOs. Technical success in revascularization of CTOs in contemporary series has been reported between 92% and 99%.[10,11] The technical failures in this study were all due to failed re-entry. For a portion of this study, no re-entry device was commercially available, contributing to this lower technical success rate. Additionally, while lesions may have the same TASC classification, a totally calcified iliac artery that can only be crossed with a subintimal technique is not the same pathology as an acutely thrombosed iliac artery that can be crossed in an intraluminal fashion, so comparisons between studies based purely on TASC classification may not be entirely valid.

In this study, 11 (11.5%) patients underwent a combined approach involving an outflow procedure in conjunction with SIA of their iliac artery CTO. Some would argue that these patients should have undergone an aortobifemoral bypass instead of a combined approach, as the patient was exposed to the physiologic stress of an open procedure. Further examining these patients reveals that the eight of these open procedures for these hybrid cases were endarterectomy and patch angioplasty, a procedure that can be performed under local or regional anesthesia. The combined approach avoids the physiologic stress of an aortic cross-clamp that an aortobifemoral bypass requires. The presence of outflow disease in conjunction with inflow disease is well demonstrated by the fact that over the course of the study, 24 (25.0%) patients would also undergo outflow procedures, both endovascular and open, in distal vessels.

This study demonstrates 3-year primary and secondary patency rates of 68% and 80%. Compared with reported aortobifemoral reconstruction patencies of 85% to 90% at 5 years, SIA for iliac artery CTOs appears to be less durable.[12] Looking at other contemporary series of endovascular treatment of iliac artery CTOs, however, reveals similar outcomes to our study. Ozkan reported primary and secondary patencies at 5 years of 63% and 93%.[10] Kondo reported a 2-year primary patency rate of 90% for primary stenting of iliac artery CTOs.[11] Both studies do not report the numbers at risk in their Kaplan-Meier analysis, and keep in mind, these two studies examine different populations from our study, likely accounting for the differences in patency. In a similar fashion, direct comparison with aortobifemoral bypass is not valid, as our practice's aortobifemoral bypass patients are now mostly a historical cohort.

Our study population had an average age of 64 and significant comorbidity profile, as evident by the fact that almost one-third of these patients had died by 60 months. Additionally, nearly one-fifth were judged to be of prohibitively high risk for operative intervention. Nevertheless, for these patients, this study demonstrates a procedural mortality rate of only 1.0% and major procedural complication rate of only 3.0%, with only one patient requiring management of their complication in the operating room. Reviewing the complications by date of procedure, the number of complications peaked in 2005 and has been steady at one to two per year, suggesting that there is a learning curve for this technique. But this low procedural complication rate confirms that SIA for iliac artery CTO is a safe intervention.

There are multiple limitations to this study due to its retrospective nature. First, over the 9 years of the study, the techniques, equipment, and experience of the surgeons have changed, giving the results reported. Second, the choice of intervention was a mutual decision between the surgeon and patient, reflecting the biases of both parties. Third, surgeons have modified the follow-up protocol thereby affecting surveillance results. Finally, short follow-up periods can be found in the database. It is not clear if these represent patients with good response to therapy, therefore, having no reason to return for follow-up or the opposite.

Despite these limitations, this study presents the largest series of iliac artery CTOs managed exclusively with SIA and selective stenting. The good midterm patencies and low procedural mortality and morbidity of SIA in the study demonstrate the value of this technique in this patient population in which one-third died by 5 years. Comparison between SIA and intraluminal techniques will require a randomized prospective study to sort out the optimal technique, as the published contemporary iliac artery CTO series comprise foreign patient populations.

CONCLUSION

This study demonstrates that not only is SIA feasible for iliac CTO, but that it is a safe and durable option. SIA provides a competitive alternative to aortobifemoral reconstruction, especially in those patients that are not candidates for open revascularization. SIA also provides excellent limb salvage and relief from claudication. With comparable patency, yet less morbidity and mortality than open revascularization, we consider SIA as a reasonable first-line option for treatment of iliac artery CTOs.

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AUTHOR CONTRIBUTIONS

Conception and design: GS, JP
Analysis and interpretation: BC, HH
Data collection: BC, HH
Writing the article: BC, HH
Critical revision of the article: GS, JP
Final approval of the article: JP
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REFERENCES

1. de Vries SO, Hunink MG. Results of aortic bifurcation grafts for aortoiliac occlusive disease: a meta-analysis. J Vasc Surg 1997;26: 558-69.
2. Kashyap VS, Pavkov ML, Bena JF, Sarac TP, O'Hara PJ, Lyden SP, et al. The management of severe aortoiliac occlusive disease: endovascular therapy rivals open reconstruction. J Vasc Surg 2008;48:1451-7.
3. Bolia A, Brennan J, Bell PR. Recanalisation of femoropopliteal occlusions: improving success rate by subintimal recanalisation. Clin Radiol 1989;40:325.
4. Hynes N, Mahendran B, Manning B, Andrews E, Courtney D, Sultan S. The influence of subintimal angioplasty on level of amputation and limb salvage rates in lower limb critical ischaemia: a 15-year experience. Eur J Vasc Endovasc Surg 2005;30:291-9.
5. Bown MJ, Bolia A, Sutton AJ. Subintimal angioplasty: meta-analytical evidence of clinical utility. Eur J Vasc Endovasc Surg 2009;38:323-37.
6. Scott EC, Biuckians A, Light RE, Burgess J, Meier GH III, Panneton JM. Subintimal angioplasty: our experience in the treatment of 506 infrainguinal arterial occlusions. J Vasc Surg 2008;48:878-84.
7. Norgen L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). J Vasc Surg 2007;45(Suppl S):S5-67.
8. Schmieder GC, Richardson AI, Scott EC, Stokes GK, Meier GH III, Panneton JM. Selective stenting in subintimal angioplasty: analysis of primary stent outcomes. J Vasc Surg 2008;48:1175-80.
9. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
10. Ozkan U, Oguzkurt L, Tercan F. Technique, complication and long-term outcome for endovascular treatment of iliac artery occlusion. Cardiovascular Intervent Radiol 2010;33:18-24.
11. Kondo Y, Dardik A, Muto A, Koizumi J, Nishibe M, Nishibe T. Primary stent placement for iliac artery chronic total occlusions. Surg Today 2010;40:433-9.
12. Brewster, DC. Direct reconstruction for aortoiliac occlusive disease. In: Rutherford RB, editor. Vascular surgery. 6th ed. Philadelphia: Elsevier Saunders; 2005, p. 1124.

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