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Mid-Term Outcomes Following Endovascular Re-Intervention for Iliac Artery In-Stent Restenosis

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Abstract

Objectives—We sought to evaluate the procedural characteristics and clinical outcomes of endovascular repair for iliac artery (IA) in-stent restenosis (ISR).

Background—An increasing percentage of patients with complex IA occlusive disease are treated with an endovascular approach, but the outcomes of IA-ISR have not been well described.

Methods—We analyzed all endovascular procedures for treatment of IA-ISR performed at our institution between July 2006–December 2010. The primary outcome was primary patency, defined as <50% stenosis as assessed by clinical examination and duplex ultrasonography (DUS).

Results—Forty-one lesions in 24 patients who underwent repeated endovascular intervention for treatment of IA-ISR. Most lesions were unilateral and involved the common IA (66%). The mean length of ISR was 30.1 ± 14.1 mm with type I (focal) and II (diffuse) ISR occurring with the greatest frequency (34% and 39%, respectively). All patients underwent balloon angioplasty; adjunctive stenting was performed in 27 (66%) of the lesions. Type II ISR lesions more frequently required stenting (13/16 lesions, $P = 0.02$ compared with other patterns of ISR). Procedural success was 100% with a mean gain of 0.13 in the ankle-brachial index ($P = 0.001$). The 6- and 12-month primary patency rates were 96% and 82%, respectively. The 12-month primary-assisted patency rate was 90% with clinically driven target lesion revascularization (TLR) in three patients.

Conclusions—Endovascular treatment of IA-ISR using an approach of balloon angioplasty followed by selective stenting is associated with high-patency rates and low rates of TLR at 1 year.

Keywords

peripheral arterial disease; iliac artery; in-stent restenosis

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INTRODUCTION

Percutaneous transluminal angioplasty (PTA) followed by primary or selective stenting is routinely used to treat iliac artery (IA) occlusive disease [1–9]. The TransAtlantic InterSociety Consensus (TASC) II working group has published guidelines for the management of peripheral arterial disease (PAD). This consensus statement recommends endovascular intervention for TASC A and B lesions [10]. Several recent studies have also advocated endovascular intervention for increasingly complex IA lesions, including TASC C and D lesions [11–14]. IA in-stent restenosis (IA-ISR) occurs with a frequency of up to 10% at 1 year and is more common at longer term follow-up and with more complex lesions [15,16].

Despite the large number of IA interventions being performed and the relative frequency of this problem, there is a paucity of data pertaining to lesion characteristics or clinical and procedural outcomes among patients with IA-ISR. The aim of this study was to identify patient and angiographic characteristics associated with the need for IA-ISR intervention as well as the procedural and clinical outcomes after endovascular treatment of IA-ISR.

METHODS

PAD-UCD Registry

The PAD-UCD Registry consists of all patients with a clinical diagnosis of PAD who underwent diagnostic angiography or therapeutic endovascular intervention at the University of California, Davis Medical Center beginning in 2006. Three vascular surgeons and one interventional cardiologist performed these procedures during the study period. For this study, the subset of patients in the registry with IA-ISR was analyzed. The study protocol was approved by the Institutional Review Board at UC Davis Medical Center.

Data Collection and Definitions

Data from 24 patients (32 limbs and 41 lesions) were retrospectively analyzed from review of electronic medical record documentation. Pre- and post-procedure clinical notes, admission history, and physical examination documentation were used to identify clinical presentation as well as post-procedure outcomes and medical management. The category of limb ischemia was defined by using the Rutherford classification [17].

Ankle-brachial pressure index (ABI) measurements and duplex ultrasound (DUS) were obtained in all patients before endovascular treatment and at follow-up. Clinical indications for repeat intervention included recurrent symptoms accompanied by either 0.10 decrease in ABI or recurrent stenosis >50% confirmed by DUS (peak systolic velocity ratio of 2.0) [18]. All patients were pretreated with aspirin 325 mg as well as a clopidogrel 300-mg loading dose prior to the procedure. Post-procedure antiplatelet therapy consisted of aspirin daily for life at a dose of 81–325 mg daily and clopidogrel 75 mg daily for at least 3 months.

Two board-certified cardiologists with experience in peripheral angiography (EA and UJ) reviewed all angiographic images to verify lesion morphology and characteristics, TASC II classification, presence of thrombus, and status of the distal run-off vessels. Quantitative angiography was performed to evaluate the pre- and postintervention minimal lumen diameter, percent diameter stenosis, lesion length, and reference vessel diameter using quantitative vascular analysis (Philips Xcelera, Philips, Amsterdam, the Netherlands). In-stent restenosis was defined as type I (focal, lesion length 30 mm), type II (diffuse, >30 mm long but within the stent), type III (proliferative, >30 mm and extending beyond the stent edge), and type IV (total occlusion; Fig. 1) [19]. Procedural data collection included the type of intervention (standard balloon angioplasty, cutting balloon angioplasty, stenting

(bare or covered), and rarely thrombolysis or thromboaspiration. Procedural success was defined as <30% stenosis at the conclusion of procedure with less than 10 mmHg peak gradient. Iliac stents were deployed selectively for initial PTA failure due to residual stenosis (>30%) or a pressure gradient of >10 mmHg.

Hemodynamic success and clinical improvement (an improvement by at least one clinical category on the Rutherford scale plus a change in ABI >0.10) were defined using the Society for Vascular Surgery and the International Society for Cardiovascular Surgery reporting standards [20]. Patients were routinely seen 30 days after the revascularization procedure. Clinical improvement was determined based on history and noninvasive vascular laboratory tests. Postoperative follow-up, consisting of a clinical and serial DUS examination, was conducted every 6 months during the first postoperative year and every 6–12 months thereafter. Lesion post-procedure outcomes were determined by clinical follow-up and DUS surveillance performed at 1, 6, and 12 months.

Patency and limb salvage rates were determined longitudinally at the most recent examination. Primary patency was defined as a patent artery or stent (after intervention for the restenosis) without recurrent restenosis or the need for further intervention. Vessel patency was evaluated with serial ABI and toe-brachial index (TBI) measures and DUS at 0–30 days, 4–6 months, and 9–12 months. Loss of patency was defined as the presence of >50% restenosis at the treatment site (peak systolic velocity ratio >2.0), or by target lesion revascularization (TLR). Major amputation was defined as any amputation above the level of the ankle joint.

Patient-specific major adverse cardiovascular events (MACE), defined as death, myocardial infarction, stroke, or major amputation were identified through electronic documentation of clinic or inpatient notes as well as the Social Security Death Index.

Outcomes

The primary end point was primary patency (<50% stenosis by DUS or angiographic assessment). Secondary outcomes included primary-assisted patency (primary patency or patency after repeat intervention for restenosis), TLR, and ipsilateral limb loss or amputation. These events were assessed at regular intervals (0–30 days, 4–6 months, and 9–12 months post-procedure). Other secondary end points included the occurrence of any major adverse cardiovascular events (MACE), defined as death, myocardial infarction, stroke, or major amputation.

Data Analysis

Median values with interquartile ranges were used to describe continuous variables, and numerical values (percentages) were used for categorical variables. Univariate analysis was used to identify predictors of restenosis. Continuous variables were compared using the Kruskal–Wallis test. Categorical values were compared by the chi-square or Fisher's exact test. Freedom from binary restenosis and freedom from TLR at 1, 6, and 12 months were analyzed with the use of Kaplan–Meier survival estimates and the log-rank test. Analysis of the change in ABI indices and TLR over time was performed using a hierarchic longitudinal mixed-model analysis. The interaction between the treatment and intervention date was used to determine if there were differences in the treatment slopes over time for the linear ABI model. The small number of TLR cases precluded investigation of any interaction in the logistic model.

All tests were performed using two-sided tests, and the critical value for statistical significance was set at a value of <0.05. Analyses were conducted using JMP (SPSS, Chicago, IL) and STATA Version 11.2 (STATA Corporation, College Station, TX). All

authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

RESULTS

During the study period, 125 patients (174 limbs) underwent angioplasty and stenting for IA stenosis. Among these, 24 patients had IA-ISR requiring repeat intervention in 41 lesions. The initial indication for stent placement in these 24 patients was claudication in 14 patients, and critical limb ischemia in the other 10 patients. The mean stent length at the time of initial implantation was 47 ± 13 mm, and the time from initial intervention to treatment for IA-ISR was 12.5 ± 6.7 months. One patient who initially underwent stent placement for claudication required treatment of IA-ISR for critical limb ischemia occurring 3 years after the initial intervention, and two patients initially treated for critical limb ischemia presented with IA-ISR manifesting as acute limb ischemia. All other patients presented with the same or lower Rutherford classification during treatment of IA-ISR as their initial intervention.

Patient indices and procedural details are summarized in Tables I and 2. The mean age was 58.5 years with predominant female gender (68%). More than half of the patients were actively smoking and a majority of the patients were taking aspirin and/or clopidogrel at the time of IA-ISR. The mean LDL was 75 ± 33 mg/dL.

The indication for revascularization of IA-ISR included critical limb ischemia in 5 patients (21%), severe claudication in 13 patients (54%), and acute limb ischemia in 2 patients (8%). Four patients (17%) were asymptomatic but had reintervention performed to maintain vessel patency and minimize limb threat after DUS suggested significant restenosis accompanied by a decrease in ABI.

The majority of the lesions were unilateral (75%) and involved the common iliac arteries (67%). The mean ISR length was 30.1 mm. Types I and II ISR patterns were the most frequent subtypes (34% and 39%, respectively), and these were seen with similar prevalence in the common and external IA (Fig. 2). On univariate analysis, there was no statistically significant association between gender, age, diabetes, smoking status, or patency rates with a specific subtype of ISR.

Procedural success was achieved in 100% of cases. The overall procedural complication rate was 4.2%, as one patient with a subacute occlusion of a left common iliac stent sustained distal embolization to the left common femoral artery that required surgical embolectomy. That patient subsequently did well and did not have recurrent restenosis at one year. All patients underwent initial balloon angioplasty, and 66% required adjunctive stenting, with subsequent placement of 19 covered stents and 8 bare metal stents. Post-procedure, there was a net gain of 0.11 in ABI ($P = 0.029$). Figure 3 shows an example of bilateral common iliac ISR treated successfully with balloon-expandable covered stents.

The mean run off score was 2.1 ± 0.8 . There was no relationship between distal runoff and TLR. Five patients underwent intervention to infrainguinal vessels during the same procedure for IA-ISR. All of these patients had critical limb ischemia and the distal interventions were performed to improve outflow and maximize the probability of limb salvage.

The 6- and 12-month primary patency rates were 96% (95% CI: 76–98%) and 82% (95% CI: 61–93%), respectively. The 12-month primary-assisted patency rate was 90%. The TLR rate was 10% at 12-month follow up (Figs. 4 and 5).

Of the three patients who underwent further reintervention, two patients had a balloon angioplasty as initial treatment for IA-ISR and were subsequently treated with covered balloon-expandable stents due to diffuse ISR. The third patient was initially treated with repeat stenting for IA-ISR and then subsequently treated with balloon angioplasty alone due to a focal restenotic lesion.

The overall survival rate was 95% at 12 months with no limb loss. One patient died of sepsis and the other from sudden cardiac death (both unrelated to the procedure). There were no other major adverse cardiovascular events during the follow-up period.

DISCUSSION

Stenting has become increasingly common in the endovascular treatment of IA disease, as stents improve the early outcomes after suboptimal or failed PTA [21–26]. Prior studies of selective IA stenting for *de novo* lesions have reported a wide range of long-term primary patency rates ranging from 59–86% at 3 years to 49–75% at 5 years, indicating that IA-ISR is frequently encountered during long-term follow up [7,15,25–30]. However, the optimal treatment for IA-ISR remains uncertain. In this study, we describe excellent mid-term results after endovascular treatment of IA-ISR.

Several patient and procedural variables have previously been associated with lower rates of restenosis after IA stenting. These include absence of diabetes, smoking, or renal insufficiency, short and less complex lesions, larger vessel diameter, lesion location (common IA vs. external IA), and intervention driven by claudication versus CLI as well as possibly younger age [29,31–33]. However, Davies et al. [33] recently reported that recurrence of iliac disease after initial intervention was associated with younger age and female gender, likely due to smaller vessel diameter. Our current cohort had many favorable characteristics including a relatively low prevalence of diabetes and renal insufficiency, young age, short lesion length, and lesions that were predominantly TASC A/B and ISR type I/II. Contrary to prior studies, IA-ISR in this series occurred in subjects who otherwise would be considered at “low risk” for IA-ISR. However, 63% of the subjects were women, supporting the possible role of gender in IA restenosis.

Earlier studies such as Kropman et al. used primarily angioplasty alone to treat in-stent restenosis (only 14% of lesions had stent replacement) while Davies et al. and this study utilized adjunctive stenting in 70% and 66% of the lesions, respectively. Of note, all three of these studies reported primary patency rates >80% at 1 year and primary-assisted patency rates >90% at 1 year, suggesting overall excellent results of endovascular intervention for IA-ISR [33,34].

In comparison with infrainguinal endovascular interventions, the treatment for IA-ISR is conventionally limited to balloon/cutting balloon angioplasty or stenting, as other modalities such as laser, rotational, and directional atherectomy techniques are not routinely employed. The current data are too limited to identify the superiority of a particular modality for treatment of IA-ISR. In a retrospective analysis of 14 IA-ISR lesions in 12 patients, Tsetis et al. [35] demonstrated 100% primary patency at a mean follow-up of approximately 2 years with cutting balloon angioplasty. In our series, the utilization of cutting balloon angioplasty was lower without significant differences among the various ISR classifications.

Schurmann et al. [9] previously reported long-term outcomes of 110 patients who underwent stent placement for occlusive IA disease. During a mean follow-up of 5.8 years, 23 patients underwent repeat endovascular intervention for restenosis, and 9 of those 23 patients required repeat stent placement. Subsequently, 12 of those 23 patients developed recurrent restenosis prompting another endovascular intervention or surgery. Procedural and lesion

characteristics were not reported, nor were the outcomes comparing PTA and restenting. All of the IA-ISR lesions in our series were initially treated with standard PTA, and selective restenting after unsatisfactory PTA was performed in 66% of the lesions. Although type 2 ISR lesions were more likely to require stenting (13 of 16 lesions), the overall benefit of stenting could not be discerned among various patterns of ISR due to small numbers in each group. However, given the high rate of stenting (66%) required after initial suboptimal angioplasty, our experience suggests that repeat stenting is often required for IA-ISR rather than PTA alone.

There is increasing evidence regarding utilization of covered stents in peripheral interventions [36]. Covered stents may lower the incidence of ISR by excluding plaque and endothelium as well as preventing the migration and proliferation of vascular smooth muscle and inflammatory cells through the stent struts [37]. In our current series, 27 (65.7%) of the IA-ISR lesions required restenting, and covered stents were placed in 19 of those lesions. The COBEST trial found that for complex, *de novo* IA lesions (TASC C and D), implantation of a covered stent was associated with significantly less binary restenosis at 18 months compared to uncovered stents, and there was a trend towards less stent occlusion [14]. However, the superiority of covered stenting compared with uncovered stent placement has not yet been proven for IA-ISR treatment. In a recent analysis of femoral–popliteal ISR treatment with excimer laser atherectomy and PTA followed by implantation of VIABAHN Endoprosthesis, a modest primary patency rate of 48% was reported; however, the TLR was low at 17.4% [38]. Our analysis did not demonstrate a difference in patency between placement of a covered stent versus an uncovered stent or any stent versus PTA, but this subgroup analysis was limited by small overall size of the cohort.

In our current series, the endovascular treatment of IA-ISR was associated with a high procedural success of 100% and a low rate of procedural complications (4.2%), which compares favorably with results in the primary endovascular repair of IA disease [2,7,15,25,29–31,33,34]. Despite the fact that more than 29% of the patients presented with acute or critical limb ischemia, there was no limb loss or need for surgical revision at 1 year. A minority of patients underwent revascularization primarily due to the findings on DUS, with a goal of maintaining patency of the IA. Progression to total occlusion may make subsequent intervention more complex with a higher likelihood of failure or complications. The high primary and primary-assisted patency rates seen in this series underscore endovascular repair as a viable option for IA-ISR.

The results of this study should be interpreted in the context of its design. The series is a single-center, retrospective study and thus has inherent limitations. There was a potential selection bias in patient selection for endovascular intervention, but in general, our clinical practice is to reintervene only in the presence of symptoms and documented restenosis by noninvasive techniques. As the number of procedures was small, this study lacks sufficient statistical power to make conclusions on the comparative effectiveness of a particular endovascular modality and therefore the results may not be fully generalizable. Long-term follow-up with a larger sample size will be helpful to determine the relative contribution of different ISR patterns to long-term patency.

CONCLUSIONS

In summary, mid-term results of endovascular repair for IA-ISR with PTA and selective restenting show acceptable mid-term patency rates and offer a viable alternative to conventional surgical bypass. Further studies are indicated to assess long-term outcomes and optimal procedural strategies for IA-ISR.

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Fig. 1.

Subtypes of iliac artery in-stent restenosis. (a) Type I restenosis showing a focal lesion <30 mm in length. (b) Type II restenosis showing diffuse hyperplasia >30 mm in length. (c) Type III restenosis showing proliferative restenosis extending beyond the stent edge. (d) Type IV restenosis showing complete occlusion of a previously placed stent. Inset panels show magnified views of each ISR pattern.

Fig. 2.
Anatomic distribution of lesions by ISR type.

Fig. 3.

Bilateral common iliac artery ISR treated successfully with balloon-expandable covered stents. (a) Bilateral common iliac artery restenosis within two previously placed balloon-expandable noncovered stents. The patient presented with severe claudication despite maximal medical therapy. (b) After initial balloon angioplasty, two balloon-expandable covered stents were simultaneously deployed within the body of the previously placed stents. (c and d) show orthogonal views after stent placement demonstrating excellent angiographic result. Patient remained asymptomatic at 12-month follow-up with no evidence of recurrent ISR by serial duplex ultrasound.

Fig. 4.
Restenosis at 12-month follow-up.

Fig. 5.
TLR at 12-month follow-up.

TABLE I

Patient and Clinical Characteristics ($n = 24$)

Age (years, mean $\pm$ SD)	58.5 $\pm$ 11.1
Male gender	9 (38%)
DM	9 (38%)
CAD	9 (38%)
Hypertension	21 (88%)
Active smoking	14 (59%)
LDL (mg/dL, mean $\pm$ SD)	75 $\pm$ 33
eGFR (mL/min)	78 $\pm$ 31
Aspirin	23 (96%)
Clopidogrel	15 (63%)
Dual antiplatelet	15 (63%)
Statin	20 (83%)
Pre-procedure rutherford class	
3	16 (67%)
4	8 (33%)
Post-procedure rutherford class (30 days)	
3	19 (80%)
4	5 (20%)
ABI	
Pre-procedure (Median, IQR)	0.75 (0.66, 0.93)
Post-procedure 1 month (Median, IQR)	0.87 (0.80, 1.01)
Indication for revascularization of IA-ISR	
Acute limb ischemia	2 (8%)
Critical limb ischemia	5 (21%)
Claudication	13 (54%)
Duplex surveillance	4 (17%)
Time from Initial Stent Placement to IA-ISR (Months, Mean $\pm$ SD)	12.5 $\pm$ 6.7

TABLE 2

Lesion and Procedural Characteristics ($n = 41$)

TASC classification of the original procedure	
A	19 (46%)
B	14 (34%)
C	6 (16%)
D	2 (4%)
ISR Type	
I (focal, <30 mm)	14 (34%)
II (diffuse, >30 mm)	16 (39%)
III (proliferative)	7 (17%)
IV (occlusion)	4 (10%)
Stent length of initial intervention (mm, Mean $\pm$ SD)	47.0 $\pm$ 13.0
Lesion length (mm, Mean $\pm$ SD)	30.1 $\pm$ 14.0
Artery diameter (mm, Mean $\pm$ SD)	7.2 $\pm$ 1.1
Lesion location	
Common iliac artery	66%
External iliac artery	34%
Bilateral disease	25%
Intervention performed	
Balloon angioplasty	32 (78%)
Cutting balloon	7 (17%)
Restenting	27 (66%)
Covered	19 (46%)
Non-covered	8 (19%)
Runoff score (Mean $\pm$ SD)	2.1 $\pm$ 0.8
Patency	
6 months	
Primary	96%
Primary assisted	96%
12 months	
Primary	84%
Primary assisted	90%
Target lesion revascularization	
6 months	0
12 months	10%
Amputation	0
Death	5%