

## Recent Advances in Endovascular Treatment of Aortoiliac Occlusive Disease

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**Key Words:** aortoiliac occlusive disease; iliac artery stenting; in-stent restenosis; outcomes.

**Summary.** The rate of endovascular interventions for iliac occlusive lesions is continuously growing. The evolution of the technology supporting these therapeutic measures improves the results of these interventions. We performed a review of the literature to report and appreciate short- and long-term results of endovascular stenting of iliac artery occlusive lesions. The Medline database was searched to identify all the studies reporting iliac artery stenting for aortoiliac occlusive disease (Trans Atlantic Inter-Society Consensus [TASC] type A, B, C, and D) from January 2006 to July 2012. The outcomes were technical success, long-term primary and secondary patency rates, early mortality, and complications. Technical success was achieved in 91% to 99% of patients as reported in all the analyzed articles. Early mortality was described in 5 studies and ranged from 0.7% to 3.6%. The most common complications were access site hematomas, distal embolization, pseudoaneurysms, and iliac artery ruptures. The complications were most often treated conservatively or using percutaneous techniques. The 5-year primary and secondary patency rates ranged from 63% to 88% and 86% to 93%, respectively; and the 10-year primary patency rates ranged from 68% to 83%. In this article, combined percutaneous endovascular iliac stenting and infrainguinal surgical reconstructions and new techniques in the treatment of iliac stent restenosis are discussed. Iliac stenting is a feasible, safe, and effective method for the treatment of iliac occlusive disease. Initial technical and clinical success rates are high; early mortality and complication rates are low. Long-term patency is comparable with that after bypass surgery.

### Introduction

During the last 2 decades, major changes have taken place in the diagnostic and treatment techniques of aortoiliac occlusive disease. Digital subtraction angiography has been almost completely replaced by computer tomography angiography, which nowadays is becoming the method of choice for pretherapeutic imaging in all vascular centers. Patients who needed aortofemoral bypass or endarterectomy in the past may now be candidates for less invasive procedures, such as balloon angioplasty and/or stenting. Historically, clinical experience has clearly established aortobifemoral bypass as the gold standard in the treatment of aortoiliac disease with the 5- and 10-year primary graft patency of 90% and 86.5%, respectively, and early mortality of 0%–3% (1–4). However, the risks of surgery are significantly greater than the risks of endovascular treatment in terms of not only mortality, but also major morbidity and delay in return to normal activities (5). As the new types of stents and technical developments have been introduced, more extensive and multifocal iliac lesions are being treated with endovascular procedures (6). The technical and

initial clinical success of percutaneous transluminal angioplasty (PTA) of iliac stenosis exceeds 90% in all the analyzed reports. The results of iliac stenting for artery occlusions in the early series (before 2005) showed the technical success rate to be from 80% to 85% (7–9). Since 2005, the technical success rate of type C and type D occlusions has been reported to be from 92% to 95% (2, 10).

### *Iliac Artery Stenting for TASC II Type B, C, and D Iliac Lesions*

The Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) document has been released regarding an optimal treatment of patients with arterial occlusive disease (11). Lesions in the aortoiliac segment have been categorized according to their localization, extension, and morphology (stenosis vs. occlusion) with implications for their treatment (Table 1).

According to the recommendations of the TASC II document, endovascular management is the method of choice for the treatment of type A lesions. Reconstructive surgery is preferred for type D lesions (12). Patients with type B and C lesions can be managed by either stenting or bypass surgery depending on the patient's medical comorbidities and the experience level of an endovascular radiologist (12).

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Table 1. TASC Classification of Aortoiliac Lesions

Type of Lesions	Lesion
Type A	Unilateral or bilateral stenosis of CIA Unilateral or bilateral single short ( $\leq 3$ cm) stenosis of EIA
Type B	Short ( $\leq 3$ cm) stenosis of infrarenal aorta Unilateral CIA occlusion Single or multiple stenosis totaling 3–10 cm involving EIA, but not extending into CFA Unilateral EIA occlusion not involving the origins of internal iliac or CFA
Type C	Bilateral CIA occlusions Bilateral EIA stenosis 3–10 cm long not extending into CFA Unilateral EAI stenosis extending into CFA Unilateral EAI occlusion that involves the origins of internal iliac and/or CFA Heavily calcified unilateral EIA occlusion with or without involvement of origins of internal iliac and/or CFA
Type D	Infrarenal aortoiliac occlusion Diffuse disease involving aorta and both iliac arteries requiring treatment Diffuse multiple stenosis involving unilateral CIA, EIA, and CFA Unilateral occlusions of both CIA and EIA Bilateral occlusions of EIA Iliac stenosis in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery

CIA, common iliac artery; EIA, external iliac artery; CFA, common femoral artery; AAA, abdominal aortic aneurysm.

However, more recent studies have reported the excellent results of endovascular stenting in TASC II type B, C, and D iliac lesions (Tables 2 and 3). Technical success was reported in all the studies and ranged from 91% to 99%. Authors describe artery thrombosis after recanalization, iliac artery rupture, or inability to cross an occluded arterial segment as the most common reasons for technical failure. Recently, Ozkan et al. (16) have reported the results of the endovascular treatment of 127 chronic iliac artery occlusions in 118 patients. Of them, 101 patients (86%) had intermittent claudication. There were 47 (39.5%), 25 (21%), and 47 (39.5%) patients with TASC B, C, and D lesion morphology, respectively. The initial technical success was achieved in 92% of the occlusions. The results of the antegrade approach were better in comparison with the retrograde approach (90% vs. 50%). The authors described major (19%) and minor (6%) complications in 28 patients (24%). One perioperative death (0.8%) was reported due to an iliac artery rupture. The primary and secondary patency rates at 5 years were 63 and 93%, respectively. The primary patency rate was higher in the patients with intermittent claudication than in the patients with critical limb ischemia ( $P=0.002$ ) (16).

Leville et al. (28) reported their experience with percutaneous transluminal recanalization in 89 consecutive patients with symptomatic iliac occlusions (TASC II B, C, and D) with a mean length of  $6.5\pm 4.8$  cm. Of all the patients, 51 were claudicants and 38 had rest pain or tissue loss. The percentage of the patients with TASC B, C, and D lesion morphology was 24.7% ( $n=22$ ), 33.7% ( $n=30$ ), and 41.6% ( $n=37$ ), respectively. Recanalization and percutaneous transluminal angioplasty/stenting of occluded iliac arteries were technically successful

in 82 patients (91%) with the success rates of 95% and 94% in the patients with TASC II type B and C lesions, respectively, as opposed to 86% in the patients with TASC II D lesions (not significant). The 3-year primary patency, secondary patency, and limb salvage rates were 76%, 90% and 97%, respectively. Intraoperative complications included flow-limiting dissection ( $n=5$ , 0.6%), which was resolved by prolonged balloon angioplasty and stent placement in all the cases. The authors reported 3 perioperative deaths (3.4%) from cardiac arrest and respiratory arrest.

Recent studies have also compared the results of endovascular recanalization of iliac artery occlusions with bypass type surgeries. Hans et al. (10) reported that 40 patients underwent aortoiliac stenting (AIS). The stents were placed bilaterally ( $n=24$ ) and unilaterally in common and external iliac arteries ( $n=16$ ). Of all the patients, 32 had intermittent claudication, rest pain ( $n=4$ ), and gangrene of the toes ( $n=4$ ). The technical success in the AIS group was 95%. However, 4 patients (10%) developed intraprocedural complications. There was no perioperative mortality. The primary patency at 4 years was  $69\pm 0.12\%$ . Aortobifemoral grafting (ABF) was performed in 32 patients under general anesthesia via a transperitoneal approach. Of them, 25 presented with intermittent claudication, rest pain ( $n=3$ ), and gangrene ( $n=4$ ). The technical success in the surgery group was 100%. The mean age of the patients in the surgery group was  $59.2\pm 7.4$  years; the patients who underwent AIS were older ( $66.6\pm 11.8$  years). The primary patency at 4 years for ABF was  $93\pm 0.07\%$ . The authors confirmed that in comparison with ABF, AIS was associated with decreased primary patency, decreased perioperative morbidity, and shorter hospital stay (10).

Table 2. Characteristics and Long-Term Results of Endovascularly Treated Iliac Occlusive Disease

Study and Year	Study Design	No. of Stented Lesions	Primary Patency, %				Secondary Patency, % (Years)
			At 1 Year	At 3 Years	At 5 Years	Long Term (Years)	
Soga et al., 2012 (13)	Retrospective	2096	92.5	82.6	77.5	NA	98.5 (5)
Ichihashi et al., 2011 (14)	Retrospective	533	95	91	88	83 (10)	NA
Jaff and Katzen, 2010 (15)	Retrospective	151	NA	91 (at 2 years)	NA	NA	NA
Ozkan et al., 2010 (16)	Retrospective	127	NA	NA	63	NA	93 (5)
Maurel et al., 2009 (17)	Retrospective	107	97	84	NA	NA	93 (3)
Koizumi et al., 2009 (18)	Retrospective	487	NA	88	82	75 (10)	NA
Higashiura et al., 2009 (19)	Retrospective	305	90	90	NA	90 (8)	NA
Moise et al., 2009 (20)	Retrospective	31	85	66	NA	NA	90 (3)
Giles et al., 2008 (21)	Retrospective	66	84	NA	NA	NA	NA
Kashyap et al., 2008 (22)	Retrospective	112	NA	74	NA	NA	95 (3)
Sixt et al., 2008 (23)	Retrospective	438	89	NA	70	NA	NA
Gandini et al., 2008 (24)	Retrospective	138	NA	90	80	68 (10)	NA
Carreira et al., 2008 (25)	Prospective	31	NA	83	75	67 (7)	86 (5)
AbuRahma et al., 2007 (26)	Retrospective	149	98	94	77	NA	NA
De Roeck et al., 2006 (27)	Retrospective	38	94	89	77	NA	94 (3)
Leville et al., 2006 (28)	Retrospective	92	NA	76	NA	NA	90 (3)
Balzer et al., 2006 (29)	Retrospective	89	NA	90	NA	NA	95 (3)

NA, not available.

Table 3. Summary of Clinical Data

Study, Year	Mean Age, Years	Male, %	Technical Success, %	Early Mortality, %	Complication Rate, %
Soga et al., 2012 (13)	72	82	98	0.7	6.4
Ichihashi et al., 2011 (14)	71	89	99	0	4.8
Jaff and Katzen, 2010 (15)	67	62	98	0	7.5
Ozkan et al., 2010 (16)	59	90	92	0.8	24
Maurel et al., 2009 (17)	62	92	96	0	2.2
Koizumi et al., 2009 (18)	71	78	96	0	2.5
Higashiura et al., 2009 (19)	71	91	98	0	5.1
Moise et al., 2009 (20)	65	29	93	0	20
Giles et al., 2008 (21)	65	74	97	0	6
Kashyap et al., 2008 (22)	64	57	96	3.6	4
Sixt et al., 2008 (23)	63	80	96	0	4.9
Gandini et al., 2008 (24)	63	75	99	0	2.0
Carreira et al., 2008 (25)	55	98	97	0	10
AbuRahma et al., 2007 (26)	68	59	97	0	24
De Roeck et al., 2006 (27)	59	89	97	2.7	5.4
Leville et al., 2006 (28)	66	58	91	3.4	12
Balzer et al., 2006 (29)	64	72	97	0	5.6

### **Influence of Runoff and Other Factors for Iliac Stent Patency**

The quality of runoff is a significant independent predictor affecting the outcomes of iliac angioplasty with selective stenting (30). According to the Committee on Reporting Standards (Society for Vascular Surgery/International Society for Cardiovascular Surgery), runoff is classified into poor runoff (a score of  $>5$  for unilateral procedures or score  $>2.5$  for bilateral outflow procedures) and good runoff (a score of  $\leq 5$  for unilateral procedures or a score of  $\leq 2.5$  for bilateral procedures) (31, 32). The analysis of Park et al. (2) and Kudo et al. (33) series indicates that poor runoff is the most important independent predictor of primary failure after both surgical and endovascular procedures used to treat TASC type B and C iliac lesions. Several older studies reported, however, that an ipsilateral superficial femoral artery occlusion did not predict either iliac bypass graft failure or stent failure (34, 35). However, most re-

cent reports support the conclusions drawn by Park et al. (2) and Kudo et al. (33). For example, Soga et al. (13) presented their retrospective multicenter analysis of primary stenting for aortoiliac artery disease. A total of 2096 patients (2601 lesions; age,  $71.3 \pm 7.5$  years; mean follow-up interval,  $31.2 \pm 15.0$  months; 82.8% with intermittent claudication) were enrolled. There were no significant differences in the primary patency rate among the types of stents and TASC II categories. By multivariate analysis, runoff lesions were an independent predictor of primary patency ( $P < 0.0001$ ) (13).

Factors negatively affecting long-term patency of iliac stenting include diabetes ( $P = 0.049$ ), severity of limb ischemia ( $P = 0.002$ ), hypercholesterolemia ( $P = 0.02$ ), and the length of occluded segments ( $P = 0.0001$ ) (16, 18, 24, 36). Female gender has also been suggested to decrease the patency of external iliac artery stents ( $P = 0.03$ ) (28). However, the results of the study by Jaff and Katzen (15) showed

that the location of a stent (common iliac, external iliac artery, or both), the degree of initial stenosis, and patient gender did not affect the success of the Zilver stent patency at 2 years.

### **Combined Percutaneous Endovascular Iliac Stenting and Intrainguinal Surgical Revascularization**

The studies of the last 5 years reported a new strategy for the treatment of multifocal atherosclerosis using combined percutaneous endovascular iliac stenting with common femoral artery endarterectomy. For example, Chang et al. (37) reported the results of 193 common femoral artery (CFA) endarterectomies and iliac stent/stent grafting in 171 patients. The indications were rest pain (32%), tissue loss (22%), and claudication (46%). External iliac artery (EIA) lesions were present in 39%, and combined common iliac artery (CIA) and EIA lesions were seen in 61% of the patients. Complete CIA/EIA occlusions were present in 41% of the patients. Stent grafts were used in 41% of the patients. The technical success was achieved in 98% of the patients. The clinical improvement was observed in 92% of the patients. Besides, the 30-day mortality was 2.3% and the 5-year survival was 60%. The 5-year primary, primary-assisted, and secondary patencies were 60%, 97%, and 98%, respectively. An endovascular reintervention was required in 14% of the patients. A combined CFA endarterectomy with iliac stenting yielded acceptable long-term results.

Recently, Nishibe et al. (38) have described their results with aortoiliac stenting and common femoral artery endarterectomy in a group of 20 patients. They had high degrees of technical and clinical success with the mean ankle-brachial index (ABI) of 0.29 and no perioperative mortality. The primary patency was 70% at 2 years, and the primary-assisted patency was 94%. The primary patency rate for intermittent claudication was significantly higher than that for critical limb ischemia, while no significant difference was found in the primary-assisted patency and survival rates between intermittent claudication and critical limb ischemia. Mousa et al. (39) and Nelson et al. (40) described similar results. The authors confirmed that an aggressive approach to surgically treating concomitant outflow lesions that are often encountered in patients with iliac occlusive disease would lead to improved results with proximal endovascular stenting.

### **Endovascular Treatment of Iliac In-Stent Restenosis**

A Dutch randomized study (primary stenting vs. selective stenting) showed that selective iliac stenting was as effective as primary stenting (41, 42). However, many series advocate routine stent placement after an otherwise uncomplicated PTA (pri-

mary stenting) in an attempt to prevent a recurrent disease (43, 44). Stents could prevent immediate recoil and obstructive plaque dissection with their mechanism of fixing the plaque against the arterial wall. However, there is a tendency for the development of intrastent intimal hyperplasia, which may induce recurrent stenosis (45, 46).

A routine iliac stent placement is a daily procedure, and it is still attempted on a large scale to prevent a recurrent disease; nevertheless, the long-term outcome of iliac stenting shows restenosis in up to 25% (47, 48). Little is known so far about the initial success and the long-term outcome of endovascular treatment of these iliac in-stent occlusions (Figs. 1–3).

Kropman et al. (49) described the long-term result of endoluminal therapy for iliac in-stent obstructions in 68 patients who underwent 84 endovascular interventions. All the patients were symptomatic: 70% had disabling intermittent claudication, 23% had rest pain, and 7% had trophic changes. All of them had a reduction of a stent diameter exceeding 50%, which was confirmed by duplex scanning and angiography. PTA alone was used to treat 72 patients with in-stent obstruction (86%); the other 12 (14%) had PTA and renewed stent placement. The mean follow-up was 35 months (range, 3 to 120 months). The primary clinical patency was 88% at 1 year, 62% at 3 years, and 38% at 5 years of follow-up. The secondary patency at 1, 3, and 5 years was 94%, 78%, and 63%, respectively. A surgical intervention was needed in 17 (20%) of the 84 extremities. The authors think that endoluminal therapy should be the treatment of the first choice for symptomatic iliac in-stent restenosis.

Recently, Ichihashi et al. (14) have described their results with systematic primary stent placement in complex iliac artery occlusive disease in 413 consecutive patients. The median follow-up term was 72 months (range, 1 to 144 months). Lesion severity in this retrospective study was classified according to TASC II as type A in 32%, type B in 37%, type C in 16%, and type D in 15% of the patients. During the follow-up, in-stent restenosis was detected in 38 patients (9.2%). Percutaneous transluminal angioplasty for in-stent restenosis was performed in 14, stenting in 16, thrombolysis in 3, and atherectomy in 5 patients. By univariate analysis, patient age ( $P=0.004$ ), lesion length ( $P=0.011$ ), and residual pressure gradient ( $P=0.000$ ) were indicated as the risk factors associated with in-stent restenosis. In multivariate analysis, the length of a lesion was an independent risk factor for in-stent restenosis (hazard ratio, 1.12,  $P=0.003$ ; 95% confidence interval, 1.01–1.24).

There are new techniques, which are becoming more and more popular in the treatment of iliac restenotic disease. Tsetis et al. (50) reported prelim-



Fig. 1. Severe in-stent restenosis in a 76-year-old man, 18 months after stenting of the left external iliac artery with a balloon expandable stent

Unpublished data of the authors.



Fig. 2. Angioplasty balloon inflated at nominal pressure  
Unpublished data of the authors.

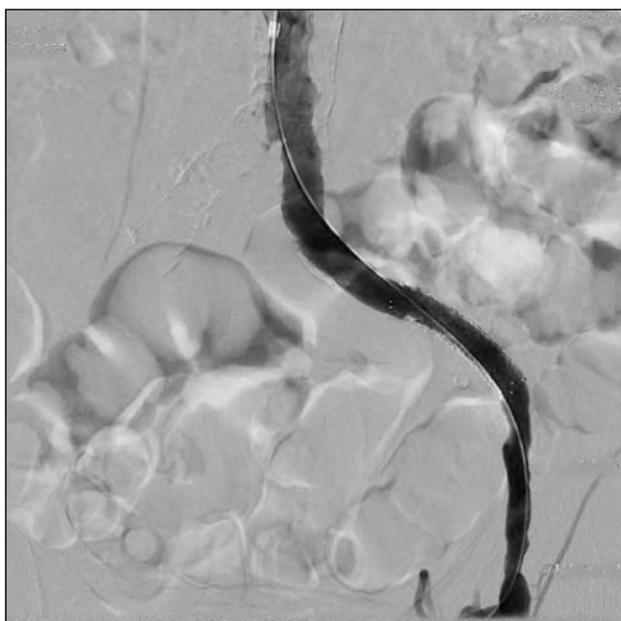


Fig. 3. A postangioplasty angiogram after a single inflation with no residual stenosis

Unpublished data of the authors.

inary experience using cutting balloon angioplasty (CBA) in symptomatic iliac artery in-stent restenosis. CBA was performed after conventional angioplasty failure in 7 lesions and as a primary treatment method in 7 lesions. During the mean follow-up of 23.6 months, no patient showed clinical deterioration, and no recurrent in-stent restenosis was detected with color duplex. Recently, Silingardi et al. (51) have reported the efficacy of a mechanical rotational thrombectomy procedure with the Rotarex

Mechanical Thrombectomy System (Straub Medical, Wangs, CH) in iliac artery in-stent restenosis in 32 selected patients. The primary patency at 30 days was 96.8%. The primary and secondary patency rates at 12 months were 58.1% and 75.5%, respectively.

#### ***Iliac Artery Stenting Complications***

Iliac stenting could be performed safely; however, its complication rates have been reported higher than those of iliac PTA alone. According to Table 3, the complication rates of iliac stenting were reported in all the studies and varied between 2.0% and 24%, whereas the rates of 3% to 7.9% were reported in the iliac PTA series (52). Early mortality after an iliac stent implantation was described in 5 studies and ranged from 0.7% to 3.6%. Ozkan et al. (16), who used stents routinely in 127 chronic iliac artery occlusions, reported 1 death (0.8%), which occurred during the perioperative period secondary to iliac artery rupture, although there was a 0.3% death rate in a series of 667 iliac PTA in a study by Johnston (52). In terms of complications, these data do not favor primary stenting over PTA alone or selective stenting. Stents do require larger access sites and more contrast media, which could contribute to higher complication rates. The most common complications were distal embolization (reported in 12 studies; range, 2% to 13%), access site hematomas (reported in 10 studies; range, 3% to 15%), pseudoaneurysms (reported in 11 studies; range, 1% to 4%), and iliac artery ruptures (reported in 5 studies; range, 0.5% to 2%). The complications were most often treated conservatively or using percutaneous techniques. Distal embolization was treated using

aspiration or thrombolysis, while thrombectomy using a Fogarty catheter or bypass techniques was described as well (14, 18, 26). Ichihashi et al. (14) concluded that the prevalence of complications was, thus, significantly higher in TASC II C/D than in TASC II A/B patient groups ( $P=0.014$ ). Moise et al. (20) reported 2 (6%) cases of perioperative limb thromboses requiring surgery. One study reported an arteriovenous fistula after an iliac stent placement (18), and other reported periprocedural stroke with a complete remission (23). Higashiura et al. (19) described a case with aneurysmal dilatation of the iliac artery with a fractured stent following Nitinol stenting for common and external iliac arterial occlusion. AbuRahma et al. (26) reported a 2.7% perioperative complication rate for the primary iliac stent group vs. 24% for the selective stent group ( $P<0.0001$ ). Most often, stent fractures were seen in an external iliac artery. The authors confirmed that stenting for occlusion should be considered as a risk factor for a Nitinol stent fracture ( $P=0.008$ ) (19). There are some theories about iliac stent fractures. One of them is related to an external iliac artery exposed to flexion by bending the hip joint (53); and the other is associated with a different biomedical construction of an Elgiloy stent vs. a Nitinol stent (19). The outcome of 2 different self-expanding stents Nitinol SMART (Cordis, Johnson&Johnson) and Wallstent

(Boston Scientific) for the treatment of iliac artery lesions was compared in a multicenter prospective randomized trial (54). The 1-year primary patencies were 94.7% and 91.1% (not significant), respectively, with similar complication and symptomatic improvement rates regardless of the type of a stent.

### Conclusions

The treatment of iliac artery occlusions can be accomplished via endovascular stenting with low morbidity rates and with acceptable patency and limb salvage rates. The fate of the iliac stent is dictated by infrainguinal disease that is often present in patients with complex iliac occlusions, severity of limb ischemia, diabetes, hypercholesterolemia, and the length of occluded segments. Patients with symptomatic iliac in-stent restenosis should be successfully treated using endoluminal therapy. The review showed that endovascular attempts should be exhausted before attempting an open surgical treatment of iliac occlusions because perioperative morbidity and long-term patency are comparable to those after bypass surgery. Iliac stenting should be considered with priority in elderly patients or in patients with severe comorbidities.

### Statement of Conflict of Interest

The authors state no conflict of interest.

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