### EVIDENCE TABLE

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<tr>
<td>1. Thrombolysis in the management of lower limb peripheral arterial occlusion—a consensus document. <em>J Vasc Interv Radiol.</em> 2003;14(9 Pt 2):S337-349.</td>
<td>Review/Other-Tx</td>
<td>N/A</td>
<td>To develop an intercontinental consensus on the use of thrombolytic therapy in occlusive peripheral arterial disease affecting lower limbs.</td>
<td>No results stated in abstract.</td>
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<td>3. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). <em>Eur J Vasc Endovasc Surg.</em> 2007;33 Suppl 1:S1-75.</td>
<td>Review/Other-Dx</td>
<td>N/A</td>
<td>To provide an abbreviated document (compared with the publication in 2000), to focus on key aspects of diagnosis and management, and to update the information based on new publications and the newer guidelines.</td>
<td>Good practice is based on a combination of the scientific evidence, patients’ preferences, and local availability of facilities and trained professionals. Good practice also includes appropriate specialist referral.</td>
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<td>4. Rossi M, Iezzi R. Cardiovascular and Interventional Radiological Society of Europe guidelines on endovascular treatment in aortoiliac arterial disease. <em>Cardiovasc Intervent Radiol.</em> 2014;37(1):13-25.</td>
<td>Review/Other-Tx</td>
<td>N/A</td>
<td>Guideline intended for use in assessing the standard for technical success and safety in aortoiliac percutaneous endovascular interventions.</td>
<td>The success of endovascular procedures is strictly related to an accurate planning based mainly on CTA or MRA. TASC II A through C lesions have an endovascular-first option Preprocedure ASA antiplatelet therapy is advisable in all cases. The application of stents improves the immediate hemodynamic and most likely long-term clinical results. Cumulative mean complication rate is 7.51% according to the most relevant literature. Most of the complications can be managed by means of percutaneous techniques.</td>
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<td>5. Ruggiero NJ, 2nd, Jaff MR. The current management of aortic, common iliac, and external iliac artery disease: basic data underlying clinical decision making. <em>Ann Vasc Surg</em>. 2011;25(7):990-1003.</td>
<td>Review/Other-Tx</td>
<td>N/A</td>
<td>To compare and contrast different treatment strategies and critically review the available literature to allow for evidence-based clinical decisions to be made about the surgical and endovascular management of aortoiliac occlusive disease.</td>
<td>No results stated in abstract.</td>
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<td>6. Cao P, Eckstein HH, De Rango P, et al. Chapter II: Diagnostic methods. <em>Eur J Vasc Endovasc Surg</em>. 2011;42 Suppl 2:S13-32.</td>
<td>Review/Other-Dx</td>
<td>N/A</td>
<td>To review diagnostic methods for CLI.</td>
<td>Noninvasive vascular studies can provide crucial information on the presence, location, and severity of CLI, as well as the initial assessment or treatment planning. ABI with Doppler US, despite limitations in diabetic and end-stage renal failure patients, is the first-line evaluation of CLI. In this group of patients, toe-brachial index measurement may better establish the diagnosis. Other noninvasive measurements, such as segmental limb pressure, continuous-wave Doppler analysis and pulse volume recording, are of limited accuracy. Transcutaneous oxygen pressure measurement may be of value when rest pain and ulcerations of the foot are present. Duplex US is the most important noninvasive tool in CLI patients combining hemodynamic evaluation with imaging modality. CTA and MRA are the next imaging studies in the algorithm for CLI. Both CTA and MRA have been proven effective in aiding the decision-making of clinicians and accurate planning of intervention. The data acquired with CTA and MRA can be manipulated in a multiplanar and 3D fashion and can offer exquisite detail. CTA results are generally equivalent to MRA, and both compare favorably with contrast angiography. The individual use of different imaging modalities depends on local availability, experience, and costs. Contrast angiography represents the gold standard, provides detailed information about arterial anatomy, and is recommended when revascularization is needed.</td>
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<td>7. Murphy TP, Cutlip DE, Regensteiner JG, et al. Supervised exercise versus primary stenting for claudication resulting from aortoiliac peripheral artery disease: six-month outcomes from the claudication: exercise versus endoluminal revascularization (CLEVER) study. <em>Circulation.</em> 2012;125(1):130-139.</td>
<td>Experimental-Tx</td>
<td>111 patients</td>
<td>To compare the benefits of optimal medical care, supervised exercise, and stent revascularization on both walking outcomes and measures of quality-of-life in patients with claudication due to aortoiliac peripheral artery disease.</td>
<td>At the 6-month follow-up, change in peak walking time (the primary end point) was greatest for supervised exercise, intermediate for stent revascularization, and least with optimal medical care (mean change vs baseline, 5.8±4.6, 3.7±4.9, and 1.2±2.6 minutes, respectively; <em>P</em>&lt;0.001 for the comparison of supervised exercise vs optimal medical care, <em>P</em>=0.02 for stent revascularization vs optimal medical care, and <em>P</em>=0.04 for supervised exercise vs stent revascularization). Although disease-specific quality of life as assessed by the Walking Impairment Questionnaire and Peripheral Artery Questionnaire also improved with both supervised exercise and stent revascularization compared with optimal medical care, for most scales, the extent of improvement was greater with stent revascularization than supervised exercise. Free-living step activity increased more with stent revascularization than with either supervised exercise or optimal medical care alone (114±274 vs 73±139 vs -6±109 steps per hour), but these differences were not statistically significant.</td>
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<td>8. Ouriel K, Castaneda F, McNamara T, et al. Reteplase monotherapy and reteplase/abciximab combination therapy in peripheral arterial occlusive disease: results from the RELAX trial. <em>J Vasc Interv Radiol.</em> 2004;15(3):229-238.</td>
<td>Experimental-Tx</td>
<td>74 patients</td>
<td>To examine the safety and efficacy of increasing doses of intra-arterial reteplase monotherapy and reteplase/abciximab combination therapy in patients with acute peripheral arterial occlusive disease.</td>
<td>Major bleeding occurred with similar frequency in patients treated with and without abciximab (15% of the pooled patients receiving reteplase monotherapy and 20% of patients receiving reteplase/abciximab combination therapy). There were no intracranial hemorrhagic events in the 74 patients. Reteplase doses of at least 0.2 U/hour were effective at dissolving thrombus and restoring patency. There was no clear dose-response relationship for reteplase. However, the addition of abciximab reduced the occurrence of distal embolic events requiring intervention (5% vs 31%; <em>P</em>=.014).</td>
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<td>9. Tepe G, Hopfenzitz C, Dietz K, et al. Peripheral arteries: treatment with antibodies of platelet receptors and reteplase for thrombolysis--APART trial. <em>Radiology.</em> 2006;239(3):892-900.</td>
<td>Experimental-Tx</td>
<td>70 patients</td>
<td>To prospectively compare the safety and efficacy of combination therapy with the glycoprotein IIb/IIa antagonist abciximab plus the third-generation thrombolytic agent reteplase vs those of therapy with the standard thrombolytic agent urokinase plus abciximab.</td>
<td>Therapeutic success ($P=0.7$) did not differ between the groups, whereas the time required for thrombolysis was lower in the urokinase-plus-abciximab group ($P=0.001$). Patients who received reteplase plus abciximab tended to develop more minor complications (mainly bleeding events) ($P&lt;0.001$). During long-term follow-up (2–4 years), no group differences were observed. The reocclusion rate was 48% (22/46) in the reteplase-plus-abciximab group and 45% (29/64) in the urokinase-plus-abciximab group. Only 2 of 120 major amputations were counted in the follow-up period.</td>
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<td>10. Wissgott C, Richter A, Kamusella P, Steinkamp HJ. Treatment of critical limb ischemia using ultrasound-enhanced thrombolysis (PARES Trial): final results. <em>J Endovasc Ther.</em> 2007;14(4):438-443.</td>
<td>Experimental-Tx</td>
<td>25 patients</td>
<td>To evaluate the safety and performance of US-enhanced thrombolysis in the treatment of acute thrombotic or embolic occlusion of the lower limb arteries.</td>
<td>The technical success rate was 100%. Total clot removal was achieved in 22 (88%) patients after 16.9 hours (range 5–24) using a mean 17 mg (range 5–25) of recombinant tissue plasminogen activator. In 8 cases, total clot removal of the main lesion was achieved after 6 hours (6 mg of recombinant tissue plasminogen activator). In 1 patient, lysis was stopped after 2.5 hours because of bleeding due to a dislocation of the introducer sheath. In 2 cases, total clot removal could not be achieved; these patients were successfully treated with thromboaspiration. At the 1-month follow-up, the treated vessel was still patent in 20 patients. 2 reocclusions occurred; 1 was treated with a bypass graft and the other with conservative therapy. There were no cases of amputation or death during follow-up. There were no side effects related to recombinant tissue plasminogen activator or the catheter system.</td>
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<td>11. Kasiraj K, Gray B, Beavers FP, et al. Rheolytic thrombectomy in the management of acute and subacute limb-threatening ischemia. J Vasc Interv Radiol. 2001;12(4):413-421.</td>
<td>Observational-Tx</td>
<td>86 patients</td>
<td>To evaluate the use of a percutaneous mechanical thrombectomy catheter (AngioJet) as an initial treatment for acute (&lt;2 weeks) and subacute (2 weeks to 4 months) arterial occlusion of the limbs.</td>
<td>Angiographic success was evaluated in 83/86 patients (guide wire unable to traverse lesion in 3 patients). The procedure failed in 13/83 (15.6%) patients, partial success was seen in 19/83 patients (22.9%), and successful recanalization was noted in 51/83 patients (61.4%). Adjunctive thrombolysis was used in 50/86 patients (58%). However, thrombolysis resulted in angiographic improvement at the site of percutaneous mechanical thrombectomy in only 7/50 of these patients (14%). Adjunctive thrombolysis was uniformly unsuccessful in patients in whom initial percutaneous mechanical thrombectomy failed. The median increase in ABI was 0.64 (95% CI: 0.43–0.81). Success was more likely in the setting of in situ thrombosis, with 61/68 (90%) procedures successful, compared to embolic occlusions, with 9/15 (60%) procedures successful ($P=0.011$). Angiographic outcome was not dependent on the duration of occlusion (acute, 51/62; subacute, 19/21; $P=0.35$) or the conduit type (graft, 28/31; native vessel, 42/52; $P=0.35$). An underlying stenosis was identified in 53 of the 70 patients (75.7%) with a successful percutaneous mechanical thrombectomy, and 51 of these 53 unmasked lesions were successfully treated. Follow-up data were available in 56 patients for patency assessment at a median of 3.9 months (range, 0.1–28.5 months). Patency at 6 months was 79% (95% CI: 65–92). Systemic complications occurred in 16.3% of patients, local complications were noted in 18.6%, and 1-month amputation and mortality rates were 11.6% and 9.3%, respectively.</td>
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<td>12. Berridge DC, Kessel D, Robertson I. Surgery versus thrombolysis for acute limb ischaemia: initial management. <em>Cochrane Database Syst Rev.</em> 2000(4):CD002784.</td>
<td>Review/Other-Tx</td>
<td>N/A</td>
<td>To determine if surgery or thrombolysis is the preferred option in the initial treatment of acute limb ischemia.</td>
<td>Patients with acute lesions of &lt;7 days duration had a significantly increased survival at 1 year for patients having thrombolysis, compared to those undergoing initial surgery [84% vs 58%, ( P=0.01 ); Odds ratio (95% CI) 0.28 (0.13,0.63)] largely associated with a reduced level of in-hospital cardio-pulmonary complications (Ouriel 1994). Lesions &lt;14 days duration fared better with initial lysis with a reduced amputation and reduced death rate at 6 months [15.3% vs 37.5%; ( P=0.001 ); Odds ratio (95% CI) 0.29 (0.12,0.72)] (STILE 1994), compared to initial surgery. Analysis of the same trial at 1 year however, revealed that native vessel thromboses had a more favorable outcome with initial surgery, largely due to continuing ischemia in the lytic group [64% vs 35%; ( P&lt;0.0001 ); Odds ratio (95% CI) 3.26(1.96,5.52)] (Weaver 1996). Bypass graft thromboses &lt;14 days old treated with initial thrombolysis were shown to have a reduced amputation rate (15% vs 47%; ( P=0.05 )). However, overall, 1 year results revealed that thrombolysis of thrombosed grafts was associated with a higher level of continued ischemia [73% vs 50%; ( P=0.010 ); Odds ratio (95%CI) 2.72(1.27,5.80)] (Comerota 1996).</td>
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## Radiologic Management of Iliac Artery Occlusive Disease

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<tr>
<td>13. Ouriel K, Veith FJ, Sasahara AA. A comparison of recombinant urokinase with vascular surgery as initial treatment for acute arterial occlusion of the legs. Thrombolysis or Peripheral Arterial Surgery (TOPAS) Investigators. <em>N Engl J Med.</em> 1998;338(16):1105-1111.</td>
<td>Experimental-Tx</td>
<td>544 patients</td>
<td>To compare vascular surgery (eg, thrombectomy or bypass surgery) with thrombolysis by catheter-directed intra-arterial recombinant urokinase as initial treatment in patients with acute peripheral arterial occlusion threatening the viability of the leg.</td>
<td>Final angiograms, which were available for 246 patients treated with urokinase, revealed recanalization in 196 (79.7%) and complete dissolution of thrombus in 167 (67.9%). Both treatment groups had similar significant improvements in mean ABI. Amputation-free survival rates in the urokinase group were 71.8% at 6 months and 65.0% at 1 year, as compared with respective rates of 74.8% and 69.9% in the surgery group; the 95% CIs for the differences were -10.5 to 4.5 percentage points at 6 months ($P=0.43$) and -12.9 to 3.1 percentage points at 1 year ($P=0.23$). At 6 months the surgery group had undergone 551 open operative procedures (excluding amputations), as compared with 315 in the thrombolysis group. Major hemorrhage occurred in 32 patients in the urokinase group (12.5%) as compared with 14 patients in the surgery group (5.5%) ($P=0.005$). There were 4 episodes of intracranial hemorrhage in the urokinase group (1.6%), 1 of which was fatal. By contrast, there were no episodes of intracranial hemorrhage in the surgery group.</td>
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| 14. Beyersdorf F, Matheis G, Kruger S, et al. Avoiding reperfusion injury after limb revascularization: experimental observations and recommendations for clinical application. *J Vasc Surg.* 1989;9(6):757-766. | Experimental-Tx | 61 rats | To test the hypothesis that reperfusion injury is the principal cause of limb loss after acute arterial occlusion and that this injury is avoidable. | 4 hours of ischemia caused a profound fall in adenosine triphosphate content (4.0 vs 26.0 mmol/L/gm of protein, $P<=0.001$). Uncontrolled reperfusion resulted in severe reperfusion injury; massive edema developed (83% vs 75%, $P<=0.01$), leg volume increased markedly (21.5% above control, $P<=0.001$), and no contractile function followed electrical stimulation. In contrast, controlled reperfusion resulted in normal water content (76.9% vs 75.0%, NS) and minimal change of leg volume (5.5% +/- 5% of control, NS), replenished adenosine triphosphate completely (24.2 vs 26.4 mmol/L/gm of protein, NS), and restored immediate contractile function in all limbs (24.3% +/- 14% of control). | 2 |

* See Last Page for Key

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<td>15. Nehler MR, Mueller RJ, McLafferty RB, et al. Outcome of catheter-directed thrombolysis for lower extremity arterial bypass occlusion. <em>J Vasc Surg.</em> 2003;37(1):72-78.</td>
<td>Observational-Tx</td>
<td>104 patients</td>
<td>To determine the clinical outcome of patients undergoing catheter-directed thrombolysis for lower extremity arterial bypass occlusion.</td>
<td>104 patients (77% male; mean age, 65 years) had 109 lower extremity arterial bypass occlusions. Catheter-directed thrombolysis restored patency in 77%. Of the 25 lower extremity arterial bypass that failed initial catheter-directed thrombolysis, 15 underwent surgical thrombectomy/revision, 4 were replaced, and 6 underwent no further interventions. Of the 84 lower extremity arterial bypass successfully lysed, 51 had residual lesions that underwent revision with interventional (n = 30) or surgical (n = 15) techniques or both (n = 6). Median hospital stay was 8 days with 3 periprocedural deaths. One quarter of catheter-directed thrombolysis procedures had bleeding or thrombotic complications or both. The mean follow-up period was 45 months. Secondary patency rates on an intention-to-treat basis (attempted thrombolysis) were 32% and 19% at 1 and 5 years, respectively. After successful catheter-directed thrombolysis, the 1-year secondary patency rate was comparable in lower extremity arterial bypass with or without residual lesions (42% vs 45%). Overall, the limb salvage rates were 73% and 55% at 1 and 5 years, respectively. The survival rate was 56% at 5 years. 10 of the 54 lower extremity arterial bypass (19%) that eventually failed after successful catheter-directed thrombolysis had 3 or more reocclusive episodes. 7 lower extremity arterial bypass (8.3%) salvaged with catheter-directed thrombolysis eventually became infected from recurrent interventions; 6 of these necessitated major amputation. 20 lower extremity arterial bypass initially salvaged with catheter-directed thrombolysis were replaced (4 immediately and 16 after episodes of recurrent ischemia). 2 patients died during hospitalization for treatment of recurrent ischemia.</td>
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<td>16.</td>
<td>Klein WM, van der Graaf Y, Seegers J, et al. Dutch iliac stent trial: long-term results in patients randomized for primary or selective stent placement. <em>Radiology.</em> 2006;238(2):734-744.</td>
<td>Experimental-Tx 279 patients</td>
<td>To determine long-term results of the prospective Dutch Iliac Stent Trial.</td>
<td>Patients who underwent PTA and selective stent placement had better improvement of symptoms (HR, 0.8; 95% confidence limits: 0.6, 1.0) than did patients treated with primary stent placement, whereas ABI (HR, 0.9; 95% confidence limits: 0.7, 1.3), iliac patency (HR, 1.3; 95% confidence limits: 0.8, 2.1), and score for quality of life for 9 survey dimensions did not support a difference between treatment groups.</td>
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<td>17.</td>
<td>AbuRahma AF, Hayes JD, Flaherty SK, Peery W. Primary iliac stenting versus transluminal angioplasty with selective stenting. <em>J Vasc Surg.</em> 2007;46(5):965-970.</td>
<td>Observational-Tx 151 patients</td>
<td>To compare the early and late clinical outcomes of primary vs selective iliac stenting at our institution.</td>
<td>The perioperative complication rate for the primary stent group was 2.7% (3 minor hematomas) vs 24% for the selective stent group (<em>P</em>&lt;.0001). The overall early clinical success rate was 97% for the primary stent group vs 83% for the selective stent group (<em>P</em>=.002), however, the rate was 100% for short stenosis (A and B lesions &lt;5 cm TASC classification) in both groups; in contrast to 93% for the primary stent group vs 46% for the selective stent group for longer stenoses (TASC C and D lesions, <em>P</em>=.0003). The overall late clinical success was comparable for both groups: 88% for the primary stent group vs 80% for the selective stent group, however, this rate was superior for the longer lesions in the primary stent group, 84% vs 46% (<em>P</em>=.007). The primary patency rates at 1, 2, 3, and 5 years were 98%, 94%, 87%, and 77% for the primary stent group vs 83%, 78%, 69%, and 69% for the selective stent group (<em>P</em>=.030). These rates were comparable in both groups for shorter lesions: 100%, 98%, 98%, and 87% for the primary stent group vs 100%, 93%, 85%, and 85% for the selective stent group (<em>P</em>=.637). However, they were superior for the primary stent group in longer lesions: 96%, 90%, and 72% vs 46%, 46%, and 28% for the selective stent group at 1, 2, and 3 years (<em>P</em>&lt;.0001).</td>
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<td>18. Galaria, II, Davies MG. Percutaneous transluminal revascularization for iliac occlusive disease: long-term outcomes in TransAtlantic Inter-Society Consensus A and B lesions. Ann Vasc Surg. 2005;19(3):352-360.</td>
<td>Observational-Tx</td>
<td>276 patients</td>
<td>To examine the long-term outcomes of TASC A and B lesions.</td>
<td>Technical success (defined by &lt;30% residual stenosis) was achieved in 98% of treated vessels. The procedure-related mortality rate was 1.8% at 30 days and 4.7% at 90 days; the procedure-related complication rate was 7%. Hemodynamic success (defined as a rise in the ABI &gt;0.15) was achieved in 82%. The average Society for Vascular Surgery symptom score was 3.4 +/- 0.9 before intervention, which improved to 1.9 +/- 0.8 following intervention. Within 3 months, 84% of patients demonstrated clinical improvement. Patient survival by life-table analysis was 38% at 10 years. The cumulative assisted patency rate was 71 +/- 7% at 10 years. The presence of 2-vessel femoral runoff, 2 or more patent tibial vessels, or both was associated with improved patency. Limb salvage was 95 +/- 2% and 87 +/- 9% at 5 and 10 years, respectively.</td>
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<td>19. Kudo T, Chandra FA, Ahn SS. Long-term outcomes and predictors of iliac angioplasty with selective stenting. <em>J Vasc Surg.</em> 2005;42(3):466-475.</td>
<td>Observational-Tx</td>
<td>104 patients</td>
<td>To review our 11-year experience of iliac angioplasty with selective stenting and to evaluate the safety, short- and long-term patency, clinical success rates, and predictive risk factors in patients with iliac artery occlusive disease.</td>
<td>There was no perioperative death. Total complication rate was 0.7% (1 groin hematoma). The mean follow-up was 21 months (median, 10; range, 1 to 94 months). Only 9 (8%) of 117 of the PTA group had subsequent stent placement for recurrent stenosis. The iliac lesions were more severe and extensive in the stent group than those in the PTA group according to TASC classification (Mann-Whitney U test [M-W], <em>P</em> &lt; .0001) and anatomic location (M-W, <em>P</em> = .0019). The technical success rate was 99%, and the initial clinical success rate was 99%. Overall, the cumulative primary patency rates at 1, 3, and 5 years were 76%, 59%, and 49% (Kaplan-Meier [K-M]). The cumulative assisted primary and secondary patency rates at 7 years were 98% and 99% (K-M). The mean number of subsequent iliac endovascular procedures was 1.4 per limb in patients with primary failure of iliac angioplasty/stenting. The continued clinical improvement rates at 1, 3, and 5 years were 81%, 67%, and 53% (K-M). The limb salvage rates at 7 year were 93% (K-M). Of 15 predictor variables studied in 151 iliac lesions, the significant independent predictors for adverse outcomes were smoking history (<em>P</em> = .0074), TASC type C/type D lesions (<em>P</em> = .0001), and stenotic ipsilateral SFA (<em>P</em> = .0002) for the primary patency rates; chronic renal failure with hemodialysis (<em>P</em> = .014), ulcer/gangrene as an indication for PTA (<em>P</em> &lt; .0001), and stenotic ipsilateral SFA (<em>P</em> = .034) for the continued clinical improvement (K-M, log-rank test and Cox regression model).</td>
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<td>20. Ye W, Liu CW, Ricco JB, Mani K, Zeng R, Jiang J. Early and late outcomes of percutaneous treatment of TransAtlantic Inter-Society Consensus class C and D aorto-iliac lesions. <em>J Vasc Surg.</em> 2011;53(6):1728-1737.</td>
<td>Meta-analysis</td>
<td>16 articles including 958 patients</td>
<td>To analyze the technical success and long-term patency of the endovascular treatment of TASC C and D aortoiliac arterial lesions.</td>
<td>16 articles consisting of 958 patients were enrolled in this meta-analysis. The pooled estimate for technical success was 92.8% (95% CI, 89.8%–95.0%, 749 cases). Primary patency at 12 months was 88.7% (95% CI, 85.9%–91.0%, 787 cases). Subgroup analyses demonstrated a technical success rate of 93.7% (95% CI, 88.9%–96.5%) and a 12-month primary patency rate of 89.6% (95% CI, 84.8%–93.0%) for TASC C lesions. For TASC D lesions, these rates were 90.1% (95% CI, 76.6%–96.2%) and 87.3% (95% CI, 82.5%–90.9%), respectively. The technical success and 12-month primary patency rates for primary stenting were 94.2% (95% CI, 91.8%–95.9%) and 92.1% (95% CI, 89.0%–94.3%), respectively; for selective stenting, these rates were 88.0% (95% CI, 67.9%–96.2%) and 82.9% (95% CI, 72.2%–90.0%), respectively. The long-term, primary patency rates for patients receiving primary stenting were significantly better than those receiving selective stenting. Publication bias was not significant for these analyses.</td>
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<td>21. Balzer JO, Gastinger V, Ritter R, et al. Percutaneous interventional reconstruction of the iliac arteries: primary and long-term success rate in selected TASC C and D lesions. <em>Eur Radiol.</em> 2006;16(1):124-131.</td>
<td>Observational-Tx</td>
<td>89 patients</td>
<td>To report the primary and long-term outcome of patients with selected TASC C or D lesions of the iliac arteries after percutaneous interventional reconstruction.</td>
<td>The primary technical success rate was 96.9% with an overall complication rate of 5.6%. The ABI improved from an average of 0.51+/-.015 before intervention to 0.79+/-.016 on the day following intervention and to 0.81+/-.017 within 3 years after intervention. Clinical improvement was observed in 97.3% of the patients in the TASC C group and in 88.5% in the TASC D group. 80/89 patients (89.9%) remained patent at 3-year follow-up. In 5 patients the reintervention was successful. The secondary patency rate was 95.5%.</td>
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### Reference Study Type Patients/Events Study Objective (Purpose of Study) Study Results

Observational-Tx 628 patients To review the outcomes and durability of R/PTAS for iliac occlusions based on the patient’s TASC stratification. R/PTAS (total, 178 stents) of occluded iliac arteries was technically successful in 84 (91%) of 92 procedures. Patients in the TASC-C and -D groups often required multiple access sites (50%) and femoral artery endarterectomy/patch angioplasty for diffuse disease (24%). The mean ABI increased from 0.45 to 0.83. Distal embolization led to major amputation and eventual death in 1 patient. 2 other deaths occurred in the perioperative period secondary to cardiorespiratory causes. 3-year primary patency, secondary patency, and limb salvage rates were 76%, 90%, and 97%, respectively, and progression of infringuinal disease led to late limb loss in 2 patients. Diabetes as a risk factor was significantly associated with decreased primary patency (57% vs 83%; \( P = .049 \)). Critical ischemia at presentation was associated with decreased patency rates as well (\( P = .002 \)), but TASC classification did not significantly alter patency rates.

Observational-Tx 218 patients To evaluate the long-term patency of iliac arterial stent placement according to individual TASC stages and demonstrate the limitations of TASC classification for iliac arterial disease. The technical success rate was 99%. 171 patients (80%) were classified under a single TASC category however, 44 patients (20%) with bilateral iliac lesions could not be classified under a single TASC stage. The number of patients and limbs in each TASC group was: TASC A (88/97), TASC B (91/97), TASC C (32/48), and TASC D (16/18). The 1, 3 and 5 year primary patencies of the iliac arterial stent for TASC A were 96%, 84%, and 81%; TASC B were 95%, 85%, and 85%; TASC C were 94%, 94%, and 78%; and TASC D were 93%, 74%, and 74%, respectively. 4 TASC groups were not statistically different for primary patency rates (\( P < .03 \)).
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<td>24. de Donato G, Bosiers M, Setacci F, et al. 24-Month Data from the BRAVISSIMO: A Large-Scale Prospective Registry on Iliac Stenting for TASC A &amp; B and TASC C &amp; D Lesions. <em>Ann Vasc Surg</em>. 2015;29(4):738-750.</td>
<td>Observational-Tx</td>
<td>325 patients</td>
<td>To evaluate the 24-month outcome of stenting in TASC A &amp; B and TASC C &amp; D iliac lesions in a controlled setting.</td>
<td>Between July 2009 and September 2010, 190 patients with TASC A or B and 135 patients with TASC C or D aortoiliac lesions were included. The demographic data were comparable for TASC A &amp; B cohort and TASC C &amp; D cohort. Technical success was 100%. Significantly more balloon-expandable stents were deployed in TASC A &amp; B lesions, and considerably more self-expanding stents were placed in TASC C &amp; D ($P=0.01$). The 24-month primary patency rate after 24 months for the total population was 87.9% (88.0% for TASC A, 88.5% for TASC B, 91.9% for TASC C, and 84.8% for TASC D). No statistically significant difference was shown when comparing these groups. The 24-month primary patency rates were 92.1% for patients treated with the self-expanding stent, 85.2% for patients treated with the balloon-expandable stent, and 75.3% for patients treated with a combination of both stents ($P=0.06$). Univariate and multivariable regression analyses using Cox proportional hazards model identified only kissing stent configuration ($P=0.0012$) and obesity ($P=0.0109$) as independent predictors of restenosis (primary patency failure). Interestingly, as all TASC groups enjoyed high levels of patency, neither TASC category nor lesion length was predictive of restenosis.</td>
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<td>25. Ichihashi S, Higashiura W, Itoh H, Sakaguchi S, Nishimine K, Kichikawa K. Long-term outcomes for systematic primary stent placement in complex iliac artery occlusive disease classified according to Trans-Atlantic Inter-Society Consensus (TASC)-II. <em>J Vasc Surg.</em> 2011;53(4):992-999.</td>
<td>Observational-Tx</td>
<td>413 patients</td>
<td>To compare long-term outcomes of systematic primary stent placement between TASC-II C/D disease and TASC-II A/B disease</td>
<td>Technical success rates in TASC-II C/D and A/B were both 99%. Procedure times for TASC-II type A, B, C, and D lesions were 98 +/- 40, 124 +/- 50, 152 +/- 55, and 183 +/- 68 minutes, respectively. Procedure time was significantly longer in TASC-II C/D (167 +/- 63 minutes) than in TASC-II A/B (112 +/- 47 minutes; ( P &lt; .001 )). The complication rate was significantly higher in TASC-II C/D (9%) than in TASC-II A/B (3%; ( P = .014 )). Cumulative primary patency rates at 1, 3, 5, and 10 years were 90%, 88%, 83%, and 71% in TASC-II C/D and 95%, 91%, 88%, and 83% in TASC-II A/B, respectively. No significant differences were apparent between groups (( P = .17 ); Kaplan-Meier method, log-rank test). In multivariate analysis, lesion length was an independent risk factor for in-stent restenosis (HR, 1.12, ( P = .03 ); 95% CI, 1.01–1.24).</td>
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| 26. Bosiers M, Iyer V, Deloose K, Verbist J, Peeters P. Flemish experience using the Advanta V12 stent-graft for the treatment of iliac artery occlusive disease. *J Cardiovasc Surg (Torino).* 2007;48(1):7-12. | Experimental-Tx | 65 patients | To evaluate the technical feasibility and safety of implanting a PTFE covered balloon expandable stent to treat iliac artery stenoses and occlusions. Additionally, the primary patency and clinical and hemodynamic efficacy at 1 year were analyzed. | In total, 91 limbs were treated in 65 patients (51 male; mean age 65 years). Stent-graft deployment was successful in 91 (100%) limbs. There were no limbs with residual stenosis >30%. There were no procedural or 30-day complications. The clinical ischemia category distribution improved significantly at 1, 6 and 12 months. The mean ABI rose significantly from 0.59 before treatment to 0.98, 0.98 and 0.99 at 1, 6 and 12 months after the procedure. Primary limb patency at 1-year was 91.1%. | 1 |
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<td>27. Wiesinger B, Beregi JP, Oliva VL, et al.</td>
<td>Experimental-Tx</td>
<td>98 patients</td>
<td>To evaluate the technical performance, safety, and 1-year clinical efficacy of PTFE-covered nitinol stents in the treatment of atherosclerotic iliac and SFA disease.</td>
<td>In total, 130 stents were placed successfully in 97 (99%) of 98 patients. 1 stent was misplaced during deployment and required subsequent surgical removal. The average stenosis grade was reduced from 98% to 6% in the SFAs and from 96% to 4% in the iliac arteries after covered stent placement. There was a significant rise of the mean ABI from 0.64 at baseline to 0.97 and 0.95 at 1 and 12 months, respectively ($P&lt;0.001$). There were 7 primary covered stent occlusions (6.5% of 107 stented lesions: 3 not treated, 2 bypassed, 2 dilated or stented) and 5 (4.7%) recurrent in-stent occlusions (1 bypassed, 2 dilated, 2 untreated) during the 1-year follow-up. Primary patency rates were 92% at 6 months and 89.8% at 12 months for the entire cohort. Secondary patency rates were 98% and 95.6%, respectively. No statistically significant differences were observed in the primary patency rates for the SFAs (89.3% at both 6 and 12 months) vs the iliac arteries (94.3% at 6 months and 90.7% at 12 months).</td>
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<td>28. Mwipatayi BP, Thomas S, Wong J, et al.</td>
<td>Experimental-Tx</td>
<td>125 patients</td>
<td>To determine if covered stents offer a patency advantage over bare-metal stents in the treatment of aortoiliac arterial occlusive disease.</td>
<td>Aortoiliac lesions treated with a covered stent were significantly more likely to remain free from binary restenosis than those that were treated with a bare-metal stent (HR, 0.35; 95% CI, 0.15–0.82; $P=.02$). Freedom from occlusion was also higher in lesions treated with covered stents than in those treated with a bare-metal stent (HR, 0.28; 95% CI, 0.07–1.09); however, this did not reach statistical significance ($P=.07$). Subgroup analyses demonstrated a significant difference in freedom from binary restenosis for covered stents in TASC C and D lesions compared with a bare stent (HR, 0.136; 95% CI, 0.042–0.442). This difference was not demonstrated for TASC B lesions (HR, 0.748; 95% CI, 0.235–2.386).</td>
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<td>29. Chang RW, Goodney PP, Baek JH, Nolan BW, Rzucidlo EM, Powell RJ. Long-term results of combined common femoral endarterectomy and iliac stenting/stent grafting for occlusive disease. J Vasc Surg. 2008;48(2):362-367.</td>
<td>Observational-Tx</td>
<td>171 patients</td>
<td>To report the long-term outcomes of common femoral artery endarterectomy with iliac stenting or stent grafting in patients with aortoiliac occlusive disease.</td>
<td>A total of 171 patients (mean age, 67 +/- 10 years; 38% female; 35% diabetic) underwent 193 common femoral artery endarterectomies and iliac stent/stent grafting. Indications were rest pain (32%), tissue loss (22%), and claudication (46%). EIA lesions were present in 39%, and combined common iliac artery and EIA lesions were seen in 61% of patients. Complete common iliac artery/EIA occlusions were present in 41% of patients. Stent grafts were used in 41% of patients. Technical success occurred in 98% of patients. Clinical improvement was seen in 92% of patients. Mean ABI increased from 0.38 +/- 0.32 to 0.72 +/- 0.24. Median length of stay was 2 days (range, 1–51 days). 30-day mortality was 2.3% and 5-year survival was 60%. 5-year primary, primary-assisted, and secondary patencies were 60%, 97%, and 98% respectively. Endovascular reintervention was required in 14% of patients; inflow surgical procedures were required in 10%. By logistic regression analysis, use of stent grafts compared with bare stents was associated with significantly higher primary patency (87% +/- 5% vs 53% +/- 7%; P&lt;.01).</td>
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<td>30. de Vries SO, Hunink MG. Results of aortic bifurcation grafts for aortoiliac occlusive disease: a meta-analysis. J Vasc Surg. 1997;26(4):558-569.</td>
<td>Meta-analysis</td>
<td>23 studies</td>
<td>To summarize mortality, morbidity, and long-term patency data of bifurcated aortoiliac or AFB graft procedures in aortoiliac occlusive disease.</td>
<td>We identified 23 studies that met the inclusion criteria. The aggregated operative mortality risk in the older studies (started before 1975) was 4.6%, as compared with 3.3% in the more recent studies (P=0.01). The aggregated systemic morbidity risk was 13.1% in the older studies and 8.3% in the more recent studies (P&lt;0.001). Limb-based patency rates for patients with claudication were 91.0% and 86.8% at 5 and 10 years, respectively, as compared with 87.5% and 81.8% for patients with ischemia. Patency rates reported in the older studies were markedly similar to those of more recent studies (P=0.58).</td>
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<td>31. Aihara H, Soga Y, Iida O, et al. Long-term outcomes of endovascular therapy for aortoiliac bifurcation lesions in the real-AI registry. <em>J Endovasc Ther.</em> 2014;21(1):25-33.</td>
<td>Observational-Tx</td>
<td>190 patients</td>
<td>To report long-term outcomes of endovascular therapy for aortoiliac bifurcation lesions.</td>
<td>The overall complication rate was 6.3%, and 1- and 5-year primary patency rates were 87% and 73%, respectively. Over a mean follow-up of 31+/-15 months, there were 36 (19.0%) restenoses, 22 (11.6%) target lesion revascularizations, and 4 (2.1%) reocclusions; stent fracture (2, 1.1%) and major amputation (2, 1.1%) were rare. Only female gender [adjusted HR 4.26, 95% CI, 1.89 to 9.71, $P&lt;0.001$] and residual diameter stenosis (adjusted HR 1.04, 96% CI, 1.01 to 1.06, $P=0.01$) were independent predictors of primary patency.</td>
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<td>32. Davenport DL, Zwischenberger BA, Xenos ES. Analysis of 30-day readmission after aortoiliac and infrainguinal revascularization using the American College of Surgeons National Surgical Quality Improvement Program data set. <em>J Vasc Surg.</em> 2014;60(5):1266-1274.</td>
<td>Review/Other-Tx</td>
<td>8414 patients</td>
<td>To analyze 30-day hospital readmissions after aortoiliac (AI) and infrainguinal (II) revascularization to further characterize readmissions and to identify modifiable targets for reducing readmission rates.</td>
<td>A total of 8414 patients were discharged after aortoiliac or infrainguinal revascularization with a 30-day readmission rate of 16.5%. 90% of all readmissions were unplanned and 54% were unplanned and related to the index procedure. Reasons for unplanned readmissions related to the procedure were infection (43.1%), diabetic/ischemic wound complications (16.5%), graft complications (13.6%), cardiac events (3.6%), neurologic events (2.9%), and deep venous thrombosis/pulmonary embolism (2.4%). Procedures were performed in the minority of all readmissions (7.7%) and included vascular intervention (28.7%), amputation (24%), debridement (14%), and incision and drainage (10%). The rate of related readmission for open revascularizations (10.9%) was double the rate for endovascular revascularizations (4.7%). Multivariate analysis identified several independent risk factors associated with unplanned readmissions related to the procedure: open procedure (odds ratio, 1.53; <em>P</em>=.43), operative time of more than 260 minutes (OR, 1.66; <em>P</em>&lt;.002), blood transfusion (OR, 1.24; <em>P</em>=.021), body mass index 30 to 35 (OR, 1.56; <em>P</em>&lt;.001), and preoperative open wound/infection (OR, 1.23; <em>P</em>=.12). Interestingly, length of hospital stay and age were not independent predictors of unplanned readmissions related to the procedure.</td>
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<td>33. Burke CR, Henke PK, Hernandez R, et al. A contemporary comparison of aortofemoral bypass and aortoiliac stenting in the treatment of aortoiliac occlusive disease. <em>Ann Vasc Surg</em>, 2010;24(1):4-13.</td>
<td>Observational-Tx</td>
<td>161 men and 131 women</td>
<td>To determine the effect of these trends on treatment outcomes in a contemporary single-institution experience with aortoiliac occlusive disease.</td>
<td>There was no difference between AFB and aortoiliac stenting groups with respect to 30-day mortality (0.8% and 1.1%, <em>P</em>=0.64), myocardial infarction (1.7% and 1.1%, <em>P</em>=0.53), cerebrovascular accident (0.0% and 1.1%, <em>P</em>=0.35), or renal failure requiring hemodialysis (3.4% and 1.2%, <em>P</em>=0.19). AFB was associated with increased surgical complication rates including the need for emergency surgery (6.8% and 1.7%, <em>P</em>=0.029), infection/sepsis (16.1% and 2.3%, <em>P</em>&lt;0.001), transfusion (16.1% and 5.7%, <em>P</em>=0.004), and lymph leak (8.5% and 0.6%, <em>P</em>=0.001). The difference between preprocedural and postprocedural ABI was greater for AFB than aortoiliac stenting (R, 0.39 and 0.18, <em>P</em>&lt;0.001; L, 0.41 and 0.15, <em>P</em>&lt;0.001). This difference was maintained when patients were stratified by TASC category.</td>
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<td>34. Kashyap VS, Pavkov ML, Bena JF, et al. The management of severe aortoiliac occlusive disease: endovascular therapy rivals open reconstruction. <em>J Vasc Surg</em>. 2008;48(6):1451-1457, 1457 e1451-1453.</td>
<td>Observational-Tx</td>
<td>169 patients</td>
<td>To compare the outcomes and durability of R/PTAS vs ABF for severe aortoiliac occlusive disease.</td>
<td>The ABF patients were younger than the R/PTAS patients (60 vs 65 years; <em>P</em>=.003) and had higher rates of hyperlipidemia (<em>P</em>=.009) and smoking (<em>P</em>&lt;.001). All other clinical variables, including cardiac status, diabetes, symptoms at presentation, TASC stratification, and presence of poor outflow were similar between the 2 groups. Patients underwent ABF with general anesthesia (96%), often with concomitant treatment of femoral or infrainguinal disease (61% endarterectomy, profundaplasty, or distal bypass). Technical success was universal, with marked improvement in ABI (0.48 to 0.84, <em>P</em>&lt;.001). Patients underwent R/PTAS with local anesthesia/sedation (78%), with a 96% technical success rate and similar hemodynamic improvement (0.36 to 0.82, <em>P</em>&lt;.001). At the time of R/PTAS, 21% of patients underwent femoral endarterectomy/profundaplasty or bypass (n = 5) for concomitant infrainguinal disease. Limb-based primary patency at 3 years was significantly higher for ABF than for R/PTAS (93% vs 74%, <em>P</em>=.002). Secondary patency rates (97% vs 95%), limb salvage (98% vs 98%), and long-term survival (80% vs 80%) were similar. Diabetes mellitus and the requirement of distal bypass were associated with decreased patency (<em>P</em>&lt;.001). CLI at presentation (tissue loss, HR [HR], 8.1; <em>P</em>&lt;.001), poor outflow (HR, 2; <em>P</em>=.023), and renal failure (HR, 2.5; <em>P</em>=.02) were associated with decreased survival.</td>
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<td>35. Chen BL, Holt HR, Day JD, Stout CL, Stokes GK, Paneton JM. Subintimal angioplasty of chronic total occlusion in iliac arteries: a safe and durable option. <em>J Vasc Surg</em>. 2011;53(2):367-373.</td>
<td>Observational-Tx</td>
<td>120 patients</td>
<td>To present our experience with 101 successful subintimal angioplasty for femoropopliteal chronic total occlusion.</td>
<td>120 patients underwent an attempted subintimal angioplasty of an iliac artery chronic total occlusion, and 101 iliac artery chronic total occlusions 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 CLI, in 37 (37%). 85 patients underwent percutaneous subintimal angioplasty, while 11 patients underwent a combined subintimal angioplasty with surgical outflow procedure. Lesions were classified as 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.</td>
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<td>36. Gandini R, Fabiano S, Chiocchi M, Chiappa R, Simonetti G. Percutaneous treatment in iliac artery occlusion: long-term results. <em>Cardiovasc Intervent Radiol.</em> 2008;31(6):1069-1076.</td>
<td>Observational-Tx</td>
<td>138 patients</td>
<td>To evaluate the long-term results of recanalization with primary stenting for patients with long and complex iliac artery occlusions.</td>
<td>Technical success was 99%. Primary patency rates were 90% (SE .024), 85% (SE .029), 80% (SE .034), and 68% (SE .052) at 3, 5, 7, and 10 years, respectively. Lesion site (P=0.022) and stent diameter (P=0.028) were shown to have a statistically significant influence on primary stent patency. Long-term results of iliac recanalization and stent placement were excellent, without major complications, even in highly complex vascular obstructions.</td>
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<td>37. Zander T, Blasco O, Rabellino M, et al. Bifurcated endograft in aortoiliac type C and D lesions: long-term results. <em>J Vasc Interv Radiol.</em> 2011;22(8):1124-1130.</td>
<td>Observational-Tx</td>
<td>14 patients</td>
<td>To report long-term outcome when using a bifurcated aortic endograft for treatment of aortoiliac occlusive disease in TASC classification C and D patients.</td>
<td>Endoprosthesis placement was performed in all patients with a technical success rate of 100%. There were no amputations or deaths at 30 days after the procedure. The mean follow-up was 62 months (range 11–96 months). 1 patient was lost during follow-up at 11 months, and another patient died of a nonrelated cause after 49 months. A single limb occlusion of the prosthesis was seen in 2 patients at 2 months and 7 months; both were successfully treated by intra-arterial fibrinolysis. At a mean follow-up of 62 months, primary patency was 85.7%, and secondary patency was 100%.</td>
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<td>38. Etezadi V, Benenati JF, Patel PJ, Patel RS, Powell A, Katzen BT. The reentry catheter: a second chance for endoluminal reentry at difficult lower extremity subintimal arterial recanalizations. <em>J Vasc Interv Radiol.</em> 2010;21(5):730-734.</td>
<td>Observational-Tx</td>
<td>34 patients</td>
<td>To investigate technical success of the use of a reentry device (Outback LTD reentry catheter) in aortoiliac and femoropopliteal artery recanalization in whom the conventional guide wires and catheters failed to reenter the true lumen.</td>
<td>True lumen reentry was achieved in 87% (n = 23) and 91% (n = 11) of patients with femoropopliteal and aortoiliac occlusions, respectively. The overall technical success rate with the device was 88% (n = 34). The device success rate in TASC II class D lesions was significantly lower than in lower lesion classes (71.4% vs 100%; (P&lt;.05)). No procedure-related complications were encountered.</td>
<td>3</td>
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<tr>
<td>39. Rezq A, Aprile A, Sangiorgi G. Pioneer re-entry device for iliac chronic total occlusion: truly a paradigm shift. <em>Catheter Cardiovasc Interv.</em> 2013;82(3):495-499.</td>
<td>Review/Other-Tx</td>
<td>1 case</td>
<td>To describe how the Pioneer catheter, a new lumen re-entry device exploiting intravascular US imaging, was used in a case of totally occluded left common iliac artery with favorable results.</td>
<td>No results stated in abstract.</td>
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## EVIDENCE TABLE

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<tr>
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<tr>
<td>40. Ko YG, Shin S, Kim KJ, et al.</td>
<td>Observational-Tx</td>
<td>151 patients</td>
<td>To investigate the procedural and clinical outcomes of subintimal angioplasty in long iliac artery occlusions and compared them with those of intraluminal angioplasty in nonocclusive stenotic iliac artery lesions.</td>
<td>Baseline characteristics showed that longer lesions and CLI were found more frequently in the subintimal angioplasty group, whereas diabetes and combined femoropopliteal lesions were present more often in the intraluminal angioplasty group. The technical success rate of subintimal angioplasty was lower than that of intraluminal angioplasty (93.0% vs 99.0%; ( P = .048 )). However, there was no significant difference in the procedure-related complications between the subintimal angioplasty and intraluminal angioplasty groups (4.0% vs 4.8%; ( P = .779 )). Primary patency rates for subintimal angioplasty and intraluminal angioplasty were 96.8% and 98.0% at 1 year, and 93.9% and 90.6% at 2 years, respectively (log rank ( P = .656 )).</td>
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<tr>
<td>41. Minko P, Katoh M, Opitz A, Jager S, Bucker A.</td>
<td>Experimental-Tx</td>
<td>5 patients</td>
<td>To demonstrate the value of a Reentry-Catheter for true lumen access after subintimal revascularization of chronic iliac artery occlusions.</td>
<td>The primary technical success rate was 100%. In all cases angioplasty was followed by stent placement to establish the subintimal tract. The mean Rutherford score decreased from 3.6 +/- 0.9 to 0.33 +/- 0.57 after 24 months, while the ABI increased from 0.67 +/- 0.06 to 1.2 +/- 0. Vessel patency was observed in all patients available for follow-up examinations.</td>
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<th>Reference</th>
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<tr>
<td>42. Kudo T, Rigberg DA, Reil TD, Chandra FA, Ahn SS. The influence of the ipsilateral superficial femoral artery on iliac angioplasty, <em>Ann Vasc Surg.</em> 2006;20(4):502-511.</td>
<td>Observational-Tx</td>
<td>127 patients</td>
<td>To evaluate the impact of the ipsilateral SFA on PTA of the iliac arteries.</td>
<td>There were no perioperative deaths. Total complication rate was 1.1% (2/183, groin hematomas). The mean follow-up was 20 months (range 1–115). 125 limbs (68%) had PTA alone for iliac lesions, and 58 (32%) had iliac stenting (a total of 91 stents). TASC iliac lesion types and the status of the ipsilateral profunda femoris artery were not significantly different among the 4 groups. 17 limbs (9%) had subsequent infrainguinal bypass: 3 in the previously bypassed SFA, 7 in the occluded SFA, 4 in the stenotic SFA, and 3 in the angioplasty SFA groups (<em>P</em>=0.19). The primary patency rate was significantly decreased in the stenotic SFA group (29% at 3 years, Kaplan-Meier log-rank, <em>P</em>&lt;0.0001) compared with the other 3 groups; however, there were no significant differences among the previously bypassed SFA, occluded SFA, and angioplasty SFA groups (67%, 67%, and 86% at 3 years, respectively; <em>P</em>=0.92). The continued clinical improvement rates were significantly decreased in the stenotic SFA group (36% at 3 years, <em>P</em>=0.0043) compared with the other 3 groups; however, there was no significant difference between the previously bypassed SFA, occluded SFA, and angioplasty SFA groups (81%, 84%, and 75% at 3 years, respectively; <em>P</em>=0.088). The assisted primary and secondary patency and limb salvage rates were not significantly different among the 4 groups (<em>p</em> &gt; 0.40). Stratified analysis in patients with TASC type B/type C, CLI, or claudicants revealed similar results.</td>
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</table>
### Reference Study Type Patients/Events

**Study Objective (Purpose of Study)**

**Study Results**

**Study Quality**


Observational-Tx 105 patients To estimate the influence of previous iliac artery stenting for iliac occlusive disease on the outcome of infrainguinal arterial reconstructions compared with those after iliac artery angioplasty alone or AFBs.

45 infrainguinal arterial reconstructions were performed in patients with an earlier iliac artery stenting repair, 33 in patients with an earlier iliac artery angioplasty repair, and 42 in patients with an earlier AFB repair. There were not significant differences between patients in the iliac artery stenting and iliac artery angioplasty groups, except for a more frequent use of PTFE grafts for infrainguinal arterial reconstructions in the iliac artery stenting group (40% vs 15%; chi(2) test, \(P=0.03\)). The 5-year primary patency rate for infrainguinal arterial reconstructions was 68% in the iliac artery stenting group, 46% in the iliac artery angioplasty group, and 61% in the AFB group. Univariate analyses revealed that primary patency rates for infrainguinal arterial reconstructions in patients with previous iliac artery stenting were significantly higher than those in the iliac artery angioplasty group (Kaplan-Meier, log-rank test, \(P=0.02\)). Previous iliac artery angioplasty repair was associated with a two-fold increased risk of IAR graft failure (relative risk, 2.2; 95% CI, 1.1-4.8; \(P=0.04\)).

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### Radiologic Management of Iliac Artery Occlusive Disease

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<tr>
<td>44. Nelson PR, Powell RJ, Schermerhorn ML, et al. Early results of external iliac artery stenting combined with common femoral artery endarterectomy. <em>J Vasc Surg</em>. 2002;35(6):1107-1113.</td>
<td>Observational-Tx</td>
<td>34 patients</td>
<td>To report our initial experience with a combined open and endovascular approach to these patients.</td>
<td>34 patients (mean age, 68 years; 23 male, 11 female) had combined endovascular and open treatment of iliofemoral occlusive disease. Indications were claudication in 41% and CLI in 59%. Femoral reconstruction included endarterectomy with patch angioplasty in all patients. EIA stent deployment incorporated the stenotic iliac segment and the proximal endpoint of the endarterectomy in all patients. 4 patients (12%) also needed common iliac angioplasty at the same time for proximal iliac disease, and 14 patients (41%) also needed distal revascularization for associated femoropopliteal or tibial disease. Technical success and hemodynamic success were achieved in 100% of patients. Clinical success was achieved in 97% of patients. The mean postoperative increase in ABI in patients with inflow procedures only was 0.36 (range, 0.1 to 0.85). The overall complication rate was 15%. With a mean follow-up period of 13 months (range, 0.5 to 28 months), 1-year primary patency and primary-assisted patency rates were 84% and 97%, respectively. No perioperative mortality was seen.</td>
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<td>45. Aburahma AF, Robinson PA, Cook CC, Hopkins ES. Selecting patients for combined femorofemoral bypass grafting and iliac balloon angioplasty and stenting for bilateral iliac disease. <em>J Vasc Surg</em>, 2001;33(2 Suppl):S93-99.</td>
<td>Observational-Tx</td>
<td>41 patients</td>
<td>To examine the selection of patients for combined femorofemoral bypass grafting and iliac balloon angioplasty and stenting for bilateral iliac occlusive disease (successively or simultaneously) and the correlation of the length and location of stenoses of the donor iliac artery to the success of femorofemoral bypass grafts.</td>
<td>Indications for surgery were limb salvage (22%), rest pain (44%), and claudication (34%). The mean follow-up time was 34.1 months. Perioperative complications were 7% for group A vs 62% for group B (<em>P</em>&lt;.0007) with no perioperative deaths or amputations. Stenting was needed in 12/13 patients (92%) in group B vs 4/28 patients (14%) in group A (<em>P</em>&lt;.0001) and in 11/12 EIA lesions vs 5/29 common iliac artery lesions (<em>P</em>&lt;.0001). The overall early success rate was 100% for group A and 62% for group B (<em>P</em>=.0028). The primary patency rates at 1, 2, and 3 years were 96%, 85%, and 85% for group A, respectively, and for group B were 46%, 46%, and 31%, respectively (<em>P</em>&lt;.01). The secondary patency rates for group A at 1, 2, and 3 years were 100%, 96%, and 87%, respectively; and for group B were 62%, 54%, and 27%, respectively (<em>P</em>&lt;.001). The overall primary and secondary patency rates for common iliac and EIA lesions were similar (72% and 72% vs 67% and 75%, respectively). The overall limb salvage rates were 96% for group A and 85% for group B. 7/13 patients (54%) of group B, in contrast with 0/28 patients in group A, had to undergo a revision of the procedure within 30 days (<em>P</em>&lt;.01).</td>
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<td>46. Timaran CH, Stevens SL, Freeman MB, Goldman MH. External iliac and common iliac artery angioplasty and stenting in men and women. <em>J Vasc Surg.</em> 2001;34(3):440-446.</td>
<td>Observational-Tx</td>
<td>67 women and 122 men</td>
<td>To estimate the influence of the anatomic location of stenting on the outcome of iliac angioplasty and stent placement in both men and women.</td>
<td>Indications for iliac angioplasty with stenting were disabling claudication (65%), limb salvage (33%), and blue toe syndrome (2%). Primary stenting was performed in 103 procedures (42%). Stents were placed selectively after iliac angioplasty mainly for residual stenosis or pressure gradient (43%). Patients with EIA stents, as compared with those who had common iliac artery stents, had more extensive lesions (TASC C lesions), poorer runoff, smaller vessel size, and less frequency of hyperlipidemia (<em>P</em>&lt;.05). Primary patency rates at 1, 3, and 5 years were 76%, 56%, and 56%, respectively, for patients with EIA stents and 92%, 85%, and 76%, respectively, for those with common iliac artery stents. Although overall primary patency rates were significantly decreased in patients with EIA lesions (KM, log-rank test, <em>P</em>=.001), stratified analyses revealed that women with EIA stents had the poorest outcome, with 61%, 47%, and 23% primary patency rates at 1, 3, and 5 years, respectively, (KM, log-rank test, <em>P</em>&lt;.001). Cox regression analysis identified EIA stenting (relative risk, 4.3; 95% CI, 2.3-7.9; <em>P</em>&lt;.001) as an independent predictor of decreased primary patency in women but not in men.</td>
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<td>47. Timaran CH, Stevens SL, Grandas OH, Freeman MB, Goldman MH. Influence of hormone replacement therapy on the outcome of iliac angioplasty and stenting. <em>J Vasc Surg.</em> 2001;33(2 Suppl):S85-92.</td>
<td>Observational-Tx</td>
<td>88 women</td>
<td>To estimate the influence of risk factors, including hormone replacement therapy, on the outcome of women undergoing iliac artery angioplasty and stent placement.</td>
<td>The patients’ average age was 63.2 years with 43% of the patients taking hormone replacement therapy. Indications for iliac angioplasty with stenting were disabling claudication (65%), limb salvage (32%), and blue toe syndrome (3%). The technical success rate was 95% (120/126 procedures). Primary stenting was performed in 28 patients (22%). Stents were placed selectively after iliac angioplasty for residual stenosis or pressure gradient (57%), iliac dissection (8%), long-segment occlusions (8%), or eccentric lesions (5%). There were no significant differences between hormone replacement therapy users and nonusers with regard to risk factors, except there was a higher frequency of diabetes in women taking hormone replacement therapy. Overall, the primary patency rate was 76% at 1 year, 67% at 3 years, and 62% at 5 years. Primary patency rates at 1, 3, and 5 years were 75%, 57%, and 49% for users of hormone replacement therapy and 77%, 74%, and 74%, respectively, for nonusers. Limb salvage rates were not statistically different between users and nonusers of hormone replacement therapy at 5 years (95% vs 96%). Univariate and Cox regression analyses identified hormone replacement therapy use (Kaplan-Meier, log-rank test, <em>P</em>=.02; relative risk, 2.4; 95% CI, 1.3–4.5; <em>P</em>=.006) and stent placement in the EIA (relative risk, 4.3; 95% CI, 2.3–7.9; <em>P</em>&lt;.001) as independent predictors of decreased primary patency.</td>
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Evidence Table Key

Study Quality Category Definitions

- **Category 1**  The study is well-designed and accounts for common biases.
- **Category 2**  The study is moderately well-designed and accounts for most common biases.
- **Category 3**  There are important study design limitations.
- **Category 4**  The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:
  a) the study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
  b) the study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
  c) the study is an expert opinion or consensus document.
- **M** = Meta-analysis

Abbreviations Key

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<th>Abbreviation</th>
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<tr>
<td>ABI</td>
<td>Ankle-brachial index</td>
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<td>AFB</td>
<td>Aortofemoral bypass</td>
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<td>CI</td>
<td>Confidence interval</td>
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<td>CLI</td>
<td>Critical limb ischemia</td>
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<td>CTA</td>
<td>Computed tomography angiography</td>
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<td>EIA</td>
<td>External iliac artery</td>
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<td>HR</td>
<td>Hazard ratio</td>
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<tr>
<td>MRA</td>
<td>Magnetic resonance angiography</td>
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<tr>
<td>R/PTAS</td>
<td>Recanalization, percutaneous transluminal angioplasty, and stenting</td>
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<tr>
<td>PTA</td>
<td>Percutaneous transluminal angioplasty</td>
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<td>PTFE</td>
<td>Polytetrafluoroethylene</td>
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<td>SFA</td>
<td>Superficial femoral artery</td>
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<td>TASC</td>
<td>TransAtlantic Inter-Society Consensus</td>
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<td>US</td>
<td>Ultrasound</td>
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Dx = Diagnostic
Tx = Treatment