

# 2018 Appropriate Use Criteria for Peripheral Artery Intervention: Guideline Mapping & References

Note: This document was created for use by the rating panel during the rating process, so is based on the AHA/ACC Clinical Practice Guidelines and pivotal clinical trials that were available at the time of rating.

## Section 1: Renal Artery Stenosis (RAS)

**Table 1.1: Chronic Kidney Disease**

Hemodynamically Significant RAS [with a Severe (70%-99%) RAS or 50%-69% RAS with Hemodynamic Significance]	
1.	<ul style="list-style-type: none"> <li>Unilateral smaller kidney (&lt; 7cm pole to pole)</li> </ul> <p><b><u>Continue or Intensify Medical Therapy:</u></b> None</p> <p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b> None</p>
2.	<ul style="list-style-type: none"> <li>Accelerating decline in renal function</li> <li>Unilateral RAS</li> </ul> <p><b><u>Continue or Intensify Medical Therapy:</u></b> None</p> <p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b> 2013 ACC/AHA Guideline on Management of Patients with Peripheral Artery Disease, pg 1565 3.3.2.3. Preservation of Renal Function Class IIa  <ul style="list-style-type: none"> <li>Percutaneous revascularization is reasonable for patients with RAS and progressive chronic kidney disease with bilateral RAS or a RAS to a solitary functioning kidney. (Level of Evidence: B)</li> </ul>                     Class IIb  <ul style="list-style-type: none"> <li>Percutaneous revascularization may be considered for patients with RAS and chronic renal insufficiency with unilateral RAS. (Level of Evidence: C)</li> </ul> </p>
3.	<ul style="list-style-type: none"> <li>Accelerating decline in renal function</li> <li>Bilateral RAS or a solitary viable* kidney with RAS</li> </ul> <p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b> 2013 ACC/AHA Guideline on Management of Patients with Peripheral Artery Disease, pg 1565 3.3.2.3. Preservation of Renal Function Class IIa  <ul style="list-style-type: none"> <li>Percutaneous revascularization is reasonable for patients with RAS and progressive chronic kidney disease with bilateral RAS or a RAS to a solitary functioning kidney. (Level of Evidence: B)</li> </ul> </p>

\* = viable is pole to pole kidney length of ≥ 7 cm.

**Table 1.2: Hypertension**

Hemodynamically Significant RAS [with a Severe (70%-99%) RAS or 50%-69% RAS with Hemodynamic Significance]	
4.	<ul style="list-style-type: none"> <li>New onset</li> <li>No medical management</li> </ul>

**Continue or Intensify Medical Therapy:**

2013 ACC/AHA Guideline on Management of Patients with Peripheral Artery Disease, pg 1565

3.3.1. Medical Treatment

Class I

- ACE inhibitors are effective medications for treatment of hypertension associated with unilateral RAS. (Level of Evidence: A)
- Angiotensin receptor blockers are effective medications for treatment of hypertension associated with unilateral RAS. (Level of Evidence: B)
- Calcium-channel blockers are effective medications for treatment of hypertension associated with unilateral RAS. (Level of Evidence: A)
- Beta blockers are effective medications for treatment of hypertension associated with RAS. (Level of Evidence: A)

Cooper CJ, Murphy TP, Cutlip DE, et al. Stenting and medical therapy for atherosclerotic renal-artery stenosis. *N Engl J Med.* 2014; 370:13-22.

**Renal stent placement (primary stenting) – Atherosclerotic lesions:**

2013 ACC/AHA Guideline on Management of Patients with Peripheral Artery Disease, pg 1565

3.3.2.2. Hypertension

Class IIa

- Percutaneous revascularization is reasonable for patients with hemodynamically significant RAS and accelerated hypertension, resistant hypertension, malignant hypertension, hypertension with an unexplained unilateral small kidney, and hypertension with intolerance to medication. (Level of Evidence: B)

3.3.2.3. Preservation of Renal Function

Class IIa

- Percutaneous revascularization is reasonable for patients with RAS and progressive chronic kidney disease with bilateral RAS or a RAS to a solitary functioning kidney. (Level of Evidence: B)

Class IIb

- Percutaneous revascularization may be considered for patients with RAS and chronic renal insufficiency with unilateral RAS. (Level of Evidence: C)

**5. • Well controlled blood pressure on  $\geq 2$  anti-hypertensive medications**

**Continue or Intensify Medical Therapy:**

Same as above

**Renal stent placement (primary stenting) – Atherosclerotic lesions:**

Same as above

**6. • Uncontrolled on  $< 3$  anti-hypertensive medications**

**Continue or Intensify Medical Therapy:**

Same as above

**Renal stent placement (primary stenting) – Atherosclerotic lesions:**

Same as above

**7. • Failure to control blood pressure on 3 maximally tolerated medications, 1 of which is a diuretic**

**Renal stent placement (primary stenting) – Atherosclerotic lesions:**

Same as above

**Table 1.3: Cardiac Destabilization**

Hemodynamically Significant RAS [with a Severe (70%-99%) RAS or 50%-69% RAS with Hemodynamic Significance]	
<b>8.</b>	<ul style="list-style-type: none"> <li>• Recurrent heart failure</li> <li>• Uncontrolled on maximal medical therapy</li> </ul>
<p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b>                      2013 ACC/AHA Guideline on Management of Patients with Peripheral Artery Disease, pg 1565</p> <p>3.3.2.4. Impact of RAS on Congestive Heart Failure and Unstable Angina</p> <p>Class I</p> <ul style="list-style-type: none"> <li>• Percutaneous revascularization is indicated for patients with hemodynamically significant RAS and recurrent, unexplained congestive heart failure or sudden, unexplained pulmonary edema. (Level of Evidence: B)</li> </ul> <p>Class IIa</p> <ul style="list-style-type: none"> <li>• Percutaneous revascularization is reasonable for patients with hemodynamically significant RAS and unstable angina. (Level of Evidence: B)</li> </ul>	
<b>9.</b>	<ul style="list-style-type: none"> <li>• Sudden-onset flash pulmonary edema</li> </ul>
<p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b>                      Same as above</p>	
<b>10.</b>	<ul style="list-style-type: none"> <li>• Uncontrolled unstable angina despite maximal medical therapy</li> </ul>
<p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b>                      Same as above</p>	

**Table 1.4: Incidentally Discovered RAS**

Hemodynamically Significant RAS [with a Severe (70%-99%) RAS or 50%-69% RAS with Hemodynamic Significance]	
<b>11.</b>	<ul style="list-style-type: none"> <li>• Unilateral RAS</li> </ul>
<p><b><u>Continue or Intensify Medical Therapy:</u></b>                      None</p> <p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b>                      2013 ACC/AHA Guideline on Management of Patients with Peripheral Artery Disease, pg 1565</p> <p>3.3.2.1. ASYMPTOMATIC STENOSIS                      CLASS IIb</p> <p>1. Percutaneous revascularization may be considered for treatment of an asymptomatic bilateral or solitary viable kidney with a hemodynamically significant RAS. (Level of Evidence: C)</p> <p>2. The usefulness of percutaneous revascularization of an asymptomatic unilateral hemodynamically significant RAS in a viable kidney is not well established and is presently clinically unproven. (Level of Evidence: C)</p> <p>3.3.3. Endovascular Treatment for RAS                      CLASS I</p> <p>1. Renal stent placement is indicated for ostial atherosclerotic RAS lesions that meet the clinical criteria for intervention. (Level of Evidence: B)</p> <p>2. Balloon angioplasty with bailout stent placement if necessary is recommended for fibromuscular dysplasia lesions. (Level of Evidence: B)</p> <p>3.3.4. Surgery for RAS                      Class I</p>	

<ul style="list-style-type: none"> <li>• Vascular surgical reconstruction is indicated for patients with atherosclerotic RAS and clinical indications for intervention, especially those with multiple small renal arteries or early primary branching of the main renal artery (<i>Level of Evidence: B</i>)</li> <li>• Vascular surgical reconstruction is indicated for patients with atherosclerotic RAS in combination with pararenal aortic reconstructions (in treatment of aortic aneurysms or severe aortoiliac occlusive disease). (<i>Level of Evidence: C</i>)</li> </ul>
<p><b>12. • Bilateral RAS or a solitary viable* kidney with RAS</b></p> <p><b><u>Continue or Intensify Medical Therapy:</u></b> None</p> <p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b> Same as above</p>

\* = viable is pole to pole kidney length of  $\geq 7$  cm.

**Table 1.5: Borderline (50%-69%) RAS without hemodynamic confirmation of severity**

<p><b>13. • Unilateral RAS, bilateral RAS, or a solitary viable* kidney with RAS</b></p> <p><b><u>Continue or Intensify Medical Therapy:</u></b> <i>Cooper, C. J., Murphy, T. P., Cutlip, D. E., Jamerson, K., Henrich, W., Reid, D. M., et al. (2014). Stenting and medical therapy for atherosclerotic renal-artery stenosis. N Engl J Med, 370(1): 13-22.</i></p> <p><i>Revascularization versus medical therapy for renal-artery stenosis. <b>ASTRAL</b> Investigators, Wheatley K, Ives N, Gray R, Kalra PA, Moss JG, Baigent C, Carr S, Chalmers N, Eadington D, Hamilton G, Lipkin G, Nicholson A, Scoble J. N Engl J Med. 2009 Nov 12;361(20):1953-62.</i></p> <p><b><u>Renal stent placement (primary stenting) – Atherosclerotic lesions:</u></b> 2013 ACC/AHA Guideline on Management of Patients with Peripheral Artery Disease, pg 1565</p> <p>3.3.2.1. Asymptomatic Stenosis Class IIb</p> <ul style="list-style-type: none"> <li>• Percutaneous revascularization may be considered for treatment of an asymptomatic bilateral or solitary viable kidney with a hemodynamically significant RAS. (<i>Level of Evidence: C</i>)</li> <li>• The usefulness of percutaneous revascularization of an asymptomatic unilateral hemodynamically significant RAS in a viable kidney is not well established and is presently clinically unproven. (<i>Level of Evidence: C</i>)</li> </ul>
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\* = viable is pole to pole kidney length of  $\geq 7$  cm.

## Section 1 References

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Van de Ven, P., J.G., Kaatee, R., Beutler, J. J., Beek, F. J. A., Woittiez, A. J., Buskens, E., et al. (1999). Arterial stenting and balloon angioplasty in ostial atherosclerotic renovascular disease: A randomised trial. *The Lancet*, 353(9149): 282-286.

Weinberg I, Keyes MJ, Giri J, Rogers KR, Olin JW, White CJ, Jaff MR. (2014) Blood pressure response to renal artery stenting in 901 patients from five prospective multicenter FDA-approved trials. *Catheterization and Cardiovascular Interventions*, 83: 603-609.

## Section 2: Lower Extremity Disease

For all Section 2 indications, please consider the following graphics from the TASC II Guidelines:

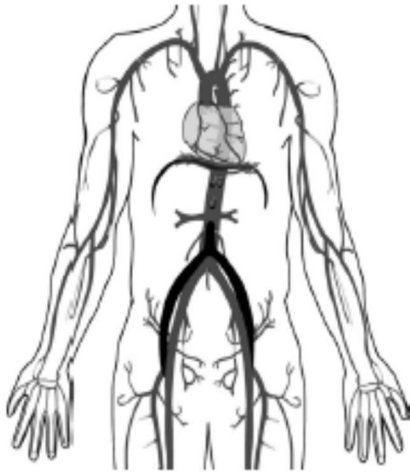
**Table F1.** TASC classification of aorto-iliac lesions

Type A lesions	<ul style="list-style-type: none"> <li>■ Unilateral or bilateral stenoses of CIA</li> <li>■ Unilateral or bilateral single short (<math>\leq 3</math> cm) stenosis of EIA</li> </ul>
Type B lesions	<ul style="list-style-type: none"> <li>■ Short (<math>\leq 3</math> cm) stenosis of infrarenal aorta</li> <li>■ Unilateral CIA occlusion</li> <li>■ Single or multiple stenosis totaling 3–10 cm involving the EIA not extending into the CFA</li> <li>■ Unilateral EIA occlusion not involving the origins of internal iliac or CFA</li> </ul>
Type C lesions	<ul style="list-style-type: none"> <li>■ Bilateral CIA occlusions</li> <li>■ Bilateral EIA stenoses 3–10 cm long not extending into the CFA</li> <li>■ Unilateral EIA stenosis extending into the CFA</li> <li>■ Unilateral EIA occlusion that involves the origins of internal iliac and/or CFA</li> <li>■ Heavily calcified unilateral EIA occlusion with or without involvement of origins of internal iliac and/or CFA</li> </ul>
Type D lesions	<ul style="list-style-type: none"> <li>■ Infra-renal aortoiliac occlusion</li> <li>■ Diffuse disease involving the aorta and both iliac arteries requiring treatment</li> <li>■ Diffuse multiple stenoses involving the unilateral CIA, EIA and CFA</li> <li>■ Unilateral occlusions of both CIA and EIA</li> <li>■ Bilateral occlusions of EIA</li> <li>■ Iliac stenoses in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery</li> </ul>

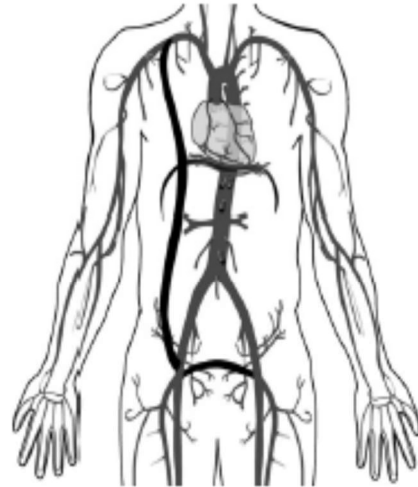
CIA – common iliac artery; EIA – external iliac artery; CFA – common femoral artery; AAA – abdominal aortic aneurysm.

**Table F3.** Estimated success rate of iliac artery angioplasty from weighted averages (range) from reports of 2222 limbs

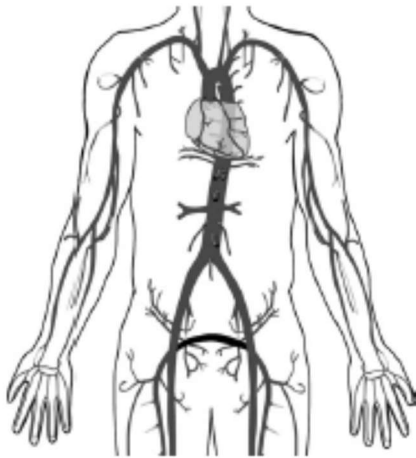
% Claudication	Technical success	Primary patency		
		1 yr	3 yr	5 yr
76% (81-94)	96% (90-99)	86% (81-94)	82% (72-90)	71% (64-75)



**Fig. F3.** Bilateral bypass from infra renal abdominal aorta to both femoral arteries.



**Fig. F4.** Axillo (bi) femoral bypass.



**Fig. F5.** Cross-over femoral bypass.



**Table 2.1: Intermittent Claudication; No Prior Guideline-Directed Medical Therapy**

<p><b>14.</b> • Any lower extremity disease</p>
<p><b><u>Initiate Medical Therapy:</u></b></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1561-1562</b></p> <p><b>2.3.2. Claudication</b></p> <p><b>2.3.2.1. EXERCISE AND LOWER EXTREMITY PAD REHABILITATION</b></p> <p><b>CLASS I</b></p> <p>1. A program of supervised exercise training is recommended as an initial treatment modality for patients with intermittent claudication. (Level of Evidence: A)</p> <p>2. Supervised exercise training should be performed for a minimum of 30 to 45 minutes, in sessions performed at least 3 times per week for a minimum of 12 weeks. (Level of Evidence: A)</p> <p><b>CLASS IIb</b></p> <p>1. The usefulness of unsupervised exercise programs is not well established as an effective initial treatment modality for patients with intermittent claudication. (Level of Evidence: B)</p> <p><b>2.3.2.2. MEDICAL AND PHARMACOLOGICAL TREATMENT FOR CLAUDICATION</b></p> <p><b>2.3.2.2.1. CILOSTAZOL</b></p> <p><b>CLASS I</b></p> <p>1. Cilostazol (100 mg orally 2 times per day) is indicated as an effective therapy to improve symptoms and increase walking distance in patients with lower extremity PAD and intermittent claudication (in the absence of heart failure). (Level of Evidence: A)</p> <p>2. A therapeutic trial of cilostazol should be considered in all patients with lifestyle-limiting claudication (in the absence of heart failure). (Level of Evidence: A)</p> <p><b>2.3.2.2.2. PENTOXIFYLLINE</b></p> <p><b>CLASS IIb</b></p> <p>1. Pentoxifylline (400 mg 3 times per day) may be considered as second-line alternative therapy to cilostazol to improve walking distance in patients with intermittent claudication. (Level of Evidence: A)</p> <p>2. The clinical effectiveness of pentoxifylline as therapy for claudication is marginal and not well established. (Level of Evidence: C)</p> <p><b>2.3.2.2.3. OTHER PROPOSED MEDICAL THERAPIES</b></p> <p><b>CLASS IIb</b></p> <p>1. The effectiveness of L-arginine for patients with intermittent claudication is not well established. (Level of Evidence: B)</p> <p>2. The effectiveness of propionyl-L-carnitine as a therapy to improve walking distance in patients with intermittent claudication is not well established. (Level of Evidence: B)</p> <p>3. The effectiveness of ginkgo biloba to improve walking distance for patients with intermittent claudication is marginal and not well established. (Level of Evidence: B)</p> <p><b>CLASS III</b></p> <p>1. Oral vasodilator prostaglandins such as beraprost and iloprost are not effective medications to improve walking distance in patients with intermittent claudication. (Level of Evidence: A)</p> <p>2. Vitamin E is not recommended as a treatment for patients with intermittent claudication. (Level of Evidence: C)</p> <p>3. Chelation (e.g., ethylenediaminetetraacetic acid) is not indicated for treatment of intermittent claudication and may have harmful adverse effects. (Level of Evidence: A)</p> <p><b><u>Endovascular Treatment:</u></b></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1561-1562</b></p> <p><b>2.3.2.3. Endovascular Treatment For Claudication</b></p> <p><b>CLASS I</b></p> <p>1. Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). (Level of Evidence: A)</p> <p>2. Endovascular intervention is recommended as the preferred revascularization technique for TASC type A iliac and femoropopliteal arterial lesions. (Level of Evidence: B)</p>

<p>3. Translesional pressure gradients (with and without vasodilation) should be obtained to evaluate the significance of angiographic iliac arterial stenoses of 50% to 75% diameter before intervention. (Level of Evidence: C)</p> <p>4. Provisional stent placement is indicated for use in the iliac arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis &gt;50%, or flow-limiting dissection). (Level of Evidence: B)</p> <p>5. Stenting is effective as primary therapy for common iliac artery stenoses and occlusions. (Level of Evidence: B)</p> <p>6. Stenting is effective as primary therapy in external iliac artery stenoses and occlusions. (Level of Evidence: C)</p> <p><b>2.3.2.3. Endovascular Treatment For Claudication</b> <b>CLASS III</b></p> <p>1. Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. (Level of Evidence: C)</p> <p>3. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. (Level of Evidence: C)</p> <p><b><u>Surgical Treatment:</u></b></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1562</b></p> <p><b>2.3.2.4. Surgery for Claudication</b> <b>CLASS I</b></p> <p>1. Surgical interventions are indicated for individuals with claudication symptoms who have a significant functional disability that is vocational or lifestyle limiting, who are unresponsive to exercise or pharmacotherapy, and who have a reasonable likelihood of symptomatic improvement. (Level of Evidence: B)</p> <p><b>CLASS IIb</b></p> <p>1. Because the presence of more aggressive atherosclerotic occlusive disease is associated with less durable results in patients younger than 50 years of age, the effectiveness of surgical intervention in this population for intermittent claudication is unclear. (Level of Evidence: B)</p> <p><b>CLASS III</b></p> <p>1. Surgical intervention is not indicated to prevent progression to limb-threatening ischemia in patients with intermittent claudication. (Level of Evidence: B)</p> <p><b>2.3.2.4.2. PREOPERATIVE EVALUATION</b> <b>CLASS I</b></p> <p>1. A preoperative cardiovascular risk evaluation should be undertaken in those patients with lower extremity PAD in whom a major vascular surgical intervention is planned. (Level of Evidence: B)</p>
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**Table 2.2: Intermittent Claudication Despite Guideline-Directed Medical Therapy – Stenotic Lesions**

<p><b>15. • Aortoiliac</b></p> <p><b><u>Continue or Intensify Medical Therapy:</u></b></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1561-1562</b></p> <p><b>2.3.2.3. Endovascular Treatment For Claudication</b> <b>CLASS III</b></p> <p>1. Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. (Level of Evidence: C)</p> <p>3. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. (Level of Evidence: C)</p> <p><b><u>Endovascular Treatment:</u></b></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1561-1562</b></p> <p><b>2.3.2.3. Endovascular Treatment For Claudication</b> <b>CLASS I</b></p> <p>1. Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular</p>
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intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). (Level of Evidence: A)

2. Endovascular intervention is recommended as the preferred revascularization technique for TASC type A iliac and femoropopliteal arterial lesions. (Level of Evidence: B)

3. Translesional pressure gradients (with and without vasodilation) should be obtained to evaluate the significance of angiographic iliac arterial stenoses of 50% to 75% diameter before intervention. (Level of Evidence: C)

4. Provisional stent placement is indicated for use in the iliac arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis >50%, or flow-limiting dissection). (Level of Evidence: B)

5. Stenting is effective as primary therapy for common iliac artery stenoses and occlusions. (Level of Evidence: B)

6. Stenting is effective as primary therapy in external iliac artery stenoses and occlusions. (Level of Evidence: C)

#### **CLASS IIa**

1. Stents (and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices, and thermal devices) can be

useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis >50%, or flow-limiting dissection). (Level of Evidence: C)

#### **CLASS IIb**

1. The effectiveness of stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of femoral-popliteal arterial lesions (except to salvage a suboptimal result from balloon dilation) is not well-established. (Level of Evidence: A)

2. The effectiveness of uncoated/uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of infrapopliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well established. (Level of Evidence: C)

#### **CLASS III**

1. Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. (Level of Evidence: C)

2. Primary stent placement is not recommended in the femoral, popliteal, or tibial arteries. (Level of Evidence: C)

3. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. (Level of Evidence: C)

### **Surgical Treatment:**

**Anderson et al (2011 PAD guidelines), Pg 1562**

#### **2.3.2.4. Surgery for Claudication**

##### **CLASS I**

1. Surgical interventions are indicated for individuals with claudication symptoms who have a significant functional disability that is vocational or lifestyle limiting, who are unresponsive to exercise or pharmacotherapy, and who have a reasonable likelihood of symptomatic improvement. (Level of Evidence: B)

##### **CLASS IIb**

1. Because the presence of more aggressive atherosclerotic occlusive disease is associated with less durable results in patients younger than 50 years of age, the effectiveness of surgical intervention in this population for intermittent claudication is unclear. (Level of Evidence: B)

##### **CLASS III**

1. Surgical intervention is not indicated to prevent progression to limb-threatening ischemia in patients with intermittent claudication. (Level of Evidence: B)

#### **2.3.3.4.1. Inflow Procedures: Aortoiliac Occlusive Disease**

##### **Class I**

1. Iliac endarterectomy, patch angioplasty, or aortoiliac or iliofemoral bypass in the setting of acceptable aortic inflow should be used for the treatment of unilateral disease or in conjunction with femoral-femoral bypass for the treatment of a patient with bilateral iliac artery occlusive disease if the patient is not a suitable candidate for aortobifemoral bypass grafting. (Level of Evidence: B)

**Norgren et al (2007 TASC II Guidelines), Pg S48A**

Recommendation #36: Treatment of aortoiliac lesions

<p>TASC A and D lesions: ...surgery is the treatment of choice for type D and lesions [C].                  TASC B and C lesions: ...surgery is the preferred treatment for good-risk patients with type C lesions. The patient's comorbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and C lesions [C].</p>	
16.	<p>• SFA and Popliteal Artery</p> <p><b><u>Continue or Intensify Medical Therapy:</u></b>                  Same as above</p> <p><b><u>Endovascular Treatment:</u></b>                  Same as above</p> <p><b><u>Surgical Treatment:</u></b>                  Same as above</p>
17.	<p>• Below the Knee</p> <p><b><u>Continue or Intensify Medical Therapy:</u></b>                  Same as above</p> <p><b><u>Endovascular Treatment:</u></b>                  Same as above</p> <p><b><u>Surgical Treatment:</u></b>                  Same as above</p>

**Table 2.3: Intermittent Claudication Despite Guideline-Directed Medical Therapy – Chronic Total Occlusion**

18.	<p>• Aortoiliac</p> <p><b><u>Continue or Intensify Medical Therapy:</u></b>                  Anderson et al (2011 PAD guidelines), Pg 1561-1562  <b>2.3.2.3. Endovascular Treatment For Claudication</b>  <b>CLASS III</b>                  1. Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. (<i>Level of Evidence: C</i>)                  3. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. (<i>Level of Evidence: C</i>)</p> <p><b><u>Endovascular Treatment:</u></b>                  Anderson et al (2011 PAD guidelines), Pg 1561-1562  <b>2.3.2.3. Endovascular Treatment For Claudication</b>  <b>CLASS I</b>                  1. Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). (<i>Level of Evidence: A</i>)                  2. Endovascular intervention is recommended as the preferred revascularization technique for TASC type A iliac and femoropopliteal arterial lesions. (<i>Level of Evidence: B</i>)                  3. Translesional pressure gradients (with and without vasodilation) should be obtained to evaluate the significance of angiographic iliac arterial stenoses of 50% to 75% diameter before intervention. (<i>Level of Evidence: C</i>)                  4. Provisional stent placement is indicated for use in the iliac arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis &gt;50%, or flow-limiting dissection). (<i>Level of Evidence: B</i>)</p>
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5. Stenting is effective as primary therapy for common iliac artery stenoses and occlusions. (*Level of Evidence: B*)

6. Stenting is effective as primary therapy in external iliac artery stenosis and occlusions. (*Level of Evidence: C*)

**CLASS IIa**

1. Stents (and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices, and thermal devices) can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis >50%, or flow-limiting dissection). (*Level of Evidence: C*)

**CLASS IIb**

1. The effectiveness of stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of femoral-popliteal arterial lesions (except to salvage a suboptimal result from balloon dilation) is not well-established. (*Level of Evidence: A*)

2. The effectiveness of uncoated/uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of infrapopliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well established. (*Level of Evidence: C*)

**CLASS III**

1. Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. (*Level of Evidence: C*)

2. Primary stent placement is not recommended in the femoral, popliteal, or tibial arteries. (*Level of Evidence: C*)

3. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. (*Level of Evidence: C*)

**Norgren et al (2007 TASC II Guidelines), Pg S48A Recommendation # 35:** Choosing between techniques with equivalent short and long-term clinical outcomes

- In a situation where endovascular revascularization and open repair/bypass of a specific lesion causing symptoms of peripheral arterial disease give equivalent short-term and long-term symptomatic improvement, endovascular techniques should be used first (*Grade: B*).

Recommendation #36: Treatment of aortoiliac lesions

- TASC A and D lesions: Endovascular therapy is the treatment of choice for type A lesions...[C].

TASC B and C lesions: Endovascular treatment is the preferred treatment for type B lesions...The patient's comorbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and C lesions [C].

**Surgical Treatment:**

**Anderson et al (2011 PAD guidelines), Pg 1562**

**2.3.2.4. Surgery for Claudication**

**CLASS I**

1. Surgical interventions are indicated for individuals with claudication symptoms who have a significant functional disability that is vocational or lifestyle limiting, who are unresponsive to exercise or pharmacotherapy, and who have a reasonable likelihood of symptomatic improvement. (*Level of Evidence: B*)

**CLASS IIb**

1. Because the presence of more aggressive atherosclerotic occlusive disease is associated with less durable results in patients younger than 50 years of age, the effectiveness of surgical intervention in this population for intermittent claudication is unclear. (*Level of Evidence: B*)

**CLASS III**

1. Surgical intervention is not indicated to prevent progression to limb-threatening ischemia in patients with intermittent claudication. (*Level of Evidence: B*)

**2.3.3.4.1. Inflow Procedures: Aortoiliac Occlusive Disease**

**Class I**

1. Iliac endarterectomy, patch angioplasty, or aortoiliac or iliofemoral bypass in the setting of acceptable aortic inflow should be used for the treatment of unilateral disease or in conjunction with femoral-femoral bypass for the treatment of a patient with bilateral iliac artery occlusive disease if the patient is not a suitable candidate for aortobifemoral bypass grafting. (*Level of Evidence: B*)

**Norgren et al (2007 TASC II Guidelines), Pg S48A**

Recommendation #36: Treatment of aortoiliac lesions

<ul style="list-style-type: none"> <li>• TASC A and D lesions: ...surgery is the treatment of choice for type D and lesions [C].</li> <li>• TASC B and C lesions: ...surgery is the preferred treatment for good-risk patients with type C lesions. The patient's comorbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and C lesions [C].</li> </ul>
<p><b>19.</b> • SFA and Popliteal Artery</p> <p><b><u>Continue or Intensify Medical Therapy:</u></b> Same as above</p> <p><b><u>Endovascular Treatment:</u></b> Same as above</p> <p><b><u>Surgical Treatment:</u></b> Same as above</p>
<p><b>20.</b> • Below the Knee</p> <p><b><u>Continue or Intensify Medical Therapy:</u></b> Same as above</p> <p><b><u>Endovascular Treatment:</u></b> Same as above</p> <p><b><u>Surgical Treatment:</u></b> Same as above</p>

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### Section 3: Critical Limb Ischemia (CLI)

For all Section 3 indications, please consider the following graphic from the TASC II Guidelines:

**Table F2.** TASC classification of femoral popliteal lesions

Type A lesions	<ul style="list-style-type: none"> <li>■ Single stenosis ≤10 cm in length</li> <li>■ Single occlusion ≤5 cm in length</li> </ul>
Type B lesions	<ul style="list-style-type: none"> <li>■ Multiple lesions (stenoses or occlusions), each ≤5 cm</li> <li>■ Single stenosis or occlusion ≤15 cm not involving the infra geniculate popliteal artery</li> <li>■ Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass</li> <li>■ Heavily calcified occlusion ≤5 cm in length</li> </ul>
Type C lesions	<ul style="list-style-type: none"> <li>■ Single popliteal stenosis</li> <li>■ Multiple stenoses or occlusions totaling &gt;15 cm with or without heavy calcification</li> <li>■ Recurrent stenoses or occlusions that need treatment after two endovascular interventions</li> </ul>
Type D lesions	<ul style="list-style-type: none"> <li>■ Chronic total occlusions of CFA or SFA (&gt;20 cm, involving the popliteal artery)</li> <li>■ Chronic total occlusion of popliteal artery and proximal trifurcation vessels</li> </ul>

CFA – common femoral artery; SFA – superficial femoral artery.



Table 3.1: Critical Limb Ischemia

21. • Aortoiliac
<p><b><u>Endovascular Treatment:</u></b></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1563</b>  <b>2.3.3.2 Endovascular treatments for CLI</b>  <b>Class I</b></p> <ol style="list-style-type: none"> <li>1. For individuals with combined inflow and outflow disease with CLI, inflow lesions should be addressed first. (Level of Evidence: C)</li> <li>2. For individuals with combined inflow and outflow disease in whom symptoms of CLI or infection persist after inflow revascularization, and outflow revascularization procedure should be performed (Level of Evidence: B)</li> <li>3. If it is unclear whether hemodynamically significant inflow disease exists, intra-arterial pressure measurements across suprainguinal lesions should be measured before and after the administration of a vasodilator. (Level of Evidence: C)</li> </ol> <p><b>Class IIa</b></p> <ol style="list-style-type: none"> <li>1. 2011 New Recommendation: For patients with limb-threatening lower extremity ischemia and an estimated life expectancy of 2 years or less in patients whom an autologous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal flow. (Level of Evidence: B)</li> <li>2. 2011 New Recommendation: For patients with limb-threatening ischemia and an estimated life expectancy of more than 2 years, bypass surgery, when possible and when an autogenous vein conduit is available, is reasonable to perform as the initial treatment to improve distal blood flow. (Level of Evidence: B)</li> </ol> <p><b>Class III</b></p> <ol style="list-style-type: none"> <li>1. Surgical and endovascular intervention is not indicated in patients with severe decrements in limb perfusion (e.g., ABI &lt;0.4) in the absence of clinical symptoms of CLI. (Level of Evidence: C)</li> </ol> <p><b>Norgren et al (2007 TASC II Guidelines)</b>  Pg S37A, Recommendation # 24:</p> <ul style="list-style-type: none"> <li>• Optimal treatment for patients with critical limb ischemia (CLI): Revascularization is the optimal treatment for patients with CLI (Grade: B).</li> </ul> <p>Pg S48A, Recommendation # 35:</p> <ul style="list-style-type: none"> <li>• Choosing between techniques with equivalent short and long-term clinical outcomes <ul style="list-style-type: none"> <li>○ In a situation where endovascular revascularization and open repair/bypass of a specific lesion causing symptoms of peripheral arterial disease give equivalent short-term and long-term symptomatic improvement, endovascular techniques should be used first (Grade: B).</li> </ul> </li> </ul> <p>Pg S48A, Recommendation # 37:</p> <ul style="list-style-type: none"> <li>• Treatment of femoral popliteal lesions <ul style="list-style-type: none"> <li>○ TASC A and D lesions: Endovascular therapy is the treatment of choice for type A lesions...[C].</li> <li>○ TASC B and C lesions: Endovascular treatment is the preferred treatment for type B lesions... The patient's comorbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and C lesions [C].</li> </ul> </li> </ul> <p><b><u>Surgical Treatment:</u></b></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1563</b>  <b>2.3.3.4. Surgery for CLI</b>  <b>CLASS I</b></p> <ol style="list-style-type: none"> <li>1. For individuals with combined inflow and outflow disease with CLI, inflow lesions should be addressed first. (Level of Evidence: B)</li> <li>2. For individuals with combined inflow and outflow disease in whom symptoms of CLI or infection persist after inflow revascularization, an outflow revascularization procedure should be performed. (Level of Evidence: B)</li> <li>3. Patients who have significant necrosis of the weight-bearing portions of the foot (in ambulatory patients), an uncorrectable flexion contracture, paresis of the extremity, refractory ischemic rest pain, sepsis, or a very limited life expectancy due to comorbid conditions should be evaluated for primary amputation of the leg. (Level of Evidence: C)</li> </ol> <p><b>CLASS IIa</b></p>

2. *2011 New Recommendation:* For patients with limb-threatening ischemia and an estimated life expectancy of more than 2 years, bypass surgery, when possible and when an autogenous vein conduit is available, is reasonable to perform as the initial treatment to improve distal blood flow. *(Level of Evidence: B)*

**CLASS III**

1. Surgical and endovascular intervention is not indicated in patients with severe decrements in limb perfusion (e.g., ABI <0.4) in the absence of clinical symptoms of CLI. *(Level of Evidence: C)*

**Anderson et al (2011 PAD guidelines), Pg 1564**

**2.3.3.4.2. Outflow Procedures: Infrainguinal Disease**

**Class I**

1. For individuals with combined inflow and outflow disease with CLI, inflow lesions should be addressed first. *(Level of Evidence: B)*

2. Bypasses to the below-knee popliteal artery should be constructed with autogenous vein when possible. *(Level of Evidence: A)*

5. Femoral-tibial artery bypasses should be constructed with autologous vein, including the ipsilateral greater saphenous vein, or if available, other sources from the leg or arm *(Level of Evidence: B)*

7. If no autologous vein is available, a prosthetic femoral-tibial bypass, and possibly an adjunctive procedure, such as arteriovenous fistula or vein interposition or cuff, should be used when amputation is imminent. *(Level of Evidence: B)*

**Class IIa**

1. Prosthetic material can be used effectively for bypasses to the below-knee popliteal artery when no autogenous vein from ipsilateral or contralateral leg or arms is available. *(Level of Evidence: B)*

**Norgren et al (2007 TASC II Guidelines), Pg S48A**

Recommendations # 37:

- Treatment of femoral popliteal lesions
  - TASC A and D lesions: ...surgery is the treatment of choice for type D lesions [C].
  - TASC B and C lesions: ...surgery is the preferred treatment for good-risk patients with type C lesions. The patient's co-morbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and C lesions [C].

**Norgren et al (2007 TASC II Guidelines), Pg S54A**

Recommendation # 40:

- Femoral below-knee popliteal and distal bypass
  - An adequate long (greater) saphenous vein is the optimal conduit in femoral below-knee popliteal and distal bypass [Grade: C]. In its absence, another good-quality vein should be used [Grade: C].

**22. • SFA and Popliteal Artery**

**Endovascular Treatment:**

Same as above

**Surgical Treatment:**

Same as above

**23. • Below the Knee**

**Endovascular Treatment:**

Same as above

**Surgical Treatment:**

Same as above

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## Section 4: Asymptomatic Artery Disease

**Table 4.1: Access in support of other life-saving interventions**

<b>24. • Access for Coronary Intervention</b>
<p><b><u>Endovascular Treatment:</u></b>                  2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, pg e65</p> <p>5.1. Vascular Access: Recommendation                  Class IIa</p> <p>1. The use of radial artery access can be useful to decrease access site complications. (Level of Evidence: A)</p> <p><b><u>Surgical Access:</u></b>                  None</p>
<b>25. • Access for Hemodynamic Support</b>
<p><b><u>Endovascular Treatment:</u></b>                  2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care</p> <p>Discusses access in the setting of needing hemodynamic support.</p> <p><b><u>Surgical Access:</u></b>                  None</p>
<b>26. • Access for Large Vascular or Valvular Intervention</b>
<p><b><u>Endovascular Treatment:</u></b>                  2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease</p> <p>2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care</p> <p><b><u>Surgical Access:</u></b>                  None</p>

## Section 5: Options for Endovascular Treatment When Deemed Appropriate or May Be Appropriate

**Table 5.1: Isolated Common Iliac Artery**

<b>27. • Discrete stenosis</b>
<p><a href="#">Intervention options: Atherectomy, Balloon Angioplasty, or Stent</a></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1561-1562</b>  <b>2.3.2.3. Endovascular Treatment For Claudication</b>  <b>CLASS I</b></p> <ol style="list-style-type: none"> <li>1. Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). <i>(Level of Evidence: A)</i></li> <li>2. Endovascular intervention is recommended as the preferred revascularization technique for TASC type A iliac and femoropopliteal arterial lesions. <i>(Level of Evidence: B)</i></li> <li>3. Translesional pressure gradients (with and without vasodilation) should be obtained to evaluate the significance of angiographic iliac arterial stenoses of 50% to 75% diameter before intervention. <i>(Level of Evidence: C)</i></li> <li>4. Provisional stent placement is indicated for use in the iliac arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis &gt;50%, or flow-limiting dissection). <i>(Level of Evidence: B)</i></li> <li>5. Stenting is effective as primary therapy for common iliac artery stenoses and occlusions. <i>(Level of Evidence: B)</i></li> </ol> <p><b>CLASS III</b></p> <ol style="list-style-type: none"> <li>1. Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. <i>(Level of Evidence: C)</i></li> <li>3. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. <i>(Level of Evidence: C)</i></li> </ol> <p><b>Norgren et al (2007 TASC II Guidelines), Pg S48A Recommendation # 35:</b> Choosing between techniques with equivalent short and long-term clinical outcomes</p> <ul style="list-style-type: none"> <li>• In a situation where endovascular revascularization and open repair/bypass of a specific lesion causing symptoms of peripheral arterial disease give equivalent short-term and long-term symptomatic improvement, endovascular techniques should be used first <i>(Grade: B)</i>.</li> </ul> <p>Recommendation #36: Treatment of aortoiliac lesions</p> <ul style="list-style-type: none"> <li>• TASC A and D lesions: Endovascular therapy is the treatment of choice for type A lesions...[C].</li> </ul> <p>TASC B and C lesions: Endovascular treatment is the preferred treatment for type B lesions...The patient's comorbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and C lesions [C].</p>
<b>28. • Diffuse disease or multiple stenoses of the CIA</b>
<p><a href="#">Intervention options: Atherectomy, Balloon Angioplasty, or Stent</a></p> <p><i>Same as above.</i></p>

**Table 5.2: Isolated External Iliac Artery**

<b>29. • Discrete stenosis</b>
<p><a href="#">Intervention options: Atherectomy, Balloon Angioplasty, or Stent</a></p> <p><i>Same as above, and</i></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1561-1562</b>  <b>2.3.2.3. Endovascular Treatment For Claudication</b></p> <ol style="list-style-type: none"> <li>6. Stenting is effective as primary therapy in external iliac artery stenoses and occlusions. <i>(Level of Evidence: C)</i></li> </ol>

<p><b>Class IIa</b></p> <p>1. 2011 New Recommendation: For patients with limb-threatening lower extremity ischemia and an estimated life expectancy of 2 years or less in patients whom an autologous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal flow. (<i>Level of Evidence: B</i>)</p> <p>2. 2011 New Recommendation: For patients with limb-threatening ischemia and an estimated life expectancy of more than 2 years, bypass surgery, when possible and when an autogenous vein conduit is available, is reasonable to perform as the initial treatment to improve distal blood flow. (<i>Level of Evidence: B</i>)</p>
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**Table 5.3: Diffuse Common Iliac Artery and External Iliac Artery**

<p><b>30.</b> • Unilateral EIA stenosis with multiple CIA stenoses</p> <p><a href="#">Intervention options: Atherectomy, Balloon Angioplasty, or Stent</a></p> <p><i>Same as above, and</i>  <b>Anderson et al (2011 PAD guidelines), Pg 1561-1562</b>  <b>2.3.2.3. Endovascular Treatment For Claudication</b>  <b>Class I</b></p> <p>1. For individuals with combined inflow and outflow disease with CLI, inflow lesions should be addressed first. (<i>Level of Evidence: C</i>)</p> <p>2. For individuals with combined inflow and outflow disease in whom symptoms of CLI or infection persist after inflow revascularization, and outflow revascularization procedure should be performed (<i>Level of Evidence: B</i>)</p> <p>3. If it is unclear whether hemodynamically significant inflow disease exists, intra-arterial pressure measurements across suprainguinal lesions should be measured before and after the administration of a vasodilator. (<i>Level of Evidence: C</i>)</p>
<p><b>31.</b> • Chronic Total Occlusion</p> <p><a href="#">Intervention options: Atherectomy, Balloon Angioplasty, or Stent</a></p> <p><i>Same as above.</i></p>

**Table 5.4: Superficial Femoral Artery (SFA) and Popliteal Artery**

<p><b>32.</b> • Length &lt;100 mm</p> <p><a href="#">Intervention options: Atherectomy, Balloon Angioplasty, Drug Coated Balloon (DCB), Bare Metal Stent (BMS), Drug Eluting Stent (DES), or Covered Stent</a></p> <p>Jaff, et al. An update on methods for revascularization and expansion of the TASC lesion classification to include below-the-knee arteries: a supplement to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)  Pg 614-616  Femoropopliteal Disease</p> <ul style="list-style-type: none"> <li>○ Open Surgery vs Endovascular Intervention</li> <li>○ Choice of Revascularization Method</li> </ul> <p>Laird, JR, and Armstrong, EJ. An Overview of Superficial Femoral Artery Stenting: The history, data, and latest advancements in stenting of the SFA and popliteal arteries.  Pg 9-11</p> <ul style="list-style-type: none"> <li>○ Superiority of SFA Stents over Balloon Angioplasty</li> <li>○ Registry Studies of SFA Stents</li> <li>○ Recent Developments in SFA Stents</li> <li>○ Drug-Eluting Stents in the SFA</li> </ul>
<p><b>33.</b> • Length ≥100 mm</p>

Intervention options: Atherectomy, Balloon Angioplasty, Drug Coated Balloon (DCB), Bare Metal Stent (BMS), Drug Eluting Stent (DES), or Covered Stent

Same as above.

**Table 5.5: Below the Knee**

**34.** • Length <100 mm

Intervention options: Atherectomy, Balloon Angioplasty, Drug Coated Balloon (DCB), Bare Metal Stent (BMS), Drug Eluting Stent (DES), or Covered Stent

An Update on Methods for Revascularization and Expansion of the TASC Lesion Classification to Include Below-the-Knee Arteries: A Supplement to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II), by The TASC Steering Committee (Jaff et al). *Catheterization and Cardiovascular Interventions* 86:611–625 (2015)

Table I. Randomized Controlled Trials of Drug-Eluting Stents in Infrapopliteal Disease

Study/Stent Type	N	CLI/IC	Control Arm	Follow-up, mo	Outcome	p
ACHILLES Sirolimus-eluting	200	CLI+IC	PTA	12	Primary patency 75% vs 57%	0.025
DESTINY Everolimus-eluting	140	CLI	BMS	12	Primary patency 85% vs 54%	<0.001
YUKON-BTX Sirolimus-eluting	161	CLI+IC	BMS	12	Primary patency 81% vs 56%	0.004
IDEAS Drug-eluting	50	CLI+IC	PCB	6	Restenosis 28% vs 58%	0.046

Abbreviations: BMS, bare metal stent; CLI, critical limb ischemia; IC, intermittent claudication; PCB, paclitaxel-coated balloon; PTA, percutaneous transluminal angioplasty

Rastan A, Tepe G, Krankenberg H et al. Sirolimus-eluting stents vs. bare-metal stents for treatment of focal lesions in infrapopliteal arteries: a double-blind, multi-centre, randomized clinical trial. *Eur Heart J* 2011;32:2274-81.

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**Anderson et al (2011 PAD guidelines), Pg 1563**

**2.3.3.2 Endovascular treatments for CLI**

**Class I**

2. For individuals with combined inflow and outflow disease in whom symptoms of CLI or infection persist after inflow revascularization, and outflow revascularization procedure should be performed (*Level of Evidence: B*)

**Class IIa**

1. 2011 New Recommendation: For patients with limb-threatening lower extremity ischemia and an estimated life expectancy of 2 years or less in patients whom an autologous vein conduit is not available, balloon angioplasty is reasonable to perform when possible as the initial procedure to improve distal flow. (*Level of Evidence: B*)

**CLASS III**

1. Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. (*Level of Evidence: C*)

3. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. (*Level of Evidence: C*)

35. • Length  $\geq 100$  mm

[Intervention options: Atherectomy, Balloon Angioplasty, Drug Coated Balloon \(DCB\), Bare Metal Stent \(BMS\), Drug Eluting Stent \(DES\), or Covered Stent](#)

Same as above.

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## Section 6: Secondary Treatment Options for Lower Extremity Disease

Table 6.1 In-stent Restenosis

Recurrent Symptoms	
36.	• Focal stenosis
<p><a href="#">Continue or Intensify Medical Therapy:</a></p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1560</b></p> <p><b>2.3.1. Cardiovascular Risk Reduction</b></p> <p><b>2.3.1.1. LIPID-LOWERING DRUGS</b></p> <p><b>CLASS I</b></p> <p>1. Treatment with a hydroxymethyl glutaryl coenzyme-A reductase inhibitor (statin) medication is indicated for all patients with PAD to achieve a target low-density lipoprotein cholesterol level of less than 100 mg per dL. (Level of Evidence: B)</p> <p><b>CLASS IIa</b></p> <p>1. Treatment with a hydroxymethyl glutaryl coenzyme-A reductase inhibitor (statin) medication to achieve a target low-density lipoprotein cholesterol level of less than 70 mg per dL is reasonable for patients with lower extremity PAD at very high risk of ischemic events. (Level of Evidence: B)</p> <p>2. Treatment with a fibric acid derivative can be useful for patients with PAD and low high-density lipoprotein cholesterol, normal low-density lipoprotein cholesterol, and elevated triglycerides. (Level of Evidence: C)</p> <p><b>Anderson et al (2011 PAD guidelines), Pg 1561</b></p> <p><b>2.3.1.6. ANTIPLATELET AND ANTITHROMBOTIC DRUGS</b></p> <p><b>CLASS I</b></p> <p>1. 2011 Updated Recommendation: Antiplatelet therapy is indicated to reduce the risk of MI, stroke, and vascular death in individuals with symptomatic atherosclerotic lower extremity PAD, including those with intermittent claudication or CLI prior lower extremity revascularization (endovascular or surgical), or prior amputation for lower extremity ischemia. (Level of Evidence: A)</p> <p>2. 2011 Updated Recommendation: Aspirin, typically in daily doses of 75 to 325 mg, is recommended as safe and effective antiplatelet therapy to reduce the risk of MI, stroke, or vascular death in individuals with symptomatic atherosclerotic lower extremity PAD, including those with intermittent claudication or CLI, prior lower extremity revascularization (endovascular or surgical), or prior amputation for lower extremity ischemia. (Level of Evidence: B)</p> <p>3. 2011 Updated Recommendation: Clopidogrel (75 mg per day) is recommended as a safe and effective alternative antiplatelet therapy to aspirin to reduce the risk of MI, ischemic stroke, or vascular death in individuals with symptomatic atherosclerotic lower extremity PAD, including those with intermittent claudication or CLI, prior lower extremity revascularization (endovascular or surgical), or prior amputation for lower extremity ischemia. (Level of Evidence: B)</p> <p><b>CLASS IIa</b></p> <p>1. 2011 New Recommendation: Antiplatelet therapy can be useful to reduce the risk of MI, stroke, or vascular death in asymptomatic individuals with an ABI less than or equal to 0.90. (Level of Evidence: C)</p> <p><b>CLASS IIb</b></p> <p>1. 2011 New Recommendation: The usefulness of antiplatelet therapy to reduce the risk of MI, stroke, or vascular death in asymptomatic individuals with borderline abnormal ABI, defined as 0.91 to 0.99, is not well established. (Level of Evidence: A)</p> <p><a href="#">Endovascular Treatment:</a></p> <p>Matsumura, J. S., Yamanouchi, D., Goldstein, J. A., Pollock, C. W., Bosiers, M., Schultz, G. A., et al. (2013). The united states StuDy for EvalUating Endovascular TreAtments of lesions in the superficial femoral artery and proximal popliteal by using the protégé EverFlex Nitinol STent SYstem II (DURABILITY II). <i>Journal of Vascular Surgery</i>, 58(1), 73-83.e1.</p> <p>Scheinert, D., Duda, S., Zeller, T., Krankenberg, H., Ricke, J., Bosiers, M., et al. (2014). The LEVANT I (lutonix paclitaxel-coated balloon for the prevention of femoropopliteal restenosis) trial for femoropopliteal revascularization: First-in-human</p>	

<p>randomized trial of low-dose drug-coated balloon versus uncoated balloon angioplasty. JACC: Cardiovascular Interventions, 7(1), 10-19.</p>
<p><b><u>Surgical Treatment:</u></b>                  Silingardi, R., Cataldi, V., Moratto R., A., I., Veronesi, J., &amp; Coppi, G. (2010). Mechanical thrombectomy in in-stent restenosis: Preliminary experience at the iliac and femoropopliteal arteries with the rotarex system. The Journal of Cardiovascular Surgery, 51(4), 543-550.</p> <p>Dippel, E.J., Makam, P., Kovach, R., George, J.C., Patlola, R., Metzger, D.C., et al. (2015). Randomized controlled study of excimer laser atherectomy for treatment of femoropopliteal in-stent restenosis: Initial results from the EXCITE ISR trial (EXCimer laser randomized controlled study for treatment of femoropoplITEal in-stent restenosis). JACC Interventions, 8(1 Pt A): 92-101.</p>
<p><b>37. • Diffuse stenosis</b></p>
<p><b><u>Continue or Intensify Medical Therapy:</u></b>                  Same as above.</p> <p><b><u>Endovascular Treatment:</u></b>                  Same as above.</p> <p><b><u>Surgical Treatment:</u></b>                  Same as above.</p>
<p><b>Asymptomatic</b></p>
<p><b>38. • Focal stenosis</b></p>
<p><b><u>Continue or Intensify Medical Therapy:</u></b>  <b>Anderson et al (2011 PAD guidelines), Pg 1563</b>  <b>2.3.1. Cardiovascular Risk Reduction</b>  <b>2.3.1.1. LIPID-LOWERING DRUGS</b>  <b>CLASS I</b>                  1. Treatment with a hydroxymethyl glutaryl coenzyme-A reductase inhibitor (statin) medication is indicated for all patients with PAD to achieve a target low-density lipoprotein cholesterol level of less than 100 mg per dL. (Level of Evidence: B)  <b>CLASS IIa</b>                  1. Treatment with a hydroxymethyl glutaryl coenzyme-A reductase inhibitor (statin) medication to achieve a target low-density lipoprotein cholesterol level of less than 70 mg per dL is reasonable for patients with lower extremity PAD at very high risk of ischemic events. (Level of Evidence: B)                  2. Treatment with a fibric acid derivative can be useful for patients with PAD and low high-density lipoprotein cholesterol, normal low-density lipoprotein cholesterol, and elevated triglycerides. (Level of Evidence: C)</p> <p><b><u>Endovascular Treatment:</u></b>                  Same as above.</p> <p><b><u>Surgical Treatment:</u></b>                  Same as above.</p>
<p><b>39. • Diffuse stenosis</b></p>

**Continue or Intensify Medical Therapy:**

*Same as above.*

**Endovascular Treatment:**

*Same as above.*

**Surgical Treatment:**

*Same as above.*

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**Table 6.2 Venous Bypass Graft Failure**

Stenotic lesions developing after 30 days	
<b>40.</b>	<ul style="list-style-type: none"> <li>● Focal stenosis</li> </ul> <p><b><u>Endovascular Treatment (Balloon Angioplasty, Stenting, and/or catheter-directed thrombolysis):</u></b></p> <p>Conte MS, Bandyk DF, Clowes AW, Moneta GL, Seely L, Lorenz TJ, et al. (2006). Results of PREVENT III: A multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery. <i>J Vasc Surg</i>, 43: 742-51.</p> <p><b><u>Surgical Treatment (Vein Patch Angioplasty or Interposition Graft):</u></b></p> <p>Ouriel, K., Veith, F. J., &amp; Sasahara, A. A. (1998). A comparison of recombinant urokinase with vascular surgery as initial treatment for acute arterial occlusion of the legs. <i>N Engl J Med</i>, 338(16), 1105-1111.</p> <p>Lumsden AB, Morrissey NJ, on behalf of FINEST trial investigators. (2015). Randomized controlled trial comparing the safety and efficacy between the FUSION BIOLINE heparin-coated vascular graft and the standard expanded polytetrafluoroethylene graft for femoropopliteal bypass. <i>J Vasc Surg</i>, 61: 703-12</p>
<b>41.</b>	<ul style="list-style-type: none"> <li>● Diffuse stenosis</li> </ul>

<p><b><u>Endovascular Treatment (Balloon Angioplasty, Stenting, and/or catheter-directed thrombolysis):</u></b> Same as above.</p> <p><b><u>Surgical Treatment (Vein Patch Angioplasty or Interposition Graft):</u></b> Same as above.</p>
<p><b>42. • Thrombosed graft</b></p>
<p><b><u>Endovascular Treatment (Balloon Angioplasty, Stenting, and/or catheter-directed thrombolysis):</u></b> Same as above.</p> <p><b><u>Surgical Treatment (Vein Patch Angioplasty or Interposition Graft):</u></b> Same as above.</p>

**Table 6.3 Prosthetic Bypass Graft Failure**

Stenotic lesions developing after 30 days	
<b>43. • Focal stenosis</b>	<p><b><u>Endovascular Treatment (Balloon Angioplasty, Stenting, and/or catheter-directed thrombolysis):</u></b> Oostenbrugge TJ, deVries JP, Berger P, Vos JA, Vonken EP, Moll FL, de Borst GJ. (2014). Outcome of endovascular reintervention for significant stenosis at infrainguinal bypass anastomoses. <i>J Vasc Surg</i>, 60: 696-701.</p> <p><b><u>Surgical Treatment (Vein Patch Angioplasty or Interposition Graft):</u></b> Ouriel, K., Veith, F. J., &amp; Sasahara, A. A. (1998). A comparison of recombinant urokinase with vascular surgery as initial treatment for acute arterial occlusion of the legs. <i>N Engl J Med</i>, 338(16), 1105-1111.</p> <p>Lumsden AB, Morrissey NJ, on behalf of FINEST trial investigators. (2015). Randomized controlled trial comparing the safety and efficacy between the FUSION BIOLINE heparin-coated vascular graft and the standard expanded polytetrafluoroethylene graft for femoropopliteal bypass. <i>J Vasc Surg</i>, 61: 703-12.</p>
<b>44. • Diffuse stenosis</b>	<p><b><u>Endovascular Treatment (Balloon Angioplasty, Stenting, and/or catheter-directed thrombolysis):</u></b> Same as above.</p> <p><b><u>Surgical Treatment (Vein Patch Angioplasty or Interposition Graft):</u></b> Same as above.</p>
<b>45. • Thrombosed graft</b>	<p><b><u>Endovascular Treatment (Balloon Angioplasty, Stenting, and/or catheter-directed thrombolysis):</u></b> Patel N, Sacks D, Patel RI, Moresco KP, Ouriel K, Gray R, Ambrosius WT, Lewis CA. (2001). SCVIR reporting standards for the treatment of acute limb ischemia with use of transluminal removal of arterial thrombus. <i>J Vasc Interv Radiol</i>. 12(5):559-70.</p> <p><b><u>Surgical Treatment (Vein Patch Angioplasty or Interposition Graft):</u></b> Same as above.</p>

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