Key Points from the New SVS Guidelines on Lower Extremity Ischemia:
Preventing the over usage of SFA stents
Frank Pomposelli MD
St. Elizabeth’s Medical Center
Tufts University School of Medicine

GRADE System;
Grades of Recommendation, Assessment, Development and Evaluation:

- Quality of Evidence:
  - high (A), moderate (B), low (C)
  - based on the risk of bias, precision, directness, consistency and size of the effect

- Recommendation:
  - strong (1), weak/conditional (2)
  - based on quality of evidence, balance between benefits and harms, patient’s values, preferences and clinical context

Practice Guidelines; Diagnosis, screening, imaging:

- 2.1. We recommend using the ABI as the first-line noninvasive test to establish a diagnosis of PAD in individuals with symptoms or signs suggestive of disease. When the ABI is borderline or normal (>0.9) and symptoms of claudication are suggestive, we recommend an exercise ABI.
- 2.2. We suggest against routine screening for lower extremity PAD in the absence of risk factors, history, signs, or symptoms of PAD.
- 2.3. For asymptomatic individuals who are at elevated risk, such as those aged >70, smokers, diabetic patients, those with an abnormal pulse examination, or other established cardiovascular disease, screening for lower extremity PAD is reasonable if used to improve risk stratification, preventive care, and medical management.
- 2.4. In symptomatic patients who are being considered for revascularization, we suggest using physiologic noninvasive studies, such as segmental pressures and pulse volume recordings, to aid in the quantification of arterial insufficiency and help localize the level of obstruction.
- 2.5. In symptomatic patients in whom revascularization treatment is being considered, we recommend anatomic imaging studies, such as arterial duplex ultrasound, CTA, MRA, and contrast arteriography.

ABI, Ankle-brachial index; CTA, computed tomographic angiography; MRA, magnetic resonance angiography

SVS Guidelines for Asymptomatic Disease and Claudication;
Overview of the project and final result:

Project:
- Twelve committee members
- Multiple meetings over 4 years
- Two commissioned systematic reviews
- Final document 40 pages, 275 references

Results:
- 53 recommendations in 6 separate categories
  - 1A 9 (all but 1 related to management of atherosclerosis, smoking cessation, exercise therapy)
  - 2C 10


Completion of the project and final result:

Project:
- Twelve committee members
- Multiple meetings over 4 years
- Two commissioned systematic reviews
- Final document 40 pages, 275 references

Results:
- 53 recommendations in 6 separate categories
  - 1A 9 (all but 1 related to management of atherosclerosis, smoking cessation, exercise therapy)
  - 2C 10

"urgent need for comparative effectiveness research in PAD"

SVS Guidelines for Asymptomatic Disease and Claudication;
Screening for asymptomatic disease:


Recommendation: No risk factors 2C

With risk factors 2C

SVS Guidelines for Asymptomatic Disease and Claudication;
Exercise training (SET) for claudication:


Comparison Data source Methodologic limitations Quality of evidence
Exercise program vs. no exercise 30 RCT enrolling 1816 patients Low risk of bias. Patients with other conditions limiting exercise excluded A (walking performance parameters) C (death, ang)

Improvements statistically significant but modest. Increased mean walking time by 4.5 minutes, distance 109 meters

Supervised exercise therapy statistically improved walking distance over unsupervised. Effect size 6.5 or 100 meters. Benefit persisted for maximal and pain free walking distance at 12 months. No change on QoL measures.

SVS Guidelines for Asymptomatic Disease and Claudication; Exercise training (SET) for claudication:

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Data source</th>
<th>Methodologic limitations</th>
<th>Quality of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise program vs. no exercise</td>
<td>30 RCT enrolling 1816 patients</td>
<td>Low risk of bias. Patients with other conditions limiting exercise excluded</td>
<td>A (walking performance parameter) C (death, amputation)</td>
</tr>
</tbody>
</table>

Improvements statistically significant but modest: increased mean walking time by 4.5 minutes, distance 109 meters

Supervised exercise vs. unsupervised 1002 patients follow up (6 weeks-1year) A (for walking performance parameter) C

Supervised exercise therapy statistically improved walking distance over unsupervised. Effect size 0.69 or 180 meters. Benefit persisted for maximal and pain free walking distance at 12 months. No change on QoL measures.

Recommendation: Supervised exercise therapy as first line treatment


SVS Guidelines for Asymptomatic Disease and Claudication; Revascularization of AIOD for intermittent claudication:

<table>
<thead>
<tr>
<th>References</th>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yilmaz, Soga, Ichihashi, Indes</td>
<td>PTA+stent</td>
<td>5</td>
<td>63-79</td>
</tr>
<tr>
<td>deVries, Rutherford, Reed, Brewerster, Chio</td>
<td>AFB</td>
<td>5</td>
<td>81-93</td>
</tr>
<tr>
<td>Cham, Melliere, Van der Vliet Chin, Rieco</td>
<td>IFB</td>
<td>5</td>
<td>73-88</td>
</tr>
<tr>
<td>Criado, Rico, Mii</td>
<td>FFB</td>
<td>5</td>
<td>60-83</td>
</tr>
</tbody>
</table>

Recommendations: Endo over open for focal disease

Endo as first line therapy iliac

Covered stents

Yilmaz, Soga, Ichihashi, Indes PTA+stent 5 63-79
<table>
<thead>
<tr>
<th>References</th>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>deVries, Rutherford, Reed, Brewerster, Chio</td>
<td>AFB</td>
<td>5</td>
<td>81-93</td>
</tr>
<tr>
<td>Cham, Melliere, Van der Vliet Chin, Rieco</td>
<td>IFB</td>
<td>5</td>
<td>73-88</td>
</tr>
<tr>
<td>Criado, Rico, Mii</td>
<td>FFB</td>
<td>5</td>
<td>60-83</td>
</tr>
</tbody>
</table>

Recommendations: Endo over open for focal disease

Endo as first line therapy iliac

Covered stents

Endo as first line therapy iliac

Covered stents

Yilmaz, Soga, Ichihashi, Indes PTA+stent 5 63-79

SVS Guidelines for Asymptomatic Disease and Claudication; Revascularization of AIOD for intermittent claudication:

<table>
<thead>
<tr>
<th>References</th>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yilmaz, Soga, Ichihashi, Indes</td>
<td>PTA+stent</td>
<td>5</td>
<td>63-79</td>
</tr>
<tr>
<td>deVries, Rutherford, Reed, Brewerster, Chio</td>
<td>AFB</td>
<td>5</td>
<td>81-93</td>
</tr>
<tr>
<td>Cham, Melliere, Van der Vliet Chin, Rieco</td>
<td>IFB</td>
<td>5</td>
<td>73-88</td>
</tr>
<tr>
<td>Criado, Rico, Mii</td>
<td>FFB</td>
<td>5</td>
<td>60-83</td>
</tr>
</tbody>
</table>

Recommendations: Endo over open for focal disease

Endo as first line therapy iliac

Covered stents

Endo as first line therapy iliac

Covered stents

Yilmaz, Soga, Ichihashi, Indes PTA+stent 5 63-79
## SVS Guidelines for Asymptomatic Disease and Claudication:

### Revascularization of AIOD for intermittent claudication:

<table>
<thead>
<tr>
<th>References</th>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yilmaz, Soga, Ichihashi, Indes</td>
<td>PTA+stent</td>
<td>5</td>
<td>63-79</td>
</tr>
<tr>
<td>deVries, Rutherford, Reed, Brewster, Chin</td>
<td>AFB</td>
<td>5</td>
<td>81-93</td>
</tr>
<tr>
<td>Chan, Melliere, Van der Vliet Chin, Rico</td>
<td>IFB</td>
<td>5</td>
<td>73-88</td>
</tr>
<tr>
<td>Criado, Rico, Mii</td>
<td>FFB</td>
<td>5</td>
<td>60-83</td>
</tr>
</tbody>
</table>

**Recommendations:**
- Endo over open for focal disease (<5cm): 1B
- Endo as first line therapy iliac: 1B
- Hybrid procedures: 1B
- AFB in extensive disease: 1B

## SVS Guidelines for Asymptomatic Disease and Claudication:

### Revascularization of femoral-popliteal occlusive disease for intermittent claudication:

<table>
<thead>
<tr>
<th>References</th>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hunnuck, Muradin, Schillinger</td>
<td>PTA</td>
<td>2</td>
<td>26-48</td>
</tr>
<tr>
<td>Schillinger, Laird, Matsumura</td>
<td>PTA+stent</td>
<td>2</td>
<td>51-68</td>
</tr>
<tr>
<td>Kedora, Shackles, Geraghty</td>
<td>Covered stent</td>
<td>1</td>
<td>53-77</td>
</tr>
<tr>
<td>Pereira, Klinkert</td>
<td>FP vein</td>
<td>5</td>
<td>70-75</td>
</tr>
<tr>
<td>Robinson, Klinkert, Pereira</td>
<td>FP prosthetic</td>
<td>5</td>
<td>40-60</td>
</tr>
</tbody>
</table>

**Recommendations:**
- Endo over open for focal disease (<5cm): 1B

## SVS Guidelines for Asymptomatic Disease and Claudication:

### Revascularization of femoral-popliteal occlusive disease for intermittent claudication:

<table>
<thead>
<tr>
<th>References</th>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hunnuck, Muradin, Schillinger</td>
<td>PTA</td>
<td>2</td>
<td>26-48</td>
</tr>
<tr>
<td>Schillinger, Laird, Matsumura</td>
<td>PTA+stent</td>
<td>2</td>
<td>51-68</td>
</tr>
<tr>
<td>Kedora, Shackles, Geraghty</td>
<td>Covered stent</td>
<td>1</td>
<td>53-77</td>
</tr>
<tr>
<td>Pereira, Klinkert</td>
<td>FP vein</td>
<td>5</td>
<td>70-75</td>
</tr>
<tr>
<td>Robinson, Klinkert, Pereira</td>
<td>FP prosthetic</td>
<td>5</td>
<td>40-60</td>
</tr>
</tbody>
</table>

**Recommendations:**
- Endo over open for focal disease (<5cm): 1B
- Salvage stenting for focal disease: 2C
SVS Guidelines for Asymptomatic Disease and Claudication; Revascularization of femoral-popliteal occlusive disease for intermittent claudication:

<table>
<thead>
<tr>
<th>References</th>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hunnick, Muradin, Schillinger</td>
<td>PTA</td>
<td>2</td>
<td>26-48</td>
</tr>
<tr>
<td>Schillinger, Laird, Matsumura</td>
<td>PTA+stent</td>
<td>2</td>
<td>51-68</td>
</tr>
<tr>
<td>Kedora, Shackles, Geraghty</td>
<td>Covered stent</td>
<td>1</td>
<td>53-77</td>
</tr>
<tr>
<td>Pereira, Klinkert</td>
<td>FP vein</td>
<td>5</td>
<td>70-75</td>
</tr>
<tr>
<td>Robinson, Klinkert, Pereira</td>
<td>FP prosthetic</td>
<td>5</td>
<td>40-60</td>
</tr>
</tbody>
</table>

Recommendations:
- Endo over open for focal disease (<5cm) 1B
- Salvage stenting for focal disease 2C
- Adjunctive stents for 5-15 cm lesion 1B

SVS Guidelines for Asymptomatic Disease and Claudication; Functional comparisons of FP bypass to exercise and EVT:

<table>
<thead>
<tr>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bypass</td>
<td>75-95%</td>
<td></td>
</tr>
<tr>
<td>Exercise training</td>
<td>10-20%</td>
<td></td>
</tr>
</tbody>
</table>

Surgical treatment demonstrated superior clinical and health related QoL outcomes (Nottingham) compared to conservative rx and EVT at 1 year.

---

SVS Guidelines for Asymptomatic Disease and Claudication; Functional comparisons of FP bypass to exercise and EVT:

<table>
<thead>
<tr>
<th>Modality</th>
<th>Follow up, yrs.</th>
<th>Patency (PAP), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bypass</td>
<td>75-95%</td>
<td></td>
</tr>
<tr>
<td>Exercise training</td>
<td>10-20%</td>
<td></td>
</tr>
</tbody>
</table>

Surgical treatment demonstrated superior clinical and health related QoL outcomes (Nottingham) compared to conservative rx and EVT at 1 year.

Sustained walking improvement and improved QoL dependent on patency.

#Koivunen K et al. Eur J Cardiovasc Nurs 2008;7:247-56

References: Modality Follow up, yrs. Patency (PAP), %

Hunnick, Muradin, Schillinger PTA 2 26-48
Schillinger, Laird, Matsumura PTA+stent 2 51-68
Kedora, Shackles, Geraghty Covered stent 1 53-77
Pereira, Klinkert FP vein 5 70-75
Robinson, Klinkert, Pereira FP prosthetic 5 40-60

Recommendations:
- Endo over open for focal disease (<5cm) 1B
- Salvage stenting for focal disease 2C
- Adjunctive stents for 5-15 cm lesion 1B
- FP for extensive, calcific disease, small caliber 1B

#Koivunen K et al. Eur J Cardiovasc Nurs 2008;7:247-56
SVS Guidelines for Asymptomatic Disease and Claudication;
Functional comparisons of FP bypass to exercise and EVT:

Probability of achieving unlimited maximal walking distance (1000 meters)*

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bypass</td>
<td>75-95%</td>
</tr>
<tr>
<td>Exercise training</td>
<td>10-20%</td>
</tr>
</tbody>
</table>

Surgical treatment demonstrated superior clinical and health related QoL outcomes (Nottingham) compared to conservative rx and EVT at 1 year

Sustained walking improvement and improved QoL dependent on patency!
Surgery in appropriate risk patients still appropriate when it is likely to provide better durability or functional improvement than ends.
>50% likelihood of sustained patency at 2 years recommended standard


Interventions for Claudication;
Conclusions:

- Supervised exercise training effective but limited availability
- EVT equivalent to surgery in the aorto-iliac segment
- EVT durability inferior to surgery in the femoral popliteal segment
- Better functional results?
- Trade off of lower morbidity, quicker recovery
- Need for reintervention should be factored into the decision making process
- Minimal standard >50% likelihood of sustained potency for 2 years
- Need for more comparative effectiveness research