Vascular screening in diabetic patients: how aggressive should we be and when to intervene?

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Disclosure

Roberto Ferraresi, MD

I have the following potential conflicts of interest to report: consulting, travel reimbursement, teaching courses, training, proctoring:

- Medtronic
- Boston Scientific
- Abbott
- LimFlow
- Terumo
- Cook
- Biotronik
- Asahi
Vascular screening in diabetic patients: how aggressive should we be and when to intervene?

1. Asymptomatic patients

2. Claudication

3. Critical limb ischemia

Should we treat asymptomatic diabetic patients with PAD?
“Although this logical course of the disease is intellectually appealing, not all patients with CLI have experienced any symptoms of previous claudication.”
Although this logical course of the disease is intellectually appealing, not all patients with CLI have experienced any symptoms of previous claudication.

"…<25% of diabetics with PAD report intermittent claudication, and in DM pts with foot ulcers rest pain is substantially less frequent than in non-DM pts…"
In diabetic pts PAD can progress to multilevel vessel obstruction with poor symptoms (sedentary + neuropathy)

Not claudication but “chronic subclinical ischemia” (TASC 2) or foot hibernation:
Should we treat asymptomatic diabetic patients with "chronic subclinical ischemia"?
3. **Chronic Subcritical Limb Ischemia: A Poorly Recognized Stage of Critical Limb Ischemia**
   John V. White, MD,* Robert B. Rutherford, MD,* and Constance Ryjewski, MS, RN*

   - 20 asymptomatic pts with chronic subcritical ischemia
   - 1.9 yy FU
   - no deaths or major amputations, and only one patient progressed to surgical intervention

4. **Incidence of critical limb ischemia and amputation outcome in contralateral limb in diabetic patients hospitalized for unilateral critical limb ischemia during 1999–2003 and followed-up until 2005**
   Ezio Faglia⁎⁎, Giacomo Clerici⁎, Manuela Mantoro⁎, Maurizio Carminati⁎, Astronella Quarantiello⁎, Vincenzo Curci⁎, Alberto Morabito⁎

   - 533 diabetic patients with unilateral CLI
   - 6-year follow up
   - 50% developed a CLI in the contralateral limb
In asymptomatic diabetic patients with PAD \( \rightarrow \) \textbf{WAIT!!!}

1. Aggressive medical care & risk-reduction strategies may reduce mortality and alter progression of limb ischemia to amputation

2. Prompt therapeutic interventions \( \rightarrow \) be ready to fight!
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Aggressive or conservative approach in diabetic claudicants?
DM+IC → not so common! <25% of diabetics with PAD report intermittent claudication…
1. DM+IC $\Rightarrow$ not so common! <25% of diabetics with PAD report intermittent claudication…

2. DM+IC $\Rightarrow$ serious prognosis for subsequent cardiovascular outcomes
1. DM+IC $\rightarrow$ not so common! <25% of diabetics with PAD report intermittent claudication…

2. DM+IC $\rightarrow$ serious prognosis for subsequent cardiovascular outcomes

3. DM+IC $\rightarrow$ more CV risk factors, CV conditions, disability and worse haemodynamic status and QoL than claudicants without diabetes
DM+IC ➔ diabetic pts with IC present a double rate of BTK disease compared to non-diabetic pts with IC

(Ferraresi, unpublished)
4) DM+IC ➔ diabetic pts with IC present a double rate of BTK disease compared to non-diabetic pts with IC (Ferraresi, unpublished)

5) DM+IC ➔ revascularization in addition to improve walking performance, is associated with a reduction in the incidence of future major cardiovascular events
1. Aggressive medical care & risk-reduction strategies

2. To preserve an adequate walking capacity could be essential in reducing future CV events

3. Consider revascularization focusing on proximal and focal lesions
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What type of screening?
Pressure measurements: ABI & ankle systolic pressure

Research: Complications
Influence of peripheral vascular calcification on efficiency of screening tests for peripheral arterial occlusive disease in diabetes—a cross-sectional study

C. E. Aubert¹,², P. Cluzel³,⁴, S. Kemen², P.-L. Michel⁵, F. Lajat-Kiss⁶, M. Dadon⁶, A. Hartemann⁵,⁶ and O. Bourron¹,²


Conclusions: Below-knee vascular calcification gave a high rate of false negative results for ankle brachial index
<table>
<thead>
<tr>
<th>Aggregated segments</th>
<th>Prevalence of disease (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Above-the-groin vessels</td>
<td>9.8</td>
</tr>
<tr>
<td>SFA</td>
<td>45.5</td>
</tr>
<tr>
<td>POP-TPT</td>
<td>46.5</td>
</tr>
<tr>
<td>Prox-BTK vessels</td>
<td>0 artery: 14.3</td>
</tr>
<tr>
<td></td>
<td>1 artery: 24.3</td>
</tr>
<tr>
<td></td>
<td>2 arteries: 37.6</td>
</tr>
<tr>
<td></td>
<td>3 arteries: 23.7</td>
</tr>
<tr>
<td>Dist-BTK vessels</td>
<td>0 artery: 13.2</td>
</tr>
<tr>
<td></td>
<td>1 artery: 25.5</td>
</tr>
<tr>
<td></td>
<td>2 arteries: 44.9</td>
</tr>
<tr>
<td></td>
<td>3 arteries: 16.4</td>
</tr>
<tr>
<td>BTA vessels</td>
<td>0 artery: 27.9</td>
</tr>
<tr>
<td></td>
<td>1 artery: 20.2</td>
</tr>
<tr>
<td></td>
<td>2 arteries: 31.5</td>
</tr>
<tr>
<td></td>
<td>3 arteries: 20.4</td>
</tr>
<tr>
<td>Arch</td>
<td>25.2</td>
</tr>
</tbody>
</table>

*Pressure measurements: ABI & ankle systolic pressure*

Disease distribution in a series of 1915 pts with PAD

Ferraresi et AL, submitted for publication 2015

52% 2-3 BTA vessel disease (arch excluded)

25% arch disease
For diagnosis of CLI in diabetic patients ..., measurement of TcPO2 is essential not only when AP is not measurable but also when this value is ≥70 mm Hg.
For diagnosis of CLI in diabetic patients ..., measurement of TcPO2 is essential not only when AP is not measurable but also when this value is ≥70 mm Hg.

Conclusion: TcPO2 levels < 34 mmHg indicate the need for revascularization, while for values ≥34 <40 mmHg this need appears less pressing, although there remains a considerable probability of amputation. TcPO2 levels greater than 40 mmHg suggest that revascularization is dependent on the severity of tissue loss and possible morbidity caused by the procedure.
Pressure measurements are imperfect diagnostic instruments in diabetics due to:

1. High rate of false negative results in calcified vessel

2. Inability to detect foot vessel disease (ABI!) which is one of the main causes of CLI!

3. In these patients TcPO2 seems to be more reliable
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| 1. Asymptomatic patients  |
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| 3. Critical limb ischemia |

When to intervene? How can we decide that a diabetic foot wound is an ischemic one and must be revascularized?
### Validation of a Diabetic Wound Classification System

The contribution of depth, infection, and ischemia to risk of amputation

*David G. Armstrong, DPM
Lawrence A. Lavery, DPM, MPH
Lawrence B. Harkless, DPM*

**Diabetes Care, volume 21, number 5, May 1998**

#### “Binary” diagnosis of ischemia: Yes or Not

<table>
<thead>
<tr>
<th>Stage</th>
<th>Grade</th>
<th>Grade of Wound Penetration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 Pre or post ulcerative lesion completely epithelialized</td>
<td>I Superficial wound, Wound penetrating to tendon or capsule, III Wound penetrating to bone or joint</td>
</tr>
<tr>
<td>A</td>
<td>No infection or ischemia</td>
<td>0%</td>
</tr>
<tr>
<td>B</td>
<td>Infection present</td>
<td>12.5%</td>
</tr>
<tr>
<td>C</td>
<td>Ischemia present</td>
<td>25.0%</td>
</tr>
<tr>
<td>D</td>
<td>Infection and ischemia present</td>
<td>50.0%</td>
</tr>
</tbody>
</table>
1. **Validation of a Diabetic Wound Classification System**

   The contribution of depth, infection, and ischemia to risk of amputation

   David G. Armstrong, DPM
   Lawrence A. Lavery, DPM, MPH
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   Diabetes Care, Volume 21, Number 5, May 1998

   “Binary” diagnosis of ischemia: Yes or Not

2. **Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)**

   L. Norgren, W. R. Hiatt, J. A. Dormandy, M. R. Nehler, K. A. Harris, and F. G. R. Fowkes on behalf of the TASC II Working Group, Örebro, Sweden and Denver, Colorado

   “Binary” diagnosis of ischemia: Yes or Not

- Toe pressures – should include toe pressures in diabetic patients (critical level <50 mmHg)
- tcPO₂ (critical level <30 mmHg)
1. Validation of a Diabetic Wound Classification System

The contribution of depth, infection, and ischemia to risk of amputation

2. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)


The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WHI)

"Binary" diagnosis of ischemia: Yes or Not

4 grades

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
### I: Ischemia
Hemodynamics/perfusion: Measure TP or TcPO₂ if ABI incompressible (>1.3)
SVS grades 0 (none), 1 (mild), 2 (moderate), and 3 (severe).

<table>
<thead>
<tr>
<th>Grade</th>
<th>ABI</th>
<th>Ankle systolic pressure</th>
<th>TP, TcPO₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>≥0.80</td>
<td>&gt;100 mm Hg</td>
<td>≥60 mm Hg</td>
</tr>
<tr>
<td>1</td>
<td>0.6-0.79</td>
<td>70-100 mm Hg</td>
<td>40-59 mm Hg</td>
</tr>
<tr>
<td>2</td>
<td>0.4-0.59</td>
<td>50-70 mm Hg</td>
<td>30-39 mm Hg</td>
</tr>
<tr>
<td>3</td>
<td>≤0.39</td>
<td>&lt;50 mm Hg</td>
<td>&lt;30 mm Hg</td>
</tr>
</tbody>
</table>

### a. Estimate risk of amputation at 1 year for each combination

<table>
<thead>
<tr>
<th></th>
<th>Ischemia – 0</th>
<th>Ischemia – 1</th>
<th>Ischemia – 2</th>
<th>Ischemia – 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>W-0</td>
<td>VL</td>
<td>VL</td>
<td>L</td>
<td>M</td>
</tr>
<tr>
<td>W-1</td>
<td>VL</td>
<td>VL</td>
<td>L</td>
<td>M</td>
</tr>
<tr>
<td>W-2</td>
<td>L</td>
<td>L</td>
<td>M</td>
<td>H</td>
</tr>
<tr>
<td>W-3</td>
<td>M</td>
<td>M</td>
<td>H</td>
<td>H</td>
</tr>
</tbody>
</table>

Legend:
- VL: Very Low
- L: Low
- M: Moderate
- H: High
- fl: Functional
When to intervene?
How can we decide that a diabetic foot wound is an ischemic one and must be revascularized?
The diagnosis of ischemia is not easy, because it is not a YES or NOT condition. In every specific wound we must consider if blood supply can be sufficient for healing or should be improved.
1. **Be suspicious and aggressive in CLI because the enemy is sly and dangerous**

2. **Never trust a single element for diagnosis: use every clue to suspect ischemia**
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