When is the endovascular option the first choice in critical limb ischemia?

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CLI

Critical Limb Ischemia

The ideal flow-chart

Primary goals
- Relieve ischemic pain
- Heal (neuro)ischemic ulcers
- Prevent limb loss
- Improve patient function and quality of life

Primary outcome
- Amputation-free survival

Multidisciplinary Approach to treatment of CLI
- Pain Control
  - Revascularization
    - Management of Ulcers
    - Amputation
    - Farmacotherapy
“...for patients with CLI, **surgical bypass grafting** has been the **gold standard**, with a 5-year limb salvage rates > 80% ...”

"Although the use of PTA /stent as a first line therapy for chronic lower extremity ischemia was been widely accepted by Cardiologist and Interventional Radiologists, many series in the Vascular Surgery Literature still recommend surgical bypass as first-line therapy for CLI.


"PTA/stent primary patency rates inferior to surgical bypass have fueled the argument that this modality should be reserved for patients who are at high surgical risk or who lack autogeneous conduit..”

...In this series, there was no periprocedural mortality and the rate of major morbidity was 3%, which is a dramatic improvement over the recently reported rate of 10% morbidity and 3% mortality after infrainguinal bypass with autogenous vein...."


...the recent development of small-diameter catheter platforms (0.014-inch and 0.018-inch), imaging techniques, and endovascular expertise, which have improved the methodology, and the introduction of flexible nitinol stents, which has created a perception of improved early patency, has promulgated the use of PTA/stent as the initial option for infrainguinal reconstruction, despite a lack of data to support this practice.

“... although a small number (8%) of patients in this series eventually required surgical bypass, clinical and hemodynamic success was maintained in most patients with repeat PTA/stent.

Given that an acceptable clinical result can be maintained with a continued low patient morbidity, it may be more appropriate to forgo the stringent confines of the primary patency definition of success in favor of maintained clinical success such as assisted patency....”

The First International Consensus on the diagnosis and Treatment of PAD was...

Management of Peripheral Arterial Disease (PAD) TransAtlantic Inter-Society Consensus (TASC)

Eur J Vasc Endovasc Surg. 2000
Int Angiol 2000
Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)


INTRODUCTION

The Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC) was published in January 2000.1-3 In a result of cooperation between fourteen medical and surgical vascular, cardiovascular, vascular radiology and cardiology societies in Europe and North America. This comprehensive document had a major impact on vascular care amongst specialists. In subsequent years, the field has progressed with the publication of the TASC II document4 and the American College of Cardiology/American Heart Association Guidelines for the Management of Peripheral Arterial Disease. Aiming to continue to reach a readership of vascular specialists, but also physicians in primary health care who see patients with peripheral arterial disease (PAD), another consensus process was initiated during 2004. This new consensus document has been developed with a broader international representation, including Europe, North America, Asia, Africa and Australia, and with a much larger discussion and dissemination of the information. The goals of this new consensus are 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, but not to add an extensive list of references. Unresolved statements are, therefore, to be found, provided they are recognized as consensus practice by the authors, with existing evidence. The recommendations are graded according to levels of evidence. It should also be emphasized that good practice is based on a combination of the scientific evidence described below, patients' preferences, and local availability of facilities and trained professionals. Good practice also includes appropriate specialist referral.

Process

Representatives of sixteen societies from Europe, North America, Australia, South Africa and Japan were elected from their respective society and were called together in 2004 to form the new Working Group. Specialists in health economics, health outcomes and evidence-based medicine were also included to elaborate on the text for the following sections: history, epidemiology and risk factors; management of risk factors; intermittent claudication; critical limb ischemia; acute limb ischemia; and technologies (intervention/revascularization and imaging).

The Working Group reviewed the literature and, after extensive correspondence and meetings, proposed a series of draft documents with clear recommendations for the diagnosis and treatment of PAD. Each participating society reviewed and commented on those draft consensus documents. The liaison member from each society then took those views back to the Working Group, where all of the amendments, additions and alterations suggested by each participating society were discussed, and the final Consensus Document was agreed upon.

The participating societies were then again invited to review the final document and endorse it if they agreed with its content. If an individual participating society did not accept any specific recommendation, this is clearly indicated in the final document. Therefore, except where such specific exclusions are indicated, this Consensus Document represents the views of all of the participating societies.

Compared with the original TASC, more emphasis has been put on diabetes and PAD. The text is presented in such a way that vascular specialists will still find most of the information they require, while general practitioners and primary health physicians will easily find guidance for diagnosis and diagnostic procedures, referral of patients and expected outcomes of various treatment options.

Grading of recommendations

Recommendations and selected statements are rated according to guidance issued by the former US Agency for Health Care Policy and Research,4 now renamed the Agency for Healthcare Research and Quality.
While the specific lesions stratified in the following TASC II classification schemes have been modified from the original TASC guidelines to reflect inevitable technological advances............
## CLI

**Critical Limb Ischemia**

Revascularization - **TASC vs TASC II**

### Femoro-Popliteal Lesions

<table>
<thead>
<tr>
<th>TASC</th>
<th>TASC II</th>
</tr>
</thead>
</table>
| Type A lesions: | - Single stenosis ≤10 cm in length  
- Single occlusion ≥5 cm in length |
| Type B lesions: | - Multiple lesions (stenoses or occlusions), each ≤5 cm  
- Single stenosis or occlusion ≤15 cm not involving the infra geniculate popliteal artery  
- Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass  
- Heavily calcified occlusion ≤5 cm in length  
- Single popliteal stenosis  
- Multiple stenoses or occlusions totaling >15 cm with or without heavy calcification  
- Recurrent stenoses or occlusions that need treatment after two endovascular interventions |
| Type C lesions: | - Chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery)  
- Chronic total occlusion of popliteal artery and proximal trifurcation vessels |
| Type D lesions: | - Complete common femoral artery or superficial femoral artery occlusions or complete popliteal and proximal trifurcation occlusions. |

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- TASC Type A iliac lesions:  
  1. Single stenosis <3 cm of the CIA or EIA (unilateral/bilateral)

- TASC Type B iliac lesions:  
  2. Single stenosis 3-10 cm in length, not involving the distal popliteal artery
  3. Heavily calcified stenoses up to 3 cm in length
  4. Multiple lesions, each less than 3 cm (stenoses or occlusions)
  5. Single or multiple lesions in the absence of continuous tibial runoff to improve inflow for distal surgical bypass

- TASC Type C femoropopliteal lesions:  
  6. Single stenosis or occlusion longer than 5 cm
  7. Multiple stenoses or occlusions, each 3-5 cm, with or without heavy calcification

- TASC Type D femoropopliteal lesions:  
  8. Complete common femoral artery or superficial femoral artery occlusions or complete popliteal and proximal trifurcation occlusions.
CLI
Critical Limb Ischemia
Revascularization - TASC vs TASC II
Infra-popliteal Lesions

TASC

TASC Type A infrapopliteal lesions:
1. Single stenoses shorter than 1 cm in the tibial or peroneal vessels

TASC Type B infrapopliteal lesions:
2. Multiple focal stenoses of the tibial or peroneal vessel, each less than 1 cm in length
3. One or two focal stenoses, each less than 1 cm, at the tibial trifurcation
4. Short tibial or peroneal stenosis in conjunction with femoropopliteal PTA

TASC Type C infrapopliteal lesions:
5. Stenoses 1–4 cm in length
6. Occlusions 1–2 cm in length of the tibial or peroneal vessels
7. Extensive stenoses of the tibial trifurcation

TASC Type D infrapopliteal lesions:
8. Tibial or peroneal occlusions longer than 2 cm
9. Diffusely diseased tibial or peroneal vessels

TASC II

No
Reported
CLI
Critical Limb Ischemia
Revascularization - TASC vs TASC II

.........the principles behind the classification remain unchanged for:

TASC A and D lesions: Endovascular therapy is the treatment of choice for type A lesions and surgery is the treatment of choice for type D lesions [C].
Critical Issue 10:

*Treatment of TASC type B and C lesions*

More evidence is needed to make any firm recommendations about the best treatment for TASC types B and C lesions.*

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TASC B and C lesions: Endovascular treatment is the preferred treatment for type B lesions and 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 type C lesions [C].
The choice of intervention, between open surgery and an endovascular procedure, can be difficult, often weighing risks to life and limb against each other in an attempt to save both.

There is increasing evidence to support a recommendation for angioplasty in patients with CLI and infrapopliteal artery occlusion where in-line flow to the foot can be re-established and where there is medical co-morbidity...
Critical Limb Ischemia
Endovascular Treatment Results

- Not as many reports have supported the general effectiveness of angioplasty in CLI, and this has yet to be determined.

- Few data have been published regarding long-term results, limited to 3 or 4 years, of PTA for CLI, which includes all anatomic lesions in the lower extremity.

Procedures
- PTA
- PTA e Stent
- Subintimal angioplasty
- Remote Endoarterectomy
- Laser angioplasty
Intermediate results of percutaneous endovascular therapy of femoropopliteal occlusive disease: A contemporary series

Mark Frederick Conrad, MD, Richard P. Cambria, MD, David H. Stone, MD, David C. Brewster, MD, Christopher J. Kwolek, MD, Michael T. Watkins, MD, Thomas K. Chung, MA, and Glenn M. LaMuraglia, MD, Boston, Mass


- **Primary patency in CLI** was **42.4 %** at 36 months with a significant difference between those with claudication (**65.6 %**, *P* .0004)

- **Assisted patency** in CLI (maintained by redo PTA/stent) was **92.8%** at 24 and 36 months

- **Limb salvage** was in CLI **89.8%** 24 and 36 months with a significant difference between those with claudication (**100%**, *P* .0007)
Intermediate results of percutaneous endovascular therapy of femoropopliteal occlusive disease: A contemporary series

Mark Frederick Conrad, MD, Richard P. Cambria, MD, David H. Stone, MD, David C. Brewster, MD, Christopher J. Kwolek, MD, Michael T. Watkins, MD, Thomas K. Chung, MA, and Glenn M. LaMuraglia, MD, Boston, Mass

Table IV. Significant factors by multivariate analysis

<table>
<thead>
<tr>
<th></th>
<th>HR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predictors of primary patency failure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHF</td>
<td>1.973</td>
<td>1.107-3.525</td>
<td>.02</td>
</tr>
<tr>
<td>TASC C/D</td>
<td>1.959</td>
<td>1.099-3.494</td>
<td>.02</td>
</tr>
<tr>
<td>Predictors of assisted patency failure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &lt;65 years</td>
<td>8.325</td>
<td>1.212-57.194</td>
<td>.03</td>
</tr>
<tr>
<td>CHF</td>
<td>7.325</td>
<td>1.035-51.854</td>
<td>.008</td>
</tr>
<tr>
<td>TASC C/D</td>
<td>7.834</td>
<td>1.696-36.180</td>
<td>.04</td>
</tr>
<tr>
<td>Predictors of limb loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>11.481</td>
<td>1.329-99.158</td>
<td>.03</td>
</tr>
<tr>
<td>CHF</td>
<td>6.686</td>
<td>1.454-30.745</td>
<td>.02</td>
</tr>
<tr>
<td>Predictors of need for eventual surgical bypass</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female gender</td>
<td>4.337</td>
<td>1.437-13.092</td>
<td>.009</td>
</tr>
<tr>
<td>CHF</td>
<td>3.648</td>
<td>1.157-11.504</td>
<td>.03</td>
</tr>
<tr>
<td>Total occlusion</td>
<td>6.269</td>
<td>1.706-23.038</td>
<td>.006</td>
</tr>
</tbody>
</table>

HR, Hazard ratio; CI, confidence interval; CHF, congestive heart failure;


**TASC C and D lesions were not predictive of limb loss**
The effectiveness of percutaneous transluminal angioplasty for the treatment of critical limb ischemia: A 10-year experience

In consideration of the good limb salvage rate showed in each subgroup (also BK group), PTA can be the primary choice for CLI due to iliac and FP groups.

Even thought the BK group had the most predisposing risk factors, endovascular procedures might be the only alternative to amputation.
Bypass versus angioplasty in severe ischaemia of the leg (Basil): multicentre, randomised controlled trial

Basil trial participants * Lancet 2005; 366: 1925–34

Table 5: Comparison of use of hospital resources by intention to treat during first 12 months from randomisation

<table>
<thead>
<tr>
<th></th>
<th>Surgery (n=228)</th>
<th>Angioplasty (n=224)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Range</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Number of admissions to hospital</td>
<td>2.14 (1.30)</td>
<td>(1–8)</td>
<td>2.06 (1.50)</td>
</tr>
<tr>
<td>Total days spent in hospital</td>
<td>46.14 (53.87)</td>
<td>(0–365)</td>
<td>36.35 (51.39)</td>
</tr>
<tr>
<td>Days spent in intensive therapy unit</td>
<td>0.13 (0.94)</td>
<td>(0–12)</td>
<td>0.04 (0.60)</td>
</tr>
<tr>
<td>Days spent in high dependency unit</td>
<td>0.65 (1.66)</td>
<td>(0–11)</td>
<td>0.18 (1.17)</td>
</tr>
<tr>
<td>Number of surgical procedures</td>
<td>0.95 (0.90)</td>
<td>(0–4)</td>
<td>0.26 (0.52)</td>
</tr>
<tr>
<td>Number of angioplasty procedures</td>
<td>0.25 (0.54)</td>
<td>(0–3)</td>
<td>1.05 (0.56)</td>
</tr>
</tbody>
</table>

*p Wilcoxon two-sample test.

Table 2: Mortality, morbidity, and re-interventions within 30 days after first intervention

<table>
<thead>
<tr>
<th></th>
<th>Angioplasty (n=224)</th>
<th>Surgery (n=228)</th>
<th>Hazard ratio (95% CI) of surgery relative to angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unadjusted</td>
<td>Adjusted</td>
<td></td>
</tr>
<tr>
<td>Amputation-free survival</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entire follow-up</td>
<td>106</td>
<td>58</td>
<td>0.39 (0.68–1.17)</td>
</tr>
<tr>
<td>Up to 6 months</td>
<td>46</td>
<td>59</td>
<td>1.67 (0.72–3.8)</td>
</tr>
<tr>
<td>After 6 months</td>
<td>60</td>
<td>48</td>
<td>0.73 (0.51–1.0)</td>
</tr>
<tr>
<td>After 2 years</td>
<td>28</td>
<td>16</td>
<td>0.44 (0.22–0.86)</td>
</tr>
<tr>
<td>All-cause mortality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entire follow-up</td>
<td>27</td>
<td>79</td>
<td>0.60 (0.6–1.2)</td>
</tr>
<tr>
<td>Up to 6 months</td>
<td>26</td>
<td>31</td>
<td>1.20 (0.72–2.0)</td>
</tr>
<tr>
<td>After 6 months</td>
<td>61</td>
<td>68</td>
<td>0.78 (0.53–1.1)</td>
</tr>
<tr>
<td>After 2 years</td>
<td>27</td>
<td>11</td>
<td>0.38 (0.19–0.7)</td>
</tr>
</tbody>
</table>

*Adjusted for age, sex, clinical manifestation group, body-mass index, current or ex-smoking status, creatinine concentration, diabetes, and events at baseline. *Exact log-rank analysis done after examination of survival curves.
In the short term (up to 6 months), a surgery-first strategy was associated with
- a significantly higher rate of morbidity
- a trend towards a higher rate of all-cause mortality
- a lower immediate failure and 12-month re-intervention rate
- a significantly greater of length of hospital stay
- a greater use of the intensive-therapy unit
- a third higher mean cost

than that of an angioplasty-first strategy.
In the medium term (after 6 months) the outcomes after these two strategies are similar with respect to amputation-free survival, all cause mortality, and HRQL.
In the long term (beyond 2 years from randomisation) a post-hoc analysis showed a significantly reduced hazard in amputation-free survival (p=0.008) and all-cause mortality (p=0.004) for surgery relative to angioplasty.

The covariates with the strongest independent effect were

Clinical stratification group, Diabete, Creatinine, Age
CLTI
Critical Limb Ischemia
due to infra-inguinal lesions
When is the Endovascular option the first choice?

- Patients who are expected to live for less than 1–2 years and have significant comorbidity should probably, when possible (TASC 2007), be offered angioplasty first, notwithstanding the high failure and re-intervention rate associated with angioplasty.

Thus, even if the procedure fails, the patient may not be disadvantaged in the short term and can go on to have surgery if regarded as appropriate.
In patients expected to live more than 2 years and who are relatively fit, the apparent improved durability and reduced re-intervention rate of surgery could outweigh the short-term considerations of increased morbidity and cost.
Despite diabetes mellitus was a significant predictor of amputation on multivariate analysis and this reflects the disease state of the patients with tissue loss and poor runoff resulting in the associated limb loss, PTA/ remains a viable option even for diabetic patients with advanced vascular disease and CLI.
Unfortunately, a sizeable minority of patients underwent repeated procedures only to eventually die or lose their leg (or both) within the first 12 months.

It suggests that some patients might have been better served by primary amputation.
Thank You
for Your Attention