Use of directional atherectomy where stenting is not an option

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Disclosure

Speaker name:

........G.Torsello.................................................................

I have the following potential conflicts of interest to report:

☒ Consulting: Medtronic, Cook, Cordis, Gore, Boston
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
So-called non-stenting zones

Background

A decade ago, the CFA and PA were viewed as a “no stent zone.”

Due to the high flexion of knee and hip and the concern for possible stent fracture surgical rather than endovascular therapy has been historically recommended.
Surgical therapy: Gold standard

Primary patency: 96% @ 7 years

Surgery is associated with excellent, durable patency and long-term freedom from reintervention
Surgical therapy: Gold standard?

<table>
<thead>
<tr>
<th>Complication</th>
<th>%</th>
<th>Risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days mortality</td>
<td>1.5-3.4%</td>
<td>Age</td>
</tr>
<tr>
<td>Local complications</td>
<td>8%</td>
<td>COPD</td>
</tr>
<tr>
<td>Combined</td>
<td>15%</td>
<td>ESRD</td>
</tr>
<tr>
<td>30 days re-operation</td>
<td>10%</td>
<td>Emergency</td>
</tr>
<tr>
<td>At least 1 complication</td>
<td>7.9%</td>
<td>SIRS/MODS</td>
</tr>
<tr>
<td></td>
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<td>ASA 4-5</td>
</tr>
</tbody>
</table>

Role of endovascular therapy?

As periop morbidity is significant, endovascular TX may represent an alternative if patency is comparable.
Observational studies have suggested that PTA is associated with acceptable short- and mid-term patency.
CFA Stent therapy: Supera Stent

VMI-CFA trial: 1 year results

DeLoose LINC 2019
CFA Stent therapy vs Surgery: Tecco trial

Gouëffic et al  J Am Coll Cardiol Intv 2017;10:1344–54
CLTI Guidelines

Global vascular guidelines on the management of chronic limb-threatening ischemia

Mike S. Conte, MD (Co-Editor),1 Andrew W. Bradbury, MD (Co-Editor),1 Philippe Kolh, MD (Co-Editor),1 John V. White, MD (Steering Committee),1 Florian Dick, MD (Steering Committee),1 Robert Fritridge, MBBS (Steering Committee),1 Joseph L. Mills, MD (Steering Committee),1 Jean-Baptiste Ricco, MD (Steering Committee),1 Kalkunthe R. Suresh, MD (Steering Committee),1 M. Hassan Murad, MD, MPH,1 and the CVG Writing Group.1 San Francisco, Calif; Birmingham, United Kingdom; Wallonia, Belgium; Niles, Ill; St. Gallen, Switzerland; Adelaide, South Australia; Houston, Tex; Poliès, France; Bangalore, India; and Rochester, Minn


ABSTRACT

Chronic limb-threatening ischemia (CLTI) is associated with mortality, amputation, and impaired quality of life. These Global Vascular Guidelines (GVG) are focused on definition, evaluation, and management of CLTI with the goals of improving evidence-based care and highlighting critical research needs. The term CLTI is preferred over critical limb ischemia, as the latter implies threshold values of impaired perfusion rather than a continuum. CLTI is a clinical syndrome defined by the presence of peripheral artery disease (PAD) in combination with rest pain, gangrene, or lower limb ulceration >2 weeks duration. Venous, traumatic, embolic, and nonatherosclerotic etiologies are excluded. All patients with suspected CLTI should be referred urgently to a vascular specialist. Accurate staging of the severity of limb threat is fundamental, and the Society for Vascular Surgery-Thrombectomy Limb Classification system based on grading of Wounds, Ischemia, and foot infection (WIF) is endorsed. Objective hemodynamic testing, including toe pressures as the preferred measure, is required to assess CLTI. Evidence-based revascularization (EBR) hinges on three independent axes. Patient risk, limb severity, and anatomic complexity (PLAN). Average-risk and high-risk patients are defined by estimated procedural and 2-year all-cause mortality. The CVG proposes a new Global Anatomic Staging System (CLASS), which involves defining a preferred target artery path (TAP) and then estimating limb-based patency (LBP), resulting in three stages of complexity for intervention. The optimal revascularization strategy is also influenced by the availability of autogenous vein for open bypass surgery. Recommendations for EBR are based on best available data, pending level I evidence from ongoing trials. Vein bypass may be preferred for average-risk patients with advanced limb threat and high-complication disease, whereas those with less complex anatomy, intermediate severity limb threat, or high patient risk may be favored for endovascular intervention. All patients with CLTI should be afforded best medical therapy, including the use of antiplatelet and anticoagulant medications and glycemic control agents, as well as counseling on smoking cessation, diet, exercise, and preventive foot care. Following EBR, long-term limb surveillance is advised. The effectiveness of nonrevascularization therapies (eg, spinal stimulation, pneumatic compression, prostanooids, and hyperbaric oxygen) has not been established. Regenerative medicine approaches (eg, cell, gene therapy) for CLTI should be restricted to rigorously conducted randomized clinical trials. The CVG promotes standardized study designs and end points for clinical trials in CLTI. The importance of multidisciplinary teams and centers of excellence for amputation prevention is stressed as a key health system initiative. (J Vasc Surg 2019;69:1355–1355)

Keywords: Chronic limb-threatening ischemia, Critical limb ischemia, Peripheral artery disease, Diabetes, Foot ulcer, Endovascular intervention, Bypass surgery, Practice guideline, Evidence-based medicine

6.29 Consider endovascular treatment of significant CFA disease in selected patients who are deemed to be at high surgical risk or to have a hostile groin.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Level of evidence</th>
<th>Key references</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 (Weak)</td>
<td>C (Low)</td>
<td>Baumann, 91 2011; Bonvini, 92 2011; Gouëffic, 93 2017; Siracuse, 94 2017</td>
</tr>
</tbody>
</table>

6.30 Avoid stents in the CFA and do not place stents across the origin of a patent deep femoral artery.

<table>
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Good practice statement

Conte et al, JVS 2019
Stenting has not been widely adopted, due to concerns regarding stent durability in this vessel segment
Directional Atherectomy + Anti-Restenotic Therapy

The DAART Concept

DA: Vessel Preparation

Anti-restenotic treatment
DAART for popliteal disease

Stavroulakis et al. JEVT. 2017;24(2):181-188
DAART for CFA

68% vs 88%, (HR): 0.64; 95 CI: 0.22 to 2.81, P= .40

DAART for CFA
DAART for Bypass anastomosis stenosis
DAART for CFA dissection after puncture
18 Months Follow UP
Percutaneous Intervention Versus Surgery in the Treatment of Common Femoral Artery Lesions (PESTO-AFC)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT02517827

Recruitment Status: Recruiting
First Posted: August 7, 2015
Last Update Posted: August 3, 2018

Study Design

- **Study Type**: Intervenional (Clinical Trial)
- **Estimated Enrollment**: 306 participants
- **Allocation**: Randomized
- **Intervention Model**: Parallel Assignment
- **Masking**: None (Open Label)
- **Primary Purpose**: Treatment
- **Official Title**: Percutaneous Intervention Versus Surgery in the Treatment of Common Femoral Artery Lesions: A Prospective, Multi-centre, Randomised Study
- **Actual Study Start Date**: August 1, 2017
- **Estimated Primary Completion Date**: December 2019
Conclusions

- Surgery still the gold standard in nonstenting zones
- Significant morbidity and mortality
- Endo therapy useful in patients unfit for surgery, restenosis after surgery, high-risk for complications
- Stent therapy comparable results with surgery at 2 years (RCT data)
- Vessel prep and DCB might be an alternative
- Additional long-term data are necessary
homepage: www.gefaesschirurgie-muenster.de

Thank you!

St. Franziskushospital Münster
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