Devices and Techniques for Extreme Interventions Below the Knee

Pathology Specific Intervention Considerations

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Indications:
Chronic Critical Limb Ischaemia
with or without
ischaemic or septic ulcer or risk of amputation.

Population:
The large majority of patients are Diabetics.

Pathology:
Diabetic Macroangiopathy substantially differs from Atherosclerosis.
Characteristics of Diabetic Arteriopathy (1)

- **Vascular calcification:** It occurs at 2 anatomic sites: in (a) the intima, where it is invariably associated with advanced state of atherosclerosis and (b) in the tunica media.

- (b): **Human medial calcification** (Mönckeberg’s Sclerosis = M.S.): it is common in Diabetics and occurs independently of atherosclerosis, implying different etiological mechanisms as long duration of Diabetes. *(It is rarely seen in the coronary tree !!!)*

*Shanahan, Cary, Salisbury, Proudfoot, Weissberg, Edmonds Circulation.1999;100:2168-2176*
“In addition and independently of atherosclerotic changes, the arteries of Diabetic patients are characterized by increased amounts of connective tissue, such as fibronectin, collagen, and glycoproteins, as well as increased amounts of calcium in the medial layer (M.S.), a constellation named “DIABETIC MACROANGIOPATHY”. (Rarely seen in the coronary tree !!!) These changes lead to a loss of compliance and elasticity of the arterial wall”.

General morphological differences and mechanical properties

- **Atherosclerotic lesions**: asymmetric plaque distribution and extension, with focal-eccentric subintimal and medial atheromasic degeneration → *irregular* loss of elasticity. (This is the Most Common condition present in the Coronary tree !!)

- **Diabetic arteriopathy**: diffuse vessel wall thickening due to connective (inelastic) degeneration and medial calcification → *diffuse* and *regular* loss of elasticity.
LAD or ... Tibial?
Specific morphological differences

- **Atherosclerotic lesions**: intimal calcification occurs in macrophage and lipid-rich atherosclerotic lesions.

- **Diabetic arteriopathy**: the media is filled with circumferential rings of calcium, and at later stages, osteocytes are present within bone trabeculae with apparent bone marrow formation. **Calcification in the media occurs in the absence of macrophages and lipid**

  **This contrast with the scattered, globular Atherosclerotic calcification of the intima, which is invariably associated with lipid and macrophages**

The Crucial Role of Macrophages on Restenosis

- Macrophage Infiltration Predicts Restenosis After Coronary Intervention in Patients With Unstable Angina.

- Macrophage Depletion by Clodronate-Containing Liposomes Reduces Neointimal Formation After Balloon Injury in Rats and Rabbits.
Despite the severity and diffusion of peripheral arterial lesions, these different characteristics of Diabetic Arteriopathy could in fact facilitate a very good immediate angiographic result. The “Stent-like appearance after Plain Old (Optimal) Balloon Angioplasty (POBA) could be frequently achieved even dilating long calcified tibial stenoses and occlusions in Diabetic subjects. Long-term Clinical result could be favorable, performing extensive-extreme interventions, including leg and foot arteries revascularization.

...however the most challenging problem remains how to cross long calcified tibial occlusions !!!
TYPE AND DISTRIBUTION OF 2,893 LESIONS in 417 Consecutive Diabetic Subjects with Ischaemic Foot Ulcer: (Graziani et al. Unpublished data)
TYPE AND DISTRIBUTION OF 2,893 LESIONS in 417 Consecutive Diabetic Subjects with Ischaemic Foot Ulcer: Occlusions (Graziani et al. Unpublished data)
WHY SHOULD BALLOON ANGIOPLASTY BE OPTIMIZED?

- BECAUSE LESIONS ARE MULTIPLE AND DIFFUSE
- BECAUSE LESIONS ARE OFTEN CALCIFIED
- BECAUSE STENT DEPLOYEMENT IN POPLITEAL AND LEG ARTERIES IS RARELY EFFECTIVE
- BECAUSE IN-STENT RESTENOSIS IS DIFFICULT TO MANAGE
- BECAUSE BALLOON ANGIOPLASTY IS EASILY REPEATABLE
“OPTIMAL BALLOON ANGIOPLASTY” IS THE GOAL IN TREATING DIFFUSE AND CALCIFIED LESIONS IN MEDIUM-SIZE AND SMALL PERIPHERAL ARTERIES

OPTIMAL BALLOON ANGIOPLASTY IS A "STENT-LIKE" FINAL ANGIOGRAPHIC RESULT

- Transluminal balloon angioplasty remains the most effective procedure to promptly restore flow, with an acceptable patency rate over time
- The performance of the procedure largely influences the needs of using Stents and also the clinical result
Why should a prolonged (>180 sec) balloon inflation be performed?

- Prolonged balloon inflation improves the immediate results of PTA and PTCA.
- Significantly fewer major dissections with a modest reduction of residual stenosis, reducing the requirement of costly and time consuming further interventions.
- Causes less arterial trauma (reduction of shear stress-related vessel wall injury) with a little advantage in lumen gain.
- But this reduced shear stress-induced vessel wall injury causes only little advantage on restenosis rate and clinical adverse events during follow-up.

OPTIMIZING THE ACUTE RESULT OF BALLOON ANGIOPLASTY (2):

Why should a gradual high-pressure balloon dilatation be performed?

- A gradual, compared to rapid, coronary angioplasty balloon inflation protocol reduces the frequency of dissection despite similar inflation pressure and balloon/vessel diameter ratio. Gradual inflations may reduce the frequency of procedure-related complications.
  
  *Cathet Cardiovasc Diagn. 1993 Jul;29(3):199-202*

- High inflation pressure improves the result after PTCA because of a greater acute luminal gain.
  
Why should dilatation be performed using a correct balloon size?

Selection of a balloon that approximates or slightly exceeds the diameter of the normal arterial diameter, yields optimal angiographic results with minimal dissections and minimal residual stenosis. (slightly bigger is better)

In Diabetic Patients, Collaterals Development is Decreased or Absent!!

- our findings suggest that Coronary Collaterals development is poorer in patients with, than in patients without Diabetes. Thus, we can speculate that Diabetes is an important factor affecting Collaterals development. Circulation. 1999;99:2239-2242

- the ability of Monocytes (Collaterals progenitors) to migrate towards a gradient of VEGF-A is severely impaired in Diabetic individuals. Cardiovasc Res. 2001 Feb 16;49(3):554-60

Obtaining **direct flow** to the foot through a Tibial artery is generally required for diabetic ischaemic ulcer healing.

Recanalization of an isolated Peroneal artery, may determine only limited improvement of TcPo2 values **(non-direct flow)**, depending on collaterals efficiency.

But due to extreme diffusion of below-the-knee stenosis and occlusions, direct flow to the Pedal or Plantar (Tibial) arteries can be achieved in no more than **63%** of the treated cases, using Catheter-Based-Techniques.
Through the Posterior Perforating Branch...
The healing process of ischaemic foot lesions could be very quick when combining revascularization and proper surgical foot care.

After healing, lesion and symptoms may not recur, even in cases of significant restenosis.

The goal remains: pain relief, ulcer healing, major amputation avoidance and limb salvage!

!! Major amputation dramatically increases the mortality rate and decreases life quality and expectation over the time !!

Rosenfield, Vale, Isner, in: Topol, Textbook of Cardiovascular Medicine, 2nd Ed. Chapter 111: Disease of Peripheral Vessels. Lippincott Williams & Wilkins, 2002
FOOT SURGERY to manage ischaemic & septic complications like abscesses and necrosis

Revascularization usually precedes surgical foot care.
Endovascular Treatment of C.L.I.: common approach

- Antegrade puncture and catheterization! (95% of cases)
- Crossing stenosis: steerable wires
- Crossing occlusions: suitable catheter-wire system (*angled wire + straight cath or angled cath + straight wire*)
- Crossing heavily calcified lesions: stiff .014 - .035 wires with hydrophilic coating and preformable stiff tip
- Balloon dilatation: new generation of low profile, very long, high pressure, 1.5-6.0 mm Ø balloon catheter
- Stenting: Provisional (*mostly self-expandable*)
- Cutting Balloon and Rotablator: in 2-3% of procedures
- Aspiration Thrombectomy or Embolectomy if necessary
- New-generation of Atherectomy-catheters: for long in-Stent restenosis
How to reopen a chronically occluded tibial artery

“different solutions for the same problem”
.035 gw in the Pedal Artery
Ideal Device Characteristics for Optimal BTK Balloon Angioplasty

- **Low profile**: able to cross occlusions without predilatation
- **Low compliance**: minimal Ø increments at high pressure
- **High resistance to abrasion**: to avoid balloon damage when crossing heavily calcified occlusions
- **Suitable balloon length and diameter**
- **Tapered to .014 guide wire**: to be used with all brands of specialized coronary wires
- **Over-The-Wire structure**: is superior to *rapid exchange* in crossability and pushability, and even allows selective injections of contrast media or drugs
New balloon catheter generation for complex & diffuse BTK lesions

- Up to 120 mm long balloons
- Very low profile
- Scratch resistant
- Low compliance
- High RBP: 16 bar (max 20 Atm)
- Over the wire coaxial design
Interventions in CLI and prevalent BTK lesions: **Device Consumption**

Study performed on **376** consecutive CLI patients, 90% diabetics

- 5 Fr Balloons: 0.7 (35%)
- 3.5 Fr Small Vessel Balloons: 1.13 (56%)
- Coronary Balloons: 0.17 (9%)
- Stent: 0.18 (17.9%), 90% Self Expandable

**EVERY PROCEDURE REQUIRED 2.0 BALLOONS AND 0.18 STENTS**

STENT IMPLANTATION WAS NECESSARY IN NO MORE THAN 18% OF CASES

IN 2% OF CASES CATHETER FIBRINOLYSIS OR ASPIRATION THROMBECTOMY WAS EMPLOYED

RARELY ROTABLATOR, CUTTING BALLOON or OTHER DEVICES WERE USED

!!! ANTEGRADE APPROACH PERFORMANCE IN 95% OF CASES !!!
The Stent Dilemma

*(To Stent or Not To Stent, That is the Question...)*

(Our Strategy, for CLI and BTK Lesions):

- Extensive use of Optimal Balloon Angioplasty (P.O.B.A.) !!
- **Provisional Stenting** in a few selected cases: Localized True Bifurcating Lesion with Plaque Shifting, Persistent Recoil, non-Removable Thrombus, Obstructive and localized Dissection
- **Elective Stenting** in Stenosis of By-pass Graft Anastomosis
- **Self-Expandable Stents** preferable in many cases
- **Avoid** putting Stents in the middle Popliteal and medium-distal Tibials
- **No Stents** in the Foot Arteries!

NB: Actually Crural Stenting (mostly using coronary Stents) accounts for about 2% of our BTK procedures.
Do we have to avoid using Balloon-Expandable Stents in some specific BTK segments?

Risk of Stent crushing during routine manual pulse palpation attempt!

Risk of Stent crushing by the Cuff during routine ABI measurement!

No Stent here!

Joint !!!
F.A.Q. about Extreme Vascular Interventions

- Is it feasible in most patients?
- How long does the benefit last?
- Is PTA intervention really effective in reducing amputation rate?
- How often does intervention need to be repeated?

Evidence on Below The Knee interventions: what is it proved?
Peripheral angioplasty as the first-choice revascularization procedure in diabetic patients with critical limb ischemia with or without foot ulcer: prospective study of 1,188 consecutive patients hospitalized and followed between 1999 and 2003.

Ezio Faglia, MD; Luca Dalla Paola, MD; Lanfroi Graziani, MD; Jacques Clerissi, MD; Massimiliano Fusaro, MD; Giacomo Clerici, MD; Livio Gabrielli, MD; Sergio Losa, MD; Andrea Stella, MD; Mauro Gargiulo, MD; Manuela Mantero, MD; Maurizio Caminiti, MD; Sasa Ninkovic, MD; Vincenzo Curci, MD; Alberto Morabito, PhD.

European Journal of Vascular and Endovascular Surgery (manuscript number EJVES2363),
Recommended for publication, October 6th, 2004.
The cumulative rate of major amputation in PTA-revascularized patients was 4.0%.

157 patients (13.2%) underwent surgical revascularization. In this group 8.3% underwent major amputation.

Out of the 47 subjects not revascularized (5 anesthesiology risk, 4 patient refusal, 38 not considered by the Vascular Surgeon as candidates for By-Pass Surgery), 34.0% underwent major amputation.

Clinical recurrence rate was 12.5%, with an incidence of 7.1% per year.

In 85.4% of clinical recurrences, a second PTA was successfully performed.
Thanks For Your Attention
END OF THE PRESENTATION
Peripheral angioplasty and limb salvage in 1,188 consecutive diabetic patients

Stenoses (number of, >4 cm of length or multiple) and Occlusions (number of, >2 cm of length or multiple) in every artery of the ischemic limb and successful PTA procedures performed

<table>
<thead>
<tr>
<th>artery</th>
<th>stenoses</th>
<th>multiple or length &gt; 4 cm</th>
<th>successful PTA</th>
<th>occlusions</th>
<th>multiple or length &gt; 2 cm</th>
<th>successful PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>iliac trunk</td>
<td>65</td>
<td>29 (44.6%)</td>
<td>65 (100%)</td>
<td>6</td>
<td>3 (50.0%)</td>
<td>6 (100%)</td>
</tr>
<tr>
<td>profunda femoral</td>
<td>31</td>
<td>16 (51.6%)</td>
<td>25 (80.6%)</td>
<td>6</td>
<td>1 (16.7%)</td>
<td>5 (83.3%)</td>
</tr>
<tr>
<td>superficial femoral</td>
<td>343</td>
<td>266 (77.6%)</td>
<td>341 (99.4%)</td>
<td>185</td>
<td>123 (66.5%)</td>
<td>142 (76.8%)</td>
</tr>
<tr>
<td>popliteal</td>
<td>221</td>
<td>92 (41.6%)</td>
<td>215 (97.3%)</td>
<td>86</td>
<td>47 (54.7%)</td>
<td>77 (89.5%)</td>
</tr>
<tr>
<td>anterior tibial</td>
<td>235</td>
<td>188 (80.0%)</td>
<td>215 (91.5%)</td>
<td>589</td>
<td>530 (90.0%)</td>
<td>142 (24.1%)</td>
</tr>
<tr>
<td>posterior tibial</td>
<td>218</td>
<td>164 (75.2)</td>
<td>185 (84.7%)</td>
<td>725</td>
<td>679 (93.7%)</td>
<td>83 (11.4%)</td>
</tr>
<tr>
<td>peroneal</td>
<td>337</td>
<td>241 (71.5%)</td>
<td>284 (84.3%)</td>
<td>342</td>
<td>257 (75.1%)</td>
<td>88 (25.7%)</td>
</tr>
</tbody>
</table>
Follow-up

- 1,169 (98.4%) patients were followed over a period of 5 years.
- The mean follow-up was 20 ± 15 months, range 0 - 60 months, median 17 months.
CLINICAL RECURRENCE

- Pain, Ulcer Worsening or its Recurrence
  ABI and TcPO$_2$ values were assessed beforehand, 3-6 days after PTA and every 3-6 months after ulcer healing and if worse (<15% of the post PTA) Duplex Scanning was used for confirmation.
  If positive, a new PTA was scheduled.
Peripheral angioplasty and limb salvage in 1,188 consecutive diabetic patients

TcPO2 values distribution by 10 mmHg classes before (N = 993) and after (N = 937) PTA in study population
Peripheral angioplasty and limb salvage in 1,188 consecutive diabetic patients

Number of patients with obstructions in the infrapopliteal arteries before and after PTA (N = 993)

- **Before PTA**
  - No obstructions: 76
  - 1 obstructed artery: 102
  - 2 obstructed arteries: 328
  - 3 obstructed arteries: 487

- **After PTA**
  - No obstructions: 326
  - 1 obstructed artery: 495
  - 2 obstructed arteries: 162
  - 3 obstructed arteries: 10
Peripheral angioplasty and limb salvage in 1,188 consecutive diabetic patients: Primary Clinical Patency

Eur J Vasc Endovasc Surg *(manuscript number EJVES2363)*

<table>
<thead>
<tr>
<th>Years</th>
<th>Patients</th>
<th>Primary Clinical Patency</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>993</td>
<td>100%</td>
<td>-</td>
</tr>
<tr>
<td>1</td>
<td>606</td>
<td>91%</td>
<td>0.89-0.93</td>
</tr>
<tr>
<td>2</td>
<td>320</td>
<td>89%</td>
<td>0.87-0.91</td>
</tr>
<tr>
<td>3</td>
<td>150</td>
<td>87%</td>
<td>0.84-0.90</td>
</tr>
<tr>
<td>4</td>
<td>57</td>
<td>86%</td>
<td>0.82-0.89</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>86%</td>
<td>0.82-0.89</td>
</tr>
</tbody>
</table>

Primary patency at clinical exam over 5 years (%). The mean follow-up was 20.2 ± 15.1 months, range 0.6 - 60 months, average 16.9 months.
### Complications and their treatment in the PTA group patients (N = 993).

<table>
<thead>
<tr>
<th>Complication</th>
<th>N</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sudden death following PTA</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2</td>
<td>intensive care unit</td>
</tr>
<tr>
<td>Angina</td>
<td>2</td>
<td>medical treatment</td>
</tr>
<tr>
<td>Cardiac arrhythmia</td>
<td>1</td>
<td>intensive care unit</td>
</tr>
<tr>
<td>Chest pain</td>
<td>1</td>
<td>investigation, no treatment</td>
</tr>
<tr>
<td>Left ventricular failure</td>
<td>1</td>
<td>medical treatment</td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>1</td>
<td>medical treatment without dialysis</td>
</tr>
<tr>
<td>Haematoma</td>
<td>3</td>
<td>transfusion</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>investigation, no treatment</td>
</tr>
<tr>
<td>Access site pseudoaneurysms</td>
<td>5</td>
<td>surgical treatment</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>surgical treatment plus transfusion</td>
</tr>
<tr>
<td>Distal thrombosis</td>
<td>7</td>
<td>thrombolysis effectiveness</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>by-pass graft</td>
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<tr>
<td></td>
<td>1</td>
<td>above the knee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>amputation</td>
</tr>
<tr>
<td>Cholesterol embolism</td>
<td>1</td>
<td>medical therapy</td>
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</table>