FRANCESCO STILO

Ischemia critica periferica:
trattamento endovascolare o chirurgico?

Trattamento chirurgico

VASCULAR SURGERY UNIT
UNIVERSITY CAMPUS BIOMEDICO OF ROME
Il sottoscritto

ai sensi dell’art. 76 comma 4 dell’Accordo Stato-Regioni del 2 febbraio 2017 e in accordo con il Codice Etico della SIMI

dichiara

per l’evento in oggetto che non vi è l’esistenza negli ultimi due anni di rapporti di natura finanziaria e lavorativa con le seguenti imprese commerciali operanti in ambito sanitario
TASC Morphological Criteria no more followed by aggressive EV therapy due to the consensus: “EV first strategy”
When should Open Surgery be the Initial Option for Critical Limb Ischaemia?  
P.F. Lawrence  

THE ACTUAL DEBATE:  
FIRST CHOICE BETWEEN EV and BYPASS FOR FEM-POP LESIONS  

DOES FAILED EV AFFECT RESULTS OF SUBSEQUENT OPEN SURGERY?
Prior failed ipsilateral percutaneous endovascular intervention in patients with critical limb ischemia predicts poor outcome after lower extremity bypass.

239 PTA in 192 pts

Above Knee TASC C and D limbs predicting factors of occlusion after stenting (\(P < .0001\))
require open operation (\(P .032\))
lose run-off vessels (\(P .0034\))

10 patients with stent failure required operation, and 50% underwent amputation.

Although these complications are infrequent, this must be considered when deciding upon the proper treatment strategy.
2000-2008
409 limbs in 298 patients were treated: 44% claudication and 56% CLI.
age <50 years (group A)
51 to 60 years (group B)
>60 years (control group C).

Overall secondary patency were significantly lower in group A (68.2%; P.045) vs B (86.8%; P .01) and C (83.9%; P < .001).
Claudicant pts in group A had an unexpectedly low 2-year freedom from major amputation after intervention of only 90%.

Predictors of loss of patency:
- age <50 years (P 0.003)
- EV revascularization (P 0.005)

Age <50 years was also an independent predictor of limb loss vs age >60 years (P 0.05).

Conclusions: EV are commonly being used in young patients with claudication, but patency rates and outcomes remain very poor.
A meta-analysis, searching PubMed, EMBASE, the Cochrane Central Register of Controlled Trials, ISI Web of Knowledge, for randomized trials that compared primary stenting with PTA in patients with infrapopliteal arterial occlusive disease.

The keywords were "stents," "angioplasty," "infrapopliteal," "tibial arteries," and "below knee."

6 prospective randomized trials.

One-year outcomes did not show any significant differences between the PTA and primary stenting groups, respectively: technical success (93.3% vs 96.2%; odds ratio [OR], 0.59; 95% confidence interval [CI], 0.24-1.47; P = .25), primary patency (57.1% vs 65.7%; OR, 0.95; 95% CI, 0.35-2.58; P = .92), secondary patency (73.5% vs 57.6%; OR, 2.08; 95% CI, 0.81-5.34; P = .13), limb salvage (82.2% vs 87.5%; OR, 0.64; 95% CI, 0.29-1.41; P = .27), and patient survival (84.0% vs 87.5%; OR, 0.79; 95% CI, 0.40-1.55; P = .49).

**TECHNICAL SUCCESS @ 1 YEAR 93%**

**SECONDARY PATENCY @ 1 YEAR 73%**

**LIMB SALVAGE @ 1 YEAR 82%**

..... ALMOST 20% OF LIMB LOSS
A retrospective review (2006-2010) of 106 patients undergoing endovascular therapy for critical limb ischemia with tissue loss

<table>
<thead>
<tr>
<th>Clinical presentation</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Rutherford class 5</td>
<td>88%</td>
</tr>
<tr>
<td>Rutherford class 6</td>
<td>12%</td>
</tr>
<tr>
<td>Ischemia with ulceration and/or gangrene of the heel</td>
<td>15%</td>
</tr>
<tr>
<td>Forefoot</td>
<td>16%</td>
</tr>
<tr>
<td>Toe(s)</td>
<td>43%</td>
</tr>
<tr>
<td>Calf/ankle</td>
<td>11%</td>
</tr>
<tr>
<td>Multiple locations</td>
<td>15%</td>
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Severity of tissue loss and severe comorbidities are associated with poorer outcomes of endovascular therapy: 50% wound healing and 20% survival at 4 yrs
TASC C and D ANATOMY AND TISSUE LOSS: A VERY ADVANCED VASCULAR DISEASE
Bradbury on behalf of the BASIL trial Investigators and Participants. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial in perspective. J Vasc Surg 2010;51

The only RCT up to now

Half of patients follow-up @5y

Recommendation is to choose the revascularization on the basis of life expectancy and presence of vein:

- < 2 years EV first
- > 2 years Surgery first; where vein is available

Vein better than prosthetic bypass in terms of AFS

Most patients would have been better served by an attempt at EV rather than prosthetic bypass if no suitable vein

...but...Patients who underwent bypass surgery after failed EV fared significantly worse than those who underwent bypass as their first treatment
….. ONE AMONG
20% of bad cases for EV...

..IS A GOOD VEIN GRAFT
ON DISEASED RUNOFF
WITH LIMB SALVAGE
Extreme Surgery

BYPASS TO THE PEDAL and PLANTAR ARTERIES
INFLOW VESSELS

ILIAC ARTERY  5.5%
COMMON FEMORAL ARTERY  37%
SUPERFICIAL FEMORAL ARTERY  12%
PROFUNDA FEMORIS  8%
POPLITEAL ARTERY  37%

92% of cases performed through autologous material
In absence of greater saphenous vein, first choice has been omolateral lesser saphenous vein

Primary patency after 24 months  65%

*Lesser Saphenous Vein (LSV) in distal revascularisation for limb salvage*

F. SPINELLI *et al.*

*Italian Journal of Vascular and Endovascular Surgery 2001; 8: 97-110*

BY-PASS with inverted ex-situ lesser saphenous and Giacomini vein
Results of a policy with arm veins used as the first alternative to an unavailable ipsilateral greater saphenous vein for infrainguinal bypass

Thomas J. Hölzenbein, Frank B. Pomposelli et al.

*J Vasc Surg 1996; 23:130-40*

Secondary patency 56,7% after 36 months

Limb salvage 67,1% after 36 months
In absence of venous material

**Venous interposition fistula following the Ascer procedure**

Primary patency after 36 months  
Spinelli 62%  
Ascer 65%

Limb salvage after 36 months  
Spinelli 66%  
Ascer 78%

**Distal revascularisation of lower limbs using prosthetic bypass and venous interposition fistula following the Ascer procedure**  
F. SPINELLI et al.  

**Complementary distal arteriovenous fistula and deep vein interposition: A five-year experience with a new technique to improve infrapopliteal prosthetic bypass patency**  
E. ASCER et al.  
*Journal of Vascular Surgery* 1996; 24: 134-143
Conclusions: patients who undergo EV and OS are not directly comparable. EV is for medically higher-risk patients. Bypass have more complex disease and are more likely to require multilevel reconstruction and infrapopliteal intervention.

December 2002 to September 2010 433 pts
(EV 295 patients, 363 limbs; OS: 138 patients, 151 limbs
30-day mortality was 2.8% in EV and 6.0% in OS (P .079).

Predictors of limb loss: poor conditions, dialysis, gangrene, infrapopliteal diseases, and diabetes.

Individualizing revascularization results in optimization of early and late outcomes with acceptable Limb Salvage.
U.S.A.M.
UltraSound Arterial Mapping

Extensive calcifications
Three leg vessels disease

HOW TO AVOID FAILURES and BAD OUTCOMES?
Preoperative morphological and functional DUS evaluation for TASC II C and D patients

PSV <20 cm/sec at ankle
SRT > 1/4 of cardiac cycle

monophasic (low outflow resistance)
Rutherford 5-6

PREDICTIVE CRITERIA
- TASC II D anatomy
- Extensive calcification
- Poor outflow

None → High-risk pt  → no vein

One or more  → Good risk pt  → EV

vein available  → EV failure

BYPASS
From January 2010 to December 2015

1273 pts with multilevel or infrapopliteal disease

726 (57%) BYPASS (BP)
547 (43%) ENDOVASCULAR PROCEDURES (EV)

… referral center for open surgery
With mostly secondary procedures (33%) .....24% of Primary Bypass
<table>
<thead>
<tr>
<th></th>
<th>BP N (%)</th>
<th>EV N (%)</th>
<th>P</th>
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<tbody>
<tr>
<td>RUTHERFORD 4</td>
<td>131 (18)</td>
<td>235 (43)</td>
<td>&gt;0.001</td>
</tr>
<tr>
<td>RUTHERFORD 5</td>
<td>378 (52)</td>
<td>186 (34)</td>
<td>&gt;0.001</td>
</tr>
<tr>
<td>RUTHERFORD 6</td>
<td>217 (30)</td>
<td>126 (23)</td>
<td>n.s.</td>
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Rutherford 4: 3% of first bp
Rutherford 5: 11% of first bp
Rutherford 6: 10% of first bp

Rutherford 4: BP 36%
Rutherford 5: BP 67%
Rutherford 6: BP 64%
LONG TERM RESULTS of CLI patients

SURVIVAL 60.9% @ 5 YEARS

AMPUTATION-FREE SURVIVAL 45.6% @ 5 YEARS

<table>
<thead>
<tr>
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<th>TOTAL</th>
<th>BP</th>
<th>EV</th>
<th>P</th>
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<tbody>
<tr>
<td>LESIONS HEALING</td>
<td>85.2%</td>
<td>93.2%</td>
<td>75.6%</td>
<td>.05</td>
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<tr>
<td>@ 24 months</td>
<td></td>
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<tr>
<td>PAIN REMISSION</td>
<td>61.2%</td>
<td>90.5%</td>
<td>48.3%</td>
<td>.01</td>
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<tr>
<td>@ 24 months</td>
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FOLOOW-UP
Mean 22.25 months
409 assistance procedures (43%)
1.5% lost of follow-up
39 amputations (27 AK, 12 BK)
CONCLUSIONS

Ev for infrapopliteal CLI or multilevel disease: 90% of technical success with 80% limb salvage at one year
20% of pts, mostly with TASC II C and D anatomy, calcifications, dialysis dependancy and tissue loss, eventually lose their limbs

Among patients with similar features, those who have a suitable vein and a fair life expectancy are best treated with an open Bypass
By offering an open bypass to such patients we could improve the results of EV, and the outcomes of the whole series

In our series Limb salvage 87% and cumulative survival 77% @12 months