A randomized comparison of endovascular versus surgery treatment of common femoral artery disease: Results from the TECCO trial
(TECCO randomized clinical trial, NCT01353651)


On behalf of AURC
Disclosure

Speaker name: Yann Gouëffic

I do not have any potential conflict of interest related to this presentation
Postoperative complications after common femoral endarterectomy

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- **1843 CFEs,** Diabetes: 33%; CLI: 36%
- CFE between 2005-2010 from the ACS-NSQIP database
- Perioperative morbimortality outcomes before and after hospital discharge
- **Morbi-mortality rates 15%**
- Average length of stay: 4.6 ± 7.5 d

**Conclusions:** CFE is not as “benign” a procedure as previously believed. The risks of death and wound complications are not insignificant, and a high percentage of these complications occurred after patients were discharged from the hospital. Patients should be carefully selected, especially in the elderly population, and close postoperative follow-up should be considered. (J Vasc Surg 2015;61:1489-94.)
Key findings:

- 360 limbs / CLI: 22.1%
- Lost of FU @ 10mo: 12.2%
- Perioperative complications: 6.4%
- Restenosis rate: 27.6%
  - TLR: 19.9%

The use of stents was identified as the only independent protective factor against procedural failure, TLR and 1-year restenosis.

Bonvini, JACC, 2011

Key findings:

- 98 limbs / CLI: 19%
- De novo / restenosis: 85/15%
- Perioperative complications: 6.4%
- Bailout stenting: 27%
  - TLR: 17/46%

Primary sustained clinical improvement was significantly better in patients in whom stents had been implanted.

Baumann, J Vasc Surg, 2011
**Pilot study 2006-2008** (Azéma, Eur J Vasc Endovasc Surg, 2011)

40 limbs – Primary stenting

Perioperative morbi-mortality rate: 5%

Iy clinical improvement @ 1y: 80%

TLR free @ 1-y: 85%

In-stent restenosis rate*: 20%

Stent fracture**: 2.5%

* Defined systolic velocity peak index > 2.4

** according Jaff M., Catheter Cardiovasc Interv 2007
TECCO trial

French multicenter randomized trial comparing surgery versus stenting for the treatment of CFA atherosclerotic lesion (From 2011 to 2015)

17 centers: CHU de Nantes (N°1), CHU de Amiens (N°2), CHU Besançon (N°3), CHU de Strasbourg (N°4), CHU de Dijon (N°5), CHU de Clermont-Ferrand (N°6), CHU de Nice (N°7), CHU de Marseille (La Timone) (N°8), CHU de Bordeaux (N°9), CHU de Lyon (N°10), CHU de St Etienne (N°11), CHU de Rouen (N°12), Clinque du Tonkin (N°13), Nouvelles Cliniques Nantaises (N°14), Clinique St Augustin (N°15), HEGP (N°16),) Hopital Henri Mondor (N°17)

TECCO randomized clinical trial, NCT01353651
Gouëffic, JACC Interv, 2017
TECCO trial protocol

Sponsor: Nantes University Hospital - TECCO trial, NCT01353651

- Investigator initiated study
- RCT multicenter and controlled
- Rigorous data collection process, independent
- Adjudication by:
  - Duplex ultrasound core laboratory
  - Data safety monitoring board
- Follow-up includes
  - 1, 6, 12, and 24-month clinical assessment
  - 1, 12 and 24-month stent x-ray
- Monitoring with 100% source data verification

- Modified intent to treat analysis / Per protocol analysis
- Sample size calculation: 120 patients
- Randomly assigned in a 1:1 ratio
- 80% power to detect a between-group difference of 20% percentage points in the morbid-mortality rate at a two-sided alpha level of 0.05 (25% in the surgery group and 5% in the stenting group).
Population

Main inclusion criteria
- Age between 40 and 90 years-old
- De novo atheromatous common femoral artery stenosis
  - Rutherford stages 3 to 6

Main exclusion criteria
- Restenosis
- Thrombosis
  - No atheromatous disease
  - Asymptomatic lesion
  - Life expectancy < 1 year
CFA lesions classification

Type 1
Nitinol

Type 2
Nitinol

Type 3
Nitinol and/or BES

Type 4
Nitinol

Azema, Eur J Vasc Endovasc Surg, 2011
Procedures

Open repair
At the discretion of the physician (bypass, endarterectomy...)

Endovascular repair
- Anaesthesis: at the discretion
- Over the bifurcation, ipsilateral or brachial approaches
- Primary stenting
- Antiplatelet treatment: at the discretion
Morbid-mortality rate at 1 month

- **General complications**: death, MACEs, major amputation
- **Local complications** that required rehospitalization and/or reintervention: hematoma, thrombosis, lymphorrhea, delayed wound healing, false aneurysm, AVF
- **Paresthesia** that required drugs
120 were included
3 were not randomized and withdrawn
1 patients with life expectancy < 1 year
2 patients without common femoral artery lesion

117 Underwent randomization

61 Were assigned to surgery group
58 Underwent assigned intervention
3 Did not undergo assigned intervention
  2 Withdrew consent
  1 Change group to stenting group

56 Were assigned to stenting group
54 Underwent assigned intervention
2 Did not undergo assigned intervention
  1 Withdrew consent
  1 Change group to surgery group

43 Completed 24 months follow-up
  5 Discontinued study
    3 lost to follow-up
    1 was withdrawn by investigator
    1 death

42 Completed 24 months follow-up
  7 Discontinued study
    4 lost to follow-up
    3 deaths
### Demographic data

#### Table: Demographic Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Surgery (N=61)</th>
<th>Stenting (N=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age – yr</strong></td>
<td>68 ± 8</td>
<td>68 ± 9</td>
</tr>
<tr>
<td>Male sex – no. (%)</td>
<td>51 (84)</td>
<td>48 (86)</td>
</tr>
<tr>
<td>Hypertension – no (%)</td>
<td>44 (72)</td>
<td>45 (80)</td>
</tr>
<tr>
<td>Hyperlipidemia – no (%)</td>
<td>40 (66)</td>
<td>37 (66)</td>
</tr>
<tr>
<td><strong>Diabetes mellitus – no (%)</strong></td>
<td>25 (41)</td>
<td>17 (31)</td>
</tr>
<tr>
<td>Smoking at baseline – no (%)</td>
<td>28 (46)</td>
<td>26 (46)</td>
</tr>
<tr>
<td>Coronary artery disease – no (%)</td>
<td>28 (46)</td>
<td>27 (48)</td>
</tr>
<tr>
<td><strong>Renal insufficiency – no (%)</strong></td>
<td>8 (13)</td>
<td>6 (11)</td>
</tr>
<tr>
<td>On dialysis – no (%)</td>
<td>1 (13)</td>
<td>1 (17)</td>
</tr>
<tr>
<td>Obesity (BMI &gt; 25) – no (%)</td>
<td>39 (64)</td>
<td>31 (58)</td>
</tr>
<tr>
<td>Statin treatment – no (%)</td>
<td>50 (82)</td>
<td>38 (68)</td>
</tr>
<tr>
<td>Antiplatelet drug – no (%)</td>
<td>57 (93)</td>
<td>50 (89)</td>
</tr>
<tr>
<td>ACE inhibitor – no (%)</td>
<td>19 (31)</td>
<td>22 (39)</td>
</tr>
<tr>
<td><strong>Rutherford stage of PAD – no (%)</strong></td>
<td>2 (3)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>2</td>
<td>2 (3)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>3</td>
<td>54 (89)</td>
<td>44 (80)</td>
</tr>
<tr>
<td>4</td>
<td>5 (8)</td>
<td>7 (13)</td>
</tr>
<tr>
<td>5</td>
<td>0 (0)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Type</td>
<td>Surgery (%)</td>
<td>Stenting (%)</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Type 1</td>
<td>6 (10)</td>
<td>9 (16)</td>
</tr>
<tr>
<td>Type 2</td>
<td>21 (34)</td>
<td>13 (23)</td>
</tr>
<tr>
<td>Type 3</td>
<td>34 (56)</td>
<td>34 (61)</td>
</tr>
</tbody>
</table>
## Intraoperative data

<table>
<thead>
<tr>
<th>Surgery (N=58)</th>
<th>Stenting (N=54)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endarterectomy</strong></td>
<td><strong>Crossover access – no. (%)</strong> 43 (78)</td>
</tr>
<tr>
<td>with venous patch (%)</td>
<td>Brachial access – no. (%) 7 (13)</td>
</tr>
<tr>
<td>with prosthetic patch (%)</td>
<td>Femoral ipsilateral – no. (%) 4 (7)</td>
</tr>
<tr>
<td>direct suture (%)</td>
<td></td>
</tr>
<tr>
<td><strong>Bypass with a prosthesis</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Eversion</strong></td>
<td></td>
</tr>
<tr>
<td>46 (69)</td>
<td>7 (12)</td>
</tr>
<tr>
<td>37 (64)</td>
<td></td>
</tr>
<tr>
<td>2 (3)</td>
<td></td>
</tr>
<tr>
<td>11 (19)</td>
<td></td>
</tr>
<tr>
<td>1 (2)</td>
<td></td>
</tr>
</tbody>
</table>
### Primary endpoint

#### Modified intent to treat analysis

<table>
<thead>
<tr>
<th></th>
<th>Surgery (n=61)</th>
<th>Stenting (n=56)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morbid-mortality rate @ 1 month, n (%)</td>
<td>16 (26)</td>
<td>7 (12.5)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

#### Per protocol analysis

<table>
<thead>
<tr>
<th></th>
<th>Surgery (n=58)</th>
<th>Stenting (n=47)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morbid-mortality rate @ 1 month, n (%)</td>
<td>16 (26)</td>
<td>3 (6.4)</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>Surgery (N=61)</td>
<td>Stenting (N=56)</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
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<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>Death, n(%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Stroke, n(%)</td>
<td>0 (0)</td>
<td>1 (1.8)</td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction, n(%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Major amputation, n(%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
</tbody>
</table>
# Local complications

*(Modified intent to treat analysis)*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Surgery (N=61)</th>
<th>Stenting (N=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>3 (5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>0 (0)</td>
<td>1 (1.8)</td>
</tr>
<tr>
<td>Lymphorrhea</td>
<td>2 (3.2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Delayed wound healing</td>
<td>10 (16.4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>False aneurysm</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Arteriovenous fistula</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>4 (6.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Local infection</td>
<td>3 (5)</td>
<td>1 (1.8)</td>
</tr>
<tr>
<td>Vascular perforation</td>
<td>0 (0)</td>
<td>1 (1.8)</td>
</tr>
</tbody>
</table>
Survival @ 24 months

Freedom from TLR @ 24 months

Patency @ 24 months

Haemodynamic improvement @ 24 months

Survival:
- Global survival (%)
- Hazard ratio, 1.3 (95% CI, 0.3-6.0)
- P=0.71

Patency:
- Patency (%)
- Hazard ratio, 1.5 (95% CI, 0.5-4.6)
- P=0.48

Freedom from TLR:
- Free from TLR (%)
- Hazard ratio, 0.8 (95% CI, 0.3-2.5)
- P=0.83

Haemodynamic Improvement:
- AB mean, 95% CI
- Baseline, M1, M6, M12, M24

No. at Risk:
- Surgery: 59, 52, 48, 44, 30
- Stenting: 55, 55, 46, 45, 31
- In patients with de novo atherosclerotic lesions of common femoral artery, the perioperative morbi-mortality rate was significantly lower among patients who underwent endovascular therapy by stenting rather than surgery.

- At 2 years of follow-up, clinical, morphological and hemodynamic outcomes are comparable.