CFA stenting experiences to date and insights into the CFA SUPERA study

Y. Gouëffic, MD, PhD
Department of vascular surgery, University hospital of Nantes, France
Disclosures

Research grants /Consulting/Honoraria for

- Abbott
- Bard
- Boston Sc
- Cook
- Medinol
- Medtronic
- Perouse
- Spectranetics
- Terumo
- WL Gore
Male, 68 years-old, rutherford 3
CFA stenting, why not?

- Surgery is « easy »
- Angioplasty alone ?
- Stent fracture, durability ?
  - Calcifications ?
- No compromise future approaches
- 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
40 limbs – Primary stenting

Perioperative morbi-mortality rate: 5%
1y 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

Azéma, Eur J Vasc Endovasc Surg, 2011
At 5 years of FU:
- Ly clinical improvement was 73%
- Freedom from TLR: 79%
- 7 open reinterventions
- 4 endo reinterventions

Conclusions: Endovascular repair of the common femoral artery and its bifurcation seems to provide sustained clinical and morphological long-term results. Fear of stent fracture and local complications due to hip mobility are no longer relevant.

TECCO trial

The TECCO trial was a randomized, multicenter trial comparing surgery versus stenting for the treatment of common femoral artery (CFA) atherosclerotic lesion. The trial was conducted from 2011 to 2015 at 17 centers across France:

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

Type 1  Type 2  Type 3  Type 4

Heavily calcified plaque – Crush risk – No compromise future approaches

Supera® peripheral vascular mimetic implant device (Abbott Vascular)
Supera® could avoid the crush risk

Osteoid metaplasia

Bone marrow

Hérisson, Atherosclerosis, 2011 - Davaine, Eur J Vasc Endovasc Surg, 2015

Carotid and femoral atherosclerotic plaques show different morphology

Fanny Hérisson1,a, Marie-Françoise Laymann1,a, Maude Côté2,a, Clémence Chasseriau3, Sophie Allagga1,a, Paul Hug1,a, Thierry Kersöö1,a, Marc Kengny1,a, Patricia Leman9,a, Domingue Heymans7,a, "Trophee<sup>®</sup> [30A] (19F), Marseille, France

ARTICLE INFO

Introduction

Carotid and femoral atherosclerotic plaques show different morphology. These differences are evidenced at histological level and are highly reproducible.

Osteoid metaplasia

Bone marrow

What The Major AEs Are

Atherosclerotic plaques are a major risk factor for cardiovascular disease and mortality. They have significant impact on surgical and endovascular procedures and outcomes. Thus, it is important to understand the mechanisms underlying the formation of plaques in the arteries.

Bone Like Arterial Calcification in Femoral Atherosclerotic Lesions: Prevalence and Role of Osteoprotegerin and Porocites

J-M. Davaine1,a, T. Guillot1,a, M. Chassignol1,a, P. Gillibert1,a, B. Resn1,a, B. Gouillart1,a, A. Proy1,a, M.A. Serres1,a, B. Hérisson1,a, M. Hérisson1,a, D. Barlaud1,a

Results: We identified 43 femoral plaques (25% of total plaques). Of these plaques, 20% had bone-like calcification and 20% had osteoid metaplasia. There was a significant correlation between osteoid metaplasia and bone-like calcification (p < .001).

The prevalence of bone-like calcification in atherosclerotic plaques has been reported to be as high as 10% and has been identified as an independent risk factor for cardiovascular mortality. Bone-like calcification also has an impact in carotid and femoral plaques.
Male, 71 years-old, rutherford 3

Pre operative angiogram

Pre-inflation
9-40mm

Supera
8-40mm
Stented CFA puncture is possible and safe with Supera® (Abbott)
Physician initiated, prospective, multicenter, single arm trial to evaluate the Supera® Peripheral Vascular Mimetic Implant Device (Abbott Vascular) for symptomatic (R 2-4) CFA disease treatment
Participating centers

Belgium
- AZ. Sint Blasius Hospital Dendermonde
  - K. Deloose (PI), J. Callaert, M. Bosiers
- OLV Hospital Aalst
  - L. Maene, R. Beelen
- ZNA Stuivenberg Hospital Antwerp
  - P. Sels, L. Van Den Eynde
- Imelda Hospital Bonheiden
  - J. Verbist, W. Van Den Eynde

France
- Hôpital Nord Laennec, CHU, Nantes
  - Y. Gouëffic
- Clinique Rhône Durance, Avignon
  - C. Brunet
Take home message

- **Open surgery of CFA** and its bifurcation is not as benign a procedure as believed.

- Endovascular repair of the CFA by **primary stenting** appears as a safe technique of revascularization at long term.

- **TECCO trial** could establish endo as an alternative to open surgery for CFA lesion.

- CFA heavily calcified plaque could make **Supera®** a good choice for this location.
Bi-Biplane X-ray at 36 months for type I CFA lesion

Biplane X-ray at 36 months for type II CFA lesion
Biplane X-ray at 36 months for type III CFA lesion

Biplane X-ray at 36 months for type IV CFA lesion

CFA and its bifurcation are fixed
Balloon expandable bioabsorbable stenting: a failed experiment?

Bioabsorbable stent vs open surgery

Technical success:
97.5/100% (NS)

1-y ly sustained clinical improvement
70/85% (NS)

1-y ly patency
80/100% (p. 0.008)

CFA occlusion was the only significant factor predicting failing CFA stenting

Conclusion: This interim analysis suggests that BASI is not an option for CFA occlusion and is only a limited option for CFA stenosis. Clinical and hemodynamic results are comparable for BASI and CFE. An increased rate of redo procedures in the BASI patients outweighs lower surgical site infection rates compared to CFE. Short-term patency rates are significantly worse in patients undergoing CFA stenting with BASI.
Male, 68 years-old, rutherford 3

Pre operative angiogram

Pre-inflation
6-40 and 8-40mm

Supera
7-40mm
Balloon expandable bioabsorbable stent vs open surgery for CFA lesions (Linni, J Endovasc Ther, 2014)

RCT 1:1 – Controlled - Single-center - Open-label trial

Conclusion: This interim analysis suggests that BASI is not an option for CFA occlusion and is only a limited option for CFA stenosis. Clinical and hemodynamic results are comparable for BASI and CFE. An increased rate of redo procedures in the BASI patients outweighs lower surgical site infection rates compared to CFE. Short-term patency rates are significantly worse in patients undergoing CFA stenting with BASI.
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