CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 23-25 2014
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER PARIS, FRANCE

Drug-eluting devices for the SFA - why and when to treat?

Diabetics: How to Obtain Long Term Results

Bertrand LEHALLE (MD; PhD)

Pôle Vaisseaux & Louis Pasteur Clinic

Nancy - FRANCE

Diabetic patient profiles

- High risk patients (co morbidity)
- High risk of infection
- Major amputations x14

  Fosse S et col. BEH 2006

- No symptoms (??) before ulcers, gangrene

- PAD : more severe/extensive lesions
  - Distal (BTK) + FEMORAL / popliteal lesions

The goal of treatment of SFA

- To remove ischemia
- To ensure an optimal distal (BTK) flow

The SFA decompensation
is a fundamental element in the prognosis of PAD
in diabetic patients

Interest of SFA Stenting

- Advantages:
  - efficacy
  - easy to use
- Disadvantages:
  - risk of in-stent restenosis
  - fracture
  - possible need for reintervention

Diabetic patients:
the goal = **sustained patency (femoro popliteal axis)**

Potential benefits of ZilverPTX (diabetic patients)

- 4-years positive data (Zilver PTX trial)

  Dake MD et al. J Am Coll Cardiol 2013

- 2-years positive data:
  Sub-group of diabetic patients (Zilver PTX trial) vs non diabetic patients

  Fanelli F et al. Cardiovasc Intervent Radiol 2013

ZILVER PTX = SAFETY AND EFFECTIVENESS

- Inflammatory context (processes furthered by the infection: ulcers, gangrene)
  vs late-phase inflammatory response (with DES)

  Tagushi I, Yoneda S et al. 2012, 2013

ZILVER PTX = A PARTICULAR VALUE IN CASE OF CLI ?

Clinical application:

implantation of ZilverPTX as a treatment of choice after SFA angioplasty in diabetic patients *(first results)*

- 207 consecutive diabetic patients (oct 2011 – nov 2013)
- Primary patency:
  - 2 years = 79.5 %
  - 18 months = 86.8%
  - 12 months = 91.4 %
- Clinical criteria:
  - Limb salvage: 100 %
  - Major amputation rate: 0 %
  - Relieving pain / dysesthesia: 100 %
  - 2 years survival rate: 95,2 %

First lesson:

"Zilver PTX = It works great !"

PTA + ZilverPTX stent in SFA disease

= has emerged as a treatment of choice for diabetic patients

To secure the PTA, the choice is made…

		Fanelli F et al. 2013
N	207	285
1 year primary patency	91.4 %	86.6 %
2 years primary patency	79.5 %	
Lesions characteristics :	> 10 cm = 79 %	> 7 cm = 51 %
	> 20 cm = 19 %	> 15 cm = 22 %
Number of lesions	1 : 15 %	1 : 87 % >1 : 13%
Population Male/Female	61 % / 39 %	73 % / 27 %
Age (year)	73.2	67.4
Hypertension	92 %	85 %
Active smoker	11 %	28 %
High risk patients/ MetS: • severe renal insufficiency / hemodialysis	31 %	
• Ischemic heart disease	35 %	
• Obesity	64 %	
• History of stroke	6 %	

Second lesson:
… “even further and rather better”

- Conditions under which patients are treated
- Multidisciplinary care

… Above and beyond these results:

Diabetes: “silent epidemic”

- 285 millions of diabetic around the world (…439 millions in 2030…)
- 400 new cases each day in France
  (5 millions patients in 2020)

- Susceptibility to wounds: 6-12 %
  - Handicaps, disabilities, impairment of quality of life
  - Leading cause of amputation (10.000/year in France - *SNIRAM 2012*)
  - High costs:
    - 30.000 prolonged hospitalization (2012 – France)
    - Up to 20.000 € (wound treatment)
    - 32.000 € (amputation) (*RAY JA et col.* Curr Med Res Opin 2005)

How best to treat our diabetic patients:

The use of ZilverPTX :

essential condition to obtain a lasting result in case of:

- CLI:
  - Limb salvage

How best to treat our diabetic patients:

The use of ZilverPTX :

essential condition to obtain a lasting result in case of:

- Grade 2 or 3: (243.000/year = “foot risk management”)
  - To reduce frequency and severity of PAD complications = Major public health issue
  - To improve the quality of life

Treatment of ischemic situations

this “early stage” benefit from endovascular therapies

Conclusions

The « zero amputation » goal is achievable:

- The use of the right treatment
  - Endovascular therapies with ZilverPTX
- The treatment of high risk and ischemic foots
- The multidisciplinary care