Drug Delivery Beyond Revascularization
3 Center European Experience

Arnaud Kerzmann, MD

CHU Liège

Liège, Belgium

Disclosures

Arnaud Kerzmann, MD

- Grant/Research Support – BD, Medicor, Medtronic

Introduction

- Femoropopliteal percutaneous transluminal angioplasty has better patency rate with paclitaxel-coated balloon than with standard angioplasty at 1[1] and 3 years[2]

- In the meta-analysis of Katsanos et al[2], risk of death is increased at 2 and 5 years when paclitaxel-coated balloons and stents are used in the femoropopliteal artery

[1]*Rosenfield K, et al. Trial of Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease. N Eng J Med 2015;9;373(2):145-53.*

[2]*Schneider PA, et al. Treatment Effect of Drug-Coated Balloons is Durable to 3 Years in the Femoropopliteal Arteries: Long-Term Results of the IN.PACT SFA Randomized Trial. Cir Cardiovasc Interv 2018;11(1):e005891.*

[3]*Katsanos K, et al. Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systemic Review and Meta-Analysis of Randomized Controlled Trials. J Am Heart Assoc 2018;7:e011245*

Introduction

- Our aim was to assess our real-life experience with application of paclitaxel-coated balloons to treat femoropopliteal occlusive disease

Material and methods

- All femoropopliteal percutaneous transluminal angioplasties with paclitaxel-coated balloons were included
- Angioplasties associated with open surgery and angioplasties of femoropopliteal bypasses were excluded
- Performed between 2015 and 2018
- In 3 different Belgian centers: University Hospital of Liège, Princess Paola Hospital of Marche-en-Famenne and Saint-Nicolas Hospital of Eupen

Material and methods

- Retrospective study
- Survival, survival without amputation, and freedom from restenosis and TLR curves were estimated using Kaplan-Meier method
- Multiple Cox regression models were used to examine prognostic factors for survival, survival without amputation, and freedom from restenosis and TLR

Results

- 324 femoropopliteal percutaneous angioplasties were performed in 274 patients
- For statistical reasons, one angioplasty per patient (the first one) was considered
- Mean follow-up of 18 ± 12 months

Table 1. Preoperative characteristics of the patients (N=274)

	N (%)	Mean ± SD
Age (years)	274	70 ± 11
Age ≥ 80	57 (20.8)	
Gender (men)	170 (62.0)	
High blood pressure	217 (79.2)	
Smoking or stopped < 3 years	151 (55.1)	
Diabetes (all types)	107 (39.1)	
Dyslipidemia (all types)	192 (70.1)	
Renal failure without dialysis	71 (25.9)	
Renal failure with dialysis	2 (0.7)	
History of myocardial infarction or coronary stent or coronary bypass	91 (33.2)	
History of stroke or TIA or carotid surgery	47 (17.2)	
Ankle brachial index (ABI)	202	0.67 ± 0.21
Rutherford	274	3.6 ± 1.0
1 to 3	187 (68.3)	
4 to 6	87 (31.7)	

	N (%)
Patency of the BTK trunks (N=274)	
0	7 (2.6)
1	29 (10.6)
2	34 (12.4)
3	203 (74.4)
Chronic total occlusion (CTO)	92 (33.6)
Stenosis	182 (66.4)
Localization	
superficial femoral	168 (61.3)
popliteal	69 (25.2)
superficial femoral + popliteal	37 (13.5)
Length of the lesion (N=274)	
0 to 5 cm	137 (50.2)
5 to 15 cm	111 (40.7)
≥ 15 cm	25 (9.1)

Table 2. Operative characteristics (N=274 procedures)

	N (%)
Predilatation	220 (80.3)
Secondary stent	12 (4.4)
Coated ballon	
Lutonix	167 (60.9)
Stellarex	4 (1.5)
IN.PACT Admiral	99 (36.1)
Lutonix + IN.PACT Admiral	2 (0.7)
Stellarex + IN.PACT Admiral	1 (0.4)
Unspecified	1 (0.4)
Associated procedure	
iliac angioplasty	12 (4.4)
BTK angioplasty	22 (8.0)
minor amputation	7 (2.6)
iliac angioplasty + minor amputation	1 (0.4)
BTK angioplasty + minor amputation	1 (0.4)
iliac angioplasty + BTK angioplasty	1 (0.4)

Table 3. Impact on death risk: multiple Cox

model	Coefficient ± SE	p-value	Hazard Ratio (95%CI)
Age (years)	0.020 ± 0.020	0.31	1.02 (0.98 ; 1.1)
Gender (1=woman)	-0.14 ± 0.40	0.72	0.87 (0.40 ; 1.9)
Dyslipidemia (all types) (1=yes)	-0.72 ± 0.39	0.069	0.49 (0.23 ; 1.06)
Renal failure (1=yes)	**1.4 ± 0.42**	**0.0007**	**4.1 (1.8 ; 9.3)**
Rutherford (0=1 to 3, 1=4 to 6)	**1.0 ± 0.46**	**0.023**	**2.8 (1.2 ; 6.9)**
Localization (1=popliteal)	0.79 ± 0.43	0.066	2.2 (0.95 ; 5.1)
Coated balloon (1=IN.PACT Admiral)	-0.24 ± 0.43	0.58	0.79 (0.34 ; 1.8)
Length of the lesion	0.088 ± 0.35	0.80	1.1 (0.55 ; 2.2)

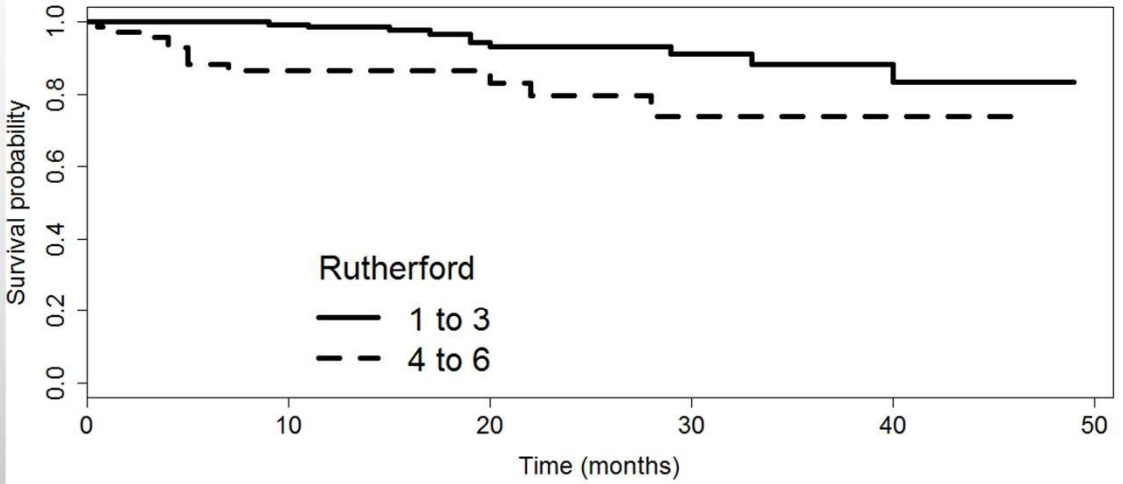


Table 4. Impact on amputation risk: multiple Cox model

	Coefficient ± SE	p-value	Hazard Ratio (95%CI)
Age (years)	0.039 ± 0.026	0.13	1.0 (0.99 ; 1.1)
Gender (1=woman)	**-2.0 ± 0.69**	**0.0040**	**0.14 (0.036 ; 0.53)**
History of stroke or TIA or carotid surgery (1=Yes)	-1.4 ± 0.78	0.077	0.25 (0.055 ; 1.2)
Rutherford (0=1 to 3, 1=4 to 6)	**2.7 ± 0.77**	**0.0004**	**15.1 (3.3 ; 68)**
Patency of the BTK trunks	**-0.72 ± 0.24**	**0.0028**	**0.49 (0.31 ; 0.78)**
Coated balloon (1=IN.PACT Admiral)	-1.2 ± 0.70	0.089	0.30 (0.077 ; 1.2)
Length of the lesion	0.66 ± 0.42	0.12	1.9 (0.85 ; 4.4)

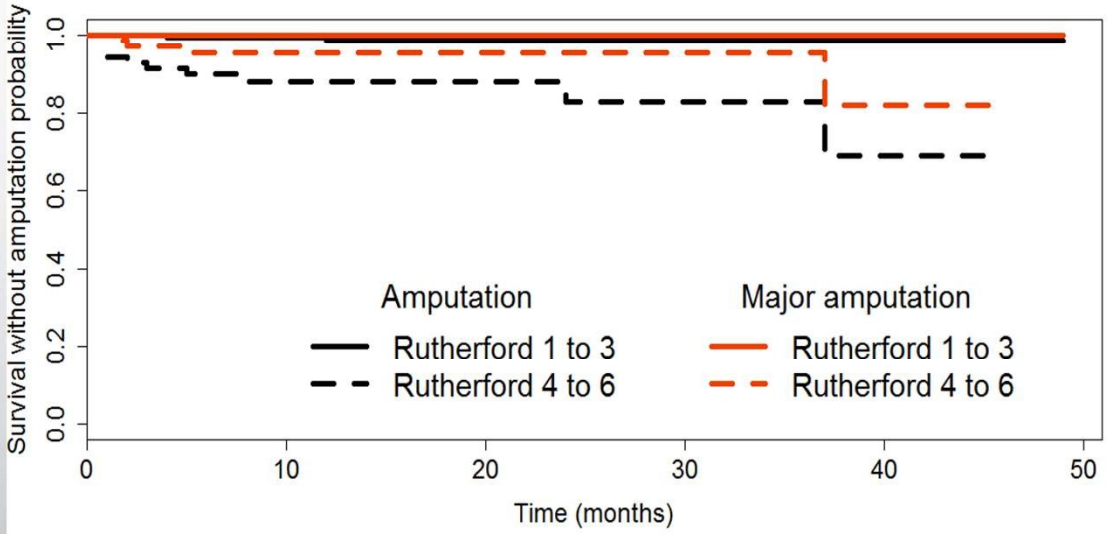
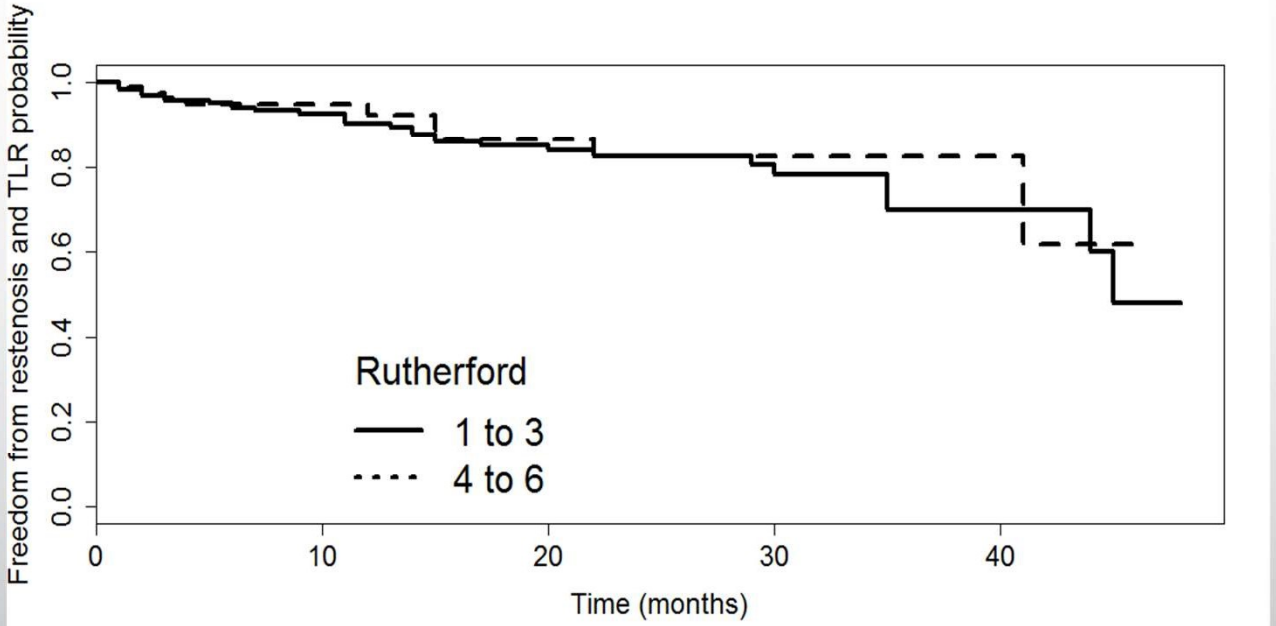


Table 5. Impact on restenosis and TLR curve: multiple Cox model

	Coefficient ± SE	p-value	Hazard Ratio (95%CI)
Age (years)	-0.007 ± 0.017	0.68	0.99 (0.96 ; 1.03)
Gender (1=woman)	0.63 ± 0.33	0.060	1.9 (0.97 ; 3.6)
Rutherford (0=1 to 3, 1=4 to 6)	-0.32 ± 0.40	0.42	0.73 (0.33 ; 1.6)
Patency of the BTK trunks	**-0.56 ± 0.18**	**0.0023**	**0.57 (0.40 ; 0.82)**
Coated balloon (1=IN.PACT Admiral)	**0.73 ± 0.34**	**0.032**	**2.1 (1.1 ; 4.1)**
Length of the lesion	**0.77 ± 0.26**	**0.0027**	**2.2 (1.3 ; 3.6)**



Conclusions

- Our real-life experience with application of paclitaxel-coated balloons in the femoropoliteal artery reveals:

- **Survival:** 91.2% at 1 year and 88.2% at 2 years

  Predicting factors:

  - Renal insufficiency
  - Rutherford category

Conclusions

- Survival **without major amputation:** 98.8% at 1 year

  Predicting factors:

  - Gender
  - Rutherford category
  - Patency of the BTK trunks

Conclusions

- Freedom from **restenosis and TLR:** 90.8% at 1 year and 82.8% at 2 years

  Predicting factors:

  - Patency of the BTK trunks
  - Length of the lesion
  - Use of IN.PACT Admiral balloon