

ABSTRACT

Background: Femoropopliteal percutaneous angioplasty has better patency rate with paclitaxel-coated balloon than with standard angioplasty. Risk of death is increased at 2 and 5 years when paclitaxel-coated balloons and stents are used in the femoropopliteal artery. Our aim was to assess our real-life experience with application of paclitaxel-coated balloons to treat femoropopliteal occlusive disease.

Methods: All femoropopliteal percutaneous angioplasties with paclitaxel-coated balloons performed between 2015 and 2018 in 3 Belgian centres were reviewed retrospectively. Survival, survival without amputation, and freedom from restenosis and target lesion revascularization (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 by 274 patients. Mean age was 70 ± 11 years old. 50% of the lesions were longer than 5 cm. 34% of the lesions were total chronic occlusions. Mean follow-up was 18 ± 12 months. Survival rate was 91,2% at 1 year and 88,2% at 2 years. Predicting factors of survival were renal insufficiency and Rutherford category. Survival without major amputation rate was 98,8% at 1 year. Predicting factors of amputation were gender, Rutherford category and patency of the BTK trunks. Freedom from restenosis and TLR rate was 90,8% at 1 year and 82,8% at 2 years. Predicting factors of freedom from restenosis and TLR were patency of the BTK trunks, length of the lesion and use of InPact Admiral balloon.

Conclusions: Our real-life experience with application of paclitaxel-coated balloons to treat femoropopliteal occlusive disease reveals efficacy of the technique. Randomized controlled trials are mandatory to assess the safety.

BACKGROUND

Femoropopliteal percutaneous transluminal angioplasty has better patency rate with paclitaxel-coated balloon than with standard angioplasty at 1 and 4 years.

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

PURPOSE

Our aim was to assess factors influencing risk of death in our real-life experience with application of paclitaxel-coated balloons to treat femoropopliteal occlusive disease.

METHODS

All femoropopliteal percutaneous transluminal angioplasties with paclitaxel-coated balloons performed between 2015 and 2018 in 3 different Belgian centres (CHU of Liège, Princess Paola Hospital of Marche-en-Famenne and Sankt-Nikolaus Hospital of Eupen) were included and reviewed retrospectively.

Angioplasties associated with open surgery and angioplasties of femoropopliteal bypasses were excluded.

Survival, 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, 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 was 18 ± 12 months.

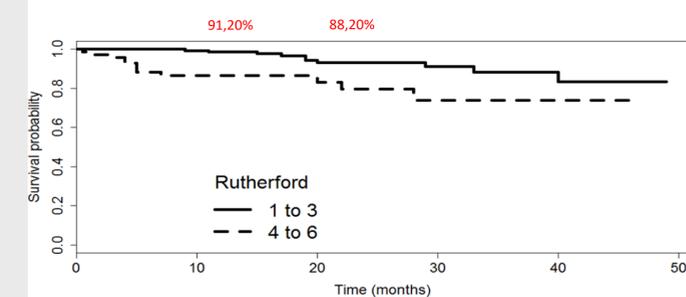
RESULTS

	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)	
Patency of the BTK trunks (N=274)		
none	7 (2.6)	
one	29 (10.6)	
two	34 (12.4)	
three	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)	
Predilatation	220 (80.3)	
Secondary stent	12 (4.4)	
Coated balloon		
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)	

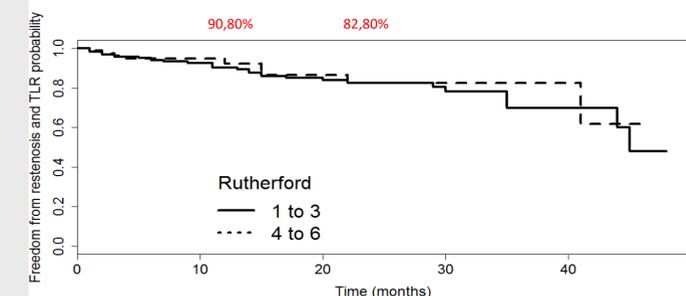
CONCLUSION

In our experience, renal failure and Rutherford classification 4-6 are the only factors influencing survival when paclitaxel-coated balloons are used in the femoropopliteal artery.

	Impact on death risk		
	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)



	Impact on restenosis and TLR curve		
	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)



DISCLOSURES

A. Kerzmann, MD

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