CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 19-21 2017
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

Paclitaxel-coated versus Plain Balloon Angioplasty in the Treatment of Infrainguinal Vein Bypass Stenosis

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Disclosure

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- ☐ I have the following potential conflicts of interest to report:
- ☐ Consulting
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☑ I do not have any potential conflict of interest

Background

- Treatment of bypass stenoses
- Vascular injury after PTA
- Neointimal hyperplasia
- Antiproliferative substances[1]
- New techniques to achieve greater efficacy[2]
- PACIFIER trial and LEVANT I study[3,4]

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2. Scheller B, Speck U, Abramjuk C, Bernhardt U, Bohm M, Nickenig G. Paclitaxel balloon coating, a novel method for prevention and therapy of restenosis. Circulation 2004;110:810-814
3. Werk M, Albrecht T, Meyer DR, Ahmed MN, Behne A, Dietz U, et al. Paclitaxel-coated balloons reduce restenosis after femoropoliteal angioplasty. Evidence from the randomized PACIFIER trial. Circ Cardiovasc Intervent 2012;5:831-40
4. Scheinert D, Duda S, Zeller T, Krankenberg H, Ricke J, Bosiers M, et al. The LEVANT I (Lutonix paclitaxel-coated balloon for the prevention of femorpopliteal restenosis) trial for femoropopliteal revascularization. JACC Cardiovasc Intervent 2014;7(1):10-19

Aim of the Study

- Patency

- Hemodynamic improvement
- Clinical improvement
- Limb salvage
- Survival

Study Endpoints

- PRIMARY
  - Primary patency
  - Secondary patency
- SECONDARY
  - Clinical improvement
  - Hemodynamic improvement
  - Limb salvage
  - Survival

Graft „at-risk“

Significant (>70%) bypass stenosis verified by duplex (peak systolic velocity < 45 cm/s or >300cm/s or peak systolic velocity ratio > 4)[5,6]

5. Mills JL Sr, Wixon CI, James DC, Devine J, Westerband A, Hughes JD. The natural history of intermediate and critical vein graft stenosis: recommendations for continued surveillance or repair. J Vasc Surg 2001;42:59-77

6. Davies AH, Magee TR, Tennant SG, Lamont PM, Baird RN, Horrocks M. Criteria for the identification of the “at-risk” infrainguinal bypass graft. Eur J Vasc Surg 1994;8:315-98.

Technique

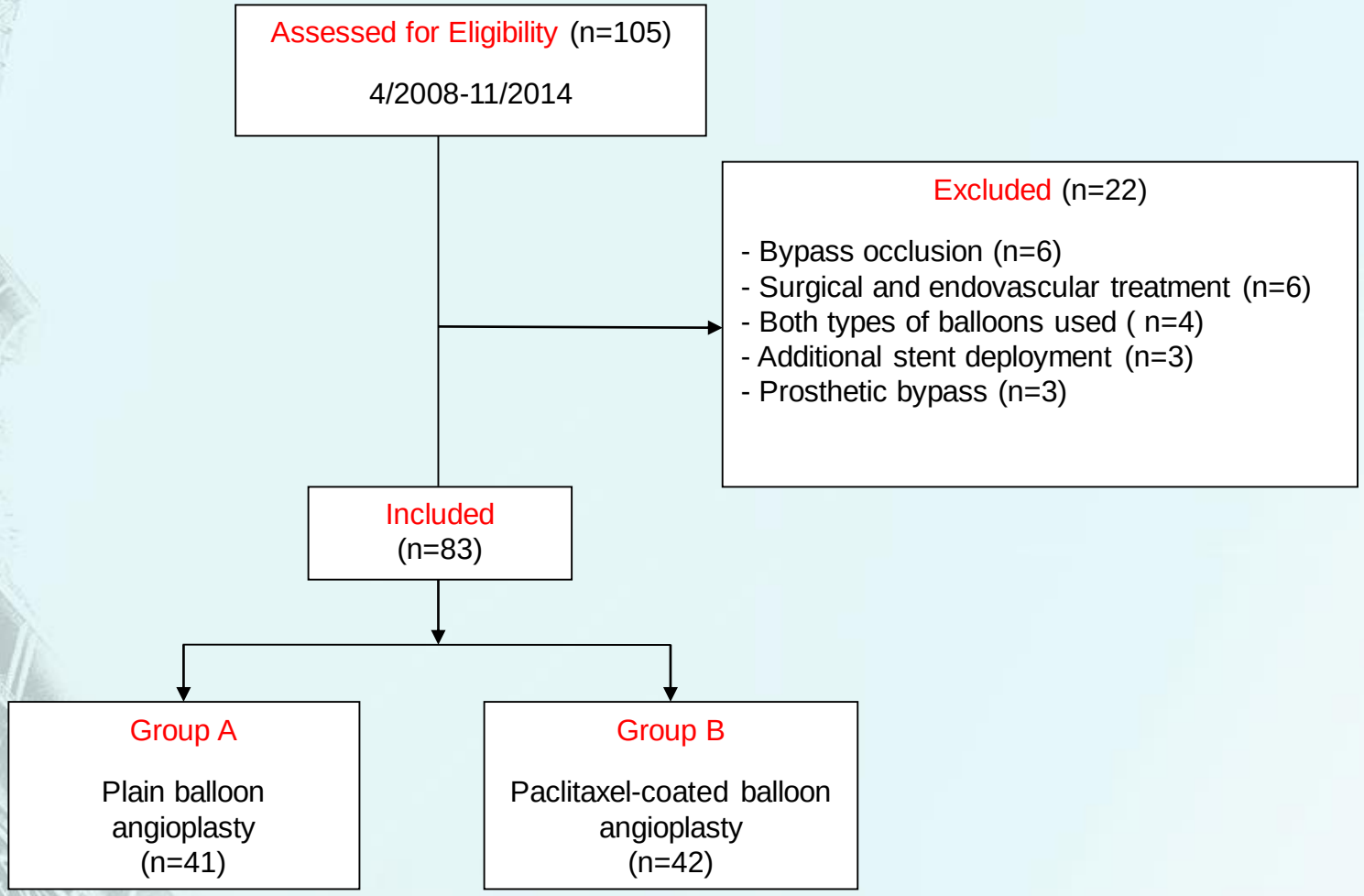
Plain balloon angioplasty (Group A)

vs

Paclitaxel-coated balloon angioplasty (Group B)

- Retrospective Design
- Follow up:
- Mean: 2.93 vs 2.18 (P = .08) for Group A and B
- No patient was lost to follow-up

Consort Diagram



Demographic Data and Cardiovascular Risk Factors

	Plain PTA (n = 41)	Paclitaxel-coated PTA (n = 42)	P Value
Mean age in years (± SD)	71 (± 10.6)	70 (± 7.38)	0.8
Female (n/%)	16/39	9/21	0.09
BMI (± SD)	25.83 (± 4.8)	25.79 (± 3.5)	0.9
Hypertension (n/%)	39/95	40/95	1.0
Hyperlipidemia (n/%)	26/63	23/55	0.5
Diabetes (n/%)	19/46	17/40	0.6
Coronary disease (n/%)	23/56	23/55	1.0
Smoking (n/%)	14/34	15/36	1.0

Indication for Bypass PTA and Bypass Characteristics

	Plain PTA (n=41)	Paclitaxel-coated PTA (n=42)	P Value
Rutherford category 2 (n/%)	2/5	10/24	0.02
Rutherford category 3 (n/%)	22/54	21/50	0.8
Rutherford category 4 (n/%)	2/5	3/7	1.0
Rutherford category 5 (n/%)	13/32	7/17	0.1
Rutherford category 6 (n/%)	2/5	1/2	0.6
GSV bypass (n/%)	29/71	28/67	0.8
Arm vein bypass (n/%)	11/27	12/29	1.0
LSV bypass (n/%)	1/2	2/5	1.0
Redo bypasses (n/%)	15/37	12/29	0.5
Below-knee bypass (n/%)	26/63	28/67	0.8

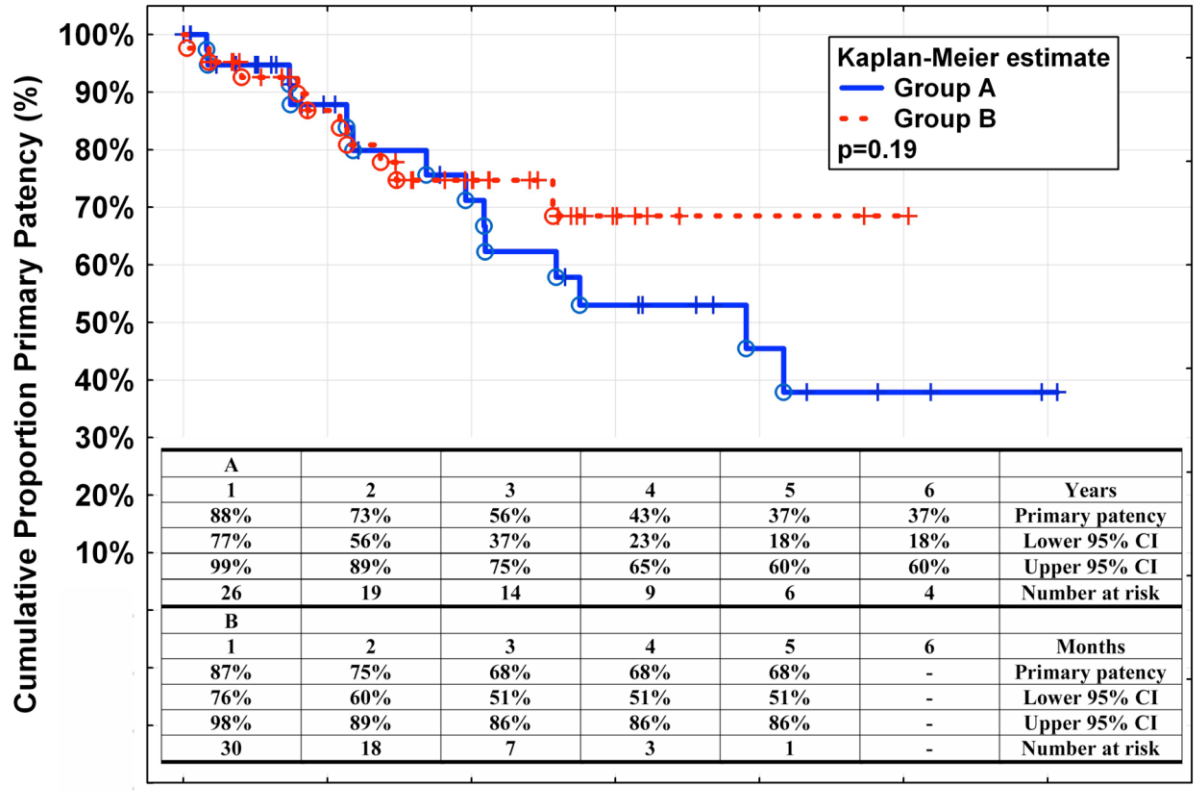
Procedural Findings

	Plain PTA (n=41)	Paclitaxel-coated PTA (n=42)	P Value
Proximal anastomosis stenosis (n/%)	8/20	7/17	0.8
Distal anastomosis stenosis (n/%)	17/41	19/45	0.8
Proximal in-graft stenosis (n/%)	3/7	13/31	0.01
Middle in-graft stenosis (n/%)	11/27	11/26	1.0
Distal in-graft stenosis (n/%)	10/24	4/9	0.08
Mean balloon length in mm (± SD)	30 (± 14.9)	51 (± 17.2)	< 0.001
Mean balloon diameter in mm (± SD)	3.7 (± 0.8)	3.8 (± 1.1)	0.8
Mean operative time in min (± SD)	45.2 (± 15.6)	47.0 (± 19.5)	0.6
Mean radiation time in min (± SD)	7.1 (± 4.7)	9.5 (± 6.9)	0.08
Mean contrast medium in ml (± SD)	109 (± 51.0)	110.3 (± 38.3)	0.9

Primary Study Endpoints

- Proximal in-graft stenosis (Cox F, p = .041)
- Redo bypass procedure (Cox F, p = .0001)
- Repeat TLR rates were 22% vs 14% (p = .17)
- 7 successful re-angioplasties for stenosis in Group A
- 3 successful re-interventions for stenosis in Group B
- 8 vs 7 bypass occlusions (p = .74)
- All re-PTA's (n = 5) for bypass occlusion failed
- In 10 cases of bypass occlusion no salvage procedure was performed

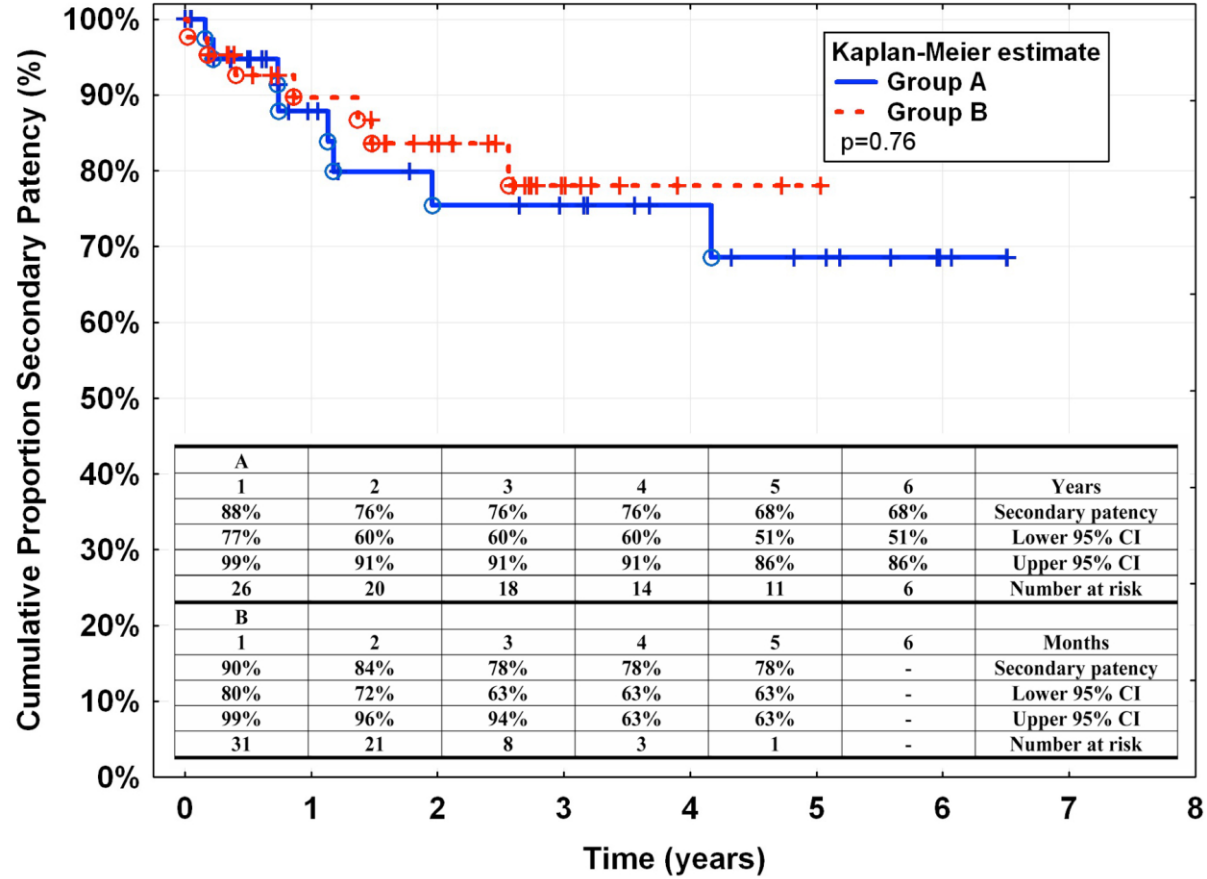
Primary Patency



A						
1	2	3	4	5	6	Years
88%	73%	56%	43%	37%	37%	Primary patency
77%	56%	37%	23%	18%	18%	Lower 95% CI
99%	89%	75%	65%	60%	60%	Upper 95% CI
26	19	14	9	6	4	Number at risk

B						
1	2	3	4	5	6	Months
87%	75%	68%	68%	68%	-	Primary patency
76%	60%	51%	51%	51%	-	Lower 95% CI
98%	89%	86%	86%	86%	-	Upper 95% CI
30	18	7	3	1	-	Number at risk

Secondary Patency



A						
1	2	3	4	5	6	Years
88%	76%	76%	76%	68%	68%	Secondary patency
77%	60%	60%	60%	51%	51%	Lower 95% CI
99%	91%	91%	91%	86%	86%	Upper 95% CI
26	20	18	14	11	6	Number at risk
B						
1	2	3	4	5	6	Months
90%	84%	78%	78%	78%	-	Secondary patency
80%	72%	63%	63%	63%	-	Lower 95% CI
99%	96%	94%	63%	63%	-	Upper 95% CI
31	21	8	3	1	-	Number at risk

Secondary Endpoints

- Hemodynamic improvement rates: 88% vs 86% (p = 1.0) for Group A and B
- Clinical improvement rates were 70% vs 73% (p = 0.8) for Group A and B
- 3 vs 1 major amputations (p = 0.36) for Group A and B
- Survival rates: 81% vs 84% (p = 0.78) for Group A and B

Conclusion

- Technical success
- Hemodynamic and clinical outcome
- Study limitations
  - Retrospective, not randomized
  - Single center
- Randomized studies probably useful