L’angioplastie fémoro-poplitée: c’est plutôt simple!

F. Saucy
Service de chirurgie vasculaire

DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

Intervenant : François SAUCY, Lausanne

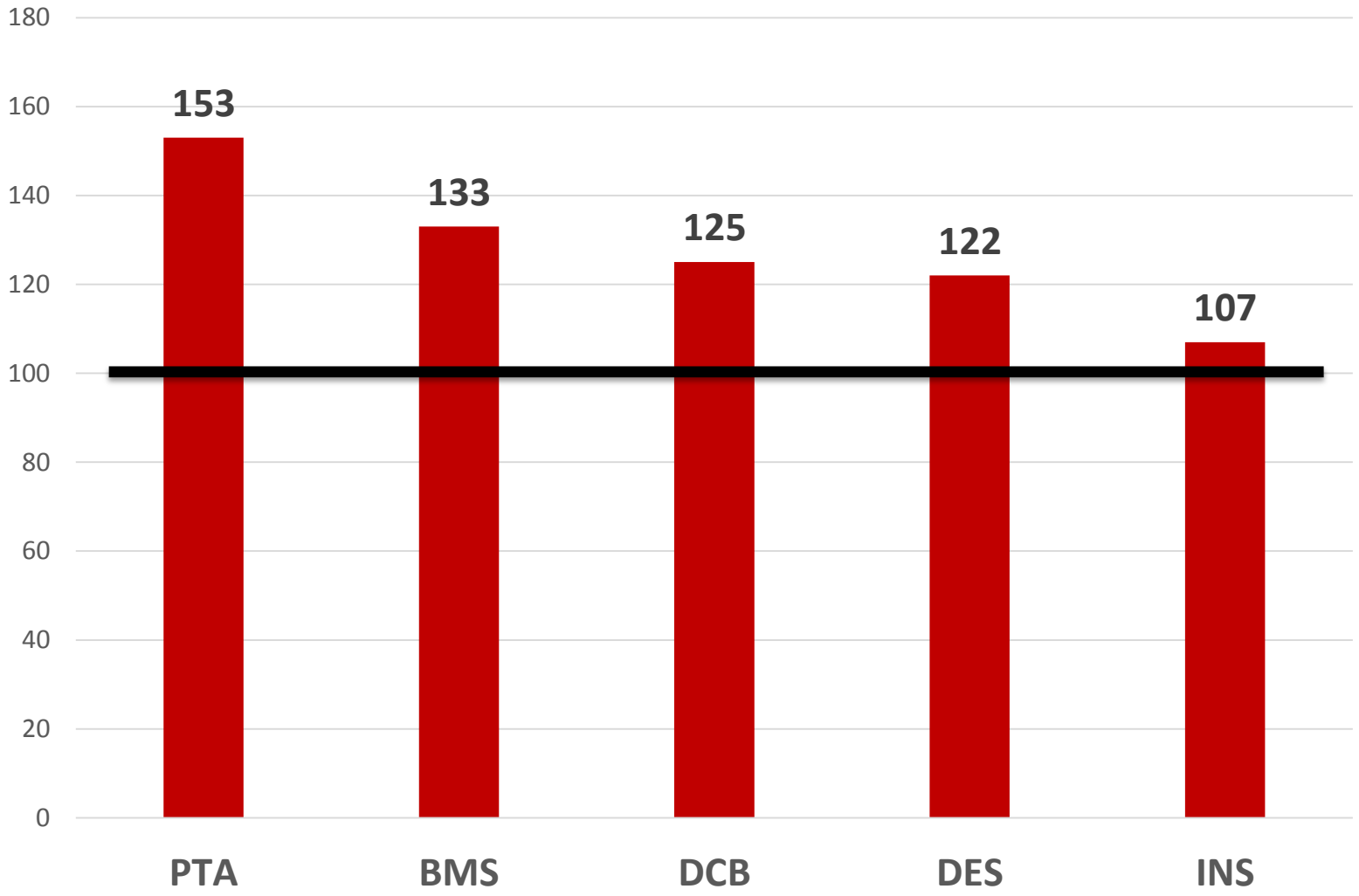
☑ Je n'ai pas de lien d'intérêt à déclarer

Succès technique: > 90-95%

Pooled 3-Year TLR Risk from IDE trials

Strategy	Pooled 3Y TLR	Trials
PTA	46.4%	RESILIENT, ZILVER PTX, LEVANT II, IN.PACT SFA
BMS	29.2%	DURABILITY II, RESILIENT, COMPLETE SE, STROLL
DES	19.4%	ZILVER PTX
DCB	24.6%	LEVANT II, IN.PACT SFA
INS	6.0%	SUPERB

Total Number of Procedures / 100 Patients over 3 years



Ansel, Veith meeting 2017

Cost to Medicare per Patient over 3 years

Treatment	Cost to Medicare Per Pt over 3Y
BMS	$ 16,158
PTA	$ 15,166
DES	$ 14,845
DCB	$ 13,421
INS	$ 13,036

Analysis based on 2015 Medicare national Average payement rates

L’angioplastie fémoro-poplitée est techniquement **simple**
dans la majorité des cas

Mais

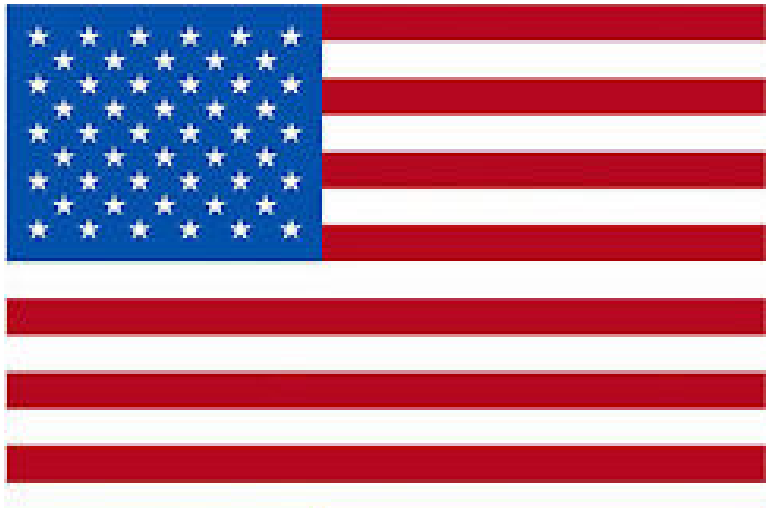
Le choix de la thérapie permettant d’augmenter la durabilité du traitement est **complexe**

Choix du traitement en fonction des lésions

« Stratégie basée sur l'évidence »

- Manque d'outcomes comparables
- Absence d'équivalence entre différents devices de la même catégorie
- RCT comparant POBA à un autre traitement n'est pas utile

Guidelines: Lequel choisir?



2017 Guideline European Society of Cardiology and European Society for Vascular Surgery

Recommendations on revascularization of femoro-popliteal occlusive lesions[c]

Recommendations	Class[a]	Level[b]
An endovascular-first strategy is recommended in short (i.e. <25 cm) lesions.[302,303]	I	C
Primary stent implantation should be considered in short (i.e. <25 cm) lesions.[304,305]	IIa	A
Drug-eluting balloons may be considered in short (i.e. <25 cm) lesions.[77,306–310]	IIb	A
Drug-eluting stents may be considered for short (i.e. <25 cm) lesions.[302,303,311]	IIb	B
Drug-eluting balloons may be considered for the treatment of in-stent restenosis.[312,313]	IIb	B
In patients who are not at high risk for surgery, bypass surgery is indicated for long (i.e. ≥25 cm) superficial femoral artery lesions when an autologous vein is available and life expectancy is >2 years.[314]	I	B
The autologous saphenous vein is the conduit of choice for femoro-popliteal bypass.[284,315]	I	A
When above-the-knee bypass is indicated, the use of a prosthetic conduit should be considered in the absence of any autologous saphenous vein.[284]	IIa	A
In patients unfit for surgery, endovascular therapy may be considered in long (i.e. ≥25 cm) femoro-popliteal lesions.[312]	IIb	C

[a] Class of recommendation

German guideline on the diagnosis and treatment of peripheral artery

Table III. Therapeutic recommendations for patients with PAD

	Grad*	LoR
All Patients with PAD who smoke are advised to stop smoking, are offered medical doctors' support, nicotine replacement therapy, and smoking cessation programs	A	1
Statins are recommended for secondary prevention of cardiovascular events and antiplatelet therapy is recommended in patients with asymptomatic and symptomatic PAD	A	1
Supervised exercise programs are offered to all patients with CI as basic therapy	A	1
Cilostazol or Naftidrofuryl are only recommended in patients with IC, if quality of life is severely reduced, maximum	Expert consensus	
A primary endovascular approach may be offered all patients with IC, if they were informed about risk factor modification and supervised exercise programs and if occlusions is suitable for endovascular interventions.	Expert consensus	
A primary endovascular approach should be considered in all aortoiliac lesions independent of the TASC class. Comorbidities, patients' preference, and experience of the endovascular and surgical teams should be considered.	Expert consensus	
Femoropopliteal lesions should be treated endovascular-first independent of the TASC class. In TASC D lesions with low risk, not impaired life expectancy (>2 years), and available autologous vein surgical bypass graft should be first choice.	B	2
In CLI infrapopliteal lesions should be treated endovascular-first. Open surgery can be recommended in case of long, complex infrapopliteal occlusions, if endovascular approach has failed or symptoms persist	Expert consensus	
Antiplatelet therapy with aspirin (100mg) or clopidogrel is recommended in all patients before, during, and after endovascular or surgical revascularisation, as long as no contraindications arise.	A	1
After infrainguinal endovascular approach with stent implantation temporary dual antiplatelet therapy can be considered to improve patency rate.	Expert consensus	
Anticoagulation with vitamin K antagonists should not regularly be considered in patients with femoropopliteal or infrapopliteal autogenous vein bypass, because of increased risk of bleeding.	A	2
Patients with PAD should be screened regularly regarding walking distance, rest pain, and ischaemic lesions	B	3

LoR: level of recommendation; * according to the Oxford Scheme of scientific evidence

NICE National Institute for Health and Care Excellence

Angioplasty and stenting

1.5.3 Offer angioplasty for treating people with intermittent claudication only when:

- advice on the benefits of modifying risk factors has been reinforced (see recommendation 1.2.1) **and**
- a supervised exercise programme has not led to a satisfactory improvement in symptoms **and**
- imaging has confirmed that angioplasty is suitable for the person. **[2012]**

1.5.4 Do not offer primary stent placement for treating people with intermittent claudication caused by aorto-iliac disease (except complete occlusion) or femoro-popliteal disease. **[2012]**

1.5.5 Consider primary stent placement for treating people with intermittent claudication caused by complete aorto-iliac occlusion (rather than stenosis). **[2012]**

1.5.6 Use bare metal stents when stenting is used for treating people with intermittent claudication. **[2012]**

NICE National Institute for Health and Care Excellence

Bypass surgery and graft types

1.5.7 Offer bypass surgery for treating people with severe lifestyle-limiting intermittent claudication only when:

- angioplasty has been unsuccessful or is unsuitable **and**
- imaging has confirmed that bypass surgery is appropriate for the person. [2012]

1.5.8 Use an autologous vein whenever possible for people with intermittent claudication having infra-inguinal bypass surgery. [2012]

Est-ce risqué de traiter des lésions fémoropoplitées en comparaison avec l'angioplastie coronarienne?

CLINICAL RESEARCH Interventional Cardiology

Cause of Death Within 30 Days of Percutaneous Coronary Intervention in an Era of Mandatory Outcome Reporting

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N=4,078

Décès à 30j: 81 (2%)

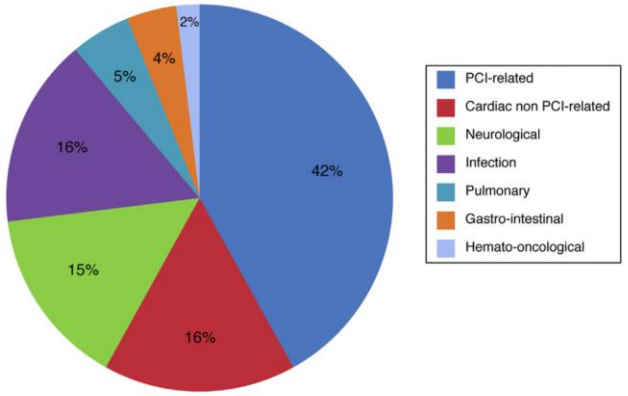

Figure 1 Etiology of 30-Day Mortality After PCI Based on Chart Review

Etiology of death (in percentage) divided into percutaneous coronary intervention (PCI)-related, cardiac non–PCI-related, neurological, infection, pulmonary, gastrointestinal, and hemato-oncological causes.

Est-ce risqué de traiter des lésions fémoropoplitées en comparaison avec l'angioplastie coronarienne?

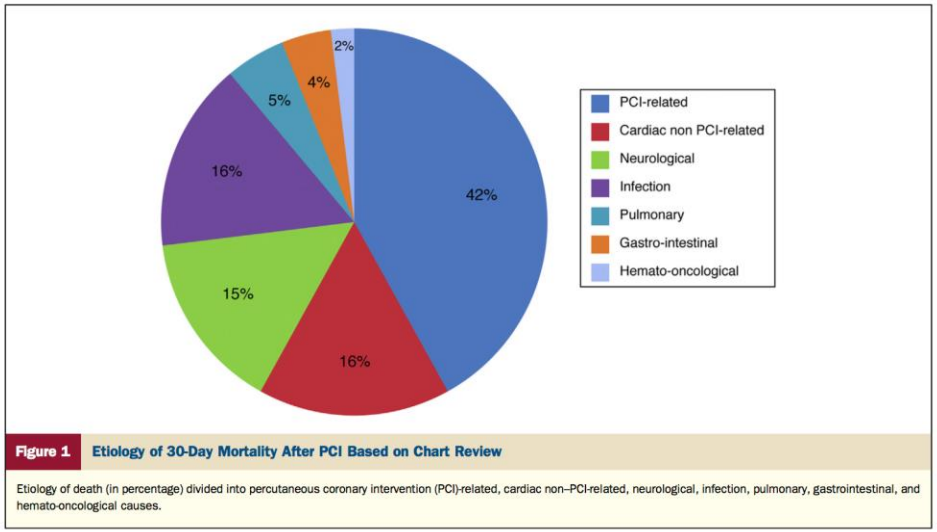

Figure 1 **Etiology of 30-Day Mortality After PCI Based on Chart Review**

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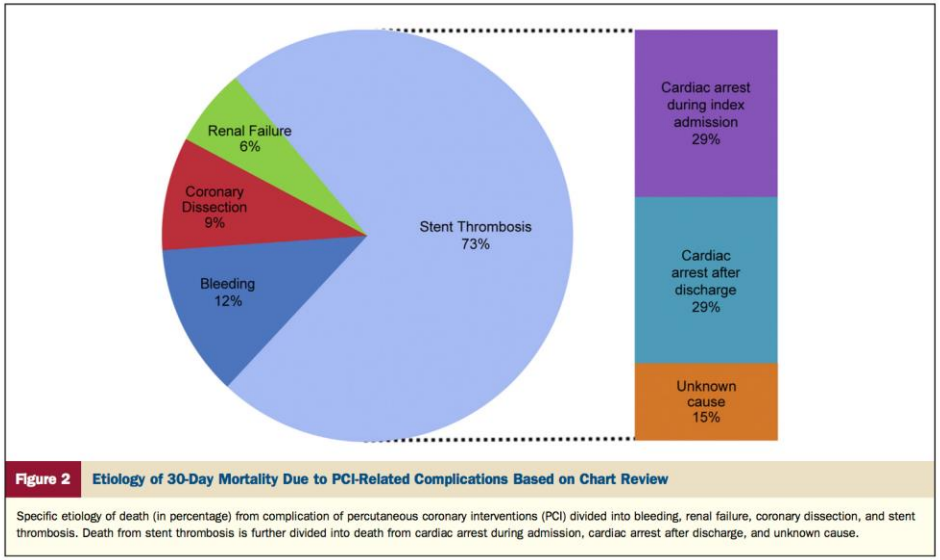
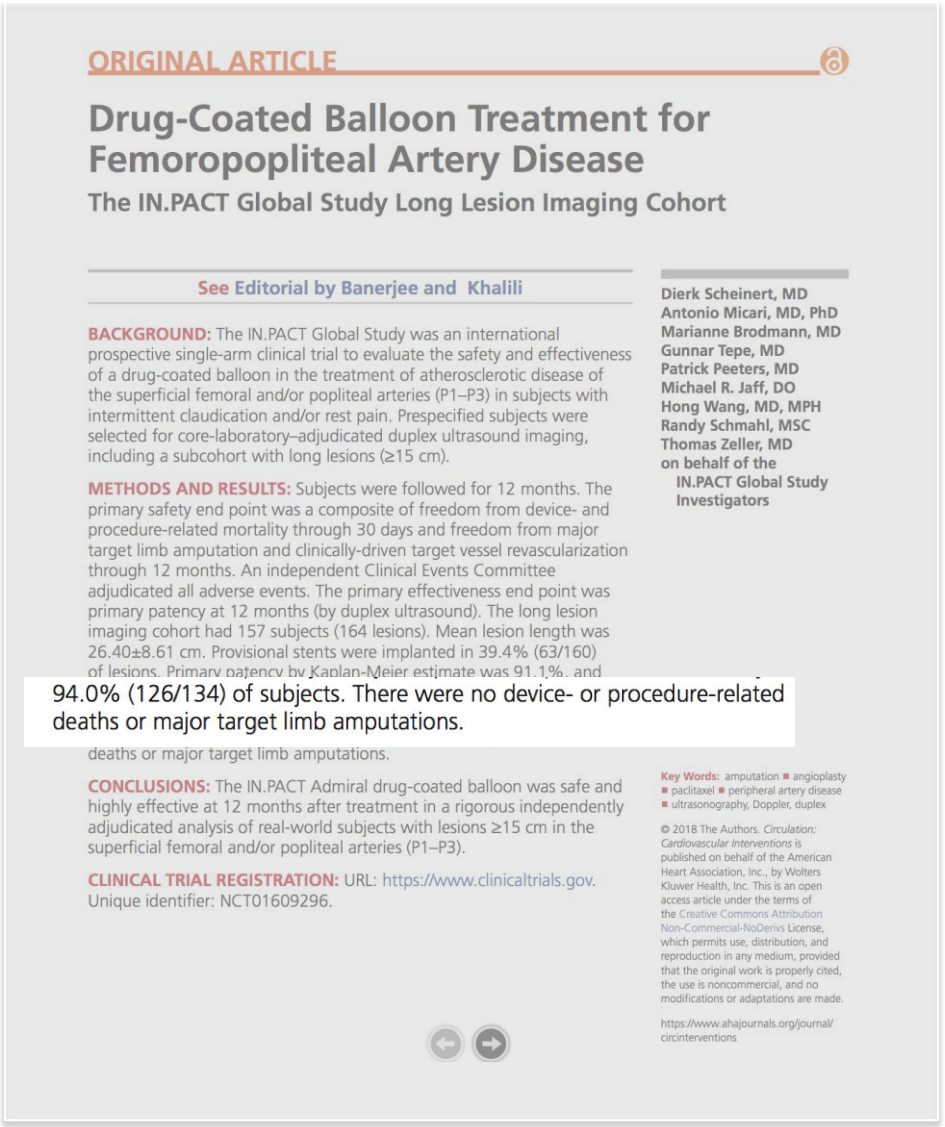


Figure 2 **Etiology of 30-Day Mortality Due to PCI-Related Complications Based on Chart Review**

Specific etiology of death (in percentage) from complication of percutaneous coronary interventions (PCI) divided into bleeding, renal failure, coronary dissection, and stent thrombosis. Death from stent thrombosis is further divided into death from cardiac arrest during admission, cardiac arrest after discharge, and unknown cause.

Est-ce risqué de traiter des lésions fémoropoplitées?



ORIGINAL ARTICLE

Drug-Coated Balloon Treatment for Femoropopliteal Artery Disease

The IN.PACT Global Study Long Lesion Imaging Cohort

See Editorial by Banerjee and Khalili

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BACKGROUND: The IN.PACT Global Study was an international prospective single-arm clinical trial to evaluate the safety and effectiveness of a drug-coated balloon in the treatment of atherosclerotic disease of the superficial femoral and/or popliteal arteries (P1–P3) in subjects with intermittent claudication and/or rest pain. Prespecified subjects were selected for core-laboratory–adjudicated duplex ultrasound imaging, including a subcohort with long lesions (≥15 cm).

METHODS AND RESULTS: Subjects were followed for 12 months. The primary safety end point was a composite of freedom from device- and procedure-related mortality through 30 days and freedom from major target limb amputation and clinically-driven target vessel revascularization through 12 months. An independent Clinical Events Committee adjudicated all adverse events. The primary effectiveness end point was primary patency at 12 months (by duplex ultrasound). The long lesion imaging cohort had 157 subjects (164 lesions). Mean lesion length was 26.40±8.61 cm. Provisional stents were implanted in 39.4% (63/160) of lesions. Primary patency by Kaplan-Meier estimate was 91.1%, and 94.0% (126/134) of subjects. There were no device- or procedure-related deaths or major target limb amputations.

CONCLUSIONS: The IN.PACT Admiral drug-coated balloon was safe and highly effective at 12 months after treatment in a rigorous independently adjudicated analysis of real-world subjects with lesions ≥15 cm in the superficial femoral and/or popliteal arteries (P1–P3).

CLINICAL TRIAL REGISTRATION: URL: https://www.clinicaltrials.gov. Unique identifier: NCT01609296.

Key Words: amputation ■ angioplasty ■ paclitaxel ■ peripheral artery disease ■ ultrasonography, Doppler, duplex

https://www.ahajournals.org/journal/circinterventions

Quels sont les outils à disposition actuellement?

1. PTA
2. BMS
3. DEB
4. DES
5. INS
6. Athérectomie
7. Laser
8. Lithotripsie

Quels sont les outils à disposition actuellement?

1. PTA
2. BMS
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Drug-coated Balloon and Long lesion of the the femoropopliteal segment

Primary Patency	@ 12 months	@13 months
Overall	91.1%	80.7%
Lesion 15-25 cm (N=105)	97.7%	89.8%
Lesion > 25 cm (N=59)	79.2%	63.7%
Provisional stenting (N=63)	89%	86.4%
No stent	92.5%	77.9%

N= 157 subjects; 164 limbs

D. Scheinert et al. In. Pact Global Study Circ Cardiovasc Int; 2018

A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial

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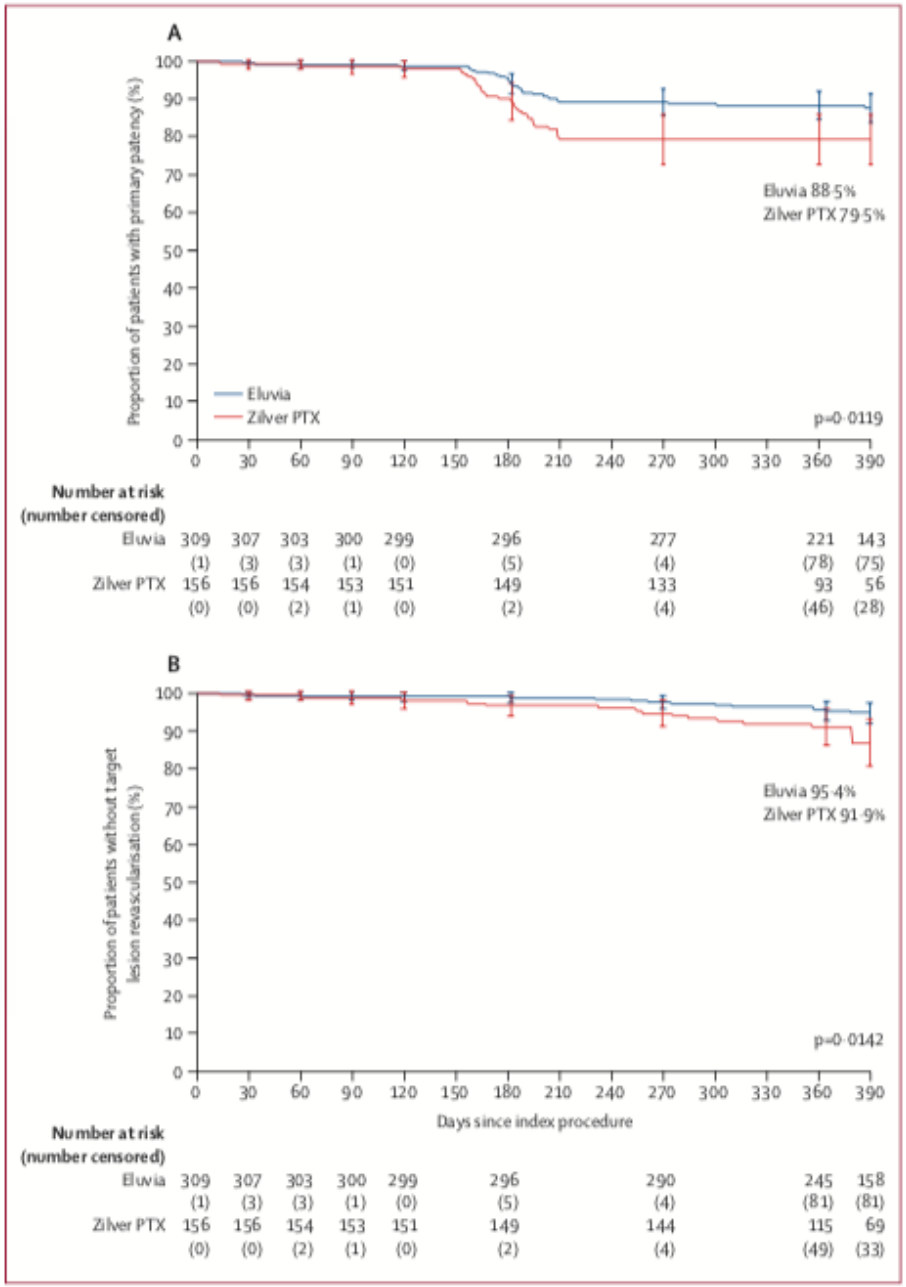
Summary

Background The clinical effect of a drug-eluting stent in the femoropopliteal segment has not been investigated in a randomised trial with a contemporary comparator. The IMPERIAL study sought to compare the safety and efficacy of the polymer-coated, paclitaxel-eluting Eluvia stent with the polymer-free, paclitaxel-coated Zilver PTX stent for treatment of femoropopliteal artery segment lesions.

Methods In this randomised, single-blind, non-inferiority study, patients with symptomatic lower-limb ischaemia manifesting as claudication (Rutherford category 2, 3, or 4) with atherosclerotic lesions in the native superficial femoral artery or proximal popliteal artery were enrolled at 65 centres in Austria, Belgium, Canada, Germany, Japan, New Zealand, and the USA. Patients were randomly assigned (2:1) with a site-specific, web-based randomisation schedule to receive treatment with Eluvia or Zilver PTX. All patients, site personnel, and investigators were masked to treatment assignment until all patients had completed 12 months of follow-up. The primary efficacy endpoint was primary patency (defined as a peak systolic velocity ratio ≤2·4, without clinically driven target lesion revascularisation or bypass of the target lesion) and the primary safety endpoint was major adverse events (ie, all causes of death through 1 month, major amputation of target limb through 12 months, and target lesion revascularisation through 12 months). We set a non-inferiority margin of –10% at 12 months. Primary non-inferiority analyses were done when the minimum sample size required for adequate statistical power had completed 12 months of follow-up. The primary safety non-inferiority analysis included all patients who had completed 12 months of follow-up or had a major adverse event through 12 months. This trial is registered with ClinicalTrials.gov, number NCT02574481.

Findings Between Dec 2, 2015, and Feb 15, 2017, 465 patients were randomly assigned to Eluvia (n=309) or to Zilver PTX (n=156). Non-inferiority was shown for both efficacy and safety endpoints at 12 months: primary patency was 86·8% (231/266) in the Eluvia group and 81·5% (106/130) in the Zilver PTX group (difference 5·3% [one-sided lower bound of 95% CI –0·66]; p<0·0001). 259 (94·9%) of 273 patients in the Eluvia group and 121 (91·0%) of 133 patients in the Zilver PTX group had not had a major adverse event at 12 months (difference 3·9% [one-sided lower bound of 95% CI –0·46]; p<0·0001). No deaths were reported in either group. One patient in the Eluvia group had a major amputation and 13 patients in each group required target lesion revascularisation.

Interpretation The Eluvia stent was non-inferior to the Zilver PTX stent in terms of primary patency and major adverse events at 12 months after treatment of patients for femoropopliteal peripheral artery disease.



ELUVIA V. Zilver PTX

88.5% V. 79.5% (p=0.0119)

Primary outcomes and mechanism of action of intravascular lithotripsy in calcified femoropopliteal lesions: Results of Disru

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Funding infor
Shockwave Medical, Inc

Procedural details	*N* = 60
Procedure duration, minutes, mean ± SD	71.1 ± 32.2
Fluoroscopy time, minutes, mean ± SD	14.9 ± 11.6
Contrast, ml, mean ± SD	106.8 ± 44.2
Embolic protection device, % (*n*)	3.3% (2)
Pre-dilatation, % (*n*)	13.3% (8)
Successful IVL delivery, % (*n*)	100% (60)
IVL pulses, mean ± SD	136 ± 75.0
Mean pressure, mmHg, mean ± SD	6.5 ± 1.5
Post-dilatation, % (*n*)	3.3% (2)
Stents, % (*n*)	1.7% (1)
Post-angiographic characteristics	
Mean luminal diameter, mm, mean ± SD	4.2 ± 0.6
Diameter stenosis, %, mean ± SD	24.2 ± 5.7
Acute gain, mm, mean ± SD	3.0 ± 0.8
Dissection, % (*n*)	
None	86.7% (51)
A	0.0%
B	6.7% (4)
C	6.7% (4)
D	1.7% (1)
Perforation, % (*n*)	0% (0)
Distal embolization, % (*n*)	0% (0)
Thrombus, % (*n*)	0% (0)
No reflow, % (*n*)	0% (0)
Abrupt closure, % (*n*)	0% (0)

Results

	30 days		
Performance results			
Target lesion patency[a]	100% (56/5		
Freedom from TLR[b]	100% (58/5		
Primary patency[c]	100% (56/5		
Safety results[c]			
Major adverse events (MAE)	1.7% (1/59		
Emergency surgical revascularization of target limb	0% (0/59)		
Unplanned target limb amputation	0% (0/59)		
Symptomatic thrombus or emboli	0% (0/59)	0% (0/58)	0% (0/57)
Perforations or Gr D dissections w/ interventions	1.7% (1/59)	1.7% (1/58)	1.8% (1/57)

72.7% (40/55)

98.3% (57/58)

71.4% (40/56)

Conclusions

Le **succès technique** de l'angioplastie du segment fémoroplité est élevé

La **durabilité** des traitements endovasculaires n'est actuellement pas assurée

Le **choix du type de thérapie** est complexe et les guidelines sont controversés

La thérapie par **élution médicamenteuse** doit être privilégiée

La **préparation du vaisseau** par PTA, athérectomie ou lithotripsie doit faire partie du traitement

Chaque device doit être **évalué indépendamment** en comparant avec un device au moins équivalent

Chaque **spécialiste interventionnel** pratiquant ce txpe de thérapie doit connaître non seulement la technique mais également les indications et les limites