Accepted Manuscript

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Patrick Björkman, M.D, Tommi Auvinen, M.D, Harri Hakovirta, M.D., Ph.D, Pekka Romsi, M.D., Ph.D, Johanna Turtiainen, M.D., Ph.D, Hannu Manninen, M.D., Ph.D, Maarit Venermo, M.D., Ph.D., Kimmo Lappalainen, M.D, Anders Albäck, M.D., Ph.D, Antti Korpela, M.D., Kimmo Mäkinen, M.D., Ph.D., Petri Saari, M.D., Ph.D., Jukka Perälä, M.D., Ph.D.

PII: S0890-5096(18)30430-8

DOI: 10.1016/j.avsg.2018.04.014

Reference: AVSG 3893

To appear in: *Annals of Vascular Surgery*

Received Date: 28 February 2018

Revised Date: 2 April 2018

Accepted Date: 10 April 2018

Please cite this article as: Björkman P, Auvinen T, Hakovirta H, Romsi P, Turtiainen J, Manninen H, Venermo M, The FinnPTX-study group, Lappalainen K, Albäck A, Korpela A, Mäkinen K, Saari P, Perälä J, Drug-eluting stent shows similar patency results as prosthetic bypass in patients with femoropopliteal occlusion in a randomized trial, *Annals of Vascular Surgery* (2018), doi: 10.1016/j.avsg.2018.04.014.

Title page

Drug-eluting stent shows similar patency results as prosthetic bypass in patients with femoropopliteal occlusion in a randomized trial

Patrick Björkman, M.D., Helsinki University Hospital, Dept. of Vascular Surgery and University of Helsinki

Tommi Auvinen, M.D., Kuopio University Hospital, Dept. of Vascular Surgery

Harri Hakovirta, M.D., Ph.D., Turku University Hospital, Dept. of Vascular Surgery

Pekka Romsi, M.D., Ph.D., Oulu University Hospital, Dept. of Vascular Surgery

Johanna Turtiainen, M.D., Ph.D., Joensuu Central Hospital, Dept. of Surgery

Hannu Manninen, M.D., Ph.D., Kuopio University Hospital, Dept. of Radiology*

Maarit Venermo, M.D., Ph.D., Helsinki University Hospital, Dept. of Vascular surgery and University of Helsinki*

*shared last authorship

The FinnPTX-study group

Kimmo Lappalainen, M.D., Helsinki University Hospital, Dept. of Radiology

Anders Albäck, M.D., Ph.D., Helsinki University Hospital, Dept. of Vascular Surgery

Antti Korpela, M.D., Lahti Central Hospital, Dept. of Surgery

Kimmo Mäkinen, M.D., Ph.D., Kuopio University Hospital, Dept. of Vascular Surgery

Petri Saari, M.D., Ph.D., Kuopio University Hospital, Dept. of Radiology

Jukka Perälä, M.D., Ph.D., Oulu University Hospital, Dept. of Radiology

Corresponding Author: Patrick Björkman, patrick.bjorkman@hus.fi, tel.

+358504288019

Word count: 2064 (excl. abstract)

The trial received a grant from the Finnish Society of Interventional Radiology

Keywords: peripheral arterial disease; drug-eluting stent; bypass; patency; femoropopliteal disease

Drug-eluting stent shows similar patency results as prosthetic bypass in patients with femoropopliteal occlusion in a randomized trial

Abstract

Introduction: Claudication and critical limb threatening ischemia (CLTI) are significant causes of mortality in the elderly. The gold standard of superficial femoral artery (SFA) revascularization is thus far considered to be the femoropopliteal bypass. The aim of this study was to compare mid-term patency between drug-eluting stents (DES) and prosthetic bypass grafts (BSX). Studies have reported comparable results for both methods. *Materials and Methods:* 46 patients with claudication or rest pain due to a 5-25 cm SFA-occlusion were randomized between DES and BSX. Follow-up was 24 months, and the primary outcome measure was overall patency. Secondary outcome measures were primary and primary assisted patency, change in ankle-brachial index (ABI), as well as amputation-free survival. *Results:* 41 patients were eventually analyzed. 6 month secondary patency was 91 % (DES) vs. 83 % (BSX) (P=.450). The corresponding numbers at 12-months in the DES and BSX groups were 74 % and 80 % (P= .750). At 24 months the respective numbers were 56 % and 71 % (P=.830). There were no statistically significant differences in primary or assisted primary patency at 1, 6, or 12 months. *Conclusions:* There were no demonstrable differences in patency rates or clinical outcomes such as ABI or major amputations between DES and BSX. Although underpowered, the results suggest non-inferiority of the DES compared to prosthetic bypass surgery. *Trial registration:* The trial was pre-registered at *ClinicalTrials.org* (NCT01450722)

Introduction

Critical limb threatening ischemia (CLTI) due to atherosclerosis causes significant morbidity especially in the elderly, and, if untreated, leads to limb loss. [1] The incidence of CLTI is estimated at 500-1000/million annually. [2] The prevalence of its milder symptomatic manifestation, intermittent claudication among 40-44 year-old men is about .4 % and 3 % among 65-69 year-olds. [3] In asymptomatic peripheral artery disease or claudication, the ischemia relatively rarely deepens over time to threaten the vitality of the limb. [4] Although intermittent claudication has a benign prognosis and can often be treated conservatively, more severe forms with extensive arterial obstructions and symptoms that impair the quality of life significantly require revascularization. Open bypass surgery (BSX) is currently considered the gold standard for treating long obstructions in the superficial femoral artery (SFA). Up to 81% two-year patency can be appreciated after bypass with a good quality saphenous vein. If synthetic graft is used, the long-term patency is somewhat lower, up to 67% according to a systematic review. [5]

Treatment of femoropopliteal occlusive disease has shifted dramatically towards endovascular methods during the last 10 years. [6] Despite this, superiority of endovascular treatment has not been definitively demonstrated. In 2010, the BASIL trial concluded that in patients with severe ischemia, femoropopliteal BSX with a vein graft was superior to primary angioplasty (BA), but that primary BA was superior to prosthetic BSX. [7] Furthermore, it was concluded that failed BA yielded worse outcomes for future ipsilateral BSX. This has been supported by subsequent studies. [8] Comparison of stenting and prosthetic bypass grafting has yielded similar results at 4-year follow-up in a RCT with 100 revascularizations and in a smaller, retrospective study. [9,10]

Drug-eluting stents (DES) have proven their worth in coronary artery lesions and to some degree in femoral occlusions. [11] While early trials failed to show benefit from DES vs. bare metal stents [12,13], subsequent studies have shown improved event-free survival up to five years. [14] Paclitaxel is a mitotic inhibitor and antiproliferative agent.[15] It is a widely used, effective agent in drug eluting stents to reduce restenosis in coronary circulation. [16] Paclitaxel binds specifically to the beta-tubulin subunit of microtubules and appears to antagonize the disassembly of this key cytoskeletal protein; this action results in accumulation of microtubule bundles and aberrant microtubule derived structures in the mitotic phase of the cell cycle. [17,18] The Zilver PTX (Cook Medical) paclitaxel-eluting stent is designed specifically for use in the SFA. It is a nitinol stent coated with paclitaxel only, without polymer or binder.

This trial is a prospective, randomized, multicenter trial comparing outcomes for prosthetic above-knee (AK) bypass vs. the ZilverPTX drug eluting stent. Bypass with a synthetic graft, instead of autogenous vein, is used as a reference standard because of the difficulty to standardize the quality of available vein and because bypasses to the proximal popliteal artery with the different graft types give comparable results. The trial was investigator initiated, and did not receive funding from the industry.

Materials and Methods

Patients were randomized at 6 hospitals in Finland (Helsinki, Oulu, Turku and Kuopio university hospitals and the central hospitals in Lahti and Joensuu). Patients were included between 2011 and 2014, follow-up ended in 2016. Patients presented with rest pain or severe claudication (Rutherford class II-IV), patients with wounds or

tissue loss were excluded. 5-25 cm SFA-lesions were eligible for inclusion. The lesions were diagnosed and measured using magnetic resonance angiography (MRA) or computed tomography angiography (CTA). Concomitant inflow or outflow procedures were not allowed. All patients provided written informed consent. Inclusion and exclusion criteria are listed in table 1. Patients were randomized to BA+DES or prosthetic AK femoropopliteal bypass. 2:1 (DES:BSX) block randomization was performed at the ward or outpatient clinic following eligibility and signed informed consent.

Bypass Surgery

Bypass surgery was performed under general anesthesia or spinal blockade from incisions to the groin and proximal popliteal artery. A 6 mm heparin-bonded polytetrafluoroethylene (PTFE) graft was used. The graft was tunneled anatomically or subcutaneously depending on surgeon´s preference. Procedures were performed under systemic heparinization with an activated clotting time (ACT) between 200 and 300 seconds.

Balloon Angioplasty and Drug-Eluting Stent

Access was obtained from the ipsilateral or contralateral common femoral artery. The occlusion was recanalized and crossed intraluminally or subintimally prior to predilatation and stent deployment. The stent was post-dilated according to instructions-for-use. Patients received 5000 IU systemic heparin during the procedure.

Follow-up and outcome measures

Follow-up was 24 months and the primary outcome measure was overall stent or graft patency. Secondary outcome measures were primary and assisted patency, change in ankle-brachial index (ABI), as well as amputation-free survival. Follow-up was performed by clinical evaluation for symptoms and by duplex ultrasound to assess patency at 1, 6, 12, and 24 months postoperatively.

Antithrombotic regime

Postoperatively, all patients except those on warfarin were started on life-long ASA treatment in both treatment groups. Patients in the DES group were on dual antiplatelet therapy (ASA 100 mg + clopidogrel 75 mg daily) for at least three months postoperatively. DES-patients on warfarin were started on low-dose (50 mg) ASA for the same period. Dual antiplatelet therapy was not prescribed after bypass surgery.

Randomization

Block randomization (2:1) was performed by concealed envelope by the research nurse at the University of Kuopio. Due to the nature of the study, neither subjects, providers nor outcomes assessors were blinded.

Statistical Analysis

Statistical analysis was performed using SPSS v. 22 (IBM, Armonk, VA, USA) Continuous variables are expressed as means and range or medians and interquartile range (IQR) and dichotomous variables as percentages. Continuous variables were compared using Mann-Whitney test and dichotomous variables using Chi-square. Patency rates were analyzed with Log-rank testing.

The study was approved by the ethical boards of Kuopio University Hospital and Helsinki University Hospital and the study design was declared and preregistered at ClinicalTrials.org (NCT01450722).

Results

46 patients were randomized. Baseline characteristics are described in table 2. 5 patients were excluded due to immediate technical failure, i.e. unsuccessful recanalization. These were salvaged by distal and/or venous bypass, and thus not eligible for intention-to-treat analysis. There were no deaths or major amputations in either group during 12-month follow-up, 1 patient in the stent group died at 24 months from procedure due to unrelated disease. The number of patients lost to follow-up at 6, 12, and 24 months was 0 (0.0 %), 6 (14.2 %) and 11 (26.2 %), respectively. In the DES-group, the median number of stents was 2 (range 1-4) with a median diameter of 6 mm.

41 patients were eventually analyzed. 6 month primary patency was 82.6 % DES) vs. 72.2 % (BSX) (P=.447) and secondary 91 % vs. 83 % (P=.450). The 12-month secondary patency in the DES and BSX groups was 74 % compared to 80 % (P= .750). There were no statistically significant differences in primary, assisted primary, or secondary patency at 1, 6, 12, or 24 months (table 3, fig 1-2). The median ABI rose from .54 to .93 in the DES-group and from .65 to 1.02 in the BSX-group after the procedures and there were no significant differences between the groups at the baseline nor during the follow-up (Table 4). Relative risk for stenting at 1 year was .96 (P= .893, any endpoint).

Discussion

In the current trial, no significant differences between femoropopliteal AK bypass with PTFE-prosthesis and endovascular recanalization and stenting with Zilver-PTX stenting could be demonstrated. At 6 months, the primary and secondary patencies were slightly, but not significantly, higher in the stent group compared to bypass, but this difference disappeared during the next six months. At 12 months the respective rates were surprisingly similar: 63.2 % vs. 66.7 % and 74 % vs. 80 %. Indeed, at two years, the patency rate was better in the BSX group (56 % vs. 71 %, P=.397) but at this stage the number-at-risk is substantially lower than at the earlier follow-ups.

For the time being, open femoropopliteal BSX is a first-hand option in many centers worldwide. Use of prosthetic grafts for AK bypasses remains popular due to many surgeons' preference to save the saphenous veins for possible future below-knee or distal bypasses and speed of the procedure. The Zilver PTX DES is designed specifically for femoropopliteal locations. A prospective, randomized trial reported significantly better 24-month event-free survival among patient receiving a DES than among those treated with PTA alone (86.6% vs. 77.6%, P< .01). [19] Primary patency at 24 months of the DES group was 74.8% vs. 32.4% for the PTA group. Patency rates at 5 years further favored the Zilver PTX. [14] The Zilver PTX trials have shown patency rates in the 80 %-range at 12 months, which are comparable to our results. The Scandinavian Thrupass study demonstrated a clear benefit in favor of bypass surgery vs. the Gore Thrupass endoluminal PTFE. [20] This trial showed a remarkable 95 % 1-year patency in the bypass treatment group, whereas the corresponding number was only 48 % for the thrupass group. In 2007, Kedora *et al* demonstrated comparable 1-year outcomes between the Viabahn covered stent (CS) and prosthetic AK femoropopliteal bypass. [21] This study included 100 limbs in a prospective setting.

In this study, 6 and 12-month patency rates were 82 % (BSX) vs. 81.8 % (CS) and 73.5 % vs. 74.2 %, respectively. In our study the patency rates were somewhat higher at 6 months and lower at 12 months, but still in comparable figures. The study by Kedora et al has been criticized for including TASC A lesions.

It should be noted that 5 cases (5/27, 18.5 %) were excluded from the DES group due to failed recanalization, whereas the primary technical success rate in the BSX group was 100 %. In one case the attempted recanalization resulted in severe distal dissection and acute ischemia, which eventually could be salvaged with a distal bypass. We did not report the results for patients with technical failures, but no statistically significant difference was seen in a sensitivity analysis including these patients. Furthermore, 1 case in the DES group received a bailout covered stent after perforation and hemorrhage. This did not compromise patency, as the DES in question was patent at 2 years.

In this trial, there was a significant difference between the groups in time from diagnosis to treatment. The time from CT or MR angiography to treatment was 60 days in the DES group and 125 days in the BSX group (P<.01). This is likely due to hospital logistics and the more rigorous medical work-up prior to bypass surgery. There was no evidence that this delay would have resulted in clinical deterioration in the BSX patients prior to surgery.

This trial is limited by the small sample size, and consequently there is a marked risk for type II error in the patency rates. The primary reason for the slow inclusion and randomization rate was the quickly somewhat ageing hypothesis and clinically

problematic setting for prosthetic bypass surgery; few surgeons would end up including the shorter SFA-lesions into this trial design, as these are routinely treated with less invasive endovascular procedures, or, indeed, venous bypass grafting. This is overall seen in decreasing rates of open AK bypass surgery and quite the opposite in successful endovascular femoropopliteal revascularizations.

Despite its limitations, we think our paper gives valuable information on the outcome after these two procedures and it seems that the DES is not inferior to prosthetic AK bypass in patients with SFA occlusion 25 cm or less. This is the only prospective trial to date comparing DES with bypass surgery, and the results do indicate that drug-eluting stents are comparable to prosthetic grafts with regard to patency. Another strength of the trial is comprehensive follow-up at 6 months, and acceptable follow-up rates up to 24 months. In anticipation of larger trials, the results from this trial loosely favor endovascular revascularization and use of DES for SFA lesions if no vein is available for grafting.

Conclusions

This is the first randomized trial comparing the DES to prosthetic bypass in above knee femoropopliteal occlusion. At 12 and 24 months after the procedure there was no statistically significant difference in primary patency, assisted primary patency or secondary patency between the groups. Although underpowered, our study suggests non-inferiority of the DES compared to PTFE-bypass in this patient group. Larger studies are needed for more definitive conclusions.

Acknowledgements

The trial was supported by a grant from the Finnish Society of Interventional Radiology

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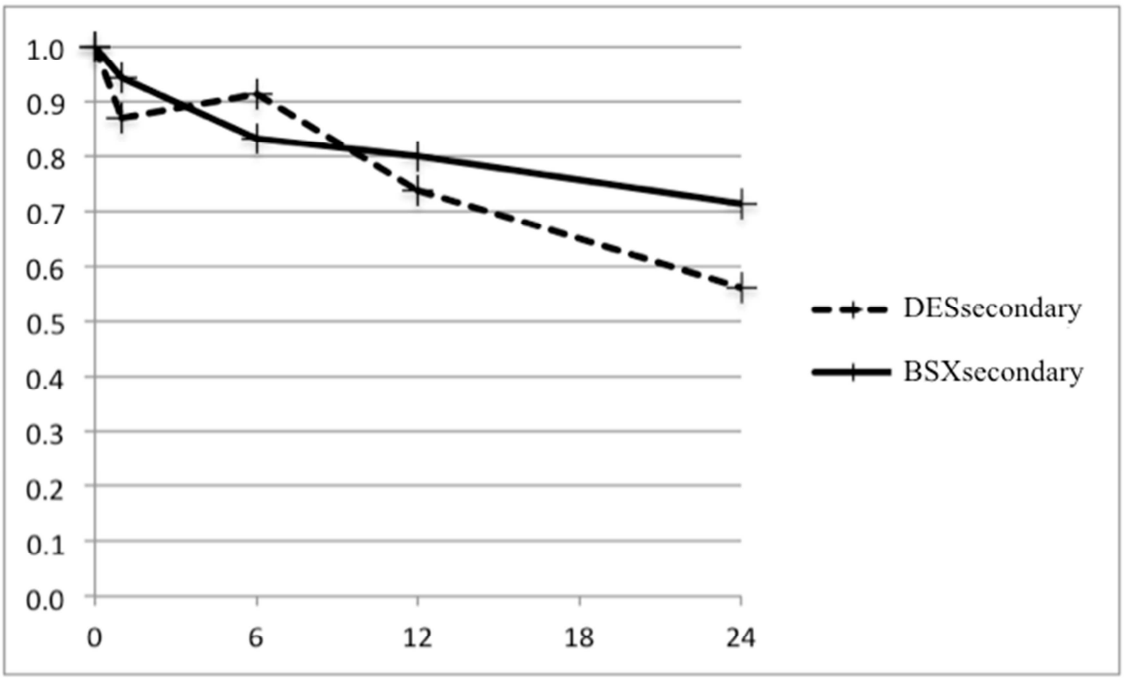
Inclusion Criteria:	**Exclusion Criteria**
Rutherford class II-IV	Previous treatment for same lesion
5-25 cm SFA occlusion	Indication for infrapopliteal treatment
Eligible for operative treatment	Iodine allergy
At least 1 vessel crural runoff	Patients undergoing hemodialysis
Written informed consent	Pregnancy

	DES (n=23)		BSX (n=18)		P-value
Male sex	17		12		.613
Age	68	48-88	67	50-84	.398
T1 Diabetes	6	26.1	4	22.2	.775
T2 Diabetes	3	13.0	2	11.1	.650
Smoking	9	39.1	6	33.3	.702
Ex-smoker	9	39.1	5	27.8	.230
TIA	2	8.7	2	11.1	.796
Stroke	3	13.0	2	11.1	.851
Coronary disease	6	26.1	5	27.8	.903
Prior AMI	1	4.3	3	16.7	.187
Dyslipidemia	13	56.5	15	83.3	.067
Chronic heart disease	2	8.7	2	11.1	.796
Hypertension	15	65.2	15	83.3	.194
Pulmonary	1	4.5	1	5.6	.884
ASA	21	91.3	14	77.8	.224
Clopidogrel	1	4.3	4	22.2	.083
Warfarin	3	13.0	2	11.1	.851
Other	2	8.6	1	5.6	.653
Statin therapy	12	52.2	14	77.8	.051
ACE/AT2-blockade	9	39.1	9	50.0	.656
Ankle Brachial Index	0.54	0-0.82	0.65	0.47-0.99	.120
SFA occlusion length	13.2	5.0-25.0 (IQR 12.3)	11.3	5.0-19.6 (IQR 7.9)	.424
Rutherford classification					

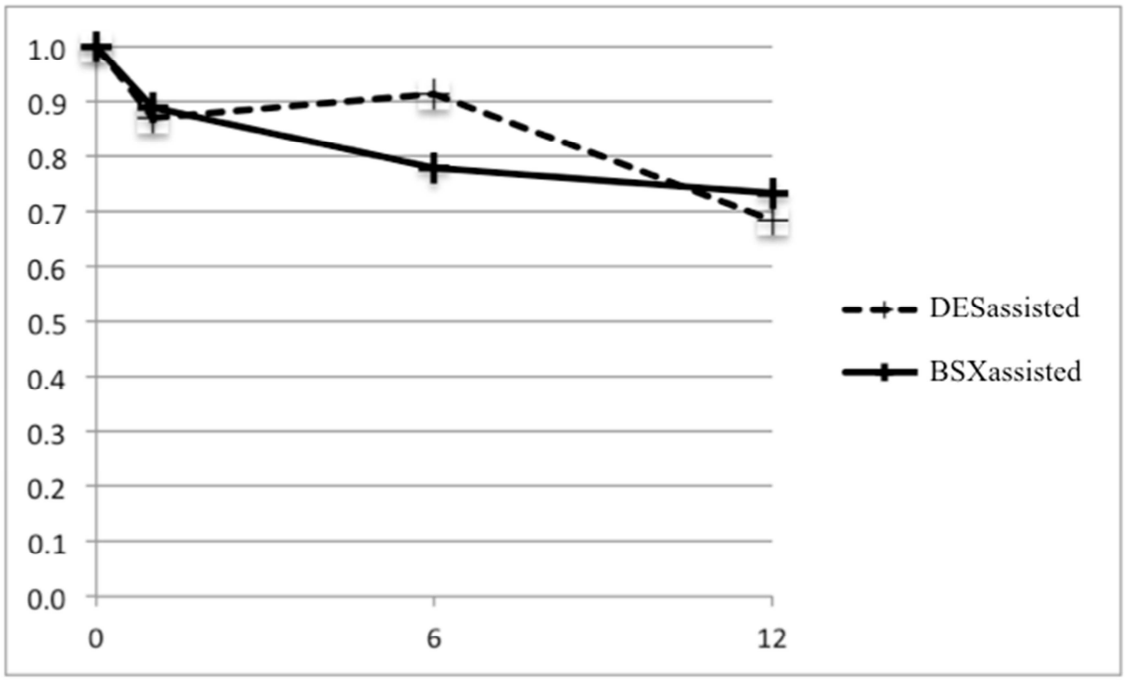
1	4	17.4	3	16.7	.359
2	7	30.4	8	44.4	
3	6	26.1	6	33.3	
4	6	26.1	1	5.6	
Crural runoff*					
3	8	34.8	5	27.8	.782
2	8	34.8	4	22.2	
1	7	30.4	2	11.1	
0	0	0	1	5.6	

	DES	BSX	P-value (log-rank)
1 m			
Primary patency (%)	87.0	88.9	.872
Assisted primary patency (%)	87.0	88.9	.872
Secondary patency (%)	87.0	94.4	.454
6 m			
Primary patency (%)	87.0	72.2	.447
Assisted primary patency (%)	91.3	77.8	.247
Secondary patency (%)	91.3	83.3	.450
12 m			
Primary patency (%)	63.2	66.7	.931
Assisted primary patency (%)	68.4	73.3	.840
Secondary patency (%)	73.7	80.0	.750
24 m			
Secondary patency (%)	56.3	71.4	.830

ABI	DES		BSX		P-value
	mean	range	mean	range	
post.op.	.93	.63-1.38	1.02	.76-1.42	.220
1 m	.99	.39-1.85	.94	.78-1.09	.620
6 m	.93	.59-2.00	.80	.31-1.12	.650
12 m	.86	.73-.98	.85	.54-1.05	.791



DES	23	23	19	16
BSX	18	18	15	14



DES	23	23	19
BSX	18	18	15