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RESEARCH ARTICLE

The Primary patency in endovascular treatment of femoropopliteal lesions with Eluvia Paclitaxel-Eluting Stent: single-centre experience

Annarita Dapoto*[1], Angie Devetti[1], Alessandro Vit[1], Andrea Pellegrin[1], Vladimir Gavrilovic[1], Nicola Marotti[1], Alessandro Pauro[1], Roberto Da Ros[2], Paolo Frigatti[3], Massimo Sponza[1]

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Abstract

Restenosis of the obstructive lesions in the superficial femoral or proximal popliteal artery, treated with angioplasty or bare nitinol stenting, frequently occurs. Paclitaxel-eluting stents have been developed to protect against restenosis with the sustained antiproliferative agent release over time. The aim of this study was to report the results about the primary patency in a cohort of patients with long and complex femoropopliteal lesions treated with the Eluvia Drug-Eluting Vascular Stent. The single-center, retrospective, single-arm, study enrolled 61 patients with chronic, symptomatic, or asymptomatic, lower limb ischemia and stenotic or occlusive lesions in the superficial femoral artery or proximal popliteal artery. Mean lesion length was 129.3 ± 88.6. Efficacy measures at 18 months included primary patency, defined as duplex ultrasound peak systolic velocity ratio of ≤ 2.4 and the absence of target lesion revascularization or bypass. The Kaplan-Meier estimate of primary patency through 18 months was on average 83% and precisely 87.5% for patients TASC II A, 91% for patients TASC II B, 83% for patients TASC II C and 73% for patients TASC II D. Six months after the initial procedure primary patency was on average 91.5% and precisely 87.5% for patients TASC II A, 91% for patients TASC II B, 89.5% for patients TASC II C and 100% for patients TASC II D. No stent fractures were identified, and no major target limb amputations occurred. This study confirmed the efficacy of the paclitaxel-eluting Eluvia stent to treat long and complex femoropopliteal lesions.

Key Words: *Critical limb ischemia; Drug-eluting stent; Peripheral artery disease; Restenosis; Target lesion revascularization*

[1] Department of Interventional Radiology, Santa Maria della Misericordia Hospital, Udine, Italy
[2] Department of Diabetology, Gorizia-Monfalcone Hospital, Italy
[3] Department of Vascular Surgery, Santa Maria della Misericordia Hospital, Udine, Italy

**Corresponding author: Annarita Dapoto, Department of Interventional Radiology, Santa Maria della Misericordia Hospital, Udine, Italy, Tel: 3405632807; Fax 0432552885; E-mail: annarita.dap@hotmail.it*

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Introduction

For patients with critical limb ischemia and claudication, percutaneous treatment involves limited risks and is therefore chosen in the first instance. Compared to surgery, percutaneous treatment correlates with significantly shorter hospital stays, fewer amputations, and a reduced rate of procedure-dependent morbidity and mortality [1].

The success of the endovascular intervention and the patency of the vessel without reintervention are influenced by the characteristics of the lesion and are often reduced for long and complex lesions. Endovascular treatment with angioplasty or bare nitinol stenting of obstructive lesions in the superficial femoral artery (SFA) or proximal popliteal artery (PPA) is routinely practiced alleviating symptoms of claudication or chronic limb-threatening ischemia. However, restenosis of the treated lesion occurs on several occasions and may necessitate reintervention [2].

To ensure that the effect of endovascular revascularization lasts longer, and that re-intervention is not necessary in many cases, paclitaxel-based antiproliferative substance-releasing systems have been planned. Paclitaxel is released during the angioplasty procedure from a drug-coated balloon. The release occurs in a single rush; however, the drug continues to act in the tissue for a time long enough to extend the duration of patency [3,4]. Although effective, balloon-based drug delivery is not able to cope with a particular need of patients who have extensive femoropopliteal lesions or vessel segments characterized by calcified parietal plaques; in these cases, it would be necessary to build a scaffolding for the vessel [5].

The prolonged elution profile caused by a polymer coating allows the drug to protect against continued initiation of restenotic pathways determined by persistent mechanical forces on the vessel wall [6] and to inhibit downstream effectors activated weeks to months after stent implantation [7,8]. The Eluvia Drug-Eluting Vascular Stent System (Boston Scientific, Marlborough, MA) combines paclitaxel with a biocompatible fluoropolymer coating on a stent scaffold and was planned to obtain sustained drug release over time [9]. This system therefore conjugates the acute luminal gain of the permanent scaffolding and the antirestenotic effect of the antiproliferative agent [10], this antirestenotic effect was also demonstrated in the MAJESTIC and IMPERIAL studies [2].

The aim of our cohort study was to evaluate the efficacy of fluoropolymer-based paclitaxel-eluting stents (Eluvia, Boston Scientific, Marlborough, Massachusetts) placed in patients with long and complex femoropopliteal lesions in avoiding the biological process of in-stent restenosis.

Materials and Methods

Study Design

This was a single-center, single-arm study with prospectively collected data. As the data analysis was retrospective, it was not considered necessary to seek the consent of the ethics committee, however it was performed in line with the requirements of the local ethics committee. All patients provided informed consent prior to the intervention.

All patients between February 2017 and November 2019 who came to our observation due to a femoropopliteal lesion and treated with

endovascular therapy by means of Eluvia drug-eluting stent placement were considered. The main criterion for stent implantation was any recoil or flow-limiting dissection after ordinary balloon angioplasty.

All patients underwent thorough clinical examination at baseline. Patient demographics and comorbidities as well as imaging and clinical data were prospectively collected and retrospectively analyzed.

Dual-antiplatelet therapy with aspirin (100 mg/day) and clopidogrel (75 mg/day) was routinely prescribed for 3 months, followed by lifelong aspirin or clopidogrel monotherapy. Patients previously taking warfarin or oral anticoagulant agents continued taking anticoagulant agents with further clopidogrel therapy for 3 months after the procedure. Patient with aspirin allergy received lifelong clopidogrel.

The primary measure outcome of this study was primary patency understood as the absence of significant restenosis or occlusion without any reintervention. Secondary outcomes were technical success rate, secondary patency rate, and absence of clinically driven target lesion revascularization (TRL). Secondary patency was understood as restored flow in the treated segment after occlusion or restenosis. Amputation-free survival was defined as the time until a major amputation of the index limb occurred.

The stent is based on the Innova bare-metal stent platform (Boston Scientific), which consists of a 6-F self-expanding nitinol stent, delivered through a triaxial delivery system. The stent architecture combines a closed-cell design at each end of the stent for more predictable deployment and an open-cell design along the stent body for optimal flexibility, strength, and fracture resistance. The paclitaxel concentration is 0.167 μg/mm^2 stent surface area [10,11].

Patient population

Sixty-one patients with chronic, symptomatic, or asymptomatic lower limb ischemia and stenotic, restenotic or occlusive lesion(s) extended for a length between 30 and 380 mm and located in the SFA or PPA (defined as TASC II classification [12]) were treated by means of Eluvia Drug-Eluting Vascular Stent System. Two patients did not respond to the follow-up call, so they were excluded.

Baseline Characteristics of enrolled patients are given in Table 1.

Arterial hyprtension was present in all but five patients (92%), 32 patients (54%) had diabetes and 34 (20%) hyperlipidemia requiring medication. Nine patients (15%) had previous interventions at the index limb.

Follow-up

Dual antiplatelet therapy was prescribed for the first 90 days, thereafter acetylsalicylic acid intake lifelong. Follow-up examinations were performed between 1 and 18 months after the initial procedure. We did not perform X-ray checks for any structural damage to the stents. As retrospective study, follow-up examinations were not equal in number for all patients and they responded to the clinical needs of the individual patient, however at least one follow-up was performed within the year following the procedure.

The patency of the treated vessels was assessed using duplex ultrasound (DUS) at each follow-up visit. Primary patency was established by a peak systolic velocity ratio ≤ 2.4 on DUS

TABLE 1

Patient Demographics and Characteristics. Values are shown as percentages (counts) or mean ± standard deviation; FP femoropopliteal; SFA superficial femoral artery; PPA proximal popliteal artery; ATK above the knee; BTK below-the-knee; m=months

Patients, n			59
Age, y			75 ± 10 (54-94)
Male sex			63% (37)
Claudicatio/critical ischemia			81% (48)
Side	Right		46% (27)
	Left		54% (32)
Smoker	Yes		15% (9)
	Former		27% (16)
	No		58% (34)
Diabetes			54% (32)
Dialysis			4% (7)
Hyperlipidemia			20% (34)
Hypertension			92% (54)
Stenosis	De novo		71% (42)
	Restenosis		29% (17)
Amputation			10% (6)
TASC II	A		14% (8)
	B		19% (11)
	C		49% (29)
	D		19% (11)
Stenosis on stent			12% (7)
Stenosis on by-pass FP			3% (2)
Primary patency, m			7.1 ± 4.8
Secondary patency, m			6.2 ± 3.1
Occlusion			17% (10)
Lesion length, mm			129.3 ± 88.6 (30-380)
Treated district	ATK	SFA	88% (52)
	BTK	SFA+PPA	12% (7)

without clinically driven TLR or bypass of the target lesion.

Follow-up were always completed a by clinical visit and included adverse event and antiplatelet medication assessments. In cases of clinical worsening or additional procedures, angiography was performed.

Statistical Analysis

Patient characteristics and clinical outcome measures are summarized with descriptive statistics. Continuous variables are presented as mean ± standard deviation. Categorical variables are expressed as frequencies and percentages. The Kaplan-Meier product-limit method was used to estimate the time-to-event rates for primary patency and freedom from TRL using a 95% confidence interval. Kaplan-Meier Analysis was performed with the Statistical Analysis System (SAS) software statskingdom.com. Paired t-tests were used to compare outcome scores regarding occlusion rate and primary and secondary patency among patient groups identified according to TASC II classification. Chi-square calculator and ANOVA were used to test association between two categorical variables and to compare the means of more samples simultaneously for independent measures. A p-value of 0.05 or less indicated statistical significance. Analyses were performed with SAS software socscistatistic.com.

Results

A total of 81 Eluvia Paclitaxel-Eluting Stents were implanted in 61 patients, ranging in size from 6X40 mm to 6X150 mm. The mean lesion length in the patients enrolled was 127.4 mm ± 87.8 mm. Balloon predilatation was performed in all patients. Residual angiographic stenosis of no greater than 30% (established as technical success) was observed for 59 patients with hemodynamic improvement observed in all patients; however, two patients had restenosis as early as 6-12 days after the procedure. At least one of the characteristics of diabetes, hyperlipidemia, hypertension, chronic kidney disease, smoke or critical ischemia was present in all patients at baseline. 53 patients (90%) had two of the aforementioned risk factors. Two patients did not respond to the follow-up call, so they were excluded.

Five patients had a single follow-up and then died from other causes not related to the study; the death was due to natural causes, linked to pathologies present in medical history. Two of them underwent follow-up at 3 months, two at 6 months and one at 12 months. During the follow-up all 5 patients had demonstrated regular primary patency. These data were considered in the statistical analysis. Four of the 5 patients were at least 80 years old; one was diabetic and undergoing dialysis, four had at least three of the risk factors mentioned above.

Forty-nine patients (83%) underwent a single clinical visit and follow-up using DUS. Thirty of them (51%) underwent it 0-6 months after the initial procedure, nineteen (32%) 6-12 months after the initial procedure, ten patients (17%) underwent follow-up at 0-6 months and subsequently 12-18 months after the initial procedure. The majority of patients (92%-54/59) reported use of dual antiplatelet therapy at both discharge and 1 month after the procedure. No stent fractures were identified via DUS evaluation and angiographic verification through 18 months nor reported in relation to adverse events after that time; no target limb major amputations occurred during the study period but 6 minor amputations.

The Kaplan–Meier estimate of primary patency through 18 months was on average 83%; stratifying for the TASC II classification, 87.5% (7/8) for patients TASC II A, 91% (10/11) for patients TASC II B, 83% (24/29) for patients TASC II C and 73% (8/11) for patients TASC II D. Six months after the initial procedure primary patency was on average 91.5% and precisely 87.5% (7/8) for patients TASC II A, 91% (10/11) for patients TASC II B, 89.5% (26/29)

for patients TASC II C and 100% (11/11) for patients TASC II D (Figure 1).

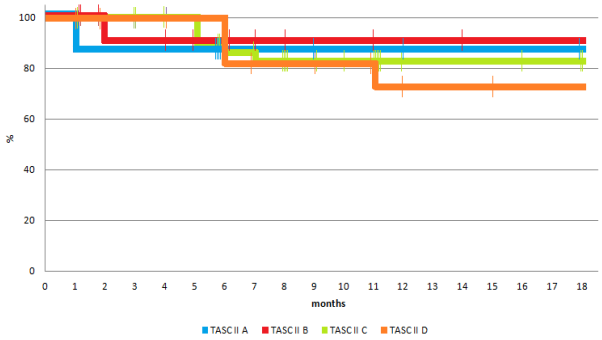

Figure 1) *Kaplan-Meier curves, primary patency. The graph shows the Kaplan–Meier estimate of primary patency through 18 months, resulting 87.5% for patients TASC II A, 91% for patients TASC II B, 83% for patients TASC II C and 73% for patients TASC II D. Six months after the initial procedure primary patency is 87.5% for patients TASC II A, 91% for patients TASC II B, 89.5% for patients TASC II C and 100% for patients TASC II D.*

A total of ten patients required a revascularization procedure to deal with blockage of the original target lesion through 18 months (17%), mainly TASC II C (5/59) and D (3/59) patients. As shown in Figure 2, the Kaplan–Meier estimate of secondary patency was at 6,6 ± 0,9 months for patients TASC II C and 8,7 ± 2,9 months for patients TASC II D; the estimate of freedom from TRL at 18 months was 83%. All results are reassumed in Table 2.

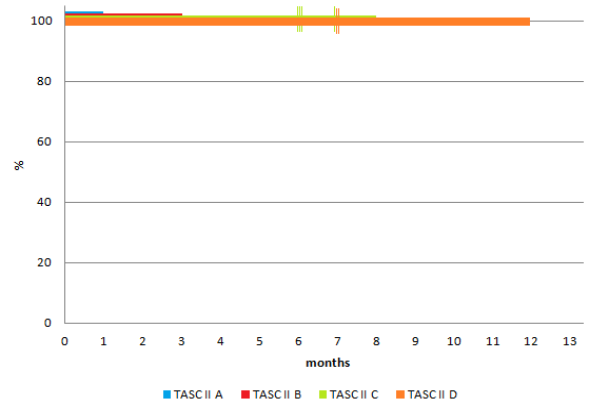

Figure 2) *Kaplan-Meier curves, secondary patency. The graph shows the Kaplan-Meier estimate of secondary patency, resulting 6.6 ± 0.9 months for patients TASC II C and 8.7 ± 2.9 months for patients TASC II D.*

Paired t-tests comparison of restricted mean primary patency time among groups of patients identified according to the TASC II classification demonstrates not statistically significant values (p-value <0.01). Statistical analysis showed that patient characteristics, habit of cigarette smoking and comorbidities have no significant effect on primary and secondary patency.

Discussion

Chronic Peripheral Obliterative Arteriopathy is widespread throughout the world and both incidence and prevalence are increasing [11,13]. One of the most common treatments of stenotic lesions of the femoropopliteal arterial axis is the placement of a stent using an endovascular approach [11]. The endovascular treatments available for patients with SFA lesions can be classified as no-antiproliferative and antiproliferative strategies [10]. Proliferative biological responses can limit the durability of the treatment, as they induce neointimal formation that causes restenosis or occlusion of the treated vessel [11].

If restenosis occurs, the treatment must be repeated to increase the duration of the vessel patency. The use of drug-eluting stents can reduce the cases of restenosis and therefore the need to repeat the procedure because they consist in a delivery system of an antiproliferative pharmaceutical agent directly to the artery wall [11].

The Eluvia drug-eluting vascular stent, designed to treating stenotic lesions of the femoropopliteal arterial axis, includes a self-expanding nitinol stent platform based on a primer layer of poly n-butyl methacrylate with a coating composed of a polymer matrix with an anti-proliferative agent (paclitaxel) [11,13,14]. IMPERIAL trial support the safety and efficacy of the Eluvia stent in arterial stenotic femoropopliteal lesions, the primary patency rate at 1 year was

TABLE 2

Results, values are shown as percentages (counts) or mean ± standard deviation; SFA superficial femoral artery; PPA proximal popliteal artery; TEA thromboendarterectomy; m=months

TASC II		**A** n=8	**B** n=11	**C** n=29	**D** n=11
Age, y		75 ± 12 (55-90)	79 ± 11 (56-94)	74 ± 9 (54-94)	75 ± 7 (61-83)
Male sex		88% (7)	64% (7)	59% (17)	55% (6)
Claudicatio/critical ischemia		25% (2)	27% (3)	17% (5)	19% (1)
Smoker	Yes	13% (1)	0% (0)	17% (5)	27% (3)
	Former	38% (3)	36% (4)	24% (7)	18% (2)
	No	50% (4)	64% (7)	59% (17)	55% (6)
Diabetes		50% (4)	27% (3)	62% (18)	64% (7)
Dialysis		0% (0)	9% (1)	3% (1)	18% (2)
Hyperlipidemia		63% (5)	45% (5)	28% (8)	18% (2)
Hypertension		88% (1)	82% (9)	93% (27)	100% (11)
Stenosis	De novo	63% (5)	91% (10)	69% (20)	64% (7)
	Restenosis	37% (3)	9% (1)	31% (9)	36% (4)
Stenosis on stent		0% (0)	9% (1)	14% (4)	18% (2)
Primary patency, m		7.9 ± 5.3	5.6 ± 4.2	7.6 ± 4.9	6.8 ± 5.3
Secondary patency, m		0 ± 0	3.0 ± 0	6.6 ± 0.9	8.7 ± 2.9
Occlusion		13% (1)	9% (1)	17% (5)	27% (3)
Lesion length, mm		61.3 ± 30.0 (30-100)	101.8 ± 26.0 (60-140)	154.7 ± 97.3 (30-380)	139.5 ± 105.8 (65-380)
Treated district	AFS	100% (8)	100% (11)	83% (24)	82% (9)
	AFS+PPA	0% (0)	0% (0)	17% (5)	9% (1)
	TEA	0% (0)	0% (0)	0% (0)	9% (1)

87% in the Eluvia group of this clinical trial [15]. In the MAJESTIC Trial Müller-Hülsbeck et al. reported that the primary patency at 2 years estimated by Kaplan-Meier analysis was 83.5% [16]. In another recent study, the one-year restenosis rate of the Eluvia group was extremely low (0%) [17].

In our study, the Kaplan-Meier estimate of primary patency for 18 months ranged from 91% to 73%. We highlight that the baseline clinical characteristics of our patients were more complex than those enrolled in the MAJESTIC study; the length of their lesions averaged more than 10cm (127.4 mm ± 87.8 mm) and 81% of patients had critical limb ischemia. Moreover, the patients enrolled in MAJESTIC study were mainly TASC II A and B; only 10% of patients were classified as TASC II C and none of the patients were TASC II D. Instead, our patients were mainly classified as TASC II C (49%) and D (19%). Despite this complexity, the patency rate observed at 18 months for patients treated with Eluvia was greater than or equal to that

observed in previous studies.

Notwithstanding the different characteristics of the studies and enrolled patients that may make comparisons more complex, our results support the durability and long-term safety of paclitaxel-eluting stents. Efficacy results shown in the SIROCCO study of sirolimus-eluting stents and in the STRIDES study of everolimus-eluting stents placed in the peripheral artery lesions were disappointing. The causes of failure were probably due to potential polymer bioincompatibility and too-short elution duration. The greater efficacy of Eluvia stent may be due to the longer duration of drug elution [15,18]. A preclinical porcine iliofemoral model demonstrated that the Eluvia stent releases paclitaxel continuously for at least 180 days and the drug maintains a constant therapeutic concentration on the artery wall [18]. The pharmacokinetic evaluation of the plasma concentration of paclitaxel after stent implantation instead showed values well below thresholds considered toxic, as demonstrated by studies carried out on cancer patients (0.05 μM or ~ 43 ng/mL) [15].

The results of this study support those of previous trials showing the efficacy and safety of paclitaxel-eluting stents for the treatment of stenotic lesions of peripheral arteries located above the knee. Furthermore, they suggest the advantage of prolonged release of paclitaxel in delaying restenosis after endovascular treatment.

Drug-coated balloon treatment is easily customized to lesion length, but standalone use in long femoropopliteal lesions has not demonstrated durability over time [18]. This study supports Eluvia's efficacy on lesions up to 380 mm long, involving the popliteal artery in 12% of patients. However, further studies are needed to evaluate whether drug-eluting stents treatment can overcome the limitations of drug-coated balloon treatment in long femoropopliteal lesions over time [2]. In preclinical models of atherosclerotic lesions of peripheral arteries treated with stents and subsequently complicated by restenosis, stents have been shown to constantly stretch the arterial wall, promoting continued neointimal growth, which could cause healing and delayed restenosis. [15].

Limitations

The retrospective nature of this study and the lack of a control group were significant limitations of this analysis. The limited number of events and the relatively small sample size allowed no meaningful analysis concerning specific subgroups, although our primary focus was the durability of treatment with the Eluvia Drug-Eluting Vascular Stent System regardless patient characteristics.

Furthermore, an 18-month follow-up is still too short to estimate late failure, which is frequently observed.

Conclusion

Previous preclinical and clinical data on endovascular treatment with the Eluvia stent show that prolonged elution of paclitaxel in the femoropopliteal arteries avoids reintervention in a large number of cases, as may actually be helpful in prolonging vessel patency after revascularization and preventing restenosis. Compared to the other trials, this study enrolled patients with more complex lesions on average; nevertheless, our results are consistent with the results found in the literature.

According with these results, it is reasonable to use a polymer-coated paclitaxel-releasing stent

in patients with SFA or PPA lesions to exploit its efficacy in prolonging intermediate-term vessel patency and to avoid a re-intervention.

Ethical Approval

This is a retrospective study therefore not subjected to the opinion of the ethics committee; however, all procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study prior to the intervention.

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