VIA MEDICA

ORIGINAL ARTICLE

Acta Angiol
Vol. 31, No. 1, pp. 1–11
DOI: 10.5603/aa.101546

ISSN 1234–950X
e-ISSN 1644–3276

Prospective, Randomized Clinical Trial Evaluating Safety and Efficacy of Cobalt-Chromium Sirolimus--Eluting Stent (PERS) Versus Cobalt-Chromium Stent (Neptun C) to Maintain Patency of Iliac Arteries in Patients Undergoing Peripheral Angioplasty

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Abstract

Introduction: *The study aimed to assess the safety and efficacy of the new cobalt-chromium sirolimus-eluting stent (PERS, Balton, Poland) compared to cobalt-chromium stent (Neptun C, Balton, Poland) in patients with symptomatic iliac artery disease undergoing endovascular revascularization.*

Materials and methods: *This was a prospective, randomized clinical study. The primary endpoint was defined as the major adverse event rate (MAE defined as death associated with stent implantation or procedure surgery, amputation above the metatarsus in the treated limb due to vascular complications, or re-intervention in a treated lesion) at 12 months. The secondary endpoints were vessel patency; implantation, procedural and clinical success, change in ankle-brachial index (ABI), mortality rate, change in peak systolic velocity (PSV) and % diameter stenosis. (ClinicalTrials.gov NCT04323033).*

Results: *40 patients were included, 20 patients in the PERS group and 20 patients in the Neptun C group. Procedural and implantation success rates were 100% in both groups. MAE rates in both groups were 0% at 12 months. Vessel patency rates were 100% in all cases at every time point (30 days, 6 months and 12 months). Clinical success at 12-month follow-up was numerically higher in the PERS group than in the Neptun C group (94.44% vs 85%), but there were no statistically significant differences in ABI change between the groups. In an ultrasound examination, % diameter stenosis did not reach 20% in any of the study groups.*

Conclusions: *The results showed a favourable safety profile of PERS stents, but the efficacy results were comparable between PERS and Neptun C stents.*

Keywords: endovascular revascularization, peripheral artery disease, PAD, LEAD, lower extremity atherosclerotic disease

Acta Angiol 2025; 31, 1: 1–11

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Received: 12.07.2024; Accepted: 3.01.2025; Early publication date: 11.03.2025

Introduction

Peripheral artery disease (PAD) is an increasing medical issue. In developed countries, PAD affects both men and women equally, and its prevalence is approximately 5% in the population aged 45–50 years and 18.6% in the population aged 85–90 years [1]. The number of deaths caused by PAD has been steadily growing, for example from 16,000 in 1990 to as much as 41,000 in 2013. A further increase in the number of patients with PAD is expected along with the ageing population and growing prevalence of obesity and diabetes [2].

Untreated PAD is associated not only with an increased risk of amputation of the affected limb and disability but also with an increased risk of myocardial infarction, ischaemic stroke or cardiovascular death. These complications additionally lower the quality of life of symptomatic PAD patients, which is initially depressed. Before the introduction of endovascular techniques, surgical methods were a gold standard. Although not all surgical procedures require general anaesthesia, they may result in longer hospitalization and an increased risk of infection. These risks incited the development of alternative revascularization methods [3].

According to the guidelines, in the case of lesions located in the iliac artery routine stent implantation is currently preferred, in contrast to popliteal interventions, where balloon angioplasty is the method of choice [4]. In a study conducted in 250 patients, comparing the use of only balloon angioplasty with stent implantation in iliac arteries, the use of stents was associated with a 2.5-fold reduction (10% vs 4%) of procedure failures [5]. In addition, a meta-analysis comparing studies on interventions in the iliac artery demonstrated a 39% reduction in the risk of reinterventions with stent implantation in comparison with balloon angioplasty. In a 4-year follow-up, only 67% of patients in the group undergoing balloon angioplasty alone had a clinical improvement (by one or more Fontaine classes) in comparison with 90% of patients who underwent stent implantation [6]. As demonstrated in another study assessing complex interventions in iliac arteries, in the group with stent implantation primary patency was 78% in the 1-year follow-up, while secondary patency at 32 months was 80%, with a reduction of the need for reintervention by 39% in comparison with balloon angioplasty [7]. Many other clinical trials demonstrated the superiority of stent use in interventions within iliac arteries in comparison with balloon angioplasty [4, 8–11].

Stents that release antiproliferative drugs (drug-eluting stents, DES) have dominated interventions in coronary arteries, as they considerably limit neointimal hyperplasia and thus reduce the need for repeated revascularisations in comparison with bare metal stents [12]. DES is also increasingly used with very good clinical effects in interventions in femoropopliteal arteries [13–15]. Additionally, despite considerable progress in the last decade in the treatment of iliac artery stenosis with self-expanding stents, the new generation of balloon-expandable stents has been significantly less developed. The latter are superior to self-expanding stents in the treatment of calcified stenoses in iliac arteries, owing to their greater radial force. This applies especially to stents made of cobalt-chromium alloys, which have a greater radial force in comparison with stents made of steel. Additionally, balloon-expandable stents can be implanted with greater precision, owing to which a more thorough covering of the treated lesion is possible [10].

Therefore, recently, Balton company has developed the PERS stent made of a cobalt-chromium alloy and coated with a biodegradable polymer that elutes an antiproliferative drug — sirolimus. A preclinical study of tissue response on a domestic swine model demonstrated very good safety and efficacy of PERS stents (data not shown).

This study aimed to assess the safety and efficacy of new-generation cobalt-chromium sirolimus-eluting PERS stent (without CE mark, Balton, Poland) in comparison with cobalt-chromium NEPTUN C® stent (Balton, Poland) in patients undergoing endovascular revascularization in iliac arteries.

Materials and methods

Device

Pers is a new peripheral stent before CE-marking manufactured by Balton. It is a cobalt-chromium stent coated with a drug and a biodegradable polymer controlling drug elution — Rezomer. Sirolimus is an active pharmaceutical agent at the concentration of 1.3 $\mu g/mm^2$. The stent was available (the 0.035'' over-the-wire system) with nominal diameters between 4 and 12 mm, and lengths between 20 and 100 mm. As a control group, a CE-marked cobalt-chromium Neptun C stent was used.

Study population and study design

The study was a prospective, randomized, multicentre clinical trial assessing the safety and effectiveness of cobalt-chromium sirolimus-eluting stent PERS in comparison to cobalt-chromium stent Neptun C in patients undergoing percutaneous revascularization within iliac arteries. 40 patients were enrolled in 3 centres in Poland. Randomization was performed using

the randomization envelope method. All patients signed the informed consent form and met all inclusion criteria and none met exclusion criteria. The inclusion criteria were:

1) *de novo* lesion or restenosis without a previously implanted stent, in a common or external iliac artery with a reference diameter of 5 to 12 mm, length up to 10 cm and stenosis ≥ 50% and ≤ 99% (in quantitative assessment by peripheral angiography), which could be treated with one stent or total occlusion of vessels up to 50 mm long,

2) ability to cross the lesion with the guidewire (assessed during diagnostic angiography),

3) ankle-brachial index (ABI) < 0.9,

4) signs of lower limb ischaaemia based on the Rutherford classification in the range from 2 to 4,

5) age ≥ 18 years.

The main exclusion criteria were:

1) life expectancy of less than two years,

2) chronic kidney disease in stage III–V,

3) lesion in the previously implanted by-pass,

4) target lesion is a chronic total occlusion of significant length, not eligible for percutaneous revascularization,

5) acute lower limb ischaemia,

6) stenosis (> 50%) or occlusion proximally to the lesion being treated,

7) angiographically confirmed thrombus in the lesion to be treated,

8) treatment required an atherectomy to deliver a stent to the treated lesion.

Patients were followed up for up to 12 months (ClinicalTrials.gov NCT04323033). The Independent Ethics Committee approved the study protocol (No KE-0254/204/2018 issued on Sept 27, 2018). The study protocol was compliant with SPIRIT guidelines [16].

Study methodology

Operators were experienced in performing endovascular procedures within the arterial system, considering the specific nature and methodology of percutaneous procedures. Each patient underwent an invasive angiographic or computed tomography evaluation before the procedure. The preferred technique was the femoral antegrade or retrograde approach. In exceptional cases, the brachial artery approach was used. After placement of the vascular sheath or the appropriate guiding catheter, unfractionated heparin in a quantity of 50–100 U/kg was administered, and angiography was performed in two contralateral projections of the treated artery along with measurements of the lesion length and diameters of the reference segments using quantitative vascular angiography (QVA). A 0.014''–0.035'' guidewire was advanced through the stenosis in the iliac artery. A balloon predilatation (balloon diameter: vessel diameter — 1:1 based on QVA measurements) was performed before stent implantation. The recommended minimum balloon inflation time was 120 seconds. Then the stent (PERS or NEPTUN C) was implanted. The stent length was selected to cover the treated lesion with a margin of 5 mm proximally and distally (stent: vessel diameter ratio — 1:1 based on QVA measurements). In case of incomplete stent expansion and poor apposition to the artery wall, post-dilatation was performed.

Before the procedure, ASA and clopidogrel were administered. Following stent implantation, dual antiplatelet therapy was prescribed for 12 months.

Follow-up

Clinical visits were performed at 1, 6, and 12 months. Clinical status, ultrasound examination, ankle-brachial index (ABI), adverse events, and medication intake were evaluated at the follow-up visits.

Endpoints

Primary endpoints:

The major adverse event rate (MAE) at 12 months follow-up, is defined as death related to stent implantation or procedure, amputation above metatarsus in the treated limb due to vascular complication or reintervention in the treated lesion (TLR).

Secondary endpoints:

— Vessel patency 30 days, 6 and 12 months after the initial procedure assessed by duplex Doppler (PSV > 2.5 m/s);

— Success of the device implantation;

— Procedural success;

— Clinical success;

— ABI change after 30 days and 12 months;

— Mortality rate after 30 days, 6 months and 12 months (cardiovascular deaths);

— Peak systolic velocity (PSV) in duplex Doppler after 30 days, 6 months and 12 months after the procedure;

— % of diameter stenosis (DS) in target lesion, based on PSV after 30 days, 6 months and 12 months after the procedure.

The device implantation success was defined as residual stenosis ≤ 30% in angiographic assessment. The device implantation success was defined as residual stenosis ≤ 30% in angiographic assessment and no serious adverse event related to the procedure during hospitalisation. Clinical success was defined as an improvement by at least one Rutherford class in comparison with the class before the invasive treatment.

Statistics

Statistical analysis was performed using the R statistical package version 3.1.2 (R Core Team, 2014). In all analyses, the significance level was set at $p < 0.05$. Descriptive statistics were used to characterize the collected data. The normality of the distribution of continuous variables was tested using the Shapiro-Wilk test. Descriptive statistics included the mean and standard deviation for variables with a normal distribution, and the median, first quartile, and third quartile for variables with a non-normal distribution. Categorical variables were presented as counts and percentages of occurrences for non-empty observations, with the percentage of non-blank observations for each parameter assessed always being at least 95%. Differences in the distribution of continuous variables between the two groups were tested using Student's t-test or the Mann-Whitney test, for variables with normal and non-normal distributions, respectively. Differences in the distribution of categorical variables between groups were tested using Fisher's exact test.

Results

Patient characteristics

20 patients were randomized to the PERS group, and 20 patients — to the Neptun C group. In the final analysis, 18 patients were included in the PERS group (2 were lost to follow-up) and 20 patients in the Neptun C group (Fig. 1). The mean age of the study population was 64.8 ± 8.3 years, and females were 50%. The study subgroups did not differ in terms of comorbidities. Patients in the Neptun C subgroup had more frequent PAD in Rutherford class 3 (80% vs. 35%, $p = 0.009$) and lower ABI values in both limbs ($p = 0.009$ and $p = 0.04$). The intermittent claudication distance values were similar between groups (Table 1).

Procedure data

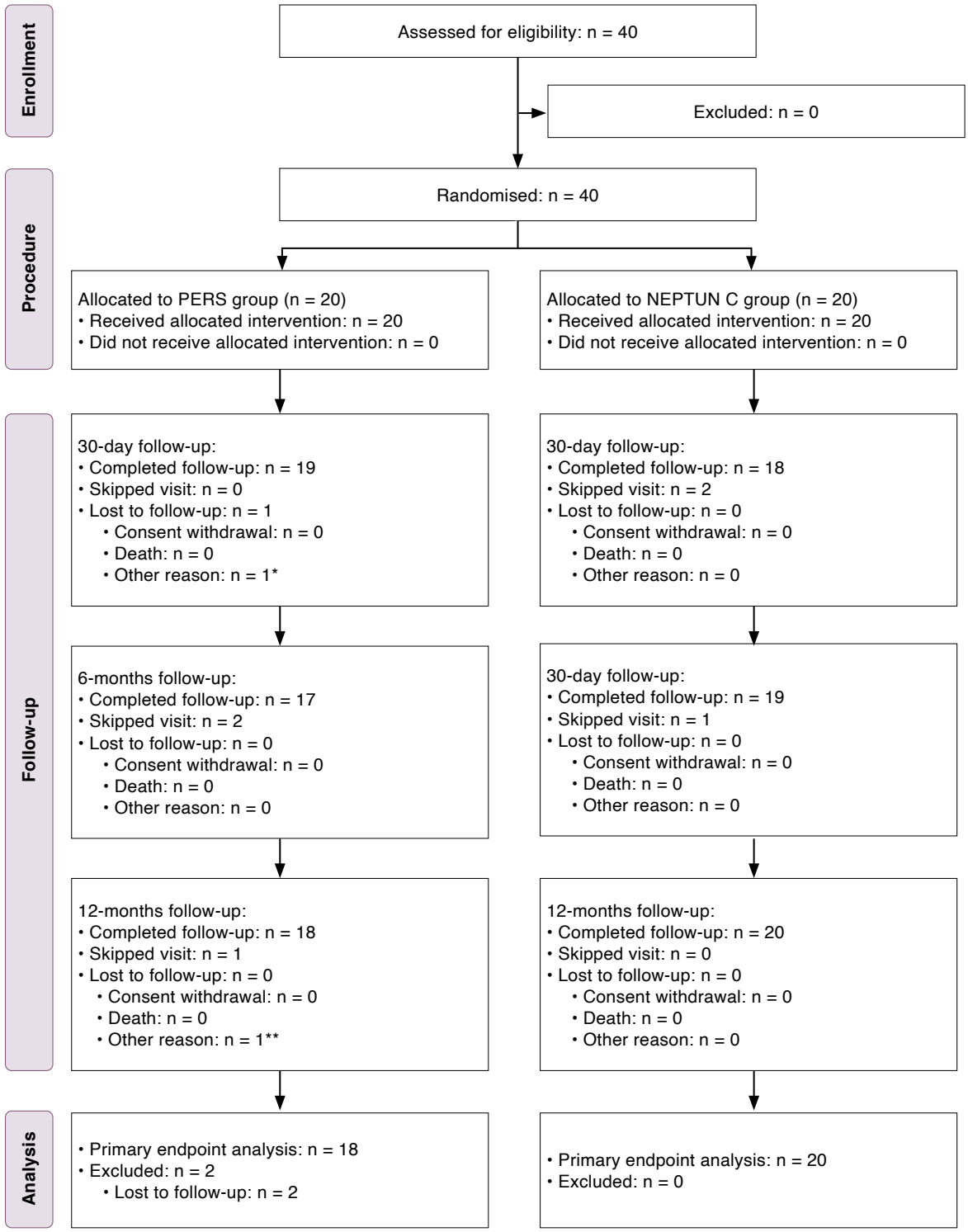
The periprocedural data did not differ between groups. Mostly, procedures were performed from femoral antegrade access (45%) followed by femoral retrograde access (40%), with 6F arterial sheath (82.5%) used. The lesions were in the common iliac artery (55.6%) followed by the external iliac artery (28.9%) and the bifurcation of the common iliac artery (15.6%). Lesions were moderately (42.2%) or highly calcified (48.9%). In 6.7% of the cases, total occlusions were treated. The mean diameter stenosis of the lesion was 79.56 ± 9.83%, and the mean lesion length was 42.29 ± 19.00 mm. Predilatation was performed in 73.3% of cases, and postdilatation in 28.9%, but postdilatation was more frequent in the Neptun C group (45.5% vs. 13%, $p = 0.02$).

The mean PERS stent nominal parameters were as follows: 7.88 ± 1.01 mm × 51.16 ± 14.79 mm, and for Neptun C — 7.42 ± 0.88 mm × 53.96 ± 16.74 ($p = 0.13$ for diameter, $p = 0.58$ for length). There were no periprocedural complications. All devices were

Table 1. Baseline characteristics

Parameter	Whole population n = 40	PERS n = 20	Neptun C n = 20	p
Age [years]	64.8 ± 8.3	63.2 ± 8.6	66.3 ± 7.9	0.24
Sex — females	20 (50)	12 (60)	8 (40)	
Body mass index [kg/m^2]	27.0 ± 4.9	25.6 ± 5.2	28.4 ± 4.2	0.07
Diabetes	15 (37.5)	7 (35)	8 (40)	1
Arterial hypertension	25 (62.5)	9 (45)	16 (80)	0.48
Dyslipidemia	21 (52.5)	8 (40)	13 (65)	0.20
Prior myocardial infarction	10 (25)	5 (25)	5 (25)	1
Prior stroke/TIA	4 (10)	3 (15)	1 (5)	0.61
Prior PTA	16 (40)	7 (35)	9 (45)	0.75
ABI (right limb)	0.75 ± 0.22	0.84 ± 0.19	0.66 ± 0.22	0.009
ABI (left limb)	0.76 ± 0.22	0.84 ± 0.20	0.70 ± 0.22	0.04
Rutherford class				
2	3 (7.5)	3 (15)	0	0.009
3	23 (57.5)	7 (35)	16 (80)	
4	14 (35)	10 (50)	4 (20)	
Intermittent claudication distance (m)	50 (20 – 100)	23 (20 – 95)	50 (23 – 127.5)	0.74

TIA — transient ischaemic stroke; PTA — percutaneous transluminal angioplasty; ABI — ankle-brachial index



Notes:
*Other reason (PERS group, 30 days): not specified
**Other reason (PERS group, 12 months): not specified

Figure 1. Study Flowchart

implanted successfully and procedural success in both groups was 100% (Table 2).

Primary endpoint and ultrasound examination results

No MAEs were noted during the 12-month follow--up, defined as death directly related to the procedure, amputation above the metatarsus in the treated limb for vascular reasons and/or TLR in the PERS group as well as in the Neptun C group.

In all patients in both groups, the treated vessel was patent at 12 months, as shown in the ultrasound examination (Table 3).

Change in Rutherford classification and intermittent claudication distance

Table 4 presents changes in Rutherford classification and intermittent claudication distance (Fig. 2). There were no statistically significant differences between subgroups at the follow-up. Based on the clinical success defined as an improvement by at least one Rutherford class in comparison with the class before the invasive treatment, the clinical success at discharge was (Pers vs. Neptun C) 66.7% vs. 68.4% (p = 0.9), at 30 days — 78.9% vs. 94.4% (p = 0.3), at 6 months — 88.2% vs. 83.3% (p = 1), and at 12 months — 94.4% vs. 85.0% (p = 0.6).

Table 2. Periprocedural data

Parameter	Whole population n = 40	PERS n = 20	Neptun C n = 20	P
Vascular access				
Femoral antegrade	18 (45.0)	7 (35.0)	11 (55.0)	0.74
Femoral retrograde	16 (40.0)	9 (45.0)	7 (35.0)	
Brachial artery	6 (15.0)	4 (20.0)	2 (10.0)	
Procedure duration	46.43 ±33.75	48.95 ± 37.85	43.90 ± 29.87	0.64
Arterial sheath				
5 F	1 (100.0)	0	1 (100.0)	1
6 F	33 (82.5)	17 (85.0)	16 (80.0)	
7 F	3 (7.5)	0 (0.0)	3 (15.0)	
8 F	3 (7.5)	3 (15.0)	0	
Lesion information	N = 45	N = 23	N = 22	–
Lesion location				
Bifurcation of the common iliac artery	7 (15.56)	3 (13.04)	4 (18.18)	0.51
Common iliac artery	25 (55.56)	14 (60.87)	11 (50.00)	
External iliac artery	13 (28.89)	6 (26.09)	7 (31.82)	
Vessel calcification grade				
None	1 (2.22)	1 (4.35)	0 (0.00)	0.53
Low	3 (6.67)	2 (8.70)	1 (4.55)	
Moderate	19 (42.22)	8 (34.78)	11 (50.00)	
High	22 (48.89)	12 (52.17)	10 (45.45)	
Lesion type				
Total occlusion	3 (6.67)	2 (8.70)	1 (4.55)	1
Stenosis	42 (93.33)	21 (91.30)	21 (95.45)	
Stenosis %	79.56 ± 9.83	80.64 ± 8.90	78.48 ± 10.79	0.49
Lesion length	42.29 ± 19.00	40.57 ± 19.88	44.09 ± 18.32	0.56
Predilatation	33 (73.33)	15 (65.22)	18 (81.82)	0.17
Stent diameter	7.65 ± 0.97	7.88 ± 1.01	7.42 ± 0.88	0.13
Stent length	52.53 ± 15.67	51.16 ± 14.79	53.96 ± 16.74	0.58
Postdilatation	13 (28.9)	3 (13.0)	10 (45.5)	0.02

Table 3. Ultrasound examination results

Parameter	Whole population	PERS	Neptun C	P
% diameter stenosis assessment (%)				
Stenosis at discharge	6.76 ± 8.84	8.00 ± 9.51	5.29 ± 8.00	0.34
30 days	8.66 ± 10.12	10.48 ± 10.24	6.41 ± 9.82	0.23
6 months	9.17 ± 10.52	8.24 ± 10.15	10.00 ± 11.06	0.62
12 months	12.22 ± 16.92	8.75 ± 10.25	15.00 ± 20.65	0.46
Peak systolic velocity assessment [cm/s]				
30 days	97.17 ± 57.81	98.11 ± 59.64	96.06 ± 57.30	0.91
6 months	105.83 ± 52.25	106.95 ± 56.07	104.82 ± 50.12	0.90
12 months	106.06 ± 61.77	99.19 ± 55.61	111.55 ± 67.20	0.56

Table 4. Rutherford classification at follow-up

Parameter	Whole population	PERS	Neptun C	P
At discharge				
0	1 (2.70)	0 (0.00)	1 (5.26)	1
1	5 (13.51)	3 (16.67)	2 (10.53)	
2	16 (43.24)	8 (44.44)	8 (42.11)	
3	12 (32.43)	5 (27.78)	7 (36.84)	
4	3 (8.11)	2 (11.11)	1 (5.26)	
30 days				
0	2 (5.41)	1 (5.26)	1 (5.56)	1
1	12 (32.43)	6 (31.58)	6 (33.33)	
2	16 (43.24)	8 (42.11)	8 (44.44)	
3	6 (16.22)	3 (15.79)	3 (16.67)	
4	1 (2.70)	1 (5.26)	0 (0.00)	
6 months				
0	–			1
1	18 (51.43)	9 (52.94)	9 (50.00)	
2	11 (31.43)	5 (29.41)	6 (33.33)	
3	4 (11.43)	2 (11.76)	2 (11.11)	
4	2 (5.71)	1 (5.88)	1 (5.56)	
12 months				
0	2 (5.26)	2 (11.11)	0	0.74
1	16 (42.11)	7 (38.89)	9 (45.00)	
2	14 (36.84)	6 (33.33)	8 (40.00)	
3	5 (13.16)	3 (16.67)	2 (10.00)	
4	1 (2.63)	0	1 (5.00)	

Change in ABI values at follow-up

Table 5 presents changes in ABI at follow-up visits. ABI change at 12 months ≥ 0.10 was observed in 68.75% of patients in the PERS group and 66.7% in the Neptun C group (p = 0.89), and ≥ 0.15 – in 62.5% of patients in the PERS group and 57.14% of patients in Neptun C group (p = 0.74).

Discussion

This premarket study showed the initial results with a new peripheral sirolimus-eluting stent PERS. This prospective, randomized clinical study supported the safety of the PERS stent, but no additional benefits of the drug-eluting PERS stent compared to the NEPTUN C

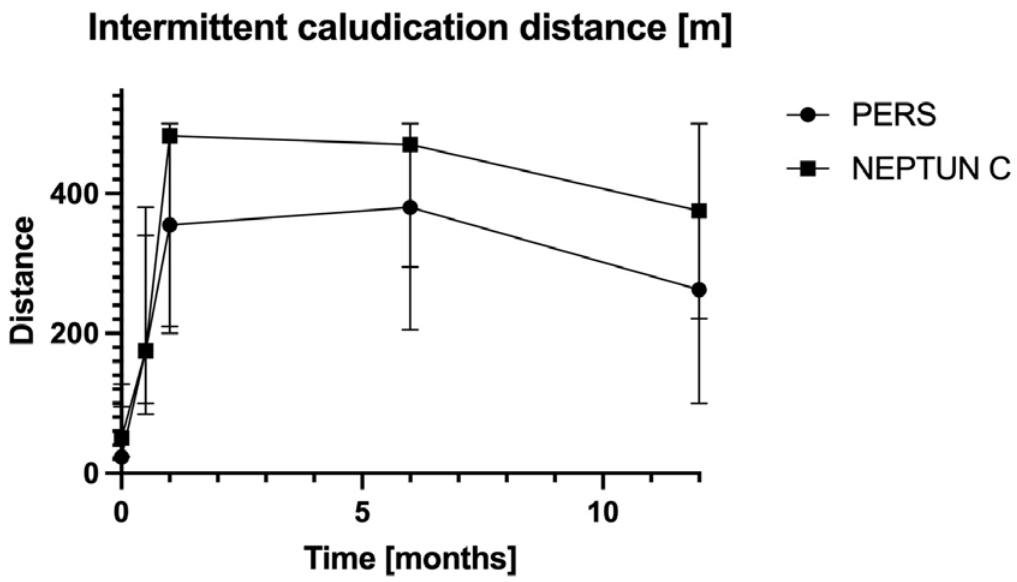


Figure 2. Intermittent claudication distance

stent were demonstrated in the long-term follow-up of patients with symptomatic iliac artery disease. The clinical success at discharge was (PERS vs. Neptun C) 66.7% vs. 68.4% (p = 0.9), at 30 days — 78.9% vs. 94.4% (p = 0.3), at 6 months — 88.2% vs. 83.3% (p = 1), and at 12 months — 94.4% vs. 85.0% (p = 0.6).

The iliac arteries are a frequently affected area by obstructive atherosclerosis, making up about a third of all cases of symptomatic peripheral artery disease [17]. Treatment options for aortoiliac disease include endovascular therapy and surgical bypass grafting. Advanced stents and endovascular methods can now achieve comparable long-term effectiveness to surgical bypass grafts in navigating complex blockages. Consequently, endovascular stent placement has become the primary choice for revascularization in patients experiencing symptomatic iliac artery stenosis [18].

Stents available for use in the aortoiliac arteries can be divided into balloon-expandable stents, self-expanding stents, and covered stents. Although significant data exist for each stent type, most clinical studies have included patients with relatively less complex diseases. In addition, little comparative data exist between stent types.

The present study used balloon-expandable stents. Balloon-expandable stents are made of a cylindrical framework formed from a metal wire attached to an angioplasty balloon. While these stents typically have strong radial force, they are less flexible compared to self-expanding stents. The original Palmaz stent, for instance, was made of stainless steel [19]. However, modern balloon-expandable iliac stents have been significantly improved with a finer mesh structure and thinner struts, such as those made from

Table 5. ABI change at follow-up visits

Parameter	Whole population	PERS	Neptun C	P
At discharge				
ABI (right limb)	0.85 ± 0.17	0.89 ± 0.15	0.82 ± 0.18	0.19
ABI (left limb)	0.89 ± 0.20	0.96 ± 0.19	0.82 ± 0.19	0.02
30 days				
ABI (right limb)	0.87 ± 0.17	0.89 ± 0.13	0.84 ± 0.21	0.37
ABI (left limb)	0.88 ± 0.16	0.91 ± 0.16	0.85 ± 0.16	0.24
12 months				
ABI (right limb)	0.89 ± 0.22	0.98 ± 0.13	0.81 ± 0.25	0.01
ABI (left limb)	0.88 ± 0.15	0.93 ± 0.15	0.83 ± 0.14	0.04

ABI — ankle-brachial index

cobalt-chromium alloy. This design enhancement provides increased flexibility while maintaining excellent radial strength. PERS and Neptun C were made of cobalt-chromium, and additionally, PERS released sirolimus.

The device success rates in both groups were 100%. There were no periprocedural complications. The typical method for endovascular treatment of obstructive iliac artery disease involves accessing the femoral artery, employing either a retrograde or antegrade-crossover approach. Although retrograde access is simpler from a technical standpoint, using a crossover sheath provides superior visualization of the lesion. Additionally, radial or brachial artery access can be utilized for endovascular treatment of the iliac arteries. Moreover, most peripheral balloons and stents currently on the market can reach the proximal to mid-iliac arteries when the radial or brachial artery is used for sheath access, including PERS and Neptun C. In the present study, the femoral antegrade approach was used in 45% of cases, femoral retrograde — in 40% of cases, and brachial artery — in 15% of cases.

Drug-eluting technology has gained broad acceptance as an effective treatment for coronary artery stenosis and blockages, demonstrating better outcomes compared to bare metal stents or plain old balloon angioplasty (POBA) [20]. Numerous studies have also demonstrated the superiority of drug-eluting stents (DES) and drug-coated balloons (DCB) over POBA in the treatment of lower limb arteries [21, 22]. Nevertheless, in a study comparing DCB and POBA in iliac arteries, the results were not so encouraging. Primary patency rates were 90.5% vs 85.7% at 6 months and 71.4% vs 75.6% at 12 months for DCB and POBA, respectively ($p = 0.784$). The TLR rate was 28.6% (6/21) in the DCB group and 20.0% (4/20) in the POBA cohort ($p = 0.434$) [23].

Similar results were obtained in the present study when using stents: DES vs. BMS. At 12 months there were no MAE in both groups as well as there were no differences in clinical parameters (ABI, intermittent claudication distance, ultrasound parameters [%DS, PSV]). This might be associated with the small number of treated patients, but also with the fact that iliac arteries have large diameters, and therefore there can be lesser significance of the drug release to prevent restenosis than the scaffold itself.

Also, the recent meta-analysis supported the use of BMS in the iliac artery treatment [24]. Two trials examined the efficacy of primary BMS implantation versus POBA with provisional BMS in 396 patients with short iliac lesions. In the STAG trial, focused on treating iliac occlusions (average length 54.1 ± 15.8 mm), patency rates remained comparable over a 2-year follow-up period. However, the study was prematurely halted due to an increased incidence of major complications in the provisional stenting group compared to primary stenting (20% vs. 5%, $p = 0.01$), primarily due to distal embolization [25]. The Dutch Iliac Stent Trial provided comprehensive data on patency, reintervention, mortality, and amputation rates up to 72 months post-intervention, with no discernible differences in outcomes at any follow-up interval [26–28].

Two randomized controlled trials compared primary stenting strategies. The ICE trial randomly assigned 660 patients to either primary self-expanding BMS or balloon-expandable BMS implantation for common or external iliac artery lesions (average length 37.5 ± 30.0 mm). Mid-term patency favoured self-expanding stents (odds ratio [OR] 2.69, 95% confidence interval [CI] 1.31–5.52), along with a lower risk of target lesion revascularization (OR 0.41, 95% CI 0.17–0.97), while safety outcomes remained similar between the two groups [29]. In the COBEST trial, covered stents showed superior mid-term patency compared to BMS (OR 3.15, 95% CI 1.29–7.66). These patency benefits were sustained in a 5-year post-hoc analysis, with no notable differences observed in mortality and amputation rates [30]. However, the COBEST trial was noted for its high risk of bias.

Study limitations

Although this was RCT, the sample size was limited which could impact the differences between the groups. Also, there were no incidents so result interpretations were more difficult.

Conclusions

The results from this prospective, randomized clinical supported the safety of the PERS stent, but no additional benefits of the PERS drug stent compared to the NEPTUN C stent were demonstrated in the 1-year follow-up of patients with symptomatic iliac artery disease.

Article information and declarations

Conflict of interest: Authors have consultancy contracts with Balton Company.

Funding: The study was financed by Balton Company.

Authors contribution: Conceptualization: PN, Investigation: PN, TP, TZ, WU, PT, SM,
Methodology: PN, TZ, Project administration: PM, TZ. Resources: PN, TZ. Writing — review & editing: PN, TZ.

Acknowledgements: The authors thank Jacek Bil, MD, PhD (JO Medical Solutions) for providing medical

writing support by Good Publication Practice (GPP3) guidelines (http://www.ismpp.org/gpp3).

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