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Evaluation of the first polish stent „Neptun" in the treatment of arteriosclerosis of the iliac arteries

Ocena pierwszego polskiego stentu „Neptun" w leczeniu zmian miażdżycowych tętnic biodrowych

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Summary

Background: Angioplasty of occluded iliac arteries connected with stent implantation demonstrated the high technical efficacy and good clinical effect of the stent. The patency of iliac vessel stents 12 months after their implantation ranged between 86 and 99%, depending on the author cited. The aim of the study was to determine the safety and clinical efficacy of iliac artery angioplasty following the implantation of the Polish stent Neptun, manufactured by Balton.

Material/Methods: The study group comprised 56 patients aged between 39 and 83 years diagnosed with stenosis or iliac artery occlusion, subjected to implantation of 75 stents. The patients were directed towards intravascular procedures on the basis of their medical history as well as clinical and imaging examinations, including Doppler ultrasound and DSA angiography. Clinical symptoms were based on Fontaine's classification, evaluated before the procedure and three days after. Considering the similar time intervals, the ankle-brachial index (ABI) was evaluated. Distant results were determined on the basis of clinical examinations in addition to the ABI estimation performed during the follow-up visit 12 months after the procedure. Thirty-seven patients required single stents, while in 9 subjects both iliac arteries were subjected to stenting, including the abdominal aortic bifurcation. In six patients, stents were implanted to both iliac arteries, the aortic bifurcation excluded. Four patients were subjected to the implantation of two stents, involving one of the iliac arteries.

Results: In all patients a positive technical and clinical effect was obtained. Improvement according to Fontaine's classification was observed in the whole study group of patients (evaluation undertaken three days after the procedure). The mean ankle-brachial index on admission was 0.62 ± 0.17. After angioplasty, this index significantly increased ($p < 0.01$) to 0.87 ± 0.19. After the one-year observation period the AB index decreased to 0.82 ± 0.18 (p=NS). Ultrasonographic control comprised 49 patients with 65 implanted stents. Complete vessel patency was confirmed in 60 (92.3%) 12 months after stent implantation.

Conclusions: Based on this evaluation, Neptun stents are safe, their technical and clinical efficacy amounting to 100% during the perioperative period. The stents assure good visualization during implantation. Their patency after the one-year observation period proved to be high, being comparable to other previously used stents. Further investigations are required, involving a longer follow-up period.

Key words: angioplasty • stent • iliac artery

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Background

Percutaneous iliac artery angioplasty with stent implantation is an effective, minimally invasive and alternative method of theapy, in comparison to classical surgical procedures applied in the treatment of aortic and iliac artery occlusion, due to atherosclerosis [1]. Especially good intravascular treatment results were obtained in case of isolated iliac artery, short segment atheromatous lesions [2].

For more than 20 years the implantation of metallic stents has been considered as a supplemental method of therapy, following unsatisfactory percutaneous angioplasty [3–5]. Other indications for stent implantation are as follows: extensive dissection of the arterial wall leading towards occlusion, symptomatic iliac artery ulceration, as well as restenosis after previous PCI (percutaneous intervention) [6, 7].

Stent implantation is undertaken in case of atheromatous arterial occlusion or complex lesions, such as multi-layer, long-segmental, eccentric and highly calcified lesions [6, 8]. Primary stent implantation in case of iliac artery occlusion is also connected with fewer complications, in comparison to PCI without stent implantation [7].

Together with endovascular techniques progress and the production of new generation stents the efficacy and distant intravascular iliac artery procedure results significantly improved.

Contemporary stents may be divided into two groups: mechanically expandable on balloon catheters (steel), such as Palmaz-stents, and self-expandable stents (nickelic-titanic stents – SMART).

Until recently only imported stents were used, in spite of the increasing demands and indications towards their application.

The aim of this study was to determine the safety, clinical efficacy and distant treatment results following iliac artery stenting with the use of the first Polish stent-Neptun mounted on the balloon catheter.

Material and methods

During the period between october 2002 and november 2004, 56 patients (67 extremities) with iliac artery stenosis or occlusion underwent treatment (implantation of 75 stents) at the Department of General and Vascular Surgery, as well as Vascular Laboratory of the Department of Radiology, Medical Academy Poznan. Patient age ranged between 39 and 83 years (mean age – 61.2 years), including 37 male and 19 female subjects.

Qualification of patients towards intravascular procedures was based on the medical history, clinical examination and imaging methods (USG – doppler and DSA angiography).

Clinical symptoms were evaluated according to Fontaine's classification, prior to the procedure and three days thereafter. The AB index was also determined at the same time.

In order to determine distant results after 12 months, clinical and ABI evaluation were undertaken during the control visit. Tables 1 and 2 demonstrated the demographic data of the investigated group.

Ultrasound doppler examinations were performed using Elegra equipment, manufactured by Siemens with two changeable frequency probes: 2.5 – 4.5 MHz and 5.5 – 9.5 MHz. Each time the examination comprised the spectrum and flow velocity measurements through the abdominal aorta and iliac arteries. The above-mentioned were always performed before DSA angiogarphy, 12 months after stent implantation, as well as in case of clinical symptoms suggestive of recurrent occlusion.

DSA angiography of the lower extremity vessels was performed by means of Seldinger's method with the placement of the diagnostic catheter in the distal segment of the abdominal aorta. A non-ionic contrast medium was introduced by means of an automatic syringe at a dose of 20–30 ml (flow: 10–20 ml/s).

The degree of arterial stenosis and length of the atheromatous lesion were estimated during DSA angiography, on the basis of catheter calibration.

Iliac artery lesions were retrospectively divided, according to the TASC classification [6]: group A – 24 patients, group B – 16 patients, group C – 11 patients, and group D – 5 patients.

Iliac artery angioplasty with stent implantation was directly performed after DSA angiography. After arterial puncture by means of Seldinger's method, a 7F, 10 cm long introducer

Table 1. Risk factors of patients with stenosis or iliac vessel occlusion (n=56).

Tabela 1. Czynniki ryzyka chorych z przewężeniem lub niedrożnością naczyń biodrowych (n=56).

Smoking	44 (78.6%)
Hypertension	25 (44.6%)
Diabetes mellitus	5 (8.9%)
Hyperlipidemia	21 (37.5%)
Coronary heart disease	12 (21.4%)
Kidney insufficiency	1 (1.8%)

Table 2. Clinical symptoms of patients with stenosis or iliac vessel occlusion-according to Fontaine's classification (n=56).

Tabela 2. Objawy kliniczne chorych z przewężeniem lub niedrożnością naczyń biodrowych – klasyfikacja wg Fontaine'a (n=56).

Claudication > 200 m (IIa)	11
Claudication between 100 – 200 m (IIb)	26
Claudication < 100 m (IIb)	8
Rest pain (III)	4
Crural ulceration (IV)	7

(Balton) was placed into the common femoral artery or both common femoral arteries. In 47 cases, 0.35J hydrophilic guides (Terumo) were used, while in 24 cases, 0.32J teflonic guides (Balton).

In all cases the Polish-Neptun stent was used, produced by Balton (Balton, Warsaw, Poland), mounted on balloon catheters. Balloon predilatation was performed in case of 44 atheromatous lesions (58.6%), while 31 (41.4%) were subjected to primary stenting. Considering initial iliac artery dilatation, 6–8mm in diameter and 2–8cm long balloon catheters were used. In 11 cases of iliac artery occlusion, intravascular subintimal patency restoration by means of Boli's method was undertaken [9, 10] (fig. 1). The diameter of implanted stents ranged between 7–10 mm, while the length – 3–8 cm.

During the performed procedures we subjectively estimated the visibility of the stent, according to the following scale: poor, good, very good.

All patients received 5000 units of unfractionated heparin during premedication. After the procedure patients received ticlopidine at a dose of 2x250 mg for a period of 3 months, and aspirin for 12 months at a dose of 150 mg, once daily.

The technical evaluation of the angioplasty with stent implantation was based on three elements: arteriographic stent localization, proper adjustment to the vascular wall (expansion), as well as presence of remaining stenoses (≤30% and >30%).

Clinical success of the procedure was obtained in case of reduction of symptoms, according to Fontaine's classification, considering patients primarily qualified towards the 2 and 3 group (one grade), and those in group 4 (two grades). In order to objectivize the clinical effect we also determined the AB index, before and after the performed procedure.

In case of clinical symptoms recurrence and AB index deterioration during the observation period, patients were subjected to control angiography.

Statistical analysis was performed by means of the t-Student test, considering related variables, as well as the chi^2 test using the STATISTICA program (Windows 5.1 (PL), manufactured by StatSoft, Inc.). $p<0.05$ was considered as statistically significant.

Characteristics of the Polish stent-Neptun

The peripheral stent (Neptun) is cut from medical steel during its production by means of a laser (316 LVM). The above-mentioned is a non-ferrous magnetic material, thus, patients with Neptun stents may be subject to MRI examinations. The balloon mounted stent is pointed out by golden markers, visible during radiological examinations.

Ready-made stents are mounted on 80 and 110 cm balloon catheters. Their diameter ranged between 4 and 10 mm, and length between 16–100 mm. The pressure applied during expansion amounted to 6 atmospheres, maximum – 10 atm. 6–8F introducers are used, depending on the diameter of the stent. The manufacturer mentioned the admissible shortening of the stent during expansion, <5% its initial length, as well as its diameter of <2% after implantation*.

Results

In case of all our patients (100%) technical success was obtained after stent implantation. In 31 of 44 stent implantation procedures, considering balloon predilatation, immediate good effects were obtained after angioplasty alone. We noted internal layer separation considering 13 of 44 procedures with predilatation (29.5%) after balloon angioplasty (fig. 2). None of the procedures posed technical difficulties, considering the insertion of the stent through the atheromatous lesion.

In 3 of 31 primarily stented lesions complications were noted during the passage of the catheter through the occluded iliac artery. In one case we observed the displacement of the stent from the balloon catheter. These patients were subjected to balloon angioplasty followed by iliac artery stenting. In the remaining 28 cases the procedure posed no difficulties.

During expansion of Neptun stents we observed the filling of the balloon in its proximal part followed by expansion of the distal part. Stent expansion at the proximal and distal

Figure 1. DSA angiography. Impatency of the right iliac artery system. Subintimal guide introduced into the abdominal aorta.

Rycina 1. Badanie DSA i.a. Niedrożność układu tętnic biodrowych po stronie prawej. Prowadnik subintimalnie przeprowadzony do aorty brzusznej.

* Technical data considering "Neptun" stents were based on the manufacturer's leaflets (Balton).

Figure 2. Subintimal iliac artery angioplasty on the right side. Visibly detached internal layer flap.
Rycina 2. Subintimalna angioplastyka tętnic biodrowych po stronie prawej. Widoczny odwarstwiony fałd błony wewnętrznej.

ends, nearly simultaneously, enabled to optimally position the stent reducing the possibility of their displacement, in relationship to atheromatous lesions.

Thirty-seven patients were subjected to single stent implantations, while nine required stents to both iliac arteries and the abdominal aortic bifurcation (*kissing stents*) (fig. 3). In six cases stents were introduced bilaterally, the abdominal aortic bifurcation excluded. Four patients required two stents on one side. A positive technical and clinical effect was observed in all patients. Incomplete stent expansion and translocation, as well as vessel perforation were absent. We observed minimal shortening of the stents during the expansion procedure, being in accordance with the producer's instructions.

During angioplasty procedures we subjectively evaluated the visibility of the stents, which turned out to be very good in 90% of cases, and good in the remaining.

After angioplasty only two local complications were observed-hematomas, without the need for surgical intervention. Directly after the procedures stent thrombosis was not observed. Peripheral emboli were also absent.

The mean AB index value before the procedure amounted to 0.62 ± 0.17. Three days after the procedure, the above-mentioned increased to 0.87 ± 0.19, being statistically significant ($p<0.01$). After 12 months the AB index decreased to 0.82 ± 0.18, being statistically insignificant.

Three days after stent implantation, according to Fontaine's classification, patients were qualified to a lower grade, in comparison to pre-procedure evaluations.

Figure 3. Neptun stents implanted into both common iliac arteries, the "kissing-stents" type of angioplasty.
Rycina 3. Stenty Neptun wszczepione do obu tętnic biodrowych wspólnych. Angioplastyka typu „kissing-stents".

Two (4.1% subjected to stent implantation) patients were admitted to the Department during the initial six months after the procedure, due to iliac artery thrombosis. In one case the patient presented with one stent, while the latter female patient was treated by means of the "kissing-stent" method. Both patients were subjected to successful "cross-over" fibrinolytic treatment. Streptokinase was used as the fibrinolytic agent, administered for 48 hours at a dose of 20000 U/hour. The efficacy of treatment was evaluated on the basis of clinical symptoms, angiographic examination, fibrinogen level reduction and prolonged thrombin time. After streptokinase, patients received intravenous heparin for a period of five days, followed by oral anticoagulation for a period of six months. Complications connected with streptokinase and oral anticoagulant administration were absent. The clinical and radiological effects were good.

Forty-nine patients with 65 implanted stents were subjected to yearly ultrasound examinations. Seven patients did not show up for control visits. Complete vascular patency was observed in case of 60 (92.3%) stents, 12 months after their implantation.

Discussion

The use of stents is an acknowledged and effective therapeutical method, considering patients with lower extremity atheromatous lesions. Stenting is especially beneficial in case of the incomplete hemodynamic and clinical effect of angioplasty [1]. In such cases stent implantation might be a planned procedure and dose not have to be preceded by predilatation angioplasty [11]. The latter is only performed in case of ineffective angioplasty with significant residual stenosis [12].

Advocates of primary stenting ascertained that the above-mentioned reduces the percentage of peripheral embolism

and arterial wall separations, possibly connected with better distant results considering stenting [11, 13]. It is worth pointing out that in the subgroup of patients subjected to stent implantations preceded by balloon predilatation the immediate good effect after angioplasty was observed in 70.5% of cases (31 of 44 procedures). In case of 13 procedures (29.5% of the predilatation group) following balloon angioplasty we observed internal layer separation.

Prospective investigations demonstrated that the percentage of complications, distant vessel patency, as well as reintervention were similar, both in case of angioplasty and primary stenting [12]. Based on our observations and literature data stent implantation should be the method of choice in case of the incomplete effect of angioplasty [12, 14], as well as during the course of arterial dissection [14]. The above-mentioned complication was observed in case of 30% of patients. Thus, primary stenting seems fully justified.

Polish Neptun stents enabled to maintain patency in 92.3% of patients, after a one year observation period. The result, being comparable to literature data, where patency after one year ranged between 91–94% [15–16].

Expandable stents mounted on balloon catheters differ from self-expandable steel or nickel stents not only by means of the implantation technique. The presence of the stent on the balloon catheter enables its precise localization, considering any segment of the iliac artery, which reduces the risk of uncontrolled stent slipping during expansion. The use of expandable balloon stents enables better control of their localization, in comparison to the use of self-expandable nitinol stents. The above-mentioned technique is also easier to perform [14, 17]. Considering the analysed material immediate technical success was obtained in 100% of cases.

The evaluated first expandable Polish stent (Neptun), manufactured by Balton was well visualized during x-ray examinations, compared to other foreign company stents.

There are different methods determining the efficacy of angioplasty or iliac artery stenting: clinical evaluation (subjective symptoms, according to Fontaine's classification, and ABI analysis), as well as radiological assessment (ultrasonography and angiography). Many authors considered treatment as effective, when residual stenosis amounted to <5–30% during angiography [11,17], and the pre- and post-stenosis pressure gradient <10 mmHg [17]. German investigators analysed ABI values, considering the objective and non-invasive evaluation of the efficacy of the procedure [11, 14, 17]. We determined the efficacy of the procedure on the basis of the clinical evaluation (pulse palpation, subjective evaluation of symptoms, according to Fontaine's classification, and ABI analysis), and complete radiological assessment.

Immediate technical efficacy was obtained in 100% of cases, and the percentage of patent stents after a one-year follow-up period amounted to 92.3%. The above-mentioned values are similar to those obtained by other authors, percentages ranging between 88–100% [1,13,14,18–19]. Clinical condition improvement, based on subjective symptoms (Fontaine's scale and the ankle-brachial index (ABI) was similar to literature data results [11,13–14]. This objectively confirms that Neptun stent properties are similar to those of other stents, treatment results being comparable to those of other authors.

The efficacy of angioplasty and iliac artery stenting depends on the length of the stenosed or occluded vessel segment [2,13,19]. Colapinto and co-authors demonstrated that the procedure was effective in 92% of cases, considering the occluded length of the vessel <5 cm. The above-mentioned amounted to 70% in case of occlusion exceeding >5 cm [2]. The patency of stents after long-lasting observations was as follows: 91–94% of patients after 6 months [14,20], 89–95% after one year [1,20], 84.2–98.2% after two years [1,18–19], and 82% after four years [1]. Our observations seem to confirm the above-mentioned, since considering 7.7% of patients with occluded iliac arteries on the side of the implanted stent, all presented with stenosis exceeding 5cm.

No significant complications were noted after stent implantation, as presented in literature data: vascular rupture, translocation or early stent thrombosis, as well as peripheral embolism. Two patients were diagnosed with hematomas at the site of the femoral artery puncture, which did not require surgical intervention. The percentage of complications following iliac artery stent implantations amounted to 6.8% [1]. Particular complications, based on literature data were observed as follows: peripheral embolism – 0–26.1% of cases (13,17], vessel dissection after percutaneous transluminal angioplasty – 10.7% of cases [18], early thrombosis – 17.4% of cases [13], stent translocation – 7.1% of cases [18], and vessel perforation – 3.6% of cases [18]. In case of our patients only vascular dissection was noted (significantly higher percentage).

In order to decrease the risk of peripheral embolism after intravascular treatment (angioplasty and eventual stent implantation), the above-mentioned should be performed in case of patients with recent (<3 months) vascular occlusions. According too other investigations such a short period from vessel closure is considered as an exclusion criterion of angioplasty and stent implantation [17].

Some authors mentioned that most iliac artery stenting complications might be treated by means of intravascular procedures. One should not forget about the high conversion rate, amounting to 12.5% of cases [18]. In the presented study conversion was absent.

Considering two cases we observed stent thrombosis, six months after the procedure. The following factors might be responsible for distant stent occlusion: residual stenosis, restenosis, as well as stent abnormalities [13]. Clinically significant restenosis (50–75%) was observed in 9–9.5% of cases [11,14,17]. It seems that delayed stent closure, due to restenosis or breakage might be connected with procedures performed on long vascular stenoses/occlusions [13]. In case of late intravascular stent impatency, angioplasty seems to be the recommended method of choice [11, 17]. Considering both described cases of late impatency, fibrinolytic treatment was initiated.

Conclusions

Analysis of the presented material enabled the following:

1. Iliac artery stenting with the use of the first Polish-Neptun stent is a safe and effective method.
2. Results following stent implantation after a period of 12 months are similar to those observed in literature data.
3. Further investigations comprising a larger number of patients and longer observation period are required.

References:

1. Vorwerk D, Gunther RW, Schurmann K, Wendt G. Aortic and iliac stenoses: follow-up results of stent placement after insufficient balloon angioplasty in 118 cases. Radiology. 1996; 198: 45–48.
2. Colapinto RF, Stronell RD, Johnston WK. Transluminal angioplasty of complete iliac obstructions. Amer J Roentgenol 1986; 146: 859–862.
3. Rousseau H, Joffre J, Puel J. Percutaneous vascular stent: Experimental studies and preliminary clinical results in peripheral arterial diseases. Int Angiol 1987; 6: 153–161.
4. Gunther RW, Vorwerk D, Bohndorf K. Iliac and femoral artery stenoses and occlusions: treatment with intravascular stents. Radiology 1989; 172: 725–730.
5. Vorwerk D, Gunther RW, Schurmann K, Wendt G. Aortic and iliac stenoses: follow-up results of stent placement after insufficient balloon angioplasty in 118 cases. Radiology 1996; 198: 45–48.
6. Management of peripheral arterial disease (PAD). TransAtlantic Inter-Society Consensus (TASC). Section B: intermittent claudication Eur J Vasc Endovasc Surg. 2000 Jun; 19 Suppl A: S47–114. Review.
7. Sapoval MR, Chatellier G, Long AL. Self-expandable stents for the treatment of iliac artery obstructive lesions: long-term succes and prognostic factors. Am J Roentgenol. 1996; 166: 1173–1179.
8. Vorwerk D, Gunther RW. Stent placement in iliac arterial lesions: tree years of clinical experience with the Wallstent. Cardiovasc Intervent Radiol. 1992; 15: 285–290.
9. Bolia A. Percutaneous intentional extraluminal (subintimal) recanalization of crural arteries. Eur J Radiol. 1998; 28: 199–204.
10. Bolia A. Subintimal angioplasty in lower limb ischaemia. J Cardiovasc Surg (Torino). 2005; 46: 385–394.
11. Djavidani B, Lenhart M, Manke C, Finkenzeller T, Zorger N, Feuerbach S, Link J. Terapie von Beckenarterienläsionen mit einem neuen vormontierten ballonexpandierbaren Stent („Flexible Iliac Bridge Stent"). Fortschr Röntgenstr 2000; 172: 911–917.
12. Tetteroo E, van der Graaf Y, Bosch JL, van Engelen AD, Hunink MG, Eikelboom BC, Mali WP. Randomised comparison of primary stent placement versus primary angioplasty followed by selective stent placement in patients with iliac-artery occlusive disease. Dutch Iliac Stent Trial Study Group. Lancet. 1998; 351 (9110): 1153–1159.
13. Müller-Leisse C, Janßen R, Hajeck KL, Korsten F, Klippels A, Kamphausen U. Perkutane Terapie langstreckiger Beckenarterienverschlüsse: Technische Durchführbarkeit, kurz- und mittelfristige Ergebnisse. Fortschr Röntgenstr 2001; 173: 1079–1085.
14. Jahnke T, Brossman J, Voshage G, Hilbert C, Müller-Hülsbeck S, Grimm J, Toellner D, Heller M. Mittelfristige Ergebnisse nach Implantation des neuen ballon-expaddiebaren VIP®-Stents In die Beckenarterien. Fortschr Röntgenstr 2000; 172: 381–385.
15. Palmaz JC, Laborde JC, Rivera FJ. Stenting of the iliac arteries with the Palmaz stent: experience from a multicenter trial. Cardiovasc Intervent Radiol. 1992; 15: 291–297.
16. Martin EC, Katzen BT, Benenati JF. Multicenter trial of the Wallstent in the iliac and femoral arteries. J Vasc Interv Radiol. 1995; 6: 843–849.
17. Müller-Hülsbeck S, Grimm J, Jahnke T, Brossmann J, Hilbert C, Heller M. Erste Ergebnisse nach Implantation des neuen ballonexpandierbaren Bridge™ – Stents in die Beckenarterien. Fortschr Röntgenstr 2000; 172: 836–841.
18. Gassel HJ, Kellersmann R, Franke S, Thiede A. Endovaskuläre Kombinationstherapie von Beckenarterienstenosen. Zentralbl Chir 2002; 127: 99–104.
19. Schneinert D, Ragg JC, Vogt A, Böttcher H, Steinkamp H, Biamino G. Stellenwert von gewebeummantelten selbexpandierenden Stents bei iliakalen arteriellen Verschlüssen oder Aneurysmen – Primär- und Langzeitergebnisse. Fortschr Röntgenstr 1998; 169: 301–309.
20. Reekers JA, Vorwerk D, Rousseau H, Sapoval MR, Gaines PA, Stockx L, Delcour CP, Raat H, Voshage G, Biamino G, Hoogeveen YL. Results of a European multicentre iliac stent trial with a flexible balloon expandable stent. Eur J Vasc Endovasc Surg. 2002; 24(6): 511–515.