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*Michał Sojka[1], Jan Sobstyl[1], Andrzej Wolski[2], Paweł Bernat[2], Radosław Krupiński[2], Małgorzata Szczerbo-Trojanowska[1]

Popliteal artery stenting in the peripheral arterial disease of the lower extremity treatment – assessment of the effectiveness and durability of the endovascular treatment

Stentowanie tętnicy podkolanowej w leczeniu choroby tętnic obwodowych kończyn dolnych – ocena skuteczności i trwałości leczenia wewnątrznaczyniowego

[1]Department of Interventional Radiology and Neuroradiology, Medical University in Lublin
Head of Department: Professor Małgorzata Szczerbo-Trojanowska, MD, PhD
[2]Department of Vascular Surgery, University Hospital No. 4 in Lublin
Head of Department: Andrzej Wolski, MD, PhD

Keywords

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Słowa kluczowe

choroba tętnic obwodowych, tętnica podkolanowa, stentowanie, leczenie wewnątrznaczyniowe

Summary

Introduction. Peripheral arterial disease (PAD) of the lower extremity affects up to 30% patients over 70 years of age or younger with a concurrent risk factors of the PAD development. The endovascular interventions has become the principal strategy for the lower extremity PAD treatment. The distinctive anatomical features of the popliteal artery, makes this segment particularly challenging for the endovascular treatment.

Aim. Assessment of the effectiveness and durability of the endovascular treatment with the stent implantation of the popliteal artery lesions.

Material and methods. Between March 2012 and October 2015, 24 patients with popliteal artery lesions underwent angioplasty with a stent implantation. All procedures were performed with Gore® Tigris® Vascular Stent. Patients were assessed with Doppler ultrasound during the follow-up at 6 and 12 months after the procedure.

Results. Total occlusion of the popliteal artery was observed in 9 patients. Other lesions were all hemodynamically significant, with the mean degree of stenosis of 89.1 ± 6.3%. The technical success of the procedure was noted in all cases. Out of 24 patients, 23 completed the follow-up at 12 months, with the in-stent restenosis rate of 13.04%. The primary patency rate was 91.30% in 6 months after the stent implantation, and 86.96% in 12 months after the procedure.

Conclusions. Gore® Tigris® Vascular Stent is an effective and safe option in the endovascular management of the atherosclerotic lesions in popliteal artery with a satisfactory durability of the treatment.

Streszczenie

Wstęp. Choroba tętnic obwodowych (ChTO) kończyn dolnych dotyczy 30% populacji powyżej 70. roku życia, jak również młodszych ze współistniejącymi czynnikami ryzyka rozwoju ChTO. Leczenie wewnątrznaczyniowe stanowi obecnie główny sposób postępowania w ChTO kończyn dolnych. Niekorzystne warunki anatomiczne tętnicy podkolanowej stanowią szczególne wyzwanie dla leczenia wewnątrznaczyniowego.

Cel pracy. Ocena skuteczności i trwałości leczenia wewnątrznaczyniowego z implantacją stentu tętnicy podkolanowej.

Materiał i metody. Pomiędzy marcem 2012 a październikiem 2015 roku wykonano zabieg angioplastyki z implantacją stentu u 24 chorych z niedrożnością/zwężeniem tętnicy podkolanowej. We wszystkich zabiegach użyto stentu Gore® Tigris®. Kontrolne badanie USG Doppler wykonano po 6 i 12 miesiącach od zabiegu.

Wyniki. Całkowita niedrożność tętnicy podkolanowej występowała u 9 chorych, u wszystkich pozostałych obserwowano zwężenia istotne hemodynamicznie – stopień zwężenia wynosił średnio 89,1 ± 6,3%. Sukces techniczny zabiegu osiągnięto

Conflict of interest
Konflikt interesów

None
Brak konfliktu interesów

Address/adres:

*Michał Sojka
Department of Interventional Radiology and Neuroradiology
Medical University in Lublin
ul. K. Jaczewskiego 8, 20-954 Lublin
tel. +48 817-244-154
michalsojka@op.pl

u wszystkich chorych. Spośród 24 pacjentów, 23 zgłosiło się na badania kontrolne po 6 i 12 miesiącach od zabiegu. Częstość występowania restenozy w stencie wyniosła 13,04%. Drożność stentu uzyskano u 91,30% chorych po 6 miesiącach od implantacji stentu i 86,96% po 12 miesiącach od zabiegu.

Wnioski. Zastosowanie stentu Gore® Tigris® w leczeniu wewnątrznaczyniowym ChTO obejmujących tętnicę podkolanową jest skuteczną i bezpieczną alternatywą z zadowalającą trwałością leczenia.

INTRODUCTION

Peripheral arterial disease (PAD) of the lower extremity affects up to 30% patients over 70 years of age or younger (50-69 years of age) with a concurrent PAD risk factors like diabetes or cigarette smoking. Interventional treatment indications are intermittent claudication at the distance of less than 200 meters (or more if it affects the quality of life) or critical limb ischemia (CLI). The latter is defined as the chronic ischemic rest pain, ulcers or gangrene in one or both legs, and is the most advanced stage of the lower extremity PAD (1).

Comparing to lower extremity bypass surgery, peripheral vascular interventions are characterized by lower procedural morbidity and mortality, fewer 30-day procedural complications, higher revascularization rates at 1 and 3 years, reduced costs, shortened hospital lengths of stay, and equal amputation rates. Due to the above comparison, the endovascular interventions has become the principal strategy for the lower extremity PAD treatment (2).

According to the TransAtlantic Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC) guidelines concerning popliteal artery disease, the endovascular revascularization is the treatment of choice for the TASC A lesions. TASC B and TASC C lesions are also suitable for the endovascular treatment if performed by the experienced operator (3). However, the distinctive anatomical features of the popliteal artery, its exposition to high mechanical forces, flexion and extension as a result of the course alongside the knee joint, makes this segment particularly challenging for the endovascular treatment (4). In most cases it is possible to perform revascularization of the popliteal artery without leaving any permanent implant. The percutaneous transluminal angioplasty, directional atherectomy, cryoplasty, focal force angioplasty and drug-coated balloons are the treatment techniques used in this condition. Nevertheless, above strategies occasionally occur insufficient and when residual stenosis, early elastic recoil or flow-limiting dissection is observed, stent implantation remains the last treatment option before surgical treatment. Before the advent of the new devices, the results of the popliteal artery stent implantation were unfavorable. Tigris® Vascular Stent (W.L. Gore, Flagstaff, USA), BioMimics 3D® Stent (Veryan, West Sussex, UK), Supera® Stent (Abbott Vascular, Santa Clara, CA, USA) and S.M.A.R.T.® Flex Vascular Stent System (Cordis Corporation, Hialeah, FL, USA) are the new generation stents which characterize as more flexible and fracture resistant, designed to give an opportunity to treat the popliteal artery disease and avoid the surgery (5).

AIM

Assessment of the effectiveness and durability of the endovascular treatment with the stent implantation of the popliteal artery lesions.

MATERIAL AND METHODS

Between March 2012 and October 2015, 24 patients with popliteal artery lesions underwent angioplasty with a stent implantation, if classified as a type A, B or C of the TASC classification. All procedures were performed with Gore® Tigris® Vascular Stent. Patients were assessed with Doppler ultrasound during the follow-up at 6 and 12 months after the procedure. During the Doppler examination the patency of the implanted stent was evaluated. All the procedures were performed under local anesthesia (10 ml of 2% lidocaine, subcutaneous injection) through the common femoral artery approach. The choice of the puncture side was contralateral to the ischemic extremity. After the initial angiography, using crossover technique the guidewire was introduced through the aortic bifurcation to the contralateral side. Over the guidewire the introducing sheath (Flexor Check Flo®, Cook Medical) of the 6 Fr diameter and 45 cm length was inserted. Initial angioplasty was performed usually with a 3-5 mm diameter balloon-catheter with a nominal pressure to match the vessel size. If residual stenosis, early elastic recoil or flow-limiting dissection was observed in the control angiography, than Gore® Tigris® Vascular Stent implantation was performed (fig. 1a-d, 2a-e). The stent diameter was selected not to exceed the oversize more than 1 mm. Afterwards post-dilatation was performed to provide proper fitting to the vessel wall and the sufficient dilatation of the inner vessel diameter. Balloon-catheters used for post-dilatation were selected specifically to the measured vessel diameter. On the final angiography the proper location and patency of the implanted stent were assessed.

RESULTS

This study includes 24 patients with the lesions in the popliteal artery: 19 men and 5 women, mean age

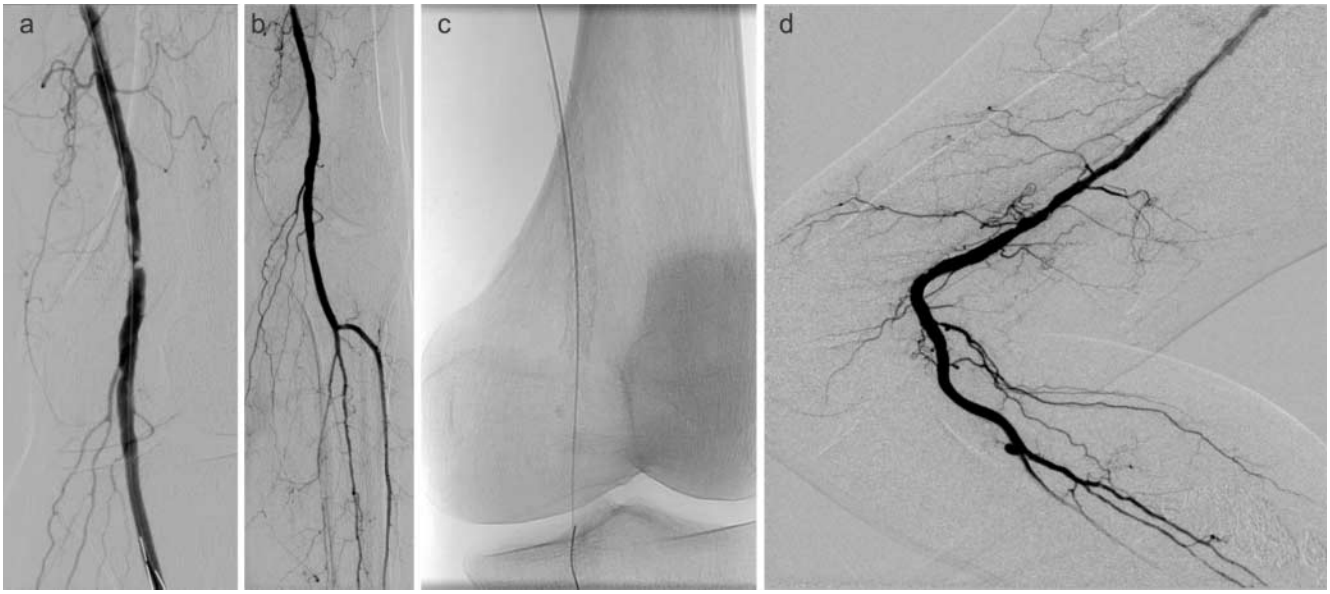

Fig. 1a-d. A 66-year-old woman with intermittent claudication of the left lower extremity at the distance of 150 m: a) DSA demonstrating a short, high-grade stenosis in the connection of the P1/P2 segments of the popliteal artery; b) DSA after the stent implantation showed a prominent blood-flow improvement in the popliteal artery with no residual stenosis, and a proper filling of the crural arteries; c) image confirming the correct stent implantation, covering the P1 and a proximal part of P2 popliteal artery segment; d) DSA of the popliteal artery with the knee in flexion demonstrating the proper filling of the artery

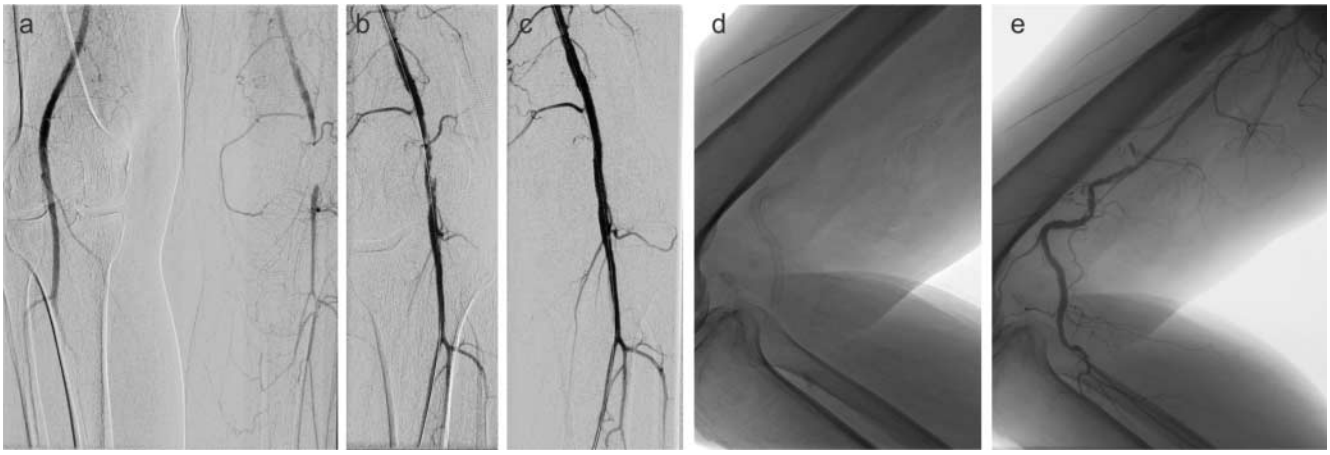

Fig. 2a-e. A 69-year-old man suffering from a rest pain of the left lower extremity: a) DSA demonstrating an occlusion of the proximal part of P2 segment of the popliteal artery, with reconstitution of the popliteal artery and its branches from the distal part of P2 segment; b) DSA after the treatment with a 4 x 20 mm balloon catheter showed resolution of occlusion with the presence of flow-limiting dissection and residual stenosis; c) DSA after stent implantation demonstrating a decent filling of the popliteal artery without features of flow-limiting dissection or residual stenosis, and improvement in the crural arteries filling; d) image confirming the correct stent implantation, and no stent collapsing despite knee flexion; e) angiography proving the proper patency of the stent with the knee in flexion

74.5 ± 13.0 years. Each of the treated patient presented the typical risk factors of the atherosclerosis like smoking cigarettes, diabetes, dyslipidemia or hypertension. 7 patients presented with CLI, the rest had intermittent claudication. Total occlusion of the popliteal artery was observed in 9 patients. Other lesions were all hemodynamically significant, with the mean degree of stenosis of 89.1 ± 6.3%. The technical success of the procedure, defined as a proper stent location and significant dilatation of the narrowed vessel resulting in the improvement of the blood-flow through the vessel was noted in 100%.

Patients were given recommendation for dual antiplatelet therapy with aspirin and clopidogrel for 3 months, and afterwards for aspirin only permanently.

At the follow-up, the physical and Doppler ultrasound examinations were performed. 23 patients showed up for the appointed evaluation at 6 and 12 months after the procedure. During the follow-up at 6 months after the treatment, in-stent restenosis was observed in 2 patients. Both patients underwent endovascular reintervention. Angioplasty with a drug eluting balloon was performed in both patients and stenoses were successfully treated. During the follow-up at 12 months after the procedure, in-stent restenosis was observed in 1 more patient, who underwent endovascular reintervention as well. The same as previously,

angioplasty with a drug eluting balloon was successfully performed. One of the patient who underwent endovascular reintervention due to the in-stent restenosis observed in the 6 months follow-up, presented with the stent occlusion in the 12 months follow-up and underwent for the lower extremity bypass surgery with a good treatment result.

To summarize 23 out of 24 patients completed the follow-up at 12 months, with the in-stent restenosis rate of 13.04%. The primary patency rate was 91.30% in the 6 months follow-up, and 86.96% in the 12 months follow-up.

DISCUSSION

The popliteal artery was considered to be a no-stenting zone (5), because of unfavorable conditions for the implanted stent, as a result of the course close to the knee joint. The emergence of the stents designed for the popliteal artery widened the possibilities of treatment of this inconvenient area.

Although these devices are available on the market for a few years, still there is a large randomized control trials deficiency evaluating their treatment efficacy and durability.

The first study evaluating Gore® Tigris® Vascular Stent was reported by Piorkowski et al., at first at 2013 with the follow-up at 6 months after the procedure, and second at 2015 with the follow-up at 12 months after the procedure. 32 patients with 40 atherosclerotic femoropopliteal lesions were treated with the stent implantation. Restenosis rate was 12.5% in the 12 months follow-up. Stent fracture was not evaluated during the study, besides 10 patient with the repeated angiogram due to the below-the-knee arteries intervention. None of the above patients showed the stent fracture (6).

Another study, involving Gore® Tigris® Vascular Stent was reported by Parthipun et al., published in 2015. A total of 54 stents were implanted in 50 limbs of 48 patients. In 6 cases, operators decided to implant 2 overlapping Tigris stents due to the length of the lesion (> 10 cm). Primary patency of the implanted stent was observed in 95.0 ± 3.5% of cases, and in-stent restenosis rate was 10.4 ± 5.0% at 6 months after stent implantation. At 12 months after the treatment primary patency rate was 69.5 ± 10.2% and in-stent restenosis rate was 51.4 ± 10.1% (7).

Comparing data from the literature to the data from the recent study, results seems comparable. Durability of the treatment is satisfying, especially when reminding how demanding is that area to treat. Properly implanted Tigris stent is not limiting the possibility of performing lower extremity surgical bypass as it was performed in 1 patient during the recent study. Due to the above features the opportunity to undergo endovascular procedure instead of surgery is an encouraging alternative for the patients.

Most of the available studies evaluating Supera® Stent focus on the femoropopliteal artery as a unit. The first retrospective Supera® Stent study, concerning the treatment of femoropopliteal atherosclerotic lesions was reported by Scheinert et al. in 2011. There were implanted 137 stents in 107 patients with the 1 year primary patency rate of 85%. After 2 years the ratio decreased to 76%. During the follow-up, no stent fractures were noted (8). To date many other studies (9-17) concerning management of the popliteal artery with the Supera stent was published. All commonly agreed that Supera stent implantation is effective and safe in the popliteal artery lesions treatment. In each publication it was also clearly marked that no stent fractures were observed during the follow-up. No studies investigating BioMimics 3D® Stent or S.M.A.R.T.® Flex Vascular Stent System were found in literature.

CONCLUSIONS

Gore® Tigris® Vascular Stent is an effective and safe option in the endovascular treatment of the atherosclerotic lesions in popliteal artery with a satisfactory durability of the treatment.

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