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Mechanical thrombectomy using Rotarex system and stent-in-stent placement for treatment of distal femoral artery occlusion secondary to stent fracture – a case report and literature review

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Summary

Background:

Treatment of peripheral arterial diseases may be distinguished into conservative and interventional management; the latter is divided into surgical and endovascular procedures. Management of peripheral artery stenosis and occlusion with vascular stents is associated with the risk of late complications such as restenosis, stent fracture or dislocation.

Case Report:

A 62-year-old woman with generalized atherosclerosis, particularly extensive in lower limb arteries, was admitted to the Department of Angiology 11 months after having an endovascular procedure performed due to critical ischemia of left lower limb. Because of stent occlusion, a decision to perform angiographic examination of lower limb arteries was made. Examination revealed occlusion of the superficial femoral artery along its entire length, including previously implanted stents. Distal stent was fractured with slight dislocation of the proximal segment. A decision was made to perform mechanical thrombectomy using a Rotarex system followed by a stent-in-stent placement procedure. Follow-up angiography and ultrasound scan performed 24 hours after the procedure revealed a patent vessel with satisfactory blood flow.

Discussion:

Nowadays, imaging diagnostics of peripheral artery stenosis involves non-invasive examinations such as ultrasound, minimally invasive examinations such as angio-MRI and MDCT, or invasive examinations such as DSA and IVUS. DSA examinations are used to confirm significant stenosis or occlusion of a vessel, particularly when qualifying a patient for endovascular treatment. Due to their anatomic location, the superficial femoral artery and the popliteal artery are subject to various forces e.g. those exerted by the working muscles. Mechanical thrombectomy and atherectomy are efficient methods of arterial recanalization used in the treatment of acute, subacute or even chronic occlusions or stenosis of peripheral vessels.

Conclusions:

Frequency of angioplasty and vascular stent implantation procedures is increased in patients with peripheral arterial disease, thus increasing the incidence of reported early and late complications such as acute stent thrombosis, restenosis and stent fractures. The Rotarex transcatheter mechanical thrombectomy system is an efficient method of treating occlusions in arterial stents. It is also safe when performed by experienced operators.

Key words:

stent fracture • mechanical thrombectomy • femoral artery occlusion

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Background

Diagnosis of peripheral arterial disease (PAD), which is a consequence of atherosclerosis, has been determined with increasing frequency in recent years. Peripheral arterial disease is increasingly more frequently considered one of civilization diseases. Treatment of peripheral arterial disease may be distinguished into conservative and interventional; the latter is divided into surgical and endovascular management. Constant technological advances in medicine increase the number of possible endovascular interventions and broaden the scope of indications. Endovascular methods include angioplasty, implantation of vascular stents, balloon catheterization, use of drug-eluting balloons or stents, thrombolytic procedures as well as atherectomy and thrombectomy. Management of peripheral artery stenoses and occlusions with vascular stents is associated with the risk of late complications such as restenosis, stent fracture or dislocation. Causes of vascular stent fractures include mechanical damage, increased muscle tone and inappropriate physical parameters of a stent relative to its anatomical location.

Case Report

A 62-year-old woman with generalized atherosclerosis, particularly extensive in lower limb arteries, with a long history of chronic peripheral arterial disease and history of angioplasty with implantation of two vascular stents into the left superficial femoral artery was admitted to the Department of Angiology eleven months after endovascular procedure due to critical ischemia of left lower limb. Patient reported significant shortening of intermittent claudication distance down to 40 m for the past two months followed by resting pain and necrotic foci on the feet first observed 2 weeks before admission. Physical examination upon admission revealed well-palpable pulse in both groins and along the right lower limb, and impalpable pulse in left popliteal fossa and along the left foot. Local ulcerations were also observed between the 3rd and 4th toe and between the 4th and 5th toe of left foot, as was a significantly reduced temperature of the shank and the foot. Ankle-brachial pressure index measured in segmental blood pressure examination was 0.31 on the left side and 0.69 on the right side. Duplex Doppler ultrasound of lower limb arteries revealed normal patency of the common femoral artery and its bifurcation and a short stump of left superficial femoral artery with stents in the superficial femoral artery occluded along their entire length; narrow popliteal artery was supplied through collateral circulation. Ultrasound image served as a basis for the suspicion of lower stent fracture (Figure 1), which was later confirmed by angiography.

Due to stent occlusion, a decision was made to perform angiographic examination of lower limb arteries. Examination revealed diffuse atherosclerotic lesions in the distal segment of abdominal aorta and in the arteries of both iliac axes; however, no significant stenosis was observed in these vessels. Patency of femoral, popliteal, anterior tibial and interosseous arteries was demonstrated in the right limb. Narrowing of the proximal and medial segments of the common femoral artery of about 50% and 30% respectively was revealed in the left limb. Deep

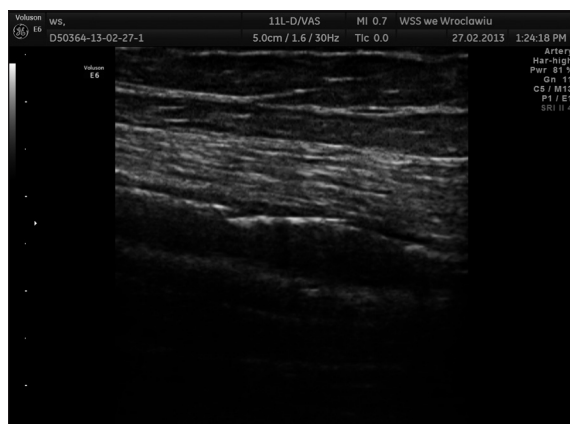


Figure 1. Site of fracture in the proximal segment of the lower stent.

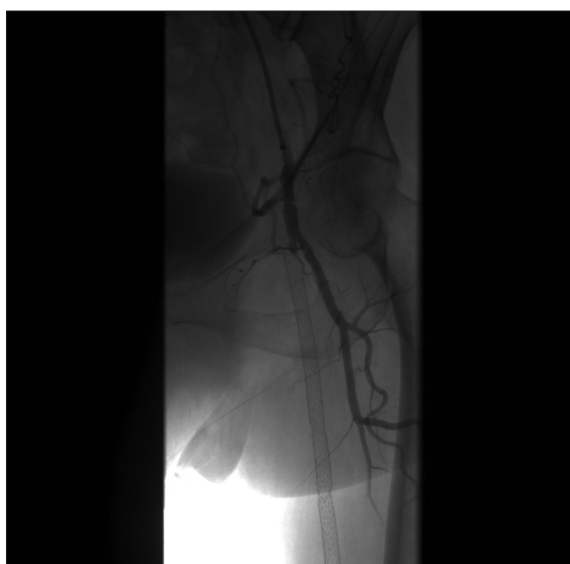


Figure 2. The stump of the superficial femoral artery.

femoral artery was patent. Superficial femoral artery was occluded along its entire length including previously implanted stents; only a short (5mm) stump was visible on the scan (Figure 2). Distal stent was fractured at the proximal segment along with slight dislocation and sloping of stent fragments (Figure 3). Blood was supplied by collateral circulation down to the popliteal artery and bifurcation. Crural arteries were patent.

Size of an introducing catheter was changed to 6F/40cm, crossing the aortic bifurcation. Subsequently, occluded section of the left superficial femoral artery (SFA) was forced through using a 0.035'' hydrophilic guidewire and a recanalization catheter. Guidewire size was changed to 0.018'' and the following procedures were carried out:

1. Mechanical thrombectomy of the occluded SFA using a StraubMedical/Rotarex S 6F/110cm atherectomy catheter (avoiding stent fracture section) (Figure 4).
2. Balloon angioplasty (PTA) of the proximal and medial segments of SFA using 4×120 mm and 5×40 mm Abbott/FoxCross balloon catheters.
3. PTA of the distal SFA segment and proximal popliteal artery (PA) segment using 4×120 mm and 3×40 mm Abbott/FoxCross balloon catheters.

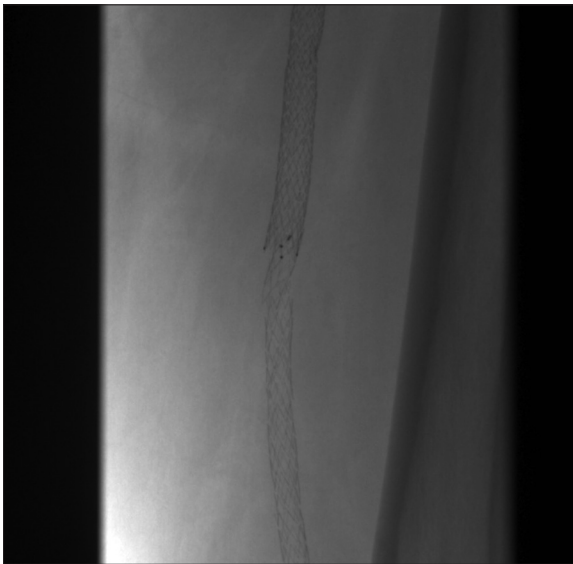


Figure 3. The fractured stent



Figure 5. Stent implanted in the distal segment of SFA.



Figure 4. Restoration of SFA patency using the Rotarex mechanical thrombectomy system.



Figure 6. Implantation of a second stent at fracture site.

4. Implantation of a 5×122 mm Boston/Epic stent in the distal SFA segment (distally to and partially overlapping with the previously implanted stent). Stent was expanded using a 4×120 mm Abbott/FoxCross balloon catheter (Figure 5).
5. An additional 7×60 mm Boston/Epic stent was inserted at the stent fracture site. Stent was expanded using a 5×40 mm Abbott/FoxCross balloon catheter (RBP pressure: 17 atm.) (Figure 6).
6. PTA of the proximal (ostial) SFA segment was performed using a 4×40 mm Biotronik/AngioSculpt cutting catheter due to apparent residual stenosis (Figure 7).

Follow-up angiography revealed full patency of femoral artery and popliteal artery (Figure 8).

Patient reported resolution of rest pain on the first day after the procedure. Follow-up segmental blood pressure

examination revealed an increase in the left-sided ankle-brachial pressure index up to the value of 0.85. Follow-up duplex-Doppler ultrasound scan of left lower limb arteries performed 24 hours after the procedure revealed proper patency of stents implanted in the left SFA with biphasic blood flow (Figure 9). Popliteal artery was properly patent with biphasic blood flow.

Discussion

Today, imaging diagnostics of peripheral artery stenoses involves non-invasive examinations – mainly ultrasound imaging, minimally invasive examinations such as angiography and MDCT, or invasive examinations such as DSA and IVUS.

Basic technique used in the diagnostics of PAD is ultrasound examination, characterized by its repeatability, widespread availability and high efficiency. This method



Figure 7. PTA using a cutting balloon catheter



Figure 8. Follow-up angiography – SFA/PA of proper patency.

is useful not only for assessing the degree of stenosis or occlusion, but also provides valuable information on the morphology of atherosclerotic plaque, including assessment of its components. It also allows for assessing patency or potential damage to vascular stents. Additionally, color-coded flow ultrasound allows for detection of loops, angular bends, aneurysms and arterial dissections [1]. High-frequency (5–12 MHz) linear transducers are used for assessment of peripheral arteries down from the origin of femoral artery; examinations of aorta and iliac axes may be carried out using lower-frequency transducers (2–3.5 MHz) [2]. Sensitivity and specificity of ultrasound imaging in detection and estimation of degree of stenosis in PAD patients is 70 and 90%, respectively [3,4]. In some places around the world, invasive intravascular ultrasound (IVUS) examinations are used in lower limb arteries in order to assess parameters of stenosis and atherosclerotic plaque morphology and instability.

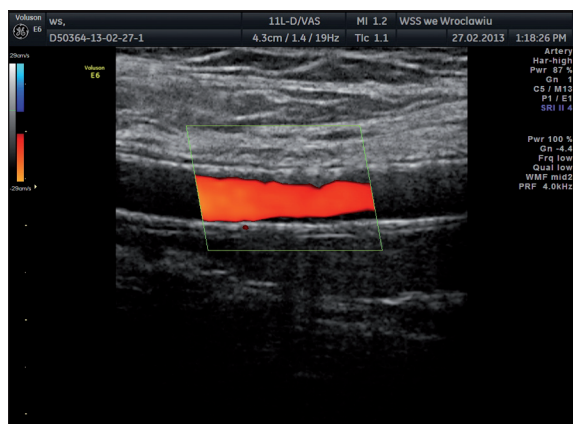


Figure 9. Follow-up ultrasound scan – biphasic flow in the distal segment of SFA.

More sophisticated imaging techniques such as computed tomography and magnetic resonance imaging are also used as adjuvant methods before endovascular interventions aimed at recanalization of stenotic vessels. Technological advances leading to increase in the number of computed tomography detector rows from 16 up to 64, 128 or 256 facilitated an increase in imaging resolution, shortening the duration of examination and more precise imaging of crural arteries, which had posed major diagnostic problems in the preceding years [5]. Currently, delayed imaging of crural arteries is recommended upon suspicion of femoral artery or popliteal artery occlusion with blood being supplied from collateral circulation. Options of 3D imaging, maximum intensity projection (MIP) and volume rendering (VR) enhance the diagnostic value of this examination. Iodine contrasts used in CT and DSA imaging are associated with the risk of contrast nephropathy and limit use of those techniques in patients with renal insufficiency. Sensitivity and specificity of angio-CT in patients with stenoses larger than 50% are as high as 95–99% [5,6]. Magnetic resonance angiography utilizes two techniques: TOFF (time-of-flight) sequence without contrast administration and contrast enhanced angiography (CE-MRA). Compared to MDCT and DSA, MRI is characterized by absence of ionizing radiation and lower nephrotoxicity of contrast agents (gadolinium compounds) [7]. Contrast-enhanced examinations are characterized by better resolution and shorter examination time, leading to less motion-related artifacts and greater diagnostic value. Unfortunately, costs and availability constitute major limitations to this method.

In contrast to DSA and MRI (TOFF sequence) computed tomography, ultrasound scans and IVUS provide additional information on the vessel wall, characteristics of atherosclerotic plaque, vascular wall calcifications or presence of soft plaque. All of the above methods are helpful in confirming presence of hypertrophic lesions within the intima, atherosclerotic plaque ulcerations or changes in the stent lumen, including bends and potential injuries.

DSA examinations are used to confirm significant stenosis or vessel occlusion, particularly when qualifying the patient for endovascular treatment. Examination involves puncturing the femoral or axillary artery according to Seldinger's technique, introducing a catheter into the aorta

or selectively into the examined artery and administering contrast agent. Contrast is delivered through an automated syringe coupled with an x-ray lamp on a C-arm. Recorded image is processed using a subtractive method. This method involves subtracting the preliminary image obtained before contrast administration from the image obtained afterwards. The result is the image of contrasted arteries without other anatomical structures, as it is in MRI. Confirmation of occlusion or stenosis within an artery, in this case within the SFA, is an indication for attempting endovascular treatment. Endovascular treatment methods include angioplasty, implantation of vascular stents, balloon catheterization, use of drug-eluting stents, thrombolytic procedures as well as atherectomy and thrombectomy. The term "angioplasty" covers a group of endovascular procedures performed under fluoroscopic guidance, including balloon angioplasty, cryoplasty, or drug-eluting balloon (DEB) angioplasty. Vascular stent implantation is often performed upon failure of angioplasty or in cases of arterial dissection. Mechanical thrombectomy and atherectomy are other efficient methods of arterial recanalization that are used in the treatment of acute, subacute or even chronic occlusions or stenoses of peripheral vessels [8]. Efficiency of mechanical thrombectomy with aspiration of released material using a Rotarex catheter is estimated in the literature at as much as 97.5% [9–11]. It is a quick and efficient method allowing for restoration of vessel patency within 30 minutes [9]. Rotarex S percutaneous *mechanical thrombectomy* device has many applications. It is a highly effective and fast thrombectomy used to treat occlusion of blood vessels, bypasses, dialysis accesses, stent-grafts, as well as stent restenosis and obstruction. Percutaneous mechanical thrombectomy device Rotarex S works similar to Archimedes screw with its spiral end rotating at a high speed.

The end of the catheter consists of a double cylinder sharpened at the edges and a helical conveyor situated in the middle (inside it), which is connected to the driving unit through magnetic coupling. Rotating device creates a vortex and the negative pressure it causes, combined with the special structure of the catheter leads to detachment, aspiration, fragmentation and removal of thromboembolic material outside the vessel and into the collection bag. A catheter must be routed in a special guidewire, which significantly increases safety of the procedure. Currently, two sizes of the device are available, 8F and 6F, which are used according to the vessel diameter – 3–5 mm and 5–8 mm respectively. Specialists are working on a new system – 4F, designed for lower limb arteries. The rotation speed of 8F system is 40000 r/min, while 6F gets as fast as 60000 r/min. The maximal capacity for aspiration of the material from the vessel is 45 ml/min in case of 6F system and 75 ml/min while using 8F system. Technical limitations and contraindications to the use of Rotarex catheter include: subintimal crossing of a guidewire through the occluded section of the vessel, vessel spasm, kinking or damage/breaking of the stent. Due to the anatomical structure use of Rotarex S is not recommended in treatment of pulmonary, coronary and cerebral vessel conditions. Adverse effects of the use of Rotarex catheter may rarely occur such as: vessel reocclusion, distal embolization, perforation, tissue hematoma, bleeding, injury/dissection of a vessel wall, arteriovenous

fistula. For the reasons mentioned earlier, careful patient selection for the treatment with use of Rotarex S is crucial. Recently, percutaneous mechanical thrombectomy gains increasingly more appreciation due to technological development. There are two kinds of PMT devices: rotating screw-like devices, e.g. Rotarex S (Straub Medical AG) and hydrodynamic devices operating on a continuous mixing zone, such as Angiojet (Bayer). Despite the differences in modus operandi of those two types of devices the outcome is exactly the same: fragmentation, aspiration and removal of the material outside the patient. In some clinical cases it is necessary to complement thrombectomy/atherectomy with angioplasty, often with simultaneous stent implantation.

Due to their anatomic location, the superficial femoral artery and popliteal artery are subject to various forces e.g. by the working muscles. These include stretching, bending, twisting, crushing and rotational forces. Therefore, stents implanted into these arteries must present with appropriate stability. Stents are made of nitinol, i.e. a nickel and titanium alloy. Nitinol belongs to the group of intelligent materials with shape memory effects and is characterized by high stability and elasticity. Self-expanding nitinol stents may be divided according to their design into open-cell and closed-cell stents. Differences in their designs additionally affect their physical properties such as radial force, elasticity or stability. Despite all of favorable design characteristics and properties of stents, post-implantation complications may occur, including acute stent thrombosis, restenosis or stent fracture. According to the literature, the incidence of stent fractures is about 0.84%. These are serious complications that may lead to restenosis or reocclusion and, in rare cases, formation of pseudoaneurysms [12,13]. Correlation between stent fractures and restenosis (66%) was observed in clinical studies [14]. Nitinol stents are significantly less prone to fractures, which makes them useful in such locations as femoral or popliteal artery [15]. In the described case, subacute lower limb ischemia occurred a course of fracture of a nitinol stent implanted into the SFA. It was diagnosed by Doppler ultrasound and angiography. Due to the nature of the changes reported in diagnostic imaging and clinical symptoms of subacute ischemia patient was referred for mechanical thrombectomy with the use of catheter. Due to the stent fracture and associated risk of a catheter becoming blocked, mechanical thrombectomy was performed only in the sections above and below the fracture. In order to secure the broken part of the stent and to maintain vessel patency, it was decided to perform a stent-in-stent implantation, as a damaged stent may be an initiation factor causing activation of both intrinsic and extrinsic coagulation pathways.

Conclusions

The frequency of angioplasty and vascular stent implantation procedures is increased in patients with peripheral arterial disease, thus increasing the incidence of reported early and late complications such as acute stent thrombosis, restenosis and stent fractures. Literature contains occasional reports of vascular stent fractures increasing the risk of restenosis and occlusion, thus resulting in the recurrence of ischemic symptoms and need for reintervention,

most commonly endovascular. In the above case, the primary procedure consisted of endovascular mechanical thrombectomy using a Rotarex catheter complete with angioplasty and implantation of two vascular stents. Transcatheter mechanical thrombectomy using a Rotarex catheter is an efficient method of treating occlusions in arterial stents. It is also a safe procedure when performed by experienced operators. Aspiration functionality allows for removing thrombotic material from the occluded vessel, reducing the risk of peripheral embolic events.

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