Thrombectomy with mechanical rotational catheter in a case series of six patients

Arterial occlusive disease of the lower extremities is a very common disorder affecting 20% of the population older than 75 years of age. Atherosclerosis is the main cause of peripheral arterial occlusive disease with lesions located in the femoropopliteal segment in more than half of the cases. Claudication is the main clinical manifestation in the chronic occlusion of the superficial femoral artery (SFA), and it may lead to chronic critical limb ischemia. Due to high morbidity and mortality rates of peripheral arterial disease, different treatment options have been suggested, including femoropopliteal bypass surgery, combined thromboendarterectomy techniques with optional stenting, and percutaneous revascularization.[2,3] Herein, we report a case series of six patients with arterial occlusive disease who underwent mechanical thrombectomy with a rotational catheter and in whom complete revascularization is achieved.

CASE REPORT

Four male and two female patients (mean age 65±10 years) with subacute superficial femoral artery (SFA) occlusion (mean lesion length: 6.1 cm, range 2 to 10 cm) for less than four weeks were included. All patients were admitted to the emergency department with a
sudden-onset Rutherford Grade 2 ischemia (severe rest pain and pallor) in the cruris of the left lower extremity. Acute thrombosis of the SFA was detected by the urgent arterial Doppler ultrasonography (USG). All patients were preoperatively heparinized and, then, were evaluated for high-risk for general or regional anesthesia by the cardiology and anesthesia consultants using the American Society of Anesthesiologists (ASA-IV edition). Due to relatively short operation time and no need for a surgical incision, thrombectomy with a mechanical rotational catheter was performed, rather than open surgery. A written informed consent was obtained from each patient.

Mechanical thrombectomy procedure

The mechanical thrombectomy system is composed of three parts: an Aspirex® S catheter (Straub Medical AG, Wangs, Switzerland), magnetic control unit, and electronic motor unit. The catheter tip is made up of two cylinders, placed one within the other. The motor unit rotates the spiral helix about 40,000 to 60,000 rounds/min, enabling it to achieve 80,000 cuts per minute. The vortex formed by the rotational movement of the catheter generates 5.8 kPa (=43.5 mmHg) negative pressure on the tip of the catheter. When the catheter is made active, solid and non-solid occlusion materials are collected by the pores on the tip of the catheter, transported to the proximal reservoir by the spiral helix and, then, emptied to the plastic collecting bag (Figures 1a, b).

Unfractionated heparin in doses sufficient to reach a target activated clotting time (ACT) of >250 seconds was administered before the insertion of the rotational catheter. The ACT levels were confirmed every 30 min, and additional doses of unfractionated heparin were applied, when necessary to maintain the target ACT level. Local anesthesia was achieved in the left femoral region with 5 mL prilocaine injection. The left common femoral artery (CFA) was punctured with a 21G needle using the Seldinger technique. A 6F angiography catheter was placed in the CFA, and the occluded segment was visualized in the arteriography. The guidewire was introduced through the lesion into the popliteal artery. A 6F mechanical thrombectomy catheter (Straub Medical AG, Aspirex® S) was primed with a heparin-treated saline solution and, then, introduced over the guidewire under the fluoroscopic guidance. The mechanical rotation was started and the thrombectomy catheter was advanced through the acute thrombus with back and forth movements to aspirate the thrombus. The same procedure was repeated backwards. This method favors the inflow of the fresh blood, which helps to maintain the catheter cool, and serves as a transport medium for the debris. In order to minimize the risk of peripheral embolization, the distal end of the stenosis was passed over very slowly to allow the catheter to aspirate all loose materials, before full blood flow was restored into the vessel. The minimum expected recanalization was at least that of the size of the catheter head's own diameter. As several passages may lead to larger recanalized diameters, a lumen of up to three times the catheter's diameter might be recovered, where less mature stenotic material was found.[4]

Technical success was defined as successful completion of the procedure, and ≤30% diameter residual stenosis after revascularization. After the completion of the procedure, total recanalization of

Figure 1. (a) The magnetic control unit. (b) The electronic motor unit.
the SFA was observed in the control angiography. After the procedure, patients were followed up two hours in the intensive care unit. A total improvement of the flow of the SFA was observed in the Doppler USG after 24 hours.

**Patient follow-up**

The patients were offered to use low-molecular-weight heparin (LMWH) for two weeks combined with oral 300 mg acetylsalicylic acid (ASA) tablets once a day. In addition, ASA treatment was continued after the cessation of LMWH treatment. The patients were examined at one, three, and six months during follow-up. None of the patients had any complaints and no side effects or complications were observed. At six months of follow-up, the patients also underwent computed tomography angiography, and no signs of restenosis or occlusion were observed.

**DISCUSSION**

In this case series, we had satisfactory results with a rotational embolectomy catheter. We achieved complete revascularization (100%) of the affected limbs in all of the patients. We used this treatment method for the patients who had a high risk for open surgical intervention. In addition, clinical worsening signs such as motor movement deficit of the affected extremity occurred in all of the patients, despite appropriate medical treatment.

General treatment for Grade 1 ischemia is heparinization with delayed revascularization, if necessary, and surgical revascularization either using the Fogarty balloon catheter or bypass with grafts for Grade 2 ischemia. However, amputation rate is between 11 and 37% with these techniques, depending on the causes of ischemia.

The percutaneous revascularization techniques include laser angioplasty, rotational and directional atherectomy, mechanical rotational thrombectomy, cutting balloon angioplasty, and crioplasty.

Percutaneous aspiration thrombectomy is another treatment method for occlusions distal to CFA with recanalization rates over 90%. Mechanical rotational thrombectomy with the Aspirex mechanical thrombectomy system is an easy and safe procedure with the advancement of the device over a guidewire with a low arterial dissection risk within a relatively short procedural time. Furthermore, the different length and sized catheters make ipsilateral and contralateral approach possible, which is particularly important in case of the affected access sites and variable diameters of the diseased target vessels.

Desgranges et al. reported excellent results for mechanical thrombectomy with short lesions (less than 12.8 cm). Lesion lengths in our patients ranged from 2 to 10 cm (mean: 6.1 cm). Similarly, we also achieved complete revascularization in our patients.

Duc et al. used another rotational embolectomy device for recanalization in native vessels for stenosis, and reported distal embolization in 26%. However, we did not observe such an event in our case series.

Post-interventional restenosis may also occur. In the literature, a patency rate of 61% was reported after mechanical rotational thrombectomy at one year of follow-up. The risk factors for restenosis can be broadly classified as patient-specific and lesion-specific. Diabetes is a factor that increases the risk for restenosis, as it is related with endothelial dysfunction associated with increased platelet activity, and more aggressive cellular response to injury. Female sex is also shown to be a predictor of restenosis in most of the studies. In addition, systemic inflammation and plasminogen activator inhibitor-1 antigen levels are related with unfavorable outcomes. Vessel diameter, lesion length, plaque burden and the quality of the distal vessel run-off can be counted as lesion-specific risk factors for restenosis. After six months of follow-up, no restenosis occurred in our patients.

Mechanical thrombectomy–related complications are reported as arterial perforation that may occur in the presence of severely calcified arteries, formation of arteriovenous fistulas and distal embolisms, all of which can also be seen in other endovascular treatments.
In conclusion, mechanical thrombectomy may be considered as an alternative treatment method for acute peripheral arterial thrombosis in high-risk open surgery patients, as it can be performed safely and effectively.

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