

Potential Breakthrough for Treatment of Peripheral Arterial Thrombotic Occlusions: Two Successful Cases with Rotarex® (Ablation and Motorized Aspiration Catheter)

Seongjun Hwang^{1,2} and Woo-Young Chung^{1,2}

- 1 Department of Internal Medicine, Seoul National University Seoul, Korea
- 2 Department of Internal Medicine, Seoul National University Boramae Medical Center, Seoul, Korea

Abstract

The Rotarex® (ablation and motorized aspiration catheter) is a novel device for endovascular treatment of arteries occluded by thrombi in the lower extremities. We here report two successful cases treated with Rotarex® devices. Eighty four year old male and seventy five year old male were admitted to hospital because of feet ulcers and gangrenous color changes. CT angiography showed distal superficial femoral artery occlusion in both patients. So we underwent thrombectomy, motorized aspiration by Rotarex® and balloon angioplasty. Their wound markedly recovered and limbs losses were minimal.

As Rotarex® (ablation and motor aspiration) is a device which has the advantage of supplying both thrombi ablation and motor aspiration percutaneously, it is believed to play a major role in the treatment of thrombi containing peripheral arterial lesions, either new or old.

Keywords: Peripheral artery disease; Thrombus; Endovascular therapy

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Introduction

Thrombi are a big obstacle to lower extremity endovascular procedures leading to poor clinical outcomes such as amputation, disability, even cardiovascular death. Unlike coronary thrombi, thrombi in superficial femoral artery are too abundant to remove, frequently longstanding making conventional aspiration poorly performing. Recently, Rotarex® catheter was introduced to real world practice helping overcoming hostile thrombi containing lesions. It's very novel in that it adopted motorized ablation and aspiration simultaneously. We here present two successful cases treated with this novel device.

Case 1

An 84-year-old man was admitted because of right foot pain for the last six months. The color of right 1st, 4th, 5th toes had turned dark reddish and purple 1 month before this admission. On physical examination, right and left dorsalis pedis pulse (DPP) were hardly palpable, right 1st, 4th, 5th toes were purple in color (**Figure 1A**) and there were 0.5 cm, 1 cm sized black and dry gangrene on right 1st, 5th toes, respectively. Therefore, his right lower leg ischemia was regarded as Rutherford category 5.

Blood pressure (BP) was 149/82 mmHg, heart rate (HR) 101 beats/min, respiratory rate (RR) 20/min, body temperature BT 36.7°C. In blood analysis complete blood count (CBC) showed white blood cell (WBC) count of 15950/mm³ hemoglobin (Hb) of



Figure 1A 84-year-old male's right foot at admission.

Corresponding author: Woo-Young Chung

✉ chungwy3023@daum.net

Seoul Metropolitan Government Boramae Medical Center, Boramae Ro 5 Gil 20, Dongjak Gu, Seoul, Korea.

Tel: 821050623023

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14.3 g/dL, platelet of 578,000/mm³ and C-reactive protein (CRP) of 2.94 mg/dL. Lower extremity CT angiography (CTA) showed total occlusion of right femoral artery and collateral vessels development (**Figure 2**).

We administered aspirin (100 mg qd), cilostazole (100 mg bid) and enoxaparin (40 mg bid subcutaneously) since admission and cefazolin for the care of cellulitis in right toes. Ankle brachial index (ABI) was not checked. On the next day, we performed urgent percutaneous transluminal angioplasty (PTA) for thrombotic occlusion in mid portion of right superficial femoral artery (SFA) (**Figure 3A**). After passing the 0.018 wire without difficulties, we ablated and aspirated much organized thrombi using Rotarex[®] thrombectomy catheter. With two runs of thrombectomy and aspiration alone, flow got much better without any distal embolization. For the residual stenosis, we performed angioplasty with 5x150 mm plain balloon. Thereafter, we subsequently underwent angioplasty for the stenoses in both anterior and posterior tibial arteries with 2.0 mm balloon. Final angiography showed markedly improved blood flow in his right leg (**Figure 3B**).

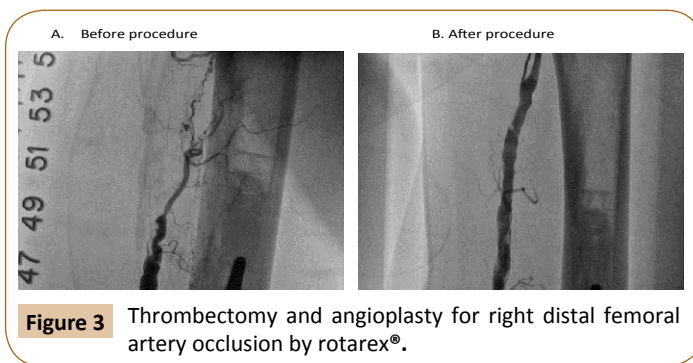


Figure 3 Thrombectomy and angioplasty for right distal femoral artery occlusion by rotarex[®].

After the successful endovascular therapy, the foot color dramatically improved, but the gangrene of 5th toe (**Figure 1B**) did not recovered and patient felt continuous pain. Right 5th toe was finally amputated on day 13 after the endovascular therapy. Heparin was terminated completing endovascular procedure. Aspirin, cilostazol, clopidogrel were prescribed for a month and then aspirin indefinitely.

Case 2

A 75-year-old man who had have a parkinsonism, was admitted to our hospital with right heel & big toe ulceration after sleeping on a Korean traditional hot floor. The wound was aggravated to have purulent discharge and foul odor (**Figure 4**).

BP was 102/54 mmHg, HR 84 beats/min, RR 20/min, BT 36°C. Right and left DPP were hardly palpable and there were large ulcers in Rt. heel and 1st toe with black color change (Rutherford category 5).

The patients was routinely taking oral medications (Trazodone 50 mg qd, Alprazolam 0.5 mg qd, Rivastigmine 18 mg patch qd, Quetiapine 25 mg tid, Levodopa/Carbidopa 100/25 mg tid, Aspirin 100 mg qd, Triflusal 300 mg qd, Isosorbide-5-mononitrate 60 mg qd, Lisinopril 5 mg qd, Carvedilol 12.5 mg bid, Nicorandil 5 mg bid) for Parkinsonism combined with dementia and coronary artery disease since 2008. Coronary artery disease had been treated with coronary stents in 2002. Initial laboratory test showed WBC count of 11200/mm³, Hb of 11.8 g/dL, platelet of 643000 /mm³ and high sensitive CRP of 7.73 mg/dL.

Lower extremity CTA showed internal iliac artery aneurysm, right superficial femoral artery occlusion (**Figure 5**), proximal popliteal artery stenosis and distal tibial artery occlusion.

A fever occurred up to 38°C and CRP was elevated up to 24.4 mg/dL on the second hospital day. However, no bacteria was isolated from his blood or wound. He was treated with piperacillin and tazobactam to cover Gram positive and Gram negative bacteria as well as anerobic bacteria.

Loading 300 mg of clopidogrel, atheorothrombi were ablated and aspirated three sessions using a Rotarex[®] thrombectomy device from right superficial femoral artery (**Figure 6**). For the residual de novo lesion after thrombectomy, we undertook angioplasty using 5x20 mm balloon. Residual stenosis was approximately 50% in diameter stenosis after that. Though there were multifocal stenoses of posterior tibial artery, we left them alone as we regarded they were not so severe to cause critical ischemia. Also,



Figure 1B 5 days after thrombectomy and angioplasty.



Figure 2 CT angiography image of lower extremities. The length of occlusive lesion was 10 cm.



Figure 4 75-year-old male right foot at admission.

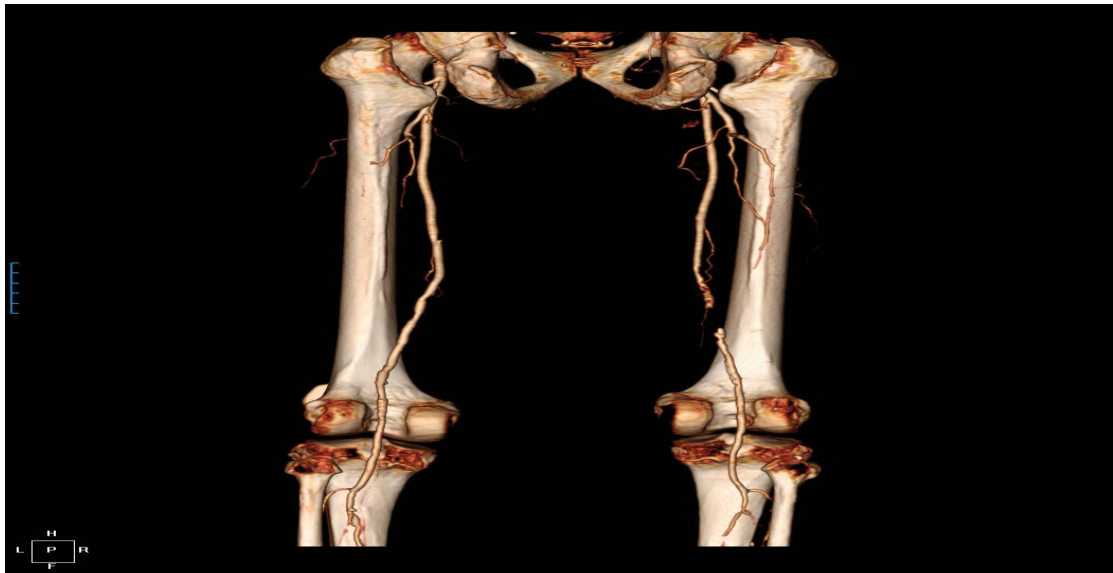


Figure 5 CT angiography 3D reconstruction image. The length of occlusive lesion was 3cm.

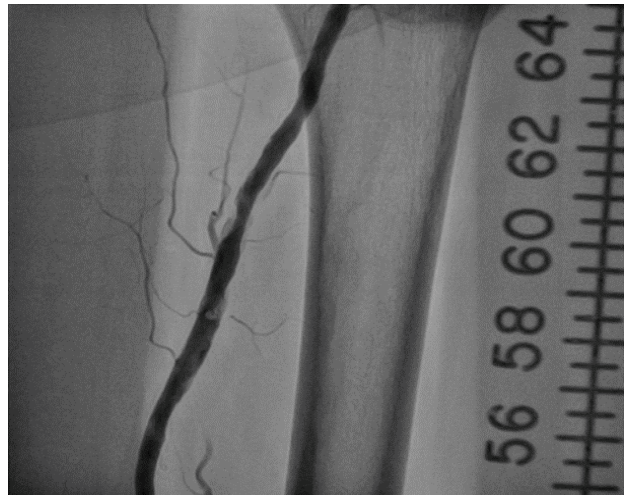
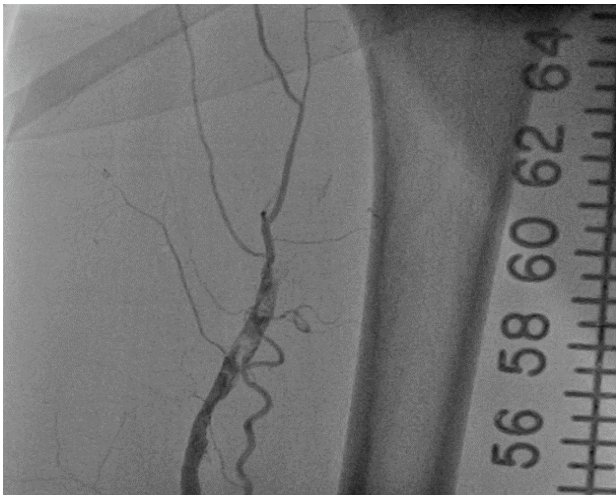


Figure 6 Thrombectomy and angioplasty of right distal superficial femoral artery occlusion by Rotarex®.

though there were occlusive lesions on the anterior tibial artery, we did not recanalize because the lesion was not responsible for patient's wound according to tibial angiosome concept. Heparin was no more used after successful endovascular procedure. Aspirin and clopidogrel and triflusal were prescribed for one month and then aspirin and triflusal were maintained.

After the successful endovascular therapy, leukocytosis disappeared and CRP got reduced to 5.3 mg/dL from 24.4 mg/dL. The patient was discharged with wound healed.

Discussion

Endovascular intervention for critical limb ischemia has been replacing the surgical treatment by virtue of recent technological advance, anti-proliferative drug delivering devices [1]. However, there were lesions that have not been overcome yet such as containing thrombi which demonstrated poor outcomes mainly attributable to distal embolization. At present, there is no effective way to remove blood clots from arterial lumen.

In the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial, there were no significant differences between bypass surgery and angioplasty regarding outcomes but for recent many years, surgical revascularization strategy became superior to angioplasty revealing better overall survival and amputation free survival [2]. This was because endovascular modality could not remove the organized thrombus effectively. Thrombus which had been pressed onto the inner wall of artery by balloon angioplasty could embolize again. Even though with stent insertion, thrombus

is not completely removed and even may be the nidus of further thrombus formation because stent itself is a foreign material.

Rotarex[®] thrombectomy catheter is a novel device recently invented in a European country. Traditionally we were doing thrombi aspiration with large bore catheter. But, large amount blood loss was inevitable and it cannot help some amount of distal embolization [3]. Rotarex[®] thrombectomy catheter can aspirate thrombi using motor console connected with proximal part making more complete aspiration possible (Figure 7A,B). It can also ablate thrombi to microparticle by rotational spiral cutter within the tip (Figure 7C), which help thrombi easier to be aspirated even though it is longstanding organized thrombi or plaque containing and minimize the probability of obstructing distal vessels even if distal embolization take place. There were additional advantages like a kind of atherectomy device that could ablate and modulate atheromatous or calcification lesion.

Due to the advantages of mentioned above, Rotarex[®] thrombectomy catheter is believed to receive attention as a solution of thrombi containing lesions or calcification lesions that were limitations of endovascular procedures.

Conclusion

As Rotarex[®] (ablation and motor aspiration) is a device which has an advantage of motor driven thrombi ablation and aspiration, it seems to play a major role in the treatment of peripheral high burden thrombi containing lesions.

A. motor console



B. Rotarex[®] catheter.



C. The tip of Rotarex[®] catheter.



Figure 7 Thrombi are pulverized by spiral shape cutter rotating, and aspirated through catheter lumen driven by motor console out of table.

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