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Percutaneous aspiration thrombectomy in the treatment of lower extremity thromboembolic occlusions

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PURPOSE
To report the immediate and midterm results of manual aspiration thrombectomy as the first thrombus removal method in the treatment of acute or early chronic arterial thromboembolism in the lower extremity.

MATERIALS AND METHODS
Retrospective review of 40 limbs in 37 nonconsecutive patients between March 2006 and March 2008 (21 female [57%], 16 male; mean age, 67 ± 10 years; age range, 42–84 years) who had percutaneous aspiration thrombectomy for lower limb arterial thromboembolism. Twenty-nine legs had acute (<14 days) and 11 legs had early chronic (15–60 days) thromboembolism. Clinical categories of limb ischemia were stage I in 12 limbs, stage IIa in 17 limbs, and stage IIb in 11 limbs.

RESULTS
Technical success was achieved in 35 limbs (88%). Complete thrombus removal was achieved in 26 of 29 limbs (90%) with acute occlusions and 4 of 11 limbs (36%) with early chronic occlusions ($P < 0.05$, χ^2 test). Amputation-free survival rate was 100% at one month, 93% at one year, and 93% at two years with Kaplan-Meier survival analysis. Freedom from symptoms of claudication or critical limb ischemia was achieved in 31 of 39 limbs (80%) at one month and 25 of 35 limbs (71%) at one year. There were three major complications and ten minor complications.

CONCLUSION
Percutaneous aspiration thrombectomy is a rapid and effective way of removing thrombus in thromboembolic occlusions of the limb arteries below the inguinal ligament. It can be used in patients with acute limb ischemia (Rutherford clinical category IIb).

Key words: • *thrombectomy* • *arteries* • *lower extremity* • *thromboembolism*

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Lower extremity arterial thromboembolism leads to sudden interruption of blood flow that can threaten the limb of a patient and requires immediate revascularization. Accurate and timely diagnosis is important to save the patient's limb and sometimes the patient's life. Treatment of acute limb ischemia aims to restore a sufficient blood flow in at least one lower limb artery or a major collateral artery. The treatment approach depends on the clinical stage based on TransAtlantic Inter-Society Consensus (TASC) document (1). In stages I (viable) and IIa (threatened: marginal), surgical embolectomy as well as thrombolysis are accepted treatment methods. In stage IIb (threatened: immediate), there is immediate threat to the limb, and surgical embolectomy is the treatment of choice, while thrombolysis is not recommended. In early stage III (irreversible), surgical thrombectomy may be utilized, but in advanced stage III cases, amputation is the treatment of choice. Surgical embolectomy has been the treatment of choice for arterial thromboembolism. However, surgery has been shown to be associated with high perioperative mortality (2). Endovascular therapy has emerged as a new treatment alternative to surgery. Both methods have benefits and drawbacks. Catheter-directed thrombolysis (CDT) has been the method of choice for endovascular treatment. Manual aspiration thrombectomy (AT), although described much earlier than CDT, has been used seldom and as an adjunctive method.

The purpose of this study is to report the immediate and midterm results of manual aspiration thrombectomy as the first thrombus removal method in the treatment of acute or early chronic arterial thromboembolism in a selected patient population.

Materials and methods

Patient population

All the procedures carried out on humans were in accordance with the ethical standards of the World Medical Association. Between March 2006 and March 2008, 40 limbs in 37 nonconsecutive patients (21 female [57%], 16 male; mean age, 67 ± 10 years; age range, 42–84 years) who had percutaneous aspiration thrombectomy for lower limb arterial thromboembolism were retrospectively evaluated. Twenty-nine legs had acute thromboembolism (<14 days), and 11 legs had chronic (15–60 days) thromboembolism. The cause of limb ischemia was thromboembolism in all the limbs. Ten patients had type II diabetes, 23 had hypertension, 21 had coronary artery disease, and 24 patients were smokers. All patients had normal kidney function with normal creatinine values.

Diagnosis of thromboembolic limb ischemia was established by clinical and imaging findings. All patients had color Doppler ultrasonography, and 14 patients had magnetic resonance angiography be-

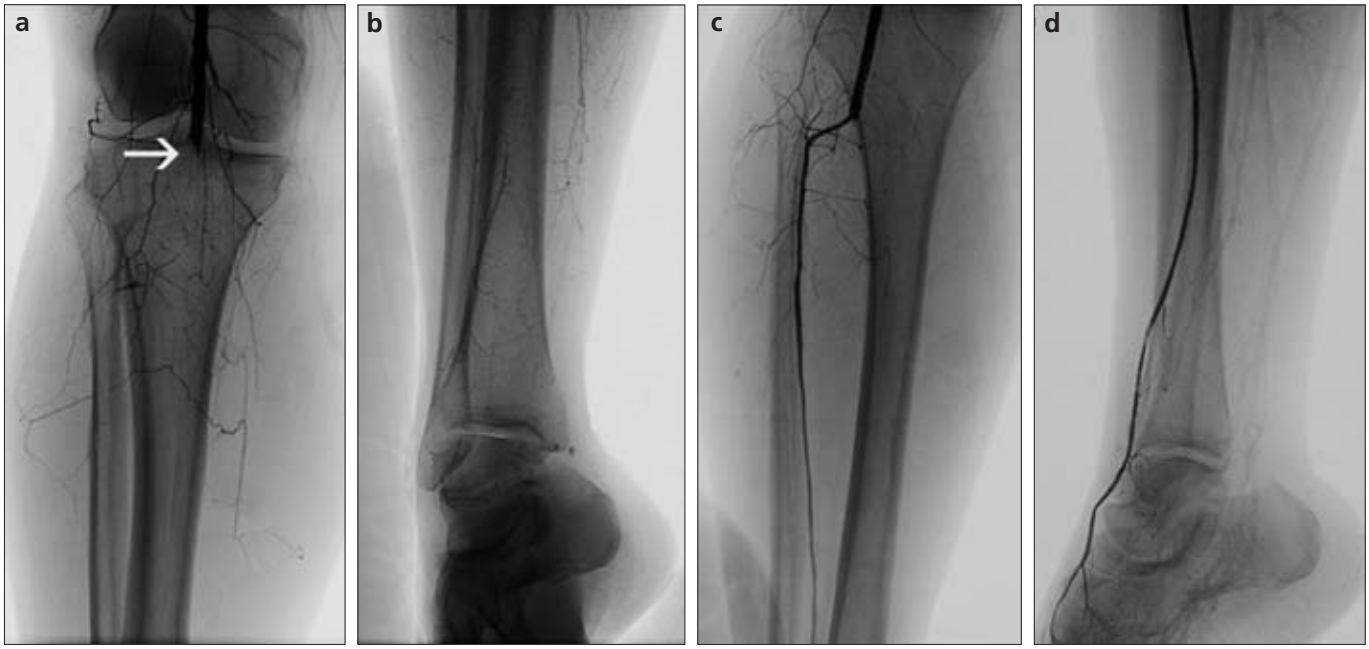

Figure 1. a–d. Angiograms of a 28 year-old-female patient with type I diabetes mellitus who presented with acute limb ischemia, Rutherford category IIb. Complete occlusion of the distal popliteal artery **(***arrow,* **a)** and of all 3 crural arteries except for a short segment of the distal anterior tibial artery **(b)** is seen. Aspiration thrombectomy alone restored patency of the popliteal and the anterior tibial arteries **(c, d)**. The other crural arteries could not be crossed with a guide wire.

fore digital subtraction angiography. Catheter-directed thrombolysis, percutaneous transluminal angioplasty (PTA), or stent placement were used as adjunctive treatment methods as required. Inclusion criteria were thromboembolic occlusion of the native arteries below the inguinal ligament. Therefore, suprainguinal occlusion or occlusions involving the common femoral artery or bypass grafts were not included in the study. Patients who had iatrogenic embolism during an endovascular procedure were also excluded.

All patients were symptomatic with severe pain (n = 36), cold and pale limb (n = 38), cyanosis (n = 12), and ulceration at the foot (n = 7). Thromboemboli were on the right in 22 limbs, and on the left in 18 limbs (3 patients had bilateral involvement). Clinical categories of limb ischemia were stage I in 12 limbs, stage IIa in 17 limbs, and stage IIb in 11 limbs. Thromboembolic occlusion involved the femoral, popliteal, and crural arteries in 12 limbs (30%), femoral and popliteal arteries in 2 limbs (5%), popliteal and crural arteries in 23 limbs (58%), and crural artery alone in 3 limbs (7%). When crural arteries were involved, all 3 had occlusion in 32 limbs, 2 crural arteries had occlusion in 6 limbs, and only one crural artery had occlusion in 2 limbs. Definitions of terms were in accordance with the standards of practice set by the Society of Interventional Radiology (3).

Procedure

All the procedures were carried out in the interventional radiology suite under local anesthesia. Written informed consent was obtained from each patient. Intravenous sedation and analgesia was administered, if required. All patients were monitored during the procedure. Access to the artery was obtained with antegrade puncture of the common or superficial femoral artery under ultrasonography guidance. Diagnostic angiography was performed through a 4-F or 5-F vascular sheath which was exchanged for a larger (6-F to 9-F) vascular sheath for AT. The guiding catheters used for AT were 7-F to 9-F for superficial femoral artery, 6-F to 7-F for popliteal artery, and 5-F for crural artery (Fig. 1). The guiding catheter (Envoy, Cordis Corporation, Miami, Florida, USA) had multipurpose or straight tip and was inserted through the vascular sheath to the most proximal part of the thrombus; suction was performed with a 20-mL syringe. Once the thrombus was engaged, the catheter was withdrawn while maintaining suction to hold the thrombus. Catheter-directed thrombolysis was performed with an end hole or multisidehole catheter as an adjunctive thromboablation method for residual thrombus that could not be aspirated. Tissue plasminogen activator (tPA) was used at a dose of 0.5 to 1 mg/h for thrombolysis. Thrombolysis was stopped in case of total clearance of thromboemboli, any complication due to thrombolytics or stagnation of thrombolysis at control angiography (at 8–12 hour intervals). PTA and stent placement were used to treat underlying severe stenoses or to treat complications (Fig. 2).

All patients had anticoagulation with heparin (5000 U bolus and 1000 U of infusion thereafter) during and after the procedure. The dose of heparin was adjusted at a target aPTT of 60–90 s. Aspirin at a dose of 300 mg/d was initiated after the treatment to be continued indefinitely. All patients with cardiogenic emboli were maintained on long-term anticoagulation with warfarin sodium. The target international normalized ratio (INR) was maintained at 2–3. All patients were followed up by clinical examination and color Doppler

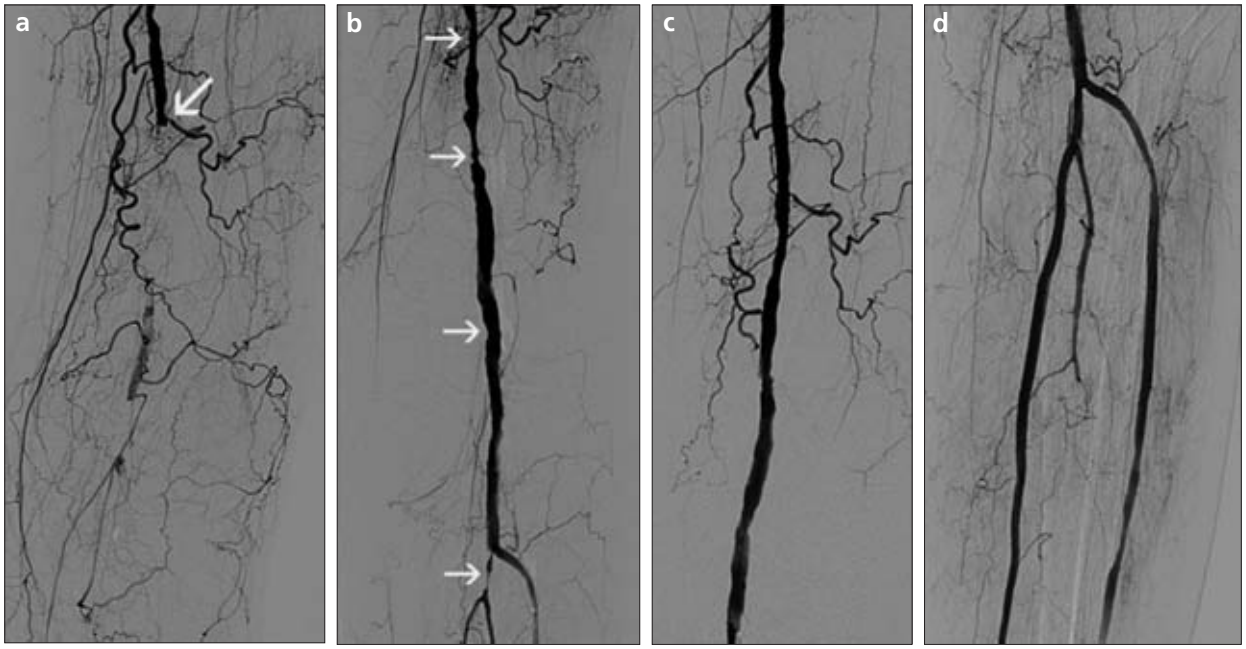

Figure 2. a–d. Angiograms of a 57-year-old-male patient who presented with coldness and rest pain of the right leg for 7 days. He had chronic complaint of claudication of the same leg. Initial angiogram **(a)** showed occlusion of the distal superficial, popliteal and proximal part of all crural arteries (*arrow*). The patent arteries revealed atherosclerotic changes. Angiogram after aspiration thrombectomy **(b)** revealed severe stenosis of the distal superficial artery and the tibioperoneal trunk (*arrows*). Final angiograms after balloon dilatation of the stenoses **(c, d)** showed good patency of the arteries.

ultrasonography at outpatient clinic at 1, 3, 6, and 12 months, and then annually. Angiography was undertaken when clinical or Doppler sonographic findings showed recurrence necessitating reintervention.

Results

Thromboembolic occlusions could be crossed successfully in all patients. Technical success (defined as successful recanalization of at least one artery segment) was achieved in 35 limbs (88%), whereas clinical success was achieved in 38 limbs (95%). Complete thrombus removal was achieved in 26 of 29 limbs (90%) with acute occlusions and 4 of 11 limbs (36%) with chronic occlusions ($P < 0.05$, χ^2 test). Technical failures were seen in acute thromboembolism in one limb and chronic thromboembolism in four limbs ($P < 0.05$, χ^2 test). Aspiration thrombectomy removed much of the proximal thrombus in three limbs, but some residual thrombus remained in the arteries distal to the ankle. CDT was initiated as the adjunctive measure in these patients, but it did not lyse the whole thrombus in a single artery. These patients had clinical improvement but were classified as technical failures. Two other patients with technical failures required surgical embolectomy (n = 1) or bypass procedures (n = 1). None of the patients required major amputation (amputation proximal to the tarsometatarsal line) right after or within the first 30 day after the procedure.

The length of occlusion ranged from 9 to 52 cm (mean, 18 cm). Aspiration thrombectomy was the only treatment method in the management of thromboembolism in 28 limbs (70%). CDT was used as an adjunctive method for residual thrombosis in 12 limbs (5 acute and 7 chronic limbs). Total tPA dose ranged from 10 mg to 36 mg (mean, 16.3 mg). Thirteen limbs (33%) had underlying severe atherosclerotic stenoses (>50% diameter stenosis) which were treated with PTA or stent placement at the same session with successful restoration of flow. Thirteen limbs had PTA, and 5 of them had stent placement after unsuccessful attempt of PTA. Stents were placed in the superficial femoral artery in 4 limbs and popliteal artery in one limb. Two stents were placed to treat the complication created by PTA (significant, flow-limiting dissection) whereas the other three stents were placed to improve the flow after PTA (residual stenosis >30% of luminal diameter). Number of endovascular interventions was one in 37 limbs, 2 in 2 limbs, and 3 in one limb. Total procedure time ranged from 25 to 150 min (mean, 63.5 min).

Limb salvage rate was 100% at one month, 93% at one year, and 93% at two years with Kaplan-Meier survival analysis. Four patients were lost to follow-up. Four patients died during the follow-up period from reasons not related to thromboembolism or the procedure. One patient who underwent three interventions on three consecutive days required above-the-knee amputation 9 months after the first intervention. Freedom from symptoms of claudication or critical limb ischemia was achieved in 31 of 39 limbs (80%) at one month and 25 of 35 limbs (71%) at one year.

There were complications in 13 limbs (33%): 2 (5%) hematomas at the puncture site (one required infusion of blood components), 6 arterial dissections (15%), and 3 extravasations (7%). One superficial femoral artery and one popliteal artery dissection limited flow and required stent placement after failed long-duration balloon inflation. Popliteal artery stents thrombosed one month after the procedure and required femoropopliteal bypass surgery. Another popliteal artery dissection required bypass surgery after failed long-

duration balloon dilatation. Other dissections and extravasations either did not require any treatment or could be treated with long-duration balloon inflations.

Discussion

This study showed that AT can effectively treat patients with acute or early chronic thromboembolism of the lower limb. The method was more effective in acute cases than in chronic ones and could clear thrombi up to 2 months of age. It could be used in Rutherford clinical category IIb patients where surgical embolectomy is the treatment of choice. Thrombolysis is not recommended in clinical category IIb patients because of possible delay in treatment and potential complications that may be due to bleeding into revascularized tissue resulting in compartment syndrome. Aspiration thrombectomy has generally been used as an adjunctive method to CDT, but this study showed that reverse was also true, and CDT could be an adjunctive to AT. Total dose of tPA used was low because AT removed most of the thrombi in most cases. Aspiration thrombectomy was especially effective in the crural arteries because it was possible to direct the guiding catheter into any crural artery that had thrombus. This was a crucial superiority of AT over surgical embolectomy with a Fogarty balloon catheter, in which direction of the balloon catheter is not possible even under angiographic guidance. Percutaneous transluminal angioplasty or stent placement was performed at the same session obviating the need for secondary procedures. Complications related to AT were mainly minor and all could be treated at the same endovascular session. Main disadvantages of AT were the need for larger vascular sheath for large guiding catheter than usual and dissection of the artery. Dissection of the popliteal artery was particularly important because endovascular treatment failed in two of the patients. The guiding catheters that we used were not produced for aspiration thrombectomy. Use of catheters specifically produced for aspiration thrombectomy might have decreased dissection complication. The longest duration of angiographic procedure in this study was 150 min with 38 min of fluoroscopy time in a patient who had 3 consecutive days of intervention.

Thromboembolic occlusion of a limb artery can occur in the presence or absence of underlying atherosclerotic involvement. If there is no underlying atherosclerotic disease of the limb, the thromboembolic event usually presents with profoundly ischemic lower extremity, whereas thromboembolic occlusion of chronically diseased lower limb artery may present only with mild progression of chronic symptoms because of the development of collateral vessels.

Preexisting arteriosclerotic occlusion of the superficial femoral artery is more prevalent today than in the past. Therefore, it is not surprising that patients with acute limb ischemia have associated arteriosclerotic lesions of the peripheral arterial tree more frequently. In such cases, the results of embolectomy can be adversely affected, but endovascular methods gain more importance because these underlying lesions can be treated at the same session.

Surgical thrombectomy using Fogarty embolectomy catheters through a femoral or popliteal approach has been the standard therapy because it is rapid and effective in cases of embolic thrombi in normal arteries (4). Success of surgical embolectomy may decrease in the presence of underlying chronic atherosclerotic changes in the artery or in the presence of chronic thrombi. In a review of 35 collected series, Blaisdell et al. (4) found 14 reports with mortality rates ranging from 15% to 24%, 11 reports with rates between 30% and 48%, and a median group of 10 series reporting mortality rates of 25% to 29%. The same wide range holds true for limb salvage, with rates between 40% and 81%. The entire series included 3,320 embolectomies, with an average limb salvage rate of 63% and an average mortality rate of 28% (4). The highest mortality rate was caused by congestive heart failure and acute myocardial infarction, with pulmonary embolism being the second major cause.

Thrombolysis has some theoretical advantages over conventional embolectomy (5). It is less invasive, reduces patient discomfort, diminishes the risks associated with anesthesia, and allows better definition of underlying atherosclerotic lesions. It does not directly damage the vascular endothelium and has the capacity to clear thrombus in the small vessels. Thrombolysis has some drawbacks that prevent its widespread use in acute limb ischemia. Treatment is not rapid, and treatment duration up to 24 hours may worsen the clinical situation of the patient in advanced cases (stage IIb). Thrombolysis is labor-intensive and patients usually require multiple visits to the angiography room and monitoring in a critical care environment. Some patients may require open surgery following thrombolysis. Bleeding at the puncture site may complicate possible surgical treatment. Thrombolysis can be less successful and more complicated than surgery in the elderly (6). Overall bleeding complication rate from thrombolysis with tPA in the treatment of arterial occlusive diseases is around 5% (7). Therefore, there has been a general decline in the use of arterial thrombolysis in the management of acute limb ischemia. Its present role is primarily in the management of acute limb-threatening ischemia, in which delay in treatment does not cause deterioration of the situation of the limb, usually Rutherford I and IIa ischemia, often as a prelude to subsequent angioplasty or surgery.

Mechanical thrombectomy techniques have become increasingly attractive for treatment of acute or chronic arterial occlusive diseases. There are many mechanical thrombectomy devices that use clot aspiration, mechanical clot destruction, or Venturi principle for thrombus removal (8). Manual aspiration thrombectomy for removal of thrombus in the lower limb arteries was first used by Snidermann et al. in 1984 (9) and then by Starck et al. in 1985 (10). Although it was used earlier than most other endovascular methods, its use was not widespread. Manual AT has been successfully used to remove thrombus in the thrombosed dialysis fistulas, lower extremity deep vein thrombosis with or without impending venous gangrene, renal vein thrombosis, and pulmonary embolism (11–15). Manual AT can solve some of the problems encountered with thrombolysis and surgical embolectomy. It is a simple, rapid, and cheap way of removing thrombi from the arterial circulation in the straight lower limb arteries. The results of AT have been favorable. Wagner et al. (16) reported clinical success in 86% of 90 patients and cumulative primary patency rates of 68% and 58% at one and four years,

respectively. Major amputation was unavoidable in 8 cases. Canova et al. (17) reported a technical success rate of 97%; two-year patency was 82%. Percutaneous aspiration thrombectomy may be labor-intensive, but it is more rapid for thrombus clearance than thrombolysis and can be successfully used in stage IIb acute limb ischemia. The method also provides an alternative therapy for thromboembolic disease when thrombolytic drugs are contraindicated and surgery is not desirable in high-risk patients. Care should be taken to prevent dissection or perforation during AT. One should also be very careful when crossing a recently dilated area to avert subintimal dissection and possible further damage. This method could be attempted prior to surgical embolectomy as an alternative to thrombolytic therapy. The technique is limited to use by physicians who have expertise with percutaneous devices and methods.

Percutaneous aspiration thrombectomy is a rapid and effective way of removing thrombus in thromboembolic occlusions of the limb arteries below the inguinal ligament and can be a very good alternative to surgery in selected patients. Although effectiveness decreases in chronic thromboemboli when compared to acute emboli, aspiration thrombectomy can remove most thrombi, even in chronic cases. Contrary to catheter-directed thrombolysis, manual aspiration thrombectomy is a rapid way of thrombus removal and can be used in patients with acute limb ischemia up to and including Rutherford clinical category IIb.

References

1. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG on behalf of the TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007; 45 Suppl S:S5–67.
2. Yaeger RA, Moneta GL, Taylor LM, et al. Surgical management of severe acute lower extremity ischemia. J Vasc Surg 1992; 15:385–393.
3. Rajan DK, Patel NH, Valji K, et al. Quality improvement guidelines for percutaneous management of acute limb ischemia. J Vasc Intervent Radiol 2005; 16:585–595.
4. Blaisdell FW, Steel M, Allen RE. Management of acute lower extremity ischemia due to embolism and thrombosis. Surgery 1978; 84:822–831.
5. The STILE investigators. Results of prospective randomized trail evaluating surgery versus thrombolysis for ischemia of the lower extremity. The STILE trial. Ann Surg 1994; 220:251–268.
6. Braithwaite BD, Davies B, Birch PA, et al. Management of acute leg ischaemia in the elderly. Br J Surg 1998; 85:217–220.
7. Semba CP, Murphy TP, Bakal CW, et al. Thrombolytic therapy with use of alteplase (rt-PA) in peripheral arterial occlusive disease: review of the clinical literature. The advisory panel. J Vasc Interv Radiol 2000; 11:149–161.
8. Vorwerk D. Mechanical thrombectomy is an alternative way to go: the European experience commentary on quality improvement guidelines for percutaneous management of acute limb ischemia. Cardiovasc Intervent Radiol 2006; 29:7–10.
9. Sniderman KW, Bodner L, Saddekni S, et al. Percutaneous embolectomy by transcatheter aspiration. Work in progress. Radiology 1984; 150:357–361.
10. Starck EE, McDermott JC, Crummy AB, et al. Percutaneous aspiration thrombectomy. Radiology 1985; 156:61–66.
11. Poulain F, Raynaud A, Bourquelot P, et al. Local thrombolysis and thromboaspiration in the treatment of acutely thrombosed arteriovenous hemodialysis fistulas. Cardiovasc Intervent Radiol 1991; 14:98–101.
12. Oguzkurt L, Tercan F, Ozkan U. Manual aspiration thrombectomy with stent placement: rapid and effective treatment for phlegmasia cerulea dolens with impending venous gangrene. Cardiovasc Intervent Radiol 2008; 31:205–208.
13. Oguzkurt L, Tercan F, Ozkan U, et al. Iliac vein compression syndrome: outcome of endovascular treatment with long term follow-up. Eur J Radiol 2008; 68:487–492.
14. Tajima H, Murata S, Kumazaki T, et al. Hybrid treatment of acute massive pulmonary thromboembolism: Mechanical fragmentation with a modified rotating pig tail catheter, local fibrinolytic therapy, and clot aspiration followed by systemic fibrinolytic therapy. AJR Am J Roentgenol 2004; 183:589–595.
15. Novelli L, Raynaud A, Pellerin O, et al. Percutaneous manual aspiration embolectomy or renal vein thrombosis due to acute pyelonephritis. Cardiovasc Intervent Radiol 2007; 30:1075–1078.
16. Wagner HJ, Starck EE, Reuter P. Long-term result of percutaneous aspiration thrombectomy. Cardiovasc Intervent Radiol 1994; 17:241–246.
17. Canova CR, Schneider E, Fischer L, et al. Long-term results of percutaneous thromboembolectomy in patients with infranguinal embolic occlusions. Int Angiol 2001; 20:66–73.