



Effectiveness of Percutaneous Aspiration Thrombectomy for Acute or Subacute Thromboembolism in Infrainguinal Arteries

서혜하부 하지동맥의 급성 또는 아급성 혈전색전증의 치료로서
경피적 흡인 혈전제거술의 유용성

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Purpose: To report the feasibility and long-term clinical outcome of percutaneous aspiration thrombectomy for treating acute or subacute arterial thromboembolism in the infrainguinal arteries.**Materials and Methods:** Thirty limbs of 29 patients were enrolled in this retrospective study between January 2004 and March 2014. Nine limbs underwent overnight catheter-directed thrombolysis followed by percutaneous aspiration thrombectomy (PAT). Eighteen limbs underwent PAT with adjunctive selective intra-arterial thrombolysis in a single session. The remaining three limbs underwent PAT alone. Balloon angioplasty ($n = 16$) or stent placement ($n = 3$) was performed as required. In-hospital mortality and complications were estimated. The primary patency rate and the rate of freedom from reintervention were calculated using the Kaplan-Meier method.**Results:** Technical success was achieved in 28 limbs. Clinical success was achieved in 27 limbs. The mean ankle-brachial index increased from 0.17 ± 0.26 to 0.98 ± 0.19 after the procedure. Three in-hospital deaths and no major amputations were recorded. Distal embolization of crural arteries occurred as a minor complication in five limbs, but no major complications occurred. The primary patency rate and the rate of freedom from reintervention were 74.9% and 90.9% at 1 year, respectively, and 66.6% and 80.8% at 2 years, respectively.**Conclusion:** PAT is a rapid and effective method to remove a thrombus from occluded infrainguinal arteries.**Index terms**Peripheral Arterial Disease
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Thrombolytic Therapy**Received** February 28, 2016**Revised** December 3, 2016**Accepted** January 25, 2017***Corresponding author:** Jung Guen Cha, MD
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INTRODUCTION

Acute limb ischemia (ALI) is a sudden decrease or worsening of limb perfusion causing a potential threat to extremity viability, and it remains one of the most common vascular surgery emergencies. According to the three well-known randomized control studies (1-3), catheter-directed thrombolysis (CDT) shows

a similar limb salvage rate and a lower mortality rate compared to surgical revascularization which has emerged as a new treatment alternative to surgery. However, CDT is a time-consuming procedure, and it is not an initial treatment, particularly in patients who need immediate revascularization. Furthermore, the complications and contraindications associated with bleeding limit the role of CDT in patients with ALI.

Percutaneous aspiration thrombectomy (PAT) is a rapid and economical technique that is often used as an adjunct to pharmacological thrombolysis to increase the lytic effect and to reduce the dose of the fibrinolytic agent. The underlying atherosclerotic stenosis detected during the procedure can be treated by balloon angioplasty or by placing a stent in the same session.

The purpose of this study was to evaluate the feasibility and long-term clinical outcome of PAT for treating acute or subacute thromboembolism in the infrainguinal arteries.

MATERIALS AND METHODS

Patients

Our Institutional Review Board approved this retrospective study with a waiver of the requirement for obtaining patient informed consent. Thirty limbs of 29 patients (23 males and 6 females; mean age, 66.1 years; range, 40–86 years) with acute or subacute thromboembolism in the infrainguinal arteries which were consecutively referred to the interventional radiology department for an endovascular procedure between January 2004 and March 2014 were enrolled in this study. Acute or subacute thromboembolism was confirmed by CT angiography in all patients and by additional duplex ultrasonography in 3 patients. The treatment strategy was dependent on the TransAtlantic Inter-Society Consensus (TASC) document. In patients with

stage I (viable, $n = 0$) and IIa (marginally threatened, $n = 25$) limbs, endovascular treatment was performed as an initial treatment method. Nine patients underwent overnight urokinase thrombolysis followed by aspiration thrombectomy during the early period of the study. With increasing experience of PAT, sixteen patients underwent PAT with adjunctive selective intra-arterial thrombolysis in order to decrease the procedure time and the bleeding complication. Five stage IIb (immediately threatened) limbs, which underwent primary surgical embolectomy followed by PAT, were included in our study (Fig. 1). Balloon angioplasty ($n = 16$) or stent placement ($n = 3$) was performed as required. Mean symptom duration was 6.4 days (range, 0.5–21 days). Symptoms were hyperacute (< 24 hours) in six patients, acute (≤ 14 days) in nineteen patients, and subacute (15 days–3 months) in five patients. The etiology of the disease was mainly attributed to native thrombosis ($n = 16$) and embolism ($n = 11$). Concurrent conditions associated with embolism included atrial fibrillation ($n = 10$, 23%), and left atrial thrombi and congestive heart failure ($n = 1$), which were confirmed by ECG and echocardiography. The causes of thrombosis included underlying *in situ* atherosclerotic stenosis ($n = 12$), bypass graft ($n = 3$), and Buerger's disease ($n = 1$). No cause was identified in three patients. Target lesions were located in the superficial femoral ($n = 10$), popliteal ($n = 15$), and crural ($n = 5$) arteries (Table 1).

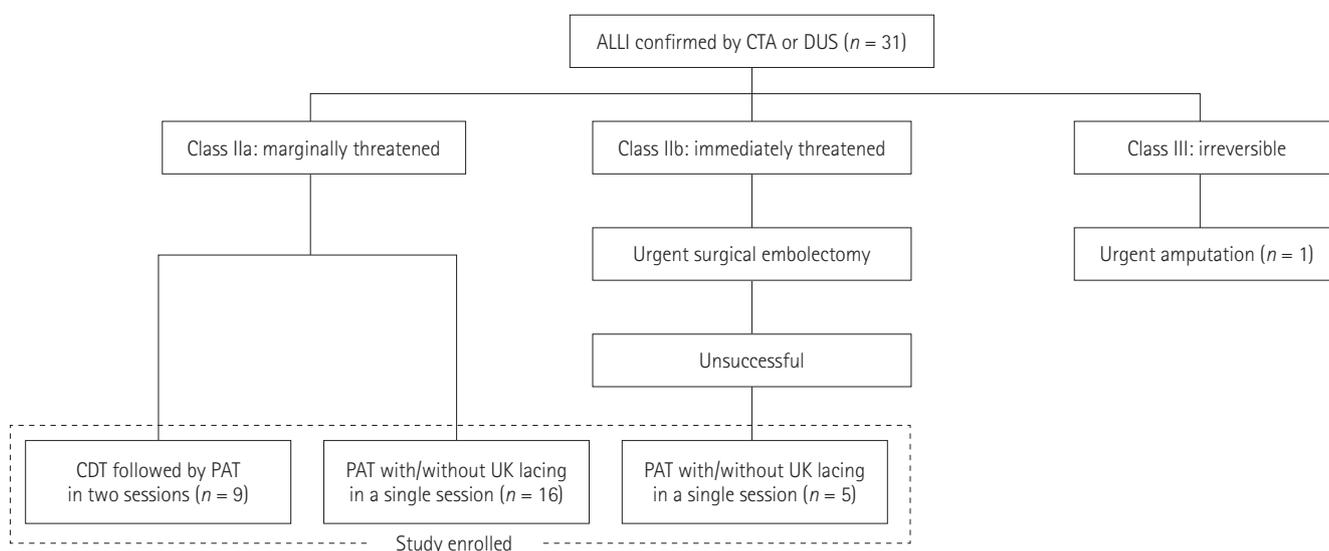


Fig. 1. Flow chart of patient selection.

ALLI = acute lower limb ischemia, CDT = catheter-directed thrombolysis, CTA = CT angiography, DUS = Doppler ultrasonography, PAT = percutaneous aspiration thrombectomy, UK = urokinase

Table 1. Baseline Characteristics of Patients

Demographics	
Age (years \pm SD)	66.1 \pm 11.7
Number of limbs	30
Gender	
Male	23
Female	6
Rutherford clinical limb stage (%)	
Stage IIa	25 (83)
Stage IIb	5 (17)
Onset of ischemic symptom (%)	
< 1 day	6 (20)
1–14 days	19 (63)
> 14 days	5 (17)
Mean symptom duration (days)	6.4
Source of embolism (%)	
Thrombosis–native artery with atherosclerosis	12 (40)
Thrombosis–bypass graft	3 (10)
Thrombosis–underlying Buerger's disease	1 (3)
Cardioembolism–atrial fibrillation	10 (33)
Cardioembolism–congestive heart failure	1 (3)
Unknown	3 (10)
Level of arterial occlusion (%)	
Superficial femoral artery	10 (33)
Popliteal artery	15 (50)
Crural arteries	5 (17)

Technique

The PAT equipment consists of a regular 6 Fr sheath for an ipsilateral approach or a 6 Fr Balkin guiding sheath (Cook Medical, Bloomington, IN, USA) for the contralateral approach; a 5 or 6 Fr guiding catheter (Envoy; Codman & Shurtleff, Inc., Raynham, MA, USA) to aspirate the thrombus from the superficial femoral and popliteal arteries; a 3 or 4 Fr aspiration catheter (Penumbra; Penumbra Inc., Alameda, CA, USA) to aspirate the thrombus from the crural arteries; and a 10-cc syringe; a 0.035-inch (Radifocus; Terumo Corp., Tokyo, Japan), 0.018-inch (V18; Boston Scientific, Natick, MA, USA), and 0.014-inch hydrophilic-coated guidewires (Journey; Boston Scientific).

Access to the artery was obtained with an ipsilateral ante-grade puncture of the common femoral artery, but a contralateral retrograde puncture was performed if an iliac lesion was identified. Diagnostic angiography was performed after inserting a 6 Fr sheath. An intravenous bolus of 3000 units of heparin was administered and 1000 units per hour were added. In 7 patients, systemic anticoagulation was performed before they ar-

rived at the angiography suite. Five of these 7 patients underwent systemic anticoagulation using 1 mg/kg of clexane (enoxaparin sodium) every 12 hours and their mean aPTT level was 46.52 secs (range, 24.4–79.3 secs). For the other two patients, 2 mg of warfarin daily were used and their INR levels were 1.26 and 1.99, respectively.

We performed the wire traversal test in all cases. A 0.035-inch guidewire was successfully passed through the occlusion in all cases, and a 5 or 6 Fr guiding catheter was advanced over the wire. A 3 or 4 Fr aspiration catheter with a 0.018-inch or 0.014-inch guidewire was used for the crural arteries. Diagnostic angiography was performed to define the distal run-off flow. The tip of the aspiration catheter was placed just beyond the embolus. Manual suction was performed with a 10-cc syringe. Once the thrombus was engaged, the catheter was withdrawn while maintaining suction to hold the thrombus. The contents of the syringe were emptied over a gauze-draped basin to separate the emboli from blood. Aspiration was repeated until sufficient flow through the occluded vascular segment was achieved. We performed selective intrathrombus infusion using urokinase ($n = 26$, < 200000 IU) before PAT in order to fragment thrombus for easy aspiration through the guiding catheter.

In total, 16 patients had thrombosis including *in situ* atherosclerotic stenosis, bypass graft, and Buerger's disease, and all of these patients underwent angioplasty for treating the underlying stenosis. A stent was inserted in three patients in order to treat residual stenosis after angioplasty.

In the nine cases of overnight CDT, thrombolysis was performed using a multi-side-hole infusion catheter (infusion set; Cook Medical). The catheter was placed with the tip about 1–2 cm above the bottom of the occlusion to leave a small untreated segment of the clot. This plug may have prevented embolization of large clot fragmentation during intrathrombus lacing of urokinase. For intrathrombus lacing, 200000 IU of urokinase was prepared, usually diluting the agent in a total of 20 cc normal saline solution. The diluted urokinase was injected through the catheter by forceful manual thrusts of a 1-cc syringe every 30 seconds for 10 minutes in the angiography room for fragmentation of thrombus in order to increase the contact surface of urokinase during overnight continuous thrombolysis. After intrathrombus lacing, the patient was referred to the surgical intensive care unit for 12 hours while maintaining catheter-directed high

dose continuous infusion of urokinase using the McNamara's scheme (4) and 500 IU/hour of heparin. PAT was performed in the same manner after 12 hours of thrombolysis.

Definition

Technical success of the procedure was defined as recanalization of the superficial femoral artery, the popliteal artery, and at least one of the crural arteries without obvious flow-limiting lesions on completion angiography. Clinical success was defined as relief of acute ischemic symptoms without amputation. Major complications were defined as any undesired event that required major therapy, prolonged hospitalization, or had permanent adverse sequelae or resulted in death. An acute limb-threatening ischemic event was defined as an episode occurring < 14 days from presentation (hyperacute < 24 h) and it was considered subacute if it occurred between 15 days and 3 months.

Statistics

All results were analyzed using the SPSS ver.22.0 software package (SPSS Inc., Chicago, IL, USA). Kaplan-Meier curves were used to calculate the primary patency rate and the rate of freedom from reintervention. The log-rank test was used to compare the survival curves between patients who underwent PAT

with/without adjuvant thrombolysis in a single session and overnight CDT followed by PAT. A p -value < 0.05 was considered statistically significant.

RESULTS

Early Results

Mean PAT procedure time was 84.9 ± 26.5 min (range, 37–136 min). Technical success was achieved in 28 limbs (93%), and clinical success was achieved in 27 limbs (90%). Technical and clinical successes were achieved in all patients with subacute thromboembolism ($n = 5$). Among the five subacute thromboembolism patients, two underwent overnight CDT followed by PAT with angioplasty and stent, respectively. The other three patients underwent PAT with/without adjuvant thrombolysis in a single session with angioplasty. Technical success rate and clinical success rate in the overnight CDT followed by PAT group was 88% and 88%, respectively, and 95% and 90% in the PAT with/without adjuvant thrombolysis in a single session group.

In all 5 patients of the class IIb group who failed surgical embolectomy, angiography showed acute thrombosis with underlying *in situ* atherosclerotic stenosis. Technical and clinical successes were achieved by PAT with adjuvant thrombolysis and

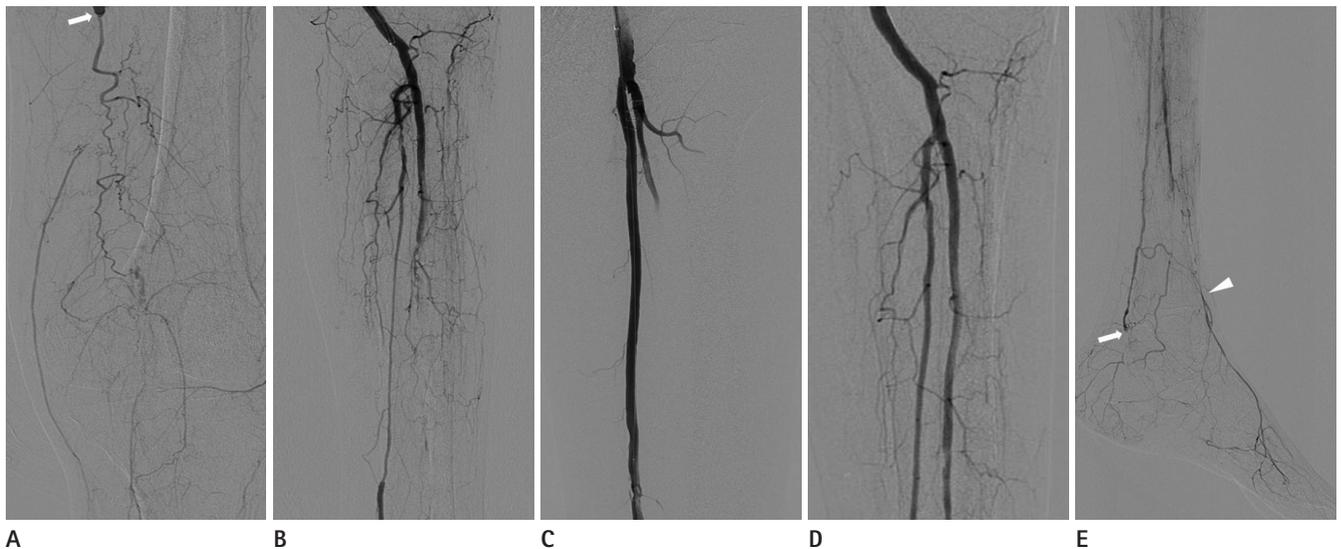


Fig. 2. Angiograms of a 74-year-old male who presented with coldness and resting pain in the left leg for 7 days. He had undergone prior surgical embolectomy. Initial angiogram (**A**) shows occlusion from the distal superficial femoral artery (arrow) to the popliteal artery. Angiogram after aspiration of the thrombus and balloon angioplasty of the superficial femoral artery (**B**) reveals embolic occlusion of the crural arteries. After aspirating the thrombi in the crural arteries, the final angiogram shows good patency of the superficial femoral (**C**), proximal posterior tibial, and common peroneal arteries (**D**). Although the final angiogram of the foot (**E**) reveals distal embolization (arrow) at the distal posterior tibial artery, collateral flow is detected from the recanalized posterior tibial artery to the dorsalis pedis artery (arrowhead). Clinical success was achieved, and the ankle-brachial index increased from 0 to 1.16.

angioplasty in all patients except for one patient who experienced clinical failure despite technical success.

The mean ankle-brachial index increased significantly from 0.17 ± 0.26 (range, 0–0.74) to 0.98 ± 0.19 (range, 0.60–1.27) after the procedure. Major complications resulting in mortality developed in three patients. One patient, who failed clinically despite technical success, had aggravation of resting leg pain and he expired 3 days after the procedure due to multi-organ failure. He had underlying severe comorbidities, such as active pulmonary tuberculosis, pulmonary edema, and respiratory acidosis, before the procedure. In the two cases of technical failure, one patient underwent bypass surgery, and the limb was salvaged. The other patient expired 4 days after the procedure due to rhabdomyolysis. One patient with technical and clinical success expired 5 days after the procedure due to multi-organ failure caused by sepsis associated with advanced cholangiocarcinoma, regardless of the reperfusion injury. The overall in-hospital mortality rate was 10%.

Distal embolization occurred as a complication in five cases (16.7%), and it was detected during the procedure. Emboli in three limbs were removed completely by repeated aspiration, whereas they could not be removed from two limbs by PAT. Nev-

ertheless, we did not perform any additional intervention, but we salvaged the limbs because sufficient collateral flow was detected from the other arteries (Fig. 2). No other procedure-related major complications that prolonged hospitalization were observed.

Long-Term Results

One limb was lost to follow-up, and 29 limbs were included in the long-term analysis. Limb salvage was achieved in all patients during the follow-up period. The mean observation period was 31 months (range, 0.1–120 months). Cumulative primary patency rate was 74.9% at 1 year and 66.6% at 2 years. No difference in the primary patency rate was observed between the PAT with/without adjuvant thrombolysis in a single session group and the overnight CDT followed by PAT group (79.2% vs. 64.8% at the 1-year follow-up; 59.4% vs. 48.6% at the 2-years follow-up, respectively; $p = 0.315$) (Fig. 3). The 1-year and 2-years primary patency rates for acute thromboembolism were 80.5% and 70.5%, respectively, and those for subacute thromboembolism were 80.0% and 40.0%, respectively. Re-occlusion despite technical success developed in four patients with acute thromboembolism during the follow-up period (4 months, 7 months, 20 months, and 36 months, respectively). One patient under-

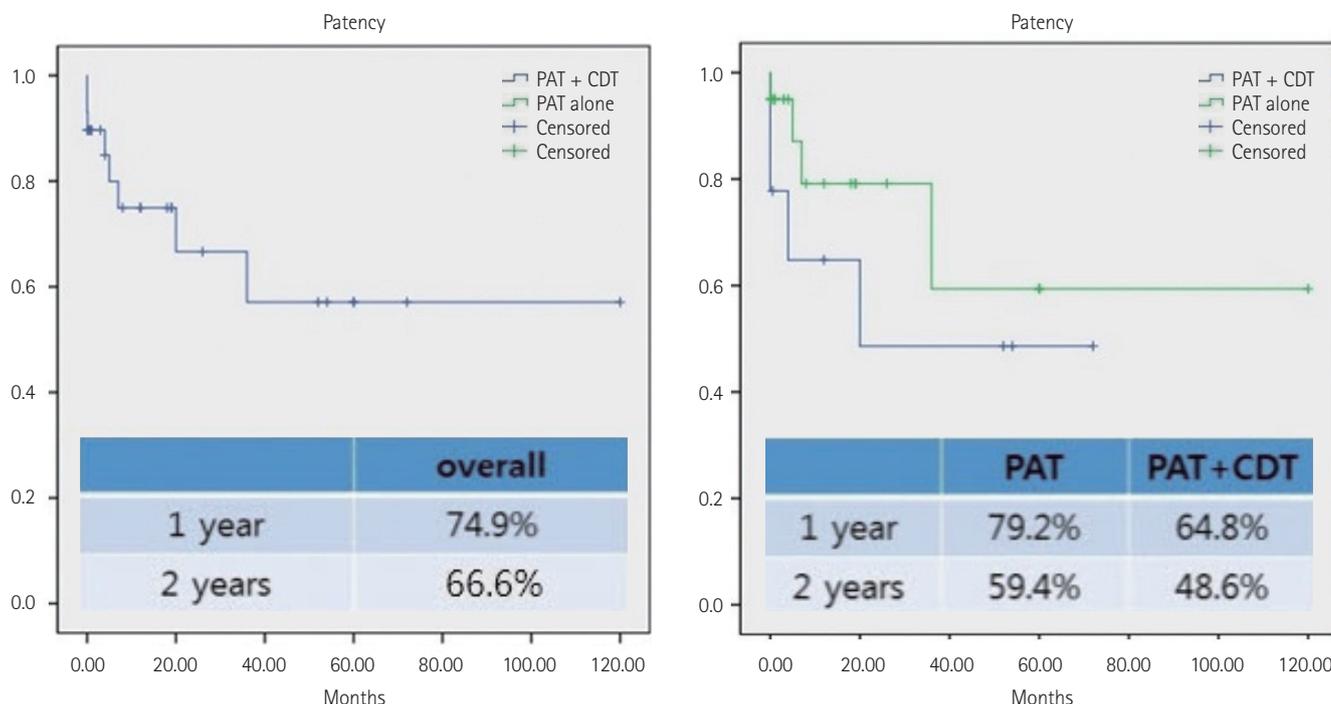


Fig. 3. Primary patency curves. PAT + CDT: overnight CDT followed by PAT group, PAT alone: PAT with/without adjuvant thrombolysis in a single session group. CDT = catheter-directed thrombolysis, PAT = percutaneous aspiration thrombectomy

went PAT again, and the other patients were managed conservatively. Two out of the five patients with subacute thromboembolism developed an occlusion of the recanalized artery at 3 days and 5 months, respectively. One patient underwent bypass surgery, and the other patient was treated with medication alone. The overall rates of freedom from reintervention (including surgical revascularization) were 90.9% at 1 year and 80.8% at 2 years, with no difference between the PAT with/without adjuvant thrombolysis in a single session group and the overnight CDT followed by PAT group (91.7% vs. 88.9% at the 1-year follow-up; 91.7% vs. 66.7% at the 2-year follow-up, respectively; $p = 0.245$) (Fig. 4).

DISCUSSION

The first attempt at percutaneous embolectomy using transcatheter aspiration to treat arterial thromboembolism was described by Sniderman et al. (5) in 1984, which is earlier than the attempt at CDT (4). No large-scale, prospective, randomized control study has evaluated the efficacy of PAT; thus, PAT is not used as a standard endovascular method to treat acute lower limb ischemia. Improvements in endovascular devices and tech-

niques have occurred over the years and have lead to favorable results following endovascular procedures including PAT and mechanical thrombectomy (6-9).

CDT is a feasible endovascular procedure, but its safety has been a point of concern. Despite the favorable long-term limb salvage rate in the STILE trial (1), the study was prematurely interrupted because the bleeding complications and technical failure in the thrombolysis group were unacceptably higher than those in the surgery group. CDT is a time-consuming procedure with reported infusion times of 8–40 hours. The reported hemorrhagic complication rates for CDT are 1–25% (10), and some studies have shown that the risk of major complications increases with the duration of thrombolytic infusion (11-13).

PAT may be labor-intensive but it allows for more rapid thrombus removal than CDT. In our study, the mean PAT procedure time was 84.9 ± 26.5 min, regardless of the time for CDT, and no bleeding complications were observed. Furthermore, no difference was found between the primary patency rate and the overall rate of freedom from reintervention between the PAT with/without a small amount adjuvant thrombolysis (< 200000 units urokinase) in a single session group and the overnight CDT followed by PAT group. Therefore, PAT with/without adjuvant

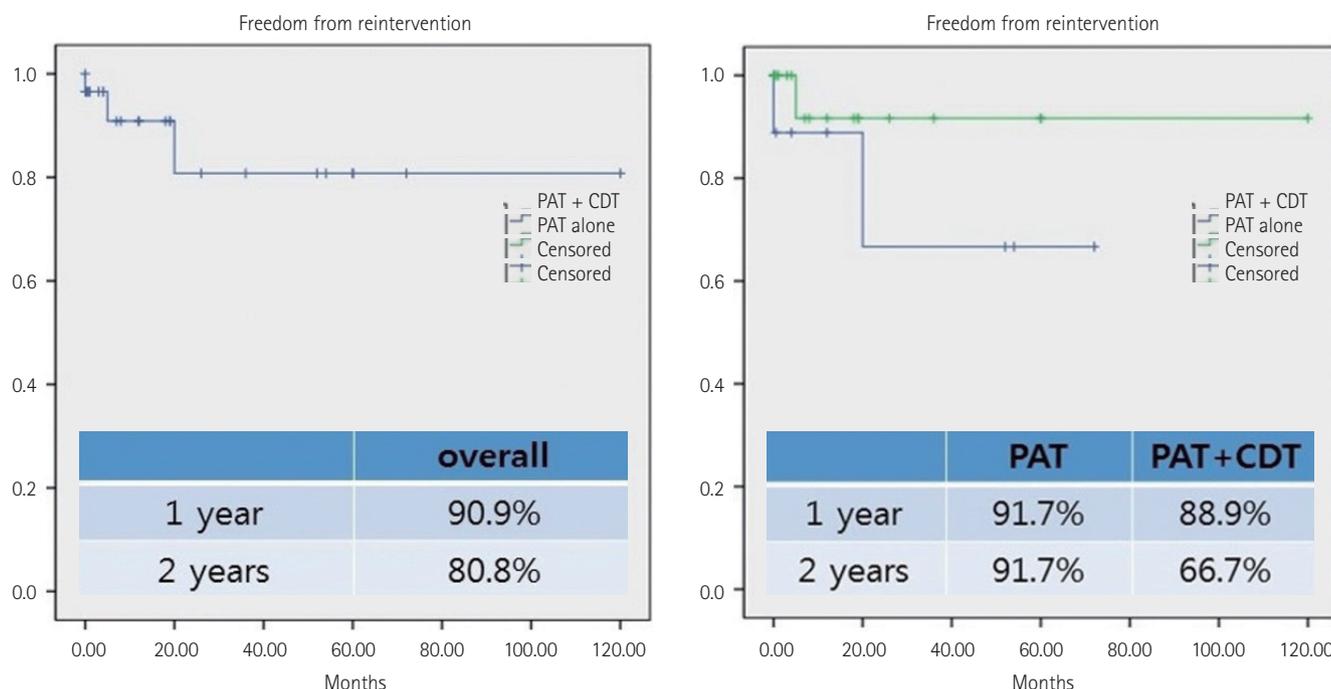


Fig. 4. Freedom from reintervention curves. PAT + CDT: overnight CDT followed by PAT group, PAT alone: PAT with/without adjuvant thrombolysis in a single session group. CDT = catheter-directed thrombolysis, PAT = percutaneous aspiration thrombectomy

thrombolysis was better than overnight CDT followed by PAT in terms of cost and patient compliance. In contrast, the advantages of CDT over PAT are less traumatic injury to the endothelium and infusion of the lytic agent into the collaterals and runoff arteries that are too small for an aspiration catheter. Zehnder et al. (9) reported a 31% PAT procedural success rate, but the primary success rate reached 90% when combined with thrombolysis and angioplasty; the limb salvage rate was 86%. Therefore, to avoid endothelial injury during PAT and to increase the success rate, we accessed the thrombus with an aspiration catheter over the guidewire and performed adjuvant thrombolysis or angioplasty.

Our study included five cases of subacute thromboembolism. Technical and clinical success was achieved in all patients. Although the recanalized artery was occluded within 6 months in two out of the five cases, PAT is technically feasible and clinically effective for treating subacute thromboembolism in the infringuinal arteries. However, large-scale, long-term studies are needed to establish the role of PAT in subacute arterial thromboembolism.

PAT is also effective in patients who have undergone prior ineffective surgical embolectomy. Although the use of a Fogarty balloon is a cheap, simple and fast method for thromboembolism, it is difficult to use it in cases with underlying chronic stenosis and a well-organized thrombus. In our study, the cause of ineffective surgical embolectomy was failure to pass a Fogarty balloon through an underlying atherosclerotic stenosis in all five cases. Both removal of the residual thrombus using PAT and balloon angioplasty with or without placement of a stent were performed in the same session. Several clinical and experimental studies have demonstrated that removal of a thrombus is frequently incomplete after surgical embolectomy, as a persistent thrombus is confirmed by angiography or fiber optic angiography in small distal arteries in 36–86% of the patients (14–16). Thus, it is recommended to perform routine angiography after surgical embolectomy (17, 18), but the application of this recommendation is limited in clinical practice. TASC II (19) recommends that surgical thromboembolism should be performed as an initial treatment in an immediately threatened limb (class IIb). However, a primary endovascular approach with use of an angiogram may be helpful in some patients who have an underlying atherosclerotic stenosis.

The considerable complications of PAT are hematoma or pseudoaneurysm at the puncture site, distal migration of the embolus, arterial dissection, and perforation. The rates of reported complications are 0–4% for arterial perforation, 0–6% for arterial dissection, and 0–14% for distal embolization (10). One report (6) demonstrated much higher complication rates of arterial dissection and perforation, which may be due to the large profile of the vascular sheaths and catheters used for the procedure. We usually used a 6 Fr guiding catheter for aspiration and we never experienced these complications. Low-profile, specially designed aspiration catheters may be helpful for decreasing the complications and enhancing the aspiration efficacy. Distal embolization was a relatively common complication in the present study (16.7%). All of these complications were detected during the procedure and were managed in the same session. Although residual thrombi in two limbs could not be aspirated, a thrombus in the main conducting artery was removed and the limb was salvaged.

The primary limitation of this study was its retrospective nature. An additional limitation is that we only reported the outcomes following PAT and did not include patients with ALI who were treated with either surgical embolectomy alone or with CDT alone. Selection bias can affect the outcomes, and comparisons with other treatment options may not be reasonable. The sample size was relatively small and the groups were asymmetric compared to those in the other reported studies. Despite these limitations, our results support the safety and long-term efficacy of PAT, regardless of the comparison with CDT.

In conclusion, PAT is a technically feasible and effective procedure for treating acute or subacute thromboembolism in the infringuinal arteries, and it shows favorable long-term clinical outcomes. Although distal embolization is relatively common, we believe that PAT can be a stand-alone procedure and an alternative to CDT or surgical embolectomy.

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서혜하부 하지동맥의 급성 또는 아급성 혈전색전증의 치료로서 경피적 흡인 혈전제거술의 유용성

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목적: 서혜하부 하지동맥의 급성 또는 아급성 혈전색전증의 치료로서 경피적 흡인 혈전제거술의 유용성을 알아보고자 한다.

대상과 방법: 2004년 1월부터 2014년 3월까지 총 29명 환자의 30개 하지가 후향적 연구에 포함되었다. 9개의 하지는 카테터 혈전용해술 후에 경피적 흡인 혈전제거술을 시행받았다. 18개의 하지는 경피적 흡인 혈전제거술과 보조적 동맥내 혈전용해술(urokinase < 200000 IU)을 한번에 시행하였다. 나머지 3개의 하지에서는 경피적 흡인 혈전제거술만 시행하였다. 필요에 따라 풍선 혈관성형술($n = 16$)이나 스텐트 삽입술($n = 3$)을 같이 시행하였다. 원내 사망률과 합병증 발생률을 산출하였다. Kaplan-Meier method를 이용하여 일차 개통률과 freedom from reintervention을 산출하였다.

결과: 기술적 성공은 28개의 하지에서 이루어졌으며 임상적 성공은 27개의 하지에서 이루어졌다. 평균 ankle-brachial index는 0.17 ± 0.26 에서 술 후 0.98 ± 0.19 로 증가하였다. 3명의 원내 사망이 발생하였으며 주요 하지절단은 발생하지 않았다. 합병증으로서 5개의 하지에서 종아리 동맥 내에 색전증이 발생하였다. 일차 개통률과 freedom from reintervention은 1년에 74.9, 90.9%였으며 2년에 66.6, 80.8%였다.

결론: 경피적 흡인 혈전제거술은 서혜하부 하지동맥의 혈전을 신속하고 효과적으로 제거하는 방법으로 양호한 장기간 임상경과를 보였다.

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