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대한영상의학회지

Endovascular Intervention as Management for Acute Limb Ischemia, Including the Rutherford Class IIb Ischemia: Korean Experience
급성 사지 허혈증의 초기 치료로서 혈관 내 중재적 시술의 임상 결과: 수술적 치료법과의 비교

Sung Mo Moon, MD[1], In Wha Kim, MD[1], Gyeong Sik Jeon, MD[1]*, Sun Young Choi, MD[2], Man Deuk Kim, MD[3], Gun Lee, MD[4]

Departments of [1]Radiology, [4]Thoracic & Cardiovascular Surgery, CHA Bundang Medical Center, CHA University, Seongnam, Korea
[2]Department of Radiology and Medical Research Institute, Ewha Womans University Mokdong Hospital, Seoul, Korea
[3]Department of Radiology, Research Institute of Radiological Science, Severance Hospital, Yonsei University College of Medicine, Seoul, Korea

Purpose: To comparatively assess the outcomes between endovascular intervention and surgery as initial management for acute limb ischemia (ALI).
Materials and Methods: From April 2004 to March 2015, the medical records of 51 patients with ALI who were treated with intervention or surgery were reviewed. Patient baseline characteristics and procedural data were collected. Clinical outcomes were compared between patients classified according to the Rutherford criteria.
Results: A total of 39 limbs of 35 patients underwent intervention, and 16 limbs of 16 patients underwent surgery. The technical success rate was 82.1% and 75.0% in the intervention and surgery groups, respectively. The intervention group showed no procedure related mortality or major complication during follow-up, but one case of compartment syndrome was reported in the surgery group. The mean follow-up period was 23.4 and 16.6 months in the intervention and surgery groups, respectively. The primary patency rate at 12 months was 89.4% and 100%, and the limb salvage rate at 12 months was 97.2% and 87.1% in the intervention and surgery groups, respectively. Among 7 patients with technical failure of intervention, immediate surgery was required in 6 cases, and 2 major and 1 minor amputations were required during follow-up.
Conclusion: Endovascular therapy is a safe and effective treatment option that reduces and delays amputation in patients with ALI.

Index terms
Peripheral Arterial Disease
Angiography
Endovascular Procedures
Mechanical Thrombolysis
Thrombolytic Therapy

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***Corresponding author:** Gyeong Sik Jeon, MD
Department of Radiology, CHA Bundang Medical Center, CHA University, 59 Yatap-ro, Bundang-gu, Seongnam 13496, Korea.
Tel. 82-31-780-5382 Fax. 82-31-780-5381
E-mail: hae0820@naver.com

INTRODUCTION

Acute limb ischemia (ALI) is defined as sudden-onset ischemic symptoms or signs within 2 weeks due to a decrease in peripheral limb perfusion. About 140 million cases of ALI occur annually, resulting mostly from an embolic event or local thrombosis (1). Due to high mortality and morbidity rates, as well as the risk of limb amputation, patients with ALI require emergency revascularization of the threatened limb (Rutherford class II) using either an open-surgical or endovascular approach, excluding an irreversible limb (Rutherford class III) that requires major amputation (2).

Previous studies from the 1990s comparing surgery and thrombolysis for initial management of ALI, including the prospective randomized trial evaluating surgery versus thrombolysis for ischemia of the lower extremity (STILE) and thrombolysis or peripheral arterial surgery (TOPAS) trials, reported no difference in limb salvage or death after ≥ 30-day follow-up, but a higher incidence of major complications, such as hemorrhage, stroke, and distal embolization in patients treated with throm-

bolysis (3, 4). These results suggest that endovascular intervention can be used as initial management in patients with ALI. However, thrombolysis is recommended for patients with a marginally threatened limb (Rutherford class IIa) due to the limited time available to restore arterial flow (5).

Recent studies reported reduced reperfusion time and lower complication rates of endovascular intervention by dose optimization, shortening of the duration of thrombolytic agent use, and improved endovascular and mechanical thrombectomy devices (6, 7). Thus, the management strategy should be based on the extended indications of endovascular intervention for threatened limbs.

In the present study, we assessed the effectiveness of endovascular intervention using current devices and pharmacologic agents as initial management for cases of ALI, as compared to surgery, including in patients with marginally and immediately threatened limbs (Rutherford classes IIa and IIb).

MATERIALS AND METHODS

Patients

This retrospective cohort study was approved by our Institutional Review Board, and the requirement for written informed consent to participate in the study was waived.

The medical records of all patients with peripheral arterial disease treated with endovascular intervention or surgery in two institutions between April 2004 and March 2015 were reviewed. Patients who presented with Rutherford classes I–IIb ischemia and sudden onset within 2 weeks were included. Exclusion criteria for endovascular intervention were significant clinically active bleeding, intracranial hemorrhage, and compartment syndrome (8). A total of 40 patients underwent endovascular intervention using aspiration thrombectomy (AT), catheter-directed thrombolysis (CDT) or additional angioplasty with/without a stent. Thirty-five of 40 patients met the inclusion criteria and were enrolled. Eighteen patients underwent surgery including embolectomy or bypass, but 2 patients with class III were excluded. Finally, 51 patients were included in the study.

Patients with a presumptive diagnosis of ALI based on ischemic symptoms (resting pain, paresthesia, sensory loss or motor weakness) and signs (coldness, cyanosis, and pulseless) from clinical history and physical examination underwent routine laboratory, electrocardiogram, and imaging studies, such as computed tomography angiography or a Doppler evaluation. Echocardiography was performed in patients with an abnormal electrocardiogram. Trans-thoracic echocardiography was performed in 23 of 51 patients. Additional trans-esophageal echocardiography was performed in 4 patients who showed suspicious findings in trans-thoracic echocardiography. Only 2 patients had a small amount of thrombus in the left atrial appendage and underwent CDT. After confirmed diagnosis of ALI on imaging, the patients were staged according to the Rutherford criteria and anticoagulated. The surgeon and interventional radiologists, in consensus, assigned the patients to either surgery or endovascular intervention based on their status. Because this study was a retrospective review based on different treatment policies for patients with ALI in the two independent institutions, there were no strict guidelines for assigning the patients to the surgery or endovascular intervention groups. However, the following cases were prioritized for surgery: occlusion of the superficial femoral artery extended to its ostium, and long segmental arterial occlusion, such as involving the entire segment of the superficial and popliteal arteries.

The follow-up included a history, routine physical examination, and laboratory tests. Imaging studies were performed for clinically suspected recurrence. Follow-up was closed at the time of death or the last patient visit.

Endovascular Interventions

Endovascular interventions were performed by interventional radiologists. Initial diagnostic arteriography demonstrated the anatomy and level of occlusion using either a contralateral or ipsilateral approach. In all patients, AT with a guiding catheter was attempted initially to remove as many fresh thrombi as possible. The guiding catheters used for AT were 8 to 9 Fr (Envoy Catheter®; Codman & Shurtleff, Rhaynham, MA, USA or Vista Brite Tip® Catheter; Cordis, Miami Lakes, FL, USA) for the superficial femoral artery to popliteal artery level, and 5 Fr (Penumbra System®; Penumbra, Alameda, CA, USA) for the crural artery level. Aspiration was performed using a directly connected 50 cc syringe. If residual thrombus remained after AT, urokinase was administered (40000–100000 units/h for infusion) through a multiple side-hole thrombolytic infusion catheter (Multi-side-port Catheter Infusion Set; Cook Medical, Bloomington, IN,

USA) positioned at the occluded site, with or without an initial bolus injection (100000–500000 units). The total amount of infused urokinase ranged from 500000 to 1600000 units, according to the extent and severity of thromboembolism. Underlying lesions accompanied by a thromboembolism were treated with further endovascular interventions, such as balloon angioplasty with/without a stent. The therapeutic effects of thrombolysis were evaluated with repeat arteriography within 12–24 h after the procedure.

Clinical Outcome

Several parameters were used to assess early and late status outcomes of ALI. "Technical success" and "clinical success" were used for the early status assessment, whereas "patency" was applied to the late status assessment based on the Society for Vascular Surgery guidelines (2). Mortality and major/minor complication rates were also estimated. "Technical success" was defined as restoration of blood flow to the foot with complete or at least 95% thrombolysis of the thromboembolism. "Clinical success" was defined as relief of acute ischemic symptoms and return to at least a pre-occlusive clinical baseline level. "Patency" was defined as uninterrupted patency without any procedure performed on the re-vascularized vessel. "Limb salvage" was defined as avoidance of inevitable major amputation by endovascular intervention. "Major and minor complications" were defined and classified according to the Society of Interventional Radiology clinical practice guidelines (8).

Assessment and Statistical Analysis

All categorical variables and clinical outcomes, such as technical and clinical success and complications, were reported as frequencies and percentages. Mean and standard deviation were used for continuous variables. Primary patency, limb salvage, and survival rates at 12 months after the endovascular intervention were assessed by the Kaplan-Meier method. Baseline characteristics and clinical outcomes were compared between the two groups using χ^2 and *t*-tests for categorical and interval scaled variables, respectively. Statistical analyses were performed using the SPSS ver. 18.0 statistical software (SPSS Inc., Chicago, IL, USA).

RESULTS

Patient Demographics and Baseline Limb Characteristics

The patient baseline and limb baseline characteristics were presented in Table 1. A total of 51 patients were included in the study. Thirty-nine limbs of 35 patients in the intervention group were compared with 16 limbs of 16 patients in the surgery group. Patients in the intervention group were more likely to be smokers or have arrhythmia. Otherwise, there was no significant difference between the two groups.

The majority of limbs were categorized as Rutherford class I

Table 1. Patient Baseline Characteristics and Severity of Ischemia

	Surgery, *n* (%)	Intervention, *n* (%)	*p* Value
No. of patients	16	35	
No. of limbs	16	39	
Sex			
Male	13 (81.3)	24 (68.6)	0.346
Age			
Mean (SD)	66.6 (10.2)	64.1 (14.5)	0.058
Underlying disease			
Hypertension	12 (75.0)	17 (48.6)	0.077
Diabetes	2 (12.5)	13 (37.1)	0.073
Hyperlipidemia	2 (12.5)	7 (20.0)	0.514
Arrhythmia	2 (12.5)	19 (54.3)	0.005
CAD	1 (6.3)	5 (14.3)	0.564
Smoking	3 (18.8)	20 (57.1)	0.006
Obesity	7 (43.8)	7 (20.0)	0.078
Others*	4 (25.0)	8 (22.9)	0.867
Rutherford classification			
Class I	8 (50.0)	20 (51.3)	0.931
Class IIa	6 (37.5)	12 (30.8)	0.629
Class IIb	2 (12.5)	7 (17.9)	0.620
Thrombosis vessel			
Native	16 (100)	34 (87.2)	0.133
Graft	-	5 (12.8)	0.133
Thrombosis location			
Aortoiliac	-	1 (2.6)	0.518
Femoropopliteal	7 (43.8)	14 (35.9)	0.586
Tibial	-	2 (5.1)	0.356
Multilevel	8 (50.0)	20 (51.3)	0.931
Brachial	1 (6.2)	2 (5.1)	0.868
Mean follow up period			
Mean (SD)	16.6 ± 10.7	23.4 ± 21.8	< 0.001

*Others include cerebral vascular disease, heart failure, Burger's disease, Protein S deficiency, and contralateral peripheral artery occlusion disease.
CAD = coronary artery disease

Table 2. Procedure Details of Surgical and Endovascular Interventions

	Class I, *n* (%)	Class IIa, *n* (%)	Class IIb, *n* (%)	Total, *n* (%)
No. of patients (surgical)	8	6	2	16
Embolectomy	6/8 (75.0)	3/6 (50.0)	2/2 (100)	1/16 (68.8)
Bypass with embolectomy	2/8 (25.0)	3/6 (50.0)	-	5/16 (21.2)
No. of patients (endovascular)	20	12	7	39
Aspiration	7/20 (35.0)	2/12 (16.7)	1/7 (14.3)	10/39 (25.6)
Aspiration + thrombolysis	13/20 (65.0)	10/12 (83.3)	6/7 (85.7)	29/39 (74.4)
Additional angioplasty ± stent insertion	11/20 (55.0)	8/12 (66.7)	6/7 (85.7)	25/39 (64.1)
Thrombolysis days (day)				
0–1	11/13 (84.6)	8/10 (80.0)	5/6 (83.3)	24/39 (82.8)
1–2	2/13 (15.4)	2/10 (20.0)	1/6 (16.7)	5/39 (17.2)
Adjuvant surgical intervention	3/20 (15.0)	3/12 (25.0)	-	6/39 (15.4)

ischemia (50.0% in the intervention group and 51.3% in the surgery group) in both groups. However, some limbs (12.5% in the surgery group and 17.1% in the intervention group) were Rutherford class IIb ischemia. The number of thromboembolisms in native vessels was greater than that in grafts in the intervention group; whereas, no case in a graft was reported in the surgery group. Most cases had multilevel thromboembolism. In cases with a single lesion, the femoropopliteal location was affected most frequently in both groups. The mean follow-up period was 16.6 months in the surgery group (range, 1–36 months) and 23.4 months (range, 1–71 months) in the intervention group.

Procedural Details and Clinical Outcomes

Procedural details and clinical outcomes were presented in Tables 2 and 3. In the surgery group, embolectomy was performed in 11 limbs (68.8%), in addition to bypass grafts in 5 limbs (21.2%). In the intervention group, AT and CDT were performed together in 29 limbs (74.4%), and 10 limbs (25.6%) underwent AT only. Additional angioplasty with/without a stent was performed in 25 patients (64.1%) to treat an underlying lesion accompanying a thromboembolism.

The overall technical success rate was slightly higher in the intervention group (82.1%) than the surgery group (75.0%; p = 0.553), without significance. The overall clinical success rate was similar in the intervention and surgery groups (84.6% vs. 87.5%; p = 0.620). In patients with class IIb ischemia, who are not conventional candidates for endovascular intervention, the success rate in the intervention group was also relatively high (85.7%). No procedural-related mortalities were observed. Below-knee amputation was performed in one patient in the surgery group due to compartment syndrome after embolectomy and bypass surgery during the follow-up period. However, only three minor complications including one pseudoaneurysm and two access-site hematomas occurred in the intervention group.

Table 3. Clinical Outcomes of Surgical and Endovascular Intervention

	Surgery, *n* (%)	Intervention, *n* (%)	*p* Value
Technical success			
All limbs	12/16 (75.0)	32/39 (82.1)	0.553
Category I	6/8 (75.0)	17/20 (85.0)	0.533
Category IIa	4/6 (80.0)	9/12 (75.0)	0.710
Category IIb	2/2 (100)	6/7 (85.7)	0.571
Clinical success			
All limbs	14/16 (87.5)	33/29 (84.6)	0.620
Category I	8/8 (100)	17/20 (85.0)	0.246
Category IIa	4/6 (80.0)	9/12 (75.0)	0.710
Category IIb	2/2 (100)	7/7 (100)	0.571
Complications			
Major*	1/16 (5.9)	-	0.115
Minor†	-	3/39 (7.7)	0.254
Amputation			
Major	1/16 (6.3)	2/39 (5.1)	0.868
Minor	1/16 (6.3)	1/39 (2.6)	0.507
Death‡			
≤ 30	0	1/39 (2.9)	0.495
> 30	0	2/39 (5.7)	0.329

*Major complications include compartment syndrome.
†Minor complications include hematoma, or pseudoaneurysm formation.
‡Causes of death were SMA occlusion, cardiac arrest, or coronary artery obstructive disease.
SMA = superior mesenteric artery

The endovascular intervention showed technical failure in 7 patients. Among them, immediate surgical intervention was required in 6 cases including 5 surgical thromboembolectomy and 1 below-knee amputation. After adjuvant surgical interven-

tion, there was no recurrence during the follow-up period (mean 40.8 months; range, 21–50 months). The remaining case was a 48-year-old female patient with Rutherford class IIb ischemia at the brachial artery. Despite technical failure of the endovascular intervention, her ischemic symptoms improved with partial recanalization and collateral flow. Therefore, no follow-up surgery was performed. This was the only clinically successful but technically failed case. Another case was a 76-year-old male patient who underwent toe amputation due to recurring ischemic symptoms and necrotic leg skin changes. However, above-knee amputation was performed eventually due to failure of wound healing.

Primary patency rate at 12 months showed no statistically significant difference between the two groups (100% in the surgery group vs. 89.4% in the intervention group; $p = 0.838$) for the entire cohort. In the intervention group, the primary patency rate at 12 months was 85.3%, 83.3%, and 66.7% ($p = 0.628$) for patients in classes I, IIa, and IIb, respectively (Fig. 1). The limb salvage rate also showed no significant difference at 12 months in the entire cohort (97.2% in the intervention group vs. 87.1% in the surgery group; $p = 0.372$) (Fig. 2). In the intervention group, 3 patients expired due to comorbidities during the follow-up period. An 87-year-old male patient expired from septic shock with bowel infarction due to superior mesenteric artery occlusion at 4 months after the procedure; a 76-year-old female patient expired from cardiac arrest during pneumonia treatment at 8 months after the procedure; and a 76-year-old male patient expired due to sudden cardiac death after 8 months. However, no death occurred within 30 days after the procedure. Four patients (2 graft thromboembolism and 2 native thromboembolism) in the intervention group had episodes of recurrent thromboembolism during the follow-up period. Repeat endovascular interventions were performed for these limbs, and the mean time until the first intervention was ~10 months (range, 2–29 months). Among them, recurred thromboembolism was reported in 2 patients with a graft after 23 and 29 months, respectively.

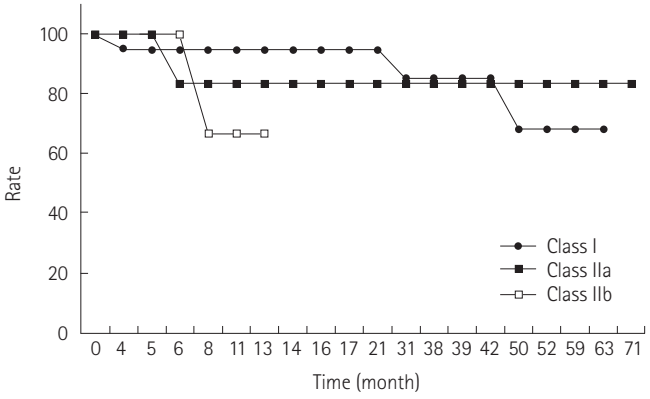

Fig. 1. Kaplan-Meier survival curve: primary patency at 12 months in intervention group (class-based analysis, $p = 0.628$).

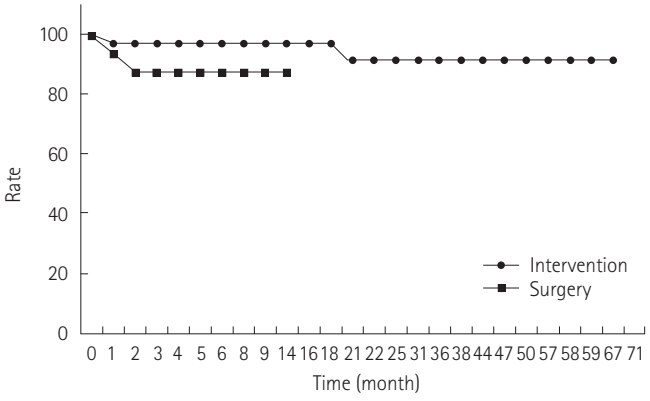

Fig. 2. Kaplan-Meier survival curve: amputation-free survival in intervention and surgery group ($p = 0.372$).

DISCUSSION

Patients with ALI, including marginally and immediately threatened limbs, were treated by endovascular intervention or surgery. The results confirmed that endovascular intervention is a safe and effective treatment option, and the clinical outcomes of the intervention group were comparable to those of the surgery group.

Comparing the baseline characteristics of the intervention and surgery group, the intervention group had a greater proportion of patients with comorbidities such as hypertension, diabetes, hyperlipidemia, arrhythmia, and smoking history, which could have affected the clinical outcomes. Despite no statistical significance due to the small number of patients, the intervention group showed a trend toward higher technical success (82.1% in the intervention group vs. 75.0% in the surgery group) and limb salvage (97.2% in the intervention group vs. 87.1% in the surgery group) rates, as compared with the surgery group. The clinical success rate (84.6% in the intervention group vs. 87.5% in the surgery group) in the intervention group was also comparable to that in the surgery group. The primary patency rate at 12 months was better in the surgery group than the intervention group, without significance. However, this result may have been affected by the heterogeneity of the comorbidities between the

two groups.

Patients with category IIb ischemia are candidates for thrombolysis according to the percutaneous ALI management guidelines; however, this is not recommended because of the delay in reperfusion and potential complications, such as systemic bleeding and compartment syndrome (8). Aspiration or mechanical thrombectomy has been used as an adjunctive or primary method with thrombolysis to overcome the disadvantages of thrombolysis. Consequently, several studies have reported high technical success and limb salvage rates in patients with ALI, including a large number with category IIb ischemia (9, 10).

Our results also showed a high technical success rate (85.7%) in patients with category IIb ischemia without limb loss during the follow-up period. These results provide extended indications of endovascular intervention as initial management for ALI. AT was successful in the removal of thromboembolism in one case of category IIb ischemia without CDT. In four cases, CDT was performed for remnant thromboembolism after AT with a duration of < 24 h. AT or AT combined with CDT enabled flow restoration within 24 h in the majority of technically successful cases (5/6) with class IIb ischemia. The guidelines do not recommend delaying the restoration of arterial flow (> 24 h) in patients with an immediately threatened limb (class IIb), because 24 h is too prolonged a duration to reestablish flow. However, the combination of AT and thrombolysis resulted in a shorter mean duration of infusion, and showed a high technical success rate in patients with category IIb ischemia in this study.

AT removes the thrombotic occlusion rapidly and reliably with expedited restoration of flow, which limits the duration of symptomatic ischemia. Thrombolysis combined with AT is usually used due to the shorter infusion duration and lower total thrombolytic dose. Indeed, thrombolysis required a mean of > 24 h to achieve flow in both the STILE and TOPAS trials (3, 4). The duration of infusion was < 24 h in the majority of patients (26/31) treated with thrombolysis in this study. A longer duration of infusion is associated with an increase in the complication rate (11), hence a short duration infusion (< 24 h) likely contributed to the lack of major complications related to thrombolysis, such as intracranial hemorrhage, in our study.

We administered urokinase for thrombolysis, as compared to recombinant tissue plasminogen activator in other studies. In the past, urokinase was the most widely used thrombolytic agent, but recombinant tissue plasminogen activators gained market dominance when urokinase was removed from the market by the Food and Drug Administration. Although urokinase has no fibrin specificity, it shows a similar thrombolysis rate and lower rate of intracranial bleeding and is more cost efficient than recombinant tissue plasminogen activators (12). Overall, the rate of major bleeding as a complication of CDT with use of a recombinant tissue plasminogen activator in patients with arterial occlusive disease is 5–16% with a 1–2% incidence of intracranial hemorrhage (13). However, no major or intracranial hemorrhage was observed with use of urokinase in our study.

For underlying atherosclerotic stenosis accompanied by a thromboembolism, balloon angioplasty was additionally performed in 25 limbs (64.1%) with/without additional stent insertion after thrombolysis. The Korean guideline for interventional recanalization of lower extremity artery does not recommend initial stent insertion for the short segmental lesions in the superficial femoral to popliteal artery, and any lesions in the infrapopliteal artery. Stent insertion is only performed for a > 30% residual stenosis after a balloon angioplasty (14).

Our study had several limitations. First, this was not a randomized comparative study, but a retrospective review of medical records. The two groups had different numbers of patients, baseline characteristics, and limb ischemia severities. Therefore, selection bias could have been introduced. Second, patients were categorized using the Rutherford classification based only on the recorded symptoms and signs, so the data could be incorrect in some patients. Last, the number of patients was small, particularly in the surgery group; hence, there was no statistical significance in the clinical outcomes. Nevertheless, the study results of higher technical success and limb salvage rates suggest that endovascular intervention is potentially a preferred treatment for patients with ALI. A larger cohort study is required to confirm these findings.

In conclusion, endovascular intervention is a safe and effective treatment option that can reduce and delay the need for amputation in patients with ALI, including those with marginally and immediately threatened limbs (Rutherford classes IIa and IIb).

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급성 사지 허혈증의 초기 치료로서 혈관 내 중재적 시술의 임상 결과: 수술적 치료법과의 비교

문성모[1] · 김인화[1] · 전경식[1]* · 최선영[2] · 김만득[3] · 이 건[4]

목적: 급성 사지 허혈증의 치료법으로서 인터벤션의 치료 결과를 평가하고, 이를 수술적 방법과 비교하였다.

대상과 방법: 2004년 4월부터 2015년 3월까지 인터벤션 혹은 수술로 치료받은 총 51명의 급성 사지 허혈증 환자들을 대상으로 후향적 연구를 진행하였다. 환자들을 Rutherford 분류에 따라 구분한 후 임상 기록, 시술 및 수술 기록을 분석하였으며, 각각의 그룹에서 치료 성과를 비교하였다.

결과: 총 35명 환자의 39개의 사지에 대해 인터벤션이 시행되었으며, 총 16명 환자의 16개의 사지에 대해 수술이 시행되었다. 기술적 성공률은 인터벤션 및 수술을 받은 환자군에서 각각 82.1% 및 75%였으며, 시술 및 수술과 관련된 사망 혹은 주요 합병증은 경과 관찰 기간 중 없었다. 하지만, 수술을 받은 환자 중 한 명에게서 구획증후군이 보고되었다. 평균 경과 관찰 기간은 인터벤션 및 수술을 받은 환자군에서 각각 23.4개월 및 16.6개월이었다. 인터벤션 및 수술을 받은 환자군에서 1년 일차개방성은 각각 89.4% 및 100%였으며, 1년 사지생존율은 각각 97.2% 및 87.1%였다. 인터벤션을 받은 환자 중 기술적 실패가 보고된 7명 중에서, 즉각적인 수술적 치료가 필요했던 6명이 보고되었으며 이 중 3명에게서 사지 절단이 시행되었다.

결론: 인터벤션은 급성 사지 허혈증의 초기 치료법으로서 안전하고 효과적이며, 급성 사지 허혈증 환자에 있어 사지 절단율을 감소시킬 수 있다.

차의과학대학교 분당차병원 [1]영상의학과, [4]흉부외과, [2]이화여자대학교 목동병원 영상의학과,
[3]연세대학교 의과대학 세브란스병원 영상의학과