

# Is Surgical Thrombo-Embolectomy in Acute Limb Ischemia Still Advantageous in Patients More Than 65 Years of Age?

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## ABSTRACT

**Objective:** In this study, we investigated the benefits of using Fogarty balloon catheterization in the treatment of acute leg ischemia with respect to amputation, fasciotomy, and mortality in older patients.

**Methods:** A total of 102 patients age >65 who had a Fogarty thrombo-embolectomy for acute thromboembolic limb ischemia were investigated retrospectively. Patients were evaluated based on Rutherford IIa and IIb criteria and duration of ischemia. Duration of ischemia was divided into 3 categories (as 0 to 4, 4 to 8, and >8 hours) to evaluate the effect of ischemia period on vital parameters and mortality. Analysis with Cox regression showed that 30-day mortality was associated with older age and number of comorbidities such as amputation and fasciotomy.

**Results:** In 102 patients >65 years of age who underwent embolectomy, rates were 7.2% fasciotomy (n = 7) and 13.7% amputation (n = 14), and 10 patients died (9.8%). According to multiple regression analysis, the surgical risk increases 1074 times when each year is added to the chronological age of over 65 years.

**Conclusion:** In a majority of cases, limb salvage can be obtained via simple embolectomy rather than risking intravenous iodinated contrast. Although alternatives in older patients are limited, the Fogarty catheter should be regarded as a first-line treatment because of its ease of use and low complication rate.

## INTRODUCTION

Thrombolysis therapy is advocated as the gold standard initial option in the treatment of acute leg ischemia and peripheral thrombosis, but it may not always be applicable in older patients owing to adverse events or poor outcomes [Theodoridis 2018]. Surgical embolectomy is a well-known invasive procedure, but eligibility criteria are not clearly defined for older patients [Liao 2020]. Fogarty catheter

embolectomy has revolutionized the treatment of peripheral arterial embolism, as it can be life saving for the patient and prevents amputation [de Donato 2018; Hess 2019].

The incidence of acute limb ischemia is ~1.5 cases per 10,000 patient years. The prevalence is <0.1% in the general population and ~5% to 10% in patients with other risk factors such as cardiovascular disease, diabetes, and previous circulatory events. Aging of the population increases the prevalence of acute limb ischemia [Fluck 2020]. The underlying pathology is mainly identified as arterial embolism and atherosclerotic arterial thrombosis. The risk of amputation is reported as 15% to 30%, whereas perioperative morbidity and mortality are 20% to 30%. Accompanying comorbidities, metabolic instability, reperfusion injury, and revascularization are indicators of poor prognosis, and a majority of older patients have multiple comorbidities. Therefore, all patients should be monitored for fluid electrolyte balance, complete blood count, coagulation parameters, and renal, cardiac, and respiratory health [Fluck 2020; Stabilini 2009].

There is no standard approach for the treatment of acute leg ischemia (ALI); surgical thrombectomy, catheter techniques, and thrombolytic regimens are still in discussion. The European Society of Cardiology (ESC) 2017 Guidelines does not clearly emphasize the principles of treating acute limb ischemia in older patients, but in 2020, the European Society for Vascular Surgery (ESVS) Clinical Practice Guidelines on the Management of Acute Limb Ischaemia detailed approach protocols with levels of evidence B or C. According to the ESVS practice guidelines, a general recommendation for initial treatment of ALI cannot be made for open surgery or thrombolysis, based on the current scientific data. Up to 1 year, there was no significant difference in limb survival or mortality between treatments. Fewer episodes of hemorrhagic stroke, severe bleeding, and distant embolization occurred in the thrombolysis group. Similar findings were published in a recent comprehensive study, with no evidence in favor of either thrombolysis or surgery. Catheter-directed thrombolysis in combination with thrombectomy may be advised for patients with Rutherford grade IIb acute limb ischemia. Long-term anticoagulation is recommended after thrombectomy (class IIb, level B) [Aboyans 2018; Björck 2020].

We believe that surgical thrombectomy is still first-line treatment for ALI in older patients. In this retrospective study, we aimed to emphasize the advantages of surgical embolectomy in terms of fasciotomy, amputation, and mortality by presenting our case series with a review of the current literature.

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Table 1. Baseline demographics

Factor	Value
Age	
Mean ± SD	73.72 ± 7.49
Median (minimum, maximum)	79.50 (65.00, 94.00)
Sex	
Male	52 (51.0)
Female	50 (49.0)
Smoking	
No	57 (55.9)
Yes	45 (44.1)
Additional operation	
No	68 (66.7)
Yes	34 (33.3)
Diabetes	
No	85 (83.3)
Yes	17 (16.7)
AF	
No	71 (69.6)
Yes	31 (30.4)
Coronary artery disease	
No	79 (77.5)
Yes	23 (22.5)
Diagnostic Tool	
Doppler	71 (69.6)
Doppler + CT angiography	31 (30.4)
ECG	
AF	33 (32.4)
No significant result	69 (67.6)

Data are n (%) unless noted otherwise.

## METHODS

This retrospective study was reviewed and approved by the ethics committee, and informed consent was obtained from all enrolled patients. Individuals who were eligible for general or local anesthesia were included in the study without any age, sex, or comorbid disease discrimination.

We retrospectively gathered data of 164 patients from the records of emergency unit, surgery operations, outpatient, and clinic records for January 2018 to January 2020 in the emergency unit of a tertiary vascular center that has vascular teams on call 24 hours a day. After applying exclusion criteria, 102 patients categorized as viable with neurological deficit (Rutherford IIa and IIb) were included in the study. Patients who were accepted for endovascular procedures, chronic occlusions, and bypass surgery; patients on medication were

Table 2. Baseline operational parameters

Parameter	Value
Involvement	
Lower extremity level	85 (83.3)
Upper extremity level	17 (16.7)
Infection	
No	69 (69.7)
Yes	30 (30.3)
Fasciotomy	
No	90 (92.8)
Yes	7 (7.2)
Amputation	
No	88 (86.3)
Yes	14 (13.7)
Mortality	
Alive	92 (90.2)
Died	10 (9.8)
Admission to hospital (h after event)	
≤4	17 (17.9)
4 to 8	51 (50.0)
>8	34 (33.3)
Pain	
No	20 (19.6)
Yes	82 (80.4)
Numbness	
No	84 (82.4)
Yes	18 (17.6)
Admission Time	
Duty	29 (28.4)
After duty	73 (71.6)

Data are n (%) unless noted otherwise.

excluded from the analysis. Transfers between hospitals were not included.

All cases of lower and upper embolectomy were included without further selection. Duration of ischemia was divided into 3 categories, 0 to 4, 4 to 8, and >8 hours, to evaluate the effect of ischemia period on vital parameters and mortality. Perioperative mortality was also investigated. The relationship of mortality and age, fasciotomy, amputation, ischemia duration, and surgery success was studied via survival analysis.

### Surgical Approach

Embolectomy was conducted via 3F to 6F Fogarty balloon catheters. Systemic intravenous heparin (60 to 70 U/kg) was given to all patients before cross-clamping. With the patient in supine

Table 3. Qualitative variable analysis according to surgery success outcome

Variable	Surgery Successful		Surgery Unsuccessful		P
	n	%	n	%	
Sex					.316a*
Male	36	69.2	16	30.8	
Female	39	78.0	11	22.0	
Smoking					.345*
No	44	77.2	13	22.8	
Yes	31	68.9	14	31.1	
Level					.005†
Lower	58	68.2	27	31.8	
Upper	17	100.0	0	0.0	
Diabetes					.768†
No	63	74.1	22	25.9	
Yes	12	70.6	5	29.4	
AF					.556*
No	51	71.8	20	28.2	
Yes	24	77.4	7	22.6	
CAD					.118*
No	61	77.2	18	22.8	
Yes	14	60.9	9	39.1	
Admission to hospital (h after event)					<.001*
≤4	17	100.0	0	0.0	
4 to 8	42	82.4	9	17.6	
>8	16	47.1	18	52.9	
Pain					.690*
No	14	70.0	6	30.0	
Yes	61	74.4	21	25.6	
Numbness					.774*
No	61	72.6	23	27.4	
Yes	14	77.8	4	22.2	
Diagnostic Tool					<.001*
Doppler	67	94.4	4	5.6	
Doppler + CT angiography	8	25.8	23	74.2	
ECG					.277*
AF	22	66.7	11	33.3	
No significant result	53	76.8	16	23.2	
Admission time					.872*
Duty	21	72.4	8	27.6	
After duty	54	74.0	10	26.0	

\* $\chi^2$  test, †Fisher exact test.

position and under local anesthesia with bupivacaine hydrochloric (Marcaine) 5% plus prilocaine hydrochloric (Priloc) 2%, a femoral

incision was made on the artery trace as an anesthesiologist observed the course of the case. Single femoral incision was adequate for

Table 4. Single-variant logistics regression analysis on surgery outcomes

Variable (Reference)	Value	P	Odds Ratio*	95% Confidence Interval	
				Lower Bound	Upper Bound
Age		.026	1.069	1.008	1.134
Gender (female)	Male	.317	1.576	0.646	3.842
Smoking (no)	Yes	.347	1.529	0.632	3.699
CX (no)	Yes	.696	1.420	0.245	8.233
Level (upper)	Lower	.057	7.448	0.939	59.100
Diabetes (no)	Yes	.764	1.193	0.378	3.771
AF (no)	Yes	.557	1.345	0.501	3.611
CAD (no)	Yes	.123	2.179	0.811	5.856
Hospital admission after event ( $\leq 4$ h)	4 to 8 h	.260	3.429	0.401	29.279
	>8 h	.008	18.000	2.140	151.402
Pain (yes)	No	.690	1.245	0.424	3.656
Numbness (yes)	No	.653	1.320	0.393	4.427
Admission Time (duty)	After	.872	1.083	0.411	2.850

\* $\beta$  coefficient.

unilateral iliac and femoral artery clots, but clots extending past the aortic bifurcation, which has a risk of clot dislodgement, was prevented by manual compression of the contralateral common femoral artery. Surgical embolectomy was introduced without wire-guided balloons, and fluoroscopic guidance was not used.

#### Patient Selection for Surgery

Surgical embolectomy was conducted on patients when applied within 8 hours of event, according to Rutherford classification IIa and IIb.

#### Data Collection

Data on age, sex, history of hypertension, diabetes, coronary artery disease (CAD), atrial fibrillation (AF), peripheral vascular disease, smoking, antiaggregant or anticoagulant medication, and duration of ischemia were obtained from the hospital registry. Doppler ultrasound and computed tomography (CT) angiographs during admission were also compiled for the study. Cases of death, amputation, fasciotomy, and secondary invasive procedures such as endarterectomy, bypass surgery, and patchplasty were classified as secondary outcome analysis and were evaluated via Cox regression graph.

#### Follow-Up

The enrolled patients were followed up for a month, and duration of hospital stay, operations, complications, discharge, and death information were obtained from clinical records. Low molecular weight heparin or standard heparin was administered to all patients in the postoperative period for 2 days. Selection of treatment modalities for ALI was made according to the patient's clinical status. Individuals who did not sufficiently benefit from surgery were given iloprost in

the postoperative period. Routine anticoagulants and antiplatelet and lipid-lowering agents were given to all patients after the procedure. Optimal international normalized ratio (INR) levels were obtained in atrial fibrillation patients using coumadin. The data after discharge period were collected from outpatient records. Death cases within 1 month after discharge were obtained from relatives via phone inquiry.

#### Statistical Analysis

We used SPSS software version 11.5 for Windows (SPSS, Chicago, IL). Quantitative variables were described with the use of mean  $\pm$  standard deviation (SD) and median (minimum, maximum), and qualitative variables were identified with n (%). Qualitative variables were compared using  $\chi^2$  and Fisher exact tests. Multivariate logistics regression analysis was used to detect surgery success. Cox regression analysis was conducted to investigate the relationship between mortality and study parameters via survival graphs. Statistical significance was predicted as  $P < .05$ .

## RESULTS

The baseline demographics of the 102 individuals >65 years of age who were admitted to the emergency unit with a diagnosis of ALI are presented in Table 1, including risk factors of smoking, diabetes, comorbid diseases, and infection.

Single-sided femoral embolectomy was performed in 102 patients (73.5%), fasciotomy in 7 (7.2%), and amputation in 14 (13.7%). After fasciotomy, renal failure developed in 2 patients and 2 patients died from myocardial infarction. In all, 10 patients died, 9.8% of the study population, 6 after amputation and fasciotomy.

Table 5. Multivariate logistics regression analysis on surgery outcomes

Variable (reference)	Value	P	Odds Ratio*	95% Confidence Interval	
				Lower Bound	Upper Bound
Constant	0.002				
Age	(per y)	.039	1.074	1.004	1.150
Admission Time ( $\leq 4$ hours)	4 to 8 h	.315	3.089	0.343	27.843
	>8 h	.012	16.590	1.875	146.818

\* $\beta$  coefficient.

Numbness and pain were the most prominent symptoms during initial admission. Regarding localization of embolism, a majority of the patients presented with lower extremity embolisms (83.3%) versus upper extremities (16.7%). Age was a statistically significant variable determining the success of surgery procedure ( $P = .022$ ): the mean patient age in successful operations was  $72.71 \pm 7.46$  years, and in unsuccessful cases,  $76.56 \pm 7.11$  years (Table 2).

The success of surgery in relation to baseline demographics of the study population is shown in Table 3. Single-variant logistics regression analysis showed that age, admission time to hospital <8 hours after event, and medication were significant parameters and thus were included in the multivariate regression model (Table 4).

The multivariate logistics regression analysis results show that 1 year of age increases the risk of surgery failure 1074 times. Patients who did not take any medication had 3.385 times the surgical failure risk of those who did. Hospital admission period played a major role in the procedural outcome: patients who received therapy within >8 hours of the event had 16.590 times the failure risk of individuals who received therapy within  $\leq 4$  hours. Subjects who received therapy within 4 to 8 hours had a failure risk of 3.089, but the value was not statistically significant. From these data, one could conclude that  $\leq 4$  hours versus 4 to 8 hours between event and admission time does not provide additional benefit (Table 5).

Cox regression analysis was conducted to detect correlation with age, amputation, fasciotomy, and surgery success. The patients were divided according to age (>80 and 65 to 80 years). Those >80 years old had a hazard ratio of 20.9, which is relatively high. The hazard ratio for amputation was 15.6, 6.5 for fasciotomy, and 12.3 for unsuccessful surgical procedures (Figure).

According to this retrospective analysis of 102 patients, we predict that early embolectomy results in fewer cases of fasciotomy, amputation, and death. Age is an independent determinant of prognosis.

## DISCUSSION

Acute ischemia of the extremities is an urgent situation for vascular surgeons. The blood flow of the involved region instantly decreases and needs urgent

intervention, as it may destroy the healthy physiology of the limb [Theodoridis 2018]. The rapid onset of the pathology not only causes accumulation of toxic materials, but it also reduces oxygen delivery to vital parts including skin, muscle, and nerves. The response of the human body to hypoxemia results in compensation of occlusion via collateral blood vessel formation. As this scenario can take place only in the long term, urgent diagnosis and clinical evaluation play a critical role in the prognosis [Liao 2020]. It is a life-threatening serious condition, risking the patient's mortality owing to systemic acid-base, electrolyte, and other abnormalities. Acute lower limb ischemia is elaborated as a sudden decrease in limb blood flow deteriorating limb viability in patients who present within 2 weeks of the acute event [de Donato 2018]. Diagnostic errors have severe consequences resulting in amputation or mortality. Acute limb ischemia usually presents with multiple comorbidities [Hess 2019].

Acute limb ischemia is a vascular emergency, and immediate intervention is crucial to save the limb and prevent a major amputation. Impaired perfusion can lead to irreversible ischemic damage, and delay in treatment can result in amputation and mortality [Fabiani 2018]. The treatment options for ALI include surgical thrombectomy, catheter-directed thrombolysis (CDT), pharmacomechanical thrombolysis, and catheter-directed thrombus aspiration. The choice of treatment varies according to the ischemic degree of the limb. Mild to moderate ischemia due to thrombosis or embolism can be eliminated via CDT. CDT is also a vital solution for those who cannot tolerate general anesthesia, for patients who have previously undergone multiple surgical or endovascular interventions, and for those with multiple comorbidities and moderate limb ischemia. Severe cases require immediate surgical revascularization [Ascher 2021]. Treatment modalities other than surgical thrombectomy are not included in this comparison, since surgery is the primary approach in our department.

Surgical embolectomy is an effective therapy for patients with lower limb arterial thromboembolic events, especially in cases affecting a single major artery. The surgical success rate may be restricted by unresolved thrombus, thrombi spread, chronic atherosclerotic disease, and vessel trauma subsequent to balloon catheter movement. Regarding the contraindications of thrombolytic treatment in older patients, such as previous intracranial bleeding, ischemic stroke, intracranial neoplasm, arteriovenous malformations, <3-month-old head

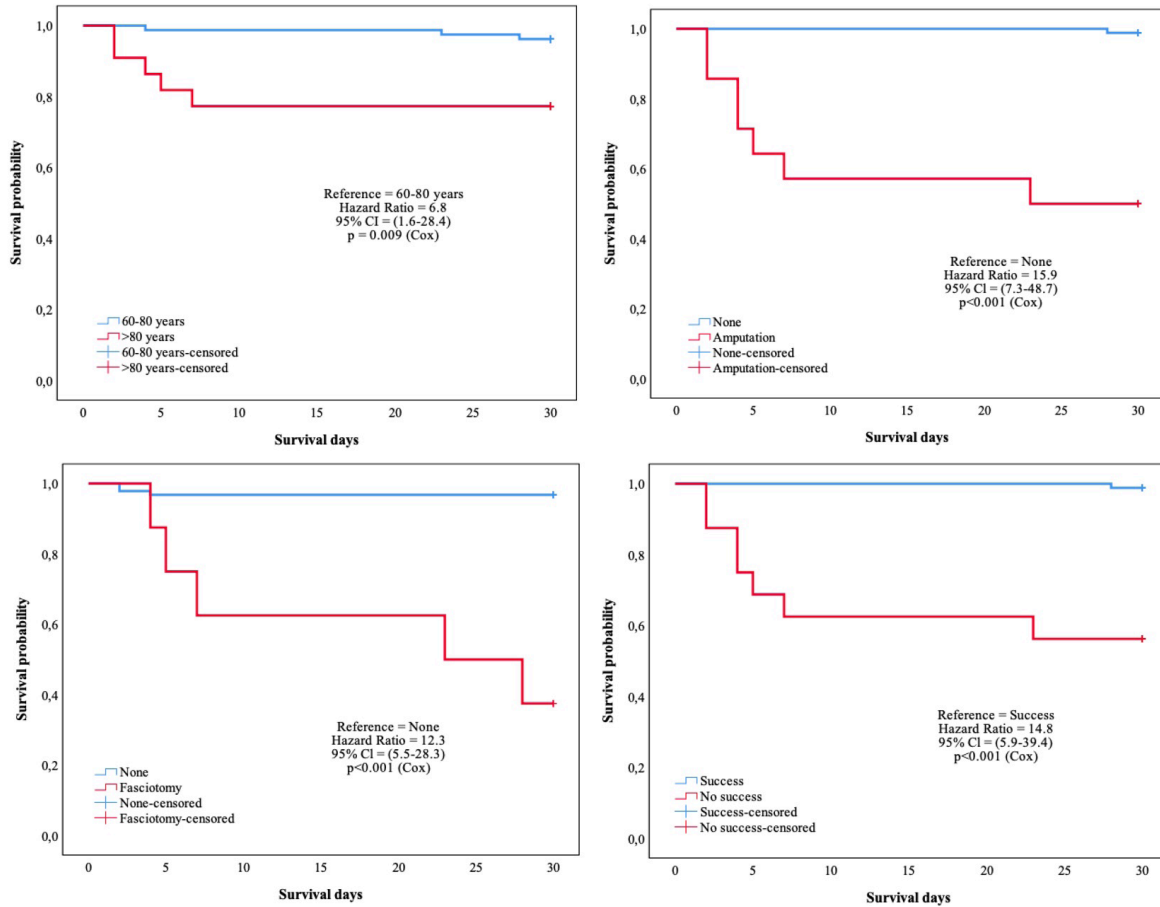


Figure 1. Cox regression analysis (correlation with age, amputation, and fasciotomy).

trauma, and coagulopathies, surgical embolectomy should be considered because of its efficacy and simplicity.

Although there was no statistical significance between the two groups, we assume that more newly formed thrombi are easier to treat, contributing to surgery success. Conversely, the presence of atherosclerosis negatively affects surgery success. As atherosclerotic pathology is prone to increase by age, surgery success should be communicated comprehensively, and thrombolytic treatment must be considered individually. The presence of AF, especially in older patients, enhances the importance of urgent intervention.

The degree of ischemic involvement is always higher in the lower extremities because of poor collateral circulation. Wolosker et al [1996] investigated the effect of surgery on embolism but did not consider the duration of ischemia. Limb amputation occurred in 16.4% of the surviving patients (versus 13.7% in our study). Wolosker et al claimed that they had promising results of embolectomy with the use of Fogarty catheter, especially in patients without necrosis. Pember-ton et al [1999] conducted a similar study in 174 patients who underwent surgery for acute native vessel limb ischemia (76%

lower limb, 24% upper limb). Fogarty catheter was used in the treatment of thrombectomy or embolectomy in 153 (89%) patients, and 37 (24%) of them immediately underwent a further procedure: 28 (18%) had on-table thrombolysis, and 14 (9%) underwent vascular reconstruction. In that study, 26 patients (15%) underwent further limb salvage surgery within 30 days. According to those results, Pember-ton et al prefer to conduct aggressive surgical intervention to achieve high limb salvage rates. However, it should be noted that in their research, the average duration of ischemia was 14 hours [Pember-ton 1999].

AF is a major risk for embolism. According to the electrocardiography (ECG) records of the enrolled population, it was detected in 31 patients in this study. The rate of surgery success was 77.4% in patients with AF and 71.8% in individuals without AF. The rate of AF was considerably high in our study (62% to 66%) compared with previous studies. Kubat et al [2020] recently showed an AF rate of 61.5% in patients 70.2 ± 17.9 years old (range 20 to 94). They also stated that urgent surgical thrombo-embolectomy should be conducted in subjects both older and younger than 80 years [Pember-ton



1999; Kubat 2020].

Older patients usually have various comorbidities and are more fragile to invasive procedures such as traditional open thrombectomy, catheter-directed thrombolysis, bypass, and anesthesia. It was previously reported that CDT achieves the same outcomes as open surgery in terms of limb salvage rate, with a faster recovery period [Obara 2018; Koraen-Smith 2018]. In patients with diabetes mellitus, chronic renal failure, and similar concomitant diseases, the clinician should consider all the aspects of endovascular surgery. The presence of atherosclerosis may jeopardize surgery success, as it may cause plaque rupture and complications from administration of contrast matter. A delicate embolectomy should be considered with a comprehensive strategic approach. In a recent retrospective analysis, Liang et al [2019] found a 30-day mortality rate of 3.6%, and limb salvage rates at 1 and 2 years were 83.8% and 74.7%, respectively. The 30-day mortality rate in our study was 9.8%, but it is not possible to compare the 2 studies as the admission period to hospital, which was found to be a significant predictor of surgery success in our article, was not stated in Liang et al's article.

Mutirangura et al [2008] investigated the impact of time in 91 patients with arterial embolism of the lower extremities. They defined early ischemia as <24 hours and late ischemia as >24 hours. The successful revascularization rate after the initial surgical embolectomy was significantly higher in patients with early acute embolism (92.6% versus 43.9%,  $P < .001$ ). Patients with late acute embolism had a higher rate of undergoing major amputation after revascularization (24.4% versus 7.4%,  $P = .106$ ). Successful outcomes were more common in patients with early acute embolism (83.9% versus 58.3%,  $P = .014$ ) [Koraen-Smith 2018]. These findings in 91 arterial embolism patients paralleled our clinical experience and the basis of our current analysis.

Hospital admission time is also another important parameter for survival. The success of surgery is rather low in patients who were admitted to the hospital more than 8 hours after the event, and mortality was quite high. Regarding these data, one can claim that the hospital admission period is a definite predictor of treatment success and mortality [Olinic 2019].

The ESVS 2020 Clinical Practice Guidelines on the Management of Acute Limb Ischaemia should be used in the evaluation of acute lower limb ischemia. According to this, the most recent version, a vascular surgeon/specialist should carry out all the clinical assessment (although not all institutions have this specialty). This practice guideline recommends the use of wire-guided embolectomy catheters under fluoroscopic conditions as class IIa, evidence level C.

### Limitations of the Study

The main limitation of this study is the relatively short follow-up period (1 month). An additional limitation is the lack of comparison for endovascular and thrombolytic treatment outcomes. Potential strengths of the surgery are cost-effectiveness and ease of use of the Fogarty catheter in the treatment of peripheral embolism, as high-tech equipment cannot be available in every institution.

### Conclusions

According to this retrospective analysis of 102 patients, hospital admission period is crucial in the prognosis of the older patients and strongly correlates with increased fasciotomy, amputation, and mortality. Age is an independent determinant of prognosis. The first-choice Fogarty catheter, with its ease of use and lower complication rate, should be regarded in the treatment of acute ischemia in the extremities, especially in older patients, in whom intravenous iodinated contrast is dangerous.

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