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# Determinants of amputation and mortality following thromboembolectomy in native acute lower limb arterial occlusions, the influence of early intervention: A retrospective cohort study

## Akut alt ekstremite nativ arteriyel tıkanıklarında tromboembolektomi sonrası amputasyon ve mortalitenin belirleyicileri; erken müdahalenin etkisi: Retrospektif kohort çalışma

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**Abstract**

Aim: In acute arterial occlusion, there is a sudden blockage of blood flow to the extremity, threatening its viability. Early/emergency intervention is required to eliminate the risk of amputation, but some of these cases receive a delayed diagnosis. The aim of this study is to evaluate the influence of surgical timing on the incidence of amputation and other factors affecting the risk of extremity loss.

Methods: A total of 154 patients who underwent thromboembolectomy were analyzed. The patients were categorized into three groups, as follows: Group 1 included patients with symptoms present for less than 12 hours, Group 2 comprised those with symptoms present for more than 12 hours but less than one week, and Group 3 included patients with symptoms present for more than one week. The groups were evaluated in terms of amputation and mortality.

Results: The incidence of amputation was significantly lower in Group 1 compared to the other two groups ($P<0.05$), and similar between Groups 2 and 3. In-hospital mortality did not significantly differ between the groups. When categorical and continuous variables were evaluated, a significant relationship was found between the risk of amputation and increasing age, female gender, diabetes, and iliac occlusion ($P<0.05$). The risk of in-hospital mortality was higher in females and in cases with cardiac arrhythmia ($P<0.05$).

Conclusion: Early surgical embolectomy is more successful in limb salvage. The risk of amputation is increased in diabetics, females, the elderly, and in proximal arterial occlusion.

**Keywords:** Amputation, Balloon embolectomy, Acute arterial occlusion

**Öz**

Amaç: Akut arter tıkanıklığı, ekstremite canlılığını tehdit eden ani bir ekstremite kan akımının tıkanması durumudur. Akut arter tıkanıklığında, ampütasyon riskini ortadan kaldırmak için erken / acil müdahale gerekir, ancak bu vakalardan bazılarında tanı gecikmiştir. Bu çalışmanın amacı, cerrahi zamanlamanın amputasyon insidansına etkisini ve ekstremite kaybı riskini etkileyen diğer faktörleri değerlendirmektir.

Yöntemler: Tromboembolektomi uygulanan 154 hasta incelendi. Hastalar üç gruba ayrıldı: Grup 1: semptomlar 12 saatten daha kısa süreli, Grup 2: semptomlar 12 saatten fazla ancak bir haftadan kısa süreli, Grup 3: semptomlar bir haftadan daha uzun süreli. Gruplar ve kohort ampütasyon ve mortaliteye göre değerlendirildi.

Bulgular: Grup 1'de amputasyon insidansı diğer iki gruba göre anlamlı olarak daha düşüktü ($P<0.05$). Ancak; Grup 2 ve Grup 3 arasında amputasyon insidansı farklı bulunmadı. Hastane içi mortalite insidansları da gruplar arasında istatistiksel olarak farklı değildi. Kategorik ve sürekli değişkenler değerlendirildiğinde, ampütasyon riski ile artan yaş, kadın cinsiyet, diyabet ve iliak oklüzyon arasında anlamlı ilişki bulundu ($P<0,05$). Kadınlarda ve kardiyak aritmi bulunan olgularda hastane içi mortalite riski daha yüksek bulundu ($P<0,05$).

Sonuç: Erken cerrahi embolektomi, uzuv kurtarmada daha başarılıdır. Diyabetiklerde, kadınlarda, yaşlılarda ve proksimal arter tıkanıklığında amputasyon riski artmaktadır.

**Anahtar kelimeler:** Amputasyon, Balon embolektomi, Akut arter tıkanıklığı

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## Introduction

Acute arterial occlusion (AAO), one of the most serious conditions threatening the limb and the life of the patient, occurs due to a sudden decrease in blood supply to the extremity [1]. The diagnosis and evaluation of AAO, a major emergency vascular pathology faced by vascular surgeons, is based on clinical examination, and errors in diagnosis can lead to the loss of the limb or even the death of the patient. Amputation and mortality rates are 8-15%, 15-40%, respectively, despite early diagnosis and treatment [2]. Acute occlusion can occur with some pathologies in which blood flow is completely ceased. In most of these cases, embolism and thrombus constitute the etiology; however, peripheral vascular dissection, thrombophilic conditions, graft thrombosis, and trauma may also lead to this pathology. Clinically, it manifests by pain, pallor, pulselessness, poikilothermia, paresthesia and paralysis ('6 Ps' finding) [3]. In early stages, the extremity is cold and pale due to the rapid decrease of blood flow. If arterial flow cannot be achieved, neuromuscular ischemia-mediated paresthesia and paralysis develop. Early diagnosis and treatment are critical after ischemia for preserving the viability of the extremity [4]. Although there are newer endovascular techniques such as pharmacologic thrombolysis, percutaneous aspiration thrombectomy (PAT), and percutaneous mechanical thrombectomy (PMT) for the reconstruction of the arterial flow, catheter embolectomy is still a good option, especially in proximal lesions [5]. Today, it is still used by many vascular surgeons as a prompt treatment option. The critical period for surgical correction is twelve hours after the onset of ischemia. However, complaints up to 14 days from the onset of symptoms are considered acute [4,6].

It is unclear whether thromboembolectomy operations performed in delayed cases in acute arterial occlusion are effective in preventing limb loss. In this study, we evaluated the effect of surgical timing on amputation risk with regards to the onset of symptoms in patients who underwent thromboembolectomy.

## Materials and methods

### Patients, procedure, and study design

This retrospective clinical study design and protocol were approved by Aydın Adnan Menderes University Faculty of Medicine Non-Interventional Clinical Research Ethics Committee (approval number: 53043469-050.04.04 / 05.07.2018) and performed in Aydın Adnan Menderes University Faculty of Medicine, Cardiovascular Surgery, Turkey. All procedures in this study were carried out in accordance with the Helsinki Declaration. Patients who underwent surgical thromboembolectomy for symptomatic arterial occlusion between January 2010 and December 2018 were reviewed. Patients' demographic and clinical characteristics, diagnosis and treatment methods were collected retrospectively from hospital records. The diagnosis of acute arterial occlusion was based on physical examination and arterial imaging (Doppler ultrasonography, computed tomography, or magnetic resonance) at the time of admission. Patients with trauma, previous bypass graft or stent thrombosis, those treated with endovascular techniques, those who had symptoms for more than 14 days and underwent further revascularization after thromboembolectomy were excluded from the study. Clinical evaluation of the selected patients was made according to the Rutherford classification and class 3 patients who were not eligible for revascularization were also excluded from the study (Table 1) [7].

Table 1: The Rutherford classification of acute limb ischemia

| Category | Description | Capillary return | Muscle paralysis | Sensory loss | Doppler signals | |
|---|---|---|---|---|---|---|
| | | | | | Arterial | Venous |
| 1. Viable | Not immediately threatened | Intact | None | None | Audible | Audible |
| 2a. Threatened | Salvageable if promptly treated | Intact/slow | None | Partial | Inaudible | Audible |
| 2b. Threatened | Salvageable if immediately treated | Slow/absent | Partial | Partial / complete | Inaudible | Audible |
| 3. Irreversible | Primary amputation | Absent staining | Complete tense compartment | | Inaudible | Inaudible |

A total of 154 patients were included in the study and categorized into three groups according to the time from the onset symptoms until surgery as follows: Group 1 included patients who had symptoms for less than 12 hours, Group 2 comprised those with symptoms present for more than 12 hours but less than one week, and in Group 3 were patients whose symptoms were present for more than one week. Preoperative data such as age, gender, presence of hypertension, diabetes mellitus, dyslipidemia, coronary artery disease, peripheral artery disease, atrial fibrillation, and malignancy, along with smoking habits, were evaluated. Whether it was a proximal (iliac artery or superficial femoral artery) or a distal embolism (popliteal artery or trifurcation arteries) was noted. The primary endpoints of the study were the amputation of the limb or mortality within 30 days of embolectomy. Postoperative revision and neurological complications were considered secondary endpoints.

### Surgical procedure

After the diagnosis of acute limb ischemia, patients were transferred to the operating room, and the operation began under local anesthesia. The main femoral artery and its branches were reached through an oblique incision made in the inguinal region. The arterial tree of the patients was carefully examined, and a transverse arteriotomy was performed from the non-calcified location of the main femoral artery. The procedure continued until the thromboembolic material was removed using Fogarty catheters of various lengths. Arteriotomy was closed using 5/0-7/0 polypropylene suture material in accordance with vessel diameter and quality. All patients were anticoagulated with heparin during the operation and afterwards and followed up with activated coagulation time (180-300). Amputations were noted regardless of whether they were major or minor and performed by the orthopedist.

### Statistical analysis

Statistical analysis was performed using SPSS 18.0 (SPSS Inc. Chicago, IL, USA) package program. The normality of distribution was evaluated with Shapiro Wilk and Levene's Tests. Continuous variables were presented as mean and standard deviation and evaluated by t-test in independent groups. Categorical variables were evaluated with Fisher's Exact Test and Chi-Square test. Post hoc chi-square analysis was performed to determine from which groups the difference originated. In case the conditions were not met, "Bonferroni correction" was applied. A *P*-value of $<0.05$ was considered significant.

## Results

The demographic characteristics of the groups are shown as percentages. A total of 154 patients, 97 men, and 57 women were included in the study (Table 2). The patients who underwent amputation and those who did not were significantly different in terms of age, gender, diabetes, symptoms, and level of obstruction ($P$<0.05) (Table 3).

Table 2: Demographic variables of groups

| | Group 1 (n: 64, %41.6) | Group 2 (n: 52, %33.8) | Group 3 (n: 38, %24.7) |
|---|---|---|---|
| Age, mean (SD) | 67.1 (13.9) | 72.4 (11.2) | 79.6 (8.7) |
| Gender (Male, %) | 44/68.8 | 28/53.8 | 25/65.8 |
| Hypertension (n, %) | 8/12.5 | 13/25.0 | 6/15.8 |
| DMT2 (n, %) | 16/25.0 | 16/30.8 | 5/13.2 |
| Dyslipidemia (n, %) | 10/15.6 | 37/71.1 | 28/73.6 |
| Coronary artery disease (n, %) | 16/25.0 | 15/29.4 | 15/39.5 |
| COPD (n, %) | 9/14.1 | 7/13.5 | 10/16.9 |
| Smoking (n, %) | 34/53.1 | 21/40.4 | 19/50.0 |
| Atrial fibrillation (n, %) | 8/12.5 | 6/11.5 | 10/26.3 |
| Peripheral artery disease (n, %) | 14/21.9 | 10/19.2 | 6/15.8 |
| CKD (n, %) | 5/7.8 | 4/7.7 | 4/10.5 |
| Malignancy (n, %) | 2/3.1 | 8/15.4 | 4/10.5 |

DMT2: Diabetes Mellitus type 2, COPD: Chronic obstructive pulmonary disease, CKD: Chronic kidney disease

Table 3: Evaluation of categorical variables according to the presence of amputation

| | | Non-Amputation n (%)[x] | Amputation n (%)[x] | $P$-value |
|---|---|---|---|---|
| Age, mean (SD) | | 70.69 (12.55) | 72.33 (13.02) | 0.011[μ]** |
| Gender | Female | 41 (33.1) | 16 (53.3) | 0.039† |
| | Male | 83 (66.9) | 14 (46.7) | |
| Diabetes | N | 103 (83.1) | 15 (50.0) | 0.000123†** |
| | Y | 21 (16.9) | 15 (50.0) | |
| Arrhythmia | N | 105 (84.7) | 25 (83.3) | 0.786‡ |
| | Y | 19 (15.3) | 5 (16.7) | |
| CAD | N | 86 (69.4) | 22 (73.3) | 0.669† |
| | Y | 38 (30.6) | 8 (26.7) | |
| Smoking | N | 66 (53.2) | 24 (80.0) | 0.080† |
| | v | 58 (46.8) | 6 (20.0) | |
| COPD | N | 104 (83.9) | 24 (80.0) | 0.612† |
| | Y | 20 (16.1) | 6 (20.0) | |
| CKD | N | 116 (93.5) | 25 (83.3) | 0.134‡ |
| | Y | 8 (6.5) | 5 (16.7) | |
| Symptom | N | 99 (79.8) | 17 (56.7) | 0.008†** |
| | Y | 25 (20.2) | 13 (43.3) | |
| Hematoma | N | 115 (92.7) | 27 (90.0) | 0.703‡ |
| | Y | 9 (7.3) | 3 (10.0) | |
| Revision | N | 116 (93.5) | 28 (93.3) | 1‡ |
| | Y | 8 (6.5) | 2 (6.7) | |
| Hyperlipidemia | N | 96 (77.4) | 26 (86.7) | 0.263† |
| | Y | 28 (22.6) | 4 (13.3) | |
| Malignity | N | 115 (92.7) | 25 (83.3) | 0.150‡ |
| | Y | 9 (7.3) | 5 (16.7) | |
| Death | N | 117 (94.4) | 27 (90.0) | 0.410‡ |
| | Y | 7 (5.6) | 3 (10.0) | |
| Nerve injury | N | 113 (91.1) | 23 (76.7) | 0.051 |
| | Y | 11 (8.9) | 7 (23.3) | |
| Obstruction level | Iliac | 74 (59.7 | 12 (40.0) | 0.002†** |
| | Popliteal | 43 (34.7) | 10 (33.3) | |
| | Infra popliteal | 7 (5.6) | 8 (26.7) | |
| Total | | 124 (100) | 30 (100) | |

CAD: Coronary artery disease, COPD: Chronic obstructive pulmonary disease, CKD: Chronic kidney disease, μ Independent groups T test, x Column percentages are calculated, † Pearson Chi-Square Test, ‡ Fisher Exact Chi-Square Test, ** $P$<0.05

Gender and arrhythmia were significantly different between survivors and non-survivors ($P$<0.05) (Table 4). The three groups were different regarding amputation ($P$=0.05), and a significant difference was found between Groups 1 and 2, and Groups 1 and 3, while Groups 2 and 3 were similar ($P$<0.05) (Table 5). All three groups were similar in terms of mortality ($P$=0.134) (Table 5).

Table 4: Evaluation of categorical variables according to the presence of death

| | | Death no n (%) | Death yes n (%) | $P$-value |
|---|---|---|---|---|
| Gender | Female | 50 (34.7) | 7 (70.0) | 0.039‡** |
| | Male | 94 (65.3) | 3 (30.0) | |
| Diabetes | N | 110 (76.4) | 8 (80.0) | 1‡ |
| | Y | 34 (23.6) | 2 (20.0) | |
| Arrhythmia | N | 124 (86.1) | 6 (60.0) | 0.05‡** |
| | Y | 20 (13.9) | 4 (40.0) | |
| CAD | N | 104 (72.2) | 4 (40.0) | 0.066‡ |
| | Y | 40 (27.8) | 6 (60.0) | |
| Smoking | N | 81 (56.3) | 9 (90.0) | 0.046‡ |
| | Y | 63 (43.8) | 1 (10.0) | |
| COPD | N | 121 (84.0) | 7 (70.0) | 0.374‡ |
| | Y | 23 (16.0) | 3 (30.0) | |
| CKD | N | 132 (91.7) | 9 (90.0) | 0.598‡ |
| | Y | 12 (8.3) | 1 (10.0) | |
| Symptom | N | 109 (75.7) | 7 (70.0) | 0.709‡ |
| | Y | 35 (24.3) | 3 (30.0) | |
| Hematoma | N | 133 (92.4) | 9 (90.0) | 0.567‡ |
| | Y | 11 (7.6) | 1 (10.0) | |
| Revision | N | 136 (94.4) | 8 (80.0) | 0.129‡ |
| | Y | 8 (5.6) | 2 (20.0) | |
| Hyperlipidemia | N | 116 (80.6) | 6 (60) | 0.218‡ |
| | Y | 28 (19.4) | 4 (40) | |
| Malignity | N | 13 1(91.0) | 9 (90.0) | 1‡ |
| | Y | 13 (9.0) | 1 (10.0) | |
| Amputation | N | 117 (81.3) | 7 (70.0) | 0.411‡ |
| | Y | 27 (18.8) | 3 (30.0) | |
| Nerve injury | N | 129 (89.6) | 7 (70.0) | 0.095‡ |
| | Y | 15 (10.4) | 3 (30.0) | |
| Obstruction level | Iliac | 80 (55.6) | 6 (60.0) | - |
| | Popliteal | 49 (34.0) | 4 (40.0) | |
| | Infra popliteal | 15 (10.4) | 0 (0.0) | |
| Total | | 124 (100) | 30 (100) | |

CAD: Coronary artery disease, COPD: Chronic obstructive pulmonary disease, CKD: Chronic kidney disease, ‡ Fisher Exact Chi-Square Test, ** $P$<0. 05

Table 5: Relationship between amputation, death and groups

| | Amputation no n (%)x | Amputation yes n (%)x | $P$-value |
|---|---|---|---|
| Group 1 | 57 (89.1) | 7 (10.9) | 0.005*‡ |
| Group 2 | 43 (41.9) | 9 (10.1) | |
| Group 3 | 24 (63.2) | 14 (36.8) | |
| | Death no n (%) | Death yes n (%) | |
| Group 1 | 62 (96.9) | 2 (3.1) | 0.134 ‡ |
| Group 2 | 49 (94.2) | 3 (5.8) | |
| Group 3 | 33 (86.8) | 5 (13.2) | |

Compared to Group 2 and Group 3, ‡ Fisher Exact Chi-Square Test, * $P$<0.05

## Discussion

Despite the advances in surgical and endovascular invasive procedures, the risk of amputation and mortality remain high in patients with acute arterial obstruction [8]. Although amputation in these cases is mostly due to late admission, its relationship with time is controversial. The longer the duration of ischemia symptoms, the worse the extremity viability. As expected, we found that the amputation rate was significantly higher in patients who underwent delayed interventions. In our opinion, the main reasons of amputation were clinical and demographic features, such as age, gender, diabetes, symptoms, and obstruction level, as well as delayed admission.

Acute artery occlusion affects approximately 2 in 2000 people per year. These patients have a higher risk for major cardiovascular events than others [4]. From this point, it is a socioeconomic health problem which affects the patients and their relatives. The primary goal must be to the prevention of limb loss and survival of patients [9]. After an acute ischemic attack, most patients are treated with appropriate treatment after admission to the hospital. Delay in the time of admission may lead to a delay in diagnosis and treatment. In a study of 103 patients retrospectively analyzed by Gulmen [10], it was emphasized that the first twelve hours are important to save the extremity in patients with acute arterial occlusion. In this study, in terms of recovery of the limb, similar results were found among patients whose admission time did not exceed twelve

hours and our study groups, which we evaluated twelve hours and one week after onset of symptoms. However, no statistical difference was found in the evaluation between the two delayed groups. Thromboembolectomy surgery can provide limb viability even in patients who have passed the twelve hours threshold after symptom onset. However, this success rate is significantly reduced in delayed patients. Collateral circulation that starts minutes after ischemia protects the limb during acute artery occlusion. Diagnosis may be delayed in patients who do not feel pain due to this limited blood flow. However, if the vascular bed is not healthy enough to maintain adequate blood flow, despite collateral circulation, high amputation and mortality risk may be encountered. The high amputation rate in delayed cases suggests that collateral circulation increases pain resistance but leads to late diagnosis.

We observed that the amputation rate increased depending on gender, diabetes, and increasing age. This may be due to the association of increased diabetes incidence with increasing age. The amputation rate increased approximately 5 times among diabetic patients compared to the non-diabetic population. Carmona et al. [11] found a 10-fold amputation risk in patients with diabetes. In the review of Narres et al. [12] including 19 studies, the amputation rate was high in diabetic patients and male individuals. The lower incidence in this study may be due to increasing endovascular developments and surgical techniques in recent years and improvement in the treatment planning of diabetic patients.

The early mortality rate in acute lower limb obstruction is between 3.6-30% [13,14]. However, long-term mortality rates are mostly investigated. In our study, mortality was approximately 19 percent and is in line with the literature [15], but low compared to older studies [16]. The reason for this may be the improvement in surgical materials and techniques. When the factors affecting mortality are examined, female gender and arrhythmia come to the fore. Hussain et al. [17] found more risks in men in their population-based study, in which early mortality was not studied. This suggests that patient groups may be affected by their demographic characteristics. We obtained similar mortality results among our study groups. However, this result should be evaluated carefully since early mortality results do not reflect long-term mortality outcomes.

**Limitations**

This study has several limitations. First, this is a retrospective single-center cohort study therefore it is difficult to interpret results to advocate recommendations that could be applicable in routine clinical practice. The sample size in the current study is also too small for extrapolation of definite judgments regarding the factors affecting mortality. We think that further, multi-center, prospective trials may aid in enlightening the effect of surgical timing on limb salvage and mortality in acute arterial occlusions.

**Conclusions**

Surgical treatment can be performed in delayed cases with lower extremity arterial occlusion for limb viability. However, the risk of amputation increases as the time from the onset of initial symptoms –which is pain in most cases- until surgical thromboembolectomy increases. The risk of mortality is high in acute arterial occlusions and we did not observe any effects of an early thromboembolectomy on in-hospital mortality in this cohort. We observed that the risk of amputation is increased in diabetics, females, the elderly, and in proximal occlusions; however, we think that further prospective, multi-center studies with a higher number of patients are needed to determine the risk of amputation in acute arterial occlusion.

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