

## C A S E R E P O R T

# A case of critical ischemia of the lower limbs: critical elements and possible medico-legal implications

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**Abstract.** Peripheral arterial disease (PAD) is an atherosclerotic process that causes stenosis and occlusion of peripheral arteries. Critical ischemia of the lower limbs is the most advanced and severe state of arterial disease. The purpose of this work is to underline the importance of a timely diagnostic-therapeutic framework in case of critical ischemia of the lower limbs, through a precise, coordinated, and multidisciplinary teamwork. A significant example is represented by the presentation of a clinical case that came to our observation following a request for compensation and which required an adequate evaluation in the medical-legal field. This work will make possible to clarify any profiles of medical professional responsibility, with specific reference to the predictability and preventability of the unfavourable events that have occurred, and which have led to a progressive worsening of the patient's clinical condition, which then resulted in the amputation of the lower limb, associated to organic deterioration and progressive complete permanent disability. In these cases, the collection of semeiotic data must be careful, meticulous, and completed by suitable instrumental investigations. These data, with the exhaustive compilation of the medical diary, play a decisive role even in the presence of adverse events and/or infrequent complications. These data allow to demonstrate, from a medico-legal point of view, that despite the implementation of all precautions codified by the specialized discipline, the adverse event, however foreseeable, is not always concretely preventable and therefore avoidable, being included in the non-negligent "complication" and not necessarily attributable to professional responsibility. ([www.actabiomedica.it](http://www.actabiomedica.it))

**Key words:** ischemia, lower limbs, medical malpractice, complication, amputation

## Introduction

Peripheral arterial disease (PAD) is an atherosclerotic process that causes stenosis and occlusion of peripheral arteries. In patients with previous coronary or cerebrovascular events, PAD occurs with a higher prevalence than previously estimated and is associated with a significant increase the prevalence of myocardial infarction, stroke and congestive heart failure (2). Different risk factors are associated with PAD, such as

male gender, smoking, diseases such as diabetes mellitus, hypertension, dyslipidaemia, hyperhomocysteinemia (3,4).

Critical ischemia of the lower limbs is the most advanced and severe state of PAD (5). This condition represents a pathological state characterized by a reduction or stoppage of the blood supply, due to embolism or thrombosis, which does not allow the life and function of the tissues included in that territory. This event, if not identified and early treated, has a poor

prognosis, with an amputation rate of 20-50% and a mortality rate of 12-17% (6,7).

Thrombosis can occur in atherosclerotic vessels, in the presence of aneurysms or inflammatory arteriopathies. Thrombosis on atherosclerotic arterial vessels of the femoro-popliteal area is frequent (> 50% of cases) and can represent an evolutionary complication of atherosclerotic aneurysms (8).

The site of arterial obstruction/occlusion is correlated to the severity of the ischemic phenomena in relation to the possibility of compensation of the collateral circulation. A greater extent of the obstruction is associated with a lower compensatory capacity of the collateral circles (9).

Arterial thrombosis of atherosclerotic vessels, associated to pre-existing stenosis of the main vessels, are better tolerated because occlusion occurs in the presence of well-developed compensatory collateral circulation which vicariates the territory downstream of the occlusion. If the duration of ischemia extends beyond certain time limits, tissue anoxia causes varying degrees of suffering and cell necrosis (10,11).

At the cutaneous level, after 10 hours of ischemia, the modifications of the nuclei and the homogenization of the deep layers are evident. These changes are reversible within a maximum of 48 hours. However, an unfavourable prognostic sign is the appearance of haemorrhagic blisters and gangrene areas. On the muscle level, instead, ischemia is considered completely reversible within 6 hours, while beyond 12 hours is irreversible. The nervous tissue remains the most sensitive tissues to ischemia. (12,13). The period of ischemia influences the urgency and the treatment and an arterial obstruction must be diagnosed and treated within 6-8 hours, to avoid irreversible ischemic events (14,15).

In cases of critical ischemia of the lower limbs, the diagnosis is based on the evaluation of anamnesis, symptoms reported by the patient and signs detected on direct examination. Instrumental investigations can confirm the clinical state and are helpful for differential diagnosis(16).

We report a case of a patient with a misdiagnosed critical lower limb ischemia and its medico-legal implications.

## Case report

In 2020, a 74-year-old woman, with previous breast cancer and cerebral vasculopathy, came to the emergency room (ER), complaining of pain and swelling in the left lower limb, manifested within the previous 48 hours. She has outcomes of cerebral hemorrhage surgically evacuated in 2010. An echocolor Doppler examination (ECD) focused on the venous system was performed which revealed a complete thrombosis of the popliteal vein, twin veins and posterior tibial venous axis of the left lower limb. Laboratory tests documented only a mild state of anemia. Therefore, the patient was discharged with diagnosis of deep vein thrombosis (DVT) and indication of medical therapy with low molecular weight heparin (LMWH) and to use compression stockings.

Eight days after discharge, the patient entered the ER of another hospital, with a hospitalization request by her family doctor for "*anemia, worsening of DVT in left lower limb, body wasting, cognitive impairment, previous cerebral hemorrhage complicated by seizures, suspected cancer recurrence from previous breast cancer*". ER doctors, after clinical and instrumental investigations, admitted her to Internal Medicine Department, with diagnosis of "*thickening of the right lung, anemia and leukopenia under investigation*".

During the recovery, distal trophic lesions were detected, and a vascular surgery consultation was requested twelve days after admission. The vascular surgeon's report described the presence of necrosis of the fifth toe in the left foot, compatible with delimited dry gangrene, and the presence of cutaneous infarction of the anterior tibial lodge. The femoral pulse was present, while the remaining pulses in the left lower limb were absent, with initial signs of sensory-motor deficit. The vascular surgeon also performed ECD, which revealed the obliteration of the superficial femoral artery. Therefore, an angio-CT examination was required. This exam confirmed a severe compromise of the arterial vessels, with extensive bilateral calcifications. Complete obstruction of the superficial femoral and anterior popliteal-tibial axis, tenuous opacification of the posterior tibial artery and peroneal artery and segmental thrombosis of the great saphenous vein was also found on the left side.

The clinical-instrumental evaluation revealed a state of chronic critical ischemia of the left lower limb, probably not treatable with direct revascularization, due to the deteriorated general conditions of the patient and the advanced hypovascularization of the affected limb. Amputation surgery was hypothesized in case of septic/metabolic complications onset or worsening of ischemic pain. Meanwhile, vasoactive therapy with prostanoids and local medications were started in association with antibiotic, analgesic and LMWH therapy. On that occasion, an interview with the patient's family members was requested to explain the therapeutic path and the severe prognosis.

During recovery, the vascular surgeons carried out numerous interviews with family members. After therapy beginning, a favorable response was seen with progressive subjective improvement, regression of foot pain, reduction of the cutaneous tibial lodge infarction, improvement of forefoot tropism and perfusion, demarcation of the left fifth finger lesion. After clinical stabilization, the patient was transferred to the vascular surgery department, to continue clinical monitoring and therapy. A further improvement of the clinical state was found, up to asymptomatic condition with demarcated non-infected lesions, so the patient was discharged.

However, during the clinical follow-up, progressive clinical worsening was detected. After two weeks, further hospitalization in the vascular surgery department was required. The patient underwent to femoral-popliteal bypass surgery, amputation of the fifth toe and distal phalanges of the second and third toes due to lack of adequate venous heritage. The postoperative course was regular, with regression of pain, healing of surgical wounds and presence of pulsations in the prosthesis. The improvement of the clinical state allowed for discharge fifteen days after surgery. The patient was monitored weekly and she never showed critical issues. At the fifth control, the patient reported foot pain with hypothermia and non-pulsating prosthesis. The ECD documented a complete obliteration of the prosthesis, with poor peripheral perfusion. The patient was hospitalized but few hours later she voluntarily left the hospital. She went to another vascular surgery center, in which thigh amputation of the left lower limb was performed, without any attempt for direct revascularization.

After five years, the aggravation of clinical patient status induced the family members to initiate a legal action for compensation against the vascular surgeons who made the first attempt to rescue the limb, for negligent, inept and imprudent conduct.

The informed consent to participate in the study was obtained from the patient, along with the patient's agreement to publish all the necessary information.

## Discussion

The lawyers proposed an "exclusive responsibility" of the first vascular team, for causing the unfavorable course, which led to thigh amputation. The decision-making inadequacy of having initially treated the patient only with pharmacological therapy was contested, associated with the belated surgical revascularization. These facts led to hypothesize a therapeutic inertia, that is a negligent, imperishable and imprudent attitude of doctors for not having correctly applied the therapies and technologies for the resolution of the pathology (17). Considering the documentary data, the following medico-legal findings were done:

- The first contact between patient and vascular surgeons took place 23 days after the onset of symptoms, no consultation was requested at the first ER admission.
- In ER documents, semeiotic findings relating to the left lower limb were not reported; only "painful swelling of the left leg" was recorded. The patient was discharged with prescription of LMWH and compression stockings.
- The lack of diagnostic accuracy from ER doctors did not allow to determine the true nature of the vascular lesions. An *ex-post* examination concluded that the symptoms reported by the patient were not exclusively related to venous thrombosis, but represented the clinical evolution of an arterial disease, in which the venous thrombotic event occurred following ischemia and hypomobility.
- The natural progression of arterial disease, aggravated by the presence of serious concomitant pathologies and the use of compression stockings without prior evaluation of the arterial pulses, caused its worsening.

- Only the first vascular surgeon visit, performed several days after the internal medicine department admission, allowed to define the true nature of the clinical status.

The vascular surgeon recorded in the medical diary a serious clinical and prognostic condition, with a realistic probability of amputation. Many times surgeons informed patient's family members about disease severity, reporting the colloquies in the clinical diary. According to Italian law, the moment of communication between doctor and patient constitutes a moment of treatment as expressed in paragraph 8 of art. 1, Law 219/2017.

- To the critic that the patient has been treated "only with pharmacological therapy", it was replied that the clinical indication was formulated according to the Italian Society of Vascular and Endovascular Surgery (SICVE) and the European Society of Cardiology (ESC) guidelines in force at the time of the event (18-19). In patients with cognitive impairment, multiple major associated pathologies, multiple injury sites, distal vascular poverty for extensive and multiple atherosclerotic lesions, a vasoactive pharmacological treatment is recommended, alternatively or waiting an attempt of direct revascularization (20-21).

An evident improvement in the patient's state was observed following infusion therapy, which led to discharge in the absence of septic complications. The possible worsening and the relative consequences had been discussed at the first vascular surgeon consultation with the patient's family.

The legal question, in relation to the conduct of the vascular surgeons, remained confined to the preliminary phase.

The arguments of the respondent part allowed the vascular surgeons to be relieved from the presumed responsibilities attributed by the applicant who based the accusation on the results of the part's medical report.

A mere defensive charge, devoid of autonomous evidentiary value, remains a defensive act and cannot be the subject of an official technical opinion, as the technical content is not able to alter its nature (Civil Cassation, section I, August 06, 2015, number 16552; and, section II, November 30, 2020, number 27297).

The procedural and clinical documents, attest that the diagnosis and the critical state, so advanced to minimize the probabilities of therapeutic success, was immediately detected and communicate by the vascular surgeons at the first contact with patient's family.

Consequently, the inadequate diagnostic completeness during the first access to ER and the subsequent recovery exonerated the vascular team from any direct responsibility and favored a long time interval between the onset of symptoms and the decisive vascular evaluation.

In the civil legislative field, as in this case, the principle of the preponderance of scientific evidence can be applied, whereby an event is to be considered caused by a specific behavior when its occurrence due to such behavior is more probable (Civil Cassation, United sections, January 11, 2008, number 582; section III, February 11, 2014, number 3010).

Adopting this criteria, through the combination of the "*relative prevalence of probability*" and the "*more likely than not*" rules, the patient was deprived of the opportunity to solve the ischemic event (Civil Cassation, section III, July 06, 2020, number 13872).

The unfortunate event highlights the importance of vascular diagnostic completeness. Physical examination should always include both the arterial and venous evaluation. Given the importance of ischemic time, is suggested to ER staff to promptly require specialist consultations in doubtful cases. Not all hospitals have an active vascular surgery service. In the specific case, however, both the first and the second hospitals were equipped with vascular surgeons, but their opinion was not asked.

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**Institutional Review Board Statement:** This study did not require the approval of the ethics committee, and did not entail any damage to the rights, safety and health of the people involved. This study has pursued as its primary objective, above all others, the well-being of the patient involved. However, the informed consent to participate in the study was obtained from the patient associated to the patient's agreement to publish all the necessary information.

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