Al-Azhar International Medical Journal

Volume 5 | Issue 7 Article 37

7-31-2024

Assesssment of the role of Thrombolytic Therapy by Using Catheter in the Treatment of Acute Lower Limb Ischemia

Omar Mokhtar Ibrahim Elhayeg
Vascular surgery, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt

Mostafa Ali Elsaied Badawy
Vascular surgery, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt

Mohamed Ibrahim Hammoda
Vascular surgery, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt,
mostafabadawy609@gmail.com

How to Cite This Article

Elhayeg, Omar Mokhtar Ibrahim; Badawy, Mostafa Ali Elsaied; and Hammoda, Mohamed Ibrahim (2024) "Assesssment of the role of Thrombolytic Therapy by Using Catheter in the Treatment of Acute Lower Limb Ischemia," *Al-Azhar International Medical Journal*: Vol. 5: Iss. 7, Article 37.
DOI: https://doi.org/10.58675/2682-339X.2555

ORIGINAL ARTICLE

Assesssment of the role of Thrombolytic Therapy by Using Catheter in the Treatment of Acute Lower Limb Ischemia

Omar M. I. Elhayeg, Mostafa A. E. Badawy *, Mohamed I. Hammoda

Department of Vascular surgery, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt

Abstract

Background: ***Acute limb ischemia is characterized by an abrupt reduction in perfusion to the affected limb, posing a risk to the condition's viability and necessitating prompt revascularization.***

Aim and objectives: ***To assess the efficacy, safety, and complications of catheter-directed thrombolysis (CDT) in acute lower limb ischemia.***

Patients and methods: ***This prospective interventional study includes 30 patients selected from attendees of outpatient Vascular Surgery clinics of Al Azhar University Hospitals. Samples were collected using a random systematic method.***

Results: ***Mean Hemoglobin g/dl was 12.78 ± 1.57. The mean Leucocyte count /microliters was 7015.07 ± 448.49. The mean platelet count *1000/microliter was 250.83 ± 22.11. The mean Ptt (sec) was 30.13 ± 2.13. The mean INR was 1.03 ± 0.09. 22 (73.3%) patients had Category IIa. 8 (26.67%) patients had Category I. 26 (86.67%) patients had Detectable Runoff vessels. 4 (13.3%) patients had No detectable Runoff vessels.7 (23.3%) patients had Peri-sheath hematoma. 4 (13.3%) patients had Hematuria. 2 (6.67%) patients had Epistaxis. 1 (3.3%) patient had Compartmental syndrome. 2 (6.67%) patients had Balloon angioplasty. 2 (6.67%) patients had Thrombectomy. 1 (3.3%) patient had Bypass. 1 (3. 3%) patient had Fasciotomy. 1 (3.3%) patient had BKA. 5 (16.67%) patients had AKA.25 (83.3%) patients had successful thrombolysis. 5 (16.67%) patients had failed thrombolysis.***

Conclusion: ***In the management of acutely ischemic limbs, CDT is a viable, risk-free, and minimally invasive substitute for surgical intervention. Nevertheless, bleeding and hematoma complications are a significant problem of this treatment.***

Keywords: Thrombolytic Therapy; Catheter; Acute Lower Limb Ischemia

1. Introduction

Acute limb ischemia (ALI) is characterized by a rapid reduction in blood flow to a limb, which might endanger the viability of the limb and necessitate urgent revascularization.[1]

ALI is a life-threatening occurrence that, if not promptly treated, can lead to both limb amputation and mortality. Arterial thrombosis is the primary factor responsible for ALI in around 30% of cases. In cases of acute ischemia, the capacity of a limb to survive is hampered due to insufficient time for developing new blood vessels to compensate for the lack of blood flow.[2]

The incidence of complications in patients with ALI is substantial, and even with prompt revascularization, the death and amputation rates within 30 days range from 10% to 15%. Additionally, patients with ALI encounter a rise in significant adverse events throughout their hospital stay, such as myocardial infarction, worsening of congestive heart failure, decline in renal function, and respiratory problems.[3]

The management of acute lower limb ischemia (ALLI) is a significant difficulty for vascular specialists, primarily due to the elevated rates of amputation and mortality. The one-year chance of survival without amputation is roughly 50-70 percent.[4]

Several different endovascular therapy approaches may be utilized. Conventional CDT is the most widely utilized and well-established among these procedures. Nevertheless, drawbacks of this method encompass the requirement for numerous treatments, ongoing care in a specialized nursing facility, and the potential for haemorrhaging.[5]

This research aimed to assess CDT's efficacy, safety, and complications in ALLI.

Accepted 21 July 2024.
Available online 31 July 2024

* Corresponding author at: Vascular surgery, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt.
E-mail address: mostafabadawy609@gmail.com (M. A. E. Badawy).

https://doi.org/10.58675/2682-339X.2555

2. Patients and methods

This prospective interventional study included 30 patients who were selected from the outpatient vascular surgery clinics of Al Azhar University Hospitals. Samples were collected using a random systematic method.

Inclusion criteria: Aged 18 years or more and Individuals suffering from ALLI.

Exclusion criteria: Individuals suffering from chronic limb-threatening ischemia, individuals experiencing ALIin the upper extremity, and individuals with chronic vascular disease who are pregnant.

Sample Size: This study is based on research done by Algaby et al. To determine the sample size, Epi Info STATCALC was utilized, taking into account the following assumptions: - A confidence level of 95% is utilized, with a power of 80% for both sides. The odds ratio was determined to be 1.115, with a margin of error of 5%. The ultimate maximum sample size extracted from the Epi-Info output was 30.[6]

Methods

All patients were subjected to:

Local examination

Pain Assessment: Ask the patient to describe the pain in their leg; inspection: Proceed with a visual inspection of the affected lower limb and surrounding areas. Skin Color and Temperature: To assess its temperature compared to the other limb's. Edema and swelling. Ulcers or Gangrene: Inspect the skin for open sores, ulcers, or blisters. Palpation: Assess pulses. Capillary Refill: how long it takes for the colour to return to the nail bed. Tenderness. Neurological Assessment: Assessing the patient's sensory and motor function in the affected leg. Sensation: Using a blunt object to gently test the patient's ability to feel touch and pressure in different leg and foot areas. Motor Function: Note any weakness or difficulty in these movements. Collateral Circulation: Examine the skin for visible collateral vessels.

Laboratory investigations

Complete blood count. Liver function tests (albumin, bilirubin, liver transaminases, prothrombin time, INR) and renal function tests (creatinine and urea).

Radiological investigation

Doppler ultrasonography of the lower extremity arteries

A linear transducer with a changeable ultrasonic frequency ranging from 9 to 15 MHz was commonly utilized. The transducer was positioned above an artery to do transverse scanning and subsequently turned by 90° to conduct longitudinal scanning. The examination was often conducted with the patient lying in the supine posture. The patient's hip was abducted and externally rotated. At the same time, the knee was flexed to facilitate access to the popliteal artery in the popliteal fossa and the posterior tibial artery in the medial calf. The left lateral decubitus posture or the prone position are the options for assessing the popliteal artery, the posterior tibial artery, and the peroneal artery. The examiner scanned the anterior tibial artery and dorsalis pedis artery while the patient was lying on their back.

Procedures

All patients were intervened within three days of the commencement of the acute insult. Every patient was closely observed within the angio suite. The patients received local anaesthetic at the location of access. The sheath was inserted. Diagnostic arteriography was initially utilized to illustrate the anatomy and location of the blockage utilizing either a contralateral or ipsilateral method. The Fountain infusion catheter, manufactured by Merit Medical Systems Inc. in South Jordan, UT 84095, United States, was utilized to administer alteplase, produced by Boehringer Ingelheim in Ingelheim, Germany, directly into the location of the thrombotic lesion. Each vial of alteplase includes 50 mg of alteplase in powder form and is accompanied by another vial containing 50 ml of solvent. After the powder is dissolved in the solvent, the resultant solution has a concentration of alteplase of 1 mg/ml. The infusion approach employed consisted of administering a bolus of 15 mg alteplase, followed by a continuous infusion of 1.5 ml/h for 24-48 hrs. The sheath and catheter were coiled in the groin, arranged, and secured. Patients in the ICU were closely followed, with particular attention given to vital signs, ischemia symptoms of the limb, and potential bleeding problems. Subsequent angiography was performed in the operating room 24 and 48 hrs following the alteplase administration to verify the treatment's technical success. Angioplasty stenting was used to address significant remaining lesions. The sheath was extracted 4 hrs after the thrombolytic drug infusion was stopped, and manual compression was utilized until satisfactory hemostasis was achieved. A compression bandage was utilized to provide pressure to the location of the artery puncture for a duration of 24 hrs.

3. Results

This table showed that in All included patients, Mean Age (year) was 40.93 ± 3.53. Mean Weight (Kg) was 71.03 ± 4.56. Mean Height (meter) was 1.7 ± 0.02. Mean duration of symptoms (Days) was 1.7 ± 0.84. In All included patients, 17 (56.67%) patients were males. 13 (43.3%) patients were females. 13 (43.3%) patients were smokers. 17 (56.67%) patients were not Smoking. (Table 1)

Table 1. Demographic data

		ALL INCLUDED PATIENTS	
AGE (YEAR) (MEAN ±SD)		40.93 ± 3.53	
SEX	Male	17	56.7
	Female	13	43.3
WEIGHT (KG) (MEAN ±SD)		71.03 ± 4.56	
HEIGHT (METER) (MEAN ±SD)		1.7 ± 0.02	
DURATION OF SYMPTOMS (DAYS) (MEAN ±SD)		1.7 ± 0.84	
SMOKING	Yes	13	43.3
	No	17	56.7

This table showed that in All included patients, 18 (60%) patients had Diabetes mellitus. 12 (40%) patients did not have Diabetes mellitus. 10 (33.3%) patients had Hypertension. 20 (66.67%) patients did not have Hypertension. 3 (10%) patients had Cesarean section. 27 (90%) patients did not have Cesarean section. 4 (13.3%) patients had Abdominal operation. 26 (86.67%) patients did not have Abdominal operation. 3 (10%) patients had Chest operation. 27 (90%) patients did not have Chest operation. 3 (10%) patients had Post stroke. 3 (10%) patients had Compensated hepatic failure. (Table 2)

Table 2. Present and past history

		ALL INCLUDED PATIENTS	
		N	%
DIABETES MELLITUS	yes	18	60
	No	12	40
HYPERTENSION	Yes	10	33.3
	No	20	66.7
CESAREAN SECTION	Yes	3	10
	No	27	90
ABDOMINAL OPERATION	Yes	4	13.33
	No	26	86.67
CHEST OPERATION	Yes	3	10
	No	27	90
POST STROKE	Yes	3	10
	No	27	90
COMPENSATED HEPATIC FAILURE	Yes	3	10
	No	27	90

This table showed that in All included patients, Mean Hemoglobin g/dl was 12.78 ± 1.57. Mean Leucocyte count /microliters was 7015.07 ± 448.49. Mean platelet count *1000/microliter was 250.83 ± 22.11. Mean Ptt (sec) was 30.13 ± 2.13. Mean INR was 1.03 ± 0.09. (Table 3)

Table 3. Laboratory tests

	ALL INCLUDED PATIENTS
HEMOGLOBIN G/DL (MEAN ±SD)	12.78 ± 1.57
LEUCOCYTE COUNT /MICROLITERS (MEAN ±SD)	7015.07 ± 448.49
PLATELET COUNT *1000/MICROLITER (MEAN ±SD)	250.83 ± 22.11
PTT (SEC) (MEAN ±SD)	30.13 ± 2.13
INR (MEAN ±SD)	1.03 ± 0.09

PTT: PARTIAL THROMBOPLASTIN TIME; INR: INTERNATIONAL NORMALIZED RATIO

This table showed that in All included patients, 22 (73.3%) patients had Category IIa. 8 (26.67%) patients had Category I. 26 (86.67%) patients had Detectable Runoff vessels. 4 (13.3%) patients had non detectable Runoff vessels. (Table 4)

Table 4. Rutherford's classification

	ALL INCLUDED PATIENTS	
	N	%
CATEGORY IIA	22	73.33
CATEGORY I	8	26.67
DETECTABLE RUNOFF VESSELS	26	86.67
NON DETECTABLE RUNOFF VESSELS	4	13.33

This table showed that in All included patients, 7 (23.3%) patients had Peri-sheath hematoma. 4 (13.3%) patients had Hematuria. 2 (6.67%) patients had Epistaxis. 1 (3.3%) patient had Compartmental syndrome. (Table 5)

Table 5. Complications

	ALL INCLUDED PATIENTS	
	N	%
PERI-SHEATH HEMATOMA	7	23.33
HEMATURIA	4	13.33
EPISTAXIS	2	6.67
COMPARTMENTAL SYNDROME	1	3.33

This table showed that in All included patients, 2 (6.67%) patients had Balloon angioplasty. 2 (6.67%) patients had Thrombectomy. 1 (3.3%) patient had Bypass. 1 (3. 3%) patient had Fasciotomy. 1 (3.3%) patient had BKA. 5 (16.67%) patients had AKA. (Table 6)

Table 6. Additional interventions required

	ALL INCLUDED PATIENTS	
	N	%
BALLOON ANGIOPLASTY	2	6.7
THROMBECTOMY	2	6.7
BYPASS	1	3.3
FASCIOTOMY	1	3.3
BKA	1	3.3
AKA	5	16.7

This table showed that 25 (83.3%) patients had successful thrombolysis. 5 (16.67%) patients had failed thrombolysis. (Table 7)

Table 7. Success rate

	ALL INCLUDED PATIENTS	
	N	%
SUCCESSFUL THROMBOLYSIS	25	83.3
FAILED THROMBOLYSIS	5	16.7

4. Discussion

Historically, the conventional approach to managing ALI has been open surgical intervention, which has been linked to a considerably elevated risk of morbidity and mortality throughout the perioperative period. In recent decades, CDT has demonstrated comparable efficacy in revascularization rates and the risk of amputation and mortality.[7]

The main results of our study were as follows:

In our study, we found that the mean age (year) was 40.93 ± 3.53, the mean weight (Kg) was 71.03 ± 4.56, the mean height (meter) was 1.7 ± 0.02, and the mean duration of symptoms (Days) was 1.7 ± 0.84. Of the included patients, 17 (56.67%) were Male, 13 (43.3%) were Female, and 13 (43.3%) were smokers.

In agreement with our results, AMR et al. aimed

To assess the safety, effectiveness, and results of CDT in treating acute thrombotic lower limb ischemia. Their research was carried out on a cohort of 20 individuals afflicted with ALIand they found that the mean age (year) was 54 (44-67) and the Male: female ratio was 11:9. Mean duration of symptoms (Days) was 7 (2-14). 8 (40%) patients were smoking.[8]

In our study, we found that 18 (60%) patients had Diabetes mellitus, 10 (33.3%) patients had Hypertension, 3 (10%) patients had a Cesarean section, 4 (13.3%) patients had abdominal surgery, 3 (10%) patients had chest surgery, 3 (10%) patients had post-stroke, and 3 (10%) patients had Compensated hepatic failure.

Furthermore, Huang et al.'s objective was to contrast the safety and efficacy of the Solitaire™ AB Stent System to conventional catheter-directed thrombolytic therapy in treating ALLI. They reported that 33 (31.1%) patients had diabetes mellitus. 74 (69.8%) patients had Hypertension.[9]

In our study, we found that the mean Hemoglobin g/dl was 12.78 ± 1.57. The mean leucocyte count/microliter was 7015.07 ± 448.49. The mean platelet count 1000/microliter was 250.83 ± 22.11. The mean Ptt (sec) was 30.13 ± 2.13. The mean INR was 1.03 ± 0.09.

Our results are consistent with those of Limtungturakul et al., who found that the mean Hemoglobin g/dl was 13.1 + 6.0. The mean platelet count 1000/microliter was 367.42 + 35.06. Mean Ptt (sec) was 42.03 + 9.8. The mean INR was 1.87 + 1.1.[10]

According to Rutherford's classification, 22 (73.3%) patients had Category IIa, 8 (26.67%) patients had Category I, 26 (86.67%) patients had Detectable Runoff vessels, and 4 (13.3%) patients had no detectable Runoff vessels.

Also, our results are consistent with those of Abdelaty et al., whose objective was to evaluate the safety and effectiveness of CDT in patients with distal occlusion and this form of ALI. Regarding Rutherford's classification, they discovered that 17(77.3%) belonged to Category IIa. 5 (22.7%) belonged to Category I. Four patients (18.2%) had no detectable runoff on the CTA or initial angiogram, while 4(18.2%) had one detectable runoff vessel.[11]

In our study, we found that regarding additional interventions required, 2 (6.67%) patients had Balloon angioplasty, 2 (6.67%) patients had Thromboscopy, 1 (3.3%) patient had Bypass, 1 (3. 3%) patients had Fasciotomy, 1 (3.3%) patient had BKA, and 5 (16.67%) patients had AKA.

Furthermore, Nasser et al. found that among the 24 CDTs conducted, 20 patients (83.3%) necessitated further interventions. Specifically, 15 patients underwent percutaneous intervention, including 12 balloon dilatations and six stentings for the superficial femoral artery (SFA). Additionally, 3 cases required aspiration thrombectomy, while 3 cases underwent open procedures involving popliteal thromboembolectomy. Furthermore, two hybrid cases involved CFA thromboendarterectomy and angioplasty for the femeropoliteal segment.[12]

Our study found that regarding success rate, 25 (83.3%) patients had successful thrombolysis. 5 (16.67%) patients had failed thrombolysis.

In our study, we found that regarding complications, 7 (23.3%) patients had Peri-sheath hematoma, 4 (13.3%) patients had Hemorrhagia, 2 (6.67%) patients had Epistaxis, and 1 (3.3%) patient had compartmental syndrome.

Also, our results are consistent with those of Abdelaty et al., who reported that regarding complications, four cases (18.2%) of patients had peri-sheath hematoma. 1 (4.5%) patient had compartmental syndrome.[11]

4. Conclusion

CDT is a very efficient, secure, and less invasive alternative to surgery for treating an acutely ischemic limb. Nevertheless, bleeding and hematoma complications are a significant problem of this treatment.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

Funding

No Funds : Yes

Conflicts of interest

There are no conflicts of interest.

References

1. FLUCK, Friederika, et al. Current treatment options in acute limb ischemia. In: RöFo-Fortschritte auf dem Gebiet der Röntgenstrahlen und der bildgebenden Verfahren. © Georg Thieme Verlag KG, 2020. p. 319-326.
2. Lian WS, Das SK, Hu XX, Zhang XJ, Xie XY, Li MQ. Efficacy of intra-arterial catheter-directed thrombolysis for popliteal and infrapopliteal acute limb ischemia. J Vasc Surg. 2020;71(1):141-148.
3. Olinic DM, Stanek A, Tătaru DA, Homorodean C, Olinic M. Acute Limb Ischemia: An Update on Diagnosis and Management. J Clin Med. 2019;8(8):1215.
4. KHANNA, Narendra Nath, et al. The Indian Consensus Statement for the Management of Lower Extremity Peripheral Artery Disease. Journal of Indian College of Cardiology, 2023, 13.Special Suppl 1: S1-S20. 8811.383634-1561/10.4103

5. Kwok CHR, Fleming S, Chan KKC, et al. Aspiration Thrombectomy versus Conventional Catheter-Directed Thrombolysis as First-Line Treatment for Noniatrogenic Acute Lower Limb Ischemia. J Vasc Interv Radiol. 2018;29(5):607-613.
6. ALGABY, Abdulaziz Z., et al. Limb Salvage in the Era of Endovascular Intervention: Observation Study. Ain Shams Journal of Surgery, 2020, 13.2: 93-99.
7. Farber A, Eberhardt RT. The Current State of Critical Limb Ischemia: A Systematic Review. JAMA Surg. 2016;151(11):1070-1077.
8. AMR, M., et al. Catheter Directed Thrombolysis in Management of Acute Thrombotic Lower Limb Ischemia. The Medical Journal of Cairo University, 2019, 87.March: 231-237.
9. Huang H, Gu J, Su H, et al. Solitaire™ Stent Thrombectomy System in the Treatment of Acute Lower-Limb Ischemia: Comparisons in Safety and Effectiveness with Conventional Catheter-Directed Thrombolysis Therapy [retracted in: Biomed Res Int. 2023 Jun 21;2023:9803031]. Biomed Res Int. 2022;2022:6997221.
10. LIMTUNGTURAKUL, Sarawut, et al. Early experience of catheter directed thrombolysis for acute limb ischemia of native vessels and bypass graft thrombosis in Thai patients. Journal of the Medical Association of Thailand, 2011, 94.2: 11.
11. Abdelaty MH, Aborahma AM, Elheniedy MA, Kamhawy AH. Outcome of catheter directed thrombolysis for popliteal or infrapopliteal acute arterial occlusion. Cardiovasc Interv Ther. 2021;36(4):498-505.
12. NASSER, Mahmoud; MOHAMED, Hany Abdelmawla; ABDELHAFEZ, Abdelaziz A. Catheter-directed thrombolysis in thrombotic acute lower limb ischemia: challenges and management. The Egyptian Journal of Surgery, 2019, 38.2: 332-337.