



A RANDOMISED PROSPECTIVE STUDY TO EVALUATE OUTCOMES IN ACUTE LIMB ISCHEMIA

General Surgery

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ABSTRACT

Acute limb ischemia (ALI) is a vascular emergency associated with a high risk for limb loss and death and requires quick revascularization by endovascular, surgical, or a hybrid approach to avoid limb loss. Acute limb ischemia (ALI) results from an acute (<2 weeks), abrupt decrease in arterial perfusion of the limb.

1. Aims And Objectives-

1. To study the mode of presentation in cases of acute limb ischemia viz. acute, acute on chronic and delayed acute limb ischemia.
2. To study the various investigations and treatment modalities in the management of acute limb ischemia.
3. To evaluate the outcomes of management.

2. **Methods-** A Randomised prospective study was conducted on 50 patients admitted in department of Surgery, Mahatma Gandhi Medical college and hospital, Jaipur (Rajasthan) India with all forms of acute limb ischemia. A careful clinical assessment of the patient was done in order to save the limb. Patients who reported after 72 hours of onset of symptoms were grouped as Delayed presentation. The patients who had previous history of arterial occlusive disease were grouped as Acute on chronic presentation. 3. **Observation And Results-** Most of the patients with ALI presented in the age group 51-60 years, with the mean age of 48 years and males affected more than females. Smoking is the most commonest risk factor associated with ALI followed by the patients having co-morbidities. 14% patients were managed conservatively by heparin and anticoagulants and rest underwent surgical management. Thrombo-embolectomy was performed in 60% of patients followed by Amputation performed in 16% of patients. 4. **Conclusion-** Acute limb ischemia threatens the viability of the extremity and the patient's survival because of systemic acid-base, electrolytes, and other abnormalities. The diagnosis and initial assessment are largely clinical, and diagnostic errors can result in a high price to the patient.

KEYWORDS

INTRODUCTION

Acute limb ischemia (ALI) results from an acute (<2 weeks), abrupt decrease in arterial perfusion of the limb, and can lead to tissue loss. Acute limb ischemia threatens the viability of the extremity and the patient's survival because of systemic acid-base, electrolytes, and other abnormalities. Causes of acute limb ischemia include acute thrombosis of a limb artery or bypass graft, stent followed by plaque rupture/disease progression in native vessels, emboli from heart or a diseased artery, dissection and trauma. Rutherford classified acute limb ischemia into 3 categories- Category I-refers to the viable that are not threatened immediately. Category II-refers to the threatened limb and is further classified into IIa-marginally threatened and salvageable limb and IIb-immediately threatened, requiring immediate revascularization if limb has to be salvage. Category III-refers to irreversibly damaged limbs. The diagnosis and initial assessment are largely clinical, and diagnostic errors can result in a high price to the patient. The incidence of symptomatic PAD increases with age, from approximately 0.3%/yr for men aged 40 to 55 years to approximately 1%/yr for men older than 75 years. In the United States, PAD affects 12% to 20% of Americans aged 65 years and older. PAD is more prevalent in nonwhite populations, and this is not completely explained by an increased incidence of comorbid diseases. Risk is increased in smokers and in patients with hypertension, dyslipidemia, hypercoagulable states, renal insufficiency, and diabetes mellitus. The prevalence of PAD is significantly higher in a younger diabetic population, affecting one in three diabetics older than 50 years. The risk of PAD also increases in individuals who are older than 50 years, male, or obese and in those with a family history of vascular disease, heart attack, or stroke.

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MATERIALS AND METHODS-

- A. Study area: Department of General Surgery of Mahatma Gandhi Medical College and Hospital, Jaipur, Rajasthan, India.
- B. Study population-Patients who are admitted in surgical ward of Mahatma Gandhi Medical College and Hospital, Jaipur presenting with Acute limb ischemia in all forms.
- C. Study period- October 2022- March 2023
- D. Sample size- 50 consecutive patients following inclusion and exclusion criteria

Inclusion Criteria-

1. All patients of acute limb ischemia presenting to a tertiary care hospital for the first time.
2. Patients with informed written consent.

Exclusion Criteria-

1. Patients with concomitant venous disease.
 2. Diagnosed cases of diabetic foot
 3. Known cases of vasculitis
 4. Previously operated cases of acute limb ischemia.
- E. Study design- Prospective randomized observational study.
- F. Study technique- 50 patients admitted in the Surgery department of MGMCH & H presenting with acute limb ischemia in all forms were included in this study randomly after taking proper consent and counselling.

OBSERVATION AND RESULTS-

Table 1: Age distribution

AGE GROUP	NO. OF PATIENTS	PERCENTAGE
<30	4	8%
31-40	10	20%
41-50	14	28%
51-60	18	36%
61-70	4	8%
TOTAL	50	100%

Almost half of the patients in the study group presented in their 5th and 6th decade of life. The mean age was 48 years. Males affected more

than females with 41 males and 9 females.

Table 2: Risk factor distribution

RISK FACTOR	NUMBER OF PATIENTS	PERCENTAGE
Smoking	25	50%
Diabetes	5	10%
Hyperlipidemia	4	8%
Cardiac disorder	4	8%
Hypertension	8	16%
Obesity	3	5%
No risk factor	2	4%

Out of these, 50% of patients had habit of smoking (the most commonest risk factor) followed by Hypertension (16%), Diabetes (10%), Cardiac disease (4%). Out of 4 Patients having cardiac disorder, 3 patients had Atherosclerotic heart disease and 1 had Rheumatic heart disease. 5 patients (10%) were found to have hyperglycemia. Of these, 4 were known diabetics while 1 patient was newly detected diabetics. 4 patients (8%) were found to have hyperlipidemia.

In our study out of 50 patients of limb ischemia, 40 patients presented with lower limb ischemia and 10 patients presented with upper limb ischemia. 34 patients had involvement of left side while 16 patients had right side involvement.

Table 3: Type of presentation

TYPE OF PRESENTATION	NUMBER OF PATIENTS
Acute	24
Acute on chronic	6
Delayed	20

The patients were asked about time of onset of symptoms and time of presentation to hospital was noted. Patients who reported after 72 hours of onset of symptoms were grouped as Delayed presentation. The patients who had previous history of arterial occlusive disease were grouped as Acute on chronic presentation. So, in our study number of patients with acute, acute on chronic and delayed acute presentation were 24, 6 and 20 respectively.

The presenting complaints were mostly acute onset pain, swelling and paresthesia. Some patients presented with pre-gangrene/gangrene or paralysis of affected limb.

On clinical examination, pallor, poikilothermia, tone, power, sensations and peripheral pulses were noted. Hand held Doppler was used routinely in all patients to confirm clinical findings.

Patients were evaluated hematological and biochemical parameters.

Cardiac workup was done routinely in all the patients either preoperatively or postoperatively. This included ECG and 2D Echocardiography.

12 patients had 2D Echo abnormality, while 8 patients had ECG changes. Out of 12 patients who had 2D Echo abnormality, 2 patients had findings suggestive of IHD, 2 patients had findings suggestive of valvular heart disease, 5 patients had nonspecific diastolic dysfunction, and 3 had nonspecific LVH.

Table 4: All patients underwent Color Doppler Flow Imaging (CDFI) to determine the level of arterial obstruction.

SITE OF OBSTRUCTION	NUMBER OF CASE	PERCENTAGE
Subclavian artery	1	2%
Axillary artery	1	2%
Brachial artery	2	4%
Radial artery	4	8%
Ulnar artery	1	2%
External iliac artery	7	14%
Femoral artery	23	46%
Popliteal artery	10	20%
Anterior tibial artery	1	2%

46% (n=23) patients had involvement of femoral artery followed by 20% (n=10) patients having popliteal artery occlusion. Among cases of upper limb ischemia, 8% (n=4) had radial artery obstruction, followed by brachial artery obstruction (4%).

ABPI (Ankle brachial pressure index) was also calculated ,10 patients

had >0.3 and 40 patients had <0.3. Patients having ABPI >0.3 were managed conservatively and patients having <0.3 underwent surgical management.

Table 5: 60% (n= 30) patients underwent thrombo-embolectomy. Out of these 30, fasciotomy was also done in 9 patients. Thrombo-embolectomy with fasciotomy was done later due to development of compartment syndrome.

MANAGEMENT	NUMBER OF PATIENTS	PERCENTAGE
Medical	7	14%
Thrombo-embolectomy	30	60%
Omentoplasty	5	10%
Amputation	8	16%
Total	50	100%

- 14% patients (n=7) were managed medically by antithrombotic therapy.
- 10% of patients (n=5) had omentoplasty done. 16% patients (n=8) underwent amputation.

DISCUSSION

The youngest patient was of 12 years of age and the oldest was 65 years. The maximum of patients was in the age group of 41-60 years. The mean age of the patients was 48 years.

Out of the 50 patients, male patients constituted 41(82%) and female 9 (18%). 25 (50%) of these patients had habit of smoking. These patients had thrombotic events compared to non-smokers who had embolic events in majority. 5 (10%) patients had diabetes and were on treatment for the same. 8 (16%) patients had hypertension and were on treatment. 3 patients had obesity as a co-morbidity.

Out of 50 patients, 4 patients had cardiac disease. Among these 1 patient had Rheumatic heart disease and 3 patients had Atherosclerotic (ischemic) heart disease. There has been a shift in the underlying heart disease from rheumatic valvular disease to atherosclerotic coronary vascular disease.

In our study 2 patients had no known risk factor at the time of presentation.

Uriel et al, Rochester trial 1994

In this study, patients with ALI less than 7 days of duration were randomly allocated to intra-arterial catheter-directed urokinase therapy or operative intervention. Less incidence of in-hospital cardiopulmonary complications and a corresponding increase in patient survival rates was seen in patients with Intra-arterial thrombolytic therapy.

The STILE trial 1994

A prospective randomized trial was conducted, comparison of either optimal surgical procedure or intra-arterial, catheter-directed thrombolysis with recombinant tissue plasminogen activator (rt-PA) or urokinase (UK) was done. Patients were classified into acute (0-14 days) and chronic (>14 days) ischemia. Study showed thrombolysis to be more effective preventing the need for amputation in patients with acute ischemia. However, surgical revascularization was found to be more effective and safer than thrombolysis in patients with chronic ischemia. No difference in efficacy or safety between rt-PA and UK was seen.

Comerota et al 1996

In this randomized trial, surgical revascularization was compared with catheter-directed thrombolysis in patients with occluded lower extremity bypass grafts. Study showed that thrombolysis of occluded lower extremity bypass grafts improved limb salvage and reduced the magnitude of the planned surgical procedure in patients with acute limb ischemia.

NATALI Database 2004

This was a retrospective review of 1,133 ALI episodes treated with CDT. At 30 days, amputation-free survival was 75.2%, amputation rate was 12.4%, and mortality was 12.4%.

Taha et al 2015

A more contemporary retrospective review in which 147 consecutive patients with ALI treated with endovascular revascularization (ER) were compared with 296 patients with open revascularization (OR). In

patients with class-II ALI, ER, or surgical OR resulted in comparable limb salvage rates. Overall mortality rates were significantly higher at 30 days and 1 year in the OR group.

In our study, management of patients was decided on the basis of stage of ischemia, duration of ischemia and ABPI. 7 patients (14%) were managed conservatively by heparin and anticoagulants and rest underwent surgical management. Thrombo-embolectomy was performed in 30 patients (60%) followed by Amputation performed in 8 patients (16%). In 9 patients fasciotomy was done after thrombo-embolectomy due to development of compartment syndrome.

CONCLUSION

Acute limb ischemia threatens the viability of the extremity and the patient's survival because of systemic acid-base, electrolytes, and other abnormalities. The diagnosis and initial assessment are largely clinical, and diagnostic errors can result in a high price to the patient. Acute ischemia often presents in a patient with multiple medical comorbidities. Therefore, careful clinical assessment of the individual is as important as assessment of the limb.

Due to inaccuracy of pulse palpation and physical examination, all patients with suspected ALI should have Doppler assessment of peripheral pulses immediately at presentation to determine if a flow signal is present.

Immediate parenteral anticoagulant therapy is indicated in all patients with Acute Limb Ischemia. A variety of modalities of treatment are available. Selection of the most appropriate intervention can be critical to the eventual outcome.

In case of clinical suspicion of compartment syndrome, the treatment of choice is a four-compartment fasciotomy.

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