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Routine versus Selective Angiography after Embolectomy in Acute Lower Limb Ischemia: A Prospective Randomized Clinical Trial

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Abstract

Background: Introduction of endovascular tools in the treatment of acute limb ischemia gave us a lot of promising outcomes, and many authors recommended the completion angiogram as a routine procedure after each open embolectomy, this recommendation was based upon some retrospective cohort studies.

Objectives: The effectiveness of routine completion angiogram after embolectomy compared to selective use of completion angiogram.

Participants: 126 patients with 134 limbs diagnosed with acute ischemia, 92 patients with 100 limbs were fulfilling the study requirements.

Intervention: The patients were randomized into Group A routine completion angiography and Group B with completion angiography done on selective basics (failure to advance the embolectomy catheter, inadequate inflow or back flow, extraction of intimal fragments).

Design of study: Prospective single center randomized controlled trial, open labelled and the method of randomization was by a closed envelop.

Main outcome measures: Primary patency rate and limb salvage rates.

Results: 92 patients (100 limbs) were enrolled in the trial and were randomized into two equal groups, each group included 50 limbs, mean age for Group A and B were (63.5 ± 12, 60 ± 16), female to male ratio in Group A 1.8 and in Group B 1.4, technical success rate was 84% in Group A and 88% in Group B (p=0.564). Using Kaplan Meier curves, primary patency rate in 12 months was 73% in Group A and 85 % in Group B (p=0.295). Limb salvage rates in 12 months was 85% in Group A and 92% in Group B (p=0.685).

Conclusion: The use of intraoperative angiogram can be used selectively after embolectomy procedures without affecting the long term patency.

Keywords: Ischemia; Thrombectomy; Embolectomy; Angiography

Introduction

Acute limb ischemia is one of the important issues in healthcare with an incidence of 26 cases per 100,000, in-hospital mortality rate of 9%, and amputation rates reach up to 30% [1,2]. In 1963, Thomas Fogarty by his invention changed the scope of treatment which had a great impact on limb salvage. However, the route of Fogarty catheter in the leg arteries is usually unpredictable; the usual passage for the catheter in a patent arterial tree below the knee is the peroneal artery (90%) followed by the posterior tibial artery (10%) [3]. The introduction of endovascular options as a tool was to improve the diagnosis and management of acute limb ischemia [4]. The use of percutaneous endovascular techniques in acute limb ischemia such as mechanical thrombectomy or intra-arterial thrombolysis were reported in many studies [5], yet, it failed to show superiority over the open surgical technique [6]. The endovascular assisted embolectomy consists of completion angiography, embolectomy under fluoroscopic guidance, embolectomy using over the wire embolectomy catheter, and correction of underlying arterial lesions, this combination increased the efficacy of surgical embolectomy and decreases amputation rates [7]. Many authors recommend the routine use of completion angiogram after open surgical treatment of acute limb ischemia; however none of the published studies were based on randomized controlled trials [8,9].

Aim of work

To compare the efficacy of routine use of completion angiogram after open embolectomy procedures versus using it on selective basis with regards to the outcomes in the management of acute lower limb ischemia.

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Patients and methods

Type of study: Prospective interventional Randomized Controlled Trial.

This Prospective study was conducted on 126 patients with 134 limbs attended to Mansoura Emergency Hospital and were diagnosed with acute limb ischemia. From March 2015 to February 2016, all cases were tested for eligibility criteria. We included Patients who were diagnosed to have acute lower limb ischemia due to native arterial occlusion Grade I, Grade IIA and Grade IIB based upon Rutherford's classification in 2009. We excluded Traumatic or iatrogenic acute limb ischemia and Grade III acute ischemia (irreversible) with major tissue loss and major amputation is inevitable, also patients with occluded bypass graft and presented with acute limb ischemia, acute limb ischemia due to intra-arterial injection and Patients with renal impairment (serum creatinine >1.2 mg/dL) or with a history of contrast-induced nephropathy were excluded. Finally, 92 patients with 100 legs were included in the study and 34 patients were excluded from the study as shown in Figure 1.

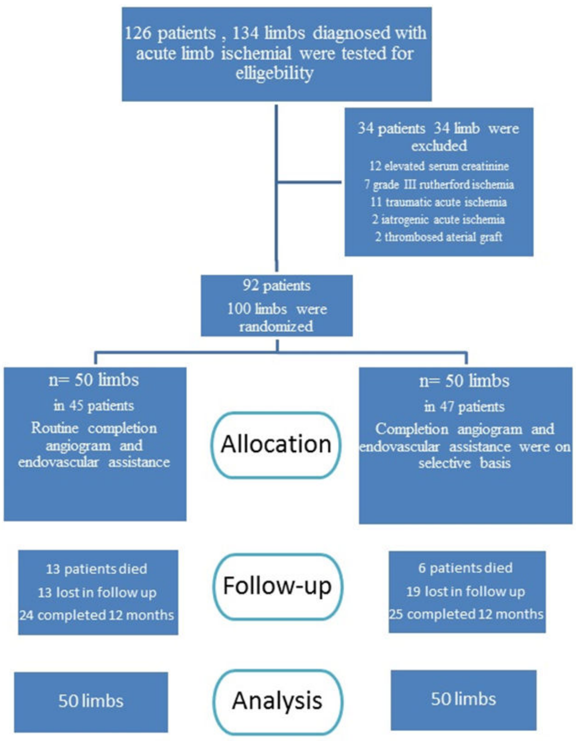

Figure 1: CONSORT flow chart.

This study received an institutional review board approval (MD/85) and registered on clinicaltrials.gov (NCT03388021), all participants had their rights to withdraw from the study at any time.

Intervention: After obtaining informed written consent including the procedure and the possible complications, patients were randomized by closed envelope method into two equal groups each group included 50 legs.

Group (A): Routine completion angiography group. The Group A underwent open revascularization followed by completion angiography and endovascular intervention on demand according to the result of completion angiogram that consisted of: embolectomy under fluoroscopic guidance done through a mobile c-arm unit (BV Pulsera; Philips Medical system, Netherlands), and using the Embolectomy Catheter over a wire (LeMaitre Vascular, Burlington, MA), treatment of stenotic lesion endovascularly using Balloon dilatation and stenting (Figure 2).

Figure 2: Abnormal angiogram after passage of standard embolectomy 5 French catheter from the right groin with inadequate antegrade flow, angiogram showed filling defects at distal aorta bilateral iliac arteries, the right figure shows the embolus extracted through bilateral femoral exposure.

Group (B): Selective completion angiography group. The Group B (control) underwent surgical embolectomy without routine completion angiography. If the results of the embolectomy were not satisfactory in the same intraoperative session such as: Failure to advance the embolectomy catheter, or obvious satisfactory inflow or backflow, or extraction of intimal fragments. Those patients underwent diagnostic angiography and according to the result of the angiography, the patient might receive an endovascular or surgical intervention.

Intraarterial thrombolysis using Alteplase was used in residual thrombosis in distal runoff vessels, and to enhance the limb perfusion. The indication of intraoperative thrombolysis was based upon Intraoperative angiogram finding and surgeon judgment.

The Surgical procedures which were reserved as bailout solutions in case of failure of endovascular options included: arterial endarterectomy with patch closure, cross femoro-femoral bypass, axillo-uni-femoral or bi-femoral bypass, femro-popliteal bypass, femro-distal bypass, infragenicular exposure, retrograde thrombectomy and fasciotomy.

Outcomes

Definitions: *Technical success:* The procedure was considered technically successful when there was an audible flow signal by Doppler over anterior or posterior tibial arteries recording 30 mmHg at ankle level two hours after the procedure.

Morbidity: Complications related to the procedure.

30 days Mortality: The death rate in the first 30-days post procedure.

Primary patency: The interval between the open procedure and the reintervention due to rethrombosis based on clinical judgment, duplex imaging or CT angiogram.

Limb salvage rate: The interval between the open procedure and the major amputation (either below or above knee amputation).

Outcome measures: *Primary outcomes:* Compare between the comparative groups according to primary patency and limb salvage rates at 12 months.

Secondary outcomes: Compare between the comparative groups according to morbidity and 30-days mortality.

Statistical analysis

The two groups were tested for equal distribution as regard to demographics, risk factors, onset of symptoms and level of occlusion by using t-test (t), or Mann-Whitney test (Z) for continuous variables and Chi-square test (χ^2) for binomial variables. The effect of the routine application of completion angiography were evaluated how it increased primary patency rate (the period until the native artery becomes occluded after our first intervention) and limb salvage rate (the period until the patient performs a major amputation) using the Kaplan Meir curves for survival analysis and log-rank test for detection of any significant differences. To reject the null hypothesis the incidence of probability should be less than 5%. All calculations were performed using SPSS version 20 (IBM Corp, Armonk, NY).

Sample size: Based on the annual admission rate of patients with acute lower limb ischemia who get admitted in our centre where the study was conducted (134 patients per year) in one year with confidence level set at 95%, a minimum sample size of 100 patients equally divided on the two groups of the study was estimated to achieve a study power of 80% with alpha set at 5%.

Method of randomization: Closed envelop method with block allocation five patients in each group.

Results

Group allocation

All these patients are sorted under randomization procedure into 2 groups: Group A, and Group B, patient characteristics for each group were as the following Tables 1 and 2.

	Group A	Group B	Factor	p-value
Number of limbs	50	50	-	-
Mean age ± std deviation	63.5 ± 12	60 ± 16	t=1.262	0.21
Median onset of symptoms (Inter quartile range IQR)	5 days (3-10)	5 days (2.75-10)	Z=0.336	0.737

Table 1: Patient demographics in both groups (continuous variables).

From these previous Tables 1 and 2, we concluded that both groups are normally distributed with regard to age, sex, the onset of symptoms, nature of occlusion, level of occlusion and ischemia severity. There was a significant difference as regard to DVT incidence among Group B with p-value=0.027 while no significant difference as regard to other risk factors (Table 3).

Immediate results

Technical success shown to be 86% in both groups with 84% in Group A and 88% in Group B with no statistical significance between both groups (p-value=0.564), the rate of complete passage of the embolectomy catheter in each group was 46%, the rate of doing completion angiography in Group A was 100% while in Group B 64% (p-value<0.001), the rate of balloon dilatation and stent placement in Group B were higher than Group A without statistical significance (p-value=0.134 and 0.558), the rate of embolectomy under fluoroscopic guidance was slightly higher in Group A with no statistical significance (p-value=0.779), and rate of using embolectomy over a wire was equal on both groups. Lytic therapy was significantly higher in Group A than Group B (p-value=0.027). Patch repair was significantly higher in Group B than Group A (p-value=0.041), while the other surgical interventions (endarterectomy, infra-popliteal exposure, and bypass) were nonsignificant in both groups, the rate of fasciotomy was nonsignificant (p-value=00.695) (Table 4).

	Group A		Group B		χ2	p-value
Patient characteristics	No.	%	No	%		
Gender					0.378	0.539
Male (%)	18	36.00%	21	42.00%		
Female (%)	32	64.00%	29	58.00%		
Nature of occlusion					0.657	0.418
Embolic	23	46.00%	19	38.00%		
Thrombotic	27	54.00%	31	62.00%		
Level of occlusion					6.344	0.274
Aorta	3	6.00%	2	4.00%		
Iliac	5	10.00%	3	6.00%		
Common Femoral	2	4.00%	2	4.00%		
Superficial femoral	26	52.00%	18	36.00%		
Popliteal	14	28.00%	23	46.00%		
Infrapopliteal	0	0.00%	2	4.00%		
Rutherford grading					4.3	0.116
Grade I	9	18.00%	4	8.00%		
Grade IIA	22	44.00%	25	50.00%		
Grade IIB	19	38.00%	21	41.00%		

Table 2: Patient demographics in both groups (binomial variables).

Regarding to mortality rate in the first 30 days, the rate varies from 8% in Group B to 16% in Group A with no significant difference between the two groups (p-value=0.218), the causes of death in Group A were: three due to rapid atrial fibrillation, two due to myocardial infarction, one due to decompensated heart failure, two due to intractable hematuria, and one due to major amputation. While the causes of death in Group B were: one due to cerebral stroke, one due to reperfusion injury, one after major amputation, and one due to pulmonary embolism (Table 5).

	Group A		Group B		χ^2	p-value
Risk factors	No.	%	No.	%		
Smoking	9	18.00%	14	28.00%	1.412	0.235
Arrhythmia	15	30.00%	16	32.00%	0.047	0.829
DM	22	44.00%	23	46.00%	0.04	0.841
HTN	30	60.00%	22	44.00%	2.564	0.109
Valvular heart disease	4	8.00%	2	4.00%	0.709	0.4
Cerebral stroke	5	10.00%	9	18.00%	1.329	0.249
Ischemic heart disease	8	16.00%	6	12.00%	0.332	0.564
PVD	1	2.00%	2	4.00%	0.344	0.558
Congestive heart failure	1	2.00%	2	4.00%	0.344	0.558
Obesity	8	16.00%	7	14.00%	0.078	0.779
Preoperative DVT	1	2.00%	7	14.00%	4.891	0.027*
COPD	1	2.00%	1	2.00%	0	1
Malignant tumor	1	2.00%	0	0.00%	1.01	0.315
TB	1	2.00%	0	0.00%	1.01	0.315
Collagen disease	1	2.00%	0	0.00%	1.01	0.315
Previous acute ischemia	1	2.00%	2	4.00%	0.344	0.558

Table 3: Patient risk factors.

	Group A		Group B		χ2	p-value
	No.	%	No.	%		
Technical success	42	84.00%	44	88.00%	0.332	0.564
Passage of embolectomy catheter						
80-61 cm	23	46.00%	23	46.00%	-	-
60-51 cm	12	24.00%	14	28.00%	-	-
50-31 cm	10	20.00%	11	22.00%	1.487	0.685
30-0 cm	5	10.00%	2	4.00%	-	-
Completion angiography	50	100.00%	32	64.00%	21.951	<0.001*
Endovascular intervention Embolectomy under fluoroscopic guidance	8	16.00%	7	14.00%	0.078	0.779
Fogarty over the wire	7	14.00%	7	14.00%	0	1
Balloon dilatation	7	14.00%	13	26.00%	2.25	0.134
Stent placement	1	2.00%	2	4.00%	0.344	0.558
Lytic therapy	15	30.00%	6	12.00%	4.882	0.027*
Adjunct surgical intervention						
Patch repair	0	0.00%	4	8.00%	4.167	0.041*
Endarterectomy	0	0.00%	1	2.00%	1.01	0.315
Fem-fem bypass	2	4.00%	0	0.00%	2.041	0.153
Fem-pop bypass	0	0.00%	0	0.00%	-	-
Interposition graft	1	2.00%	0	0.00%	1.01	0.315
Axillofemoral bypass	0	0.00%	0	0.00%	-	-
Popliteal exposure	2	4.00%	1	2.00%	0.344	0.558
Fasciotomy	4	8.00%	3	6.00%	0.154	0.695

Table 4: Immediate results.

	Group A		Group B		χ^2	p-value
	No.	%	No.	%		
30 days mortality rate	8	16.00%	4	8.00%	1.515	0.218
Cause of mortality						
Myocardial infarction	2	25.00%	0	0.00%	1.2	0.273
Cardiac arrhythmia	3	37.50%	0	0.00%	2	0.157
Cerebral stroke	0	0.00%	1	25.00%	2.182	0.14
Reperfusion syndrome	0	0.00%	1	25.00%	2.182	0.14
Post-amputation	1	12.50%	1	25.00%	0.3	0.584
Hematuria	2	25.00%	0	0.00%	1.2	0.273
Pulmonary embolism	0	0.00%	1	25.00%	2.182	0.14

Table 5: 30 days mortality in both groups.

The rate of cardiac complications (arrhythmia, myocardial infarction, and decompensated heart failure) was more in Group A but didn't reach statistical significance (p-value>0.05), cerebral strokes were noticed in two patients in Group B but with no significant difference, the incidence of hematuria was 6% in Group A (p-value=0.079), a case of reperfusion syndrome reported in Group B and was the cause of death in this patient, the contrast-induced nephropathy didn't develop at any group (Figures 3 and 4).

As regard to local complications; postoperative hematoma incidence, surgical site infection, and compartmental syndrome were more in Group A with mo statistical significance (p-values=0.307, 0.307, 0.695), while rate of arterial perforation and pseudoaneurysm formation were more in Group B with no statistical significance (p-value=0.646), there were no cases reported with postoperative bleeding or arteriovenous fistula (Table 6).

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Figure 3: Completion angiogram revealed extravasation of the dye outside the tibioperoneal trunk, patient developed compartmental syndrome on table, immediate exposure over tibioperoneal trunk and direct repair of small hole and release of four leg compartment were done.

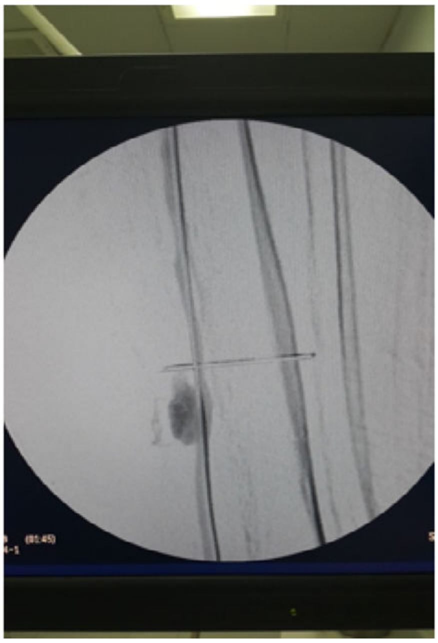

Figure 4: Completion angiogram revealed arterial perforation and pseudoaneurysm formation at the middle third of posterior tibial artery.

	Group A		Group B		χ^2	p-value
	No.	%	No.	%		
Morbidity						
Cardiac arrhythmia	1	2.00%	0	0.00%	1.01	0.315
Myocardial infarction	2	4.00%	0	0.00%	2.041	0.153
Cardiac failure	2	4.00%	0	0.00%	2.041	0.153
Cerebral stroke	0	0.00%	2	4.00%	2.041	0.153
Reperfusion syndrome	0	0.00%	1	2.00%	1.01	0.315
Pulmonary embolism	0	0.00%	1	2.00%	1.01	0.315
Hematuria	3	6.00%	0	0.00%	3.093	0.079
Contrast induced nephropathy	0	0.00%	0	0.00%	-	-
Hematoma	3	6.00%	1	2.00%	1.042	0.307
Surgical site bleeding	0	0.00%	0	0.00%	-	-
Surgical site infection	3	6.00%	1	2.00%	1.042	0.307
Arterial perforation (Figure 5)	2	4.00%	3	6.00%	0.211	0.646
Compartmental syndrome (Figure 4)	4	8.00%	3	6.00%	0.154	0.695
Arteriovenous fistula	0	0.00%	0	0.00%	-	-

Table 6: Morbidity rates in both groups.

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Late results

Patients were followed up for 12 months in each group, follow-up was based on clinical examination to exclude any signs of acute ischemia with measurement of ankle peak systolic pressure, if less than 30mmHg a decision for reintervention was made, if there was non-viable limb a decision for amputation was made. Long-term results divided into primary patency of arterial tree after embolectomy and limb salvage rates (Table 7).

	Group A (N=50)		Group B (N=50)	
	No	%	No	%
Completed 12 months of follow-up	24	48%	25	50%
Died during follow-up	13	26%	6	12%
Lost during follow-up	13	26%	19	38%

Table 7: Patient status during 12 months of follow-up.

Primary patency

Using the Kaplan Meier survival analysis the two groups were tested for any significant to reject the null hypothesis, when log-rank test applied it showed no significant difference between two groups as regard to primary patency rates at 12 months which were 73% in Group A and 85% in Group B (Figure 5 and Table 8).

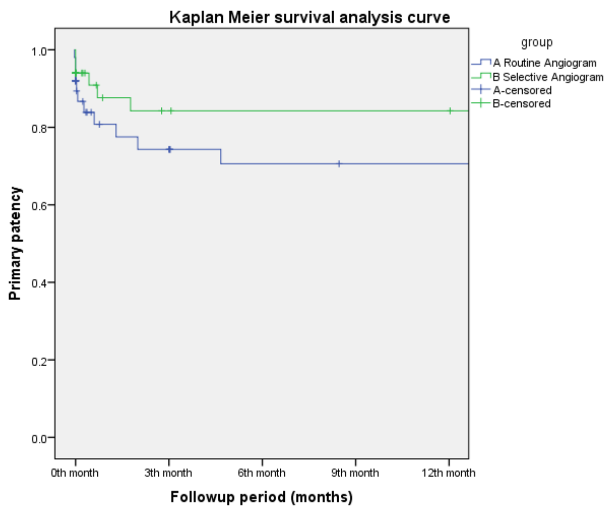

Figure 5: Kaplan Meier survival analysis curve.

	Chi-Square	Difference	Significance
Log Rank (Mantel-Cox)	1.095	1	0.295

Table 8: Log-rank test for comparison of primary patency between both groups.

Limb salvage rates

Using the Kaplan Meier survival analysis the two groups were tested for any significant to reject the null hypothesis, when log-rank test applied it showed no significant difference between two groups as regard to Limb salvage rates at 12 months which were 85% in Group A and 92% in Group B (Figure 6 and Table 9).

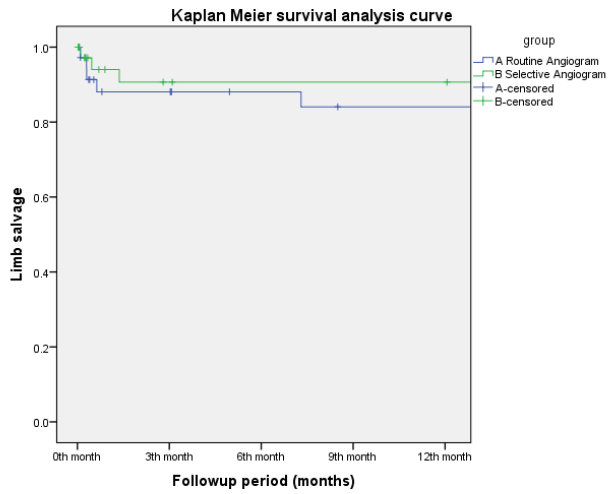

Figure 6: Kaplan Meier survival analysis curve.

	Chi-Square	Difference	Significance
Log Rank (Mantel-Cox)	0.164	1	0.685

Table 9: Log-rank test for comparison of limb salvage between both groups.

Discussion

The use of fluoroscopic imaging as a visual feedback for embolectomy to increase the effectiveness of the procedures was first reported by Parsons and his colleagues using canine models in 1996, and reported by Lipsitz and Veith in humans in 2001 [10,11]. This point of research based on many studies that used the intraoperative diagnostic procedures like conventional angiography, angioscope, and intravascular ultrasound found residual thrombosis attached to the arterial walls after embolectomy [12,13], this made many authors conclude that routine angiography should be done after open revascularization [14-16].

In 2010, Zaraca and his colleagues reported on 380 cases of acute ischemia of the lower limb went for embolectomy in the past 12 years, intraoperative angiogram was done from 1991 to 1997 on selective basis (inadequate backflow, failure to advance the embolectomy catheter distally) including 216 cases (Group A), and were done from 1998 to 2003 routinely in 164 cases (Group B), both groups were equally distributed regarding age, gender and risk factors, transluminal angioplasty was done in 7.2% of Group A while was done in 17.2% in Group B, after 2 years of follow-up, the completion angiogram lead to significant increase in the primary patency in Group B when it was used routinely (P=0.001), but no significant difference was detected between both groups in terms of limb salvage (P=0.72) [16].

In our study we reported on 100 cases went for embolectomy in one year, intraoperative angiogram was done on routine basis in 50 cases

(Group A) and selectively (inadequate backflow, failure to advance the embolectomy catheter distally, extraction of intimal segments) in 50 cases (Group B), both groups in spite of randomization were equally distributed according to age, gender and risk factors except for the incidence of deep vein thrombosis which was significantly higher in Group B (P=0.027), angioplasty was done in 26% of cases on Group B and 14% of the cases in Group A, after 12 months of follow-up, there was no statistical significance between both groups as related to primary patency (P=0.295) and limb salvage (P=0.685).

This prospective randomized clinical trial is an important trial dealing with limb salvage in acute limb ischemia, its design allowed to answer one of the important questions facing the vascular surgeon in operative theatre after doing open embolectomy, do we need a confirmatory angiogram after each case or better save this option for selected cases. The design of the study allowed the use of endovascular techniques in both groups whenever needed, based on the result of the angiogram. The randomization process led to exclude any selection bias, without affecting the ethical consideration for preventing any of the two groups from getting the benefit of endovascular option whenever needed.

Technical success of our center compared to our reporting showed 86% in both groups and this was attributed to the usage of endovascular techniques besides the use of completion angiogram as compared to previous studies, taking into consideration that the onset of symptoms was reported as 86% of the patient were presented more than 24 hours and median onset of 5 days, this has turned many cases into challenging situations and led to increase the perioperative mortality that ranged from 8% to 16% in our study, while most reports ranged from 5% to 12% [1,17].

Although the outcomes of both modalities were not significant, the higher rate of patency was in the group that used the angiogram on selected bases, and this seemed to be a cost-effective protocol in countries with limited resources; however, this outcome may be related to the small sample size, the high mortality rate, or the high number of patients missed during follow-up, hopefully in the near future further studies may reveal this truth clearly.

In our study the results showed patency and limb salvage rates quite similar to the previous studies despite the lack of logistics and the late presentation of some cases, a lot of efforts are being made in our center to increase the follow-up efficacy, provide healthcare resources and raise the medical awareness for acute limb ischemia in the community. We recommend recruitment of more patients, raising research funds and collaborating with other centers to increase the level of evidence in the future studies.

Conclusion

Completion angiography after open revascularization is a useful modality and improves the outcomes of acute limb ischemia management; however, it can be done on selective criteria and not routinely without affecting the long term patency.

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