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ORIGINAL ARTICLE

Evaluation of role of Endovascular Intervention in Treatment of Patients with Critical Lower Limb Ischemia

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ABSTRACT

Objective: The aim of this work is to evaluate the role of endovascular intervention in limb revascularisation , wound healing , pain relief and limb salvage for patients complaining from critical lower limb ischemia (CLI) in the vascular surgery department in Zagazig university hospitals.

Methods: This is a Prospective cohort study. The study was carried on Zagazig university Hospitals .

Sample size: Assuming that attendance rate of patients with CLI in vascular surgery department is 3/month so total total sample were 18/6months (period from September 2018 till February 2019) .

Conclusion: Endovascular intervention is considered a safe and efficient technique in the treatment of critical limb ischemia, the technique has many advantages over open surgical procedure , being tolerable, easy, safe and effective with general anaesthesia avoidance and has low mortality and morbidity .

Key words; Critical Limb Ischemia, Percutaneous trans-luminal angioplasty, Peripheral vascular disease

INTRODUCTION

Critical limb ischemia (CLI) is serious and complicated stage of peripheral arterial disease (PAD) , defined by appearance of ischemic rest pain or tissue loss reflecting the development of serious condition due to severe affection of limb perfusion. Comparing with other manifestation of PAD, intermittent claudication, CLI has a bad prognosis within a year after the initial diagnosis, with 1-year amputation rates about 12% and mortality about 50% at 5 years and 70% at 10 years[1].

CLI incidence is estimated to be 500 to 1000 per million / year in europe, with rates suspected to be high as risk factors such as DM, smoking and metabolic syndrome increase worldwide. Without revascularization 20% to 40% will require major amputation (above knee amputation or below knee amputation)[2].

CLI is threatening condition that requires immediate intervention to revascularise the affected segments (stenosis or occlusion).Treatment for CLI can be complex and variable, but the golden goal should always be to relieve the pain and increase limb perfusion to save the leg , improve quality of life and prevent major amputations[3].

Treatment options for CLI include modifying risk factors, revascularization via bypass grafting or angioplasty, and wound debridement for tissue loss [4].

Endovascular intervention is the least invasive option involving insertion of catheter into the artery to allow access to diseased part of the artery (stenosis or occlusion) including percutaneous angioplasty , atherectomy and stenting . in the last 2 decades there is increased rate of endovascular intervention more than four-folds[5].

Percutaneous angioplasty and stenting of the PAD is the best treatment of choice in most cases of patients with CLI due to reduced complications, morbidity, mortality, and reduced in-hospital stay and cost[6].

Percutaneous transluminal angioplasty (PTA) has the advantage of being less cost and simpler than stent. PTA doesn`t use foreign body that may increase risk and possibility for intimal hyperplasia. PTA prevent material fatigue and fractures associated with stents. In addition, the possibility of re-intervention in the diseased segments that previously treated ny PTA .The presence of stent may prevent re-intervention . Moreover, PTA secures collaterals that may be affected by stent placement[7].

now, several new techniques like bare metal stents made from nitinol, drug-eluting stents , covered stents, and drug-coated balloons that aim to increase patency rates , blood flow, limb salvage and quality of life [1].

PATIENTS AND METHODS

This is a Prospective cohort study. The study was carried on Zagazig university Hospitals. Assuming that attendance rate of patients with CLI in vascular surgery department is 3/month so total accessibility sample were 18/6months (period from September 2018 till February 2019) .

Written informed consent was obtained from all participants and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria of the patients included in the study:

Patients age more than 30years old with critical lower limb ischemia .

Exclusion criteria :

Patients with a history of contrast allergy,
Patients below 30 years old .
patients with impaired renal functions.
Patients with acute ischemia.

Methodology:

All patients were subjected to:

Patient history:

All subjects gave a complete full history taking including demographic features (age and sex), clinical variables (site of lesions, severity, duration, family history) disease and smoking habits.

Angioplasties were performed by vascular surgeons. Clinical indications will include symptomatic peripheral arterial disease with rest pain, ischemic ulcers, or ischemic tissue loss/gangrene (Rutherford stages 3–6).

Procedure and hospitalization:

All patients with inclusion criteria underwent a baseline clinical examination to collect all data before the intervention. It includes medical history, drug record, physical examination and clinical picture of critical limb ischemia according to the Rutherford classification.

The baseline vascular risk factors were history of smoking, presence of arterial hypertension, diabetes mellitus, renal insufficiency (s. creatinine ≥ 1.2 mg/dL in males or ≥ 0.9 mg/dL in females), hypercholesterolemia (total cholesterol ≥ 190 mg/dL)and cardiac problems. Evidence of disease was assessed by color-flow duplex ultrasound scan and CT angiography.

Interventions details:

Arterial Access:

Antegrade, ipsilateral technique :- puncture in CFA is preferred.If the lesion is very close to origin of SFA this technique is not preferred.

Contralateral femoral technique :- performmed through across over sheath in very close lesion.

Retrograde ipsilateral technique :- puncture of the popliteal artery in case of SFA occlusion flush with the vessel origin and patent popliteal artery.

Access from the upper limb approach :- usually using the lower brachial artery access.

Angiography using contrast medium.

Crossing the Lesion:

The standard tools for revascularizion of the lesions consist of using hydrophilic guidewire and catheter.

After crossing the wire through the diseased artery , the catheter advanced beyond the lesion then removal of the wire followed by injecting the contrast to image the whole artery.

Deploying the Balloon/Stent:

Angioplasty:

A balloon catheter with appropriate caliber and length, is advanced over the wire crossing the distal extent of the lesion (or proximal lesion if the approach using the popliteal artery).

Inflate the balloon till available inflation power . The inflation time is not standard. Inflation times vary from 1 minute to a few minutes.

Prior to inflation , we should inform the patients that they may experience some pain that not severe.

Stent Insertion:

In case of full inflation, but the stenosis persists, indicating elastic recoil, we should insert appropriate stent according to diameter.

In case of a flow-limiting dissection, prolonged balloon inflation should be done to take the flap back to its site. In this case the balloon is kept inflated for up to 5 min. If this fails, a stent is indicated if the flap didn`t come back with prolonged balloon inflation.

Thus, recognized indications for stent insertion in the diseases segment are:

Elastic recoil after PTA. Flow-limiting dissection. Residual stenosis more than 30%.

Subintimal angioplasty:

Usually a transluminal approach is intended to be used in all patients. Anyhow, sometimes the intraluminal approach fails and the technique of the subintimal approach can be used. It is important to notice that with subintimal approach a reentry device may be used to reenter the true lumen again.

Endpoint:

The endpoint of the technique is continuous forward flow of contrast with no evidence of significant (>30%) residual stenosis.

We should exclude distal embolization that may caused by procedure by assessment of The run-off vessels.

After completion of procedure , we should remove the access sheath followed by strict manual compression for full haemostasis and prevent formation of haematoma with serious complications.

After revascularization, we should perform debridement of all necrotic tissues .

Primary outcome parameters:

Technical success proved by completion angiogram.

Distal pulse retrieval.

Secondary outcome parameters:

Limb Salvage.

relief of the rest pain.

Healing of the wounds.

Follow-up:

patients were assessed at follow up visits on clinical basis (pain relief), duplex u/s scan follow up and wound healing at 1 month and 6 months after procedure. Data is collected in table form sheets and analysis will be done regarding all aspects of the procedures, results and complications.

Statistical analysis:

Continuous variables were presented as the mean±SD if normally distributed or median(range) if not normally distributed. Normality was checked by Kolmogorov-Smirnov test. Homogeneity of variance was checked by Levene's test.

Categorical variables were presented by the count (percentage).

Fisher's Exact Test: for (2X2) (RXC). It is an alternative to chi-squared test to discover if there is a relationship between two categorical variables when the expected cell count is less than five.

Independent-samples t-test: is used to determine if a difference exists between the means of two independent groups on a continuous dependent variable.

Mann-Whitney *U* test (nonparametric alternative to independent-samples t-test).

Threshold for significance: *P*-value <.05 indicates a significant difference, *P*≤.01 indicates a highly significant difference, *P*≤.001 indicates a very highly significant difference while, *P*≥.05 indicates a non-significant difference.

RESULTS

The 18 patients included in our study with Clinical indications that included symptomatic peripheral arterial disease with ischemic rest pain, ischemic ulceration, or ischemic tissue loss/gangrene (Rutherford stages 4–6).

Regarding demographic characteristic: The largest percentage of the studied patients was male (77.8%) with age ranged from 51 to 73 years old .Their mean age was 61.67 years ,as shown in table 1.

Regarding risk factors: All of the studied patients were diabetics, half of them were hypertensive. Two thirds of them were smokers. The largest percentage of them had positive history of coronary heart disease and hyperlipidemia, as shown in table 2.

Regarding clinical presentation: The largest percentage presented with rest pain followed by gangrene, as shown in table 3.

The largest percentage of the studied patients had SFA involvement, as shown in table 4.

the overall limb salvage in our study was (83.3%) while 3 (16.7%) underwent major amputations.

2 patients (11%) undervent complications while 1 patient had distal SFA artery perforation and 1 patient had hematoma at the access site, as shown in table 7.

Regarding wound healing and pain relief; at 1 month ,7 patients showed good healing while 3 patients did not, 9 patients reported pain relief. After 6 months follow up(after exclusion of mortality and amputation) 4 patients showing good healing while 3 patients showing poor healing ,9 patients showing pain relief , as shown in table 6.

The overall patency rate after 1month and 6 months follow up was 77% and 72% respectively.

Tables

Table (1) distribution of the studied patients according to demographic characteristic:

	N	**%**
Gender**:**		
Male	14	77.8
Female	4	22.2
	Mean ± SD	**Range**
Age (years)	61.67 ± 5.93	51 - 73

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Table (2) distribution of the studied patients according to risk factors:

	N	%
Diabetes mellitus**:**		
No	0	0
Yes	18	100
Hypertension**:**		
No	9	50
Yes	9	50
Smoking:		
No	6	33.3
Yes	12	66.7
CHD:		
No	7	38.9
Yes	11	61.1
CVS:		
No	15	83.3
Yes	3	16.7
Hyperlipidemia:		
No	8	44.4
Yes	10	55.6
LDL (10):		
Mean± SD	131.8 ±11.49	
Range	110 - 145	

Table (3) distribution of the studied patients according to clinical presentation:

	N	%
Presentation**:**		
• Ulcer	1	5.6
Rutherford category 6		
Heel		
• Rest pain	9	50
Rutherford category 4		
• Gangrene	8	44.4
Rutherford category 6	2	25
Big toe	1	12.5
2nd toe	2	25
4th and 5th toes	2	25
Heel	1	12.5
Sole		

Table (4)distribution of the studied patients according to revascularized artery

	N=41 artery	%
Artery :		
CIA		
Left	6	115
Right	2	3.8
EIA		
Left	6	11.5
Right	2	3.8
SFA		
Left	6	11.5
Right	5	9.6
ATA		
Left	2	3.8
Right	2	3.8
PTA		
Left	4	7.7
Right	3	5.8
Left peroneal	2	3.8
Right POP	1	1.9

Table (5) comparison between the groups of patients subjected to different angioplasty techniques and risk factors:

	Balloon dilatation	Stent	X^2	P
	N (%)	N (%)		
Diabetes:				
No	0 (0)	0 (0)	0	1
Yes	11 (100)	7 (100)		
Hypertension :				
No	6 (54.5)	3 (42.9)	Fisher	1
Yes	5 (45.5)	4 (57.1)		
Smoking :				
No	3 (27.3)	3 (42.9)	Fisher	0.627
Yes	8 (72.7)	4 (57.1)		
CHD :				
No	5 (45.5)	2 (28.6)	Fisher	0.637
Yes	8 (54.4)	5 (71.4)		
CerebroVascular Stroke :				
No	11 (100)	4 (57.1)	Fisher	0.043*
Yes	0 (0)	3 (42.9)		
Hyperlipidemia:				
No	7 (63.6)	1 (14.3)	Fisher	0.066
Yes	4 (36.4)	6 (85.7)		

Table (6) comparison between the groups of patients subjected to different angioplasty techniques regarding followup:

	Balloon dilatation	Stent	X^2	P
	N (%)	N (%)		
One month patency:				
No	1 (9.1)	3 (42.9)		
Yes	10 (90.9)	4 (57.1)	Fisher	0.245
Six months patency:				
No	2 (18.2)	3 (42.9)	Fisher	1
Yes	9 (81.8)	4 (57.1)		
	0.182	0.142		
Healing at 1 month:				
Poor	2 (33.3)	1 (25)	Fisher	1
Good	3 (66.7)	3 (75)		
Healing at 6 months:				
Poor	2 (50)	1 (33.3)	Fisher	1
Good	2 (50)	2 (66.7)		
Pain at 1 month:				
Not relieved	0 (0)	0 (0)	0	1
Relieved	5 (100)	4 (100)		
Pain at 6 month:				
Not relieved	0 (0)	0 (0)	0	1
Relieved	5 (100)	4 (100)		

Table (7) comparison between the groups of patients subjected to different angioplasty techniques regarding complications:

	Balloon dilatation	Stent	X^2	P
	N (%)	N (%)		
Complications:				
No	10 (91)	6 (86)	Fisher	1
Yes	1 (9)	1 (14)		
Prevention of amputation (limb salvage)				
No	1 (9.1)	2 (28.6)	Fisher	0.528
Yes	10 (90.9)	5 (71.4)		
Mortality :				
No	9 (81.8)	6 (85.7)	Fisher	1
Yes	2 (18.2)	1 (14.3)		

DISCUSSION

Critical limb ischemia (CLI) is one of the most widespread PAD that leads to significant morbidity and mortality. The outcomes of developing CLI are often severe, from both economic and health -related quality-of-life stand points; even after revascularization. At one year, about one third of patients have undergone amputation, only 25% of patients have resolution of their symptoms, 20%

continue to have symptoms, and 25% are dead[8].

The objectives of treatment of CLI are to provide sufficient blood flow to relive rest pain symptoms, to heal skin lesions, and ultimately prevention of the most annoying complication that is major amputation. These objectives can be achieved by either surgical bypass or endovascular procedure. The ideal revascularization procedure is the one that avoid general anesthesia, has a lesser systemic stress, and has fewer serious complications[9].

For patients with CLI, surgical bypass grafting (preferably with saphenous vein) remains the best option of long term revascularization, with 5-year limb salvage rates exceeding 80% in patients presenting with a non-healing ulcer or rest pain[10].

To date, there is still a debate on the best strategy between open surgery and endovascular revascularization. Some studies discussed that angioplasty has shown good results in term of short-term survival, limb salvage and complications which favorably made angioplasty as a tempting first-choice treatment in CLI patients especially for infrainguinal lesions[11].

This study was designed to evaluate the role of endovascular intervention on limb salvage, wound healing, and pain symptoms relief.

Regarding patients' characteristics, in our study the majority of cases were male (77.8%) with mean age of 62 years old.

A look into the patients' characteristics in the meta- analysis done by **Antoniou et al.**[13] revealed that the average of male gender was 75.2% and the mean age of all patients included in the study was 70 years old.So, the percent of male gender in our study was comparable to other studies on patients with symptomatic chronic occlusive lower limb ischemia. On the other hand, we had lower mean age. This could be explained by the fact that we are a developing country with low health care standards in comparison to the developed countries and that leads to low life expectancy in the general population. As regard to patency; in our study at 1 month follow-up, the rate of patency as assessed with Duplex scan was observed in 90.9% (10/11) of the patients who managed with dilatation alone that declined to 81.8% (9/11) after 6 months follow up.

On the other hand, in stented patients ; 57.1% (4/7) of patients continued with open vessels at 1 month follow up that did not change after 6 months duplex screen.

This difference in patency is attributed to the aggressive nature of occlusive lesions and early intimal hyperplasia in stenting group.

Regarding salvagability ,**Brosi et al.** [11] mentioned the symptomatic outcome after PTA procedure.In patients presenting with rest pain without foot ulcer, the disappearance of pain was considered limb salvage successful. In patients with foot ulcers we considered limb salvage successful when the rest pain, if formerly present, disappeared and the plantar stand was maintained, even when achieved by a tarsal-metatarsal amputation.Any above-the-ankle amputation, including the Syme amputation, was considered a failure. The overall limb salvage in our study was (83.3%) while 3 (16.7%) underwent major amputations. The reason beneath the fact that the limb salvage is higher than patency rates is that all of the cases had critical limb ischemia and endovascular intervention may provide sufficient blood supply needed for healing then by the time the vessels is occluded the demand of blood supply is decreased and the collateral developed is enough for the tissue viability.

This was in concordance with the overall limb salvage reported by **Antoniou et al.**[13] at 1 year follow up of 89.1% .

In our study, 3 (16 %) patients died within 1 month after procedure As regard **Antoniou et al.**[13] showing that 1 patient (0.9%) of 111 patients died within 1 month.

CONCLUSION

Endovascular intervention is considered a safe and efficient technique in the treatment of critical limb ischemia, the technique has many advantages over open surgical procedure , being tolerable, easy, safe and effective with

general anaesthesia avoidance and has low mortality and morbidity .

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