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Endovascular versus Open Surgical Reconstruction in Long Segment Superficial Femoral Artery Occlusive Disease

Ayman Ahmed Talaat, Ramez Mounir Wahba, Ahmed Ashraf Kamel
Department of General Surgery, Faculty of Medicine, Ain Shams University
Corresponding author: Ahmed A. Kamel, Mobile: 01005100357; Email: ahmad.fouda777@gmail.com

ABSTRACT

Background: The concept of endovascular intervention has been well supported by the continuous advance in technology in long segment (superficial femoral artery) SFA occlusions. The rapid evolution of stent design, deployment approaches and adjunctive therapy made the practice of (percutaneous transluminal angioplasty) PTA safer and more predictable and has reduced superficial femoral artey surgery.

Objectives: To compare the safety and effectiveness of endovascular treatment versus open surgical bypass in treatment of superficial femoral artery occlusive disease.

Patients and Methods: This prospective study included 30 patients presenting to the Vascular Department in Cairo University Hospitals with femoropopliteal occlusive disease for whom percutaneous transluminal angioplasty with or without stenting was done for 15 cases. Femoropopliteal bypass surgery with saphenous or synthetic graft was done for 15 cases between March 2017 and January 2018. The procedure, possible complications, benefits, risks and other alternative interventions were all explained to the patients and an informed consent was obtained.

Results: In endovascular cases: 1/15(6.66%) cases, developed small haematoma at the site of puncture which resolved by conservative management. After 6 months follow up,6/15 cases (40%) had intact pedal pulsation, 6/15 cases (40%) had popliteal pulsation with marked improvement of their complaints (disappearance of rest pain in 3 cases, the other 3 cases which had gangrene, line of demarcation appeared). 1/15 case (6.66%) showed popliteal pulse at 3 months follow up which disappeared at 6 months but the patient had good circulation with improvement of rest pain. So, successful cases were 13/15(86.66%) at 6 months follow up. 2 /15 cases(13.33%) showed occlusion, by Duplex 1 case of them showed occlusion of stent and 1 case showed return to original occlusion. **In open surgical cases:** Postoperative wound infection at groin incision developed in 3/15(20%) cases, 2 cases of them were managed conservatively by IV antibiotic and repeated dressing, and one developed secondary haemorrhage in which ligation of femoral artery was done and the limb became gangrenous and Above knee amputation was done. After 6 months follow up, 5/15 cases (33.33%) had intact pedal pulsation, 7/15 cases (46.66%) had popliteal pulsation with marked improvement of their complaints. Disappearance of rest pain occurred in 3 cases, while 3 cases which had gangrene, line of demarcation appeared and 1 case which had non healing ulcer, healing of ulcer started to occur. So successful cases 12/15(80%) at 6 months follow up. Thus, 3/15 cases (20%) failed, 1 case developed wound infection at groin incision followed by secondary haemorrhage in which ligation of the graft was done, the limb was worsen ended in above knee amputation. The other 2 cases showed occlusion of graft, 1 case ended in above knee amputation, the other below knee amputation was done in which the stump became gangrenous followed by above knee amputation.

Conclusion: Percutaneous transluminal angioplasty (PTA) has obtained a definite place in the management of peripheral arterial occlusive disease of the lower limb. It was widely accepted as a first line of treatment for many patients with SFA occlusive disease. The low complication rate and relatively non-invasive nature of PTA made it an increasing popular intervention.

Keywords: Percutaneous transluminal angioplasty, Peripheral vascular disease, SFA lesions, Bypass surgery.

INTRODUCTION

The SFA remains the most difficult peripheral artery in which to maintain reliable long-term patency despite the rapidly increasing availability of endovascular therapy tools. This paradox is most likely a result of its long course within the adductor canal, which exposes it to unique mechanical forces unlike any other vascular territory [(1)]. It is more prone to the development of advanced atherosclerotic lesions than other vessels [(2)].

The concept of endovascular intervention has been well supported by the continuous advance in technology. The rapid evolution of stent design, deployment approaches and adjunctive therapy made the practice of PTA safer and more predictable and has reduced the incidence of procedure related adverse events in long segment SFA lesions, particularly the need for emergency surgery.

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AIM OF THE WORK

The aim of the work is to compare the safety and effectiveness of endovascular treatment versus open surgical bypass in treatment of superficial femoral artery occlusive disease.

PATIENTS AND METHODS

This prospective study included 30 patients presenting to the Vascular Department in Cairo University Hospitals with femoropopliteal occlusive disease. Percutaneous transluminal angioplasty with or without stenting was done for 15 cases and femoropopliteal bypass surgery with saphenous or synthetic graft was done for the other 15 cases between March 2017 and January 2018.The procedure, possible complications, benefits, risks and other alternative interventions were all explained to the patients and an informed consent was obtained.

Methodology: ***Clinical assessment:*** History taking and clinical examination was done for all patients including: Age and gender. Major risk factors for atherosclerosis including; diabetes mellitus, smoking, hypertension and ischemic heart disease. **The study was approved by the Ethics Board of Ain Shams University.**

Pre-procedural investigations: Routine laboratory tests: complete blood picture, kidney and liver function tests, coagulation profile, blood glucose level and lipid profile. Duplex scanning: patients were scheduled for duplex scanning before intervention and at 6 months follow up. The following measures were taken: Anatomical site, occlusion or stenosis (single or multiple). Runoff status distal to the affected segment. New lesions detected at follow up.

Selection criteria for our study: **Inclusion criteria:** Incapacitating claudication interfering with the work or lifestyle. Critical limb ischemia (ischemic rest pain, minor tissue loss, non healing ulcer or focal gangrene). Patients with lesions TASC type C (Multiple stenosis or occlusions totaling>15 cm with or without heavy calcification or recurrent stenosis or occlusions that need treatment after two endovascular interventions). **Exclusion criteria:** Proximal aorto-iliac disease or infrapopliteal disease. Known intolerance to study medications or contrast agents. Non salvageable limb.

In endovascular cases: all cases sheath number 6 French (6F) was used. The ipsilateral femoral approach was used in 10/15(66.66%) limbs and the contralateral (crossover) approach was used in 5/15(33.33%) limbs. Balloon angioplasty was done in all cases treated by endovascular management (15 limbs). Stenting was carried out in 12/15 (80%) patients, 2 stents were placed in 3/15(20%) cases.

In open surgical cases: reversed Saphenous vein graft used in 9/15(60%) of cases and synthetic graft used in 6/15(40%) of cases.

RESULTS

In endovascular cases: 1/15(6.66%) case, developed small haematoma at the site of puncture which resolved by conservative management.

After 6 months follow up, 6/15 cases (40%) had intact pedal pulsation, 6/15 cases (40%) had popliteal pulsation with marked improvement of their complaints (disappearance of rest pain in 3 cases, the other 3 cases which had gangrene, line of demarcation appeared). 1/15 case (6.66%) showed popliteal pulse at 3 months follow up which disappeared at 6 months but the patient had good circulation with improvement of rest pain. So, successful cases 13/15(86.66%) at 6 months follow up. 2/15 cases (13.33%) showed occlusion, by Duplex 1 case of them showed occlusion of stent and 1 case showed return to original occlusion.

In open surgical cases: Postoperative wound infection at groin incision developed in 3/15 (20%) cases, 2 cases of them were managed conservatively by IV antibiotic and repeated dressing, and one developed secondary haemorrhage in which ligation of femoral artery was done and the limb became gangrenous and Above knee amputation was done.

After 6 months follow up, 5/15 cases (33.33%) had intact pedal pulsation, 7/15 cases (46.66%) had popliteal pulsation with marked improvement of their complaints (disappearance of rest pain in 3 cases, other 3 cases which had gangrene, line of demarcation appeared,1 case which had non healing ulcer, healing of ulcer started to occur). So, successful cases 12/15(80%) at 6 months follow up.

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Table (1): Master table of endovascular cases

	age	Sex	Risk factor	Lesion	Presentation	Acces site	Sheath size	PTA	Stenting	complication	Result Oday	Result 3 months	Result 6 months
Case 1	55	M	D	Rtsfa	Rest pain	Retrograde	6F	Yes	2 stents	-	Pedal	Pedal	Pedal
Case2	49	M	D,H	Rtsfa	Rest pain	Antegrade	6F	yes			Pedal	Pop	Absent pop,good circulation
Case3	64	M	D	Rtsfa	Gangrene	Antegrade	6F	yes	Yes	-	Pedal	Pop	Pop
Case4	52	M	D	Rtsfa	Rest pain	Antegrade	6F	yes	Yes	-	Pedal	Occlusion	Occlusion
Case5	54	M	H	LTsfa	Rest pain	Antegrade	6F	yes	2 stents	-	Pedal	Pedal	Pop
Case6	51	M	H	Rtsfa	Rest pain	Antegrade	6F	yes	Yes	Small haematoma	Pedal	Pop	Pop
Case7	72	F	D,H,C	Rtsfa	Gangrene	Antegrade	6F	yes	Yes	-	Pedal	Pop	Pop
Case8	57	F	D	LTsfa	Ulcer	Retrograde	6F	yes	-	-	Pedal	Pedal	Pedal
Case9	52	M	D	Rtsfa	Rest pain	Antegrade	6F	yes	2 stents	-	Pedal	Pedal	Pedal
Case 10	62	M	D,C	Rtsfa	Ulcer	Retrograde	6F	yes	Yes	-	Pedal	Pedal	Pedal
Casell	67	M	-	LTsfa	Gangrene	Antegrade	6F	yes	-	-	Pedal	Occlusion	Occlusion
Casel2	54	M	D	Rtsfa	Rest pain	Antegrade	6F	Yes	Yes	-	Pedal	Pedal	Pop
Casel3	64	F	D,C	Rtsfa	Gangrene	Antegrade	6F	Yes	Yes	-	Pedal	Pop	Pop
Casel4	59	M	D,H,C	Rtsfa	Rest pain	Retrograde	6F	yes	Yes	-	Pedal	Pedal	Pedal
Casel5	53	M	D,H	Rtsfa	Rest pain	Retrograde	6F	yes	Yes	-	Pedal	pedal	Pedal

Table (2): Master table of open surgical cases.

	Age	Sex	Risk Factor	Lesion	Rest pain	Ulcer	Gangrene	Saphenous	synthetic	Complication	Result0 day	Result 3 months	Result 6 months
Case 1	53	M	H	LTsfa	Yes				Yes		pedal	pedal	Pedal
Case2	51	F	D	LTsfa		yes		Yes			pedal	Pop Healing ulcer	Pop Healed ulcer
Case3	63	M	D, H	Rtsfa	Yes				Yes	Wound infection	pedal	Pedal	Pedal
Case4	67	M	-	LTsfa	Yes	-	-	Yes	-	-	Pop	Pop	Pop
Case5	55	F	D,H,C	LTsfa	Yes			Yes			pedal	Pedal	Pedal
Case6	57	F	-	LTsfa	-	-	yes		Yes-	-	Pop	Pop	Pop
Case7	80	M	D	LTsfa	-	-	yes	Yes	-	-	pedal	Pop	Pop
Case8	39	F	D, H,C	Rtsfa	Yes			Yes		Wound infection	pedal	Pedal	Pop
Case9	62	M	D	LTsfa	Yes	-	-	Yes	-	-	Pop	Pop	Pop
Case 10	46	F	D	Rtsfa	Yes				Yes	Wound infection	pedal	Ligation	AKA
Case 11	58	M	D, H	Rtsfa			yes		Yes		pedal	Pedal	Pedal Forefoot amputation
Case 12	46	F	D	LTsfa			yes	Yes			pedal	Occlusion	BKA
Case 13	50	M	D, H	LTsfa	Yes			Yes			pedal	Pedal	Pedal
Case 14	54	F	D,C	Rtsfa	Yes	-	-	Yes	-	-	Pop	Occlusion	AKA
Case 15	56	M	D	Ltsfa			Yes		Yes		Pop	Pop	Pop

Table (3): Main clinical features of endovascular cases at follow up

No.of patients	Duration	Outcome
1(6.66%)	3 months	Pop pulse at 3 months then disappear at 6 months
6(40%)	6 months	Pedal puse present
6(40%)	6 months	Pop pulse &improvement of symptoms
3(20%)	6 months	Line of demarcation of preexisting gangrene

Table (4): Main clinical features of surgical cases at follow up

No. of patients	Duration	Outcome
5(33.33%)	6 months	Return of pedal pulse
7(46.66%)	6 months	Return of popliteal pulse&improvement of rest pain in 3 patients& Line of demarcation of preexisting gangrene in 3 patients&healing of ulcer in 1 patients
3(15%)	6 months	Major amputation

DISCUSSION

This study was done on 30 patients, 15 cases were managed by endovascular management (PTA with or without stenting) and 15 cases were managed by open surgical management for femoropopliteal occlusive disease who fulfilled the selection criteria.

The advantages of angioplasty rather than surgery are obvious: lower initial morbidity and mortality, no need for general anesthesia, shorter hospital stay, and less trauma. Increasingly, outpatient angioplasty is now feasible [3].

1) Predictors of Outcome

Multiple clinical risk factors were examined as predictors of short-term patency including:

A) Patient demographics:

In our study, risk factors were examined as predictors of success including age, sex, diabetes, hypertension, smoking history and coronary artery disease.

The patient's age varied between 39 and 80 years old with a mean of 59.5. They included 20 males (66.66%) and 10 females (33.33%), 21 patients (70%) were smokers, 24 patients (80%) were diabetics, 12 patients (40%) were hypertensive, 6 patients (20%) had coronary artery disease.

These factors did not affect patency rate within a relative short period of follow up.

DeRubertis et al. [4] evaluated prospectively 1000 consecutive percutaneous infra-inguinal interventions between 2001 and 2006 performed for claudication (46.3%) or limb-threatening ischemia (53.7%; rest pain in 27.7% and tissue loss in 72.3%). Mean age was 71.4 years old and 57.3% were male. Comorbidities included hypertension (84%), coronary artery disease (51%), diabetes (58%) and tobacco use (52%). Overall 30-day mortality was 0.5%. Predictors of primary patency included diabetes and coronary artery disease (CAD). 24-month secondary patencies for patients with diabetes were 59 ± 4% compared with 76 ± 3% for nondiabetics. Twenty-four month secondary patencies for patients with CAD were 61 ± 3% compared with 73 ± 3% for patients without a history of CAD.

B) Lesion characteristics

According to the Trans Atlantic Inter-Society Consensus (TASC) classification, we had all cases (30) with TASC type C lesions. Endovascular management treated 15 cases and open surgical management treated 15 cases.

1) Endovascular management:

In our study, 13/15 cases (86.66%) had success rate without restenosis or occlusion, and 2 cases (13.33%) showed occlusion at 6 months follow up. Total number of deployed stents in our study were 12 stents in 15 patients.

Cvetanovski et al. [5] who performed femoropopliteal PTA in 20 limbs between 2002 and 2008. Their ages ranged from 41 to 75 years old with mean age of 58 years. The follow-up period lasted for 6 months and the percentage of initially successful stenting was 85%. It failed in 2 patients (10%). It was technically unsuccessful in 1 patient, or 5%. Patency after 6 months was 75%.

DeRubertis et al. [4] reported that Interventions for TASC D (complex) lesions had a 24-month secondary patency rate of 55% ± 2% compared with 70% ± 1% for those for TASC A/B/C lesions.

Johnston [6] reported 81% success rate at 1 month for occlusions compared to 94% for stenosis and primary patency rate of 69% at 18 months among 42 patients with long-segment (10-40 cm) stenosis.

2) Open surgical management:

In our study, 12/15 cases (80%) had success rate with improvement of the limb (disappearance of rest pain in 3 cases, other 3 cases which had gangrene, line of demarcation appeared, 1 case which had non healing ulcer, healing of ulcer started to occur), and 3 cases (15%) major amputation was done (above knee amputation in 2 cases and below knee amputation in 1 case) at 6 months follow up

Cvetanovski et al. [5] who performed femoropopliteal bypass surgery in 50 limbs between 2002 and 2008. The follow-up period lasted for 6 months and the patency rate was 85%.

Overall success rate 13/15 (86.66%) for the patients managed by angioplasty in comparison to 12/15 (80%) for the patients managed by open bypass surgery.

CONCLUSION

Percutaneous transluminal angioplasty (PTA) has obtained a definite place in the management of peripheral arterial occlusive disease of the lower limb. It was widely accepted as a first line of treatment for many patients with

SFA occlusive disease. The low complication rate and relatively non-invasive nature of PTA made it an increasing popular intervention.

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