

## Comparative Study between Surgical Bypass and Angioplasty in Treatment of Superficial Femoral Artery Occlusion

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### ABSTRACT

**Background:** Critical limb ischemia is the most advanced stage of peripheral arterial occlusive disease. the prognosis is poor, with amputation rates up to 30 % and mortality up to 25 % after 1 year. **Aim of the Work:** to compare the results of primary bypass versus primary percutaneous transluminal angioplasty (PTA) in symptomatic superficial femoral artery (SFA) occlusive lesions in terms of complications, restenosis, symptom recurrence, re-interventions, major amputation and mortality. **Patients and Methods:** This prospective randomized comparative study was conducted in the Vascular Surgery Department at Al-Azhar University Hospitals. The study included 30 patients randomized into two groups (15 patients for Bypass surgery and 15 patient for angioplasty) suffering from SFA occlusion. Satisfying all the inclusion criteria mentioned below, after the clearance from the ethical committee was obtained, all patients were included in the study. **Results:** The present study was conducted on 30 patients, 19 males (63.33%) and 11 females (36.67%). . The early patency rate was 93.33% in the group with 'Bypass', and 86.67% in the group with angioplasty. The late limb salvage rate in the group with 'Bypass was 73.33 % while in the group with PTA was 66.66 %. Mortality occurred in two patients (13.3 %). **Conclusion** Endovascular intervention is the preferred method of revascularization in many scenarios; surgical revascularization is reserved for specific clinical scenarios and for cases where percutaneous therapy is not feasible or durable. **Keywords:** Bypass surgery, Endovascular Treatment, Revascularisation, Femoral Artery Occlusion.

### INTRODUCTION

Peripheral arterial disease (PAD), defined as a chronic occlusive disease of the lower extremities, is a major and growing health problem, estimated to affect more than 200 million individuals around the globe. Aging of the world's population, combined with diabetes, smoking, dyslipidemia, and hypertension are the critical risk factors and significant socio-economic disparities exist. Most individuals with PAD are asymptomatic, and the most common symptom is intermittent claudication (IC). A small minority (< 10%) develop chronic limb-threatening ischemia (CLTI). Progression of disease from IC to CLTI may occur in up to 20% of patients, associated with similar risk factors but especially diabetes, smoking, and renal disease<sup>(1)</sup>. Treatment of CLI aims at wound healing, improvement in the quality of life, limb loss prevention, and prolonged survival. Current strategies propose open or endovascular revascularization, but not specifically targeted to the location of ischemia<sup>(2)</sup>. The treatment options for PVD include modification of atherosclerotic risk factors, medical treatment, surgery and endovascular revascularization, including balloon percutaneous transluminal angioplasty (PTA), thrombolysis<sup>(3)</sup>.

The two principal treatment alternatives are bypass surgery and balloon angioplasty has many possible relative advantages and disadvantages. In certain practices, percutaneous transluminal angioplasty (PTA) with or without stenting has consequently not only replaced bypass as the primary mode of revascularization, but it also challenges conservative measures as the primary therapy<sup>(4)</sup>. With respect to patency, for long superficial femoral artery

(SFA) stenoses or occlusions, surgery is better than PTA<sup>(5)</sup>.

### AIM OF THE WORK

to compare the results of primary bypass versus primary angioplasty in symptomatic superficial femoral artery occlusive lesions in terms of complications, restenosis, symptom recurrence, re-interventions, major amputation, and mortality.

### PATIENTS AND METHODS

- **Study design:** a prospective randomized comparative study. **The study was approved by the Ethics Board of Al-Azhar University. Patients gave consent for either type of treatment, surgery or angioplasty.**
  - **Study population:** diabetic patients with the femoral arterial occlusive disease.
  - **Patient's number:** it is the study of 30 patients.
  - **Study venue:** Al-Azhar University Hospitals.
- Inclusion criteria in the study:**
1. Patients with age between 40 - 80 years.
  2. Symptomatic patients after failing medical management.
  3. A 5–15 cm occlusive lesion of the superficial femoral artery.
  4. Patients with TransAtlantic Inter-Society Consensus (TASC) B, C.
  5. Patients with disabling claudication.

### Exclusion criteria in the study:

- 1 Patients with multi-level arterial lesions i.e. aortoiliac, femoropopliteal.
2. Acute on top of chronic ischemia.
3. Asymptomatic patients.

4. Buerger's disease.
5. Non-disabling Claudication patients.
6. Highly calcified lesions.
7. Patients with creatinine > 1.7 mg/dl.
8. Poor general condition (e.g. decompensated heart failure).

**Methods**

The patients were subjected to the following:

**1-Clinical data for every patient was recorded in a printed vascular Sheet:**

**A-History:**

- **Personal history:** Name, Age, Sex, Occupation, Residence, and Special habits.
- **Complaint:** Rest pain or Tissue loss.
- **Present history:** Analysis of complaint: Onset, Course. Duration Risk factors Diabetes Smoking Hypercholesterolemia, Ischemic heart disease, Hypertension, Renal impairment
- **Past history:** Neurological, Cardiac, Operations, Drug intake, Hepatic disease, Lung disease, Similar conditions, Vascular procedure or Allergies.

**Family history**

**B-Examination:**

**1. General examination:** Temperature, Respiration, Pulse, Weight, Head and neck, Heart and Abdomen.

**2. local examination:**

- Exposure (from umbilicus downwards).
- Color changes:pallor ,cyanosis,mottling.
- Trophic changes: hair loss ,dry skin.
- Tissue loss: ulcer or gangrene if present.
- Arterial pulsations in both sides.

**3. Investigations:** labs and imaging.

- Lab: CBC,HB%,S.Creat.,
- Imaging:duplex US,CTA,MRA.

**RESULTS**

The two groups were comparable as regards the age and sex distribution.

**Table 1: Distribution of the studied patients regarding their sex.**

	Bypass		PTA	
	N.	(%)	N.	(%)
Sex				
Male	9	60%	10	66.67 %
Female	6	40%	5	33.33 %

Patients' mean age was similar in both treatment groups: (57.2 years) in the bypass group and (58.2 years) in the PTA group.

The associated comorbidities were IHD the associated risk factors were D.M., smoking, hypertension, and dyslipidemia. This was equally distributed among study cases.

Symptoms and signs of patients included in this study are shown in table 2.

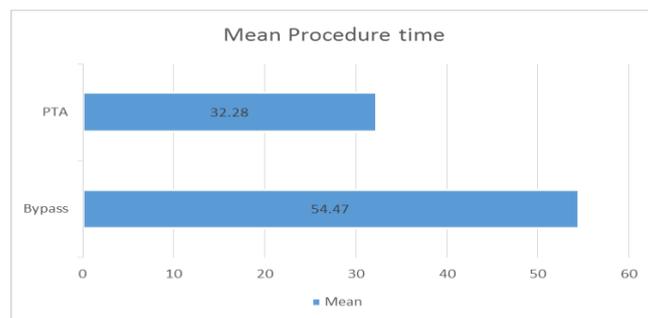
**Table 2: Symptoms and signs of patients included in this study.**

Symptoms and signs	Bypass	PTA
Rest pain	4	3
Ischemic Ulcers	3	2
Toe Gangrene	3	4
Disabling Claudication	5	6

According to the inclusion criteria, all patients had SFA arterial occlusive disease. No associated infra-genicular lesions were found.

The proximal anastomosis was done from CFA and the distal anastomosis was done on supragenicular popliteal artery.

The procedure time was estimated from the time of infiltration of local or spinal anesthesia to the end of the procedure. It ranged from 60 min to 125 minutes in the Bypass group and from 31 min to 55 minutes in the PTA group. This was statistically significant (P-value: 0.041).



**Figure 1: Procedure time**

The hospital stay ranged from 5 to 21 days in the Bypass group and from 4 to 7 days in the PTA group. This was statistically significant (P-value: 0.035).

**Table 3: hospital stay**

Hospital stay (days)	Bypass	PTA	P-value
Mean	8.6±3.3	5.1±7.9	<b>0.035</b>

Early results including patency, limb salvage and amputation rate were followed one month postoperatively.

The early patency rate was 93.33% in the group with 'Bypass', and 86.67% in the group with 'PTA'.

**Table 4: The early results**

Early results	Bypass	PTA
Patency	14 (93.33%)	13 (86.67%)
Limb salvage	13 (86.67%)	14 (93.33%)
Amputation	2 (13.33 %)	1 (6.6 %)

All of the above patients received 5000 IU heparin during the operation.

Minor complications occurred during the operation and postoperatively. None of these

complications led to serious morbidity. Sometimes more than one minor complication occurred in the same patient as ecchymosis and seroma formation.

No peri-operative mortality was reported in the present study in both groups.

**Table 5: Postoperative complications of both groups**

Complications	Bypass	PTA
<b>Minor complications:</b>		
Ecchymosis	1	5
Lymphorrhoea	2	0
Pain and paresthesia	3	0
<b>Major complications:</b>		
Bleeding	2	0
Acute thrombosis	1	0
Infection	3	0
Pseudo-aneurysm	0	1
Groin hematoma	0	1
Perforation of the artery	0	0
Arterial dissection	0	0
Acute renal failure	0	1

**Table 6: The 3-month results**

Results	Bypass	PTA
Redo operations	1 (6.6%)	2 (13.3%)
Limb salvage	11 (73.3%)	12 (80%)
Amputation	4 (26.67%)	3 (20 %)

Limb salvage is freedom from major amputation. Toe, ray, or trans-metatarsal amputations were considered as minor amputations

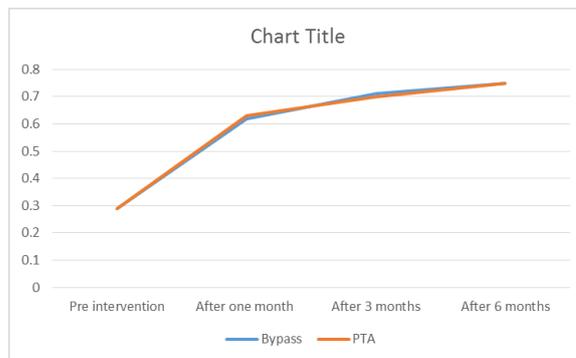
During the whole follow-up period, 5 (33.33 %) amputations were performed in the group of the bypass, and 4 (26.67 %) in the group of PTA.

**Table 7: late results (At 6 months postoperatively)**

Late results	Bypass	PTA
Primary Patency	11 (73.33 %)	10 (66.66 %)
Limb salvage	10 (66.67 %)	11 (73.33 %)
Amputation	5 (33.33 %)	4 (26.67 %)
Mortality	1 (6.67 %)	1 (6.67 %)

The late limb salvage rate in the group with 'Bypass' was 73.33 % while in the group with PTA was 66.66 %.

The pre-intervention mean ankle brachial pressure index( ABPI) for the 30 patients was 0.29±0.2, which improved to 0.58±0.17 immediately post-intervention (P<0.001). When evaluated after 1-month post-procedure, it improved to 0.62±0.19 (P<0.001), after 3 months to 0.70±0.20, after 6 months to 0.75±0.20. (P< 0.001).



**Figure 2: ABI Changes**

**Mortality** occurred in two patients (13.3 %); one of them due to myocardial infarction and the other one due to cerebral infarction. No other patients were lost during the period of follow-up. Mortality was not related to the procedure but was attributed to the associated co-morbidities.

**DISCUSSION**

This study is a randomized trial comparing bypass PTA with surgery for the treatment of superficial femoral artery occlusion. Although power analysis showed a required number of 200 patients to detect a 15% difference in treatment success, our inclusion, unfortunately, ended with a total number of 30 patients. This is a major drawback limiting the power of our study.

Most of the patients were presented with critical limb ischemia 19 patients in both groups (63.33%), of which 7 patients (23.33%) had rest pain and 12 patients (40%) had tissue loss and gangrene. Intermittent claudication was presented in 11 patients (36.67%). Patients' mean age was similar in both treatment groups: (57.2 years) in the bypass group and (58.2 years) in the PTA group. There were 19 males (63.33%) and 11 females (36.67%). The bypass group had sex distribution (60% males versus 40% females), whereas the PTA group had (66.67% males versus 33.33% female). However, the distribution of sex between the two groups was not significantly different.

After bypass surgery, the 6<sup>th</sup> months' primary patency was 73.33 % however primary patency after PTA was 66.66% with an absolute reduction of risk factors. This reflects that there is no major difference between the two modalities.

The apparent increase in ABI in both groups postoperatively at 1, 3 and 6 months as shown in the results reflects the high success rates of revascularization in both groups as raised from (0.3) preoperative to reach (0.75) at 6 months postoperative.

The limb salvage of bypass surgery in the studied group of patients was 10 patients from 15 approximately (66.67%) and 5 patients (33.33%) was submitted to minor amputation (toe or ray) in 3 patients and major amputation in 2 patients while in PTA the limb salvage was 11 from 15 approximately

(73.33 %) and 4 patients (26.67 %) was submitted to minor amputation (toe or ray) in 3 patients and major amputation in 1 patient which is not significantly different but in favor of PTA, but regarding the studied groups the patients with bypass had more advanced disease.

Close follow up of the patients postoperative demonstrated that the group of the patients who were strict to the medical treatment and risk factors modification had a better prognosis and high patency rates in both groups. The incidence of complications was higher in bypass group as infection (3 patients), bleeding (2 patients) lymphorrhea (2 patients) and that was closely related to the nature of the surgery compared to the PTA. while regarding the occlusion and re-intervention was in favor of bypass group (1 patient 6.6%) while (2 patients 13.3%) in PTA.

We performed our trial on a homogenous patient group; an isolated lesion of the SFA combined with symptoms classified according to the TASC classification. In daily practice patients eligible for our study seem to be rare; the patient either has asymptomatic isolated lesion of the SFA or severe intermittent claudication based on multilevel peripheral arterial occlusive disease as if the risk factor was present it does not only involve the SFA but mostly affect the whole arterial tree in different degrees but in long run.

All investigators were closely involved in the preparation of the study protocol. During regular site visits at the hospital, ABI, Doppler and duplex scanning of the target limb were standardized and monitored.

A similar study was done at the University of Rochester Experience with SFA interventions between 1986 and 2004. As a part of a retrospective review, they identified 329 patients who underwent endoluminal intervention of the SFA and 666 patients who underwent surgical bypass. Technical success was 93% in the endoluminal group with a 10% morbidity rate, mostly due to access-related issues. Primary patency rates for endoluminal therapy at 1 and 6 years were 75% and 50%, respectively. Limb salvage for endoluminal therapy at 1 and 2 years was 84% and 70%, respectively. Compared with the open bypass group, the patency of TASC B and C lesions treated endoluminal was statistically worse than that for open femoropopliteal bypass. Early failure of an endoluminal intervention did not result in increased morbidity, mortality or subsequent surgical bypass<sup>(6)</sup>.

Another study was done at Johns Hopkins Bay view Medical Center between September 1, 2005, and June 30, 2012. Only 104 patients among which 61 received PTA, whereas 43 received surgical bypass. Approximately, one-half of the patients presented with critical limb ischemia, of which 23 patients (22%) had rest pain and 30 patients (29%) had tissue loss and gangrene. Intermittent claudication was the presenting symptom in 51 patients (49%). The

distribution of intermittent claudication vs critical limb ischemia was similar in both treatment groups. Patients' mean age was similar in both treatment groups: 65.8 (95% confidence interval, 62.8-68.7) in the bypass group and 65.6 (95%) in the PTA group. There were 61 males (58.7%) and 43 females (41.4%). The PTA group had similar sex distribution (54% males vs 46% females), whereas the bypass group had more males (65% males vs 35% female). However, the distribution of sex between the two groups was not significantly different. They demonstrated a trend toward reduced risk of primary patency failure among patients receiving PTA compared with those undergoing bypass procedures). However, this trend was lost after adjusting for patients' characteristics and lesions' TASC B and C. Females had an almost two-fold increase in the hazard of patency failure. The limb salvage rate was similar in both groups (90.7% in the bypass group vs 93.5% in the PTA group<sup>(7)</sup>).

## CONCLUSION

Surgical bypass for the primary treatment of disabling claudication showed improved freedom from re-stenosis and symptom relief despite treatment of more extensive disease but was associated with increased mean length of stay and wound infection. Finally, we conclude that: bypass surgery is equal to percutaneous transluminal angioplasty in terms of primary patency for the treatment of superficial femoral artery occlusion.

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