Outcome after angioplasty versus bypass surgery in patients with superficial femoral artery lesions

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Background
Management of patients with lower limb ischemia owing to superficial femoral artery lesions is very challenging, as there are two modalities for management, either with angioplasty or bypass surgery, after risk factor modification, exercise, and medical treatment. Every method has its advantages and disadvantages regarding patency, improvement of symptoms, and complications.
Aim
To compare the outcome after angioplasty versus bypass surgery in patients with superficial femoral artery lesions.
Patients and methods
During the period from July 2017 to May 2019, this study was carried out as an interventional prospective comparative study on 52 patients with superficial femoral artery lesion divided into two groups: group A and group B. The study was conducted in Vascular Surgery Unit, Department of Surgery Suez Canal University Hospital, to compare the outcome after angioplasty versus bypass surgery in patients with superficial femoral artery lesions.
Results
After 1-year follow-up, on comparison of both procedures, the results showed better patency rate in bypass surgery group (84.6%) than angioplasty group (61.5%). There was a slight decrease in ankle brachial index with time in bypass surgery group, with mean of 0.83±0.12, whereas in angioplasty group was 0.73±0.14. Symptoms showed better improvement in bypass surgery group than angioplasty group. Complications were higher in bypass surgery group (hematoma, wound infection, and thrombosis) than angioplasty group.
Conclusion
We found that bypass surgery had more complications but better results in patency and in improvement of symptoms. On the contrary, we found that angioplasty had less painful maneuver, less complications, and was suitable for high-risk patients, but had short time of patency.

Keywords:
angioplasty, bypass surgery, superficial femoral artery, Trans-Atlantic Inter-Society

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Introduction

Peripheral arterial disease includes a group of diseases in which blood vessels become stenosed or blocked. The most common cause of peripheral vascular disease is atherosclerosis. Atherosclerosis is a disease in which fatty plaques form in the subintimal space. Other processes such as blood clots further diminish blood flow in the blood vessels. Both veins and arteries may be affected, but the disease is usually arterial. All the symptoms and consequences of peripheral vascular disease are related to diminished blood flow and diminished tissue perfusion that leads to tissue hypoxia. Peripheral vascular disease is a progressive disease that can lead to gangrene of the affected area [1].

The prevalence of peripheral arterial disease has been evaluated in several epidemiologic studies to be is in the range of 3–10%, increasing to 15–20% in persons over 70 years [2–4].

Half of the patients were male, most were over the age of 65 years, 73% had at least one additional risk factor at diagnosis, 10% experienced a subsequent stroke, 10% experienced a myocardial infarction, and 49% had a survival rate of 5.9 years. Annual mortality (8.2%) was higher among patients with peripheral arterial disease than after a myocardial infarction (6.3%) but slightly lower than that in patients experiencing a stroke (11.3%). Patients with comorbid disease (e.g.,

diabetes) were at the highest risk of death and other events [5].

The most common clinical manifestation of peripheral arterial disease in lower limbs is intermittent claudication involving the pelvis, upper thigh, and calf area. Patients who present with critical limb ischemia usually have multisegmental disease with involvement of the infrainguinal arteries [6].

The femoropopliteal segment remains the most challenging area with respect to recurrence after endovascular treatment. The superficial femoral artery is the longest artery in the human body and is fixed between two major flexion points, the hip and the knee. During movements like walking or climbing stair, various forces are exerted on this vessel, including flexion, longitudinal stretching, and lateral compression and torsion. Furthermore, the artery goes through a major muscle group at the site of the Hunter's canal, leading to additional external compression during muscular workout. Atherosclerosis in this vessel is uniquely characterized by the presence of diffuse disease, a large plaque burden, and a propensity for progression to occlusion [7].

The best way to manage peripheral arterial disease remains unresolved. For patients with intermittent claudication, supervised exercise therapy and optimal medical management are the mainstays of therapy [8,9]. If these treatments are ineffective, endovascular therapy (EVT) and bypass surgery may be required. Generally, it is claimed that the outcome of bypass surgery is substantially better than that of balloon angioplasty [10]. According to the Trans-Atlantic Inter-Society Consensus (TASC)-II guidelines, the long-term patency of bypass surgery is superior to that of EVT in patients with intermittent claudication. In particular, in claudication patients with TASC-II C and D lesions, bypass surgery with a graft remains the best treatment for infrainguinal peripheral arterial disease [11]. EVT can play an important role in revascularization, especially for high-operative-risk patients lacking adequate graft for bypass. Although the EVT has advanced and outcomes have improved, few reports have compared EVT and bypass surgery in claudication patients with TASC-II C and D femoropopliteal disease [12,13].

Therefore, this study was established to compare the outcome after angioplasty versus bypass surgery in patients with superficial femoral artery lesions.

Patients and methods

Study design

The was a prospective comparative study. The study was ethically approved by the institutional ethical committee of faculty of medicine suez canal university hospital informed consent was obtained from all participants included in the study.

Study place

This study was conducted in the Vascular Surgery Unit, Surgery Department, Suez Canal University Hospital.

Inclusion criteria

The following were the inclusion criteria:

(1) Both sexes.
(2) Adults more than 40 years of age.
(3) Patients who presented with lower limb ischemia owing to isolated superficial femoral artery with stenosis more than 50% and longer than more than 15 cm for revascularization.
(4) This includes patients experiencing limiting intermittent claudication.
(5) All patients should have ankle brachial index less than 0.9.
(6) Patients presented with resisting ulcer for healing.
(7) Patients presented with rest pain or gangrene.

Exclusion criteria

The following were the inclusion criteria:

(1) Mixed lesions (aortoiliac–tibial).
(2) Any associated form of severe chronic illness such as terminal malignancy, chronic liver disease, and congestive heart failure.
(3) Patient with extensive lower limb gangrene, which includes the heel.
(4) Patients having renal impairment.
(5) Mental or psychological disorders.
(6) Allergy to the dye.
(7) Patient who refuse to participate in the study.

Data collection

After obtaining approval of the institutional research ethics committee, patients were divided into two groups: group A was the angioplasty group, and group B as the bypass group.

Patients were chosen with shuffled deck of cards (even: bypass and odd: angioplasty).

Procedures and methods

The patients underwent the following:

(1) Detailed history.
(2) Full vascular examinations.
(3) Imaging and investigations (CTA and duplex).

Group A

Under local anesthesia, the following technique was used:

Technique

Every case was studied individually and according to the mentioned criteria. The procedure was done in the operation room under complete aseptic technique, and mobile C arm (flat panel C arm 15 kW) with vascular imaging capabilities. The common femoral artery was punctured using a single-piece 18-G needle. After selective wiring of the superficial femoral artery, an 11-cm long, 6-F introducer sheath is placed.

Angiographic images were obtained, and 3000 U of heparin was given intra-arterially. The first attempt to cross the lesion(s) either transluminally or subintimally was done with the guide-wire/catheter combination. After crossing the lesion and confirming the luminal position, dilatation was done using an appropriately sized balloon. A postprocedure angiogram was performed, and balloon dilation would be repeated for any residual stenosis greater than 30%; if the final result was not satisfactory, or dissection occurred, stenting was performed.

Catheters and guide-wires were removed, and manual compression of the accessed artery, followed by a compressive bandage, was performed in all procedures.

Technical success was defined as restored patency with no stenosis greater than 30% as per reporting standards at the scene of angioplasty. A poor result was defined as improvement in patency but with stenosis greater than 30%, whereas failure was defined as no change in patency.

Group B

Under spinal anesthesia or general anesthesia, the following technique was applied:

Technique

(1) The common femoral artery and its divisions were exposed. All these vessels were encircled by rubber slings.
(2) The first part of popliteal artery above the knee level was exposed.
(3) Then a tunnel was fashioned from the femoral triangle to the proximal popliteal space by blunt dissection in the subsartorial plane.
(4) Proximal and distal anastomosis.
(5) At completion, the flow should be pulsatile down to its distal end.
(6) Routine wound closure was done after meticulous hemostasis, and drains were used.

Follow-up for both groups

Ankle brachial index, symptoms, pulses, and duplex were assessed in the following intervals:

(1) Next day.
(2) After 1 week.
(3) After 4 weeks.
(4) After 3 months.
(5) After 6 months.
(6) After 1 year.

Results

During the period from July 2017 to May 2019, this study was carried out as an interventional prospective comparative study on 52 patients with superficial femoral artery lesion. The study was conducted in Vascular Surgery Unit, Department of Surgery Suez Canal University Hospital, to compare the outcome after angioplasty (with or without) stent versus bypass surgery in patients with superficial femoral artery lesions.

Descriptive data

The general homogeneity of the two groups was confirmed, as there was no statically significant difference between the two groups, considering all noncontrollable variables. The mean age of the patients who underwent angioplasty was 62.19±8.03 years, ranging from 45 to 74 years. However, the mean age of the patients who underwent bypass was 61.38 ±8.32 years, ranging from 48 to 75 years. The male to female ratio was 15 : 11 in the angioplasty group, whereas in the bypass group was 17 : 9 (Table 1).

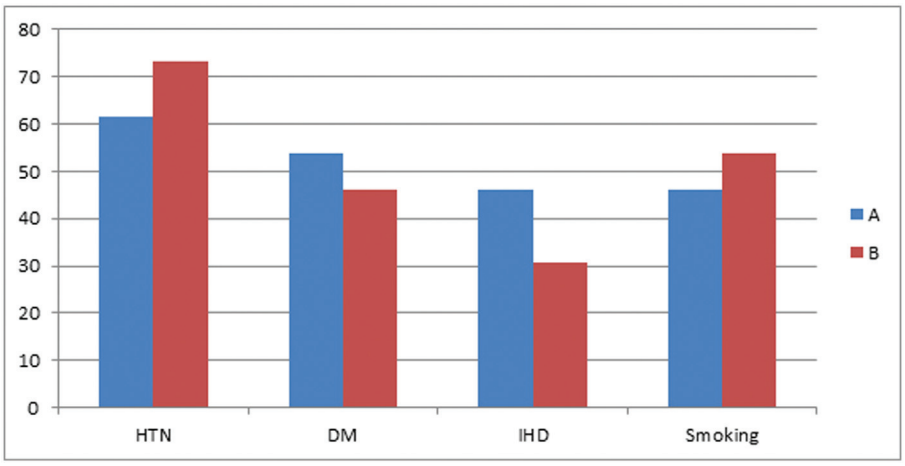
Risk factors

Regarding the risk factors of the patients, in group A, hypertension was the most common risk factor (61.5%)

Table 1 Demographic data among the patients

	A		B		*P* value
Age (years)					
Mean±SD	62.19±8.03		61.38±8.32		0.577
Range	45–74		48–75		
Sex					
Male	15	57.7%	17	65.4%	0.851
Female	11	42.3%	9	34.6%	

Figure 1



Combined bar chart showing the percentage of risk factors among the patients.

Table 2 Frequency distribution of the studied patients according to Rutherford classification and signs of the cases

Symptoms and signs	Group		*P* value
	A [*n* (%)]	B [*n* (%)]	
Claudication pain	15 (57.7)	18 (69.2)	0.398
Rest pain	6 (23.1)	3 (11.5)	0.28
Minor tissue loss	5 (19.2)	2 (7.7)	0.452
Major tissue loss	3 (11.5)	5 (19.2)	0.452

followed by diabetes mellitus (53.8%) and then ischemic heart diseases and smoking were 46.2%. In group B also, hypertension was the most common risk factor (73.1%) followed by diabetes mellitus (46.2%), then smoking was 53.8%, and the least was ischemic heart diseases (30.8%). There was no statically significant difference between the two groups according to risk factors, as *P* value was more than 0.05 (Fig. 1).

Presenting symptoms and signs

According to Rutherford classification, in group A, the most common presentation of the cases was claudication pain (57.7%), followed by rest pain (23.1%), then minor tissue loss was 19.2%, and the least was major tissue loss (28.6%). In group B, the most common presentation of the cases was claudication pain (69.2%), followed by major tissue loss (19.2%), then rest pain (11.5%), and the least was minor tissue loss (7.7%). There was no statically significant difference between the two groups according to presenting symptoms, as *P* value was more than 0.05 (Table 2).

Ankle brachial index before and after intervention

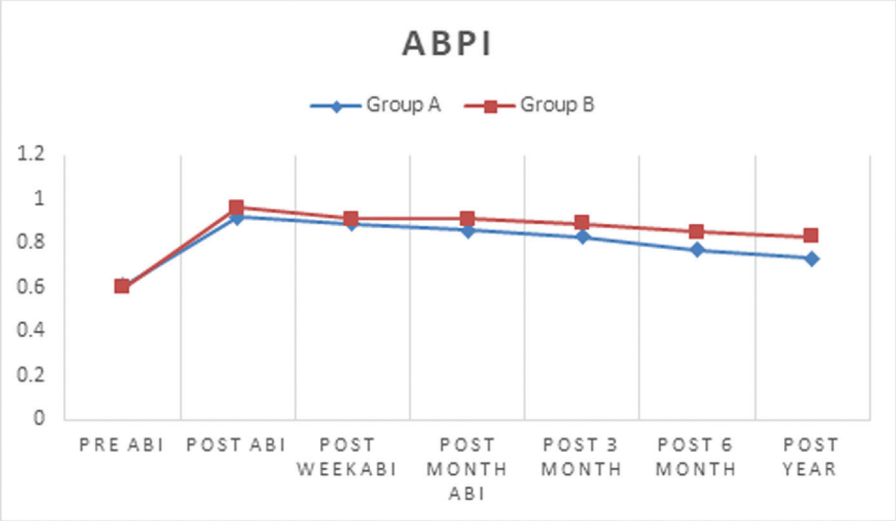
Regarding ankle brachial index, preintervention mean was 0.6 for both groups. After intervention, in group A, the mean was 0.92 the next day, 0.83 after 3 months, and 0.73 after 1 year. After intervention, in group B, the mean was 0.96 the next day, 0.89 after 3 months, and 0.83 after 1 year. There was no statistically difference between the two groups (from preoperative till 1 month after operation), but at 3-month follow-up till 1 year, there was a statistically significant difference between the two groups, with *P* value less than 0.05 (Fig. 2).

Regarding the follow-up by duplex after intervention, in group A, three cases had insignificant stenosis the next day after intervention, two cases had significant stenosis and one case had insignificant stenosis 3 months after intervention, and 10 cases had significant stenosis and one case had insignificant stenosis 1 year after intervention. In group B, two cases had thrombosis the next day after intervention, one case had significant stenosis and one case had insignificant stenosis 3 months after the intervention, and four cases had significant stenosis and four cases had insignificant stenosis 1 year after intervention (Table 3).

Regarding the patency rate, there was a decline in patency in group A more than group B. The patency rate in group A after 1 year was 61.5% and in group B was 84.6%. There was no statistically significant difference between the two groups in patency till 1 month after operation, but at 3-month follow-up till 1 year, there was a statistically significant difference between the two groups, with *P* value less than 0.05 (Fig. 3).

Regarding rest pain follow-up after intervention, in group A, there were no cases that complained of rest pain the next day after intervention, two cases

Figure 2



This chart shows the progression of ABPI before and after the intervention.

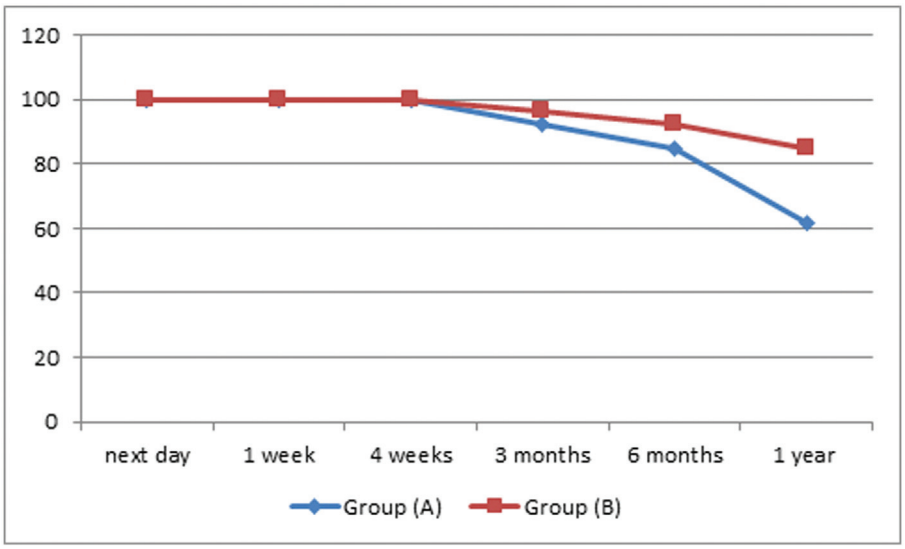
Table 3 Frequency distribution of the studied patients according to the findings of arterial Duplex after intervention

	Findings	Group			
		A		B	
Duplex after next day	Patent	23	88.5%	24	92.3%
	Insignificant stenosis	3	11.5%	0	0.0%
	Significant stenosis	0	0.0%	0	0.0%
	Thrombosis	0	0.0%	2	7.7%
Duplex after 1 week	Patent	23	88.5%	26	100.0%
	Insignificant stenosis	3	11.5%	0	0.0%
	Significant stenosis	0	0.0%	0	0.0%
	Thrombosis	0	0.0%	0	0.0%
Duplex after 4 weeks	Patent	23	88.5%	24	92.3%
	Insignificant stenosis	3	11.5%	2	7.7%
	Significant stenosis	0	0.0%	0	0.0%
	Thrombosis	0	0.0%	0	0.0%
Duplex after 3 months	Patent	23	88.5%	24	92.3%
	Insignificant stenosis	1	3.8%	1	3.8%
	Significant stenosis	2	7.7%	1	3.8%
	Thrombosis	0	0.0%	0	0.0%
Duplex after 6 months	Patent	21	80.8%	21	80.8%
	Insignificant stenosis	1	3.8%	4	15.4%
	Significant stenosis	4	15.4%	1	3.8%
	Thrombosis	0	0.0%	0	0.0%
Duplex after 1 year	Patent	15	57.7%	18	69.2%
	Insignificant stenosis	1	3.8%	4	15.4%
	Significant stenosis	10	38.5%	4	15.4%
	Thrombosis	0	0.0%	0	0.0%

developed rest pain after 3 months, and three cases developed rest pain after 1 year. In group B, there were no cases that complained of rest pain the next day and 3 months after intervention, and only one case developed rest pain after 1 year (Table 4).

Regarding limiting claudication pain follow-up after intervention, in group A, there were no cases that complained of limiting claudication pain the next day and 3 months after intervention and nine cases developed limiting claudication pain after 1 year. In group B, there were no cases that complained of limiting claudication pain the next day and 3 months after intervention, and only two case developed limiting claudication pain after 1 year (Table 5).

Figure 3



This figure shows the patency rate along the study.

Table 4 Frequency distribution of the studied patients according to the improvement in rest pain after intervention

	Groups			
	A		B	
Rest pain next day	0	0.0%	0	0.0%
Rest pain after 1 week	0	0.0%	0	0.0%
Rest pain after 4 weeks	1	3.8%	0	0.0%
Rest pain after 3 months	2	7.7%	0	0.0%
Rest pain after 6 months	2	7.7%	1	3.8%
Rest pain after 1 year	3	11.5%	1	3.8%

Table 5 Frequency distribution of the studied patients according to the improvement in limiting claudication pain after intervention (*N*=26 for each group)

	Groups			
	A		B	
Limiting pain after next day	0	0.0%	0	0.0%
Limiting pain after 1 week	0	0.0%	0	0.0%
Limiting pain after 4 weeks	0	0.0%	0	0.0%
Limiting pain after 3 months	0	0.0%	0	0.0%
Limiting pain after 6 months	4	15.4%	1	3.8%
Limiting pain after 1 year	9	34.6%	2	7.7%

Regarding complications occurred, in group A, four cases developed hematoma. In group B, four cases developed hematoma and two cases developed wound infection, and also two cases had thrombosis (Table 6).

Hematoma in both groups was treated conservatively by compression and antiedematous medications, and only one case in group B was treated by surgical evacuation the next day of intervention.

Table 6 Frequency distribution of the studied patients according to the complications occurred

	Groups			
	A		B	
Complications				
Hematoma	4	15.4%	4	15.4%
Wound infection	0	0.0%	2	7.7%
Thrombosis	0	0.0%	2	7.7%
No complication	22	84.6%	18	69.2%

Wound infection was treated by antibiotics, with good dressing of wounds twice daily.

Thrombosis occurred in two cases the next day of intervention in group B; thrombectomy was done and distal pulse was regained.

Discussion

This study took place in the Department of Surgery, Vascular Surgery Unit, Suez Canal University Hospital, for patients who were referred to Vascular Surgery Unit in the period between July of 2017 and May of 2018.

There is always a debate between angioplasty and open surgical bypass by synthetic graft regarding management of long superficial femoral artery lesions TASC C, as every method has its advantages and disadvantages, like patency, complications, and improvement of symptoms.

In this study, 52 patients were enrolled and divided into two groups; each group included 26 patients to

compare between the outcome of angioplasty of long lesions of superficial femoral artery in group A and open surgical bypass in group B.

We observed that most of patients in both groups were males (57.7% in group A and 65.4% in group B). This was closely related to the results reported by van der Zaag *et al.* [14] and closely related to the results reported by Saxon *et al.* [15].

This is may be explained by the observation that smoking is more common in males than females, which increase the risk of chronic lower limb ischemia in males.

The mean age of our study was 62 years old in group A and 63 years old in group B; this correlates with other studies that showed the mean age of 65 years old, as reported by Aihara *et al.* [16], and also related to the study of Sigvant *et al.* [17] and the study of Kannel and McGee [18].

This may be explained, as chronic diseases such as diabetes, hypertension, and ischemic heart diseases in addition to hyperlipidemia are more common in elderly patients than younger one; in addition, age is a known risk factor for peripheral vascular diseases.

Hypertension was the most common risk factors in both groups (61.5% group A and 73.1% group B). It was closely related to the study of Kedora *et al.* [19] and also the study of van der Zaag *et al.* [14].

This confirms the relation between atherosclerosis and development of hypertension and peripheral arterial diseases owing to its effect on vessels peripherally and centrally.

In this study, 53.8% were diabetics in group A and 46.2% in group B; these results were closely related to other studies, as was reported in the studies of Conrad *et al.* [20] and Saxon *et al.* [15].

This also correlates with Selvin and Erlinger [2], a meta-analysis study which reported that with every 1% increase in hemoglobin A1c, there is a corresponding 26% increased risk of peripheral arterial diseases (PAD).

We also found that ischemic heart diseases were 46.2% in group A and 30.8% in group B. Islam and Robbs [21] also reported the same results, and Saxon *et al.* [15] had the same results in their study.

Smoking was reported in both groups, with a percentage of 46.2% in group A and 53.8% in group B. Enwerem *et al.* [22] found that the percentage of smoking in their study was 65 and 70% of both groups. Saxon *et al.* [15] reported similar results of our study, with percentages of 51 and 45%.

This confirms the strong relation between smoking and progression of PAD, as smokers have a four-fold higher risk of developing PAD compared with nonsmokers. Results from the Edinburgh Artery Study found that the relative risk of PAD was 3.7 in smokers compared with 3.0 in exsmokers [8].

Regarding the presenting symptoms according to Rutherford classification, in our study, we found limiting claudication (Rutherford I) in 57.7% of patients in group A and 69.2% in group B. Islam and Robbs [21] found that in 36 and 45% in both groups. Enwerem *et al.* [22] also reported 49% of patients had limiting claudication pain, which was related to our results.

On the contrary, van der Zaag *et al.* [14] found that limiting claudication was the least, with percentage of 13 and 28%.

Rest pain (Rutherford II) was presented in this work, with 23.1% in group A and 11.5% of group B. Nasser *et al.* [23] showed in their study resting pain in 9%, which was slightly close to our result.

However, Islam and Robbs [21] found higher results in 38 and 43%, respectively, in both groups.

With exercise, occlusive lesions in the arterial supply of the leg muscles limits the increase in blood flow, resulting in a mismatch between oxygen supply and muscle metabolic demand, which is associated with the symptom of claudication [24].

The pain is caused by ischemia, areas of tissue loss, ischemic neuropathy, or a combination of these, but in severe cases, it can be continuous [25].

We found in our study, 19.2% in group A and 7.7% in group B had minor tissue loss (Rutherford III). Linnakoski *et al.* [26] reported in their study that 26 and 25% had minor tissue loss.

Moreover, we found in our result that 11.5% in group A and 19.2% in group B had major tissue loss (Rutherford IV). Linnakoski *et al.* [26] reported in their study that 9 and 11% had minor tissue loss. Islam and Robbs [21], found in their study 26 and 12% had major tissue loss.

Most of these results are closely related to our results.

In this study, we found ankle brachial index before intervention (pre-ABPI), with mean of 0.61 in group A and group B. Aihara *et al.* [16] found in their study (pre-ABPI), mean of 0.46 in group A and 0.6 in group B, which are similar to our results.

In our work the type of lesions 61.5% stenosis and 53.8% occlusion in group A and 38.5% stenosis and 46.1% occlusion in group B.

On other hand van der Zaag *et al.* [14], stated in their study that 9.7% of patients had stenosis and 90.3% had occlusions.

In this work, ankle brachial pressure index (ABPI) showed progression after intervention in both groups as follows: in group A, 1 day after intervention, the mean was 0.92, then after 3 months was 0.83 and then after 1 year was 0.73, and in group B, 1 day after intervention, mean was 0.96, then after 3 months was 0.89, and then after 1 year was 0.83. Linnakoski *et al.* [26] found in their study the follow-up of ABPI was 0.71 (SD±0.41) for the surgical group and 0.82 (SD±0.28) for the endovascular group.

Aihara *et al.* [16] reported that ABPI progressed from 0.46 to 0.95 in bypass group and from 0.60 to 0.89 in endovascular therapy, which is close to our results.

In our study, we found the following regarding improvement of limiting claudication pain in patients: four (15.4%) cases developed pain again in group A and one (3.8%) case in group B after 6 months of intervention, and after 1 year of intervention, nine (34.6%) cases developed pain again in group A and only two (7.7%) cases in group B.

Rest pain developed again in two (7.7%) cases in group A and one (3.8%) case in group B after 6 months of intervention, and after 1 year of intervention, three (11.5%) cases developed pain again in group A and only one (3.8%) case in group B.Antusevas *et al.* [27] reported similar results to our results.Patency rate was followed along 1 year and assessed by duplex scan. We found in our study after 3 months of intervention two cases developed significant stenosis (7.7%) group A and one (3.8%) case developed significant stenosis group B. After 6 months of intervention, four (15.4%) cases developed significant stenosis in group A and one (3.8%) case developed significant stenosis in group B. After 1 year of intervention, 10 (38.5%) cases developed significant stenosis in group A and four (15.4%) cases developed significant stenosis in group B.

van der Zaag *et al.* [14] found in their study 60% in angioplasty group had occlusion and 29% had occlusion in bypass group. Saxon *et al.* [15] reported 62% had occlusion in angioplasty group and 33% in bypass group. These results are closely related to our results.

In our study, regarding hospital stay after intervention, the mean was 2.19 days, with maximum of 4 days, in group A, and with mean of 9.96 days in group B. Linnakoski *et al.* [26] found in their study that hospital stay was significantly longer in the bypass group compared with the endovascular group (4.1 days, SD, ±2.5 and 1.2 days, SD, ±1.1), which is close to our results.

Our study revealed four cases (15.4%) in both groups developed hematoma. Linnakoski *et al.* [26] reported 15 (20%) cases in angioplasty group and eight (12%) cases in bypass group developed hematoma, which is closely related to our results. Saxon *et al.* [15] reported only one case with hematoma.

Wound infection occurred in two (7.7%) cases in our study. Aihara *et al.* [16] reported four (3.6%) cases developed wound infection. Linnakoski *et al.* [26] reported seven (11%) cases with infection. These results are close to our results.

Conclusion and recommendation

We found in angioplasty group better satisfaction to the patient, short period of hospital stay, less painful maneuver, less complications, and suitable for high-risk patients, but it had short time of patency.

On the contrary, we found in bypass surgery group less patient satisfaction than angioplasty group, longer period of hospital stay, and more complication, but it had better results in patency and in improvement of symptoms.

Based on the results of this study, we recommend the following:

(1) Above-knee surgical bypass in patients has superficial femoral artery lesions as it has longer time of patency rate with better improvement in symptoms with exception of high-risk people, so we can use angioplasty.
(2) Further studies should be conducted in this subject regarding long-time follow-up of more than 1 year with bigger sample size.

(3) As most of our patients presented with aggressive lesions, screening programs of peripheral vascular diseases (PVD) may help in early detection of cases.
(4) There should be prevention and adequate control of chronic diseases, such as diabetes, hypertension, and ischemic heart diseases, as they are prevalent in PAD.

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Nil.

Conflicts of interest
There's always a debate between angioplasty & bypass surgery in management of SFA lesions regarding patency rate.

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