Endovascular Treatment of Superficial Femoral Artery Lesions: Balloon versus Stent Angioplasty

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ABSTRACT

Background: Percutaneous transluminal angioplasty and stent deploying are the most commonly performed therapeutic interventions for chronic limb ischemia. These are relatively inexpensive, easily performed, and associated with fewer complications.

Objectives: To assess the epidemiology of superficial femoral artery disease and to compare the endovascular treatment patency rate by balloon and stent.

Methods: In this prospective randomized comparative study, sixty patients were candidates for interventional angiography at Ghazi – Al hariri surgical subspecialties hospital in Bagdad, Iraq from the 1st of October 2015 to the 30th of December 2015. They were followed for six months. We classified the patients into two groups (group 1 balloon 32 patients and group 2 stent 28 patients). We compared between them according to age, gender, side of lesion, presenting symptoms, duration, risk factors, associated affected arteries, site of stenotic lesions, means of stenosis by duplex preoperatively, during angiography and postoperatively by duplex at 1st ,3rd and 6th months also by means of lesion lengths, complications and mortality rate.

Results: The most common age group was (60 – 69) years with 27 patients (45%) in both groups. The male gender was 44 patients (73.4%). The left lower limb was mostly affected and operated in 34 patients (56.7%). Most patients present with claudication (38 patients). The mean of stenosis percentage picked up by preoperative angiography was slightly higher than that watched by duplex study (70-85% by angiography to 70-75% by duplex). The mean of restenosis percentage for balloon, stent groups were up to (31.25%), (3.57%), respectively, at 6th month postoperatively. One patient with mild extravasation in balloon group was occurred during the procedure and one patient only with recurrent thrombosis was picked up in 1st month of follow up in stent group.

Conclusion: The stent deploying has more patency and less residual stenosis than percutaneous transluminal angioplasty alone.

Keywords: **Stent, Percutaneous transluminal angioplasty, Ischemia, Interventional angiography.**

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The commonest cause of peripheral vascular disease is atherosclerosis. It affects 4% of person above 40 years and (15-20%) of those above 70 years. The vast majority of chronic limb ischemia cases are caused by atherosclerotic peripheral arterial disease (95%)[(1)].

The patients may be asymptomatic or symptomatic with claudication that affects calf muscles and this expressed as claudication distance. Also, patients may have rest pain that is constant and localized at metatarsophalangeal joints of foot and relieved with dependency, therefore patients expressed sleep on chair with hanging their feet critical limb ischemia is a persistent rest pain and / or tissue loss. The pain should be for at least for two weeks for reliable diagnosis. Further deterioration will lead to ulceration and gangrene[(2)].

Diagnostic angiography is the gold standard modality of diagnosis, but it's applications is decrease with further development of CTA, MRA and duplex study in many countries[(3)].

Revolution of endoluminal technology led to development of many percutaneous techniques through the last twenty years like percutaneous transluminal angioplasty (PTA), endoluminal stenting and directional atherectomy. These are cheap, easily to be done and less complications[(4)].

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PTA is a technique commonly done for Infra-inguinal vascular occlusion with about 90% success rate and 38-58% five-year primary patency rate. For lesion less than 3 cm, PTA is of good results while it is limited with lesion of 7-10 cm length. For concentric lesions, PTA is of better results than for eccentric one, this is applied also for stenotic lesions than for occlusive one. Heavy calcifications of vessels have negative impact on patency rate of PTA[3].

The aim of this study is to assess the epidemiology of superficial femoral artery disease and to compare the endovascular treatment patency rate by balloon and stents

Methods

This is a prospective randomized comparative study which was done at Ghazi – Al Hariri surgical subspecialties hospital in Bagdad, Iraq, from 1st of October 2015 to 30th of December 2015 and followed for six months later on. We collected eighty-five patients and took sixty of them for whom interventional angiography was done for them. Twenty-five patients were excluded. We classified the patients into two groups (G1 balloon 32 patients and G2 stent 28 patients) according to procedure was done.

We excluded the trauma patients, previous vascular open surgery or interventional angiography, stenosis < 30%, length of lesion > 10 cm, if no distal runoff vessel was present and causes other than atherosclerosis. The data in this study characterized by:

- Both genders were included randomly.
- Patient symptoms were categorized by Fontaine classification, (Table 1).
- The patients with superficial femoral artery disease were included only as diagnosed with duplex study.
- CTA not considered as routine for patients.
- The intervention was done via antegrade or retrograde femoral approach.
- The total occlusive vessels were considered as 100% stenosis.
- The balloon angioplasty was done for stenosis > 30%.
- The stent intervention was done if the residual stenosis more than 30% after PTA and this also affected by length of lesion and associated affected arteries.
- Balloon expanding stents (stainless steel) were used only as other types of stents are not available in the center until the last period of study, therefore, they not included in this study.
- Restenosis was considered if luminal diameter > 50%.

Table 1: Fontaine classification.

FONTAINE CLASSIFICATION	
STAGE	CLINICAL
I	Asymptomatic
IIa	Mild claudication
IIb	Moderate to severe claudication
III	Ischemic rest pain
IV	Ulceration or gangrene

We compared between the two groups according to age, gender, side of lesion, presenting symptoms, duration, risk factors, associated affected arteries, femoral approach, site of stenosis in SFA, means of stenosis by duplex preoperatively, during angiography and postoperatively by duplex at 1st ,3rd and 6th months also by means of lesion length, complications and mortality rate.

History and clinical examination were taken from all patients as claudication, rest pain, ulceration, gangrene, vital signs and lower limb pulses. All patients were send for general blood investigations as hemoglobin level, ESR, glucose level, renal indices, lipid profile and virology screen and also they send for chest X- ray and duplex study of lower limbs. Duplex study was send to show diffuse atherosclerotic changes, total occlusion of vessels, site, length and percentage of stenosis and distal runoff. Anti-platelets as aspirin was stopped 5 days before procedure and continued on low molecular weight heparin (LMWH). All patients were admitted 24 hours before procedure with good hydration and preparation the site of arterial puncture.

During the procedure, all patients received prophylactic antibiotics in form of cephalosporin just before arterial puncture. Sterilization of inguinal region by using of betadin solution and then draping was done. Heparin injection 5000 I.U intravenously before arterial puncture. Arterial puncture was done either antegrade or retrograde approaches via common femoral artery in mid-inguinal point by using the Seldinger technique. We used different sizes of Seldinger needle, needle guide wire, arterial sheath and arterial guide wires and catheters according to artery size and lesion. Then, 100-200 cc of 0.9% isotonic saline was given. Then we did balloon angioplasty with or without stent deploying. We used an iodinated based radiopaque contrast diluted with 0.9% isotonic saline (1:3). Monitoring of blood pressure, heart rate, O_2 saturation and ECG were also done.

After the procedure, puncture site compressed either manually or by sand bag for 30 minutes. All patients admitted and monitored in the ward for 24 hours and discharge home after that. All patients continued on antibiotics, analgesia, good hydration, aspirin 100 mg daily, clopidogril 75 mg daily, cilostazole 100 mg daily, and LMWH twice daily at hospital, and continue on aspirin 100 mg daily forever and clopidogril 75 mg daily for 3 months at home.

The all data collected in the study was arranged in tables. The continuous variables expressed as means while desecrate variables expressed as numbers (percentage). Chi square test was used for desecrate variables comparison such as side of lesions and the risk factors while Anova test was used for continuous variables comparison such as in stenosis rate of lesion. If P- value < 0.05 is considered significant.

Results

The most common age group was 60-69 years with 27 patients (45%) in both groups, (Table 2).

The male gender was more than female gender underwent the procedures with 44 male patients (73.4%) in both groups and 16 females (26.6 %).

Smoking was the most common risk factor for both patients' groups and the second common risk factor was hypertension and diabetes, (Table 3).

Most of the patients present with intermittent claudication; Fontaine class II, (20 patients) and (18 patients) in balloon and stent groups, respectively (Table 4).

The left lower limb was mostly affected and operated with total number 34 patients (56.7%), (Table 5).

Antegrade femoral approach was done in (46 patients) while the retrograde femoral approach was done in 14 patients.

The most common site of lesion in SFA is the distal third of artery (33 patients), (Table 6).

CFA is mostly associated with SFA in balloon group (4 patients), while pop. A is associated with SFA mostly in stent group (6 patients), (Table 7).

Ten patients are symptomatic at 6th months in G1 balloon group while only one patient in G2 stent group at 6th month, (Table 8).

The mean of stenosis percentage picked up by preoperative angiography was slightly higher than that watched by duplex study (70-85% by angiography to 70-75% by duplex) for both groups, (Table 9).

The mean of restenosis percentage for balloon, stent groups were (31.25 %), (3.57 %), respectively, at 6th month (Table 9).

Complications were seen in two patients, the first one was in G1 group with extravasation and mild SFA dissection and the second one, was in G2 group, had stent thrombosis. The mortality rate was zero %.

Table 2: The numbers of patients related to their ages in both study groups (G1 balloon and G2 stent).

Age (years)	G1 Balloon	G2 Stent	Total	%	P- value
30 - 39	3 (9.4%)	2 (7.2%)	5	8.3	0.057
40 - 49	4 (12.5%)	3 (10.7%)	7	11.7	0.38
50 - 59	6 (18.8%)	5 (17.8%)	11	18.3	0.5
60 - 69	15 (46.8%)	12 (42.8%)	27	45	0.33
70 - 79	4 (21.5%)	6 (21.5%)	10	16.7	0.052
Total	32	28	60	100	

Table 3: The numbers of patients in all groups of study in relation to risk factors.

Risk factor	G1 Balloon	G2 Stent	Total	P- value
Smoking	17 (53.1%)	23 (82.1%)	40 (66.6%)	0.10
Alcohol	0 (0%)	2 (7.1%)	2 (3.3%)	0.15
Hyperlipidemia	9 (28.1%)	8 (28.6%)	17 (28.3%)	0.77
DM	12 (37.5%)	9 (32.1%)	21 (35%)	0.42
Hypertension	9 (28.1%)	14 (50%)	23 (38.3%)	0.18
Family history	10 (31.2%)	9 (32.1%)	19 (31.7%)	0.73

Table 4: The numbers and percentage of patient's symptoms in relation to procedures with the mean of symptoms duration in weeks.

Fontaine class	G1 Balloon	G2 Stent	Total	P- value
II	20 (62.5%)	18 (64.3%)	38 (63.3%)	0.79
III	9 (28.1%)	8 (28.6%)	17 (28.3%)	0.58
IV	3 (9.4%)	2 (7.1%)	5 (8.3%)	0.64
Duration (weeks)	6	5		0.41

Table 5: The numbers of patients underwent the procedure related to side (left, right or bilateral) of lower limb lesions.

Side	G1 Balloon	G2 Stent	Total	%
Right	16 (50%)	18 (64.3%)	34	56.7
Left	14 (43.7%)	7 (25%)	21	35
Bilateral	2 (6.3%)	3 (10.7%)	5	8.3
Total	32	28	60	100

Table 6: The number of patients in relation to site of lesions in both study groups.

Site of lesion	G1 Balloon	G2 Stent	Total
Proximal third	5 (15.6%)	4 (14.3%)	9 (15%)
Middle third	10 (31.2%)	8 (28.6%)	18 (30%)
Distal third	17 (53.2%)	16 (57.1%)	33 (55%)
Total	32	28	60

Table 7: The numbers of patients with affected arteries that associated with diseased superficial femoral artery.

Associated arteries	G1 balloon	G2 Stent	P- value
CIA	0 (0%)	2 (7.1%)	0.15
EIA	0 (0%)	4 (14.3%)	0.038
CFA	4 (12.5%)	4 (14.3%)	1
Pop.A	2 (6.2%)	6 (21.4%)	0.12
ATA	3 (9.4%)	4 (14.3%)	0.68
PTA.	3 (9.4%)	4 (14.3%)	0.68
Peroneal A	3 (9.4%)	4 (14.3%)	0.68
Not associated no.	24 (75%)	18 (64.3%)	0.09

Table 8: The number of symptomatic patients in both study groups in 1st, 3rd and 6th months follow up.

	Time (months)	Fontaine II	Fontaine III	Fontaine IV
G1 balloon	1st	0 (0%)	2 (6.2%)	3 (9.4%)
	3rd	3 (9.4%)	2 (6.2%)	2 (6.2%)
	6th	6 (18.7%)	2 (6.2%)	2 (6.2%)
G2 stent	1st	1 (3.6%)	1 (3.6%)	2 (7.1%)
	3rd	1 (3.6%)	0 (0%)	1 (3.6%)
	6th	1 (3.6%)	0 (0%)	0 (0%)

Table 9: The mean of stenosis percentage in both groups of study by preoperative Doppler, intraoperative, 1st, 3rd and 6th months postoperatively and it shows also mean of lesion length.

	Means	G1 balloon	G2 stent	P- value
Preop. Assessment	Lesion length (cm)	4.5	2.5	0.022
	Stenosis (%) by preop. Doppler	70	75	0.27
	Stenosis (%) by angiography	70	85	0.42
Follow up assessment	1st month (%) of restenosis	15.6	14.28	0.001
	3rd month (%) of restenosis	21.87	7.14	0.001
	6th month (%) of restenosis	31.25	3.57	0.001

Discussion

All patients underwent balloon angioplasty if the stenosis was more than 30% of lumen diameter at time of angiography and underwent stent deploying if the residual stenosis was > 30% after PTA. The patients continue on antiplatelet after the procedure to decrease incidence of restenosis that caused by re-thrombosis or development of intimal hyperplasia.

The most common age of patients, who were underwent endovascular surgery in this study whether balloon angioplasty or stent deploying, was 60-69 years old (27 patients, 45%, p- value 0.33), (Table 2), that is because increase age will increase the risk of peripheral arterial disease and atherosclerosis and this is comparable to other studies such as Banergee et al study in which the mean of age was (63.2 years) [5] and in Hajibandeh et al study in which the mean of age was 67 years [6].

The most common gender that was studied was male gender with (44 patients, 73.4%, p- value 0.55) for both groups of the study and this is also due to increase the risk of atherosclerosis of peripheral vessels in male gender. This is comparable with Hajibandeh et al study in which (477 males of 744 patients, 64.1%) was studied [6] and in Farraj et al study in which the percentage of male gender was (18 males of 30 patients, 60%)[7].

The common risk factors of PVD in this study, (Table 3), were smoking, hypertension and diabetes mellitus [40 patients (66.6%, p-value 0.10), 23 patients (38.3%, p- value 0.42) and 21 patients (35%, p- value 0.18), respectively as these separately or collectively increase the risk of atherosclerosis then it will increase the peripheral vascular disease. This is like Wyss et al study (with 3406 patients included) in which hypertension and smoking (95%-CI 0.65-0.94, p – value 0.010) are a strong risk factors for intermittent claudication but not for critical limb ischemia, and diabetes occurred mostly in critical limb ischemia (95%-CI 1.68-2.36, $p < 0.001$)[8].

Regarding the clinical features, (Table 4), in both study groups, the most common feature was intermittent claudication about (20 patients, 18 patients, p- value 0.79) with mean duration of about (6 and 5 weeks, p-value 0.41) for balloon and stent groups, respectively. That is because intermittent claudication is early symptom of chronic limb ischemia that is picked up early in comparable to other symptoms. This is comparable to Albier et al study in which (31 of 66 patients) was studied with intermittent claudication [9].

Regarding the side of SFA lesion that underwent the procedure, the left side was the common side, (Table 5). That is with (34 patients, 56.7% on left and 21 patients, 35% on right side) from them (68%) right sided

patients and (32%) left sided one, respectively. This is may be the right side leg is more dependent one for exercise and walking, therefore, less susceptible for atherosclerosis.

As in table 6, the most common site of stenosis in SFA was in distal third with (33 patients, 55%), this may be due to shearing force at distal third of SFA, when at adductor canal, the SFA enter to become popliteal artery in popliteal fossa that is affected by muscle contraction [10] .

Antegrade femoral approach was done in (46 patients) while the retrograde femoral approach was done in (14 patients). As there are (14 patients) with common iliac, external iliac and common femoral arteries stenosis, we selected the antegrade femoral approach for them because this approach more likely to interfere with most stenosis of SFA, while retrograde approach was used in 14 patients only to interfere with the stenoses of CIA, EIA and CFA than antegrade one.

As PVD is a part of systemic vascular disease, that is mean it may affect any other vessels in the body. As demonstrated in table 7, the most common arteries affected in association with SFA were CFA and popliteal artery (in 8 of 60 patients for each artery, p-value 1 and 0.12, respectively), and leg arteries (in 21 of 60 patients, p-value 0.68) in this study. This is comparable to Albier et al study in which (96 lesions in 66 limbs, 45 lesions in SFA associated with 28 lesions of popliteal artery and 21 lesions of tibial arteries) [8] .

Regarding the symptoms of patients in postoperative follow up, (Table 8), in balloon group there were 5 patients with Fontaine III and IV (two with Fontaine III and 3 with Fontaine IV) in 1st month that increase to 10 patients at 6th months (six with Fontaine II , 2 with Fontaine III , 2 with Fontaine IV) that is because gradual restenosis of artery by atherosclerosis process, while in stent group at 1st month, there were 4 patients with symptoms (one with Fontaine II, 1 with Fontaine III, 2 with Fontaine IV) that were decrease to only one symptomatic patient (Fontaine II) at 6th months later on because effectiveness of stent in prevention the restenosis, this is the same noncompliant patient whose refuse the medications after the procedure.

The mean of stenosis percentage of lesions by duplex study preoperatively was (70% and 75%, p- value 0.27) in balloon and stent groups, respectively, while the mean of stenosis percentage obtained during angiography was (70% and 85%, p-value 0.42) in both groups, respectively, (Table 9). This mean the slight more accuracy rate of angiography over the duplex study in evaluation of stenosis in peripheral vascular disease. As we know, the duplex study is operator dependent and the angiography has the accurate measurements, this declares the more accuracy rate of angiography in picking up the stenosis rate. This is comparable to Elsharawy et al study, with (63 patients). Accuracy of diagnosis was (83%) in arteriography, (80%) in duplex study [11]

The mean of restenosis percentage of lesions that is picked up by duplex study in 1st, 3rd, and 6th months is (15.6, 21.87 and 31.25%) for balloon group while (14.28, 7.14 and 3.57%) for stent group with the mean of lesion length (4.5 and 2.5 cm) for both groups, respectively, and significant (p- value 0.001), (Table 9). Restenosis means that the luminal diameter after interventional angioplasty and stent deploying more than 50% stenosed. That is mean, the primary patency was (84.4, 78.13 and 68.75%) for balloon group and (85.72, 92.86 and 96.43%) for stent group in 1st, 3rd and 6th months, respectively. This is may be due to long lesion in balloon group in comparison to stent group and effect of stent in decreasing the restenosis rate, therefore the restenosis more with balloon G2. This is agree with Albier et al study in which the primary patency was (94 and 84%) for balloon and stent groups, respectively, with mean of lesion length was (12 cm)[8] and unlike Armstrong et al study which has primary patency of lesions (less than 15 cm) treated with balloon angioplasty versus stenting was (66% vs. 63%) at 1 year (p=0.7)[12] and this is may be due to long period of follow up and long segment treated in comparison to our study and disagree with Wilson et al study in which, the success rate after PTA group alone was (92%, 88.4%,

58.3%) at initial procedure, 6 months and one year after procedure, respectively, while in stenting group, the patency was (71.1%) at one year[13].

In relation to complications and mortality rate in this study, it was demonstrated in only one patient with recurrent thrombosis in stent group (3.57%) who was non-complaint patient and refused the treatment postoperatively and one patient with mild dissection of artery in balloon group (3.125%) without mortality or amputation rate in both groups. The mild dissection was technical complication that was caused by over inflation of balloon, lead to extravasation of contrast in soft tissue and it does not need to be treated. The overall complication rate was (3.3%) in all (60) patients in this study. This is disagreeing with Rantam et al study, from (123 patients) with both balloon and stent interventions, there were (five groin hematomas, two vessel ruptures, one retroperitoneal hematoma, and one distal embolization) and five patients of nine were stented[14] while in Balduf et al study, there was (2.7% of 119 patients) with peripheral arterial stenosis or occlusion complications included an external iliac artery dissection and deep venous thrombosis with overall complication rate was (2.1%)[15] .

In conclusions; The left side limbs in right sided patients are more affected limbs and below knee vessels are more common associated vessels with SFA disease. The stent deploying has more patency rate and less residual stenosis than PTA alone. The endovascular surgery has less complications and mortality rate with good early mobility and discharge home.

We recommend for clinical identification of chronic limb ischemia and confirm that by duplex scan and diagnostic angiography with early referral of any case with PVD to endovascular center to manage it.

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