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FEMOROPOPLITEAL BYPASS FOR CHRONIC LOWER LIMB ISCHEMIA: REVIEW OF 48 CASES.

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Abstract

Femoropopliteal bypass (FPB) refers to revascularization of the ischemic lower limb using venous or synthetic graft to bypass occluded superficial femoral or proximal popliteal artery. Our aim was to evaluate the outcome of FPB for critical limb ischemia (CLI) or severe intermittent claudication (IC) in 2 vascular centres in Baghdad, Iraq.

Forty eight patients (39 male) with CLI or IC were studied over 19 months. The mean age was 57.5±13.2 yr. All except 5 were studied retrospectively by medical charts review. Diagnosis included Doppler ultrasonography (DUS) and angiography. Standard operative technique was followed.

Atherosclerosis was the main etiology (n=45, 93.7%). The main presentation was CLI (n=43, 89.6%). Diabetics stayed longer whereas patients receiving synthetic or vein grafts had similar hospitalization periods. DopplerUS was done in 33.4% of patients; and was conclusive in 43.8%. Angiography was done in 17 patients (35.4%); all except one had CT angiography. The predominant graft was the PTFE (n=34). There was one death (2.1%).

Despite drawbacks of the study, early complications were nil, mortality was low, and twenty five out of 30 grafts (83.3%) remained patent during 6 months -1 year follow-up period. Longer follow-up is needed to evaluate the late outcome.

Introduction

irst performed in 1949¹, femoro-popliteal bypass (FPB) refers to revascularization of the ischemic lower limb using either an autologous vein or synthetic graft to bypass an occlusion of the superficial femoral (SF) or the proximal popliteal artery². The first indication for this procedure is critical limb ischemia (CLI) whilst the next is severe intermittent claudication. A practical and simple definition of CLI is that proposed by the European Working Group on CLI³. This group defined CLI as the presence of ischemic rest pain requiring analgesia for more than two weeks, or ulceration, or gangrene of the lower extremity with an ankle systolic blood pressure ≤50 mm Hg and/or toe systolic pressure $\leq 30 \text{ mmHg}^3$. Although, chronic CLI in the vast majority cases are related to advanced of atherosclerotic disease, other diseases have to be kept in mind by the clinician,

especially in young patients, those with ulcers in atypical locations, or those with few or no risk factors for CLI³. The presence of CLI is a clear indication to pursue an aggressive arterial revascularization to prevent limb loss and its increased mortality and associated morbidity³. The use of venous grafts have improved significantly patency rate compared with prosthetic grafts when anastomosed at the knee level (68% versus 38% at 5 yr.) or below (50% versus 12% at 5 yr); and therefore should be the preferred conduit for these anatomic sites³. The aim of this study was to evaluate the outcome of FPB for chronic lower limb ischemia in 2 tertiary vascular surgical centres in Baghdad, Iraq.

Materials and Methods

Over 19 month period (January, 1st 2012 to July, 31st 2013), forty eight patients (39 males and 9 females) with symptoms and

signs of peripheral arterial disease (PAD) of lower limbs who were admitted to Ibnand Baghdad Medical Alnafis Citv Teaching Hospitals, Baghdad, Iraq and received a FPB graft were included in this combined retro- and prospective study. Patients' informed consents and approval of Chairmen of Iraqi Board for Medical Specializations and Scientific Council of Thoracic and Cardiovascular Surgery were obtained. In the prospective group (n=5), a detailed history was taken from every patient looking for specific symptoms of PAD such as intermittent claudication, rest pain, tissue loss, ulceration and gangrene as well as symptoms of atherosclerosis elsewhere in the body. Risk factors such as diabetes mellitus smoking. (DM), hypertension (HT), and ischemic heart disease (IHD) were identified. General physical and vascular examination of the affected and normal extremities was then performed. Peripheral pulses, discoloration, atrophy, non-healed ulcers were looked for. The diagnostic work up included lipid and blood sugar measurement as well as Doppler ultrasonography (DUS) and peripheral angiography. In this study, DUS of lower limb arteries was considered a conclusive test if its findings were consistent with those of angiography or were sufficient to take a decision on surgery, otherwise it was considered inconclusive. In the retrospective group (n=43), the pertinent information was obtained by reviewing the medical records. Smokers were strongly advised to quit. The selection of patients with CLI for surgery was based on angiographic findings (patent inflow vessels, segmental arterial occlusion and good distal run-off). The preoperative preparation was standard. Operations were done either under general (GA) or spinal

anaesthesia depending on particular patient' risk factors and decision of anaesthesiologist. The standard procedure of FPB described in operative textbooks was performed². The ipsilateral great saphenous vein (GSV) was harvested unless it was unavailable or unsuitable; in such a case a prosthetic graft (PTFE- Gore-Tex) was chosen. Patients with gangrenous parts of the limbs usually received conservative amputations whereas those with poor inflow vessels had additional vascular interventions such as ileofemoral or aortofemoral bypass.

The patients were carefully monitored postoperatively for potential early complications and they were discharged home if there were no complications. Warfarin was given to patients with synthetic grafts; the dose being controlled by regular Prothrombin Test (PT) and International Normalized Ratio (INR). Follow up visits were arranged to the hospital as well as to the private clinics. The complications and mortality were noticed. To overcome the problem of deficient follow up information, the surgeons in charge of these patients were personally contacted.

Statistical analysis was performed using ztest for 2 population proportions and T-test for 2 dependent means.

Results

The total number of patients was 48 (39 males, 81.2% and 9 females, 18.8%). The youngest two patients were a man and a lady each 25 years old whilst the oldest was a man of 85. The mean age was 57.5 ± 13.2 SD yrs. Table (I) displays the age and sex distribution of the patients. The peak was in the 6th decade.

Tuble It inge und Genuer Distribution						
Total, n (%)	Females,	Males	Age (yr)			
	n	, n				
3 (6.2)	1	2	20-30			
4 (8.3)	2	2	31-40			
6 (12.5)	0	6	41-50			
14 (29.2)	2	12	51-60			
13 (27.1)	3	10	61-70			
6 (12.5)	1	5	71-80			

 Table I: Age and Gender Distribution

2 (4.2)	0	2	81-90
48 (100)	9 (18.8)	39	Total, n (%)
		(81.2)	

Table II shows the etiology vs. gender and patient's ages. Although atherosclerosis comprised the main etiology in most patients; three patients younger than 30 had

non-atherosclerotic causes (Burger's disease, mitral valve disease-MVD- with thromboembolism and unsuccessful repair of traumatic arteriovenous fistula of PA).

Total	>30	<30	Female	Male	Etiology	
	yrs	yrs				
45	45	0	8	37	Atherosclerosis	
1	0	1	0	1	Burger's Disease	
1	0	1	1	0	Thrombo-embolic sequel of MVD	
1	0	1	0	1	Unsuccessful repair of traumatic	
					popliteal AVF	
48	45	3	9	39	Total	

Table II: Etiology vs. Gender and Age

Table III displays important statistics in graft used in this series was the Gore-Tex this study. Majority of patients (n=36) were operated upon under GA. The predominant

(n=34).

Table III. Important Statistics					
Patients, n	Variable				
34, 14	Residence, Baghdad, other governorates				
39,9	Hospitals; INTH*, BMCTH**				
8	Involved surgeons				
2012, 2013	Years of study				
27: 21	Patients per year; 2012: 2013				
43, 5	Retrospective, prospective				
3	Previous FPB on the same limb				
1	Previous FPB on the other limb				
1	Previous ileo-femoral graft				
2	Previous endovascular therapy				
1	Previous exploration and repair of post-				
	traumatic popliteal AVF; aneurysmectomy				
	and repair of artery and vein by end to end				
	anastomosis 20 days earlier				
17, 30, 1	Side of FPB; R, L, Bilateral				
4	Endarterectomy				
36, 8, 4	Type of anaesthesia; GA, SA, not-				
	mentioned				
34, 10, 4	Type of graft; Gore-Tex, RGSV, unknown				
22, 12	Gore-Tex graft size; 6 mm, 8 mm				
9, 1	Side of GSV; ipsilateral, contralateral				
9	Immediate positive distal pulse obtained				
1 (2.1%)	Mortality				
**BMCTH: Baghdad	*INTH: Ibn-Alnafis Teaching Hospital.				
Medical City Teaching					
Hospital.					

Table III. Important Statistics

Table IV: Risk Factors				
Patient,	Risk Factor			
n				
32, 5,	Smoking, non-			
11	smokers,			
	unknown			
	smoking			
	history			
27	DM			
20	HT			
15	IHD			
1 out of	Hyperlipidemia			
9				
patients				
(11.1%)				
had a				
high				
lipid				
profile.				
2	Stroke			
1	Obesity			
1	Deep vein			
	thrombosis			
	(DVT)			

Table IV displays the risk factors; smoking and DM were on the top of the list.

Table V shows hospitalization periods. patients receiving synthetic or vein grafts Diabetic patients apparently stayed longer had similar hospitalization periods without than non-diabetics (however, the difference a statistically significant difference. was not statistically significant) whereas

I able V: Hospitalization Periods						
Period	Range (dys)	Mean (dys)	P value			
Total hospital stay admission to discharge	2-26	9.5±5.8SD				
Preoperative	1-18	3.4±3.25 SD	P value: The result was significant at p< 0.05			
Postoperative	1-14	5.54±3.65SD				
For diabetics	2-23	10.3± 5.8 SD	P value: The result was not significant at $p < 0.05$			
For non- diabetics	2-26	8.3 ± 5.6 SD				
For vein graft receivers	5-15	9.8 ± 3.8 SD	P value: The result was not significant at p< 0.05			
For synthetic graft receivers	2-26	9.5 ± 6.3 SD				

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The clinical presentations are shown in Table (VI). The predominant symptom was chronic leg pain (intermittent claudication or rest pain).

Patient,	Clinical	Patient,	Clinical
n	presentation	n	presentation
6	Neuropathy	43	Leg pain (intermittent claudication or rest pain
4	Past history of leg amputation	10	Coldness of leg and foot
1	Toe gangrene	9	Discoloration
1•	History of shell injury	3	Leg swelling
1•	Pulsating popliteal mass (aneurysm)	3	Non-healing ulcers
1•	Secondary varicose veins of leg	3	Toe amputation
• The sar	ne patient.	5	Unknown (not documented in the medical records)

Table (VI):	Clinical	Prese	ntations

Results of echocardiography, DUS and angiography are summarized in Table VII. DUS of lower limb arteries was done in 33.4% of patients; was conclusive in seven out of sixteen, which is 43.8%. Angiography was done in seventeen patients only (35.4%); the conventional technique was used in one patient whereas all others had CT angiography. Bilateral occlusive or stenotic lesions were diagnosed in almost two thirds (64.7%) of the examined patients. Echocardiography was done in 23 patients (47.9%); it revealed a normal EF in fifteen out of 23 (65.2%) whilst eight patients (34.8%) had a low EF and thirteen (56.5%) had evidence of IHD.

Details					Investigation
Total, n	Not done		Inconclusive	Conclusive, n (%)	Doppler USG of lower
(%)	n (%)		n (%)		limb arteries
48 (100)	32 ((66.6)	9 (18.8)	7 (14.6)	
	Not do	ne or not	Conventional	CT angiography	Peripheral angiography
	mentioned		Angiography		
48 (100)	00) 31 (64.6)		1(2.1)	16(33.3)	
Total 17 (100)			Bilateral lesions	Unilat. occlusive or	Angiographic Findings
			11 (64.7)	stenotic lesions 6 (35.3)	
Not done or not IHD		IHD	Low EF	Normal EF*	Echocardiography
mentioned					
48 (100)	25	13	8	15	
	(52)	(56.5)			

Table VII: Summary of Relevant Investigations

* Normal EF is 55-70 % with a mean of 58 %.

There was one death (2.1%) of undetermined cause. The early outcome of the present series of patients was very good with no reported complication. Information relevant to late outcome was available for 30 patients only (62.5%). Most of them (25 out of 30, 83.3% were very good with intact pedal pulses 6 month-1 yr postoperatively whilst the remaining five (16.7%) had late graft thrombosis revised successfully in 3.

Discussion

Age and Sex The risk of atherosclerotic disease increases after the age of 50. CLI in young patients is less likely caused by atherosclerosis³. In this study, 45 patients were above the age of 30; all were caused by atherosclerosis. The peak was in the 6th decade. Three patients younger than 30 had non-atherosclerotic etiologies (Burger's disease, MVD with thrombo-embolism and unsuccessful repair of traumatic AVF of popliteal artery). The vast majority of our patients were males (39, 81.2%). This coincides with other studies³⁻⁵.Clinical Features Majority of patients (n=42) had features of CLI. Six patients had peripheral neuropathy, most likely related to high incidence of DM (27 patients, 56.3%). In five instances. the medical records mentioned nothing about the patients' symptoms and signs. It is worthy to notice that none of the patients in this study had measurement of Doppler ankle or toe systolic pressure or ankle-brachial index (ABI). The reason for this could be the unavailability of the necessary equipments. Risk Factors Smoking was on the top of the list followed by DM, hypertension and IHD. Smokers have 2.5 times the risk of developing PAD of non-smokers⁴. Smoking cessation is a key modifiable risk factor for increasing survival and reducing the potential for disease progression. Smoking increases the risk of leg amputation, the risk of developing coronary heart disease or stroke, and mortality among PAD patients⁴. Diabetes mellitus affects CLI in many Premature and advanced wavs. atherosclerosis, together with peripheral

neuropathy, impaired cellular immunity and impaired wound healing make CLI a complex problem among diabetics. It has been shown that DM significantly increases the risk of CLI (up to 4 times compared to the general population). Furthermore, it is estimated that 40% to 45% of all amputee are diabetics and a diabetic patient with CLI is 10 times more likely than non-diabetic to amputation⁵. require an Neuropathy increases the risk of severe toe and foot lesions due to the absence of pain during and after trauma and the lack of early recognition of wounds that require prompt Regarding attention³. the period of hospitalization, when diabetics were compared with non-diabetics in this study, it appeared that diabetic patients stayed longer in hospital (a mean of 10.3 day vs. 8.3 day); however, this difference was statistically non-significant. This extra duration was most likely required to control the blood sugar prior to and after surgery. Ischemic heart disease is the most common cause of fatal events among patients with peripheral atherosclerosis⁶. Patients with atherosclerosis suffer may from concomitant IHD that requires coronary bypass surgery. Their GSV might be implanted during cardiac surgery prior to lower limb surgery⁶ and hence, it would not be available for FPB. Preoperative assessment of cardiac status is crucial in patients with CLI scheduled for FPB. In the present series few patients had history of percutaneous trans-luminal coronary angioplasty (PTCA) and coronary artery stent deployment prior to admission.

Lipid profile was available in 9 patients only; all had normal results except one patient (11.1%). This apparent good lipid control may be related to statin therapy in most of these patients prior to surgical consultation. Two patients had stroke which is an indicator of associated atherosclerotic carotid artery disease whilst obesity and DVT were observed once. Obesity is considered a risk factor as it prevents the patient from participating in an effective exercise program⁷. Deep vein thrombosis was recognized in a patient suspected to have Burger's disease. The latter is characterized by involvement of small- and medium-sized arteries and veins of the upper and lower extremities^{8,9}.

Hospitalization Period. We have observed that some patients (n=6) in this study stayed for a relatively short period (2-3 days) whilst most of them spent 5 or 7 days. This could be related to shortage of beds in these two hospitals which care for a huge number of trauma patients, victims of the ongoing terrorism. However, we think it was safer to admit a patient with FPB a bit longer especially if he had received a synthetic graft and lived outside Baghdad to monitor for potential early complications and optimize his warfarin therapy with serial PT and INR measurement.

On average the postoperative stay was longer than the preoperative (5.5 day vs. 3.4 day) (This difference was statistically significant). This could be explained by the fact that most patients were investigated as outpatients and once admitted were ready for surgery apart from diabetics who usually required longer preoperative stay to control their high blood sugar by insulin therapy. The postoperative period was on the average longer to look after any potential complications before discharge.

Work-up Duplex US of lower limb arteries was done in 33.4% of patients; was conclusive in seven out of sixteen, which is 43.8%. We think that DUS of lower limb arteries could be better used if there was an expert operator. It has the advantage of being non-invasive and it may obviate the need for angiography by providing the surgeon with information necessary to make a decision on operation.

Angiography was done in seventeen patients only (35.4%); the conventional technique was used in one patient whereas all others had CT angiography. Bilateral stenotic or occlusive lesions were diagnosed in almost two thirds (64.7%) of the examined patients. This highlights the widespread nature of atherosclerosis.

Until MRA and duplex scanning become widely available, contrast angiography will remain the gold standard for the evaluation of patients with distal arterial occlusive disease¹⁰. Peripheral CT angiography is increasingly used to evaluate patients with peripheral arterial disease¹¹. Both vascular surgeon and interventional radiologist should be familiar with this latest vascular imaging technique¹¹. CT angiography has the advantages of wide availability, high spatial resolution, and relative freedom from operator dependence. The average diagnostic imaging costs are significantly lower with CT compared with MR and catheter angiography¹¹.

Surgery .The predominant graft type in this study was the synthetic (Gore-Tex; PTFE); used in 34 patients. GSV grafts were used in 10 patients only. In view of the wellknown advantages of the vein grafts over the synthetic grafts, we think that vein grafts were under used. This is probably due to the shorter operating time needed for the synthetic graft (no time for harvesting the graft, just exposure of vessels, making a tunnel and doing two anastomoses) or the unavailability or unsuitability of the vein grafts in the studied patients. However, synthetic grafts are liable for infection, especially in the groin, more susceptible to graft thrombosis and ischemic complications, need anticoagulant therapy with its inherent serious complications such as bleeding. Therefore, we think it was better to use the GSV more frequently particularly in our patients with low compliance with anticoagulant therapy and difficult access to the necessary monitory blood tests. The issue is especially important for patients coming from remote governorates. Graft patency and limb salvage are superior with SV compared with PTFE in patients undergoing FPB^{12} . In contrast, patients undergoing FPB grafting with PTFE are at greater risk of ischemic complications from graft occlusion and more frequently require emergency limb revascularization as a result of graft occlusion than patients receiving SV

grafts¹². It is generally accepted that autologous SV is the best conduit for infrainguinal revascularization, particularly when the vein is of normal size and free of sclerotic segments. However, proponents of the preferential use of PTFE for FPB grafting cite advantages of this approach such as decreased operative time, lower morbidity from a more limited dissection, and preservation of the SV for future revascularization¹².

Ischemic HD is the most common cause of fatal events among patients with peripheral arteriosclerosis. DM is also a wellrecognized risk factor for death⁶. The single death in this series occurred to a 57 years old man in the first postoperative day. He was diabetic and a known case of IHD, however, the exact cause of death was uncertain. Kobayashi et al⁶ reported 2.4% mortality slightly higher than ours (2.1%).

This study has several drawbacks such as poor documentation, deficient follow-up making comparison of outcome with other studies hard to achieve, none of the patients had ABI measurement, underuse of DUS with high inconclusive results indicating low operator skill, underuse of vein grafts and early discharge of some patients which may risk their life from undetected complications such as bleeding.

Conclusion

Despite the drawbacks of the study, early complications were nil, mortality was lower than was reported, and twenty five out of 30 grafts remained patent during 6 months-1 year follow-up period. Longer follow-up is needed to evaluate the late outcome.

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