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Research

Long-Term Follow up of Peripheral Arterial Intervention

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Abstract

The major cause of lower extremity Peripheral vascular disease is atherosclerosis. Risk factors for atherosclerosis such as cigarette smoking, diabetes, dyslipidemia, hypertension, and hyper-homocysteinemia increase the likelihood of developing lower extremity Peripheral vascular disease. Lower extremity Peripheral vascular disease is a common syndrome that affects a large proportion of most adult populations worldwide. Peripheral arterial disease can be present in sub-clinical forms that can be detected by use of sensitive vascular imaging techniques, which may reveal early manifestations of arterial disease before it is detected by either limb-pressure measurements or clinical symptoms. When so defined, as, for example, by measurement of the intimal-medial thickness (IMT) in the carotid or femoral artery, early forms of Peripheral vascular disease are easily detected in populations at risk. Claudication, a symptomatic expression of lower extremity Peripheral vascular disease, defines a significantly smaller subset of the total population with the disease. The prognosis of patients with Peripheral vascular disease is characterized by an increased risk for cardiovascular ischemic events due to concomitant coronary artery disease and cerebro-vascular disease. These cardiovascular ischemic events are more frequent than ischemic limb events in any lower extremity Peripheral vascular disease cohort, whether individuals present without symptoms or with atypical leg pain, classic claudication, or critical limb ischemia. Atherosclerosis of peripheral vessels or peripheral vascular disease is the most common cause of symptomatic stenosis in human vascular tree. The pathogenic mechanisms that lead to peripheral vascular disease are similar to those of coronary artery disease. Approximately 100 million people have peripheral vascular disease, only one half of whom manifests symptoms. Peripheral vascular disease is the leading cause of limb amputation; the annual rates of limb loss are 2% in non diabetic patients and 7% in diabetic patients. The prevalence of peripheral vascular disease in those older than 65 years is even greater. The most common symptom is pain in one or both legs (claudication), which usually occurs walking. In advanced cases, ulcers or gangrene can develop. Therapeutic goals for peripheral vascular disease include relief of symptoms and preservation of organs and tissues. Aggressive risk-factor reduction and pharmacologic treatments are the keystones in patient care. Once the affected luminal diameter is compromised by 75% or more, the risk of ischemia and limb loss becomes high. After this point, medical therapy, such as anti platelet and vasodilators, become less effective, and revascularization becomes necessary. In the past, surgical revascularization has been performed with an acceptable risk. The work of pioneers, such as Dotter and Gruntzig, has opened up a novel era of percutaneous revascularization with techniques such as percutaneous transluminal angioplasty (PTA), a less invasive option in the management of PVD. Over the past 30 years, PTA has experienced steady growth and recently, it has become the first-line therapy for Peripheral vascular disease. Increased emphasis on containing and reducing the healthcare expenditures has also enhanced the use of PTA (as compared with surgical procedures), which can be performed as a same-day procedure that saves overall costs. Recent developments

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in treatment options for peripheral arterial disease have improved the prognosis; more patients survive longer. Newer treatment options for peripheral arterial disease, such as anti-platelet and claudication therapies, have aimed at preventing adverse cardiovascular events, limb loss, and the need for surgical interventions. In addition to these clinical benefits, the same treatment options enhance the quality of life (QOL) for with PAD by helping those live more productive and satisfying lives. The endovascular treatment of lower extremity PAD continues to evolve, with the expectation of improvement in acute success rates and safety and the anticipation of improving long-term durability with newer technologies ranging from local drug delivery to bio-absorbable stents. Percutaneous procedures will continue to replace open surgery. The current evidence base to support decision making is quite shallow compared with the field of coronary intervention, and reporting standards for PAD intervention are generally lacking, but there is an increasing resolve on the part of physician investigators, government regulators and payers, and industry to undertake the difficult but necessary task of collecting more definitive data.

Key Words: Atherosclerosi; Peripheral Vascular Disease; Peripheral Arterial Disease; Endovascular Therapy

Introduction

Peripheral arterial disease (PAD) is one manifestation of systemic atherosclerosis. The prevalence of PAD increases with the age of the population [1,2].

It is important to remember the significant association of coincident coronary artery disease and cerebrovascular disease in these patients, because it represents the major cause of major morbidity and mortality in the PAD population. Remarkable technological advances in the past decade, along with patient preference, have shifted revascularization strategies from traditional open surgical approaches toward lower-morbidity percutaneous endovascular treatments [3].

Catheter-based revascularization of the lower extremities was first performed by Dotter [4] and advanced by Gruentzig [5], who employed then newly developed inflatable balloon catheters that could dilate vascular stenosis.

The availability of stents, more than any other advance, has fueled the growth of catheter-based procedures by improving the safety, durability, and predictability of percutaneous revascularization. Endovascular therapy offers several distinct advantages over open surgical revascularization for selected lesions [6,7].

It is performed with local anesthesia, which enables the treatment of patients who are at high risk for general anesthesia. The morbidity and mortality from catheter-based therapy is extremely low, especially compared with open surgical revascularization. After successful percutaneous revascularization, patients are ambulatory on the day of treatment, and unlike after vascular surgery, they can often return to normal activity within 24 to 48 hours of an uncomplicated procedure. Endovascular therapies generally do not preclude or alter subsequent surgery and may be repeated if necessary. Multiple specialties, including interventional cardiology, have contributed to the advancement of the field of peripheral vascular intervention over the past several decades [8].

The recognition of an unmet need for a trained cadre of clinicians to care for patients with PAD prompted the development of a core curriculum document (COCATS-11) [9] and a multispecialty societal competency statement [10].

The American Heart Association and American College of Cardiology have published guidelines and recommendations for the diagnosis and treatment of PAD (2). Improved patient and physician awareness of PAD and the availability of high-quality noninvasive diagnostic imaging have increased the number of patients seeking treatment for PAD.

In this study, the aim of the work is to prospectively assess the long-term outcome of percutaneous transluminal interventions for the treatment of peripheral vascular disease and to assess the influence of varying outcome criteria on the success rate at 12 months after percutaneous intervention for peripheral arterial disease and to suggest a reporting method that can be used in studies that report results of intervention as measured by parameters of daily clinical practice.

Patients and Methods

This study is a prospective registry that was conducted on patients with symptomatic peripheral arterial disease who underwent percutaneous transluminal angioplasty.

The study assessed the influence of varying factors (baseline clinical, demographic, and imaging) criteria on the success rate at 12 months after percutaneous intervention for symptomatic peripheral arterial disease. It also suggested a standardized reporting template that can be used for reporting results of studies relating to peripheral vascular interventions.

Comparison and interpretation of results associated with endovascular revascularization for peripheral arterial disease have been hampered by the different outcome criteria that are applied to classify outcomes as successes or failures.

The current peripheral Intervention Registry was established for the quality assessment and improvement of current practice by monitoring the outcomes of percutaneous vascular interventions for symptomatic peripheral arterial disease affecting the lower extremities.

Inclusion Criteria

All patients with symptomatic peripheral arterial disease referred for percutaneous transluminal angioplasty constituted the population of the study.

Methods

Data regarding each patient at the time of the intervention and details about the procedure performed were entered prospectively in the current peripheral Intervention Registry. The data were recorded using standardized forms and entered into a computerized database. Because the registry did not involve experimental tests or treatment, but included the registration of daily practice, only oral informed consents were necessary.

Full history taking

Clinical examination

a. Blood pressure and pulse.

b. Auscultation (Heart & Chest).

c. Affected lower extremity (Lt, Rt, Both).

d. Type of ischemia (claudication, critical limb ischemia or acute).

e. Pallor.

f. Peripheral cyanosis.

g. Absent peripheral pulse and level.

h. Paresthesia and paresis.

Laboratory Investigations

a. Serum creatinine.

b. Fasting blood Sugar.

c. Lipid profile (cholesterol, LDL, HDL, TG).

d. CBC (hemoglobin, WBC, PLT).

ECG

a. Normal.

b. Atrial fibrillation.

c. ST segment-T wave changes.

d. Left ventricular hypertrophy.

e. Old myocardial infarction.

f. Ventricular pre-mature beats.

Echo

a. Segmental wall motion abnormalities.

b. Left ventricle end diastole diameter.

c. Left ventricle end systole diameter.

d. Left atrium diameter.

e. Ejection fraction.

Method of Assessment

a. The entire arterial segment from the iliac bifurcation to the origin of the anterior tibial artery was evaluated at baseline and follow-up examinations with color-coded duplex ultrasonography (US).

b. Angiography.

c. MRA.

d. MSCT.

Angiography and Angioplasty Data

a. Site of lesion.

b. TASC class.

c. Type of artery: Native / Graft.

d. Lesion Characteristics.

e. Angioplasty balloons data (Size, number of inflations and inflation pressure, brand).

f. Stents data (Size, type, brand).

g. Post deployment balloons (Size, number of inflations and inflation pressure, hand).

Immediate Outcome

a. Procedure success.

b. In-hospital mortality.

c. In-hospital morbidity.

Procedure Details

a. Vascular access.

b. Sheath (size, brand).

Premedication (Aspirin, Clopidogrel).

Twelve-month follow up:

Data regarding 12 months follow-up after the procedure were collected and entered in the Peripheral Intervention Registry.

1. Patient state (alive or dead).
2. Recurrence of LL ischemia.
3. Causes of the recurrence of LL symptoms (Target lesion, Target vessel or other vessel).
4. Type of ischemia (Claudication, critical limb ischemia or acute ischemia).
5. absent peripheral pulsations.
6. Presence of ischemic ulcer, infection, gangrene or rest pain.

Methods of Assessment

a. Patient continued symptomatic improvement.

b. Clinical examination.

c. In all patients the information obtained by duplex scanning. Peak systolic velocity ratios greater than 2.5 or sonography stenosis of 50% or more was defined as recurrent stenosis [11].

d. Angiography [12].

e. MSCT.

f. MRA.

Management

a. Endovascular.

b. Surgical.

c. Medical treatment.

Statistical Analysis

The collected data was revised, coded, tabulated and introduced to a PC using Statistical package for Social Science (SPSS 15.0.1 for windows; SPSS Inc, Chicago, IL, 2001). Data was presented and suitable analysis was done according to the type of data obtained for each parameter.

1. Descriptive statistics (mean, standard deviation and range for numerical data and frequency and percentage of non-numerical data).

2. Analytical statistics (independent-sample t test, chi-square test and Mann-Whitney test).

Level of significance (p value):

- $P > 0.05$: Non significant (NS).
- $P < 0.05$: Significant (S).
- $P < 0.01$: Highly significant (HS).

Results

Table (1) shows the baseline characteristics of the registry population. Most interventions were performed for treatment of below inguinal ligament above knee 48%. Above inguinal ligament interventions were performed in 32% of the population, while below knee interventions was performed in 6.7%. Combined above and below inguinal ligament were performed in 7.3 % of cases while Combined below inguinal and below knee were done in 6% of patients.

Based on the definition of clinical and technical success the intervention success rate was 87.3% (figure 1).

In-hospital mortality occurred in 3.3 % of patients. Such deaths were related to DIC, septicemia from leg gangrene, and uncontrollable bleeding; and were mainly attributable to associated comorbidities. In-hospital morbidity (hypotension, access site complication, limb amputation, renal failure and urgent surgical intervention) occurred in 8.7 % of patients (table 2).

259 different balloons were used in the study populations of this registry, balloons were used either for PTA as standalone technique for revascularization, to pre dilate the lesions before stent deployment, or to inflate a deployed self expandable stent. On the other hand 185 stents were deployed in the patients of this registry (table 3).

Number of lesions , age as well as elevated serum creatinine level significantly influenced the in hospital mortality of the study group, while other variables such as number of stents, and TASC D showed a non significant association with in hospital mortality (table 4).

Creatinine level and TASC D lesions significantly influenced the in hospital morbidity of the study group, while other variables such as age, number of stents, and number of lesions showed a non significant association with In hospital morbidity (table 5).

Table (6) shows the significant influence of the diabetes mellitus on the in hospital mortality, (all patients who died in hospital were diabetics) whereas there is no significant correlation between diabetes mellitus and in hospital morbidity.

84% of patients were alive one year after the intervention, while the other 16 % were dead. The major causes of death were: sudden cardiac death (12%), leg gangrene (3%), other causes as intestinal obstruction and strokes (1%). The rate of recurrence of the LL symptoms was 15%, of which only 7 % were due to target lesion restenosis or re-occlusion (46.6% of all recurrent), and the remainder 8% was due to other lesions (53.4% of all recurrent), confirmed mainly by duplex. The presentation of patients with recurrent symptoms was: claudication (10%), critical lower limb ischemia (4%), and acute limb ischemia (1%). The management of patients with recurrent symptoms at one year was: endovascular revascularization (10.3%), surgical revascularization (5.1%), whereas (84.6%) of patients with recurrence of lower limb symptoms were placed on medical treatment (table 7).

Advanced age significantly influenced one year outcome of the patients, while other variables such as number of lesions, number of stents, and TASC D lesions showed a non significant association with one year outcome (table 8).

Table (9) shows that number of lesions significantly increased with bilateral LL affection, while there is no significant relation with age, number of stents, creatinine or TASC D classification.

Table (10) shows that bilaterality was significantly associated with smoking, hypertension and positive Family history. No differences among single or bilateral lesions as regard procedural success, in hospital mortality, in hospital morbidity, 1 year mortality and recurrence of LL symptoms at one year.

Table (11) shows that the mean age was significantly high in diabetics Elevated creatinine level was also significantly elevated among diabetic patients.

Table (12) shows that the diabetes mellitus is significantly associated with hypertension and dyslipidemia in PVD patients. Diabetes mellitus also significantly raised the incidence of long lesions and significantly increased the in hospital mortality.

Table (13) shows the significant correlation between the procedure failure and the elevated level of serum creatinine.

Table (14) compares between procedure success and failure, its relation with many risk factors as well as the impact of procedure success on immediate and long term outcome. Procedure success was significantly related to the type of ischemia of the limb, with significant elevation of failure rate associated with critical lower limb ischemia, intervention on in stent re-stenotic lesions was also associated with significantly higher failure rate as compared to other lesions. Procedure failure also significantly increased the in hospital mortalities and morbidities level.

Table (15) shows the significant relations between the elevated level of serum creatinine and TASC D lesions with the recurrence of lower limb symptoms one year following the intervention.

Table (16) denoted that long lesions significantly affected the recurrence of lower limb symptoms one year following the intervention, while other factors show no significance.

The relation of lesions with different variables, including in hospital and one year follow up. Smoking significantly increased the incidence of supra-inguinal lesions, whereas diabetes and critical limb ischemia were significantly associated with infra-inguinal lesions. One year follow up mortality was significantly associated with infra-genicular lesions (table 17).

Table 1: Baseline characteristics of the patients and treated lesions

Characteristic	Value
Age (yr):	
Mean	58.00
SD	9.747
Sex (% of patients):	
Male	79.3
Female	20.7
Risk Factors: (% of patients)	
Smoking	70.7
Diabetes	66.4
Hypertension	57.1
Elevated S.Cr. level > 1.5 mg/dl.	9.60
Dyslipidemia	73.0
Distribution according to type of ischemia and affected LL: (% of patients):	
CLI	56.8
Claudication	43.2
Single limb	65.0
Both limbs	35.0
Type of lesions according to TASC classification: (% of patients):	
TASC A	40
TASC B	30
TASC C	18
TASC D	12
History of: (% of patients)	
Cardiovascular disease	72
Aortic aneurysm	0.7
Previous lower limb surgeries	17.6
Abused drugs	15.6
Distribution of patients according to Site of lesion:	
Above inguinal ligament	32.0
Below inguinal ligament; above knee	48.0
Below knee	6.7
Combined above and below inguinal ligament	7.3
Combined below inguinal and below knee	6.0

Figure 1 : Intervention success rate

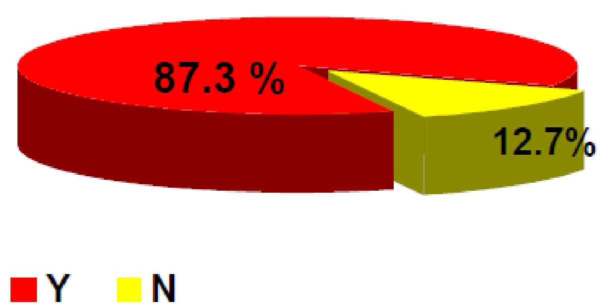

Table 2: Immediate and in-hospital results

Characteristic	Value %
Success rate (% of patients):	
Yes	87.3
No	12.7
Failure rates:	
Technical failure	5
Clinical failure	7.7
Percentage of patients according to In hospital mortality	3.3
Percentage of patients according to causes of In hospital mortality:	
DIC	0.7
Septicemia from leg gangrene	0.7
Bleeding	0.7
Cardiac arrest	1. 2
Percentage of patients according to In hospital morbidity:	8.7
Percentage of patients according to causes of in hospital morbidity:	
Hypotension	1.3
Hematoma	2.8
Hemorrhage	1.0
Dissection	1.0
Limb amputation(major, minor)	0
Renal failure	1.3
Urgent surgical intervention	1.3

Table 3: Balloons and stents, numbers and size

	N		Minimum	Maximum	Mean	Std. Deviation
Pre stent balloons	138	Diameter mm.	2	10	4.80	1.919
		Length mm.	10.00	80.00	31.2542	12.50047
		Pressure atm.	1	15	8.00	2.656
		No. of inflations	1	19*	3.47	2.938
Stents	185	Diameter mm.	5	10	7.22	1.171
		Length mm.	15	150	69.19	27.734
		Pressure atm.	8	17	12.20	3.194
Post stent deployment balloons	121	Diameter	2	10	6.47	1.586
		Length	19	80	37.57	17.693
		Pressure atm.	4	18	10.10	2.981
		No. of inflations	1	8*	3.05	1.664

*In a case with multiple bilateral lesions and the available balloon was only 20 mm length.

Table 4: Factors affecting the immediate and in-hospital mortality

Factor	In Hospital Mortality	Mean	S.D	t/Z	P	Sig
Age	No	57.88	9.569	-2.092	.042	S
	Yes	68.40	15.093			
No of stents	No	1.61	.693	-.488	.650	NS
	Yes	1.80	.837			
Number of lesion	No	1.33	.688	-2.107	.037	S
	Yes	2.00	1.000			
Creatinine >1.5 mg/dl	No	1.18	.353	-3.319	.001	HS
	Yes	1.72	.421			
TASC D	No	1.01	1.017	.679	.496	NS
	Yes	1.40	1.342			

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 5: Factors affecting the immediate and in-hospital morbidity

Factor	In hospital morbidity	Mean	Std. Deviation	t/Z	P	Sig
Age	No	58.19	9.437	.773	.441	NS
	Yes	56.00	12.871			
Number of stents	No	1.59	.701	-2.020	.074	NS
	Yes	2.00	.535			
Number of lesions	No	1.36	.715	.243	.808	NS
	Yes	1.31	.630			
Creatinine >1.5 mg/dl	No	1.18	.305	-2.140	.034	S
	Yes	1.43	.801			
TASC D	No	1.09	1.037	-2.470	.013	S
	Yes	.38	.650			

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 6: Diabetes mellitus and its relation with in hospital mortality and morbidity

			In hospital mortality		P-Value	Sig.
			No	Yes		
DM	No	% within In hospital mortality	34.7%	.0%	.046	S
	Yes	% within In hospital mortality	65.3%	100.0%		
			In hospital morbidity			
			No	Yes		
DM	No	% within In hospital morbidity	35.3%	15.4%	.146	NS
	Yes	% within In hospital morbidity	64.7%	84.6%		

Table 7: One year follow up results

One year follow up criteria	Value %
Patient state:	
Alive	84.0
Dead	16.0
cause of death:	
Leg gangrene	3.0
Sudden cardiac death	12.0
Others	1.0
Recurrence of LL symptoms	15
Site of recurrence responsible for symptoms:	
Target lesion	7
Other lesion	8
Type of ischemia:	
Claudication	10
CLI	4
Acute	1
Management of patients with recurrence of LL symptoms:	
Endovascular	10.3
Surgical	5.1
Medical ttt	84.6

Table 8: Factors affecting one year outcome results

Factor	Patient state	Mean	Std. Deviation	t/Z	P	Sig.
Age	Alive	57.12	9.862	-2.338	.021	S
	Dead	63.50	10.752			
No of stents	Alive	1.60	.746	-.089	.929	NS
	Dead	1.63	.744			
Number of lesions	Alive	1.30	.576	-.487	.628	NS
	Dead	1.38	.619			
Creatinine >1.5 mg/dl	Alive	1.24	.422	.592	.555	NS
	Dead	1.18	.274			
TASC D	Alive	1.06	1.068	-.533	.469	NS
	Dead	1.21	1.122			

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 9: Relation between patients presenting with unilateral or bilateral symptomatic LL

	Affected Lower Limb	N	Mean	Std. Deviation	t/Z	P	Sig.
Age	Single limb	138	57.63	9.686	-1.583	.116	NS
	both limbs	12	62.25	9.845			
Number of lesions	Single limb	138	1.28	.670	-4.933	.0001	HS
	both limbs	12	2.25	.452			
No. of stents	Single limb	104	1.60	.704	-1.322	.189	NS
	both limbs	10	1.90	.568			
Creatinine > 1.5 mg/dl	Single limb	134	.09	.287	-.865	.388	NS
	both limbs	12	.17	.389			
TASC D	Single limb	135	1.04	1.043	.681	.497	NS
	both limbs	12	.83	.835			

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 10: Comparison between the single and bilateral LL affection

	Affected LL		P value	Sig.
	Single	Bilateral		
Type of ischemia: - Claudication	41.9%	58.3%	0.271	NS
- CLI	58.1%	41.7%		
Smoking	68.1%	100.0%	0.02	S
Diabetes Mellitus	65.0%	83.3%	0.196	NS
Hypertension	54.8%	83.3%	0.05	S
+ve Family history	34.6%	66.7%	0.028	S
Procedure success	87.7%	83.3%	0.664	NS
In hospital mortality	3.6%	0%	0.502	NS
In hospital morbidity	9.4%	0%	0.266	NS
1 year mortality	16.3%	12.5%	0.778	NS
1 year Recurrence of LL symptoms.	21.1%	16.7%	0.796	NS

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 11: Comparison between diabetics and non diabetic patient

	DM	Mean	Std. Deviation	t/z	P	Sig
Age	No	53.56	8.362	-4.112	.0001	HS
	Yes	60.18	9.708			
Number of lesions	No	1.36	.898	.052	.958	NS
	Yes	1.35	.594			
No of stents	No	1.48	.599	-1.747	.083	NS
	Yes	1.71	.736			
Creatinine >1.5 mg/dl	No	1.1143	.31820	-2.086	.039	S
	Yes	1.2469	.38311			
TASC D	No	.94	1.029	-.893	.426	NS
	Yes	1.08	1.027			

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 12: Comparison between diabetics and non diabetic patient

		DM		P	Sig.
		No	Yes		
Type of ischemia	Claudication	50.0%	39.2%	0.209	NS
	CLI	50.0%	60.8%		
Hypertension	No	70.0%	28.9%	0.001	HS
	Yes	30.0%	71.1%		
Dyslipidemia	No	37.5%	21.5%	0.043	S
	Yes	62.5%	78.5%		
Lesion Calcification	No	70.0%	45.5%	0.005	HS
	Yes	30.0%	54.5%		
Long lesion	No	60.0%	40.4%	0.024	S
	Yes	40.0%	59.6%		
Procedure success	No	16.0%	11.1%	0.398	NS
	Yes	84.0%	88.9%		
In hospital mortality	No	100.0%	94.9%	0.046	S
	Yes	0%	5.1		
In hospital morbidity	No	96.0%	88.9%	0.146	NS
	Yes	4.0%	11.1%		
Patient state after 1 y follow up	Alive	93.3%	80.0%	0.096	NS
	Dead	6.7%	20.0%		

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 13: Relations of procedure success

	Procedure success	Mean	Std. Deviation	t/z	P	Sig.
Age	No	56.37	14.975	-.780	.437	NS
	Yes	58.24	8.798			
Creatinine >1.5 mg/dl	No	1.3579	.65347	2.001	.047	S
	Yes	1.1791	.29958			
No of stents	No	1.75	.707	.534	.594	NS
	Yes	1.61	.698			
Number of lesion	No	1.79	1.134	1.881	.075	NS
	Yes	1.29	.601			
TASC D	No	1.47	1.219	1.751	.094	NS
	Yes	.96	.983			

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 14: Comparison between procedure success and failure

		Procedure success		P	Sig.
		No	Yes		
Gender	Male	84.2%	78.6%	0.574	NS
	Female	15.8%	21.4%		
Hypertension	No	47.4%	42.2%	0.670	NS
	Yes	52.6%	57.8%		
Dyslipidemia	No	21.1%	27.9%	0.533	NS
	Yes	78.9%	72.1%		
Smoking	No	21.1%	30.5%	0.4	NS
	Yes	78.9%	69.5%		
Affected Lower Limbs	Single limb	89.5%	92.4%	0.664	NS
	Both limbs	10.5%	7.6%		
Type of ischemia	Claudication	10.5%	48.1%	0.002	HS
	CLI	89.5%	51.9%		
Lesions Calcification	No	42.1%	55.7%	0.266	NS
	Yes	57.9%	44.3%		
Long lesions	No	42.1%	48.1%	0.625	NS
	Yes	57.9%	51.9%		
In-stent restenosis	No	73.7%	93.1%	0.006	HS
	Yes	26.3%	6.9%		
In hospital mortality	No	73.7%	100.0%	0.001	HS
	Yes	26.3%	0%		
In hospital morbidity	No	73.7%	93.9%	0.003	HS
	Yes	26.3%	6.1%		
Patient state 1 y follow up	Alive	84.6%	83.9%	0.948	NS
	Dead	15.4%	16.1%		

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 15: Relations of lower limb symptoms recurrence with different factors

	Recurrence of LL ischemia:	Mean	Std. Deviation	t	P	Sig
Age	No	57.44	10.799	.240	.811	NS
	Yes	56.75	7.844			
Number of lesion	No	1.28	.552	-.214	.831	NS
	Yes	1.31	.602			
No of stents	No	1.65	.785	.929	.357	NS
	Yes	1.42	.669			
Creatinine >1.5 mg/dl	No	.812	.38180	3.184	.031	S
	Yes	1.2507	.25876			
TASC D	No	.98	1.025	-2.066	. 048	S
	Yes	1.31	1.352			

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 16: Factors that influence recurrence of symptoms one year following the intervention

		Recurrence of LL ischemia		P	Sig.
		No	Yes		
Gender	Male	71.4%	50.0%	109	NS
	Female	28.6%	50.0%		
Hypertension	No	40.0%	50.0%	.472	NS
	Yes	60.0%	50.0%		
Dyslipidemia	No	24.6%	18.8%	.627	NS
	Yes	75.4%	81.3%		
Smoking	No	28.3%	25.0%	791	NS
	Yes	71.7%	75.0%		
DM	No	31.1%	31.3%	.994	NS
	Yes	68.9%	68.8%		
Affected Lower Limbs	Single limb	91.8%	93.8%	.796	NS
	Both limbs	8.2%	6.3%		
Type of ischemia	Claudication	48.3%	37.5%	.440	NS
	CLI	51.7%	62.5%		
Lesions Calcification	No	49.2%	68.8%	.163	NS
	Yes	50.8%	31.3%		
Long lesions	No	54.1%	68.8%	.041	S
	Yes	45.9%	31.3%		
In-stent restenosis	No	40.7%	37.5%	818	NS
	Yes	59.3%	62.5%		
In hospital morbidity	No	86.9%	100.0%	126	NS
	Yes	13.1%	.0%		

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Table 17: Comparison and relations of different sites of lesions

		Site of lesion				P	Sig.
		Above inguinal ligament	Below inguinal ligament above knee	Below knee	combined lesions		
Smoking	No	10.9%	36.6%	70.0%	25.0%	0.001	HS
	Yes	89.1%	63.4%	30.0%	75.0%		
DM	No	51.1%	29.2%	10.0%	20.0%	0.012	S
	Yes	48.9%	70.8%	90.0%	80.0%		
Type of ischemia	Claudication	63.8%	35.2%	10.0%	40.0%	0.002	HS
	CLI	36.2%	64.8%	90.0%	60.0%		
Procedure success	No	14.6%	11.1%	.0%	20.0%	0.434	NS
	Yes	85.4%	88.9%	100.0%	80.0%		
In hospital mortality	No	100.0%	95.8%	100.0%	90.0%	0.178	NS
	Yes	0%	4.2%	.0%	10.0%		
In hospital morbidity	No	91.7%	88.9%	100.0%	95.0%	0.607	NS
	Yes	8.3%	11.1%	0%	5.0%		
Patient state 1y follow up	Alive	97.3%	81.8%	28.6%	83.3%	0.001	HS
	Dead	2.7%	18.2%	71.4%	16.7%		
Recurrence of LL symptoms 1y follow up	No	90.3%	68.6%	100.0%	77.8%	0.153	NS
	Yes	9.7%	31.4%	.0%	22.2%		

P>0.05: Non significant (NS), P< 0.05: Significant (S). P<0.01:Highly significant (HS)

Discussion

In this registry, we explored the outcome measures available to report success rates in immediate and one year follow-up after percutaneous interventions for symptomatic peripheral arterial disease performed in daily clinical practice and the factors affecting the different outcome criteria of the endovascular intervention. The immediate and in hospital outcomes were a reflection of the clinical and technical success, whereas reporting of one year follow up was based on clinical evaluation as well as objective data, mainly on imaging tests.

Tests that were used routinely in daily clinical practice include the arterial duplex, ABI and the patient's self-evaluation of symptoms.

From the patient's perspective, and probably also the treating physician's perspective, the most relevant outcome is the symptomatic outcome.

Symptomatic change, however, is highly subjective; symptoms may be affected by the patient's attitude about his or her health status, the placebo effect, and the patient–doctor relationship. The ABI, on the other hand, is not affected by these potential biases. A thorough inspection of the feet by the physician is imperative to look for limb ulcers or tissue breakdown, especially between the toes. A leg elevation test can elicit rest pain and/or pallor upon limb elevation for 2 to 3 minutes and slow return of rubor and decreased pain upon return to the dependent position.

Our registry showed that PVD is more common in age more than 60 years with male predominance. In our study 70% of patients were smokers. 73% were dyslipidemic, 66.5%, diabetics, 57 % were hypertensive.

Numerous studies have elucidated the risk factors for lower extremity atherosclerotic occlusive arterial disease [13, 14,15,16].

Analysis of the Framingham Heart Study for risk factors and intermittent claudication risk demonstrate that male gender is a significant risk factor for the development of symptomatic PAD, although not all studies have found a similar association [17]. Age is a consistent risk factor for PAD [18,19].

In the Bogalusa study, Berenson et al., using autopsy data, showed convincing evidence that atherosclerosis may begin at a very young age and is not unique to middle aged and older individuals with other risk factors [20].

The incidence of symptomatic PAD in subjects aged > 70 years is approximately 5%, with asymptomatic disease several times higher [18,21].

In subjects with type 2 diabetes mellitus, the UKPDS study clearly showed that intermittent claudication is 3.4 times more frequent among men with diabetes mellitus and 5.7 times more frequent among women with diabetes. The risk of amputation or death from peripheral vascular disease was closely associated with the glycosylated hemoglobin A1C level, although intensive medical treatment did not seem to reduce this risk significantly [22].

As with CAD, tobacco smoking is closely linked to PAD. The severity of PAD is directly proportional to the number of cigarettes smoked. On average, the diagnosis of PAD is made 10 years earlier in smokers than nonsmokers. Overall, PAD is three times more prevalent in smokers [23].

The degree of hypertension is also closely linked to the development of PAD [24].

Atherosclerotic PAD itself may contribute to hypertension, thus establishing a cycle of PAD and hypertension. Indeed, the treatment of hypertension may unmask previously asymptomatic PAD, presumably by decreasing the pressure gradient across the diseased vessel.

In the third National Health and Nutrition Examination Survey, PAD prevalence was significantly greater with tobacco use, African American ethnicity, glomerular filtration rate (GFR) of less than 60 mL /min, diabetes mellitus (DM), and hypercholesterolemia [22].

The risk of PAD progressing to critical limb ischemia (CLI) is increased with DM, tobacco use, ABI less than 0.5 (OR, 2.5), age greater than 65 years, and hypercholesterolemia. The extent to which the PAD prevalence increases depends on the number of risk factors present at diagnosis of peripheral arterial disease.

Compared to patients with no risk factors at diagnosis, presence of one or more risk factors increases the likeness of PAD, and risk increase for increasing numbers of risk factors, compared to no risk factor [24,25].

In our registry, most of the patients with PVD presented with critical lower limb disease with non healing ulcer, and the majority of procedures were performed for the superficial femoral artery followed by iliac arteries interventions.

Clinical success rate in this study was 87.3% and the procedures were associated with some morbidity and mortality. The incidence of in hospital mortality was 3.3% and the main cause of death was related mainly to associate co-morbidities in these patients especially coronary artery disease. The resultant in hospital morbidity was 8.7% and minor hematoma was the major cause of morbidity followed by contrast induced nephropathy, hypotension, hemorrhage and access site dissection and these factors are predictors of procedural failure.

The procedural success rate in the LACI trial was 88%, and the 6-month limb salvage rate was 93%. Endovascular intervention for CLI as reported by Kandzari et al. [26] had a procedural success rate of 99% with a 1% major adverse event rate and no unplanned amputations. Heparin-coated, small-diameter, balloon-expandable stents were used for the treatment of tibial disease by Feiring et al. with good results [27].

A meta-analysis of six PTA studies (1,300 patients) has established the high technical success of PTA for aorto-iliac occlusive disease, with a combined immediate technical success for stenoses and occlusions of 91 percent [28]. Long-term success rates of PTA vary from 53 to 70 percent at five years, depending on the severity of disease and which diseased blood vessel was treated [29].

In a quality-of-life study of patients treated with PTA for iliac artery occlusive disease, walking distance improved by 20 percent 24 months after PTA. Physical functioning also improved, along with a significant decrease in pain [30].

The Veterans Administration Cooperative Study Group 276 found that, in a group of patients with claudication randomized to bypass surgery or angioplasty, no significant outcome difference was found at four years, but the early mortality rate was better with angioplasty. Angioplasty failure did not preclude performing subsequent bypass grafting or increase the rate of limb loss [31].

In a Swedish study comparing angioplasty with surgery, significantly shortened length of hospital stay was found in patients undergoing angioplasty for claudication or chronic limb ischemia, compared with a surgery group. Similar success and complication rates were found at one year [32].

In a literature review and multivariate sensitivity analysis evaluating quality adjusted life years as the main effectiveness measure, a Dutch-American study group favored angioplasty as the first-line treatment modality for claudication [33].

The current registry studied the influences of many factors on the immediate outcome; we demonstrated that number of lesions, elevated serum creatinine level and diabetes mellitus were independent factors for immediate and in hospital mortality after lower limb peripheral vascular intervention.

The same factors also influenced the in hospital morbidity, the elevation of serum creatinine level and TASC D lesions were independent factors for the in hospital morbidity, while number of lesion and diabetes mellitus showed no significant correlation with the in hospital morbidity.

Factors affecting the one year patency rate included: advanced age, which was demonstrated to be an independent factor for one year patency and recurrence of symptoms, whereas other variables such as number of lesion, number of stents, and TASC D lesions showed a non significant association with one year outcome.

The incidence of restenosis varies considerably depending upon the vascular bed but appears to be highest in the infrainguinal vessels, particularly in the femoropopliteal and tibial arteries, where it remains the Achilles' heel of percutaneous peripheral interventions [34,35].

The restenosis process in the periphery does not appear to stop at the 6-month mark, as seen with bare metal stents in the coronary arteries, but continues for a longer time, possibly years, after the intervention [34,36].

In a meta-analysis of 1003 patients undergoing percutaneous peripheral interventions of the superficial femoral artery (SFA), the patency rates at 1, 3 and 5 years were 59%, 52%, and 45%, respectively [34]. In the renal arteries, restenosis continues to be seen at 22 months after intervention [36].

In our registry the recurrence of symptoms one year after the intervention had occurred in 15% of survivors, and among those with recurrence only 46% presented with target lesion restenosis, confirmed by one or more imaging modalities. Only 26% of patients with recurrent symptoms presented with critical limb ischemia requiring revascularization mainly by endovascular intervention. The rest of patients presented with claudication and were treated mainly by exercise and medical therapies.

The recurrence of lower limb symptoms one year following the intervention influenced by elevated level of serum creatinine, endovascular intervention of TASC D lesions and long lower limb lesions interventions.

Faglia et al. [37], from a consecutive series of 1,191 diabetic patients with peripheral vascular disease referred for endovascular consultation, provisional stenting were feasible in 84%, and during a median follow up of 23 months, the major amputation rate was only 1.7% (4% on intention-to-treat analysis).

The clinical recurrence rate was 11.3%. Bypass surgery was performed in 157 patients (13.2%) with an 8.3% major amputation rate. Of the 47 subjects who were not re-vascularized (five anesthesiology risk, four patient refusal; 38 were not considered by the vascular surgeon as candidates for bypass surgery), 34% underwent major amputation.

Nicolas et al. [38] studied the predictors of target lesion revascularization in a consecutive cohort of patients from two medical centers. They concluded that Younger age and longer treated vessel length are independent predictors of target lesion revascularization in patients undergoing peripheral arterial intervention.

Patients undergoing peripheral vascular interventions represent an important cohort in which secondary vascular disease prevention is likely to be particularly effective and cost-effective.

Cardiologists are doing an increasing share of peripheral vascular interventions, and there is an opportunity to have a far-reaching impact by focusing beyond the intervention [39,40].

Cardiovascular specialists have an opportunity not only to provide high-quality and appropriate vascular interventions, but also to seize the peri-procedural moment in aggressively treating the underlying atherosclerotic process through lifestyle modifications and effective pharmacological therapies. Ultimately, the attention to these disease management opportunities is more likely to affect both quality and quantity of life than the procedures themselves.

Findings from the current registry highlighted another relation between smoking, hypertension and positive family history with single and bilateral lower limb affection. We found that number of lesions; smoking, hypertension and positive family history were significantly associated with bilateral lower limb affection.

Gallino et al.(41) reported predictors of 5-year patency post percutaneous peripheral interventions in 411 patients (482 lower limb arteries). Patients with stenoses or occlusions <3 cm had a favorable long-term patency rate of 74% at 5 years. In contrast, patients with femoro-popliteal occlusions presenting with pain at rest, diabetes, occlusions 3 cm, or poor distal runoff had an elevated rate of reocclusion.

Capek et al. [42] described factors negatively influencing long-term patency after femoro-popliteal percutaneous peripheral interventions at a mean follow-up of 7 years in 217 treated vessels; these included diabetes mellitus, diffuse atherosclerotic cardiovascular disease, or threatened limb loss. Also, technical factors that correlated with failure were lesion length, moderate eccentricity, and a poor post angioplasty appearance.

In our registry comparison was made between diabetics and non-diabetics patients, as might be expected; diabetes mellitus was a strong risk factor for a subsequent peripheral vascular disease. Advanced age, elevated serum creatinine level, hypertension and dyslipidemia, were significantly noticed among diabetics. Lesions morphology were also different between the two groups, long lesions as well as calcifications were significantly common in diabetics. In addition diabetes mellitus was a powerful predictor of in hospital morbidity.

Multiple clinical predictors of reduced patency in the lower limb have been reported. Patency rates seem also to be worse in patients with limb ischemia and total occlusions compared to claudicants.

In one study, the 5-year patency rate after femoro-popliteal angioplasty was 55% for claudicants, 29% for limb ischemia, and 36% for total occlusions [43].

Also, the patency rate was reportedly lower in patients with fewer runoff vessels [44,45].

In 347 patients who underwent endovascular treatment for claudication in 481 limbs, Davies et al. [44] noted that vessels with compromised and poor runoff had significantly lower freedom from recurrent symptoms and from restenosis at 5 years' follow-up.

In addition, in one study, diabetes was an independent predictor of restenosis but not plasma homocysteine [46]. Furthermore, plasma viscosity, low platelet count, longer lesion length, and lack of hypertension were associated with restenosis at 12 months [47].

Successful outcome after lower extremity intervention is dependent on various potential risk factors; in our registry we retrospectively examined success after lower extremity intervention and evaluated the impact of a many factors on procedure success. Elevated serum creatinine and critical limb ischemia are independent factors for procedural failure. Intervention after instent restenosis was also associated with higher incidence of procedure failure.

In comparison with procedure success, procedural failure was associated with significant high risk of in hospital mortality and in hospital morbidity. It is mainly due to prolonged time of intervention, increased contrast volume and associated comorbidities.

Smoking is a major risk factor for the development of atherosclerosis, particularly in the peripheral arteries [48,49].

Consistently, in the present study, smokers were more associated with above inguinal ligament lesions, while below knee lesions were more frequent with diabetics and those presented with critical limb ischemia.

Site of lesion also affected the outcome after percutaneous peripheral intervention; in our study infra-genicular lesion was an independent factor for one year mortality following endovascular intervention, as most of those patients presented with CLI and were diabetics.

Giles et al. [50] reported a high rate of restenosis and re-intervention in 163 patients (176 limbs) undergoing infra-popliteal angioplasty with bailout stenting. At 1 and 2 years, primary patency rates were 53% and 51%, respectively, and freedom from secondary restenosis and re-intervention were 63% and 61%, respectively.

Sarac et al.(51) also reported their experience with 167 tibial vessels treated with Silver Hawk atherectomy for limb ischemia. Cumulative 1-year primary and secondary patency rates were 43% and 57%, respectively, which did not appear to differ from historic angioplasty findings. Tobacco use, renal disease, diabetes, and tissue loss were all predictors of patency loss.

Our study is limited by its relatively small number of patients, but excellent overall follow up was achieved. Also, operator bias in treating patients might have influenced the target lesion revascularization rate in the absence of pre-defined prospective criteria for re-intervention.

Furthermore, there were no set criteria for lesion revascularization in this study. The presence of claudication or limb ischemia, however, was the driving factor to retreat these patients, as asymptomatic patient were not treated in this cohort.

The procedure success did not influence the patient state one year after the intervention as the patients with procedural failure may had other endovascular or surgical interventions.

Conclusion

Dramatic shifts in the management of peripheral vascular disease have occurred toward endovascular intervention together with an overall decline in mortality and morbidity. There seems to be a significant mortality and morbidity advantages for endovascular as compared with traditional surgery. The increasing safety of vascular interventions should be considered when deciding which patients to treat with the caveat that independent factors of outcomes should be respected.

A Global Strategy to Achieve Optimal Outcome with Percutaneous Peripheral Interventions is Offered

1. Obtain excellent acute angiographic results with less dissection and recoil.
2. Protect the distal tibial vascular bed.
3. Reduce smooth muscle cell proliferation with pharmacological intervention.

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