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Cohort Study

Frequency of recurrence of peripheral artery disease among angioplasty and stenting patients☆

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ABSTRACT

Background: Peripheral artery disease (PAD) is a cardiovascular disease that is characterized by obstruction of peripheral artery. It is associated with comorbidities, reduced quality of life and mortality. The aim of this study was to determine the frequency of recurrence of PAD among patients who underwent angioplasty or stenting and associated risk factors.

Methods: In this retrospective study, all patients referred to the cardiovascular center of (XXX) with the diagnosis of lower extremity PAD were included. Patients' demographic information, age, gender, smoking status, history of diabetes, history of hypertension, dyslipidemia, number of vessels, type of stent, recurrence of the disease, and size of the lesion were obtained from the hospital database. Endovascular revascularization therapy was either performed by angioplasty or stenting method. The data were analyzed by SPSS v21.

Results: Of 88 patients included in this study, 12.5% were reported with restenosis. Gender, age, size of the lesion, the status of smoking, history of hypertension, and dyslipidemia were not significantly associated with the recurrence of stenosis, $p > 0.05$. There was a significant relationship between the vessels involved and the type of revascularization method and the recurrence of the PAD.

Conclusion: Endovascular revascularization technique and type of vessel involved in PAD are significant factors contributing to restenosis in our population of study. However, further studies with a greater sample size are required in this area.

1. Introduction

Peripheral arterial disease (PAD) is characterized by blockage of one or more peripheral arteries as a result of atherosclerosis, thrombosis, embolism, scoliosis, and fibromuscular dysplasia [1]. PAD is strongly associated with major cardiovascular events and symptoms [2]. It reduces the quality of life [3]. PAD is the third leading cause of atherosclerosis vascular morbidity following stroke and coronary heart disease [4].

In general, only 10–30% of PAD patients experience varying degrees of claudication. Severe limb ischemia is approximately 400–450 million per year and amputation occurs in 112–225 million cases per year [5,6]. The risk factors for coronary atherosclerosis causing peripheral atherosclerosis include diabetes, dyslipidemia, and hypertension [7]. The prevalence of PAD in smokers is 2–4 times higher than in non-smokers [8]. Smoking is seen to have a dose-dependent relation with PAD [4]. Approximately 50% of diabetic and foot ulcer patients are reported with PAD [9]. Furthermore, due to the absence of claudication and rest pain in diabetic patients, diagnosis of PAD is presented with severe tissue loss [10]. Fat metabolism disorders also increase the prevalence of PAD up to 1.3 to 2.2 times [11].

The gender-based epidemiology of PAD is divided into high-income and low to middle-income countries [12]. PAD is significantly greater among women in high-income countries whereas, not much of the gender based differences are seen in low to middle-income countries [13]. Furthermore, the incidence of PAD is higher in low to middle-income countries [14].

PAD is diagnosed by segmental pressure measurement, ankle-brachial index (ABI) [15], treadmill exercise test, pulse volume recording, Doppler ultrasonography, duplex ultrasound, magnetic

; PAD, Peripheral arterial disease; ABI, ankle-brachial index; EVT, endovascular therapy.

☆ This study was approved by the Research Ethics Board of Lorestan University of Medical Sciences (IR.LUMS.REC.1396.719).

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resonance angiography, computed tomographic angiography, and contrast angiography[16]. Endovascular revascularization therapy includes balloon angioplasty or stent [17]. Revascularization is recommended in all patients with claudication in addition to medical therapy [18,19].

The aim of this study is to evaluate the rate of recurrence of PAD among angioplasty and stent patients and the relationship of restenosis with the patient and disease-associated factors.

2. Methods

Study population, sampling method, and sample size: In this retrospective study, all patients referred to the cardiac center for diagnosis of lower extremity PAD by ankle-brachial index (ABI) measurement or arterial ultrasound were enrolled. Involvement of common and external iliac artery or femoral artery was confirmed by angiography. The sampling method was census and all subjects were included in the study. Patients with pregnancy, kidney or hematological disease, previous history of angioplasty/stenting, and infections were excluded from the study. File of patients presented with postoperative complications was also not included.

2.1. Procedure EVT

All patients received endovascular therapy (EVT) by 5000 units of heparin before treatment. Para-synthesis of the inguinal region was accomplished through the iliac artery followed by stenting using the two types of balloon self-propelled stents (Scuba™ Stent System) was inserted in a balloon-type stent (dynamic balloon expandable stent by Biotronik Berlin Germany) Aspirin (maintenance dose of 75–162 mg) and prasugrel (maintenance dose of 10 mg) was administered orally to the patients as dual antiplatelet drug therapy after EVT jet determination. Also, medications prescribed before EVT for the treatment of hypertension and hyperlipidemia were continued. Patient records from 2015 to 2016 were used to obtain the data regarding the stage of the disease and related risk factors.

All patients were fully informed about treatment, trials and risks and informed consent was obtained before the study. The size of the lesion was divided into two groups: non-recurrence and recurrence and total.

The amount of degree of stenosis preoperatively and postoperatively after digital subtraction angiography in 2 directions was calculated by the manufacturer's software. Cases with residual postoperative stenosis of less than 30% were considered as initial success in the follow-up of patients at 1, 3, 6 months after EVT, and then through office visits at 6-month periods. Recurrent stenosis was defined as a decrease of more than 0.1 in ABI and more than 50% of stenosis confirmed by ultrasound or angiography. All patients were understudy until the end, and no patients were excluded for reasons such as death or follow-up. After collecting the data and entering them in SPSS version 21 in the descriptive section, we calculated appropriate indices and plotted charts and used chi-square, and independent T-test to investigate the relationship between variables. P<0.05 was statistically significant. The risk factors were analyzed using odds ratio (OR) with confidence interval (CI) of 95%.

This study was approved by the Research Ethics Board of (XXX).

Unique identifying number is: researchregistry7278.

The methods are reported in accordance with STROCSS 2021 guidelines [20].

3. Results

In this study 95 patients with PAD were enrolled, 7 of whom were referred directly for coronary artery bypass graft after angiography and no stenting was performed. Of 88 patients who underwent stenting, the mean age of the patients was 70.77 ± 7.08 years. Our patients included 77.3% men and 22.7% women. 51.1% of these patients were non-smokers and 60.2% were diabetic. Among non-diabetic patients, hypertension (53.4%) and dyslipidemia (62.5%) were the main causes of PAD(Table 1).

As shown in Table 2, most of the patients had common iliac (35.2%) and the lowest involvement external iliac, and 11.4% had common femoral involvement. The most commonly used stent was the Scuba™ Stent System (71.6%) and the least type was marise stent & dynamic stent was used in only one patient (1.1%). There was no recurrence of the disease in 87.5% of the studied patients and there was recurrence in 12.5% of the control patients.

The mean age in the relapse group was higher than the non-relapse group (73.72 vs 70.35 years) but independent *t*-test did not show a statistically significant difference, (p = 0.14). The mean lesion size in the recurrence group was higher than the non-recurrence group (56.91 vs. 48.05), but the difference was not statistically significant, (p = 0.09) (Table 3).

The mean recurrence of disease in men was 1.32 times higher than in women (72.7% vs. 27.3%, OR = 1.32, CI = 0.31–5.54) however, the difference was not significant, p = 0.70. The rate of recurrence was 0.34 times higher in nonsmokers than smokers (72.7% vs. 27.3%, OR = 0.34, Cl = 0.08–1.40, 95%) which was also not significantly different, p = 0.13. The recurrence rate in non-diabetic patients was 3.37 times more than diabetic patients (81.8% vs. 18.2%, OR = 3.37%, CI = 0.68–16.67, 95%). The two group was not seen to be significantly different in terms of recurrence rate, p = 0.12.Recurrence was among hypertensive patients was 2.59 times more than patients without hypertension (72.7% vs. 27.3%, OR = 2.59, CI = 0.64–10.53). The difference was not statistically significant, p = 0.17. The rate of relapse in patients with dyslipidemia was not statistically significant, p = 0.45 It was 0.58 times higher in patients without dyslipidemia (72.7% vs. 27.3% OR = 0.58 Cl = 0.14–2.39, 95%).

As shown in Table 4, the rate of relapse in patients with vascular involvement of external iliac + common iliac was significantly higher than in other patients (p = 0.04). Patients with scuba stents were statistically significantly higher than other types of stents (p = 0.009).Also, the rate of recurrence of the disease in patients using balloon retransmitted stenting was significantly more than recurrence in patients with self-prophylactic stenting (63.6% vs. 36.4%, OR = 0.09, Cl = 0.02, P = 0.007).

4. Discussion

This is the first study conducted to evaluate the frequency of recurrence of pelvic PAD among angioplasty and stenting patients and associated factors [21,22]. It was seen that 12.5% of the patients had recurrence after stenting. The frequency of recurrence was higher in men than women, nonsmokers, nondiabetic and hypertensive patients, as well as in those with dyslipidemia, although these differences were not statistically significant (P>0.05). Vascular involvement, type of stent used, and stenting method were significantly associated with recurrence of stenosis (P<0.05). There are several studies conducted to evaluate the frequency of recurrence in patients with PAD angioplasty [23,24].

Table 1
Frequency and percentage of demographic variables in the studied patients.

Demographic variables		Number	%
Sex	Male	68	77.3
	Female	20	22.7
Status of a smoker	Non smoking	45	51.1
	Smoking	43	48.9
Diabetes	No	53	60.2
	Yes	35	39.8
high blood pressure	No	41	46.6
	Yes	47	53.4
Dyslipidemia	No	33	37.5
	Yes	55	62.5

Table 2
Frequency and percentage of the main demographic variables studied.

Demographic variables		Number	%
Involved vessels	External iliac	21	23.8
	External iliac + common iliac	26	29.5
	External iliac + common femoral	10	11.4
	common iliac	31	35.2
Type of stent	Marise& scuba	7	8.0
	Marise stent & dynamic	1	1.1
	Scuba stent	63	71.6
	Dynamic stent	17	19.3
Recurrence of disease	Yes	77	87.5
	No	11	12.5

Table 3
Mean and standard deviation of age and size of lesion in two groups of non-recurrence and recurrence and total individuals.

Variables	non-recurrence	recurrence	Total	p-value
	Standard deviation + mean	Standard deviation + mean		
Age	70.35 ± 6.97	73.72 ± 7.47	70.77 ± 7.08	0.14
Size of the lesion	48.5 ± 15.51	56.91 ± 21.11	49.16 ± 16.43	0.09

Table 4
Frequency and percentage of studied variables by recurrence and non-recurrence groups.

Demographic variables		Recurrence N(%)	non-recurrence N(%)	p-value
Involved vessels	External iliac	1(9.1)	18(23.4)	0.04
	External iliac + common iliac	5(45.4)	23(29.9)	
	External iliac + common femoral	3(27.3)	7(9.1)	
	common iliac	2(18.2)	29(37.7)	
Type of stent	Marise& scuba	3(27.3)	4.(5.2)	0.009
	Marise stent & dynamic	1(9.1)	0(0.0)	
	Scuba stent	6(54.5)	57(74.0)	
	Dynamic stent	1(9.1)	16(20.8)	
Method of stenting	self-prophylactic stenting	4(36.4)	4(5.2)	0.007
	balloon retransmitted stenting	7(63.6)	73(94.8)	

Stenting and related factors have been reported in different populations that have reported different results [25].

In a study by Fishman et al., 31.6% of the patients in stent group and 42.1% in angioplasty balloon group were reported to present restenosis [26]. The rate of restenosis in patients with angioplasty balloon was significantly more than in the stent group ($p = 0.046$), these results are consistent with our findings. Serruys et al., reported that the use of stents significantly reduces restenosis rate from 32% to 22% [27]. Of the 827 patients, the frequency of restenosis was 16% in the stent group and 31% in the balloon angioplasty group. Erbel et al. showed that non-stent angioplasty was associated with 32% restenosis rate and stent angioplasty led to 18% restenosis[28].

There are also different results regarding the effect of demographic factors of age and gender on the prevention of restenosis. These two factors have been suggested as independent predictors of restenosis after angioplasty in different studies. In the present study, the rate of restenosis was higher in men than women (72.7% vs. 27.3%), however, this difference was not statistically significant ($p = 0.70$). In the study by Heidland et al. and Gurlek et al. age and sex did not contribute to the increased risk of restenosis, which was consistent with our study results [29, 30]. Gurlek et al. and Taira et al. showed that smoking does not increase the risk of restenosis[31]. Our findings are parallel with those reported for these studies.

Diabetes is also a predictive risk factor for restenosis. Nonetheless, in our study, restenosis was non-significantly higher in nondiabetic patients relative to diabetic ones (81.8% vs. 18.2%). In a study by Kastrati et al. diabetes increased the risk of recurrent stenosis (OR = 1.86) [32]. Lee et al. reported an increased risk of restenosis among diabetes stent angioplasty patients, but discrepancies regarding the role of diabetes in recurrent stenosis and angioplasty with and without stents have been reported[33]. Ali, Ahmed [34] concluded that diabetic patients with hypertension are presented with significantly greater frequency of PAD [35]. Gurlek et al. study showed that hypertension was associated with an increased risk of restenosis after angioplasty, which is contrary to our findings(30). In the present study, the rate of recurrence of stenosis in patients with vascular involvement in external iliac + common iliac was significantly higher as compared to the femoral artery ($p = 0.04$).

Recurrence of stenosis was 0.58 times higher among patients with dyslipidemia. A study by Gary, Rief [36] showed that recurrence is significantly associated with increased apoB, high-density lipoprotein, and cholesterol and decreased low-density lipoprotein.

Our study does not include the complete cardiovascular history of the patients and the findings are drawn from a small sample size involving a single race. Furthermore, stents of two different brands were used which might have contributed to the biased results.

5. Conclusion

Our study reported that the incidence of recurrence of stenosis in non-smokers, non-diabetic and hypertensive patients, and those with dyslipidemia was more common than patients without recurrence of stenosis. However, the difference was not significant. The stent type, the type of vessel involved, and stenting method used are likely to be involved in restenosis.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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No funding was secured for this study.

Author contribution

Dr. Amir Shakarami: conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript. Dr. Alireza Gheini and Dr. Parsa Namdari: Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript. Dr. Ali Pooria and Dr. Mehrdad Namdari: Coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content.

Consent

Not applicable.

Registration of research studies

1. Name of the registry: N/a
2. Unique Identifying number or registration ID: N/A
3. Hyperlink to the registration (must be publicly accessible): N/A

Guarantor

Mehrdad Namdari.

Human and animal rights

No animals were used in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

Availability of data and material

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Declaration of competing interest

The authors deny any conflict of interest in any terms or by any means during the study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2021.103146.

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