The evaluation of the success rate, complications and mid-term follow up results of patients with peripheral arterial disease of lower limb treated using endovascular therapy: A single center study

Mohammad Hasan Namazi (1)
Fatemeh Abedi (1)
Morteza Safi (1)
Hossein Vakili (1)
Habibollah Saadat (1)
Saeed Alipour Parsa (1)
Isa Khaheshi (1)
Soroush Veisi (2)

(1) Cardiovascular Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
(2) Faculty of medicine, Tehran University of Medical Sciences, Tehran, Iran

Corresponding author:
Soroush Veisi
Faculty of medicine, Tehran University of Medical Sciences,
Tehran, Iran

Received: December 25, 2017; Accepted: December 30, 2017; Published: March 1, 2018. Citation: Mohammad Hasan Namazi et al. The evaluation of the success rate, complications and mid-term follow up results of patients with peripheral arterial disease of lower limb treated using endovascular therapy: A single center study. World Family Medicine. 2018; 16(3):34-38. DOI: 10.5742/MEWFM.2018.93302

Abstract

Background: Peripheral arterial diseases (PAD) as a highly prevalent disease all over the world is one of the major causes of limb amputations. Endovascular treatments have surpassed surgery in the past decades and are recommended in most of the cases but there is not adequate data regarding the safety and success rate of the procedure. In this study we evaluated the success rate, complications and follow up results of lower limb endovascular interventions.

Methods: 80 consecutive patients went under the procedure from January 2016 to February 2017. Demographic data, comorbidities and risk factors, ABI, Rutherford and Fontaine score before and after the procedure and six months later and periprocedural complications were recorded for each patient. Analyses were done using Chi-square, Wilcoxon signed rank test, Mauchly's test of sphericity and estimated marginal means with a P-value <0.05 indicating significance.

Results: There were 80 patients in this study (87.5% males). Mean age ± SD was 63.98 ± 9 years. The most common complications were hypertension (78.8%), cardiac disease (77.5%) and smoking (71.3%). PTA for the lesions below the knee was done in 66.3% of the participants. Drug balloon and stents were used in 18.8% and 42.5% of the individuals respectively. More than 50% of the patients had no complication. Dissection (23.8%), contrast-induced nephropathy (10%) and hematoma (10%) were the most common complications. ABI, Rutherford and Fontaine scores showed significant improvement after the procedure and after the six months and creatinine levels didn't exhibit any significant increase overall.

Conclusion: Endovascular treatments for lower limb arterial disease are a safe procedure with a low rate of complications despite the existence of comorbidities in patients with PAD, and satisfactory results in mid-term follow up for patients with both below and upper the knee lesions.

Key words: peripheral artery disease, lower limb, endovascular therapy, Iran

Introduction

Peripheral arterial disease (PAD) is estimated to affect more than 200 million people all over the world (1).With trauma being the second leading cause, PAD remains the first cause of all limb losses accounting for about half of all amputations. It is estimated that the number of limb amputations due to vascular disorders will still increase in the next 30 years (2). PAD places a high burden on social, economic and health resources as the patients deal with higher rates of hospitalization, work and daily activity impairment and health-care related expenditure (3).

Percutaneous Transluminal Angioplasty (PTA) has been used as a revascularization method in different medical conditions such as lower extremities ischemia for the past decades (4). Given the lower amount of invasiveness, the risk of peri-procedural complications in PTA tend to show a marked decrease in comparison with the surgical interventions (5). Currently, endovascular procedures are the preferred treatment for some of the various types of stenosis and occlusions (e.g. Type A and B of Inter-Society Consensus classification –TASC II) (6, 7).

In this study, we aimed to evaluate the success rate of the procedure after completion, complications and follow up results within six months.

Methods

Patients

80 patients were enrolled in this study from January 2016 to February 2017, all of whom were candidates for endovascular intervention based on their clinical signs and symptoms including rest pain, ischemic ulcer and disabling claudication as well as failure to respond to medical therapy. The Institutional Review Board approved the study protocol, and patients provided informed written consent.

Demographic data was obtained for each patient. Patients were assessed for comorbidities and risk factors including hypertension, diabetes mellitus, hyperlipidemia and smoking. Previous history of renal, carotid and PAD interventions were recorded as well as a history of ulcer and amputation.

In each procedure, the time patient was exposed to the contrast, total time of procedure, time of fluorescent exposure, and the use of drug balloon or stent were recorded. Patients underwent an evaluation for Ankle-Brachial Index (ABI); creatinine and hemoglobin before the procedure and right after the procedure was done. These three factors were also measured after six months for the follow-up. An evaluation for the complications including hematoma, dissections, contrast-induced nephropathy, under-operation CVA, MI and mortality was done after the procedure.

Rutherford and Fontaine score was measured for each patient before the procedure and six months after the procedure.

Statistical Analysis

Statistical Package for the Social Sciences software (SPSS Inc, Chicago, IL USA) was used to analyze all data. Categorical data are presented as counts and percent while continuous data are presented in mean ± SD. The association between comorbidities and predisposing factors with the level of PTA was tested using Chi-square test. Patients' ABI was compared using Mauchly's test of sphericity in each step. Fontaine and Rutherford score before and six months after the procedure was compared using Wilcoxon-signed ranks test. Estimated marginal Means for creatinine levels before and after the procedure was calculated as well as six months later and pairwise comparisons were done.

Results

There were 80 consecutive patients (70 males, 87.5%) studied over a 6 months period. The mean age for the patients was 63.98 ± 9 years (ranging from 36 to 80). Hypertension (78.8%), cardiac disease (77.5%), smoking (71.3%), diabetes mellitus (56.3%), hyperlipidemia (50%), and a history of CABG (36.6) were the most common comorbidities. 12.5% of patients had a previous carotid intervention. 6.3% had a renovascular disease but none had undergone a renal intervention. 17.3% of patients had experienced previous PAD and 16.3% had a past PAD intervention (13 out of 14). 26 patients (32.5%) had ulcer and 3 patients (3.8%) had an amputation history.
Of these, 53 (66.3%) underwent PTA for the vessels below the knee and 27 (33.7%) had the lesions above the knee. Drug-balloon was used in 15 patients (18.8%) and stents were utilized in 34 patients (42.5%). Most of the patients (n = 45, 56.3%) completed the procedure without any complications but 8 out of the 35 developed a contrast-induced nephropathy (10%), 19 patients presented with dissection (23.8%), and hematoma was found in 8 of them (10%). No CVA or MI was detected in any of the patients. After six months, there were 56 (70%) patients of stage I, 2 (2.5%) in stage IIA, 19 (23.8%) in stage IIB and 3 (3.8%) in stage III based on Fontaine classification system. Based on Rutherford score, the distribution of patients was 53 (66.3%) with a grade of 0, 4 (5%) with a grade of I, 20 (25%) with a grade of II and 3 (3.8%) with a grade of III after six months.

Ulcers were present in only 4 (5%) of the patients after six months.

There was no association between gender, hyperlipidemia, family history, opium use, cardiac disease, MI, CABG, past carotid or PAD intervention, amputation and the level of vascular involvement ($P>0.05$). On the other hand, hypertension, smoking, diabetes, insulin dependency, history of CVA, and the existence of ulcer showed a significant association with the PTA level ($P<0.05$). No association between the occurrence of complication or its type and the PTA level was observed ($P=0.212$). Although ulcer existence and Fontaine score after six months showed no significant association with the PTA level, Rutherford score displayed significance ($P=0.031$). (Table 1)

Table 1: The comorbidities and factors prevalence and association with the level of the PTA

Factors		Number	Percent	Association with the PTA level	P-value
Sex	Male	70	87.5%	No	0.09
	Female	10	12.5%		
Hypertension		**63**	**78.8%**	**Yes**	**0.002**
Hyperlipidemia		40	50%	No	0.48
Diabetes		**45**	**56.3%**	**Yes**	**0.001**
Smoking		**57**	**71.3%**	**Yes**	**0.013**
Family History		11	13.8%	No	0.38
Opium		24	30%	No	0.64
Insulin		**24**	**30%**	**Yes**	**0.034**
Cardiac disease		62	77.5%	No	0.28
MI		22	27.5%	No	0.45
CABG		29	36.3%	No	0.38
Past carotid intervention		10	12.5%	No	0.79
Past PAD intervention		14	17.5%	No	0.43
Amputation		3	3.8%	No	0.21
Ulcer		**26**	**32.5%**	**Yes**	**0.004**
Drug balloon		15	18.8%	No	0.52
Stent		**34**	**42.5%**	**Yes**	**<0.001**
Complications		35	43.7%	No	0.21
Ulcer after six months		4	5%	No	0.7
Fontaine after six months		-	-	No	0.1
Rutherford after six months		-	-	**Yes**	**0.03**

Table 2: The distribution and changes of Rutherford classification of patients before and six months after the procedure

		Rutherford six months after the procedure				Total
		0	1	2	3	
before the procedure	1	1	0	0	0	1
	2	13	2	1	0	16
	3	24	2	4	2	32
	4	15	0	15	1	31
Total		53	4	20	3	80

ABI scores showed a significant increasing trend just after the intervention and six months post-procedure (P<0.001). Mean ± SD values for ABI was 0.71 ± 0.26 before treatment, 0.80 ± .0.22 after the treatment and 0.84 ± 0.20 six months after the procedure.

Rutherford scores were compared before the procedure and six months later. Results show that 77 individuals (96.2%) presented better score (lower grades) at six months and only three didn't show any progress. Of these three one had a score of 2 and two had a score of 3 (P<0.001). Most patients with any initial Rutherford score were evaluated "asymptomatic" along with a zero Rutherford score. In twenty of the cases a Rutherford score of 4 showed a two-step decline and patients were relieved from rest pain. More details of the comparisons are presented in Table 2.

Wilcoxon-signed Rank test for Fontaine score showed similar results to Rutherford score. Out of 80 patients, 77 (96.2%) got a better score in the six-month evaluation and 3 showed no change. Fifty-six patients who were at stages II and III became symptom-free at six months after the procedure. Table 3 shows more details of the comparisons.

Table 3: The distribution and changes of Fontaine classification of patients before and six months after the procedure

		Fontaine six months after the procedure				Total
		I	IIA	IIB	III	
Fontaine before the procedure	IIB	15	1	1	0	17
	III	26	1	3	2	32
	IV	15	0	15	1	31
Total		56	2	19	3	80

Although there was a rise in mean creatinine levels after the procedure no significant difference was observed in any data sets of before, after and six months later compared two by two.

Discussion

Our data here show that there has been a regression of the disease stage in 96% percent of patients enrolled in this study in a 6 months follow-up period after a procedure of PTA either below or above the knee. There was an alleviation from the intolerable symptom of rest pain in 31 patients of which 15 were completely free of symptoms. The total number of patients who did not show any symptoms after 6 months was 56 based on Fontaine score which accounted for 70% of all participants.

Several other studies presented similar results of success and follow-up patency rate as our study. Korkmaz et al. reported a primary patency rate of 84% and freedom from re-intervention for 8 years at a 76% rate in a similar single-center study(8). Another study done by Guo et al. showed a successful revascularization rate of 95% and a 77% first-year primary patency rate for the TASC II D lesions (7, 9). These results together seem promising and a prediction of the shift from open surgery to newer endovascular techniques doesn't seem unreasonable.

More than half of the patients were complication-free after the procedure despite the high prevalence of comorbidities among the patients. There were no major complication such as MI or death following the procedure and according to Axisa et al. the occurrence of such complications or those requiring emergent therapy is rare (10). In the study of Korkmaz et al. dissection and hematoma were complications in 12.1% and 3.2% as opposed to 23.2% and 10% of cases in our study respectively (8). These complications were not so emergent or life-threatening to pose a high negative mark on the decision of choosing PTA as a choice of treatment. Although contrast-induced nephropathy was present in 10% of patients following the treatment overall long-term creatinine levels didn't show a significant change, thus not adding any worries to the procedure.

Our study had some limitations with the length of follow-up period being the most important one. Data from other similar papers suggest that risk of re-occlusion and the need for re-intervention increases with time therefore studies with long-term follow-ups can show the patency rate more accurately (8, 9, 11). Another limitation was the study being carried out in a single center without the diversity of equipment and expertise therefore not representing a bigger population.

In conclusion, there has been a paradigm shift in terms of management for peripheral arterial diseases in the recent years. Gradually, a preference fo using endovascular techniques has been established mainly as a result of approximately equal or yet better outcomes along with a lower rate of complications and higher feasibility. There is a new arising trend of treating arterial diseases of higher severity through endovascular means.

References

1. Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet (London, England). 2013;382(9901):1329-40.
2. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050. Archives of Physical Medicine and Rehabilitation. 2008;89(3):422-9.
3. Marrett E, DiBonaventura Md, Zhang Q. Burden of peripheral arterial disease in Europe and the United States: a patient survey. Health and Quality of Life Outcomes. 2013;11:175-.
4. Becker GJ, Katzen BT, Dake MD. Noncoronary angioplasty. Radiology. 1989;170(3):921-40.
5. Ouriel K. Peripheral arterial disease. The Lancet. 2001;358(9289):1257-64.
6. Robertson L, Paraskevas KI, Stewart M. Angioplasty and stenting for peripheral arterial disease of the lower limbs: an overview of Cochrane Reviews. Cochrane Database of Systematic Reviews. 2017(2).
7. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FGR. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Journal of Vascular Surgery.45(1):S5-S67.

8. Korkmaz K, Gedik HS, Budak AB, Gunaydin S, Cagli K. Endovascular Repair of Peripheral Arterial Disease: Midterm Results From a Single Center. Innovations (Philadelphia, Pa). 2017;12(4):287-92.
9. Guo X, Xue G, Huang X, Xie H, Liang W, Zhang J, et al. Outcomes of endovascular treatment for patients with TASC II D femoropopliteal occlusive disease: a single center study. BMC cardiovascular disorders. 2015;15:44.
10. Axisa B, Fishwick G, Bolia A, Thompson MM, London NJM, Bell PRF, et al. Complications following peripheral angioplasty. Annals of The Royal College of Surgeons of England. 2002;84(1):39-42.
11. Baril DT, Chaer RA, Rhee RY, Makaroun MS, Marone LK. Endovascular interventions for TASC II D femoropopliteal lesions. J Vasc Surg. 2010;51(6):1406-12.