

Evaluating the Success of Endovascular Treatment in Patients with Peripheral Artery Disease

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Abstract

Background: Atherosclerosis is a systemic disease of large- and medium-sized arteries in which the diameter of the artery is narrowed due to accumulation of fat and fibrous materials between the intima and medial layers of the vessels. Atherosclerosis of non-cardiac arteries is called Peripheral Artery Disease (PAD). Although endovascular treatments demonstrated high success rates, treatment failure is still regarded as a great concern. Therefore, the purpose of this study was to evaluate the success rates and risk factors of Percutaneous Transluminal Angioplasty (PTA) in patients with PAD.

Methods: In this retrospective cohort study, the medical records of all the patients referring to Shariati Hospital and Tehran Heart Center with complaints of severe claudication, treated *via* PTA during 2007-13 were collected from the archives. Required data were extracted from the records and then were analyzed by SPSS software V24.

Results: Of the 111 patients included in this study, 2 underwent PTA three times. Two PTAs were performed on 17 subjects and the rest only had one PTA. Based on the results, the first PTA in 96 patients (86.5%) was successful, in 12 subjects (10.8%) was acceptable and in three cases was unsuccessful. Considering the acceptable results as successful, a success rate of 97.3% was calculated. It was revealed that 17 subjects needed a second PTA which is indicative of a 15.7% re-stenosis rate. According to the analysis performed to identify the risk factors of treatment failure, the differences regarding length of the lesion ($p < 0.001$) and serum HDL level ($p = 0.005$) were statistically significant.

Conclusion: The success rate of PTA for treatment of PAD was found to be considerably high which promotes its application as the treatment of choice. However, the risk factors identified in this study seem to be accidental findings due to a small sample size of patients in one of our comparison groups.

Keywords: Percutaneous transluminal angioplasty, Peripheral artery disease, Risk factors

Introduction

Peripheral Artery Disease (PAD) is one of the leading causes of disability and mortality in developed countries. The atherosclerotic blockage and stenosis of peripheral arteries is among the main causes of PAD which mostly occurs in the feeding arteries into the lower extremities (1). PAD has a prevalence of 12%, mainly affecting older individuals; it is a strong predictor of cardiovascular events, often accompanied by atherosclerosis in the coronary and cranial arteries. Furthermore, PAD and coronary atherosclerosis share their risk factors. At the same time, PAD presents with no symptoms in most patients (2-5). The most common symptom is intermittent claudication, presenting as cramping, pain, fatigue, or discomfort in the muscles of the calves, thighs, or buttocks. The pain starts by walking and is alleviated through rest. More severe symptoms include rest pain, necrosis, and gangrene (6,7). Since the most important finding in patients with cardiovascular problems is atherosclerosis, and its existence in peripheral arteries is closely related to cardiovascular disease, therefore early diagnosis of PAD can be an important factor in predicting cardiovascular events (8-11).

Smoking, high blood pressure (bp), diabetes, hyperlipidemia, and homocysteinemia and male sex are the major risk factors for PAD (12,13). Seniors older than 70 years old, individuals between the ages of 50-69 with a history of smoking or diabetes, people between the ages of 40-49 years old suffering from diabetes as well as at least another risk factor for atherosclerosis, patients experiencing claudication after exercise, individuals suffering from ischemic rest pain, any individual displaying weakened pulse in their extremities, individuals with diagnosed atherosclerosis in other parts of the body such as coronary or carotid arteries, and patients suffering from renal artery stenosis are mostly at the risk of PAD according to the American Heart Association guidelines (AHA/ACC2016) (14-18).

Even though using endovascular treatments for PAD has a high rate of success, clinical failure due to renewed stenosis is an important concern (19,20). The rate of inflammation is one of the factors believed to predict the outcomes in PAD patients undergoing endovascular treatments. High rates of inflammation markers such as C-Reactive Protein (CRP) and fibrinogen before intervention are associated with worse outcomes in

the long term as well as higher number of overall interventions (21-25). Higher rate of brachial intima-media thickness (b-imt) is another risk factor associated with secondary stenosis following peripheral artery angioplasty (26). The use of endovascular treatment for PAD has been increasing in Iran for the past few years. However, there have been no studies examining the outcomes of this treatment in Iranian clinical settings. Therefore, in this study, an attempt was made to follow up patients who underwent endovascular interventions in Shariati Hospital and Tehran Heart Center between the years 2007-2014. Evaluating the success rates for the treatment as well as risk factors associated with negative outcomes were the main focus of this paper.

Materials and Methods

This is a cohort study without any comparison group on patients who referred to Shariati Hospital and Tehran Heart Center with claudication or wounds between the years 2007-2014. The patients were treated by an endovascular treatment team consisting of a vascular surgeon and an interventional cardiologist with three years of experience in endovascular treatments at the beginning of the program. The medical records for patients who underwent endovascular treatment for PAD in these years were retrieved from the archives. The participants meeting the inclusion criteria were included and those meeting the exclusion criteria were not part of the study. Next, a systematic search of the hospital records was used to gather data regarding the patient demographics, risk factors, basic test results, basic clinical symptoms, preoperative stenosis according to the preoperative angiography, and complications after endovascular treatment. Furthermore, information regarding the endovascular procedure including residual stenosis, the number of embedded stents, and major cardiovascular events was obtained through studying the existing operation reports.

The inclusion criteria were: 1) Patients with PAD, 2) Patients who underwent endovascular treatment in Shariati Hospital or Tehran Heart Center, 3) Patients who gave their informed consent to be included, and 4) Patients with chronic or acute vascular ischemia. The exclusion criteria included: 1) Having no atherosclerosis, 2) Patients with pregnancy, and 3) Known allergies to heparin, aspirin, or other

anticoagulant medicines. Exposure was defined as endovascular treatment of PAD including the use of angioplasty with balloons as well as insertion of stents. The primary outcome was defined as initial sustained clinical improvement in the first twelve months. The secondary outcome was defined as primary and secondary patency, technical success, minor and major complications, Major Adverse Cardiovascular Events (MACEs), and restenosis of arteries.

The main outcomes were initial sustained clinical improvement, an improvement of one point or higher on the Rutherford scale for patients with intermittent claudication, wound recovery, and disappearance of resting pain for patients with chronic peripheral ischemia without the need for *in vivo* revascularization of target limb. Primary patency was defined as the patency percentage before surgical or endovascular intervention in the target area or the areas surrounding it. Secondary patency was defined as the patency percentage after endovascular intervention in the target or surrounding arteries. The major complication was not achieving more than 30% of normal diameter of artery in post-procedure angiogram.

Ethical consideration

This study was approved by TUMS's ethical council with ethical code No. IR.TUMS.REC.1394.1640.

Results

In all, 111 patients met the criteria to be included in this retrospective cohort study. Patients were mostly men (81.9%). The mean age of participants was 61.59 ± 10.6 , with a range of 30-87.

The results of the pre-operative angiography indicated complete occlusion in 27 (25%) patients while 36 (33.3%) patients had a stenosis of 90-99%. In 34 (31.5%) patients, stenosis was between 70-90%. Only 9 (8.3%) people had stenosis of 50-70%. The stenosis of the remaining two patients (1.9%) was between 30-50%. Stenosis rates decreased after performing Percutaneous Transluminal Angioplasty (PTA). It was found that 82 (83.6%) patients achieved stenosis rates lower than 30%. In 14 patients, the final rates were between 30-50%, and in one patient it was between 70-90%. These results signify that PTAs were successful in 96 (86.5%) of cases. The results were acceptable for 12 (10.8%) of the remaining

patients. Only three operations failed to improve patency.

After initial procedure, 17 patients displayed symptoms. Among the 17, four were estimated to have completely blocked arteries, five to have stenosis of 90-99%, six to have stenosis between 70-90%, and two to have stenosis of 50-70%. The second procedure reduced these stenosis rates. It revealed that 14 patients had stenosis rates lower than 30% and one patient had a rate between 30-50%. Only two cases had complete blockage even after the procedure. According to these results, 15 of the 17 performed PTAs were successful. The results were considered unacceptable in one case and there was a failure in the remaining one.

In order to study the factors influencing the success of PTA procedures, the differences between the 108 successful cases and the three failures were examined within the scope of study. All three patients with unsuccessful PTAs had lesion lengths longer than 10 cm; statistical analysis indicated the observed differences were significant ($p < 0.001$). Similarly, the observed difference between High-Density Lipoprotein (HDL) rates were statistically significant ($p = 0.005$); with the rates being lower in the successful group.

Among those who needed a second PTA procedure, 13 were those with secondary stenosis rates of less than 30% and three had rates between 30-50%. None of these patients were among those who had unsatisfactory results after their first procedure. Therefore, stenosis rates after the first PTA procedure ($p = 0.832$), or the success of the first procedure ($p = 0.604$) did not predict the need for a second operation.

Discussion

In 1964, Ditter and Judkins performed the first angioplasty procedure on the femoropopliteal artery. Since then, this procedure has been widely used to treat PAD. Consequently, there has been widespread research in various techniques for performing PTAs, risk factors predicting failure, and other related fields. In this study, 111 individuals admitted with complaints of severe claudication, wounds, or both were treated with PTA by an endovascular treatment team. These patients' course of treatment and the factors influencing the final results were studied.

Among the 111 participants, three patients underwent PTA three times, 17 had two procedures, and the remaining individuals required only one operation. Grouping the results deemed merely acceptable alongside the successful cases, the initial success rate for this method, calculated based on secondary patency rates, was 97.35; it was a higher success rate than reported in previous studies. For example, Gallino *et al* (27) reported an 84% success rate for PTA procedures on the iliac artery and a 58% success rate for operations on the femoropopliteal artery. Similarly, Johnston *et al* (28) reported a success rate of 88.6%, while Sullivan *et al* (29) outlined a success rate of 87.8% calculated according to the ABI index. Bonvini *et al* (30) reported a failure rate of 7% in 2011. Based on the increased success rates in the more recent studies, perhaps the better results are obtained by improved techniques, surgical conditions, and equipment for endovascular surgery.

Seventeen patients who participated in the study required a second procedure, which was a result of stenosis in 15.7% of patients. These numbers match those reported by Davies *et al* (31) in 2010; they had studied the outcomes of PTAs performed on the SFA artery and reported stenosis rates of 16%.

After initial procedure, 17 patients remained symptomatic. Among the 17, four were estimated to have completely blocked arteries, five to have stenosis rates between 90-99, six to have stenosis between 70-90%, and two to have stenosis rates between 50-70%. The procedure reduced the stenosis rates. In the end, 14 patients had stenosis rates lower than 30% and one patient had a rate between 30-50%. Only two cases had complete blockage even after the procedure. In 14 (82.35%) patients, the second PTA procedure was successful, in one patient the results were unacceptable, and the procedure failed in one patient. Overall, the statistics in this study indicate that PTA is an acceptable and appropriate treatment for PAD, confirming Bonvini (30) and Giugliano's (32) conclusions.

In order to study the factors influencing the success

of PTA procedures, the differences between the 108 successful cases and the three failures were examined in the context of this study's variables. All three patients with unsuccessful PTAs had lesion lengths longer than 10 cm; statistical analysis indicated that the observed differences were significant ($p < 0.001$). These results were in accordance with conclusions obtained by Gallino *et al* (27) who had found that lesions larger than 3 cm result in lower success rates for PTA.

Among the quantitative variables examined in this study, only differences in HDL levels significantly affected the outcomes. Lower HDL levels were correlated with better outcomes ($p = 0.005$). Considering the low number of patients whose procedures were unsuccessful, this finding seems to be clinically insignificant, since previous studies have indicated a link between higher HDL levels and a lower risk for vascular disease (33,34).

Among those who needed a second PTA procedure, 13 were among those with post-operation stenosis rates of less than 30% and three had rates between 30-50%. None of these patients were among those who had had unsatisfactory results after their first procedure. Therefore, stenosis rates after the first PTA procedure ($p = 0.832$) did not predict the need for a second operation.

The results of this study did not support a link between diabetes and PTA success rates, even though previous studies by Gallino (27), Johnston (28), Cambria (35), Giugliano (32) had found a statistically significant relationship between diabetes and PTA success.

Conclusion

In addition to diabetes, there were other factors which had been found to affect PTA results in previous studies but did not show such effect in the current cohort. These differences may have been caused by the relatively low number of failure cases; if the number of successful PTAs matched unsuccessful PTAs, other significant relationships may have been discovered.

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