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Short and Medium-Term Results of Aspirational Atherectomy in Occulative Peripheral Artery Diseases

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Abstract

BACKGROUND/AIMS: In this prospective cross-sectional study, the short and mid-term results of aspirational atherectomy in lower extremity occlusive peripheral arterial diseases (PADs) were evaluated.

MATERIALS AND METHODS: The research was conducted between May 2017 and September 2018 at the Cardiovascular Surgery Clinic of a university hospital. A total of 34 patients who had lower extremity occlusive PAD and underwent aspirational atherectomy were included in the study. During the follow-up visits at the 24th hour, 1st month, 6th month, and 1st year, the patients' physical examinations, complaints, Rutherford and Fontaine clinical staging, and Transatlantic Intersocietal Consensus II (TASC II) classifications of the lesions before the procedure were obtained. Demographically, gender, age, smoking, peripheral procedure history, and chronic diseases were evaluated.

RESULTS: The frequency of Fontaine 3 or less, which was 47.1% before the operation, increased to 79.4% in the 6th month ($p<0.05$). The frequency of Rutherford scores of 2 or lower increased from 47.1% before the operation to 79.4% at 6 months ($p<0.05$). The rate of those with a Fontaine score of 3 or less was 85.3% in the first month after the operation, and it decreased to 79.4% in the sixth month ($p>0.05$). Similarly, while the rate of those with a Rutherford score of 2 or less was 85.3% in the first month, it decreased to 79.4% in the sixth month ($p>0.05$). The proportion of patients with Fontaine 3 and below and Rutherford 2 and below decreased from 79.4% in the 6th month to 76.5% in the 12th month. There was no significant difference between both Fontaine and Rutherford scores at 6 and 12 months after the operation ($p<0.05$)

CONCLUSION: Amputation rates may be further reduced by shortening the follow-up intervals and applying a multidisciplinary approach in diabetic patients with TASC II D lesions.

Keywords: Critical leg ischemia, aspirational atherectomy, occulative peripheral artery diseases

INTRODUCTION

Peripheral artery disease (PAD) is a health problem that begins with excessive fatty deposits on the walls of blood vessels.[1] These deposits form when blood vessels narrow due to atherosclerosis and are unable to send enough blood to the areas they supply.[2-4] Chronic diseases (CD) cause increased morbidity and mortality among pulmoner arteriyel hipertansiyon (PAH) cases.[5-7] Therefore, treatment for PAH covers a wide spectrum, including assessing, monitoring, and treating risk factors, as well as medications, surgical and endovascular interventions, and life modifications.

Endovascular aspiration atherectomy is one of the treatment methods for PAH.[8] In 1984, the American Medical Association recognized that endovascular procedures may be an alternative to coronary artery bypass grafting.[9] After becoming widely accepted in the medical world, these methods were first introduced in the United States of America in 1989, adding intervention practice to the curriculum of selected health care professionals.[10-12] Endovascular interventions include percutaneous transluminal angioplasty (PTA), stent placement, and atherectomy procedures. When using PTA and stenting, the atherosclerotic plaque is pressed against the vessel wall, and thus patency of the lumen is ensured.[13,14] However, such applications may result in complications

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such as barotrauma and dissection that threaten lumen patency. The main mechanism of operation of atherectomy devices is to remove plaque that narrows or completely blocks the lumen using various methods.

The Rutherford and Fontaine classifications are used PAH, the most recent being the Transatlantic Intersocietal Consensus (TASC), a document that emerged from a meeting in 2000 to assess recommendations for epidemiology, treatment, and surveillance. The guidelines were revised in 2007 and renamed TASC II.[15-17] With the development of endovascular interventions, many recent studies have shown that they also produce successful results in TASC II C and D lesions. However, more clinical data are needed regarding the results of endovascular aspiration atherectomy in cases of PAH. Therefore, this study aimed to evaluate the short- and medium-term outcomes of patients who were diagnosed with PAH and followed up and underwent endovascular aspiration atherectomy.

MATERIALS AND METHODS

Patient Group

A total of 34 patients, diagnosed with PAD between January 2017 and September 2018, aged 18 to 85 years, who had near claudication, ischemic rest pain, ischemic ulcer, or tissue loss, Rutherford stage 3 and higher, Fontaine stage 2/b and higher, were included. The research data were collected within the scope of the first author's master thesis and a scientific project, for which permission was also obtained for the years 2017-2018.

Although there is no study directly compatible with our study, the closest study was conducted by Sixt et al.[17] In the power analysis performed on the sample of this study using G*power 3.1.9.2, the effect value was found to be 0.7500000. With this effect value, the minimum number of patients to be included was determined as 21, with a 95% confidence interval and a significance level of 0.05.

Patients who were seen by a physician before the procedure and were using insulin or oral antidiabetic medications were considered to have diabetes. Hypertension (HT) patients were those who were diagnosed by a physician and started antihypertensive treatment. Patients seen by a cardiologist and treated after coronary angiography were assessed as having chronic artery disease (CAD). Patients diagnosed with renal failure, receiving routine hemodialysis treatment, were assessed as having chronic kidney disease (CKD). Patients who were seen by a neurologist and had a history of stroke were assessed as having left ventricular hypertrophy based on a review of their medical records. Before the procedure, patients' height and weight were measured, and their body mass index (BMI) was calculated and recorded. Patients who smoked before the procedure were recorded as active smokers. Bleeding or hematoma in the intervention area during the first 30 days after the procedure was considered a complication. The study included patients whose lesions were suitable for interventional procedures and atherectomy, and who had short-distance claudication, ischemic pain at rest, and ischemic ulceration. Patients were excluded if they lacked consent, or had arterial dissection, loss of motor function, or known drug allergies.

Surgical Method

After obtaining informed consent from the patients and administering a local anesthetic (prilocaine 2% subcutaneously), a sheath was placed using the Seldinger technique according to the location and classification of the lesion (TASC II classification), and 5000 units of heparin were administered intravenously. A 7 French sheath was inserted using an anterograde approach in 26 patients (76.5%) and a retrograde approach in 8 patients (23.5%). After this, an appropriate amount of contrast agent (OMNIPAQUE 300 mg/100 mL) was injected, and an image was taken. The lesion was crossed using a hydrophilic guidewire (0.035-0.0014 hydrophilic Radiofocus, Terumo, Tokyo, Japan) and, if necessary, a support catheter (NAVICROSS®, also from Terumo, Tokyo, Japan). Asuction catheter for atherectomy was passed over the guidewire to access the lesion and the lumen was opened. After the procedure, a drug-coated balloon (In.Pact Admiral, Medtronic, Dublin, Ireland; Lutonix, Bard, GA, USA) was attached to the lesion. During use, the balloon was inflated to the appropriate pressure values and then allowed to rest for three minutes. Then, the balloon with the drug was deflated and control angiography was performed. After the procedure, patients were treated with heparin for 24 hours (25,000 units/24 hours) and received ASA 100 mg and clopidogrel 75 mg during follow-up.

Statistical Analysis

Nominal and ordinal data were identified by their frequency distributions. Measurement parameters were determined by the median and range. When analyzing differences, the McNemar test was used because of linearization deviations.[18,19] All analyses were conducted in SPSS 25.0 for Windows with 95% confidence intervals and a significance level of 0.05.

Ethical Considerations

This study was carried out with the approval of the Clinical Research Ethics Committee of the Faculty of Tayfur Ata Sökmen Medicine of the Hatay Mustafa Kemal University (approval number: 04, date: 01.03.2018).

RESULTS

17.6% of the patients were female and 82.4% were male. The age range was 28 to 85 years and the BMI was 21 to 35.5. Half of the patients were smokers. The distribution of comorbidities was as follows: 73.5% HT, 61.8% diabetes mellitus, 17.6% hyperlipidemia, 17.6% CAD, 8.8% CKD, and 2.9% cerebrovascular event. The length of stay was 1 to 7 days and had a median value of 1.4. The complaints included 40.6% complaints of foot and leg pain, 49.3% complaints of rest pain, 17.4% complaints of color change, and 5.8% complaints of short distance claudication (Table 1).

Fontaine score was 3 or less in 47.1% of the patients, and above 3 in 52.9% of the patients. At the end of the first month, the percentage of those with a Fountaine score of 3 or less was 85.3%, and the percentage of those with a score above 3 was 11.8%. While the Rutherford score was 2 or less in 47.1% before the operation, this rate increased to 85.2% after the operation. The differences in Fontaine and Rutherford scores before the operation and at the first month were statistically significant ($p<0.05$) (Table 2).

The frequency of Fontain 3 or less, which was 47.1% before the operation, increased to 79.4 in the 6th month ($p<0.05$). The frequency of Rutherford scores of 2 or less increased from 47.1% before the operation to 79.4% in the 6th month ($p<0.05$) (Table 3).

Table 1. Baseline and clinical parameters of patients

Parameter	Value
Gender, n (%)	
Female	6 (17.6)
Male	28 (82.4)
Age, years, median (min.-max.)	62.5 (28.0-85.0)
BMI, kg/m^2, median (min.-max.)	24.6 (21.0-35.5)
Smoking, n (%)	17 (50.0)
Comorbidity, n (%)	
HT	25 (73.5)
DM	21 (61.8)
Hyperlipidemia	6 (17.6)
CAD	6 (17.6)
CKD	3 (8.8)
CVE	1 (2.9)
Hospitalization duration, day, median (min.-max.)	1.4 (1.0-7.0)
Complaint, n (%)	
Wound on foot and leg	14 (40.6)
Rest pain	17 (49.3)
Color change	6 (17.4)
Short distance claudication	2 (5.8)
Intervention method, n (%)	
Anterograde	26 (76.5)
Retrograde	8 (23.5)
TASCII classification, n (%)	
Type B femoro-popliteal	11 (31.9)
Type C femoro-popliteal	5 (14.5)
Type C	4 (11.6)
Type C femoral, type D popliteal	1 (2.9)
Type D femoro-popliteal	4 (11.6)
Type D	6 (17.4)
Type D SFA stent occlusion	1 (2.9)
Type D long CIA occlusion	1 (2.9)
Type D long EIA whole occlusion	1 (2.9)

HT: Hypertension, DM: Diabetes Mellitus, CAD: Chronic Artery Disease, CKD: Chronic kidney disease, CVE: Cerebrovascular event, BMI: Body mass index, TASC II: Transatlantic intersocietal consensus II, CIA: Common iliac artery, EIA: External iliac artery, Min.: Minimum, Max.: Maximum.

Table 2. Fontaine and Rutherford distributions and differences between pre-operation and 1st month

	Pre-operation	1st month	p
Fontaine, n (%)			
3 and under	16 (47.1)	29 (85.3)	0.000[a]
Over 3	18 (52.9)	4 (11.8)	
Rutherford, n (%)			
2 and under	16 (47.1)	29 (85.3)	0.000[a]
Over 3	18 (52.9)	4 (11.8)	

[a]Mc Nemar test.

The rate of those with a Fontaine score of 3 or less was 85.3% in the 1st month after the operation, and it decreased to 79.4% in the 6th month (p>0.05). Similarly, while the rate of those with a Rutherford score of 2 or less was 85.3% in the 1st month, it decreased to 79.4% in the 6th month (p>0.05) (Table 4).

The proportion of patients with Fontaine 3 and below and Rutherford 2 and below decreased from 79.4% in the 6th month to 76.5% in the 12th month. There was no significant difference between the Fontaine and Rutherford scores at 6 and 12 months after the operation (p<0.05) (Table 5).

DISCUSSION

In this research, the procedural outcomes and short- and mid-term outcomes of 34 patients who underwent aspiration atherectomy for PAD were analyzed. Results showed that 6 and 12 months after operation, patients had stable Fontaine and Rutherford scores, showing success of treatment.

In studies of PA risk factors in the literature, CD and cigarette use influence disease progression.[20-22] However, in our study, the presence

Table 3. Fontaine and Rutherford distributions and differences between pre-operation and 6th month

	Pre-operation	6th month	p
Fontaine, n (%)			
3 and under	16 (47.1)	27 (79.4)	0.000[a]
Over 3	18 (52.9)	7 (20.6)	
Rutherford, n (%)			
2 and under	16 (47.1)	27 (79.4)	0.000[a]
Over 3	18 (52.9)	7 (20.6)	

[a]Mc Nemar test.

Table 4. Fontaine and Rutherford distributions and differences between 1st month and 12th month

	1st month	6th month	p
Fontaine, n (%)			
3 and under	29 (85.3)	27 (79.4)	0.250[a]
Over 3	4 (11.8)	7 (20.6)	
Rutherford, n (%)			
2 and under	29 (85.3)	27 (79.4)	0.250[a]
Over 3	4 (11.8)	7 (20.6)	

[a]Mc Nemar test.

Table 5. Fontaine and Rutherford distributions and differences between 6th month and 12th month

	6th month	12th month	p
Fontaine, n (%)			
3 and under	27 (79.4)	26 (76.5)	0.999[a]
Over 3	7 (20.6)	8 (23.5)	
Rutherford, n (%)			
2 and under	27 (79.4)	26 (76.5)	0.999[a]
Over 3	7 (20.6)	8 (23.5)	

[a]Mc Nemar test.

of diabetes, HP, coronary artery disease, duration and amount of smoking, which are among the risk factors for PAH, did not have a statistically significant effect on the recurrence of complaints after the interventional procedure and the course of clinical staging. Although there may be many reasons for this situation, it can be stated that the single-center nature of the study and the relatively small number of samples also had an impact on the study results.

TASC II C lesions are difficult to treat endovascularly.[23-25] When examining 10 patients (29.41%) in our study, it was observed that they had TASC II C lesions, the procedure was successful in all these patients and there was no change in their complaints and clinical stages during the 1st period treatment. Follow-up for one year. TASC II A and B lesions are effectively treated endovascularly with high success rates especially using new technologies.16-21 As explained in detail in the results section of our study, this is similar to the literature with a high success rate for TASC A and B lesions, and no recurrence of complaints during 1 year of follow-up. It is important to demonstrate the feasibility of endovascular interventions with low mortality, morbidity, and procedural complication rates in groups with TASC II C and D lesions and comorbidities where surgical procedures are at high risk.

Study Limitations

The most important limitation of the study is the small number of patients. The number of patients was limited in terms of both the prevalence and incidence of the case, and the follow-up period. Generally, after the diagnosis phase in public health institutions or university hospitals, the treatment process is disrupted due to consultation with other health institutions, relocation, or other reasons. This is the case in longitudinal studies and is a limiting factor in the research.

Contributions of the Study

The most important aspect of the study is that it offers an effective solution to a health problem with high mortality and morbidity, and provides source data for clinical practices with few studies in this field.

Another implication of the study is that, according to the results obtained from the study, the hospitalization period for patients after the procedure is short and the success rate of the procedure is high. The wide age range of patients in this study, from 28 to 85 years, and the fact that the study was conducted in patients with additional risk factors for PAH and high comorbidity make it important.

CONCLUSION

Aspiration atherectomy should be considered as an important option in the treatment of surgically high-risk patients. Regardless of the patient's clinical level and complaints, short- and medium-term results are quite successful, and it has been shown that amputation rates can be further reduced by shortening the follow-up intervals and applying a multidisciplinary approach in patients with TASC II D lesions. It is clear that age is an important factor in the prognosis of PAH and that the elderly will constitute the patient population that we will encounter more frequently in our clinical practice. In addition, surgical interventions generally pose a high risk in this group of patients, as additional risk factors are frequently present in these patients.

MAIN POINTS

- The research offers an effective solution to a health problem with high mortality and morbidity, and provides source data for clinical practices, in a field with few studies. Peripheral artery disease (PAD) is an important health problem, but there have not been sufficient data on the disease and its progression. This article supports clinical data on PAD.
- The hospitalization period for patients after the procedure is short and the success rate of the procedure is high. The research supports clinical usage of the procedure with quantitative data.
- The wide age range of patients in this study, from 28 to 85 years, and the fact that the study was conducted in patients with additional risk factors for PAH and high comorbidity makes it important. Thus, research provides clinical insights on PAD for a large demographic profile.

ETHICS

Ethics Committee Approval: This study was carried out with the approval of the Clinical Research Ethics Committee of the Faculty of Tayfur Ata Sökmen Medicine of the Hatay Mustafa Kemal University (approval number: 04, date: 01.03.2018).

Informed Consent: Informed consent forms have been obtained from the patients.

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Footnotes

Authorship Contributions

Surgical and Medical Practices C.L., Concept: C.L., O.V.D., Design: C.L., O.V.D., Data Collection and/or Processing: C.L., Analysis and/or Interpretation: C.L., Literature Search: C.L., Writing: C.L.

DISCLOSURES

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