Advances in Medical Sciences 65 (2020) 197–201

Contents lists available at ScienceDirect

Advances in Medical Sciences

journal homepage: www.elsevier.com/locate/advms

Original research article

Gender differences and long-term clinical outcomes in patients with chronic total occlusions of infrainguinal lower limb arteries treated from retrograde access with peripheral vascular interventions

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ARTICLE INFO

Keywords:
Peripheral artery disease
Endovascular revascularization
Retrograde access
Clinical outcomes
Gender differences

ABSTRACT

Purpose: We sought to investigate gender-related differences in clinical outcomes after peripheral vascular interventions (PVIs) from retrograde access in patients with chronic total occlusions (CTOs) of the infrainguinal arteries.

Patients and methods: A total of 939 consecutive patients undergoing PVI were enrolled in the study. Patients with peripheral artery diseases (PAD) and CTOs were treated with PVI from retrograde access according to the local protocol. The participants were divided according to gender. Retrograde access included distal puncturing to reach the CTO. The mean follow-up lasted 1,144.9 ± 664.3 days. Baseline characteristics, procedural and long-term outcomes were compared according to gender.

Results: Women represented 37.4% of the study population, and more frequently suffered from hypertension (92% vs. 86%, $p = 0.001$) and diabetes (54% vs. 46%, $p = 0.02$). Males more often presented with chronic obstructive pulmonary disease (14.8% vs. 6.8%, $p = 0.0003$), coronary artery disease (45.4% vs. 32.7%, $p = 0.0001$), smoking (60.4% vs. 45%, $p = 0.007$) and prior PVI (25% vs. 17%, $p = 0.005$). The Kaplan-Meier survival curves at 5 years did not reveal gender-related differences in mortality ($p = 0.8$), whereas men were at a significantly higher risk of re-PVI during the follow-up period ($p = 0.047$). Male gender was an independent predictor of re-PVI (Hazard ratio: 1.276; 95% confidence interval: 1.015–1.614, $p = 0.03$).

Conclusion: Males are at increased risk of re-PVI compared to females with PAD and CTOs of infrainguinal arteries treated with PVI from retrograde access.

1. Introduction

Peripheral artery disease (PAD) is an age-related, increasing social, economic and medical condition [1]. Although changing lifestyle plays an important role in PAD treatment, advanced stages of the disease often require peripheral vascular intervention (PVI). At many experienced academic centers, interventional methods have become the first-line of treatment allowing limb-salvage procedures in patients with an operative risk that precludes open surgery. The retrograde approach is used in selected cases when conventional endovascular techniques fail in occlusion management. Retrograde access includes distal puncturing to reach the obstruction, and depending on the location of the lesion, covering various locations, this includes pedal access. Publications are available regarding predictors of clinical outcomes in patients with PAD treated with angioplasty [2,3]. Clinical evaluation was mainly based on the frequency of amputations and revascularizations, which are referred to as major adverse lower-limb events (MALE), and mortality. Among the confirmed predictors of amputations in patients with PAD

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https://doi.org/10.1016/j.advms.2020.01.004
Received 15 May 2019; Received in revised form 10 September 2019; Accepted 21 January 2020
Available online 31 January 2020

treated with antegrade access, we may find, for example: ulcerations, increased serum C-reactive protein level, diabetes mellitus or younger age [2]. While the predictors of survival include body-mass index, non-ambulatory status or lower left ventricle ejection fraction [2]. The relationship between gender and clinical presentation, treatment and outcomes in patients with PAD undergoing PVI, has been investigated in several studies [4]. Varying incidences of PAD among men and women depending on the age group have been reported [1]. Also, differences in the results of PAD treatment between women and men are seen in many factors, such as the prevalence of comorbidities (including diabetes), the frequency of PAD diagnosis and endovascular treatment, vascular diameter, the age at treatment or procedural factors [1]. The published studies are not consistent in predicting outcomes after endovascular treatment in patients with PAD, and some of them revealed poorer outcomes in females [5,6], while the others showed no gender-related differences [6]. The relationship between gender and outcomes in patients with PAD and chronic total occlusions (CTOs), treated with PVI from retrograde access, is less investigated. Due to more advanced atherosclerosis, usually disseminated, multi-segmental, and in many cases, presented as critical lower limb ischemia, the results in this group of patients may differ significantly from those treated from antegrade access. The features mentioned above, including CTO of the infrainguinal arteries, different clinical image and other spectrums of atherosclerosis risk factors, may have an impact on the clinical outcomes and their relationship with gender. What is more, so far, they have not been analyzed in such a large group of patients.

The aim of the current study was to assess the relationship between gender and long-term clinical outcomes in patients with PAD and CTOs treated with endovascular interventions and retrograde access.

2. Patients and methods

2.1. Study population

This research was planned as a prospective observational study of consecutive patients who underwent retrograde recanalization of CTO localized in the superficial femoral artery (SFA), popliteal artery (PA) or below-the-knee arteries. At three experienced and collaborating centers, we enrolled all consecutive patients after at least one unsuccessful antegrade recanalization of CTO, qualified for the retrograde approach. The cohort of this study consisted of 939 consecutive patients, among whom 588 were men (62.6%). Females were significantly older in comparison to males (71 ± 10.8 years vs. 65.8 ± 10 years, $p < 0.0001$) (Table 1).

Antegrade failure was defined as inability to wire the distal part of the vessel after the occlusion via access site, located in the contralateral artery or proximal to the CTO lesion. According to the local protocol, patients were screened for concomitant diseases, risk factors and medication prior to the procedure. In all patients before the procedure, ankle-brachial index was examined and severity of PAD was assessed according to the Rutherford and/or Fontaine scales.

2.2. Methods

The decision regarding retrograde recanalization and access site was based on prior angiography. The procedure of retrograde recanalization was performed under local anesthesia and required two access sites: antegrade and retrograde. Both proximal and distal punctures were performed under the guidance of vascular ultrasound and/or fluoroscopy. The selection of antegrade access site type was determined by many factors, including anatomical conditioning, type of vascular lesions, technical possibilities, type of occlusion, its length and probability of blood flow restoration. For the proximal access site, the contralateral femoral artery was usually used, and 6 French (Fr) vascular sheaths were among the most popular. The distal access site was usually chosen in the reconnection area of the artery (needle: 12–15 mm, 21G). In some cases, 4 Fr vascular sheaths were needed to obtain support during the procedure. In a few cases, the distal access site was also used for the revascularization of more peripheral parts of the artery. A hydrophilic stiff, J-shaped 0.035" guidewire (Terumo Corporation, Shibuya, Tokyo, Japan) was used for the antegrade access site. Occlusions were crossed from the retrograde access site with a soft V18 non-hydrophilic 0.018" guidewire (Boston Scientific, Marlborough, Massachusetts, USA). After crossing the occlusion with a wire via the retrograde approach, predilatation was performed using a balloon catheter. Stent implantation was based on the decision of the operator. After the procedure, the distal sheet was immediately removed, and the proximal one was maintained up to 4 h when the femoral artery was punctured, which was conditioned by unfractionated heparin use. In periprocedural treatment, all patients received double antiplatelet therapy: aspirin 75 mg – permanently, and clopidogrel 75 mg for 3 months, a high dose of statin and according to local protocol, low-molecular-weight heparin for 4 weeks. Additional treatment was accordant with individual risk factors and comorbidities.

Table 1
Baseline clinical characteristics.

Variables	Female N = 351	Male N = 588	*p*
Age, years	71 ± 10.8	65.8 ± 10.6	<0.0001
BMI, kg/m^2	26.8 ± 5	27.5 ± 5.4	0.33
Hypertension, %	91.4	86.4	0.02
Diabetes mellitus, %	54.1	46.3	0.02
Renal failure, %	16.2	15.6	0.81
Coronary artery disease, %	32.8	45.4	0.0001
Hyperlipidemia, %	77.8	87.8	0.15
Stroke/TIA, %	8.5	8.8	0.02
Smoking, %	45	60.4	0.008
COPD, %	6.8	14.8	0.0003
Prior PTA, %	17.1	25	0.005
Acute limb ischemia, %	6	4.4	0.28
Critical limb ischemia, %	61.5	53.1	0.01
Intermittent claudication, %	32.5	42.9	0.002
Fontaine scale, %			
1	0.3	0	0.002
2A	4.8	5.4	
2B	29.3	37.4	
3	15.7	18.4	
4	49.9	38.6	
Rutherford scale, %			
1	3.7	5.1	0.0002
2	12.2	19.7	
3	16.2	17.3	
4	17.1	18.9	
5	17.1	13.3	
6	33.6	25.7	

Abbreviations: COPD - chronic obstructive pulmonary disease; BMI - body mass index; PTA - percutaneous transluminal angioplasty; TIA - transient ischemic attacks.

2.3. Follow-up

In the long term follow-up, which lasted 1,144.9 ± 664.3 days, patients were evaluated for major adverse cardiac and cerebrovascular events (MACCE) as well as MALE. Data were collected between 2006 and 2016. In this study, MACCE were predefined as death, stroke/transient ischemic attack (TIA), myocardial infarction, percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). MALE was defined as amputation, target lesion re-intervention, target vessel re-intervention and surgical treatment. Due to shortages in the available database, the level of amputation was not highlighted in the present study and alike high-, mid- and low-amputations, they were included in the overall amputation rate. The protocol complied with the Declaration of Helsinki, and all participants provided written informed consent before enrollment.

2.4. Statistical analysis

Continuous variables are expressed as mean ± standard deviation or median and interquartile range. Categorical variables are introduced as numbers and percentages. Normality of distribution was assessed with the Shapiro-Wilk test. The Mann Whitney U test was used for non-normally distributed continuous variables. Survival analyses were performed using the Kaplan-Meier method while univariate and multivariate Cox regression analyses were used to find significant predictors of re-PVI during the follow-up. All baseline characteristics and procedural data were tested as possible co-variates. Results are presented as hazard ratios (HR) with 95% confidence intervals (CI). All tests were two-tailed and the p-value < 0.05 was considered statistically significant. All analyses were performed with JMP®, Version 13.1.0 (SAS Institute INC., Cary, NC, USA). The sample size was not counted because the present study was based on the database registry, the original purpose of which was not to assess the impact of gender on clinical outcomes. All calculated analyzes were lesion-based. In the case of bilateral involvement, one limb was included in the analysis and this was recognized as one PVI, which in some cases, could be multi-segmental. The treated lesion concerned the limb which was clinically more affected by ischemia.

2.5. Ethical issues

The study protocol complied with the 1964 Declaration of Helsinki with its later amendments, and all participants provided informed written consent before enrollment. The protocol of the current study has not been approved by local bioethics committee, due to its retrospective nature, and no consent is required for such type of a study.

3. Results

3.1. Clinical features

In general, there were significant differences between genders when considering concomitant diseases. Men more frequently presented with coronary artery disease (45.4% vs. 32.7%, $p = 0.0001$), chronic obstructive pulmonary disease (COPD; 14.8% vs. 6.8%, $p = 0.0003$) and were more often smokers (60.4% vs. 45%, $p = 0.007$), while women more often suffered from hypertension (91.4% vs. 86.4%, $p = 0.001$) and diabetes (54.1% vs. 46.3%, $p = 0.02$). The baseline characteristics of the population are shown in Table 1.

3.2. Procedural indices and biochemical parameters

Hemoglobin and creatinine concentrations in the serum were statistically significantly lower in females compared to males ($p = 0.0048$ and $p = 0.0005$, respectively). There were no statistically significant differences between genders in procedure and fluoroscopy time, contrast volume or time from procedure to discharge, whereas the overall hospitalization time was statistically significantly longer in females ($p = 0.0094$). Females were qualified for the procedure with more advanced and disseminated atherosclerotic lesions according to the Trans-Atlantic Inter-Society Consensus (TASC) II classification. The procedural success rate attained 88.8% and there were no statistically significant differences between both groups. Women suffered from intraprocedural complications more often (7.93% vs. 5.40%, $p = 0.0094$), including residual dissection (5.79% vs. 2.58%, $p = 0.02$). This is presented in Table 2.

3.3. Clinical outcomes

There were no statistically significant differences between males and females in the frequency of particular study endpoints which included: strokes/TIA ($p = 0.5$), myocardial infarctions ($p = 0.7$), amputations ($p = 0.07$), deaths ($p = 0.68$), lower limb bypasses ($p = 0.74$) and percutaneous thrombectomies or thromboendarterectomies ($p = 0.15$). Also, the mean time to the first adverse event did not differ statistically significantly between males and females during the follow-up period for these particular study endpoints (Table 3). Men were at a higher risk of re-PVI at the 60-month follow-up (41.2% vs. 35.8%; $p = 0.047$). Re-PVI free survival probability for men and women is shown in Fig. 1. The male gender was found in univariate and multivariate Cox regression analysis to be an independent predictor of re-PVI (HR: 1.276; 95% CI: 1.015–1.614, $p = 0.03$). Univariate and multivariate Cox regression analyses confirmed that alongside gender, chronic occlusion of superficial femoral artery (HR: 1.71; 95% CI: 1.11–2.68, $p = 0.013$) and procedural failure (HR: 2.15; 95% CI: 1.06–3.96, $p = 0.03$) were also statistically significant predictors of re-PVI. After adjustment to male gender, re-PVI was statistically significantly associated with diabetes (HR:1.19; 95% CI 0.95–1.48, $p = 0.03$), COPD (HR: 0.75; 95% CI: 0.51–1.07, $p = 0.03$), prior PVI (HR: 1.34; 95% CI: 1.04–1.71, $p = 0.008$) and age (HR: 0.99; 95% CI: 0.98–1.001, $p = 0.02$).

Table 2
Biochemical, procedural and atherosclerotic lesion characteristics.

Variables	Female N = 351	Male N = 588	p
Hemoglobin, g/dL	12.9 ± 1.3	13.9 ± 1.7	0.005
Platelet count, *1000/μL	228.9 ± 59.2	209.3 ± 64.2	0.07
Creatinine, μmol/L	75.9 ± 23.8	91 ± 26.5	0.0005
eGFR mL/min/1.73 m^2	54.3 ± 12	57.5 ± 9.2	0.044
Procedure time, sec	2737.2 ± 1834.4	2768.2 ± 2039.4	0.6
Fluoroscopy time, sec	812.1 ± 584.1	832.9 ± 759.5	0.4
Contrast volume, mL	112.9 ± 69.7	126.1 ± 92.7	0.26
Intraprocedural complications, %	7.9	3.8	0.009
Time from PTA to discharge, days	3.5 ± 1.9	3.1 ± 2.3	0.53
Hospitalization time, days	5.7 ± 4.9	5.2 ± 5.2	0.009
TASC II classification, %			
A	14.6	21.6	0.003
B	17.7	21.6	
C	15.7	14.6	
D	52	42.2	

Abbreviations: GFR - glomerular filtration rate; PTA - percutaneous transluminal angioplasty; TASC - Trans-Atlantic Inter-Society Consensus.

Table 3
Clinical outcomes.

Variables	Female N = 351	Male N = 588	P
Re-PTA, %	30.86	36.93	0.059
Time to re-PTA, days	354.66 ± 456.6	331.33 ± 479.1	0.12
Stroke/TIA, %	3.14	2.44	0.52
Time to stroke/TIA, days	277.82 ± 359.9	70.3.86 ± 882.5	0.11
Myocardial infarction (MI), %	3.72	3.31	0.73
Time to MI, days	838.92 ± 640.6	773.11 ± 589.4	0.76
Death, %	14	13.07	0.68
Time to death, days	574.4 ± 657.8	616.68 ± 584.3	0.51
Amputation, %	19.94	15.26	0.07
Time to amputation, days	127.79 ± 193.4	184.53 ± 439.4	0.46
Lower extremity bypass (LEB), %	5.43	4.92	0.74
Time to LEB	231.88 ± 298.1	254.71 ± 299.78	0.9
PTE/TEA, %	0.32	1.43	0.15
Time to PTE/TEA, days	6 ± 0	76 ± 77.3	0.27

Abbreviations: PTA - percutaneous transluminal angioplasty; PTE - percutaneous thrombectomy; TEA - thromboendarterectomy; TIA - transient ischemic attacks.

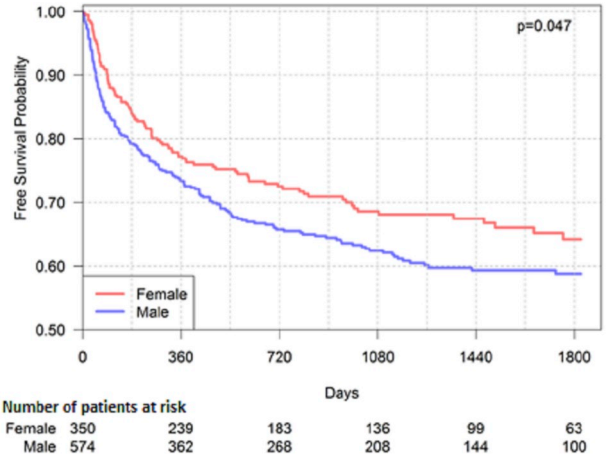

Fig. 1. Re-PVI free survival probability assessed at five years of the follow-up period.

4. Discussion

The main finding of the present study is that in the group of patients with PAD and CTOs treated with PVI from retrograde access, males were at a higher risk of re-PVI during the long-term follow-up period. According to the available database, there could be at least a few explanations for this observation. In our study, females represented 37.4% of the cohort, which remains in line with data presented in studies related to PAD treatment and is sanctioned by many factors [1]. Among them, we include age, poorer diagnosis of PAD in females, different symptoms which are related to a different spectrum of concomitant diseases such as diabetes and diabetic neuropathy [1]. Another issue is that the incidence of PAD rapidly increases during the climacteric period and after the fifth decade - it is at least equally frequent in both genders [7]. The disparity between epidemiological data and representation of the trial cohort may be rooted in sociological issues. The fact of the aging population as a progressive phenomenon is undeniable and its structure demonstrates the subpopulation of women as a majority [8]. In older age, it is common to confuse symptoms of PAD with osteoarthritis or osteoporosis. Females more often present asymptomatic PAD [9]. It has been suggested that women are less likely to be hospitalized or to undergo invasive procedures, and when they do, they are older and afflicted with a more advanced disease, which is concordant with the results of our study [10,11]. This explains why females undergo PVI at an older age and at more advanced stages of the disease. As confirmation, we may underline the fact that Rutherford's category III and IV occurred significantly more often in the female population than in males. Also, according to the TASC II classification, more advanced atherosclerosis was found in females. This is a consequence of differences in symptoms between genders. It can also be concluded that the consequence of this is greater difficulty with crossing the CTO in females, due to the fact that the atherosclerotic lesions are more advanced and occur at older age. Undoubtedly, it resulted in a greater number of peri-procedural complications. This, however, was not reflected in the frequency of retrograde access procedures among genders. Despite the factors mentioned above, the frequency of re-PVI was higher among men. Therefore, it can be suspected that there were other factors outweighing and determining the greater re-PVI rate in men. Both, diabetes and younger age, were confirmed as predictors of negative events in the group of patients with PAD undergoing PVI [12,13]. A similar relationship was demonstrated for TASC lesions and lower body-mass index, which is described as the obesity paradox [2,4]. It seems that factors such as coronary artery disease, younger age, smoking, COPD and hyperlipidemia prevail over the location of changes, clinical advancement or the presence of diabetes and have determined the higher frequency of re-PVI in the follow-up period in men. The other probable factors behind the lower re-PVI prevalence during follow-up among women are their compliance with post-treatment recommendations. More careful drug use and compliance with lifestyle modification recommendations, related to smoking, physical activity and diet, may be of crucial importance here. There are many studies assessing the need for reinterventions after PVI, but the presented results are often discrepant. Davies et al. [14] reported a higher frequency of repeated reinterventions in women. Similarly, DeRubertis et al. [6] noted an association between female gender and a higher incidence of reintervention. In a study investigating 3,338 patients undergoing peripheral vascular interventions, Ferranti et al. [10] found no significant differences between genders in terms of re-PVI. Analogic data related to a retrograde technique are scarce and do not include gender-related differences [15,16]. In the current study, male gender was linked to more frequent incidences of reintervention in comparison to women. It is an interesting finding regarding more advanced diseases in females, which remains in line with reports stating that women, despite more severe PAD, are less likely to undergo invasive procedures than men [1]. The presented results are burdened with a certain probability of bias and require further research among larger and more diverse populations.

Female gender has been recognized as a risk factor for periprocedural complications. There are many studies documenting wound issues after peripheral artery bypass surgery [17,18]. Development of PVI improved rates of procedural intricacies in both women and men and diminished the gap between these groups [19]. The results of our study remain in line with the findings in previously published papers [5,6,10]. In the present study, women had significantly higher incidences of intraprocedural complications and minor vascular complications compared to men. Based on the clinical data of the study in question, especially the age and stage of PAD, one may note that the greater number of peri-operative complications is associated with atherosclerotic lesions more challenging for the operator. This relationship seems to be crucial regarding the difference in the frequency of complications between women and men.

4.1. Limitations of the study

Several limitations could be attributed to the current study. One of them is the sample size which may bring some bias to the present study. Another potential factor is different completion time and shorter duration in selected patients during the follow-up period. Additional important limitation is the small number of procedural operators. There was also a significant possibility that more ill patients had out-of-hospital events and did not make it to follow-up.

5. Conclusions

Male gender was identified as an independent predictor of re-PVI in the group of patients with PAD and CTOs treated with percutaneous angioplasty from retrograde access. Chronic occlusion in the superficial femoral artery and procedural failure were associated with re-PVI in women. Further studies are needed to investigate gender disparities in outcomes after retrograde access procedures.

Financial disclosure

The authors have no funding to disclose.

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Literature Search: Artur Pawlik, Rafał Januszek.

Funds Collection: n/a.

Declaration of competing interest

The authors declare no conflict of interests.

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