

Development of Peripheral Artery Disease

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Abstract

Introduction: Data on peripheral artery disease (PAD) development and progression in the Czech Republic is not available. Among our patients with this diagnosis, we selected those followed at our clinic for more than 1 year.

Results: The group included 198 patients; 40% were women. Mean age was 68 (+9,5) years. Thirty-one percent had diabetes mellitus and 64% were smokers. Two percent had undergone an amputation. Revascularization (predominantly endovascular procedures) had been performed in 15.6%. When admitted to our care, claudication was present in 72% and chronic limb threatening ischemia (CLTI) in 3%. Mean follow-up duration was 6.1 years. A worsening of claudication was observed in 34% and CLTI developed in 3.5%. An amputation was needed in 2% of the patients. Clinical deterioration was observed in 28%, especially smokers. Patients without claudication (27.8%) were older, more of them were women (56%), they included fewer smokers and had higher ankle brachial index (ABI) values. Their rate of clinical deterioration was similar to that in patients with claudication. Lower limb revascularization procedures (predominantly endovascular) were performed in 16.7% of the patients after being admitted to our care, and later in additional 15%. In total, revascularization was performed in 28% of the patients. These patients were younger, they had a history of a cerebrovascular accident less commonly and their prevalence rate of diabetes mellitus was lower, both lower limbs were involved more commonly, and naturally, clinical worsening was observed more commonly in these patients.

Conclusion: Among our patients with PAD followed for more than 6 year on average, claudication worsening occurred in 34% and CLTI developed in 3.5% of the patients. An amputation was needed in 2%. The course of the disease in patients with and without claudication was similar.

Keywords

Peripheral artery disease, Claudication, Amputation, Revascularization.

As follows from epidemiological studies, peripheral artery disease (PAD), assessed according to the decrease of the ankle brachial index, affects 9–29% of the population aged over 50 [1]. PAD has been estimated to affect 40 million persons in Europe [2]. Twenty to 59% of patients are asymptomatic [3]. According to literature, 21% of asymptomatic patients develop problems during 5 years or even 21% during 1 year. In patients with claudications, the risk of developing ischemic pain at rest is 30% and that of developing a skin ischemic condition is 23% in 10 years [1]. According to US guidelines [3], chronic limb threatening ischemia (CLTI) develops in 11–20% patients with known PAD diagnosis. More favorable data can be found in more recent literature. Only 1.1% of patients with claudications develop CLTI – and 0.2% undergo a major amputation – in 5 years [4]. Considering these differences in the data, we attempted to evaluate the course of the disease in our patients.

The Patient Group and the Methods

The patients are followed at our vascular

outpatient clinic. They were diagnosed with PAD if their ankle brachial index (ABI) value was 0.9 and less, or based on the history of lower limb revascularization. Atherosclerosis was the cause. A clinical assessment was performed. ABI values of both lower limbs and arm pressures were measured using pletysmography (VaSera 1500, Fukuda Denshi) in most cases, or using Doppler ultrasonography in rare cases. The ABI (ankle systolic pressure / higher arm systolic pressure) was calculated. The diagnosis of PAD was supported by color-assisted duplex sonography of lower limb arteries. Claudications, ischemic pain at rest and skin ischemic conditions (CLTI) [5] were assessed according to the guidelines. The claudication distance was estimated with the patient. Lower limb pain occurring after more than 1000 m was not considered as claudication. Body weight and body height were used to calculate the body mass index (BMI) (kg/m²). Patients who quit smoking in the past 5 years were also considered as smokers. Associated diseases were diagnosed based on the records

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or based on the history and therapy. All diabetic patients had type 2 diabetes. The effects of the therapy were followed only in some patients. Patients followed for 1 and more years at our clinic were included in the group. They were treated according to the guidelines in cooperation with general practitioners, internists or diabetologists. Some patients came to follow-up visits irregularly. Those considered for potential revascularization due to unpleasant claudications or their worsening, or due to CLTI, were referred to clinics in Prague, most commonly to the 2nd Department of Internal Medicine at the General University Hospital, Prague 2. Some patients were not indicated or revascularization, and some refused the proposed procedure. In some patients, various revascularization procedures were combined and repeated. Claudication worsening, development of CLTI, amputation and revascularization were considered as clinical deterioration during patient therapy and follow-up.

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RESULTS

Table 1: Composition of the patient group with peripheral artery disease followed at our clinic for 1 and more years.

Number	198	Minimum	Maximum
Age (years)	67.95	37	92
Females	40.4%		
Weight (kg)	77.5	45	135
Height (cm)	169.19	145	190
BMI (body mass index)	27.1	18.6	50.2
Ischemic heart disease	25.25%		
Cerebrovascular accident	6.06%		
Hypertension	72.7%		
Hyperlipoproteinemia	57.56%		
Diabetes mellitus	31.31%		
Smokers	64.14%		
Ex-smokers	18.68%		
Non-smokers	17.18%		
Revascularization PTA	11.60%		
Surgery	6.60%		
Total	15.60%		
Amputation	2.02%		
Asymptomatic patient	5.05%		
Other problems	22.73%		
Claudication, occurrence	71.72%		
Claudication (m)	299.8	20	1000
CLTI	3.03%		
Blood pressure (mmHg) Systolic	158.42	110	230
Diastolic	86.93	64	120
Pulse pressure	74.86	32	120
Ankle systolic pressure (mmHg)	101.41	0	187
ABI (ankle brachial index)	0.6463	0	1.1
Only 1 lower limb affected	42.92%		

PTA – angioplasty and other endovascular procedures. CLTI – chronic limb threatening ischemia.

The composition of the group of patients with PAD is shown in Table 1. Our group includes 198 patients with PAD who have been in our care for more than 1 year. Mean age was 67.9 years, range

37–92. The group included 40.4% females. Mean BMI was 27.1, range 18.6–50.2. One quarter of the patients had the history of a cardiac disease (IHD, arrhythmia). Hypertension was common (in 73%) and was insufficiently treated. Hyperlipidemia was present in 58% and diabetes mellitus in 31% of the patients. The rate of cigarette smokers was 64%. Revascularization of lower limb arteries had been done in 15.6%, and endovascular procedures in 11.6% of the patients. Two percent of the patients had undergone amputations. One patient with diabetes and chronic renal insufficiency had undergone an amputation at the thigh and 3 patients had had amputations of the toes. Claudications were reported by 72% patients with the mean claudication distance of 300 m (range 20–1000 m). Ischemic pain at rest or an ischemic ulcer were present in 3%. Mean ABI of the more severely affected limb was 0.6463 (range 0–1.1). Only one lower limb (ABI 0.9 and less) was affected in 43% patients.

The results of care of our patients are shown in Table 2. After receiving the patients to our care, revascularization was performed in 16.7%, mostly endovascular procedures with a good effect. The patients were followed for at least 1 year, with the average of over 6 years. The number of patients with only 1 limb affected decreased from 43% to 26%. During the follow-up, revascularization were performed in 15.6% patients, and some underwent repeated procedures. Endovascular procedures predominated. In total, revascularization was performed in 32.3% patients. Before coming to our care, revascularization had been done in 15.6% patients; subsequently, revascularization procedures were repeated somewhat more commonly in these patients. Claudications worsened in 34.5% patients. Chronic limb threatening ischemia (CLTI) developed in 3.5% patients. An amputation was performed in 2%. In one patient with diabetes and chronic renal insufficiency with the history of amputation at the thigh, high amputation needed to be performed in the other limb. One additional patient had an amputation at the thigh. Two patients had amputations of the toes, one of them also metatarsal amputations in the other lower limb. This patient with atrial fibrillation was afraid of medications and embolism may have been involved in the clinical condition. Combined information on clinical deterioration was present in 28% patients. The blood pressure and at the arm and ankles (ABI) remained virtually unchanged. Clinical deterioration (worsening of claudications, CLTI development, the requirement of revascularization) occurred in 28% patients.

Table 2: Follow-up results in patients with peripheral artery disease.

	Incidence or mean	minimum	maximum
Revascularization in the 1st half of the year PTA	14.6%		
Surgery	3.03%		
Total	16.7%		
Follow-up duration (years)	6.11	1	30
Only 1 lower limb involved	26.3%		
Revascularization PTA	13.1%		
Surgery	8.1%		
Total	15.6%		
Claudication worsening	34.5%		
Critical ischemia (CLTI)	3.53%		
Amputation (2x high, 2x low)	2.02%		
Clinical deterioration	28.3%		
Blood pressure (mmHg) Systolic	152.0	110	229
Diastolic	82.1	60	120
ABI (ankle brachial index)	0.6472	0	1.1

PTA – angioplasty and other endovascular procedures.

Based on the comparison of patients with and without clinical deterioration (Table 3), the differences were mostly statistically insignificant. Only those with deterioration were smokers more commonly ($P<0.05$) and were followed for a longer period at our clinic.

Furthermore, we compared patients with and without claudications (Table 4). Patients without claudications were older ($P<0.01$), had no history of revascularization of the carotid artery ($P<0.05$) and had diabetes mellitus more commonly ($P<0.05$). They had a higher ankle systolic pressure ($P<0.001$) and higher ABI values ($P<0.01$). Patients with claudications were younger, some had undergone revascularization of the carotid artery, had diabetes mellitus less commonly and more often they were smokers ($P<0.01$) and had lower ABI values. Of the patients not reporting claudications at the first examination, 14% developed claudications later. Importantly, the rates of CLTI development and of amputations were similar in both groups.

Table 5 shows patients undergoing revascularization of lower limbs compared to the others. Revascularization was performed in 27.8% patients, represented by endovascular procedures in more than 2/3. Patients with revascularization were younger, had the history of a cerebrovascular accident less commonly and had diabetes

mellitus less commonly; both lower limbs were affected more commonly in them and they also experienced clinical deterioration more commonly. The rate of amputations did not differ. Taking into account lower limb revascularizations performed also before coming to our care, the rate rises to 38.4%.

DISCUSSION

Various groups of patients with peripheral artery disease differ especially in the number of patients, their origin, number of females, smokers, diabetics, those with claudications, asymptomatic patients, number of those with CLTI, number and types of revascularization procedures, etc. Some studies involve persons of epidemiological studies, some patients are from a single site, some from several or even dozens or hundreds of sites, or they are only male; some include only patients with claudications while other include hospitalized patients. There are differences in follow-up duration. The follow-up period is clearly shorter in pharmaceutical studies. The composition of our patient group is similar to that of the Compass study with rivaroxaban [6] or Euclid study with ticagrelor [7]. Our group has more females, more smokers, and unfortunately, our patients clearly have higher blood pressure values, and fewer have had lower limb revascularization. Compared to the Cavasic study of Austrian sites [8] with 255 men with claudications, the age in our group is clearly higher (59 years vs 72 years), our group includes 40% women, more smokers (53% vs 64%) and diabetic patients (15% vs 31%). ABI is lower in our group (0.71 vs 0.65). Clearly, our group involves higher-

Table 3: Comparison of patients with peripheral artery disease who were stable during the follow-up and of patients who have deteriorated.

	Clinical condition		Difference	Statistical significance
	Stable, 71.13%	Deteriorated, 28.87%		
				P
Follow-up duration (years)	5.33	8.11	2.78	0.000
Age (years)	68.95	65.8	-3.15	0.078
Females	40.56 %	37%	-4.02	0.602
Weight (kg)	77.6	77.2	-0.4	0.861
Height (cm)	169.3	169.2	-0.1	0.905
BMI (body mass index)	27.1	27.1	0	0.674
History IHD	24.6%	25%	0.4	0.864
CA revascularization	2.2%	1.8%	-0.4	0.649
CVA	6.52%	5.3%	-1.22	0.744
Hypertension	73.19%	71.4%	-1.79	0.571
Hyperlipidemia	56.5%	60.7	4.2	0.625
Diabetes mellitus	34.7%	23.2%	-11.5	0.105
Smokers	59.45%	76.8%	17.35	0.040
LL revascularization	12.3%	25%	12.7	0.162
Amputation	0.7%	3.6%	2.9	0.331
Asymptomatic patients	5.8%	3.6	-2.2	0.642
Patients with claudications	69.6%	76.8	7.2	0.321
Claudication distance (m)	296	318.3	22.3	0.494
Blood pressure (mmHg) Systolic	160.01	155.14	-4.87	0.157
Diastolic	73.02	86.2	13.18	0.293
Ankle systolic pressure (mmHg)	102.2	99.5	-2.7	0.282
ABI (ankle brachial index)	0.646	0.643	-0.03	0.671
Only 1 lower limb involved	45.65%	39.3%	-6.35	0.671
Revascularization in the 1st half of the year	17.4%	16.1%	-1.3	0.652

IHD – ischemic heart disease; CA – carotid artery; CVA – cerebrovascular accident; LL – lower limbs. Statistically significant differences are highlighted in bold.

Table 4: Comparison of patients with claudications and those reporting no claudications.

Patients with peripheral artery disease		Patients with claudications	Patients without claudications	Difference	Statistical significance P
Number		143 (72.2%)	55 (27.8%)		
Age (years)		66.7	71.2	4.5	0.005
Females		34.5%	56.4%	21.9	0.009
Weight (kg)		77.6	77.0	-0.6	0.976
Height (cm)		169.6	167.8	-1.8	0.300
BMI (body mass index)		27	27.5	0.5	0.467
History	IHD	26.8%	21.6%	-5.2	0.536
	CA revascularization	3.5%	0	-3.5	0.025
	CVA	5.6	7.7%	2.1	0.649
	Hypertension	73.0%	76.9%	3.9	0.543
	Diabetes mellitus	26.9%	45.1%	18.2	0.019
	Smokers	71.6%	50.0%	-21.6	0.007
	Disease of the locomotor system	29.8%	40.4	10.6	0.190
	LL revascularization	14.9%	18.2%	3.3	0.595
	Amputation	0.7%	3.6%	2.9	0.141
Baseline condition	No problems	0	18.5%		
	Critical ischemia	2.8%	3.6%	0.8	0.782
Blood pressure (mmHg)	Systolic	157.0	162.2	-5.2	0.139
	Diastolic	86.9	86.8	-0.1	0.962
	Pulse	70.3	76.0	5.7	0.073
	Ankle systolic	96.5	113.7	17.2	0.000
ABI		0.630	0.703	0.08	0.006
Only 1 lower limb involved		40.8%	47.3%	6.5	0.348
Revascularization after receiving to care		18.3%	12.7%	5.6	0.285
Disease development					
Follow-up duration (years)		6.57	4.92	-1.65	0.019
Claudication – worsening or new onset		28.9%	14.5%	-14.4	0.018
Chronic limb threatening ischemia		2.8%	3.6%	0.8	0.386
Amputation		1.4%	1.8%	0.4	0.336
Lower limb revascularization		16.2%	14.5%	-2.3	0.740
Clinical deterioration		30.3%	21.8%	-8.5	0.307

IHD – ischemic heart disease; CA – carotid artery; CVA – cerebrovascular accident. Statistically significant differences are highlighted in bold.

Table 5: Comparison of patients with peripheral artery disease, with and without lower limb revascularization while in our care. Only statistically significant differences are shown.

	Patients with revascularization	Patients without revascularization	Difference	Statistical significance P
Number (%)	27.8%	72.2%		
Age (years)	65.7	68.8	3.1	0.043
Cerebrovascular accident	2%	8%	4	0.037
Diabetes mellitus	19%	38%	19	0.005
Only 1 lower limb involved	22%	51%	29	0.000
Follow-up duration (years)	8.4	5.2	-3.2	0.001
Claudication worsening	58%	12%	-46	0.000
Clinical deterioration	65%	14%	-51	0.000

risk patients. The population of the above-mentioned Japanese study [4] with 1107 patients with newly diagnosed claudications was about the same, only the patients had lower BMI values (22.4%) and dyslipidemia was less common (29.4%).

According to the known TASC II document o 2007 [9], the rate of asymptomatic patients is 20–50%, typical claudications are present in 10–35% and other pain in lower limbs is present in 30–40%. According to US guidelines of 2024 [3], 20–59% of patients with

evidence of PAD are asymptomatic and up to 80% suffer from claudications. In our group, 72% patients had claudications. Other problems related to lower limbs were present in 23%, and only 5% were asymptomatic. A decreased ABI value was found in these patients at a preventive examination, or the ability to walk of these patients was limited by dyspnea or other pain. Initially, 14.5% patients had no claudications and these occurred during the follow-up period. In the Euclid study [10], claudications occurred in 25.2% of previously asymptomatic patients after 12 months. As reported by

Sigvant [11] in their large metaanalysis, 7% of asymptomatic patients develop claudications after 6.3 years. Importantly, the course of the disease in asymptomatic patients is similar to that in persons with claudications. This is confirmed by our results, as well (Table 4).

Claudications worsened in 34.5% patients during the follow-up. As reported by the Austrian study [8] in men with claudications, 33% patients deteriorated during 5 years. TASC reported worsened claudications in 10–20% [9] and the Japanese study in 19.1% [4].

Critical limb threatening ischemia (CLTI) developed after more than 6 years of follow-up in 3.5% of our patients. As reported by TASC [9], critical ischemia develops in 5–10% patients after 5 years. According to Sigvant [11], 21% patients with claudications develop critical limb threatening ischemia during their life, and 4–27% undergo an amputation! The Japanese study of 2017 (4) reports CLTI only in 1.4% after 5 years!

Clinical deterioration (worsening of claudications, CLTI development, the requirement of revascularization) occurred in 28.3% of our patients after more than 6 years. The Japanese study reported deterioration in 20.5% after 5 years. The Austrian authors reported deterioration in 33% patients after 5 years.

TASC provides information on amputations only in persons with critical limb threatening ischemia. In the pharmaceutical study with Compass [6] which lasted only about 21 months, amputations occurred in 1% of patients in the arm with aspirin alone. A reduction by 50% was observed in the arm with aspirin and rivaroxaban 2x2.5 mg! In our group, the patients were followed for the mean of 6.11 years and amputations occurred in 2%. According to the metaanalysis of Sigvant [11], 4–27% of patients with claudications had an amputation! In the Austrian study of 2017 [8], most similar to our study, amputations were observed in 2.76%. The Japanese authors [4] report a remarkably low rate of amputations – 1% in 5 years.

Revascularization (mostly endovascular procedures) was performed in 38.4% of our patients, and 22.4% had repeated revascularization procedures. Fifteen percent had revascularization before coming to our care and 28% in our care. In Austria, revascularization was performed in 33% patients; of these, 61% underwent surgery [8]! In Japan, revascularization was done in 63% and similarly to our group, endovascular procedures predominated over surgeries. Our results are similar to those of Austria. The results of care of Japanese physicians are better. In this respect, a role is played by the less severe health condition of the followed patients with PAD and a double rate of revascularization procedures. A role is also played by the good health of the population, low rate of cardiovascular disease, and long age.

In the past century, people were very much afraid of the Buerger disease for frequent amputations of lower as well as upper limbs in low- or middle-age patients. Today, the peripheral artery disease causes less fear. The risk of amputation is not high unless the disease is insufficiently treated. However, the risk of death is 3 times higher compared to the regular population, and these patients die mostly of cardiovascular disease [9,11,12]. As regards internal treatment of patients with PAD, there is a lot to be done in the correction of risk factors. The antiplatelet therapy using acetylsalicylic acid (100 mg) combined with rivaroxaban (2x2.5 mg) provides a great benefit. Unfortunately, this therapy is reimbursed in the Czech Republic only if the patient has had a myocardial infarction or has multiple coronary arteries involved. Also, the indications for revascularization are still

in the process of being specified and revascularization procedures keep improving [1,3].

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