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Demographic and Comorbidity Pattern of Patients with Critical Limb Ischemia

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Aim: The present study aimed at identifying the pattern of patients with critical limb ischemia (CLI) compared with those with peripheral arterial occlusive disease (PAOD).

Materials and methods: A four-year retrospective study was conducted with patients hospitalized in the Second Surgical Clinic at the Emergency County Hospital Cluj-Napoca. The medical charts of patients with PAOD (n=466) and CLI (n=223) were reviewed and data were collected.

Results: The study included 689 patients; mean age 67 years for PAOD patients and 65 years for CLI patients. A significantly higher percentage of patients were male in both groups (79.25%, $P < 0.0001$). Most of the patients in both groups had received at least a secondary education ($P < 0.0001$). Most of the subjects in both groups were smokers (>71.30%) with no difference between groups ($P = 0.566$). No significant differences were found between the groups in comorbidities (diabetes, arterial blood hypertension, cardiac ischemia, rhythm disorders, $P > 0.05$). There were more CLI patients that were overweight than overweight patients with PAOD ($P = 0.0004$). High serum cholesterol (>200 mg/dL) and triglycerides (>150 mg/dL) levels were found in the CLI group ($P < 0.05$). Age was identified as a risk factors for amputation (OR = 1.03, 95%CI [1.01−1.05], $P = 0.0012$).

Conclusions: The profile of a patient with critical limb ischemia and peripheral arterial occlusive disease is a 65-67-year-old male smoker with at least a secondary education. The CLI patient is overweight with pathological serum levels of cholesterol and triglycerides.

BACKGROUND

Critical limb ischemia is defined by Trans-Atlantic Inter-Society Consensus (TASC) II as tissue loss associated with either an ankle pressure less than 70 mm Hg or toe pressure less than 50 mm Hg.[1] Several symptoms that worsen along the time were described to be directly connected with CLI, such as rest pain associated with either an ankle pressure less than 50 mm Hg or toe pressure less than 30 mm Hg, absent or diminished pulse of the dorsalis pedis artery, posterior tibial artery or popliteal artery and femoral artery, smooth, dry skin of the legs or feet, severe pain or numbness in the legs and feet, toe or foot sores, recurrent infections or slowly healing ulcers, and finally gangrene.[1,2] The treatment for CLI aims to relieve the ischemic pain, to heal ulcers thus preventing limb loss, and improvement of patient quality of life.[3] Early revascularization surgery (bypass techniques) is recommended for delaying and preventing amputation. For maintaining a good vascularization of the leg, efficient pharmacotherapy with anticoagulant drugs, vasodilator drugs and vasopressor drugs is used.[1,4] Approximately 30% of CLI patients are not taken into consideration for revascularization because of the late stage of the disease. Therefore, limb amputation is the only option that may preserve the lives of these patients, even if it does not solve the

cause of the problem nor prevents the recurrence of the same condition.[4]

One in a thousand people is diagnosed every year with CLI in Europe[1], one third requires amputation, and one quarter dies within a year mainly because of a late diagnosis[4]. The main risk factor for CLI is generalized atherosclerosis – this requires a complex treatment from the early stages of the disease followed by a multidisciplinary approach with the view to confer the patients a better long term prognosis.[1,4,5]

AIM

To identify the predictors for amputation according to the demographics, co-morbidities, clinical and paraclinical data of patients with critical limb ischemia compared with those with peripheral arterial occlusive disease.

MATERIALS AND METHODS

A retrospective study was conducted between January 2010 and March 2015 with the patients hospitalized for critical lower limb ischemia and respectively for other peripheral arterial occlusive disease (PAOD) in the Second Surgical Clinic at the Emergency County Hospital Cluj-Napoca. The Second Surgery Hospital is a university hospital that offers medical care to almost 3 million citizens in the north-west region of Romania.

Medical charts were reviewed as the source of raw data in our study. All subjects with CLI or PAOD as discharge diagnosis were eligible for the study. Patients with grade II category 4 of CLI - ischemic rest pain (Rutherford classification of PAD) were included in the CLI group. This term refers to a condition characterized by ischemic pain at rest with presence of ulcers or gangrene in one or both legs due to a preexistent arterial occlusive disease. It is the most severe form of peripheral arterial disease. Patients with grade I category 3 of CLI - severe claudication (Rutherford classification of PAD) were included in PAOD group. PAOD is a common circulatory problem caused by atherosclerosis and thrombus formation and characterized by narrow arteries which reduce the blood flow to the limbs. Subjects with incomplete charts or missing data were excluded from the study. The following data were collected from the medical charts: demographics (gender, age, environment, and smoking and educational status), medical co-morbidities (type 2 diabetes, arterial hypertension, ischemic heart disease, and heart rhythm disorder), symptoms at admission (type of pain - continuous pain, pain that remits on treatment), treatment options (medical or surgical), and discharge status. Patients with acute ischemia, peripheral vascular disorders of inflammatory or immunological origin, venous ulcers, neuropathic ulcers, or Buerger's disease were excluded. Furthermore, incomplete charts or missing data also led to the exclusion of patients from the study.

The study was conducted according to the principles of the Declaration of Helsinki and was approved by the Ethical Committee of Iuliu Haţieganu University of Medicine and Pharmacy Cluj-Napoca (No. 475/22.10.2015).

Statistical analysis

In this study qualitative data were summarized as percentages and associated 95% confidence interval (herein given in square brackets) computed using an exact method.[6] Z-test for proportions was used to compare groups on qualitative data. Normally distributed quantitative data were summarized as mean ± standard deviations; otherwise median and interquartile range (defined as Q1 - Q3, where Q1 = first quartile and Q3 = third quartile, given in round brackets throughout the article) were used. The Student t-test for independent samples was used to compare groups whenever qualitative data proved normally distributed; otherwise, the Mann-Whitney test was applied. Logistic regression analysis was conducted to identify the risk factors for amputation. The Fisher exact test was applied to test associations in contingency tables. The Statistics software (StatSoft, v. 8) was used in the analysis. A $P < 0.05$ was considered statistically significant for all analyses.

RESULTS

Six hundred and eighty-nine subjects met the inclusion criteria and were included in the study. The investigated sample comprised a significantly higher percentage of patients with PAOD than patients with CLI (67.63%, 95%CI [64.01−71.12] vs. 32.37%, 95%CI [28.88−35.99]; Z-statistic=-19.78, $P < 0.0001$).

As expected, the overall percentage of men was significantly higher than that for women (men:women = 79.25%:20.75%, Z-statistic=-37.8666, $P < 0.0001$). This difference is also observed in both groups (**Table 1**). The differences between groups in gender, living location, education, age, duration of disease and body mass index are given in **Table 1**.

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Most patients from both groups were smokers (PAOD:CLI = 68.88%:71.30%), with no significant differences between groups (Z-statistic=-0.5739, P=0.566). Except overweight, no differences between the groups were found in the comorbidities (**Table 2**). Note that most of the patients in both groups were overweight.

Abnormal serum cholesterol levels (≥200 mg/dL) were found in both groups with higher percentage in CLI compared with PAOD group (CLI:PAOD = 41.26%:33.05%; Z-statistic=-2.10, P = 0.0356). Similar results were also obtained for triglycerides, with significantly higher percent of pathological values (≥150 mg/dL) in CLI compared with PAOD group (CLI:PAOD=38.57%:29.18%, Z-statistic=-2.47, P = 0.0136).

Most of the subjects included in the study received vasodilator and anticoagulant treatment (**Table 3**) while necrectomy was the major surgery for the CLI patients and amputation for PAOD patients (**Table 3**).

Table 1. Demographics of the study patients

Variable	PAOD (n=466)	CLI (n=223)	P
Gender[a]			1.87 (0.0621)
Female	22.75	16.59	
Male	77.25	83.41	
P	<0.0001	<0.0001	
Location[a]			-0.09 (0.9295)
Urban	48.07	48.43	
Rural	51.93	51.57	
P	0.0954	0.3481	
Education			-1.71 (0.0867)
With higher education	36.70	43.50	
With at least secondary education	63.30	56.50	
P	<0.0001	<0.0001	
Age (years)[b]	67 (60−75)	65 (58.5−73)	1.65 (0.0999)
Duration of disease (weeks)[b]	4 (3−12)[i]	28 (20−52)[ii]	-14.46 (<0.0001)
BMI (kg/m^3)[b]	25.71 (23.53−27.68)[iii]	26.26 (24.80−27.17)[iv]	-1.67 (0.0955)

[a]%; Z test for proportions; [b]median (Q1-Q3), where Q1 = first quartile, Q3 = third quartile; BMI = body mass index; [i]n=458; [ii]n=222; [iii]n=428; [iv]n=211

Table 2. Comorbidities expressed as percentages and associated 95% confidence intervals and differences between groups

Comorbidity	PAOD (n=466)	CLI (n=223)	P
Overweight	45.71 [41.20−50.43]	60.09 [53.37−66.37]	-3.53 (0.0004)
Diabetes	32.83 [28.54−37.34]	33.18 [26.91−39.91]	-0.09 (0.9271)
Arterial blood hypertension	78.11 [74.03−81.73]	78.03 [72.20−83.41]	0.02 (0.9811)
Ischemic heart disease	43.35 [86.10−94.17]	45.29 [38.57−52.02]	-0.48 (0.6312)
Rhythms disorders	16.95 [13.73−20.82]	13.45 [9.42−18.83]	1.18 (0.2388)

Table 3. Treatment strategies (per cent) and comparisons between groups

	PAOD (n=466)	CLI (n=223)	P
Drugs received in treatment			
Vasodilator	93.78	91.93	0.90 (0.3674)
Anticoagulant	63.73	69.06	-1.38 (0.1686)
Prostaglandin	17.38	17.49	-0.04 (0.9716)
Invasive treatment			
Necrectomy	13.52	19.28	-1.96 (0.0499)
Disarticulation	11.37	13.00	-0.62 (0.5364)
1 toe	2.58	5.38	-1.87 (0.0608)
>1 toe	8.80	3.65	2.46 (0.0140)
Amputation	17.81	16.59	0.40 (0.6928)
Foot	1.50	2.24	-0.70 (0.4870)
Thigh	14.81	13.45	0.48 (0.6340)
Calf	1.50	0.90	0.65 (0.5163)
Other surgical methods*	14.81	5.38	3.60 (0.0003)

*bypass surgery, endovascular surgery

Significantly more complications (such as hemorrhage, or sepsis) were observed in PAOD group compared with CLI (PAOD:CLI=12.88%:5.83%, Z-statistic=2.8128, P=0.0049).

Most patients were cured or in remission at discharge, with significantly higher percentage of cured patients in the CLI group than in the PAOD group, and significantly higher percentage of remission in PAOD group than in the CLI group (**Fig. 1**).

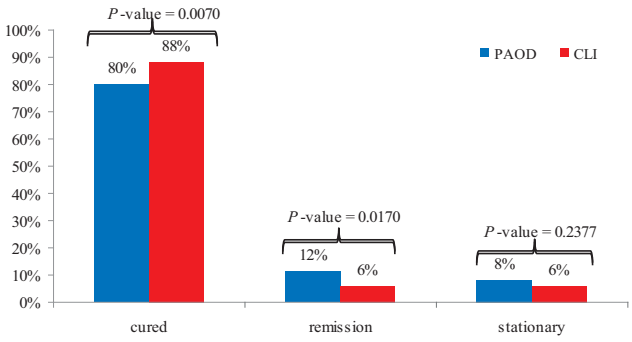

Figure 1. Patient's status at discharge.

There were no lethal outcomes for patients receiving prostaglandins, while most patients in this group were in remission at discharge (**Table 4**).

Without exception, all patients who underwent a bypass surgery (at different levels) were cured or in remission at discharge. The percentages of cured patients varied from 60% (femoral-tibial bypass, n=5) to 90% (aortofemoral bypass, n=10) while the percentages of subjects in remission varied from 4.76% (aortobifemoral bypass, n=21) to 40.00% (femoral-tibial bypass, n=5). Just one subject died in the group who had bypass surgery (aortofemoral bypass).

Table 4. Association between the applied procedures and different factors

	Cured	Remission	Stationary	Deceased
Prostaglandins = yes	10	93	17	0
Prostaglandins = no	302	194	50	23

Fisher exact test: P = 0.012

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Only 2.76% (95%CI [1.60−4.21]) of all patient died, without significant differences between groups (P = 0.5685).

No significant differences were found in the duration of hospital stay between the groups (PAOD: median=11, IQR = (7−16); CLI: median=11, IQR = (6−15); Mann-Whitney test =1.0342, P = 0.3011).

Significant differences in the duration of hospital stay were observed in the patients with toe disarticulation (Kruskal Wallis test = 31.14, P < 0.0001) and in those with different discharge status (Kruskal Wallis test = 146.25, P < 0.0001). Subjects with toe disarticulations stayed more days in hospital (median = 14.5 days for one toe and 17.5 days for more than 1 toe) compared with those without toe disarticulation (median = 11 days, (Q1-Q3) = (6-15)). The cured patients stayed longer in hospital (median = 14, IQR = (11-18), n = 312) compared with patients in remission (median = 8, IQR = (4-14), n = 287) or stationary (median = 6, IQR = (4-8), n = 67).

Univariate regression analysis identified just the age as a significant risk factor for amputation (OR = 1.03, 95%CI [1.01−1.05], P = 0.0012). The age of patients with amputation was significantly higher than that of the patients without amputation (without vs. with amputation: 66 years (59−74) versus 68 years (61−79), Mann-Whitney test = 2.8717, P = 0.0041).

DISCUSSION

This study describes demographic and co-morbidities pattern of patients with peripheral arterial occlusive disease and critical lower limb ischemia to identify those factors that are characteristics for CLI compared with PAOD. As expected, the study sample contained more patients with PAOD (67.63%, P <0.0001) than with CLI, since PAOD precedes CLI in the evolution of the arterial disease. However, this result shows that a higher amount of patients was diagnosed and taken under medical care at an early stage of disease. This is a good thing due to the fact that allows application of other methods than invasive surgery (e.g. drug-eluting stents, balloon angioplasty[4,5]) such as therapeutic schemas (e.g. antiplatelet therapy as an evidence level 1A, treated for hyperlipidemia as an evidence level 1A[7]) and/or preventions strategies (such as smoking cessation). The adherence to the current guidelines of aspirin, statins, angiotensin-converting enzyme inhibitors (ACEIs), and smoking abstinence varied from 60% (ACEIs) to 84% (aspirin) among patients with vascular disease.[8]

Conversely, the frequency of CLI in our study is almost ten times higher than the reported one of 1 to 3%[9]; this high frequency could be explained by the fact that the hospital where the study was conducted provides services to Transylvania. Another explanation is the fact that patients with vascular diseases present themselves to medical services in the late stages of the disease and therefore the evolution of the pathology is advanced, so at admission we had more patients with CLI than with PAOD.

The disease is known to be more frequent in men than in women, and our study confirms this finding reported on the same population (79.80%).[10] Similar results with a higher frequency for men than women were previously reported.[9,11] This higher frequency among men may be explained by the lack of protection against atherosclerosis compared with women before menopause (estrogen protection), who after menopause tend to be equally affected, another explanation is that there is a higher percentage of men who smoke compared with women.[12]

No significant differences among subjects who live in rural and urban areas were found (see **Table 1**) even if a slightly higher percentage were from rural areas where the access to medical information could be easier. No difference between subjects from rural and urban areas was previously identified and reported by Hirsch et al.[9] The risk factors and pathology are the same in both groups.

A significantly higher percentage of subjects in both groups had at least a secondary education (see **Table 1**) which suggests that the disease could have an educational component, more likely being found in subjects with a lower level of education. This may be accounted for by the hypothesis that persons with higher levels of education tend to attend their doctors while the disease is still in its early stages of development and thus may prevent or cease the evolution of the pathology. Corey revealed that persons with lower education level have an increased mortality rate after amputation.[13] That may be as well put on the above statement because those with higher levels of education care for them more and may adopt a preventing style instead of presenting to medical services in late advanced disease stages.

The median age of subjects in PAOD group was 67 years and respectively 65 years for the subjects in CLI group, without significant differences between groups (P > 0.05, **Table 1**). Furthermore, no difference was observed in regard of body mass index, while the duration of disease was as

expected significantly higher for the patients with CLI compared with those with PAOD ($P < 0.001$, **Table 1**). However, a significantly higher percentage of subjects were overweight in the CLI group than in the PAOD group ($P < 0.001$, **Table 2**). Murata et al. have shown that survival rate is higher if a subject is overweight compared with normal weight in patients with endovascular treatment.[14]

Smoking is known as a risk factor for arterial disease and our results showed that the frequency of smoking in both groups was higher than 68% without difference between groups ($P > 0.5$). It is known that smoking is a risk factor for arterial disease.[15] Davies showed that smoking exacerbates the existing risk factors and had a negative influence on the evolution of the pathology and even its response to treatment.[7] The problem still remains because it is hard for subjects to quit smoking and even if they quit, they do it in the late stages of the disease and this makes no instant impact on the disease's prognosis. No differences between groups were observed in regard of presence of comorbidities (diabetes, arterial blood hypertension, cardiac ischemia, and/or rhythm disorders) ($P > 0.6$, **Table 2**). Ostchega et al. identified current smoking, previous smoking, diabetes mellitus, not controlled or untreated hypertension as significant risk factors associated with PAOD in persons aged 60 and older.[16] Sotoda et al. reported an odds ratio for PAOD of smokers versus non-smokers that range from 1.7 to 7.4[17], while Lu at al. reported that there is a substantial evidence of an association between active smoking and PAOD[18]. Conversely, Emdin et al. showed no association of smoking status with PAOD while the median of BMI on PAOD subjects was similar to the median of BMI in our PAOD group.[19] Furthermore, smoking cessation proved not to be necessarily associated with a reduction of the risk in PAOD patients.[20]

A higher percentage of subject with CLI had higher serum levels of both cholesterol (>200 mg/dL) and triglycerides (>150 mg/dL) compared with PAOD group ($P < 0.05$). Framingham demonstrated that elevated cholesterol increases the risk for CLI.[21] It is known that dyslipidemia (that includes high levels of triglycerides) is an important risk factor for PAOD and CLI. Elevated serum triglycerides have been found on patients with critical limb ischemia.[22] This difference between PAOD and CLI regarding the levels of cholesterol may be put under the idea that CLI is the final stage of the disease and therefore patients with CLI have more risk factors and higher levels of cholesterol and triglycerides.

As treatment strategies (medical and surgical) compared between the two groups revealed statistical differences in necrectomy ($P = 0.0499$), disarticulation of more than one toe ($P = 0.0140$), and other surgical methods such as bypass surgery and endovascular surgery ($P = 0.0003$, **Table 3**). There are many ways to try to salvage the limb such as debridement of the wound or arthroplasty. Revascularization methods remain the first option for most patients with arterial occlusive disease. It is also known that this pathology is evolving faster and has a poor prognosis. Most of the patients needed major amputation to prevent the infection or gangrene from spreading.[23] Medical treatment includes vasodilators, anticoagulants, prostaglandins and vasoactive drugs that extend the time until the surgical procedure is indicated. These medical treatments were observed in studies with inconclusive results according to the pathology.[24]

More complications were observed in the PAOD group ($P = 0.0049$). It should be taken into consideration that more of the PAOD patients suffer surgical interventions of limb salvage (endovascular surgery, bypass) than the ones with CLI.

Regarding the status of "cured" at discharge we found significant differences between the PAOD and CLI groups ($P = 0.0070$) with a higher number of CLI patients. Regarding the "remission" status there were significant differences between the two groups ($P = 0.0170$) with a higher number of PAOD patients. Also, no patient who received prostaglandins treatment died ($P = 0.012$, **Fig. 1**). It is known that PAOD is an evaluative disease and many patients with PAOD may be considered at risk for CLI.[1] These means that some of the patients with PAOD are not properly „cured" at discharge and in fact it is only a „remission" status, and more patients with CLI were discharged as cured because by the surgical point of view they were indeed cured.

It is known that prostaglandins prevent platelet and leukocyte activation, thus protecting the endothelium. Brock et al. showed the benefit of the prostaglandin treatment and the chances of saving both legs and survive.[25] In another study, prostaglandins treatment failed to reduce death and amputation rate.[26] Prediction of response is difficult to anticipate and due to this, prostaglandins are used in certain chosen cases.

Also all patients who undergo bypass at different levels were cured at discharge such as 60% for bypass fem-ATA to 90% for bypass Aobifem,

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to 40% for bypass fem-ATA. Murphy revealed in his study a bypass potency of 74% at 8 years after stent placement suggesting the durability of these procedures.[27] In addition, there were almost 3% of patients who died in the whole sample with no statistical difference between groups.

No significant differences regarding the hospitalization stay were observed between investigated groups. However, differences between hospitalization stay observed among subjects with toe disarticulation ($P < 0.0001$) and among those with different discharge status ($P < 0.0001$) were identified. Subjects with toe disarticulation stayed more days in hospital (median 14 days) compared with those without toe disarticulation (median 11 days). Also the "cured" patients stayed more (median 14 days) than those in "remission" status (median 8 days) and those in "stationary" status (median 6 days). These differences may be explained by the fact that those who underwent surgery stayed longer in hospital due to recovery and the "stationary" ones were those without surgical intervention. Patients with a surgical procedure need intensive treatment and thus a longer hospitalization stay.

The study identified age as a risk factor for amputation ($P = 0.0012$). In our study groups the age of those who had amputation is higher than that of those without amputation ($P = 0.0041$). It is known that the PAOD prevalence increases with age.[5] Shojaiefard showed that necrotic lesions and neuropathy are independent factors that predict amputation.[28] Patients who undergo a disarticulation procedure are more likely to be candidates for a future major procedure such as amputation.[5]

Despite the rigorous design, our study has several limitations. The first limitation of the study regards the fact that it is a retrospective one and data was collected form the medical charts, the charts being written by different physicians with different experience. This fact sustains the possibility of occurring errors regarding the subjectivity of every examiner. The second limitation is also associated with the retrospective collection of data. In this regards the factors that influence the prognosis or those related with the quality of life of these patients could not be evaluated.

CONCLUSION

Our study showed that the profile of patient with critical limb ischemia and peripheral arterial occlusive disease is a 67-year-old male smoker with education up to a secondary level, and with pathological serum levels of cholesterol and triglycerides. The CLI patient is an overweight while the PAOD patient show more complications related with the treatment.

Patients' age proved to be a significant risk factor for amputation and this result could be explained by both the duration of disease and the longer history of smoking of patients.

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Демографическая модель и сопутствующие заболевания у пациентов с критической ишемией конечностей

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Цель: Настоящее исследование имеет целью установление профиля пациентов с критической ишемией конечностей (КИК) в сопоставлении с профилем пациентов с облитерирующим эндартериитом периферических артерий (ОЭПА).

Материалы и методы: Было проведено четырёхлетнее ретроспективное исследование пациентов, госпитализованных во Второй хирургической клинике в Окружной больнице неотложных случаев Клуж-Напока. Нами были проанализированы медицинские карты пациентов с ОЭПА (n=466) и КИК (n=223) и были обобщены данные.

Результаты: В исследование были включены 689 пациентов; средний возраст составлял 67 лет для пациентов с ОЭПА и 65 лет для пациентов с КИК. Сравнительно более высокий процент среди пациентов приходился на лиц мужского пола и в обеих группах (79.25%, $P < 0.0001$). У большинства пациентов и в обеих группах было минимум среднее образование ($P < 0.0001$). Большинство субъектов и в обеих группах являлись курящими (> 71.30%) без различий между группами ($P = 0.566$). Не установлено значительных различий между группами в отношении сопутствующих заболеваний (диабет, артериальная гипертония, ишемия миокарда, нарушения ритма, $P > 0.05$). Установлено большее количество пациентов с КИК с наднорменным весом по сравнению с пациентами с наднорменным весом и ОЭПА ($P = 0.0004$). Были установлены высокое содержание холестерина в сыворотке (>200 mg/dL) и триглицеридов (>150 mg/dL) в группе КИК ($P < 0.05$). Возраст был определён как фактор риска для ампутации (OR = 1.03, 95%CI [1.01–1.05], $P = 0.0012$).

Заключение: Профиль пациента с критической ишемией конечностей и с облитерирующим эндартериитом периферических артерий включает 65-67 летних лиц мужского пола, курящих, с образованием не ниже среднего. У пациента с КИК наднорменный вес и патологические уровни холестерина и триглицеридов.