

VILNIUS UNIVERSITY

SAULIUS SUDIKAS

TREATMENT OF ILIAC AND FEMORAL ARTERY ATHEROSCLEROTIC
LESIONS BY COMPOUND ENDOVASCULAR AND OPEN SURGERY METHODS.
EVALUATION OF RESULTS

Summary of doctoral dissertation
Biomedical sciences, Medicine (06 B)

Vilnius 2012

The Study was carried out at Vilnius University during 2008 – 2012.

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The Summary of the Doctoral Dissertation was mailed on September 14, 2012.

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VILNIAUS UNIVERSITETAS

SAULIUS SUDIKAS

KLUBO IR ŠLAUNIES ARTERIJOS ATEROSKLEROZINIŲ PAŽEIDIMŲ
GYDYMAS MIŠRIU ENDOVASKULINĖS IR ATVIROSIOS CHIRURGIJOS
METODU. REZULTATŲ ĮVERTINIMAS

Daktaro disertacijos santrauka
Biomedicinos mokslai, medicina (06 B)

Vilnius, 2012

Disertacija rengta 2008–2012 metais Vilniaus universitete

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Disertacija bus ginama viešame Medicinos mokslo krypties tarybos posėdyje 2012 m. spalio mėn. 17 d. 14 val. Vilniaus miesto klinikinės ligoninės Didžiojoje auditorijoje.

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Disertacijos santrauka išsiuntinėta 2012 m. rugsėjo mėn. 14 d.

Disertaciją galima peržiūrėti Vilniaus universiteto bibliotekoje.

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Abbreviations

ABI	–	ankle-brachial index
CLI	–	critical limb ischemia
COPD	–	chronic obstructive pulmonary disease
PAD	–	peripheral artery disease
PTA	–	percutaneous transluminal angioplasty

1. INTRODUCTION

1.1. Scientific problem

Nowadays, the incidence of peripheral arterial diseases is increasing constantly. The age of the patients who undergo vascular reconstructive operations is increasing. It is obviously demonstrated that the risk of open surgery is much higher for patients who are older than 70 years, in comparison with the younger ones. Therefore, open reconstructive surgery is increasingly replaced by endovascular interventions. A lot of large studies have been performed, in order to assess the efficacy of endovascular procedures. The results of these studies have shown that the indications for PTA and implantation of a stent for a certain segment of patients may be wider than these determined in TASC 2007 guidelines. Therefore, new recommendations were issued (TASC 2010) with the newly formulated indications for endovascular operations. Since 2012, the articles containing criticism of these guidelines are being published; the main point of criticism includes the allegation that the guidelines are insufficiently based on the clinical trials. As the matter of fact, some factors influencing the outcomes of endovascular surgery, especially the patency of the artery, were omitted or underestimated while creating the guidelines. Therefore, we tried to evaluate not only the influence of local stenosis or occlusion that may be corrected by means of endovascular approach, but the influence of pathology of other distal arteries, also. The other aim of the research in our study was to evaluate the ability of the iliac artery PTA to reduce the lower extremity ischemia by itself. This raises another problem that has to be solved – what criteria are to be used, in order to determine whether an additional surgical or endovascular procedure is required to improve peripheral blood circulation further and avoid progression of ischemia. So, our study, performed using optimal selection of clinical material, resulted in correction of indications for endovascular surgery of the iliac artery in accordance with other factors, including peripheral artery pathology, stage of leg ischemia and risk factors of atherosclerosis assessed clinically.

1.2. General Aim of the Thesis

To evaluate efficacy of percutaneous transluminal angioplasty in reduction of the lower limb ischemia and to investigate the influence of this procedure on the lower limb salvage rate.

1.3. Specific aims

1. To assess the criteria for evaluation of efficacy of the iliac artery PTA.
2. To evaluate the results of early post-operative period after the iliac artery PTA (1–7 days after PTA).
3. To evaluate long-term results of PTA (1, 3, 6 months and 1 year after the operation) in accordance with limb salvage rate.
4. To determine the prognostic factors of the successful iliac artery PTA.
5. To evaluate the dependence of successful PTA on the degree of generalization of atherosclerosis in other parts of cardiovascular system.
6. To evaluate the incidence of risk factors of atherosclerosis, including smoking, arterial hypertension and diabetes mellitus.

1.4. Work Originality and Significance

According to the recent literature the indications for the iliac artery PTA are based on the anatomy of the pathologic process of these arteries the length and the localization of the damaged segment playing the most significant role. Recommendations presented in the International Consensus TASC II 2007 and validated by comprehensive multicentral studies give a complete characteristic of the iliac artery pathology which can be treated by the method of PTA or stenting with very high patency rate. Unfortunately, very important clinical and anatomical conditions are missing as factors influencing the results of the procedure. These are as follow: the stage of the lower limb ischemia, general morbidity, risc factors of atherosclerosis, changes of the ankle-brachial index.

And what is more, the impact of the occlusive disease in the below inguinal and below-knee arteries on the results of the procedures is outlined rather scaresly.

Therefore this work gives an analysis of the least investigated factors which supposedly can determine the effectiveness of the transluminal angioplasty or stenting of the iliac artery.. The influence of the deep femoral artery occlusion as well as impact of stenosing and occlusive process of the superficial femoral, the popliteal and crural arteries on the results of the iliac artery PTA were investigated. The influence of other localizations of atherosclerotic disease and atherosclerosis risk factors on the results of the iliac artery PTA was also taken into consideration. The prognostic criteria for the longevity of the peripheral circulation improvement and the probability of saving the lower limb were clarified.

1.5. Statements defended

- PTA of the iliac artery improves blood circulation of the lower extremity and reduces symptoms of chronic limb ischemia.
- The effectiveness of angioplasty of the iliac artery depends on the type and localization of atherosclerotic lesion of the artery. Arterial hypertension is one of prognostic factors.
- The angioplasty of the iliac artery as self-sufficient procedure alone or in combination with arterial reconstructive or endovascular operation saves the limb for many patients suffering from rest pain or gangrene.

2. MATERIAL AND METHODS

The study has been carried out in the Center of Vascular surgery of the Clinic of Heart and Vascular Diseases (Faculty of Medicine, Vilnius University) at Vilnius University City Hospital.

The study included patients who underwent the treatment of the iliac artery percutaneous transluminal angioplasty at the 1st and 2nd Departments of Vascular Surgery of Vilnius University City Hospital since 01–09–2009 till 31–10–2010. The study did not include the patients treated with stenting method.

The data were collected from 01–09–2009 to 31–10–2011.

Patients

The first stage of the investigation included the examination of the patients who later underwent angioplasty of the iliac artery.

Patient demographics, risk factors, arterial blood flow of the lower limbs, concomitant pathology, blood tests, electrocardiograms, ankle-brachial index, angiographical data and results, complications after PTA, information about additional operations during the short-term period (up to 7 days after angioplasty) were analyzed.

The study included the patients who underwent angioplasty of the common or/and external iliac artery stenosis (>50%) and for whom the restoration of the lumen was confirmed by means of angiography. The study did not include the patients treated with stenting method. For 33 patients PTA of the common iliac artery was performed, 91 patients underwent PTA of the external iliac artery and 22 patients had PTA of the common and external iliac arteries.

The short-term results were evaluated analyzing the clinical investigation, laboratory and imaging data obtained in the early post-PTA period covering the time from admission to up to 7 days after angioplasty.

For investigation of the long-term outcome letters have been sent (or contacted by phone) to all discharged and still not operated patients or their families asking for information about the fate of patients or inviting them to visit a vascular surgeon at

Vilnius University City Hospital. In case of patient's death the information regarding the cause of death was received. In total, the data of all 146 patients were available.

Patients, for whom additional interventions were not performed, were invited to visit a vascular surgeon or the data were collected by phone at 1, 3, 6 and 12 months after the PTA. From the responses received we found that 4 patients had died. The causes of death were ascertained on the background of the information provided by the Department of Statistics using ICD–10. The cause of death of certain patients was available from the documents presented by relatives.

The condition of all patients who presented for examination at the Center was evaluated by one specialist. In 86 (58.9 %) patients who presented for examination at the Center of Vascular Surgery the clinical evaluation was performed by history, symptoms and signs, measurement of the peripheral arterial blood flow, ankle-brachial index, the change in risk factors (smoking, arterial hypertension). Comorbidities and other localizations of atherosclerotic occlusive arterial disease were assessed. The causes of death were ascertained on the background of the information provided by the Department of Statistics using ICD–10. The cause of death of certain patients was available from the documents presented by relatives.

The data on vascular operations performed in the late postoperative period because of lower limb ischemia were also obtained from electronic database of the Center of Vascular Surgery.

The inclusion date for each patient was considered a date of angioplasty, the end of the observation – the first an additional intervention, one year after the PTA or the date of death.

While analyzing the data in the short-term postoperative period, patients were divided into two groups: 1. patients who underwent iliac PTA and no further interventions during 12 months of observation were performed; 2. patients who underwent iliac PTA and had additional intervention.

A general patients' condition was evaluated according to a history, physical examination findings and test results and concomitant cardiovascular and other pathology such as coronary heart disease, stroke, diabetes, renal disorders and arterial hypertension. Smoking habit was clarified from the history. Concomitant cardiac pathology and postoperative complications were evaluated in scores according to Detsky modified

cardiac risk index. Detsky score is designed for operative risk assessment. The sum of the scores shows the degree of postoperative complications' risk (Table 1, 2).

According to the criteria of World Health Organization arterial hypertension is diagnosed if the systolic blood pressure is ≥ 140 mm Hg and the diastolic blood pressure equals ≥ 90 mm Hg.

The renal function was assessed by K⁺ (3.5 to 5.1 mmol/l), urea (up to 65 years – 1.73–8.3 mmol/l, and > 65 years of age – <11.9 mmol/l) and creatinine (women 44–80 μ mol/l, men 62–106 μ mol/l) levels in the blood.

Diagnosis of diabetes mellitus was established on the background of history. In all patients diabetes had been diagnosed previously. All patients had type II diabetes mellitus.

Risk factors	Points
1. Age older than 70 years	5
2. History of myocardial infarction:	
Last infarction within 6 month	10
Last infarction more than 6 month ago	5
3. Unstable angina within last 6 month	10
4. Angina pectoris:	
Canadian angina class 3	10
Canadian angina class 4	20
5. Alveolar pulmonary edema:	
Pulmonary edema within one week	10
Pulmonary edema at any time	5
6. Suspected critical aortic stenosis	20
7. Arrhythmia	5
8. Emergency surgery	10
Data interpretation	
0–15 points – Class 1, low risk	
20–30 points – Class 2, moderate risk	
>30 points – Class 3, high risk	

Table 1 . Modified Detsky cardiac risk index factors, their values and interpretation

For every patient angiography was performed and evaluated by two experienced radiologists. The evaluation included identification of narrowing site and measurement of the stenosis length. Inflow (aorta and iliac arteries) and outflow (the femoral, popliteal, and tibial artery) were evaluated, also. In all cases the iliac artery stenosis before PTA was $> 50\%$.

Outflow was evaluated by preoperative femoral, popliteal, and tibial artery angiography image. The femoral and popliteal arteries were evaluated in accordance with the recommendations set out in the TASC. Obstruction of the deep femoral artery and tibial arteries was also evaluated.

Statistics

Discrete nominal variables were analyzed in 2xk and 2x2 tables, the difference between variables in table rows and columns was assessed using Pearson's χ^2 test or Fisher's exact test. For independent groups analysis of quantitative data Student's t test was used. The chosen level of significance was $\alpha = 0.05$, the statistical significance of differences was considered when error possibility was $p < 0.05$.

All averages were represented with standard deviation (SD).

Multivariate analysis with binary logistic regression was performed. The overall pattern of statistical significance was assessed with reference to coefficient of determination (Nagelkerke R Square).

In logistic regression models the impact of various factors is assessed in the odds ratio (OR), its statistical significance is assessed using the OR 95 % confidence intervals (CI). The data were processed using Microsoft Office Excel 2007, and statistical data processing program SPSS 17.0 (2008).

3. RESULTS

3.1. Patients' assessment by age and gender

The total of 146 iliac PTA included 131 (87.9 %) male and 15 (12.1 %) female patients. Male and female ratio was 8.7:1. The mean age of the patients was 70.1 ± 9.9 years. The mean age of female patients was 80.4 ± 7.45 , whereas the mean age of males was 69.2 ± 9.7 ($p > 0.05$).

The women in the group of additional intervention were found to be significantly older than men ($p < 0.05$).

3.2. Patient assessment by Detsky and risk factors

The evaluation of risk by Detsky showed that the difference on average risk score between women and men was insignificant. Male as compared with female had more comorbidities, but the difference was insignificant. Mean Detsky score was 10.7 ± 9.7 . The median Detsky score in additional intervention group was less than the same of sufficient angioplasty group (9.4 ± 9.3 and 12.8 ± 10.7 , respectively). The the difference was statistically significant ($p < 0.05$) but both of these values are considered to indicate a small risk by Detsky. Late postoperative mortality rate depended on the Detsky score.

The rate of concomitant mortality is shown in Table 1. The difference of Detsky risk index factors and other cardiovascular diseases (i.e. history of stroke, ischemic heart disease, coronary by-pass grafting, atrial fibrillation or other rhythm disturbances) between the groups of sufficient angioplasty and additional interventions was insignificant.

Chronic renal insufficiency was diagnosed in 5 cases (3.4 %): 3 in additional intervention and 2 in sufficient angioplasty group. The difference was insignificant ($p > 0.05$). No patients needed dialysis.

Fourteen participants of the study (9.6%) suffered from diabetes mellitus 9.6% (additional intervention group 11.4%, sufficient angioplasty group, 6.9%, $p > 0.05$). All

patients had type II diabetes mellitus. Diabetes mellitus had no significant effect on mortality, the prevalence of this factor in both groups was similar.

COPD did not significantly influenced the need of additional procedures ($p>0.05$). The prevalence of COPD was significantly higher in male as compared to female ($p<0.05$).

In our study, 24 (16.4%) patients had the history of a stroke (13 in additional intervention group and 11 in sufficient angioplasty group). The incidence of former stroke was higher in sufficient angioplasty group (19,0 % vs. 14,8 %), but the difference was not statistically significant ($p> 0.05$).

Hypertension

Arterial hypertension (with ECG confirmed hypertrophy of the left ventricle) had a significant influence on a need of additional procedures ($p<0.05$). Arterial hypertension and left ventricular hypertrophy were detected in 91% of the cases (85.4% in sufficient angioplasty group and 95.5% in the additional intervention group, $p <0.05$). This difference is statistically significant. All the female participants of the study (100%) suffered from arterial hypertension and left ventricle hypertrophy. The incidence of arterial hypertension in male patients was higher in the group of additional intervention as compared with the group of sufficient angioplasty (95.1 % vs. 82.0 %, respectively; $p <0.05$).

Smoking

The overall smoking rate among the participants of our study was 73.9% (additional intervention group 76.1%, sufficient angioplasty group, 70.7%), $p>0.05$). This difference was not statistically significant ($p>0.05$). The prevalence of smoking in both group was significantly higher in male as compared to female ($p<0.05$).

Factor	Number of patients	%	p value
<i>Addition intervention/ sufficient angioplasty group</i>			
Smoking	67 41	76,1 70,7	0,46298
Coronary heart disease	83 54	94,3 93,1	0,76522
History of myocardial infarction	16 17	18,2 29,3	0,11568
Coronary artery bypass graft surgery	5 8	5,7 13,8	0,09220
Arterial hypertension with hypertrophy of the left ventricle	84 49	95,5 84,5	0,02274
History of stroke	13 11	14,8 19,0	0,50357
Diabetes mellitus	10 4	11,4 6,9	0,36971
Heart rhythm disturbances	21 14	23,9 24,1	0,96970
Chronic obstructive pulmonary disease	32 25	36,4 43,1	0,41401
Chronic renal insufficiency	3 2	3,4 3,4	0,98984

Table 1. Evaluation of other diseases and risk factors

3.3 Hospital stay

The mean hospital stay in sufficient PTA group was 7.1 ± 3.7 days, whereas in the group of additional interventions the mean hospital stay was 12.3 ± 6.7 days ($p < 0.05$). In event of intermittent claudication or rest pain, the average hospital stay after PTA was

4.5 ± 2.3 days. In event of gangrenous ulcer stage, hospitalization lasted longer – until the effect of PTA was confirmed (mean 9.1 ± 4.5 days).

3.4. Type of iliac obstructive disease

In all the cases analyzed, the angiography performed after angioplasty showed the restoration of artery lumen (stenosis of the iliac artery before PTA in all patients was > 50%). PTA of the common iliac artery (CIA) was performed for 33 (20.6 %) patients, 91 (58.9 %) patients underwent PTA of the external iliac artery (EIA) and 22 (15.1 %) patients had PTA of the common and external iliac arteries (Figure 1). The incidence of the lesion of the left and right iliac arteries was quite similar (50.7 % and 49.3 %, respectively).

In all groups, male and female distribution was similar. The comparison of anatomical lesion localization in age groups together, as well as in men and women groups separately in the same or in the different age groups, showed no significant difference ($p>0.05$).

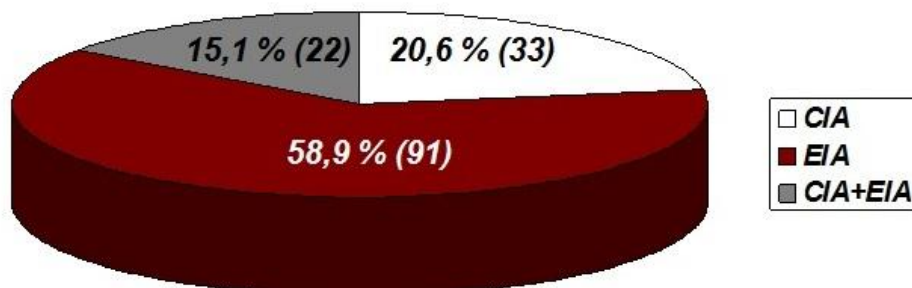


Figure 1. Distribution of affected iliac arteries

Length of iliac obstructive disease

According to the length of the artery obstructed, a number of angioplasty balloons were used. Six millimeters and shorter angioplasty balloons were used in 88 (60.3 %) cases, 8mm and longer were used in 58 (39.7 %) cases ($p=0.00045$). The evaluation of the length and localization of the stenosis of iliac artery showed no statistically significant differences between the age groups and between male and female patients ($p>0.05$).

Although the 6 mm and shorter stenosis was more common, the length of the iliac artery stenosis had no significant impact on the long term PTA results. In assessing the length of the stenosis, the difference in both groups was insignificant ($p>0.05$) (Table 2).

Length of stenosis	≤6 mm	≥8 mm	p value
Additional intervention	52 (59.1 %)	36 (40.9 %)	>0,5
Sufficient PTA	37 (63.8 %)	21 (36.2 %)	>0,5

Table 2. Distribution of the length of the stenosis in the sufficient angioplasty and additional intervention groups

3.5. Evaluation of the early and long-term results of the iliac artery angioplasty

PTA after 7 days, 1, 3, 6 and 12 months was sufficient, respectively, in 86 (58.9%), 78 (53.4 %), 71 (48.6 %), 66 (45.2 %) and 58 (39.7 %) of the patients: a pattern of variables by gradual function shows a significant gradual dependence on time and the number of patients ($p = 0.000826$) (Figure 2, 3). The comparison of the result in age groups together, as well as in men and women groups separately in the same or in the different age groups, showed no significant difference ($p>0.05$).

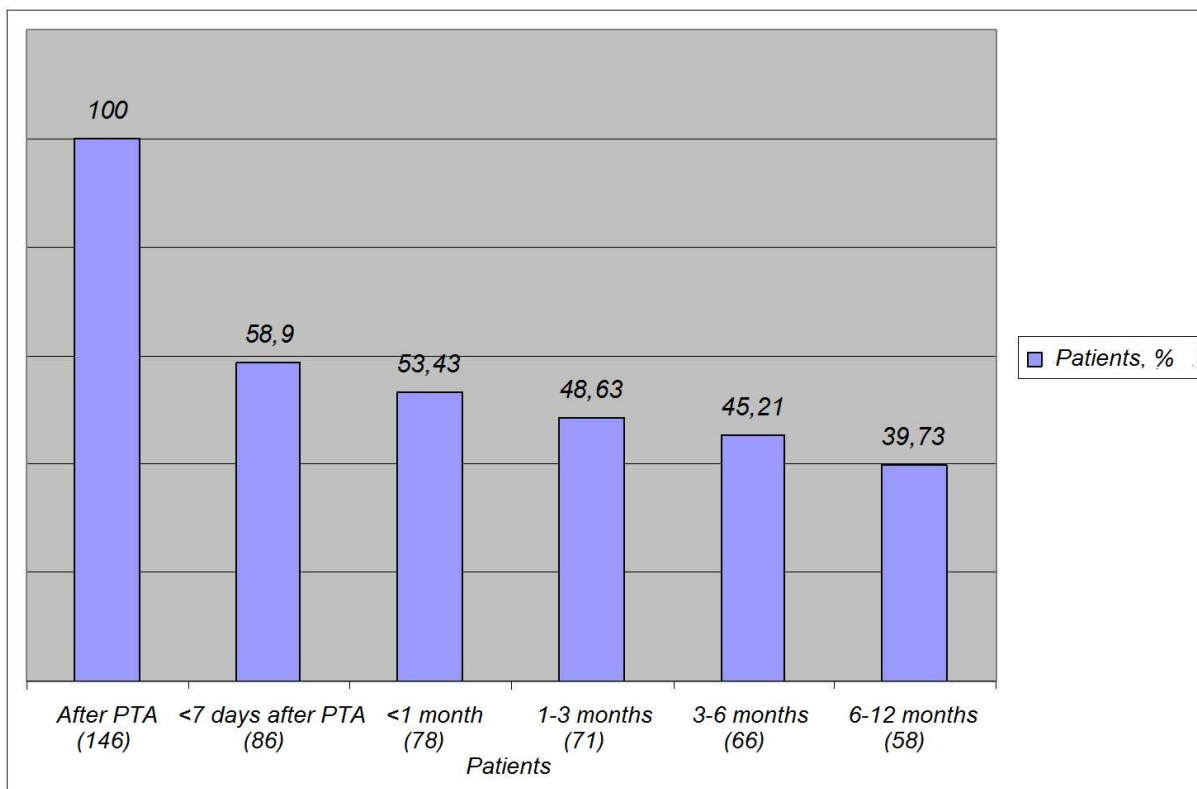


Figure 2. Decline of the patients with sufficient PTA over time

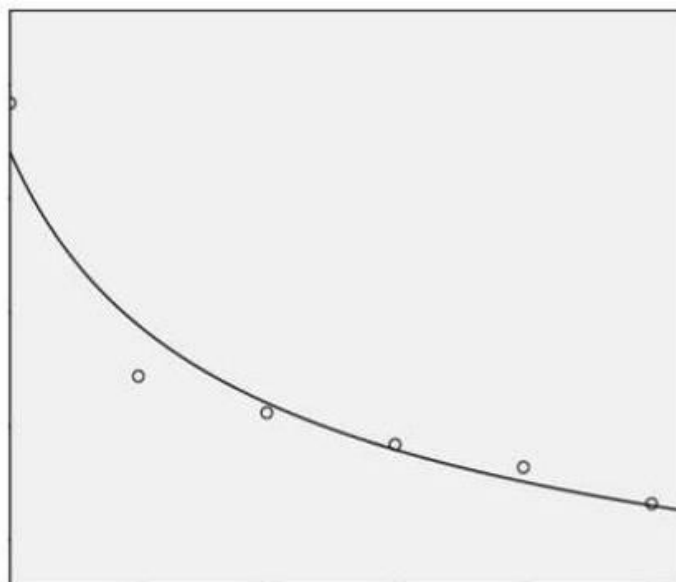


Figure 3. Significant gradual dependence on time and the number of patients
($p = 0.000826$)

Additional operations

Since the 1st of September, 2009 till the 31st of October 2010, 146 patients underwent the iliac artery percutaneous transluminal angioplasty. During the one-year follow – up after PTA, 58 patients needed no additional interventions. For the remaining 88 patients an additional intervention to improve arterial blood flow was performed. Most common operation was a by-pass (53 (60.2%)), less frequently the femoral artery endarterectomy and PTA were performed (Table 3). The evaluation of distribution of additional operations regarding age or gender, showed no significant differences ($p>0.05$). The gangrenous damage and infeasible reconstructive operation below the inguinal ligament resulted in primary amputation in eight patients (in six patients the amputations were performed during the same hospitalization) (Table 4). Most of the operations were performed during the same hospitalization. Further distribution of the operations was similar.

Additional operation	Number of patients
Bypass	53 (60.2 %)
Endarterectomy	14 (15.9 %)
PTA	13 (14.8 %)
Amputation	8 (9.1 %)
Total:	88

Table 3. Additional operations

	The same hospitalization	<1 month	1–3 months	3–6 months	6–12 months	Total
Bypass	40	4	4	1	4	53
Endarterectomy	12	0	1	1	0	14
PTA	2	3	1	3	4	13
Amputation	6	1	1	0	0	8
Total	60	8	7	5	8	88

Table 4. Additional operations over time

3.6. Anatomical aspects – lesions of the femoro–popliteal arteries according to the TASC

The femoral and popliteal artery were evaluated in accordance with TASC guidelines. In the sufficient angioplasty group mostly TASC A (32.8 %) and B (27.6 %) lesions of femoro–popliteal artery were observed – 60.3 per cent of patients in total. In additional intervention group femoro–popliteal lesion of TASC A and B types was detected in 39.8 per cent of the patients (14.8 % TASC A and 25.0 %, respectively). This distribution of TASC A and B femoro–popliteal lesion types in both groups showed significant difference ($p = 0.01490$). In sufficient angioplasty group fewer patient had TASC C (29.3 %) and TASC D (10.3 %) lesion types in the femoro–popliteal segment compared with 36.4 % TASC C and 23,9 % TASC D lesion in additional intervention group. Difference of distribution of TASC C and D lesion types in sufficient angioplasty group (39.7 %) vs. additional intervention group (60.2 %) was statistically significant ($p = 0,01490$) (Table 5). The comparison of impairment of the femoral and popliteal arteries regarding age and gender, while evaluating general results and the results in the groups of additional intervention and sufficient angioplasty, showed no statistically significant difference ($p>0.05$).

TASC lesion type <i>Addition intervention/ sufficient angioplasty group</i>	Number of patients	%	p value
A+B	35	39,8	<0,05
	35	60,3	
C+D	53	60,2	<0,05
	23	39,7	

Table 5. Distribution of lesions of femoro–popliteal arteries according to the TASC

3.7. Anatomical aspects – importance of the deep femoral artery

The occlusion of the deep femoral artery (above the first branches) was found in seven patients. All of them (100%) needed additional surgery in order to ensure arterial blood flow of the extremity – this represents 8.0 % of all patients who needed additional intervention. In the group of sufficient PTA the deep femoral artery was not occluded for all 58 patients. Thus the need for supplementary interventions was directly dependent on the deep femoral artery occlusion ($p < 0.05$). The occlusion of the deep femoral artery and the need of additional operations did not depend either on the ischemic stage by Fontaine, or concomitant lesion of the superficial femoral artery according TASC ($p > 0.05$). The occlusion of the deep femoral artery may also be used as prognostic indicator: even though 2 patients complained only of intermittent claudication, ischemia progressed so rapidly that during 12 months they also needed an additional operation (Table 6).

Fontaine stage of ischemia	Number of patients	p value
II b	2	>0.05
III	1	>0.05
IV a	1	>0.05
IV b	3	>0.05
Lesions of femoro–popliteal arteries		
TASC B	2	>0.05
TASC C	3	>0.05
TASC D	2	>0.05

Table 6. Occluded deep femoral artery and the ischemic stage by Fontaine and lesions of femoro–popliteal arteries according to the TASC

Hemodynamically significant stenosis of the deep femoral artery in the same segment was detected in 6 patients (10.3 %) in sufficient PTA group and in 6 patients (6.8 %) in the additional intervention group and showed no significant difference ($p>0.05$). The comparison of the deep femoral artery lesions regarding age and gender, showed no significant difference ($p>0.05$).

3.8. Anatomical aspects – lesion of crural arteries

We have evaluated the patency of the anterior tibial artery, tibio-peroneal trunk, posterior tibial and peroneal arteries. All tibial arteries were patent more frequently in sufficient angioplasty group, when compared with the additional intervention group (18.4% vs. 6.5%, respectively, $p < 0.05$) (Table 107oz). The incidence of occlusion of three and four tibial arteries was higher in the group of additional intervention, when compared with sufficient angioplasty group (24.7% and 10.2%, respectively, $p < 0.05$). The difference found while assessing occlusion of one and two tibial arteries was not statistically significant ($p>0.05$) (Table 7).

The difference in assessing one or two tibial artery occlusion and the need of additional intervention was not statistically significant ($p > 0.05$).

Tibial arteries <i>Addition intervention/ sufficient angioplasty group</i>	Number of patients	%	p value
All patent	5	6,5	<0.05
	9	18,4	
1 occluded	25	32,5	>0.05
	19	38,8	
2 occluded	29	37,7	>0.05
	15	30,6	
3 or 4 occluded	19	27,7	<0.05
	5	10,2	

Table 7. Lesion of crural arteries

3.9. Patient distribution according to Fontaine stages of ischemia

The grade of ischemia of the lower extremity was evaluated by Fontaine classification. In the group of sufficient angioplasty the majority of the patients (24; 41.4 %) suffered from intermittent claudication (ischemic stage II by Fontaine), while in the additional intervention group claudication as a main complaint was less frequent. (22; 25,0 %). This difference was statistically significant ($p = 0,03709$). The rate of patients who complained of rest pain (ischemic stage III by Fontaine) in both groups was similar (23; 39.7 % in sufficient angioplasty group vs. 36; 40.9 %) and showed no significant difference ($p > 0.05$). Significantly more patients in the additional intervention group (30; 34.1 %) complained of the non-healing ulcers or gangrenous changes (ischemic stage IV by Fontaine) compared with sufficient angioplasty group (11; 19.0 %; $p = 0,04659$). Critical limb ischemia (ischemic stages III and IV by Fontaine) was more often found in additional intervention group compared with the sufficient angioplasty group (66; 75.0 % vs. 34; 58.6 %, respectively). This difference was statistically significant ($p = 0,03709$) (Table 8). The comparison of patient distribution according to Fontaine stages of ischemia in age groups together, as well as in men and women groups separately in the same or in the different age groups, showed no significant difference ($p > 0.05$).

Fontaine stage of ischemia	Number of patients	%	p value
<i>Addition intervention/ sufficient angioplasty group</i>			
II (a+b)	22	25,0	<0.05
	24	41,4	
III+IV	66	75,0	<0.05
	34	58,6	
IV (a+b)	30	34,1	<0.05
	11	19,0	

Table 8. Patient distribution according to Fontaine stages of ischemia

3.10. The change of ankle-brachial index

Our study showed that the mean ankle-brachial index before iliac angioplasty was 0.41 ± 0.14 , it increased after the intervention on average by 0.64 ± 0.13 . The mean ankle-brachial index was lower in critical ischemia compared with claudication ($p < 0,05$). No significant differences in the same ischemia stages by Fontaine in additional intervention and sufficient angioplasty group were detected. In sufficient angioplasty group, the ABI increase by ≥ 0.15 after PTA of iliac artery was detected more frequently than in additional intervention group ($p < 0.05$).

We also have found important data regarding the change in foot arterial pressure in patients with 4th ischemia stage according to Fontaine. In the subgroup of patients who had amputation free survival after iliac angioplasty the increase of the foot arterial blood pressure by 30 mmHg or more was detected. The significance of this factor is very close to the statistical reliability.

4. DISCUSSION

4.1. Additional interventions after iliac artery PTA and stage of ischemia

For a long time atherosclerotic iliac artery stenosis or occlusion was mainly associated only with intermittent claudication. The first article, stating that the iliac artery impairment is related primarily to claudication, was published in 1952 (Kekwick A 1952). It may seem strange, but even after 60 years the approach remains similar. The study analyzing the patients suffering from intermittent claudication and obstruction of the iliac and femoral arteries was conducted in 2012 (Ichihashi S 2012). Study reported that in 87% of the cases the angioplasty of the iliac artery prolonged walking distance, so the reconstruction of the occluded femoral artery was not imminent. But the researchers stressed that the results should not be applied for the patients with critical limb ischemia. The treatment using only the angioplasty of iliac artery when critical limb ischemia is present will not be effective without distal reconstruction. So the researchers did not even include these patients in the study.

The fact that the iliac artery angioplasty is effective particularly during the stage of claudication is stated in recent multicenter study (Frans FA 2012). The benefit of angioplasty of the iliac artery in critical limb ischemia is ignored. Sometimes, the studies, analyzing both claudication and critical limb ischemia groups are even criticized as a non-homogeneous; iliac artery angioplasty without additional interventions must be limited to the patients with intermittent claudication (Maurel B 2009).

As our study has shown, less than one-third of patients complained of claudication (31.5%), while the majority of patients – 68.5% – had critical limb ischemia (rest pain, 40.4%, ischemic ulcers and / or tissue loss, 28.1 %). However, clinical improvement during the same hospitalization after iliac angioplasty (without additional interventions) was 58.9%, and after 1 year – 39.7%. This result is much better than in the group of patients suffering from claudication. Bearing in mind that in patients with claudication the ischemia has progressed during 12 months and they also had to undergo surgery. In the group of sufficient PTA, only 41.4% of patients complained of claudication, remaining 58.6% had critical limb ischemia (19.0% ischemic ulcers and/or tissue loss), but after angioplasty of iliac artery, improvement of the blood flow made it possible to avoid additional interventions during 12 months.

Primary patency and success of the iliac artery angioplasty may depend on the condition of outflow (Sixt S 2008, Greiner A 2003). The fact that PTA of the iliac artery may need additional open surgery or endovascular interventions such as the common femoral artery endarterectomy, femoro-popliteal bypass or angioplasty is stated in a number of clinical studies (Kashyap VS 2008, Hans SS 2008, Sharafuddin MJ 2008, Park KB 2007, Piffaretti G 2007, Balzer JO 2006, De Roeck A 2006, Domanin M 2005, Rzucidlo EM 2003, Nyman U 2000). In most cases additional interventions were performed shortly after the iliac PTA, sometimes during the next hospitalization (Balzer JO 2006).

There are no objective criteria (e.g., ankle-brachial index or outflow status) to predict the success or failure of PTA of the iliac arteries specifically.

The need for further intervention after the iliac artery PTA is not determined only by Fontaine stages. For example, in one study, immediate additional intervention after iliac angioplasty was performed for 30% of patients: most of them complained of claudication (50%), 25% had rest pain and 25% ulcer / gangrene (Kudo T 2005). Most common

additional intervention in the arteries below the inguinal ligament were endovascular procedures (24%), rarely – open surgery (6%). In another study after the iliac artery angioplasty additional intervention during the same hospitalization had to be performed for 21% of the patients (Kashyap VS 2008). 53% of them complained of claudication, the remaining 47% had critical limb ischemia (28% – ulcer / gangrene). Prevailing interventions were common femoral endarterectomy, less frequent – femoro–popliteal bypass. Additional interventions during the same hospitalization were performed in 37% of the patients who suffered from claudication (59%), rest pain (12%), ulcer / gangrene (29%) (Timaran CH 2003). The most common operation was femoropopliteal bypass (77%).

In our study, an additional intervention during the same hospitalization was performed in 41.1% of the patients. Their complaints included claudication(31.5%), rest pain (40.4%), ischemic ulcers and / or tissue loss (28.1%). Critical limb ischemia resulted in higher number of additional interventions. The most common additional intervention was bypass operation (68.2%).

The data from our study correspond to the results reported by the other authors (Rzucidlo EM 2003). In this study, iliac artery PTA has been limited to patients with critical limb ischemia: 65% of cases rest pain and 35% tissue loss. Critical limb ischemia resulted in higher number of additional interventions: arteries below the inguinal ligament were reconstructed in 53% of the patients. Predominant operation was common femoral artery endarterectomy.

In our study, the need of additional intervention after the iliac artery angioplasty increased from 41.1% during the same hospitalization to 46.6% during the first month and was gradually increasing during the follow–up period. In another studies additional interventions during late (more than 1 month after iliac PTA) follow–up are rarely evaluated (Timaran CH 2003). The researchers consider that additional interventions below the inguinal ligament are indicated only when no clinical effect is achieved by means of PTA of the iliac artery or, perhaps, when limb–threatening ischemia is present (Kudo T 2005, Timaran CH 2003).

Therefore, the need of additional interventions during the early period after the iliac artery PTA is highly determined by the stage of ischemia according to Fontaine.

However, one may not maintain that angioplasty for a patient suffering from claudication will be sufficient in all cases or that critical limb ischemia is an unquestioned indication for additional operation. There are other important factors to consider such as ankle-brachial index change or status of the femoral, popliteal, and tibial arteries.

During the 12 months of follow-up, restenosis of the iliac artery occurred in 3 cases (2.1 %). All these patients underwent additional operations of arteries below the inguinal ligament before the restenosis was diagnosed. In other patients (97.9%) the primary patency achieved by means of PTA was present throughout the follow-up. Additional outflow improving interventions were needed due to rapid progress of atherosclerosis in the femoral, popliteal or calf arteries. This progression such as occlusion at the site of previous stenosis or new stenotic lesion has always been found on repeated angiography. Patients' average age was 70.1 years. In elderly patients progression of the atherosclerosis is very fast. Within a year severe progression of ischemia can occur (Norgren L 2007). Epidemiological studies confirmed that the incidence of PAD depends on the age and the incidence is increasing particularly rapidly over the 70 years of age (Norgren L 2007, Selvin E 2004, Hiatt WR 1995, Criqui MH 1985). We found that during 1-year the progress of ischemia can be substantial and require additional interventions to ensure the limb blood flow.

4.2. Additional interventions after iliac artery PTA. The impairment of distal arteries

Factors influencing the results of angioplasty of the iliac artery is another item widely discussed in nowadays scientific literature. Such factors as TASC type, length of the stenosis and indications for stenting are analyzed in details. However, the condition of the outflow arteries is rarely examined. Several authors agree that the poor outflow can limit the effect of the iliac artery angioplasty (Ozkan U 2009, Balzer JO 2006, Kudo T 2005, Galaria II 2005, Timaran CH 2003, Bosch JL 1997, Khan W 1995). Some of the authors suggest that poor outflow can even be an independent negative factor (Timaran CH 2003, Bosch JL 1997). But there the consensus ends.

Anatomically outflow arteries after iliac angioplasty can be divided into two levels: femoro–popliteal and tibial. The impact of the femoro–popliteal artery on the iliac angioplasty has rarely been analyzed. According to some authors, the results of iliac angioplasty were better in the patients who had patent the superficial and deep femoral arteries (Galaria II 2005), and the superficial femoral artery occlusion had negative influence on outcomes (Balzer JO 2006, Khan W 1995). However, the data are inconsistent. Other authors argue that the superficial femoral artery stenosis > 50% leads to worse results of the iliac artery PTA, but complete occlusion of the artery has no influence (Kudo T 2006, Kudo T 2005, Jorgensen B 1992). Neither stenosis, nor occlusion localization, nor length of lesion of the superficial femoral artery are examined in details.

Our work includes a detailed assessment of atherosclerosis in the femoro–popliteal arteries for the patients who underwent the iliac artery angioplasty. Atherosclerotic lesion was evaluated using the latest trans–Atlantic TASC II recommendations, where femoral popliteal lesions were classified as A, B, C and D types (Norgren L 2007). In our study, we found no difference in the iliac artery stenosis type, length or localization between the groups of sufficient angioplasty and group of additional intervention. However, the lesions of the femoral artery varied significantly. Type A and B lesions prevailed in the group of sufficient angioplasty (60.3%), and type A lesions were the most common (32.8%, $p < 0.05$). Type C and D lesions prevailed in the group of additional intervention (60.2%, $p < 0.05$), and the incidence of D type lesions was higher (23.9%, $p < 0.05$). The lesions of C and D type include multiple or disseminated femoral artery stenosis or occlusion, therefore we suppose that the higher grade of the lesion of the femoral popliteal artery results in poorer outcome of this artery angioplasty and increased need of additional interventions.

The deep femoral artery is the main collateral artery of the lower extremity; however the evaluation of condition of this artery in case of the iliac artery lesion is uncommon. According to (Galaria II 2005), patent deep femoral artery improves the results of iliac angioplasty only if it is accompanied by a patent superficial femoral artery. According to other authors, the role of the deep femoral artery becomes especially evident when the superficial femoral artery is occluded: the results of angioplasty of the iliac artery may

be positive (reflected by decrease of ischemia stage) when the superficial femoral artery is occluded, but the deep femoral artery is patent (Khan W 1995). However, the data concerning this point are not uniform; some of the authors suppose that the condition of the deep femoral artery has no effect on efficacy of iliac angioplasty (Kudo T 2006). We found out that the occlusion of the deep femoral artery was an independent factor negatively influencing the results of angioplasty of the iliac artery. In the group of additional intervention 7 (8.0%) of the patients had occlusion of the deep femoral artery and in the group of sufficient angioplasty all the patients were free of occlusion of the deep femoral artery. Thus, the need for additional interventions was directly related to the deep femoral artery occlusion ($p < 0.05$). The occlusion of the deep femoral artery and the need of additional interventions did not depend either on concomitant lesion of the superficial femoral artery (according TASC), or the stage of ischemia (according Fontaine) ($p > 0.05$). The occlusion of the deep femoral artery may be considered as a prognostic factor: 2 out of 7 patients complained only of intermittent claudication, yet atherosclerosis and ischemia had progressed so rapidly that within 12 months they had to undergo an additional intervention.

The relationship between the efficacy of angioplasty of the iliac artery and the condition of the tibial arteries was discussed in one article (Galaria II 2005). According to the authors, two or more tibial patent arteries, both by themselves and in combination with two patent femoral arteries, improve patency of the iliac artery and efficacy of iliac angioplasty. We evaluated the patency of the anterior tibial artery, tibio-peroneal trunk, posterior tibial and peroneal arteries. All tibial arteries were patent more frequently in the group of sufficient angioplasty, when compared with the additional intervention group (18.4% vs. 6.5%, respectively, $p < 0.05$). The incidence of the occlusion of three and four tibial arteries was higher in the group of additional intervention (24.7% vs. 10.2%, respectively, $p < 0.05$). The difference in assessing one or two tibial artery occlusion and the need of additional intervention was not statistically significant ($p > 0.05$). We suggest that the condition of tibial arteries presents an independent factor that influences efficacy of iliac angioplasty, regardless of condition of the femoral arteries.

4.3. Additional interventions. PTA of the iliac artery and ankle-brachial index

In our study, the mean ankle-brachial index before the iliac artery angioplasty was 0.41 ± 0.14 ; after the intervention this index has increased on average by 0.64 ± 0.13 . The low initial overall index corresponds to the distribution of the patients according to the stages of ischemia: 100 patients (68.5%) in our study had critical limb ischemia and 46 (31.5%) suffered from claudication. Our findings correspond to the data of other authors: the higher number of the patients with claudication determines the higher ABI; the higher number of the patients suffering from critical ischemia of the limbs determines the lower ABI (Table 9). The overall mean change in ABI of 0.23 ± 0.13 is also comparable with other authors' results.

ABI before PTA	Claudication, %	ABI before PTA	ABI change	First author, year
0,30	0 % (only CLI)	$0,59 \pm 0,04$	$0,19 \pm 0,04$	(Rzucidlo EM 2003)
0,36	51 %	0,82	0,46	(Kashyap VS 2008)
0,51	88,8 %	$0,79 \pm 0,16$	$0,28 \pm 0,16$	(Balzer JO 2006)
0,54	59 %	no data	no data	(Timaran CH 2003)
$0,55 \pm 0,19$	>50 %	$0,63 \pm 0,19$	$0,08 \pm 0,19$	(Khan W 1995)
$0,55 \pm 0,22$	80 %	$0,82 \pm 0,21$	$0,27 \pm 0,21$	(Hans SS 2008)
0,56	80 %	0,91	0,35	(Nawaz S 1999)

Table 9. The ABI change after PTA of iliac artery and the frequency of claudication

We followed European Society for Vascular Surgery and TASC guidelines, stating that the change of ABI needs to be at least 0.15 to be considered as clinically significant (Becker F 2011, Norgren L 2007). In our study in sufficient angioplasty group the ABI increase of ≥ 0.15 was more frequently detected than in additional intervention group ($p < 0.05$). These results are consistent with literature data, indicating that the need of additional intervention and relapse/continuation of the symptoms are related to increase

of ABI for ≤ 0.10 (Kudo T 2005) and hemodynamic changes are considered as positive when ABI increases by >0.1 at rest (Nawaz S 1999, Rutherford RB 1997) or >0.15 (Becker F 2011, Norgren L 2007, Galaria II 2005).

We have also found an important finding regarding the change in foot arterial pressure in patients with 4th ischemia stage according to Fontaine. In this subgroup of patients who had amputation free survival after iliac angioplasty the increase of foot arterial blood pressure by 30 mmHg or more was detected. The significance of this factor is very close to the statistical reliability. Similar data could not be found in the literature.

4.4. Additional interventions after PTA of the iliac artery and atherosclerosis risk factors, overall morbidity

Arterial hypertension

The prevalence of arterial hypertension in patients with PAD varies and ranges from 60–70% in patients suffering from claudication to approximately 90% and more in patients who had a limb amputation (Hans SS 2008, Kashyap VS 2008, Balzer JO 2006, Galaria II 2005, Kudo T 2005, Abou-Zamzam AM 2003, Timaran CH 2003). In our study, arterial hypertension and left ventricular hypertrophy was detected in 91% of the cases (85.4% in sufficient angioplasty and 95.5% in the additional intervention group, $p < 0.05$). PAD in elderly progresses rapidly, and arterial hypertension further increases the risk (Norgren L 2007). The average age of participants of our study was 70.1 years.

It was found out that arterial hypertension can accelerate the development of atherosclerosis (Sumpio BE 2004). Under normal conditions, the walls of the veins are not affected by atherosclerotic process; however, the situation becomes quite different with the increase of blood pressure. For example, venous atherosclerosis occurs when the vein is used for bypass surgery: it is believed that this phenomenon takes place mainly due to an increase of blood pressure (Pomposelli FB 2005, Sumpio BE 2004).

Arterial hypertension may promote atherosclerosis directly by affecting the vessel wall structure and function (Mitchell ME 2005, Sumpio BE 2004). Higher blood pressure increases endothelial permeability, resulting in migration of macromolecules such as

lipoproteins to the intima. Arterial hypertension impairs endothelial function: it increases free oxygen radical production and decreases nitric oxide (NO) activity in cells (Luscher TF 1994, Panza JA 1990, Vallance P 1989). Endothelial dysfunction not only impairs the tonicity of the vessels, but, in long term, affects the vascular structure, also (Hiatt WR 2005).

Mechanical force changes smooth muscle cell function, thereby also promoting the progression of atherosclerosis (Sumpio BE 2004). Smooth muscle cells sustain cyclic blood pressure waves in the vessel wall. In the case of arterial hypertension, the pressure to the vessel wall is increasing. Increased pressure causes changes of smooth muscle cells form, distribution, proliferation and matrix production, resulting in developing atherosclerotic lesions. It is believed that hypertension also affects vessel wall remodeling by changing the balance between cell proliferation and apoptosis (Fleischmann D 2001, Xu C 2001).

Due to changes in the arterial wall elasticity decreases and increases the stiffness (Hausberg M 2005). This process is accelerated in elderly (Cheng KS 2002). When the arteries become rigid, or hard and can not expand, the additional burden falls on the left ventricle. As a result left ventricular hypertrophy develops – this is often the first sign of uncontrolled blood pressure (Kannel WB 2005, Palmieri V 2005).

In arterial hypertension peripheral vascular resistance increases (Schoen FJ 1994). Hypertension accelerates atherosclerosis development unequivocally, detrimental are both systolic and diastolic pressures (Schoen FJ 1994, Wilson PW 1994). The higher the pressure, the faster atherosclerosis develops (Mitchell ME 2005, Zarins CK 2005, Borghi C 2002, Lewington S 2002, Vasan RS 2001, Schoen FJ 1994). In older than 45 years of age arterial hypertension is a stronger risk factor than hypercholesterolemia (Schoen FJ 1994). It is known that arterial hypertension causes inhibition of regression and promotes the growth of atherosclerotic plaque even if blood cholesterol levels are reduced (Xu C 1991, Zarins CK 1980). Available evidence suggests that hypertension per se may play a key role in the formation and progression of atherosclerosis (Zarins CK 2005).

Arterial hypertension is associated with all cardiovascular diseases including peripheral arterial disease (Norgren L 2007). Arterial hypertension increases the incidence of intermittent claudication by 2.5 time in men and 3.9 time in women (Fowkes GR 1992, Kannel WB 1985). In our study arterial hypertension with left ventricular hypertrophy

was found in all female patients (100%). There was higher prevalence of arterial hypertension in men of the additional intervention group compared with additional angioplasty group (95.1 % and 82.0 %, respectively; $p < 0.05$). The results confirmed that the influence of hypertension in men with advanced PAD is lower. For the people from 40 to 70 years each increase in systolic blood pressure of 20 mmHg or diastolic 10 mmHg doubles the cardiovascular risk (The JNC 7 report 2003). However, the relative risk of developing PAD for hypertension is less than for diabetes or smoking (Norgren L 2007). Hypertension is considered to be a major risk factor for PAD (The JNC 7 report 2003). However, available data do not state that an effective control of blood pressure will change the progression of PAD. There is a lack of data about the lower blood pressure influence to the course and prognosis of PAD (Singer DRJ 2008). Our study showed that better control of hypertension and absence of the left ventricular hypertrophy were directly related to better long-term results of iliac angioplasty.

However, other studies do not tend to overestimate the role of arterial hypertension in PAD. It is suggested that arterial hypertension has minimum influence on the change of arterial diameter (Paivansalo MJ 2000). It is noted that the anatomical localization of atherosclerosis in patients with PAD depends on the risk factors (Haltmayer M 2001). Lesion of aorto-iliac arteries and tibial arteries are characteristic to specific risk factors, while the femoral-popliteal segment is considered to be a transitional zone (Haltmayer M 2001). Smoking is associated with the development of atherosclerosis in the proximal segment of artery, diabetes mellitus in the distal segment of the arteries (Ozkan U 2009, Haltmayer M 2001), older age – with the femoral-popliteal disease or multilevel lesion (Ozkan U 2009, Soor GS 2008). Studies examining the risk factors of atherosclerosis development mention arterial hypertension only as one of the many secondary indicators. It is supposed that there is no relationship between hypertension and the progression of iliac artery stenosis to occlusion (Ferrari FB 2004).

Smoking

In our study the overall rate of smokers was 73.9% (additional intervention group 76.1%, sufficient angioplasty group, 70.7%, $p > 0.05$). Although smoking is a major risk factor for development of atherosclerosis, we couldn't determine its influence on the efficacy of iliac artery angioplasty. In both groups smoking prevalence was high, and the difference of quitting was statistically insignificant. The incidence of smoking in the iliac artery angioplasty ranges from 41% to 81% (Hans SS 2008, Balzer JO 2006, Kropman RHJ 2006, Kudo T 2005, Rzucidlo EM 2003, Timaran CH 2003, Nawaz S 1999). Difference between sufficient angioplasty and additional intervention groups were also not found (Timaran CH 2003).

Diabetes mellitus

In our study, the overall rate of diabetes mellitus was 9.6% (additional intervention group 11.4%, sufficient angioplasty group 6.9%, $p > 0.05$). The fact that diabetes is a relatively small risk factor for iliac artery atherosclerosis is supported by other studies in which the frequency of diabetes ranged from 9% to 28% (Hans SS 2008, Kashyap VS 2008, Balzer JO 2006, Galaria II 2005, Nawaz S 1999). It should be noted that the higher incidence of renal failure or hemodialysis depends on the higher rate of diabetes mellitus. In our study, 3.4% of the patients suffered from renal insufficiency.

Comorbidity

We failed to find the studies comparing the efficacy of angioplasty of the iliac artery and cardiovascular risk according to Detsky's Modified Cardiac Risk Index. The studies usually evaluate the role of certain cardiovascular or other concomitant disease, paying no attention to general morbidity of the patient. In our study, the median Detsky score in additional intervention group was lower than in the group of sufficient angioplasty (9.3 vs. 12.7, respectively), but the difference was not statistically significant ($p > 0.05$) and

both of these scores indicate the 1st class or low risk group according to Detsky. Therefore, we suggest that general morbidity caused by concomitant diseases (coronary heart disease, history of stroke, chronic obstructive pulmonary disease, renal failure) had no influence on the results of angioplasty of iliac artery.

We present the comparison of incidence of certain diseases at the time of angioplasty with the data reported by other authors.

Coronary heart disease

The average incidence of coronary heart disease in our study was 93.8%. There was no significant difference between the group of sufficient angioplasty and the group of additional intervention, regarding coronary heart disease ($p < 0.05$). The data reported by other studies are similar (Timaran CH 2003). Incidence of coronary artery disease in patients undergoing iliac artery angioplasty ranged from 60 to 81% (Kudo T 2005, Rzucidlo EM 2003, Timaran CH 2003).

History of stroke

In our study, 16.4% of the patients suffered from stroke previously. The data reported by other authors are similar (17%) (Kudo T 2005).

Chronic obstructive pulmonary disease

In our study, the incidence of COPD was 39.0%. The incidence of COPD in our study was higher than reported by other authors (11–21%); however, the smoking rate among our patients was also higher (Hans SS 2008, Kudo T 2005).

5. CONCLUSIONS

1. The increase of ankle-brachial index and decrease of ischemia assessed by means of Fontaine stages of limb ischemia are reliable the iliac artery PTA efficacy criteria.
2. The effect of PTA of the iliac artery and the need for additional circulation-restoring procedure become evident during the early postoperative period (1–7 days after PTA).
3. The effect of angioplasty of the iliac artery decreases gradually during one year follow-up after procedure. Additional endovascular procedure or open surgery of the femoral, popliteal and the crural arteries is needed, in order to stop the progression of ischemia. The majority of these operations or procedures are reconstructive operations of the femoral, popliteal and the crural arteries.
4. The effectiveness of the iliac artery PTA depends on the stage of lower limb ischemia. The need of an additional intervention is determined by the nature of lesion of the femoral arteries and the increase in ankle-brachial index for less than 0.15.
5. The morbidity (coronary artery disease, post-stroke condition, chronic obstructive pulmonary disease, chronic kidney insufficiency) was homogenous both in patients who had only PTA and in patients, who needed additional interventions.
6. Among the examined risk factors of peripheral artery disease only arterial hypertension and hypertrophy of the left ventricle had the influence on the progression of the disease and the efficacy of PTA. The progression of the disease did not differ between patients with diabetes mellitus and smokers.

6. SANTRAUKA LIETUVIŲ KALBA

IVADAS

TIRIAMOJI PROBLEMA

Sergamumas periferinių arterijų liga didėja. Senėja pacientai, kuriems tenka atlikti kraujotaką atkuriančias operacijas. Aiškiai įrodyta, kad vyresniems nei 70 metų pacientams atvirosios operacijos sudaro daug didesnę riziką nei jaunesniems. Todėl atvirosios rekonstrukcinės operacijos vis dažniau keičiamos endovaskulinėmis. Jų veiksmingumui įvertinti atlikta daug didelių studijų, kurios parodė, kad tam tikrai daliai pacientų indikacijos atlikti PTA ir stentavimą gali būti platesnės, nei nustatyta TASC 2007 rekomendacijų. Todėl buvo priimtos naujos rekomendacijos (TASC 2010) su naujai suformuluotomis endovaskulinių operacijų indikacijomis. 2012 m. pasirodė publikacijų, kurios kritikuoja naująsias rekomendacijas kaip nepakankamai pagrįstas klinikiniais tyrimais. Iš tikrųjų šios rekomendacijos sudarytos neatsižvelgiant į daugelį veiksnių, kurie daro įtaką endovaskulinės operacijos rezultatui, ypač jo ilgalaikiškumui. Todėl iškėlėme tikslą ištirti, kokį poveikį turi ne tik lokali stenozė ar okliuzija, kuri gali būti pašalinta endovaskuliniu metodu, bet ir kitų žemiau esančių arterijų patologija. Kita mūsų tyrinėjimų sritis – klubo arterijos PTA, kaip savarankiškos operacijos, geba sumažinti galūnės išemiją. Čia savaime iškyla dar viena spręstina problema – kokiais kriterijais būtų galima nustatyti, ar reikalinga papildoma chirurginė arba endovaskulinė periferinę kraujotaką pagerinanti procedūra, kad būtų sustabdytas išemijos progresavimas. Taigi, savo tyrimais, kurie atlikti maksimaliai išgryninus klinikinę medžiagą, patikslinome indikacijas atlikti klubo arterijos endovaskulinę operaciją, priklausomai nuo kitų veiksnių, tokių kaip periferinių arterijų patologija, išemijos stadija, pėdos kraujotaka bei kliniškai nustatomi aterosklerozės rizikos veiksniai.

DARBO TIKSLAS

Nustatyti klubo arterijų perkutaninės transluminalinės angioplastikos veiksmingumą mažinant apatinių galūnių išemiją ir ištirti, kokios įtakos ši gydomoji procedūra turi galūnių amputacijos dažniui.

DARBO UŽDAVINIAI

1. Nustatyti kriterijus PTA veiksmingumui įvertinti.
2. Įvertinti artimuosius pooperacinius rezultatus (iki 7 dienų po PTA).
3. Įvertinti vėlesnius PTA rezultatus pagal galūnės išsaugojimo dažnį po 1, 3, 6 mėn. ir 1 metų.
4. Nustatyti teigiamo klubo arterijos PTA rezultato prognozinį veiksnį.
5. Įvertinti PTA rezultato priklausomybę nuo aterosklerozės išplitimo kitose širdies ir kraujagyslių sistemos dalyse.
6. Nustatyti aterosklerozės rizikos veiksnių – rūkymo, padidėjusio arterinio kraujo spaudimo, diabeto dažnį.

DARBO NAUJUMAS

Pagal naujausią literatūrą klubo arterijų perkutaninės transluminalinės angioplastikos indikacijos yra grindžiamos šių arterijų pažeidimų anatomija. Čia svarbiausia susiaurėjusio ar užakusio segmento ilgis ir jo vieta. Tarptautiniu sutarimu pateiktose rekomendacijose (TASC II, 2007; Europos Kraujagyslių chirurgijos draugija, 2011), patvirtintose išsamiomis mokslinėmis studijomis, yra apibūdinti klubo arterijų pažeidimai, kuriuos gydant PTA arba stentavimu gaunami geriausi rezultatai. Tačiau pasigendama dėmesio klinikiams veiksniams, tokiems kaip išemijos stadija, bendras ligotumas ir aterosklerozės rizikos faktoriai, kulkšnies-žasto indekso pokytis.

Dar mažiau tyrinėta kojų arterijų aterosklerozinio pažeidimo įtaka klubo arterijų endovaskulinės chirurgijos rezultatams.

Todėl šiame darbe išanalizuotas mažiausiai tyrinėtų faktorių poveikis klubo arterijos perkutaninės transluminalinės angioplastikos veiksmingumui. Išnagrinėta, kaip giliosios ir paviršinės šlaunies, pakinklio, blauzdos arterijų patologija, aterosklerozės išplitimas kitose arterinės sistemos vietose bei aterosklerozės rizikos faktoriai paveikia PTA rezultatus. Išaiškinti kriterijai, padedantys prognozuoti kraujotakos pagerėjimą po angioplastikos ilgesniam pooperaciniam laikotarpiui ir nustatyti galūnės išsaugojimo tikimybę.

GINAMIEJI TEIGINIAI

1. Klubo arterijos PTA pagerina kojos kraujotaką ir sumažina išemiją.
2. Klubo arterijos PTA veiksmingumas priklauso nuo lokalių veiksnių – kojos arterijų aterosklerozinio pažeidimo pobūdžio ir vietos. Prognozinis kriterijus yra ir arterinė hipertenzija.
3. Esant nuolatiniams skausmams ir gangrenai klubo arterijos PTA, kaip savarankiška gydomoji procedūra arba papildyta kita kojos kraujotaką atkuriančia atvirąja ar endovaskuline operacija, galūnę išsaugo daugeliui pacientų.

DARBO METODOLOGIJA

TYRIMO VIETA IR LAIKOTARPIS

Tyrimas buvo atliktas Vilniaus universiteto Medicinos fakulteto Širdies ir kraujagyslių klinikos Kraujagyslių chirurgijos centre, esančiame Vilniaus miesto universitetinėje ligoninėje (nuo 2011 m. – Vilniaus miesto klinikinė ligoninė).

Tirti pacientai, kuriems Vilniaus miesto universitetinėje ligoninėje nuo 2009 m. rugsėjo 1 d. iki 2010 m. spalio 31 d. buvo atlikta klubo arterijų perkutaninė transluminalinė angioplastika dėl >50 % stenozės.

Duomenys rinkti nuo 2009 m. rugsėjo 1 d. iki 2011 m. spalio 31 dienos.

TIRIAMIEJI

Pirmame tyrimo etape ištirti pacientai, kuriems buvo ketinama atlikti ir atlikta klubo arterijų angioplastika.

Registruoti pacientų demografiniai duomenys, rizikos veiksniai, apatinių galūnių arterinės kraujotakos būklė, gretutinė kitų organų sistemų patologija, atliktų bendro ir biocheminio kraujo tyrimų, elektrokardiogramos, kulkšnies–žasto indekso, klubo arterijų angiografinio tyrimo rezultatai, susiaurėjusio arterijos segmento ilgis, angioplastikos rezultatai, komplikacijos, ankstyvuojų laikotarpiu (iki 7 parų po angioplastikos) atliktos papildomos operacijos.

Į tyrimą įtraukti pacientai, kuriems atlikta bendrosios ir (ar) išorinės klubo arterijos stenozės (>50 %) angioplastika ir angiografiškai patvirtintas arterijos spindžio atsistatymas. Stentavimo metodu gydyti ligoniai į tyrimą neįtraukti.

Iš viso į tyrimą įtraukti 146 pacientai: iš jų 33 (20,6 %) atlikta bendrosios klubo arterijos, 91 išorinės klubo arterijos (58,9 %), 22 (15,1 %) bendrosios ir išorinės klubo arterijų stenozių perkutaninė transliuminalinė angioplastika. Techninė pirminė angioplastikos sėkmė (arterijos spindžio atkūrimas) siekė 100 %.

Išanalizuoti ankstyvieji gydymo rezultatai. Ankstyvuojų pooperaciniu laikotarpiu laikytas laikas iki 7 parų po angioplastikos.

Antrame tyrimo etape pagal turimus pacientų kontaktinius duomenis išsiųsti laiškai su kvietimais (arba susisiekti telefonui) visiems pacientams, kuriems po klubo arterijų PTA ankstyvuojų laikotarpiu neatlikta papildomų intervencijų. Gauta informacijos apie visus pacientus. Pacientai, kuriems nebuvo atliekama papildomų intervencijų, kviešti atvykti arba apklausti telefonu po 1, 3, 6 ir 12 mėn. nuo PTA.

Iš gautų atsakymų sužinota, kad 4 pacientai jau yra mirę. Kai kurių pacientų mirties priežastis buvo nurodyta jų artimųjų atsiųstuose atsakymuose. Visų mirusių pacientų mirties priežastys (pagal TLK–10) bei datos buvo patikslintos raštu kreipiantis į Statistikos departamentą.

Papildomų duomenų apie buvusiems pacientams vėlesniu laikotarpiu atliktas kitas kraujagyslių operacijas gauta peržiūrėjus VMUL Kraujagyslių chirurgijos centre veikiančią operacijos protokolų elektroninę duomenų bazę.

Paciento tyrimo pradžia laikyta angioplastikos data, o pabaiga – pirmoji atlikta papildoma intervencija, vieneri metai po angioplastikos arba mirties data.

Likę 86 (58,9 %) pacientai atvyko ambulatorinio ištyrimo. Jiems įvertinta ir fiksuota galūnių arterinė kraujotaka bei jos patologija, aterosklerozės progresavimas, išmatuotas kulkšnies-žasto indeksas, rizikos veiksnių pokytis (hipertenzijos korekcija, metimas rūkyti).

VERTINIMO METODIKA

Analizuojant gautus ankstyvojo ir vėlyvojo laikotarpio po angioplastikos duomenis, pacientai buvo suskirstyti į dvi grupes – pakankamos ir nepakankamos klubo arterijų angioplastikos. Pacientai, kuriems per 12 mėn. po angioplastikos nebuvo atlikta jokia kita atviroji ar endovaskulinė arterijų operacija ar amputacija, priskirti pakankamos angioplastikos grupei. Kiti pacientai priskirti nepakankamos angioplastikos grupei.

Visų pacientų bendra būklė buvo vertinama pagal anamnezės duomenis ir objektyvių tyrimų rezultatus, fiksuojami žalingi įpročiai (rūkymas), gretutinė širdies ir kraujagyslių bei kitų sistemų patologija – koronarinė širdies liga, miokardo infarktas, insultas, prieširdžių virpėjimas ir kiti ritmo sutrikimai, cukrinis diabetas, inkstų funkcijos sutrikimai, arterinė hipertenzija.

Gretutinė širdies patologija ir pooperacinių komplikacijų rizika buvo vertinama balais pagal Detsky modifikuotą širdies rizikos indeksą. Detsky skalė skirta prieš operaciją įvertinti širdies pooperacinių komplikacijų rizikai atliekant ne širdies operacijas, todėl taikytina ruošiant pacientą arterijų rekonstrukcinėms operacijoms. Ši skalė balais vertina rizikos veiksnius. Susumavus balus nustatomas pooperacinių komplikacijų rizikos laipsnis.

Pagal Pasaulio sveikatos organizacijos kriterijus, arterinė hipertenzija pacientams diagnozuota, kai sistolinis arterinis kraujo spaudimas (AKS) buvo ≥ 140 mm Hg ir diastolinis AKS ≥ 90 mm Hg.

Inkstų funkcija buvo vertinama pagal K^+ (3,5–5,1 mmol/l), šlapalo (iki 65 m. amžiaus – 1,73–8,3 mmol/l, >65 m. amžiaus – <11,9 mmol/l) ir kreatinino (moterims 44–80 μ mol/l, vyrams 62–106 μ mol/l) koncentraciją kraujyje.

Cukrinio diabeto diagnozė fiksuota iš anamnezės duomenų. Pirmą kartą cukrinio diabeto diagnozė nebuvo nustatyta nė vienam pacientui. Visi pacientai sirgo antro tipo cukriniu diabetu.

Visiems pacientams angiografiją atliko ir angiogramas vertino du patyrę radiologai. Nustatytos arterijų susiaurėjimo ar užakimo vietos. Įverti pritekėjimo baseinai – aorta ir klubinės arterijos, bei nuotėkio baseinai – šlaunies, pakinklio ir blauzdos arterijos. Nustatytas klubo arterijos susiaurėjimo laipsnis (>50 %), kuri arterijos vieta ir kokia jos dalis pažeista.

Nuotėkio baseinas buvo vertinamas pagal priešoperacinį šlaunies, pakinklio ir blauzdos arterijų angiografinį vaizdą. Šlaunies ir pakinklio arterijos vertintos laikantis rekomendacijų, išdėstytų TASC. Įvertintos ir gilioji šlaunies bei blauzdos arterijos.

STATISTIKA

Diskretūs nominalieji kintamieji buvo analizuojami naudojant Pirsono χ^2 nepriklausomumo kriterijų arba Fišerio tikslųjį testą.

Daugiamatė analizė atlikta pasitelkiant binarinę logistinę regresiją. Bendras modelio statistinis patikimumas buvo įvertintas remiantis determinacijos koeficientu (angl. *Nagelkerke R Square*).

Įvairių veiksnių įtaka įvertinta šansų santykiu, jo statistinis reikšmingumas – panaudojant 95 % pasikliautinuosius intervalus.

Nepriklausomų grupių kiekybinių duomenų analizei taikytas Stjudento t testas. Reikšmingumo lygmeniu pasirinkta $\alpha=0,05$, t. y. skirtumo statistinis reikšmingumas laikytas patikimu, kai $p<0,05$.

Visi vidurkiai pateikti su standartiniu nuokrypiu (SD).

Duomenys apdoroti naudojant *Microsoft Office Excel 2007*, statistinio duomenų apdorojimo programą *SPSS Statistics 17.0* (2008).

TYRIMŲ REZULTATAI

PACIENTŲ PASISKIRSTYMAS PAGAL AMŽIŲ, LYTĮ

Tyrimo dalyvavo 146 pacientai – 131 vyras (87,9 %) ir 15 moterų (12,1 %). Vyrų ir moterų santykis 8,7 : 1. Pakankamos intervencijos grupę sudarė 50 (86,2 %) vyrų ir 8 (13,8 %) moterys. Papildomos intervencijos grupę sudarė 81 (92,0 %) vyras ir 7 (8,0 %) moterys. Vyrų ir moterų santykis abiejose grupėse reikšmingai nesiskyrė ($p>0,05$).

Vidutinis pacientų amžius $70,2 \pm 9,9$ metų. Bendras vyrų ir moterų amžiaus vidurkis reikšmingai nesiskyrė ($p>0,05$).

Pakankamos angioplastikos grupėje bendras pacientų amžiaus vidurkis $70,2 \pm 9,96$ metų, papildomos intervencijos grupėje bendras amžiaus vidurkis $70,1 \pm 9,95$ metų. Abiejų grupių amžiaus skirtumas statistikai nereikšmingas ($p>0,05$). Palyginus pakankamos angioplastikos ir papildomos intervencijos grupių vyrų amžiaus vidurkius, reikšmingo skirtumo nerasta ($p>0,05$). Palyginus pakankamos angioplastikos ir papildomos intervencijos grupių moterų amžiaus vidurkius nustatyta, kad moterys papildomos intervencijos grupėje daug vyresnės ($p<0,05$). Pakankamos angioplastikos grupėje vyrų ir moterų amžiaus vidurkis reikšmingai nesiskyrė ($p>0,05$). Papildomos intervencijos grupėje moterys gerokai vyresnės nei vyrai ($p<0,05$).

PACIENTŲ ĮVERTINIMAS PAGAL DETSKY RIZIKOS SKALĘ IR SERGAMUMĄ KITOMIS LIGOMIS

Bendras pacientų Detsky širdies rizikos balų skaičius buvo $10,7 \pm 9,7$. Įvertinus pacientus pagal Detsky širdies rizikos skalę nustatyta, kad bendrai vyrų ir moterų balų vidurkis reikšmingai nesiskyrė. Bendras vidutinis vyrų rizikos balų skaičius buvo didesnis negu moterų, tačiau skirtumas buvo nereikšmingas. Vidutinis Detsky balų skaičius papildomos intervencijos grupėje buvo mažesnis nei pakankamos angioplastikos grupėje (atitinkamai $9,4 \pm 9,3$ ir $12,8 \pm 10,7$ balo). Gautas skirtumas statistikai reikšmingas ($p>0,05$), tačiau abi šios vertės priklauso mažos Detsky rizikos klasei.

Mirę pacientai turėjo daugiau gretutinės patologijos ($p < 0,05$). Visi stebėjimo laikotarpiu mirę pacientai priklausė vidutinės arba didelės Detsky rizikos klasei.

Pacientų sergamumo kitomis ligomis dažnis pateikiamas 6.1 lentelėje. Detsky širdies rizikos indekso veiksnių bei kitų širdies ir kraujagyslių ligų (tokių kaip būklė po insulto, išeminė širdies liga, aortokoronarinių jungčių operacija, prieširdžių virpėjimas ar kiti ritmo sutrikimai) skirtumas pakankamos angioplastikos ir papildomos intervencijos grupėse reikšmingai nesiskyrė.

Lėtinis inkstų funkcijos nepakankamumas nustatytas 5 tiriamiesiems (3,4 %) – trims papildomos intervencijos ir dviem pakankamos angioplastikos grupėje. Šis skirtumas nėra statistikai reikšmingas. Pacientams hemodializės neprireikė.

Cukriniu diabetu sirgo 14 tyrimo dalyvių (9,6 %), iš jų 10 (11,4 %) papildomos intervencijos ir 4 (6,9 %) pakankamos angioplastikos grupėje. Šis skirtumas statistikai nereikšmingas ($p > 0,05$). Visi pacientai sirgo antro tipo cukriniu diabetu.

Sergamumas LOPL pakankamos angioplastikos ir papildomos intervencijos grupėse reikšmingai nesiskyrė. Bendrai ir abiejose grupėse atskirai vyrų sergamumas LOPL buvo didesnis nei moterų ($p < 0,05$).

Būklė po insulto nustatyta 24 (16,4 %) pacientų, iš jų 13 (14,8 %) papildomos intervencijos ir 11 (19,0 %) pakankamos angioplastikos grupėje ($p > 0,05$).

Arterinė hipertenzija. Arterinė hipertenzija (su EKG patvirtinta kairiojo skilvelio hipertrofija) reikšmingai dažniau nustatyta papildomos intervencijos grupėje. Arterinė hipertenzija su kairiojo skilvelio hipertrofija nustatyta 91,0 % visų pacientų (85,4 % pakankamos angioplastikos ir 95,5 % papildomos intervencijos grupėje). Šis skirtumas statistikai reikšmingas ($p < 0,05$). Arterinė hipertenzija su kairiojo skilvelio hipertrofija nustatyta visoms abiejų grupių tyrimo dalyvėms moterims (100 %). Papildomos intervencijos grupės vyrams arterinė hipertenzija nustatyta dažniau nei pakankamos angioplastikos grupės (atitinkamai 95,1 % ir 82,0 %). Šis skirtumas statistikai reikšmingas ($p < 0,05$).

Rūkymas. Iš viso rūkančių pacientų buvo 73,9 % (76,1 % pakankamos angioplastikos ir 70,7 % papildomos intervencijos grupėje). Šis skirtumas statistikai nereikšmingas

($p < 0,05$). Metusių rūkyti skaičius abiejose grupėse taip pat reikšmingai nesiskyrė. Bendrai ir abiejose grupėse atskirai rūkančių vyrų buvo daugiau nei moterų ($p < 0,05$).

6.1 lentelė. Sergamumas kitomis ligomis ir rizikos veiksniai

Veiksny	Pacientų skaičius	%	p vertė
<i>Papildomos intervencijos / pakankamos angioplastikos grupė</i>			
Rūkymas	67 41	76,1 70,7	0,46298
Išeminė širdies liga	83 54	94,3 93,1	0,76522
Buvęs infarktas	16 17	18,2 29,3	0,11568
Aortokoronarinių jungčių operacija	5 8	5,7 13,8	0,09220
Arterinė hipertenzija su kairiojo skilvelio hipertrofija	84 49	95,5 84,5	0,02274
Buvęs insultas	13 11	14,8 19,0	0,50357
Cukrinis diabetas	10 4	11,4 6,9	0,36971
Aritmija	21 14	23,9 24,1	0,96970
Lėtinė obstrukcinė plaučių liga	32 25	36,4 43,1	0,41401
Lėtinis inkstų funkcijos nepakankamumas	3 2	3,4 3,4	0,98984

HOSPITALIZACIJOS TRUKMĖ

Vidutinė hospitalizacijos trukmė buvo $10,3 \pm 6,2$ dienos. Pakankamos angioplastikos grupėje vidutinė gydymo ligoninėje trukmė buvo $7,1 \pm 3,7$ dienos, papildomos intervencijos grupėje – $12,3 \pm 6,7$ dienos. Šis skirtumas statistikai reikšmingas ($p < 0,05$). Jei pacientas skundėsi protarpiniu šlubumu ar ramybės skausmais, vidutinė hospitalizacijos trukmė po klubo arterijos PTA pakankamos angioplastikos grupėje buvo $4,5 \pm 2,3$ dienos. Jei buvo išsivysčiusios išeminės opos ar gangrena, hospitalizacija truko ilgiau – kol buvo įsitikinta PTA veiksmingumu (vidutiniškai $9,1 \pm 4,5$ dienos). Šis skirtumas statistikai reikšmingas ($p < 0,05$).

KLUBO ARTERIJOS PAŽEIDIMO LOKALIZACIJA IR STENOZĖS ILGIS

Visais tirtais atvejais po angioplastikos arterijos spindis atsistatė ar likusi stenozė buvo $< 30\%$ (prieš PTA klubo arterijos stenozė $> 50\%$). 33 pacientams (20,6 %) atlikta bendrosios klubo arterijos, 91 (58,9 %) – išorinės klubo arterijos, 22 (15,1 %) – bendrosios ir išorinės klubo arterijų PTA. Kairiosios ir dešinėsios klubo arterijos pažeidimo dažnis buvo panašus – 74 (50,7 %) ir 72 (49,3 %) pacientams.

Visose klubo arterijos pažeidimo grupėse pacientų pasiskirstymas pagal lytį buvo panašus ($p > 0,05$). Pakankamos angioplastikos ir papildomos intervencijos grupėse pažeidimas pagal klubo arterijos lokalizaciją reikšmingai nesiskyrė ($p > 0,05$).

Pagal klubo arterijos stenozės ilgį buvo naudota keletas angioplastinių balionų: 6 mm ir trumpesni angioplastikos balionai naudoti 88 (60,3 %) atvejų, 8 mm ir ilgesni balionai – 58 (39,7 %) atvejų. Reikšmingo skirtumo vertinant stenozės ilgį ir lokalizaciją klubo arterijoje nenustatyta, stenozės ilgis įvairių amžiaus grupių pacientų vyrų ir moterų nesiskyrė ($p > 0,05$).

Nors 6 mm ir trumpesnė klubo arterijos stenozė buvo nustatoma dažniau, stenozės ilgis vėlyviesiems PTA rezultatams įtakos neturėjo. Pakankamos angioplastikos ir papildomos intervencijos grupėse klubo arterijos stenozės ilgių skirtumas buvo statistikai nereikšmingas ($p < 0,05$) (6.2 lentelė).

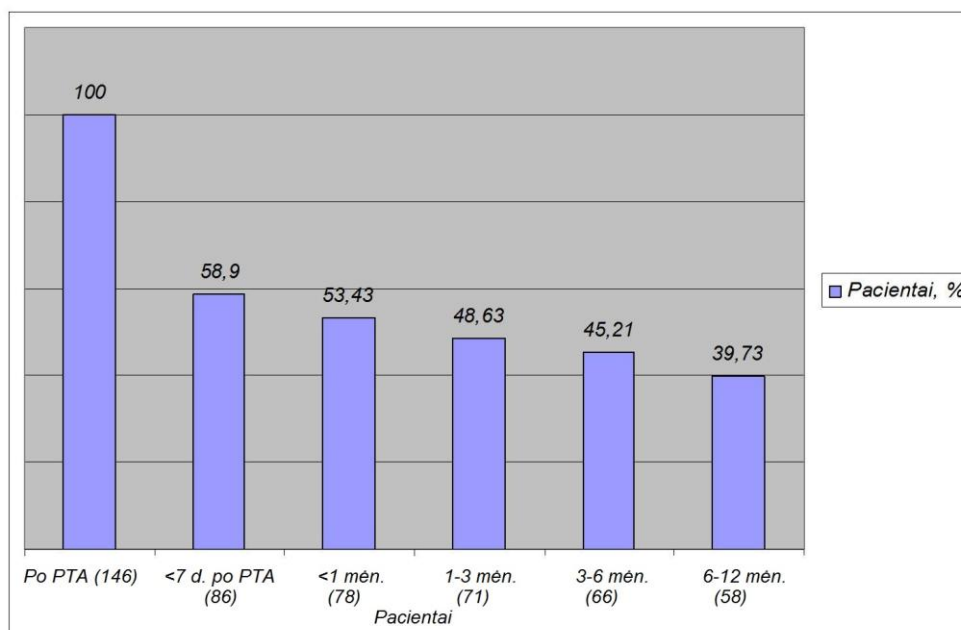
6.2 lentelė. Klubo arterijos stenozės ilgis papildomos intervencijos ir pakankamos angioplastikos grupėse

Stenozės ilgis	≤6 mm	≥8 mm	p vertė
Papildoma intervencija	52 (59,1 %)	36 (40,9 %)	>0,5
Pakankama angioplastika	37 (63,8 %)	21 (36,2 %)	>0,5

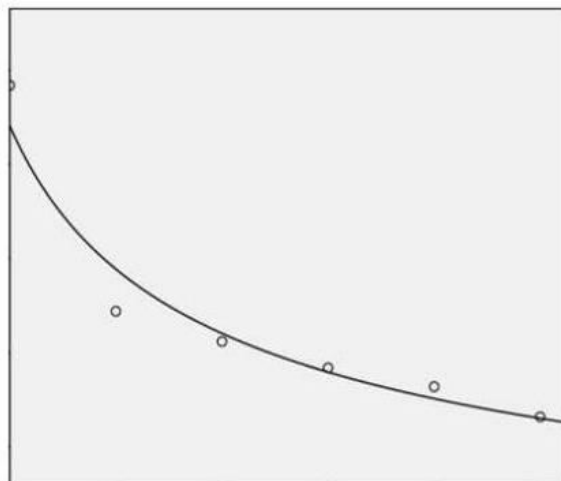
ANKSTYVIEJI IR VĒLYVIEJI KLUBO ARTERIJOS ANGIOPLASTIKOS REZULTATAI

Po 7 dienų, 1, 3, 6 ir 12 mėnesių PTA buvo pakankama procedūra atitinkamai 86 (58,9 %), 78 (53,4 %), 71 (48,6 %), 66 (45,2 %) ir 58 (39,7 %) pacientų: kintamųjų dėsningumas pagal laipsninę funkciją tikrai rodo laiko ir pacientų skaičiaus laipsninę priklausomybę ($p=0,000826$) (6.1, 6.2 pav.). Vertinant ankstyvuosius ir vėlyvuosius PTA rezultatus, reikšmingo priklausomybės nuo amžiaus ar lyties skirtumo nenustatyta ($p<0,05$).

6.1 pav. Pakankamos angioplastikos grupės mažėjimas stebimu laikotarpiu



6.2 pav. Laiko ir pacientų skaičiaus laipsninė priklausomybė ($p=0,000826$)



Papildomos intervencijos

Nuo 2009 rugsėjo 1 d. iki 2010 spalio 31 d. 146 pacientams atlikta klubo arterijos stenozės perkutaninė transluminalinė angioplastika. Per vienerius metus nuo atliktos angioplastikos 58 pacientams nereikėjo papildomų kraujotaką gerinančių intervencijų. Kitiems 88 pacientams reikėjo atlikti papildomą operaciją. Dažniausiai buvo atliekamos jungčių suformavimo operacijos (53 (60,2 %)), rečiau – šlaunies arterijų endarterektomija ir PTA (6.3 lentelė). Galūnės gangreniniai pokyčiai ir negalimumas atlikti arterijų žemiau kirkšnies raiščio rekonstrukciją lėmė, kad aštuoniems pacientams buvo atlikta pirminė amputacija, iš jų šešiams – tos pačios hospitalizacijos metu (6.4 lentelė).

Daugiausia papildomų intervencijų atlikta tos pačios hospitalizacijos metu, vėliau jų skaičius mažėjo tolygiai. Vertinant papildomų intervencijų pasiskirstymo priklausomybę nuo amžiaus ar lyties, reikšmingo skirtumo nenustatyta ($p<0,05$).

Klubo arterijos pakartotinė stenozė (angioplastikos vietoje) stebėjimo laikotarpiu nustatyta ir pakartotinė PTA atlikta keturiems pacientams (2,7 % visų ligonių).

Minėtiems pacientams iki pakartotinės klubo arterijos angioplastikos buvo atlikta papildoma arterijų žemiau kirkšnies raiščio operacija.

6.3 lentelė. Papildomos operacijos

Papildoma operacija	Pacientų skaičius
Jungčių suformavimas	53 (60,2 %)
Endarterektomija	14 (15,9 %)
PTA	13 (14,8 %)
Amputacija	8 (9,1 %)
Iš viso	88

6.4 lentelė. Papildomos operacijos stebėjimo periodu

Papildoma operacija	Ta pati hospitalizacija	<1 mėn.	1–3 mėn.	3–6 mėn.	6–12 mėn.	Iš viso
Jungčių suformavimas	40	4	4	1	4	53
Endarterektomija	12	0	1	1	0	14
PTA	2	3	1	3	4	13
Amputacija	6	1	1	0	0	8
Iš viso	60	8	7	5	8	88

ŠLAUNIES IR PAKINKLIO ARTERIJŲ PAŽEIDIMAS PAGAL TASC

Šlaunies ir pakinklio arterijos vertintos pagal angiografinį vaizdą remiantis rekomendacijomis, pateikiamomis TASC II. Pakankamos angioplastikos grupėje dauguma šlaunies ir pakinklio arterijų pažeidimų buvo TASC A (19 pacientų; 32,8 %) ir TASC B (16 pacientų; 27,6 %) tipo. Kartu abu šie pažeidimo tipai buvo 60,3 % visų

pakankamos intervencijos grupės pacientų. Papildomos intervencijos grupėje TASC A ir B šlaunies ir pakinklio arterijų pažeidimo tipai sudarė 39,8 % (atitinkamai, 14,8 % TASC A ir 25,0 % TASC B). Šis skirtumas buvo statistiškai patikimas ($p < 0,05$) (6.5 lentelė). Pakankamos angioplastikos grupėje mažesnei daliai pacientų nustatytas TASC C (29,3 %) ir TASC D (10,3 %) arterijų pažeidimo tipas, palyginti su 36,4 % TASC C ir 23,9 % TASC D dažniu papildomos intervencijos grupėje. Bendras C ir D tipų dažnis pakankamos angioplastikos ir papildomos intervencijos grupėse skyrėsi statistiškai patikimai (atitinkamai 39,7 % ir 60,2 %; $p < 0,05$).

Palyginus šlaunies ir pakinklio arterijų pažeidimą pagal amžių ir lytį tiek vertinant bendrus rezultatus, tiek atskirai – papildomos intervencijos ir pakankamos angioplastikos grupėse, skirtumas nebuvo statistikai reikšmingas ($p > 0,05$).

6.5 lentelė. Pacientų pasiskirstymas pakankamos angioplastikos ir papildomos intervencijos grupėse pagal šlaunies ir pakinklio arterijos TASC pažeidimo tipą

TASC tipas	Pacientai	%	p vertė
<i>Papildomos intervencijos / pakankamos angioplastikos grupė</i>			
A+B	35	39,8	<0,05
	35	60,3	
C+D	53	60,2	<0,05
	23	39,7	

GILIOSIOS ŠLAUNIES ARTERIJOS SVARBA

Gilioji šlaunies arterija (iki pirmųjų šakų) buvo užakusi septyniems pacientams, iš jų visiems (100 %) arterinei galūnės kraujotakai užtikrinti reikėjo atlikti papildomą intervenciją – tai sudaro 8,0 % visų pacientų, kuriems reikėjo papildomos operacijos. Pakankamos angioplastikos grupėje gilioji šlaunies arterija buvo praeinama visiems 58 pacientams. Todėl papildomos intervencijos poreikis tiesiogiai priklausė nuo giliosios

šlaunies arterijos užakimo ($p < 0,05$). Užakusi gilioji šlaunies arterija ir papildomų intervencijų poreikis nepriklausė nei Fontaine'o išemijos stadijos, nei nuo paviršinės šlaunies arterijos gretutinio pažeidimo pagal TASC ($p > 0,05$). Giliosios šlaunies arterijos užakimą galima laikyti ir prognozinio veiksnio: nors 2 iš 7 pacientų skundėsi tik protarpiniu šlubumu, aterosklerozė ir išemija progresavo taip sparčiai, kad per 12 mėnesių jiems prireikė papildomos intervencijos. Palyginus giliosios šlaunies arterijos užakimą pagal amžių ir lytį tiek vertinant bendrus rezultatus, tiek atskirai – papildomos intervencijos ir pakankamos angioplastikos grupėse, skirtumas nebuvo statistikai reikšmingas ($p > 0,05$).

Hemodinamiškai reikšmingas giliosios šlaunies arterijos susiaurėjimas tame pačiame segmente nustatytas šešiams (10,3 %) pakankamos angioplastikos ir šešiams (6,8 %) papildomos intervencijos grupės pacientams. Šis skirtumas nebuvo statistikai reikšmingas ($p > 0,05$).

BLAUZDOS ARTERIJŲ ATEROSKLEROZINIO PAŽEIDIMO SVARBA

Iš 146 tyrimo dalyvių pagal atliktas angiogramas prieš klubo arterijos angioplastiką blauzdos arterijas buvo galima įvertinti 126 pacientams (86,3 %), iš jų 77 (87,5 %) papildomos intervencijos grupės ir 49 (84,5 %) pakankamos angioplastikos grupės. Šis skirtumas nebuvo statistikai reikšmingas ($p > 0,05$). Vertintas priekinės blauzdos arterijos, blauzdos šėivinio kamieno, užpakalinės blauzdos arterijos ir šėivinės arterijos užakimas. Visos blauzdos arterijos buvo dažniau praeinamos pakankamos angioplastikos grupėje, palyginti su papildomos intervencijos grupe (atitinkamai 18,4 % ir 6,5 %; $p < 0,05$). Papildomos intervencijos grupėje dažniau pasitaikė visų trijų arba keturių blauzdos arterijų užakimas (atitinkamai 24,7 % ir 10,2 %; $p < 0,05$). Skirtumas vertinant vienos ar dviejų blauzdos arterijų užakimą nebuvo statistikai reikšmingas ($p > 0,05$) (6.6 lentelė). Palyginus blauzdos arterijų užakimą pagal amžių ir lytį tiek vertinant bendrus rezultatus, tiek atskirai – papildomos intervencijos ir pakankamos angioplastikos grupėse, skirtumas nebuvo statistikai reikšmingas ($p > 0,05$).

6.6 lentelė. Pacientų pasiskirstymas papildomos intervencijos ir pakankamos angioplastikos grupėse pagal blauzdos arterijų užakimą.

Blauzdos arterijų užakimas <i>Papildomos intervencijos / pakankamos angioplastikos grupė</i>	Pacientai	%	p vertė
Visos blauzdos arterijos praeinamos	5	6,5	<0,05
	9	18,4	
Užakusi viena blauzdos arterija	25	32,5	>0,05
	19	38,8	
Užakusios dvi blauzdos arterijos	29	37,7	>0,05
	15	30,6	
Užakusios trys arba keturios blauzdos arterijos	19	27,7	<0,05
	5	10,2	

PACIENTŲ PASISKIRSTYMAS PAGAL FONTAINE'Ų IŠEMIJOS STADIJAS

Apatinių galūnių išemijos sunkumo laipsnis buvo vertinamas pagal Fontaine'o klasifikaciją. Pakankamos angioplastikos grupėje daugiausia pacientų (24; 41,4 %) skundėsi protarpiniu šlubumu (II išemijos stadija), o papildomos intervencijos grupės pacientams protarpinis šlubumas kaip pagrindinis skundas pasitaikė rečiau (22; 25,0 %). Šis skirtumas buvo statistikai reikšmingas ($p < 0,05$) (6.7 lentelė). Papildomos intervencijos grupėje gerokai daugiau pacientų (30; 34,1 %) skundėsi negyjančiu opėjimu ar gangreniniais pokyčiais (IV išemijos stadija pagal Fontaine'o klasifikaciją), palyginti su pakankamos angioplastikos grupe (11; 19,0 %). Šis skirtumas buvo statistikai reikšmingas ($p < 0,05$). Kritinė galūnės išemija (III ir IV išemijos stadijos) dažniau nustatyta papildomos intervencijos grupėje, palyginti su pakankamos angioplastikos grupe (atitinkamai 75,0 % ir 58,6 %; $p < 0,05$).

Palyginus Fontaine'o išemijos stadijų pasiskirstymą pagal pacientų amžių ir lytį tiek vertinant bendrus rezultatus, tiek atskirai – papildomos intervencijos ir pakankamos angioplastikos grupėse, skirtumas nebuvo statistikai reikšmingas ($p > 0,05$).

6.7 lentelė. Pacientų pasiskirstymas pagal Fontaine'o išemijos stadijas

Fontaine'o išemijos stadija	Pacientai	%	p vertė
<i>Papildomos intervencijos / pakankamos angioplastikos grupė</i>			
Protarpinis šlubumas (II a+b)	22	25,0	<0,05
	24	41,4	
Kritinė galūnės išemija (III + IV)	66	75,0	<0,05
	34	58,6	
Gangrena ir (ar) išopėjimas (IV a+b)	30	34,1	<0,05
	11	19,0	

KULKŠNIES-ŽASTO INDEKSO POKYTIS

Tyrimo metu kulkšnies–žasto indeksas buvo neišmatuojamas (manžetė neužspaudė arterijų) devyniems pacientams, iš jų šešiams papildomos intervencijos ir trims pakankamos angioplastikos grupės. Šis skirtumas statistikai nereikšmingas ($p > 0,05$). Visų pirmiau išvardytų pacientų duomenys į tolesnius skaičiavimus neįtraukti.

Mūsų tiriamiesiems nustatytas vidutinis kulkšnies-žasto indeksas $0,41 \pm 0,14$ po klubo arterijos angioplastikos padidėjo vidutiniškai iki $0,64 \pm 0,13$. Vidutinis kulkšnies-žasto indeksas kritinės išemijos grupėje buvo žemesnis, palyginti su protarpinio šlubumo grupe ($p < 0,05$). Tos pačios Fontaine'o klinikinės stadijos pradinis (prieš PTA) kulkšnies-žasto indeksas papildomos intervencijos ir pakankamos angioplastikos grupėse reikšmingai nesiskyrė ($p < 0,05$). Po PTA pakankamos angioplastikos grupėje KŽI padidėjo 0,15 ir daugiau didesniai skaičiui pacientų, palyginti su papildomos intervencijos grupe ($p < 0,05$).

Buvo nustatytas svarbus arterinio kraujospūdžio pokytis po PTA pacientams, kurių išemija atitiko Fontaine'o IV klinikinę stadiją. Šio pogrupio pacientams, kurie po klubo arterijos PTA išvengė galūnės amputacijos ir nebuvo atliktos papildomos intervencijos, arterinis kraujospūdis pėdoje padidėjo 30 mmHg ir daugiau. Minėti rezultatai yra netoli statistinio patikimumo lygmens.

IŠVADOS

1. Kriterijai PTA veiksmingumui įvertinti – kulkšnies–žasto indekso pokytis, išemijos sumažėjimas pagal Fontaine'o galūnės išemijos stadijas.
2. Klubo arterijos PTA pakankamas efektas ir papildomų intervencijų poreikis daugiausia išryškėja ankstyvuojų pooperaciniu laikotarpiu (iki 7 dienų po PTA).
3. Klubo arterijos PTA rezultatai laipsniškai blogėja per vienerius metus. Išemijos progresavimui sustabdyti reikalinga šlaunies, pakinklio ir blauzdos arterijų papildoma endovaskulinė arba atviroji operacija, dažniausiai – rekonstrukcinės arterijų operacija.
4. Klubo arterijų angioplastikos veiksmingumas priklauso nuo išemijos stadijos. Papildomos intervencijos poreikį po PTA lemia šlaunies arterijų pažeidimo pobūdis, kulkšnies–žasto indekso pokytis mažiau negu 0,15.
5. Bendras pacientų sergamumas kitomis ligomis (išeminė širdies liga, būklė po insulto, obstrukcinė plaučių liga, inkstų funkcijos nepakankamumas) pakankamos angioplastikos ir papildomų intervencijų grupėje buvo vienodas.
6. Iš tirtų periferinių arterijų aterosklerozės rizikos veiksnių ligos progresavimui ir PTA rezultatui turėjo įtakos tik arterinė hipertenzija su kairiojo skilvelio hipertrofija. Rūkymo ir cukrinio diabeto dažnis abiejose grupėse nesiskyrė.

7. LIST OF PUBLICATIONS

1. Sudikas S, Triponis V, Ščerbinskas S, Stanevičiūtė E. Comparison of Angioplasty Results of the Iliac and the Infrainguinal Arteries. *Medicinos teorija ir praktika* 2011; 17(4)
2. Sudikas S, Triponis V, Stanevičiūtė E. The impact of endovascular intervention and open surgery on the incidence of lower extremity amputations. *Seminars in Cardiovascular Medicine* 2012; 18: 2

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