

Midterm results of endovascular treatment of iliac artery lesions: analysis of 59 cases

Resultados a médio prazo do tratamento endovascular das lesões de artérias ilíacas: análise de série de 59 casos*

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Abstract

Background: Endovascular treatment of peripheral arterial occlusive disease has become increasingly frequent in the past few years. Because it is a less invasive procedure, lower morbidity and mortality rates are associated with this form of treatment. **Objectives:** To describe the endovascular procedures performed in iliac arteries for the treatment of peripheral arterial occlusive disease. **Methods:** This retrospective study assesses 59 cases of iliac artery angioplasty performed according to a specific protocol from January 2004 to February 2010. **Results:** Mean age of patients was 62 years (minimum: 42, maximum: 89). Thirty seven were male (62.72%) and 22 female (37.28%). The main indications for treatment were moderate to severe intermittent claudication in 30 cases (50.84%) and rest pain or trophic lesions (critical ischemia) in 29 cases (49.15%). Postoperative follow-up included ankle-brachial index measurements and a duplex ultrasound at 30 days, 3 months, 6 months, 12 months, and every 6 months thereafter. Minimum follow-up time was 3 months, and maximum, 72 months (6 years), with primary and secondary patency rates of 91.37 and 94.82%, respectively. **Conclusions:** The results of this case series, combined with literature review results, allow to conclude that the endovascular approach is an effective and safe option to treat peripheral arterial occlusive disease in iliac arteries.

Keywords: peripheral arterial disease; angioplasty; iliac artery; atherosclerosis.

Resumo

Contexto: O tratamento da doença arterial oclusiva periférica por via endovascular vem apresentando aumento progressivo nos últimos anos. Por se tratar de procedimento pouco invasivo, possui a vantagem de propiciar menos morbimortalidade. **Objetivos:** O presente trabalho tem como objetivo verificar as intervenções endovasculares no território das artérias ilíacas para doença arterial oclusiva periférica. **Métodos:** Trata-se de estudo retrospectivo, avaliando, através de protocolo específico de coleta de dados, 59 casos de angioplastias de artérias ilíacas realizadas no período de janeiro de 2004 a fevereiro de 2010. **Resultados:** A idade média dos pacientes foi de 62 anos (mínima: 42, máxima: 89), sendo 37 do sexo masculino (62,72%) e 22 do sexo feminino (37,28%). As principais indicações para tratamento foram a claudicação intermitente limitante ou incapacitante em 30 casos (50,84%) e a manifestação de dor em repouso ou lesão trófica (isquemia crítica) em 29 casos (49,15%). Acompanharam-se os pacientes no pósoperatório, com medidas do índice tornozelo-braço e duplex-*scan*, aos 30 dias, três meses, seis meses, 12 meses e, posteriormente, de seis em seis meses. O seguimento mínimo foi de três meses e o máximo de 72 meses (seis anos), com perviedade primária de 91,37% e secundária de 94,82%. **Conclusões:** Os resultados desta série de casos e a revisão da literatura permitiram concluir que a abordagem endovascular é uma opção eficaz e segura para o tratamento da doença arterial oclusiva periférica no território das artérias ilíacas.

Palavras-chave: doença arterial periférica; angioplastia; artéria ilíaca; aterosclerose.

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INTRODUCTION

Peripheral arterial occlusive disease is responsible for thousands of amputations in Brazil every year. In the United States, about 100,000 amputations a year are due to lower extremity atherosclerosis¹.

Chronic ischemia of lower limbs secondary to peripheral atherosclerotic disease may lead to intermittent claudication or critical ischemia, whose symptoms include rest pain and trophic lesion. Incidence increases with population age, as well as with risk factors, such as smoking, diabetes and hypercholesterolemia.

Patients with chronic lower limb ischemia have not only a high risk of limb amputation, but also higher morbidity and mortality rates due to ischemic heart and cerebrovascular diseases. Critical ischemia, which includes rest pain and tissue loss, is associated with an annual mortality rate of about 20%^{2.3}. Seldinger, in 1953, Dotter, in 1964, Grutzing, in 1974, and Palmaz, in 1985, were the pioneers of minimally invasive procedures in vascular surgery. Since their time, new devices, such as guide wires, catheters, balloons and *stents*, have been developed for endovascular interventions every year⁴⁻⁷.

The development of endovascular techniques to treat peripheral arterial diseases has enabled the use of minimally invasive methods and reduced morbidity and mortality in comparison with the rates obtained with conventional surgery.

In the region of the iliac artery, endovascular treatment has been associated with low morbidity and mortality when compared with open surgery. Procedures are performed under local anesthesia and percutaneously, which results in less surgical trauma to patients with multiple comorbidities. Patient recovery is rapid, and patency rates in the long term are comparable to those of open surgery.

OBJECTIVE

This study described and evaluated the results of a series of patients that underwent iliac artery angioplasty, as well as mid and long term results according to the following factors:

- primary patency rates;
- secondary patency rates;
- mortality rates;
- · complications associated with procedure;
- · amputation rates.

METHOD

From January 2004 to February 2010, 59 patients underwent endovascular interventions in the iliac artery. Data were collected retrospectively using a specific protocol presented to patients at the time of hospitalization. The protocol included data about patient age and sex, clinical severity of arterial disease (claudication, rest pain or tissue lesion), comorbidities and risk factors of atherosclerosis (smoking, diabetes, hypertension, dyslipidemia), laboratory tests and diagnostic procedures and vascular assessment. All patients signed an informed consent term at the time of hospitalization and granted permission for the performance of procedures. The consent term was the one used in the hospital where the patients underwent operation, approved by the Ethics Committee of the institutions where the study was conducted.

The patients underwent operations in two tertiary hospitals: a private hospital with 400 beds and a cardiovascular service; and a public hospital with 500 beds and a Residence Program in Vascular Surgery and a C-arm in the operating room for the performance of vascular interventions.

The procedures were performed under local anesthesia and sedation; the patients were hospitalized after angioplasty and discharged in the next morning. Antiplatelet therapy with 200 mg/ day of acetylsalicylic acid (AAS) and 75 mg/day of clopidogrel was initiated three to five days before the intervention. The use of 75 mg/day of clopidogrel was continued for 30 days after the operation, combined with 200 mg/day of AAS. After 30 days, clopidogrel was discontinued, but AAS at 200 mg/ day was maintained.

All 59 patients underwent postoperative followup, which included clinical examinations, anklebrachial index measurements and a duplex ultrasound or CT angiogram at 30 days, 3 months, 6 months, 12 months, and every 6 months thereafter. Follow-up was performed by the author in the outpatient service of the public hospital and in his private office in the case of his private patients.

The protocol for data collection is shown in the supplementary annex (Annex 1).

Description of angioplasty technique

Vascular access

Access to the iliac artery was via retrograde ipsilateral puncture of the common femoral artery. Two techniques can be used for this puncture: puncture of the anterior wall of the artery only, using an arterial puncture needle; or use of a piercing technique and a Jelco 16G catheter. In patients without a femoral pulse, techniques for puncturing without a pulse were adopted, always using a puncture needle⁸:

- radioscopy to identify the site at the intersection of the mid third and the medial third of the femur head;
- duplex scan guided puncture;
- injection for road-mapping from contralateral access;
- · directions using previous angiograms;
- visualization of calcifications in the artery;
- lateral orientation to guide wire placed in the femoral vein.

In cases of ostial lesions of the common iliac artery, the bilateral puncture of femoral arteries was necessary to avoid the occlusion of the contralateral iliac artery by displacement of plaques from the bifurcation when the kissing balloon technique was used.

Interventions in the aortic bifurcation

This technique was used in cases of bilateral ostial lesions of the common iliac arteries. The technique had the following steps⁹:

- retrograde right femoral puncture:
- placement of 6F or 7F introducer;
- retrograde left femoral punctures;
- placement of 6F or 7F introducer;
- arteriogram;
- road mapping;
- placement of 260-cm standard or stiff hydrophilic guide wires bilaterally through the lesions; and
- use the kissing balloon or kissing stent technique simultaneously.

Unilateral iliac lesion

In cases of unilateral iliac lesions, several techniques were used, as described below.

When the lesion is less than 2 cm from the aortic bifurcation, a contralateral puncture is also necessary.

Contralateral puncture may also be useful for angiographic control during the procedure.

Brachial access may also be used in case of occlusions, because the lesion may often be recanalized more easily; and, also, in cases of lesions of the external iliac arteries close to the inguinal ligament when there is not enough space to position the introducer. A pigtail catheter positioned via brachial access may also be used for angiographic control during the procedures. In any case, this access is used only in selected cases of iliac artery angioplasty.

Use of stents

Stents were used selectively according to indications:

- inadequate result of balloon angioplasty with extensive dissection or limiting flow, or with a pressure gradient greater than 11 mmHg;
- occlusions;
- · ostial lesions; and
- calcified plaques or large ulcerations.

In ostial or calcified lesions, the balloonexpandable stent was used because of its greater radial force and more accurate release. When the lesion reached the common and external iliac arteries, or when the lesions were very long and in tortuous segments, self-expanding nitinol stents were used because of their marked flexibility.

Figures of cases in the series

Case 1

Patient with trophic lesion in fifth toe, stenosis of left common iliac artery and subocclusion of left external iliac artery treated with angioplasty and balloon-expandable stent in left common iliac artery and self-expanding stent in the distal third of the common iliac artery and external iliac artery (Figures 1a-c).



Figure 1. Case 1: (a) arteriogram: stenosis in left common iliac artery and subocclusion in left external iliac artery; (b) expanding balloon stent in common iliac artery and self-expanding balloon in external iliac artery; (c) final angiogram.

Case 2

Patient with disabling intermittent claudication and bilateral ostial stenosis of the common iliac artery. Treatment with a balloon-expanding kissing stent (Figures 2a-c).

Case 3

Patient had undergone stent angioplasty of left common iliac artery four years before and had in-stent restenosis and stenosis of renal artery. A neobifurcation was prepared with kissing stents and stent angioplasty of renal artery (Figures 3a-e).

Case 4

Patient with trophic lesion of left foot. Aortogram revealed total left common iliac artery occlusion and proximal ulcerated plaque in right common iliac artery. Treatment with balloon-expanding kissing stent (Figures 4a-d).

RESULTS

Mean patient age was 62 years (minimum: 42; maximum: 89); 37 were male patients (62.72%) (Figure 5).

The predominant risk factors were smoking, in 72% of the cases, and diabetes, in 30%.

The main treatment indications were limiting or disabling intermittent claudication in 30 cases (50.84%) and rest pain or trophic lesion (critical ischemia) in 29 cases (49.15%) (Figure 6).

Lesions were classified as TASC A in 39 cases (66.10%), TASC B in 13 (22.03%), TASC C in two (3.38%) and TASC D in five (8.47%) (Figure 7).

Patients had stenosis in the iliac arteries in 42 cases (71.18% of the cases in the series) and occlusions in 17 cases (28.81% of the cases in the series).

Initial technical success was achieved in 56 cases (94.91%). Three were classified as technical failures: two had bilateral lesions, but recanalization

of at least one side was achieved (partial technical failure). In one of the patients, with a TASC D lesion, there was no canalization in either side (treatment failure). He died on the 10th postoperative day due to complications of underlying diseases: chronic obstructive pulmonary disease (COPD), diabetes and sepsis.

The patients underwent postoperative follow-up, which included c ankle-brachial index measurements and a duplex ultrasound scan at 30 days, 3 months, 6 months, 12 months, and every 6 months thereafter. Minimum follow-up was three months, and maximum, 72 months (six years), and mean followup was 22 months. There was a small loss to followup, and it was not possible to calculate late survival.

During postoperative follow-up, there were:

- two occlusions (3.38%): one patient with occlusion at 12 months after the procedure was asymptomatic and was treated only clinically, without another intervention. Another patient had occlusion 30 days after the procedure and underwent aortobifemoral bypass;
- three restenosis occurred in the first 12 months after angioplasty (5.08%): two underwent another angioplasty, which was successful, and the other, aortobifemoral bypass because there were severe diffuse lesions of the common and external iliac arteries bilaterally; and
- a major amputation (iliac angioplasty followed by posterior distal femoral tibial bypass. Iliac angioplasty was patent, but the bypass occluded in the first week after operation, and the patient underwent amputation of the thigh).

These data show primary patency in 91.37% and secondary patency in 94.82% (Table 1).

A patient had more serious complications: perforation of leg artery in a combined infrapopliteal procedure that required postoperative fasciotomy due to compartment syndrome. The patient had chronic renal failure with hemodialysis and had a coagulation disorder, which contributed to the development of



Figure 2. Case 2: (a) angiogram shows bilateral ostial stenosis of common iliac arteries; (b) balloon-expanding kissing stents, 9x39 mm; (c) final aortogram.

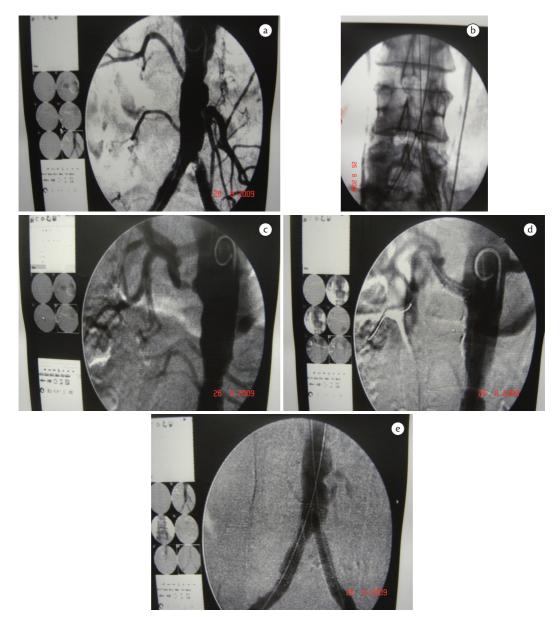


Figure 3. Case 3: (a) intrastent restenosis originating in left common iliac artery; (b) new bifurcation with balloon-expanding kissing stents; (c) severe stenosis in right renal artery; (d) balloon-expanding stent in right renal artery; (e) final aortogram.

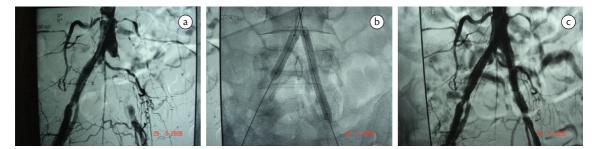
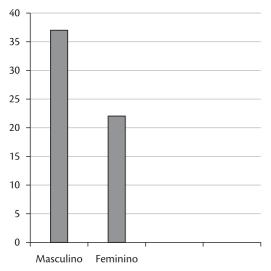
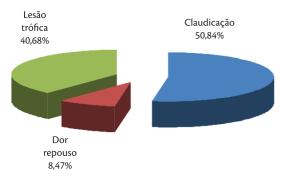


Figure 4. Case 4: (a) arteriogram shows left common iliac artery occlusion and proximal ulcerated plaque in right common iliac artery. (b) balloon-expanding *kissing stents*, 7×29 mm in right side and 7×59 mm in left side; (e) final aortogram.







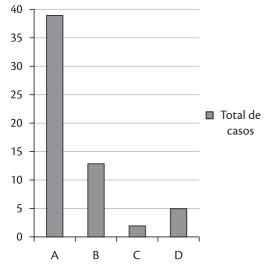


Figure 6. Patient distribution according to degree of ischemia.

Figure 7. Patient distribution according to TASC classification.

Table 1. Primary and secondary patency rates.

Patency	Patency rates (%)		
Primary	91.37		
Secondary	94.82		

the compartment syndrome and the need to undergo fasciotomy. She recovered satisfactorily.

There were no pseudoaneurysms, retroperitoneal hematoma, arterial occlusions or need of blood transfusion.

There were two deaths in the first 30 days after operation (3.3% mortality) not associated with the angioplasty. A kidney transplant recipient, who was hospitalized with acute pancreatitis and developed acute ischemia of the right lower limb, required fibrinolysis and angioplasty of the common iliac artery and limb perfusion was restored. Ten days after the procedure, she died due to complications of acute pancreatitis (respiratory failure and sepsis). Another patient, with a TASC D lesion in which recanalization was not achieved, already described above, died due to COPD complications, diabetes and sepsis.

DISCUSSION

Although open surgery, particularly aortobifemoral bypass, apparently results in better patency in the long term than endovascular surgery in the aortoiliac region, the risks of open surgery are much higher than those of endovascular treatment, not only in terms of mortality, but also in regard to morbidity and patient return to usual daily activities. A meta-analysis of 25 studies about aortobifemoral bypass found 4.4% deaths and 12.2% complications, in addition to 91% patency at five years for patients with claudication and 87% for those with critical ischemia¹⁰.

However, studies about the use of an endovascular approach showed that, in a series of 151 cases of angioplasty of the iliac arteries, there were no deaths and only one minor complication (inguinal hematoma), whereas assisted primary and secondary patency was 98% at seven years. Most lesions treated in this series were stenosis and TASC A or B lesions¹¹. Therefore, the approach for each patient should take into consideration general health and type of lesion.

In a retrospective study with 138 patients with iliac occlusions treated with angioplasty and stents, patency rates were 90%, 85%, 80% and 68% at three, five, seven and 10 years. According to the authors, an initial endovascular approach seems to be justifiable for most patients, particularly older patients and those with severe comorbidities, because it is less invasive than surgery¹². Another retrospective study with 937 patients found 73% primary patency, 88% assisted primary patency and 90% secondary patency at 10 years, with mortality rates lower than

1%¹³. Pedron et al.¹⁴ studied a series of 24 cases of iliac occlusion treated with angioplasty and found technical success rates of 91.7% and patency of 71% at 1 year¹⁴. Moreira et al.¹⁵ evaluated neointimal hyperplasia using intravascular ultrasound 8 months after the procedure in 30 patients that underwent angioplasty of the iliac arteries and stenting, and found that it was self-limited and did not lead to significant restenosis in any of the cases¹⁵.

In our study, most patients had TASC A or B lesions (88.13% of the cases) and stenosis (42 patients, or 71.18% of the cases), and primary (91%) and secondary (94%) patency rates were also high, whereas morbidity and mortality rates were low. These findings suggest that the endovascular approach should be the first treatment alternative in case of stenosis and TASC A and B lesions. If the endovascular treatment fails for a patient, there remains the option of undergoing another angioplasty procedure or attempting open surgery. Of the three patients with restenosis in our series, two underwent another angioplasty and one, open surgery, as shown in the results of postoperative follow-up. Of the two that had occlusion during follow-up, one underwent surgery, and the other was treated only clinically.

Initial technical and clinical success of angioplasty in the treatment of stenosis in iliac arteries is greater than 90% in practically all publications in the literature. This rate may reach almost 100% in the case of focal stenosis. In contrast, the success rate in the case of occlusions is about 85% and depends on fibrinolysis. The development of advanced materials and the availability of more advanced techniques have resulted in greater technical success when recanalizing occlusions¹⁶.

Several recent studies have also confirmed the efficacy and safety of this method. A study with a series of 118 patients with occlusion of the iliac artery treated with primary stenting found a secondary patency of 93% at five years of follow-up¹⁷.

However, the indications of interventions, be them open surgery or endovascular approach, have not changed. In the case of patients with claudication, they should be treated first clinically, with the indication of smoking cessation, walking, control of risk factors, use of antiplatelet drug, **CONCLUSIONS** vasodilating drugs and statins. Invasive treatments are indicated in the following conditions, according to recommendations of the Brazilian Society of Angiology and Vascular Surgery¹⁸.

· limiting claudication;

- disabling claudication;
- no improvement with clinical treatment;
- · rest pain; and
- trophic lesion.

In the series of patients in this study, these criteria were used to indicate interventions. The decision about invasive treatment for patients with claudication should also be made based on the individual context of each patient. Age, social life, fitness and professional status should be taken into consideration, and the simple application of only a rigid classification system should be avoided. In some specific cases, patients with moderate to severe claudication may become candidates for invasive treatment. Quality of life questionnaires may be used to decide whether or not an invasive procedure should be used and to select patients that will have the greatest benefit from that type of intervention¹⁹. Angioplasty may improve the quality of life of patients with claudication when compared with clinical treatment and physical exercises alone²⁰.

The decision about a selective or routine use of stenting to treat iliac arteries remains controversial²¹. The Dutch Iliac Stent Trial (DIST) conducted a prospective and randomized comparative study of selective and routine stenting of 279 patients with claudication, and found similar results in both groups, without statistically significant differences²². However, a meta-analysis comparing six studies with 1,300 patients that underwent angioplasty of the iliac artery without stenting and eight studies with 816 patients that underwent stenting suggested that the use of stents seems to bring immediate success and better long term results²³. Another study with a series of patients investigated the use of routine stenting in 90 lesions of the external iliac artery in patients with claudication and found that primary and secondary patency rates were 84% and 93% at three years of follow-up²⁴.

In our sample, we chose to use stenting selectively in the cases of unsatisfactory results of angioplasty, ostial or calcified lesions or presence of ulcerated plaque. Stents were also used routinely in cases of occlusion.

According to studies in the literature, angioplasty in iliac arteries is currently accepted as the method of choice for the treatment of lesions in this anatomic site, particularly because of its low morbidity and mortality rates and its good long term results.

Findings in this study showed that:

- the primary patency rate for angioplasty in the iliac arteries was 91.3%;
- the secondary patency rate for angioplasty in the iliac arteries was 94.82%;
- the rate of mortality in the first 30 days after operation was 3.3%;
- the rates of complications associated with the procedure were low (1 case of arterial perforation); and
- the rate of amputations was low (1 case in the series). Endovascular treatment is an efficacious, long-

lasting and safe option for the treatment of peripheral occlusive arterial disease in iliac arteries, particularly TASC A and B lesions with low complication rates and high patency rates, as demonstrated in this study, in which most lesions that underwent treatment received that classification.

Angioplasty in iliac arteries is a low-risk, lowmortality procedures with patency results that compare with those achieved when conventional surgery is used.

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Author contributions

Conception and design: LGB Analysis and interpretation: LGB Data collection: LGB Writing the article: LGB Critical revision of the article: LGB Final approval of the article*: LGB Statistical analysis: LGB Overall responsibility: LGB *All authors should have read and approved of the final version of

the article submitted to J Vasc Bras.

Annex 1

PROTOCOL FOR PERIPHERAL ANGIOPLASTY - DATA COLLECTION

Name Sex	FICATION (attach tag) ation number						
 Inter distanc Disal Rest Tissu 	bling claudication	ms Acute occlusi thrombolysis Deep vein thr Other:	U		Risk factors Smoking Diabetes hypertension Renal failure Hyperlipidemia		
LLL:							
Pulses			Doppler ultrasound				
	RLL:	LLL:			RLL:	LLL:	
Femora	1		1	Dorsalis pedis artery			
Popliteal			Posterior tibial artery				
Dorsali				,			
Posterio				Ankle-brachial index			
rosterik				and brachar macx			
Rutherf I II III IV V VI	ord Arteriogran	n / Angio-CT / Angio-۸	ARI / D	uplex (lesion descripti	on)	TASC A B C D	
Lesion a	anatomy						
lliac arteries			Femo	moral popliteal segment			
A 1	Stenosis < 3 cm CIA or EIA (uni	lateral or bilateral)	A 1		except when origin in	SFA or distal popliteal	
B 2	Stenosis, single lesion 3-10 cm		D D	artery Crawsis (see Insister	-in als la sien 2 5 and 1 a	e de acia a distal	
B 3 B 4			B 2	Stenosis/occlusion, single lesion 3-5 cm not affecting distal popliteal artery			
C 5			B 3	highly calcified stenosis, up to 3 cm			
C 6			Β4	Multiple stenosis/occlusions, each lesion < 3 cm			
C 7			B 5	Single or multiple lesion in the absence of continuous tibial			
D 8 Multiple, diffuse stenosis in CIA, EIA and CFA			runoff to improve inflow for bypass				
	D 9 Unilateral occlusion of CIA and EIA		C 6 C 7	Stenosis/occlusion, single lesion greater than 5 cm			
D 10 Bilateral occlusion of EIAD 11 Diffuse disease affecting aorta and both iliac arteries		D8	Multiple stenosis/occlusions 3-5 cm Complete occlusion of CFA or SFA or PA or TFT				
D 12	lliac stenosis in patient with AA		00	complete occlusion			
	pliteal lesions						
5 1 1							

- A1 Stenosis, single lesion smaller than 1 cm in tibial or fibular arteries
- B2 Multiple focal stenosis, lesions of tibial or fibular arteries, each smaller than 1 cm
- B3 One or two lesions, focal stenosis, each smaller than 1 cm in the tibial trifurcation
- B4 Tibial or fibular stenosis associated with femoral popliteal angioplasty
- C5 Stenosis, lesion 1-4 cm long
- C6 Occlusions 1-2 cm long in tibial or fibular artery
- C7 Long stenosis, lesion in tibial trifurcation
- D8 Occlusions > 2 cm in tibial or fibular artery
- D9 Diffuse disease in tibial or fibular artery

Endovascular approach Treatment description: Date:

Surgical team:

Segment treated

- 🗌 aorta
- Iliac arteries
- □ Femoral artery
- □ Popliteal artery
- □ Infrapopliteal artery
- Carotid artery
- \Box a. subclavian artery

Access:

- □ Ipsilateral femoral artery
- □ contralateral femoral artery
- Anterograde femoral
- 🗆 R brachial
- 🗆 L brachial
- 🗆 radial
- □ axillary
- venous

Complications:

Immediate postoperative AB index (24 h): POSTOPERATIVE FOLLOW-UP 1) 30 DAYS ABI Imaging findings 2) 3 MONTHS ABI Imaging findings 3) 6 MONTHS ABI Imaging findings 4) 1 YEAR ABI Imaging findings 5) SUBSEQUENT FOLLOW-UP RECORD ABI AND IMAGING FINDINGS A) B) C)

- D)
- D)

- □ Venous graft
- Synthetic graftArteriovenous fistula
- Renal
- mesenteric
- vein:
- Filter of vena cava
- Pre-dilatation
- Balloon: Post-dilatation Balloon:
- Stent: _____ No. of stents ____
- Sizes:
- Expanding balloon
- Self-expanding balloon
- surgery time (min)