**Original
Article**

Comparison of the Incidence of Complications and Secondary Surgical Interventions Necessary in Patients with Chronic Lower Limb Ischemia Treated by Both Open and Endovascular Surgeries

Dariusz Janczak, MD, PhD,^{1,2} Maciej Malinowski, MD,^{1,2} Wojciech Bąkowski,²
Katarzyna Krakowska,² Karol Marschollek,² Paweł Marschollek,²
and Mariusz Chabowski, MD, PhD^{1,2}

Background: Peripheral arterial disease (PAD) affects 3%–10% of the population before the age of 70 years and 15%–20% after that age.

The aim of the study was to compare the incidence of complications and secondary interventions in patients who underwent each type of treatment.

Methods: We analyzed 734 medical records of the Department of Surgery at the 4th Military Teaching Hospital in Wrocław. In total, 394 were operated on with open surgery; an endarterectomy (59.39%), a vascular prosthesis implantation (31.01%), or both of these techniques (6.6%), and 340 patients had angioplasty with (50.59%) or without stenting (49.41%).

Results: There were no statistically significant differences in the incidence of corresponding complications. The exception was the infection of the wound; significantly fewer were reported in the case of endovascular procedures ($p = 0.0087$). There were 12 occasions (3.53%) during endovascular surgeries when intraoperative conversion or re-operation using the open method occurred. In the case of open surgery, the mean hospital stay was 7.77 days (median: 8, mode: 8), while for endovascular management it was equal to 4.68 days (median: 4, mode: 3), $p < 0.0001$.

Conclusion: The endovascular method results in a similar re-operation rate and number of complications as open surgery.

Keywords: peripheral arterial occlusive disease, chronic lower limb ischemia, open surgery, endovascular surgery, complications

¹Division of Surgical Specialties, Department of Clinical Nursing, Faculty of Health Science, Wrocław Medical University, Wrocław, Poland

²Department of Surgery, 4th Military Teaching Hospital, Wrocław, Poland

Received: November 28, 2016; Accepted: January 21, 2017

Corresponding author: Mariusz Chabowski, MD, PhD. Department of Surgery, 4th Military Teaching Hospital, 5 Weigla Street, 50-981 Wrocław, Poland.

Email: mariusz.chabowski@gmail.com

©2017 The Editorial Committee of *Annals of Thoracic and Cardiovascular Surgery*. All rights reserved.

Introduction

More than 98% of lower extremity arteries stenoses occur due to an atherosclerosis, leading to progressive ischemia of the legs which consequently may cause necrosis and limb loss.¹⁾ The most common symptoms encountered by the patient are easy leg fatigue, paresthesia, intermittent claudication, and rest pain. However, the patient may not report any of these symptoms. Signs such as blue or pale skin on the limb or lack of pulse

below the obstruction may also be observed. Epidemiological studies show that 3%–10% of the population suffers from chronic ischemia of the lower limbs (peripheral arterial disease [PAD]), and this percentage increases with age: over the age of 70 years, the disease is already present in 15%–20% of the population. The authors of *TransAtlantic InterSociety II Consensus (TASC II)* also indicate that in patients with critical limb ischemia (CLI), 20% of them die within the first year after diagnosis.²⁾ A high mortality and a worse prognosis are associated with the frequent co-occurrence of hypertension, ischemic heart disease, chronic kidney disease, and diabetes mellitus type II.³⁾ In the case of less severe lower-extremity atherosclerosis, a conservative treatment is the first choice. An important part of it is a reduction of the parameters considered as risk factors for PAD: high blood pressure, hypercholesterolemia, or hyperhomocysteinemia. Attention is also drawn to elevated levels of inflammatory markers, especially α -defensins and C-reactive protein in patients at increased risk.⁴⁾ It is believed that chronic cigarette smoking is a greater risk factor for PAD than for coronary heart disease.⁵⁾ In patients with more severe lesions and shorter claudication distance, surgical intervention is necessary. A choice of the best method of treatment is becoming more difficult and requires specific diagnostics. It is essential to determine the location and extent of the changes, as well as to analyze the patient's general state together with any chronic diseases and presented symptoms. At present, two methods are most commonly used in the treatment of patients with PAD.

Open surgery is a longer practiced and thus better known procedure, which consists of performing an endarterectomy, placing prosthesis or vascular patches in place of damaged vessel, ensuring its continuity and patency. This method is deemed as being highly invasive. A newer method is percutaneous transluminal angioplasty (PTA), first performed in 1964 at Oregon Health Science University by Charles T. Dotter and his intern Melvin P. Judkins. It involves the percutaneous introduction of a catheter balloon into an appropriate artery, which, in the narrowed part of the artery, expands by filling with a contrast agent. The process is observed by intra-operative X-ray. PTA is much less invasive, leading to an essentially shorter hospital stay. According to Polish recommendations, published in 2009 and established in accordance with the guidelines of *TASC II*, only changes assigned to category D are clearly not to be managed using endovascular procedures.⁶⁾ Depending on the location they are classified as

Fig. 1 Patients' distribution by age.

following: an aorto-iliac section: an infrarenal aorto-iliac occlusion, diffuse changes involving both the aorta and iliac arteries, multiple unilateral stenoses, bilateral occlusion of the iliac arteries, an accompanying infrarenal abdominal aortic aneurysm; a femoro-popliteal segment: chronic total occlusion of the common femoral, superficial femoral or popliteal artery; and tibial arteries: a lack of patent collateral circulation. Other conditions may be treated either using the open or endovascular method.

The aim of the study was to compare the incidence of complications and the necessity for re-operation within 6 months of the initial surgery. The open and endovascular methods were compared.

Materials and Methods

We retrospectively analyzed 734 medical records from the Department of Surgery at the 4th Military Teaching Hospital in Wrocław. The patients were treated for chronic lower limb ischemia in the course of *atherosclerosis obliterans* from October 2010 to December 2014. The patients' distribution by age is shown in **Fig. 1**. Hospitalized patients were subjected to a diagnostic process before surgery in order to determine the severity of lesions. Patients were qualified for angiosurgical treatment on the base of imaging methods (carotid duplex ultrasound [CDUS], computed tomography angiography [CTA], and digital subtraction angiography [DSA]) and clinical symptoms assessed with the Rutherford classification. Endovascular management was preferred as a first-line therapy. Patients, in whom the PTA was unsuccessful or preliminary medical imaging had predicted a failure of angioplasty, were treated with open surgeries. The distributions of lesions' location and TASC classification are presented in **Tables 1** and **2**. For surgical

Table 1 The distribution of lesions' location in both the analyzed groups

Location	Percentage	
	Open surgeries (%)	Endovascular surgeries (%)
Aorto-iliac	11.29	16.67
Femoro-popliteal	47.58	55.83
Multilevel	41.13	27.50

Table 2 TASC qualification of vascular lesions in the groups managed with open and endovascular surgeries

Type	Percentage	
	Open surgeries (%)	Endovascular surgeries (%)
A	1.61	24.17
B	21.77	36.67
C	25.81	25.83
D	50.81	13.33

TASC: TransAtlantic InterSociety Consensus

treatment, patients with CLI were qualified: rest pain (Rutherford classification IV) was present in 24.81% for open and 18.53% for endovascular surgeries; tissue loss (Rutherford classification V–VI) was claimed in 32.97% and 14.68%, respectively, for open and endovascular treatment. There were also managed patients with severe intermittent claudication (Rutherford classification III), if the symptoms significantly impair their normal activity. In open surgeries, it was 42.22% of patients, and in endovascular, it was 66.79%. Out of all, 394 were treated by open surgery and 340 by PTA. In patients operated on conventionally, an endarterectomy (59.39%), vascular prosthesis implantation (34.01%), or both techniques (6.6%) were performed. In patients undergoing endovascular surgery, a balloon angioplasty with (50.59%) or without stenting (49.41%) was carried out.

In the group of patients who underwent open surgery, the number of women amounted to 132 (33.5%) and the number of men totaled 262 (66.5%). In the group treated by angioplasty, the number of women was 111 (32.65%) and the number of men stood at 229 (67.35%). Using the chi-squared test, the uniformity of the compared groups in terms of sex was determined ($p = 0.868$). The mean age of the patients treated by open surgery was equal to 65 years, and endovascularly, it was equal to 64 years. The Student's t-test for independent groups showed the uniformity of age structure in the groups under analysis ($p = 0.267$).

The incidence of comorbidities in both groups was also taken into consideration. **Table 3** contains this statement. It should be mentioned, however, that in the case of nicotine use the percentage of patients in both groups may have been underestimated due to insufficient medical data concerning stimulants. The incidence of complications was statistically evaluated using Fisher's exact test, while the average length of hospitalization was compared using the t-test for independent groups. The established level of significance was $\alpha = 0.05$.

All the patients provided written informed consent to have their data used in this study. This study was approved by the Medical University Ethics Committee.

Results

The registered complications and the number of surgical interventions performed within 6 months of the initial surgery in patients treated by open and endovascular methods are shown in **Table 4**. A comparative analysis of both groups showed no statistically significant differences in the incidence of corresponding complications. Only in the case of wound infection, it was revealed that there was a significantly lower number of them in the group of endovascular procedures ($p = 0.0087$). During 12 angioplasty procedures (3.53%), intraoperative conversion or re-operation using the open method occurred.

We also compared the average length of hospitalization of patients in both groups. In the group of open surgery, it amounted to 7.77 days (median: 8, mode: 8), while for endovascular treatment, it equaled 4.68 days (median: 4, mode: 3). The statistical significance was determined as $p < 0.0001$. Patients who did not have post-operative complications were discharged from the hospital with improved flow and blood supply to the lower limbs. The increasing popularity of endovascular procedures is also visible in the Department of Surgery at the 4th Military Teaching Hospital in Wrocław. While in 2012, approximately 100 operations were performed using this method (34% of all treatment), in 2014 there were about 180 of them, accounting for almost 58% of all surgical interventions in patients with chronic ischemia of the lower limbs (**Fig. 2**).

Discussion

The increasing popularity of endovascular surgery is the reason why the debate on the appropriate choice of a method for surgical treatment of CLI is controversial.

Table 3 The most common comorbidities recorded in patients treated by open and endovascular surgeries

Concomitant disease	The number of patients in the group treated by open surgery	The number of patients in the group treated by endovascular surgery
Ischemic heart disease	109 (27.7%)	77 (22.6%)
Noninsulin-dependent diabetes mellitus	100 (25.4%)	84 (24.7%)
History of myocardial infarction	64 (16.2%)	58 (17%)
History of stroke	25 (6.3%)	29 (8.5%)
Heart failure	22 (5.6%)	13 (3.8%)
COPD	19 (4.8%)	20 (5.9%)
Permanent atrial fibrillation	15 (3.8%)	12 (3.5%)
Chronic kidney disease	13 (3.3%)	24 (7%)
Alcohol use disorder	13 (3.3%)	9 (2.6%)
Smoking (ever)	197 (50%)	223 (65.6%)

COPD: chronic obstructive pulmonary disease

Table 4 The number of complications in patients treated using open surgery (n = 394) and angioplasty (n = 340)

Complication	Open surgery	Endovascular angioplasty	Statistical significance (p)
Re-ischemia of the operated limb requiring surgical intervention	26 (6.60%)	16 (4.71%)	0.339222
Infection of the surgical wound	16 (4.06%)	3 (0.88%)	0.008681*
Amputation	9 (2.28%)	2 (0.59%)	0.071302
Re-ischemia of the opposite to operated limb requiring surgical intervention	6 (1.52%)	3 (0.88%)	0.515825
Bleeding from the wound, hematoma	4 (1.02%)	6 (1.76%)	0.52633
Death	4 (1.02%)	0 (0%)	0.128041
Limb edema	3 (0.76%)	1 (0.29%)	0.628045
Peroneal nerve palsy	2 (0.51%)	0 (0%)	0.502028
Retroperitoneal hematoma	2 (0.51%)	1 (0.29%)	1
Hemorrhage to the gastrointestinal tract	2 (0.51%)	0 (0%)	0.502028
Lymphorrhea	2 (0.51%)	0 (0%)	0.502028
False aneurysm	2 (0.51%)	2 (0.59%)	1
Dyspnea	2 (0.51%)	0 (0%)	0.502028
Respiratory failure	1 (0.25%)	0 (0%)	1
Circulatory failure	1 (0.25%)	0 (0%)	1
Psychotic symptoms	1 (0.25%)	0 (0%)	1
Wound dehiscence	1 (0.25%)	0 (0%)	1
Deep vein thrombosis	0 (0%)	1 (0.29%)	0.463215

*The differences in complications incidence between both groups are significant with $p < 0.05$

Published in 2007, *TASC II* includes recommendations for invasive treatment of PAD and makes the choice between open and endovascular surgeries dependent on the location and the extent of vascular lesions. In many cases, the decision is also based on other factors, such as age and the patient's general condition. According to the guidelines, type A changes are indicative of endovascular treatment, while in changes categorized as types B and C such treatment can be applied. However, endovascular treatment is not considered suitable for category D changes.²⁾

The aim of our study was to compare the incidence of complications and of the necessity to re-operate on patients operated on by the two methods: open surgery

and angioplasty. The available literature does not provide clear answers to the problems addressed in our research. In the multicenter, randomized trial bypass versus angioplasty in severe ischaemia of the leg (BASIL), patients diagnosed with CLI were divided by the implemented method of surgical treatment.^{7,8)} The results showed no statistically significant differences between the endovascular and open methods, both in the number of amputations performed within 6 months after surgery and in the patients' declared quality of life. At the same time, it indicated an increased incidence of early complications (within 30 days) and higher costs associated with open surgery. However, long-term observations show greater survival rates among patients undergoing classic surgery.

Fig. 2 Changes in the numbers of operations performed using the open and endovascular methods at the 4th Military Teaching Hospital in Wrocław for the years from 2011 to 2014.

Dosologlu et al. reported comparable results of the hemodynamic effects and the number of amputations required in the long term. The authors also highlight the fact that the endovascular method was preferred in patients in a more severe clinical condition, whereas patients with more extensive changes were recommended for open treatment.⁹⁾

Cull et al. and Suding et al. note that, in the case of endovascular procedures, the number of performed amputations did not significantly change.^{10,11)} However, Cull et al. argue that the amount of necessary re-interventions is higher compared to open surgery.¹⁰⁾

A similar percentage of postoperative complications reported in this analysis in our opinion justifies focusing on other advantages and disadvantages of both techniques when selecting the most appropriate method for a particular patient. The proper qualification of patients for treatment has a crucial impact on achieving good results, a fact which is also emphasized by other authors.^{5,12,13)}

Bodzon et al. reported that patients with advanced limb ischemia, not qualified for open surgery, can be treated using angioplasty with satisfactory results as long as the nature of the atherosclerotic lesions permits such management.¹⁴⁾

In the case of relatively young patients being qualified for angioplasty, we should consider the fact that there is a smaller amount of data available on the long-term complications. The limited usefulness of this method in this particular group of patients is also highlighted by Morbi et al.¹⁵⁾

The differences in the incidence of complications in the two groups are not statistically significant. Only the infection of the wound occurred significantly more often in patients undergoing open surgery, which can be associated with the greater invasiveness of the technique.

The average age of patients in both groups was similar. It can be noted that the age distribution of patients treated with angioplasty has shifted to the right, towards higher values, compared to the corresponding distribution in the group treated by open surgery. Also, the presence of comorbidities associated with patients in both groups stands at a similar level. Among those that could have a considerable impact on the course of treatment, patients undergoing endovascular surgery were diagnosed with chronic kidney disease significantly more frequently.

Hospitalization time was remarkably shorter (60.8%) during endovascular procedures. Other authors represent similar results.^{8,16–18)} The longer hospitalization associated with open surgery is related to higher costs and reduced comfort of the patients and their families.

Conclusion

We conclude that the endovascular method leads to a similar re-operation rate and number of complications as open surgery. Angioplasty is becoming increasingly more popular and more frequently used. The severe condition of a patient, their age, plus any concomitant diseases are all indications that point to considering an endovascular procedure so that the treatment is less invasive and the results of the treatment are maintained at an appropriate level.

Authors' Contributions

Dariusz Janczak: research concept and design

Wojciech Bąkowski, Katarzyna Krakowska, Karol Marschollek, and Paweł Marschollek: collection and/or assembly of data

Wojciech Bąkowski and Karol Marschollek: data analysis and interpretation

Katarzyna Krakowska, Paweł Marschollek, and Mariusz Chabowski: wrote the article

Maciej Malinowski and Mariusz Chabowski: critical revision of the article

Dariusz Janczak, Maciej Malinowski, and Mariusz Chabowski: final approval of article

Disclosure Statement

The authors received no financial support for this research and/or the authorship of this article.

References

- 1) Olin JW, Sealove BA. Peripheral artery disease: current insight into the disease and its diagnosis and management. *Mayo Clin Proc* 2010; **85**: 678-92.
- 2) Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *Eur J Vasc Endovasc Surg* 2007; **33**: S1-75.
- 3) Owens CD, Ho KJ, Conte MS. Risk factors for failure of lower-extremity revascularization procedures: are they different for bypass and percutaneous procedures? *Semin Vasc Surg* 2008; **21**: 143-53.
- 4) Urbonaviciene G, Frystyk J, Flyvbjerg A, et al. Markers of inflammation in relation to long-term cardiovascular mortality in patients with lower-extremity peripheral arterial disease. *Int J Cardiol* 2012; **160**: 89-94.
- 5) Schermerhorn ML, Cronenwett JL, Baldwin JC. Open surgical repair versus endovascular therapy for chronic lower-extremity occlusive disease. *Annu Rev Med* 2003; **54**: 269-83.
- 6) Endovascular treatment of peripheral artery and aortic diseases - Polish guidelines 2009. *Chirurgia Polska* 2009; **11**: 1-12. (in Polish)
- 7) Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. *Lancet* 2005; **366**: 1925-34.
- 8) Bradbury AW, Adam DJ, Bell J, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL) trial: An intention-to-treat analysis of amputation-free and overall survival in patients randomized to a bypass surgery-first or a balloon angioplasty-first revascularization strategy. *J Vasc Surg* 2010; **51**: 5S-17S.
- 9) Dosluoglu HH, Lall P, Harris LM, et al. Long-term limb salvage and survival after endovascular and open revascularization for critical limb ischemia after adoption of endovascular-first approach by vascular surgeons. *J Vasc Surg* 2012; **56**: 361-71.
- 10) Cull DL, Langan EM, Gray BH, et al. Open versus endovascular intervention for critical limb ischemia: a population-based study. *J Am Coll Surg* 2010; **210**: 555-61, 561-3.
- 11) Suding PN, McMaster W, Hansen E, et al. Increased endovascular interventions decrease the rate of lower limb artery bypass operations without an increase in major amputation rate. *Ann Vasc Surg* 2008; **22**: 195-9.
- 12) Brosi P, Dick F, Do DD, et al. Revascularization for chronic critical lower limb ischemia in octogenarians is worthwhile. *J Vasc Surg* 2007; **46**: 1198-207.
- 13) Beard JD. Which is the best revascularization for critical limb ischemia: Endovascular or open surgery? *J Vasc Surg* 2008; **48**: 11S-6S.
- 14) Bodzoń W, Krzanowski M, Maga P, et al. Endovascular treatment of severe lower leg ischemia in patients not suitable for open surgery. *Chirurgia Polska* 2007; **9**: 18-24.
- 15) Morbi A, Gohel MS, Hamady M, et al. Lower-limb ischemia in the young patient: management strategies in an endovascular era. *Ann Vasc Surg* 2012; **26**: 591-9.
- 16) Hynes N, Mahendran B, Manning B, et al. The influence of subintimal angioplasty on level of amputation and limb salvage rates in lower limb critical ischaemia: a 15-year experience. *Eur J Vasc Endovasc Surg* 2005; **30**: 291-9.
- 17) Egorova NN, Guillerme S, Gelijns A, et al. An analysis of the outcomes of a decade of experience with lower extremity revascularization including limb salvage, lengths of stay, and safety. *J Vasc Surg* 2010; **51**: 878-85, 885.e1.
- 18) Kudo T, Chandra FA, Kwun WH, et al. Changing pattern of surgical revascularization for critical limb ischemia over 12 years: endovascular vs. open bypass surgery. *J Vasc Surg* 2006; **44**: 304-13.