

The association between periprocedural factors and the late outcome of percutaneous stenting of lower extremity arteries. A retrospective cohort study

Paweł Grzełazka¹, Klaudia Koza¹, Adrianna Trofimiuk¹, Karol Suppan², Marcin Wasielewski², Joanna Wiśniewska², Jacek Budzyński³

¹Student Scientific Group, Chair of Vascular and Internal Diseases, Faculty of Health Sciences, Ludwik Rydygier Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University in Torun, Poland

²Clinic of Vascular and Internal Diseases, Jan Bizioł University Hospital No. 2, Bydgoszcz, Poland

³Chair of Vascular and Internal Diseases, Faculty of Health Sciences, Ludwik Rydygier Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University in Torun, Poland

Postępy Kardiol Inter 2015; 11, 2 (40): 108–113
DOI: 10.5114/pwki.2015.52283

Abstract

Introduction: About 20–30% of the population have peripheral artery disease. Many of them require intervention, with a percutaneous procedure currently being the first choice. However, the outcomes of these interventions need regular evaluation due to continuous progress in endovascular techniques and the devices used.

Aim: The aim of this study was to analyze procedural factors influencing the outcome of endovascular intervention in patients stented for the first time due to lower extremity atherosclerosis.

Material and methods: The medical documentation of 91 patients with at least 1 year of follow-up after stenting of a lower limb artery was retrospectively evaluated. Uni- and multivariate analyses were performed.

Results: The mean observation time was 544.4 ± 502.9 days. The primary patency of a stent after such a follow-up was 68.1%. Cox proportional hazard analysis revealed that the risk of target lesion revascularization was affected by the following (hazard risk, 95% confidence interval): the number of vascular segments with significant lesions (13.14, 2.28–75.8); critical limb ischemia (5.68, 1.23–26.2); localization of the target lesion in an aorto-iliac in comparison with a femoro-popliteal vascular segment (0.37, 0.14–0.7); aorto-iliac lesion class according to the TASC-II consensus (1.96, 1.1–3.8); and claudication distance (1.02, 1.01–1.03).

Conclusions: The common primary patency of a stent implanted into either an aorto-iliac or a femoro-popliteal vascular segment was similar to that found in other reports. The main factors affecting the outcome of the endovascular procedures performed were mainly related to atherosclerosis severity, not to the type of technique or device used.

Key words: peripheral artery disease, endovascular therapy, outcome, in-stent restenosis, procedural risk factors.

Introduction

Percutaneous interventions are currently recognized as the first-line therapy of choice in patients with leg ischemia, especially as it seems to be increasingly effective, in respect of technical success, possible extent of the intervention in the vascular bed, risk of periprocedural trauma and complications, late outcome [1–3] as well as the possibility to repeat the procedure [4]. On the other hand, endovascular therapy has some strangulations which influence early and late percutaneous procedure outcome and stent failure. These are categorized as: (a) mechanical (e.g. vascular compliance, vessel dissection, recoil), (b)

biological (e.g. proliferative response of smooth muscle, vascular remodeling), and (c) procedural (lesion advancement, distal embolization, stent, stent radial force, stent outward force, time of intervention, radiation, contrast medium dose, and local complications in the puncture site) [5–7]. Of these factors, in-stent restenosis (ISR) has drawn much of the attention of investigators [8–15], although in every patient needing leg revascularization all the factors mentioned should be taken into account.

It might be assumed that the recognition of risk factors for ISR may help in the individualization of patients' qualification for respective endovascular treatment

Corresponding author:

Jacek Budzyński MD, PhD, Clinic of Vascular and Internal Diseases, Dr Jan Bizioł University Hospital No. 2, 75 Ujejskiego St, 85-168 Bydgoszcz, Poland, phone: +48 52 365 51 48, +48 52 365 55 84, fax: +48 52 365 55 84, e-mail: budz@cps.pl

Received: 25.01.2015, **accepted:** 23.02.2015.

methods. They are divided into demographic and clinical, as well as angiographic and procedural [12, 16]. The last two may be related to operator experience and the quality of the device.

Aim

In our study we found that in patients treated for the first time due to lower extremity atherosclerosis the common primary patency of a stent implanted into either an aorto-iliac or femoropopliteal vascular segment was mainly related to atherosclerosis severity, not to the type of technique or device used.

Material and methods

The medical documentation of 91 consecutive patients treated endovascularly between 2008 and 2013 with stenting due to lower extremity artery atherosclerosis was retrospectively evaluated. The inclusion criteria were as follows: a) first time stenting of lower extremity arteries due to chronic leg ischemia; b) complete follow-up, for at least 1 year with visits at 1, 3, 6, and 12 months after the endovascular procedure, and further follow-up at least 6 months after that. The exclusion criteria were: a) stent occlusion due to thrombosis or fracture; b) lack of compliance with changes suggested by the medical team (life style, medication); and c) surgical revascularization during the follow-up after stenting.

In accordance with the requirement for uniform reporting standards [17], the following parameters were analyzed: age, gender, smoking habits, hypertension, dyslipidemia (defined as increased blood low-density lipoprotein (LDL) cholesterol concentration above 100 mg/dl, and/or triglyceride blood concentration above 150 mg/dl, or hypolipemic treatment on admission for a first endovascular procedure), diabetes mellitus, a history of coronary artery disease (CAD), percutaneous coronary intervention (PCI), a coronary artery bypass graft (CABG), congestive heart failure (CHF), stroke, chronic kidney disease with a blood creatinine level of > 2 mg/dl, weight, height, body mass index (BMI), bilateral ankle-brachial index (ABI), and claudication distance. The following parameters associated with an endovascular procedure were also analyzed: (a) clinical inclusion criteria (Rutherford category, life-activity limiting claudication vs. critical limb ischemia [defined as Rutherford categories 4, 5 and 6]); (b) angiographic criteria (the segment of lesion localization according to the TASC II consensus (aorto-iliac, femoro-popliteal, BTK, multi-level) [1], number of affected vascular segments, side of the lesion, lesion severity (stenosis or occlusion), and inflow and outflow situation in adjacent levels); (c) devices used during the procedure (vascular approach, balloon and stent type, diameter and length); (d) the effect of the intervention (Rutherford category, post-procedural ABI and walking distance); and (e)

in-hospital cardiovascular complications (acute coronary syndrome, stroke, CHF exacerbation) or acute kidney injury (AKI) within 7 days of being discharged.

Standard devices were used during the endovascular procedures. However, all the patients were prescribed at least aspirin, clopidogrel, and statins.

The patients were followed up at 1, 3, 6 and 12 months after the procedure and every 6 months subsequently. At each observed follow-up visit, symptom severity and a color-coded duplex ultrasound examination were evaluated. The need for revascularization was considered when resting leg pain, or life-limiting claudication accompanied a decrease in ABI value, when an ultrasonography sign of at least 50% vessel diameter reduction (peak systolic velocity index > 2.4) was recorded or when complete vessel occlusion appeared.

Main outcomes measured

The main efficacy outcomes of the analysis were taken as follows: freedom from target lesion revascularization (TLR) and target limb amputation (TLA) [17]. The TLR was defined as repeat percutaneous (endovascular) revascularization of a lesion anywhere within the stent or the 5 mm border proximal or distal to the stent due to symptom recurrence and target lesion occlusion. This was treated with angioplasty or stent-to-stent implantation. The TLA was defined as minor or major amputation of a previously stented limb.

The safety outcomes were also retrospectively analyzed. These outcomes were established as a major adverse event (MAE) and were as follows: in-hospital TLA as a result of endovascular procedure complication, periprocedural acute coronary syndrome (ACS), stroke, CHF exacerbation, AKI, or death. The TLA was defined as a minor or major amputation of a previously stented limb during hospitalization within which an endovascular procedure was performed. Post-procedural AKI was defined as an abrupt increase in creatinine blood concentration within 7 days following the endovascular procedure.

Ethics

The study protocol was approved by the local Bioethics Committee of Nicolaus Copernicus University in Torun and the Collegium Medicum in Bydgoszcz, Poland (139/2014). All procedures were conducted in compliance with the Declaration of Helsinki amended in 2000.

Statistical analysis

Statistical analysis was conducted using a licensed version of the statistical software Statistica PL 10.0 for Windows. The normal distribution of the study variables was checked using the Shapiro-Wilk test. The results were mainly presented as the mean \pm standard deviation (SD) or n , %. The statistical significance of differences

between patients needing an end-point procedure and those not needing such a procedure was verified using the unpaired Student *t*-test and Fisher's exact test (Table I). Survival analysis was conducted for the 91 subjects. Cox's F test, the log-rank test in the Kaplan-Meier method for two groups (Figures 1, 2) and Cox proportional hazard analysis were used (Table II).

Results

Ninety-one patients were included. The mean observation time was 544.4 ± 502.9 days. Within this follow-up period, 29/91 (31.9%) subjects needed TLR. Only an additional three patients needed endovascular intervention concerning lesions localized outside the prior implanted stent (target extremity revascularization – TER). Minor

Table I. Clinical data of patients with and without TLR

Parameter	TLR N = 29	TLR-free N = 62	Value of <i>p</i>
Age [years]	63.2 ± 9.5	62.9 ± 8.4	0.86
Gender, male, <i>n</i> (%)	24 (83)	49 (79)	0.68
Smoking, <i>n</i> (%)	14 (48)	33 (53)	0.66
Hypertension, <i>n</i> (%)	19 (66)	44 (71)	0.60
Diabetes mellitus, <i>n</i> (%)	10 (35)	16 (26)	0.40
Dyslipidemia, <i>n</i> (%)	16 (55)	55 (89)	0.0002
BMI [kg/m ²]	25.5 ± 4.8	28.5 ± 4.8	0.14
History of CAD, <i>n</i> (%)	13 (45)	25 (42)	0.78
Past stroke, <i>n</i> (%)	4 (14)	5 (8)	0.43
History of CHF, <i>n</i> (%)	4 (14)	12 (20)	0.48
Creatinine > 2 mg/dl, <i>n</i> (%)	2 (7)	4 (7)	0.97
Claudication distance [m]	101.3 ± 49.7	68.6 ± 46.1	0.10
Critical limb ischemia, <i>n</i> (%)	12 (41.4)	15 (24.2)	0.078
ABI prior to intervention	0.61 ± 0.19	0.59 ± 0.15	0.80
Rutherford category (3/4/6), <i>n</i> (%)	19 (66)/2 (7)/8 (28)	46 (74)/6 (10)/10 (16)	0.44
Lesion level (A-I/F-P/multi-level), <i>n</i> (%)	6 (22)/6 (22)/17 (56)	10 (17)/18 (29)/34 (54)	0.81
Number of levels with hemodynamically significant lesions	1.6 ± 0.5	1.5 ± 0.5	0.34
Target lesion level (A-I/F-P), <i>n</i> (%)	7 (30)/22 (70)	19 (30)/43 (70)	0.99
Target lesion class (A/B/C/D), <i>n</i> (%)	2 (4)/7 (25)/9 (33)/11 (38)	6 (10)/11 (18)/19 (31)/26 (41)	0.76
Occlusion in A-I, <i>n</i> (%)	4 (14)	9 (15)	0.99
Occlusion in F-P, <i>n</i> (%)	22 (79)	38 (61)	0.40
Run-off improvement in BTK arteries, <i>n</i> (%)	6 (20)	19 (30)	0.17
Nitinol self-expanding stent, <i>n</i> (%)	25 (86)	48 (77)	0.63
Number of stents	2.0 ± 0.0	1.4 ± 0.7	0.08
Stent length [mm]	110 ± 60	97 ± 56	0.37
Stent diameter [mm]	6.7 ± 1.2	8.4 ± 3.2	0.59
Post-intervention ABI	0.86 ± 0.29	0.75 ± 0.22	0.38
Post-intervention ABI increase by 0.15, <i>n</i> (%)	17 (59)	46 (74)	0.15
Rutherford category improvement, <i>n</i> (%)	15 (52)	44 (71)	0.32

TLR – patients with target lesion revascularization, TLR-free – patients without TLR, BMI – body mass index, CAD – coronary artery disease, CHF – congestive heart failure, ABI – ankle-brachial index, TASC – Inter-Society Consensus for the Management of Peripheral Arterial Disease; target lesion localization: 1 = aorto-iliac, 2 = femoro-popliteal, 3 = below the knee, 4 = multi-site; number of vascular level affected: lesions in the 1–4 previously enumerated vascular beds; aorto-iliac lesion type according to TASC II: A, B, C, D [1], A-I – aorto-iliac; femoro-popliteal lesion class according to TASC II: A, B, C, D [1], F-P – femoro-popliteal, BTK – below the knee.

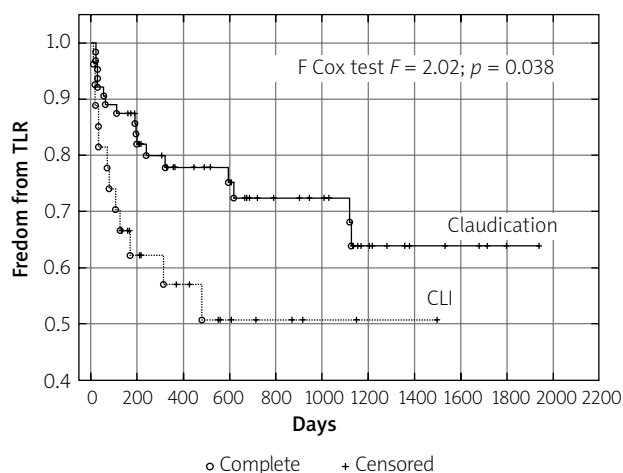


Figure 1. Kaplan-Meier freedom-from-TLR curves for patients with and without critical limb ischemia

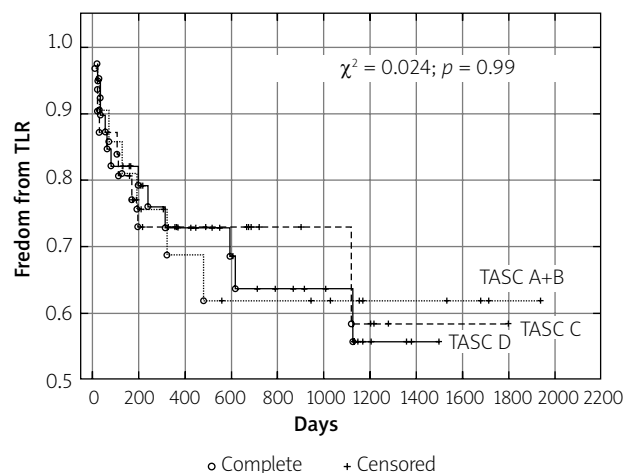


Figure 2. Kaplan-Meier freedom-from-TLR curves depending on the TASC class of target lesion

or major leg amputation was performed in 5 (5.5%) patients. The mean period between the first endovascular procedure and TLR and TLA was 221 ± 304 days and 455 ± 521 days, respectively. The mean time between TLR and TLA was 314 ± 484 days. A comparison of demographic and clinical data for patients who needed TLR and those who did not require it is presented in Table I.

The Kaplan-Meier analysis showed that an effective outcome of endovascular procedures, expressed as freedom from TLR, was significantly better in patients with claudication than in subjects with critical limb ischemia (Figure 1). Lesion class according to the TASC II consensus [1] had no statistically significant influence on the length of time free from TLR (Figure 2). Kaplan-Meier analysis did not reveal any statistically significant effect on TLR risk for the following: number of treated vascular segments; primary lesion severity (stenosis or occlusion); type of stent (expandable or self-expanding balloon); number of stents used; improvement in Rutherford category after the procedure; and an increase in ABI value by 0.15 following the procedure.

Next, the above-mentioned procedural variables were introduced into the survival analysis to assess the factors affecting stent patency during follow-up. The significant Cox regression model showed that the risk of TLR was increased the most (13 times) by the need for intervention in more than one vascular segment (aorto-iliac, femoro-popliteal, peripheral or multi-level) (Table II). Individuals with artery stenting in an aorto-iliac vascular segment had the risk of TLR reduced by approximately 70% compared to infrainguinal intervention (hazard ratio, HR = 0.31; 95% CI: 0.14–0.7; Table II). However, in 27% of the subjects, intervention in a femoro-popliteal segment needed angioplasty of below-the-knee (BTK) arteries at the same time to improve run-off (Table I). The other independent (significant) factors increasing the risk of TLR were: the presence of critical limb ischemia (HR = 5.68),

a rise in aorto-iliac lesion class (HR = 1.96), and, paradoxically, claudication at longer distances. In none of the patients did an established clinical safety end-point occur.

Discussion

This study conducted a retrospective analysis of procedural factors influencing the outcome of endovascular interventions performed in selected patients with chronic leg ischemia. We found that the only factor distinguishing patients with or without TLR was dyslipidemia, which was more prevalent in patients without this end-point (Table I). Moreover, we found that both the period of freedom from TLR and the occurrence of TLR risk were mainly influenced by factors related to the severity of the patients' symptoms (critical limb ischemia vs. claudication, Figure 1) and angiographic lesion localization and advancement (Figure 2). Generally, patients treated due to local lesions, concerning only one vascular segment, especially when it was localized in an aorto-iliac segment of the vascular bed, had better prognoses than subjects with femoro-popliteal and multi-level abnormalities (Table II).

The majority of our observations corroborate the results obtained by other authors [16, 18, 19]. It is known that the stenting of iliac arteries has a better late outcome than for femoral arteries [1]. The effect of endovascular therapy was also better in patients with claudication compared to those with critical limb ischemia and multi-level vascular abnormalities (Figure 1; Table II). Whereas, in our analysis, the influence of stent type and size as well as lesion severity on a TLR-free period (Figure 2) did not achieve statistical significance, this seems to disagree with the majority of studies which showed the importance of stented vessel patency before a procedure (occlusion had a worse prognosis), lesion severity (graded in classes A–D according to the TASC consensus), length and type of implanted stent in relation to freedom

Table II. Cox proportional-hazards regression model for target lesion revascularization (TLR). $\chi^2 = 27.8$; $p = 0.033$

Parameter	β -coefficient	β 95% CI	Value of p	Hazard ratio	Hazard ratio 95% CI
Claudication distance	0.02	0.01–0.03	0.039	1.02	1.01–1.03
Rutherford category	0.25	–0.21–0.72	0.29	1.29	0.81–2.1
Critical limb ischemia	1.74	0.21–3.27	0.026	5.68	1.23–26.2
Lesion localization	–1.17	–1.94–0.40	0.003	0.31	0.14–0.7
Number of vascular segments with significant lesions	2.58	0.82–4.33	0.004	13.14	2.28–75.8
A-I stented lesion TASC class	0.67	0.10–1.25	0.02	1.96	1.1–3.5
Occlusion in A-I	1.21	–0.32–2.74	0.12	3.35	0.73–15.5
F-P stented lesion TASC class	0.35	–0.16–0.87	0.18	1.42	0.85–2.4
Occlusion in F-P	–0.69	–1.89–0.51	0.26	0.50	0.15–1.7
Type of stent	0.18	–1.13–1.49	0.78	1.20	0.33–4.4
Number of stents	0.44	–0.96–1.84	0.54	1.55	0.38–6.3
Stent length [mm]	0.01	–0.01–0.02	0.17	1.01	0.99–1.0
Stent diameter [mm]	–0.01	–0.12–0.09	0.79	0.99	0.89–1.1
ABI of treated limb	3.35	–6.89–13.59	0.52	28.53	0.001–79.6
ABI increase by 0.15 after procedure	0.14	–3.15–3.4	0.93	1.15	0.042–30.9
Rutherford category improvement	–0.61	–1.8–0.58	0.31	0.54	0.16–1.8

TASC – Inter-Society Consensus for the Management of Peripheral Arterial Disease, target lesion localization: 1 = aorto-iliac, 2 = femoro-popliteal; 3 = below the knee, 4 = multi-site; number of affected vascular levels: lesions in the vascular beds previously enumerated 1 to 4; aorto-iliac lesion class according to TASC II: A, B, C, D [1]; A-I – aorto-iliac; femoro-popliteal lesion class according to TASC II: A, B, C, D [1]; F-P – femoro-popliteal; ABI – ankle-brachial index.

from TLR [3, 7, 11]. However, some reports suggest that in the case of subintimal angioplasty, lesion length and the type and diameter of the implanted stent are not as important for late scaffold patency as the presence of a normal vessel above and below the occlusion to allow access [1]. The type of bare metal stent also had no effect on stent patency [1]; patients treated with DEB or DES were not included in this current analysis because we use them only in individuals with ISR.

One of our observations which is worth underlining was the necessity of performing angioplasty of BTK arteries at the time of femoro-popliteal vessel stenting in 25/65 patients (38%) to improve their run-off (Table I). In the study by Bae *et al.* [20], the presence of a dorsal arch (HR = 0.66, $p = 0.047$) and dyslipidemia (HR = 5.81, $p = 0.031$) were significant factors affecting the recurrence of symptoms after endovascular treatment of occlusive femoro-popliteal lesions. Moreover, other studies have shown the importance of BTK outflow quality for the patency of stents implanted into femoro-popliteal vascular segments [1, 21]. In this way, our data and the reference data have shown the necessity for a complete analysis of an angiogram of the whole of the treated leg to verify whether a stent implanted into a femoral artery will have

enough run-off right up to the foot. On the other hand, the data show the importance of protecting BTK arteries against loss of outflow due to periprocedural distal embolization [22].

As with most researchers, we could not avoid some methodological shortcomings that could have influenced the strength of the deductions based on our results. The main limitations of the paper are the retrospective type of analysis, small sample size, and the lack of random selection of patients included in the analysis (potential selection bias). Moreover, such a small number of patients makes it impossible to divide patients according to the level of the stenting performed, whether aorto-iliac or femoro-popliteal, which certainly affects the risk assessment of TLR and TER [1]. However, in spite of these limitations, several analyses have achieved statistically significant results, which allowed us to summarize the outcomes of our center.

Conclusions

The common primary patency of stents implanted into either aorto-iliac or femoro-popliteal vascular segments was 68.1% after a follow-up of at least 1.5 years and was similar to that found in other reports. Freedom

from TLR was significantly shorter in patients with critical limb ischemia. Other factors, including TASC class, expressing both the length and severity of lesions, had no significant effect on the prevalence of this end-point in the study. The independent predictors of TLR occurrence were related to the severity of the disease. None of the analyzed technique- and device-related factors affected the risk in established efficacy and safety outcomes. This suggests the need for a PAD screening program, detailed analysis of leg symptoms, especially for patients with a diagnosis of other cardiovascular diseases, accurate control of atherosclerosis risk factors, and a recommendation for adequate "cardiovascular medication".

Conflict of interest

The authors declare no conflict of interest.

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