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Original Research Article

Factors affecting primary patency of stenting for TransAtlantic Inter-Society (TASC II) type B, C, and D iliac occlusive disease

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ABSTRACT

Background and objective: The purpose of our study was to evaluate 1- and 2-year results and the influence of risk factors on the outcome in the patients undergoing iliac artery stenting for TASC II type B, C, and D iliac lesions.

Materials and methods: In this prospective nonrandomized study conducted between April 15, 2011, and April 15, 2013, 316 patients underwent angiography with a diagnosis of aortoiliac atherosclerotic disease. Of these, 62 iliac endovascular procedures (87 stents) were performed in 54 patients.

Results: The indications for revascularization were disabling claudication (Rutherford 2, 5.9%; Rutherford 3, 35.2%), rest pain (Rutherford 4, 22.2%), and gangrene (Rutherford 5, 16.7%). The overall complication rate was 9.2%. The cumulative primary stent patency at 1 and 2 years was 83.0% ± 5.2% and 79.9% ± 5.8%, respectively. Early stent thrombosis in ≤30 days was detected in two patients (3.7%). The primary patency rates for the stents ≤61 mm at 12 and 24 months were 90.6% ± 4.5% and 86.6% ± 5.8%, respectively; those for the stents >61 mm were 67.7% ± 10.9% and 60.2% ± 12.0%, respectively ($P = 0.016$). The multivariate Cox regression analysis enabled the localization of a stent in both the CIA and the EIA (hazard ratio [HR], 3.3; 95% confidence interval [CI], 1.1–9.5; $P = 0.021$) and poor runoff (HR, 3.2; 95%, CI 1.0–10.0; $P = 0.047$) as independent predictors of decreased stent primary patency.

Conclusions: The localization of a stent in both iliac (CIA and EIA) arteries and poor runoff significantly reduce the primary stent patency. Patients with stents >61 mm have a higher risk of stent thrombosis or in-stent restenosis development.

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1. Introduction

During the last decade, major changes have taken place in the diagnostic and treatment techniques of aortoiliac occlusive disease. Patients who required aortofemoral bypass or endarterectomy in the past now may be the candidates for less invasive procedures, such as balloon angioplasty and/or stenting. Percutaneous transluminal angioplasty (PTA) and stenting are the first methods of choice for the treatment of iliac artery atherosclerotic lesions [1]. As new types of stents and technical developments have been introduced, more extensive and multifocal iliac lesions can be treated with endovascular procedures [2]. The Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) document has been released regarding the optimal treatment of patients with arterial occlusive disease [1]. Lesions in the aortoiliac segment have been categorized according to their localization, extension, and morphology (stenosis vs. occlusion) with implications for their treatment. According to the recommendations of the TASC II document, endovascular management is the method of choice for the treatment of type A lesions. Reconstructive surgery is preferred for type D lesions. Patients with type B and C lesions can be managed by either stenting or bypass surgery, depending on patients' medical comorbidities [1]. In this aspect, the results of iliac stenting for artery occlusions in the early series (before 2005) showed the technical success rates to be from 80% to 85% [3,4]. Since 2005, the technical success rate of type C and type D lesions have been reported to be from 92% to 95% [5,6]. The authors reported 1-year primary stent patency rates to be from 85% to 93% and 5-year primary patency rates from 70% to 80.5% in TASC II type D lesions [7–10]. According to these results, endovascular treatment of iliac artery occlusion can be successfully performed in older patients with severe cardiac pathology as an alternative method to open surgery without vascular prosthesis implantation and the risk of graft infection. Moreover, the risks of surgery are significantly greater than the risks of endovascular treatment, not only in terms of mortality, but also in terms of major morbidity and delay in return to normal activities [1]. In previous studies, authors have reported controversial results of iliac artery stenting patency depending on the localization of stents, the length of iliac artery atherosclerotic lesions, and the degree of limb ischemia before stenting [7,9–12]. The purpose of our study was to evaluate 1- and 2-year results and the influence of risk factors on the outcome in the patients undergoing iliac artery stenting for TASC II type B, C, and D iliac lesions.

2. Materials and methods

Between April 15, 2011, and April 15, 2013, the patients ($n = 316$) underwent angiography with a diagnosis of aortoiliac atherosclerotic disease. Of these, 62 iliac endovascular procedures (87 stents) were performed in 54 patients. The patients were included in the study if their stenotic or occlusive lesion at the iliac arteries was considered suitable for stenting and a successful lesion passage was achieved. All the patients had evidence of chronic limb ischemia classified according to Rutherford. The analysis excluded the patients with TASC II type A lesions, abdominal aorta or iliac artery aneurysms, and extra-anatomic bypasses. The study protocol was approved by Kaunas Regional Biomedical Research Ethics Committee (No. BE-2-16). The patients' demographic data, procedural and lesion-specific factors, outcomes, and complications were defined according to the criteria prepared and revised by the Ad Hoc Committee on Reporting Standards [13,14].

The endovascular procedures were performed in an angiography suite under the control of Innova 350 (GE Medical Systems, USA) by an interventional radiologist. Under local anesthesia, an ipsilateral or a contralateral approach with a 6-French introducer was used depending on the clinical situation. Perioperative anticoagulation with heparin 5000 IU was performed.

The strategy of primary stenting was based on the reports by Vorwerk et al. [15] and Nawaz et al. [16]. Residual stenosis of more than 30% following repeated angioplasty and a flow-limiting dissection were used as additional criteria for stenting, too. Balloon-expandable (BE) stents (Visi-Pro™, EV3 and SCUBA, Medtronic/Invatec) were used preferentially for more focal lesions and severely calcified lesions. Self-expandable stents (PROTEGE™ EverFlex™, EV3; Absolute, Abbott; Misago®, Terumo; MARIS PLUS, Medtronic/Invatec) were usually placed for a long segment diseased or when the contralateral approach for stenting was used. The length of lesions was categorized according to the criteria of the Society of Cardiovascular and Interventional Radiology (SCVIR) [17] and was classified into three categories: lesions of 3–5 cm, lesions of 5–10 cm, and lesions greater than 10 cm in length. After stent implantation, aspirin (100 mg per day) and clopidogrel (75 mg per day) were prescribed for 6 months if no contraindications were detected. After 6 months, aspirin (100 mg per day) was recommended for lifelong use.

The patients were followed up 1, 3, 6, 9, 12, 18, and 24 months after stent implantations. The follow-up was obtained in all the patients and was performed using color Doppler ultrasonography. The clinical assessment consisted of a physical examination, a symptomatic evaluation, and ankle-brachial pressure index (ABI) measurements. The indications for secondary interventions included clinical symptoms associated with a >0.15 decrease in the ABI or detection of stenosis >50% by sonography. In these cases, computed tomography angiography or digital subtraction angiographies were performed.

The following data were identified for each limb: the location of the lesion (common iliac artery [CIA], external iliac artery [EIA], or both), EIA stenosis or occlusion that involves the origins of the internal iliac and/or common femoral artery (CFA), TASC II lesion types, and the status of the ipsilateral superficial femoral artery (SFA) and profunda femoris (PF) (patent, >50% stenosis, or occluded) [1]. Runoff of the ipsilateral SFA or PF stenosed (50%–99%) and occluded were categorized as poor runoff. The demographic data, the patients' risk factors, and all the potentially independent predictors were statistically analyzed and correlated during the outcome. Iliac artery PTA and stent placement were considered technically successful if there was <30% residual stenosis and the brachiofemoral pressure gradient was lower than 5 mm Hg.

The stent primary and assisted primary patencies were defined according to Rutherford et al. [14].

Hemodynamic success and clinical improvement were defined according to the reporting standards of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery [14].

2.1. Statistical analysis

The statistical analysis was carried out with the software of IBM SPSS Statistics 20 (IBM SPSS Inc., Chicago, IL). The quantitative data are presented as the mean and the standard deviation (SD). For testing the statistical hypothesis, the significance level of 0.05 was selected. For comparing the means of two dependent groups, the paired-samples *t* test was used. For testing the statistical hypothesis about the independence of two variables, the chi square test was used. The primary patency and the assisted primary patency were determined with the Kaplan–Meier method and the log-rank test. The Cox proportional hazards model was used for the multivariate analysis to assess the influence of various risk factors on the primary patency. On the basis of the receiver operating characteristic (ROC) method, the prognostic value of the stent length was determined.

3. Results

In total, 54 patients (62 limbs) underwent iliac artery stent (IAS) implantations (87 stents) (Table 1). The patients' demographic and clinical characteristics are shown in Table 2. The number of the lesions in each category was as follows: 13 lesions of 3–5 cm, 45 lesions of 5–10 cm, and four lesions of more than 10 cm. Primary stenting was performed in 41 patients (75.9%) (Fig. 1). Elective stenting was performed for residual stenosis or pressure gradient following PTA in nine patients (16.7%), and a dissection following balloon angioplasty was performed in four patients (7.4%). The mean length of the stents was 57.9 ± 20.0 mm (range, 27.0–120 mm). Sixteen stents were placed in type B lesions (18.4%), 50 stents in type C lesions (57.5%), and 21 stents in type D lesions (24.1%) (Table 3). After stent implantation, 14 additional concomitant surgical procedures were performed: five common femoral artery endarterectomies, seven infrainguinal bypass procedures, and two femoral profundoplasties due to EIA occlusion that involved the origins of the CFA or/and the PF.

The mean follow-up was 15.4 months (range, 0.1–24.0). The ABI significantly increased in all the patients following stenting. The ABI was 0.34 (SD, 0.09) before the procedure and 0.79 (SD, 0.15) following stenting ($P < 0.001$). Early (≤30 days) stent thrombosis was detected in two patients (3.7%): in the first case, a self-expandable stent (7 mm × 80 mm) was implanted in TASC II type C lesion of the EIA; in the second

Table 1 – Iliac artery endovascular procedures and number of stents.

Stents	Procedures	Procedures (%)	Stents (%)
One stent	40	64.5	46.0
Two stents	19	30.7	43.7
Three stents	3	4.8	10.3
Total	62	100	100

Table 2 – Clinical characteristics of patients.

Characteristic	Value, N (%)
Gender	
Male	49 (90.7)
Female	5 (9.3)
Age, mean (SD), years	67.9 (9.9)
<70 years	30 (55.6)
≥70 years	24 (44.4)
Smoking	
Smoke	23 (42.6)
Do not smoke	20 (37.0)
Quit smoking	11 (20.4)
Hypertension	
No	20 (37.0)
Yes	34 (63.0)
Ischemic heart disease	
No	20 (37.0)
Yes	34 (63.0)
Diabetes	
No	52 (96.3)
Yes	2 (3.7)
Symptoms	
Claudication	33 (61.1)
Rutherford Category 2	14 (25.9)
Rutherford Category 3	19 (35.2)
Critical limb ischemia	
Rutherford Category 4	12 (22.2)
Rutherford Category 5	9 (16.7)

Table 3 – Limb-based distribution, characteristics, and procedural factors of 62 stenting (62 limbs treated) procedures for TASC II iliac artery lesions.

Variable	Value, N (%)
Iliac artery disease	
Stenosis	37 (59.7)
Occlusion	25 (40.3)
EIA involvement	
No	19 (30.6)
Yes	43 (69.4)
TASC II stratification of iliac artery lesions	
B	13 (21.0)
C	36 (58.0)
D	13 (21.0)
Runoff of ipsilateral CFA	
Open	57 (91.9)
Stenosed (50%–99%)	5 (8.1)
Runoff of ipsilateral SFA	
Open	27 (43.5)
Stenosed (50%–99%)	7 (11.3)
Occluded	28 (45.2)
Runoff of ipsilateral PF	
Open	60 (96.8)
Stenosed (50%–99%)	2 (3.2)
Occluded	0

EIA, external iliac artery; CFA, common femoral artery; SFA, superficial femoral artery; PF, profunda femoris.

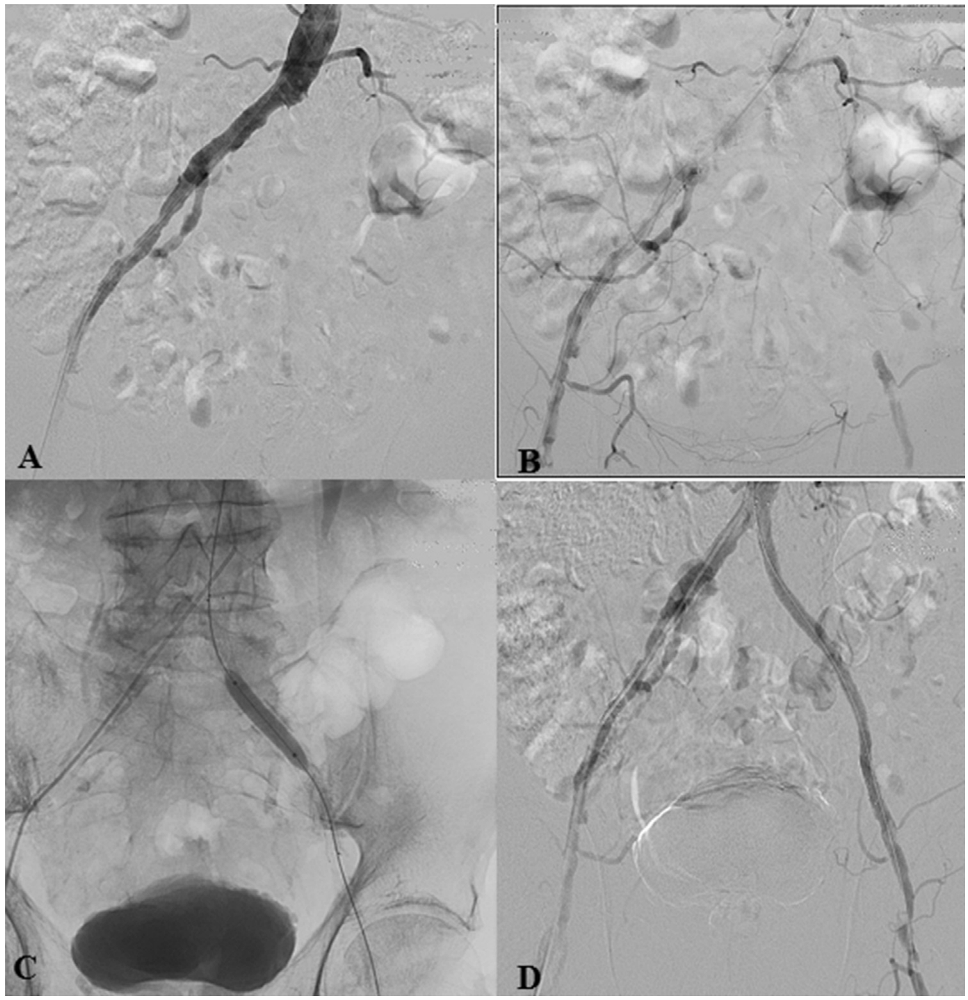


Fig. 1 – Aortograms showing a complete occlusion of the left iliac arteries from aortic bifurcation (A); filling of stenosed left CFA through collaterals (retrograde recanalization, predilatation, and stenting with a self-expandable stent (7 mm × 120 mm) covering the whole lesion were performed) (B); the stent postdilated with the same size balloon (C); and the fully patent left CIA and EIA and stenosis of the patent left CFA (endarterectomy of the CFA was performed after stenting) (D).

case, a self-expandable stent (8 mm × 120 mm) was implanted to treat unilateral occlusion of both the CIA and the EIA (type D lesion). Both patients had rest pain (category 4 according to Rutherford classification). The postprocedural aortograms showed fully patent stents with acceptable runoff vessels in both cases. Thrombectomies using a Fogarty catheter were unsuccessful and unilateral iliofemoral bypass was performed in both cases. Improvement of subjective symptoms was also observed in all the patients. At the end of the follow-up, 36 patients (66.6%) were asymptomatic (Rutherford stage 0); six patients (11.1%) were categorized as stage 1 of atherosclerotic occlusive disease, five patients (9.3%) as stage 2, and seven (13%) as stage 3.

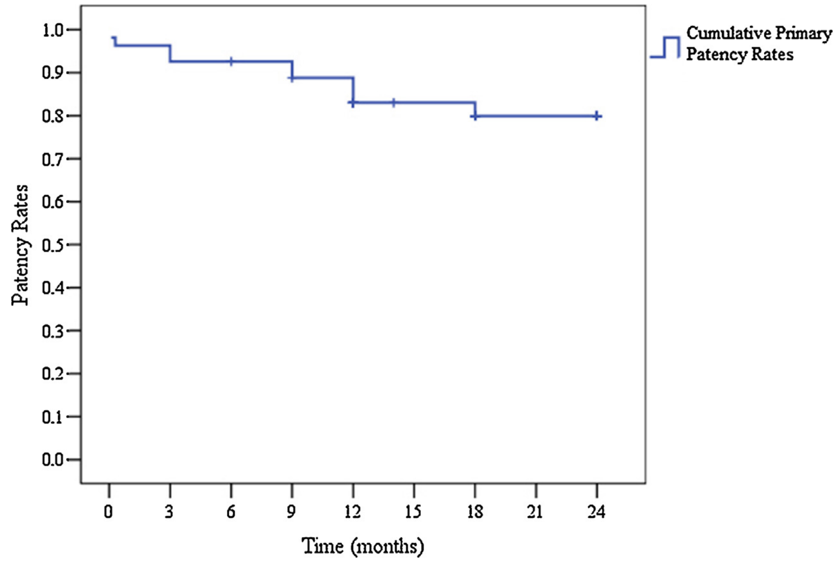
The cumulative primary stent patency at 1 and 2 years was 83.0% ± 5.2% and 79.9% ± 5.8%, respectively (Fig. 2). During the follow-up, five patients died: four patients (after 4, 10, 12.5, and 12.5 months) due to myocardial infarction and one patient (after 13 months) after implantation due to colon carcinoma. In three patients (5.5%), in-stent restenosis (>50%) was detected at 9, 18, and 18 months: one in TASC II type C lesion and two in TASC II type D lesions. These cases were successfully corrected by PTA. The primary assisted stent patency at 1 and 2 years was 87.9% ± 4.6% and 78.2% ± 6.7%, respectively (Fig. 3).

The 2-year stenting primary patency was 79.2% ± 7.2% in the patients with claudication and 77.2% ± 9.3% in the patients with critical limb ischemia (CLI) (Fig. 4).

The stent length had an effect on the primary patency according to the ROC analysis (Fig. 5), with the area under the curve (AUC) of 0.698 for the stent length. The stent length around a 61-mm cut point produced a sensitivity of 58.3% and a specificity of 76.0%.

The primary patency rates at 12 and 24 months were 90.6% ± 4.5% and 86.6% ± 5.8% for the stents ≤61 mm and 67.7% ± 10.9% and 60.2% ± 12.0% for the stents >61 mm, respectively ($P = 0.016$) (Fig. 6).

The intraprocedural complications developed in five patients (9.2%): distal embolization (four patients, 7.4%) was corrected by embolectomy using a Fogarty catheter and a flow-limiting

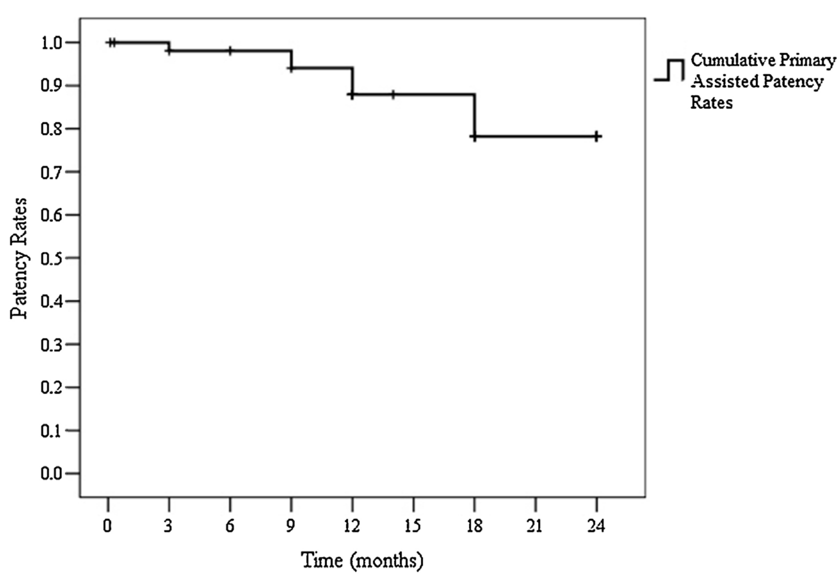


Patients								
N = 54	50	49	46	28	27	13	13	13
SE	0.036		0.043	0.052			0.058	

Fig. 2 – Kaplan–Meier curve estimates for the primary patency rates in the patients treated with iliac artery stenting.

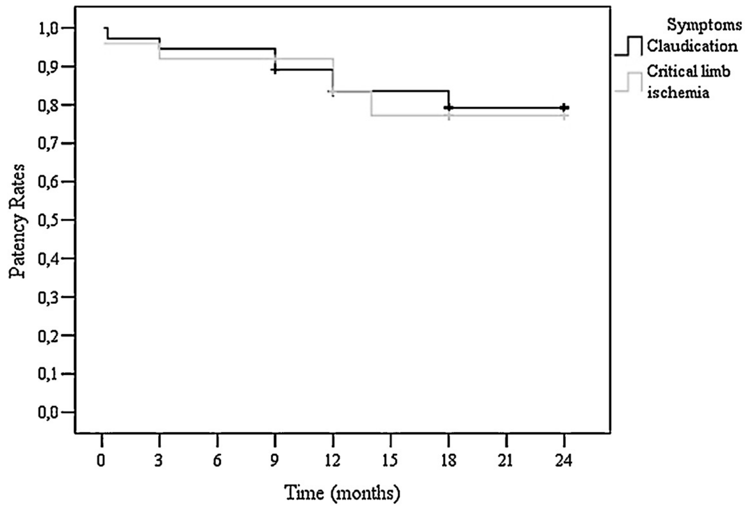
dissection in the distal external iliac artery in one patient (1.8%) was corrected with the placement of an additional stent. Progression of infrainguinal occlusive disease resulted in an above-the-knee amputation 7 and 14 months following iliac stenting in two patients. No stent infections were detected during the follow-up. The univariate analysis showed that poor runoff in the stented limb tended to have a negative impact on the primary stent patency (HR, 2.968; 95% CI, 0.945–9.321; $P = 0.062$). The multivariate analysis showed that the localization of a stent in both iliac (CIA and EIA) arteries and poor runoff significantly decreased the primary stent patency (Table 4).

The multivariate Cox regression analysis showed a higher risk of stent thrombosis or in-stent restenosis development in



Patients								
N = 54	51	49	47	29	27	13	12	12
SE	0.019		0.033	0.046		0.067		
Estimate	0.981		0.941	0.879		0.782		

Fig. 3 – Kaplan–Meier analysis of the assisted primary patency rates in the patients treated with iliac artery stenting.



Breslow $P = 0.947$

Months	3	6	9	12	15	18	21	24
Claudication (Rutherford Category 2+3)								
N = 37	35		33	31		30		
SE	0.037		0.051	0.061		0.072		
Estimate	0.946		0.892	0.836		0.792		
Critical limb ischemia (Rutherford Category 4+5)								
N = 25	23			21	20			
SE	0.054			0.075	0.093			
Estimate	0.92			0.836	0.772			

Fig. 4 – The limb-based Kaplan–Meier curve for the primary stent patency rates depending on the symptoms of limb ischemia.

case of the stents >61 mm (HR, 3.605; 95% CI, 1.143–11.371; P = 0.029).

4. Discussion

In the present prospective study, the primary patency rates following IAS at 1 and 2 years were 83.0% and 79.9%, respectively. Our results are relatively similar to those determined by Moise et al. [18] and Giles et al. [19], who have reported the primary patency rate for 1 year to be 85% and 84%, respectively, with iliac stent placement. Soga et al. [10] have shown the primary iliac stent patency at 1 and 3 years to be 92.5% and 82.6%, respectively. In a recent large-scale prospective multicenter trial BRAVISSIMO, the authors have revealed the primary stent patency rates at 12 months to be 93.1% for the total patient population treated for TASC A, B, C, and D aortoiliac lesions [20].

The morbidity and mortality rates in our study were low with early complication rates 9.2%. No technical defects could be identified in two (3.7%) early stent occlusions. In both cases, the stent was placed in both iliac (CIA and EIA) arteries across the inguinal ligament. Recently, Revuelta Suero et al. [21] have reported 1.9% of early iliac stent occlusions in 99 consecutive patients followed by successful reinterventions. The authors propose the proximity of the device to the inguinal ligament as the most likely cause of reocclusions. Ozkan et al. [9] have reported 7% of early iliac artery stent thrombosis. In our study, primary stenting was mainly performed in the iliac artery lesions of 5–10 cm and longer. Primary stenting has been preferred in most studies of extensive iliac artery lesions because stent placements without predilatation reduce the risk of artery rupture and decrease the risk of distal embolism [5,22,23]. In the present study, distal embolization following stent implantation was detected in four patients (7.4%). Other authors have reported distal embolization range to be from 2% to 13% [24–26].

In our series, we analyzed the influence of the stage of limb ischemia on the iliac artery stenting outcomes. The 2-year stenting primary patency was 79.2% in the patients with claudication (category 2 + 3 according to Rutherford) and 77.2% in the patients with CLI (category 4 + 5 according to Rutherford). Ozkan et al. [9], who analyzed the 5-year stent patency of 118 patients, reported that the primary patency rate was higher in the patients with intermittent claudication than in the patients with CLI (categories 4, 5, and 6 according to

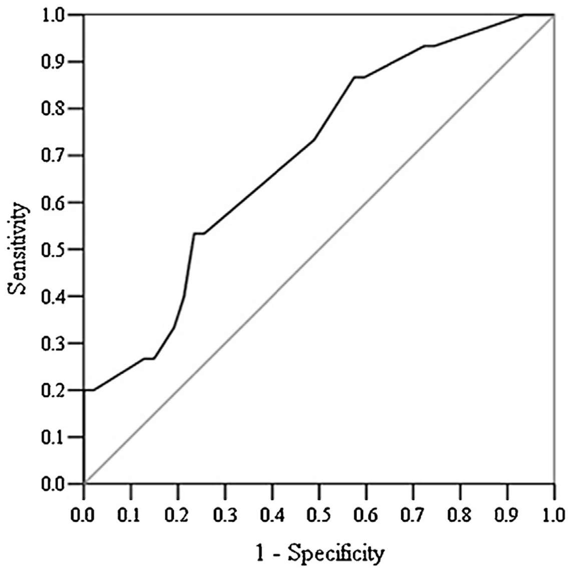
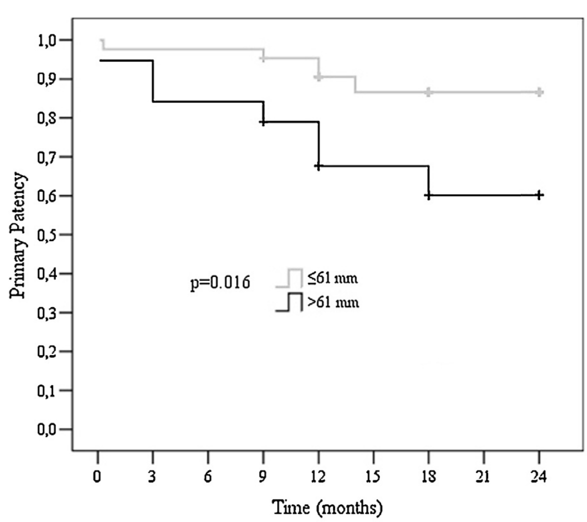


Fig. 5 – ROC curve for the stent by an optimal cut point of stent length 61 mm (sensitivity 58.3%, specificity 76.0%, AUC 0.698).

Rutherford classification) (66% and 31%, respectively, P = 0.002). Nishibe et al. [11] have shown the primary stent patency after two years to be 70%. The stent patency in the patients with claudication was significantly higher compared



Months	3	6	9	12	15	18	21	24
≤ 61 mm								
N = 43	42		41	39	38			
S.E.	0.023		0.032	0.045	0.058			
Estimate	0.977		0.953	0.906	0.866			
> 61 mm								
N = 19	16		15	13		12		
SE	0.084		0.094	0.109		0.12		
Estimate	0.842		0.789	0.677		0.602		

Fig. 6 – Kaplan–Meier analysis of the primary stent patency rates according to the stent length.

Table 4 – Independent factors influencing primary iliac stent patency.

	Coefficient	HR	95% CI	P
EIA and CIA stenting	1.1218	3.381	1.199–9.531	0.021
Poor runoff (SFA and PF)	1.164	3.203	1.018–10.083	0.047

EIA, external iliac artery; CIA, common iliac artery; SFA, superficial femoral artery; PF, profunda femoris; HR, hazard ratio; CI, confidence interval.

with CLI ($P < 0.05$). However, Soga et al. [10], who analyzed 2147 stented iliac arteries after 5 years, found no statistically significant difference in the primary stent patency of claudication and gangrene groups (77.6% and 78.2%, respectively, P = 0.14), which confirms our results.

According to the ROC curve (sensitivity 58.3%, specificity 76.0%, AUC 0.698) in the present study, the stent length of >61 mm had a lower primary patency after 12 and 24 months, $67.7\% \pm 10.9\%$ and $60.2\% \pm 12.0\%$, respectively, in comparison with the stent length of ≤61 mm (P = 0.016). Recently, Revuelta Suero et al. [21] have analyzed 99 consecutive patients with occlusive EIA disease. The stent length around an 80-mm cut point produced a sensitivity of 44.4% and a specificity of 71.1%. The lesion and the stent length did not have any effect on primary patency according to the ROC analysis [21]. Scheinert et al. [27] examined 212 patients and found that the primary patency of iliac artery stents longer than 10 cm was significantly lower compared with stents shorter than 10 cm ($P < 0.05$). However, other authors have not found statistically significant differences in patency rates between the iliac artery stent length and localization [7,8,28,29].

Park et al. [6] analyzed 206 patients with iliac artery stents and found that stent localization in both iliac arteries reduced the primary stent patency (HR, 0.088; P = 0.048), which was also confirmed by the results obtained in the current study (Table 4). However, the multivariate analysis presented by Lee et al. [12] showed that the anatomic localization of a stent did not have a negative impact on the primary iliac stent patency. Timaran et al. [30] in his study demonstrated that the localization of a stent in the external iliac artery reduced the primary iliac artery stent patency (P = 0.007).

According to the data by Timaran et al. [30], stenosed or occluded runoff are independent factors that reduce the iliac artery stenting outcome (P = 0.001). But in our study, the univariate analysis showed that poor runoff in the stented limb tended to have a negative impact on the primary stent patency (95% CI, 0.945–9.321, P = 0.062). Soga et al. [10] examined 2147 patients with iliac artery atherosclerotic lesions, and the univariate analysis showed that poor runoff significantly reduced the primary stent patency at 5 years (HR, 2.05; 95% CI, 1.67–2.52, $P < 0.0001$).

5. Conclusions

Iliac stenting is an effective minimal invasive treatment modality of TASC II type B, C, and D lesions of the iliac artery.

The localization of a stent in both iliac (CIA and EIA) arteries and poor runoff significantly reduce the primary stent patency. Patients with stents of >61 mm in length have a higher risk of stent thrombosis or in-stent restenosis development.

Conflict of interest

The authors state no conflict of interest.

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