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Clinical Research

Long-Term Follow-Up of Endovascular Treatment for Trans-Atlantic Inter-Society Consensus II Type B Iliac Lesions in Patients Aged <50 Years

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Background: To study the initial and long-term results of endovascular treatment in patients aged <50 years with Trans-Atlantic Inter-Society Consensus-II type B unilateral iliac lesions and chronic limb ischemia.

Methods: From January 2000 to February 2010, 60 consecutive endovascular interventions were performed on 23 women and 37 men aged ≤50 years. After successful treatment, all patients were followed up at 1, 3, 6, and 12 months after the procedure and every 6 months thereafter.

Results: Successful percutaneous revascularization of the iliac artery was achieved in 56 patients (93.3%). The early vascular-related complication rate was 6.7%. The primary patency rates at 1, 3, and 5 years were 88%, 59%, and 49%, respectively. Cox univariate analysis revealed that an age range of 45 to 50 years (hazard ratio [HR]: 0.290; 95% confidence interval [CI]: 0.152−0.553; $P = 0.0001$), lower preprocedural ankle-brachial index (HR: 2.438; 95% CI: 1.04−5.715; $P = 0.047$), lesion length >5 cm (HR: 0.838; 95% CI: 0.746−0.943; $P = 0.003$), and diabetes (HR: 2.005; 95% CI: 1.010−3.980; $P = 0.047$) had significant influence on decreasing primary patency.

Conclusions: Endovascular treatment of TASC-II type B iliac lesions in patients aged <50 years is a safe procedure with low procedural risk. Primary patency rates at 1, 3, and 5 years were 88%, 59%, and 49%, respectively.

INTRODUCTION

The Trans-Atlantic Inter-Society Consensus (TASC-I)[1−3] classification was revised in 2007 and expanded in the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC-II) classification.[4] Although endovascular treatment (EVT) should be the preferred treatment for type B lesions, much clinical information such as patient comorbidities, fully informed patient preference, and the local operator's long-term success rates must be considered when choosing between endovascular and surgical revascularization for type B lesions. Most importantly, the current recommendations do not take into account patients' age. Atherosclerotic disease among patients aged <50 years has been considered as premature atherosclerosis.[5] Patients with premature atherosclerosis have a high incidence of risk factors and a poor prognosis after surgical treatment or EVT.[5−7]

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Ann Vasc Surg 2012; 26: 1057–1063
DOI: 10.1016/j.avsg.2011.09.008

Published online: March 12, 2012

Most of the articles on endovascular intervention for iliac artery disease have dealt with older populations; however, reports on endovascular iliac treatment in patients with premature atherosclerosis are limited to a few series.[7,8]

To further elucidate this important issue, in this article, we report 60 consecutive patients aged <50 years who had undergone iliac endovascular reconstruction, with the aim to evaluate the safety, short- and long-term patency, clinical success rates, and predictive risk factors of this type of intervention in patients with premature onset of iliac atherosclerosis.

PATIENTS AND METHODS

Patients

From January 2000 to February 2010, 60 consecutive patients aged <50 years underwent EVT for unilateral iliac artery stenoocclusive disease classified as TASC-II type B iliac lesions, at the Institute for Cardiovascular Disease ''Dedinje'', Belgrade, Serbia. Type B lesion was defined as unilateral common iliac artery or external iliac artery (EIA) occlusion, with single or multiple stenoses involving the EIA. For patients treated before 2007, lesion classification was performed retrospectively by a vascular surgeon blinded to procedural outcome. The patient population consisted of 37 men and 23 women. All patients had evidence of chronic limb ischemia. Patients with arteritis, acute ischemia, aneurysm, and pseudoaneurysm were excluded from this analysis. Preoperative evaluation included clinical examination and ankle-brachial index (ABI). Medical records were reviewed for demographic data, procedural and lesion-specific factors, complications, and outcome variables. These factors were defined according to the criteria prepared and revised by the Ad Hoc Committee on Reporting Standards (Society for Vascular Surgery/International Society for Cardiovascular Surgery).[9,10] Distal runoff score was calculated according to the Committee on Reporting Standards (Society for Vascular Surgery/International Society for Cardiovascular Surgery), which categorizes scores as poor runoff (score >5) and good runoff (score ≤5).[9,10] From 2000 to 2005, we used digital subtraction angiography (Siemens, Erlangen, Germany), and since 2005, multislice computed tomography angiography (Lightspeed VCT, GE Healthcare, Milwaukee, WI) has been used.

Follow-Up and Definitions

During follow-up, patients were examined by the attending surgeon at 1, 3, and 6 months in the first year and every 6 months thereafter. We performed duplex ultrasound scanning in addition to symptom and clinical examination (presence of a palpable femoral artery pulse) in all patients with successful EVT. Indications for repeat intervention included recurring symptoms accompanied by >0.15 decrease in ABI, peak systolic velocity >300 cm/sec, or recurring stenosis (>60%) confirmed by duplex ultrasound or arteriography.[10] All vessel stenoses or occlusions diagnosed using the aforementioned criteria and requiring revisions were considered primary patency failures. Assisted primary patency was defined as patency after reintervention performed on the treated segments to impending occlusion or progression of stenosis. Secondary patency was defined as patency after reintervention performed on the treated segments after occlusion. It is a general policy at our institution that on admission, patients have to sign an informed consent form that allows the use of their data for retrospective analysis. Approval from the local ethical committee for this particular study was obtained.

Endovascular Treatment

The EVTs were performed in the angiography department by interventional radiologists after consultation with the attending vascular surgeon. We performed all procedures using local anesthesia. All subjects received a bolus of 100 IU/kg heparin before treatment. In all procedures, arterial access was obtained from the common femoral artery, with a 5- or 6-F sheath or guiding catheter using an ipsilateral or contralateral retrograde femoral approach. Stent and balloon diameters were determined according to the reference vessel diameter in the vicinity of the lesion. In general, for heavily calcified, fibrotic, or short focal lesions, we used balloon-expandable stents. In case of occlusions, long-segment disease, and tortuous anatomy, as well as in the areas in which there was an abrupt change of vessel diameter, we used self-expanding stents. For the balloon-expandable stents, a stent diameter equivalent to the reference diameter was selected, whereas for other self-expanding stents, a stent diameter 1 mm larger than the reference vessel diameter was chosen. Expansion after stent implantation was performed by adjusting the balloon diameter and inflation pressure to minimize the difference between the arterial wall in the vicinity of the lesion and the stent. Additional expansion was performed in cases of insufficient expansion or insufficient adhesion between the blood vessel wall and stent. After the procedure,

a control angiogram was obtained, and the translesion pressure gradient was recorded. Patients in whom postoperative residual stenosis was <30% and where the gradient across the treated lesion was <5 mm Hg were classified as an initial success.

Concomitant Medications

Acetylsalicylic acid (100 mg/d) and ticlopidine (250 mg twice daily) or clopidogrel (75 mg/d) were administered for >3 days before the procedure. After 2002, dual antiplatelet therapy was administered to all patients for 12 months after the intervention, and continued with acetylsalicylic acid. Patients experiencing side effects, such as bleeding, appetite loss, headache, or palpitation, were treated with a single agent. Statins were administered in 51 of 60 (85%) of patients on discharge. Data regarding cholesterol and triglyceride levels were not systemically collected. On discharge, angiotensin-converting enzyme inhibitors were prescribed in 44 of 60 (73%) patients, and β-blockers were prescribed in 20 of 60 (33%). All patients were advised to quit smoking and to make lifestyle changes as needed (weight management, physical activity, low-cholesterol, and low-sodium diet).

Statistical Analysis

Standard descriptive statistics were used. Kaplan–Meier curves were constructed to assess primary, assisted primary, and secondary patency, as well as to assess survival and limb salvage during the follow-up period. Cox univariate and multivariate analyses were performed to assess predictors of long-term patency, survival, and limb salvage. Patency rates were calculated only for patients in whom initial EVT was successful, whereas mortality and limb salvage rates were calculated for all patients. Individual differences were considered to be statistically significant for $P < 0.05$. SPSS version 16.0 (SPSS Inc, Chicago, IL) was used for all statistical calculations.

RESULTS

Initial Results

Successful percutaneous revascularization of the iliac artery was achieved in 56 patients (93.3%), whereas the percutaneous approach failed in four patients (6.7%) due to the inability to cross the lesion with a wire. Balloon-expandable stents were used in 13 patients, whereas self-expandable stents were used in 31 patients. In two procedures, both self-expanding and balloon-expandable stents were used. A single stent was used in 32 lesions (53%), and 2 stents were used in 14 lesions (23%). Ten patients (18%) were treated with percutaneous transluminal angioplasty (PTA) alone. The mean diameter of balloon-expandable stents was 7.57 ± 1.23 mm, and the mean diameter of self-expandable stents was 8.48 ± 1.41 mm. We used the following balloon-expandable stents: Palmaz Blue stent (Cordis, Warren, NJ), Genesis stent (Cordis, Warren, NJ), Express stent (Boston Scientific Corp, Natick, MA), and Neptun stent (Balton, Warsaw, Poland); and the following self-expandable stents: Wallstent (Boston Scientific Corp, Natick, MA), SelfX stent (Abbot Vascular, Redwood City, CA), S.M.A.R.T. stent (Cordis, Miami Lakes, FL), Bridge stent (Medtronic AVE, Minneapolis, MN), and Jaguar stent (Balton, Warsaw, Poland). Baseline demographic characteristics of enrolled patients, indication for treatment, lesion characteristics, and preoperative ABI are shown in Tables I and II.

No in-hospital deaths occurred. Vascular-related complications that required further surgical treatment included two stent thromboses within 24 hours after the procedure and two groin hematomas. Six patients with early stent thrombosis and unsuccessful EVT underwent secondary bypass surgery, including four iliofemoral and two aortobifemoral bypasses. There were no occurrences of stent infection or distal embolization. Systemic complications were two contrast allergies, one gastrointestinal bleeding, and one acute myocardial ischemia. These complications were successfully resolved in all cases. The median ABI after procedures was 0.97 (range, 0.83–1.0).

Follow-Up Data

The median follow-up period was 50.6 ± 34.2 months. Four patients (6.7%) were lost during the follow-up period. Four secondary endovascular repeat interventions were performed a median of 28 months after the EVT. During follow-up, 18 patients underwent a secondary bypass procedure (aortobifemoral, 12; iliofemoral, 6). Primary patency rates at 1, 3, and 5 years were 88%, 59%, and 49%, respectively (Fig. 1). Primary assisted and secondary patency rates were 100%, 100%, and 85% and 98%, 93%, and 80% at 1, 3, and 5 years, respectively (Figs. 2 and 3). No patient in this series died within the first 30 days of intervention. Six (10.8%) patients died during follow-up: four patients from heart disease and two patients from cerebrovascular disease. Patient survival after 1, 3, and 5 years was 100%, 92%, and 89%, respectively (Fig. 4). Limb salvage was

Table I. Demographic characteristics of enrolled patients

Characteristic	$n = 60$ (%)
Median age	47.4 ± 3.4 yr
Male sex	37 (61.7)
Smoking	54 (90)
HTA	40 (66.7)
HLP	44 (73.3)
DM	25 (41.7)
Family	29 (48.3)
CAD	20 (33.3)
CVD	6 (10)

HTA, hypertension; HLP, hyperlipoproteinemia; DM, diabetes mellitus; Family, family history of atherosclerotic disease; CAD, coronary artery disease; CVD, cerebrovascular disease.

Table II. Indication for treatment and lesion characteristics

Characteristic	$n = 60$ (%)
Claudication	51 (85)
CLI	8 (13.3)
Blue toe syndrome	1 (1.7)
Preinterventional ABI	0.65
Unilateral CIA occlusion	20 (33.3)
Occlusion EIA	17 (28.3)
Single or multiple stenosis involving the EIA	23 (38.3)
Lesion side (left)	36 (60)
Average lesion length (mm)	40.1 ± 10.7
Average target artery diameter (mm)	7.46 ± 1.1

CLI, critical limb ischemia; CIA, common iliac artery; EIA, external iliac artery; ABI, ankle-brachial index.

98%, 95%, and 91% for years 1, 3, and 5, respectively (Fig. 5). When results were analyzed in terms of lesion location, it became evident that the occlusion rate was similar in patients who had EIA and common iliac artery lesions (47% vs. 45%, $P = 0.58$). Primary patency rates for PTA alone at 1, 3, and 5 years were 79%, 51%, and 35%, respectively. Primary patency rates for 45- to 50-year-old patients at 1, 3, and 5 years were 82%, 50%, and 39%, respectively.

During follow-up, 12 patients underwent various cardiovascular interventions: five patients underwent coronary angioplasty; four patients, aortocoronary bypass grafting; two patients, carotid endarterectomy; and one patient, subclavian artery angioplasty.

Although patients were strongly advised to quit smoking on hospital discharge for the index procedure, only 12 of 54 (22.2%) patients quit smoking after discharge, and only 6 of 54 (11.1%) of them were not smoking after 3 years.

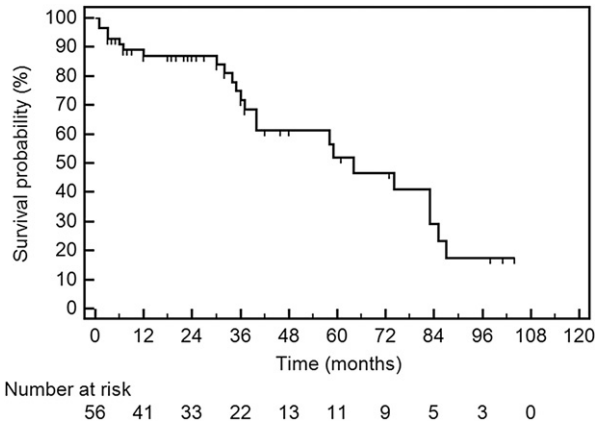

Fig. 1. Kaplan–Meier curves depicting primary patency in the patients with successful EVT.

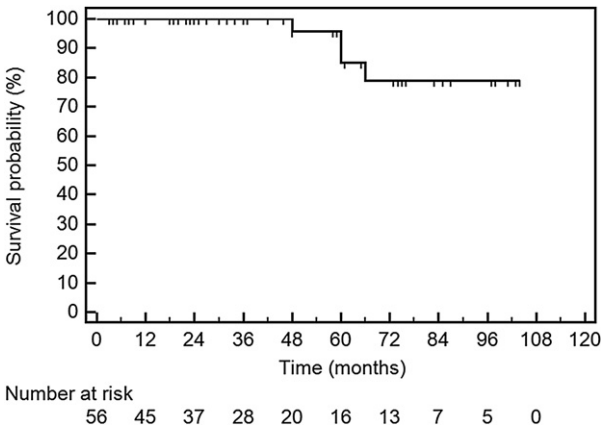

Fig. 2. Kaplan–Meier curves for primary assisted patency.

Predictors of Prognosis

Cox univariate analysis, which included age range (<40, 40–45, 45–50 years), sex, risk factors, indication for treatment, preoperative ABI, poor runoff, stent use, lesion length, target artery diameter, and angiographic findings (stenosis/occlusion), revealed that age range of 45 to 50 years ($P = 0.0001$), lower preprocedural ABI ($P = 0.047$), lesion length ($P = 0.003$), and diabetes ($P = 0.047$) were associated with decreased primary patency. In addition, Cox multivariate analysis showed that an age range of 45 to 50 years ($P = 0.011$) and diabetes ($P = 0.014$) were associated with higher frequency of restenosis (Table III). For limb salvage, Cox univariate analysis, using the same variables, revealed that lower preoperative ABI ($P = 0.027$), critical limb ischemia ($P = 0.011$), and poor runoff ($P = 0.043$) were the independent predictors of reduced limb salvage in patients.

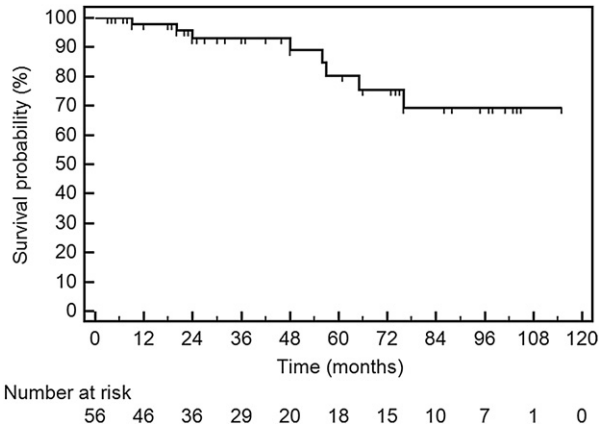

Fig. 3. Kaplan–Meier curves for secondary patency.

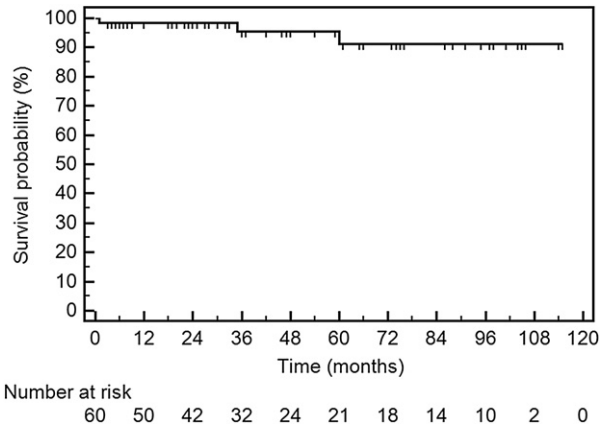

Fig. 5. Kaplan–Meier curves for the limb salvage.

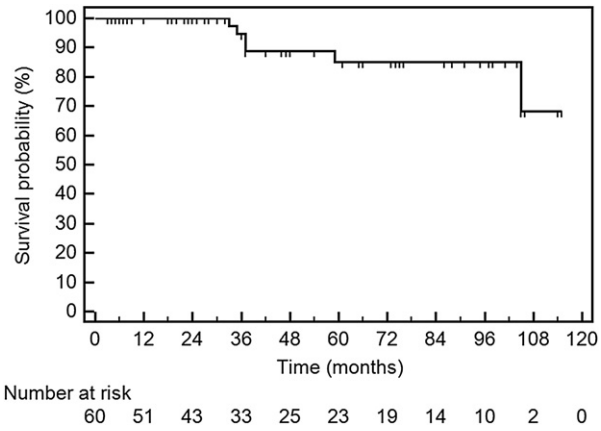

Fig. 4. Kaplan–Meier curves depicting mortality for all treated patients.

DISCUSSION

The main finding of our study is that EVT TASC-II type B iliac lesions in patients aged <50 years have low procedural risk. Primary patency rates at 1, 3, and 5 years were 88%, 59%, and 49%, respectively. Predictors of poor primary patency in our group were age range of 45 to 50 years, lower preprocedural ABI, lesion length >5 cm, and diabetes, whereas only age range of 45 to 50 years and diabetes were predictive of restenosis during follow-up.

Approach to Revascularization

During the past three decades, many techniques have been used for the treatment of aortoiliac stenoocclusive disease. Studies on endovascularly treated iliac occlusions published before 1995 demonstrated a low primary patency rate.[11] In recent years, innovations in endovascular therapy and new types of stents have expanded the use of endovascular procedures to more extensive aortoiliac occlusive disease. Recommendations for the treatment of aortoiliac lesions were given in the TASC-II document,[4] published in 2007, which represents a comprehensive review of management for peripheral arterial occlusive disease. Although general recommendations are given, treatment of type B lesions can vary. In addition, no specific recommendations are given for younger patients, although it is known that the surgical treatment or EVT of patients with premature atherosclerosis is associated with poor long-term results.[6,7] Reed et al.[12] reported significantly higher 5-year primary patency rates after surgical revascularization in older patients: 66% ± 8% (<50 years), 87% ± 5% (aged, 50–59 years), and 96% ± 2% (>60 years), respectively ($P < 0.05$), with no significant differences between the groups in 5-year survival rate. Contrary to the previous study by Reed et al.,[12] Mingoli et al.[13] found similar patency rates after 5 years in patients aged <45 years after aortobifemoral bypass grafting compared with the patients >45 years (81.6% vs. 80%). However, 10-year survival rate was significantly lower in young patients in this series (29.0% vs. 46.9%; $P < 0.005$), which was mainly caused by myocardial infarction among younger patients.

Percutaneous Intervention in Younger Patients

Despite numerous studies on endovascular iliac artery treatment in the literature, only a few series stratify patients with respect to age. Levy et al.[7] analyzed the results of PTA in patients aged <45 years. The study evaluated 32 patients undergoing 53 PTA procedures for treatment of 46 legs with ischemia. PTA was performed in 28 iliac arteries. Of these, 27% experienced no hemodynamic

Table III. Predictors of restenosis after successful endovascular treatment by Cox univariate and multivariate analyses

	Univariate analysis			Multivariate analysis		
Variable	HR	95% CI	*P* value	HR	95% CI	*P* value
Age (category)	0.290	0.152−0.553	0.0001	0.395	0.197−0.808	0.011
Gender (male)	1.880	0.957−3.694	0.067			
Treatment indication	0.801	0.429−1.497	0.487			
Preoperative ABI	2.438	1.04−5.715	0.047	1.062	0.260−4.350	0.212
Poor runoff	0.651	0.244−1.737	0.391			
Lesion length (cm)	0.838	0.746−0.943	0.003	0.971	0.766−1.230	0.805
Target artery diameter (mm)	1.399	0.959−2.041	0.082			
Angiographic findings						
Occlusion	0.768	0.452−1.303	0.327			
Stenosis	0.335	0.106−1.064	0.064			
Risk factor						
Smoking	1.000	0.434−2.307	1.000			
DM	2.005	1.010−3.980	0.047	2.511	1.206−5.227	0.014
HTA	2.025	0.968−4.236	0.061			
HLP	2.071	0.963−4.454	0.063			
Family	0.971	0.492−1.916	0.933			
Stent use	1.658	0.664−4.138	0.279			

ABI, ankle-brachial index; CI, confidence interval; DM, diabetes mellitus; HR, hazard ratio.

improvement, and the 3-year primary patency rate was only 66%. Eight patients required secondary procedures within 1 year of iliac PTA. Similar to our results, Siskin et al.[8] reported the primary patency rates of 86%, 72%, and 65% and the secondary patency rates of 90%, 88%, and 88% at 1, 2, and 3 years, respectively, with iliac artery stents in 42 patients aged <50 years. During the follow-up, 22 (39.3%) of our patients needed repeat endovascular intervention or secondary bypass surgery because of endovascular intervention failure. Similar, previous studies[7,8] reported that patients with premature atherosclerosis have greater need for subsequent repeat reconstruction, either surgical or endovascular.

Predictors of Outcome

Koizumi et al.[14] recently reported that lesion length, pre- and postprocedural stenosis rates, and stent use were significant factors ($P < 0.05$) associated with restenosis after EVT. Timaran et al. reported[15] that poor runoff ($P < 0.001$), female gender ($P = 0.007$), EIA stenting ($P = 0.008$), and history of smoking ($P = 0.04$) negatively affect the patency after EVT of type B and type C iliac lesions. In addition, female gender has also been associated with decreased patency of EIA stents.[16] Also, Gandini et al. found that lesion site ($P = 0.022$) and stent diameter ($P = 0.028$) have a statistically significant influence on primary stent patency.[17] We found that lower preprocedural ABI, age category 45 to 50 years, and lesion length >5 cm were associated with significantly decreased primary patency. Also, similar to Leville et al.'s analyses,[18] patients without diabetes have better primary patency. Our data corroborate the results of other studies[19,20] and reveal that young patients also had high rates of associated atherosclerotic risk factors, including smoking, hypertension, and dyslipidemia. The mortality rate in our study was 11% and 24% at 5 and 10 years, respectively. Results of comparative studies are controversial; some authors found similar survival rates in both the young and older patients,[12,21] and others noted a lower survival rate in the young patients.[13] Most articles report[19,22] that cardiovascular disease is the predominant cause of long-term mortality in young patients with symptomatic lower-extremity atherosclerosis. Similarly, all deaths in our study were caused by cardiovascular disease.

We identified two patients with early stent thrombosis, and both of them were on dual antiplatelet therapy. It is not clear why thrombosis occurred. Possible explanation may include 1) resistance to clopidogrel, and 2) presence of risk factors for thrombosis, such as iliac artery occlusion, subintimal recanalization, and critical limb ischemia. Patients were not tested for clopidogrel resistance, but both of them had iliac artery occlusion and critical limb ischemia. Similarly, Ozkan et al.[23] found that presence of critical limb ischemia ($P = 0.03$), subintimal

recanalization ($P = 0.03$), and major complication ($P = 0.02$) were the independent predictors of early stent thrombosis in patients with iliac artery occlusion. The high rate of secondary surgical procedures in our patient population is due to the general practice in our hospital that in the case of initial failure of endovascular procedure we proceed with surgical revascularization, as it is believed that there is a high probability for the failure of the second endovascular procedure in this setting.

Study Advantages and Limitations

The major advantage of the study is that we report patients from a single center who were treated by only two operators, which allows for a uniform interventional approach. On the other hand, the major limitation of the study is that this was not a randomized trial. Additionally, we have enrolled a relatively small number of patients over a long time interval during which techniques and materials used for a percutaneous approach have significantly changed. Because of the small number of patients, we did not perform subgroup analysis (i.e., PTA alone vs. stent placement).

CONCLUSIONS

EVT for TASC-II type B iliac lesions in patients aged <50 years is a safe procedure with low procedural risk. Primary patency rates at 1, 3, and 5 years were 88%, 59%, and 49%, respectively.

This manuscript was partly funded by grant 41002 given by the Ministry of Science and Technological Development of the Republic of Serbia.

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