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The treatment of complex femoropopliteal atherosclerotic lesions: Conclusions from the unselected patient cohort

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Abstract

Introduction: *Endovascular techniques have revolutionized the treatment of lower extremity artery disease (LEAD). Despite this, the treatment of complex femoropopliteal lesions is a field of debate. This report summarizes the current experience in the treatment of complex femoropopliteal lesions in the author's center.*

Material and methods: *This is a retrospective, observational cohort study of patients with complex (TASC C and D) femoropopliteal lesions. The patients were treated using either endovascular procedure or surgical bypass. Details of the procedure, complications, mortality and amputation rate, primary and secondary patency rates, and reinterventions were analyzed.*

Results: *The study included 201 patients. One hundred thirty patients received endovascular treatment (ET), whereas in 67 a femoropopliteal bypass (FB) was implanted. The hybrid approach was utilized in 4 patients. ET was preferred in primary (88.5% vs. 47.8%, $p < 0.001$), shorter (25 vs. 30 cm, $p < 0.02$), TASC C lesions (63.1% vs. 40.3%, $p < 0.003$). Complications were more common in FB group (26.9% vs. 13.8%, $p < 0.03$). Reinterventions were similar. The postoperative stay was shorter in the ET group (1 vs. 6 days, $p < 0.001$). Primary and secondary patency rates for autologous vein reconstruction were insignificantly higher than for ET. Primary and secondary patency in patients with synthetic bypass was significantly inferior to autologous vein conduit (AVC) and endovascular procedure. The limb salvage at 3 years was highest in the ET group (94.1%) and the difference was significant ($p < 0.04$, and $p < 0.001$ for AVC and synthetic bypass, respectively).*

Conclusions: *ET is preferred in primary and shorter lesions and is related to the shorter postoperative stay. It carries a lower risk of major amputation than surgery. Autologous vein conduit provides highest primary and secondary patency rates. Both treatment options (surgery and endovascular) should be considered in patients with long femoropopliteal lesions to assure the optimal outcome.*

Key words: limb ischemia, TASC classification, endovascular, surgery, results

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Introduction

Though endovascular techniques revolutionized the treatment of lower extremities artery disease (LEAD), long superficial femoral/popliteal artery (SFA/PA) lesions are still recognized as a field of controversy [1]. Some data indicate that the endovascular approach produces less durable results compared to surgical treatment [2, 3]. Many new endovascular technologies emerged in recent years and gained wide acceptance, including

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Table 1. Factors affecting the allocation of patients to the particular treatment group

Surgical bypass	Endovascular procedure
Failed endovascular attempt	Primary intervention
Occlusion after the second endovascular treatment	None/mild calcifications
Severe calcifications	Lack of adequate greater saphenous vein
Perceived low endovascular treatment durability	High-risk surgery (ASA 4)
Uncooperative patient	High risk of infection
Low-risk surgery (ASA 1–3)	

laser excision, mechanical debulking, and drug-coated balloons/stents [4–10]. Also, the experience in the endovascular treatment of long femoropopliteal lesions has grown. Despite the progress in endovascular treatment, many surgeons consider long lesions an indication to surgical management [10, 11]. On the other hand, a physician trained in both operative and endovascular techniques may offer well-tailored, individualized therapy to the patients [12]. In this study, contemporary practice in the treatment of complex femoropopliteal lesions in the author's center is evaluated.

Material and methods

This study was conducted on a cohort of LEAD patients with complex femoropopliteal lesions, successfully revascularized in the authors' center [13]. All patients gave fully informed consent to the offered procedure and were treated according to the Helsinki Declaration. The medical records of all patients with LEAD treated at the author's center between NOV. 2011 and MAR. 2017 were reviewed. Those with complex, femoropopliteal lesions were identified. The following preprocedural data were collected: demography, comorbidities, vascular treatment history, lesion extent, and ischemia severity. Digital subtraction angiography (DSA) and angio-CT images were analyzed to assign the adequate TASC class of the lesion. The outflow compromise was classified according to the number of significantly stenosed/occluded tibial vessels: 0 – no significant stenosis/occlusion observed, 1 – one artery significantly stenosed/occluded, 2 – two arteries significantly stenosed/occluded, 3 – three arteries significantly stenosed/occluded. This classification is reciprocal to the previously published and emphasizes the extent of the disease (the more arteries are involved, the higher is the score) [13]. The treatment plan was individually adjusted, considering the factors listed in Table 1. In complex situations, both treatment options were presented to the patient's decision. The endovascular procedure was conducted according to a standardized protocol. Following local anesthesia (1% lidocaine), the contralateral femoral artery was punctured (preferentially). Angiography confirmed the adequate qualification. At the beginning of the procedure, 50 IU per kilogram of unfractionated heparin (UFH) was administered. After crossing the aortic bifurcation, the operator inserted a 45–55 cm long 6 Fr straight or contralateral sheath (Flexor™, COOK, Bloomington, IN, USA). Then J-wire was exchanged to 0.035" hydrophilic, curved guidewire (ZIPwire™ Boston Scientific, Marlborough, MA, USA or AqWire™, EV3, North Plymouth, MN, USA). A diagnostic 4 Fr catheter (vertebral or modified Bernstein in most cases) was inserted. The subintimal loop technique was utilized to cross the lesion. If the passage was difficult, stiffer 0.014" and 0.018" guidewires (Astato 20 and 30, Asahi Intecc Co. LTD, Japan, or Spartacore, Abbott Vascular, Abbott Park, IL, USA) were utilized. In the case of reentry problems, a collateral-through reentry technique was employed to facilitate the procedure. Reentry devices were not utilized due to the reimbursement restrictions. After the lesion was crossed, it was dilated using a plain angioplasty balloon (in most cases Admiral Xtreme®, Medtronic, Dublin, Ireland). Aggressive dilatation was avoided (the maximal balloon diameter matched the size of the artery below the lesion). If the angioplasty was not sufficient in TASC C lesions, or a TASC D lesion was treated, self-expandable, nitinol stents were always implanted. The maximal oversize was one millimeter, but in the last two years, oversizing was generally avoided. No drug-coated devices were used due to reimbursement restrictions. After the procedure completion, the puncture site was secured by prolonged (6 hours) local compression or closure device (StarClose SE® or Perclose Proglide®, Abbott Vascular, Abbot Park, IL, USA). All patients were prescribed a lifelong statin and acetylsalicylic acid (ASA) (75 mg, once daily) as well as clopidogrel (75mg once daily) for 8 weeks following the procedure.

Patients assigned to surgery had ipsilateral great saphenous vein (GSV) duplex ultrasound (DUS) assessment before the surgery. Veins over 3 mm in diameter, without signs of previous thrombosis or significant focal dilatations/stenoses, were considered suitable. If only

a portion of the vein was adequate for the reconstruction, a combined vein/prosthetic bypass was created. The contralateral GSV was harvested in one patient. If the vein was unsuitable, a synthetic e-PTFE or reinforced e-PTFE bypass (Atrium, Getinge AB, Göteborg, Sweden) was inserted. Following the exposure of the common femoral and popliteal arteries and harvesting of GSV, a bolus of intravenous 50 IU per kilogram of heparin was administered. Then, the bypass was implanted in the conventional end-to-side manner, using continuous polypropylene sutures (Prolene®, Ethicon, Bridgewater, NJ, USA, or Surgilene®, Medtronic, Dublin, Ireland). During the postoperative period, the patients were daily evaluated until discharge. Patients with GSV bypass were prescribed lifetime statins and ASA (75 mg once daily). Those with artificial bypass or redo surgery were recommended a lifelong antithrombotic treatment (warfarin or acenocoumarol in a dose maintaining INR between 2 and 3). Further follow-up comprised of clinical assessment in the outpatient clinic according to the following schedule: 2–3 weeks, then 3, 6, 12 months, and then at 6–9 months intervals. The patients were instructed to report immediately if a sudden deficit of the perfusion occurred (signs of acute limb ischemia or limited walking capacity). During ambulatory visits, details on walking distance, capillary refill, and peripheral pulses were collected. Arterial duplex ultrasound was performed: routinely at 6–12 months interval and if perfusion deficit occurred.

Definitions: The primary patency was defined as the time of freedom from an occlusion/ binary restenosis in the endovascular group and freedom from occlusion/binary stenosis of bypass or its anastomoses. The secondary patency was defined as the time of freedom from a definite target lesion occlusion or a definite bypass occlusion. Binary stenosis/restenosis was defined as a narrowing of the vessel, resulting in a blood-flow speed increase of at least 2.5 times the speed above the stenosis, measured in DUS or over 50% stenosis in the previously treated vessel segment revealed in angio-CT.

Statistics

The following parameters were evaluated: demography, comorbidities, ischemia severity, lesion details, procedures, the hospital stay, periprocedural complications, hospital, and follow-up mortality and amputations, primary and secondary patency rates and reinterventions. Numeric and nominal data were evaluated (mean, median, percentage) and compared using adequate statistical tests (Mann-Whitney test, χ^2 test, Fisher exact test). The distribution of numeric data was assessed using the Shapiro-Wilk test for normality. Primary and secondary patency, as well as limb salvage, were assessed using Kaplan-Maier survival analysis. The analysis of the impact of Rutherford's class, the presence of critical limb ischemia, previous vascular procedures, lesion length, TASC classification, outflow compromise, and complications on the primary and secondary patency was carried out. A relation of the following factors to limb loss was evaluated: age, sex, the critical limb ischemia, Rutherford class, previous vascular procedures, the lesion length, TASC II class, outflow compromise, smoking status, and complications. All analyses were accomplished using Fisher exact, χ^2, and Mann-Whitney tests. The logistic regression model was used to analyze factors correlating with limb survival. The multivariate Cox regression model was used to assess predictor variables for time-dependent outcomes. All multivariate tests were performed using MedCalc Statistical Software version 16.4.3. A p value < 0.05 was considered significant.

Results

Two hundred one patients with long lesions in the femoropopliteal segment (TASC II C and D) treated between N0V.2011 and MAR.2017 were evaluated. One hundred thirty patients received the endovascular procedure, whereas 67 patients were operated (femoropopliteal, below the knee bypasses). In 4 patients, a hybrid procedure was performed. During the analyzed period, an increasing number of endovascular procedures occurred ($p = < 0.001$, χ^2 test for trend). Details of demography, comorbidities, and lesions are presented in Table 2. Some significant differences between treatment groups were identified (hybrid procedures were not considered due to a small number of patients). The prevalence of renal insufficiency and stroke was higher in the endovascular group (EG) (7.7% vs. 0%, $p = 0.017$, and 10% vs. 0%, $p = 0.005$, Fisher exact test), whereas Rutherford 6 ischemia class and previous vascular interventions were more frequent in the surgical bypass group (SB) (25.4% vs. 6.2%, $p < 0.001$ and 52.2% vs. 11.5%, $p < 0.001$, respectively, χ^2 test). The lesions in the FB group were longer (30 vs. 25 cm, $p = 0.015$, Mann-Whitney test), and more severe (type D 59.7% vs. 36.9%, $p < 0.0024$, χ^2 test). Outflow compromise was similar in both groups.

Twelve patients (9.2%) with TASC C lesions received plain angioplasty. Angioplasty with stent implantation was recorded in 118 patients (90.8%). Iliac Complete™ (Medtronic, Dublin, Ireland) and Innova™ (Boston Scientific, Marlborough, MA, USA) were most frequently utilized [71.4%, (142 stents) and 14.1% (28 stents), respectively]. In the FB group, the prosthetic graft was utilized in 42 patients (62.7%), whereas 25 patients received GSV bypass (37.3%). The complications occurred in 36 patients (17.9%). No death was

Table 2. Demography, Rutherford classification, comorbidities and lesion characteristics (only significant differences presented)

	All# % (n)	Endovascular treatment % (n)	Surgical bypass % (n)	p
n	201	130	67	
Age (SD) years	66 (9.2)	66.2 (9.3)	65.5 (9.1)	ns
Sex (%)	73.1	72.3	89.6	< 0.006**
BMI (range)	26 (18–40)	26 (18–40)	28 (18–35)	ns
CAD (%)	32.3	36.9	25.4	ns
Hypertension (%)	61.7	64.6	59.7	ns
DM (%)	37.3	42.3	29.9	ns
AF (%)	7.5	9.2	4.5	ns
COPD (%)	9	9.2	9	ns
Hyperlipidemia (%)	3	2.3	4,5	ns
CRF (%)	5	7.7	0	0.017***
CHF (%)	5.5	6.2	4.5	ns
Stroke (%)	6.5	10	0	0.005***
Cancer (%)	3	3.1	1.5	ns
Hypothyroidism (%)	3.5	3.8	3	ns
Smoker (%)	79.3	76.8	80.6	ns
CLI (%)	64.2	62,3	68.7	ns
Rutherford 3 (%)	35.3	37.7	31.3	ns
Rutherford 4 (%)	25.9	26.9	20.9	ns
Rutherford 5 (%)	26.4	29.2	22.4	ns
Rutherford 6 (%)	12.4	6.2	25.4	< 0.001**
Primary intervention (%)	74.1	88.5	47.8	0.0**
Lesion Length (cm)	27	25	30	0.015*
TASC C	54.2	63.1	40.3	< 0.003**
TASC D	45.8	36.9	59.7	
Outflow compromise				
0	39.3	40.8	37,3	ns
1	26.9	28.5	20.9	ns
2	25.9	23.8	29.6	ns
3	8	6.9	9	ns

including 4 hybrid procedures; !p calculated for endovascular treatment and surgical bypass groups; * Mann-Whitney test; ** χ^2 test; *** Fisher exact test
AF: atrial fibrillation; BMI: body mass index; CAD: coronary artery disease; CHF: chronic heart failure; CLI: critical limb ischemia; COPD: chronic obstructive pulmonary disease; CRF: chronic renal failure; DM: diabetes

recorded during the periprocedural period. The median postprocedural hospital stay was shorter for endovascular patients (1 vs. 6 days, p < 0.001, Mann-Whitney test). Thirty patients (14,9%) were lost to follow-up. The median follow-up was 26 months (range 1–69 months). The mortality rate at follow-up was 9.9% (17 patients) (Table 3.). The causes of death were not related to the vascular procedure: cardiac – 9 patients, advanced cancer – 4 patients, infections, and multiorgan failure – 4 other patients.

Primary patency rate after 12, 24, and 36 months were 55.3%, 43.8%, and 37.6%, respectively. Detailed analysis revealed that primary patency was highest for autologous reconstruction (70.8%, 70.8%, and 60.7% at 12, 24, 36 months, respectively). Results for EG were inferior (59.8%, 46.2%, and 38.1% at 12, 24, 36 months, respectively), but the difference was not significant (p=0.17, log-rank test). Prosthetic reconstruction produced the worst results (35%, 21.3%, and 21.3% at 12, 24, 36 months, respectively) that were inferior

Table 3. The treatment outcomes summary

	All[#] (%)	Endovascular treatment (%)	Surgical bypass (%)	p[!]
Postprocedural stay median (days)	1 (1–77)	1 (1–32)	6 (4–77)	< 0.001*
Complications	17.9	13.8	26.9	< 0.03**
Lost to follow-up	14.9	15.4	14.9	ns
Median follow-up				
in months	26	24	34	0.02*
Occlusion/restenosis at follow-up[+]	52.2	45.8	63.6	0.02**
Reinterventions	28.9	23	38.1	0.03**
Death	9.9	9.1	12.3	ns
Limb salvage	86.2	94.6	70	< 0.001**

[#]including 4 hybrid procedures; !p calculated for endovascular treatment and surgical bypass groups; * Mann-Whitney U test; ** [2]test, [#] including 4 hybrid procedures; [+] at least one incident of occlusion/restenosis

to both autologous graft and endovascular treatment (both p < 0,001, log-rank test). Only complications and grade 3 outflow compromise affected primary patency in multivariate analysis (HR 2.53, 95% CI 1.5–4.29, p < 0.001, and HR 2.59, 95% CI 1.16–5.78, p = 0.02, respectively, Cox proportional hazard regression).

Secondary patency rates after 12, 24, and 36 months were 66.7%, 53.6%, and 41.7%, respectively. The following results were recorded for autologous reconstruction: 74%, 74%, and 68.7% at 12, 24, and 36 months, respectively. Corresponding numbers for EG were 75.7%, 64%, and 54.9% at 12, 24, and 36 months, respectively). The difference was not significant (p = 0.42, log-rank test). Results of prosthetic reconstruction were disappointing (45.3%, 27.3%, and 27.3% at 12, 24, and 36 months, respectively), and significantly inferior to both autologous graft and endovascular treatment (p < 0.005, p < 0.001, respectively, log-rank test). Complications (HR 2.78, 95% CI 1.59–4.86, p < 0.001, Cox proportional hazard regression) and grade 3 outflow compromise (HR 2.48, 95% CI 1.07–5.72, p = 0.03, Cox proportional hazard regression) increased the risk of secondary patency loss. In contrast, primary intervention (HR 0.51, 95% CI 0.29–0.91, p = 0.02, Cox proportional hazard regression) was protective. Reinterventions occurred in 28.9% (52 patients).

Amputation free survival for the whole studied population at 12, 24, and 36 months was 89%, 86.6%, and 86.6%, respectively. The limb survival in the autologous reconstruction patients was 90.6% at 12, 24, and 36 months. Corresponding numbers for EG were 95,4% at 12, and 94,1% at 24 and 36 months, respectively). The difference was significant (p < 0.04, log-rank test). Results of prosthetic reconstruction were inferior to both autologous graft and endovascular treatment (70.4% at 12 months and 63.7% at 24 and 36 months, respectively), and significantly inferior to both (p < 0.008 and p < 0.001, respectively, log-rank test)

Endovascular treatment decreased the risk of limb loss (HR = 0.28, 95% CI 0.14–0.56, p<0.001, log-rank test). Significant relation between major amputation and the following factors was identified in the univariate analysis: CLI (p < 0.001, χ^2 test), type of lesion (p = 0.009, χ^2 test), TASC class (p = 0.03, χ^2 test), outflow compromise (p = 0.04, χ^2 test), prosthetic bypass (p < 0.001, χ^2 test), and complications (p = 0.009, χ^2 test). After multivariate analysis, synthetic bypass (OR 14.18, 95% CI 3.372.4–59.62, p < 0.001, logistic regression), complications (OR 3.51, 95% CI 1.08–11.46, p < 0.04, logistic regression), and noncritical ischemia (OR 0.06, 95% CI 0.007–0.58, p < 0.01, logistic regression) occurred significant (Table 4).

Discussion

Complex femoropopliteal lesions were considered an indication to surgical treatment for a long time. However, a significant treatment shift towards endovascular management is observed recently [14, 15]. The growing experience, new devices and technics, and patient's expectations are changing the landscape of treatment in this challenging area of vascular practice. The material presented above confirms this trend. Endovascular treatment is the first choice therapy in most patients with complex femoropopliteal lesions or burdened with high surgical risk. A femoropopliteal bypass is still an essential tool in the treatment of patients with unfavorable anatomy or expected low endovascular procedure durability. Nowadays, patients are referred to the vascular surgeon late, after previous, often multiple endovascular interventions, with significant

Table 4. The impact of selected factors on major amputations in the univariate and multiple regression analysis (an analysis of 176 patients)

	test	p
Sex	χ^2test	ns
Age	Mann-Whitney test	ns
Noncritical limb ischemia	χ^2test	**< 0.001***
Type of lesion (primary vs. recurrent)	χ^2test	**0.009**
Lesion length	Mann-Whitney test	ns
TASC class	χ^2test	**0.03**
Outflow compromise	χ^2test	**0.04**
Smoking	χ^2test	ns
Synthetic bypass	χ^2test	**< 0.001***
Complications	χ^2test	< 0.001*

* significant factors in the multiple regression analysis

outflow compromise. They frequently suffer from limb-threatening ischemia. All these factors increase the complexity of the surgical intervention. This trend, observed by others, was also clearly discernible in the material presented above [13]. Bypass patients suffered from more advanced (Rutherford 6) critical limb ischemia, had longer and more complex lesions than in the endovascular group. These factors adversely affect the durability of the procedure and increase the risk of treatment failure and limb loss [16–18]. Presented results, even though almost 2/3 of patients suffered from critical limb ischemia, and no drug-coated technology was utilized (national healthcare provider reimbursement restrictions) are encouraging. Treatment outcomes – 54.9% secondary patency rate and 76.1% amputation-free survival at 36 months follow-up – are similar to the results from other centers. Drug-eluting techniques will probably improve the outcomes in the future [19, 20]. Although autologous conduits yield the best primary and secondary patency rates, a frequent lack of suitable vein decreases the value of the surgical treatment [21]. In this series, 37% of patients qualified to surgical management had suitable GSV. Frequent prosthetic graft use negatively affected the limb salvage in the surgical treatment arm.

It must be underlined that prosthetic reconstruction strongly related to limb loss in multivariate analysis. Possibly, collaterals ligation and formation of a scar in the area of surgical access alter the development of collateral circulation and impair blood supply to the foot in case of bypass occlusion. Endovascular procedures leave the collaterals intact in most cases and allow sufficient flow to develop. I believe the reduction in the amputation rate is the key argument in the debate on the optimal treatment of patients with long femoropopliteal lesions.

Significant outflow compromise (grade 3) negatively affected both the primary and secondary patency rates in the presented material. The impact of run-off compromise on the durability of vascular treatment in the femoropopliteal area remains unclear. Published results regarding operative as well as endovascular therapy are conflicting [22–26]. Regarding the results presented above, it seems reasonable to establish patency of at least one tibial artery during the procedure. The strength of this study is that it describes an unselected, "real-world" patient cohort. The only inclusion criteria were anatomic suitability (TASC C and D lesions) and immediate postprocedural success. No exclusions regarding the extent of the disease, the severity of ischemia (Rutherford 3–6), comorbidities, etc., gave a unique insight into the problem of vascular treatment in this demanding cohort of patients. The paradigm of patient-oriented therapy is appreciated. Despite the lack of randomization and possible selection bias, this study is an important voice in the ongoing debate on the best treatment strategy in patients with complex femoropopliteal lesions.

Limitations

A portion of patients (approximately 15%) was lost to follow-up in this study. It is a common situation in studies concerning limb ischemia [11]. The major reason, given during phone contacts, was a disregard of medical advice due to procedure success and lack of ischemia symptoms. Probably, a better education focusing on the impact of the follow-up on the long-term outcome would decrease the number of patients lost to follow-up.

Conclusions

Vascular bypass and endoluminal techniques play complementary roles in the treatment of complex femoropopliteal lesions. The patients with primary, type TASC C lesions are preferentially treated using endovascular techniques. Surgical bypass is preferred in more complex cases and secondary interventions. The results of prosthetic reconstruction yields inferior results to the autologous vein conduit and endovascular management. The endovascular treatment carries a lower risk of major amputation than the surgery. Grade 3 outflow compromise and complications negatively affect the durability of the procedure. The results presented above support the "endovascular first" strategy in the treatment of complex femoropopliteal lesions.

Conflict of interest

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