

Hybrid procedures and femoral endarterectomy in diabetic patients

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Abstract. – OBJECTIVE: The aim of the study is to evaluate the safety and effectiveness of common femoral endarterectomy (CFE) in critical limb ischemia (CLI) associated with proximal and distal endovascular (EV) revascularization in diabetic (type 1 and type 2) and non-diabetic patients.

PATIENTS AND METHODS: We analyzed patients from January 2008 to December 2011 who underwent one-staged hybrid procedures. Patients were divided into three groups: group 1 = EV reconstruction proximal to the CFE, group 2 = EV procedures distal to the CFE, group 3 = both proximal and distal EV procedures. Patients were evaluated at 6 and 36 months after the procedures, and the mean follow-up was 42 ± 20.3 months.

RESULTS: A total of 43 (79% men; aged 74.4 ± 8.6 years) out of 635 (5.5%) patients operated for CLI fulfilled the inclusion criteria; 23 (53.5%) had type 1 or type 2 diabetes mellitus (DM). DM patients were younger than controls ($p = 0.048$). The patient distribution was 14 in Group 1 (32.5%), 24 in Group 2 (55.8%) and 5 in Group 3 (11.7%). CFE was successful in all cases, while associated EV procedures were successful in 90.7% of patients. Peri-operative morbidity and mortality were 11.6% and 2.3%, respectively. Survival rates at 6 and 36 months were 93% and 71.9%, respectively. Three patients (6.98%) underwent a major amputation. The cumulative limb salvage was 95.2% at 6 months and 92.1% at 36 months. No recurrent CFE stenosis was observed. No differences in survival, amputation or patency rates emerged between DM and non-DM patients or among the three EV revascularization groups.

CONCLUSIONS: Hybrid procedures are safe and effective both in CLI patients with or without DM, and they should be taken into consideration whenever indications are present.

Key Words:

Peripheral arterial disease, Diabetic angiopathies, Endarterectomy, Femoral artery, Endovascular procedure.

Introduction

Endovascular (EV) treatment is highly considered as the first option for both iliac and infrainguinal lesions in patients with critical limb ischemia (CLI)^{1,2}. Nevertheless, the femoral bifurcation (FB), one of the most frequent localizations of atherosclerotic disease, continues to be treated successfully with open surgery, even if many authors³ have reported different series of EV treatment of the FB. Common femoral endarterectomy (CFE) alone may not be sufficient to obtain a valid revascularization of the limb because such cases are frequently associated with proximal or distal lesions in patients with CLI; in those patients, correction of multilevel arterial lesions is necessary to obtain an adequate distal blood flow in order to reduce the risk of amputation, especially in diabetic (DM) patients⁴.

Multilevel lesions with FB involvement are traditionally treated with open surgery, but many authors have used hybrid procedures (HP) combining the surgical and EV approaches in order to integrate the effectiveness of traditional surgery with the mini-invasivity of EV revascularization. CFE can be associated with proximal or distal EV procedures⁴⁻⁷. The aim of this study is to evaluate the safety and effectiveness of CFE at the level of the FB in CLI associated with proximal and distal EV revascularization in DM and non-DM patients.

Patients and Methods

Patients

A retrospective data analysis was performed for all patients treated between January 2008 and December 2011 for CLI due to multilevel peripheral arterial disease involving at least the FB. Patients were submitted to one-staged HP

comprising CFE and EV procedures of either the iliac axis, infrainguinal arteries (including the superficial femoral artery, the popliteal artery and the infra-genicular vessels), or both. All the information including patient characteristics (demographic data and risk factors for atherosclerosis), intra-operative details and follow-up were prospectively collected in a computer database (Microsoft Excel®). All patients underwent preoperative evaluation with physical examination, measurement of ankle-brachial pressure index (ABPI), and either duplex ultrasonography (DUS), digital subtraction angiography (DSA) or computed tomography angiography (CTA). Rutherford classification was used to determine the clinical category at the time of presentation, as specified by the reporting standards⁸. Iliac and femoro-popliteal lesions were defined according to the TransAtlantic InterSociety Consensus II (TASC II), but the iliac lesions were classified without considering FB disease; otherwise, all would have been considered as C or D TASC II lesions. Iliac lesions were included in the study only if unilateral⁵.

All the iliac lesions were treated with primary stenting. In the femoral-popliteal-tibial area, angioplasty was always preferred, with stenting reserved for those with inadequate angiographic results, such as in significant residual stenosis or flow-limiting dissections. In those cases, a bailout stenting was performed. Covered stents were not used and intra arterial by pass was not performed.

The patients included in the study were divided into three groups according to the type of planned HP: group 1 included patients who underwent EV procedures proximal to the CFE, group 2 included patients with EV procedures distal to the CFE, and group 3 included patients who underwent CFE with both proximal and distal EV procedures. HP was performed in the operating room with an OEC 9800 system (General Electric Medical Systems, Salt Lake City, UT, USA) under local or general anesthesia at the discretion of the treating physicians. The FB was exposed through a longitudinal inguinal incision. All patients were anticoagulated with standard unfractionated heparin during the procedure. Iliac lesions were crossed before the CFE, as previously described by Dosluoglu et al⁹. In cases involving the femoro-popliteal district, the guide was placed after the CFE but before the patch angioplasty. Open arterial reconstruction preceded EV revascularization in all patients, and all the procedures were performed under continu-

ous blood flow. The guide wire placed before the CFE or patch angioplasty was passed through the patch during the suture.

CFE was performed through a longitudinal arterial incision, and the profunda femoral artery (PFA) itself was always checked and submitted to endarterectomy if necessary. A patch angioplasty was then performed using a vein or polyester patch (Thin Wall Carotid Patches®, Vascutek Terumo, Inchinnan, Scotland, UK) and a running suture closure with Prolene 6.0 (Prolene®, Polypropylene suture, Ethicon, Cincinnati, OH, USA). After the patch angioplasty, one or two 7 French sheaths were placed through the patch upwards and/or downwards depending on the type of EV procedure planned. The Prolene 6.0 suture was placed after removal of the sheaths. Technical success was defined as residual stenosis of less than 30% as demonstrated on intra-operative arteriography. Hemodynamic success was defined as an increase in the ABPI by more than 0.1⁸. According to the American Heart Association, clinical improvement was defined as an improvement by at least one clinical Rutherford category except when actual tissue loss was present, in which case success was defined as an increase of at least two categories¹⁰. Perioperative morbidity and mortality included complications and death occurring within 30 days of the surgical intervention. Primary patency of FB and the reconstructed arterial segment precluded the absence of restenosis or the need of reintervention. Assisted primary patency was defined as a patent artery that required at least one intervention to treat a recurrent stenosis. Secondary patency was defined as an occluded artery that required at least one intervention to restore patency. Failure was defined as the development of recurrent stenosis or occlusion not amenable to EV intervention.

The postoperative surveillance program consisted of clinical examination, ABPI measurement and color duplex ultrasonography at 1, 3, and 6 months and at 6-month intervals thereafter. Patients with reappearance of clinical symptoms, signs of CLI or the presence of a recurrent stenosis > 70% (a peak systolic velocity greater than 2.5-fold) were considered for reintervention.

Survival, patency and limb salvage analyses were performed using the Kaplan-Meier life table method. The differences in survival, limb salvage and patency rates were determined using the log-rank test. The χ^2 -test was used to evaluate the differences among the groups of patients for categorical variables (χ^2 for independent groups,

two-tailed *p*-value). The differences in the ABI and other continuous variables were analyzed using the paired Student's *t*-test. Cox regression analysis was performed to identify patient-related factors predictive of survival as well as primary and assisted primary patency. Statistical significance was assumed for *p*-values < 0.05. Statistical analysis was performed with a computer-based statistical software package (SPSS 21 for OSX, SPSS Inc., Chicago, IL, USA). The local Ethical Committee Institutional Review Board approved the study, and all patients provided informed consent before treatment.

Results

Patients and Procedure

A total of 43 (34 men and 9 women; mean age 74.4 ± 8.6 years) out of 635 (5.5%) patients operated for CLI were considered. Group 1 (EV procedures proximal to the CFE) consisted of 14 (32.5%) patients, group 2 (EV procedures distal to the CFE) included 24 (55.8%) patients and group 3 (CFE with both proximal and distal EV procedures) comprised 5 (11.7%) patients. The incidence of type 1 and type 2 DM in the full cohort was 53.5% (23 patients), with no appreciable differences among the groups. There was no difference between the DM and non-DM population regarding demographic and perioperative characteristics, except for the younger age of the DM patients (72 ± 8.77 vs. 77.15 ± 7.62 years; *p* = 0.048) (Table I).

All patients presented critical limb ischemia; 12 (27.9%) were treated for rest pain (Rutherford 4°), and the remaining patients presented leg necrotic lesions, including 16 (37.2%) at Rutherford 5° and 15 (34.8%) at Rutherford 6° with major tissue loss. Seven (16.3%) patients had a previous vascular procedure on the same leg; 2 of these had received an iliac angioplasty, 1 was submitted to iliacofemoral bypass and 4 had received femoropopliteal angioplasty. To study the lesion morphology, patient legs were analyzed by CTA in 8 cases (18.6%), DSA in 21 patients (48.8%) and DUS in all cases. CFE was performed with vein patch in 3 cases (7%) and with polyester patch in 40 (93%). Fourteen patients (32.5%) were treated by CFE and stenting on the iliac artery (group 1), 24 (55.8%) by CFE plus angioplasties or stenting on femoropopliteal district or tibial vessels (group 2), while EV revascularization was performed both proximal and distal to the CFE in 5 cases (11.7%) (group 3). Most patients were submitted to general anesthesia (32 cases; 74.4%); local anesthesia was used in 4 (9.3%) cases, and epidural anesthesia was preferred in 7 (16.3%) cases.

Immediate Results

CFE was successfully performed in all cases, whereas the EV procedures achieved a technical success rate of 90.7%. Not all EV recanalizations were successful; 4 of the distal cases (9.3%) were a complete failure due to the impossibility of passing the lesion with the catheter. Three cases (two Rutherford 5 and one Rutherford 4) had

Table I. Demographic and surgical data: comparison between the diabetic and non-diabetic populations.

	Diabetic (23)	Control (20)	<i>P</i>
Men, no (%)	17 (73.9%)	17 (85.0%)	0.467
Mean age (y) + SD	72 ± 8.77	77.15 ± 7.62	0.048
RC stage 4°, no (%)	8 (34.7%)	4 (20.0%)	0.179
RC stage 5°, no (%)	7 (30.4%)	9 (45.0%)	0.324
RC stage 6°, no (%)	8 (34.7%)	7 (35.0%)	0.988
HTN, no (%)	17 (73.9%)	16 (80.0%)	0.728
Dyslipidemia, no (%)	8 (34.7%)	8 (40.0%)	0.761
CIHD, no (%)	8 (34.7%)	8 (40.0%)	0.761
CD, no (%)	3 (13.0%)	2 (10.0%)	1.000
COPD, no (%)	4 (17.4%)	4 (20.0%)	1.000
CKD, no (%)	5 (21.7%)	2 (10.0%)	0.420
OT (min) + SD	245.43 ± 62.175	249.00 ± 35.378	0.822
LOS (days) + SD	7.30 ± 5.571	6.20 ± 2.166	0.410

RC, Rutherford classification; HTN, hypertension; CIHD, chronic ischemic heart disease; CD, cardiac dysrhythmia; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; LA, local anesthesia; EA, epidural anesthesia; GA, general anesthesia; OT, operative time; LOS, length of stay.

an improvement of ABPI > 0.3 , and thus other open surgical procedures were not attempted. One patient with an extensive necrotic lesion (Rutherford 6) did not present at intraoperative angiography any distal target vessel to attempt a surgical bypass. This last patient was subsequently submitted to major amputation.

Mean ABPI increased significantly from 0.31 ± 0.042 preoperatively to 0.82 ± 0.167 after re-vascularization ($p < 0.05$). A hemodynamic success rate of 100% was achieved. Only 5 patients (11.62%) had complications; two patients with chronic kidney disease showed kidney function deterioration (without the need for hemodialysis), two had an acute myocardial infarction (AMI), and one had bleeding that required a surgical repair. These complications were successfully managed with appropriate medical or surgical treatments, except for one patient who died from AMI, resulting in a perioperative mortality of 2.3%. Two amputations (4.7%) were performed in the immediate postoperative period; one patient with extensive septic gangrene was submitted to below-the-knee amputation (instead of above the knee) despite successful revascularization. The second amputation is described above. No wound complication, requiring surgical reintervention or prolonged antibiotic therapy, occurred.

Outcome on Follow-Up

None of the patients were lost to follow-up, and 81.4% of patients presented more than two years of follow-up (mean follow-up 42 ± 20.3 months).

During the follow-up, 15 patients died (34.9%) but only 1 from a cause directly linked to surgical intervention (2.3%) after postoperative myocardial infarction. In fact, most of these patients died from stroke or heart attack, due to their high cardiovascular risk (7 AMI, 1 stroke, 1 congestive heart failure, 1 infective pneumonia, 1 septic complication after late amputation, 1 acute renal failure, 1 chronic kidney disease, 1 neoplasia). The survival rates at 6 and 36 months were 93% and 71.9%, respectively (Figure 1).

Regarding the clinical outcome of these patients, and excluding patients submitted to major amputation or those with perioperative death, at the end of their follow-up, 31 of the patients (72.1%) showed no symptoms linked to the peripheral artery disease. In addition, 6 patients (13.9%) presented claudication, and 2 (4.7%) patients presented improvement of the lesion but died before complete lesion healing. The mean clinical improvement, as reported by Pentecost et al¹⁰, was 2.51 ± 0.96 , and

37 patients achieved 3 points, such that their Rutherford score improved by 2 or more points; only 3 (6.98%) patients showed no improvement after the revascularization.

Among all patients, only 3 (6.98%) needed a major amputation after the revascularization. Two of these have been described in the immediate results. The last patient underwent amputation 30 months after recurrence of critical ischemia; the clinical condition of the patient did not allow any revascularization due to myocardial infarction. Therefore, the cumulative limb salvage rate was 95.2% after 6 months and 92.1% at 36 months (Figure 1).

Regarding patency, the primary rate was 85.3% at 6 months and 82.2% at 36 months (Figure 2). The primary assisted patency rate was 90.3% at 6 months and 87.1% at 3 years (Figure 2). In this study, there was no difference between primary assisted and secondary patencies because no patients had a total occlusion of the revascularization. There was no recurrent FB stenosis, occlusion or patch infection in any of the patients during the follow-up period.

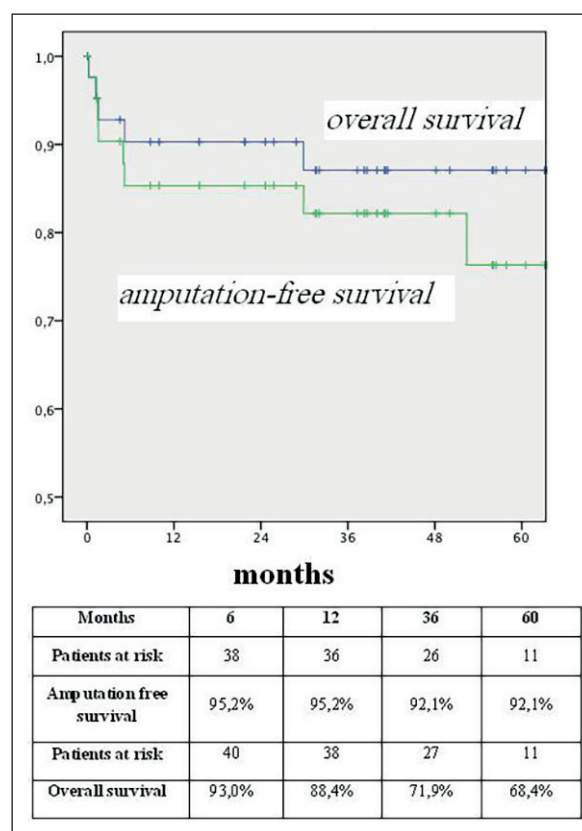


Figure 1. Cumulative overall survival and amputation-free survival.

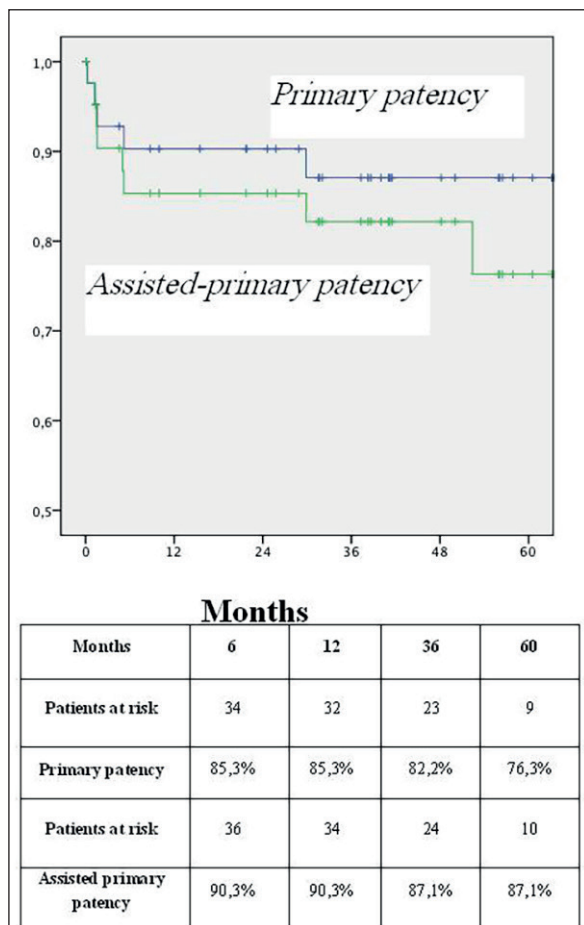


Figure 2. Cumulative primary and assisted primary patencies.

Cox regression analysis was performed for overall survival, primary patency and assisted primary patency but not for amputation because the rate was very low (Table II). The analysis revealed that extensive necrotic lesion (Rutherford 6), cardiac dysrhythmia, CKD and post-surgical complications were independent predictors of decreased survival rate. In addition, primary patency was negatively influenced by femoro-popliteal TASC degree, Rutherford 6 degree and hypertension. Furthermore, Cox regression analysis confirmed Rutherford 6 degree as the main risk factor for the end of primary assisted patency. Regarding mortality ($p = 0.786$), limb salvage ($p = 0.832$), and patency rates (primary patency, $p = 0.621$; assisted primary patency, $p = 0.399$), there were no significant differences among the three groups. The DM and non-DM populations did not differ in mortality ($p = 0.811$; Figure 3), limb salvage ($p = 0.630$; Figure 4) or patency rates (primary patency, $p = 0.495$; assisted primary patency, $p = 0.709$).

Discussion

Atherosclerosis is a multilevel disease, and almost 25% of patients with CLI require multilevel arterial revascularization to improve their poor prognosis¹¹⁻¹³.

Table II. Overall survival, primary patency, assisted primary patency: univariate and multivariate analysis.

	Overall Survival		Primary patency		Assisted primary patency	
	KM (<i>p</i>)	COX (<i>p</i>)	KM (<i>p</i>)	COX (<i>p</i>)	KM (<i>p</i>)	COX (<i>p</i>)
Sex	0.420		0.896		0.334	
Age > 75 years	0.091		0.772		0.474	
Iliac TASC II (A-B vs. C-D)	0.989		0.716		0.915	
Infringuinal TASC II (A-B vs. C-D)	0.262		0.044	0.011	0.034	0.950
RC stage (4 vs. 5-6)	0.053	0.056	0.704		0.606	
RC stage (4-5 vs. 6)	0.856		0.042	0.043	0.014	0.025
HTN	0.506		0.021	0.006	0.259	
Dyslipidemia	0.061		0.091		0.338	
CIHD	0.780		0.616		0.474	
CD	0.004	0.022	0.744		0.486	
COPD	0.024	0.448	0.061		0.141	
Diabetes	0.811		0.495		0.709	
CKD	0.027	0.037	0.297		0.383	
Previous revascularization	0.686		0.569		0.987	
Postoperative complication	0.002	0.003	0.375		0.483	

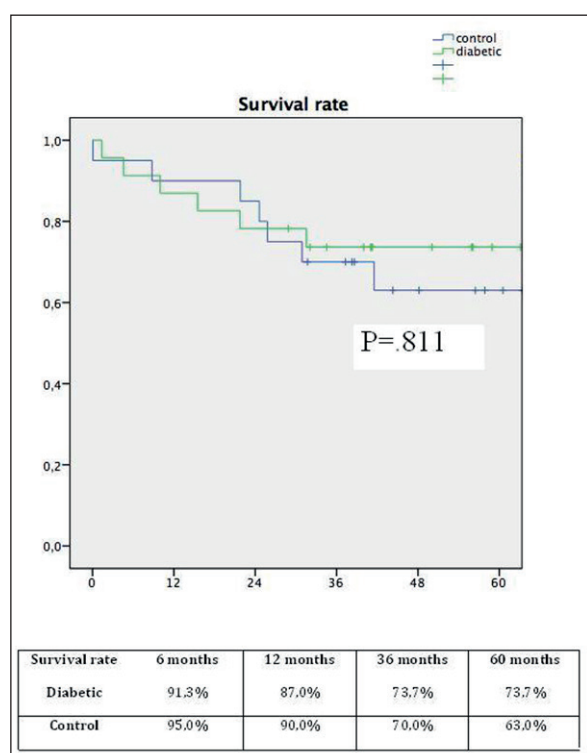


Figure 3. Comparison between overall survival of diabetic and non-diabetic patients.

The aim of multilevel revascularization should be to ensure adequate distal blood flow in the most durable and least invasive manner. Mini-invasivity is necessary because patients with CLI, as evident from this work, are elderly people often affected by many other diseases that lead to a higher perioperative risk. This is also confirmed by the survival rate at three years, which was approximately 70% despite a high rate of clinical improvement (greater than 90%).

CFE provides excellent results in the short- and long-term (technical success in 100% of cases and primary patency greater than 90% at 5 years) and an acceptable invasivity (total complication rate 7.9%), as shown by several authors^{14,15}. The EV treatment of FB has been described in numerous studies, most with small sample sizes. In 1987, Johnston et al¹⁶ showed unsatisfactory results (clinical success rate of 78% at one month with a fall to 58% and 36% at 1 and 3 years, respectively). Bonvini et al¹⁷ showed good results, with a primary patency rate around 65% at 36 months; however, in this study, patients were not affected by CLI but primarily by claudication, and the mean follow-up was less than 12 months. Even new device, such as drug-eluting balloon,

demonstrated worse findings respect CFE and they should be used only in patients not suitable for CFE¹⁸. A systematic review concluded that endovascular intervention of FB disease is associated with a lower patency rate and increased rates of subsequent revascularization procedures. The authors suggested a standardization of the endovascular technique¹⁹. Those previously published results were considerably worse than those obtained in the present study (primary patency rate of 100% if we consider only the FB), which includes a longer follow-up in a selected population of CLI patients. EV treatment failure is likely due to the characteristics of plaques at this level (bulky and calcified with a high risk of recoiling). Furthermore, there is a potential risk of dissection with PFA obstruction and risk of stent fracture due to mechanical stress (typical of anatomical districts with high mobility, such as the groin or knee)^{20,21}. For all these reasons, the EV treatment of FB should be selectively reserved for very specific cases.

FB is the main vascular access for EV procedures, and CFE allows both proximal and distal procedures to be performed with excellent results. This allows the surgeon to perform com-

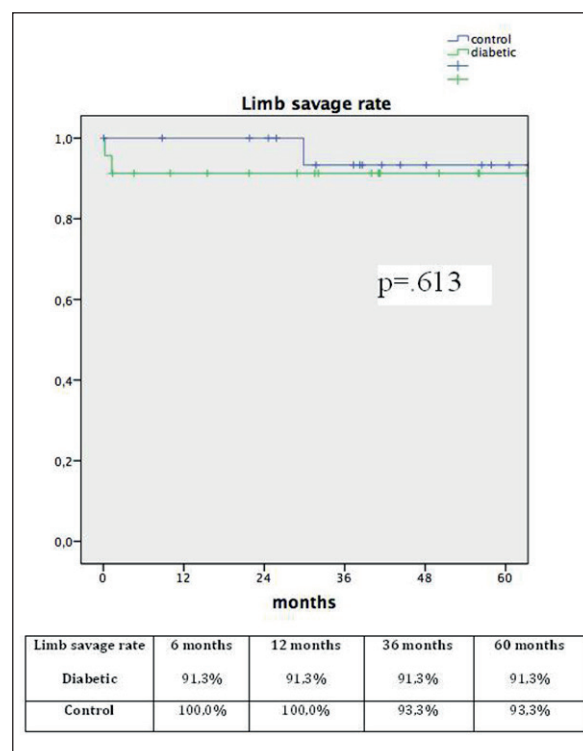


Figure 4. Comparison between limb salvage of diabetic and non-diabetic patients.

plex revascularization through a single groin incision. Even compromised patients at high risk for complex bypass can be treated in a minimally invasive manner. In fact, researches on simultaneous multilevel bypass have shown excellent results in limb salvage but non-negligible mortality and morbidity rates (19% and 61%, respectively)^{22,23}. In contrast, Dougherty et al²⁴ reported a very low mortality and morbidity rate (1.4% and 11%, respectively) in patients treated with hybrid procedures and obtained comparable results for limb salvage. Although the present series included older patients with numerous risk factors, the perioperative mortality and morbidity rates were 2.3% and 11.6%, respectively. CFE was associated with distal and/or proximal EV procedures. The log-rank analysis did not show significant differences among the three groups with regard to patency, limb salvage or survival. This is in contrast to the results reported by Antoniou et al²⁵ in 2009 showing that EV procedures, performed both proximal and distal, obtained worse results, likely due to the increased aggressiveness of atherosclerotic disease²⁵. Compared with other studies^{25,26}, similar but with a shorter follow-up, this study presents analogous results despite a higher mean age and a higher proportion of patients with tissue loss (72.1%). However, the EV failure rate is not negligible, especially for lesions distal to the CFE; despite this, CFE is often sufficient to ensure hemodynamic and clinical improvement for most patients. Despite femoral patch infection is described in literature, this complication did not occur in this series; this could be related to the accurate preparation of the operatory field avoiding any contact of the patch with the skin²⁷. Even major wound complications, the Achilles's heel of the procedure, did not occur and it could be explained by the longitudinal cutaneous surgical incision laterally to the FB that reduces the risk of lymphatic complications²⁸. Even if femoral district disease is not frequently related to DM, good results have been confirmed without differences between DM and non-DM patients^{29,30}. The weaknesses of the study are its retrospective nature and the relatively small number of patients. Nevertheless, the complexity and variety of atherosclerotic lesions make prospective randomized studies extremely difficult. Thus, a retrospective analysis can provide a solid rational basis to validate a technique if presenting good results in a substantial percentage of patients.

Conclusions

Hybrid procedures involving CFE and proximal or distal EV revascularization are safe and effective in patients with DM, as in controls with CLI and multilevel lesions involving FB, and they should be taken in consideration whenever the relevant indications are present.

In the wait for new EV devices capable of effectively treating the entire vascular district of the lower limbs, hybrid treatment in patients with CLI and multilevel lesions can present excellent results in the midterm. Those results must be considered the benchmark for future EV revascularization of the femoral bifurcation.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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