Gender-related outcomes in the endovascular treatment of infrainguinal arterial obstructive disease

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Gender-related outcomes in the endovascular treatment of infrainguinal arterial obstructive disease

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Objective: **The purpose of this study was to retrospectively analyze early and midterm results of endovascular infrainguinal peripheral revascularizations in female patients in our single-center experience, paying particular attention to clinical, anatomic, and technical factors affecting perioperative and follow-up outcomes.**

Materials and Methods: **From January 2000 to December 2010, 258 endovascular interventions for femoropopliteal disease were performed. Interventions were retrospectively divided into two groups: interventions performed in women (80 interventions, group 1) and interventions performed in men (178 interventions, group 2). The two groups of patients were compared in terms of demographic data, common risk factors for atherosclerosis, and comorbidities. Early (intraoperative and <30-day) results were analyzed in terms of technical success, conversion to open surgery, primary patency, secondary patency, and, for patients with critical limb ischemia, limb salvage. The follow-up program consisted of clinical and duplex scanning examinations with ankle-brachial index (ABI) measurement within the third postoperative month, at 6 and 12 months, and yearly thereafter. Follow-up results were analyzed in terms of survival, primary and secondary patency, assisted primary patency, and, for patients with critical ischemia, limb salvage.**

Results: **There were no differences between the two groups in terms of risk factors for atherosclerosis, comorbidities, clinical, and anatomic status. Technical success was 96.9% and technical failure rates were 1.2% in group 1 and 3.9% in group 2 ($P = .2$). Three in-hospital deaths were recorded, all in group 2, whereas in-hospital thromboses occurred in five patients, two in group 1 and three in group 2; with conversion to surgical bypass in all these cases, and in three of the cases, major amputation was necessary (two in group 1 and one in group 2). Cumulative 30-day mortality was 1.1%, with no difference between women (no deaths) and men (three deaths, 1.6%; $P = .4$). Overall amputation rate at 30 days was 1.2%, again with no differences between the two groups (2.5% and 0.6%, respectively; $P = .4$); also, the rate of perioperative thrombosis (overall 2.7%) was similar between the two groups (2.5% and 3.3%, respectively; $P = .9$). Mean duration of follow-up was 17 months (range, 1-85 months). Estimated 36-month survival rates were 95% in group 1 and 84.5% in group 2 ($P = .4$; log-rank, 0.7). Cumulative primary patency rates at 36 months were 38% in group 1 and 42% in group 2 ($P = .4$; log-rank, 0.5). Assisted primary patency at 36 months was 45.1% in group 1 and 60.5% in group 2, whereas secondary patency rates were 63.5% and 76%, respectively ($P = .8$; log-rank, 0.03).**

Conclusion: **Endovascular treatment of femoropopliteal occlusive disease provides similar results between men and women at an intermediate follow-up. There is, however, a trend toward poorer results in women requiring further analysis at a longer follow-up period. (J Vasc Surg 2012;55:105-12.)**

Peripheral arterial occlusive disease (PAOD) in women has been reported to be less frequent than in men[1]; however, arterial occlusive disease in women increases significantly during menopause and after, and the incidence of the disease in women and men in their sixth and seventh decades has been reported to be at least identical.[2] In spite of these evidences, women have been demonstrated to have less peripheral arterial disease (PAD)-related inpatient hospitalizations and procedures than men.[3] As a consequence, it has been difficult to deeply analyze the impact of gender on the results of femoropopliteal revascularizations. The few studies in the literature concerning open surgical revascularization report conflicting data, either supporting equivalent long-term outcomes between men and women[4] or recognizing female gender as a risk factor for adverse outcomes after infrainguinal bypass surgery for limb salvage.[5] When the results of endovascular procedures are examined, the paucity of data becomes even greater: while few data do exist concerning the outcomes of iliac endovascular interventions in females,[6] we are aware of only one previous article reporting gender-related perioperative and follow-up outcomes after infrainguinal peripheral angioplasty.[7]

The purpose of this study was to retrospectively analyze early and midterm results of endovascular infrainguinal peripheral revascularizations in female patients in our single-center experience, paying particular attention to clinical, anatomic, and technical factors affecting perioperative and follow-up outcomes.

METHODS

From January 2000 to December 2010, 505 consecutive endovascular procedures for PAOD in 480 patients

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were performed at our institution. Data concerning these interventions were prospectively collected in a dedicated institutional database containing main anatomic, clinical, diagnostic, and technical variables. This database also contains perioperative (<30 days) results and all relevant clinical and diagnostic data collected during follow-up.

A post-hoc analysis of this prospective database was carried out and 258 interventions performed for femoropopliteal disease in 246 patients were found.

Interventions were retrospectively divided into two groups: interventions performed in women (80 interventions, group 1) and interventions performed in men (178 interventions, group 2).

The two groups of patients were compared in terms of demographic data, common risk factors for atherosclerosis, and comorbidities. Risk factors and comorbidities included arterial hypertension (defined as blood pressure greater than 130/80 mm Hg or the need for antihypertensive drugs), hyperlipemia (defined as triglycerides and cholesterol values >200 mg/dL), coronary artery disease (history of myocardial infarction, angina, previous coronary revascularization), diabetes mellitus (defined as the need for specific drugs), and chronic renal failure (defined as the presence of serum creatinine values higher than 1.5 mg/mL).

Clinical status was defined on the basis of Rutherford's classification,[8] while anatomic characteristics of the lesions were defined on the basis of TransAtlantic Inter-Society Consensus (TASC) II guidelines.[9]

Preoperative diagnostic assessment consisted of ankle-brachial index (ABI) measurement and duplex scanning in all the patients and computed tomography angiography of the aorto-iliac and femoral-popliteal axes in selected cases.

In patients presenting with recent (<14 days) worsening of symptoms or Rutherford class upgrade and the evidence of thrombosis, preoperative catheter-directed thrombolysis with urokinase (Urochinasi Crinos; Crinos SPA, Milan, Italy) was attempted. Thrombolytic treatment was administered in a bolus of 100,000 IU, followed by continuous infusion with a delivery rate of 70,000 IU/hour. In all the patients, 1.000 to 1.500 IU/hour of sodium heparin were administered via the same catheter to maintain values of activated partial thromboplastin time (aPTT) two times higher than normal value.

Angiographic controls were performed daily or more, when necessary, and lytic infusion lasted until patency of occluded vessels was achieved or for a maximum of 3 days when unsuccessful. Thrombolysis was defined successful in the presence of restored patency of the targeted vessel, even in the presence of significant residual stenosis, which was routinely treated at the end of thrombolytic treatment.

All the interventions were performed by vascular surgeons in the operating room in the first period of the experience and then in the angiographic suite, with the patient under local anesthesia, supplemented with intravenous sedation or analgesia when required.

The access to femoral-popliteal axis was gained via an ipsilateral femoral approach in the presence of lesions involving the medium and distal third of the superficial femoral artery and/or popliteal and tibial vessels; when the proximal part of the superficial femoral artery was involved, contralateral access was performed. In cases of complex lesions involving the femoral bifurcation, a hybrid approach was performed in which a surgical femoral endarterectomy with or without patch angioplasty was followed by endovascular treatment of the infrainguinal lesion.

After the placement of the introducer sheath, administration of 5000 IU of intravenous sodium heparin was performed in all the cases.

In superficial femoral artery (SFA) long occlusive lesions, arterial recanalization was achieved in most cases with a subintimal technique followed by angioplasty and stenting. In SFA short lesions, and after an initial intraluminal angioplasty, a policy of self-expanding stenting as a bailout procedure was adopted. In popliteal and below-the-knee lesions, angioplasty was routinely performed and stenting was limited only to selected cases when dissection of the tibial vessels occurred.

Intraoperative and perioperative data included type of access, procedure performed (isolated percutaneous transluminal angioplasty [PTA] or stenting), type, number and length of stents, associated procedures (both surgical and endovascular), concomitant treatment of outflow vessels, and postoperative medical treatment (single or dual antiplatelet therapy, or oral anticoagulants).

Early (intraoperative and <30 days) results were analyzed in terms of technical success (defined as a <20% residual stenosis at completion angiography), conversion to open surgery (defined as technical failure followed by immediate surgical repair), primary patency (defined as uninterrupted patency without procedures performed on or at the margin of the treated segment), secondary patency (defined as restored patency through the original treated segment), and, for patients with critical limb ischemia, limb salvage (defined as the avoidance of above or below-knee amputation).

The follow-up program consisted of clinical and duplex scanning examination with ABI measurement within the third postoperative month, at 6 and 12 months, and yearly thereafter. All studies were performed using an Acuson Sequoia 512 Ultrasound System (Acuson Corporation, Mountain View, Calif) and followed the current guidelines.[10]

Loss of primary patency was diagnosed when ABI deterioration was associated with duplex evidence of significant (>70%) restenosis, requiring or not a secondary intervention to maintain arterial patency, or thrombosis of the treated segment.

Follow-up results were analyzed in terms of survival, primary and secondary patency, assisted primary patency (defined as the success of procedures carried out on a still patent segment to prevent its thrombosis), and, for patients with critical ischemia, limb salvage.

Statistical analysis was performed by means of SPSS 15.0 for Windows (SPSS, Chicago, Ill); early results were analyzed with χ^2 test and Fisher exact test, when necessary.

Table I. Demographic data, risk factors, and comorbidities

	Group 1 (80 int.)	*Group 2 (178 int.)*	P *value*
Median age, years	75.3	71.5	.006
History of smoking	32 (40%)	156 (87.5%)	<.001
Hyperlipemia	49 (61%)	103 (58%)	.7
Arterial hypertension	63 (78%)	134 (75%)	.6
Diabetes mellitus	32 (40%)	71 (39%)	.9
Coronary artery disease	26 (32.5%)	59 (33%)	.9
Chronic renal failure	5 (6%)	15 (8.5%)	.7

Int., At time of intervention.

Table II. Clinical and anatomic status

	Group 1 (80 int.)	*Group 2 (178 int.)*	P *value*
Rutherford classification			
Class 3	40 (50%)	105 (59.5%)	.1
Class 4	15 (19%)	30 (17%)	.7
Class 5	23 (29%)	38 (21%)	.3
Class 6	2 (3%)	5 (2.5%)	.8
TASC II classification			
Type A	14 (17.5%)	29 (16%)	.6
Type B	22 (28%)	45 (25%)	.5
Type C	18 (22.5%)	53 (30%)	.1
Type D	26 (32%)	51 (29%)	.8

Int., At time of intervention; *TASC,* TransAtlantic Inter-Society Consensus.

Follow-up data were analyzed by life-table analysis (Kaplan-Meier test) and results in the two groups were compared by means of the log-rank test. Univariate and multivariate analysis (Cox regression) of the factors affecting primary and secondary patency in the whole group were performed. In Cox regression analysis, the factors with statistical significance at univariate analysis were included. Statistical significance was defined as a *P* value less than .05.

RESULTS

Demographic data, clinical, and anatomic status. There were no differences between the two groups in terms of risk factors for atherosclerosis and comorbidities, except for a higher percentage of smokers and past-smokers among men. Patients in group 1 were significantly older than patients in group 2 at the time of intervention (Table I). Interventions were performed for critical limb ischemia in 40 cases (50%) in group 1 and in 73 cases (40.5%) in group 2 ($P = .1$), while the remaining patients had severe intermittent claudication. Also, the kind of arterial lesions was similar in terms of TASC II classification; in group 1, 44 patients (55%) had TASC II C and D lesions, while the corresponding value in group 2 was 58% (104 patients; $P = .6$). Rutherford and TASC II classifications in both groups are reported in Table II. Overall mean preoperative ABI was 0.42 (SD 0.23), and it was similar in group 1 and 2 (0.42 ± 0.23 and 0.43 ± 0.23, respectively; $P = .7$).

Operative details. In the whole study group, percutaneous contralateral femoral access was used in 190 cases; 47 patients had percutaneous ipsilateral femoral access, while one patient had percutaneous brachial access. In 20 interventions, the ipsilateral open surgical femoral approach was used. Female patients had more frequent contralateral access (68 cases, 85%) than male patients (122 cases, 68.5%; $P = .02$); in male patients, ipsilateral access was more frequently used (41 cases, 23%) than in female patients (six cases, 7.5%; $P = .04$). Open surgical femoral approach was used in six women (7.5%) and in 14 men (8%; $P = .8$). The distribution of the treated arterial segments is reported in Table III.

The lesions were successfully crossed in all but five cases, one in group 1 and four in group 2.

Isolated PTA was performed in 34 cases in group 1 (42.5%) and in 61 cases in group 2 (34%; $P = .4$); in the remaining 158 cases, one or more stents were placed. The mean number of placed stents was 1.2 ± 1.3 in group 1 and 1.3 ± 1.2 in group 2 ($P = .7$); the mean length of treated arterial segments was 100.8 ± 81 mm in group 1 and 130 ± 75 mm in group 2 ($P = .08$). Twenty different types of commercially available stents were used; in 130 cases, nitinol stents were used, and in 12 cases, a steel stent was used, whereas the remaining 16 patients had a covered stent placed. There were no differences between men and women in the distribution of the different kinds of placed stents (Table III).

In 24 patients (eight in group 1 and 18 in group 2) with recent symptom impairments and angiographic evidence of femoropopliteal occlusion, intra-arterial thrombolysis with urokinase was performed. Mean duration of thrombolytic treatment was 60 hours (range, 24-72 hours) and thrombolysis was successful in all but two cases. All the patients were treated with PTA with or without a stent of the targeted lesion within 24 hours from the cessation of urokinase administration.

Concomitant open surgical interventions were performed in 21 cases, six in group 1 and 15 in group 2 ($P = .8$). In the 20 patients who had a surgical femoral approach, the intervention consisted of femoral endarterectomy and patching; one adjunctive male patient with critical limb ischemia had the concomitant open repair of an 8-cm abdominal aortic aneurysm.

In 27 cases (five in group 1 and 22 in group 2; $P = .2$), an associated endovascular procedure of the iliac arteries (in all but one case ipsilateral) was performed; four of these patients, all in group 2, were among those undergoing femoral endarterectomy.

Postoperative medical treatment consisted of dual antiplatelet therapy in 206 cases and of single antiplatelet therapy in 39 cases; in 13 patients who took oral anticoagulant before the procedure, the therapeutic regimen was continued also after the discharge. There were no differences between the two groups in terms of postoperative medical treatment.

Perioperative and early (<30 days) results. Technical success was 96.9%. As already mentioned, in five cases (one in group 1 and four in group 2), it was not possible to cross the lesions. In three of these patients, surgical bypass was

Table III. Technical details

	Group 1 (80 int.)	*Group 2 (178 int.)*	P *value*
Treated arterial segments			
Superficial femoral	38 (47.5%)	78 (44%)	.2
Superficial femoral and popliteal	9 (11%)	23 (13%)	.7
Superficial femoral, popliteal, and tibial	27 (33.5%)	54 (30%)	.8
Isolated tibial	6 (8%)	23 (13%)	.09
Angioplasty alone	34/80 (42.5%)	61/180 (34%)	.4
Type of stent			
Nitinol	39/45 (86%)	91/113 (80%)	.6
Steel	3/45 (7%)	9/113 (8%)	.8
Covered stent	3/45 (7%)	13/113 (12%)	.6

Int., At time of intervention.

performed (immediate in two patients and delayed in one); the remaining patients (one man and one woman) refused the surgical option and were medically managed. Three adjunctive male patients had intraoperative thrombosis of the treated arterial segment and also underwent surgical bypass (immediate in two cases and delayed in the remaining one). Technical failure rates were 1.2% in group 1 and 3.9% in group 2 ($P = .2$).

Three in-hospital deaths were recorded, all in group 2, in two cases due to acute myocardial infarction and to acute respiratory failure in the other one. In-hospital thromboses occurred in five patients, two in group 1 and three in group 2; conversion to surgical bypass was performed in all these cases, and in three cases, major amputation was necessary (two in group 1 and one in group 2). All the patients who had an amputation had been operated on for critical limb ischemia. One male patient developed a pseudoaneurysm of the contralateral common femoral artery used for the access and underwent open surgical repair.

At 30 days, neither adjunctive thromboses nor deaths were recorded. Cumulative 30-day mortality was 1.1%, with no difference between women (no deaths) and men (three deaths, 1.6%; $P = .4$). Overall amputation rate at 30 days was 1.2%, again with no differences between the two groups (2.5% and 0.6%, respectively; $P = .4$); also the rate of perioperative thrombosis (overall 2.7%) was similar between the two groups (2.5% and 3.3%, respectively; $P = .9$).

Follow-up results. Mean duration of follow-up was 17 months (range, 1-85 months); 216 of the 233 patients (93%) who had technical success had regular postoperative follow-up visits.

During follow-up, 13 new deaths occurred, four in group 1 and nine in group 2. The cause of death was cardiac in eight cases and cancer in two cases; one patient suffered from fatal acute respiratory failure, one patient died of an acute accidental overdose of psychotropic drugs, and in the remaining case, the death was caused by a car accident. Estimated 36-month survival rates were 95% (SE 0.02) in group 1 and 84.5% (SE 0.05) in group 2 ($P = .4$; log-rank 0.7).

Significant restenosis of the treated vessel occurred in 29 cases in the whole study group, 12 in group 1 and 17 in group 2. In all but six cases, the restenosis was successfully treated with new endovascular procedures, in 11 cases with PTA, in five cases with stent placement, and in seven cases with cutting-balloon. In the remaining patients, the restenosis was asymptomatic and they were medically managed without developing occlusion or clinical impairment during follow-up.

Fifty-one new thromboses were recorded during follow-up, 18 in group 1 and 33 in group 2. Patients with thrombosis were medically managed in 17 cases; a new endovascular procedure was performed in 28 cases, whereas six patients had direct conversion to open surgical bypass. In 12 of the 28 patients who had endovascular reinterventions, further reinterventions for the development of novel restenoses or occlusions were required (one more in five cases, two more in four cases, and three more in three cases). In four of these patients, conversion to open surgery was necessary.

Five new amputations occurred, one in group 1 and four in group 2, all in patients operated on for critical limb ischemia; in one male patient, the amputation was performed in spite of the patency of the treated arterial segment due to the wide extension of leg and foot ulcers.

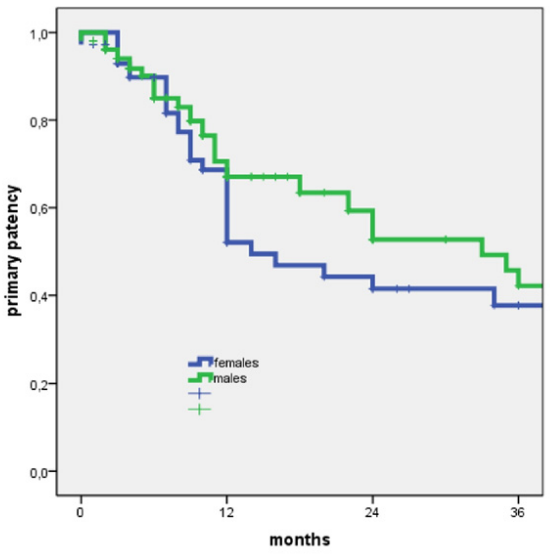
Cumulative primary patency rates at 36 months were 38% (SE 0.07) in group 1 and 42% (SE 0.07), in group 2 ($P = .4$; log-rank 0.5; Fig 1).

Assisted primary patency at 36 months was 45.1% (SE 0.08) in group 1 and 60.5% (SE 0.07) in group 2 ($P = .2$; log-rank 1.1; Fig 2), while secondary patency rates were 63.5% (SE 0.09) and 76% (SE 0.07), respectively ($P = .8$; log-rank 0.03; Fig 3).

Thirty-six-month freedom from any (open or endovascular) reintervention rates were 52.5% (SE 0.07) in group 1 and 51% (SE 0.08) in group 2 ($P = .7$; log-rank 0.2); the rates of conversion to surgical bypass at 3 years were 14.9% (SE 0.08) and 10.8% (SE 0.04), respectively ($P = .6$; log-rank 0.3).

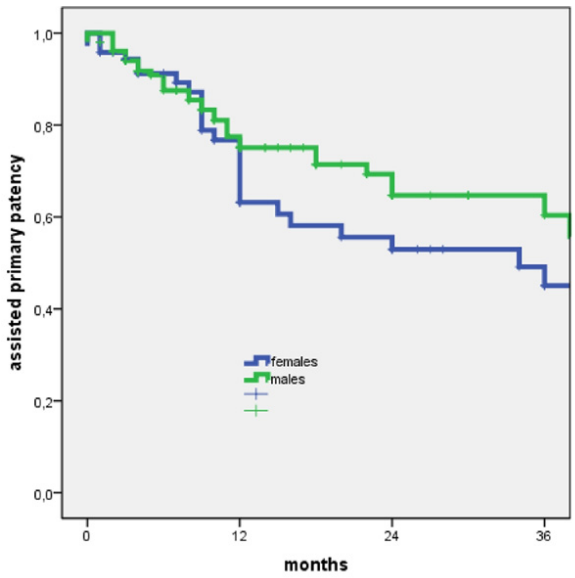
In patients with critical limb ischemia, limb salvage rates at 36 months were 79% (SE 0.1) and 91% (SE 0.05), respectively ($P = .7$; log-rank 0.2).

At univariate analysis, the presence of critical limb ischemia and of TASC II C and D lesions were found to



Months	0	12	24	36	S.E.
Group 1 – females (n. at risk)	73	28	15	8	7,7
Group 2 – males (n. at risk)	156	59	26	12	7,3

Fig 1. Kaplan-Meier curve for primary patency during follow-up with numbers of patients at risk and standard error (*SE*).



Months	0	12	24	36	S.E.
Group 1 – females (n. at risk)	73	33	19	11	8,2
Group 2 – males (n. at risk)	156	64	29	14	6,8

Fig 2. Kaplan-Meier curve for assisted primary patency during follow-up with numbers of patients at risk and standard error (*SE*).

significantly affect long-term primary patency; at multivariate analysis, only the presence of C and D lesions had statistical significance (Table IV); as far as secondary patency is concerned, the presence of critical limb ischemia, of TASC II C and D lesions, and the use of stents were found to significantly affect it at univariate analysis, while at multivariate analysis, only the presence of C and D lesions and the use of stents maintained their significance (Table V).

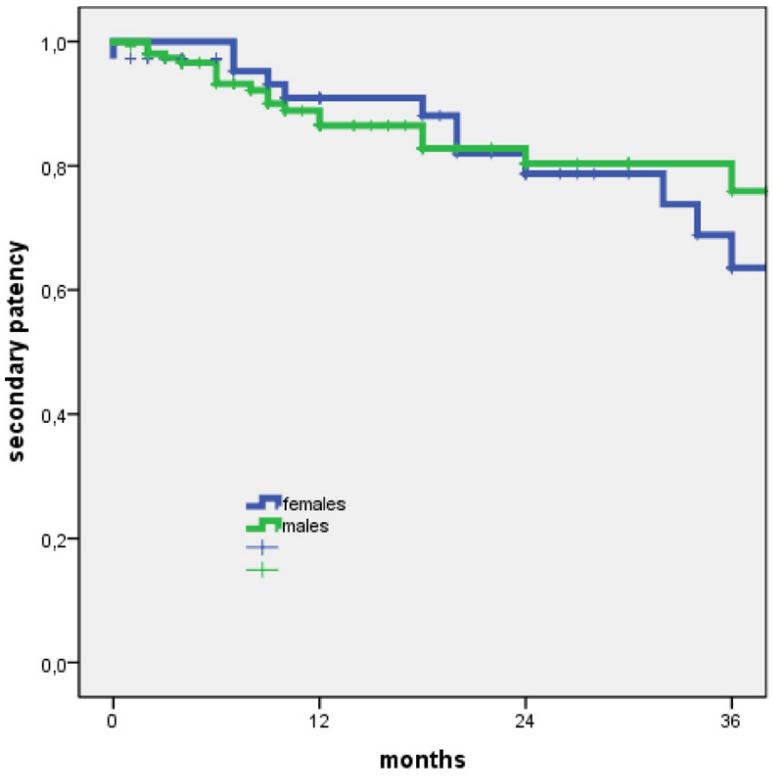
DISCUSSION

Gender-related outcomes periodically turn out in the scientific community and women are often considered at higher risk of perioperative adverse events in different vascular districts.[11,12]

In the everyday practice, it is well recognized that the treatment of vascular lesions in women, particularly if they are diabetics, is often challenging and technically demanding, requiring skill and experience to treat them uneventfully.

Despite this anecdotal example, gender-related results in patients affected by PAOD are reported in a conflicting way. Nguyen et al[5] investigated the role of race and gender in a large trial enrolling patients with critical limb ischemia undergoing femoropopliteal bypasses with vein. They concluded that the synergism between the two investigated factors could have led to worse outcomes in black female subjects. On the other hand, in their review analyzing the results of surgical infrainguinal revascularizations, Harthun et al[4] found contradictory reported results in women. In fact, most of the examined studies were retrospective analysis from a single institution and, unfortunately, the majority of those studies compared dissimilar patient group: only two studies compared men and women who had no significant differences regarding age, smoking history, and incidence of diabetes. In spite of these limits, the authors concluded that there did not seem to be significant differences between men and women regarding the most important outcome measurements (limb salvage, graft patency, and mortality).

In recent years, the introduction and wide diffusion of endovascular techniques has been changing the paradigm of treatment of PAD, and endovascular surgery currently allows the treatment of patients who once would have been probably excluded from any possibility of revascularization. For this reason, an endovascular approach has been suggested as the first-line therapy in most patients, even if the recently published bypass versus angioplasty in severe ischemia of the leg trial[13] raised some concerns about the long-term durability of endovascular procedures. A direct consequence of this increase in endovascular procedures is the reduction of gender-related disparities in the treatment and outcomes of PAD, leading to an overall improvement of results also in women.[3] In spite of this fact, however, there are few data in the literature analyzing the influence of gender on the results of endovascular treatment of PAD. A recent revision of a large multistate database[3] analyzed the rate of in-hospital mortality after endovascular interventions and found a significant higher mortality in women than in men, even in the presence of significant improve-



Months	0	12	24	36	S.E.
Group 1 – females (n. at risk)	73	38	24	12	9,5
Group 2 – males (n. at risk)	156	73	33	17	6,2

Fig 3. Kaplan-Meier curve for secondary patency during follow-up with numbers of patients at risk and standard error (*SE*).

Table IV. Univariate and multivariate analysis of factors affecting primary patency in the whole group

	Univariate analysis				*Multivariate analysis*		
	Log-rank	P *value*	*95% CI*	*OR*	*95% CI*	*OR*	P *value*
Female gender	0.5	.4	0.7-1.8	1.1			
Chronic renal failure	1.7	.4	0.3-1.8	0.8			
Diabetes	1.7	.4	0.1-1.8	0.4			
Critical limb ischemia	3.3	.05	0.9-2.3	1.5	0.7-1.8	1.1	.5
TASC C-D vs A-B lesions	9.6	.002	1.2-3.3	2	1.1-3.3	1.9	.01
Stent placement	0.9	.3	0.7-2	1.2			
Treated limited to the SFA	0.4	.5	0.5-1.3	0.8			
Single vs double antiplatelet treatment	2.5	.09	0.8-3.4	1.6			

CI, Confidence interval; *OR,* odds ratio; *SFA,* superficial femoral artery; *TASC,* TransAtlantic Inter-Society Consensus.

ments of the results during the years; however, the analysis did not separate between aortoiliac and femoropopliteal localizations and other main outcomes (such as patency and limb salvage rates) were not considered in the results. The same limits are present in another monocentric study,[14] where women were not found to have a significantly higher perioperative mortality in comparison with men; however, women had a greater than 10-fold higher risk of hemorrhagic complications. Finally, Timaran et al[6] found that the female gender was among the independent predictors of poor outcome after iliac stenting in patients with anatomically complex lesions, suggesting a persistent role for open

Table V. Univariate and multivariate analysis of factors affecting secondary patency in the whole group

	Univariate analysis				*Multivariate analysis*		
	Log-rank	P *value*	*95% CI*	*OR*	*95% CI*	*OR*	P *value*
Female gender	0.02	.8	0.5-2	1			
Chronic renal failure	0.9	.6	0.2-4.5	1			
Diabetes	1.6	.3	0.1-3.4	0.5			
Critical limb ischemia	6.8	.009	1.2-4.7	2.3	0.9-4	1.9	.06
TASC C-D vs A-B lesions	7.6	.006	1.3-6.3	2.8	0.9-5.3	2.2	.05
Stent placement vs PTA	5.9	.01	1.1-9.5	3.3	1.2-10.4	3.6	.01
Treated limited to the SFA	0.1	.7	0.4-1.7	0.8			
Single vs double antiplatelet treatment	3.4	.07	0.2-3.8	0.9			

CI, Confidence interval; *OR,* odds ratio; *PTA,* percutaneous transluminal angioplasty; *SFA,* superficial femoral artery; *TASC,* TransAtlantic Inter-Society Consensus.

surgery in this setting. Also, in our previous report on endovascular management of iliac stenosis and occlusion, we found an increased risk of thrombosis in female patients at univariate analysis, even if this rate was not statistically significant.[15]

In this study, we have analyzed the effect of gender on the results of endovascular procedures in patients with infrainguinal disease, and, to the best of our knowledge, there is only one other article in the literature making such an analysis. In fact, DeRubertis et al[7] compared the results of 447 endovascular procedures performed in women with those obtained in 553 procedures performed in men.

In our series, female patients were older than the male patients at the time of the intervention, and this is a common finding in the literature,[3,7,16] whereas men more frequently had a history of smoking. No other significant differences were found in terms of comorbidities, risk factors, or clinical and anatomic status between the two groups, even if there was a trend toward a higher percentage of patients with critical limb ischemia among women, similarly to what was reported in the article from DeRubertis et al.[7] Also, the technical details and the intraoperative strategy did not differ between the two groups, thus guaranteeing the homogeneity of the groups and the reliability of our results. Perioperative and early results were satisfactory, with an excellent rate of technical success and significant hemodynamic improvement in both groups; men had a trend toward poorer technical success rates, while women had a higher percentage of perioperative amputations. Of interest is the observation that both women with perioperative thrombosis underwent major amputation, while this occurred in only one of six men. This finding could suggest that the rescue of acutely thrombosed segments is more difficult among women; however, the limited number of events does not allow us to draw any firm conclusion in this sense.

Follow-up results demonstrated satisfactory primary, assisted primary, and secondary patency rates, with no statistical difference between the groups. These results are similar with those in other series,[7] where no differences in terms of primary and secondary patency and limb salvage rates between women and men were reported, even though women tend to present with more severe infrainguinal occlusive disease than men. Also the rates of amputations and conversions to surgical bypass were similar in our series, suggesting the safety and the effectiveness of the endovascular approach also in women. However, even if primary and assisted primary patency rates did not reach a statistical significance, there was a trend for poorer primary and assisted primary patency rates in women (possible type 1 statistical error). One can suppose that at a longer follow-up time with a larger number of patients and events, this difference becomes significant, suggesting the need for deeper and longer analysis.

As expected, subgroup analysis demonstrated that the anatomic complexity of the lesions is the main predictor of follow-up outcomes; interestingly, the use of a stent was associated with poorer secondary patency rates during follow-up. The explanation of this result is difficult; although several studies suggested the benefit of stenting in comparison with PTA alone in early and long-term outcomes,[17] a recent article from Robinson et al[18] did not report any correlation between procedural characteristics and secondary patency rates in patients undergoing repeated endovascular procedures. Our observation, however, seems to confirm what most surgeons can observe in their everyday practice, that it is really difficult to deal with thrombosed stents at the femoropopliteal level.

This study has several limits; it is a retrospective monocentric study, with a limited number of patients and events, and a still short mean follow-up time. On the other hand, in our opinion, its strength lies beyond the novelty of the topic, also in the clinical and anatomic homogeneity of the two groups, allowing a significant comparison between them.

CONCLUSIONS

Endovascular treatment of femoropopliteal occlusive disease provides similar results between men and women at an intermediate follow-up. There is, however, a trend toward poorer results in women, requiring further analysis at a longer follow-up period.

AUTHOR CONTRIBUTIONS

Conception and design: RP, CP
Analysis and interpretation: WD, RP

Data collection: AF, GP
Writing the article: WD, RP
Critical revision of the article: DA, WD
Final approval of the article: CP, RP
Statistical analysis: WD, AF
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Overall responsibility: CP

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