

Comparison of Long-Term Outcome after Endovascular Therapy versus Bypass Surgery for Superficial Femoral Artery Disease

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Abstract

Background: Recent advances in endovascular therapy (EVT) have increased its utility in the management of peripheral artery disease. We assessed long-term outcomes after EVT versus bypass surgery for superficial femoral artery (SFA) lesions.

Methods: Revascularization procedures for SFA lesions were performed in 107 limbs (52 limbs undergoing bypass surgery and 55 limbs undergoing EVT) at our facility between January 2007 and December 2015.

Results: The average period of postoperative monitoring was 41.9 months and 31.1 months in the bypass and EVT groups, respectively. Risk factors were similar when comparing the two groups. In the bypass group, TransAtlantic Inter-Society Consensus (TASC) II type C/D lesions were present 47 limbs (90.4%). In the EVT group, type A/B lesions were present in 54.2 limbs (98.2%). The primary patency rates at 1 and 5 years were 84.1% and 62.8%, respectively, in the bypass group and were 68.0% and 49.7%, respectively, in the EVT group ($p=0.127$). The secondary patency rates did not significantly differ between the two groups, either.

Conclusion: There was no statistical significance between the bypass and the EVT groups with regard to long-term patency. In both groups, revision was sometimes required, so postoperative care is important.

Keywords: Peripheral arterial diseases; Endovascular therapy; Bypass surgery

Introduction

Minimally invasive endovascular therapy (EVT) has recently been applied for the management of arteriosclerosis obliterans (ASO) with good clinical results. Short-term outcomes are also good when this strategy used for inguinal artery lesions (e.g., superficial artery lesion), but long-term results may not be as good as for those with bypass surgery [1,2]. The goal of the present study was to analyze long-term outcome after EVT versus bypass surgery for superficial femoral artery (SFA) disease.

Materials and Methods

Subjects

A total of 107 limbs (86 patients) underwent revascularization for SFA lesions at our facility between January 2007 and December 2015. All patients had Fontaine stage \geq II symptoms (intermittent claudication) preoperatively. Patients undergoing revascularization were divided into two groups (bypass or EVT), with 52 limbs (43 patients) undergoing bypass surgery (bypass) and 55 limbs (43 patients) undergoing EVT.

Data

Sex, patient age at operation, smoking status, and comorbidities (e.g., hypertension, diabetes mellitus, ischemic heart disease, cerebrovascular disease, hyperlipidemia, hemodialysis, and atrial fibrillation) were recorded. Patient symptoms were identified and classified according to Fontaine stage. Ankle-brachial pressure index (ABI) for each patient was recorded preoperatively and at early and late postoperative time points. Lesion characteristics identified on diagnostic angiography were reported in accordance with the TransAtlantic Inter-Society Consensus (TASC) II classification [3].

Treatment strategy

Revascularization procedure was selected according to the TASC II classification. EVT was selected for TASC II type A/B lesions, and bypass surgery was selected for TASC II C/D lesions.

Bypass surgery techniques

All procedures were performed under general anesthesia. The common femoral artery and popliteal artery (above knee) were exposed. After systemic heparinization, arteries were clamped. Artificial vascular graft or saphenous vein graft (in-situ or reversed) was used with bypass graft. Bypass graft was performed in a side-to-end anastomosis to the native common femoral artery and popliteal artery using 5-0 or 6-0 polypropylene sutures in a continuous fashion. If, intimal hypertrophy was present at the anastomosis site, endarterectomy was added. After anastomosis, angiography was sometimes performed to evaluate the bypass graft.

EVT techniques

The procedure was performed under local anesthesia. Vascular access was obtained through the common femoral artery, in either an antegrade or retrograde fashion, according to anatomical characteristics and lesion location. After puncturing the common femoral artery and

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Received June 02, 2016; Accepted June 08, 2016; Published June 16, 2016

Citation: Yanase Y, Fukada J, Tamiya Y (2016) Comparison of Long-Term Outcome after Endovascular Therapy versus Bypass Surgery for Superficial Femoral Artery Disease. J Vasc Med Surg 4: 270. doi:[10.4172/2329-6925.1000270](https://doi.org/10.4172/2329-6925.1000270)

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inserting an adequate sheath, all patients were given unfractionated heparin. After diagnostic angiography, a 0.025-inch guidewire (Radifocus® Guidewire M, Terumo, Japan) was advanced to cross the target lesion. All lesions underwent pre-dilation with a balloon that was undersized with respect to the vessel diameter. When dissection occurred or when the target lesion had not sufficiently expanded, an adequate sizing stent (S.M.A.R.T. stent®, Cordis Corp., Miami Lakes, FL, USA) was implanted. Then, post-dilatation was performed with an adequate sized balloon.

Statistical analysis

Age and ABI are expressed as means ± standard deviation. Pre- and postoperative ABI were compared using the Wilcoxon signed-rank test. Between-group comparisons were analyzed using the Mann-Whitney U test or χ^2 test. Primary patency was defined as no requirement for revision after first bypass or EVT lesion, while secondary patency was defined as patency that was maintained with some revision, such as re-EVT or thrombectomy for the bypass graft. Kaplan-Meier curves (log-rank test) were used to compare primary and secondary patency rates between the bypass surgery and the EVT groups. $P < 0.05$ was considered statistically significant.

Results

Of the 107 limbs, 52 underwent bypass surgery, while 55 underwent EVT. Patient characteristics are listed in Table 1. In the bypass group and EVT groups, there were 41 men and 11 women, and 43 men 12 women, respectively. Mean age was 72.7 ± 6.8 and 74.1 ± 8.5 years, respectively. No significant difference was noted in concomitant diseases (hypertension, diabetes mellitus, ischemic heart disease, cerebrovascular disease, hyperlipidemia, smoking, hemodialysis and atrial fibrillation) between the two groups. In the bypass group and EVT group, Fontaine stage II lesions were present in 38 cases and 50 cases, respectively, and stage III–IV lesions (critical limb ischemia) were present in 14 cases and five cases, respectively. In the bypass group, TASC II C/D lesions comprised the majority of cases ($n=47$, 90.4%). On the other hand, TASC II A/B lesions comprised the majority of cases in the EVT group ($n=54$, 98.2%).

The mean follow-up period was 41.9 ± 29.6 months in the bypass group and 31.1 ± 27.6 months in the EVT group. Technical and procedural success was achieved in almost bypass and EVT cases, with the exception of one case in the EVT group. In that case, we were unable to reanalyze a chronic total occlusion.

In the bypass group, an artificial vascular graft (Dacron or expanded polytetrafluoroethylene) was used in 42 cases, and a saphenous vein graft was used in 10 cases. In the EVT group, a stent was used in 46 cases, and the mean number of stents was 1.05 ± 0.65 . Nine cases underwent plain old balloon angioplasty (POBA) alone.

Perioperative complications occurred in six cases in the bypass group (11.5%) and in four cases in the EVT group (7.2%). There was no statistical differences between two groups with regard to perioperative complications ($p=0.671$). Preoperative and long-term mean ABI were 0.55 ± 0.15 and 0.83 ± 0.25 ($p<0.001$), respectively, in the bypass group, and 0.66 ± 0.19 and 0.83 ± 0.18 , respectively in the EVT group ($p<0.001$). The postoperative ABI statistically improved in both groups.

During follow-up, revision was performed in 10 cases (19.2%) in the bypass group and in 16 cases (29.1%) in the EVT group. There was no statistical difference between the two groups with regard to revision ($p=0.235$). There were no perioperative deaths in either group. During

follow-up, nine patients (17.3%) died in the bypass group, and three patients (5.5%) died in the EVT group. During follow-up, amputation of lower extremity was performed in two cases (3.8%) in the bypass group and in one case (1.8%) in the EVT group (Tables 2 and 3).

On Kaplan-Maier analysis, the 1- and 5-year primary patency rates were 84.1% and 62.8%, respectively, in the bypass group and were 68.0% and 49.7%, respectively, in the EVT group. Moreover, 1- and 5-year secondary patency rates were 91.4% and 79.9%, respectively, in the bypass group and were 84.8% and 74.6%, respectively, in the EVT group. There was no statistical difference between the two groups with regard to primary and secondary patency rate ($p=0.127$, $p=0.597$) (Figures 1 and 2).

Discussion

In our institute, EVT is selected for TASC II type A/B vascular lesions and bypass surgery is selected for TASC II type C/D vascular lesions. Although bypass surgery is invasive, revascularization is

	Femoropopliteal bypass (n=52)	Endovascular therapy (n=55)	p value
Sex (male/female)	41/11	43/12	0.933
Age at operation, years	72.3 ± 6.8	74.1 ± 8.5	0.399
Hypertension	44 (84.6%)	47 (85.5%)	0.903
Diabetes mellitus	24 (46.2%)	32 (58.2%)	0.213
Ischemic heart disease	26 (50.0%)	32 (58.2%)	0.396
Cerebrovascular disease	21 (40.4%)	22 (40.0%)	0.968
Hyperlipidemia	20 (38.5%)	25 (45.5%)	0.464
Smoking	46 (88.5%)	43 (78.2%)	0.155
Hemodialysis	1 (1.9%)	4 (7.2%)	0.394
Atrial fibrillation	15 (28.9%)	9 (16.4%)	0.122
Fontaine II	38 (73.1%)	50 (90.9%)	0.016
Fontaine III–IV	14 (26.9%)	5 (9.1%)	
TASC II type A · B	5 (9.6%)	54 (98.2%)	<0.005
TASC II type C · D	47 (90.4%)	1 (1.8%)	

CLI: Critical Limb Ischemia.

Table 1: Patient characteristics.

	Femoropopliteal bypass (n=52)	Endovascular therapy (n=55)	p value
Technical success	52/52 (100%)	54/55 (98.2%)	0.978
Early Complications	6 (11.5%)	4 (7.3%)	0.671
Acute graft occlusion	4	0	
Pseudo aneurysm	0	2	
Wound complication	1	0	
Ileus	1	0	
Re-coil	0	1	
Dissection	0	1	
Revision	10 (19.2%)	16 (29.1%)	0.235
Hospital deaths	0	0	-
Long-term deaths	9 (17.3%)	3 (5.5%)	0.052
Amputation	2 (3.8%)	1 (1.8%)	0.961

Table 2: Overall outcome.

	Preoperative ABI	Long-term ABI	p value
Femoropopliteal bypass (n=52)	0.55 ± 0.15	0.83 ± 0.25	<0.005
Endovascular therapy (n=55)	0.66 ± 0.19	0.83 ± 0.18	<0.005

ABI: Ankle brachial pressure index.

Table 3: ABI data.

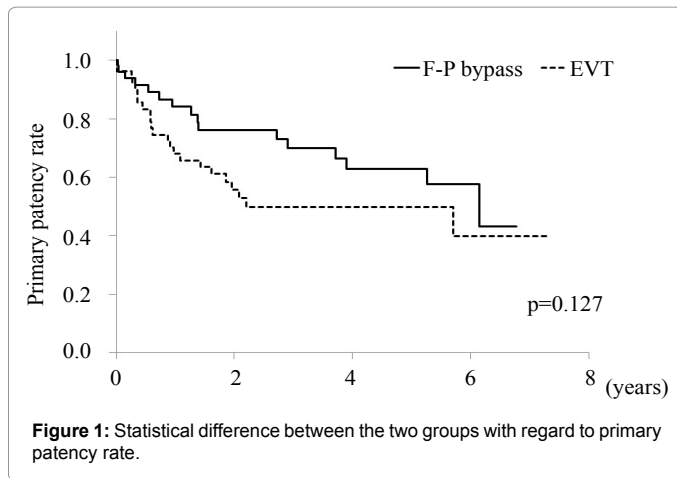


Figure 1: Statistical difference between the two groups with regard to primary patency rate.

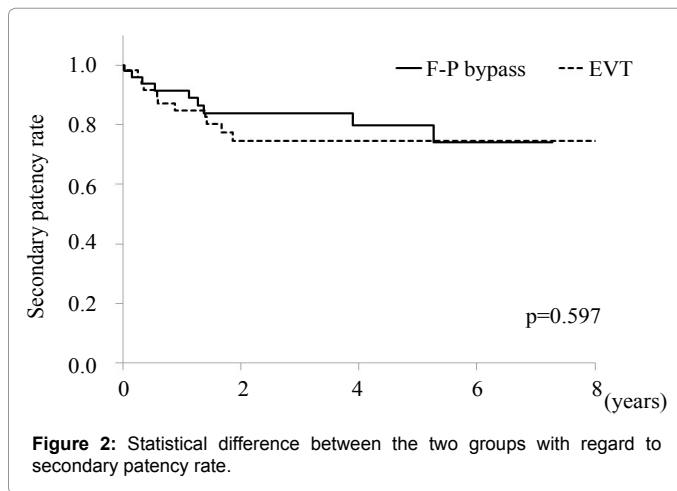


Figure 2: Statistical difference between the two groups with regard to secondary patency rate.

achieved regardless of the type of vascular disease if anastomosis is possible. On the other hand, EVT is less invasive, but here are concerns regarding the potential for restenosis of treated lesions.

The present study showed that there was no statistical difference between the bypass and EVT groups with regard to complication, frequency of revascularization and primary/secondary patency. However, there were more severe vascular lesions (e.g., TASC type C/D and Fontaine stage III/IV) in the bypass group than in the EVT group. Therefore, these two groups cannot be directly compared. Malas et al. reported that bypass surgery was chosen more frequently than EVT for severe vascular lesions, and the result of bypass surgery was therefore worse than that of EVT [4]. Our study showed that outcomes were similar when comparing bypass surgery for TASC type C/D lesions and EVT for TASC type A/B lesions. This suggests that bypass surgery is a better revascularization procedure than EVT for SFA lesions, currently.

However, there are ongoing advancements in the EVT technique. For example, the Crosser CTO recanalization system (Bard, Inc., Murray Hill, NJ, USA) [5] can facilitate recanalization for chronic total obstruction in the true lumen route. Use of a drug-eluting balloon may also help reduce restenosis [6]. These innovations will improve outcomes and expand the indications for EVT. In the future, EVT may be the first choice for the treatment of SFA lesions excluding the non-stenting zone (e.g., common femoral artery, popliteal artery).

On the other hand, Policy of guideline for bypass surgery is reconsidered. ECC guidelines [7] state that a good-quality saphenous vein graft should be the first choice for use as a femoropopliteal bypass, as long-term patency is favorable. In addition, the probability of needing saphenous vein graft for subsequent CABG is extremely low. Thus, few patients would benefit from a policy of saving vein for future operations [8]. Therefore, a saphenous vein graft should be used for femoropopliteal artery bypass to maintain good primary patency [9]. Moreover, the use of a heparin-bonded artificial graft "Propaten" (W. L. Gore & Associates, Flagstaff, AZ, USA) is expected to improve graft patency [10].

The present study demonstrated that revision after revascularization was sometimes needed in the follow-up period for both the bypass group and the EVT group. This suggests that we should recognize that a superficial artery lesion is a progressive disease. However, the secondary patency of the bypass and EVT groups were acceptable. We should regularly assess vascular flow of the lower extremity with ABI or duplex scan and be ready to perform revision if needed.

Conclusion

The secondary patency rate of the bypass and EVT groups were similar and acceptable. Therefore, we conclude that bypass surgery or EVT should be selected according to severity of the vascular lesion.

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