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Comparisons between prosthetic vascular graft and saphenous vein graft in femoro-popliteal bypass

Keun-Myoung Park, Young Wook Kim, Shin-Seok Yang, Dong-Ik Kim

Division of Vascular Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea

Purpose: Infrainguinalfemoropopliteal bypass (IFPB) is recommended to peripheral arterial disease (PAD) with a long occlusion of the superficial femoral artery (SFA). The aims of our study were to determine the patency of graft materials, and identify the risk factors of graft failure.
Methods: From January 1995 to April 2011, we had performed 380 IFPBs in 351 patients, including 302 femoro-above the knee (AK) bypasses and 78 femoro-below the knee (BK) bypasses. We compare age, sex, severity of ischemia between polytetra-uoroethylene (PTFE) graft and saphenous vein (SV) graft, and evaluate patency rate rates of the two groups.
Results: The primary patency rates at 5 years for SV (n = 76 limbs) and PTFE grafts (n = 226 limbs) in AK were 85.2% and 64.5% (log rank = 0.03), and the secondary patency rates at 5 years for SV and PTFE grafts in AK were 88.2% and 79.0% (log rank = 0.13). The primary patency rates at 5 years for SV (n = 50 limbs) and PTFE grafts (n = 28 limbs) in BK were 63.2% and 40.0% (log rank = 0.08), and the secondary patency rates at 5 years for SV and PTFE grafts in BK were 71.6% and 55.5% (log rank = 0.18).
Conclusion: There was no statistical significant difference in secondary patency rates between SV and PTFE in IFPB. PTFE grafts as SV grafts can be a good alternative bypass material in IFPB instead of SV grafts.
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Key Words: Polytetrafluoroethylene, Saphenous vein, Graft, Patency

INTRODUCTION

Infrainguinalfemoropopliteal bypass (IFPB) grafting to treat lower limb ischemia is one of the most common procedures undertaken by vascular surgeons. IFPB for the treatment of peripheral arterial disease (PAD) with long occlusion, defined as TransAtlantic Inter-Society Consensus (TASC) II C or D lesions of the superficial femoral artery (SFA), has better long-term results than percutaneous transluminal angioplasty (PTA) [1,2].

Many studies of IFPB have attempted to determine the best material and technique for revascularization of the lower extremities in PAD [3]. Since its inception in the 1940s, IFPB has developed significantly in terms of surgical technique, graft type, anticoagulant medication use and patient selection [4-6]. Various graft types have been used including autologous vein, human umbilical vein, synthetic polymers, polytetra-uoroethylene (PTFE) and Dacron; and most recently, heparin-bonded synthetic polymers in IFPB [7,8]. Saphenous vein (SV) grafts are considered to be the gold standard for bypasses with a distal anastomosis to below the knee (BK). However, a classic randomized trial published in 1986 demonstrated the superiority of vein grafts in BK revascularization [9], whereas above the knee (AK), PTFE grafts was re-equivalent to SV grafts for 20 months and was not significantly inferior thereafter [9,10]. In the era of endovascular therapy such as subintimal recanalization, flexible or covered stents in the area of the

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Corresponding Author: Dong-Ik Kim
Division of Vascular Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, 81 Irwon-ro, Gangnam-gu, Seoul 135-710, Korea
Tel: +82-2-3410-3467, **Fax:** +82-2-3410-0040
E-mail: dikim@skku.edu

SFA, usefulness of PTFE grafts was questionable comparing SV grafts. Moreover, the comparison between PTFE grafts and SV grafts remain poorly understood in Korean people. To our knowledge, no study has investigated IFPBs over 300 patients in single institution of Korea.

The specific aims of our study are to determine the long-term patency of the two types of graft materials, especially of the PTFE graft, and to identify factors for predictiveness of graft failure in IFPB in Korea.

METHODS

We retrospectively reviewed the database of patients who underwent IFPB due to long occlusion (over 10 cm) of the SFA using SV and PTFE (Goretex, W. L. Gore and Associates inc., Newark, DE, USA) grafts at a single institute between September 1995 and December 2011. IFPB performed for patients with nonatherosclerotic disease or vascular trauma were excluded from this study. We excluded bypasses below the popliteal artery, as in the tibial artery or peroneal artery.

Patients underwent surgery under either general or spinal anesthesia. The operating surgeon inspected the popliteal artery and the SV in AK bypasses. The decisions regarding whether to treat, and which type of graft to use, were made by the attending surgeons. We performed IFPB in SFA lesion with one more patent tibial artery. However, in BK bypasses with dissection and cut of gastrocnemius, PTFE graft was only used if SV graft was not available (SV < 2.5 mm). During IFPB, proximal anastomosis was taken from the common, superficial, or deep femoral artery and distal anastomosis was above or below the knee popliteal artery. Grafts were usually passed through the subfacial layer by tunneling. Distal anastomosis to below knee popliteal artery was performed with dissection or cutting of gastrocnemius muscle regardless of incision location. Postoperatively, antiplatelet medication (aspirin with or without clopidogrel) were prescribed to all the patients and lipid-lowering medication (e.g., statin) was routinely prescribed for patients with hyperlipidemia unless there was contraindication. Grafts surveillance was performed periodically at 1 month after bypass surgery, and thereafter every 6 months with duplex ultrasonography or computed tomography of the bypass graft.

For failed grafts, short (≤2 cm) stenotic lesions were treated with PTA or patch angioplasty while longer (>2 cm) stenotic lesions were treated with an interposition graft or graft extension using autogenous vein.

We analysed age, sex, coexisting factors (hypertension, smoking, hyperlipidemia, ischemic heart disease, chronic obstructive lung disease, cerebral ischemic disease), severity of ischemia, outflow between SV graft group and PTFE graft group, and examined patency rates to compare the long-term outcomes of IFPB. The chi-square test was used to compare the characteristics between SV and PTFE groups. End of primary

Table 1. Characteristics of patient who underwent infrainguinalfemoropopliteal bypass

Variable	AK-V (n = 76)	AK-P (n = 226)	P-value	BK-V (n = 50)	BK-P (n = 28)	P-value
Demographics						
Age (yr)	67.1 ± 10.2	66.5 ± 8.13	0.635	67.4 ± 8.6	66.3 ± 10.0	0.631
Male sex	64 (87)	213 (94)	0.423	45 (90)	27 (96)	0.411
Indication						
Claudication	54 (71)	168 (75)	0.549	35 (70)	20 (71)	1.000
Critical limb ischemia	22 (29)	58 (25)		15 (30)	8 (29)	
Comorbidity						
Smoking	45 (59)	157 (69)	0.121	35 (71)	19 (68)	0.799
Hypertension	54 (71)	154 (68)	0.670	32 (64)	16 (57)	0.630
Coronary artery disease	24 (32)	80 (35)	0.579	17 (34)	12 (43)	0.472
Diabetes mellitus	31 (41)	96 (42)	0.893	23 (46)	15 (54)	0.638
Cerebrovascular disease	13 (17)	49 (18)	1.000	8 (16)	3 (10)	0.737
Chronic renal failure	6 (8)	20 (9)	0.986	5 (10)	2 (7)	1.000
Hyperlipidemia	21 (27)	75 (33)	0.336	12 (24)	10 (3)	0.302
Number of patent tibial artery	2.42 ± 0.74	2.37 ± 0.69	0.745	1.93 ± 0.54	2.01 ± 0.64	0.554
Previous treatment[a]	12 (17)	43 (19)	0.546	15 (30)	7 (25)	0.456
TASC II Classification			0.468			0.691
B	5 (7)	11 (5)		152 (4)	1 (4)	
C	30 (42)	89 (40)		12 (24)	7 (25)	
D	37 (51)	128 (45)		36 (72)	20 (71)	

Values are presented as mean ± standard deviation or number (%).
AK-V, femoro-above knee popliteal bypass with sapheous vein graft; AK-P, femoro-above knee popliteal bypass with PTFE graft; BK-V, femoro-below knee popliteal bypass with sapheous vein graft; BK-P, femoro-below knee popliteal bypass with PTFE graft; PTFE, polytetrafluoroethylene; TASC, TransAtlantic Inter-Society Consensus.
[a]Vascular treatment (endovascular or surgical) for same target lesion with infrainguinalfemoropopliteal bypass.

Table 2. Details and result of infrainguinalfemoropopliteal graft

Variable	AK-V (n = 76)	AK-P (n = 226)	BK-V (n = 50)	BK-P (n = 28)
PTFE graft				
7-mm Graft		215 (95)		24 (86)
Other		11 (5)		3 (14)
SV graft				
Reversed	72 (97)		47 (94)	
In situ	2 (3)		3 (6)	
Postoperative mortality	1 (2)	2 (1)	1 (2)	
Graft occlusion	4 (5)	60 (27)	12 (24)	14 (50)
Amputation	1 (2)	11 (5)	2 (4)	2 (7)

Values are presented as number (%).
AK-V, femoro-above knee popliteal bypass with saphenous vein graft; AK-P, femoro-above knee popliteal bypass with PTFE graft; BK-V, femoro-below knee popliteal bypass with saphenous vein graft; BK-P, femoro-below knee popliteal bypass with PTFE graft; PTFE, polytetrafluoroethylene; SV, saphenous vein.

and secondary patency rate was defined as graft occlusion regardless of failing graft. Primary and secondary patency rates were calculated using the Kaplan-Meier method, and comparisons were conducted using log rank tests. The variables from the univariate analysis with the log-rank test were used in Cox's proportional hazard model for multivariate analysis.

RESULTS

From January 1995 to December 2011, we performed 380 IFPBs in 351 patients (302 femoro-above knee popliteal bypasses and 78 femoro-below knee popliteal bypasses) with PTFE grafts or SV grafts.

For AK bypasses, SV grafts were used in 76 limbs and PTFE grafts were used in 226 limbs. For BK bypasses, SV grafts were used in 50 limbs and PTFE grafts were used in 28 limbs.

The 351 patients included in the study had a median age of 66.7 years (range, 24–90 years) and the majority of patients (55%) were men. Seventy-nine percent (277 patients) of patients were

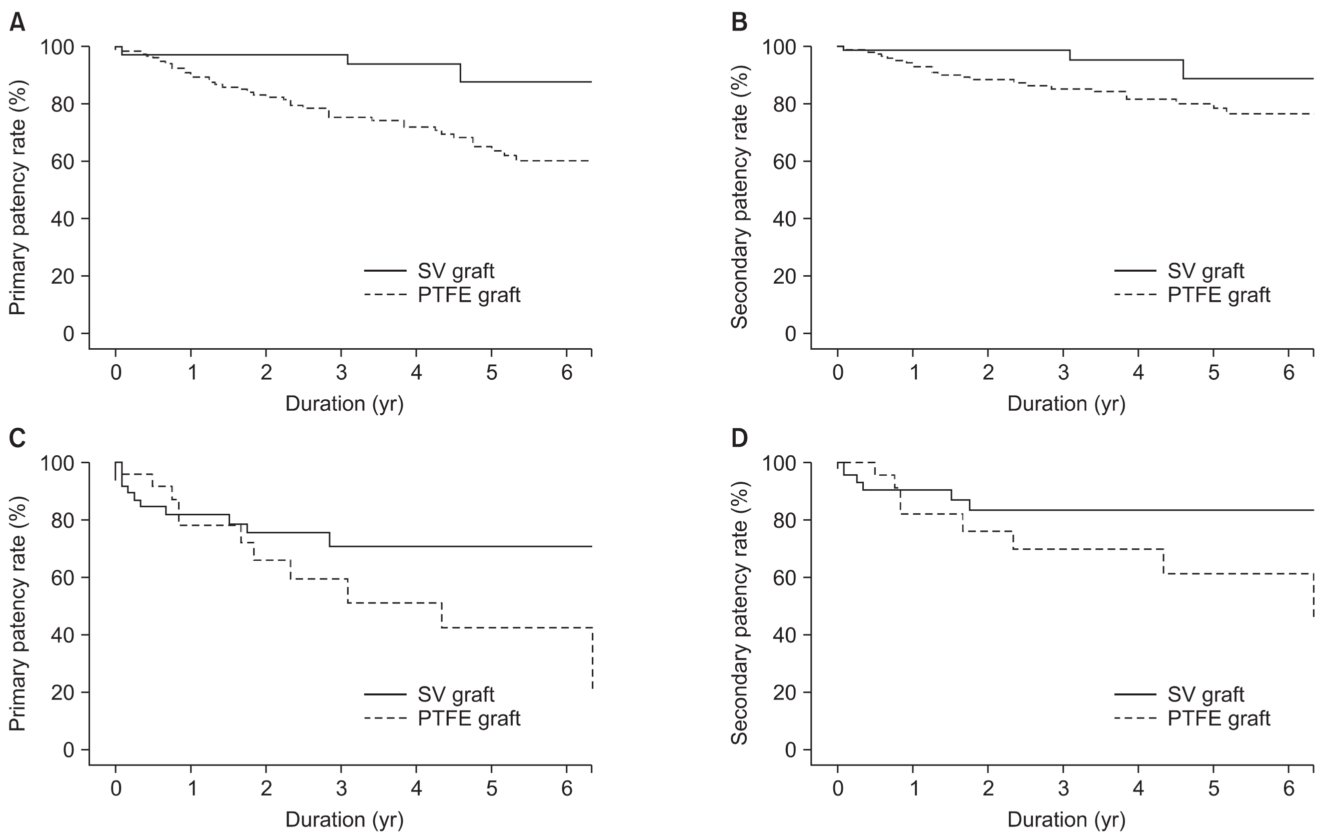

Fig. 1. Comparison of patency rate between saphenous vein (SV) graft (continuous line) and polytetrafluoroethylene (PTFE) graft (dotted line) for 5 years. Primary (A) and secondary (B) patency rates in above-knee femoro-popliteal bypass. Primary (C) and secondary (D) patency rates in below-knee femoro-popliteal bypass. The primary patency rates at 5 years for the SV and PTFE grafts in above the knee (AK) were 85.2% and 64.5% (log-rank = 0.03) (A), respectively, and the secondary patency rates at 5 years for the SV and PTFE grafts in AK were 88.2% and 79.0%, respectively (log rank = 0.13) (B). The primary patency rates at 5 years for the SV and PTFE grafts in below the knee (BK) were 63.2% and 40.0% (log rank = 0.08) (C), respectively, and the secondary patency rates at 5years for the SV grafts and PTFE grafts in BK were 71.6% and 50.5% (log rank = 0.18) (D), respectively.

treated for claudication, but 21% (74 patients) were treated for critical limb ischemia.

There were no significant differences in characteristics or indications for surgery between the patients receiving SV or PTFE grafts in the AK and BK bypass groups (Table 1). Table 2 shows the details of SV graft and PTFE graft. PTFE grafts usually used 7-mm graft with no cuff or vein patch, and reversed SV graft was used. Postoperative mortality were 4 cases (1 pneumonia, 2 myocardiac infarctions, 1 cerebrovascular disease)

The median duration of follow-up was 56.8 months (range, 1–189 months). During follow-up, 57 patients died (38%), 27 patients were lost to follow-up (7.7%). In the AK bypass group, 64 grafts (SV, 4; PTFE, 60) failed. On the other hand, 26 grafts failed in the BK bypass group (SV, 7; PTFE, 11) (Table 2).

The 5-year primary and secondary patency rates for AK bypass were 69.7% and 81.2%, respectively, compared to 54.6% and 63.5%, respectively, for BK. Fig. 1 shows primary and secondary patency rates between SV versus PTFE graft in AK and BK bypass. The primary patency rates at 5 years for the SV and PTFE grafts in AK were 85.2% and 64.5% (log rank = 0.03) (Fig. 1A), respectively, and the secondary patency rates at 5 years for the SV and PTFE grafts in AK were 88.2% and 79.0%, respectively (log rank = 0.13) (Fig. 1B). The primary patency rates at 5 years for the SV and PTFE grafts in BK were 63.2% and 40.0% (log rank = 0.08) (Fig. 1C), respectively, and the secondary patency rates at 5 years for the SV grafts and PTFE grafts in BK were 71.6% and 50.5% (log rank = 0.18) (Fig. 1D), respectively. There were no significant differences in limb salvage rate between SV and PTFE graft in IPFB (log rank = 0.25) (Fig. 2).

Composite hazard ratio analysis identified multiple combinations of characteristics and anatomic variables that increased the risk of graft occlusion. Number of patent tibial artery and location of distal anastomosis were associated with the development of graft occlusion on multivariate analysis (Table 3).

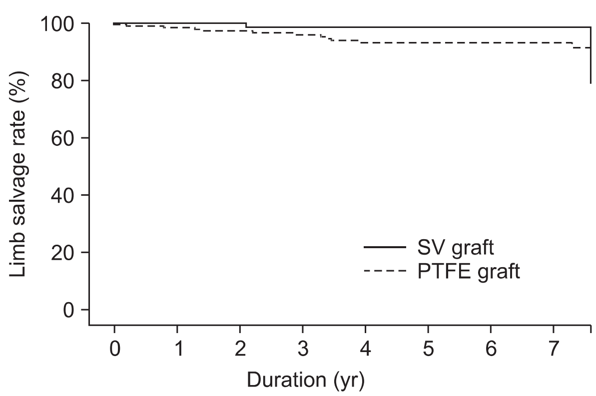

Fig. 2. Comparison of limb salvage rate of saphenous vein (SV) graft (continuous line) with polytetrafluoroethylene (PTFE) graft (dotted line) for 5 years.

DISCUSSION

In the era of new endovascular therapy such as subintimal recanalization, laser-assisted techniques, and flexible or covered stents on the SFA, conventional vascular surgery appears to be on the decline [11-13]. Nevertheless, while it is appealing to use endovascular treatment for SFA in TASC C and D lesions and reserve surgery for cases of failed endovascular therapy, the long-term results of PTA are currently inferior to those of surgery [1,2]. Therefore, IFPB remains as the gold standard in most vascular centers for chronic occlusions of the SFA that are over 15 cm [1]. But, TASC II C, D lesions are treated with primary endovascular treatment in many vascular centers [14-16].

Questions regarding which is the best bypass material to use seems to have been answered. Several studies, including two published meta-analyses, supported the superiority of vein grafts, even for AK bypasses [3,17,18]. Nevertheless, many vascular surgeons are reluctant to use available SV grafts for

Table 3. Cox's proportional hazard model for multivariate analysis of risk factor related with graft failure

Variable	Univariate analysis		Multivariate analysis	
	Hazard ratio (95% CI)	Significance (P-value)	Hazard ratio (95% CI)	Significance (P-value)
Age	-	-	1.019 (0.988–1.050)	0.239
Male sex	1.402 (0.548–3.587)	0.438	2.319 (0.891–6.034)	0.085
PTFE graft	2.624 (0.978–5.389)	0.072	2.904 (0.961–6.197)	0.078
BK[a] bypass	2.050 (1.044–3.689)	0.031	3.103 (1.676–5.745)	0.000
Critical limb ischemia	1.161 (0.604–2.073)	0.378	1.029 (0.578–1.830)	0.924
No. of patent tibial artery	-	-	0.349 (0.125–0.783)	0.028
Hypertension	1.524 (0.292–1.946)	0.432	0.788 (0.437–1.419)	0.427
Diabetes	1.503 (0.256–2.888)	0.429	1.420 (0.228–2.774)	0.455
Smoking	1.144 (0.618–2.105)	0.396	1.163 (0.620–2.182)	0.638
Hyperlipidemia	0.756 (0.344–1.409)	0.440	0.894 (0.475–1.682)	0.729

CI, confidence interval; PTFE, polytetrafluoroethylene.
[a]Distal anastomosis site is below knee popliteal artery with dissection and cut of gastrocnemius muscle.

IFPB because of the potential future need for a more distal bypass [10]. For AK bypass, the use of PTFE is thought to be as efficient as the use of SV grafts for 2 years [9,10]. An advantage of PTFE is the significantly shorter operation time. One can consider using PTFE as a bypass graft material in patients with short life expectancies and high operative risk [19,20].

The best evidence that one treatment is superior to another comes from randomized controlled trial (RCT). Several studies of SV versus PTFE grafts have been performed, and have sufficient power to either support or reject the hypothesis that SV graft is superior to PTFE graft. Several noncontrolled studies have been performed, but IFPBs require reevaluation for many reasons. First, although there is continual development of surgical skills and material, competing endovascular treatments often improve at a much faster rate. Second, patients with short life expectancies, past history of infrainguinal revascularization and high operative risk, have increased.

Our data show significant differences in primary patency rates between SV and PTFE graft in IFPB performed for AK and BK bypass. However, there were no significant differences in secondary patency rates between SV and PTFE graft in IPFB. The results of our study were different from the results of most RCTs. If early detection of graft failure can be done, there were many options such as thrombectomy or thrombolysis in PTFE graft. Approach and manipulation of PTFE graft is easier than that of vein graft. The difficulty of management in graft failure also derived from small vein or artery size of Asians comparing that of western people. In thrombolysis and thrombectomy of vein graft, there were rare successful cases at our institution. Thus, secondary patency rate of PTFE graft was higher than that of vein graft. This study was retrospective and the patients were not randomized. We did not control for the indication for surgery or the choice of graft material. The recorded demographic and clinical characteristics did not show difference between the two groups, so the groups should be compared with caution. The number of patients eligible for follow-up at 6 years was greater than in that of previously published RCTs and the analysis of the patients lost to follow-up did not alter the conclusions. A Cochrane review concluded that there was no clear evidence for the preference of SV or PTFE as a conduit for a bypass in this location [3].

However, IFPB remains as the gold standard for long segment occlusions of the SFA in many RCT [17,18]. The SV is also considered the most durable conduit for IFPB, but the overall results of this study show that SV and PTFE grafts have comparable secondary patency rates in IFPB.

There was no statistically significant difference in secondary patency rates and limb salvage rates between SV and PFTF in IFPB. If an SV is available, SV grafts would be better. However, if the SV is absent or not suitable for bypass grafting with suitable outflow, PTFE can be a good alternative bypass material in IFPB.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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