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Original Article

Long-term survival, amputation and graft-related complications following femoropopliteal bypass surgery

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Abstract

Aim: Peripheral arterial disease (PAD) is caused by atherosclerosis and affects the lower extremity arteries. Surgical methods including infrainguinal bypass play an indispensable role in the treatment of PAD. We aimed to investigate the long-term outcomes of femoropopliteal bypass surgery primarily focusing on survival, amputation and graft related complications (thrombosis and graft infection).
Material and Methods: A total of 77 patients who underwent isolated femoropopliteal bypass surgery between January 2015 and January 2022 were retrospectively analyzed. Clinical characteristics and demographic data of the patients, preoperative and postoperative Rutherford categories were noted. Amputation, survival, and graft-related complication rates were reviewed.
Results: During the follow-up period (average of seven years), the overall mortality was 44.2%. Overall survival rates were observed to be lower in patients with chronic renal failure ($p<0.05$). A significant decrease of postoperative Rutherford stages were found compared to the preoperative stages ($p<0.001$). Amputation occured in 37.6% of the cases and the rate of graft-related complications were 11.6%. The graft-related complications were found to be significantly lower in autogenous vein grafts compared to prosthetic grafts ($p<0.01$). The graft type had no significant effect on amputation-free survival. However major amputation-free survival was observed to be higher in cases when a vein graft was used ($p=0.02$).
Conclusion: Femoropopliteal bypass surgery provides a significant improvement in the clinical severity of chronic PAD. The use of saphenous vein grafts provides benefit to reduce graft-related complications and improve major amputation-free survival.

Keywords: Femoropopliteal bypass, risk factors, graft failure

INTRODUCTION

Femoropopliteal bypass surgery is one of the well-known treatment options for infrainguinal peripheral arterial disease (PAD) [1]. The use of great saphenous vein (GSV) graft is associated with optimal hemodynamic performance and a lower risk of graft-related infection, achieving a 5-year primary patency rate of approximately 70% [2].

The outcomes following lower limb revascularisation are influenced by a variety of factors including patient-related variables such as the indications for surgery, patient comorbidities, anatomical distribution of the disease (quality and level of both inflow and the outflow) and the technical considerations (graft selection, technical errors etc.) [3]. Femoropopliteal bypass surgery carries a risk of significant posptoperative complications, among which graft failure and major limb amputation represent the most critical adverse outcomes [4].

The primary objectives of our study were to investigate the effects of patient related factors and conduit type on long-term postoperative complications and survival after femoropopliteal bypass surgery.

MATERIAL AND METHODS

The long-term results of patients who underwent femoropopliteal

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bypass surgery due to lower extremity arterial disease at Aydın Adnan Menderes University Cardiovascular Surgery Clinic between January 01, 2015 and January 01, 2022 were retrospectively studied. The research was approved by the Non-Interventional Ethics Committee of Aydın Adnan Menderes University Faculty of Medicine with protocol number 2022/77 (26.05.2022).

Lower extremity vascular trauma patients and the patients with occlusive arterial disease who had previously received endovascular treatment were not included in the study. In total, the data of 77 patients who met the study criteria was analyzed. Since the study was retrospective, all eligible patients within the specified time period were included, without a predefined sample size. The sampling method can be described as non-probability consecutive sampling.

The demographic variables, risk factors for peripheral arterial disease and medications used were questioned using the case report form. Rutherford classifications of patients were used to determine the clinical status of the extremity; adjusted using data such as walking distance, presence of gangrene or ulcer [5]. The primary endpoints of the study were mortality, overall survival, amputation, and graft-related complications. Above-knee and below-knee amputations are classified as major amputations, while ankle and distal amputations are classified as minor amputations.

All surgical procedures were performed by the Aydın Adnan Menderes University Cardiovascular Surgery team. The graft selection was mainly based on surgeon's decision and intraoperative evaluation of the vasculature. Current international guidelines were taken into account on deciding the choice of graft. Polytetrafluoroethylene (PTFE) graft was used as the prosthetic graft and GSV was used as the autologous vein graft. Composite grafts were not used in any of the patients in this study. PTFE grafts were exclusively placed in the supragenicular region, while saphenous vein grafts were utilized for both supragenicular and infragenicular bypasses. In the study, saphenous vein grafts were not categorized as supragenicular or infragenicular.

Surgical Technique

Informed consent was obtained from the patients before the operations. Patients were operated under spinal or general anesthesia. All patients were administered cefazolin as prophylaxis before the procedure. In all operations, 5000 units of heparin were administered intravenously (IV) and an activated clotting time (ACT) of 200-300 seconds was targeted. Additional dose of heparin was administered when needed. In all patients, postoperative circulation was monitored by checking distal pulses and arterial flows with a handheld Doppler ultrasonography device. Postoperative medical treatment comprised routine use of antiplatelets and statins and anticoagulants when indicated.

Statistical Analysis

Statistical analyses were performed using SPSS 26.0 (SPSS Inc. Chicago, IL) package program. Data were evaluated using descriptive statistics (number, percentage, standard deviation, mean value, median), Chi-square test, T-test in independent groups, Kruskal Wallis, Mann-Whitney U and Wilcoxon tests. Expected patency and survival analyses were performed using the Kaplan-Meier method. Statistical significance was set at $p < 0.05$.

RESULTS

Of the patients with an average follow-up period of 7 years, 71 (92.2%) were male and 6 (7.8%) were female. The mean age of the patients was 67.7±10.5 years. 80% of the patients were smokers. 74% of the patients had diabetes and 63% of these patients had insulin-dependent diabetes. 77.9% of the patients had hypertension, 6.5% had carotid artery disease, 54.5% had hyperlipidemia, 22.1% had chronic obstructive pulmonary disease (COPD) and 62.3% had coronary artery disease. The rate of the patients with chronic renal failure (CRF) was 11.7% and 10.4% of these patients were on hemodialysis. The demographic data and the co-morbidities are presented in Table 1.

Table 1. Distribution of patients according to demographic characteristics and comorbidities

Patient Characteristics (n:77)	Number	Percentage
Age (Mean±SD)	67.75	±10.57
Gender		
Male	71	2
Female	6	±10.57
Smoking	62	80.5
Diabetes	57	74
Insulin Usage	49	63.6
Hypertension	60	77.9
Coronary Artery Disease	74	62.9
Carotid Artery Disease	63.6	6.5
Hyperlipidemia	77.9	54.5
Atrial Fibrillation	48	6.5
Chronic Obstructive Pulmonary Disease	5	22.1
Chronic Renal Failure	42	11.7
Hemodialysis	6.5	10.4
HbA1c (median, iqr)	54.5	±3.3

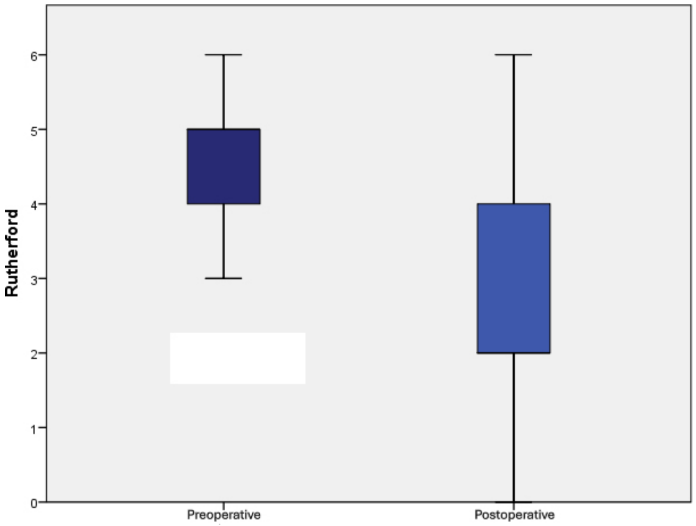

Figure 1. Preoperative and postoperative Rutherford categories

The mean Rutherford category before the procedure was found to be 5 (1) for 77 extremities. After the procedure, the average of Rutherford category was 2 (2.5) (Figure 1). In the saphenous vein graft group, the median preoperative Rutherford category was 5, while the median postoperative category was 3. In the synthetic graft group, the median value before the procedure was 5, while the median value after the procedure was 2. In the synthetic graft group, Rutherford category improvement in the postoperative period was found to be significantly higher than in the saphenous vein graft group (p<0.001). Preoperative and postoperative Rutherford categories of saphenous vein and synthetic grafts are presented in Table 2.

Table 2. Preoperative and postoperative Rutherford categories of vein and synthetic grafts

	Rutherford Category		Percentage
	Preoperative	**Postoperative**	**<0.001***
Saphenous vein graft, median (iqr)	5 (2)	3 (3)	
Synthetic graft, median (iqr)	5 (1)	2 (1)	

* According to the Mann-Whitney U test (p value:0.001)

Of the patients who underwent femoropopliteal bypass surgery, 49 (63.6%) were revascularized using saphenous grafts and 28 (36.4%) were revascularized using synthetic grafts. In our study, graft thrombosis and infection leading to graft removal during the follow-up period were defined as graft-related complications. Graft-related complications were detected in 9 of 77 patients (11.6%). Graft thrombosis occurred in 7 patients, and 2 required graft removal. Graft thrombosis was observed in six of the patients who underwent surgery by using synthetic grafts and only in one patient who received autogenous saphenous vein graft. Table 3 shows the relation of clinical and demographic characteristics of patients and graft-related complications. Among the clinical variables examined in our study, the only factor which increased the risk of graft-related complications was found to be the use of a prosthetic graft.

Table 3. The relation of clinical and demographic characteristics of patients and graft-related complications

	(+) (n= 9)	(+) (n=68)	P value
Age (Mean±SD)	68.93 ± 10.6	64.82 ± 10.14	0.950+
Gender			0.538*
Male	8 (11.3)	63 (88.7)	
Female	1 (16.7)	5 (83.3)	
Smoking	7 (11.3)	55 (88.7)	0.560*
Diabetes	5 (8.8)	52 (91.2)	0.172*
Insulin Usage	4 (8.2)	45 (91.8)	0.182*
Hypertension	6 (10)	54 (90)	0.313*
Coronary Artery Disease	6 (12.5)	42 (87.5)	0.541*
Carotid Artery Disease	0 (0)	5 (100)	0.528*
Hyperlipidemia	4 (9.5)	38 (90.5)	0.724*
Atrial Fibrillation	0 (0)	5 (100)	1*
Chronic Obstructive Pulmonary Disease	1 (5.9)	16 (94.1)	0.674*
Chronic Renal Failure	0 (0)	9 (100)	0.588*
Hemodialysis	0 (0)	8 (100)	0.585*
Graft Type (n,%)			0.01*
Saphenous Vein Graft	2 (4.1)	47 (95.2)	
Synthetic Graft	7 (25)	21 (75)	

\+ T-test , * Ki-Square test (p:0.001)

During the follow-up period, 29 (37.7%) patients had amputation. Below the knee and above the knee amputations were considered as major amputations, and amputations distal to the foot and ankle were considered as minor amputations. There were 8 cases of major and 21 cases of minor amputations in cohort. We have analysed the risk of amputation among patients with diabetes and chronic renal failure based on insulin dependence (dependent or independent) and hemodialysis status (receiving or not). The relations of clinical and demographic variables with amputation are presented in Table 4. Although diabetes and CRF were found to have a significant effect on amputation, multivariate analysis using logistic regression showed that having these diseases alone did not increase the risk of an amputation.

Table 4. The relations of clinical and demographic variables with amputation			
	(+) (n=29)	(-) (n=48)	P value
Age (Mean±SD)	70.58±12.95	65.12±8.87	0.121+
Gender			**0.406***
Male	26 (36.6)	45 (63.4)	
Female	3 (50)	3 (50)	
Smoking	23 (37.1)	39 (62.9)	0.29*
Diabetes	26 (45.6)	31 (54.4)	**0.013***
Insulin Usage	24 (49)	25 (51)	**0.006***
Hypertension	25 (41.7)	35 (58.3)	0.14*
Coronary Artery Disease	20 (41.7)	28 (58.3)	0.246*
Carotid Artery Disease	1 (20)	4 (80)	0.372*
Hyperlipidemia	13 (31)	29 (69)	0.137*
Atrial Fibrillation	1 (20)	4 (80)	0.372*
Chronic Obstructive Pulmonary Disease	7 (41)	10 (58.8)	0.473*
Chronic Renal Failure	7 (77.8)	2 (22.2)	0.012*
Hemodialysis	6 (75)	2 (25)	0.029*
Graft Type (n,%)			**0.319***
Saphenous Vein Graft	8.3 (3.36)	7.6 (4.55)	0.823#
Synthetic Graft	17 (34.7)	32 (65.3)	
Graft-Related Complication (n,%)	12 (42.9)	16 (57.1)	

Acccording to #Mann-Whitney U test, +T-test , *Ki-Square test

Table 5. The relationship between clinical and demographic characteristics of patients and mortality			
	(+) (n=34)	(-) (n=43)	P value
Age (Mean±SD)	73.25±11.96	64.07±9.23	**<0.001+**
Gender			0.544*
Male	31 (43.7)	40 (56.3)	
Female	3 (50)	3 (50)	
Smoking	27 (43.5)	35 (56.5)	0.526*
Diabetes	26 (45.6)	31 (54.4)	0.433*
Insulin Usage	25 (51)	24 (49)	0.085*
Hypertension	26 (43.3)	34 (56.7)	0.499*
Coronary Artery Disease	23 (47.9)	25 (52.1)	0.269*
Carotid Artery Disease	2 (40)	3 (60)	0.611*
Hyperlipidemia	16 (38.1)	26 (61.9)	0.173*
Atrial Fibrillation	3 (60)	2 (40)	0.389*
Chronic Obstructive Pulmonary Disease	10 (58.8)	7 (41.2)	0.135*
Chronic Renal Failure	8 (88.9)	1 (11.1)	**0.005***
Hemodialysis	8 (100)	0 (0)	**0.001***
Graft Type (n,%)	7.3 (3.92)	8 (3)	0.446#
Saphenous Vein Graft			**0.024***
Synthetic Graft	17 (34.7)	32 (65.3)	
Graft-Related Complication (n,%)	17 (60.7)	11 (39.3)	
Amputation (n,%)	2 (22.2)	7 (77.8)	0.284*

According to #Mann-Whitney U test, +T-test , *Ki-Square test

The mortality rate during the follow-up period was 44.2% (34 patients died). Table 5 indicates the relationship between clinical and demographic characteristics of patients and mortality. It was detected that increasing age, CRF (hemodialysis dependent or independent) and the graft type were significantly associated with the mortality rate (p values: 0.001, 0.005, 0.024, respectively). However, the logistic regression analysis revealed that only increasing age and the presence of chronic renal failure were independently associated with an increased risk of mortality. In the study population, each one-year increase in age was associated with a 1.14-fold increase in the risk of mortality, while the presence of chronic renal failure increased the mortality risk by 33.3 times. On the other hand, we have observed that the use of synthetic grafts and the presence of graft-related complications had no significant effect on mortality.

In our study, one-year and three-year amputation-free survival (major+minor amputations) analyses were performed using the Kaplan-Meier method. One-year amputation-free survival was 51.1%, and three-year amputation-free survival was 35.4%. Amputation-free survival was determined as 29.1 months during the 12-month median follow-up period (Figure 2).

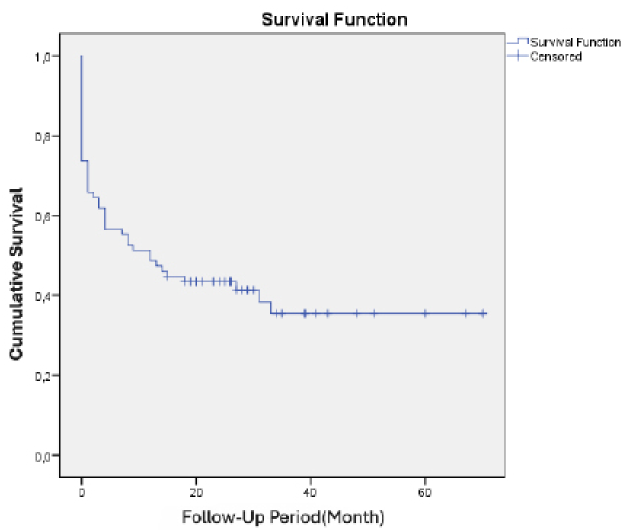

Figure 2. Amputation-free survival analysis

The effects of diabetes and insulin-dependent diabetes on amputation-free survival were also evaluated, and insulin-dependent diabetes was found to have a statistically significant impact on amputation-free survival (p=0.011) (Figure 3). In patients with insulin-dependent diabetes, the 1-year and 3-year amputation-free survival rates were found to be 37.5% and 29%, respectively, whereas in non-insulin-dependent patients, these rates were 75.3% and 44.1%, respectively.

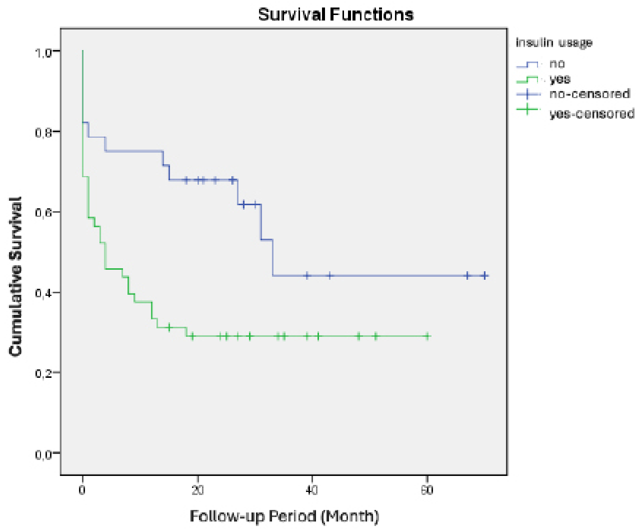

Figure 3. Amputation-free survival analysis in insulin dependence

Among patients with CRF, the 6-month and 1-year amputation-free survival rates were 33.3% and 0%, respectively. (p=0.002). In patients without CRF, 1-year amputation-free survival was reported as 55.2%. Amputation-free survival rates in patients with hemodialysis dependent CRF have been found to be lower than in those who were not on hemodialysis (Figure 4). Amputation-free survival rates in hemodialysis-dependent patients were 37.5% at 6 months and 12.5% at 9 months. Hemodialysis dependency in patients with CRF was found to have a statistically significant impact on amputation-free survival (p=0.007).

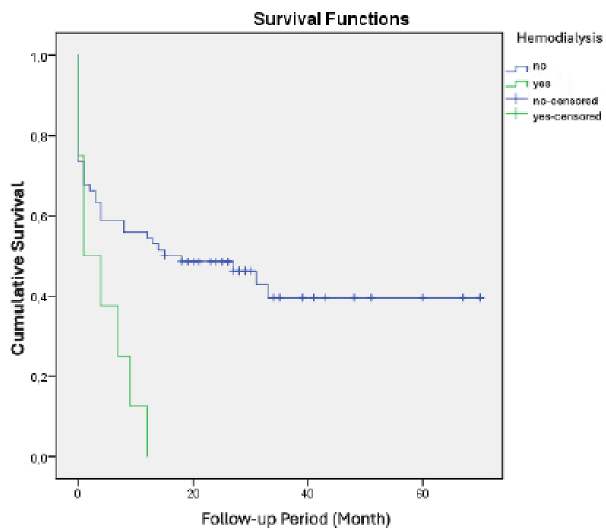

Figure 4. Amputation-free survival analysis in hemodialysis status

In our study, no significant association was observed between the selected graft type and amputation-free survival (p=0.25). Amputation-free survival rates at one and three years were

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53.1% and 35.7%, respectively, in patients who underwent surgery with a saphenous vein graft, compared to 44.4% and 29.6% in those operated on with synthetic graft. However, a significant relationship was found between graft type and major amputation-free survival (p=0.03). In patients with a saphenous vein graft, 1-year and 3-year major amputation-free survival rates were 69.6% and 62.8%, respectively, whereas in those with a synthetic graft, these rates were 55.6% and 37%, respectively (Figure 5).

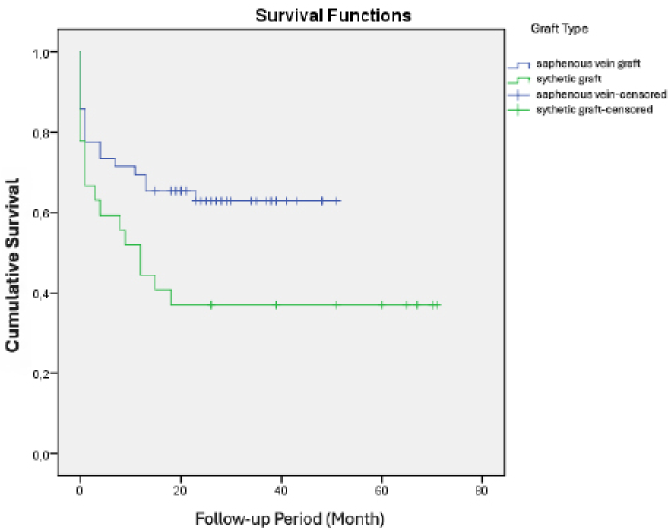

Figure 5. Analysis of major amputation-free survival according to graft type

DISCUSSION

In this study, we observed an apparent improvement in clinical disease severity after femoropopliteal bypass surgery as observed by a reduction in Rutherford stage. This finding is in line with the current literature reporting successful outcomes of surgical revascularization after femoropopliteal bypass [6].

The ESC guideline recommended that autologous vein graft should be primarily used in infrainguinal bypass surgery [7]. The use of autologous vein grafts is supported by several advantages including their elasticity, low surface thrombogenicity, resistance to infections, long-term viability, and ability to be nourished through diffusion [8]. Nevertheless, the use of prosthetic conduits becomes a necessity when the vein has a small diameter that is incompatible to be used as a graft, has an insufficient length or when there is a history of phlebitis [9].

In our study, saphenous graft was used in 49 (63.6%) of 77 patients and PTFE graft was used in 28 (36.4%) patients. The use of prosthetic grafts resulted in a more prominent decrease of the Rutherford stage as compared to the use of autogenous vein grafts. In a recent study conducted by Kluckner et al. on 332 patients, clinical improvement before and after femoropopliteal bypass surgery was evaluated with the Rutherford classification and the improvement in the Rutherford category was higher following bypass procedures performed with a saphenous vein graft [10]. The results we obtained in our study may be related to the fact that the adaptation process of the saphenous vein graft to arterial flow has not yet been completed [11].

In terms of surgical complications that may occur in long-term after infrainguinal bypass, graft failure (thrombosis) and graft infection are of great importance. Such complications may eventually lead to loss of the distal flow and amputation [12]. There are studies suggesting that these complications may vary depending on the type of graft material used. Betz et al. reported better long term (5 years) patency with vein grafts when compared to prosthetic grafts in patients undergoing femoropopliteal bypass for TransAtlantic Inter-Society Consensus II (TASC II), type D (TASC D) lesions. In another study, the patients who were operated for claudication 5-year primary patency and amputation-free survival rates were found to be superior to prosthetic grafts with the use of saphenous vein graft [13]. Moreover, in a study involving 1315 femoropopliteal bypass procedures over a 25-year follow-up period, the use of prosthetic grafts was identified as a risk factors for graft infection [14].

In our study, graft-related complications were defined as graft thrombosis and the need for graft removal for infection. A statistically significant difference was identified in the incidence of these complications according to the type of the graft used suggesting that graft selection may influence postoperative outcomes. Graft-related complications were observed to be significantly increased when a PTFE graft was employed. Various factors may play a role in the etiology of graft thrombosis and graft infections, such as diabetes, the presence of distal ulcers or gangrene, multiple limb revascularizations, and the use of prosthetic grafts [15]. However, in our study, considering the demographic characteristics and comorbid conditions of the patients, no association was found between other parameters in terms of graft-related complications other than the type of graft used.

Amputation is considered as a significant outcome in patients who undergo surgical lower limb revascularization. Many studies have identified patient-dependent factors associated with amputation in the evaluation of infrainguinal bypass surgery outcomes. In the EUCLID study, several risk factors associated with amputation were identified, including diabetes, Rutherford stage 4-6, a prior history of amputation, and an ankle-brachial index of less than 0.8 [16]. Amputation-free survival analyses were performed across these groups and we observed that insulin-dependent diabetes and hemodialysis-dependent chronic renal failure had a significant negative impact on amputation-free survival. In our study, the use of autogenous vein grafts was observed to significantly improve major amputation-free survival compared to the use of prosthetic grafts. We believe this may be related to the higher frequency of graft-related complications when the prosthetic grafts were used.

Mortality is a primary endpoint after surgery and closely related to amputation following arterial revascularization. In a study analyzing mortality risk after infrainguinal bypass, the 1-year and 3-year mortality rates were reported as 47.9% and 70.6%, respectively [17]. In our study, mortality occurred in 34 of 77 patients (44%).

In patients undergoing infrainguinal bypass surgery for peripheral arterial disease, risk factors affecting survival have been reported as advanced age (> 80), presence of COPD, advanced CRF, and bed dependency [18]. In a cohort study conducted by Ying Yu Luo et al. involving 3732 patients, CRF was identified as the most important factor affecting all-cause mortality in cases of PAD [19]. In our study, the factors found to be associated with increased mortality were advanced age, chronic renal failure (hemodialysis dependent and independent) and the use of synthetic grafts. However, in logistic regression analysis, only increased age and the presence of CRF were found to be significantly associated with mortality. Each one-year increase in age was associated with a 1.14-fold increase in the risk of mortality, while the presence of CRF alone increased the risk of mortality by 33.3 times.

CONCLUSION

According to our results, the use of autogenous vein grafts did not have a statistically significant impact on overall survival or amputation-free survival. However, when compared to PTFE grafts, saphenous vein grafts significantly increased major amputation-free survival rate and reduced graft thrombosis and infections leading to graft removal in long-term.

Ethics Committee Approval: The research was approved by the Non-Interventional Ethics Committee of Aydın Adnan Menderes University Faculty of Medicine with protocol number 2022/77 (26.05.2022).

Patient Consent for Publication: Not necessary for this manuscript.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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