

Predictors of Time to Graft Failure Following Infrainguinal Arterial Reconstruction

Patrick D. Hallihan, Niamh Ni Choileain, Eddie Myers, H. P. Redmond, Greg F. Fulton

Department of Surgery, Cork University Hospital, Wilton, Ireland

E-mail: nnc1@eircom.net

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Abstract

Infrainguinal arterial reconstruction increases limb salvage rates, however, the factors that predict time to graft failure remain ill-defined. The aim of this study was to define such predictors. A retrospective analysis of infrainguinal arterial reconstructions performed for symptomatic peripheral arterial disease refractory to medical/interventional therapies over a 6 year period was performed. Demographics and adverse outcomes were analysed and statistical significance was determined using Chi-squared analysis, the Student *t* test and the Wilcoxon signed-rank test. 170 procedures were analysed. The male to female ratio was 4:3. The median age was 70.1 years. The post-operative complication rate was 12%. On univariate analysis, female gender, the use of a synthetic graft, and the presence of critical ischaemia at the time of surgery were predictive of time to graft failure ($p \leq 0.05$, $p \leq 0.03$, $p \leq 0.02$ respectively). On multivariate analysis, the 3 most significant predictors of graft failure were the occurrence of a post-operative complication, female gender and a high ASA grade. The presence of diabetes mellitus and smoking did not adversely affect graft outcome, ($p \leq 0.23$, $p \leq 0.20$ respectively). This study suggests that female gender adversely affects graft patency while a history of smoking and the presence of diabetes mellitus do not. Our findings also suggest that the occurrence of a post-operative complication, and a high ASA grade at time of surgery are additional important predictors of early and late graft failure.

Keywords: Infrainguinal, Vascular Surgery, Bypass, Graft, Patency

1. Introduction

Infrainguinal arterial reconstruction is an effective treatment for symptomatic peripheral arterial disease, (PAD), in patients who remain symptomatic despite medical and intervention therapies [1-4]. Treatment of symptomatic PAD involves risk factor reduction as well as pharmacological and radiological intervention. However, in patients whose symptoms remain refractory to conservative management, arterial reconstruction may be necessary. Time to graft failure in lower limb bypass surgery has been shown to be adversely affected by the construction of a distal anastomosis and the use of prosthetic graft material [5]. Prosthetic grafts are a suitable alternative to autologous vein when the distal anastomosis is above the knee joint [6]. Continued smoking post-operatively, (but not a prior history of smoking), also predicts graft failure [7]. Conflicting evidence regarding the effect of gender on graft patency exists. Several studies have identified

female gender as an adverse prognostic indicator in lower limb bypass surgery but evidence to the contrary also exists [8]. In this study we constructed multivariate models in order to determine all possible predictors of graft failure.

2. Methods and Materials

Data relating to patients who underwent infrainguinal arterial reconstruction for symptomatic peripheral arterial disease refractory to medical/interventional therapies over a six year period from January 1998 to December 2004 was retrieved from the theatre register and hospital in-patient enquiry databases. Databases were accessed by one of the authors, (PH). Patients who required revision surgery for graft failure were excluded from the study. Critical limb ischaemia was defined as chronic rest pain or the presence of ischaemic skin lesions, either ulcers or gangrene. All operations were performed by a consultant

vascular surgeon or a senior vascular trainee. The primary endpoint was the time to graft failure while secondary endpoints included the post-operative complication rate, need for revision surgery, length of hospital stay and overall patient survival. Primary graft patency was determined by ankle-brachial pressure indices (ABPIs) and duplex ultrasonography. Data analysis included patient demographics, vascular risk factors, operative indication, ASA grade, graft material used at time of surgery and type of surgical bypass performed. Reconstructive surgery was only offered to patients who discontinued smoking. Compliance with smoking cessation was monitored using CO breath testing. Target artery selection varied with indication for surgery and degree of patency as per pre-operative angiography. Autologous vein was the preferred conduit for all procedures. Ipsilateral long saphenous vein was the conduit of choice followed by the contralateral long saphenous and upper limb basilic veins respectively. In patients with inadequate autologous vein, a prosthetic graft was used with a Miller vein cuff. Veins were deemed unsuitable if they were varicose or thrombosed or found to be non-compliant as determined by absence of response to injection of papaverine. Suitable veins included those that were not dilated or varicose and veins which were not affected by thrombophlebitis. At the end of the bypass procedure, graft patency was determined by duplex ultrasound. Post-operatively, grafts were followed-up with duplex ultrasonography and ABPIs performed before discharge, every three months for 1 year and every 6 months thereafter. The median follow up was 32 months (range 6 - 64 months). Suspected graft occlusion was confirmed angiographically. All patients were commenced on prophylactic aspirin and a statin post-operatively. Patients with concomitant chronic atrial fibrillation were commenced on warfarin therapy.

Statistical analysis was performed using SPSS 12.0 for Windows (SPSS Inc., Chertsey, UK). Univariate analyses were conducted with either the Pearson chi-square/Fisher's exact test or the Student *t* test for comparing continuous variables. Cumulative graft patency rates were calculated using the Kaplan-Meier method and comparisons between graft survivals were made using the Wilcoxon sign-rank test ($p \leq 0.05$ significant). A Cox proportional hazards model was employed to examine the relationship between graft patency and potential influential variables. Based on this, multivariate models were constructed in order to define which combination of variables best predicted outcome in terms of graft patency. The following variables were entered with graft patency as the outcome variable: age, gender, smoking, diabetes mellitus, ASA grade, graft type, inflow, outflow, and the overall complication rate. A stepwise procedure

was used to select the variables that were significant in the model.

3. Results

187 patient records were analysed. Complete records were available in 170 patients who were then entered in the study. **Table 1** shows demographic data, risk factors, and associated medical conditions. Procedures were classified as femoral-above-knee-popliteal, femoral-distal and popliteal-distal bypasses, (**Table 2**). The 30-day mortality rate was 3.5% while the 5-year mortality rate was 17.1%. There were no peri-operative deaths and 1 post-operative death. The mean length of hospital stay was 14.1 ± 1.2 days (range 2 - 91 days). The complication rate was 12% (**Table 3**). The post-operative intervention rate was 20.6% ($n = 35$). 21 patients (14.5%) required further arterial reconstruction, 2 (1.2%) required graft angioplasty, and 12 (7.1%) needed a thrombectomy. No patient required amputation.

Overall, primary cumulative graft patency rates at 1 month and 5 yrs were 91.8% and 75.3% respectively. All graft occlusions were associated with recurrence of lower extremity symptoms. Univariate analysis revealed that the use of a synthetic graft was significantly associated

Table 1. Demographic data, risk factors and medical comorbidities of patient population.

GENERAL PATIENT CHARACTERISTICS	n, (%)
Sex—male	97, (57)
female	73, (43)
Age median +/- SEM, (range)	70.2 +/- 0.7, (51-88)
ASA median, (range)	3, (2-5)
Vascular risk factors	
Prior history of smoking	92, (54)
Diabetes mellitus	43, (25)
type 1	8, (19)
type 2	35, (81)
Hypercholesterolaemia	18, (11)
Hypertension	44, (26)
Comorbid conditions	
Ischaemic heart disease	79, (41)
Cerebrovascular disease	20, (13)
Chronic lung disease	29, (17)
Chronic renal failure	23, (14)

Table 2. Indication for surgery, graft type and type of procedure.

CHARACTERISTICS OF SURGERY	n, (%)
Indication:	
Intermittent claudication	27, (16)
Critical ischaemia	143, (84)
—with rest pain	37, (26)
—with tissue loss	106, (74)
Conduit:	
Reversed vein	93, (55)
<i>In-situ</i> vein	18, (11)
Synthetic graft	59, (35)
Anastomotic sites:	
Femoral-above-knee-popliteal	145, (85)
Femoral-distal	14, (8)
Popliteal-distal	11, (7)

Table 3. Morbidity and mortality rates.

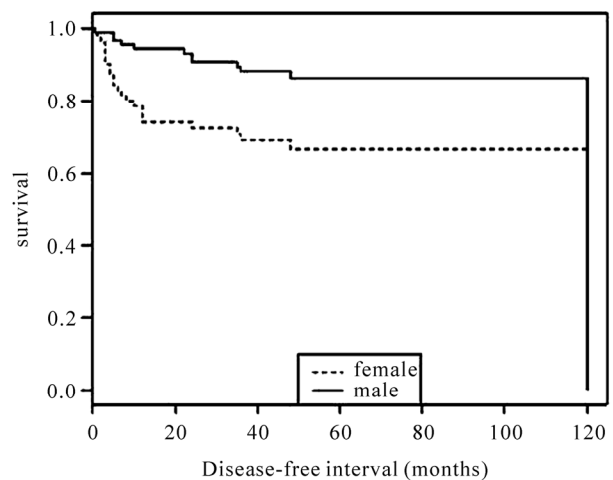
COMPLICATIONS	n
General Complications	
Lower respiratory tract infection	2
Pulmonary embolus	1
Myocardial infarction	2
Cardiac dysrhythmia	1
Total	6
Procedure-related complications	
Thromboembolic events	3
Compartment Syndrome	1
Haematoma	6
Seroma	2
Wound infection	3
Pseudoaneurysm	1
Total	16
Mortality	
30 day	2
5 year	42
Amputation-free survival	
30 day	170
5 year	47

with an increased 30 day graft failure rate, ($p \leq 0.03$). Female gender was associated with both 30 day and 5 year graft failure, ($p \leq 0.01$, $p \leq 0.01$ respectively). Female gender also influenced the 5-year mortality rate ($p \leq 0.03$). In addition, the presence of critical ischaemia at the time of surgery was significantly associated with graft failure at 5 years, ($p \leq 0.02$). In our study, even though use of a synthetic graft and the construction of an infragenicular anastomosis were associated with lower graft patency rates, statistical significance was not reached, ($p \leq 0.09$, $p \leq 0.15$). There was no statistically significance difference between femoral-popliteal and femoral-distal bypass graft patency rates (77% vs. 67% respectively). However, femoral-distal bypasses using synthetic graft material were associated with significantly reduced patency rates compared with autologous vein grafts, ($p \leq 0.001$). 35% of subjects received prosthetic grafts and females were significantly more likely to receive a synthetic graft than males, ($p \leq 0.02$).

On multivariate analysis, the 3 most significant predictors of graft patency were the occurrence of a post-operative complication, gender and ASA grade. Kaplan-Meier survival curves were constructed in order to calculate patient graft patency rates and curves were compared using the Wilcoxon signed-rank test. Females had significantly reduced graft patency rates compared with their male counterparts ($p \leq 0.01$), (**Figure 1**). Interestingly however, neither the presence of diabetes ($p \leq 0.20$), (**Figure 2**), nor a prior history of smoking, ($p \leq 0.23$), (**Figure 3**), was significantly associated with graft failure.

4. Discussion

Despite advances in both the medical and endovascular management of peripheral arterial disease, infrainguinal

**Figure 1. Disease-free survival in males vs. females.**

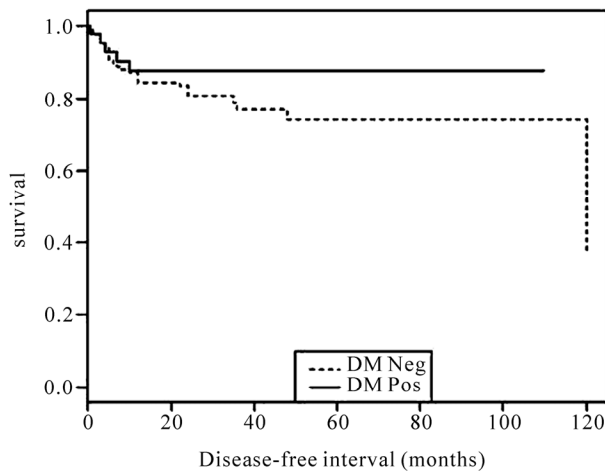


Figure 2. Disease-free survival in diabetics vs. non diabetics.

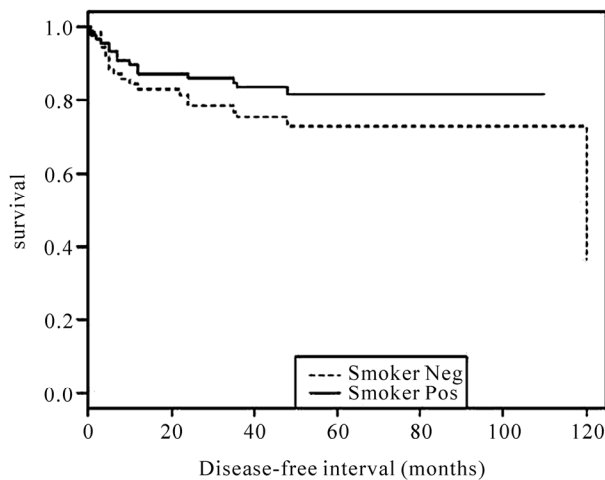


Figure 3. Disease-free survival in smokers vs. non smokers.

arterial reconstruction remains a necessary and effective treatment in select patients. Identification of predictors of graft failure facilitates appropriate patient selection and follow-up. Here, using a Cox-proportional hazards model to perform multivariate analyses, we identified the occurrence of a post-operative complication, female gender, and a high ASA grade as predictors of graft failure.

Previously, studies have attempted to identify factors associated with reduced graft patency in lower limb bypass procedures. In a review of 373 femoral-popliteal bypass grafts, Budd *et al.* found that the factors that consistently correlated with reduced late graft patency were graft material and the site of distal anastomosis. They also suggested that prosthetic grafts are a suitable alternative to autogenous vein when the distal anastomosis is above the knee, [8]. Other studies have postulated that the risk factors for graft occlusion in femoral-popliteal bypass include the construction of an infragenicular distal anastomosis, an early revision procedure, or contin-

ued smoking post-operatively [9,10]. In our study, however, even though use of a prosthetic graft and the construction of an infragenicular anastomosis were associated with lower graft patency rates, statistical significance was not reached. Our rates of morbidity and mortality, re-intervention, length of hospital stay and amputation-free survival are comparable to other published data [11,12]. The autologous and synthetic graft rates are also comparable [11,12].

We found that the occurrence of a post-operative complication, female gender, and a high ASA grade significantly reduced the long-term patency of infrainguinal grafts. Several studies in lower limb bypass surgery have reported that female sex has an adverse effect on graft patency [11-13]. The cardiology and cardiac surgery literature report higher morbidity and mortality rates in women compared with men as well as lower graft patency rates [15-17]. Several factors have been implicated for this, including older age at presentation in females and a greater number of comorbidities, diffuse rather than focal atheromatous disease in females, smaller vessel size and the influence of oestrogenic hormones [18,19]. In contrast, Roddy *et al.* have shown that female gender does not influence outcome following bypass surgery, but is associated with significantly increased wound complication rates compared with males [20]. In this study, females had significantly lower graft patency rates on both univariate and multivariate analysis. However, significantly more females underwent bypass with synthetic graft material than did males. This may be explained by the fact that females generally have a higher incidence of venous disease than males [19,20] as well as a smaller calibre long saphenous vein [20]. In many cases therefore, it may not have been possible to use autologous vein as the conduit of choice for females included in the study. Interestingly, when all of the above variables were entered into a Cox proportional hazards model, female gender was found to be the most powerful predictor of early graft failure.

There are a number of methods for classifying patients as low or high risk for a given operation. One of these is the classification system set forth by the American College of Anaesthetists (ASA) [21,22]. In our study, the median ASA grade was 3—reflecting the multiple comorbidities of this patient population. We found that a high ASA grade was also significantly associated with lower graft patency rates on multivariate analysis. This finding emphasises the importance of pre-operative patient risk stratification and optimisation for surgery.

Diabetes mellitus was not associated with time to graft failure on either univariate or multivariate analysis. In recent years, comparable graft patency and limb salvage rates between diabetic and non-diabetic patients have

been reported [23]. Some groups have even reported improved graft patency rates and operative mortality in diabetics [24,25], as we did in this study. Gahtan *et al.* retrospectively reviewed 170 patients undergoing infrainguinal arterial bypass over a 5-year period. They concluded that DM did not affect graft patency, operative morbidity or overall survival but it did affect the length of post-operative stay [26]. Ahchong *et al.* found that diabetes mellitus adversely affects hospital mortality and long-term survival, but not graft patency [27]. In our study, there was no significant difference between diabetic and non-diabetic complication rates or overall mortality rates.

Smoking is one of the major risk factors associated with the development and progression of peripheral arterial disease [28,29]. A host of studies have attempted to define the role of smoking in the pathogenesis of venous and prosthetic graft occlusion [30-33]. In our study, pre-operative smoking was not associated with lower graft patency rates. This is in accord with a recent large meta-analysis which reported that continued smoking after lower limb bypass surgery results in an at least a threefold increased risk of graft failure. Smoking cessation, even if instigated after the operation, restored graft patency towards the patency of patients who had never smoked [34]. These findings highlight the importance of implementing smoking cessation strategies for patients eligible for lower limb bypass surgery.

In infrainguinal bypass surgery, the decision as to which conduit to use is mostly based on the site of the planned distal anastomosis and the availability of adequate autologous long saphenous vein. It is universally accepted that autologous saphenous vein is the superior conduit for infrainguinal revascularization, particularly when the vein is of normal size and free of sclerotic segments. However, many studies have reported acceptable results with synthetic grafts for femoro-popliteal bypass grafting, particularly in 'claudicants' and when the distal anastomosis is supragenicular [35-37]. The preferred conduit in our study was reversed long saphenous vein. Overall, the graft material was not associated with variable graft patency rates. However, when the different surgical subgroups are examined separately, femoral-distal bypass with synthetic graft material is associated with significantly reduced patency rates than femoral-distal bypass using vein grafts. This finding concurs with many of those described in the published vascular literature to date [38,39].

5. Conclusion

We conclude that among the demographic and operative factors which can predict graft failure, the most impor-

tant are female gender, the presence of critical ischaemia at time of primary surgery, the occurrence of a post-operative complication and high ASA grade. A pre-operative history of smoking was not shown to adversely affect long-term graft patency. Similarly, the presence of diabetes mellitus was not associated with graft failure, though the number of diabetics in this patient population is relatively low and larger series may be required in order to prove this conclusively. We submit that these data may be of benefit in pre-operative patient selection, patient counselling, ensuring close patient follow-up and risk stratification.

6. References

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