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Predictors of Early Graft Failure After Infrainguinal Bypass Surgery: A Risk-adjusted Analysis from the NSQIP

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ABSTRACT

Introduction and objectives: Infrainguinal bypass surgery (BPG) is accompanied by significant 30-day mortality and morbidity, including early graft failure. The goal of this study is to identify patient- and procedure-specific factors which predict the rate of early graft failure in contemporary practice.
Methods: Data was obtained from the private sector National Surgical Quality Improvement Program, a prospective, validated database collected between 2005 and 2008 from 211 hospitals, using primary and modifier Current Procedural Terminology codes for BPG. The primary endpoint was graft failure at 30 days. Procedural parameters, patient demographics and clinical variables were analyzed by univariate and multivariate methods.
Results: There were 9217 BPG procedures (limb salvage, 49%; infrapopliteal distal anastomosis, 43%; prosthetic 32%) with patient variables: age 67 ± 12 years, male 64%, diabetes 44%, dialysis 7.4%. Mortality was 2.4%, major morbidity was 17.3%, and graft failure rate was 6.3% at 30 days. Multivariate predictors of graft failure demonstrated correlation (p-value, OR) with female gender ($p = 0.0054$, 1.29), limb salvage indication ($p < 0.0001$, 1.60), infrapopliteal anastomosis ($p < 0.0001$, 2.15), composite graft ($p = 0.0436$, 1.82), current smoking ($p = 0.0007$, 1.36), impaired sensorium ($p = 0.0075$, 2.13), emergency procedure ($p < 0.0001$, 2.03), previous vascular procedure ($p = 0.0005$, 1.39), and platelets >400K ($p = 0.0019$, 1.49). High-risk composite constructs utilizing these significant predictive factors can identify cohorts of patients with up to a 98-fold increase in odds of early graft failure.
Conclusions: These results describe common risk factors that correlate with early graft thrombosis including the unique description of its association with thrombocytosis. Additional risk factors thus identify a subset of patients who are at highest risk for early BPG failure. This data may be used to refine patient selection.

Introduction

Infrainguinal bypass surgery (BPG) has been shown to be associated with significant morbidity and mortality. Recent work has demonstrated a 30-day mortality rate of 2.7%, and a major complication rate of 18.7%. Earlier studies have elucidated some patient and procedural factors which are associated with early and late morbidity and mortality after BPG, including dyspnea, functional dependence, renal failure, and limb salvage indication.[1–6] Importantly, approximately 40% of major complications after BPG are related to early graft failure.

Various studies have highlighted an incidence of early BPG failure between 4.0 and 7.4%.[2,7–9] While some evidence describing risk factors for overall morbidity after BPG is available, the data describing the specific complication of early BPG failure is somewhat more limited.[1,5,10,11] The high incidence of early BPG failure is concerning, especially given that little has been written regarding the specific etiologic factors that predispose to this major complication.

The advancing age of the population and the concomitant rise in number of patients with peripheral arterial disease, coupled with the increasing limitations on healthcare dollars make the identification of high-risk patient groups of paramount importance. Complications after BPG can lead not only to marked increase in hospital costs, but these complications are also a poor prognostic indicator for patient outcomes and limb salvage.[12–19] Accordingly, the decision to undertake BPG, rather than non-operative therapy or primary amputation, should be made while carefully considering the associated peri-procedural morbidities,

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as well as the patient-specific factors which may drive unfavorable outcomes.

The primary aim of this study is to identify patient-specific and peri-procedural factors which may predict early BPG failure in contemporary practice. This data, in turn, will be explored to identify the groups at highest risk for early BPG failure. Using this information, the vascular surgeon will be able to improve patient selection and refine the treatment paradigm of lower extremity occlusive disease, thus potentially minimizing BPG failure.

Methods

Patient population

From 2005 to 2008, as many as 211 hospitals participated in the American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP). The ratio of academic to community medical centers was approximately 3:2 throughout this time period. Information from 635,265 patients was collected through the ACS-NSQIP over these four years, and this data is contained in the Participant Use File (PUF). After obtaining Institutional Review Board (IRB) approval, this validated data source was queried by Current Procedural Terminology (CPT) code to identify patients undergoing any open BPG using either vein or prosthetic material with a target of either the popliteal or tibial vessels (Table 1). These codes are standardized numbers assigned to every service, a medical practitioner may provide to a patient including medical, surgical and diagnostic services. From within that cohort of patients, an additional search for modifier or adjunct CPT codes was completed to delineate those patients who underwent BPG under specific circumstances (i.e., re-do, arm vein harvest, etc) (Table 1).

Data set

The NSQIP data collection methodology has been previously outlined.[20–22] In summary, it is a validated, prospectively collected database containing clinical variables. The data represents a systematic sample of each member-hospital's caseload, and is modified in order to be compliant with the Health Insurance Portability and Accountability Act (HIPAA) by omitting hospital, provider, or patient protected health information.[21,23] In each participating medical center, a dedicated surgical clinical nurse reviewer is responsible for collecting pre-operative risk factors, intra-operative variables, and 30-day post-operative mortality and morbidity outcomes for patients undergoing major procedures.[20–22,24] During routine site visits, the completeness and validity of the data are ensured.[25]

Table 1
CPT codes.

Primary CPT Codes:	
35556	Bypass graft with vein; femoral-popliteal
35566	Bypass graft with vein; femoral-tibial, peroneal, or other distal vessels
35571	Bypass graft with vein; popliteal-tibial or tibial/peroneal trunk-tibial
35583	In-situ vein bypass; femoral-popliteal
35585	In-situ vein bypass; femoral-anterior tibial, posterior tibial, or peroneal
35587	In-situ vein bypass; popliteal-tibial, peroneal
35656	Bypass graft, other than vein; femoral-popliteal
35666	Bypass graft, other than vein; femoral-tibial or peroneal
35671	Bypass graft, other than vein; popliteal-tibial or peroneal
Modifier/Adjunct CPT Codes:	
35500	Harvest of upper extremity vein (1 segment) for lower extremity bypass
35572	Harvest of femoropopliteal vein (1 segment) for vascular reconstruction
35681	Bypass graft; composite, prosthetic and vein
35682	Bypass graft; autogenous composite, two segments of vein (2 locations)
35683	Bypass graft; autogenous composite, three or more segments (2 locations)
35685	Placement of vein patch/cuff at distal anastomosis of bypass; synthetic conduit
35686	Creation of distal AV fistula during lower extremity bypass (non-hemodialysis)
35700	Reoperation, femoral-popliteal or femoral(popliteal)-tibial, peroneal, other distal vessels, more than 1 month after original operation

CPT = Current Procedural Terminology.

The pre-operative variables collected for the NSQIP describe the patient's demographic characteristics and their associated comorbidities for undergoing a variety of surgical procedures. The ACS-NSQIP database captures information regarding common outcomes for surgical procedures at 30 days. The information collected is not procedure-specific, and thus specific vascular surgical complications are not assessed.

Statistical analysis – univariate comparisons

The cohort of patients was divided into those who experienced an early graft failure, and those who did not. The occurrence of graft failure was determined by the response for the "graft failure" variable entered by the independent nurse reviewers. The "graft failure" variable is a validated data point collected by the NSQIP nurse reviewers. The definition of this variable is: "Mechanical failure of an extracardiac graft or prosthesis requiring return to the operating room, interventional radiology, or a balloon angioplasty." While it is not specific to lower extremity bypass conduit for all NSQIP patients, in the subset of patients undergoing lower extremity bypass, this variable can be considered to specifically refer to the vascular conduit.

Pre-operative, operative, and post-operative variables were evaluated for these two groups. Post-operative variables include, but are not limited to death, major morbidity, and any morbidity. Major morbidity includes all of the measured outcomes, with the exception of urinary tract infection, superficial wound infection, DVT, and peripheral nerve injury. For each comparison, the Fisher's Exact test was used for discrete variables, the *t*-test with equal variances was used for normally distributed continuous variables, and the Wilcoxon rank-sum test was used for non-normally distributed continuous and ordinal variables.

Statistical analysis – multivariate modeling

The occurrence of early graft failure was modeled using stepwise logistic regression. The number of candidate predictors was determined by the frequency of graft failure within the cohort. In addition to those variables that were deemed clinically relevant, all pre-operative and demographic variables which were missing in less than 10% of the patients AND which correlated with the outcome of graft failure on univariate analysis ($p < 0.15$) were considered for inclusion in the final risk-adjustment model. Additionally, the CPT-defined adjunct/modifier variables which met the same criteria were also considered for inclusion in the model. Of note, none of these variables were forced into the multivariate model. A significance level of 0.05 was the threshold chosen for the stepwise procedure, and thus was the threshold for a variable to remain in the model.

For possible combinations of comorbidities (i.e., "high-risk composites"), individual regression parameter estimates from the multivariate model for early graft failure were used to calculate composite odds ratios. These composite odds ratios demonstrate the effects of a combination of comorbidities in a cluster.[26]