Published in final edited form as:
Ann Vasc Surg. 2013 July ; 27(5): 646–654. doi:10.1016/j.avsg.2012.07.024.

Contemporary outcomes in vascular patients who require pre-operative coronary stent

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Abstract

The documented risks of pre-operative coronary revascularization prior to vascular surgery have led to a marked reduction in the role of percutaneous coronary intervention (PCI) during pre-operative risk stratification. However, many patients with peripheral arterial disease are first identified immediately after a PCI for an acute coronary syndrome. We sought to determine the risks associated with these patients who then go on to have a peripheral arterial intervention (open operation or endovascular procedure). We hypothesized that there was no difference in outcomes in patients whose medical condition required PCI with coronary stent placement prior to a vascular operation compared to a control cohort of non-stented patients who underwent a vascular operation alone. We report the vascular operative outcomes in a contemporary cohort of vascular patients who had PCI with coronary stent placement for an acute event.

METHODS—We performed a retrospective cohort analysis utilizing administrative data, of 3,678 vascular patients from 2005 to 2010 at a tertiary care hospital. Two groups were defined: patients with preoperative PCI and coronary stent placement within one year prior to vascular operation (N=101, mean age 66±1.22 years, 51.5% male) and patients with no PCI prior to vascular operation (N=3,577, mean age 60±.27 years, 46.37% male). Cardiovascular risk factors and complications derived from ICD-9 codes were used to parse data following open peripheral vascular surgery, endovascular repair, or amputation. Primary outcomes were death, non-fatal myocardial infarction, major adverse cardiac event (MACE, defined as death, MI or subsequent coronary revascularization) or bleeding.

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Society for Clinical Vascular Surgery Annual Symposium, March 16th 2011, Orlando, FL

RESULTS—Univariate analysis showed significant differences in both demographic and outcome analysis in patients with and without prior coronary stent. Patients with a recent PCI followed by a vascular procedure were more likely to undergo an endovascular procedure (75.3% vs 64.5%, OR = 1.67, p = 0.028). These patients also had 11 of 20 cardiovascular risk factors significantly greater than those without a prior PCI. Multivariate sub-group analysis indicated that patients with a prior coronary stent were more likely to have an episode of congestive heart failure (CHF) after 1 year of surgery (16.8%, p= 0.045). Additionally, an acute cardiac ischemic event was more likely within 1 year (2.0%, p= 0.036) and beyond 1 year (4.0%, p= 0.022) of surgery. Importantly, there was no significant increase in death, MI, MACE, or bleeding in patients with pre-operative coronary stent.

CONCLUSION—Patients who underwent PCI with coronary stent and then went on to require a vascular procedure had significantly more CV risk factors and were more likely to have an endovascular procedure than those patients without preoperative PCI. When controlling for CV risk factors and procedure type, there was no significant difference in death, MI, MACE or bleeding complications between the groups.

INTRODUCTION

Recent reports from the American Heart Association confirm that peripheral arterial disease (PAD) is a marker for atherosclerosis, a systemic disease; the sex- adjusted relative risk of death from cardiovascular disease in patients with PAD is 3.34 and for coronary heart disease is 2.13. The extent of PAD is extensive with nearly 8 million Americans older than 65 years of age affected.[1]

Vascular surgeons are often asked to evaluate patients with recent acute coronary events requiring percutaneous coronary intervention (PCI). This often occurs during a period of time when discontinuation of antiplatelet agents is discouraged (within 12 months) or during the post PCI period (within 4–6 weeks) where subsequent operative efforts are felt to be associated with higher event rates. These patients would typically be excluded from trials looking at elective vascular cases.

In a landmark series, Hertzer *et al.* reported on over 1000 patients who underwent routine coronary angiography prior to undergoing vascular surgery.[2] The authors showed that selective pre-operative artery bypass graft surgery in patients with severe coronary artery disease (CAD) lowered perioperative and long-term mortality when compared to those who did not undergo coronary artery bypass grafting (CABG). However, this was not a randomized controlled trial. The randomized, controlled Coronary-Artery Revascularization before elective major vascular surgery (CARP) trial helped to define the role of coronary revascularization prior to undergoing elective vascular surgery.[3] Coronary revascularization failed to improve any outcome measure, including death or myocardial infarction (MI). As a result, the protocol followed at many institutions, including our institution, for vascular surgery candidates is based on appropriate risk stratification with revascularization reserved for the sub-group of patients that are felt to have unstable cardiac symptoms.

We sought to evaluate vascular surgery patients who would have been excluded from the CARP trial given the acute coronary need for revascularization. We hypothesized that there was no difference in outcomes in patients who required PCI with coronary stent placement who then went on to have an urgent or emergent vascular operation compared to patients who had a vascular operation without a coronary inervention. With this in mind, we sought to explore the real-world contemporary risk of vascular surgery within one year of PCI with coronary stent placement, by comparing outcomes with respect to death, MACE (Major Adverse Cardiac Event) and bleeding complications when compared to a control vascular surgery patients without PCI and coronary stent. MACE was defined as death, MI or

coronary artery bypass graft (CABG) revascularization. We analyzed outcomes of coronary stented or non-stented vascular patients based on the type of vascular procedure that was performed to assess differences between open, endovascular, and amputation procedures as well as the type of stent placed: drug-eluting stent (DES) or bare metal stent (BMS). Furthermore, we compared outcomes of operations of stented vascular patients that occurred within one day of PCI and operations that were between one day and one year after PCI, thus assessing the outcomes of more urgent cases.

METHODS

Data Acquisition

This study protocol was approved by the University of Chicago institutional review board (IRB). Retrospective chart review was conducted for all patients at the University of Chicago Medical Center from October 2005 to March 2010. International classification of disease (ICD-9 CM) billing codes were used to compile patient information from a hospital database (Table 1).

Study Population

Patients were classified into two groups: patients who underwent a vascular procedure within a year after coronary stent placement (N = 101), and patients who underwent a vascular procedure without any history of coronary stent placement (N = 3,577). The latter group had a total of 3,961 vascular operations due to multiple procedures performed on some patients. In this group of patients that had no prior coronary stent but had multiple vascular procedures, only data from the index procedure was analyzed for risk factors and outcomes. Both groups were identified and data was acquired from the hospital administrative database using ICD-9 CM coding data.

The population of patients with a prior coronary stent was limited to patients who only had a single vascular operation within one year following their last coronary stent. Furthermore, if a patient had multiple coronary stents, patient risk factor data was only counted once from the most recent coronary stent procedure. We excluded any patients who had any heart operation as the single procedure after PCI. Moreover, in patients with no prior PCI placement, we only studied the index procedure, excluding any patient who had an operation on the heart as the index procedure. Excluded heart operation ICD-9CM codes were: 36–36.9, 38.7, 39.8, 38.93.

Demographic Data and Statistical Analysis

We identified 20 demographic and clinical risk factors, 27 procedures, and 32 outcomes designated by ICD-9 CM codes for both groups (see Table 1). Primary outcomes were death, non-fatal myocardial infarction, major adverse cardiac event (MACE, defined as death, MI or subsequent coronary revascularization) or bleeding requiring transfusion or re-operation. Secondary outcomes included congestive heart failure (CHF), angina and acute ischemic events. Primary and secondary outcomes were evaluated from follow-up data occurring within 30 days, within 1 year and beyond 1 year after surgery. Bleeding complications were also stratified based on patients who required transfusion or any other intervention based on the Agency for Healthcare Research and Quality (AHRQ) protocol. The demographics, procedures and outcomes were compared between both groups of patients using t-tests for continuous variables or chi-square tests for categorical variables. For each outcome, the risk factors that were significantly different between the groups from the univariate analysis ($p < 0.05$) were then used for further multivariate analysis, with the outcome serving as the dependent variable and the risk factors as the independent variables. Sub-group analysis was performed to compare outcomes between procedures, to compare

differences in outcomes between patients who had placement of DES or BMS prior to surgery. Also, we compared differences in outcome between vascular operations performed within one day and between one day and one year of PCI in stented patients. Statistical analysis was carried out using Stata11 (College Station, TX).

RESULTS

From 2005 to 2010, 101 patients (51.5% male) underwent PCI with coronary stent placement followed by a vascular procedure within one year, with an average age of 66 ± 1.22 years (mean ± SD). 56.4% (n=57) of patients with prior coronary stent had DES placement, 38.6% (n=39) had BMS placement and 5.0% (n=5) had both DES and BMS during their index stent placement. The average time between coronary stent and vascular procedure was 45.3 days, with 66 (65%) of the surgical operations occurring within a day of the coronary stent placement. Excluding patients who had their procedure done within a day of stenting, the days between stent and procedure ranged from 11 days after stent placement to 356 days. 3,577 patients (46.4% male), with a mean age of 60.3 ±0.3 years (Table 2), underwent a vascular procedure without any prior coronary stent placement. In total, 20 cardiovascular (CV) risk factors and 27 vascular procedures were identified. Procedures were further sub-classified into three groups: endovascular, open-repair and amputation. Patients with prior coronary stent placement were significantly more likely to undergo endovascular procedures (75.3%, n=76) than patients with no prior coronary stent placement (64.5%, n=2312), p = 0.028 (Table 2).

Univariate analysis of demographic data identified 11 risk factors that were significantly different between the groups (Table 2). The results confirmed that the stented group had risk factors that corresponded to an acute coronary event with significant differences in: coronary artery disease; acute MI (29.7% vs 1.3%, OR = 31.1, p< 0.001), angina (7.9% vs 0.8%, OR = 11.3, p < 0.001), acute ischemic heart disease (5.9% vs 0.6%, OR = 10.7, p< 0.001), CHF (39.6% vs 13.6%, OR = 4.2, p < 0.001), past myocardial infarction (30.7% vs 8.0%, OR = 5.1, p< 0.001); and chronic ischemic heart disease (86.1% vs 23.7%, OR = 20.0, p < 0.001). We also demonstrated that patients with a recent PCI and stent were more likely to undergo an endovascular procedure (75.3% vs 64.5%, OR = 1.7, p = 0.028).

Primary and secondary outcomes are shown in Table 3. Outcomes that were significantly different between groups included in-hospital MACE (36.6% vs 9.7%, OR = 5.4, MACE, p< 0.001), MACE beyond one year (4.0% vs 1.4%, OR =1.9, p= 0.048), in-hospital ST-elevation MI (STEMI) (7.9% vs 0.5%, OR = 17.0, p< 0.001), in-hospital non-ST-elevation MI (NSTEMI) (25.7% vs 1.3%, OR = 26.6, p< 0.001), NSTEMI beyond one year (1.0% vs 0.1%, OR = 11.9, p=0.033), CHF within one year (17.8% vs 10.8%, OR = 1.8, p= 0.029), CHF beyond one year (16.8% vs 8.2%, OR = 2.3, p= 0.003), angina within one year (4.6% vs 0.8%, OR = 6.6, p< 0.001), acute ischemia within one year (2.0% vs 0.4%, OR = 5.5, p= 0.026), and acute ischemia beyond 1 year (4.0% vs 0.1%, OR = 36.8, p< 0.001). Since it approached significance (1.0% vs 0.1%, OR = 7.1, p = 0.074), death within 30 days was included in the multivariate analysis. Several outcomes were not part of the multivariate analysis because there was insufficient data, these included STEMI within 30 days and within one year, and bleeding complications within 30 days and within one year.

Multivariate analysis was performed to analyze outcomes while controlling for risk factors and procedures. Of the 12 outcomes that were significantly different between groups by univariate analysis, only three remained significantly different after controlling for risk factors and procedures using multivariate analysis (Table 4): CHF beyond one year (OR = 1.9, p= 0.045), acute myocardial ischemia within one year (OR = 6.6, p= 0.036) and acute myocardial ischemia greater than one year (OR = 6.8, p = 0.022). Therefore, these

complications were significantly more common in patients who underwent a vascular procedure after a coronary stent placement.

Multivariate sub-group analysis looked specifically at outcomes from each procedure, and compared outcomes between DES and BMS patients. Patients who had a coronary stent placement followed by an amputation experienced a significantly increased occurrence of in- hospital MACE, (p= 0.031, Table 5) although sample size (n=5) limits this conclusion. There was no significant difference between outcomes of patients with DES placement compared with BMS placement prior to surgery. Because 66 operations were performed within one day of undergoing the PCI, we attempted to identify any difference in outcome with these acute care patients. There was no significant difference observed in any of the outcomes with multivariate analysis. Furthermore, looking at the 66 patients who had at least one vascular operation performed within one day of stent placement, 57 only had a single procedure performed. Of these, 86.0% (n=49) had only an endovascular procedure, 1.8% (n=1) had an amputation and 12.3% (n=7) had only an open repair. Likewise, 7 patients had two procedures within one day of stenting (both endovascular and open repair), and two patients had three procedures (endovascular repair, open repair and amputation) within one day of stenting. Moreover, 58 endovascular procedures were performed within one day of stenting. 48 of these procedures were a single endovascular procedure, whereas 10 patients had two endovascular procedures performed within one day.

DISCUSSION

Patients with atherosclerosis or aneurysms who require an operation with an anticipated event rate of ≥ 5% are considered to be “High Risk” by current standards.[1] Coronary artery disease is a primary cause of perioperative complications after vascular surgery.[4] Coronary revascularization and specifically PCI, are mainstays of care in high risk cardiovascular patients with angina or a large ischemic burden. This is despite evidence from the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial,[5] which demonstrated that for patients with stable angina, PCI with bare metal coronary stentswas no better than optimal medical therapy in preventing myocardial infarction (MI) or death. Similarly, the role of prophylactic coronary revascularization in patients awaiting vascular surgery has also been recently called into question on the basis of several studies, including the Coronary Artery Revascularization Prophylaxis (CARP) study.[3] This prospective, randomized trial found that pre-operative revascularization failed to affect mortality or the occurrence of postoperative MI. Sub-group analysis showed that CABG or PCI did improve survival in patients with left main disease.[6]

That prophylactic PCI prior to vascular surgery is not associated with an improved outcome was also supported by data from the randomized DECREASE V (Dutch echocardiographic Cardiac Risk Evaluation Applying Stress Echocardiography) trial,[7] specifically involving ”high risk” cardiovascular patients with extensive coronary artery disease. The DECREASE V trial was a prospective randomized trial designed to obtain efficacy and safety estimates in high risk vascular patients who underwent pre-operative revascularization. The study showed that patients with pre- operative coronary stent placement did not have improved outcomes (all cause mortality, MI, or composite) in either the 30 day or one year perioperative period.[7] In all of these studies (COURAGE, CARP, AND DECREASE V), the vascular operation was the indication for the coronary intervention. We sought to evaluate a group of patients where the primary indication for PCI with stent was a recent or on-going coronary event. The demographics of the patients that we studied (Table 2) indicate that those with a stent had it due to a primary coronary event. This is reflected by 30% of the PCI with stent group presenting with acute coronary ischemia, 40% with ongoing CHF, 86% with chronic ischemic heart disease, 8% with

ongoing angina and 6% with a diagnosis of other acute ischemia. Thus, we isolated a group of patients where ongoing coronary problems were the indications for PCI and stent prior to a vascular operation.

Our first aim was to decipher the risk factor profile of our cohort, and determine the inherent differences between our study groups. From the demographic data and univariate analysis it can be determined that the two patient populations were heterogenous, with 11 of 20 cardiovascular risk factors or procedures significantly different between the two groups. The Revised Cardiac Risk Index is a validated paradigm for stratifying cardiac risk prior to non-cardiac surgery.[8] The more risk factors the patient has, the higher the risk of perioperative complications. Based on the number of risk factors, the group of patients that had a coronary stent before surgery should have had a significantly greater number of adverse outcomes. This seemed to be confirmed as univariate analysis indicated that 12 out of the 32 outcomes were significantly worse in the coronary stent group. Given the heterogeneity between the two groups, a multivariate analysis was performed with respect to outcomes. The multivariate analysis showed that the risks for death, MI, MACE and bleeding were similar between the two groups. The data indicate only three outcomes were statistically different: CHF beyond one year after surgery, acute ischemic event within one year, and an acute ischemic event beyond one year after surgery. Our data also show that there is no significant difference in the development of STEMI, however there was an increased likelihood of a diagnosis of acute ischemia after one year. This diagnosis failed to correlate with an increase of MI suggesting that this code was utilized as a marker for follow-up examinations of coronary stent patients, including angiogram studies. Thus, the data support our hypothesis that patients who undergo PCI with coronary stent who then require vascular surgery are at no increase risk for death, MI, MACE or bleeding compared to vascular operation alone.

Death and acute MI may occur from in-stent-thrombosis or subsequent restenosis, whereas bleeding is usually due to anti-platelet therapy medications or access site complications after a PCI procedure.[6, 9] Anti-platelet therapy is indicated because coronary stent thrombosis may result from the hypercoagulable state induced by the stress of surgery and the denudation of the endothelial wall by the stent, potentially leading to a thrombogenic state that can lead to vessel occlusion and subsequent ischemia.[6, 10] To reduce the risk of coronary stent thrombosis, dual anti- platelet therapy is necessary for both BMS and DES for one month and one year, respectively.[10] This anti-platelet therapy includes aspirin and thienopyridine which, through different mechanisms, result in irreversible inhibition of platelet function and thus a prolongation of bleeding time. Patients delaying surgery after coronary stent placement tend to have less bleeding complications and better outcomes once these agents are held in preparation for the intervention.[7] It has been shown that the longer the time period between PCI and non-cardiac surgery (NCS), the better the outcome. American Heart Association/American College of Cardiology (AHA/ACC) guidelines suggest waiting at least 4 weeks before undergoing elective non- cardiac surgery after BMS placement, and waiting 8–12 months in a patient with prior DES placement, under the Class III recommendations of preoperative coronary revascularization with CABG or PCI.[9] Furthermore, PCI with DES, the most common type of coronary stent used today, has FDA and AHA/ACC recommendations for uninterrupted dual antiplatelet therapy for 12 months, based on a continued rate of very late coronary stent thrombosis events, which appear to occur at approximately 0.6% per year and are more common with discontinuation of such agents.[1] Recent data demonstrates that discontinuation of clopidogrel during this first year after DES for any reason carries with it greater than 30-fold higher likelihood of stent thrombosis in the week after discontinuation.[11–12] Based on these data we sought to evaluate for bleeding complications and other acute coronary events. Sub-group analysis comparing patients whose coronary stent placement was DES compared to those without BMS showed no significant difference in any of the outcomes.

The average time between coronary stent and surgery (45 days), as well as the fact that 66 of the surgeries were performed within a day of the coronary stent placement, indicate that the nature of many of the surgeries were patients with acute care needs. To that end, in these stented patients, we saw no significant increase in outcomes of patients who had a vascular operation within a day of the PCI placement compared to those who had a PCI placement between one day and one year. Thus, early operative intervention in that high risk window where dual anti-platelet therapy is standard did not result in any increase risk of either primary or secondary outcomes, including MI, bleeding or death.

A sub-group analysis was performed to address the question of whether or not there was a difference in outcome based on the type of vascular operation performed. Procedures were grouped in three categories: open operation, amputation and endovascular. These groups were chosen to be studied since they cover a wide range of non-cardiac operations that are often seen in high risk cardiovascular patients. We showed through univariate analysis that there is a significant increase ($p=0.028$) in the number of endovascular operations performed within a year after coronary stent placement. This finding is interesting and clearly suggests that patients with prior coronary stents are more likely to undergo an endovascular approach to vascular operations. Furthermore, results of the sub-group analysis indicate that patients undergoing amputations who had prior PCI with coronary stent were more likely to have a MACE in-hospital ($P=0.031$). This may reflect the overall end stage nature of the vascular disease, but must certainly be looked at as a potential type II error given the fact that only five patients had amputations. Thus, patients who underwent PCI with coronary stent placement, were more likely to undergo an endovascular procedure than an open procedure, but there was no difference in death, MI or MACE between open or endovascular procedures.

Vascular complications after PCI have a reported incidence between 1% and 14%[13] with more recent studies of 3%.[14] Major vascular complications that may require surgical intervention include pseudoaneurysms, access site complications, retroperitoneal hematomas and fistula formation. Thus, it is important to evaluate the indications for acute vascular operation in those patients with previous PCI placement. Due to the limitations of ICD-9 billing codes, we could not accurately correlate a diagnosis code to a specific procedure that was performed. Despite this limitation, however, we could elucidate from our results that the subset of patients who had a complication from PCI placement followed by vascular operation would fall under the acute category of vascular operations occurring within one day of stenting. These patients were shown to have no significant difference in outcomes as those who had less emergent operations after stent placement.

This study describes the implications of recent coronary stent placement on vascular procedure patient profiling. There are inherent limitations in part due to the retrospective nature of the analysis, and also due to the inherent shortcomings of an administrative database. In this study, we compared risk factors and outcomes between the groups, which may reflect the difference in treatment options given patients conditions. The multivariate analysis was able to assess how the risk factors we examined jointly attributed to the outcomes, although we were limited to the variables we collected. It is possible that there were unknown factors that contributed to the differences between the groups. However, the aim of the study was to assess whether stent placement contributed to different MACE outcomes, while controlling any risk factors that differed between the groups. Given the data, the findings may be limited to our sample only. There is also a selection bias since we chose only certain procedures to study. Furthermore, as we only used our hospital database, we could not exclude patients who may have had a coronary stent placement in a different institution and had surgical intervention at our hospital. We also were not able to obtain complete medication information for patients undergoing coronary stent. More importantly,

we could not control for the degree of CAD, or ischemia by chart review, and could not correct for the operator's decisions as whether to proceed with PCI or not.

To conclude, vascular procedures that were performed soon after PCI with coronary stent placement resulted in no significant increase risk of death, MI, MACE or bleeding in our sample. Despite that, patients who required PCI with coronary stent tended to have significantly more cardiovascular risk factors than those who did not. The type of coronary stent did not seem to affect outcome.

Acknowledgments

Dr. Skelly is funded by NIH K-08-HL091053 as well as by the American Vascular Association/American College of Surgeons and NHLBI Jointly Sponsored Mentored Clinical Scientist Development Award.

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Table 1

ICD-9CM Billing codes used to identify risk factors, outcomes and procedures.

RISK FACTORS(ICD-9 Code)
Smoking (v15.82, 305.1)
Diabetes (250, 250.4, 250.8)
Cardiovascular (272, 401.9, 402, 403.9, 405.91, 410, 411, 412, 413, 414, 428, 433, 496)
Kidney Disease (585.6, 585.9)
OUTCOMES (ICD-9 Code)
Bleeding Complication (998.11, 998.12)
STEMI (410.11, 410.31, 410.41, 410.42, 410.81, 410.9, 410.91, 410.92)
NSTEMI (410.71)
CHF (428.0, 428.3, 428.22, 428.2, 428.33, 428.32)
Angina (413.1, 413.9)
Other Acute Ischemia (411.1)
CABG (36.1–36.19)
PROCEDURES (ICD-9 Code)
DES Stent (36.07)
BMS Stent (36.06)
Open Operation (38.1–39.9)
Amputation (83.4–84.3)
Endovascular (88.41–88.48, 39.7)

DES, drug eluting coronary stent; *BMS,* bare-metal coronary stent.

Ann Vasc Surg. Author manuscript; available in PMC 2014 July 01.

Table 2

Demographic data and univariate analysis comparison of demographics of patients with pre-operative coronary stent with vascular operation and patients with vascular operation without pre-operative coronary stent.

RISK FACTOR	VASCULAR OPERATION (n=3,577)	CORONARY STENT And VASCULAR OPERATION (n=101)	Odds-Ratio	95% Conf. Interval	P-Value
Average Age at Procedure	60.11	65.74			0.0005
Smoking at surgery	588(16.44%)	24(23.76%)	1.58	.99–2.52	0.053
History of smoking	691(19.32%)	30(29.70%)	1.76	1.14–2.73	0.01
Essential Hypertension	1,547(43.25%)	62(61.39%)	2.09	1.39–3.13	<0.001
Secondary Hypertension	8(.22%)	1(.99%)	4.46	.55–36.01	0.16
Hypertensive Chronic Kidney Disease	651(18.20%)	26(25.74%)	1.56	.99–2.45	0.056
Cerebrovascular Disease	277(7.74%)	13(12.87%)	1.76	.97–3.19	0.063
CHF	486(13.59%)	40(39.60%)	4.17	2.77–6.28	<0.001
COPD	206(5.76%)	14(13.86%)	2.63	1.47–4.71	0.001
Diabetes Mellitus	681(19.04%)	35(34.65%)	2.26	1.48–3.42	<0.001
Diabetes with Renal Manifestation	49(1.37%)	3(2.97%)	2.2	.68–7.19	0.19
Diabetes with other manifestations	112(3.13%)	3(2.97%)	0.95	.30–3.03	0.927
Hyperlipidemia	912(25.50%)	75(74.26%)	8.43	5.36–13.25	<0.001
Chronic Kidney Disease	392(10.96%)	21(20.79%)	2.13	1.30–3.49	0.003
End Stage Renal Disease	435(12.16%)	11(10.89%)	0.88	.47–1.66	0.7
Coronary Artery Disease - Acute MI	48(1.34%)	30(29.70%)	31.07	18.60–51.89	<0.001
Other Acute Ischemia	21(.59)	6(5.94%)	10.69	4.22–27.10	<0.001
Old MI	286(8.00%)	31(30.69%)	5.1	3.28–7.91	<0.001
Angina	27(.75%)	8(7.92%)	11.31	5.00–25.56	<0.001
Chronic Ischemic Heart Disease	849(23.73%)	87(86.14%)	19.97	11.30–35.30	<0.001
PROCEDURES					
Endovascular	2312(64.54%)	76(75.25%)	1.67	1.06–2.64	0.028
Open Repair	1293(36.10%)	33(32.67%)	0.86	.56–1.31	0.48
Amputation	356(9.94%)	5(4.95%)	0.47	.19–1.17	0.104

CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction

Ann Vasc Surg. Author manuscript; available in PMC 2014 July 01.

Table 3

Univariate analysis comparing outcomes between patients with pre-operative coronary stent with vascular operation and patients with vascular operation without pre-operative coronary stent.

OUTCOME	VASCULAR OPERATION (n=3,577)	CORONARY STENT AND VASCULAR OPERATION (n=101)	Odds-Ratio	95% Confidence Interval	P-Value
In Hospital MACE *	346(9.67%)	37(36.63%)	5.4	3.55–8.21	< 0.001
MACE * within 30 days	18(.50%)	1(.99%)	1.98	.26–14.96	0.51
MACE * within 1 yr	48(1.34%)	2(1.98%)	1.49	.36–6.20	0.587
MACE * beyond 1 yr	51(1.43%)	4(3.96%)	1.85	1.01–8.05	0.048
In Hospital Death	119(3.33%)	1(.99%)	0.29	.04–2.10	0.221
Death within 30 days	5(.14%)	1(.99%)	7.14	.83–61.71	0.074
Death 1 year	30(.84%)	1(.99%)	1.18	.16–8.76	0.87
Death beyond 1 yr	29(.81%)	2(1.98%)	2.47	.58–10.50	0.22
In Hospital ST-MI	18(.50%)	8(7.92%)	17.01	7.21–40.10	< 0.001
STMI beyond 1 year	15(.42%)	1(.99%)	2.37	.31–18.16	0.405
In Hospital NSTEMI	46(1.29%)	26(25.74%)	26.61	15.62–45.32	< 0.001
NSTEMI within 1 year	3(.08%)	1(.99%)	11.91	1.22–115.5	0.033
NSTEMI beyond year	3(.08%)	1(.99%)	11.91	1.22–115.5	0.033
Bleeding beyond 1 yr	10(.28%)	1(.99%)	3.57	.45–28.13	0.227
CHF within 30 days	159(4.45%)	3(2.97%)	0.66	.21–2.10	0.479
CHF within 1 year	387(10.82%)	18(17.82%)	1.79	1.06–3.01	0.029
CHF beyond 1yr	294(8.22%)	17(16.83%)	2.26	1.32–3.86	0.003
Angina within 30 days	4(.11%)	1(.99%)	8.93	.99–80.64	0.051
Angina within 1 year	28(.78%)	5(4.95%)	6.6	2.49–17.46	< 0.001
Angina beyond 1yr	33(.92%)	1(.99%)	1.07	.15–7.93	0.944
Other AI within 30 days	7(.20%)	1(.99%)	5.48	.62–41.84	0.129
Other AI within 1 year	13(.36%)	2(1.98%)	5.54	1.23–24.87	0.026
Other AI beyond 1yr	4(.11)	4(3.96%)	36.84	9.07–149.45	< 0.001

* *MACE* defined as event of death, MI or CABG revascularization

ST-MI, ST elevated myocardial infarction*; NSTEMI*; non-ST elevation myocardial infarction; *CHF*, congestive heart failure; *AI*, acute myocardial ischemia.

Table 4

Multivariate analysis of outcomes comparing outcomes of patients who received a coronary stent prior to a vascular procedure compared to vascular operation alone, while controlling for risk factors and procedures

	Coronary Stent and Operation vs Operation only		
OUTCOME	**Odds Ratio**	**95% confident Interval**	**p-value**
In Hospital MACE *	0.8	.37–1.73	0.572
MACE beyond 1 yr	2.17	.63–7.50	0.22
Death within 30 days	3.92	.26–59.89	0.326
Death beyond 1 yr	1.85	.34–10.21	0.479
In hospital ST-MI	2.69	.88–8.20	0.082
In hospital NSTEMI	1.32	.30–5.86	0.716
NSTEMI beyond 1 year	2.51	.09–66.96	0.583
Bleeding beyond 1 yr	7.15	.68–75.43	0.102
CHF within 1 year	0.96	.52–1.75	0.886
CHF beyond 1yr	1.88	1.01–3.49	0.045
Angina within 30 days	3.28	.20–54.78	0.408
Angina within 1 year	1.58	.44–5.69	0.48
Other AI within 1 year	6.57	1.13–38.03	0.036
Other AI beyond 1yr	6.8	1.31–35.32	0.022

* MACE defined as event of death, MI or CABG revascularization

ST-MI, ST elevated myocardial infarction; *NSTEMI*; non-ST elevation myocardial infarction; *CHF*, congestive heart failure; *AI*, acute myocardial ischemia.

Table 5

Sub-group multivariate analysis comparing outcomes for each individual procedure in patients undergoing coronary stent prior to operation compared to operation alone.

	Open Operation			Amputation			Endovascular		
OUTCOME	**Odds ratio**	**95% Conf. Interval**	**P-Value**	**Odds Ratio**	**95% Conf. Interval**	**P-value**	**Odds Ratio**	**95% Conf. Interval**	**P-Value**
In Hospital MACE *	0.86	0.26–2.85	0.805	14.04	1.27–154.53	0.031	1.33	0.56–3.18	0.521
Death beyond 1 year of operation	n/a	n/a	n/a	n/a	n/a	n/a	2.59	0.35–19.07	0.349
Bleeding with operation beyond 1 year	13.81	0.89–214.57	0.061	n/a	n/a	n/a	8.66	0.62–120.37	0.11
CHF within 1 year of operation	0.68	0.26–1.79	0.438	0.29	.02–3.62	0.337	0.65	0.30–1.37	0.254
CHF beyond 1 year of operation	1.41	0.56–3.53	0.465	0.66	.05–9.09	0.755	0.97	0.43–2.18	0.94

* MACE defined as event of death, MI or CABG revascularization

CHF, congestive heart failure