Outcomes of Lower Extremity Revascularization (LER) in Patients on Dialysis

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OBJECTIVES: Dialysis patients with peripheral vascular disease (PVD) are at high risk for complications following surgical bypass, and it is not clear if endovascular interventions have affected survival and limb salvage in this patient population. We sought to characterize the outcomes of endovascular and open revascularization in dialysis patients treated for claudication or critical limb ischemia (CLI).

METHODS: The United States Renal Data System (USRDS) was utilized to review all patients undergoing LER in dialysis patients in the United States between 2005-2008. Diagnoses and procedures were identified by ICD-9 and CPT codes respectively. Primary outcomes were mortality and limb salvage. Bivariate associations were tested using the chi-squared test, and predictors were identified using Cox regression models.

RESULTS: A total of 12,029 incident dialysis patients underwent LER (24% endo, 76% open). CLI was the indication in 79.9% of endo LER, and 72.8% of open LER. Major amputation rate within 30 days for CLI patients was 15.1% (15.7% endo, 13.1% open, p=.002), and for claudicants was 5.2% (5.2% endo, 4.9% open, p=.771). At 1 year, 32.0% of CLI patients (33.0% endo, 29.1% open, p<0.001), and 14.4% of claudicants (14.0% endo, 16.4% open, p=.254) had undergone major amputation. The mortality rate at 30 days for CLI patients was 7.8% (7.2% endo, 9.8% open, p=.001), and for claudicants was 5.2% (4.7% endo, 7.9% open, p=.018). At 1 year the mortality rate was 38.4% for CLI patients (37.6% endo, 40.9% open, p=.005) and 25.7% for claudicants (25.7% endo, 25.2% open, p=.820). There were no significant differences between estimated survival for endo and open procedures at 1 year when stratified by clinical indication. Estimated limb salvage differed significantly between open and endo LER only among CLI patients, with open LER associated with improved limb salvage (p=.001) (Figure). Significant predictors of post-LER mortality were older age (p<.001) and congestive heart failure (p=.001).

CONCLUSIONS: Mortality and amputation rates following LER for dialysis patients are significant, particularly for patients with CLI. Although open LER is associated with improved limb salvage compared to endo LER, mortality is greater at 30-days and 1-year. Given the high overall mortality rates, the presence of dialysis-dependence questions the indication for LER, especially for claudication.
OBJECTIVES: Long-term results comparing percutaneous transluminal angioplasty ± stent (PTA/S) and surgical bypass (BPG) for critical limb ischemia (CLI) in patients who have had no prior intervention have not been extensively reported. We detail our results with 3-year follow-up.

METHODS: We reviewed all lower extremity revascularization procedures at our institution from January 2005 to December 2010, where 943 patients presented for CLI and underwent a first time intervention. Outcomes included complications, restenosis, symptom recurrence, reinterventions, minor and major amputations and mortality. Predictors for reintervention and amputation were identified using a Cox regression model.

RESULTS: Of the 943 patients, 541 underwent BPG and 402 underwent PTA/S. BPG were above the knee in 58% (40% vein) and below the knee in 42% (100% vein). Mean age was 70.5 (BPG) versus 72.4 (PTA/S; \( P = .03 \)), with more males undergoing BPG (64% vs. 52%; \( P<.01 \)). Mean length of stay (LOS) was 10 days (BPG) versus 7.4 days (PTA/S; \( P = .02 \)), with 3-year reintervention rates significantly lower in patients undergoing BPG (42% vs. 54%; \( P<.01 \)). There were no differences in perioperative mortality (3% vs. 2%; not significant [NS]). Wound infection was 11% in BPG patients; however, BPG showed improved freedom from restenosis (78% vs. 67% at 3 years; odds ratio [OR], 1.6; 95% confidence interval [CI], 1.2-2.1). A Cox regression model of all patients showed that a reintervention within 3 years was predicted by PTA/S (OR, 1.6; 95% CI, 1.1-2.3) (see Figure) and a history of smoking (OR, 1.3; 95% CI, 1.0-1.6). Major amputations were predicted by gangrenous indications (OR, 1.9; 95% CI 1.1-3.5) and were not predicted by procedure type.

CONCLUSIONS: BPG for the primary treatment of critical limb ischemia showed improved freedom from restenosis and significantly fewer reinterventions than PTA/S within 3 years, but was associated with increased LOS and wound infection. Perioperative mortality and 3-year amputation rates were similar between procedure types.
OBJECTIVES: Acute lower extremity ischemia secondary to thromboembolism is a common problem treated by vascular surgeons. Contemporary data regarding this problem are sparse. This report examines a 10 year single-center experience with acute lower extremity thromboembolism and describes the surgical management and outcomes observed.

METHODS: Consecutive patients treated surgically for acute lower extremity embolization from January 2002 to September 2012 were identified using ICD-9 and CPT codes. Iatrogenic cases and cases secondary to trauma were excluded. Demographic, co-morbidity, presentation, operative management, postoperative morbidity, and mortality data were abstracted from the electronic medical record. Data were examined using count (%), median or mean ± SD, and product-limit survival analysis.

RESULTS: The identified study sample included 170 patients. Mean age was 69 years, 47% of patients were female, and 80% were white. Eighty-two patients (49%) had a known history of atrial fibrillation and 4 (2%) had a warfarin associated INR ≥ 2.0. Eighty-three percent presented greater than 6 hours after symptom onset. Nine percent presented with a concurrent stroke. Femoral artery exposure for embolectomy was the preferred initial mode of treatment. Additional popliteal exposure for inadequate clearance of tibial occlusion was required in 4% of cases, 10% of cases employed a popliteal-only approach for isolated distal occlusions, and local instillation of thrombolytic agents was employed in 16% of cases. Fasciotomies were performed in 39% of cases. Unexpected return to the operating room occurred in 24% of cases. Eleven patients (6%) required bypass for limb salvage during the initial hospitalization. Amputation was required during the index hospitalization in 26 patients (15%) and following initial discharge in an additional 6 patients (4%). In-hospital or 30-day mortality was 18 percent. Median length of stay was 8 days. Thirty-four percent of patients required discharge to a skilled facility. Recurrent embolization occurred during follow-up in 23 patients (14%) at a median interval of 1.6 months. Amputation-free and overall survival estimates for the study sample at five years were 75% and 49%, respectively.

CONCLUSIONS: Despite advances in contemporary medical care, lower extremity arterial embolization remains a condition that is associated with significant morbidity and mortality. Furthermore, the condition is resource intensive to treat and could be prevented (either initially or in recurrence) in a substantial subset of patients.
Trends in the Utilization and Cost of Ambulatory Endovascular Procedures

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OBJECTIVES: Endovascular therapy is used increasingly for the treatment of claudication and limb threat (PAD). These procedures may be performed in the inpatient, hospital associated ambulatory or freestanding ambulatory settings though utilization and costs in the ambulatory setting have not been studied. We aim to evaluate trends in the utilization and cost of endovascular procedures across healthcare settings.

METHODS: The State Ambulatory Surgery Databases (SASD) and State Inpatient Databases (SID) of Florida, New Jersey, California and Maryland from 2005 to 2009 were queried for patients undergoing elective endovascular procedures for PAD. Utilization trends for these procedures were stratified by indication (claudication vs. critical limb ischemia (CLI)) and service location (freestanding ambulatory, hospital associated ambulatory, inpatient). As freestanding data was available for Florida only, comparison of healthcare charges across locations was restricted to this state. Inpatient charges for cases with length of stay > 1 day were excluded from cost analysis.

RESULTS: We identified 101,910 procedures; 64,722 (64%) for claudication and 37,188 (36%) for CLI. Overall procedure volume increased 57% from 2005 to 2009. Utilization of ambulatory facilities (freestanding and hospital associated) for claudication increased 84% from 2005 to 2009 (6,188 to 11,547) while inpatient procedures declined 11% from peak utilization in 2007 to 2009 (4,421 to 3,947). Freestanding procedures for claudication showed most pronounced increase with 444% (47 to 256) over the study period. Procedures for CLI increased in all service locations (Ambulatory: 2606 to 4936, 89%; Inpatient: 3173 to 3619, 14%). Total charges for treatment of claudication in freestanding centers were only 53% of hospital associated ambulatory centers ($14,727 vs. $27,945) while total charges for treatment of CLI were similar in freestanding vs. hospital associated ambulatory centers ($26,704 vs. $27,072). Inpatient charges far exceeded both ambulatory locations (Claudication: $39,900; CLI: $41,368).

CONCLUSIONS: Freestanding and hospital associated ambulatory endovascular procedure utilization are increasing for both claudication and CLI. Treatment of claudicsants in freestanding centers appears to be particularly cost effective.
**Dacron® vs. polytetrafluoroethylene grafts for above-knee lower limb arterial bypass**

**Abstract**

**OBJECTIVES:** Surgical revascularisation for lower limb ischaemia remains an important component for optimisation of quality of life and symptomatology in patients with peripheral arterial disease. The objective of this meta-analysis is to establish which prosthetic graft, Dacron or PTFE, has the better long-term patency in patients undergoing an above-knee femoro-popliteal arterial bypass.

**METHODS:** This meta-analysis was performed using Cochrane and PRISMA guidelines. An electronic search of all relevant databases was performed from 1990 to 2013 using the Medical Subject Headings: ‘Dacron’, ‘PTFE’, ‘above knee’, ‘femoropopliteal’, ‘bypass’. The inclusion criteria were randomised controlled trials, use of Dacron vs. PTFE prosthetic conduits and completion of an above-knee femoro-popliteal arterial bypass involving adult patients aged over eighteen years presenting with disabling claudication, rest pain or tissue loss, occlusion of the superficial femoral artery and reconstitution of the above-knee popliteal artery. Graft patency rates were calculated using RevMan 5.1 software. When multiple studies were evaluated while original patency rates were documented when only one study result was available.

**RESULTS:** Ninety-one publications were reviewed. After exclusion of duplicate, non-randomised and alternative bypass surgery studies, four randomized controlled trials were identified involving 957 patients comprising 476 Dacron and 481 PTFE above-knee lower limb arterial bypasses. Mean age reported was 66 years and all patients had generalised cardiovascular co-morbidities and risk factors. Two studies evaluated 6mm grafts, one assessed 8mm grafts while the other study included graft sizes between 5mm and 8mm. Although primary and secondary patency rates at 12-months were not significantly different (RR 0.47, p=0.52 & RR 0.84, p=0.52), 24- and 60-month primary patency rates were better with Dacron compared to PTFE grafts (RR 0.81, p=0.03 and 52% vs. 36%, p=0.04). Statistical analysis also supported higher secondary patency rate for Dacron at 24- (RR 0.75, p=0.02) and 60-months (70% vs. 51%, p=0.01). Ten-year patency rates were similar. Antiplatelet / anticoagulation therapy was prescribed in 85% of patients in one trial. However, exact best medical therapy strategies were not described in the other studies. There was no difference in amputation, overall morbidity or mortality rates between the two surgical graft populations.

**CONCLUSIONS:** Current evidence suggests that Dacron prosthetic grafts are superior to PTFE grafts in above-knee femoro-popliteal arterial bypass procedures. Further randomised trials targeting standardisation of confounding variables particularly graft size and best medical therapy are warranted.
Silver Dressing Reduces Femoral Wound Complications and Cost in High-Risk Vascular Surgery Patients

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OBJECTIVES: Femoral wound infection remains a significant problem for both open surgical procedures and minimally-invasive endovascular procedures. The purpose of this study was to evaluate the impact of a silver-impregnated dressing (Ag) versus sterile gauze (control) in high-risk patients undergoing vascular procedures involving open femoral artery exposure.

METHODS: Utilizing a retrospective database, high-risk cases involving open femoral artery exposure were identified over a 44-month time period (10/2009 - 6/2013). High-risk patients were defined as those with a Hemoglobin A1c (HbA1c) > 8 mg/dL, Body Mass Index (BMI) > 30 kg/m² or the presence of tissue loss. Ag dressing was utilized in high-risk patients during the last 18 months of the study period. Inclusion criteria and 30-day infection-related outcomes were compared with univariate statistical methods. Overall institutional savings was calculated.

RESULTS: The Ag group (n=113) was well-matched to the control (n=198) with respect to high-risk inclusion criteria (Table). Use of Ag dressing was associated with a decreased overall rate of wound complications and a significant reduction in the requirement for operative debridement (Table, *P <0.05). The estimated cost savings for one year of using a silver dressing instead of sterile gauze was $130,000.

CONCLUSIONS: Ag dressing use is associated with decreased femoral infection-related complications and institutional cost in a cohort of high-risk patients. These data demonstrate that selective use of an Ag dressing results in decreased morbidity and resource utilization, which is especially important within the evolving context of value-based care and reimbursement models.

<table>
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<tr>
<th></th>
<th>Ag (n=113)</th>
<th>Control (n=198)</th>
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<tr>
<td>BMI &gt; 30 kg/m² (%)</td>
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<tr>
<td>HbA1c &gt; 8 mg/dL (%)</td>
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<tr>
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OBJECTIVE: Short-term results of endovascular intervention for femoro-popliteal lesions have been extensively reported, however, there exists a paucity of long-term objective data related to outcomes of these interventions. We sought to characterize these long-term results including patency, limb salvage and mortality.

METHODS: From May 2003 to July 2009 all patients who underwent endovascular balloon angioplasty and/or stenting for TASC II B, C and D lesions were identified in a retrospective fashion. Patient demographics, clinical characteristics, arterial noninvasive data and angiographic anatomic data were evaluated.

RESULTS: A total of 285 limbs in 188 patients (mean age 74, range 69-94) were treated. Lesion distributions by TASC II classification B, C and D were 144 (50.53%), 39 (13.68%) and 102 (35.79%) respectively. Critical limb ischemia (CLI) was the indication for intervention in 43.5% of patients. Kaplan Meier five year primary and primary assisted patency rates based on TASC II classification were B: 56.0%, 88.9% C: 47.0%, 75.9% D: 34.2%, 59.7% respectively (p=0.634 and 0.128). Diabetes was the sole adjusted predictor of loss of primary patency (HR 1.5, 1.02-2.45, p=0.04). Re-interventions to maintain patency were required in 27.1% of TASC II B, 38.5% of TASC II C and 22.6% of TASC II D lesions (p=NS) and mean time to re-intervention based on TASC II classification B, C and D of 26, 22 and 20 months (p=NS). 17 patients were converted to open revascularization and two patients underwent major amputation during follow up. Mortality at 5 years was 48.7%. CLI as indication for intervention was the sole adjusted predictor of death (HR 2.3, 1.47-3.60, p<.001).

CONCLUSION: Long-term patency of endovascular interventions for complicated femoro-popliteal lesions are acceptable across TASC II classification and are associated with excellent limb salvage. Mortality in this patient cohort is significant with CLI being identified as the sole predictor of death.
OBJECTIVE: Endovascular repair (ER) of popliteal artery aneurysms (PAA) has emerged as a minimally invasive alternative to open repair (OR). This study compares patency rates in those undergoing ER and OR of PAAs.

METHODS: A retrospective chart review was performed to identify PAAs repaired between 1998 and 2012. Graft patency was based on either clinical (presence of palpable pulses) and/or radiologic examination.

RESULTS: A total of 69 patients with 79 PAAs underwent repair. Thirty-two patient (36 limbs) underwent OR while 38 patients (43 limbs) underwent ER. All ERs utilized the Viabahn endoprosthesis (W.L. Gore, Flagstaff, AZ), while ORs were utilized autologous great saphenous vein or prosthetic grafts. Postoperative treatment consisted of antiplatelet therapy, anticoagulation or both. The patient cohorts were similar at baseline between the OR and ER groups (p>0.05) - mean age 70.6 ± 13.1 versus 74.5 ± 9.0 years; mean diameter of 3.21 ± 1.54 cm versus 2.77 ± 0.88 cm; mean runoff of 2.06 ± 0.80 versus 2.0 ± 0.76 vessels; and symptomatic aneurysms in 41.7% versus 30.2% of cases. 55.8% of cases were performed under loco-regional anesthesia in the ER group, compared to 44.4% in the OR group. Length of stay was significantly shorter in the ER group, 1.95 ± 2.05 versus 6.38 ± 5.05 days in the OR cohort (p<0.001). Mean follow up was significantly longer in the OR group, 75.3 ± 68.5 months versus 33.8 ± 27.3 months (p<0.05). The secondary patency improved to 90% and 90.5% (Figure 1). One patient undergoing OR required an amputation. Single vessel runoff was associated with higher occlusion rates among all patients undergoing repair (p=0.004) and the ER cohort (p=0.003), but not the OR group. Furthermore, patients with good run-off (two or three vessels) undergoing ER had fewer instances of graft occlusion, 3.1% versus 24% (p=0.036).

CONCLUSION: Patients undergoing OR had a decreased primary patency, however, close surveillance and prompt reinterventions resulted in secondary patency comparable to ER. Patients with good run-off had improved primary patency with ER.
OBJECTIVES: With aging of the adult population, a significant increase in the number of procedures performed for lower extremity ischemia has occurred. Surgical site infection (SSI) following infrainguinal bypass surgery can lead to markedly increased patient morbidity and hospital cost. The ability to identify risk factors leading to these events may allow for modification of treatment strategy or perhaps select patients better served by alternative methods of revascularization.

METHODS: The National Surgical Quality Improvement Program (NSQIP) database from 2005-2011 was queried. Patients undergoing infrainguinal revascularization by open bypass were identified. Wound infection was classified as superficial if it included only skin or subcutaneous tissue. Deep infection was noted if it involved the deep soft tissues, fascia, muscle layers, or graft. Preoperative risk factors and patient demographics were compared. Those factors found to be significant were placed in a step-wise multivariate Cox proportional hazards regression model to determine their individual significance.

RESULTS: During the period of study, 20,505 infrainguinal bypass operations were identified, and SSI was found to complicate 2363 (11.6%). In 1469 cases (7.2%), the SSI was found to be superficial and in 894 (4.4%) it was found to be deep. On multivariate analysis, hypertension was a significant predictor of superficial wound infection (p < 0.05). Emergency operation, dialysis dependence, previous coronary intervention, and female sex were significant predictors of deep wound infection (p<0.05 for each). The presence of diabetes, shortness of breath, and operative time greater than four hours was predictive of both (p<0.05 for each).

CONCLUSIONS: A number of peri-operative risk factors are associated with an increased risk of SSI following infrainguinal bypass operations. While the length of operation may be subject to modification, the majority of risk factors are not. In patients with co-morbidities predictive of an increased risk of SSI, alternative methods of revascularization may be preferable.
The increased use of CTA and MRA as the sole imaging modalities prior to infrainguinal bypass has had no effect on outcomes

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OBJECTIVE: Angiography remains the gold standard imaging modality prior to infrainguinal bypass. Computed tomography angiography (CTA) and magnetic resonance angiography (MRA) have emerged as non-invasive alternatives for pre-operative imaging. We sought to examine contemporary trends in the utilization of CTA and MRA as isolated imaging modalities prior to infrainguinal bypass and to compare outcomes following infrainguinal bypass in patients who underwent CTA or MRA versus those who underwent conventional angiography.

METHODS: Patients undergoing infrainguinal bypass within the Vascular Study Group of New England were identified (2003-2012). Patients were stratified by pre-operative imaging modality: CTA/MRA alone or conventional angiography. Trends in utilization of these modalities were examined and demographics of these groups were compared. Primary end points included primary patency, secondary patency, and major adverse limb events (MALE) at 1-year as determined by Kaplan-Meier analysis. Multivariable Cox proportional hazards models were constructed to evaluate the effect of imaging modality on primary patency, secondary patency, and MALE.

RESULTS: In 3327 infrainguinal bypasses, CTA/MRA alone was used in 517 cases (15%) and angiography was used in 2810 cases (85%). In the CTA/MRA group, CTA was used more frequently than MRA (82% vs. 18%). Use of CTA/MRA alone increased over time, with 58 (11%) bypasses from 2003-2005, 215 (42%) bypasses from 2006-2009, and 244 (47%) bypasses from 2010-2012 (P<0.001). Patients with CTA/MR alone, compared to patients with angiography, more frequently underwent bypass for claudication (31% vs. 25%, P=0.0004) or acute limb ischemia (14% vs. 5%, P<0.0001), had aneurysmal disease (10% vs. 5%, P<0.0001), and less frequently had undergone a prior endovascular intervention (20% vs. 30%, P<0.0001). These patients more frequently had prosthetic conduits utilized (36% vs. 29%, P=0.001), and less frequently had tibial/pedal targets (31% vs. 40%, P=0.0002). After adjusting for confounders, multivariable analysis demonstrated that use of CTA/MRA alone was not associated with a significant difference in 1-year primary patency (HR 0.97; 95% CI, 0.80-1.17; P=0.74), secondary patency (HR 1.31; 95% CI, 1.00-1.72; P=0.05), or MALE (HR 1.08; CI 0.90-1.31; P=0.41) (FIGURE).

CONCLUSION: CTA and MRA are being increasingly utilized as the sole preoperative imaging modality prior to infrainguinal bypass. This shift in practice patterns appears to have no measurable effect on outcomes at 1-year.