

PP36.

Outcome Following Loss of Primary Patency After Endovascular Intervention of Superficial Femoral and Popliteal Arteries

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Objective: To evaluate outcomes following loss of primary patency (LPP) in superficial femoral (SFA) and popliteal (Pop) arteries treated by endovascular intervention (EVI)

Methods: The medical records of all SFA/Pop EVI performed by 2 Vascular Surgeons between 2005- 2008 were reviewed to identify LPP defined as occlusion or need for re-intervention documented by duplex or angiography. TASC II, EVI type, Rutherford Score (RS) and Rutherford Improvement Scores (RIS) were recorded. Analysis was completed with SPSS 15.

Results: LPP occurred in 38 patients (31%) at 8.6 ± 5.4 months. Twenty-four (63%) of these patients had EVI for critical limb ischemia (Rutherford Class 4-6). Mean follow up (FU) was 20 ± 11 months. Neither TASC II, RS at primary EVI (PEVI) or EVI type had significant impact on RIS at LPP. RIS at LPP was worse than before PEVI in 55%. Re-intervention was performed in 79% of LLP patients. Patients who never showed significant improvement between PEVI and LPP were unlikely to improve at FU (Table I) despite a trend to undergo multiple re-interventions (55% vs. 13%; $p=0.06$). Survival and limb salvage at 24 months were 75% and 92%. Healing occurred in 46% of tissue loss patients at 11.9 ± 11.6 months.

Conclusion: EVI of the SFA/Pop arteries are not benign procedures. LPP occurred in nearly 1/3 of patients and 55% of those patients became worse than prior to PEVI. Despite reasonable limb salvage, healing occurred in only 46% and was delayed. Aggressive re-intervention after PLL may not improve outcome in patients who did not demonstrate significant interval improvement after PEVI.

Table 1

Classification:PEVI/LPP interval	Improved RIS @ FU entire group N(%)	Improved RIS@ FU re-intervened N(%)
Improvement →	19(82%)	15(88%)
Worsening		
Unchanged/ Worsening	3(20%)	2(15%)
P Value (Significance)	0.013	0.007

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PP37.

Contemporary Results with Endovascular Therapy for Acute Limb Ischemia

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Objective: Endovascular therapies play an increasing role in the treatment of acute limb ischemia. The purpose of this study was to assess outcomes in patients treated for acute limb ischemia (ALI) with intra-arterial thrombolysis and/or percutaneous mechanical thrombectomy (PMT).

Methods: Consecutive patients (n = 76) with ALI of the lower extremities treated via intra-arterial methods between January 1, 2005 and December 31, 2006 were identified and reviewed. Overall estimates of patency, limb salvage, and survival at 1 and 2 years were made using Kaplan-Meier estimation. Hazard ratios from Cox proportional hazards models were used to estimate differences in risk between groups for patency and survival.

Results: Patients with ALI (82 limbs) presenting with native artery or graft thrombosis (76%) underwent thrombolysis and PMT (46%) under local anesthesia (96%) for an average of 1.6 days. Adjunctive procedures were required in 94% of patients to treat the culprit lesion with solely open revascularization in 16%. One patient had a major bleeding episode, but there was no intracranial hemorrhage in this cohort. 30-day amputation and mortality rates were 14% and 6%. Primary patency at 1 and 2 years were 52.1% (95% CI, 39.3- 64.8), and 41.6% (95% CI, 27.9-55.4), while secondary patency rates at 1 and 2 years were 74.6% (95% CI, 63.7-85.5), and 67.5% (95% CI, 55.1-80.0) respectively (median follow up=22.5 months). Limb salvage at 1 and 2 years was 86.5% (95% CI, 77.7-95.3) and 81.9% (95% CI, 71.5-92.3). Patients on dialysis (HR, 3.82; 95% CI, 2.22-6.59; $P<0.001$) and elevated creatinine levels (HR 1.16; 95% CI, 1.05- 1.29; $P=0.004$) were associated with primary patency loss. Overall survival at 1 and 2 years was 83.4% (95% CI, 74.4- 92.4) and 81.6% (95% CI, 72.1-91.1). Women were at an increased risk for mortality (HR, 16.93; 95% CI, 2.18-131.58; $P=0.007$) while those with COPD (HR, 3.12; 95% CI, 0.93-0.45; $P=0.065$) trended towards increased risk.

Conclusions: ALI remains a challenging clinical entity. Endovascular therapy is a safe and durable treatment option for patients presenting with lower extremity ALI. Patients with impaired renal function are associated with worse long term patency outcomes. Female patients are associated with decreased overall survival.

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PP38.

Results with Viabahn-Assisted Subintimal Recanalization for Severe Superficial Femoral Artery Occlusive Disease

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Objectives: Many investigators including Transatlantic Inter-Society Consensus (TASC) recommend against primary endovascular treatment for severe (TASC C and D) superficial femoral artery (SFA) disease. Vein bypass is preferable, but may not be appropriate due to comorbidities or lack of suitable vein. This study reviews our results with Viabahn stent graft-assisted subintimal recanalization (VASIR) for TASC C and D SFA atherosclerosis.

Methods: Thirteen males and fourteen females, mean age 73 ± 11 years underwent 28 VASIR for severe (TASC C 8/28, TASC D 20/28; 4/28 no continuous infrapopliteal run-off artery) SFA disease. Indications were claudication (14/28 limbs), ischemic rest pain (6/28), and tissue loss (8/28). VASIR was chosen instead of bypass due to comorbidities or lack of vein. Patients received aspirin and, if not already taking warfarin, they also received clopidogrel. Patients were examined with ABI and duplex scan at 1 month, then every 3 months after VASIR.

Results: VASIR was technically successful in all. ABI averaged $.47 \pm .17$ pre-procedure, $.89 \pm .20$ post-procedure, and increased by $.15$ or more in every case. Median follow-up is 20 months. There were 3 perioperative (<30 days) and 7 later failures including revision prior to any thrombosis. One patient required amputation. Four have died, two with patent grafts, none from causes related to VASIR, all more than 30 days post-VASIR. Estimated one year primary and secondary patency were $70 \pm 11\%$ and $73 \pm 10\%$. Failure was not significantly associated with indications, comorbidities, or runoff status. There was a clear distinction between patients with early failure and the rest of the patients. None of 8 patients with failure in the first 8 months after surgery has a patent graft. However, of 17 grafts primarily patent at 8 months, only two have failed (one thrombosed, one required preemptive balloon angioplasty). Furthermore, although warfarin was not prescribed as part of the protocol, no patient taking warfarin before and who resumed warfarin after VASIR (n=4) suffered failure.

Conclusions: Despite significant early failures, we found VASIR to be durable in those who did not suffer early failure. VASIR is an acceptable alternative to vein bypass in selected patients with severe SFA disease. Warfarin may be valuable to reduce the risk of failure after VASIR.

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PP39.

Major Limb Amputations Have Decreased in New York State During the Last Decade

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Background: Over the past decade, dramatic shifts in the management of vascular disease have increased safety and reduced mortality. This study examines the impact of these changes on limb salvage success.

Methods: NY State in-patient hospital discharge data from 1998-2007 were queried for patients who underwent either open or endovascular (endo) lower extremity revascularization procedures (LER) or amputations. Patients were selected by cross referencing ICD9 diagnostic and procedural codes. Proportions were analyzed by chi-squared analysis, continuous variables by t test and trends by the Cochran-Armitage test.

Results: Over time the combined rate of LE surgery decreased by 13%, with major shifts occurring in the type of surgery. While the per capita (100,000 population, age>40) volume for endo LER doubled (34.6 to 71.7), the number of major amputations and open LER declined by 38% (44.5 to 30.3) and 40% (104.2 to 62.2), respectively. Interventions for patients with critical ischemia (CI) declined by 17% (88.1 to 73.5), but those for claudication increased by 61% (17.7 to 28.6). Endo LER interventions for both claudication and CI nearly tripled (286%, 271%). Though the total

number of surgeries on patients age 80+ with CI has increased, rate per capita decreased by 14%, compared to a 20% decline in other age groups. The incidence of significant comorbidities has substantially increased; for claudicants: diabetes by 19%, HTP 30%, COPD 40%, CAD 21% and renal 230%; for patients with CI: HTP, COPD, and CAD incidence was higher (23%, 32%, 8% respectively) but diabetics decreased by 6%. Cardiac, respiratory and infection complications after amputation have increased by 29%, 28% and 10%. For LER, respiratory complications increased 9% but cardiac and infection complications actually decreased (8 and 27%) Similar trends were observed for patients with combined LER and amputation. Length of stay (LOS) declined significantly in all groups with an overall decrease of 30% (p<.05).

Conclusion: Despite the fact that patients, whether treated for claudication or CI, are sicker, older and have more complications, the rate of major amputations and LOS has significantly decreased due presumably to widespread and successful use of endo LER and/or to earlier interventions driven by the safety of endo LER.

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PP40.

An Algorithm for Optimal Utilization of Percutaneous Closure Devices

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Purpose: To introduce an algorithm which has been successful in minimizing complications related to the use of percutaneous closure devices.

Introduction: The following algorithm was implemented as follows: Perclose was the default closure device used, except in cases where the artery was very calcified or had dense scar tissue, in which case the Angioseal was the first choice. If a Perclose failed, the Angioseal was attempted. If an Angioseal failed, pressure was held for 15-30 minutes without pecking. If holding pressure failed, a Femostop (Radi Medical) was applied.

Methods: The author made 201 punctures in 191 (103 male, 88 female) patients undergoing endovascular procedures from April 2006 to October 2008. Risk factors included arrhythmia (n=12, 6.28%), coronary artery disease (n=55, 28.80%), congestive heart failure (n=9, 4.71%), diabetes (n=73, 38.22%), dialysis (n=9, 4.71%), hyperlipidemia (n=43, 22.51%), hypertension (n=119, 62.30%), COPD (n=13, 6.81%), history of MI (n=26, 13.61%), TIA/CVA (n=7, 3.66%). ASA classifications were I (n=9, 4.71%), II (n=35, 18.32%), III (n=115, 60.21%) and IV (n=23, 12.04%). Failure of the closure device was defined as persistent bleeding requiring manual pressure, formation of a hematoma, blood transfusion, or hospitalization. Failure of the algorithm was defined as formation of a hematoma, blood transfusion or hospitalization.

Results: Perclose was selected as the first choice in 78.11% (n=157) of punctures and the Angioseal was selected in 17.80% (n=44). The failure rate for each device was 15.91% (n=7) for Angioseal and 8.92% (n=14) for Perclose. The overall failure rate was 10.45%. All Angioseal failures were successfully treated with manual compression. Perclose failures were ultimately treated with an attempt at another closure device (n=6), manual compression (n=6), or a Femostop (n=2). Average recovery time was 1 hour 37 minutes (range: 23 minutes to 4 hours 48 minutes; SD: 39 minutes). 99.48% (n=190) of patients were discharged same day; 0.52% (n=1) was admitted for thromboemboli. The final failure rate of the algorithm was zero.

Conclusion: The described algorithm minimizes closure device-related complications. Implementation of this algorithm increases the safety of performing endovascular interventions in an office angi suite.

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PP41.

Long Term Results of Open Versus Endovascular Revascularization of Superficial Femoral Artery Occlusive Disease: A Case Control Series

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Background: For patients with superficial femoral artery (SFA) occlusive disease the most appropriate treatment has yet to be determined. We performed a case control comparison of long term results of femoral popliteal bypass and SFA endovascular interventions to examine the characteristics of patients and procedures to optimize results.

Methods: All femoral-popliteal bypasses and SFA interventions performed for consecutive patients with symptoms Rutherford 3 to 6 between 2001 and 2008 were reviewed. Kaplan Meir survival analyses were performed to assess time-dependent outcomes. Log rank analyses, univariate and multivariate analyses were performed.

Results: During the study period 152 limbs in 141 patients (66% male, mean age 66±22 years) underwent femoral-popliteal bypass; 233 limbs in 204 patients (49% male, mean age 70 ± 11 years) underwent SFA intervention. Surgery was performed less commonly for claudication (46% vs. 56%), and more commonly for critical ischemia (54% vs 44%). Six year primary, primary assisted and secondary patency rates were 56%, 64% and 75% respectively for bypass patients. Six year primary, primary assisted and secondary patency rates were 40%, 67% and 85% respectively for SFA interventions. Six years limb salvage for surgery was 80%; six year limb salvage rate was 92% for SFA interventions. Complications occurred in 21% in the surgery group and in 1.2% of the endovascular group. Re-intervention was required in 24% of surgery patients and in 14% of endovascular patients. Failure of SFA intervention led to bypass in 5% of patients, however prior failed intervention did not change target artery. Predictors of failed patency for both the surgery and SFA intervention group were female gender, diabetes, creatinine > 1.8, and critical limb ischemia. However, limb salvage was no different for all groups.

Conclusions: Though long term patency and limb salvage were equivalent in this case controlled study of femoral popliteal bypass versus SFA interventions, re-intentions and complications occurred at a higher rate in the surgery group. Women, diabetics and renal failure patients had sustained patency less frequently with both treatments; however, limb salvage was not disadvantaged for any group. SFA stent placement should therefore be initial therapy for patients with SFA occlusive disease.

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PP42.

Blood Transfusion is Associated With Increased Morbidity and Mortality After Lower Extremity Revascularization

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Background: In adult ICU, trauma, and surgical patients, blood transfusion is associated with increased morbidity and mortality as well as increased risk of venous /arterial thrombotic events and mortality in hospitalized cancer patients. We analyzed data from the NSQIP database to examine the effect of intraoperative blood transfusion in patients undergoing lower extremity revascularization(LER).

Methods: We queried the ACS NSQIP database from 2005 to 2007. CPT codes were used to identify LER procedures which were grouped into thromboendarterectomy(TEA), bypass with vein(BV) or prosthetic graft (BP). Multivariable analysis adjusted transfusion impact for clinical risk factors, procedure group and complexity.

Results: Our query resulted in 8799 patients, 66.8 ± 12.0 years of age, of whom 5569 (63.3%) were male. 12% underwent TEA, 42% underwent BP and 46% underwent BV. Composite mortality was 2.9%, morbidity 25.5%. Transfusion rates varied across procedure group from 14.5% in TEA patients, 20.1% in BV patients, to 27.1% in BP patients. Intraoperative transfusion was associated with increased morbidity and mortality; after adjustment for clinical risk factors, procedure type and complexity, transfusion remained significantly predictive of poorer outcomes:

Table. 30-day outcomes for lower extremity revascularization; patients transfused intraoperatively versus not. Unadjusted rates and odds ratios adjusted for all significant ACS NSQIP clinical risk factors, procedure group and complexity

Outcome	Not transfused	Transfused	P-value	Adjusted odds ratio (95% CI)	P-value
N/ %	6827/77.6%	1971/22.4%			
Mortality	1.9	6.2	<.001	2.2 (1.6-2.9)	<.001
Morbidity	21.7	38.8	<.001	1.7 (1.5-2.0)	<.001
Graft Failure	4.8	7.8	<.001	1.4 (1.2-1.8)	.001
Return to O.R.	15.4	26.8	<.001	1.5 (1.3-1.7)	<.001
Wound Complication	10.5	14.4	<.001	1.3 (1.1-1.6)	<.001
Sepsis/Shock	5.0	12.9	<.001	1.9 (1.6-2.3)	<.001
Pulmonary Complication	3.5	14.5	<.001	3.0 (2.5-3.7)	<.001
Renal Insuff./Failure	1.0	3.0	<.001	1.9 (1.3-2.8)	.002