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Lower Extremity Arterial Reconstruction in Octogenarians and Older

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Abstract

Background—Despite previous single-institution studies showing that lower extremity arterial reconstruction (LEAR) in octogenarians and older may be undertaken with acceptable postoperative morbidity and mortality, there continues to be significant reluctance, in the vascular surgical community, to undertaking these complex revascularization procedures in this very elderly population. We undertook this study in an effort to determine the outcomes of LEAR in octogenarians and older on a national level.

Methods—The American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP) Database was queried to identify all patients who underwent LEAR between January 1, 2005 and December 31, 2009. Patient demographics and presenting comorbidities were recorded, and multivariate analyses were performed to compare outcomes in patients 80 and older to that in younger patients.

Results—There were 19,028 patients who underwent open infrainguinal LEAR during this time period. Patients ≥ 80 comprised 18% (3,486 patients); and patients < 80 years comprised 82% (15,542 patients). Multivariate analysis demonstrated that patients ≥ 80 years of age had an increased likelihood of mortality (OR 1.79, 95% CI 1.42-2.26), cardiovascular (OR 1.46, 95% CI 1.12-1.89), respiratory (OR 1.37, 95% CI 1.12-1.67) and renal (OR 1.57, 95% CI 1.27-1.95) complications. There was, however, no significant difference in the likelihood of graft failure (OR 1.04, 95% CI 0.86-1.27), wound infection (OR 0.92, 95% CI 0.79-1.06), or major amputation (OR 0.59, 95% CI 0.13-2.74) between these two groups.

Conclusion—LEAR in octogenarians is associated with an increased risk of postoperative morbidity and mortality, but no increased risk of wound infection, amputation or graft failure.

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Introduction

With an increasingly aging population, the prevalence of peripheral arterial disease (PAD) – a condition closely related to advancing age – has continued to increase. According to the Center for Disease Control, PAD affects 27% of men and 21% of women 80 years of age and older as compared to 5-7% of the population under 50. According to the US Census Bureau, the population of Americans 65 and over is expected to reach 83.7 million, or 20% of the total population by 2030.^{1, 2} This increasing elderly segment in our society will be expected to lead to an increasing need for PAD diagnosis and treatment including surgical revascularization.

Unfortunately, however, there exists a wide variability in the treatment approaches offered to elderly patients with PAD.^{3, 4} This inconsistency may partly be related to varying reports of treatment outcomes in this age group. Certain studies have reported that octogenarians undergoing lower extremity arterial reconstruction (LEAR) have higher rates of postoperative mortality and systemic complications as well as higher amputations rates.^{2, 5} Other studies have demonstrated that octogenarians have similar morbidity and mortality rates as compared to younger patients.⁵⁻⁷ Still, others have suggested that specific patient characteristics, such as good preoperative functional status and low operative risks need to be present in order to obtain favorable postoperative outcomes in octogenarians.⁸

In light of differing reports regarding outcomes of LEAR in the very elderly, we sought to determine, on a national level, the outcomes of infrainguinal arterial reconstruction in octogenarians and older as compared to younger patients.

Methods

A retrospective study was conducted using data from the American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP) Database from 2005 to 2009. Patients who underwent an open revascularization procedures were identified using the appropriate American Medical Association's Current Procedural Terminology codes (Table 1). Patient demographics and presenting comorbidities were determined (Table 1). We performed a univariate analysis (Table 2) to determine the characteristics of patients undergoing lower extremity open revascularization regardless of their age. Comorbidities were defined as follows: Cardiac comorbidity was defined as a history of congestive heart failure within 30 days before surgery; a history of myocardial infarction 6 months before surgery; previous percutaneous coronary intervention; previous cardiac surgery; or a history of angina within one month before surgery. Renal comorbidity was defined as acute renal failure within 24 hours prior to surgery or a preoperative history of dialysis. Pulmonary comorbidity was defined as a history of severe chronic obstructive pulmonary disease, current pneumonia or ventilator dependence within 48 hours prior to surgery. Neurologic comorbidity was defined as a history of cerebral vascular accident, history of transient ischemic attack, impaired sensorium within 48 hours before surgery or preoperative coma. Diabetes was defined as a diagnosis of insulin-dependent or non-insulin dependent diabetes mellitus. Bivariate analysis was then conducted using Pearson's Chi Square for categorical variables and Student t-test for continuous variables to determine any relationship between

the variables and outcome (Tables 3 & 4). Investigated patient outcomes included postoperative morbidity and mortality. Postoperative complications were grouped as, cardiac, respiratory, renal, neurologic, infectious, amputations and graft failure. Cardiac complications were defined as cardiac arrest or myocardial infarction. Respiratory complications were defined as pneumonia, unplanned intubation, pulmonary embolism, or ventilator dependence > 48 hours. Renal complications represented progressive renal insufficiency and acute renal failure. Infectious complications included superficial surgical site infections (SSI), deep incisional SSI, organ space SSI or wound disruption (dehiscence). Univariate and bivariate analyses were initially performed. Next, multivariate regression analyses were performed comparing the outcomes between the two age groups while controlling for demographics, preoperative comorbidities, body mass index, smoking and functional status. All statistical analyses were performed using STATA/MP, version 11.0 (StataCorp, College Station, TX). Statistical significance was defined as $P < 0.05$ (Tables 5 & 6).

Results

There were 19,028 patients who were identified in ACS-NSQIP as having undergone LEAR from 2005 to 2009. Univariate analysis (Table 2) revealed that this was a primarily White (79.08%) male (63.16%) population <80 years of age (81.68%) with independent functional status (82.5%). Furthermore, bivariate analysis of the population sample revealed that the majority of patients were non-diabetic (65% non-diabetics in ≥80 and 59% in <80), non-smokers (88% non-smokers in ≥80 and 52% in <80), and functionally independent (70% independent in ≥80 and 85% in <80) preoperatively as listed in Table 3. Cardiac comorbidities were present in 42.6% in ≥80 and 39.7% in <80. Preoperative comorbidities were similar in the two groups (Table 3).

Patients ≥80 years old represented 18% of the population ($n=3,486$) and those <80 82% ($n=15,542$), table 2. Mortality rate was 2.4% for those <80 and 5.4% for those ≥80. Upon multivariate analysis, there was greater than an 80% increase in the risk of mortality for patients ≥80 as compared to patients <80 (OR=1.81, 95%CI 1.44-2.28). There was also an increased risk for cardiac, respiratory and renal complications for the ≥80 group (Table 5). Outcomes were not statistically different between the two groups for sepsis, wound infections, amputations, and graft failures. There was, however, a slight increase in length of stay for those ≥80 compared to <80 (OR=1.09, 95%CI 1.04-1.14). The average postoperative lengths of stay were 6.3 and 5.8 days for ≥80 and <80 respectively.

Bivariate and multivariate analyses depicted that preoperative dependent functional status of the patient – partial and total - was associated with an increased risk of adverse outcomes in virtually every category including mortality, cardiac, respiratory and renal complications as well as major amputations, graft failure, wound infections, sepsis, and length of stay. Obesity (BMI ≥30) was associated with a significant increase in mortality, respiratory complications and length of stay. African-American ethnicity was an independent risk factor associated with significantly worse outcomes in renal complications, amputations, graft failures, sepsis, and length of stay.

Table 6 illustrates the contributions of associated factors and comorbidities to the likelihood of mortality in those ≥ 80 undergoing LEAR compared to their younger counterparts as a reference. Preoperative renal comorbidity and dependent functional status were associated with the highest risk of mortality in those greater than 80 years old (OR= 4.25, 95%CI 3.32-5.45) & (OR= 3.8, 95%CI 3.12-4.64). Female gender and pulmonary comorbidity were also found to be independent risk factors associated with increased odds of mortality in those ≥ 80 when compared to younger patients. Cardiac comorbidities, diabetes and smoking were not noted to increase the risk of mortality in the ≥ 80. Interestingly, obesity seemed to have a protective effect, decreasing the risk of mortality in these elderly patients, (OR= 0.43, 95%CI 0.31-0.59).

Discussion

The topic surrounding age as a predictor of outcomes in LEAR has been debated in the literature over the years²⁻⁸. As the US population continues to age, the need to evaluate interventional outcomes has become increasingly paramount. Currently, in this country, it is estimated that over 11 million of the population is over the age of 80 with an increase of more than 1.5 million over the past decade alone.⁹ PAD is increasingly prevalent in this age group and vascular surgeons continue to treat increasingly elderly patients. The superiority in outcomes when comparing revascularization versus either no intervention or primary amputation in elderly patients with severe PAD has been well described.^{7, 10-15} Furthermore, functional outcomes and overall costs have also been studied and favor limb salvage over amputation in the elderly.¹⁵⁻¹⁸ The outcomes of specifically open, infrainguinal LEAR in those ≥ 80 on a national level, however, have been less well defined. Our study represents the largest retrospective review of 30-day outcomes following open LEAR in patients ≥ 80. A detailed description of the data collection, sampling process, and inclusion/exclusion criteria is available from the ACS-NSQIP website.¹⁹ Using this database, we were able to demonstrate that in patients ≥ 80 there are systemic differences in postoperative morbidity and mortality compared to patients < 80, but not differences in outcomes specific to the revascularization procedure itself i.e. graft failure, amputation and wound infection.

Overall, our 30-days mortality rate of 5.4% in those ≥ 80 was significantly higher than 2.1% in younger patients. Other studies have reported similar rates for operative mortality in those ≥ 80 ranging from 0-6%.^{6, 8, 20-25} Others, however, such as Brosi et. al.²⁶ and de Leur et. al.²⁷ report significantly higher mortality approaching 20-22%. It is noteworthy that five of the six patients that died in the study by Brosi et. al. had undergone suprainguinal reconstruction procedures whereas the study by de Leur et. al was based on only 16 patients ≥ 80 undergoing open LEAR. Despite these low numbers, one cannot simply ignore the fact that the risk of mortality increases with age. In our study, we demonstrated an 80% increased likelihood of death attributable to age ≥ 80. This mortality difference in older patients has also been reported by others such as Koskela et. al.²¹ On the other hand, a report by O'mara²⁰ & Chang⁶ showed age ≥ 80 to be an insignificant risk factor. In their study, O'mara and Chang demonstrated no differences in mortality or clinical outcomes (graft patency rates and limb salvage rates) in patients ≥ 80 undergoing open infrainguinal LEAR compared to their younger counterparts, even up to 5 years postoperatively.^{6, 20} Yet again, Schanzer et. al. identified five independent risk factors that were associated with survival and limb salvage in

patients with critical limb ischemia undergoing LEAR. In their report, age 75 was found to be associated with > 60% increased mortality odds ratio at 1 year following surgery.²⁸

In addition to mortality, we identified an increased risk of systemic complications in the 80 year group. This age group exhibited higher odds of cardiovascular, respiratory and renal complications compared with their younger counterparts. This higher risk remained even after adjusting for comorbidities and other associated factors between the two age groups in multivariate analysis. This finding is similar to what others have previously reported with postoperative cardiac complication rates ranging from 3-20%.^{8, 21, 22, 26, 28}

Despite a significant increase in systemic complications in the very elderly, clinical success and procedure-related outcomes were unaffected by age. In our study there were no differences noted between the age groups for graft patency, amputation and/or wound infection rates within the 30-day postoperative period. This is consistent in what has been previously reported in the literature with many reporting outstanding graft patency, limb salvage and amputation free survival exceeding 70%-80% up to 3 years.^{6, 8, 20, 22, 29, 227, 25}

In an effort to understand the causality of this increased mortality rate in those 80 years undergoing LEAR we investigated the effects of multiple associated factors and comorbidities on mortality using multivariate analysis comparing the two age groups. Preoperative dependent functional status was associated with increased odds of mortality consistent with previous reports.^{8, 22, 29} Interestingly, we found that in patients older than 80 cardiac comorbidity did not increase the odds of mortality whereas pulmonary and renal comorbidities seemed to greatly increase the odds of mortality when compared to their younger counterparts.

Also noteworthy, obesity was found to have a protective effect in patients undergoing LEAR by decreasing the odds ratio associated with perioperative mortality from 1 (normal weight) to 0.83 ($P < .05$).³⁰ This effect has been termed the “obesity paradox” and reported in several vascular operations such as carotid endarterectomy, and lower extremity revascularization.^{31, 361} In a previous report, we showed that the odds ratio associated with mortality following leg bypass was 0.8 in overweight, 0.5 in the obese, and 0.8 in morbidly obese patients.³⁰ One explanation for this phenomenon may be related to reports that obesity is associated with decreased levels of adipokine adiponectin, and a decreased level of adiponectin is associated with lower mortality rates.^{33, 34}

Our multivariate analysis revealed that African Americans experienced a higher rate of complications - overall complication rate (OR= 1.41 $P = 0$), amputations (OR=2.99 $P = .02$), graft failure (OR= 1.39 $P = 0$), and sepsis (OR= 1.42 $P = 0$). In previously published data, we also showed that African Americans have lower limb-salvage revascularization rates as compared with the Caucasians presenting with critical limb ischemia.^{35, 36} Other investigators have also written about this disparity.³⁷⁻³⁸ Directing additional resources to studying and correcting this healthcare disparity should prove valuable to our African American vascular patients.

As can be expected, elderly patients are more likely to have comorbidities than their younger counterparts. However, it is essential to remember that age should not be the most important

risk marker to assess the potential operative complications. Like other groups, elderly patients can be frail and weak, but also can be physically fit and active. Thus, it is important to rely on proven health indicators to optimize their preoperative health conditions and lower their operative risks. Such health markers may include albumin level, functional independence status, cognitive function, and type and severity of comorbidities.⁴⁰⁻⁴¹ Given their propensity to be associated with greater comorbidities, it is critical that the octogenarians should have appropriate medical evaluation to reduce their risks and optimize their overall health conditions prior to undergoing major revascularization procedures.

Limitations of our study include the retrospective nature of the study. Furthermore, the significant imitations inherent in to large data base studies such as treatment bias, dependence on accurate coding, potential for sampling errors, lack of long-term follow-up have been well described.³⁹ These limitations, notwithstanding, the NSQIP data base provides both a robust as well as a diverse sample of surgical patients, the analysis of which can lead to significant insight into outcomes of vascular surgical care on a national level.

In conclusion, this study represents the largest evaluation (to our knowledge) of open LEAR in patients 80 years old. Our study suggests that LEAR is associated with a significantly increased risk of mortality, cardiac and respiratory complication but no differences in amputation or early graft failure. Renal and pulmonary comorbidities along with dependent functional status were found to have the highest impact on mortality following LEAR in this elderly patient population.

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Table 1
LEAR and amputation CPT Codes

CPT (Current Procedural Terminology) Codes
Open infrainguinal revascularization procedures: 35302-06, 35371-2, 35556, 35566, 35570-1, 35583, 35585, 35587, 35656, 35661, 35666, 35671.
Major amputations: 27590, 27598, 27880, 27592, 27882.

Table 2
Univariate Analysis of Patients who received revascularization

Characteristics	N	%
Sex		
Male	12,018	63.15
Female	7,009	36.84
Ethnicity		
Caucasian	14,126	79.08
Black	2,729	15.28
Hispanic	766	4.29
Other	242	1.35
Age		
<80	15,542	81.68
80	3,486	18.32
Comorbidities		
Cardiac Comorbidities	18,178	95.53
Pulmonary Comorbidities	2,751	14.46
Renal Comorbidities	1,348	7.08
Diabetes	7,647	40.18
Smoker	7,888	41.45
Weight Class		
Normal Weight	7,005	37.75
Overweight	6,368	34.32
Obese	3,368	18.15
Morbid Obese	1,811	9.76
Functional Health Status Before Surgery		
Independent	15,699	82.5
Partially Independent	2,916	15.32
Totally Independent	413	2.17
Complications		
Any Complications	5,628	29.58
Major Complications	4,368	22.96
Return to OR	3,308	17.38
Death	513	2.7
Cardiovascular Complications	395	2.08

Characteristics	N	%
Respiratory Complications	755	3.97
Renal Complications	590	3.1
Neurological Complications	138	0.72
Sepsis	831	4.37
Wound Infection	2,033	10.68
Amputation	26	0.14
Graft Failure	906	4.76

Table 3
Patient Demographics and Preoperative Comorbidities (n=19,028)

	< 80 %	80 %
Sex		
Male	65.7	51.9
Female	34.3	36.8
<i>p</i> -value	0.0	
Ethnicity		
White	78	83.9
Black	16.5	9.9
Hispanic	4.3	4.4
Other	1.2	1.9
<i>p</i> -value	0.0	
Weight Class		
Underweight (BMI <25)	3.8	5.8
Normal (BMI 18-24.9)	30.9	46.2
Overweight (BMI 25-29.9)	34.5	33.7
Obese (BMI 30-34.9)	19.7	11.2
Morbidly Obese (BMI >35)	11.2	3.2
<i>p</i> -value	0.0	
Smoker *	48.2	11.6
<i>p</i> -value	0.0	
Diabetes Mellitus	41.3	35.4
<i>p</i> -value	0.0	
Cardiac comorbidities	39.7	42.6
<i>p</i> -value	<0.1	
Respiratory comorbidities	14.3	15
<i>p</i> -value	0.3	
Renal comorbidities	7.4	5.6
<i>p</i> -value	0.0	
Preoperative Functional Health Status		
Independent	85.3	70.2
Partially dependent	12.9	26
Totally dependent	1.8	3.8
<i>p</i> -value	0.0	

* Smoker defined as active smoker within 1 yr of operation

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Table 4
Postoperative Complications

	< 80 %	80 %	<i>P</i> -value
Death	2.1	5.4	0.0
Cardiovascular Complications	1.9	3.1	0.0
Respiratory Complications	3.6	5.8	0.0
Renal Complications	1.1	1.5	0.0
Amputation	0.2	0.1	0.2
Graft Failure	4.8	4.8	0.0
Wound Infection	11.1	9.1	0.0
Sepsis	4.1	5.6	0.0

Table 5
Risk-Adjusted Multivariate Analysis

Complications	< 80	80	
		Odds Ratio	95% CI
Death	Reference	1.81	1.44-2.28
Cardiovascular complications	Reference	1.47	1.13-1.92
Respiratory complications	Reference	1.37	1.13-1.68
Renal complications	Reference	1.08	0.75-1.56
Amputation	Reference	0.59	0.13-2.74
Graft Failure	Reference	1.06	0.87-1.29
Wound Infection	Reference	0.93	0.8-1.07
Sepsis	Reference	1.22	1.0-1.49
Length of stay	Reference	1.09	1.04-1.14

CI= Confidence Interval

Table 6
Multivariate Analysis of Associated Variables Affecting Mortality

Associated Factors/Pre-Operative Comorbidities	Mortality		
	<80	80	
		OR	95% CI
Female	Reference	1.28	1.05-1.56
Cardiac	Reference	0.76	0.45-1.29
pulmonary	Reference	2.26	1.81-2.81
Renal	Reference	4.25	3.32-5.45
Diabetes	Reference	0.94	0.76-1.16
Smoking	Reference	0.83	0.66-1.05
Obesity (BMI ≥ 30)	Reference	0.43	0.31-0.59
Dependent functional status	Reference	3.8	3.12-4.64

CI = Confidence interval ; OR = odds ratio