Frailty is Not Associated with Worse Outcomes following Lower Extremity Angiograms for Limb Ischemia in Nonagenarians

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Background: Endovascular interventions are performed routinely with minimal risk in younger populations. The safety and efficacy of endovascular interventions in nonagenarians is under examined. We sought to examine the following (1) mortality and limb salvage rates in the nonagenarian population and (2) whether frailty was associated with outcomes following lower extremity (LE) interventions for both acute limb ischemia (ALI) and chronic limb threatening ischemia (CLTI).

Methods: A retrospective review of patients ≥90 years who underwent a LE angiogram for ALI or CLTI over a 12-year period at a single institution was performed. Primary outcomes were 30-day and 12-month limb salvage and mortality rates. Patient demographics, 30-day complications, and 12-month target vessel reintervention (TVR) were reviewed. Frailty scores were calculated using the 11-factor modified frailty index (MFI-11).

Results: From 2009 to 2021, 76 patients (36% male) with a mean age of 93 (range: 90−102) underwent endovascular procedures for ALI ($n = 13$) and CLTI ($n = 63$). 30-day amputation and mortality rates were 6% and 8%, respectively. Patient demographics, preoperative functional status, and TVR rates were not different between patients who had early amputation (≤30 days) and those who achieved limb salvage. Seventy-two patients (94%) had follow-up data at 30 days. There was an 8% mortality rate at 30 days. Of those alive at 30 days, 94% of patients had successful limb salvage. Fifty-eight patients had complete follow-up data at 12 months. Of the patients alive at 12-month follow-up (75%), the limb salvage rate was 98%. Patients with amputation at 30 days had a significantly higher mortality rate at 12 months compared to those who did not (83% vs. 19%; $P < 0.01$). Based on MFI-11 scoring, 35% of the population was considered frail (≥0.27). Frail patients did not have significantly different 30-day outcomes (limb salvage: 94% vs. 88%; mortality 8% vs. 9%, $P = 0.41$ and 0.94, respectively) or 12-month outcomes (limb salvage: 82% vs. 94%; mortality: 32% vs. 22%, $P = 0.28$ and 0.39, respectively).

Conclusions: Endovascular procedures can be done safely in nonagenarians with low mortality and amputation rates. Patients with early amputation are at significantly higher risk of death at 12 months. Frailty, as measured by a validated index, was not associated with early or late outcomes. When compared to immediate amputation, nonagenarian patients and their families should be counseled as to the benefit from a minimally invasive endovascular procedure.

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INTRODUCTION

Endovascular procedures are frequently performed in patients for peripheral arterial disease (PAD) with good results and at minimal risk to most patients. However, there is a paucity of data examining the safety and efficacy of lower extremity (LE) angiograms for limb ischemia in the elderly.[1–5] Frailty indices have been employed with increasing frequency in an attempt to assist physicians with risk stratification and to predict outcomes for patients prior to surgical procedures. Although more prevalent in the general surgery literature, several frailty indices have been studied in patients undergoing vascular procedures. The 11-factor modified frailty index (MFI-11) has been validated as a tool to evaluate frailty and stratify a vascular patient's risk; however, nonagenarian patients are largely excluded from these studies and some of the studies are broad in their application to patients beyond limb ischemia.[6–8] This is increasingly relevant for the treatment of PAD as the population of the United States ages, particularly in geographic areas in which the elderly population has a more robust functional status than the national average.

The relationship between frailty score and postoperative outcomes following LE vascular interventions has been investigated.[9] Outcomes following LE bypass procedures suggest that frailty is predictive of postoperative outcomes.[9,10] However, few studies have examined whether frailty is associated with worse outcomes following endovascular procedures. Given that the elderly would appear to be a high-risk population, it follows that any intervention in this cohort would be considered high-risk as well. The additional challenge of treating patients with limb ischemia makes such a prediction even more poignant. Examining which of these patients may safely undergo an intervention is of particular interest to vascular surgeons and patients wishing to make informed decisions regarding their care.

The goal of this study was to examine nonagenarian patient outcomes following LE endovascular procedures performed for limb ischemia at a single institution. The relationship between frailty and patient outcomes was also studied.

METHODS

Approval to conduct this study was granted by the Institutional Review Board of Santa Barbara Cottage Hospital. A retrospective review was performed for patients ≥90 years of age who underwent a LE angiogram for limb ischemia over a 13-year period at a single institution. Patient charts were identified by search of the electronic medical records (EMRs), using age ≥90 years and International Classification of Diseases procedure codes. The patient list was then manually reviewed to include only LE angiograms, both with and without interventions. Patients with incomplete follow-up and those who underwent interventions for traumatic injuries were excluded from this cohort. Any patient who had a combined endovascular and open procedure was also excluded. An amputation above the ankle was considered a major amputation and failed limb salvage. Minor toe and midfoot amputations were not considered major amputations in this cohort and were considered successful limb salvage.

Patients were classified with a diagnosis of either chronic limb threatening ischemia (CLTI), including Rutherford class 4–6; and acute limb ischemia (ALI), including Fontaine class IIa, IIb, and III. Patient comorbidities, demographics, intraoperative details, and in-hospital and long-term outcomes were collected by manual chart review from the EMR.

Primary outcomes were 30-day and 12-month limb salvage and mortality rates.

Secondary outcomes included 30-day hospital readmissions, target vessel reinterventions within 12 months, and procedure-related complications. Complications were categorized as pulmonary, cardiac, or access-related which occurred within 30 days of the procedure. An additional endovascular procedure on the same patient on the same target lesion as the index intervention was defined as a reintervention. Multiple procedures on a patient in which interventions were performed on the contralateral limb were categorized as unique procedures and not considered reinterventions.

Risk-stratification of patients was performed with the validated MFI-11 (Table I). As described elsewhere, calculation of the MFI-11 was performed by dividing the number of factors present by the total number of factors examined to yield a frailty score for each patient, expressed as a decimal.[6,7] Patients with a frailty score ≥0.27 were categorized as frail.

Statistical Analysis

Statistical analysis was performed using R Version 3.5.1.[11] Descriptive analyses were conducted for the following: comorbidities, medical history,

Table I. Modified frailty index factors (MFI-11), listed from most common to least common, of nonagenarians undergoing lower extremity angiograms for limb ischemia

Frailty factors indicated in patients ($N = 72$)	n (%)
Hypertension	63 (88)
CAD	35 (49)
Functionally dependent	28 (39)
Congestive heart failure	26 (36)
Dementia	19 (27)
CVA	15 (21)
Cerebrovascular problems	14 (19)
Cognitive impairment	12 (16)
COPD	10 (14)
Myocardial infarction	8 (11)
Delirium	5 (7)

CAD, coronary artery disease; CVA, cerebrovascular accident; COPD, chronic obstructive pulmonary disease.

perioperative details, indications, procedures, complications, 30-day readmission, and 12-month TVR. Frail and nonfrail patient outcomes (limb salvage and mortality) at 30 days and at 12 months were compared. Posthoc analyses were conducted to compare 12-month mortality rates for patients with and without limb salvage at 30 days. A Chi-Squared test for Independence was used to test for all significant differences. A P value of <0.05 was considered statistically significant.

RESULTS

From 2009−2021, 76 patients underwent a LE angiogram for limb ischemia. Four patients were lost to follow-up within the first month and were excluded from further analysis. The remaining 72 patients (28 males (39%); range 90−99) had complete documentation at 30 days. Fifty-eight patients had complete follow-up at 12 months (43% male). The most frequent comorbidities in the cohort (Table II) included hypertension (86%), hyperlipidemia (61%), chronic kidney disease not on hemodialysis (44%), and atrial fibrillation (43%). 28% of patients were diabetic. Only 1 patient had end-stage renal disease on hemodialysis. The majority of patients were independently ambulatory ($n = 32$, 45%) or ambulatory with the assistance of a device ($n = 28$, 39%). Only a minority of patients ($n = 11$, 15%) were nonambulatory. The mean body mass index (BMI) was 28 (SD ± 4.2) and 34 patients (51%) had a history of or presently smoked tobacco products.

The 72 patients with follow-up data were classified into presenting with acute or chronic

Table II. Baseline characteristic of nonagenarian patients undergoing lower extremity angiograms for limb ischemia

Baseline characteristics ($N = 72$)	n (%)
Demographics	
Age[a]	93 (90−99)
Male sex	28 (39)
BMI[b], $n = 68$	23 (4.2)
Medical history and comorbidities	
Chronic obstructive pulmonary disease	8 (11)
Atrial fibrillation	31 (43)
History of tobacco, $n = 67$	34 (51)
Cerebrovascular disease	16 (22)
Hypertension	62 (86)
CAD	33 (46)
Diabetes	21 (29)
Chronic kidney disease	32 (44)
Dialysis	1 (1)
Dementia	13 (18)
Obesity	4 (6)
Hyperlipidemia	44 (61)
Preoperative functional status, $n = 71$	
Ambulatory	32 (45)
Nonambulatory	11 (15)
Walk with assistance	28 (39)

[a]Mean (range).
[b]Mean (standard deviation).

symptoms. The majority of patients ($n = 60$, 83%) were treated for symptoms of CLTI. Fifty CLTI patients (83%) presented with nonhealing wounds; 18 (30%) presented with rest pain. A subset of patients exhibited both. The remaining patients ($n = 12$, 17%) were treated for ALI. An intervention was performed in most cases ($n = 62$, 87%), the remainder had diagnostic angiograms performed (Table III). Interventions included mechanochemical thrombolysis with or without catheter placement (8%), atherectomy (36%), balloon angioplasty (72%), and stent placement with angioplasty (25%). For patients who presented with symptoms of CLTI, 22 patients (37%) underwent mechanochemical lysis. For patients presenting with ALI, 8 (72%) patients had multilevel disease and 5 (42%) underwent mechanochemical lysis during the intervention.

Most patients ($n = 49$, 70%) were classified as American Society of Anesthesiologists level III. The remainder were level II ($n = 16$; 23%) or IV ($n = 5$; 7%). The type of intraoperative anesthesia varied (Table IV) and included general anesthesia (endotracheal tube or laryngeal monitored airway) in 50% of patients. The remaining patients received either monitored anesthesia care (MAC) and local anesthesia (46%) or local anesthesia only (4%).

Table III. Indications, procedures, primary outcomes, and secondary outcomes of nonagenarians undergoing lower extremity angiograms for limb ischemia classified by diagnosis (acute limb ischemia—ALI and chronic limb threatening ischemia—CLTI)

Indications, procedures, and secondary outcomes by diagnosis	ALI ($n = 12$)	CLTI ($n = 60$)	Total ($N = 72$)
Indication	*n* (%)	*n* (%)	*n* (%)
Rest pain	7 (58)	18 (30)	25 (35)
Wound	1 (8)	50 (83)	51 (71)
History of claudication	2 (17)	17 (28)	19 (27)
Procedures			
Any intervention	10 (83)	52 (87)	62 (86)
Thrombolysis	5 (42)	22 (37)	27 (38)
Atherectomy	3 (25)	36 (60)	39 (54)
Balloon angioplasty	6 (50)	52 (87)	58 (81)
Stent angioplasty	3 (25)	31 (52)	34 (47)
Multilevel — Yes	8 (72), $n = 11$	15 (74), $n = 57$	50 (74), $n = 68$
Vessel runoff			
0	1 (8)	4 (7)	5 (7)
1	3 (25)	18 (31)	21 (30)
2	5 (42)	30 (52)	35 (50)
3	3 (25)	6 (10)	9 (13)
Complications			
Total	4 (33)	7 (12)	11 (15)
Pulmonary	1 (8)	4 (7)	5 (7)
Cardiac	3 (25)	2 (3)	5 (7)
Access-related	0 (0)	1 (2)	1 (1)
30-Day readmission	2 (20), $n = 10$	14 (24), $n = 59$	16 (23), $n = 69$
12-Month target vessel reintervention	2 (25), $n = 8$	7 (13), $n = 59$	9 (14), $n = 67$
	ALI ($n = 12$)	CLTI ($n = 60$)	*P* value
30-Day limb salvage	12 (100)	54 (90)	0.18
30-Day mortality	2 (17)	4 (7)	0.25
	ALI ($n = 7$)	CLTI ($n = 52$)	
12-Month limb salvage	7 (100)	46 (88)	0.34
12-Month mortality	2 (29)	13 (25)	0.84

Thirty-day and 12-month mortality and limb salvage rates were reviewed. The 30-day mortality rate was 8%. The limb salvage rate in patients alive at 30 days was 94%. At 12 months, the mortality rate was 25%. The limb salvage rate for patients alive at this interval was 98% (Table V).

There were no intraoperative deaths. The readmission rate at 30 days was 25%. The 30-day postoperative complication rate was 12% (Table III). Cardiopulmonary complications were the most frequent morbidity and occurred in 10 patients (14%). One additional patient suffered an access-related complication requiring nonoperative intervention.

The MFI-11 index was used to categorize patients based on frailty status. Overall, 35% of our study population was considered frail based on a MFI-11 score cutoff of 0.27. There was no statistical difference for mortality or limb salvage rates between frail and nonfrail patients at 30 days ($P = 0.41$ and 0.94, respectively) or 12 months ($P = 0.38$ and 0.28, respectively; Table VI).

Posthoc analysis revealed that patients with amputation at 30 days had a significantly higher mortality rate at 12 months compared to those who did not (83% vs. 19%; $P < 0.01$) (Fig. 1). Of the patients alive at 12 months, 98% experienced successful limb salvage compared to 67% for those expired at 12 months. Although it was not significant, 30-day mortality following procedures performed for ALI was higher compared to those performed for CLTI (17% vs. 7%; $P = 0.25$) and no difference in 12-month mortality was observed (29% vs. 25%; $P = 0.84$; Table III).

DISCUSSION

The importance of preoperative risk stratification, particularly in the elderly patient population, has

Table IV. Preoperative, intraoperative, and postoperative details of nonagenarians undergoing lower extremity angiograms for limb ischemia

Preoperative, intraoperative, and postoperative details ($N = 72$)	n (%)
Preoperative	
EGFR $\leq$ 30, $n = 71$	4 (6)
Creatinine[a]	1.16 (0.57)
Anticoagulant	27 (38)
ASA81	26 (36)
Plavix	8 (11)
Statin	39 (54)
Operative	
Diagnosis	
CLTI	60 (83)
ALI	12 (17)
ASA, $n = 70$	
2	16 (23)
3	49 (70)
4	5 (7)
Anesthesia, $n = 70$	
General	35 (50)
Local	3 (4)
MAC	32 (46)
Postoperative	
EGFR $\leq$ 30, $n = 71$	
Creatinine[a], $n = 58$	1.14 (0.59)
Anticoagulant	28 (39)
ASA 81	47 (65)
Clopidogrel	20 (28)
Statin	44 (61)

ASA, American Society of Anesthesiologists.
[a]Mean (standard deviation).

Table V. Limb salvage and mortality at 30 days and 12 months for nonagenarians undergoing lower extremity angiograms for limb ischemia by diagnosis

30-day and 12-month limb salvage and mortality	
Patients with 30-day follow-up	72
Alive at 30 days	66 (92%)
Limb salvage of alive patients	62/66 (94%)
Deceased at 30 days	6 (8%)
Limb salvage of deceased patients	3/6 (50%)
Patients with 12-month follow-up	59
Alive at 12 months	44 (75%)
Limb salvage of alive patients	43/44 (98%)
Deceased at 12 months	15 (25%)
Limb salvage of deceased patients	10/15 (67%)

been well established. Unfortunately, there is currently a dearth of data supporting the utilization of frailty indices as a potential indicator of outcome in patients of advanced age. In our study, we examined risk stratification of nonagenarians by the MFI-11 frailty index and the relationship to postoperative outcomes. As the life expectancy in the United States is expected to increase, the number of nonagenarians with PAD will also increase, necessitating close examination of outcomes in this patient population.

The overwhelming majority of patients with limb ischemia, both acute and chronic, who do not receive an intervention will progress to limb loss. This may occur from hours to several weeks or months. The life expectancy of a monopedal nonagenarian suffering from limb ischemia is severely limited.[12] Similarly, the life expectancy of a nonagenarian with untreated CLTI is less than 15 months.[13] For these reasons, unless a patient is a prohibitive surgical risk, an endovascular attempt at limb salvage would be considered by most surgeons. It is imperative for the vascular surgeon to educate the patient and family about the risks of the procedure as well as anticipated postprocedure outcomes.

Our mortality and limb salvage rates at 30 days (8%, 94%) and 12 months (28%, 97%) were not different from those in younger cohorts. The prognosis for the general population presenting with CLTI is poor, with a reported 12-month mortality rate of 22%.[14] Studies that include the elderly demonstrate an even worse prognosis, with 12-month mortality rates as high as 49%.[1,5] Our 12-month mortality rate of 28% suggests endovascular procedures may be performed in nonagenarian patients with acceptable outcomes. While our patient population had the typical comorbidities that one would expect in the CLTI population, they were likely healthier with fewer risk factors than the average CLTI patient. For instance, it is not surprising that only 1 patient had end stage renal disease on hemodialysis. In this way, the most comorbid patients likely never reached 90 years. Although likely underpowered for subset analyses, the trend toward increased 30-day mortality in the ALI group is not unexpected, as the nature of the underlying pathology leads to a more severe presentation.

Our 30-day and 12-month limb salvage rates of >90% were not different from reports on octogenarians following similar procedures for CLTI.2 As has been established elsewhere, we identified patients who underwent early amputation were at an increased risk of mortality within 12 months, highlighting the importance of revascularization in these patients. The reintervention rate in our patient population was 14%.[1]

Although MFI-11 is the most frequently utilized frailty index in the vascular surgery literature, patients at extremes of age are markedly

Table VI. Limb salvage and mortality at 30 days and 12 months for frail and nonfrail nonagenarians, as measured by the MFI-11, undergoing lower extremity angiograms for limb ischemia

Limb salvage and mortality rates at 30 days and 12 months			
MFI-11	Frail ($n = 25$)	Not frail ($n = 47$)	*P* value
30-Day limb salvage	22 (94)	44 (88)	0.41
30-Day mortality	2 (8)	4 (9)	0.94
	Frail ($n = 22$)	Not frail ($n = 37$)	*P* value
12-Month limb salvage	18 (82)	35 (97)	0.26
12-Month mortality	7 (32)	8 (22)	0.38

underrepresented. We examined whether an association exists between frailty and postoperative outcomes in this cohort. The largest retrospective study to date that examines the relationship between MFI-11 and vascular surgical outcomes were a review from the National Surgical Quality Improvement Program (NSQIP) administrative database.[15] They also found that the MFI-11 was a poor predictor of morbidity and mortality in the LE endovascular subgroup. However, their cohort was different from ours in that the mean age of their population was 69 years and the oldest patient was 77 years old. Nevertheless, they concluded that the MFI-11 was not predictive in this age group given the low inherent morbidity from these procedures.

Eslami et al concluded that MFI-11 has a higher predictive ability for 30-day mortality following elective LE bypass compared to other risk indices. Yet again, in their retrospective review of the NSQIP database, patients over the age of 90 were excluded, so it is unclear whether this advantage holds for less invasive procedures in this age group.[7]

It has been demonstrated that the effect of frailty decreases with patient age. In a prospective study of patients 60 years and older undergoing elective vascular procedures, an alternative frailty index was associated with 30-day mortality. However, advanced age was found to diminish this effect.[16] This appears to be congruent with our findings.

It is plausible that other frailty tools or factors not included in the calculation of MFI-11 may be more predictive. A significant percentage of our sample was classified as frail by MFI-11 criteria, which can limit the ability to effectively risk stratify this population. To address this issue, Morisaki et al. compared the performance of MFI-11 to a new diagnostic criterion of frailty (CLI Frailty Index), which incorporated markers of nutritional status, muscle mass, and ambulatory status. Only the latter was found to be superior in predicting 2-year amputation-free survival following LE revascularizations.[17] Multivariate analyses from other studies show factors not included in MFI-11 may contribute to patient outcomes. These findings suggest the evaluation of frailty in the elderly may be more complex than the sum of their comorbid conditions, as is considered in the calculation of the MFI-11 score. Alternatively, the diminished predictive ability of MFI-11 in this population may be attributed to the inability to account for differing levels of severity within its components. It is, however, important to acknowledge that the specific components and binary response to each category allows for rapid calculation of the MFI-11 score, does not require patient input, and may be completed retrospectively, lending itself to research and clinical utility. While more detailed indices or those which include more subjective measurements of health status may be more sensitive, concerns have been raised regarding their reproducibility and clinical utility.

We acknowledge the limitations of this study. Our cohort was a small number from a single institution and some patients were lost to follow-up. The retrospective design can lead to errors in documentation. Due to limitations of chart review, we utilized the Fontaine classification for retrospective classification of wounds. It is possible that other measures, such as the SVS wound, ischemia, foot infection score, may provide more comprehensive information and would be useful in future, prospective studies. Differentiating outcomes as they relate to frailty for nonurgent compared to emergent indications is also an important area of further research. In addition, there is almost certainly an inherent selection bias in this cohort. It is probable that those nonagenarians who were too frail were excluded from consideration by the surgeon and were therefore not a part of this cohort. We also did not examine postprocedural functional status or quality of life following endovascular procedures. A future prospective study focused on either of these outcomes in this population may be pertinent.

Complementary to national database studies, our single-institution study represents a ''real-world''

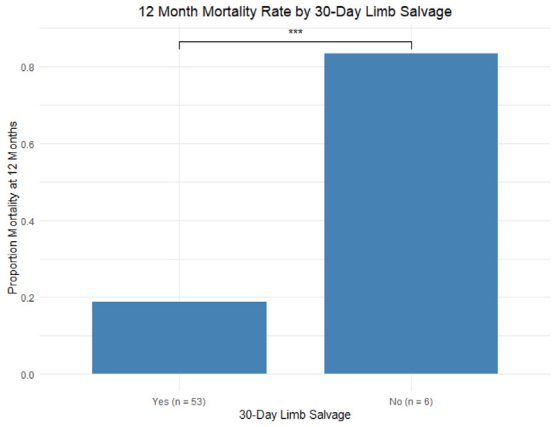

Fig. 1. Twelve-month mortality rate by 30-day limb salvage in nonagenarians undergoing lower extremity angiograms for limb ischemia (19% vs. 83%, $P < 0.01$).

experience of how a frailty index could be utilized. In this population, likely due to the low morbidity from endovascular procedures in general, the MFI-11 was not associated with mortality or limb salvage rates. Nevertheless, we argue that endovascular procedures can be performed with low morbidity and mortality in the nonagenarian population. We argue that a frailty index is unlikely to add any significant value to the vascular surgeon's personal assessment when predicting how a nonagenarian with limb ischemia will tolerate a LE angiogram.

CONCLUSION

This study demonstrates that our low mortality and high limb salvage rates were comparable to those reported elsewhere for younger cohorts. This suggests that endovascular procedures for limb ischemia are well tolerated in nonagenarian patients despite increased frailty in this population. Considering the high 12-month mortality rate in patients undergoing major amputation and presuming a significant progression to limb loss in the absence of any intervention, endovascular limb salvage attempts are indicated and reasonable to perform in this population. While frailty indices may aid in predicting morbidity and mortality in other populations, this was not true in our cohort. Not surprisingly, patients with early major amputations had significantly higher mortality rates at both 30 days and 12 months.

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