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Statement of Purpose

Identify variables associated with poor healing outcomes in patients that underwent an initial foot amputation for treatment of a diabetic foot infection

Poor healing outcome defined as:

- Non-healing amputation site resulting in subsequent major lower extremity amputation
- Subsequent death prior healing of amputation site

Methodology

Patient Selection

- Epic database search
 - Oct 2010 - May 2018
- Inclusion criteria:
 - Male or female with Type 1 or 2 Diabetes diagnosis (ICD9/10 diagnosis codes)
 - First non-traumatic LE amputation distal to ankle at HCMC (ICD 9/10 procedure codes)
 - Patients aged 18-84 years

- Exclusion criteria:
 - Traumatic amputations
 - No follow up after index procedure

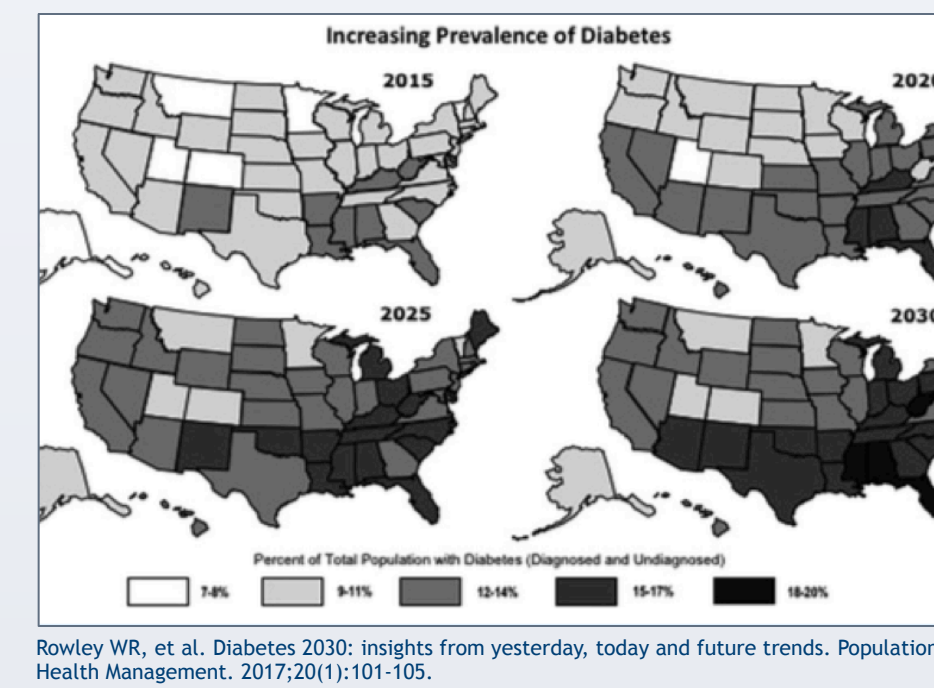
- Variables assessed
 - Demographics
 - Comorbidities
 - Vascular status and vascular intervention(s)
 - Case urgency
 - Level of amputation
 - Length of hospitalization

Statistical Analysis

- Student's t-test for continuous data and chi-square or fisher's exact test for categorical data
- Logistic regression used to examine associations between variables and poor healing outcome
- Multivariable logistic regression included covariates significant at a univariate level (P<.20).
- Two-tailed p value <0.05 was considered statistically significant

Literature Review

- Worldwide diabetes population is expected to exceed half a billion by 2030¹
 - 54.9 million Americans (54% increase)²
- Increasing prevalence of major complications and deaths³
 - Annual number new amputations projected to increase by >13000
 - Annual number deaths projected to increase by >106000



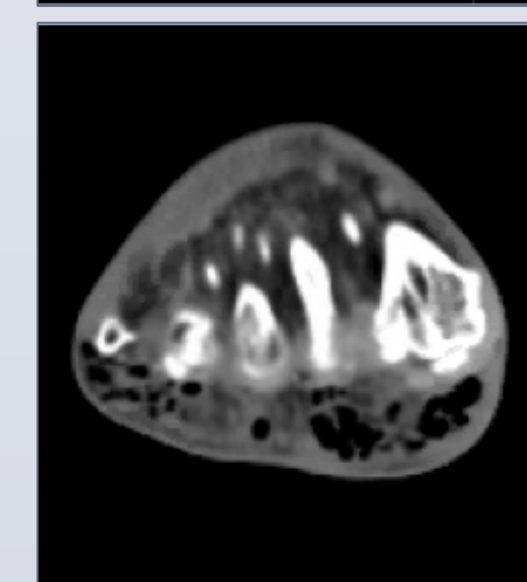
- Infected foot ulcers = most common cause of hospitalization and complications^{3,4}
 - Risk of amputation is 30-40x higher than non-diabetic population

Risk factors reportedly associated with amputation:⁴⁻⁶

- Male gender
- Diabetes >10 years
- Hyperglycemia, HbA1c>8
- Insulin-dependence
- Vascular disease
- Previous amputation
- Low socioeconomic status
- Smoking
- Renal impairment
- Neuropathy

High complication rates⁷⁻¹⁰

- >10% hospital readmission within 30 days
- 29% reamputation rate within 1 year in foot amputations
- 50-80% 5 year mortality rate after major amputation



Results

There were 155 patients that met inclusion criteria (115M, 40F), with a mean age of 57.4 years (range 31-83 years). Patient demographic and comorbidities are included in Table 1. Patients with a history of peripheral arterial disease (PAD), chronic kidney disease (CKD), end-stage renal disease (ESRD) and cerebrovascular accident (CVA) demonstrated significantly less healing of amputation sites than patients without these comorbidities (Table 2). There was also significantly less healing in patients with non-palpable pulses, severely impaired transcutaneous oxygen measurements (TCO2) (<20mmHg), a need for an angiogram or bypass procedure, emergent case type and more proximal level of initial amputation (Tables 3 & 4). Patients that did not heal were found to have an increased length of index hospitalization, unplanned readmission(s), subsequent procedure(s) and a higher 5 year mortality rate (Table 4). There were 7 variable from the univariate model selected for multivariable logistic regression, with the final multivariable analysis identifying ESRD and CVA as independent predictors of non-healing (Table 5).

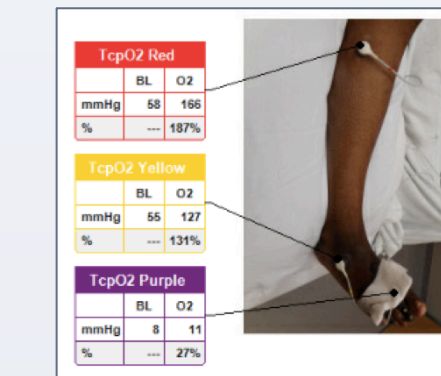
Mean age ± SD (years)	57.4 ± 10.9
Gender n (%)	Male 115 (74.2)
	Female 40 (25.8)
Mean BMI ± SD (kg/m ²)	30.93 ± 7.3
Race n (%)	White 73 (47.1)
	Non-white 82 (52.9)
Tobacco Use, n (%)	58 (37.4)
Homelessness, n (%)	11 (7.1)
HTN, n (%)	124 (80.0)
HLD, n (%)	91 (58.7)
PAD, n (%)	94 (60.6)
Neuropathy, n (%)	147 (94.8)
CKD, n (%)	55 (35.5)
ESRD/dialysis-dependent, n (%)	22 (14.2)
CHF, n (%)	26 (16.8)
CVA, n (%)	17 (11.0)
CAD, n (%)	50 (32.2)
COPD, n (%)	9 (5.8)

	Healed		p value	
	No	Yes		
Mean Age (years)	58.5	57	0.43	
Gender (%)	Male	70.2	75.9	0.45
	Female	29.8	25.8	
Mean BMI ± SD (kg/m ²)	30.3	31.2	0.49	
Race (%)	White	42.5	49.1	0.45
	Non-white	57.4	50.9	
Tobacco Use (%)	44.6	34.2	0.29	
Homelessness (%)	8.5	6.5	0.65	
HTN (%)	85.1	77.8	0.29	
HLD (%)	63.8	56.5	0.39	
PAD (%)	78.7	52.8	0.002*	
Neuropathy (%)	93.6	95.4	0.65	
CKD (%)	55.3	26.9	0.001*	
ESRD/dialysis-dependent (%)	29.8	7.4	0.001*	
CHF (%)	21.3	14.8	0.32	
CVA (%)	27.7	3.7	<0.001*	
CAD (%)	38.3	29.6	0.29	
COPD (%)	4.3	6.5	0.59	



Results Cont.

	Healed		p value
	No	Yes	
Non-palpable pulses (%)	66	37	0.001*
Severely Impaired TCO2 (%)	41.7	14.3	0.012*
Angiogram or bypass procedure (%)	53.2	22.9	<0.001*
HBOT (%)	44.7	40	0.59



Urgency of Case (%)		Healed		p value
		No	Yes	
Urgency of Case (%)	Emergent	52.9	47.1	0.005*
	Urgent	25	75	
	Semi-urgent	20	80	
Level of Initial Amputation (%)	Other/Met head/Sesamoid	0	2.8	0.001*
	Toe	27.7	60.2	
	Partial Ray/Ray	53.2	31.5	
	TMA	14.9	4.6	
	Chopart	4.3	0.9	
Mean Length of Index Hospitalization (days)		15	6.3	<0.001*
Unplanned readmission (%)		67.8	28.7	<0.001*
Subsequent Surgery (%)		83	34.3	<0.001*
Mean Number of Procedures		2.66	1.62	<0.001*
Mean Follow Up (Months)		11.6	15.2	0.46
5 Year Mortality Rate		56.4	43.6	<0.001*

	Univariate Analysis			Multivariable Analysis		
	OR	95% CI	p value	OR	95% CI	p value
Age	0.99	0.96-1.02	0.42			
Sex	1.34	0.62-2.88	0.46			
Race	0.77	0.38-1.53	0.45			
BMI	1.02	0.98-1.07	0.49			
Smoking Status	0.79	0.51-1.23	0.3			
Homeless	0.74	0.21-2.68	0.65			
HTN	0.61	0.24-1.54	0.39			
HLD	0.74	0.36-1.49	0.39			
PAD	0.3	0.14-0.67	0.003*	1.32	0.34-5.14	0.69
Neuropathy	1.4	0.32-6.13	0.65			
CKD	0.3	0.14-0.61	0.001*	1.15	0.36-3.68	0.81
ESRD/dialysis-dependent	0.19	0.07-0.49	0.001*	0.22	0.05-1.00	0.05*
CHF	0.64	0.27-1.5	0.32			
CVA	0.1	0.03-0.33	<0.001*	0.18	0.04-0.80	0.02*
CAD	0.68	0.33-1.39	0.29			
COPD	1.56	0.31-7.8	0.59			
Non-palpable pulses	3.29	1.60-6.76	0.001*	1.45	0.44-4.72	0.54
TCO2	0.5	0.27-0.94	0.3	0.66	0.32-1.34	0.25
Angio/bypass	0.26	0.12-0.54	<0.001*	0.4	0.13-1.22	0.11
HBOT	0.82	0.41-1.65	0.59			
Case Urgency	2.41	1.32-4.40	0.004*			
Initial Amputation Level	0.58	0.39-0.87	0.009*			
Length of Hospitalization	0.83	0.77-0.90	<0.001*			
Unplanned Readmission	0.19	0.09-0.41	<0.001*			

Analysis and Discussion

- Patients with diabetic foot infections leading to amputation have complex medical histories
 - Multiple chronic comorbidities:
 - 94.8% neuropathy
 - 80% hypertension
 - 60% PAD
- Patients with non-healing amputation sites are at increased risk for:
 - Unplanned readmission
 - Subsequent procedures include below or above knee amputation
 - Early mortality

Analysis and Discussion Cont.

- End-stage renal disease and history of cerebrovascular accident are independent predictors of poor healing after minor lower extremity amputation
- Chronic renal insufficiency and dialysis-dependence have previously been described as predictors of readmission, reamputation and death after an initial amputation^{11,12}
 - Consistent with findings from this study
- History of CVA has not been previously described as a predictor of poor healing or complication following lower extremity amputation
- Management of diabetic foot infections and amputations requires a multidisciplinary approach to optimize outcomes
 - Risk factor identification

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