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Prevalence and risk factors for diabetes-related foot complications in Translating Research Into Action for Diabetes (TRIAD)

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Abstract

Aims—The objective was to describe the prevalence of diabetes-related foot complications in a managed care population and to identify the demographic and biological risk factors.

Methods—We assessed the period prevalence of foot complications on 6,992 patients using ICD-9 diagnosis codes from health plan administrative data. Demographic and biological variables were ascertained from surveys and medical record reviews. We defined four mutually exclusive groups: any Charcot foot, DFU with debridement, amputation ± DFU and debridement, and no foot conditions.

Results—Overall, 55 (0.8%) patients had Charcot foot, 205 (2.9%) had DFU with debridement, and 101 (1.4%) had a lower-extremity amputation. There were 6,631 patients with no prevalent foot conditions. Racial/ethnic minorities were less likely to have Charcot foot (OR=0.21; 95%CI: 0.10, 0.46) or DFU (OR=0.61; 95% CI: 0.44, 0.84) compared to non-Hispanic Whites, but there were no racial/ethnic differences in amputation. Histories of micro- or macrovascular disease were associated with a two- to four-fold increase in the odds of foot complications.

Conclusion—In managed care patients with uniform access to health care, we found a relatively high prevalence of foot complications, but attenuation of the racial/ethnic differences of rates reported in the literature.

Keywords

charcot; foot ulcer; amputation; diabetes

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Introduction

Diabetes can lead to a number of debilitating foot complications, including Charcot neuroosteoarthropathy, diabetic foot ulceration (DFU), and lower extremity amputation. Charcot neuroosteoarthropathy is a destructive joint disorder initiated by trauma to an insensate limb that leads to inflammation and collapse of the normal foot architecture (1). The prevalence of Charcot neuroosteoarthropathy among patients with diabetes has been reported to be between 0.1% and 0.9% (2-4). It has been estimated that 63% of patients with Charcot neuroosteoarthropathy will develop a foot ulcer (5), and the co-occurrence of Charcot and DFU confers a 12-fold higher risk of amputation (6). Peripheral polyneuropathy, foot deformities, and peripheral vascular disease contribute to DFU and amputation. It is estimated that people with diabetes have a 25% lifetime risk of developing a foot ulcer (7), and 84% of lower extremity amputations have been attributed to non-healing DFUs (8).

In the United States, as many as 15% of people with diabetes will have lower extremity amputations during their lifetime (9), and substantially higher rates are associated high-risk foot conditions like Charcot neuroosteoarthropathy and DFU (10). While the causal pathways leading to Charcot and DFU, or eventually, lower-extremity amputation, may differ, they are all identified by comprehensive foot examination including inspection of the dermatologic and musculosketal systems, sensory examination, and pulse evaluation, and with appropriate treatment, often are preventable (11). The American Diabetes Association (ADA) has concluded that preventive care teams, defined as multidisciplinary teams that utilize risk assessment tools, patient education, and therapeutic footwear, can decrease the risk of DFU and amputation by 50-85% (12). Managed care organizations, which provide access to care and prevention, should be well positioned to screen and prevent foot complications. Studies have not yet reported on the prevalence and risk factors of diabetic foot complications in managed care organizations other than in the VA (6,10,13-15). Our objective was to describe the prevalence of diabetes-related foot complications in a managed care population and to identify the demographic and biological risk factors associated with each of the three major diabetes-related foot complications.

Materials and Methods

Study population

Translating Research Into Action for Diabetes has been described elsewhere (16). Briefly, TRIAD studied a random sample of adults with diabetes enrolled in 10 managed care health plans in eight states (California, Hawaii, Indiana, Michigan, New York, New Jersey, Pennsylvania, and Texas) that served ~180,000 patients with diabetes. Patients were eligible to participate if they were at least 18 years old, lived in the community, were not pregnant, had diabetes for at least 1 year, spoke either English or Spanish, were continuously enrolled in the health plan for at least 18 months, used at least one service during that time, and could give informed consent. Institutional review boards at each participating site approved the study.

In 2000-2001, we administered a survey by computer-assisted telephone interview or in writing by mail. In addition, centrally trained reviewers used standardized collection methods to abstract medical records. Health plan administrative data were collected for 1999 through 2003. The analytic sample for this study included participants who had survey and medical record data at baseline and were members of a site participating in the 2010-2013 TRIAD Legacy Study (N=6,992).

Outcomes

We used 1999-2003 health plan administrative data to determine the period prevalence of the three specific foot conditions: Charcot neuroosteoarthropathy, diabetic foot ulcer (DFU), and amputation. Charcot neuroosteoarthropathy, referred to as Charcot foot, was defined as the presence of the International Classification of Diseases, 9th Revision (ICD9), diagnosis code 713.5 in any inpatient or outpatient records (14). DFUs were defined using either ICD9 codes 707.1× or 707.9 in any inpatient or outpatient records (15). To try to narrow the scope to persons with prevalent DFUs, we also required that the participant have at least one CPT code for debridement (11040, 11041, 11042, 11043, or 11044). Amputation was defined as the presence of at least one ICD9 procedure code for amputation (84.11, 84.12, 84.13-84.16, or 84.17-84.19), ICD9 status code for amputation (v49.7), or CPT code for amputation (27590-8, 27880-9, 28800, 28805, 28810, 28820, or 28825) in any inpatient or outpatient records (10).

Covariates

Variables that we investigated as possible predictors of each of the three foot conditions included demographic variables (age, sex, race/ethnicity, education, income, and smoking), diabetes-specific variables (type of diabetes, duration of diabetes, insulin use, and hemoglobin A1c), and biological variables (body mass index, systolic and diastolic blood pressure, low density lipoprotein cholesterol, triglycerides, history of microvascular complications, history of macrovascular complications, and Charlson comorbidity index). Smoking was considered present if the participant had ever smoked as defined by a positive response to either self-report of current smoking some days or every day, or a history of smoking in the past three years from medical record review. Type 1 diabetes was defined by insulin use (without the use or oral antidiabetic agents) and age at diagnosis of diabetes < 30 years; all others were defined as having type 2 diabetes. History of microvascular disease was defined as a history of retinopathy, nephropathy, or neuropathy from medical record review. History of macrovascular disease was defined as a history of stroke, myocardial infarction, or peripheral vascular disease from medical record review. The number of comorbidities was defined using the Charlson index, a weighted measure of comorbid conditions associated with mortality (17). Other variables included in Table 1, including health-related quality of life (EQ5D), mobility, physical activity, and foot care behaviors, were used to describe the population with foot conditions and were not included as possible predictors of foot complications because they may have been influenced by the presence of Charcot foot, DFU, and amputation. Limits were set on outliers for certain variables as such: time others spend on your foot care (60 min per day), time you spent on foot care (7 hrs per week), and time you spent exercising (120 min per day).

Statistical Analysis

We defined each person as having none or one or more foot conditions and examined the occurrence of prevalent conditions using a Venn diagram (Figure 1). We then used a hierarchy to place each person with a foot condition into one of three mutually exclusive groups: any Charcot foot, DFU and debridement only, or amputation with or without DFU and debridement. We described the percent distribution of categorical variables and the mean ± standard deviation of continuous variables for people in each of the three groups. Chi-square and t-tests were conducted to compare each group separately to the reference group of people with no foot conditions.

Three separate mulitvariate logistic regression models were constructed to predict Charcot foot, DFU, or amputation. Each model used the population with no foot conditions as the reference group. The models were adjusted for clustering at the provider group and health plan level. We constructed the multivariate models first by including sex and race/ethnicity

in each model and then including all variables that were statistically significant at a p-value of < 0.05 in bivariate analyses. Insulin use and duration of diabetes were highly correlated (p<0.0001) so we chose to only include duration of diabetes in the models.

All analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC).

Results

At baseline, the average age of TRIAD participants was 61 (±13) years and mean duration of diabetes was 12 (±10) years. Between 1999-2003, 55 (0.8%) patients had a diagnosis of Charcot foot, 205 (2.9%) had a diagnosis of at least one DFU with incident debridement, and 101 (1.4%) had a lower extremity amputation procedure or a status code for a prevalent amputation. There were 6,631 (94.8%) patients with no foot conditions.

In the bivariate models (Table 1), patients with Charcot foot were more likely to be men, less likely to be a racial/ethnic minority, and more likely to have a longer duration of diabetes, to use insulin, and to have microvascular disease. They also were more likely to have a higher BMI, a history of macrovascular disease, and a higher Charlson comorbidity index compared to patients with no foot conditions. Patients with DFU were more likely to be older and less likely to be a racial/ethnic minority. They were more likely to have a longer duration of diabetes and use insulin, a higher hemoglobin A1c level, a history of microvascular and macrovascular disease, and a higher Charlson comorbidity index compared to patients with no foot conditions. Patients with a lower extremity amputation were more likely to be men, have a lower income, have a longer duration of diabetes and use insulin, have a higher hemoglobin A1c level, have a history of microvascular and macrovascular disease, and have a higher Charlson comorbidity index compared to patients with no foot conditions.

Patients with any of the three foot conditions reported poorer quality of life and more problems walking than patients with no foot conditions. Patients with a foot condition were significantly more likely to check their feet daily and spend more time on daily foot care (Table 1).

In the multivariate models (Table 2), racial/ethnic minorities were less likely to have Charcot foot (OR=0.21; 95% CI:0.10, 0.46) than non-Hispanic Whites. Longer duration of diabetes and higher body mass index were associated with Charcot foot. Patients with a history of microvascular disease were almost four times as likely to have Charcot foot as patients without microvascular disease (OR=3.62; 95%CI: 1.92, 6.82) and patients with a history of macrovascular disease were almost twice as likely to have Charcot foot as patients without macrovascular disease (OR=1.87; 95%CI: 1.07, 3.27). hemoglobin A1c was not associated with Charcot foot.

Compared to non-Hispanic Whites, racial/ethnic minorities were less likely to have DFU (OR=0.61; 95% CI: 0.44, 0.84). Longer duration of diabetes and higher hemoglobin A1c levels were associated with DFU. Patients with a history of microvascular (OR=2.32; 95%CI: 1.65, 3.27) or macrovascular disease (OR=2.23; 95% CI: 1.59, 3.12) were over twice as likely to have DFU compared to those without a history of microvascular or macrovascular disease (Table 2).

Compared to women, men were more likely to have a lower-extremity amputation (OR=2.40; 95% CI: 1.41, 4.07). Longer duration of diabetes and higher hemoglobin A1c levels were associated with amputation. Patients with a history of microvascular (OR=3.09; 95%CI: 1.79, 5.34) or macrovascular disease (OR=3.36; 95% CI: 1.96, 5.75) were over

three times as likely to have an amputation compared to those without a history of microvascular or macrovascular disease (Table 2).

Discussion

In our study of managed care patients, we found a relatively high prevalence of foot complications, particularly given uniform access to health care for all patients. Racial/ethnic minorities were less likely to have Charcot foot and DFU, and there were no racial/ethnic or income differences in the prevalence of lower-extremity amputation. Few studies have evaluated the racial/ethnic differences in the prevalence of Charcot foot (1). In one small study of foot pathology, Lavery et al. reported that Charcot foot was more common among non-Hispanic Whites (4). Likewise, Stuck et al. (14) found that African Americans were less likely to have Charcot foot. In keeping with these reports, we also found racial/ethnic minorities to be less likely to have Charcot foot. Previous literature has suggested that patients with lower socioeconomic status and minorities with diabetes, particularly African Americans, are more likely to have DFU and lower extremity amputation and to have a more severe (i.e., more proximal) amputation than patients with higher socioeconomic status and non-Hispanic Whites (18- 21). However, our work confirms a previous study (22) that found no difference in amputation rates among blacks, whites, and Latinos with access to good quality healthcare.

A major strength of our study is the evaluation of Charcot foot among a managed care population with diabetes. Charcot foot is an infrequent complication that may be underdiagnosed, even among populations with diabetes. Previous reports of Charcot foot indicate a prevalence of 0.1-0.9% among patients with diabetes (2- 4), which is in keeping with our findings. Unlike previous investigations that have found no association between sex and Charcot foot, we found that men were marginally more likely to have Charcot foot than women. Additional research is needed to understand the reason for sociodemographic differences in the prevalence of Charcot foot. It has been hypothesized that the presence of peripheral neuropathy, combined with the biomechanical loading of obesity, confers greater risk of Charcot foot (14). We found a significant independent association between BMI and Charcot foot as well as between microvascular disease and Charcot foot. Although we did not have enough statistical power to evaluate the interaction between BMI and peripheral neuropathy in our study population, our findings suggest the importance of body size and loss of protective pain sensation in the pathology of Charcot foot. We were able to investigate the BMIs among the two racial/ethnic groups and found that non-Hispanic whites (31.5 kg/m^2) had a similar BMI to racial/ethnic minorities (31.4 kg/m^2) (p=0.4290), indicating that the difference in risk for Charcot foot by race/ethnicity was likely not due to differences in obesity.

For all three foot conditions, the strongest associations were observed with history of microvascular and macrovascular disease. History of microvascular disease was associated with a two- to four-fold increase in the odds of foot complication, and history of macrovascular disease was associated with a two- to three-fold increase in the odds of foot complications. In sensitivity analyses (results not shown), we evaluated each component of the microvascular summary variable (retinopathy, nephropathy, and neuropathy) and the macrovascular summary variable (stroke, MI, and PVD) separately in our multivariate models for DFU and amputation. Retinopathy and nephropathy were moderately associated with the odds of DFU (approximately 1.8-fold increase), and neuropathy was strongly associated (approximately 2.6-fold increase) with DFU. Nephropathy and neuropathy were both associated with an approximately 2.3-fold increase in the odds of lower-extremity amputation, but retinopathy was not associated with amputation. PVD was the strongest and only statistically significant contributor to the association between macrovascular disease

and DFU and amputation, which is not surprising since impaired circulation resulting from PVD may decrease wound healing. This is also consistent with prior reports in this area (23-24). Likewise, loss of protective sensation is associated with Charcot foot, DFU, and amputation.

In addition to microvascular and macrovascular disease, all three foot conditions were associated with longer duration of diabetes. There were also important differences between Charcot foot, DFU, and amputation with respect to other risk factors. BMI was associated with Charcot foot but not with DFU or amputation. Our findings are consistent with those previously reported for obesity with Charcot foot and amputation (14; 25). Our findings differ from Sohn and colleagues for obesity and foot ulcer risk. Their study reported a j-shaped relationship of increased risk of foot ulcer for those BMI's <25 or greater than 40 (26). Hemoglobin A1c was associated with DFU and amputation, but not Charcot foot. We hypothesize that it is the combination of peripheral neuropathy from long-standing diabetes, whether the diabetes is well-controlled or not, and the biomechanical loading of obesity which plays a substantial role in the development of Charcot foot. This differs from the development of amputation which is more impacted by the degree of micro- and macrovascular complications that develop at differing rates in patients with varying levels of control of their diabetes.

This study has some limitations. Identification of foot conditions relied on data recorded for administrative purposes. These data may not accurately represent a patient's clinical status. However, previous studies have reported that compared to medical records, ICD-9 codes have 93% sensitivity and 91% specificity to identify DFU, and that Charcot arthropathy identified by ICD-9 codes can be confirmed by medical records 92% of the time (6, 15). Administrative data do not allow for identification of the foot affected so we do not know if the conditions were unilateral or bilateral. Additionallydue to the relatively low prevalence of Charcot foot and subsequently limited statistical power, we combined all racial/ethnic minority groups into a single category and compared them to non-Hispanic Whites. As such, heterogeneity within racial/ethnic minorities may have been masked and it is possible that African Americans, Hispanics, and Asians have important differences in the prevalence and correlates of diabetes-related foot complications. We did not observe an association between smoking and foot complications. However, due to survey measurement, the dichotomization of smoking may have resulted in misclassification and biased the results of our bivariate analysis of smoking and foot complications. BMI was measured by self-report, which also may have resulted in misclassification.

Early detection of feet at risk and appropriate management are the most important factors in preventing diabetes-related foot complications. In our study of managed care patients with uniform access to health care, we found a relatively high prevalence of foot complications, but attenuation of the racial/ethnic differences of rates reported in the literature. Multidisciplinary preventive health care teams may reduce high rates of amputation in persons with diabetes.

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L.M. researched the data, contributed to the discussion, and wrote, reviewed, and edited the manuscript, K.Y. contributed to the discussion, and wrote, reviewed, and edited the manuscript, W.H. and J.W. contributed to the discussion and reviewed and edited the manuscript. L.M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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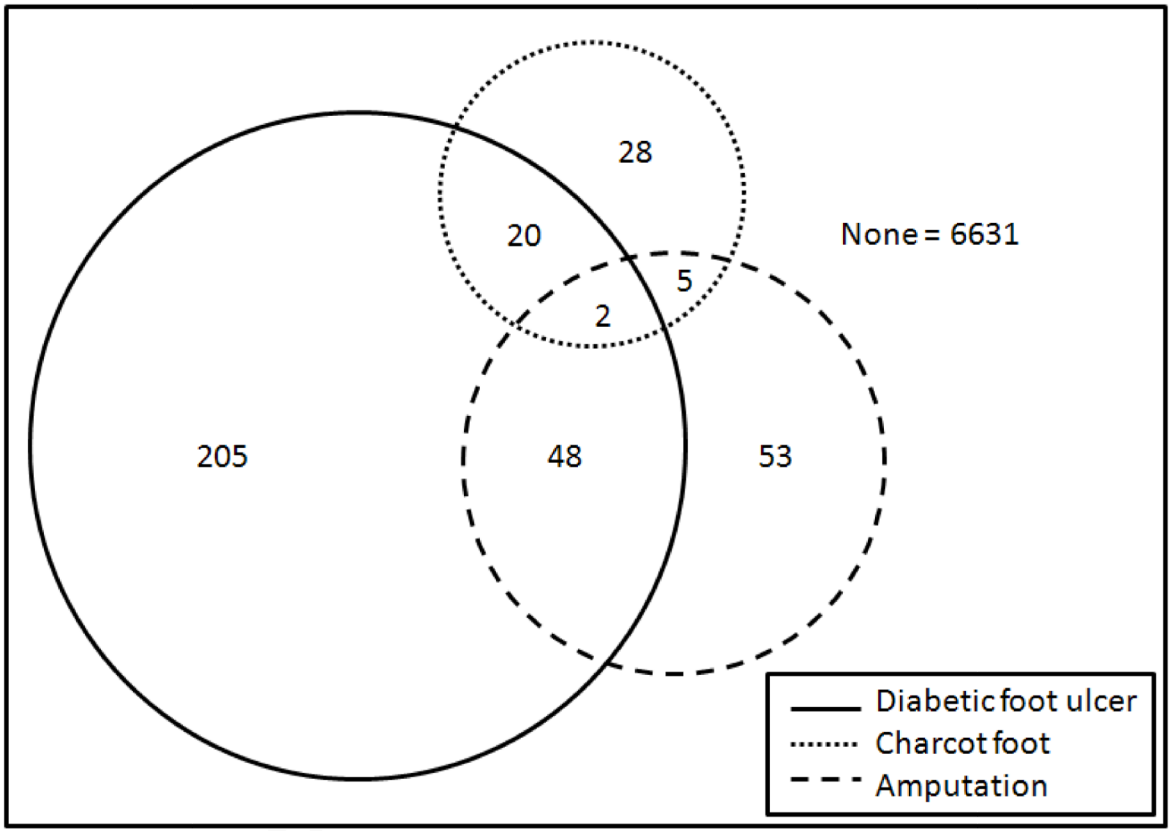

Figure 1.
Coinciding counts of prevalent foot conditions for patients with survey and chart review data, Translating Research Into Action for Diabetes N=6,992.

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Table 1

Distribution of baseline sociodemographic and biological risk factors stratified by type of foot condition for patients with survey and chart review data, Translating Research Into Action for Diabetes N=6,992. Data are mean (standard deviation), median (interquartile range), or N (%).

Characteristic	No foot condition	Charcot	P-value (vs none)	DFU with debridement	P-value (vs none)	Amputation ± DFU	P-value (vs none)
N	*6631*	*55*		*205*		*101*	
Age (years)	61 ± 13	60 ± 10	0.3295	65 ± 13	0.0002	62 ± 12	0.5136
Sex			0.0268		0.3621		<0.0001
Male	2989 (45%)	33 (60%)		99 (48%)		67 (66%)	
Female	3642 (55%)	22 (40%)		106 (52%)		34 (34%)	
Race/ethnicity			<0.0001		0.0028		0.8966
Non-Hispanic White	3184 (50%)	44 (83%)		119 (61%)		48 (49%)	
Other	3165 (50%)	9 (17%)		76 (39%)		49 (51%)	
Education			0.6831		0.4831		0.1201
Some high school or less	1706 (26%)	11 (20%)		50 (25%)		33 (34%)	
High school degree	1824 (28%)	18 (33%)		49 (24%)		30 (31%)	
Some college	1820 (28%)	17 (31%)		65 (32%)		23 (26%)	
College degree or higher	1177 (18%)	9 (16%)		38 (19%)		10 (10%)	
Annual income			0.8123		0.6855		0.0491
<$15,000	1996 (34%)	15 (30%)		57 (31%)		38 (44%)	
$15,000-39,999	1801 (30%)	15 (30%)		58 (31%)		28 (32%)	
>$40,000	2137 (36%)	20 (40%)		71 (38%)		21 (24%)	
Smoking (% yes)	2206 (33%)	18 (33%)	0.9325	60 (29%)	0.2309	38 (38%)	0.3567
Insulin use (% yes)	2113 (32%)	33 (60%)	<0.0001	104 (51%)	<0.0001	59 (58%)	<0.0001
Duration of diabetes (years)	12 ± 10	18 ± 10	<0.0001	16 ± 11	<0.0001	18 ± 10	<0.0001
Type of diabetes			0.9493		0.1453		0.2010
Type 1	336 (5%)	3 (6%)		15 (8%)		8 (8%)	
Type 2	5933 (95%)	51 (94%)		178 (92%)		88 (92%)	
Body Mass Index (kg/m^2)	31 ± 7	34 ± 8	0.0085	32 ± 7	0.0830	30 ± 7	0.1305
History of Microvascular disease	2178 (33%)	39 (71%)	<0.0001	117 (57%)	<0.0001	68 (68%)	<0.0001

Characteristic	No foot condition	Charcot	P-value (vs none)	DFU with debridement	P-value (vs none)	Amputation ± DFU	P-value (vs none)
History of Macrovascular disease	1278 (19%)	22 (40%)	0.0001	86 (42%)	<0.0001	58 (58%)	<0.0001
Systolic blood pressure (mmHg)	137 ± 19	140 ± 18	0.3347	135 ± 19	0.1985	138 ± 20	0.8208
Diastolic blood pressure (mmHg)	77 ± 11	76 ± 11	0.4357	74 ± 11	0.0003	75 ± 14	0.2348
Low density lipoprotein cholesterol (mg/dL)	114 ± 34	106 ± 36	0.1687	112 ± 32	0.6655	108 ± 38	0.1460
Triglycerides (mg/dL)	209 ± 188	274 ± 384	0.2647	202 ± 123	0.4771	221 ± 160	0.5772
Hemoglobin A1c (%)	7.9 ± 1.8	8.0 ± 1.6	0.9853	8.4 ± 2.2	0.0069	8.6 ± 2.5	0.0166
Charlson comorbidity index	2.2 ± 1.6	3.0 ± 1.9	0.0013	3.0 ± 1.9	<0.001	3.7 ± 1.8	<0.0001
Foot care behaviors							
Check feet daily	1976 (62%)	35 (83%)	0.0040	107 (76%)	0.0006	58 (82%)	0.0006
Time others spend on your foot care (hours per week)	0 (0, 0)	0 (0, 0)	0.1271	0 (0, 0.25)	0.0002	0 (0, 1)	0.0017
Time for foot care (minutes per day)	5 (0, 10)	10 (5, 15)	0.0191	5 (2, 15)	0.0081	15 (5, 30)	<0.0001
EQ5D	0.72 ± 0.27	0.63 ± 0.29	0.0251	0.66 ± 0.26	0.0037	0.56 ± 0.33	<0.0001
Mobility			<0.0001		<0.0001		<0.0001
No problems walking	3296 (54%)	8 (16%)		59 (31%)		19 (21%)	
Some problems/confined to bed	2800 (46%)	41 (84%)		129 (69%)		73 (79%)	
Physical activity							
Time exercising (minutes per day)	15 (0, 30)	10 (0, 30)	0.7636	14 (0, 30)	0.0136	15 (0, 30)	0.5155

Abbreviations: DFU, diabetic foot ulcer

Table 2

Multivariate association (OR; 95% CI) between baseline sociodemographic and biological risk factors and foot conditions for patients with survey and chart review data, Translating Research Into Action for Diabetes.

	Charcot foot		DFU with debridement		Amputation ± debridement	
	OR (95% CI)	***P***	**OR (95%CI)**	***P***	**OR (95% CI)**	***P***
Age, years	---		1.01 (0.99, 1.03)	0.22	---	
Sex						
Female	Ref		Ref		Ref	
Male	1.68 (0.94, 3.02)	0.08	1.04 (0.76, 1.43)	0.80	2.40 (1.41, 4.07)	0.001
Race/ethnicity						
non-Hispanic White	Ref		Ref		Ref	
Other	0.21 (0.10, 0.46)	<0.001	0.61 (0.44, 0.84)	0.003	1.03 (0.61, 1.74)	0.91
Annual income						
<$15,000	---		---		1.84 (0.97, 3.50)	0.07
$15,000 - $40,000	---		---		1.28 (0.68, 2.41)	0.82
>$40,000	---		---		Ref	
Duration of diabetes, years	1.03 (1.02, 1.05)	<0.001	1.02 (1.01, 1.03)	0.005	1.02 (1.01, 1.04)	0.002
History of microvascular disease	3.62 (1.92, 6.82)	<0.001	2.32 (1.65, 3.27)	<0.001	3.09 (1.79, 5.34)	<0.001
History of macrovascular disease	1.87 (1.07, 3.27)	0.03	2.23 (1.59, 3.12)	<0.001	3.36 (1.96, 5.75)	<0.001
Body mass index, kg/m^2	1.06 (1.03, 1.09)	<0.001	---		---	
Hemoglobin A1c, %	---		1.18 (1.08, 1.29)	<0.001	1.18 (1.04, 1.33)	0.01

Abbreviations: DFU, diabetic foot ulcer