Trends in Initial Lower Extremity Amputation Rates Among Veterans Health Administration Health Care System Users From 2000 to 2004

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OBJECTIVE—To evaluate temporal trends in rates of initial lower extremity amputation (ILEA) among patients with diabetes in the Veterans Health Administration (VHA).

RESEARCH DESIGN AND METHODS—Retrospective administrative data analysis of VHA clinic users with diabetes in fiscal years (FY) 2000 to 2004 (1 October 1999–30 September 2004). We calculated annual age– and sex–standardized rates of initial major, minor, and total amputations for the overall population and for various racial/ethnic groups (African Americans, Hispanics, and whites). Trends in ILEA risk were evaluated with and without adjustment for demographic characteristics and other potential risk factors, including presence of microvascular and macrovascular diseases, and antiglycemic treatment.

RESULTS—Study populations of VHA patients with diabetes and without prior amputations ranged from 405,580 in FY 2000 to 739,377 in FY 2004. Age- and sex-standardized ILEA rates decreased by 34% (7.08/1,000 patients in FY 2000 to 4.65/1,000 patients in FY 2005) during the 5-year period. Minor and major amputation rates decreased by 33% (4.59 to 3.06/1,000) and 36% (2.49 to 1.59/1,000), respectively. Of major amputations, below-knee rates decreased from 1.08 to 0.87/1,000 (−19%), and above-knee decreased from 1.41 to 0.72/1,000 (−49%). Similar trends were seen for all racial groups. ILEA risk decreased by 28% (odds ratio 0.72 [95% CI 0.68–0.75]) when FY 2004 was compared with FY 2000 in the model, adjusting for demographic characteristics. This risk decrease was 22% in the model adjusting for all independent variables (odds ratio 0.78 [95% CI 0.74–0.82]).

CONCLUSIONS—Downward 5-year trends in ILEA rates were observed for all amputation levels and among all racial groups, even after adjustment for risk differences over time.

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Lower extremity amputations (LEAs) are a catastrophic complication of diabetes, often leading to loss of ambulatory status, permanent disability, and high operative mortality (1). LEAs are considered to be a prevention quality indicator, that is, a condition for which onset or hospital admission is potentially preventable by timely and effective ambulatory care (2). Reducing the rate of LEAs was a major objective of Healthy People 2010 (3). Several recent U.S. studies have reported population trends in LEA rates. Among Medicare fee-for-service beneficiaries, rates fell by 26% from 1992 to 2001 (4), and amputation rates decreased by 37% from 1998 to 2004 in the U.S. population with diabetes (5).

Interpretation of the clinical and policy significance of these findings is tempered, however, by methodologic limitations of the studies. First, the findings of "decreased" amputation rates could be partly attributed to a "denominator" effect. The incidence of LEAs is extremely uncommon in the first 10 years after diagnosis, even when a fasting blood glucose <140 mg/dL was used as the basis for diagnosis (6). There have been secular trends in diagnostic criteria and screening intensity for diabetes (7); for example, diabetes is diagnosed earlier as a result of a 1997 change by the American Diabetes Association in the fasting blood glucose level from 140 to 126 mg/dL.

As a consequence, there may have been more patients with diabetes of more recent onset in the later years of these studies. Because these patients would increase the number in the denominators but not be expected to increase the number of lower extremity amputations over a short period of time, they would tend to bias LEA rates downward. Therefore, when trends of amputations over time are evaluated, it is necessary to adjust for possible differences in risk factors of amputations in the denominators (or study populations) over time.

Furthermore, reliance on total amputations (2–5) as the only outcome in evaluating access to and quality of foot care may not be appropriate for several reasons: first, the functional outcomes of minor and major amputations differ markedly (8). Second, an increased emphasis on foot care and surveillance programs could lead to earlier recognition of limb-threatening conditions that could increase rates of minor amputations while decreasing rates of major amputations (9). Thus, the ratio of major/minor amputations (10), as well as simultaneous evaluation of major and minor amputations (11), have been proposed to evaluate quality of foot care. In contrast to U.S. Federal Agencies (2,3), the Organization for Economic Collaboration and Development Health Indicators Project recommended that reporting of LEA rates

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should be confined to major amputations (12). Finally, because repeat amputations would represent a failure of multidisciplinary salvage programs, evaluation of initial amputations may better reflect the effectiveness of primary prevention through surveillance (13).

The Veterans Health Administration (VHA) is the largest integrated health care system in the U.S. and has a national electronic health care record and data warehouse that stores the medical records of each patient. The VHA and some regional health plans both provide more complete patient information compared with Medicare data as a result of the availability of linked pharmacy, laboratory, and claims data. However, the VHA offers a different perspective in population-based outcomes research compared with the regional health plans, because it is a national system that functions as a "safety net," in that access is based on entitlement without consideration of pre-existing conditions (14). We have previously used combined patient-level VHA and Medicare databases to develop risk prediction models for total (15) and minor and major amputations (11) and evaluated rates of initial versus repeat amputations (16). The objective of this study was to evaluate risk-adjusted trends in initial minor, major, and total amputations among veterans in fiscal years (FYs) 2000–2004 and to determine whether trends in rates varied across racial and ethnic groups.

RESEARCH DESIGN AND METHODS

Study population

For this serial cross-sectional study, we used the Diabetes Epidemiology Cohorts data, a database of all VHA patients with diabetes since 1998 containing linked longitudinal patient records derived from inpatient and outpatient services in the VHA or in the private sector and covered by Medicare (17). Diabetes was determined using a previously validated approach based on prescriptions for diabetes medication in the current year or having 2 or more days with diabetes-specific International Classification of Diseases–Clinical Modification, 9th edition (ICD-9-CM) codes (250.xx, 357.2, 362.0, 366.41) from inpatient stays or outpatient physician visits during the prior 2 years. For each year in FYs 2000–2004, we identified patients with diabetes who were alive at the beginning of the year and had no prior amputation in the previous 24 months. Patients enrolled in Medicare Health Maintenance Organization plans in the previous 24 months (<3%) were excluded because their health information was not available.

Outcome measures

First, we removed individuals from the numerator and denominator who had evidence of any prior amputation. These included the presence of ICD-9-CM procedure codes for any LEA (84.1×) as well as post-amputation codes and lower limb prosthetic codes (997.60, 997.61, 997.62, 997.69, V497.×, V521.×) in any field in either VHA or Medicare inpatient records, as described previously (16).

Second, we defined our study outcomes, an initial LEA (ILEA) hospitalization, as one with the presence of ICD-9-CM procedure codes for any LEA (84.1×). Minor amputations were defined as toe (84.11), transmetatarsal (84.12–84.13), and distal transtibial (including Symes, 84.14) amputations. Major amputations were defined as transtibial (below-knee, 84.15, 84.16) and transfemoral (above-knee, 84.17–84.19). Multiple procedures with the same ICD-9-CM code on the same day were considered to be a single amputation because there are no modifiers to enable identification of bilateral amputations. Different amputation codes during the same hospitalization were assigned as a single procedure at the highest anatomic level.

Independent variables

Demographic variables included age (<55, 55–64, 65–74, and ≥75 years), sex, race/ethnicity (white, African American, Hispanic, other [e.g., Asian American, Native American, etc.], and unknown), marital status (married, other, and unknown), census regions (Northeast, Midwest, South, West, and unknown), and census rural/urban continuum (0 = extremely urban to 9 = extremely rural). Using the veterans' VHA enrollment priority status, which determines payment status and eligibility for services in the VHA based on their status of military-connected disability and income, patients were characterized as severely disabled, moderately disabled, poor, co-pay required, and unknown.

Variables reflecting health status included macrovascular (coronary artery disease, congestive heart failure, arrhythmia, stroke, and peripheral vascular disease), microvascular (chronic renal pathophysiology, diabetic nephropathy, acute renal failure, end-stage renal disease, dialysis, diabetic retinopathy, and ulcer), and metabolic complications (uncontrolled diabetes and short-term complication of diabetes). The ICD-9-CM diagnoses codes were used to determine the presence of these medical conditions. Neuropathy was not included because our prior work indicated that it was so poorly coded (~2%) as to be unreliable (15).

Finally, diabetes medications (no medications or oral medications only, oral medications with insulin, and insulin only) were included as a proxy for the duration of type 2 diabetes, recognizing that individuals with type 1 diabetes would be included in the insulin-only category. The independent variables were ascertained for each year of comparison; the information from the previous years was used for missing values. All missing data were treated as a separate category in each variable for the statistical analysis except for sex. Patients without sex information (0.01–0.02%) were removed from the statistical analysis.

Statistical techniques

First, to help evaluate the changes in population characteristics across years of comparisons, we obtained the frequencies and percentages of subcategories in the independent variables as described for each year of comparison (Table 1). Second, we evaluated ILEAs across the 5 years of study. For each of the 5 years, we obtained counts of the denominator, major (above- and below-knee), and minor amputations. We then calculated annual crude rates of ILEAs and rates directly standardized to the age and sex composition of our study population in FY 2000 (18). ILEA rates were also computed separately for initial minor and major (below- and above-knee) amputations and for various racial/ethnic groups (Hispanics, African Americans, and whites). The statistics for age- and sex-standardized rates are presented in Table 2.

To compare ILEA rates over the 5 years, we used logistic regression models, combined data across the years, and included year as an independent categoric variable. The year variable was also treated as a continuous measure to evaluate the robustness of the findings. We report odds ratios (ORs) and 95% CIs. Independent variables were added to the models to help adjust for population differences over the years of comparisons based on a previously validated model (15). In building

Table 1—*Profiles of population with diabetes and no prior amputations in the VHA: FY 2000–2004*

Variable	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004
Denominator	405,580	454,221	514,970	651,752	739,377
Age category					
18–44 years	13,606 (3.36)	14,105 (3.11)	14,432 (2.80)	14,669 (2.25)	15,130 (2.05)
45–54 years	65,104 (16.05)	72,458 (15.96)	74,513 (14.47)	75,974 (11.66)	76,193 (10.31)
55–64 years	74,267 (18.31)	88,013 (19.38)	110,286 (21.42)	139,722 (21.44)	176,809 (23.91)
65–74 years	135,093 (33.31)	143,998 (31.71)	159,533 (30.98)	203,212 (31.18)	223,817 (30.27)
75–84 years	108,735 (26.81)	124,455 (27.41)	141,809 (27.54)	194,707 (29.88)	216,104 (29.23)
≥85 years	8,714 (2.15)	11,082 (2.44)	14,315 (2.78)	23,358 (3.58)	31,278 (4.23)
Missing	61 (0.02)	110 (0.02)	82 (0.02)	110 (0.02)	46 (0.01)
Sex					
Female	10,484 (2.58)	12,101 (2.66)	13,893 (2.70)	16,977 (2.60)	19,348 (2.62)
Male	395,035 (97.40)	442,010 (97.31)	500,995 (97.29)	634,715 (97.39)	719,983 (97.38)
Missing	61 (0.02)	110 (0.02)	82 (0.02)	60 (0.01)	46 (0.01)
Race/ethnicity					
African American	73,320 (18.08)	80,290 (17.68)	87,553 (17.00)	97,417 (14.95)	104,530 (14.14)
Hispanic	13,077 (3.22)	14,853 (3.27)	16,282 (3.16)	18,381 (2.82)	20,025 (2.71)
Other	7,702 (1.90)	8,571 (1.89)	9,602 (1.86)	11,254 (1.73)	12,390 (1.68)
White	302,086 (74.48)	337,414 (74.28)	383,164 (74.41)	498,024 (76.41)	560,365 (75.79)
Missing	9,395 (2.32)	13,093 (2.88)	18,369 (3.57)	26,676 (4.09)	42,067 (5.69)
Marital status					
Married	242,060 (59.68)	273,994 (60.32)	316,160 (61.39)	419,032 (64.29)	482,832 (65.30)
Not married	160,643 (39.61)	177,092 (38.99)	195,837 (38.03)	228,862 (35.11)	252,135 (34.10)
Missing	2,877 (0.71)	3,135 (0.69)	2,973 (0.58)	3,858 (0.59)	4,410 (0.60)
Census region					
Northeast	67,120 (16.55)	74,025 (16.30)	83,462 (16.21)	104,967 (16.11)	118,459 (16.02)
Midwest	89,922 (22.17)	98,497 (21.68)	112,518 (21.85)	147,419 (22.62)	167,421 (22.64)
South	172,623 (42.56)	195,461 (43.03)	222,063 (43.12)	281,547 (43.20)	321,683 (43.51)
West	60,431 (14.90)	68,259 (15.03)	77,707 (15.09)	95,894 (14.71)	108,261 (14.64)
Missing	15,484 (3.82)	17,979 (3.96)	19,220 (3.73)	21,925 (3.36)	23,553 (3.19)
Rural-urban continuum					
Metro extremely urban	116,308 (28.68)	128,694 (28.33)	143,906 (27.94)	177,675 (27.26)	201,173 (27.21)
Metro 1	12,495 (3.08)	14,195 (3.13)	16,496 (3.20)	21,615 (3.32)	24,916 (3.37)
Metro 2	100,866 (24.87)	112,940 (24.86)	128,529 (24.96)	164,021 (25.17)	184,121 (24.90)
Nonmetro 3	40,852 (10.07)	46,316 (10.20)	53,102 (10.31)	70,187 (10.77)	79,100 (10.70)
Nonmetro 4	19,065 (4.70)	21,531 (4.74)	24,595 (4.78)	32,413 (4.97)	36,589 (4.95)
Nonmetro 5	14,706 (3.63)	16,581 (3.65)	19,013 (3.69)	24,735 (3.80)	27,399 (3.71)
Nonmetro 6	38,452 (9.48)	43,171 (9.50)	49,245 (9.56)	62,402 (9.57)	69,303 (9.37)
Nonmetro 7	32,944 (8.12)	36,751 (8.09)	41,669 (8.09)	53,879 (8.27)	59,873 (8.10)
Nonmetro 8	6,678 (1.65)	7,405 (1.63)	8,364 (1.62)	10,548 (1.62)	11,636 (1.57)
Extremely rural	9,684 (2.39)	10,899 (2.40)	12,396 (2.41)	16,338 (2.51)	18,175 (2.46)
Missing	13,530 (3.34)	15,738 (3.46)	17,655 (3.43)	17,939 (2.75)	27,092 (3.66)
Veterans priority status					
1–SC disability, 50%	76,993 (18.98)	87,608 (19.29)	104,712 (20.33)	129,438 (19.86)	149,988 (20.29)
2–SC disability, 30–40%	33,301 (8.21)	36,401 (8.01)	39,738 (7.72)	45,466 (6.98)	49,836 (6.74)
3–Other disability, POW	49,153 (12.12)	56,513 (12.44)	58,623 (11.38)	69,961 (10.73)	76,692 (10.37)
4–Catastrophic disability	32,184 (7.94)	35,674 (7.85)	37,169 (7.22)	40,910 (6.28)	43,784 (5.92)
5–Poverty	168,976 (41.66)	186,151 (40.98)	201,741 (39.18)	234,043 (35.91)	251,933 (34.07)
6–Other	3,933 (0.97)	3,343 (0.74)	3,033 (0.59)	3,518 (0.54)	3,861 (0.52)
7–Copay	35,085 (8.65)	44,411 (9.78)	65,464 (12.71)	125,425 (19.24)	159,964 (21.63)
Missing	5,955 (1.47)	4,120 (0.91)	4,490 (0.87)	2,991 (0.46)	3,319 (0.45)
Microvascular disease	158,899 (39.18)	177,162 (39.00)	201,768 (39.18)	250,383 (38.42)	279,424 (37.79)
Macrovascular disease	219,054 (54.01)	241,533 (53.18)	272,795 (52.97)	355,926 (54.61)	400,559 (54.18)
Metabolic disease	113,023 (27.87)	122,305 (26.93)	131,169 (25.47)	92,875 (14.25)	80,604 (10.90)
Diabetes medication profile					
No diabetes medications	90,855 (22.40)	100,083 (22.03)	111,704 (21.69)	156,804 (24.06)	184,470 (24.95)
OHA only	194,465 (47.95)	225,577 (49.66)	262,912 (51.05)	331,657 (50.89)	374,659 (50.67)
OHA and insulin	54,365 (13.40)	65,627 (14.45)	75,571 (14.67)	88,390 (13.56)	100,331 (13.57)
Insulin only	65,895 (16.25)	62,934 (13.86)	64,783 (12.58)	74,901 (11.49)	79,917 (10.81)

Data are *n* (%). OHA: oral hypoglycemic agents; POW: prisoner of war; SC, service-connected.

Table 2—*ILEA counts and rates: *FY 2000–2004***

	FY 2000		FY 2001		FY 2002		FY 2003		FY 2004		Five-year reduction
Variable	*n*	Rate	*n*	Rate	*n*	Rate	*n*	Rate	*n*	Rate	%
Denominator	405,580		454,221		514,970		651,752		739,377		
ILEA	2,870	7.08	3,019	6.64	3,101	5.98	3,492	5.24	3547	4.65	−34.30
Level of amputation											
Minor amputation	1,862	4.59	1,946	4.28	2,000	3.86	2,261	3.42	2299	3.06	−33.30
Major amputation	1,008	2.49	1,073	2.36	1,101	2.12	1,231	1.82	1247	1.59	−36.10
BK	436	1.08	511	1.12	537	1.04	615	0.92	675	0.87	−19.40
AK	572	1.41	562	1.23	564	1.09	616	0.9	572	0.72	−48.90
Ratio of major/minor	0.54		0.55		0.55		0.54		0.54		
Ratio of AK/BK	1.31		1.10		1.05		1.00		0.85		
Race/ethnicity											
White	2,116	7.01	2,237	6.61	2,272	5.86	2,620	5.18	2664	4.63	−34.00
African American	614	8.38	624	7.76	655	7.47	661	6.63	672	6.3	−24.80
Hispanic	79	6.04	92	6.28	91	5.49	100	5.59	91	5.16	−14.60
Other	56	7.27	57	6.7	76	8.01	70	6.16	58	4.47	−38.50

*Rates are standardized to the age and sex distribution of the population in FY 2000 and presented as per 1,000 patients with diabetes and no prior amputation, alive as of the beginning of the year. AK, above knee; BK, below knee.

risk-adjustment models, we first included only the year variable in the model (model 1), followed by models with demographic variables (model 2), followed by adding the variable representing microvascular diseases (model 3), and then adding the remaining independent variables (model 4), which we defined as a full risk-adjustment model. To further evaluate the effect of diabetes severity, we removed the diabetes medication variable from model 4 to create model 5. In addition, we evaluated model 4 only among individuals with microvascular diseases (model 6). Results from these models are presented in Table 3. Finally, we evaluated trends of amputation by the race/ethnicity categories. The study was approved by the institutional review boards at East Orange Veterans Affairs Medical Center (VAMC) and Bedford VAMC.

RESULTS—Our study population increased from 405,580 in FY 2000 to 739,377 in FY 2004, an 82% increase. As reported in Table 1, missing data were minimal and did not change over time, with the exception that missing race/ethnicity data increased from 2.3 to 5.7%. Overall, some patient factors changed over time. The number of married individuals increased from 60 to 65%; the percentage of individuals receiving insulin (alone or with oral agents) decreased from 29.7% in FY 2000 to 24.9% in FY 2004. Most dramatically, the percentage of individuals with metabolic diseases decreased from 27.9% in FY 2000 to 10.9% in FY 2004.

Table 2 reports counts, ratios of types of ILEAs, and age- and sex-standardized rates of ILEAs. Compared with FY 2000, the number of total (2,870 to 3,547), minor (1,862 to 2,299), and major amputations (1,008 to 1,247) all increased by ~24%. The counts of above-knee amputation were relatively unchanged, although below-knee amputations increased from 436 in FY 2000 to 675 in FY 2004. When comparing the ratios of types of amputations across the years, the ratios of major/minor amputations showed little change; however, the ratios of above-knee/below-knee amputations progressively decreased from 1.31 in FY 2000 to 0.85 in FY 2004.

Age- and sex-standardized ILEA rates declined by 34% over the 5-year period, from >7 to <5/1,000 patients. The rate for minor amputations decreased 33%, from 4.59/1,000 in FY 2000 to 3.06/1,000 in FY 2004, and the rate for major amputations reduced 36%, from 2.49 to 1.59/1,000. Among major amputations, the rate for below-knee amputations decreased 19%, from 1.08 to 0.87/1,000, and the rate for above-knee amputations reduced 49%, from 1.41 to 0.72/1,000. Rates decreased across all racial/ethnic groups, with whites showing a greater decline (−34%) than African Americans (−25%) or Hispanics (−15%).

Table 3 reports results for evaluation of ILEA trends based on logistic regression models with and without adjustment for risk factors. Results from the first model that contains only the "year" variable showed that the ORs (95% CI) decreased, along with the progression of years, when all years after FY 2000 were compared with FY 2000, from 0.94 (0.89–0.99) in FY 2001 to 0.68 (0.64–0.71) in FY 2004. Results from models 2 to 4, in that different risk factors were entered into the models, also show similar downward trends. In model 4, where all selected risk factors were included, ORs slightly decreased from 0.97 (0.92–1.02) in FY 2000 to 0.78 (0.74–0.82) in FY 2004, a 22% reduction in the 5-year period ($P < 0.01$). When the results were rerun using year as a continuous variable, the downward trend remained significant for model 1 (0.90 [0.895–0.91]) and model 4 (0.95 [0.94–0.96]). Model 5 (model 4 minus diabetes medication variable) and model 6 (model 4 based on individuals with microvascular conditions) showed similar downward trends to the main analyses.

On the basis of model 4, we evaluated whether the rates of decline for African Americans and Hispanics were comparable with those in the white population by adding an interaction term of continuous scale of "year" and "race/ethnicity." Results showed that these three groups were not significantly different from each other (African American vs. white, $P = 0.91$; Hispanic vs. white, $P = 0.37$, data not shown).

CONCLUSIONS—The age- and sex-standardized rates of initial lower extremity amputations reduced from 7.08/1,000 veterans in FY 2000 to 4.65/1,000 veterans in FY 2004 who used the VHA health care system—a marked decrease of 34%.

Table 3—*Risk of ILEAs for the years of comparison (FY 2000–FY 2004): results from logistic regression models*

		FY 2001*	FY 2002*	FY 2003*	FY 2004*	Year†
Model	FY 2000	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Model 1 (no risk adjustment)	Ref	0.94 (0.89–0.99)	0.85 (0.81–0.89)	0.76 (0.72–0.79)	0.68 (0.64–0.71)	0.90 (0.90–0.91)
Model 2 (only demographics)	Ref	0.95 (0.90–1.00)	0.86 (0.82–0.91)	0.79 (0.75–0.83)	0.72 (0.68–0.75)	0.92 (0.91–0.93)
Model 3 (demographics + microvascular disease)	Ref	0.95 (0.90–1.00)	0.86 (0.81–0.90)	0.80 (0.76–0.84)	0.73 (0.70–0.77)	0.92 (0.91–0.93)
Model 4 (full risk-adjustment model)	Ref	0.97 (0.92–1.02)	0.88 (0.84–0.93)	0.85 (0.81–0.90)	0.78 (0.74–0.82)	0.95 (0.94–0.96)
Model 5 (model 4 without diabetes medications)	Ref	0.96 (0.91–1.01)	0.87 (0.83–0.92)	0.84 (0.80–0.89)	0.78 (0.74–0.82)	0.94 (0.93–0.95)
Model 6 (model 4 subselected for patients with microvascular disease)	Ref	0.97 (0.92–1.02)	0.88 (0.84–0.93)	0.84 (0.80–0.89)	0.77 (0.73–0.81)	0.94 (0.93–0.95)

*Categoric measure. †Continuous measure.

A similar decrease was noted in major (−36%) and minor (−33%) amputations. Although the population with diabetes increased dramatically, 82%, during the 5-year period, the absolute numbers of minor and below-knee amputations increased only moderately, and the counts of above-knee amputations had little change. A more important finding was a significant downward trend for ILEAs, even after we adjusted for population characteristics and risk factors of amputations. This indicates that the observed downward trend cannot be ascribed only to population differences across years of comparisons.

Our evaluation of major amputations found that the rates of above-knee amputations had much greater decrease (−49%) during the 5-year study period than rates of below-knee amputations (−19%). Furthermore, the counts of below-knee amputations gradually increased and above-knee amputations remained the same during the 5-year period, resulting in gradually decreased ratios of above-knee/below-knee amputations from 1.31 in FY 2000 to 0.85 in FY 2004. Therefore, the decrease in the rate of major amputations can be attributed more to the decrease in above-knee than in below-knee amputations.

The risk-adjusted models show a decrease of the magnitude of the contrast between years of comparisons. For example, for the contrast between the last and first years, the OR (95% CI) changed from 0.68 (0.64–0.71) without risk adjustment (model 1) to 0.72 (0.68–0.75) with adjustment for demographic factors (model 2), and to 0.78 (0.74–0.82) with risk adjustment for all independent variables (model 4, full risk-adjustment). In other words, the risk reduction in the 5-year period was 22% (model 4) rather than 32% (model 1) when differences in selected important risk factors of ILEA across years of comparison were considered. This shrinkage of the contrast between years of comparisons supports the importance of adjusting for important risk factors in assessing the trend of ILEA in patients with diabetes. These results and the comparison of the absolute numbers of amputations and the populations at risk together give evidence for the presence of a "denominator effect."

Our data show that African Americans, Hispanics, and whites all experienced similar downward trends. When adjustments are not made for potential confounders, whites show a higher decrease rate (−34%), followed by African Americans (−25%) and Hispanics (−15%). When risk-adjusted, the rates of decrease in the latter two groups were not different from whites. We note that African Americans continued, through the years of comparisons (2000–2004), to have the highest rates. The rate for Hispanics, although lower than whites in years 2000–2003, became higher than whites in 2004. These results must be viewed with caution because our databases do not contain variables, such as education, income, smoking, and health behaviors, which are essential for understanding racial differences. In addition, there were small numbers of Hispanic (as well as the other non-white, non-black, and non-Hispanic racial groups) who incurred amputations. Continuing evaluation of the annual trends of amputations by patients' racial/ethnic groups in future studies will help improve our understanding of racial/ethnic differences in ILEA rates.

Our finding of a 34% decrease in initial total amputations was of comparable magnitude to a 37% decrease in the age-adjusted total amputation rates from 1998 to 2006 based on national estimates of the prevalence of diabetes (5) and a 26% decrease in the age- and sex-adjusted total amputation rates from 1992 to 2001 in Medicare beneficiaries with diabetes (4). On the other hand, a recent study from the U.K. (19) reported no significant decrease in the rates of total, major, and minor amputations in individuals with diabetes (27.5 to 25.0/10,000) from 2004 to 2008; however, methodological differences prevent direct comparisons. In contrast to our study, these other studies did not adjust for denominator effects and did include repeat amputations. However, our finding of a 36% decline in initial major amputations over a 5-year period is consistent with findings of a 48.8% decrease (94.4 to 48.3/10,000) in the incidence of the first major amputation within a 10-year period (1997–2007) from a national registry of Finnish individuals with diabetes (20).

In the late 1990s, the VHA implemented a national program of foot risk screening and referral, conducted largely in primary care (21). As determined from medical record reviews, 95% of veterans had a visual examination, 84% had palpation of pulses, and 78% had undergone a sensory examination by 1998. In addition, ~83% of patients had a monofilament examination, and 85% of individuals with risk factors were referred to foot specialists in 2004 (13). We are unable to ascertain whether veterans at higher risk for lower extremity complications received subsequent preventive foot care, such as education or prescription of therapeutic shoes, in the VHA or in the private sector. Nonetheless, our findings suggest that implementation of a universal program of foot screening, tracked through performance measures, may have contributed to a decrease in LEAs.

This study has several strengths. Our findings extend prior studies by addressing the denominator effect through risk adjustment of selected important risk factors of LEA. We used individual-level data to ascertain risk factors and other population variables and included them in statistical models for risk adjustment to minimize possible biases resulting from differences in these factors. The individual-level data also allowed us to determine the maximal amputation level (major vs. minor) per episode when a patient underwent multiple amputations and hence allowed for accurate estimates of total and type-specific amputations. The availability of longitudinal data allowed us to distinguish initial from repeat amputations. Furthermore, the simultaneous evaluation of trends in major and minor amputation rates provided important additional information beyond total amputation rates alone.

We also note several limitations. There is undercoding of key risk factors for LEAs, such as insensate foot (neuropathy) and identification of chronic kidney disease (23). Mental health functioning may be a risk factor for amputation (24) but cannot be ascertained from administrative databases. In addition, because most veterans are dually enrolled in Medicare (~75% in each year), the results cannot be ascribed completely to care provided within the VHA system. However, these are limitations common to analyses of administrative data (4,5,19,20).

In conclusion, downward 5-year trends in initial amputation rates among veterans with diabetes were observed for all types of LEA and among all racial groups, even after adjustment for possible differences in risk of the patient population. Our study demonstrates the value of using multiple sources of individual-level data to facilitate *1)* the derivation of risk factors of outcomes and *2)* the evaluation of possible factors contributing to the denominator effects. Such information can inform public health efforts (Healthy People 2020) to understand trends in amputation rates over the next decade (25).

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