Economic Disease Burden of Diabetic Foot Ulcers in End-Stage Renal Patients

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Introduction

- Diabetes is the leading cause of end-stage renal disease (ESRD) in the United States and elsewhere around the world.[1]
- The risk of diabetic complications, including diabetic foot ulcers (DFU) and lower extremity amputations increases when patients have chronic kidney disease (CKD).[2-4]
- Diabetic patients with ESRD have a 10-fold increase in lower extremity amputations over diabetic patients without ESRD.[5]

Objective

This study evaluates the burden of DFU through a retrospective analysis of new onset DFU among diabetic patients with ESRD in a claims-based analysis.

Methods

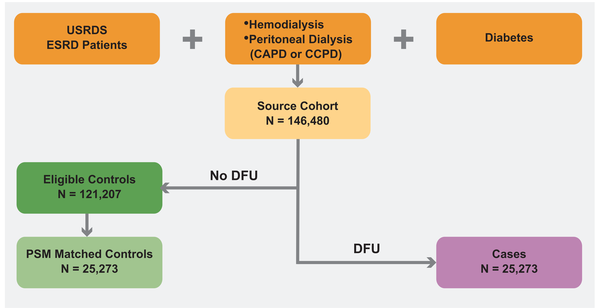
Population

- Patients were included in this study based on the schema shown in Figure 1.

Time Periods

- Case patients were those whose DFU diagnosis preceded 01 April 2009 (prevalent case patients): index date of 01 April 2009.
- Case patients who developed DFU after 01 April 2009 commenced study time on the date of DFU diagnosis. For eligible controls, a random, arbitrary index date was assigned from all possible patient start months (pre-randomization of start month) to match the observed distribution in case patients.
- Patients continued to contribute study data until the earliest of death, dialysis discontinuation, change in insurance status to other than Medicare Part A and Part B primary, end of study (31 December 2010).

Figure 1. Study Schema



Analysis

- A propensity score match technique was applied to all possible controls. DFU status was the dependent variable and was predicted on the basis of all the confounder variables.
- Part A and B claims were converted to 2010 fixed dollars through the conversion provided by the US Consumer Price Index inflation adjustment for 2009 claims.[6]
- Generalized linear mixed models were calculated assuming a log normal distribution due to the right-skewed nature of all outcomes. Outcomes were fit using the Proc Glimmix procedure in SAS version 9.3. Each model contained fixed effects terms of sequential time (month), and an indicator for DFU case-control status was included with random effects term for subject (USRDS_ID). A first-order autoregressive correlation structure accounted for the repeated measure design. Point estimates and confidence intervals were generated and then converted to the original scale for ease of interpretation. Models were segmented by case prevalence versus incidence category—whereby the PSM-matched controls represented those individuals who were matched in the PSM match.

Results

Table 1. Comparison of DFU Patients to Matched Controls

	Matched controls	Diabetic foot ulcer cases (N = 25,273)	Std Diff (N = 25,273)
Age (y); mean + SD	63.7 + 12.4	63.6 + 12.3	-0.7%
Female sex	43.2%	43.3%	0.1%
Race			
White	60.0%	60.0%	0.1%
Black	33.9%	33.6%	0.0%
Hispanic	3.8%	4.0%	0.7%
Other/unknown	2.3%	2.4%	0.2%
Modality/access			
HD	94.8%	94.6%	-0.8%
PD	5.2%	5.4%	0.8%
Dry weight (kg)	88.9 + 23.7	89.2 + 23.8	1.0%
Heart failure	36.9%	36.8%	-0.2%
Atherosclerotic heart disease	25.5%	25.4%	0.1%
Other cardiac disease	NA	NA	NA
Cerebrovascular disease	9.0%	9.3%	1.0%
Peripheral vascular disease	19.7%	20.2%	0.6%
Hypertension	86.5%	86.4 %	-0.2%
Amputation	NA	NA	NA
COPD	5.9%	6.4%	1.7%
Malignancy	2.9%	3.2%	1.3%
Alcohol dependence	0.6%	0.9%	2.2%
Drug dependence	0.5%	0.7%	2.0%
Inability to ambulate	4.5%	5.1%	2.3%
Inability to transfer	1.5%	1.7%	1.7%
Needs assistance with daily activities	NA	NA	NA
Institutionalization	NA	NA	NA

Abbreviations: HD, hemodialysis; PD, peritoneal dialysis; COPD, chronic obstructive pulmonary disease; Std diff, standardized difference.

Figure 2. Overall Comparison of ESA Utilization Between Diabetic Foot Ulcer Patients and Matched Controls

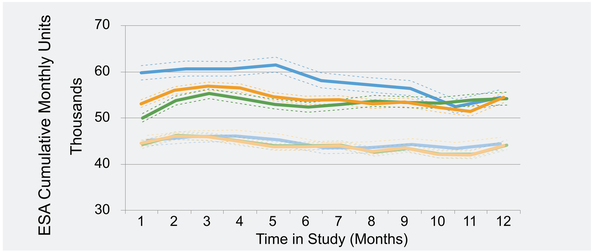


Figure 3. Comparison of Inpatient Costs Between Diabetic Foot Ulcer Patients and Matched Controls

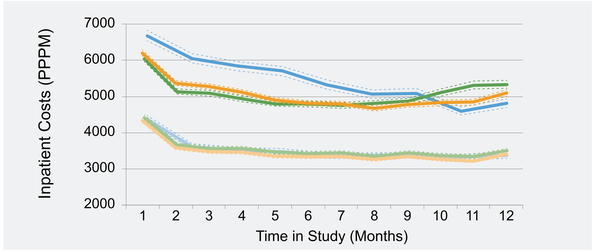
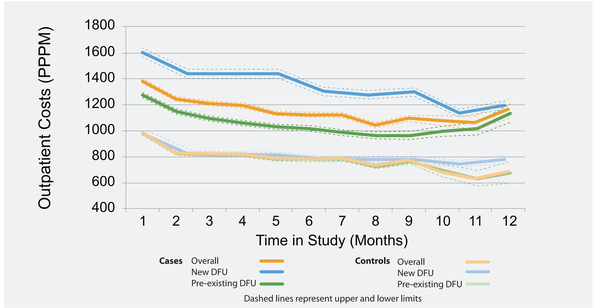


Figure 4. Comparison of Outpatient Costs Between Diabetic Foot Ulcer Patients and Matched Controls



Discussion

- After PSM, controls and case population were similar with regard to age, sex, race, weight, comorbidity burden, modality/access, alcohol and drug dependence, and inability to ambulate or to transfer.
- Overall ESRD patients with DFU used more ESA (51,416 versus 56,977 units/month), had higher inpatient costs (range $4,668 versus $6,209 USD/month), and higher outpatient costs ($1,046 versus $1,384 USD/month).
- Stratified analysis of new DFU and pre-existing DFU patients compared with controls showed similar trends; new DFU patients had the highest ESA usage (52,282 to 61,286 units/month), the highest inpatient costs ($4,572 to $6,661 USD/month), and the highest outpatient costs ($1,138 to $1,601 USD/month). Consistent differences were seen between patients with and those without DFU.

Conclusions

For diabetic ESRD patients, DFU is potently and independently associated with greater ESA utilization and inpatient and outpatient health care costs. Trials are warranted to assess whether targeted therapies may reduce health economic burden.

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