Does rapid diffusion of HbA1c testing affect amputation rates?

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Abstract

Background—The association of speed of diffusion of HbA1c testing with temporal changes in outcomes of primary importance to patients with diabetes, such as amputation, remains an issue of debate. We investigated these correlations

Methods—We performed a retrospective cohort study of diabetics, based on Medicare fee-for-service claims data from 2002–2012. We examined the association of the rate of diffusion of HbA1c testing with changes in amputation rates. Our unit of analysis was the hospital referral region, a definition of tertiary care markets defined in the Dartmouth Atlas of Health Care.

Results—From the 11,096,270 diabetics followed in our study for a mean follow up of 4.1 years, 106,340 (0.23%) underwent lower extremity amputations. The speed of diffusion of HbA1c testing had a moderate association with the speed of diffusion of lower extremity amputations, after adjusting for multiple factors including baseline regional amputation and testing rates (adjusted difference –0.7%; 95% CI, –1.0% to –0.3%). The risk-adjusted HRR-level speed of diffusion of testing demonstrated significant correlation with the risk-adjusted HRR-level diffusion of amputations ($r=0.250$, $P<0.001$).

Conclusions—We observed a moderate association of the speed of diffusion of HbA1c testing with the speed of diffusion of lower extremity amputations among Medicare patients with diabetes. Improvements in performance in quality metrics such as HbA1c testing may not immediately translate into tangible patient outcomes.

Keywords

diabetes; HbA1c testing; lower extremity amputation; temporal diffusion patterns; Medicare

INTRODUCTION

Diabetes affects 11.8 million Americans over the age of 65 and is a major contributor to mortality and debilitating morbidity.^{1–3} Overall, the rate of complications related to diabetes has decreased in recent years, after prioritizing the treatment of this disease as a public

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health problem.^{2,4–12} Long-term glycemic control, as evidenced by HbA1c testing, was cited as a key metric in minimizing the complications and cost of care for diabetics.^{13–16}

In establishing these guidelines, many argued that better adherence to diabetic testing recommendations was an underlying factor that led to fewer diabetes-related complications, such as amputation.^{2,6,13} Testing this hypothesis directly is difficult. Many regions adopted HgA1c recommendations rapidly, while other parts of the United States were less ideally prepared for this process. Differences across settings in the speed of diffusion of HbA1c testing offer an opportunity for a “natural experiment”. In these experiments, associations between the rate of adoption of diabetic testing and complications such as amputation can be studied.

We hypothesized that differences in the speed of diffusion of an effective intervention such as HbA1c testing might explain the variation seen in diabetic related complications, such as amputations. Even if testing is not by itself causal, it is likely a proxy for a healthcare system responsive to evidence favoring prevention. To test this hypothesis, we performed a longitudinal cohort study of fee-for-service Medicare beneficiaries diagnosed with diabetes. We demonstrated temporal and regional trends in the diffusion of HbA1c testing, and investigated their association with the speed of diffusion of lower extremity amputations among diabetics.

METHODS

Cohort creation

After approval by the Dartmouth Committee for Protection of Human subjects, we used all data from a 100% sample from 2005–2012, and a 20% sample from 2002–2004 of Medicare beneficiaries enrolled in fee-for-service programs or non-risk bearing health maintenance organizations. We identified diabetics by a definition of diabetes used before in the literature.^{17–19} For that purpose, we used all inpatient, and outpatient facility claims, as well as Carrier (MD and other professionals) claims. The Carrier and outpatient claims are restricted to specific visit claims. A person is identified as diabetic if they have at least 1 inpatient diagnosis or 2 claims from physician contact on 2 different days (separated by 7 days).

Primary outcome

The primary outcome variable was the occurrence of a major above or below-knee amputation. Amputation events were defined based on methodology used in prior literature.^{17–19} Forefoot or minor amputation were examined, but not included in our main analysis. In sensitivity analyses where they were included, this did not change our findings significantly.

We used the Hospital Referral Region (HRR) as the geographic region of interest for the regional analyses.^{19,20} The Dartmouth Atlas of Health Care identifies 306 such regions. An HRR is a region served by a hospital or group of hospitals that offers cardiovascular and neurosurgical procedures, so that each HRR includes at least one tertiary care hospital. All

ZIP codes in the United States were assigned to HRR on the basis of the migration patterns of hospital use among the elderly population.

Exposure variables

Our main exposure variable was the use of HbA1c testing. HbA1c testing was identified based on methodology described in prior literature.^{17–19} We studied HbA1c testing aggregated by hospital referral regions.

Several regional level variables were used as covariates. A county level variable for health status, obesity, and smoking was created based on the Behavioral Risk Factor Surveillance System (BRFSS) database by the Centers for Disease Control and Prevention (CDC). These were weighted and transformed to HRR level regional variables. Additionally, we used multiple patient level covariates. Sex-age categories (<65 years, 65–69, 70–74, 75–79, 80–84, 85–99) were created, as well as three ethnicity and race categories (black, Hispanic, with white being the reference). The enrollee's ZIP code was used to match the 2010 Census data on income and poverty, which in turn was used to calculate the mean income in each HRR. The lagged Charlson Comorbidity Score (CCS) was used to adjust for the patient's general health status. A one-year look-back period was used to determine the patient's comorbidity burden. Finally, we used indicator variables for disability, and dual-eligibility for Medicaid and Medicare.

Statistical analysis

The analysis was performed at the regional (HRR) claims level. For this analysis, we investigated the association of the annual change in amputation rate with the annual change in HbA1c testing rate, using a multiple linear regression analysis. We used the following HRR level covariates for adjustment: regional percentage of racial categories, regional health status, regional percentage smoking, lagged (baseline) amputation rate, and regional rate of disability and poverty, regional Charlson Comorbidity Score, and median regional income. In sensitivity analysis, we repeated this model substituting lagged amputation rate with lagged HbA1c testing. The associations identified did not change, and therefore these results are not reported further.

The level of statistical significance was set at $P < 0.05$ and all analyses are based on two sided tests. SAS 9.4 (SAS Institute, Cary, North Carolina), and Stata 13 (StataCorp, College Station, TX) were used for the analysis.

RESULTS

Patient characteristics

From the 11,096,270 diabetics followed during the study period, 106,340 (0.23%) underwent amputation. The baseline characteristics of our cohort in several time periods can be seen in Table 1. Most patient characteristics remained stable overtime, with a slight increase in disability and the overall comorbidity burden.

Diffusion of hemoglobin A1c testing and amputation

There was significant variation across the United States in the speed of diffusion of HbA1c testing, with a generally increasing temporal trend. Differences in baseline HRR rates were more pronounced at the beginning of the study. Figure 1 demonstrates a map of the HRR-level speed of diffusion of HbA1c testing across the United States. Most dramatic increases were observed in HRR of the South, which started from lower baseline. Amputation rates demonstrated a steady decline at the same time. Figure 2 demonstrates a map of the HRR-level speed of diffusion of amputations across the United States. The West, the Midwest, and the Northeast showed the largest decreases in amputation rates.

Multivariable analysis

When adjusting for multiple factors in multivariable models, the speed of diffusion of HbA1c testing had a moderate association with decreased rates of lower extremity amputations (adjusted difference -0.7% ; 95% CI, -1.0% to -0.3%). Additionally, increasing population of obese patients at the HRR level was associated with increased rates of amputations (adjusted difference 0.5% ; 95% CI, 0.04% to 0.5%), whereas increasing healthy days at the HRR level were associated with decreased rates of amputations (adjusted difference -4.7% ; 95% CI, -8.0% to -1.4%). The risk-adjusted HRR-level speed of diffusion of testing demonstrated (Figure 3) significant correlation with the risk-adjusted HRR-level speed of diffusion of amputations ($r=0.250$, $P<0.001$).

DISCUSSION

In this observational study, we demonstrated that increasing speed of diffusion of HbA1c testing had a moderate association with temporal trends in regional amputation rates among diabetics covered by Medicare. Although, long-term glycemic control has been associated with lower rates of diabetic complications,^{13–16} testing for HbA1c does not necessarily reflect that appropriate steps are taken by local health systems or patients for risk-factor modification, and improved outcomes. In the context of standardizing evidence-based interventions (such as HbA1c testing), quality of providers is frequently judged based on their responsiveness to national recommendations.^{7,9,11,14} The translation of satisfying these metrics to tangible patient outcomes remains an issue of debate.

Our analysis demonstrates that, in response to national guidelines and benchmarking, there has been an accelerated diffusion in HbA1c testing. However, the baseline testing rates of most regions dictates the speed of future diffusion. In particular, regions with the highest baseline utilization had slower diffusion of additional testing (due to the limited margin for improvement). The impact on amputations of small adjustments in these already well-organized systems was, as expected, small. Systems that demonstrated more rapid diffusion of testing rates, started from a lower initial point, and likely had overall inferior organizational and operational characteristics in comparison to their counterparts. Achieving quality metrics, such as HbA1c testing, in an expedited fashion might not have an effect on outcomes if not associated with downstream interventions.

The moderate association of diffusion of testing with changes in amputation rates may be indicative of inefficiencies in the healthcare delivery systems. Prior reports have highlighted the lack of association of the volume and cost of diagnostic and therapeutic interventions with patient outcomes.^{21,22} Our study provides limited guidance on the potential impact of reducing regional disparities in utilization. From a clinical perspective, it is important to recognize that this analysis does not address the question of how the amount of care for an individual patient in a specific case would affect the patient's clinical outcome. From a policy perspective, our study does not indicate whether it is possible to reduce overutilization and spending without affecting patient outcomes. However, if the United States as a whole could safely achieve outcomes similar to the most efficient regions, significant savings could be achieved. Further research in that direction is needed.

The present study has several limitations. First, residual confounding could account for some of the observed associations. Second, coding inaccuracies can affect our estimates. We used validated definitions of diabetes and testing to maximize our sensitivity. Claims for amputations, as well as other procedures, are generally accurate since they are directly associated with reimbursement. Third, our data is based on the Medicare population, with potentially different results for the commercially insured. Fourth, we cannot control perfectly for the severity of diabetes, since claims do not provide detailed vascular history (i.e. claudication, prior ulcer), the use of insulin, or the level of HbA1c. However, we used CCS as an indicator of general comorbidity burden, and several independent county levels indicators of health status (i.e. healthy days). Finally, causality cannot easily be established based on ecologic data.

Conclusions

There is wide regional variation in the rates of HbA1c testing and lower extremity amputations among diabetics. We examined the association of their temporal diffusion patterns. We demonstrated that increasing diffusion of HbA1c testing was associated with decreasing annual change in amputation rates at the HRR level, but the effect was small. Changes in healthcare delivery are necessary to translate performance in quality metrics to tangible patient outcomes.

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Figure 1. HRR level U.S. map demonstrating the percent rate of diffusion of HbA1c testing among diabetics. Differences presented reflect changes between the years 2002 to 2005 and 2010 to 2012.

Figure 2.
HRR level U.S. map demonstrating the percent rate of diffusion of major leg amputations among diabetics. Differences presented reflect changes between the years 2002 to 2005 and 2010 to 2012.

Figure 3. HRR level bubble plot demonstrating the correlation of change in amputation rate and change in HbA1c testing. ($r=0.250$, $P<0.001$) The size of each bubble represents the number of observations in the corresponding HRR.

Patient characteristics

Table 1

	TOTAL	2000–2005	2006–2009	2009–2012	P-value
N, %	45,380,336 (100.0)	4,045,753 (8.9)	22,556,461 (49.7)	18,778,122 (41.4)	
Age, SD	75.4 (7.2)	75.2 (6.9)	75.4 (7.1)	75.5 (7.3)	<0.0001
% African American	11.5	12.2	11.4	11.6	<0.0001
% Hispanic	2.4	2.4	2.3	2.4	<0.0001
% Female	54.9	56.4	55.2	54.3	<0.0001
% Disabled	12.8	11.7	12.3	13.6	<0.0001
% Medicaid	20.0	20.2	19.7	20.3	<0.0001
% <150% poverty	23.56	24.32	23.60	23.35	<0.0001
Charlson Comorbidity score, mean (SD)	1.63 (2.2)	1.51 (2.1)	1.62 (2.2)	1.68 (2.2)	<0.0001
% CHF	17.1	19.3	17.4	16.4	<0.0001
% Renal disease	13.6	6.6	12.8	16.0	<0.0001
% Cerebrovascular disease	8.5	8.9	8.4	8.4	<0.0001
% Dementia	5.4	5.1	5.4	5.4	<0.0001
N unhealthy days, SD	1.75 (1.0)	1.58 (1.0)	1.76 (1.0)	1.77 (1.0)	<0.0001
% Adults BMI>30	20.11	18.33	20.26	20.32	<0.0001
% Smoking	81.83	80.70	81.77	82.15	<0.0001
Median income (IQR), \$	53,983 (20,915)	52,539 (20,281)	53,840 (20,823)	54,466 (21,141)	<0.0001
% Leg amputation	0.234	0.370	0.242	0.197	<0.0001
% AIC current year	80.3	76.2	80.1	81.3	<0.0001