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High-Deductible Insurance and Delay in Care for the Macrovascular Complications of Diabetes

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Background: Little is known about the long-term effects of high-deductible insurance on care for chronic medical conditions.

Objective: To determine whether a transition from low-deductible to high-deductible insurance is associated with delayed medical care for macrovascular complications of diabetes.

Design: Observational longitudinal comparison of matched groups.

Setting: A large national health insurer during 2003 to 2012.

Participants: The intervention group comprised 33 957 persons with diabetes who were continuously enrolled in low-deductible (≤$500) insurance plans during a baseline year followed by up to 4 years in high-deductible (≥$1000) plans. The control group included 294 942 persons with diabetes who were enrolled in low-deductible plans contemporaneously with matched intervention group members.

Intervention: Employer-mandated transition to a high-deductible plan.

Measurements: The number of months it took for persons in each study group to seek care for their first major macrovascular symptom, have their first major diagnostic test for macrovascular disease, and have their first major procedure-based treatment was determined. Between-group differences in time to reach a midpoint event rate were then calculated.

Results: No baseline differences were found between groups. During follow-up, the delay for the high-deductible group was 1.5 months (95% CI, 0.8 to 2.3 months) for seeking care for the first major symptom, 1.9 months (CI, 1.4 to 2.3 months) for the first diagnostic test, and 3.1 months (CI, 0.5 to 5.8 months) for the first procedure-based treatment.

Limitation: Health outcomes were not examined.

Conclusion: Among persons with diabetes, mandated enrollment in a high-deductible insurance plan was associated with delays in seeking care for the first major symptoms of macrovascular disease, the first diagnostic test, and the first procedure-based treatment.

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Patients with diabetes are at risk for macrovascular disease, including coronary heart disease, cerebrovascular disease, and peripheral artery disease (1–5). Macrovascular disease causes 70% of deaths and can profoundly affect patient well-being (6–17). Access to primary care, acute care, diagnostic tests, preventive medications, and advanced interventions can help prevent or delay macrovascular complications, such as myocardial infarction, stroke, and amputation (3, 18–26).

The RAND Health Insurance Experiment (27) and a study of a single employer (28) found that high levels of cost sharing reduce use of many health services, but other studies have found that such reductions do not occur in all clinical situations (27, 29–32) or subgroups of people (27, 31, 32). High-deductible plans, which require potential out-of-pocket spending of approximately $1000 to $7000 per person per year for most nonpreventive care, have become an increasingly common feature of U.S. commercial health insurance. In 2018, 58% of workers with individual plans had deductibles of $1000 or more, and 26% had deductibles of $2000 or more (33).

Recent research has found that low-income (but not high-income) patients with diabetes in high-deductible health insurance plans have short-term increases in emergency department visits for acute complications of diabetes (32) and high-severity conditions (31). We hypothesized that patients with diabetes might also experience changes over a longer period after an employer-mandated switch from a low-deductible to a high-deductible plan.

Methods

Study Population

Our study population comprised commercially insured persons in the Optum database who were enrolled between 1 January 2003 and 31 December 2012. This database includes enrollment information and all medical, pharmacy, and hospitalization claims for approximately 43 million members of 1 large national health insurance plan. We included only members with employer-sponsored insurance; we excluded those with individually purchased insurance because of concerns about selection.

We considered an insurance plan to have a low deductible if the annual amount was $500 or less and a

See also:

Editorial comment 1
Summary for Patients 2

Web-Only
Supplement

high deductible if the annual amount was $1000 or more. For smaller employers, we determined the deductible from a benefits table obtained from the health insurer. This table mostly included employers with fewer than 100 employees but also included a modest number of larger employers. For employers not represented in the benefits table (mostly large employers), we used an algorithm with a sensitivity and specificity greater than 96% to impute deductible amounts from actual out-of-pocket spending by persons who used health services (**Table 1** of the **Supplement**, available at Annals.org).

Persons in this study were not able to choose a low- versus a high-deductible plan because each employer provided only 1 level of deductible each year. Some employers offered a low-deductible plan throughout the study, and others that offered a low-deductible plan early in the study switched to a high-deductible plan for the rest of the study.

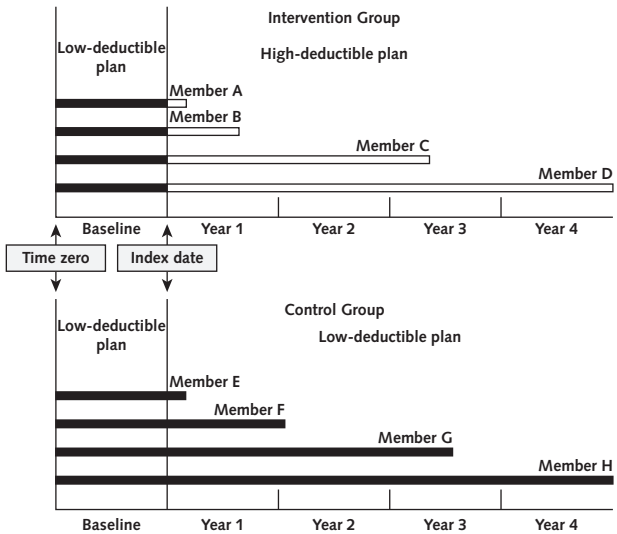
We defined the index date for employers who switched to high-deductible plans as the first day of the month when the switch occurred. We defined the index date for employers who did not switch plans as the first day of the month when their yearly account was renewed. If an employer had multiple potential index dates (for example, 5 continuous years with a low-deductible plan or 4 years with a low-deductible plan followed by 1 year with a high-deductible plan), we randomly selected 1 index date. Persons entered the study at different times because their employers had different index dates. Therefore, for each person, we defined "time zero" as 12 months before the employer's index date and treated the interval between time zero and the index date as the baseline period. We used the employer's index date as the beginning of follow-up (**Figure 1**). For each person, we measured the number of months from time zero to the first outcome measure in the baseline period and from the index date to the first outcome measure during follow-up.

A person was eligible for the study if their employer was present in the database for at least 1 year before and 1 year after the index date (20 344 218 persons from 192 458 employers [**Figure 1** of the **Supplement**]), they were aged 12 to 64 years and met criteria for diabetes (**Table 2** of the **Supplement**) (716 715 persons from 61 099 employers), their first diabetes diagnosis occurred before the index date (486 208 persons from 51 585 employers), and they were continuously enrolled for at least 1 year before and 1 month after the index date (353 337 persons from 44 457 employers). These criteria yielded 34 744 persons among 11 808 employers who switched to high-deductible plans and 318 593 persons among 32 431 employers who kept low-deductible plans (**Table 1**).

Study Design

We conducted an observational, longitudinal, before–after study by comparing matched groups. Longitudinal study designs are less subject to bias than cross-sectional designs (34). The intervention group comprised persons who were in low-deductible insurance plans for 1 year and then were switched to high-deductible plans for an additional 1 month to 4 years. The control group consisted of matched persons who remained in low-deductible plans throughout the study (**Figure 1**). We matched participants on the propensity of the employer to mandate high-deductible insurance and the propensity of persons to work for such employers (divided into tertiles) (35, 36) (section I.c. of the **Supplement**), employer size (0 to 99, 100 to 999, or ≥1000 employees), baseline tertile of mean out-of-pocket expenditure per person at the employer, mean out-of-pocket expenditures per person at baseline ($0 to $500, $501 to $999, $1000 to $2499, or ≥$2500), months of follow-up, and presence of a study outcome at baseline.

Figure 1. Study design showing example members of the intervention group (*top*) and the matched control group (*bottom*).



We used coarsened exact matching to match participants (37–39) (sections I.d. and I.e. of the **Supplement**), which is similar to exact matching but differs in that it uses categories instead of exact values (for example, 5-year age groups rather than age in years). The software for this type of matching creates weights for each stratum that adjust for differences between study groups in the proportion of persons in the stratum.

Our final study groups were an intervention group of 33 957 persons from 11 575 employers matched with a control group of 294 942 persons from 31 443 employers (**Table 1**).

Person-Level Outcome Measures

Our principal outcome measures were the differences between groups in the time to the first major symptom, the first major diagnostic test, and the first procedure-based treatment for aggregated coronary heart disease, cerebrovascular disease, and peripheral artery disease (**Tables 3** and **4** of the **Supplement**). We

also analyzed 9 secondary measures that disaggregated the primary measures by disease type. The "major symptoms" measure was intended to include conditions that represent recognizable macrovascular disease at a stage where intervention can prevent subsequent major complications and that patients can identify themselves so that they can decide whether to delay care. We did not include myocardial infarction, stroke, and amputation in this measure because patients have much less discretion in decisions to present for care.

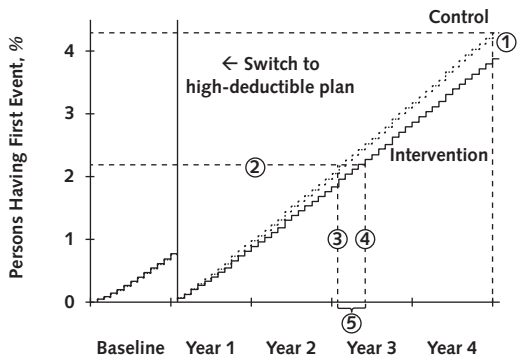
We defined major symptoms as angina and acute and subacute forms of ischemic heart disease for coronary heart disease; transient ischemic attack for cerebrovascular disease; and intermittent claudication, resting ischemic pain, extremity thrombosis or embolism, lower-limb ulcer, cellulitis, extremity abscess, and acute osteomyelitis for peripheral artery disease. Major diagnostic tests were defined as electrocardiographic exercise tolerance test, stress echocardiography, cardiac angiography, cardiac perfusion imaging, computed to-

Table 1. Baseline Characteristics of the Intervention and Control Groups Before and After Coarsened Exact Matching*

Characteristic	Before Coarsened Exact Matching			After Coarsened Exact Matching†		
	Intervention Group	Control Group	Standardized Difference‡	Intervention Group	Control Group	Standardized Difference‡
Participants (employers), *n*	34 744 (11 808)	318 593 (32 431)	–	33 957 (11 575)	294 942 (31 443)	–
Aged >40 y on index date, *n (%)*	29 003 (83.5)	262 292 (82.3)	0.0305	28 337 (83.4)	247 203 (83.8)	−0.0099
Mean age on index date (SD), *y*	49.4 (10.4)	49.5 (10.8)	−0.0072	49.4 (10.4)	49.7 (10.5)	−0.0340
Female, *n (%)*	15 788 (45.4)	148 934 (46.7)	−0.0262	15 472 (45.6)	133 738 (45.3)	0.0044
Participants, by neighborhood characteristics, *n (%)*						
Proportion of residents living below poverty level	–	–	0.0581	–	–	0.0321
<5.0%	12 815 (36.9)	125 658 (39.5)		12 511 (36.8)	111 440 (37.8)	
5.0%–9.9%	9204 (26.5)	83 780 (26.3)	–	8988 (26.5)	79 683 (27.0)	–
10.0%–19.9%	8240 (23.7)	70 419 (22.1)	–	8091 (23.8)	68 077 (23.1)	–
≥20.0%	4451 (12.8)	38 279 (12.0)	–	4367 (12.9)	35 741 (12.1)	–
Missing	34 (0)	457 (0)	–	–	–	–
Proportion of residents with less than high school education	–	–	0.0625	–	–	0.0313
<15.0%	16 468 (47.4)	160 559 (50.5)		16 085 (47.4)	144 052 (48.8)	
15.0%–24.9%	9122 (26.3)	80 536 (25.3)	–	8922 (26.3)	76 271 (25.9)	–
25.0%–39.9%	6573 (18.9)	55 571 (17.5)	–	6456 (19.0)	54 177 (18.4)	–
≥40.0%	2547 (7.3)	21 470 (6.7)	–	2494 (7.3)	20 442 (6.9)	–
Missing	34 (0)	457 (0)	–	–	–	–
Race/ethnicity, *n (%)*§	–	–	0.1014	–	–	0.0367
Hispanic	4165 (12.0)	38 892 (12.2)		4072 (12.0)	32 639 (11.1)	
Asian	839 (2.4)	11 373 (3.6)	–	802 (2.4)	6941 (2.4)	–
From black neighborhood	1151 (3.3)	12 463 (3.9)	–	1127 (3.3)	8812 (3.0)	–
From mixed neighborhood	5223 (15.1)	54 072 (17.0)	–	5090 (15.0)	44 086 (14.9)	–
From white neighborhood	23 311 (67.2)	201 179 (63.3)	–	22 866 (67.3)	202 463 (68.6)	–
Missing	55 (0)	614 (0)	–	–	–	–
Mean ACG score (SD)‖	1.9 (3.0)	2.0 (2.9)	−0.0023	1.9 (2.9)	2.0 (3.0)	−0.0307
U.S. region, *n (%)*	–	–	0.2225	–	–	0.0474
West	3159 (9.1)	36 685 (11.5)	–	3057 (9.0)	28 025 (9.5)	–
Midwest	11 797 (34.0)	96 879 (30.4)	–	11 530 (34.0)	98 468 (33.4)	–
South	17 205 (49.5)	142 275 (44.7)	–	16 878 (49.7)	149 909 (50.8)	–
Northeast	2571 (7.4)	42 571 (13.4)	–	2492 (7.3)	18 540 (6.3)	–
Missing	12 (0)	183 (0)	–	–	–	–
Participants, by employer characteristics, *n (%)*						
Number of employees	–	–	1.0751	–	–	0
0–99	13 907 (40.0)	44 136 (13.9)		13 388 (39.4)	116 285 (39.4)	
100–999	17 381 (50.0)	107 389 (33.7)	–	17 144 (50.5)	148 908 (50.5)	–
≥1000	3456 (9.9)	167 068 (52.4)	–	3425 (10.1)	29 749 (10.1)	–
Number of employees with diabetes	–	–	1.0774	–	–	0.1788
1–2	9009 (25.9)	26 506 (8.3)	–	8700 (25.6)	61 952 (21.0)	–
3–12	13 115 (37.7)	53 150 (16.7)	–	12 762 (37.6)	103 715 (35.2)	–
13–100	10 939 (31.5)	111 436 (35.0)	–	10 823 (31.9)	104 897 (35.6)	–
≥100	1681 (4.8)	127 501 (40.0)	–	1672 (4.9)	24 378 (8.3)	–

* Percentages may not sum to 100 due to rounding.
† The coarsened exact matching algorithm created 8160 matching strata, of which 3684 were matched between groups.
‡ Indicates the difference in means between the intervention and control groups divided by the SD of the difference in means. Lower values indicate greater similarity, and values <0.2 indicate minimal differences between groups.
§ See the Covariates section of the text for category definitions.
‖ A score of 1.0 represents the mean of the population in which the score was developed.

Figure 2. Steps in estimating the delay for the intervention group to reach half the final event rate of the control group during follow-up.



1. Determine control group's final event rate using a parametric regression survival time model with a Weibull distribution and marginal effects methods (e.g., 4.3%).
2. Calculate half this final event rate (2.2%).
3. Estimate time for the control group to reach this 2.2% event rate using same methods as in step 1.
4. Use the same approach to estimate time for the intervention group to reach this 2.2% event rate.
5. Use nonlinear combinations of estimators to determine the difference in months to reach the 2.2% event rate between the intervention and control groups (e.g., approximately 4 mo).

mography angiography of coronary vessels, and cardiac magnetic resonance imaging for coronary heart disease; brain and neck vessel angiography, brain imaging, and ambulatory cardiac monitoring and echocardiography (to detect atrial fibrillation and clot) for cerebrovascular disease; and magnetic resonance angiography, arteriography, and intravascular ultrasonography for peripheral artery disease. Finally, we defined procedure-based treatment as percutaneous coronary intervention and coronary artery bypass grafting for coronary heart disease; cerebrovascular endarterectomy and stenting for cerebrovascular disease; and peripheral artery angioplasty, stenting, endarterectomy, bypass, and thrombectomy for peripheral vascular disease.

Population-Level Outcome Measure

To estimate the difference between groups in the time to each outcome (Figure 2; section I.e. of the Supplement), we estimated the interval during follow-up between the index date and the date when the control group reached half its event rate at the end of follow-up, estimated the interval during follow-up between the index date and the date when the intervention group reached half the event rate that the control group achieved at the end of follow-up, and calculated the difference between these intervals. We believe this difference provides an intuitive measure of any delays that an average patient with diabetes in our sample might experience after a mandated switch to high-deductible insurance. We used the same approach to assess potential delays during the baseline year.

Covariates

We used version 10 of the Johns Hopkins ACG System (40, 41) to calculate participants' baseline morbidity score (section I.b. of the Supplement). We used block group data from the 2000 U.S. Census (42–44) to create categories (43, 45) defining neighborhoods with less than 5%, 5% to 9.9%, 10% to 19.9%, and at least 20% of residents living below the poverty level. Similarly, we defined categories of residence in neighborhoods with less than 15%, 15% to 24.9%, 25% to 39.9%, and at least 40% of residents having less than a high school education. We used geocoding to classify participants as from white, black, Hispanic, or mixed neighborhoods, and we classified participants as Hispanic or Asian using the E-Tech system (Ethnic Technologies), which analyzes full names and geographic locations of individuals (46). Other covariates included age (12 to 39 and 40 to 64 years), sex, U.S. region (West, Midwest, South, or Northeast), employer size (as a continuous variable or with categories of 0 to 99, 100 to 999, or ≥1000 employees) (section I.b. of the Supplement), number of employees with diabetes at each employer (1 or 2, 3 to 12, 13 to 100, or >100), calendar month of the first detected diabetes diagnosis, and calendar month of the index date.

Statistical Analysis

We compared characteristics of our study groups by using a standardized differences approach (47). A parametric regression survival time model with a Weibull distribution was used to estimate delays in care (48). For the baseline period, we modeled the interval between time zero and the first study outcome at the person level. We adjusted for age group, sex, race/ethnicity, category of number of employees per employer, and U.S. region. We used the same approach for the follow-up period to estimate the interval between the index date and the first study outcome at the person level. These models incorporated weights from the coarsened exact matching algorithm. For the baseline analyses, persons were censored when they reached the end of the baseline period. For the follow-up analyses, persons were censored if they left the sample (for example, because of disenrollment), reached age 65 years (when Medicare coverage begins), or reached the end of follow-up (4 years after the index date). The coefficient of interest from the baseline and follow-up regression models was a binary variable that indicated membership in the intervention group. The coefficient for this term was an adjusted hazard ratio indicating the independent association of high-deductible group membership with the outcome of interest. These hazard ratios were used to estimate baseline and follow-up delays (Figure 2; section I.e. of the Supplement). We applied a Bonferroni–Holm correction (49) that tested each effect estimate for 6 hypotheses with a desired α level of 0.05. We conducted a sensitivity analysis that used the same approach but included baseline and follow-up events in the same model and included an interaction term between study period (baseline vs. follow-up) and study group (high- vs. low-deductible

group) to determine whether adjustment for baseline differences between groups altered interpretation of the findings.

We also assessed whether a Cox proportional hazards model, which has fewer assumptions, would yield similar adjusted hazard ratios (section I.f. of the Supplement). Because the patients with diabetes in our study were nested within employers and employer effects on outcome measures might be important, we ran sensitivity analyses on a 1:1 matched sample that both included and excluded clustering of persons within employers when estimating SEs (section I.g. of the Supplement). We calculated the E-value (50) for our adjusted hazard ratios to determine the strength of the association of unmeasured factors that would be required to make the reported association between delay and switching to a high-deductible insurance plan either zero or nonsignificant. Finally, we performed a sensitivity analysis in which we did not match on employer- or person-level out-of-pocket spending categories.

Institutional Approval

This study was approved by the Harvard Pilgrim Health Care Institute Institutional Review Board.

Role of the Funding Source

This study was supported by grants R01-DK100304 and 1P30-DK092924 from the National Institute of Diabetes and Digestive and Kidney Diseases. The funding source had no role in the design, conduct, or reporting of the study.

RESULTS

After matching was done and matching-generated weights were applied, all standardized differences between the intervention and control groups at baseline were less than 0.2 (Table 1), indicating minimal differences (51). The mean age in both groups was approximately 50 years, and 45% of participants were female. Thirty-five percent to 37% lived in neighborhoods where at least 10% of residents lived below the poverty level, 25% to 26% lived in neighborhoods where at least 25% of residents had less than a high school education, and 11% to 12% were Hispanic.

Persons with high-deductible insurance plans had increases in out-of-pocket medical expenditures ranging from 43% (95% CI, 35% to 51%) to 53% (CI, 42% to 63%) per follow-up year versus baseline and relative to those in the control group (Figure 3; Table 5 of the Supplement).

During the baseline period, no statistically significant differences in time to any measure were observed between the intervention and control groups (Table 2 and Figure 4). During follow-up, however, the delay for the intervention group was 1.5 months (CI, 0.8 to 2.3 months) for seeking care for the first major macrovascular disease symptom, 1.9 months (CI, 1.4 to 2.3 months) for the first major diagnostic test, and 3.1 months (CI, 0.5 to 5.8 months) for the first procedure-based treatment. Estimates remained statistically significant after Bonferroni–Holm adjustment, except for time to the first procedure-based treatment, which had a corrected *P* value of 0.074 (Table 6 of the Supplement).

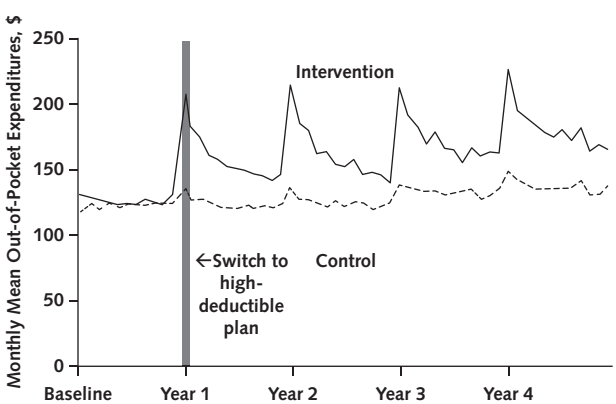
In analyses of secondary measures that were disaggregated by macrovascular disease type, adjusted hazard ratios for times to the first major symptom and the first diagnostic test had similar magnitudes and directions as the aggregated hazard ratios (Table 2; Figure 2 of the Supplement). In contrast, for the first procedure-based treatment, findings were not consistent when disaggregated by macrovascular disease type. The difference for the intervention group at follow-up was 3.9 months (CI, 1.2 to 6.7 months) for coronary heart disease but −0.7 month (CI, −7.6 to 6.2 months) for cerebrovascular disease and −0.5 month (CI, −5.3 to 4.2 months) for peripheral artery disease.

During follow-up, the adjusted hazard ratios were 0.94 (CI, 0.91 to 0.97) for seeking care for the first major symptom, 0.91 (CI, 0.90 to 0.93) for the first diagnostic test, and 0.91 (CI, 0.85 to 0.98) for the first procedure-based treatment. Table 7 of the Supplement shows hazard ratios disaggregated by macrovascular disease type. The E-values (and the limit of their CI closest to the null) were 1.32 (1.21) for seeking care for the first major symptom, 1.41 (1.35) for the first diagnostic test, and 1.51 (1.25) for the first procedure-based treatment of coronary heart disease.

The adjusted hazard ratios from Cox proportional hazards models and the corresponding E-values were nearly identical to those generated with our primary analytic approach (Tables 8 and 9 of the Supplement).

Results of sensitivity analyses that accounted for potential baseline differences in measures (Table 10 of the Supplement) were similar to results of the primary analysis. Comparison of 1:1 coarsened exact matching samples that did (Tables 11 and 13 of the Supplement)

Figure 3. Monthly mean out-of-pocket medical expenditures before and after the index date in the intervention and control groups.



Expenditures indicate the extent of the actual cost-sharing increase experienced by high-deductible health plan members. The intervention group experienced peaks at the beginning of each benefit year, which tapered as members exceeded their annual deductible. The vertical line is centered at the index month, when intervention group members were switched to high-deductible health plans.

Table 2. Estimated Intervals Between Time Zero or the Index Date and Achievement of Half the Respective Final Baseline or Follow-up Period Rate of Control Participants Among the Intervention and Control Groups

Event	Estimated Interval During Baseline Period (95% CI), *mo**			Estimated Interval During Follow-up (95% CI), *mo*†		
	Intervention Group	Control Group	Intervention vs. Control Group‡	Intervention Group	Control Group	Intervention vs. Control Group‡
First major symptom§	6.5 (6.2 to 6.8)	6.6 (6.4 to 6.8)	−0.1 (−0.3 to 0.2)	23.9 (22.9 to 24.9)	22.3 (21.7 to 23.0)	**1.5 (0.8 to 2.3)**
Coronary heart disease	8.1 (7.5 to 8.7)	8.1 (7.6 to 8.6)	0 (−0.4 to 0.5)	30.0 (27.8 to 32.2)	28.5 (26.9 to 30.1)	1.4 (−0.1 to 3.0)
Cerebrovascular disease	7.3 (6.4 to 8.3)	7.5 (6.8 to 8.3)	−0.2 (−0.9 to 0.5)	32.3 (28.4 to 36.1)	28.9 (26.3 to 31.5)	**3.4 (0.6 to 6.1)**
Peripheral artery disease	6.2 (5.9 to 6.6)	6.4 (6.1 to 6.6)	−0.1 (−0.4 to 0.2)	24.1 (22.8 to 25.4)	22.3 (21.5 to 23.1)	**1.8 (0.8 to 2.9)**
First diagnostic test§	6.4 (6.3 to 6.6)	6.5 (6.3 to 6.6)	0 (−0.2 to 0.1)	20.9 (20.4 to 21.5)	19.0 (18.7 to 19.4)	**1.9 (1.4 to 2.3)**
Coronary heart disease	7.3 (7.0 to 7.6)	7.3 (7.1 to 7.5)	0 (−0.2 to 0.2)	27.1 (26.1 to 28.1)	24.6 (24.0 to 25.3)	**2.5 (1.7 to 3.2)**
Cerebrovascular disease	6.5 (6.3 to 6.7)	6.6 (6.4 to 6.7)	−0.1 (−0.2 to 0.1)	22.2 (21.5 to 22.8)	20.5 (20.1 to 20.9)	**1.7 (1.1 to 2.2)**
Peripheral artery disease	7.8 (7.2 to 8.4)	7.6 (7.2 to 8.1)	0.1 (−0.3 to 0.6)	31.5 (29.3 to 33.6)	28.2 (26.7 to 29.6)	**3.3 (1.7 to 4.9)**
First procedure-based treatment§	10.2 (8.6 to 11.7)	10.3 (8.9 to 11.6)	−0.1 (−0.9 to 0.8)	37.6 (33.5 to 41.7)	34.5 (31.4 to 37.5)	**3.1 (0.5 to 5.8)‖**
Coronary heart disease	9.9 (8.4 to 11.5)	10.0 (8.6 to 11.3)	0 (−0.9 to 0.8)	37.1 (32.9 to 41.3)	33.1 (30.2 to 36.1)	**3.9 (1.2 to 6.7)**
Cerebrovascular disease	8.1 (4.8 to 11.3)	8.6 (5.8 to 11.3)	−0.5 (−2.7 to 1.8)	38.3 (26.5 to 50.2)	39.1 (28.7 to 49.4)	−0.7 (−7.6 to 6.2)
Peripheral artery disease¶	7.0 (5.0 to 9.0)	7.0 (5.5 to 8.5)	0 (−1.5 to 1.6)	26.4 (20.1 to 32.8)	27.0 (22.2 to 31.8)	−0.5 (−5.3 to 4.2)

* Defined as the interval between time zero and achievement of half the final baseline rate among control participants, estimated using a parametric regression survival time model with a Weibull distribution and adjusted for age group, sex, race/ethnicity, category of number of patients with diabetes per employer, and U.S. region.
† Defined as the interval between the index date and achievement of half the final follow-up rate of control participants, estimated using the same modeling approach as for baseline measures.
‡ Estimand of interest, reflecting the delay in the intervention group relative to the control group. Boldface values are statistically significant.
§ Primary measure; results are aggregated across coronary heart disease, cerebrovascular disease, and peripheral artery disease.
‖ Results did not remain statistically significant after application of the Bonferroni–Holm correction for 6 primary hypotheses in which the formula was as follows: (target α level [0.05])/(number of tests [6] − rank number of pair ranked by degree of significance − 1).
¶ Adjustment for peripheral artery disease treatment estimates did not include race or age group because of very low event rates among Asian persons, black persons, and members of the younger age group.

and did not (Tables 12 and 14 of the Supplement) account for employer-level clustering produced nearly identical results. Our sensitivity analysis in which we did not match on categories of baseline employer- or person-level out-of-pocket spending yielded adjusted effect estimates that were smaller than the primary results but were in the same direction (Tables 15 and 16 of the Supplement).

DISCUSSION

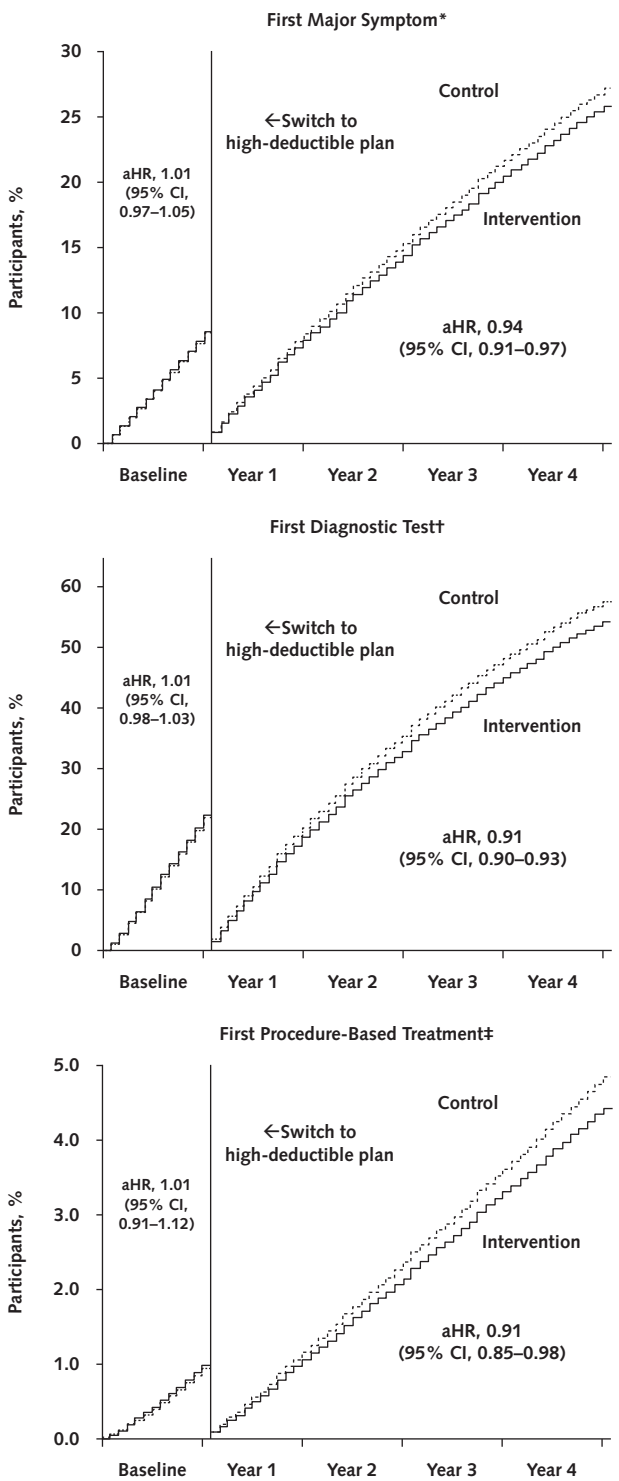
Patients with diabetes whose employers switched to high-deductible insurance plans had delays in seeking care for the first major symptoms of the macrovascular complications of diabetes, having their first major diagnostic test for such complications, and having their first procedure-based treatment compared with persons in the control group. These results suggest that patients with diabetes who are switched to high-deductible health plans are affected by the increased out-of-pocket costs they face for medical services. The delay in procedure-based treatments was driven by delays in coronary heart disease treatment, and we did not detect similar changes for cerebrovascular or peripheral artery disease.

Although our methods did not allow us to distinguish whether the changes we detected represent delays or ultimate reductions in the measures we studied, previous research (31, 32, 51) suggests that delays might be more likely. For example, a recent short-term study demonstrated that enrollment in high-deductible plans was associated with delayed outpatient visits for acute diabetes complications, a pattern that might have led to patients presenting to the emergency department with adverse health outcomes (32).

Our study indicates that these delays or reductions persisted over a relatively long follow-up and occurred even for services that are used for life-threatening conditions. These findings raise the possibility that patients in high-deductible plans present with more advanced disease; experience more adverse events, such as strokes, myocardial infarctions, and amputations; and have a higher death rate. However, previous research found that intermediate health end points were unchanged among persons with high cost sharing, raising the possibility that major adverse outcomes of macrovascular disease will be unchanged. For example, the RAND Health Insurance Experiment found generalized reductions in use of health services under high-level cost sharing but did not detect changes in cholesterol level and blood pressure in the overall population with high cost sharing (not a population with diabetes) (52).

We recommend that clinicians and care management teams monitor the type of insurance that patients with diabetes have and consider further outreach and education for those with high-deductible plans. Employers with high-deductible plans might also consider reduced cost sharing for patients with diabetes (53–55). Moreover, until the effects of high-deductible plans on long-term macrovascular complications of diabetes are better understood, policymakers and employers should remain cautious in encouraging uptake of such plans among vulnerable patients with diabetes, especially given

Figure 4. Weighted and adjusted time-to-event plots showing time to the first major macrovascular disease symptom (*top*), the first diagnostic test (*middle*), and the first procedure-based treatment (*bottom*) after a mandated switch to a high-deductible health plan compared with contemporaneous control group members who remained in low-deductible plans.



recent evidence of adverse short-term health outcomes (31, 32).

Future research about high-deductible insurance and macrovascular complications of diabetes should assess whether persons with high-deductible plans ultimately require more intensive work-ups and more advanced treatments. Studies should also measure the costs of diagnosis and treatment for macrovascular complications of diabetes and measure rates of clinically meaningful outcomes, such as stroke, myocardial infarction, amputation, and death. We were unable to measure these because our sample was too small for reliable detection of such infrequent events and because obtaining complete death data after 2011 is problematic given incomplete data from the Social Security Administration (56).

Our study included 3 key elements to minimize bias. First, it was restricted to employers that mandated a low- or high-deductible insurance plan and did not allow employees to choose. Second, we used matching to balance key employer characteristics given that employers self-select into insurance types. Finally, key individual-level characteristics within employer types were also balanced because these characteristics could influence outcome measures.

Our study also had limitations. We were unable to detect adverse clinical outcomes. The study was observational, and analyses were therefore at risk for the effects of unmeasured confounders (for example, the possibility that employers in the high-deductible group might have, at the same time as their insurance switch, changed workplace policies that made it more difficult for employees to leave work to get health care). E-value calculations indicated that unmeasured confounders with hazard ratios of approximately 1.3 to 1.5 could make our primary findings nonsignificant, but this was after matching and adjustment had controlled for some confounding. Because the duration of our baseline period was not comparable to the duration of follow-up,

Plots were derived from parametric regression survival time models with a Weibull distribution, with adjustment for age group, sex, race/ethnicity, number of patients with diabetes per employer, and U.S. region and using weights derived from the coarsened exact matching algorithm. The vertical line in each graph is centered at the index month, when intervention group members were switched to high-deductible plans. Symptom, diagnostic test, and procedure codes are shown in Table 4 of the Supplement. aHR = adjusted hazard ratio.

* Includes angina, acute and subacute forms of ischemic heart disease, transient ischemic attack, intermittent claudication, resting ischemic pain, extremity thrombosis or embolism, lower-limb ulcer, cellulitis, extremity abscess, and acute osteomyelitis.

† Includes electrocardiographic exercise tolerance test, stress echocardiography, cardiac angiography, cardiac perfusion imaging, computed tomography angiography of coronary vessels, cardiac magnetic resonance imaging, brain and neck vessel angiography, brain imaging, ambulatory cardiac monitoring, echocardiography, magnetic resonance angiography, arteriography, and intravascular ultrasonography.

‡ Includes percutaneous coronary intervention; coronary artery bypass grafting; cerebrovascular endarterectomy and stenting; and peripheral artery angioplasty, stenting, endarterectomy, bypass, and thrombectomy.

we were unable to make a valid comparison between delays in the baseline and follow-up periods in the intervention versus the control group. However, such a comparison of adjusted hazard ratios showed that our findings were similar when we adjusted for differences in measures at baseline. Although we knew the exact deductible level of most smaller employers, we had to impute this from claims for almost all large employers. However, we do not believe that this materially affected our results because of the high sensitivity and specificity of the imputation method (**Table 1** of the **Supplement**). We did not have access to some information about individual persons' health insurance expenses (such as premiums and health savings account balances). Our diagnostic testing measures were not always specific to the relevant macrovascular complication. Our analyses were unable to account for competing risks because of incomplete death data, the complexity of mapping all possible transition states, and the uncertainty that a given sequence of events was correctly constructed in claims data. Our findings are not generalizable to persons with uncommonly high deductibles, newly insured persons, or patients with newly diagnosed diabetes. Finally, our measures did not distinguish appropriate care from unnecessary care, and a proportion of the changes we detected could represent forgoing unnecessary or low-value services.

In conclusion, mandated enrollment in a high-deductible insurance plan among persons with diabetes was associated with delays in seeking care for the first major symptoms of macrovascular disease, the first diagnostic test, and the first procedure-based treatment over 4 years of follow-up.

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