Title

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Changes in medication use after dementia diagnosis in an observational cohort of diabetes patients

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Abstract

Background/objective—Clinical guidelines recommend avoidance of polypharmacy in patients with dementia. We assessed changes in medication use following a diagnosis of dementia among patients with type 2 diabetes.

Design—Difference-in-differences analysis of pre-post changes in the number of dispensed chronic medications, comparing patients with and without newly diagnosed dementia.

Setting—Integrated health care delivery system, Kaiser Permanente Northern California (KPNC).

Participants—Patients with type 2 diabetes, enrolled in a baseline survey, ≥50 years of age without prevalent dementia. During 5 years of follow-up, we identified 193 patients with a new diagnosis of dementia and used risk-set sampling to randomly select 5 reference subjects per case, matched on 5-year age categories and sex (965 matched patients). This resulted in an analytic sample of 1,158.

Measurements—The exposure was new diagnosis of dementia. Our primary outcome was the change in the number (count) of current chronic medications (total, cardiovascular (blood pressure and lipid control), and diabetes) at three time points: (a) pre-index date (one year prior to the index

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date); (b) index date (date of diagnosis of dementia or matched reference date); and (c) post-index date (up to one year subsequent to the index date).

Results—After adjustment, the overall number of chronic medications and the subset of cardiovascular medications declined following a dementia diagnosis and among age, sex, and time-matched reference individuals, but the decline was significantly greater among the dementia group (−0.71 medications compared to reference, $p<0.05$). The number of diabetes medications declined in both groups, but the declines were not statistically different (−0.18 medications compared to reference, $p<0.05$).

Conclusions—Patients and their providers reduced use of cardio-metabolic medications subsequent to a diagnosis of dementia as recommended in national guidelines.

Keywords

polypharmacy; dementia; diabetes

Introduction

Any chronic condition care management strategy must weigh the risks and benefits of treatment, but the optimal balance is dynamic and may shift with function, well-being, and health status. The goal of chronic disease management is typically to prevent long-term complications of a disease but, as life expectancy shortens, the opportunity for patients to realize the benefits of long-term use of medications diminishes. At the same time, polypharmacy and the associated risks of adverse events (e.g., falls[1]) may increase with age. For our oldest and sickest patients, clinicians may modify chronic condition care management strategies by discontinuing medications to reduce the risks of polypharmacy and de-emphasize prevention of long-term complications [2–4].

An excellent example of a clinical scenario where chronic disease management may require individualization is found in an older adult with diabetes and incident dementia. Both observational studies and clinical trials have demonstrated that for many older patients with diabetes, the harms of aggressive glycemic control in the short-term will outweigh the long-term benefits of preventing microvascular and cardiovascular complications.[1,2,5–7] Polypharmacy becomes a particular concern for older adults with incident dementia and comorbid diabetes. Administering medications may be a significant burden on caregivers and the diagnosis of dementia often necessitates a change in strategy with a reduction in the number of diabetes or cardiovascular medications used to prevent long-term complications. For over a decade, diabetes care guidelines for older adults have advised a de-intensification of treatment for patients with dementia, based on the changing balance of risks and benefits.[8–11]

Despite these guidelines, little is known about changes in medication use following a diagnosis of dementia in real-world, clinical practice. We evaluated changes in the number of medications dispensed for glycemic, blood pressure (BP) and lipid control before and after an incident diagnosis of dementia in a large cohort of older patients with diabetes, to determine whether medication simplification occurred as recommended.

Methods

Study Setting

The study design is based on a prospective follow-up of a large, multi-ethnic cohort of fully-insured, older patients with diabetes ("The Diabetes & Aging Study"). All study subjects received care from a large, non-profit, integrated health care delivery system, Kaiser Permanente Northern California (KPNC).[6] KPNC currently provides care to over 3 million health plan members (25–30% of the population of the San Francisco Bay and Sacramento metropolitan region of northern California). The membership is ethnically and socioeconomically similar to the overall population living in the geographical region.[12] KPNC provides care to a population through employer-based plans, Medicare, Medicaid and the new health insurance exchange. KPNC is not a fee-for-service or claims-based healthcare delivery system, but rather provides prepaid care that integrates all outpatient, inpatient, laboratory and pharmacy services. KPNC uses a state-of-the-art electronic medical record (EMR) that comprehensively captures data on all health plan members, including processes of care, inpatient and outpatient utilization, medical diagnoses, procedures and costs. The health plan maintains a "closed pharmacy system" (pharmacy benefits are only honored at health plan pharmacies) with comprehensive capture of pharmacy utilization for the 96% of members with pharmacy benefits, as well as identification of patients who transfer their prescriptions to out-of-plan pharmacies.[13,14]. This cohort has been described in detail previously.[15]

All subjects were identified in the *KPNC Diabetes Registry* ("Registry") using health plan data and a validated algorithm.[16] The Registry was first established in 1993 and is updated annually from automated databases of pharmacy data, laboratory data, hospitalization records, and outpatient diagnoses using standardized criteria.[15] The Registry has an estimated sensitivity of 99% based on chart review validation.[15] These data have been used previously to characterize the natural history of diabetic complications and mortality across a variety of sub-populations in numerous epidemiologic and health services investigations.[14,15,17–19]

Sample selection

Several of the variables we required for this analysis were not contained in EMR data (e.g., education); thus, we focused analysis on a cohort of 20,188 diabetes patients who responded to the DISTANCE Survey (184-item questionnaire conducted during May 2005 to January 2007).[20] We excluded 109 individuals who had unclear dementia status or evidence of prevalent dementia (previous dementia diagnoses based on codes listed below) and 978 with type 1 diabetes.[21]

During a 5-year follow-up starting with each subject's survey date, we identified incident cases of clinically-recognized dementia according to a validated method [22] using outpatient and inpatient reports of one or more ICD-9 CM diagnostic codes of uncomplicated senile dementia (290.0), Alzheimer's disease (331.01), vascular dementia (290.4), or dementia not otherwise specified (290.1). The date of the initial diagnosis of dementia was used as the index date. In this analytic cohort, we identified 193 patients with an incident diagnosis of

dementia (after excluding 47 who lacked continuous prescription medication benefits as part of their insurance coverage). We then used risk-set sampling to randomly select 965 reference patients by selecting 5 cohort members with no dementia diagnosis per each incident dementia case, group-matched on 5-year age categories and sex, all of whom had continuous prescription medication benefits. The index date (month/year) for each reference patient was the dementia diagnosis date of the matched exposed patient. This resulted in a total analytic sample of 1,158.

Outcome

Our primary outcome was the change in number (count) of current chronic medications at three time points: (a) the pre-index date, defined as one year prior to the index date; (b) the index date; and (c) the post-index date, defined as one year subsequent to the index date or end of follow-up if censored before one year. We used the same algorithm for counting medications as in our previous work among this population [23]; that is, for each point in time (i.e., pre-index, index, post-index), we identified every medication that was dispensed with ≥30-day supply within the prior 6 months based on outpatient pharmacy dispensing records

We categorized all medications by indications: dementia, cardiovascular (lipid-lowering and anti-hypertensive), diabetes, or other. A clinician researcher (U.S.) reviewed the list of prescribed medications to categorize them by class, using internal classification data. If a medication contained two different active ingredients, even if they were in different classes, we assigned each ingredient to its appropriate type and counted each as one medication in the total medication count--up to 3 active ingredients per prescribed medication. The categories were necessary because we hypothesized that clinicians might add medications to control dementia symptoms while discontinuing diabetes or cardiovascular medications, and a total count would mask these differences. The “other” category included antihistamines, aspirin, calcium, and magnesium, but in general we excluded medications that are not typically indicated for long-term use. Because we used prescription medication dispensing data, we did not capture over-the-counter medication use. For patients using multiple medications from the same general class of medications (e.g., diuretics), we counted each distinct medication within the class as an individual drug. Diabetes medications included insulin and oral hypoglycemic medications; cardiovascular medications included blood pressure and cholesterol management medications; and dementia medications included medications such as cholinesterase inhibitors (donepezil, galantamine, rivastigmine, tacrine), Memantine, Vitamin E, antipsychotics to treat behavioral disturbances associated with dementia, and antidepressants (since depression is common in patients with dementia, and some people use these to treat behavioral disturbances as well).

Covariates

We constructed a directed acyclic graph (DAG) depicting hypothesized causal relationships and temporal ordering between our exposure (diagnosis of dementia), outcome of interest (number of medications for chronic conditions), and related variables (see Appendix). We used established DAG rules for determining the subset of covariates needed to estimate the unbiased direct effect of incident dementia diagnosis on medication count and risk factor control.[24,25] Our final adjusted models included self-reported education, race and social

support, and clinical records for duration of diabetes, A1c, BP, LDL, BMI, counts of outpatient visits in the 12 months prior to index date, counts of hospitalizations in the 12 months prior to index date, SF-8 physical function score[26], and Charlson co-morbidity score in the calendar year of the pre-index date.[27–29] Because we matched on age and sex to identify the reference population, we did not adjust for these characteristics.

Analysis

We employed a difference-in-differences (DID) analytic framework based on a pre-post design with a reference group.[30–33] The reference group provides an estimate of the expected background change in the outcome which is then subtracted from the change observed in the incident dementia group to estimate a net causal effect. This conservative approach yields a DID estimate for the change in medication count or risk factor control associated with incident dementia diagnosis (the exposure) above and beyond the expected change in medication count or risk factor control due to factors such as secular trends, aging, or regression-to-the-mean.

For initial, unadjusted analyses of medication count outcomes (total and by medication category), we graphically examined differences in medication counts at each time point (Figure 1) and used paired t-tests between the first (i.e., pre-index) and last (i.e., post-index) time point to examine whether differences were significant. For adjusted analyses, we calculated the DID estimate using least-squares regression models, also examining the change between the first and last time points. Our models adjusted for pre-index number of medications as well as all covariates listed above (Table 2). We found very little clustering of patients by physician in the study sample, and so we did not account for physician clustering in our adjusted models (data not shown.)

Data preparation was performed using SAS software, version 9.3. All analyses were performed in Stata 12, including the *diff* package with bootstrapped confidence intervals for the DID models.

Results

The final cohort of 1,158 patients included 193 clinically-recognized, incident dementia cases. Because we matched on age and gender, these variables did not differ between cases and reference patients: 47% were female, and 75% were aged over 70 years (Table 1). Overall, 93% of patients had diabetes for ≥5 years, 50% had a high school diploma or less, and 76% were non-white (25% Asian, 19% black, 17% Latino). The only significant differences between the groups were that patients with incident dementia were more likely to have had a diabetes duration ≥ 20 years (33% vs 21%, p=0.001) and a higher mean Charlson score (3.4 vs 2.8, p=0.001) compared to reference patients.

The mean pre-index number of chronic medications used by patients who developed clinically recognized dementia was slightly more than among reference patients: 6.8 vs 6.3 medications, respectively (p=0.05, Figure 1). In the post-index period, the number of medications decreased in both groups, but this decrease was greater in dementia patients than in reference patients (a 1.3 and 0.5 reduction in the number of medications,

respectively, p=0.004). As expected, use of dementia medications increased in the participants diagnosed with dementia (data not shown). For the reference patients, the mean number of diabetes or cardiovascular medications did not change, but dementia patients experienced a decrease in numbers of both medication types. At pre-index, 983 (85%) were on one or more diabetes medications and 1098 (95%) were on one or more CV medications. At the post-index time point, 938 (81%) were on one or more diabetes m medications and 1063 (92%) were on one or more CV medications. There were no differences in the proportions using these medications by dementia diagnosis (P>0.05 for all.)

After adjusting for education, race, social support, duration of diabetes, pre-index A1c, BP, LDL, BMI, count of outpatient visits in the 12 months prior to index date, pre-index count of hospitalizations in the 12 months prior to index date, pre-index co-morbidity score and pre-index SF8, we found a significantly greater decline in overall and cardiovascular medication count among dementia patients compared to reference patients. Diabetes medications declined very slightly, but significantly between the groups (Table 2).

Discussion

This observational study of older patients with diabetes found that the overall number of medications, and diabetes and cardiovascular medications in particular, declined following a dementia diagnosis, and the difference was greater than expected compared to age, sex, and time-matched reference individuals. Our results suggest that providers in this integrated health care delivery system are de-intensifying their patients' use of long-term diabetes and cardiovascular medications following a dementia diagnosis, as recommended in current care guidelines.

Prior studies of diabetes management in older populations have found continued aggressive glycemic treatment[34,35], despite clear evidence that harms outweigh benefits[36,37]. Some have suggested that clinicians do not individualize diabetes treatment sufficiently, leading to over-treatment of diabetes in elderly patients[38]. Conversely, there is also evidence that there is under-prescribing in managing elders with comorbidities [39]. Clearly, optimizing prescribing for elders requires addressing both over and under-prescribing. We did observe small decreases in diabetes medication in those with dementia compared to the reference group. It is possible that for this population with diagnosed dementia, clinicians are more willing to de-intensify diabetes treatment than among elders more generally. A growing recognition of the harms of overtreatment may also have influenced these findings[40].

This study has several strengths. It examined a well-characterized cohort with relatively uniform access to care over time with robust clinical and survey data capture. The difference-in-differences approach accounts for changes in medication prescribing practices over time and other secular trends while controlling for confounding by individual characteristics. However, there are limitations to note. We used physician diagnosis of dementia to identify incident cases of dementia, which may under-ascertain dementia and therefore introduce a conservative bias. Moreover, we cannot verify that medication discontinuation occurred because of dementia diagnosis; it may have been due to resultant frailty, adverse effects, or patient preference. In this observational study, we cannot ascertain

whether the dementia diagnosis directly led to a change in care management strategy with a reduction in prescribed medication use; however, our selection of a closely matched reference population and adjusted analysis should improve the comparability of the two groups. Unfortunately, we did not have the statistical power in this very diverse cohort to examine differences by race/ethnicity. Finally, this analysis includes patients cared for in an integrated health system; these results may not generalize to other types of health care delivery systems.

Overall these results suggest that health care providers are simplifying medication regimens for diabetes patients with dementia. This may be a deliberate result of provider-patient-caregiver decision-making about medications. This encouraging finding deserves additional research regarding the patient-, provider- and system-level mechanisms that drive recommended changes in burden of medication use among older patients with dementia and other chronic conditions. More research is also needed to determine the long-term consequences of de-intensification versus maintenance versus intensification of diabetes care in order to solidify the evidence-base for care recommendations for our sickest and most complex patients.

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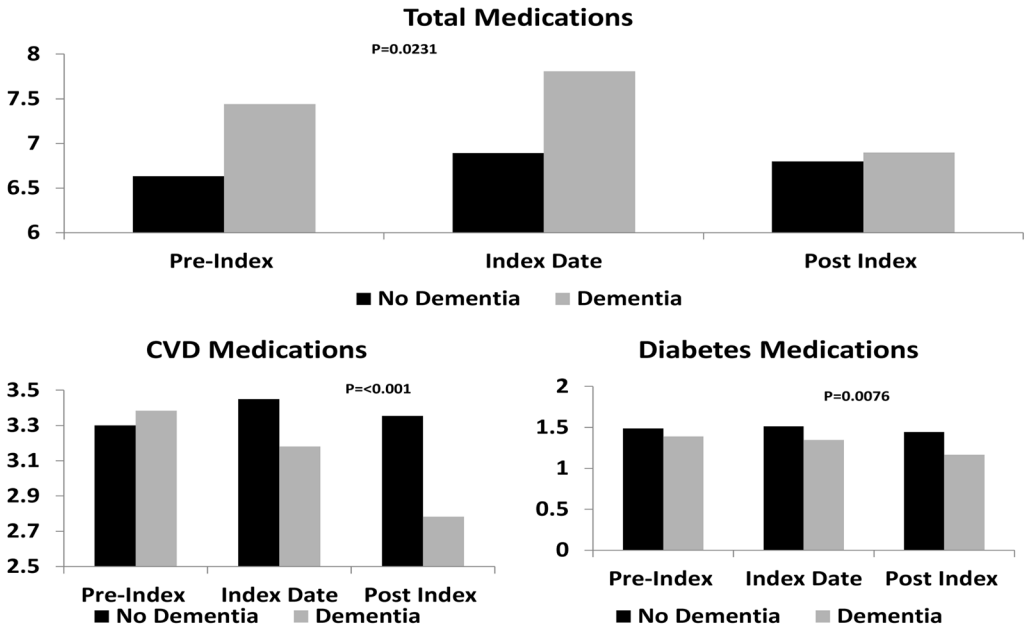

Figure 1.
Medications

Table 1

Sample Characteristics (N=1158)

	Total	No dementia	Dementia	P-value
	N=1158	**N=965**	**N=193**	
% Female	546 (47)	455 (47)	91 (47)	1.0
Age				1.0
50–59	54 (5)	45 (5)	9 (5)	
60–69	240 (21)	200 (21)	40 (21)	
70–79	828 (72)	690 (72)	138 (72)	
80+	36 (3)	30 (3)	6 (3)	
Race/Ethnicity				0.08
Asian	169 (15)	148 (15)	21 (11)	
Black	223 (19)	175 (18)	48 (25)	
Filipino	110 (10)	95 (10)	15 (8)	
Latino	200 (17)	168 (17)	32 (17)	
White	279 (24)	240 (25)	39 (20)	
Other/Multiracial	138 (12)	108 (11)	30 (16)	
Missing	39 (3)	31 (3)	8 (4)	
Education				0.45
High school or less	575 (50)	476 (49)	99 (51)	
Some college	275 (24)	224 (23)	51 (26)	
College graduate	281 (24)	241 (25)	40 (21)	
Missing	27 (2)	24 (2)	3 (2)	
% Married	739 (64)	638 (66)	118 (62)	0.29
Social support				0.03
No	117 (10)	89 (9)	28 (14)	
Yes	680 (59)	564 (58)	116 (60)	
Missing	361 (31)	312 (32)	49 (25)	
Duration of diabetes				<0.01
<5 years	76 (7)	62 (6)	14 (7)	
5–9 years	345 (30)	308 (32)	37 (19)	
10–19 years	474 (41)	395 (41)	79 (41)	
20+ years	256 (22)	195 (20)	61 (32)	
Missing	7 (1)	5 (1)	2 (1)	
Mean Charlson comorbidity index (s.d.)	2.9 (1.9)	2.8 (1.8)	3.4 (2.1)	<0.01
Mean SF8 Score (s.d.)	45.2 (10.3)	44.8 (10.1)	43.4 (11.2)	0.023
Quartiles				

	Total	No dementia	Dementia	P-value
	N=1158	**N=965**	**N=193**	
Q1: <38.1	196 (16.7)	152 (15.8)	41 (21.2)	0.30
Q2: 38.1–47.5	194 (16.8)	159 (16.5)	35 (18.1)	
Q3: 47.6–53.7	194 (16.8)	164 (17.0)	30 (15.5)	
Q4: >53.7	193 (16.7)	161 (16.7)	32 (16.6)	
Missing	384 (33.2)	329 (34.1)	55 (28.5)	
Pre-Index Clinical Measures, (s.d.)				
A1c,%	7.11 (1.18)	7.11 (1.10)	7.15 (1.61)	0.786
LDL, mmol/ml	87.1 (28.1)	86.6 (27.5)	89.9 (31.2)	0.227
Systolic BP, mg/Hg	131.1 (16.6)	130.7 (16.3)	133.0 (17.7)	0.110
BMI, kg/m^2	29.8 (5.8)	29.9 (5.7)	29.3 (5.9)	0.324
Mean Utilization, prior year (s.d.)				
Outpatient Visits	12.11 (11.6)	11.53 (11.4)	15.1 (12.1)	0.0001
Hospitalizations	0.9 (1.9)	0.6 (1.2)	2.2 (3.4)	<0.0001

Table 2

Adjusted Regression Results

	Dementia		No Dementia		Difference in difference*
	Mean # meds at baseline	**Mean # meds at follow-up**	**Mean # meds at baseline**	**Mean # meds at follow-up**	**(Δ in meds for dementia minus Δ in meds for those without dementia**
Total medications	7.10	6.56	6.56	6.73	−0.71
Diabetes medications	1.44	1.22	1.48	1.44	−0.18
Cardiovascular medications	3.57	2.97	3.50	5.55	−0.65
Dementia medications	0.35	0.86	0.08	0.10	0.49

Adjusted for education, race, social support, duration of diabetes, baseline A1c, BP, LDL, BMI, baseline # outpatient visits, baseline # hospitalizations, baseline co-morbidity score and quartile of PCS-8 physical functioning score. (Matched on age and sex, not specifically controlled for).

*p<0.05 for all