Does Opioid Therapy Affect Quality of Care for Diabetes Mellitus?

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Objective: To examine whether veterans who received chronic opioid therapy had worse diabetes performance measures than patients who did not receive opioids.

Study Design: Retrospective cohort study.

Methods: We identified all patients with diabetes mellitus receiving care in US Department of Veterans Affairs facilities during 2004. Cases received at least 6 prescriptions for chronic opioids during 2004, while controls were randomly selected from among patients with diabetes who received no opioids. We compared process measures (glycosylated hemoglobin and low-density lipoprotein cholesterol levels tested and an eye examination performed) and outcome measures (glycosylated hemoglobin level ≤9.0% and low-density lipoprotein cholesterol level ≤130 mg/dL) between groups.

Results: Cases (n = 47,756) had slightly worse diabetes performance measures than controls (n = 220,912) after adjustment for covariates. For example, 86.4% of cases and 89.0% of controls had a glycosylated hemoglobin test during fiscal year 2004 (adjusted odds ratio, 0.69; P <.001). Among cases, receipt of higher-dose opioids was associated with additional decrement in diabetes performance measures, with a dose-response relationship.

Conclusions: Chronic opioid therapy among patients within the Veterans Affairs system is associated with slightly worse diabetes performance measures compared with patients who do not receive opioids. However, patients receiving higher dosages of opioids had additional decrements in diabetes performance measures; these patients may be appropriate targets for interventions to improve their care for pain and diabetes.

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For author information and disclosures, see end of text.

Understanding the role of clinical complexity as a determinant of quality of care is a major research goal.[1] In previous studies,[2-9] the effect of clinical complexity on quality of care has varied depending on the diagnoses, the clinician and patient, and the clinical environment. Seeking to harmonize these mixed results into a unifying theory, Piette and Kerr[10] proposed that symptomatic conditions may have a greater effect on quality of care than asymptomatic conditions and that conditions with dissimilar management goals ("discordant conditions") may have a greater effect than those with similar goals ("concordant conditions").

By this reasoning, chronic pain could have a considerable adverse effect on quality of care for unrelated conditions. Pain is highly symptomatic, and pain management is discordant with the management of other conditions.[11] While the use of opioids to treat chronic noncancer pain is increasingly accepted,[12] opioid therapy may present additional challenges due to the potential for abuse, dependence, and diversion and due to conflicts over appropriate dosages.[13-19] However, opioid therapy could also facilitate care for unrelated conditions. Patients receiving opioids may visit the clinic more often, allowing more opportunities for medical management.[10] Adequate treatment of pain may improve the patient's functional status and quality of life,[12] allowing greater focus on self-care activities.

Diabetes mellitus, a common, costly, and highly morbid condition,[20,21] is a good condition in which to examine this possibility. Adequate management of diabetes requires collaboration among clinicians and the patient within a system of care,[22-27] and explicit guidelines and diabetes performance targets exist with which to examine the adequacy of diabetes care.[28-30] Krein et al[31] showed that among patients with diabetes, chronic pain is a barrier to the completion of self-care activities such as taking medications, exercising, and pursuing a prudent diet. However, the effect of pain on process and outcome measures of diabetes care is unknown. In addition, no study has specifically examined the effect of opioid therapy on the quality of care for unrelated chronic conditions, but there is reason to believe that opioid therapy may impart more complexity and challenge than pain alone.[32]

To clarify whether the net effect of opioid therapy is to promote or impede care for diabetes, we analyzed a large database of patients with diabetes in the US Department of Veterans

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Affairs (VA) and identified those receiving chronic opioid therapy. We compared patients receiving chronic opioids versus patients not receiving opioids regarding selected diabetes performance measures. We hypothesized that the distractions and concerns associated with chronic opioid therapy, as well as perhaps other characteristics of patients with chronic pain, would be reflected in worse diabetes performance measures. We also hypothesized that among those receiving opioids there would be a dose-response relationship between higher opioid dosages and decrements in diabetes performance measures.

METHODS

Study Sample

We identified subjects from the Diabetes Epidemiology Cohort, which comprises all patients with diabetes seen in the VA.[21] The Diabetes Epidemiology Cohort links administrative, laboratory, and pharmacy data from the VA with Medicare claims, providing a rich data set for analysis.[21,33] We first looked at all veterans treated for diabetes during fiscal year (FY) 2004 whose diabetes had been diagnosed before the start of FY 2002. Based on earlier work,[21] we defined patients as having diabetes if they had at least 2 *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) codes for diabetes or any prescriptions for antiglycemic medications within a 2-year period.

We excluded patients who had an *ICD-9-CM* diagnosis of malignant neoplasm (other than basal or squamous carcinoma of the skin) within 2 years of study inception. The management of cancer-related pain is qualitatively different; moreover, diabetes performance measures may not apply to patients with active malignant neoplasms. We also excluded all patients receiving methadone hydrochloride or buprenorphine hydrochloride–naloxone hydrochloride for treatment of opioid dependence. Finally, we excluded patients who had fewer than 2 VA primary care visits in FY 2004, as a large portion of their diabetes care may not appear in our database.

This study was approved by the Institutional Review Board of Bedford VA Medical Center.

Independent Variable: Chronic Opioid Therapy

Our independent variable was the prescription of chronic opioids. We considered the following "major" opioids: codeine, fentanyl citrate, hydrocodone, hydromorphone hydrochloride, methadone, morphine sulfate, and oxycodone; all are Schedule II or III controlled substances according to the US Drug Enforcement Administration.[34] Any formulation suitable for outpatient administration was considered, including tablets, patches, elixirs, and sprinkles. We also included formulations that combine opioids with other drugs such as acetaminophen. Buprenorphine, butorphanol, nalbuphine hydrochloride, pentazocine, and propoxyphene, which are less potent, were considered "minor" opioids.[34]

Patients who received at least 6 prescriptions for major opioids during FY 2004, with or without additional minor opioids, constituted the chronic opioid group (cases). This cutoff of 6 prescriptions was chosen to distinguish treatment for chronic pain from treatment for acute pain and is consistent with previous definitions of chronic pain.[17,18] Patients who received any major or minor opioids during FY 2004 but did not meet criteria for the case group were excluded from the study. We randomly selected controls from among the remaining patients, who had received no opioids during FY 2004, to achieve a control group approximately 4 times as numerous as the case group.

Dependent Variables: Diabetes Performance Measures

Our 3 process measures, which could be completed at any time during FY 2004, were testing of glycosylated hemoglobin (A1C) level, testing of low-density lipoprotein cholesterol (LDL-C) level, and a dilated eye examination. Our 2 outcome measures were at least 1 A1C level of 9.0% or less and at least 1 LDL-C level of 130 mg/dL or less during FY 2004 (to convert A1C level to proportion of total hemoglobin, multiply by 0.01; to convert cholesterol level to millimoles per liter, multiply by 0.0259). If no test results were available among VA data, patients were considered to have levels above these thresholds. These diabetes performance measures are based on VA clinical practice guidelines for diabetes and reflect a minimal standard of care.[28,29] We also examined lower targets for glycemic and lipemic control (ie, A1C level ≤8.0% and LDL-C level ≤100 mg/dL).

Covariates

Age was divided into the following 4 categories: 54 years or younger, 55 to 64 years, 65 to 74 years, and 75 years or older. Race/ethnicity was categorized into the following 4 groups: white non-Hispanic, black non-Hispanic, all others, and missing. The VA priority status, which characterizes the degree of entitlement to VA care, was defined as follows: poverty, full disability, partial disability, or none of the above.

More or less intensive management of diabetes may be indicated depending on life expectancy and comorbidities.[29] We focused on the following complications of diabetes by identifying conditions with at least 1 *ICD-9-CM* code during FYs 1997 through 2004: cellulitis, gangrene/ulcer, other diabetic infections, congestive heart failure, other heart diseases, cerebrovascular disease, peripheral vascular disease, renal disease, and diabetic eye disease. Mental health conditions may also

affect diabetes care.[2-5] Using similar *ICD-9-CM* code–based definitions, we identified the following mental health conditions: major depression, bipolar disorder, anxiety disorders, posttraumatic stress disorder, and schizophrenia. We also recorded the number of VA primary care visits; more visits might allow more opportunities to complete diabetes performance measures. We also examined pain diagnoses, dividing them into the following 4 broad categories: neuropathic pain, musculoskeletal pain, chronic headache, and psychogenic pain. Using *ICD-9-CM* codes, we categorized patients according to whether or not they had any diagnoses in each category (vs none).

We hypothesized that patients receiving higher daily doses of opioids might be at risk for additional decrements in diabetes performance measures, as the receipt of higher dosages suggests difficulties in pain management and possibly physiologic tolerance and an increased risk of dependence.[13,17,35] We used a standard equivalency table[36] to convert all opioid dosages to oral morphine equivalents. We calculated a mean daily dose of opioid therapy in FY 2004 for each patient in the study and categorized patients into quartiles based on their daily opioid doses.

Finally, we assigned each patient to 1 VA medical center so that we could control for site of care. Our assignment was based on the site the patient visited most often for diabetes care during FY 2004. If 2 sites were visited equally, we selected the site visited closest to the end of the year.

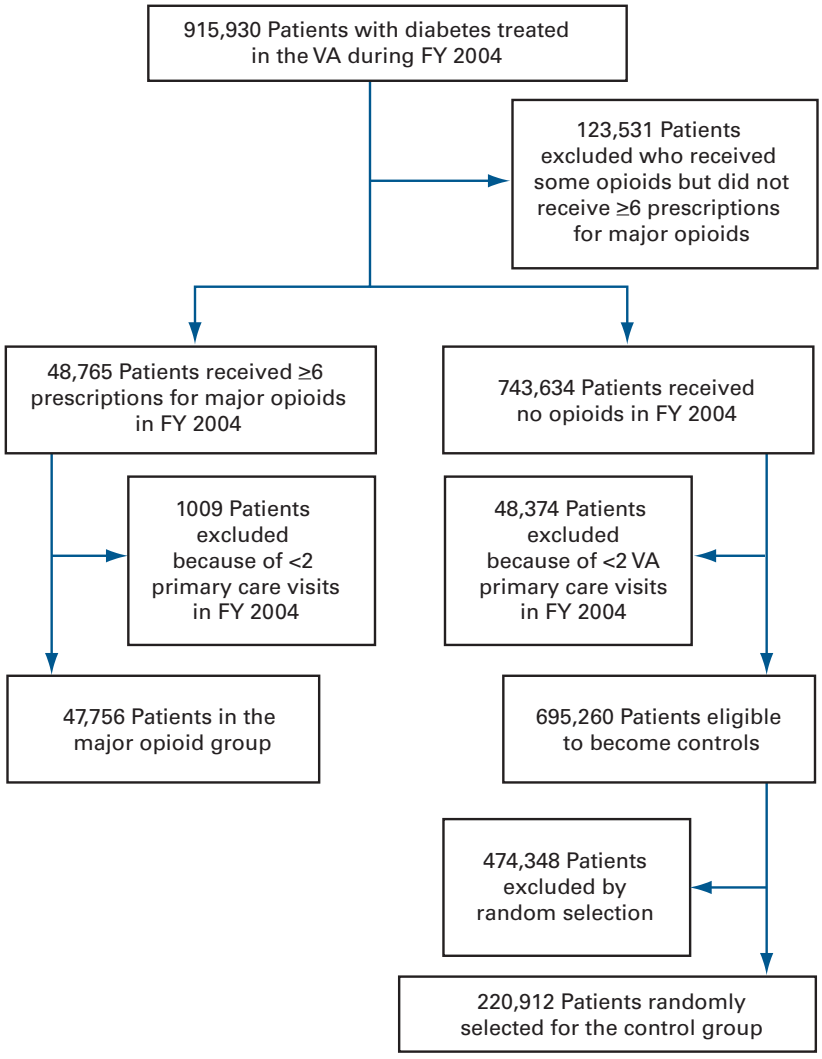
Statistical Analysis

We began our analysis with bivariate comparisons of demographics, comorbidities, and healthcare utilization between cases and controls. Using χ^2 tests, we then performed unadjusted comparisons of the proportions fulfilling each of the 5 diabetes performance measures. We performed adjusted analyses using generalized estimating equations to account for the clustering of outcomes by site of care, while adjusting for other covariates (sex, age, race/ethnicity, VA priority status, pain diagnoses, diabetic complications [including neuropathic pain], mental health conditions, and the number of VA primary care visits during the study). We did not adjust for eye disease when studying the eye examination process measure.

To investigate the possible effect of missing data on our results, we repeated key analyses among subsets of patients who were likely to have complete data. We restricted process measures to patients 65 years or older, who would presumably use Medicare when not using the VA and thus would have complete data for process measures. We restricted outcome measures to patients who had an A1C or LDL-C test within the VA at least once during the study (ie, those for whom laboratory values were available).

Finally, we added the mean daily opioid dose to our models and examined its ability to risk stratify the cases regarding diabetes performance measures. Our analyses were conducted us-

Figure. Inclusions and Exclusions for the Case and Control Groups



FY indicates fiscal year; VA, US Department of Veterans Affairs.

Table 1. Demographics of the Study Groups[a]

Demographic	% Cases (n = 47,756)	% Controls (n = 220,912)
Sociodemographics		
Male sex	96.8	98.0
Age group, y		
≤54	22.9	11.0
55-64	37.4	24.8
65-74	23.5	32.6
≥75	16.2	31.6
Race/ethnicity		
White non-Hispanic	75.9	68.4
Black non-Hispanic	11.8	12.0
All others	4.6	6.6
Missing	7.7	13.0
VA priority status		
Poverty	36.2	39.0
Full disability	41.2	20.4
Partial disability	15.1	17.0
None of the above	7.5	23.5
Comorbidities		
Pain conditions		
Musculoskeletal pain	85.6	48.9
Neuropathic pain	8.0	4.6
Chronic headache	0.9	0.3
Psychogenic pain	1.5	0.2
Diabetic complications		
Any	70.9	60.5
Cellulitis	26.2	16.0
Gangrene/ulcer	12.9	10.0
Other diabetic infections	9.9	4.4
Congestive heart failure	16.9	13.9
Other heart diseases	20.8	17.2
Cerebrovascular disease	12.9	10.5
Peripheral vascular disease	24.0	20.4
Renal disease	9.7	7.2
Diabetic eye disease	23.0	22.1
Mental health diagnoses		
Any	36.8	15.9
Major depression	22.6	10.0
Anxiety disorders	14.1	5.1
Posttraumatic stress disorder	6.6	2.3
Substance abuse disorders	6.2	1.7
Bipolar disorder	4.3	1.7
Schizophrenia	2.6	1.2
Healthcare utilization		
No. of primary care visits in FY 2004		
2-3	33.3	56.6
4-5	25.6	25.4
6-8	21.1	12.0
≥9	20.0	6.0
Any Medicare utilization in FY 2004	71.9	73.4

FY indicates fiscal year; VA, US Department of Veterans Affairs.
[a] P <.001 for all comparisons.

ing SAS version 9.1 (SAS Inc, Cary, NC).

RESULTS

Demographics

The Figure shows the exclusions that led to our case and control groups. We compared summary statistics between cases and controls (Table 1). Cases were younger (eg, 60.3% were <65 years vs 35.8% of controls). Despite their younger age, they were more likely to have at least 1 diabetic complication (70.9% vs 60.5%) and to have each particular diabetic complication. They were also more than twice as likely to have at least 1 mental health condition (36.8% vs 15.9%) and to have each specific mental health condition. They had more VA primary care visits than controls (eg, 41.1% vs 18.0% had ≥6 primary care visits). Despite the differences in age and VA primary care utilization, the 2 groups used Medicare at similar rates.

Among the cases (Table 2), most (67.4%) received only short-acting opioid formulations. The most commonly prescribed opioid was hydrocodone, followed by short-acting oxycodone, codeine, and long-acting morphine. Thirty-nine percent received more than 1 opioid during FY 2004. Among 89.4% of cases for whom dosage information was available, the mean total daily dose (in milligrams of morphine) was 88.9 mg. The median total daily dose was much lower (22.7 mg), indicating a rightward skew to this distribution. Opioid dose quartile was found to be highly

collinear with the duration of action of the drugs received. For example, patients receiving only short-acting drugs were unlikely to be in the highest-dose quartile (3.2%) compared with patients receiving only long-acting drugs (77.0%) or both long-acting and short-acting drugs (56.1%). All patients for whom dose quartile was unavailable were receiving only short-acting drugs; therefore, it seems likely that most of them were also receiving lower total daily doses.

Comparison of Diabetes Performance Measures

An unadjusted comparison of diabetes performance measures between cases and controls is given in Table 3. There were small differences between groups, all of which attained statistical significance because of large sample size. Among process measures, cases were less likely to have their A1C level tested (86.4% vs 89.0%) and to have their LDL-C level tested (75.9% vs 80.3%) but were more likely to have an eye examination performed (67.0% vs 66.3%). Among outcome measures, cases were slightly less likely to have A1C control (75.9% vs 76.5%) and LDL-C control (65.2% vs 66.1%).

To evaluate the effect of missing data on our results, we repeated our analysis of process measures among patients 65 years or older, whose data would presumably be more complete. While diabetes performance measures were slightly improved in both groups, between-group differences were unaffected. Similarly, for outcome measures, we restricted our analysis to patients who had at least 1 test within the VA. While diabetes performance measures improved considerably in both groups, between-group differences did not change appreciably (eg, A1C level ≤9.0% increased from 75.9% in cases and 76.5% in controls to 91.8% and 92.6%, respectively). Examination of stricter targets for glycemic control (A1C level ≤8.0%) and for lipemic control (LDL-C level ≤100 mg/dL) worsened diabetes performance measures, but between-group differences remained slight.

In unadjusted analyses that accounted for the clustering of outcomes by site of care (Table 3), odds ratios echoed the unadjusted proportions. After adjustment for covariates, cases now lagged behind controls for each of our 5 diabetes performance measures, with effect sizes somewhat widened (eg, the odds ratio for A1C level measurement was 0.78 before adjustment and 0.69 after adjustment). Between-group differences remained small for outcome measures even after adjustment for covariates (adjusted odds ratios, 0.90 and 0.87 for A1C level ≤9.0% and LDL-C level ≤130 mg/dL, respectively).

After stratification by opioid dosage, higher daily doses predicted worse performance on all 5 diabetes measures we studied (Table 4). For example, patients in the highest-dose quartile had an odds ratio of 0.55 for having their A1C level tested and an odds ratio of 0.79 for having an A1C level of 9.0% or less compared with controls.

Table 2. Opioid Therapy Among 47,756 Cases

Opioid Therapy	Value
Long-acting vs short-acting opioid, %	
Short acting only	67.4
Long acting only	9.5
Both long and short acting	23.0
Specific drugs, %[a]	
Short acting	
Hydrocodone	52.4
Oxycodone, short acting	34.1
Codeine	23.4
Morphine sulfate, short acting	4.8
Hydromorphone hydrochloride	1.1
Long acting	
Morphine, long acting	17.3
Methadone hydrochloride	8.4
Fentanyl citrate patch	7.2
Oxycodone, long acting	4.5
No. of different drugs received, %	
1	60.7
2	28.4
3	8.4
≥4	2.5
Total daily dose, mg of morphine[b]	
Mean [SD]	88.9 [824.4]
Median (interquartile range), mg of morphine	22.7 (11.0-55.7)

[a]Percentages exceed 100% because some patients received more than 1 kind of opioid.
[b]Dosage information was missing for 10.6% of patients.

DISCUSSION

Patients receiving chronic opioid therapy had only slightly worse diabetes performance measures than those not receiving opioids; the difference was smaller than we had anticipated. Within the opioid group, the receipt of higher daily opioid doses predicted further decrements in all of our diabetes performance measures, with a dose-response relationship. This suggests that the small difference in diabetes performance measures between cases and controls is largely attributable to patients receiving higher dosages of opioids. Resources should be focused on improving care for patients receiving high dosages of opioids. For example, a mean daily dose exceeding 60 mg of morphine (our highest-dose

Table 3. Comparison of Diabetic Performance Measures Between Cases and Controls

Variable	% Cases (n = 47,756)	% Controls (n = 220,912)	*P*	Odds Ratio (95% Confidence Interval)[a] Unadjusted	Odds Ratio (95% Confidence Interval)[a] Adjusted
Process measures					
A1C level measured	86.4	89.0	<.001	0.78 (0.72-0.86)	0.69 (0.63-0.76)
LDL-C level measured	75.9	80.3	<.001	0.77 (0.71-0.84)	0.71 (0.66-0.78)
Eye examination performed	67.0	66.3	.001	1.03 (0.99-1.08)	0.80 (0.77-0.84)
Outcome measures					
A1C level ≤9.0%	75.9	76.5	.006	0.97 (0.91-1.04)	0.90 (0.84-0.96)
LDL-C level ≤130 mg/dL	65.2	66.1	<.001	0.96 (0.89-1.04)	0.87 (0.82-0.94)
Stricter outcome measure targets					
A1C level ≤8.0%	67.7	68.4	.007	0.97 (0.92-1.02)	0.97 (0.91-1.02)
LDL-C level ≤100 mg/dL	50.5	49.4	<.001	1.05 (0.99-1.10)	0.98 (0.93-1.04)

A1C indicates glycosylated hemoglobin; LDL-C, low-density lipoprotein cholesterol.
SI conversion factors: To convert A1C level to proportion of total hemoglobin, multiply by 0.01; to convert cholesterol level to millimoles per liter, multiply by 0.0259.
[a]Odds ratios are the odds of completing diabetes performance measures among cases compared with controls. An odds ratio of less than 1 indicates that cases are less likely than controls to complete a diabetes performance measure. Unadjusted odds ratios account for the clustering of outcomes by site of care using general estimating equations. Adjusted odds ratios also account for sociodemographics, comorbidities, and number of primary care visits in FY 2004.

quartile) could trigger an automatic consultation with a nurse care manager.

The receipt of chronic opioid therapy is a compound concept that includes elements of pain, provider prescribing patterns, and medication utilization. Krein et al[31] previously showed that chronic pain distracts patients with diabetes from self-care tasks, including adherence to diet, exercise, and medication use. In that study, taking a medication for pain seemed to mitigate the negative effect of pain on some self-care activities, possibly because well-treated pain is less all-consuming.[31] To our knowledge, our study is the first to examine the relationship between a specific therapy for pain (opioid use) and process and outcome measures of diabetes care. Our study reminds us of the potential to use large clinical databases (such as those available within the VA) to answer meaningful questions about the care received by previously understudied groups of patients.

Our study has some limitations. First, we did not control for pain scores or for the severity of pain. It may be that our finding of a dose-response relationship for opioid therapy may partly or wholly reflect the effect of increasing severity of pain. Future research might be able to separate the effect of opioid therapy from that of pain severity, but given the subjective nature of any measure of pain, this would require detailed data and might still be of questionable validity.

Second, the highly integrated nature of VA care and the standardized clinical care provided throughout the VA may have minimized the detrimental effects of opioid therapy in our study. In non-VA settings, opioid therapy may affect diabetes care more negatively.

Third, our VA cohort was mostly male and had a high incidence of poverty, comorbidity, and disability. These factors limit the generalizability of our findings to other populations.

Fourth, we were unable to capture some elements of care that occurred outside the VA. However, our reanalysis of subsets of patients with complete data suggested that, while incomplete data capture affected rates of diabetes performance measure completion, it did not greatly alter between-group comparisons.

Fifth, our data set was insufficiently detailed to identify patients who were abusing prescription opioids. Defining prescription drug abuse in clinical practice is challenging,[37] identifying it from paper medical record review can be difficult,[38] and identifying it from automated data is even more problematic. It is plausible that our finding of a dose-response curve for opioid therapy is partially due to an

Take-Away Points

Within the Veterans Affairs system, patients who received opioids for chronic pain had slightly worse diabetes performance measures than patients who did not receive opioids.

- Comparisons included measurement of glycemic and lipemic control, achievement of moderate or better glycemic and lipemic control, and a yearly eye examination.
- Among the group receiving opioids, the receipt of higher daily opioid doses predicted worse results for all 5 diabetes performance measures. A dose-response relationship was observed, lending additional credibility to this finding.

Table 4. Completion of Diabetes Performance Measures Among 268,668 Subjects for Whom Opoid Dosage Information Was Available[a]

Variable	Opioid Dose Quartile (95% Confidence Interval)[b]					Test for Linear Trend *P*
	Controls (n = 220,912)	Lowest (n = 10,670)	Lower (n = 10,675)	Higher (n = 10,677)	Highest (n = 10,678)	
Process measures						
A1C level measured	1 [Reference]	0.82 (0.72-0.93)	0.74 (0.66-0.83)	0.63 (0.56-0.71)	0.55 (0.49-0.62)	<.001
LDL-C level measured	1 [Reference]	0.76 (0.68-0.84)	0.73 (0.66-0.81)	0.67 (0.61-0.74)	0.64 (0.57-0.72)	<.001
Eye examination performed	1 [Reference]	0.90 (0.84-0.96)	0.80 (0.75-0.85)	0.77 (0.73-0.83)	0.72 (0.67-0.77)	<.001
Outcome measures						
A1C level ≤9.0%	1 [Reference]	1.03 (0.94-1.11)	0.92 (0.85-1.00)	0.82 (0.75-0.90)	0.79 (0.71-0.88)	.002
LDL-C level ≤130 mg/dL	1 [Reference]	0.93 (0.85-1.02)	0.86 (0.79-0.93)	0.83 (0.76-0.89)	0.82 (0.74-0.90)	.003

A1C indicates glycosylated hemoglobin; LDL-C, low-density lipoprotein cholesterol.
SI conversion factors: To convert A1C level to proportion of total hemoglobin, multiply by 0.01; to convert cholesterol level to millimoles per liter, multiply by 0.0259.
[a]Results are adjusted for sociodemographics, pain diagnoses, comorbidities, and number of primary care visits in fiscal year 2004. Regression analyses were performed using generalized estimating equations to account for the clustering of outcomes by site of care.
[b]Opioid dosage information was missing for 10.6% of subjects. The other 89.4% were categorized into quartiles by dosage.

increasing prevalence of prescription drug abuse in the higher-dosage categories. In addition, quartiles of opioid dosage may reflect the physical tolerance that naturally develops over time with chronic opioid therapy, necessitating higher dosages of this medication.[39] A more complete examination of the effect of prescription drug abuse on the quality of care for unrelated conditions would ideally be conducted with a detailed paper medical record review rather than with automated data.

Sixth, our comorbidity data were not sufficiently detailed to identify patients for whom tight glycemic or lipemic control would not be indicated because of limited life expectancy. We addressed this by having modest expectations for glycemic and lipemic control (ie, an A1C level of ≤9.0% and an LDL-C level of ≤130 mg/dL). Although the application of more stringent standards to some patients may be of questionable value,[5,29,40-42] these targets should apply to most, if not all, patients.

In summary, patients receiving chronic opioids to treat pain had slightly worse diabetes performance measures than patients who did not receive opioids. However, stratification by opioid dosage revealed that patients receiving high dosages had additional decrements in diabetes performance measures. Efforts should be focused on improving the quality of care in such patients for pain and for diabetes.

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