Surgical Outcomes of Total Knee Replacement According to Diabetes Status and Glycemic Control, 2001 to 2009

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Background: Poor glycemic control in patients with diabetes may be associated with adverse surgical outcomes. We sought to determine the association of diabetes status and preoperative glycemic control with several surgical outcomes, including revision arthroplasty and deep infection.

Methods: We conducted a retrospective cohort study in five regions of a large integrated health-care organization. Eligible subjects, identified from the Kaiser Permanente Total Joint Replacement Registry, underwent an elective first primary total knee arthroplasty during 2001 through 2009. Data on demographics, diabetes status, preoperative hemoglobin A1c (HbA1c) level, and comorbid conditions were obtained from electronic medical records. Subjects were classified as nondiabetic, diabetic with HbA1c < 7% (controlled diabetes), or diabetic with HbA1c ≥ 7% (uncontrolled diabetes). Outcomes were deep venous thrombosis or pulmonary embolism within ninety days after surgery and revision surgery, deep infection, incident myocardial infarction, and all-cause rehospitalization within one year after surgery. Patients without diabetes were the reference group in all analyses. All models were adjusted for age, sex, body mass index, and Charlson Comorbidity Index.

Results: Of 40,491 patients who underwent total knee arthroplasty, 7567 (18.7%) had diabetes, 464 (1.1%) underwent revision arthroplasty, and 287 (0.7%) developed a deep infection. Compared with the patients without diabetes, no association between controlled diabetes (HbA1c < 7%) and the risk of revision (odds ratio [OR], 1.32; 95% confidence interval [CI], 0.99 to 1.76), risk of deep infection (OR, 1.31; 95% CI, 0.92 to 1.86), or risk of deep venous thrombosis or pulmonary embolism (OR, 0.84; 95% CI, 0.60 to 1.17) was observed. Similarly, compared with patients without diabetes, no association between uncontrolled diabetes (HbA1c ≥ 7%) and the risk of revision (OR, 1.03; 95% CI, 0.68 to 1.54), risk of deep infection (OR, 0.55; 95% CI 0.29 to 1.06), or risk of deep venous thrombosis or pulmonary embolism (OR, 0.70; 95% CI, 0.43 to 1.13) was observed.

Conclusions: No significantly increased risk of revision arthroplasty, deep infection, or deep venous thrombosis was found in patients with diabetes (as defined on the basis of preoperative HbA1c levels and other criteria) compared with patients without diabetes in the study population of patients who underwent elective total knee arthroplasty.

Level of Evidence: Prognostic Level II. See Instructions for Authors for a complete description of levels of evidence.

Disclosure: One or more of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of an aspect of this work. In addition, one or more of the authors, or his or her institution, has had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. No author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete **Disclosures of Potential Conflicts of Interest** submitted by authors are always provided with the online version of the article.

JBJS | Express

This article was chosen to appear electronically on February 27, 2013, in advance of publication in a regularly scheduled issue.

A commentary by Paul Manner, MD, is linked to the online version of this article at jbjs.org.

Diabetes mellitus is an increasingly prevalent condition among individuals of all ages in the United States, and it substantially elevates the risk for many serious health problems. Diabetes can interfere with the body's ability to recover from illnesses or injuries unrelated to the diabetes. Obesity is highly prevalent among patients with diabetes and is also associated with increased risk for osteoarthritis. An estimated 52% of individuals with diabetes also have arthritis and may eventually require knee or hip replacement[1]. Although total joint replacement is performed to improve function and quality of life, the results of several studies suggest that patients with diabetes may be at higher risk for postoperative complications such as myocardial infarction[2-7] and have worse functional outcomes[8-10], higher hospital charges[2,3,11], and increased postoperative mortality[7].

The results of recent studies suggest that poor glycemic control in diabetic patients may be associated with an increased prevalence of wound infection[11,12] and higher mortality[11]. These studies, however, were limited because of their dependence on ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification) discharge diagnosis codes to determine glycemic control status and outcome status as well as by an inability to track outcomes beyond hospital discharge.

The expected increase in demand for joint replacement procedures in patients with diabetes, the potentially increased risk for infection and other complications in these patients, and the generally increasing cost per procedure emphasize the need to mitigate preoperative risk factors to ensure the best possible outcomes. One potentially modifiable risk factor in diabetic patients undergoing total knee replacement is preoperative glycemic control. In the present study, we used preoperative laboratory measurement of glycated hemoglobin, hemoglobin A1c (HbA1c), to classify subjects according to glycemic control status. We hypothesized that diabetic patients with an HbA1c level of ≥7% would be more likely to require revision surgery, develop infections, experience deep venous thrombosis or pulmonary embolism, have an incident myocardial infarction, and be rehospitalized in the first year following primary knee arthroplasty compared with nondiabetic patients or diabetic patients with an HbA1c level of <7%.

Materials and Methods

Study Design, Setting, and Subjects

This retrospective cohort study was conducted within five regions (Colorado, Hawaii, Northern California, Northwest, and Southern California) of Kaiser Permanente (KP), a large integrated health-care system serving a large racially, ethnically, and socioeconomically diverse population in the United States. Eligible cohort members included all KP enrollees who were eighteen years of age or older and underwent a primary total knee replacement during the study period of 2001 through 2009.

All patients who underwent knee replacement were identified with use of the KP Total Joint Replacement Registry (TJRR)[13]. For subjects who underwent multiple knee replacement procedures, only the first primary replacement identified in the registry was considered to be the index surgery. Clinical information on each cohort member from two years prior to the index surgery to one year after the surgery was collected from the electronic health records and was used to determine the presence of preexisting or comorbid conditions and to assess outcomes. The information collected included enrollment information, demographics, all inpatient and outpatient diagnoses, all medications dispensed, HbA1c laboratory results, and inpatient hospital admissions after the index surgery.

Exposure Variable

The primary exposure variable in the study was the preoperative glycemic status. Patients with diabetes were identified on the basis of the presence in the medical record of (1) an HbA1c result of ≥6.5%, (2) two ambulatory care (outpatient or emergency department) visits with a diagnosis code of 250.xx within any twenty-four-month period, or (3) one inpatient admission with a primary or secondary diagnosis code of 250.xx. Subjects with a diagnosis code indicating gestational diabetes (648.xx) were not considered to have diabetes for the purposes of this study.

Patients were classified as nondiabetic, diabetic with good glycemic control (HbA1c < 7.0%), and diabetic with poor glycemic control (HbA1c ≥ 7.0%). In patients with diabetes, glycemic control status was assigned on the basis of the latest HbA1c value prior to the date of the index surgery. All HbA1c tests were conducted as part of each patient's ongoing diabetes care and management. Subjects who met the definition for diabetes but did not have HbA1c results (n = 86) were excluded.

Outcome Variables

We examined three surgical outcomes that are routinely collected and validated as part of the operation of the TJRR: the need for revision arthroplasty, deep infection, and deep venous thrombosis (DVT) or pulmonary embolism (PE). Revision surgery was defined as removal or exchange of at least one prosthetic component. For the present study, only revisions that occurred within one year after the primary arthroplasty were included. Deep infection was defined according to the guidelines of the Centers for Disease Control (CDC)[14], and only infections within one year of the procedure were included. DVT was defined as deep venous thrombosis in the lower extremities within ninety days of the procedure, and PE was defined as venous thrombi traveling to the lungs within ninety days of the procedure[15]. DVT and PE were each confirmed by means of diagnostic imaging (venography, ultrasonography, or Doppler ultrasonography) to identify the anatomical location of the thrombus, or by means of an autopsy if the patient died. Symptomatic patients with a clinical diagnosis of DVT or PE and an indeterminate imaging study were also considered to have the DVT or PE outcome. DVT and PE were combined into a composite outcome in the analysis.

Additionally, we looked at incident myocardial infarction and rehospitalization for any cause. Incident myocardial infarction was identified on the basis of the presence of the ICD-9-CM code 410.xx during the first postoperative year in a patient without prior evidence of having had a myocardial infarction. Ascertainment of myocardial infarction on the basis of the ICD-9 code alone has previously been demonstrated to have high accuracy[16]. Finally, all-cause rehospitalization was ascertained from inpatient claims during the first postoperative year.

Potential Confounders

Potential confounders were selected a priori on the basis of a review of the literature and surgeon input, and they included age, sex, body mass index (BMI), preoperative health status according to the American Society of Anesthesiologists (ASA) score, morbidity burden according to the Deyo adaptation[17] of the Charlson Comorbidity Index[18], use of perioperative antibiotic prophylaxis (yes or no), and use of antibiotic cement in the joint replacement procedure (yes or no).

The Deyo score was calculated with use of all available inpatient and outpatient diagnosis codes during the two years prior to the date of the index surgery. The component for diabetes was excluded from the Deyo score calculation. Information on the ASA score, osteoarthritis status, and use of antibiotic prophylaxis were all ascertained with use of measures routinely gathered for inclusion in the TJRR. The ASA score is a 5-point ordinal score indicating overall preoperative systemic health and fitness for surgery.

Statistical Analyses

Demographic and clinical characteristics were compared across the three preoperative glycemic status subgroups (patients without diabetes, patients with

TABLE I Demographic and Clinical Characteristics According to Diabetes and Glycemic Control Status

	Glycemic Status		
Characteristic	No Diabetes, N = 32,924	Diabetes with HbA1c < 7.0%, N = 5042	Diabetes with HbA1c ≥ 7.0%, N = 2525
Demographics			
Male sex*	11840 (36.0)	2151 (42.7)	1086 (43.0)
Age in yr†	68 (61-75)	69 (63-75)	67 (61-73)
White race*	19634 (59.6)	2930 (58.1)	1298 (51.4)
Clinical characteristics*			
Body mass index in kg/m^2			
<25	10782 (32.7)	1233 (24.4)	578 (22.9)
25-29.9	8870 (26.9)	992 (19.7)	475 (18.8)
≥30	13272 (40.3)	2817 (55.9)	1472 (58.3)
Osteoarthritis	31663 (96.2)	4906 (97.3)	2462 (97.5)
Preexisting comorbid conditions			
Myocardial infarction	198 (0.6)	81 (1.6)	30 (1.2)
Congestive heart failure	1001 (3.0)	384 (7.6)	176 (7.0)
Proliferative retinopathy	1 (<0.01)	51 (1.0)	63 (2.5)
Chronic kidney disease	1149 (3.5)	623 (12.4)	309 (12.2)
Preoperative status*			
Deyo score			
0: no comorbidity	21991 (66.8)	2018 (40.0)	907 (35.9)
1-3: average comorbidity	10155 (30.8)	2140 (42.4)	1175 (46.5)
4+: severe comorbidity	778 (2.4)	884 (17.5)	443 (17.5)
ASA score‡			
1: normal, healthy patient	933 (2.8)	39 (0.8)	16 (0.7)
2: mild systemic disease	20667 (64.4)	2042 (41.2)	978 (39.8)
3: severe systemic disease	10375 (32.3)	2784 (56.2)	1431 (58.2)
4-5: life-threatening disease/moribund	193 (0.6)	88 (1.8)	33 (1.3)
Operative characteristics*			
Intravenous antibiotic prophylaxis	30195 (91.7)	4651 (92.2)	2321 (91.9)
Antibiotics in cement	3239 (9.8)	807 (16.0)	408 (16.2)
Outcomes*			
Revision surgery within 1 yr	345 (1.1)	88 (1.7)	31 (1.2)
Deep infection within 1 yr	216 (0.7)	58 (1.2)	13 (0.5)
Deep venous thrombosis within 90 d	159 (0.5)	29 (0.6)	12 (0.5)
Pulmonary embolism within 90 d	189 (0.6)	30 (0.6)	10 (0.4)
Rehospitalization within 1 yr	8643 (26.4)	1571 (31.2)	755 (29.9)
Myocardial infarction within 1 yr	255 (0.8)	101 (2.0)	36 (1.4)

*Values are given as the number of patients, with the percentage in parentheses. †Values are given as the median, with the interquartile range in parentheses. ‡Data were not available for all patients. The percentages are based on the number of patients with data.

diabetes and good glycemic control, and patients with diabetes and poor glycemic control). The chi-square test was used for categorical variables. Some variables that were ultimately modeled as linear continuous variables (BMI and Deyo score) were categorized for descriptive purposes. Age was summarized with use of the median and interquartile range.

Patients without diabetes were the reference group for all analyses. As the first step in the logistic regression analysis, the unadjusted association between preoperative glycemic status and each outcome was estimated. Patients who died or were lost to follow-up within the first postoperative year were included with the group of patients who were followed for the full year. Each potential confounder was independently added to the unadjusted model. Any such covariate that effected a >10% change in the primary predictor estimate was retained for possible inclusion in the final multivariate model. All potential confounders identified in this manner were then entered simultaneously into the multivariate model. These covariates were then deleted from the model one by one, beginning with the variable whose deletion resulted in the smallest change in the primary predictor estimate. When deletion of a covariate from the full multivariate model would have resulted in a total change of >10% in the estimate, the model was considered to be complete[19].

The eligible patients for this study included all those who had undergone initial primary knee replacement during the nine-year study period. Revision

TABLE II Unadjusted and Multivariate Models for Five Postoperative Outcomes

	Unadjusted		Adjusted*	
	OR	95% CI	OR	95% CI
Revision				
No diabetes	1.00	—	1.00	—
Diabetes, HbA1c < 7%	1.67	1.32, 2.12	1.32	0.99, 1.76
Diabetes, HbA1c ≥ 7%	1.17	0.81, 1.70	1.03	0.68, 1.54
Deep infection				
No diabetes	1.00	—	1.00	—
Diabetes, HbA1c < 7%	1.76	1.32, 2.36	1.31	0.92, 1.86
Diabetes, HbA1c ≥ 7%	0.78	0.45, 1.37	0.55	0.29, 1.06
DVT or PE				
No diabetes	1.00	—	1.00	—
Diabetes, HbA1c < 7%	1.17	0.88, 1.55	0.84	0.60, 1.17
Diabetes, HbA1c ≥ 7%	0.84	0.54, 1.31	0.70	0.43, 1.13
Incident myocardial infarction				
No diabetes	1.00	—	1.00	—
Diabetes, HbA1c < 7%	2.61	2.07, 3.29	1.92	1.46, 2.54
Diabetes, HbA1c ≥ 7%	1.85	1.30, 2.62	1.40	0.93, 2.11
All-cause rehospitalization				
No diabetes	1.00	—	1.00	—
Diabetes, HbA1c < 7%	1.27	1.19, 1.35	1.08	1.00, 1.16
Diabetes, HbA1c ≥ 7%	1.19	1.09, 1.30	0.98	0.88, 1.08

*Adjusted for sex, age at time of primary surgery, body mass index, and the Deyo adaptation of the Charlson Comorbidity Index.

surgery (one of the outcomes investigated) and replacement of the contralateral knee in the same individual were excluded.

Source of Funding

This study was funded through internal operational funds provided by the Kaiser Permanente Center for Effectiveness and Safety Research (CESR). CESR facilitates inter-regional research conducted by the research programs in each of the eight regional entities (Colorado, Georgia, Hawaii, Mid-Atlantic States [Virginia, Maryland, District of Columbia], Northern California, Northwest [Oregon, Washington], Ohio, and Southern California) that form the Kaiser Permanente integrated health-care organization.

Results

The TJRR recorded information on 40,491 patients who underwent an initial primary knee replacement during the period from January 2001 through December 2009. Of these patients, 32,924 (81.3%) were classified as not having had diabetes mellitus prior to the index surgery, 5042 (12.5%) as having had controlled diabetes (HbA1c < 7.0%), and 2525 (6.2%) as having had uncontrolled diabetes (HbA1c ≥ 7.0%).

The controlled diabetes group was slightly older than both the nondiabetic group and the uncontrolled diabetes group. The patients with diabetes were more likely than the nondiabetic patients to be male (42.8% compared with 36.0%), be obese (56.7% compared with 40.3%), and have a severe comorbidity burden (17.5% compared with 2.4%) (Table I). The time between the most recent HbA1c test prior to surgery and the surgery date was longer for those classified as having controlled diabetes (median, 10.0 weeks; interquartile range [IQR], 3.3 to 22.0 weeks) than for those with uncontrolled diabetes (median, 6.6 weeks; IQR, 2.4 to 15.4 weeks). The median HbA1c value was 6.2% (IQR, 5.9% to 6.6%) for the group with controlled diabetes compared with 7.6% (IQR, 7.2% to 8.1%) for the group with uncontrolled diabetes.

The proportion of patients who underwent revision arthroplasty in the year after the index surgery was 1.1% (464) in the entire study cohort. A greater proportion of those with controlled diabetes (1.7%) underwent revision compared with those who were nondiabetic (1.1%) or had uncontrolled diabetes (1.2%) (Table I). Deep infection developed in 287 patients (0.7%), 392 patients (1.0%) had an incident myocardial infarction, and 10,969 (27.1%) were rehospitalized in the year after surgery (Table I).

For each of the five outcomes, the final multivariate model included adjustments for sex, age at time of the primary surgery (modeled as a continuous variable), BMI (continuous), and Deyo score (continuous). Further adjustments for other clinical or surgical variables effected changes of <10% in the estimates. The results of the multivariate analysis for the risk of revision surgery were compatible with a wide range of possible effects, including possible increased or decreased risk, in patients with uncontrolled diabetes compared with patients without diabetes (odds ratio [OR], 1.03; 95% confidence interval [CI], 0.68 to 1.54) (Table II). The results for both deep infection (OR, 0.55; 95% CI, 0.29 to 1.06) and DVT or PE (OR, 0.70; 95% CI, 0.43 to 1.13) were compatible with possible reductions in risk in patients with uncontrolled diabetes compared with patients without diabetes (Table II), but neither finding reached significance. Uncontrolled diabetes did not appear to be associated with an increased risk of incident myocardial infarction (OR, 1.40; 95% CI, 0.93 to 2.11) or all-cause rehospitalization (OR, 0.98; 95% CI, 0.88 to 1.08), although the CIs indicated the possibility of some increase in risk (Table II).

Discussion

This cohort study yielded estimates of the associations between glycemic control and surgical outcomes after total knee replacement surgery. Although we hypothesized that individuals with uncontrolled diabetes would have poorer surgical outcomes than those without diabetes or those with diabetes and well-controlled glycemic status, we observed no clear associations between poor glycemic control and any of the five measured outcomes. This is in contrast to the findings of previous studies in which increased risks of adverse surgical outcomes among individuals with poor glycemic control were reported. Significant increases in the risk of deep infection, ranging from 1.6-fold[12] to 2.3-fold[11], have been reported previously; additionally, a significant 3.2-fold increase in the risk of pulmonary embolism among patients with diabetes compared with patients without diabetes was reported in one prior study of patients who had undergone major orthopaedic surgery[20].

There are several possible reasons why the results in the present study differed from those in the previous studies. With the exception of all-cause rehospitalization, all of the outcomes that we examined were rare in the cohort in the present study. In addition, the infection and DVT or PE outcomes were systematically validated as part of ongoing quality control activities of the TJRR instead of having been identified solely with use of diagnosis codes. Patients with uncontrolled diabetes were also rare in the cohort, even with the low threshold between good and poor glycemic control. In this setting of both rare exposure and rare outcomes, making precise estimates of associations is difficult.

The manner in which we defined poor glycemic control also differed from that in previous studies. The study by Marchant et al.[11] identified glycemic control status (controlled compared with uncontrolled diabetes) with use of an algorithm based exclusively on ICD-9 codes. In the present study, we used both ICD-9 codes and laboratory-based criteria to determine diabetes status, and we used the preoperative HbA1c results closest to the date of surgery for classifying subjects according to glycemic control. Jämsen et al.[12] also used HbA1c results to classify glycemic control status, but their estimates were adjusted only for age and sex. Our unadjusted models did provide significant estimates in support of our hypotheses, but adjustment for age, sex, BMI, and other comorbidities attenuated the association. This suggests that other factors besides glycemic control, such as BMI or other comorbid conditions, may be more strongly predictive of adverse surgical outcomes than the perioperative HbA1c level is. The severity of diabetes or the presence of diabetes-related complications could also be explored as possible predictors of poor surgical outcomes.

Although we believe that our study includes several advances, it is also subject to some potential limitations. The time between the most recent HbA1c test and the date of surgery varied considerably within the cohort. Collecting HbA1c information prospectively as part of the preoperative work-up would facilitate more consistent assessment of glycemic control status and allow better comparison across patients. The threshold chosen to distinguish good control from poor control might also be inadequate. An HbA1c goal of <7% for an elderly patient with diabetes is probably appropriate if the patient is healthy, but if the patient has comorbidities, the rate of adverse outcomes may be increased unless glycemic control is tighter[21-23]. Inclusion of frail elderly patients with an HbA1c value of <7% in the "controlled" group and inclusion of elderly patients with adequate glycemic control despite a value of ≥7% in the "uncontrolled" group may have affected the results. We did consider different thresholds in the present study. However, Kaiser Permanente focuses resources on chronic disease management through proactive involvement of clinicians and case managers with patients, with the net effect of reducing the number of patients with uncontrolled diabetes in our health-care system (a fact that may explain why our overall rate of complications was lower than that reported in previous studies). Increasing the threshold virtually eliminated the category of patients with uncontrolled diabetes. This dramatically reduced the already small number of outcome events in the uncontrolled group, further reducing our ability to quantify differences in risks.

Some of the patients in our study may have been misclassified with respect to glycemic control status, but we did not identify any patterns suggestive of systematic misclassification. If such systematic misclassification did exist, however, it would serve to attenuate our estimates of risk, possibly preventing the identification of a real association[24]. We might also have misclassified patients as nondiabetic if they had diabetes but had not yet been formally diagnosed as such. This type of misclassification would have had the effect of making our reference group (those without diabetes) more similar to the diabetes groups, which would also have biased our odds ratio estimates toward the null hypothesis.

Although having diabetes has previously been associated with several adverse surgical outcomes[2-7,9,10], the role of the actual glucose level at the time of surgery remains ambiguous. Other factors, such as absolute disease status (diabetes compared with no diabetes) or BMI, may be more predictive than the HbA1c level. Alternative measures of diabetes severity, including secondary complications of diabetes or the type of diabetes medication, may also be more important than the preoperative HbA1c level with regard to surgical outcomes. Finally, our cohort comprised patients who actually underwent surgery. There may remain some unmeasured factors involved in the clinical decision-making about whether to avoid or delay this elective surgery in patients with very unstable diabetes or very high HbA1c levels. We have no information about how patients who were evaluated for surgery but did not undergo it might have differed from those who were included in our study.

In conclusion, in a study of a large cohort of patients undergoing elective primary total knee arthroplasty within a large managed care organization, we were unable to demonstrate that patients with uncontrolled diabetes (defined as an HbA1c level of ≥7%) had a higher risk of revision surgery, deep infection, deep venous thrombosis or pulmonary embolism, incident myocardial infarction, or all-cause rehospitalization. Regardless, patients with diabetes remain at high risk for a number of adverse health outcomes affecting many organ systems, and continuing to review all available information about the overall health and stability of these vulnerable patients, including perioperative glycemic control status, remains prudent. ■

NOTE: The authors acknowledge the programming and data management contributions of the following people, without whom this project would not have been accomplished: Christina L. Clarke, Bruce Folck, Daniel Ng, John V. Parker, Karen Riedlinger, and Kari L. Walker. They also acknowledge all of the hard-working surgeons, their patients, and the staff who contribute to and manage the Kaiser Permanente Total Joint Replacement Registry.

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