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Association between diabetes mellitus and total hip arthroplasty outcomes: an observational study using the US National Inpatient Sample

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ABSTRACT

Objectives To investigate the association of diabetes with postoperative outcomes in patients undergoing primary total hip arthroplasty (THA).

Design Retrospective cohort study using data from the US National Inpatient Sample (NIS).

Setting Study cohort was hospitalisations for primary THA in the USA, identified from the 2016–2020 NIS.

Participants We identified 2 467 215 adults in the 2016–2020 NIS who underwent primary THA using International Classification of Diseases, 10th Revision codes. Primary THA hospitlizations were analysed as the overall group and also stratified by the underlying primary diagnosis for THA.

Outcome measures Outcome measures of interest were the length of hospital stay>the median, total hospital charges>the median, inpatient mortality, non-routine discharge, need for blood transfusion, prosthetic fracture, prosthetic dislocation and postprocedural infection, including periprosthetic joint infection, deep surgical site infection and postprocedural sepsis.

Results Among 2 467 215 patients who underwent primary THA, the mean age was 68.7 years, 58.3% were female, 85.7% were white, 61.7% had Medicare payer and 20.4% had a Deyo-Charlson index (adjusted to exclude diabetes mellitus) of 2 or higher. 416 850 (17%) patients had diabetes. In multivariable-adjusted logistic regression in the overall cohort, diabetes was associated with higher odds of a longer hospital stay (adjusted OR (aOR) 1.38; 95% CI 1.35 to 1.41), higher total charges (aOR 1.11; 95% CI 1.09 to 1.13), non-routine discharge (aOR 1.18; 95% CI 1.15 to 1.20), the need for blood transfusion (aOR 1.19; 95% CI 1.15 to 1.23), postprocedural infection (aOR 1.62; 95% CI 1.10 to 2.40) and periprosthetic joint infection (aOR 1.91; 95% CI 1.12 to 3.24). We noted a lack of some associations in the avascular necrosis and inflammatory arthritis cohorts (p>0.05).

Conclusion Diabetes was associated with increased healthcare utilisation, blood transfusion and postprocedural infection risk following primary THA. Optimisation of diabetes with preoperative medical management and/or institution of specific postoperative pathways may improve these outcomes. Larger studies are needed in avascular necrosis and inflammatory arthritis cohorts undergoing primary THA.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Our study uses the most current National Inpatient Sample (NIS) data, which uses International Classification of Diseases, 10th Revision coding, offering the most accurate and comprehensive view of total hip arthroplasty (THA) hospitalisations across the USA, ensuring broad applicability and relevance of our findings.

⇒ The NIS does not have a present-on-admission indicator so we only included postoperative complications that were specifically listed as postprocedural or initial encounters, ensuring that we did not include preoperative existing conditions or old diagnoses as postoperative complications.

⇒ Our study stratifies by the underlying condition for THA, allowing for nuanced analysis of trends and outcomes within groups and within the overall US population.

⇒ This is an observational study and therefore none of the associations can be assumed to be causal, and all findings must be interpreted accordingly.

⇒ The NIS does not include federal military or Veteran's hospitals so findings may not be applicable to these populations.

INTRODUCTION

Primary total hip arthroplasty (THA) is an effective surgical treatment for end-stage hip joint disease[1]; its utilisation is increasing.[2] As the obesity epidemic continues and the US population ages, obesity-related chronic conditions such as diabetes mellitus are becoming more common. It is important to understand the impact of diabetes on THA outcomes. Studies have shown that comorbidities, such as diabetes, may increase the risk of adverse outcomes including infections, thromboembolism, fracture and death,[3–5] given altered osteoblast and osteoclast function in people with diabetes.

Previous retrospective studies examined primary total knee arthroplasty (TKA) and primary THA outcomes in people with diabetes.[6–8] Diabetes was associated with

higher short-term complications after THA in some studies,[7 8] but not in others.[6] The relevance to current THA populations is limited since data were examined only up to 2005,[6–8] some studies combined TKA and THA populations,[6 8] and one study only examined California state data.[7] In a systematic review of observational studies to 2011, diabetes was associated with increased risk of surgical site infections, based on 50 infections in people with diabetes undergoing THA.[9] A recent 2023 American College of Rheumatology and American Academy of Hip and Knee Surgeons (AAHKS/ACR) guideline for optimal timing of elective THA indicated that THA may be conditionally delayed to improve glycaemic control in diabetes, to improve outcomes, but this was based on low-quality evidence.[10] Given the evidence gap, we need updated robust analyses of representative data with large sample to examine this question. The glycaemic control in diabetes may be worse in people with associated conditions such as osteoarthritis or inflammatory arthritis,[11–13] which might lead to an increased risk of postoperative complications by the underlying diagnosis of THA. In this study, we used the US National Inpatient Sample (NIS), a large, nationally representative database. We assessed the effect of diabetes on the healthcare utilisation and clinical outcomes of all-comers who underwent primary THA and compared the impact of diabetes on these outcomes, with the overall sample stratified by the underlying primary indication for primary THA.

METHODS

Data source

We used data from the NIS published by the Agency for Healthcare Research and Quality Healthcare Cost and Utilisation Project (HCUP) from 2016 to 2020.[14] The NIS is the largest all-payer inpatient database publicly available in the USA. It consists of over 7 million inpatient stays, a 20% stratified sample of all discharges from US hospitals from 49 states, representing 98% of the US population. The NIS contains information on all hospital stays, regardless of payer. Using sample weights, the NIS can be used to provide national estimates. For each discharge, International Classification of Diseases, 10th Revision (ICD-10) clinical modification (ICD-10-CM) codes and procedure coding system (ICD-10-PCS) codes are available.[14] All authors who accessed the NIS data filled out the appropriate HCUP Data Use Agreements (DUA). We prepared our manuscript in accordance with the Equator Network's The Strengthening the Reporting of Observational Studies in Epidemiology guidelines.

Study cohort

We identified primary THA in adults using the ICD-10-PCS codes for the primary procedure code including any of the following: 0SR9*, 0SRA*, 0SRB*, 0SRE*, 0SRR* and 0SRS*.[15–17] We determined the underlying arthritis/joint disease condition using ICD-10-CM codes in the primary position. Diabetes was identified using

ICD-10-CM codes in the secondary diagnosis position: E10*, E11* and E13*.[18–20] We excluded patients with the following primary underlying diagnoses for primary THA that were unlikely to be correct: periprosthetic fracture around internal prosthetic joint (M97*); intraoperative and postoperative complications, not classified elsewhere (M96*); medical and surgical care, not elsewhere classified (T80–T88*); sepsis/infections (A40*, A41*, A69*) or orthopaedic aftercare (Z47*).

Study outcomes and covariates

Outcomes of interest were healthcare utilisation outcomes: length of hospital stay (LOS), total charges, discharge disposition, mortality and postoperative outcomes using the initial encounter with an ICD-10-CM codes for the following: blood transfusions, prosthetic dislocation, prosthetic fracture, postprocedural infections, periprosthetic joint infections (PJIs), deep surgical site infections and postprocedural sepsis (online supplemental table 1; see ICD-10 codes). Due to a lack of present-at-admission indicators in the NIS, we only included the ICD-10-CM codes for periprocedural or for an initial encounter for the listed postoperative outcomes to ensure that no chronic or preoperative occurrences of these complications were included. Most healthcare utilisation variables have been clearly defined by the NIS. The hospital length of stay (LOS) and total hospital charges were categorised by the cohort median, as previously.[21–23] Inpatient mortality was defined as patients who died during hospitalisation, as per the NIS documentation.[14] Discharge disposition was dichotomised to routine (i.e, to home) and non-routine discharge from the hospital.

Statistical analyses

We used complex weighting procedures to produce nationally representative estimates in accordance with HCUP guidelines.[14] We calculated the utilisation rates (%) of primary THA for adults with diabetes. We assessed time trends across diabetes prevalence among all primary THA across years using the Cochran Armitage test. Due to the COVID-19 pandemic and the associated decrease in primary THA in 2020, we used 2016–2019 for time-trend analyses. We assessed trends in outcomes in people with diabetes who underwent primary THA across these years, using χ^2 tests on categorical data and Wilcoxon tests for continuous variables. We performed multivariable-adjusted regression analyses to examine the association of diabetes with healthcare utilisation and clinical outcomes after primary THA, adjusted for age, sex, race, expected primary payer, Deyo-Charlson Comorbidity Index score, median household income for ZIP code, elective versus non-elective admission, and hospital bed size, control/ownership, census region, and teaching status. The Deyo-Charlson Index is a weighted medical comorbidity index derived from administrative databases that is associated with important outcomes after hospitalisation.[24] It includes myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease,

dementia, chronic pulmonary disease, rheumatic disease, peptic ulcer disease, liver disease (mild), renal disease (mild to moderate), hemiplegia or paraplegia, any malignancy, liver disease (moderate to severe), renal disease (severe), HIV infection (no AIDS), metastatic solid tumour, AIDS, diabetes and diabetes with chronic complications. ICD-10 codes and weights used to represent severity for each condition followed previously published guidelines.[25] We used a modified Deyo-Charlson index excluding diabetes and diabetes with chronic complications to avoid double-counting. We calculated ORs and 95% CIs. We considered all p values <0.05 as statistically significant. We used SPSS V.29 and R V.4.3.1 (Vienna, Austria) to perform these analyses.

Patient and public involvement
None.

RESULTS

COHORT CHARACTERISTICS
Between 2016 and 2020, 2 467 215 patients underwent primary THA, of whom 416 850 (17%) patients had diabetes (table 1). The mean age of patients undergoing THA was 68.7 years, 58.3% were female, 85.7% were white, 61.7% had Medicare payer and 15% had a Deyo-Charlson index of two or higher (online supplemental table 2). The underlying diagnoses were hip osteoarthritis (OA; N=1 761 960; 71.4%), traumatic fracture (N=532 910; 21.6%), avascular necrosis (AVN; N=78 275; 3.2%) and inflammatory arthritis (IA; N=3520; 0.1%) (includes rheumatoid arthritis (RA), spondylarthritis, including ankylosing spondylitis and psoriatic arthritis), and other diagnoses (N=90 550; 3.7%; online supplemental table 2). The median LOS was 2 days and median total hospital charges were US$56 891. There were slight changes in outcomes over time in the overall cohort (online supplemental table 3).

Comparing to patients without diabetes, patients with diabetes were on average 2.5 years older (70.8 vs 68.3 years; table 1), a lower proportion was female (53.7% vs 59.2%), white (79.9% vs 86.9%) and had an underlying diagnosis of OA (64.8% vs 72.6%). The cohort with diabetes had a higher proportion of people with a modified Deyo-Charlson score ≥2 (23.7% vs 12.9%), and the cohort with diabetes a higher mean Deyo-Charlson comorbidities, and Medicare as the primary payer (70.3% vs 60.0%; table 1). Hospital characteristics were similar in both patients with and without diabetes, but a higher proportion of people with diabetes were hospitalised in the South region (38.5% vs 34.7%; online supplemental table 4).

The crude rate of outcomes was worse in the diabetes cohort, who had a longer median hospital stay (3 days vs 2 days), higher median hospital charges

Table 1 Patient characteristics of patients undergoing primary THA 2016–2020, stratified by the presence of diabetes mellitus

	Patients with diabetes mellitus (N=416 850; 17%)	Patients without diabetes mellitus (N=2 050 365; 83%)
Age in years, mean (SD)	70.8 (10.8)	68.3 (12.5)
Sex, N (%)		
Male	193 165 (46.3)	835 655 (40.8)
Female	223 650 (53.7)	1 214 525 (59.2)
Race/ethnicity, N (%)		
White	322 605 (79.9)	1 719 900 (86.9)
Black	43 055 (10.7)	128 415 (6.5)
Hispanic	22 115 (5.5)	71 300 (3.6)
Asian or Pacific Islander	6585 (1.6)	20 395 (1.0)
Other	9450 (2.3)	39 880 (2.0)
Underlying diagnosis, N (%)		
Osteoarthritis	270 470 (64.8)	1 491 490 (72.7)
Avascular necrosis	9795 (2.3)	68 480 (3.3)
Traumatic fracture	118 345 (28.4)	414 564 (20.2)
Inflammatory arthritis*	520 (0.1)	3000 (0.1)
Other	17 720 (4.3)	72 830 (3.6)
Deyo-Charlson Comorbidity Index, N (%)		
0	199 935 (48.0)	1 315 355 (64.2)
1	118 165 (28.3)	471 430 (23.0)
≥2	98 750 (23.7)	263 580 (12.9)
Primary expected payer, N (%)		
Medicare	292 540 (70.3)	1 227 735 (60.0)
Medicaid	17 660 (4.2)	95 055 (4.6)
Private insurance, self-pay, no charge, or other	106 165 (25.5)	724 815 (35.4)
Median household income for ZIP code, N (%)		
0–25th percentile	104 880 (25.5)	407 285 (20.2)
26th–50th percentile (median)	112 980 (27.5)	514 290 (25.4)
51st–75th percentile	105 870 (25.8)	541 505 (26.8)
76th–100th percentile	86 905 (21.2)	557 750 (27.6)
Elective versus non-elective admission, N (%)		
Non-elective admission	134 530 (32.3)	484 415 (23.7)

Continued

Table 1 Continued

	Patients with diabetes mellitus (N=416 850; 17%)	Patients without diabetes mellitus (N=2 050 365; 83%)
Elective admission	281 615 (67.7)	1 563 040 (76.3)

*The presence of one or more of the following conditions based on the respective ICD-10 codes: rheumatoid arthritis, spondyloarthritis including ankylosing spondylitis and/or psoriatic arthritis.
ICD-10, International Classification of Diseases, 10th Revision; THA, total hip arthroplasty.

Figure 1 Time-trends in the underlying diagnosis of primary THA among people with diabetes mellitus. The number of total primary THA and those with underlying diagnosis of osteoarthritis decreased in 2020, as expected during the early phase of COVID-19 pandemic in 2020, among people with diabetes mellitus. All other underlying diagnoses for THA were stable in numbers across 2016–2020. THA, total hip arthroplasty.

(US$60 006 vs US$56 279), and higher rates of non-routine discharge (73.5% vs 65.4%; table 2). The crude rates of blood transfusion and each prosthetic complication were numerically higher in diabetes versus non-diabetes cohort (table 2).

Time trend analysis

We noticed a slight, consistent increase in the proportion of patients with diabetes among the entire cohort who underwent primary THA between 2016 and 2020: 16.08% in 2016, 16.67% in 2017, 16.70% in 2018, 17.08% in 2019 and 18.46% in 2020, an absolute increase of 0.98% between 2016 and 2019, which was statistically significant (p<0.001; online supplemental table 5).

Between 2016 and 2019, among people with diabetes, the number of people with OA as an underlying diagnosis increased slightly, and as expected during the COVID-19 pandemic in 2020, it decreased in parallel to the overall number undergoing primary
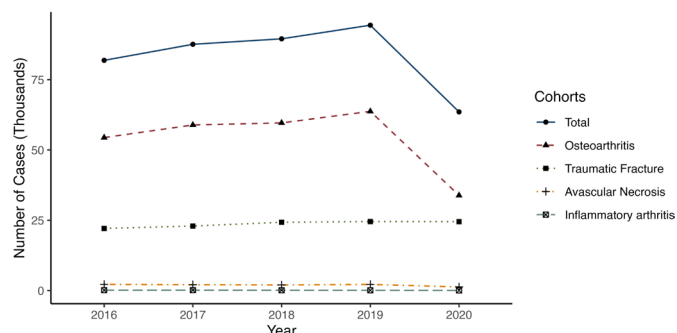
THA (figure 1; online supplemental table 5). The rates for IA, AVN, traumatic fracture and other diagnoses stayed stable across 2016–2020 (figure 1).

Compared to those without diabetes, in patients with diabetes, we noticed significantly shorter median hospital LOS, 3 vs 2 days (−33.3; p<0.001), and lower rates of non-routine discharge, 76.7% vs 70.1% (−8.4%; p<0.001 and the need for blood transfusion, 7.1% vs 4.8% between 2016–2019 (−32.7%; p<0.001; table 3). We also noted significantly higher total hospital charges, US$56 561 vs US$60 143 (6.3% higher; p<0.001), and higher rates of prosthetic fracture, 0.7% vs 1.3% (90.2% higher; p<0.001) and post-procedural infection, 0.6% vs 1.1% (89.8% higher; p<0.001; table 3), respectively.

Table 2 Unadjusted differences in outcomes in people with versus without diabetes mellitus

	Patients with diabetes mellitus (N=416 850; 17%)	Patients without diabetes mellitus (N=2 050 365; 83%)
Length of hospital stay in days, median (IQR)	3 (2–4)	2 (1–3)
Total hospital charges in $, median (IQR)	60 006.0 (42 817.3–87 373.0)	56 279.0 (40 378.0–80 944.0)
Inpatient mortality, N (%)	2200 (0.5)	7140 (0.4)
Non-routine discharge, N (%)	306 315 (73.5)	1 340 755 (65.4)
Complications (initial visit), N (%)		
Need for blood transfusion	24 850 (6.0)	81 105 (4.0)
Prosthetic fracture	4110 (1.0)	19 095 (0.9)
Prosthetic dislocation	980 (0.24)	4290 (0.21)
Post-procedural infection*	215 (0.03)	410 (0.02)
Periprosthetic joint infection (PJI)	130 (0.03)	240 (0.01)
Deep surgical site infection (SSI)	15 (0.004)	*
Post-procedural sepsis	70 (0.02)	155 (0.01)

*Postprocedural infection included the presence of one or more of the following conditions based on the respective ICD-10 codes: PJI, deep SSI and/or postprocedural sepsis.
ICD-10, International Classification of Diseases, 10th Revision.

Table 3 Time-trends in postprimary THA outcomes in people with diabetes mellitus from 2016 to 2020

	All patients	Study time periods					Comparison of 2019–2016	
	2016–2020	2016	2017	2018	2019	2020	Last–first period (% difference)	P value*
Length of hospital stay in days, median (IQR)	3 (2–4)	3 (2–4)	3 (2–4)	2 (1–4)	2 (1–4)	3 (1–5)	**–33.3%**	**<0.001**
Total hospital charges in $, median (IQR)	60 006.0 (42 817.3–87 373.0)	56 561.0 (41 441.0–81 954.0)	57 593.0 (41 522.0–82 790.0)	59 690.0 (42 731.0–86 601.0)	60 143.0 (42 798.0–88 911.0)	67 938.0 (47 422.0–100 943.3)	**6.3%**	**<0.001**
Non-routine discharge, N (%)	306 315 (73.5)	62 640 (76.7)	64 955 (74.2)	64 870 (72.5)	66 155 (70.1)	47 965 (75.1)	**–8.4%**	**<0.001**
Inpatient mortality, N (%)	2200 (0.5)	430 (0.5)	450 (0.5)	420 (0.5)	365 (0.4)	535 (0.8)	–26.4%	0.06
Complications (initial visit), N (%)								
Need for blood transfusion	24 850 (6.0)	5850 (7.1)	5290 (6.0)	5330 (6.0)	4540 (4.8)	3840 (6.0)	**–32.7%**	**<0.001**
Prosthetic fracture	4110 (1.0)	480 (0.6)	760 (0.9)	860 (1.0)	1050 (1.1)	960 (1.5)	**89.8%**	**<0.001**
Prosthetic dislocation	980 (0.2)	180 (0.2)	170 (0.2)	230 (0.2)	200 (0.2)	200 (0.3)	–3.6%	0.87
Postprocedural Infection†	215 (0.05)	15 (0.02)	35 (0.04)	50 (0.06)	60 (0.06)	55 (0.06)	**247.1%**	**0.04**
Periprosthetic joint infection (PJI)	130 (0.03)	15 (0.02)	35 (0.04)	25 (0.03)	25 (0.03)	30 (0.05)	44.6%	0.61
Deep surgical site infection (SSI)	15 (0.004)							
Postprocedural sepsis	70			20 (0.02)	30 (0.03)	20 (0.03)		

Bold font in the last tow columns titled Last–first period (% difference) and p-value indicate statistically significant changes with a p-value of <0.05
*Significant p values are bolded.
†Postprocedural infection included the presence of one or more of the following conditions based on the respective ICD-10 codes: PJI, deep SSI and/or postprocedural sepsis.
‡Unable to be shown or calculated due to HCUP guidelines (cells with values less than 20 can not be presented).
HCUP, Healthcare Cost and Utilisation Project; ICD-10, International Classification of Diseases, 10th Revision; THA, total hip arthroplasty.

All these trends were seen in the overall cohort, except that inpatient mortality decreased non-significantly in the DM cohort (0.5% vs 0.4%; –26.4%; p=0.06) and decreased significantly in the overall primary THA cohort (0.4% vs 0.3%; –26.6%; p<0.001; online supplemental table 3).

Multivariable-adjusted analysis
In multivariable-adjusted regression in the overall cohort, diabetes was associated with higher adjusted odds of a longer hospital stay, higher hospital charges, non-routine discharge, the need for blood transfusion, postprocedural infection and PJI (table 4; online supplemental figure 1).

In the OA cohort, we replicated all significant associations from the overall cohort except for the increased risk of postprocedural infection and PJI (online supplemental table 6). The traumatic fracture cohort showed all the associations as noted in the total cohort except postprocedural infection, and PJI; interestingly, and only in this cohort, diabetes was associated with a decreased risk of prosthetic fracture and prosthetic dislocation. In the AVN cohort,

diabetes was only associated with an increased risk of a longer hospital stay and non-routine discharge (online supplemental table 6). We noted no significant associations in the inflammatory arthritis cohort that had the smallest sample size of 3520 (online supplemental table 6). Sensitivity analysis that additionally adjusted for the underlying diagnosis of THA confirmed all findings (online supplemental table 7).

DISCUSSION
We used contemporary nationally representative US data to examine outcomes in people with diabetes undergoing primary THA. We used an approach that allowed us to exclude historic/past complications. The 2023 ACR and AAHKS Clinical Practice Guideline for optimal timing of TJA for moderate to severe osteoarthritis recommends delaying surgery for candidates with poorly controlled diabetes as this patient population has increased risk of poor outcomes, including increased LOS, following TJA, but the recommendation was conditional and based on low quality evidence.[10 26] Our study fills this important

Table 4 Multivariable-adjusted association* of diabetes mellitus with postprimary THA outcomes from NIS 2016–2020, overall cohort

	All diagnoses (N=2 467 215)	
	aOR (95% CI)§	P value§
Length of hospital stay above the median (>2 days))	**1.38 (1.35 to 1.41)**	**<0.001**
Total hospital charges above the median (>US$58 002)	**1.11 (1.09 to 1.13)**	**<0.001**
Non-routine discharge	**1.18 (1.15 to 1.20)**	**<0.001**
Inpatient mortality	0.96 (0.86 to 1.08)	0.48
Need for blood transfusion	**1.19 (1.15 to 1.23)**	**<0.001**
Prosthetic fracture	0.94 (0.86 to 1.01)	0.10
Prosthetic dislocation	1.00 (0.85 to 1.17)	0.96
Post-procedural infection†	**1.62 (1.10 to 2.40)**	**0.02**
Periprosthetic joint infection (PJI)	**1.91 (1.12 to 3.24)[a]**	**0.02**
Deep surgical site infection (SSI)	‡	
Postprocedural sepsis	1.27 (0.68 to 2.36)[a]	0.46

*Multivariable-adjusted model includes age, sex, census region of hospital, race, hospital teaching status, median household income for ZIP code, expected primary payer, Deyo-Charlson score, hospital bed size, elective versus non-elective admission and control/ownership of hospital. Each of the following variables was removed from multivariable regression due to quasi-complete separation, which persisted even after dichotomisation of the variable: (a) race; (b) elective admission; (c) hospital location/teaching status; (d) expected primary payer; (e) hospital control/ownership; (f) Deyo-Charlson Comorbidity Index; (g) Hospital Census Region and (h) median household income for ZIP code.
†Includes PJI, deep SSI and postprocedural sepsis.
‡Multivariate regression could not be performed reliably due to quasi-complete separation which persisted even after the removal of several variables.
§Bold font indicates statistically significant differences with a p-value of <0.05
aOR, adjusted OR; NIS, National Inpatient Sample; THA, total hip arthroplasty.

knowledge gap. To our knowledge, this is among the first studies to assess the impact of diabetes on primary THA outcomes in a nationally representative sample, stratified by the underlying diagnosis. The proposed mechanisms for these poor outcomes infections in patients with diabetes include intraoperative physiological stress for diabetes-induced complications, extended LOS[10 27] and impaired wound healing resulting in increased incidence of surgical site infections.[28]

Previous studies that reported an association of diabetes with poor THA outcomes had several limitations in that they (1) were single-centre studies,[29–32] (2) used non-nationally representative data sets[7] or (3) used ICD-9 codes[6 8 33–35] and most used non-recent data. Studies of postoperative complications that used ICD-9 codes are limited since ICD-9 codes do not allow differentiation between complications associated with the index hospitalisation versus pre-existing diagnoses and conditions in the US NIS. Our study limited analyses of postoperative complications to only those specified by an ICD-10-procedure code or those with ICD-10-diagnosis code for initial encounter, to avoid erroneously counting prior diagnoses and procedures as postindex primary THA complications. We also excluded primary THA cases with erroneous codes for primary underlying diagnosis of primary THA, such as periprosthetic fractures. Due to the limitations of previous analyses, and an increasing prevalence of diabetes with high rates of undiagnosed diabetes,[36 37] updated analyses are needed. Our study has several significant findings of interest that warrant further discussion.

In a population-based Danish study, revision rate due to deep infection was higher in people with diabetes, with an OR of 1.45 (95% CI 1.00 to 2.09) and in those with diabetes with complications, 2.11 (95% CI 1.00 to 2.09) at maximum follow-up of 11 years.[38] In a systematic review of observation studies to 2011, based on 50 infections in people with diabetes undergoing THA (two single-centre, retrospective studies, including 1967–1980 and 1997–2007 periods)[32 39] and one population-based study from 1996 to 2005,[38] diabetes was associated with increased risk of surgical site infections with an OR of 2.04 (95% CI 1.52, 2.76).[9] In our study based on 3255 postprocedural infections in 2 467 215 hospitalisations for primary THA, diabetes was associated with 1.62 times odds of postprocedural infection (included PJI, deep SSI and postprocedural sepsis) and 1.91 times odds of PJI. Our study quantifies the infection risk associated with diabetes in a contemporaneous nationally representative primary THA population. It also confirms early findings from primarily single-centre studies with small sample sizes and extends it to a national sample of primary THA in the USA. Thus, our study adds to the growing evidence of this link and indicates that this should be incorporated into clinical decision-making. The 2023 ACR/AAHKS Clinical Practice Guidelines recommend that diabetes be well managed based on the clinician's assessment and do not specify a particular threshold for glycaemic control.[10] The guidelines acknowledge insufficient evidence in the literature to support specific measurement limits for glycaemic control.[10]

We found that diabetes was associated with a longer hospital stay (>2 days) and non-home discharge in the overall cohort with ORs of 1.38 and 1.18, respectively, and for each underlying diagnosis (OA, fracture, AVN), except for the IA cohort. Similar associations were noted for total hospital charges above the median. Diabetes was associated with an unadjusted 0.7-day longer hospital stay compared with those without diabetes, similar to a finding from the US National Surgical Quality Improvement Programme data findings of a difference of 0.3 days

in THA.[40] Diabetes is associated with delayed wound healing[41 42] and increased risk of other medical comorbidities,[43 44] which is a risk factor for major postoperative complications[45]—both can lead to increased LOS and non-home discharge postprimary THA.

We included all-comers with diabetes, that is, type 1 and type 2 diabetes mellitus, similar to previous studies.[6 46] We used the following ICD-10 codes: E10*, type 1 diabetes mellitus, E11*, type 2 diabetes mellitus and E13*, Other specified diabetes mellitus. We combined these codes because of the similar pathophysiology for infection risk, wound healing and some of the other systemic effects of hyperglycaemia. Both type 1 and type 2 diabetes have similar risks of chronic inflammation, immune dysregulation and impaired glucose control, contributing to similar complications across both types.[8 47]

We found that diabetes was associated with increased blood transfusion risk, overall and in the OA and fracture cohorts. This adds to the current knowledge. This can be attributed to the association of diabetes with anaemia,[48–51] slow wound healing[41 42] and higher rates of postoperative anaemia[52] due to potentially more intraoperative blood loss. The mechanisms of anaemia in people with diabetes are multifactorial that include renal insufficiency, low erythropoietin levels, nutritional deficiency, associated autoimmune diseases and iatrogenic causes (oral antidiabetic drugs, ACE inhibitors and ARBs).[48 53 54] The anaemia associated with diabetes is responsive to treatment[54]; optimising nutritional deficiencies and erythropoietin levels prior to primary THA may reduce the effects of anaemia and the need for blood transfusion.

The lack of some overall diabetes–outcomes associations in the AVN and IA cohort indicates that the underlying diagnosis and pathophysiology likely impact the risk of diabetes-associated complications. The IA cohort was small, and the analysis was likely underpowered, despite including US national data. Future studies of large multi-nation registry data across may be needed to address outcomes in these groups.

In our THA cohort, diabetes had a prevalence of 17%, similar to its prevalence in older adults (≥65 years) and in TKA populations,[55 56] but higher than that reported in previous studies of THA.[8 9] Increasing rates of diabetes in the US THA populations have been reported by Bolognesi et al[6] and Marchant et al[8] who used data from 1988 to 2003 and 1988 to 2005 NIS data, respectively. The prevalence of diabetes in THA cohort is twice its prevalence in the general population.[56] Diabetes is associated with an increased risk of OA (most common underlying diagnosis of THA), AVN, RA and hip fractures,[57–59] which partially explain the enriching of THA population for diabetes.

Our study has various strengths. We used the most up-to-date NIS data, which is a nationally representative sample of THA hospitalisations in the USA. We only included postoperative complications that were specifically listed as postprocedural or initial encounters. The NIS has no present-at-admission indicators, and secondary diagnosis listing is not limited to initial encounters only. Therefore,

limiting postoperative complications to initial encounter diagnoses only was a critical step in preventing the inclusion of pre-existing conditions as complications. We included multiple cohorts by the underlying diagnoses and compared the outcomes among these, allowing additional insights.

Our study findings should be interpreted considering several limitations. The NIS is an observational database. Therefore, relationships cannot be deemed as causal, but rather only as an association. This is because observational data does not allow evidence to establish causality, as opposed to a randomised trial. Observational studies such as ours are unable to control for all potential confounding variables leaving the possibility of residual confounding. Results should be interpreted with caution. The NIS does not include federal military, or Veteran's hospitals, which leads to a challenge with generalisability to these populations. The NIS treats each hospitalisation as separate, therefore, bilateral THA may be counted as unilateral. Since simultaneous bilateral THA is <1% of all THA cases, this bias is negligible. There may be variation in coding of conditions, especially for secondary diagnoses, which can lead to misclassification bias both for outcomes and for Deyo-Charlson comorbidity index. The NIS has no longitudinal data, limiting the study of long-term outcomes.

In conclusion, diabetes was an independent risk factor for clinical and healthcare utilisation outcomes after primary THA in a contemporary US cohort. Given the high prevalence of diabetes and the ongoing obesity epidemic, the impact is significant. Studies need to examine if preoperative optimisation of diabetes achieved in those undergoing elective primary THA can potentially reduce these risks and improve outcomes. Preoperative management of high-risk patients with diabetes and multicomorbid conditions may be least resource-intensive and most rewarding. Interventional trials are needed in patients with diabetes undergoing primary THA to test effectiveness of interventions to improve THA outcome.

Competing interests JAS has received consultant fees from ROMTech, Atheneum, Clearview healthcare partners, American College of Rheumatology, Yale, Hulio, Horizon Pharmaceuticals/DINORA, ANI/Exeltis, USA Inc., Frictionless Solutions, Schipher, Crealta/Horizon, Medisys, Fidia, PK Med, Two labs Inc., Adept Field Solutions, Clinical Care options, Putnam associates, Focus forward, Navigant consulting, Spherix, MedIQ, Jupiter Life Science, UBM LLC, Trio Health, Medscape, WebMD, and Practice Point communications; the National Institutes of Health; and the American College of Rheumatology. JAS has received institutional research support from Zimmer Biomet Holdings. JAS received food and beverage payments from Intuitive Surgical Inc./Philips Electronics North America. JAS owns stock options in Atai life sciences, kintara therapeutics, Intelligent Biosolutions, Acumen pharmaceutical, TPT Global Tech, Vaxart pharmaceuticals, Atyu biopharma, Adaptimmune Therapeutics, GeoVax Labs, Pieris Pharmaceuticals, Enzolytics Inc., Seres Therapeutics, Tonix Pharmaceuticals Holding Corp., and Charlotte's Web Holdings, Inc. JAS previously owned stock options in Amarin, Viking and Moderna pharmaceuticals. JAS is on the speaker's bureau of Simply Speaking. JAS was a member of the executive of Outcomes Measures in Rheumatology (OMERACT), an organization that develops outcome measures in rheumatology and receives arms-length funding from 8 companies. JAS serves on the FDA Arthritis Advisory Committee. JAS is the co-chair of the Veterans Affairs Rheumatology Field Advisory Board (FAB). JAS is the editor and the Director of the University of Alabama at Birmingham (UAB) Cochrane Musculoskeletal Group Satellite Center on Network Meta-analysis. JAS previously served as s a member of the following committees: member, the American College of Rheumatology's (ACR) Annual Meeting Planning Committee (AMPC) and Quality of Care Committees, the Chair of the ACR Meet-the-Professor, 21 Workshop and Study Group Subcommittee and the co-chair of the ACR Criteria and Response Criteria subcommittee. SC and KCR have no conflicts of interest.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study was approved by the Institutional Review Board at University of Alabama at Birmingham (X120207004). All patient data are deidentified and are reported according to the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilisation Project (HCUP) guidelines.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data may be obtained from a third party and are not publicly available. The authors cannot provide the data used in the study. The NIS is published online by the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilisation Project (HCUP) and is available for purchase at https://hcp-us.asrq.gov/.

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Supplemental Table 1. Underlying conditions and post-operative complications of interest and the corresponding ICD-10 codes

ICD-10 Code	Description
Primary THA Codes	
0SR9	Replacement of Hip Joint, Right
0SRA	Replacement of Hip Joint, Acetabular Surface, Right
0SRB	Replacement of Hip Joint, Left
0SRE	Replacement of Hip Joint, Acetabular Surface, Left
0SRR	Replacement of Hip Joint, Femoral Surface, Right
0SRS	Replacement of Hip Joint, Femoral Surface, Left
Diabetes Mellitus Diagnosis Codes	
E10	Type 2 diabetes mellitus
E11	Type 2 diabetes mellitus
E13	Other specified diabetes mellitus
Underlying Condition Codes	
Osteoarthritis (OA)	
M16	Osteoarthritis of hip
Avascular necrosis (AVN)	
M87	Osteonecrosis
Traumatic Fracture:	
S720	Fracture of head and neck of femur
S721	Per trochanteric fracture

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S722	Subtrochanteric fracture of femur
inflammatory Arthritis (IA)	
M45	Ankylosing spondylitis
M0765	Enteropathic arthropathies, hip
L405	Arthropathic psoriasis
M05	Rheumatoid arthritis with rheumatoid factor
M06	Other rheumatoid arthritis
M460	Spinal enthesopathy
M461	Sacroiliitis, not elsewhere classified
M468	Other specified inflammatory spondylopathies
Post-Operative Complication Codes for the index primary THA	
Blood Transfusion	
30233N1	Transfusion of Non-autologous Red Blood Cells into Peripheral Vein, Percutaneous Approach
Prosthetic Fracture	
T84010A	Broken internal right hip prosthesis, initial encounter
T84011A	Broken internal left hip prosthesis, initial encounter
T84018A	Broken internal joint prosthesis, other site, initial encounter
T84019A	Broken internal joint prosthesis, unspecified site, initial encounter
M9665	Fracture of pelvis following insertion of orthopedic implant, joint
M96661	Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate right leg

M96662	Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate left leg
M96669	Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate unspecified leg
M9701XA	Periprosthetic fracture around internal prosthetic right hip joint, initial encounter
M9702XA	Periprosthetic fracture around internal prosthetic left hip joint, initial encounter
Prosthetic Dislocation	
T84020A	Dislocation of internal right hip prosthesis, initial encounter
T84021A	Dislocation of internal left hip prosthesis, initial encounter
T84028A	Dislocation of other internal joint prosthesis, initial encounter
T84029A	Dislocation of unspecified internal joint prosthesis, initial encounter
Post Procedural Infection	
Deep surgical site infection	
T8142XA	Infection following a procedure, deep incisional surgical site, initial encounter
Post-procedural sepsis	
T8144XA	Sepsis following a procedure, initial encounter
Periprosthetic joint infection	
T8450XA	Infection and inflammatory reaction due to unspecified internal joint, initial encounter
T8451XA	Infection and inflammatory reaction due to internal right hip prosthesis, initial encounter
T8452XA	Infection and inflammatory reaction due to internal left hip prosthesis, initial encounter
T8459XA	Infection and inflammatory reaction due to other internal joint prosthesis, initial encounter

Supplemental Table 2. Characteristics of all patients undergoing primary THA from 2016-2020

	All Patients (N=2,467,215)
Age in years, mean (SD)	68.7 (12.3)
Sex, N (%)	
Male	1,028,820 (41.7)
Female	1,438,175 (58.3)
Race/Ethnicity, N (%)	
White	2,042,505 (85.7)
Black	171,470 (7.2)
Hispanic	93,415 (3.9)
Asian or Pacific Islander	26,980 (1.1)
Other	49,330 (2.1)
Underlying Diagnosis, N (%)	
Osteoarthritis	1,761,960 (71.4)
Traumatic Fracture	78,275 (3.2)
Avascular Necrosis	532,910 (21.6)
Inflammatory Arthritis[1]	3,520 (0.1)
Other	90,550 (3.7)
Deyo-Charlson Comorbidity Index, N (%)	
0	1,515,290 (61.4)
1	589,595 (23.9)
≥2	362,330 (14.7)
Primary Expected Payer, N (%)	

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Medicare	1,520,275 (61.7)
Medicaid	112,715 (4.6)
Private Insurance, self-pay, no charge or other	830,980 (33.7)
Median Household Income for ZIP Code, N (%)	
0-25th percentile	512,165 (21.1)
26th-50th percentile (median)	627,270 (25.8)
51st to 75th percentile	647,375 (26.6)
76th to 100th percentile	644,655 (26.5)
Elective versus non-elective admission, N (%)	
Non-Elective Admission	618,945 (25.1)
Elective Admission	1,844,655 (74.9)
Hospital Bed size, N (%)	
Small	727,980 (29.5)
Medium	693,605 (28.1)
Large	1,045,630 (42.4)
Census Region of Hospital, N (%)	
Northeast	478,000 (19.4)
Midwest	611,936 (24.8)
West	871,215 (35.3)
South	506,064 (20.5)
Location/teaching status of hospital, N (%)	
Rural	221,865 (9.0)

Urban nonteaching	610,150 (24.7)
Urban teaching	1,635,199 (66.3)
[1]includes rheumatoid arthritis, spondyloarthritis, ankylosing spondylitis and psoriatic arthritis	

Supplemental Table 3. Time-trends in all Post-primary THA outcomes from 2016-2020

	All Patients	Study Time Periods					Comparison of 2019 to 2016	
	2016-2020	2016	2017	2018	2019	2020	Last–first period (% difference)	p-value
Length of hospital stay in days, median (IQR)	2 (1-3)	2 (2-3)	2 (1-3)	2 (1-3)	2 (1-3)	2 (1-4)	0%	*
Total hospital charges in $, median (IQR)	56,891.0 (40,766.8-82,031.0)	54,350.5 (39,517.0-77,111.5)	55,134.0 (40,036.0-78,659.0)	56,732.0 (40,421.0-81,591.0)	57,723.5 (41,135.0-83,707.0)	54,350.5 (39,517-77,111.5)	**6.2%**	**<0.001**
Non-routine discharge, N (%)	1,647,070 (66.8)	354,780 (69.7)	355,770 (67.8)	351,500 (65.6)	349,835 (63.3)	235,185 (68.3)	**-9.2%**	**<0.001**
Inpatient mortality, N (%)	9,340 (0.4)	2,020 (0.4)	1,800 (0.3)	1,795 (0.3)	1,610 (0.3)	2,115 (0.6)	**-26.6%**	**<0.001**
Complications (Initial Visit), N (%)								
Need for blood transfusion	105,955 (4.9)	26,170 (5.1)	23,580 (4.5)	21,425 (4.0)	19,040 (3.4)	15,740 (4.6)	**-32.9%**	**<0.001**
Prosthetic fracture	23,205 (0.9)	2,890 (0.6)	4,575 (0.9)	5,060 (0.9)	5,865 (1.1)	4,815 (1.4)	**87.1%**	**<0.001**
Prosthetic dislocation	5,270 (0.2)	1,060 (0.2)	985 (0.2)	1,055 (0.2)	1,205 (0.2)	965 (0.3)	4.8%	0.63
Post-procedural Infection[1]	625 (0.03)	55 (0.01)	75 (0.01)	115 (0.02)	180 (0.03)	200 (0.06)	**201.7%**	**<0.001**

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Periprosthetic joint infection	370 (0.01)	55 (0.01)	75 (0.01)	75 (0.01)	80 (0.01)	85 (0.02)	34.1%	0.46

[1] significant p-values are bolded

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Supplemental Table 4. Hospital characteristics of patients undergoing primary THA 2016-2020,

stratified by the presence of diabetes mellitus

	Patients **with** diabetes mellitus (N= 416,850; 17%)	Patients **without** diabetes mellitus (N= 2,050,365; 83%)
Hospital Bed size, N (%)		
Small	113,115 (27.1)	614,865 (30.0)
Medium	121,035 (29.0)	572,570 (27.9)
Large	182,700 (43.8)	862,930 (42.1)
Census Region of Hospital, N (%)		
Northeast	72,505 (17.4)	405,495 (19.8)
Midwest	108,130 (25.9)	503,806 (24.6)
South	160,465 (38.5)	710,750 (34.7)
West	75,750 (18.2)	430,314 (21.0)
Location/teaching status of hospital, N (%)		
Rural	40,450 (9.7)	181,415 (8.8)
Urban nonteaching	103,395 (24.8)	506,755 (24.7)
Urban teaching	273,005 (65.5)	1,362,195 (66.4)
Control/ownership of hospital, N (%)		
Government, nonfederal	37,800 (9.1)	176,955 (8.6)
Private, not-profit	316,675 (76.0)	1,566,145 (76.4)
Private, for-profit	62,375 (15.0)	307,266 (15.0)

Supplemental Table 5. Utilization Rates for THA for patients with diabetes mellitus

Year	Number of patients with Diabetes Mellitus who underwent THA	% of THA Population	P-value based on the Cochran Armitage Test for time trend from 2016 to 2019 [1]
2016	81,870	16.08	
2017	87,570	16.67	
2018	89,520	16.70	**<0.001**
2019	94,360	17.08	
2020 *	63,530	18.46	

[1] Cochran Armitage test run including data from 2016-2019 after excluding 2020 due to COVID-19 related variation in healthcare delivery related to elective surgery such as the THA; this was a pre-specified approach, similar to other time-trends analyses in our study.

*2020 was not included in time-trends analyses since it was the first year of COVID-19 pandemic, where tremendous shift in healthcare setup and delivery to combat COVID-19 pandemic were expected to impact THA utilization and complication, since it is an elective procedure in most settings

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Supplemental Table 6. Multivariable-adjusted association* of diabetes mellitus with post-primary THA outcomes from NIS 2016-2020, stratified by the underlying diagnosis

	Osteoarthritis (N=1,761,960)		Traumatic fracture (N=532,910)		Avascular necrosis (N=78,275)		Inflammatory arthritis[1] (N=3,520)	
	aOR (95% CI)	p-value	aOR (95% CI)	p-value	aOR (95% CI)	p-value	aOR (95% CI)	p-value
Length of hospital stay above the median [> 2 days])	**1.41 (1.38-1.44)**	**<0.001**	**1.36 (1.27-1.46)**	**<0.001**	**1.42 (1.27-1.58)**	**<0.001**	1.36 (0.87-2.12)	0.18
Total hospital charges above the median [> $58,002]	**1.10 (1.07-1.12)**	**<0.001**	**1.12 (1.08-1.16)**	**<0.001**	1.07 (0.96-1.19)	0.24	1.28 (0.78-2.12)	0.33
Non-routine discharge	**1.18 (1.15-1.21)**	**<0.001**	**1.48 (1.38-1.58)**	**<0.001**	**1.12 (1.00-1.25)**	**0.04**	0.95 (0.58-1.55)	0.84
Inpatient mortality	1.15 (0.73-1.81)[a]	0.54	0.96 (0.84-1.09)	0.49	1.53 (0.26-9.10)[a,d,e,f]	0.64	**	
Need for blood transfusion	**1.18 (1.10-1.25)**	**<0.001**	**1.19 (1.13-1.24)**	**<0.001**	1.14 (0.91-1.43)	0.25	1.35 (0.59-3.09)	0.48
Prosthetic fracture	1.13 (0.99-1.28)	0.07	**0.75 (0.65-0.85)**	**<0.001**	0.76 (0.39-1.47)	0.41	**	
Prosthetic dislocation	1.19	0.13	**0.70**	**0.03**	1.66	0.22	**	

	(0.95-1.48)		**(0.51-0.97)**		(0.74-3.72)		
Post-procedural infection[2]	0.79 (0.23-2.65)[a,b]	0.79	1.37 (0.79-2.36)	0.26	1.09 (0.11-11.27)[a,b,d,g]	0.93	**
Periprosthetic joint infection (PJI)	0.42 (0.06-3.21)[a,b,c]	0.40	1.67 (0.70-3.94)[a]	0.25	2.14 (0.18-26.21)[a,b,c,d,g]	0.55	**
Deep Surgical Site Infection (SSI)	**		**		**		**
Post-procedural sepsis	2.06 (0.39-10.99)[a,b,c,d,e,f,h]	0.40	**		**		**

[1]includes rheumatoid arthritis, spondyloarthritis, ankylosing spondylitis and psoriatic arthritis

[2]Includes periprosthetic joint infection (PJI), deep surgical site infection (SSI), and post-procedural sepsis

*Multivariable-adjusted model includes age, sex, census region of hospital, race, hospital teaching status, median household income for ZIP code, expected primary payer, Deyo-Charlson score, hospital bed size, elective versus non-elective admission, and control/ownership of hospital

Each of the following variables were removed from multivariable regression due to quasi-complete separation, which persisted even after dichotomization of the variable: [a] Race; [b] Elective admission; [c] Hospital location/teaching status; [d] Expected primary payer; [e] Hospital control/ownership; [f] Deyo-Charlson Comorbidity Index; [g] Hospital Census Region; and [h] Median household income for ZIP code

** Multivariate regression could not be performed reliably due to quasi-complete separation which persisted even after the removal of several variables.
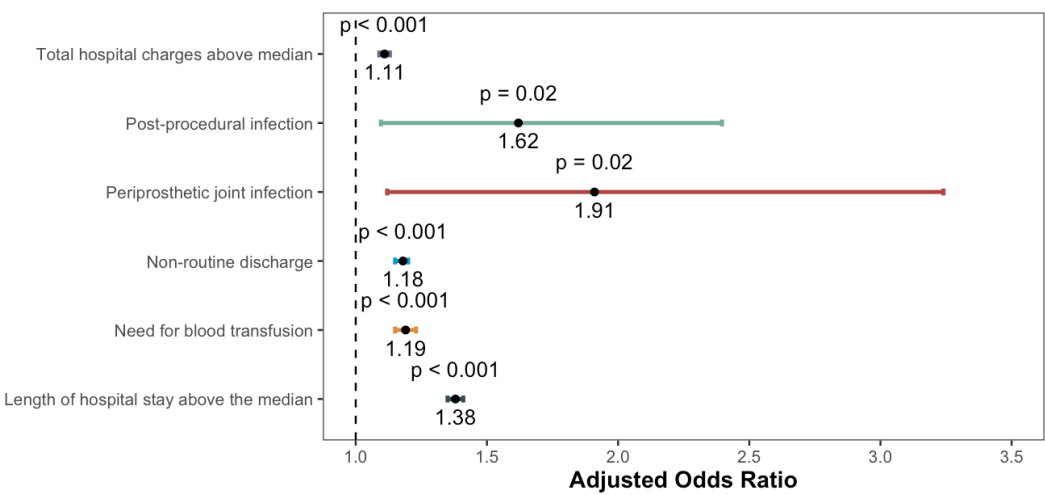
aOR, adjusted odds ratio; CI, confidence interval

Analysis for other diagnoses (N=273,280) not shown and is available on request. This included primary diagnoses of pathological fracture (N=15,805), osteoporosis (N=29,890), non-fracture prosthetic complications (N=159,415), periprosthetic fracture (N=8,730), sepsis (N=3,930), and secondary malignant neoplasm (N=2,420)

Supplemental Table 7: Sensitivity analysis[1]: Multivariable-adjusted association of diabetes mellitus with post-primary THA outcomes from NIS 2016-2020, adjusting the main model additionally for the underlying diagnosis for primary THA

	Adjusted Odds Ratio (95% CI)	p-value
Length of hospital stay above the median [> 2 days]	**1.40 (1.37-1.43)**	**<0.001**
Total hospital charges above the median [> $58,002]	**1.11 (1.09-1.14)**	**<0.001**
Non-routine discharge	**1.18 (1.16-1.21)**	**<0.001**
Inpatient mortality	0.96 (0.86-1.08)[a]	0.49
Need for blood transfusion	**1.20 (1.15-1.24)**	**<0.001**
Prosthetic fracture	0.95 (0.87-1.03)	0.18
Prosthetic dislocation	1.01 (0.86-1.19)	0.92
Post-procedural infection[2]	**1.72 (1.16-2.55)[a]**	**0.01**
Periprosthetic joint infection (PJI)	**2.09 (1.23-3.57)[a,b]**	**0.01**
Deep surgical site infection (SSI)	*	
Post-procedural sepsis	1.25 (0.67-2.33)[a,b]	0.48

[1] Multivariable-adjusted model includes age, sex, census region of hospital, race, hospital teaching status, median household income for ZIP code, expected primary payer, Deyo-Charlson score, hospital bed size, elective versus non-elective admission, hospital control/ownership and underlying diagnosis

[2] Includes periprosthetic joint infection (PJI), deep surgical site infection (SSI), and post-procedural sepsis; [a] Underlying condition and/or [b] Race were excluded from multivariable regression due to quasi-complete separation. Each variable was first dichotomized and then removed since the separation persisted

Supplemental material

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Supplemental Figure 1

Supplemental Figure 1 Legend. The adjusted odds ratios are from the logistic regression model,
including the entire THA population, that assessed diabetes mellitus as a predictor for poor clinical and
healthcare utilization outcome using the NIS data from 2016 to 2020. Only associations that were
statistically significant with p-value <0.05 are shown. The point estimates are adjusted odds ratios, and
the whiskers represent the 95% confidence intervals. The null hypothesis is represented by the dark
dotted line crossing 1.0.