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Age and Obesity Are Risk Factors for Adverse Events After Total Hip Arthroplasty

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Abstract

Background Defining the epidemiology of adverse events after THA will aid in the development of strategies to enhance perioperative care.

Questions/purposes We identified (1) risk factors for adverse events in Medicare beneficiaries while hospitalized after THA and (2) trends in the rates of adverse events.

Patients and Methods Data were abstracted from medical records of 1809 Medicare beneficiaries who underwent THA from 2002 to 2007. We used the hierarchical generalized linear modeling approach to assess the odds of change in adverse events over time, the association of adverse events with outcomes, and the relationship of adverse events with patient characteristics by modeling the log-odds of adverse events as a function of demographic and clinical variables adjusted for year variable.

Results The overall rate of adverse events was 5.8%; the 30-day mortality rate was 1.00%. Increased age, obesity, and year of procedure were risk factors for experiencing any adverse event. Annual rates of adverse events from 2002 to 2007 were 9.1%, 8.2%, 4.9%, 4.1%, 3.5%, and 3.0%, respectively. Experiencing any adverse event was associated with an increased length of stay and an increased chance of readmission but not with an increased chance of mortality. The annual rate of all adverse events decreased from 2002–2004 to 2005–2007 (odds ratio = 0.83; 95% confidence interval, 0.74–0.92).

Conclusions Older and obese patients should be counseled regarding their increased risk for the development of adverse events after THA. The cause of the decline in the rate of adverse events between two time periods is unclear and warrants further investigation to confirm and identify the cause.

Each author certifies that he has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with this article.

Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at Stanford University Medical Center, Qualidigm Inc, and Massachusetts General Hospital.

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Introduction

It has been estimated 59.4 million Americans (18.2%) will be diagnosed with arthritis by the year 2020 [9]. Osteoarthritis of the hip is among the most common causes of disability and morbidity in the United States [3]. THA is a cost-effective treatment for advanced arthritis of the hip [1]. It is expected the costs and the utilization of THA will continue to rise over the next few decades [8].

The Institute of Medicine's 1999 report, *To Err Is Human: Building a Safer Health System* [7], claimed 44,000 to 98,000 patients in US hospitals each year die due

to preventable medical errors at a cost of $17 to $28 billion per year. The authors challenged industry, government, healthcare providers, and consumers to achieve a 50% reduction in the number of medical errors in the next 5 years. This report sparked a national discourse that led to the creation of a broad range of patient safety initiatives by, among others, the US Department of Health and Human Services, the Joint Commission on Accreditation of Healthcare Organizations, and the American Academy of Orthopaedic Surgeons.

The Medicare Patient Safety Monitoring System (MPSMS) was a nationwide surveillance project aimed at identifying the rates of specific adverse events in Medicare beneficiaries [5]. The surveillance system identified adverse events from inpatient medical records and administrative claims data [5]. In addition to data on hip and knee arthroplasty procedures, the MPSMS captured data on other common adverse events experienced by inpatients. The MPSMS was created under the auspices of the Department of Health and Human Services Patient Safety Task Force, which was created in 2001. The Centers for Medicare and Medicaid Services led the coordination and development of the MPSMS. By providing a better understanding of the rates of and risk factors for the development of adverse events, the MPSMS hoped to improve patient safety.

Large, population-based studies using claims data for Medicare beneficiaries (Medicare Parts A and B) and data from the Veterans Affairs' (VA) National Surgical Quality Improvement Program (NSQIP) provide detailed analyses of the outcomes of THA and TKA [6, 10, 11]. While these databases provide national samples, they have several limitations. The ambiguity of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and current procedural terminology (CPT) codes, the lack of clinical information, and the absence of laterality documentation could potentially lead to misrepresentation of the true rates when Medicare claims data are used. While the data from the VA NSQIP are generated using medical record abstraction, the sample represents a VA patient population and is not representative of the general US population. Further, the VA NSQIP is a quality assurance database, and substantial amounts of missing data may preclude further analysis of multiple predictors of interest. The MPSMS project, by using medical record abstraction and claims data, should provide accurate data on rates of adverse events in this patient population.

We therefore used data generated from medical record abstraction to document the rates of adverse events during the index hospitalization of Medicare beneficiaries who had a THA for osteoarthritis from 2002 to 2007. We identified (1) patient-level risk factors associated with the occurrence of these adverse events and (2) any trends in the rates of events from 2002 to 2007.

Patients and Methods

The MPSMS was a national surveillance project created in 2001 under the leadership of the Centers for Medicare and Medicaid Services to determine the rates of specific medical adverse events within the hospitalized Medicare population. The MPSMS defines an adverse medical event as "an unintended, measurable harm, injury or loss more likely associated with the patient's interaction with the health care delivery system than from any attendant disease process" [5]. The MPSMS sample was a subset of the Hospital Payment Monitoring Program (HPMP) record sample. The HPMP sample, which represents approximately 40% of all Medicare fee-for-service payments, was randomly selected each month from the Medicare National Claims History (NCH) File by the Centers for Medicare and Medicaid Services from a pool of approximately 1 million Medicare beneficiary hospital discharges across 50 states, Washington DC, Puerto Rico, and the Virgin Islands.

The study sample was drawn from the MPSMS database that included more than 180,000 hospital discharges between January 1, 2002, and December 31, 2007. All 1809 THA patients in this sample of greater than 180,000 patients were analyzed for the MPSMS. These 1809 THA patients were treated in hospitals from all 50 states. Hospitals forwarded the selected medical records to the Clinical Data Abstraction Centers for data abstraction on a monthly basis. The overall average aggregate agreement rate across all data elements of the MPSMS data is greater than 97% [5]. The agreement rates range from 96% to 99% for variables used to identify exposures and 94% to 99% for identification of adverse events. This analysis suggests the abstractors were accurate in their data collection. For this study, all patients included in the sample had to have a THA for degenerative arthritis during their hospitalizations.

Abstracted patient characteristics included demographics (age, gender, race) and selected common clinical characteristics and comorbidities, including congestive heart failure, chronic obstructive pulmonary disease, cerebrovascular disease, obesity, cardiovascular disease, diabetes, history or current smoking, and use of corticosteroids (Table 1). Age was divided into four groups (younger than 65 years, 65–74 years, 75–84 years, and 85 years or older), gender was coded as female versus male, and race was categorized as white versus others.

The primary outcome was the adverse event (Table 2). Secondary outcomes included 30-day and in-hospital mortalities, length of stay (LOS), and 30-day readmissions. The 30-day all-cause mortality was defined as any death within 30 days after the procedure and the in-hospital mortality was defined as all-cause death within the index

Table 1. Patient characteristics

Characteristics	2002–2004		2005–2007		p Value	Overall	
	Total (number)	Rate (%)	Total (number)	Rate (%)		Total (number)	Rate (%)
Total	1014	100.0	795	100.0		1809	100.0
Demographics							
Mean age (years) (SD)	74.1 (9.1)		73.3 (8.8)		0.02	73.8 (9.0)	
Age group							
< 65 years	71	7.0	67	8.4	0.49	138	7.6
65–74 years	434	42.8	354	44.5		788	43.6
75–84 years	417	41.1	308	38.7		725	40.1
> 84 years	92	9.1	66	8.3		158	8.7
White	950	93.7	795	100.0	0.64	1,745	96.5
Female	636	62.7	498	62.6	0.87	1,134	62.7
Comorbidity							
Cancer	181	17.9	144	18.1	0.89	325	18.0
Congestive heart failure	75	7.4	49	6.2	0.30	124	6.9
Chronic obstructive pulmonary disease	188	18.5	131	16.5	0.25	319	17.6
Cerebrovascular disease	92	9.1	68	8.6	0.70	160	8.8
Diabetes	158	15.6	116	14.6	0.56	274	15.1
Corticosteroids	38	3.7	33	4.2	0.66	71	3.9
Obese	106	10.5	108	13.6	0.04	214	11.8
Smoking	95	9.4	81	10.2	0.56	176	9.7

Table 2. Definitions of adverse events

Adverse event	Definition
Acute or early deep infection	Physician diagnosis
Dehiscence	Physician diagnosis
Necrosis	Physician diagnosis
Hematoma	Any physician diagnosis of hematoma not meeting the criteria for major bleeding/hematoma
Nerve injury	Physician diagnosis
Major bleeding/hematoma	In Year 1, major bleeding/hematoma was defined as "a localized collection of blood or transfusion of $\geq$ 4 units of packed red blood cells." This definition was revised after Year 1 to "any return to the operating room for hemostasis/evacuation of hematoma, hemoglobin drop > 2.0 g/dL compared to value obtained on the first postoperative day, or transfusion of $\geq$ 4 units of blood postoperatively."
Dislocation	Physician diagnosis
Cardiovascular complications	Physician diagnosis of myocardial infarction, congestive heart failure, or arrhythmia requiring treatment
Periprosthetic fracture	Physician diagnosis
Obesity	Physician diagnosis
Urinary tract infection	Culture with > 10^5 organisms/mL and no more than 2 common pathogens or physician diagnosis of urinary tract infection and ordering of antibiotic
Deep venous thrombosis/ pulmonary embolism	Positive Doppler or duplex ultrasound, venography, MR venography, ventilation perfusion scan (high probability or medium probability with positive lower extremity ultrasound for deep venous thrombosis), CT scan, or pulmonary angiogram
Pneumonia	Evidence of infiltrate, consolidation, or cavitation on chest radiograph, a physician diagnosis of pneumonia, and treatment with an antibiotic

hospitalization. LOS was calculated as a difference between dates of discharge and admission. If a patient was discharged on the same date of admission, his/her LOS was defined as 1 day. The 30-day readmission was categorized in two ways: (1) the rate of all-cause readmission that only counts the first rehospitalization within 30 days after

discharge from the index hospitalization, regardless of the condition of a rehospitalization, and (2) the cause of readmission that counts as any rehospitalization within 30 days after discharge. The NCH database was used to obtain the in-hospital mortality and readmission information, and the Medicare Enrollment database was linked to obtain the 30-day mortality information.

Postprocedure events were captured if the specific terms were found anywhere in the medical record. Abstractors were registered nurses and nurse practitioners. The abstractors used the algorithms created by physicians specifically for this project. The physicians responsible for defining these algorithms were from a variety of specialties, including infectious disease, general internal medicine, nephrology, pulmonology, critical care, neurology, cardiology, general surgery, and orthopaedic surgery. The medical record included progress notes, nursing notes, procedure notes, consultations, history and physical examinations, discharge summaries, intraoperative anesthesia records, operating room circulating nurse notes, emergency department notes, laboratory results, transfusion records, nursing admission assessments, radiology reports, and pathology reports. The adverse events were specifically defined by the technical experts of the MPSMS (Table 2).

We divided the sample into two subperiods (2002–2004 and 2005–2007) to seek changes in the patterns of adverse events and outcomes. We elected to do this to assure the validity of the statistical analysis, as the rate of two of the variables measured (age and obesity) changed from 2002 to 2007. Descriptive and bivariate analyses were conducted to compare patient characteristics, observed adverse events, and outcomes between the two periods (see Table 1 for variables included); a chi square test was used to compare dichotomous and categorical variables and a t test to compare continuous variables. We used the hierarchical generalized linear modeling (HGLM) approach to assess the association of adverse events with the outcomes and to assess the odds of change in adverse events over time. This modeling approach was also used to assess the relationship of adverse events with patient characteristics by modeling the log-odds of adverse events as a function of patient demographic and clinical variables adjusted for year variable, which was coded as 1 to 6 denoting 2002 to 2007. All HGLMs were fitted with a random state-specific effect to account for within-state correlation of the observed adverse events and outcomes and to separate within-state variation from between-state variation. The 95% confidence interval (CI) was calculated for each estimate obtained from models. All of the statistical analyses were conducted with SAS® Version 9.1.3 (SAS Institute Inc. Cary, NC), and HGLMs were estimated using the GLIMMIX macro in SAS®.

Results

The risk factors associated with an increased chance of experiencing any adverse event while hospitalized included increased age ($p < 0.027$), obesity (odds ratio [OR] = 1.20; CI, 1.02–1.42; $p < 0.032$), and year of procedure (OR = 0.94; CI, 0.91–0.97; $p < 0.001$). Female gender, cancer, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes mellitus, use of corticosteroids, and smoking were not risk factors for adverse events (Fig. 1).

Of the 1809 patients in this sample who underwent a THA from 2002 to 2007, 105 (5.8%) suffered at least one adverse event during their index hospitalization. There were a total of 136 adverse events in these 105 patients. The rates of in-hospital complications by year from 2002 to 2007 were 9.1% (41 of 453), 8.2% (21 of 255), 4.9% (15 of 306), 4.1% (10 of 242), 3.5% (nine of 257), and 3.0% (nine of 296), respectively. The rate of all adverse events decreased ($p < 0.001$) from 2002–2004 (77 of 1014, 7.6%) to 2005–2007 (28 of 795, 3.5%) (OR = 0.83; CI, 0.74–0.92). The most common adverse events (index hospitalization) were major bleeding/hematoma (2.7%), urinary tract infection (2.0%), cardiovascular (0.6%), venous thromboembolic events (0.33%), and pneumonia (0.33%) (Table 3). There were changes in the characteristics of the sample from 2002 to 2007. When the patients were divided into two groups based on the year of their procedure (2002–2004 and 2005–2007), patients who underwent THA were younger ($p < 0.023$) in the later time period (74.1 ± 9.1 years versus 73.3 ± 8.8 years). The rate of obesity increased ($p < 0.041$) from 10.5% (106 of 1014) in the period 2002–2004 to 13.6% (108 of 795) in the period 2005–2007 (Table 1). There were no changes in any of the other patient characteristics and comorbidities between the two time periods.

Patients who experienced any adverse event during their index hospitalization had a higher ($p < 0.001$) likelihood

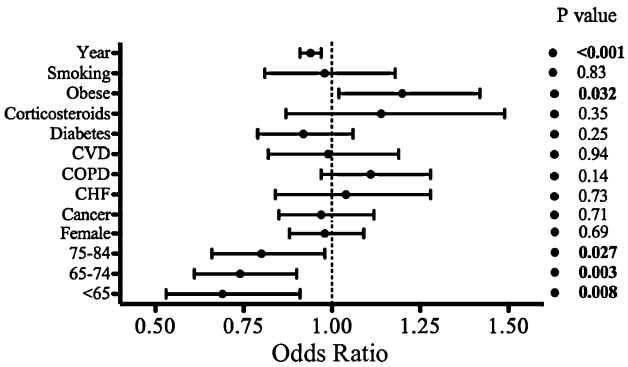

Fig. 1 This graph illustrates the association between adverse events and patient characteristics. The ORs were drawn from the HGLM approach. CVD = cerebrovascular disease; COPD = chronic obstructive pulmonary disease; CHF = congestive heart failure.

Table 3. Specific adverse events

Adverse event	2002–2004	2005–2007	Overall
Exposed cases			
Total (number)	1014	795	1809
Adverse event (number)	77	28	105
Rate (%)	7.6	3.5	5.8
Type of adverse event (number)*			
Acute or early deep infections	3	1	4
Dehiscence	1	0	1
Necrosis	1	0	1
Hematomas	7	4	11
Nerve injury	1	0	1
Major bleeding/hematoma	30	18	48
Dislocation	3	1	4
Cardiovascular complications	6	4	10
Return to the operating room	2	3	5
Periprosthetic fracture	0	1	1
Revision during the index hospital stay	2	0	2
Urinary tract infection	27	9	36
Deep venous thrombosis/ pulmonary embolism	5	1	6
Pneumonia	6	0	6

* Patients may have more than one adverse event.

Table 4. Associations between adverse events and outcomes using HGLM

Outcome	Estimate*	95% CI	p Value
Mortality (30 days from procedure)			
With adverse events	1.00	0.93–1.08	0.98
Without adverse events (reference)	1.00		
Readmission (30 days from discharge)			
With adverse events	1.31	1.03–1.67	0.028
Without adverse events (reference)	1.00		
Length of stay			
With adverse events	1.66	1.59–1.93	< 0.001
Without adverse events (reference)	1.00		

* For mortality and readmission, the estimate is an odds ratio; for length of stay, the estimate is the mean length of stay at log score; all estimates were adjusted for patient characteristics (age, gender, congestive heart failure, chronic obstructive pulmonary disease, cerebrovascular disease, diabetes, obesity, corticosteroids, smoking status, and cancer; HGLM = hierarchical generalized linear modeling; CI = confidence interval.

of staying in the hospital for a longer period of time (OR = 1.66; CI, 1.59–1.93) (Table 4). From 2002 to 2004, the mean LOS for patients who experienced an adverse event (6.8 ± 4.8 days) was longer ($p < 0.001$) than the LOS for those patients who did not experience an adverse event (4.2 ± 2.0 days). From 2005 to 2007, the mean LOS for patients who experienced an adverse event (5.3 ± 3.4 days) was longer ($p < 0.001$) than the LOS for those patients who did not experience an adverse event (3.8 ± 1.6 days). Experiencing any adverse event during the index hospitalization increased the risk of being readmitted to the hospital in the 30 days after discharge (OR = 1.31; CI, 1.03–1.67; $p = 0.028$) (Table 4).

The 30-day postprocedure mortality rate was 1.0% (18 of 1809). The mortality rate during the index hospitalization was 0.39% (seven of 1809). Experiencing any adverse event during the index hospitalization did not increase the risk of death in the first 30 days after the procedure (OR = 1.0; CI, 0.93–1.08; $p = 0.97$). There were 14 deaths from 2002 to 2004 and four deaths from 2005 to 2007.

Discussion

Defining the epidemiology of adverse events after THA will aid in the development of strategies to enhance perioperative care. We therefore used data generated from medical record abstraction to document the rates of adverse events during the index hospitalization of Medicare beneficiaries who had a THA for osteoarthritis from 2002 to 2007. We identified (1) patient-level risk factors associated with the occurrence of these adverse events and (2) any trends in the rates of events from 2002 to 2007.

Our study is subject to some limitations. First, we used administrative claims data to determine posthospitalization adverse events (death and readmission) experienced within 30 days of the procedure or discharge, as ICD-9-CM and CPT codes are ambiguous and claims data may lack clinical detail [2]. This data source utilized medical chart abstraction by nonphysicians, although physicians developed these algorithms to allow other healthcare providers to efficiently abstract the relevant data. This method is less costly than physician review, and it is likely this method allowed for detection of more adverse events than would have been possible using inpatient claims data alone. Second, some of the adverse events (infection, wound dehiscence, necrosis, etc) were defined as "physician diagnosis" and were thus subject to physician judgment. Third, the majority of the patients in this study were white. While this is representative of the current US Medicare population, it is not representative of the entire US population. Fourth, the 1809 Medicare patients in this study may not be representative of the entire Medicare population.

Of the 1809 THA patients in the Medicare HPMP sample, 105 (5.8%) suffered at least one adverse event during their index hospitalization. Increased age, obesity, and year of procedure were identified as risk factors for

developing a complication during the index hospitalization. Adverse events were associated with a longer LOS and an increased risk of readmission but not with an increased risk of mortality. The annual rate of all adverse events from 2002 to 2007 was 9.1%, 8.2%, 4.9%, 4.1%, 3.5%, and 3.0%, respectively. Several studies show increased age is a risk factor for the development of adverse events after THA [6, 11, 14]. Additional risk factors reported previously included male gender [11, 14], black race [11], any medical comorbidity [11], chronic obstructive pulmonary disease [6], dependent functional status [6], and an American Society of Anesthesiologists score of 3 or 4 [6].

Our data suggest the year of the procedure was a risk factor as well: having a THA from 2002 to 2004 imposed a greater risk of developing any adverse event than having THA from 2005 to 2007. The annual rate of the total number of adverse events decreased from 2002–2004 to 2005–2007. This may have been influenced by small changes in the rates of individual adverse events such as major bleeding and urinary tract infection. Given that the physicians and hospitals did not have any feedback on their "performance" during the study period, it remains unclear exactly why rates decreased. A general increase in public awareness of adverse event rates, as discussed earlier, may have influenced these observations. Further, the national trend toward earlier hospital discharge may have shifted some adverse events from the index hospitalization to the postdischarge period. We are actively investigating this topic.

The rate of mortality in the first 30 days after THA in this sample (1.0%) is the same as the rate for a 1995 Medicare population in the first 90 days after the same procedure [11] (Table 5). It remains higher than the rate of 0.7% reported from three other large observational studies [6, 12, 13] in the modern era. Further, the mortality rate from this study is substantially higher than the rate of 0.3% reported by a single surgeon from 1969 to 1996 [4], as well as the 0.3% rate reported from a single high-volume institution from 1969 to 1997 [14].

Table 5. Mortality rates after primary THA

Study	Time period (days)	Mortality rate (%)
Mahomed et al. [11]	90	1.0
Ibrahim et al. [6]	90	0.7
Dearborn and Harris [4]	90	0.3
National Joint Replacement Registry of England and Wales [12]	90	0.7
Scottish Arthroplasty Project [13]	90	0.7
Parvizi et al. [14]	30	0.15–0.94
Huddleston et al.	30	1.0

In summary, we identified increasing age, obesity, and year of procedure as patient-level risk factors associated with the occurrence of any adverse event after THA in Medicare patients from 2002 to 2007; the annual rate of all adverse events decreased between 2002–2004 and 2005–2007; and the 30-day mortality rate was unchanged compared to a 1995 Medicare population. Our findings suggest the rate of adverse events after THA in Medicare beneficiaries remains low. While the low annual mortality rates and the decreasing annual rates of adverse events are encouraging, further study is warranted to elucidate causative factors and/or associations.

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