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Primary Knee

Failure to Optimize Before Total Knee Arthroplasty: Which Modifiable Risk Factor is the Most Dangerous?

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A B S T R A C T

Background: Complications after total knee arthroplasty (TKA) are devastating for patients, and surgeons are held accountable in alternative payment models. Optimization of modifiable risk factors has become a mainstay in the preoperative period. We sought to evaluate the consequence of failure to optimize key risk factors in a modern cohort of patients who underwent TKA.
Methods: The American College of Surgeons National Surgical Quality Improvement Program database was searched to identify patients who underwent TKA in 2017-2018. Patients were considered optimized if they had a body mass index <40kg/m^2, had albumin >3.5g/dL, were nonsmokers, and were nondiabetic. Patients were then grouped based on the previous 4 risk factors. Thirty-day readmission, infection, general complications, and mortality were analyzed and compared between the groups.
Results: Overall, 84,315 patients were included in the study. A total of 31.6% of patients were not considered optimized. Body mass index >40kg/m^2, albumin <3.5, smoking, and insulin-dependent diabetes were all found to be associated with postoperative infection, readmission, mortality, and complication in general ($P < .05$). When compared, the nonoptimized group was found to have significantly higher risk of readmission (5 vs 3%), infection (2 vs 1%), general complications (8 vs 5%), and mortality (0.35 vs 0.1%) (all $P < .001$). Logistic regression showed that those with albumin less than 3.5g/dL had 3.7-fold higher odds of infection and 7.2-fold higher odds of 30-day mortality.
Conclusion: Despite knowledge that modifiable risk factors significantly influence postoperative outcomes, surgeons continue to operate on patients who are not optimized. Among the modifiable risk factors analyzed, hypoalbuminemia appears to be the strongest risk factor for all complications evaluated. Special attention should be paid to preoperative nutritional optimization.
Level of Evidence: Retrospective cohort study, level IV.

Primary total knee arthroplasty (TKA) is one of the most common procedures performed in the world and has led to increased mobility and improved function in patients with symptomatic end-stage osteoarthritis of the knee [1]. As the population ages, it is expected that the rate of TKA will increase by 67% to nearly 3.5 million surgeries annually by 2030 [2]. Complication rates are relatively low, and survivorship is high [3]. However, when complications and failures do occur, they can be a major cause of morbidity and even mortality and a major cost burden to the health care system [4,5]. The most commonly encountered complications after TKA are periprosthetic fracture, infection, aseptic loosening, deep vein thrombosis, and anemia requiring blood transfusion [5–9].

The United States health care system is the most expensive health care system in the world per capita [10]. With this in mind, the Centers for Medicare and Medicaid Services has placed a new emphasis on quality improvement programs and has implemented specific programs increasing quality of services within orthopedic

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surgery. These initiatives focus on readmission rates within a 30-day period after total joint arthroplasty (TJA) as a measure of quality of care [11,12]. With the increasing number of TKAs being performed, an increasing cost to the health care system, and new focus on quality of care and its implications on reimbursement, there has been a push to optimize patients medically in the preoperative period to minimize the risk of complications and improve postoperative quality of life [8,13–15]. Diabetes status, body mass index (BMI), preoperative nutritional status, and tobacco use are all identified risk factors associated with worse outcomes and higher complication rates after TKA [16–19]. These risk factors are all modifiable and may be optimized before elective TJA.

In the present study, we aimed to determine the frequency of TKA in patients who were not optimized in the modifiable risk categories of interest. Furthermore, we sought to determine the consequences of failure to optimize by evaluating complications after TKA in nonoptimized and optimized cohorts. Finally, we compared each risk factor for the relative strength of association with its complication after surgery.

Materials and Methods

The data for this study were sourced from the 2017 and 2018 Participant Use Data Files (PUF) from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database. The PUFs are patient-level, aggregate data that are compliant with the Health Insurance Portability and Accountability Act. As such, PUFs do not contain any patient or hospital identifiers, and with the execution of a data use agreement, any research with these data does not require the review and approval of an institutional review board. All primary TKA surgeries between January 2017 and December 2018 were identified using the 27447 Current Procedural Terminology code. Patient demographics, medical conditions, laboratory values, and complications were extracted and analyzed.

Outcome Variables and Risk Factors

We extracted patient gender, age, BMI, serum albumin levels, current tobacco use, and diagnosis of insulin-dependent diabetes mellitus (IDDM). We additionally recorded the occurrence of infection, readmission, any complication, and mortality within 90 days postoperatively. The category ‘any complication’ encompassed the following complications: superficial and deep wound infection, organ space infection, wound dehiscence, pneumonia, unplanned intubation, deep venous thrombosis, pulmonary embolism, renal insufficiency, stroke, coma, cardiac arrest, myocardial infarction, postoperative transfusion, implant failure, sepsis, septic shock, and mortality.

Patient Cohort

Overall, 84,315 patients were included in the study. Initial search yielded 137,638 patients. Ultimately, 53,323 patients were excluded because of age, yielding the final patient cohort of 84,315. When analyzing risk factors, 39,163 patients did not have albumin levels recorded; therefore, they were excluded from that variable.

Statistical Methods

BMI, albumin, tobacco use, and diabetes were analyzed as dichotomous variables. BMI <40 kg/m^2 was compared with BMI $\geq$40 kg/m^2 [20], albumin <3.5 g/dL was compared with $\geq$3.5 g/dL, current use of tobacco was compared with no current use, and having insulin-dependent diabetes was compared with having noninsulin-dependent diabetes as well as to not having diabetes. If a patient was missing values for a risk factor, they were excluded in the analysis of that specific risk factor. We also compared patients who were medically optimized in risk factors of BMI, albumin, smoking, and diabetes with those not optimized in one or more risk factors. If patients had missing data for one or more of these risk factors, they were considered not medically optimized if they had any risk factor that was not optimized. If they had missing data but were optimized in all the risk factors for which data were present, they were excluded from analysis of patients who were medically optimized versus those not medically optimized. At the bivariate level, categorical variables were statistically compared using chi-squared tests. For all categorical data, frequency and percentages are reported. Four multivariable logistic regression models were used to evaluate the risk factors associated with infection, readmission, any complication, and mortality. Model testing revealed multicollinearity when the optimized variable was included with each individual risk factor. Furthermore, model fit statistics indicated that the regression models that included BMI, albumin, tobacco use, and diabetes were the best fitting models. For all logistic regression models, odds ratios (OR) and Wald 95% confidence intervals are reported. An a priori level of significance of .05 was defined. All data were managed and analyzed using SAS/STAT software, version 9.4, (SAS Institute INC., Cary, NC, USA).

Sources of Funding

No external sources of funding were used for this study.

Results

Overall, 84,315 patients were included in the study. Fifty-two thousand and thirty-three women were included, and 32,282 men were included. Mean age of the study cohort was 72 years old (range, 68-77). Greater than 10% of patients had a BMI >40kg/m^2 (8461 of 84,315), 5.9% of patients had albumins <3.5g/dL (2555 of 42,597 patients), 4.4% of patients were active smokers (3503 of 80,812 patients), 4.5% of patients carried the diagnosis of insulin-dependent diabetes (3382 of 84,315), and 14.6% of patients had noninsulin-dependent diabetes (12,366 of 84,315). Of those analyzed, 31.6% of patients were not considered optimized (26,643 of 84,315 patients).

Bivariate analysis showed that patients with BMI >40kg/m^2 had a higher incidence of postoperative infection (P < .0001), readmission (P < .0001), and all complications (P < .0001). In addition, those patients with albumin <3.5g/dL, active tobacco users, and those with insulin-dependent diabetes were found to have a higher incidence of postoperative infection, readmission, mortality, and all-cause complications (P < .05 for all variables) (Table 1). In total, patients who were not considered “optimized” had a 1.8% incidence of postoperative infection, 5.1% readmission rate, a 6.6% complication rate, and a 0.3% mortality rate compared with a 1.1%, a 3.5%, a 5.3%, and a 0.1% rate, respectively, in those patients who were considered optimized (P < .05) (Table 2).

A multivariable logistic regression model (Table 3) was used to quantify the adjusted effect that each modifiable risk factor had on the risk of each of the postoperative adverse events, after adjusting for patient age and gender. Each of the 4 logistic regression models estimated that morbid obesity significantly increased the risk of adverse events after TKA. More specifically, compared with patients with a BMI <40kg/m^2, patients with a BMI greater than or equal to 40kg/m^2 had a twofold increase in the odds of infection (OR 2.1; 95% confidence limit (CL) 1.7-2.7), 50% higher odds of readmission (OR 1.5; 95% CL 1.3-1.7), 30% higher odds of all-cause complications (OR 1.3; 95% CL 1.2-1.5), as well as nearly a twofold increased odds of mortality (OR 1.9; 95% CL 1.1-3.5). The adjusted analyses also

Table 1
Bivariate Analysis of Individual Risk Factors.

BMI	Infection	Yes	*P*-Value	Readmission	Yes	*P*-Value	Any Complication	Yes	*P*-Value	Mortality	Yes	*P*-Value
	No			No			No			No		
>= 40	8266 (98%)	195 (2%)	<.0001	8080 (95.5%)	381 (4.5%)	<.0001	7865 (93%)	596 (7%)	<.0001	8443 (99.8%)	18 (.2%)	.1833
<40	74,796 (99%)	803 (1%)		72,987 (97%)	2612 (3%)		71,614 (95%)	3985 (5%)		75,484 (99.85%)	115 (.15%)	
Albumin												
>=3.5	42,185 (99%)	412 (1%)	<.0001	41,074 (96%)	1523 (4%)	<.0001	40,452 (95%)	2145 (5%)	<.0001	42,543 (99.9%)	54 (.1%)	<.0001
<3.5	2458 (96%)	97 (4%)		2338 (92%)	217 (8%)		2114 (83%)	441 (17%)		2528 (99%)	27 (1%)	
Smoke												
No	79,882 (99%)	930 (1%)	<.0001	77,964 (96%)	2848 (4%)	.0108	76,426 (95%)	4386 (5%)	0.0424	80,690 (99.85%)	122 (.15%)	.0173
Yes	3430 (98%)	73 (2%)		3351 (96%)	152 (4%)		3285 (94%)	218 (6%)		3492 (99.7%)	11 (.3%)	
Diabetes												
Insulin	3760 (98%)	72 (2%)		3608 (94%)	224 (6%)		3469 (91%)	363 (9%)		3818 (99.6%)	14 (.4%)	
No	67,353 (99%)	764 (1%)	<.0001	65,872 (97%)	2245 (3%)	<.0001	64,686 (95%)	3431 (5%)	<.0001	68,022 (99.9%)	95 (.1%)	.0015
Noninsulin	12,199 (99%)	167 (1%)		11,835 (96%)	531 (4%)		11,556 (93%)	810 (7%)		12,342 (99.8%)	24 (.2%)	

BMI, body mass index.

resulted in significantly higher risk of postoperative complications for patients with poor nutritional status compared with those with better nutritional status. It was found that patients with albumin levels <3.5g/dL had 3.8 (95% CL 3.0-4.7) times increased odds of infection, 2.3 (95% CL 2.0-2.7) times higher odds of readmission, 3.7 (95% CL 3.3-4.1) times higher odds of all-cause complications, and 7.2 (95% CL 4.5-11.6) times higher odds of mortality. Active smokers also had significantly higher risks of postoperative complications. It was estimated that smokers had a twofold increase in the odds of infection (OR 2.0; 95% CL 1.4-2.7) and 40% higher odds of readmission (OR 1.4; 95% CL 1.2-1.8) and all-cause complication (OR 1.4; 95% CL 1.1-1.7). In this patient population, smoking was not an independent risk factor for mortality. Diabetic patients had 40% higher odds of readmission (OR 1.4; 95% CL 1.2-1.6) and all-cause complications (OR 1.4; 95% CL 1.3-1.5). However, diabetic patients in this study sample did not have significantly risks of infection or mortality after TKA.

Discussion

The present study confirmed that patients who were not medically optimized in each of the 4 categories evaluated had a higher risk of postoperative infection, readmission, mortality, and general complication rates. The most significant risk factor was found to be poor nutritional status. Those who had preoperative albumin levels of less than 3.5g/dL had 3.7 times higher odds of infection and 7.2 times higher odds of 30-day mortality. To our knowledge, this is the first study to compare the relative effects of multiple preoperative modifiable risk factors from a large national database regarding their effects on postoperative outcomes.

Table 2
Analysis Showing Results of Optimized Patients Versus Nonoptimized.

Risk Factor	Optimized	Yes	*P*-Value
	No		
Infection			
No	15,991 (98%)	34,962 (99%)	<.0001
Yes	360 (2%)	289 (1%)	
Readmission			
No	15,529 (95%)	34,093 (97%)	<.0001
Yes	822 (5%)	1158 (3%)	
Any complication			
No	15,003 (92%)	33,596 (95%)	<.0001
Yes	1348 (8%)	1655 (5%)	
Mortality			
No	16,294 (99.65%)	35,216 (99.9%)	<.0001
Yes	57 (.35%)	35 (.1%)	

Patients with morbid obesity (BMI >40kg/m^2) were found to have significantly higher risk of readmission, postoperative infection, mortality, and complications in general. This is consistent with previous studies that evaluated BMI and its effects on patient outcomes after elective TJA. Obesity affects approximately 35% of the adult population in the United States of America (BMI >30 kg/m^2), with around 5% being considered morbidly obese [21]. The obesity epidemic has had profound effects on the US population as a whole and has major implications in those undergoing elective TKA. This poses a major dilemma for arthroplasty surgeons in providing care to patients in need but not putting patients at risk for postoperative complications when overweight. D'Apuzzo et al [22] examined obesity and its effect on outcomes after TKA. They found, similar to the present study, that morbid obesity leads to an increase in all complications evaluated compared with those with normal ranged BMIs. These findings have led to an emphasis on weight loss before elective TKA. Although inferior outcomes have been observed, recent studies have shown that the average BMI of patients undergoing TKA has been increasing; in addition, those with higher BMIs undergo TKA at a younger age than their counterparts with normal ranged BMIs [23,24]. In addition, the knee joint appears to be affected at a higher rate and ultimately leads to arthroplasty in obese patients more often than the hip joint [25]. With hopes to prevent these inferior outcomes, some joint arthroplasty surgeons have implemented programs to encourage weight loss and refrain from operating on patients with a BMI > 40kg/m^2 [26,27]. This is in line with the senior author's practice. Patients are referred to weight loss specialists before TKA if their BMI is > 40 kg/m^2. If patients are deemed candidates for bariatric weight loss surgery, then they are ultimately referred to a bariatric surgeon, although mixed results have been seen in patients undergoing bariatric surgery before TJA [28]. It is unclear why patients who undergo bariatric surgery and ultimately lose weight still do not have outcomes similar to patients with normal BMI. It may be due to the fact that patients who undergo bariatric weight loss surgery are at risk for macronutrient malnutrition, most commonly protein malnutrition [29]. This may ultimately lead to chronic malnutrition, low albumin, and place patients at an increased risk of complications postoperatively. Regardless, elective TKA is only performed when patients achieve a BMI of <40kg/m^2. Ample resources are provided to the patient, and weight loss progress is monitored with frequent clinic visits with the goal of creating a sustainable relationship that leads to improved outcomes and decreased postoperative complications.

Tobacco use in the form of cigarette smoking was also found to be a risk factor for worse outcomes when compared with patients who do not smoke cigarettes. A recent systematic review evaluated

Table 3
Logistic Regression Analysis Demonstrating Odds Ratios (OR).

Risk Factor	Infection			Readmission			Any Complication			Mortality		
	OR	95% Wald Confidence Limits		OR	95% Wald Confidence Limits		OR	95% Wald Confidence Limits		OR	95% Wald Confidence Limits	
BMI												
<40	—	—	—	—	—	—	—	—	—	—	—	—
>= 40	**2.113**	1.677	2.661	**1.511**	1.311	1.741	**1.338**	1.185	1.512	**1.929**	1.058	3.516
Albumin												
>=3.5	—	—	—	—	—	—	—	—	—	—	—	—
<3.5	**3.757**	2.992	4.717	**2.317**	1.995	2.691	**3.667**	3.275	4.104	**7.221**	4.514	11.552
Smoking												
No	—	—	—	—	—	—	—	—	—	—	—	—
Yes	**1.971**	1.416	2.743	**1.429**	1.151	1.775	**1.37**	1.136	1.65	2.196	0.945	5.1
Diabetes												
No	—	—	—	—	—	—	—	—	—	—	—	—
Yes	1.082	0.879	1.333	**1.399**	1.253	1.563	**1.41**	1.285	1.547	1.478	0.912	2.395
Gender												

Confidence intervals not including 1 represent statistically significant findings (bolded).
BMI, body mass index.

tobacco use and its effects on outcomes after primary joint arthroplasty [30]. They found that patients who were currently or who had previously used tobacco had an increased risk of wound complications and prosthetic joint infection (PJI) when compared with those who had no history of tobacco use. The effects tobacco has on the musculoskeletal system have been well defined [31]. It affects wound healing by decreasing oxygen tension, increasing carbon monoxide, and altering microvascular blood flow. Smoking cessation, although found to have major impact on outcomes after TKA, is very difficult to achieve and sustain. Hart et al [32] found that roughly 7% of patients continue to smoke after TJA. In addition, of those who are able to quit, only 45% remain smoke free after surgery. With this in mind, there has been a concerted effort to help patients with smoking cessation. Boylan et al [33] found that smoking cessation programs are not only effective in helping with quitting tobacco but also cost-effective for the health care system as a whole. One previous study recommended a preoperative smoking cessation program starting 6-8 weeks before surgery [34]. If difficult to achieve cessation, some authors have advocated for routine cotinine level testing to ensure transparency and motivate patients to continue with cessation [35].

The deleterious effects diabetes has on the musculoskeletal system have been well defined [36]. The present study found that patients with insulin-dependent diabetes have significantly higher rates of readmission, infection, mortality, and complications in general. Several studies have found associations between diabetes and inferior outcomes after TJA. Lovecchio et al [37] found patients with NIDDM and IDDM had increased odds of experiencing a postoperative medical complication but only those with IDDM had increased 30-day mortality. There has been a question as to whether glycemic control over a long period of time matters or whether only hyperglycemia in the perioperative period leads to poor outcomes. Chrastil et al [38] evaluated patients with diabetes in the perioperative period. They found perioperative hyperglycemia to be more closely associated with PJI than hemoglobin A1c. This highlights the importance of maintaining good glycemic control in the preoperative and postoperative periods and not just setting a goal hemoglobin A1C for patients to achieve to have surgery. In our study, we did not have the ability to assess glycemic control given that hemoglobin A1C level was not available.

One key finding in the present study was that patients with low albumin levels (<3.5g/dL) had 3.7-fold higher odds of infection and 7.2-fold higher odds of 30-day mortality. This highlights the importance of perioperative nutrition in patients undergoing elective TKA. Albumin has been found to be a reliable marker of nutritional status and ultimate predictor of PJI after elective TJA [39]. The findings of the present study are consistent with previous studies that have shown poor nutrition to be a major risk factor for poor outcomes and even mortality after TKA. Nelson et al [40] recently evaluated the same NSQIP database that was used in the present study. They found that low albumin was associated with increased mortality and several other complications. In addition, they found that low serum albumin was more predictive of worse outcomes than morbid obesity. Studies have shown that around 8.5% of patients undergoing elective TJA were malnourished (as measured by low serum albumin levels) [41]. With this in mind, and the poor outcomes that can be seen in malnourished patients, it is currently the senior author's practice to obtain albumin level on every patient scheduled for surgery. If they are malnourished (as defined by < 3.5g/dL), then surgery is postponed and the patient is referred to a nutritionist for optimization. Surgery is performed when serum albumin is above 3.5 g/dL. If this is not achievable despite sincere diligent effort, the risk of surgery is defined clearly and the surgeon helps the patient make an informed choice. It is unknown whether reversal of hypoalbuminemia normalizes the risk of poor outcomes after elective TJA, however. This is an area of interest for future research.

The present study's results should be interpreted in light of several limitations. First, this is a secondary analysis of a large national database which could compromise the quality of the data. In NSQIP, the data are monitored with a high degree of scrutiny by institutionally appointed nurses and have been shown to have a high degree of accuracy and reliability [42]. Second, we only examined the years of 2017 and 2018, so trends are not able to be assessed. With regard to study design, a major weakness is that diabetes was treated as a modifiable, dichotomous risk factor. Although a patient cannot control whether their diabetes is present or not, they can strictly monitor glycemic control; ideally, perioperative glycemic control would have been analyzed as this may be a better indicator of postoperative outcomes and risk of complications. In addition, it would have been beneficial to analyze diabetes as a continuous variable, by analyzing hemoglobin A1c, rather than dichotomous as it currently is. Previous studies have demonstrated that the diagnosis of insulin-dependent diabetes alone is not a risk factor but rather poorly hyperglycemia is a risk factor [38,43]. It is apparent that a patient with insulin-dependent diabetes and hemoglobin A1c of 11.0% and uncontrolled hyperglycemia in the perioperative period is at a far different risk than a patient with insulin-dependent diabetes and hemoglobin A1c of 6.0%. However, the NSQIP data do not include glycated hemoglobin measures. In addition, the present study was not able to analyze the direct cost of complications and their impact on society as a whole. Several previous studies have reported on the large economic burden that complications and revision arthroplasty place on our society [44,45]. Although the present study could not determine direct costs of these complications and failure to optimize patients preoperatively, using these previous studies, it can be concluded that the economic burden is large and should further encourage surgeons to ensure optimization before elective TJA to decrease chances of poor outcomes. Finally, we did not truly assess failure to optimize, but rather looked at all patients who had nonoptimized values as a cohort. For example, we do not know how many patients with a normal albumin level who had surgery once had a level <3.5 g/dL, so the precise effect of optimization of risk factors is likely missed. Therefore, the lack of precision in the measures of the modifiable risk factors will introduce statistical bias into the point measures. Although this bias would be toward the null, our analysis yields meaningful clinical results with a large sample size.

Our current approach for preoperative optimization is to obtain a history (including tobacco use and history of diabetes), physical examination (including BMI), and x-rays to determine if a patient would benefit from elective primary TKA. All TKA candidates are sent to a primary care physician for preoperative medical optimization. The presence of diabetes with hemoglobin A1C $\geq$ 8.0%, BMI $\geq$40 kg/m2, current tobacco use, or hypoalbuminemia with a level < 3.5g/dL should be identified, and patients should be informed of risk associated with these issues. Surgery is postponed until risk factors are optimized. We have anecdotally found that protein supplementation does reverse low albumin, but we have not assessed the effect of this maneuver on complications.

Conclusion

Despite knowledge that modifiable risk factors significantly influence postoperative outcomes, patients continue to undergo elective TKA in up to 31% of the time, even in modern practice. Among the modifiable risk factors analyzed, hypoalbuminemia appears to be the strongest risk factor for all complications evaluated. With the many preoperative optimization efforts we currently undertake, special attention should be paid to preoperative nutrition.

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