의학박사 학위논문

양측 인공 슬관절 전치환술시 수술 간격에 따른 내과적, 외과적 합병증 발생률 비교: 국민건강보험 청구 데이터를 이용한 빅데이터 분석

Simultaneous bilateral total knee arthroplasty itself does not increase the risk of short-term major medical complications compared with those of staged bilateral total knee arthroplasty: An analysis of 58,838 patients based on the National Insurance Database in Korea from 2009 to 2019

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이 논문을 의학박사학위 논문으로 제출함.

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Controversy exists regarding the safety of simultaneous compared to staged bilateral TKA. The optimal interval for staged bilateral TKA has not yet been determined.

Purpose

This study aimed to analyze and compare the postoperative medical and surgical complications of bilateral TKA and determine the optimal intervals in staged bilateral TKA.

Methods

This study included 58,583 patients who underwent bilateral TKA between January 2009 and July 2019 using the Korean National Insurance Database; data on patient characteristics, including demographics, hospital type, and comorbidities, were collected. Major medical complications, such as acute myocardial infarction, pneumonia, intracranial hemorrhage, and ischemic stroke, within 30 days and surgical complications, including infection and revision, within 90 days of bilateral TKA were assessed. Patients were categorized into six groups according to operative interval: simultaneous, 1–7, 8–14, 15–30, 31–90, and 91–180 days. The 30-day medical and 90-day surgical complication rates were compared among the six groups. The annual trends in complication rates were evaluated and factors for postoperative complications were assessed using multivariable logistic regression analysis to adjust for confounding variables.

Results

Of the 58,838 patients, 24,379 underwent simultaneous bilateral TKA, while 34,459 underwent staged bilateral TKAs. The number of bilateral TKAs increased from 2,276 in 2009 to 8,703 in

2018. The proportion of patients who underwent simultaneous TKA increased from 9.8% in 2009 to 57.3% in 2018. The 30-day medical complication rates of simultaneous and staged bilateral TKA were 2.0% and 2.2%, respectively and were not significantly different ($p = 0.069$). The medical complication rate in simultaneous bilateral TKA decreased annually from 6.7% in 2009 to 1.7% in 2013 (relative risk [RR] = 0.69, 95% confidence interval [CI] 0.60 to 0.79, $p < 0.001$). During the same period, simultaneous bilateral TKA showed higher medical complication risk than that in staged bilateral TKA (RR = 1.40, $p = 0.005$, 95% CI 1.10 to 1.78). Conversely, in the five years after 2014, the medical complication rates of simultaneous bilateral TKA were significantly lower (1.9%) than those of staged bilateral TKA (2.2%) ($p = 0.023$). However, this difference was minimal. After adjusting for confounding factors, simultaneous bilateral TKA and intervals between 8 and 14 days did not significantly increase the risk of postoperative medical complications. Cardiopulmonary comorbidities (angina, ischemic stroke, heart failure, and chronic obstructive pulmonary disease) and age (> 70 years) were associated with postoperative medical complications. The 90-day surgical complication rates of simultaneous and staged bilateral TKA were 0.2% and 0.2%, respectively and were not significantly different ($p = 0.562$).

Conclusion

The complication rate of simultaneous bilateral TKAs has recently decreased and is comparable to that of staged bilateral TKAs. Simultaneous bilateral TKA did not increase the incidence of post-operative complications. An interval of one to two weeks would be suitable for staged bilateral total knee arthroplasty. Cardiopulmonary comorbidities were associated with a higher risk of major medical complications after bilateral total TKAs. With regard to careful preoperative patient evaluation and consideration of surgeons' preferences and patients'

desires, simultaneous bilateral TKA could be an appropriate option for patients requiring bilateral TKAs.

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Introduction

Total knee arthroplasty (TKA) is an effective and successful treatment for symptomatic advanced knee osteoarthritis (OA).[1,2] The annual incidence of TKA has increased in the previous two decades. The annual incidence of primary TKA in the United States increased more than 2.5 times from 274,025 in 2000 to 680,150 in 2014 and is expected to grow by up to 85% by 2030.[3] Similarly, in Korea, the number of TKAs also increased two-fold, from 29,980 in 2008 to 60,558 in 2018.[4]

Knee OA is more prevalent and progressive in old age and often involves both knees.[5,6] Approximately 5% of cases presenting with knee OA have been reported to have bilateral knee disease, and up to one-third of patients develop bilateral disease within two years of initial unilateral presentation.[7] This bilateral involvement increases with age and the severity of knee OA. One study found that approximately 65% of elderly patients (≥65 years old) with advanced knee osteoarthritis who were TKA candidates showed bilateral knee OA.[8] In addition, elderly patients often have multiple comorbidities. At least 85% of patients with TKA have at least one comorbidity and 32.5% have three or more comorbidities.[9] Given these circumstances, the treatment for symptomatic advanced bilateral knee osteoarthritis patients requiring TKA is challenging, and there is marked controversy in treatment strategies regarding the intervals between two TKAs, including simultaneous and staged TKAs. In simultaneous bilateral TKA, two TKAs are performed in a single event of anesthesia. By contrast, staged bilateral TKA is two TKAs performed under separate anesthesia events at intervals. Recently, simultaneous and staged bilateral TKA accounted for 7% and 15% of all primary TKAs, respectively, in the United States.[10]

The advantages of simultaneous bilateral TKA include decreased overall hospital length of stay,

shorter anesthetic time, and lower medical cost than staged bilateral TKA. Moreover, some studies have shown no difference in complications between bilateral TKA and staged TKA.[11-13] Whereas other studies have demonstrated that simultaneous bilateral TKA is associated with increased cardiopulmonary complications, transfusions, morbidity, and mortality.[14-16] Regarding this controversy, the decision should be made primarily by the evaluation of the risk of potential life-threatening complications rather than minor advantages such as medical cost.

With continued improvements in surgical techniques, perioperative management, anesthetic techniques, patient blood management, and postoperative pain control strategies to optimize the results of primary TKA, the perioperative complication and transfusion rates in primary TKA have decreased over the previous two decades. Recently, simultaneous bilateral TKA has been performed on an outpatient basis in selected cases, and a study reported comparable complications rate with an in-hospital basis.[17]

Most studies comparing the complication rate between simultaneous and staged bilateral TKA analyzed the complication rates without considering annual effects. Few studies have investigated the annual trend of perioperative complication rates in simultaneous and staged bilateral TKA based on nationwide cohorts. Furthermore, the optimal intervals in terms of minimizing postoperative complications have not been determined.

Therefore, this study aimed to investigate the annual trend of major medical and surgical postoperative complication rates after simultaneous and staged bilateral TKAs, compare the postoperative medical and surgical complications between two types of bilateral TKAs, and determine the optimal intervals in staged bilateral TKAs.

Materials and Methods

1. Database

This nationwide retrospective cohort study used data from the Korean National Health Insurance claims database. In Korea, healthcare services are covered by National Health Insurance, which is compulsory for all Korean citizens. Medical claims are reviewed and evaluated by a public institution, the Health Insurance Review and Assessment Service (HIRA). All data are stored in the HIRA database, which primarily comprises two parts: the diagnosis code based on the International Classification of Diseases, 10th Revision (ICD-10) and the procedure code based on the electronic data interchange (EDI) code. The database contains all claims data for both inpatients and outpatients, including demographic information, diagnosis, procedure, prescribed drug information, and hospital type. HIRA provides data to researchers following approval from the official review committee. This study was reviewed and approved by the institutional review board of our institution.

2. Study population

Claims data of patients who underwent primary total knee arthroplasty between January 2009 and July 2019 were extracted from the database using the procedure codes (EDI) N2072 and N2077 for primary TKA. Patients who underwent bilateral primary TKA were identified if they had two procedural codes for primary TKA.

Based on the operation type, the cases were categorized into two groups: simultaneous TKA and staged bilateral TKA. Simultaneous bilateral TKA was defined as a procedure in which two primary TKAs were performed under the same anesthesia event. Staged bilateral TKA was defined as a case in which two primary TKA were performed under two separate anesthesia

events on different days. Patients with more than a six-month interval between two TKAs were excluded because the procedure may have been performed due to worsening of the symptoms on the opposite side after the index primary TKA rather than the planned operation. Patients who underwent staged bilateral TKA were stratified into five groups according to the time interval between the two TKAs: 1–7, 8–14, 15–30, 31–90, and 91–180 days.

Inaccurate data that were not clearly defined were also excluded. These included (1) patients identifying as revision total knee arthroplasty code prior to primary total knee arthroplasty code, (2) patients claiming multiple primary or revision codes (more than three times) on the same day, (3) patients claiming multiple hospitalizations on the same day, and (4) patients claiming an exceeding number of anesthesia codes than primary TKA codes (more than three times) (Figure 1).

3. Patient characteristics and comorbidities

Patient demographics, including age, sex, hospital type, and comorbidities, including atrial fibrillation, liver cirrhosis, pulmonary embolism, deep vein thrombosis, angina, end-stage renal disease, chronic kidney disease, ischemic stroke, intracranial hemorrhage, hypertension, diabetes mellitus, dyslipidemia, heart failure, peripheral arterial disease, chronic obstructive pulmonary disease, cancer, and metastatic cancer, were evaluated. Comorbidities within one year prior to TKA were included and were identified as ICD-10 and specific drug prescription codes, as described in a previous retrospective cohort study using the Korean National Health Insurance claims database.[18] A detailed definition of comorbidities is presented in Supplementary Table 1.

4. Major medical and surgical complications

The outcomes of interest were the rates of major postoperative medical complications within 30 days and major postoperative surgical complications within 90 days after TKA. Major medical complications included potentially life-threatening diseases, such as acute myocardial infarction, pneumonia, ischemic stroke, and intracranial hemorrhage. The major surgical complications included periprosthetic joint infections and revision TKA. For staged bilateral TKAs, postoperative complications were evaluated based on the time point of the second operation. Both medical and surgical complications were identified with a combination of specific ICD and procedural codes. (Supplementary Table 2)

5. Statistical analysis

Patient characteristics, comorbidities, medical and surgical complications rates were compared between the six groups. Categorical variables were compared using Pearson's chi-squared test, and one-way analysis of variance was used to compare continuous variables. The annual trends in the 30-day medical complication rate were analyzed by estimating the relative risk using a log-linear Poisson regression analysis. Multivariable logistic regression analysis was used to identify risk factors associated with medical and surgical complications after bilateral TKAs. Adjusted odds ratios of risk factors were calculated using multivariable logistic regression after adjusting for age, sex, hospital type, comorbidities, and operation types, and are presented with a 95% confidence interval (CI). All analyses were performed using the SAS Enterprise software version 6.1 (SAS Institute, Cary, NC, USA). Statistical significance was set at $P < 0.05$.

Results

A total of 564,925 patients who underwent primary TKAs from January 2009 to July 2019 in Korea were identified in the database. After excluding inaccurate data and cases with more than six months of intervals between the two TKAs, 58,838 patients who underwent bilateral primary TKA were enrolled in the final analysis. Simultaneous bilateral TKA was performed in 24,379 patients. According to the intervals between the two TKAs, staged bilateral TKAs were identified in 11,674 on 1-7 days, 5,710 on 8-14 days, 6,202 on 15-30 days, 6,601 on 31-90 days, and 4,272 on 91-180 days, respectively (Figure 1). Patient characteristics and comorbidities by operative type are presented in Table 1. The number of patients who underwent bilateral TKAs increased from 2,276 in 2009 to 8,703 in 2018. The proportion of simultaneous bilateral TKA increased from 9.8% in 2009 to 57.3% in 2018 (Figure 2).

1. Medical complication rate

The mean 30-day medical complication rates of simultaneous and staged bilateral TKA between 2009 and 2019 were 2.0% and 2.2%, respectively, indicating no significant differences (P = 0.069) (Table 2). However, the medical complication rates of simultaneous and staged bilateral TKAs showed a different trend (Figure 3). Specifically, the medical complication rates in staged bilateral TKAs showed no difference over time. Whereas the medical complication rate in simultaneous bilateral TKA decreased 0.69 times a year from 6.7% in 2009 to 1.7% in 2013 (95% CI, 0.60-0.79, P<0.001). Within the same period, simultaneous bilateral TKA showed a 1.4-times greater risk for medical complications than staged bilateral TKA. (95% CI: 1.10-1.78, P = 0.005). In contrast, from 2014 to 2019, the mean medical complication rate of simultaneous bilateral TKA was 1.9%, which was significantly lower than the 2.2% of staged bilateral TKA. However, the absolute difference was minimal at 0.3%.

The most common major medical complication after bilateral TKA was pneumonia at 1.3% of total cases, and the incidence of acute MI, ICH, and stroke were less than 1%. The major medical complication rates after simultaneous bilateral TKA and staged bilateral TKA with 8-14 day intervals were not significantly different at 2.0% and 2.0%, respectively. The complication rate of staged bilateral TKA with 15-30 day intervals was 2.69%, significantly higher than that of simultaneous and other intervals (P = 0.040) (Figure 4).

2. Surgical complication rate

The 90-day surgical complication rates of simultaneous and staged bilateral TKA were not significantly different at 0.2% and 0.2%, respectively (P = 0.562). The overall revision rates of simultaneous and staged bilateral TKAs were not significantly different at 0.1% and 0.1%, respectively. However, the infection rate at intervals of three to six months was 0.4%, which was significantly higher than that of simultaneous or staged TKA with other intervals (P = 0.004) (Table 3).

3. Risk factors for perioperative complication

After adjusting for confounding factors in the multiple variable logistic regression analysis, operation intervals were significantly associated with major medical complications after bilateral TKAs (P = 0.001). Simultaneous bilateral total knee arthroplasty did not increase the risk of 30-day major medical complications compared with staged bilateral TKA. Specifically, when simultaneous bilateral TKA was used as a reference, the interval of 8-14 days was not statistically significant. The intervals of 1-7 days (OR 1.23, 95% CI 1.05 - 1.45, P=0.013), 15-30 days (OR 1.48, 95% CI 1.23 - 1.79, P<0.001), 31-90 days (OR 1.25, 95% CI 1.03 - 1.53, P=0.025), and 91-180 days (OR 1.27, 95% CI 1.01 - 1.61, P=0.045) significantly increased the risk of medical complications following bilateral TKA. Among the comorbidities, angina (OR

1.29, 95% CI 1.12-1.50, P<0.001), ischemic stroke (OR 1.39, 95% CI 1.16 - 1.67, P<0.001), heart failure (OR 1.61, 95% CI 1.34-1.93, P<0.001), and chronic obstructive pulmonary disease (OR 1.52, 95% CI 1.33-1.73, P<0.001) were associated with major medical complications after bilateral TKA. Moreover, older age (≥70 years), male sex, and hospital type (clinics, hospitals, and general hospitals) were identified as significant risk factors for the 30-day major medical complication rates after bilateral TKA. The detailed ORs are listed in Table 4. For surgical complications, the intervals between 91 and 180 days (OR 2.63, 95% CI 1.53 – 4.50, P = 0.0004) and male sex (OR 2.89, 95% CI 1.93-4.32, P<0.001) significantly increased the risk of 90-day surgical complications after bilateral TKA (Table 5).

Discussion

The primary finding of the present study was that simultaneous bilateral TKA did not increase the risk of short-term major medical complications compared with staged bilateral TKA, even after adjusting for differences in baseline patient characteristics. In Korea, the proportion of simultaneous bilateral TKA cases gradually increased from 2009 to 2019 in the total bilateral TKA cases. The medical complication rate of simultaneous bilateral TKA decreased during the study period and was comparable to that of staged bilateral TKA over the last five years.

The primary consideration for patients with symptomatic bilateral advanced OA who require TKA is the interval between TKAs. There is a concern that TKA may increase the risk of life-threatening complications, as it could be a stressful event for elderly patients. In particular, this concern might be highlighted in bilateral TKAs. Therefore, the timing decision should be primarily approached in terms of safety rather than cost-effectiveness. Over the past decades, numerous studies based on data from single-center to nationwide large cohorts have been conducted to compare the perioperative complication and mortality rates after simultaneous and staged bilateral TKAs and to investigate the safety of simultaneous bilateral TKA. While some studies have shown no differences in perioperative complications between simultaneous and staged bilateral TKAs,[13,19,20] several systematic reviews have shown a trend toward increased risk in simultaneous bilateral TKA.[14-16]

In a previous meta-analysis that evaluated the safety of simultaneous bilateral TKA, the simultaneous bilateral TKAs have a 2.49 odds ratio for increased cardiac complication rate and a 2.20 odds ratio for increased mortality.[15] However, this risk evaluation was based on a comparison with unilateral TKAs. A recent systematic review compared mortality and complication rates between simultaneous and staged bilateral TKA in 29 studies published

between 2000 and 2020.[16] There was an odds ratio of 2.24 for increased risk of mortality and an odds ratio of 1.42 for increased risk of neurologic complications in simultaneous bilateral TKA. In a study by Tsay et al. that accounted for the largest weight in the aforementioned systematic review, they analyzed the 30-day medical complications of 27,301 simultaneous bilateral TKA and 45,419 staged bilateral TKA using national hospital discharge data in the United States between 2005 and 2014.[10] They found that simultaneous bilateral TKAs had a statistically significant increased odds ratio for multiple complications compared to staged bilateral TKAs. However, the absolute values of all complication rates were less than 1-2%. Specifically, the incidence of myocardial infarction was 0.6% and 0.3% in simultaneous and staged bilateral TKAs, respectively, and the incidence of ischemic stroke was 0.3% and 0.2% in simultaneous and staged bilateral TKAs, respectively. The complication rate in the present study was similar to that in previous studies. In the present study, the rates of AMI of simultaneous and staged-bilateral TKAs were 0.4% and 0.7%, respectively, and the rate of ischemic stroke was 0.4% in both simultaneous and staged bilateral TKAs.

Unlike previous studies showing an increased risk in simultaneous bilateral TKA, the present study showed that simultaneous bilateral TKA did not increase the major complication rate compared to staged bilateral TKA. Before a direct comparison with previous studies, it should be noted that the complication rates of simultaneous and staged bilateral TKAs may have improved and changed in different patterns over time. Since previous studies included broad study periods, this should be interpreted with consideration of the timeframe effect. The present study investigated annual trends and found that the certain declined changes in the major complication rate in simultaneous bilateral TKA. Specifically, in the first four years from 2009 to 2013 during the 10-year study period, the mean major medical complication rates in

simultaneous and staged bilateral TKA were 2.8% and 1.9%, respectively, indicating a 1.4-fold increased relative risk of 30-day major medical complications in simultaneous bilateral TKAs, which is consistent with the findings of Tsay et al.'s study and a recent systematic review. Whereas, in the last six years from 2014 to 2019, the complication rate of simultaneous bilateral TKA was 1.9%, which was comparable to the 2.2% of staged bilateral TKA, showing 0.3% of minimal differences.

Similarly, in a more recent large cohort study using the National Readmission Database between 2016 and 2017, the 30-day major complication rates, including cerebrovascular accidents, myocardial infarction, and pneumonia, did not differ between simultaneous and staged bilateral TKAs.[12] It could be speculated that appropriate patient selection and optimized perioperative patient management may have lowered the risk of simultaneous bilateral TKAs. Over the previous decades, advances in surgical techniques and implant designs have improved the survival rate of TKA, reaching a certain plateau. Recently, attention has been focused on safer, less painful, and faster recovery after TKA. The complication rate of primary TKA has decreased over the previous decade. In a study comparing 30-day complication rates after primary TKA between three divided periods using the National Surgical Quality Improvement Program (NSQIP) Registry between 2006 and 2016, the 30-day complication rate decreased from 5.37% during 2006 and 2009 to 3.86% during 2010 and 2013, and to 3.13% during 2014 and 2016.[21]

The optimal interval between the two operations in staged bilateral TKA remains controversial. The present study showed that intervals between one to two weeks were optimal in terms of the 30-day major complication rate. It is unclear why one to two-week intervals did not increase the risk of 30-day major complications among the different intervals. However, this may be

associated with a recovery of immune response after surgical stress. Interleukin-6 (IL-6) is a critical marker for the induction and control of acute-phase protein response after surgery. A previous study showed that the IL-6 level is elevated within one day after TKA and normalized on postoperative day seven.[22] In the acute immune response phase after TKA, the second TKA may act as a second hit, which exaggerates the immune response.[23] Similar to the present study, in a study investigating the optimal intervals using a nationwide cohort database, staged bilateral TKA with a one to three days interval was associated with an increased complication rate compared to simultaneous and bilateral staged TKA with a four to seven day interval.[24] Therefore, intervals of less than one week between two TKAs should not be recommended.

In addition to the operation intervals, the present study found that older age (≥70), angina ischemic stroke, heart failure, and chronic obstructive pulmonary disease were associated with major medical complications after bilateral TKAs. Similar to the results of the present study, previous studies have also reported increased perioperative complications in patients with cardiopulmonary disease after bilateral TKA. Wang et al. developed a novel scoring system for risk stratifying patients who underwent simultaneous bilateral TKA using data from 4,640 patients in the NSQIP database.[25] Older age (≥75), high body mass index (≥34), hypertension requiring medication, and pulmonary disease were independent risk factors. Similarly, Poultsides et al. identified pulmonary hypertension and congestive heart failure as significant risk factors for major complications in simultaneous bilateral TKAs. This suggests that bilateral TKAs are a stressful procedure in patients with decreased cardiopulmonary function.[26] Therefore, physicians should be aware that cardiopulmonary function after bilateral TKA could worsen in these patients, in which case, perioperative screening and optimized patient management should be emphasized.

The present study found that the 90-day revision rate was equivalent between simultaneous and staged bilateral TKAs. Moreover, the absolute values of revision rates were extremely low, at approximately 0.1%, regardless of operative intervals. This result is consistent with a recent systematic review which demonstrated that the early revision rate was not significantly different at one year postoperatively between simultaneous and staged bilateral TKAs.[19] In terms of surgical infections, previous studies have demonstrated that long intervals tend to increase the risk of surgical site infection more than short intervals and simultaneous TKAs. Abdelaal et al. showed a higher incidence of periprosthetic joint infection in intervals of more than 90 days compared to intervals of less than 90 days in staged bilateral TKAs.[27] Poultsides et al. showed that simultaneous bilateral TKAs were associated with lower infection rates compared to those of staged bilateral TKAs.[26] Similar to previous studies, the present study also showed that intervals between three and six months were associated with increased surgical site infection. A possible explanation for these results might be that the two separate TKAs allow for additional exposure to the infectious organism and elevate the risk of bacteremia.

The present study had several limitations. First, this was a retrospective cohort study based on claims codes. Therefore, inherent potential bias, including errors in claims and data acquisition, may exist because of the retrospective design. However, previous studies have validated the accuracy of the HIRA coding system to be 70% to 90%, indicating an acceptable level of analysis.[28,29] Second, we could not identify patients who dropped out after the first TKA and delayed the second TKA in the planned staged bilateral TKAs. Since the patients who develop complications after first TKA have increased risk of same complication at second TKA, the complication rate in the longer intervals could have overestimated.[30] Third, miscellaneous

factors, including surgeons and the health care system were not considered in the present study. For example, the simultaneous bilateral TKA may be more performed by experienced surgeons and well-trained surgical teams. This might lead to a lower complication rate in simultaneous bilateral TKA. Finally, the mixed effect between risk factors was not evaluated. Specifically, when simultaneous bilateral TKA was performed in patients with high-risk comorbidities, it was not determined whether the risk of complications would exceed each risk level owing to synergic effects. A previous study showed a comparable complication rate between simultaneous and unilateral TKA in the patients with less than two risk factors, but the differences in the complication rate between simultaneous and unilateral TKA increased in the patients with more than two risk factors.[25] Further study should be addressed to evaluate the stratified risk according to the number of risk factors.

Conclusion

The complication rate of simultaneous bilateral TKAs has recently decreased and is comparable to that of staged bilateral TKAs. Simultaneous bilateral TKA did not increase the incidence of post-operative complications. An interval of one to two weeks would be suitable for staged bilateral total knee arthroplasty. Cardiopulmonary comorbidities were associated with a higher risk of major medical complications after bilateral total TKAs. With regard to careful preoperative patient evaluation and consideration of surgeons' preferences and patients' desires, simultaneous bilateral TKA could be an appropriate option for patients requiring bilateral TKAs.

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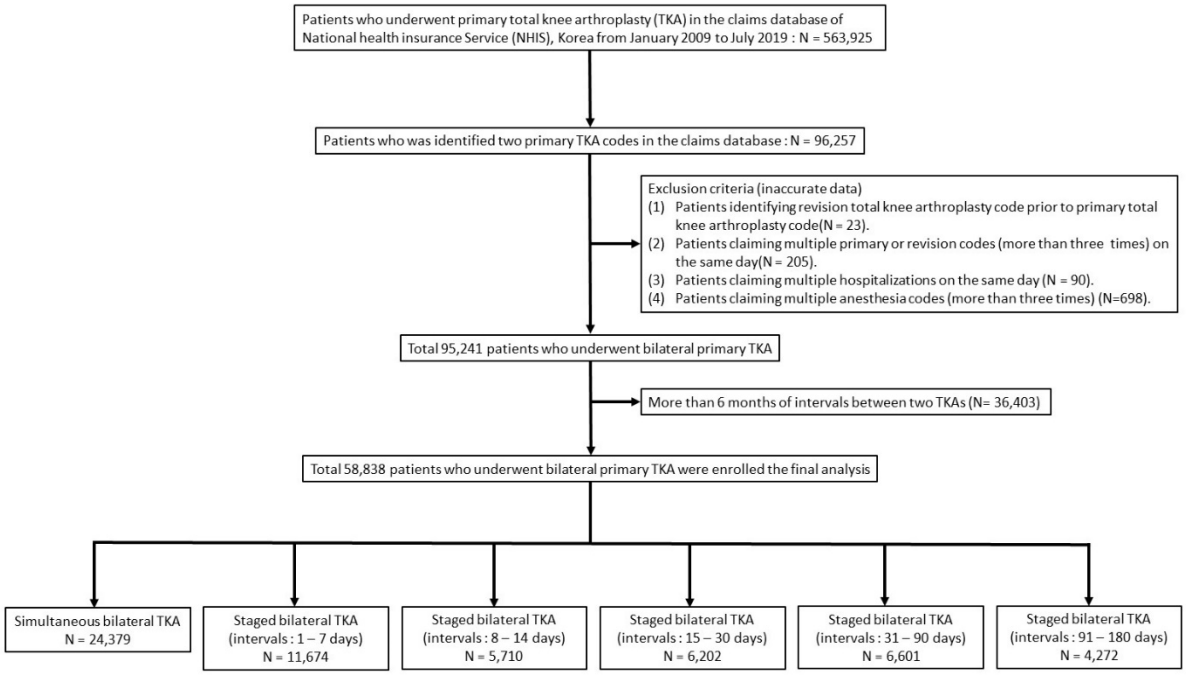

Figure 1. Flow chart depicting data selection and categorization of the study

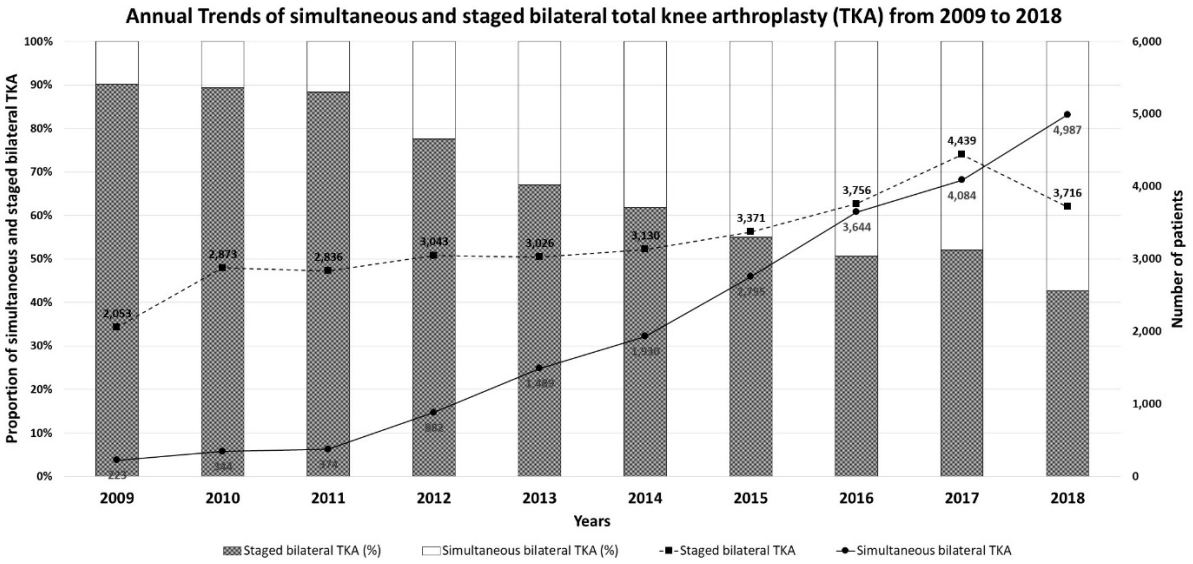

Figure 2. Annual trends of simultaneous and staged bilateral total knee arthroplasty from 2009 to 2019

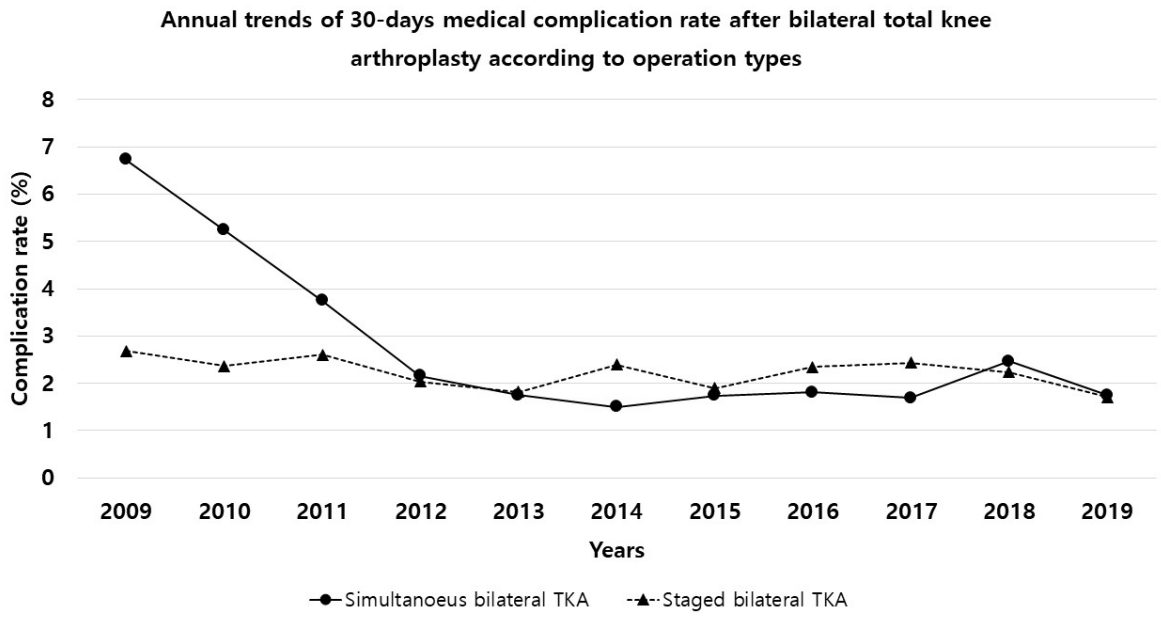

Figure 3. Annual trends of 30-days medical complication rate after bilateral total knee arthroplasty according to operation type

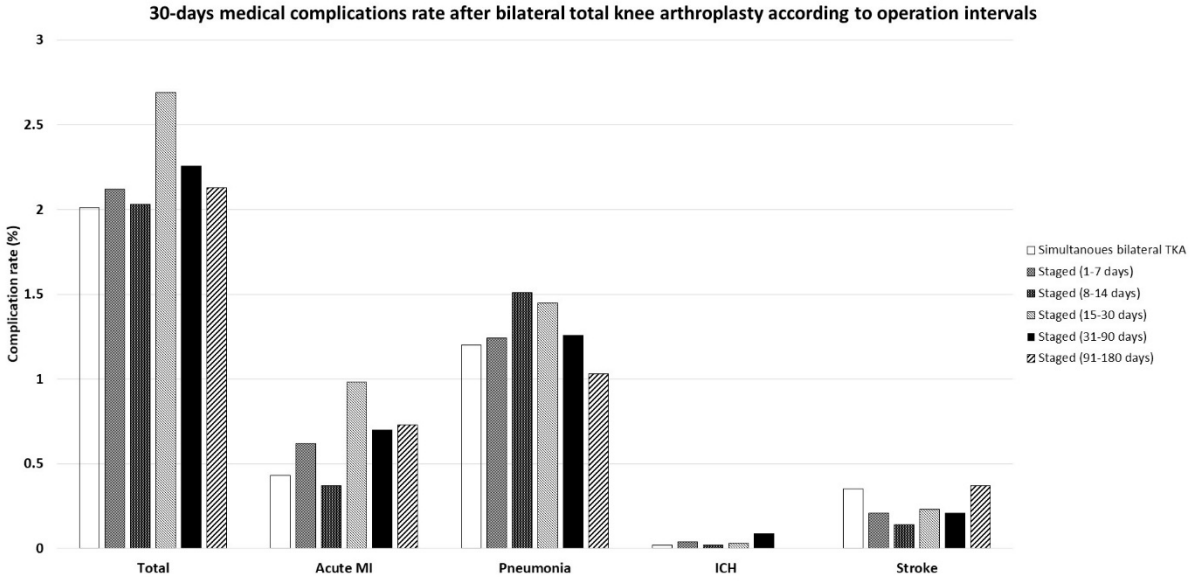

Figure 4. 30-day medical complication rates after bilateral total knee arthroplasty according to operation intervals

MI, myocardial infarction; ICH, intracranial hemorrhage

Table 1. Baseline characteristics of patients with primary bilateral TKAs by the operation intervals in Korea 2009 to 2019 [a]

			Staged					
	Total	Simultaneous	Intervals (1-7 days)	Intervals (8-14 days)	Intervals (15-30 days)	Intervals (31-90 days)	Intervals (31-90 days)	P-value
Patients, n	58,838	23,379	11,674	5,710	6,202	6,601	4,272	
Characteristics								
Age, Mean ± SD	71.3 ± 6.8	71.7 ± 6.7	70.9 ± 6.5	70.8 ± 6.7	71.2 ± 6.8	71.0 ± 7.4	70.8 ± 7.4	<0.001
Age distribution, n, (%)								<0.001
<65	9,267 (15.8)	3,399 (13.9)	1,843 (15.8)	1,000 (17.5)	958 (15.4)	1,243 (18.8)	824 (19.3)	
65-69	13,074 (22.2)	5,331 (21.9)	2,725 (23.3)	1,279 (22.4)	1,442 (23.3)	1,367 (20.7)	930 (21.8)	
70-74	16,670 (28.3)	7,005 (28.7)	3,522 (30.2)	1,670 (29,2)	1,723 (27.8)	1,648 (25.0)	1,102 (25.8)	
75-79	13,782 (23.4)	5,875 (24.1)	2,635 (22.6)	1,318 (23.1)	1,435 (23.1)	1,590 (24.1)	929 (21.7)	
≥80	6,045 (10.3)	2,769 (11.4)	949 (8.1)	443 (7.8)	644 (10.4)	753 (11.4)	487 (11.4)	
Sex, (%)								<0.001
Male	7,768 (13.2)	4,383 (18.0)	1,095 (9.4)	452 (7.9)	518 (8.4)	796 (12.1)	524 (12.3)	
Female	51,070 (86.8)	19,996 (82.0)	10,579 (90.6)	5,258 (92.1)	5,684 (91.6)	5,805 (87.9)	3,748 (87.7)	
Hospital types, (%)								<0.001
Clinic, hospital	25,610 (43.5)	6,331 (26.0)	5,858 (50.2)	3,615 (63.3)	3,645 (58.8)	3,991 (60.5)	2,170 (50.8)	

Table 1. (Continued)

			Staged					
	Total	Simultaneous	Intervals (1-7 days)	Intervals (8-14 days)	Intervals (15-30 days)	Intervals (31-90 days)	Intervals (31-90 days)	P-value
General hospital	27,583 (46.9)	16,610 (68.1)	4,536 (38.9)	1,602 (28.1)	2,250 (36.3)	1,524 (23.1)	1,061 (24.8)	
Tertiary hospital	5,645 (9.6)	1,438 (5.9)	1,280 (11.0)	493 (8.6)	307 (5.0)	1,086 (16.5)	1,041 (24.4)	
Comorbidities								
Atrial fibrillation	1,470 (2.5)	678 (2.8)	247 (2.1)	102 (1.8)	124 (2.0)	207 (3.1)	112 (2.6)	<0.001
Liver cirrhosis	371 (0.6)	164 (0.7)	44 (0.4)	27 (0.5)	32 (0.5)	62 (0.9)	42 (1.0)	<0.001
Pulmonary embolism	92 (0.2)	34 (0.1)	17 (0.1)	4 (0.1)	10 (0.2)	18 (0.3)	9 (0.2)	0.081
Deep vein thrombosis	429 (0.7)	186 (0.8)	68 (0.6)	32 (0.6)	43 (0.7)	58 (0.9)	42 (1.0)	0.034
Angina	8,361 (14.2)	3,611 (14.8)	1,442 (12.4)	703 (12.3)	860 (13.9)	1,043 (15.8)	702 (16.4)	<0.001
End stage renal disease	44 (0.1)	16 (0.1)	10 (0.1)	4 (0.1)	3 (0.0)	7 (0.1)	4 (0.1)	0.832
Chronic kidney disease	929 (1.6)	489 (2.0)	113 (1.0)	63 (1.1)	73 (1.2)	114 (1.7)	77 (1.8)	<0.001
Ischemic stroke	4,260 (7.2)	1,841 (7.6)	768 (6.6)	349 (6.1)	442 (7.1)	532 (8.1)	328 (7.7)	<0.001
Intracranial hemorrhage	89 (0.2)	37 (0.2)	6 (0.1)	9 (0.2)	10 (0.2)	17 (0.3)	10 (0.2)	0.012

Table 1. (Continued)

			Staged					
	Total	Simultaneous	Intervals (1-7 days)	Intervals (8-14 days)	Intervals (15-30 days)	Intervals (31-90 days)	Intervals (31-90 days)	P-value
Hypertension	38,063 (64.7)	16,047 (65.8)	7,469 (64.0)	3,548 (62.1)	3,946 (63.6)	4,285 (64.9)	2,768 (64.8)	<0.001
Diabetes mellitus	13,475 (22.9)	5,869 (24.1)	2,527 (21.6)	1,223 (21.4)	1,347 (21.7)	1,507 (22.8)	1,002 (23.5)	<0.001
Dyslipidemia	37,755 (64.2)	16,327 (67.0)	7,262 (62.2)	3,354 (58.7)	3,918 (63.2)	4,156 (63.0)	2,738 (64.1)	<0.001
Heart failure	3,732 (6.3)	1,536 (6.3)	680 (5.8)	339 (5.9)	389 (6.3)	496 (7.5)	292 (6.8)	<0.001
Peripheral artery disease	12,096 (20.6)	5,073 (20.8)	2,406 (20.6)	1,184 (20.7)	1,248 (20.1)	1,359 (20.6)	826 (19.3)	0.330
Chronic obstructive pulmonary disease	10,182 (17.3)	4,401 (18.1)	1,811 (15.5)	884 (15.5)	1,102 (17.8)	1,233 (18.7)	751 (17.6)	<0.0001
Cancer	3,088 (5.2)	1,507 (6.2)	535 (4.6)	223 (3.9)	282 (4.5)	335 (5.1)	206 (4.8)	<0.001
Metastatic cancer	150 (0.3)	76 (0.3)	22 (0.2)	7 (0.1)	13 (0.2)	20 (0.3)	12 (0.3)	0.067

TKA; total knee arthroplasty

[a] Data were collected between January 2009 and July 2019.

Table 2. Annual trends of 30-day medical complication rates after bilateral total knee arthroplasty based on operation intervals

Operation types		2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019[a]	Total
Simultaneous bilateral TKA	Total number, n	223	344	374	882	1,489	1,930	2,755	3,644	4,084	4,987	3,667	24,379
	Medical complications, n (%)	15 (6.7)	18 (5.2)	14 (3.7)	19 (2.2)	26 (1.7)	29 (1.5)	48 (1.7)	66 (1.8)	69 (1.7)	123 (2.5)	64 (1.7)	491 (2.0)
Staged bilateral TKA	Total number, n	2,053	2,873	2,836	3,043	3,026	3,130	3,371	3,756	4,439	3,716	2,216	3,4459
	Medical complications, n (%)	55 (2.7)	68 (2.4)	74 (2.6)	62 (2.0)	55 (1.8)	75 (2.4)	64 (1.9)	88 (2.3)	108 (2.4)	83 (2.2)	38 (1.7)	770 (2.2)

TKA, total knee arthroplasty.

[a] Data were collected between January 2009 and July 2019.

Table 3. Medical (30-day) and surgical (90-day) complication rates after bilateral primary total knee arthroplasty based on operation intervals

	Simultaneous TKA	Staged TKA					p-value
		Intervals (days)					
		1–7	8–14	15–30	31–90	91–180	
Patients, n	24,379	11,674	5,710	6,202	6,601	4,272	
Medical complications (30-day), n (%)							
Acute MI	106 (0.4)	72 (0.6)	21 (0.4)	61 (1.0)	46 (0.7)	31 (0.7)	<0.001
Pneumonia	293 (1.2)	145 (1.2)	86 (1.5)	90 (1.5)	83 (1.3)	44 (1.0)	0.212
ICH	6 (0.0)	5 (0.0)	1 (0.0)	2 (0.0)	6 (0.1)	0 (0.0)	0.159
Stroke	86 (0.4)	25 (0.2)	8 (0.1)	14 (0.2)	14 (0.2)	16 (0.4)	0.018
Surgical complications (90-day), n (%)							
Infection	26 (0.1)	19 (0.2)	5 (0.1)	4 (0.1)	8 (0.1)	16 (0.4)	0.004
Revision	21 (0.1)	4 (0.0)	3 (0.1)	3 (0.1)	7 (0.1)	5 (0.1)	0.282

ICH, intracranial hemorrhage; MI, myocardial infarction; TKA, total knee arthroplasty.

Table 4. Risk factor analysis for 30-day medical complications after bilateral total knee arthroplasty

	Unadjusted odds ratio	95% CI	p-value	Adjusted odds ratio	95% CI	p-value
Operation intervals (days)			0.028			0.001
Simultaneous TKA	Reference			Reference		
Staged TKA						
1–7	1.06	0.91 to 1.24	0.444	1.23	1.05 to 1.45	0.013
8–14	1.05	0.85 to 1.28	0.669	1.21	0.98 to 1.50	0.076
15–30	1.37	1.15 to 1.64	<0.001	1.48	1.23 to 1.79	<0.001
31–90	1.15	0.95 to 1.39	0.146	1.25	1.03 to 1.53	0.025
91–180	1.10	0.88 to 1.38	0.421	1.27	1.01 to 1.61	0.045
Age, years			<0.001			<0.001
< 65	Reference			Reference		
65–69	1.30	1.04 to 1.61	0.019	1.24	1.00 to 1.54	0.054
70–74	1.39	1.13 to 1.71	0.002	1.29	1.05 to 1.59	0.015
75–79	1.77	1.44 to 2.17	<0.001	1.62	1.32 to 1.99	<0.001
≥ 80	2.58	2.06 to 3.21	<0.001	2.28	1.82 to 2.86	<0.001
Sex						

Table 4. (Continued)

	Unadjusted odds ratio	95% CI	p-value	Adjusted odds ratio	95% CI	p-value
Female	Reference			Reference		
Male	1.47	1.27 to 1.71	<0.001	1.42	1.22 to 1.65	<0.001
Hospital types			<0.001			<0.001
Clinic, hospital	1.74	1.35 to 2.23	<0.001	1.80	1.40 to 2.31	<0.001
General hospital	1.77	1.38 to 2.27	<0.001	1.83	1.42 to 2.36	<0.001
Tertiary hospital	Reference			Reference		
Comorbidities						
Atrial fibrillation	1.28	0.93 to 1.77	0.131			
Liver cirrhosis	0.77	0.34 to 1.72	0.521			
Pulmonary embolism	1.58	0.50 to 4.99	0.439			
Deep vein thrombosis	1.35	0.76 to 2.40	0.309			
Angina	1.59	1.38 to 1.83	<0.001	1.29	1.12 to 1.50	0.001
End stage renal disease	2.23	0.54 to 9.21	0.268			
Chronic kidney disease	1.52	1.04 to 2.21	0.029	1.15	0.78 to 1.68	0.478
Ischemic stroke	1.64	1.37 to 1.96	<0.001	1.39	1.16 to 1.67	0.001

Table 4. (Continued)

	Unadjusted odds ratio	95% CI	p-value	Adjusted odds ratio	95% CI	p-value
Intracranial hemorrhage	2.79	1.13 to 6.89	<0.001	2.29	0.92 to 5.71	0.076
Hypertension	1.17	1.03 to 1.32	0.013	1.02	0.90 to 1.15	0.801
Diabetes mellitus	1.05	0.92 to 1.19	0.510			
Dyslipidemia	1.18	1.05 to 1.33	0.007	1.08	0.95 to 1.22	0.259
Heart failure	2.06	1.73 to 2.45	<0.001	1.61	1.34 to 1.93	<0.001
Peripheral artery disease	1.25	1.10 to 1.43	0.001	1.13	0.99 to 1.29	0.080
Chronic obstructive pulmonary disease	1.71	1.51 to 1.95	<0.001	1.52	1.33 to 1.73	<0.001
Cancer	1.09	0.85 to 1.39	0.495			
Metastatic cancer	2.30	1.08 to 4.92	0.032	1.83	0.85 to 3.96	0.124

CI, confidence interval; TKA, total knee arthroplasty

Table 5. Risk factor analysis for 90-day surgical complications after bilateral total knee arthroplasty

	Adjusted odds ratio	95% CI	p-value
Operation intervals (days)			0.026
Simultaneous TKA	Reference		
Staged TKA			
1–7	1.11	0.66 to 1.87	0.698
8–14	0.88	0.42 to 1.88	0.750
15–30	0.71	0.32 to 1.57	0.396
31–90	1.34	0.75 to 2.42	0.323
91–180	2.63	1.53 to 4.51	<0.001
Sex			
Female	Reference		
Male	2.89	1.93 to 4.33	<0.001

CI, confidence interval; TKA, total knee arthroplasty

Supplementary table 1. Definition of each comorbidities using ICD-10 code and drug prescription code

	ICD-10 code	Diagnostic definition
Atrial fibrillation	I480-484, I489	Admission or outpatient department ≥1
Liver cirrhosis	K74, K70.2-70.3. K71.7, K76.1	Admission ≥1 or outpatient clinic ≥2
Pulmonary embolism	I26	Admission ≥1
Deep vein thrombosis	I802, I803	Admission or outpatient department ≥1
Angina	I20.0, I20.1, I20.8, I20.9	Admission or outpatient department ≥1
End stage renal disease	N185,Z49 Dialysis code: V001, V003, O7020, O7061	Dialysis ≥2
Chronic kidney disease	N18, N19	Admission ≥1 or outpatient department ≥2
Ischemic stroke	I63, I64	Admission or outpatient department ≥1
Intracranial hemorrhage	I60-62	Admission ≥1 or RBC transfusion ≥1
Hypertension	I10-I13, I15; and minimum 1 prescription of anti-hypertensive drug (thiazide, loop diuretics, aldosterone antagonist, alpha-/beta-blocker, calcium-channel blocker, angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker).	Admission ≥1 or outpatient department ≥2
Diabetes mellitus	E11-E14; and minimum 1 prescription of anti-diabetic drugs (sulfonylureas, metformin, meglitinides, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, α-glucosidase inhibitors, and insulin).	Admission ≥1 or outpatient department ≥2

Supplementary Table 1. (Continued)

	ICD-10 code	Diagnostic definition
Dyslipidemia	E78	Admission or outpatient department ≥1
Heart failure	I50	Admission or outpatient department ≥1
Peripheral arterial disease	I70, I73	Admission or outpatient department ≥2
Chronic obstructive pulmonary disease	J41-44	Admission or outpatient department ≥1
Cancer	C00–C26, C30–C34, C37–C41, C43, C45–C58, C60–C76, C81–C85, C88, C90–C97	Admission or outpatient department ≥1
Metastatic cancer	C77–C80	Admission or outpatient department ≥1

RBC, red blood cell

Supplementary table 2. Definition of medical (30-day) and surgical (90-day) complication after bilateral TKA using ICD-10 and procedural codes

	ICD-10 code	Procedural code	Conditions
Medical complications	I480-484, I489		
Acute myocardial infarction	I21, I22		
Pneumonia	J10-18		
Intracranial hemorrhage	I60-62		Brain imaging (CT or MRI) ≥1
Stroke	I6, I64		Brain imaging (CT or MRI) ≥1
Surgical complications			
Infection	T814, T845, T847	N0021, N0024, N0710, N0718, N0684, N0687	ICD-10≥1 code or procedural code≥1
Revision TKA		N3712, N3717, N3722, N3727	

TKA, total knee arthroplasty; CT, computed tomography; MRI, magnetic resonance imaging

국 문 요 약

단계적 양측 인공 슬관절 치환술과 비교하여 동시 양측 인공 슬관절 치환술의 안정성에 대한 의문이 있으며 단계적 양측 인공 슬관절 치환술의 적절한 간격은 아직 불명확하다. 이 연구의 목적은 양측 인공 슬관절 치환술을 시행한 환자의 수술 간격에 따른 수술 후 내외과적 합병증 발생을 비교 분석하고 적절한 수술 간격을 도출하는 것이다. 심사평가원 데이터베이스를 이용하여 2009년 1월부터 2019년 7월까지 양측 인공 슬관절 치환술을 받은 환자의 연령, 기저질환, 의료 기관등을 수집하였으며 수술 후 30일이내 급성 심근 경색, 폐렴, 뇌출혈, 뇌졸증의 주요 내과적 합병증과 90일 이내 감염, 재수술의 주요 외과적 합병증을 분석하였다. 환자군은 수술 간격에 따라 1–7, 8–14, 15–30, 31–90 과 91–180일로 분류하였으며 각 군별 수술 후 주요 내외과적 합병증을 비교하였다. 연도별 합병증의 변화를 평가하였으며 수술 후 합병증에 영향을 미치는 인자를 다변량 회귀분석을 통하여 산출하였다. 총 58,838명의 환자 중 24,379 명은 동시 양측 인공 슬관절 치환술을 시행 받았으며 34,459명의 환자는 단계적 양측 인공 슬관절 치환술을 시행 받았다. 양측 인공 슬관절 치환술을 시행 받은 환자는 2009년 2,276명에서 2018년 8,703명으로 증가하였으며 그 중 동시 양측 인공 슬관절 치환술이 차지하는 비율은 2009년 9.8%에서 2018년 57.3%로 증가하였다. 수술 후 30일 이내 주요 내과적 합병증은 동시와 단계적 방법이 각각 2.0%와 2.2%로 유의한 차이를 보이지 않았다. 동시 양측 인공 슬관절 치환술의 내과적 합병증은 2009년 6.7%에서

2013년 1.7%로 감소하였으며 같은 기간 동시 양측 인공 슬관절 치환술은 단계적 양측 인공 슬관절 치환술보다 높은 합병증 위험도를 보여주었다. 반면에 2014년 이후 5년간은 동시 양측 인공 슬관절 치환술이 단계적 양측 인공 슬관절 치환술에 비해 더 낮은 합병증율을 보였다. 교란 변수를 보정한 이후 동시 인공 슬관절 치환술과 8-14일 간격의 단계적 인공 슬관절 치환술이 내과적 합병증의 위험도를 높이지 않았다. 90일 이내 외과적 합병증은 동시와 단계적 양측 인공 슬관절 치환술 각각 2.0%로 통계적으로 차이가 없었다. 결론적으로 동시 양측 인공 슬관절 치환술의 합병증은 점차 감소하고 있으며 단계적 양측 인공 슬관절 치환술과 비슷한 수준이다. 단계적 인공 슬관절 치환술의 경우 8-14일이 내과적 합병증을 높이지 않았다. 심폐질환을 가진 환자에서 양측 인공 슬관절 치환술 이후 주요 내과적 합병증의 위험성이 증가하였다. 면밀한 수술전 환자 파악, 술자와 환자의 기호에 따라 동시 양측 인공 슬관절 치환술은 양측 인공 슬관절 치환술을 필요로 하는 환자에게서 적절한 치료 방법이 될 수 있다.