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ORIGINAL PAPER

A prospective comparative study of staged total knee arthroplasty: ninety-day versus seven-day interval

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Abstract

Purpose The optimal interval between staged bilateral total knee arthroplasty (STBTKA) is unclear. Studies have reported STBTKA being performed at the same admission, with a seven day interval. The safety and outcomes of patients submitted to same-admission STBTKA (SA-STBTKA) are questionable and need further investigation.

Methods A prospective non-randomized study was performed to compare the early postoperative outcomes, systemic complications, and surgical-related complications between the first and second knees, as well as between SA-STBTKA and STBTKA groups. From July 2018 to November 2019, a total of 430 patients were recruited. Analyzed parameters included the Knee Society score (KSS), Knee Society functional score (KSFS), range of motion (ROM), Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain score, WOMAC stiffness score, and WOMAC score for daily life difficulty.

Results Pre-operatively, the demographic data and functional scores were not significantly different between the two groups. The KSS, WOMAC pain score, and WOMAC stiffness score of the second knee in the STBTKA group were significantly better than those of the first knee. A total of 426 patients completed the last follow-up one year after surgery, and the post-operative functional scores were not significantly different between the two groups and between the two knees within the same group. Before the second operation, more systemic complications were identified in the SA-STBTKA group, while the rate of surgical complication was not significantly different when compared to STBTKA patients.

Conclusions With equivalent post-operative function and a higher frequency of minor complications, SA-STBTKA should be cautiously selected as a treatment option for bilateral osteoarthritis.

Keywords Total knee arthroplasty · Staged · Same-admission · Complications

Introduction

In the past 30 years, definite effects of total knee arthroplasty (TKA) have been confirmed in relieving pain, correcting deformities, and restoring the range of motion for patients with end-stage knee osteoarthritis (OA) [1]. In the upcoming decade, it is predicted that the population eligible for TKA for symptomatic knee OA will be continuously increasing due to extended life span, increasing incidence of obesity, and demand for a high quality of life [2]. According to previous literature, knee OA often affects bilateral joints in up to 30% of patients, presenting with similar symptoms in both knees, leading these patients to require bilateral TKA [3].

However, nearly 20% of patients are unsatisfied with the post-operative outcomes of TKA. Studies have been carried out to investigate the best timing to perform bilateral TKA to maximize the benefits and minimize potential risks [4]. However, until now, a consensus has not been reached on whether the bilateral TKA should be performed simultaneously or in a staged manner. Staged bilateral TKA (STBTKA) is often defined as two sequential primary TKA procedures at an interval of 90 to 365 days at separate admissions [5]. STBTKA allows full rehabilitation of the first knee before the contralateral operation; however, it is inconvenient for patients due to the prolonged length of stay (LOS), enhanced cost, the need for a second admission and anaesthesia, and the delayed improvement of both knees. In recent literature, promising success has been demonstrated in reducing the complication rate of simultaneous bilateral TKA to a comparable, or even lower level to the STBTKA through a fast-track

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recovery setting including blood management, venous thromboembolism (VTE) prophylaxis, and multimode analgesia [6, 7]. However, the safety of simultaneous bilateral TKA is still questioned and often linked with increased morbidity and mortality risks in several studies [8–10].

As a compromise of both simultaneous bilateral TKA and STBTKA, same-admission staged bilateral TKA (SA-STBTKA) has been proposed with the second TKA being performed after a seven day interval. One of the major concerns of the shorter interval protocol is that the increased post-operative overall inflammatory state may affect rehabilitation and increase the risks of complication [10]. However, in several studies, the complication rate, total cost, and LOS of SA-STBTKA were reported to be lower when compared with those of STBTKA, with similar functional scoring [11, 12]. As a result, the safety of SA-STBTKA is still questionable due to the lack of prospective studies with a large and balanced sample size.

In this study, the purpose was to prospectively compare the early functional results and complications between SA-STBTKA and STBTKA, and determine if SA-STBTKA is a safe and convenient protocol for patients with severe bilateral knee OA.

Materials and methods

This is a prospective non-randomized comparative study that was approved by the Ethics Committee of our institution (QYFYWZLL26061). From July 2018 to November 2019, a total of 430 patients were included in this study and written consent was obtained. The inclusion criteria were (1) patients with grade IV OA according to the Kellgren-Lawrence classification of bilateral knee and (2) patients suitable for simultaneous bilateral TKA, evaluated by a team of anaesthetists, internists, and orthopaedic surgeons. Patients with inflammatory arthritis were excluded. Patients that were ineligible for simultaneous bilateral TKA due to severe cardiac compromise, advanced pulmonary disease, renal failure, and other systemic conditions were also excluded from this study.

Patients included in this study were divided into two groups according to their own decision after discussion with the surgeon. In the SA-STBTKA group, patients received staged bilateral TKA during the same admission at an interval of seven days. In the STBTKA group, patients were discharged after the first operation, and TKA of the other knee was performed at a second admission 90 to 120 days later. The demographic details of patients, pre-operative range of motion (ROM), Knee Society Score (KSS), Knee Society Function Score (KSFS), and Western Ontario and McMaster Universities Arthritis Index (WOMAC) score were recorded. The complete blood counting (CBC), arterial blood gas (ABG), and C-reactive protein (CRP) were also recorded before surgery.

All TKA procedures were performed by a senior surgeon in our institution, and the same knee prosthesis (ADVANCE®, MicroPort Orthopedics Inc., China) was used in all the patients. General anaesthesia supplemented with an adductor canal block was used in all the patients. The operation included routine use of a pneumatic tourniquet throughout the surgery, a mid-vastus approach to expose the joint, the intramedullary guide with a 5° of valgus to cut the distal femur, an extramedullary guide to cut the tibial plateau and cement the implant, a drainage tube before closure, and an intra-articular usage of tranexamic acid (1.5 g) after closure. The post-operative protocol consisted of the removal of the drainage tube after 24 hours, intravenous cefuroxime or clindamycin injection to prevent infection, subcutaneous injection of enoxaparin (4000 IU daily) for venous thromboembolism (VTE) prophylaxis, sequential intravenous followed by oral administration of non-steroid anti-inflammatory drugs (NSAIDs) to control post-operative pain, and subcutaneous injection of erythropoietin (EPO, 10000 IU, daily for 3 days). Daily continuous passive motion (CPM) was also applied to help post-operative rehabilitation. A blood transfusion was administered if the post-operative rehabilitation was affected by anaemia (Hb <80 g/L).

The final follow-up was conducted one year after surgery. Patients were invited to the outpatient department, and early outcomes were evaluated by senior residents through the ROM, KSS, KSFS, and WOMAC scoring systems. Self-reported outcomes were also evaluated using the Forgotten Joint Score (FJS).

Statistical analysis

The statistical analysis was performed by SPSS 15.0 (SPSS Inc, Chicago, IL). Clinical data were presented as mean ± standard deviation (SD). The Student *t*-test was used to compare continuous variables between the two groups, while the paired *t*-test was used to compare continuous variables within the same group. Fisher's exact test was used to determine differences in categorical variables. $P<0.05$ was considered statistically significant.

Results

A total of 426 patients successfully received staged bilateral TKA, among which 209 patients were in the SA-STBTKA group and 217 patients were in the STBTKA group. Four patients dropped out of this study due to complications of the first knee surgery and refused the operation of the other knee. Pre-operative data is displayed in Table 1. Before the second operation, both the averaged serum CRP level and the

Table 1 Demographics information and preoperative data

Parameters	SA-STBTKA group (*n*=209)	STBTKA group (*n*=217)	*P* value
Age (year)	68.14 ± 8.35	68.68 ± 8.02	0.49
Male (%)	10.0%	9.7%	
BMI (kg/m^2)	27.32 ± 4.38	27.72 ± 4.21	0.34
ROM (degrees)			
First knee	76.51 ± 17.61	75.79 ± 16.86	0.66
Second knee	77.69 ± 17.96	77.09 ± 21.21	0.75
P value	0.49	0.48	
KSS			
First knee	35.42 ± 10.61	34.7 ± 9.89	0.47
Second knee	36.09 ± 8.39	37.46 ± 10.25	0.13
P value	0.47	0.005	
KSFS			
First knee	38.48 ± 14.72	38.96 ± 15.77	0.75
Second knee	39.16 ± 14.52	39.92 ± 16.99	0.62
P value	0.63	0.54	
WOMAC pain			
First knee	24.04 ± 10.93	23.91 ± 10.27	0.90
Second knee	22.86 ± 10.65	21.81 ± 9.45	0.28
P value	0.26	0.03	
WOMAC stiffness			
First knee	13.92 ± 8.43	14.04 ± 7.59	0.51
Second knee	12.18 ± 7.31	12.64 ± 7.22	0.88
P value	0.02	0.04	
WOMAC daily life	55.81 ± 11.34	55.24 ± 10.77	0.59
Preoperative serum CRP			
First knee	0.76 ± 0.45	0.69 ± 0.57	0.81
Second knee	20.46 ± 17.75	1.08 ± 0.82	<0.0001
P value	<0.0001	0.22	
Patients with abnormally high level of CRP (> 5 mg/L)			
First knee	1	1	0.99
Second knee	165	1	<0.0001
P value	<0.0001	0.99	

proportion of patients with abnormally high levels of serum CRP were significantly higher in the SA-STBTKA group compared to those in the STBTKA group ($P<0.001$). Regarding the function of the knee, there were no pre-operative differences between the two groups. Within the SA-STBTKA group, only the WOMAC stiffness score of the second knee was significantly higher ($P=0.02$) than that of the STBTKA group. Meanwhile better KSS ($P=0.005$), WOMAC pain score ($P=0.03$), and WOMAC stiffness score ($P=0.04$) of the second knee were identified within the STBTKA group, compared to those of patients submitted to SA-STBTKA.

Post-operatively, the accumulated LOS was shorter ($P<0.001$) and the total cost was lower ($P<0.001$) in the SA-STBTKA group, while the early clinical outcomes evaluated one year after TKA showed equivalent ROM, KSS, KSFS, WOMAC score, and FJS in both knees between the two groups (Table 2). In reference to the complications, the rate of systemic complication before the second operation in the SA-STBTKA group was significantly higher ($P=0.03$, Table 3). Seven systemic complications were identified in patients of the SA-STBTKA group before the second operation, including three patients with minor pulmonary compromise, indicated by $FiO_2<300$ identified by ABG, one patient with type I respiratory failure, one with frequent premature atrial beat, one with atrial fibrillation, and one with frequent ventricular premature beat. In the STBTKA group, two systemic complications were identified before the second operation. One patient had pleural effusion with unknown aetiology detected by chest computerized tomography (CT), and the other patient was diagnosed with occult myocardial infarction,

Table 2 Post-operative data between interval groups

Parameters	SASTBTKA group	STBTKA group	*P* value
Accumulative LOS (day)	14.86 ± 2.81	16.78 ± 3.26	0.001
Total cost (¥)	72432 ± 6462	76801 ± 3428	0.001
ROM (degrees)			
First knee	106.78 ± 10.87	106.65 ± 13.11	0.91
Second knee	106.5 ± 13.19	106.33 ± 11.92	0.89
P value	0.81	0.79	
KSS			
First knee	85.67 ± 9.47	85.82± 9.15	0.87
Second knee	85.42 ± 7.61	85.78 ± 8.62	0.65
P value	0.77	0.96	
KSFS			
First knee	77.64 ± 14.23	78.65 ± 13.67	0.46
Second knee	76.96 ± 13.08	77.57 ± 14.99	0.65
P value	0.61	0.43	
WOMAC pain			
First knee	5.95 ±2.24	6.21 ± 3.71	0.38
Second knee	6.31 ± 2.98	6.43 ± 1.23	0.59
P value	0.16	0.41	
WOMAC stiffness			
First knee	2.59 ± 2.21	2.29 ± 1.56	0.12
Second knee	2.35 ± 1.29	2.44 ± 1.12	0.44
P value	0.18	0.28	
WOMAC daily life	18.75 ± 12.92	19.63 ± 13.52	0.49
FJS			
First knee	64.07 ± 20.73	66.45 ± 21.23	0.24
Second knee	62.91 ± 22.28	63 ± 19.74	0.96
P value	0.58	0.08	

detected by echocardiography. The systemic conditions identified after the second operation as well as the surgical-related complications before and after the second operation were comparable between the two groups.

Discussion

TKA has become an effective solution for patients suffering of end-stage knee OA; up to one-third of these patients complain about similar bilateral symptoms. Thus, simultaneous bilateral TKA has become a common procedure due to its huge socio-economic advantage in reducing LOS, benefiting early rehabilitation and saving costs. However, a recent prospective study conducted by Kulshrestha et al. linked simultaneous bilateral TKA with significantly higher rates of procedure-related complication [13]. Several previous retrospective studies also reported similar results [14, 15]. Clinically, for those who are not medically eligible for simultaneous bilateral TKA, STBTKA is another treatment option. Lowered morbidity and mortality have been observed in STBTKA; however, some studies argue against STBTKA since the separated procedure may lead to delayed rehabilitation and increased total costs [11]. As a compromise, SA-STBTKA has been addressed to facilitate rehabilitation as well as reduce the medical risk. Generally, SA-STBTKA refers to staged bilateral TKA performed at an interval of two to seven days, during the same admission. However, SA-STBTKA is rarely reported, and controversial conclusions were reached [11, 12, 16, 17]. Considering the patient's preference and surgeon's decision, randomization and blinding of these kinds of studies are not possible; thus, the significant lack of level-I study on this topic makes the feasibility of SA-STBTKA debatable. To our knowledge, this is the first prospective study comparing post-operative functional outcomes and complications between SA-STBTKA and STBTKA. The most important finding of this study is that the post-operative functions of bilateral knees were comparable between the SA-STBTKA and STBTKA groups. However, SA-STBTKA was related to higher rates of systemic complications before the second

Table 3 Complications

Complications	SA-STBTKA group	STBTKA group	*P* value
Systematic complications			
Before second operation	*N*=210	*N*=220	
Respiratory failure (RF)	1		
Pulmonary compromise	3	1	
Cardiac compromise	3	1	
Total	7	2	0.03
After second operation	*N*=209	*N*=217	
Delirium	1		
Allergy		1	
Femoral neck fracture		1	
Anemia needs blood transfusion	2		
Total	3	2	0.99
Surgical complications			
Before second operation	*N*=210	*N*=220	
Infection		1	
Wound complications	1	2	
Injury of medial collateral ligament	1		
Intraoperative fracture	1	1	
Total	3	4	0.99
After second operation	*N*=209	*N*=217	
Infection	2	2	
Wound complications	2	2	
Intraoperative fracture	1		
Total	5	4	0.75

procedure, while the complication rate after the second operation was similar between the two groups. Meanwhile, the accumulated LOS was shorter and the accumulated cost was lower in the SA-STBTKA group.

Existing studies that compared SA-STBTKA with STBTKA have a selection bias due to their retrospective nature. Small or unbalanced sample sizes also compromise their conclusions [11, 12, 16, 17]. Besides, in these studies, the average interval in the STBTKA group was up to two years. As a result, the homogeneity of the two knees was questionable, leading to a biased interpretation of the results. Thus, the patients included in this study were selected following strict criteria. Only patients with grade IV osteoarthritis of both knees were included to guarantee homogeneity within as well as between the two groups. However, when analyzing the preoperative data, we noticed that in the STBTKA group, the KSS of the second knee was nearly three points higher. Significantly better WOMAC pain score and WOMAC stiffness score of the second knee were also found. In contrast, in the SA-STBTKA group, only the WOMAC stiffness score of the second knee was better, while most function scorings were not significantly different between the two knees. This difference between the two groups may largely lead to different patient decisions on surgical plans. Patients with equivalent symptoms of both knees prefer a more aggressive protocol with shorter interval (SA-STBTKA) while patients who choose STBTKA often have more severe symptoms in one knee although the same K-L grading was identified. Compared to the first knee, poorer outcomes of the second knee have been reported in STBTKA and researchers attributed this to increased patient expectations and pain sensitization [18–20]. According to our data, the post-operative outcomes were equivalent between the two groups, as well as between the two knees within the same group. Although we failed to detect statistical differences in objective outcomes, 65 patients (29.9%) in the STBTKA group somehow reported a worse subjective feeling of the second knee, compared to only 38 patients (18.2%) in the SA-STBTKA group. Despite increased patient expectations, we believe that our data support the pain sensitization hypothesis. It is likely that in the SA-STBKTA group, the use of NSAID drugs before the second operation, as well as the overlapping usage period after the second operation, could lower the pain sensitization, thus leading to better subjective feelings.

One of the major concerns against a shorter interval between surgery in STBTKA is the high systemic inflammatory

response before the second operation, which may affect the rehabilitation of both knees and increase the rate of complications. Richardson et al. found a significantly increased odds ratio (OR) of manipulation under anaesthesia (MUA) in STBTKA within three months [9]. In another study, the lowest MUA rate was observed in patients receiving STBTKA at 13- to 24-weeks' interval [10]. Thus, 90 days was advocated as the minimum interval between the staged TKA at the 2013 consensus conference [7]. However, the debate on the appropriate interval has never reached a conclusive answer. In a recent retrospective study, Crawford et al. manually divided the interval of STBTKA into three to six weeks, seven to 12 weeks, 13 to 24 weeks, and more than 24 weeks, and found that the post-operative function was not deteriorated by shorter intervals, while the early medical and surgical complications in the shortest interval group were significantly lower [21]. Their study, to our best knowledge, provides the first evidence that an interval as short as three weeks between STBTKA is feasible.

Clinically, CRP is one of the most widely used serum markers reflecting an inflammatory state due to its quick reactive characteristic. After TKA of the first knee, a peak in circulating CRP was recorded at the third post-operative day (POD) due to surgical trauma and did not go back to normal before the second surgical operation in SA-STBTKA [22]. Although few researchers have reported that SA-STBKTA is not inferior to STBTKA, we are also apprehensive that the elevated inflammatory state may cause poorer outcomes in both knees. In our study, the inflammatory marker serum CRP was around two to three times higher than normal in most patients at POD6 and more systemic complications before the second operation were observed. Indeed, all these systemic complications were minor and asymptomatic, which were found by examinations and had little influence on the surgical protocol. However, the increased number of complications has damaged our confidence in the safety of a seven day interval. Moreover, it seemed that increased systemic inflammation did not influence the second operation, since we observed equivalent post-operative functions and similar rates of systemic and surgical complications in SA-STBTKA and STBTKA groups.

Our study has some limitations that need to be noted. First, selection bias was inevitable due to non-randomized allocation in this study. We tried to minimize this bias by strictly controlling the homogeneity of the included patients and the knee implant. Second, all patients included in the study were medically eligible for simultaneous bilateral TKA. However, clinically, both STBTKA and SA-STBTKA are treatment options for patients who are not medically suitable for simultaneous bilateral TKA. As a result, the conclusion reached in this study should be cautiously interpreted in clinical practice. Finally, the sample size in this study is still inadequate in order to identify differences between some low-risk complications. According to the calculation conducted by Kulshrestha et al., the 90-day cardiopulmonary morbidity and mortality rate of unilateral TKA was around 2%, and at least 977 patients in each group are needed to identify the non-inferiority of SA-STBTKA [13]. Thus, the sample size of our study is far smaller than their calculation and inevitably compromises our conclusions. However, SA-STBTKA is not a common procedure in our centre and several other reasons have limited our sample size. On the one hand, fast-track simultaneous bilateral TKA successfully balances patient safety, shorter LOS, and less total cost. On the other hand, the safety of SA-STBTKA is still questionable with an abnormal serum CRP, which limits the application of this procedure.

In conclusion, compared with STBTKA, although the serum CRP level of the SA-STBTKA group is significantly higher, the post-operative outcomes of the first and second knees of SA-STBTKA are equivalent. However, for patients who underwent SA-STBTKA, the complication rate before the second operation is significantly higher, while the complication rate after the second operation is similar between the two groups. Therefore, SA-STBTKA should be cautiously selected as an alternative treatment option for bilateral knee osteoarthritis.

Availability of data and materials None.

Code availability None.

Author contribution HX and ZXF performed all the analyses and wrote the paper. GQS collected the data and participated in writing and revising the paper. YZW performed the TKA procedures. SX designed the whole study.

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Declarations

Ethics approval This study is approved by the Ethics Committee of our institution (QYFYWZLL26061).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication Patients signed informed consent regarding publishing their data and photographs.

Conflict of interest The authors declare no competing interests.

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