



DOI: 10.31636/pmjua.v7i1.3

Patient's safety during simultaneous bilateral total knee arthroplasty

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Abstract. *As the utilization of total knee arthroplasty increases and the population ages, the number of patients who require surgical treatment of both knees is rising. These procedures may be conducted simultaneously or sequentially; the simultaneous bilateral approach is increasingly considered the preferred option because it permits a symmetric recovery while avoiding risks associated with an additional operation, anesthetic, hospitalization, and recovery period while reducing the costs associated with sequential procedures. Despite these advantages, concerns have been raised regarding increased risks for deep vein thrombosis, pulmonary embolism, cardiac complications, and mortality. Results reported in the literature with regards to the relative safety of these procedures have been conflicting; however, it is agreed upon that careful patient selection is essential for reducing risk associated with simultaneous bilateral total knee arthroplasty. A set of guidelines have been established which may be used to help guide the management of patients with bilateral degenerative joint disease seeking knee replacement surgery.*

Key words: *bilateral total knee arthroplasty, simultaneous bilateral total knee arthroplasty, staged bilateral total knee arthroplasty, total knee arthroplasty.*

Introduction

A significant percentage of patients undergoing primary unilateral total knee arthroplasty (TKA) complain of bilateral knee involvement [1]. Approximately 7% of patients will undergo surgical treatment of both knees simultaneously during the same hospitalization, and 15% will seek treatment of the contralateral knee within 1 year [2]. With the utilization of TKA rising exponentially with the aging US population, the number of patients seeking surgical treatment of both knees will inevitably rise as well [3]. Patients may elect to undergo both procedures performed under the same anesthetic, either by 1 surgical team working sequentially or 2 surgical teams in parallel. This

is referred to as simultaneous bilateral TKA (SBTKA). Alternatively, a staged bilateral TKA (StBTKA) may be performed under 2 anesthetic events, either during the same hospitalization or different hospitalizations within 1 year of each other [4].

SBTKA is advantageous for several reasons. Patients may experience faster, symmetric recovery although avoiding risks associated with an additional operation, anesthetic, hospitalization, and recovery period [5]. Several studies have reported that long-term functional outcomes with regards to knee scores, range of motion increases, and patient satisfaction are similar to those undergoing

both unilateral TKA (UTKA) and StBTKA [5, 6]. Cost savings are a definitive benefit of SBTKA, with savings of \$28,800 over StBTKA [7]. Most of the controversy surrounding SBTKA, however, has related to higher rates of deep vein thrombosis (DVT), pulmonary embolism (PE), cardiac complications, and mortality compared with UTKA or StBTKA [4, 8–10]. In the consensus statement published by the Consensus Conference on Bilateral Total Knee Arthroplasty Group in 2013, 81% of participating orthopedic surgeons agreed that SBTkAs were associated with a higher risk of complications than unilateral or staged procedures [11]. Recent literature suggests that SBTKA is safe provided that there is appropriate patient selection [12, 13].

A nuanced understanding of these surgical options is necessary to optimize and personalize surgical planning. Given that SBTKA may potentially increase surgical and rehabilitation efficiency although achieving cost savings, it is important to clarify the previously reported outcomes for this treatment strategy.

The purpose of this review is to explore the common complications associated with SBTKA and StBTKA, as well as efforts undertaken to mitigate these concerns. Consensus guidelines for risk factor and complication avoidance in BTKA will also be established. This set of decision-making criteria should be used to help guide management of patients with bilateral degenerative joint disease seeking surgery.

Review of literature

Despite the proposed benefits of SBTKA, it is widely held among orthopedic surgeons that SBTKA is associated with a higher risk of complications when compared with UTKA or StBTKA [11]. Most of this belief may be because of the lack of definitive literature demonstrating the true risks of each treatment option. Ideally, a prospective study in which patients were randomized into 1 of 2 BTKA treatment arms would be carried out, but the sample sizes required to achieve adequate power for such an analysis would be very large [4].

Most of the published literature has therefore consisted of small retrospective cohort studies or retrospective studies of large databases, and are subject to several biases inherent to studies of this nature. Studies may have been subject to a misclassification bias, in which patients who did not have the second operation in a 2-stage BTKA due to a complication were misclassified into the UTKA treatment group, causing complication rates for StBTKA to appear lower than they actually are [4].

Some studies have assumed for their comparisons that the risks of StBTKA are simply twice those of UTKA, which may be inaccurate [14, 15]. In addition, a number

of studies compare outcomes between SBTKA and UTKA, despite the inherent differences between these 2 patient populations [4, 16, 17]. These potential sources of error have likely contributed to the wide spectrum of published results and should be kept in mind when analyzing the safety of these procedures.

Deep vein thrombosis (DVT)

Studies comparing DVT risk between simultaneous and StBTKA have demonstrated mixed results, with meta-analyses ultimately reporting no statistically significant difference in rates. In 2003, Bullock et al. [16] found a DVT rate of 1.6% in 255 SBTkAs compared with 4.4% in 512 UTKAs, which was not significantly different. These results are supported by Leonard et al., [17] who also reported similar rates of 3.3% and 5.4% in the SBTKA and UTKA groups, respectively.

In 2006, a study by Hutchinson and colleagues, in which 1304 patients underwent SBTKA, StBTKA, and UTKA, reported relatively high asymptomatic DVT rates of 17.6%, 16.8%, and 11.1% in the SBTKA, StBTKA, and UTKA groups, respectively. BTKA was found to have significantly greater proportion of DVT than UTKA, but the difference between the simultaneous and staged groups was not significant [18].

Meta-analyses conducted by Restrepo et al., [8] Hu et al. [9], and Fu et al. [10], and Hussain et al. [19], some of which included the previously mentioned studies, found odds ratios of 0.99, 1.25, 1.07, and 0.89 relative to StBTKA or UTKA, none of which were statistically significant [10].

More recent findings have described much lower rates, and strengthened the notion that simultaneous and staged procedures carry similar risks of DVT [2, 5, 20, 21]. A study by Bini et al. [20] on 2441 SBTkAs and 4231 StBTKAs in the Kaiser Permanente Total Joint Replacement Registry found similar DVT rates of 0.3% and 0.1%, respectively. This may be explained by an improvement in DVT prevention protocols, which routinely include a combination of early mobilization, mechanical prophylaxis, and pharmacologic prophylaxis.

Pulmonary embolism (PE)

PE has been cited as a serious concern after BTKA when compared with UTKA, although simultaneous and staged procedures may carry similar risks. This is likely related to a higher cumulative embolic load produced after tourniquet release, cement use, surgical intervention in both lower extremities, and a prolonged initial period of immobility [22–26].

In an analysis of the Medicare patient population, Barrett et al. [2], reported that a 0.81% PE rate in the first 3 months of patients who had a single procedure, compared with 1.44% of patients who underwent a simultaneous

procedure. They acknowledged that the combined risk of both operations in a 2-stage procedure may be equivalent to or exceed the risk of a simultaneous bilateral procedure. However, they suggested that it may be appropriate instead to perform the first stage of a 2-stage procedure, and then decide whether to proceed with the second stage depending on whether complications develop.

Based on data from 11 articles, Restrepo et al. [8] in their meta-analysis found the overall odds ratio to be significant at 1.82. The largest contributing study was by Ritter et al. [27] and included 2 050 SBTKA, 1 796 UTKA, and 152 StBTKA procedures. The percentage of patients who had thrombophlebitis or PE was 0.9% in the SBTKA group, significantly >0.3% of patients who suffered from these complications in the UTKA group but similar to 0.7% of patients in the staged group.

In their meta-analysis, Fu and colleagues similarly found the SBTKA group to be at a 1.39 times higher risk of PE, pooling data from 9 articles. A retrospective study of a large hospital database by Meehan et al. [21] examining 11,445 SBTkAs and 23,715 StBTkAs was weighted at 89.3%. They found that the 60-day rate of PE was 9.6 per 1000 patients in the SBTKA cohort compared with 6.8 and 5.2 in the StBTKA cohort and UTKA cohorts, respectively.

The meta-analyses of Hu et al. [9] and Hussain et al. [19] showed no difference in risk between SBTKA and StBTKA, likely because of their exclusion of studies comparing SBTKA with UTKA.

Cardiac Complications

There is an evidence that patients undergoing simultaneous procedures are at an increased risk of cardiovascular events, including myocardial infarction (MI), arrhythmia, and congestive heart failure (CHF), relative to those undergoing a unilateral procedure [4, 16, 27]. This may be because of diminished end-organ reserve, higher physiological stress after undergoing a bilateral procedure, or larger fluid shifts, and may be exacerbated by preexisting heart disease and advanced age [26].

Restrepo et al. [8] found that the odds ratio for a cardiac complication after SBTKA was 2.49, higher than any other complication analyzed. However, the other meta-analyses, which excluded any comparisons between bilateral and unilateral procedures, did not find that those undergoing SBTKA were at a higher risk of cardiac complications than those undergoing StBTKA. Ritter et al. [27] found similar rates between all 3 treatment options, with rates of 1.5%, 1.3%, and 1.0% in the simultaneous, staged, and unilateral groups, respectively.

In a study by Memtsoudis and colleagues using Nationwide Inpatient Sample (NIS) data from 1998 to 2006, it was found that the incidence of cardiac complications in patients undergoing BTKA was 1.67%, significant-

ly >0.94% of patients who experienced an event after UTKA; however, similar rates were reported for those undergoing simultaneous procedures and staged procedures (1.69% vs. 1.61%, respectively). It should be noted that the staged procedures in this study were performed on different days during the same hospital admission.

Mortality

Many studies have demonstrated higher mortality rates following simultaneous procedures than staged or unilateral procedures. This is supported by 3 of 4 meta-analyses, with Restrepo et al. [8], Hu et al. [9], and Hussain et al. [19], reporting overall mortality odds ratios of 2.24, 3.20, and 2.24, respectively [10]. When subgroup analyses were conducted, the risk of mortality relative to StBTKA was highest in the first 30 postoperative days [9, 19].

In a study on the Swedish Knee Arthroplasty Register, Stefánsdóttir et al. [15] evaluated differences in 30-day mortality among 48,931 TKA recipients, of whom 1 139 had simultaneous bilateral procedures and 3 432 had separate admission, staged bilateral procedures. They found that the 30-day mortality after SBTkAs was 7.53 times higher than after the second of staged TKA and 3.77 times higher than after a UTKA. PE as a cause of death was significantly greater for the SBTKA group than either the StBTKA or UTKA groups. However, conflicting data have been published as well.

In the institutional study by Ritter et al. [27], no significant differences were found in mortality within the first 2 weeks, 3 months, or 1 year postoperatively between the simultaneous bilateral and unilateral groups.

In Bini et al. [20] registry study, there were no significant differences in 90-day mortality between SBTKA and StBTKA. In the Memtsoudis and colleagues study on NIS data, there was no difference in inhospital mortality between simultaneous and staged groups (0.29% vs. 0.26%).

Discussion

It is ultimately believed that neither simultaneous nor staged procedures are superior to each other with regard to clinical outcomes, but that decisions with regards to which treatment is optimal should be made on an individual basis [11, 27]. A strict set of inclusion and exclusion criteria should be adhered to when determining which approach is best suited for the patient. To mitigate potential risks, one must consider patient selection based on age and comorbidities, while employing evidence-based perioperative management strategies.

Age

Previously published guidelines by the Hospital for Special Surgery state that patients 75 years and older are

excluded as candidates for simultaneous bilateral procedures [28]. Other institutional guidelines and a critical analysis review of the risks and benefits of SBTKA do not identify a strict cutoff, but only suggest that the procedure be avoided in extremes of age [4]. These recommendations are based on many studies which have found increased age to be an independent risk factor for higher mortality and complications (including MI and neurological complications) in the postoperative period after SBTKA [16, 27, 29–32]. This is likely because of an age-related decline in baseline end-organ function and resultant inability to withstand the embolic load after tourniquet release [33]. However, because of the distinction between physiological and chronologic age, it is important to acknowledge the difficulties in defining a strict age cutoff. One study on patients above 80 years of age who underwent SBTKA found that complication and mortality rates were equivalent to those found in the general population and patients aged 80 years or above undergoing UTKA, as long as appropriate pre-operative screening was performed and patients with prior cardiopulmonary disease were excluded [34].

Comorbidities

Previously published guidelines state that patients with an American Society of Anesthesiologists classification of ≥ 3 (implying severe systemic disease) be excluded from SBTKA procedures, which the majority of orthopedic surgeons agree with [4, 28]. Congestive heart failure (CHF) and pulmonary hypertension have been identified as the 2 most significant risk factors for morbidity and mortality after SBTKA [13]. In light of this, patients with a history of cardiac and pulmonary conditions, including CHF, obstructive sleep apnea, and chronic obstructive pulmonary disease have been excluded [11, 28]. In patients symptomatic of cardiopulmonary disease, pre-operative testing should include echocardiography to assess for poor left ventricular function ($< 40\%$), right heart strain, and pulmonary hypertension [11, 28]. Because of the lack of definitive evidence regarding MI and venous thromboembolism risk, recommendations warn against performing the procedure in patients with ischemic heart disease (as determined by a history of angina or a positive stress test) or prior venous thromboembolism [4, 11, 28].

Other conditions which preclude patients from receiving SBTKA include diabetes mellitus, morbid obesity ($\text{BMI} > 40 \text{ kg/m}^2$), renal failure, cerebrovascular disease, chronic liver disease, and peripheral vascular disease of the lower extremities [11, 28]. Institutional studies in which these guidelines were followed have demonstrated similar morbidity and mortality between simultaneous and StBTKA groups [13].

Perioperative and Postoperative Management

Given the risk for emboli to cause an insult to end-organ function after tourniquet release, efforts should be taken to protect against this. Dorr et al. [35] recommended that pulmonary artery pressure be monitored intraoperatively with a pulmonary artery catheter, which could detect derangements in pulmonary vascular resistance, possibly indicative of a blood or fat embolus. In their study, the second surgery in an SBTKA was canceled if the pulmonary vascular resistance was more than double the baseline, or above 200 dyne/s/cm^5 .

With regards to intraoperative blood loss, early results found that blood loss and rates of postoperative anemia requiring transfusion were higher after SBTKA surgery, whereas others found that rates were comparable between SBTKA and StBTKA cohorts [5, 36]. In recent years, however, tranexamic acid (TXA) has been routinely used to decrease overall blood loss and reduce transfusion requirements in patients undergoing TKA [48]. These results have been duplicated in SBTKA patients; in 1 study, the mean blood loss in an experimental group receiving 15 mg/kg of TXA was 50% that of a control group not receiving TXA [38].

Jules-Elysee et al. [39] published results from a study in which 3 doses of 100 mg hydrocortisone were administered 8 hours apart in patients undergoing SBTKA. The authors found that urinary levels of desmosine, a marker of lung injury, found to be higher after SBTKA, and serum levels of interleukin-6, which have been linked to acute respiratory distress syndrome, post-operative confusion, and fever, were significantly lowered relative to a control group receiving a placebo [39, 40]. The authors concluded that administration of hydrocortisone before SBTKA may provide a lung-protective effect.

Conclusion

On the basis of studies showing a correlation between increased age and risk for death and complications, previously published guidelines by the Hospital for Special Surgery state that patients aged 75 years or above should be excluded as candidates for simultaneous bilateral procedures; others have suggested a cutoff of age 80 years or above. However, because of the distinction between physiological and chronologic age, there are difficulties in identifying a stringent strict age cutoff after which SBTKA would not be advisable. Clinical judgment, coupled with careful assessment of patient comorbidities, should be the primary driver when identifying patients who might qualify for SBTKA.

Some criteria that definitely exclude patients from SBTKA are next:

1. ASA 3 or 4.

2. Ischemic heart disease, as evidenced by a positive stress test on aggressive treatment with antiplatelet or anticoagulation medication.
3. Poor ventricular function (LVEF < 50%).
4. Oxygen-dependent pulmonary disease.
5. Renal insufficiency or end-stage renal disease, Cr > 1.6.
6. Steroid-dependent asthma or COPD.
7. Pulmonary hypertension (PAP > 45).
8. Renal dialysis Chronic liver disease (Childs class B or worse).
9. Previous cerebrovascular accident.
10. Sleep study-proven obstructive sleep apnea Insulin-dependent diabetes mellitus.
11. History of hemoglobin < 11 g/dL (**ASA** — indicates American Society of Anesthesiologists; **COPD** — chronic obstructive pulmonary disease; **LVEF** — left ventricular function; **PAP** — pulmonary arterial pressure; **SBTKA** — simultaneous bilateral total knee arthroplasty).

A high BMI should not be considered an absolute contraindication to SBTKA, although caution and clinical judgment are warranted in patients with a BMI > 40 kg/m².

If SBTKA cannot be performed, what is the appropriate time frame for the second side operation?

The group generally agreed that 3 months is an appropriate interval between the first and second intervention because it allows adequate time for a return to metabolic baseline. However, some specific situations (such as patients with severe contracture deformities) may warrant shortening the interprocedural interval. Staggered bilateral interventions conducted during the same hospitalization are not recommended unless there is a strongly compelling medical rationale.

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Безпека хворого при одночасному двосторонньому тотальному ендопротезуванні колінного суглоба

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Резюме. Зі збільшенням використання тотального ендопротезування колінного суглоба та постарінням населення зростає кількість пацієнтів, які потребують хірургічного лікування обох колін. Ці процедури можуть проводитися одночасно або послідовно; одночасний двосторонній підхід все частіше вважається кращим варіантом, оскільки він дозволяє симетричне відновлення, уникаючи ризиків, пов'язаних з додатковою операцією, анестезією, госпіталізацією та періодом відновлення, одночасно зменшуючи витрати, пов'язані з послідовними процедурами. Незважаючи на ці переваги, були висловлені занепокоєння щодо підвищення ризику тромбозу глибоких вен, тромбоемболії легеневої артерії, серцевих ускладнень та смертності. Результати, наведені в літературі щодо відносної безпеки цих процедур, були суперечливими; однак всі автори погоджуються, що ретельний відбір пацієнтів є важливим для зниження ризику, пов'язаного з одночасним двостороннім тотальним ендопротезуванням колінного суглоба. Було створено набір рекомендацій, які можуть бути використані, щоб надавати допомогу пацієнтам з двостороннім дегенеративним захворюванням суглобів, які потребують операції тотального ендопротезування колінного суглоба.

Ключові слова: двостороннє тотальне ендопротезування колінного суглоба, симультанне двостороннє тотальне ендопротезування колінного суглоба, етапне двостороннє тотальне ендопротезування колінного суглоба, тотальне ендопротезування колінного суглоба.

Безопасность больного при одновременном двустороннем тотальном эндопротезировании коленного сустава

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Резюме. С увеличением использования тотального эндопротезирования коленного сустава и старением населения растет количество пациентов, нуждающихся в хирургическом лечении обоих колен. Эти процедуры могут проводиться одновременно или последовательно; одновременный двусторонний подход все чаще считается лучшим вариантом, поскольку он позволяет симметричное восстановление, избегая рисков, связанных с дополнительной операцией, анестезией, госпитализацией и периодом восстановления, одновременно уменьшая расходы, связанные с последовательными процедурами. Несмотря на эти преимущества, было выражено беспокойство по поводу повышения риска тромбоза глубоких вен, тромбоемболии легочной артерии, сердечных осложнений и смертности. Результаты, приведенные в литературе относительно безопасности этих процедур, были противоречивы; однако все авторы соглашаются, что тщательный отбор пациентов важен для снижения риска, связанного с одновременным двусторонним тотальным эндопротезированием коленного сустава. Был создан набор рекомендаций, которые могут быть использованы, чтобы оказывать помощь пациентам с двусторонним дегенеративным заболеванием суставов, нуждающимся в операции тотального эндопротезирования коленного сустава.

Ключевые слова: двустороннее тотальное эндопротезирование коленного сустава, симультанное двустороннее тотальное эндопротезирование коленного сустава, этапное двустороннее тотальное эндопротезирование коленного сустава, тотальное эндопротезирование коленного сустава.