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## ASSESSMENT OF SAFETY OF BILATERAL TOTAL KNEE ARTHROPLASTY IN SINGLE SITTING

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ABSTRACT

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Background: Total knee Arthroplasty (TKA) is a procedure in which the damaged cartilage in the knee is replaced with artificial bearing surfaces. It is one of the most clinically successful and cost effective medical procedures developed during the last century but safety aspect needs to be addressed appropriately. Objective: To assess safety of bilateral total knee arthroplasty in single sitting Material and Methods: This ambispective observational study was carried in tertiary care teaching hospital in Pune city of Maharashtra state, India. All patients underwent standard preoperative workup. Those patients deemed fit to undergo total knee replacement in single sitting were included in the study. The patients with adequate pulmonary and cardiac reserve were declared fit to undergo SBTKA . For safety analysis local complications related to the wound and operative site and systemic complications related to patient's co-morbidity and systemic status were analysed. Statistical Analysis: Mean, standard deviation, percentages and proportions were used for descriptive statistics. Results: Total 52 patients underwent Simultaneous bilateral total knee arthroplasty (SBTKA) for both knees . The study included 14 men and 38 women (1:3) , mean age was  $63 \pm 7$  years old (48–75). either with diagnosis as Osteoarthritis (83%) or Rheumatoid arthritis (17%). Infection was seen in 2 patients (4%). 2 patients (4%) complained of anterior knee pain which was persistent even with analgesics, of which one was diagnosed as post op infection. There was one death. This patient was morbidly obese, operated for SBTKA for RA both knees, who on preop evaluation was moderate risk. One patient had persistent inflammatory effusion over the operated knee which delayed the functional recovery and prolonged the stay. There were 5 patients having temperature > 100 °F for > 48 hrs. (10%). GI & urinary problems were seen in 11 patients (21%). Urinary catheterization for > 24 hrs. was required in 5 patients (10%). Urinary tract infection was seen in 2 patients (4%). 2 patients had post op ileus (4%). Post op confusion was seen in 6 patients (12%), which were observed in ICU for electrolyte imbalance and hypovolemia. Conclusion: Larger studies needed to be carried out to determine the safety of bilateral knee joint replacement Total knee Arthroplasty in single setting for more conclusive evidence.

# KEYWORDS : Total Knee Arthroplasty, Bilateral, Single sitting, Safety

## INTRODUCTION:

Total knee Arthroplasty (TKA) is a procedure in which the damaged cartilage in the knee is replaced with artificial bearing surfaces. It is one of the most clinically successful and cost effective medical procedures developed during the last century (1-3).

Published studies in the literature have consistently reported TKA as an efficacious and cost-effective means of alleviating pain and restoring function with consistent improvement in the quality of life after failed conservative treatment. (4, 5) A large number of patients with severe end-stage degenerative joint disease have symptomatic bilateral knee joint affliction, necessitating bilateral knee joint replacement (6-8)

Despite these advantages, the safety of simultaneous bilateral total knee arthroplasty (SBTKA) remains controversial owing to the concerns over peri-operative morbidity and mortality (9,10). Some studies have voted against and questioned the safety and relative risk of SBTKA and demanded further critical evaluation(11,12). Advances in surgical techniques and improvement in the prostheses used have improved outcomes and reduced recovery time. Indeed, among patients with two damaged knees, many are now electing simultaneous total knee replacement, avoiding a second surgery, hospital stay and rehabilitation.

The question then arises whether SBTKA is a safe operation to perform in this setting and the orthopedic surgeon must then decide. There are known benefits of performing bilateral arthroplasty during one anaesthetic session, in a single sitting. Patient convenience, reduced length of stay in the hospital and a potentially shortened period of rehabilitation and disability are some of the appeals. Then again, the fear of increased complications dissuades some surgeons from performing bilateral arthroplasty during one anaesthetic session. Considering this issue, a study with an objective to determine safety of bilateral total knee arthroplasty in single sitting was carried out.

## MATERIAL AND METHODS:

This ambispective observational study was carried on tertiary care teaching hospital in Pune city of Maharashtra state of India.

All the patients with age less than 75 years, with clinical and radiological evidence of significant bilateral arthritis, requiring surgical intervention in both the knees who consented for SBTKA were included in the study. Strict exclusion criteria included age more than 75 years, any previous history of local infection within last one year, any previous surgery performed over the knees, remote source of infection, extensor mechanism dysfunction, peripheral vascular disease and patients unwilling to consent for SBTKA.

Before surgery all patients were subjected to a comprehensive medical evaluation. Preliminary preoperative workup for physician fitness, 2D Echocardiography for cardiac fitness and pre-anaesthetic checkup was done in all the patients to be deemed fit for SBTKA. The patients with adequate pulmonary and cardiac reserve were declared fit to undergo SBTKA. The level of anesthetic risk was outlined by the American Society of Anesthesiologists (ASA) classification system (61/13).

All SBTKAs were performed using same technique under single, combined spinal and epidural Anaesthesia, in a sequential manner. All patients were catheterized for urine output calculation. Both knees were prepared at the same time Peri-operative intravenous antibiotics were given 30 minutes prior to incision and continued until postoperative day 2 to 5

# eri- Ethical considerations:

depending upon the surgeon preference. To reduce perioperative blood loss, tranexamic acid was given intravenously after the incision (20mg/kg) and then 3 hourly (20mg/kg) for next 6 hours. Tourniquet was used in all cases. The tourniquet inflation pressures ranged from 300 to 350 mm Hg. The same surgical technique was used in all cases. A standard midline incision and medial parapatellar approach was used for all procedures. Intramedullary femoral alignment rods were used for all procedures, with overdrilling of the femoral entry point before intramedullary rod insertion. Intramedullary alignment guide was used only on femoral side. Posterior stabilized (PS) prosthesis was used in all cases. Patella was resurfaced in cases with patellofemoral joint malalignment. The second knee was begun only after the tourniquet was released on the first knee. Drapes were retained for second knee. A bulb-suction drain was inserted in each reconstructed knee and was removed in 48 hours or if total output for a 12-hour period was <20 mL. The same postoperative protocol was used in all cases. Patients with known comorbidity i.e. grading II or III as per ASA grading or more intraoperative blood loss were nursed in Intensive Care Unit (ICU) for observation. Vital signs, oxygen saturation (SPO2) and fluid intake/output were monitored up to 24 hours in all patients. Haemoglobin levels were checked and the decision to transfuse patients with blood postoperatively was based on the following criteria: patients symptomatic with tachycardia, shortness of breath, chest pain, fatigue, or dizziness with activity or hemoglobin <8.5 mg/dl in patients with cardiovascular comorbidity. Care was taken to avoid electrolyte imbalance and hyponatremia. Deep vein thrombosis prophylaxis entailing intravenous low molecular weight heparins either enoxaparin or dalteparin or fondaparinux for 12 hours after surgery and then oral anticoagulants either rivaroxaban or dabigatran for 2 weeks after discharge were given. The urinary catheter was removed 24 hours after surgery. To facilitate early recovery, multimodal pain management was given and included patient-controlled analgesia with epidural pumps. Bulky dressings were removed on 2nd postoperative day. DVT stockings were put on both the knees Patient was put on active physiotherapy for quadriceps and hamstring muscles. Depending on the ability of the patient to actively extend his/her knee, patient was mobilized on a walker by the 2nd day of surgery till the day of discharge. The Patients were discharged from the hospital when they were able to transfer independently from bed to chair and able to ambulate from the bed to the bathroom and back to the bed with the use of a walking aid. Range of motion of both the knees  $>75^\circ$  also was a requirement before discharge. Most of the patients were discharged after suture removal on the 12th day.

#### Information was obtained on following parameters:

- Intraoperative blood loss,
- Postoperative drainage,
- Change in hemoglobin,
- Transfusion requirement,
- Complications,
- Need for ICU admission and
- Mean hospital stay.

Any other major event including complications was also recorded. Complications were defined as local, pertaining to the operative site, or systemic, relating to the patients' general medical condition.

## Statistical Analysis :

Data was collected using a structured proforma on Excel software (Microsoft, Seattle, USA). Measurements were expressed as means and standard deviations for continuous variables and percentages for categorical variables and was analysed. The study was conducted according to the Declaration of Helsinki; the protocol was reviewed and approved by the institutional ethics committee of the institute. A written informed consent was taken from all patients after explaining the procedure.

#### **RESULTS:**

Total 52 patients were included in the study, which included 14 men and 38 women (1:3), mean age was 63  $\pm$  7 years old (48–75). Mean age was lesser (62  $\pm$  7) in patients with Rheumatoid arthritis.

The indication of surgery was osteoarthritis in 43 patients (83%) and Rheumatoid arthritis in 9 patients (17%). 14 patients had hypertension (28%) of which isolated hypertension was found in 5 patients (10%), 4 patients (8%) were having both Diabetes and hypertension, 6 patients were hypothyroid along with hypertensive (12%) out of which 3 patients had hypothyroidism alone (6%), 2 patients had filariasis (4%) a finding seen only in tropical setup; 4 patients were morbidly obese (8%), of which one patient had hypertension as well as diabetes; 2 patients each, had anemia before surgery(4%) which required pre op blood transfusion, varicose veins over the legs(4%), previous history of stroke (4%); one patient each, had asthma, chronic renal failure, gastro-esophageal reflux disease,(2% each). 21 patients were having no co-morbidity (40%)..

The mean initial Knee Society Clinical Score (KCS) score62 was  $41 \pm 11$  points (13-65 points). The mean initial Knee Society Functional Score (KFS) score62 was 42  $\pm$  9 points (20-65 points). The American Society of Anesthesiologists (ASA) 61 score was ASA one in 2 cases (4%), ASA two in 36 cases (69%), and ASA three in 14 cases (27%). The mean hospital stay was 9.1 ± 3.5 days (4–19). Mean pre op hemoglobin was 12.3  $\pm$  1.5 g/dL (10.0–17 g/dL) and post op Hb was  $9.2 \pm 1.4$  g/dL (6.0–13.0 g/dL). Mean blood loss including drain output was  $553ml \pm 209ml$  (200-1250). Mean decrease in Hb was 3.1  $\pm$  1.3 g/dL (0.6–7 g/dL). There were 2 preoperative transfusions in patients who had Hb <10g/dl. Twenty six patients (50 %) received a postoperative transfusion with a mean 1.1 ± 1.4 units (0-6units). Blood substitutes were preferred over blood in 10 patients, while 31 patients received both blood as well as intra venous blood substitutes (60%).

The patients were assessed 6 weeks post operatively for any signs of post-operative infection. Once post-operative infection was ruled out clinically the patient was assessed clinically, functionally and radiologically using the Knee Society Score at 3 months. 2 patients with post-operative infection were not assessed for KSS. One patient had died. These 3 patients were not included in the post op KSS.

The post op complications were categorized into

 Local complications related to the wound and operative site.
 Systemic complications related to patient's comorbidity and systemic status.

#### Local complications included

1. Infection: Infection was seen in 2 patients (4%),

2. Pain over the operated knee: 2 patients (4%) complained of anterior knee pain which was persistent even with analgesics, of which one was diagnosed as post op infection.

3. Swelling and soakage of dressing: wound hematoma with soakage of dressing in 3 patients (6%) with delayed wound healing.

Both the patients who developed infection, had the infection in the first operated knee. One patient recovered completely without any operative intervention, with oral empirical antibiotics for 6 weeks. This patient also had other comorbidities like obesity, diabetes mellitus, hypertension and UTI. Another patient developed infection immediately post op. Despite salvage procedures, infection refused to settle after 3 months and the patient underwent unilateral knee arthrodesis of the affected side (right). The other knee was uninfected. There was one death in our study. This patient, morbidly obese, operated for SBTKA for RA both knees, who on preop evaluation was moderate risk. One patient had persistent inflammatory effusion over the operated knee which delayed the functional recovery and prolonged the stay. She recovered completely with medicines and rest. There were 5 patients having temperature  $> 100^{\circ} \text{ F}$ for > 48 hrs. (10%). GI & urinary problems were seen in 11 patients (21%). Urinary catheterization for > 24 hrs. was required in 5 patients (10%). Urinary tract infection was seen in 2 patients (4%). 2 patients had post op ileus (4%). Post op confusion was seen in 6 patients (12%), which were observed in ICU for electrolyte imbalance and hypovolemia. All recovered completely with medical management. Criteria for Fat embolism syndrome included mental status changes or confusion with associated abnormal arterial blood gas. In no patient did we find any evidence of fat embolism. Mean ICU stay was 0.5 days  $\pm$  1.5 (0-11 days). Depending upon the intraoperative hemodynamic status and co-morbidity, with discussion with the anaesthetist, those patients who were considered high risk were shifted to ICU for immediate post op monitoring. 17 patients were kept in ICU (33%), out of which 15 were for postoperative observation for one day whereas 2 had a prolonged stay with associated complications. One patient recovered completely within 2 days and was shifted out of ICU. The other patient expired due to sepsis and multi organ failure, was in ICU for 11 days. Analysis was done to find out whether patients having comorbidities were more prone for post op ICU monitoring. Of all the patients shifted to ICU, only 3 were not having any co-morbidity, other all patients were having comorbidities. ASA grading for these patients was grade one in 2 patients (4%), grade two in 9 patients (18%), and grade three in 6 patients (12%).

#### DISCUSSION:

TKA continues to be one of the most successful and effective orthopedic operative procedures and is considered to be extremely safe. Most patients with arthritis of the knee undergo unilateral TKA, however many patients present with symptomatic arthritis of both knees. The question then arises whether SBTKA is a safe operation to perform in this setting and the orthopedic surgeon must then decide. There are known benefits of performing bilateral arthroplasty during one anaesthetic session, in a single sitting. Patient convenience, reduced length of stay in the hospital and a potentially shortened period of rehabilitation and disability are some of the appeals. Many authors believe that the decision to perform SBTKA should be based on the patient's expectations and needs and the recommendation of the surgeon based on the known risks of the surgical procedure and any associated medical disorders of the patient. The rates of cardiac, pulmonary, and neurological complications have been reported to be relatively greater in most of the studies for SBTKA. The concern of likelihood of these complications certainly should take priority over the potential benefits of the procedure before offering simultaneous arthroplasties to patients with bilateral knee arthritis. There is a great deal of variation in the type and incidence of perioperative complications reported in published studies, and it is not possible to single out a predominant complication associated with SBTKA. Furthermore, comparison of the rates of clinically relevant adverse events from study to study and over time is complicated by the differing endpoints and lack of uniformity in the criteria used for diagnosis of adverse events. However, all these authors agree that although the risk was increased, the rate was still acceptable, and they do not question SBTKA as a valid therapeutic strategy.

The question arises how to assess the risk? Most papers cited knee replacement scoring systems. Some authors described their use of the American Society of Anaesthetists (ASA) grading system. Others clearly implied a pre-operative assessment of medical co-morbidity

Cardiac complications can be potentially life threatening and have been consistently reported to be higher following SBTKA than following unilateral knee arthroplasties or staged bilateral procedures. As per Lynch et al study (13) cardiovascular complications were observed after 22% of bilateral procedures compared with 6% of unilateral procedures. Similar findins were observed Bullock et al study. In present study patients undergoing SBTKA did not show any significant difference from staged TKR published in the selected studies. Pulmonary embolism and fat embolism are 2 serious complications reported with relatively higher incidence with SBTKA, culminating in higher mortality in these patient groups. However, in a recent study on a large patient population group, Barrett et al concluded that the risk of developing symptomatic pulmonary embolism in patients with simultaneous bilateral procedures is 80% higher than in those with staged bilateral or unilateral knee arthroplasty, with the absolute risk being low in either case, thus suggesting that the sum of the risks associated with the 2 operations of a staged procedure may equal or exceed the risk of SBTKA (15). Neurological complications have been reported more commonly with SBTKA than unilateral or staged procedures in some cases, with confusion being the most frequently reported complication. Luscombe et al in their recent published study observed that SBTKA was associated with increased morbidity with respect to wound and deep prosthetic infections, bilateral results being statistically higher than the unilateral group (16). Gradillas, Volz found a high superficial infection rate in their bilateral group, four times the results for the unilateral group, which was considered attributable to the high number of rheumatoid patients in their study (8). The infection rate in our study was greater than that observed in the other studies may be due to small sample size. 2 patients had deep infection (4%) out of which one patient recovered without any surgical intervention and the other had to undergo Knee arthrodesis of the infected knee.

### CONCLUSION AND RECOMMENDATION:

Simultaneous bilateral total knee arthroplasty (SBTKA) may be good choice for patient and hospital but for assessment of safety profile of present study recommended larger studies as well as comparative studies for more conclusive evidence.

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