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Clinical Outcome Evaluation of Primary Total Knee Arthroplasty in Patients with Diabetes Mellitus

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: The aim of this study was to evaluate the safety and clinical outcome of primary total knee arthroplasty in patients with diabetes mellitus.

Material/Methods: Among the patients who were treated with total knee arthroplasty, there were 98 patients (116 knees) associated with diabetes. Osteoarthritis was diagnosed in 90 patients and rheumatoid arthritis was diagnosed in 8 patients. Various degrees of preoperative knee deformities were found in 82 knees. The average fasting blood glucose was 9.8±3.6 mmol/L at admission.

Results: The clinical efficacy of TKA was satisfactory in patients with diabetes mellitus. Diabetic patients do not seem to have a significantly higher risk for infection and DVT after TKA. At the final follow-up time point, no prosthesis loosening was found and no revision was needed in any patients. The mean HSS scores increased and the excellent rate was 100%.

Conclusions: Using perioperative comprehensive assessment of heart and lung function, and by preventing infection and the formation of DVT, we achieved satisfactory early clinical efficacy of TKA in patients with diabetes mellitus.

MeSH Keywords: Arthroplasty, Replacement, Knee • Diabetes Mellitus • Perioperative Period

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Background

Studies have shown that the incidence of diabetes at all ages is increasing; the global number of diabetic patients was 135 million in 1998, and is expected to reach 300 million by 2025. [1] A large population-based study of diabetes in China also shows that the prevalence of diabetes among people over age 60 in China can be as high as 20.4% [2]. This reduces the patient's ability to recovering from disease and trauma, and also can lead to obesity, as well as increasing the incidence of osteoarthritis and the need to undergo joint replacement. In the United States, a 15-year study of 750 000 joint replacement patients found that 8.55% were diabetics [3]. Due to various reasons, hip and knee replacement are also increasingly common among diabetic patients, and the proportion may be as high as 52% [4,5].

Diabetic patients have low body resistance, poor tissue-healing ability, and high incidence of perioperative complications; the incidence of stroke, urinary tract infections, intestinal obstruction, bleeding, and death were increased by 3.42-, 1.97-, 2.47-, 1.99-, and 3.23-fold, respectively [6]. For total knee arthroplasty (TKA) patients with diabetes, diabetes increases the incidence of conditions such as deep venous thrombosis (DVT) and infections [3,7]. However, this view is not universally accepted, and some scholars believe that the incidence of complications such as DVT, deep infection, and revision surgery is no different between diabetic and non-diabetic patients [8].

In the face of such a huge diabetic population, the potential risk of perioperative and possible postoperative adverse effects need further exploration, such as how to adjust and control blood sugar, strengthen perioperative management, improve perioperative safety and efficacy of diabetic patients undergoing joint replacement, and how to understand the opposite point of view.

We retrospectively analyzed 98 patients (116 knees) with type 2 diabetes undergoing primary total knee arthroplasty from January 2015 to December 2015 to: (1) clarify the problems and clinical curative effect of TKA in patients with diabetes mellitus in the perioperative period; (2) investigate whether diabetes increases TKA postoperative infection and incidence of DVT; and (3) explore glycemic control for diabetes patients during the TKA perioperative period.

Material and Methods

Patients

The study protocol and amendments were approved by our local institutional review board. Our study sample consisted of 98 patients (116 knees) with osteoarthritis or rheumatoid arthritis undergoing TKA treatment from January 2015 to December 2015; all were diagnosed with type 2 diabetes and none had serious heart, liver, kidney, vascular, or other complications during the initial surgery, and all finished the complete follow-up. Patients requiring insulin for diabetes control and those with prior knee surgeries were excluded. Among the 98 patients, there were 19 males (23 knees) and 79 females (93 knees), the age range was 47–83 years old (average 65.5 years), and there were 90 osteoarthritis (OA) patients and 8 rheumatoid arthritis (RA) patients. Out of the total of 98 patients, there were 81 patients with hypertension, 4 with arrhythmia, 2 with asthma, 1 with rheumatic heart disease, and 2 with asymptomatic bacteriuria.

There were various degrees of deformity in the group of 82 knees before the operations. Claudication and severe knee pain existed in all patients and restricted their everyday life significantly. The hospital special surgery (HSS) knee scores [9] ranged from 25 to 55 points (average 36.8±11.6).

Regulation of blood sugar and complications

Fasting blood glucose ranged from 5.2 to 17.9 mmol/L (mean (9.8±3.6 mmol/L) urinary glucose (–) to (+++) at hospital admission. According to the diagnostic criteria for diabetes, patients were diagnosed with type 2 diabetes if they had clinical manifestations of diabetes along with fasting blood glucose at least 7.0 mmol/L or postprandial 2-h blood glucose at least 11.1 mmol/L. Seventy-four patients had a clear history of diabetes mellitus at admission; 17 received long-term insulin injections, and 35 took oral hypoglycemic agents. Blood glucose was satisfactorily controlled in all of these 74 patients and average fasting blood glucose was (6.2±0.6) mmol/L; 22 patients controlled diabetes without regular medication and the other 24 patients were diagnosed with type 2 diabetes after being admitted to the hospital.

Fasting blood glucose and 2-h blood glucose after meals were assessed in all patients during the perioperative period; 74 patients with satisfactory blood glucose control maintained their previous medication or insulin programs, 22 patients without regular medication and 24 patients diagnosed with type 2 diabetes after being admitted to the hospital needed to control blood sugar, which included a strict diabetic diet and taking insulin before meals. The targets for blood glucose control were fasting blood glucose <7.8 mmol/L and 2-h postprandial blood glucose <10 mmol/L.

Eighty-one hypertensive patients were given oral antihypertensive drugs to control blood pressure to less than 140/90 mmHg. Four patients with arrhythmia underwent 24-h dynamic electrocardiography before surgery. Two patients with asthma were treated with the combination of bronchial dilation agents and corticosteroids; they were in clinical remission and

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blood gas analysis and pulmonary function tests were normal, so no special treatment was applied during the perioperative period. One patient with rheumatic heart disease received a color Doppler ultrasound heart examination before surgery, and there was no clear contraindication for surgery. Two patients with asymptomatic bacteriuria were urged to drink extra water, cleaning their perineum every day, and underwent alkaline urine and diuretic therapy for 5 days, after which their routine urine examination results were normal.

Operation method

All patients suspended medication or insulin on the morning of surgery, and blood glucose monitoring was performed once every 4 h after the operation. The patients began to eat on the evening of the day of surgery, and resumed their preoperative glycemic control regimens. Cefuroxime 1500 mg was administered during a period of 30 min and clindamycin 600 mg was given 2 h preoperatively to allergy patients for infection prevention. Preoperative dual-branch color Doppler ultrasound examinations showed no venous thrombosis. Surgery was conducted under tourniquet with femoral nerve block and general anesthesia. No patellar replacement was performed in this group of patients. After periarticular infiltration injection with 200 mg ropivacaine diluted to 60 ml, a drainage tube was routinely placed. A dose of 10 mg/kg tranexamic acid was administered by intravenous drip 15 min before closing the incision.

Postoperative treatment

After the operation, the knee was braced in extension position, and quadriceps exercises were started after awakening from anesthesia. On the day of surgery, patients were required to perform straight leg raising exercises in bed. Patients were allowed to stand wearing a limb support 6–8 h postoperatively. Drainage tubes in all patients were removed on the first postoperative day, after which they began knee flexion and extension exercises, as well as walking with a walker device.

Cefuroxime 1500 mg or clindamycin 600 mg were given postoperatively to prevent infection. We did a routine inspection at 1, 3, 5 days postoperatively. Patients whose hemoglobin was <70 g/L received transfusion therapy. Patents whose hemoglobin was >70 g/L and <100 g/L, but had manifestations of severe anemia (e.g., loss of appetite, listlessness, inability to function, exercise or activity palpitations, and other severe anemia symptoms) received transfusion therapy as appropriate. Treatments to prevent DVT were started immediately after surgery. The physical prevention included sole vein pump and double-limb intermittent compression, and drug prevention included subcutaneous enoxaparin. After discharge from the hospital, patients received oral rivaroxaban 10 mg once daily for 2 weeks. Double lower-limb venous color Doppler ultrasound examination was performed at 5 days after surgery or on the discharge day to look for a clear DVT formation. Patients with severe swelling of the affected limb and pain, and for whom there was a high degree of suspicion of DVT formation were immediately had a color Doppler ultrasound examination. To check for possible asymptomatic DVT, lower-extremity venous color Doppler ultrasound was again performed on outpatients 3 weeks after surgery.

Follow-up

Patients had regular clinical follow-up at 1, 2, and 3 weeks and at 1, 2, 3, 6, 9, and 12 months after discharge from the hospital. As of April 2016, all patients had completed follow-up, which included knee flexion, extension activity, HSS score, knee joint positive, lateral X-ray films, and lower limbs standing full-length X-ray film.

Safety and efficacy evaluation

HSS [9] scores were used to evaluate knee joint function. The best possible score was 100 points, including pain (30 points), function (22 points), range of motion (18 points), strength (10 points), flexion deformity (10 points), and joint stability (10 points). A score >85 is excellent, 70 to 84 is good, 60 to 69 is fair, and <60 is poor.

We referenced the last follow-up positive and lateral radiographs of knee joint to determine whether there was prosthesis loosening or osteolysis. At the same time, the operation safety was evaluated, including perioperative complications and mortality, length of stay at hospital, total blood loss, blood transfusion, blood transfusion rate, and the revision surgery rate. The total blood loss was calculated by Gross equation, [10] according to the height, weight, and the red blood cell volume (Hct) before and after the operation. At last follow-up, knee extension and flexion angle were measured by 2 graduate students with a long-arm protractor, then they calculated the range of motion of knee joint and average value.

Statistical method

All statistical analyses were performed by SPSS Software for Windows, version 21.0 (SPSS, Chicago, IL). Knee flexion and extension activity were measured by 2 graduate students, and the differences were analyzed by the Kappa repetition test. All statistical tests were 2-sided, and the threshold of statistical significance was set at α=0.05.

Results

After admission but before surgery, the average fasting blood glucose of the patients was (6.9±1.3) mmol/L, the highest

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was 9.7 mmo/L, 2-h postprandial blood glucose average value was (10.8±1.84) mmo/L, and the maximum was 12.8 mmo/L.

The operation times ranged from 60 to 95 min, with an average time of 78±16 min. The intraoperative blood loss was less than 30 ml, and the postoperative drainage volume was 75 to 340 ml, with an average value (224.7±98.6) ml. According to the Gross equation, the total blood loss was 598 to 1102 ml, and the average value was (712.6±95.72) ml. Sixteen patients received allogeneic red blood cell suspension infusion; the amount of blood transfused was 1 to 2 U, the average amount was (1.4±0.2) U, and the blood transfusion rate was 16.3% (16/98).

All patients resumed eating on the day of surgery, and ate at least 2 meals with less sugar and more salt, and drinking fluids. On the first day after the operation, they returned to normal diet, consisting mainly of high-protein food. All patients were instructed to perform straight leg raising and quadriceps exercises in bed after awakening from anesthesia, and on the day of surgery patients could stand while wearing a leg brace. On the first postoperative day, patients were required to begin knee flexion and extension exercises. Postoperative color Doppler ultrasonography showed 5 patients had venous thrombosis formation in leg muscles, but there was no deep vein thrombosis, and not special treatment was required. Three weeks after surgery, we again performed outpatient double lower limbs vein color Doppler ultrasonography when sutures were removed, and not thrombosis was found. The length of hospital stay ranged from 9 to 22 days, with an average time of (15±3) days.

Efficacy evaluation

The patients were followed-up for 7 to 14 months, with an average of 8.6±2.8 months. At the last follow-up, the average HSS score of the knee joint was increased from average of 36.8±11.6 to 89.4±12.3 points, including "excellent" in 77 patients and "good" in 21 patients (the good rate was 100%). The average range of motion of the knee joint increased from 72.4±16.2° to 110.1±17.8°. Wound healing of 2 patients was delayed, then their knees were immobilized in extension position temporarily removal of sutures was delayed; their wound finally healed after 2 weeks. At last follow-up, none of the patients had the deep infections. The X-ray examination showed no loosening or displacement of the prosthesis, and there was no need for revision surgery.

Consistency check

According to the consistency test of the knee joint flexion and extension degrees measured by 2 independent assessors, the Kappa values were 0.778 and 0.783 ($P<0.001$), respectively, showing good consistency in measurement of the degree of knee activity.

Discussion

Osteoarthritis (OA) of the knee is a common joint disease [11] and is characterized by pain, joint deformity, muscle weakness, joint instability, and stiffness [12–16]. Total knee arthroplasty is a most common surgical intervention treatment for end-stage knee osteoarthritis and is a cost-effective intervention for improving function, reducing pain, and enhancing the final quality of life in patients with knee OA. Diabetes mellitus (DM) is the most common chronic health condition around the world. It is predicted that the global prevalence of DM will increase from the present 6.4% to 7.7% by 2030 [17]. It has also been reported that patients with DM have more perioperative complications after TKA compared with other patients without diabetes mellitus [3,18]. Because the number of TKA operations is now continuously increasing [19], it is very important to clarify process of perioperative care for diabetic patients with TKA.

The most important finding of the present study is that diabetic patients seemed to have greater knee flexion angle and final improvement in the functional activities after TKA when compared with their preoperative results. On the other hand, this study showed that there was little improvement in muscle strength of the involved limb. Obviously, diabetes mellitus is associated with decreased muscle strength and quality of life in older adults [20,21], and a recent study [22] confirmed that diabetes mellitus adversely affects the knee flexion ROM and the final functional outcomes after TKA surgery. Also, diabetic patients had worse muscle strength at all follow-up time points in this study, suggesting that clinicians such as orthopedic surgeons should pay more attention to muscle weakness in diabetic patients during their rehabilitation period after TKA surgery. Watts et al. [23] found that although type II diabetes did not increase the risk of failure relative to non-diabetic patients, insulin dependence further increased the risk of reoperation, revision, and deep infection. A large prospective study [24] of fast-track total hip arthroplasty (THA) and TKA found no association between type 2 diabetes *per se* and impaired postoperative outcome.

An instructional course lecture [25] identified some modifiable risk factors which significantly contribute to poor clinical outcome following TKA, including morbid obesity; poorly controlled diabetes and nutritional deficiencies; *Staphylococcus aureus* colonization; tobacco use; venous thromboembolic disease; cardiovascular disease; neurocognitive, psychological, and behavioral problems; and physical deconditioning and fall risk. Subsequently, clinical intervention would be warranted to address modifiable risk factors before proceeding with TKA. This research suggests the value of perioperative comprehensive assessment of heart and lung function, and preventing infection and the formation of DVT. The early clinical efficacy of TKA was satisfactory in patients with diabetes mellitus. Zhao et al. [26]

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reported that the incidence of DVT at 14 days after TKA was significantly higher in patients with than without diabetes. However, a study of 40 491 patients who underwent elective TKA [8] found no significantly increased risk of deep venous thrombosis in patients with diabetes compared to patients without diabetes. This study found that diabetic patients do not seem to have a significantly higher risk for infection and DVT after TKA. Blood glucose does not have to be controlled if it is within the normal range, but intervention is needed to treat uncontrolled high blood glucose and low blood glucose.

There are also several limitations to our present study, the first of which is the small sample size. At a single center, enough patients could not be recruited due to the lack of eligible diabetic patients with TKA. Second, postoperative diabetes assessment in most patients was not performed (at 1, 2, 3, 6, 9, and 12 months), and this could have affected some clinical outcomes. Third, the study did not enroll a cohort of patients without diabetes mellitus for comparison as a control group. Fourth, we did not evaluate all possible patient-level predictor variables (such as smoking) or other laboratory data (such as nutritional status), which could be confounding factors for surgical site infections and wound complications in patients after TKA, although we did consider age, sex, BMI, and transfusion as possible confounders. Finally, we performed a retrospective review of data from our hospital database, and a retrospective study may be subject to selection bias. However, selection bias was reduced by consecutive enrollment of the study patients.

Conclusions

Patients with diabetes mellitus had satisfactory results from perioperative comprehensive assessment of heart and lung function, preventing infection, and the formation of DVT, showing the early clinical efficacy of TKA. Diabetic patients do not seem to have a significantly higher risk for infection and DVT after TKA. Blood glucose does not have to be controlled if it is within the normal range, but intervention is needed to treat uncontrolled high blood glucose and low blood glucose. A larger sample of clinical research is needed to determine whether diabetes increases the incidence of deep venous thromboembolism and deep infection in patients after TKA.

Disclosure

The authors declare no competing financial interests.

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