



Outcomes of Foot and Ankle Surgery in Diabetic Patients Who Have Undergone Solid Organ Transplantation



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ABSTRACT

Foot and ankle problems are highly prevalent in patients with diabetes mellitus (DM). Increased rates of surgical site infections and noninfectious complications, such as malunion, delayed union, nonunion, and hardware failure, have also been more commonly observed in diabetic patients who undergo foot and ankle surgery. DM is a substantial contributor of perioperative morbidity in patients with solid organ transplantation. To the best of our knowledge, postoperative foot and ankle complications have not been studied in a cohort of diabetic patients who previously underwent solid organ transplantation. The aim of the present study was to evaluate the outcomes of foot and ankle surgery in a cohort of diabetic transplant patients and to compare these outcomes with those of diabetic patients without a history of transplantation. We compared the rates of infectious and noninfectious complications after foot and ankle surgery in 28 diabetic transplant patients and 56 diabetic patients without previous transplantation and calculated the odds ratios (OR) for significant findings. The diabetic transplant patients who underwent foot and ankle surgery in the present cohort were not at an increased risk of overall complications (OR 0.83, 95% confidence interval [CI] 0.33 to 2.08, $p = .67$), infectious complications (OR 0.54, 95% CI 0.09 to 3.09, $p = .49$), or noninfectious complications (OR 1.14, 95% CI 0.41 to 3.15, $p = .81$). Four transplant patients (14.3%) died of non-orthopedic surgery-related events during the follow-up period; however, no deaths occurred in the control group. Diabetic patients with previous solid organ transplantation were not at an increased risk of developing postoperative complications after foot and ankle surgery, despite being immunocompromised. The transplant patients had a greater mortality rate, but their premature death was unrelated to their foot and ankle surgery. Surgeons treating transplant patients can recommend foot and ankle surgery when indicated. However, owing to the increased mortality rate and comorbidities associated with this high-risk group, we recommend preoperative clearance from the transplant team and medical consultations before performing surgery.

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Diabetes mellitus (DM) is a highly prevalent disease among orthopedic surgery patients, especially within the specialty of foot and ankle surgery. According to the Centers for Disease Control and Prevention's National Diabetes Fact Sheet 2014, an estimated 29.1 million Americans (9.1% of the population) have DM (1). DM is a global problem, with an estimated 285 million adults worldwide diagnosed with this disease in 2010, and this is projected to substantially increase to 439 million adults by 2030 (2). The complications of DM are

associated with significant economic burdens. The International Diabetes Federation estimated that \$376 billion global health expenditures were spent in 2010 to prevent and treat DM and its complications. By 2030, the International Diabetes Federation projected expenditures will exceed \$490 billion (2). Patients with poorly controlled DM have been shown to be at a greater risk of the development of complications such as Charcot neuroarthropathy (CN), peripheral neuropathy, peripheral vascular disease, osteomyelitis, and renal-related metabolic bone disease, among others.

Postoperative orthopedic infectious complications of DM after foot and ankle surgery have been well documented in published studies. A retrospective study reported that diabetic patients who underwent foot and ankle surgery experienced an approximately fivefold increase in the rate of postoperative deep surgical site infections compared with patients without DM (13.2% versus 2.8%, respectively) (3). A recent prospective study demonstrated that patients with complications

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of DM, including neuropathy, peripheral arterial disease, and nephropathy, experienced a sevenfold increase in surgical site infection risk compared with patients without DM and without neuropathy and a nearly fourfold increase in risk compared with patients with uncomplicated DM (4). Diabetic patients have also been shown to experience greater rates of noninfectious orthopedic complications after foot and ankle surgery (5,6). Common complications have included impaired fracture healing, malunion, delayed union, nonunion, hardware failure, revision surgery, and amputation (7,8). In addition, diabetic patients with comorbidities such as heart disease, chronic obstructive pulmonary disease, hypertension, and previous hospitalizations have been shown to experience an increased risk of requiring long-term bracing, ranging from 15 months to 8 years after the initial foot and ankle fracture presentation, compared with their counterparts without DM (47% versus 14%, respectively) (9).

In addition to foot-related complications, diabetic patients have a greater risk of the development of end-stage renal disease, coronary artery disease, and cardiomyopathy. Similarly, diabetic patients can have end-stage liver disease due to hepatitis, nonalcoholic fatty liver disease, and cirrhosis. Consequently, the rates of cardiac, pancreatic, renal, and liver transplantation have dramatically increased in this population within the previous 4 decades, largely owing to the continued success of immunosuppressive agents and biologic agents. Although diabetic patients have undergone solid organ transplantation with modest success rates, previous studies have demonstrated that the manifestations of DM significantly increase the risks and complications associated with transplantation. A retrospective study reported a 40% decrease in the mean 5-year survival rates after orthotopic liver transplantation in diabetic patients compared with nondiabetic patients (10). Another retrospective study described lower mean 5-year survival rates and graft survival rates for diabetic patients after renal transplantation compared with nondiabetic patients (83% versus 93% and 74% versus 79%, respectively) (11). The success of simultaneous renal and pancreatic transplantation has also been reported (12). In addition to greater rates of mortality, solid organ transplantation has been associated with an increased risk of postoperative infections owing to the chronic use of immunosuppressive agents and antimicrobial prophylactic treatment-induced resistance. Additionally, 1 study reported that diabetic patients who underwent renal transplantation experienced an approximately twofold increase in overall bone fracture incidence compared with patients without DM (13).

Because of these comorbidities and the long-term immunosuppression, surgeons have traditionally been reluctant to operate on diabetic patients with previous solid organ transplantation owing to the presumed increased postoperative risks and complications. To the best of our knowledge, complications after foot and ankle surgery in diabetic patients who have previously undergone solid organ transplantation have not been studied. We hypothesized that the postoperative complication rates after foot and ankle surgery would be greater for diabetic transplant patients than for diabetic patients without a history of transplantation. The aim of the present study was to evaluate the outcomes of foot and ankle surgery in a cohort of diabetic patients with a history of solid organ transplantation and compare these outcomes with those of diabetic patients without a history of transplantation.

Patients and Methods

Approval was obtained from our local institution review board before beginning the present retrospective case-control study. We reviewed the foot and ankle surgical database of the senior author (D.K.W.), searching for diabetic patients who had previously undergone solid organ transplantation. A comprehensive foot and ankle registry was created in our division in January 2005, in which the data for every surgical patient were prospectively entered at the time of their surgery. Demographic data were entered into the spreadsheet, as were the "International Classification of Diseases,

Ninth Revision" diagnosis codes for transplantation (V42.0), cardiac transplantation (V42.1), liver transplantation (V42.7), pancreatic transplantation (V42.83), and renal transplantation (V42.07) (14). Postoperative complications were recorded prospectively in the comprehensive foot and ankle registry by categorically denoting the absence (0) or presence (1) of specific complications. Once transplant patients had been identified from the comprehensive foot and ankle registry, the electronic inpatient and outpatient records and digital radiographs were reviewed from those patients who had undergone surgery by the senior surgeon (D.K.W.) from January 2005 until June 2013.

Our study group included patients with DM who were aged ≥ 18 years and had undergone previous solid organ transplantation and, subsequently, foot and ankle surgery. For the purposes of the present study, we defined solid organ transplantation as pancreatic, renal, hepatic, cardiac, and/or lung transplantation. The inpatient and outpatient records identified 28 consecutive patients who fit the study group inclusion criteria. Their data were abstracted by the first author (R.H.Z.), who also determined the values to be used in the present research project.

The exclusion criteria included transplant patients who had previously been treated for active soft tissue infection (Current Procedural Terminology code 28002, "International Classification of Diseases, Ninth Revision" code 682) or osteomyelitis (Current Procedural Terminology code 28005, "International Classification of Diseases, Ninth Revision" code 730) (14,15). Patients with active infections were excluded, because one of the outcomes of interest was the occurrence of postoperative infection.

We used 2-to-1 control-to-study match criteria to select 56 control patients with DM and without a history of solid organ transplantation who had undergone foot and ankle operative procedures similar to those of the study group counterparts. The 2-to-1 match was used to increase the power of the present study and, at the same time, minimize the loss with the small number of case-control sets available from our database (16). A sample size estimation was not performed, because a pilot study had not been performed and no previous studies have addressed this topic. The control group was matched for sex, age, and length of orthopedic surgery time. The patients in the present study were matched according to the operative time rather than the specific foot and ankle procedure to increase the inclusion criteria pool and control for variability. For the purposes of the present study, we assumed that, in general, patients with similar operative times had undergone similar categories and complexities of foot and ankle reconstruction. We extracted the following baseline characteristics from each patient in the study: sex, age, operative time, solid organ transplantation history, follow-up period after orthopedic surgery, diabetic status, duration of DM, blood glucose level, hemoglobin A1c (HbA1c), creatinine, Michigan Neuropathic Screening Instrument (MNSI) score, history of insulin use, American Society of Anesthesiologists classification, body mass index (BMI), and neuropathic status.

Peripheral neuropathy was clinically diagnosed using the MNSI score (score ≥ 2.5) (17). This validated instrument relies on Semmes-Weinstein monofilament testing, vibration testing using the 128-Hz tuning fork, an Achilles reflex assessment, the presence or absence of ulceration, and the presence or absence of deformity such as claw toes or CN. Diabetic neuropathy was confirmed in patients using a quantitative neurologic examination, coupled with nerve conduction studies (18). Four plantar sites (first and fifth metatarsal heads, plantar hallux, and heel) were tested using the 5.07 Semmes-Weinstein monofilament. These 4 sites represented a slight modification from the original description of the MNSI. Patients who could sense all 4 sites with their eyes closed received a score of 0 for each foot. Patients who were unable to sense the monofilament in 1 of the 4 sites received a score of 0.5 for each foot. Patients who were unable to sense ≥ 2 of the 4 sites received a score of 1.0 for each foot. Vibratory sensation was evaluated using the 128-Hz tuning fork at the dorsal hallux. Patients who felt the vibration consistent with the duration that the examiner felt while holding the 128-Hz tuning fork received a score of 0 for each foot. Patients who initially felt the vibration but were unable to sense it after 5 seconds of dampening by the examiner received a score of 0.5 for each foot. Patients who were unable to sense the vibration at all or with noted absence within 5 seconds received a score of 1.0 for each foot. The Achilles reflexes were evaluated in a standard musculoskeletal manner. An intact reflex without reinforcement received a score of 0 for each foot. An intact reflex with reinforcement (clapping the hands and fingers together with the Jendrassik maneuver) received a score of 0.5 for each foot. An absent reflex received a score of 1.0 for each foot. Patients with a foot ulcer received a score of 1.0 for each foot. Patients without foot ulcers received a score of 0 for each foot. For the purposes of the present study, we defined neuropathic deformity as multiple claw toes involving both feet or the presence of CN. Claw toes and CN were evaluated both clinically and radiographically. The presence of a deformity received a score of 1.0, and the absence of a deformity received a score of 0. The maximum score per foot was 5, and the combined maximum total score for both feet was 10. The MNSI was used as a measure of peripheral neuropathy in our diabetic patient population (17).

Malunion was defined as healed bone fractures or arthrodeses in less than optimal positions. Delayed union was defined as bone fractures or arthrodeses that had not healed within 6 months of the foot and ankle operation. Nonunion was defined as the absence of bone healing after 1 year. Owing to the high prevalence of patients with neuropathy, the presence of pain was an unreliable marker of nonunion. Thus, we relied on the radiographic findings to include hardware failure. All complications were determined by the single academic foot and ankle surgeon (D.W.K.) who performed the operations. The data obtained regarding diabetic status, insulin use, and neuropathic status were recorded using a binary yes (1) or no (0) system, in which patients either had or did not have the complication documented in their electronic medical records.

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