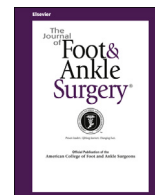


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Association Between Hemoglobin A1c and Surgical Morbidity in Elective Foot and Ankle Surgery



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ABSTRACT

The current guidelines for the management of diabetes in adults have recommended strict glycemic control, with a target hemoglobin A1c of 7.0%. Increasing evidence has shown that strict glycemic control decreases the risk of developing the organ system complications associated with diabetes. Elevated hemoglobin A1c levels have been theorized as a risk factor for complications after elective foot and ankle surgery. To test this hypothesis, we reviewed the Department of Veterans Affairs national administrative and clinical databases for a 6-year period (January 2008 to December 2013). During this period, 21,854 diabetic patients had a recorded hemoglobin A1c measurement within 1 year before undergoing elective foot and ankle surgery. We then identified those patients who had experienced postoperative complications within 30 days of elective foot or ankle surgery using the International Classification of Diseases, ninth revision, codes. The complications were classified into 4 groups: infection, wound healing, mechanical failure, and cardiovascular/pulmonary. The overall 30-day postoperative complication rate was 3.2%. The most common complication was infection (42.3%), followed by mechanical failure (33.4%), cardiovascular/pulmonary (18.4%), and wound healing (5.8%). The average hemoglobin A1c of a patient who had experienced a complication was 6.29% compared with 6.11% for a patient who had not experienced 1 of the 4 complications ($p < .001$). Logistic regression analysis revealed that for each 1% increase in hemoglobin A1c, the odds of developing a complication increased by 5%. More significant was the 1.78 times increased risk of developing a complication for patients with neuropathy (95% confidence interval 1.45 to 2.20; $p = .0001$). Even more notable was the associated risk of complications after elective foot and ankle surgery for those patients with comorbid conditions. Patients demonstrated 3.08 times the risk of developing a complication when the patient had 2 to 3 identified comorbid conditions associated with diabetes mellitus (95% confidence interval 2.42 to 3.92; $p = .0001$). The present retrospective observational investigation has demonstrated glycemic control influences the postoperative complication rates in elective foot and ankle surgery. However, the data collected from the present study have also demonstrated that the complication rates are multifactorial. Comorbid conditions and the presence of peripheral neuropathy also play a significant role in determining a patient's risk of complications after elective foot and ankle surgery.

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The US Centers for Disease Control has estimated that >29.1 million Americans have diabetes. This represents >9% of the population, with expectations that this proportion will continue to increase (1). Several observational studies have suggested that persons with diabetes are more likely to develop postoperative infections and/or have delayed ability to achieve bony union when undergoing surgery of the foot and ankle. The cost and outcomes of their perioperative care (i.e., rate of

mortality, postoperative complications, length of hospital stay, and rate of hospital readmission) also appear to be greater compared with similar nondiabetic patient populations (2–7). Evidence has been increasing that poor glycemic control, as represented by the hemoglobin A1c (HbA1c) level, increases the risk of development of end-stage organ failure, peripheral neuropathy, and foot-specific diabetic complications such as peripheral vascular disease, foot ulcers, infection, and Charcot foot arthropathy. Those with poorly controlled diabetes are also more likely to develop complications after foot surgery or fracture treatment than those without diabetes (5–14).

The American Diabetes Association recognizes that diabetes can be diagnosed with a HbA1c level of >6.5%. Evaluation of HbA1c and diabetes control is determined by the glycemic levels during the previous 3 months, with a target HbA1c level of 7.0% (15,16).

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The goal of the present investigation was to evaluate a large cohort of patients with diabetes who had undergone elective foot and ankle surgery to determine whether glycemic control and the presence of peripheral neuropathy and other comorbid conditions were predictors of 30-day postoperative complications. Our hypothesis was that patients with poor glycemic control, peripheral neuropathy, and a greater number of comorbid conditions would be more likely to experience complications after elective foot and ankle surgery in patients with diabetes.

Patients and Methods

We undertook a large retrospective examination of persons with diabetes who had undergone elective foot and ankle surgery. After institutional review board approval from the Department of Veterans Affairs, we used administrative and clinical data from the Department of Veterans Affairs. We identified all patients with diabetes who had undergone elective foot or ankle surgery during a 6-year period from January 1, 2008 to December 31, 2013. The patients were identified for inclusion using the Current Procedural Terminology codes specific to foot and ankle surgery (Supplemental Table S1) and an International Classification of Diseases, ninth revision (ICD-9) diagnosis of diabetes (ICD-9 codes 250.00 to 250.93). Patients were included if they had had a HbA1c level obtained in accordance with the published guidelines from the American Diabetes Associations (i.e., within 1 year of surgery if the value was <6.5%, within 6 months of surgery if the value was 6.6% to 7%, and within 3 months of surgery if the value was >7%) (16). The patients were excluded if the surgery was emergent or if they had had an identified diabetic foot ulcer or foot infection within 1 year before the index surgery. The patients were also excluded if they had a comorbid diagnosis that could affect the accuracy of the HbA1c values (i.e., sickle cell anemia, iron deficiency anemia, blood transfusion within 1 year, and dialysis within 3 months of surgery; Table 1).

A power analysis was conducted before data extraction. Preliminary data extraction by our research team showed that approximately 8000 elective foot and ankle procedures are performed each year at Veterans Affairs facilities. We planned to use 4 years of data and calculated 32,000 assumed procedures would be identified during the period. We assumed a baseline complication rate of 3% from previously published data (4,14). We expected that those with an HbA1c >7% would have a complication rate of 18% and an α error of 0.05; the power would equal 0.99. However, once we began the study and applied the exclusion criteria, we only identified approximately 21,000 patients with complete data. Thus, the data collection was extended from a 4- to a 6-year period, and we reassessed power using an $n = 21,000$ and identified an effect size of 1.64. This revised sample provided us with sufficient power to detect significant differences (power = 0.99).

Complications occurring during the 30-day postoperative period were identified using ICD-9 codes (Supplemental Table S2). The identification was done through a detailed ICD-9 code search; however, no medical record review was completed. The complications were grouped into 4 categories: infection (including both superficial and deep infections), wound healing, mechanical failure (defined as hardware failure, nonunion, or malunion), and cardiovascular/pulmonary. The demographic data and independent variables included gender, age, race, marital status, body mass index, and comorbid conditions. The presence of peripheral neuropathy was included if the patient had a diagnosis code for this condition recorded in the medical record before surgery. In addition, a Charlson comorbidity index score was calculated for each case. The comorbid conditions included myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, dementia, chronic pulmonary disease, rheumatologic disease, peptic ulcer disease, mild liver disease, hemiplegia or paraplegia, renal disease, any malignancy, moderate liver disease, and acquired immunodeficiency syndrome or human immunodeficiency virus.

Table 1
Inclusion and exclusion criteria

Criteria
Inclusion
Diagnosis of diabetes
Documented hemoglobin A1c value (≤ 1 yr of surgery if <6.5%, within 6 mo if 6.6% to 7%, and ≤ 3 mo if >7%)
Elective surgery of the foot and/or ankle
Exclusion
History of diabetic foot ulceration ≤ 1 yr of surgery
History of sickle cell anemia
History of iron deficiency anemia
History of blood transfusion ≤ 1 yr of surgery
History of dialysis within 3 mo of surgery
Emergent surgery of the foot or ankle

Statistical Analysis

The results were considered statistically significant at a p value of $\leq .05$. The categorical variables were described using frequencies and proportions, and continuous variables were described using the mean \pm standard deviation. Chi-square analysis was used to determine whether an association was present between the demographic variables and the occurrence of complications after surgery. Student's t test was used to compare the mean HbA1c values between patients with and without complications. Logistic regression analysis was used to control for covariates in determining the association between HbA1c values and the odds of developing a complication within 30 days of surgery. The correlation between the HbA1c level and peripheral neuropathy was also calculated to determine how strongly these variables were related to each other and to the surgical outcomes. Furthermore, logistic regression analysis with a 3-way interaction among HbA1c, the number of comorbid conditions, and the presence of peripheral neuropathy was used to examine the interaction and contribution of all 3 factors on the odds of developing a complication.

Results

A total of 21,854 patients with diabetes who met the study eligibility criteria had undergone elective foot or ankle surgery in Veterans Affairs medical facilities during a 5-year period. The cohort consisted of 84% male patients, with average age of 50 to 64 years, and 64% were white. The overall complication rate was 3.2%. The most commonly performed elective procedures included hammertoe and bunionectomy (23% and 22.7%, respectively), and the greatest complication rates were for procedures of much lower frequency, including sesamoidectomy ($n = 148$; complication rate of 10.8%) and flatfoot reconstruction ($n = 293$; complication rate of 9.9%). A total of 296 surgical site infections (42.3%; which included both superficial and deep infections), 233 mechanical failures (33.4%), 129 cardiovascular/pulmonary occurrences (18.4%), and 41 wound healing complications (5.8%) occurred (Fig. 1). From the 21,854 patients included, 75% had no comorbid conditions other than diabetes, 18% had 1 other comorbid condition, 5% had 2 to 3 other comorbid conditions, and <1% had >4 comorbid conditions.

The HbA1c values ranged from 4.5% to 10%. On average, the HbA1c had been taken 30.8 ± 65.9 days before surgery. The mean HbA1c value for the patients with any complication (6.29%) was significantly greater than for those who had not experienced a complication (6.11%) within 30 days ($p < .001$). The HbA1c was significantly greater for those with infection compared with those without infections (6.41% versus 6.11%; $p < .001$). No significant differences were found in the HbA1c values in the other complication groups compared with those for the patients without complications, including wound healing ($p < .47$), mechanical failure ($p < .14$), and cardiovascular/pulmonary ($p < .69$) groups. The risk of the development of any complication or the development of a wound infection increased with increasing HbA1c values (Fig. 2). Logistic regression analysis revealed that each 1% increase in HbA1c increased the odds of a complication developing by 5%.

Male gender, white race, number of comorbid conditions, elevated HbA1c value, and a diagnosis of peripheral neuropathy were all

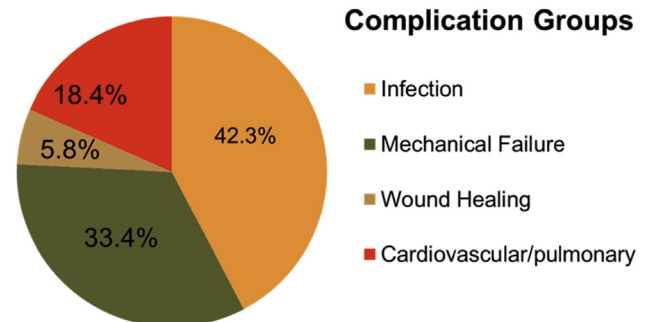


Fig. 1. Distribution of complications encountered ($N = 21,854$).

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