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Is Reoperation Higher Than Expected after Below-the-knee Amputation? A Single-center Evaluation of Factors Associated with Reoperation at 1 Year

Liam H. Wong BS, Erik Woelber MD, Alden Wyland BS, Jordan Arakawa BA, Kenneth R. Gundle MD, Zachary M. Working MD, James E. Meeker MD

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Abstract

Background Below-the-knee amputation (BKA) is relatively common among patients with vascular disease, infection, trauma, or neoplastic disease. Many BKAs are performed in patients with incompletely treated medical comorbidities, and some are performed in patients with acute high-energy trauma or crush injuries, malignant neoplasm undergoing time-sensitive limb removal, and diabetes with active infection or sepsis. Consequently, revision is common. Prior studies of outcomes after BKA, including several based on the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) database, have follow-up periods that do not cover the entire at-risk period.

Questions/purposes (1) What is the survivorship free from unplanned reoperation within 1 year of BKA? (2) What patient characteristics are associated with reoperation within 1 year of BKA?

Methods We retrospectively studied all BKAs performed by the orthopaedic surgery service at a Level 1 trauma center from 2008 to 2018, as identified by Current Procedural Terminology (CPT) codes. Twenty-eight percent (38 of 138) underwent amputation as treatment for traumatic injury, 57% (79 of 138) for infection, and 15% (21 of 138) for malignancy. A total of 17% (23 of 138) had a final follow-up encounter before the 1-year study minimum, without differential loss to follow-up by surgical indication ($p = 0.43$) or hemoglobin A1c ($p = 0.71$). Median (range) follow-up was 570 days (6 to 3375). The primary outcome was survivorship from unplanned reoperation within 1 year of BKA index surgery or last planned reoperation, as determined by Kaplan-Meier estimation. Secondarily, we identified patient characteristics independently associated with reoperation within 1 year of BKA. Collected data included age, indication, BMI, diabetes, hemoglobin A1c level, closure method, and substance use. Unplanned reoperation was defined as irrigation and débridement, stump revision, or revision to a higher-level amputation; this did not include planned reoperations for BKAs closed in a staged manner. Factors associated with reoperation were determined using multivariate logistic regression analyses. All endpoints and variables related to patients and their surgical procedures were

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Each author certifies that his institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

L. H. Wong, A. Wyland, J. Arakawa, School of Medicine, Oregon Health and Science University, Portland, OR, USA

E. Woelber, K. R. Gundle, Z. M. Working, J. M. Meeker, Department of Orthopaedics and Rehabilitation, Oregon Health and Science University, Portland, OR, USA

K. R. Gundle, Operative Care Division, Portland VA Medical Center, Portland, OR, USA

L. H. Wong ✉, School of Medicine, Oregon Health and Science University, 2730 S.W. Moody Avenue Portland, OR 97201 USA, Email: wonli@ohsu.edu

Wolters Kluwer

extracted from electronic medical records by someone other than the operating surgeon.

Results Using Kaplan-Meier estimation, 38% of patients (95% confidence interval 29 to 46) who underwent BKA had an unplanned reoperation within 1 year of their index surgery. Twelve percent of patients (95% CI 7 to 17) who underwent BKA did not reach 30 days with the limb survivorship free from unplanned reoperation. The median (range) time between the initial surgery and reoperation was 54 days (6 to 315). After controlling for potential confounding variables like age, gender, platelet count, albumin, and the reason for undergoing amputation, a hemoglobin A1c level greater than 8.1% (relative to A1c ≤ 8.1%) was the only variable independently associated with increased odds of reoperation (odds ratio 4.6 [95% CI 1.3 to 18.1]; $p = 0.02$).

Conclusion BKA carries a higher risk for reoperation than currently reported in studies that use 30-day postoperative follow-up periods. Clinicians should critically assess whether BKA is necessary, especially in patients with uncontrolled diabetes assessed by hyperglycemia. Before planned BKA, patients should have documented glycemic control to minimize the odds of reoperation. Because many of this study's limitations were due to its retrospective single center design, we recommend that future work cover a clinically appropriate surveillance period using a larger cohort such as a national database and/or employ a prospective design.

Level of Evidence Level III, therapeutic study.

Introduction

Below-the-knee amputation (BKA) is relatively common among patients with vascular disease, infection, trauma, or neoplastic disease. Many BKAs are performed in patients with incompletely treated medical comorbidities, and some are performed in patients with acute high-energy trauma or crush injuries, malignant neoplasm undergoing time-sensitive limb removal, and diabetes with active infection or sepsis. Consequently, revision is common.

Prior studies investigating these issues have often used a follow-up period of 30 days [4, 7, 18]. Some of these studies use national databases such as the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) database, reporting reoperation proportions between 9% and 16% [4, 7]. Hospital-centered database studies have also found relatively low reoperation proportions using this short-term follow-up period [18]. However, using a 30-day reporting window may significantly underestimate the number of patients who go on to repeat procedures [1, 20]. A case series using institutional data found the average time to conversion to above-the-knee amputation was 77 days, well outside the 30-day surveillance period [3]. Most prior studies have evaluated reoperation proportions for BKAs performed by non-orthopaedic surgeons [4, 7, 18]; furthermore, studies that have used a 1-year postoperative observation period have focused on outcomes after dysvascular lower-limb amputations [3, 9, 13, 21]. This is notable because orthopaedic surgeons perform BKAs on a different patient population than general or vascular surgeons, including a higher proportion of trauma and tumor patients, and fewer patients with peripheral arterial disease.

We therefore used retrospectively collected data from our Level 1 trauma center to ask: (1) What is the survivorship free from unplanned reoperation within 1 year of BKA? (2) What patient characteristics are associated with reoperation within 1 year of BKA?

Patients and Methods

Study Design and Setting

We conducted an institutional review board-approved, retrospective review of all BKAs performed by the orthopaedic surgery service at a Level 1, academic trauma center from January 1, 2008 to December 31, 2018.

Participants

From January 1, 2008 to December 31, 2018, 138 patients undergoing BKA were retrospectively identified using CPT codes for BKA (27880, 27881, and 27882). Twenty-eight percent (38) underwent amputation as treatment for traumatic injury, 57% (79) for infection, and 15% (21) for malignancy (Table 1). A total of 17% (23) had a final follow-up encounter before the 1-year study minimum, without differential loss to follow-up by surgical indication ($p = 0.43$) or hemoglobin A1c ($p = 0.71$). Median (range) follow-up was 570 days (6 to 3375). Four percent of patients (6 of 138) had staple closure with the remainder undergoing suture closure. The most common indications for reoperation included infection (41%; 20 of 49 patients), wound dehiscence (35%; 17 of 49 patients), and wound necrosis (8%; 4 of 49 patients) (Table 2).

Description of Experiment, Treatment, or Surgery

BKAs were performed in either a single operation or in a staged fashion. The final planned BKA closure was designated as the definitive BKA date for survival analysis. Postoperatively, limbs were observed for several days while patients underwent physical therapy. Patients returned to the clinic for a postoperative appointment 2 weeks after surgery, with follow-up at further intervals directed by their clinical course. The median (range) length

Table 1. Patient major variables

Variable	Overall (n = 138)
Age in years, mean ± SD	51 ± 17
Men, % (n)	68 (94)
BMI in kg/m^2, mean ± SD	31 ± 9
Psychiatric disorder, % (n)	20 (27)
Diabetes, % (n)	28 (39)
Chronic obstructive pulmonary disease, % (n)	11 (15)
Chronic kidney disease, % (n)	9 (12)
Cardiac issue (such as coronary artery disease, aortic stenosis, prior myocardial infarction), % (n)	18 (25)
Indication, % (n)	
Infection	57 (79)
Trauma	28 (38)
Tumor	15 (21)
American Society of Anesthesiologists class, mean ± SD	3 ± 1
Albumin level in g/dL, mean ± SD	3 ± 1
Unplanned or emergent surgery, % (n)	26 (36)
Suture closure, % (n)	96 (132)

of stay after the index surgery was 7 days (2 to 78). Thirty-eight percent (52 of 138) of patients who underwent BKA were discharged to a skilled nursing facility and 60% (83 of 138) were discharged home.

Variables, Outcome Measures, Data Sources, and Bias

The primary outcome was survivorship free from unplanned reoperation within 1 year of BKA index surgery or last planned reoperation, as determined by Kaplan-Meier estimation. Unplanned reoperation was defined as irrigation and débridement, stump revision, or revision to a higher-level amputation; this did not include planned reoperations for BKAs performed in a staged manner. The 1-year postoperative observation window began at index surgery or last planned reoperation. For patients who had more than one unplanned reoperation, we included only the first reoperation. Repeat procedures within 1 year postoperatively that were not performed on the ipsilateral lower extremity did not qualify as reoperations. All endpoints were extracted from electronic medical records by someone other than the operating surgeon.

Table 2. Reoperations: indications and surgeries performed

Outcome measure	Overall (n = 49)
Indication for reoperation	
Infection, % (n)	41 (20)
Wound dehiscence, % (n)	35 (17)
Wound necrosis, % (n)	8 (4)
Neuroma, % (n)	4 (2)
Heterotrophic ossification, % (n)	6 (3)
Other indication, % (n)	6 (3)
Type of reoperation	
Irrigation and débridement, % (n)	65 (32)
Irrigation and débridement with bone shortening, % (n)	25 (12)
Irrigation and débridement with hardware removal, % (n)	4 (2)
Revision to higher level, % (n)	6 (3)

Our secondary study outcome was identification of patient characteristics independently associated with reoperation within 1 year of BKA, as determined by multivariate logistic regression analyses. All endpoints and variables related to patients and their surgical procedures were extracted from electronic medical records by someone other than the operating surgeon (Table 3). The index surgery was determined to be unplanned based on individual surgical indications according to the preoperative and operative notes; however, in ambiguous cases, BKAs were classified as unplanned if the time from admission to amputation was less than 72 hours and had not been scheduled in advance in the clinic or with a primary care physician. Hemoglobin A1c values were taken within 3 months before index surgery. Of 66 patients with documented eligible A1c values, two (3%) received a blood transfusion before hemoglobin A1c quantification; these patients underwent BKA due to trauma, and both had normal A1c values documented both before and after transfusion.

Statistical Analysis

All statistical analyses were performed using R version 3.6.2 (R Foundation, Vienna, Austria).

Reoperation-free limb survivorship was determined using Kaplan-Meier estimations employing the package survival, accounting for patients lost to follow-up using right-censoring. Differential loss to follow-up was analyzed using the Fisher's exact test.

To determine factors associated with reoperation, we performed a purposeful selection of variables that had a known or suspected association with reoperation after BKA [6, 12]. Loess curves were used to determine whether continuous variables were transformed into categorical variables. This included hemoglobin A1c level. A log rank test was performed using the maxstat package to optimize the separation of A1c into two groups using their association with reoperation as an outcome; this yielded a

Table 3. Variables collected during record review

Category	Variables collected
Physical characteristics	Age, gender, BMI, American Society of Anesthesiologists class
Comorbidities	Diabetes, dementia, bleeding disorder, chronic obstructive pulmonary disease, chronic kidney disease, renal insufficiency, cardiac issue, hepatic cirrhosis, preoperative ventilator use
Presurgical laboratory and examination values	Albumin level, white blood cell count, hematocrit level, platelet count, creatinine level, most recent hemoglobin A1c level, blood glucose level, erythrocyte sedimentation rate, C-reactive protein, respiratory rate, heart rate, and temperature before surgery
Substance use	Smoking, methamphetamine or intravenous drug use, alcohol use
Social factors	Homelessness, transfer from an outside facility, discharge location
Surgical factors	Indication (tumor, infection, trauma), planned versus unplanned procedure, procedure length, estimated blood loss, tourniquet time, closure type (suture versus staples)
Outcomes and hospital factors	Reoperation within 1 year, time to reoperation, readmission within 1 year, length of stay, death, change in hematocrit level from preoperative to postoperative

calculated cutoff of 8.1%, creating a categorical variable of patients with a hemoglobin A1c level > 8.1% and ≤ 8.1%. Univariate logistic regression analyses were performed by using variables extracted from the patients' records (including age, indication, diabetes, substance use, platelets, and BMI) and advancing those that were associated with a p value < 0.10 to a multivariable model (see Table; Supplemental Digital Content, http://links.lww.com/CORR/A414). The following factors were advanced and considered in a backwards stepwise multivariable logistic regression model using Akaike information criteria for elimination [2]: BMI (odds ratio 1.05 [95% confidence interval 1.01 to 1.09]; p = 0.02), erythrocyte sedimentation rate (OR 0.98 [95% CI 0.96 to 1.00]; p = 0.05), trauma as an indication for surgery (OR 1.97 relative to infection as an indication [95% CI 0.88 to 4.42]; p = 0.098), and hemoglobin A1c level greater than 8.1% (OR 4.4 [95% CI 1.28 to 17.01]; p = 0.02). Akaike information criteria uses both goodness of fit and a penalty for additional predictors to yield a parsimonious model [2].

To assess for collinearity, a variance inflation factor of 5 was used, and variables were eliminated based on their clinical utility and/or by assessing other features of the variable, such as reliability in reporting and lack of data. The backwards stepwise logistic regression analysis yielded a multivariate model with hemoglobin A1c level, erythrocyte sedimentation rate, and surgical indication as predictor variables. The erythrocyte sedimentation rate was eliminated because of multicollinearity with the hemoglobin A1c level (variance inflation factor = 8.0) and lack of data (58%). Repeating the regression yielded a final model with BMI (OR 1.05 [95% CI 0.99 to 1.11]; p = 0.14) and hemoglobin A1c level (OR 4.60 [95% CI 1.3 to 18.1]; p = 0.02) as predictors, although only the hemoglobin A1c level reached the p < 0.05 threshold for significance. Survival analysis was performed for this variable. We then repeated this survival analysis using a restricted subgroup of diabetic patients [12].

All analyses were preplanned. All Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis checklist elements were addressed [16].

Results

Survivorship from Unplanned Reoperation Within 1 Year of BKA

Using Kaplan-Meier estimations, 38% of patients (95% CI 29 to 46) who underwent BKA had an unplanned reoperation within 1 year of their index surgery. Twelve percent of patients (95% CI 7 to 17) who underwent BKA did not reach 30 days of limb survivorship. According to Kaplan-Meier estimation, the proportion of unplanned reoperations at 1 year was 47% (95% CI 28 to 61) for patients undergoing BKA due to trauma, 32% (95% CI 20 to 42) for infection, and 44% (95% CI 17 to 62) for malignancy. The median (range) interval between the initial surgery and reoperation was 54 days (6 to 315). Six percent (8 of 138) of patients died within 1 year, before having an unplanned reoperation; six of those patients underwent BKA for infection, and one each for trauma and malignancy. Of the six patients who underwent staple closure, 50% (95% CI 23 to 100) underwent a reoperation within 50 days by Kaplan-Meier estimates. All 28 patients who underwent planned staged operations had an incisional vacuum-assisted dressing placed between surgeries; 44% of those patients (95% CI 22 to 60) did not reach 1 year of limb survivorship free from an unplanned reoperation, which was similar to the limb survivorship in the unrestricted cohort. Seventy-nine percent (22 of 28) of patients who underwent staged operations had an incisional vacuum-assisted dressing at final closure; by Kaplan-Meier estimation, 56% of these patients (95% CI 29 to 73) underwent an unplanned reoperation. Additionally, 42% (95% CI 30 to 59) of the patients who underwent BKA were readmitted within 1 year. Only 4.4% (95% CI 0.5 to 8.1) of patients in our study underwent a revision to above-the-knee amputation based on Kaplan-Meier estimation.

Factors Independently Associated with Reoperation After BKA

After accounting for potential confounding variables like age, platelet count, and BMI, only a hemoglobin A1c level greater than 8.1% (relative to A1c $\leq$ 8.1%) was independently associated with an increased risk of reoperation after BKA (OR 4.6 [95% CI 1.3 to 18.1]; $p = 0.02$). In the 66 patients for whom data on A1c was available, the mean A1c was 6.8 $\pm$ 1.8%). In the subset of patients who were diabetic ($n = 39$), the mean hemoglobin A1c level was 7.8 $\pm$ 1.8%. Survival analysis demonstrated that patients with a hemoglobin A1c level greater than 8.1% had greater odds of undergoing reoperation than those with a hemoglobin A1c level below this cutoff both in the entire cohort ($p = 0.004$) (Fig. 2A) and in the subgroup of diabetic patients ($p = 0.01$) (Fig. 2B). Seventy-five percent (95% CI 23 to 92) of patients with hemoglobin A1c values greater than 8.1% did not reach 1-year limb survivorship free from an unplanned reoperation, according to Kaplan-Meier estimates.

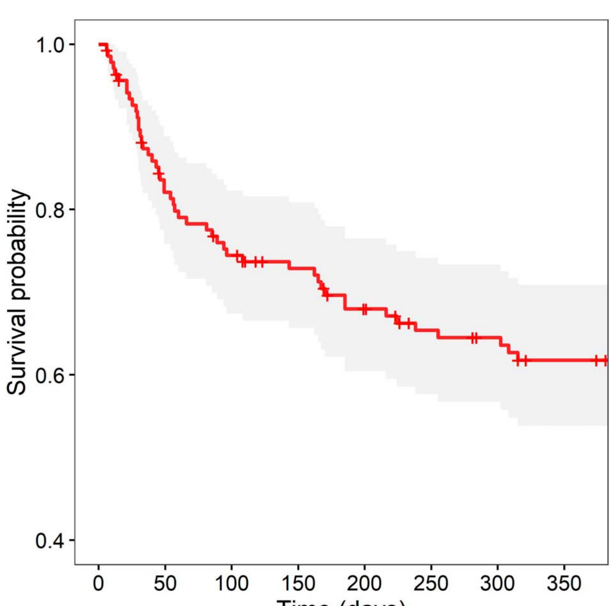

Fig. 1 This figure shows the Kaplan-Meier survival curve for reoperation after BKA.

Discussion

Background and Rationale

Patients undergoing BKA are at high risk for complications requiring reoperation. Much of the evidence describing BKA reoperation proportions and associated risk factors for reoperation has used a 30-day surveillance period or is limited to operations performed by vascular or general surgeons. We investigated reoperation during a 1-year postoperative window after BKA and report 38% of patients had an unplanned reoperation using Kaplan-Meier estimation. In determining factors associated with reoperation, we found that patients with uncontrolled diabetes as assessed by hyperglycemia are even more likely to undergo reoperation within 1 year (75%). Twelve percent of patients who underwent BKA did not reach 30-day survival free from reoperation, demonstrating that although our results at 30 days are similar to prior studies, most reoperations likely occur outside of this 30-day window.

Limitations

We note multiple limitations to our study. Our single-center study design resulted in a small sample size, which was a notable limitation for several reasons. First, when identifying potential predictors using univariate analysis, we risked identifying spurious associations due to the high number of analyses performed (31) relative to our limited population size (138 patients). Consequently, the identification of hemoglobin A1c as a potential predictor variable may have been due to chance alone. However, although this initial screen may have misidentified potential predictors, these variables were then subject to later elimination during multiple regression modeling. This method helped identify a factor associated with reoperation that is consistent with other lower extremity studies. Second, several variables were too infrequent to detect a statistically significant difference in survivability. For example, we observed a relatively high proportion of early reoperation in patients who underwent staple closure, with 50% undergoing a reoperation within 50 days. However, only six patients had staple closure, leaving our study inadequately powered to characterize this association. Third, our small sample size risked sparse-data bias, creating misleading effect sizes due to analysis of uncommon events. Evidence for this is observed in the odds ratio and large confidence interval for the association of hemoglobin A1c with reoperation. However, we observed that hemoglobin A1c affected reoperation survivability for both individuals with and without diabetes, and our finding is consistent with other lower extremity studies that identify elevated hemoglobin A1c levels as a factor independently associated with complications [22].

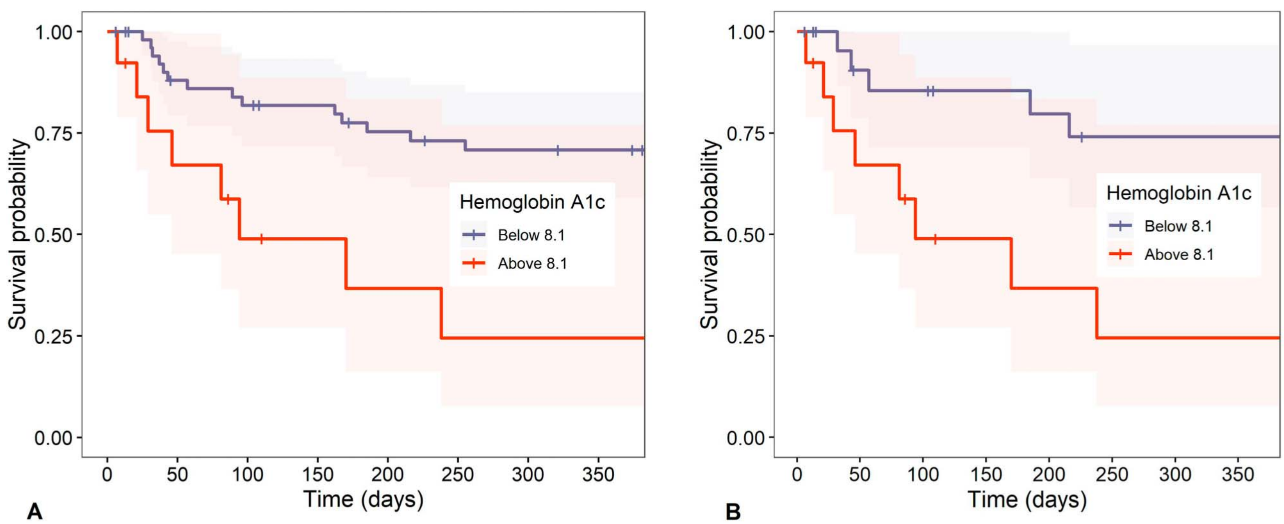

Fig. 2 A-B These graphs show unplanned reoperations in (**A**) all patients with known hemoglobin A1c levels based on a hemoglobin A1c cutoff of 8.1% (p = 0.004) and (**B**) the restricted subgroup of patients with diabetes (p = 0.01).

Other limitations included study fragility: due to low sample size or data missingness, a low number of events may quickly skew data, leading to spurious conclusions. This is more common in retrospective studies like ours where data collection is limited by the availability of data at the time of the index surgery. However, most of the variables in our study had less than 5% missing data and there was a perioperative hemoglobin A1c value for every patient with diabetes.

Given its retrospective design, our study is prone to transfer bias: patients with insufficiently long or incomplete follow-up could affect our results, particularly if there were differential follow-up between groups. However, the Kaplan Meier method censors patients with incomplete follow-up by design. Furthermore, only 17% (23 of 138) of patients were lost to follow-up or had died within 1 year, and there was no differential loss to follow-up by surgical indication or hemoglobin A1c.

Because this study was conducted at a single Level 1 academic center, there may be limited external validity due to the specific patient populations seen at academic centers. However, numerous orthopaedic surgeons employing a variety of surgical techniques participated in patient care during the 10-year study period, which increases the generalizability of our findings. There is a logical—though unproven—difference in the patient populations undergoing BKA by orthopaedic and general/vascular surgeons, particularly with regard to the proportion of patients with profound macrovascular disease. Even though a specific focus on orthopaedic patients makes this study more relevant to orthopaedic surgeons, we acknowledge the exclusion of many patients at our institution who underwent BKA with general surgery teams or for vascular disease, whose reoperation proportions over a 1-year period may demonstrate interesting, novel, or clinically relevant findings that now elude our identification.

Even with these limitations, our study provides insight into real variabilities in outcomes within an academic center and demonstrates the need for further research in this area. Because many of this study's limitations were due to its retrospective single center design, we recommend that future work use a larger cohort such as a national database and/or employ a prospective design over a clinically meaningful surveillance period.

Survivorship Free from Unplanned Reoperation Within 1 Year of BKA

In our cohort of orthopaedic patients undergoing BKA, 38% underwent an unplanned reoperation within 1 year of their index surgery using Kaplan-Meier estimation (Fig 1). The proportion of patients undergoing reoperation following BKA was greater than proportions reported in prior studies (Table 4), which include both hospital-centered and national database studies [4, 7, 18], as well as studies of dysvascular lower-limb amputations [3, 18, 21]. Interestingly, our reoperation proportion within 30 days (12%) was similar to these studies (7%-16%) [4, 7, 18]. Additionally, one study of dysvascular lower-limb amputations demonstrated that 23% of transtibial amputations underwent one or more revisions to the same or higher level within 1 year, which is more similar to our results [9]. Furthermore, our reoperation proportion is more consistent with 2-year rehospitalization proportions in

Table 4. Comparison of reoperation proportions in literature

Study	Number of patients	Length of follow-up	Reoperation proportion
This study	138	1 year	38%
This study	138	30 days	12%
Ciufo et al. [7]	4631	30 days	9.6%
Belmont et al. [4]	2911	30 days	15.6%
Phair et al. [18]	486	30 days	6.6%
Aulivola et al. [3]	704	Unclear follow-up period	13.2%
Wooster et al. [21]	592 (includes all lower extremity amputations)	1 year	26.2%

severe trauma patients that underwent lower-extremity amputation (30%-34%) [5, 14]. This suggests that studies of amputations using the traditional 30-day observation window may report results similar to ours if their surveillance periods were extended to a more clinically relevant 1-year period. The concern that using 30-day postoperative windows underestimates reoperation proportions has been expressed in both general orthopaedic surgeries [1] and orthopaedic trauma surgeries [20]. Surgeons and patients should be aware that the proportion of patients who undergo reoperation following BKA are underestimated in current evidence.

Factors Independently Associated with Reoperation After BKA

Of all the patient factors we evaluated, only an elevated hemoglobin A1c level was associated with an increased likelihood of reoperation, whether or not a preoperative diagnosis of diabetes was present. This result is similar to other foot and ankle studies where patients with uncontrolled diabetes with hemoglobin A1c level ≥ 8% had a greater probability of developing a surgical site infection in both univariate (OR 2.51) and multivariate (OR 2.75) regression analysis, but diabetes alone was not an independent risk factor for infection (OR 0.49) [22]. Other studies have found that patients with uncontrolled diabetes exhibit greater odds of surgical complications and revisions after degenerative lumbar spine surgery [11], neurosurgery [8], and total joint arthroplasty [15]. In a prior study using a large database, BKA reoperation during the 30-day follow-up period was associated with preoperative ventilator use (OR 2.38), bleeding disorder (OR 1.30), recent smoking (OR 1.34), and transfer from an outside facility (OR 1.28) [7]. These variables are most relevant for this short 30-day postoperative follow-up period, and, due to our relatively small sample size, we were not able to identify similar associations. Instead, our results highlight a different association between reoperation and uncontrolled diabetes as demonstrated by hyperglycemia. This suggests that other patient characteristics may be associated with BKA reoperation if given a longer postoperative observation window. Our results align with previous findings in which poorly controlled diabetes was more predictive of complications or reoperations than diabetes alone. When analyzed without thresholds for A1c, diabetes has been associated with increased odds to undergo irrigation and débridement (OR 2.0) and amputation (OR 7.4) after ankle fractures [19], and is also associated with reoperation after fracture care (OR 5.5) [10] and total hip arthroplasty (OR 1.5 for reoperation due to deep infection) [17].

Conclusion

BKA carries a higher risk for reoperation than currently reported in studies that use 30-day postoperative follow-up periods. This risk is even greater in patients with poorly controlled diabetes assessed by hyperglycemia. Clinicians should critically assess whether BKA is necessary, especially in patients with uncontrolled diabetes. Prior to planned BKA, patients should have documented glycemic control to minimize the risk of reoperation. To further investigate factors associated with reoperation after BKA, we recommend that future work use a larger multicenter cohort and employ a prospective design covering a clinically appropriate surveillance period.

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