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Risk factors for reoperation, readmission, and early complications after below knee amputation

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ABSTRACT

Background: Many patients undergoing below knee amputations (BKA) return for subsequent unplanned operations, hospital readmission, or postoperative complications. This unplanned medical management negatively impacts both patient outcomes and our healthcare system. This study primarily investigates the risk factors for unplanned reoperation following BKA.

Methods: Below knee amputations from the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) database from the years 2012–2014 were identified by CPT code 27880 for amputation through the tibia and fibula. Our query identified 4631 BKA cases, including 30 day complications. Multivariate logistic regression modeling was performed on several patient demographic and disease factors to assess for independent predictors of unplanned reoperation. Secondary outcomes of unplanned and related readmissions (related to the procedure), major complications, minor complications, and mortality were also included in the analysis.

Results: Of 4631 BKAs identified, 9.63% (446/4631) underwent unplanned reoperations and 8.75% (405/4631) had unplanned and related readmissions. Major complications were experienced by 12.8% (593/4631) and minor complications by 8.7% (401/4631). Thirty day mortality rate was 5.14% (238/4631). The most common procedures for unplanned operations were thigh amputations (128/446, 28.7%), debridement/secondary closure (114/446, 25.6%), and revision leg amputations (46/446, 10.32%). Factors associated with an increased risk of unplanned reoperation included patients transferred from another facility (Adjusted Odds Ratio [AOR] = 1.28; p = .04), recent smokers (AOR = 1.34; p = .02), bleeding disorder (AOR = 1.30; p = .02), and preoperative ventilator use (AOR = 2.38; p = .01).

Conclusion: Patients that were ongoing/recent smokers, had diagnosed bleeding disorders, required preoperative ventilator use, or were transferred in from another facility were associated with the highest risks of reoperation following BKA. This patient population experiences high rates of reoperation, readmission, complication, and mortality.

Introduction

While below knee amputation (BKA) rates are falling, these remain a common life-saving and palliative procedure [1]. In the U.S., the age adjusted rate of diagnosed diabetes increased by 137% from 1990 through 2009 and stands at 7% of the population as of 2014 [2]. Despite upstream interventions, 0.9% of all diabetics in the United States eventually require a BKA [1]. Peripheral arterial disease as a whole remains significant as well, affecting 12–20% of Americans over 65 years old [3]. Historically, amputations were viewed as a failure in the management of these diseases and attracted minimal scrutiny because of their last resort association. Due to advances in prosthetics and rehabilitation, the effectiveness of BKA is being investigated more closely as well as associated risk factors, complications, and mortality [4–8]. BKA efficacy is also becoming a priority given the changing landscape concerning reimbursement and a growing emphasis on reducing expenditures.

Despite improvements in BKA technique and identification of potential hazards, the number of BKA patients with complications requiring subsequent OR visits and readmission is notable [9]. Analysis of this population is critical because these patients face increased risk of mortality and continued medical care following amputation, and also place a great economic burden on the healthcare system due to the multitude of procedures following amputation failure [5], [10,11]. To the best of our knowledge, there is limited literature with large cohorts that investigates risk factors associated with negative outcomes after BKA, particularly reoperation.

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The present study draws on a cohort of greater than 4600 patients undergoing BKAs from the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) database between 2012 and 2014. The purpose of this study is to investigate the association of patient demographics, comorbidities, and other surgical factors with short term unplanned reoperations and readmissions that were related to the amputation, with goals of predicting and reducing the need for unexpected medical care.

Materials and methods

Data source

The ACS NSQIP data from January 1, 2012 to December 31, 2014 was used, with Current Procedural Terminology code 27880 (Amputation, leg, through tibia and fibula) to identify cases of BKA. Trained Surgical Clinical Reviewers abstract data from patient charts at over 650 participating hospitals, which are then compiled to produce the NSQIP database. The data collected encompass over 150 variables for operative patients, including preoperative risk factors, intraoperative variables, and 30 days postoperative outcomes such as mortality, complications, and readmission [12,13]. Cases before 2012 were excluded given that variable of interest "unplanned reoperations" was introduced in 2011 and "unplanned, related readmissions" was introduced in 2012. Exclusion criteria from the database can be reviewed in the user guide, but include age less than 18 years, returns to the operating room as a complication of another case, and trauma [12].

Patient population

We identified 4631 BKA cases from January 1, 2012 to December 31, 2014. Patient demographics, surgical factors, and comorbidities obtained from the database are outlined in Table 1 and organized

Table 1
Demographics and comorbidities of below knee amputation (BKA) patients from the 2012–2014 National Surgical Quality Improvement Program (NSQIP) database.

	No Reoperations N (%)	1+ Reoperations N (%)	Total N (%)	p-value
N	4185	446	4,631	
Age in years				0.26
Mean (+/- SD)	64.6 (13.3)	63.9 (12.9)	64.5 (13.3)	
<50	515 (12.31)	52 (11.66)	567 (12.24)	
50 to 59	955 (22.82)	121 (27.13)	1,076 (23.23)	
60 to 69	1191 (28.46)	129 (28.92)	1,320 (28.50)	
70 to 79	903 (21.58)	85 (19.06)	988 (21.33)	
>79	621 (14.84)	59 (13.23)	680 (14.68)	
Male	2779 (66.40)	291 (65.25)	3,070 (66.29)	0.62
Race & ethnicity				0.07
White, non-Hispanic	2344 (56.01)	267 (59.87)	2,611 (56.38)	
Black, non-Hispanic	1028 (24.56)	95 (21.30)	1,123 (24.25)	
Other, non-Hispanic	139 (3.32)	17 (3.81)	156 (3.37)	
Hispanic	431 (10.30)	33 (7.40)	464 (10.02)	
Unknown/Missing details	243 (5.81)	34 (7.62)	277 (5.98)	
Admission from home	948 (22.65)	124 (27.80)	1,072 (23.15)	0.03
Operative time				0.003
<60 min.	1589 (37.97)	203 (45.52)	1,792 (38.70)	
>=60 & <90	1438 (34.36)	146 (32.74)	1,584 (34.20)	
>=90	1158 (27.67)	97 (21.75)	1,255 (27.10)	
Emergency case	389 (9.30)	56 (12.56)	445 (9.61)	0.03
Wound classification				0.34
Clean	2847 (68.03)	299 (67.04)	3,146 (67.93)	
Clean/Contaminated	303 (7.24)	24 (5.38)	327 (7.06)	
Contaminated	338 (8.08)	40 (8.97)	378 (8.16)	
Dirty/Infected	697 (16.65)	83 (18.61)	780 (16.84)	
ASA Class				0.12
ASA 1/2	155 (3.70)	11 (2.47)	166 (3.58)	
ASA 3	2415 (57.71)	242 (54.26)	2,657 (57.37)	
ASA 4/5	1607 (38.40)	193 (43.27)	1,800 (38.87)	
BMI				0.95
Underweight (<18.5)	169 (4.04)	18 (4.04)	187 (4.04)	
Normal (>=18.5 & <25.0)	1212 (28.96)	136 (30.49)	1,348 (29.11)	
Overweight (>=25.0 & <30.0)	1203 (28.75)	126 (28.25)	1,329 (28.70)	
Obese (>=30.0)	1477 (35.29)	155 (34.75)	1,632 (35.24)	
Smoking within one year	1059 (25.30)	148 (33.18)	1,207 (26.06)	<0.001
Dependent functional status	1135 (27.12)	118 (26.46)	1,253 (27.06)	0.95
Dyspnea	425 (10.16)	51 (11.43)	476 (10.28)	0.40
Ventilator dependence	42 (1.00)	14 (3.14)	56 (1.21)	<0.01
COPD	415 (9.92)	55 (12.33)	470 (10.15)	0.11
CHF	330 (7.89)	23 (5.16)	353 (7.62)	0.04
Hypertensive on medications	3372 (80.57)	372 (83.41)	3,744 (80.85)	0.15
Acute renal failure	188 (4.49)	21 (4.71)	209 (4.51)	0.83
On dialysis	872 (20.84)	101 (22.65)	973 (21.01)	0.37
Open wound/wound infection	2858 (68.29)	297 (66.59)	3,155 (68.13)	0.46
Diabetes	2937 (70.18)	296 (66.37)	3,233 (69.81)	0.10
Steroid use	258 (6.16)	33 (7.40)	291 (6.28)	0.31
Weight loss	89 (2.13)	12 (2.69)	101 (2.18)	0.44
Bleeding disorder	959 (22.92)	135 (30.27)	1,094 (23.62)	<0.001
Preoperative Transfusion	447 (10.68)	63 (14.13)	510 (11.01)	0.03
Preoperative SIRS/Sepsis/Shock	942 (22.51)	130 (29.15)	1,072 (23.15)	<0.001
Ascites	17 (0.41)	1 (0.22)	18 (0.39)	0.56

by occurrence of reoperation. Patient age was stratified by decade, with 567 (12%) patients less than 50, 1076 (23%) from 50 to 59, 1320 (29%) from 60 to 69, 988 (21%) from 70 to 79, and 680 (15%) greater than 79 years of age. Overall mean patient age was 64.5 years, without significant difference between the reoperation (63.9) and no reoperation (64.6) groups ($p = 0.3$). Males comprised 66% of the cohort at 3070 patients. The majority of patients were white, at 2611 patients (56%), with 1123 (24%) black patients, 464 (10%) Hispanic, and 156 (3%) identifying as "other."

Outcomes

The primary outcome of interest was unplanned reoperation, specified as a binary indicator and defined by NSQIP as any patient that had "an unplanned return to the operating room for an operative procedure related to either the index or concurrent procedure" performed within the 30-day postoperative period that NSQIP records [4]. This variable includes all surgeries not planned as initial follow-up to the index procedure. The procedures performed in the unplanned reoperation were evaluated to characterize the course of treatment following BKA. Only CPT codes that accounted for more than 1% of reoperations were included in this list. The reoperation procedures were subsequently categorized into three groups: thigh amputation, leg amputation, debridement/secondary closure/scar revision as outlined in Table 2. These categories were determined based on similarities among CPT categorization/descriptions.

A secondary outcome of importance was the incidence of unplanned readmissions related to the initial amputation. Indications for readmission were reviewed by ICD-9 code, and were obtained via the NSQIP variable for "unplanned and related readmission."

Other outcomes of interest included death and composite binary indicators to represent the occurrence of any (major or minor), at least one major, or at least one minor complication as defined by NSQIP occurring within 30 days of the initial BKA. Major complications included organ and deep space surgical site infections (SSI), wound dehiscence, pulmonary embolism, deep vein thrombosis, cardiac arrest, myocardial infarction, cerebrovascular accident, unplanned intubation, failure to wean from mechanical ventilation, sepsis, shock, acute renal failure, and renal insufficiency. Minor complications included superficial surgical site infections, pneumonia, and catheter-associated urinary tract infection (UTI).

Independent risk factors

Selection of risk factors for reoperation, readmission, complications, and mortality were based on clinical experience of the senior author and reports from previous literature [5,14]. Demographic risk factors included in the analysis were age, gender, and race/ethnicity. Perioperative factors included admission source, degree of wound contamination, American Society of Anesthesiologists (ASA) Physical Status Classification before surgery, body mass index (BMI), smoking status (within 1 year), surgical time, dependency status (independent, partially/totally dependent), ascites, bleeding disorder, dialysis, congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), hypertension with medication use, steroid use, transfusion, ventilator use, wound infection, weight loss, diabetes mellitus (Type 1 or Type 2), dyspnea (rest or exertion) and disseminated cancer. Peripheral vascular disease was unable to be assessed, as NSQIP discontinued collection of this variable in 2012.

Statistical analysis

For descriptive statistics, we first determined the distribution of various patient demographics, comorbidities, and clinical factors among patients who did and did not undergo reoperations following the BKA. We used chi-square tests and Fisher exact tests to test if there was a difference in the distribution of these characteristics between the two groups. Separate multivariate logistic regressions were estimated to examine the adjusted associations between the outcomes and risk factors. Adjusted odds ratios (AOR) and 95% confidence intervals (CI) were reported. We used the variance inflation factor to rule out multicollinearity, the Pregibon link test to check model specification, the C-statistic to assess model discrimination, and the Hosmer-Lemeshow test to assess model calibration. All statistical analysis was performed using Stata/MP, version 14.1. All statistical tests were 2 tailed and estimates with $p < .05$ were considered statistically significant.

Results

In our cohort of 4631 patients, we found 9.6% (446) patients underwent unplanned reoperations and 8.8% (405) required unplanned and related hospital readmissions within 30 days of index surgery. The mortality rate in the 30 day postoperative period was 5.1% (238).

Major complications were experienced by 12.8% (593) patients and 8.7% (401) of patients experienced minor complications. Of the 14 major complications evaluated, the five most frequently experienced by patients in this cohort included unplanned intubation (133, 2.9%), cardiac arrest (95, 2.1%), wound dehiscence (87, 1.9%), sepsis (85, 1.8%), and deep SSI (85, 1.8%). Minor complications included superficial SSI (171, 3.7%), pneumonia (130, 2.8%), and catheter associated UTI (124, 2.7%). These results are summarized in Table 3.

The most common procedures performed as unplanned reoperations were thigh amputations (128, 28.7%), debridement/secondary closure (114, 25.6%), revision leg amputations (46, 10.3%). Independent risk factors associated with an increased rate of unplanned reoperation in multivariate analysis included patients with preoperative ventilator use (AOR = 2.38; CI

Table 2
CPT codes included in each of three groups for reoperation.

Reoperation Group	CPT Codes	CPT Description
Thigh Amputation	27590	Amputation, thigh, through femur, any level;
	27596	Amputation, thigh, through femur, any level; re-amputation
Revision Leg Amputation	27880	Amputation, leg, through tibia and fibula;
	27886	Amputation, leg, through tibia and fibula; re-amputation
Debridement/	10180	Incision and drainage, complex, postoperative wound infection;
Secondary Closure	11042	Debridement, subcutaneous tissue; first 20 sq cm or less;
	11043	Debridement, muscle and/or fascia; first 20 sq cm or less;
	11044	Debridement, bone; first 20 sq cm or less;
	13160	Secondary closure of surgical wound or dehiscence, extensive or complicated;
	27884	Amputation, leg, through tibia and fibula; secondary closure or scar revision

[1.23,4.58]; p = .01), ongoing smokers (AOR = 1.34; [1.05,1.71]; p = .02), bleeding disorder (AOR = 1.30; [1.04,1.62]; p = .02), and transfer from another facility (AOR = 1.28; [1.01,1.62]; p = .04). Surgical time greater than 90 min was associated with decreased rates of reoperation (AOR = 0.67; [0.51,0.88]; p < .01).

Patient risk factors associated with an increased rate of unplanned related readmission included patient age greater than 79 years (AOR = 1.65; [1.03, 2.63]; p = .04), smoking within the past year (AOR = 1.38; [1.07,1.78]; p = .01), transfer from another facility (AOR = 1.29]; [1.01,1.65]; p = .04), and bleeding disorders (AOR = 1.27; [1.00,1.61]; p = .05).

The risk factor most strongly associated with increased 30 day mortality was increasing age, with risk rising incrementally per decade of life. Compared to patients less than 50 years of age, patients aged 60–69 (AOR = 3.17; [1.38,7.32]; p = .01), 70–79 (AOR = 5.49; [2.32,12.99]; p < .01), and greater than 79 (AOR = 8.54; [3.57,20.45]; p < .01) experienced significantly higher mortality rates. Other risk factors for mortality included contaminated wound class (AOR = 1.68; [1.06,2.66]; p = .03), an underweight BMI of <18.5 (AOR 1.87; [1.04,3.38]; p = .04), functional dependence (AOR 1.42; [1.04,1.93]; p = .03), preoperative ascites (AOR 4.06; [1.23,13.45]; p = .02), preoperative dialysis (AOR 2.25; [1.62,3.14]; p < .01) or ventilator requirements (AOR 3.27; [1.47,7.28]; p < .01), sepsis/shock (AOR 1.85; [1.34,2.55]; p < .01), and a history of dyspnea at rest or with exertion (AOR 1.54; [1.02,2.32]; p = .04)

The risk of major complications increased with several medical risk factors, including renal failure (AOR 1.68; [1.18,2.39]; p < .01) and preoperative dialysis requirements (AOR 1.29; [1.03,1.63]; p = .03), preoperative ventilator use (AOR 2.76; [1.45,5.24]; p < .01), preoperative sepsis/shock (AOR 1.31; [1.05,1.62]; p = .01), preoperative steroid usage (AOR 1.44; [1.04,1.99]; p = .03), and dyspnea at rest or with exertion (AOR 1.47; [1.12,1.94]; p = .01). Three of the four most common complications were minor complications. Minor complications were more frequently associated with preoperative ascites (AOR 4.19; [1.43,12.25]; p = .01) and preoperative hypertension on medication (AOR 1.49; [1.08,2.04]; p = .01).

Table 3
Outcomes of interest, including individual complication rates.

	N	% of total
Outcomes: Within 30 days of primary BKA		
Unplanned reoperation (all surgeries)	446	9.63
Unplanned Related readmissions	405	8.75
Mortality	238	5.14
Complications		
One or more complication	858	18.53
Major complications	593	12.81
Minor complications	401	8.66
Individual complications		
Superficial surgical site infection	171	3.69
Unplanned intubation	133	2.87
Pneumonia	130	2.81
Urinary tract infection	124	2.68
Cardiac arrest	95	2.05
Wound dehiscence	87	1.88
Sepsis	85	1.84
Deep surgical site infection	85	1.84
Failure to wean	81	1.75
Myocardial infarction	81	1.75
Shock	66	1.43
Acute renal failure	58	1.25
Deep vein thrombosis	44	0.95
Renal insufficiency	30	0.65
Cerebrovascular accident	24	0.52
Pulmonary embolism	11	0.24
Organ/Space surgical site infection	8	0.17

Discussion

This retrospective study of BKAs from the NSQIP database suggests that the odds of unplanned reoperation within 30 days of a BKA are greater for patients that are transferred from another facility, have a bleeding disorder, continue to smoke, or require preoperative ventilator use. These findings are important for operative planning and patient counseling, but tend to be non-modifiable by the treating surgeon, particularly in an urgent setting. It is important to be aware of these risk factors, even as they are out of the surgeon's control, as they may indicate alterations in preoperative patient workup in non-urgent settings or adjust the postoperative care plan in particularly high-risk patients.

Previous studies using the NSQIP database have looked at risk factors for complications and readmission for lower extremity amputations as a whole whereas this study focused specifically on BKA [5,14]. Belmont et al did explore BKAs individually using the NSQIP database, evaluating risk factors associated with complications. Reoperation was identified as a complication, therefore risk factors for reoperation itself were not evaluated [4]. The notable difference in our study is the inclusion of a larger and more recent BKA cohort for the variables being studied, which includes the addition of "unplanned and related admissions" and "unplanned operations" to the NSQIP database since 2011.

Of note, the risk factors of diabetes and wound infections were not associated with reoperation or readmission in this study. While it may be expected that these factors increase morbidity, they were present in a large majority of the cohort, with 70% diabetics and 68% presenting with open wound/infections. With this level of prevalence, and the strong association of these risk factors and need for a BKA, we feel that a statistical comparison becomes difficult.

The current study's evaluation of BKA reoperation between 2012 and 2014 corroborates the Curran et al [5] NSQIP findings in lower extremity amputations showing most reoperation procedures to be more proximal amputations. These findings reinforce the importance of risk assessment and management in this population, as transition from a BKA to above knee amputation is associated with a significant increase in metabolic demand, functional limitations, and mortality for the patient [15–18]. "Unplanned reoperation" includes any surgery that was not an expected return to the operating room from the index procedure. As such, a revision BKA after guillotine amputation should not play a role in this association.

The finding that continued smoking is associated with increased risk of reoperation and surgical times greater than 90 min are associated with decreased reoperation correlates with previous findings from O'Brien et al concerning lower extremity amputations overall. Smoking status has also been indicated as a risk factor for complications in other studies, though two NSQIP studies did not find such an association with smoking [4,5,9,14]. The decreased association with longer surgery times (>90 min) is counterintuitive, but may be explained by a more meticulous surgery, patients undergoing definitive amputation (rather than guillotine), or a surgery performed in patients that could tolerate a longer anesthesia time. This finding should be balanced with the increase in complications, particularly wound complications, with increasing surgical time, which has been shown in multiple areas of orthopaedics [19,20].

Previous studies have used reoperation as a proxy for amputation failure [14]. While this work does focus on reoperation, we considered reoperation as an incomplete definition of amputation failure. Extended acute medical care, in the setting of unplanned and related readmission, was an important secondary outcome in our study. Unplanned readmission places a significant

cost on the patient and medical system. It also causes delays in patient rehabilitation and increases exposure to health-care associated infections [11]. This outcome shared the risk factors of recent smoking history, bleeding disorder, and transfer from another facility with our primary outcome of reoperation. It also was associated with patient age >79 years.

There was a large group of variables associated with 30-day mortality and some level of postoperative complication in this patient cohort. We feel that these findings provide valuable information, especially considering likely underreporting of mortality in the setting of patient death at home or in a rehabilitation facility. A recent study by Wukich et al demonstrated a significant increase in 5-year mortality after BKA with increasing age and end-stage renal disease, which aligns with our findings regarding age and renal function [21]. Unfortunately, many of these risk factors remain out of the surgeon's control. While a clinician would expect patients of advanced age and greater comorbidities to experience more postoperative morbidity and mortality, these findings provide evidence, rather than anecdote, for expected outcomes. Control of diabetes, smoking, nutritional status, and appropriate post-discharge support systems and postoperative care plans could reduce the risk of patient mortality and major complications. These individual factors and their role in BKA patients' postoperative course remain an area of interest for further study and quality improvement.

The limitations of this study stem from the use of a database. The NSQIP database does not allow for medium- or long-term follow-up. While we are afforded useful data on the 30-day importance of the risk factors described, we are unable to obtain any longitudinal associations from this data set and overall incidence of complications is therefore underestimated. Despite this, our finding that major (13%) and minor (9%) complication rates remain high helps to highlight these important areas for improvement. Due to the quality control of the NSQIP database and inclusion of multiple hospitals, we feel that the associations described here are robust findings. The data presented in the NSQIP database is abstracted by trained and audited Surgical Clinical Reviewers, rather than from billing data. The database also is populated based on systematic sampling algorithms to further prevent bias by case type at larger institutions. This provides more accurate and unbiased clinical data from the patient record than other administrative databases. As it encompasses multiple hospitals, it also has the advantage of including patient readmission or treatment at other hospitals, improving the capture rate of these variables [12].

In conclusion, ongoing smokers, patients with bleeding disorders, preoperative ventilator use, and transfer from another facility are associated with increased odds of reoperation following BKA. Reoperation and readmission rates remain high in this patient population. Clinicians treating patients with these risk factors should have a higher expectation of the need for further medical care. This study isolates the associations of many patient characteristics with unplanned medical care requirements after BKA. Patients with these risk factors could be a focus for quality improvement, and structuring of postoperative support systems to reduce patient mortality, morbidity, and economic burden.

Conflicts

David Ciufo, MD, has no potential conflicts of interest with this work.

Caroline Thirukumaran, MBBS, PhD, has no potential conflicts of interest with this work.

Russel Marches, BS, has no potential conflicts of interest with this work.

Irvin Oh, MD, has no potential conflicts of interest with this work.

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