Risk Factors for Early Failure of Surgical Amputations: An Analysis of 8,878 Isolated Lower Extremity Amputation Procedures

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BACKGROUND: There are very few data currently published on risk factors for early failure of lower extremity amputation procedures.

STUDY DESIGN: All patients from the 2005–2010 American College of Surgeons NSQIP database who underwent isolated lower extremity amputation were included for analysis (excluding patients with earlier operation within 30 days, patients undergoing an open amputation, and patients undergoing another procedure during amputation). Multivariate logistic regression was used to determine predictors of early amputation failure (defined as need for reoperation within 30 days postoperatively) after adjustment for a number of preoperative and intraoperative variables.

RESULTS: A total of 8,878 patients were included for analysis (4,258 below-knee amputations [BKA]; 3,415 above-knee amputations; and 1,205 transmetatarsal amputations). Overall rate of early amputation failure was 12.7% (12.6% for BKA, 8.1% for above-knee amputations, and 26.4% for transmetatarsal amputations; p < 0.0001). Several pre- and intraoperative variables appeared to be independently associated with early amputation failure, including emergency operation, transmetatarsal amputation (reference = BKA), sepsis (reference = no sepsis), septic shock (reference = no sepsis), end-stage renal disease, systemic inflammatory response syndrome (reference = no sepsis), intraoperative surgical trainee participation, body mass index ≥30, and ongoing tobacco use. Characteristics associated with decreased early amputation failure include age 80 years or older (reference = younger than 65 years), locoregional anesthesia, above-knee amputation (reference = BKA), operative time 40 to 59 minutes (reference = <40 minutes), operative time ≥80 minutes (reference = <40 minutes), and operative time 60 to 79 minutes (reference = <40 minutes).

CONCLUSIONS: Increased operative time and heightened supervision of participating surgical trainees can decrease the risk of early amputation failure. In addition, specific clinical situations, such as sepsis or emergency procedures, should prompt vascular surgeons to consider either an open amputation procedure or a more proximal closed amputation. (J Am Coll Surg 2013;216:836–844. © 2013 by the American College of Surgeons)
fail and in which a staged amputation approach should be pursued. The purpose of our analysis was to use information from the American College of Surgeons NSQIP Participant User Files to describe lower extremity amputation level-specific postoperative failure rates and the predictors of early amputation failure.

METHODS

The data source for our analysis was the 2005–2010 American College of Surgeons NSQIP Participant User Files. We included all patients with a primary CPT code for either above-knee (AKA, CPT 27590), below-knee (BKA, CPT 27880), or transmetatarsal (TMA, CPT 28805) amputation. Patients undergoing any other type of procedure during index operation were excluded from our analysis to minimize potential inclusion of patients who underwent early reoperation for reasons not directly related to their amputation. Patients undergoing any earlier operation within 30 days of index amputation were also excluded to minimize the potential inclusion of patients whose index operation actually served as a revision of a previous amputation procedure. Patients with preoperative DNR orders and those with missing variables for any predictor variables were also excluded from our analysis.

The primary predictor variable for our analysis was lower extremity amputation level (as defined by the previously described primary CPT codes). Other potential predictor variables reflecting demographics or acute/chronic comorbid condition included patient age (younger than 65 years, 65 to 79 years, 80 years or older), sex, body mass index (≤25, 25 to 29, ≥30), diabetes mellitus (none vs non–insulin-dependent vs insulin-dependent), ongoing tobacco use, chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease (composite variable that includes myocardial infarction within 6 months of the procedure, angina within 30 days of the procedure, earlier percutaneous coronary intervention, and/or earlier coronary artery revascularization surgery), hypertension requiring medication, history of percutaneous or open revascularization procedure for peripheral vascular disease, ongoing rest pain and/or gangrene of the lower extremities, end-stage renal disease requiring dialysis, cerebrovascular disease (composite variable including earlier cerebrovascular accident and/or history of transient ischemic attack), impaired sensorium at time of operation, known malignant disease (composite variable including tumor of the central nervous system, disseminated cancer, chemotherapy within 30 days of the procedure, and/or radiotherapy within 90 days of the procedure), chronic steroid usage, bleeding disorder, preoperative functional status (independent vs partially and/or completely dependent), American Society of Anesthesiologists physical status classification (1 to 3 vs 4 or higher), presence of an infected wound preoperatively, malnourishment (as indicated by weight loss >10% within 6 months of the index procedure and/or a preoperative albumin level <3.5 mg/dL), preoperative sepsis classification (none vs systemic inflammatory response syndrome vs sepsis vs septic shock), and need for preoperative blood transfusion. Potential predictor variables reflecting complexity of the index operation included operative time (<40 minutes, 40 to 59 minutes, 60 to 79 minutes, or ≥80 minutes), anesthesia modality (general vs locoregional), intraoperative participation of a surgical trainee, incisional wound classification (clean/clean-contaminated vs contaminated vs dirty/infected), need for intraoperative blood transfusion, and attending surgeon specialty (vascular surgeon vs nonvascular surgeon).

The primary outcomes variable for our analysis was early amputation failure, which we defined as the need for reoperation within 30 days of the index procedure. Secondary outcomes variables included 30-day postoperative mortality, wound complication rate (including superficial surgical site infection, deep incisional surgical site infection, organ/space surgical site infection, and/or wound dehiscence), nonwound complication rate (including pneumonia, unplanned reintubation, pulmonary embolism, mechanical ventilation for ≥48 hours postoperatively, urinary tract infection, progressive renal insufficiency, acute renal failure requiring dialysis, myocardial infarction, stroke, comatose state for ≥24 hours, cardiopulmonary arrest, graft/prosthetic failure, peripheral nerve injury, deep venous thrombosis, systemic sepsis, and/or septic shock), and postoperative length of hospitalization.

A descriptive analysis was first performed to summarize the preoperative and intraoperative characteristics of patients undergoing lower extremity amputation procedures, with and without stratification by level of amputation. The association between amputation level and each of these characteristics was determined using Pearson chi-square tests. A similar analysis was performed to determine primary and secondary outcomes after lower extremity amputation, again with and without stratification by level of amputation. The univariate association between amputation level and outcomes were determined using Pearson chi-square tests for categorical variables and Kruskal–Wallis testing for postoperative length of hospitalization. Multivariate logistic regression analysis was used to determine independent predictors of early failure after lower extremity amputation. All of these preoperative and intraoperative characteristics that have a univariate association with early amputation failure at the p < 0.20 level were included as potential predictor variables in the regression model.
Finally, we compared the postoperative outcomes of patients with and without early amputation failure after adjustment for other perioperative characteristics and the presence or absence of other postoperative complications (when applicable). We used separate multivariate logistic regression models for our analyses of 30-day mortality, 30-day wound complication rate, and 30-day nonwound complication rate. For our analysis of postoperative length of stay, we created a multivariate linear regression model that used the natural logarithm of postoperative length of stay as the outcomes variable. All statistical analysis was performed using Stata Version 11.0 (StataCorp).

RESULTS
A total of 8,878 patients undergoing primary lower extremity amputation were included for analysis (4,528 BKA, 3,415 AKA, and 1,205 TMA). Demographic and comorbid patient characteristics, stratified by amputation type, are shown in Table 1. In general, patients undergoing more proximal amputation were significantly more likely to exhibit certain chronic comorbid conditions or acute preoperative physiologic derangements than patients undergoing more distal amputation. For example, patients undergoing AKA had a higher incidence of chronic obstructive pulmonary disease, cerebrovascular disease, and nonindependent functional status than patients undergoing BKA or TMA. Similarly, a higher proportion of patients undergoing AKA were malnourished, had acute impairment in their mental status preoperatively, or received a high American Society of Anesthesiologists physical status classification when compared with patients undergoing BKA or TMA.

Table 2 depicts the intraoperative characteristics of patients undergoing lower extremity amputation, again stratified by the level of amputation. There were no clinically significant differences based on amputation level in the need for emergent operation, the subspecialty of the attending surgeon, or the presence of a surgical trainee intraoperatively. Patients undergoing TMA appeared more likely to receive locoregional anesthesia compared with patients undergoing AKA or BKA, and less likely to require intraoperative blood transfusion. Conversely, patients undergoing TMA appeared to be much more likely to have an incisional wound classification of “dirty/infected” than patients undergoing BKA or AKA. Finally, patients undergoing BKA appeared to be the most likely group to require operations lasting longer than 1 hour, followed by patients undergoing AKA and then patients receiving TMA.

Table 3 shows the postoperative outcomes of patients undergoing lower extremity amputation. Overall early failure rate was 12.7%, which appeared to be highest for patients undergoing TMA (26.4%) and lowest for patients undergoing AKA (8.1%). Overall 30-day postoperative mortality was 7.1%, 30-day wound complication rate was 9.1%, and nonwound complication rate was 13.7%. Table 3 also shows postoperative outcomes stratified by amputation level, although the statistical comparisons shown in this Table are not adjusted for other potentially confounding variables.

Table 4 shows those preoperative and intraoperative factors that were found to be significantly associated with early amputation failure on multivariate analysis. Amputation level served as an independent predictor of failure, with TMA procedures associated with higher failure rates and AKA procedures associated with lower failure rates compared with patients undergoing BKA procedures. Several other acute and chronic comorbid conditions appeared to predict a greater incidence of early amputation failure, and other factors (especially the use of locoregional anesthesia and operative times >40 minutes) were significantly associated with a lower risk of early amputation failure.

Postoperative outcomes stratified by the presence or absence of early amputation failure are shown in Table 5. After adjustment for patient- and procedure-related factors and for the presence/absence of other postoperative complications, the presence of early amputation failure did not have a statistically significant association with 30-day postoperative mortality. However, patients who experienced early amputation failure did have a significantly higher incidence of both wound and nonwound complications and a significantly longer length of postoperative hospitalization.

DISCUSSION
Our analysis of 8,878 patients undergoing lower extremity amputation demonstrates a 30-day postoperative amputation failure rate of 12.7% and identifies several risk factor failures. In addition, although early amputation failure does not appear to influence subsequent postoperative mortality, its occurrence is associated with a substantial increase in the incidence of both wound and nonwound complications and a 2-fold increase in the length of postoperative hospitalization.

Our analysis demonstrates that the early failure rate for TMA procedures is 26.4%, which is considerably higher than the rates of 12.6% for BKA and 8.1% for AKA. This is consistent with the findings of Landry and colleagues, who reported the longer-term healing rate after TMA to be only 53%. Based on that finding, they concluded that TMA should only be offered to those patients who show the greatest potential for rehabilitation.
Our study shows that >14% of patients undergoing TMA are either partially or totally dependent on assistance for the completion of activities of daily living, a finding that suggests the procedure is not being performed infrequently on patients with very poor rehabilitation potential. Conversely, our finding that AKA is associated with the lowest adjusted rate of early amputation failure supports the use of this primary amputation level in patients who have a substantial physical or cognitive disability, and who are therefore unlikely to realize the theoretical benefits associated with more distal amputation.6

Our analysis also identifies several comorbid conditions that are independently associated with primary amputation failure, including the presence of any degree of sepsis and...
the need for emergency amputation. These findings would suggest that a staged approach, not primary amputation, is the best strategy for patients who require BKA but who display signs of sepsis or other evidence of systemic illness. Such an approach can ultimately reduce the risk of conversion to AKA. We have also identified several potentially modifiable technical factors that can contribute to risk of early amputation failure. First, we found that patients undergoing amputation under locoregional anesthesia are less likely to suffer early amputation failure compared with patients who received general anesthesia during their procedure. This is in contradistinction to the recently published findings of Ghanami and colleagues, who were unable to identify any advantage in terms of postoperative morbidity to the use of locoregional anesthesia during lower extremity bypass grafting procedures. However, other investigators may offer some advantage to general anesthesia in terms of more effective postoperative analgesia and less severe medium-term phantom limb pain. We have demonstrated that the intraoperative participation of surgical trainees during amputation procedures serves as a Table 3. Postoperative Outcomes of 8,878 Patients Undergoing Lower Extremity Amputation

<table>
<thead>
<tr>
<th>Outcomes variable</th>
<th>All patients (n = 8,878)</th>
<th>AKA (n = 3,415)</th>
<th>BKA (n = 4,258)</th>
<th>TMA (n = 1,205)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early amputation failure, n (%)</td>
<td>1,130 (12.7)</td>
<td>277 (8.1)</td>
<td>539 (12.6)</td>
<td>318 (26.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>30-day mortality, n (%)</td>
<td>626 (7.1)</td>
<td>353 (10.3)</td>
<td>242 (5.7)</td>
<td>31 (2.6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Wound complications, n (%)</td>
<td>805 (9.1)</td>
<td>233 (6.8)</td>
<td>425 (10.0)</td>
<td>147 (12.2)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Nonwound complications, n (%)</td>
<td>1,903 (21.4)</td>
<td>833 (24.4)</td>
<td>905 (21.3)</td>
<td>165 (13.7)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Postoperative length of hospitalization, d, median (IQR)</td>
<td>6 (4–9)</td>
<td>5 (4–9)</td>
<td>6 (4–9)</td>
<td>6 (3–10)</td>
<td>0.047</td>
</tr>
</tbody>
</table>

*Univariate association between level of amputation and preoperative characteristics using Pearson chi-square tests. AKA, above-knee amputation; BKA, below-knee amputation; TMA, transmetatarsal amputation.
an independent predictor of increased early amputation failure risk. This finding is consistent with other reports suggesting that intraoperative trainee participation can increase the risk of technical complications after infrainguinal bypass grafting and other procedures.\textsuperscript{13,14} Although trainees must necessarily be actively involved in the technical conduct of surgical procedures to progress to a desired degree of autonomy, the findings of our study suggest that attending surgeons should strive to optimize the degree of intraoperative supervision that is given to these trainees. Finally, our analysis shows that longer operative times are associated with decreased risk of early amputation failure, a finding that emphasizes the importance of meticulous technique and tissue handling during amputation procedures.

During lower extremity amputation procedures, the choice of where to amputate can sometimes be very complex and is dependent on a number of factors, such as acuity of illness, the disease process necessitating amputation, and both the surgeon’s and patient’s perceptions of the overall risk-to-benefit ratio associated with more distal amputation. Our analysis identifies several comorbid conditions that are independently associated with early amputation failure. Knowledge of these risk factors will assist surgeons in identifying those patients in whom a more aggressive primary amputation strategy is more likely to fail, and who might

Table 4. Preoperative and Intraoperative Characteristics Independently Associated with Early Amputation Failure after Adjustment for Patient- and Procedure-Related Factors

<table>
<thead>
<tr>
<th>Characteristic associated with increased early amputation failure</th>
<th>Adjusted odds ratio* for early amputation failure</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency operation</td>
<td>2.15</td>
<td>1.79–2.59</td>
</tr>
<tr>
<td>Transmetatarsal amputation (Ref = BKA)</td>
<td>1.91</td>
<td>1.59–2.29</td>
</tr>
<tr>
<td>Sepsis (Ref = no sepsis)</td>
<td>1.78</td>
<td>1.48–2.14</td>
</tr>
<tr>
<td>Septic shock (Ref = no sepsis)</td>
<td>1.67</td>
<td>1.12–2.48</td>
</tr>
<tr>
<td>End-stage renal disease</td>
<td>1.39</td>
<td>1.19–1.63</td>
</tr>
<tr>
<td>SIRS (Ref = no sepsis)</td>
<td>1.39</td>
<td>1.15–1.67</td>
</tr>
<tr>
<td>Intraoperative surgical trainee participation</td>
<td>1.37</td>
<td>1.20–1.57</td>
</tr>
<tr>
<td>Body mass index $\geq$30 (Ref = $&lt;25$)</td>
<td>1.29</td>
<td>1.09–1.52</td>
</tr>
<tr>
<td>Ongoing tobacco use</td>
<td>1.18</td>
<td>1.00–1.38</td>
</tr>
</tbody>
</table>

*Adjusted for all patient- and procedure-related factors that maintained a univariate association with early amputation failure at the $p < 0.20$ level.

BKA, below-knee amputation; Ref, reference group; SIRS, systemic inflammatory response syndrome.

Table 5. Effect of Early Amputation Failure on Other Postoperative Outcomes

<table>
<thead>
<tr>
<th>Postoperative outcomes</th>
<th>No early amputation failure ($n = 7,748$)</th>
<th>Early amputation failure ($n = 1,130$)</th>
<th>Independent impact of early amputation failure on outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative mortality, n (%)</td>
<td>554 (7.2)</td>
<td>72 (6.4)</td>
<td>AOR* 0.80 (0.59–1.07); $p = 0.14$</td>
</tr>
<tr>
<td>Wound complications, n (%)</td>
<td>463 (6.0)</td>
<td>342 (30.3)</td>
<td>AOR* 6.89 (5.80–8.19); $p &lt; 0.0001$</td>
</tr>
<tr>
<td>Nonwound complications, n (%)</td>
<td>1,511 (19.5)</td>
<td>392 (34.7)</td>
<td>AOR* 2.09 (1.78–2.44); $p &lt; 0.0001$</td>
</tr>
<tr>
<td>Postoperative length of stay, d, median (IQR)</td>
<td>5 (4–8)</td>
<td>10 (6–17)</td>
<td>B Coefficient* 0.42 (0.38–0.46); $p &lt; 0.0001$</td>
</tr>
</tbody>
</table>

*Independent effect of early amputation failure on categorical outcomes variable after adjustment for patient- and procedure-related factors and presence/absence of other postoperative complications.

\textsuperscript{1}Independent effect of early amputation failure on natural logarithm of postoperative length of hospital stay after adjustment for patient- and procedure-related factors and presence/absence of other postoperative complications.

AOR, adjusted odds ratio; IQR, interquartile range.
therefore benefit from either a staged amputation approach or a more proximal primary amputation level. In addition, the findings of our analysis emphasize the potential influence of anesthesia modality and the importance of attending supervision of surgical trainees and of meticulous technique as determinants of successful primary lower extremity amputation.

Our analysis has several important limitations. First, we use early reoperation after index amputation as a proxy for early amputation failure, even though the data source used for our analysis does not identify the indication for reoperation. It is therefore possible that patients from our study sample underwent reoperation for some reason unrelated to their amputation procedure. To minimize this possibility, we excluded all patients who received any other concurrent procedure during their index operation, either by the vascular surgery team or some other surgery team. Second, the American College of Surgeons NSQIP does not provide information on the exact timing of reoperations that occur within 30 days of the index procedure. For this reason, the significant association that we demonstrated between early amputation failure and wound/nonwound complications cannot be inferred to mean that early amputation failure increases the risk of other complications, or vice versa.

CONCLUSIONS

Despite these limitations, we believe that the findings of our study will prove useful to vascular surgeons who must determine which patients are most likely to benefit from either a staged amputation strategy or a more proximal-level amputation. In addition, our analysis emphasizes the importance that anesthetic modality, intraoperative supervision of surgical trainees, and meticulous technique have in determining the early success of primary lower extremity amputations.

Author Contributions

Study conception and design: O’Brien, Scarborough
Acquisition of data: Scarborough
Analysis and interpretation of data: O’Brien, Scarborough
Drafting of manuscript: O’Brien, Scarborough
Critical revision: Cox, Shortell

REFERENCES


Discussion

DR JULIE ANN FREISCHLAG (Baltimore, MD): This is certainly an element of the vascular surgery practice that perhaps we don’t discuss enough. Using the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database between 2005 and 2010, these authors looked at above-knee amputations, below-knee amputations, and transmetatarsal amputations at the 30-day interval—not only death, but wound and other complications. The failure rate of healing an amputation was 12.7%, which was less than I actually expected. Amputation failure rate was related to wound and nonwound complications, longer length of stay, and the typical vascular risk factors of obesity, tobacco use, and end-stage renal disease. But those are the patients who face amputation.