Revision Rate and Risk Factors After Lower Extremity Amputation in Diabetic or Dysvascular Patients

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abstract

This article reports the revision rate and possible risk factors for lower extremity amputations in patients with diabetes mellitus or peripheral arterial disease (PAD). Data were collected from 421 patients with diabetes mellitus or PAD who underwent amputations of the lower extremity at the authors’ institution from 2002 to 2012. There was a 25.2% overall revision rate. Mean time from amputation to revision was 244 days (range, 2-2590 days). Patients with diabetes mellitus had a significantly higher rate of revision to a more proximal level compared with patients without diabetes mellitus (type 1: odds ratio [OR]=3.73; 95% confidence interval [CI], 1.21-11.52; P=.022; and type 2: OR=2.3; 95% CI, 1.07-4.95; P=.033). A significant increase in revision rates was observed from Fontaine stage 0 to IV (stage 0: 17.9%; stage IV, 34.7%; P=.03). Risk factors for revision were diabetic nephropathy (OR=2.26; 95% CI, 1.4-3.63; P=.001) and polyneuropathy (OR=1.68; 95% CI, 1.03-2.73; P=.037). Patients who underwent revision amputation had a significantly younger mean age than patients who did not undergo revision amputation (65.23 years [range, 40-92 years] vs 68.52 years [range, 32-96 years]; P=.013). Anticipated amputation in this patient population requires a multidisciplinary approach with optimization of the patient’s health. In the authors’ clinical practice, the determination of the appropriate amputation level is performed individually for each patient, considering the risk factors identified in this study and the patient’s expected mobilization potential, social background, and acceptance of a more proximal primary amputation level. [Orthopedics. 2016; 39(1):e149-e154.]

Lower extremity amputation is considered the last possible surgical management option when limb salvage is impossible. In the United States, approximately 185,000 amputations are performed annually; approximately 16% of these are related to trauma. Amputations secondary to dysvascular disease account for 54% of these cases, and two-thirds of these cases have a comorbid diagnosis of diabetes mellitus. An estimated 1.6 million patients were living with the loss of a limb in 2005 in the United States. It is expected that in 2050 this number will rise to 3.6 million. The number of amputations is expected to rise from less than 1 million in 2005 to 2.3 million in 2050. Those undergoing amputations due to dysvascular conditions will account for most of the increase because the prevalence of diabetes mellitus is expected to double by 2030.

Nonhealing diabetic foot ulcers may lead to wet gangrene, osteomyelitis, and sepsis. This cascade and ischemia refractory to revascularization with chronic nonhealing wounds can require amputa-
tion (Figure 1). The selection of the appropriate amputation level is critical to the final outcome. The amputation level is defined by preexisting necrosis, gangrene, and infection and the expectation of effective wound healing, which is mainly dependent on sufficient arterial blood supply. The energy required for walking increases, and the customary walking speed decreases as the amputation level moves proximally. As a result, better functional outcomes are usually associated with joint-level preservation. Primary amputation at more proximal levels is associated with lower rates of morbidity and mortality at the expense of decreased mobility. Several risk factors have been shown to influence stump healing and reamputation rates. Previous vascular surgery predisposes to higher revision rates. Other factors such as age, sex, smoking, malnutrition, and diabetes mellitus may adversely affect stump healing.

The authors sought to evaluate risk factors for revision amputation in a polymorbid patient population with diabetes mellitus and/or peripheral arterial disease (PAD) due to a lack of data in the literature in this specific patient population. Their research questions included the following: (1) How high is the revision rate after lower extremity amputations in patients with diabetes mellitus or PAD? (2) Is diabetes mellitus a risk factor for revision surgery after lower extremity amputation? (3) Is PAD a risk factor for revision surgery after lower extremity amputation? (4) What are other risk factors for revision surgery in this patient population after lower extremity amputation?

**Materials and Methods**

A retrospective review was undertaken with the aim of identifying all patients who underwent primary amputation of the lower extremity at the authors’ institution between January 1, 2002, and January 1, 2012. Informed consent was obtained from all participants included in the study. Cases were identified electronically using the in-house patient database, filtering all surgeries performed by the team for “technical orthopedics” and manually extracting all patients who underwent an amputation or revision of an amputation. Patients were excluded if a primary amputation was performed due to trauma, at another institution, or for reasons not related to diabetes mellitus or PAD (Figure 2).

A total of 421 patients met the inclusion criteria. Patient demographics and clinical data were derived from the institutional electronic medical records. In all cases, amputation level was determined by a senior orthopedic surgeon (T.B., M.C.B.). All amputations were performed by or under the direct supervision of an attending orthopedic surgeon (T.B., M.C.B.). Information collected included demographic data, level and type of amputation, whether the revision was performed at the same level or a more proximal level, time from amputation to first revision, and presence of polyneuropathy or diabetic nephropathy. Risk factors like smoking and alcohol and their amounts consumed were extracted. Regarding diabetes mellitus, date of diagnosis, type (1 or 2), duration, and treatment (none, insulin, oral antidiabetics) were determined from medical records. Peripheral arterial disease was graded using Fontaine stages 0 to IV, and it was noted whether ipsilateral peripheral transluminal angioplasty (PTA) or peripheral bypasses were performed prior to amputation.

Data were analyzed using IBM SPSS Statistics version 20.0 (IBM Corp, Armonk, New York). Logistic regression was performed to identify the significant
predictors of revision amputation. Differences of categorical variables were analyzed using chi-square tests. Differences of continuous variables were analyzed using \( t \) tests. The level of statistical significance was set to \( \alpha = 0.05 \).

**RESULTS**

Over the 10-year period, 421 consecutive patients with diabetes mellitus or PAD underwent lower extremity amputations. This included 292 (69.4%) men and 129 (30.6%) women. Mean patient age was 68.84 years (range, 32-96 years). Amputation levels are shown in Table 1. Forty-seven (11.2%) patients underwent bilateral lower extremity amputation during the study period. The overall revision rate was 25.2% (n=106), half of which (n=53) were at the same level and half (n=53) at a more proximal level. Revision at the same level generally involved soft tissue revisions and, in some cases, shortening of the stump. More than one revision was performed in 26 patients (24.5% of revisions). Sixteen (61.5%) of these patients were first revised at the same level as the primary amputation. Second revisions were performed successfully in 6 patients at the same level (1 toe revision, 5 below-knee amputations) and in 10 patients at a more proximal level (Table 1).

Mean time to revision was 244 days (range, 2-2590 days). The reasons for revision amputation in this population were necrosis (n=33), soft tissue infections (n=23), osteomyelitis (n=21), wound-healing problems (n=13), fall onto the stump (n=8), hematoma evacuation (n=3), ischemic pain (n=3), obstruction of the bypass (n=1), and soft tissue surplus (n=1). Same-level revisions were favored when a limited soft tissue infection or osteomyelitis was observed on magnetic resonance images and a sufficient wound-healing potential was expected. The indications for revision surgery at the same level were superficial and deep infections (soft tissue, n=11; osteomyelitis, n=10).

The diagnosis of type 1 or 2 diabetes mellitus was an independent risk factor for a revision amputation at a more proximal level (type 1: odds ratio [OR]=3.73; 95% confidence interval [CI], 1.21-11.52; \( P = 0.02 \); and type 2: OR=2.3; 95% CI, 1.07-4.95; \( P = 0.03 \)). The use of insulin was a risk factor for a revision to a more proximal level (OR=1.77; 95% CI, 1.12-2.8; \( P = 0.035 \)). Diabetes mellitus was present for a mean of 20.56 years (range, 0-58 years). This time interval considers the date of amputation and diagnosis of diabetes mellitus (Table 2).

Patients with PAD graded using Fontaine stages 0 through IV are listed in Table 3. There was a significant correlation between patients who underwent PTA or peripheral bypass surgery and revision surgery (\( P = 0.03 \) and \( P = 0.015 \), respectively). A significant increase in revision rates was observed from Fontaine stage 0 (17.9%) to I (21.3%), IIa or IIb (20.8%), III (30.8%), and IV (34.7%) (\( P = 0.03 \)).

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**Table 1**

<table>
<thead>
<tr>
<th>Level of Primary Amputation</th>
<th>No. of Cases (% of All Amputations)</th>
<th>No. of Revisions</th>
<th>No. of Same-Level Revisions</th>
<th>Second Revision After Same-Level Revision</th>
<th>Revision to Proximal Level</th>
<th>Second Revision After Proximal-Level Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toes</td>
<td>261 (62)</td>
<td>49</td>
<td>21</td>
<td>Same level: 1; 14 to BKA; 1 to TMT</td>
<td>1 Syme to BKA; 1 Chopart to BKA; 1 TMT to BKA</td>
<td></td>
</tr>
<tr>
<td>TMT</td>
<td>33 (7.8)</td>
<td>10</td>
<td>6</td>
<td>To proximal level: 3 to BKA; 2 to TMT</td>
<td>1 BKA</td>
<td>Same level: 1 BKA</td>
</tr>
<tr>
<td>Lisfranc</td>
<td>4 (1)</td>
<td>2</td>
<td>1</td>
<td>1 to BKA</td>
<td>1 BKA</td>
<td></td>
</tr>
<tr>
<td>Chopart</td>
<td>4 (1)</td>
<td>2</td>
<td>0</td>
<td>2 to BKA</td>
<td>2 to BKA</td>
<td></td>
</tr>
<tr>
<td>Syme</td>
<td>3 (0.7)</td>
<td>3</td>
<td>2</td>
<td>2 to BKA</td>
<td>1 to BKA</td>
<td></td>
</tr>
<tr>
<td>BKA</td>
<td>97 (23)</td>
<td>35</td>
<td>29</td>
<td>Same level: 5</td>
<td>Same level: 1 BKA</td>
<td></td>
</tr>
<tr>
<td>Knee exarticulation</td>
<td>3 (0.7)</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OKA</td>
<td>15 (3.6)</td>
<td>5</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip exarticulation</td>
<td>1 (0.2)</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: BKA, below-knee amputation; OKA, over-the-knee amputation; TMT, transmetatarsal.

* Bona-Jaeger, mediotarsal exarticulation; Chopart, transtarsal exarticulation preserving the talus and calcaneus; Lisfranc, tarso-metatarsal exarticulation; Syme, ankle exarticulation and removal of malleoli.
Polyneuropathy was a risk factor for a revision amputation (OR=1.68; 95% CI, 1.03-2.73; \( P=0.037 \)), as was diabetic nephropathy (OR=2.26; 95% CI, 1.4-3.63; \( P=0.001 \)) (Table 3). Patients who underwent revision amputation had a significantly younger mean age of 65.23 years (range, 40-92 years) compared with patients who did not undergo revision amputation (68.52 years [range, 32-96 years]) (\( P=0.013 \)).

None of the following were predictive of revision surgery: smoking, alcohol consumption, direct supervision of the amputation by a senior attending orthopedic surgeon, body mass index, sex, history of smoking or alcohol use, duration of diabetes mellitus, and preoperative glycated hemoglobin (HbA1c) (Table 4).

### DISCUSSION

Lower extremity amputations are becoming an increasingly important topic, especially in the current demographic situation of an aging population and increasing incidence of diabetes mellitus.\(^3^6\) In this single-center retrospective analysis of all levels of lower extremity amputation, the overall revision rate was 25.2% for patients with diabetes mellitus and PAD. Van Damme et al\(^12\) reported a similar high revision rate for amputations in dysvascular patients with diabetes mellitus and PAD. Van Damme et al\(^12\) reported a similar high revision rate for amputations in dysvascular patients with diabetes mellitus and PAD. In a study analyzing reamputation rates in Medicare beneficiaries with dysvascular lower extremity amputation, Dillingham et al\(^13\) reported that a progression to an ipsilateral higher amputation level occurred in 20.3% after foot or ankle amputations and 25% after toe amputations; in contrast, the ipsilateral revision rate to a higher level after an initial transtibial amputation was 9.4%. Barber et al\(^14\) reported an overall reamputation rate of 15% in a prospective study of lower limb amputations. Wahlberg et al\(^15\) reported a 24% reamputation rate in 219 dysvascular patients who underwent amputation.

In the current study, mean time to revision was 244 days. These results are analogous to those of Ebskov and Josephsen,\(^16\) who reported that the majority of ipsilateral reamputations occurred within the first year. Kanade et al\(^17\) reported that the second ipsilateral amputations in their study population oc-
curred after an average of 21 weeks. Patients with diabetes mellitus had a higher rate of revision to a more proximal level than those without. This finding was also observed by Dillingham et al. Patients who injected insulin for glycemic control had a higher rate of revision than patients who did not inject insulin. This finding is in contrast to a review of 52 transmetatarsal amputations that demonstrated that noninsulin-requiring diabetes mellitus was the only factor significantly associated with the need for revision amputation at a higher level.

A significant increase in revision rates was observed from Fontaine stage 0 to IV in the current study. In addition, the authors were able to show that prior PTA or bypass surgery on the ipsilateral leg was a risk factor for revision surgery. Patients with polyneuropathy or diabetic nephropathy, both risk factors for impaired wound healing and infection, had a significantly increased risk of undergoing revision surgery in this study population. It is known that a patient with diabetes mellitus and end-stage renal disease and uremia has a 10-times-higher risk of lower extremity amputation than that of a patient with diabetes mellitus without uremia.

The male predominance among the current study population was also observed in other studies. Patients who underwent revision surgery were significantly younger than the control group. This may be explained by the fact that younger patients who refuse a transtibial amputation may be more accepting if transmetatarsal amputation was at least attempted. None of the following were predictive of revision amputation: body mass index, sex, history of smoking or alcohol, supervision of the surgery by a senior attending orthopedic surgeon, duration of diabetes mellitus, and preoperative HbA1c.

There are limitations inherent to the retrospective design of this study; however, the study includes 421 patients, covers a period of 10 years, and includes all lower extremity amputations. Therefore, it may be more accurate in capturing risk factors and revision rates in a study population of patients with diabetes mellitus and PAD than other prospective studies that have limited sample sizes.
CONCLUSION

In the authors’ clinical practice, the determination of the appropriate amputation level is performed individually for each patient, considering the risk factors identified in this study and the patient’s expected mobilization potential, social background, and acceptance of a more proximal primary amputation level. Considering the given data, a particular level of amputation cannot be recommended in patients with diabetes mellitus or PAD. Multidisciplinary preoperative assessments by an orthopedic and vascular surgeon, physical therapist, prosthetist, psychologist, and social worker can maximize ultimate functional status. Because of the high prevalence of comorbid conditions in the amputee population, optimization of each patient’s health by internal medicine specialists is mandatory.

REFERENCES