Risk of Reamputation in Diabetic Patients Stratified by Limb and Level of Amputation

A 10-year observation

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OBJECTIVE — This study examined the risk of reamputation, stratified by original level of amputation, in a population of diabetic patients. We also illustrated reamputation rates by ipsilateral and contralateral limbs.

RESEARCH DESIGN AND METHODS — The study population included 277 diabetic patients with a first lower-extremity amputation performed between 1993 and 1997 at University Hospital in San Antonio, Texas. Reamputation episodes for the ipsilateral and contralateral limbs were recorded through 2003. Using a cumulative incidence curve analysis, we compared the reamputation rate by limb. Cumulative rates of reamputation were calculated for each limb at each amputation level at 1, 3, and 5 years.

RESULTS — Cumulative rates of reamputation per person were 26.7% at 1 year, 48.3% at 3 years, and 60.7% at 5 years. Ipsilateral reamputation per amputation level at the 1-, 3-, and 5-year points were toe: 22.8, 39.6, and 52.3%; ray: 28.7, 41.2, and 50%; midfoot: 18.8, 33.3, and 42.9%; and major: 4.7, 11.8, and 13.3%. For contralateral reamputation, the rates at 1, 3, and 5 years were toe: 3.5, 18.8, and 29.5%; ray: 9.3, 21.6, and 29.2%; midfoot: 9.4, 18.5, and 33.3%; and major: 11.6, 44.1, and 53.3%.

CONCLUSIONS — This study showed that a patient is at greatest risk for further same-limb amputation in the 6 months after the initial amputation. Although risk to the contralateral limb rises steadily, it never meets the level of that of the ipsilateral limb. This finding will help clinicians focus preventive efforts and medical resources during individualized at-risk periods for diabetic patients undergoing first-time amputations.

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Foot ulcers and lower-extremity amputations (LEAs) are disabling complications of diabetes that can lead to significant increases in mortality and morbidity (1,2), most notably recurrent amputation at increasingly higher levels. It has been shown that a history of ulceration increases the risk of amputation (3,4), as do prior amputations (4). Several studies have reported reamputation rates (5–15). However, the results of these studies are too general to apply to individual patients; some studies combined reamputation episodes of both ipsilateral and contralateral limbs (5–7) and others addressed reamputation of only one extremity (8–10). Reamputations at specific levels have been studied (11–15), but how the rates differ by level of amputation is still unknown. In addition, many of these studies included reamputations for patients with existing amputations. The true reamputation rate of first-time amputations has not been reported before this study.

In this retrospective cohort study, we aimed to *1*) illustrate the difference between the reamputation risk for ipsilateral and contralateral limbs and 2) stratify the risk of reamputation by the original level of amputation. With these findings, we hope to help clinicians estimate individualized risk for patients based on the level of first-time amputation.

RESEARCH DESIGN AND METHODS

In this retrospective cohort study, we identified 453 consecutive diabetic patients who were admitted for LEA at University Hospital, the facility associated with the University of Texas Health Science Center at San Antonio, from 1 January 1993 to 31 December 1997. We defined LEA as the surgical removal of bones by transection at any level of lower extremity. Autoamputations or resections of the partial bone with the distal end intact were excluded. The procedures performed were identified from ICD-9-CM codes 84.11–84.18, and diabetes was identified from any of 250 related codes. Medical records of each identified patient with an amputation were reviewed; patient cases were excluded if the patients had a traumatic LEA ($n = 5$), history of LEAs ($n = 53$), incomplete records regarding the history of their LEA ($n = 54$), or insufficient follow-up (<10 months; $n = 64$). After all exclusions, the study population consisted of 277 diabetic patients who presented to the center for their first LEA.

Medical records of original amputations were reviewed, and the date, extremity, and level of amputation were identified. Subjects were divided into four groups according to the original level of their amputation: toe, ray, midfoot (transmetatarsal amputation [TMA], Lisfranc, or Chopart), or major (Syme, transtibial, transfemoral, or hip disarticulation). Patients' sex, ethnicity, and age at the time of the amputation were identified. Efforts were made to identify the vascular status of each patient, but we had no routine record of vascular studies before 1995.

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Abbreviations: LEA, lower-extremity amputation; PAD, peripheral arterial disease; TMA, transmetatarsal amputation.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Demographics of study population per original amputation level*

	All patients	Toe	Ray	Midfoot	Major	*P*
n	277	61	114	38	64	—
Male	188 (67.9)	37 (60.7)	81 (71.1)	31 (81.6)	39 (60.9)	0.08
Ethnicity						
White	33 (11.9)	12 (19.7)	9 (7.9)	4 (10.5)	8 (12.5)	
Hispanic	221 (79.8)	47 (77.0)	95 (83.3)	26 (68.4)	53 (82.8)	
Black	22 (7.9)	1 (1.6)	10 (8.8)	8 (21.1)	3 (4.7)	
Others	1 (0.4)	1 (1.6)[a,b]	0 (0.0)[a]	0 (0.0)[b,c]	0 (0.0)[c]	a: 0.01; b: 0.04; c: 0.03
Age at first amputation	53.8 ± 10.4	53.3 ± 10.9	52.4 ± 10.5[a]	51.7 ± 9.5[b]	58.0 ± 9.4[a,b]	a: 0.002; b: 0.01
PAD	117 (42.2)	29 (47.5)[a]	34 (29.8)[a,b]	13 (34.2)[c]	41 (64.1)[b,c]	a: 0.02; b: <0.0001; c: 0.003
End-stage renal disease	31 (11.2)	7 (11.5)[a]	4 (3.5)[a,b]	4 (10.5)	16 (25.0)[b]	a: 0.03; b: <0.0001
Left or/and right bypass	66 (23.8)	21 (34.4)[a]	27 (23.7)	8 (21.1)	10 (15.6)[a]	a: 0.01
Smoker						
Yes	89 (32.1)	16 (26.2)	42 (36.8)	17 (44.7)	14 (21.9)	
No	105 (37.9)	26 (42.6)	46 (40.4)	13 (34.2)	20 (31.3)	
Quit	37 (13.4)	11 (18.0)	17 (14.9)	0 (0.0)	9 (14.1)	
Unknown	46 (16.6)	8 (13.1)	9 (7.9)	8 (21.1)	21 (32.8)	0.22
Deceased by 31 December 2003	95 (34.3)	20 (32.8)[a]	29 (25.4)[b]	10 (26.3)[c]	36 (56.3)[a,b,c]	a: 0.008; b: 0.0006; c: 0.003
Follow-up time (years)						
Average	4.7 ± 2.9	5.4 ± 2.7[a]	5.4 ± 2.5[b]	4.4 ± 3	3.3 ± 2.9[a,b]	a: 0.0006; b: 0.0001
Range	0.005–10.6	0.09–9.9	0.02–10.6	0.008–10.4	0.005–10.6	
Median (interquartile)	5.2 (2.2–6.8)	5.6 (2.7–7.7)	6.1 (3.5–7.1)	4.1 (2.0–6.6)	2.8 (0.4–5.9)	

Data are *n* (%), means ± SD, or median (interquartile range).

Patients identified as having peripheral arterial disease (PAD) were those with a history of lower-extremity bypass surgery or those whose record indicated ICD-9-CM code 440, 443, or 444. End-stage renal disease was identified by code 585 or 586 or CPT codes for hemodialysis, peritoneal dialysis, or transplantation.

Reamputation episodes

Reamputations performed on the ipsilateral or contralateral limb were recorded through 31 December 2003 (the end of the study period), the patient's date of death, or the patient's last clinical encounter for those censored before the end of observation. The last clinical encounter day within our system was identified for each subject by appointment log, and death dates were determined using the National Death Index. Care was taken to include consideration of reamputation of any limb. Medical records were also reviewed for nonrecorded reamputations performed outside of our center.

A "reamputation episode" was defined as the removal of bones to advance one amputation level higher. Therefore, any soft tissue surgeries such as debridement, incision and drainage, or secondary closure were excluded, as were revision surgeries performed at the same level. We also identified any reamputation performed on the same limb within a 2-week period and counted only the last level of amputation. In these cases, the earlier episodes were disregarded because we considered those surgeries as further debridement surgery and not true amputation.

In this study, we focused only on the first reamputation episode per limb because we were interested in differentiating limbs that received reamputation from the limbs that were not reamputated during the observational period. Time without reamputation for each limb was calculated from the date of original amputation to the date of reamputation, end of the observation period, patient censorship, or patient death. The cumulative reamputation rates for each limb and level were calculated from the cumulative incidence of reamputation at 1, 3, and 5 years.

Statistical methods

All statistical analyses were conducted using SAS Version 9.1 (SAS Institute, Cary, NC). A two-sided $P < 0.05$ was considered statistically significant. The *P* value of multiple comparisons was adjusted with Bonferroni correction. Continuous and discrete variables from the demographic data were presented as means ± SD and frequency with the percent, respectively. The continuous valuables were examined using ANOVA with the Tukey-Kramer post hoc test. We plotted cumulative incidence curves for ipsilateral and contralateral reamputation episodes to illustrate the risk of reamputation for each limb. We used χ^2 or Fisher's exact test to compare the reamputation risk among different levels of patients with an amputation. Because the age distribution was significantly different among the groups, Cox proportional hazards regression analyses were performed to estimate the hazard ratio adjusting for age.

RESULTS — The mean age of the subjects was 53.8 ± 10.4 years, and 67.9% of the subjects were male. Most subjects (79.8%) were Hispanic, and the median observational period (first amputation to death, last encounter, or study end date of 31 December 2003) was 5.2 ± 2.8 years (range 2 days to 10.5 years). Ray amputation was the most frequent type of first LEA (41.2%), followed by major (23.1%), toe (22.1%), and midfoot (13.6%) amputation.

Demographic characteristics of subjects by their first amputation level

Demographic data for each amputation group and the results of the χ^2 test are

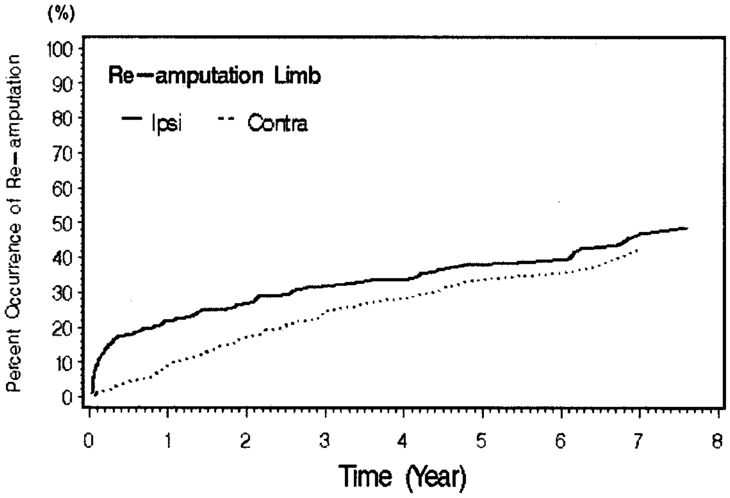

Figure 1—*Reamputation rates per limb.*

shown in Table 1. Subjects who had a major amputation as their first amputation were significantly older than those who had a midfoot ($P = 0.01$) or ray ($P = 0.002$) amputation.

PAD was more common in toe and major amputation groups than in ray and midfoot amputation groups (toe vs. ray: $P = 0.02$; major vs. ray: $P < 0.001$; major vs. midfoot: $P = 0.03$) as well as end-stage renal disease (toe vs. ray, $P = 0.03$; major vs. ray, $P < 0.001$). By the end of the study period, 34.3% of the subjects were deceased. Those with major amputations were more likely to be deceased than any other amputee group (major vs. toe: $P = 0.008$; major vs. ray: $P = 0.006$; major vs. midfoot: $P = 0.003$). There was no statistical significance in the distribution of sex or ethnicity among groups.

Reamputation rate: ipsilateral versus contralateral limb

The reamputation rate for each limb was illustrated by cumulative incidence curves (Fig. 1). Statistical tests could not be performed to compare these two curves because they are dependent on each other (i.e., a patient can have one reamputation episode to the contralateral with no ipsilateral reamputation or a patient can have reamputation bilaterally). However, these curves illustrated a clear difference by limb for each specific time period, and they varied depending on the length of time after the original amputation.

Overall rate of reamputation

Cumulative rates of reamputation to either the ipsilateral or contralateral limb, whichever occurred first, were calculated to compare with the previously reported rates. The overall reamputation rates for all subjects at 1, 3, and 5 years were 26.7, 48.3, and 60.7%, respectively.

Rate of reamputation on ipsilateral limb by level of original amputation

The cumulative reamputation rates of the ipsilateral limb for each level at 1, 3, and 5 years are shown in Fig. 2. The numerical values for each rate at 1, 3, and 5 years were as follows: toe: 22.8, 39.6, and 52.3%; ray: 28.7, 41.2, and 50%; midfoot: 18.8, 33.3, and 42.9%; and major: 4.7, 11.8, and 13.3%. There was a statistically significant difference between toe and major (1 year: $P = 0.01$; 3 years: $P < 0.01$; 5 years: $P < 0.001$) and between ray and major (1 year: $P < 0.001$; 3 years: $P = 0.001$; 5 years: $P < 0.001$). The hazard ratio adjusted for age was calculated and showed that an increase in one original level of amputation would decrease the reamputation rate by 34% (hazard ratio 0.66; $P = 0.0002$).

Rate of reamputation on contralateral limb by original amputation level

Cumulative reamputation rates on the contralateral limb for each level at 1, 3, and 5 years are shown in Fig. 3. Numerical values for each were as follows: toe: 3.5, 18.8, and 29.5%; ray: 9.3, 21.6, and 29.2%; midfoot: 9.4, 18.5, and 33.3%; and major: 11.6, 44.1, and 53.3%. There was no statistically significant difference at 1 year, but a significant difference was found at year 5 between toe and major ($P = 0.01$) as well as at years 3 and 5 between ray and major (3 years: $P = 0.01$; 5 years: $P = 0.01$). The major group had a higher reamputation risk to the contralateral limb than did the toe and ray amputation groups. The hazard ratio adjusted for age was calculated but showed no statistical significance.

CONCLUSIONS

— In this retrospective cohort study, we stratified reamputation risk by limb and amputation level. This is the first study to clearly demonstrate the difference in reamputation rates by limb using the same subjects.

The overall reamputation rate to the ipsilateral or contralateral side found in our study was significantly higher than previously reported rates. The prospective study done by Larsson et al. (5) reported cumulative reamputation rates at 1, 3, and 5 years as 14, 30, and 49%, respectively. Our rates are higher by 10% in every time period; we speculate there are two reasons for these differences: *1*) we had a significantly higher number of Hispanics, a population that has been shown to have a higher risk of amputation (16–19); and *2*) most of the patients in our study had minor amputations and thus had more limb levels to potentially be amputated with lower

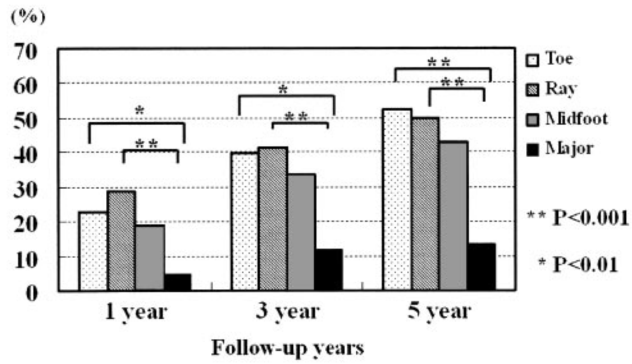

Figure 2—*Cumulative rate of ipsilateral reamputation by level of original amputation.*

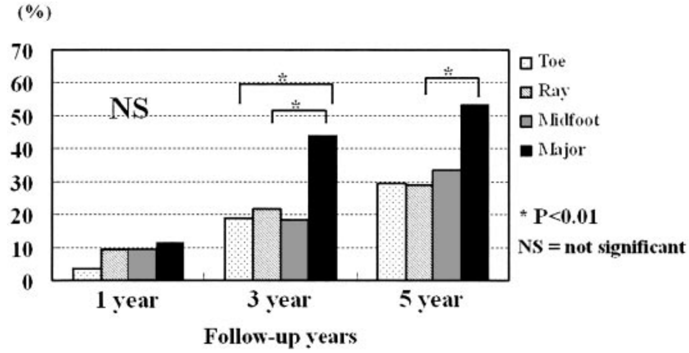

Figure 3—*Cumulative rate of contralateral reamputation by level of original amputation.*

mortality, whereas Larsson et al. (5) had more subjects with major amputations.

Our results showed that ipsilateral limbs had a significantly higher reamputation rate than contralateral limbs, especially in the first 6 months after the initial amputation. This observation correlates well with those from previous studies by Ebskov and Josephson (20) using data from the Danish Amputation Registry and Mueller et al. (15). Many factors could have contributed to this observation. LEA causes a change in the biomechanics of the amputated limb and potentially creates higher pressure areas and/or new bony deformities (21,22). The poor selection of the original amputation level may leave patients with nonhealing stumps, thereby necessitating reamputation. For an amputation to be successful, patients must comply with wound care and off-loading, and careful discharge planning and patient education may be necessary for a better outcome in this period.

The reamputation rate of the contralateral limb in our study was low in the first 6 months, probably because of the patients' decreased activity level. However, as amputated sites healed and patient mobility was regained, we observed an increase in reamputation occurring in the contralateral limb, whereas the frequency of ipsilateral reamputation slowed by comparison. In the end, the reamputation rate of the contralateral limb became almost as high as the rate for the ipsilateral limb.

Our findings were reasonable given that patients with more distal amputations had the higher reamputation rate. Only one earlier study compared the difference in reamputation rates by original level of reamputation. Larsson et al. (5) found no significant difference in the total rate of reamputations between a major and minor amputation, but the rate of new major amputations was significantly higher for patients with a major amputation. That group used a cumulative rate, combining contralateral and ipsilateral reamputation; their results might have been different if they had differentiated by limb.

There have been various reports on reamputation rates for a particular level of amputation. Nehler et al. (23) reported a high incidence of intermediate-term persistent and recurrent infection leading to a modest rate of limb loss in diabetic patients undergoing primary digit amputations for sepsis. Dalla Paola et al. (11) found that ~10% of the 89 diabetic patients who had a first ray amputation received reamputation within the 16-month follow-up, and Murdoch et al. (12) reported that 51% of patients with a first ray amputation had ipsilateral reamputation within 10 months. Our study included the same subjects as those in Murdoch et al.'s study. The TMA has long been advocated as a stable level of amputation. Muller reported in his 4.5-year follow-up study that 28% of his TMA patients required higher amputation (15), and other studies showed equally consistent results (13,14). However, none of these studies indicated how censored subjects were treated.

We found that patients with major amputations had a significantly higher risk of contralateral reamputation. We speculate this was because these patients relied solely on the contralateral limb for ambulation, thus making the limb more susceptible to trauma. Also, because we found PAD was more common in patients with a major amputation, it is reasonable to speculate that PAD affected remnant limbs, thereby resulting in an increase in reamputation to the contralateral side. Bodily and Burgess (10) studied the reamputation rate of patients with a major amputation from critical limb ischemia and found that 8 of 22 diabetic patients had a reamputation (36.3%) to their contralateral limb at 2-year follow-up. Reported rates of contralateral reamputations vary at years 3 (23–30%) and 5 (28–51%) (8,9).

The limitations of our study included the lack of several important variables, such as type and duration of diabetes, extent of neuropathy, and presence of infection. Neurological and vascular status are crucial variables for prognosis in diabetic patients. However, in this study, we had to rely on ICD-9-CM codes to document the presence of PAD and lacked neurological assessment variables. Our lesser ability to rely on the presence of PAD and the lack of neurological data limited our study in seeking the etiology of reamputation.

This was also a one-center retrospective study, and our subjects were unique in that they were mostly Hispanic and younger than those in previous reports. Therefore, our results cannot be extrapolated to many other facilities. One reason for our subjects being younger than other study populations is that we eliminated subjects with a history of LEA. In other studies, most study subjects had a history of LEA and thus tended to be older than those who never had LEA.

Detailed mortality data were not presented in this study because we eliminated the effect of those who died by performing a cumulative incidence curve analysis. In this way, we could properly present the reamputation rate of the surviving amputation patients, which many former studies failed to do. Although we chose to do so for the purpose of this study, we cannot neglect the importance of mortality. We reported that 34% of the subjects died by the end of the observation period of our study. More detailed mortality has been investigated and will be presented in a follow-up study for better understanding of the prognosis of this cohort.

In our study, a podiatry/orthopedic department treated most of the subjects, with readily available specialized referrals to other departments such as vascular surgery and a wound care unit. The protocol of diabetic foot management was standardized using the University of Texas wound classification system. The decision to perform LEA is influenced by the medical structure of the facility and professional opinions (24). Therefore, a facility with a different medical structure and different specialties may find different results from ours.

Although we did not discuss the ethnic and socioeconomic characteristics of our subjects, both variables have been shown to influence prognosis (17–19,25–27). We did have insurance data for each subject, but we were unable to present these data in this study due to length limitations.

Despite the above-noted limitations, we believe that our study provides a more in-depth understanding of reamputation risk in diabetic individuals by stratifying their risk per limb and per level. Our findings suggest that the rates of ipsilateral reamputation are different from those of the contralateral limb and that the level of amputation portends a different level of reamputation risk. These findings will help clinicians focus preventive efforts and more effectively use medical resources during individualized at-risk periods for diabetic patients undergoing first-time amputations.

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