Functional Status of Persons With Diabetes-Related Lower-Extremity Amputations

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OBJECTIVE — It is reasonable to predict that diabetes-related lower-extremity amputations have a detrimental impact on quality of life. However, we are unaware of any study in the medical literature describing the functional level of diabetic patients with amputations. The objective of this study was to evaluate amputations among diabetic patients and to determine the functional level of these patients with the Sickness Impact Profile (SIP).

RESEARCH DESIGN AND METHODS — We enrolled 124 patients with diabetes. Case subjects ($n = 35$) were defined as patients who had undergone amputation of the lower-extremity, and control subjects ($n = 89$) were defined as patients who had not undergone amputation. Study participants received a standard history and physical examination.

RESULTS — Both the physical dimension scores (33.5 ± 14.9 vs. 22.3 ± 14.7, $P < 0.001$) and the total SIP scores (27.6 ± 9.9 vs. 22.5 ± 10.3, $P = 0.013$) were significantly higher for amputees. However, the psychosocial dimension scores were not significantly different between case and control subjects (14.9 ± 8.9 vs. 15.2 ± 10.0, $P > 0.05$). Post hoc analysis showed that the group of patients who had undergone transtibial amputation had a significantly higher total impairment score than patients who had not undergone amputation ($P = 0.039$). This is in contrast to patients with toe or midfoot amputations, for whom total impairment scores were not significantly higher than those for the control subjects. Interestingly, bilateral amputees did not have significantly higher scores on either SIP dimension compared with unilateral amputees.

CONCLUSIONS — These findings exemplify the detrimental physical and psychosocial health status of patients with diabetes-related lower-extremity amputation.

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Diabetes continues to be the most common underlying cause of lower-extremity amputation in the U.S. Despite goals set by Healthy People 2000, the declaration of the Veterans Administration and Saint Vincent's to reduce amputations among individuals with diabetes by 40 or even 50%, the incidence has not decreased (1–4). In fact, one study reported an 8% increase in amputations from 61 of 10,000 in patients with diabetes in 1990 to 66 of 10,000 in patients with diabetes in 1995 (5). After diabetic patients undergo amputation, their risk of developing a foot ulcer or of requiring a second amputation increases dramatically (6–8). In addition, the in-hospital and 5-year mortality experience after an amputation is very high. A total of 5–10% of amputees die during hospitalization, and as many as 50% of patients with diabetes die within the 5-year period after amputation (9,10). In addition to death, amputation of the contralateral limb and disability are frequent sequelae of diabetes-related amputation of a limb (11,12). It is generally assumed that lower-extremity amputations have a significantly deleterious impact on quality of life. However, to our knowledge, there are no studies or reports in the literature that quantitatively assess how amputations affect the lifestyle or functional status of patients with diabetes. Therefore, the objective of this study was to evaluate amputations among patients with diabetes and to determine the functional status of patients with diabetes who had undergone amputation of the lower-extremity.

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Abbreviations: SIP, Sickness Impact Profile.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

RESEARCH DESIGN AND METHODS

— Data were collected as part of a case-control study. A total of 35 patients with diabetes who had undergone amputation and 89 control subjects with diabetes who had not undergone amputation were enrolled. The case group had amputations ranging from toe level to transfemoral. After providing informed consent, all patients were enrolled sequentially. The presence of diabetes was based on World Health Organization criteria (13). Descriptive statistics for this population are summarized in Table 1.

Study participants underwent history and physical examination to evaluate exposure variables, including demographic data, general medical and surgical history, diabetes and history of diabetes-related complications, and neurovascular status of the lower-extremities. We assessed peripheral sensory neuropathy using a Biothesiometer (Biomedical Instrument, Newbury, OH) to determine vibration perception threshold at the distal great toe (14). Impaired sensation, or loss of protective sensation, was defined as a vibration perception threshold >25 V (15). Lower-extremity peripheral vascular disease was evaluated by calculating an an-

Table 1—*Description data*

	History of amputation	No history of amputation	*P*
n	35	89	
Age (years)	56.8 ± 9.9 (31–74)	52.4 ± 9.9 (30–71)	0.031
Men	77.1	56.2	0.03 (OR 2.5, CI 1.0–7.1)
Duration of diabetes (years)	19.8 ± 7.0 (3.0–35.0)	11.2 ± 9.4 (0.1–35)	<0.001
HbA_{1c}(%)	9.4 ± 2.3 (6.1–15.6)	9.7 ± 2.6 (3.0–13.6)	NS
BMI (kg/m^2)	29.2 ± 5.3 (21.9–43.2)	29.6 ± 6.1 (20.0–52.7)	NS
Coronery artery disease	20.6	16.7	NS
Missing pulse	85	58.3	0.005 (OR 4.1, CI 1.5–11.8)
ABI (left)	1.18 ± 0.52 (0.19–2.00)	1.11 ± 0.33 (0.07–2.00)	NS
ABI (right)	1.13 ± 0.41 (0.10–1.90)	1.14 ± 0.33 (0.50–2.00)	NS
ABI <0.8 left foot	18.2	11.4	NS
ABI <0.8 right foot	19.2	10.0	NS
VPT (left)	36.4 ± 13.4 (9.0–50.0)	23.9 ± 13.5 (2.0–50.0)	<0.001
VPT (right)	37.0 ± 12.4 (5.0–50.0)	23.1 ± 2.0 (2.0–50.0)	<0.001
VPT >25 V (left foot)	83.9	38.6	<0.001 (OR 8.3, CI 2.9–23.8)
VPT >25 V (right foot)	84.4	39.8	<0.001 (OR 8.1, CI 2.9–23.3)

Data are *n*, means ± SD (range), or %. ABI, ankle brachial index; OR, odds ratio; VPT, vibratory perception threshold.

kle-brachial systolic blood pressure index and assessing pedal pulses. Impaired vascular supply was defined as an ankle-brachial index <0.8 or absence of any pedal pulse (6,16). Coronary artery disease was defined as presence of angina pectoris or history of coronary disease.

The Sickness Impact Profile (SIP) was administered to all subjects. This survey was developed at the University of Washington by Bergner et al. (17). The aim of this survey was to provide a measure of perceived health status that is sensitive enough to detect changes or differences in health status that occur over time or between groups (17). The SIP consists of 136 questions in 12 categories (Table 2). The questions concern various aspects of the patient's functional status. The survey can be categorized into three different areas: a physical dimension, a psychosocial dimension, and independent categories. The physical dimension can be divided into ambulation, mobility, and body care and movement; the psychosocial dimension consists of social interaction, alertness behavior, emotional behavior, and communication. Sleep and rest, eating, work, recreation and pastimes, and home management comprise the independent categories. The SIP score and the separate category scores can range from 0 to 100. In general, a score ranging from 0 to 3 represents little or no disability, a score from 4 to 9 represents mild disability, a score from 10 to 19 represents moderate disability, and a score >20 represents severe disability (17).

The technique for scoring the SIP questionnaires has been described previously (17,18). Our questionnaire was delivered in either English or Spanish, according to patient's preference. Student's *t* test was used for independent samples to compare values for the physical and psychosocial dimensions, as well as for the total SIP score, between case and control subjects. Subsequently, the case group was divided into patients with low-level amputations and patients with high-level amputations. Amputations were defined as mid-level when a limb salvage procedure was performed. These procedures included toe, transmetatarsal, Lisfranc, and Charcot amputations. High-level amputations were defined as more proximal amputations and included transtibial and transfemoral amputations. Case subjects were also divided into two groups, based on whether they had undergone unilateral or bilateral amputations. An analysis of variance with a Gabriel's post hoc test was performed on all participants in the study to investigate any differences between individuals with low-level amputations, individuals with high-level amputations, and the control subjects. The same test was used on unilateral amputees, bilateral amputees, and control subjects to find any differences in functional level. Furthermore, we used a χ^2 test with odds ratio and 95% CI to assess differences in dichotomous variables between the case and control subjects. For all analyses, we used an α of 0.05.

RESULTS — Individuals who had undergone diabetes-related amputation had significantly higher impairment scores than control subjects in both the physical dimension and total SIP (Table 3). In contradistinction, the psychosocial dimension functional scores were not significantly different between patients with diabetes who had or had not undergone amputation. Analysis of the amputation group, stratified by amputation level, suggests that patients with a higher amputation level are more debilitated (Table 4). Only two patients underwent an additional proximal amputation after the initial amputation. In these cases, the most proximal amputation was taken for analyzing purposes. Post hoc analysis showed that the group of patients who had not undergone amputation had a significantly better physical functional level than patients who had undergone toe or midfoot amputation ($P = 0.019$) and pa-

Table 2—*The Sickness Impact Profile*

Dimension	Items describing behavior related to:	Selected items
Independent categories	Sleep and rest	I sit during much of the day / I sleep or nap during the day
	Eating	I can only feed myself with someone's help
	Work	I am not working at all / I often act irritable toward my work associates
	Home management	I am not doing any of the maintenance or repair work around the house that I usually do
	Recreation and pastimes	I am going out for entertainment less / I am not doing any of my usual physical recreation or activities
I. Physical	Ambulation	I walk shorter distances or stop to rest often / I do not walk at all
	Mobility	I stay within one room / I stay away from home only for brief periods of time
	Body care and movement	I do not bathe myself at all but am bathed by someone else / I am very clumsy in body movements
II. Psychosocial	Social interaction	I am doing fewer social activities with groups of people / I isolate myself as much as I can from the rest of the family
	Alertness behavior	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things
		I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is
	Emotional behavior	I laugh or cry suddenly / I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen
	Communication	I am having trouble writing or typing / I do not speak clearly when I am under stress

tients who had undergone a transtibial or higher amputation ($P = 0.001$). No significant differences were found in either physical or psychosocial functional status between the group with low-level amputations and the group with high-level amputations. The group of patients with high-level amputations reported a significantly higher total impairment score than patients who had not undergone amputation ($P = 0.039$). In contrast, patients who had undergone a toe or midfoot amputation did not report a significantly higher total impairment score than patients who had not undergone amputation.

Furthermore, patients who had not undergone amputation had a significantly higher self-reported physical functional level than patients with a unilateral amputation ($P = 0.002$) and patients with a bilateral amputation ($P = 0.031$). Surprisingly, post hoc analysis showed no significant difference in physical functional level between patients with a bilateral amputation compared with either control subjects or patients with a unilateral amputation. No significant differences were found in psychosocial functional level between control subjects, patients with a unilateral amputation, and patients with bilateral amputations.

CONCLUSIONS — The results of this study suggest that patients who have undergone diabetes-related amputation of a limb have a worse functional level than patients without an amputation. Furthermore, patients with a more proximal amputation seem to be more functionally impaired than those with a more distal amputation or those who have not undergone amputation.

Although the SIP was not originally designed for a population of patients with diabetes in the narrow sense, we believe the data offer face validity because they were validated for patients undergoing rehabilitation and outpatients with chronic medical problems (19). Table 5 displays data gathered with SIP from patients with various diseases from different studies. For the data from the general female population, 112 women of different age groups were interviewed (20). These patients served as a control group in a study with SIP in a group of 99 women with rheumatoid arthritis (age 56.5 ± 11.4 years, duration of rheumatoid arthritis 13.7 ± 11.2 years). They also served as a control group for 15 women with advanced rheumatoid arthritis. No average age or duration of disease was reported for these patients. The other group of patients with rheumatoid arthritis consisted of 79 patients (56 men and 23 women) (21). A total of 89% of these patients were of white race. The average duration of disease was 12 years. The data of the other control group, referred to in Table 5 as the general population group, were collected as part of a prospective cohort study of 329 subjects with an average age of 35 ± 11.5 years (22). A total of 70% of this group were men, 75% of whom were of white race. The data shown in Table 5 under the category of trauma were collected from the same cohort of patients 6 months after the individuals sustained

Table 3—*Comparison of the different SIP dimensions*

	Psychosocial dimension	Physical dimension	Total SIP
Case subjects	14.9 ± 8.9	33.5 ± 14.9*	27.6 ± 9.9†
Control subjects	15.2 ± 10.0	22.3 ± 14.7*	22.5 ± 10.3†

Data are *n*. *$P < 0.001$; †$P = 0.013$.

Table 4—*Result of the analysis of variance of the SIP*

	No amputation (n = 89)	Midlevel amputation (n = 26)	High amputation (n = 9)	P	No amputation (n = 89)	Unilateral amputation (n = 23)	Bilateral amputation (n = 12)	P
Psychosocial dimension	15.2 ± 10.0	15.1 ± 9.1	14.0 ± 8.5	0.945	15.2 ± 10.0	14.8 ± 9.4	14.9 ± 8.2	0.986
Physical dimension	22.3 ± 14.7	31.0 ± 14.7	40.6 ± 13.9	$<$0.001	22.3 ± 14.7	33.7 ± 15.3	33.1 ± 14.9	0.001
Total score SIP	22.5 ± 10.3	26.6 ± 10.3	30.5 ± 8.9	0.029	22.4 ± 10.3	27.7 ± 10.7	27.5 ± 8.9	0.046

Data are means ± SD.

fracture of the lower-extremity. Data on chronic low back pain were collected from 107 patients (66 men and 41 women) (23). The average age was 39.7 ± 9.5 years and the duration of pain was 36.4 ± 34.7 months. On average, these patients underwent 1.22 ± 1.4 surgical procedures.

When compared with other reports using SIP on different populations, it seems that the diabetic amputee group in our study is affected far more profoundly than individuals with chronic ailments such as rheumatoid arthritis, trauma, and chronic low back pain (Table 5). An exception might be advanced rheumatoid arthritis. It seems that advanced rheumatoid arthritis has an even more devastating effect on physical functional status than amputation in the presence of diabetes. Surprisingly, the psychosocial impairment of advanced rheumatoid arthritis seems somewhat less than that of diabetes or diabetes-related amputation. It can be concluded that the data mentioned in Table 5 can serve as a comparison for the data we found in our study. However, the data must be compared with care, because the groups are not entirely equal in assembly.

A possible shortcoming of the study is the presence of more severe disease in the group of patients with amputations. In general, patients who have undergone amputation of the lower-extremity have a longer history of diabetes and, therefore, have developed more complications of this multisystemic disease. This is indeed demonstrated in Table 1, in which the high prevalence of peripheral vascular disease neuropathy can be noticed in the patients who have undergone amputation. Although the results suggest that patients who have undergone amputation have a worse functional level, more research is needed to fully assess the direct impact of the lower-extremity amputation on functional status.

To our knowledge, no studies in the literature have quantified the relationship between diabetes-related lower-extremity amputation and self-reported functional level. Investigators from orthopedic or rehabilitation medicine specialties usually define amputation outcomes as ambulatory capacity or functional independence. Vascular or general surgeons, on the other hand, are more likely to define outcomes as successful revascularization or simply on limb salvage and wound healing of the stump. In this study, we attempt to assess the self-reported functional level of a patient undergoing amputation of the lower-extremity. Therefore, this study might add a new perspective to the outcome of diabetes-related limb amputation.

Our data suggest that the detrimental effect of amputation becomes more significant when the amputation level is more proximal. This supports the need for surgeons to attempt foot salvage procedures before performing a major amputation.

Table 5—*SIP scores per category*

SIP Categories	Female general population (20)	General population (22)	Diabetes with amputation	Diabetes without amputation	Trauma (22)	Chronic lower back pain (23)	Rheumatoid arthritis (21)	Rheumatoid arthritis (20)	Advanced rheumatoid arthritis (20)
Total SIP		2.5	27.6	22.5	9.5	23.8	15.6	22.1	32.9
Physical impairment		1.3	33.5	22.3	8.2	17.7	14.0	21.4	41.4
Ambulation	4.7	1.1	25.8*	15.7	16.1	20.5	21.0	26.0	
Body care and movement	2.8	0.9	50.8*	35.0	5.7	15.8	12.7	19.3	
Mobility	2.5	1.1	40.1*	28.7	6.0	20.2	10.4	21.1	
Psychosocial impairment		2.5	14.9	15.2	6.8	24.7	11.3	11.0	13.1
Emotional behavior	7.9	2.1	14.6	17.5	9.6	30.6	13.2	16.7	
Social interaction	6.1	3.0	31.0	27.3	8.2	31.0	11.7	12.2	
Alertness behavior	5.0	3.0	6.7	8.0	6.0	24.2	13.0	7.6	
Communication	1.4	1.4	2.0	2.7	1.9	8.6	6.9	7.4	
Independent categories									
Work	2.6	8.8	33.8*	25.0	32.3	57.6	46.5	41.7	
Sleep and rest	10.3	5.1	17.9	20.3	12.8	28.4	17.6	26.7	
Eating	1.6	1.2	7.2	7.9	1.2	2.7	3.5	5.0	
Home management	4.1	2.6	28.0	22.8	14.5	33.7	26.3	41.9	
Recreation and pastimes	13.8	4.2	16.5	13.5	17.6	35.9	26.7	31.2	

*$P < 0.05$.

Controversy exists in the literature regarding the success of these minor amputations, because there is often a need for reamputation and more proximal foot amputations (24). The data from this study, however, suggest that the effect of these minor amputations is less deleterious to a patient's lifestyle than one major amputation. Because we only had two patients who received additional more proximal amputations, our data do not allow us to identify a possible cumulative effect of these reamputations on physical or psychosocial impairment level.

We were surprised to discover the high level of impairment among subjects who had diabetes but no history of amputation. In fact, with the instrument used in this study, we could not detect a significant difference in the psychosocial dimension scores between amputees and nonamputees. We believe this may be due to factors surrounding perception of one's limb. In the absence of sensation, a patient may "psychologically disown" a limb well before any inciting event precipitates amputation (25,26). Another explanation is offered by Deyo et al. (21) in their study on patients with rheumatoid arthritis. In these patients, the same discrepancy was found between self-reported physical and psychosocial impairment. Deyo et al. (21) suggest that this relatively lesser psychosocial impact might be a result of the patients' control over their physical disabilities. Over time, patients might cope with their physical limitations and alter their functional expectations (21). This psychological mechanism might very well play a role in diabetic patients who have undergone amputation.

The incidence of diabetes is growing rapidly and requires a physician that is dedicated to handling the many issues that plague patients with this disorder, from diabetic foot and wound care to nutrition, eye examinations, glucose control, education, renal disease, and peripheral vascular disease. As demonstrated by the data from this and other reports, diabetes seriously affects a patient's self-reported functional status. The information gathered with the SIP can be used to evaluate the extent and the nature of patients' impairments more appropriately.

Previous reports in the medical literature have emphasized the financial costs and the effect of lower-extremity amputations on subsequent morbidity and mortality (9,27–29). Amputations in patients with diabetes have a significant impact on functional level. Amputation has the most significant impact on the physical aspect of lifestyle, specifically affecting ambulation, body care and movement, and mobility. It also affects the overall lifestyle and ability to perform daily tasks to a significant degree, as outlined in the SIP questionnaire. Although we disapprove of performing distal amputations that have a negligible chance of healing, the astute clinician should be compelled to respect this impact when planning lower-extremity salvage procedures involving amputation of all or part of the foot.

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