

# Diabetes-related lower-extremity amputation incidence and risk factors: a prospective seven-year study in Costa Rica

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## Suggested citation

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## ABSTRACT

**Objective.** To analyze the incidence and determinants of lower-extremity amputation (LEA) in people with diabetes in a low-income community in Costa Rica.

**Methods.** Data on LEA incidence were collected during a seven-year follow-up (2001–2007) in a diabetes patient cohort (n = 572). Risk factors were analyzed using the Cox proportional hazards regression model and baseline variables from the year 2000 (socio-demographic characteristics, comorbidity, metabolic control, treatment, and chronic microvascular complications).

**Results.** LEA incidence was 6.02 per 1 000 person-years (8.65 in men and 4.50 in women). Known risk factors (sex, years of diabetes, elevated glycosylated hemoglobin [HbA1c], retinopathy, insulin therapy, and prior amputation) were highly significant.

**Conclusions.** Those most likely to undergo LEA among Costa Rican diabetic patients were men with 10 or more years of diabetes and average HbA1c  $\geq$  8% who used insulin and had diabetic retinopathy. Patients on insulin therapy were at greatest risk, especially those with a previous amputation. Diabetic patients with the above-mentioned profile should be considered to be at very high risk of LEA and followed closely by the health care system.

## Key words

Diabetes mellitus, type 2; lower extremity; amputation; risk factors; diabetes complications; Costa Rica.

Diabetes mellitus type 2 (diabetes) is currently considered a pandemic, affecting both developed and developing countries. This disease is largely associated with economic development, urbanism, and an aging population (1, 2). In recent years, diabetes has attracted increasing concern worldwide because of its impact on the quality of life of those with the disease, and their family members; the growing costs to national health systems; and the indirect costs of

the productivity losses associated with diabetes-related disability and premature death—all of which are related to diabetes chronic complications. Diabetes is the cause of approximately 66% of nontraumatic lower-extremity amputations (LEAs) and 30%–45% of renal failure cases requiring renal replacement therapy (dialysis). It is also the leading cause of blindness in adults (3–5).

Diabetic peripheral neuropathy, which can cause ulceration gangrene, leading to amputation, is one of the most frequent chronic complications of the disease (6). This condition occurs among 60%–70% of people who have been diagnosed with diabetes for 10 or more years. The relative risk of neuropathy is at least seven

times higher and the risk of LEA 18–30 times higher among those with diabetes versus the general population (6, 7). Foot ulceration is found prior to 85% of amputations among diabetic patients, and about 25% of diabetic amputees require a contralateral amputation. The survival rate for diabetic patients following amputation is only about 50% at three years (7–9). Diabetes-related LEA is related to age, years of diabetes, and poor metabolic control of the disease (8).

In Costa Rica, diabetes has a high prevalence in the adult population (approximately 8%) (10) and is the most costly disease for the Social Security system (*Caja Costarricense de Seguro Social*, CCSS) (11). Despite the fact that all

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diabetes chronic complications, including LEA, have a great impact on diabetic individuals as well as society as a whole, to the best of the authors' knowledge no study to date has analyzed the incidence and risk factors of LEA in Costa Rica's diabetic population. To help fill this gap, the current study analyzed data on incidence of LEA collected over a seven-year follow-up and baseline characteristics of a cohort of diabetic patients in a low-income community in Costa Rica.

## MATERIALS AND METHODS

This prospective study was conducted at the primary health care level in San José Province, Costa Rica, from 2001–2007. The research was approved by the ethics committee of the University of Costa Rica.

### Study population

The cohort of diabetic patients ( $n = 572$ ) was identified at the primary health care level in the year 2000 in Health Area 3 of Desamparados ("Desamparados 3"), a marginal urban health area (12). Based on its epidemiological surveillance data for the year 1999, 399 persons with diabetes were already receiving primary care attention regularly. New diabetic patients were diagnosed in 2000 through a screening of adults aged 20 years and older living in the area ( $n = 15\,827$ ) using the 1997 American Diabetes Association (ADA) criteria. Four screening strategies were used: 1) opportunistic screening by physicians during regular checkups; 2) selective screening by primary health care technical assistants during their yearly round of home surveillance visits; 3) screening of captive populations (nursing home residents, factory workers, etc.) during programmed visits; and 4) screening at community health fairs and national health activities such as World Diabetes Day (November 14). The screening consisted of a fasting glucose test administered to all adults with at least one risk factor for diabetes. A total of 173 individuals were diagnosed with diabetes with this strategy.

At baseline (the year 2000), the cohort was characterized as predominantly female (63.1%) with a low level of education (35.0% with only a third-grade level or less education, and 16.3% with no schooling) and middle- or lower-level income (21.4% were insured by the state

and 6.7% were uninsured). More than 46.9% were 65 years old or older. Overall, the cohort's metabolic control was poor (more than 60% had an average glycated hemoglobin [HbA1c] level  $\geq 8\%$ ), with no differences between sexes. There was a high prevalence of associated diseases, such as hypertension (58%), and overweight-obesity (70.7%), both of which were statistically higher in women. There were no statistical differences by sex for dyslipidemia (78.8%), ischemic heart disease (21%), or myocardial infarction (6.7%). About 75% of the cohort experienced diabetes onset before age 60; among those patients, average number of years with diabetes was 7. There was a high prevalence of secondary complications of diabetes, including retinopathy (19.6%), neuropathy (30.6%), and nephropathy (33.6%) (13). For the most severe complications of neuropathy, such as foot ulcers and amputations, there was a prevalence of 2.5%.

### Procedures

Follow-up of the study cohort was conducted for seven years (2001–2007) and included 1) review of patients' medical records every two years during medical checkups at the primary care level of the Costa Rican health system, and 2) determination of the presence or absence of LEA, and (when present) the level of amputation. For the purposes of this study, LEA was defined as loss of some part of the lower extremity, excluding amputation due to traumatic causes.

### Statistical analysis

Baseline variables from 2000 (socio-demographic characteristics, comorbidity, metabolic control, and chronic microvascular complications) were analyzed by presence or absence of LEA during the seven-year follow-up period. Univariate analysis was performed using an unpaired Student's *t*-test for quantitative variables and Pearson's chi-squared test for qualitative variables. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using logistical regression. For the multivariate analysis, a regression analysis using the Cox proportional hazards model (Wald's forward, step-wise method) was employed. In addition to sex and age, the analysis included all variables with a significance level  $< 0.1$  in the uni-

variate analysis. Risks and confidence intervals were obtained at 95%.  $P < 0.05$  was considered statistically significant. All analyses were performed using the Statistical Package for the Social Sciences software suite (SPSS 11, IBM, Chicago, Illinois, USA).

## RESULTS

### Development of LEA during follow-up

Of the initial cohort from the year 2000 ( $n = 572$ ), 23 were lost at the beginning of the first year of follow-up and excluded from the study. The remaining 549 individuals (340 women and 188 men) were observed for an average of 6.26 years, resulting in a total of 3 489 person-years (PY) observed. During this period, 21 individuals or 3.8% of the cohort, including 11 men (5.5%) and 10 women (2.9%), suffered one or more LEAs. The LEA incidence rate per 1 000 PY was 6.02 (8.65 in men and 4.50 in women).

### Baseline cohort characteristics by presence/absence of LEA

Table 1 shows a comparison of the diabetic cohort's socio-demographic and clinical characteristics at baseline by presence or absence of LEA over the follow-up period using univariate analysis. Of the 25 characteristics examined, only nine showed a statistical association ( $P < 0.05$ ) with risk of LEA: having insulin therapy; having a level of HbA1c  $\geq 8\%$ ; being diagnosed with ischemic heart disease;  $\geq 10$  years of diabetes; being diagnosed with any of the three chronic diabetes-related microvascular complications (neuropathy, nephropathy, and retinopathy); having an ascending level of glucose; and having an ascending level of HbA1c.

Over the seven-year follow-up period, 50% of the 12 diabetic individuals who had an LEA prior to 2001 had a reamputation (indicating a 52.30 times higher risk of LEA ( $P < 0.0001$ ) for diabetic patients who had a previous amputation versus those who did not), and 75% of those with reamputations died during the follow-up period. Having a previous foot ulcer was also a risk factor for LEA, with those suffering from this condition 54.6 times more likely to undergo an amputation.

There were no differences in the risk of LEA for age, education, health insurance

**TABLE 1. Characteristics of a diabetes patient cohort (n = 572)<sup>a</sup> at baseline (year 2000) by presence/absence of lower-extremity amputation (LEA) over a seven-year follow-up period, Costa Rica, 2001–2007**

Characteristics	With LEA (n = 21)	Without LEA (n = 528)	P-value	Odds ratio <sup>b</sup> (95% CI <sup>c</sup> )
<b>Demographics</b>				
Sex: male (%)	52.4	35.6	0.163 <sup>d</sup>	1.99 (0.83–4.77)
Age (years)				
≥ 65 (%)	38.1	31.8	0.546 <sup>d</sup>	1.32 (0.54–3.24)
Mean ±SD <sup>e</sup>	60.6 ± 12.0	58.3 ± 12.8	0.425 <sup>f</sup>	1.02 (0.97–1.06)
Living without partner (%)	38.1	35.0	0.774 <sup>d</sup>	1.14 (0.46–2.80)
< 7 years of schooling (%)	90.5	84.8	0.754 <sup>g</sup>	0.59 (0.14–2.58)
Uninsured (%)	4.8	5.9	0.831 <sup>g</sup>	0.80 (0.10–6.17)
<b>Clinical parameters</b>				
Current or former smoker (%)	47.6	40.9	0.540 <sup>d</sup>	1.31 (0.55–3.15)
Years of diabetes (mean ±SD)	12.9 ± 6.6	6.9 ± 6.9	< 0.001 <sup>f</sup>	1.07 (1.01–1.14)
Age of diabetes onset (years) (mean ±SD)	47.6 ± 12.6	51.3 ± 12.6	0.185 <sup>f</sup>	1.07 (0.97–1.07)
With insulin therapy (%)	90.5	36.1	< 0.001 <sup>g</sup>	16.79 (3.87– 72.9)
Body mass index ≥ 30 (kg/m <sup>2</sup> ) (%)	35.0	43.5	0.449 <sup>d</sup>	0.70 (0.27–1.78)
Mean ±SD	29.7 ± 5.6	30.0 ± 5.6	0.810 <sup>f</sup>	0.99 (0.89–1.10)
Cholesterol ≥ 200 (mg/dL) (%)	75.0	59.1	0.155	2.08 (0.74–5.80)
Mean ±SD	213.5 ± 32.7	212.8 ± 52.9	0.937 <sup>f</sup>	0.99 (0.98–1.01)
Low HDL cholesterol (< 40 in men; < 50 in women) (mg/dL) %	70.0	58.9	0.320 <sup>d</sup>	1.63 (0.62–4.31)
Mean ±SD	34.6 ± 10.7	38.6 ± 13.5	0.205	0.98 (0.93–1.04)
LDL cholesterol ≥ 130 (mg/dL) %	53.3	45.9	0.572 <sup>d</sup>	1.35 (0.48–3.77)
Mean ±SD	127.8 ± 21.8	129.6 ± 38.6	0.857 <sup>f</sup>	1.00 (0.97–1.04)
Triglycerides ≥ 150 (mg/dL) %	70	69.6	0.968 <sup>d</sup>	1.01 (0.39–2.70)
Mean ±SD	317.9 ± 226.3	241.5 ± 197.1	0.091 <sup>h</sup>	1.00 (0.99–1.00)
Triglycerides ≥ 250 and HDL cholesterol < 35 (mg/dL) (%)	40.0	22.9	0.077 <sup>d</sup>	2.25 (0.89–5.62)
Glycosylated hemoglobin ≥ 8% %	89.5	45.0	< 0.001 <sup>d</sup>	10.39 (2.37–45.43)
Mean ±SD	10.1 ± 2.3	8.0 ± 2.2	< 0.001 <sup>g</sup>	1.51 (1.20–1.89)
Glucose (mg/dL) (mean ±SD)	235.8 ± 82.7	177.3 ± 79.4	0.001 <sup>g</sup>	1.01 (1.00–1.01)
Hypertension (%)	52.4	58.6	0.574 <sup>d</sup>	0.78 (0.33–1.86)
<b>Presence of comorbidity (%)</b>				
Ischemic heart disease	40.0	20.2	0.033 <sup>g</sup>	2.63 (1.05–6.61)
Myocardial infarction	15.0	6.1	0.109 <sup>g</sup>	2.74 (0.761–9.84)
Chronic renal failure <sup>i</sup>	14.3	6.3	0.155 <sup>g</sup>	2.48 (0.69–8.83)
Diabetic nephropathy <sup>j</sup>	70.0	31.9	0.001 <sup>d</sup>	4.98 (1.88–13.18)
Diabetic neuropathy <sup>k</sup>	71.4	28.9	< 0.001 <sup>d</sup>	6.16 (2.35–16.17)
Diabetic retinopathy	60.0	17.9	< 0.001 <sup>d</sup>	6.89 (2.73–17.39)
Foot ulcer	23.8	0.6	< 0.001 <sup>g</sup>	54.58 (11.99–248.40)
Previous amputation	28.6	0.8	< 0.001 <sup>g</sup>	52.30 (13.35–204.85)

<sup>a</sup> Twenty-three individuals were lost in the first year of follow-up and excluded from the study.

<sup>b</sup> Baseline (reference) group.

<sup>c</sup> CI: confidence interval.

<sup>d</sup> Based on Pearson's chi-squared test ( $P < 0.05$ ).

<sup>e</sup> SD: standard deviation.

<sup>f</sup> Based on Student's *t*-test ( $P < 0.05$ ).

<sup>g</sup> Based on Fisher's exact test ( $P < 0.05$ ).

<sup>h</sup> Based on Mann-Whitney U test ( $P < 0.05$ ).

<sup>i</sup> Glomerular filtration rate < 60 mL/min/1.73 m<sup>2</sup>.

<sup>j</sup> Presence of micro- or macroalbuminuria, nephrotic syndrome, and/or chronic renal failure.

<sup>k</sup> Clinical signs, symptoms, and loss of sensitivity as measured by 5.07/10-g Semmes-Weinstein monofilament device.

status, living with or without a partner, being a current or former smoker, body mass index (BMI), or lipid levels. No association was found between risk of LEA and being diagnosed with hypertension or myocardial infarction.

### Cox proportional hazards models

The results of multivariate analysis using six different Cox proportional hazards model are shown in Table 2. Models 1 and 2 measured the variables (con-

tinuous and categorical, respectively) with significance < 0.1 in the univariate analysis, excluding insulin therapy and presence of chronic microvascular complications (neuropathy, nephropathy, and retinopathy), and adding age and sex. Models 3 and 4 measured the same set of variables as Models 1 and 2, respectively, plus insulin therapy. Model 5 measured the same variables as Models 3 and 4, plus presence of chronic microvascular complications. Model 6 measured the same variables as Model 5, plus "having a previous amputation." Results indicated insulin therapy, male sex, and HbA1c ≥ 8% were independently associated with LEA until the addition of chronic microvascular complications (in Model 5), which eliminated the HbA1c variable as a predicting factor. In this model, neuropathy and nephropathy were also eliminated as risk factors, and retinopathy emerged as the greatest predictive factor. In Model 6, having a previous amputation eliminated all other variables as predicting factors except insulin therapy.

### DISCUSSION

While studies have been published on the frequency of diabetes in Latin America (1), and prevalence can be estimated from primary data in a significant number of countries in the region (14), very few research studies have been conducted on the prevalence and incidence of diabetic neuropathy and LEA associated with diabetes. Many authors have noted the scarcity of research on this diabetic complication in developing countries, including Latin America (15–17). Motivated by the increased frequency of diabetes, Moxey et al. (16) conducted a literature review from 1989 to the present to learn about global variability in incidence of LEA. They identified a total of 48 studies indexed in PubMed and the Cochrane Library, none of which were conducted in Latin America. With the aim of improving diabetic care, the Latin American Diabetes Association (*Asociación Latinoamericana de Diabetes*, ALAD) (17) developed a guide for the management of diabetic polyneuropathy that presents the epidemiology of this complication for some countries (Argentina, Brazil, Colombia, and Mexico) utilizing a limited number of prevalence data. These data were generated using a variety of methodolo-

**TABLE 2. Results of six Cox proportional hazards models incorporating various characteristics of a diabetes cohort ( $n = 572^a$ ) followed up for seven-year period, Costa Rica, 2001–2007**

Characteristics	Hazard ratio	95% CI <sup>b</sup>	P-value
Model 1 (continuous values)			
Sex: male	3.81	1.41–10.29	0.0083
HbA1c <sup>c</sup> (%)	1.47	1.19–1.83	0.0005
Years of diabetes	1.08	1.02–1.15	0.0070
Model 2 (categorical values)			
Sex: male	3.02	1.17–7.77	0.0220
HbA1c $\geq$ 8%	1.95	1.23–3.09	0.0043
$\geq$ 10 years of diabetes	2.01	1.18–3.40	0.0100
Model 3 (continuous values)			
Sex: male	3.62	1.38–0.01	0.0088
HbA1c (%)	1.32	1.05–0.02	0.0187
Years of diabetes	1.07	1.01–0.03	0.0302
With insulin therapy	6.48	1.38–0.02	0.0181
Model 4 (categorical values)			
Sex: male	2.91	1.14–7.38	0.0249
HbA1c $\geq$ 8%	8.85	1.97–39.79	0.0045
With insulin therapy	5.07	1.12–22.87	0.0346
Model 5			
Sex: male	2.69	1.06–6.81	0.0375
With insulin therapy	9.18	2.00–42.09	0.0043
With diabetic retinopathy	3.44	1.29–9.17	0.0136
Model 6			
With insulin therapy	10.95	2.47–48.48	0.0016
With previous amputation	16.58	5.30–51.80	0.0000

<sup>a</sup> Twenty-three individuals were lost in the first year of follow-up and excluded from the study.

<sup>b</sup> CI: confidence interval.

<sup>c</sup> Glycated hemoglobin.

gies (cross-sectional descriptive studies, case-control studies, and longitudinal studies) (18–21), in different health care settings (primary care and hospital-level) (18–22), among patients with special clinical characteristics (patients with foot ulcers) (23), and thus are not easily comparable.

The relative absence of published data in Latin America should not be interpreted as evidence that the diabetic foot is a minor problem in this region. On the contrary, it is a serious public health problem (24–26), and one that can be prevented (27). According to ALAD (17), 34.7% of diabetic patients in Argentina have diabetic polyneuropathy; 58.2% of those in Brazil have diabetic foot complications; 13% of diabetic patients in Chile with foot injuries required amputation; and in Mexico, between 2004 and 2005, hospital discharges for diabetic foot increased by 10% and the number of amputations increased by 4%.

The current study is the first in Costa Rica to investigate LEA incidence in diabetic patients at the community level, and the associated risk factors. The results provide information for identifying diabetic patients at high risk of amputation in monitoring and health surveil-

lance, which could help prevent this complication in the primary health setting. The incidence rate of LEA was 6.02 per 1 000 PY.

In the general population, and within the diabetic population, the rate of LEA varies by geographic location, ethnic group, and type of community (rural/urban) (28–31). For developing countries, reported incidence rates for LEA secondary to diabetes vary from 13.7 to as high as 18.0 per 1 000 PY, as reported in studies conducted in the 1990s among Pima Indians (32, 33). In developed countries, the rates range from 1.7 to 2.9 (3, 34–37).

While several studies in developing countries provide hospital statistics, there is very little indexed literature comparable with community-based results, especially for Latin America countries. The third edition of the International Diabetes Federation Diabetes Atlas (38) provides data on LEA incidence in the diabetic population for two countries in the region: Brazil (1.81 per 1 000 PY) (21) and Barbados (9.36 per 1 000 PY) (39). The data from Brazil are from a study conducted in Rio de Janeiro that estimated the rate of LEA using a capture-recapture technique and re-

gional amputee registries, and found an annual rate of LEA incidence of 1.8 per 1 000 PY (21), a prevalence similar to that in developed countries. Those results conflict with data presented in the 2000 Annual Report of the Municipal Health Secretariat for the city of Rio de Janeiro (40) that showed 73.2% of LEAs occurred in people with diabetes, indicating an LEA incidence of 8.8 per 1 000 diabetic individuals—a rate similar to that in Barbados, and higher than the rates found in the current study.

The results of the current study on LEA incidence in Costa Rica are similar to those found in research conducted 15 years ago in a predominantly white population in the United States (41), and in European countries such as Germany (which indicated a rate of 5.4 per 1 000 PY) (42). Currently, however, in both North American and Europe, LEA incidence has dropped dramatically, to much lower rates than those found in Costa Rica, primarily because of programs aimed at improving the diabetic diet, and revascularization. The drop in LEA prevalence can be seen in France (which has a current rate of 3.78%) (43); Great Britain (2.85 per 1 000 PY) (44); the United States (0.8 per 1 000 PY) (45); and other countries (3, 35). While Costa Rica has a good health system (46), according to epidemiological indicators, it is not addressing LEA incidence with the state-of-the-art measures that have been shown to lower rates in other countries. The level of LEA incidence found in the current study for a low-income area of Costa Rica is similar to that found in economically disadvantaged populations in developed countries, such as African Americans in the United States, among whom LEA incidence rates were as high as 8.3/1000 in 1996 but dropped to 5.3/1000 by 2002 (45). Another study, conducted along the U.S.–Mexico border in Texas (47), showed that diabetic people who lived near the border had higher incidence (5.36 per 1 000 PY) than those further inside the state (3.99 per 1 000 PY). According to the researchers, the higher incidence among the border population was most likely related to a lower level of education, a low income, not having medical insurance, and other barriers to health care access. The cohort in the current Costa Rican study is poorly educated with low-income levels but has good access to health services, which could explain why LEA incidence

rates in this population are similar to those found among poor populations in developed countries.

With regard to sex, LEA incidence in the Costa Rican community was higher in men, a finding that correlates with other international studies (3, 28–33, 39, 45). In other studies conducted in Latin America, the frequency of LEA was also found to be more prevalent in males (48). While there were not significant differences by sex in the univariate analysis of the current study, when sex was incorporated into the six Cox proportional hazard models it becomes an independent risk factor in four of them, together with HbA1c  $\geq$  8%, years of diabetes, use of insulin, and having retinopathy. In five of the multivariate models, the risk of being male versus female varied from 26% to 40%, according to the different variables included in the models. The risk was higher in the model where age, HbA1c level, and years of diabetes were used as continuous variables. This risk was only eliminated when having a previous amputation was incorporated into the model—a finding consistent with previous studies (49)—probably because having a previous amputation was shown here and in other studies (50) to be the strongest risk factor for LEA. Several hypotheses were considered to explain why males are more at risk in this cohort. The authors believe the higher risk for men is mainly due to barriers associated with access to health care, one of which could be men's reluctance to seek medical consultations if they do not perceive themselves to be critically ill. Also, in the area studied in Costa Rica, much of the employment of men is informal, leaving them largely excluded from Costa Rica's social security system and thus lacking good access to care when serious health events occur. Whatever the reasons, outpatient statistics of the health care system confirm that men utilize health services less than women (51). Therefore, delayed diagnosis and/or deficient routines of medical care may be contributing to the higher incidence of LEA in males in Costa Rica, indicating a potential need for the health care system to devise a primary care strategy that help ensure that men with diabetes receive good care.

Disease progression (years of diabetes) and elevated HbA1c, which are known

risk factors for chronic complications of diabetes (6, 33), were also present as independent risks in the multivariate analysis. The finding that use of insulin was a risk factor is of particular interest. It is known that after 10 years of disease progression, most patients need insulin therapy, and that the more years of disease progression, the greater likelihood of insulin use. In Model 3, when treatment with insulin was included, it had a higher independent risk than elevated HbA1c and years of diabetes. Model 4 demonstrates the colinearity between progression of the disease and insulin therapy: when years of diabetes is included in the model as a categorical variable (" $\geq$  10 years of diabetes"), it disappears as a risk, but the risk of insulin therapy remains the same. When the three chronic microvascular complications are incorporated into the model, years of diabetes and HbA1c level are eliminated as risks, diabetic retinopathy emerges as an important risk factor, and insulin therapy remains as a high risk. When the variable of previous amputation is incorporated, only use of insulin remains as a risk (all other risk factors are eliminated).

Therefore, a typology of risk for amputation in diabetic patients would be male patients with 10 or more years of diabetes and an average HbA1c  $\geq$  8% who use insulin and have diabetic retinopathy, but those most at risk are patients with insulin therapy—and their risk increases if they have had a previous amputation. These factors should be considered as indicating very high risk for diabetic patients and, in turn, signaling the need for close monitoring by health care professionals. Having incidence of any disease as an indicator in a primary care setting allows for measurement of the impact of interventions made in a specific region by comparing incidence through points in time. For example, the data generated by the current research will allow any studied health area to monitor the quality of comprehensive care of diabetic patients using incidence of LEA as an indicator.

### Recommendations

Diabetic foot care is considered a feasible intervention with a high level of cost-effectiveness for developing coun-

tries (15). Therefore, factors that hinder the proper care of diabetic patients should be identified and addressed, to reduce medical complications, along with the associated individual and social burdens. In addition to barriers to accessing health care and education at all levels, these factors include the lack of follow-up records of patients and monitoring of complications (15, 52). It is well known that valid and reliable health statistics are essential for planning and implementing health policy in all settings. Almost all LEAs are done in hospital settings, so they could be easily and properly registered in hospital discharge data, making incidence of LEA a valuable indicator in decision-making to improve the quality of care for diabetic patients in developing countries. This indicator has been previously used in control programs on quality of care for people with diabetes conducted in Latin America (52), and some countries, such as Chile, have proposed LEA as an indicator for monitoring and evaluating some of the priority components of diabetic patient management, using the QUALIDIAB-Chile program (<http://qualidiabchile.minsal.cl/>) (53). Future research evaluating the efficacy of diabetic care in terms of survival, function/disability, and quality of life, to measure diabetes' impact on individuals, the health system, and the economic development of Latin American countries, is also recommended.

### Conclusions

These results and the information in the consulted literature show the high frequency and importance of LEA associated with diabetes in Costa Rica and elsewhere in Latin America. Although the data can not be generalized to all of Costa Rica, they can be used as an estimate of what is happening in the metropolitan area of San José (especially the low-income areas), where 75% of Costa Ricans live. They may also help in planning intervention programs targeting prevention of LEA in diabetic patients at the primary, secondary, and/or tertiary level, including those focusing on disability, rehabilitation, and prosthetics, with the ultimate end of reducing the number of amputations.

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## RESUMEN

### **Incidencia y factores de riesgo de la amputación de extremidades inferiores relacionada con la diabetes: estudio prospectivo de siete años en Costa Rica**

**Objetivo.** Analizar la incidencia y los determinantes de la amputación de extremidades inferiores (AEI) en personas diabéticas de una comunidad con bajos ingresos de Costa Rica.

**Métodos.** Se recopilieron datos sobre la incidencia de la AEI durante un período de seguimiento de siete años (del 2001 al 2007) en una cohorte de pacientes diabéticos ( $n = 572$ ). Se analizaron los factores de riesgo usando el modelo de regresión de Cox de riesgos proporcionales y los valores de referencia del año 2000 de las variables (características sociodemográficas, comorbilidad, control metabólico, tratamiento y complicaciones microvasculares crónicas).

**Resultados.** La incidencia de la AEI fue de 6,02 por 1000 personas-año (8,65 en varones y 4,50 en mujeres). Los factores de riesgo conocidos (sexo, años de evolución de la diabetes, glucohemoglobina [HbA1c] elevada, retinopatía, tratamiento con insulina y amputación previa) fueron muy significativos.

**Conclusiones.** Los pacientes diabéticos costarricenses con mayor probabilidad de sufrir una AEI fueron los varones con 10 o más años de evolución de la diabetes y un promedio de HbA1c  $\geq 8\%$  que eran tratados con insulina y padecían una retinopatía diabética. Los pacientes en tratamiento con insulina presentaban el mayor riesgo, especialmente los que habían sufrido una amputación anterior. Los pacientes diabéticos con el perfil descrito anteriormente deben considerarse como de riesgo muy elevado de AEI y deben ser seguidos de cerca por el sistema de atención de salud.

## Palabras clave

Diabetes mellitus tipo 2; extremidad inferior; amputación; factores de riesgo; complicaciones de la diabetes; Costa Rica.