

Lower extremity amputations in diabetic patients: a case-control study

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Keywords

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Abstract

Objective

Lower extremity amputation is an increasing problem among diabetic patients and an important public health problem. The study purpose was to identify factors associated with lower extremity amputation.

Methods

A matched case-control study was carried out among diabetic patients. Cases were selected in public health programs of the city of São Paulo, Brazil. One hundred and seventeen cases of diabetics with lower extremity amputation were compared to 234 controls of diabetics without amputation, matched by sex, age, and duration of disease. Sociodemographic variables, life habits (smoking and alcohol drinking), clinical aspects, and health education in diabetes were included. Univariate analyses and conditional logistic regression method were applied to data.

Results

Data showed evidence of association for: smoking, last glucose test ≥ 200 mg/dl, presence of peripheral somatic neuropathy and vibratory perception (tuning fork 128 Hz), and peripheral vascular disease. Diabetes treatment and attending nursing appointments for diabetes education were important factors for preventing lower extremity amputation in diabetic patients.

Conclusions

The knowledge of determinants and intervening factors for this condition will lead to cost reduction and better quality of care delivered in public health services.

INTRODUCTION

Diabetes mellitus (DM) is a major public health concern not only in Brazil but also worldwide. The epidemiological impact of diabetes is evidenced by the growing morbidity and mortality rates, and by causing permanent disabilities such as blindness, diabetic retinopathy, end-stage renal failure and lower extremity amputations (LEA) (ADA,¹ 1999).

In 1995, 10% of diabetes patients in the United States underwent some kind of amputation (NIH,¹²

1995). Of all LEA, 50% is carried out in diabetics. Studies show that 85% of LEA are preceded by foot ulceration (NIH,¹² 1995; ADA,² 1999). Among risk factors in LEA DM patients are: long duration of the disease, prolonged hyperglycemia, dyslipidemia, smoking and drinking, neuropathy, peripheral vascular disease, and prior ulcers (Reiber,¹³ 1992; LEA,⁹ 1995; Adler et al,⁴ 1999; Moss et al,¹¹ 1999).

This study aims at identifying LEA associated factors in DM patients and determining prevention and intervention measures.

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METHODS

A matched case-control study was carried out (Rothman,¹⁵ 1986). Cases were type 2 diabetes patients (DM2) who underwent LEA in the city of São Paulo, Brazil, between March 1991 and September 2000. For those patients who underwent more than one amputation, data refer to the first intervention. Controls were DM2 patients who had never undergone LEA. Two controls were selected for each case, totaling 234 and 117 patients, respectively. Exclusion criteria included those patients who were diagnosed DM as of the amputation and those whose medical charts were incomplete.

Confounding factors such as gender, age, and duration of diabetes were considered in the case-control matching. The exploratory variables were:

- sociodemographic characteristics (place of birth, schooling, skin color, occupation);
- habits (smoking and drinking, current or past, amount and duration); clinical features (high blood pressure and treatment, sort of diabetes treatment, blood glucose levels, patient's self-monitoring, presence and assessment of clinical signs of diabetic sensorimotor polyneuropathy and vasculopathy, chronic lesions in lower extremities, peripheral vascular bypass surgery, infection prior to amputation, osteomyelitis, level of amputation); and information on DM health education (DM counseling, frequency of nursing visits, identifying signs and circumstances contributing to the condition onset).

The det aleta tool was built based on models used in British care services, references and practice. This study also abided by the opinions issued by the Ethics Committee at the study hospitals and the School of Public Health of the University of São Paulo.

Statistical analysis involved building frequency distribution tables, ascertainment of association between exploratory and confirmatory variables (case and control) using Pearson's chi-square test for qualitative variables and Student's t-test for quantitative variables. Statistical significance was assessed based on the p-value. In the multivariate analysis, odds ratio (OR) was used as a measure of association (Snedecor & Cochran,¹⁶ 1989).

It was adopted the conditional logistic regression model. The analysis was first performed in a full model including variables selected through univariate analysis ($p \leq 0.20$), which were eliminated one by one (backward elimination) (Hosmer & Lemeshow,⁶ 1989). Elimination was based on similarity ratio (Rothman,¹⁵ 1986). The database was stored using Epi Info® and statistical analysis was carried out using Stata 6, version 6.

RESULTS

Cases and controls aged on average 66.1 years (SD 13.0) and 65.4 years (SD 12.2), respectively. Of them, 64% were male, 91.5% were Brazilian and the mode of disease duration ranged between 10 and 14 years. Whites were 78% of cases and 71% of controls.

The initial modeling process included the following selected variables for gross analysis: schooling, occupation, smoking and drinking, high blood pressure, DM treatment, documented peripheral neuropathy and vasculopathy, chronic lesions, last blood glucose test result, DM counseling, and attending nursing visits.

In the first multivariate analysis, neuropathy assessment, presence of lesions, and DM counseling were factors that yielded statistically significant differences. It was ascertained that chronic lesions were very commonly seen among cases since OR was infinite. Thus, a new model was created where this variable was excluded because it per se explained the phenomenon, overshadowing a potential influence of remaining variables.

In the final model, the new OR values were adjusted to the remaining factors (Table).

Explanatory variables are associated with confirmatory variables in smoking, DM treatment, blood glucose above 200 mg/dl, peripheral neuropathy and vasculopathy, in addition to attending nursing visits.

DISCUSSION

Several variables have a relation with the etiology of DM2 and its complications. Some variables are described as LEA risk factors and include sociodemographic, environmental and genetic characteristics, lack of access to health services (or inadequacy of health policies, which do not provide treatment equity or education on diabetes), duration of disease, unhealthy habits, and hyperglycemia. Most risk factors are associated to and could be prevented by primary prevention and appropriate health care. However, LEA in DM patients has steadily increased (Spichler et al,¹⁷ 1998; Moss et al,¹¹ 1999).

The simultaneous onset of diabetic retinopathy and neuropathy – ensuing visual impairment, generalized edema and other complications – interfere with patients' self-monitoring, treatment and foot care, which are essential to preventing the foot-at-risk factor, thus preventing amputation. This indicates that strictly screening these patients is essential since they are more exposed to risk of lower extremity skin ulceration.

Table - Multivariate analysis (final model) of lower extremity amputation in diabetes mellitus patients.

Variables	Case (N)	Control (N)	OR (gross)	OR (adjusted)	95% CI	Z (Wald)	p-value
Smoking							
Non-smoker	44	152	1	1			
Smoker	26	23	5.10	4.62	[1.09 - 19.50]	2.082	0.037
Former smoker	37	57	2.49	3.12	[1.00 - 9.73]	1.961	0.050
DM treatment							
Yes	90	227	0.11	0.03	[0.00 - 0.31]	-2.887	0.004
No	17	5	1	1			
Blood glucose (mg/dl)							
<150	32	87	1	1			
150 —200	21	64	0.99	2.19	[0.58 - 8.20]	1.163	0.245
>200	54	81	2.06	6.11	[1.65 - 22.64]	2.706	0.007
Neuropathy							
Yes	97	138	6.03	3.40	[1.04 - 11.08]	2.027	0.043
No	10	94	1	1			
Vasculopathy							
Yes	95	76	21.16	11.82	[3.47 - 40.21]	3.953	0.000
No	12	156	1	1			
Nursing visits							
Yes	16	147	0.08	0.06	[0.02 - 0.20]	-4.606	0.000
No	91	85	1	1			

OR - Odds ratio
DM - Diabetes mellitus

Therefore, there is a need of implementing diabetes prevention and control programs stressing on education, promoting early diagnosis and care, treatment and special care in treating chronic complications (Gamba,⁵ 1998; Rivera,¹⁴ 1998; Spichler et al,¹⁷ 1998).

There was also found an association between amputation and smoking. Patients who continued to smoke were more susceptible to LEA. The tobacco plays a clear role in the etiology of peripheral vasculopathy and thus the foot-at-risk, a predisposing amputation factor (ADA,³ 2000). Not much has been done for diabetic patients who smoke or drink in DM prevention, control and treatment programs (DMPCTP). Most often, patients are referred to specialized treatment, which are overwhelmed and are not able to cope with demand, failing to provide adequate health care.

A key risk factor that was not addressed in this study was dyslipidemia. Although it was included in the study protocol, it did not prove feasible because was not found in most charts. Dyslipidemia was only mentioned in control charts, which leads one to believe that relevant DMPCTP aspects are not being assessed appropriately. The same was found concerning exercising, which is also necessary for DM control.

High blood pressure contributed to the development and progression of chronic DM complications. In DM2 patients, high blood pressure is nearly always seen in a syndrome including glucose intolerance, insulin resistance, obesity, dyslipidemia, and coronary disease, which are intervening factors in neuroischemic ulcers and and LEA (ADA,³ 2000). High blood pressure is a major DM risk factor for LEA if untreated. This has been shown in the present study and other studies

(Reiber et al,¹³ 1992; Moss et al,¹¹ 1999). This variable, however, was not included in the final model. A possible explanation is that when there are other variables, the association between LEA and high blood pressure is not as strong. Nevertheless, high blood pressure is a risk factor among diabetics when compared to the non-diabetic general population (ADA,³ 2000; Brazilian Ministry of Health,¹⁰ 2000).

There is a general consensus that about 25% of DM2 cases require insulin for diabetes metabolic control. In Brazil, this proportion is 8%, which possibly suggests poor medical training. Among adult Brazilian DM patients, 40% take oral hypoglycemic drugs, slightly lower than in developed countries. It is estimated that 40% of DM2 patients achieve metabolic control through an appropriate diet and habit change (Brazilian Ministry of Health,¹⁰ 2000).

Drug therapy tends to fail when daily care is overlooked. The only factor that can lead to positive self-monitoring practices is DM education, since it improves compliance to treatment and blood glucose control (Lavery et al,⁸ 1998; Rivera,¹⁴ 1998; UKPDS,¹⁸ 1998; ADA,³ 2000).

It is key to DM patient care to help them identify early signs and symptoms of chronic complications. Brazilian health providers generally do not perform on a regular basis simple actions such asking patients to take off their shoes for examination. Identifying distal symmetric polyneuropathy and peripheral vasculopathy is recommended worldwide (Weitz et al,¹⁹ 1996)

Reiber et al¹³ (1992) estimate that the likelihood of DM patients who do not receive vibratory stimulus to the skin having an amputation is 15.5 times greater compared to those who do. In this study, the variables

related to distal symmetric polyneuropathy and peripheral vasculopathy, adjusted to the other variables, were found to be associated to LEA. The clinical assessments when DM patients were admitted to undergo amputation surgery were detailed and showed the pre-clinical condition. The association between neuropathy and artery insufficiency highlights the need of carefully assessing these signs. However, this is still not a routine practice in DM patient care (Lavery,⁸ 1998; Rivera,¹⁴ 1998). The Consensus Development on Diabetic Foot Wound Care (ADA,² 1999) strictly recommends that peripheral sensitive assessment be part of the routine physical examination of diabetics.

The best indicator of blood glucose control is glycosylated hemoglobin testing (HbA1c). However, such data were only found in two charts among cases after amputation. On the other hand, a higher proportion was found among controls. It is known that blood glucose control of patients in public care services does not occur on a regular basis because medical visits are scheduled for three months to a year's time. When analyzing blood glucose, there was seen an association only for glucose greater than 200 mg/dl. However, blood glucose mean and median (mean 191 mg/dl and median 169 mg/dl) seen in the control group are above the levels recommended by the Brazilian Diabetes Association (Brazilian Ministry of Health,¹⁰ 2000).

It's worth noting that study protocols of patients with chronic ulcers and LEA should include identifying the precursor event triggering the sequence of events resulting in the condition and exploring future education and care actions to be taken. The results showed that most cases (60%) did not receive appropriate care due to their poor metabolic control, lack of information, treatment non-compliance, and lack of financial resources. These were followed by lack of skin integrity, poor hygiene, foot numbness evidenced by trauma related to inappropriate footwear and other, nail trimming, onychomycosis, ingrown toenail, accidents after removal of plantar callosity by pedicurists or family members, and inadequate treatment of neuroischemic lesions and sudden signs of peripheral ischemia. Therefore overcoming those problems related to adequate, low-cost and low-complexity technology could thus change the progression of LEA and contribute to the prevention of disabilities, which are burdensome and lead to irreversible physical, mental, and social conditions (Rivera,¹⁴ 1998; Moss et al,¹¹ 1999).

Chronic neuroischemic lesions, and infections and osteomyelitis that follow contribute greatly to LEA among DM patients. These clinical signs are important predisposing factors to the diabetic foot and deserve special assessment and care (Krasner & Kane,⁷

1997). Therefore, it is necessary to address it focusing on risk management, and using the appropriate care technology and education to optimize wound healing and scar formation processes of chronic ulcers in diabetics. This is precisely when the nursing staff in the public health services plays its most significant role because attending nursing visits is a very important protective factor of diabetes. Nursing visits promote care, education and motivation patients need to be able to actively take part in their treatment, through self-monitoring, thus optimizing compliance to clinical treatment. This is when health educators play their leading actual role (Gamba,⁵ 1998).

Health education has a major impact on positive behavior toward habit change and on compliance to clinical treatment. These measures should be the driving forces in health care programs for diabetics. They should be an essential part of public health services, thus supporting psychotherapeutic techniques, which are key for treating chronic diseases.

Metabolic and infection control, nursing care, foot care and dressing according to modern techniques for treating wounds, and in compliance with disease basics and physiology of wound healing and scar formation, in addition to adapting special orthosis, all effectively affect LEA risk factors (Krasner & Kane,⁷ 1997; ADA,² 1999).

The study reveals the problems and challenges faced by diabetes health professionals, nurses and educators endeavoring to reduce DM LEA risk factors while seeking to change the current scenario. The methods used and the results obtained in this study have allowed to identify effective measures for DM prevention, control, treatment, and education.

In this regard, determiners and intervening factors for this condition lead to cost reduction and to improvement of the care provided in the public health services.

Controlling glucose levels, receiving diabetes treatment and attending nursing visits are important aspects of LEA prevention in DM patients. Thus, health education in DM should be an important part of health care models, especially those regarding nursing. Treating neuroischemic wounds should comply with clinical criteria for risk management and make use of appropriate technology.

Health services, addressing health and education, associated to procedures and specialized training can put aside the reductionist view of treatment and open the doors to a new reality, with the perspective of restoring health practices which effectively contribute to the improvement of DM patients' care and life quality.

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