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Original Article

Prevention of lower-limb lesions and reduction of morbidity in diabetic patients☆,☆☆

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ABSTRACT

Objective: To assess the impact of a diabetic foot outpatient clinic on reducing the morbidity of this disease, with emphasis on lower-limb lesions.
Methods: This was a prospective observational study with a target population of 30 cases out of a total of 77 patients in the diabetic foot outpatient clinic. The inclusion criterion was that data relating to laboratory tests, clinical examinations, neuropathic and vascular tests and the elbow-arm index needed to be available from all the patients, with repetition after 18 months of follow-up, so as to analyze their evolution. The statistical analysis was done using the McNemar chi-square test for dependent samples.
Results: The patients' mean age was 61 years. All of them had type 2 diabetes mellitus (DM), which had started 14.5 years previously, on average, and 20% had neuropathies. After 18 months, there was no change in the frequency of lesions in diabetes target organs ($p = 1.000$) or in the neuropathy rate ($p = 1.000$). However, there were significant improvements in neuropathic symptoms, from 70% to 36.7% ($p = 0.035$), and in peripheral arterial disease, from 73.3% to 46.7% ($p = 0.021$). There was also a decrease in ulcers from 13.3% to 10% ($p = 1.000$).
Conclusions: Creation of specialized outpatient clinics for prevention of diabetic foot is a viable investment, which has low cost compared with the high costs generated through the complications from this disease. This approach noticeably improves the patients' quality of life, with reduction of morbidity.

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Prevenção de lesões de membros inferiores e redução da morbidade em pacientes diabéticos

Palavras-chave:
Diabetes *mellitus*
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RESUMO

Objetivo: Avaliar o impacto de um ambulatório de pé diabético na redução da morbidade da doença, com ênfase nas lesões dos membros inferiores.
Métodos: Estudo prospectivo, observacional, com população alvo de 30 casos do total de 77 pacientes do ambulatório de pé diabético. O critério de inclusão foi que todos os pacientes tivessem exames laboratoriais, exame clínico, testes neuropático e vascular e índice tornozelo-braço repetidos após 18 meses de acompanhamento, o que permitiu analisar sua evolução. A análise estatística foi feita com o teste qui-quadrado de MacNemar para amostras dependentes.
Resultados: A média de idade dos pacientes foi de 61 anos, todos portadores de *diabetes mellitus* (DM) tipo 2, iniciada em média havia 14.5 anos, e 20% eram neuropatas. Após 18 meses, não houve mudança na frequência de lesão em órgão alvo da diabetes (p = 1000) e no índice de neuropatia (p = 1000). Obteve-se, no entanto, melhoria significativa dos sintomas neuropáticos de 70% para 36.7% (p = 0.035), bem como da doença arterial periférica de 73.3% para 46.7% (p = 0.021). Foi observada ainda diminuição de 13.3% para 10% das úlceras (p = 1000).
Conclusões: A criação de ambulatórios especializados em prevenção do pé diabético é investimento viável, de baixo custo quando comparado aos altos custos gerados pelas complicações dessa doença. Essa abordagem melhora sensivelmente a qualidade de vida do paciente, com a redução da morbidade.

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Introduction

Diabetes mellitus (DM) causes degenerative complications that have human and socioeconomic repercussions and have become an important public health problem.[1] Among these complications are lesions in target organs, including retinopathy, nephropathy and accelerated atherosclerosis, with increased risks of myocardial infarction or stroke, and lesions that affect the feet, which are the most frequent type.[2] According to the definition of the International Consensus on Diabetic Foot, this condition is understood to consist of infection, ulceration and/or destruction of the deep tissues, in association with neurological abnormalities and various degrees of peripheral vascular disease in the lower limbs.[2] The prevalence of ulcers on the feet of the diabetic population is between 4% and 10%, and 85% of amputations of the lower extremities among these patients are preceded by ulceration.[2] Approximately 40–60% of all non-traumatic amputations of the lower limbs are performed on diabetic patients.[1,2] Three years after amputation of a lower limb of a diabetic individual, the percentage survival is 50%, while over a five-year period, the mortality rate ranges from 39% to 68%.[3]

One very important factor relating to development of ulcers on the feet is the presence of peripheral motor-sensory neuropathy, which has been associated with loss of sensitivity to pain and loss of perception of pressure, temperature and proprioception.[4–8] This leads to diminished perception of wounds or trauma. Four out of every five ulcers on diabetic individuals are precipitated by external trauma.[2] Furthermore, motor neuropathy gives rise to atrophy and weakening of the intrinsic muscles of the feet and generates deformities such as crooked toes and abnormal gait patterns, which evolve to calluses and pressure ulcers. Cases of greater severity lead to Charcot foot, which is a progressive disease characterized by joint displacement, pathological fractures and debilitating deformities.[8,9] Autonomic neuropathy also leads to reduction or total absence of sudoriparous secretion and leads to skin desiccation, with cracks and fissures.[8,10]

Peripheral vascular disease (PVD) is an important risk factor for ulceration and amputation.[6,11–13] It results from atherosclerosis of peripheral arteries, leads to obstruction of distal arteries and arterioles, hinders blood flow and deprives the tissues of adequate supplies of oxygen, nutrients and antibiotics, which impairs ulcer healing and may consequently lead to gangrene.[14] Gangrene is four times more common among individuals with diabetes than in the general population, and its incidence gradually increases with age and with the duration of the disease.[15]

Ulcers generally result from trivial, mild and repeated trauma, such as erroneous fit and use of footwear, or even from walking barefoot.[8,12] Approximately 70–100% of ulcers present signs of peripheral neuropathy with varying degrees of PVD. Infection is only rarely considered to be the direct cause of an ulcer.[16] However, infected ulcers present a higher risk of subsequent amputation.[2]

In view of the high costs of ulcers and amputations, both for individuals and for society, preventive care for diabetic foot has a positive effect on the cost–benefit relationship. It has now been demonstrated that up to 50% of amputations and ulcerations could be prevented through early diagnosis and

adequate treatment.[1,17,18] With this aim in mind, an interdisciplinary care program for diabetics (PAID) was started in January 2006, by the hypertension, diabetes and obesity control clinic of the municipal health department of the city where this study was conducted. This program promotes specialized multidisciplinary follow-up for diabetic patients and aims to educate patients and to implement prevention and early diagnosis and treatment of lesions in target organs.

Objective

To evaluate the impact of the PAID diabetic foot outpatient clinic for reducing morbidity among diabetic patients, with emphasis on lower-limb lesions.

Materials and methods

The present study was approved by the institution's research ethics committee under protocol no. 1437.128.2008. It had support from the National Council for Scientific and Technological Development (CNPq) through its institutional program for scientific initiation bursaries. This was a prospective observational study on cases, with a target population formed by 30 of the 77 patients of the PAID diabetic foot outpatient clinic. These patients were recruited spontaneously among those who, by April 2011, after 18 months of follow-up, had undergone complete repetition of their initial clinical and laboratory tests.

The participants in this study were over the age of 18 years, without distinction regarding sex or ethnicity. They were free to refuse to participate at any time, without any modification in the way in which they were attended by the researcher. Confidentiality and privacy were guaranteed. A free and informed consent statement was signed by all participants.

All individuals who did not agree to participate were excluded, as were all those who did not participate in the entire clinical and laboratory reevaluation performed after 18 months of follow-up.

The multiprofessional PAID team is composed of a vascular surgeon, an endocrinologist, a dermatologist, a nephrologist, a psychologist and a nutritionist. All the patients were followed up and were referred to cardiologists, orthopedists or ophthalmologists working for the municipal authority, whenever necessary.

Description of the functioning of the PAID diabetic foot outpatient clinic:

1. Initial medical evaluation, with peripheral neurological clinical tests (diabetic neuropathy was classified in accordance with the Portuguese-language versions of the Neuropathic Symptom Score and Neuropathic Impairment Score devised by Moreira et al.[19]) and arterial evaluation by means of the ankle-brachial index (ABI) (systolic arterial pressure of the ankle divided by the systolic arterial pressure of the arm, both measured with the patient in the supine position, using a portable Doppler device).[2] Repetition of the neurological and vascular tests 18 months later.
2. Laboratory tests.
3. Return visits were scheduled in accordance with the international diabetic foot consensus and the practical guidelines for management and prevention of diabetic foot (2007): annual returns, if neuropathy was absent; half-yearly returns, if neuropathy was present; three-monthly returns, if neuropathy was present in association with signs of peripheral vascular disease and/or deformities of the feet; or between every one and three months in cases of amputation or previous ulceration.[1]
4. The patients were systematically advised regarding care to be taken for avoiding lesion formation. For this, talks were given periodically, leaflets were distributed and guidance was given during consultations.
5. The wounds were treated on an outpatient basis. In cases of infected wounds that were greater than 2 cm in diameter or showed clinical signs of sepsis, the patients were sent to a referral hospital.

The data were entered into the Epi Info software (version 3.5.1). Statistical comparisons were made using the McNemar chi-square test for dependent samples, when the variables were categorical; or using the Student's *t* test for dependent samples, when the variables were of numerical type. *P*-values < 0.05 were considered significant. The statistical analysis was performed using the SPSS software, version 15.

Results

Seventy-seven patients participated in the first evaluation of the study, on the day when they were first registered at the outpatient clinic. There were 33 males (42.9%) and 44 females (57.1%). Of these, 30 underwent complete repetition of the initial set of neurological and vascular tests and laboratory tests, after 18 months of follow-up.

Thirteen of these were male (43.3%) and 17 were female (56.7%), and all of them presented type 2 DM, which had started on average 14.5 years earlier. The patients' mean age was 61 years and the standard deviation was 9.01.

At the first evaluation, four patients (13.3%) were seen to have undergone previous amputation. Amputation of the fourth toe of the right foot of one patient was seen at the second evaluation.

Some type of lesion in a target organ (heart, kidney, retina or microvasculature of the feet) was seen in 90% of the patients, and the frequency of this did not change after 18 months ($p = 1.000$). The rates of cardiac diseases (40%; $n = 12$) and renal diseases (23.3%; $n = 7$) did not change ($p = 1.000$), while retinopathy showed a non-significant increase from 53.3% ($n = 16$) to 63.3% ($n = 19$) ($p = 0.453$). Furthermore, the patients did not present any occurrences of stroke and/or acute myocardial infarction over this period.

Tables 1–6 present the results relating to the data evaluated in this study.

Over the 18-month period, the patients did not present any significant alterations in palpation of the pulse in the lower limbs ($p = 1.000$).

Table 1 – Perception of the capacity for self-care of the feet (*n* = 30).

	First evaluation		Second evaluation		*p*
	Ab Fr	R Fr (%)	Ab Fr	R Fr (%)	
Full self-care	22	73.3	12	40.0	0.004
Partial self-care	7	23.3	17	56.7	
Inability to perform self-care	1	3.3	1	3.3	

Ab Fr = absolute fraction; R Fr = relative fraction.

Table 2 – Clinical examinations on the feet (*n* = 30).

	First evaluation		Second evaluation		*p*
	Ab Fr	R Fr (%)	Ab Fr	R Fr (%)	
Previous ulcer	14	46.7	15	50.0	1.000
Amputation	4	13.3	5	16.7	1.000
Deformity of the feet	6	20.0	6	20.0	1.000
Nail mycosis	19	63.3	15	50.0	0.125
Mycosis between toes	14	46.7	5	16.7	0.012
Active ulcer	4	13.3	3	10.0	1.000
Cracks	3	10.0	3	10.0	1.000
Use of appropriate footwear	14	46.7	25	83.3	0.013

Table 3 – Neuropathic sign score[19] (*n* = 30).

	First evaluation		Second evaluation		*p*
	Ab Fr	R Fr (%)	Ab Fr	R Fr (%)	*p* = 0.102
Normal	24	80.0	19	63.3	
Mild	3	10.0	7	23.3	
Moderate	3	10.0	4	13.3	

Table 4 – Neuropathic impairment symptom score[19] (*n* = 30).

	First evaluation		Second evaluation		*p*
	Ab Fr	R Fr (%)	Ab Fr	R Fr (%)	*p* = 0.035
Normal	3	10.0	8	26.7	
Mild	6	20.0	11	36.7	
Moderate	17	56.7	7	23.3	
Severe	4	13.3	4	13.3	

Table 5 – Diagnosis of diabetic neuropathy according to the combination indicated by Moreira et al.[19] between the neuropathic symptom score and the neuropathic impairment score (*p* = 1.000).

	First evaluation		Second evaluation		*p*
	Ab Fr	R Fr (%)	Ab Fr	R Fr (%)	*p* = 1.000
Neuropathic patients	6	20.0	6	20.0	
Non-neuropathic patients	24	80.0	24	80.0	

Table 6 – Peripheral arterial disease based on the ankle-brachial index (ABI) (*n* = 30).

	First evaluation		Second evaluation		*p*
	Ab Fr	R Fr (%)	Ab Fr	R Fr (%)	
Normal: 0.91–1.30	8	26.7	13	43.3	0.129
Mild obstruction: 0.70–0.90	8	26.7	6	20.0	
Moderate obstruction: 0.40–0.69	8	26.7	5	16.7	
Poorly reduced: >1.30	6	20.0	6	20.0	
Abnormal ABI: <0.90 or >1.30	22	73.3	17	46.7	0.021

Discussion

It has been well established that 85% of the problems resulting from diabetic foot can be presented through specialized care[2,7,8,12,20,21] and that up to 50% of amputations and ulcerations can be presented through early diagnosis and appropriate treatment.[1,17,18] Identification and classification of patients who are at risk (such as those with diabetic neuropathy, peripheral arterial disease and structural deformities),[2] early aggressive treatment and individual, family and community education form a solid basis for preventing limb amputation.[22] These actions were targeted in the PAID diabetic foot outpatient clinic.

Out of the 30 patients who participated in the study, 90% presented some type of lesion in a target organ (heart, kidney, retina or microvasculature of the feet), and the frequency of these lesions remained unchanged 18 months later ($p = 1.000$). This shows that caring for the whole patient should form part of the approach.[23]

After 18 months of follow-up at the PAID diabetic foot outpatient clinic, the perception regarding the full conditions of self-care of the feet (Table 1) varied from 73.3% at the first evaluation to 40% at the second, and the perception regarding the capacity for partial self-care varied from 23.3% to 56.7%, which indicates that a significant number of patients ($p = 0.004$) perceived that they would need specialized follow-up in order to receive the appropriate preventive and/or curative treatment. Diabetic patients who do not adhere to their treatment have a 50-fold greater chance of ulceration of the foot and a 20-fold greater chance of having to undergo amputation than those who follow the guidance correctly.[24] One study demonstrated that 22 out of 23 amputations below the knee were performed on patients who had never received any information about therapeutic care or preventive measures.[2]

At the start of the follow-up, 46.7% of the patients were using appropriate footwear. Eighteen months later, 83.3% were using appropriate footwear ($p = 0.013$) (Table 2). Inappropriate footwear predisposes the feet to extrinsic trauma and is considered to be a precipitating factor for ulceration of the feet.[25] Many studies have demonstrated that when protective footwear is available, prevention of ulcer recurrence is achieved in 60–85% of the patients.[2] The ideal footwear reduces the pressure on the feet to below the threshold for ulceration. Footwear and its insoles should be inspected frequently and exchanged when necessary. If the footwear that is habitually used cannot be adapted because of orthopedic deformities or lesions due to excessive contact area, manufacture of special footwear should be indicated.[5,8,11,13,21]

After 18 months, the rate of mycosis between the toes had reduced from 46.7% to 16.7% ($p = 0.012$), nail mycosis had diminished from 63.3% to 50% ($p = 0.125$) and the crack rate remained at 10% (Table 2). In one study, mycosis between the toes was considered to be responsible for 20.8% of the ulcers of the feet, onychomycosis for 52.5%, calluses and cracks for 49.5%, dried and flaking skin for 63.4% and nail cleanliness and improper nail cutting for 73.3%.[26] Basic hygiene measures such as properly washing the feet and drying them carefully, using hydrating cream or oil and cutting the nails properly and not excessively closely (to be done by a chiropodist) avoids the appearance of these triggering factors for diabetic foot, and such measures are systematically implemented at PAID.[27]

In the initial evaluation, 13.3% of the patients had a history of amputation and 46.7% had previously had an ulcer, which had been cured (Table 2). This is a high number of patients with histories of high risk of amputation according to the risk classification of the international diabetic foot consensus.[1] Over the 18-month follow-up, the number of patients with active ulcers decreased from four (13.3%) to three (10.0%), which demonstrates that the objective of preventing the appearance of new ulcers was achieved. After these 18 months, it was seen that only one amputation had been performed: the fourth toe of the right foot of one patient (3.4%). Thus, the final evaluation showed that five patients had histories of amputation (16.7%). This was an excellent result, in comparison with the literature, in which amputation rates of around 43–85% have been reported among patients undergoing multidisciplinary approaches.[1,2,12]

In making the diagnosis of neuropathy, which is an important risk factor for development of ulceration on the feet,[2,4–8] the criteria of Moreira et al.[19] were used (Tables 3–5). At PAID, 20% of the patients presented neuropathies (Table 5), and this proportion did not increase over the 18-month period ($p = 1.000$). This finding is important, given that when peripheral neuropathy becomes established, it is irreversible.[28,29] Therefore, it is important for individuals with a recent diagnosis to have adequate control over the risk factors, and for prophylaxis to be implemented for individuals without risk factors, such as rigorous control over blood glucose levels, guidance regarding smoking and alcohol consumption, and control over arterial hypertension, dyslipidemia and vasculopathy.[30]

With the treatment implemented at PAID, significant improvements in the symptoms of peripheral neuropathy were observed ($p = 0.035$) (Table 4). There was a decline in the proportion of patients with moderate to severe symptoms, from 70% to 36.7% over the 18-month period. There was a non-significant decrease in the number of patients with signs of diabetic neuropathy at normal levels, from 80% to 63.3% ($p = 0.102$) (Table 3), which shows that it was easier to reverse the symptoms (which reflect an earlier stage of neuropathy) than the signs (which represent a more advanced stage of neuropathy).[19]

Distal perfusion is another important risk factor for ulceration and amputation.[2,6,11–13] Over the 18-month period, our patients did not present any statistically significant changes in palpation of the lower-limb pulse. However, there was a significant improvement in the ABI ($p = 0.021$), since the incidence of peripheral arterial disease decreased from 73.3% to 46.7% according to this index (ABI < 0.90 or > 1.30) (Table 6). This improvement can be attributed to the appearance of collateral circulation, probably resulting from treatment consisting of regular walks, controlling the risk factors (such as systemic arterial hypertension and dyslipidemia), changes in habits (such as elimination of smoking and controlling the diet) and use of statins, platelet antiaggregants and hemorheological drugs.[30]

Conclusion

Creation of diabetic foot prevention and control programs within the primary and secondary healthcare sectors is a viable investment, given its low cost, in view of the important human and socioeconomic repercussions of the disease. This has a positive impact through noticeably improving patients' quality of life and reducing the vascular and neuropathic symptoms and occurrences of ulceration and amputation.

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Conflicts of interest

The authors declare that there were no conflicts of interest.

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