Effects of nursing care on patients in an educational program for prevention of diabetic foot

Riscos associados à mortalidade em pacientes atendidos em um programa de prevenção do pé diabético

Efecto del cuidado de enfermería en pacientes atendidos en un programa de prevención del pie diabético

Suzana Fiore Scain[a]
Elenara Franzen[a]
Vânia Naomi Hirakata[b]

ABSTRACT

Objectives: Identify in patients with type 2 diabetes what changes in the feet would be associated with demographic, clinical, biochemical and treatment characteristics and which would increase the risk of mortality.

Methods: Retrospective longitudinal study evaluating the alterations in feet of outpatients attended at a nursing visit. Data from the clinical history and foot exam were collected from 918 medical records of a convenience sample.

Results: At 10 years, the cumulative mortality attributable to peripheral polyneuropathy was 44.7%, to peripheral artery disease was 71.7%, to both conditions were 62.4%, and to amputation was 67.6%. After multivariate analysis, duration of nursing follow-up remained as the only protective factor against death (p < 0.001).

Conclusions: The risk of death in these patients decreased when they had consultations with a nurse educator. Ischemic feet, amputation, and coronary artery disease remained independent risk factors.

Keywords: Diabetes mellitus. Mortality. Diabetic foot. Nursing care. Ambulatory care.

RESUMO

Objetivos: Identificar em pacientes com diabetes tipo 2 quais alterações nos pés estariam associadas às características demográficas, clínicas, bioquímicas e de tratamento e quais delas aumentariam o risco de mortalidade.

Métodos: Estudo longitudinal retrospectivo que avaliou as alterações nos pés de pacientes externos atendidos em consulta de enfermagem. Os dados da história clínica e do exame dos pés foram coletados de 918 prontuários de uma amostra por conveniência.

Resultados: Em 10 anos, a mortalidade cumulativa atribuída a polineuropatia sensitiva periférica foi 44,7%, pela doença vascular periférica 71,7%, pela associação das duas condições 62,4% e pela amputação 67,6%. Após análise multivariável, o tempo de acompanhamento com enfermeiros permaneceu como único fator de proteção para a mortalidade (p < 0,001).

Conclusão: O risco de morrer nesses pacientes diminuiu quando consultaram com enfermeiros educadores. Permaneceu como fator de risco independente pacientes com pé isquêmico, amputação e doença arterial coronariana.

Palavras-chave: Diabetes mellitus. Mortalidade. Pé diabético. Cuidados de enfermagem. Assistência ambulatorial.

RESUMEN

Objetivos: Identificar en pacientes con diabetes tipo 2 que alteraciones en los pies estarían asociadas a las características demográficas, clínicas, bioquímicas y de tratamiento y cuáles de ellas aumentarían el riesgo de mortalidad.

Métodos: Estudio longitudinal retrospectivo que evaluó los cambios en los pies de pacientes externos atendidos en consulta de enfermería. Los datos de la historia clínica y del examen de los pies fueron recolectados de 918 prontuarios, una muestra por conveniencia.

Resultados: En 10 años, la mortalidad acumulativa atribuida a la polineuropatía sensitiva periférica fue 44.7%, por la enfermedad vascular periférica 71.7%, por la asociación de las dos condiciones 62.4% y por la amputación 67.6%. Después del análisis multivariable, el tiempo de acompañamiento con enfermeros permaneció como único factor de protección para la mortalidad (p < 0,001).

Conclusión: El riesgo de morir en estos pacientes disminuyó cuando consultaron con enfermeros educadores. Se mantuvo como factor de riesgo independiente pacientes con pie isquémico, amputación y enfermedad arterial coronaria.

Palabras clave: Diabetes mellitus. Mortalidad. Pie diabético. Atención de enfermería. Atención ambulatoria.

[a] Hospital de Clínicas de Porto Alegre (HCPA), Serviço de Enfermagem Ambulatorial. Porto Alegre, Rio Grande do Sul, Brasil.

[b] Hospital de Clínicas de Porto Alegre (HCPA), Unidade de Bioestatística. Porto Alegre, Rio Grande do Sul, Brasil.

■ INTRODUCTION

Diabetes mellitus (DM) is characterized by persistent hyperglycemia that causes chronic complications and increases the risk of mortality of the patients. Diabetic foot is the final event of the chronic complications of DM, and the major pathophysiological factors of ulceration and lower limb infections include diabetic neuropathy, plantar pressure, and trauma. Other contributing factors include peripheral arterial disease (PAD) of varying degrees and disturbances in the healing process and in immunological defense[1]. The association of DM and foot ulceration increases the risk of amputations, and two amputations occur every minute in the world indicating that this group of patients are socially and economically more vulnerable, and many of them have a shorter life expectancy[2]. The risk is partly attributed to the enormous incidence of cardiovascular diseases (CVD) accounting for up to 80% of deaths in individuals with type 2 diabetes mellitus (DM2) and is higher than that of the general population. Diabetic foot ulcer patients have a much greater increase in mortality risks compared to non-ulcerated diabetic patients[3].

In order to achieve better results than those currently available in the prevention of events such as complications of the disease and its consequences, and in the treatment of DM, self-care is considered essential and diabetes self-management education is recommended[4-5].

Considering the vulnerability of patients with DM2, the present study aimed to identify which foot changes are associated with demographic, clinical, biochemical and therapeutic characteristics and which may increase the risk of mortality.

■ METHOD

Retrospective longitudinal study that assessed the changes in the feet of outpatients with DM2 who attended nursing appointments. Associations were made with the etiological classification of the diabetic foot ulcer and demographic, clinical, biochemical and therapeutic characteristics, and those that increased the risk of mortality were identified.

The study population consisted of 918 patients with DM2 who had their feet examined in at least two nursing consultations of an educational program for the prevention and treatment of diabetic foot in a high-complexity general university hospital, in Rio Grande do Sul, Brazil, in the 1997-2009 period. Patients were referred to the nurses by physicians of various specialties.

This project (08-608) was approved by the Research Ethics Committee of Hospital de Clínicas de Porto Alegre, on January 7, 2009, and the researchers signed a Research Use Statement for access to data.

Data was collected from the records of the patients who had appointments with the nurse, considering the patient's entry into the educational program, i.e. time zero. The data collected included information on gender, age and clinical history data: use of medication, known DM duration, hospitalizations, history of smoking, comorbidities (dyslipidemia, hypertension, obesity); presence of stroke, coronary artery disease (CAD), myocardial infarction, congestive heart failure, *angina pectoris*, PAD and diabetic peripheral neuropathy (DPN). In foot checks, the Semmes-Weinstein monofilament (SWM) test, 10 grams was used to screen loss of protective sensation; palpation of the dorsal pedis and/or posterior tibial pulses for the identification of PAD, and Wagner classification was used, in degrees (zero to 3) for the ulcers[6]. Finally, the feet were classified into normal (without ulcers and absence of DPN and PAD), neuropathic (sensitivity and deformities), ischemic (presence of PAD) and mixed (DPN and PAD). Based on this evaluation, the nurses provided guidance on self-care for prevention of diabetic foot and/ or reduction of risks, to change the patients' attitudes towards the condition[2].

In their foot checks, the patients were encouraged to be careful to any changes such as: corns, ulcers, blisters, changes in skin color, temperature and humidity, and sore or swollen sites. The patients received instructions on how to wash and dry their feet, cut their nails, and warned of the importance of wearing appropriate socks and shoes. The patients were also advised not to use sharp objects or improper products on their feet and received information (tips), in plain language, on how to prevent diabetic foot in systemic care, as follows: avoid/quit smoking, manage their blood sugars, cholesterol and blood pressure and perform periodic foot checks [1]. The nurses applied compression bandaging to the ulcer (if any), and the patients were advised on how to apply the bandaging at home. Such information was also made available to the patients in writing. The presence of family members has always been encouraged. At the end of each appointment, the patients were given a folder with tips on preventive care and another one including information on glucose level, lipid profile, blood pressure and weight.

The nursing appointments lasted from 30 minutes to one hour, and the patient's return date was scheduled, according to the risk. A telephone line was available for clarification of doubts. Patients who experienced aggravation of their foot problems, requiring appointments other than those scheduled were instructed to seek the nurse for a re-evaluation. Depending on the severity of the case, the pa-

tients were also examined by a physician and, if necessary, were referred to an emergency or returned to their homes.

Biochemical data included glycated hemoglobin (A1C), total cholesterol and its fractions, and triglycerides.

Statistical analysis

The descriptive characteristics were presented as mean (±) and standard deviation for continuous variables and as relative and absolute frequencies for categorical variables

The level of significance was 0.05 and Professional Statistics (SPSS), version 18.0 was used.

Univariate analysis was performed through simple Cox regression and Kaplan-Meier estimations for each of the variables separately. Then, the relative risk of death (through hazard ratio) with a 95% confidence interval was determined. Subsequently, all the variables with p <0.20 were analyzed concomitantly through Cox multiple regression, but in three different models (for etiological classification of the diabetic foot, for ulcer and for amputation), due to the strong association between them. The multicollinearity of the variables, measured by Variance Inflation Factor (VIF), was strong. In the final model, the variables had a p value <0.05.

■ RESULTS AND DISCUSSION

Demographic, biochemical, clinical and patient characteristics are summarized in Table 1. The 918 patients had a mean glycemic control not within the target range and High Density Lipoprotein (HDL-C) 46.8 ± 13 mg/dL were within the recommended standards[7]. Regarding the type of treatment of diabetes adopted, 9.0% only changed their diet and did physical exercises. Most patients with hypertension took an antihypertensive drug. Lipid-lowering drugs were preventively prescribed for 51 patients. Five hundred fourteen patients had changes in their feet, 46.6% had DPN and 39.5% had PAD.

Table 1 - Demographic, biochemical, clinical and therapeutic characteristics of patients in nursing consultation. Porto Alegre, RS. Brazil, 1997-2009

Characteristics	n = 918
Known DM duration, years*	10.8 (±8.1)
Age*	62.4 (±10.4)
Male gender	434 (47.3)
Follow-up duration, years**	2.0 (0.1-4.6)
Amplitude	0.1-23.1
Hospitalization	217 (23.7)
Smoking	358 (39.0)
Glycated hemoglobin (A1C)	7.9 (±2.2)
Triglycerides*	184.2 (±152.0)
Total Cholesterol*	200.2 (±51.0)
LDL-Cholesterol *	116.4 (±42.2)
HDL-Cholesterol*	46.8 (±13.0)
Comorbidities	
Dyslipidemia (hypercholesterolemia)	375 (46.1)
Coronary Arterial Disease	299 (32.6)
Hypertension	780 (85.0)
Obesity	427 (46.5)
Stroke	65 (7.1)
Classification of the diabetic foot	
Normal	404 (44.0)
Ischemic	102 (11.1)
Neuropathic	215 (23.4)
Mixed (Neuro-ischemic)	197 (21.5)

Ulcer	162 (17.2)
Amputation	125 (13.6)
Medications prescribed	
Anti-hypertensive drugs	759 (82.5)
Antidyslipidemic drugs	426 (46.9)
Antihyperglycemic agents	
None	82 (9.0)
Oral	401 (44.2)
Insulin	155 (17.1)
Both	270 (29.7)

Source: Research data, 1997-2009.
DM, Diabetes mellitus; LDL, *Low Density Lipoprotein*; HDL, *High Density Lipoprotein*. Data are presented in %, unless otherwise noted. * Mean and standard deviation; ** Median.

During the 12 years of the study, the 158 deaths recorded in the hospital and their primary causes were identified. The most frequent primary causes of death among 158 patients were cardiovascular diseases (35.4%) and infections (34.8%). Congestive heart failure (CHF) and acute myocardial infarction (AMI) were the prevalent cardiovascular diseases, and unspecified sepsis and pneumonia, the most common infections. Cardiovascular diseases were significantly more severe than expected in 19.8% in patients with ischemic feet, and cerebrovascular disease in 7.5% in patients with normal feet. Infections due to diabetic foot were the primary cause of death in 5 patients.

The 5-year and 10-year survival rates of diabetic patients, respectively, according to the classification of diabetic foot (a), the onset of ulcers (b) and the occurrence of amputations (c) are shown in Figure 1.
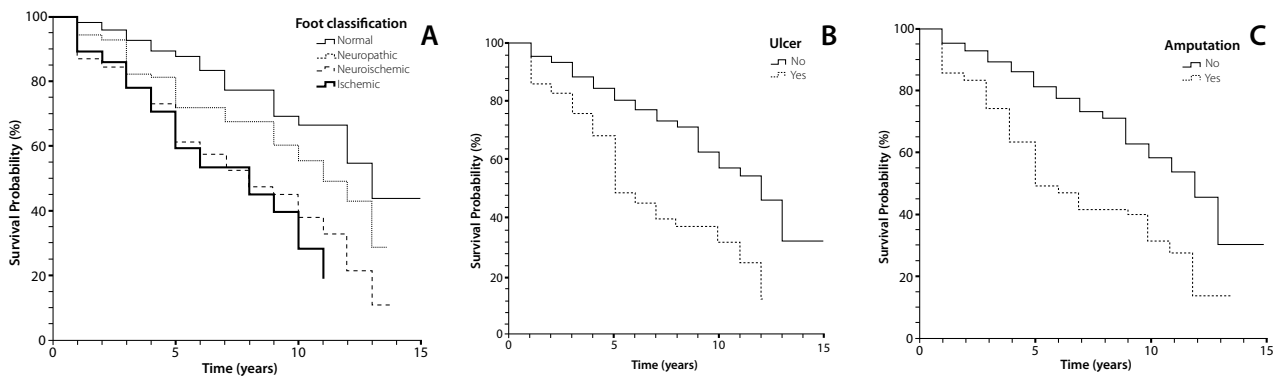

Figure 1 – Cumulative survival according to: **A)** Diabetic foot classification **B)** foot ulcer **C)** amputation
Source: Research data, 1997-2009.

The 10-year survival rate (Figure 1A) was 66.6% for patients with normal feet; 55.3% for patients with neuropathic feet; 37.6% for patients with mixed feet, and 28.3% for patients with ischemic feet. The median of survival was 11 years (p <0.013) for the patients with neuropathic feet; 8 years, for those with mixed and ischemic feet (both with p <0.001), which differed significantly from the patients with normal feet (13 years).

The 10-year survival rate of patients without a history of ulcers (Figure 1B) was 57.5%, median of 12 years, and for those who had ulcers, 32.3%, median of 5 years (p <0.001).

The 10-year survival rate of patients without amputation (Figure 1C) was 58.2%, median of 12 years and of patients with amputation, 32.4%, median of 5 years (p <0.001). Patients with normal feet had a 13-year survival, 2 years more than those with neuropathic feet, 5 years more than those with ischemic feet, and 8 years more than those with ulcers and amputations.

Patients with foot problems (56%) had a 10-year cumulative mortality rate for DPN of 44.7%, for PAD, of 71.7%, and the association of the two conditions (mixed feet) at 62.4%. Patients with ulcer (17%) and those with am-

putation (13%) had a 10-year cumulative mortality rate of 67.7%. The presence of ulcers significantly increased mortality risks, though with percentage values lower than those found in other studies[8].

Risk factors for mortality are summarized in Table 2. After univariate analysis, the following significant risk factors for mortality were identified: known duration of disease, age, glycated hemoglobin test (A1C), CAD, stroke, ischemic, neuropathic and mixed foot; ulcer, amputation and insulin use. The protective factors were duration of follow-up with nurses, obesity and the use of antidyslipidemic drug.

After multivariate analysis, follow-up time with nurses (95% CI, 0.66 (0.61-0.71) remained the only protective factor against mortality. Each additional year of patient follow-up by nurses reduced by 34% the risk of mortality for all diabetic foot classifications in the three models analyzed. The variables ischemic foot (CI, 2.41 (1.42-4.11), amputation (CI 2.51 (1.69-3.7), and CAD, 72 (1.22-2.44) were predictive of the risk of mortality.

Table 2 – Simple Cox regression (unadjusted hazard ratios) and multiple Cox regression (adjusted hazard ratios) analyzes of the risk factors for mortality. Porto Alegre, RS. Brazil, 1997-2009

Risk factors	Cox multiple regression			
	HR (IC95%)	M1†: HR (IC95%)	M2‡: HR (IC95%)	M3§: HR (IC95%)
Foot classification				
Normal	1 (reference)	1	–	–
Ischemic	3.07 (1.96-4.8)	2.41 (1.42-4.11)*	–	–
Neuropathic	1.66 (1.1-2.5)	1.22 (0.75-1.98)	–	–
Mixed	2.74 (1.85-4.06)	1.53 (0.94-2.49)	–	–
Ulcer	2.48 (1.8-3.41)	–	1.3 (0.89-1.89)	–
Amputation	2.36 (1.72-3.25)	–	–	2.51 (1.69-3.7)*
Known DM duration	1.02 (1-1.04)	1.02 (1.00-1.05)*	1.02 (1-1.05)*	1.02 (1-1.05)*
Age	1.05 (1.03-1.06)	1.02 (1-1.04)*	1.02 (1.01-1.04)*	1.03 (1.01-1.04)*
Male gender	1.39 (1.03-1.88)	1.1 (0.73-1.65)	1.16 (0.78-1.72)	0.98 (0.66-1.45)
Follow-up duration	0.64 (0.6-0.69)	0.66 (0.61-0.71)*	0.67 (0.62-0.72)*	0.6 (0.61-0.71)*
Hospitalization	1.13 (0.82-1.54)	–	–	–
Smoking	1.02 (0.75-1.37)	–	–	–
Glycated hemoglobin (A1C)	1.12 (1.04-1.21)	1.09 (1-1.17)*	1.09 (1.01-1.18)*	1.07 (0.99-1.16)
Dyslipidemia (Hypercholesterolemia)	1.27 (0.91-1.78)	–	–	–
Coronary Arterial Disease	1.72 (1.28-2.31)	1.72 (1.22-2.44)*	1.8 (1.28-2.55)*	1.59 (1.12-2.27)*
Hypertension	0.85 (0.55-1.32)	–	–	–
Obesity	0.55 (0.4-0.76)	0.75 (0.51-1.09)	0.72 (0.49-1.05)	0.84 (0.57-1.24)
Stroke	1.95 (1.26-3.03)	0.83 (0.45-1.55)	1.23 (0.69-2.19)	1.35 (0.76-2.41)
Use of Anti-hypertensive drugs	1.27 (0.8-2)	–	–	–
Use of Antidyslipidemic drugs	0.6 (0.44-0.81)	0.89 (0.6-1.31)	0.85 (0.57-1.25)	0.86 (0.59-1.27)
Antihyperglycemic agents				
None	1 (reference)	1	1	1
Oral	1.04 (0.58-1.88)	1.38 (0.61-3.12)	1.36 (0.61-3.01)	1.17 (0.52-2.61)
Insulin	2.1 (1.13-3.88)	2.05 (0.89-4.75)	1.92 (0.83-4.42)	1.62 (0.69-3.76)
Both	0.88 (0.47-1.64)	1 (0.41-2.39)	1.07 (0.46-2.53)	0.95 (0.4-2.25)

Source: Research data, 1997-2009.

DM, Diabetes mellitus; HR, *Hazard ratios*. * p < 0, 05; M1†: Multivariable analysis for type (classification) of the foot, adjusting for the other variables with p < 0.20 in univariate analysis; M2‡: Multivariable analysis for ulcer, adjusting for the other variables with p < 0.20 in univariate analysis; M3§: Multivariable analysis for amputation, adjusting for the other variables with p < 0.20 in univariate analysis.

Mortality risk increased by 2.4 times (141%) in the group of patients with ischemic feet compared to those with normal feet, and 2.5 times (151%) in the group of amputees. CAD increased mortality risk by 72% for all patients with foot problems; 80% when adjusted for the presence of ulcers and 59% in those with amputation.

The baseline characteristics of the study participants are typical of adults with DM2: aged over 60 years, mean duration of DM of 10 years and A1C not within the target range. The following characteristics presented clinical risk factors for CVD already well known in patients with DM: high rates of hypertension, almost half with dyslipidemia and obesity, a significant percentage of smokers. Presence of CAD, PAD and DPN are associated with foot ulcers, gangrene and amputations. The lipid profile is typical of patients with DM2, except for High Density Lipoprotein (HDL), although gender differences were not analyzed[7]. These factors reveal that this group of patients is at greater risk of morbidity and mortality, having the same frequent causes of mortality, sepsis and cardiovascular events that resulted in multiple organ failure described in other studies[8-9].

Although duration of DM, age, A1C not within the target range, stroke and the presence of ulcers are considered contributing factors to increased mortality risk, the findings of this study are consistent with no (no-risk) effect[10]. Patients with ulcers have a shorter life expectancy and are at much greater risk for all the conditions that cause mortality compared to diabetic patients without a history of ulcer[7,11]. The risk is partly attributed to the enormous incidence of cardiovascular diseases, which occurred in this group but regarding ulcers, the risk was demonstrated in bivariate analysis and did not persist after adjustment for the other variables associated with mortality. Although the present study does not aim to assess ulcer treatment, the fact that patients are regularly assisted by nurses with extensive experience in ulcer treatment, regularly and on an ongoing basis may have made a difference.

The three models investigated did not detect higher mortality rates in patients who use insulin. The recommended drug treatment is expected to reduce A1C to the desired levels of control, or at least improve glycemic control, through a positive influence on disease progression and its consequences[12].

The present study found that patients who had their feet examined by nurses and who have attended the follow-up appointments over the years lived longer because they minimized the risks of long-term diabetes on their feet. Educational interventions were used to change pa-tient behavior and encourage self-care. These two aspects may have contributed to improve knowledge, train skills and establish a patient-nurse dialogue on attitudes related to foot hygiene, selection of appropriate footwear, better emergency management and appropriate treatment of ulcers and amputations[13]. Moreover, the permanent guidance provided by nurses on systemic care, such as not smoking, manage blood sugar levels, cholesterol and blood pressure, and taking medications correctly, impacted the results, which is consistent with recommendations from other studies[12,14].

The nurses carried out periodic educational efforts during the appointments, and we believe that part of the effects of the educational interventions persist. The delivery of folders with information on preventive foot care, insulin administration and healthy habits to the patients, as well as the nurses' willingness to clarify possible doubts through telephone calls may also have produced positive effects. Available data have shown that the length (duration) of exposure to educational activities, rather than the mere patient-educator contact, produce a change of attitude[15]. It is also possible that these patients are more motivated to adhere to treatment because some of them have been exposed to other educational environments (groups of insulin administration and education about the disease), and thus are more likely to participate in and accept diabetes educational activities, for a longer time and, thus, more willing to change their habits[16]. Other factors deserve consideration, as follows: all patients had free access to medications, to several health professionals, as well as to the tests and procedures needed to control their health. This degree of accessibility may partly explain the differences found.

Coronary artery disease, PAD and amputations were determinant risk factors for mortality. Macrovascular disease when associated with diabetes is more frequent and the most clinically relevant cause of morbidity and mortality[1]. Ischemic heart disease is the leading cause of mortality, and prognosis after a more severe ischemic event remains an independent risk for the development of CHF and as an independent predictor in neurological ischemic events that vascular complications are more frequent and intense in diabetic individuals[17-19].

The high cardiovascular risk associated with diabetic foot may be related to the cumulative effect associated with neuropathy and peripheral arterial disease, which are known to be associated to increase in cardiovascular morbidity[7,14,18]. Diabetic peripheral neuropathy is one of the most important risk factors for both the development of ulcers and amputations in feet in patients with DM. The

loss of sensitivity causes permanent damage to the tissues and may lead to the development of ulcers[2,13]. Data indicate that poor glycemic control, foot ulcers, cardiovascular disease and peripheral arterial disease are independent risk factors for the incidence of amputations[17-20].

Diabetic foot is a heterogeneous condition, with many risk factors, and the presence of PAD is a determining factor. In the present study, the risk of death was higher in patients with PAD alone (ischemic foot), and when it was associated with DPN (neuropathic foot), the risk was increased (mixed foot). Patients with DPN were those that most resembled the patients with normal feet, which may indicate that the disease causes morbidity but not mortality. Corroborating other studies, the cumulative effect of PAD and the occurrence of amputations increased the risk of death of diabetic patients[17-20].

One limitation of this retrospective study may be the absence of important information in the patients' records.

■ CONCLUSION

Foot care of patients with DMs, which was also explained to them during the appointments with nurse educators, reduced the risk of death in these patients. The independent risk factors were as follows: patients with ischemic foot, with amputation and with coronary artery disease. Known DM duration, age, glycated hemoglobin not within the target range, presence of ulcer, and use of insulin did not increase the risk of mortality.

Health care should be understood in a broader context of social determinants, such as access to treatment (including education) for patients with conditions that require substantial self-care, such as DM.

Diabetic foot is a heterogeneous condition with several risk factors that have a significant impact on the progression and outcome of the disease. Therefore, further studies are needed to assess the cumulative effect of these factors.

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■ **Corresponding author:**
Suzana Fiore Scain
E-mail: suzana.scain@gmail.com