Type 2 diabetes and kidney transplant: comparative study on medication adherence

Diabetes tipo 2 e transplante renal: estudo comparativo sobre adesão medicamentosa

Diabetes tipo 2 y trasplante renal: estudio comparativo sobre la adhesión farmacológica

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Abstract

Objective: To investigate medication adherence in type 2 Diabetes Mellitus among kidney transplant recipients and non-transplant recipients.

Methods: Comparative study between patients assisted at the Diabetes Center (Group 1 without kidney transplant) and at the Post-Renal Transplant Outpatient Clinic of the Hospital do Rim e da Hipertensão (Group 2 with kidney transplant), both in the city of São Paulo. The sample consisted of people over 18 years of age with a previous diagnosis of type 2 diabetes using medication for glycemic control. The data collection period was from October 2017 to October 2018. The following was applied to participants: socio-clinical form, instrument for Measuring Adherence to Medication Treatment in Diabetes Mellitus (oral antidiabetics and insulin) and the Anxiety and Depression scale. The project was approved by the Research Ethics Committee as 0712/2017.

Results: Sample composed of 107 patients (Group 1: 56 and Group 2: 51), higher percentage of men, mean age of 63.3 years, from the metropolitan region of São Paulo, retired, married, overweight, without symptoms of anxiety and depression. Even though patients self-reported adherence to medication for diabetes control, results of glycated hemoglobin ranged between 8.3 and 8.7% between groups, both above 7%.

Conclusion: When analyzing the relationship between self-reported adherence, glycated hemoglobin, anxiety and depression, a statistically significant correlation could not be found. The parameters evaluated in this study did not allow establishing a cause and effect relationship.

Resumo

Objetivo: Investigar a adesão medicamentosa no Diabetes Mellitus tipo 2 entre transplantados renais e não transplantados.

Métodos: Estudo comparativo entre pacientes assistidos no Centro de Diabetes (Grupo 1 sem transplante renal) e no Ambulatório de Pós-Transplante Renal do Hospital do Rim e da Hipertensão (Grupo 2 com transplante renal), ambos na cidade de São Paulo. A amostra foi composta por maiores de 18 anos, com diagnóstico de diabete tipo 2 prévio e em uso de medicamentos para o controle glicêmico. A coleta de dados ocorreu de outubro de 2017 a outubro de 2018. Aplicou-se aos participantes: formulário sócio clínico, instrumento de Medida de Adesão ao Tratamento Medicamentoso no Diabetes Mellitus (antidiabéticos orais e insulina) e a escala de Ansiedade e Depressão. O projeto foi aprovado no Comitê de Ética e Pesquisa como 0712/2017.

Resultados: Amostra composta de 107 pacientes (Grupo 1: 56 e Grupo 2: 51), maior porcentagem de homens, média de idade de 63,3 anos, provenientes da região metropolitana de São Paulo, aposentados, casados, com sobrepeso, sem sintomas de ansiedade e depressão. Os pacientes autorreferiram ter

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adesão aos medicamentos para o controle do diabetes, porém os resultados da hemoglobina glicada variaram entre 8,3 e 8,7% entre os grupos, ambos acima de 7%.

Conclusão: Ao analisar a relação entre a adesão autorreferida, hemoglobina glicada, ansiedade e depressão não foi possível evidenciar correlação estatisticamente significante. Os parâmetros avaliados neste estudo não permitiram estabelecer a relação de causa e efeito.

Resumen

Objetivo: Investigar la adhesión farmacológica en la Diabetes mellitus tipo 2 en trasplantados renales y no trasplantados.

Métodos: Estudio comparativo entre pacientes atendidos en el Centro de Diabetes (Grupo 1 sin trasplante renal) y en los Consultorios Externos de Postrasplante Renal del Hospital del Riñón y de la Hipertensión (Grupo 2 con trasplante renal), ambos en la ciudad de São Paulo. La muestra fue formada por mayores de 18 años, con diagnóstico previo de diabetes tipo 2 y en uso de medicamentos para control glucémico. La recopilación de datos se realizó de octubre de 2017 a octubre de 2018. Se aplicaron los siguientes instrumentos a los participantes: formulario socio-clínico, instrumento de Medida de Adhesión al Tratamiento Farmacológico (antidiabéticos orales e insulina) y escala de Ansiedad y Depresión. El proyecto fue aprobado por el Comité de Ética e Investigación con el número 0712/2017.

Resultados: Muestra formada por 107 pacientes (Grupo 1: 56 y Grupo 2: 51), mayor porcentaje de hombres, promedio de edad 63,3 años, provenientes de la región metropolitana de São Paulo, jubilados, casados, con sobrepeso, sin síntomas de ansiedad y depresión. Los pacientes autodeclararon adherir a los medicamentos para el control de la diabetes, pero los resultados de la hemoglobina glicosilada variaron entre 8,3 y 8,7 % entre los grupos, más de 7 % en ambos.

Conclusión: Al analizar la relación entre la adhesión autodeclarada, la hemoglobina glicosilada, la ansiedad y la depresión, no se observó correlación estadísticamente significativa. Los parámetros evaluados en este estudio no permitieron establecer una relación de causa y efecto.

Introduction

Diabetes Mellitus (DM) corresponds to a global pandemic.[1] In Brazil, 12.5 million people aged between 20 and 79 years have diabetes, representing the fourth country with the highest number of people with DM; in 2019, 4.2 million people died worldwide as a result of the disease and its complications.[1,2] As type 2 diabetes (DM2) represents 90-95% of the total amount, it is the most common type.[2]

Of DM2 patients, 20-40% progress to Chronic Kidney Disease (CKD).[2,3] The relationship between DM and CKD is a consequence of the microvascular impairment of renal glomeruli (given the increase in the glomerular basement membrane, thickening of tubular basement membrane and diffuse sclerosis), increased urinary albumin excretion, and reduced glomerular filtration rate.[4]

When advanced, chronic kidney disease has renal replacement therapies: peritoneal dialysis, hemodialysis and kidney transplant (KT); the latter is the therapeutic option with better prognoses when related to mortality and quality of life.[5]

In Brazil, 6,283 kidney transplants were performed in 2019 and the waiting list had 25,163 active members waiting for a kidney.[6] With the COVID-19 pandemic, the number of transplants decreased significantly; 4,805 were performed in 2020, leading to the increase in active waiting list to 26,359 people.[7]

In addition to taking care of pre-existing DM2, after undergoing kidney transplant, the recipient is faced with the challenge of maintaining glycemic control and using immunosuppressive drugs, which are essential for non-rejection of the graft, but may lead to glycemic alterations. Glucocorticoids cause insulin resistance; calcineurin inhibitors inhibit the degradation of insulin granules and glucose transporters; and antiproliferative agents (mTOR inhibitors) can increase insulin resistance and decrease insulin secretion.[2,5,8,9]

Therapeutic adherence is essential for a promising evolution of transplantation and minimization of comorbidities that cause and/or are associated with this process.[5] The rate of non-adherence to medications in DM ranges between 17 and 86% and one of the reasons is the absence and/or low presence of symptoms.[10,11]

According to the World Health Organization, the definition of adherence comprises the following concept: "the extent to which a person's behavior – taking medication, following a diet and/or executing lifestyle changes – corresponds with the agreed recommendations from a healthcare provider"; that is, the person follows the recommendations given regarding the care for health. This concept seeks to understand individuals broadly and the various factors exerting influence in non-adherence to treatment, such as: the individual, disease, health beliefs, treatment with quality of life and relationship with the institution - health team.[12,13]

The treatment of DM consists of pharmacological and nonpharmacologial measures (physical activities and diet), in addition to the importance of signs of anxiety and depression.[2]

Depression is a highly prevalent and underdiagnosed comorbidity in diabetic patients; on average, a third of patients has not had an adequate diagnosis. The presence of symptoms of anxiety and depression can make self-care difficult given the low self-esteem, pessimism about the future and about symptoms of the disease; thus causing non-adherence to treatment.[2]

The motivating factor for the study was the difficulty encountered by patients with DM2 in maintaining a glycated hemoglobin lower/equal to 7% and the increased complexity of treatment after undergoing kidney transplant. Thus, adherence to medication for DM2 among kidney transplant recipients and non-transplant recipients was investigated.

Methods

This was a comparative study between patients with DM2 without kidney transplant (Group 1) and DM2 with kidney transplant (Group 2). The study sites were the Outpatient Clinic of the Hospital do Rim e da Hipertensão (HRIM) and the Diabetes Center of the Universidade Federal de São Paulo, both located in the city of São Paulo. Data were collected from October 31, 2017 to October 17, 2018. The sample was by convenience, as patients were recruited considering the possibility of collection in each outpatient clinic once a week, non-simultaneously; they were invited to participate in the study while waiting for their consultations or in the post-consultation period.

The inclusion criteria comprised patients diagnosed with DM2 for at least one year, over 18 years of age and using oral antidiabetic drugs and/or insulin. Group 1 consisted of patients who did not undergo kidney transplant; Group 2 was composed of patients who had undergone kidney transplant for a minimum of one year and a maximum of 10 years earlier. Exclusion criteria were patients undergoing renal re-transplantation or other types of transplants.

After the interviews, the researcher sought to complete patients' information using the electronic medical record, in which some data were incomplete. Such patients were not excluded from the study because this was not a randomized study.

During the approach of eligible patients, 76 subjects reported not having continuous access to medicines and supplies to control DM2. As patients were analyzed in a punctual and non-longitudinal way and they could not quantify the number of times they could not have access to medicines and supplies, the researcher chose to exclude them, based on the belief that this could interfere with their adherence and imply in research bias. The final sample consisted of 107 patients (Group 1: 56 and Group 2: 51).

The following were used in comparative evaluation: socio-clinical form (age, sex, education, time of diagnosis, profession, marital status, children, self-reported color/race, clinical and family history), instrument for Measuring Adherence to Medication Treatment in Diabetes - Oral Antidiabetics and for Measuring Adherence to Medication Treatment in Diabetes – Insulin, and Hospital Anxiety and Depression Scales. The instruments for Measuring Adherence to Medication Treatment in Diabetes - Oral Antidiabetics and for Measuring Adherence to Medication Treatment in Diabetes - Insulin are composed of seven questions each, ranging from "Never" to "Always" (1 – 6), the results between 1 and 4 are considered non-adherence and 5 and 6 as adherence to medication treatment.[14] The values of Hospital Anxiety and Depression scales range from 0 - 21 in each scale, classified between 0 - 7 absence of symptoms, 8 – 10 mild symptoms, 11 – 15 moderate symptoms, and 16 – 21 severe symptoms.[15,16] The results of laboratory tests and clinical data were obtained via the patient's electronic medical record, considering the following data with a maximum retrospective time of one year from the date of the interview: weight, height, fasting glucose, glycated hemoglobin, urea and creatinine. Based on weight and height, the Body Mass Index (BMI) was calculated.[17] Creatine, age, sex and color were used to

calculate the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) according to guidelines from the Brazilian Society of Nephrology.[18] The glycemic target established by the Brazilian Society of Diabetes was glycated hemoglobin lower/equal to 7%.[2]

Statistical analysis was performed using the mean, median, minimum and maximum values, standard deviation, absolute and relative frequencies. The inferential analysis used to investigate the relationship between self-reported adherence and glycated hemoglobin, anxiety, and depression was the Fisher's Exact test or its extension.[19] An alpha significance level of 5% was used in all analyzes. Data were entered into Excel 2010 for Windows spreadsheets for adequate information storage. Statistical analyzes were performed using the R statistical program version 3.3.2.[20]

The project was submitted to the Research Ethics Committee of the participating institutions and approved under number 2.317.366 (Certificate of Presentation of Ethical Appreciation: 70470417.0.0000.5505).

Results

The mean age of participants (107 subjects) was 63.3 years (median= 64 years, minimum=46 years / maximum=82 years, standard deviation of 8.3 years); mean time since diagnosis of DM2 was 20.4 years (median= 20 years, minimum=4 years / maximum=45 years, standard deviation of 9.4 years), although on average, DM2 treatment was of 19.1 years (median= 18 years, minimum=2 years / maximum=45 years, standard deviation of 9.5 years). Regarding clinical history, most patients had arterial hypertension 85 (79%), followed by CKD 58 (54%), dyslipidemia 51 (48%) and hypothyroidism 24 (22%). Regarding family history, there was a prevalence of diabetes in 83 (78%) interviewees, followed by heart disease 34 (32%), arterial hypertension 26 (24%) and acute myocardial infarction 22 (21%). In the characterization of kidney transplant, most patients received the kidney from deceased donors 45 (88%), with a mean of 4.1 years of transplant (median=4 years, standard deviation of 2.4 years). Table 1 contains the socio-clinical characteristics.

Table 1. Sociodemographic and clinical characteristics of DM2 patients with kidney transplant and without kidney transplant

Variables	Group 1 (n=56) n(%)	Group 2 (n=51) n(%)	Total (n=107) n(%)
Sex			
Male	26(46)	39(76)	65(61)
Female	30(54)	12(24)	42(39)
Color			
Mixed race	23(41)	32(63)	55(51)
White	27(48)	11(22)	38(36)
Black	2(4)	6(12)	8(8)
Asian	4(7)	1(2)	5(5)
Indigenous	0(0)	1(2)	1(1)
Origin			
Metropolitan region of Sao Paulo	53(95)	30(59)	83(78)
Hinterland of São Paulo	3(23)	16(31)	19(18)
Another state	0(0)	5(10)	5(5)
Retired			
Yes	39(70)	28(55)	67(63)
No	17(30)	23(45)	40(37)
Schooling			
Illiterate	1(2)	6(12)	7(7)
Incomplete primary education	26(46)	20(39)	46(43)
Complete primary education	6(11)	5(10)	11(10)
Incomplete secondary education	2(4)	3(6)	5(5)
Complete secondary education	12(21)	9(18)	21(20)
Incomplete higher education	1(2)	3(6)	4(4)
Complete higher education	8(14)	5(10)	13(12)
Marital status			
Married	35(63)	36(71)	71(66)
Single	7(13)	5(10)	12(11)
Widowed	9(16)	3(6)	12(11)
Divorced	5(9)	6(12)	11(10)
Separated	0(0)	1(2)	1(1)
Number of children			
None	4(7)	3(6)	7(7)
Only one	6(11)	5(10)	11(10)
Two to three	33(59)	27(53)	60(56)
Four or more	12(21)	16(31)	29(27)
Body mass index (BMI) (Kg/m^2)			
Normal (18.5 a 24.9)	9(16)	19(37)	28(26)
Overweight (25.0-29.9)	23(41)	16(31)	39(36)
Grade I obesity (30.0-34.9)	22(39)	15(29)	37(34)
Grade II obesity (35.0-39.9)	1(2)	1(2)	2(2)
Grade III obesity (40.0 or more)	1(2)	0(0)	1(1)
Vision problem			
No vision problem	35(78)	13(25)	48(45)
Diabetic retinopathy	13(23)	23(45)	36(34)
Cataract	5(9)	13(25)	18(17)
Glaucoma	3(5)	2(4)	5(5)

With regard to renal function, the evaluation calculation shows that the majority in Group 1 had mild alterations and in Group 2, severe alterations

(Table 2). When asked about how they performed the follow-up of DM2 with a medical team, in Group 1, 100% of treatment was performed with an endocrinologist and in Group 2, 35% performed follow-up with an endocrinologist and 29% did not perform DM2 follow-up treatment. The glycemic profile between groups is described in table 2.

Table 2. Renal function and glycemic profile of non-transplanted and transplanted DM2 patients

Variables	Group 1 n(%)	Group 2 n(%)	Total n(%)
Renal function (CKD-EPI) (ml/min/1.73m²)	53(100)	48(100)	101(100)
Stage 1 (> than 90)	17(32)	0(0)	17(17)
Stage 2 (60 – 89)	22(42)	14(29)	36(36)
Stage 3A (45-59)	7(13)	12(25)	19(19)
Stage 3B (30-44)	5(9)	19(40)	24(24)
Stage 4 (15-29)	2(4)	6(13)	8(8)
Stage 5 (< que 15)	0(0)	0(0)	0(0)
Self-reported adherence	56(100)	51(100)	107(100)
Adherence	54(96)	48(94)	102(95)
Non-adherence	2(4)	3(6)	5(5)

	Group 1		Group 2	
Glycemic profile	Blood glucose (mg/dl)	Glycated hemoglobin (%)	Blood glucose (mg/dl)	Glycated hemoglobin (%)
N	54	45	40	51
Mean	150	8.3	168	8.7
Median	129	7.6	126	8.8
Minimum	30	5.7	51	6.1
Maximum	294	13.7	654	12.2
Standard deviation	62	1.8	116	1.7

Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI)

Most patients had no symptoms of anxiety (77%) and depression (79%), and of those who did, most had mild symptoms of anxiety (10%) and depression (11%). When analyzing the relationship between self-reported adherence, glycated hemoglobin, anxiety and depression, it was not possible to establish a statistically significant correlation (Table 3).

Table 3. Distribution of self-reported adherence of transplanted and non-transplanted DM2 patients according to glycated hemoglobin, anxiety and depression

Variables	Non-adherence n(%)	Adherence n(%)	Total n(%)	p-value
Group 1 (DM2 without kidney transplant)				
Glycated hemoglobin	2(100.0)	45(100.0)	47(100.0)	>0.999
Above 7%	2(100.0)	30(66.7)	32(68.1)	
Up to 7%	0(0)	15(33.3)	15(31.9)	
Anxiety	2(100.0)	54(100.0)	56(100.0)	>0.999
No symptom	2(100.0)	41(75.9)	43(76.8)	
Mild symptom	0(0)	8(14.8)	8(14.3)	
Moderate symptom	0(0)	2(3.7)	2(3.6)	
Severe symptom	0(0)	3(5.6)	3(5.4)	
Depression	2(100.0)	54(100.0)	56(100.0)	0.357
No symptom	1(50.0)	44(81.5)	45(80.4)	
Mild symptom	1(50.0)	3(5.6)	4(7.1)	
Moderate symptom	0(0)	4(7.4)	4(7.1)	
Severe symptom	0(0)	3(5.6)	3(5.4)	
Group 2 (DM2 with kidney transplant)				
Glycated hemoglobin	3(100.0)	47(100.0)	50(100.0)	0.534
Above 7%	2(66.7)	37(78.7)	39(78.0)	
Up to 7%	1(33.3)	10(21.3)	11(22.0)	
Anxiety	3(100.0)	48(100.0)	51(100.0)	0.072
No symptom	2(66.7)	37(77.1)	39(76.5)	
Mild symptom	0(0)	3(6.3)	3(5.9)	
Moderate symptom	0(0)	8(16.7)	8(15.7)	
Severe symptom	1(33.3)	0(0)	1(2.0)	
Depression	3(100.0)	48(100.0)	51(100.0)	0.276
No symptom	2(66.7)	37(77.1)	39(76.5)	
Mild symptom	0(0)	8(16.7)	8(15.7)	
Moderate symptom	1(33.3)	3(6.3)	4(7.8)	
Severe symptom	0(0)	0(0)	0(0)	
Groups 1 and 2				
Glycated hemoglobin	5(100.0)	92(100.0)	97(100.0)	>0.999
Above 7%	4(80.0)	67(72.8)	71(73.2)	
Up to 7%	1(20.0)	25(27.2)	26(26.8)	
Anxiety	5(100.0)	102(100.0)	107(100.0)	0.306
No symptom	4(80.0)	78(76.5)	82(76.6)	
Mild symptom	0(0)	11(10.8)	11(10.3)	
Severe	0(0)	10(9.8)	10(9.3)	
Severe symptom	1(20.0)	3(2.9)	4(3.7)	
Depression	5(100.0)	102(100.0)	107(100.0)	0.347
No symptom	3(60.0)	81(79.4)	84(78.5)	
Mild symptom	1(20.0)	11(10.8)	12(11.2)	
Moderate symptom	1(20.0)	7(6.9)	8(7.5)	
Severe symptom	0(0)	3(2.9)	3(2.8)	

Fisher's Exact Test or its extension

Discussion

The profile of patients observed in this study differs from that of the literature. In the literature, we found a predominance of females and a mean time of DM2 diagnosis of 10 years. The similarities found were: educational level (predominance of incomplete primary school), mean age (60 years), married, presence of obesity, clinical history of arterial hypertension and if patients were on combination therapy.[10,21,22]

There is a small difference between groups regarding glycemic profile (Table 2), maintaining the same glycemic pattern, which may have an impact on the evolution of changes in renal function and graft survival. In the studied sample, 78% of pa-

tients had a family history of diabetes, emphasizing the epidemiological importance of family history and the need for lifestyle changes of the individual and those around him/her. Effective control of glycemic indices is complex and requires extensive knowledge of available treatments and their combinations. Research shows that treatment with a multidisciplinary team can help to save US$ 277.78 throughout a one-year period for the health service, reduce by 0.20%-1.60% the serum levels of glycated hemoglobin, reduce the need for hospitalization, increase the quality of life and education in diabetes and, when individualized, it adds patients' experiences to their treatment.[23–25]

In Table 3, when patients were asked about their adherence to the use of DM2 medication, the self-reports indicated adherence to medication treatment, but the same was not observed when comparing the glycemic profile, which was greater than the established target of 7% in glycated hemoglobin. This result may be associated with clinical inertia (the difficulty in achieving, maintaining or intensifying therapy when glycemic control has not been achieved).[26] In a study on adherence to DM2 treatment, only 15.8% self-reported not being adherent to medication treatment, while 84.2% reported adherence to medication treatment. Glycated hemoglobin was used as one of the measures of metabolic control, and levels were altered in most participants (75.1%), similar to our study (73.2%), in which a statistically relevant relationship with variables of sex, age, education, time of diagnosis and metabolic control was also not found.[10] In Brazil, a large study on access and adherence to drug treatment for DM was published, and 80% self-reported their health as regular or good and 66% considered that DM did not limit their activities, allegations similar to what was observed in our study.[27]

Other studies report that subjective measures, such as self-report, may cause overestimation of adherence, which may demonstrate errors arising from the patient's memory and/or distortions.[28] The same may have occurred with the use of the self-reported questionnaire in the present study, and the answers obtained may be overestimated due to patients' fear of being judged by health professionals. Although the confidentiality of answers was clarified when applying the informed consent form, questions may have led patients to respond positively about their adherence.

Although data in the literature are similar to those found in this study, there was a distortion in the self-perception of treatment adherence when comparing the altered glycemic profile observed in both groups (glycated hemoglobin: 8.3% in Group 1 versus 8.7% in Group 2).

Poor adherence requires early diagnosis and is associated with several causes, such as family and social support, life beliefs, expectations with the transplant, access to the health service, available medication, acceptability of the medication, complex therapeutic scheme proposed, absence of symptoms, time of diagnosis, knowledge and understanding of the disease and treatment, among others, and the participation of a multidisciplinary team is important for patient and family education.[2,29,30]

Other points related to non-adherence found in the literature are: lack and motivation to change life habits, lack of knowledge about the disease and its complications, lack of help from caregivers or family members with the treatment, low self-esteem, need to take medications more than once a day, depression, personal problems, the occurrence of adverse reactions such as hypoglycemia and diarrhea, increasing presence of associated diseases, lack of evident symptoms of the presence of the disease being treated, negative portrayal of the disease and treatment, in addition to passivity of the patient in the relationship with health professionals and in the choice of treatment.[28,31]

According to the Brazilian Society of Diabetes, the percentage of young people diagnosed with DM2 that has depression is of 15-22% and individuals with DM are two to three times more likely to have depression than the general population, in addition to nutrition-related disorders.[2] The relevance of the psychological issue and the impact of interventions by the multidisciplinary team in the increase of quality of life and change of behavior in DM2 treatment are highlighted in the literature.[23] A low concentration of symptoms related to anxiety and depression was observed in data collected in this

study; of patients who presented anxiety symptoms, a higher percentage of mild symptoms was observed in Group 1 and of moderate symptoms in Group 2. As for depression symptoms, a higher percentage of mild symptoms was found in both groups, and only in Group 1 participants presented severe symptoms.

The scientific literature researched for the discussion of medication adherence presented the importance of the multidisciplinary team composed of nurses, nutritionists, physical trainers, pharmacists, cardiologists, nephrologists and psychologists, considering the fixed points for the treatment and prevention of complications. However, care focused on the individualized needs of each patient cannot be forgotten, taking into account their needs, support network and a real understanding of their health status and responsibilities.[2,23–25]

Conclusion

The conclusion reached was the lack of a statistically significant relationship between self-reported adherence, glycated hemoglobin and symptoms of anxiety and depression. The parameters evaluated in this study did not allow establishing a cause and effect relationship.

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Collaborations

Procópio FO, Rangel EB, Roza BA, Sá JR and Schirmer J contributed to the study design, data analysis and interpretation, article writing, relevant critical review of the intellectual content and approval of the final version to be published.

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