



Which diseases are associated with polypharmacy in a geriatric population?

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Abstract

Objective: To investigate the prevalence of polypharmacy and its associated factors in the Primary Care setting of Caicó city (Rio Grande do Norte state, Brazil). **Method:** A quantitative prevalence study of 295 older adults was conducted. **Results:** The prevalence of polypharmacy was 22%. Participants were predominantly aged 60-79 years (76%), brown (50.5%), married (43.1%), educated to primary (incomplete) level (60.3%) and had an income of 1-3 minimum wages (74.2%). The most used medications were angiotensin-receptor blockers (26.1%), statins (20.3%) and thiazide diuretics (19.3%). The multivariate logistic regression model showed that polypharmacy was associated with *diabetes mellitus*, systemic arterial hypertension, generalized anxiety disorder, gastritis, heart failure, coronary artery disease and age >80 years. **Conclusion:** Polypharmacy prevalence was high and strongly associated with advanced age and number and type of comorbidity. These results highlight the need for greater health promotion actions and policies, continuous professional education, enhanced team work and longitudinal systemic care provision to address the iatrogenic risk of use of multiple medications by older adults.

Key words: Polypharmacy.
Aged. Primary Care.

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INTRODUCTION

Aging is a natural, complex, dynamic, progressive and continuous process involving a series of biological, social and behavioral changes, accompanied by a gradual decline in human physiological reserves^{1,2}.

Therefore, older adults are the population group most affected by chronic Non-Communicable Diseases (NCDs) and by degenerative conditions. Given this process with a burden of organic dysfunctions impacting quality of life to a lesser or greater degree, older adults are more likely to require routine pharmacological treatment, often translating to daily use of numerous medications. This scenario is exacerbated by the use of further drugs through self-medication, a common practice in Brazilian society³.

In general, daily long-term use of 5 medications or more (polypharmacy) can lead to serious health complications if not carefully monitored by trained professionals².

Although medical training and scientific output in this area have sought to focus efforts on promoting more rational prescribing of medications in the context of promoting quaternary health, it is not uncommon to encounter prescriptions containing pharmacological redundancy, incorrect dosages, and potentially serious drug-drug interactions⁴. This situation increases the risk of adverse reactions and side-effects associated with medications or the use of potentially inappropriate medications for all older patients due to their drug-disease and drug-syndrome interactions².

The city of Caicó, situated in the interior of Rio Grande do Norte state, is a region historically renowned for poor healthcare and a high proportion of older adults, partly explained by the migratory phenomenon involving the exodus of the younger population to major urban centers. Thus, the present study makes a social contribution and features an innovative aspect in choosing an issue that is underserved by public policy and lacks investigations elucidating the health needs of the older population⁵.

The aim of this study was to investigate the prevalence of polypharmacy and its associated factors in the Primary Care setting of Caicó city (Rio Grande do Norte state, Brazil).

METHOD

A cross-sectional quantitative study was conducted. The study sample comprised participants aged ≥ 60 years, of both genders, who were registered users of the Family Health Strategy (ESF) and resided in the urban area of the city of Caicó, Rio Grande do Norte state, Brazil. Individuals who were bedridden, presented cognitive impairment as reported by the caregiver and/or Primary Health team, or had no carer, were excluded because some of the information required was collected via interview.

The sample effect was based on the total number of older adults registered in the Basic Health Care Information System (SISAB) on December 2015 for the urban area of the city, i.e. 8.347 individuals. The sample calculation was determined for a confidence interval of 95%, statistical power of 85%, non-response margin of 20% and estimated polypharmacy rate of 39.4% in the older population, based on the study by Pagno et al⁶. as reference. The calculation yielded a sample size of 366 participants.

Participants were recruited randomly and stratified proportionally across 5 Primary Health Units (UBSs) according to the total number of older adults registered in the respective catchment areas. Data collection was performed via previously scheduled home visits made by the primary health team between May 2021 and February 2023, during which interviews were conducted. A standardized structured questionnaire was applied collecting information for the following variables: sociodemographic data (sex, age, race/color, marital status, education, living arrangements (number and relationship of dwellers), dwelling status, number of rooms, income, and whether holder of private health insurance plan); medications used; self-reported comorbidities; and self-rated health status (very poor, poor, fair, good or very good; whether hospitalized in past 12 months, appetite loss, sleep problems,

tobacco or alcohol use, engagement in physical activity, and difficulties carrying out everyday tasks). The questionnaire was applied by previously trained medical students and took an average of 22 minutes to complete. The questionnaire design was based on a pilot study of 33 older adults who were not included in the final study sample.

The data were first analyzed using descriptive statistics and expressed as measures of central tendency and dispersion. Bivariate analysis was carried out using Poisson's chi-square test or its non-parametric equivalent (Fisher's exact test), where applicable. Binary Logistic Regression with the stepwise entry model was used as the analysis tool at multivariate level, with most important events as the outcome ($p < 0,20$), which were previously determined on the bivariate association test outlined. However, only variables yielding results with a p-value < 0.05 were retained in the final model. Crude and adjusted prevalence ratios (PR) were estimated, together with their respective 95% confidence intervals (95%CI). The residuals were observed according to the criteria of the Hosmer's & Lemeshow test and multivariate outliers were analyzed using studentized values.

The present study was designed in accordance with the Recommendations and Regulations for Research involving Humans, pursuant to Resolution nos. 466/2012 and 510/2016 of the National Board of Health, and approved by the Research Ethics Committee of the Universidade Federal do Rio Grande do Norte, School of Medical Science - FACISA/UFRN, under permit no. 4.331.783/2020. All participants signed the Free and Informed Consent Form and received guaranteed professional support for situations of risk through pharmaceutical care intervention based on the Dader method⁷ and assistance from the Primary Care team (APS) at the center where the participant was registered.

DATA AVAILABILITY

The complete dataset underpinning the results of the present study are available on figshare from [<https://figshare.com/s/b63af0a05cd10ff840fa>].

RESULTS

The COVID-19 pandemic hampered data collection due to lockdowns, leading to a 19.4% loss in sample size, giving a total of 295 respondents.

Study participants were predominantly aged 60-79 years, brown, married, educated to primary (incomplete) level, homeowners, had an income of 3 minimum wages, held no private health plan, and were followed by Primary Care health professionals. The profile of participants is presented in Table 1.

The most used medications were angiotensin-receptor blockers (ARB), statins, thiazide diuretics, beta blockers and metformin (Table 2).

Of the group of study participants, 48.1% (142) rated their health as good, 10.5% (31) reported at least 1 hospitalization in the past 12 months, 36.3% (107) reported sleep problems, 16.6% (49) loss of appetite, 56.9% (168) reported regular alcohol use, 65.4% (193) declared as smokers, and 70.2% (207) sedentary. In addition, 28.5% (84) of participants reported sustaining a fall in the last year and 27.5% (81) stated having difficulty performing everyday tasks.

The study results showed that 22% (65) of participants were exposed to polypharmacy. The independent variables exhibiting a statistically significant association on bivariate analysis, determined using the chi-square or Fisher's exact tests depending on sample distribution, with polypharmacy are presented in Table 3.

Table 1. Sociodemographic profile of study participants (n=295). Caicó city, Rio Grande do Norte state, 2023.

Variables	n (%)
Sex	
Female	162 (54.9%)
Male	133 (45.1%)
Age (years)	
60-79	225 (76.3%)
≥80	70 (23.7%)
Color	
White	113 (38.3%)
Brown	149 (50.5%)
Black	24 (8.1%)
Yellow	8 (2.7%)
Indigenous	1 (0.3%)
Marital status	
Single	48 (16.3%)
Widowed	78 (26.4%)
Divorced	24 (8.1%)
Civil union	18 (6.1%)
Married	127 (43.1%)
Education	
Illiterate	56 (19.0%)
Primary (incomplete)	178 (60.3%)
Primary (complete)	14 (4.7%)
Secondary (incomplete)	9 (3.1%)
Secondary (complete)	25 (8.5%)
Higher	13 (4.4%)
Living arrangements	
Spouse	128 (43.4%)
Son/Daughter(s)	89(30.2%)
Alone	49 (16.6%)
Other relatives	28 (9.5%)
Non-family	1 (0.3%)
Dwelling status	
Rented	49 (16.7%)
Loaned	14 (4.8%)
Owned	232 (78.6%)
Family income (MW*)	
<1.1	45 (15.3%)
1.1-3	219 (74.2%)
3.1-5	24 (8.1%)
5.1-10	4 (1.4%)
>10	3 (1.0%)

to be continued

Continuation of Table 1

Variables	n (%)
Private health plan holder	
No	273 (92.5%)
Yes	22 (7.5%)
Registered UBS user	
No	38 (12.9%)
Yes	257 (87.1%)
Followed by UBS professionals	
No	39 (13.2%)
Yes	256 (86.8%)

*MW: minimum wage, where 1 MW = BRL 1,045.00 (2020).

Table 2. Medications most used by study participants (n=295). Caicó city, Rio Grande do Norte state, 2023.

Variables	n (%)
Angiotensin-receptor blockers	
Yes	77 (26.1)
No	218 (73.9)
Statins	
Yes	60 (20.3)
No	235 (79.7)
Thiazide diuretics	
Yes	57 (19.3)
No	238 (80.7)
Beta blockers	
Yes	51 (17.3)
No	244 (82.7)
Metformin	
Yes	50 (16.9)
No	245 (83.1)
Antiplatelet agents	
Yes	42 (14.2)
No	253 (85.8)
Angiotensin-converting enzyme inhibitors	
Yes	39 (13.2)
No	256 (86.8)
Calcium channel blockers	
Yes	34 (11.5)
No	261 (88.5)
Selective serotonin reuptake inhibitors	
Yes	27 (9.2)
No	268 (90.8)
Proton-pump inhibitors	
Yes	21 (7.1)
No	274 (92.9)

to be continued

Continuation of Table 2

Variables	n (%)
Levothyroxine	
Yes	21 (7.1)
No	274 (92.9)
Sulphonylureas	
Yes	20 (6.8)
No	275 (93.2)
Long-acting benzodiazepenes	
Yes	19 (6.4)
No	276 (93.6)
Atypical dopamine receptor blockers	
Yes	14 (4.7)
No	281 (95.3)
Anticoagulant agents	
Yes	9 (3.1)
No	286 (96.9)
Insulin	
Yes	9 (3.1)
No	286 (96.9)
Intermediate-acting benzodiazepenes	
Yes	9 (3.1)
No	286 (96.9)
Serotonin and noradrenalin reuptake inhibitors	
Yes	8 (2.7)
No	287 (97.3)
Chlorthalidone and atenolol	
Yes	7 (2.4)
No	288 (97.6)
Olmesartan + hydrochlorothiazide	
Yes	7 (2.4)
No	288 (97.6)
Glitazones	
Yes	5 (1.7)
No	290 (98.3)
Potassium-sparing diuretics	
Yes	5 (1.7)
No	290 (98.3)
Propatylnitrate	
Yes	5 (1.7)
No	290 (98.3)
Potassium channel blockers	
Yes	5 (1.7)
No	290 (98.3)
Nonsteroidal anti-inflammatory drugs	
Yes	5 (1.7)
No	290 (98.3)

Table 3. Association of sociodemographic, self-rated health and comorbidity variables with polypharmacy (n=295). Caicó city, Rio Grande do Norte state, 2023.

Variable	Polypharmacy		PR*	CI**	p-value
	Yes (%)	No (%)			
Coronary Artery Disease			4.23	2.62 - 6.83	<0.001
Yes	14(77.8)	4(22.2)			
No	51(18.4)	226(81.6)			
Dyslipidemia			2.87	1.85 - 4.45	<0.001
Yes	21(50)	21(50)			
No	44(17.4)	209(82.6)			
Systemic Arterial Hypertension			2.71	1.62 - 4.53	<0.001
Yes	52(29.5)	124(70.5)			
No	3(10.9)	106(89.1)			
<i>Diabetes Mellitus</i>			2.64	1.71 - 3.98	< 0.001
Yes	33(39.8)	50(60.2)			
No	32(15.1)	180(84.9)			
Generalized Anxiety Disorder			2.27	1.40 - 3.69	0.001
Yes	16(43.2)	21(56.8)			
No	49(19)	209(81)			
Heart failure			4.00	1.90 - 8.42	0.002
Yes	5(83.3)	1(16.7)			
No	60(20.8)	229(79.2)			
Hyperthyroidism			2.10	1.14 - 3.87	0.017
Yes	9(42.9)	12(57.1)			
No	56(20.4)	218(79.6)			
Gastritis			2.37	1.09 - 5.16	0.030
Yes	5(50)	5(50)			
No	60(21.1)	225(78.9)			
Heart arrhythmia			2.11	1.07 - 4.15	0.031
Yes	7(43.8)	9(56.3)			
No	58(20.8)	221(79.2)			
Alcohol use			1.54	1.01 - 2.36	0.047
Yes	35(27.6)	92(72.4)			
No	30(17.9)	138(82.1)			
Age ≥80 years			1.53	0.97 - 2.41	0.071
Yes	21(30.0)	49(70.0)			
No	44(19.6)	181(80.4)			
Good self-rated health			0.67	0.44 - 1.04	0.077
Yes	25(17.6)	117(82.4)			
No	40(26.1)	113(73.9)			
Osteoarthritis			1.67	0.93 - 3.00	0.100
Yes	10(34.5)	19(65.5)			
No	55(20.7)	211(79.3)			

to be continued

Continuation of Table 3

Variable	Polypharmacy		PR*	CI**	<i>p</i> -value
	Yes (%)	No (%)			
Rheumatoid arthritis			2.33	0.86 - 6.26	0.123
Yes	3(50)	3(50)			
No	62(21.5)	227(78.5)			
Difficulty performing everyday tasks			1.35	0.86 - 2.13	0.209
Yes	22(27.2)	59(72.8)			
No	43(20.1)	171(79.9)			

*PR: Prevalence Ratio; ** CI: Confidence Interval.

The following variables were tested at bivariate level, but not considered for logistic modeling ($p > 0.20$) because the model is at risk of inflation by multicollinearity above this cut-off point: gender, holding health plan; UBS user registration and care; major depressive disorder; osteoarthritis; osteoporosis; rheumatoid arthritis; herniated disc; benign prostatic hyperplasia; asthma; Chagas disease; labyrinthitis; glaucoma; trigeminal neuralgia; cancer; Alzheimer disease; Parkinson disease; tremor; stroke; hospitalization in last 12 months; sleep problems; appetite loss; tobacco use; engagement in physical activity; fall events in last 12 months; dwelling; marital status; skin color; education and income.

Some conditions were reported in the study but, owing to low prevalence, could not be statistically tested using the current study design,

namely: mood disorder; fibromyalgia; psoriasis, atherosclerosis, venous insufficiency; peripheral artery disease; chronic obstructive pulmonary disease; hyperthyroidism; alcoholism, pulmonary emphysema; gout; obesity; gastroesophageal reflux disease; cataracts; hepatic steatosis; nephrolithiasis; schizophrenia; deep vein thrombosis; thrombophilia; anemia; leprosy; and HIV.

The final model proved significant, exhibiting 47.7% sensitivity, 94.8% specificity, overall fit of 85.7%, Nagelkerke R-squared value of 37.8%, significant Omnibus and Wald tests ($p < 0.001$). Analysis of residuals was assured by the non-significant Hosmer-Lemeshow test ($p = 0.531$), and by the 4% (13) presence of studentized residuals above 2 standardized units, characterizing a random distribution of residuals and absence of multivariate outliers, respectively (Table 4).

Table 4. Binary Logistic Regression Model for polypharmacy of study participants. Caicó city, Rio Grande do Norte state, 2023.

Variables in equation	B*	S.E.**	Wald	Df***	Sig ^b	PR ^c (95 %CI) ^d
Diabetes mellitus	1.341	0.352	14.540	1	<0.001	3.825 (1.919-7.621)
Systemic arterial hypertension	1.258	0.415	9.176	1	0.002	2.518 (1.559-7.939)
Generalized anxiety disorder	1.392	0.429	10.540	1	0.001	4.021 (1.736-9.316)
Gastritis	1.535	0.760	4.081	1	0.043	4.640 (1.047-20.571)
Heart failure	3.120	1.208	6.666	1	0.010	22.647 (2.120-241.930)
Coronary heart disease	3.282	0.665	24.373	1	<0.001	26.624 (7.235-97.974)
Age ≥ 80 years	0.732	0.375	3.800	1	0.050	2.079 (1.006-4.337)

*Beta zero value; **Standard Error; ***Degrees of freedom; ^bsignificance; ^cAdjusted Prevalence Ratio; ^dConfidence Interval of Prevalence Ratio.

DISCUSSION

The prevalence of polypharmacy in the older adults assessed was 22%. The study results provide scientific evidence supporting a multiple association of polypharmacy with Diabetes Mellitus (DM), Systemic Arterial Hypertension (SAH), Generalized Anxiety Disorder (GAD), gastritis, Heart Failure (HF), Coronary Heart Disease (CHD) and age ≥ 80 years in the older adults assessed.

Cardiovascular diseases are of major epidemiological significance in Brazil, representing the sole factor associated with 31% of all deaths in the country. Of these conditions, CHD and HF are the most prevalent in the Primary Care setting and their clinical management involves the use of numerous medications⁸⁻¹⁰. These two heart conditions are often associated with other underlying diseases, such as DM, SAH and GAD^{2,9}, and also with diseases in the multiple model devised in this study, further supporting the scientific evidence on the validity of the profile presented.

In the context of this morbidity profile, the prescribing of additional drugs to the treatment already implemented should be supported by a longitudinal care plan developed in an interprofessional manner. Failure to adopt this shared approach increases the risk of unwanted secondary pharmacological effects, drug-drug interactions and errors during self-administration of medications, jeopardizing treatment efficacy or leading to harmful consequences for patients^{9,11}. Indeed, there is evidence supporting the association between concomitant use of multiple drugs and negative health outcomes, such as hospital readmission, and greater risk of hospitalization and mortality¹¹.

In older individuals, the adverse effects stemming from the inappropriate association of multiple drugs, drug-drug interactions and adverse reactions, or collateral effects, should be considered in the context of the natural physiological decline inherent to the aging of patients^{1,2}. However, measuring the effects of age on individual homeostasis is currently hard to achieve by primary care professionals in Brazil because, besides the locoregional disparities in care quality, the high demand, working conditions, scant

resources and other health needs of the population, are factors limiting professional practice¹².

Even if this was feasible, the concomitant use of 4 or more medications, irrespective of therapeutic management, is associated with an increase in falls, *delirium*, bleeding, fatigue, tremor, hallucinations, depression, anxiety, urinary incontinence, appetite loss, diarrhea and constipation in older adults^{2,10}. This scenario raises doubts as to the viability and effectiveness of carrying out homeostasis assessments in older individuals at a population level.

Therefore, besides a change in practices of health professionals, further clinical studies on the risks of using numerous medications in older patients should be conducted. After all, this population, proportionally, uses more medications than any other age group. Despite this fact, the majority of studies in the area center their analyses on robust younger adults, as opposed to conducting longitudinal investigations involving the older population with multimorbidity¹³⁻¹⁵.

Consequently, clinical prescriptions may lack the proper theoretical support, particularly in cases where 5 or more medications are used concomitantly. This situation can lead to other clinical conditions, which may promote a prescribing cascade of new drugs in an attempt to treat the resultant symptoms, creating a vicious cycle and posing a greater risk of polypharmacy^{8,16,13}.

The older population is the age group in Brazil with the highest prevalence of DM and SAH, where both these conditions were found to be associated with polypharmacy in the present study. The two diseases share similar risk factors and complications, albeit microvascular, such as retinopathy, neuropathy and nephropathy, or macrovascular, such as stroke, infarction and CHDs in general¹⁴.

Previous studies investigating the association of DM and SAH with polypharmacy, both national and international, have found similar evidence, lending credence to the results of the present study. Barella et al.¹⁵, in a study in Rio Grande do Sul, reported a prevalence of SAH of 67.5% in a sample of 203 older adults engaging in polypharmacy. In international studies involving 5,639 older adults^{17,18}, SAH and

DM were associated with polypharmacy at rates of 80% and 82.4%, respectively.

An explanatory element that may contribute to the phenomenon is the fact that therapies for SAH and DM are often used in combination. According to the Brazilian Society of Diabetes¹⁹, up to 4 medications of different classes may be used to meet the needs of insulin therapy. Even when this limit has been reached, a further oral antidiabetic drug, such as metformin, may be associated. The Brazilian Arterial Hypertension Guideline²⁰, however, does not establish a maximum for anti-hypertensive agent use, but recommends the use of up to 4-5 medications until reaching refractory hypertension, defined as uncontrolled hypertension despite the use of 5 or more anti-hypertensive drugs.

In this context, an in-depth analysis of the clinical condition of older adults with SAH and/or DM, one of the most common situations in primary care in Brazil, requires a pharmacological approach tailored to the specificities and needs of older individuals. The devising of clinical protocols, based on these more routine scenarios, which can provide decision support for professionals of health services, should be incentivized and implemented in an effort to promote safer, more integrated healthcare for people aged 60 or older.

Another condition found to be associated with polypharmacy was GAD. It is no coincidence that GAD is one of the most prevalent mental disorders in older individuals in the primary care and outpatient setting, where the condition is associated with a high utilization of health services and polypharmacy²¹. Given its impact on older adults, this group need treatment which often requires introduction of drug therapy, generally starting with Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)²². Both therapeutic options are prone to causing adverse effects, such as agitation, insomnia, sexual dysfunction and excess intestinal gases, typically treated with other medications. In this sense, GAD can be associated with increased risk of polypharmacy in different ways, where communication between professionals managing geriatric patients plays a key role in reducing this risk.

Neumann-Podczaska et al.²³ assessed medical prescriptions of 4,793 older adults. Based on their results, the authors concluded that the prevalence of polypharmacy increased with advancing age. The study²³ revealed a peak prevalence of polypharmacy of 79.6% and of excessive polypharmacy of 36.4% (use of at least 10 medications) in individuals aged 90 or older, consistent with the findings of the present study showing a significant association of polypharmacy in the oldest-old, i.e. individuals aged ≥ 80 years.

Amid the increasing longevity of the Brazilian population, the importance of the strategic role of primary care in devising longitudinal therapeutic plans is clear, encouraging measures for the prevention and diseases and illnesses, health promotion, rational prescribing of medications and tests, practices centered on the logic of the healthcare system and interprofessional approaches such as quaternary prevention measures for the older population, with direct impact on the issue of polypharmacy.

This study serves as a warning in highlighting the deleterious effects of polypharmacy on the health of older individuals, predominantly in the context of chronic NCDs, a leading cause of death among older adults in the Northeast region of Brazil⁵. This scenario can be changed by implementing public policies directed toward primary health to ensure wider coverage and effectiveness of services, improving medical care in places such as Caicó city, Rio Grande do Norte state.

Limitations of the study include the fact that, owing to lockdowns during the pandemic, where older adults were the group worst affected by the more severe form of the disease, the length of the study exceeded the original timeline. Given the effects of the pandemic, the data collection period was extended to ensure losses did not exceed the 20% allowed for the sample.

CONCLUSION

The prevalence of polypharmacy in the present study was 22%, amounting to 65 older adults exposed to this phenomenon. The multivariate analysis revealed that coronary artery disease, heart failure, *diabetes mellitus*, systemic arterial hypertension, generalized

anxiety disorder and age > 80 years were associated with polypharmacy. Hence, health professionals that care for older individuals with multiple comorbidities should work in an interprofessional manner, foster longitudinal care plans and encourage measures for the prevention of diseases and illnesses, health promotion, rational prescribing of medications and tests, thereby practicing quaternary prevention to impact and reduce polypharmacy.

Efforts to reduce polypharmacy should also include more clinical studies investigating the risks of use of multiple medications by older adults and devising clinical protocols which can provide decision support for health professionals and thus promote safer, more integrated care for the population group aged 60 or older.

AUTHORSHIP

- Ingrid Maria de Oliveira Leite - Substantial contributions to the study conception and design; data analysis and interpretation; producing the first drafts of the article; writing the article; approval of the final version for publication; vouching for all aspects of the study.

- Lívia Ramos Farias Leite - Substantial contributions to the study conception and design; data analysis and interpretation; producing the first drafts of the article; writing the article; critical review; approval of the final version for publication; vouching for all aspects of the study.
- Gustavo Guerreiro Gondim Barbosa - Substantial contributions to the study conception and design; producing the first drafts of the article; writing the article; approval of the final version for publication; vouching for all aspects of the study.
- Khálife Wenzel Lima Silva - Substantial contributions to the study conception and design; producing the first drafts of the article; writing the article; approval of the final version for publication; vouching for all aspects of the study.
- Diego Bonfada - Substantial contributions to the study conception and design; data analysis and interpretation; critical review; approval of the final version for publication; vouching for all aspects of the study.

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