Pharmaceutical care reducing the impact of the COVID-19 pandemic on the cardiovascular health of hypertensive and diabetic patients

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ABSTRACT

Introduction: The COVID-19 pandemic has impacted the provision of health services to patients with chronic diseases, and the Medication Therapy Management, an integral part of pharmaceutical care can lead to an improvement in clinical parameters impacted by the pandemic. The objective of this study was to assess the clinical impact of MTM-PC on systemic arterial hypertension and diabetes mellitus (DM) in comparison with the changes imposed by the COVID-19 pandemic in the primary healthcare scope. **Methods:** This is a quasi-experimental, single-arm, before-and-after study, with data collection from July 1, 2019 to October 31, 2022. Data from patients at the pharmaceutical services, of the teaching-Pharmacy of UFJF, were included in the study and were divided into pre-pandemic and pandemic period, considering baseline data and the data related to the reintroduction of face-to-face care in the office as an endpoint.. Data were collected on blood pressure, lipidic profile, glycemia, use of statins and acetylsalicylic acid, cardiovascular risk, and psychosocial data, consequences of social isolation on mental health, medication prescription and life habits. Data were analyzed using the MINITAB v19 software, considering a significance level of 5%. **Results:** During the pandemic without MTM-PC it was found that blood pressure and HDL increased comparing the pre-pandemic with the pandemic without MTM-PC, respectively, SBP 117.5±8.86 and 134.75±12.43; DBP 71.25±3.54 and 83.25±11.65; HDL 45.25±7.80 and 52.38±12.52. Comparatively, it was verified that the blood pressure values were maintained and, the MTM-PC changed parameters like HbA1c 7.890±1.798, [p=0.028] and 7.325±1.30; HDL48.00±6.00 and 59.00±10.56, [p=0.020]. There was a change in both mean of cardiovascular risk, the global scale 13.69±8.08 to 22.38±7.28 and the optimized scale 8.35±6.71 to 16.10±5.83, [p=0.38], with a break in the trend of increased risk with the MTM-PC. The therapeutic load of drugs used for hypertension and diabetes remained below the limit value of 75%. **Conclusion:** There was evidence that the pandemic changed parameters such as blood pressure and cardiovascular risk. Additionally, the MTM-PC may be able to reduce the impact of the pandemic on glycated hemoglobin, improve HDL cholesterol levels and break a trend of increased cardiovascular risk.

KEYWORDS: Hypertension, Diabetes mellitus, Pharmaceutical services, COVID-19.

INTRODUCTION

Non-communicable chronic diseases (NCDs), a term that includes cardiovascular diseases, cancer, diabetes and chronic respiratory diseases, are among the main causes of death in the world, in addition to reducing the number of healthy life years of the population[1]. In Brazil, NCDs are responsible for a large percentage of premature deaths, that is, between 30 and 69 years[2]. Diabetes Mellitus (DM) and Arterial Hypertension stand out, being the most prevalent diseases among NCDs, in addition, they are very costly for the Brazilian public health system[3,4].

In addition to chronic diseases, emerging and resurgent pathogens represent major challenges for global public health[5]. In March 2020, the World Health Organization declared COVID-19[6] a pandemic. Considering that the main containment measure is social isolation, it was necessary to reorganize or discontinue the offering of routine health services, especially those aimed at monitoring patients with chronic diseases. This scenario, however, can be considered a threat to the health of people with NCDs, and may lead to an increase in the number of deaths from preventable causes[7].

Considering that most patients with the aforementioned conditions are users of polypharmacy

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and that the prescription of the wrong dose is one of the main errors encountered, it is necessary to manage the patient's pharmacotherapy regarding the treatment of their clinical conditions[8].

One way to manage the therapeutic drug load in order to improve the effectiveness and safety of the pharmacotherapy in question is to use the total therapeutic load[9]. A standard method of calculation is the sum of the ratio between the prescribed daily dose and the average therapeutic dose of the drugs used for a given health condition.

However, there are new ways of calculating the therapeutic load that consider the individuality of the subject and the indication of pharmacotherapy for calculating the load, which makes it possible to compare the therapeutic intensity of a high-dose monotherapy and a polypharmacy with low-dose drugs, for example an instrument known as PharmEqui®[10].

In this context, the pharmaceutical professional stands out, being the health professional most accessible to the population, who can provide continuity of care to patients with chronic diseases, in addition to providing reliable information on the prevention, detection and management of coronavirus infections[11,12]. Therefore, several strategies were created in order to maintain pharmaceutical care during this period of social isolation[12].

Among the services developed by the pharmacist in pharmaceutical care, the Medication Therapy Management (MTM-PC) stands out, which is developed through pharmaceutical consultations with the objective of solving Problems Related to Pharmacotherapy, promoting a holistic and individualized care system to the patient in their biopsychosocial dimension[13]. The MTM-PC is capable of contributing to the control of blood pressure in patients with hypertension in 93% of the patients treated and reducing the risk of worsening their health and death in patients with DM. In addition, through cost-effectiveness studies, it contributes to the reduction of medication costs for both patients and the public health system (SUS)[14,15].

In general, with the advent of the COVID-19 pandemic, health care had to be modified, which generated impacts that are still not very well dimensioned on health systems and the health of patients[16]. In this context, pharmaceutical services needed to go through changes but they were not paralyzed. Many services were modified to work remotely, such as pharmaceutical care services that have been developed through telecare, which are important to maintain the link between patients and their health care[11,17].

The present study aimed to evaluate the clinical impact of pharmaceutical care on systemic arterial hypertension and DM in view of the changes imposed by the COVID-19 pandemic in the scope of primary health care.

MATERIALS AND METHODS

Type of study

This is a quasi-experimental, single-arm, before-and-after study, which consisted of observing events related to the clinical parameters and pharmacotherapy profile of hypertensive and diabetic patients to be related to the cause, the intervention by pharmaceutical care and changes in the clinical profile of patients caused by the COVID-19 pandemic. Data were collected between the period from July 1, 2019 to October 31, 2022.

Place of study and recruitment of research participants

The participants were selected among the users of the Pharmaceutical Office of the University Pharmacy of the Faculty of Pharmacy of the Federal University of Juiz de Fora, whose study population consisted of the West health district of Juiz de Fora - MG.

The University Pharmacy (FU-UFJF) is inserted in the public health network in the city of Juiz de Fora-MG as a regional within the scope of primary health care, called West Pharmacy. Since 2016, with the Unified Health System (SUS) agreement, FU-UFJF has been dispensing medicines, mainly the basic component, to users of the health system in the region of the São Pedro neighborhood and surroundings.

FU-UFJF adapts to a model of humanized service, without queues with individualized service by tables and an air-conditioned environment. Provides for teaching-research-extension activities related to the University and provides pharmaceutical care services, including Medication Therapy Management (MTM-PC), carried out in the pharmaceutical office[18].

With the decree of the COVID-19 pandemic, in March 11, 2020, pharmaceutical services began to function in an essential way for health care. For safety reasons, the FU-UFJF pharmaceutical office did not work and had as action the telecare targeting to maintain the bond of patients and general screening of their health. In September 2021, with the easing of social distancing standards, the Pharmaceutical Office returned to face-to-face services.

Inclusion and exclusion criteria:

Inclusion criteria: users over 18 years of age, of both sexes, without specification of education, with diabetes, hypertension or both health conditions, who were included in pharmacotherapeutic follow-up until March 31, 2020 and who returned to face-to-face care after the period of social isolation.

Exclusion criteria: users who were assisted by the service, but who were discontinued and did not have a face-to-face or telecare return; users whose last appointment at the pharmacist's office was prior to July/2019; users who did not have laboratory tests or records of objective data or who lack important data for the analyses, users who did not have a record of at least 3 pharmaceutical consultations between the period from November 2021 to October 2022, the period in which there was the face-to-face return of pharmaceutical consultations, described here as a pandemic period with MTM-PC.

Study design and data collection

Data were collected using physical and digital medical records, divided into two periods: data from the patients' past history, before the pandemic, data during the pandemic, and data after the completion of the strict regime of social isolation, with face-to-face return to activities of the Pharmacist's Office. The study was developed in two phases.

In its first phase, the eligibility of patients monitored at the FU-UFJF pharmaceutical office was verified. Among the patients registered in the service, those who, during the pandemic, maintained a relationship with the FU-UFJF through pharmaceutical teleconsultations, carried out by residents, were selected.

The record of capillary blood glucose and blood pressure present in the patients' medical records came from measurements taken in the office by means of prior scheduling, considering the biosafety criteria related to COVID-19, and were not characterized as pharmaceutical consultations. The other results of exams collected respected the periods of the study in view of the records in medical records.

Thus, a minimum of two measures recorded for each clinical variable was stipulated. Patients who had DM2, hypertension or both were selected sequentially. In this way, diabetic, hypertensive users or both who had at least one pharmaceutical consultation record between July 1, 2019 and March 17, 2020, period for historical control (pre-pandemic), were elected.

In the study second phase, using physical and digital medical records, information was collected such as physiological parameters: systolic and diastolic blood pressure (SBP) and (DBP), lipid profile, biochemical markers: capillary blood glucose, glycated hemoglobin (HbA1c), use of statins and acetylsalicylic acid, and additional data for the calculation of cardiovascular risk.

Psychosocial data were collected in pharmaceutical consultations through five questions structured in a pharmaceutical questionnaire for COVID-19, namely: Question 1: Did you have COVID-19?; Question 2: Do you feel more motivated after the rigid period of social isolation?; Question 3: During the pandemic, have you been feeling (or have you often felt) anxious or discouraged, without interest in things?; Question 4: Have your eating habits deteriorated compared to the current period before the pandemic?; Question 5: Have there been any changes (addition/increase of dose/medicine

modification) in the prescription of controlled drugs before the pandemic or in the current period?

After the initial collection for selection of eligible patients, data were tabulated into two periods for analysis, namely: First period: pre-pandemic, which was subdivided into two groups, pre-pandemic without MTM-PC, considered as a historical control, called the pre-pandemic baseline and, with the MTM-PC, called the pre-pandemic endpoint, referring to the period from July 1, 2019 to March 17, 2020; Second period: also subdivided into two groups, these being pandemic without MTM-PC, called pandemic baseline, period from March 18, 2020 to October 31, 2021; and Pandemic with MTM-PC, identified as a pandemic endpoint, referring to November 1, 2021 to October 31, 2022.

Data referring to medical prescriptions were also stratified in the two periods of analysis. To define the therapeutic load, the maximum doses of the drugs prescribed were consulted in their leaflet, on the UpToDate® Clinical Decision Support website and in scientific articles, with the most recent package insert accessed by ANVISA›s Electronic medicine leaflet collection being the preferred document for the collection of this given away.

Through the daily dose prescribed for each patient and the maximum doses collected, using the PharmEqui® app, the therapeutic load used for the treatment of arterial hypertension and diabetes was calculated for each user, comparing the same user in the three studied periods.

From the data collected, using the ASCVD plus application, the ASCVD Risk (Atherosclerotic Cardiovascular Risk) was calculated, which is a calculation performed using nominal variables such as gender, skin color and age, clinical parameters of the patient such as lipid profile, blood pressure and clinical history, such as diagnosis of diabetes, smoking and use of aspirin and statins, with the objective of estimating the chances of the patient developing some cardiovascular disease in the next 10 years[19].

The ASCVD Risk had three different estimates expressing different realities of cardiovascular risk. The global or general risk is the cardiovascular risk taking into account modifiable and non-modifiable patient factors. The optimal risk considers non-modifiable factors and the real or optimized risk is calculated based on the difference between the global risk and the optimal risk, expressing only the modifiable factors, demonstrating the effects of a proposed intervention.

Analysis

Data were analyzed using MINITAB v19 software. Descriptive statistics was performed to obtain summary, mean and median measures, and dispersion measures, standard deviation and interquartile range, which can be represented by boxplot graphs.

The variables were conditioned into continuous, categorical and ordinal and evaluated regarding the distribution of their data, thus assuming a parametric or non-parametric distribution according to the characteristics of the variables. Considering the comparison in two periods, before and during the pandemic, dependent samples, the hypothesis tests to be used were defined, in order to compare as an alternative hypothesis whether there was a difference in the parameters tested before and during the pandemic, considering their respective baselines (without MTM-PC) and endpoint (with MTM-PC).

Hypothesis tests were run considering a significance level of 5% and test power of 80%. As the paired t-student test was run for parametric continuous variables, in this case the variables related to the clinical parameters of lipid profile, blood pressure and diabetes; the Mann-Whitney test was run for non-parametric variables, in this case for the therapeutic load variable, and One-way ANOVA for testing countable data or comparing more than two groups (comparing cardiovascular risk classification), as well as chi-square for categorical data in a contingency analysis, in some analyzes of responses related to biopsychosocial assessment.

Fisher's exact statistical tests for contingency samples and the t-student test for repeated samples with equal variance were run for categorical and continuous variables, respectively, in order to perform the bivariate analysis of responses to questions related to COVID-19 in comparison with the variation of the clinical parameters of the patients.

The calculated ASCVD Risk was classified into global, optimized and ASCVD stratification. The global ASCVD Risk is the risk that each patient has of developing cardiovascular disease in

the next 10 years. Optimized ASCVD Risk is the cardiovascular risk of developing cardiovascular disease after the interference of an action, and the ASCVD stratification is the classification.

Ethic

This study was submitted to the Research Ethics Committee of the Federal University of Juiz de Fora, number CAAE 59458922.9.0000.5147, and was approved by the said research committee with opinion number 5,727,489.

RESULTS

The population of the West Region of Juiz de Fora consists of approximately 40,000 inhabitants[20] and, among the residents belonging to the region of São Pedro and Santos Dumont, 139 are registered users at the Pharmaceutical Office of the University Pharmacy of the UFJF. The exclusions and definition of the final number of participants are detailed in the flowchart (Figure 1).

The final n was 8 participants, 1 patient with only arterial hypertension and 7 with diabetes and arterial hypertension. Three patients declared themselves black and five declared themselves white. The mean age of pre-pandemic participants was 62.5 (±5.96) and post-pandemic was 64.33 (± 6.22), the youngest participant was 56 (55 before the pandemic) years old and the oldest was 71 (69 before the pandemic) years old (Table 1).

Through the questions incorporated in the pharmaceutical consultations, whose answers are found in the table below, it was possible to carry out an assessment of the impact of the pandemic on the psychosocial conditions of the users. It is noteworthy that two of the eight patients had COVID-19 (25%), one male and one female. There was a higher percentage for maintaining/improving pre-pandemic eating habits (87%). In addition, the relevance of COVID-19 in clinical parameters such as: total cholesterol, triglycerides and blood glucose is highlighted (Table 2).

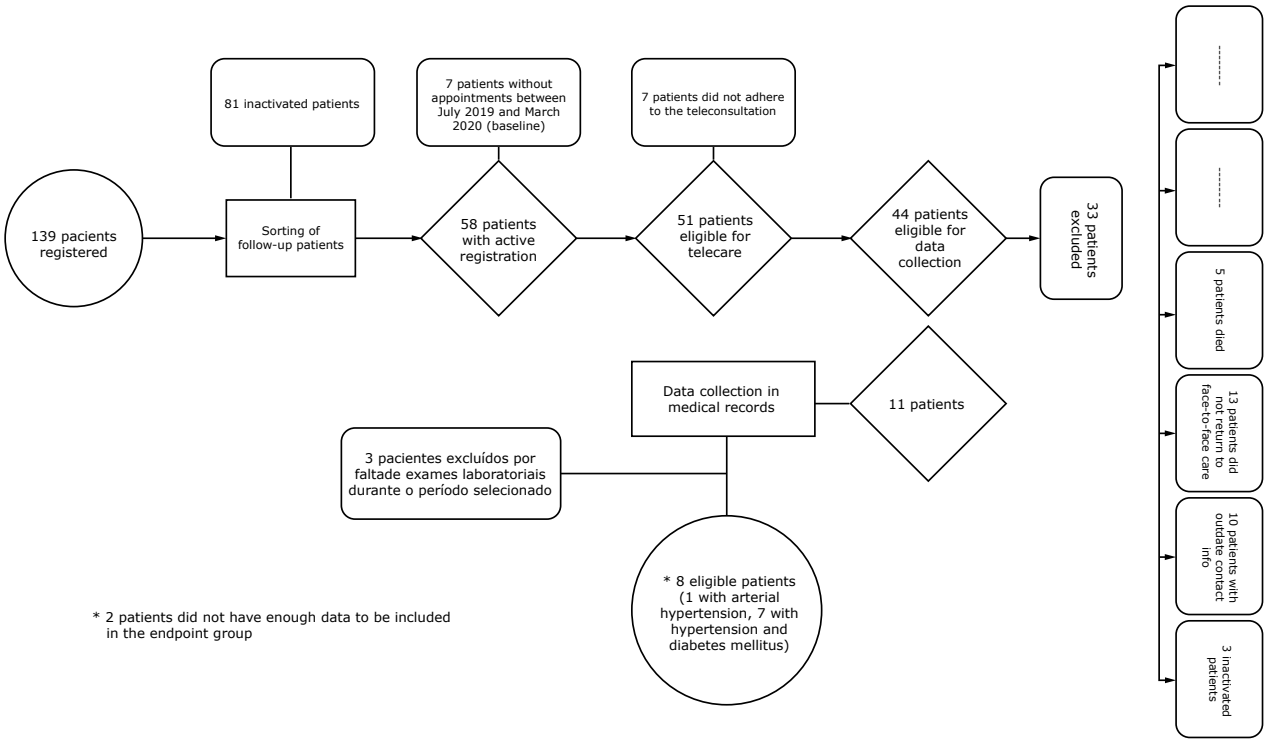


Figure 1: Flowchart of the final sample number for collecting data from diabetic and hypertensive patients.

Table 1

Profile of patients regarding sociodemographic data and the concomitant presence of diabetes and hypertension

	Number of participants	%
Gender		
Woman	4	50
Man	4	50
Skin color		
Black	3	37,5
White	5	62,5
Comorbidities		
Systemic arterial hypertension	1	12,5
Type 2 diabetes mellitus and systemic arterial hypertension	7	87,5
Age Group pre-pandemic		
Adults (20 to 64 years old)	4	50
Seniors (65 years or older)	4	50
Age Group Pandemic		
Adults (20 to 64 years old)	3	37,5
Seniors (65 years or older)	5	62,5

Table 2

Bivariate analysis for the association of the modification of the patients' clinical parameters with the answers to the questions related to the patient's habits and perceptions regarding COVID-19.

Variables	Question 1		Statistic
	Yes N (measure)	No N (measure)	
Gender			p=0,786
Man (%)	1 (50)	3 (50)	
Woman (%)	1 (50)	3 (50)	
Skin color			p=0,036*
Black (%)	2 (100)	0 (0)	
White (%)	0 (0)	6 (100)	
Age group			p=0,346
Adult (%)	0 (0)	2 (33)	
Senior (%)	2 (100)	4 (67)	
SBP (mmHg)	2 (14,0±5,6)	6 (18,3±20,6)	p=0,605
DBP (mmHg)	2 (16,5±9,2)	6 (10,5±11,3)	p=0,264
CT (mg/dL)	2 (25,5±10,6)	6 (-11,5±22,5)	p=0,037*
HDL (mg/dL)	2 (14,5±7,8)	6 (4,6±6,8)	p=0,068
LDL (mg/dL)	2 (5,0±5,6)	6 (-10,2±22,7)	p=0,203
TG (mg/dL)	2 (30,0±12,7)	6 (-30,0±31,4)	p=0,022*
Glycemia (mg/dL)	2 (75,5±106,7)	6 (-26,2±46,5)	p=0,042*
Optimized cardiovascular risk (absolute value)	2 (8,5±0,7)	6 (8,2±10,6)	p=0,483
Statin usage			p=0,537
No change (%)	2 (100)	5 (83,3)	
Reduced (%)	0 (0)	1 (16,7)	
ASA usage			p=0,206
No change (%)	2 (100)	3 (50)	
Reduced(%)	0 (0)	3 (50)	

(Continuation)

Table 2

(Continuation)

Variables	Question 2		Statistic
	Yes N (measure)	No N (measure)	
Gender			p=0,157
Man (%)	1 (25)	3 (75)	
Woman (%)	3 (75)	1 (25)	
Skin color			p=0,999
Black (%)	1 (25)	1 (25)	
White (%)	3 (75)	3 (75)	
Age group			p=0,102
Adult (%)	2 (50)	0 (0)	
Senior (%)	2 (50)	4 (100)	
SBP (mmHg)	4 (16,7±23,7)	4 (17,7±12,8)	p=0,528
DBP (mmHg)	4 (9,0±6,6)	4 (15,0±13,8)	p=0,767
CT (mg/dL)	4 (-15,7±23,4)	4 (11,2±23,1)	p=0,924
HDL (mg/dL)	4 (4,0±4,2)	4 (10,2±10,1)	p=0,850
LDL (mg/dL)	4 (-19,5±16,6)	4 (6,7±15,7)	p=0,969
TG (mg/dL)	4 (-1,7±31,7)	4 (-28,2±45,0)	p=0,186
Glycemia (mg/dL)	4 (3,5±99,9)	4 (-6,0±50,8)	p=0,435
Optimized cardiovascular risk (absolute value)	4 (4,2±5,8)	4 (12,2±10,4)	p=0,884
Statin usage			p=0,285
No change (%)	3 (75)	4 (100)	
Reduced (%)	1 (25)	0 (0)	
ASA usage			p=0,465
No change (%)	3 (75)	2 (50)	
Reduced(%)	1 (25)	2 (50)	

Variables	Question 3		Statistic
	Yes N (measure)	No N (measure))	
Gender			p=0,157
Man (%)	1 (25)	3 (75)	
Woman (%)	3 (75)	1 (25)	
Skin color			p=0,999
Black (%)	1 (25)	1 (25)	
White (%)	3 (75)	3 (75)	
Age group			p=0,999
Adult (%)	1 (25)	1 (25)	
Senior (%)	3 (75)	3 (75)	
SBP (mmHg)	4 (19,2±20,2)	4 (15,2±17,5)	p=0,387
DBP (mmHg)	4 (16,5±9,4)	4 (7,5±10,8)	p=0,128
CT (mg/dL)	4 (-11,2±19,7)	4 (6,7±31,1)	p=0,817
HDL (mg/dL)	4 (4,25±4,1)	4 (10,0±10,4)	p=0,828
LDL (mg/dL)	4 (-11,7±14,7)	4 (-1,0±26,2)	p=0,749
TG (mg/dL)	4 (-19,7±53,7)	4 (-10,2±23,5)	p=0,621
Glycemia (mg/dL)	4 (7,5±98,9)	4 (-10,0±51,4)	p=0,382
Optimized cardiovascular risk (absolute value)	4 (5,0±4,7)	4 (11,5±11,7)	p=0,829

(Continuation)

Table 2

(Continuation)

Statin usage			p=0,285
No change (%)	3 (75)	4 (100)	
Reduced (%)	1 (25)	0 (0)	
ASA usage			p=0,465
No change (%)	2 (50)	3 (75)	
Reduced(%)	2 (50)	1 (25)	

Variables	Question 4		Statistic
	Yes N (measure)	No N (measure)	
Gender			p=0,285
Man (%)	0 (0)	4 (57,2)	
Woman (%)	1 (100)	3 (42,8)	
Skin color			p=0,537
Black (%)	0 (0)	2 (28,6)	
White (%)	1 (100)	5 (71,4)	
Age group			p=0,064
Adult (%)	1 (100)	1 (14,3)	
Senior (%)	0 (0)	6 (85,7)	
SBP (mmHg)	1 (20,0±0,0)	7 (16,8±19,3)	p= .
DBP (mmHg)	1 (10,0±0,0)	7 (12,3±11,4)	p= .
CT (mg/dL)	1 (-20,0±0,0)	7 (0,3±26,9)	p= .
HDL (mg/dL)	1 (0,1±0,0)	7 (8,14±7,9)	p= .
LDL (mg/dL)	1 (-13,0±0,0)	7 (-5,4±21,9)	p= .
TG (mg/dL)	1 (-36,0±0,0)	7 (-12,0±40,8)	p= .
Glycemia (mg/dL)	1 (-66,0±0,0)	7 (8,0±74,3)	p= .
Optimized cardiovascular risk (absolute value)	1 (2,0±0,0)	7 (9,1±9,3)	p= .
Statin usage			p=0,686
No change (%)	1 (100)	6 (85,7)	
Reduced (%)	0 (0)	1 (14,3)	
ASA usage			p=0,408
No change (%)	1 (100)	4 (57,1)	
Reduced(%)	0 (0)	3 (42,9)	

Variables	Question 5		Statistic
	Yes N (measure)	No N (measure)	
Gender			p=0,285
Man (%)	1 (100)	3 (42,8)	
Woman (%)	0 (0)	4 (57,2)	
Skin color			p=0,537
Black (%)	0 (0)	2 (28,6)	
White (%)	1 (100)	5 (71,4)	
Age group			p=0,537
Adult (%)	0 (0)	2 (28,6)	
Senior (%)	1 (100)	5 (71,4)	
SBP (mmHg)	1 (30,0±0,0)	7 (15,4±18,2)	p= .
DBP (mmHg)	1 (0,1±0,0)	7 (13,7±10,1)	p= .
CT (mg/dL)	1 (26,0±0,0)	7 (-6,28±9,5)	p= .
HDL (mg/dL)	1 (1,0±0,0)	7 (8,0±8,1)	p= .

(Continuation)

Table 2

(Continuation)

LDL (mg/dL)	1 (28,0±0,0)	7 (-11,3±16,3)	p= .
TG (mg/dL)	1 (-12,0±0,0)	7 (-15,4±41,8)	p= .
Glycemia (mg/dL)	1 (53,0±0,0)	7 (-9,0±75,8)	p= .
Optimized cardiovascular risk (absolute value)	1 (24,0±0,0)	7 (6,0±6,8)	p= .
Statin usage			p=0,686
No change (%)	1 (100)	6 (85,7)	
Reduced (%)	0 (0)	1 (14,3)	
ASA usage			p=0,408
No change (%)	1 (100)	4 (57,1)	
Reduced(%)	0 (0)	3 (42,9)	

Caption: Question 1: Have you had COVID-19? Question 2: Do you feel more motivated after the rigid period of social isolation? Question 3: During the pandemic, have you been feeling (or have you often felt) anxious or discouraged, without interest in things? Question 4: Have your eating habits deteriorated compared before the pandemic with the current period? Question 5: Have there been any changes (addition/increase of dose/medicine modification) in the prescription of controlled drugs before the pandemic or in the current period?). N= absolute number; SBP = Systolic blood pressure; DBP Diastolic blood pressure; CT= total cholesterol; HDL = High-density lipoprotein; LDL = Low-density lipoprotein; TG= Triglycerides; ASA= Acetylsalicylic acid.*Refers to rejection of the null hypothesis by Fisher's exact statistical test for categorical variables or by Student's t-test for continuous variables of repeated samples with equal variance, respecting a significance level of 5% (p <0.05). Measurements of continuous variables such as SBP, DBP, ColT, HDL, LDL, TG, Glycemia and cardiovascular risk were performed by the mean difference between baseline in the pre-pandemic period and endpoint in the pandemic period. The presentation of continuous variables is given by the mean difference and the standard deviation of this difference (mean difference ± standard deviation). p=., means that it was not possible to carry out the statistics because there was only one "yes" answer, which did not allow calculating an average with standard deviation for this category.

Data referring to clinical parameters and comparisons performed, as well as statistical analyses, are shown in table 3 and figure 2 below.

The analysis of the ASCVD risk stratification and the evaluation of the cardiovascular risk of the patients in the analyzed periods can be seen in tables 4, 5 and in figure 3 below.

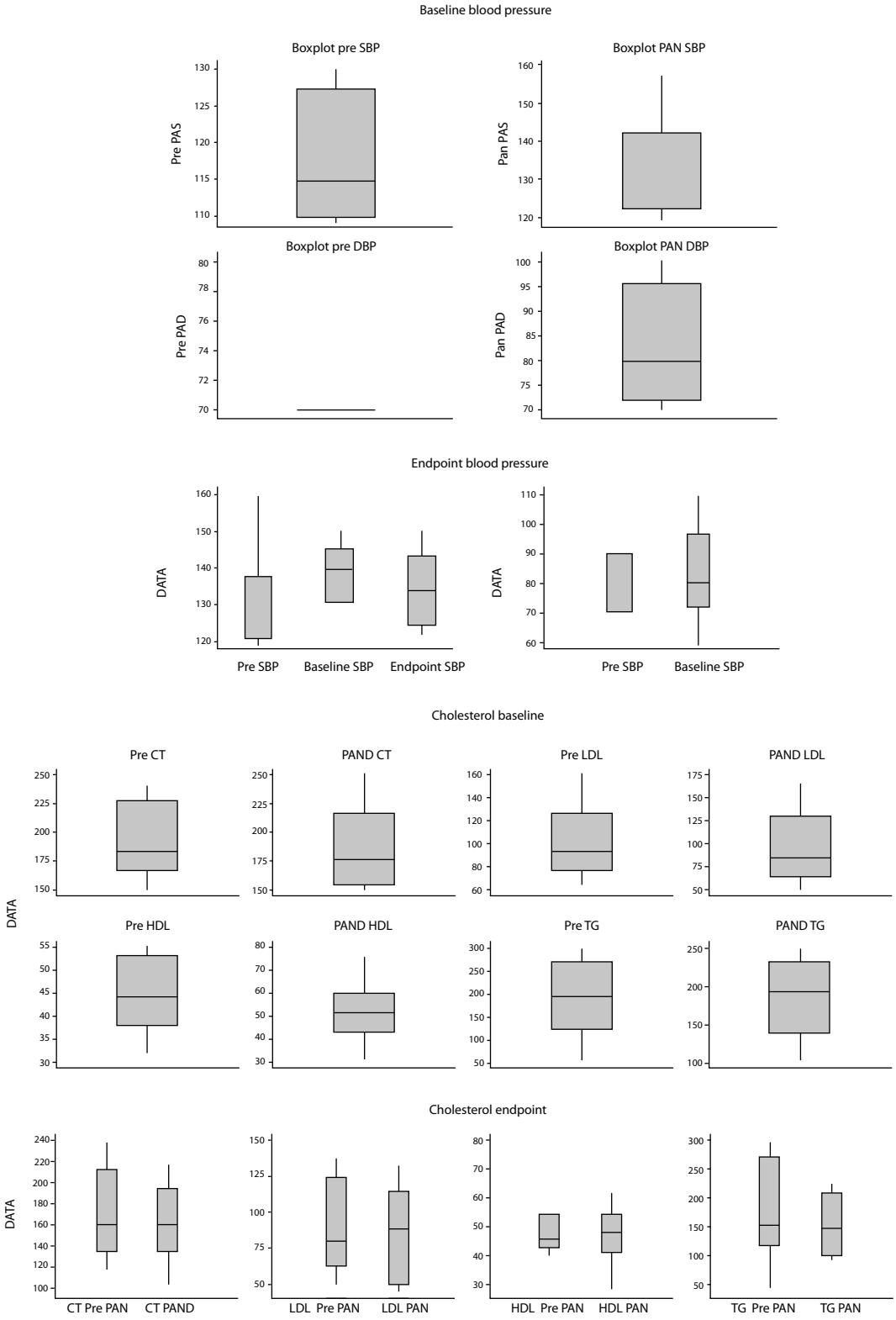
Data regarding the use of statins, acetylsalicylic acid and the drugs used in the treatment of the studied conditions are shown in table 6.

Table 3

Comparison of clinical parameters in the study periods analyzed.

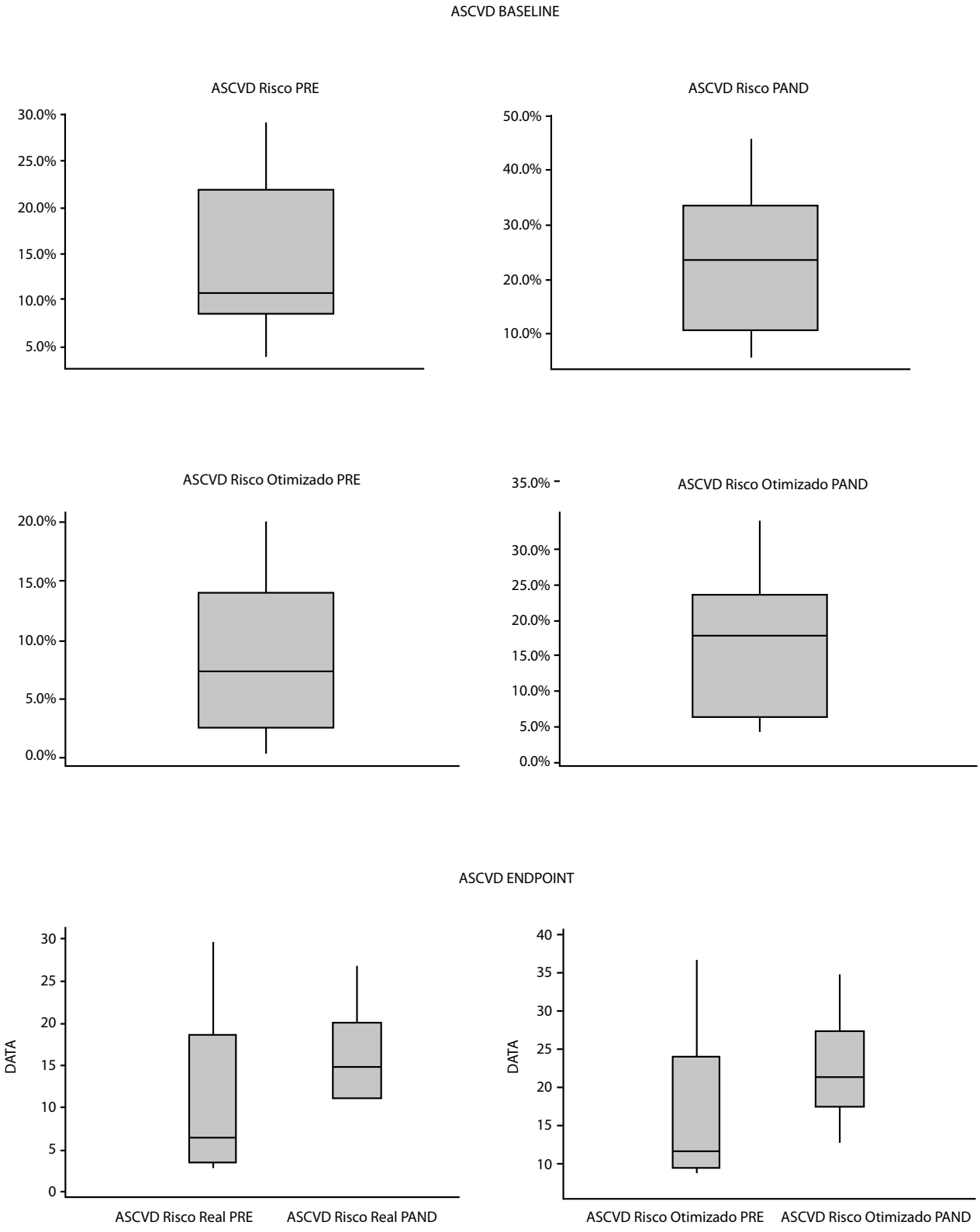
Clinical parameter	Baseline pre-pandemic (Mean±SD)	Baseline Pandemic (Mean±SD)	Endpoint pre-pandemic (Mean±SD)	Endpoint Pandemic (Mean±SD)	p-value baseline	p-value endpoint	p-value (Baseline pandemic x Endpoint Pandemic)
SBP†	117,5± 8,86	134,75±12,43	128,33±16,02	133,92±11,20	0,028	0,373	0,888
DBP‡	71,25± 3,54	83,25±11,65	76,67±10,33	78,25±12,04	0,015	0,702	0,928
Capillary blood glucose	198,3± 36,0	196,9±61,1	164,8±49,3	160,6±41,9	0,964	0,610	0,336
Glycated hemoglobin	8,895± 1,629	9,632±1,423	7,890±1,798	7,325±1,30	0,450	0,885	0,028
Total Cholesterol	187,8± 33,90	185,5±36,6	172,5±42,1	173,0±32,2	0,813	0,918	0,441
LDL	104,40±32,30	98,10±38,50	88,6±33,3	88,4±29,8	0,411	0,969	0,416
HDL	45,25±7,80	52,38±12,52	48,00±6,00	59,00±10,56	0,039	0,097	0,020
Triglycerides	189,60±81,70	174,60±59,60	181,7±84,9	128,00±55,1	0,310	0,380	0,083

Caption: †Systolic blood pressure. ‡Diastolic blood pressure. SD= Standard Deviation. LDL = low density lipoprotein. HDL = High Density Lipoprotein. The t-student test for repeated samples was performed for continuous variables.



Caption: SBP = Systolic blood pressure; DBP Diastolic blood pressure; CT= total cholesterol; HDL = High-density lipoprotein; LDL = Low-density lipoprotein; TG= Triglycerides; PAND= pandemic; Pre= pre-pandemic.

Figure 2: Boxplot graphic presentation of data behavior regarding blood pressure and lipid profile



Caption: ASCVD = *Atherosclerotic cardiac disease*; PAND= pandemic; PRE= pre-pandemic

Figure 3: Boxplot graphic presentation of the data behavior regarding the ASCVD risk score

Table 4

Analysis of the ASCVD risk stratification of the study patients

ASCVD risk rating	Baseline pre-pandemic n (%)	Baseline Pandemic n (%)	Endpoint pre-pandemic n (%)	Endpoint pandemic n (%)	p-value (ANOVA one-way)
Low	1 (12,5)	0 (0)	1 (17)	1 (17)	
Intermediate	5 (62,5)	4 (50)	3 (50)	4 (67)	0,075
High	2 (25,0)	4 (50)	2 (33)	1 (17)	

Caption: ASCVD = *Atherosclerotic cardiac disease*.

Table 5

Cardiovascular risk assessment of diabetic and hypertensive patients before and during the pandemic with MTM developed in pharmaceutical care.

ASCVD escore	Baseline pre-pandemic (Mean±SD)	Baseline Pandemic (Mean±SD)	Endpoint pre-pandemic (Média±DP)	Endpoint Pandemic (Média±DP)	p-value baseline	p-value endpoint	p-value Baseline pandemic x Endpont pandemic
Global (general)	13,69±8,08	22,38±7,28	16,53±10,64	17,93±7,75	0,038	0,073	0,413
Real (optimized)	8,35±6,71	16,10±5,83	10,72±10,33	11,38±6,51	0,038	0,097	0,308
Stratification ASCVD	1,125±0,6410	2,83±0,41	2,17±0,75	2,00±0,63	0,256	0,149	0,201

Caption: *Standard Deviation; ASCVD = Atherosclerotic heart disease. The t-student test for repeated samples was performed.

Table 6

Use of drugs related to diabetes and hypertension prescribed in the periods before and during the pandemic.

	Baseline pre pandemic	Baseline pandemic	Endpoint pre pandemic	Endpoint pandemic	p-value baseline	p-value endpoint	p-value Baseline pandemic x Endpoint pandemic
Number of patients using medication for primary and secondary prevention of CVDs							
Statina							
yes n(%)	7 (87,5)	8 (100)	5 (83)	6 (100)	0,334	0,391	1,000†
no n(%)	1 (12,5)	0 (0)	1 (17)	0 (0)			
Aspirin							
yes n(%)	5 (62,5)	8 (100)	3 (50)	4 (67)	0,019	0,821	0,595†
no n(%)	3 (37,5)	0 (0)	3 (50)	2 (33)			
Number of drugs for the treatment of hypertension and diabetes							
Antihypertensive (Mean±SD*)	2,87±1,46	3,00±1,41	2,5±1,6	2,6±1,2	0,864	0,971	0,528‡
Antidiabetic (Mean±SD*)	2,00±0,82	2,43±1,13	1,5±1,4	2,2±1,8	0,433	0,768	0,933‡

The drugload was calculated and analyzed only for patients in the intervention group, that is, those who received the MTM-PC after the period of social isolation. Drugs for the treatment of hypertension had an average drugload of 57.67(±18.25) and 55.08(±14.30) [p=0.8102] and for DM of 47.4(±45 .1) and 59.4(±31.2) [p=0.6015] with MTM-PC before and during the pandemic, respectively.

DISCUSSION

Psychosocial questions were considered only for the endpoint group and, in the period selected for data collection, 33% of patients reported having contracted COVID-19, half reported feeling more motivated after the relaxation of social isolation rules and feeling more anxious or discouraged during the pandemic.

The results of this study are consistent with those seen in the literature, since the period of social isolation and uncertainty about its duration, associated with fear of infection or worsening of the COVID-19 condition, has been shown to cause moderate to severe symptoms of anxiety, depression and stress, in addition to being related to a long period away from school and work, which further contributes to the development of problems related to mental health[21,22].

Only one patient (16%) reported a worsening of diet during the pandemic and the majority (67%) reported having maintained the eating habits they followed before the period of social isolation, which confers less influence of diet on certain clinical parameters evaluated in this study. Our results have shown that having COVID-19 can influence blood glucose control 75.5 ± 106.7 mg/dL [p=0.042] and lipid profile parameters such as total cholesterol, 25.5 ± 10.6 mg/dL [p=0.037] and triglycerides 30.0±12.7 mg/dL [p=0.022]. However, there was no evidence for the influence of the pandemic, such as social isolation and changes in eating and living habits on clinical parameters.

According to Manfrinato et al[23], Malta et al[24] and Souza et al[25], the eating habits of Brazilian adults worsened during the pandemic, with an increase in the consumption of foods with low nutritional content, such as fast food and processed foods. However, populations with chronic diseases, and especially the elderly population, began to choose better the foods they eat during the pandemic and have closer family care for the management of their health, which can be referred to the population of this study[26].

Another counterpoint to the literature that outlined the profile of the patients in this study is the non-change in dose or inclusion of psychotropic medications, although half of the patients reported feeling more anxious and discouraged during the pandemic. This characteristic can predict the need for specialized health care as an impact of this pandemic, a factor not measured by this study[27,28]. This is an important fact, as the fear of being infected with COVID-19 can lead to a reduction in quality of life[29].

Hypertension, especially in the elderly, was the comorbidity that most appeared in patients who died from COVID-19, in addition to the degree of hypertension also being associated with the severity of the infection[30]. In the present study, it was possible to verify that there was an increase in the mean blood pressure of the participants, when comparing the periods before and during the pandemic, especially observed during the period in which the patients did not receive MTM-PC, in the SBP of 117.5±8.86 to 134.75±12.43 [p=0.028] and; in DBP from 71.25±3.54 to 83.25±11.65 [p=0.015].

With the return of MTM-PC in the pandemic, it was noted that there was no change in SBP [p=0.373] and DBP [p=0.702] when compared to the pre-pandemic period. The same was verified when comparing with the baseline with endpoint in the pandemic period, it was noted that the parameters did not change [p=0.888] for SBP and [p=0.928] for DBP. The change in blood pressure was not a factor evidenced as an impact of COVID-19 on the clinical profile of patients[31,32,] this fact may indicate that in our study the interruption of MTM-PC in the pandemic may have been a factor that contributed to the increase of SBP and DBP.

A systematic review demonstrated that pharmaceutical care was able to improve adherence to pharmacotherapy through health education, as well as blood pressure control during the pandemic, and still substantially reduce health costs with hypertensive patients[33]. It should be noted that although there was no statistical significance, the mean blood pressure decreased with the reintroduction of pharmaceutical care when compared to baseline.

In addition, our results showed an increase in the mean value of glycated hemoglobin (HbA1c) of the baseline participants during the pandemic period and a reduction in this value when comparing the baseline and endpoint, that is, the influence of the pandemic on this parameter. during the pandemic with and without the MTM-PC. This is highlighted by the fact that it is a factor that did not change at baseline when compared to the pre-pandemic [p=0.450] and pandemic [p=0.885] moments. It is known that there was a tendency towards an increase in glycated hemoglobin during the pandemic in patients who were monitored in the context of primary health care[34], as shown in our study.

This fact is associated with changes in the patients' lifestyle, such as increased consumption of low-nutrient foods, reduced physical exercise and worsening sleep quality[35]. As most of the patients in the study reported not noticing changes in their dietary pattern during the pandemic, it is believed that MTM-PC may be more strongly associated with HbA1c control due to the tendency towards an increase in its interruption and a reduction in your feedback.

With regard to cholesterol and blood fractions values, it is possible to verify that there was an improvement in the average of all fractions during the pandemic, it was not a statistically important difference, with the exception of HDL, which was modified by the impact of the pandemic in a way positive [p=0.039] and also positively with the baseline MTM-PC [p=0.020]. This fact is consistent with the participants' assessment of their eating habits during the pandemic. Similar to this work, a cohort study carried out in Italy with diabetic patients showed an improvement in the lipid profile, with the exception of the tendency to increase triglycerides in diabetic patients[36,37].

There was there was a tendency for worsening the cardiovascular risk impacted by the pandemic, since 1 low-risk patient became intermediate risk (50%) and two of such classification became high risk (50%). This clinical perception was also quantified by the ASCVD risk scores, which in the global and real score showed a real increase during the pandemic at baseline [p=0.038 and p=0.038], however, there was no evidence of change in the endpoint [p=0.073 and p= 0.097], which was also defined in this way in the comparison between baseline and endpoint in the pandemic [p= 0.413 and p=0.308].

The increase in cardiovascular risk in the population seems to be a trend of the impact of the pandemic, however, this study's results showed that the MTM-PC can break this upward trend, as demonstrated by the means measured in the pre-pandemic endpoint and in the pandemic[38]. Given that all patients started to use statins during the pandemic, regardless of the pharmaceutical care services, it was observed that there was no increase in the use of statins both for baseline and endpoint, not even when compared in the pandemic period.

The increase in the use of acetylsalicylic acid during the pandemic when MTM-PC was not available stands out. There was an increase in relation to the impact of the pandemic without MTM-PC, from five to eight patients [p=0.019], but the change was irrelevant when evaluating the endpoint, with the presence of MTM-PC [p=0.812] as well as for the difference between baseline and endpoint in the pandemic period. It is estimated that there was a trend towards an increase in the consumption of acetylsalicylic acid by 6.22% during the first year of the pandemic[39].

The increased use of statins and acetylsalicylic acid may be related to their cardioprotective and immunomodulatory characteristics, which have been associated with a reduced risk of unfavorable outcomes in patients infected with COVID-19[40], as well as their associated increased cardiovascular risk. to the clinical impact of the pandemic, as evidenced in our study.

The acetylsalicylic acid has a variety of therapeutic effects such as reducing the inflammatory response, pain and fever, inhibiting platelet activation and aggregation and blocking the spread of RNA viruses, effects that have been investigated in the literature because they may be associated with the lowest risk of mortality from COVD-19[41,42].

The profile of drug use for the treatment of chronic diseases, especially diabetes and hypertension, has been heavily investigated during the pandemic. The literature showed that there was no change in the prescription of antihypertensive drugs in primary care during the pandemic, as well as in the prescription of hypoglycemic agents, with the exception of Insulin[43], which was also evidenced in our study.

However, the drugload evaluated with the MTM-PC during the pandemic showed a tendency towards a reduction in the load of antihypertensive drugs (57.67±18.25 to 55.08±14.30) and an increase in the burden of hypoglycemic agents (47 .4±45.1 to 59.4±31.2). Despite not being significant changes [p=0.8102 and p=0.6015], it can be evidenced qualitatively that the MTM-PC was a preponderant factor for the rational use of medication, in which none of the therapies exceeded 75% of the therapeutic load , which could

affect treatment safety and not optimize therapeutic effectiveness[10,13].

The hypothesis is that the increase in the therapeutic burden of antihypertensive drugs may be associated with the increase in blood pressure during the pandemic and, consequently, have led to the need to increase the prescribed doses of these drugs. With the subsequent trend towards a reduction in blood pressure after the period of social isolation and, with the help of the MTM-PC for the management of pharmacotherapy, it was possible to adjust the prescription, which was observed in the trend towards a lower therapeutic burden in favor of a pharmacotherapy with greater effectiveness and safety[13].

The patients' glycated hemoglobin remained constant before and during the pandemic, with a reduction in the mean value due to the MTM-PC. This fact may be associated with the adjustment of the dose of hypoglycemic agents, which explains the tendency towards an increase in the therapeutic burden of these drugs in the period after social isolation.

It is noteworthy that the therapeutic burden calculated by PharmEqui® is data that allows the comparison of medication consumption to assess the effectiveness and safety of pharmacotherapy among patients using different doses and medications for the same health condition[10]. Patients using a therapeutic load above 75% tend to have greater problems related to the safety of pharmacotherapy, such as an increase in adverse reactions[10,44].

It was possible to highlight the role of pharmaceutical care in maintaining the therapeutic load within the values considered safe, by suggesting changes in doses or inclusion of new drugs in the therapy, in order to avoid the occurrence of adverse reactions. This maintenance of the therapeutic burden is in line with the fundamentals of the MTM-PC, since the objectives of the MTM-PC are to improve adherence to drug treatment, detect and reduce the chances of adverse effects and provide information to patients about their health conditions and medications they use [45].

It is worth noting the importance of the MTM-PC in managing the care of hypertensive and diabetic patients in terms of biopsychosocial aspects, as the pharmacist is able to identify health needs, refer the patient as well as provide interventions related to the Problem Related to Pharmacotherapy (PRFs).

In this sense, it is important to highlight that the pharmaceutical profession is undergoing a new meaning in terms of clinical characterization. Process that begins in professional training, which must adjust to the model of training by competences, concepts brought in Miller's pyramid, which is formed from top to bottom as follows: do (action); show how to do it (performance); know how to do it (competence). Thus, the articulation with other professionals for patient care tends to be strengthened in the face of advances in the profession[13].

The present study has some limitations, such as the fact that the historical control shows failures that are repeated and may be biased in the clinical results, which does not occur in a randomized double-blind trial. However, there is an improvement in some clinical parameters when comparing the baseline with the endpoint and, as this is an analysis between dependent groups, it can be said that such influential factors could be seen in the baseline analysis of both groups, in the pre-pandemic period.

Although there are statistical tests that provide greater robustness in the analysis of dependent samples with baseline comparison, in three or more time periods, it was not possible to apply some of these tests due to the low number of patients. However, the analyzes of more than two time periods divided into two comparative moments was an alternative to the low sample number that is capable of increasing the alpha error, but reducing the beta error, which means greater precision to state what the results of this study showed as a parameter change, but less precision to say that there really was no change in parameters that did not show statistical significance.

CONCLUSION

This study was able to demonstrate that there is evidence that the COVID-19 pandemic causes changes in some clinical parameters of diabetic and hypertensive patients, such as: considerable increase in systolic and diastolic blood

pressure, change in lipid profile, with a tendency to increase of cardiovascular risk. Furthermore, biopsychosocial impact factors related to eating habits and changes caused by the pandemic did not infer the clinical parameters of diabetic and hypertensive patients, with the exception of whether or not they had COVID-19, which impacted on the control of blood glucose, triglycerides and total cholesterol.

Additionally, pharmaceutical care may be able to improve some of these clinical parameters impacted by the pandemic on patients' health. It is noteworthy that the MTM-PC may have been a factor for the improvement of glycated hemoglobin and HDL cholesterol and, perhaps a factor for reducing the trend of increased blood pressure and cardiovascular risk, a hypothesis that could be more accurate in the case of the evaluation of a larger sample number with the follow-up of the patients for a longer period. In addition, the MTM-PC was able to maintain the therapeutic burden of patients within a desirable limit, up to 75% of the burden, thus enabling better control of the emergence of adverse events.

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Contribution

NCR, Substantial contribution to study design, data collection and interpretation, and manuscript writing;
VFM, Participation in the writing of the preliminary version;
MSC, Participation in the preparation of the study, data analysis, writing, review and approval of the final version.

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