FARMÁCIA / PHARMACY

Assessment of cardiovascular risk factors of type two diabetes mellitus patients: cross-sectional study in Brazilian public primary health care

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ABSTRACT. Type 2 diabetes mellitus (T2DM) has a high prevalence, with prospects for a significant increase. In 2021, T2DM caused one death every five seconds, most related to cardiovascular disease. Controlling cardiovascular risk factors (low-density lipoprotein [LDL-cholesterol] and blood pressure [BP]) significantly reduces these deaths. The objective of this study was to evaluate the prevalence of T2DM patients who have adequate BP and LDL-cholesterol control. Additionally we assessed the prevalence of patients who achieved the fasting blood glucose and glycated hemoglobin targets. We carried out a cross-sectional study in primary health care (PHC) units of the public health system (*Sistema Único de Saúde - SUS*) in the municipalities of Bernardino de Campos and Salto Grande, São Paulo State. Inclusion criteria were: diagnosis of T2DM, aged ≥ 18 years, attended by the PHC of these municipalities, who underwent a complete lipidogram examination within 12 months before the start of the study. Data were collected during home visits (age, sex, illnesses, drugs used, date and result of the last LDL-cholesterol, fasting blood glucose, and glycated hemoglobin laboratory tests, and the patients' BP was measured). A total of 481 patients met the inclusion criteria and accepted to participate in the study, while 572 patients were excluded because they had not undergone a complete lipidogram within 12 months prior to the start of the study. Only 24.7 % of the patients had BP and LDL-cholesterol within the recommended target. It was verified that 148 patients (30.7 %) had fasting blood glucose and glycated hemoglobin within the target. A low rate of patients achieved the BP and LDL-cholesterol cholesterol targets, with an average interval between performing the last LDL-cholesterol test above the frequency recommended by the guidelines of the Brazilian Society of Diabetes.

Keywords: type 2 Diabetes Mellitus; heart disease risk factors; cholesterol, LDL; hypertension.

Introduction

In 2021, one death from type 2 diabetes mellitus (T2DM) was recorded every five seconds, which corresponds to 6.7 million deaths in the world; with 214,175 deaths in Brazil (International Diabetes Federation [IDF], 2021). A significant number of these deaths were caused by cardiovascular disease (CVD). Patients with T2DM have an increased incidence of CVD by two to four times, and mortality by 1.5 to 3.5 times (Booth, Kapral, Fung, & Tu, 2006; ++Emerging Risk Factors Collaboration et al., 2010).

This increase in the incidence and mortality related to CVDs in patients with T2DM is associated with frequently coexisting comorbidities in these patients, such as hypertension and dyslipidemia. Several studies have found that adequate control of blood pressure (BP) and low-density lipoprotein (LDL-cholesterol) prevents the onset and progression of CVD in people with T2DM (Pedro-Botet, Chillarón, Benaiges, & Flores-Le Roux, 2016; Khunti, Kosiborod, & Ray, 2018).

It is extremely important for health services to know the frequency of patients who do not achieve adequate BP and LDL-cholesterol control, because this makes it possible to assess the effectiveness of the care provided to these patients, and whether there is a need to adopt new strategies and health policies to reduce CVD-related mortality in T2DM patients. For example, the National Health and Nutrition Examination Surveys (NHANES) from 1998 – 2010 found that almost half of patients with T2DM did not have adequate control of BP (48.9%) and LDL-cholesterol (43.8%) (Casagrande, Fradkin, Saydah, Rust, & Cowie, 2013).

However, there are a scarce number of studies carried out in primary health care (PHC) of the public health system (Sistema Único de Saúde- SUS), the body responsible for monitoring the majority of Brazilians with T2DM, which evaluated the frequency of patients with T2DM who achieve adequate of control of BP and LDL-cholesterol. In this sense, the objective of this study was to evaluate the frequency of patients with T2DM assisted in PHC of the SUS who achieve adequate BP and LDL-cholesterol control.

Methodology

Study design and setting

A cross-sectional study was carried out from June to October 2022, in PHC units in the municipalities of Bernardino de Campos and Salto Grande, in the state of São Paulo. Bernardino de Campos has 11,158 inhabitants and three PHC health units, while Salto Grande has 9,364 inhabitants and three PHC health units.

Ethical issues

This project was approved by the ethics committee for research involving human beings of the Faculty of Medicine of Marília under CAAE nº 57857822.1.0000.5413.

Participants

The inclusion criteria were: patients with a medical diagnosis of T2DM, hypertension and dyslipidemia, aged ⩾ 18 years, attended at the PHC health units in these municipalities, who underwent a complete lipidogram examination within 12 months prior to the date of the beginning of the study.

Study size

No sample size calculation was carried out, we included in the study every eligible patient who accepted to participate in the study.

Data sources

The identification of patients who met the inclusion criteria was performed using the patient's electronic medical record. The research team went to the home of all eligible patients and invited them to participate in the study. The analysis of information available in the patient´s electronic medical records, the visits, and interview were carried out by clinical pharmacists with experience in pharmacotherapy follow-up of patients with T2DM, and a doctoral degree in health sciences. There were no specific training for these activities since these clinical pharmacists had experience in realizing these procedures.

Patients who agreed to participate in the study signed the informed consent form and subsequently answered the questions: name, age, sex, education, diseases they present, and drugs they use; a structured questionnaire was used to assess these data. The BP of the patients was measured during the visit of the research team, following the Brazilian Guidelines on Arterial Hypertension - 2020 (Barroso et al., 2020), which recommend three measurements in each arm, with an interval of five minutes between each measurement, and the value of the simple average of the six measurements performed was considered as the patient's BP.

The LDL-cholesterol, fasting blood glucose, and glycated hemoglobin results were collected from the patient's electronic medical record; in the health care units studied the physician must register the results of these lab tests of each patient during the medical appointment. The most recent results of the lab tests were used in the study.

Quantitative variables

The BP, LDL-cholesterol, fasting blood glucose, and glycated hemoglobin targets were determined for each patient using the criteria recommended by the Brazilian Society of Diabetes Guideline Ed. 2022. The BP target for T2DM patients without clinical coronary disease was < 130/80 mm Hg^{-1} if well tolerated, < 130/80 mm Hg^{-1} (avoid BP < 120/70 mm Hg^{-1}) for T2DM patients with clinical coronary disease, 130-139/70-79 mm Hg^{-1} for elderly > 80 years old, and 140-139/80-89 mm Hg^{-1} for frail elderly > 80 years old. The LDL-cholesterol target was < 50 mg dL^{-1} for patients with very high cardiovascular risk, < 70 mg dL^{-1} for patients with high cardiovascular risk, and < 100 mg dL^{-1} for patients with intermediary or low cardiovascular risk. The fasting

blood glucose target was 80–130 mg dL^{-1} for adults, 80–130 mg dL^{-1} for healthy elderly, 90–150 mg dL^{-1} for frail elderly, and 100–180 mg dL^{-1} for very frail elderly. The glycated hemoglobin target was < 7.0 % for adults, < 7.5% for healthy elderly, < 8.0% for frail elderly, and avoid symptoms of hyper and hypoglycemia for very frail elderly (Diretriz da Sociedade Brasileira de Diabetes, 2022).

Statistical methods

Data were entered and analyzed through aStatistica 8 database and descriptive statisticswere used to evaluate the results. The data weretested for normal distribution using the Quantile-Quantile plots and Kolmogorov-Smirnovtest, before selection of the form to express thevalues. Values were expressed as absolute frequency, relative frequency, and mean (standard deviation), as appropriate.

Results

Participants

A total of 1,313 patients were aged ⩾ 18 years, had a medical diagnosis of T2DM, hypertension, and dyslipidemia, had lab results of LDL-cholesterol, fasting blood glucose, and glycated hemoglobin. However, less than half of these patients (572 patients; 43.6%) had undergone a complete lipidogram within 12 months prior to the beginning of the study, and consequently, did not meet all the inclusion criteria. Figure 1 describes the flowchart of the study. Table 1 describes the date of the last complete lipidogram of the excluded patients.
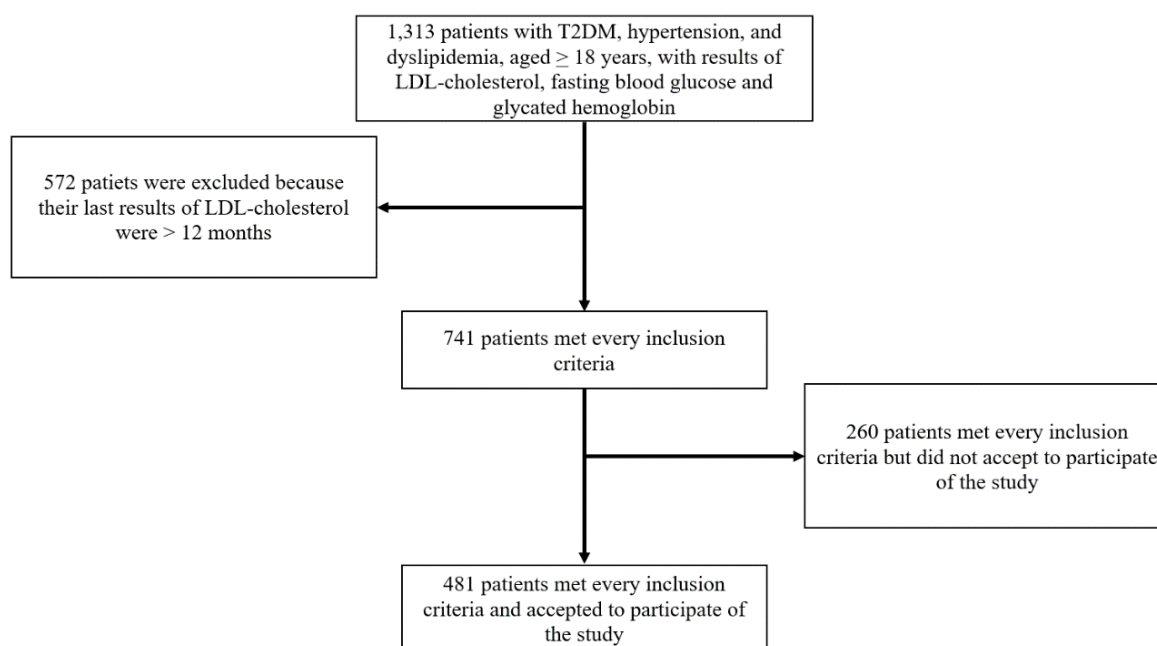

Figure 1. Flowchart of the study.

Table 1. Date of the last complete lipidogram examination of the excluded patients. N= 572.

Period of time	n (%)
13 – 24 months before the start of the study	308 (53.8)
25 – 36 months before the start of the study	206 (36.0)
> 36 months before the start of the study	58 (10.2)

A total of 741 patients met all study inclusion criteria, and 481 accepted to take part.

Descriptive data

Table 2 describes the demographic, clinical, and therapeutic characteristics of the patients. Every patient used one or more antidiabetic drugs.

Table 2. Demographic, clinical, and therapeutic characteristics of the studied population. N = 481.

Variable	Result
Age, average (SD) years	61.6 (2.9)
Female sex, n (%)	313 (65.1)
Schooling, n (%)	
• Incomplete primary education	166 (34.5)
• Complete primary education	315 (65.5)
Diseases present, average (SD)	3.7 (0.9)
Drugs they use, n (%)	
• Metformin	400 (83.2)
• Glibenclamide	373 (77.5)
• Losartan	306 (63.6)
• Hydrochlorothiazide	291 (60.5)
• Amlodipine	287 (59.7)
• Simvastatin	283 (58.8)
Drugs they use, average (SD)	4.2 (0.7)

Table 3 describes the frequency of patients with T2DM who achieved the BP and/or LDL-cholesterol target. More than 40 % of the patients did not achieve the goal for any of the analyzed variables, and only 15.8 % of the patients achieved the BP and LDL-cholesterol goal.

Every patient that achieved target BP and LDL-cholesterol used two or more anti-hypertensive drugs and statin. Among the patients who achieved only target BP, all of them used two or more anti-hypertensive drugs, and 27 patients use statin. Among the patients who achieved only target LDL-cholesterol, all of them use statin, and 84 patients use one or more anti-hypertensive drugs. Among the patients who did not achieve target BP and LDL-cholesterol, none of them use statin, and 117 patients use one or more anti-hypertensive drugs.

Table 3. Frequency of patients with type 2 diabetes mellitus who achieved blood pressure and LDL-cholesterol goals. N = 481.

Variable	n (%)
Patients who achieved target BP and LDL-cholesterol	76 (15.8)
Patients who achieved only the BP goal	91 (18.9)
Patients who achieved only the LDL-cholesterol goal	116 (24.1)
Patients who did not achieve BP and LDL-cholesterol target	198 (41.2)

A total of 148 (30.8%) achieved fasting blood glucose and glycated hemoglobin. While a total of 13 (2.7%) patients and 10 (2.0%) patients achieved only fasting blood glucose and glycated hemoglobin, respectively. A total of 310 (64.5%) patients did not achieve fasting blood glucose and glycated hemoglobin.

Discussion

This is one of the first studies that evaluated the frequency of patients with T2DM, hypertension, and dyslipidemia seen in PHC of the SUS who achieve adequate BP and LDL-cholesterol control. It was verified that only 15.8% of the patients achieved adequate BP and LDL-cholesterol control, and more than half of patients with T2DM (56.4%) had not undergone a complete lipidogram within 12 months prior to the start of the study. Other studies corroborate the results found, showing that the strategies adopted in the follow-up of patients with T2DM, hypertension, and dyslipidemia are not effective for the control of DM and associated comorbidities, and that the laboratory exam of complete lipidogram is not accomplished at the recommended frequency by the guidelines of the Brazilian Society of Diabetes (Duro, Assunção, Costa, & Santos, 2008; Gama, Guimarães, & Rocha, 2017; Diretrizes..., 2022).

The low frequency of patients who achieved adequate control of BP and LDL-cholesterol can be explained by the fact that patients with T2DM often do not have a medical appointment for long periods of time; and medical prescriptions are renewed without contact between the doctor and the patient. Thus, the patient is not evaluated regarding the achievement of therapeutic objectives, resulting in new health problems. The high frequency of patients with a complete lipidogram more than 12 months old may also be associated with automatic renewal of prescriptions, since without doctor-patient contact, requesting laboratory monitoring tests becomes more difficult (Conselho Regional de Medicina do Estado de São Paulo [Cremesp], 2012). This

serious problem in the monitoring of patients with T2DM could be solved with the insertion of other health professionals such as nurses and pharmacists, who can take a patient-centered multidisciplinary approach (Ferreira et al., 2019).

In the city of Florianópolis, nurses can request and evaluate laboratory tests for monitoring patients with T2DM, as well as renew prescriptions for certain drugs in situations specified in the care protocol of the PHC health units (Florianópolis, 2017). With the adoption of this care protocol, patients with T2DM began to be evaluated more frequently by a health professional, and also led to the carrying out of laboratory tests following the recommendations of the guideline of the Brazilian Society of Diabetes (Florianópolis, 2017).

A randomized controlled clinical trial carried out at SUS PHC health units found that the inclusion of clinical pharmacists in the multidisciplinary team monitoring patients with T2DM significantly increased the frequency of adequate BP control (26.8% baseline versus 86.6% after 36 months of follow-up; p < 0.001) and LDL-cholesterol (59.8% baseline versus 80.4% after 36 months of follow-up; p < 0.001); and also ensured that the laboratory examination of the complete lipidogram was performed at the frequency recommended by the guidelines of the Brazilian Society of Diabetes. The economic analysis verified that the inclusion of the clinical pharmacist presented a positive cost-effectiveness relation. In this study, clinical pharmacists during a pharmaceutical consultation, collected and organized patient data, analyzed the presence of problems related to pharmacotherapy, prepared a care plan and evaluated the results of interventions in the care plan; clinical pharmacists requested laboratory tests to monitor the effectiveness and safety of pharmacotherapy and made suggestions for changes in drug and non-drug treatment to physicians (increase in dose, inclusion of new drugs, suspension of drugs, among others) (Obreli-Neto et al., 2015). Other studies also found that the inclusion of clinical pharmacists in the multidisciplinary team monitoring patients with T2DM significantly increased the frequency of adequate control of BP and LDL-cholesterol, however, these studies were not carried out in PHC health units of the SUS, but in private pharmacies and outpatient clinics at Brazilian universities (Borges, Guidoni, Ferreira, Freitas, & Pereira, 2010; Correr, Melchiors, Fernandez-Llimos, & Pontarolo, 2011).

Unfortunately, the examples described above occur only in a small number of municipalities in Brazil. In other countries (examples: Canada, United States of America, and England), where the performance of nurses and pharmacists in the multidisciplinary PHC team for monitoring patients with T2DM occurs widely and is part of public health policies, there is already robust evidence that patient-centered multidisciplinary care is more effective than the physician-centered model in reaching the appropriate BP and LDL-cholesterol goal. (Weeks, George, Maclure, & Stewart, 2016; Nogueira, Otuyama, Rocha, & Pinto, 2020; Zhang, Zheng, Ma, Liu, & Ding, 2022).

Strengths and limitations

The present study has limitations, such as the reduced number of municipalities that were evaluated, requiring caution in extrapolating these results to other locations. Additionally, information such as illnesses and medications used were reported by patients and extracted from patient´s medical records, and situations may occur where patients or health professionals forgot to mention illnesses they have and drugs they use. However, this is one of the first studies that evaluated the frequency of patients with T2DM, hypertension, and dyslipidemia assisted in PHC of the SUS who achieved adequate control of BP and LDL-cholesterol. The size of municipalities directly affects the health services offered to the population. Unlike previous studies that were conducted in populous municipalities, the present study was conducted in municipalities with < 20,000 inhabitants, and according to the Brazilian Institute of Geography and Statistics (IBGE) 67.7 % of Brazilian municipalities have a population < 20,000 inhabitants (Instituto Brasileiro de Geografia e Estatística [IBGE], 2021). Therefore, our results are probably closer to what happens in cities with < 20,000 inhabitants, than studies carried out in more populous cities.

Conclusion

A low frequency of patients with T2DM, hypertension, and dyslipidemia treated at PHC units who achieved adequate BP and LDL-cholesterol control was verified, and many patients had not undergone a complete lipidogram laboratory examination for more than 12 months. These results demonstrate the need to adopt new follow-up strategies for these patients.

Acknowledgments

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