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Analysis of drug interactions and epidemiological profile of individuals with diabetes mellitus in primary care

Análise das interações medicamentosas e perfil epidemiológico de indivíduos com diabetes *mellitus* na atenção primária

Análisis de interacciones farmacológicas y perfil epidemiológico de individuos con diabetes mellitus en atención primaria

Leila Zanatta[1], Fernanda Norbak Dalla Cort[II], Nathália Silva Mathias[III], Carla Argenta[IV]

Abstract: Aim: to analyze drug interactions and the epidemiological profile of individuals with diabetes mellitus (DM). **Method**: quantitative study with the application of a questionnaire to 42 patients with DM belonging to a Family Health Center (FHC). Data were collected in 2018, in three stages: meeting at the CSF, home visits and searching electronic medical records; followed by analysis of drug interactions in the Drug Interactions Checker Drug Information and DrugBank databases. **Results**: the mean age of the patients was 68.36 years. The total number of associations between drugs was 1355 (mean 32.26 / patient). The total number of medications that interact was 479 (11.40 interactions /patient). In 65% the combinations did not interact, 4% were mild interactions, 26.05% moderate and 1.70% severe. **Conclusion**: the number of drug interactions is significant, with a moderate degree predominating. The age of patients and the presence of comorbidities can be associated with polymedication, contributing to the occurrence of these interactions.
Descripors: Diabetes Mellitus; Hypoglycemic Agents; Nursing; Polypharmacy

Resumo: Objetivo: analisar as interações medicamentosas e o perfil epidemiológico de indivíduos com diabetes *mellitus* (DM). **Método**: estudo quantitativo com aplicação de questionário a 42 pacientes com DM pertencentes a um Centro de Saúde da Família (CSF). Os dados foram coletados em 2018, em três etapas: encontro no CSF, visitas domiciliares e busca em prontuário eletrônico; seguido de análise das interações medicamentosas nas bases *Drug Interactions Checker Drug Information* e *DrugBank*. **Resultados**: a idade média dos pacientes foi de 68,36 anos. O

[1] Farmacêutica, Doutora em Farmácia, Universidade do Estado de Santa Catarina – UDESC, Chapecó, SC, Brasil. E-mail: leila.zanatta@gmail.com, ORCID: https://orcid.org/0000-0003-0935-4190

II Enfermeira, Universidade do Estado de Santa Catarina – UDESC, Chapecó, SC, Brasil. E-mail: fernandanorbak@outlook.com, ORCID: https://orcid.org/0000-0003-1609-4972

III Enfermeira, Universidade do Estado de Santa Catarina – UDESC, Chapecó, SC, Brasil. E-mail: nathalya.mathiass@hotmail.com ORCID: https://orcid.org/0000-0003-3352-5885

IV Enfermeira, Doutora em Enfermagem, Universidade do Estado de Santa Catarina – UDESC, Chapecó, SC, Brasil. E-mail: carla.argenta@udesc.br ORCID: https://orcid.org/0000-0002-9729-410X

número total de associações entre fármacos foi de 1355 (média de 32,26/paciente). O total de medicações que interagem foi de 479 (11,40 interações/paciente). Em 65% as combinações não interagiram, 4% foram interações leves, 26,05% moderadas e 1,70% graves. **Conclusão**: a quantidade de interações medicamentosas é expressiva, predominando as de grau moderado. A idade dos pacientes e presença de comorbidades podem estar associadas à polimedicação, contribuindo para ocorrência dessas interações.
Descritores: Diabetes *mellitus*; Hipoglicemiantes; Enfermagem; Polimedicação

Resumén: **Objetivo:** analizar como interacciones medicamentosas y el perfil epidemiológico de individuos con diabetes mellitus (DM). **Método:** estudio cuantitativo con aplicación de cuestionario a 42 pacientes con DM pertencentes en el Centro de Salud de la Familia (CSF). Os dados foram coletados em 2018, em três etapas: encontro no CSF, visitas domiciliares e busca em prontuário eletrônico; seguido de análise das interações medicamentosas nas bases Comprobador de interacciones de medicamentos Información sobre medicamentos e DrugBank. **Resultados:** una idade media dos pacientes fe de 68,36 años. Número total de asociaciones entre religiones de 1355 (medios de 32.26/paciente). O total de medicamentos que interagencian la fe de 479 (11.40 interacciones/paciente). Em 65% como combinações não interagiram, 4% foram interações leves, 26.05% moderadas y 1.70% grave. Conclusión: una cantidad de interacõs medicamentosas é expressiva, predominando como de grau moderado. A idade dos pacientes y presença de comorbidades podem estar asociado a polimedicação, contribindo para ocorrência dessas interações.
Descriptores: Diabetes Mellitus; Hipoglucemiantes; Enfermería; Polifarmacia

Introduction

Diabetes Mellitus (DM) is characterized by a set of signs and symptoms resulting from a deficiency in the regulation of the metabolism of carbohydrates, lipids and proteins, caused by the lack of insulin secretion or by the decrease in tissue sensitivity to it.[1] Among the various types of DM the most common are type 1 DM and type 2 DM. Type 1 occurs due to the absence of insulin secretion, being subdivided into A1 and A2 due to the presence or absence of circulating autoantibodies.[1] Type 2 DM is initially caused by decreased tissue sensitivity to the metabolic effect of insulin, which is called insulin resistance.[1] Its treatment can be of a medicated or non-medicated nature, which involves physical activity, healthy eating habits, smoking cessation and glycemic control.

Due to the chronicity of this condition, these individuals have a tendency to clinical deterioration over time, providing complications derived from risk factors such as advanced age plus DM, or even the lack of control of glycemic levels.[2] In view of this, these factors determine

the need for an expanded look at the emergence of possible drug interactions, since they occur when there is a combination of drugs, whose effects and reactions can be altered as a result of these combinations.[3] The combined use of two or more drugs can be used in therapy to enhance the pharmacological effect and thus maximize the effectiveness of the treatment, however, it can cause severe toxicity in the body, as well as, the ineffectiveness of drugs.[4]

In this context, polypharmacy stands out, which is characterized by the use of five or more medications due to one or multiple health problems.[4] The integration of various drugs, makes it possible to increase errors in medical prescription, intensify drug interactions, as well as the risks of adverse effects, inadequate consumption, increase the probability of non-adherence to treatment and maximize the chances of morbidity and mortality.[4]

Thus, nursing, together with other health professionals, accompanies and guides patients with DM in several dimensions such as, in educational actions, in the prevention of diseases associated with DM, seeking to align the treatment and the individual's situational reality and his family, expanding the look of the user in an integral way, encouraging the importance of self-care, providing guidance on treatment, whether it be medicated or not, and stimulating the user's autonomy process.[5]

Based on the information described, the following research question arose: what is the frequency and severity of drug interactions in patients with DM treated at a Family Health Center (FHC)? In the search for answers to this question, the present study aims to analyze drug interactions and the epidemiological profile of individuals with diabetes mellitus.

Method

This is a cross-sectional study, with a quantitative approach, conducted in the second half of 2018, involving 42 individuals with type 1 and 2 DM registered in a FHC in the municipality of Chapecó, Santa Catarina. The sample size was determined based on the study

that emphasizes that the sample must have a minimum number five times greater than the number of variables to be analyzed.[6]

To users with DM who covered the selected FHC area, a printed invitation was given through the Community Health Agents (CHA) to participate in the meeting to be developed at the Center where the data collection took place. Not reaching the desired number of participants, there was a need to carry out the collection through home visits. Visits to users were carried out according to the CHA schedule, established by the coordinating nurse of the service, who randomly assigned patients diagnosed with type 1 and 2 DM registered in that territory and who met the inclusion criteria for participation in the research. The visits were carried out until the calculated sample number was reached. In addition, to complement the questionnaire data that patients were unable to answer, an electronic medical record was searched based on their registration number and/or full name.

As inclusion criteria, patients of both genders, who lived in the municipality in question and who attended the FHC were accepted, covering participants over 18 years of age, without stipulating a maximum age. Also, be diagnosed with DM and be using two or more medications. The exclusion criterion, on the other hand, included patients who had some cognitive deficit, which prevented them from answering the questions individually or even with the help of researchers.

Data related to the sociodemographic profile, lifestyle, health conditions and drug interactions were obtained through the application of a questionnaire that was built and adapted by the researchers based on the literature.[7-8] It contained mixed questions (open and closed) and was applied to patients with DM present at the meeting. At first, subjects of relevance to the DM were approached and later the participants were invited to participate in that research.

Among the characteristics assessed through the questionnaire are: 1) sociodemographic characteristics (gender, age, marital status, race, education, profession); 2) health conditions; 3)

lifestyle habits (use of teas, physical activity, food, smoking, drinking alcohol); 4) care related to the disease (blood glucose monitoring, need to perform specific procedures due to diabetes, time of diagnosis, frequency of consultations, difficulty in healing); 5-8) drug treatment (number and type of drugs commonly or continuously used, dosage, self-medication practice).

All data collected were compiled in Microsoft® Excel spreadsheets and presented as absolute and relative or average frequency. For the analysis of drug interactions, verifiers available for free on the online Drug Interactions Checker Drug Information and DrugBank platforms were used. From the analysis made on the platforms, the interactions were classified according to the intensity of the effects as: "severe", when their effects may offer risk of death and require immediate medical intervention; “Moderate”, when their effects may cause a worsening of the patient's clinical condition, making it necessary to change the medication plan; “Mild”, classified as small clinical effects that generally do not require changes in pharmacological therapy; and “does not interact”, when drugs do not interact with each other.[9] For those pharmacological combinations not described in the on-line verifiers, a search was made in scientific articles, which did not allow characterizing the severity of the interaction, only if it occurred or not (which was defined by the authors as “interacts”).

The research was developed according to the guidelines of Resolution 466/12 of the National Health Council for research carried out on human beings, submitted to the UDESC Research Ethics Committee (REC), opinion No. 795133173.0000.0118 and approved on February 27 2018. All participants were kept confidential of the data used. In the tabulation and data analysis stage, the anonymity of the participants was guaranteed through numerical identification.

Results

Frequency distribution of sociodemographic data, lifestyle and health conditions of individuals with DM, in the studied area, is shown in Tables 1 and 2. In the interviewed individuals, the average age was 68.36 years. Race information was self-reported and made up mostly of whites. In addition, most of them had incomplete primary education, with a sample consisting mainly of widowers and retirees (Table 1).

Table 1- Distribution of sociodemographic variables of individuals with DM interviewed. Municipality of Chapecó/SC, 2018.

Variable	N	%
Gender		
Female	26	61,90%
Male	16	38,10%
Race		
White	33	78,57%
Black	8	19,05%
Brown	1	2,38%
Education		
Incomplete elementary school	21	50%
Complete elementary school	10	23,82%
Incomplete High School	3	7,14%
Complete High School	3	7,14%
Complete Undergraduate Education	3	7,14%
Illiterate	2	4,76%
Marital Status		
Widower	16	38,10%
Divorced	14	33,33%
Married	11	26,19%
Single	1	2,38%
Profession		
Retired	23	54,77%
Housewife/husband	15	35,71%
Cook	02	4,76%
Driver	02	4,76%

Source: Author's database (2018).

The questionnaire also had questions about the occurrence of other conditions such as Systemic Arterial Hypertension (SAH), visual problems and obesity, in which the interviewee indicated in a self-reported way, whether they were consistent with their situation or not. In

many cases, the patient had more than one comorbidity, which resulted in a total "N" greater than that of the sample (Table 2).

Other items in the questionnaire, shown in Table 2, relate the frequency of physical activities and care with food, smoking and alcohol use by patients with DM. There is also information about care related to the disease, such as frequency of consultations, time of DM treatment and use of medicinal plants as complementary therapy.

Table 2 - Distribution of variables related to the lifestyle and health conditions of individuals with DM interviewed. Municipality of Chapecó/SC, 2018.

Variable	N	%
Associated diseases		
Systemic arterial hypertension	34	80,95%
Visual problems	17	40,48%
Obesity	09	21,43%
Use of medicinal plants		
Yes	25	59,52%
Chamomile tea (*Chamomilla recutita*)	04	16,00%
Cow Paw (*Bauhinia forficata*)	04	16,00%
Marcela tea (*Achyrocline satureioides*)	03	12,00%
White mulberry (*Morus alba*) – relevant to DM	02	8,00%
Insuline tea (*Cissus sicyoides*) – relevant to DM	02	8,00%
Jambolão (*Syzygium cumini*) – relevant to DM	01	4,00%
Espinheira santa (*Maytenus ilicifolia*) – relevant to DM	01	4,00%
Did not specify the type of plant	08	32,00%
Frequency of physical activity		
Never excercise	18	42,86%
Sometimes	13	30,95%
Twice a week	07	16,67%
Three times a week	04	9,52%
Feed control		
Tries to control it	22	52,38%
Do not control it	12	28,57%
Control it sometimes	08	19,05%
Monitoring blood glucose rates		
Sometimes	26	61,90%
Daily	06	14,29%
Once a week	06	14,29%
Every fifteen days	01	2,38%
Once a month	01	2,38%

Only on consultations	01	2,38%
Never	01	2,38%
Frequency of consultation		
Frequently	10	23,81%
When necessary	10	23,81%
Between 2-4 months	10	23,81%
Every 6 months	08	19,05%
Once a year	03	7,14%
Did not know how to answer	01	2,38%
Time of treatment		
Less than 5 years	09	21,43%
5-10 years	12	28,57%
11-20 years	11	26,19%
+ 20 years	08	19,05%
Do not remember	02	4,76%
Smokers		
No	41	97,62%
Yes	01	2,38%
Alcoholic beverages Consumption		
Do not consume	35	83,33%
Consume	7	16,67%

Source: Authors data base (2018).

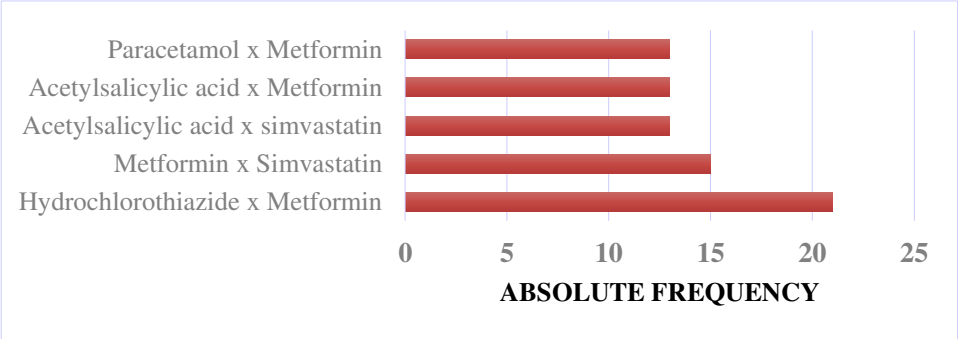
Another factor addressed was the perception of the difficulty in healing. Of the interviewees, 7.14% feel the effects of the lack of effective healing. Regarding the need to perform procedures due to DM complications, cataract surgery (1 patient), limb amputation (two patients), and a liver transplant were mentioned. Injuries and uninterrupted wounds in the lower and upper limbs were mentioned by two of the interviewees.

Through the analysis of the questionnaires and medical records, the list of drugs used by the 42 patients was obtained. The frequency of pharmacological combinations (drug 1 + drug 2) observed was 1355, which were analyzed on the online platforms to determine whether or not there were interactions between drugs. To identify the average per patient of pharmacological combinations, the total of them (1355) was divided by the number of participants in the research (n = 42), thus producing an average of more than 32.26 drug combinations / per patient . Of these, the most frequent were: 1 °) metformin and hydrochlorothiazide; 2) metformin and

simvastatin and metformin and paracetamol; 3 °) acetylsalicylic acid and metformin, acetylsalicylic acid and simvastatin and paracetamol and metformin.

After analyzing the pharmacological combinations, it was found that of the 1355 combinations, 479 (35.35%) resulted in some degree of drug interaction, generating an average of 11.4 interactions / per patient. Among the most frequent are hydrochlorothiazide and metformin, metformin and simvastatin, acetylsalicylic acid and simvastatin, acetylsalicylic acid and metformin and paracetamol and metformin (Figure 1). In addition, the majority of respondents reported that they withdrew the drugs at the reference CSF. The others reported that they bought drugs from pharmacies in laboratories different from those provided by UHS.

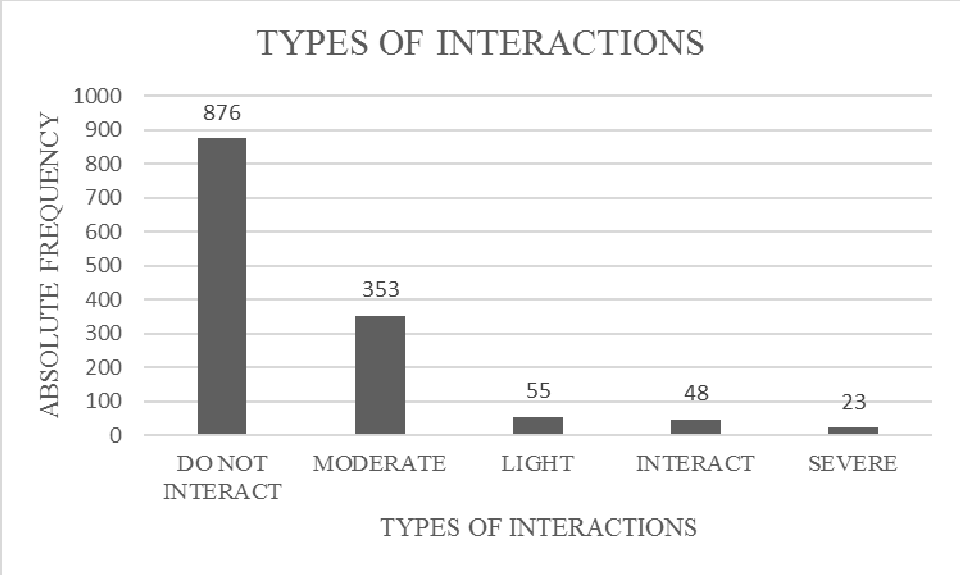
Figure 1 - The five most frequent drug interactions observed in DM patients surveyed. Municipality of Chapecó/SC, 2018.



Source: Authors' Database (2018).

To analyze interactions' ocurrance and intensity, we obtained a 64,65% as non integrant and a total of 4,06% for light interactions. 26,05% were on the moderate category and 1,70% of results were severe. In the Interact item, 3,54% of total was accounted for (Figure 2).

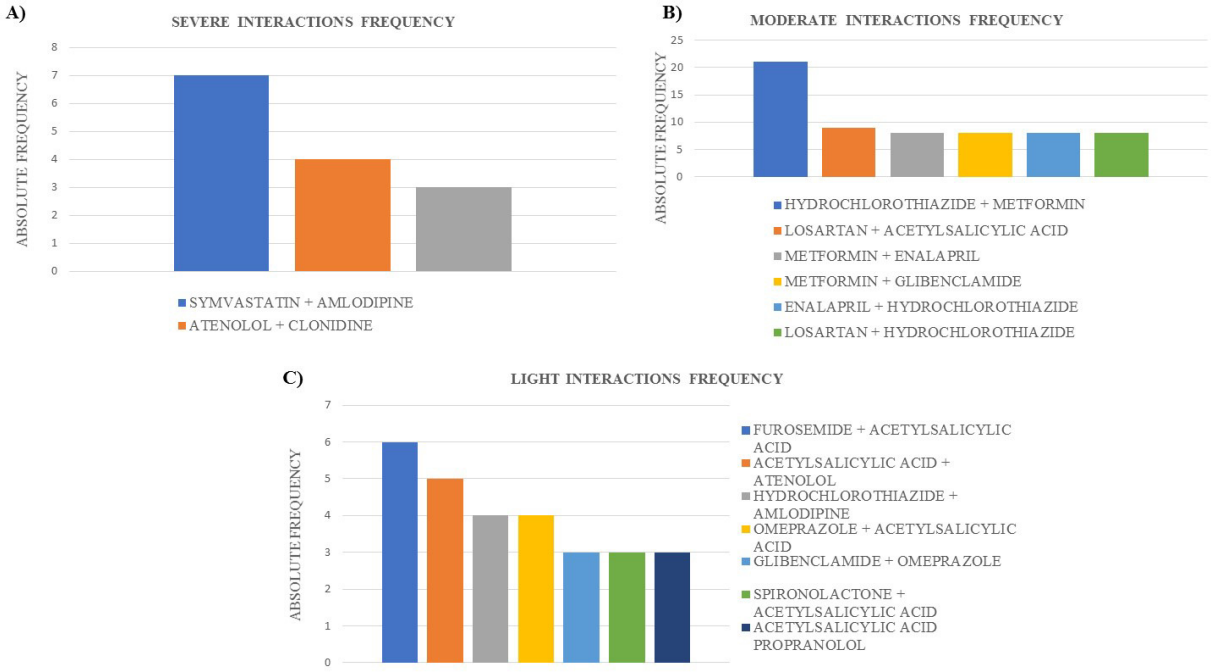
Figure 2 – Frequency of Interactions analyzed according to type. Municipality of Chapecó/SC, 2018.



Source: Authors' Database (2018).

In severe interactions, the most prevalent combinations were between simvastatin and amlodipine, atenolol and clonidine and losartan and spironolactone (Figure 3A). Among the moderate drug interactions, the combination of hydrochlorothiazide and metformin was the most observed (Figure 3B). As for mild interactions, the most frequent were furosemide and acetylsalicylic acid and acetylsalicylic acid and atenolol (Figure 3C).

Figure 3 - Interactions most frequently observed according to their severity (a) severe, b) moderate and c) mild. Municipality of Chapecó/SC, 2018.



Source: Authors' Database (2018).

The counting of drug associations classified only as interacting resulted in three appearances for metformin and nimesulide, as well as, hydrochlorothiazide and nimesulide, nimesulide and atenolol, hydrochlorothiazide and Dorflex® (dipyrone, caffeine and orphenadrine citrate), and hydrochlorothiazide and dipirone. Of the combinations of drugs that do not interact, the most frequent was between metformin and simvastatin fifteen times. Thirteen times, simvastatin and acetylsalicylic acid, acetylsalicylic acid and metformin, metformin and paracetamol appear.

Discussion

Physiologically, men and women have numerous differences, as well as their habits and life habits can differentiate, making them more or less susceptible to certain diseases.[10] Unlike what was observed in this study, men are the most affected by DM worldwide.[10] Age is another factor that contributes to the development of DM. In this study, the majority were elderly

people diagnosed with type 2 DM, corroborating national data that suggest a prevalence of patients with DM of approximately 20% in the age group 35 to 79 years, although the International Diabetes Federation (IDF) estimates 8, 8% in the world population.[1]

In type 2 DM, the race factor is also considered a risk condition for its development, with blacks, Hispanics or Pima Indians being the most susceptible to this condition.[1] In addition, the patient's race type may be related to different conditions such as access to and use of health services, in addition to being linked to economic factors, habits and behaviors.[11] Likewise, the level of education is a risk factor for the disease, as it influences the availability of access to information.[12] In this context, this study demonstrates that 50% of patients have incomplete elementary education, suggesting this as a factor that causes failures in self-care, such as low frequency of consultations and monitoring of blood glucose and lack of physical exercise.

Smoking is also considered a threat to the development of DM, since studies relate this combination to factors such as: high levels of cortisol, high markers of inflammation and oxidative stress and centralized obesity. In addition, nicotine clearly restricts insulin secretion.[1] The same caution applies to the consumption of alcoholic beverages since alcohol affects both food and blood glucose.[1]

Diseases associated with DM, most reported in the research were SAH, retinopathy and obesity. SAH is a common comorbidity of DM. The individual who has both has several pathophysiological mechanisms that leave them at a greater risk of developing cardiovascular and renal disorders.[1] Diabetic retinopathy is one of the most relevant conditions that cause irreversible visual loss worldwide [1] and obesity is associated with an increase in insulin demand due to tissue resistance, which causes an increase in blood glucose and consequent hyperinsulinemia.[13]

DM is a chronic disease, with no therapies developed to cure it so far. For this reason, factors such as high cost and unwanted adverse effects caused by the drugs, propitiate the

search for natural substances that are beneficial in reducing blood glucose. However, it is important to note that many medicinal plants can interact with antidiabetics and interfere with treatment effectiveness.[14] Among the teas used for the hypoglycemic effect by those surveyed and which have scientific proof, are the tea of Bauhinia variegata and Bauhinia forficata, species also known as pata-de-vaca, jambolão (Eugenia jambolana or Syzygium cumini), of mulberry leaf (Morus alba L.) and insulin tea (Cissus sicyoides).[1,15-16] Of all the plants mentioned in the research, the holy espinheira (Maytenus ilicifolia) was the only one that did not present scientific evidence proving its hypoglycemic effect.

Other effective glycemic control practices recommended by the Brazilian Diabetes Society[1] are frequent physical activity and the adoption of an adequate diet.[1] In addition, for a better therapeutic result it is important to monitor blood glucose. However, many times, this control is affected by lack of resources, unavailability of material in the network free of charge, the patient's inability to go to the reference FHC, wear of the application sites, among other factors.[17]

Regarding the data on potential drug interactions in this group of individuals with DM, they corroborate data from the literature that point to moderate risk interactions as the most frequent among patients with DM, and among them is the association of hydrochlorothiazide and metformin.[18-19] In addition, it is clear that the most prevalent were those whose drugs are used to treat the referred comorbidities or else resulting from self-medication, which usually involves analgesics and anti-inflammatory drugs. This last class is among the main ones involved in drug interactions in patients with DM.[20]

Analyzing the “severe” drug interactions, more frequent among those surveyed, the combination of simvastatin and amlodipine predominated. Attention should be paid to the significant increase in simvastatin in the bloodstream when this association occurs. The main complications are hepatotoxicity and rhabdomyolysis.[21] Therapy can be discontinued if there are

symptoms such as dark urine, nausea, vomiting, jaundice, among others.[21] When using atenolol and clonidine, blood pressure is likely to decrease, and the patient may experience symptoms such as headaches, dizziness and episodes of syncope. In the case of spironolactone and losartan hyperkalaemia may occur, with progression to renal failure and cardiac arrest.[2,11] It should be noted that the consequences of these serious interactions are potentially fatal or capable of causing irreversible damage to the patient.[9]

As for the moderate interactions, hydrochlorothiazide and metformin was the combination that prevailed, and the blood glucose levels that can be altered should be observed. In the combination of metformin and enalapril, the effect of metformin may increase with the consequent development of hypoglycemia.[22]

In light interactions, the most frequent combination was between furosemide and acetylsalicylic acid. In this category, clinical criteria are not extremely relevant in all cases. In the case that salicylates are used in anti-inflammatory dosages, there may be a reduction in the diuretic and natriuretic effects in loop diuretics. They generally do not cause harm and do not require changes in therapy.[8,21] In addition, mild interactions do not require a change in therapy or immediate intervention because they are not clinically relevant.[23]

It is worth noting that many of the drug interactions analyzed were due to self-medication, especially when they involve analgesics and anti-inflammatory drugs. It is associated with financial, political and cultural factors and has been adhered to by a large part of the population.[24] Due to the variety of products manufactured by the industry, the ease of commercialization, the range of medical information obtained in an accessible way through blogs, websites and social networks, self-medication has become a public health problem, awakening in the prevention agencies to health concern. Thus, requiring the development of strategies related to the wrong non-incentive of drugs.[24]

Based on these findings, it is clear that the patient's follow-up needs to take place in an integral manner, together with the team, so that the treatment definition connects with their disorders. In the nursing consultation, choose to emphasize the issues of life habits that interfere in the patient's treatment process, encouraging attendance in consultations and the adequate control and monitoring of blood glucose levels. In addition, advising on the use of teas and the risks of self-medication.[5] When looking for health services is outside the context of insertion of the user, it is important to guide the patient to carry along in consultations, prescriptions or even boxes of medicines so that there is no duplication in prescriptions or the risk of interaction between medicines.

Conclusion

The results obtained in this study allowed to establish the epidemiological profile of patients with DM treated at a FHC in the city of Chapecó/SC. From these data, the health team, usually led by the nurse, can establish care measures aimed at the glycemic control of these patients considering their economic and social reality.

Pharmacological combinations analysis, in this group of patients with DM, draws attention due to the intensity of different effects that may arise as a result of interactions between drugs. These data, at the same time that they generate an “alert” of the need for greater care in the prescription and dispensing of medications for this public, also allow a reflection on how nursing can act to avoid these damages. Since self-medication is one of the factors resulting in the number of interactions, care, intrinsic follow-up and guidance to patients on the subject are relevant, as it influences the course of their treatment..

In view of this, the nurse has a role in this process through continuous monitoring, guidance on the use of drugs, inclusion of groups to share experiences, integration with the multiprofessional team to work at all levels of health. The control of risk factors associated with

DM, through health promotion measures, can contribute to reduce the incidence of the disease and its chronic complications, as well as to reduce the costs generated by the system.

Despite the methodological limitations of the study, mainly regarding the sample size and access to free systems for evaluating drug interactions, the results described here will redirect the practice of professionals who serve this population, in the Family Health Centers of the Municipality, in order to to reduce the risks associated with their pharmacological treatment.

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Corresponding Author

Leila Zanatta
E-mail: leila.zanatta@udesc.br
Address: Rua Sete de Setembro, 91-D – Centro, Chapecó-SC.
Zip Code: 89801-140

Authors Contributions

1 – Leila Zanatta
Conception and planning of the research Project, analysis of the datas, reduction and critical revision.

2 – Fernanda Norbak Dalla Cort
Conception and planning of the research Project, analysis of the datas, reduction and critical revision.

3- Nathália Silva Mathias
Conception and planning of the research Project, analysis of the datas, reduction and critical revision.

4 – Carla Argenta
Reduction and critical revision

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