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Drug utilization and factors associated with polypharmacy in individuals with diabetes mellitus in Minas Gerais, Brazil

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Abstract *The objective of this study was to evaluate the use of drugs and the factors associated with polypharmacy in patients with diabetes mellitus (DM) in Minas Gerais. Descriptive analysis of drugs in use and logistic regression to estimate the association between socio-demographic and clinical characteristics with polypharmacy were performed. Of the 2619 respondents, 56.5% were in polypharmacy. Drugs for DM, agent in renin-angiotensin system, and diuretics are the most frequently used. Factors such as age, comorbidities and increased access to health services were associated with polypharmacy. It was observed high prevalence of polypharmacy, which requires a suitable care and better quality of drug use in this population.*

Key words *Diabetes mellitus, Drug utilization, Polypharmacy, Pharmacoepidemiology*

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Introduction

Diabetes Mellitus (DM) is a chronic complex disease, which requires continuous medical assistance and the use of multifactorial strategies for risk reduction, besides the search for glycemic control[1]. It is presented as a worldwide epidemic, representing a great challenge for the health systems all over the world[2,3].

The world prevalence of DM is estimated in 387 million people and is expected an increase to 592 million people for the coming year of 2035, between 20 and 79 years old[4]. In Brazil, the DM prevalence achieves 8.7% of the population above 20 years old, which corresponds to 11.6 million people. Out of this portion, 3.2 million would be undiagnosed[5].

About 75% of type 1 DM cases are diagnosed in individuals with age lower than 18 years. Besides, an incidence of type 2 DM is estimated in 2.3% a year in individuals with age lower than 20 years; a proportion that will increase significantly the prevalence of this disease in this age group of the population[6].

On the other hand, it is being configured as an important health condition in the aging process, as 26% of patients aged above 65 years has DM, and this number should increase quickly in the next decades. The older individuals with diabetes have higher rates of early death, functional inability, and coexisting diseases than individuals without DM[7], and it takes to a decrease in their quality of life[8].

In this context, patients with DM have a higher risk to present polypharmacy than other patients[7,9], and this phenomenon is defined by most of the studies as the simultaneous use of five or more medications[10-12]. The prevalence of polypharmacy in elderly in the United States has increased significantly, from 30.6% to 35.8%, and the risk for major drug interaction has increased from 8.4% to 15.1%, in a period of five years. These results become even more relevant when the consumption of food supplements in this population is observed, as vitamins and omega 3, which suggests the necessity of greatest care and follow-up of the patients using multiple medications and having chronic diseases[10]. It is observed, therefore, an increasing worry with polypharmacy and its impact on the morbidity, mortality, and the costs related to patient and Healthcare Services[13].

Recent studies in different populations of DM patients have evaluated the disease prevalence[14-18] and demonstrated its increase in the last decades, with estimations indicating that such increase will remain over the years[16-18]. Other studies have reported that the number of medications in use is elevated[14,19,20]. However, studies evaluating the factors associated to polypharmacy in the DM populations have not been observed. So, this study has as purpose to evaluate the polypharmacy prevalence and its associated factors, describing also the profile of medications utilization in DM patients in Minas Gerais, Brazil.

Methods

Sample

A household survey was realized in 63 municipal areas of Minas Gerais, being 61 inland municipalities, the State capital Belo Horizonte, and Contagem, between January and February of 2014. All these cities possessed pharmaceutical services structured and functioning. The criteria for the selection by convenience of the inland cities were: urban population higher than two thousand inhabitants; , to have a unit of the State Pharmacy (*Rede Farmácia de Mina*s) in activity at least 2 years; *f* to possess access to internet in the service; to present consent from the Municipal Health Secretary, and manifestation of interest to be participating in the project, expressed by the local pharmacist. The study population was composed of individuals bearing DM, without any restriction, who agreed to participate and signed the Informed Consent Form. The selected municipal areas are part of all the 13 health macro-regions of the Minas Gerais.

The sample for every municipal area has been selected randomly, considering the census sectors adopted by the Brazilian Institute of Geography and Statistics (IBGE) for the respective urban perimeter. The investigators received localization maps referring to each selected sector, which were walked house by house, without return in case of absent dweller, according to the following groupings: a) for Belo Horizonte and Contagem, with populations of 2.4 million and 650 thousand inhabitants[21], respectively, 122 and 25 census sectors were selected; b) for municipal areas with urban population higher than 5,000 inhabitants and a minimum of ten census sectors of IBGE, five sectors were drawn; c) for municipal areas with urban population between 2,000 and 5,000 inhabitants and with less than ten IBGE census sectors, all possible houses were visited.

The sample size calculation was executed considering the DM prevalence of 8.7% over the

reference population of Minas Gerais in 2013, which was of 20.593.366 inhabitants[21]; corresponding to the estimation of 1,791,623 individuals with DM, a level of confidence of 95%, estimated prevalence of 50% for different outcomes of prevalence, maximal tolerated error of 2%. Taking as a base these parameters, the minimal final sample was estimated in 2,398 individuals, to which a margin of 10% was added to cover possible losses. Then, a total of 2,638 individuals should be interviewed.

Study variables

The dependent variable was the occurrence of polypharmacy, defined as the use of five or more medications; an information that was obtained from the question: In the last 15 days, have you utilized medications?. The response to this question should be proven by means of the respective package presentation or medical prescription.

The independent variables were sex, age group, marital status, schooling, race, health self-perception, self-reported DM type, average time of DM diagnosis, number of self-reported comorbidities, frequency of medical consultations in the last year, public or private health plan, regular practice of physical activity, and interruption of normal activities in the last 15 days.

Data analysis

The descriptive analysis was developed by means of the distribution of frequencies of medications in use, according to anatomical therapeutic classification (ATC) in first, second, and fifth level for the entire sample. For the variable number of medications, the average and standard deviation (SD) were obtained.

The factors associated to polypharmacy were analyzed, being constituted two comparison groups: without polypharmacy (reference group), defined as the use of zero to four medications, and polypharmacy, defined as the use of five or more medications. A bivariate analysis has been developed for comparison of frequencies, being utilized the Pearson's chi-squared test. Were included in the multivariate analysis the variables that presented p-value < 0.20 in the bivariate analysis, utilizing the model of multiple logistic regression. Only the variables with the *p*-value < 0.05 remained in the final model. The data analysis was executed utilizing the software SPSS® version 22.0.

Ethical considerations

The Independent Ethics Committee of the Federal University of Minas Gerais has approved the study.

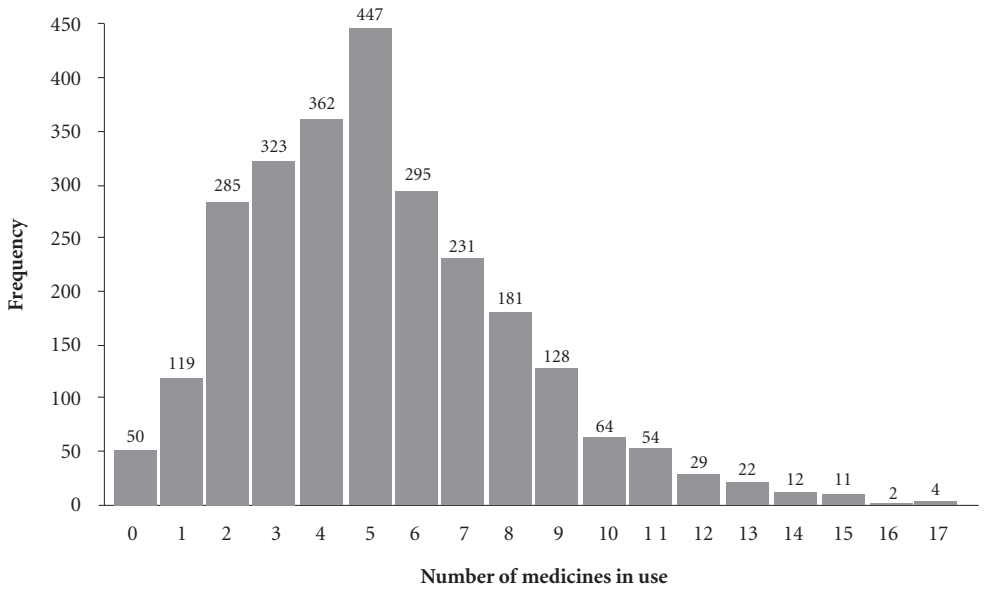
Results

A total of 2,619 persons with DM was interviewed, being that 2,192 (83.7%) stated to have type 2 DM and 272 (10.4%) to have type 1 DM. Around 6% did not know to report about their DM type. The average age was 61.3 ± 16.4 years. The average time of DM diagnosis was of 9.9 ± 8.8 years.

When considering all study participants, a consumption of 13,629 medications was reported for the treatment of several diseases, with an amplitude of 0 to 17 medications in use per person, according to Graphic 1. The average number of medications utilized was of 5.2 ± 2.9.

About 60% of medications were acquired in public pharmacies and 35% were generic. The drugs with action on the cardiovascular system were the most utilized, followed by drugs with action in the alimentary tract and metabolism, and in the nervous system. The more frequent therapeutic classes in use were medications utilized for DM, agents acting in the renin-angiotensin system, the diuretics, lipid modifier agents, and thrombolytic agents. The more frequent medications in use were metformin, losartan, glibenclamide, and simvastatin (Table 1). These results correspond to the more prevalent comorbidities observed in the study, which were hypertension, with 76%; dyslipidemia, with 44%; and obesity, with 32%. In addition, 31% of patients reported that have or have had depression; and an important participation of antidepressants was observed among the agents actuating in the nervous system.

Among the interviewed persons, 56.5% – error margin in the CI 95% corresponding to 3.4% – were in polypharmacy. The group of polypharmacy presented higher frequency of female sex, with more advanced age and more time of diagnosis as compared with the group without polypharmacy. A larger number of comorbidities associated to DM, medical consultations in the last year, and interruptions of normal activities were verified in this group, in addition to lower regular practice of physical activity and worst self-perceived health. All these variables showed statistical significance in their association with



Graphic 1. Histogram of the frequency distribution of the number of medicines in use by the interviewees.

polypharmacy in the bivariate analysis (Table 2).

The analysis of logistic regression indicated that the factors associated positively and significantly to the occurrence of polypharmacy in DM patients are age above 40 years, bad or very bad self-perceived health, presence of five or more comorbidities, average time of diagnosis above 10 years, four or more medical consultations in the last year, absence of regular physical activity, interruption of normal activities in the last 15 days, and access to a private health plan. (Table 3).

Discussion

The prevalence of polypharmacy in this study, considered as using five or more medications, was of 56.5%. According to literature, the occurrence of polypharmacy in DM patients in Brazil varies from 26.7% to 46.3%, proportions lower than the one found in our study[14,15,22]. An Indian study reports a prevalence of polypharmacy in type 2 DM individuals of 25.5% in younger patients and 41.6% in older patients[23]. Qato et al.[10] have demonstrated a significant increase of polypharmacy prevalence between elderly within an interval of five years, which was associated mainly to an increase in the consumption of alimentary supplements and multiple prescriptions of medications in patients with comorbidities.

Another aspect, related to increasing of polypharmacy, results from the fact that individuals with DM are more prone to be in polypharmacy situation[7,12]. This could be partially explained by the increase in the dose of in-use medications or the prescription of new medications, when the adherence to proposed treatment and the adequate control of DM and comorbidities are not achieved[24,25]; which could lead to a higher risk of drug interactions.

The medications acting on the cardiovascular system were the most utilized ones, followed by medications acting in the alimentary tract and metabolism, and nervous system, as observed in the studies developed by Pereira et al.[20] in hypertensive and diabetic patients, and by Baldoni et al.[26] in elderly. Bauer Nauck[19] have identified that the medications most utilized by DM patients, within a center specialized in the treatment of DM in Germany, were those addressed to alimentary tract and metabolism, followed by those utilized for the cardiovascular system and nervous system. In the study of Guidoni et al.[27], the medications most utilized by patients with DM were those for the cardiovascular system, nervous system, blood and hematopoietic organs, and alimentary tract and metabolism. In other studies, with elderly patients, the most utilized drugs were those for the cardiovascular and nervous systems, and the alimentary tract and metabolism[14,15]. In

Table 1. Distribution of pharmaceutical specialties per groups and subgroups, according to Anatomic Therapeutic Classification (ATC).

Level I (N = 13629)[1]	%	Level II (n = 2619)[2]	%	Level V (n = 2619)[2]	%
Cardiovascular (C)	40.0	Agents that act in the renin-angiotensin system (C09)	56.1	Losartan (C09CA01)	32.1
		Diuretics (C03)	39.4	Simvastatin (C09CA01)	29.2
		Lipid modifier agents (C10)	32.6	Hydrochlorothiazide (C03AA03)	23.9
		Beta-blockers (C07)	23.8	Enalapril (C09AA02)	15.2
		Calcium channels blockers (C08)	18.7	Amlodipine (C08CA01)	14.4
		Cardiac therapy (C01)	6.3	Furosemide (C03CA01)	13.3
		Others**	6.8	Atenolol (C07AB03)	11.1
Alimentary Tract and Metabolism (A)	35.4	Medications utilized in diabetes (A10)	94.5	Metformin (A10BA02)	68.6
		Oral antidiabetic agents (A10B)	84.5	Glibenclamide (A10BB01)	31.5
		Insulins and analogs (A10A)	30.2	NPH Insulin (A10AC01)	27.1
		Medications for disorders related to acidity (A02)	18.7	Omeprazole (A02BC01)	16.0
		Vitamins (A11)	6.9	Glimepiride (A10BB12)	5.7
		Others**	4.5	Gliclazide (A10BB09)	5.6
Nervous (N)	10.2	Psychoanaleptic agents (N06)	16.5	Clonazepam (N03AE01)	6.6
		Anti-epileptic agents (N03)	11.1	Fluoxetine (N06AB03)	4.6
		Psycholeptic agents (N05)	9.9	Amitriptyline (N06AA09)	3.7
		Analgesic agents (N02)	5.4	Diazepam (N05BA01)	2.6
		Others**	3.4	Sertraline (N06AB06)	2.3
Blood and hematopoietic organs (B)	6.9	Antithrombotic agents (B01)	30.4	Acetylsalicylic Acid (B01AC06)	27.3
		Others**	2.4		
Hormones, except insulins (H)	2.1	Thyroid therapy (H03)	8.8	Levothyroxine (H03AA01)	8.6
		Others**	3.1		
Musculoskeletal (M)	2.0	Anti-inflammatories and anti-rheumatic agents (M01)	5.0	Allopurinol (M04AA01)	1.9
		Antigout preparations (M04)	2.0	Alendronate (M05BA04)	1.5
		Others**	2.3	Ibuprofen (M01AE01)	1.4
Respiratory (R)	1.3	Agents against airways obstructive diseases (R03)	2.6	Formoterol + Budesonide (R03AK07)	1.4
		Antihistaminic agents for systemic use (R06)	1.8		
		Others**	0.6		
Others*	2.2				

1 = Total of medications in use by the interviewed; 2 = Total of interviewed people. * Sum of medications of ATC codes Level I in use not presented separately (D, G, J, L, P, S e V), because presenting lower frequency of use. ** Sum of medications of ATC codes Level II in use not presented separately (example: C02, C04, C05 for ATC Level I = C) because presenting lower frequency of use.

general, the similarity between utilized medications is due to more prevalent comorbidities associated to DM, hypertension, dyslipidemia, and depression, also observed in our study[2,28].

According to American Diabetes Association (ADA), hypertension and dyslipidemia are commonly found in patients with DM that present, also, higher prevalence of depression than the people without DM; and this could difficult the treatment management of patients[28,29]. There is strong evidence that depression in people with diabetes increases the risk for complications related to this disease. The depression has been associated with hypoglycemia, to complications related to DM, as well as to the perception of functional limitations resulting from the DM[2,29].

The more frequent therapeutic classes were the medications utilized in diabetes, agents acting on the renin-angiotensin system, the diuretics, and lipid modifier agents; corroborated

Table 2. Bivariate association of sociodemographic and clinical variables with the polypharmacy in patients with DM in Minas Gerais.

Variables	Without polypharmacy	Polypharmacy	Total	
	n (%)	n (%)	N	%*
Gender			**p < 0.001**	
Male	415 (51.2)	398 (48.8)	811	31.0
Female	724 (40.0)	1084 (60.0)	1808	69.0
Marital Status			**p < 0.001**	
Single	229 (57.7)	168 (42.3)	397	15.2
Married	583 (44.6)	725 (55.4)	1308	49.9
Widowers	208 (32.0)	443 (68.0)	651	24.9
Others	119 (45.2)	144 (54.8)	263	10.0
Schooling			**p < 0.001**	
< 4 years	420 (37.2)	708 (62.8)	1128	43.1
4 years or more	719 (48.2)	772 (51.8)	1491	56.9
Age			**p < 0.001**	
< 40 years	188 (78.7)	51 (21.3)	239	9.1
40 to 59 years	408 (52.1)	375 (47.9)	783	29.9
60 years or more	543 (34.0)	1054 (66.0)	1597	61.0
Race or color			**p = 0.069**	
White	470 (41.2)	671 (58.8)	1141	43.6
Brown	477 (44.4)	598 (55.6)	1075	41.0
Black	175 (48.9)	183 (51.1)	358	13.7
Others	14 (41.2)	20 (58.8)	34	1.3
Self-perceived health			**p < 0.001**	
Very good/good	539 (54.8)	445 (45.2)	984	37.6
Regular	498 (40.5)	733 (59.5)	1231	47.0
Bad/Very bad	100 (24.9)	302 (75.1)	402	15.3
Type of DM			**p = 0.123**	
I	130 (47.8)	142 (52.2)	272	10.4
II	940 (42.9)	1252 (57.1)	2192	83.7
DM diagnosis			**p < 0.001**	
< 10 years	750 (51.9)	694 (48.1)	1444	55.1
10 years or more	389 (33.1)	786 (66.9)	1175	44.9
Comorbidities			**p < 0.001**	
< 5	841 (61.2)	533 (38.8)	1374	52.5
5 or more	298 (23.9)	947 (76.1)	1245	47.5
Medical consultations			**p < 0.001**	
< 3	601 (57.1)	451 (42.9)	1052	40.2
3 or more	538 (34.3)	1029 (65.7)	1567	59.8
Private Healthcare Plan			**p = 0.001**	
Yes	308 (38.6)	490 (61.4)	798	30.5
No	831 (45.6)	990 (54.4)	1821	69.5
Does regular physical activity			**p < 0.001**	
Yes	559 (51.8)	521 (48.2)	1080	41.2
No	579 (37.6)	959 (62.4)	1538	58.7
Failure to hold habitual activity in the last 15 days			**p < 0.001**	
Yes	198 (28.8)	489 (71.2)	687	26.2
No	941 (48.7)	991 (51.3)	1932	73.8

Without polypharmacy: 0 to 4 medications in use; Polypharmacy: ≥ 5 medications in use. (n) Number of interviewed per variable within the categories polypharmacy or without polypharmacy. (%) Variable percentage within the categories polypharmacy or without polypharmacy. (N) Number of interviewed per variable respecting to total of interviewed people. (%*) Percentage of variable respecting to total of interviewed people. Without information was not considered in the analysis. *p*-value: < 0.20.

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Table 3. Associated factors to polypharmacy in patients with DM in Minas Gerais.

Variables	Polypharmacy		
	OR	CI 95%	
Age			
< 40 years	**1.00**		
40 to 59 years	**2.46**	1.68	3.61
60 or more	**4.58**	3.18	6.60
Self-perceived health			
Very good/Good	**1.00**		
Regular*	**1.12**	0.92	1.37
Bad/Very bad	**1.73**	1.26	2.38
Comorbidities			
< 5	**1.00**		
5 or more	**3.45**	2.84	4.19
Diagnosis of DM			
< 10 years	**1.00**		
10 years or more	**1.64**	1.36	1.98
Medical consultations in the last year			
< 4	**1.00**		
4 or more	**1.79**	1.48	2.16
Regular Physical Activity			
Yes	**1.00**		
No	**1.47**	1.22	1.78
Failure to hold habitual activity in the last 15 days			
No	**1.00**		
Yes	**1.30**	1.03	1.64
Private Healthcare Plan			
No	**1.00**		
Yes	**1.39**	1.13	1.70

OR: Odds Ratio. * Not significant. *p*-value: < 0.05.

by the studies of Guidoni et al.[27] and Bauer and Nauck[19]. The hypertension treatment in patients with DM, suggested by ADA and by the IV Brazilian Guidelines on Hypertension, should include angiotensin converter enzyme inhibitor or antagonist of angiotensin receptor and, if the use of such agents is impossible, the application of diuretics, which was observed in this present study[28,30].

Among the most utilized medications according to ATC classification, only glimepiride and sertraline are not available in the Unified Health System (SUS)[31,32]. Besides, almost two-thirds of medications were acquired by means of public pharmacies. Such a result indicates an important participation of SUS in the access to medications in Minas Gerais, during the period of investigation. A factor contributing for this was the implementation of *Rede Farmácia de Minas*, inserted in the State Program for Pharmaceutical Assistance Restructuring, as a strategy to amplify the access and rational use of medications in the SUS context[33].

Studies in patients with DM associating polypharmacy with its explicative variables have not been found. Only studies in elderly have investigated the number of utilized medications with their associated factors. In this context, it is possible to perceive that the population of this study presents characteristics like those of elderly population, with an average age of 61.3 years and more than 60% of the interviewed people declaring to be 60 years old or more. So, studies developed in elderly population have been utilized for comparison.

Respecting to age, as higher the age group of DM patients, higher the odds for a patient to be in polypharmacy, which is in accordance with results from other studies[11,19,34,35]. The patients' average age was like that found in the studies of Araújo et al.[22] and Bauer and Nauck[19] in DM patients of Fortaleza, Brazil, and Bad Lauterberg im Harz, in Germany.

Another factor contributing to the increase in the number of medications is the higher number of comorbidities[7,24,35,36]. At this point, the observation is that many individuals can not to obtain an adequate control of their health conditions. In the study of Gomes et al.[36], developed in DM patients presenting also different comorbidities, less than 30% of patients achieved the target of blood pressure control, about 25% achieved the body mass index < 25 Kg/m², 21% achieved the control of LDL-Cholesterol level and 46% achieved the adequate control of glycated hemoglobin. The presence of a higher number of comorbidities, associated with an inadequate control of these health conditions, contributes a lot to the increase in the number of in-use medications.

To have consulted the physician four or more times during the last year is associated with polypharmacy in DM patients, which has also been observed in other studies with elderly patients[35,36]. Linjakumpu et al.[37] have pointed out that the increase of utilization of health services by the most older people could be responsible for the higher use of medications. The importance of the continued medical education, the observance of clinical protocols and therapeutic guidelines, the quality of medical prescription and pharmaceutical orientation should be reinforced here, to contribute to a better use of the high number of in-use medications by the DM patients. This demonstrates the importance of a

multidisciplinary care in health, which involves actions of health education, self-care, adherence to proposed measures, not pharmaceutical interventions, among other[37-40].

The average time of diagnosis above 10 years showed an association with polypharmacy. According to the Booklet of Basic Attention – Diabetes[41] and Lipska et al.[42], with the progressive increase of diagnosis time, it is possible to observe the appearance of microvascular and macrovascular complications in the patients, mainly when they are not informed about their disease, on occasion of the diagnosis. Besides, it is observed that in nine years, 75% of DM patients need to make use of more than one medication for their glycemic control. Both factors increase the number of in-use medications and favor the presence of polypharmacy[43].

The bad or very bad health self-perception showed association with polypharmacy, an aspect observed also in other studies[11,44]. According to Santos et al.[44], the patients presenting a worst health self-perception, when using several medications, are searching for a solution to their health problems. In a study developed in Canada, a higher report of bad or very bad health self-perception has been observed respecting to observed in our study, associated mainly to the presence of depression and deficiencies associated or resulting from DM, besides the presence of other chronic comorbidities[45].

The absence of regular physical activity and the cessation of normal activities are factors associated with polypharmacy in type 2 DM patients. According to the Brazilian Society of Diabetes (2015), the physical activity, associated with a food plan, could be beneficial to help in the glycemic control, in the weight loss, and in the increase of muscle mass, which should collaborate for the reduction of insulin resistance and better disease control[2]. Besides, Silva et al.[46] have reported that the interruption of normal activities is related to the use of a larger number of medications.

It was observed that the availability of a health plan was associated with polypharmacy, as reported by other studies[11,46]. According to Duarte (2012), people having a health plan possess higher income and more easy access to healthcare professionals and medications available in the market[47]. In a study developed with DM patients linked to Medicare, in the United States, it has been observed that a half of the individuals with inadequate glycemic control had not their treatment intensified along five years, which could lead to DM complications and contributes for the polypharmacy increase[48].

The limitations of this study are related to utilization of a reminder period of 15 days for the evaluation of medications use, which could generate a recall bias. We tried, however, to minimize such bias by means of the confirmation of use through the presentation of used products packages and respective prescriptions. Besides, the transversal method does not allow the establishment of cause-effect relationships. The data collection was executed in work schedules of people, from 08:00 am to 06:00 pm, which could have contributed for the selection of an older sample, composed by people inactive in terms of work. It is suggested that new studies should evaluate the possible benefits and harms of polypharmacy, of medication association and the influence of these conditions in the quality of life of DM patients, with the purpose to achieve a better use of medications and optimize the healthcare provided to these patients.

The polypharmacy presents a relevant prevalence among DM patients in Minas Gerais. Most of the interviewed people were using polypharmacy, which increases the risk for adverse reactions, cumulative toxicity, and drug interactions. This present study has brought deeper knowledge about the factors related to polypharmacy and it is expected that such information could contribute for the optimization of healthcare provided to patients with such a health condition, reinforcing the necessity of educational actions in health and the search for a better use of medications. Factors such as population aging, the increase of comorbidities, and the access to healthcare services contribute to increasing the number of medications utilized by the DM population. Because of that, there is the necessity to become available a sufficient number of enabled professionals to provide the adequate healthcare, improve the quality of medications use, and minimize the negative consequences in the health of this population.

Collaborations

MRR Silva has participated in the study planning and data collection, data analysis, and article writing. LM Diniz has collaborated on the project elaboration, data collection planning, results analysis, and critical review of the article. JBR Santos has collaborated in the data analysis and article writing. EA Reis contributed for the data analysis and critical review of the article. AR Mata and VE Araújo contributed to the planning and supervision of data collection and critical review of the article. J Álvares contributed for the project elaboration, data collection planning and critical review of the article. FA Acurcio collaborated for the project elaboration and orientation, data collection planning, results analysis and critical review of the article. All the authors have approved the version to be published.

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The authors declare to be free of conflicts of interest.

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