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Dietary patterns as predictors of adverse antidiabetics reactions - A cross-sectional study of polish diabetes sufferers

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Abstract

Background: Diabetes mellitus (DM) is a multifaceted problem. There is a need to coordinate the diet with pharmacological interventions, because of the possible interaction between the two. The present study aimed to identify the factors related to the dietary habits of people suffering with diabetes that may increase the risk of adverse reactions to anti-diabetic medication.

Methods: Between 2019 and 2020, patients with DM (N=203), aged 18-65, were enrolled for analysis. A quantitative and cross-sectional survey was applied. The study employed a Dietary Habits and Nutrition Beliefs Questionnaire devised in Poland for people aged 15–65 years (KomPAN) and a self-designed questionnaire as research tools.

Results: The majority of the patients with DM studied confirmed the use of a low carbohydrate diet in relation to their disease (87.7%). The mean pHDI-10 score for the study group was 22.55±8.67 points and the mean nHDI-14 score was 15.00±9.88 points. The place of residence, education and general financial situation of the subjects had a statistically significant effect on the results ($p<0.05$). The majority of subjects reported regular use of anti-diabetic medication (77.8%). Of those treated with oral medication, 61.1% had experienced adverse effects and 49.3% had been hospitalized as a result. Of those treated with insulin, 40.9% reported adverse effects.

Conclusions: Health professionals should be proactive in giving people with DM, particularly those who are less educated, financially disadvantaged, aged 41-55 and are working, adequate counseling about dietary recommendations from the very onset of their illness.

Key points:

- Treatment and prevention of DM severity is a system of individual, complementary components, which unfortunately are sometimes seen as disconnected - particularly in relation to diet.
- The study revealed quite poor adherence of people with DM to dietary patterns.

- Food intake can, in some situations, affect the efficacy of diabetes medication, either by making its effects stronger, weaker or causing a variety of adverse effects.
- Adherence to therapeutic recommendations, including regular use of medication and adherence to dietary recommendations, helps to avoid the occurrence of adverse and often dangerous drug-food interactions

KEYWORDS
diabetes, dietary patterns, diet-index, drug-food interactions

1| INTRODUCTION

Diseases of civilisation, including diabetes, are the most significant health challenges facing the world today. Diabetes is the only non-communicable disease recognized by the United Nations (UN) as a 21st century epidemic and one of the top 10 causes of disability worldwide. According to the latest data from the International Diabetes Federation (IDF), approximately 415 million people worldwide are already living with diabetes and it is estimated that this number could rise to 642 million by 2040. [1,2,3] Diabetes should be seen as a multifaceted problem. It is not only a tragedy for those affected, but also a problem for their families and society as a whole, which is burdened by the enormous costs of treating the disease and its consequences. Therefore, experts point to the need for an interdisciplinary view of the disease that goes beyond narrowly defined medical problems. [3,4,5] Treatment and prevention of disease severity is a system of individual, complementary components. Adequate nutrition, physical activity, the use of hypoglycaemic agents and a lifestyle focused on avoiding harmful factors are important in improving the overall health of patients and in preventing and treating the chronic complications of diabetes. [6,7] However, the components of this system are sometimes seen as disconnected - particularly in relation to diet. Although most people with diabetes agree that diet is crucial to managing the condition, there is also a view that blood sugar levels are controlled by medication and that diet alone is ineffective. Research data confirms that the need for dietary self-discipline is a major concern for many patients. [8,9,10] Literature also emphasizes the need for professional counselling to coordinate the diet with pharmacological interventions, including hypoglycaemic treatment, because of the possible interaction between the two. [6,11,12] Dietary habits have a significant impact on pharmacological treatment. The bioavailability of medication or level of potency may be altered in a variety of ways such as by the consumption of alcohol or caffeine, by taking medication either when malnourished or immediately before a meal or even by chewing the drugs. Such actions may, consequently, lead to conditions that are dangerous for the patient.[13,14] Therefore, this study aimed to determine which factors related to the dietary habits of people with diabetes increase the risk of adverse effects of the anti-diabetic medication prescribed.

2 | MATERIAL AND METHODS

2.1 | Data Collection

This quantitative descriptive cross-sectional survey design was conducted between March 2019 and February 2020 in inpatient and outpatient diabetes facilities in southern Poland. The study included patients aged between 18 and 65 years on the day of the survey. The initial total number of people meeting the age criterion was 231 (100%), consisting of 114 (49.4%) inpatients and 117 (50.6%) outpatients. The following exclusion criteria were used: lack of patient consent to participate in the study, diagnosis of gestational diabetes, not taking anti-diabetic medication or insulin and use of therapy for less than six months. In addition, at the data coding stage, respondents' answers were verified using the screening questions included in the KomPAN questionnaire. On this basis, 28 participants were rejected. Finally, 203 participants (100%) were qualified for the study, consisting of 101 participants (49.7%) being treated in hospital (H) and 102 participants (50.3%) being treated as outpatients in a diabetes clinic (A). Prior to enrolment, all participants were informed of the purpose of the study, how the study would be conducted, that anonymity would be maintained, and that they could withdraw from the study at any time. After reviewing the preliminary information, each interviewee was asked to give written consent to participate in the study and was given a copy. The interview was always conducted by the author of the study, in a secluded room, with privacy and protection of personal data. The study design received approval from the Bioethics Committee in Bielsko-Biala (Poland) (No. 2018/11/15/3 of 15.11.2018).

2.2 | Research Tool

The study used a standardised research tool in the form of the Dietary Habits and Nutrition Beliefs Questionnaire developed in Poland for people aged 15–65 years old (KomPAN) (version v.1.1.) and a self-designed questionnaire. The KomPAN questionnaire is an improved and extended version of its prototype - the QEB questionnaire. It is divided into four sections: (A) eating habits; (B) frequency of food intake; (C) views on food and nutrition; (D) lifestyle and personal information. This article considers sections A and B. According to the authors' guidelines for the questionnaire, each subject is assessed on the basis of the frequency of consumption of the food in question - Pro-healthy Diet Index 10 (pHDI10) and Non-Healthy Diet Index 14 (nHDI 14). The pHDI-10 index determines the sum of the frequency of consumption of 10 groups of so-called healthy foods (wholemeal bread; buckwheat groats, oatmeal, wholemeal pasta or other coarse-grained cereals; milk; fermented dairy drinks, e.g. yoghurt, kefir; cottage cheese; foods from so-called white meat, e.g. chicken, turkey, rabbit; fish; foods from pulses, e.g. beans, peas, soya, lentils; fruit and vegetables). The nHDI-14 index determines the sum of the frequency of consumption of 14 groups of so-called unhealthy foods (white bread; white rice, pasta or small grains; fast food; butter as an ingredient in baking or other dishes; lard as an ingredient in baking or other dishes; yellow cheese; cold cuts, sausages or frankfurters;. red meat dishes, e.g. pork, beef, veal, mutton, lamb, game; confectionery; tinned meat products; sweetened carbonated or non-carbonated drinks ; energy drinks and alcoholic beverages). [15,16] The KomPAN validation conducted on the Polish population revealed that its repeatability was from moderate to very good. The internal reliability of the pHDI-10 ranged from 0.66 to 0.71 and for the nHDI-14 it ranged from 0.37 to 0.60. Kappa statistics were above 0.40 for all analysed variables. [17] The author's questionnaire included a brief introduction for the research candidate and a metric in which the respondent was asked to provide their socio-demographic data, such as gender, age, education, marital status, place of residence, occupational situation and an indication of their health and financial situation.

2.3 | Data Analysis

All data was analysed and verified statistically using the R program (R Project for Statistical Computing, www.r-project.org, version 3.5.5), the PSPP program (https://www.gnu.org/software/pspp/) and MS Office 2019. Quantitative features were presented with the arithmetic mean (M) and standard deviation (SD). Correlation coefficients and statistical modelling techniques were used to analyse the strength, form and direction of the interdependence of the phenomena. P-values below 0.05 were considered significant.

3 | RESULTS

3.1 | Patient characteristics

A total of 203 people with diabetes participated in the study: 102 outpatients (A) and 103 who were hospitalised at the time of the study (H). The average age of the participants was 46.6 ± 13.6 years old (18-65 years old). The analysis showed no statistically significant differences in socio-demographic data nor in disease situation between the groups. Table 1 provides an overview of the socio-demographic characteristics of the participants and Table 2 provides information on the clinical characteristics of the participants.

3.2 | Characteristics and comparison of selected dietary habits and assessment of the quality of diet amongst the study population.

The majority of the people with diabetes in the study confirmed the use of a low carbohydrate diet in relation to their disease (87.7%). Only 34.5% of respondents reported eating the recommended number of meals (5 or more per day), with women significantly more likely to report this ($\chi2=11.25$; $p=0.024$). In contrast, those aged 41-55 years ($\chi2=17.27$; $p=0.027$) and those who were working ($\chi2=19.53$; $p=0.001$) were statistically less likely to report eating this number of meals. Eating all meals at regular times was reported by 30.5% of respondents and eating only some meals was reported by half of respondents (50.7%). Irregular meal consumption was declared by 18.7% of the subjects. Statistically significantly more regular consumption of all meals was reported by subjects in group A ($\chi2=7.34$; $p=0.025$) and subjects over 55 years of age ($\chi2=13.37$; $p=0.010$). It was statistically less likely, however, to be reported by those in a relationship ($\chi2=9.88$; $p=0.007$) and those who were working ($\chi2=14.42$; $p=0.001$). Analysis of the frequency of snacking between meals showed that 34.5% of respondents snacked several times a day, 25.6% several times a week, 11.8% once a day, 6.9% once a week and 4.9% 1-3 times a month. Analysis of the types of snacks consumed showed that these were: vegetables (97.1%), fruit (75.9%), sweetened drinks and dairy desserts (85.3%), sweet snacks (78.2%), unsweetened dairy drinks and desserts (64.7%), salty snacks (58.2%) and nuts, almonds and seeds (48.8%). The analysis also showed that Group A respondents were less likely to consume fruit between meals on weekdays and more often chose unsweetened drinks and dairy desserts as well as salty snacks ($\chi2=19.24$; $p=0.007$). This was similar to the female respondents ($\chi2=15.03$; $p=0.036$). Furthermore, the higher the education level of the respondents, the less likely they were to report consuming nuts, almonds or seeds and the more likely they were to report consuming sweetened beverages and dairy desserts ($\chi2=26.51$; $p=0.022$). The results of the pHDI-10 and nHDI-14 indices with regard to the respondent's location at the time of the study are shown in Table 3. In addition to the respondent's location, the results of both indices were statistically significantly influenced by the respondents' level of education. Those with a higher level of education had a significantly higher healthy diet index ($p=0.011$) and a significantly lower unhealthy diet index ($p=0.044$) than those educated to a vocational level or below. It also appeared that the overall financial situation of the subjects influenced the pHDI-10 score ($p=0.018$). It was shown that those with an above-average financial situation had a higher healthy eating index. The variable that correlated significantly with the nHDI-14 score was

the number of minors in the household. Those living with two or more minors had a significantly higher unhealthy diet index (p=0.013) than those living with one minor.

3.3 | Prevalence of adverse reactions to medication and the relationship to the dietary habits of the subjects

The majority of respondents reported taking their anti-diabetic medication regularly (77.8%). 10.8% of respondents did not know how to answer this question and 11.4% admitted to taking their medication irregularly. Further details of anti-diabetic medication use are shown in Table 4. Analysis of the incidence of potential adverse drug reactions among the respondents showed that the majority of those treated with oral anti-diabetic medication had experienced adverse reactions (61.1%). These were statistically significantly more frequent in those aged 41-55 years than in the other age groups (p=0.048). The most common symptoms reported were taste disorders, abdominal pain, loss of appetite, nausea and diarrhoea. Less than half of oral medication users were unable to give a clear answer when asked if they thought their side effects were meal-related t (43.3%), around one in three thought they were not meal-related (37.8%), and 14.2% said that certain foods made their side effects worse. Half of the respondents had never been hospitalized because of an adverse reaction to oral medication (49.3%), and this was significantly more likely to be reported by those who said they always took their anti-diabetic medication regularly ($\chi2=18.39$; p=0.018). Meanwhile, 32.5% of the respondents confirmed having been hospitalized due to adverse drug reactions, while the remaining respondents could not remember whether such a situation had occurred (18.2%). Of the insulin-treated respondents, 40.9% said they had experienced adverse effects from taking insulin. Most often, they reported symptoms of hypoglycaemia, such as sweating, difficulty concentrating and anxiety, but local changes in the subcutaneous tissue at the injection sites, in the form of atrophy or hypertrophy were also described. Almost half (48.3%) did not associate the occurrence of the adverse reaction with meals, 33.3% could not say whether it was related to a meal they had eaten, and 9.2% of respondents said that too long a time between taking insulin and eating was associated with the adverse reaction. The relationship between the method of taking oral anti-diabetic medication and the occurrence of adverse events was also analysed in detail. The results showed that adverse events were statistically significantly more frequent in those who took their medication less often with still water, more often with coffee or with no liquids at all ($\chi2=16.21$; p=0. 023). These people were also less likely to deny an association between these adverse events and ingested foods ($\chi2=55.89$; p=0.001) and were less likely to report ‘never’ and more likely to report ‘rarely’ ($\chi2=11.85$; p=0.018) with order to the consumption of alcoholic beverages less than 2 hours before or after taking their medication. A statistically significant association between the severity of healthy or unhealthy dietary characteristics and the occurrence of adverse oral medication reactions was not confirmed. In the case of people taking insulin, it was shown that there was a statistically significant higher incidence of adverse effects in those who reported too long a time between eating and taking their medication and who chose the response ‘hard to say’ ($\chi2=38.94$; p=0.001). The study also confirmed that those who experienced adverse effects with the use of insulin were statistically significantly more likely to have a moderate intensity of unhealthy dietary characteristics (nHDI-14) and less likely to have a low intensity ($\chi2=4.49$; p=0.034) of unhealthy dietary characteristics.

4 | DISCUSSION

As recommended in diabetes guidelines, adopting a healthy diet is an important part of clinical management, especially in type 2 diabetes mellitus (T2D). A diet for sufferers of diabetes aims to balance carbohydrate and lipid metabolism, normalize blood pressure and achieve a healthy body weight. In addition, it should also focus attention on the individual’s dietary and cultural preferences, age, gender, level of physical activity, economic status and, importantly, maintain their pleasure in eating. [18] There is no one-size-fits-all diet for all

people with diabetes. Different dietary strategies can be used in the management of diabetes, such as a low carbohydrate diet, the Mediterranean diet, the DASH approach or the low GI diet. [17,19,20,21] In our study, as in the study by Kołpa, et al. [22], the vast majority of subjects confirmed the use of a low carbohydrate diet, but it should be remembered that carbohydrate intake is one of the primary drivers of optimal glycaemic control. However, closer examination of the information provided by the study participants revealed quite poor adherence to dietary patterns. One of the main principles of a healthy diet to help maintain glycemic control is to eat an adequate number of meals per day, preferably 4-5 (for those patients treated with oral anti-diabetic medication) or 5 or more (for those treated with insulin). In addition, the timing of these meals is important. [22]. Our own study found that the majority of respondents (62%) eat 3-4 meals per day, and only 34.5% eat 5 or more meals per day. Only 30.5% reported eating all their meals regularly. Other respondents admit that they only occasionally follow these recommendations or even admit that their meals are completely irregular, especially those aged 41-55, who are working and in relationships. The results of the study by Górska-Ciebiada, et al. [23] are also partly consistent in this respect. When analysing the diet quality of the subjects in the present study, it was found to be characterised by a low pHDI-10, especially for patients in group H. A better financial situation and a higher level of education level were also found to be important factors for the more frequent use of a diet with health-promoting characteristics. These study findings are consistent with literature. [23,24,25] The poor financial situation of people with diabetes, which may be a result of high expenditure on medication, is an important barrier to adherence to a healthy diet, as it forces them to buy cheaper and, therefore, often less healthy products. Moreover, a higher education may contribute to better health literacy skills, meaning a better decision-making ability for adhering to dietary rules and other self-care behaviours. Adherence to a healthy dietary pattern, is a strong predictor for sustained future metabolic control, hence it is important to educate people with diabetes in this area. [17,25,26]

Food intake can, in some situations, affect the efficacy of diabetes medication, either by making its effects stronger, weaker or causing a variety of adverse effects. In this study, the majority of people confirmed the occurrence of a variety of adverse symptoms that they thought were related to the use of oral medications (61.1%), while 40.9% were related to the use of insulin. Almost half of respondents had been hospitalised because of these symptoms (49.3%). The literature reports that among the many elements of self-care in diabetes, adherence to medication is relatively high. [25,26,27] However, the effectiveness of therapy can be affected by various dietary behaviours, and people with diabetes may not even be aware of these potential negative effects. About 40% of respondents said that the side effects were definitely not related to food, or that it was difficult for them to say. It is now known, for example, that the liquids used to take medication can have a variety of effects on its efficacy. Water is the safest liquid to take with any preparation, whereas taking medication with tea, coffee or juices, especially grapefruit juice, will interfere with drug absorption and metabolism. It has been reported in the literature that an interaction between medication and grapefruit juice occurs when 250 ml of the liquid has been drunk. [11,15] Based on the results of the present study, it can be concluded that people who experienced adverse effects were significantly more likely to report drinking coffee with their medication or drinking nothing at all, and were more likely to be unaware of the relationship between adverse events and food intake. [5,6,8] Another factor that may interfere with the proper action of anti-diabetic medication is the timing of their use or their combination with stimulants. In particular, a number of medical publications have drawn attention to the worrying phenomenon of not taking a break between alcohol consumption and medication. The present study showed that people with adverse effects reported that they may well have consumed alcoholic beverages less than 2 hours before or after taking their medication. Patients do not know or forget that alcohol is

metabolised in the body simultaneously with medication. A single dose of alcohol has a significant effect on inhibiting the metabolism of drugs, whereas alcohol abuse stimulates the enzyme system, accelerates metabolism and, as a result, eliminates the drug. In the case of diabetes, it has been confirmed that alcohol consumed with anti-diabetic medication, especially oral sulfonylureas, negatively affects glycaemic control and can even lead to its loss. Alcohol also has the potential to cause hypoglycaemia, and, moreover, where hypoglycaemia already exists, alcohol may be aggravate it. Flushing, sensations of warmth, dizziness, nausea and tachycardia may be experienced. [12,28] Other factors that can affect the efficacy of anti-diabetic medication are the timing and regularity of its use. Experts state that oral anti-diabetic medication should be taken before a meal (about 30 minutes before), during a meal, or shortly after a meal, however medication of this type should also be taken with regularity. [13,25] Analysis of the results of this study showed that, among patients taking oral anti-diabetic medication, regular use was associated with a lower incidence of side effects and the need for hospitalisation, whereas, in patients treated with insulin, the occurrence of adverse events and hospitalisation for these reasons correlated significantly with too long a time elapsing between taking the medication and eating a meal.

4.1 | Limitations of the study

The obtained retrospective data may be biased since the information regarding self-care strategies might be misremembered, possibly resulting in an over- or underestimation of dietary patterns. Although recall biases cannot be avoided we followed the recommendations of the KomPAN authors regarding the verification of the compliance in the answers given by the respondents. Lack of compliance resulted in the respondent being removed from the data set. Thus we minimised recall bias. Another limitation lies in the way the study sample was collected and in the relatively small sample size, what could hinder the generalization of the results. Notwithstanding the above, we believe that this study offers a valuable insight into the analysed research problem. The third limitation of the study is related to the fact that other parts of the questionnaire (C and D), which could provide a comprehensive view of the research problem have not been discussed in this article. However, it was decided that for a clear overview it would be better to present a fragment of the data, as the extensiveness of the survey could obscure clarity. The remainder of the data will be presented in subsequent articles.

5 | CONCLUSIONS

Adherence to therapeutic recommendations, including regular use of medication and adherence to dietary recommendations, helps to avoid the occurrence of adverse and often dangerous drug-food interactions. In order to adhere to self-care attributes in this area people with diabetes, especially those who are less well-educated, financially disadvantaged, aged 41-55 years and working should be educated and motivated from the very onset of their illness. Health professionals should be proactive in giving adequate counselling about dietary recommendations.

TABLE 1. Socio-demographic characteristics of the study population (N=203)

Characteristic	Total n (%)
Sex	
Women	104 (51.2)
Men	99 (48.8)
Education	
Basic level	9 (4.4)
Vocational level	38 (18.7)
Higher basic level	101 (49.8)
University level	55 (27.1)
Marital status	
Married/with a partner	145 (71.4)
Single	58 (28.6)
Place of residence	
Country	103 (50.7)
Town	100 (49.3)
Professional activity	
Currently working	127 (62.6)
Not currently working	76 (37.4)
Overall financial situation	
< Average income	10(4.9)
Average income	148(72.9)
> Average income	45(22.2)
Household financial position	
Very poor	0(-)
Modest	15(7.4)
Average	74(36.5)
Good	100(49.3)
Very good	14(6.8)
No. of people in household	
One - two	68(33.5)
Three - four	83(40.8)
Five or more	52(25.7)
No. of minors in the household	
None	106(52.2)
One	44(21.7)
Two or more	53(26.1)

Notes: N: Number of respondents; n: group size

TABLE 2. Clinical characteristic of the study population (N=203)

Variables	**Total**	
	n (%) or M ±SD	**Range**
Type of diabetes		
T1D	60 (29.6)	
T2D	130 (64.0)	
Don't know	13 (6.4)	
Diabetes duration [Years]	10.1 ±9.5	0.6-58
Taking oral hypoglycaemic drugs [Yes]	123 (61.2)	
Taking insulin [Yes]	91 (45.3)	
Self-assessment of health status		
Worse than peers	45 (22.2)	
Same as peers	133 (65.5)	
Better than peers	25 (12.3)	

Notes: T1D: Type 1 diabetes mellitus; T2D: Type 2 diabetes mellitus

TABLE 3. Analysis of pHDI-10 i nHDI-14 results by the place of the study

Ressondents	**Dietary Index**					
	pHDI-10			**nHDI-14**		
	M±SD	Min-Max	p*	M±SD	Min-Max	p*
Group A (N=102)	23.70±8.22	5-46		11.10±8.56	0-45	
Group H (N=101)	21.39±9.00	4-41	**0.047**	18.93±9.60	1-44	**< 0,001**
Total (N=203)	22.55±8.67	4-46		15.00±9.88	0-45	

Notes: N: number of respondents; M: arithmetic mean; SD: standard deviation; Min: minimum; Max: maximum; Me: median; p*: significant statistical level; * U Mann's-Whitney test

TABLE 4. The way of taking anti-diabetic medication

Variables	Total n (%)
How do you take your anti-diabetic medication? (N=123)	
Swallow it whole	105(85.4)
Bite it	10(8.1)
Chew it	0(-)
Crumble it	6(4.9)
Difficult to say	2(1.6)
When do you take your oral anti-diabetic medication in relation to meals? (N=123)	
More than one hour before a meal	
Less than one hour before a meal	6(4.9)
During a meal	27(22.0)
Less than one hour after a meal	54(43.9)
More than one hour after a meal	29(23.6)
Not connected to a meal	1(0.8)
Difficult to say	5(4.1)
	4(3.3)
With what drink do you usually take your anti-diabetic medication? (N=123)	
Still water	58(47.2)
Sparkling water	19(15.4)
Coffee	5(4.1)
Tea	25(20.3)
Milk or a dairy product	1(0.8)
Fruit juice	0(-)
Grapefruit juice	1(0.8)
Carbonated drink	2(1.6)
Alcohol	0(-)
Something else	0(-)
I don’t take the medication with a drink	15(12.2)
When do you take insulin in relation to meals? (N=91)	
More than one hour before a meal	4(4.4)
Less than one hour before a meal	30(33.0)
During a meal	28(30.8)
Less than one hour after a meal	11(12.1)
More than one hour after a meal	1(1.1)
Not connected to a meal	11(12.1)
Difficult to say	8(8.8)
How often do you drink alcohol less than 2 hours before or after taking medication?(N=126)	
Never	
Rarely	80
Difficult to say	25
Often	18
Always	2
	1

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