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ARE DIETARY SUPPLEMENTS DANGEROUS? ASSESSING HOW SOCIETY PERCEIVES THE USAGE OF DIETARY SUPPLEMENTS – RESULTS OF THE PRELIMINARY ANALYSIS OF NATIONWIDE SURVEY DATA

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A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Dietary supplements (DSs) are concentrated sources of nutrients and/or other substances, whose purpose is to supplement the normal diet. Their consumption in Poland has been on the rise, leading to numerous concerns. However, current legislation does not provide any background for a relevant pharmacovigilance system. Therefore, little is known about their adverse effects (AEs) or patterns of use in Poland. To shed some light on this, we conducted a nationwide survey.

Aim of the study: To assess the prevalence of, and the reasons for, the use of dietary supplements in Poland via national survey with a collection and an analyse of supposed adverse effects of dietary supplements.

Material and methods: The study was conducted using an online survey based on the original questionnaire. In this report, we present the results of the analysis of the first 200 responses.

Results: As many as 55.5% (111) of respondents were 'definitely sure' or 'rather sure' about DSs safety. However, 70.5% (141) believed that they could have negative effects. Over 3/4 (153) of respondents used DSs themselves, and 61.0% (122) used them within last 12 months. Of those using DSs, 11.1% (17) reported diverse AEs, with GI tract irritation and mental disturbances being the most common (experienced by 35.3% (6), and 17.6% (3) of those reporting AEs, respectively).

Conclusions: Respondents had mixed feelings about DS safety. Despite that, they used these products frequently. Of a note is high incidence of adverse effects experienced by DS users. This undoubtedly points to the need for a relevant pharmacovigilance system.

KEYWORDS: dietary supplements, safety, adverse effects

Background

According to the European Food Safety Authority, dietary supplements (DSs) are concentrated sources of nutrients or other substances with a nutritional or physiological effect, whose purpose is to supplement the normal diet (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their constituents [1].

Many people seem to believe that a special diet based on the intake of certain nutrients may increase their overall capacity to perform diverse activities [2]. Indeed, many studies have reported that continued usage of supplements on a daily basis is beneficial for primary and secondary prevention of some diseases and improves quality of life [3,4]. The use of dietary supplements varies by age, sex, and race/ethnicity. Use is also

common in patients with chronic or recurrent illnesses, who also receive care from health professionals [5,6].

Despite the overwhelming use of dietary supplements across different populations, an overall pattern of negative effects related to their use has not been well-studied [7]. Moreover, because there are no trustworthy sources of information on the use and real safety of dietary supplements, the general population may share unrealistic beliefs about the impact of those supplements on physical and mental performance, and overall health [8].

At present, the popularity of dietary supplements across different social groups are on the rise in Poland. People increasingly want to buy "a pill for everything," often without contact and consultation with their doctor. Many ads on TV, in newspapers, and on the Internet encourage them to buy these products. Analyses of the International Euromonitor have demonstrated a rising consumption of vitamins and dietary supplements in Poland, driven mainly by health and wellness, convenience, and increasingly hectic lifestyles [9]. In many cases, DSs are too often used beyond objective indications, without objective need.

Unfortunately, current legislation does not establish nor support any effective system of dietary supplement pharmacovigilance. Thus, the true prevalence of adverse effects related to the use of dietary supplements in Poland is completely unknown.

Aim of the study

The aim of this study was to assess the prevalence of, and the reasons for, the use of dietary supplements in Poland via national survey. We especially wanted to collect and analyse information of supposed adverse effects of dietary supplements. As the study is still ongoing, in this paper we present the results of the analysis of the first 200 responses.

Material and methods

Based on the literature review and the experience of the members of the project team, the first draft of the survey questionnaire was designed. The major dimensions we wanted to assess with the questionnaire were: the level of knowledge users possessed about dietary supplements, reasons for taking dietary supplements by different user groups, details on the practice of dietary supplement use, and experience with adverse effects of dietary supplements.

To allow for content validation, feedback of the study group was analysed, and relevant changes to the draft were introduced. The second, modified version of the questionnaire was drafted, and was made available online on the surveying platform. This version was piloted in about 20 volunteers (not involved in the questionnaire preparation) to prove its readability and further fine-tune the tool. Volunteers of different age/gender were invited to the pilot through direct contacts. Their feedback was analysed and the final version of the survey tool was prepared accordingly. It contained approximately 30 questions (mainly closed-ended), including questions related to respondents' demographics.

This version of the questionnaire was used in the final study. A nationwide online survey was opened on the SurveyMonkey platform on June 9th, 2017, and the invitations were sent to the open public by different channels. The survey will be continued until we obtain the target number of 1,000 responses.

Data collected so far from the first 200 respondents has been analysed and presented in a form of descriptive statistics.

Results

Among 200 respondents whose responses we have analysed in this publication, more than half (54.5% – 109) constitute women. The average age of respondents was 26.8 ± 7.5 years. Similar percentages of respondents had secondary and higher education (41.0% (82) and 42.5% (85), respectively); over a half of them (51.0% – 102) lived in cities with populations of over 100,000.

Respondents expressed mixed feelings regarding DS safety. On one hand, 55.5% (111) of them were 'definitely sure' or 'rather sure' about DSs safety (fig. 1).

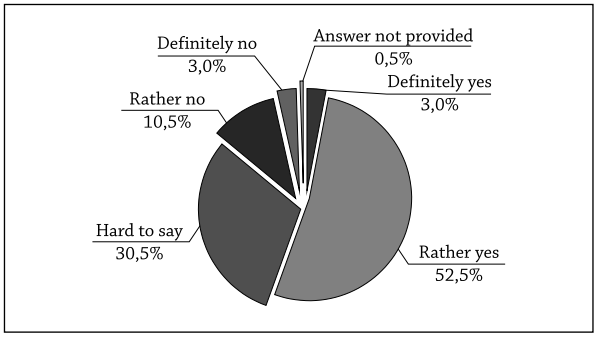

Figure 1. Respondents' beliefs regarding dietary supplement safety (answers to the question 'Are the dietary supplements safe?' n=200).

At the same time, in most cases they knew that DSs were not undergoing any safety tests prior to entering the market (as many as 51.0% (102) of respondents answered 'rather not' or 'definitely not' to the question asking whether DSs undergo any safety testing prior to launch at the market). Moreover, as many as 70.5% (141) of them believed that they could have negative effects.

Despite these mixed feelings, over 3/4 of respondents (76.5% – 153) used DSs themselves, and 61.0% (122) used them within last 12 months. The types of DSs used most often were those containing vitamins and minerals, non-saturated fatty acids, and probiotic bacteria, being used by 65.5% (131), 31.5% (63), and 28.0% (56) of respondents, respectively.

As far as the main reasons for DS usage, most of the respondents claimed it was an easier way to replenish nutritional deficiencies compared to diet change,

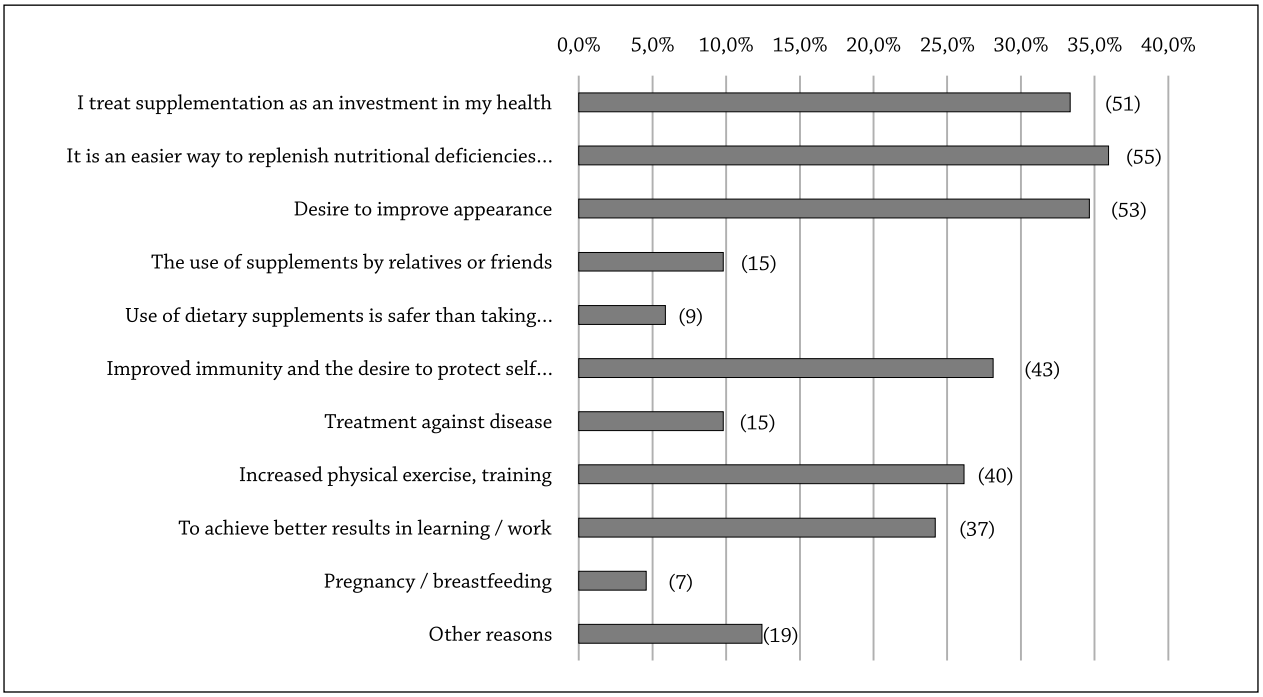

Figure 2. Main reasons why respondents used DS. (Respondents could provide multiple answers; percentages are calculated for those respondents who admit to using dietary supplements; n=153).

desire to improve one's appearance, or treated supplementation as an investment in one's health (35.9% – 55, 34.6% – 53 and 33.3% – 51 respectively). Nearly 1/4 of them took dietary supplements due to increased physical exercise/training (26.1% – 40) or to achieve better results in learning or at work (24.2% – 37). For details of the answers see fig. 2.

Of those using DSs, 11.1% (17) reported diverse AEs, with GI tract irritation and mental disturbances being the most common (experienced by 35.3% (6), and 17.6% (3) of those reporting AEs, respectively, see fig. 3).

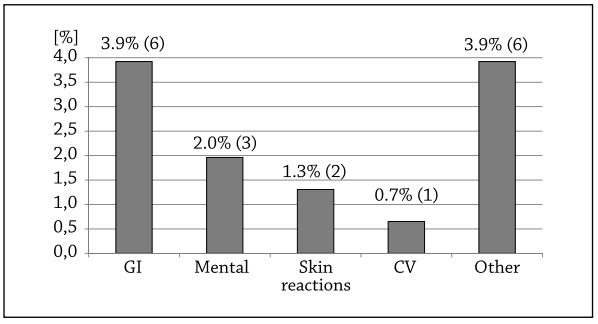

Figure 3. Adverse effects of dietary supplements reported by their users, by classes (Respondents could provide multiple answers; percentages are calculated for those respondents who admit to using dietary supplements; n=153). Legend: GI – gastro-intestinal tract disturbances, Mental – mental problems/disturbances, CV – cardiovascular problems

Discussion

Currently, in Polish legislation, there is a gap which enables nearly unlimited marketing of dietary supplements. This may create a false image of remedies that are very effective, and completely free of any adverse effects. Consequently, the sale of the DSs is rising every year. According to the estimates from the Supreme Chamber of Control (NIK), the dietary supplement market in Poland will reach 4 billion PLN in 2017. This market continues to grow even though, at present, dietary supplements are remedies of uncertain quality [13]. As reported most recently by the Guardian [14] and NIK [15], they may even contain illegal ingredients and thus could be dangerous for one's health.

Being aware that dietary supplements are not tested for their safety before introduction to the market, and could be even dangerous, well-educated respondents to our survey were still generally happy to use them.

Undoubtedly, an excessive consumption of dietary supplements is not effect-neutral to their users. It can lead to the substance accumulating within the body with possible negative health consequences [10].

Several studies performed so far have shown different levels of knowledge of lay people when it comes to dietary supplements – especially on the legal aspects of their introduction to the market [11]. In Poland, this knowledge is particularly low [12]. Most users are not aware of what the dietary supplements are, or what they contain. This could create conditions for DS overuse, with a wide variety of consequences. Often, customers are also happy to take more than one supplement at the same time, exposing them to interactions between supplements. Another important interaction risk comes with the use of dietary supplements in tandem with their over-the-counter (OTC) medications and/or prescription medications.

A recent report by the Supreme Audit Office (*Najwyższa Izba Kontroli*) revealed that the control of dietary supplements in Poland was lacking at all steps

prior to reaching the market. First, to introduce a new DS to the market, the manufacturer is only required to notify the General Sanitary Inspectorate, and without further testing a product can be advertised and sold in the stores. Moreover, advertisements of the dietary supplements were often misleading, thus making it impossible to properly assess whether a product was in fact an OTC drug or a DS. Further points were made on the quality control of DSs. The General Sanitary Inspectorate had insufficient control on dietary supplements which, for example, allowed products containing hazardous health ingredients such as *E. faecium* or psychoactive substances (e.g. amphetamine-like) to be introduced to the market [13].

The pathway that dietary supplements currently follow when being introduced to the Polish market is very similar to introduction in the United States. Manufacturing of dietary supplements is regulated by the Dietary Supplement Health and Education Act of 1994 and companies are required to produce them in a quality manner without contaminants or impurities, according to Good Manufacturing Practice and labelling regulations. On the other hand, the Food and Drug Administration (FDA) must be notified if the DS contains a new ingredient or if adverse events occur [16–18].

Conclusions

Our study shares all the limitations typical of online surveys. Still, it is a comprehensive response to the growing trend of dietary supplement consumption in Polish society, examining the level of general knowledge about dietary supplements, as well as the prevalence and reasons for their use. The major strength of this study rests on this: for the first time, using a structured survey, we demonstrated the presence of adverse effects related to dietary supplements, and we showed the extent of those effects in Polish consumers. This may allow for expanded research over the use of dietary supplements in Poland. Moreover, this could trigger changes in national legislation, and support the creation of functional pharmacovigilance system.

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