

PLANT-BASED FOOD SUPPLEMENTS: HOW DO PHYSICIANS PERCEIVE THEM?

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ABSTRACT

There is an increased interest and growing use of plant-based food supplements (PBFS) among patients. In most cases, this occurs without recommendation from doctors and without doctors' knowledge. Very often PBFS are co-administered with drugs that put users at risk of adverse interactions and places professional responsibility upon doctors to establish and consult the use of PBFS.

AIM. To investigate physicians' professional opinion(s) about PBFS.

MATERIAL AND METHODS. A survey questionnaire, specifically designed for the purposes of the study, was directly administered to 108 primary care physicians. The questionnaire included a section with a 5-point Likert-type scale which established consent with 5 statements clarifying physicians' perceptions about PBFS.

RESULTS. Conviction that PBFS may have positive effect on health are found in more than half of respondents (72.2%). 62.8% of respondents perceive the natural origin of PBFS as a guarantee of their safety. An equal/identical percentage of participants (62, 9%) are aware of the possibility for interactions between PBFS and concomitantly administered drugs. The opinion that the health claims of PBFS are not always proven is shared by 66.8 % of respondents and the need for more stringent regulatory measures is supported by 73.4 %.

CONCLUSION. Physicians generally have positive attitudes towards PBFS. They realize the potential risks associated with their use and the need for more stringent regulatory requirements for these products.

Keywords: *dietary supplements, attitude, perception, doctors*

INTRODUCTION

Over the past few decades, there has been a general rise in interest toward and use of food supplements (FS). (6, 12). Plant-based food supplements (PBFS) are some of the most commonly used FS among patients in both Europe and US. (15, 25, 30) The popular misconception that PBFS, as natural products, are useful and harmless, is the main reason why patients self-medicate without informing physicians about their use. (5, 7, 8, 26) But "safe" and "natural" are not synonymous. PBFS contain multiple biologically active substances, with still uncharacterized pharmacological activity, and their use, as well as drugs, can lead to various adverse reactions (ARs). (19, 28, 29). Frequent and concomitant use of PBFS with prescription and non-prescription drugs creates opportunity for herb-drug interactions, some of which could be dangerous. (16). These potential risks place professional responsibility upon physicians to communicate with their patients in order to establish and consult proper use of PBFS. Studies have shown that physicians do not routinely ask patients if they are taking PBFS. (1, 11) Key factors that influence their willingness to discuss this topic with patients is their perception, attitude and knowledge regarding PBFS. Doctor-patient communication will contribute to the right integration of PBFS in treatment regimens and will thus reduce risks, associated with their use. Scientists' attention has long been drawn to the significance of the problem and a number of studies have clarified physicians' level of acceptance and knowledge about this specific product category. (1, 10, 11, 18) To our knowledge, such studies have not been conducted in Bulgaria. The results that we publish are part of a broader study aimed to establish physicians' perception, practice, and awareness about PBFS.

METHODS

This study was conducted in Stara Zagora city, during June-September 2014.

For the purposes of the study PBFS were defined as "nutritional supplements designed to

supplement the normal diet, derived from natural plants and represent a concentrated source of herbal ingredients with nutritional and physiological effect, alone or in combination with vitamins, minerals or other substances with non-vegetable origin; available in dosage forms such as capsules, tablets, lozenges, sachets of powder, ampoules and vials with liquid, and other similar liquid or powder form designed to be administered in a pre-dosed small quantities "

SAMPLE

We restricted the study only to physicians performing outpatient care in Stara Zagora – general practitioners and specialists. Participants were chosen using convenience sample on the basis of convenience of access to them. A total of 120 physicians were visited in the offices of their outpatient practices and they were asked to participate in the study by answering the questions in the questionnaire. Of these, 12 refused to participate in the study, citing lack of time. Respondents were guaranteed confidentiality.

STUDY QUESTIONNAIRE

Primary data were collected using a self-administered questionnaire, specifically designed for the purposes of the study. The questionnaire included four sections - three sections for establishing physicians' perception, practice and knowledge on PBFS and one to clarify the demographic (sex, age) and professional characteristics (years of medical practice, specialty) of participants. The questions were formulated after a comprehensive review of the medical literature. (10, 11) The questionnaire was pre-tested in a pilot study on 23 physicians and updated with the offered recommendations. Here we analyze only the answers in a section one, where we clarified physicians' perception about PBFS through a five point Likert - scale for establishing degree of agreement with five statements: "PBFS are beneficial in health care management", "Health claims on PBFS are not always proven", "PBFS are safe due to their natural origin", "PBFS can interact with prescribed drugs", "The government should take more stringent regulatory measures for FS and in particular PBFS". Respondents were asked to determine their level of agreement with a given statements. To express their opinion participants could choose between 5 options: "strongly agree" rather agree ", "neutral", "rather disagree", "strongly disagree". To simplify the presentation of results, we grouped the responses into 3 groups: "agree", "disagree" and "neutral". The group „agree" consists of the sum of respondents "strongly agree" and "rather agree". The group "disagree" consists of the sum of respondents "strongly disagree" and "disagree" To quantify the responses, we adopted a method developed by Lujain Anwar Alkhazrajy, according to which any statement can obtain from 1 to 5 points: 5 points for "strongly agree", 4 for "rather agree", 3 for "neutral", 2 for "rather disagree" and 1 point for "strongly disagree." (1) Thus, the maximum score for each participant is 25 and the minimum 5. We considered that a score from 0 - 10 indicated a negative perception, score from 11 - 15 indicated a neutral perception, and score from 16 - 25 indicated a positive perception.

STATISTICAL ANALYSIS

Frequencies (numbers, percentages), means and standard deviation (SD) for variables were evaluated.

The data was analyzed using the Statistical Program for Social sciences (SPSS), Version 19.0.

RESULTS

From a total 108 participants, approximately two thirds were women (64.8%). Almost half of the respondents were at the age of 50 years. Most participants had between 11 and 30 years of professional experience. General practitioners were the largest group of respondents (42.6%). The demographic and professional characteristics of respondents are given in Table 1.

Demographics	Total № (%)
N	108
Gender	
Male	38 (35.2)
Female	70 (64.8)
Age	
≤ 40	6 (5.6)
41-50	47 (43.5)
51-60	44 (40.7)
≥ 60	11 (10.2)
Years of medical practice	
≤ 5	1 (0.9)
5-10	1 (0.9)
11-20	43 (39.8)
21-30	49 (45.4)
≥ 30	14 (13.0)
Speciality	
General practioner	46 (42.59)
Internist	34 (31.48)
Other	28 (25.93)

Table.1. Demographic and professional characteristics of respondents.

Maximum score for each statement was five. None of the statements did not receive maximum score equal to 5. Likert scale means between 3.61 and 4.31 were evaluated for the level of agreement with different statements.

Of the five proposed statement "PBFS are beneficial in healthcare management" received the second highest level of support from participants. **(Likert scale mean 4.00, SD ± 0.986)** Most of the respondents believed that PBFS are beneficial in health care **(72.3%)**. "Strongly agree" were 38% (n= 41) of participants and 34,3% (n=37) identified themselves as "rather agree" with this statement. Disagreement with this statement is found in 7.5% (n = 8) - 1.9 % of the participants were "strongly disagree" and 5.6 % were "rather disagree". "Neutral" was the preferred identification in 20.4% (n = 22) of respondents.

Statement	Strongly agree (%)n	Rathe agree (%)n	Neutral (%)n	Rather disagree (%)n	Strongly disagree (%)n
PBFS are beneficial in healthcare management	38.0% (n=41)	34.3% (n=37)	20.4% (n=22)	5.6% (n=6)	1.9% (n=2)
Health claims on PBFS are not always proven .	34.7% (n=37)	31.5% (n=34)	24.1% (n=26)	8.3% (n=9)	1.9% (n=2)
PBFS are safe because of its natural origin	25.0% (n=27)	35.2% (n=38)	15.7% (n=17)	24.1% (n=26)	
PBFS may interact with drugs	34.3% (n=37)	27.8% (n=30)	21.3% (n=23)	12.0% (n=13)	4.6% (n=5)

The government should take more stringent regulatory measures for FS and in particular PBFS	59.3% (n=64)	24.1% (n=26)	9.3% (n=10)	3,7% (n=4)	3,7% (n=4)
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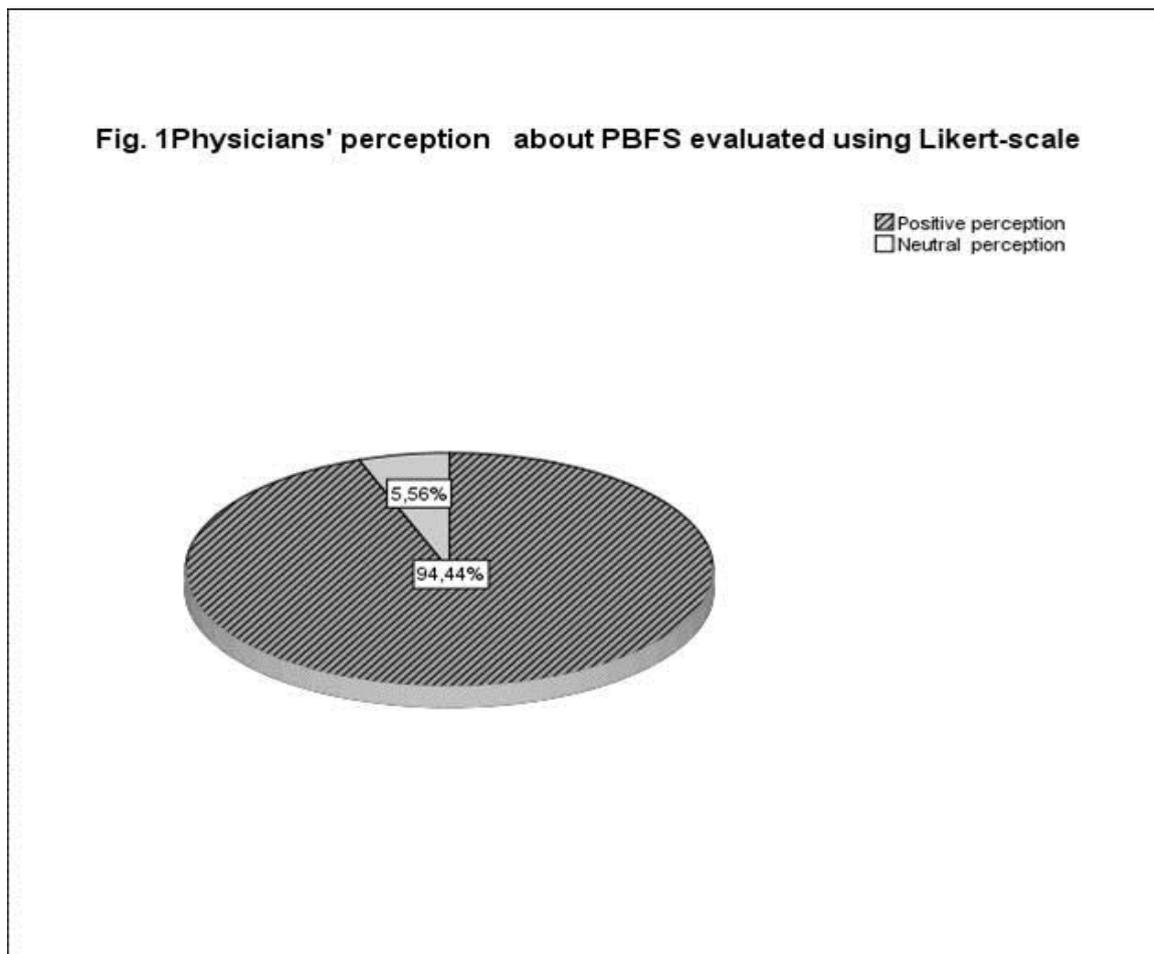
Table 2 Perception regarding PBFS among surveyed physicians

Slightly lower level of agreement we found for statement “Health claims on PBFS are not always proven“(Likert scale mean **3.86, SD ± 1. 018**). More than half of participants (66.2%) supported this statement. "Strongly disagree" with this statement was the response of only 1.9% (n = 2), and 8.3% (n=9) answered with “rather disagree”.

Agreement with the statement "PBFS are safe because of its natural origin" were established at 60.2% of respondents – 25.0 % (n = 27) were “strongly agree” and 35.2% (n = 38) were identified themselves as a "rather agree " with the above statement. “Rather disagree” with this statement were 24.1% (n=26), and not a single participant "strongly disagree" with it. In 15.7% (n=17) of respondents, there was a lack of opinion on the safety of PBFS. (Likert scale mean **3.61, SD ± 1.118**)

Support for the statement "PBFS may interact with drugs" was at 62.1% (n = 67), while those who disagreed with it were 16.6 % (n=18), and 21.3 % (n=23) had no opinion. (Likert scale mean **3.79, SD ±1.192**)

Agreement with the need for more stringent regulatory measures to FS, and especially PBFS, was found in 83.4% (n= 90) of respondents. Only a minority of participants (7.4%, n= 8) did not consider it necessary to improve regulatory control over these products.



According to the adopted methodology for comprehensive evaluation of physicians' perception regarding PBFS, 94, 4% of respondents were between 16 - 25 points, which we interpreted as positive acceptance of PBFS. The rest were between 11-15 points which correspond to neutral opinion. (Fig.1.)

We did not find statistically significant differences in the perception of PBFS in different groups by gender, age and professional characteristics of respondents.

DISCUSSION

Since physicians' perception, practice, and awareness for these products have not been the subject of another study in Bulgaria, the present study should be seen as a pilot one.

Our findings, namely the high rate of conviction in the positive health effect of PBFS, are similar to results from other studies, though comparisons, for various reasons, are difficult. (9,10). In a study of Ghia Canna J and Jha Rajesh K 85% of respondents perceive PBFS as useful in health care for patients and in the study of Clement YN, Williams AF, Khan K, et al. such perception had 60.4% of the participants. (9, 10) At this stage of our work, we cannot comment on the reasons for this conviction among our respondents. It is possible that it rests on the centuries-old empirical experience of humanity with the use of plants with medicinal purposes and that it is not related to physicians' level of knowledge of PBFS (20). Most doctors during their academic education do not acquire knowledge in this area and it is no surprise that there seems to be a gap between perception and knowledge of PBFS (10). Several studies indicate that physicians are aware of lack of knowledge and expressed willingness for further training in this area. (10, 11) Although limited

number of available evidence for the effectiveness of many PBFS, growing number of reputable resources that support the efficacy of these products. Physicians should use them and increase your awareness. This will improve their confidence and interactions with patients about PBFS and bridge the current gap. (2, 17)

Over half of our respondents believe that it is possible that health and other claims on FS labels do not rest on scientific evidence. Because these statements strongly influence consumer choice, if they are vague and misleading, they can get consumers to make the wrong decision. (18) Undoubtedly, the personal responsibility of consumers for their own health, requires that they be carefully informed about receiving FS. On the other hand the professional responsibility of doctors for patients' health requires that they be aware of the regulations and help patients to make informed choices. Regulation (EU) № 432/2012 of 16 May 2012 contain a list of permitted health claims for disclosure based on generally accepted scientific evidence. (23)

Most people have the wrong opinion that PBFS are completely safe because of their natural origin. (5, 7, 8, 12, 26) In comparison with conventional drugs, most PBFS indeed have a wide margin of safety, but the presence of biologically active ingredients, as in synthetic drugs, may cause various ARs. (13, 19, 22, 28, 29). ARs may be due both to the nature of herbs and to other factors, such as misuse of products, physiological and pathological features of the body (sex, age, genetic terrain, concomitant diseases and therapies), poor quality of products. No small part of ARs also can be due to the interaction of PBFS with concomitantly used other FS or drugs. In The Natural Medicines Comprehensive Database a huge number of possible adverse interactions between natural products and conventional drugs are described. (27) Although most documented interactions have no serious consequences, it is not a rule. (21) In our study 62,1% of respondents were aware of the possibility of interactions between PBFS and drugs, and 60.2% found PBFS safe. This underestimation of the risks associated with interaction between PBFS and conventional medicines we interpret as an indirect confirmation of the established in other studies lack sufficient knowledge of PBFS, especially related to the herb-drug interaction. (11, 14)

A small number of patients, and even some physicians, are aware that FS are regulated differently from drugs and this causes a false sense of security regarding their efficacy and safety. (3, 4) Legislative frameworks that regulate the production and marketing of FS are different in different countries, but overall, the production of these products are not subject to the same stringent requirements as that of drugs. Classifying them as a specific category allows manufacturers to market the products without the obligation to submit evidence of efficacy and safety to the regulatory authorities. The lack of preclinical studies leads to a lack of pharmacokinetic and pharmacodynamic data, information on adverse effects, interactions and contraindications. (12) In our study, we did not include specific questions to assess familiarity with current legislation pertaining to FS / PBFS, but indirect information is contained in the high level of agreement with the claim „The government should take more stringent regulatory measures for FS and in particular PBFS ”. Obviously, a significant proportion of our respondents are aware that weaknesses in the regulation create the possibility of adulteration, substitution, contamination, which puts at risk the health of consumers. (24)

Despite the differences in the degree of agreement with various statements, as an overall result we recorded a positive perception of PBFS by the majority of participants. Future studies should establish a link between positive perception and practical behavior of physicians in terms of PBFS.

CONCLUSION

Our study showed that doctors have a positive perception about PBFS. They accept them as beneficial to health option, but consider that more stringent regulatory requirements are necessary to

ensure the quality of these products. There is some underestimation of the risks associated with interaction between PBFS and conventional medicines, which indicates the need for further training in this area.

The limited number of participants does not allow us to use the obtained results to draw generalizations applicable to the entire medical community. Future studies with a larger randomized sample needed.

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