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Risks of nutritional supplements consumption by pregnant women

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ABSTRACT

During pregnancy the demand for nutrients, energy, vitamins and minerals increases. The diet used during pregnancy and before conception should provide the best conditions for the development of young, but often it is insufficient to cover the demands for both a pregnant woman and the fetus. Therefore pregnant woman, in the case of nutritional deficiencies and inability to cover them as the part of the daily diet, is often obliged to supplement the nutrition that she and the baby need. Moreover, the deficit of the nutritional elements during this period may increase the risk of various types of disorders complicating the pregnancy and affecting the development and the health of the baby. The working scheme of medicines may be changed due to nutritional supplements through the increase of their excretion, decrease in their absorption and/or disruption of metabolism. Many adverse events can occur due to the simultaneous application of both nutrition supplements and medicinal products. Therefore, the decision of including a supplementary diet should be made very carefully and individually for every patient. The use of nutrition supplements for expectant mothers should always be consulted with a physician or a pharmacist.

Keywords: pregnant woman, nutritional supplements, interactions with drugs, vitamins, minerals, adverse events.

Introduction

The literature defines nutritional supplements as products being the source of concentrated nutrients and other components having a physiological effect on human body [1]. Their use may mitigate the risk of occurrence of certain diseases [2]. However, it should be stressed, that according to the Polish Law, nutritional supplements are not medicinal products but are treated as nutritional products [3, 4]. Currently, both in Polish and English literature, there is a lack of unambiguous guidelines on diet supplementation during the period of pre-conception, pregnancy, post-partum and lactation.

Nutritional supplements

Balanced vitamin and nutrient intake should be accompanied by a proper diet and/or use of multi-

tamin preparations. Following recommendations of the EU, each active component of a nutritional supplement should produce its expected effect, and the size of dose should exceed the minimum dose proven to be preventive and therapeutic. Additionally, the amount of vitamins and minerals constituting the nutritional supplement composition should be adjusted to the appropriate diet to minimize the risk of exceeding a safe dose [5]. Moreover, specialists emphasize that nutritional supplementation, in particular, during pregnancy, post-partum period, and lactation period should be controlled by a physician [6].

It should be emphasized that the lack of detailed regulations on the components contained in nutritional supplements other than vitamins or minerals causes both Polish and European market of the nutritional-supplements to be characterized by a very wide vari-

ety of its products. Based on the information included in the European Commission report [7], there are over 400 substances that can be used for the production of nutritional supplements. While, over a half of all nutritional supplements available on the EU nutritional markets are vitamins and minerals, both in the form of separate substances and vitamin complexes. The remaining nutritional supplements available on the EU market are classified into six categories [7]:

1. amino acids, e.g., L-arginine,
2. enzymes, e.g., lactase, papain,
3. prebiotics and probiotics, e.g., inulin, *Lactobacillus acidophilus*, *Bifidobacterium* species, yeasts,
4. essential fatty acids, e.g., gamma-linolenic acid, fish oil (DHA/EPA), linseed oil (*Linum usitatissimum*), borago seed oil (*Borago officinalis*),
5. plant compounds, e.g., aloe (*Aloe vera*), ginkgo (*Ginkgo biloba*), ginseng (*Panax ginseng*), garlic (*Allium sativum*), green tea extract (*Camellia sinensis*), *Garcinia cambogia* extract, guarana extract (*Paullinia cupana*),
6. other substances, such as lycopene, lutein, Q10 coenzyme, taurine, carnitine, inositol, chitosan, spirulina, soybean isoflavones.

Food supplements present on EU markets contain mostly plant raw materials traditionally originated from Europe. Pharmacopoeial raw materials are also contained in composition of nutritional supplements. However, the latter should be used in considerably lower doses than those specified for them as medicinal doses. Following manufacturer declarations of nutritional supplement, currently available preparations exhibit a wide range of effects on the whole organism and its individual systems and/or organs [8, 9]. The nutritional supplements available on the nutritional market have the capability to support the immune system; support the musculoskeletal system; delay the aging process; enhance skin, hair, and nails' appearance; support functioning of the organs of hearing and vision; support the process of weight loss; support the functioning of the cardiovascular system; support the functioning of the digestive system; support the functioning of the organisms during the period of greater physical effort [9].

Risks of nutritional supplement use

As mentioned earlier, nutritional supplements may exhibit nutritional and/or other physiological effect. Contrary to medicinal products, nutritional supplements do not exhibit metabolic effect. However, dif-

ferences in the classification of individual substances are observed, primarily due to the similar appearance of product packaging, wide distribution of nutritional supplement advertisements, and the fact that a potential consumer often has difficulties in distinguishing nutritional supplements from medicinal products (particularly those occurring in the form of tablets or capsules). Also the differences in nutritional supplement classification in individual EU member states and non-Community countries, as Norway or Switzerland, play significant role in this context. The lack of harmonization of the European Union law and law of the European countries that do not belong to the EU in reference to nutritional supplements creates a situation that in certain countries these products are admitted to the market circulation as nutritional supplements, while in others are admitted as medicinal products, thus being subjected to completely different regulations [9].

Following the regulations of the Act on the nutritional and nutrition safety of August 25, 2006 (Journal of Laws of 2006, No. 171, Item 1225 with subsequent amendments), labeling, presentation, and advertisement of nutritional supplements cannot contain information stating or suggesting to the potential buyer that a balanced and varied diet cannot provide enough nutrients for the normal functioning of the system. In addition, the cited Act indicated that labeling, presentations, and advertisements of nutritional supplement, similar to other nutritional products, cannot mislead the consumer and shall neither attribute a nutritional product, including nutritional supplement, the property of preventing or treating diseases, nor refer to such properties. The assumption referring to the avoidance of misleading consumers primarily refers to the characteristics of the nutritional product (nutritional supplement), including its name, type, properties, composition, shelf life, source, place of origin, and/or manufacture/production methods. All products covered by the Act on the nutritional and nutrition safety [12] should not mislead consumers by suggesting that a nutritional product, including nutritional supplements, exhibits effects or properties, which in reality it does not possess.

Oftentimes, the cause for irregular nutritional supplement or dermocosmetics usage was the incidence of different side effects resulting from their use by a pregnant woman. Nutritional supplements introduced to the market circulation may pose a risk for the health and even life of their consumers. These preparations often contribute to better implementation of

dietary recommendations. However, the use of nutritional supplements should relate to the existing risk of vitamin or mineral overdosing, which in turn may cause disclosure of negative side effects of their overdosing. Ensuring the safety of nutritional supplement use is a responsibility of their manufacturers. Nutritional supplement manufacturers are obliged to provide labels with information on the possible contraindications of their usage, possible interactions with other nutritional supplements or medicines for both sold on the basis of medical prescription and over-the-counter medicines, possible interactions with other nutritional components, and the possible need to consult the usage of specific nutritional supplements with a physician or dietician before its application [11].

Following the current state of knowledge, improper use of nutritional supplements, unjustified supplementation, consumption of higher nutritional supplement doses than those suggested by the manufacturer, lack of reliable information on labels of nutritional supplements, and concomitant application of a larger amount of supplements may be linked to the risk of adverse effects. The literature mentions the most common types of this kind of action: incidence of discolors and skin changes, color change of stool and/or urine, increased risk of lung cancer in smokers using higher than recommended beta-carotene supplementation, or intensification of antithrombotic effect with the concomitant use of vitamin E supplements and antithrombotic medicines [13].

In many cases, the vitamin and mineral supplementation may contribute to better or proper implementation of dietary recommendations. However, nutrition experts are warning that although nutritional supplements are treated in the Community law as nutritional products for particular nutritional uses, their usage can be linked to the incidence of certain side effects. There are reports indicating that the use of high dosages of certain nutritional supplements may be harmful to health. Therefore, an individual diet supplementation without the confirmation of the real health requirements of a person using nutritional supplements may pose a risk of exceeding the upper safe levels of their consumption [14].

Nutritional supplements may alter the effect of medicines used by the patient. The most common changes involve a decrease of the absorption of active substances contained in medicines. This assumption primarily refers to antibiotics, anti-tremor medicines, preparations used in the therapy of cardiovascular diseases, and numerous other medications.

The concomitant use of nutritional supplements and medicines may also contribute to the increase of drug excretion from the organism. In the case of both decreased absorption and increased excretion of medicines, a decrease of the amount of medications in the organism occurs, thus decreasing their therapeutic effect. In such a situation, the therapy proposed by the physician may not give the projected effects, bring effects at a later-than-assumed date, or cause postponed effects. A very important adverse effect resulting from the interaction between the co-application of medications and nutritional supplements is also the disturbance or change to the metabolism of the taken preparations [15].

Very common interactions between co-applied medications and nutritional supplements are interactions between plant and medicinal preparations. The existence of these interactions is primarily caused by the presence of active compounds such as flavonoids, furanocoumarins, alkaloids, terpenes, glycosides, anthocyanins, catechins, saponins, and anthraquinones. The mentioned compounds may interact with a certain medicinal substance, competing for the receptor-binding site. Such phenomena occur in the case of certain weight-loss-aiding products. Their effect is focused on the increase of intestinal peristalsis. This in turn may lead to a decrease of absorption of numerous medicines. Similar effect is exhibited by preparations containing mucus, in particular linseed, marshmallow, and narrow leaf plantain, reducing the availability of the used drug in the intestinal mucosa, thus weakening the intestinal absorption of these medicines. Interactions between medicines and nutritional supplement that contain plant components may also lead to the situation, where the plant components contained in nutritional supplements influence the metabolism of therapeutic substances. Such influence may cause a decrease or increase of the medicine's concentration in the blood of the patient, thus changing the efficiency of the conducted pharmacotherapy [10].

Another very common interaction type is interaction of medications used with nutritional supplements containing high amounts of vitamins. This results primarily from the widespread perception of nutritional supplements as being safe, accompanied by the lack of knowledge on the negative influence of too high vitamin supply or interaction between vitamins and certain medication groups [15]. Folic acid, constituting one of the most commonly used nutritional supplements intake by women planning to get pregnant and pregnant women, decreases phenytoin concentration

in the blood. This may contribute to the decreased efficacy of the medication, while phenytoin exhibits the capability of decreasing folic acid level in the blood serum. Thus, folate level examination every six months is recommended for the patients treated with phenytoin, and, if necessary, administering folic acid at higher doses is suggested [10, 16].

A variety of interactions with co-applied medications may also occur for numerous minerals. Mixing of nutritional supplements containing mineral preparations with antibiotics may contribute to the decrease of absorption of these medicines, and thus decrease their action and disclose possible complications resulting from uncured infection. Therefore, it is recommended to consult a physician or pharmacist about the possibility of using a certain nutritional supplement with medication [15].

One of preparation groups used by, i.e., pregnant women is nutritional supplement containing magnesium. It should be emphasized that the use of magnesium with other medications may have an adverse effect on their absorption or metabolism. The concomitant use of magnesium supplements and medications used in arterial hypertension treatment contributes to a decrease of the effect of medication via decrease of its bioavailability. Moreover, researchers demonstrated that the use of Mg considerably decreases Fe absorption, which may eventually lead to the development of anemia. In addition, Mg belongs to the group of substances decreasing absorption of antibacterial medications, decreasing the effect of antithrombotic, antifungal, antipsychotic, anti-anxiety medications, and cardiac glycosides that increase the strength of the contraction of heart muscle and decrease the contraction rate [17].

The concomitant intake of supplements containing Mg and medications dilating the bronchi or medications used in the Parkinson's disease leads to the increased effect of these medications, which may cause the occurrence of adverse symptoms in the patient, including nausea, vomiting, headaches, skeletal muscle tremors, insomnia, irritation, reduced blood pressure, and cardiac disorders [17].

Many women planning to get pregnant and who are pregnant use calcium supplements in order to supply the increased demand for this mineral. Calcium used without the consultation with a physician or pharmacist can decrease the effect of Ca channel blockers, particularly in the case of patients with angina or patients with cardiac arrhythmia. In addition, Ca, similar to the majority of minerals, decreases absorption of

the majority of antibiotic groups used in the respiratory infections and urinary infections. As demonstrated by specialists, the decrease of antibiotic concentration in the blood of patient also using calcium supplements may reach up to 50%. Such a decrease of antibiotic concentration may eventually cause the therapy to become ineffective. Calcium ions may also cause the increase of toxicity of cardiac glycosides, which are used in the therapy of cardiac arrhythmia [18].

In addition, due to the elevated risk of anemia, numerous women planning to get pregnant and who are pregnant use nutritional supplements containing Fe. However, it should be emphasized that the concomitant use of Fe preparations and certain medications may entail adverse health consequences. Iron decreases the effect of antibacterial medications. It has a negative effect on the absorption of drugs to treatment for the Parkinson's disease by significantly decreasing the absorption of these preparations. It also decreases the absorption of the preparations used in the treatment for arterial hypertension. It should be remembered that bisphosphonates, i.e., preparations used in therapy of bone diseases, exhibit the capability of binding Ca and Fe while this ability contributes to the decrease of medication absorption in the blood [19].

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Conflict of interest statement

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