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ORIGINAL ARTICLE

EVALUATION OF PRENATAL VITAMIN-MINERAL PREPARATIONS IN THE CONTEXT OF RECOMMENDED DIETARY SUPPLEMENTATION. ARE PREGNANT WOMEN SUPPLIED WITH WHAT THEY SHOULD GET?

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ABSTRACT

Background. The composition of preparations, intended for pregnant women is an important issue of proper dietary supplementation. The range of such products on the market is very wide and their composition is not regulated by law. **Objectives.** To evaluate the composition of preparations for pregnant women in the context of 2014 Polish Gynecological

Society (PTG) recommendation and the 2020 recommendation of the Polish Society of Gynecologists and Obstetricians (PTGiP).

Materials and methods. A range of preparations was collected in pharmacies and e-pharmacies in 2019. The nutrient content was determined based on the information on the unit packaging or the pharmacy's website. The content of folic acid, vitamin D, iodine, DHA, and iron was assessed.

Results. There were 33 vitamin-mineral preparations (VMPs) on offer on the analyzed market. All preparations contained folic acid, of which 55% contained precisely the dose recommended by the PTG, and 45% of the preparations is compliant in this respect with the recommendation of the PTGiP. Ninety seven percent of VMPs contained vitamin D. Fifty percent of them did not contain this vitamin at the dose recommended by the PTG, and half of the preparations do not meet the PTGiP recommendation either. Ninety seven percent of VMPs contained iodine. Out of them 44% contained a too low dose of iodine, by the PTG standards, but only 9% of preparations do not meet the PTGiP recommendation in this respect. DHA was a component contained in 73% of VMPs. Among them, 33% contained the dose recommended by the PTG for women who eat little fish and 88% of the preparations are in line with the new recommendation PTGiP. Eighty two percent of preparations contained iron, which in the light of the PTGiP recommendation is debatable.

Conclusions. The composition of many VMPs did not reflect experts' recommendations regarding the type and amounts of particular nutrients.

Key words: dietary supplements, vitamins, minerals, pregnancy, dietary recommendations

STRESZCZENIE

Wprowadzenie. Skład preparatów, przeznaczonych dla kobiet ciężarnych jest ważną kwestią prawidłowej suplementacji diety. Rynek takich produktów jest bardzo szeroki, a ich skład nie jest regulowany prawnie.

Cel. Ocena preparatów dla kobiet w ciąży, w kontekście rekomendacji Polskiego Towarzystwa Ginekologicznego (PTG) z 2014 r. oraz najnowszych zaleceń Polskiego Towarzystwa Ginekologów i Położników (PTGiP) z 2020 r., dotyczących stosowania witamin i składników mineralnych w czasie ciąży.

Material i metody. Asortyment preparatów został zebrany w aptekach, w czterech dzielnicach Warszawy oraz metodą online w sześciu e-aptekach. Zawartość składników odżywczych ustalono na podstawie składu preparatów, zamieszczonego na opakowaniu jednostkowym lub podanego na stronie internetowej apteki. Pod uwagę wzięto składniki, które w diecie kobiet ciężarnych należy uzupełniać tj. kwas foliowy, witaminę D, jod, DHA, a dodatkowo oceniono także zawartość żelaza.

Wyniki. W obrocie handlowym znajdowały się 33 asortymenty preparatów witaminowo-mineralnych. Wszystkie preparaty zawierały kwas foliowy, z czego 55% zawierało dawkę taką, jak zalecało PTG, a 45% preparatów jest zgodne z zaleceniami PTGiP. 97% preparatów zawierało witaminę D, ale 50% z nich dostarczało zbyt małej dawki tego składnika, w stosunku do obu rekomendacji. 97% preparatów zawierało jod, z czego 44% nie dostarczało dawki zalecanej przez PTG, ale tylko 9% nie spełnia w tym zakresie zaleceń PTGiP. DHA zawarty był w 73% preparatów witaminowo-mineralnych. 33% tych preparatów zawierało w dawce dziennej ilość DHA rekomendowaną przez PTG, a 88% zawierało minimalną dawkę ustaloną przez PTGiP. Powszechnym składnikiem preparatów było żelazo (82% preparatów), które w świetle zaleceń PTG wymaga suplementacji tylko u kobiet z ryzykiem niedokrwistości, a w świetle zaleceń PTGiP tylko w przypadkach niedoboru udokumentowanego wynikami badań.

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Wnioski. Skład wielu preparatów witaminowo-mineralnych nie odzwierciedla rekomendacji ekspertów, odnośnie suplementacji poszczególnych składników odżywczych w okresie ciąży.

Słowa kluczowe: suplementy diety, witaminy, składniki mineralne, ciąża, zalecenia żywieniowe

INTRODUCTION

During pregnancy, the need for many nutrients increases. For most vitamins, the increased demand, compared to women who are not pregnant, ranges from 6% to 50%, and for minerals from 9% to 50%. This applies to folic acid, iron, and zinc to the greatest extent and much less so to vitamin B12, choline, and selenium. It is worth emphasizing that according to the most recent nutritional standards for the Polish population (2020), there has been no increase in the need for calcium, phosphorus, potassium, vitamin D, vitamin K, and biotin in pregnant women. Other ingredients that are particularly important during pregnancy include docosahexaenoic acid (DHA): omega-3 fatty acid, which should be daily taken in the additional amount of 100-200 mg during pregnancy [20].

Research shows that the dietary intake of some nutrients is highly deficient. In pregnant Polish women, the amount of folic acid covers only 27-55% of the demand, for iodine, it is 38-65%, for iron 34-48%, for calcium 60-84%, and in the case of vitamin D, whose deficiency affects the entire population, the diet covers 12-25% of the nutritional requirement of expectant mothers [3, 15, 19, 34, 40]. At the same time, some studies indicate that some vitamins and minerals are consumed in excessive amounts. The intake of vitamin A reaches 156% of the nutritional standard, of vitamin E 140% [6, 40], of vitamin B12 146% [16, 40], and even higher is the intake of phosphorus (166-235%) [3, 16, 40] and manganese (250-300%) [16, 40]. The situation is less clear when it comes to other nutrients. Some studies reveal deficiencies of magnesium (71-87% of the norm) and zinc (77-89% of the norm) [3, 15, 16]; others indicate that their intake covers the demand [40]. Evident deficiencies in the diet of pregnant women appear in DHA, the intake of which, in the light of a few existing studies in Poland, amounts to 60-280 mg daily [4, 12, 35], with recommendations standing at 350-450 mg [20].

Due to the high requirement for individual nutrients, their particular importance for the course of pregnancy, and their limited dietary intake, it is recommended that they be taken in the form of preparations. According to the most recent 2020 recommendation issued by the Polish Society of Gynecologists and Obstetricians (PTGiP), dietary supplementation in pregnant women should include four nutrients folic acid, vitamin D, DHA and, in pregnant women with no history of thyroid disease, also iodine. Iron, which is widely regarded as a critical nutrient during pregnancy due to new scientific reports on the adverse effects of its excessive intake, should only be taken if hemoglobin or ferritin levels are reduced [42]. The same nutrients were listed in the recommendations of Polish Gynecological Society (PTG) back in 2014, albeit their position was more flexible for iron and admitted its legitimate application, provided that the patient was featuring the risk of developing anemia [43]. Both cited positions specify a daily dose of folic acid, vitamin D, iodine, DHA, and iron to be possibly taken, and as regards other components, the experts agreed that routine supplementation for all pregnant women was not advisable.

Research to-date indicates that dietary supplementation with vitamins and minerals is commonly used in Poland and concerns 79-98% of pregnant women [9, 13, 14, 9, 36, 37]. The same percentage appears in other countries: the US, Canada, and Australia (78%-98% of women) [5]. Most women (74-77%) use VMPs during that period [11, 23, 36]. The market of dietary supplements is currently vast, and their composition is not regulated by law, therefore significant differences may appear.

OBJECTIVES

The aim of the study was to assess the composition of preparations intended for pregnant women as to the type of nutrients contained and their respective doses, in terms of the PTG recommendation [43] and the most recent PTGiP recommendation [42]. The article also discusses the issue of maximum doses of vitamins and minerals in the daily dose of supplements proposed in 2019 in Poland by the Panel on Dietary Supplements (an advisory body to the Chief Sanitary Inspector) [30, 31, 32, 33]. Besides, the study sought to address the discrepancies between the information provided on the labels of dietary supplements, indicating to what extent they cover nutritional requirements and scientifically established nutrition standards.

MATERIAL AND METHODS

An assortment of preparations addressed to pregnant women, intended both for the entire period of pregnancy and for individual trimesters, was collected in pharmacies in four districts of Warsaw (Centrum, Mokotów, Ursynów, and Gocław) between April and May 2019, and sourced online in six pharmacies (e-zikoapteka.pl, doz.pl, cefarm-24.pl, apteline.pl, i-apteka.pl, e-melissa.pl) between June and November 2019. The analysis did not include preparations used for pregnancy planning and during breastfeeding. The content of vitamins, minerals, and other nutrients in a daily dose of preparation was determined based on the unit packaging or the pharmacy's website. For the doses of 1-2 tablets/capsules a day, the maximum dose was used. The average nutrient content in the analyzed preparations was calculated, considering only the preparations containing specific nutrients.

The doses of components requiring supplementation in all pregnant women, i.e., folic acid, vitamin D, iodine, DHA, and additionally iron, were juxtaposed with the recommendations of the PTG in 2014, and of the PTGiP in 2020 [43, 42].

RESULTS

Characteristics of the preparations

In total, the study covered 33 vitamin-mineral preparations (VMPs) available on the Polish market, six preparations presented as *omega-3* fatty acids (DHA), four single folic acid preparations, and one preparation containing iron combined with vitamin C. Of the 33 VMPs, only one had the status of an over-the-counter drug (OTC), and the remaining preparations were dietary supplements.

The nutrient that was contained in all VMPs was folic acid. The next most commonly available ingredients were vitamin D and iodine, present in 32 preparations (97%), followed by iron, present in 27 VMPs (82%) (Table 1 and Table 2). Among vitamins, vitamin K was the least frequently used, contained in four preparations (12%), and in the case of minerals, phosphorus (1 preparation – 3%) and molybdenum and chromium (3 preparations – 9%).

In the composition of 24 VMPs (73%) additionally DHA was present, and the composition of 12 (36%) was featuring EPA (Table 2). Apart from vitamins, minerals, and *omega-3* fatty acids, only few preparations contained also plant ingredients: ginger extract (one preparation), chamomile extract (one preparation); amino acids: arginine and taurine (one preparation), glycine and aspartic acid (one preparation) and soy protein, which is a source of many amino acids (one preparation). In addition, inositol was present in one preparation.

Composition of VMPs vs. recommended dietary supplementation

Folic acid

All commercially available VMPs contained between 400 and 800 μ g of folic acid, with an average daily dose of 545.5 μ g. Most of them contained the exact dose recommended by PTG, i.e., 400 μ g of folic acid (18 preparations – 55%), and the second

most numerous group were preparations containing 800 μ g (9 preparations – 27%) (Table 1). Single folic acid preparations for pregnant women contained on average 450 μ g of this nutrient (ranging between 200 – 800 μ g) (Table 3).

Thirty nine percent of VMPs and 50% of single folic acid preparations contained calcium L-methylfolate or (to a lesser extent) glucosamine salt of (6S)-5methyltetrahydrofolic acid: the forms of the vitamin which are directly active in human body.

Vitamin D

The average content of vitamin D in preparations containing this vitamin (32 preparations – 97%) was 30.4 μ g (1216 IU). Only 16 VMPs (50%) contained 50 μ g (2000 IU) of vitamin D. At the same time as many as six preparations (19%) contained only 5 μ g (200 IU) in a daily dose, and another five preparations (16%) only 10 μ g (400 IU) of this vitamin (Table 1).

Iodine

Among preparations containing iodine in their composition (32 preparations – 97%) the average amount of iodine was 175.3 µg. Most of them (17 preparations, i.e. 53%) contained 200 µg of iodine, whereas three preparations (9%) had a dose lower than 150 µg (75 – 140 µg) (Table 2).

Iron

In the group of 27 iron-containing VMPs (82%), the average dose was 28.5 mg, which is close to the requirement for pregnancy (27 mg). The largest number of preparations (17 preparations – 63%) supplied 26-30 mg of this element, while three preparations (11%) contained a large amount of iron – 60 mg of iron in a daily dose (Table 2). A single iron preparation addressed to pregnant women stood out as supplying 32 mg of iron.

DHA

In the preparations, which next to vitamins and minerals also contained DHA (24 preparations – 73%), the latter's dose ranged from 50 to 800 mg, 343 mg on average. Among them, eight preparations (33%) contained at least 600 mg DHA, and 21 preparations (88%) contained at least 200 mg DHA (Table 2). In preparations being the only source of *omega*-3 fatty acids, the daily dose of DHA was higher (on average 441 mg) and ranged from 250 to 600 mg (Table 4).

DISCUSSION

In recent years, hand in hand with the overall market growth for dietary supplements, there has also been an increase in preparations on offer for pregnant women. In 2014, Warsaw pharmacies had 20 VMPs

Folic	aciu (µg)	400	400	800	800	800	400	800	600	400	400	400	400	400	400	600	400	400	400
С	(mg)	100	100	0	0	100	120	110	180	80	80	0	0	80	0	110	0	0	0
Choline	(mg)	0	0	125	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biotin	(gµ)	150	35	0	0	200	0	60	100	50	150	0	0	50	0	60	0	0	0
B12	(βη)	1.2	2.6	4	0	4	ю	3.5	2.7	2.6	9	0	0	2.6	0	3.5	0	0	1.25
B6	(mg)	2.2	1.9	2.6	0	2.6	1.9	1.9	2.2	1.8	10	0	0	2	0	1.9	0	0	0.7
Pantothenic	aciu (mg)	10.3	9	0	0	10	9	9	10	9	9	0	0	9	0	6	0	0	0
Niacin	(mg)	17.8	22	0	0	19	16	15	20	18	20	0	0	18	0	15	0	0	0
Riboflavin	(D2) (mg)	5	1.7	0	0	1.8	1.6	1.6	1.6	1,5	7	0	0	1.6	0	1.5	0	0	0
Thiamin	(D1) (mg)	1.66	1.4	0	0	1.55	1.4	1.2	1.5	1.4	5	0	0	1.4	0	1.2	0	0	0
К	(βη)	0	0	0	0	0	0	0	0	0	70	0	0	0	0	0	0	0	0
Щ	(mg)	10	24	0	0	15	12	13	24	15	12	0	0	10	0	13	0	0	0
D	(bd)	10	12.5	50	50	12.5	5	20	10	50	10	0	20	10	50	5	25	50	50
Α	(bd)	500	500	0	0	1081	501	0	500	0	333	0	0	0	0	334	0	0	0
Name of the	preparation	Acti vita-miner Prenatal + DHA	Centrum Femina DHA	Composita Mama DHA	DuphaVit Pregna	Elevit Pronatal	Falvit mama	Femibion Natal 1	Femibion Natal 2 Plus	Feminovit + DHA	Fertil Care	Folik Mama 1	Folik Mama 2 /3	LedeeVit	LadeeVit Optima	Mama activ Doppelherz	Mama dha	Mama DHA Premium +	Mama Premium activ Doppelherz
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0	0	85	0	0	0	0	0	50	0	0	0	0	80	100		101.1 (50.0; 180.0)		85
0	0	0	0	0	125	125	125	2	0	0	0	0	0	0		100.4 (2.0; 125.0)		450
0	0	30	0	0	0	0	0	150	0	0	0	0	50	150		95 (30.0; 200.0)		30
0	0	2.6	0	2.6	4	4	1	4	0	0	0.375	0	2.5	1.2	amins	2.8 (0.375; (0.0)		2.6
0	0	1.9	0	1.9	2.6	2.6	1.25	1.25	0	2.24	2.24	0	1.4	2.2	rticular vit	2.3 (0.7; 10.0)		1.9
0	0	0	0	0	0	0	0	5	0	0	0	0	6	10.3	containing pa	7.2 (5.0; 10.3)	r vitamins [1]	6.0
0	0	18	0	0	0	0	0	10	0	0	0	0	16	17.8	eparations	17.3 (10.0; 22.0)	t women fo	18
0	0	1.4	0	0	0	0	0	1	0	0	0.21	0	1.4	2	ax.) in the pr	1.5 (0.21; 2.0)	nt of pregnan	1.4
0	0	1.4	0	0	0	0	0	0.85	0	0	0.21	0	1.1	1.66	ontent (min.; n	1.5 (0.21; 5.0)	uily requireme	1.4
0	0	0	0	0	0	0	0	0	0	11.25	11.25	11.25	0	0	vitamin co	25.9 (11.25; 70.0)	Da	55
0	0	15	0	12	0	11.7	0	10	0	0	0	0	12	10	Average	13.7 (10.0; 24.0)		10
50	50	5	50	5	50	50	50	5	50	50	50	50	5	10		30.4 (5.0; 50.0)		15
0	0	333	0	0	0	0	0	300	0	0	0	0	180	500		460.2 (180; 1081)		770
Omegamed optima DHA z alg	Omegamed optima Forte DHA z alg	Pharmaton Matruelle	Pregna Plus	Pregnal Evital	Prenatal classic	Prenatal duo	Prenatal uno	Solgar Witaminy i Minerały Prenatalne	Symvital Mama	TRIMID 1	TRIMiD 2	TRIMID 3	Vita-min plus Mama	Vita-miner Prenatal				

EPA (mg)	44	0	120	0	0	0	0	0	43	0	0	0	32	40	44	34	68	130
DHA (mg)	220	200	600	250	0	0	0	200	200	0	300	300	160	600	200	600	800	600
Chromium (µg)	0	40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Selenium (µg)	20	30	0	0	0	55	0	0	60	50	0	0	60	0	0	0	0	0
Phosphorus (mg)	0	0	0	0	125	0	0	0	0	0	0	0	0	0	0	0	0	0
Copper (mg)	1	0.5	0	0	1	1	0	1	1	1	0	0	1	0	0	0	0	0
Molybdenum (µg)	0	0	0	0	0	50	0	0	50	0	0	0	0	0	0	0	0	0
Manganese (mg)	-	2	0	0	1	1.5	0		0	0	0	0	1	0	0	0	0	0
Zinc (mg)	15	11	0	0	7.5	10	0	15	11	15	0	0	10	0	10	0	0	0
Iodine (µg)	150	175	220	200	0	200	150	150	150	140	150	150	200	200	100	200	200	200
Magnesium (mg)	50	60	200	0	100	0	0	70	0	150	0	200	75	60	06	200	200	100
Calcium (mg)	200	140	0	0	125	240	0	0	0	200	0	0	0	0	200	0	0	0
Iron (mg)	28	27	27	30	60	20	0	28	27	17	0	0	27	26	15	0	0	26
Name of the preparation	Acti vita-miner Prenatal + DHA	Centrum Femina DHA	Composita Mama DHA	DuphaVit Pregna	Elevit Pronatal	Falvit mama	Femibion Natal 1	Femibion Natal 2 Plus	Feminovit + DHA	Fertil Care	Folik Mama 1	Folik Mama 2	LedeeVit	LadeeVit Optima	Mama activ Doppelherz	Mama DHA	Mama DHA Premium +	Mama Premium activ Donnelherz

0	0	30	0	40	0	70	0	0	0	0	0	0	0	0		63	30 130		- 450
200	600	150	50	200	0	600	0	0	600	200	200	200	0	0		343	50 800		350 -
0	0	30	0	0	0	0	0	12.5	0	0	0	0	0	0		55.8	12.5 40		not established
0	0	60	0	0	55	55	0	12.5	0	0	0	0	0	20	r minerals	43.4	12.5 60		60
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	ing particula	125	125 125		700
0	0	1	0	0	0	0	0	1	0	0	0	0	1	1	ons contain	1.0	0.5 1.0	ninerals [1]	1
0	0	50	0	0	0	0	0	0	0	0	0	0	0	0	the preparatic	50.0	50 50	t women for m	not established
0	0	0	0	0	0	0	0	0.5	0	0	0	0	1	1	l maximum ir	1.1	0.5 2	ent of pregnan	2
0	0	11	0	0	0	0	0	7.5	0	0	0	0	10	15	nimum and	11.4	7.5 15	requireme	12
200	200	200	200	200	200	200	150	75	200	150	150	200	200	150	content, mi	175.3	75 220	Daily	220
0	0	10	0	0	0	0	0	225	200	0	75	150	50	50	rage mineral o	115.8	10 225		360
0	0	0	0	0	0	0	0	650	0	0	0	0	100	200	Ave	228.3	100 650		1000
30	30	27	27	26	60	60	0	14	27	18	20	30	14	28		28.5	14 60		27
Omegamed optima DHA z alg	Omegamed optima Forte DHA z alg	Pharmaton Matruelle	Pregna Plus	Pregnal Evital	Prenatal classic	Prenatal duo	Prenatal uno	Solgar Wit. i minerały prenatalne	Symvital Mama	TRIMiD 1	TRIMiD 2	TRIMiD 3	Vita-min plus Mama	Vita-miner Prenatal		Average	Minimum Maximum		

Name of the preparation	Folic acid in a daily dose (µg)
Folian Naturell	400
Folian forte Naturell	800
Kwas foliowy DOZ Product	400
Myo Folic	200
Folic acid conten	t
Average	450
Minimum	200
Maximum	800

Table 3. Single folic acid preparations for pregnant women

Table 4. Single DHA preparations for pregnant women (quantities of components in a daily dosage)

Name of the preparation	DHA (mg)	EPA (mg)	Other omega-3 fatty acids (mg)							
DHA z alg DOZ Product	250	-	-							
Mumomega	300	42	-							
Möller's Baby tran norweski	600	400	200							
Omegamed pregna DHA z alg	400	-	-							
Pregna 250 DHA	500	-	-							
Prenatal DHA	600	70	-							
Component content in preparations containing particular components										
Average	441	171	200							
Minimum	(250;	(42;	(200;							
Maximum	600)	400)	200)							

for the period of pregnancy [38], and this market has now grown by 65% (33 preparations). In 2014, the bulk of preparations (70%) were registered as dietary supplements, and 25% had the status of dietary foods for special medical purposes. Currently, after the legislation on dietetic products was repealed as of 20 July 2016 [24], almost all preparations are dietary supplements.

One of the ingredients recommended for all pregnant women is folic acid (a B vitamin). Research indicates that in pregnancy, unlike in its preceding period, almost all women take folic acid in the form of multi-component preparations (77% out of 83% of women using supplementation) [39]; therefore, the formulation of such preparations is an essential issue for correct supplementation. In light of the PTG recommendation, the routine use of folic acid in a dose of 400 μ g a day concerned only the first trimester of pregnancy [43]. On the other hand, according to the

latest recommendation of the PTGiP, women who are not at increased risk of fetal neural tube defects should take $400 - 800 \ \mu g$ of folic acid a day in the first trimester of pregnancy and $600 - 800 \ \mu g$ in the following trimesters [42]. All commercially available VMPs contained folic acid, of which more than half contained the exact dose recommended by the PTG. Of the four single folic acid preparations, one provided only 200 µg of this vitamin, which does not correspond with all previous recommendations issued by Scientific Societies. However, the PTGiP has recently modified the dose and the period of intake of folic acid, among others, increasing its amount in the second and third trimester of pregnancy to 600 µg at least [42]. Consequently, 55% of preparations, with their current formulation, will not meet the latest recommendations, and this finding applies to an even greater extent to single folic acid preparations (75%). Simultaneously, it should be emphasized that so far, the routine dose of folic acid has been 400 µg [43], and presumably, therefore most VMPs contain such an amount of this vitamin. It is also evident that the manufacturers of preparations must be allowed some time to possibly change the formulation of their products in the context of the amended recommendations.

In none of the analyzed preparations, either single or multi-component, the dose of folic acid would exceed the upper safe level (UL) of 1000 µg per day, which means that the correct use of such preparations, in combination with the usual dietary intake of folates, should be safe. Nevertheless, as one study showed, more than 33% of the studied population of pregnant women took folic acid from two sources - in the form of a single preparation and a VMP, which resulted in exceeding the UL [36]. At this point, it is important to highlight that in 2019, the Panel on Dietary Supplements (PDS) opined that the daily dose of folic acid in supplements for pregnant women should not exceed 800 µg. Furthermore, it recommended placing a warning on the labels of supplements: "in pregnant women, use after consultation with a doctor." [30].

In the last decade, an increasing number of scientific studies have pointed to genetically determined folic acid metabolism problems due to enzyme deficiencies in a significant proportion of the white population [1, 18, 41]. This means that dietary supplementation with folic acid, which requires conversion to 5-methyltetrahydrofolate (5-MTHF) to become bioactive in the body, may prove ineffective in such individuals. An alternative is to use metafolin, i.e., the calcium salt of L-5-methyltetrahydrofolate acid (L-5-MTHF), and glucosamine salt of (6S)-5-methyltetrahydrofolic acid, which are reduced, active forms of folate that directly enters the human bloodstream[1,7,27]. These compounds were approved for use in dietary supplements by the Commission

Regulation [8, 9], and were also included in the list of chemical forms of folates in the Polish regulation [25]. Although the PTGiP emphasizes that currently there are no indications for the use of reduced forms of folic acid, among analyzed preparations L-5-MTHF or glucosamine salt of (6S)-5-methyltetrahydrofolic acid were used in almost 40% of VMP and in every second single folic acid preparation, usually in combination with the standard form of folic acid, constituting half of the total folate dose contained in the product.

With respect to vitamin D, according to the PTG recommendation, pregnant women should take 2000 IU (50 µg) of vitamin D daily [43]. New recommendations of PTGiP condition the dosage of this vitamin with the patient's BMI. Women with normal body weight are recommended to take 1500 -2000 IU $(37.5 - 50 \mu g)$ of vitamin D, and women with obesity – after consultation with a doctor – a higher dose, even up to 4000 IU (100 µg) [42]. Only half of the VMPs contained the PTG-recommended dose of this vitamin and the same situation occurs with regard to the PTGiP recommendations. Although there has been a significant improvement made in this respect, compared to the market situation analyzed in 2014, when only 15% of preparations had an adequate amount of vitamin D [38], nevertheless most preparations still provide a low dose of this vitamin, even as little as 5-10 μ g (200 – 400 IU). As shown by numerous studies, such a daily dose is not able to increase vitamin D concentration in the blood of patients to the level recommended in pregnancy [2, 28, 29]. Given that an even higher dose of vitamin D has been recommended for pregnant women with obesity (as much as 4000 IU - 100 μ g), it should be noted that the PDS expressed the position on the daily dose of this vitamin in supplements which should not exceed 2000 IU (50 µg) [31]. Therefore, women with obesity will need to have their vitamin D intake individually determined by a physician, next to the VMP that they may be using.

The iodine dose to be taken by pregnant women in line with the PTG recommendation so far, was 200 µg a day [43]. Considering the most recent PTGiP recommendations, all pregnant women (without a history of thyroid disease) are advised to take a dose of $150 - 200 \ \mu g$ a day [42]. The situation concerning iodine content in preparations for pregnant women has definitely improved over the years. In 2005, it was present only in a few VMPs (43%) [36], while currently, iodine is a component of 97% of VMPs. Fifty three percent of currently analyzed preparations contained its dose, complying with the PTG recommendations (200 µg), but as much as 91% will meet the PTGiP recommendations in this respect (150-200 μ g). It should be noted that one VMP did not contain this mineral, but since that preparation has the status of a drug, information about the absence of iodine is included in the package insert for patients. As a result, women using this preparation should be aware that such an essential nutrient should be supplemented separately. In the light of the resolution of the PDS, the maximum level of iodine in supplements for pregnant women should not exceed 200 μ g in a daily dose [32], which is in line with the recommendations on dietary supplementation.

Iron is a fairly controversial mineral in the context of dietary supplementation. According to the PTG, if risk factors for anemia appear in pregnancy, women should take 26 – 27 mg of iron [43]. The latest position of the PTGiP emphasizes that iron should only be taken by women with anemia, whereas in the case of women without anemia but with reduced ferritin levels, dietary supplementation with low doses of iron, i.e., up to 30 mg a day, may be allowed from week 16 of pregnancy onward [42]. Therefore, according to the most recent recommendations, iron should not be used by pregnant women on their own, so its presence in most vitamin-mineral preparations (82%) can be problematic. Iron has been in any case present in all VMPs for years; therefore, 78-80% of pregnant women taking such preparations also took iron [11, 36]. Both cited experts' recommendations indicate that low doses of iron (up to 30 mg) should be taken in justified situations, and yet three preparations contained 60 mg of this mineral. The maximum dose of iron in supplements for pregnant women set by the PDS in 2019 is 30 mg, so the composition of some preparations will most likely need to be changed in the future. According to the Panel's resolution, such supplements should also be provided with a warning: "product for pregnant women, use after consultation with a doctor." [33]. Although the resolutions of the Panel mentioned above do not have the status of law, it should be assumed that they will be taken into account in the evaluation of dietary supplements carried out by inspection authorities.

A vital nutrient during pregnancy is DHA, and because of its low dietary intake, the need for supplementation has been stressed for years. For women who did not eat much fish, the PTG recommended a DHA intake of at least 600 mg [43]. The PTGiP suggests that all pregnant women should take DHA in a dose of at least 200 mg a day and that higher doses should be considered for women with low fish consumption [42]. In Poland, only 3-19% of pregnant women consume fish according to the recommendations (at least twice a week) [4, 10, 17, 35]; therefore, higher doses of supplementation practically apply to most pregnant women. Although there have been changes in the composition of preparations in terms of DHA content in recent years, despite recommendations existing for years, this

ingredient was not present in 27% of vitamin-mineral preparations, and in some, its dose was less than 200 mg. A study conducted in 2014-2015 found that VMPs contained an average of 130 mg of DHA [35] and currently, the situation is much more favorable. The average DHA content in VMPs was 343 mg, and in preparations containing only *omega-3* fatty acids 441 mg. Still, it should be remembered that women who do not eat fish should make use of additional DHA preparations next to VMP. According to the recently published study by *Knapik* et al., polyunsaturated fatty acids are supplemented by less than 25% of pregnant women [14], whereas the study by *Wierzejska* et al. shows that 28% of pregnant women take DHA [35].

Concerning the remaining vitamins and minerals, experts from Scientific Societies now state that their routine supplementation is not recommended and should only apply to women for whom it is medically justifiable [42, 43]. However, some experts believe that multivitamin-mineral supplementation is essential, pointing to most components' deficiencies, especially among women with gestational diabetes [16]. A cautious approach to universal supplementation also prevails in the United States, where the supply of these nutrients in the form of preparations is recommended only for mothers at risk of deficiencies thereof [5]. In general, it is felt that dietary supplementation should be tailored to the patient's needs to the maximum extent, which may prove most beneficial and protect the patient against excessive intake of nutrients [5, 16, 21, 43]. Caution of widespread intake of VMPs is further corroborated by studies demonstrating a link between dietary supplementation and an increase in body weight and body fat in newborns [22].

Apart from components that should be taken by all patients, the most frequently used vitamin in analyzed preparations was vitamin B6 (22 preparations), B12 (21 preparations), and magnesium (20 preparations). In the case of eight vitamins, the average content of particular vitamins exceeded pregnant women's requirements by 7-316%. Compared to the recommended intake, the highest doses concerned biotin (316%), even though, according to the nutritional standards, the need for biotin does not increase during pregnancy. High amounts of some nutrients in preparations have been observed for years. Studies conducted in 2005-2007 showed that the amount of some vitamins provided by VMPs covered up to 667% of the requirement for pregnant women, and the dose of minerals up to 227%. High doses in the preparations were recorded mostly for vitamin B6, B12, and biotin, and negligible and practically irrelevant in the pool for magnesium [36]. Also the study by Hamulka et al. conducted in 2008 showed that dietary supplements were supplying vitamin C, B2, folic acid, and iron above the norm (120-128%) [11]. In none of the preparations analyzed

in the study did the content of vitamins and minerals exceed their UL. Next to the content of vitamins in the daily dose of preparations, there is also a problem of an inappropriate approach to diet supplementation. Studies indicate that 4.7 - 22% of pregnant women take several preparations simultaneously, which results in exceeding the recommended intake 5-fold or even 6-fold [11, 36].

discussing the When composition of the preparations and the extent to which they cover pregnant women's requirements, one cannot fail to mention legal regulations concerning the labelling of dietary supplements. On their packaging, like in all food products, the quantity of vitamins and minerals is expressed as a percentage of the Reference Intake (RI) [26]. At present, RI has been determined for an average adult, so this value does not reflect the recommended intake for pregnant women, whose nutrient requirements increase. A good example is that of folic acid, for which RI stands at 200 µg, and according to the nutrition standards, the requirement for pregnant women is 600 µg. This means that in the case of 400 µg of this vitamin in the daily dose of a supplement (which was generally found in the analyzed preparations), the label indicates the amount covering 200% of RI, while during pregnancy, this only supply 66% of the recommended intake. The second issue is many years' delay in providing an amended regulation of RI, in line with changing nutritional standards based on new scientific data. A good example here is vitamin D, for which RI still stands at 5 μ g, while in light of nutrition standards, the amount necessary in the diet of all adults and pregnant women is 15 µg. As it was the case with folic acid, a supplement offering a dose of 5-10 µg of vitamin D (often contained in preparations) is labeled as providing 100-200% of RI, whereas, for the currently determined requirement, it only supplies 33-66%. Pregnant women may not be aware of such differences, and perhaps doctors or pharmacists either. Therefore, the legislation relating to labelling of dietary supplements needs to be revised, following changing nutritional standards, to avoid misinterpretation by patients regarding the amount of nutrients.

CONCLUSIONS

All 33 evaluated VMPs contained folic acid. Fifty five percent of them provide the exact amount of this nutrient according to recommendation PTG (2014), but less than half of preparations meet the new recommendation PTGiP (2020).

Ninety seven percent of VMPs contained vitamin D. Fifty percent of them contain too low dose of this vitamin in relation to both recommendations. Ninety seven percent of VMPs contained iodine. Out of them 44% did not contain a dose of iodine recommended by PTG, but only 9% of preparations do not meet the PTGiP recommendation.

Seventy three percent of VMPs contained DHA. One-third of them provided the dose recommended by the PTG and 88% of preparations meet the new recommendation PTGiP.

Eighty two percent of VMPs contained iron. Sixty three percent of them contain this mineral in dose compliant with PTG recommendation, but according to the PTGiP recommendation iron should not be taken by all pregnant women on their own accord.

The composition of many VMPs did not reflect experts' recommendations regarding the type and amounts of particular nutrients.

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Conflict of interest

The author declare no conflict of interest.

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