Short Communication

Prevalence of inappropriate dietary supplement use among pregnant women in Japan

Yoko Sato PhD[1], Tomoko Nakanishi RD[1], Tsuyoshi Chiba PhD[1], Kaori Yokotani MS[1], Koujirou Ishinaga RD[2], Hidemi Takimoto MD[3], Hiroaki Itoh MD[4], Keizo Umegaki PhD[1]

[1]*Information Center, National Institute of Health and Nutrition, Tokyo, Japan*
[2]*Department of Nutrition and Health Promotion, Hiroshima Jogakuin University, Hiroshima, Japan*
[3] *Department of Nutritional Education, National Institute of Health and Nutrition, Tokyo, Japan*
[4]*Department of Obstetrics and Gynecology, Hamamatsu University School of Medicine, Hamamatsu, Japan*

We investigated the characteristics of dietary supplements and their use by 1,076 Japanese pregnant women, the majority of whom were in mid- to late pregnancy. The subjects completed a self-reported survey on their sociodemographic characteristics, supplement use, and attitudes towards diet. The overall prevalence of supplement use did not change before and after pregnancy (75%); however, daily use increased by approximately two-fold with pregnancy (20.2% versus 37.2%). After the onset of pregnancy, supplements containing folic acid were taken for fetal health. Daily users were more likely to be older, have a greater awareness of the risk of neural tube defects (NTD), view supplement use as acceptable, have less diet anxiety, and have more advisers regarding diet. Respondents used supplements containing folic acid alone or with other ingredients. Folic acid intake is recommended to reduce the risk of NTD. However, supplement use began after pregnancy recognition, suggesting a lack of knowledge on the appropriate timing of folic acid use. Information about supplements was obtained mostly from newspapers, magazines, flyers, and stores. These results indicate that more accurate information regarding the optimal timing of folic acid intake and the safety of dietary supplements must be disseminated.

Key Words: dietary supplements, pregnancy, folic acid, information, Japan

INTRODUCTION

The use of dietary supplements is increasing worldwide, including among pregnant women. It has been shown that 72% to 86% of pregnant women in the United States and 81% to 94% of those in European countries use dietary supplements.[1-4] Nutritional status during pregnancy plays an important role in the well-being of both mother and fetus; therefore, pregnant women tend to use dietary supplements for fear of nutritional deficiencies. Among nutrients, folic acid has received a great deal of attention. It is well known that periconceptional use of folic acid supplements reduces the risk of neural tube defects (NTD) in infants.[5,6] Because of this beneficial effect, health authorities in numerous countries recommend periconceptional folic acid intake in fertile women.[5,7] In pregnant women not at risk of malnutrition, the necessity of nutrients supplied via dietary supplements is unclear, with the exception of folic acid. A variety of dietary supplements are available in the marketplace; some contain folic acid alone, while others contain additional vitamins and minerals or herbal ingredients. Some studies have pointed out that the safety of dietary supplements containing herbal ingredients is not conclusive for pregnancy, and evidence-based data are lacking.[8,9] Furthermore, unlike the United States, there is no clear definition on what constitutes a dietary supplement in Japan, allowing the existence of a variety of dietary supplements in the marketplace. The Japanese government does not regulate the quality, safety and efficacy of most of these products. With the increased availability of dietary supplements in the marketplace and heightened awareness of folic acid requirements during pregnancy, dietary supplement use in pregnant women is expected to increase in Japan. However, few reports have examined this topic. Thus, in this study we conducted a questionnaire survey to examine the current status of dietary supplement use, and their characteristics, by pregnant women.

METHODS

A cross-sectional survey was conducted from January through November 2010. We used an anonymous, self-reporting survey. The questionnaire was distributed at maternity hospitals and public health centers. The forms were mailed to the party conducting the survey and were returned by mail after completion.

Corresponding Author: Dr Keizo Umegaki, Information Center, National Institute of Health and Nutrition, 1-23-1 Toyama, Shinjuku-ku, Tokyo 162-8636, Japan.
Tel: +81-3-3203-5721; Fax: +81-3-3202-3278
Email: umegaki@nih.go.jp
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Subjects

We identified 3,650 pregnant women in 18 prefectures in Japan. Responses were obtained from 1,076 pregnant women (effective recovery rate: 29.5%), with a mean age of 32.2±4.4 years and a mean gestational age of 25.7±6.8 weeks.

Completion of the survey was considered informed consent. This study was conducted with the approval of the Research Ethics Committee of the National Institute of Health and Nutrition of Japan.

Questionnaire

The questionnaire topics were as follows.

Background characteristics: age, gestational age, number of people in the household, education level, smoking status.

Dietary supplement use before and during pregnancy: supplement use was defined according to four categories ("daily use", "occasional use", "past use", and "have never used"). For each user, questions were asked about ingredients in the supplements and the purpose of their use. Additionally, the pregnant supplement users were asked for the prenatal label, information source, supplier, observations/notes at purchase, important points when purchasing, consulted person(s), and precautions for use. Additionally, folic acid supplement users were asked what other ingredients were contained in the product.

With regard to attitudes towards diet, in order to assess the respondents' level of knowledge on food, questions were asked about their awareness of the standard dietary intake, the dietary balance guide and NTD risk with folic acid intake. The standard dietary intake refers to "Dietary Reference Intakes for Japanese (2010)",[7] which was formulated by the Ministry of Health, Labour, and Welfare of Japan. The dietary balance guide[10] was prepared by the Ministry of Health, Labour, and Welfare and the Ministry of Agriculture, Forestry, and Fisheries of Japan. Furthermore, questions were asked regarding supplement use during pregnancy, anxiety regarding diet during pregnancy, adviser(s) for diet and supplement use, and the number of items of concern regarding diet selected from a list.

Statistical analysis

The distribution of sociodemographic and other characteristics was presented as percentages, and comparisons of these characteristics between daily supplement users during pregnancy and non-daily users were performed using the chi-square test and t-test for categorical and continuous variables, respectively. Prevalence odds ratios (OR) and the corresponding 95% confidence intervals (95% CI) from logistic regressions were used to determine the factors associated with daily supplement use by pregnant women while adjusting for all the other variables included in the model. Variables that were not significantly multicollinear were included in the final regression model after being identified by a multicollinearity test using Spearman's rank correlation. The awareness of dietary reference intake was excluded because of its significant multicollinearity. Adjustments were made for the following variables: age, gestational age, geographical area, education level, smoking status, supplement use during pregnancy, awareness of NTD risk, awareness of the dietary balance guide, diet anxiety during pregnancy, number of advisers, and the number of items of concern regarding diet.

Table 1. Dietary supplement use before and during pregnancy

	Before pregnancy n (%)	During pregnancy n (%)
Total	1,076 (100)	1,076 (100)
Dietary supplement use		
Have used	806 (74.9)	810 (75.3)
Daily	217 (20.2)	400 (37.2)
Occasional	373 (34.7)	245 (22.8)
Past	216 (20.1)	165 (15.3)
Have never used	270 (25.1)	266 (24.7)
Alterations due to pregnancy		
Frequency of use		
Increased		374 (34.8)
Decreased		253 (23.5)
No change		449 (41.7)
Number of use		
Increased		262 (24.3)
Decreased		352 (32.7)
No change		461 (42.9)

Missing values were excluded.

Participants using supplements during pregnancy were divided into two groups: users of only folic acid supplements ("Only folic acid") and users of supplements containing additional ingredients or only non-folic acid ingredients ("Not only folic acid"), and comparisons were made based on the status of their use. Inter-group comparisons were performed using the chi-sqaure test and t-test for categorical and continuous variables, respectively.

Data were analyzed using PASW Statistics 18.0 for Windows, and the level of significance was set at $p<0.05$.

RESULTS

Supplement use before and during pregnancy

Of the total respondents, 74.9% (n = 806) had used supplements before pregnancy, and 75.3% (n = 810) used supplements during pregnancy (Table 1). Daily users increased from 20.2% (n = 217) before pregnancy to 37.2% (n = 400) after pregnancy. Alterations in the frequency and number of supplements used due to pregnancy varied among individuals.

Characteristics of daily users during pregnancy

In the multivariable analysis, the five characteristics associated with daily supplement use during pregnancy included: higher age (OR = 1.06, 95% CI = 1.02-1.09), approval of supplement use during pregnancy (65.6%, OR = 21.0, 95% CI = 4.93-89.8), higher awareness of NTD risk (70.2%, OR = 2.81, 95% CI = 1.79-4.40), lack of diet anxiety (the other OR = 0.5-0.57), and greater number of advisers (OR = 1.18, 95% CI = 1.01-1.38) (Table 2). There were no statistical differences in daily supplement use during pregnancy among variables such as gestational age, geographical area, education level, and smoking habits.

Table 2. Sociodemographic and other characteristics associated with daily supplement use during pregnancy

Characteristics	n	Supplement use during pregnancy		*p*-value[†]	Odds ratio	(95% CI)[‡]	*p*-value[§]
		Daily users (%)	Others (%)				
Total	1,076	37.2	62.8				
Age[¶]		32.9 ± 4.1	31.7 ± 4.5	<0.01	1.06	(1.02-1.09)*	<0.01
Gestational age, weeks				<0.01			
>28	426	35.2	45.1		0.58	(0.32-1.05)	0.07
16-28	523	56.8	47.1		0.95	(0.53-1.70)	0.87
<16	81	8.0	7.8		1.00		
Geographical area				<0.01			
Tohoku	27	2.5	2.5		1.04	(0.36-3.05)	0.94
Kanto	808	81.3	71.4		1.34	(0.79-2.28)	0.27
Chubu	66	4.8	7.0		1.03	(0.39-2.72)	0.95
Kansai, Chugoku, Shikoku	92	5.0	10.7		0.57	(0.27-1.20)	0.14
Kyushu	83	6.5	8.4		1.00		
Education level				0.57			
Junior high school, high school	182	15.6	17.8		1.45	(0.93-2.26)	0.10
Junior College, technical school	409	39.8	37.2		1.18	(0.86-1.61)	0.31
University, graduate college	480	44.6	45.0		1.00		
Smoking				0.70			
Current, past	231	20.9	22.0		1.05	(0.73-1.51)	0.79
Never	841	79.1	78.0		1.00		
Opinion of supplement use during pregnancy				<0.01			
Allowable	504	65.6	36.6		21.0	(4.93-89.8)*	<0.01
Only if absolutely necessary	509	33.9	56.1		6.77	(1.58-28.9)*	0.01
Should not be used at all	51	0.5	7.3		1.00		
NTD[††]risk				<0.01			
Understand	624	70.2	51.0		2.81	(1.79-4.40)*	<0.01
Have heard about it	251	19.5	25.6		1.70	(1.04-2.79)*	0.03
Do not know	199	10.3	23.4		1.00		
Dietary reference intake				<0.01			
Understand	232	26.6	18.7				
Have heard about it	586	52.1	56.0				
Do not know	256	21.3	25.3				
Dietary balance guide				0.11			
Understand	444	45.7	39.1		0.92	(0.60-1.42)	0.71
Have heard about it	445	38.9	43.3		0.88	(0.58-1.35)	0.56
Do not know	179	15.4	17.6		1.00		
Diet anxiety during pregnancy				0.31			
Always	62	5.6	5.9		0.53	(0.25-1.09)	0.09
Often	185	16.7	17.7		0.51	(0.29-0.90)*	0.02
Sometimes	457	42.8	42.8		0.57	(0.35-0.94)*	0.03
Occasionally	263	23.0	25.6		0.50	(0.29-0.86)*	0.01
None	101	11.9	8.0		1.00		
Number of advisers regarding diet[§]		1.7 ± 1.0	1.7 ± 0.9	0.50	1.18	(1.01-1.38)*	0.04
Number of items cared for diet[§]		4.0 ± 2.1	3.8 ± 2.0	0.20	1.02	(0.95-1.10)	0.54

[†] Categorical variables: *p*-values were calculated using the chi-square test. Continuous variables: *p*-values were calculated using t-tests. Missing values were excluded.
[‡] Logistic regression analysis.
[§] *p*-values were calculated using logistic regression analysis.
[¶] Mean ± SD.
[††] NTD: Neural tube defect.
* Indicates a significant difference at $p < 0.05$, compared to the reference group

Details of supplement use during pregnancy

Before pregnancy, respondents (n = 806) used supplements such as those containing vitamin C (42.4%), folic acid (34.7%) and other B vitamins (26.8%), iron (24.7%), collagen (22.8%), calcium (15.8%), and vitamin E (13.4%). During pregnancy, on the other hand, of all respondents (n = 810), most used folic acid supplements (93.8%). The reported non-folic acid-containing supplements contained iron (48.3%), calcium (26.0%), B vitamins other than folic acid (22.2%), vitamin C (13.1%), and others (such as herbal ingredients, protein, fibers, L-cysteine, green vegetable juice (*aojiru*), chlorella, brewer's yeast, maca, royal jelly, oyster extract, vegetable powder, aloe, and plum). The main purposes of dietary supplement use were "nutritional supplementation" (44.0%), "beauty" (42.7%) and "health promotion" (28.0%) before pregnancy, and "health of the fetus" (80.9%) and "nutritional supplementation" (48.6%) during pregnancy.

The characteristics and the details of supplement use during pregnancy of the "Only folic acid" and "Not only folic acid" groups were compared. The "Not only folic acid" group had a higher age (31.7 ± 4.4, $p < 0.01$) and a greater incidence of smoking (26.0%, $p = 0.03$), whereas

Table 3. Status of supplement use by pregnant women

	n	Only folic acid (%)	Not only folic acid (%)	*p*-value[†]
Total	810	34.0	66.0	
Frequency of use				<0.01
Daily	400	36.7	55.9	
Occasional	245	25.8	32.5	
Past	165	37.5	11.6	
Label about pregnancy use[‡]				
For pregnancy	406	45.0	53.8	0.02
Available for pregnant woman	225	31.0	26.7	0.20
No label	249	25.8	33.9	0.02
Information source[‡]				
Newspapers, magazines, flyers	270	33.5	33.3	0.96
television, radio	18	2.2	2.3	0.96
Stores	343	38.5	44.8	0.08
Websites	132	18.3	15.4	0.30
Family, friends	213	28.6	25.4	0.34
Supplier[‡]				
Pharmacies	556	72.4	67.4	0.14
Supermarket, convenience store	59	9.1	6.4	0.16
Department store	24	1.5	3.8	0.07
Via mail order	80	4.8	12.6	<0.01
Internet shop	93	7.7	13.5	0.02
Specialty health food store	24	0.7	4.1	0.01
Observed/Noted at purchase[‡]				
Mark (as a quality certificate)	107	12.9	13.9	0.70
Extensively marketed	44	6.1	5.3	0.67
Well-known manufacturer	433	54.4	55.2	0.82
Natural materials	171	21.3	21.9	0.84
Inexpensive	145	20.2	17.5	0.37
Nutritional labels	311	30.0	44.3	<0.01
Without additives	182	25.1	22.1	0.35
Non-allergenic	21	1.5	3.2	0.16
Topical substance	28	3.8	3.4	0.79
Foods for nutrient function claims	93	11.0	12.2	0.63
Important points when purchasing				<0.01
Efficacy	102	8.8	14.8	
Safety	665	83.8	83.1	
Neither	31	7.4	2.1	
Consulted with:[‡]				
Pharmacist	45	2.6	7.2	0.01
Nutritionist	41	3.3	6.0	0.10
Physician	174	20.1	22.6	0.41
Nurse, midwife	83	10.0	10.6	0.82
Store clerk	30	2.2	4.5	0.11
Family, friends	251	30.9	31.0	0.97
None	317	43.1	37.9	0.16
Precautions for use[‡]				
Observe specified quantity	713	90.8	87.6	0.17
Do not take more than 2 types of supplements	87	11.8	10.3	0.54
Eat regular meals	381	38.6	51.9	<0.01
Nothing in particular	30	2.9	4.1	0.40

[†] *p*-values were calculated using the chi-square test. Missing values were excluded.
[‡] Multiple answers allowed within the category (% of those who selected).

gestational age, geographical area and education level were not significantly different from the "Only folic acid" group (data not shown). The ratio of daily users in the "Not only folic acid" group was greater than that in the "Only folic acid" group (Table 3). Many pregnant women used products labeled as "for pregnancy" or "available for pregnant women". However, some used products with no such label, and the ratio of woman using these products with no such label was greater in the "Not only folic acid" group than in the "Only folic acid" group. There were no significant differences between the two groups with respect to the source(s) of obtained information; the major sources were "newspapers, magazines, flyers", "stores", and "family and friends".

The products were purchased mainly at pharmacies in both groups. The "Not only folic acid" group purchased more via mail order, at internet shops and specialty health food stores, and was more concerned with the presence of nutritional labels compared to the "Only folic acid" group. At the time of purchase, both groups prioritized the importance of safety above all (approximately 83%). However, the "Not only folic acid" group placed more value on efficacy compared to the "Only folic acid" group. In taking supplements, many pregnant women did not seek

consultation from others. Any consultation, if sought, was with family members and/or friends, and physicians. The precautions taken for use were "Observe the specified quantity" in almost 90% of respondents. The "Not only folic acid" group was more likely to "Eat regular meals" than the "Only folic acid" group.

DISCUSSION

The present study revealed three problems underlying supplement use by Japanese pregnant women: the increase in habitual use during pregnancy; a lack of exact knowledge about appropriate intake timing; and unawareness of product safety.

Pregnancy is a state of increased macro- and micronutrient requirements. Therefore, the use of dietary supplements is beneficial when sufficient nutrients cannot be consumed. However, apart from circumstances of malnutrition, insufficient evidence is available to support a recommendation for dietary supplement use in pregnant women. In this study, we observed that 75% of pregnant women in Japan took dietary supplements, which was comparable with that during pre-pregnancy. The utilization rate of supplements during pregnancy in this study was slightly lower than the rate of >80% observed in other countries,[1-3] but was similar to that among coeval Japanese non-pregnant women.[11] We also observed that daily use of dietary supplements increased approximately two-fold due to pregnancy, with increases of 34.8% and 24.3% in the frequency and numbers, respectively, and only 4.8% of women showed a negative opinion on supplement use. These results suggested that pregnant women are amenable to taking dietary supplements, resulting in increased dietary supplement use by these women. Previous studies have shown that dietary supplement users tend to derive more micronutrients from their diet than non-users in Japan.[12] Habitual supplement use may increase the risk of excessive intake of certain substances and their adverse effects.

In the present study, five characteristics were significantly related to daily supplement use during pregnancy. These included higher age, higher awareness of NTD risk, approval of supplement use during pregnancy, lack of diet anxiety, and greater number of advisers. Other characteristics, such as gestational age, were not significantly related. Some studies have shown that higher age and more knowledge regarding diet were associated with dietary supplement use during pregnancy,[2,3,8] and a similar tendency was found in the present study. However, education level and awareness of the dietary balance guide were not associated, and no constant tendency was shown between daily supplement use and knowledge about diet (Table 2). These results suggest that, among Japanese pregnant women, information derived from social interactions may be more influential on habitual supplement use than knowledge about diet. These results also showed that those who were daily supplement users during pregnancy were confident about supplement use, but misunderstood the appropriate intake timing of folic acid. Because neural tube closure is complete by 28 days post-conception in humans,[6] the Japanese government recommends the intake of 400 μg/day of synthetic folic acid from fortified foods or dietary supplements for all women who plan to become pregnant starting approximately one month before pregnancy until the first trimester of pregnancy.[7] However, we found that most women began folic acid supplementation for the "health of the fetus" only after becoming aware of their pregnancy, and they continued the supplementation until the mid- or late stages of pregnancy. Folic acid intake is useful in preventing NTD in babies, but may also induce adverse effects. In recent years, adverse reactions such as increased risk of childhood asthma and decreased birth height have been shown in children whose mothers took folic acid supplements during pregnancy.[13-15] Adverse reactions such as Stevens-Johnson syndrome and anaphylaxis have also been shown to occur in pregnant women.[16, 17] Therefore, it is necessary to increase the awareness of proper folic acid intake and NTD risk.

In Japan, folic acid is the only nutrient that is recommended to be taken by pregnant women in a synthetic form, either from fortified foods or as a dietary supplement. Thus, in this study, we divided the participants into two categories, namely, those who used folic acid only and those who used folic acid with others ingredients, to analyze the survey data. We found that 66% of pregnant supplement users had taken supplements containing non-folic acid ingredients, some of which contained herbal ingredients. Little is known regarding the benefits and/or detriments of these products. Consumption during pregnancy may induce adverse reactions and the attention of users has been drawn to this point.[8,9]

The present study suggested that pregnant supplement users did not have adequate understanding of dietary supplements and had excessive expectations of their use; this expectation may stem from their dietary supplement information source. Most pregnant women who reported using dietary supplements during pregnancy had not consulted their physician, and instead obtained their information from newspapers, magazines, flyers and stores. Unfortunately, this information can often be unscientific, biased towards benefits only, and lack safety warnings because the information is usually intended for product promotion.[18-20] Non-folic acid supplement users, in particular, are prone to influence by the available information. In this study, non-folic acid users were daily users, purchased products via mail order and internet shops, used products not specifically labeled as being safe for prenatal use, and cited the importance of efficacy more frequently than only folic acid users (Table 3). When purchasing dietary supplements, most pregnant women prioritized the selection of safer products. However, some women tended to select products with ingredients from natural sources, so as to avoid synthetic additives. Overall, the findings indicate that much improvement is needed for the provision of information regarding the safety of dietary supplements.

The present research had several limitations. The participants of this study were not representative of the entire pregnant population of Japan because the cooperative geographical area included in this survey was limited and the effective response rate was low. A high number of participants were from the Kanto area because it was where the majority of the participating hospitals and public health centers were located, and because of the high

population density of the area, where approximately one-third of the Japanese population is found. Furthermore, the survey was cross-sectional and did not allow for causal inferences. Finally, we were unable to collect information about financial status due to constraints related to respondent burden. However, to the best of our knowledge, this is the first report to show dietary supplement use, with respect to folic acid, before and during pregnancy in Japan.

In conclusion, we found that 37% of Japanese pregnant women took daily dietary supplements, most of which contained folic acid (94%), and anticipated potential fetal health benefits (81%) despite the inappropriate timing of folic acid intake. We also revealed that the pregnant women were unaware of safety issues regarding dietary supplements. Therefore, it is necessary for healthcare professionals to advise pregnant women about when folic acid intake is recommended and what health risks are involved with the different kinds of dietary supplements available on the market.

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AUTHOR DISCLOSURES

There is no conflict interest on the part of any of the authors.

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[1]*Information Center, National Institute of Health and Nutrition, Tokyo, Japan*
[2]*Department of Nutrition and Health Promotion, Hiroshima Jogakuin University, Hiroshima, Japan*
[3] *Department of Nutritional Education, National Institute of Health and Nutrition, Tokyo, Japan*
[4]*Department of Obstetrics and Gynecology, Hamamatsu University School of Medicine, Hamamatsu, Japan*

日本懷孕婦女膳食補充劑不適當使用的盛行率

我們研究 1076 名多數為中後孕期的懷孕婦女，其膳食補充劑的使用及其特性。研究對象完成一個自填式問卷，包括社會人口學特性、補充劑使用及飲食態度的調查。整體的補充劑使用盛行率在懷孕前後並未改變(75%)；然而，懷孕後每日使用者增加近兩倍(20.2%提高至 37.2%)。在剛懷孕後，含葉酸補充劑的使用是為了胎兒健康。每日使用者多數年紀較大、對神經管缺陷(NTD)的風險認知較高、認為補充劑使用是可接受的、較少飲食焦慮並且接觸較多提供飲食意見者。受調查者使用單獨含葉酸或是混合其他成分的補充劑。葉酸攝取被認為可降低 NTD 危險性。然而，意識到懷孕後才開始使用補充劑，顯示缺乏對適當時機使用葉酸補充劑的認知。補充劑的資訊獲得大部分來自報紙、雜誌、傳單及商店。這些結果顯示更多關於葉酸攝取的理想時機及膳食補充劑的安全正確資訊需要被傳播。

關鍵字：膳食補充劑、懷孕、葉酸、資訊、日本