ISSN 2434-2688

Asian Journal of Dietetics

Vol.1 No.4, 2019

AJD
ASIAN JOURNAL OF DIETETICS

Official journal of the Asian Federation of Dietetic Associations (AFDA)

ISSN2434-2688

Asian Journal of Dietetics
Vol.1 No.4 2019

Contents

Originals

ORIGINAL

Low Iodine Diet Compliance before Radioactive Iodine Treatment and Scanning

Norshariza Jamhuri, Aini Masitah Mohamed, Siti Nuraini Ahmad Samwil, Aeininhayatey Abdullah, Zuwariah Abd. Rahman, Ho Chiou Yi*

Department of Dietetics and Food Services, National Cancer Institute (NCI), Ministry of Health Malaysia, Putrajaya, Malaysia.

(Received October 1, 2019)

ABSTRACT Radioactive iodine (RAI) therapy is commonly used in thyroid cancer patients after surgery to destroy residual tissue and prevent disease recurrence. A low iodine diet (LID) is prescribed two weeks before RAI and patient's compliance with LID is essentials to ensure the successful ablation rate. This study aimed to determine the level of LID compliance and effectiveness of current practice in delivering the information. There were 31 respondents been recruited and level of knowledge on LID, compliances to the diet, and sources of LID information were investigated. Advice on LID was given in two weeks before treatment and a self-answered feedback form were administered to all respondents prior to ward admission. Compliance rate towards LID advice was 93.6% whereby 48.4% had moderate knowledge on LID and 74.2% had moderate LID compliance. About 32.3% respondents admitted that they having difficulties in LID compliance within two weeks. Significant association were observed between levels of knowledge ($p < 0.01$) and occupational status ($p < 0.05$) with levels of compliances towards LID. No significant association were observed between levels of knowledge and sources of LID information. Overall, high compliances rate towards LID were achievable among patients undergo RAI treatment might be due to Malaysian's general iodine intake which is below from the recommended iodine intake. Patient's occupation and knowledge on LID had influences person's compliances towards restriction on iodine intake in food.
Keywords: Low iodine diet, radioactive iodine, compliance.

INTRODUCTION

Thyroid cancer is a disease with the appearance of abnormal cells in the thyroid gland. There are anaplastic thyroid cancers, follicular thyroid cancer, hurtle cell thyroid cancer, medullary thyroid cancer, and papillary thyroid cancer (*1)*. According to Malaysian National Cancer Registry Report 2007-2011, thyroid cancer had been ranked 17th in Malaysian males and 9th in females; the incidence rate was the highest among Malay population in both sexes (*2*). Radioactive iodine therapy (RAI) post thyroidectomy is one of the treatments for thyroid cancer to destroy residual tissue and prevent disease recurrence (*1*). There are several factors that might influence the likelihood of successful ablation and subsequently alter the effectiveness of the dose. The influence factors include the severity of the initial disease, the amount of residual thyroid tissue left after surgery (*3*), the radiation dose delivered by I-131, initial dose rate and the radioiodine uptake in the neck (*4- 6*).

Studies showed that there was a positive relationship between radioiodine uptake and dietary iodine consumption (*7*). As part of the RAI treatment, a low-iodine diet (LID) is generally recommended to patients before RAI treatment *(8)*. The LID aims to deplete whole-body iodine and then optimize RAI uptake in thyroid cells. An optimal radioactive iodine update might increase the effectiveness of the RAI treatment (*5*). Currently, there are several LID guidelines available which include recommendation of LID defined by an intake <50 µg/day for two weeks before I-131 ablation by American Thyroid Association, two-week LID before I-131 ablation by the British Thyroid Association, a three-week LID before I-131 administration by the European Thyroid

*To whom correspondence should be addressed: dtho@nci.gov.my

Cancer Taskforce and LID for 2-4 weeks before radioiodine scanning by the American Association of Clinical Endocrinologists (*5, 9, 10*). Sohn et al. (2013), included 295 post-surgical papillary thyroid carcinoma patients, showed that excessive iodine intake (UIE >250 µg/g Cr) before RAI treatment was associated with poor RAI outcomes (*11*). Yoo and colleagues (2012) demonstrated that the success rate of RAI for patients undergoing less strict LID and very strict LID was 80.3% and 75.6% respectively and concluded that very strict LID may not improve the success rate of initial RAI ablation therapy (*12*). However, the extent of patients' compliance with LID was remained unclear. Previous studies reported that there was patients' feedback regarding the palatability and facility of LID whereby they claimed that it was hard to comply with LID before RAI and subsequently they withdrew from medications (*5, 6*). Reasons for non-compliance to LID included unpalatable and difficult to comply with LID (*10*). Moreover, studies demonstrated that misconceptions, which caused by a lack of proper counseling, would reduce the compliance of LID (*8, 13*).

In the current setting, there are two methods to convey of LID information to patients who were scheduled for RAI which were a phone call or face-to-face interview and at least two weeks before ward admission. The level of compliance toward LID among these patients was undetermined. Hence, the current study aimed to determine patients' compliances with LID before RAI treatment and scanning as well as the effectiveness of current practice in delivering the information on LID towards patients' compliances.

METHODS

Selection of respondents

A cross sectional study was conducted among patients two weeks before radioiodine scanning and treatment in National Cancer Institute. Patients who undergoing RAI treatments or scanning and able to communicate verbally were approached. Consented subjects were recruited in this study. Respondents with communication problem and those who chose not to provide informed consent were excluded from this study. According to Browne RH (1995) (*14*), recommendation of a minimum sample size of 30 samples per group as a rule of thumb and justifies based on rationale about feasibility and precision about the mean and variance. Ethical approval was obtained from Medical Research and Ethical Committee (MREC), Ministry of Health with reference number NMRR 17-2206-37811.

Data Collection

All consented respondents involved in this study were educated on the preparation and management of LID before the radioiodine scanning and treatment session. During the session, a healthcare staff will inform respondents regarding food to avoid such as fish, seafood and others. Then the respondents maintained the LID for two weeks before RAI. Data collection was conducted via feedback forms that were given to all consented respondents before the admission to the nuclear medicine ward and be filled up by respondents themselves. The feedback form was divided into four main sections as follow; Section A (Socio-demographic), Section B (Knowledge on LID Intake), Section C (Compliances towards LID) and Section D (Sources of LID information). Section A was regarding the information on age, weight, height, education level, marital status, ethnic, religion and employment status were obtained from the respondents. Height and weight were measured by staff nurse during admission using *Detecto* scale.

In section B, the knowledge of LID was evaluated through five items including the type of food allowed and not allowed to eat (scale: yes, no). Meanwhile, in section C, evaluations on respondents' compliance were done based on twelve questions on a high iodine food item checklist (scale: yes, no, not sure). Patients were then classified as having high, moderate and low knowledge if answered 5 "No", 3-4 "No" and 2 and below the question "No", respectively. Then, patients were classified as high compliance, if answered 17 "No answer". Moderate and low compliance was indicated if patients answered 9-16 "No" answer and 8 and below "No" answer, respectively.

Data Analysis

All data were analysed using the IBM SPSS Statistic version 22.0 (Armonk, NY: IBM Corp). Continuous data such as age, weight and height were presented in means, standard deviation while categorical data such as educational level, marital status, ethnic, religion and occupation were presented in frequency and percentage. Categorical data was analysed using Chi-square or Fisher's exact test. A value of $p < 0.05$ is considered statistically significant.

RESULTS

A total of 31 respondents who received radioiodine scanning and treatment, were recruited. Socio-demographic characteristic of study group is given in Table 1. The result shows that 48.4% and 74.2% respondents had moderate knowledge on LID and moderate compliance towards LID respectively as in Table 2. As shown in Table 3, Fisher's exact test indicated that there was a significant association between levels of knowledge and levels of compliances towards LID ($p<0.05$). However, there

was no significant association between levels of knowledge and type of information media, ethnic group and occupation. As shown in Table 4, Fisher's exact test indicated that there was no significant association between levels of knowledge with a person of delivery information (p>0.001). In Table 5, several questions were asked to determine the source of LID information that is given to respondents. There were 96.8% of respondents admitted that they were informed on LID and 93.6% of respondents were compliance with LID advice.

Table 1. Socio-demographic characteristic of respondents

Characteristics	**n (%)**
Ethnics	
Malay	21 (67.7)
Chinese	4 (12.9)
Indian	5 (16.1)
Others	1 (3.2)
Religion	
Islam	22 (71)
Buddha	2 (6.4)
Hindu	4 (12.9)
Christian	3 (19.7)
Occupation	
Employed	14 (45.1)
Unemployed	17 (54.8)
Marital Status	
Single	5 (16.1)
Married	23 (74.2)
Divorced	3 (9.7)
Education Level	
Primary	4 (12.9)
Secondary	19 (65.5)
Tertiary	8 (27.5)

Table 2. Respondents' knowledge and compliances towards Low Iodine Diet (LID)

Characteristic	**n (%)**		
	Low	**Moderate**	**High**
Level of knowledge	6 (19.4)	15 (48.4)	10 (32.3)
Level of Compliances	2 (6.5)	23 (74.2)	6 (19.4)

Table 3. Association between ethnic, occupation, media of delivery information, respondents' level of knowledge and compliances towards LID

Variable	***n***	**Compliances, n (%)**			***p value*** [a]
		Low	**Moderate**	**High**	
Knowledge					<0.01*
Low	6	1 (6.7)	5 (83.3)	0 (0)	
Moderate	15	1 (6.7)	14 (93.3)	0 (0)	
High	10	0 (0)	4 (40.0)	6 (60.0)	
Ethnic					0.136
Malay	21	2 (9.5)	16 (76.2)	3 (14.3)	
Chinese	4	0 (0.0)	1 (25.0)	3 (75.0)	
Indian	5	0 (0.0)	5 (100.0)	0 (0.0)	
Others	1	0 (0.0)	1 (100.0)	0 (0.0)	
Occupation					0.027*
Employed	14	1 (7.1)	10 (71.4)	3 (21.4)	
Unemployed	17	1 (58.8)	13 (76.5)	3 (17.6)	
Media of Delivery Information					
Phone	13	2 (15.4)	9 (69.2)	2 (15.4)	0.316
Interview	18	0 (0.0)	14 (77.8)	4 (22.2)	

[a]*Fisher's exact test; n = frequencies; *p<0.05*

Table 4. Association between levels of knowledge with person of delivery information

Variable	***n***	**Knowledge, n (%)**			***p value*** [a]
		Low	**Moderate**	**High**	
Person of deliver information					0.359
Staff nurse	23	5 (21.7)	11 (47.8)	7 (30.4)	
Doctor	8	1 (12.5)	4 (50)	3 (37.5)	

[a]*Fisher's exact test; n = frequencies*
**p<0.05*

Table 5. Source of information on low-iodine diet (LID)

Statement (Answer)	**Yes (%)**
Have you been advised on low iodine diet prior to Radioactive Iodine (RAI) treatment?	96.8
Do you practice diet low in iodine before Radioactive (RAI) treatment?	93.6
Who inform you regarding a low iodine diet prior to treatment Radioactive Iodine (RAI) treatment?	
Staff nurse	74.2
Doctor	25.8
When were you informed on the diet low in iodine?	
One-month prior treatment	67.7
2 weeks' prior treatment	9.7
Others	22.6
Where do you get information on low-iodine diet?	
Phone	41.9
Interview	58.1
Do you have difficulty to follow low-iodine diet for 2 weeks?	
Yes	32.3
No	67.7

DISCUSSION

Low iodine diet (LID) was defined by an intake less than 50µg per day for two weeks by American, British and European Thyroid Association (*15*) while Korean Thyroid Association defined LID by an intake less than 100µg per day (*16*). LID was always prescribed to patients undergoing RAI treatment to increase the radio-iodide accumulation in thyroid remnants. In thyroid carcinoma, decrease uptake and shorter effective half-life of radio-iodide cause negative effect towards the dose of radiation in tumor tissue when compared to normal tissue (*4*). One method used to enhance uptake is to deplete the plasma inorganic iodide pool before the administration of radio-iodide[6]. A study by Lee *et al*. (2014) in Korea shows that a strict LID for one week is sufficient to achieve an adequate decreased of the body iodine pool before RAI (*4*). In theory, low plasma iodide concentration will increase the expression of sodium iodide symporter and leads to a higher specific activity of radio-iodide (*15*). Prescription of LID will limit iodide intake in achieving depletion of iodide in the body and enhances the uptake of radioactive iodine by remaining thyroid cells, increasing the effectiveness of radioactive iodine treatment (*17*).

The iodine content of foods varies with geographic location ranging from 30µg/100g to 800µg/100g based on the World Health Organisation (WHO)/Food and Agriculture Organization of the United Nations (FAO) (*18, 19*). The coastal regions of the world are much richer in iodine content than the soils further inland. Population living near the sea and consuming seaweeds and reef fish, such as the Korean population have 'more than adequate' iodine intake in their diet *(16).* Present findings showed high compliances with LID is due to the normal eating habits of Malaysian whereby there was moderate to low intake of iodine in their daily food intake (*11*). Urinary iodine excretion, thyroid size using ultrasonography, thyroid-stimulating hormone (TSH) and thyroglobulin are the indicators recommended by the WHO/United Nations Children's Fund (UNICEF)/International Council for Control of Iodine Deficiency Disorders (ICCIDD) (2007) for assessing iodine nutrition iodine nutrition worldwide (*19, 20*). A urinary iodine on centration of above 100µg/L corresponds to a dietary iodine intake of 150µg/day (*21).*

The present finding resulted in higher knowledge improved LID compliance and consistent with study finding by Moon (2012) where patients were confident in avoiding food with high iodine content and selecting food with low iodine content and did not view these items as barriers (*21*). Chung et al. (2013) suggested that if the respondents adequately educated, and if their compliance was regularly monitored, one week of LID may be sufficient before RAI therapy (*22*). Choi et al. (2008) also reported that most of the respondents could achieve iodine level below recommendations, after two weeks of stringent LID and advice from a specialized dietitian (*21, 23*). The compliances towards LID were associated with employment status which was supported by Galobardes B. (2001) whereby food availability in the workplace environment or social network and peer-groups does influence compliance towards dietary advice (*24*). Food intake and food habit among employed patients might be influenced by peers and social environment. However, other factors such as cultural, religious beliefs and food costs were not measured which may influence dietary intake (*24).*

CONCLUSION: High compliances rate towards LID were achievable among patients undergo RAI treatment might be due to Malaysian's general iodine intake is lower than the recommended iodine intake. Proper nutrition education for thyroid patients is effective to enhance compliance and to reduce perceived barriers on the low iodine diet.

Acknowledgement

We would like to thank the Director General of Health Malaysia for his permission to publish this article.

Funding Statement

This study is not funded by any organization.

Conflict of Interest

This study has no conflict of interest.

REFERENCES

1) Haugen BR, Alexander EK, Bible KC, Doherty GM, Mandel SJ, Nikiforov YE, Pacini F, Randolph GW, Sawka AM, Schlumberger M, Schuff KG. 2015 American Thyroid Association management guidelines for adult patients with thyroid nodules and differentiated thyroid cancer: the American Thyroid Association guidelines task force on thyroid nodules and differentiated thyroid cancer. Thyroid. 2016 Jan 1;26(1):1-33
2) Azizah AM, Nor Saleha IT, Noor Hashimah A, Asmah ZA, Mastulu W. Malaysian national cancer registry report 2007–2011. Malaysia cancer statistics, data and figure. Putrajaya: National Cancer Institute, Ministry of Health. 2016.
3) Beierwaltes WH, Rabbani R, Dmuchowski C, Lloyd RV, Eyre P, Mallette S. An analysis of" ablation of thyroid remnants" with I-131 in 511 patients from 1947-1984: experience at University of Michigan. Journal of nuclear medicine: official publication, Society of Nuclear Medicine. 1984 Dec;25(12):1287-93.
4) Lee M, Lee YK, Jeon TJ, Chang HS, Kim BW, Lee YS, Park CS, Ryu YH. Low iodine diet for one week is sufficient for adequate preparation of high dose radioactive iodine ablation therapy of differentiated thyroid cancer patients in iodine-rich areas. Thyroid. 2014 Aug 1;24(8):1289-96.
5) Morris LF, Wilder MS, Waxman AD, Braunstein GD. Reevaluation of the impact of a stringent low-iodine diet on ablation rates in radioiodine treatment of thyroid carcinoma. Thyroid. 2001 Aug 1;11(8):749-55.
6) Yang DU, Gao YH, Feng ZY, Meng FG, Fan LJ, Sun DJ. Serum Thyroglobulin—A Sensitive Biomarker of Iodine Nutrition Status and Affected by Thyroid Abnormalities and Disease in Adult Populations. Biomedical and environmental sciences. 2017 Jul 1;30(7):508-16.
7) Pittman Jr JA, Dailey III GE, Beschi RJ. Changing normal values for thyroidal radioiodine uptake. New England Journal of Medicine. 1969 Jun 26;280(26):1431-4.
8) Sawka AM, Ibrahim-Zada I, Galacgac P, Tsang RW, Brierley JD, Ezzat S, Goldstein DP. Dietary iodine restriction in preparation for radioactive iodine treatment or scanning in well-differentiated thyroid cancer: a systematic review. Thyroid. 2010 Oct 1;20(10):1129-38.
9) Maxon HR, Thomas SR, Boehringer A, Drilling J, Sperling MI, Sparks JC, Chen IW. Low iodine diet in I-131 ablation of thyroid remnants. Clinical nuclear medicine. 1983 Mar;8(3):123-6.
10) Maxon HR, Thomas SR, Hertzberg VS, Kereiakes JG, Chen IW, Sperling MI, Saenger EL. Relation between effective radiation dose and outcome of radioiodine therapy for thyroid cancer. New England Journal of Medicine. 1983 Oct 20;309(16):937-41.
11) Sohn SY, Choi JY, Jang HW, Kim HJ, Jin SM, Kim SW, Suh S, Hur KY, Kim JH, Chung JH, Kim SW. Association between excessive urinary iodine excretion and failure of radioactive iodine thyroid ablation in patients with papillary thyroid cancer. Thyroid. 2013 Jun 1;23(6):741-7.
12) Yoo ID, Kim SH, Seo YY, Oh JK, Chung SK. The success rate of initial 131 i ablation in differentiated thyroid cancer: comparison

between less strict and very strict low iodine diets. Nuclear medicine and molecular imaging. 2012 Mar 1;46(1):34-40.

13) Rosenthal MS. Patient misconceptions and ethical challenges in radioactive iodine scanning and therapy. Journal of nuclear medicine technology. 2006 Sep 1;34(3):143-50
14) Browne RH. On the use of a pilot sample for sample size determination. Stat Med 1995;14: 1933–1940.
15) Selamat R, Mohamud WN, Zainuddin AA, Rahim NS, Ghaffar SA, Aris T. Iodine deficiency status and iodised salt consumption in Malaysia: findings from a national iodine deficiency disorders survey. Asia Pacific journal of clinical nutrition. 2010 Dec 1;19(4):578-85.
16) Ju DL, Park YJ, Paik HY, Kim MJ, Park S, Jung KY, Kim TH, Choi HS, Song YJ. Dietary evaluation of a low-iodine diet in Korean thyroid cancer patients preparing for radioactive iodine
21) Moon JA, Yoo CH, Kim MH, Lee SM, Oh YJ, Ryu YH, Lee YS, Chang HS, Park CS, Lee KE. Knowledge, self-efficacy, and perceived barriers on the low-iodine diet among thyroid cancer patients preparing for radioactive iodine therapy. Clinical nutrition research. 2012 Jul 1;1(1):13-22.
22) Chung JH. Low iodine diet for preparation for radioactive iodine therapy in differentiated thyroid carcinoma in Korea. Endocrinology and Metabolism. 2013 Sep 1;28(3):157-63.

therapy in an iodine-rich region. Nutrition research and practice. 2016 Apr 1;10(2):167-74.

17) Perros P, Boelaert K, Colley S, Evans C, Evans RM, Gerrard BA G, Gilbert J, Harrison B, Johnson SJ, Giles TE, Moss L. Guidelines for the management of thyroid cancer. Clinical endocrinology. 2014 Jul;81:1-22.
18) WHO/FAO. Iodine. In: Vitamin and mineral requirements in human nutrition. 2nd Edition. Report of a Joint FAO/WHO Expert Consultation. FAO. 2004 pp 303-317
19) World Health Organization. Assessment of iodine deficiency disorders and monitoring their elimination: a guide for programme managers. 2007.
20) Ma ZF, Venn BJ, Manning PJ, Cameron CM, Skeaff SA. The sensitivity and specificity of thyroglobulin concentration using repeated measures of urinary iodine excretion. European journal of nutrition. 2018 Jun 1;57(4):1313-20.
23) Choi JH, Kim HI, Park JW, Song EH, Ko BJ, Cheon GJ, Kim BI. Analysis of urine iodine excretion decrease by two-week stringent low iodine diet for remnt thyroid ablation with radioactive iodine in Korean patients with thyroid cancer; prospective study. Nucl Med Mol Imaging. 2008 Oct 1;42(5):375.
24) Galobardes B, Morabia A, Bernstein MS. Diet and socioeconomic position: does the use of different indicators matter?. International journal of epidemiology. 2001 Apr 1;30(2):334-40

ORIGINAL

Substituting Pre-Germinated Brown Rice for White Rice Reduced Body Weight in Healthy Overweight Vietnamese Women

Vu Anh Linh*[1], Bui Thi Nhung[2], Le Danh Tuyen[2], Nguyen Do Van Anh[2], Yukihiko Ito[3], Kei Yui[3], Shigeru Yamamoto[1]

[1]*International Nutrition, Graduate School of Human Life Science, Jumonji University, Saitama 352-8510, Japan,*
[2]*National Institute of Nutrition, Hanoi, Vietnam,*
[3] *FANCL Research Center, Yokohama 244-0806, Japan*

(Received October 1, 2019)

ABSTRACT *Background:* Pre-germinated brown rice (PGBR) is slightly germinated by soaking brown rice (BR) in water, which reduces the hardness of BR and makes it easier and tastier to eat. There are studies that have shown the effectiveness of PGBR on high blood glucose and cholesterol concentrations mainly in diabetes mellitus (DM) patients but only a few have investigated the effect on body weight, perhaps because the subjects are usually instructed to reduce their energy intake and body weight. We observed a decrease in body weight in our previous study in pre-diabetes subjects who were not on energy restriction or drug treatment. Therefore, for confirmation, we conducted this study in healthy persons. *Purpose:* To study the effect of PGBR on weight reduction in healthy overweight Vietnamese women. *Design:* The study was a randomized control trial that was conducted in 72 healthy overweight women. All participants were randomly assigned to consume PGBR or white rice (WR) as staple foods for 16-wks. Anthropometric parameters, blood pressure, physical activity, and a nutrition survey were conducted at baseline, 8-wk, and 16-wk. Fasting blood was withdrawn and biochemical analysis was conducted at baseline and 16-wk. Acceptability was ascertained by questionnaire after the study. *Results:* After the 16-wk intervention, body weight in the PGBR group decreased from 63.3 ± 6.5 kg to 61.2 ± 6.5 kg ($p < 0.001$), while body weight in the WR group was maintained. Waist and hip circumferences in the PGBR group decreased, for waist -3.6 ± 2.0 cm;($p < 0.001$) and hip -1.8 ± 2.2 cm; ($p < 0.001$) but not in the WR group. Serum total cholesterol and triacylglycerol concentrations (mg/dL) were abnormally high in the both groups at baseline, however, at 16-wk in PGBR group decreased from 205 to 182 ($p < 0.001$) and from 133 to 108 ($p < 0.05$), respectively, but not in WR group. Energy intakes (kcal/day) in the PGBR group decreased significantly ($p < 0.05$) at baseline, 8-wk, and 16-wk were 1912, 1857 and 1803, respectively but not in the WR group (1902, 1882 and 1879, respectively). *Conclusion:* These findings suggest positive effects of PGBR on controlling body weight in overweight healthy women as well as on the blood lipid and sugar profiles.
Keywords: Body weight, obesity, pre-germinated brown rice, dietary fiber, Vietnamese.

INTRODUCTION

In Asian countries, as well as the rest of the world, the incidence of obesity has| been rising rapidly. For example, the percentage (%) of adult women aged 20 and older with Body Mass Index (BMI) higher than 25 in 2014 was 48.6 in Malaysia, 39.7 in Thailand, 32.5 in Singapore,

*[1] To whom correspondence should be addressed: shigeruy@juminji-u.ac.jp

30.9 in Taiwan, 30.6 in Indonesia, 27.4 in China, 27.2 in Korea, 20.7 in India and 17.6 in Japan (1). For Vietnamese adults aged 25-64 years, the prevalence (%) of overweight and obesity (BMI higher than 25) was 20.3 and that of non-communicable diseases was: high blood pressure 20.3, diabetes mellitus and impaired fasting blood glucose 5.7 and high blood cholesterol 32.4 (2).

There are studies that whole grains can prevent obesity, diabetes and heart disease (3-8). Brown rice (BR) is a whole grain, however, people prefer white rice (WR) because BR itself has an unappealing taste and texture. WR is made by polishing BR and removing its surface, which makes WR softer and tastier than BR. According to a Vietnam national nutrition survey in 2009-2010, more than 66% of the energy consumption came from WR (9).

Pre-germinated brown rice (PGBR) is slightly germinated by soaking BR in water; it becomes softer in texture and has a taste close to that of WR. It maintains the various qualities of BR, for example, the fiber in BR (10, 11). We have been studying the effects of PGBR on blood glucose and lipids, mostly in DM patients (12-15). We did not observe the effect of PGBR on body weight in most of these studies, because once patients are diagnosed as DM, they are taught to reduce energy intake and body weight decreases. However, in our previous study we studied the effects on blood glucose and lipids in pre-diabetes persons without any dietary or drug management (15). Unexpectedly, we observed a decrease in body weight, which made us interested in observing the effect of PGBR on body weight in healthy overweight persons, therefore this study was conducted.

MATERIALS AND METHODS

***Setting and participant study*:** The study protocol was approval by the Scientific and Ethical Committee of the National Institute of Nutrition, Hanoi, Vietnam**.** The study was designed in conformity with the Declaration of Helsinki on Human Studies. A total of 473 women living in 2 communes in suburban Hanoi City, Vietnam, were screened for body anthropometrics and were asked their medical history. All participants were fully informed of the content and schedule of the study. The eligibility criteria for participants were the following: 1) age range: 30-65 y, 2) BMI: 23-35 kg/m^2. The exclusion criteria for participants were the following: 1) those who were currently pregnant or had plans for pregnancy during the study period (by interview), 2) who were currently suffering from serious diseases such diabetes, kidney, mental, hepatic (by medical history), 3) who were using or had plans for weight loss therapy during the study period, 4) who were using or planning to use weight loss supplements or medicine during the study period, 5) who were already eating brown rice or PGBR. After screening, 72 participants met the inclusive criteria.

***Study design*:** The study was a randomized control trial that was conducted in 72 healthy overweight women. Subjects were randomized to be divided into PGBR (n=36) and WR (n=36) groups. All participants in the PGBR group were instructed to use PGBR as their staple food for 16-wk, and all participants in WR group were instructed to use WR as their staple food for 16-wk. At baseline and 16-wk of the study, blood samples and physical activity of both groups were determined. At baseline, 8-wk, and 16-wk, anthropometrics parameters, blood pressure, and nutrition survey were conducted. All participants were free-lifestyle living and instructed that they should not change lifestyles and food habits during the study period. The primary outcome was body weight loss.

***Trial foods*:** Both PGBR and WR samples were made from the same Japonica rice variety named Hoshinoyume, and obtained from Hokkaido, Japan (FANCL Tokyo, Japan). All participants were provided aseptic packaged boiled PGBR and WR. They were about 160g (about 220 kcal) which can be distributed at normal temperature and is eatable only by heating with a microwave oven for about 2 minutes or in boiling water for about 15 minutes.

Anthropometric measurements and blood pressure: Body height and weight were measured in the morning after a 12h-night fast and with light clothing and barefoot. Body mass index (BMI) was calculated by body weight per height squared (kg/m^2). Waist circumference was measured at the midpoint between the lower margin of the last palpable rib and the top of the

iliac crest. Hip circumference was measured around the widest portion of the buttocks. Body fat percentage was measured by the bioelectrical impedance method using the Omron scale (HBF-212b, Omron Co., Kyoto, Japan). Blood pressure was measured by using a standardized automated sphygmomano-meter (Omron HEM-6113, Tokyo, Japan) after 10 minutes of resting in seated position.

Blood sample: Total 10 ml of blood was withdrawn via venipuncture after a 12h-night fast. Serum glucose was measured with the use of an enzyme-couple kinetic assay and blood serum was kept at -80^{o}C until analysis. Serum total cholesterol and triacylglycerol were measured by the enzymatic method. Serum HDL-cholesterol and LDL-cholesterol were measured by the enzymatic and direct methods. All measurements were conducted by AU480 analyzer-Beckman coulter-USA at the laboratory of the National Institute of Nutrition, Hanoi, Vietnam.

***Nutrition survey and physical activity*:** We used a 24h dietary recall for 3 days (2 weekend days and 1 weekday) at baseline, 8-wk, and 16-wk. Each participant was interviewed by a skilled dietitian from the National Institute of Nutrition, Hanoi, Vietnam. Energy, carbohydrate, lipid, and dietary fiber intake were calculated based on the Vietnamese Food Composition Table 2007 (16). Physical activity at baseline, 8-wk, and 16-wk was assessed by pedometer for steps measurement. Each time steps were measured for 3 consecutive days.

Acceptability: Overall taste, softness and stickiness were evaluated by scores from 1 to 3 (3, good; 2, moderate; 1, poor)

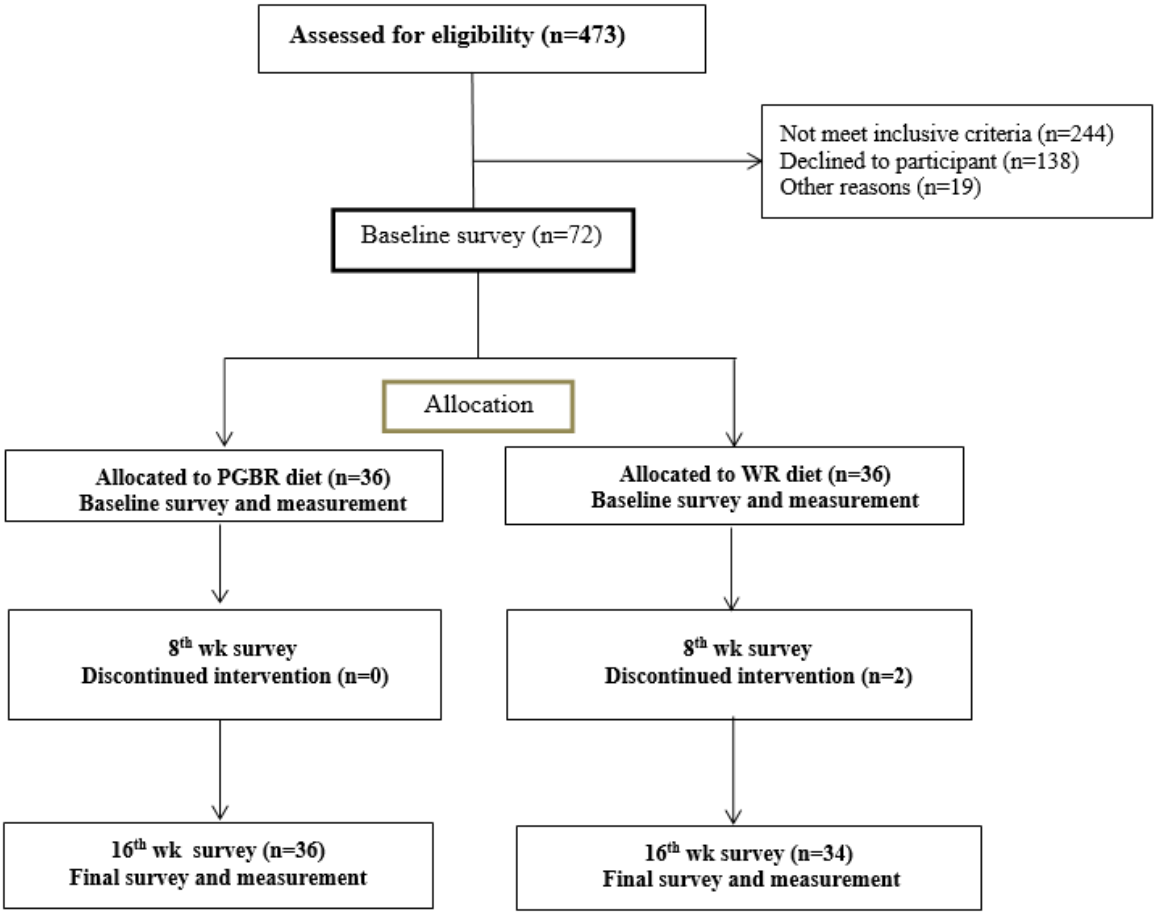

Fig.1. Flow chart of the study

***Statistical methods*:** Data were analyzed by using JMP version 11 (SAS Institute Inc., Cary, NC). Values are reported as means ± standard deviations (SD). Quantitative variables were checked for normal distribution and compared by the Student *t*-test, *p*-values of less than 0.05 (with 2-sided) were considered statistically significant for all the analyses. Baseline characteristics of the 2 groups were compared using Student's *t*-test. Within-group differences were compared using the paired Student *t*-test.

RESULTS

Baseline characteristic of participants: The 72 enrolled participants were randomly assigned to the PGBR group (n=36) or the WR group (n=36). A total of 70 participants completed the study (2 participants in the WR group discontinued intervention due to personal reasons). Table 1 shows baseline characteristics of the study population. There was no significant difference in age ($p = 0.86$), body height ($p = 0.80$), body weight ($p = 0.55$), body fat percentage ($p = 0.71$), waist circumference ($p = 0.55$), hip circumference ($p = 0.90$), systolic blood pressure ($p = 0.06$), diastolic blood pressure ($p = 0.94$), total cholesterol ($p = 0.48$), LDL-cholesterol ($p = 0.68$), HDL-cholesterol ($p = 0.06$), triacylglycerol ($p = 0.66$), or blood glucose ($p = 0.16$) between the PGBR and WR groups at baseline. ***Change of body weight and body composition and blood pressure:*** Table 2 shows that the body weight and BMI in the PGBR group decreased from 63.3 ± 6.6 kg and 27.2 ± 2.5 at baseline to 62.1 ± 6.5 kg ($p < 0.001$) and 26.6 ($p < 0.001$) at 8-wk and 61.2 ± 6.5 kg ($p < 0.001$) and 26.3 ± 2.5 ($p < 0.001$) at 16-wk, while those in the WR group were not significantly different.

In addition, body fat percentage and waist and hip circumferences decreased significantly from 38.3 ± 3.2 %, 87.3±6 cm and 99.4 ± 5.1 cm at baseline to 37 ± 2.9 % ($p < 0.001$), 84.6 ± 6.1 cm ($p < 0.001$) and 97.8 cm ($p < 0.001$) at 8-wk, and to 35.3 ± 2.2 % ($p < 0.001$), 83.7 ± 5.8 cm ($p < 0.001$) and 97.6 cm ($p < 0.001$) at 16-wk, while only waist circumference in the WR group decreased significantly from 88.2 ± 7.3 cm at baseline to 86.5± 7.1 cm ($p < 0.05$) at 16-wk. In the PGBR group there was a slight decrease in systolic blood pressure (mmHg) from 127.4 ± 10.8 at baseline to 123.6 ± 10 ($p < 0.05$) at 8-wk and 119.8 ± 12.1 ($p < 0.001$) at 16-wk but in the WR group there was slight increase from 79.6 ± 7.3 at baseline to 82 ± 9.1 ($p < 0.05$) at 8-wk and 81.7 ± 8 ($p < 0.05$) at 16-wk.

Table 1. General characteristics of subjects

	PGBR (n=36)			WR (n=34)			P-values
	Mean	±	SD	Mean	±	SD	
Age (year)	43.3	±	7.0	43.6	±	7.7	0.81
Height (cm)	152.6	±	4.9	152.3	±	5.2	0.83
Weight (kg)	63.3	±	6.6	64.4	±	8.7	0.53
BMI (kg/m^2)	27.2	±	2.5	27.7	±	3.6	0.61
Body fat (%)	38.3	±	3.2	38.6	±	4.0	0.66
Waist circumference (cm)	87.3	±	6.0	88.2	±	7.3	0.61
Hip circumference (cm)	99.4	±	5.1	99.2	±	6.0	0.94
Systolic blood pressure (mmHg)	127.4	±	10.8	122.8	±	9.0	0.09
Diastolic blood pressure (mmHg)	79.6	±	7.3	81.5	±	8.0	0.84
Total cholesterol (mg/dL)	204.6	±	42.9	199.0	±	16.5	0.48
LDL cholesterol (mg/dL)	132.8	±	46.1	128.9	±	29.4	0.46
HDL cholesterol (mg/dL)	47.7	±	10.2	43.6	±	6.7	0.08
Triacylglycerol (mg/dL)	170.9	±	60.2	170.0	±	85.1	0.73
Blood glucose (mg/mL)	94.8	±	7.2	96.9	±	4.6	0.28

All values are means and standard deviations

P values obtain from independent sample t-test between PGBR and WR groups

However, mean values of both systolic blood pressure and diastolic blood pressure in the PGBR group were within normal range. The others parameters in table 2 were not significantly different in comparison with baseline data.

Blood biochemical parameters: The change in blood parameters are indicated in table 3. Concentrations of blood parameters (mg/dL) in the PGBR group at baseline and 16-wk decreased; total cholesterol from 204 ± 42.9 to 182.1 ± 31.6 ($p < 0.001$), LDL-cholesterol from 132.8 ± 46.1 to 108.4 ± 28.8 ($p < 0.05$), triacylglycerol from 170.9 ± 60.2 to 135.2 ± 71.7, and glucose from 94.8 ± 7.2 ($p < 0.05$) but in the WR group none of these changed. HDL-cholesterol of both the PGBR and WR groups increased significantly at 16th-wk in comparison with baseline ($p < 0.05$).

Nutrition survey and physical activity: Table 4 shows the energy and nutrient intakes and physical activity of the PGBR and WR groups at baseline, 8-wk, and 16-wk. In the PGBR group, energy, protein and carbohydrate at 16-wk decreased significantly in comparison with baseline ($p < 0.05$). Dietary fiber intake of the PGBR group at baseline was 6.5 ± 1.7 g and increased to 12.6 ± 2.6 g ($p < 0.001$) at 8-wk and 14.0 ± 3.6 g ($p < 0.001$) at 16-wk. In the WR group, none of these items changed significantly.

Fig. 2 shows the comparison of scores of overall taste, softness and stickiness between PGBR and WR. They were evaluated by scores from 1 to 3 (3 good; 2 moderate; 1 poor). WR was softer and more sticky than PGBR ($p<0.05$) but the overall taste was similar.

Table 2. Change in anthropometric parameters and blood pressure

	PGBR (n=36)						White rice (n=34)					
	Baseline		8-wk		16-wk		Baseline		8-wk		16-wk	
	Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD	
Weight (kg)	63.3 ± 6.6		62.1 ± 6.5**		61.2 ± 6.5**		64.4 ± 8.7		64.4 ± 8.8		63.8 ± 9.0	
BMI (kg/m^2)	27.2 ± 2.5		26.6 ± 2.5**		26.3 ± 2.5**		27.7 ± 3.3		27.7 ± 3.4		27.5 ± 3.4	
Body fat (%)	38.3 ± 3.2		37.0 ± 2.9**		35.3 ± 2.2**		38.2 ± 4.0		38.6 ± 4.0		38.0 ± 4.2	
Waist circumference (cm)	87.3 ± 6.0		84.6 ± 6.1**		83.7 ± 5.8**		88.2 ± 7.3		88.0 ± 6.8		86.5 ± 7.1*	
Hip circumference (cm)	99.4 ± 5.1		97.8 ± 4.9**		97.6 ± 5.0**		99.2 ± 6.0		99.3 ± 5.9		98.8 ± 6.1	
Systolic blood pressure (mmHg)	127.4 ± 10.8		123.6 ± 10.0*		119.8 ± 12.1**		122.8 ± 9.0		124.0 ± 13.1		120.9 ± 10.1	
Diastolic blood pressure (mmHg)	79.6 ± 7.3		82.0 ± 9.1*		81.7 ± 8.0*		79.5 ± 6.0		81.5 ± 8.0		80.1 ± 7.8	

All values are means and standard deviations

*, ** Significantly different compared to baseline by paired *t*-test; p<0.05 and p<0.001, respectively

Table 3.Blood parameters of PGBR and WR groups at baseline and final

	PGBR (n=36)				WR (n=34)			
	Baseline		16-wk		Baseline		16-wk	
	Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD	
Total cholesterol (mg/dL)	204.6 ± 42.9		182.1 ± 31.6**		199.0 ± 16.5		205.6 ± 22.7	
LDL cholesterol (mg/dL)	132.8 ± 46.1		108.4 ± 28.8*		128.9 ± 29.4		122.5 ± 26.5	
HDL cholesterol (mg/dL)	47.7 ± 10.2		50.7 ± 10.0*		43.6 ± 6.7		47.1 ± 9.1*	
Triacylglycerol (mg/dL)	170.9 ± 60.2		135.2 ± 71.7*		178.7 ± 86.8		170.0 ± 85.1	
Blood glucose (mg/mL)	94.8 ± 7.2		90.2 ± 10.9*		96.9 ± 4.6		98.7 ± 8.6	

All values are means and standard deviations

*, ** Significantly different compared to baseline by paired *t*-test; p<0.05 and p<0.001, respectively

Table4.Nutrient intakes and physical activity

	PGBR (n=36)									WR (n=34)								
	Baseline			8-wk			16-wk			Baseline			8-wk			16-wk		
	Mean	±	SD	Mean	±	SD	Mean	±	SD	Mean	±	SD	Mean	±	SD	Mean	±	SD
Energy (Kcal)	1911.7	±	271.8	1857.2	±	218.0	1803.1	±	211.5*	1901.9	±	186.9	1882.8	±	190.2	1878.9	±	205.6
Protein (g)	69.5	±	11.5	69.7	±	9.7	66.3	±	12.0*	70.4	±	12.0	68.7	±	10.0	69.2	±	8.1
Lipid (g)	46.0	±	8.4	44.8	±	8.1	46.4	±	7.4	41.5	±	8.1	40.5	±	6.5	42.5	±	6.8
Carbohydrate (g)	304.9	±	53.3	293.9	±	45.7	280.1	±	35.1*	311.8	±	41.7	310.9	±	36.7	304.8	±	39.7
Fiber (g)	6.5	±	1.7	12.6	±	2.8**	14.0	±	3.6**	6.5	±	2.6	6.5	±	3.3	6.8	±	1.8
Physical activity (steps)	6978	±	2821	7498	±	3732	7085	±	3514.1	6869	±	2523	7268	±	3540	6886	±	2100

All values are means and standard deviations

*, ** Significantly different compared to baseline by paired *t*-test; $p<0.05$ and $p<0.001$, respectively

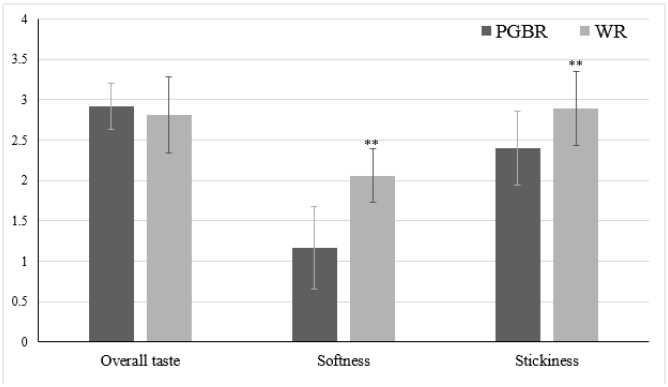

Fig. 2. Acceptability of PGBR (3 good; 2 moderate; 1 poor) ** Statistically different ($p<0.01$)

DISCUSSION

The present 16-wk randomized, controlled trial suggests that replacing WR with PGBR might have beneficial effects for controlling body weight in healthy overweight and obese women. The main focus of the study was reduction of body weight with PGBR; body weight (kg) of the PGBR group decreased from 63.3 to 61.2 (a 2.1 kg decrease in 16-wk), while the WR group changed only slightly, from 64.4 to 63.8 (only a 0.6 kg decrease). We also observed a decrease in waist and hip circumferences and beneficial effects in blood lipid profiles. It is well-known that body weight is controlled by energy balance: energy IN (food intake) and energy OUT (physical activity). We measured physical activity by pedometer and did not observe any difference at baseline, 8-wk, and 16-wk in either group. (Table 4). From these data total energy intake and physical activity (steps), it might be inferred that body weight in the PGBR group may have decreased from reducing their energy balance.

However, in our previous study of DM patients who had received nutrition education from doctors or dietitians (12-14), we did not observe a reduction of body weight in the PGBR group except for one study conducted in pre-DM patient without nutrition education (15). In the present study, we selected healthy overweight subjects without any health problems and confirmed clearly that PGBR was useful in reducing body weight.

In this study all the WR and PGBR was supplied by us for the whole study period (4 months). Rice is the subjects' staple food and subjects ate rice at least twice over 3 meal times (breakfast, lunch and dinner). Both the WR and PGBR were same strain of rice produced in the

same area and packets of about 60g (250-300kcal) are available in the market. Packets could be stored at normal temperatures and made edible by heating in a microwave oven for about 2 minutes or in boiling water for about 15 minutes. The use of this pre-packaged rice made the study easier for subjects as well as for the researchers and dropouts were limited to only a few. Researchers were not concerned with rice for other family members.

With regard to the decreased energy intake in the PGBR group, we had to determine whether the taste of PGBR was acceptable to the subjects. People prefer WR to BR, because WR is softer and tastier than BR. WR is made by polishing BR and removing its surface. PGBR is slightly germinated by soaking BR in water. In the process, the BR skin is broken apart and becomes soft. From our sensory test, we found that although the PGBR was a little harder and less sticky than WR, the taste was evaluated as high as WR. From these results we concluded that the decrease of energy intake in the PGBR group was not due to its taste.

Dietary fiber might affect body weight through multiple pathways, including through modulation of insulin secretion and control of satiety (17-19). In our study, the intake of dietary fiber (g/day) in the PGBR group was 12.6 at 8-wk and 14.0 at 16-wk and much higher than that at baseline (6.5). There was no change in the WR group being 6.5, 6.5 and 6.8 at baseline, 8-wk and 14.0 at 16-wk, respectively.

Many studies have investigated the relation of low glycemic (GI) index foods and body weight. PGBR contains higher dietary fiber and has a lower GI than WR (8). Previous studies showed that rapid absorption of glucose after consumption of high GI foods could lead to sharp rises in blood glucose and insulin levels; thus, glucose enters body tissues, inhibits lipolysis and induces lipogenesis and obesity. (20, 21).

Increased fiber makes the subjects feel full for a longer time, which might be associated with reduced hunger or increased satiety, leading to reduced total energy intake (22-25). Birketvedt et al (26) found that the addition of dietary fiber to a low-calorie diet significantly improved weight loss, with the placebo group losing 5.8 kg and the fiber-supplemented group losing 8.0 kg in overweight subjects.

With a longer chewing time and slower digestion and absorption, nutrient receptors in the gastrointestinal tract are stimulated for a longer time; this will prolong feedback to the satiety center in the brain and reduce energy intake (22, 23).

However, fiber alone is not enough to explain the effect of PGBR on body weight, because PGBR has various functional ingredients different from WR (27) and we do not know their possible effects on body weight. PGBR is richer than WR in vitamins, minerals and dietary fiber, γ-oryzanol, and ferulic acid and acylated steryl glucosides.

In conclusion, the present study shows that replacing WR with PGBR for a 16-wk intake could reduce body weight in healthy overweight women. From these findings, the rapid increase in overweight and obesity in Vietnam could be controlled by the use of PGBR.

Conflict of interests

The authors declare no conflict of interests regarding the publication of this article.

Acknowledgments

The authors are grateful to all participants and the staff members of the National Institute of Nutrition, Hanoi, and local public health officials for collaborating in the study. This study was supported by Jumonji University and the US-Japan Medical Science Program. We would like to thank Andrew R. Durkin, Professor Emeritus of Indiana University, Bloomington, IN, USA, for his careful editing of the English of this article.

REFERENCES

1) Bahar Karam Thailand Overweight prevalence second in Southeast Asia 2014 https://www.thailand-business-news.com /asean/49065-thailand-ranks-second-asean-prevalence-obesity-mcot-net.html (accessed on Aug 15, 2019).
2) Nguyen TT, Hoang MV. 2018. Review Article Non-communicable diseases, food and nutrition in Vietnam from 1975 to 2015: the burden and national response. Asia Pac J Clin Nutr. **27**:19-28 19
3) Liu S, Willett WC, Manson JE, Hu FB, Rosner B, Colditz G. 2003. Relation between changes in intakes of dietary fiber and grain products and changes in body

weight and development of obesity among middle-aged women. Am J Clin Nutr **78**:920-7.

4) Bazzano LA, Song Y, Bubes V, Good CK, Manson JE, Liu S. 2005. Dietary intake of whole grain and refined grain breakfast cereals and weight gain in men. Obes Res **13**:1952-60.
5) Sahyoun NR, Jacques PF, Xhang XL, Juan W, McKceown NM. 2006. Whole grain intake is inversely associated with metabolic syndrome and mortality in order adults. Am J Clin Nutr **83**:124-31.
6) McKeown NM, Yoshida M, Shea MK, Jacques PF, Lichtenstein AH, Rogers G, Booth SL, Saltzman E. 2009. Whole grain intake and cereal fiber are associated with lower abdominal adiposity in older adults. J Nutr **139**:1950-5.
7) Shimabukuro M, Higa M, Kinjo R, Yamakawa K, Tanaka H, Kozuka C, Yabiku K, Taira S, Sata M, Masuzaki H. 2014. Effects of the brown rice diet on visceral obesity and endothelial function: The BRAVO study. Br. J. Nutr **111**:310–320.
8) Kondo. K, Morino. K, Nishio. Y, Ishikado. A, Arima. H, Nakao. K, Nakagawa. F, Nikami. F, Sekine. O, Nemoto. K, Kondo. K, Morino. K, Nishio. Y, Ishikado. A, Arima. H, Nakao. K, Nakagawa. F, Nikami. F, Sekine. O, Nemoto. K. 2017. Fiber-rich diet with brown rice improves endothelial function in type 2 diabetes mellitus: A randomized controlled trial. Plos One 29;12: e0179869
9) National Institute of Nutrition. 2010. National Nutrition Survey 2009-2010. Hanoi Medical Publisher, Hanoi (in Vietnamese).
10) Seki T[1], Nagase R, Torimitsu M, Yanagi M, Ito Y, Kise M, Mizukuchi A, Fujimura N, Hayamizu K, Ariga T.2005 Insoluble fiber is a major constituent responsible for lowering the post-prandial blood glucose concentration in the pre-germinated brown rice. Biol Pharm Bull. **28**:1539-41.
11) Patil SB, Khan MK. Germinated brown rice as a value added rice product: A review. J Food Sci Technol. 2011;48:661-667.).
12) Ito Y, A Mizukuchi., M Kise, H Aoto, S Yamamoto, R Yoshihara. 2005; Postprandial blood glucose and insulin response to pre-germinated brown rice in healthy subjects. J. Med Invest. **52**: 159-164
13) Ito Y, Shen M, Kise M, Hayamizu K, Yoshino G, Yoshihara R. 2005. Effect of pre-germinated brown rice on postprandial blood glucose and insulin level in subjects with hyperglycemia. Jpn. J. Food Chem. 12:80-84.
14) Hsu TF, Kise M, Wang MF, Ito Y, Yang MD, Aoto H. 2008. Effects of pre-germinated brown rice on blood glucose and lipid levels in free-living patients with impaired fasting glucose or lipid levels. J Nutr Sci Vitaminol. **54:** 163-168.
15) Bui TN[1], Le TH, Nguyen do H, Tran QB, Nguyen TL, Le DT, Nguyen do VA, Vu AL, Aoto H, Okuhara Y, Ito Y, Yamamoto S, Kise M. 2014. Pre-germinated brown rice reduced both blood glucose concentration and body weight in Vietnamese women with impaired glucose tolerance. J Nutr Sci Vitaminol. **60:** 183-187.
16) National Institute of Nutrition 2007. Vietnamese Food Composition Table. Hanoi Medical publishing house. (in Vietnamese)
17) Heaton KW. 1973. Food fibre as an obstacle to energy intake. Lancet **2**:1418-21.
18) Lavin JH, Wittert GA, Andrews J, Yeap B, Wishart JM, Morris HA, Moriy JE, Horowitz M, Read NW. 1998. Interaction of insulin, glucagon-like peptide 1, gastric inhibitory polypeptide, and appetite in response to intraduodenal carbohydrate. Am J Nutr **68**:591-8.
19) de Vries J, Miller PE, Verbeke K. 2015. Effects of cereal fiber on bowel function: a systematic review of intervention trials. World J Gastroenterol; **21**:8952-63.
20) Pawlak DB, Bryson JM, Denyer GS, Brand-Miller JC. 2001. High glycemic index starch promotes hypersecretion of insulin and higher body fat in rats without affecting insulin sensitivity. J Nutr **131**:99-104.

21) Ludwig DS. 2002. The glycemic index: physiological mechanisms relating to obesity, diabetes, and cardiovascular disease. JAMA **287**:2414-23.
22) Wrick KL, Robertson JB, Van Soest PJ, Lewis BA, Rivers JM, Roe DA, Hackler LB. 1983. The influence of dietary fiber source on human intestinal transit and stool output. J Nutr;**113**:1464-79.
23) Andrade AM, Greene GW, Melanson KJ. 2008. Eating slowly led to decreases in energy intake within meals in healthy women. J Am Diet Assoc **108**:1186-91.
24) Scisco JL, Muth ER, Dong Y, Hoover AW. 2011. Slowing bite-rate reduces energy intake: an application of the bite counter device. J Am Diet Assoc **111**:1231-5.
25) Li J, Zhang N, Hu L, Li Z, Li R, Li C, Wang S. 2011. Improvement in chewing activity reduces energy intake in one meal and modulates plasma gut hormone concentration in obese and lean young Chinese men. Am J Chin Nutr **94**:709-16.
26) Birketvedt GS, Aaseth J, Florholmen JR, Ryttig K. 2000. Long-term effect of fibre supplement and reduced energy intake on body weight and blood lipids in overweight subjects. Acta Med **43**:129 –32.
27) Patil SB, Khan MK. 2011. Germinated brown rice as a value added rice product: A review. J Food Sci Technol. 48:661-66

ORIGINAL

Adolescents' Habitual Nutrient Intake Adequacy was Independent of Milk Provision in School Lunch in Japan: A Cross-sectional Study of Japanese Junior High School Female Students

Mai Matsumoto[1, 2], Ayumi Masumoto[3], Azusa Sakamoto[2],
Aki Saito[1], Shinji Ikemoto[2] *

[1] *Department of Nutritional Epidemiology and Shokuiku, National Institutes of Bioinnovation, Health and Nutrition., Shinjuku-ku, Tokyo, Japan*
[2] *Department of Human Nutrition, SEITOKU University., Matsudo-shi, Chiba, Japan*
[3] *Saitama city., Saitama-shi, Saitama, Japan*

(Received November 30, 2019)

ABSTRACT *Background and purpose*. Intake of dairy products in adolescence may be of importance in improving nutritional status. Most school lunch programs provide milk in Japan. The aim of this study was to assess the difference in habitual nutrient intake adequacy between Japanese junior high school girls who received milk in their school lunch program and those who did not. *Methods.* Participants were students aged 12-15 years who had school lunch with (n=306) or without milk (n=210). Dietary habits during the preceding month were assessed using a brief self-administered diet history questionnaire for Japanese children and adolescents (BDHQ15y). Inadequacy of each nutrient intake was assessed by the cut-point method, which showed that 14 nutrients were below the estimated average requirement (EAR) and five nutrients were outside the range of the dietary goal (DG). The overall nutritional inadequacy in participants was assessed by the number of nutrients consumed, which did not meet the Dietary Reference Intake for Japanese, 2015 version. *Results.* The intake of niacin, vitamin B_{12}, iron, copper, and salt-equivalent was higher, whereas intake of calcium was lower in students that did not provide milk with their school lunch compared to those that consumed milk ($p<0.05$). Total nutritional inadequacy and nutritional inadequacy for each nutrient separately did not differ significantly between the two groups. *Conclusion.* Our results showed that habitual nutrient intake adequacy for Japanese junior high school female students was independent of milk provision in school lunch programs. Further studies are needed to determine alternative factors that possibly influence dietary intake among Japanese adolescent girls.
Keywords: Milk, School lunch, Adolescent, Nutritional adequacy, Japan.

INTRODUCTION

Adolescence is a critical period during which lifetime habits are established (1). The eating patterns in adolescence also persist into adulthood (2–4). Therefore, nutritional quality during this period is important because it can influence adult morbidity and mortality (5).

Dairy products provide an abundant source of nutrients such as protein, vitamins and minerals and, particularly, calcium (6). Calcium is an essential nutrient for bone mineralisation and rigidity (7, 8). It has been suggested that nutrients from dairy products are essential for building and maintaining strong bones and increasing bone density (9). Especially, the bone mineral accrual rate is the highest during lifetime and approximately 95% of the bone mass peak is acquired in adolescence (10). Thus, adequate dairy intake is necessary for the development and maintenance of the bone mass peak during adolescence and fundamental for bone health later in life (7, 8). Studies have also indicated that intake of milk and other dairy products may improve the overall nutritional quality of adolescents' diets (11, 12). Moreover, the beneficial roles of dairy products have been examined in relation to a variety of chronic diseases including hypertension, metabolic syndrome, type 2 diabetes and cardiovascular disease (6, 13-15). Higher consumption of dairy products and calcium has been associated with a lower prevalence of overweight or obesity (16). Consumption of dairy products in adolescence may be important in a healthy nutritional status.

Currently, 88.1% of junior high schools in Japan provide school lunches based on the School Lunch Act enacted in 1954.17 This school lunch program is based on the combination of main staple food (grains), main dishes (fish, meat, poultry or soy products), side dishes (vegetable and soup, etc.) and milk, therefore most junior high schools provide milk to students every day (full meal which provides main staple food, main

dish, side dish and milk: 82.6%, supplementary meal which provides main dish, side dish and milk: 0.4%, milk only: 5.2%) (17). Under this Japanese school lunch program, the same lunch menu is provided to all children in each school. There are no alternative choices except for special cases, such as students with a food allergy. School lunches provide approximately 30% of the daily dietary intake and the school lunch programs in Japan appear to improve total diet quality in Japanese students (18). The nutrient content of school lunches is regulated by the Gakkou-Kyushoku-Jissi-Kijun (Standards for the School Lunch Program). The nutritional standards for most of nutrients are set at 33% of the daily reference values of Dietary Reference Intakes for Japanese, 2015 (DRIs) (19) such as recommended dietary allowance (RDA) or tentative dietary goal to prevent lifestyle-related diseases (DG). However, the nutritional standard for calcium for the school lunches is set at 450 mg per serving, which is 50% of the RDA (900 mg per day), due to the difficulty in obtaining calcium from the habitual Japanese dietary intake. Indeed, milk significantly contributes to the required calcium intake, because 200 ml (1 serving for school lunches) of milk provides approximately 230 mg of calcium (20).

Previous studies examined school lunches and dietary intake in relation to dairy products or milk. For example, a 3-day dietary record showed that the number of Japanese children aged 10-11 years with insufficient calcium intake, who had a school lunch including milk, was lower compared to children who did not consume milk at lunch (21). Another study reported that Japanese children who were provided with school lunches had greater calcium intake than children who brought their own lunches to school from home (22). A US study showed that the daily calcium intake of female students aged 12 to 18 years who were drinking milk during school lunch was greater than those who did not (23), although the food items in school lunches were consumed by the students ad-lib. Studies have indicated that the intake of milk and other dairy products may improve the overall nutritional quality of adolescents' diets (11, 12). Milk in school lunches may influence the overall dietary intake among adolescents, even though the menus of school lunches in Japan are designed to meet the nutrient standards. However, as milk has been regarded as a necessary item in school lunches in Japan, there has been no study on habitual dietary intake among students in relation to milk supply at school. There is very rare but 0.01% of junior high schools which have not always provided milk on school lunches in Japan because milk does not match with typical Japanese diet with rice as the main staple food. A previous study showed that the higher frequency of meal combining main staple, main dish and side dish led to greater nutrient intake, especially higher calcium intake (24), which might suggest the needlessness for milk on school lunch every day. Here, the aim of this study was to assess the influence of milk in school lunch on habitual nutrient intake adequacy of Japanese junior high school female students.

METHODS

Study population. A set of two self-administered questionnaires (i.e., a diet history questionnaire and lifestyle questionnaire) were distributed by teachers to 742 junior high school female students who attended either a public junior high school that provided school lunch with milk every day (school lunch with milk group) or two private junior high schools that did not always provide school lunch with milk (school lunch without milk group) in Kanto urban region, Japan in June 2016. The content of school lunch in two private junior high schools was the same. Students were asked to answer the questionnaires on their own, or in cooperation with their parents, if necessary. The completed questionnaires were examined by the research staff, and those with missing information were returned to the students for completion. Both questionnaires were completed by 575 female students.

We excluded students with missing data (n=17), with milk allergy (n=8) and with a reported energy intake less than half the energy requirement for the lowest physical activity category, according to the Japanese DRIs or equal to or more than 1.5 times the energy requirement for the highest physical activity category (<1075 kcal/day or ≥4050 kcal/day; n=34) (25). Thus, the final participant list consisted of 516 junior high school female students categorized into the following two groups: school lunch with milk (n=306) and school lunch without milk (n=210). Written informed consent was obtained from all participants and their parents. The present study was granted ethical approval by the Ethics committee of SEITOKU University in accordance to the guidelines of Helsinki Declaration (approval number H27U056).

Dietary assessment. Habitual dietary intake per day during the preceding month were assessed using a brief self-administered diet history questionnaire for Japanese children and adolescents (BDHQ15y) (26). BDHQ15y was developed based on the adult version of the validated a brief self-administered diet history questionnaire (BDHQ) that enquires about the dietary history during the preceding month (27, 28). BDHQ15y is a 4-page structured questionnaire consisting of 67 questions regarding the frequency of intake of food items commonly cooked and consumed in Japan. Daily food, energy and selected nutrient intake were calculated using an ad-hoc computer algorithm for BDHQ15y based on the Standard Tables of Food Composition in Japan (29). The validity of BDHQ15y was verified by a study on the relationship between selected food intake and blood biomarker levels (26). Milk was categorised either as full-fat or low-fat milk. Additionally, food groups were categorized based on the previous study (27). Any self-estimated dietary assessments cannot avoid under- or over-reporting of dietary intake (30, 31). Therefore, in order to render the comparison between the reported nutrient intake and the Japanese DRI values practically possible, we adjusted the reported dietary intake based on the

assumption that each participant reported her estimated energy requirement (EER) when her physical activity level was at the second level. The following calculation was used: Dietary intake (unit/day) = reported dietary intake (unit/day)/reported energy intake (kcal/day) × EER (kcal/day). The percentage of daily energy intake was calculated using the crude value for total fat and carbohydrate intake. Additionally, food intake values were energy-adjusted using the density method (i.e. the percentage of energy for energy-providing nutrients and their amounts per 1000 kcal for food groups and other nutrients) to minimise the influence of dietary misreporting.

Information regarding the school lunch menus (number of days that a main staple, main dish, side dish, soup and milk were provided in the school lunch and the mean values of nutrient supply through the school lunch during the survey month) was obtained from each school dietician. The components of each lunch were identified by the dieticians based on the Gakkou-Kyushoku-Jissi-Kijun and its guideline as follows: main staple food (grains: rice, bread, noodles and pasta), main dishes (fish, meat, poultry or soy products), side dishes (vegetable, mushrooms and seaweeds) and soup (miso soup and other soup).

Other variables. Body weight and height were self-reported as part of the BDHQ15y. The body mass index (BMI) was calculated as weight (kilograms) divided by the square of height (meters). In the BDHQ15y, participants also reported the frequency of their exercise such as sports club activities per week for the past month (everyday, 4-6 days/week, 2-3 days/week, a day/week or never). Additionally, participants reported on the following variables by completing a self-administered lifestyle questionnaire: employment status of father (full-time, part-time, housekeeping or other), employment status of mother (full-time, part-time, home manager or other), milk intake frequency at home (everyday, 5-6 days/week, 3-4 days/week, 1-2 days/week or never) and milk intake frequency during school lunch (everyday, 3-4 days/week, 1-2 days/week or never).

Determination of habitual nutrient intake inadequacy. Inadequacy of each nutrient intake was determined by comparing nutrient levels with each dietary reference value according to the Japanese DRIs, using a previously reported method (22, 32, 33). In the Japanese DRIs, different types of reference values are established according to their purpose. The estimated average requirement (EAR) is set to avoid insufficient intake of nutrients and DG is set to prevent lifestyle-related diseases.

The intake level below EAR was considered as inadequate using the cut-point method for 14 nutrients with known EARs: protein, vitamin A expressed as retinol activity equivalents, vitamin B_1, vitamin B_2, niacin expressed as niacin equivalent, vitamin B_6, vitamin B_{12}, folate, vitamin C, calcium, magnesium, iron, zinc, and copper. The intake level outside the range of DG values was considered as not meeting the standard for five nutrients with DG: total fat, carbohydrate, total dietary fiber, sodium expressed as salt-equivalent and potassium.

Statistical analysis. All statistical analyses were performed using the IBM SPSS statistics software package (version 22.0, SPSS Inc., Chicago, IL, USA). The differences of characteristics between school lunch with milk and without milk groups were compared using the chi-square test for categorical variables and the independent t-test for continuous variables. The difference of the mean nutrient supply in school lunches per meal between school lunch with milk and without milk was compared using an independent t-test.

Potential confounding factors considered in the first analysis were sex, working status and number of children which were found to be substantially different ($p<0.05$) between groups categorized by nutrition knowledge level. The difference of the habitual nutrients intake of the present study participants was assessed by analysis of co-variance (ANCOVA) adjusted the confounding variables of exercise (everyday, 4-6 days/week, 2-3 days/week, a day/week or never), work status of father (full-time or others) and work status of mother (full-time, part-time or others). The nutritional inadequacy of each nutrient was represented as the percentage of participants whose intake was below the EAR or outside the range of the DG in each group and the logistic regression analysis was used to examine the difference of the prevalence of not-meeting DRIs adjusted the confounding variables of exercise (everyday, 4-6 days/week, 2-3 days/week, a day/week or never), work status of father (full-time or others) and work status of mother (full-time, part-time or others).

The overall nutritional inadequacy of participants was determined based on the number of nutrients that did not meet the DRI values of the 14 nutrients with EAR and 5 nutrients with DG. Differences in the number of nutrients that did not meet DRIs between school lunch with milk and without milk groups were assessed by covariate analysis adjusted the confounding variables of exercise (everyday, 4-6 days/week, 2-3 days/week, a day/week or never), work status of father (full-time or others) and work status of mother (full-time, part-time or others).

Additionally, the difference of the habitual food groups intake between with and without milk groups was assessed by analysis of covariance (ANCOVA) adjusted the confounding variables of exercise (everyday, 4-6 days/week, 2-3 days/week, a day/week or never), work status of father (full-time or others) and work status of mother (full-time, part-time or others).

RESULTS

The characteristics of study participants are shown in Table 1. The mean BMI did not differ significantly between the two groups, while the

Table 1. Characteristics of 516 junior high school female students having school lunch with milk or without milk

	ALL (n=516)		School lunch with milk (n=306)		School lunch without milk (n=210)		p*
Grade							
1	176	(34.1)	105	(34.3)	71	(33.8)	0.857
2	187	(36.2)	113	(36.9)	74	(35.2)	
3	153	(29.7)	88	(28.8)	65	(31.0)	
Body height (cm)	154.5	± 7.8	155.1	± 6.2	153.5	± 9.6	0.016
Body weight (kg)	45.7	± 7.5	45.6	± 7.5	45.9	± 7.5	0.648
Body mass index (kg/m^2)	19.3	± 6.0	18.9	± 2.5	19.9	± 8.8	0.052
Number of days exercising							
Everyday	231	(44.8)	167	(54.6)	64	(30.5)	<0.001
4-6 days/week	78	(15.1)	46	(15.0)	32	(15.2)	
2-3 days/week	61	(11.8)	26	(8.5)	35	(16.7)	
1 day/week	49	(9.5)	19	(6.2)	30	(14.3)	
Never	97	(18.8)	48	(15.7)	49	(23.3)	
Energy intake (kcal/day)	2103	± 547	2158	± 563	2024	± 515	0.006
Milk intake (g/1000kcal)	75	± 80	89	± 82	54	± 72	<0.001
Work status of father							
Full-time	445	(86.2)	279	(91.2)	166	(79.0)	<0.001
Others	71	(13.8)	27	(8.8)	44	(21.0)	
Work status of mother							
Full-time	109	(21.1)	45	(14.7)	64	(30.5)	<0.001
Part-time	204	(39.5)	129	(42.2)	75	(35.7)	
Others	203	(39.3)	132	(43.1)	71	(33.8)	
Number of days drinking milk at home							
Everyday	120	(23.3)	75	(24.5)	45	(21.4)	0.343
5-6 days/week	38	(7.4)	26	(8.5)	12	(5.7)	
3-4 days/week	63	(12.2)	31	(10.1)	32	(15.2)	
1-2 days/week	108	(20.9)	64	(20.9)	44	(21.0)	
Never	187	(36.2)	110	(35.9)	77	(36.7)	
Number of days drinking milk at school lunch							
Everyday		-	265	(86.6)		-	-
3-4 days/week		-	11	(3.6)		-	
1-2 days/week		-	7	(2.3)		-	
Never		-	23	(7.5)		-	

Data are represented as n (%) or mean ± standard deviation.
**The p values are shown for chi-square test for categorical variables and for independent t test for continuous variables between school lunch with milk and without milk.*

mean body height was higher in school lunch with milk group than without milk group(p=0.016). The number of participants who engaged in habitual exercise was greater in the school lunch with milk group than in the school lunch without milk group (p<0.001). The percentage of fathers working full time was greater and mothers working full time was less in the school lunch with milk group than in the school lunch without milk group (p<0.001). Daily milk intake (89±82 g/1000 kcal vs. 54±72 g/1000 kcal, p<0.001) and energy intake (2158±563 kcal/day vs. 2024±515 kcal/day, p=0.006) in the school lunch with milk group were significantly greater than in the school lunch without milk group. There was no difference in the frequency of milk consumption at home between the two groups.

Table 2. Number of days in the survey month that each item was provided in school lunch

	School lunch with milk (n=19)	School lunch without milk (n=21)
Main staple	19 (100.0)	21 (100.0)
Main dish	14 (73.7)	16 (76.2)
Side disj	16 (84.2)	20 (95.2)
Soup	10 (52.6)	13 (61.9)
Milk	19 (100.0)	1 (4.8)

Data are represented as n (%).

Table 2 shows the number of days that a main staple, main dish, side dish, soup and milk were provided at school lunches in the two groups. Main staple was provided every day, and main dish and side dish was also provided in most days.

The mean values of nutrient supply through the school lunches with and without milk per meal are shown in Table 3. Supply of energy, protein, carbohydrate, vitamin A, vitamin B_1, vitamin B_2, and calcium was significantly greater in the school lunch with milk than the school lunch without milk.

The daily nutrient intake and each nutrient and overall nutritional inadequacy among 516 junior high school female students eating school lunch are shown in Table 4. Intake of niacin, folate, iron and salt-equivalent was higher in the school lunch without milk group than the school lunch with milk group. The total number of nutrients not meeting EAR and DG did not differ significantly between the two groups. Table 5 shows the habitual foods intake of the present study participants. The daily intake of other vegetables, mushrooms, and fish and shellfish among the students in school lunch without milk group were more than those in with milk group (p=0.028, 0.016 and 0.007, respectively). The only dairy products intake among the students in school lunch without milk groups was more than those in with milk group (p=0.003).

Table 3. Mean values of nutrient supply per meal by the school lunch

	Reference value†	School lunch with milk (total 19 meals)		School lunch without milk (total 21 meals)		p*
		Mean	SD	Mean	SD	
Energy (kcal/meal)	820	778	39	733	66	0.013
Protein (g/meal)	30	29.1	3.6	24.4	3.8	<0.001
Fat (g/meal)	22.8 - 27.3	22.7	4.2	25.0	5.6	0.158
Carbohydrate (g/meal)	—	114.4	12.4	95.5	24.0	0.004
Vitamin A (μgRAE/meal)‡	300	471	155	194	80	<0.001
Vitamin B_1 (mg/meal)	0.5	0.68	0.25	0.41	0.13	<0.001
Vitamin B_2 (mg/meal)	0.6	0.61	0.08	0.36	0.11	<0.001
Vitamin C (mg/meal)	35	40.1	19.4	49.7	38.6	0.336
Calcium (mg/meal)	450	388	63	147	68	<0.001
Iron (mg/meal)	4	3.2	1.2	2.9	0.9	0.329
Total dietary fiber (g/meal)	6.5	6.1	1.5	5.5	1.2	0.182
Sodium (salt equivalent) (g/meal)	< 3	3.3	0.8	3.0	0.5	0.149
Number of meals milk was provided	—	19		1		

SD, standard deviation.

† Nutrient standards for school lunch for 12- to 14-year-old students by the Gakkou-Kyushoku-Jissi-Kijun (Standards for the School Lunch Program).

‡ Sum of retinol, β-carotene/12, α-carotene/24, and cryptoxanthin/24.

** p values are shown for independent t test between school lunch with milk and without milk..*

Table 4. Daily nutrient intakes and prevalence of not meetin g EAR and DG among 516 junior high school female students eating school lunch[a]

	Reference value[b]	School lunch with milk (n=306)	Inadequacy[c] (%)	School lunch without milk (n=210)	Inadequacy[c] (%)	p[†]	OR (95% CI)[‡]
Nutrient with EAR							
Protein (g)	≥45	80 ± 1	0	81 ± 1	0	0.203	-
Vitamin A (μgRAE)[d]	≥500	793 ± 23	17.3	820 ± 28	18.6	0.471	1.121 (0.686 - 1.832)
Vitamin B_1 (mg)	≥1.1	0.95 ± 0.01	80.7	0.95 ± 0.01	81.9	0.821	0.989 (0.606 - 1.614)
Vitamin B_2 (mg)	≥1.2	1.7 ± 0.03	6.5	1.7 ± 0.03	10.5	0.813	1.432 (0.726 - 2.826)
Niacin (mgNE)[e]	≥12	16 ± 0.2	14.1	17 ± 0.3	8.6	0.009	0.592 (0.316 - 1.109)
Vitamin B_6 (mg)	≥1.1	1.3 ± 0.02	20.3	1.4 ± 0.02	20.0	0.050	0.992 (0.617 - 1.594)
Vitamin B_{12} (mg)	≥1.9	8.2 ± 0.2	0.3	8.8 ± 0.3	0	0.083	-
Folate (μg)	≥190	384 ± 8	4.2	411 ± 10	1.9	0.034	0.356 (0.108 - 1.175)
Vitamin C (mg)	≥80	131 ± 3	14.4	141 ± 4	13.8	0.060	0.894 (0.520 - 1.537)
Calcium (mg)	≥700	874 ± 17	29.7	831 ± 20	37.6	0.106	1.300 (0.873 - 1.936)
Magnesium (mg)	≥240	285 ± 3	20.3	289 ± 4	19.5	0.572	0.930 (0.577 - 1.500)
Iron (mg)	≥10.0	8.6 ± 0.1	77.5	9.1 ± 0.1	71.4	0.025	0.773 (0.502 - 1.191)
Zinc (mg)	≥7.0	9.9 ± 0.1	2.0	9.9 ± 0.1	1.0	0.957	0.382 (0.066 - 2.218)
Copper (mg)	≥0.6	1.2 ± 0.01	0	1.3 ± 0.02	0	0.075	-
Total number of nutrients with not-meeting EAR	-	2.9 ± 0.1	-	2.8 ± 0.2	-	0.622	-
Nutrient with DG							
Fat (%energy)	20-30	30 ± 0.3	54.9	30 ± 0.4	57.1	0.515	1.131 (0.773 - 1.655)
Carbohydrate (%energy)	50-65	54 ± 0.4	30.4	54 ± 0.5	35.7	0.930	1.344 (0.897 - 2.014)
Total dietary fiber (g)	≥16	13 ± 0.2	83.0	13 ± 0.3	78.6	0.082	0.729 (0.448 - 1.185)
Sodium (salt-equivalent) (g)	<7.0	12.0 ± 0.1	98.4	12.6 ± 0.2	100	0.022	-
Potassium (mg)	≥2400	2772 ± 41	30.7	2843 ± 50	31.4	0.284	0.910 (0.602 - 1.376)
Total number of nutrients with not-meeting DG	-	3.0 ± 0.1	-	3.0 ± 0.1	-	0.767	-

Data are represented as mean ± standard error or %.
CI, confidence interval; DG, tentative dietary goal for preventing life-style related disease; DRI, Dietary Reference Intakes; EA estimated average requirement; OR, odds ratio.
[a] Adjustment of reporting error was performed according to the following: Nutrient intake = reported nutrient intake / report energy intake × estimated energy requirement.
[b] DRIs for 12-14 years old Japanese girl. The estimeated energy requirement of physical activity level Ⅱ is 2400 kcal/day.
[c] Percentage of subjects whose nutrient intake was not-meeting DG or EAR of DRIs. Each nutrient intake was compared with ea DRI value, using the cut-point methods.
[d] Sum of retinol, β-carotene/12, α-carotene/24, and cryptoxanthin/24.
[e] Sum of niacin and protein/6000.
[†] The p values are shown for covariate analysis to analyze difference between school lunch with or without milk groups adjust the confounding variables of exercise(everyday, 4-6 days/week, 2-3 days/week, a day/week or never), work status of fath (full-time or others) and work status of mother (full-time, part-time or others).
[‡] OR (95% CI) are shown for a logistic regression analysis to analyze the presence of nutritional inadequacy school lunch witho milk group compared with milk group adjusted the confounding variables of exercise(everyday, 4-6 days/week, 2-3 days/week day/week or never), work status of father (full-time or others) and work status of mother (full-time, part-time or others).

Table 5. Daily food group intakes among 516 junior high school female students eating school luch with milk or without milk(g/1000kcal)†

	School lunch with milk (n=306)	School lunch without milk (n=210)	p‡
Cereals	208.8 ± 3.7	208.8 ± 4.6	0.996
Rice	160.2 ± 4.0	157.9 ± 4.9	0.726
Bread	21.4 ± 0.8	21.4 ± 1.0	0.977
Noodles	27.2 ± 1.3	29.5 ± 1.5	0.257
Pulses	29.9 ± 1.1	31.5 ± 1.4	0.366
Potatos	15.5 ± 0.6	14.8 ± 0.7	0.486
Sugar	2.5 ± 0.1	2.6 ± 0.2	0.477
Confectioneries	44.2 ± 1.7	43.5 ± 2.0	0.777
Fat and oil	7.7 ± 0.2	7.8 ± 0.2	0.816
Fat	0.6 ± 0.1	0.6 ± 0.1	0.567
Oil	7.2 ± 0.2	7.2 ± 0.2	0.944
Fruits	33.1 ± 1.9	36.2 ± 2.3	0.319
Total vegetables	120.8 ± 4.3	134.0 ± 5.2	0.056
Green and yellow vegetables	45.9 ± 1.8	48.7 ± 2.2	0.346
Other vegetables	60.4 ± 2.3	68.6 ± 2.8	0.028
Pickled vegetables	4.8 ± 0.4	5.4 ± 0.4	0.288
Mushrooms	4.2 ± 0.3	5.3 ± 0.3	0.016
Seaweeds	5.5 ± 0.3	6.0 ± 0.4	0.332
Beverages	310.2 ± 10.4	338.5 ± 12.7	0.094
Fruit and vegetable juice	28.5 ± 2.8	31.9 ± 3.4	0.454
Green tea	195.3 ± 7.5	205.5 ± 9.1	0.400
Black tea	35.4 ± 4.8	46.0 ± 5.9	0.176
Soft drinks	51.0 ± 4.5	55.2 ± 5.5	0.569
Fish and shellfish	29.1 ± 1.0	33.6 ± 1.2	0.007
Meat	37.5 ± 1.0	39.7 ± 1.2	0.188
Eggs	18.1 ± 0.6	18.4 ± 0.7	0.804
Dairy products	137.7 ± 5.6	111.0 ± 6.8	0.003

Data are represented as mean ± standard error.

† Adjustment of reporting error was performed according to the following: Food group intake = reported food group intake / reportedenergy intake × 1000(kcal).

‡ The p values are shown for covariate analysis to analyze difference between school lunch with or without milk groups adjusted the confounding variables of exercise (everyday, 4-6 days/week, 2-3 days/week, a day/week or never), work status of father (full-time or others) and work status of mother (full-time, part-time or others).

DISCUSSION

The present study examined the influence of milk in school lunch on the habitual nutrition intake among Japanese junior high school female students. To our knowledge, this is the first study to examine the difference in habitual nutrient intake adequacy between junior high school students who were and were not always provided with milk on their school lunches. Our findings suggested that there might be no difference in habitual nutrient intake adequacy between school lunches with and without milk.

Our study found no difference between groups in nutritional inadequacy for each nutrient and overall nutritional inadequacy in relation to milk supply in school lunches. Although we hypothesised that school lunch with milk would reduce the proportion of inadequacy for calcium intake compared to school lunch without milk, we found no difference in the percentage of students who were below EAR for calcium between school lunch with milk and without milk. A previous study showed that the proportion of elementary school students with a calcium intake below EAR was lower in the school lunch with milk compared to the school lunch without milk (21). In contrast, in our study, the calcium intake and nutritional inadequacy related to calcium did not differ between the two groups. The study design may account for the disparate results. The previous study compared calcium intake from 3 days' dietary records to calcium intake estimated by excluding milk in the school lunches from the records, whereas our study compared the habitual dietary intakes, assessed with a questionnaire, of junior high school female students who had a school lunch with milk every day to those having a school lunch that did not provide milk every

day. Therefore, the results may not be comparable, and further study is needed. In the present study, the habitual niacin, folate, iron and sodium intakes were significantly greater in the school lunch without milk group than the school lunch with milk group. It has been reported that the percentages below EAR for iron and out of DG range for fat and dietary fibre were higher, whereas only calcium intake was lower, in elementary school female students eating homemade lunch compared to those eating the school lunch (22). In that previous study, daily salt and iron intakes were greater and only daily calcium was lower in the homemade lunch box group compared to the school lunch program group. Additionally, in homemade lunch boxes , staple foods, such as rice, were the main item followed by some main dish items, such as meat and fish and side dish items, such as vegetables, but hardly any dairy products were included (34). These studies can partly explain the current results regarding the higher iron intake and lower calcium intake among our participants in the school lunch without milk group. However, the results on nutritional inadequacy in the present study were different from the previous study comparing homemade boxed lunch with school lunch. The reason for this difference may be explained by the fact that school lunches were made according to certain nutrient standards regardless of milk supply. Indeed, in the present study, more side dishes and soup were provided in the school lunches without milk group. This may be because school lunches without milk were required to meet the nutrient standards for each nutrient, especially regarding vitamins and minerals, using side dishes and soup, which mainly consisted of vegetables, pulse, and seaweeds, instead of milk. Additionally, there were differences in the supply per meal of energy, protein, carbohydrate, vitamin A, vitamin B_1, vitamin B_2, and calcium by the school lunch between the two study groups. In detail, the supply of nutrients such as energy, protein, carbohydrate, vitamin A, vitamin B_1, vitamin B_2 and calcium was higher in school lunch with milk than school lunch without milk. Moreover, the number of the nutrients which met the standard value by Gakkou-Kyushoku-Jissi-Kijun of school lunch with milk was more than those of school lunch without milk. Thus, milk may play an important role in meeting the nutrient requirements in school lunches. However, no difference was observed in the habitual intake of these nutrients between two groups among students who participated in the present study. Especially, the calcium supply in the school lunch with milk and without milk groups was 388 mg/day and 147 mg/day, respectively, which showed that the difference of the calcium supply between two groups was just the amount of milk supply per day. One possible reason of this could be that the source of calcium intake by Japanese is not only from dairy products but also from soybeans, fish, seaweed or vegetables, which are rich in calcium, protein, vitamin group and iron (29). A Japanese study reported that young adults who had more frequency of meal combining main staple, main dish and side dish were greater consumption of calcium (24). Indeed, the habitual intake of dairy products including milk among participants in school lunch with milk was more than those in without milk, while the habitual other vegetables, mushrooms and fish intakes by participants in the school lunch without milk group were higher than those in the school lunch with milk group. In other words, when the intake of calcium-rich food is sufficient, milk in school lunch may be dispensable for the calcium intake adequacy in adolescents. In addition, these foods are cooked with salt seasoning, which was reported as the main source of sodium in the Japanese diet (35). This may partly explain the current result that daily intakes of niacin, folate and sodium may be higher among participants in the school lunch without milk group.

The percentage of individuals not drinking milk at home (35%) in this study was similar to that in a Japanese previous study (36), and the difference in daily milk intake between the two groups of this study (about 84 ml/EER) was less than 50% of the amount of milk (200 ml) provided in the school lunch. Milk was consumed by 65% of the present study participants at home. Therefore, the amount of daily milk intake was mainly influenced by the amount of milk consumed at home. Similar results have been observed in a British study that compared dietary intake according to lunch type (school meal vs. packed meal). In that previous study, students that ate the school meal consumed more milk than those eating packed lunch during school lunchtime, although this difference was not observed in overall nutrient intake (37). These results suggest that the influence of the home/family environment is stronger than that of the school environment on milk consumption. Additionally, previous studies reported that the diet of adolescents was influenced by their parents, including the home environment (38, 39). These may partly explain the current result that the nutrition adequacy among female junior high school students was not likely to be affected by the school lunch with or without milk. In other words, nutritional adequacy among adolescents might be influenced by the home environment including household income, parent's nutrition knowledge, employment, and dietary intake. Another study has shown that the prevalence of inadequate nutrient intake was clearly higher on a non-school day than a school day for almost all nutrients among Japanese elementary school and junior high school students (18). These results, consistent with our findings, demonstrate that school lunches may have contributed to the dietary intake quality during adolescence and dietary intake may have been influenced by the dietary habits at home rather than school.

Several limitations of this study need to be mentioned. First, the participants were selected from three schools in Kanto urban region in Japan, not a random selection. Also, there were several demographic difference between the two groups, which indicates the probability of that our results might be influenced by the difference in those characteristics. However, the participants in the school lunch without milk group were of particular value, because they were enrolled among 0.1% of schools in Japan that do not always provide milk everyday on school lunch. Our selection of the subjects was the only way to fulfil the purpose of this study. Further studies are needed to validate our findings regarding the total Japanese adolescent population. Second, we used BDHQ15y to assess dietary intake although its ability to estimate dietary intakes has been validated on limited foods and nutrients. Third, we could not include intake from dietary supplements in the analysis because reliable composition tables of dietary supplements were

lacking in Japan. Fourth, household income, education and nutritional habits of participants' parents were not investigated. Those factors were reported to influence children's diets (38-40). Although the employment status of participant's parents was examined in this study, this information is not necessarily equivalent to household income. Finally, we did not examine whether the participants had their first menstruation, although the EAR for iron changes depending on menstruation. It was reported that 585 out of 4769 female students (12.3%) aged 12-15 years did not have their first menstruation and most of them were 12 years old (36). Because junior high school female students were considered to have their first menstruation shortly, they would need higher iron intake that takes menstruation into consideration. Thus, we considered that the EAR for iron of female individuals with menstruation were more appropriate to assess nutritional adequacy in this study.

CONCLUSION The results of this study showed that habitual nutrient intake adequacy of Japanese junior high school female students was independent of milk provision in school lunch, although milk may help meet the standard requirements of school lunch programs. Therefore, other factors such as the home/family environment may affect the nutritional adequacy among adolescent girls. Further studies are needed to determine alternative factors that possibly influence dietary intake among Japanese adolescent girls.

Acknowledgement

The authors would like to express their thanks to N Hiroki and A Noguchi who provided the school lunch menu and their nutrients information and each school teachers who distributed the questionnaires.

Conflict of interest and funding disclosure

The authors declare that they have no conflict of interests. This study was supported by Milk Education Research Council and Japan Daily Association.

REFERENCES

1) Cavadini C, Siega-Riz AM, Popkin BM. US adolescent food intake trends from 1965 to 1996. West J Med. 173(6):378-383. 2000.
2) Kelder SH, Perry CL, Klepp KI, Lytle LL. Longitudinal tracking of adolescent smoking, physical activity, and food choice behaviors. Am J Public Health. 84(7):1121-1126. 1994.
3) Lien N, Lytle LA, Klepp KI. Stability in consumption of fruit, vegetables, and sugary foods in a cohort from age 14 to age 21. Prev Med (Baltim). 33(3):217-226. 2001.
4) Lytle LA, Seifert S, Greenstein J, McGovern P. How do children's eating patterns and food choices change over time? Results from a cohort study. Am J Health Promot. 14(4):222-228. 2000.
5) Grosso G, Mistretta A, Turconi G, Cena H, Roggi C, Galvano F. Nutrition knowledge and other determinants of food intake and lifestyle habits in children and young adolescents living in a rural area of Sicily, South Italy. Public Health Nutr. 16(10):1827-1836. 2013.
6) Lamarche B. Review of the Effect of Dairy Products on Non-Lipid Risk Factors for Cardiovascular Disease. J Am Coll Nutr. 27(6):741S-746S. 2008.
7) Golden NH, Abrams SA. Optimizing Bone Health in Children and Adolescents. Pediatrics. 134(4):e1229-e1243. 2014.
8) Bueno AL, Czepielewski MA. The importance for growth of dietary intake of calcium and vitamin D. J Pediatr (Rio J). 84(5):386-394. 2008.
9) Heaney RP. Dairy and bone health. J Am Coll Nutr. 28 Suppl 1:82S-90S. 2009.
10) Teegarden D, Proulx WR, Martin BR, et al. Peak bone mass in young women. J Bone Miner Res. 10(5):711-715. 1995.
11) Agostoni C, Rottoli A, Trojan S, Riva E. Dairy products and adolescent nutrition. J Int Med Res. 22(2):67-76. 1994.
12) Parker CE, Vivian WJ, Oddy WH, Beilin LJ, Mori TA, O'Sullivan TA. Changes in dairy food and nutrient intakes in Australian adolescents. Nutrients. 4(12):1794-1811. 2012.
13) Malik VS, Sun Q, Van Dam RM, et al. Adolescent dairy product consumption and risk of type 2 diabetes in middle-aged women. Am J Clin Nutr. 94(3):854-861. 2011.
14) Elwood PC, Pickering JE, Givens DI, Gallacher JE. The Consumption of Milk and Dairy Foods and the Incidence of Vascular Disease and Diabetes: An Overview of the Evidence. Lipids. 45(10):925-939. 2010.
15) Tremblay A, Gilbert J-A. Milk products, insulin resistance syndrome and type 2 diabetes. J Am Coll Nutr. 28 Suppl 1:91S-102S. 2009.
16) Keast DR, Hill Gallant KM, Albertson AM, Gugger CK, Holschuh NM. Associations between yogurt, dairy, calcium, and vitamin D Intake and Obesity among U.S. children aged 8-18 years: NHANES, 2005-2008. Nutrients. 7(3):1577-1593. 2015.
17) Ministry of Education Science Sports and Culture. Survey for the School Lunch Program (in Japanese). http://www.mext.go.jp/b_menu/toukei/chousa05/kyuushoku/kekka/k_detail/icsFiles/afieldfile/2017/01/18/1381230_1_2_1.pdf. Published 2017. Accessed November 28, 2018.
18) Asakura K, Sasaki S. School lunches in Japan: their contribution to healthier nutrient intake among elementary-school and junior high-school children. Public Health Nutr. 20(9):1523-1533. 2017.
19) Ministy of Health Labour and Welfare. Dietary Reference Intakes for Japanese, 2015. Toyko: Daiichi Shuppan Publishing Co., Ltd.; 2014.
20) The Counsil for Science and Technology Ministry of Education Science Sports and Culture. Standard Tables of Food Composition in Japan, 2015 (Seventh Edition). Tokyo: Official Gazette Co-operation.; 2015.
21) Nozue M, Jun K, Ishihara Y, et al. How does fortification affect the distribution of calcium and vitamin B-1 intake at the school lunch for fifth-grade children? J Nutr Sci Vitaminol (Tokyo). 59(1):22-28. 2013.
22) Kohri T, Kaba N, Itoh T, Sasaki S. Effects of the National School Lunch Program on Bone Growth in Japanese Elementary School Children. J Nutr Sci Vitaminol (Tokyo). 62(5):303-309.

2016.
23) Murphy MM, Douglass JS, Johnson RK, Spence LA. Drinking Flavored or Plain Milk Is Positively Associated with Nutrient Intake and Is Not Associated with Adverse Effects on Weight Status in US Children and Adolescents. J Am Diet Assoc. 108(4):631-639. 2008.
24) Kakutani Y, Kamiya S, Omi N. Association between the Frequency of Meals Combining "Shushoku, Shusai, and Hukusai" (Staple Food, Main Dish, and Side Dish) and Intake of Nutrients and Food Groups among Japanese Young Adults Aged 18-24 Years: a Cross-Sectional Study. J Nutr Sci Vitaminol (Tokyo). 61(1):55-63. 2015.
25) Murakami K, Miyake Y, Sasaki S, Tanaka K, Arakawa M. Dietary glycemic index and glycemic load in relation to risk of overweight in Japanese children and adolescents: the Ryukyus Child Health Study. Int J Obes. 35(7):925-936. 2011.
26) Okuda M, Sasaki S, Bando N, et al. Carotenoid, Tocopherol, and Fatty Acid Biomarkers and Dietary Intake Estimated by Using a Brief Self-Administered Diet History Questionnaire for Older Japanese Children and Adolescents. J Nutr Sci Vitaminol (Tokyo). 55(3):231-241. 2009.
27) Kobayashi S, Murakami K, Sasaki S, et al. Comparison of relative validity of food group intakes estimated by comprehensive and brief-type self-administered diet history questionnaires against 16 d dietary records in Japanese adults. Public Health Nutr. 14(7):1200-1211. 2011.
28) Kobayashi S, Honda S, Murakami K, et al. Both comprehensive and brief self-administered diet history questionnaires satisfactorily rank nutrient intakes in Japanese adults. J Epidemiol. 22(2):151-159. 2012.
29) The Council for Science and Technology Ministry of Education Culture Sports and Technology. Standard Tables of Food Composition in Japan - 2010. Tokyo: Official Gazette Co-operation.; 2010.
30) Murakami K, Miyake Y, Sasaki S, Tanaka K, Arakawa M. Characteristics of under- and over-reporters of energy intake among Japanese children and adolescents: The Ryukyus Child Health Study. Nutrition. 28(5):532-538. 2012.
31) Murakami K, Sasaki S, Takahashi Y, et al. Misreporting of dietary energy, protein, potassium and sodium in relation to body mass index in young Japanese women. Eur J Clin Nutr. 62(1):111-118. 2008.
32) Okubo H, Sasaki S, Murakami K, Takahashi Y. Nutritional adequacy of four dietary patterns defined by cluster analysis in Japanese women aged 18-20 years. Asia Pac J Clin Nutr. 19(4):555-563. 2010.
33) Kobayashi S, Asakura K, Suga H, Sasaki S. Living status and frequency of eating out-of-home foods in relation to nutritional adequacy in 4,017 Japanese female dietetic students aged 18–20 years: A multicenter cross-sectional study. J Epidemiol. 27(6):287-293. 2017.
34) Kohri T. Usefulness of a Handmade Box Lunch as a Common Dietary Education Tool to School Children and Parents. J Child Heal. 73(5):663-671. 2014. (in Japanese).
35) Asakura K, Uechi K, Masayasu S, Sasaki S. Sodium sources in the Japanese diet: difference between generations and sexes. Public Health Nutr. 19(11):2011-2023. 2016.
36) Tamura Y, Saito I, Asada Y, Kishida T, Yamaizumi M, Kato T. A cross-sectional survey of factors influencing bone mass in junior high school students. Environ Health Prev Med. 18(4):313-322. 2013.
37) Harrison F, Jennings A, Jones A, et al. Food and drink consumption at school lunchtime: the impact of lunch type and contribution to overall intake in British 9–10-year-old children. Public Health Nutr. 16(6):1132-1139. 2013.
38) Serra-Majem L, Ribas L, Ngo J, et al. Food, youth and the Mediterranean diet in Spain. Development of KIDMED, Mediterranean Diet Quality Index in children and adolescents. Public Health Nutr. 7(7):931-935. 2004.
39) Sweeting H, West P. Dietary habits and children's family lives. J Hum Nutr Diet. 18(2):93-97. 2005.
40) Al-shukaily L. Effect of Mothers Nutritional Knowledge and Attitudes on Omani Children's Dietary Intake. Oman Med J. 26(4):253-257. 2011.

ORIGINAL

Science-based Ratings of Safety and Effectiveness of Ingredients of Health Foods Distributed in Japan Differ among Health Food Categories

Hiroko Hashida[1], Mayumi Okuma[1], Fumio Shimura[1], Yuko Yamazaki[2*]

[1] *Department of Food and Nutritional Sciences, Graduate School of Human Life Sciences, Jumonji University, 2-1-28, Sugasawa, Niiza, Saitama 352-8510, Japan.*
[2] *Department of Food and Nutrition, Faculty of Human Life. Jumonji University, 2-1-28, Sugasawa, Niiza, Saitama 352-8510, Japan.*

(Received October 1, 2019)

ABSTRACT ***Background and purpose.*** Health foods are increasingly popular in Asian countries including Japan. Professionals such as dietitians have a role to help consumers use health foods based on scientific evidence on safety and effectiveness in order to prevent health or economic problems. This requires knowledge and utilization of health food legal systems and reliable information sources. Health foods in Japan are divided into "Food with Health Claims" (FHC) as defined in the Health Promotion Act etc. and "So-called health foods" treated as general foods without legal regulations. FHC are further categorized into "Foods with Nutrient Function Claims" (FNFC), "Foods for Specified Health Uses" (FOSHU), and "Food with Function Claims" (FFC). There may be differences, as yet unknown, among categories in the safety and effectiveness evaluation of health food ingredients distributed in Japan. The verification of these differences was considered to be useful for nutrition practice activities in Asia and is the subject of the present study. ***Method.*** The safety and effective evaluation of health food ingredients in each category, FNFC, FOSHU, and "Popular Health Foods in Japan" (PHFJ), were compared and examined based on the ratings in the book version of the Natural Medicine Comprehensive Database (NMCD). In order to enable non-parametric statistical analysis, we converted the language ratings (nominal variables) by NMCD to rating scores (ordinal variables). ***Results.*** The ratio of ingredients unlisted in the NMCD was significantly higher for FOSHU. The average rank of FNFC ingredients was significantly higher in safety, effectiveness, and total rating scores than those of FOSHU and "PHFJ without FNFC+FOSHU" ingredients, but there was no significant difference between FOSHU and PHFJ. The average rank of ingredients of "FFC in PHFJ" was significantly higher in safety, effectiveness, and total rating scores than those of "non-FHC in PHFJ". Ingredients of Health foods distributed in Japan differed in their safety and effectiveness assessments by NMCD due to differences in legal regulations and systems. Also, the reliability of scientific evidence on safety and effectiveness seemed to be related to sales. ***Conclusion.*** The findings obtained in this study would serve as a reference for Asian professionals to know the Japanese health food regulatory systems and promote the use of health food based on scientific evidence on safety and effectiveness. In addition, the findings would be useful for Asian countries to develop health food systems.

Keywords: health food, scientific evidence, safety, effectiveness, legal systems, category

INTRODUCTION

In Asian countries, including Japan, there has been increasing attention to a variety of foods that are manufactured, sold, and used with suggestions or claims to be useful for health maintenance and promotion (1-4). These new kinds of foods are collectively called health foods in Japan (5, 6).

*To whom correspondence should be addressed: mitikawa@jumonji-u.ac.jp

Abbreviations: FHC, Foods with Health Claims; FNFC, Foods with nutrient function claims; FOSHU, Food for specified health uses; FFC, Foods with Function Claims; PHFJ, popular health foods in Japan; NMCD, Natural Medicines Comprehensive Database

Health foods, however, are sometimes associated with health or economic problems because of their diversity in terms of quality, safety and effectiveness (7, 8). The safe and secure use of health foods without problems requires consumer behaviour based on scientific information on safety and effectiveness. In turn, experts such as dieticians in charge of nutrition practice activities are required to have basic knowledge and related skills as information providers (4, 7). Legal systems of health foods and re liable sources of information are also key principle for providing fair and impartial information to consumers.

In Japan, health foods are classified into "foods with health claims" (FHC) stipulated by the Health

Promotion Act (7, 8) and so-called health foods that fall under general foods. Currently, FHC are further categorized into "Foods with Nutrient Function Claims" (FNFC), "Foods for Specified Health Uses" (FOSHU), and "Food with Function Claims" (FFC) (4, 5, 8, 9).

FNFC products are taken for the purpose of supplementing/ complementing nutritional ingredients when normal dietary intake is difficult due to aging, disorders in eating habits, etc. FNFC is under a legal system of standard regulation. Thus, to sell FNFC products, it is necessary to comply with government standards established from solid and extensive scientific evidence that has been historically accumulated on safety and effectiveness. Products that meet the standards can claim specified nutrient functions as FNFC (4, 10, 11).

FOSHU products contain some specific ingredients and can claim by labeling that those who take them for specified health purposes in their daily diets can expect the purposes. FOSHU is under a legal system of individual approval. In order to sell FOSHU products, the labeling of health claims must be approved by the Commissioner of Consumer Affairs Agency. The labeling is approved, as a general rule, through science-based strict screening by the government regarding the safety and effectiveness of each product (7, 12).

FFC products can be labeled with function claims based on scientific evidence under the responsibility of each food business operator. Because FFC is under a legal system of notification. Information on the evidence supporting the safety and effectiveness of the product must be submitted to the Commissioner of Consumer Affairs Agency before the product is placed on the market. FFC products are not individually pre-approved by the government unlike FOSHU and also do not comply with the strict standards established by the government unlike FNFC (4, 12). This status is similar to that of health foods other than FHC products in that their safety and effectiveness are under self-assessment, do not necessarily meet the standards established by the government, and have not been evaluated by the government.

In a general sense, health foods that comply with the governmental standards or approved by the government are presumed to be safer and more effective than those that do not. However, as far as we know, this speculation has not been verified and has to be resolved. Resolving this issue may be beneficial for nutrition practitioners in Asian countries to provide information on the safe and secure use of health foods.

Based on these backgrounds, we examined and compared how the safety and effectiveness of ingredients were evaluated for each category of health foods distributed in Japan. The categories of health food ingredients investigated were those of FNFC, FOSHU, and popular health food in Japan (PHFJ). The safety and effectiveness of health food ingredients in each category were compared and examined based on the evaluation by the book version of the Natural Medicines Comprehensive Database (NMCD). For comparison between categories by nonparametric statistical analysis, we converted language ratings (nominal variables) by NMCD to rating scores (ordinal variables). Through these procedures, we objectively demonstrated an intuitive prediction that health foods that comply with or are approved by government standards are safer and more effective than those that do not. The knowledge gained will be useful for the practice of Asian nutrition specialists and for the development of health food systems in Asian countries.

METHODS

1. Construction of ingredient lists by health food categories

To find the terms that correspond to ingredients in the original lists written in Japanese, we consulted the following information resources (13, 14). The English names of the ingredients in the lists shown below match the names used in NMCD monographs. In this paper, the notation of component, material, and ingredient, etc. are unified into “ingredient”.

1) Ingredients of Foods with Nutrient Function Claims (FNFC)

As of July 2019, the ingredients of FNFC approved for nutrient function claims are as follows: n-3 fatty acids, 6 minerals (zinc, potassium, calcium, iron, copper, magnesium), and 13 vitamins (niacin, pantothenic acid, biotin, vitamin A, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, vitamin K, folic acid) (10). A list of these nutritional ingredients was constructed according to the criteria described below.

2) Ingredients of Foods for Specified Health Uses (FOSHU)

A list of approved FOSHU products (February 12, 2019 Final revision: Excel file) was downloaded from a webpage on administrative guidance of food labeling under the Consumer Affairs Agency of the Cabinet Office (15). In this FOSHU product list, 1,064 products are shown in ascending order of permission date with serial numbers, product names, applicants, types of food. Other items shown are as follows: ingredients involved in health functions (also simply described as ingredients in this report), display contents with permission, intake instructions, standard daily intake amount, classification, permission day, permission number. Based on this 1,064-product list, we have constructed a FOSHU ingredient list with 64 ingredients, using the Excel sorting function to sort ingredients of the 1,064 products and consolidate duplicate ingredients into one. This 64-ingredient list was further cleaned up and subjected to statistical analysis with the addition of information on safety and effectiveness as described below.

3) Ingredients of Popular Health Foods in Japan (PHFJ)

The popularity of a health food is probably reflected in its sales amount. Therefore, in this paper, we treated health food ingredients with high annual sales as popular health food ingredients in Japan. In particular, ingredients published in the annual magazine “Health Food Report®” (16) were used for list construction. Since the initial list thus constructed contained ingredients of FNFC and FOSHU, these ingredients were excluded to gain the PHFJ ingredient list composed of FFC and non-FHC ingredient

2. Collection and processing of information on the evaluation of safety and effectiveness of health food ingredients by NMCD monograph

We searched information on the safety and effectiveness of health food ingredients using the

book version of NMCD (17), a collection of monographs titled by ingredient names. NMCD is excellent in quality and quantity as a health food ingredient database, and is characterized by a safety and effectiveness rating (18). For the convenience of statistical analysis, ratings by language (nominal variables) in NMCD were converted into rating scores (ordinal variables) as previously reported (18). In brief: Likely Safe (2), Possibly Safe (1) Possibly Unsafe (-1), Likely Unsafe (-2), and Unsafe (-3). Similarly: Effective (3), Likely Effective (2), Possibly Effective (1), Possibly Ineffective (-1), Likely Ineffective (-2), Ineffective (-3). A rating score of "0" was given to the language rating of "INSUFFICIENT RELIABLE EVIDENCE to RATE". Ingredients unlisted in NMCD and those with rating of "insufficient reliable information available" were not assigned rating scores and were excluded from statistical analysis.

In adding rating scores to the lists for each categories of ingredients, a few more considerations were taken into account. An ingredient with a high effectiveness rating but a low safety rating cannot be used safely and securely. Therefore, the total score, the sum of safety and effectiveness scores, was regarded as an index of usefulness. For the safety rating, evaluation by intake of the health food, dietary supplement or drug was selected. When the rating in NMCD was on oral ingestion with the amount of ordinary food, the rating score was decreased by 1 point.

The effectiveness ratings added in the lists were those for health and medical uses such as effects on body structures and functions other than simple nutrient supplementation effects, and reduction of disease risks. The effectiveness of FNFC and FOSHU ingredients were selected only for NMCD ratings on functions approved or specified under the government regulation in Japan. When the effectiveness rating of PHFJ ingredients involve a wide range of functions, we selected the health purpose with the highest rating.

3. Statistical comparison between health food categories of the safety and effectiveness rating of ingredients

Results of mean rating score were expressed as mean ± standard deviation. In the comparison of the number of ingredients listed or unlisted in NMCD, when there was a significant difference in chi-square test, residual analysis was performed. In the comparison of the scores among 3 groups, when there was a significant difference in the Kruskal-Wallis test, the Steel-Dwass test was subsequently performed. In addition, the Mann-Whitney test was performed to compare 2 groups. BellCurve for Excel version 3.20 (Social Survey Research Information Co., Ltd.) software was used.

Table 1. Ingredients of Foods with Nutrient Function Claims (FNFC)

No.	Nutrient	Rating score			Nutrient Function Claims of FNFC *
		Safety	Effectiveness	Total	
1	n-3 Fatty acid	2	-	-	Maintain skin
2	Zinc	2	1	3	Maintain normal taste and helps to maintain healthy skin and mucous membranes.
3	Potassium	2	1	3	Maintain proper blood pressure.
4	Calcium	2	2	4	Development of bone and teeth.
5	Iron	2	3	5	Necessary in the red blood cell formation.
6	Copper	2	2	4	Form red blood cells and helps the proper function of many body enzymes and bone formation.
7	Magnesium	2	3	5	Development of bone and teeth. Maintain proper blood circulation, and helps proper function of many body enzymes and energy generation.
8	Niacin	2	2	4	Maintain skin and mucosa health.
9	Pantothenic acid	2	3	5	Maintain skin and mucosa health.
10	Biotin	2	2	4	Maintain skin and mucosa health.
11	Vitamin A	2	3	5	Maintain vision in the dark. Maintain skin and mucosa healthy.
12	Vitamin B1	2	3	5	Produce the energy from carbohydrate and to maintain skin and mucosa health.
13	Vitamin B2	2	3	5	Maintain skin and mucosa health.
14	Vitamin B6	2	3	5	Produce energy from protein and to maintain skin and mucosa health.
15	Vitamin B12	2	3	5	Aids in red blood cell formation.
16	Vitamin C	2	3	5	Maintain skin and mucosa health and has anti-oxidizing effect.
17	Vitamin D	2	3	5	Promotes absorption of calcium in gut intestine and aids in the growth of bone.
18	Vitamin E	2	3	5	Protect fat in the body from being oxidized and to maintain the cell health.
19	Vitamin K	2	3	5	Maintain proper blood coagulability.
20	Folic acid	2	3	5	Aids in the red blood cell formation, and contributes the normal growth of the fetus.
	mean ± SD	2.00 ± 0.00	2.58 ± 0.69	4.58 ± 0.69	

Note: This table should not use for the purpose of providing information to consumers because the information is very limited. Refer to the NMCD for details of ingredient.

*: "Nutrient Function Claims of FNCN" are shown in simplified forms (reference 10, 11).

RESULTS

1. Lists of Health Food Ingredients with Information on Safety and Effectiveness

1) Ingredients of Foods with Nutrient Function Claims (FNFC)

Nutrient function claims of FNFC are regulated by the Food Labeling Law, and 20 nutrients are currently approved to be used as functional ingredients in FNFC products. NMCD contains monographs on all these ingredients except n-3 fatty acids. For n-3 fatty acids, monographs of the equivalent ingredients DHA (docosahexaenoic acid), EPA (eicosapentaenoic acid), fish oil, and α-linolenic acid were available instead.

Table 2. Ingredients of Foods for Specified Health Uses (FOSHU)

No.	Functional ingredient【NMCD monograph name】	Rating score			Health claims approved as FOSHU *1
		Safety	Effectiveness	Total	
1	Agar【AGAR】	1	-	-	Gastrointestinal conditions
2	Reduced molecular weight sodium alginate【ALGIN】	1	-	-	Gastrointestinal conditions, Blood cholesterol level
3	Barley young leaf, barley【BARELY】	2	-	-	Gastrointestinal conditions, Blood sugar levels
4	Plant sterol【BETA-SITOSTEROL】	2	2	4	Blood cholesterol level
5	Bifidobacteria【BIFIDOBACTERIA】	2	1	3	Gastrointestinal conditions
6	Psyllium seed coat-derived dietary fiber【BLOND PSYLLIUM】	2	3	5	Gastrointestinal conditions
7	Calcium【CALCIUM】	2	2	4	Osteogenesis (Reduction of disease-risk)
8	Calcium hydrogen phosphate / CPP-ACP (Casein phosphopeptide – amorphous calcium phosphate as calcium) / POs-Ca (Phosphorylated oligosaccharide calcium)【CALCIUM】	2	1	3	Dental health
9	Lactotripeptide【CASEIN PEPTIDE】	-	0	-	Blood pressure
10	Chitosan【CHITOSAN】	1	0	1	Blood cholesterol level
11	DHA･EPA【DHA･EPA】*2	2	0	2	Blood triacylglycerol level
12	Green tea-derived fluorine【FLUORIDE】	2	3	5	Dental health
13	Fructo-oligosaccharides【FRUCTO-OLIGOSACCHARIDES】	1	0	1	Gastrointestinal conditions
14	Gamma-aminobutyric acid (GABA)【GABA】	-	-	-	Blood pressure
15	Tea catechins, Tea polyphenol【Green tea】	1	1	2	Blood cholesterol level
16	Guava leaf polyphenol【GUAVA】	1	-	-	Blood sugar levels
17	Monoglucosyl hesperidin【HESPERIDIN】	1	-	-	Blood triacylglycerol level, Blood pressure
18	Kudzu flower extract (Tectorigenin)【KUDZU】	1	-	-	Body fat
19	Lactobacillus【LACTOBACILLUS】	2	2	4	Gastrointestinal conditions
20	Medium chain triglycerides【MEDIUM CHAIN TRIGLYCERIDE】	2	-	-	Body fat
21	*Bacillus subtilis* K-2 (spore)【NATTOKINASE】	1	-	-	Gastrointestinal conditions
22	Quercetin glycoside (as isoquercitrin)【QUERCETIN】	1	-	-	Body fat
23	Soy oligosaccharide, Soy isoflavone, Soy protein, Beta conglycinin【SOY】	2	1	3	Gastrointestinal conditions, Osteogenesis, Blood triacylglycerol level, Blood cholesterol level
24	High molecular weight black tea polyphenol (as theaflavin)【TEAFLAVIN】	-	-	-	Blood triacylglycerol level
25	Vitamin K2 (menaquinone-4, menaquinone-7)【VITAMIN K】	2	0	2	Osteogenesis
26	Wheat bran / Whole wheat and wheat hulls-derived dietary fiber【WHEAT BRAN】	2	1	3	Gastrointestinal conditions
27	MBP® (Milk Basic Protein) (as cystatin 20μg)【WHEY PROTEIN】	2	-	-	Osteogenesis
28	Xylitol【XYLITOL】*2	1	2	3	Dental health
	mean ± SD	1.56 ± 0.51	1.19± 1.05	3.00± 1.25	

Note: This table should not use for the purpose of providing information to consumers because the information is very limited. Refer to the NMCD for details of ingredient.

*1: "Health claims approved as FOSHU" are shown in simplified forms (reference 11, 15).

*2: Approved for products at contain mixture functional ingredients (DHA and EPA), (Xylitol, maltitol, calcium hydrogen phosphate, and fukuronori extract).

Table 3. Ingredients of FOSHU products unlisted in NMCD monographs

No.	Functional ingredient	No.	Functional ingredient
1	Acetic acid	19	Lactulose
2	Apple-derived procyanidins	20	L-arabinose
3	Broccoli, cabbage-derived S-methylcysteine sulfoxide (natural amino acid)	21	Maltitol
4	Chinese gutta percha (as geniposidic acid)	22	Neokotalanol
5	Chlorogenic acids (as 5-caffeoylquinic acid)	23	Nori (*Porphyra yezoensis*) oligopeptide (as Ala-Lys-Tyr-Ser-Tyr)
6	Coffee bean mannooligosaccharide (as mannobiose)	24	Oolong tea polymerized polyphenols (as oolonghomobisflavan B) *
7	Erythritol	25	Palatinose
8	Eucalyptus extract (as macrocarpal C)	26	Polydextrose
9	Fukuronori (*Gloiopeltis furcata*) extract (as funoran)	27	Polyglutamic acid
10	Galacto-oligosaccharides	28	Products of propionic acid bacteria (as 1, 4-dihydroxy-2-naphthoic acid)
11	Globin protein degradation product (as Val-Val-Tyr-Pro)	29	Royal jelly-derived peptides (Val-Tyr, Ile-Tyr, Ile-Val-Tyr)
12	Glucosyl ceramide	30	Sardine peptide (as Val-Tyr)
13	Highly cross-linked phosphate cross-linked starch (as dietary fiber)	31	Sesame peptide (as Leu-Val-Tyr)
14	Indigestible dextrin	32	*Streptococcus thermophilus*
15	Indigestible recrystallized amylose (as α-1, 4 glucan aggregate)	33	Water-soluble corn bran fiber
16	Isoleucyltyrosine	34	Wheat-derived albumin
17	Isomaltooligosaccharides	35	Xylooligosaccharide
18	Lacto-sucrose	36	Yang long flavonoids (as hyperoside and isoquercitrin)

*: Although there is the NMCD monograph of oolong tea, it was excluded from Table 2 because there was no description as oolonghomobisflavan.

Table 1 shows the NMCD evaluation of the safety and effectiveness of each ingredient as rating scores (ordinal variables) converted from ratings (nominal variables) by the procedure above. In addition, the nutrient functions that were evaluated for effectiveness are shown in simplified forms.

NMCD has rated all the 20 nutrient function ingredients including n-3 fatty acid-equivalent fatty acids as “likely safe”, thus the mean rating score of the safety of FNFC ingredients was 2.00 ± 0.00.

Table 1 excludes the effectiveness rating of n-3 fatty acid-equivalent fatty acids. This is because the monographs provide no information on the effectiveness of the allowed nutrient function labeling to help maintain the skin. The effectiveness ratings of 19 ingredients other than n-3 fatty acid-equivalent fatty acids are tallied as follows: “Effective (rating score of 3; 13)”, “Likely Effective (rating score of 2; 4)”, and “Possibly Effective (rating score of 1; 2)”. Thus, the mean rating score ± standard deviation was 2.58 ± 0.69. The total mean rating score and standard deviation of the 19 ingredients were very high at 4.58 ± 0.69, of which 13 ingredients had the highest score of 5.

2) Ingredients of Foods for Specified Health Uses (FOSHU)

FOSHU products contain some ingredients for specified health use and can be sold with labelling of health claims approved by the Commissioner of Consumer Affairs Agency (7, 12). The official list (last revised on February 12, 2019) of FOSHU products, downloaded from the website of the Consumer Affairs Agency of the Cabinet Office, contained 1,064 products (15). Functional ingredients of these 1,064 products were organized and integrated into 64 ingredients by putting together the same and similar ingredients. Searching of the 64 ingredients by the English term, converted from Japanese name using several sources (13, 14), we found NMCD monographs corresponding to 28 ingredients but not to the remaining 36 ingredients. The 28 ingredients for which monographs were found are listed in Table 2, together with the rating scores derived from NMCD ratings in nominal variables of the safety and effectiveness. The effectiveness rating scores in this table are limited to those for specified health uses approved to the FOSHU products. Calcium is also approved as a “reduction of disease-risk FOSHU” other than “ordinary FOSHU” (11). Therefore, two health claims, osteogenesis and dental health, are included in Table 2.

Table 2 shows the 28 FOSHU ingredients whose monographs are contained in NMCD, and a considerable number of them have been used as functional ingredients in many FOSHU products as follows: Chitosan (49 products), Tea catechin (45 products), Lactobacillus (37 products), and others. Twenty-five of the 28 ingredients were evaluated for safety by NMCD as follows: "Likely safe (rating score of 2; 14)", "Possibly safe (rating score of 1; 11)". The mean safety score for the 25 ingredients was 1.56 ± 0.51.

For 16 ingredients in Table 2, NMCD monographs have rated the effectiveness of health function claims approved for FOSHU products as follows: "Effective (rating score of 3; 2)", "Likely Effective (rating score of 2; 4)", and "Possibly Effective (rating score of 1; 5)". Five ingredients of the 28 ingredients were rated as "INSUFFICIENT RELIABLE EVIDENCE to RATE (rating score of 0)" for the effectiveness in health functions approved to for FOSHU products. Ratings for effectiveness of 12 ingredients were not described in NMCD monographs. The mean effectiveness rating score of the 16 ingredients was 1.19 ± 1.05. In addition, the mean total score, the sum of safety rating score and effectiveness rating score, was 3.00 ± 1.25. Of the 36 ingredients unlisted in NMCD monographs (Table 3), indigestible dextrin (to improve gastrointestinal condition, blood sugar levels, blood triacylglycerol level) had an outstanding occupancy rate of about 36.2% (385 products) as a functional ingredient used in FOSHU products. Although FOSHU products are individually approved through a fair and strict governmental review, most of their functional ingredients have not been monographed by NMCD (56%: 36/64).

3) Ingredients of Popular Health Foods in Japan (PHFJ)

The popularity of a health food is probably reflected in its sales amount. Therefore, in this paper, we handled health food ingredients with high annual sales as popular health food ingredients in Japan. In particular, ingredients enumerated in the annual magazine "Health Food Report®", a valuable and concise information resource on the health food market status in Japan, were selected for list construction.

Table 4 shows the top 49 PHFJ ingredients enumerated in the "Health Food Report®" in order of sales amounts, with English keywords for searching NMCD monographs, along with NMCD rating scores on their safety and effectiveness. This table also shows the overlap between the top 49 PHFJ ingredients and FHC ingredients. We could find NMCD monographs corresponding to 40 ingredients out of the 49 PHFJ ingredients (Table 4). However, monographs matching "Multi-vitamin", "Amino acids", and "Vitamin B complex" were undetectable, because these keywords did not specify a single ingredient. Thirty seven of the 49 PHFJ ingredients were also used for health foods in any of the FHC category. (FNFC, FOSHU, and FFC). According to NMCD monographs, the safety of the 37 PHFJ ingredients are rated as follows in tally: "Likely safe (rating score of 2; 17)", "Possibly Safe (rating score of 1; 20)". The safety of gamma-aminobutyric acid and ornithine was not described in the monographs. The mean safety score of the 37 ingredients was 1.46 ± 0.51.

For 36 ingredients in Table 4, NMCD monographs have rated the effectiveness on health function as follows: "Effective (rating score of 3; 4)", "Likely Effective (rating score of 2; 5)", "Possibly Effective (rating score of 1; 16)", "INSUFFICIENT RELIABLE EVIDENCE to RATE (rating score of 0; 10)", and "Possibly Ineffective (rating score of -1; 1)". Ratings for effectiveness of 4 ingredients were not described in NMCD monographs. The mean effectiveness rating score of the 36 ingredients was 1.03 ± 1.00. In addition, the mean total score, the sum of safety rating score and effectiveness rating score, was 2.57 ± 1.36.

"PHFJ without FNFC + FOSHU" in Table 4 shows the PHFJ ingredients excluding those that overlap with FNFC and FOSHU. Of the 49 ingredients of PHFJ, 28 ingredients did not overlap with FNFC or FOSH, 3 of which were unlisted on the NMCD. For the remaining 25 ingredients, the mean safety score was 1.32 ± 0.48, the mean efficacy score was 0.81 ± 0.81, and the mean total score was 2.25 ± 1.12.

2. Statistical comparison between health food categories of the safety and effectiveness rating of ingredients

Whether the ratio of the ingredients listed in NMCD differed among health food categories was performed by chi-square test and subsequent residual analysis. As shown in Table 5, the ratio of ingredients unlisted in NMCD was found to be significantly higher in FOSHU ingredients.

In Table 6, NMCD rating scores of ingredients were statistically compared among health food categories. PHFJ ingredients were analyzed excluding those that overlapped with FNFC and FOSHU ingredients ("PHFJ without FNFC+ FOSHU"). The means of the safety, effectiveness, and total scores of the ingredients in each category increased in the order of "PHFJ without FNFC+FOSHU" < FOSHU < FNFC. The rating score, however, is an ordinal variable and not suitable for testing the difference between the mean values. Therefore, we used the Kruskal-Wallis test, an independent multi-group nonparametric test method, and found that there were significant differences in rating scores of ingredients among the three categories FNFC, FOSHU, and "PHFJ without FNFC+FOSHU" (Table 6). Multiple comparisons of post-hoc by the Steel-Dwass method showed that the average rank of FNFC ingredients was significantly higher in safety, effectiveness, and total rating scores than those of FOSHU and "PHFJ without FNFC+FOSHU" ingredients (Table 6). PHFJ consists of FHC (FNFC, FOSHU, and FFC) and legally undefined health foods other than FHC (Table 4). FFC is a legally defined category of health foods but is neither approved by the government nor strictly regulated by government standards. Thus, the comparison may be meaningful between the FFC included in PHFJ ("FFC in PHFJ") and PHFJ excluding FHC ("non-FHC in PHFJ"). As shown in Table 7, the average rank of ingredient of "FFC in PHFJ" was significantly higher in safety, effectiveness, and total rating scores than those of "non-FHC in PHFJ".

Table 4. Ingredients of Popular Health Foods in Japan (PHFJ)

Ranking	Ingredient【NMCD monograph name】*1	Rating score			Symptoms described in the effectiveness of NMCD	Overlapping with FHC *2
		Safety	Effectiveness	Total		
1	Multi-vitamin【UNLISTED】					A
2	Vitamin C【VITAMIN C (ASCORBIC ACID)】	2	3	5	Vitamin C deficiency	A
3	Vitamin E【VITAMIN E】	2	3	5	Vitamin E deficiency	A
4	*Aojiru* (green juice)【CABBAGE (Kale)】*3	1	0	1	Cancer, etc.	
5	Protein 【WHEY PROTEIN】	2	1	3	Athletic performance	B
6	Calcium【CALCIUM】	2	3	5	Hypocalcemia	A, B
7	Enzyme (fermented plant extract)【UNLISTED】					
8	Collagen【GERATIN】	1	0	1	Osteoarthritis	C
9	Dietary fiber【BLOND PSYLLIUM (Dietary fiber)】	2	3	5	Constipation	B, C
10	Amino acid【UNLISTED】					C
11	Lactic acid bacteria【LACTOBACILLUS】	2	2	4	Rotaviral diarrhea	B, C
12	Blueberry【BLUEBERRY】	1	-	-		
13	Royal jelly【ROYAL JELLY】	1	0	1	Hyperlipidemia	B
14	Aloe【ALOE】	1	1	2	Constipation	C
15	Ginkgo biloba【GINKGO】	2	1	3	Age-related memory impairment, etc.	C
16	Turmeric【TURMERIC】	1	1	2	Dyspepsia	C
17	Glucosamine【GLUCOSAMINE SULFATE】	2	2	4	Osteoarthritis	C
18	Yeast【BREWER'S YEAST】	1	1	2	Premenstrual syndrome	
19	Sesame【UNLISTED】					B
20	DHA【DHA (DOCOSAHEXAENOIC ACID)】	2	1	3	Coronary artery disease	A, B, C
21	Vitamin B complex【UNLISTED】					A
22	Reishi【REISHI MUSHROOM】	1	0	1	Postherpetic neuralgia	
23	Astaxanthin【ASTAXANTHIN】	1	-	-		C
24	EPA【EPA (EICOSAPENTAENOIC ACID)】	2	1	3	Coronary artery disease	A, B, C
25	Gamma-aminobutyric acid【GABA (GAMMA-AMINOBUTYRIC ACID)】	-	-	-		B, C
26	Chlorella【CHLORELLA】	1	0	1	Fibromyalgia, Glioma	
27	Korean ginseng【GINSENG, PANAX】	1	1	2	Diabetes	
28	*Shijimi* (fresh water clam)【UNLISTED】					
29	Ginger【GINGER】	2	1	3	Morning sickness	C
30	Soy isoflavone【SOY】	2	1	3	Breast cancer (prevention)	B, C
31	Dextrin (indigestible dextrin)【UNLISTED】					B, C
32	Nattokinase【NATTOKINASE】	1	0	1	Deep vein thrombosis	B
33	Hyaluronic acid【HYALURONIC ACID】	-	-	-		C
34	Polyphenol 【COCOA】	2	1	3	Hypertension (as cacao polyphenol)	B, C
35	Lutein【LUTEIN】	2	2	4	Lutein deficiency	C
36	Agaricus【AGARICUS MUSHROOM】	1	0	1	Chemotherapy	
37	Olive 【OLIVE】	2	2	4	Constipation (as olive oil)	C
38	Ornithine【ORNITHINE】	-	-1	-	Athletic performance	C
39	Catechin【GREEN TEA (Epigallo Catechin Gallate)】	1	1	2	Hyperlipidemia	B, C
40	Kudzu flower-derived isoflavone 【KUDZU】	1	0	1	Alcoholism, Angina	B, C
41	Vinegar【APPLE CIDER VINEGAR】	1	0	1	Diabetes, Gastroparesis	B, C
42	Coenzyme Q10【COENZYME Q-10】	2	2	4	Coenzyme Q-10 deficiency	C
43	Ceramide (N-acylsphingosine)【UNLISTED】					B, C
44	Garlic【GARLIC】	2	1	3	Hypertension	C
45	Placenta【UNLISTED】					
46	Propolis【PROPOLIS】	1	0	1	Common cold	
47	Maca【MACA】	1	1	2	Sexual desire	
48	French marine pine bark extract【PYCNOGENOL】	1	1	2	Allergic rhinitis	C
49	Lactoferrin【LACTOFERRIN】	1	1	2	Hepatitis C	C
	PHFJ: mean ± SD	1.46 ± 0.51	1.03 ± 1.00	2.57 ± 1.36		
	PHFJ without FNFC+FOSHU *4: mean ± SD	1.32± 0.48	0.81 ± 0.81	2.25± 1.12		

Note: This table should not use for the purpose of providing information to consumers because the information is very limited. Refer to the NMCD for details of ingredient.

*1: This is the order of top-selling rankings from the "Health Food Report®" (Reference 16), up to 49th. The NMCD monograph name is shown in【】. The mixture ingredients showed【unlisted】because it cannot be specified as one ingredient.

*2: Overlapping ingredients with FHC, A: FNFC, B: FOSHU, C: FFC.

*3: *Aojiru* with index number 16056 was described as "kale juice" in "Standard food composition table in Japan-2015- (7th revised edition)".

*4: PHFJ ingredients excluding those that overlapped with FNFC and FOSHU ingredients.

Table 5. Comparison of the number of listed and unlisted health food ingredients in the three categories of the NMCD monograph

	Listed	(%)	Unlisted	(%)	residual analysis *2	
FNFC	20	(100)	0	(0)	*P <0.001*	Listed > Unlisted
FOSHU	28	(44)	36	(56)	*P <0.001*	Listed < Unlisted
PHFJ without FNFC+FOSHU	24	(86)	4	(14)	*P <0.01*	Listed > Unlisted
Chi-square test *1	*p<0.001*					

*1,2: After the chi-square test, residual analysis was performed.

Table 6. Analysis of rating score of FNFC, FOSHU, and PHFJ without FNFC+FOSHU ingredients

	Safety*1			Effectiveness*1			Total*1		
	mean ±SD	n*2	average rank (n = 67)	mean ±SD	n*2	average rank (n = 56)	mean ±SD	n*2	average rank (n = 54)
FNFC	2.00 ± 0.00	20	20.00 ^{x,a}	2.58 ± 0.69	19	12.79 ^{b,c}	4.58 ± 0.69	19	12.21 ^{d,e}
FOSHU	1.56 ± 0.51	25	34.74 ^{x}	1.19 ± 1.05	16	32.25 ^{b}	3.00 ± 1.25	15	29.80 ^{d}
PHFJ without FNFC+FOSHU	1.32 ± 0.48	22	42.84 ^{a}	0.81 ± 0.81	21	37.19 ^{c}	2.25 ± 1.12	20	37.60 ^{e}
Kruskal-Wallis test *3	*p < 0.001*			*p < 0.001*			*p < 0.001*		

*1: Data are the mean ± standard deviation and average rank.

*2: The score of ingredients unlisted in NMCD was regarded as a missing value and excluded from statistical analysis.

*3: The Kruskal-Wallis test was performed on the differences between categories for each rating score, and the Steel-Dwass test was used for multiple comparisons between three groups with significant differences. Same superscript letters are significantly different.; a, b, c, d, e: ($p < 0.001$); x: ($p < 0.01$).

Table 7. Analysis of rating score of FFC and non-FHC in PHFJ

	Safety *1			Effectiveness *1			Total *1		
	mean ±SD	n *2	average rank (n = 22)	mean ±SD	n *2	average rank (n = 21)	mean ±SD	n *2	average rank (n = 20)
FFC in PHFJ	1.54 ± 0.52	13	9.00	1.08 ± 0.86	13	8.00	2.83 ± 1.03	12	8.00
non-FHC in PHFJ *3	1.00 ± 0.00	9	13.00	0.38 ± 0.52	8	13.00	1.38 ± 0.52	8	12.00
Mann–Whitney *U* test *4	*p < 0.01*			*p < 0.05*			*p < 0.01*		

*1: Data are the mean ± standard deviation and average rank.

*2: The score of ingredients not listed in NMCD was regarded as a missing value and excluded from statistical analysis.

*3: PHFJ excluding FHC (FHC: Food with Health Claims, categorized into FFC, FOSHU and FFC).

*4: Mann–Whitney *U* test was performed on the differences between categories.

We further investigated the relationship between the rating of health food ingredients and their sales amounts. For PHFJ ingredients overlapping with FNFC and FOSHU ("FNFC+FOSHU in PHFJ"), strong positive correlations were found between effectiveness, and total rating scores and sales amounts ($r = 0.76$, $r = 0.74$, respectively) (Fig. 1). However, such correlations were not observed for PHFJ ingredients other than "PHFJ without FNFC+FOSHU".

DISCUSSION

Health foods are increasingly popular in Asian countries including Japan (1-4). Professionals such as dietitians have a role to help consumers use health foods based on scientific evidence on safety and effectiveness in order to prevent health or economic problems. This requires knowledge and utilization of health food legal systems and reliable information sources. As described in the Introduction, in Japan, due to differences in legal regulations, health foods are classified as FHC and so-called health foods, and FHC is further categorized as FNFC, FOSHU, and FFC (4, 5, 8, 9). FNFC, FOSHU, and FFC are under legal systems of standard regulation, individual approval, and notification, respectively. The status of FFC is similar to that of health foods other than FHC. Because both products neither necessarily comply the standards established by the government nor receive evaluation by the government for their safety and effectiveness. Therefore, the safety and effectiveness of health food products may differ

among health food categories. In turn, the safety and effectiveness of health food products are probably most strongly influenced by the safety and effectiveness of ingredients. However, so far, it is unclear whether the evaluation of safety and effectiveness of health food ingredients distributed in Japan differs among categories. Based on these considerations, we examined and compared how the safety and effectiveness of ingredients were evaluated for FNFC, FOSHU, and popular health foods including FFC but excluding FNFC and FOSHU. For this purpose, the evaluations by NMCD monographs of each ingredients were extensively and deeply examined. NMCD is a well-established information source of health food ingredients with an abundant number (more than 1,100) of listed ingredients and with excellent quality characterized by its ratings of the safety and effectiveness of ingredients (17).

In this study, we used a unique approach of assigning a rating score to the rating of safety and effectiveness in NMCD monographs of each ingredient. This enabled statistical comparison and examination between categories of health food ingredients, so that some objective findings described in the result2 were obtained. Here, we will discuss these objective findings and will not mention other interesting but detailed findings in the list of health food ingredients by category.

As shown in Table 5, the ratio of ingredients listed in NMCD monographs was significantly lower in FOSHU ingredients than FNFC and "PHFJ without FNFC+FOSHU" ingredients. This situation is probably due to both characteristics of FOSHU products and NMCD editorial policy. FOSHU products are individually reviewed strictly by the government for safety and effectiveness and allowed to be labeled for specified health uses (7, 12). Each FOSHU product thus guarantees to some extent the safety and effectiveness of the product per se and its ingredients. Planning and development of almost all FOSHU products have been achieved by Japanese companies, from basic research on their functional ingredients to product design. Distribution and use of FOSHU products are also almost limited to Japan.

On the other hand, NMCD is a database compiled by a United States civilian agency. In the US, health claims by foods, such as structure/function claims, general well-being claims, and nutrient deficiency disease claims, are exclusively permitted to dietary supplements defined by the Dietary Supplement Health and Education Act of 1994 (19). Unlike

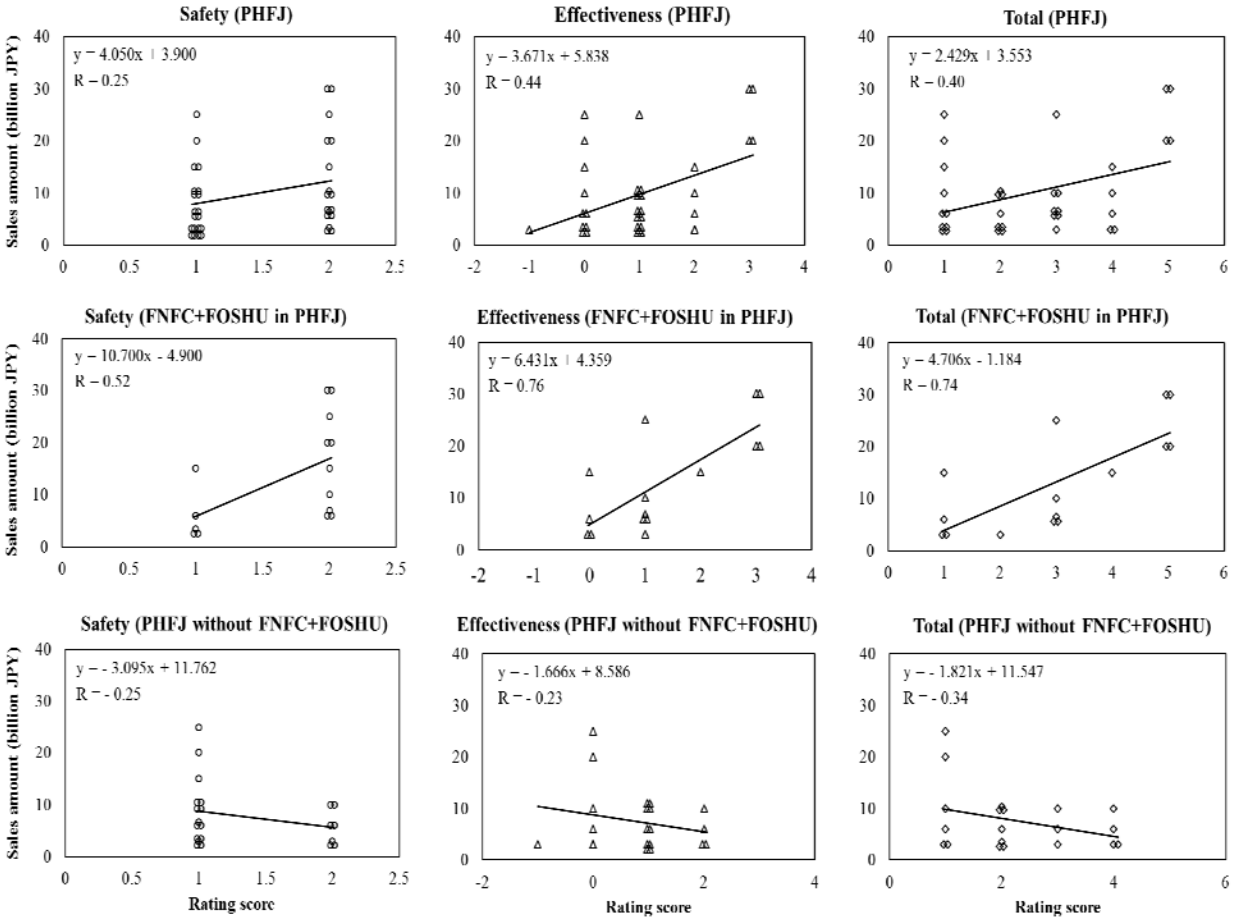

Fig 1. Correlation between rating score and market size about PHFJ
"Sales amount" was referred to Reference 16. "Rating score" was based on the data in Table 4.

FNFC and FOSHU in Japan, dietary supplements are self-assessed for safety and effectiveness, so that they do not necessarily meet government-established standards and also are not evaluated by the government. NMCD evaluates the safety and effectiveness of dietary supplements with these characteristics from a third-party perspective. NMCD is an extremely valuable information source for consumers to use dietary supplements safely and securely based on scientific evidence. Therefore, it is natural that the target of evaluation by NMCD is mainly the ingredients of dietary supplements that are widely distributed in the United States, not the ingredients of FOSHU that are locally distributed in Japan.

FNFC products can be marketed in compliance with governmental standards, which are established based on historically and internationally recognized strong and extensive evidence on safety and effectiveness. Therefore, it can be easily assumed that the safety and effectiveness of the FNFC ingredients are higher than those of the other categories. In this study, we could objectively confirm the validity of this assumption. Post-hoc multiple comparisons by the Steel-Dwass procedure subsequent to the Kruskal-Wallis test showed that the average rank of FNFC ingredients was significantly higher in safety, effectiveness, and total rating scores than those of FOSHU and "PHFJ without FNFC+FOSHU" ingredients (Table 6).

Since FOSHU products are approved through the individual and strict review by the government (7, 12), each FOSHU ingredient is guaranteed to some extent for safety and effectiveness. However, there was no statistically significant difference between the safety, effectiveness and total scores of the FOSHU ingredients and those of the "PHFJ without FNFC+FOSHU" ingredients (Table 6). Again, one of the reasons for this is probably that FOSHU is unique to Japan and NMCD is a database constructed by a civilian institution in the US. Most FOSHU ingredients are unlisted in NMCD monographs as shown in Table 5, even though FOSHU ingredients have scientific bases for their safety and effectiveness to endure various criticism upon strict approval reviews. The fact that many academic papers on FOSHU ingredients are written in Japanese may also make FOSHU ingredients difficult to be properly evaluated.

The Mann–Whitney *U* test showed that the average ranks of ingredients of "FFC in PHFJ" were significantly higher in safety, effectiveness, and total rating scores than those of "non-FHC in PHFJ" (Table 7). In other words, within the top 49 health foods by sales, FFC ingredients were superior in terms of these evaluation indicators to the ingredients of health foods legal undefined. The results in Table 7 suggest that food business operators are steadily committed to the research, development, and product design of FFC based on scientific bases of safety and effectiveness rather than the experience and the oral tradition with poor evidence in order to fulfill their responsibilities.

Sales amounts of health foods possibly reflect consumer preference and consumption behavior. Interestingly, upon analysis from this point of view, we found positive correlations between sales amounts and effectiveness rating scores of PHFJ ingredients (Fig. 1). Further sub-analysis revealed positive correlations between the sales amounts and the safety, effectiveness, and total rating scores of ingredients of PHFJ overlapping with FNFC and FOSHU (Fig. 1). Such correlations were not observed for PHFJ ingredients other than FNFC and FOSHU ingredients. According to these results, many consumers are presumably taking consumption behavior based on the scientific basis of safety and effectiveness of health foods. Although details are unknown, information on the category of health foods, health claims in labeling, consultation with advisory staff such as dietetics, and other factors may facilitate consumer's informed-choices.

In this study, we have obtained new objective findings about Japanese health foods by assigning rating scores for the safety and effectiveness ratings of each ingredient in NMCD monographs. The NMCD is a comprehensive database constructed from extensive surveys of research papers on the effects of health food ingredients on human subjects and provides rating based on predetermined criteria for study design and scale. The information provided by NMCD, including interactions with drugs, is comprehensive and suitable for providing various information to consumers. In addition to providing information to consumers about each product, NMCD can be used to statistically understand the state of health food ingredients as in this study. The Internet version of NMCD (20), where information is constantly updated, is convenient for providing information to consumers, but in this study, the book version was used from the viewpoint of the invariance of information.

The overall evidence in this study suggests that health foods distributed in Japan differed in their safety and effectiveness ratings by NMCD due to differences in their legal regulations and systems. Also, the safety and effectiveness ratings also seemed to relate to sales amounts. Information on the category of health foods, health claims in labeling, consultation with advisory staffs, and others may facilitate consumer's informed-choices.

In Asian countries where health foods are gaining popularity, specialists such as dietitians have a role to help consumers use health foods based on scientific evidence on safety and effectiveness to prevent health and economic problems. The findings obtained in this study would serve as a reference for Asian professionals to understand the Japanese health food regulatory systems and promote the use of health food based on scientific evidence on safety and effectiveness. In addition, the findings would be useful for Asian countries to develop health food systems of their own.

Acknowledgements:

We would like to thank Andrew R. Durkin, Professor Emeritus of Indiana University, Bloomington, IN, USA, for his careful editing of the English of this article.

Conflict of interests:

The authors declare no conflict of interests regarding the publication of this article.

REFERENCES

1) Health Industry Marketing News ONLINE. "East Asian market greatly expanded (total of 3.5 trillion Japanese yen in 3 countries in FY2017)"http://www.him-news.com/news/view/4439. 6 June 2019. (in Japanese). Accessed October 31, 2019
2) Takeda T. "Overseas expansion of functional food business in TPP era", Seibutsu-kogaku kaishi. 94: 610-614. 2016. (in Japanese)
3) The Health Industry News. "The health food market increased 2% to 1,227 Billion Japanese yen. The demand for the elderly is not high. The target is 50s". https://www.kenko-media.com/health_idst/archives/8020. 9 January 2018. (in Japanese). Accessed October 31, 2019.
4) Yamada K, Tanaka H, Ishimi Y, Umegaki K, Ide R. Foods with Health Claims: Current Status and Related Issues. J Jpn Soc Nutr Food Sci. 70: 91-99. 2017. (in Japanese)
5) Ministry of Health, Labor and Welfare. Health Foods (Internet site). https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/hokenkinou/index_00010.html. Accessed October 31, 2019.
6) Ministry of Health, Labor and Welfare. Health Foods (Pamphlet). https://www.mhlw.go.jp/content/000535155.pdf. p 9. February 2019. Accessed October 31, 2019.
7) Umegaki K. Positive and Negative Aspects of Food with Health Claims in Japan. J Nutr Sci Vitaminol. 61 Suppl: S133-5. 2015.
8) Umegaki K. Safety and Effectiveness of Food with Health Claims and Its Effective Use. Jpn. J. Nutr. Diet. 77: 67-75. 2019. (in Japanese)
9) Consumer Affairs Agency, Government of Japan. Outline of Food Labelling Systems for Health and Nutrition. https://www.caa.go.jp/en/policy/foodlabeling/pdf/food_labeling_191001_0001.pdf. Accessed October 31, 2019.
10) Consumer Affairs Agency. <For business operators> Guidelines for nutrition labelling based on the Food Labeling Act [Second Edition] (Corrected on May 18, 2018)-Food Labeling Standards, appendix 11. https://www.caa.go.jp/policies/policy/food_labeling/food_labeling_act/pdf/food_labeling_act_180518_0001.pdf. 50-51. May 2018. (in Japanese). Accessed October 31, 2019.
11) Yamada K, Sato-Mito N, Nagata J, Umegaki K. Health claim evidence requirements in Japan. J Nutr. 138: 1192S-8S. 2008.
12) Consumer Affairs Agency, Government of Japan. (Guidance for Industry) The system of "Foods with Function Claims" has been launched! (Pamphlet). https://www.caa.go.jp/policies/policy/food_labeling/information/pamphlets/pdf/151224_2.pdf. December 2015. p 3. Accessed October 31, 2019.
13) National Institutes of Biomedical Innovation, Health and Nutrition, “Information system on safety and effectiveness for health foods”. https://hfnet.nibiohn.go.jp/.(inJapanese) Accessed October 31, 2019.
14) Japan Health Food and Supplement Information Center, "All of health foods and supplements [ingredients] 2017, Natural medicine database".2017. Dobunshoin, Tokyo. (in Japanese)
15) Consumer Affairs Agency. List of licenses for “food for specific health use (approved) [Excel datafile]”.https://www.caa.go.jp/policies/policy/food_labeling/health_promotion/#m02. As of February 12, 2019. (in Japanese) Accessed October 31, 2019.
16) Yamanoshita syuppan. In: Health Food Report® "Material market trends in 2019", p 2-3. 2019. Yamanoshita syuppan, Tokyo. (in Japanese).
17) Jellin, J.M., Gregory, P.J., et al. Pharmacist's Letter/Prescriber's Letter Natural Medicines Comprehensive Database 2013. 2012. Therapeutic Research Faculty, CA.
18) Yamazaki Y, Hashida H, Shimura F. Evaluation of Safety and Effectiveness of Popular Herbal Supplement Ingredients Using the Natural Medicines Comprehensive Database. Jpn. J. Nutr. Diet. 69: 267-279. 2011. (in Japanese)
19) Food and Drug Administration; FDA. Structure/Function Claims. https://www.fda.gov/food/foodlabelingnutrition/structurefunction-claims. Accessed November 2, 2019.
20) Therapeutic Research Center. Natural Medicines database.https://trchealthcare.com/natural-medicines. Accessed November 2, 2019.

ORIGINAL

Evaluation of Factors Affecting Food Wastage among Hospitalized Patients on Therapeutic Diet at Ministry of Health (MOH) Hospitals

Norshariza J[1], Siti Farrah Zaidah MY[2], Basmawati B[3], Leow C[3], Lina I[4], Norafidza AAP[5], Khalizah J[6], John Kong JP[7], Lim SM[8]*

[1]*National Cancer Institute, Putrajaya*
[2]*Disease Control Division, Ministry of Health Malaysia*
[3]*Hospital Tuanku Jaafar, Seremban*
[4]*Hospital Melaka, Melaka*
[5]*Seremban Health Clinic, Negeri Sembilan*
[6]*Hospital Queen Elizabeth, Kota Kinabalu, Sabah*
[7]*Bintulu Health Clinic, Sarawak*
[8]*Hospital Teluk Intan, Perak*

ABSTRACT

High food wastage is associated with reduced energy intakes leading to malnutrition-related complications in hospitals. This study aims to determine food wastage prevalence among hospitalized patients on therapeutic diets and associated factors affecting food waste. Association of contributing factors with food waste among inpatients on therapeutic diets in 21 study sites were investigated. This study was conducted from October 2016 to November 2016 where 2759 subjects were randomly recruited. Overall, 47.4% therapeutic diet were wasted. 52.4% vegetables had been wasted followed by protein (48.4%), carbohydrate (44.5%) and desserts (44.3 %). Food wastage was significant higher among female (50.7%), centralized food serving system (49.7%), outsource food service system (56.8%) and during dinner time (58.5%). Physical factors like eating and swallowing difficulties; psychological factors (alone, abandoned, stress and food belief) and food quality factors; unclean food and delay eating time were found significantly associated with higher food waste at $p<0.01$. Food wastage was also significantly affected by nutritional impact symptoms (NIS) like abdominal distension, diarrhoea, dysphagia, lethargy, nausea, poor appetite, poor dentition and vomiting. Several factors had been identified as associated factors affecting food waste. A negative and high correlation was observed between energy and protein intake with food wastage suggesting that a reduction in energy and protein intake will lead to higher food waste. With this knowledge, necessary measures can be plan and implement to reduce food waste and improves the therapeutic diet deliverance in improving hospitalized patients' nutritional status.

Keywords: Food waste, food wastage, nutrition impact symptoms, therapeutic diet

INTRODUCTION

Food waste is one of the issues that become a global concern nowadays[1]. An estimated one-third of all food that is produced worldwide is wasted, which amounts to about 1.3 billion tonnes per year[2]. Food waste can be defined as any edible foods or leftover from some process, cooked or uncooked food[3]. The causes of food waste are numerous, and occur at the stage of production, processing, retailing and consumption[4]. Statistics from Solid Waste Corporation of Malaysia

*To whom correspondence should be addressed: <dtshariza@nci.gov.my>

(SWCorp) showed that in 2015 the food waste in Malaysia reached 15,000 tonnes daily, including 3,000 tonnes that was still fit for consumption and should not have been discarded[5]. According to Williams & Walton, 2011, food waste related to clinical issue in hospital settings had become the most challenging in food waste reduction strategies[6].

Food wastage is commonly reported in Malaysian hospitals. In a review article summarizing literatures on the extent of plate waste occurring in hospital settings until 2012, a median plate waste of 30% with a wide range of 6% to 67% were reported in 32 international studies[6]. In hospitals, 50% of the total waste generated in a ward environment was food[7,8]. Several studies had shown that the problem of food wastage in hospitals ranges from 17% to 67%[9,10]. It was estimated that plate waste in hospitals can add up to 30 percent to food costs[9]. In year 2000, an estimation of the cost of wasted food in British hospitals was worth £28 million[11]. Food wastage in hospitals has always been much higher than other food service sectors. Restaurants, cafes, hotels, schools and workplace canteens usually have levels of plate waste of less than 15%, in which hospitals plate waste can be two or three times higher[7].

High food wastage is associated with reduced energy and protein intakes and has an impact on malnutrition-related complications in hospitals, as well as financial and environmental costs[12]. The wasted food contains energy, protein, and important micro nutrients that could have been consumed by hospitalized patients of whom 40% are at risk of under nutrition[13]. Hospital malnutrition could delay patients' recovery, thus extending the length of the stay and contributing to its worsening[12]. There are several reasons that have been associated with high level of plate waste in hospitals including appetite variations. Meal waste in hospitals could also be caused by alterations in the sensorial quality of foods served[14]. In a study done in the United State of America, loss of appetite along with taste loss was the most common reasons found which made up 28% of the reasons inpatients consumed less than half of the main starter[15]. In a Swiss study, half of the inpatients declared they had less appetite than at home[16]. As expected, illness often can affect appetite and the senses of taste or smell. Reduced activity during hospitalization, side effects of treatment drugs, nausea or gastrointestinal symptoms, can also interfere with the normal desire to eat. Diet prescriptions, such as texture modification or therapeutic diet like low salt diet, could reduce the sensory appeal of food, and it has been estimated that being on a special diet doubles the risk of insufficient energy intake[17].

Reducing food waste should be of prime concern to health care multidisciplinary team including food service providers, medical and nursing staff, dieticians and catering's staff. Reducing in food wastage helps cut costs while supporting patients to consume their food which lead to better clinical outcome through improve nutritional. This study aims to determine the prevalence of food wastage among hospitalized patients who received therapeutic diets and evaluate its association with gender, ethnic, mealtime, diagnosis, type of therapeutic diet received, nutrition impact symptoms, psychological and physiological factors, food quality as well as food serving and food service system.

METHODS

Selections of subjects: A cross sectional study was conducted to determine prevalence of food wastage and its association with energy and protein intake adequacy among inpatients receiving therapeutic diets in 21 study sites comprising of number of state and number hospital specialist government hospital under the Ministry of Health, Malaysia from October 2016 to November 2016. Eligible subjects were inpatients aged above 18 years old who received therapeutic diet and able to take orally with no communication barriers in medical wards with at least 48 hours of admission. In patients who received normal diet, on Ryle's tube feeding (RT feeding) or parenteral nutrition, with psychiatric disorder, diagnosed with HIV/AIDS, pregnant woman or bedridden and Nil by Mouth (NBM) patients were excluded. The sample size needed in this study was 2759 included 10% calculation for attrition and calculated based on power sample of 80% and confidence interval 95%, an expected difference of 5% and standard deviation (SD) of 134 the nutritional value wasted by patient in a pilot study on nutrition impact symptoms (NIS) and food wastage[18] in National Cancer Institute, Putrajaya and at the proportionate sampling were used to recruit the subjects in respective study sites. A

replacement of new subjects was applied when the appointed subjects refused.

Ethical approval was obtained from Medical Ethical and Research Committee, Ministry of Health (NMRR-16-1482-31605). Additionally, permission to conduct the study was obtained from the Director of selected hospitals with informed consent approved by the Ethical Committee signed by subjects or authorized representative in the presence of witness were also obtained. A total of 2587 subjects were recruited in this study constituted with 50.1% male subjects (n=1296) and female, 49.9% (n=1291). Social-demographic and clinical data such as age, ethnicity, gender, marital, employment and educational status and clinical diagnosis are listed in **Table 1** were obtained from subject's file and a face-to face interview.

Data collection: Food wastage in this study was indicated as any food that is discarded or uneaten. A visual estimation method was used to measure proportion of leftovers food using semi quantitative 5-point scale (all, ¾, ½, ¼, none) (Williams & Walton, 2011). An illustration of food wastage was done according to pictograph as a standard measurement of observation for the usage of Data Collector in this study. Observation was done during lunch or dinner only and the wastage was categorised into 4 main groups; carbohydrate, protein, vegetables and desserts. All observation on the food wastage was recorded in the Data Collection Form designed for the study.

Table 1: Characteristics of the Study Population

Study Characteristic		Frequency (n)	Percentage (%)
Gender	Male	1296	50.1
	Female	1291	49.9
Educational level	No education	396	15.4
	Primary	824	32.1
	Secondary	1146	44.6
	Diploma	118	4.6
	Bachelor	83	3.2
Marital status	Single	296	11.5
	Married	2100	81.5
	Divorced	29	1.1
	Widowed	153	5.9
Ethnic	Malay	1643	63.5
	Chinese	439	17.0
	India	333	12.9
	Bumiputera Sabah	84	3.2
	Bumiputera Sarawak	56	2.2
	Others	32	1.2
BMI (kg/m^2)	Underweight	204	8.0
	Normal	1238	48.5
	Overweight	713	27.9
	Obese	396	15.5
Diagnosis	Diabetes mellitus	1620	62.6
	Hypertension	1643	63.5
	Renal Disease	632	24.4
	Hyperlipidaemia	357	13.8
	Heart Disease	502	19.4
	Gout	100	3.9
	Wound	43	1.7
	DVT/AF	40	1.5
	Others	692	28.0

Data analysis: The data analysis was conducted using IBM SPSS version 22. Descriptive date is expressed as mean and standard deviation. Independent T-Test and One-way ANOVA were conducted for analysis of the mean difference in normally distributed data. Categorical data were analysed using Chi-square or Fisher's exact test. Pearson's and Spearman's correlation were used to analyse correlation between numerical data.

Table 2: Average Food Wastage by Study Site and Food Group

Item		N	Food Wastage (%) Mean (±SD)
Overall		2587	47.4 (± 31.3)
Study Sites	Hospital Tuanku Jaafar, Seremban	200	46.2 (± 31.6)
	Hospital Selayang	141	62.0 (± 29.6)
	Hospital Tunku Ampuan Rahimah	183	35.0 (± 31.1)
	Hospital Serdang	44	40.5 (± 28.7)
	Hospital Kuala Lumpur	122	29.9 (± 28.9)
	Hospital Sultanah Nur Zahirah	52	63.8 (± 27.8)
	Hospital Raja Perempuan Zainab II	87	63.5 (± 25.4)
	Hospital Sultanah Aminah	133	44.6 (± 28.0)
	Hospital Pakar Sultanah Fatimah	153	52.3 (± 36.5)
	Hospital Sultan Ismail	84	59.2 (± 28.6)
	Hospital Sultanah Bahiyah	159	53.5 (± 27.2)
	Hospital Sultan Abdul Halim	134	36.3 (± 30.3)
	Hospital Tuanku Fauziah	82	47.5 (± 28.4)
	Hospital Melaka	193	38.0 (± 32.1)
	Hospital Pulau Pinang	109	55.2 (± 26.6)
	Hospital Raja Permaisuri Bainun	192	48.9 (± 33.7)
	Hospital Taiping	107	37.4 (± 24.5)
	Hospital Sultan Haji Ahmad Shah	51	60.8 (± 29.2)
	Hospital Tengku Ampuan Afzan	105	48.2 (± 30.6)
	Hospital Umum Sarawak	139	48.3 (± 31.4)
	Hospital Queen Elizabeth	117	52.8 (± 24.8)
Food Group	Carbohydrate	2587	44.5 (± 37.1)
	Protein	2587	48.4 (± 39.2)
	Vegetables	2587	52.4 (± 40.1)
	Fruits/desserts	2587	44.3 (± 45.8)
Type of Carbohydrate	Rice	2188	42.8 (± 36.9)
	Porridge	353	52.5 (± 35.9)
	Mixed Porridge	30	66.7 (± 39.0)
	Pureed	9	69.4 (± 46.4)
	Blended	7	53.6 (± 50.8)
Type of Dessert	Fruit	2067	32.8 (± 42.2)
	Jelly	59	65.3 (± 40.2)
	Pudding	79	60.1 (± 43.4)

RESULTS

A total of 2587 (93.7%) subjects were successfully recruited into this study. In this study, male subjects constituted 50.1% of the sample studied compared to female, 49.9% .63.5% study subjects were Malay, followed by Chinese (17.0%) and Indian (12.9%). 44.6% subjects received secondary education, 81.5% were married and more than 60% were diagnosed with diabetes mellitus and hypertension. The mean age of subjects was 57±14.8 years old. Based on WHO (2006) BMI classification, most of the subjects 48.5% had normal weight. Overweight and obese subjects were 27.9% and 15.5% respectively. Only 8% of study's subjects were underweight.

.

Food Wastage: Overall food wastage in therapeutic diet served in 21 Ministry of Health hospitals was 47.4% ranging from 16% to 79%. Table 2 presents the average food wastage by study site where Hospital Sultanah Nur Zahirah, Kuala Terengganu, Terengganu had the highest percentage of food wastage (63.8 %), followed by Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan (63.5%), Hospital Selayang, Selangor (62.0%) and Hospital Sultan Ahmad Shah, Temerloh, Pahang (60.8%). Hospital Kuala Lumpur had the lowest percentage of food wastage (29.9%).

Table 3: Comparing Mean Food Wastage with Study Characteristics

Study Characteristic		N	Food Wastage (%) Mean (± SD)	*p*-value[a]
Gender	Male	1296	44.2 (± 32.5)	<0.001
	Female	1291	50.7 (± 29.7)	
Food Serving System	Bulk	798	42.2 (± 31.6)	<0.001
	Centralised	1789	49.7 (± 30.9)	
Food Service System	In-house	2203	45.8 (± 31.4)	<0.001
	Outsource	384	56.8 (± 29.1)	
Referral to Dietitian	Yes	617	47.6 (± 32.2)	0.883
	No	1964	47.4 (± 30.9)	
Time of Meal Observed	Lunch	2447	46.8 (± 31.4)	<0.001
	Dinner	138	58.5 (± 27.3)	
Ethnic	Malay	1643	47.5 (± 31.1)	0.082[b]
	Chinese	439	48.7 (± 33.0)	
	India	333	43.6 (± 31.2)	
	Bumiputera Sarawak	56	54.3 (± 26.0)	
	Bumiputera Sabah	84	46.7 (± 29.3)	
	Others	32	46.7 (± 31.3)	
Educational level	No education	396	53.0 (± 30.5)	<0.001[b]
	Primary	824	49.2 (± 30.5)	
	Secondary	1146	45.1 (± 31.2)	
	Diploma	118	42.7 (± 34.1)	
	Bachelor	83	42.1 (± 33.8)	
Marital status	Single	296	40.8 (± 31.9)	<0.001 [b]
	Married	2100	48.3 (± 31.5)	
	Divorced	29	29.1 (± 21.9)	
	Widowed	153	52.2 (± 25.5)	
BMI (kg/m^2)	Underweight	204	56.3 (± 31.6)	<0.001 [b]
	Normal	1238	50.0 (± 31.2)	
	Overweight	713	43.9 (± 31.2)	
	Obese	396	41.3 (± 29.7)	
Age group, years old	Young adult (18 – 30)	159	40.7 (± 32.6)	<0.001 [b]
	Middle age adult (30 – 50)	587	43.0 (± 31.0)	
	Senior adult (> 50)	1841	49.4 (± 31.0)	

[a] *Independent t-test;* [b]*One – way Anova; Significant tested by p<0.05*

Vegetables had become the highest wastage among the food groups (52.4%) in most of the government hospitals, followed by protein (48.4%), carbohydrate (44.5%) and desserts (44.3 %). Moreover, among types of carbohydrate wasted the most was pureed diet (69.4%) compared to others. For dessert, the data shows that jelly had the highest food wastage (65.3%), followed by pudding (60.1%) and fruit (32.8%). Food wastage was significant higher among female (50.7%), centralised food serving system (49.7%), outsource food service system (56.8%) and during dinner time (58.5%).

Table 4: Food Wastage and Nutritional Impact Symptoms and Factors Influencing Nutritional Status (Physical, Psychological and Food Quality)

Factors	N	Food wastage (%) Mean (SD)	*p*-value[a]
NIS			
Abdominal Distension			<0.001
Yes	125	57.9 (30.6)	
No	2462	46.9 (31.2)	
Ascites			0.87
Yes	61	48.1 (32.9)	
No	2526	47.4 (31.2)	
Constipation			0.56
Yes	105	49.2 (30.5)	
No	2482	47.3 (31.3)	
Diarrhoea			<0.001
Yes	92	60.4 (30.8)	
No	2495	46.9 (31.2)	
Dysphagia			<0.001
Yes	43	70.1 (26.0)	
No	2544	47.0 (31.2)	
Early satiety			0.099
Yes	132	51.1 (26.2)	
No	2455	47.2 (31.5)	
Edema			0.81
Yes	75	48.3 (29.5)	
No	2512	47.7 (31.3)	
Lethargy			<0.001
Yes	299	63.4 (28.2)	
No	2288	45.3 (31.1)	
Nausea			<0.001
Yes	235	62.2 (27.9)	
No	2352	45.9 (31.2)	
Poor appetite			<0.001
Yes	952	62.7 (26.0)	
No	1635	38.5 (30.7)	
Poor dentition			<0.001
Yes	194	59.9 (26.9)	
No	2393	46.4 (31.4)	
Vomiting			<0.001
Yes	125	60.1 (30.2)	
No	2462	46.8 (31.2)	
Physical			
Difficulties to eat			<0.001
Yes	209	67.1 (27.2)	
No	2374	45.7 (31.0)	
Difficulties in swallowing			<0.001
Yes	125	71.8 (24.9)	
No	2458	46.2 (31.1)	
Delay eating time			<0.001
Yes	26	70.9 (20.8)	
No	2557	47.2 (31.3)	
Psychological			
Alone			<0.001
Yes	67	59.5 (29.6)	
No	2516	47.1 (31.3)	
Abandoned			0.005
Yes	85	56.8 (28.7)	
No	2498	47.1 (31.3)	
Stress			<0.001
Yes	134	64.9 (24.8)	
No	2449	46.5 (31.3)	
Food Belief			
Yes	97	53.6 (25.7)	
No	2486	47.2 (31.5)	
Food quality			
Unclean food			0.030
Yes	9	63.2 (18.1)	
No	2574	47.4 (31.3)	
Big portion			0.431
Yes	79	49.2 (20.2)	
No	2504	47.4 (31.6)	
Physical Contamination			0.488
Yes	6	38.5 (30.0)	
No	2577	47.4 (31.3)	

[a] *Independent T-Test; Significant at p<0.05, NIS=Nutrition Impact Symptoms*

Table 5: Correlation between Energy and Protein Intake with Food Wastage

Mean Intake ±SD	Food Wastage (%) Mean±SD	*r*	*p*-value[a]
Energy intakes (kcal)			
794.6 ±487.8	47.4±31.3	- 0.951	<0.001
Protein intakes (g)			
35.2 ±24.3	47.4 ±31.3	- 0.873	<0.001

[a]*Pearson's correlation test, r=Correlation Coefficient*

No significant difference was observed on food wastage among subjects whether referred to dietician or not. Food wastage also differs significantly among educational level groups, marital status groups and BMI groups. Subjects with no education had significantly the highest mean food wastage and differ significantly when compared to subjects with secondary, diploma or bachelor education. This study also observed that divorced subjects had significantly the lowest food wastage percentage when compared to married, single and widowed subjects. Food wastage among young adults and middle age adults was not significantly different but both of these groups had mean food wastage that differ significantly with the senior adult group ($p<0.001$). There were no significant difference between food wastage with ethnic group and dieticians' consultation as shown in Table 3

According to BMI group, mean total of food wastage for underweight and normal weight subjects was statistically significant ($p<0.001$) compared to overweight group; obese group. As observed mean food wastage was the highest in underweight groups (56.3%), followed by normal BMI subjects (50.0%), overweight (43.9%) and obese subjects (41.3%)

Table 4, shows findings on mean food wastage affected by nutritional impact symptoms (NIS). Abdominal distension, diarrhoea, dysphagia, lethargy, nausea, poor appetite, poor dentition and vomiting are among the NIS that shows significant difference when compared with subjects without the symptoms. This study did observed that there were significant associations between food wastage with physical factors; eating difficulties ($p<0.001$), swallowing difficulties ($p<0.001$), delay eating time ($p<0.001$), psychological factors; alone ($p<0.001$), abandoned ($p=0.005$), stress ($p<0.001$), and food belief ($p<0.001$), and food quality factors; unclean food ($p<0.001$).

Table 5 shows significant association between energy and protein intake with food wastage ($p<0.001$). A negative and high correlation was observed between energy and protein intake with food wastage. This suggests that a reduction in energy and protein intake will lead to higher food wastage.

DISCUSSION

Throughout this study our food wastage findings were consistent with a local study[9] conducted in a Penang district hospital involving normal diet. Almost half (47.4%) of the therapeutic diet served in MOH hospitals in Malaysia had been wasted and it was expected to be higher than the wastage of normal diet as shown in the above study. Similar findings were observed where female subjects had a significantly higher plate waste compared to male. Strengthened by another local research[19] states that food wastage is more common in women for most of the food items. There was no apparent reason for why female patients wasted more food other than to surmise that females might be a little more fussy when it comes to food intake. Among the food categories, it can be seen wastage consistently reported to be highest in the vegetables groups (52.4%) compared with other categories as observed from others studied. Probable factors contributing to vegetables wastage include preference towards vegetables or the preparation of vegetables dishes[9,20], or it might be a result of poor cooking practices[6].

Food serving systems practised by hospitals under Health Ministry can be divided into two systems, either bulk systems or centralised systems. This study showed higher proportions of food waste in centralised systems compared to bulk systems. In the bulk systems freshly prepared dishes are wheeled in trolleys into the wards pantry instead of at the patient bedside. It is thus able to retain the temperature of the freshly prepared

foods and ensure foods are always warm enhance patients's appetite. In contrast, however two studies reported an increase in total food waste through the adoption of a bulk system[21,22].

Additionally the pattern on dinner contributing to the highest mean percentage food waste (58.5%), compared to lunch (46.8%). Data for breakfast consumption could not be collected for this study which focuses on lunch and dinner only. Home cooked food brought by caretakers after working hours, and the absences of clear policy to control home or retail food deliver services from patient's care takers or retailer may contribute to higher food wastage during dinner.

There is greater food wastage as age increases. These figures, however, are difficult to interpret because of the nature of each patient's illness. However, since illness can often affect appetite and the senses of taste or smell[23]. According to age group, senior adult had the highest food wastage when compared to younger population. Age related decline in functional ability (dysphagia and lethargy) and dental problems (poor dentition) can significantly affect food consumption that can contribute towards wastage[24]. Difficulties to eat and swallowing had significantly affects food wastage as consequences of reduction in oral intake.

Besides that, this study affirmed the observation some of the factors that influencing to food waste. Nutritional impacts symptoms (NIS) were also found significantly contribute to food waste. According to Williams & Walton (2011), food waste related to clinical issues is the most challenging issue in food waste reduction. Approximately 30% of hospitalized patients are at nutritional risk, often experiencing eating problems, unpredictable changes in appetite, and requiring different food items and services making the development of strategies to ensure relevant food is provided but does not become wasted very challenging[21,25,26]. In this present study, we found that almost all NIS was significant causes of food waste among patients at hospitals. This is not unexpected, since illness can often affect appetite and the sense of taste and smell. Drug causing nausea and gastrointestinal symptoms can also interfere normal desire to eat and impaired oral intake. These conditions can affect appetite and sense of smell which leads toward further food wastage[6].

Another important consideration in food waste studies was the assessment of energy and protein intakes as it can reflect nutrient intake and influences cost of the hospital. Food waste is a great importance as it can reflect nutrient intakes, and high levels of food waste can be indicative of poor health status[27]. Studies showed that food waste can significantly cause reduction in calorie and protein intake. These finding applicable to patients who have a higher susceptibility changer to preferences, reduce of appetite therefore increase of malnutrition risk. Many diet prescriptions, such as texture modification or low salt, reduce the sensory appeal of food, and it has been estimated that being on a special diet doubles the risk of insufficient energy intake[6]. Another probable reason is that they tend to limit food intake especially to achieve good control of blood glucose as in a diabetic diet[19].Therefore, including effective routine monitoring of patients' food choices, food intakes and food waste should be part of strategy to ensure patients are being served with a portion size that will enhance consumption and increase energy and protein contributions to the total daily recommended intake.

There are other factors contributing to food waste which need to be considered for improvement. Those reason include physical factors (difficulties to eat, difficulties in swallowing, delay eating time), psychological factor (alone, abandoned, stress, food belief) and food quality (unclean food, big portion, physical contamination). Furthermore, physical constraints such as eating in bed, having immobilized limbs or age-related declines in functional ability and dental problems, can all significantly affect food consumption[6]. This is a complex area of research, but there is some evidence suggesting that dining room environment and the consequent social interaction can improve dietary intakes[28].

CONCLUSION: This study was aimed to evaluate of factor affecting food wastage and had revealed an important to see from various aspects and factors that can affect food waste in hospitals. Further evaluation should be conducted to see how it may contribute to foods waste, before any possible strategies can be taken as an action for implementation. By finding the common reason for plate waste generation among patients in this study, it will help in gaining knowledge to further improve the quality of food and services in hospitals. A reduction in food wastage can helps on cost-effectiveness, optimize productivity and at the same time can encourage patients to eat their

food and lead to better clinical outcomes through improved nutritional care. *Acknowledgement*
We would like to thank the Director General of Health Malaysia for his permission to publish this article
Funding Statement
This study is not funded by any organization.

Conflict of Interest
This study has no conflict of interest

REFERENCES

1. Zulkiply N.A., Chik C.T. (2015) Theory and Practice in Hospitality and Tourism Research - Proceedings of the 2nd International Hospitality and Tourism Conference 2014, pp. 361-364.
2. Food and Agriculture Organization of the United Nations (FAO), the State of Food Security and Nutrition in the World, 2018
3. Environmental Protection Agency (EPA). (2012). Municiple Solid Waste, from www.epa.gov/epawaste/non-haz/municipal/ index.htm
4. Galanakis, Charis M. (2015). Food Waste Recovery: Processing Technologies andIndustrial Techniques. San Diego: Elsevier-Academic Press. p.4. ISBN 9780128003510
5. Malaysia Kini. (2016). Battling food waste. Malaysia Kini. Retrieved from http://www.malaysiakini.com/letters/359487
6. Williams, P.; Walton, K. Plate waste in hospitals and strategies for change. Eur. e-J. Clin. Nutr. Metab.2011,6,235–241
7. Alam, M. M., Sujauddin, M., Igbal, G. M. A., & Huda, S. M. S. Report: Healthcare waste characterization in Chittagong Medical College Hospital, Bangladesh. Waste Management and Research, 26(3), 291–296. (2008).https://doi.org/10.1177/0734242X07087661
8. Mattoso, V. D. B., & Schalch, V. (2001). Hospital waste management in Brazil: A case study. Waste Management & Research, 19(6), 567–572.
9. Lily Zakiah MD, Saimy I, Maimunah AH. Plate Waste among Hospital Inpatiets.2005.
10. Malaysian Journal of Public Health Medicine.Vol. 5(2):19-24
11. Baharom B. Food Wastage and Nutritional Intake in Hospital Tuanku Jaafar Seremban: Visual plate Waste Study. 2010.
12. Cereda E, Pedrolli C..Food waste: other issues and settings should be considered (letter to the editor). Nutr Bull, 34, 9-238. (2009)
13. Lisa A. Barker, Belinda S. Gout, and Timothy C. Crowe. (2011). Hospital Malnutrition: Prevalence, Identification and Impact on Patients and the Healthcare System.Int. J Environ Res Public Health;8 (2):514-527
14. Ofei, K. T., Holst, M., Rasmussen, H. H., & Mikkelsen, B. E. (2015). Effect of meal portion size choice on plate waste generation among patients with different nutritional status. An investigation using Dietary Intake Monitoring System (DIMS). Appetite, 91, 157–164.
15. Mavrommatis Y, Moynihan P J, Gosney M A, Methven L. Hospital catering systems and their impact on the sensorial profile of foods provided to older patients in the UK. Appetite 2011; 57: 14-20
16. McLymont V, Cox S & Stell F. (2003). Improving patient meal satisfaction with room service meal delivery. J Nurs Care Qual. 2003 Jan-Mar; 18(1):27-37.
17. Stanga Z, Zurfluh Y, Roselli A, Sterchi A, Tanner B, Knecht G. Hospital food: a survey of patients' perceptions. Clin Nut 2003; 23: 241-246.
18. Thibault R, Chikhi M, Clerc A, Darmon P, Chopard P, Genton L, Kossovsky MP, Pichard C. Assessment of food intake in hospitalised patients: A 10-year comparative study of a prospective hospital survey. Clin Nut 2011; 30: 289-296.
19. Norshariza J, Zuwariah AR, Betti Sharina HL, Kufrizan K, Nuzulliah O. Symptoms Or Side Effects Of Cancer Or Cancer Treatments: Does Nutrition Impact Symptoms Will Affect Food Waste In Dietetic And Food Service Department, National Cancer Institute, 2015 (*unpublished*)
20. Shahar S, Chee K Y, Wan Chik WCP. 2002. Food intakes and preferences of hospitalised geriatric patients. BMC Geriatrics. http://www.biomedcentral.com/14712318/2/3

21. Williams P. Food preferences of 500 inpatients in an Australian teaching hospital. J Food Nutr 1988; 45: 34-40.
22. Hartwell H, Edwards JSA. A comparative analysis of ‘plated’ and ‘bulk trolley’ hospital food service systems. Food Serv Technol 2003; 3: 133–42.
23. Edwards JSA, Nash AHM. The nutritional implications of food wastage in hospital food service management. Nutr Food Sci 1999; 99 (2): 89–98.Food and Agriculture Organization (FAO).http://www.fao.org/food-loss-and-food-waste/en/Food Loss and Food Waste. Accessed March 7, 2018.
24. Díaz A V, García Á C. 2013. Evaluation of factors affecting plate waste of inpatients in different healthcare settings. Nutr Hosp. 2013; 28(2):419-427 ISSN 0212-1611 • CODEN NUHOEQ S.V.R. 318
25. Huang H-C and Shanklin C. An integrated model to measure service management and Physical constraints' effect on food consumption in assisted-living facilities. J Am Diet Assoc 2008; 108: 785-792
26. Dupertuis, Y. M., Kossovsky, M. P., Kyle, U. G., Raguso, C. A., Genton, L., & Pichard,
27. (2003). Food intake in 1707 hospitalised patients: a prospective comprehensive hospital survey. Clinical Nutrition, 22(2), 115-123.
28. Hartwell, H. J., Edwards, J. S., & Symonds, C. (2006). Food service in hospital: development of a theoretical model for patient experience and satisfaction using one hospital in the UK National Health Service as a case study. Journal of Foodservice, 17(5‐6), 226-238.
29. Deutekom EJ, Philipsen H, Ten Hoor F, Huyer Abu-Saad H. Plate waste producing situations on nursing wards. Int J Nurs Stud 1991; 28: 163–74.
30. Walton, K, Williams, P., Tapsell L. C. 2006. What do stakeholders consider the key issues affecting the quality of foodservice provision for long-stay patients? Journal of Foodservice, 2006, 17(5-6), 212-22

CASE REPORT

Role of Partial Hydrolysed Guar Gum in Chemotherapy Induced High Output Stoma in Patient with Ileostomy

Ho Chiou Yi[1,3], Atiki Falparado Ahmad[2,3], Woo Sze Sian[2,3], Tharmasilen A/L Selvarajoo[2,3], Norshariza Jamhuri[1,3], Zuliehaiza Kahairudin[1,3]

[1]Department of Dietetic and Food Service, National Cancer Institute, Ministry of Health, Malaysia
[2]Department of Surgical Oncology, National Cancer Institute, Ministry of Health, Malaysia
[3]Nutritional Therapy Team, National Cancer Institute, Ministry of Health, Malaysia

ABSTRACT

Introduction: High and excessive stoma output from ileostomy, is frequently observed in patients with ileostomy under radiation and chemotherapy thus deteriorate illness. As part of treatment, partially hydrolysed guar gum (PHGG) was used to resolve the problems effectively. **Case presentation**: An Indian male age 68, Mr S, with no underlying illnesses, diagnosed with rectal and prostate adenocarcinoma underwent laparoscopic anterior resection with covering ileostomy, followed by three month chemotherapy. After second cycle of chemotherapy, he developed persistent high stoma output (>2litres/day) leads to lethargy due to dehydration leads to the cessation. As parenteral nutrition and semi elemental diet does not benefit the patient, instead standard Oral Nutrition Supplement (ONS) with added PHGG and high protein high calories low residue diet was initiated concurrent with anti-motility and anti-secretory medications. Subsequently, stoma output reduced and soft in consistency and patient able to resume treatment. **Discussion**: Chemotherapy induced high-output stoma, a common problem in cancer patients, not only directly impact on patient's nutritional status but may also compromise treatment efficacy because of consequent dosing alterations or discontinuation. The obstacle that often faced with ileostomy patient is consistent high stoma output despite fluid restrictions and conservative management of stoma output with regular doses of anti-motility and anti-secretory agents, transition period to wean off TPN, promote gut adaptation and to achieve energy requirement with normal stoma output. PHGG is a water-soluble, non-gelling fibre that has provided therapeutic benefits which can provide a dichotomous features whereby normalizing effect in stool. **Conclusion**: Incorporating PHGG in feeding regime showed positive outcomes in quickly improves stoma output in patient with ileostomy as well as nutritional intake.

Keywords: Partially Hydrolysed Guar Gum, ileostomy

INTRODUCTION

One of complication following radiation and chemotherapy on colorectal cancer was excessive and high stoma output which frequently observed in patients, resulting in deterioration in nutritional outcome that leads towards treatment interruption. Gastrointestinal (GI) mucosal barrier within the radiation volumes with severe mucositis might cause diarrhoea, nausea, emesis and severe malabsorption followed by infections with dehydration and electrolyte disorders[1]. Partially hydrolysed guar gum (PHGG) was proven to be effective in the treatment of acute diarrhoea in intensive care setting[2] which had been adapted into high stoma nutritional management. Purpose of this case report is to share our clinical experience about role of PHGG in chemotherapy induced high stoma output in patient with ileostomy

---

Corresponding author: Ho Chiou Yi
Email: dtho@nci.gov.my

CASE PRESENTATION: A 68 year old Indian male, Mr S, with no underlying illnesses, diagnosed with a double primary of rectal adenocarcinoma Stage 3 and prostate adenocarcinoma stage 4 Gleason score of 4+3. He underwent a laparoscopic Anterior Resection with covering ileostomy and followed by chemotherapy. Post second cycle of chemotherapy, he experienced 8% weight loss within 1-month, developed persistent high stoma output and lethargy due to dehydration even withholding chemotherapy for seven days. Patient was referred to Nutritional Therapy Team (NTT) consist of surgical team, dietitian and pharmacist. Nutritional diagnosis was altered gastrointestinal function related to compromise gastrointestinal (GI) tract function due to radiotherapy as evidence by high stoma output. Initially, stoma output was more than two litres per day. Anti-motility and anti-secretory medications were prescribed with high protein high calories low residue diet plus standard oral nutrition supplement (ONS) support at first phase but stoma output remained high. Despite dosage increment in anti-motility and anti-secretory medication, nil-per-oral and initiation of Total Parenteral Nutrition (TPN) strategy during the second phase, stoma output remains unsatisfactory. Semi-elemental ONS was prescribed concurrently with partial TPN with same medications dosage then but patient not complied with semi-elemental ONS due to unpleasant taste and stoma output did not show any improvement. Thus, standard ONS with PHGG was initiated, four times a day with modified high protein high calories low residue diet and wean off TPN were allowed with same dosage of anti-motility and anti-secretory medications. Finally, the stoma output reduced with soft consistency stools upon discharged. In addition, total daily energy and protein intake increased after started with PHGG.

DISCUSSION

Human intestine works on approximately 8-10litres of fluid daily, most of fluid is absorbed by the jejunum and the ileum while estimated 1.5litres reaches the colon, of which 100 ml is excreted[3]. Most chemotherapeutic agents target rapidly dividing cells, and effects on these cells within the gastrointestinal tract can lead to a variety of symptoms. Chemotherapy treatment might induce severe mucositis and cause high-output stoma in patient with ileostomy. High-output stoma usually is considered as output greater than 1.5litres/day[4]. The chemotherapy-induced high-output stoma not only directly impact on patient's nutritional status but may also compromise treatment efficacy because of consequent dosing alterations or discontinuation[5]. High-output stoma can lead to dehydration, renal dysfunction, and electrolyte abnormalities[4,6].

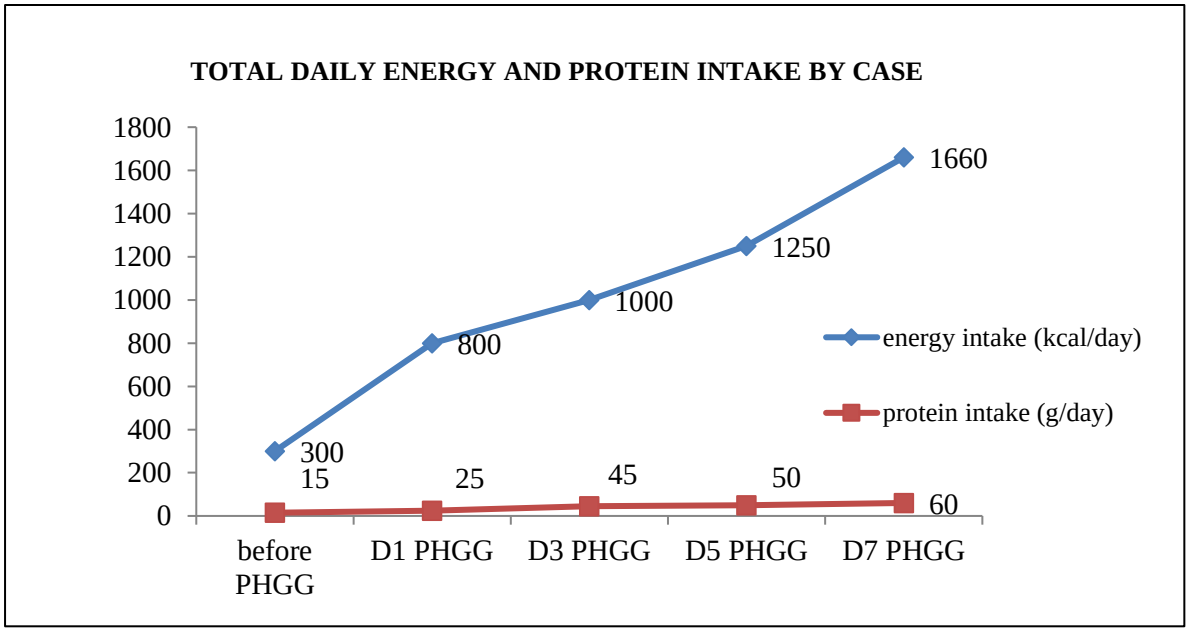

Figure 1: Total Daily Energy and Protein Intake

The presented patient was on parenteral nutritional support and reported a consistent high stoma output despite fluid restrictions and consuming glucose-saline solutions collectively with regular doses of anti-motility and anti-secretory agents. The challenge of high output stoma in ileostomy patient is to wean off TPN, promote gut adaption and achieve energy protein requirement with normal stoma output[7,8]. In the effort of reducing and controlling ileostomy output, patient should be educated and complied with the management. Appropriate high stoma output management includes restriction of fluids, medications, and dietary modification[9]. High calories high protein low residue normal diet was prescribed to compensate for malabsorption by hyperphagia. Oral Nutrition Supplement (ONS) may be necessary with insufficient intake (less than 60% from requirement) to optimise oral intake and minimize nutritional depletion[10,11]. However, unpleasant taste and higher cost of semi-elemental and elemental ONS might affect the long term compliance of ONS[12].

Other than management as stated above, soluble fibre supplement, such as guar gum, might be considered in the intervention plan[7]. PHGG is a water-soluble, non-gelling fibre that has provided therapeutic benefits. In clinical trials, PHGG decreased symptoms in constipation-predominant and diarrhoea-predominant forms of IBS and decreased abdominal pain. Soluble fibre such as guar gum can provide a dichotomous feature whereby stool normalizing effect to soften hard stool (increase Biomass frequency) in constipation and firm watery stool (decrease Biomass frequency) in diarrhea[9]. Current case study showed consistent findings that PHGG showed positive effect in improving ileostomy consistency and output and subsequently prevent complications of high output.

Limitation

Long-term nutritional effect of PHGG was not explained in this case report. The reduction in stoma output following the introduction of PHGG and normal diet could be a mere coincidence. As a result, findings from a case report cannot be generalized unless a cause-effect relationship from a representative population is established. Case reports aim to contribute to a change in the clinical practice. Numerous discoveries and major advancements in medicine started with a case report.

CONCLUSION: Optimal multidisciplinary management including nutritional management is crucial in management of high output in patient with ileostomy induced by chemotherapy and oncologic outcomes. PHGG in ileostomy nutritional management showed improvement of volume and consistency of stoma output and positive outcomes in term of nutritional intake. We hope this case report to can be used as an example of the effect of integration partially hydrolysed guar gum in nutritional management of oncologic treatment induced high output in ileostomy patients.

Acknowledgement

We would like to thank the Director General of the Health Ministry of Malaysia for permission to publish this article.

Conflict of interest

The authors declare no conflict of interest arising from the findings for the reported case and its management.

REFERENCES

1) Grabenbauer GG, Holger G. Management of radiation and chemotherapy related acute toxicity in gastrointestinal cancer. Best Practice & Research Clinical Gastroenterology. 2016 Aug 1;30(4):655-64.
2) Rushdi TA, Pichard C, Khater YH. Control of diarrhea by fiber-enriched diet in ICU patients on enteral nutrition: a prospective randomized controlled trial. Clinical Nutrition. 2004 Dec 1;23(6):1344-52.
3) Kiela PR, Ghishan FK. Physiology of intestinal absorption and secretion. Best practice & research Clinical gastroenterology. 2016 Apr 1;30(2):145-59.
4) Villafranca JJ, López-Rodríguez C, Abilés J, Rivera R, Adán NG, Navarro PU. Protocol for the detection and nutritional management of high-output stomas. Nutrition journal. 2015 Dec;14(1):45.
5) Robertson JP, Wells CI, Vather R, Bissett IP. Effect of diversion ileostomy on the occurrence and consequences of chemo-therapy-induced diarrhea. Diseases of the Colon & Rectum. 2016 Mar 1;59(3):194-200.
6) Baker ML, Williams RN, Nightingale JM. Causes and management of a high‐output

stoma. Colorectal disease. 2011 Feb;13(2): 191-7.

7) Matarese LE, O'Keefe SJ, Kandil HM, Bond G, Costa G, Abu‐Elmagd K. Short bowel syndrome: clinical guidelines for nutrition management. Nutrition in clinical Practice. 2005 Oct;20(5):493-502.
8) Neelis EG, Olieman JF, Hulst JM, de Koning BA, Wijnen RM, Rings EH. Promoting intestinal adaptation by nutrition and medication. Best Practice & Research Clinical Gastroenterology. 2016 Apr 1;30(2):249-61.
9) McRorie Jr JW, McKeown NM. Understanding the physics of functional fibers in the gastrointestinal tract: an evidence-based approach to resolving enduring misconceptions about insoluble and soluble fiber. Journal of the Academy of Nutrition and Dietetics. 2017 Feb 1;117(2):251-64.
10) Acosta PJ, Borschel MW, Reynolds PA, Cordle CT, Duska-McEwen GO, inventors; Abbott Laboratories, assignee. Palatable elemental medical food. United States patent US 6,245,803. 2001 Jun 12.
11) Pironi L, Arends J, Bozzetti F, Cuerda C, Gillanders L, Jeppesen PB, Joly F, Kelly D, Lal S, Staun M, Szczepanek K. ESPEN guidelines on chronic intestinal failure in adults. Clinical nutrition. 2016 Apr 1;35(2):247-307.
12) Sica J, Burch J. Management of intestinal failure and high-output stomas. British jour--nal of nursing. 2007 Jul 12;16(13):772-7.

Letter to Editor

Nutrition and Health between Vegetarians and Non-Vegetarians

Key words: Health diets, vegetarianism, non-communicable chronic diseases

Dear Editor:

As a 35 years-long lacto-ovo-vegetarian, I have been always asked by others why my family converted and what health benefits had been. To answer them, the comparison about nutrition and health between vegetarians and non-vegetarians was summarized here.

There are different types of vegetarian depending on their different food components namely, semi-vegetarians (vegetables with dairy products, eggs and fish), lacto-ovo-vegetarians (with milk and eggs), pescatarians (with fish) and vegans or "Jay" (no milk and eggs) (1). Generally, vegetarian foods have no meat, poultry, seafood, or any animal products including eggs, milk, honey, etc. Vegetarians consume more vegetables, fruits and grains. Compared to meat foods, plant-based foods contain more healthy compounds including vitamins, minerals, dietary fiber and essential non-nutrients. Plant-based diets have been widely known and popular especially among people with health concern. A numerous research articles have reported the health benefits of vegetarian diet in the prevention and healing of non-communicable chronic diseases (NCDs) including obesity, cardiovascular diseases, type-2 diabetes, some cancer types and hypertension (1,2).

By the evidence-based review, the American Dietetic Association (ADA) and Dietitians of Canada (DC) concluded that appropriately planned vegetarian diets, including vegetarian and vegan diets, are nutritionally adequate and may be beneficial to the prevention and treatment of certain diseases (3, 4). The vegetarian diet was found to lower risk of death from ischemic heart disease. As compared to the non-vegetarians, vegetarians had about 32% lower cholesterol levels and blood pressures, which reduce the risk of cardiovascular disease (CVD) and certain types of NCDs (4, 5). Hypercholesterolemia is a major risk factor of CVDs including coronary heart disease and ischemic stroke, as well as peripheral arterial disease (6, 7).

The well-planned plant diets are confirmed to be appropriate for persons from birth to adults and aging stages as well as sportsman. However, statistically, vegetarians are not always healthier than non-vegetarians. The variable difference of dietary components among vegetarian individuals can lead to the unbalanced diets. The deficiency of essential nutrients such as vitamin B_{12} and iron causes mild and severe anemia as well as some essential amino acids (lysine and methionine.) and fatty acids (omega-3 and -6), among vegetarians and vegans (8-11). To have adequate and balanced intake of the essentials, vegetarians should be educated about sources of specific nutrients, food ingredients and right cooking for their healthy life.

However, a vegetarian diet has both advantages and disadvantages. Its healthful benefit has been found to reduce the risk of heart disease, obesity, hypertension, type 2 diabetes and some types of cancer, leading to a longer life expectancy. Adversely, the higher prevalence of mild hyper-homocysteinemia in vegetarians may decrease the preventive effect of vegetarian nutrition in cardiovascular disease. Therefore, vitamin B_{12} deficiency may reduce the risk of CVD prevention, vegetarians should be advised to consume vitamin B_{12} supplement, as well as fermented-plant foods and dried purple laver (nori) which contain high vitamin B_{12} and its analogs (12, 13).

Most non-vegetarians are not us0ed to and do not like such veggie foods due to the lack of meaty flavor and taste. There are many vegetarian meat alternatives (tofu, soy products, tempeh, beans) and mocking meat products made from a mixture of konjac, shitake mushroom and soy meal in the market, so the main vegetarian benefits and disadvantages are related to health rather than taste. (13)

Not only for the health benefits, has vegetarianism also emphasized the compassion to all lives. Most of Thai and Taiwanese vegetarians are “Jay” vegans which belong to and have faith in Mahayana Buddhism, They are more restricted than general vegetarians, since they don’t consume meat, poultry, seafood, or any animal products including eggs, milk, honey, etc. Besides, Jay vegetarians also prohibit 5 kinds of pungent vegetables including garlic, onion, single-head garlic, chive and tobacco. Spiritually, they have to follow basic Buddhist precepts by thinking, speaking and doing right behaviors especially during the 10-days Jay Vegetarian Festival during September October. “Jay” actually comes from a Chinese word, Jain” (no killing) which saves a great the number of animals.

In conclusion, there are different types of vegetarians according to a variability of food components. Compared to non-vegetarians, they mainly consume plant foods containing more essential compounds and non-nutrients. The health benefits of vegetarian diet in the prevention of NCDs have been reported. ADA and DC concluded that appropriately planned vegetarian diets are nutritionally adequate and may be beneficial to the prevention and treatment of certain diseases including CVDs, atherosclerosis and hypertension. However, the variable difference of dietary components among vegetarian individuals can lead to the unbalanced diets. To have adequate and balanced intake of the essentials, vitamin B_{12} and omega-3 fatty acids, vegetarians should need more education about sources of specific nutrients for their healthy life.

Maitree Suttajit
Department of Biochemistry,
Faculty of Medicine, Chiangmai University,
Chiang Mai, Thailand
Email:maitree.suttajit@gmail.com

REFERENCE

1) Tonstad S, Butler T, Yan R, Fraser GE. Type of vegetarian diet, body weight, and prevalence of type 2 diabetes. Diabetes Care. 2009;32 (5):791–796.
2) Li D. Effect of the vegetarian diet on non-communicable diseases. J Sci Food Agric. 2014 Jan 30;94(2):169-73.
3) American Dietetic Association; Dietitians of Canada. Position of the American Dietetic Association and Dietitians of Canada: Vegetarian diets. J Am Diet Assoc. 2003 Jun; 103(6):748-65.
4) Craig WJ, et al. American Dietetic Association. Position of the American Dietetic Association: vegetarian diets. J Am Diet Assoc. 2009; 109(7): 1266-82.
5) Tammy Y N, Tong et al. Risks of ischemic heart disease and stroke in meat eaters, fish eaters, and vegetarians over 18 years of follow-up: results from the prospective EPIC-Oxford study. BMJ 2019; 366:l4897.
6) Mahmood SS, Levy D, Vasan RS, Wang TJ. The Framingham heart study and the epidemiology of cardiovascular disease: A historical perspective. Lancet. 2014; 383:999–1008.
7) Kannel WB. Lipids, diabetes, and coronary heart disease: insights from the Framingham Study. Am Heart J. 1985;110(5):1100–1107.
8) Craig WJ. Health effects of vegan diets. Am J Clin Nutr. 2009;89:1627S–1633S.
9) Saunders AV, Davis BC, Garg ML. Omega-3 polyunsaturated fatty acids and vegetarian diets. Med J Aust. 2013 Aug 19; 199 (S4):S22-6.
10) Pawlak R. Is vitamin B_{12} deficiency a risk factor for cardiovascular disease in vegetarians? Am J Prev Med. 2015 Jun; 48(6):e11-26.
11) Wiwanitkit, V. *et. al*.. Red blood cell parameters of Thai vegansc compared with non‐vegetarians. J Nutri Environ Med. 2009; 14. 303-306.
12) Krajcovicová-Kudlácková M, *et al.*Homo-cysteine levels in vegetarians versus om-nivores. Ann Nutr Metab. 2000;44(3):135-8
13) Takenaka S, *et. al*. Feeding dried purple laver (nori) to vitamin B_{12}-deficient rats significantly improves vitamin B_{12} status. Br J Nutr. 2001Jun;85(6):699-703

Letter to Editor

Philippines President Rodrigo R. Duterte Supports Nutrition

Dear Editor,

No less than the president of the Philippines, His Excellency, Rodrigo Roa- Duterte is a staunch supporter of nutrition. He already signed into law Republic Act 11148 - the First 1,000 Days Law. The law seeks to scale up the national and local health and nutrition programs through a strengthened integrated strategy for maternal, neonatal, child health and nutrition in the **first 1,000 days** of life.

Another executive order, Republic Act 11037 mandates that a national feeding program for undernourished children in public elementary school, kindergarten and day care centers. The feeding program will be implemented in three components:

A. School-based Feeding Program. Under-nourished children from Kindergarten to Grade 6 will be given at least one fortified meal for not less than 120 days in a year. This will be carried out by the Department of Education.

B. Supplemental Feeding Program for Day Care Children. Undernourished children from 3 to 5 years of age in day care centers will be given at least one fortified meal for not less than 120 days in a year. This will be implemented by local government units and the Department of Social Welfare and Development.

C. Milk Feeding Program. Fortified meals and cycle menu are to include fresh milk and fresh milk-based food products, to be implemented by the Department of Agriculture, Philippine Carabao Center and the Cooperative Development Agency.

The Republic Act 10862 or the Nutrition and Dietetics Law of 2016 was enacted to regulate and standardize the practice of nutrition and dietetics in the Philippines, with a provision on Medical Nutrition Therapy through the application of Nutrition Care Process for purposes of disease prevention, treatment and management. Administrative Order 2019-0033 was recently signed by the Secretary of Health, Dr. Francisco T. Duque III that shall provide the mandate and direction for public and private hospitals to operationalize and institutionalize the Nutrition Care Process in their respective facilities.

Finally, the Nutritionist-Dietitians' Association of the Philippines (NDAP), the Association of Integrated Nutritionist-Dietitians (AIPO) recognized by the Professional Regulations Commission has 33 chapters nationwide and (two) 2 international chapters- Qatar and United Arab Emirates, NDAP celebrates its 65th Anniversary and Annual Convention on February 26-28, 2020 at the Conrad Hotel, Manila where speakers from the Academy of Nutrition and Dietetics and the Asian Federation of Dietetics Association shall share their expertise on the theme "Frontiers of Nutrition: The Cutting Edge Science in Nutrition and Dietetics.

Prof. Zenaida F. Velasco,
President of Nutrition and Dietetic Association of Philippine