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□ **Original Article** □

The Effects of Low-Calorie Diet with Raw-Food Formula§ on Obesity and Its Complications in the Obese Premenopausal Women*

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ABSTRACT

Recently interests on raw-food diets are rapidly increasing in relation to chronic diseases prevention in Korea, but studies on raw-food diets have been hardly performed by nutritionists. This study was performed to investigate the effects of low-calorie diets using a raw-food formula in the form of freeze-dried powder on obesity and its complications in the obese women (body mass index (BMI) ≥ 25kg/m^2) for eight weeks. Forty premenopausal women (mean BMI 28.04kg/m^2, mean age 28.33years old) participated in this diet intervention, and were controlled by eating 1 regular meal, 1 − 2 snacks and 2 raw-food formula (140kcal/pack) meals a day within the 1500 − 1300kcal ranges. Anthropomentric measurements, body compositions, physical exercise, and obesity-related risk factors were assessed before (the initial), during (the 4th week) and after (the 8th week) the study. All the data was analyzed by paired t-test, repeated measures ANOVA, and nonparametric rank test at $p < 0.05$ level. Obesity was significantly increased during this study, and it was decreased in weight (−4.59%, $p < 0.000$), BMI (−4.56%, $p < 0.000$), body fat percent (−6.18%, $p < 0.000$), fat mass (−10.19%, $p < 0.000$), waist and hip circumferences (−5.69%, $p < 0.000$ and −2.55%, $p < 0.000$) and WHR (−3.24%, $p < 0.000$). Energy expenditure of physical exercise was increased as much as 70kcal/day during the study ($p = 0.000$), but it did not have any correlations with weight loss and changes of body compositions. Biochemical measurements including blood triglyceride ($p < 0.006$) and leptin ($p < 0.000$) levels were significantly decreased, LDL cholesterol level was increased ($p < 0.05$), but all the blood lipid levels were in the normal ranges. Fatty liver echogenicity and menstrual irregularity were improved after the diet intervention ($p < 0.000$ and $p < 0.034$). In conclusion, this 8-week low-calorie diet intervention using raw-food formula was effective for obese premenopausal women in reducing obesity and its risk factors so as not to proceed towards comorbidities. However, the variation of blood lipid levels should be observed for a longer period. (*J Community Nutrition* 4(2) : 99~108, 2002)

KEY WORDS : low-calorie diet · raw-food formula · obesity · blood lipids · fatty liver · premenopausal women.

Introduction

Obesity is a state that fat is over-accumulated in the body, and it is generated by an imbalance between energy intake and energy expenditure for a long time (Schults 1983). Such a type of obesity is termed simple or essential obesity and about 95% of obese people are included in this type (Kim 1990).

In Korea, 18.9% of the adult female population were overweight (BMI ≥ 25kg/m^2) and 1.5% were obese (BMI ≥ 30 kg/m^2) in 1995 (MHW 1997). Three years later, the obese population was greatly increased up to 26.3% (BMI ≥ 25kg/m^2) and 2.4% (BMI ≥ 30kg/m^2) in 1998 (MHW 2000).

Obesity causes not only distorted appearances but also many health-related problems. Excessive fat mass in the body

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is a causal factor which generates abnormal metabolism or endocrine disorders (Bosello et al. 1997). So obesity tends to increase serum levels of triglyceride, total cholesterol, LDL cholesterol and free fatty acids (Kissebah and Krakower 1994), and reproduction disorders (Zimoff et al. 1995), non insulin-dependent diabetes mellitus (Bray 1985), breast cancer (Stoll 1995), hypertention (Havlick and Hubert 1983), cardiovascular disease(Blumenthal et al. 2000) and finally the death rate (Piziak 1983).

For lowering of energy intake, so many commercial products such as very-low-calorie (VLC) formulas (400 – 800 kcal/day) have been used popularly for several tens of years (ADA repots 1990). However, so many side effects have been also reported during and after the VLC diet, for example, osteoporosis, dehydration, mineral imbalance, nervousness, gallstone, arrhythmia, hyperuricemia, weakness, menstrual irregularity, lowering metabolic rates (Arari et al. 1992 ; Lee 1997 ; Lee, Huh 1997 ; NTFPTO 1993 ; Pi-Sunyer 1993) and yoyo-effect (Wadden et al. 1992).

Worldwide interests on food safety were spread rapidly after the crisis of "mad-cow" disease, O-157 infection and food toxicity in the processed foods (Grimm 2001), so lots of people became more and more interested in natural food diets and tried to change their dietary lifestyles. Meeting these international trends, interests in raw-food diets are rapidly increasing in relation to chronic disease prevention in Korea, but clinical human studies on raw-food diets have been hardly performed by nutritionists.

Therefore, this study was designed to investigate the effects of low-calorie diets using raw-food formula on obesity and its complications in obese premenopausal women (body mass index ≥ 25kg/m^2) when the raw-food formula was substituted to two regular meals in a daily diet for eight weeks. Raw-food means uncooked food in the glossary of a dictionary, but it is defined more precisely as natural food which is not processed by heat, seasonings and artificial additives in this study, and it was provided in the form of freeze-dried powder in the diet intervention.

Subjects and Methods

1. Subjects

Obese premenopausal women in Seoul and Kyungki-do were recruited from want ad on a web site, and subject selection criteria were BMI ≥ 25kg/m^2 and premenopausal women aged from 20 to 39 years. Subjects who are pregnant or lactating or menopaused, and who had mental problems or metabolic diseases, such as, diabetes mellitus (DM), coronary artery disease (CAD), hypothyroidism and gallstones were excluded from 310 volunteers at the first interview. Only sixty-one subjects who are suitable for this study consented to participate in this eight-week diet intervention. Forty subjects were entirely in compliance with this study, showing a compliance rate 65.6%.

2. Diet intervention

Forty subjects participated in the diet intervention for 8 weeks, and they were treated to have 1 regular meal and 1 – 2 snacks during the day time, and to substitute 2 meals with a raw-food formula at breakfast and supper. Raw-food formula was taken by being dissolved in a cup of milk or calcium-fortified soy milk. A pack (40g) of raw-food formula is consisted of carbohydrate 30g, protein 4g, fat 0.5g, dietary fiber 3g and minor nutrients 2.5g in the form of freeze-dried powder, yielding 140kcal. Trained dietitians educated and monitored the subjects to have balanced low-calorie diets

Table 1. Dietary prescriptions using food exchange tables[1] during the diet intervention

Menu	Formula[2]	Grains	Fish & Meats		Fat & Oil	Milk	Vegetables	Fruits
			Low-fat	Middle-fat				
1st week (1500kcal)	2	3.5	2	2	2	2	8	2
2 – 8th week (1300kcal)	2	3	2	1	1	2	7	2

Unit : total serving frequencies of one serving size a day

1) This is an application of food exchange tables for diabetes mellitus (KDA 1995)

2) Raw-food formula : one serving size, a pack (40g) has 140kcal (carbohydrate 30g, protein 4g, fat 0.5g, dietary fiber 3g and minor nutrients 2.5g). Ingredients of formula are brown rice, sprouted brown rice, pumpkin (*Cucurbita spp*), kale (*Brassia oleracea L. var. acephala DC*), sorghum (*Sorghum nervesum*), Job's tears or adlay (*Coix lacryma-jobil. var. mayuen STAPF*), soybean, carrot (*Daucus carota L.*), burdock (*Arctium lappa L.*), cabbage (*Brassica oleracea var. capitata L*), *Angelica keiskei*, mugwort (*Artemisia spp.*), pine needle (*Pinus densiflora Sieb. and Zucc.*), *Ganoderma lucidum Karst*, *Cortinellus edodes*, laver (*Porphyra tenera KJELLMAN*), sea tangle (*Laminaria japonica Areschon*), sea mustard (*Undaria pinnafifida SURINGAR*), *Rehmannia glutinosa var. Purpurea Makino*, *Lycium chinense*, *Astragallus membraaceus Bunge*, *Morus alba L.*, green tea leaves, *Cichorium endiva*, *Cichorium intybus L.*, *Citrus aurantium LINNE*, *Capsicum annuum L.*, *Spirulina*, soybean peptide, *Lactobacillus acidophilus*, and brewer's yeast.

during the diet intervention period, and the subjects selected their own food freely and recorded all the foods ingested during the study period. Dietary energy intakes were prescribed to the subjects that 1500kcal for the 1st week, contributed from carbohydrate (57.1%), protein (20.3%) and fat (22.6%), and that 1300kcal for the rest periods from carbohydrate (61.6%), protein (20.0%) and fat (18.9%). Minor nutrients were also prescribed to the subjects according to Recommended Dietary Allowances (RDA) for Koreans (KSN 2000) during the study period, and about 2/3 of Korean RDAs were fulfilled by the raw-food formula per day except cholesterol. Dietary prescriptions are shown in Table 1 and Table 2.

Nutrition education was held every other week (totally 5 times). The contents were focused on how to eat a low-calorie diet, such as, application of food exchange tables to daily diet, using food diaries, choosing low-calorie foods and low-calorie cooking methods, etc. All the subjects were counseled by trained dietitians once or twice per week by phone to encourage compliance throughout the study period, and to monitor dietary intake and food behaviors.

3. Personal questionnaire

The subjects were interviewed by trained interviewers using a structured personal questionnaire on general characteristics, such as, socioeconomic status and living conditions before the study. Questions on menstrual irregularity, menarche and obesity onset age were also included in this questionnaire.

Physical activity was determined in the time unit of a week (7 days) using a structured questionnaire before and after the study, not as total energy expenditure but as energy expenditure of physical exercise . The intensity of the exercise was categorized as three levels : low (slow-walking for exercise, light-stretching at standing posture etc.), medium (fast-walking, slow-cycling, bowling, hiking on the ground etc.) and high (golf, hiking on the mountain, aerobic dancing fast-cycling, doing stepper etc.) levels. Energy expenditure factor was weighted respectively as 0.043, 0.068 and 0.092 kcal/kg/min according to the intensity of the exercise levels. Average energy expenditure of physical exercise per day was calculated by the following process : multiply body weight (kg) by exercise duration (minute) at one try by exercise frequency per week by energy expenditure weighted factor at each level, then sum the energy value at each level up, and finally divide the total sum into 7 days (KDA 1999b)

4. Anthropometry and body compositions

Body weight, height and body compositions were measured by a trained regular nurse before the study (initial), during the study (the 4th week), after the study (the 8th week) BMI was calculated as {body weight (kg) /height (m)^2}, and ideal body weight was calculated as BMI method {height (m) × height (m) × 21}. Percentage of body fat, lean body mass, body water and basal metabolic rate (BMR) were measured with the bioelectrical impedance method (Cha et al. 1997) using a body composition analyzer (Inbody 3.0, Biospace Co., Ltd., Korea). Waist and hip circumferences were measured at Initial and at the 8th week, and waist-to-hip ratio (WHR) was computed as an indication of the index of body fat distribution (Gibson 1990).

5. Biochemical measurements and blood pressure

Venous blood specimens following 12-hour fasting were collected at Initial and at the 8th week. It was measured enzymatically by Auto-analyzer (Hitachi 7150, Tokyo, Japan) in blood lipids (total cholesterol (TC), triglyceride (TG), high-density-lipoprotein cholesterol (HDL-C), fasting blood sugars (FBS) and uric acids. Low-density-lipoprotein cholesterol (LDL-C) was indirectly calculated from the Friedwald (1972) formula as {TC − (HDL-C) − TG/5}. It was determined by enzymatic comparative colorimetry for blood

Table 2. Minor nutrient prescriptions according to Korean RDAs[1)] for women during the diet intervention

Nutrients	Vitamin A (μgRE)	Vitamin D (μg)	Vitamin E (mg α-TE)	Vitamin C (mg)	Vitamin B_1 (mg)	Vitamin B_2 (mg)	Niacin (mg NE)
Contents	700	5	10	70	1.0	1.2	13
Nutrients	**Vitamin B_6 (mg)**	**Folic acid (μg)**	**Calcium (mg)**	**Phosphorus (mg)**	**Iron (mg)**	**Zinc (mg)**	**Cholesterol[2)] (mg/kcal)**
Contents	1.4	250	700	700	16	10	Under 100

1) Korean RDAs, 7th Revision (KSN 2000) for women aged from 20 to 39.
2) Normal range of cholesterol intake should be under 300mg per day.
A pack (40g) of raw-food formula fulfills about 1/3 of Korean RDAs : vitamin A 231.0μgRE, vitamin D 1.65μg, vitamin E 3.3mg α-TE, vitamin C 18.15mg, vitamin B1 0.33mg, vitamin B2 0.369mg, niacin 4.29mg NE, vitamin B6 0.462mg, folic acid 82.5μg, calcium 154.04mg, phosphorus 117.04mg, iron 5.28mg, zinc 3.3mg, but cholesterol is not detected.

free fatty acids (FFA), by immunoradiometric assays (IRMA) for human leptin. Systolic and diastolic blood pressure was measured by a specialist using a pressure gauge at a stable state, and the heart rate was counted for 60 seconds.

6. Ultrasonography

Upper abdominal ultrasonography was conducted by an Ultrasonograph to determine fatty liver and to discriminate subjects having gallstones. Two of sixty-one subjects had gallstones, so they were excluded from this study. Fatty liver echogenicity was determined at Initial and at the 8^{th} week, and fatty liver severity was classified to four degrees : normal, mild, moderate and severe states.

7. Statistical analysis

Obesity and body compositions were analyzed at Initial, at the 4^{th} week and at the 8^{th} week by repeated measures ANOVA and compared by LSD's multiple test. WHR and biochemical measurements were analyzed at Initial and at the 8^{th} week by paired t-test. Fatty liver and menstrual irregularity were analyzed by the nonparametric Wilcoxon signed rank test. All the data was represented as mean ± SEM, and statistical significances among time-dependent variables were analyzed at $p < 0.05$ level using SPSS version 10.0 (Noh 2001).

Results and Discussion

1. General characteristics

Socioeconomic status of the forty subjects are shown in Table 3. Age distribution was 55.5% in the twenties and 45.0% in the thirties, and mean age was 28.33 years old (Table 4). All of the subjects had higher education and 72.5% of them had college educations. Fifty percent of the subjects were employed, and the rest were housewives (37.5%) or college students (10.0%). Married subjects were 57.5%, and nuclear family types were for the most part (82.5%). Family income was dominant in the level over 2,000,000won/month (60.0%), and it was due to employed women-power for a living.

Physical characteristics of the subjects are shown in Table 4 Mean height was slightly higher than its age-matched standards (KNS 2000). Mean BMI was 28.04 ± 0.46kg/m^2, so the subjects were assessed as pre-obese states which increase risks of comorbidities in worldwide criteria (WHO 1998), or as obese-class I states which have moderate risks of comorbidities according to Asian criteria (WHOWPR-IASO 2000) Mean obesity onset age was 14.88 years old, and it meant that our subjects became obese during and after their puberty period, and it was after menarche.

Table 3. Socioeconomic status of the subjects (n = 40)

Characteristics	Frequency (%)	Characteristics	Frequency (%)
Age (year)		*Marital status*	
20 – 29	22 (55.0)	Married	23 (57.5)
30 – 39	18 (45.0)	Non-married	17 (42.5)
Education level		*Family types*	
High school	11 (27.5)	Extended family	5 (12.5)
College ≤	29 (72.5)	Nuclear family	33 (82.5)
		Alone	2 (5.0)
Occupational status		*Family income (10,000won/mth)*	
Housewives	15 (37.5)	≤ 100	1 (2.5)
Professional	11 (27.5)	101 – 200	15 (37.5)
Office workers	7 (17.5)	201 – 300	18 (45.0)
Service jobs	2 (5.0)	301 – 500	4 (10.0)
College students	4 (10.0)	501 ≤	2 (5.0)
Unemployed	1 (2.5)		

2. Effects of diet intervention

1) Anthropometry and body compositions

Changes of obesity and body compositions during the diet intervention are shown in Table 5. It was reduced during the diet intervention as time passed through at each point of the 4^{th} week and the 8^{th} week, especially in mean body weight (−4.59%, $p < 0.000$), BMI (−4.56%, $p < 0.000$), PIBW (−4.56%, $p < 0.000$), body fat percent (−6.18%, $p < 0.000$) and fat mass (−10.19%, $p < 0.000$). Improvement of obesity was greater during the first four weeks than the last four weeks. Mean LBM (−1.22%, $p < 0.023$), soft lean mass (−1.23%, $p < 0.027$) and body water (−1.23%, $p < 0.024$) were significantly decreased at the 4^{th} week, but the drops

Table 4. Physical characteristics of the subjects (n = 40)

Characteristics	Subjects
Age (yr)	28.33 ± 0.77
Height (cm)	161.52 ± 0.84
Weight (kg)	73.27 ± 1.47
Ideal body weight (kg)	54.84 ± 0.57
BMI (kg/m^2)	28.04 ± 0.46
PIBW (%)	133.55 ± 2.17
Menarche age	13.03 ± 0.26
Obesity onset age	14.88 ± 1.28

Mean ± SEM
Ideal body weight : height (m) × height (m) × 21
BMI (body mass index) : weight/height (m)^2
PIBW (percentage of ideal body weight) : (weight/IBW) × 100

Table 5. Changes of obesity and body compositions during the diet intervention (n = 40)

Variables	Diet intervention period			p-value
	Initial	4th week	8th week	
Weight (kg)	73.27 ± 1.47[a]	70.69 ± 1.48[b]	69.91 ± 1.47[c]	0.000
BMI (kg/m^2)	28.05 ± 0.46[a]	27.06 ± 0.47[b]	26.77 ± 0.48[c]	0.000
PIBW (%)	133.55 ± 2.17[a]	128.85 ± 2.21[b]	127.46 ± 2.27[c]	0.000
Body fat (%)	37.23 ± 0.63[a]	35.62 ± 0.69[b]	34.93 ± 0.73[c]	0.000
Fat mass (kg)	27.48 ± 0.94[a]	25.40 ± 0.95[b]	24.68 ± 0.98[c]	0.000
LBM (kg)	45.80 ± 0.76[a]	45.30 ± 0.78[b]	45.24 ± 0.74[b]	0.023
Soft lean mass (kg)	43.22 ± 0.72[a]	42.74 ± 0.74[b]	42.69 ± 0.71[b]	0.027
Body water (L)	31.69 ± 0.53[a]	31.33 ± 0.55[b]	31.30 ± 0.52[b]	0.024
BMR (kcal)	1451.60 ± 26.58[a]	1427.70 ± 25.02[b]	1442.41 ± 25.33[a]	0.009

Mean ± SEM LBM : lean body mass
BMR : basal metabolic rate measured by bioelectrical impedance method (Cha et al. 1997)
Values with different alphabets within the same row are significantly different each other by repeated measures ANOVA adjusted for LSD's multiple comparison test at $p < 0.05$.

Table 6. Total weight loss[1)] during the diet intervention (n = 40)

Weight loss ranges (kg)	Frequency (%)	Mean ± SEM (kg)
<2.0	13 (32.5)	0.85 ± 0.33
2.0 – 3.9	12 (30.0)	2.71 ± 0.16
≥ 4.0	15 (37.5)	6.06 ± 0.40
Total	40 (100.0)	3.36 ± 0.40

1) Weight at the 8th week – weight at initial

Table 7. Changes of energy expenditure of physical exercise during the diet intervention (n = 40)

Variable	Diet intervention period		p-value
	Initial	8th week	
Exercise expenditure (kcal/day)	42.91 ± 10.56	112.97 ± 11.96	0.000

Mean ± SEM
Values in the same row are significantly different by paired t-test at $p < 0.05$.

were not significant at the 8th week. Mean BMR was significantly reduced at the 4th week ($p < 0.009$), but was recovered at the 8th week, only reduced 0.63% of initial value. The percentages of losses in weight, BMI, body fat percent and fat mass were superior to ones in LBM, soft lean mass and body water. Furthermore, BMR was returned into the initial level within the 8 weeks. These changes during the diet intervention can be evidences indicating very meaningful effects on treatment of obesity and prevention of weight-regain (Hensrud et al. 1994 ; Kreizman et al. 1992). These were similar to the results of a 12-week multidisciplinary weight management program in the obese premenopausal women (Park 2000).

Total weight loss during the diet intervention is shown in Table 6. Mean weight loss was 3.36 ± 0.40kg, and it meant that weight loss was proceeded in the rate of almost 0.5kg/week. In the case of weight loss for 4.0kg and over, mean weight loss was 6.06 ± 0.40kg and the loss was proceeded in the rate of under 1.0kg/week. Weight loss rate in this study is so desirable for obese people to loose weight and to improve obesity with minimal side effects (KDA 1999A, KSSO 2001), such as, osteoporosis, dehydration, mineral imbalance, nervousness, gallstone, arrhythmia, hyperuricemia, weakness, menstrual irregularity, lowering metabolic rate etc which occur when weight is rapidly reduced in the rate over 1.0kg/week by commercial very-low-calorie diets (VLCD) or fasting or imbalanced low-calorie diets (Arari et al. 1992, Lee 1997, Lee, Huh 1997, NTFPTO 1993, Pi-Sunyer 1993).

Changes of energy expenditure of physical exercise during the diet intervention were also measured, and they are shown in Table 7. Exercise activity was increased as much as 70.06kcal/day during the diet intervention ($p < 0.000$), however this increase did not have any correlations with the changes of weight ($r = 0.128$, $p = 0.432$), BMI ($r = 0.160$, $p = 0.323$), fat mass ($r = -0.005$, $p = 0.977$), body fat percent ($r = -0.072$, $p = 0.660$) and LBM ($r = 0.239$, $p = 0.138$). It seemed that the increase of energy expenditure of physical exercise during this study was not enough to affect on weight loss and body compositions. On the contrary, the restricted energy by the diet intervention had actual influence on improvement of obesity, and it was considered as the rest energy (350kcal/day) which was subtracted the increase of energy expenditure (70kcal/day) of physical exercise from total restricted energy (420kcal/day) according to the mean weight reduction rate of 0.42kg/week (Table 6).

In the case of central obesity, it was changed into slimmer

Table 8. Changes of central obesity during the diet intervention (n = 40)

Variables	Diet intervention period		p-value
	Initial	8^{th} week	
Waist circumference (cm)	85.07 ± 1.17	80.23 ± 1.17	0.000
Hip circumference (cm)	102.08 ± 0.76	99.48 ± 0.77	0.000
WHR	0.833 ± 0.007	0.806 ± 0.007	0.000

Mean ± SEM
WHR : waist circumference to hip circumference ratio
Values in the same row are significantly different by paired t-test at p<0.05.

configuration of the subjects, showing significant losses in waist and hip circumferences(respectively, −5.69%, $p < 0.000$; −2.55%, $p < 0.000$), and WHR(−3.24%, $p < 0.000$). It is shown in Table 8. Central obesity for women is decided when WHR is over 0.80(Sonnichsen et al. 1993, WHOWPR-IASO 2000), or waist circumference is over 80cm (WHOWPR-IASO 2000). According to these criteria, all the subjects were centrally obese, but the severity of central obesity was significantly improved during the diet intervention($p < 0.000$). Central obesity is a widely recognized factor which increases the incidence of metabolic syndrome, in other words, syndrome X which includes hypertension, dyslipidemia, glucose intolerance, insulin resistance and so forth(Grundy 1999, Kim 2002, Reaven 1988). It is recognized that visceral fat is over-accumulated in the abdominal cavity in central obesity. Visceral fat causes increase of total cholesterol and triglyceride levels, but decrease of HDL cholesterol level in the blood, by actively accelerating lipolysis of visceral fat and by disturbing clearance of insulin in the liver(Bouchard et al. 1993). So, improvement of central obesity is very important in lowering the incidence of obesity-related complications, and also WHR and waist circumference are easy, economic and effective tools to assess the central obesity(Claude et al. 1990).

In fact, we had some difficulties in interpreting these results for generalization because of sampling biasness, and in proving which of these results came from the effects of "raw-food formula, itself" or of "low-calorie diet, itself" or of "both of them" because of the absence of a control group. But, this article showed the positive availability of "raw-food formula" in treatment of obesity and its complications as an effective material for the low-calorie diet. Lots of scientists have already reported that low-calorie diet had significant effects on management of obesity in their articles, many commercial formulas were tested as materials for the low-calorie diet(Arai et al. 1992, Kim 1999, Lee et al. 1999, Sweeney et al. 1993). The materials partially used in this study for low-calorie diet were "natural foods" that are not processed, or purified heavily, and not added food-additives (Noh, Huh 2000), more specifically non-cooked "raw-foods" in the form of freeze-dried. The best diet for better health and management of obesity would be having balanced general diets everyday with various natural foods(Park 2000), but it is also difficult to maintain that kind of desirable dietary life in today's complex industrial society. That is why we chose raw-food formula as substitute for regular meals, in contrast with existing diet formulas composed of highly purified or processed ingredients. Raw-food formula consisted of various grains, vegetables, sea weeds, beans, mush rooms, and yeast fungi(Table 1), so the ingredients of the raw-food formula were very close to the foods in the general diet.

We also selected freeze-drying method(−40℃, 0mmHg, 3 − 12hr) in processing the raw-foods and then powdered them to mix as a formula. There are several reasons why we chose this procedure to make raw-food formula instead of eating food itself. First, it is very convenient to carry along with many kinds of food everywhere and at anytime because the bulky food switched to a small package of powder. Second, when foods were freeze-dried, destruction of nutrients in the raw-food is much lower than in other processing (or cooking) methods, such as, baking, blanching, boiling, drying freezing and frying, especially in the minor nutrients, such as vitamin C, thiamin, riboflavin, provitamin A, some soluble minerals and so forth(Ensminger et al. 1994). Third, freeze-dried foods have great restoration to the original state with the minimal changes of food compositions when water is added(Kim, Choi 1995 ; Lee, Choi 1995 ; Park et al. 1993) Fourth, this method makes it possible to make specific purpose foods which replace meals without adding food additives or supplements. Fifth, freeze-dried foods can be preserved much longer period than other foods because of the absence of moisture. And last, it is available enough to develop and manufacture commercial products on a massive scale. However, further studies are needed on the differences of effects of raw-food diets according to the processing methods, and on the medical effects of raw-food formulas in the human bodies.

Table 9. Changes of biochemical measurements and blood pressure during the diet intervention (n = 40)

Variables	Diet intervention period		p-value
	Initial	8^{th} week	
TC (mg/dl)	169.95 ± 4.15	173.33 ± 3.44	0.331
TG (mg/dl)	108.45 ± 7.49	89.45 ± 6.97	0.006
HDL-C (mg/dl)	50.05 ± 1.71	51.40 ± 1.66	0.336
LDL-C (mg/dl)	98.21 ± 3.60	104.04 ± 3.52	0.039
TC/HDL-C	3.52 ± 0.12	3.50 ± 0.13	0.849
FFA (μEq/L)	896.19 ± 47.18	861.05 ± 58.16	0.484
FBS (mg/dl)	93.88 ± 1.48	91.83 ± 1.59	0.279
Uric acid (mg/dl)	4.66 ± 0.20	4.65 ± 0.19	0.926
Leptin (ng/ml)	18.69 ± 1.08	11.87 ± 1.58	0.000
SBP (mmHg)	118.90 ± 1.97	111.53 ± 2.14	0.000
DBP (mmHg)	68.15 ± 1.43	64.00 ± 1.77	0.021
Heart rate (frequency)	80.83 ± 1.50	76.33 ± 2.08	0.009

Mean ± SEM
TC : total cholesterol, TG : triglyceride, FFA : free fatty acids
HDL-C : high density lipoprotein cholesterol
LDL-C : low density lipoprotein cholesterol
FBS : fasting blood sugar
SBP : systolic blood pressure, DBP : diastolic blood pressure
Values in the same row are significantly different by paired t-test at $p < 0.05$.

2) Biochemical measurements and blood pressure

Changes of biochemical measurements and blood pressure during the diet intervention are shown in Table 9. It was not significantly changed after the diet intervention in FBS, uric acid and blood lipids, such as, TC, HDL-C, FFA and TC/HDL-C ratio. Blood TG level was significantly decreased (−17.52%, $p < 0.006$), and it was inferred by suppression of 50 − 80% of activity of lipoprotein lipase in lipocytes (Carter et al. 1983). On the other hand, blood LDL-C level was increased (+5.94%, $p < 0.039$), but still remained in the lower level of normal ranges. It was an opposite result comparing with other studies which reported reduction of LDL-C level after weight loss (Anderson et al. 1999), but it could be explained by the report of Park (2000) that the fluctuation of blood LDL-C level was not only affected by diet intervention but also by factors such as exercise, stress and food behavior. Independently of diet intervention, all the biochemical measurements were in the normal ranges (CAHTG 2000), but only blood FFA level was abnormally higher than norm (176 − 586 μEq/L). High level of FFA was caused by acceleration of lipolysis, especially, in the abdominal fat cells, so it is higher in those who are centrally obese (Stromblad, Bjorntorp 1986).

Blood leptin level was decreased along with the body fat loss during the diet intervention (−34.49%, $p < 0.000$), so it became similar to the normal counterparts (11.0 ± 3.0ng/ml) after the diet intervention. Leptin is a factor regulating appetite, which it is produced and secreted from obese genes in white fat cells (Trayhurn et al. 1999), then it suppresses the appetite continuously by combining with neuron receptors in the brain (Brunner et al. 1997). Accordingly, increases in body weight and body fat mass cause increases in blood leptin level to suppress appetite, so obese people have higher blood leptin level than normal people (Boden et al. 1996).

Systolic ($p < 0.000$) and diastolic ($p < 0.021$) blood pressure were reduced after the diet intervention, and the heart rate for 60 seconds was also decreased ($p < 0.009$). However, they were not out of the normal ranges (Whitney et al. 2002).

In conclusion, blood TG and leptin levels were significantly reduced according to the decreases in energy consumption, body weight and fat mass during the diet intervention. However, other biochemical measurements were generally not changed after the 8-week diet intervention, it was due to that subjects' initial levels were in the normal ranges except FFA and those who had metabolic diseases were already excluded before the diet intervention, even though they were still centrally obese (Table 8).

Table 10. Changes of fatty liver echogenicity during the diet intervention (n = 40)

Grades	Diet intervention period		p-value
	Initial	8^{th} week	
Normal	19 (47.5)	32 (80.0)	0.000
Mild	12 (30.0)	8 (20.0)	
Moderate	9 (22.5)	− (0.0)	
Severe	− (0.0)	− (0.0)	
Total	40 (100.0)	40 (100.0)	

Frequency (%)
Values between Initial and 8^{th} week are significantly different by Wilcoxon Signed Ranks Test at $p < 0.05$

3) Other complications

Changes of fatty liver echogenicity during the diet intervention are shown in Table 10. Subjects who had fatty liver were the majority (52.5%) at initial, but the severity of fatty liver was so improved that 80.0% of the subjects were normal at the 8^{th} week ($p < 0.000$). It showed excellent effects of the diet intervention on obesity-related complications. Such a surprising result was due to improvement of central obesity (Sjostrom 1992), as indicated by reduction of WHR and waist circumference (Table 8).

Table 11. Changes of menstrual irregularity during the diet intervention (n = 40)

Grades	Diet intervention period		p-value
	Initial	8th week	
Regular	27(67.5)	31(77.5)	0.034
Irregular	13(32.5)	9(22.5)	
Total	40(100.0)	40(100.0)	

Frequency(%)
Values between Initial and 8th week are significantly different by Wilcoxon Signed Ranks Test at $p < 0.05$

Changes of menstrual irregularity during the diet intervention are shown in Table 11. Percentage of the subjects who had irregular menstruation (32.5%) were significantly decreased to 22.5% after the diet intervention ($p < 0.034$). As women are obese for longer periods of time, menstrual irregularity is easily apt to occur, then amenorrhea, and finally it can be a cause of infertility (Zimoff et al. 1995), so it is very meaningful to improve obesity and menstrual irregularity for women who are in the child-bearing period.

Results as mentioned above showed that the losses of body weight and fat mass affected not only improvement of obesity, but also improvement of obesity-related complications, such as, dyslipidemia, insulin resistance and endocrine disorders (Bosello et al. 1997, Bray 1985).

Summary and Conclusion

This study was performed to investigate the effects of low-calorie diet using raw-food formula which is in the form of freeze-dried powder on obesity and its complications in obese premenopausal women for 8 weeks (mean BMI 28.04kg/m^2, mean age 28.33years old). The subjects were recruited from a web site, and they had advanced education and income back-grounds. Forty subjects participated in this diet intervention, and were instructed to eat 1 regular meal, 1 − 2 snacks and to substitute 2 regular meals (breakfast and supper) for raw-food formula (140kcal/pack) a day within the 1500 − 1300kcal ranges.

Mean body weight (−4.59%), BMI (−4.56%), PIBW (−4.56%), body fat percent (−6.18%) and fat mass (−10.19%) were significantly reduced during the diet intervention as time passed through at each point of the 4th week and the 8th week (respectively at $p < 0.000$). Mean LBM (−1.22%), soft lean mass (−1.23%) and body water (−1.23%) were also decreased after the 4th week (respectively at $p < 0.05$), but the drops were not significant any more at 8th week. Mean BMR was decreased at the 4th week ($p < 0.009$), but was returned to the initial level at the 8th week (−0.63%). Mean weight loss was 3.36 ± 0.40kg in the reduction rate of almost 0.5kg/week. This reduction rate is so desirable for obese people to improve obesity without any side effects (KDA 1999a, KSSO 2001), and to prevent weight-regain (Hensrud et al. 1994). Energy expenditure of physical exercise was increased about as much as 70kcal/day during the study ($p = 0.000$), but it did not have any correlations with weight loss and changes of body compositions. Also reduced were waist (−5.69%) and hip (−2.55%) circumferences, and WHR (−3.24%) after the diet intervention (respectively, $p < 0.000$), so central obesity was improved to decrease the risk factors related comorbidities, such as hypertention, hyperlipidemia, glucose intolerance, fatty liver, menstrual irregularity and so forth (Grundy 1999, Kim 2002).

Biochemical measurements including blood triglyceride (−17.52%, $p < 0.006$) and leptin (−34.49%, $p < 0.000$) levels were significantly decreased, LDL cholesterol level was increased (+5.94%, $p < 0.039$), but all the blood lipid levels except FFA were in the normal ranges (CAHTG 2000) after the diet intervention. There were no significant changes in FBS, uric acid and blood lipids such as TC, HDL-C, FFA and TC/HDL-C ratio after the diet intervention, because biochemical initial values were in the normal ranges and those who had metabolic diseases were already excluded before the diet intervention, even though they were still centrally obese (Table 8). Elevation of blood LDL-C level after the diet intervention was due to extra-diet effects, such as exercise, stress and food behavior (Park 2000), and abnormally high blood FFA level was caused by acceleration of lipolysis, especially in abdominal fat cells (Stromblad & Bjorntorp 1986). Blood leptin level was decreased along with the body fat loss (−34.49%, $p < 0.000$), so it became similar to the normal counterparts (11.0 ± 3.0ng/ml) after the diet intervention (Boden et al. 1996). Systolic and diastolic blood pressure was also reduced after the diet intervention ($p < 0.000$, $p < 0.021$).

Other complications of obesity, such as, fatty liver ($p < 0.000$) and menstrual irregularity ($p < 0.034$) were significantly improved. The subjects who had fatty liver at initial (52.5%) decreased at the 8th week (20.0%), and who had irregular menstruation (32.5%) reduced at the 8th week (22.5%) after the diet intervention.

In conclusion, this 8-week low-calorie diet intervention substituted 2 meals for raw-food formula was significantly effective for obese premenopausal women in reducing obesity without critical side effects, and in decreasing risk factors so as not to proceed towards comorbidities. In particular, lots of losses in body fat mass and waist circumference caused improvement of central obesity and could work as key factors lowering metabolic syndromes, even though the variations of blood lipid levels should be observed for a longer period. After all, these results showed the positive availability of "raw-food formula" as an effective material for the low-calorie diet in the improvement of obesity and its complications, and we also suggest that further studies should be made on the differences among "raw-food diet", "generally cooked diet", and "other types of diet" with the same energy level at various points of view, especially in the medical actions in the human bodies.

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References

ADA reports (1990) : Position of the American dietetic association : very-low-calorie weight loss diet. *J Am Diet Assoc* 90(4) : 722-726

Anderson RE, Wadden TA, Bartlett SJ, Zemel B, Verde TJ, Franckowiak SC (1999) : Effects of lifestyle activity vs structured aerobic exercise in obese women : a randomized trial. *J Am Med Assoc* 27 ; 281(4) : 335-340

Arari K, Miura J, Ohno M, Yokoyama J, Ikeda Y (1992) : Comparison of clinical usefulness of V-S-C diet and supplemental L-C diet. *Am J Clin Nutr* 56 : 275s-276s

Blumenthal JA, Sherwood A, Gullette EC, Babyak M, Waugh R, Georgiades A, Craighead LW, Twwdy D, Feinglos M, Appelbaum M, Hayano J, Hinderliter A (2000) : Exercise and weight loss reduce blood pressure in men and women with mild hypertention : effects of cardiovascular, metabolic, and hemodynamic functioning. *Arch Intern Med* 160(13) : 1947-1958

Boden G, Chen X, Mozzole M, Ryan I (1996) : Effect of fasting on serum leptin in normal human subjects. *J Clin Endocrinol Metab* 81(9) : 3419-3423

Bosello O, Armellini F, Zamboni M, Fitchet M (1997) : The benefits of modest weight loss in type II diabetes. *Int J Obes* 21 : s10-s13

Bouchard C, Despres J, Mauriege P (1993) : Genetic and nongenetic determinants of regional fat distribution. *Endocrine Reviews* 14 : 72-93

Bray GA (1985) : Complication of obesity. *Ann Intern Med* 21 : 1172-1174

Brunner L, Nick HP, Cumin F, Chiesi M, Baum HP, Whitebread S, Stricker-Krongrad A, Levens N (1997) : Leptin is a physiologically important regulator of food intake. *Int J Obes* 21 : 1152-1160

CAHTG (2000) : Diagnosis and treatment of hyperlipidemias. The Committee of Acts on Hyperlipidemia Treatment Guidelines, Han Medical Press, Seoul, Korea

Carter GD, Holland SM, Alahband-Zadeh J, Rayman G, Dorrington-Ward P, Wise PH (1983) : Investigation of hirsutism : testosterone is not enough. *Ann Clin Biochem* 20 : 262-263

Cha KC, Shon CM, Kim KJ, Choi SH (1997) : Segmental bioelectrical impedance analysis (SBIA) for determining body composition. *Korean J Community Nutrition* 2(2) : 179-186

Claude B, Bray GA, Hubbard VS (1990) : Basic and clinical aspects of regional fat distribution. *Am J Clin Nutr* 52 : 945-950

Ensminger AH, Ensminger ME, Konlande JE, Robson JRK (1994) : Foods & Nutrition Encylopedia, 2nd Ed., vol.2, pp.2146-2187, CRC Press, USA

Friedwald WT, Levy RI, Fredrickson DS (1972) : Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. *Clin Chem* 18 : 499-502

Gibson RS (1990) : Principles of nutritional assessment. NY Oxford, Oxford University press, USA

Grimm HU (2001) : Aus Teufels Topf Die neuen Risiken beim Essen translated by Oh EK, Mosek Publishing Co., Seoul, Korea

Grundy SM (1999) : Hypertriglyceridemia, insulin resistance, and the metabolic syndrome. *Am J Cardiol* 83 : 25f-29f

Havlick RJ, Hurbert HB (1983) : Weight and hypertension II. *Ann Intern Med* 98 : 855-859

Hensrud DD, Weinsier RL, Darmell BE, Hunter GR (1994) : A prospective study of weight maintenance in obese subjects reduced to normal body weight without weight-loss training. *Am J Clin Nutr* 60 : 688-694

KDA (1995) : Diet guidelines for diabetes mellitus, 2nd Ed., Korean Diabetes Association, Eui-Hak Press, Seoul, Korea

KDA (1999a) : Obesity. In : Manual of Medical Nutrition Therapy, 2nd Ed., pp.217-238, Korean Dietetics Association, Seoul, Korea

KDA (1999b) : Nutrition Assessment. In : Manual of Medical Nutrition Therapy, 2nd Ed., pp.11-57, Korean Dietetics Association, Seoul, Korea

Kim KO, Choi HJ (1995) : Optimization of the preparation of rice-based infant foods using freeze drying process. *Korean J Food Sci Technol* 27 : 680-689

Kim SM, Lee DJ, Kim KM (1999) : Predictors of weight loss effects in low calorie diet. *J Korean Society for the Study of Obesity* 8(2) : 72-78

Kim SR (2002) : Central obesity and metabolic syndrome. *J Korean Society for the Study of Obesity* 11(1) : 49s-53s

Kim YS (1990) : Classification and assessment of obesity. *Korean J Nutrition* 23(5) : 337-340

Kissebah AH, Krakower GR (1994) : Regional adiposity and morbidity. *Physiol Rev* 74 : 761-811

KNS (2000) : Recommended dietary allowances for Koreans, 7th Rev., Korean Nutrition Society, Chung-Ang Press, Seoul, Korea

Kreitzman SN, Coxon AY, Szaz KF (1992) : Glycogen storage : illusions of easy weight loss, excessive weight regain and distortions in estimates of body composition. *Am J Clin Nutr* 56 : 292s-293s

KSSO (2001) : Clinical obesity, 2nd Ed., Korean Society for the Study of Obesity, Korea Medical Publishing Co.,Seoul, Korea

Lee DJ (1997) : Side effect of very low-calorie diet and its prevention. *J Korean Society for the Study of Obesity* 6 (1) : 35-44

Lee JH, Huh KB (1997) : Practical usages of very low-calorie diet. *J Korean Society for the Study of Obesity* 6 (1) : 19-26

Lee JH, Jang YS, Park HY, Kim OY, Ryu HJ, Chae JS (1999) : Beneficial effect of weight reduction in overweight middle-aged men. *J Korean Society for the Study of Obesity* 8 (2) : 154-163

Lee MS, Choi HS (1995) : Volatile flavor components of Commelina communis L. as influenced by drying methods. *Korean J Food Sci Technol* 27 : 380-386

MHW (1997) : Reports of Korean National Health Examination Survey in 1995. Ministry of Health and Welfare, Seoul, Korea

MHW (2000) : Reports of Korean National Health Examination Survey in 1998. Ministry of Health and Welfare, Seoul, Korea

Noh HJ (2001) : Survey and Statistical Analysis by SPSS Korean version 10.0, Hyung-Seol Press, Seoul

Noh WS, Huh SH (2000) : Health supplement food and functional food, 2nd Ed., Hyo-il Press, Seoul, Korea

NTFPTO (1993) : Very low-calorie diets. National Task Force on the Prevention and Treatment of Obesity. *J Am Med Assoc* 270 : 967-974

Park NH, Kim BS, Bae SC (1993) : Prediction of sublimation drying time for carrot in freeze-drying. *Korean J Food Sci Technol* 23 : 313-320

Park YS (2000) : Effects of multidisciplinary weight management program on food behavior, obesity and comorbidity risk factors in the obesity premenopausal women. A doctoral dissertation in Hanyang University, Seoul, Korea

Pi-Sunyer FX (1993) : Short-term medical benefits and adverse effects of weight loss. *Am Intern Med* 119 : 722-726

Piziak VK (1983) : Medical management of obesity. *Postgrad Med* 1 : 158-172

Reaven GM (1988) : Role of insulin resistance in human disease. *Diabetes* 37 : 1595-1607

Schultz Y (1983) : Micronutrients and energy balance in obesity. *Metab Clin Exp* 44 : 7-11

Sjostrom LV (1992) : Morbidity of severely obese subjects. *Am J Clin Nutr* 55 (2) : 508s-515s

Sonnichsen AC, Ritter MM, Mohrle W, Richter WO, Schwandt P (1993) : The waist-to-hip ratio corrected for body mass index is related to serum triglycerides and high-density lipoprotein cholesterol but not to parameters of glucose metabolism in health premenopausal women. *Clin Invest* 71 : 913-917

Stoll BA (1995) : Timing of weight gain to breast cancer risk. *Ann Oncol* 6 : 245-248

Stromblad G, Bjorntorp P (1986) : Reduced hepatic insulin clearance in rats with dietary-induced obesity. *Metabolism* 35 : 323-327

Sweeney ME, Hill JO, Heller PA, Baney R, DiGirolamo M (1993) : Severe vs moderate energy restriction with and without exercise in the treatment of obesity : efficiency of weight loss. *Am J Clin Nutr* 57 : 127-134

Trayhurn P, Hoggard N, Mercer JG, Rayner DV (1999) : Leptin : fundamental aspects. *Int J Obes* 23 (1) : 22s-28s

Wadden TA, Barlett S, Letizia KA, Foster GO, Stunkard AJ, Conill A (1992) : Relationship of dieting history to resting metabolic rate, body composition, eating behavior, and subsequent weight loss. *Am J Clin Nutr* 56 (1) : 203s-208s

Whitney EN, Cataldo CB, Rolfes SR (2002) : Chapter 26. Nutrition and disorders of the heart, blood vessels, and lungs. In : Understanding normal and clinical nutrition, 6th Ed., Wadsworth/ Thomson Learning, USA

WHO (1998) : Obesity. Preventing and managing the global epidemic. World Health Organization, Geneva

WHOWPR-IASO (2000) : The Asia-Pacific perspective : Redefining obesity and its treatment, World Health Organization Western Pacific Region, International Association for the Study of Obesity, International Obesity Task Force

Zimoff B (1995) : Normal abnormalities in obesity. *Acta Med Scand* 723 : 153s-160s