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The Effects of Combination of Functional Beverage(Garcinia Cambogia, L-Carnitine, and Soy Peptide) and Exercise on the Improvement of Body Fat

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Abstract–Background : There is abundance of studies on the decrease in body fat through limited calorie intake or exercise; however, studies focusing simultaneously on functional foods and exercise are rare. This study was aimed to identify the effects of combination of a functional beverage and exercise on body composition and biochemical metabolic profiles. Method : Eighty-one healthy volunteers (69 females aged 19 to 50 years and 12 males aged 19 to 55 years), who maintained their body weight stable with 23 or higher in BMI (kg/m^2) and 25% or higher body fat for the last three months, were recruited in the study through written advertisement. All the subjects gave their informed consent, and the study was conducted in accordance with the Declaration of Helsinki. The study design was a randomized double-blind placebo-controlled parallel group design. All participants were given 12-week programed- exercise, which was performed 3 times a week. One bottle (100 ml) of test (Garcinia cambogia 300 mg, L-carnitine 20 mg, Soy peptide 1,000 mg) or placebo solution was given daily 30 min before each session of programed-exercise. BMI (body mass index), %fat, local fat amount (visceral and mid-thigh), waist circumference, skin fold thickness and some biochemical metabolic parameters like glucose, insulin and free fatty acids, etc in the blood were measured and compared before and after 12-week intervention within groups as well as between groups according to the protocol. Results : Twenty six volunteers were dropped out and fifty five volunteers completed the study. At the end of 4, 8, and 12 weeks, approximately 1.98%, 3.00% and 3.50% losses of initial body weight were observed, respectively, in the test group ($P < 0.01$), and 0.29,%, 0.74%, 1.60%, respectively, in the placebo group ($P > 0.05$). BMI changed by 2.40%, 3.41% and 4.46%, respectively, in the test group, and 0.38%, 0.95% and 1.75%, respectively, in the placebo group, at each period of time. The reductions of body weight and BMI were significantly higher in the test group than in the placebo group at each period of time ($P < 0.05$). Conclusions : It is thought that the combination of functional beverage, which contains mostly garcinia cambogia, L-carnitine, and soy peptide, and exercise have synergy effects on reducing body fat.

Keywords ☐ Garcinia Cambogia, Hydroxy Citric Acid, L-Carnitine, Soy Peptide, Improvement of the Body Fat, Exercise

As the standard of living for Koreans has improved, their diet has become more westernized, which has resulted in a dramatic increase in the number of obese people caused by the excessive intake of nutrients and lack of exercise. According to Framingham's study, the relative frequency of health complications is increased by an increase in body weight(Yim *et al.*, 1999) The more obese a person is, the more serious the degree of danger is for coronary heart disease. In addition, it was identified that obesity is the cause for a decline in physical fitness, a drop in reserved power of the heart and lung functions, and a decrease in immunity against disease as well as for chronic degenerative diseases called 'X-syndrome' or 'Deadly quartet.' In other words, obesity is related to complications such as diabetes mellitus, hyperlipidemia, hypertension and coronary artery disease(Mun *et al.*, 1999 ; Anderson *et al.*, 1987). Obesity caused by the excessive accumulation of body fat has been long thought to be a problem of nutrition in western countries including the US and it was reported that 25~36% of adults suffer from obesity(Alison *et al.*, 1995). In general, 23~25 kg/m^2 in BMI is classified as excessive body weight and more than 25 kg/m^2 in BMI is considered to be obese in Korea(Ministry *et al.*, 1998). According to a survey result of national health and nutrition carried out in Korea in 1998, set on the basis of 25 kg/m^2 in BMI, 26.0% of males and 26.5% of females went beyond the basis, while 1.7% of males and 3.0% of females suffered from severe obesity(over 30 kg/m^2 in BMI). Since then, obesity has become a social issue in Korea(International Obesity Task Force 2000). The % body fat measured by the impedance method has been recently used as a

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reference mark of obesity(Skelton *et al.*, 1992); Males and females with over 25% and over 30% body fat are considered obese, respectively.

Regular exercise has a primary preventive effect and a secondary preventative effect on myocardial infarction and ischemic heart disease as well as on improving mild to moderate hypertension. The simultaneous intervention of jogging 20km or more and dieting has various effects on an improvement in health; for hyperlipidemia, a drop in cholesterol and an increase of HDL-C; for type 1 diabetes, an increase in insulin sensitivity and a decrease in insulin resistance; for asthma, an improvement in breathing ability; for mental problem, stress release and improvement in depressive feeling caused by a change in serotonin level in the brain. Therefore, regular exercise helps reverse a decline in body functions caused by a lack of exercise, helps correct obesity, prevents chronic degenerative diseases and delays the aging process, resulting in a more healthier life(Yim, 1998). The amount of energy consumption must exceed the amount of energy intake to result in a decrease in fatty mass. An abundance of studies on the obese for the purpose of body weight loss and a decrease in body fat reported that dieting or aerobic exercise or both show positive effects(Ross *et al.*, 1991). Dieting and aerobic exercise are frequently used to decrease fat in the abdomen and viscera(Ross *et al.*, 1991 ; Mayo *et al.*, 2003). The guidelines for exercise instruction have recently suggested a simultaneous doing of aerobic exercise and resistance exercise for the improvement of muscular functions and bones(Schulze *et al.*, 2002; Keuning *et al.*, 2001). In other words, flexibility exercise, aerobic exercise, and resistance exercise must be appropriately included in training programs to maintain and improve health and physical fitness of people, including the aged and patients with cardiac impairment(Treuth *et al.*, 1995). It is known that resistance exercise increases the amount of muscle rather than decreasing body fat, but there is also some studies reporting that it decreases body fat or visceral fat(Treuth *et al.*, 1995 ; Fujioka *et al.*, 1991). According to Ahn Yong-jun and *et al.*'s (1999) study on obese female college students, the group that was given only the low calorie(900 kcal/day) limited diet, showed a loss in lean body mass(LBM) as well as a decrease in % body fat(Ahn *et al.*, 1999). Therefore, long-term low calorie diet in the obese can increase the negative health effect(Stefanic, 1993 ; Wadden *et al.*, 1990). If one goes on a diet with an unreasonable limit, it can overstrain one's body. Therefore, regular exercise along with the appropriate dieting program is highly recommended(Seong, 2000).

There is abundance of studies on the decrease in body fat through limited calorie intake or exercise; however, studies focusing simultaneously on functional foods and exercise are rare. As more people are becoming interested in functional foods, the government of Korea requires (Korea Food & Drug Administration's notice #2002-6) functional food manufacturers to prove their efficacies and safety through clinical trials. Therefore, this study was aimed to identify the effects of combination of functional beverage, containing mostly garcinia cambogia (40% hydroxy citric acid), L-carnitine, and soy peptide, and exercise on the decrease in body fat and metabolic profile.

MATERIALS AND METHODS

Subjects

Eighty-one healthy volunteers(69 females aged 19 to 50 years and 12 males aged 19 to 55 years), who maintained their body weight stable with 23 or higher in BMI(kg/m^2) and 25% or higher body fat for the last three months, were recruited in the study through written advertisement. All the subjects gave their informed consent, and the study was conducted in accordance with the Declaration of Helsinki. Health status and food intake of subjects were checked through history, physical examination, laboratory tests and questionnaires. When exercise was not scheduled, they were recommended to take the

Table I. Enrollment and drop out rate of subjects

Group	Enrollment	Drop out (%)	Completion	Adverse effects (%)
Active	40	12(30.0)	28	2(7.1)
Placebo	41	14(34.1)	27	1(3.4)
Total	81	26	55	3

Table II. Main ingredients of the test beverage and the placebo beverage

Contents		Test beverage	Placebo beverage
Main ingredients	Garcinia cambogia	300 mg	
	L-carnitine	20 mg	
	Soy peptide	1,000 mg	
	Dietary fiber	3,430 mg	
	Niacin	20 mg	
Supplementary ingredients	Grapefruit extract	1,700 mg	1,700 mg
	Sucralose	15 mg	15 mg
	HFCS	4,000 mg	4,000 mg
	Malic acid	200 mg	200 mg
	Tartaric acid	150 mg	150 mg
	Sodium citrate	30 mg	30 mg

Both the test beverage and the placebo beverage are made and supplied by Cheil Jedang Co.

functional beverage before meals.(Table I)

Material and Method

The test beverage was made of transparent yellow liquid and 100 ml of one bottle contained ingredients as shown in Table II. The placebo beverage, which was made of supplementary ingredients except for the main ingredients of the test beverage, was similar in taste and color to the test beverage. They could not be differentiated. The active group and the placebo group was given one bottle(100 ml) of the test beverage(garcinia cambogia 300 mg, L-carnitine 20 mg, soy peptide 1,000 mg) and the placebo beverage daily for 12 weeks, 30 minutes before exercising, respectively.(Table II)

Study Design

Study design was constructed in the randomized double-blind placebo-controlled parallel group fashion(Kim, 2002) and the random assignment table was made according to assignment codes provided by the computer program. Then the test beverage or the placebo beverage was allocated according to the random assignment table. The samples(test and placebo beverages) were labeled with the same appearance for the validity of the double-blind method and maintenance, so subjects and investigators could not know information on the samples and could not differentiate between them. After results from each subject were evaluated, investigators were allowed to open the codes after the final judgment on effects and safety of the samples was performed. The investigator was allowed to keep one sealed random assignment table and open it in case of an adverse event. Details on assignment codes were not open to the public until the clinical trial was terminated. The investigator distributed the sample to subjects, beginning with code #1 according to the order selected. When the sample was missing or damaged, the extra sample (by code number) was used and the double-blinded status could thus be maintained. The total period of the clinical trial was 12 weeks. As scheduled, each subject's body weight was measured and subjects kept a diary on meals and exercise. They were also administered several tests such as an anthropometric assessment, biochemical test(blood sugar and insulin, serum lipid, liver and kidney function tests), and computed tomography(CT) of the abdomen and the mid-thigh. Subjects were prohibited from taking any obesity-related medicine, supplementary health foods, and hormone agents during the study. All subjects were instructed to take one bottle of the functional beverage daily and participate in the 12-week exercise program 3 times a week. The general safety of the sample was also evaluated by analyzing adverse events such as digestive discomfort.

Table III. Progress and contents of exercise program

Order	Activity	Content	Duration(min)
1	warm up exercise	- light walking, stretching	10~15
2	main exercise	- aerobic exercise - running machine, ergometer - step machine, arm ergometer	30
		- strengthening exercise - bench press, semisquat - leg extension, leg curl - back estension	20
3	cool down exercise	- light walking, stretching	5~7

Exercise Program

Subjects participated in the exercise program for 12 weeks; both of the active group and the placebo group exercised under the same conditions. Type, intensity, amount control, frequency, duration and progress of exercise are as follows: 1) Type and intensity of exercise : Aerobic exercise(VO_{2max} : 60~70%) and circuit weight training(40% 1RM) for muscular strength. 2) Control of the amount of exercise : 200~250 kcal(1st month : 0-4 weeks), 250~300 kcal(2nd month : 5-8 weeks), 300~400 kcal (3rd month : 9-12 weeks). 3) Frequency of exercise : 3 times a week. 4) Duration of exercise : 60~90 minutes. 5) Progress in exercise : When subjects feel that aerobic exercise is light, increase the intensity of exercise. For circuit weight training, when they feel that it's light by station, remeasure 1RM and reflect the measurement on the intensity of exercise. The amount of exercise was applied with flexibility to each subject and it varied depending on each subject. Subjects were allowed to feel exercise intensity according to ratings of perceived exertion (RPE : Borgs' Scale). This was to prevent(Borg, 1982) accidents during exercise. Details on exercise by order, activity, and time are shown in Table III.

Measurement Parameters

Anthropometric Assessment : Anthropometric assessments were performed in the 0th(initial visit), 4th, 8th and 12th weeks. Fat mass, % body fat, lean body mass, height and BMI were measured, using the biospace body fat analyzer (InBody 3.0). A well-trained expert accurately measured skin wrinkle thickness, waist and hip circumferences because those measurements could be erroneous due to the measurer's lack of experience. The caliper was used to measure the skin wrinkle thickness. For males, the front region of the thigh, the abdom-

inal region, and the armpit level line were measured, while for females, the triceps brachii muscle, the front region of the thigh, and the suprailiac region were measured. The anatomical location and measurement method of the designated regions are as follows: (1) Femoral region : Vertically hold the front region of the central thigh between the coxa and the knee joint. (2) Abdominal region : Vertically hold a region 2.5 cm away from the navel. (3) Armpit level line : Vertically hold a region in the same height of the 5th rib along the armpit level line. (4) Triceps brachii muscle : With the arms placed down, vertically hold a central region between the acromion process (the shoulder) and the olecranon process(the elbow). (5) Suprailiac region : Diagonally hold a region linked to the armpit level line and the iliac crest. (6) Waist : With the legs spread out at an interval of 25~30 cm and the body weight evenly balanced, measure the central region under the last rib and in parallel with the iliac spine at 0.1cm unit. (7) Hip : With the heels up and the hip maximally pulled, measure the largest hip's circumference.

Blood Pressure : The blood pressure was measured in the 0th, 4th, 8th and 12th weeks. Upon visiting the center, subjects were allowed to rest for more than 10 minutes. The systolic blood pressure and the diastolic blood pressure were measured by an automatic sphygmomanometer.

Computed Tomography(CT) of the Abdomen and the mid-Thigh : GE CT Scan (Gemense 2000i : USA) was used to measure fat areas of the lower abdomen and the mid-thigh. The measurement was carried out twice {0th(initial visit) and 12th weeks}. Computed Tomography (CT) for measurement of abdominal fat and thigh fat was done at the 4th lumber spine level and mid-thigh level, respectively.

Blood Biochemical Test : Blood tests such as triglyceride (TG), total cholesterol (TC), HDL-cholesterol, LDL-cholesterol, FFA, glucose, insulin were performed in the 0th, 8th, and 12th weeks. The subjects' blood was collected after a minimum of 12 hours of fasting before breakfast. The serum of the blood sample was separated and then the lipid and blood sugar were analyzed by an automatic analytical instrument. The serum was separated and then the insulin was analyzed by an automatic analytical instrument, using the EIA method. GOT, GPT, creatine and BUN were also measured using an automatic analytical instrument.

Statistics

Chi-square test or t-test was performed to see whether there was a difference between the two groups. SAS Version 8.2 was used for statistical analysis. At the 5% significance level, when p-value was less than 0.05, data was considered to be statistically significant. Each test value was compared with those at the time of screening, and then a paired t-test was carried out. The t-test was performed to compare the changes in the active group and the placebo group at each stage.

RESULTS

General Characteristics of Subjects

The general characteristics of 55 subjects who completed

Table IV. General characteristics of subjects(N = 55)

Variable	Active (N = 28)	Placebo (N = 27)
Sex(N)	M(1), F(27)	M(1), F(26)
	mean ± SD	
Age(yrs)	36.61 ± 10.71	34.96 ± 11.74
Height(cm)	159.86 ± 4.99	159.44 ± 5.89
Weight(kg)	68.40 ± 8.96	67.11 ± 8.76
BMI(kg/m^2)	26.74 ± 2.99	26.34 ± 2.35
% Fat(%)	33.48 ± 4.48	33.01 ± 3.63
Fat mass(kg)	23.09 ± 5.45	22.28 ± 4.48
Waist(cm)	83.46 ± 8.35	82.56 ± 6.55
Hip(cm)	97.39 ± 5.16	97.03 ± 5.15
WHR	0.86 ± 0.06	0.85 ± 0.06
FST(mm)	32.63 ± 9.23	34.31 ± 7.98
TST(mm)	22.71 ± 5.98	23.58 ± 4.72
SIST(mm)	22.99 ± 6.50	23.83 ± 6.04
ATFA(cm^2)	323.84 ± 101.63	315.85 ± 88.57
VFA(cm^2)	76.32 ± 29.84	85.84 ± 38.32
ASFA(cm^2)	250.43 ± 91.54	235.09 ± 71.10
TFA(cm^2)	114.56 ± 32.59	114.31 ± 28.36
TG(mg/dL)	133.89 ± 76.65	119.56 ± 65.64
TC(mg/dL)	180.68 ± 26.30	179.26 ± 31.90
HDL-C(mg/dL)	45.93 ± 8.65	53.52 ± 9.45
LDL-C(mg/dL)	117.36 ± 27.20	110.26 ± 30.41
FFA(μEq/L)	667.11 ± 273.23	550.63 ± 256.07
Fasting Glucose(mg/dL)	81.54 ± 8.21	88.33 ± 14.13
Insulin(U/L)	7.35 ± 5.80	8.51 ± 7.92

WHR; waist hip ratio, FST; femoral skinfold thickness,
TST; triceps skinfold thickness, SIST; suprailiac skinfold thickness,
ATFA; abdominal total fat area, VFA; visceral fat area,
ASFA; abdominal subcutaneous fat area, TFA; thigh fat area,
TG; triglyceride, TC; total cholesterol, FFA; free fatty acid

Table V. Changes of food intake

Variable	Group(N)	0 wk	P#	4 wk	P#	8 wk	P#	12 wk	P#
		mean±SD							
Food Intake(Cal)	Active (28)	1735 ± 585	0.66	1629 ± 500	0.37	1525* ± 446	0.53	1793 ± 1083	0.14
	Placebo (27)	1908 ± 623		1753 ± 614		1783 ± 581		1704† ± 528	

0 wk VS each period of time:*P<0.05, active VS placebo
The amount of food intake(Cal) was measured by food frequency method.

Table VI. Changes of weight, body fat, body shape, and skin fold thickness

Variable	Group(N)	Baseline	4 week	P#	8 week	P#	12 week	P#
		mean ± SD						
Weight(kg)	Active (28)	68.40 ± 8.96	67.05*†# ± 9.32	0.03	66.35*†# ± 9.18	0.01	65.70*†# ± 8.99	0.02
	Placebo (27)	67.11 ± 8.76	66.92 ± 8.79		66.62 ± 8.69		66.04† ± 8.81	
BMI (kg/m2)	Active (28)	26.74 ± 2.99	26.10*†# ± 2.93	0.03	25.83*†# ± 2.93	0.01	25.55*†# ± 2.78	0.02
	Placebo (27)	26.34 ± 2.35	26.24 ± 2.40		26.09 ± 2.37		25.88*† ± 2.49	
% Fat(%)	Active (28)	33.48 ± 4.48	32.18† ± 4.92	0.03	32.45† ± 4.69	0.04	31.74*†# ± 4.82	0.04
	Placebo (27)	33.01 ± 3.63	33.03 ± 3.34		33.17 ± 3.32		32.50 ± 3.87	
Fat mass(kg)	Active (28)	23.09 ± 5.45	21.78*† ± 5.56	0.02	21.72*† ± 5.43	0.02	21.03*†# ± 5.33	0.04
	Placebo (27)	22.28 ± 44.48	22.20 ± 4.30		22.20 ± 4.41		22.44 ± 6.04	
Waist(cm)	Active (28)	83.46 ± 8.35	82.86 ± 8.85	0.52	82.09† ± 9.04	0.55	81.16*†# ± 7.92	0.62
	Placebo (27)	82.56 ± 6.55	82.41 ± 6.62		81.70 ± 6.70		80.69* ± 6.56	
Hip(cm)	Active (28)	97.39 ± 5.16	97.50 ± 5.14	0.36	97.43 ± 4.68	0.44	96.08† ± 4.27	0.02
	Placebo (27)	97.03 ± 5.15	97.70 ± 5.63		97.46 ± 4.86		97.61 ± 5.69	
Waist Hip Ratio	Active (28)	0.86 ± 0.06	0.85 ± 0.07	0.93	0.84† ± 0.07	0.84	0.84 ± 0.06	0.32
	Placebo (27)	0.85 ± 0.06	0.84 ± 0.05		0.84* ± 0.05		0.83†* ± 0.05	
FST (mm)	Active (28)	32.63 ± 9.23	29.88*†# ± 8.67	0.29	27.05*†# ± 8.39	0.83	25.85*†# ± 7.81	0.62
	Placebo (27)	34.31 ± 7.98	31.10*†# ± 8.28		28.46*†# ± 7.80		26.87*†# ± 7.54	
TST (mm)	Active (27)	22.71 ± 5.98	20.67*† ± 5.81	0.52	18.16*†# ± 5.17	0.65	15.92*†# ± 4.63	0.52
	Placebo (26)	23.58 ± 4.72	21.03*†# ± 4.14		19.53*†# ± 4.40		17.45*†# ± 4.02	
SIST (mm)	Active (27)	22.99 ± 6.50	19.65*†# ± 7.46	0.98	18.00*†# ± 7.32	0.68	16.84*†# ± 6.56	0.71
	Placebo (26)	23.83 ± 6.04	20.47*†# ± 5.58		18.35*†# ± 4.14		17.27*†# ± 5.06	

within group significance: *P < 0.05, **P < 0.01, ***P < 0.001, #active VS placebo
FST; femoral skinfold thickness, TST; triceps skinfold thickness, SIST; suprailiac skinfold thickness

the 12-week clinical trial are shown in Table IV. There were no significant differences of the baseline parameters between the active group and the placebo group.

Table VII. Changes of abdominal fat and mid-thigh fat

Variable	Group(N)	Baseline	12week	P#
		mean ± SD		
ATFA(cm^2)	Active (28)	323.84 ± 101.63	300.80†† ± 110.47	0.70
	Placebo (27)	315.85 ± 88.57	304.40$^{\#\dagger}$ ± 85.37	
VFA(cm^2)	Active (28)	76.32 ± 29.84	71.99 ± 35.81	0.41
	Placebo (27)	85.84 ± 38.32	78.93$^{\#\dagger}$ ± 34.25	
ASFA(cm^2)	Active (28)	250.43 ± 91.54	230.28†† ± 91.03	0.77
	Placebo (27)	235.09 ± 71.10	225.31† ± 74.69	
TFA(cm^2)	Active (28)	114.56 ± 32.59	100.92$^{\#\dagger\dagger}$ ± 32.19	0.89
	Placebo (27)	114.31 ± 28.36	103.13†† ± 31.80	

within group significance : $^{\dagger}P < 0.05$, $^{\dagger\dagger}P < 0.01$, $^{\dagger\dagger\dagger}P < 0.001$, #active VS placebo
ATFA; abdominal total fat area, VFA; visceral fat area, ASFA; abdominal subcutaneous fat area, TFA; thigh fat area,

Changes of Food Intake

The active group and the placebo group showed a significant decrease of food intake at 8th week and 12th week after intervention, respectively. But there were no significant differences between the active group and the placebo group at all period of time(Table V).

Changes in Body Weight, BMI (body mass index), Waist and Body Fat

At the end of 4, 8, and 12 weeks, approximately 1.98%, 3.0% and 3.5% losses of initial body weight were observed, respectively, in the test group ($P < 0.01$), and 0.29%, 0.74%, 1.60%, respectively, in the placebo group ($P > 0.05$). Body mass index(BMI) changed by 2.40%, 3.41% and 4.46%, respectively, in the test group, and 0.38%, 0.95% and 1.75% , respectively, in the placebo group, at each point of time. The reductions of body weight and BMI were significantly higher in the test group than in the placebo group at each point of time

Table VIII. Changes of TG, TC, HDL-C, LDL-C, glucose and insulin

Variable	Group(N)	Baseline	8week	P#	12week	P#
			mean ± SD			
Triglyceride (mg/dL)	Active(28)	133.89 ± 76.65	109.27†† ± 77.37	0.60	114.63 ± 84.88	0.71
	Placebo(27)	119.56 ± 65.64	102.15 ± 60.76		94.15†† ± 42.14	
Total cholesterol (mg/dL)	Active(27)	180.68 ± 26.30	184.00 ± 29.31	0.39	192.11$^{\#\#}$ ± 29.68	0.76
	Placebo(26)	179.26 ± 31.90	179.00 ± 19.24		191.44†† ± 31.92	
HDL-C (mg/dL)	Active(27)	45.93 ± 8.65	51.39† ± 8.06	0.04	46.48 ± 6.29	0.02
	Placebo(26)	53.52 ± 9.45	51.22 ± 9.30		46.26†† ± 7.58	
LDL-C (mg/dL)	Active(27)	117.36 ± 27.20	112.96 ± 33.41	0.80	118.04 ± 37.86	0.81
	Placebo(26)	110.26 ± 30.41	109.78 ± 26.05		109.78 ± 33.16	
FFA (μEq/L)	Active(27)	667.11 ± 273.23	753.50 ± 302.44	0.36	707.67 ± 287.84	0.84
	Placebo(26)	550.63 ± 256.07	734.67$^{\#}$ ± 294.66		604.93 ± 248.95	
Glucose (mg/dL)	Active(28)	81.54 ± 8.21	82.27 ± 9.59	0.34	78.93 ± 10.26	0.33
	Placebo(27)	88.33 ± 14.13	85.56 ± 22.51		90.15 ± 26.71	
Insulin(u/L)	Active(28)	7.35 ± 5.80	6.00 ± 2.42	0.85	9.83 ± 16.40	0.37
	Placebo(27)	8.51 ± 7.92	6.79 ± 5.63		7.77 ± 3.70	

within group significance : $^{\dagger}P < 0.05$, $^{\dagger\dagger}P < 0.01$, $^{\dagger\dagger\dagger}P < 0.001$, #active VS placebo
LDL; Low-density lipoprotein, HDL; high-density lipoprotein, FFA;free fatty acid

($P < 0.05$)(Table VI). In addition, the active group also showed a more significant decrease in % body fat (%BF) and fat mass 4, 8 and 12 weeks after intervention than the placebo group ($P < 0.05$). Decreases in body weight and body fat were also seen in the placebo group, but they were not significant.(Table VI) The active group showed a significant decrease (1.45%) in waist circumference 8 weeks after intervention and it significantly decreased by up to 2.76% in 12 weeks. However, a significant decrease in waist hip ratio(WHR) was found in the active group only 8 weeks after intervention. (Table VI) The two groups showed significant decreases in skin wrinkle thickness in the front region of the thigh, triceps brachii muscle, and the suprailiac region 4, 8, and 12 weeks after intervention.(Table VI) Both groups showed an improvement in body shape caused by changes in waist circumference and skin-fold thickness. According to the CT analysis, the active group and the placebo group showed a significant decrease of 7.12% and 3.63% in the total area of abdominal fat after 12 weeks, respectively ($P < 0.01$). Interestingly, 5.68% and 8.05% decreases in abdominal visceral fat were seen in the active and placebo groups respectively. The active group showed a significant decrease (8.05%) in the subcutaneous fat in the abdomen while the placebo group indicated a 4.17% decrease. The active group also showed a significant decrease(11.01%) in the femoral fat while the placebo group indicated a 9.72% decrease. Both the active group and the placebo group showed significant local fat reduction in the abdomen and thigh(Table VII).

Blood Biochemical Changes

The two groups showed a tendency to decrease in TG of the biochemical metabolic examination as time passed while they showed a significant increase in TC. No significant changes were observed in LDL-C in both groups. The placebo group showed a significant increase in FFA 8 weeks after intervention while the active group did not show any change. The active group indicated a significant increase in HDL-C in 8 weeks while the placebo group showed a significant decrease in HDL-C in 12 weeks(Table NIII). Both groups did not indicate any significant change in blood sugar and insulin levels in 8 and 12 weeks, respectively.

Adverse Event

Two of the active group and one of the placebo group reported loose stool and light dysmenorrhea, respectively, but recovered completely soon.

DISCUSSION

Obesity occurs when more fat is abnormally accumulated in the body due to an unbalanced composition and decomposition of fat in the fat cells. The excessive accumulation of body fat not only distorts body shape, but also is a major cause for cardiovascular diseases such as hypertension, hyperlipidemia, and coronary heart diseases, and for chronic degenerative diseases like diabetes mellitus, osteoarthritis, etc. It's been known that the simultaneous intervention of diet, exercise, and behavior therapy is effective to treat obesity. According to the data from a comparison of patients suffering from obesity who participated in the weight control program and patients who did not, the term of compliance for participants was increased by 180%, 150%, 100% in England, New Zealand, and Germany, respectively. Those who continued the program also showed twice as much weight loss than those who discontinued the program. The weight control program provides an opportunity for patients suffering from obesity to be given regular and continuous weight management and education as well as helping them to efficiently control their weight(Jung *et al.*, 2001). People need to reduce calorie intake and increase the burning of calories for the prevention and cure of obesity. Many of them try dietary remedies such as going on a diet to reduce calorie intake. Super-low calorie diets have a positive effect on dramatic weight loss, but periodically causes weight regain due to overconsumption after an initial decline in calories which is called 'restrained eater syndrome' following a decline in metabolism. In addition, it results in protein loss and is not appropriate in terms of the overall maintenance of health and physical fitness. Patients suffering from obesity need an appropriate exercise regimen along with diet, but this is not easy to do. They need to make an extra effort to incorporate regular exercise into their busy schedules, therefore, they seeks alternatives to supplement a lack of exercise. There is an abundance of studies on the decrease in body fat through limited calorie intake or exercise however, studies focusing simultaneously on functional foods and exercise are rare. As more people are becoming interested in health, they are also becoming more interested in various functional foods which can help them control body weight. According to Lee Jong-ho's study related to hydroxycitric acid(HCA) which is a functional food material, when subjects took a functional beverage for 8 weeks with regular meals, they lost weight by about 1.3 kg on average(Lee *et al.*, 2001). 60% of them showed over a 1 kg weight loss and 40% showed no change. The authors added that the weight loss

is minimal, but the subjects still lost weight while having their regular meals, which shows that the functional beverage is effective. The authors insisted that if one took it along with a low-calorie meal, the effect would be greater.

Garcinia cambogia, belonging to the garcinia species in the *guttifera* family, contains 10~30% HCA(hydroxy citric acid : active substance) in its fruit skin. HCA has a similar configuration to that of citric acid and it is known to be a potent inhibitor of citrate cleavage enzyme, that is, ATP: citrate lyase, which catalyzes the extramitochondrial cleavage of citrate to oxaloacetate and acetyl-CoA: citrate + ATP + CoA- > acetyl-CoA + ADP+ Pi + oxaloacetate. The inhibition of this reaction limits the availability of acetyl-CoA units required for fatty acid synthesis and lipogenesis during a lipogenic diet, that is, a diet high in carbohydrates. Weight gain occurs when the limited capacity for storing glycogen in the liver and muscles is attained, and beyond this point excess glucose is converted into fat and stored in fat cells throughout the body. HCA is considered to exert its antiobesity effect through this machanism(Jena *et al.*, 2002).

L-carnitine has been known to facilitate the influx of long-chain fatty acids into mitochondria during energy metabolism. McCarty insisted that joint administration of HCA and carnitine should promote hepatic lipid oxidation, gluconeogenesis, and satiety (McCarty, 1994). Sustained aerobic exercise requires a severalfold increase in hepatic glucose output. An increasing proportion of this elevated glucose output must be provided by gluconeogenesis. Thus, McCarty insisted that preadministration of HCA may potentiate this effect and the utility of this technique may be greatest in exercise regimens designed to promote weight loss(McCarty, 1995; McCarty, 1995). Animal studies(Saito, 1989; Saito, 1990; Saito, 1990) showed that soy peptide activates the sympathetic nerve system and the functions of the brown adipose tissues, which results in the acceleration of fat combustion. Komatsu *et al* reported that soy protein peptides increased diet-induced thermogenesis in children as well as in adults(Komatsu *et al.*, 1991 : Komatsu *et al.*, 1992). Based on the previous several studies, we hypothesized that fat reducing effect of HCA can be maximized by combining with L-carnitine and soy peptide.

According to several animal studies(Sullivan *et al*, 1974; Sullivan *et al*, 1977; Greenwood *et al*, 1981), HCA showed a significant weight loss induced by the suppression of appetite and food intake. But there were no data, which demonstrated significant food intake reduction in humans. In our study, the active group and the placebo group showed a significant decrease of food intake at 8th week and 12th week after intervention, respectively. But there were no significant differences between the active group and the placebo group at all period of time(Table V). Our study revealed that the active group showed a significant decrease in body weight, BMI, % body fat(%BF), and fat mass 4 weeks after intervention, and these figures were significantly different from those of the placebo group.(Table VI) A 1.35 kg weight loss was found in the active group, and this value is about 2.8 times than that(0.49 kg) of the placebo group which only exercised for 8 weeks, and it is around 1.3 times than that (1.07 kg) of the 12th week placebo group. The active group indicated a 2.05 kg weight loss in 8 weeks and this value is twice the figure of the group(1.07 kg) who only exercised for 12 weeks. A 1.31 kg loss in fat mass was seen in the active group 4 weeks after intervention, and this value is about 16 times the figure of the group (0.08 kg) who only exercised for 8 weeks and it is about 8.1 times that of the 12th week placebo group(0.16 kg). In 8 weeks, the active group showed a 1.37 kg loss in fat mass which is 8.6 times than that of the group(0.16 kg) who only exercised for 12 weeks. In addition, a 1.3% loss in % body fat was found in the active group 4 weeks after intervention, and this value is about 7.6 and 2.5 times than that of the 8th week placebo group(0.17%) and the 12th week placebo group(0.51%), respectively. These results are similar to those of a study where subjects showed loss in body weight and % body fat after taking L-carnitine, which is one of the main ingredients in the functional beverage(LONZA Ltd(Swiss) & Easybiosystem corp, 2000). Like the results of a study(Muramatsu *et al.*, 1994) indicating that weight loss and a significant increase in lean body mass(LBM) were seen in a group who took soy-peptide(a catalyst which accelerates oxidization of fatty acid), it is thought that the main ingredient of the functional beverage showed a synergy effect with exercise. Furthermore, according to Choi Mi-ja's study, female college students who major in dance showed a decrease of 14.23 mm on average in 4 subcutaneous fat layers while female college students of other majors indicated a decrease of 18.15 mm on average(Choi, 1998). Both groups showed a significant improvement in body shape, but there was no significant difference among each group. It can be interpreted that the improvement in body shape did not result from the functional beverage's effect, but from exercise. In Lee Jong-ho's study on 33 females(The active group : 15, The placebo group : 18), the active group group took one bottle of FatDown® daily for 8 weeks without restraint of exercise and diet(Lee *et al.*, 2001). 5.1% decrease of visceral fat area and 10.6% decrease of calf fat area were reported in the active group. Our study did not

show significant difference in abdominal fat mass between the active group and the placebo group, but a significant loss(7.1%) in the total amount of abdominal fat was seen in the active group 12 weeks after intervention. In addition, the active group also indicated a significant loss(8.05%) in subcutaneous fat in the abdomen 4 weeks after intervention. Losses in fat mass in the abdomen and the mid-thigh of the active group were larger than those of the placebo group(Table VI). The placebo group which only exercised for 12 weeks showed 3.6% and 4.2% losses in the total amount of fat and subcutaneous fat in the abdomen, respectively. The figures for the active group were twice than that of the placebo group which only exercised for 12 weeks. In Thorn's study, the test group took 1,320 mg of hydroxy citrate and consumed 1,200 cal daily for 8 weeks. According to results(Thorn, 1996), 6.4 kg and 3.8 kg losses in body weight were seen in the test group and the control group, respectively. The active group in our study indicated less loss (about 1.3 kg loss in 4 weeks, 2 kg loss in 8 weeks, and 2.7 kg loss in 12 weeks) in body weight compared to that of Thorn's study, but it can be meaningful in that this study showed a significant change in body weight with relatively low dose HCA and without restraint of diet. This tells us that the combination of functional beverage and exercise might have a synergy effect. According to Lee Jong-ho's study, the active group who took FatDown® without restraint of exercise and diet showed significant decreases in % body fat, % ideal body weight, and BMI 4 weeks after intervention, and also indicated a tendency to lose fat in the abdomen and the calf 8 weeks after intervention. Taken together, there might be a synergistic effect on fat reduction among the functional beverage ingredients as well as between functional beverage and exercise. According to several studies, coronary heart disease(CHD) has a positive correlation(Anderson *et al.*, 1987 ; Levi, 1981) with TC and LDL-C, but it has a negative correlation(Gordon *et al.*, 1989) with HDL-C. In other words, a person with a lower degree of danger in CHD has low LDL-C and VLDL-C, but higher HDL-C(Gillen *et al.*, 1991 ; Williams *et al.*, 1986). In general, athletes with endurance and staying power have higher HDL-C than those people who are inactive. This phenomenon is considered to be related to a desirable change of fat in the blood and lipoprotein - as a result of regular aerobic exercise(Hartung *et al.*, 1980). Therefore, there is an abundance of studies on reactions of fat in the blood and lipoprotein stimulated by exercise. This study indicated that a significant decrease of TC in 12 weeks after exercise was seen in both groups. A decrease in TG after an exercise program is thought to be due to an increase in fat oxidization. This is to supplementarily store up TG in the muscular cells which were partially decreased during exercise or due to an increase in hormones(catecholamin and growth hormone) during exercise and increase in lipoprotein lipase(LPL : lipid oxidizing enzyme) caused by long-term exercise(Annuzzi *et al.*, 1987). This is thought to be a desirable adaptation phenomenon. It is interesting to see changes in HDL-C. A significant increase(11.89%, $p < 0.05$) in HDL-C 8 weeks after intervention was found in the active group, but it returned to its baseline level in 12 weeks, while the placebo group showed a tendency to decrease HDL-C in 8 weeks, but indicated a significant decrease(15.53%, $p < 0.01$) in HDL-C in 12 weeks. Some studies indicated that garcinia cambogia(Ramos *et al.*, 1995; Preuss *et al.*, 2002) and soy-peptide(Komatsu *et al.*, 1990) inhibited the bio-synthesis of fat, accelerated lipid metabolism, which finally resulted in a decrease in neutral fat in the blood and the liver, but they did not mention the effects of garcinia cambogia and soy-peptide on HDL-C. Therefore, it is not clear whether HDL-C was affected by garcinia cambogia and soy-peptide which are main ingredients of the functional beverage used in that clinical trial or not. In our study, the group who regularly took the functional beverage showed an increase in HDL-C or maintained its level as time passed, but the placebo group indicated a decrease in HDL-C in 12 weeks. This tells us that more studies focusing on those results are needed in the near future. In cases of LDL-C and free fatty acids, there was no significant difference found in both groups, but a significant increase in TC was seen in 12 weeks. This can be explained by a possible increase in VLDL-C. It is known that as people get older, resistance against insulin increases. Moreover, the increase in resistance against insulin is closely related to an increase in body fat regardless of age.

Diet maintenance and exercise used to be the only therapies to treat diabetes mellitus when insulin was not available in the past. In general, regular exercise is known to decrease resistance against insulin as well as increase insulin sensitivity. This study showed that there were no significant differences in insulin and glucose in the blood between the two groups as well as within each group during the study. The reason for the absence of any significant differences in blood glucose and insulin is thought that only healthy volunteers were includeded in this study. Any significant change in biochemical metabolic tests such as GOT(AST), GPT(ALT), BUN and Creatinine was not found in the active group nor the placebo group. As test results showed only physiological changes in the normal range, it is thought that the functional beverage is not toxic to the functions

of the liver and the kidney.

In conclusion, it is thought that the combination of functional beverage, which contains mostly garcinia cambogia, L-carnitine, and soy peptide, and exercise have synergy effects on reducing body fat. More studies on the degree of improvement in body fat according to gender and degree of exercise need to be carried out.

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