Title: Beneficial effects of a new indigestible dextrin-containing beverage on lipid metabolism and obesity-related parameters

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[Abstract]

Beneficial effects of a new indigestible dextrin-containing beverage on lipid metabolism and obesity-related parameters

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To evaluate the effects of a new indigestible dextrin (ID) -containing beverage on lipid metabolism and obesity-related parameter, a placebo-controlled double-blind clinical trial was performed. The subjects used were 18 males with mild hypertriglyceridemia (triglyceride levels : 150 mg/dl～ 250 mg/dl). They were given for 4 weeks either the ID-containing (16.5 g/day) beverage (ID group) or control beverage (placebo group). The results revealed that serum triglyceride levels were reduced significantly in the ID group (197.2 ± 23.7 mg/dl to 155.5 ± 33.7 mg/dl ; $p<0.01$), and this reduction was significantly different from that with the placebo group ($p<0.05$). Also, there was a tendency for total cholesterol, VLDL, and beta-lipoprotein levels to be lower in the ID group ($p<0.1$). Meanwhile, serum RLP-cholesterol levels were significantly reduced in the ID group (9.5 ± 2.7 mg/dl to 6.9 ± 3.1 mg/dl : $p<0.01$). With respect to body weight and BMI, significant reductions became evident in the ID group 2 weeks after the initiation of the trial. Similarly, both body fat ratio (BFR) and waist/hip ratio (WHR) were significantly reduced at 4 w (BFR : 26.7 ± 4.0 % to 24.6 ± 4.3 % ; $p<0.01$, WHR : 0.95 ± 0.03 to 0.92 ± 0.03 ; $p<0.01$) in the ID group, and these reductions were statistically different from those with the placebo group (both $p<0.01$). During the test period, no evidence of side effects was obtained. In conclusion, our present data indicated that the regular use of the ID-containing beverage is effective in reducing serum lipid levels in subjects with mild hypertriglyceridemia, thus suggesting its clinical usefulness for the prevention of arteriosclerosis and obesity.

Key words : indigestible dextrin, triglyceride, hypertriglyceridemia, obesity

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[Summary]

1. METHODS

1) Schedule for Administration

Date: May 10, 2000～July 5, 2000

Place: Center for Health Care, Osaka University of Foreign Studies

Administration: Subjects took a 250-ml test drink at each mealtime, 3 times per day for the 4-week administration period.

2) Subjects

18 male adults whose serum triglyceride values were 150～250 mg/dl were selected. Those people who might be secondary hyperlipidemia, took medicine or dietary supplements on a daily basis, or were under medical treatment for hyperlipidemia or were judged by a doctor to need medical treatment for hyperlipidemia, were excluded.

The subjects were divided into two groups, the test group who were administrated the test sample containing indigestible dextrin, and the placebo group.

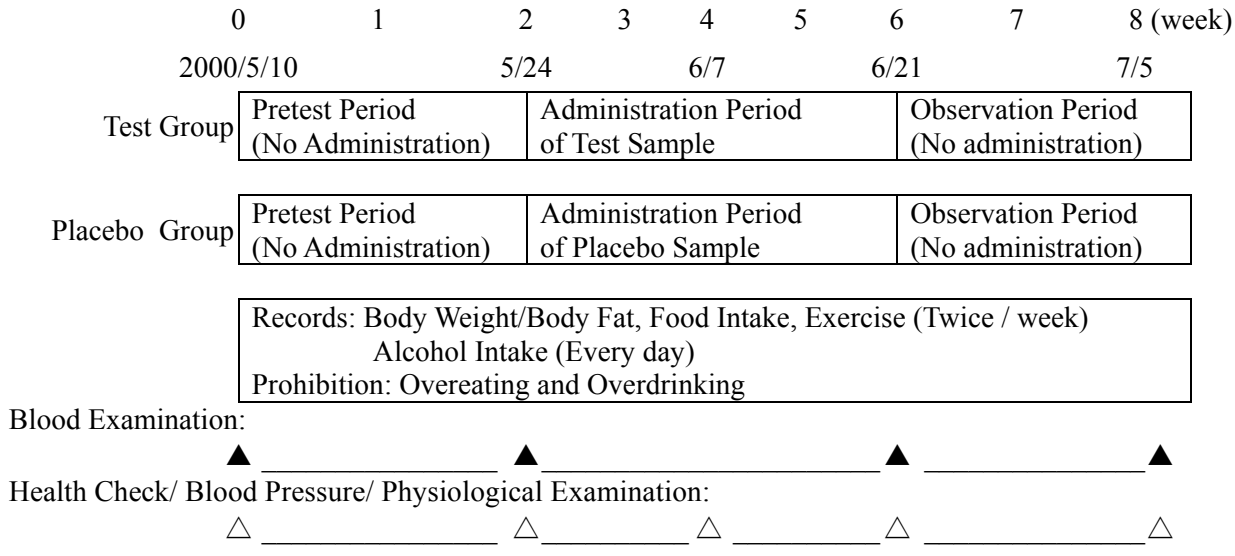


Figure 1. Schedule of Administration

Table 1. Background of Subjects

	Test Group (n=10)	Placebo Group (n=8)
Age (years old)	36.2 ± 10.4	34.9 ± 10.3
Body Weight (kg)	77.9 ± 8.3	80.1 ± 18.3
BMI (kg/ m^2)	26.6 ± 2.2	27.5 ± 4.8
Body Fat Ratio(%)	26.7 ± 4.0	26.5 ± 4.7
Waist/ Hip Ratio	0.95 ± 0.03	0.93 ± 0.03
Systolic Blood Pressure (mmHg)	132.6 ± 14.3	133.1 ± 16.0
Diastolic BP (mmHg)	77.7 ± 18.0	81.4 ± 18.3
Triglyceride (mg/ dl)	197.2 ± 23.7	194.0 ± 31.6
Total Cholesterol (mg/ dl)	229.4 ± 32.0	208.5 ± 31.3
HDL-Cholesterol (mg/ dl)	50.4 ± 7.4	42.4 ± 8.1
RLP-Cholesterol (mg/ dl)	9.5 ± 2.7	8.1 ± 2.1
β-lipoprotein (mg/ dl)	477.7 ± 84.5	450.6 ± 34.5

t-test: no significant difference

3) Test Drinks
Based: 250-ml tea drink (Barley, Job's tear, Green tea, Oolong tea, Roasted tea, Vitamin C)
Test Sample: Indigestible Dextrin 2.178% (5.5 g/ bottle)
Placebo Sample: W/O Indigestible Dextrin

2. RESULTS

1) Energy Intake, Alcohol Intake, and Exercise Amount

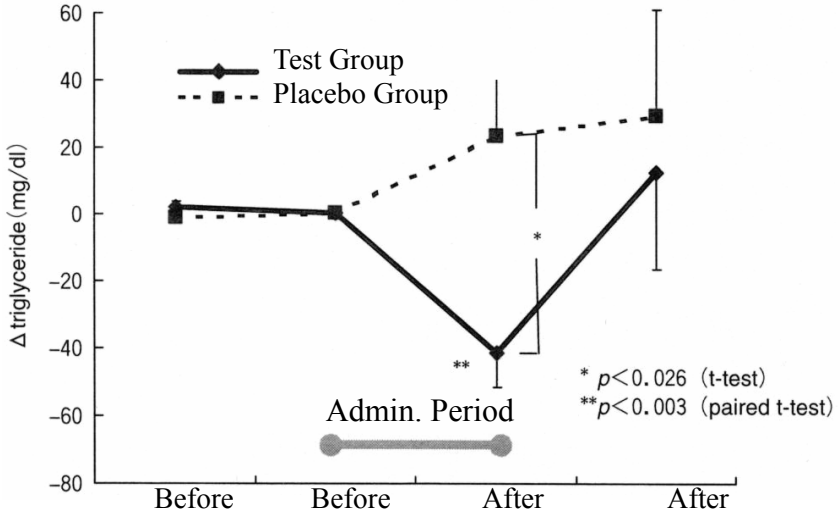
Table 2. Energy Intake, Alcohol Intake, and Exercise Amount during the Test Periods

		Period		
	Group	Pretest	Administration	Observation after test
Energy Intake (kcal/day)	Test	2272 ± 350	2376 ± 620	2470 ± 678 (*)
	Placebo	2015 ± 444	2017 ± 375	1740 ± 262
Protein (g/day)	Test	78.4 ± 19.4	82.9 ± 25.8	88.3 ± 29.6 (*)
	Placebo	65.9 ± 16.0	68.9 ± 12.0	61.9 ± 15.9
Fat (g/day)	Test	71.2 ± 15.6	79.2 ± 27.1	84.9 ± 27.8 (*)
	Placebo	66.8 ± 23.6	65.9 ± 20.6	57.6 ± 17.4

Carbohydrate (g/day)	Test	293.0 ± 31.4	298.5 ± 67.9	301.5 ± 89.1 (*)
	Placebo	256.7 ± 20.1	251.4 ± 36.1	212.6 ± 24.9* (*)
Cholesterol (mg/day)	Test	386.6 ± 206.7	441.5 ± 236.7	430.8 ± 182.3 (*)
	Placebo	323.2 ± 153.8	279.7 ± 111.7	282.9 ± 149.3 (*)
Dietary Fiber (g/day)	Test	10.8 ± 2.4 (*)	11.4 ± 3.1	11.2 ± 3.7 (*)
	Placebo	8.7 ± 1.1 (*)	8.8 ± 1.8	7.9 ± 1.7 (*)
Alcohol Intake (g/week)	Test	100.9 ± 116.1	137.7 ± 209.4	169.2 ± 228.5
	Placebo	128.9 ± 97.4	128.9 ± 44.6	79.1 ± 44.5
Pedometer (unit/day)	Test	8053 ± 2308	8613 ± 2037	8470 ± 3428
	Placebo	9611 ± 3300	8300 ± 2149	9953 ± 5405

note) "Energy Intake" does not contain calories from the test drinks.
*p<0.05 (paired t-test)
(*)p<0.05 (t-test)

2) Blood Examination



Mean ± SEM

Figure 2. Changes in Serum Triglycerides

(Continued to the next page)

3. CONCLUSION

(1) Serum triglyceride levels were significantly lowered in the test group, while the placebo group did not show significant changes. Changes in triglyceride levels by administration were significantly different between the two groups.
(2) There was a tendency for total serum cholesterol, VLDL, and β-lipoprotein to be lower in the test group. Those values in the placebo group were not changed meanwhile.
(3) Body weight and BMI were decreased significantly in the test group with the 2-week administration of the test sample. Body fat ratio and waist/hip ratio were also decreased significantly in the test group by the 4-week administration of the test sample. Those reductions had significant differences from those in the placebo group.
(4) Through all the test periods, no abnormal changes were observed in the values for the blood examination, and medical examination and self-announcement indicated no adverse reactions by taking the test sample.

(Continued from the previous page, **2. RESULTS**, 2) Blood Examination)

Table 3. Changes in Values of Blood Examination

	Normal Range (Referential Values)	Group	Before Pretest Period	Before. Admin. (After Pretest)	After Admin. Period	After Observation After Test Period	Intraindividual difference: Δ btwn bfr & aft Admin.	Intraindividual difference: Signif Δ btwn Groups
Triglyceride (mg/dl)	50—149	Test G	199.1 ± 24.6	197.2 ± 23.7	155.5 ± 33.7**	209.4 ± 101.2	−41.7 ± 32.8	$p = 0.026$
		Placebo G	192.6 ± 34.5	194.0 ± 31.6	217.1 ± 86.2	223.1 ± 97.1	23.1 ± 75.7	
Total Cholesterol (mg/dl)	150—219	Test G	227.1 ± 29.2	229.4 ± 32.0	219.0 ± 35.5+	211.3 ± 39.4	−10.4 ± 14.9	n.s
		Placebo G	211.4 ± 32.4	208.5 ± 31.3	204.6 ± 38.0	204.1 ± 33.6	−3.9 ± 20.8	
HDL-Cho (mg/dl)	41—86	Test G	50.3 ± 6.3	50.4 ± 7.4	48.5 ± 7.1	45.2 ± 5.8*	−1.9 ± 6.2	n.s
		Placebo G	42.1 ± 8.5	42.4 ± 8.1	43.0 ± 11.1	42.4 ± 12.4	0.6 ± 8.5	
RLP-Cho (mg/dl)	−7.5	Test G	9.6 ± 2.8	9.5 ± 2.7	6.9 ± 3.1**	10.2 ± 8.2	−2.6 ± 2.0	$p = 0.059$
		Placebo G	8.0 ± 2.0	8.1 ± 2.1	9.1 ± 5.1	11.1 ± 7.0	1.0 ± 5.2	
β-lipoprotein (mg/dl)	190—500	Test G	477.5 ± 80.8	477.7 ± 84.5	439.2 ± 97.9+	461.9 ± 117.3	−38.5 ± 57.1	n.s
		Placebo G	448.5 ± 34.5	450.6 ± 34.5	454.6 ± 78.1	466.5 ± 58.6	4.0 ± 73.4	
Lipoprotein Detm, LDL (mg/dl)	190—580	Test G	620.2 ± 133.4	624.4 ± 133.6	594.5 ± 159.6	588.7 ± 168.3	−29.9 ± 84.2	n.s
		Placebo G	611.5 ± 72.0	608.9 ± 79.2	584.6 ± 98.8	591.0 ± 87.1	−24.3 ± 66.7	
VLDL (mg/dl)	−210	Test G	269.0 ± 72.8	270.6 ± 73.1	230.8 ± 68.3+	245.3 ± 83.9	−39.8 ± 67.0	n.s
		Placebo G	251.4 ± 23.5	252.9 ± 18.5	237.5 ± 80.9	217.0 ± 84.2	−15.4 ± 84.8	
Fasting Blood Sugar (mg/dl)	70—110	Test G	97.3 ± 17.1	96.7 ± 17.8	87.8 ± 13.3*	84.4 ± 15.1**	−8.9 ± 11.2	n.s
		Placebo G	85.3 ± 7.9	85.0 ± 7.9	79.1 ± 9.2+	78.9 ± 5.5*	−5.9 ± 8.2	
HbA_1c (%)	4.3—5.8	Test G	5.5 ± 0.8	5.5 ± 0.7	5.2 ± 0.7	5.3 ± 0.7	−0.3 ± 0.6	$p = 0.056$
		Placebo G	4.9 ± 0.2	4.9 ± 0.2	4.8 ± 0.2	4.9 ± 0.2	−0.1 ± 0.2	

+$p<0.1$ *$p<0.05$ **$p<0.01$ (paired t-test)

3) Physical Examination

Table 4 Changes in Values in Physical Examination

	Group	Before Pretest Period	Before. Admin. (After Pretest)	During Admin. Period (Aft 2-wk Admin)	After Admin. Period	Intraindividual difference: Δ btwn bfr & aft Admin.	Intraindividual difference: Signif Δ btwn Groups	After Observation After Test Period
Systolic Blood Pressure (mmHg)	Test G	136.7 ± 14.1	132.6 ± 14.3	137.2 ± 15.4	131.4 ± 11.3	−1.2 ± 13.0	n.s.	132.4 ± 14.6
	Placebo G	132.8 ± 13.1	133.1 ± 16.0	137.1 ± 14.7	134.0 ± 10.1	0.9 ± 11.0		135.5 ± 10.3
Diastolic Blood Pressure (mmHg)	Test G	81.7 ± 20.8	77.7 ± 18.0	82.9 ± 17.4+	80.1 ± 15.4	2.4 ± 9.5	n.s.	81.1 ± 16.7
	Placebo G	78.0 ± 16.5	81.4 ± 18.3	81.9 ± 16.6	77.1 ± 16.5	−4.3 ± 15.6		82.4 ± 15.8
Body Weight (kg)	Test G	77.9 ± 8.2	77.9 ± 8.3	77.4 ± 8.0*	77.3 ± 8.6+	−0.6 ± 5.6	n.s.	77.5 ± 7.8
	Placebo G	80.3 ± 18.4	80.1 ± 18.3	80.2 ± 18.3	79.8 ± 18.3	−0.3 ± 1.4		79.5 ± 17.2
BMI (body mass index)	Test G	26.6 ± 2.2	26.6 ± 2.2	26.4 ± 2.1*	26.4 ± 2.3+	−0.2 ± 0.3	n.s.	26.4 ± 2.0
	Placebo G	27.5 ± 4.7	27.5 ± 4.8	27.5 ± 4.7	27.4 ± 4.8	−0.1 ± 0.5		27.3 ± 4.5
β-lipoprotein (mg/dl)	Test G	26.9 ± 4.0	26.7 ± 4.0	25.8 ± 3.5	24.6 ± 4.3**	−2.1 ± 2.0	$p = 0.009$	25.1 ± 4.9*
	Placebo G	28.4 ± 5.7+	26.5 ± 4.7	26.1 ± 5.8	27.2 ± 4.9	0.8 ± 2.0		26.6 ± 4.3
Lipoprotein Detm,	Test G	0.94 ± 0.02	0.95 ± 0.03	0.93 ± 0.04*	0.92 ± 0.03**	−0.02 ± 0.02	$p = 0.003$	0.93 ± 0.03
	Placebo G	0.93 ± 0.02	0.93 ± 0.03	0.92 ± 0.04	0.93 ± 0.04	0.00 ± 0.02		0.92 ± 0.03

+$p<0.1$ *$p<0.05$ **$p<0.01$ (paired t-test)