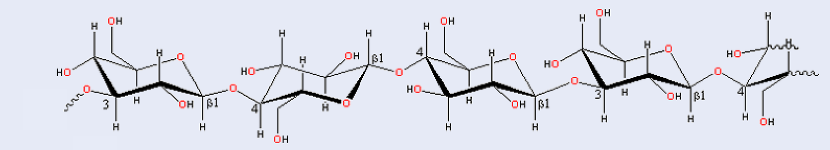
The effect of daily consumption of β-glucan-enriched bread on serum cholesterol and plasma glucose levels of type 2 diabetic persons



Oat β-glucan

P. Tsapogas[1], S. Liatis[1], C. Dimosthenopoulos[1], E. Chala[2], E. Kapantais[2], S. Grammatikou[1], K. Makrilakis[1], N. Katsilambros[1];

[1]First Dep. Propaedeutic Medicine, Athens University Medical School, Laiko General Hospital; [2]Department of Diabetes, Obesity, and Metabolism, Metropolitan Hospital, Athens, Greece.

Conclusion: In persons with type 2 DM, the daily consumption of bread enriched with 3 g beta-glucan from oat leads to a significant reduction of total-Cholesterol and LDL-Cholesterol within 3 weeks.
In adition, HbA1c showed a significant reduction in the β-glucan group, and this was not observed in the placebo group.

Background and Aims:

Certain studies have shown that the water-soluble dietary fiber beta-glucan, a natural component of oat, has hypocholesterolaemic actions, at least in normal subjects. The aim of this study was to evaluate whether the enrichment of bread with b-glucan can improve serum cholesterol levels in patients with type 2 diabetes mellitus (DM) and secondarily whether it affects glycaemic control and fasting insulin levels.

Patients and Methods:

This was a double-blind, randomized, placebo controlled study, lasting 3 weeks. Sixty-three persons, who regularly consumed at least 120 g bread daily, were selected from a pool of type 2 diabetic patients attending the outpatient diabetic clinic of our hospital. To be included in the study, patients needed to have an LDL-C value above 100 mg/dL (the primary target for LDL-C in patients with diabetes [ADA standards of care]). Patients were not receiving statin therapy. Those patients with a history of CVD or those with abnormal ECG findings at baseline were excluded from the study. All participants gave their written consent to the study, which was approved by the Ethics Committee at Laiko University Hospital in Athens.
The patients were randomized in two groups using computerized software. One group received a β-glucan-enriched bread, and the second group an indistinguishable bread loaf without β-glucan. The participants were asked to visit the Diabetes Center clinic on two occasions separated by a 3-week interval. All antihypertensive and antidiabetic medications remained stable during the 3-week period. A dietitian explained the study and instructed the participants on how to consume the study bread (4 small slices of bread, 30 g each, daily, which provided 3g of β-glucan per day in the β-glucan group) instead of their regular bread. Participants who wished to consume more bread than the amount provided were instructed to add bread of their usual kind. All patients were asked to record their daily bread consumption in a diary provided for this purpose.
Fifty-five patients completed the study (32 men, 23 women, aged 62.76±9.6 years. Each subject consumed 120 g of bread daily for 3 weeks, enriched with 3 g of b-glucan from oat (Group A, n=26) or not-enriched [regular bread (Group B, n=28)]. None of them were receiving hypolipidaemic treatment and their antidiabetic regimen remained stable throughout the study. Demographics comparing the two groups are shown in **Table 1**

Table 1. Demographics of Group A vs Group B

	Group A (β-glucan)		Group B (common bread)		
	n	Mean ±SD	n	Mean ±SD	p A vs B
M/W	14/13		18/10		0.350
Age (Years)	27	60.85 ±9.53	28	64.5 ±9.42	0.159
Weight (Kg)	27	82.5±12.7	28	75.8±11.6	0.045
BMI (kg/m2)	27	29.8±4.5	28	27.4±4.2	0.043
Waist (cm)	27	99.1±10.6	28	96.3±9.8	0.316
S.BD (mmHg)	27	141.6±17.6	28	131.2±11.0	0.019
D.BD (mmHg)	27	84.8±9.8	28	80.5±9.0	0.110
Total Cholesterol (mg/dl)	27	237.7±30.3	28	211.5±28.9	0.002
HDL-Cholesterol (mg/dl)	27	50.1±11.2	28	47.4±9.6	0.351
LDL-Cholesterol (mg/dl)	27	156.9±28.8	28	143.4±26.7	0.078
Triglycerides (mg/dl)	27	153.9±82.1	28	103.3±36.6	0.006
Glucose (mg/dl)	27	150.3±45.1	28	140.5±54.0	0.468
Insulin(μU/ml)	25	18.77±20.6	25	12.05±7.0	0.147
HOMA IR	23	8.05±12.7	26	4.44±4.4	0.206
HbA_{1c} (%)	23	7.10±1.57	26	6.96±1.32	0.610

Bread formula

Two types of bread were selected from the marketused: The β-glucan enriched bread was prepared of 7760 g (273.7 ounces) wheat flower; 2600 g (91.7 ounces) oat flower OBC N15 (manufacturer); 1100 g (38.8 ounces) leaven; 200 g (7.05 ounces) malt; 240 g (8.46 ounces) yeast; 230 g (8.11 ounces) salt; and 8950 g (315.7 ounces) water. All flower of the control bread was wheat flower. This formula provides bread loaves of 480 g (17 ounces), with a daily consumption of 3 g of oat β-glucan, for four days. Each 100 g of the bread contained 170 kcal; 12.34 g protein, 2.2 g fat; 25.24 g carbohydrates; 390 mg Sodium; and 17.59 g fibers (of which 3 g oat β-glucan in the studied bread). Bread was distributed weekly by courier

Measurement of body weight, height, waist circumference, and seated blood pressure were obtained during their visits. Fasting serum glucose was measured by the exokinase method using an Olympus AU640 analyzer. Glycated haemoglobin (A1c) was measured on whole blood by Tina-quant immunological assay standardized according to IFCC, and transferable to DCCT/NGSP using a Roche/Hitachi analyzer (Roche Diagnostics GmbH, Germany). Total fasting serum cholesterol, high-density lipoprotein cholesterol (HDL-C), (Olympus kits); triglycerides (GPO-POD method); and fasting serum insulin (in duplicate) by BioSource INS-Irma immunoradiometric assay kits (Biosource Europe S.A., Belgium. Low-density lipoprotein cholesterol (LDL-C) was estimated using the formula: LDL-C = total cholesterol – HDL-C – (0.46)TG/5. Non-HDL-cholesterol was estimated by substracting HDL-C from TC. The HOMA-IR index (a measure of insulin resistance) was computed using the formula: fasting plasma glucose (mg/dL) multiplied by fasting serum insulin (μU/mL) multiplied by 0.8. Low HOMA-IR values indicate high insulin sensitivity, whereas high HOMA-IR values indicate low insulin sensitivity (insulin resistance).

Statistical analysis

Analysis of the data was performed using the SPSS statistical package (SPSS 11.50.0, IL, USA). All data were assessed for normal distribution of the values. Skewed data were analyzed using non-parametric methods. Categorical data were compared using the chi-square test. Comparisons of normally distributed data within groups were performed by the paired-samples Student's t-test. Comparisons of normally distributed data between groups were performed by the independent samples Student's t-test or by ANOVA. Simple correlations were performed using the Pearson's or Spearman's correlation coefficient, as appropriate. Multivariate linear regression analysis was used in order to test for independent associations. P values (two-tailed) < 0.05 were considered statistically significant.

Results 1 : At the end of the study, both groups showed a statistically significant reduction of BMI (-0.400, p=0.002 and -0.2 Kg/m2, p=0.035 for Group A and Group B respectively) and waist circumference (-1.0 p=0.017 and -0.4 cm, and 0.027 for Group A and Group B respectively). **Table 2, Figures 1 and 2**
Group A showed a significant reduction in systolic blood pressure (141.7mmHg baseline vs. 133.9 mmHg at the end of study, p=0.007) while in group B there was a tendency for a lower systolic blood pressure (131.2mmHg baseline vs. 127.4 mmHg at the end of study, p=0.244). **Table 2**

Table 2: Weight, BMI, Waist circumference, Systolic and Diastolic Blood Pressure of the two groups at baseline and at the end of the study

	Group A			Group B			A vs B
	Baseline	End	P	Baseline	End	P	P (End)
Weight (Kg)	82.5±12.7	81.5±12.5	0.002	75.8±11.6	75.4±11.4	0.035	0,081
BMI (Kg/m2)	29.8±4.5	29.4±4.5	0.002	27.4±4.2	27.2±4.1	0.032	0,086
Waist (cm)	99.1±10.6	97.4±9.8	0.010	96.3±9.8	95.3±9.0	0.027	0,405
S BD (mmHg)	141.6±17.6	133.9±13.9	0.007	131.2±11.0	127.4±15.7	0.083	0,244
D BD (mmHg)	84.8±9.8	84.1±9.7	0.731	80.5±9.0	78.7±8.4	0.327	0,685

Figure 1: BMI boxplots of the two groups at baseline and at the end of the study

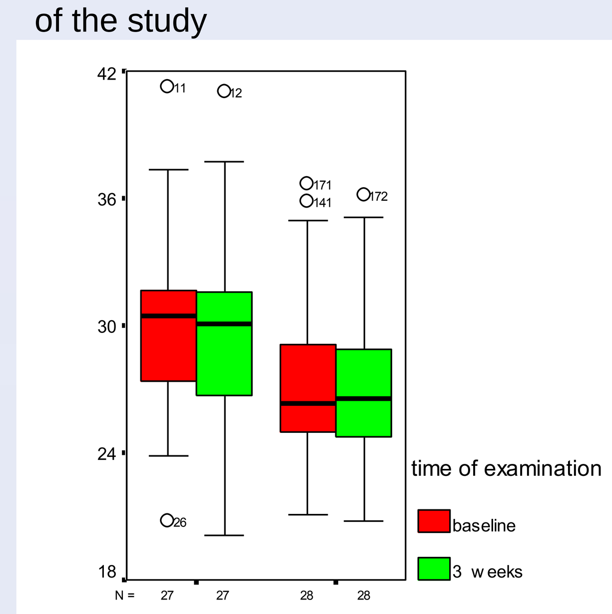
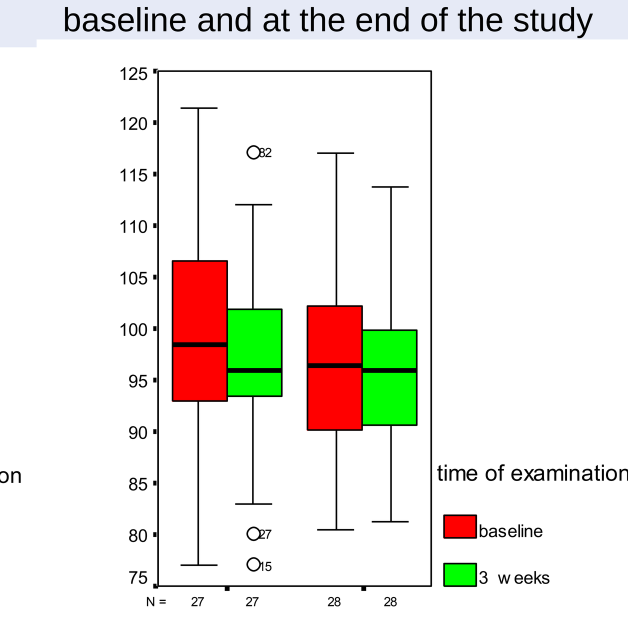


Figure 2: Waist circumference boxplots of the two groups at baseline and at the end of the study



Results 2: Group A showed a statistically significant reduction of total-Cholesterol and LDL-Cholesterol compared to Group B (decrease of total-Cholesterol by 24.5 mg/dl vs. decrease by 1.2 mg/dl, [p=0.013], and decrease of LDL-C by 19.7 mg/dl vs. decrease by 1.10 mg/dl, [p=0.015] respectively). No statistically significant changes were observed in HDL-Cholesterol and triglycerides. **Table 3, Figures 3-6**

Table 3: Total, HDL-, LDL-Cholesterol and Triglycerides of the two groups at baseline and at the end of the study

	Group A			Group B			A vs B
	Baseline	End	p	Baseline	End	p	P (End)
Total Cholesterol	237.7±30.3	213.2±34.8 -10.1%	0.006	211.5±28.9	210.3±30.3	0.742	0.013
HDL-Cholesterol	50.1±11.2	48.6±11.0	0.326	47.4±9.6	47.0±12.4	0.817	0.638
LDL-Cholesterol	156.9±28.8	137.2±31.1 -12.6%	0.006	143.4±26.7	142.8±27.2	0.874	0.015
Triglycerides	153.9±82.1	136.6±71.4	0.252	103.3±36.6	102.2±35.9	0.828	0.307

Figure 3: Total Cholesterol boxplots of the two groups at baseline and at the end of the study

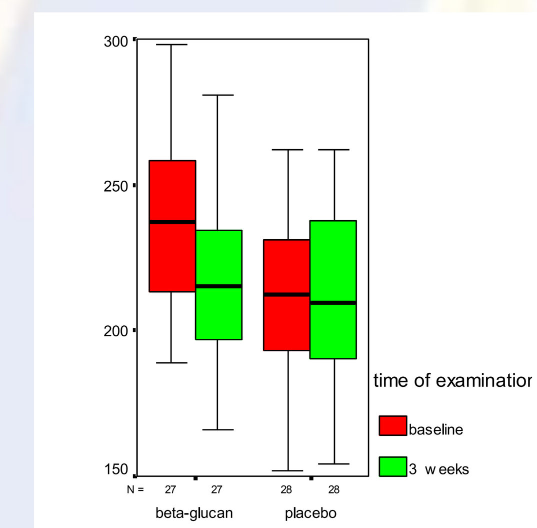


Figure 4: LDL-Cholesterol boxplots of the two groups at baseline and at the end of the study

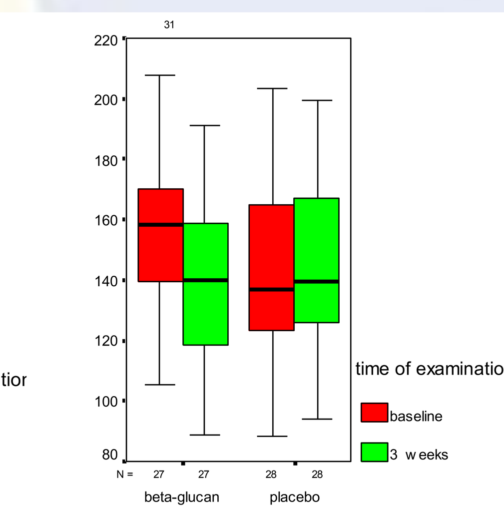


Figure 5: HDL-Cholesterol boxplots of the two groups at baseline and at the end of the study

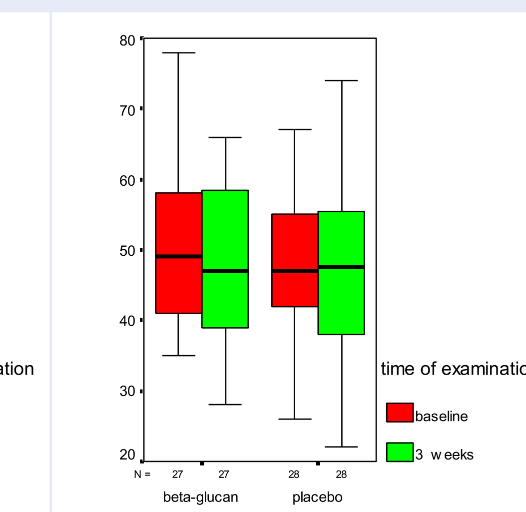


Figure 6: Triglyceride boxplots of the two groups at baseline and at the end of the study

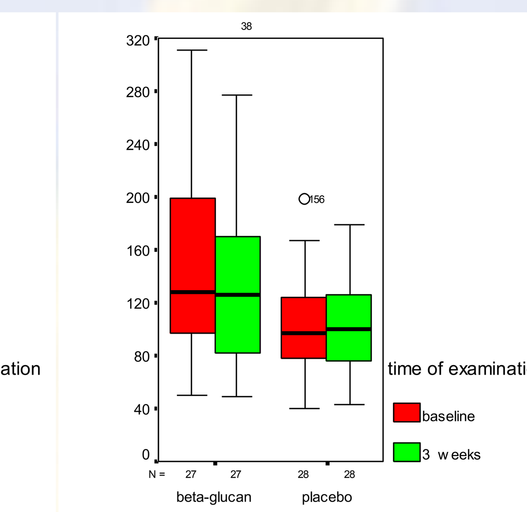
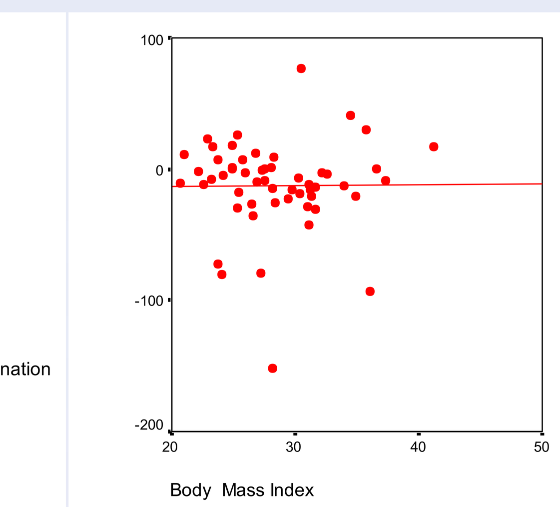


Figure 7: Pearson correlation between baseline BMI and total cholesterol reduction



Results 3: In order to deal with the problem of the statistical significance of the baseline values of BMI, Pearson Correlation has been calculated in all 55 subjects, between baseline BMI and total cholesterol reduction. The reduction of total cholesterol was independent of baseline BMI. **Figure 7**

Results 4: Group A also showed a greater decrease in fasting glucose and insulin levels compared to Group B (decrease of plasma glucose by 7.65 mg/dl vs. decrease by 2.82 mg/dl, and of serum insulin decrease by 2.31 μU/ml vs. increase by 1.43 μU/ml) but these differences did not reach statistical significance (p=0.61 and p=0.23, respectively). Both groups showed a significant reduction in HbA1c (group A: 7.07% baseline vs. 6.85% at the end of study, p=0.002, and group B: 7.01% baseline vs. 6.83%. p=0.042). Mean differences in HbA1c in the two groups were -0.220 (group A) and -0.188 (group B), p=0.764.
The HOMA insulin resistance index was not statistically different in the 2 groups (Group A vs. Group B -1.776 vs. +0.132, p=0.29). **Table 4, Figures 8 and 9**

Table 4: Total, HDL-, LDL-Cholesterol and Triglycerides of the two groups at baseline and at the end of the study

	Group A				Group B				AvsB
	N	Baseline	End	P(paired test)	N	Baseline	End	P (paired test)	P End
Blood Glucose (mg/dl)	27	150.3±45.1	141.6±39.3	0.118	28	140.5±54.0	137.7±38.9	0.707	0.522
HbA_{1c} (%)	25	7.10±1.57	6.85±1.34	0.001	25	6.96±1.32	6.79±1.28	0.062	0.464
Insulin (μU/ml)	23	18.77±20.6	16.04±16.5	0.217	26	12.05±7.0	13.24±9.1	0.482	0.151
HOMA-IR	23	8.05±12.7	6.37±9.2	0.166	26	4.44±4.4	4.52±3.4	0.940	0.253

Figure 8: Blood glucose boxplots of the two groups at baseline and at the end of the study

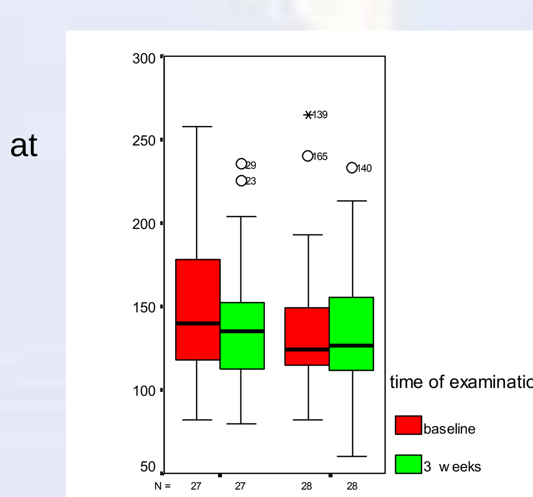
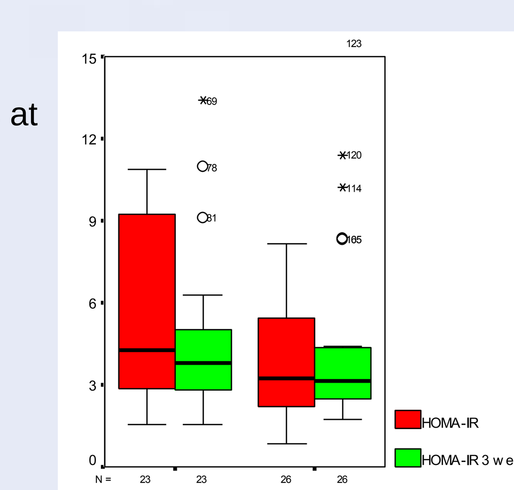


Figure 9: HOMA-Index boxplots of the two groups at baseline and at the end of the study



Discusssion

To our knowledge, this is the first study – with the exception of one small pilot study with eight male individuals [1] – to examine the long-term (non-acute) effects of β-glucan enriched diet in lipid profile and glucose control of patients with type 2 diabetes.
The FDA implied that the amount of soluble fiber needed to effect cholesterol levels is about 3g per day and, to qualify for the health claim, the whole oat-containing food must provide at least 0.75g of soluble fiber per serving. This was the reason why this amount of consumption (3g per day) was selected for intervention in the present study.
The hypocholesterolaemic effect of b-glucan might be explained by the increase in the binding of bile acids in the intestinal lumen, which leads to a decrease in the enterohepatic circulation of cholesterol to bile acids and a subsequent increase in the hepatic conversion of cholesterol to bile acids

(1) Pick ME, Hawrysh ZJ, Gee MI, Toth E, Garg ML, Hardin RT. Oat bran concentrate bread products improve long-term control of diabetes: a pilot study J Am Diet Assoc. 1996;96:1254-61.