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# Dietary Compliance among Men Participating in a Controlled Feeding Study of Fiber Supplementation

**Yoon, Hei-Ryeo**

*Department of Nutrition and Medical Dietetics, University of Illinois at Chicago, Chicago IL 60607, USA*

## ABSTRACT

The study was undertaken to assess the degree to which subjects were compliant with a specific metabolic diet in a controlled outpatient feeding study. The study consisted of a two-week control period in which subjects consumed a control diet consisting of 38 - 40% fat, 18 - 20% protein, 40 - 42% carbohydrate, followed by a three-week experimental period during which each subject consumed the control diet plus one of the four fiber supplements(20g/day) assigned on a random basis on the trust day. All meals were prepared and eaten in a metabolic feeding laboratory, with the exception of Saturday and Sunday meals that were packed for take-out. Fifty-seven healthy adult men, aged 18 - 65 years participated in the study. Dietary compliance index(CI) defined as the percent deviation of actual consumption from the prescribed food's and unconsumed prepared foods. The CI reflected the additional 'non-prescribed foods' and unconsumed 'prescribed foods'. A CI was calculated for all subjects. A CI of 5% or more was defined as poor compliance. Overall, dietary compliance was substantially improved for the entire group over the course of the study. Significant increase in compliance for energy and macronutrient intake occurred between the baseline and experimental periods. Within a non-obese group, dietary compliance for energy improved from 5.5% to 3.3% by the end of the study(week 1vs week 5, respectively, $p<0.05$). However, between non-obese and obese group, dietary compliance was not different. (*Korean J Nutrition* 31(5) : 957~964, 1998)

**KEY WORDS** : dietary compliance · compliance index(CI) · metabolic diet · controlled feeding study.

## Introduction

Dietary compliance is of paramount important in any effort to test the influence of a dietary intervention on disease risk factors and outcomes. It is a widely held belief that good compliance over months or years is difficult to achieve, especially with very restrictive dietary regimens. Haynes and colleagues defined compliance as "the extent to which a person's behavior(in terms of taking medication, following diets, or executing life style changes) coincides with medical or health advice". Compliance with the treatment regimen was an issue for consideration by any person involved in the care of chronically ill patients. Researchers, however, simply can not expect all subjects, perhaps, to adhere to the experimental regimens of diet they prescribe. Moreover, it is typically difficult for researchers to distinguish which subjects are compliant and which are not[2]. Actually, published reports of compliance behavior showed wide variations, e.g., from 4 percent to 100 percent, in the extent to which patients default[3][4]. Davis estimated that approximately 40 to 45 per-

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cent of patients fail to follow their physicians medical recommendations[5]. Kaplan De-Nour and Czaczkes have identified dietary restriction as a primary source of frustration for these patients[6]. Only 55 percent of their patients were rated as excellent, good and fair adherers. Even among the best adherers, there was a persistent tendency to abandon their prescribed dietary regime and to indulge in binge eating. Abram and co-workers had reported in a survey consisting of 3478 patients drawn from 201 dialysis centers in the U.S.A. a suicide rate of more than four hundred times that in the general population[7].

It is usually misleading to compare compliance rate from different studies. This was due to the wide variations in operational definitions of compliance among investigators, the lack of a truly objective measure of compliance with certain recommendations, such as special diets, and the loss of precision which entered into estimates of compliance based on several quite different medical recommendations[8].

Difficulty in distinguishing compliance from noncompliance can pose a serious obstacle to analyzing the results of the study and noncompliance may be the most significant problem facing dietary studies. The importance of noncompliance relates to the degree to which it interferes with achievement of a therapeutic goal[9]. The rate of noncompliance is greatest among those therapies that require life-style changes, such as exercise of diet regimens[10]. It is now accepted that compliance is related to the simplicity of the regimen and the patients' perception of the effectiveness of the ongoing treatment[2]. Chubon reported that adherence to prescribed dietary regimens is the most difficult aspect of compliance[11]. While the absolutely 'compliant' and the absolutely 'noncompliant' patients only occur rarely, there are periods of good and of poor compliance in the same patient. Thus, taking into account the data of all patients included in the study, there will be a broad spectrum of compliance[12].

The purpose of the present study is to evaluate the dietary compliance of men to a diet supplemented with fiber in an outpatient controlled feeding study with the primary definition of compliance being percent of deviation in actual diet consumed from the prescribed diet.

## Material and Methods

### 1. Subject

One hundred healthy adult men between the ages of 18 and 65 years were recruited from the University of Illinois at Chicago campus community and surroundings by means of posters and newspaper advertisements. Seventy men were selected for the study based upon the following criteria : 1) Weight for height and age between the 25$^{th}$ and 85$^{th}$ percentile of the Health and Nutrition examination Survey(NHANES 1), United States reference population. 2) Fasting serum cholesterol levels greater than the 50$^{th}$ percentile for age, race and sex based upon the Lipid Research Clinics reference population. 3) Normal health status as determined by a pre-study physical examination. Among the 70 men, 13 dropped out of the study, therefore, 57 subjects were available for the study. The purpose and other details of the study were discussed with the subjects by the study coordinator before entering the study. Subjects received individual attention from study personnel to address concerns regarding various aspects of the study throughout the study period.

### 2. Experimental design

The study consisted of a two week baseline diet period followed by a three week experimental period. During the experimental period, each subject consumed the baseline diet plus one of the four fiber supplements(20g/day), snowite oat fiber, snowite oat gum, beet fiber, and psyllium(Metamucil R), assigned on a random basis to each subject.

The study diet was designed to be a typical example of the American diet, which contained 38 - 40 percent of the energy from fat, 18 - 20 percent of the energy from protein and 40 - 42 percent of the energy from carbohydrate. Dietary fiber levels were at the levels of the typical American diet(13 - 20g/day). Cholesterol was 500mg and the p:s ratio was 0.5 for all energy levels. The diet consisted of a 4-day cycle menu fed at an energy level intended to maintain each person's baseline weight over the five week study period. Participant's energy level was adjusted if needed to minimize weight fluctuation. Diets were

**Table 1.** Diet composition

| Energy (Kcal) | Protein (g) | Fat (g) | Carbohydrate (g) | Dietary fiber (g) |
|---|---|---|---|---|
| 2300 | 86 | 110 | 250 | 15 |
| 2500 | 96 | 115 | 267 | 14 |
| 2800 | 111 | 130 | 302 | 16 |
| 3100 | 122 | 142 | 333 | 17 |
| 3500 | 137 | 163 | 379 | 19 |
| 3800 | 148 | 176 | 412 | 21 |
| 4100 | 169 | 194 | 437 | 22 |
| 4500 | 185 | 209 | 480 | 24 |
| 4900 | 198 | 223 | 511 | 25 |

developed for 2300Kcal, 2500Kcal, 2800Kcal, 3100 Kcal, 3500Kcal, 3800Kcal, 4100Kcal, 4500Kcal and 4900Kcal(Table 1). Initial energy levels for each subject were calculated and prescribed based on BEE (Basal Energy Expenditure) and the degree of individual activity. Energy level adjusted to maintain body weight by changing from one energy level to another as needed when a study subject deviated 2 pounds from a baseline weight for 3 days.

In order to provide for discretionary intake, a snack in the form of a pre-weighed study cookie was provided that met all the diet specifications so that subjects could snack without altering their diet pattern. The number of study cookies consumed daily was recorded and calculated into the use for each subject. Diets were developed using the Nutrition Data System(NDS), University of Minnesota.

Throughout the study, subjects were restricted to the consumption of the study diets. Only water and diet soda were allowed ad libitum. The meals were served 3 times a day. Breakfast and dinner were served at the Nutrition and Metabolism laboratory(NML) and lunch was packed for carrying out every day except during the weekend. Meals for the weekend were packed and carried out on Saturday morning. Arrangements for paced meals apart from the NML were made by individual request confirmed by the study supervisor.

### 3. Dietary intake assessment

The dietary intake was assessed in the following manner : Leftover(unconsumed) portions from a subject's tray for each meal were measured and the nutrient composition was calculated weekly using NDS. Each day, subjects recorded "non-study foods"(additional intake) and allowable unit cookies consumed on a dietary form. The nutrient composition for additional intake, snacks and unconsumed portions of prescribed diet were calculated using NDS.

**Table 2.** Demographic information of the subjects(n=57 men)

| Variable | n | % |
|---|---|---|
| Age (y) | | |
| Mean | 27±8 | 70 |
| 18-29 | 40 | 19 |
| 30-39 | 11 | 19 |
| 40-49 | 5 | 9 |
| >50 | 1 | 2 |
| Ethnicity | | |
| Asian | 16 | 28 |
| Black | 10 | 18 |
| Hispanic | 6 | 11 |
| White | 25 | 44 |
| Marital status | | |
| Married | 11 | 19 |
| Single | 45 | 79 |
| Education | | |
| 0-6 years | 0 | |
| 7-9 years | 0 | |
| 10-12 years | 1 | 2 |
| Some college | 29 | 51 |
| Post graduate | 24 | 42 |
| Others | 3 | 5 |
| BMI | | |
| Mean | 25±7 | |
| 27 | 39 | 68 |
| >27 | 18 | 32 |

One subject did not report marital status.
Column percent sum does not equal 100 because of rounding.

### 4. Compliance index(CI)

The index of dietary compliance was an estimate of actual dietary intake relative to assigned portion or prescribed energy level. Compliance index(CI) reflects two factors : 1) subjects' unconsumed portion of prescribed intake and 2) additional intake(e.g. non-study foods and unit food prescribed with the study) in relative to prescribed intake by week, calculated for the five week period. Formulas to compute actual intake and compliance index are presented below :

Actual daily intake=prescribed intake unconsumed portion+additional intake

Compliance index(%)= | (additional intake-uncons-

umed portion) | /prescribed intake × 100

A value of less than 5 percent CI for energy and macronutrients was arbitrarily established as the lowest limit of acceptable compliance(e.g.> 5% represents unacceptable compliance).

### 4. Statistical analysis

Data for compliance index are presented as mean s.d., Tukey's studentized range(HSD) test using the Statistical Analysis System(SAS) computer package was conducted to assess the statistical significance of changes in compliance index for energy and macronutrients; fat, protein, and carbohydrate. Multiple regression analysis was examined to study the relationships between the compliance, age, and ethnicity.

## Results

The demographic characteristics of study subjects are presented in Table 2. The mean age of subjects entering the study was 27±8 years, and mean weight and height were 80±14.8kg and 173±8.4cm, respectively. Among the 57 subjects, average BMI was 25±7. Thirty nine men were classified as a. nonobese(BMI≤27) and 18 men were classified as obese(BMI>27). The prescribed energy levels for subjects were distributed between 2300 Kcal and 4900 Kcal(Table 1).

Table 3 shows actual and prescribed intake for energy and macronutrients over the 5 week period as well as the ratio of actual to prescribed intake. The average actual daily intake has been adjusted for the additional and unconsumed prescribed portion during the study periods. During the control period in the first week, subjects consumed an average 4.8 percent above the prescribed energy intake, which declined slightly over the course of the study. This pattern was generally applicable to the macronutrients as well. It was evident that consumption of all three nutrients; fat, protein, and carbohydrate, exceeded

**Table 3.** Average actual and prescribed intake for energy and macronutrients(n=57)

| | Prescribed intake | Actual intake | % A/P | CI (%) |
|---|---|---|---|---|
| Energy(kcal) | | | | |
| Week 1 | 3115±501 | 3254±471 | 104.8±5.1 | 4.9±5.0[a] |
| Week 2 | 3142±513 | 3282±516 | 104.6±5.2 | 4.6±5.1 |
| Week 3 | 3171±503 | 3269±510 | 103.3±6.0 | 3.9±4.5 |
| Week 4 | 3137±500 | 3243±518 | 103.4±5.2 | 3.7±5.0 |
| Week 5 | 3111±501 | 3204±505 | 103.1±4.8 | 3.2±4.8[b] |
| Fat(g) | | | | |
| Week 1 | 144±24 | 149±22 | 104.0±4.9 | 4.2±4.8 |
| Week 2 | 146±24 | 151±24 | 104.1±5.2 | 4.3±5.0[a] |
| Week 3 | 147±24 | 150±24 | 102.6±5.8 | 3.4±5.2 |
| Week 4 | 145±23 | 149±25 | 102.5±6.7 | 3.4±5.0 |
| Week 5 | 144±23 | 147±24 | 102.5±4.7 | 2.8±4.5[b] |
| Protein(g) | | | | |
| Week 1 | 122±21 | 126±19 | 104.0±4.8 | 4.3±4.3 |
| Week 2 | 123±21 | 128±21 | 104.2±5.1 | 4.4±4.8 |
| Week 3 | 125±20 | 128±20 | 103.0±5.9 | 3.7±4.2 |
| Week 4 | 123±21 | 127±21 | 103.1±5.0 | 3.5±4.5 |
| Week 5 | 122±21 | 125±21 | 102.6±4.7 | 3.0±4.4 |
| Carbohydrate(g) | | | | |
| Week 1 | 338±53 | 354±50 | 105.1±4.9 | 5.2±4.9[a] |
| Week 2 | 339±53 | 356±54 | 105.3±5.5 | 5.3±5.5[b] |
| Week 3 | 341±52 | 352±55 | 103.2±7.1 | 4.2±4.9 |
| Week 4 | 339±52 | 351±53 | 103.7±5.3 | 4.0±5.1 |
| Week 5 | 336±52 | 347±52 | 103.4±5.1 | 3.5±5.0[c] |

All values indicate means.d.
A/P indicate percent ratio of actual intake to prescribed intake.
CI indicates compliance index
Values with different superscrpts are significantly different at $p<0.05$ by Tukeys studentized rage(HSD) test

100 percent of prescribed intake with variation ranging from 2.5 to 5.3 percent. The average intake of carbohydrate(5.1 – 5.3%) was slightly higher than that of protein(4.0 – 4.2%) and fat(4.0 – 4.1%) at baseline than at the end of the study. Table 3 also shows that the compliance index for energy significantly increased between week 1(baseline) and week 5(experimental period)($p<0.05$) by Tukey's studentized range (HSD) analysis. Compliance index for fat intake at the second week significantly improved over the course of the study(second vs. fifth week, $p<0.05$). Compliance index for carbohydrate intake in week 5 had significantly improved in comparison to week 1 and 2($p<0.05$). However, for protein intake the CI did not reflect any difference between weeks($p>0.1$).

**Table 4.** Distribution of obesity by ethnic group(n=57)*

| | Asian | Black | Hispanic | White |
|---|---|---|---|---|
| Non-obese | | | | |
| (n) | 14 | 5 | 2 | 18 |
| (%) | 87.5 | 50.0 | 33.3 | 72.0 |
| Obese | | | | |
| (n) | 2 | 5 | 4 | 7 |
| (%) | 12.0 | 50.0 | 66.7 | 28.0 |
| Total | | | | |
| (n) | 16 | 10 | 6 | 25 |
| (%) | 100.0 | 100.0 | 100.0 | 100.0 |

*Significant difference($p<0.05$) by Fishers exact test was found among ethnic groups

Non-obese and obese groups were classified based on BMI to analyze actual intake and prescribed intake of energy and macronutrients. Distribution of obesity by ethnic group showed a significant difference($p<0.05$) using Fisher's exact test ; black and Hispanic groups have higher percentages of obese persons than Asian and white groups(Table 4).

Compliance index for energy intake within non-obese subjects improved over the study period with a significant difference between week 1(5.5±5.0%) and week 5(3.0±3.0%)($p<0.05$) while no difference was seen in the obese group. The compliance index for carbohydrate intake improved significantly bet-

**Table 5.** Actual and prescribed intakes for energy and macronutrient in non-obese and obese groups

| | Non-obese(n=39 | | | Obese(n=18) | | |
|---|---|---|---|---|---|---|
| | Prescribed intake | Actual intake | CI(%) | Prescribed intake | Actual intake | CI(%) |
| Energy(kcal) | | | | | | |
| Week 1 | 3023±462 | 3180±461 | 5.5±5.0[a] | 3315±523 | 3416±464 | 3.6±5.0 |
| Week 2 | 3077±494 | 3226±528 | 4.5±5.1 | 3285±540 | 3403±479 | 4.2±5.2 |
| Week 3 | 3108±485 | 3212±506 | 4.3±4.4 | 3307±530 | 3392±510 | 2.9±4.7 |
| Week 4 | 3077±480 | 3193±521 | 4.1±5.4 | 3269±532 | 3351±507 | 2.7±3.8 |
| Week 5 | 3050±471 | 3146±500 | 3.3±5.0[b] | 3245±552 | 3329±507 | 3.1±4.2 |
| Fat(g) | | | | | | |
| Week 1 | 140±22 | 146±22 | 4.6±4.7 | 154±25 | 158±22 | 3.2±4.8 |
| Week 2 | 143±23 | 149±25 | 4.6±4.8 | 152±25 | 157±23 | 3.8±5.7 |
| Week 3 | 144±22 | 148±23 | 3.9±4.3 | 153±25 | 156±24 | 2.2±3.7 |
| Week 4 | 143±22 | 146±25 | 3.7±5.4 | 151±25 | 155±24 | 2.7±3.8 |
| Week 5 | 141±22 | 145±24 | 2.8±4.8 | 150±26 | 153±25 | 2.6±4.0 |
| Protein(g) | | | | | | |
| Week 1 | 118±19 | 123±19 | 4.7±4.2 | 131±22 | 133±19 | 3.3±4.4 |
| Week 2 | 121±20 | 126±21 | 4.6±4.7 | 129±22 | 133±19 | 3.9±4.9 |
| Week 3 | 122±20 | 126±20 | 4.2±4.1 | 130±22 | 133±21 | 2.7±4.3 |
| Week 4 | 122±20 | 125±22 | 3.9±4.9 | 129±23 | 131±21 | 2.5±3.4 |
| Week 5 | 119±20 | 123±21 | 3.1±4.6 | 128±23 | 130±22 | 2.7±4.0 |
| Carbohydrate(g) | | | | | | |
| Week 1 | 328±50 | 346±49 | 5.7±4.7[a] | 359±55 | 372±50 | 4.1±5.3 |
| Week 2 | 333±52 | 351±56 | 5.6±5.5[b] | 351±54 | 366±48 | 4.7±5.5 |
| Week 3 | 334±49 | 345±55 | 4.5±4.8 | 356±55 | 367±54 | 3.3±5.0 |
| Week 4 | 333±50 | 347±55 | 4.2±5.5 | 352±55 | 362±50 | 3.3±4.1 |
| Week 5 | 329±49 | 341±52 | 3.5±5.2[c] | 349±58 | 360±52 | 3.6±4.7 |

All values indicate means.d.
CI indicates compliance index
Values with different superscripts are significantly different at $p<0.05$ by Tukeys studentized range(HSD) test

**Table 6.** Relationship of compliance with age and ethnicity

| | Intercept | | | | Regression coefficient | | |
|---|---|---|---|---|---|---|---|
| | White(n=25) | Asian(n=16) | Black(n=10) | Hispanic(n=6) | Age | P-value | $R^2$ |
| Week 1 | 6.2 | 5.7 | 1.8 | 1.7 | 0.004 | 0.077 | 0.147 |
| Week 2 | 8.0 | 7.0 | 4.7 | 2.4 | -0.067 | 0.108 | 0.133 |
| Week 3 | 4.1 | 3.8 | 1.1 | -0.5 | 0.032 | 0.102 | 0.136 |
| Week 4 | 3.2 | 2.7 | 0.4 | 0.1 | 0.052 | 0.419 | 0.071 |
| Week 5 | 1.5 | 2.2 | -0.09 | 0.4 | 0.076 | 0.448 | 0.068 |

The regression equation is CI=intercept+(regression coefficient)×(age) for each ethnic group

ween week 1 and 2 versus week 5 in the non-obese group during the study period(5.7±4.75% vs. 3.5±5.2%)($p<0.05$), but not in the obese group. The compliance index for fat and protein, however, did not show any difference within non-obese subjects during the five week period($p>0.1$). Overall the compliance index for energy and the three macronutrients tended to be better for the obese group than the non-obese group although no statistically significant difference was discerned between the groups in any of the weeks by repeated measure analysis($p>0.1$). In general dietary compliance improved over the course of the study for non-obese subjects. However for obese subjects, compliance remained better than for non-obese through the study.

Multiple regression analysis was performed to examine the relationship between non-compliance index and age and ethnicity(Table 6). Result showed that white and Asian groups showed lower compliance during the five weeks than black and Hispanic groups. However, no statistically significant relationship was observed between these variables($p>0.1$).

## Discussion

This study assessed the compliance to a controlled metabolism diet in a five week outpatients feeding study of fiber supplementation. The design allowed for an objective assessment of dietary compliance through quantitative evaluation of the amount of the prescribed diet consumed, and the amount of prescribed diet not consumed as well as the additional intake of 'non-study foods' by all subjects. A compliance index(CI) of less than or equal to 5 percent was established as the limit at compliance would be defined as acceptable of good. Conversely, a CI greater than 5 percent was defined as unacceptable or poor dietary compliance. Findings indicate that during the study, subjects' compliance to diet remained acceptable to good overall and that compliance improved as the study progressed. The addition of the fiber supplement at the beginning of week 3 to the control diet did not appear to have an adverse effect on compliance.

For the entire group, the reductions in the CI for carbohydrate(from 5.2±4.9% to 3.5±5.0%) and fat (from 4.2±4.8% to 2.8±4.5%) were in turn reflected in the reduced CI for energy by the end of the study. This demonstrated increasing dietary compliance by the subjects as the study progressed. Within weight groups, non-obese subjects showed a significant improvement in compliance by the end of the study while no such change in the compliance was observed for obese subjects. Several factors might possibly account for the findings of good compliance among subjects in the study overall, including the short study period, subject payment, supervision by study staff, high degree of individual attention received by subjects from study personnel and compliance monitoring with feedback. Reid[13] reported that long periods of dietary treatment could adversely affect dietary compliance. Investigators also suggest the patients' attitude toward treatment influences cooperation and the compliance is proportional to the strength of motivation[14][15]. The subjects in this study exhibited a high degree of motivation and were a volunteer group, and according to Becker[16], highly motivated volunteer subjects might increased the likelihood of good dietary compliance. Subjects also received information throughout the study as to progress and resolution of problems. Studies show that continuing education and providing the subjects with a description and implications of treatment enhances dietary compliance. Haynes and

Sackett[17] reported that education is an important strategy for improving compliance to treatment regiments.

The addition of a fiber supplement(20g/day) did not appear to adversely affect dietary compliance in this study. The opposite finding might have been expected. On the other hand the supplement could have decreased appetite(due to increased feeling of fullness at mealtime) or have caused an increased intake of "non-study foods", thereby decreasing compliance after the third week of the study. Studies have in fact shown that the addition of fiber can reduce appetite resulting in significant weight reduction among obese people[18]. Harber, et al.[19] Showed that dietary fiber could decrease hunger feeling significantly at meal time, which allows the individual to ingest fewer calories and lose weight. However, in this study compliance remained good to acceptable indicating that fiber supplement did not affect the dietary compliance among subjects in a controlled outpatient feeding study.

Regression analysis in this study showed that compliance was not related to age and ethnicity for the entire group. According to the study by Cobb, et al. [20], young patients were more likely to comply to their regimen than older patients suggesting a relationship between compliance and age. In contrast, subsequent investigations have led to the conclusion that age was probably not significantly related to compliance[8].

In conclusion, the results here demonstrated that good dietary compliance can be achieved in short-term controlled outpatient feeding study with attention to factors that enhance compliance. Since there has been an increased interest in the cause of diseases relevant to diet, dietary compliance is the most fundamental factor to assess the effectiveness of possible treatment in any controlled clinical trial testing the influence of relationship of diet to disease. With the achievement of good dietary compliance in this study. The results are encouraging relative to current concerns about studies to quantitate the impact of diet on various diseases. Compliance in controlled feeding studies of a longer duration remains to be reported.

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