

# Study reports on effects of Yile grain and vegetable powder on glycometabolism of type 2 diabetes patients

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Yile grain and vegetable powder is a health food containing natural crops such as grain, vegetable, algae and eumycete, et al, which can be directly edible without cooking. Yile grain and vegetable powder is confirmed by ARESO test of FDA in America to be secure and contain no toxic components; it is approved by State Import and Export Quarantine Bureau to be qualification foods. The results of animal experiment demonstrate that Yile grain and vegetable powder can improve glycometabolism and lipid metabolism disorder suffered by rats with diabetes to some extent, and elevate survival rate of model rats bearing diabetes model.

For observing the effects of Yile grain and vegetable powder on blood sugar content of type 2 diabetes patients and the safety of Yile grain and vegetable powder, patients with type 2 diabetes who take Yile grain and vegetable powder are clinically observed from July 2006 to December 2006, and the summary is as follows:

## General data

31 cases are included in this study, and one case is lost to follow-up after one month. 30 cases accomplish clinical observation including 18 male patients and 12 female patients whose ages are between 40 and 65 years old with the mean value of  $53.57 \pm 8.32$  years; and their disease causes are between 1 and 3 years with the mean value of  $2.1 \pm 0.5$  years.

## Experiment protocol

### 1 Diagnosis criteria

Diagnosis of diabetes abiding by WHO diagnosis criteria(1999).

1.1 Exhibiting typical symptom, fasting blood glucose  $\geq 126\text{mg/dl}(7.0\text{mmol/l})$  or OGTT2h blood sugar  $\geq 200\text{mg/dl}(11.1\text{mmol/l})$  or random blood sugar  $\geq 200\text{mg/dl}(11.1\text{mmol/l})$

1.2 Exhibiting no typical symptom, only fasting blood glucose  $\geq 126\text{mg/dl}(7.0\text{mmol/l})$  or OGTT2h blood sugar  $\geq 200\text{mg/dl}(11.1\text{mmol/l})$  or random blood sugar  $\geq 200\text{mg/dl}(11.1\text{mmol/l})$ , all of which should not be on the same day, after repeating the test, people who still reach that level above can be diagnosed with diabetes.

## 2 Criteria of experiment case:

### 2.1 Inclusion criteria

- 2.1.1 Type 2 diabetes patients in compliance with diabetes **diagnosis criteria**
- 2.1.2 Patients who never receive insulin treatment
- 2.1.3 Patient taking hypoglycemic drug for no more than three years
- 2.1.4 Patients between 40 and 65 years old
- 2.1.5 Patients who sign the inform consent

### 2.2 Exclusion criteria

- 2.2.1 Patients who are not in compliance with inclusion criteria
- 2.2.2 Women with pregnancy or lactation
- 2.2.3 Patients who have drug allergy history, allergic constitution, and are allergic to components contained in test article
- 2.2.4 Patients with co-current serious primary diseases such as cardiovascular, brain, respiratory, liver, kidney and hematopoietic system disease et al or psychosis
- 2.2.5 Patients with acute metabolic disorder such as diabetes mellitus ketoacidosis et al within a month or concurrent infection

### 2.3 Rejection criteria

- 2.3.1 Patients who are confirmed not to be qualified following inclusion
- 2.3.2 Patients taking products which are forbidden by experimental protocol, due to disobeying clinical observation program they should be rejected
- 2.3.3 Patients who never take test article should be rejected
- 2.3.4 Patients without any evaluation records following taking test article

### 2.4 Dropping-out criteria

The subjects who are in compliance inclusion criteria and do not complete observation due to some reasons are dropping-out ones. Their statistical analysis should be conducted in accordance with real conditions.

## 3 Treatment plan

Patients included are the ones who continually take oral antidiabetic drug for more than 3 months and do not achieve expected blood sugar control. They orally take Yile grain and vegetable powder once in the morning and at night respectively in combination with original treatment plan.

### 3.1 Control method

Own control method is adopted.

### 3.2 Administration time

Three months.

### 3.3 Case number

30 cases of Type 2 diabetes are clinically observed.

### 3.4 Grain and vegetable powder for observation

#### 3.4.1 Name and specification of product by observation

Yile grain and vegetable powder, Korea Yile Corporation, 40 g/pack, approval document number: J21000421448.

All the grain and vegetable powder observed are qualified.

#### 3.4.2 Administration method

In the condition of keeping original treatment plan, Yile grain and vegetable powder is orally taken twice per day for 40 g in total. It should be taken in combination with mineral water or defatting milk once in the morning and once at night respectively. Lunch adopts natural food(requirements for natural food are: no fast food such as instant noodle, hamburger etc, mainly vegetable and protein).

## 4 Indexes for observation

### 4.1 Safety index

4.1.1 Vital sign: such as blood pressure, respiration, heart rate, et al.

4.1.2 Routine test of blood, urine: once before and after the treatment

4.1.3 Electrocardiogram, liver function(ALT, AST), kidney function( BUN, Cr): once before and after the treatment

4.1.4 Adverse events: recording in detail any time

4.1.5 Serum iron: once before and after the treatment.

4.1.6 Serum albumin: once before and after the treatment.

### 4.2 Therapeutic index

#### 4.2.1 Clinical symptom

Statistical therapeutic scores from symptom observation are adopted to express the degree of improvement.

Clinical symptoms are classified into three grades: mild, moderate and serious, all of which are marked by 1, 2, 3 points. Observation is performed once a month and scores are adopted to express degree of seriousness. Statistics is adopted for analyzing results.

#### 4.2.2 Blood sugar observation

Fasting blood sugar, and blood sugar 2 hours after meal in patient is tested respectively prior to treatment and 4, 8, 12 weeks after treatment.

#### 4.2.3 Glycosylated hemoglobin

Test is performed once before and after the treatment respectively.

#### 4.2.4 Blood fat

Once before and after the treatment respectively.

#### 4.2.5 Body mass index

Once before and after the treatment respectively.

#### 4.2.6 Diet diary

Patients are required to make diet diary(recording three meals a day and other dietary condition with no missing).

## 5 Scoring method for clinical symptom

Scoring method for clinical symptom is established referring to “clinical study guidance on new Chinese tradition medicine” published by Ministry of Public Health in 2002.

### **Increase of water intake**

Mild(1): a slight increase of water intake

Moderate(2): increasing more than a half time comparing to normal water intake

Serious(3): increasing more than one time comparing to normal water intake

### **Sense of hunger**

Mild(1): significant sense of hunger

Moderate(2): unbearable hunger prior to meal

Serious(3): unbearable hunger generally in combination with hypoglycemia reaction

### **Increase of urination**

Mild(1): urine volume of 2-2.5 L/d

Moderate(2): urine volume of 2.5-3 L/d

Serious(3): urine volume of more than 3 L/d

### **Body weight loss**

Mild(1): slightly thin

Moderate(2): significant thin

Serious(3): extremely thin

### **Agitation and tantrum**

Mild(1): occasional agitation

Moderate(2): frequent agitation and tantrum

Serious(3): uncontrollable agitation and tantrum

### **Hypodynamia**

Mild(1): not being able to participate in physical works

Moderate(2): being able to perform light physical labor

Serious(3): only perform routine activities

### **Abdominal distension**

Mild(1): occasional abdominal distension after meal

Moderate(2): frequent abdominal distension after meal

Serious(3): constant abdominal distension and gastric distention

## **Stool**

Mild(1): defecation discomfort, or soft feces, hard feces

Moderate(2): defecation discomfort, or soft feces 2-3 times/day, hard feces 2-3 times/day

Serious(3): defecation discomfort, or soft feces more than 3 times/day, hard feces more than 3 times/day

## **Insomnia**

Mild(1): sleep for 3-5 hours/night

Moderate(2): sleep for 1-3 hours/night

Serious(3): hard to sleep

## **6 Statistical process**

### **6.1 Data management**

6.1.1 Each case enrolled must fill the form of case observation which can not be provided to the third part in any form without the written consent.

6.1.2 Patients who are qualified for observation must seriously record any items in the form of case observation in detail without any missing.

### **6.2 Data process**

Statistical analysis is performed on data and statistical analysis report is written. Primary researcher writes study report.

### **6.3 Statistical analysis**

SPSS12.0 software is adopted to arrange and analyze data. Measurement data of non-normal distribution are expressed by median and average rank. Non-parameter Comparison Two-Independent-Samples Tests are employed to determine significance.

## **7 Therapeutic evaluation**

As for clinical symptoms, blood sugar, blood fat, glycosylated hemoglobin, serum iron, body mass index, albumin, et al, corresponding statistical method is adopted for comparison.

## **8 Observation requirements**

Researcher should honestly, seriously fill every item of the case report form in detail to ensure validity, reliability of contents in case report list form. All observation results and findings during clinical observation process should be validated to guarantee the reliability of data.

## Results

### 1 Effects of Yile grain and vegetable powder on clinical symptom

The Table 1 demonstrates that symptom scores of type 2 diabetes patients following taking Yile grain and vegetable powder improve greatly comparing to that prior to the treatment, and there is statistically significant difference between them,  $P < 0.05$ .

Table 1 Comparison of symptom scores before and after the treatment  
(median, average rank)

group	number	clinical symptom score	
		median	average rank
Before treatment	30	9.00	42.07
After treatment	30	2.00	18.93 <sup>*</sup>

※: Comparing to scores before treatment,  $P < 0.05$

### 2 Effects of Yile grain and vegetable powder on blood sugar

The Table 2 demonstrates that after taking Yile grain and vegetable powder, both fasting blood sugar and blood sugar 2 hours after meal in patient decrease significantly, and there is statistically significant difference between them,  $P < 0.05$ , which means Yile grain and vegetable powder achieves better assisting effects of decreasing blood sugar.

Table 2 Blood sugar changes before and after the treatment (median, average rank)

	Number	Before treatment		After treatment		P
		Median	Average rank	Median	Average rank	
Fasting blood sugar	30	8.05	38.92	7.00	22.08 <sup>*</sup>	$< 0.05$
Blood sugar 2 hours after meal	30	9.70	36.48	9.00	24.52 <sup>*</sup>	$< 0.05$

※: Comparing to scores before treatment,  $P < 0.05$

### 3 Effects of Yile grain and vegetable powder on glycosylated hemoglobin

The Table 3 demonstrates that after taking Yile grain and vegetable powder, glycosylated hemoglobin decreases significantly, and there is statistically significant difference between them,  $P < 0.05$ .

Table 3 Glycosylated hemoglobin changes before and after the treatment (median, average rank)

Group	Number	Glycosylated hemoglobin	
		Median	Average rank
Before treatment	30	7.45	38.55
After treatment	30	6.90	22.45 <sup>*</sup>

※: Comparing to scores before treatment,  $P < 0.05$

#### 4 Effects of Yile grain and vegetable powder on blood fat

The Table 4 demonstrates that after taking Yile grain and vegetable powder, TG and LDL of patients decrease comparing to that prior to treatment, and there is statistically significant difference between them,  $P < 0.05$ . whereas TC and HDL demonstrate no significant changes.

Table 4 Blood fat changes before and after the treatment (median, average rank)

	Number	Before treatment		After treatment	
		Median	Average rank	Median	Average rank
TC	30	4.42	29.48	4.64	31.52
TG	30	1.79	33.28	1.62	27.72*
HDL	30	1.18	31.10	1.11	29.90
LDL	30	2.62	33.25	2.56	27.75*

※: Comparing to scores before treatment,  $P < 0.05$

#### Safety evaluation

##### 1 Adverse event

No adverse events are noted in 30 patients included during the observation process.

##### 2 Routine blood, liver, kidney condition before and after the treatment

30 patients included in this group all undergo blood, urine, stool routine test and serum albumin, serum iron as well as liver, kidney function examination, and no abnormalities are observed following the treatment.

#### Discussion

Raw food contains many nutrients and enzyme which play an important role in maintaining normal metabolism and keeping health of human body. Cooking may greatly decrease the content of nutrients and enzyme in food. Yile grain and vegetable powder which is a great health food adopts rapid cooling method to make the temperature of vegetable and grain of organic farming grade reduce to  $-40\text{ }^{\circ}\text{C}$  for refreshing and removing water. Therefore the vegetable and grain are prepared into powders without fire processing, and 97% nutrients are kept. The main components of Yile grain and vegetable powder includes grain: brown rice,  $\alpha$ - brown rice, yellow rice, sorghum, coix lacryma-jabi, black rice, barley, black sesame, soybean, black bean, red bean, brazilian mushroom rice, red rice barley; vegetables: Brassica oleracead with green leaves, dahurian angelica root, cabbage, water dropwort, turnip leaves, carrot, edible burdock, radish, root of straight ladybell, pumpkin, cauliflower, chive, barley seedling powder, potato; fruits: pomelo, golden apple, grosvenor momordica fruit; mushroom: shiitake fungus, mythic fungus; seaweed: laver, sea tangle, undaria pinnatifida, spirulina, dry musci; others: yeast, lactobacillus, spirulina, oligosaccharide,

red rice, extract of lactobacillus, et al 45 natural food containing abundant and balanced nutrients and guaranteed in accordance with organic farming grade for safety.

30 patients in this group are all the type 2 diabetes ones who undergo routine lifestyle intervention or orally take antidiabetic drug without achieving satisfactory blood sugar control. In the condition of keeping original treatment plan, they all take Yile grain and vegetable powder for assisting treatment, and the results demonstrate that after taking Yile grain and vegetable powder, both fasting blood sugar and blood sugar 2 hours after meal, glycosylated hemoglobin, decrease significantly comparing to that prior to treatment and clinical symptoms all improve significantly with  $P < 0.05$  following statistical process, which means Yile grain and vegetable powder achieves assisting effects of decreasing blood sugar, blood fat and improving clinical symptoms on type 2 diabetes patients. No adverse events are noted during the treatment process. 30 patients included in this group all undergo blood, urine, stool serum albumin, serum iron as well as liver, kidney function examination without finding any toxic and adverse effects.

### **Conclusion**

The results in this study demonstrate that Yile grain and vegetable powder achieves assisting effects of decreasing blood sugar and improving clinical symptoms on type 2 diabetes patients with safety, efficacy and convenience of orally taking, which is worth promotion and application.