Study reports on effects of Yile grain and vegetable powder on glycometabolism of patients with low sugar tolerance

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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 ARESCO 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 patients with low sugar tolerance and the safety of Yile grain and vegetable powder, patients with low sugar tolerance who take Yile grain and vegetable powder are clinically observed from July 2006 to December 2006, and the summary is as follows:

General data

30 cases are included in this study including 11 male patients and 19 female patients whose ages are between 40 and 65 years old with the mean value of 52.77±7.73 years

Experiment protocol

1. **Diagnosis criteria**

   Diagnosis criteria: Adopting IGT diagnosis criteria established by WHO in 1999: blood sugar≥7.8mmol/L but <11.1mmol/L 2 hours after oral glucose tolerance test(OGTT) of 75 g, and fasting blood sugar≥6.1mmol/L but <7.0mmol/L.

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 the treatment of antidiabetic drug
   - 2.1.3 Patients between 40 and 65 years old
   - 2.1.4 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

2.3 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. Statistical analysis should be conducted in accordance with real conditions.

3 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 patients with low sugar tolerance 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	10.0	42.48
After treatment	30	2.50	18.52※

※: 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 OGTT in patient decrease significantly, and there is statistically significant difference between them, $P<0.05$, however, fast blood sugar only decreases by 0.1 mmol/L without clinical significance. And all the results above manifest that Yile grain and vegetable powder achieves certain assisting effects of decreasing blood sugar following meals.

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	5.80	32.83	5.70	28.17	
Blood sugar 2 hours after meal	30	8.70	36.87	8.18	24.13※	<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	5.90	35.52
After treatment	30	5.70	25.48※

※: 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	4.93	32.13	4.92	28.87
TG	30	1.62	31.87	1.51	29.13※
HDL	30	1.20	31.07	1.16	29.93
LDL	30	2.70	34.78	2.57	26.22※

※: 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 ℃ 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, α- 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 pinnitafida, spirulina, dry musci; others: yeast, lactobacillus, spiruliña, 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 included in this group are all ones with low sugar tolerance who undergo no medication intervention. Basing on intervention of original lifestyle, 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 OGTT, glycosylated hemoglobin, TG, LDL 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 patients with low sugar tolerance. 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 patients with low sugar tolerance with safety, efficacy and convenience of orally taking, which is worth promotion and application.