

OBSERVATION OF EFFECTS WITH NATURAL MEDICINE AND FOOD IN METABOLIC SYNDROME

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ABSTRACT

Objective: To observe the effects of natural medicine and food in the treatment of metabolic syndrome.

Methods: 30 patients with metabolic syndrome who visit our outpatient department at South area of Guang'anmen Hospital were randomly divided into control group (n=15) and treatment group(n=15).The control group was given standard treatment of metabolic syndrome, which is lifestyle intervention and drug treatment; the treatment group added water-soluble dietary fiber and dietary prescription on the basis of standard treatment. The body mass index, blood sugar, blood lipids and TCM symptom scores were compared between the treatment group and the control group after 12W.

Results: Treatment group was better than control group in the improvement of relevant indicators and TCM symptom scores (P<0.05).

Conclusion: Natural medicine and food can improve the effect of metabolic syndrome, show the advantages of traditional Chinese Medicine, celet materials in food-grade and confirm the theory of medicine and food homology.

Keywords: Metabolic syndrome, natural medicine and food, diet therapy, dietary fiber, medicine and food homology, major bupleurum decoction.

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Introduction

Metabolic syndrome (MS) is a general term for a group of metabolic diseases that can cause atherosclerosis due to hyperinsulinemia caused by insulin resistance. Its manifestations include abnormal glucose metabolism, dyslipidemia, obesity, hypertension, hyperinsulinemia, hyperuricemia, hypercoagulable state of blood and microalbuminuria. With the aging of the population, changes in dietary structure and lifestyle, the prevalence of metabolic syndrome in the population is increasing year by year. The overall prevalence rate in China is higher in the north than in the south, in the cities than in the countryside, and in women than in men⁽¹⁾. Stand-

ardized treatment of MS mainly includes improving lifestyle⁽²⁾, regulating blood lipid⁽²⁾, lowering blood pressure⁽³⁾ and improving insulin resistance. People have a natural hobby and enthusiasm for diet, and traditional Chinese medicine has a cultural concept of homology of medicine and food since ancient times. After development, the theory of homology of medicine and food and the discipline of medicinal diet have created a new situation after the founding of New China⁽⁴⁾. Drugs have four natures and five flavors, as do foods, which can also be used to guide the treatment of diseases. At the same time, studies also show that dietary fiber has preventive and therapeutic effects on metabolic syndrome⁽⁵⁻⁶⁾. This study is based on the fact that MS TCM syndrome

differentiation belongs to liver and stomach stagnation heat⁽⁷⁻⁸⁾. The specific composition is prepared by selecting bitter melon, cassia seed, aloe, hawthorn, lotus leaf, betel nut, yellow mustard seed, ginger and jujube according to the nature and taste of Major Bupleurum Decoction and the catalogue of homology of medicine and food published by the State Food and Drug Administration.

Patients with MS were randomly divided into control group and treatment group. The control group was given standardized treatment of metabolic syndrome, namely lifestyle intervention+medication; On the basis of standard treatment, the treatment group was added with water-soluble dietary fiber and dietotherapy prescription to explore the influence of natural medicine and food on various indexes and TCM symptom scores. The results are reported as follows.

Materials and methods

General information

This study is a prospective, randomized controlled and blank controlled clinical trial, including 30 patients with MS who visited the endocrinology department of our hospital from July 2017 to June 2018. According to the random number table, the patients were randomly divided into control group and treatment group. There was no significant difference between the two groups in general clinical data such as gender, age and various indicators ($P>0.05$), as shown in Table 1.

Index	Control group (n=15)	Treatment group (n=15)
Gender (male)	9	9
Age	54±10	53±10
BMI	27.36±2.13	27.19±2.28
FPG	9.10±3.34	8.71±3.63
2hPG	10.30±3.01	10.71±3.63
TG	2.65±1.44	2.51±1.42
HDL-C	1.18±0.28	1.19±0.3

Table 1: Comparison of general clinical data between the two groups.

TCM diagnostic criteria

TCM syndrome type standard determines The characteristics of liver-stomach stagnation and heat syndrome type according to Diagnostics of Traditional Chinese Medicine and Guiding Principles for Clinical Research of New Chinese Medicine⁽⁹⁾.

- Main symptoms: bitter taste, distention in chest and hypochondrium, impatience and irritability,

thirsty and fond of drinking, constipation;

- Concurrent syndrome: red face, insomnia, bad breath, upset, emotional depression, eating more and hunger, and dark urine;
- Red tongue, yellow greasy tongue coating, taut and slippery pulse.

Inclusion and exclusion criteria

Inclusion criteria:

- Diagnostic criteria of MS of China diabetes association in 2004(10);
- It conforms to the TCM syndrome differentiation standard of stagnation of heat in liver and stomach;
- Patients aged 18-65 (male or female);
- Voluntary completion of the clinical trial.

Exclusion criteria:

- Those who do not meet the diagnostic criteria of MS and the symptoms of Chinese medicine after being selected;
- Younger than 18 years old, or over 65 years old;
- Pregnant or lactating women;
- Patients with primary diseases such as cardiovascular, cerebrovascular disease and liver and kidney dysfunction and other diseases, mental disorders;
- Allergic constitution and allergic to multiple drugs;
- Those who don't know enough about this research, don't want to participate, or can not cooperate.

Research methods

The control group was treated with MS standard, that is, lifestyle intervention+medication.(10,000 steps per day, individualized calorie calculation scheme and smoking cessation+Metformin 1000mg 2/day for blood glucose reduction; Fosinopril sodium 10mg 1/day for blood pressure reduction; Atorvastatin calcium tablets 10mg 1/day for lipid regulation). The standard treatment were the same between the treatment group and the control group.

The difference was that water-soluble dietary fiber 10g 2/day and the dietotherapy prescription (daily prescription dosage is balsam pear 50g, cassia seed 10g, aloe 10g, hawthorn 30g, lotus leaf 30g, betel nut 10g, yellow mustard 6g, ginger 10g and jujube 10g) were added for 2/day. It lasts for 12W.

Effect evaluation and statistical analysis

The effect evaluation standard of physical and chemical indicators, refers to the treatment targets of MS⁽¹⁰⁾ and the Guiding Principles for Clinical Research of New Traditional Chinese Medicine⁽⁹⁾.

Significant

FPG <6.0mmol/L, 2hPG <7. 8mmol/L; Blood lipid test reaches any of the following: TG decreased ≥40%, HDL-C increased ≥0.26mmol/L;

Effective

FPG <7.8mmol/L, 2hPG <8. 4mmol/L; Blood lipid test reaches any of the following: TG decreased ≥40% and <40%, HDL-C increased ≥0.104mmol/L and <0.26mmol/L;

Invalid

The above targets were not achieved.

The curative effect evaluation standard of TCM symptom score refers to Guiding Principles for Clinical Research of New Traditional Chinese Medicine⁽⁹⁾.

Nimodipine method is adopted to judge the curative effect by integral reduction rate, which is (integral before treatment-integral after treatment)/ integral before treatment×100%.

Significant

Clinical symptoms and signs improved obviously, and the total score of symptoms decreased by 70%;

Effective

Clinical symptoms and signs were improved, and the total symptom score decreased by 30%;3. Invalid Clinical symptoms and signs were not improved or aggravated obviously, and the total symptom score decreased lower than 30%.

SPSS10.0 was used for statistical analysis. The measurement data was represented by ($\bar{x}\pm s$), and the count data was expressed in%.

Independent sample T-test and Chi-square test were used respectively. The difference was statistically significant with P<0.05.

Results

Efficacy of physical and chemical indexes

Comparison of clinical curative effect of physical and chemical indexes after 12 weeks of treatment, the total effective rate of the treatment group was better than that of the control group, but there was no statistical difference.

The effective rate of treatment group was higher than that of control group, and the difference was statistically significant (P<0.05). See Table 2.

Group	n	Significant	Effective	Invalid	Effective rate%	Significant rate%
Control group	15	4	7	4	73.33	26.67
Treatment group	15	10	4	1	93.33	66.67*

Table 2: Comparison of clinical efficacy of physical and chemical indexes between the two groups.

Note: Compared with control group, *P<0.05.

TCM symptom scores

Comparison of TCM symptom scores between two groups After 12 weeks of treatment, the total effective rate of the treatment group was better than that of the control group Group, the difference was statistically significant. The effective rate of treatment group was higher than that of control group, and the difference was statistically significant (P<0.05). See Table 3.

Group	n	Significant	Effective	Invalid	Effective rate%	Significant rate%
Control group	15	5	8	2	86.67	33.33
Treatment group	15	11	3	1	86.67	73.33*

Table 3: Comparison of curative effect of TCM symptom score between the two groups.

Note: Compared with control group, *P<0.05.

Physical and chemical indexes before and after treatment

There was no significant difference in body mass index, fasting blood glucose, postprandial blood glucose, triglyceride and high density lipoprotein levels between the two groups before treatment.

After treatment, the body mass index, fasting blood glucose, 2h postprandial blood glucose and triglyceride in the two groups were lower than those before treatment (P<0.05). High density lipoprotein was higher than that before treatment. The improvement degree of the treatment group was better than that of the control group (P<0.05). See Table 4.

Group		BMI (kg/m ²)	FPG (mmol/L)	2hPG (mmol/L)	TG (mmol/L)	HDL-C (mmol/L)
Control group	Before	27.36±2.13	9.10±3.34	10.30±3.01	2.65±1.44	1.18±0.28
	After	26.03±2.14 [#]	6.24±0.58 [#]	6.71±1.42 [#]	1.57±0.52 [#]	1.31±0.45
Treatment group	Before	27.15±2.28	9.11±2.98	10.71±3.63	2.51±1.42	1.19±0.31
	After	24.93±1.62 [#]	6.04±0.75 [#]	6.23±1.01 [#]	1.37±0.43 [#]	1.36±0.38

Table 4: Comparison of physical and chemical indexes before and after treatment.

Note: [#]P<0.05 compared with that before treatment. Compared with the control group, *P<0.05.

Discussion

The onset of MS is a chronic and progressive process, which is difficult to be detected in the early stage and easily missed diagnosis. Most of them have entered the middle and late stage when they were discovered. At this time, many concomitant diseases such as type 2 diabetes, hypertension, cardiovascular diseases and chronic kidney diseases often appeared. Therefore, early intervention treatment of MS is very important to improve prognosis and quality of life. Dietary fiber, as a substance in food, has been proved to be effective in preventing and treating MS in many studies^(5, 11-13). After 4 months of intensive intervention with dietary fiber, BMI, waist-hip ratio, TC, LDL-C, postprandial blood glucose and visceral fat index in the treatment group were significantly improved compared with those in the control group⁽¹⁴⁾; in terms of symptom improvement, studies have shown that water-soluble dietary fiber can significantly improve symptoms of patients with chronic transit constipation, shorten transit time of colon, regulate intestinal flora and maintain intestinal microecology, and shorten treatment cycle. Considering its mechanism of action, water-soluble dietary fiber can undergo glycolysis reaction in colon, and produce short-chain fatty acids, which can promote the growth of probiotics such as *Bifidobacterium* and *Lactobacillus* in intestinal tract, and promote the normal peristalsis of colon by improving intestinal probiotics⁽¹⁵⁻¹⁷⁾.

This study aims to observe the therapeutic effect of natural medicine and food in MS. Dietary fiber (DF), proposed by Chinese Nutrition Society, refers to indigestible carbohydrates in plant food or raw materials, which have glycosidic bond >3 , can not be digested and absorbed by human small intestine, and have health significance for human body, including some non-starch polysaccharides (cellulose, hemicellulose, lignin, plant mucilage, pectin, etc.), resistant starch, dextran and other oligosaccharides, etc. Dietary fiber can be divided into two categories: water-insoluble and water-soluble. The dietary fiber selected in this study is water-soluble dietary fiber, which is extracted from plants and belongs to natural medicinal food in essence.

The concept of homology of medicine and food can be traced back to ancient times. Literally, homology of medicine and food means that medicine and food have the same origin. As far as traditional Chinese medicine is concerned, there is no absolute dividing line between medicine and food. Many

medicines are foods and have satiety; Many foods are drugs themselves, which have the effect of curing diseases. After the stage of germination-development-prosperity-all-round development-perfection, it has become a major feature of ancient Chinese medical theory and an important part of Chinese food culture⁽¹⁸⁾.

The dietotherapy prescription used in this study is based on the theory that the nature and taste of traditional Chinese medicine return to the meridian, the four natures and five flavors and the homology of medicine and food, aiming at exploring the advantages of traditional Chinese medicine in treating MS through the partial matching of food materials with basic treatment. Taking MS of liver-stomach stagnation type as an example, liver belongs to wood, spleen and stomach belong to soil, liver and spleen function is out of balance, and it is common to have stagnation of soil and stagnation of liver and stomach. Its pathogenesis includes stagnation of fire in shaoyang, disadvantage of cardinal, dryness in Yangming and stagnation of fu-qi⁽¹⁹⁾.

Clinical Guide to Medical Cases Three Elimination" contains: "Mood depression, internal fire spontaneous combustion, is a serious illness." Depression and anger hurt the liver, and the liver qi stagnated, resulting in long-term depression, fever, internal burning, burning of lung and stomach yin and fluid, resulting in consumptive thirst. Heat hurts yin fluid and essence in the stomach, resulting in dry mouth; The liver is in charge of relieving diarrhea, the spleen and stomach are in charge of transporting and transforming water and dampness, the two viscera are damaged, the metabolism of water and liquid is disordered, and the transportation and transformation have no right.

There is a phenomenon that liver and stomach stagnate heat and injure yin⁽⁸⁾. In treatment, prescriptions for relieving liver and stomach stagnation heat, such as Major Bupleurum Decoction, are mainly bitter and cold, mainly entering the liver, stomach and large intestine meridians, dredging fu-organs to relieve heat, and less pungent and warm products, which are pungent and bitter, and regulate qi activity; collect drugs with acid, astringe yin to prevent consumption of yin fluid; Bitter is the opposite of sweetness, acid is the neutralization of sweetness, and the combination of bitter and acid is the natural partner of hypoglycemic, which has a good curative effect on hypoglycemic⁽⁸⁾, while hyperglycemia often exists in MS. The overall medication choice integrates pungent taste, relieving bitterness, clear-

ing stomach, and making sweet taste with bitter and acid taste. The pungent taste warms the spleen and eliminates dampness, while the bitter taste clears the stagnation of fire in the stomach, while the hard combination relieves stagnation of fire and removes blood stasis⁽²⁰⁾.

The composition of the dietotherapy prescription is guided by the theory of Chinese medicine, and the ingredients with therapeutic effect are selected and made into formula granules. It is pointed out in "The Theory of Su Wen Zhi Zhen Da Lun" that "cold syndrome should be treated with heating therapy, while heat syndrome should be treated with cooling therapy". Taking MS with liver and stomach stagnation as an example, hot diseases should be mainly treated with cold food.

According to the theory of meridian tropism, heat is in the liver and stomach, and it is advisable to enter the liver and stomach meridians; In addition, according to the compatibility of traditional Chinese medicine, it is possible to use less pungent and warm herbs, and to relieve bitterness and regulate qi activity; collect drugs with acid, astringe yin to prevent consumption of yin fluid; bitter is the opposite of sweetness, acid is the neutralization of sweetness, and the combination of bitter and acid helps to lower blood sugar. Referring to Major Bupleurum Decoction, combined with the theory above, bitter gourd, aloe and cassia seed are the main dietotherapy prescriptions: bitter gourd is bitter and cold, and belongs to stomach and spleen meridians; aloe vera is bitter and cold, and it belongs to the liver and large intestine⁽²¹⁾; cassia seed is bitter and cold, and belongs to liver and large intestine meridian⁽²¹⁾; the three are used together to clear the heat of liver and stomach, relieve heat and relieve internal organs; with yellow mustard seed used as medicine and food, it is warm and pungent in nature and belongs to the lung and stomach meridians; Hawthorn is warm and sour, belonging to spleen, stomach and liver meridians⁽²¹⁾; Areca nut tastes bitter, pungent and warm, and belongs to the stomach and large intestine⁽²¹⁾; lotus leaf tastes bitter and flat, and belongs to liver, spleen and stomach meridians⁽²¹⁾; Jujube is sweet and warm, belonging to spleen, stomach and heart meridian⁽²¹⁾; Ginger is warm and belongs to lung, spleen and stomach meridians⁽²¹⁾.

All the ingredients are used together, and they play the roles of pungency disperses while bitterness descends, relieving stagnation, clearing the stomach, neutralizing bitterness and sour with sweetness. According to the formula of Major Bupleurum De-

coction, the food materials with corresponding properties and tastes are selected, and the granules are prepared, the harms are removed, and the properties are selected. Patients with stagnation of heat in liver and stomach often suffer from constipation, halitosis and insomnia. In improving symptoms, Cassia seed may regulate the content of vasoactive intestinal polypeptide (VIP), down-regulate the myoelectric activity of colon and the expression of aquaporin 3 (AQP3), reduce the absorption of water in colon, reduce the edema of intestinal wall, improve the sensitivity of intestinal mucosa, and stimulate the intestinal mucosa and increase intestinal peristalsis by increasing the volume of intestinal contents, thus alleviating slow transit constipation in mice⁽²²⁾.

Aloe-emodin can relieve constipation in mice, and its mechanism may be realized by raising substance P (SP) and VIP in mice colon⁽²³⁾. "Introduction to Medicine" contains: "People with bad breath have hot stomach"; patients with liver-stomach stagnation heat syndrome have bitter taste, upset, impatience and irritability. In fact, liver depression can not rise, qi activity is abnormal, which affects the harmony and decline of stomach, qi stagnation in middle-jiao, and heat is turned over for a long time, and halitosis can be seen due to accumulated heat fumigation.

Therefore, in the treatment, cassia seed and aloe clear heat and drain liver; Lotus leaf is similar to agastache rugosa and Eupatorium adenophorum, and it has the effects of removing filth, clearing away dampness and removing turbidity⁽²⁴⁾. Studies have shown that a proper dose of jujube polysaccharide can improve the sleeping time of mice, prolong the sleeping time, and help relieve fatigue⁽²⁵⁾.

In terms of physical and chemical indicators, modern studies have shown that *Momordica charantia* has hypoglycemic effect⁽²⁶⁻²⁸⁾, and experimental studies have confirmed that total saponins of *Momordica charantia*, the main component of *Momordica charantia*, can improve insulin resistance and lower blood sugar in type 2 diabetic rats⁽²⁹⁾. Meta-analysis of many literatures shows that aloe can reduce blood sugar in diabetic rats to a certain extent⁽³⁰⁾. Cassia seed has the functions of lowering blood pressure, regulating fat, lowering cholesterol and triglyceride, and raising high density lipoprotein⁽³¹⁾. Arecoline, the main component of betel nut, can improve the disorder of glucose and lipid metabolism in type 2 diabetes mellitus⁽³²⁾. Hawthorn total flavonoids has a mechanism similar to calcium antagonist, and can reduce angiotensin level, so it can lower blood pressure; hawthorn pectin pentose, hawthorn flavonoids

and other components can reduce blood lipid and resist arteriosclerosis; Hawthorn can also reduce blood sugar and insulin resistance⁽³³⁾. Lotus leaf has significant lipid-lowering and weight-reducing effects⁽³⁴⁾. Yellow mustard seed contains sinapine thiocyanate, which has antihypertensive effect⁽³⁵⁾.

Conclusion

Efficacy of physical and chemical indexes

The obvious efficiency of natural medicine and food adjuvant therapy for MS with liver and stomach stagnation heat represented by dietary fiber and dietotherapy prescription is better than that of standard treatment control group, which shows that natural medicine and food adjuvant therapy for MS can improve the curative effect, which coincides with modern pharmacological research.

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