

Clinical Study on Treatment of Sjogren's Syndrome by Combination of Chinese Traditional Medicine

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To investigate the curative effects on patients with Sjogren's syndrome (SS) treated with traditional Chinese medicine and three forms of prepared western medicine transfer factor. 126 patients with Sjogren's syndrome were divided into three groups randomly. A group was treated to take xue fu zhu yu oral liquid and transfer factor hypodermic injection. B group was treated to take xue fu zhu yu oral liquid and transfer factor oral liquid. C group was treated to take xue fu zhu yu oral liquid and transfer factor capsules. The effective rate for three groups were respectively 85.7% and 83.3% and 80.9%. No obvious change, not found recurrence cases. There is no significant difference between the three groups ($P > 0.05$). There is no significant difference between the three curative effects.

Key words: Sjogren's syndrome (SS) ; Transfer factor ; Xue fu zhu yu ; Clinical study.

Drying syndrome (Sjogren's syndrome, SS) is a common own immune deficiency disorder, major violations WaiFenBi glands, including lacrimal and salivary gland, cause dry eye dry mouth. Clinical patients have saliva and tear secretion reduce, performance for the eyes and mouth dry. Drying syndrome is a kind of systemic disease, glands of the viscera as respiratory tract, enteron, kidneys, muscles, joints, blood vessels may also be involvement, cause a variety of clinical manifestations. Because of the salivary gland lesions and appear dry mouth, multiple dental caries, mumps wait for a symptom, called dry mouth disease. Affected by lacrimal that found the sticky secretion) decreased, thus presents dry eyes, foreign body sensation, less the symptom such as tears, called dry eye syndrome. Drying syndrome can exist alone can also occur in another clear diagnosis of autoimmune diseases, the former called primary drying syndrome, the latter is called secondary drying syndrome. At present the treatment of western medicine means of a single, mostly with replacement therapy as the main

treatment method, if there is a system damage criterion with glucocorticoid and immunosuppressant therapy. Traditional Chinese medicine treatment of sjogren's syndrome is one of the features of our country, there has been a large number of traditional Chinese medicine treatment of sjogren's syndrome study published randomized controlled trials, but its overall quality how is not clear. In the past 9 years, we use the method of combining traditional Chinese and western medicine treatment for this disease, effectively improving symptoms. In the present study, the traditional Chinese medicine combined with three types of transfer factor were utilized to treat drying syndrome, to evaluatethe clinical curative effect .

MATERIALS AND METHODS

Materials

In this paper, the 126 cases of primary drying syndrome patients, randomly divided into three groups with 42 each group, with clinical observation and comparative analysis; among them 16 male, 110 female, age 30-80 years old, 0.5-16 years history.

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Into and exclusion standard**Inclusion criteria standard:**

Western medicine diagnosis accord with the 2008's preliminary study of primary sjogren's syndrome PSS international diagnosis classification standard¹; Chinese medicine diagnosis accord with the syndrome of deficiency of both qi and blood diagnosis stemdord from "Practical doctor of traditional Chinese medicine rheumatology"². If some has two symptom of the mouth, eye, rheumatoid arthritis ,he world be diagnosed with SS^{1,2}.

Exclusion standard (systemic or local interference factors)

- 1) Patients with parotid gland enlargement in 49 cases, the throyh CT examination, swollen glands, eliminating space-occupying lesions.
- 2) For nearly three months pationts who have taken slow action drugs and non-steroidal anti-inflammatory drug ;
- 3) On pationts who have drug allergy;
- 4) Pationts who have fundus lesions;
- 5) Pationts who merges pulmonary infection, kidney and other important organs damage .

Literature exclusion standard

- 1) Repeatiny classic works;
- 2) The clinical literature of the sjogren's syndrome's treatment which has non-chinese medicine participation.

Methods**Inspection Methods**

Schirmer's Test: with shi mo's Test (Schirmer/s Test) check the lacrimal secrete a function. In natural light, with 35 mm x 5 mm of filter paper, with the end in 5 mm fold, fold in the palpebral conjunctiva sac disposal of the third and third in the border, the eyes closed for five minutes, take off the filter paper, filter paper length measurement moist. If less than or equal to 8 mm is determined asabnormalities.

VitC Test

The hollow improved sugar test was used to determine salivary gland secretion. The fruit of VitC 0.1 g/piece, placed in patients with back 1/3 junction central tongue center. During the examination, patients are not allowed to talk, eat, drink, move tongue back tablets, saliva can swallow. The evaluation is sugar melt completely in 30 min: normal, more than 30 min: The used time

of this group patients is 60 ~ 480min. Unusual the histopathological examination: regular disinfection art district, local anesthesia slice take her lower lip gland organization, doctors diagnosed after pathologists check.

Immunological tests

Humoral immune function, lymphatic cellular immune function, fight nuclear antibody, the resistance, resistance to SSA antibody SSB antibody.

Observation Indicators

The blood, urine, and dung routine before and after treatment; The examination of cardiac, liver, kidney function.

Treatment

The 126 cases were randomly divided into three groups with 42 each group.

Group A

TF injection, (xian gold flower enterprise group Co., LTD , approved by the H20013360), specifications, the Chinese peptide, 3 mg 100 DNA ug), 3 times per day, 2 capsules each time oral; + therapeutic oral liquid, (jilin AoDong yanbian pharmaceutical company, approved by the Z10950063) twice per day, 10 ml each time, oral.

Group B

TF oral liquid, (xian gold flower enterprise group Co., LTD approved by H20013288 100 mg of peptides, 300 DNA ug) twice a day, 10 ml each time oral; + therapeutic oral liquid, (jilin AoDong yanbian pharmaceutical company, approved by Z10950063) twice a day, , 10 ml each time, oral.

Group C

TF capsule, subcutaneous injection (specifications 3 mg of peptides, 100 ug DNA), twice per week, every time two (each equivalent to 1 x 10⁹ white blood cells extract); + therapeutic oral liquid, (jilin AoDong yanbian pharmaceutical company, approved by the Z10950063) twice a day, every day, 10 ml each time, oral.

Three groups of patients followed the doctor's instructions, month period of treatment, each course review 1 time, test salivary glands and lacrimal secrete function were evaluated in 1 month follow-up. Six course evaluation results. Total follow-up time for nine years.

Curative effect sex observation

- 1) The clinical presentations of the first onset: such as mouth and eye dry, joint pain, skin lesions etc.

- 2) The clinical presentations in treatment: mouth and eye dry, enlargement of parotid gland , rampant caries, etc.
- 3) The main symptoms change before and after treatment: Such as xerocheilia ,thirsty to drink, dry eye.
- 4) Tongue demonstration and water consumption changes before and after treatment. d\$Laboratory tests: RFOANA0SSA/SSB0ESR0IgG0IgA0IgM.

Curative effect observation

Curative effect evaluation standard consults “Chinese traditional medicine new drug clinical research guiding principle” in the treatment of rheumatism therapeutic effect evaluation standard for^[3] are as follows:

Cure

The symptoms of mouth and eye dry disappeared (improvement rate e”95%), peripheral duct expansion degree reduced significantly in Parotid combats, the other symptoms of the whole body improved; the results of lab tests improved wholly.

Show effect

The symptoms of mouth and eye dry disappeared basically and improved obviously (improvement rate ≥ 50%), peripheral duct expansion degree reduced, in parotid contrast, the other symptoms of the whole body improved; more than 2 results of the lab tests improved.

Effect

The symptoms of mouth and eye dry changed for the better (improvement rate ≥30%);peripheral duct expansion degree changed a litte in parotid contrast ,one or two indicate of lab tests improved .

Invalid

The symptoms of mouth and eye dry for the before and after treatment, (improvement rate < 30%); Parotid gland imaging peripheral duct expansion degree is changeless, The laboratory

test results no improvement. The whole period namely mouth dry, eye dry, joint pain score, after averaging period additive.

Statistical methods

Application SPSS10.0 software for data statistical analysis. According to the results of clinical symptoms, schirmer’s test and VitC test rate classified treatment comparison have been proceeded, record the percentage. Between-group comparison uses chi-square test, when P>0.05, it has statistical significance (Table 1).

RESULTS

Treatment outcome after six courses

Three groups results

GroupA’s total effective rate is 85.71%, GroupB’s total effective rate is 83.33%, GroupC’s total effective rate is 80.95%. The comparisons of three groups’(recovery+Powerfully + effective) total effective rate have no significant difference (P > 0.05), so we think they have statistical significance. Table 2.

Treatment outcome after 3 years

Three groups of results (recovery + powerfully + effective) A group total effective rate 85.7%, the total effective rate 83.3%, group B C group total effective rate 80.9%. Comparing the result of three groups have no obvious difference (P > 0.05), thought to have statistical significance. Table 3.

Treatment outcome after 3-9 years

3-9 years after curative effect evaluation

Three groups of results A group total effective rate 85.7%, the total effective rate 83.3%, group B C group total effective rate 80.9%. Comparing the result of three groups have no obvious difference (P > 0.05), thought to have statistical significance. Table 4.

Nine years later three groups treatment effect (recovery + powerfully) number contrast.

Table 1. Clinical Curative Standard

Therapy effect	Symptoms	Shi mo’s tes	Contain VitC test
The aluminium wheels	disappear	>10mm/5min	< 30min/0.1g
Show effect	Significantly reduce	7 ~ 9/5min	31 ~ 50min/0.1g
Good turn	Slightly reduce	4 ~ 6/5min	51 ~ 80min/0.1g
No effect	No change or worsen	0 ~ 3mm/min	> 81min/0.1g

Table 2. The Number Comparison of Three Groups' Treatment Effect After Six Courses (%)

Therapy effect	Group A n (42)	Group B n = 42 (%)	Group C = 42 (%)
Thealuminium wheels	5(11.90%)	4(9.52%)	3(7.14%)
Show effect	20(47.62%)	19(45.24%)	18(42.86%)
Good turn	11 (26.19%)	12(28.57%)	13(30.95%)
The total effective rate	36(85.71%)	35(83.33%)	34(80.95%)
No effect	6(14.29%)	7(16.67%)	8(19.00%)
\$plan	42(100%)	42(100%)	42(100%)

Table 3. Three Treatment Group Contrast Effect Number After 3Years (%)

Therapy effect	Group A n=42 (%)	Group B n=42 (%)	Group C n=42 (%)
Thealuminium wheels	7 (19.44%)	6 (17.14%)	5 (14.7%)
Show effect	20 (55.56%)	19 (54.29%)	18 (52.94%)
Good turn	9 (25.0%)	10 (28.57%)	11 (32.35%)
The total effective rate	36 (85.7%)	35 (83.3%)	34 (80.9%)
No effect	6 (14.3%)	7 (16.7%)	8 (19.1%)
\$plan	42 (100%)	42 (100%)	42 (100%)

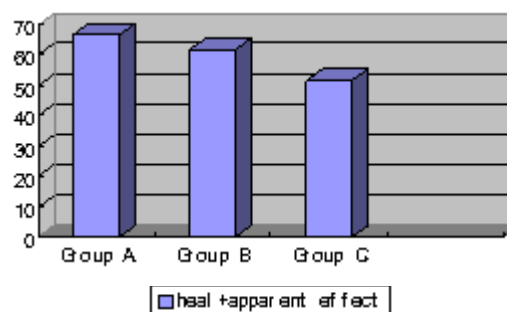
Table 4. Three Treatment Group Contrast Effect Number After 3-9 Years (%)

Therapy effect	Group A n=42 (%)	Group B n=42 (%)	Group C n=42 (%)
Thealuminium wheels	11 (26.2%)	10 (23.8%)	10 (23.8%)
Show effect	17 (40.5%)	16 (38.1%)	14 (33.3%)
Good turn	8 (19.0%)	9 (21.4%)	10 (23.8%)
The total effective rate	36 (85.7%)	35 (83.3%)	34 (80.9%)
No effect	6 (14.3%)	7 (16.7%)	8 (19.1%)
\$plan	42 (100%)	42 (100%)	42 (100%)

DISCUSSION

TCM Syndrome Differentiation of Making

XuZhiHong's study shows that the disease for blood loss, stagnation qi stagnancy and blood stasis, the immune function is low. Remove blood stasis, and do the gas should nourish "Yin" and nourish dryness, improve microcirculation for therapeutic⁴. In addition, some clinical characteristics and other connective tissue disease phase overlap, the general and local performance is diversity, Many good hair at secretion in change period, physiological functions, as immune function decline after middle-aged women, rates ranging from 0.5 ~ 3%⁵. The ratio of men to women is about 1:9 ~ 10⁶. Drying syndrome of traditional Chinese medicine "dry disease" category, when is "fire dry", Yin to dry for the root cause, for the agent's liver and kidney root. And the two buccal biaoben huanji enlargement "bag piece; Yu fire dry Yin, dry mouth

**Fig. 1.** 3-9 years later three groups treatment effect comparison number (%)

Gan Yan; Blood stasis, operation, blood, body fluid in the not reach, so drink does not quench thirst; XieKui Yin deficiency, blood without a leader, so see dizzy, inspect content is bad; Blood without a liver, eyes moisten so lost eye, dry without tears, photophobia eye red; Blood stasis on skin, hair spot, color of skin dark.⁷ WongFangShi etc⁸ the disease will be divided into four type: (1) Yin hot

and dry type;(2) qi and Yin deficiency type; (3) blood stasis block type, (4) hot and humid stasis type. LiGuiAn etc^[9] the disease will be divided into four type: (1) the dry gas type lung injury, to appropriate the clear lung dryness, fluids, cough. Party to clear dry save lung tonga minus. (2) the spleen and stomach Yin deficiency type, to appropriate tonifying spleen benefit stomach fluids, thirst. Party to benefit stomach soup taste. (3) liver-kidney Yin deficiency type, treat liver and kidney function, the appropriate zi Yin bright eye. Party to qi chrysanthemum hope to add and subtract. (4) qi and Yin deficiency type, to appropriate tonifying qi and Yin, fluids, dryness, square to pulse promoting drink flavored.

This paper used the party containing the modified oral liquid 11 taste Chinese medicine: raw land, angelica, sichuan arch, peachseed beef shanks, root, ZhiKe, balloonflower, radix, liquorice.

So cool blood heat. Angelica raises blood dryness, go and do not hurt the Yin blood sedimentation. ShuGan antipyretic samples. Sichuan arch, peachseed root four taste medicine administering blood sedimentation line. The remove blood stasis and beef shanks blood lead blood to the downside. ZhiKe, balloon flower thoracotomy gas line, make prudent blood flow line is angry machine, namely "gas for the blood is handsome line blood line" of the mechanism. The medicine with licorice. In short, and come to the new, blood biochemical for Tianjin night, so that all the parts of the dry and eliminate symptoms.

The Modern Medical Research

Domestic and foreign scholars generally think that the occurrence of sjogren's syndrome has much to do with autoimmunity, endocrine, heredity, virus infection, hormone, etc. The exact cause is not clear. Drying syndrome is a major involvement WaiFenBi gland of chronic inflammatory autoimmune diseases. It is always found in the persons who are middle age, or older, meanwhile 90% of them are female, Breaking performances are eye dry, mouth and nose dry, no tears, (if condition aggravation) no saliva, and eating along with water some female patients may have vagina dry and always feel very painful. Clinical unless the salivary glands and lacrimal damaged and appear dry mouth, and dry eye outside, still have more involvement of system. It is a diffuse connective tissue disease. The disease

can exist alone become primary drying syndrome, and also be associated with hair another clear diagnosis of autoimmune diseases, such as systemic lupus erythematosus, rheumatoid arthritis, systemic sclerosis, etc. Says secondary drying syndrome. Because of the salivary gland lesions and appear dry mouth, multiple dental caries, mumps wait for a symptom, called dry mouth disease. Affected by lacrimal that found the sticky secretion) decreased, thus presents dry eyes, foreign body sensation, less the symptom such as tears, called dry eye syndrome. If two symptoms of mouth dry, eye dry, rheumatoid arthritis exist, it can be diagnosed as sjogren's syndrome. Patients labtests always have, do normal and cellular immunity. Such as sedimentation speed-raising, serum gamma globulin, immunoglobulin G significant rise, complement low and so on. The early disease easily ignored, early treatment is very key.

Because of drying syndrome so far is still not completely clear, drying syndrome as an autoimmune disease, there are two major kinds of features: (1) WaiFenBi glands of lymphocyte assault embellish, mainly is T lymphocytes assault embellish; (2) the B lymphocytes high reactivity, for the performance of the peripheral blood and damage to local appear a variety of auto-antibodies⁸.

The laboratory test showed that, humoral immune function hyperthyroidism, lymphocytes immune function is low. Transfer factor (Transfer factor TF) to the body's immune function has two-way adjustment function, enhance meshy endodermis system to gobble up the function, make lymphatic active cells increased, killer functions strengthened, by inhibiting hyperthyroidism humoral immune, improve the low cellular immunity, make the body's immune system to balance⁹.

Transfer factor (Transfer factor TF) capsules, oral liquid and injection, from health pigs or cow spleen as raw material, make including peptide, amino acid and more nucleotide, etc.; A variety of immune adjustment factor were found in TF, can be the donor lymphocyte some special or non-specific immune cells to transfer receptor, in order to improve the patients and triggered the body's immune defense function, improving the body's immune status.

The study found the drug clinical

symptom relief or disappears; Laboratory two checks, according to the results of the body's immune system to keep the two in the normal balance state. According to Table 2, table 3, contrast the effective number of the three groups, with treatment extended, recovery and significant efficiency gradually increasing; Total effective rate have no obvious change, recovery and significant efficiency increase gradually. Table 3 shows, 3-9 years later Three dosage form factor combined proprietary Chinese medicine liquid transfer modified treatment drying syndrome curative effect do not show statistical difference ($P > 0.05$). That figure 1, 3-9 years later recovered and significant efficiency, A group of 29 cases, accounting for 66.7%; B group of 26 cases, accounting for 61.9%; C group of 24 cases, accounting for 57.1%; In short, invalid number did not increase.

The treatment effect of three groups shows that, there are no recurrence cases. But in clinical, oral transfer factor capsule or oral liquid, already safety goes to the lavatory again, to avoid the injection pain to patients. At the same time give clinical work provided convenience. The effective prescription treatment of sjogren's syndrome who are many, but only observe curative effect in the near future, we should strengthen the long-term outcome of tracking observation, in order to comprehensively evaluate the curative effect of justice.

Affect Curative Effect factors

Clinical observation of the past few years, the author thinks that the disease and age of onset, medical history, has a direct bearing on course. In short, heal age cases under 50 years old, the history in the six months to 3 years of light patients. Invalid cases are 70 years old and the history of over 10 years' heavy patients. Course lasting 2~16 years. Two groups of patients have no significant difference in gender, age, course of disease. Therefore, the authors found early detection, early diagnosis and early treatment are the keys to improve the curative effects. Older, medical history long heavy patients hope to extend the use of time, can improve the therapeutic effect. After nearly nine years of clinical tracking follow-up, to the clinical cure after withdrawal, 1-2 years and recurrence of 5 cases, to continue using combine traditional Chinese and western medicine treatment

method of the drug, still a satisfactory curative effect. We will continue to study after combining traditional Chinese and western medicine treatment drying syndrome, for longer periods, prevent recurrence and reach the purpose of can completely healed. Make the organization pathology and immunology abnormal completely normal.

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