Clinical Study

Observation on clinical effects of acupoint thread-embedding method for non-alcoholic fatty liver disease

穴位埋线治疗非酒精性脂肪性肝病临床疗效观察

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Abstract

Objective: To observe the clinical effects of acupoint thread-embedding method for non-alcoholic fatty liver disease (NAFLD) in pattern of liver qi stagnation and spleen deficiency.

Methods: A total of 180 cases in conformity with the diagnostic criteria of NAFLD in pattern of liver qi stagnation and spleen deficiency were randomly divided into a treatment group and a control group, 90 cases in each group, and finally 88 cases in the treatment group and 90 cases in the control group were recruited for statistics. The treatment group was managed by acupoint thread-embedding method, and the control group was treated by oral administration of Polyene Phosphatidylcholine capsules. Both groups were treated for 6 months. Before and after the treatment, liver enzymology, blood fat test, abdominal B ultrasonic examination, and assessment of clinical effects were respectively processed.

Results: After treatment, alanine transaminase (ALT), aspartate transaminase (AST), total cholesterol (TC), and triglyceride (TG) decreased in the treatment group, and were significantly different from those in the control group after treatment (all P < 0.05). There was no statistically significant inter-group difference in the degree of fatty liver (by B ultrasound examination) before treatment (P > 0.05). After treatment, the improvement degree of fatty liver in the treatment group was more significant than that in the control group (P < 0.05). The total effective rates were 89.8% in the treatment group and 76.7% in the control group, with a statistically significant difference between the two groups (P < 0.05).

Conclusion: The acupoint thread-embedding method can reduce the levels of ALT, AST, TC and TG in NAFLD patients, and can improve the pathologic degree of fatty liver and its clinical effects are remarkably better than that of oral medications.

Keywords: Acupoint Therapy; Embedding Therapy; Liver-qi Stagnation and Spleen Deficiency; Non-alcoholic Fatty Liver Disease; Syndrome Differentiation Treatment

【摘要】目的:观察穴位埋线对肝郁脾虚证型非酒精性脂肪性肝病(non-alcoholic fatty liver disease, NAFLD)的临床 疗效。方法:将180 例符合纳入标准的肝郁脾虚证型 NAFLD 患者随机分为治疗组和对照组,每组90 例,最终纳入 统计治疗组88 例,对照组90 例。治疗组采用局部穴位埋线,对照组给予口服多烯磷酯酰胆碱胶囊,两组均治疗6 个月,治疗前后分别检测肝脏酶学及血脂检测、腹部 B 超及评价两组临床疗效。结果:治疗后治疗组血清谷丙转 氨酶(alanine transaminase, ALT)、谷草转氨酶(aspartate transaminase, AST)、总胆固醇(total cholesterol, TC)、甘油三 酯(triglyceride, TG)水平均较本组治疗前下降,且与对照组治疗后差异有统计学意义(均 P<0.05)。治疗前两组患者 腹部 B 超检查显示脂肪肝的程度接近,差异无统计学意义(P>0.05);治疗后治疗组脂肪肝的改善程度较对照组显 著,组间差异有统计学意义(P<0.05)。治疗组总有效率为 89.8%,对照组为 76.7%,组间差异有统计学意义 (P<0.05)。结论:穴位埋线可降低 NAFLD 患者 ALT、AST、TC 和 TG 水平,显著改善脂肪肝病变程度,且临床疗效 显著优于口服药物。

【关键词】穴位疗法; 埋藏疗法; 肝郁脾虚; 非酒精性脂肪性肝病; 辨证论治 【中图分类号】R246.1 【文献标志码】A

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Non-alcoholic fatty liver disease (NAFLD) is a metabolic stress-induced liver injury closely associated with insulin resistance and genetic susceptibility. The disease tends to increase in its incidence annually and now has become the second major liver disease threatening the human healthy. Currently, there is no specific therapy for it. It is believed by the medical practitioners of the modern times that liver qi stagnation and spleen deficiency are the basic pathogenesis of NAFLD. Pattern of liver qi stagnation and spleen deficiency of NAFLD in pattern of liver qi stagnation and spleen deficiency from July of 2012 to June of 2014. Now, the report is given as follows.

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Diagnostic criteria of Western medicine^[4]

No history of alcoholic drinking or alcoholic drinking in less than 140 g/week of alcohol volume; exclusion of fatty liver caused by viral hepatitis, drug-inudced liver diseases, total parenteral nutrition, hepatolenticular degeneration, autoimmune liver disease; non-specific symptoms and signs such as lassitude, indigestion, insidious pain in the liver area and hepatosplenomegaly besides the clinical manifestations of the primary disease; metabolic syndrome-related components including overwight and (or) visceral obesity, increased fasting glucose, blood fat metabolic disturbance, and hypertension; mild and moderate elevation (less than the upper limit of five-time normal value) of serumalanine transaminase (ALT), aspartate transaminase (AST) levels, usually ALT elevation in predominance: liver imaging manifestation in conformity with the diagnostic criteria of diffuse fatty liver disease; histological change of liver biopsy in conformity with the pathological diagnosis of fatty liver.

The diagnosis could be made if the above 1-5 items and 6th or 7th item were present.

1.1.2 Criteria of pattern identification in traditional Chinese medicine $(TCM)^{[5]}$

The patterns were identified based upon the main points of the pattern of liver qi stagnation and spleen deficiency.

Major symptoms: Distending and full sensation or wandering pain in the right hypochondriac region, frequently induced by vexation and anger, a pale tongue with teeth marks, and a thin and white or greasy tongue coating.

Minor symptoms: Abdominal distension, loose stools, abdominal pain for diarrhea, listlessness,

lassitude, depression, worries, frequent sighing, a wiry or thready pulse.

Pattern of liver qi stagnation and spleen deficiency could be identified if over two items of the major symptoms and minor symptoms were present.

1.2 Inclusion criteria

In conformity with the above diagnostic criteria and criteria of TCM pattern identification, at the age of 18-60 years old; without administration of medications for fatty liver in the recent four weeks; willing to participate in the study and having signed informed consent.

1.3 Exclusion criteria

In conformity with the observing and inclusion criteria but at the age below 18 or above 60; women in pregnancy or lactation, and those allergic to absorbable surgical sutures; blood platelet count $<80\times10^9/L$; severe impairment of hepatic functions [total bilirubin (TBIL)>51 µmol/L, ALT>400 U/L, AST>400 U/L] and patients with liver cirrhosis; those trying body weight reduction or other clinical trials within 3 months; those taking ursodesoxycholic acid and oxalic acid agents or vitamin E; those unable to follow the stipulated treatment or those with incomplete data, which might influence the therapeutic evaluation; and diabetics.

1.4 Statistical methods

The SPSS 13.0 version statistical software was used for data processing, with α =0.05. The data were expressed by mean ± standard deviation (\overline{x} ±s). The measuring data were analyzed by *t*-test. The counting data were processed by Chi-square test.

1.5 General data

In accordance with the inclusion criteria, totally 180 cases of NAFLD patients in pattern of liver qi stagnation and spleen deficiency were selected from the Gastroenterology and Acupuncture Departments of the three hospitals and were divided into a treatment group and a control group by random digital table, 90 cases in each group. Because 2 cases dropped out in the treatment group, finally 88 cases were recruited for statistics. Please see Figure 1 for clinical management, in comparison of the general data in the patients between the two groups, the differences were not statistically significant (all P > 0.05), indicating the comparability (Table 1).

Table 1.	. Compariso	on of general	data of the	two groups	$(\overline{x} \pm s)$
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C		Gender (case)		Mean age	Mean duration	
Groups	п	Male	Female	$(\overline{x} \pm s, year)$	$(\overline{x} \pm s, \text{month})$	
Treatment	88	37	51	46.2±12.6	17.5±3.2	
Control	90	36	54	43.8±16.3	16.8±3.6	



Figure 1. Clinical management process

2 Treatment Methods

2.1 Treatment group

Acupoints: Bilateral Ganshu (BL 18), Taichong (LR 3), Fenglong (ST 40), Zusanli (ST 36), Sanyinjiao (SP 6), in alternative use of the two sides.

Tools: Thread-embedding needle was made of No.7 disposable sterile syringe as the needle tube and flat needle (Jiachen brand, Jiachen Acupuncture Instrument Co. Ltd., Wujiang, China) of 0.30 mm in diameter and 42 mm in length as the needle core. A medical absorbable surgical suture (Model 3-0, Sino-foreign Joint Hangzhou Huawei Medical Appliance Co., Ltd., China) about 1 cm was input into the needle tube, with the suture end at the same level of the needle.

Method: After the patient took a supine position with the lower limbs exposed and Zusanli (ST 36), Fenglong (ST 40) and Sanyinjiao (SP 6) were located, 0.5% lodophor solution was applied to the above areas for an outward circular disinfection. By tightening the topical skin of the acupoint with the left hand and holding the thread-embedding needle with the right hand, the doctor quickly inserted the needle perpendicularly into the acupoint, in depth of about 1.5-3 cm, to the muscle layer, by manipulating the needle with lifting, thrusting and twisting technique. When the patient felt a sore, distending and numb sensation, the doctor pushed the needle core to implant the suture into the acupoint, and then took out the needle. If no suture end was seen outside, the acupoint was covered with a piece of band-aid. After the local skin of Taizhong (LR 3) was disinfected, and 2% Lidocaine was injected into the skin of the acupoint for subcutaneous anesthesia, the needle was inserted for embedding the thread by the above method. After the patient was told to take a prone position, Ganshu (BL 18) was located and managed for embedding the thread by the above method. The needle was inserted, with a 45° angle to

the skin, toward the spine. Ganshu (BL 18), Taichong (LR 3), Fenglong (ST 40) and Susanli (ST 36) were punctured with the reducing method by the lifting, trusting and twisting technique. Sanyinjiao (SP 6) was punctured with the reinforcing method. Bath was not advisable in the day of thread embedding. The thread-embedding method was given once every seven days.

2.2 Control group

In accordance with 2010 revised-edition of Diagnostic and Therapeutic Guideline of Non-alcoholic Fatty Liver Disease^[6], Polyene Phosphatidylcholine capsules were recommended for oral administration. Polyene Phosphatidylcholine capsules (each capsule contains 228 mg of Polyene Phosphatidylcholine, Beijing Aventis Pharmaceutical Co., Ltd.) were given for oral administration after meal, 2 capsules each time, 3 times per day.

The therapeutic effects were assessed after the treatment for 6 months in the two groups.

3 Therapeutic Effects and Results

3.1 Test items

3.1.1 Liver enzymology and blood lipid test

The levels of ALT, AST, total cholesterol (TC) and triglyceride (TG) were tested respectively before and after treatment.

3.1.2 Abdominal B ultrasonic examination

B ultrasonic examination was used to judge the mild, moderate and severe fatty liver^[7]: ① diffuse echo was enhanced in the near area of the liver (stronger than the kidney and spleen) and reduced gradually in the far area; ② the intrahepatic duct structure was not showed clearly; ③ The liver was enlarged in mild and moderate degree, with round and dull marginal angle; ④ color Doppler blood flow image indicated the decrease or difficult display of intrahepatic color blood flow signals, but the courses of intrahepatic vessels were normal; ⑤ the echo display from the capsule of the right robe of the liver and diaphragm was not clear or not complete.

Mild fatty liver was diagnosed based upon ① and one item of 2-@. Moderate fatty liver was diagnosed based upon ① and two items of 2-@. Severe fatty liver was diagnosed based upon ①, two items of 2-@, and 5.

The abdominal B ultrasonic examination was performed in the two groups before and after treatment.

3.2 Criteria of therapeutic effects^[5]

Cure: Clinical symptoms and signs disappeared. Liver enzymology (ALT, AST) and blood lipid (TC, TG) went back to normal. B ultrasonic examination showed that the liver morphology and parenchyma went back to normal.

Remarkable effect: Clinical symptoms and signs disappeared basically. ALT decreased \geq 50%. Blood lipid was improved in TC decreased \geq 20% or TG decreased \geq 40%. B ultrasonic examination indicated the reduction of two grades, from severe degree to mild degree.

Effect: Clinical symptoms and signs disappeared partially. ALT decreased by >30%, but <50%. Blood lipid was improved in TC decreased by \ge 10% but <20% or TG decreased by \ge 20% but <40%. B ultrasonic examination indicated that severe fatty liver dropped down to moderate degree or moderate fatty liver dropped down to mild condition.

Failure: The symptoms and signs were not alleviated obviously. ALT decreased by < 30%. There was no obvious improvement in blood lipid. B ultrasonic examination indicated no change in the degree of fatty liver.

3.3 Therapeutic results

3.3.1 Comparison of liver enzymology and blood lipid

between the two groups

The values of ALT and AST, TC and TG were close to those before treatment in the two groups, without statistically significant differences (all P>0.05). After treatment, in the treatment group, ALT, AST, TC and TG were decreased significantly than those before

treatment, and with statistically significant differences in comparison with those in the control group (all P < 0.05). The findings indicated that the treatment group had better effects in decreasing ALT, AST, TC and TG than the control group (Table 2).

3.3.2 Comparison of the results of abdominal B ultrasonic examinations between the two groups

Before treatment, B ultrasonic examinations of the abdomen indicated the fatty liver degrees of patients in the two groups were close, without statistically significant difference (P>0.05). After treatment, fatty liver degree was improved remarkably in the treatment group than that in the control group, with a statistically significant difference (P<0.05). The findings indicated that the treatment group could remarkably improve the severity of fatty liver in the patients with NAFLD (Table 3).

3.3.3 Comparison of clinical effects between the two groups

The total effective rate was 89.8% in the treatment group, obviously higher than that in the control group, with a statistically significant difference (P < 0.05), indicating that the clinical effect was remarkably better in the treatment group than in the control group (Table 4).

Table 2. (Comparison of liver enzym	ology and blood lipid lev	el before and after the treatmen	t between the two groups ($\overline{x} \pm s$)
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Groups	n	Time	ALT (U/L)	AST (U/L)	TC (mmol/L)	TG (mmol/L)
Treatment 88	00	Before treatment	76.13±24.20	63.52±18.41	6.36±1.23	2.96±0.28
	88	After treatment	$36.81{\pm}20.50^{1)2)}$	31.57±12.32 ¹⁾²⁾	$3.57 \pm 0.72^{(1)2)}$	$1.37 \pm 0.12^{1)2)}$
Control	90	Before treatment	78.26±21.07	65.34±16.25	6.12±1.07	2.90±0.33
		After treatment	53.13±22.32	49.61±11.58	5.30±0.65	2.26±0.18

Note: Compared with the same group before treatment, 1) $P \le 0.05$; compared with the control group after treatment, 2) $P \le 0.05$

Table 3. Comparison of abdominal B ultrasonic examinations results before and after treatment between the	two groups
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Groups	n	Time	Normal	Mild	Moderate	Severe
	00	Before treatment	0	29	43	16
Treatment	After treatment 26^{1} 36^{1}	36 ¹⁾	22 ¹⁾	4 ¹⁾		
Control	00	Before treatment	0	28	45	17
	90	After treatment	13	30	35	12

Note: Compared with the control group, 1) P < 0.05

Table 4. Comparison of clinical effects between the two groups (case)

Group	п	Cure	Remarkable effect	Effect	Failure	Total effective rate (%)
Treatment	88	26	36	17	9	89.8 ¹⁾
Control	90	13	27	29	21	76.7

Note: Compared with the control group, 1) $P \le 0.05$

4 Discussion

NAFLD is a commonly and frequently encountered disease in clinic and belongs to the scope of 'liver lump', 'hypochondriac pain' and 'masses' in TCM. It was first recorded in Nan Jing (Classic of Difficult Issues), also termed literally Fei (fat) Qi disease, referring to the accumulation of the internal fat in the liver. The pathomechanism of this condition lies in liver qi stagnation coupled with spleen deficiency. Emotional distress may cause liver gi stagnation. The stagnant liver gi may affect the transportation and transformation of the spleen. causing internal turbid-dampness. Alternatively, improper diet may damage the spleen and stomach, resulting in turbid-dampness. The impaired spleen may affect the function of the liver in maintaining the free flow of gi, further leading to turbid-dampness, phlegm and stasis. In summary, this condition is located in the liver but associated with the spleen, stomach and kidney. Its contributing factors include phlegm, turbid-dampness and stasis. The root cause of this condition is deficiency of the spleen and kidney. However, patients often manifest as phlegm and stasis^[5-6]. Consequently, the treatment strategies are to soothe liver qi, strengthen the spleen and resolve dampness and phlegm. Acupoint thread-embedding method is a new acupoint- stimulating therapy, integrating acupuncture, thread- embedding method and bleeding method together and producing the multiple stimulating effects, characterized by the advantages of strong stimulation, persistent effect and no obvious adverse reaction^[7-9]. Ganshu (BL 18) is the Back-Shu point of the liver. It is said in Su Wen (Essential Questions): 'yang is treated for yin problem', indicating that Ganshu (BL 18) can be used to treat its corresponding liver disease. Taichong (LR 3) is the Yuan-Primary point of the Liver Meridian of Foot Jueyin, and is an important acupoint to soothe the liver and regulate qi. Fenglong (ST 40) is the Luo-Connecting point of the Stomach Meridian of Foot Yangming and is an important acupoint to treat phlegm, for dissolving visible and invisible phlegm, and to regulate the spleen and stomach, promote transportation and transformation, and remove turbid phlegm for eradicating the source of phlegm production. Zusanli (ST 36) is the He-Sea point of the stomach, good at regulating the spleen and stomach functions and building up the postnatal foundation. Sanyinjiao (SP 6) is an important acupoint of the Spleen Meridian of Foot Taiyin and is also an intersecting point of the three foot meridians, having the effects to regulate the liver and spleen, strengthen the spleen and replenish the kidney, dissolve phlegm and dredge the collaterals. Zusanli (ST 36) is combined with Sanyinjiao (SP 6) to strengthen the spleen, benefit qi and regulate the spleen and stomach. It has been proven by the studies in the

modern times that electric stimulation at Ganshu (BL 18) and Taichong (LR 3) can obviously improve the liver functions of the patients with non-alcoholic steatohepatitis, reduce blood lipids and resist hepatic fibrosis^[10-12]. Acupuncture at Fenglong (ST 40) can decrease TC contents in serum. Acupuncture or thread embedding at Zusanli (ST 36) can reduce TC, TG levels in serum^[13-15]. Acupuncture or moxibustion or thread embedding at Sanyinjiao (SP 6) can produce the effects to reduce serum TC, TG and low-density lipoprotein cholestero (LDL-C)^[16-19]. The above acupoints are combined appropriately targeting the pathogenesis of this disease, jointly producing the effects to soothe the liver, regulate qi, eliminate qi stagnation, strengthen the spleen, remove dampness and dissolve phlegm.

This study indicates that acupoint thread-embedding method can reduce the levels of ALT, AST, TC and TG, relieve the severity of fatty liver, remarkably better than oral administration of Polyene Phosphatidylcholine capsules in the therapeutic effects, indicating that this therapy is better in the therapeutic effects and worthy of clinical popularization and application.

Conflict of Interest

The authors declared that there was no conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from all individual participants included in this study.

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