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Clinical Research on the Comprehensive Curative Effect of Acupuncture and Traditional Chinese Medicine for Pelvic Inflammatory Sequelae

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ACDEF 1,2 Penyuan Mao
BD 3 Shujie Liu
EF 1 Jianguo Xue
AE 4 Yuejun Wu

AEG 1,5 Changqing Wang

- 1 Institute of Literature in Chinese Medicine, Nanjing University of Traditional Chinese Medicine (TCM), Nanjing, Jiangsu, P.R. China
- 2 Department of Human Affairs, Obstetrics and Gynecology Hospital Affiliated to Nanjing Medical University, Nanjing, Jiangsu, P.R. China
- 3 Department of Traditional Chinese Medicine (TCM), Obstetrics and Gynecology Hospital Affiliated to Nanjing Medical University, Nanjing, Jiangsu, P.R. China
- 4 Clinical Laboratory, Jiangsu Province Hospital of Traditional Chinese Medicine (TCM), Nanjing, Jiangsu, P.R. China
- 5 School of Health Policy and Management, Nanjing Medical University, Nanjing, Jiangsu, P.R. China

Corresponding Authors: Source of support: Yuejun Wu, e-mail: yangniu1845@sina.com, Changqing Wang, e-mail: cqwang@njmu.edu.cn

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Background:

This randomized, controlled trial was designed to assess whether acupuncture plus an oral administration of Chinese herbal medicine provides greater relief of symptoms than oral administration of Chinese herbal medicine alone for treatment of pelvic inflammatory sequelae.

Material/Methods:

Sixty-two patients ages 22 to 45 years with pelvic inflammatory sequelae were randomly assigned into one of 2 groups: an herbal group (n=30) and an herbal with acupuncture group (n=32). Both groups were treated for 3 courses of 3 months each.

Results:

Significant improvement of clinical symptoms and signs of pelvic inflammatory sequelae occurred in both treatment groups. The total effective rate for the herbal group was 83.33%, and for the herbal with acupuncture group it was 100% (P=0.354 for difference between groups). During treatment, 5 patients had adverse reactions of nausea, loss of appetite, and diarrhea. After adjustment of the herb prescription, all adverse reactions

Conclusions:

Our results highlight the benefit of oral administration of Chinese herbal medicine along with acupuncture; this had a greater clinical curative effect rate than oral administration of Chinese herbal medicine alone when treating pelvic inflammatory sequelae.

MeSH Keywords:

Acupuncture • Clinical Research • Herbal • Pelvic Inflammatory Sequelae • Traditional Chinese Medicine

Full-text PDF:

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Background

Pelvic inflammatory sequelae (PIS) is a condition in which female pelvic organs, surrounding connective tissue, and pelvic peritoneum become chronically inflamed; it can occur when acute pelvic inflammation is not thoroughly treated or a patient with a weak constitution has a long course of disease [1]. PIS is a common and frequently-occurring gynecological disease that may include chronic endometritis, chronic salpingitis, ovaritis, and chronic connective tissue inflammation. PIS is also a common cause of heterotopic pregnancy, infertility, pelvic pain, and pelvic adhesion disease. It not only causes great pain, but also has a serious effect on women's physical and mental health due the repeated nature of its attacks.

Symptoms vary extensively and, as a result, large-scale epidemiological data are lacking [2]. Western medicine's use of antibiotics is not always effective in treating PIS. However, traditional Chinese medicinal herbal treatment is effective and advantageous for treating infertility, chronic pelvic pain, and other chronic diseases in clinical application [3]. Traditional Chinese medicine suggests that the pathogenesis of PIS involves non-closed uterine orifice, weakened immune systems, wind-cold and dampness-heat, or wind pathogen invasion after menstrual period and delivery, all of which can suppress positive vibrations, wind pathogen stagnates in the uterus and competes with positive vibrations, which further consume gi and blood, and the disease can attack repeatedly and be difficult to cure [4]. The treatment of PIS and dampnessheat in the lower energizer should focus mainly on clearing heat and promoting diuresis, dispersing blood stasis, and relieving pain. Acupuncture therapy can stimulate faster blood flow, improve pelvic hemorheology, improve thick, sticky, coagulant and gathering conditions of blood, improve microcirculation, promote tissue repair and regeneration, accelerate loosening of adhesive connective tissue, and regulate the immune function of the body [5].

In December 2015, we initiated a prospective randomized controlled trial in China to assess the effectiveness of acupuncture combined with oral administration of traditional Chinese medicinal herbs for treatment of PIS.

Material and Methods

Participants and ethics

Our institution obtained ethics approval from the Institutional Ethics Review Board before recruiting patients. All patients were recruited from traditional Chinese medicine acupuncture gynecological clinics of the institutions from December 2015 to October 2017.

Diagnostic criteria

All 62 patients in the study had a history of antibiotic use without improvement of PIS; more than half had a history of acute pelvic inflammation, and most complained of lower abdominal and low back pain. The lower abdomen felt full on occasion, often after labor or intercourse, discomfort that was aggravated during defecation or menstruation, and increased leukorrhea and menstruation were present (Table 1).

The above clinical examination results match those indicated by *Obstetrics and Gynecology* (8th Edition) of the People's Medical Publishing House (PMPH), 258–264 [2].

Symptoms were irregular menstruation and leukorrhagia, with low-grade fever, hypogastralgia, lumbago, lower abdomen pain, and lumbosacral soreness, which may be aggravated by fatigue, sexual intercourse, and defecation. Gynecologic examination revealed that the uterus had restricted movement or fixed adhesions. Palpable bar and cord-like objects can be felt on one or both sides of the uterus if salpingitis was present, along with mild tenderness; bearing down pain and tenderness may occur on one or both sides of the uterus if pelvic parametritis is present; an enclosed mass may be felt on one or both sides of the pelvic cavity. Auxiliary examination used ultrasonography to exclude tumors and other lesions.

Primary index

The specific standard for diagnosis of pelvic inflammation includes endometritis confirmed with endometrial biopsy histology and transvaginal ultrasonography, or an MRI that shows the fallopian tubes that are thickened and have hydrops, with or without pelvic effusion and tubal ovarian mass or laparoscopy-detected signs of pelvic inflammation. However, brightness-mode ultrasonic examination was universally used in clinical diagnosis due to the invasiveness or high cost of the aforementioned procedures [2]. Therefore, ultrasonic examination was the primary index for our research.

Inclusion criteria

Pelvic inflammatory disease occurs most commonly in sexually active menstruating women and is less common in women who are not sexually active, have not yet begun menstruation, or are post-menopause. It typically results from the spread of adjacent organ inflammation [2], and based on this, the age range of participants was set as 22–45 years. Patients with irregular menstruation, dysmenorrhea, pelvic venous congestion syndrome, endometriosis, adenomyoma of uterus, and other reproductive organ conditions were excluded from the study, as were those unwilling to participate or who withdrew from the study at any time (Figure 1).

 Table 1. Demographic characteristics of the subjects.

Variables	Acupuncture	Acupuncture and Herbal group			P	
Subjects (n)						
All	32		30		0,80	
Age (y)						
Mean (±SD)	30.3±8.1		29.8±8.5		0,81	
Disease course (m)						
Mean (±SD)	3.	6±1.4	3.4±1.5		0,59	
Abortion history						
Yes	32	(100.00)	30 (100.00)		1,00	
No	0	(0.00)	0	(0.00)		
Childbearing history						
Yes	27	(84.38)	26	(86.67)	1,00	
No	5	(15.62)	4	(13.33)		
Menorrhagia, n (%)						
Never	2	(6.25)	3	(10.00)	0.05	
Rarely	9	(28.12)	7	(23.33)	0,85	
Frequently	21	(65.63)	20	(66.67)		
Low-grade fever						
Yes	2	(6.25)	1	(3.33)	1,00	
No	30	(93.75)	29	(96.67)		
Leukorrhagia						
Yes	28	28 (87.50)		(90.00)	1,00	
No	4	(12.50)	3	(10.00)		
Hypogastralgia, n (%)						
Yes	7	(21.88)	6	(20.00)	1,00	
No	25	(78.12)	24	(80.00)		
Dyspareunia, n (%)						
Never	1	(3.13)	0	(0.00)	0.04	
Rarely	26	(81.25)	28	(93.33)	0,34	
Frequently	5	(15.62)	2	(6.67)		
Abdominal tenderness, n (%)						
Yes	30	30 (93.75)		29 (96.67)		
No	2	(6.25)	1	(3.33)		
ndometritis, n (%)						
Yes	6	(18.75)	6	(20.00)	1,00	
No	26	(81.25)	24	(80.00)		

Table 1 continued. Demographic characteristics of the subjects.

Variables	Acupuncture a	and Herbal group	Herb	Р	
Salpingitis, n (%)					
Yes	15	(46.87)	15	(50.00)	1,00
No	17	(53.13)	15	(50.00)	
Pelvic drops, n (%)					
Yes	4	(12.50)	4	(13.33)	1,00
No	28	(87.50)	26	(86.67)	
Pelvic connective tissue inflammation, n (%)					
Yes	4	(12.50)	3	(10.00)	1,00
No	28	(87.50)	27	(90.00)	
Salpingo-ovaritis					
Yes	2	(6.25)	1	(3.33)	1,00
No	30	(93.75)	29	(96.67)	
Cystic salpinx					
Yes	1	(3.13)	1	(3.33)	1,00
No	31	(96.87)	29	(96.67)	

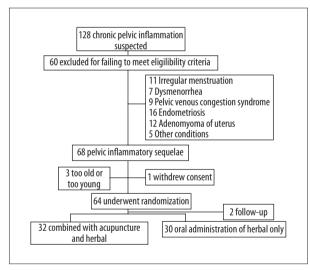


Figure 1. Profiles of enrollment, screening, and randomization.

Study procedures

Patients participating were randomly assigned to one of 2 groups by means of a computer-generated, random-numbers list using block randomization stratified by center. The 2 groups included an herbal group and an acupuncture plus herbal group. The block size was unknown to study center personnel. Participants, health-care providers, and outcome adjudicators were all blind to treatment allocations, but data analysts were not.

Given ethical consideration, we included both treatments for 3 courses of therapy in each group. In the herbal group, patients were treated with an oral administration of traditional Chinese medicine for 9 months. In the acupuncture plus herbal group, patients received both acupuncture and oral administration of traditional Chinese medicine, also of 9 months. The 2 treatments were done sequentially at the same visit.

Herbal group

Treatment was an oral administration of traditional Chinese medicine that included: 15 g Sargent gloryvine, 15 g Herba patriniae, 10 g Semen coicis, 10 g Cortex ailanthi, 10 g Rhizoma cyperi, 10 g Rhizoma corydalis, 10 g Szechwan chinaberry fruit, 10 g Semen litchi, 10 g Semen citri reticulatae, 10 g powder for dissipating blood stasis, 10 g beautiful sweetgum fruit, 10 g Rhizoma acori graminei, 10 g Eucommia ulmoides, and 10 g Radix dipsaci. The following adjustments were made according to specific symptoms: for patients with a deficiency of vital energy, we added 10 g Astragalus membranaceus, and 10 g Codonopsis pilosula; for patients with severe soreness of waist, we added 10 g parasitic Loranthus, 10 g Eucommia ulmoides, and 10 g Radix dipsaci; for patients with poor appetite: added 3 g Endothelium corneum gigeriae galli and 10 g raw malt; for patients with gastral cavity pantothenic acid, we added 15 g Calcined corrugating; and for patients with acute pain, we added 6 g frankincense and 6 g myrrh. All traditional

Chinese medicine was in a granular form (Jiangyin Tianjiang Pharmaceutical Co., Ltd.), and patients were instructed to take it twice daily after mixing with 200 ml warm water, at the beginning and end of the day; half an hour after a meal was recommended. A course of treatment lasted 3 months, and clinical efficacy was measured after 9 months.

Acupuncture with herbal group

The same herbal treatment described above was given in the same manner.

In addition, acupuncture treatment targeted the following acupoints: Guan yuan, Zigong, Xuehai, Zusanli, Yinlingquan, and Sanyinjiao. Zhongwan was added for patients with poor appetite and Shenshu was added for those with a deficiency of kidney energy. Manipulation methods included mild reinforcing and attenuating, with the needle retained for 30 min. To further improve the curative effect, a Xianhe CQ-27 TDP lamp made in Chongqing was used to warm and lubricate channels during acupuncture therapy [6], a practice commonly known as "Shen Deng." The patient was in a supine position, and the lamp positioned over the patient's hypogastric region at a distance of approximately 30 cm; the distance was adjusted to ensure the patient felt comfortably warm.

Patients received alternate day treatment lasting 30 min each time. A course of treatments lasted 3 months and 3 courses were completed. The acupuncture treatment was not given during the menstrual period or if the patient was experiencing an acute attack.

Observation outcomes

Using the curative effect criteria for PIS in *Clinical Guidelines* of New Drugs for Traditional Chinese Medicine [7], observation outcomes were divided as follows.

Primary outcomes

Cure: The clinical symptoms and signs of abdominal distention, swelling pain, and lumbar sacral pain disappeared after treatment; gynecologic examination and B-scan ultrasonography results returned to normal.

Secondary outcomes

Remarkable effect: The clinical symptoms and signs of abdominal distention, swelling pain, and lumbar sacral pain were remarkably alleviated after treatment; gynecologic examination and B-scan ultrasonography results showed minor abnormalities.

Effective: The clinical symptoms and signs of abdominal distention, swelling pain, and lumbar sacral pain were relatively alleviated after treatment; gynecologic examination and B-scan ultrasonography results showed some recovery.

Ineffective: The clinical symptoms and signs of abdominal distention, swelling pain, and lumbar sacral pain remained unchanged after treatment; gynecologic examination and B-scan ultrasonography results were also unchanged.

Total effective rate

Percent effective rate=(number of cure cases + number of remarkable cases + number of effective cases)/(number of cure cases + number of remarkable cases + number of effective cases + number of ineffective cases)*100%.

Sample size

Based on the previously reported morbidity for PIS of 28% [8], we set the permissible error at δ =0.06 and confidence degree as 95%. Therefore, a minimal sample size of 29 per group was needed. We increased the sample size to 32 in each group to account for potential missing data and dropouts during the study course.

Statistical methods

SPSS v. 18.0 software was used for all data analyses. Data are reported as mean \pm SD. Count data are represented by the number of cases or percentages, and the χ^2 test was used to test significance. Statistical significance was set at P<0.05. Where there were few samples, Fisher's exact probability method was used for analysis.

Results

Ultrasonic examination results

Ultrasonography and gynecologic examination results showed significant improvement in the clinical symptoms and signs of pelvic inflammatory sequelae, such as pelvic inflammatory effusions or lumps, uterine activity, and adhesion in the acupuncture plus herbal treatment group (Table 2). The most visually striking results were seen in patients with pelvic hydrops. For example, B-scan ultrasonography of a patient from the acupuncture with herbal group imaged pelvic hydrops=7.77 cm before treatment; after 1 course of treatment (3 months) the depth of water accumulation in her pelvic cavity was reduced to 2.43 cm, and she was in early pregnancy.

 Table 2. Comparison of curative effect.

Variables	Acupuncture and Herbal group			Herbal group		P	
subjects (n)							
All		32			30	0,80	
Menstrual blood volume, n (%)							
Menorrhagia		28	(87.50)	23	(76.67)	0.42	
Eumenorrhea		4	(12.50)	7	(23.33)	0,43	
Low-grade fever, n (%)							
Yes		0	(0.00)	1	(3.33)	1,00	
No		32	(100.00)	29	(96.67)		
eukorrhagia, n(%)							
Yes		2	(6.25)	5	(16.67)	0,37	
No		30	(93.75)	25	(83.33)		
Hypogastralgia, n (%)							
Yes		1	(3.13)	2	(6.67)	0,61	
No		31	(96.87)	28	(93.33)		
Dyspareunia, n (%)							
Never		2	(6.25)	1	(3.33)	1,00	
Rarely		28	(87.5)	27	(90.00)	1,00	
Frequently		2	(6.25	2	(6.67)		
Abdominal tenderness, n (%)							
Yes		2	(6.25)	6	(20.00)	0,14	
No		30	(93.75)	24	(80.00)		
Endometritis, n (%)							
Cure, n (%)		0	(0.00)	0	(0.00)		
Remarkable effect, n (%)	(12.5)	4	(1	(3.33)	0,24	
Effectiveness, n (%)		2	(6.25)	5	(16.67)		
Ineffectiveness, n (%)		0	(0.00)	0	(0.00)		
Salpingitis, n (%)							
cure, n (%)		0	(0.00)	0	(0.00)		
Remarkable effect, n (%)		10	(31.25)	4	(13.33)	0,09	
Effectiveness, n (%)		5	(15.63)	9	(30.00)		
Ineffectiveness, n (%)		0	(0.00)	2	(6.67)		

Table 2 continued. Comparison of curative effect.

Variables	Acupuncture a	nd Herbal group	Herbal group		P
Pelvic Drops, n (%)					
Cure, n (%)	1	(3.13)	0	(0.00)	
Remarkable effect, n (%)	3	(9.38)	1	(3.33)	0,26
Effectiveness, n (%)	0	(0.00)	2	(6.67)	
Ineffectiveness, n (%)	0	(0.00)	1	(3.33)	
Pelvic connective tissue inflammation, n (%)					
Cure, n (%)	0	(0.00)	0	(0.00)	
Remarkable effect, n (%)	2	(6.25)	1	(3.33)	1,00
Effectiveness, n (%)	2	(6.25)	1	(3.33)	
Ineffectiveness, n (%)	0	(0.00)	1	(3.33)	
Salpingo-ovaritis					
Cure, n (%)	0	(0.00)	0	(0.00)	
Remarkable effect, n (%)	1	(3.13)	0	(0.00)	1,00
Effectiveness, n (%)	1	(3.13)	0	(0.00)	
Ineffectiveness, n (%)	0	(0.00)	1	(3.33)	
Cystic salpinx					
Cure, n (%)	0	(0.00)	1	(3.33)	
Remarkable effect, n (%)	0	(0.00)	0	(0.00)	1,00
Effectiveness, n (%)	1	(3.13)	0	(0.00)	
Ineffectiveness, n (%)	0	(0.00)	0	(0.00)	

Table 3. Comparison of clinical curative effect between 2 groups [n (%)].

Variables	Herl	bal group	Acupunture	with herbal group	P
Subjects (n)		30		32	
Cure, n (%)	1	(3.33)	1	(3.13)	1.000
Remarkable effect, n (%)	7	(23.33)	20	(62.50)	0.002
Effectiveness, n (%)	17	(56.67)	11	(34.38)	0.078
Ineffectiveness, n (%)	5	(16.67)	0	(0.00)	0.022
Total effective rate, n (%)	25	(83.33)	32	(100.00)	0.354

Clinical curative effect

There were 128 females registered as outpatients with suspected PIS at the traditional Chinese medicine acupuncture gynecological clinic of our institution. Figure 1 presents the patients' screening profiles and the reasons 60 patients were excluded as subjects during the enrolment period. In addition,

3 patients were outside the appropriate age range, and 1 with-drew consent. Thus, 64 females with PIS were included and randomly assigned to the 2 groups, but 2 did not finish all the treatments in the herbal group. After 3 courses of treatments, the total effective rate of acupuncture plus herbal treatment was 100%, while that of the herbal treatment was 83.33% (P=0.354 for difference between groups); the effective rate

of acupuncture plus herbal was significantly higher than for herbal treatment alone (Table 3).

Adverse reactions

During treatment, 5 patients had adverse reactions that included nausea, loss of appetite, and diarrhea. Two of these patients were in the acupuncture plus herbal group and 3 were in the herbal only group; these reactions were discomforts of the digestive tract in response to the orally administered herbal medicines. The oral herb prescription was slightly adjusted for these patients, after which all adverse reactions disappeared.

Discussion

The results of this randomized, controlled trial indicate that traditional Chinese medicine treatments are an effective method for treating PIS. Further, the curative effect rate of acupuncture plus herbal medicine was significantly higher than that of herbal medicine alone.

The benefit of traditional Chinese herbal medicines for treating reproductive organ disease has been observed in other studies. Zhang Li [9] used Sargent gloryvine and Herba patriniae soup to treat 34 patients with obstruction of fallopian tubes, with a total effective rate of 88.24%. Ma et al. [10] used Hu Hongying soup, whose main components are Sargent gloryvine and Herba patriniae, to treat PIS with damp and heat and saw an exact curative effect as well as significant improvement of symptoms and signs. Liang et al. [11] used a Wucao decoction and garlic extract to treat 115 patients with PIS; the Wucao decoction contained ingredients from Herba patriniae and had a total clinical effective rate of 92.2%. Our herbal prescription was also based on the traditional Sargent gloryvine [12] and Herba patriniae soup. Sargent gloryvine has the function of dispelling the wind and killing parasites, activating blood to promote menstruation, relieving internal heat, and detoxifying, and has a relatively strong inhibitory effect on Streptococcus and Staphylococcus aureus. Herba patriniae has the function of breaking up silting and pus, clearing away heat and toxic materials, and significantly inhibits Pseudomonas aeruginosa, Staphylococcus aureus, Typhoid bacillus, Escherichia coli, and Shigella dysenteriae [13,14]. In addition to these herbs, we added Cortex ailanthi to clear heat and promote diuresis; Semen coicis to invigorate the spleen to eliminate dampness; and Rhizoma cyperi, Corydalis tuber, Szechwan chinaberry fruit, and Shixiao powder to promote vital energy, disperse stagnation, and relieve pain. Semen litchi and Semen citri reticulatae were messenger drugs for the liver channel, to allow beautiful sweetgum fruit and Rhizoma acori graminei to strengthen the spleen, expel damp, and relieve pain. Eucommia ulmoides and Radix dipsaci were added for their ability to tonify the

kidneys, strengthen the waist, and relieve pain [15]. In traditional Chinese medicine therapy, acupuncture is used to stimulate specific regions of the body and maximally activate inherent regulatory functions for their beneficial role in recovery. The whole process has features such as bidirectionality, integrality, integrity, and multiple targets [16], that are advantages of acupuncture therapy, but can also cause instability [17]. Acupuncture therapy combined with medicine can overcome this instability and thus effect a permanent cure.

PIS could also be included in the disease categories such as "abdominal mass", "leukorrheal disease," and "woman abdominal pain" [18]. in traditional Chinese medicine, these diseases occur mainly due to the negative influences of dampness and heat, as well as exogenous evil [19]. They can also occur because the patient's body is in a state of weakness, via a mechanism where vital energy is in a state of discord, causing meridian blocking [20]. In addition, emotional pain may lead to the disease due to liver depression. Clinically, acupuncture positions mainly adopt Ren channel, Chong channel, and liver, spleen and kidney meridians, based on the principle of local selecting of acupoints according to channel and for tonification and purgation to occur in combination. The acupoint Sanyinjiao can tonify the spleen, excrete dampness, regulate the liver and kidneys, and is the main acupoint for treating digestive, urinary, and reproductive system diseases, especially gynecological disease. Acupuncture can also enhance human immunocompetence and has obvious regulating effects on the lower energizer. Guanyuan has the function of tonifying flow, regulating the yin channel and blood, and is beneficial in treating irregular menstruation, dysmenorrhea, amenorrhea, morbid leucorrhea, and other symptoms; it is also one of the key acupoints for treating gynecological disease. Xuehai can invigorate and nourish the circulation of blood and regulate menstruation and acupuncturing Yinlingquan can remove dampness and hotness of the spleen meridian. Making full use of all acupoints together can clear heat, promote diuresis, promote blood circulation to remove blood stasis, regulate liver, spleen and kidneys [1], and promote dredging of channels [21].

At the same time, a TDP lamp can promote local blood circulation in the pelvic cavity, improve organizational and nutritional status, boost metabolism, accelerate the movement of the medicine into the lesion, eliminate edema, and relieve uterine smooth muscle spasm, taking advantage of tepid optimal stimulation [22]. Thus, when combined with oral administration of traditional Chinese medicine, this treatment method not only has no pain or adverse effects, but also helps patients avoid dysbacteriosis caused by long-term use of antibiotics. The modification of the herbal prescription from *Sargent gloryvine* and *Herba patriniae*, combined with acupuncture and heat therapy, to treat PIS can improve pelvic blood circulation, accelerate elimination of inflammation, dredge fallopian tube

cavities to avoid re-adherence, and improve local microcirculation, regulating connective tissue metabolism, endocrine and immune function of the body, strengthening the fallopian tube's ability to deliver oosperm, and improving fertilization conditions inside the fallopian tube. Furthermore, it can resolve hard lumps, manage vital energy, activate blood, disperse blood stasis, and relieve pain, clear away heat and toxic materials, promote tissue softening, inhibit proliferation of connective tissue, and promote functional recovery of hardened fallopian tubes to the fullest extent [9].

Traditional Chinese medicine advocates "treatment based on syndrome differentiation", indicating that patients with different corporeity should not be treated according to the same method, even if they have the same disease symptoms [23]. Thus, we propose to enlarge sample collection in future research to increase research value. There is currently no chemical component analysis of *Sargent gloryvine* and *Herba patriniae*, and this requires further research and verification. Long-term clinical practice and retrospective literature reviews show no reports of patients whose hepatic and renal function was damaged by administration of the *Sargent gloryvine* and *Herba patriniae* soup. Moreover, no single herb is used in high doses in Chinese herbal compound prescriptions; reliably sourced

Chinese herbal compound prescriptions will not cause toxicity or adverse effects, and the combination of herbs in one prescriptions can induce effects of interaction, detoxification, and synergy [24]. A liver and kidney function examination index was not included in this study; future studies can include this observational index to more systematically and comprehensively carry out scientific research. In addition, future research can usefully include self-reports and lab tests to allow for better long-term follow-up. Unfortunately, 2 of the 64 patients who completed the screening and met all the requirements abandoned treatment due to job change.

Conclusions

This research demonstrates that traditional Chinese medicine therapy has curative effects on PIS, which can make up for deficiencies in Western drug therapy and is thus worthy of further popularization and use. Our research demonstrates that oral administration of Chinese herbal medicine combined with acupuncture therapy has better clinical curative effect than oral administration of Chinese herbal medicine alone when treating PIS and has few adverse effects. As a result, it has won recognition and a good reputation for success among patients with PIS.

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