

## Original Article

# Cai's gynecology chronic pelvic formula with acupuncture alleviates chronic pelvic pain and reduces recurrence in patients with pelvic inflammatory disease sequelae

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**Abstract:** Objective: To assess the efficacy of Cai's Gynecology Chronic Pelvic Formula combined with acupuncture in managing chronic pelvic pain (CPP) secondary to pelvic inflammatory disease (PID) sequelae, and its effect on recurrence. Methods: A retrospective study assessed medical records from 240 CPP patients undergoing treatment between February 2019 and February 2024. Patients were divided into a control group (standard treatment,  $n = 120$ ) and an observation group (standard treatment plus Cai's Chronic Pelvic Formula combined with acupuncture,  $n = 120$ ), with treatment lasted for 28 days and follow-up for 6 months. The symptom scores (Visual Analog Scale, Self-rating Anxiety Scale and Self-rating Depression Scale), inflammatory markers [C-reactive protein (CRP), tumor necrosis factor-alpha (TNF- $\alpha$ ), interleukin-6 (IL-6), and cancer antigen 125 (CA125)], efficacy rates, and recurrence rates were all employed to measure treatment outcomes. Cox regression was leveraged to identify recurrence risk factors, while a nomogram model was developed and validated by Receiver Operating Characteristic (ROC), calibration curves, and decision curve analysis (DCA). Results: The observation group had significantly lower post-treatment Traditional Chinese Medicine symptom scores, inflammatory markers (CRP:  $P < 0.001$ ; TNF- $\alpha$ :  $P = 0.003$ ; IL-6:  $P = 0.004$ ), and CA125 ( $P < 0.001$ ) versus the control group. The observation group also demonstrated shorter symptom resolution time ( $P < 0.05$ ), with higher total treatment efficacy in comparison to the control group (93.46% vs. 79.70%;  $P = 0.002$ ). In addition, the observation group showed lower recurrence rates (14.2% vs. 28.3%;  $P = 0.008$ ) as well as postponed recurrence time when compared to the control group. Cox regression analysis identified treatment protocol (HR = 0.41, 95% CI: 0.24-0.71), disease duration (HR = 1.32, 95% CI: 1.08-1.62), and pre-treatment CRP level (HR = 1.18, 95% CI: 1.02-1.36) as independent recurrence predictors. In addition, the nomogram demonstrated high accuracy in predicting disease recurrence (C-index = 0.852), with both ROC (AUC = 0.837) and calibration curves confirming its reliability. DCA indicated high clinical net benefit of the studying treatment protocol. Conclusion: Cai's Gynecology Chronic Pelvic Formula combined with acupuncture could significantly alleviate CPP and inflammation, and decrease recurrence rates. The nomogram may be used as a validated tool for predicting the disease recurrence, with benefits when integrated into clinical practice as a novel therapeutic strategy.

**Keywords:** Cai's gynecology chronic pelvic formula, acupuncture, chronic pelvic pain, recurrence rate, clinical efficacy, cox regression analysis

## Introduction

Pelvic Inflammatory Disease (PID) is a prevalent infectious condition primarily resulting from bacterial infections in the female reproductive system. It typically presents as acute

pelvic inflammation, which may progress to a chronic condition in severe or inadequately managed cases, leading to fallopian tube and ovarian structural compromises and chronic pelvic pain (CPP) as long-term sequelae [1, 2]. Of particular clinical significance among these

sequelae is CPP, which profoundly impairs patients' quality of life [3]. Studies have indicated that CPP is highly prevalent, often persistent, and difficult to cure, posing substantial psychological and functional burdens on affected individuals [4].

Conventional treatments for CPP generally include pharmacotherapy, physical therapy, and surgical interventions. However, these approaches frequently yield limited therapeutic outcomes and may be associated with adverse effects [5]. Therefore, the effective management or resolution of CPP remains a major clinical challenge.

In recent years, Traditional Chinese Medicine (TCM) has gained increasing recognition in the treatment of PID and its sequelae. Cai's Gynecology Chronic Pelvic Formula, a classical TCM prescription, has demonstrated notable clinical efficacy and is widely applied in gynecologic practice [6]. This formula functions by regulating Qi and blood, promoting meridian circulation, and modulating endocrine activity, thereby reducing inflammation, alleviating pain, and facilitating recovery [6]. In addition, acupuncture - a key modality within TCM - has been shown to exert significant therapeutic effects on CPP and various disorders in the female reproductive system [7]. By stimulating specific acupoints, acupuncture induces both local and systemic physiologic responses, supporting organ regulation and enhancing the body's innate self-healing capacity.

Despite the clinical potential of both therapies, limited research has focused on the combined application of Cai's Gynecology Chronic Pelvic Formula and acupuncture for CPP management [8]. Existing studies have predominantly evaluated each intervention in isolation. While monotherapies may yield short-term benefits, their effectiveness in addressing the complex etiology of CPP is often insufficient, with high recurrence rates remaining a concern. The pathogenesis of CPP is multifactorial, involving persistent inflammation, neuropathic alterations, endocrine dysregulation, and chronic pelvic tissue injuries.

Cai's Gynecology Chronic Pelvic Formula alleviates pelvic inflammation and improves systemic health by regulating Qi, invigorating blood

flow, and eliminating dampness, thus mitigating chronic pain [9]. Concurrently, acupuncture stimulates targeted acupoints to unblock meridians, regulate internal energy and blood flow, reduce inflammation, and support tissue repair. These actions promote local Qi and blood circulation, relieve muscle tension, and diminish pain symptoms [10]. Therefore, the combination of the two modalities may offer enhanced therapeutic benefits in the treatment of CPP.

This study aims to clinically assess the efficacy of combining Cai's Gynecology Chronic Pelvic Formula with acupuncture in managing PID sequelae, with particular focus on symptom relief and recurrence prevention. Through longitudinal follow-up and data analysis, we sought to determine whether this integrative approach could effectively alleviate CPP, sustain treatment benefits, and reduce disease recurrence rates. The findings of this study may contribute valuable theoretical and practical insights for the clinical application of TCM in CPP management, advancing the integration of TCM into modern medical practice.

## Methods and materials

### Sample size calculation

A sample size was determined using a formula described in a previously-published paper [7], which reported a total effective rate of 70% for the control group and 93% for the observation group. The formula was used to compare the two-sample proportion ( $n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \times (p_1(1 - p_1) + p_2(1 - p_2))}{(p_1 - p_2)^2}$ ). With expected effective rates of the first group  $p_1 = 0.9333$  and the second group  $p_2 = 0.70$ , an  $\alpha$  value of 0.05, and a statistical power ( $\beta$ ) of 0.2, the required sample size per group was calculated to be 40. Considering a 10% dropout rate, the total sample size needed was 88 patients. The final sample size was determined based on actual clinical conditions.

### Case selection

This retrospective study included 240 CPP patients who were treated at Shangluo Traditional Chinese Medicine Hospital between February 2019 and February 2024. The study

was approved by the ethics committee of Shangluo Traditional Chinese Medicine Hospital.

**Inclusion criteria:** Patients were eligible for the study if they were women aged between 18 and 50; they met the diagnostic standards for CPP in both modern medicine and TCM; they had no plans for pregnancy within the following three months; they had a history of sexual activity and no history of uterine or adnexal resection; their medical records were complete.

**Exclusion criteria:** Patients were excluded if they had other known causes of CPP, such as endometriosis or gynecologic tumors; they had a positive cervical smear for pathogens (e.g., *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma hominis*), neurological or psychiatric disorders, recent use (within one month) of antibiotics or similar TCM formulations, and any condition that could interfere with efficacy evaluation. Patients with severe cardiovascular disease, hepatic or renal dysfunction, or other serious comorbidities were also excluded. Individuals with known drug allergies or a history of allergic reactions to the study medications were not eligible for inclusion.

As a result, a total of 240 eligible patients were included and divided into two groups, with 133 undergoing standard treatment only in the control group and 107 receiving standard treatment in addition to Cai's Gynecology Chronic Pelvic Formula combined with acupuncture in the observation group.

### *Treatment protocols*

**Control group:** Patients received standard Western pharmacological therapy, consisting of oral Metronidazole Vitamin B6 tablets (Disha Pharmaceutical Group, Batch No. 201205, 0.2 g/tablet), two tablets each time, twice daily, and oral Levofloxacin Hydrochloride Capsules (Disha Pharmaceutical Group, Batch No. 201102, 0.1 g/capsule), two capsules each time, three times daily. The total treatment duration was 28 days. Patients were advised to abstain from sexual activity during treatment.

**Observation group:** In addition to the conventional Western medications, patients in this

group received acupuncture and Cai's Gynecology Chronic Pelvic Formula. Acupuncture was performed using sterile, disposable needles (Changchun Aikang Medical Instrument Co., Ltd.) at specific acupoints, including Zhongji, Qihai, Guilai, Ganyu, Shenxu, Xuehai, Sanyinjiao, and Taichong. Needle insertion depth ranged from 10-15 mm. Techniques such as lifting-thrusting and twirling were employed until the patient experienced sensations of soreness, numbness, distention, or heaviness. Moxibustion was applied by attaching a moxa stick to the needle handle, maintaining a 2-3 cm distance from the skin for 30 minutes per session. This treatment was performed every other day for 28 days, suspended during menstruation, and resumed three days post-menstruation. Cai's Gynecology Chronic Pelvic Formula included *Chuanlianzi* 10 g, *Beibaijiao* 30 g, *Daxueteng* 15 g, *Mudanpi* 10 g, *Fuling* 12 g, *Guizhi* 3 g, *Chishao* 10 g, *Yanhusuo* 12 g and *Yazi Cao* 15 g. The decoction process involved boiling the herbs in water twice. The first time with 400 mL water to yield 200 mL decoction, and the second with 200 mL water to yield 100 mL decoction. The two decoctions were combined and taken twice daily, one hour after meals, for 28 days. Patients were also advised to avoid sexual activity during this period.

### *Data collection*

Clinical and laboratory data were obtained from outpatient follow-up records and the hospital's electronic medical record system. Clinical data included demographic information (age, BMI, disease duration), social history (marital status, ethnicity, education level, histories of pregnancy, smoking and alcohol consumption), TCM symptom scores (e.g., lower abdominal pain, menstrual irregularities, breast tenderness, fatigue), as well as pain and psychological assessments using Visual Analog Scale (VAS), Self-rating Anxiety Scale (SAS) and Self-rating Depression Scale (SDS). Treatment efficacy was evaluated based on symptom improvement.

Laboratory data included levels of inflammatory biomarkers such as C-reactive protein (CRP), tumor necrosis factor-alpha (TNF- $\alpha$ ), interleukin-6 (IL-6), and cancer antigen 125 (CA125) before and after treatment. Additional indicators included duration of sacral pain, time to

resolution of lower abdominal distension, pelvic mass, and abnormal vaginal discharge. Adverse events were recorded to assess the safety profile of the treatment regimens.

### *Laboratory index testing*

Peripheral venous blood samples (5 mL) were collected after an overnight fast, both before and after the 28-day treatment course. Samples were centrifuged at 1500 rpm for 10 minutes, and the serum was extracted for testing. ELISA kits (Wuhan Sanying, Catalog Nos. KE10128, KE10002, KE10007) were used to measure CRP, TNF- $\alpha$ , and IL-6. CA125 levels were determined by chemiluminescence using the Immulite 2000 analyzer (Siemens, Germany).

### *Functional scoring criteria*

(1) VAS: The scale was used to assess the intensity of pain. It employs a 10 cm line to represent the degree of pain. Patients marked point on the line that corresponds to their pain intensity. The score ranges from 0 to 10, with 0 point indicating "no pain" and 10 points indicating "extreme pain" [11]. (2) SAS: The scale was used to assess anxiety symptoms. It consists of a series of questions concerning patients' anxiety experiences over a period of time. The score ranges from 20 to 100, with 20 indicating no anxiety and 100 indicating severe anxiety [12]. (3) SDS: The scale was employed to assess patients' depressive symptoms. This scale consists of 20 questions regarding patients' recent emotional and behavioral state. The score ranges from 0 to 100, with higher scores indicating severer depressive symptoms [13].

### *TCM symptom scoring*

Based on relevant diagnostic criteria, TCM symptom scores were evaluated in four aspects: lower abdominal pain, menstrual disorders, breast tenderness, and fatigue. Scores were assigned based on severity: 0 (no symptoms), 2 (mild), 4 (moderate), and 6 (severe). Higher scores indicated severer symptoms [14].

### *Clinical efficacy assessment*

Effective rate: (1) Markedly effective: Complete resolution of CPP, normal gynecological exam

results, and ultrasound showing no abnormalities in the uterus or adnexa, with disappearance of pelvic masses and fluids. (2) Effective: Partial alleviation of CPP, improvement in gynecological exam results, and ultrasound showing reduced pelvic masses or fluid accumulation. (3) Ineffective: No improvement in CPP or its clinical indicators. Clinical efficacy = (Markedly effective + Effective)/Total cases  $\times$  100% [15].

### *Follow-up*

Patients were followed up for 6 months to monitor their disease recurrence rate. The first follow up was conducted by telephone 3 months post-treatment to assess changes in patients' conditions. Additional follow-up visit was scheduled at 6 months post-treatment for further evaluation of long-term efficacy and recurrence rates. Recurrence was defined as the reappearance or worsening of related symptoms.

### *Outcome measures*

*Primary outcome measures:* Comparison of clinical efficacy, TCM symptom scores, and prognostic factors influencing recurrence.

*Secondary outcome measures:* Comparison of baseline data, changes in inflammatory markers and CA125, symptom resolution times, changes in VAS, SAS and SDS scores, and adverse reactions. The recurrence nomogram model was constructed and internal verification was carried out.

### *Statistical analysis*

SPSS 27.00 software was used for statistical analysis of categorical and continuous data. Categorical data were compared using Chi-square tests. Continuous data were tested for normality using the Kolmogorov-Smirnov test, and normal distributed data were analyzed using independent t-tests, while non-normal data were analyzed with the rank-sum test. Repeated Measures ANOVA was used for group comparisons, with Tukey's post-hoc test for multiple comparisons. Survival analysis and recurrence rate analysis were conducted using R 4.3.3 software. Cumulative Incidence Function was used to evaluate survival curves, and Cox regression analysis was employed to assess the impact of related factors on prognosis. Nomograms were constructed using the

**Table 1.** Comparison of baseline data between the observation group and the control group

Variable	Total (n = 240)	Control Group (n = 133)	Observation Group (n = 107)	Statistic Value	P Value
Age (years)	35.08 ± 7.06	34.95 ± 7.44	35.23 ± 6.59	0.312	0.756
BMI (kg/m <sup>2</sup> )	23.13 ± 3.16	23.21 ± 3.31	23.02 ± 2.97	-0.47	0.639
Disease Duration (months)	15.03 ± 5.22	15.01 ± 5.19	15.05 ± 5.28	0.058	0.954
Marital Status					
Married	220	124	96	0.958	0.328
Unmarried	20	9	11		
Ethnicity					
Han	229	126	103	0.315	0.574
Other	11	7	4		
Education Level					
Junior High School	58	28	30	1.579	0.454
High School	104	60	44		
University or Higher	78	45	33		
Pregnancy History					
Yes	207	112	95	1.046	0.306
No	33	21	12		
Smoking History					
Yes	78	47	31	1.096	0.295
No	162	86	76		
Alcohol History					
Yes	39	20	19	0.322	0.57
No	201	113	88		

Note: BMI: Body Mass Index.

rms package to predict survival probability and recurrence risk based on clinical parameters. The model's performance was evaluated using Receiver Operating Characteristic (ROC) curves, and calibration curves were plotted to assess the agreement between predicted and observed outcomes. Decision Curve Analysis (DCA) was also performed to evaluate the net clinical benefit of the predictive model at different threshold probabilities. Relevant R packages including survival, survminer, patchwork, cowplot, and rms were used for survival analysis, graphical representation, and nomogram construction. All statistical tests were two-sided, and a *P*-value of < 0.05 was considered significant.

## Results

### Baseline data

Baseline data of patients were compared. The results showed that age (*P* = 0.756), BMI (*P* = 0.639), disease duration (*P* = 0.954), marital status (*P* = 0.328), ethnicity (*P* = 0.574), educa-

tion level (*P* = 0.454), pregnancy history (*P* = 0.306), smoking history (*P* = 0.295), and alcohol history (*P* = 0.570) all showed no significant differences (**Table 1**).

### TCM symptom scores

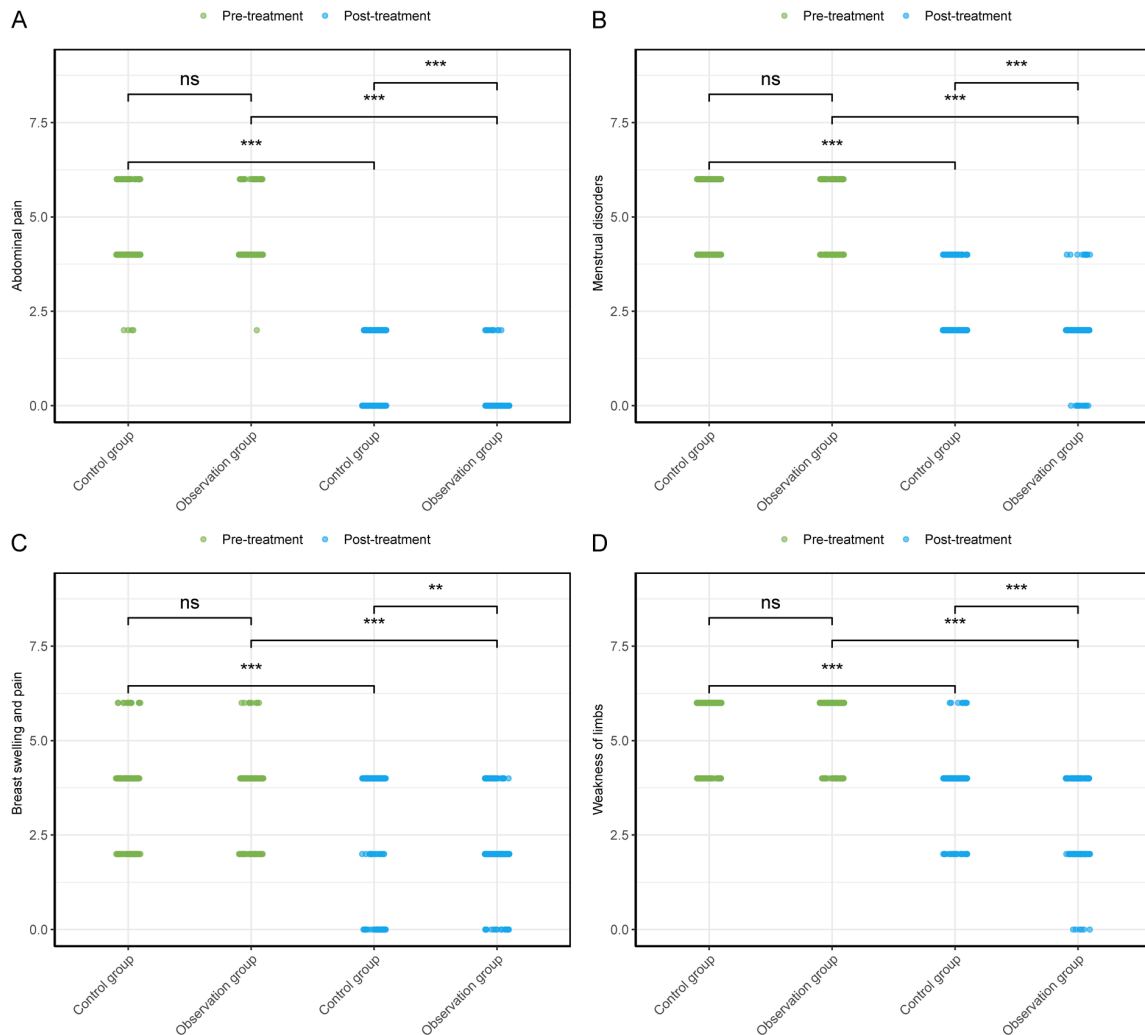
Before treatment: No significant differences in TCM symptom scores (including lower abdominal pain, menstrual irregularities, breast tenderness, and fatigue) were observed between the two groups prior to treatment (*P* > 0.05). After treatment: Both groups exhibited a significant reduction in TCM symptom scores compared to baseline levels (*P* < 0.0001). Between groups: Post-treatment scores for lower abdominal pain, menstrual irregularities, breast tenderness, and fatigue were significantly lower in the observation group than those of the control group (*P* < 0.05) (**Figure 1**).

### Inflammatory markers and CA125 changes

Before treatment: There were no significant differences in CRP, TNF-α, IL-6, or CA125 levels



## Acupuncture and Cai's formula in pelvic disease



**Figure 1.** Changes in TCM symptom scores before and after treatment. A. Changes in lower abdominal pain scores before and after treatment. B. Changes in menstrual disorder scores before and after treatment. C. Changes in breast tenderness scores before and after treatment. D. Changes in fatigue scores before and after treatment. Note: ns  $P > 0.05$ , \*\* $P < 0.01$ , \*\*\* $P < 0.001$ ; TCM: Traditional Chinese Medicine.

between the two groups before treatment ( $P > 0.05$ ). After treatment: Both groups showed significant reductions in CRP, TNF- $\alpha$ , IL-6, and CA125 levels compared to pre-treatment levels ( $P < 0.0001$ ). Between groups: The observation group had significantly lower levels of CRP, TNF- $\alpha$ , IL-6, and CA125 than the control group after treatment ( $P < 0.001$ ) (Figure 2).

### Symptom resolution time

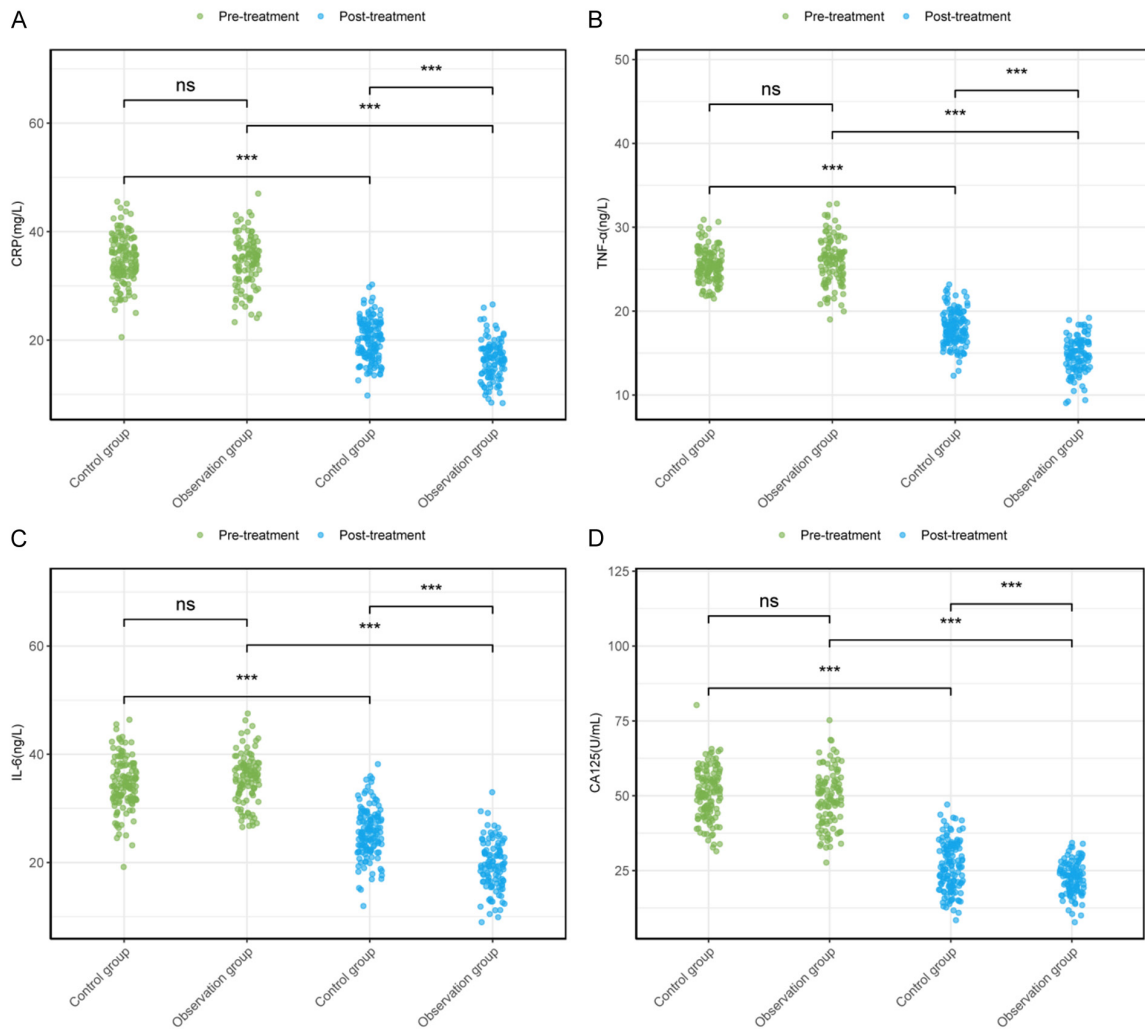
A statistical analysis of symptom resolution time for sacral pain, lower abdominal distension, pelvic mass disappearance, and abnormal vaginal discharge showed that the observation group demonstrated significantly shorter

resolution time for all symptoms compared to the control group (all  $P < 0.0001$ ) (Figure 3).

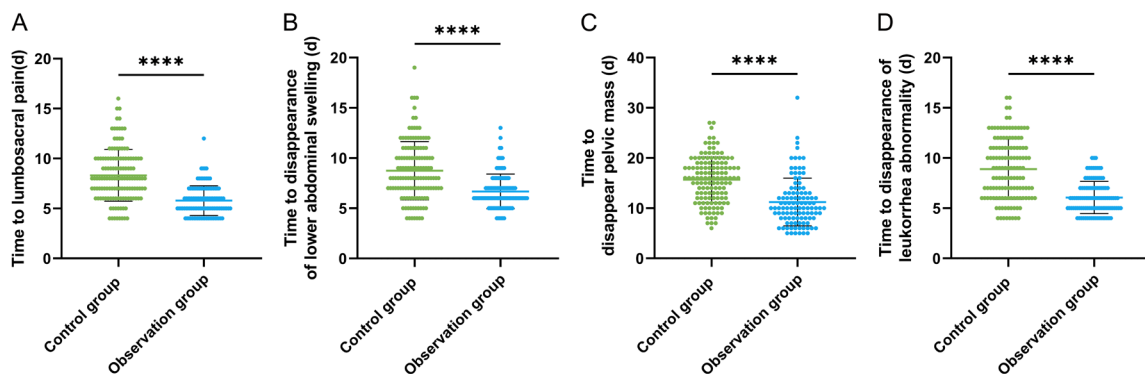
### Changes in VAS, SAS, and SDS scores

Before treatment: No significant differences were observed in VAS, SAS, or SDS scores between the two groups prior to treatment ( $P > 0.05$ ). After treatment: Both groups demonstrated a significant decrease in VAS, SAS, and SDS scores compared to pre-treatment levels ( $P < 0.0001$ ). Between groups: The observation group exhibited significantly lower VAS, SAS, and SDS scores than the control group post-treatment ( $P < 0.001$ ) (Figure 4).

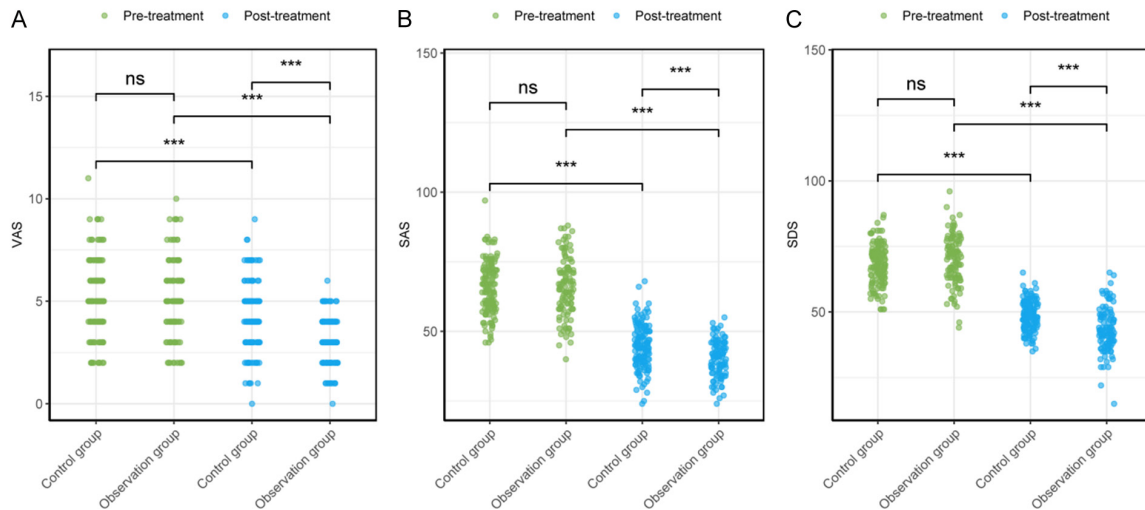
## Acupuncture and Cai's formula in pelvic disease



**Figure 2.** Changes in inflammatory factors and CA125 before and after treatment. A. Changes in CRP before and after treatment. B. Changes in TNF- $\alpha$  before and after treatment. C. Changes in IL-6 before and after treatment. D. Changes in CA125 before and after treatment. Note: ns  $P > 0.05$ , \*\*\* $P < 0.001$ ; CRP: C-Reactive Protein, TNF- $\alpha$ : Tumor Necrosis Factor Alpha, IL-6: Interleukin-6, CA125: Carbohydrate Antigen 125.



**Figure 3.** Comparison of symptom resolution time after treatment. A. Comparison of lumbar pain resolution time. B. Comparison of lower abdominal distension resolution time. C. Comparison of pelvic mass resolution time. D. Comparison of abnormal vaginal discharge resolution time. Note: \*\*\*\* $P < 0.0001$ .



**Figure 4.** Changes in VAS, SAS and SDS scores before and after treatment. A. Changes in VAS scores before and after treatment. B. Changes in SAS scores before and after treatment. C. Changes in SDS scores before and after treatment. Note: ns  $P > 0.05$ , \*\*\* $P < 0.001$ . VAS: Visual Analog Scale, SAS: Self-rating Anxiety Scale, SDS: Self-rating Depression Scale.

**Table 2.** Comparison of clinical efficacy between the observation group and the control group after treatment

Group	Markedly Effective	Effective	Ineffective	Total Effective Rate
Control Group	60 (45.11%)	46 (34.59%)	27 (20.30%)	106 (79.70%)
Observation Group	65 (60.75%)	35 (32.71%)	7 (6.54%)	100 (93.46%)
$\chi^2/Z$ Value		2.946		9.231
$P$ Value		0.003		0.002

#### Clinical efficacy

Patients in the observation group showed a significantly higher total clinical efficacy rate compared to those in the control group post-treatment ( $P = 0.002$ ). The efficacy rate was 79.70% in the control group and 93.46% in the observation group. Further rank-sum test analysis suggesting a markedly lower efficacy rate in the control group than that in the observation group validated this result ( $P = 0.003$ ) (Table 2).

#### Adverse reactions

There was no significant difference in the total incidence rate of adverse reactions between the two groups. In the control group ( $n = 133$ ), 5 patients (3.76%) experienced gastrointestinal discomfort, 5 patients (3.76%) had dizziness, and 1 patient (0.75%) had local itching, with a total incidence rate of 8.27%. In the observation group ( $n = 107$ ), 3 patients (2.80%) had

gastrointestinal discomfort, 2 patients (1.87%) experienced dizziness, and 5 patients (4.67%) had local itching, with a total incidence rate of 9.35%. Between the control group and the observation group, the differences in the occurrence rates of gastrointestinal discomfort, dizziness, and local itching showed no significant difference ( $P = 0.682, 0.387, 0.053$ ). There was no difference in total incidence rates of adverse reactions ( $P = 0.770$ ) (Table 3).

#### Comparison of baseline data between patients with recurrence and non-recurrence

A statistical analysis on within-6-month recurrence post-treatment revealed a recurrence rate of 26.67%, with 64 patients showing recurrent symptoms. The average time to recurrence was 97.5 days. Baseline data of patients with recurrent symptoms showed significant differences compared to those without. Specifically, patients suffering from symptom recurrence had a longer disease duration ( $P <$



**Table 3.** Comparison of adverse reaction occurrence between the observation group and the control group after treatment

Group	Gastric Discomfort	Dizziness	Local Itching	Total Incidence Rate
Control Group (n = 133)	5 (3.76%)	5 (3.76%)	1 (0.75%)	11 (8.27%)
Observation Group (n = 107)	3 (2.80%)	2 (1.87%)	5 (4.67%)	10 (9.35%)
$\chi^2$ Value	0.168	0.748	3.74	0.086
P Value	0.682	0.387	0.053	0.77

0.001) and received a different treatment regimen ( $P < 0.001$ ). Additionally, pre-treatment CRP ( $P = 0.002$ ) and CA125 ( $P < 0.001$ ) levels were higher in patients with recurrence in comparison to those without, as were the pre-treatment VAS ( $P < 0.001$ ) and SAS scores ( $P < 0.001$ ). These results indicated that patients with recurrent symptoms demonstrated higher disease duration, inflammatory markers (CRP and CA125), and symptom scores (VAS and SAS) compared to patients with no such symptoms. However, no significant differences were found in BMI, marital status, ethnicity, education level, pregnancy history, smoking history, alcohol history, pre-treatment lower abdominal pain, menstrual irregularities, breast tenderness, fatigue, TNF- $\alpha$ , IL-6 levels, or SDS scores between the two populations ( $P > 0.05$ ) (Table 4).

#### *Cox regression analysis of prognostic factors for recurrence*

Univariate Cox regression analysis identified treatment regimen ( $P = 0.001$ , HR = 0.390), disease duration ( $P < 0.001$ , HR = 1.154), pre-treatment CRP level ( $P = 0.001$ , HR = 1.100), CA125 level ( $P < 0.001$ , HR = 1.069), VAS score ( $P < 0.001$ , HR = 1.588), and SAS score ( $P < 0.001$ , HR = 1.099) as prognostic factors for symptom recurrence. Multivariate Cox regression analysis further confirmed treatment regimen ( $P < 0.001$ , HR = 0.230), disease duration ( $P < 0.001$ , HR = 1.139), pre-treatment CRP level ( $P = 0.043$ , HR = 1.066), CA125 level ( $P = 0.002$ , HR = 1.044), as well as VAS ( $P < 0.001$ , HR = 1.501) and SAS scores ( $P < 0.001$ , HR = 1.078) as significant independent prognostic factors for symptom recurrence (Figures 5, 6).

#### *Nomogram model for predicting survival probability and symptom recurrence risk in CPP patients*

A nomogram model was constructed to predict the survival probability and symptom recur-

rence risk of CPP patients based on clinical data such as treatment regimen, disease duration, pre-treatment CRP and CA125 levels as well as pre-treatment VAS and SAS scores (Figure 7A). The model was internally validated, showing good performance across 60-day, 90-day, and 180-day survival probabilities. The C-index of the model was 0.852 (0.833-0.871), indicating good discriminatory power. The AUC values for the 60-day, 90-day, and 180-day survival predictions were 0.85825, 0.84879, and 0.91087, respectively, with 95% confidence intervals of 0.7963-0.9202, 0.783-0.9145, and 0.8697-0.952. Statistical tests confirmed the model's robustness with  $p$ -values  $< 2e-16$  for likelihood ratio, Wald, and logrank tests (Figure 7B-D).

#### **Discussion**

This study demonstrated that the combination of Cai's Gynecology Chronic Pelvic Formula and acupuncture provided significantly greater clinical benefits than conventional treatment alone. Specifically, patients in the observation group exhibited significantly lower TCM symptom scores after treatment compared to those of the control group, indicating that the combined therapy effectively alleviated core CPP-related symptoms such as lower abdominal pain, menstrual irregularities, breast tenderness, and fatigue. These findings are consistent with previous studies showing the efficacy of the combined therapy in managing CPP and its associated symptoms. For instance, Liang et al. [16] reported that electroacupuncture significantly relieved PID-associated CPP, while Lin et al. [17] conducted a meta-analysis demonstrating that acupuncture improved pain and quality of life of CPP patients. Similarly, Armour et al. [18] found that acupuncture was effective in reducing pain and enhancing quality of life in cases of CPP secondary to endometriosis.

**Table 4.** Comparison of baseline data between patients with and without recurrence

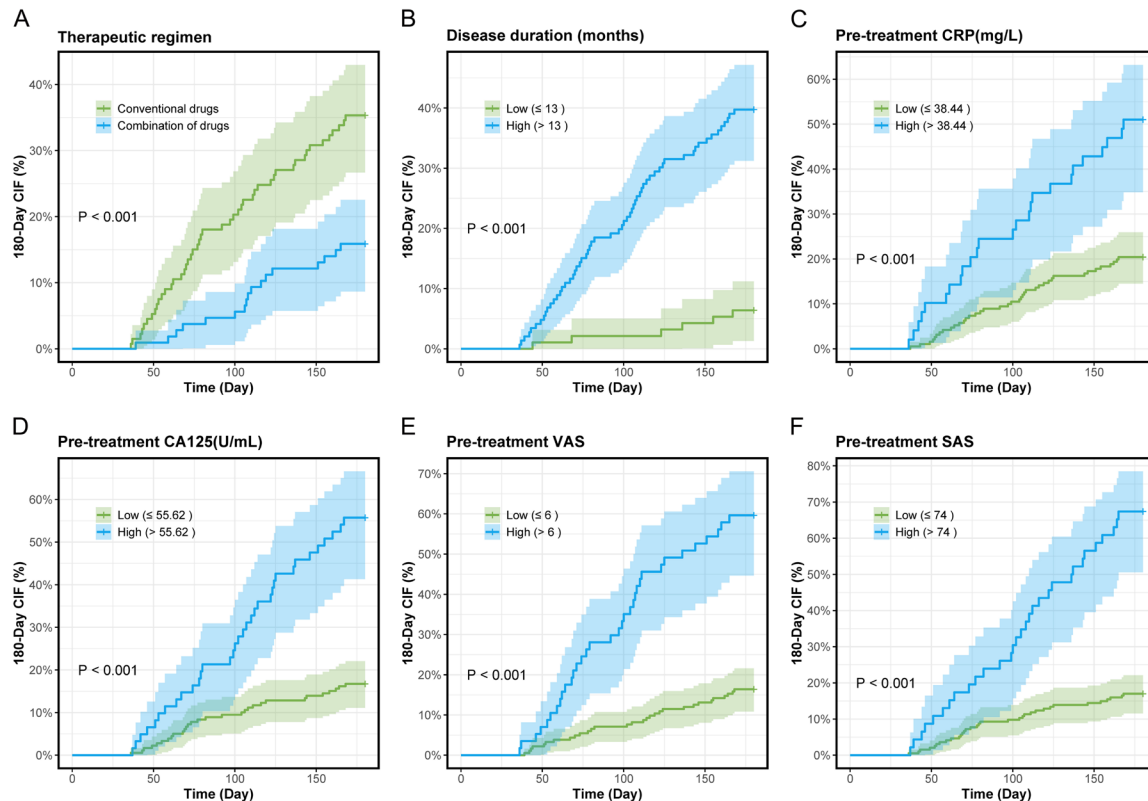
Variable	Total	Control Group (n = 133)	Observation Group (n = 107)	Statistic Value	P Value
Treatment Protocol	133	47	86	11.471	< 0.001
Routine Medication	107	17	90		
Combined Medication	133	47	86		
Age (years)	35.08 ± 7.06	36.28 ± 7.69	34.64 ± 6.79	-1.601	0.111
BMI (kg/m <sup>2</sup> )	23.13 ± 3.16	23.30 ± 3.06	23.07 ± 3.20	-0.498	0.619
Disease Duration (months)	15.03 ± 5.22	18.34 ± 3.97	13.82 ± 5.10	-6.419	< 0.001
Marital Status					
Married	220	60	160	0.496	0.481
Unmarried	20	4	16		
Ethnicity					
Han Chinese	229	61	168	0.002	0.963
Other	11	3	8		
Education Level					
≤ Middle School	58	14	44	0.927	0.629
High School	104	31	73		
≥ College	78	19	59		
Pregnancy History					
Yes	207	55	152	0.007	0.932
No	33	9	24		
Smoking History					
Yes	78	19	59	0.315	0.575
No	162	45	117		
Alcohol History					
Yes	39	12	27	0.401	0.527
No	201	52	149		
Pre-treatment Lower Abdominal Pain	4.00 (4.00, 4.00)	4.00 (4.00, 6.00)	4.00 (4.00, 4.00)	0.739	0.46
Pre-treatment Menstrual Disorder	6.00 (4.00, 6.00)	4.00 (4.00, 6.00)	6.00 (4.00, 6.00)	0.446	0.656
Pre-treatment Breast Tenderness	4.00 (2.00, 4.00)	4.00 (2.00, 4.00)	4.00 (2.00, 4.00)	0.2	0.842
Pre-treatment Fatigue	6.00 (4.00, 6.00)	6.00 (4.00, 6.00)	6.00 (4.00, 6.00)	0.306	0.76
Pre-treatment CRP (mg/L)	34.66 ± 4.51	36.17 ± 4.54	34.11 ± 4.38	-3.194	0.002
Pre-treatment TNF-α (ng/L)	25.59 (24.20, 27.01)	25.62 (24.76, 26.87)	25.59 (23.96, 27.10)	0.817	0.414
Pre-treatment IL-6 (ng/L)	35.02 ± 4.57	35.71 ± 4.82	34.77 ± 4.47	-1.413	0.159
Pre-treatment CA125 (U/mL)	50.05 ± 8.69	54.62 ± 8.44	48.40 ± 8.19	-5.16	< 0.001
Pre-treatment VAS	5.00 (4.00, 6.00)	7.00 (5.00, 7.25)	5.00 (3.00, 6.00)	6.228	< 0.001
Pre-treatment SAS	65.82 ± 9.85	73.42 ± 9.20	63.06 ± 8.56	-8.132	< 0.001
Pre-treatment SDS	68.88 ± 8.45	68.25 ± 7.87	69.10 ± 8.67	0.69	0.491

Note: BMI: Body Mass Index, CRP: C-Reactive Protein, TNF-α: Tumor Necrosis Factor Alpha, IL-6: Interleukin-6, CA125: Carbohydrate Antigen 125, VAS: Visual Analog Scale, SAS: Self-Rating Anxiety Scale, SDS: Self-Rating Depression Scale.

In addition to symptom relief, the combined treatment was associated with significant reductions in inflammatory markers (CRP, TNF-α, IL-6) and CA125 levels, further suggesting that it modulated the inflammatory and immune responses. Prior studies have supported this mechanism: Zhang et al. [19] reported that fine moxibustion could improve PID sequelae by regulating immune function and reducing systemic inflammation. Liu et al. [20]

and Abdulaziz et al. [21] also found that combining acupuncture or neurogenic acupoint cupping therapy with conventional treatments significantly reduced inflammation and improved clinical outcomes in CPP patients.

Time-to-symptom-resolution analyses revealed that the observation group experienced significantly faster resolution of sacral pain, lower abdominal distension, pelvic masses, and



**Figure 5.** CIF curve for patients' recurrence rate. A. CIF curve for patients with different treatment protocols. B. CIF curve for patients with disease duration > 13 months vs ≤ 13 months. C. CIF curve for patients with pre-treatment CRP > 38.44 months vs ≤ 38.44 months. D. CIF curve for patients with pre-treatment CA125 > 55.62 months vs ≤ 55.62 months. E. CIF curve for patients with pre-treatment VAS > 6 months vs ≤ 6 months. F. CIF curve for patients with pre-treatment SAS > 74 months vs ≤ 74 months. Note: CIF: Cumulative Incidence Function, CPP: Chronic Pelvic Pain, CRP: C-Reactive Protein, CA125: Carbohydrate Antigen 125, VAS: Visual Analog Scale, SAS: Self-Rating Anxiety Scale.

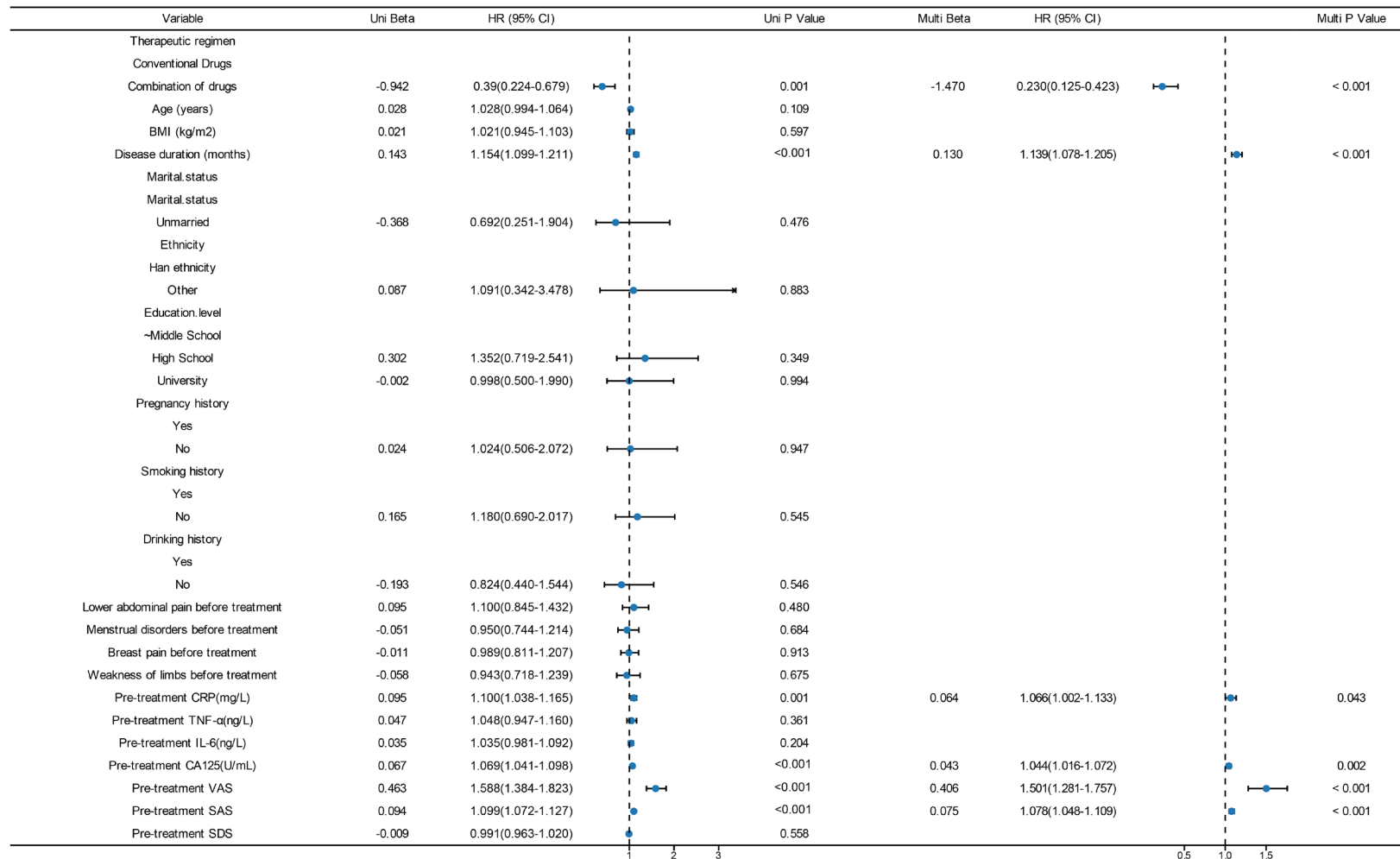
abnormal vaginal discharge compared to the control group. These findings suggest that the integration of Cai's Gynecology CPP Formula with acupuncture not only enhances treatment efficacy but also accelerates recovery. Similar outcomes have been reported by Liu et al. [20], who showed that acupuncture combined with ibuprofen significantly shortened symptom resolution time, and by Abdulaziz et al. [21], who demonstrated that neurogenic acupoint cupping therapy reduced pain and improved recovery timelines.

The combination treatment also resulted in greater improvements in VAS, SAS, and SDS scores, indicating significant reductions in pain, anxiety, and depressive symptoms. The observation group showed greater improvements than the control group, suggesting a superior capacity of the combined therapy to address both physical and emotional issues of CPP

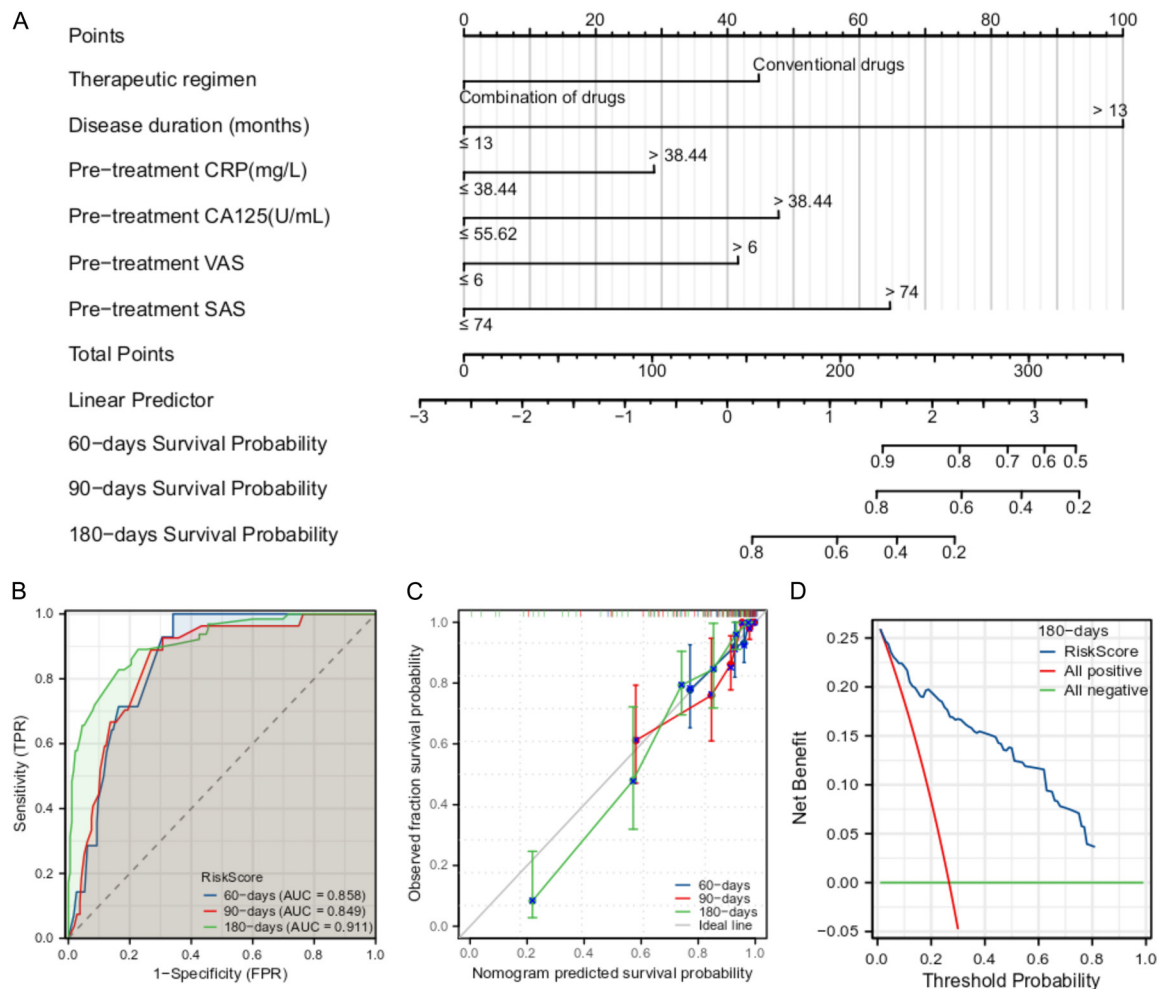
patients. These findings echo those of Lin et al. [17], who found that acupuncture effectively reduced pain and improved emotional well-being in CPP patients, as well as in other chronic pain conditions such as endometriosis.

In terms of clinical efficacy, the total effective rate in the observation group reached 93.46%, significantly surpassing the 79.70% observed in the control group. Moreover, the observation group exhibited a longer recurrence-free interval and a lower recurrence rate, indicating that the combined therapy may offer sustained benefits beyond the initial treatment period. These findings align with Zhang et al. [19], who reported prolonged efficacy and reduced recurrence window following fine moxibustion therapy. Collectively, these results support the view that the combination of acupuncture and TCM enhances therapeutic outcomes by improving

# Acupuncture and Cai's formula in pelvic disease



**Figure 6.** Univariate and multivariate cox regression analysis of prognostic factors for symptom recurrence in patients. Note: CPP: Chronic Pelvic Pain, CRP: C-Reactive Protein, CA125: Carbohydrate Antigen 125, VAS: Visual Analog Scale, SAS: Self-rating Anxiety Scale, SDS: Self-rating Depression Scale.



**Figure 7.** Nomogram for survival prediction and recurrence risk in CPP patients. A. The nomogram presents points based on various clinical predictors such as treatment regimen, disease duration, CRP, CA125, VAS, and SAS scores. B. ROC curve for the model's predictive ability with AUC values for 60-day (0.85825), 90-day (0.84879), and 180-day (0.91087) survival probabilities. C. Calibration plot showing observed vs. predicted survival probabilities for 60-day, 90-day, and 180-day survival outcomes. D. Decision curve analysis showing net benefit for 180-day survival prediction, comparing risk scores and clinical decisions (all positive and all negative). Note: CPP: Chronic Pelvic Pain, CRP: C-Reactive Protein, CA125: Carbohydrate Antigen 125, VAS: Visual Analog Scale, SAS: Self-Rating Anxiety Scale, ROC: Receiver Operating Characteristic, AUC: Area Under the Curve.

symptoms, regulating immune and endocrine functions, and reducing recurrence rates.

The therapeutic mechanism of Cai's Gynecology Chronic Pelvic Formula lies in its capacity to regulate Qi and blood, dispel dampness, relieve pain, and unblock meridians. Pharmacological studies suggest that this formula alleviates pelvic inflammation and pain by modulating endocrine function and improving pelvic blood flow. Herbal components such as *Chuanlianzi* [22], *Beibai Jiangcao* [23], and *Daxueteng* [24] possess anti-inflammatory and blood-activating properties. *Fuling* and *Mudanpi* contribute to endocrine regulation

and immune modulation. Acupuncture complements this mechanism by stimulating specific acupoints to regulate organ systems, improve microcirculation, and alleviate local muscle tension and pain [25]. Needling points such as Qihai, Ganshu, and Shenshu enhances the body's self-healing capabilities and helps restore systemic balance [17]. Numerous studies [26, 27] confirm acupuncture's efficacy in treating gynecologic disorders, relieving pain, and regulating hormonal function with minimal side effects.

The synergistic effect of combining Cai's Gynecology Chronic Pelvic Formula and acu-



puncture lies in their complementary actions - while the herbal formula enhances systemic regulation, acupuncture promotes local circulation and nervous system modulation. This dual-action approach strengthens therapeutic outcomes, accelerates symptom resolution, reduces inflammation, and aligns with the TCM principle of treating disease before its onset. Compared to monotherapies, the combined treatment offers more comprehensive, sustained benefits with a lower likelihood of symptom recurrence.

Cox regression analysis was employed in the study to identify independent prognostic factors for symptom recurrence. Univariate analysis revealed that treatment regimen, disease duration, and pre-treatment levels of CRP, CA125, VAS, and SAS significantly influenced recurrence risk. Multivariate Cox regression confirmed these as independent predictors. Notably, patients receiving the combined treatment had significantly lower recurrence rates, whereas those with longer disease duration and elevated baseline inflammatory markers and emotional distress scores faced increased recurrence risk [28, 29]. These findings emphasize the importance of early diagnosis and comprehensive treatment, especially for patients with prolonged disease duration or elevated risk indicators. They also highlight the added value of therapies that address not only physical but also emotional and immunological dimensions of disease.

Despite the encouraging outcomes, this study has limitations. As a retrospective, single-center analysis with a relatively small sample size, it is subject to patient selection bias and limited external validity. Future research should employ multi-center and prospectively randomized controlled trials with larger sample size to validate these findings. Additionally, the current TCM symptom scoring criteria lack broad standardization and external validation, warranting further refinement and consensus-building for reliable use. Although this study supports the efficacy of Cai's Gynecology Chronic Pelvic Formula and acupuncture, the underlying mechanisms remain insufficiently elucidated. Integrating genomics, proteomics, and other modern investigative tools could help identify biomarkers and clarify molecular pathways, thereby enabling more personalized and precise treatment strategies.

## Conclusion

The combination of Cai's Gynecology Chronic Pelvic Formula and acupuncture yielded significant clinical benefits in the treatment of CPP. It effectively alleviated symptoms, reduced symptom recurrence rates, and improved overall quality of life of patients. This integrative therapeutic approach not only embodies the principles of syndrome differentiation and holistic care central to TCM, but also provided robust clinical evidence for its relevance and efficacy in modern medical practice.

## Disclosure of conflict of interest

None.

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