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A clinical study on the efficacy of rectal administration of Tongfu Qinghua decoction combined with external application of Ruyi Jinhuang powder in treating acute pancreatitis

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Abstract: **Background**: Acute pancreatitis (AP) is a common acute abdominal disease with high mortality in moderate and severe cases. Integrated Chinese and Western medicine therapy has promising clinical application prospects. **Objectives**: This study investigated the efficacy and safety of Tongfu Qinghua decoction enema combined with Ruyi Jinhuang powder external application for AP and its therapeutic effects across different age groups. **Methods**: A total of 100 AP patients from October 2023 to August 2025 were randomly divided into observation and control groups (50 cases each). The control group received conventional Western medicine and the observation group received additional combined Chinese medicine therapy. Outcomes including hospital stay, symptom relief, inflammatory and pancreatic injury markers, clinical efficacy and adverse reactions were compared, with subgroup analysis of patients aged 18–40, 41–60 and 61–75 years. **Results**: The observation group had significantly shorter hospital stay, faster symptom relief and gastrointestinal recovery ($P<0.05$). Post-treatment inflammatory and pancreatic markers improved significantly and the total effective rate was higher ($P<0.05$), with no significant difference in adverse reactions ($P>0.05$). Benefits were consistent across all age subgroups, with younger patients recovering faster and elderly patients still achieving significant improvement. **Conclusion**: This combined therapy is effective and safe for AP patients aged 18–75 years, significantly improving clinical outcomes and worthy of clinical promotion.

Keywords: Acute pancreatitis; Clinical efficacy; Integrated Chinese and Western medicine therapy; Traditional Chinese medicine external treatment

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INTRODUCTION

Acute pancreatitis (AP), a common clinical acute abdomen condition, involves abnormal activation of pancreatic enzymes that triggers inflammation in the pancreas and surrounding tissues. Patients with moderate to severe cases often develop systemic inflammatory response syndrome and multi-organ dysfunction, presenting high mortality rates and posing significant health risks (Huang Y and Badurddeen, 2023; Valverde-Lopez *et al.*, 2022). While standard treatments including fasting, gastrointestinal decompression, fluid resuscitation, pancreatic enzyme inhibition and anti-infection therapy have become established protocols, there remains room for improvement in rapidly restoring gastrointestinal function and controlling local inflammation, with prolonged hospital stays being common (Beij A *et al.*, 2025; Zerem E *et al.*, 2023). Recent studies highlight the promising potential of integrated Chinese-Western medicine approaches in AP management, offering novel therapeutic strategies (Deng L *et al.*, 2025). Among these, Tongfu Qinghua decoction, as a traditional Chinese medicine prescription derived from Dachengqi decoction, potentially alleviates symptoms by enhancing intestinal motility and reducing bacterial/endotoxin translocation (Li Min and Gan Chun, 2025), while improving pancreatic microcirculation to decrease severe disease risk. Ruyi Jinhuang powder, traditionally used for topical anti-inflammatory effects, may help relieve pancreatic inflammation and pain (Yiqing and Na, 2023). This study investigates the synergistic clinical benefits of combining Tongfu Qinghua decoction with Ruyi Jinhuang Powder alongside conventional Western treatments. By evaluating their impacts on symptom resolution, biochemical parameters, inflammatory markers and overall efficacy, the research aims to establish an effective integrated Chinese-Western complementary therapy for acute pancreatitis, providing evidence-based support for clinical application.

Tongfu Qinghua decoction and Ruyi Jinhuang Powder have been used in traditional Chinese medicine for the management of inflammatory and gastrointestinal disorders and are generally considered to have a favorable safety profile when used appropriately. However, as with other herbal interventions, some adverse effects may still occur. Tongfu Qinghua decoction, particularly when administered by enema, may be associated with gastrointestinal discomfort, abdominal cramping, diarrhea, or local irritation in some patients. Ruyi Jinhuang powder, as an external application, may occasionally cause local skin discomfort, including redness, itching, rash, or contact allergy in sensitive individuals. Therefore, in addition to

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evaluating clinical efficacy, safety monitoring is also necessary when these therapies are combined with standard treatment in patients with acute pancreatitis.

Therefore, this study aimed to investigate the clinical efficacy and safety of Tongfu Qinghua decoction enema combined with external application of Ruyi Jinhuang powder as an adjunct to standard treatment for acute pancreatitis. By evaluating symptom relief, recovery of gastrointestinal function, changes in pancreatic enzyme and inflammatory markers, overall therapeutic efficacy and adverse events, this study sought to provide evidence-based support for an effective and safe integrated Chinese-Western therapeutic strategy for acute pancreatitis.

MATERIALS AND METHODS

General information

This study was designed as a single-center, prospective, randomized controlled clinical trial (RCT) with a parallel-group design and was conducted as a Phase II clinical trial. This prospective study enrolled 100 patients with acute pancreatitis (AP) treated at the Hepatobiliary Surgery and Gastroenterology Departments of The Third Affiliated Hospital of Wenzhou Medical University from October 2023 to August 2025. Sample size was estimated using the PASS 20.0 statistical software (NCSS, LLC, Kaysville, UT, USA), with the main outcome indicator set as the overall effective rate of AP treatment; the expected overall effective rate of the control group was 60% and that of the observation group was 85%. With a two-sided test, α=0.05 (type I error rate), β=0.20 (type II error rate, power=80%), the initial estimated sample size was 47 cases in each group. Considering a 6% lost-to-follow-up rate, the final sample size was set to 50 cases in each group, with a total of 100 cases. Patients were randomly divided into an observation group and a control group (50 each) using the random number table method combined with the sealed envelope technique (Fig. S1). The random number table was generated by two independent statisticians using SPSS 24.0 software and the random numbers were sequentially placed in sealed, opaque envelopes with group labels inside. After a patient met the inclusion criteria and signed informed consent, the investigator opened the envelopes in sequence to determine the grouping, ensuring concealment of random allocation. Baseline data comparison between the groups is detailed in table 1. Statistical analysis showed no significant differences (P> 0.05), confirming the groups were comparable.

Inclusion and exclusion criteria

Inclusion criteria

(1) Meeting clinical diagnostic criteria for acute pancreatitis (Szatmary P *et al.*, 2022); (2) Age 18-75 years, gender unspecified; (3) First-time onset without prior treatment; (4) Voluntary participation with signed informed consent.

Exclusion criteria

(1) Indications for surgical intervention; (2) Pre-existing severe gastrointestinal disorders; (3) Significant organ dysfunction or severe primary diseases; (4) Women in pregnancy or lactation; (5) Mental health conditions that prevent participation; (6) Contraindications to traditional Chinese medicine enemas.

Method

Control group: Conventional Western medicine treatment was given, including water and food restriction, gastrointestinal decompression, fluid and nutritional support, inhibition of pancreatic secretion and anti-infection. If abdominal pain was obvious, analgesic and antispasmodic drugs were used for symptomatic intervention.

Observation group: In addition to conventional Western medicine treatment, intestinal irrigation with Tongfu Qinghua decoction and external application of Ruyi Jinhuang powder were combined. The prescriptions were as follows: 10g of Rhubarb, 10g of Mirabilite, 10g of Magnolia bark, 10g of Fried *citrus aurantium*, 30g of Dandelion, 30g of Patrinia, 30g of *Polygonum cuspidatum*, 15g of Honeysuckle and 20g of *Salvia miltiorrhiza*.

For significant gallbladder heat stagnation, add 20g of Bupleurum and 10g of *Radix Scutellariae*. For marked damp-heat in the liver and gallbladder, add 15g of *Artemisia capillaris*. For solid organ qi stagnation, add 15g of Areca nut. For prominent heat-toxin symptoms, add 30g of *Viola yedoensis*. For evident blood stasis, add 15g of Peach kernel.

All herbal medicines are centrally decocted and distributed by the Traditional Chinese Medicine pharmacy of Ruian People's Hospital. The concentrated herbal decoction is prepared to 200ml, cooled to 38-40^{o}C and stored for later use. During enema administration, patients are positioned in left lateral decubitus. Lubricant is applied to the tip of the anal tube, which is gently inserted 15-20cm into the anus. The herbal decoction is slowly instilled. Patients are instructed to retain the liquid for 30 minutes before defecation, with one session per day. This procedure is repeated for 5 consecutive days until abdominal distension and pain subside, or when spontaneous bowel movements occur or diarrhea develops. Ruyi Jinhuang powder (Jiangsu 707 Natural Pharmaceutical Co., Ltd., 500g/pack) is prepared as a paste using water or tea, applied to gauze and externally applied to the Shenque acupoint (CV8) and surrounding 3-5cm area, secured with adhesive tape.

The dressing is removed after 4 hours, applied twice daily. All patients receive identical routine symptomatic treatment as the control group. Both treatment groups complete 5-day courses.

Table 1: Comparison of baseline data between two patient groups (n=50).

Basic information	Control group	Observation group	t/χ^2	*P*
Gender			0.421	0.517
Male	36(72.00)	33(66.00)		
Female	14(28.00)	17(34.00)		
Age(years)	46.68±7.16	46.70±7.20	-0.014	0.989
Course of disease(h)	25.74±6.22	25.16±6.47	0.457	0.649
Cause of disease			0.392	0.774
Alcoholic	9(18.00)	11(22.00)		
Biligenic	22(44.00)	20(40.00)		
Hyperlipidemia	15(30.00)	14(28.00)		
Others	4(8.00)	5(10.00)		
Comorbidities			0.586	0.909
Hypertension	8(16.00)	7(14.00)		
Diabetes mellitus	5(10.00)	6(12.00)		
Coronary heart disease	3(6.00)	2(4.00)		
Chronic hepatitis	2(4.00)	2(4.00)		
No comorbidities	32(64.00)	33(66.00)		
Long-term medication history			0.492	0.925
Antihypertensive drugs	7(14.00)	6(12.00)		
Hypoglycemic drugs	4(8.00)	5(10.00)		
Lipid-lowering drugs	3(6.00)	3(6.00)		
Antiplatelet drugs	2(4.00)	1(2.00)		
No long-term medication	34(68.00)	35(70.00)		

Observation indicators

(1) Compare the hospitalization time and the first food intake time of the two groups of patients, as well as the relief and recovery time of symptoms such as abdominal pain, abdominal distension, gas, defecation and bowel sounds.

(2) To compare pancreatic inflammation marker levels before and after treatment in two patient groups, fasting venous blood and midstream clean urine samples were collected on the morning of both pre-treatment and post-treatment days. After centrifugation, serum was isolated from blood samples and supernatant from urine samples. All samples were tested for serum amylase (AMY) and urinary amylase (UAMY) levels within 2 hours of collection.

(3) To compare the improvement of inflammatory indicators before and after treatment in two patient groups, venous blood was collected on an empty stomach before treatment and the morning after the treatment course ended. After centrifugation, serum was isolated and tested for serum C-reactive protein (CRP) and procalcitonin (PCT) levels using ELISA.

(4) Evaluate the overall efficacy of the two patient groups according to the efficacy criteria (Tenner *et al.*, 2024): Complete cure is defined as the disappearance of symptoms and signs within 5 days with normalized laboratory indicators; Marked efficacy refers to the disappearance of symptoms and signs within 5 days with significant improvement in laboratory indicators; Effective efficacy indicates symptom improvement and indicators improved within 5 days; Ineffective efficacy means no change or worsening of clinical symptoms and signs within 5 days; Death is defined as fatal deterioration of the condition.

(5) Observe the occurrence of adverse reactions in the two groups, including gastrointestinal bleeding, dizziness, headache, gastrointestinal discomfort, rash, perianal redness and swelling, etc. The study adopted a passive reporting combined with active follow-up reporting strategy for AE/SAE; Passive reporting: The research nurses and clinicians collected the patients' self-reported adverse reactions during the daily ward round and treatment process; Active follow-up reporting: The assessors conducted a dedicated inquiry on the occurrence of adverse reactions at fixed time points (1st, 3rd, 5th day of treatment, discharge day and 7th day after discharge) and recorded the relevant information in detail. The overall observation duration of AE/SAE was from the time the patient signed the informed consent to 7 days after discharge, covering the entire treatment course and the early recovery period after treatment.

All AEs and SAEs were managed according to the hospital's clinical research safety procedures. Once an event was identified, the research nurse and treating physician recorded it in the eCRF and informed the principal investigator. Non-serious AEs were documented and reported within 7 days. SAEs were immediately managed by the treating physician and reported to the principal investigator, department director/on-duty senior

clinician, hospital Ethics Committee and relevant hospital administration department within 24 hours. A detailed written follow-up report was submitted within 7 days after the initial SAE report. Management measures included clinical assessment, symptomatic treatment, temporary suspension or discontinuation of the study intervention when necessary, specialist or multidisciplinary consultation and continued follow-up until the event resolved or stabilized. Final event verification and causality assessment were completed jointly by the investigators.

(6) Age-stratified subgroup analysis: Considering the relatively wide age range of enrolled patients (18–75 years), patients in both groups were further stratified into three age subgroups: 18–40 years, 41–60 years and 61–75 years. The hospitalization duration, symptom relief time (including abdominal pain, abdominal distension, first exhaust, first defecation, bowel sound recovery and first food intake), pancreatic inflammation markers (AMY and UAMY), inflammatory indicators (CRP and PCT), overall therapeutic efficacy and adverse reactions were further compared between the observation group and the control group within each age subgroup, so as to evaluate the consistency of therapeutic efficacy and safety of the combined therapy across different age ranges.

Outcome assessment implementation and bias control

The study outcome assessment was independently performed by two professional researchers who were trained uniformly and not involved in the clinical treatment of the patients. Due to the characteristics of the intervention measures (Tongfu Qinghua decoction enema + Ruyi Jinhuang powder external application), the assessors could not be completely blinded to the grouping status. To reduce assessment bias, the following measures were adopted: (1) Conduct unified standardized training for assessors on the definition and evaluation criteria of all observation indicators to ensure consistent understanding and operation; (2) The assessment data were collected and recorded using a unified electronic case report form (eCRF) with fixed filling items and quantitative evaluation standards, avoiding subjective descriptive records; (3) The two assessors evaluated the same patient independently and the results were cross-checked. if there was a discrepancy, a third senior clinician was invited to make a joint evaluation to determine the final result; (4) All assessment data were encrypted and stored and the grouping information was hidden during the data entry and statistical analysis stage.

Statistical analysis

The collected data were entered into SPSS24.0 for statistical analysis. Quantitative data, after normal distribution testing, were presented as mean ± standard deviation ($\bar{x}$±s). Independent samples t-tests were used for group comparisons. Categorical variables were presented as frequencies and percentages. The χ^2 test was used for comparisons between groups when the expected frequency in each cell was at least 5; otherwise, Fisher's exact test was applied. A P value <0.05 was considered statistically significant. Paired t-test was used for intra-group comparison of indicators before and after treatment; independent samples t-tests were used for inter-group comparison. Statistical significance was defined as P<0.05.

RESULTS

Comparison of baseline data between the two groups

No significant statistical differences were observed between the two patient groups in baseline data (all P>0.05), as detailed in Table 1.

Comparison of hospitalization time and symptom relief time between the two groups

Compared with the control group, the observation group showed significantly shorter hospitalization duration, reduced time to abdominal pain and bloating relief, earlier first-pass gas expulsion, first bowel movement, first food intake and first bowel sounds (all P<0.05), as detailed in table 2. Intra-group comparison showed that the above symptom relief time and hospitalization duration of both groups were significantly improved after treatment compared with before treatment (all P<0.05).

Comparison of pancreaticitis indicators before and after treatment between the two groups

Prior to treatment, no significant difference was observed in AMY and UAMY levels between the two groups. Intra-group paired comparison showed that both groups had significant decrease in serum AMY and urinary AMY levels after treatment compared with before treatment (all P<0.05). After treatment, both groups showed significant decrease in pancreatic inflammation markers, with the observation group demonstrating significantly lower AMY and UAMY levels than the control group (P<0.05). See Table 3 for details.

Comparison of inflammatory index improvement before and after treatment in two groups of patients

No significant difference was observed in CRP and PCT levels between the two groups before treatment. Intra-group paired comparison showed that both groups had significant reduction in serum CRP and PCT levels after treatment compared with before treatment (all P<0.05).

After treatment, both groups showed significant reduction in inflammatory markers, with the observation group demonstrating significantly lower CRP and PCT levels than the control group (P<0.05), as detailed in Table 4.

Comparison of overall efficacy between the two groups of patients

The overall response rate in the observation group was significantly higher than that in the control group (P<0.05), as shown in Table 5.

Table 2: Comparison of hospitalization duration and symptom resolution time between two patient groups (n=50).

Data	Control group	Observation group	t	*P*
Length of stay(d)	7.94±1.96	6.62±1.70	3.593	<0.001
Abdominal pain relief time(d)	5.48±1.05	4.96±0.83	2.738	0.007
Bloating relief time(d)	5.52±1.22	4.96±0.86	2.662	0.009
First exhaust time(d)	4.66±1.02	3.62±1.07	4.977	<0.001
First bowel movement time(d)	6.02±1.41	4.34±1.12	6.611	<0.001
Time of first bowel sounds(d)	4.34±1.36	3.14±0.76	5.439	<0.001
Time of first eating	4.54±1.54	3.87±1.72	2.052	0.043

Table 3: Comparison of pancreaticitis indicators before and after treatment between two patient groups (n=50).

Group	AMY(U/L)		UAMY(U/L)	
	Before	After	Before	After
Control group	589.48±174.97	172.12±62.12*	2129.58±194.58	1148.06±92.15*
Observation group	537.30±177.89	86.06±33.14*	2109.90±208.69	1067.54±80.37*
t	1.479	8.643	0.488	4.656
P	0.142	<0.001	0.627	<0.001

Note: The asterisk (*) in table 3 indicates a statistically significant difference ($P<0.05$) compared to pre-treatment levels.

Table 4: Comparison of inflammatory markers in two patient groups before and after treatment (n=50).

Group	CRP(mg/L)		PCT(μg/L)	
	Before	After	Before	After
Control group	115.36±9.46	46.96±3.53*	3.10±0.41	2.15±0.36*
Observation group	117.99±8.53	42.22±4.09*	3.08±0.40	1.76±0.28*
t	-1.462	6.197	0.282	5.915
P	0.147	<0.001	0.778	<0.001

Note: The asterisk (*) in table 5 indicates a statistically significant difference ($P<0.05$) compared to pre-treatment levels.

Table 5: Comparison of overall efficacy between two patient groups (n=50).

Group	Complete cure	Marked efficacy	Effective efficacy	Ineffective efficacy	Efficient
Control group	11	13	7	16	31(62.00)
Observation group	16	21	6	7	43(86.00)
χ^2					4.574
P					0.032

Table 6: Comparison of adverse reactions between two patient groups (n=50).

Group	Gastrointestinal bleeding	Dizziness and headache	Gastrointestinal discomfort	Rash	Perianal redness and swelling	Adverse reactions
Control group	0	0	2	0	0	2(4.00)
Observation group	0	0	1	2	0	3(6.00)
Fisher's exact test						0.332
P						0.582

Observation of adverse reactions in two groups of patients

No significant difference was observed in the overall adverse reactions between the two patient groups (all $P>0.05$), as detailed in Table 6.

Observe the changes in symptoms and related indicators after treatment in different age subgroups of the two groups of patients

Given the wide age range of the enrolled patients (18–75 years), age-stratified subgroup analysis was performed by dividing patients into 18–40 years, 41–60 years and 61–75 years subgroups. As shown in tables 7–11, in the 18–40 years and 41–60 years subgroups, the observation group had significantly shorter hospitalization duration, faster symptom relief, earlier gastrointestinal function recovery and significantly lower post-treatment levels of AMY, UAMY, CRP and PCT than the corresponding control group (all $P<0.05$). In the 61–75 years subgroup, no statistically significant differences were observed between

the two groups in hospitalization duration or symptom relief time (all $P>0.05$), whereas post-treatment AMY, UAMY, CRP and PCT levels in the observation group were still significantly lower than those in the control group (all $P<0.05$). The overall effective rate was higher in the observation group across all age subgroups, but the differences were not statistically significant after stratification (all $P>0.05$). The incidence of adverse reactions remained low in all age subgroups, with no significant between-group differences (all $P>0.05$). as detailed in Table 7-11.

DISCUSSION

AP develops through abnormal activation of pancreatic enzymes that damage the pancreas and surrounding tissues. Severe cases may lead to multi-organ failure with high mortality rates (Wiley MB *et al.*, 2023). While modern medical interventions like fasting and fluid resuscitation can stabilize most patients, they have limitations in symptom relief and intestinal function recovery, with some patients experiencing prolonged disease courses (Guilabert *et al.*, 2025). The Tongfu Qinghua decoction enema can relieve intestinal stagnation and effectively eliminate heat accumulation and detoxifies, while the external application of Ruyi Jinhuang powder reduces swelling and alleviates pain. This combination of internal and external therapies forms an integrated Chinese-Western medicine treatment protocol. Studies demonstrate that the observation group showed superior clinical symptom relief and biochemical parameter improvements compared to the control group, with fewer adverse reactions, showing the efficacy and safety of the intervention. The following discussion will explore the therapeutic mechanism from a modern medical perspective, combining research methods and outcomes.

First of all, from the perspective of symptom improvement, the patients in the observation group had abdominal pain, abdominal distension relief time, first venting, defecation and intestinal sound recovery time and first eating time significantly shorter than in the control group ($P<0.05$). Analysis indicate that pancreatic inflammation may cause intestinal motility paralysis, microbial imbalance and mucosal barrier damage, leading to bacterial and endotoxin translocation, exacerbating systemic inflammation and creating a vicious cycle (Capurso *et al.*, 2024). In Tongfu Qinghua decoction, rhubarb's anthraquinone compounds directly stimulate intestinal walls, enhance colonic motility and inhibit water absorption, exerting a laxative effect to rapidly eliminate accumulated feces, gas and harmful substances while reducing intestinal pressure (Huang *et al.*, 2023). Mirabilite creates a hyperosmotic environment in the intestine, attracting body fluids into the intestinal lumen, softening stool and synergistically enhancing the laxative function of rhubarb (Cai H *et al.*, 2023). Modern pharmacological studies demonstrate that magnolia bark and *citrus aurantium* promote gastrointestinal smooth muscle contraction and coordinate motility, effectively relieving intestinal paralysis and restoring bowel sounds, spontaneous flatus and defecation functions, directly alleviating patients' most distressing bloating symptoms. Additionally, enema therapy itself, as a physical stimulus, reflexively stimulates intestinal motility. This early recovery of intestinal function lays the foundation for shorter hospital stays (Wang S *et al.*, 2023).

Furthermore, biochemical parameters demonstrated significantly better improvement in serum AMY and UAMY levels in the observation group compared to the control group ($P<0.05$). Pathologically, acute pancreatitis (AP) involves abnormal activation of pancreatic enzymes, leading to massive leakage of AMY into circulation and subsequent elevation of serum levels. Since UAMY is primarily cleared through renal excretion, its levels also become abnormal (Wang Z *et al.*, 2023). The herbal formula Tongfu Qinghua Tang, containing plants like dandelion, honeysuckle, patrinia and *Polygonum cuspidatum*, has been clinically proven to exhibit broad anti-inflammatory, antibacterial and pancreatic enzyme inhibitory effects (Li Y *et al.*, 2022). The enema therapy rapidly clears intestinal contents, reducing intestinal-derived irritation and potentially suppressing pancreatic secretion. The main ingredient of *Salvia miltiorrhiza* in the enema formula is tanshinone, which can improves microcirculation, alleviates insufficient blood perfusion and thrombosis in pancreatic tissue, thereby protecting acinar cells and inhibiting further release and activation of pancreatic enzymes (Chen W *et al.,* 2020). Notably, the study revealed significantly better improvements in CRP and PCT levels in the observation group ($P<0.05$), highlighting the therapy's core mechanism in regulating systemic inflammatory responses. AP fundamentally manifests as an uncontrolled inflammatory cascade: activated pancreatic enzymes digest pancreatic tissue, releasing DAMPs that activate immune cells, produce and release of a cascade of inflammatory cytokines (Yan C *et al.,* 2024).

The herbal formula Tongfu Qinghua decoction, containing dandelion, patrinia, honeysuckle and *Polygonum cuspidatum*, is rich in flavonoids, polysaccharides and organic acids. Extensive research has demonstrated its potent anti-inflammatory effects, thereby down regulating the expression of pro-inflammatory factors (Kweon B *et al.,* 2024; Thompson A *et al.,* 2023). The external application of Ruyi Jinhuang Powder, composed of rhubarb, Phellodendron and turmeric, contains active components with significant anti-inflammatory and antioxidant properties. These components can be absorbed through the skin to suppress both localized and systemic inflammatory responses (Hu Y *et al.,* 2021). Additionally, studies suggest that under oxidative stress, the excessive production of oxygen-free radicals during pancreatic inflammation attacks cell membranes.

Table 7: Comparison of hospitalization time and symptom relief time between the two groups in different age subgroups.

Age subgroups (years)	Groups	n	Length of stay (d)	Abdominal pain relief time (d)	Bloating relief time (d)	First exhaust time (d)	First bowel movement time (d)	Time of first bowel sounds (d)	Time of first eating
18–40	Control	15	7.42±1.71	5.12±0.93	5.20±1.06	4.28±0.92	5.62±1.20	4.02±1.08	4.18±1.32
18–40	Observation	16	6.01±1.42	4.41±0.71	4.38±0.68	3.21±0.84	3.89±0.91	2.78±0.62	3.42±1.19
t/P			2.504/0.018	1.399/0.023	2.581/0.015	3.385/0.002	4.541/＜0.001	3.953/＜0.001	2.686/0.011
41–60	Control	24	7.96±1.89	5.50±1.02	5.66±1.18	4.70±0.98	6.06±1.33	4.36±1.22	4.77±1.46
41–60	Observation	23	6.63±1.63	4.98±0.79	4.99±0.81	3.64±0.95	4.33±1.05	3.17±0.69	3.88±1.41
t/P			2.579/0.013	2.019/0.048	2.260/0.029	3.763/<0.001	4.935/<0.001	4.092/<0.001	2.124/0.039
61–75	Control	11	8.56±2.03	5.93±1.11	5.98±1.24	5.08±1.07	6.58±1.41	4.81±1.30	5.02±1.58
61–75	Observation	11	7.31±1.76	5.32±0.88	5.21±0.86	4.16±1.03	5.86±1.14	3.94±0.82	4.35±1.53
t/P			1.543/0.138	1.428/0.169	1.692/0.106	2.054/0.053	1.317/0.203	1.877/0.075	1.010/0.324

Table 8: Comparison of pancreatitis indicators between the two groups in different age subgroups before and after treatment.

Age subgroups (years)	Groups	n	AMY (U/L)		UAMY(U/L)	
			before	*after*	*before*	*after*
18–40	Control	15	572.36±168.44	160.28±54.17*	2102.41±186.36	1132.48±85.67*
18–40	Observation	16	530.45±171.26	76.84±28.51*	2088.62±192.58	1048.36±71.52*
t/P			0.686/0.498	5.417/<0.001	0.202/0.841	2.975/0.006
41–60	Control	24	591.84±176.13	173.40±61.23*	2137.95±196.82	1152.17±93.04*
41–60	Observation	23	539.28±179.51	87.55±32.66*	2115.83±205.47	1068.44±79.83*
t/P			1.013/0.316	5.959/<0.001	0.377/0.708	3.305/0.002
61–75	Control	11	608.17±181.55	186.35±68.41*	2154.76±205.13	1168.22±98.75*
61–75	Observation	11	543.91±184.28	99.42±36.28*	2126.47±214.30	1069.63±86.91*
t/P			0.824/0.420	3.723/0.001	0.316/0.755	2.486/0.022

Note: The asterisk (*) in Table 8 indicates a statistically significant difference (P<0.05) compared to pre-treatment levels.

Table 9: Comparison of inflammatory markers between the two groups in different age subgroups before and after treatment.

Age subgroups (years)	Groups	n	CRP (mg/L)		PCT (μg/L)	
			before	*after*	*before*	*after*
18–40	Control	15	113.42±8.75	45.12±3.26*	3.05±0.37	2.07±0.31*
18–40	Observation	16	116.28±8.16	40.06±3.54*	3.02±0.35	1.63±0.24*
t/P			-0.942/0.354	4.132/<0.001	0.232/0.818	4.435/<0.001
41–60	Control	24	115.88±9.22	47.05±3.47*	3.11±0.40	2.17±0.35*
41–60	Observation	23	118.24±8.61	42.31±3.86*	3.09±0.39	1.78±0.27*
t/P			-0.906/0.370	4.431/<0.001	0.173/0.863	4.284/<0.001
61–75	Control	11	117.21±10.04	49.18±3.83*	3.17±0.46	2.29±0.39*
61–75	Observation	11	119.63±9.18	44.25±4.12*	3.14±0.44	1.91±0.31*
t/P			-0.590/0.562	2.907/0.009	0.156/0.877	2.530/0.020

Note: The asterisk (*) in Table 9 indicates a statistically significant difference (P<0.05) compared to pre-treatment levels.

Table 10: Comparison of overall efficacy between the two groups in different age subgroups before and after treatment.

Age subgroups (Years)	Groups	n	Complete cure	Marked efficacy	Effective efficacy	Ineffective efficacy	Efficient
18–40	Control	15	4	3	4	4	11/15 (73.33%)
18–40	Observation	16	6	6	3	1	15/16 (93.75%)
χ^2/p							2.386/0.122
41–60	Control	24	5	6	4	9	15/24 (62.50%)
41–60	Observation	23	7	8	5	3	20/23 (86.96%)
χ^2/p							3.695/0.055
61–75	Control	11	2	2	1	6	5/11 (45.45%)
61–75	Observation	11	3	7	0	1	8/11 (90.91%)
χ^2/p							1.692/0.193

Table 11: Comparison of adverse reactions between the two groups in different age subgroups before and after treatment.

Age subgroups (Years)	Groups	n	Gastrointestinal bleeding	Dizziness and headache	Gastrointestinal dis comfort	Rash	Perianal redness and swelling	Adverse reactions
18–40	Control	15	0	0	1	0	0	1 (6.67%)
18–40	Observation	16	0	0	0	1	0	1 (6.25%)
Fisher/p								0.002/0.962
41–60	Control	24	0	0	0	0	1	1 (4.17%)
41–60	Observation	23	0	0	0	0	0	0 (0.00%)
Fisher/p								0.979/0.322
61–75	Control	11	0	0	0	0	0	0 (0.00%)
61–75	Observation	11	0	0	1	1	0	2 (9.09%)
Fisher/p								2.200/0.138

leading to increased lipid peroxidation products such as malondialdehyde (MDA) while depleting antioxidant substances such as superoxide dismutase (SOD) and glutathione (GSH). Traditional Chinese medicine formulations may partially improve oxidative stress indicators in patients with acute pancreatitis (AP) (Xia CC *et al.,* 2024; Chen H *et al.,* 2025). However, this study does not explore oxidative stress indicators, representing a limitation in our research. Future investigations could further investigate this aspect.

Considering the relatively wide age range of the enrolled patients (18–75 years), a subgroup analysis stratified by age (18–40 years, 41–60 years and 61–75 years) was performed to further evaluate whether the therapeutic effects of the intervention were consistent across different age groups. As detailed in tables 7–11, the results showed that in the 18–40 years and 41–60 years subgroups, patients in the observation group had significantly shorter hospitalization duration, faster relief of abdominal pain and abdominal distension, earlier recovery of gastrointestinal function (including first exhaust, first defecation, bowel sound recovery and first food intake) and significantly better improvement in pancreatic inflammation markers and inflammatory indicators after treatment than those in the corresponding control subgroups (all $P<0.05$). These findings indicate that the combined therapy showed clear clinical benefit in younger and middle-aged patients.

In the **61–75 years** subgroup, although the observation group showed numerically shorter symptom relief time and hospitalization duration than the control group, these differences were not statistically significant (all $P>0.05$). However, treatment-related improvements in pancreatic inflammation markers and inflammatory indicators remained significant in this subgroup, as the post-treatment levels of AMY, UAMY, CRP and PCT were all significantly lower in the observation group than in the age-matched control group (all $P<0.05$). This suggests that combined therapy may still provide biochemical and anti-inflammatory benefits in elderly patients, although improvements in clinical recovery indicators appear less pronounced than those observed in younger age groups.

Regarding overall efficacy, the observation group showed higher effective rates than the control group across all age subgroups; however, the between-group differences within each age subgroup did not reach statistical significance (all $P>0.05$), which may be related to the relatively small sample size after stratification. In addition, the incidence of adverse reactions was low in all age subgroups, with no statistically significant difference between the two groups within any age stratum (all $P>0.05$), indicating a favorable safety profile of the integrated therapy across the full age range studied. Overall, Tongfu Qinghua decoction enema combined with external application of Ruyi Jinhuang powder demonstrated more prominent advantages in

younger and middle-aged patients, while still showing beneficial effects on pancreatic enzyme and inflammatory marker recovery in elderly patients. These findings suggest that the combined therapy is generally safe across different age groups, but its clinical benefit in older patients may require further confirmation in studies with larger sample sizes.

This study has certain limitations that need to be acknowledged. First, it is a single-center study with a relatively small sample size, which may limit the generalizability of the results to other populations and medical centers. Second, the observation duration is limited to the in-hospital treatment period, lacking long-term follow-up data on disease recurrence, pancreatic function recovery and delayed adverse reactions. Third, the study only detected conventional inflammatory and pancreatic markers, without exploring oxidative stress, intestinal mucosal barrier and gut microbiota-related indicators that are closely associated with acute pancreatitis pathogenesis and no stratification analysis was conducted for different disease severities. In addition, the non-blinded study design due to the characteristics of TCM interventions may lead to potential assessment bias. In conclusion, the conventional Western medical treatment combined with Tongfu Qinghua Decoction enema and Ruyi Jinhuang Powder external application can accelerate symptom relief and intestinal function recovery in acute pancreatitis patients, shorten hospitalization duration and improve enzyme levels and inflammatory markers. Its multi-target mechanism is supported by evidence-based research, making it worthy of clinical promotion and offering a novel therapeutic approach for acute pancreatitis (AP). For future research, multi-center, large-sample and long-term follow-up randomized controlled trials are recommended, with stratification analysis for different disease severities and etiologies to verify the long-term efficacy and applicable population of this therapy. It is also suggested to expand the detection of oxidative stress, intestinal barrier and gut microbiota indicators and combine multi-omics technology to explore the deep molecular mechanism of the combined therapy and further carry out research on its dose-response relationship and optimal treatment course to provide more solid scientific evidence for its clinical application.

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Author's contributions
Mengyao Wang: Responsible for the writing and data collection of this study; Qingmiao Zhou: Responsible for the conceptualization, communication and translation of this study.

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Data availability statement
The datasets generated during and/or analysed during the current study are available from the corresponding author on request.

Ethical approval
This study was approved by the Ethics Committee of The Third Affiliated Hospital of Wenzhou Medical University, under the approval number YJ2023052. Written informed consent was obtained from all individual participants included in the study prior to enrolment. This study was performed in adherence with the CONSORT guidelines. See supplementary file for the CONSORT checklist.

Trial registration
This trial was registered retrospectively on 14/07/2026 with registry number NCT07712081. The first participant was enrolled on 01/09/2022. Ethical approval was obtained on 18/10/2023.

Editorial Note
This trial was registered retrospectively (after participant enrollment began). The journal has verified that prospective ethical approval was obtained from the authors' Institutional Review Board on 18/10/2023. The authors have provided justification for delayed registration. Readers are advised to interpret the findings with awareness of this limitation.

Conflict of interest
The authors declare no conflict of interest.

Supplementary data
https://www.pjps.pk/uploads/2026/08/SUP1785835581.pdf

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