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Clinical observation of the treatment of acute pancreatitis with traditional Chinese medicine compound preparation[☆]

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ABSTRACT

Introduction: Acute pancreatitis (AP), a prevalent gastrointestinal disorder characterized by pancreatic autodigestion, currently lacks targeted therapeutic agents despite its clinical significance. In contemporary medical practice, traditional Chinese medicine (TCM) formulations have gained increasing clinical traction for AP management in China. This retrospective controlled trial systematically investigated the therapeutic potential of a novel compound herbal formulation, with a focused evaluation of its clinical efficacy and safety profile in the management of acute pancreatitis (AP).

Methods: This retrospective study enrolled 363 acute pancreatitis (AP) patients, stratified into two cohorts: 235 patients receiving traditional Chinese medicine (TCM) intervention, and 128 patients allocated to the control group. Both cohorts received standardized therapeutic interventions upon hospitalization. Clinical parameters including time to first defecation, admission intra-abdominal pressure, C-reactive protein (CRP) levels, postoperative intra-abdominal pressure at 48-hour intervals, incidence of adverse reactions and complications, and prognostic outcomes were systematically monitored and recorded throughout the treatment course.

Results: The clinical investigation demonstrated that patients administered a TCM-based therapeutic regimen exhibited significantly accelerated time to first bowel movement compared with the control cohort following hospital admission ($p<0.001$). Comparative analysis revealed no statistically significant intergroup differences in abdominal pressure reduction, C-reactive protein (CRP) levels, or clinical recovery status at baseline assessment. However, subsequent to 48 hours of therapeutic intervention, the TCM group demonstrated statistically superior reductions in both intra-abdominal pressure ($p<0.001$) and serum CRP concentrations ($p<0.001$) relative to conventional treatment recipients. Notably, the TCM intervention cohort exhibited a significantly lower incidence of adverse reactions and post-treatment complications ($p<0.001$) .

Conclusion: The treatment group administered TCM, a Chinese herbal compound formulation, exhibited significantly superior clinical efficacy in multiple outcome measures compared to conventional therapy. Specifically, TCM demonstrated enhanced constipation relief, more substantial reduction in inflammatory markers, greater mitigation of intra-abdominal pressure, and lower incidence of adverse reactions during acute pancreatitis management.

1. Introduction

Acute pancreatitis (AP) represents a prevalent gastrointestinal disorder and ranks among the most prevalent acute abdominal pathologies necessitating hospital admission. The principal etiological factors underlying AP are biliary disorders and excessive alcohol consumption, with a global incidence approximating 34 cases per 100,000 person-years [1–3]. Notably, epidemiological data indicate a persistent escalation in AP incidence over recent decades [3–7]. Disease severity, stratified as mild, moderate, or severe according to the Revised Atlanta Classification [8], is contingent upon the extent of pancreatic parenchymal and peripancreatic tissue injury, particularly the development. Acute pancreatitis (AP) manifests clinically as acute upper abdominal pain accompanied by characteristic symptoms including nausea,

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vomiting, pyrexia, and elevated serum amylase levels. Approximately 20% of AP cases progress to severe acute pancreatitis (SAP), a critical condition defined by pancreatic parenchymal necrosis and multiorgan dysfunction [8–12]. Epidemiologically, AP represents a leading cause of prolonged hospitalization, substantial healthcare expenditures, and in-hospital mortality. Notwithstanding advancements in therapeutic interventions and critical care management, SAP-induced multiorgan failure persists as a formidable clinical challenge with associated mortality risks [2,13]. Previous The clinical management of SAP continues to present formidable clinical challenges. While targeted pharmacological therapies for acute pancreatitis remain under development, emerging evidence underscores the critical importance of implementing comprehensive early intervention strategies. These protocols encompass timely disease severity stratification, optimized fluid resuscitation regimens, multimodal analgesic approaches, and precision nutritional support systems. Current clinical studies demonstrate that appropriate initial therapeutic interventions can effectively modulate disease progression kinetics and significantly reduce hospitalization durations [14–17].

Accumulating empirical evidence indicates that Traditional Chinese Medicine (TCM) demonstrates therapeutic potential as an adjunctive intervention in critical care settings. The natural compounds found in the herb Andrographis paniculata offer a safer, natural adjunctive treatment option for patients with beta thalassemia [18]. Current clinical applications encompass complementary therapeutic modalities for acute cardiovascular pathologies, cerebral ischemic events, and acute pancreatic inflammation. Nevertheless, comprehensive evaluation of their safety profiles and clinical efficacy requires rigorous validation through methodologically robust randomized controlled trials. The scientific community emphasizes the necessity of implementing standardized clinical research protocols to substantiate TCM's therapeutic claims and facilitate its integration into evidence-based critical care practice [19]. Consequently, clinical data from patients diagnosed with AP were systematically collected at Wuming Hospital of Guangxi Medical University between June 2016 and May 2019. Building upon standard therapeutic protocols, this investigation incorporated TCM compound prescription granules as an adjuvant therapy. A preliminary assessment was conducted to evaluate both the clinical safety profile and therapeutic efficacy of this integrated approach. The findings offer valuable theoretical foundations and clinical evidence to inform future applications of TCM compound formulations in AP management, while establishing methodological references for subsequent pharmacological research in this domain.

2. Clinical data and methods

2.1. Experimental design

This study employed a dual methodological approach combining retrospective data analysis with a controlled trial design. The research protocol received formal approval from the Scientific Ethics Committee of Guangxi Medical University (Ethical Review Number: WM-2025 (03)).

2.2. Patient selection

A retrospective analysis was conducted on 560 patients initially diagnosed with acute pancreatitis at our institution between June 2016 and May 2019, all of whom manifested the damp-heat excess syndrome pattern through Traditional Chinese Medicine (TCM) syndrome differentiation. The diagnostic criteria for damp-heat excess syndrome were defined as follows: this clinical pattern in TCM refers to a pathophysiological state characterized by the co-existence and accumulation of exogenous dampness and heat pathogens within the organism, resulting in functional disturbances of visceral organs and meridians. The core pathomechanism involves the intricate interaction between dampness and heat pathogens, characterized by persistent cohabitation of turbid dampness and heat toxins that exhibit marked therapeutic resistance. The study cohort comprised 382 male (68.2%) and 178 female (31.8%) participants, with a mean age of 55.82±17.7 years. Inclusion criteria were strictly defined as: (1) met the revised Atlanta classification criteria for AP diagnosis; (2) maintained complete clinical documentation with age parameters between 18-80 years; (3) demonstrated minimum hospitalization duration of 7 days. The exclusion criteria comprised: (1) Acute pancreatitis (AP) during the gestational period; (2) Prior diagnosis of chronic pancreatitis; (3) Undergoing surgical interventions or early therapeutic measures preceding hospital admission; (4) Severe comorbidities affecting the digestive system; (5) Documented hypersensitivity to pharmacological agents employed in the current investigation; (6) Concurrent malignancies or hematological/immunological disorders; (7) Age $<$18 years or $>$80 years at presentation. Study participants were stratified into two cohorts based on therapeutic intervention: the experimental group receiving compound herbal formulations and the control group undergoing conventional treatment. The final cohort comprised 363 eligible participants, with 235 subjects allocated to the herbal treatment group and 128 to the conventional therapy group, as delineated in Fig. 1. Comparative analysis of baseline demographic and clinical characteristics between groups is presented in Table 1, demonstrating comparability in baseline characteristics prior to intervention.

2.3. Treatment methods

Following hospital admission, the conventional treatment group received active administration of therapeutic interventions in strict accordance with current clinical diagnosis and treatment protocols. The comprehensive therapeutic regimen comprised five principal components: acid suppression therapy, enzymatic inhibition management, intravenous fluid resuscitation, anti-inflammatory mediator regulation, and systematic organ function preservation strategies. Building upon conventional therapeutic protocols, the compound TCM intervention group received a formulated prescription comprising TCM granules. This pharmacological composition incorporated 13 herbal components.

A traditional Chinese medicine compound preparation and its preparation method and application, wherein the raw material components include main materials and auxiliary materials, with the main materials comprising: 20 g of raw rhubarb (added later), 6 g of senna leaves (added later), 10 g of magnolia bark, 10 g of immature bitter orange, 12 g of raw scutellaria root, 10 g of coptis root, 12 g of corydalis rhizome, 10 g of costus root, 12 g of kudzu root, 15 g of giant knotweed rhizome, 6 g of bupleurum root, 4 g of tangerine peel, and 12 g of red peony root. The auxiliary materials include starch, mannitol, and sodium carboxymethyl starch.

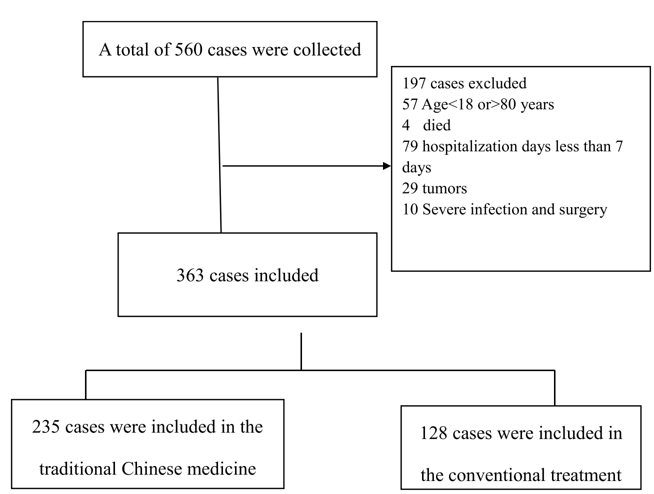

Fig. 1. *Flow chart of inclusion and exclusion of all AP patients collected.

Table 1
*Baseline characteristics of the Chinese medicine group and the conventional group, basic characteristics were not different except gastritis (P>0.05).

variable	TCM (n=235)	Conventional (n=128)	T/χ 2 value	P value
General Information				
Male	158(67.23)	94(75.2)	1.5	0.22
Age ($\overline{X} \pm s$)	54.75 ±15.41	51.56±14.96	1.91	0.06
Basic diseases				
hypertension	47(20)	20(15.63)	1.05	0.31
gastritis	53(22.55)	48(37.5)	9.22	0.002
Diabetes	38(16.17)	14(10.94)	1.85	0.17
Heart disease	9(3.83)	6(4.69)	0.15	0.70
Kidney failure	72 (30.63)	41 (32.03)	0.08	0.78
hepatic disease	159 (67.66)	77 (60.16)	2.05	0.15
SAP	11(4.68)	2(1.56)	2.33	0.13

1. Extraction: First, the required amount of the main material (excluding rhubarb and senna leaves) is crushed according to weight ratio, mixed evenly with water or an equal volume of grain-based liquor (above 60% alcohol), soaked for 3–8 hours, and extracted 1–4 times. The resulting extracts are combined, filtered to remove residues, and concentrated to obtain a concentrated solution. Rhubarb and senna leaves are separately processed and extracted with water.
2. Drying: The main material is dried with an inlet air temperature of 90–110°C and an outlet air temperature of 65–80°C. The concentrated solutions of rhubarb and senna leaves are dried with an inlet air temperature of 20°C and an outlet air temperature of 80°C.
3. Granulation: The mixture of the extract and the required amount of auxiliary materials is uniformly blended and then prepared into granules using conventional pharmaceutical preparation methods to form the traditional Chinese medicine compound preparation.

2.4. Observation indicators

The principal clinical parameters documented in patients encompassed: time interval between hospital admission and first defecation, initial intra-abdominal pressure measurement, C-reactive protein (CRP) levels, dynamic changes in intra-abdominal pressure and CRP levels at 48 hours post-treatment, incidence of adverse reactions and complications, along with prognostic outcomes and related clinical indicators.

2.5. Statistical processing

Statistical analyses were conducted using SPSS 26.0 (IBM Corp.) and graphical representations were generated with GraphPad Prism 10 (Version 10.0.0). Normally distributed continuous variables were expressed as mean ± standard deviation ($\bar{x} \pm s$), with intergroup comparisons performed using Student's t-test. One-way analysis of variance (ANOVA) was applied for multi-group comparisons of continuous variables. Categorical variables were presented as frequencies and percentages (n,%), analyzed through chi-squared tests. Statistical significance was defined as a two-tailed P-value < 0.05 for all inferential analyses.

3. Results

3.1. Comparative analysis of baseline demographic and clinical parameters between TCM and conventional treatment cohorts upon hospital admission

All enrolled patients underwent rigorous clinical monitoring and standardized therapeutic interventions following hospital admission. Initial comparative analysis revealed that, with the exception of pre-existing gastritis diagnoses which demonstrated statistical significance ($p < 0.05$), both cohorts exhibited comparable baseline demographic and clinical parameters without significant intergroup variation ($p > 0.05$). Comprehensive evaluation of population characteristics confirmed adequate balance between the two study groups across all measured variables, with no statistically discernible differences observed ($p > 0.05$), as detailed in Table 1. The multivariate analysis examining the influence of confounding factors on treatment effect—including the timing of first defecation following admission, changes in intra-abdominal pressure, and variations in C-reactive protein response—is presented in Tables 2, 3, and 4. The stratified analysis delving into the potential impacts of various hepatic and gastrointestinal conditions—including liver diseases, gastritis, and severe pancreatitis—on the timing of initial defecation post-admission, dynamic fluctuations in intra-abdominal pressure, and longitudinal variations in C-reactive protein levels is comprehensively presented as meticulously detailed in Tables 5, 6, and 7.

Baseline feature table:

Table 2, 3, and 4 illustrate the regression analysis of confounding factors influencing treatment outcomes. Crucially, the detailed regression outcomes across variables reveal that all nine baseline characteristic independent variables demonstrated statistical stability in T-tests, exhibiting P-values consistently exceeding 0.05. This statistical landscape confirms these independent variables did not xhibit statistically significant influence on the dependent variable - specifically, the duration from hospital admission to first bowel movement, fluctuations in abdominal pressure, and variations in C-reactive protein concentrations. Notably, a striking divergence emerged between treatment modalities: comparative analysis showed substantial differences.

Tables 5, 6, and 7 were meticulously crafted to explore the influence of gastritis, liver disease, and SAP on therapeutic efficacy, focusing specifically on three pivotal metrics: the timing of initial bowel movement post-admission, fluctuations in intra-abdominal pressure, and variations in C-reactive protein concentrations. The dependent variables—"time of the first bowel movement upon admission,"" changes in abdominal pressure," and "changes in C-reactive protein levels"—served as critical indicators for assessing clinical progression. The independent variables encompassed age, gender, hypertension, diabetes, cardiac disease, renal insufficiency, and group. To account for the potential influences of these factors, a stratified regression analysis was employed. The first layer comprised " age,"" gender," "hypertension,"" diabetes,"" cardiac disease,"" renal insufficiency," and "group." The second layer featured "gastritis." Finally, the third layer encompassed "liver disease." The fourth layer incorporated "SAP," with the explanatory power of these factors quantified through ΔR^2 for three key metrics: "time of first bowel movement upon admission," "abdominal pressure variations," and "C-reactive protein level fluctuations." After adjusting for covariates including "age," "gender," "hypertension," "diabetes," "cardiac disease," "renal insufficiency," and "group," the analysis revealed no statistically significant influence of "gastritis," "liver disease," or "SAP" on bowel movement timing, intra-abdominal pressure dynamics, or inflammatory biomarker changes (all P-values >0.05). The quantity change was negligible (Δ=0). Consequently, gastritis, liver disease, and SAP demonstrated no significant impact on therapeutic outcomes, specifically regarding the timing of first in-hospital bowel movement, changes in abdominal pressure, and C-reactive protein response levels. Notably, a statistically significant difference emerged between TCM treatment protocols and conventional therapeutic approaches.

3.1. Comparison of baseline characteristics between Chinese medicine group and conventional group at admission

All patients underwent rigorous testing and active treatment upon admission. At the time of admission, apart from having gastritis as a common underlying condition, there were no significant differences (P

Table 2
shows the regression analysis of the first stool time after admission as the dependent variable.

model						The 95.0% confidence interval for B		Collinear statistics	
	Unstandardized coefficient B	The standard is wrong	Standardized coefficient Beta	t	conspicuousness	lower limit	superior limit	tolerance	VIF
(constant)	-19.31	15.73		-1.23	0.22	-50.25	11.62		
age	0.05	0.07	0.04	0.71	0.48	-0.09	0.19	0.53	1.88
sex	-1.77	1.75	-0.04	-1.01	0.31	-5.22	1.67	0.96	1.04
hypertension	-2.15	2.23	-0.04	-0.96	0.34	-6.53	2.24	0.96	1.05
gastritis	-3.54	1.84	-0.07	-1.92	0.06	-7.15	0.08	0.933	1.07
diabetes mellitus	-3.66	2.53	-0.06	-1.45	0.15	-8.63	1.31	0.82	1.23
Heart disease	3.98	4.14	0.04	0.96	0.34	-4.16	12.11	0.93	1.08
hepatic disease	-3.39	2.02	-0.07	-1.68	0.09	-7.36	0.58	0.67	1.48
renal inadequacy	3.43	1.81	0.07	1.89	0.06	-0.14	6.99	0.89	1.12
SAP	1.72	4.04	0.02	0.43	0.67	-6.22	9.66	0.97	1.03
group (TCM)	33.87	1.70	0.73	19.97	P<0.000	30.53	37.20	0.96	1.04
R	R^2=0.55								
F	F=43.38, P<0.0001								

Dependent variable: first defecation time

Table 3
is the regression analysis table with abdominal pressure change value as the dependent variable.

model						The 95.0% confidence interval for B		Collinear statistics	
	Unstandardized coefficient B	The standard is wrong	Standardized coefficient Beta	t	conspicuousness	lower limit	superior limit	tolerance	VIF
(constant)	9.16	3.13		2.93	0.00	3.01	15.31		
age	0.00	0.01	0.01	0.21	0.83	-0.03	0.03	0.53	1.88
sex	0.05	0.35	0.01	0.15	0.89	-0.63	0.74	0.96	1.04
hypertension	-0.09	0.44	-0.01	-0.21	0.84	-0.96	0.78	0.96	1.05
gastritis	0.45	0.37	0.06	1.22	0.22	-0.27	1.17	0.93	1.07
diabetes mellitus	0.20	0.50	0.02	0.41	0.69	-0.79	1.19	0.82	1.23
Heart disease	0.84	0.82	0.05	1.02	0.31	-0.78	2.45	0.93	1.08
hepatic disease	0.06	0.40	0.01	0.14	0.89	-0.73	0.85	0.67	1.48
renal inadequacy	-0.53	0.36	-0.07	-1.48	0.14	-1.24	0.18	0.89	1.12
S ap	-1.013	0.803	-0.06	-1.261	0.208	-2.591	0.566	0.974	1.027
group	-3.12	0.337	-0.444	-9.254	<0.0001	-3.783	-2.457	0,958	1.044
R^2				R^2=0.22					
F				F=1 0.11	P<0.0001				

Dependent variable: change in abdominal pressure

Table 4
is the regression analysis table with C protein reaction change value as the dependent variable.

model						The 95.0% confidence interval for B		Collinear statistics	
	Unstandardized coefficient B	The standard is wrong	Standardization coefficient Be ta	t	conspicuousness	lower limit	superior limit	tolerance	VIF
(constant)	56.84	22.19		2.56	0.01	13.20	100.49		
age	-0.02	0.10	-0.01	-0.15	0.88	-0.21	0.18	0.53	1.88
sex	1.75	2.47	0.03	0.71	0.48	-3.12	6.61	0.96	1.04
hypertension	1.97	3.15	0.03	0.63	0.53	-4.22	8.15	0.96	1.05
gastritis	1.93	2.59	0.04	0.74	0.46	-3.18	7.03	0.93	1.07
diabetes mellitus	-5.43	3.57	-0.08	-1.52	0.13	-12.44	1.59	0.82	1.23
Heart disease	2.10	5.84	0.02	0.36	0.72	-9.38	13.57	0.93	1.08
hepatic disease	-0.72	2.85	-0.01	-0.25	0.80	-6.32	4.89	0.67	1.48
renal inadequacy	-0.69	2.56	-0.01	-0.27	0.79	-5.72	4.35	0.89	1.12
S ap	4.05	5.698	0.033	0.033	0.711	0.478	-7.157	15.256	0.974
group (TCM)	-26.20	2.393	-0.507	-0.507	-10.949	<0.0001	-30.91	-21.496	0.958
R^2				R^2=0.28					
F				F=13.54	P<0.0001				

a Dependent variable: C protein response change value

Table 5
Regression analysis of gastritis, liver disease and SAP on the first stool in hospital (N=363).

	Model 1		Model 2		model 3		model 4	
	β	p	β	p	β	p	β	p
(constant)	-30.1	0.02	-23.94	0.06	-16.05	0.24	-19.31	0.22
age	0.10	0.89	0.11	0.06	0.05	0.48	0.051	0.48
sex	-2.07	0.24	-2.01	0.25	-1.8 2	0.30	-1.77	0.31
hypertension	-2	0.37	-2.46	0.27	-2.1	0.35	-2.1 5	0.34
diabetes mellitus	-3.11	0.22	-2.97	0.24	-3.6	0.15	-3.66	0.15
Heart disease	3.96	0.34	3.82	0.3	4	0.33	3.9 8	0.34
renal inadequacy	2.91	0.11	3.42	0.06	3.4 5	0.06	3.4 3	0.06
group (TCM)	34.33	0.00	33.82	0.00	33.8 8	0.00	33.8 7	0.00
gastritis			-3.15	0.06	-3.6	0.05	-3. 54	0.06
hepatic disease					-3.37	0.1	-3.39	0.09
SAP							1.72	0.67
R^2	0.54		0.55		0.55		0.55	
Adjusted R^2	0.55		0.55		0.55		0.55	
F price	60.4		53.71		48.3		43.4	
P value	0.00		0.00		0.00		0.00	

Dependent variable: first defecation time

Table 6
Regression analysis of abdominal pressure changes in gastritis, liver disease and SAP (N=363).

	Model 1		Model 2		model 3		model 4	
	β	p	β	p	β	p	β	p
(constant)	8.19	0.001	7.3 4	0.004	7.23	0.008	9.16	0.004
age	0.004	0.76	0.002	0.84	0.003	0.82	0.003	0.83
sex	0.09	0.80	0.08	0.82	0.0 8	0.82	0 .05	0.89
hypertension	-0.18	0.69	-0.11	0.80	-0.12	0.79	-0.09.	0.84
diabetes mellitus	0.18	0.71	0.16	0.74	0.17	0.74	0.2.	0.69
Heart disease	0.81	0.33	0.8 3	0.32	0.82	0.32	0.84.	0.31
renal inadequacy	-0.47	0.19	-0.54	0.13	-0.54	0.13	- 0.53.	0.14
group (TCM)	-3.19	0.000	-3.12	0.000	-3.13	0.000	-3.12.	0.000
gastritis			0.4 9	0.18	0.4 9	0.18	0.45.	0.22
hepatic disease					0.0 5	0.91	0.06.	0.89
SAP							-1.01	0.21
R^2	0.22		0.22		0.22		0.22	
Adjusted R^2	0.2		0.2		0.2		0.2	
F price	13.94		12.45		11.03		10.11	
P value	0.00		0.00		0.00		0.00	

Dependent variable: abdominal pressure change value

Table 7
Regression analysis of the change value of C protein response in gastritis, liver disease and SAP (N=363).

	Model 1		Model 2		model 3		model 4	
	β	p	β	p	β	p	β	p
(constant)	66.1	0.000	62.97	0.001	64.53	0.001	56.84	0.01
age	0.001	0.99	-0.003	0.974	-0.02	0.88	-0.02	0.88
sex	1.64	0.51	1.60	0.52	1.64	0.51	1.75	0.48
hypertension	1.77	0.57	2.01	0.52	2.08	0.51	1.97	0.53
diabetes mellitus	-5.1	0.15	-5.17	0.14	-5.3	0.14	-5.43	0.13
Heart disease	2.04	0.73	2.11	0.72	2.15	0.71	2.1	0.72
renal inadequacy	-0.39	0.88	-0.64	0.80	-0.64	0.80	- 0.69	0.79
group (TCM)	-26.45	0.000	-26.2	0.000	-26.18	0.000	26.2	0.000
gastritis			1.79	0.49	1.77	0.49	1.93	0.46
hepatic disease					-0.67	0.82	-0.72	0.80
SAP							4.05	6 0.48
R^2	0.28		0.28		0.28		0.28	
Adjusted R^2	0.26		0.26		0.26		0.26	
The F value was	19.31		16.93		15.01		13.54	
P value	0.00		0.00		0.00		0.00	

Dependent variable: C protein response change value

<0.05) in other baseline characteristics between the two groups. The baseline characteristics of the two groups were basically balanced, and statistical tests showed no significant differences (P> 0.05). For specific data, see Table 1.

We also conducted a regression analysis of confounding factors on treatment outcomes (the time of the first bowel movement upon admission, changes in abdominal pressure, and changes in C-reactive protein) as shown in Tables 2, 3, and 4. Specifically, we examined the regression of each variable, and it was found that all nine baseline characteristic independent variables passed their T-tests, with P-values all greater than 0.05. This indicates that the independent variables had no significant impact on the dependent variables: the time of the first bowel movement upon admission, changes in abdominal pressure, and changes in C-reactive protein. However, there were significant differences between conventional treatment and traditional Chinese medicine ($P < 0.0001$). For the effects of gastritis, liver disease, and SAP on treatment outcomes, i.e.However, the time of the first bowel movement upon admission, changes in abdominal pressure, and changes in C-reactive protein, stratified analyses as shown in Tables 5, 6, and 7 revealed that these conditions did not significantly affect the treatment outcomes. Instead, traditional Chinese medicine treatment showed a statistically significant difference compared to conventional treatment.

3.2. Comparison of time to first defecation between TCM and conventional treatment groups

As demonstrated in Fig. 2, comparative analysis of time to initial defecation (hours) post-admission revealed statistically significant differences between the two groups: TCM prescription granule group (10.41 ± 7.96 hours) versus conventional treatment group (44.31 ± 23.38 hours) ($t = -20.20$, $p < 0.001$). The TCM group exhibited superior efficacy in accelerating gastrointestinal motility compared to conventional therapeutic interventions. This outcome indicates that TCM granules significantly enhanced gastrointestinal peristalsis relative to standard treatment protocols.

3.3. Comparative Analysis of Post-Therapeutic Intra-Abdominal Pressure Between TCM and Conventional Treatment Groups

As illustrated in Fig. 3, preliminary evaluations showed no statistically significant disparity in intra-abdominal pressure (IAP) between the two groups at initial hospitalization ($p=0.13$). Subsequent analyses revealed that the TCM intervention cohort attained a pronounced reduction in IAP levels following 48 hours of targeted therapy, with post-treatment measurements (6.10 ± 3.20 mmHg) demonstrating statistically significant improvement relative to baseline values (2.90 ± 2.57 mmHg) ($t=-9.74$, $p<0.001$), as detailed in Fig. 4. Furthermore, in managing acute pancreatitis (AP), TCM exhibits superior efficacy in reducing intra-abdominal pressure compared to conventional treatment protocols.

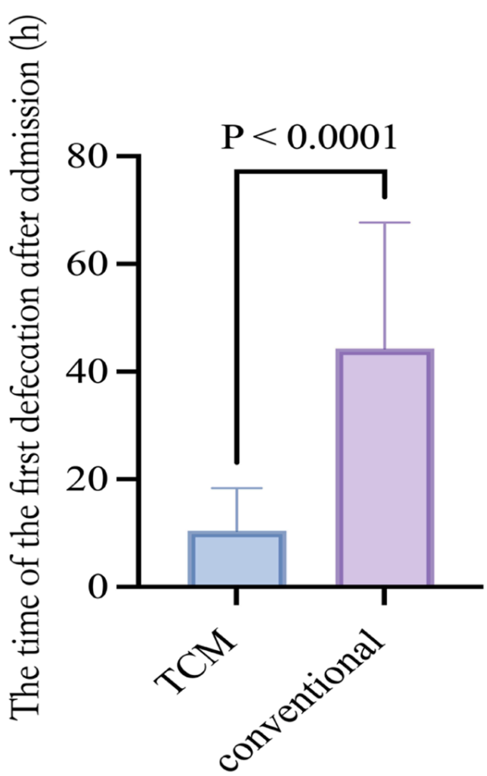

Fig. 2. *presents the comparative analysis of initial defecation time post-admission between the Traditional Chinese Medicine (TCM) group and the conventional treatment group.

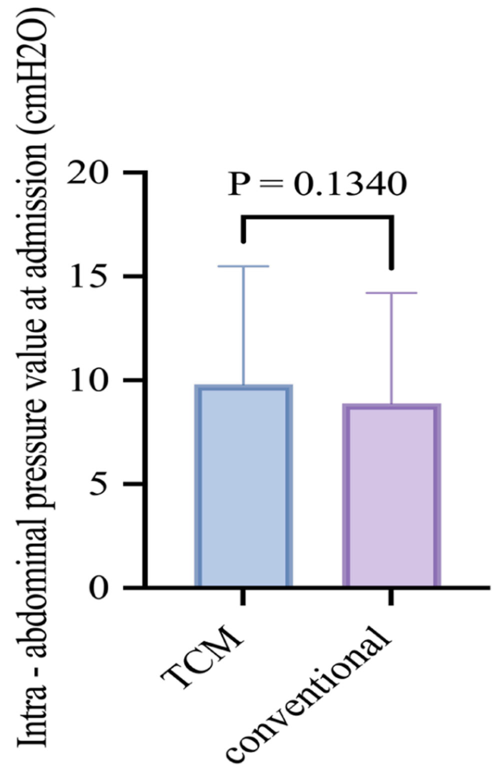

Fig. 3. demonstrates comparative results of intra-abdominal pressure (IAP) measurements recorded at the time of admission for both cohorts.

3.4. Comparison of CRP values at admission and post-treatment changes between TCM and conventional treatment groups

As illustrated in Fig. 5, comparative analysis of serum C-reactive protein (CRP) levels (mg/L) demonstrated comparable baseline values between the TCM intervention group (64.68 ± 24.41) and conventional treatment group (64.79 ± 23.57), with no statistically significant intergroup difference ($t=-0.04$, $P=0.97$). Following 48 hours of therapeutic intervention, the TCM group exhibited significantly greater CRP reduction (39.12 ± 23.93) compared to the conventional treatment group (12.30 ± 14.88), demonstrating statistically robust intergroup disparity ($t=11.52$, $P<0.001$) as illustrated in Fig. 6. The TCM intervention group demonstrated significantly superior anti-inflammatory efficacy and enhanced elimination of inflammatory mediators in AP treatment compared to the conventional therapeutic regimen.

3.5. Comparative analysis of recovery outcomes and adverse reactions in TCM versus conventional treatment groups

Statistical analysis employing Pearson's chi-square test demonstrated no statistically significant disparity in clinical improvement and cure rates between the compound TCM intervention cohort and the conventional treatment cohort ($\chi^2=1.4$, $p=0.24$). Prognostic evaluation and recovery trajectory analysis further corroborated the absence of significant intergroup differences in therapeutic outcomes. No statistically significant differences were observed in clinical outcomes or

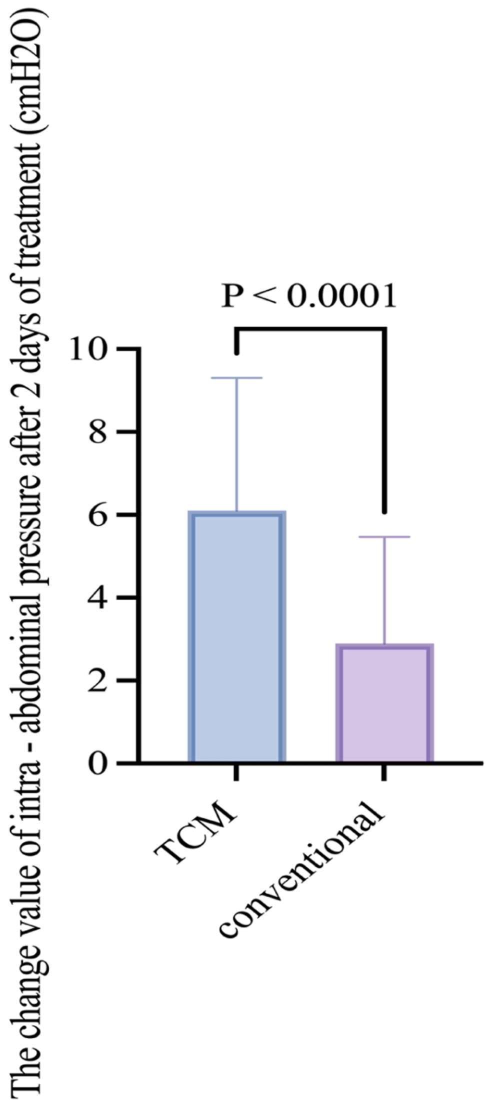

Fig. 4. examines the differential progression of IAP values between the two groups at 48 hours post-admission.

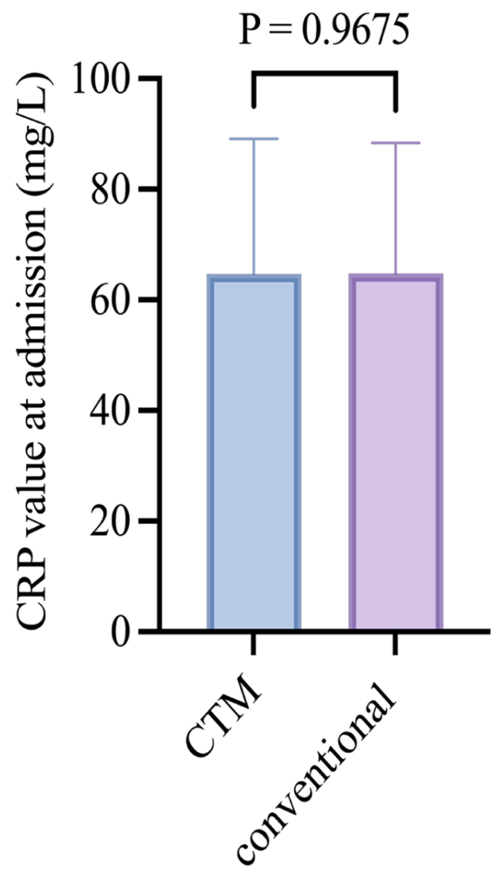

Fig. 5. delineates the comparative C-reactive protein (CRP) levels observed upon initial hospitalization.

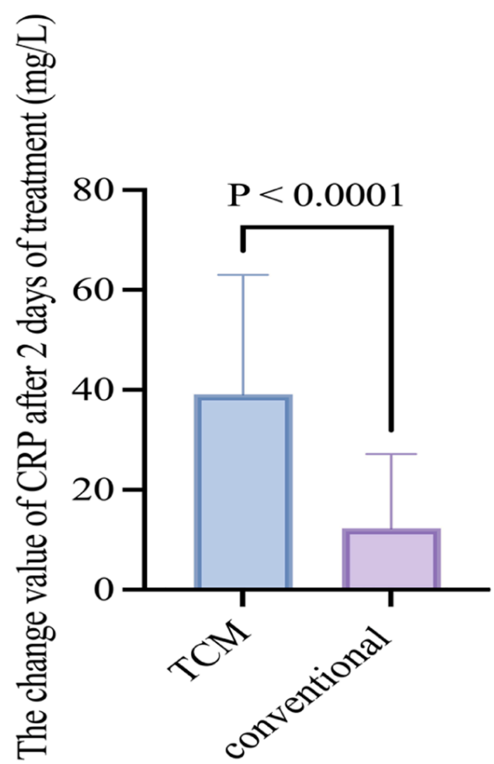

Fig. 6. illustrates the therapeutic response through comparative CRP level variations documented 48 hours following intervention in both treatment arms.

recovery rates between the two therapeutic groups. Comparative analysis of adverse reactions and complications demonstrated statistically significant differences ($\chi^2 = 40.75$, $p < 0.001$), with the traditional Chinese medicine (TCM) group exhibiting a lower incidence rate compared to the conventional treatment cohort. While both groups achieved comparable prognostic results and recovery trajectories, the TCM intervention group manifested a superior safety profile characterized by reduced frequency of treatment-related complications and adverse events relative to conventional therapeutic approaches.

It is important to note that improper use of TCM can also lead to adverse reactions.

3.6. Comparison among the three subgroups of the TCM group

To investigate whether therapeutic outcomes in the TCM group exhibited modality-dependent variations, patients were stratified into three subgroups based on medication delivery modalities: nasogastric feeding subgroup, rectal administration subgroup, and peroral administration subgroup. Comparative analysis of critical clinical parameters including time to first defecation post-admission, post-treatment intra-abdominal pressure alterations, and CRP level fluctuations across subgroups was conducted as illustrated in Fig.s 7-11, which demonstrated

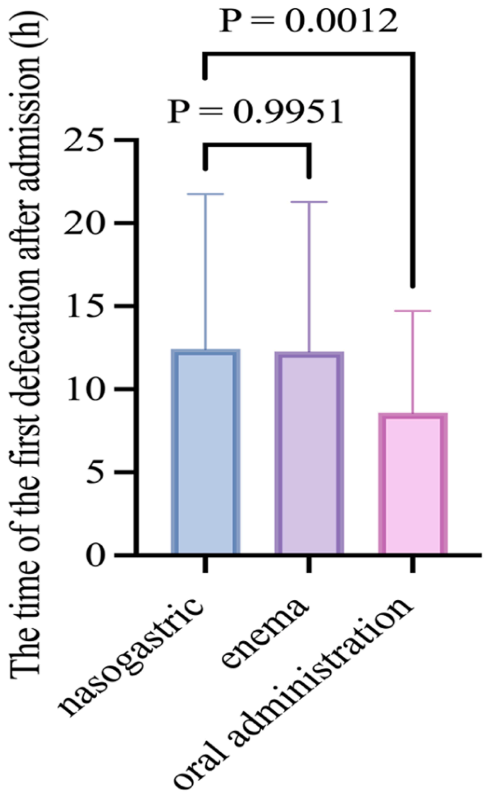

Fig. 7. presents a comparison of the first defecation time upon admission among the three subgroups within the TCM cohort.

*As depicted in Fig.s 7-11, the treatment group administered TCM was stratified into three distinct subgroups based on differing modes of administration: the nasogastric feeding group, the enema group, and the oral group. A comparative analysis was carried out on parameters such as initial defecation time, baseline abdominal pressure measurements, baseline C-reactive protein (CRP) levels, and the subsequent changes in abdominal pressure and CRP values post-treatment across these subgroups. Specifically.

statistically significant differences in therapeutic responses among the intervention modalities. Statistical analyses of post-admission gastrointestinal function recovery indicators revealed significant intergroup variations. The time to initial defecation demonstrated no significant difference between nasogastric feeding and enema groups ($p=0.995$), whereas a statistically significant disparity emerged between nasogastric feeding and oral administration groups ($p=0.001$) as illustrated in Fig.s 7. Regarding baseline intra-abdominal pressure measurements, the comparison between nasogastric feeding and enema groups approached but did not reach statistical significance ($p=0.052$), while nasogastric feeding versus oral administration groups demonstrated statistically significant differences ($p<0.001$) as illustrated in Fig.s 8. Statistical analyses revealed differential outcomes across TCM groups. The intrada variation comparison between nasogastric feeding and enema groups demonstrated no statistically significant difference ($p=0.17$), whereas nasogastric feeding versus oral administration exhibited marked significance ($p<0.001$) as illustrated in Fig.s 9. Regarding admission CRP values, no significant disparity emerged between nasogastric and enema groups ($p=0.66$), but nasogastric feeding showed clinically relevant differences compared to oral administration ($p=0.0006$) as illustrated in Fig.s 10. Post-treatment CRP dynamics at 48-hour follow-up mirrored this pattern: nasogastric-enema comparisons remained non-significant ($p=0.66$), while nasogastric-oral contrasts maintained strong significance ($p<0.001$) as illustrated in Fig.s 11.

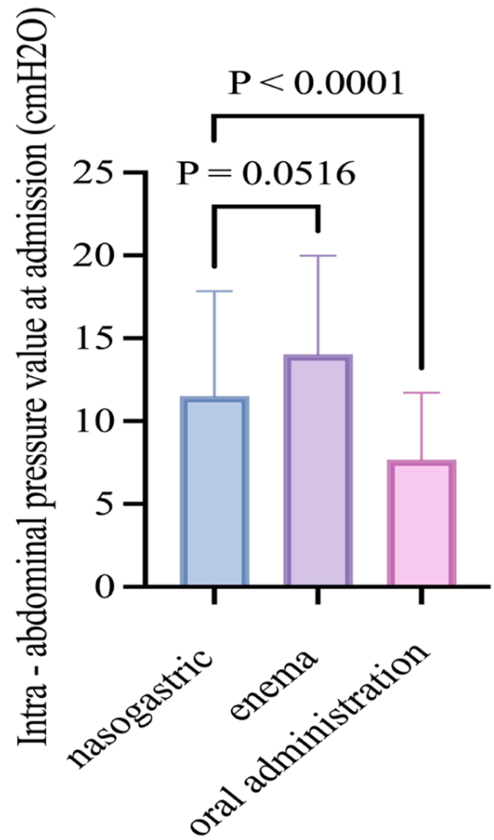

Fig. 8. illustrates the comparison of abdominal pressure values at admission across the nasogastric feeding, enema, and oral treatment groups.

4. Discussion

A limited subset of acute pancreatitis (AP) cases progress to moderately severe and severe forms, characterized by pancreatic necrosis and subsequent systemic multiple organ failure [16,20]. The development of multiorgan dysfunction syndrome represents the predominant mortality determinant in severe acute pancreatitis (SAP) patients and constitutes a significant contributor to disease-associated morbidity [9]. Implementing effective therapeutic interventions during the early stages of AP constitutes a critical strategy for clinical reversal and healthcare resource optimization, particularly those administered within the initial 48-hour therapeutic window. Traditional Chinese Medicine (TCM) has historically demonstrated distinct therapeutic advantages in the management of AP. Clinical evidence indicates that the integrative approach combining TCM with Western medical interventions yields substantial clinical benefits in AP treatment. Specifically, TCM herbal formulations exhibit significant pharmacological effects in gastrointestinal function restoration, inflammatory response modulation, and immune system enhancement. These therapeutic mechanisms contribute to effective prevention and management of disease complications, thereby reducing both mortality rates and associated socioeconomic burdens [21]. However, it should be noted that the clinical application of TCM in critically ill patient populations remains relatively limited in contemporary medical practice.

This study demonstrates that the formulated compound TCM prescription stimulates intestinal motility in AP patients, reduces intra-abdominal pressure, and mitigates systemic inflammatory responses without elevating the incidence of treatment-related complications. The therapeutic efficacy of TCM manifests through multi-pathway and multi-target mechanisms, including but not limited to: 1) enhancement of gastrointestinal peristalsis and intestinal barrier function; 2) modulation of cytokine networks and inflammatory mediators; 3)

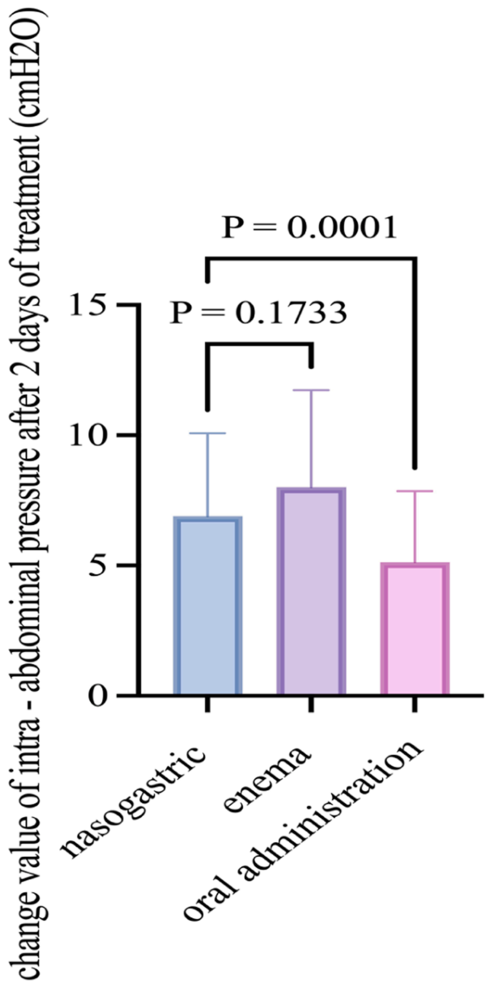

Fig. 9. shows the comparison of abdominal pressure changes after 48 hours of treatment in the nasogastric feeding treatment group, enema treatment group and oral treatment group.

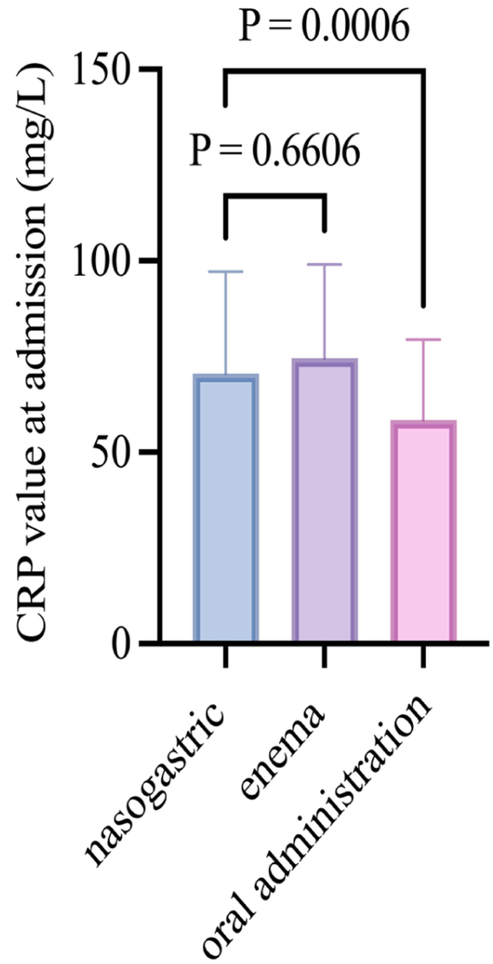

Fig. 10. shows a comparison of CRP values at admission for the nasogastric feeding, enema, and oral treatment groups.

improvement of microcirculatory dynamics and hemorheological parameters; 4) regulation and preservation of pancreatic enzyme activity. This study provides a theoretical foundation for the development of this herbal compound formulation and its clinical application in treating AP. The proposed TCM compound formulation exerts the following therapeutic effects:

Primary therapeutic mechanisms involve purgative and detoxification effects: Crude Rhei Radix et Rhizoma exhibits potent cathartic properties by effectively evacuating gastrointestinal contents, thereby facilitating toxin elimination through intestinal clearance. Delayed administration enhances its purgative potency, while Senna Folium synergistically contributes to laxative effects. The combined pharmacodynamic action significantly augments therapeutic efficacy in catharsis. Furthermore, a consensus exists in traditional Chinese medicine regarding the principal treatment strategy for severe acute pancreatitis (SAP), which predominantly employs heat-clearing and purgative methodologies. The specific representative prescriptions include Chengqi Decoction, Qingyi Decoction, and single-flavor rhubarb, etc. Rhubarb, a staple in TCM, is known for its diverse pharmacological effects, encompassing actions such as purgation, clearing heat and fire, detoxification, cooling blood, resolving stagnation, removing collateral obstructions, and alleviating jaundice. "Removing to eliminate accumulation" refers to the process in which drugs remove the stagnation in the stomach and intestines and relieve constipation, thus treating related gastrointestinal problems [22]. Raw rhubarb plays a pivotal role in achieving this effect. Researchers conducted a comparative analysis using a mouse model of heat-induced constipation. They found that raw rhubarb has a stronger laxative effect than processed rhubarb. This may be due to its ability to stimulate intestinal smooth muscle contraction, a process mediated by increased secretion of intestinal acetylcholinesterase (Ach E) and SP.ase in intracellular Ca2+ concentration. Raw rhubarb and its formulations can be utilized for treating constipation, gastrointestinal disorders, and intestinal obstruction. The way of supplementing raw rhubarb extract improved the defecation frequency and consistency of middle-aged constipation patients without affecting the safety indicators, thereby confirming its reliability and safety in cases of non-severe constipation. Some studies have shown that this therapeutic effect may be related to the regulation of the intestinal microbiota by raw rhubarb. Folium Sennae contains anthraquinone glycosides, such as sennosides, as the main active ingredients, and is an effective laxative. Folium Sennae has been widely used in the clinical treatment of constipation and intestinal preparation, and it also provides an effective cleaning effect in the intestinal preparation for patients with colon cancer. The chemical inflammatory reaction of acute pancreatitis leads to a series of clinical symptoms such as gastrointestinal paralysis, weakened peristalsis, abdominal distension, elevated abdominal pressure, and dyspnea. Individually packaged raw rhubarb and senna leaves can improve the excretory function of the gastrointestinal tract and help eliminate inflammatory mediators and factors from the body. The administration of senna leaf significantly shortens the time to defecation, typically within 6-10 hours, and is associated with a decrease in intra-abdominal pressure and CRP values [23].

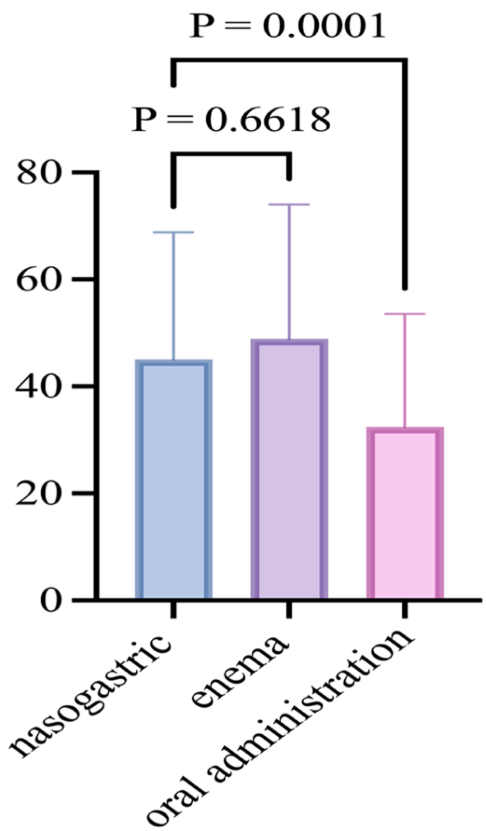

Fig. 11. depicts the comparison of CRP value changes 48 hours post-treatment in the nasogastric feeding, enema, and oral treatment groups.

Second, promoting qi circulation and eliminating accumulation: Magnolia bark (Magnolia officinalis) and immature bitter orange harmonize to enhance qi circulation, dispel accumulations, and alleviate feelings of fullness and distension. Costus root facilitates qi circulation and alleviates pain, contributing to overall well-being. Tangerine peel regulates qi, invigorates the spleen, and, in concert, fosters a smooth qi flow within the gastrointestinal tract. There are also qi-regulating drugs such as magnolia officinalis and immature bitter orange in the formula. They activate potential key genes and participate in pathological changes such as intestinal motility, gastric mucosal barrier function, and inflammatory response through pathways such as the interleukin-17, tumor necrosis factor, and endocrine resistance signaling pathways [24].

Third, clearing heat and drying dampness: Scutellaria baicalensis and Coptis chinensis clear heat, dry dampness, detoxify, and eliminate damp-heat pathogens. Their main effects include clearing various heats, eliminating carbuncles, draining pus, and regulating the gastrointestinal tract and gallbladder. They also protect the gastrointestinal mucosa.ora and are widely used in digestive system diseases. The water extract of Coptis chinensis can inhibit the colonization of Helicobacter pylori in the stomach and exert antioxidant and anti-ulcer effects [25]. Studies have demonstrated that the active components of scutellaria baicalensis and coptis chinensis, including baicalin, can effectively treat ulcerative colitis by targeting key inflammatory mediators such as TP53, TNF, IL-6, JUN, ESR1, and by modulating signaling pathways like the cancer pathway, TNF signaling pathway, and IL-17 signaling pathway. The effective core components of scutellaria baicalensis and coptis chinensis can intervene in the inflammatory response through targets, restore intestinal homeostasis, and repair the intestinal mucosal barrier, thus playing a role in treating ulcerative colitis [26].

Fourth, promoting blood circulation and relieving pain: Tetrahydropalmatine and other alkaloids in Corydalis Rhizoma are its main analgesic components for activating blood, moving qi, and alleviating pain [27]. The chemical constituents in Polygonum cuspidatum are diverse, including stilbenes, quinones, flavonoids, and resveratrol terpenoids. The pharmacological effects of Polygonum cuspidatum primarily involve anti-inflammatory, antioxidant, antithrombotic, antibacterial, liver-protective, immunomodulatory, and microcirculation-improving actions [28]. Polygonum cuspidatum also has the effect of promoting blood circulation and dispersing stasis, exerting certain therapeutic effects on pain caused by qi stagnation and blood stasis. Gegen Qinlian Decoction can improve intestinal inflammation levels and promote the expression of tight junction proteins in mice with diarrhea due to intestinal dampness-heat syndrome, and its mechanism may be related to the repair of intestinal mechanical barrier function [29]. Therefore, CRP, which represents inflammatory response, decreases rapidly. The prescription also includes Aucklandiae Radix and Bupleuri Radix to regulate qi and relieve pain, demonstrating excellent efficacy in alleviating pain symptoms of acute pancreatitis. The combined use of these herbs achieves comprehensive effects such as purgation, restoration of gastrointestinal function, anti-inflammatory action, antibacterial activity, immunomodulation, microcirculation improvement, and qi-regulating pain relief. Thus, this formula is used to treat conditions related to acute pancreatitis, such as gastrointestinal stagnation and internal dampness-heat accumulation, manifesting as constipation, abdominal distension, abdominal pain, diarrhea, tenesmus, etc. It may also have certain regulatory effects on other related symptoms caused by dampness-heat or qi stagnation and blood stasis, such as jaundice and hypochondriac pain.

We categorized the TCM group into three subgroups based on varying administration techniques, and upon comparing these subgroups, our analysis revealed that the nasogastric feeding and enema subgroups exhibited more pronounced severity. For instance, indices such as the time to defecate upon initial admission, intra-abdominal pressure levels, CRP values, and adverse reactions were consistently higher in the nasogastric feeding and enema subgroups compared to the oral administration subgroup, which aligns with expectations. When patients are severely ill, they typically cannot tolerate oral administration, and alternative methods such as nasogastric feeding or enema are commonly employed. Moreover, patients with milder symptoms tend to prefer oral treatment upon admission, which may lead to an imbalance in the grouping and potentially introduce bias in the comparison of outcomes.

Limitation

This study has some limitations: 1. This study only uses CRP as an indicator to measure inflammatory response, but the value of CRP may be influenced by various factors such as delayed diagnosis and comorbidities in patients. 2. This is a retrospective study with imbalanced group distribution, where there is a significant difference in sample size between the two groups (235 cases in the traditional Chinese medicine compound treatment group and 128 cases in the conventional treatment group), which may lead to biased comparison results; additionally, the TCM group was divided into three subgroups based on different administration methods for analysis, showing that the nasogastric and enema groups had more severe conditions compared to the oral group in terms of initial bowel movement time, abdominal pressure values, CRP levels, and adverse reactions, which aligns with routine treatment choices in clinical practice. Patients with more severe conditions typically do not opt for oral treatment but instead use nasogastric or enema methods, those with milder symptoms opt for oral treatment, potentially contributing to the imbalanced group distribution and introducing bias in the comparison results. 3. Patient dropout or voluntary discharge before study completion hindered the observation of compound TCM's effects on long-term prognosis and survival outcomes. 4. The compound TCM used in this study is a hospital-The prescribed formula has not yet been formulated into finished dosage forms, and the preparation and extraction methods for Traditional Chinese Medicine (TCM) granules remain unstandardized, hindering its promotion It is anticipated that this study will be promoted and implemented across multiple centers. 5. This is a clinical study that began clinical application in 2016, with its formula mechanism primarily based on the TCM theory of "the six fu organs function through unblocking and descending, and all diseases arise from stasis." In this study, the use of two antidiarrheal drugs, rhubarb and senna leaf, was flexibly adjusted according to the condition, yet further research on their pharmacological mechanisms within Western medicine remains unconducted. It is anticipated that further exploration will be conducted on the pathogenesis and intervention methods of AP. 6. When comparing the baseline characteristics of the two groups, an analysis of the impact of gastritis ($P<0.05$) can be conducted from the following two perspectives: the possible influence of gastritis on intra-abdominal pressure includes inflammation and gastric dilation, as well as indirect effects such as vomiting or abdominal distension, while also considering the cumulative effect of complications; the potential impact of gastritis on CRP is reflected in its elevation during acute gastritis as an indicator of acute phase inflammation, but it usually shows no significant change in chronic gastritis unless there is active inflammation or Helicobacter pylori infection. The patients included in this study had mild gastritis and were excluded severe digestive system diseases. Moreover, in our stratified analysis of gastritis within this model, the condition exhibited no statistically significant impact on either the timing of initial defecation post-admission, changes in intra-abdominal pressure, or variations in C-reactive protein levels. 7. A limitation to the generalisability of the study is that it did not consider gender/sex issues.

In conclusion, this TCM prescription can promote defecation in patients with AP, reduce abdominal pressure and reduce inflammatory response, without increasing adverse reactions and complications, which is a beneficial choice for the treatment of AP in the future.

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Human Ethical Statement

The study was reviewed and approved by the Institutional Research Ethics Committee of Wuming Hospital affiliated to Guangxi Medical University, with reference number WM-2025 (03), and strictly in accordance with the Helsinki Declaration and Good Clinical Practice principles.

Statement of interests

The authors state that they have no known competing financial interests or personal relationships that appear to influence the work reported in this article.

Data availability

The data will be provided as required.

Express one's thanks

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CRediT authorship contribution statement

Xiao Teng: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Methodology, Investigation, Formal analysis, Data curation. **Shanfeng Sheng:** Visualization, Supervision. **Mingyuan Pan:** Visualization, Supervision. **Yuyang Li:** Visualization, Supervision. **Zheng Li:** Writing – review & editing, Visualization, Validation, Supervision, Resources, Project administration, Investigation, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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