Clinical Effect of Modified Gegen Qinlian Decoction Combined with Western Medicine on Children with Rotavirus Enteritis with Damp-Heat Syndrome

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Abstract [**Objectives**] To explore the clinical effect of Modified Gegen Qinlian Decoction combined with western medicine on children with rotavirus enteritis with damp-heat syndrome and its influence on myocardial enzymes. [**Methods**] One hundred and eighty children with rotavirus enteritis with damp-heat syndrome were randomly divided into control group and observation group, with 90 cases in each group. The control group was given western medicine symptomatic treatment, and the observation group was given Modified Gegen Qinlian Decoction treatment on the basis of the control group. Both groups were treated for 5 d. The clinical efficacy, symptom disappearance time, myocardial zymogram indicator level and TCM syndrome scores were compared between the two groups. [**Results**] After 5 d of treatment, the total effective rate of the observation group was 94.44%, which was significantly higher than that of the control group (84.44%) ($P<0.05$). The time of diarrhea, fever, vomiting, dehydration and fecal RV turning negative in the observation group were shorter than those in the control group, and the differences were statistically significant ($P<0.05$). After 5 d of treatment, the serum levels of creatine kinase (CK), creatine kinase isoenzyme (CK-MB), aspartate aminotransferase (AST), lactate dehydrogenase (LDH) and α-hydroxybutyrate dehydrogenase (α-HBDH) in the two groups were lower than those before treatment. The levels of the above five myocardial enzymes in the observation group were lower than those in the control group, and the differences were statistically significant ($P<0.05$). After 5 d of treatment, the scores of defecation frequency, abdominal distention, thirst, dysphoria, fatigue and anorexia in the two groups were lower than those before treatment. The scores of the above five TCM syndromes in the observation group were lower than those in the control group, and the differences were statistically significant ($P<0.05$). [**Conclusions**] Modified Gegen Qinlian Decoction combined with western medicine can quickly relieve the symptoms and signs of children with rotavirus enteritis with damp-heat syndrome, shorten the course of disease, and reduce myocardial injury.

Key words Rotavirus enteritis, Children, Damp-heat syndrome, Gegen Qinlian Decoction, Myocardial zymogram, TCM syndrome

1 Introduction

Rotavirus enteritis is the main clinical cause of acute diarrhea in children, and it can be transmitted by fecal-oral or respiratory aerosol, resulting in diarrhea, fever and other symptoms. If the disease is not effectively controlled, dehydration, water-electrolyte imbalance, and even death may occur[1]. For rotavirus enteritis, western medicine often uses drugs for symptomatic treatment, including fluid infusion, regulation of intestinal flora and protection of intestinal mucosa, but the therapeutic effect varies among individuals[2]. According to the theory of Traditional Chinese medicine, the pathogenesis of rotavirus enteritis in children is the accumulation of damp-heat in the middle energizer. Children's spleen is often insufficient, due to the invasion of damp-heat evil, damage to the spleen and stomach, damp-heat accumulation, downward flow into the intestinal tract, diarrhea occurs. Gegen Qinlian Decoction, a classical prescription in *Treatise on Febrile Diseases*, can clear the intestines, relieve fever, relieve exterior syndrome, promote the production of body fluid, eliminate dampness and stop diarrhea. Studies have found that rotavirus enteritis often causes myocardial injury and even leads to myocarditis or cardiogenic shock[3]. This study was to observe the clinical efficacy of Modified Gegen Qinlian Decoction combined with western medicine in the treatment of children with rotavirus enteritis with damp-heat syndrome and its effect on myocardial enzymes.

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2 Data and methods

2.1 Clinical data

2.1.1 Diagnostic criteria. The diagnostic criteria were in line with the diagnostic criteria of diarrhea in *Zhu Futang Practical Pediatrics*[4]. The patient children had diarrhea with or without vomiting and fever, and the stool was positive for rotavirus (RV) antigen. Mild infection: frequency of bowel movement less than 5 times daily, no fever and dehydration symptoms; moderate infection: stools 5 to 10 times daily, accompanied by vomiting, fever, less tears, decreased urine volume, irritability and other moderate dehydration symptoms; severe infection: The frequency of bowel movement is more than 10 times a day, accompanied by severe dehydration symptoms such as oliguria or anuria, acidosis, hypotension, and cold limbs.

2.1.2 Syndrome differentiation standard was in line with the standard of syndrome differentiation of damp-heat diarrhea in *Pediatrics of Traditional Chinese Medicine*[5]. Main symptoms: frequency of bowel movement, urgent or unpleasant diarrhea, vomiting, abdominal distention, thirst and irritability, burning anus; secondary symptoms: fever, fatigue, loss of appetite, shortness of urine; tongue and vein: red tongue, yellow greasy, slippery pulse.

2.1.3 Inclusion criteria. The patient met the criteria for diagno-

sis and syndrome differentiation; the age was 0 to 5 years old; the onset time was less than 5 d; the patient did not receive any drug treatment related to the disease 5 d before participating in the study; the parents of the patient gave informed consent and signed the informed consent form.

2.1.4 Exclusion criteria. Stool culture of *Staphylococcus*, dysentery *Bacillus* and other pathogens infected; allergic reaction to the therapeutic drugs used in this study; patients with severe malnutrition, congenital heart disease and severe genetic metabolic diseases; combined with heart, liver, kidney and other organ dysfunction.

2.1.5 General data. 180 cases of rotavirus enteritis with damp-heat treated in Xi'an City Gaoling Maternal and Child Health Hospital from June 2021 to June 2023 were selected. Children with syndrome were randomly divided into control group and observation group, 90 cases in each group. There were 50 males and 40 females in the control group, with an average age of (1.37 ± 0.58) years; the average course of disease was (5.17 ± 1.57) d. The severity of the disease was mild in 53 cases, moderate in 30 cases, and severe in 7 cases. There were 48 males and 42 females in the observation group; the average age was (1.32 ± 0.50) years; the average course of disease was (5.26 ± 1.81) d; the severity of the disease was mild in 51 cases, moderate in 33 cases, and severe in 6 cases. There was no significant difference in general data between the two groups ($P > 0.05$), which was comparable. This study was reviewed and approved by the Medical Ethics Committee of the Xi'an City Gaoling Maternal and Child Health Hospital (Approval No.:20221015-68).

2.2 Treatment methods

2.2.1 Control group. Give western medicine symptomatic treatment, such as intravenous rehydration or oral rehydration salts to correct acid-base imbalance, electrolyte disorders and dehydration. Mild and moderate children were treated with oral Bifidobacterium Tetravaccine Tablets (Hangzhou Yuanda Biopharmaceutical Co., Ltd., GYZZ S20060010), 0.5 g each time for ≤1 year old, 1 g each time for >1 year old, 3 times daily. Montmorillonite powder (Hainan Simcere Pharmaceutical Co., Ltd., GYZZ H19990307) was taken orally, 1.5 g each time for ≤1 year old and 3 g each time for >1 year old, three times daily. The treatment lasted for 5 d. When severe children's condition improved and they could take medicine, they should take the above medicines orally for treatment.

2.2.2 Observation group. The patients in the control group were treated with Modified Gegen Qinlian Decoction. Prescription: 10 g of Puerariae Lobatae Radix (Gegen), 6 g of Scutellariae Radix (Huangqin), 6 g of Coptidis Rhizoma (Huanglian), 3 g of Glycyrrhizae Radix Et Rhizoma (Gancao). Addition and subtraction according to symptoms: added 6 g of Aucklandiae Radix (Muxiang) and 6 g of Paeoniae Radix Alba (Baishao) for patients with abdominal pain, and added 5 g of PINELLIAE RHIZOMA PRAEPARATUM CUM ZINGIBERE ET ALUMINE (Jiangbanxia) for patients with vomiting, and added 6 g of Bupleuri Radix (Chaihu) for fever patients. One dose per day, decocted with water twice, mixed with the decoction, took 60 mL of decoction, 10 mL each time for children less than 2 years old, 20 mL each time for children 2 to 4 years old, 30 mL each time for children more than 4 years old, twice a day for 5 d.

2.3 Observation indicators and statistical method

2.3.1 Observation indicators. (i) Clinical efficacy. (ii) Disappearance time of symptoms, including the disappearance of diarrhea, fever, vomiting and dehydration, and the time of RV turning negative. (iii) Myocardial zymogram indicators. Before treatment and 5 days after treatment, fasting venous blood was collected in the morning, and serum creatine kinase (CK), creatine kinase isoenzyme (CK-MB), aspartate aminotransferase (AST), lactate dehydrogenase (LDH) and α-hydroxybutyrate dehydrogenase (α-HBDH) were detected by BS-830 immunoturbidimetry (Shenzhen Mindray Bio-Medical Electronics Co., Ltd.). (iv) TCM syndrome integral. Before treatment and after 5 d of treatment, frequency of bowel movement, abdominal distention, thirst, dysphoria, fatigue and anorexia were scored as 0, 1, 2 and 3 points, respectively according to no, mild, moderate and severe symptoms, and the higher the score, the more serious the symptoms[6].

2.3.2 Statistical methods. SAS 9.4 statistical software was used for data analysis. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$), independent sample t test was used for comparison between groups, paired sample t test was used for comparison within groups before treatment and after 5 days of treatment; enumeration data were expressed as percentage (%), χ^2 test was carried out. $P < 0.05$ indicates a statistically significant difference.

3 Results and analysis

3.1 Efficacy criteria After 5 d of treatment, the efficacy criteria were formulated according to the *Expert Consensus on the Principles of Diagnosis and Treatment of Diarrhea in Children*[7]. Marked effective: after 3 d of treatment, the stool frequency and character were normal, the stool RV turned negative, other symptoms disappeared, and the TCM syndrome score was reduced by > 90%; effective: after 3 to 5 d of treatment, the stool frequency and character were improved, the stool RV turned negative or weakly positive, other symptoms were relieved, and the TCM syndrome score was reduced by 40% to 90%; ineffective: the above criteria were not met.

3.2 Comparison of clinical efficacy between the two groups

It can be seen from Table 1 that after 5 days of treatment, the total effective rate of the observation group was 94.44%, which was higher than that of the control group (84.44%), and the difference was statistically significant ($P < 0.05$).

Table 1 Comparison of clinical efficacy of the two groups ($n = 90$)

Group	Marked effective	Effective	Ineffective	Total effective rate//[case (%)]
Observation	70	15	5	85(94.44)
Control	49	27	14	76(84.44)
χ^2			113.154	
P			<0.001	

3.3 Comparison of disappearance time of symptoms between the two groups It can be seen from Table 2 that the time of diarrhea disappearance, fever abatement, vomiting disappearance, dehydration disappearance and fecal RV negative conversion in the observation group was shorter than that in the control group, and the differences were statistically significant ($P<0.05$).

Table 2 Comparison of disappearance time of symptoms between the two groups ($\bar{x}\pm s$, $n=90$)

Group	Diarrhea disappearance time//d	Fever disappearance time//h	Vomiting disappearance time//d	Dehydration disappearance time//d	Fecal RV negative conversion time//d
Observation	2.24±0.27	16.87±5.25	1.17±0.87	1.41±0.49	3.72±0.91
Control	3.29±0.15	20.33±5.61	1.48±0.82	1.68±0.65	4.13±0.99
t	5.995	3.915	2.453	3.095	2.093
P	0.001	0.001	0.015	0.002	0.038

3.4 Comparison of myocardial enzyme levels before and after treatment in the two groups As indicated in Table 3, before treatment, there was no significant difference in serum CK, CK-MB, AST, LDH and α-HBDH levels between the two groups ($P>0.05$). After 5 d of treatment, the levels of the above five myocardial zymogram indicators in the two groups were lower than those before treatment, and the levels of the above five myocardial zymogram indicators in the observation group were lower than those in the control group, and the differences were statistically significant ($P<0.05$).

Table 3 Comparison of myocardial zymogram indicators before and after treatment in the two groups ($\bar{x}\pm s$, $n=90$, U/L)

Group	Time	CK	CK-MB	AST	LDH	α-HBDH
Observation	Before treatment	55.91±8.77	118.69±12.32	49.45±2.68	242.37±10.19	212.01±11.14
	5 d after treatment	31.44±3.93①②	78.92±7.68①②	34.64±3.17①②	116.81±11.12①②	107.78±15.47①②
Control	Before treatment	56.82±4.91	117.08±12.80	50.21±8.83	244.98±14.27	212.81±13.52
	5 d after treatment	43.36±6.98①	94.52±9.44①	43.88±3.57①	150.80±11.30①	135.63±12.47①

NOTE ① Compared with the group before treatment, $P<0.05$; ② Compared with the control group after 5 d of treatment, $P<0.05$. The same below.

3.5 Comparison of TCM syndrome scores before and after treatment in the two groups As shown in Table 4, before treatment, there was no significant difference in the scores of frequency of bowel movement, abdominal distension, thirst, dysphoria, fatigue and anorexia between the two groups ($P>0.05$). After 5 d of treatment, the scores of the above five TCM syndromes in the two groups were lower than those before treatment, and the scores of the above five TCM syndromes in the observation group were lower than those in the control group, and the differences were statistically significant ($P<0.05$).

Table 4 Comparison of TCM syndrome scores before and after treatment in the two groups ($\bar{x}\pm s$, $n=90$, points)

Group	Time	Frequency of bowel movement	Abdominal distention and fullness	Thirst and dysphoria	Fatigue	Anorexia
Observation	Before treatment	2.04±0.77	1.93±0.71	2.02±0.65	1.73±0.73	1.83±0.55
	5 d after treatment	0.65±0.25①②	0.50±0.25①②	0.56±0.14①②	0.59±0.15①②	0.54±0.24①②
Control	Before treatment	2.08±0.78	1.98±0.68	2.04±0.64	1.74±0.70	1.85±0.58
	5 d after treatment	0.83±0.14①	0.73±0.15①	0.74±0.35①	0.77±0.24①	0.88±0.39①

4 Discussion

Rotavirus enteritis is a common acute diarrhea disease in children, it often occurs in summer and autumn[8]. RV is a non-enveloped double-stranded RNA virus, which can replicate in the villous epithelial cells of small intestinal mucosa after infection, resulting in increased intestinal secretion and permeability, absorption dysfunction and diarrhea[9]. Bifidobacterium Tetravaccine Tablets were used in the control group of this study, which could effectively inhibit the colonization and invasion of pathogenic bacteria and promote the restoration of ecological balance of intestinal flora in children[10]. Montmorillonite powder is a protective agent of intestinal mucosa, which can adsorb pathogens and toxins, and interact with intestinal mucin to prevent the attack of pathogenic bacteria and enhance intestinal barrier function[11]. Jiang Youzhi *et al.*[12] found that the combination of Bifidobacterium and montmorillonite powder has positive significance in controlling diarrhea in children with RV infection, but there are some shortcomings such as slow onset and long treatment time.

The rotavirus enteritis belongs to the category of diarrhea in traditional Chinese medicine. According to TCM theory, the disease is located in the spleen and stomach, and the pathogenesis is damp-heat accumulation. Children's viscera are weak, invasion of exogenous pathogens or improper diet can easily lead to spleen failure in transportation and transformation, accumulation of dampness into heat, accumulation of dampness and heat, inability to secrete clear and turbid, forcing down the intestines, resulting in diarrhea. In *Plain Questions*, there is a saying that "sudden injection and pressing down all belong to heat" and "excessive dampness leads to diarrhea". Damp-heat accumulation in the middle energizer is susceptible to pathogenic factors, so damp-heat syn-

drome is the most common diarrhea in children. Gegen Qinlian Decoction has the functions of relieving exterior syndrome, clearing heat, eliminating dampness and stopping diarrhea. In the prescription, Puerariae Lobatae Radix is used as a sovereign drug for relieving exterior syndrome, clearing heat, lifting spleen qi and stopping diarrhea. Scutellariae Radix and Coptidis Rhizoma are both minister drugs, both of which are bitter and cold in nature, can clear heat, dry dampness, thicken intestines and stop diarrhea. The combination of Puerariae Lobatae Radix, Scutellariae Radix and Coptidis Rhizoma can enhance the effect of clearing heat and relieving diarrhea. Glycyrrhizae Radix Et Rhizoma is courier drug and can harmonize the middle warmer, relieve the urgency, and harmonize various medicines. Addition and subtraction according to symptoms: Aucklandiae Radix and Paeoniae Radix Alba are added for patients with abdominal pain to promote the circulation of qi, regulate blood and relieve pain; Pinelliae Rhizoma Praeparatum Cum Zingibere Et Alumine can be added for patients with vomiting to lower the adverse flow of qi and stop vomiting; Bupleuri Radix can be added for patients with excessive heat to relieve exterior syndrome, reduce fever, and raise yang to stop diarrhea. Pharmacological studies have shown that flavonoids and saponins in Gegen Qinlian Decoction have anti-inflammatory and antiviral effects. Coptidis Rhizoma contains berberine and coptisine, which can inhibit bacteria, regulate intestinal flora and relieve diarrhea. The glycyrrhizic acid and liquiritin in the Glycyrrhizae Radix Et Rhizoma have the functions of enhancing immunity and reducing intestinal secretion, Glycyrrhizae Radix Et Rhizoma combined with Coptidis Rhizoma can enhance bacteriostasis and anti-diarrhea effect[13-14].

The results of this study showed that after 5 d of treatment, the symptom disappearance time of the observation group was shorter than that of the control group, the TCM syndrome score was lower than that of the control group, and the clinical efficacy was better than that of the control group, suggesting that Modified Gegen Qinlian Decoction combined with western medicine can rapidly improve the clinical symptoms and signs of children with rotavirus enteritis with damp and heat syndrome, inhibit the development of the disease, shorten the course of disease, and has good curative effect. Studies have found that RV infection can directly damage myocardial cells, and inflammatory reaction after infection can cause degeneration and necrosis of myocardial cells, leading to myocardial damage[15]. The incidence of rotavirus enteritis combined with myocardial damage in children is as high as 50% – 70%, but most children do not have typical symptoms such as fatigue, sighing and arrhythmia in the early stage of the disease, and only show elevated levels of CK, CK-MB, LDH, AST and other myocardial enzymes[16]. Therefore, myocardial zymogram indicators can be used as an important indicator for early monitoring of myocardial injury in children with rotavirus enteritis. Among them, CK-MB almost only exists in myocardial cells, with high specificity, and its level rises rapidly in a short period of time after myocardial injury, which is positively correlated with the severity of myocardial injury[17-18]. After 5 days of treatment, the levels of CK, CK-MB, AST, LDH and α-HBDH in the observation group were lower than those in the control group. It is suggested that Modified Gegen Qinlian Decoction is helpful to improve the level of myocardial enzymes and reduce myocardial injury in children with rotavirus enteritis with damp and heat syndrome. The reason may be that Gegen Qinlian Decoction has the function of anti-virus and enhancing immunity, which helps to regulate the balance of water and electrolyte, thus alleviating myocardial injury[19].

To sum up, Modified Gegen Qinlian Decoction combined with western medicine can quickly relieve the symptoms and signs of children with rotavirus enteritis with damp-heat syndrome, inhibit the development of the disease, shorten the course of disease, and reduce myocardial injury. The treatment effect is good.

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(To page 72)

Chinese medicine categorizes chronic superficial gastritis as a condition characterized by fullness and epigastric pain. A prevalent dialectical syndrome associated with this condition is liver-stomach disharmony. Consequently, Chaihu Shugan Powder is frequently employed as a therapeutic intervention[8]. In the aforementioned formula, Radix Bupleuri can improve food accumulation and alleviate gastrointestinal qi stagnation in patients. Rhizoma Ligustici wallichii has the effect of promoting blood circulation and qi circulation and relieving pain. Rhizoma Cyperi possesses properties that alleviate depression, regulate qi, and relieve pain, while also addressing sensations of fullness and discomfort in the chest, hypochondrium, and epigastrium. Both Fructus Aurantii and Pericarpium citri reticulatae have the effects of regulating qi, alleviating issues in the middle warmer, relieving flatulence, and removing stagnation, thereby improving sensations of fullness and pain caused by food stagnation. The combination of Radix Paeoniae Alba and Radix Glycyrrhizae serves to clear heat and toxins, nourish the blood, soften the liver, and alleviate abdominal distension and pain. The combination of all the medicinal agents serves to eliminate blood stasis and resolve masses, promote blood circulation, alleviate pain, and soothe the liver while promoting the flow of qi[9-10]. The results of this study showed that the total effective rate for the treatment group was 88.89%, while the control group exhibited a total effective rate of 80.56%. The curative effect of the treatment group was significantly superior to that of the control group. This evidence supports the conclusion that the classical prescription of Chaihu Shugan Powder has a significant effect on alleviating stomachache caused by chronic superficial gastritis, demonstrating a higher total effective rate compared to conventional western medicine treatments.

Studies have shown that the clinical efficacy of Chaihu Shugan Powder is significantly higher than that of omeprazole alone in the treatment of chronic superficial gastritis. This formulation has been shown to significantly reduce the recurrence rate among patients, thereby warranting its broader application in clinical settings.

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(From page 69)

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