

Efficacy of Shenqi Runchang Tongbian Decoction in Treatment of Children with Constipation and Its Effect on Clinical Symptoms of Children

Huang Yuanqin

Li Xiaoqian

he Huizhen

Li Lin

Xu Hui

Huang Yuanqin, Li Xiaoqian, he Huizhen, and Li Lin, Xu Hui*, Department of Pediatrics, Traditional Chinese Medicine Hospital of Pukou District, Nanjing City, Jiangsu Province, Nanjing 211800, Jiangsu, China, Corresponding author: Xu Hui, Email: 293094515@qq.com

Abstract Objective: To investigate the efficacy of Shenqi Runchang Tongbian Decoction in the treatment of children with constipation and its effect on the clinical symptoms of children. **Methods:** From January 2016 to January 2020, 100 patients with constipation were randomly divided into two groups. The control group was treated with lactulose oral solution, and the study group was treated with Shenqi Runchang Tongbian Decoction. Both groups were administered with drugs for 14 days, and the two groups were followed up on the 28th day. The effectiveness of the two groups was compared before treatment and during follow-up. The changes of various symptom scores were compared before treatment, after treatment and during follow-up, and the changes of primary symptom score, secondary symptom score and total score were compared before treatment, after treatment and during follow-up. **Results:** After treatment, the effectiveness of the study group was higher than that of the control group at follow-up ($P < 0.05$). After treatment and during the follow-up, the scores of facial color, lips, sleep, urination, hand-foot-heart-chest, appetite, halitosis, abdominal distension and abdominal pain, defecation duration, defecation difficulty, defecation frequency and stool property of the two groups were lower than those before treatment ($P < 0.05$). There was no significant difference in the scores of facial color, sleep, urination and hand-foot-heart-chest symptoms before and after treatment of the control group and the study group ($P > 0.05$). There was no significant difference in the scores of facial color, lips, sleep, urination and hand-foot-heart-chest symptoms before treatment and during follow-up between the control group and the study group ($P > 0.05$). The scores of lip symptoms after treatment in the study group were lower than those in the control group ($P < 0.05$). The scores of appetites, halitosis, abdominal distension and abdominal pain, defecation duration, defecation difficulty, defecation frequency, stool property after treatment and during follow-up in the study group were lower than those in the control group ($P < 0.05$). The total score, the secondary symptom score and the primary symptom score of the two groups before treatment and during follow-up were lower than those before treatment ($P < 0.05$). The total score, the secondary symptom score and the primary symptom score in the study group were lower than those in the control group after treatment and during follow-up ($P < 0.05$). **Conclusion:** The treatment of children with constipation with Shenqi Runchang

Tongbian Decoction can improve the secondary symptoms and primary symptoms of children and improve the comprehensive curative effect, especially in the aspects of improving appetite, halitosis, abdominal distension and abdominal pain, defecation duration, defecation difficulty, defecation frequency and stool property. It can effectively enhance the gastrointestinal function and promote the rehabilitation of children. It is worthy of being popularized in clinical practice.

Key words: Gastrointestinal function; Primary symptoms, Secondary symptoms; Shenqi Runchang Tongbian Decoction; Constipation; Efficacy

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Pediatric constipation is mainly caused by change of defecation law, its clinical morbidity is high, and it is a common pediatric disease. Once the child patient presents irregular defecation state, defecation generally exceeds 2 days, the interval is significantly increased, the defecation is blocked, the defecation property is hard, and the defecation frequency is significantly reduced, a few children may have desire of defecation but cannot defecate¹. In recent years, due to the influence of many factors, such as the increase of artificial feeding proportion and the change of children's diet structure, the incidence of constipation in children is becoming higher and higher. If the child is ill, the risk of inducing multiple diseases will be increased, and the psychological state, physical development and gastrointestinal function of the child patient will be seriously affected². Since the functions of various organs in children have not been fully developed and mature, the immunity and resistance are weak, and the traditional western medicine treatment for constipation is not suitable for pediatric treatment. Therefore, it is of great significance for the healthy development of the patient to reasonably formulate the treatment scheme in combination with the actual needs of the child patient and promote the normal defecation as soon as possible³. In this study, Shenqi Runchang Tongbian Decoction was used in the treatment of children with constipation to investigate the efficacy of treatment and the effect on the clinical symptoms of the children.

DATA AND METHODS

General data

From January 2016 to January 2020, 100 child patients with constipation were randomly divided into two groups: control group (n = 50), aged 2-11 years, mean age (6.6 ± 4.4) years, mean duration of disease (13.5 ± 1.6) months, including 26 males and 24 females, with mild 12 cases, moderate 32 cases and severe 6 cases. In the study group, there were 50 cases, aged 1-12 years, mean age was (6.4 ± 4.7) years, mean disease course was (13.3 ± 1.5) months, among which there were 28 males and 22 females, and the disease condition was mild in 10 cases, moderate in 30 cases and severe in 10 cases.

The general data of children in the two groups were comparable ($P > 0.05$).

Inclusion criteria: All the criteria for diagnosis of pediatric constipation were met; the clinical data were complete; the stomach was weakened, with smooth pulse, halitosis, dry mouth and yellow coating of tongue; the stool was dry, with abdominal fullness; the defecation time was > 3 days, and the defecation time was prolonged; the compliance was good, and the child's family members signed the informed consent form; the child's family members had no psychiatric diseases; the communication was good; the consciousness was clear.

Exclusion criteria: Congenital dysfunction of important organs such as liver and kidney; patients with severe gastrointestinal organic diseases; children with congenital physiological and consciousness disorders; patients with other gastrointestinal diseases.

METHODS

The child's parents were told to establish a complete defecation reflex for the child. Every morning before going to the toilet to defecate, they insisted on using warm water to fumigate their buttocks, eat less oily, sweet, refined food or food with a strong flavor, eat more green fruits and vegetables, and have a light diet. Both groups were given basic treatment.

The control group was treated with lactulose oral solution. On the basis of basic treatment, lactulose oral solution was given according to the actual situation of the child, and the dose was taken in the morning in the fasted state, 15ml per day for the child aged ≥ 7 years and 5-10ml per day for the child aged < 7 years, and the dose could be increased or decreased according to the circumstances.

The study group was treated with Shenqi Runchang Tongbian Decoction. In basic treatment, the patient took Shenqi Runchang Tongbian Decoction for treatment, and the formula was as follows: Radix Rhubarb 6g, Hawthorn 15g, Semen Trichosanthis 10g, Radish Seeds 12g, Angelica Sinensis 10g, Mangnolia Officinalis 10g, Aurantii Fructus Immaturus 12g, Rhizoma Atractylodis 18g, Radix Astragali 10g, Radix Pseudostellariae

18g. One dose per day, decocted by Chinese pharmacy, taken once in the morning and once in the evening. A total of 150ml was taken by children aged ≥ 7 years old, 90ml was taken by children aged 3–6 years old, and 60ml was taken by children aged < 3 years old.

Both groups received medication and conditioning continuously for 14 days, and each sub-condition of the children was recorded. On the 28th day, the children in both groups were followed up, and each sub-condition was recorded in detail once before treatment, once after treatment and once during follow-up.

Observation indicators

Compare the effectiveness of the two groups.

Compare the changes of various symptom scores between the two groups.

Compare the changes of primary symptom score, secondary symptom score and total score between the two groups.

Statistical methods

The data were analyzed by SPSS 18.0, where the counts were tested by χ^2 (%) and the values were measured by t test ($\bar{x} \pm s$), $P < 0.05$ indicated significant difference.

RESULTS

Compare the effectiveness of the two groups

The effectiveness of the study group after treatment and during follow-up was higher than that of the control group ($P < 0.05$). See Table 1 for details.

Table 1.
Comparison of Effectiveness of the Two Groups (case, %)

Group	Number of cases	Recovered		Produce effect		Effective		Ineffective		Total effective rate	
		After treatment	At follow-up	After treatment	At follow-up	After treatment	At follow-up	After treatment	At follow-up	After treatment	At follow-up
Control group	50	1 (2.0)	0 (0.0)	12 (24.0)	10 (20.0)	30 (60.0)	29 (58.0)	7 (14.0)	11 (22.0)	43 (86.0)	39 (78.0)
Study group	50	5 (10.0)	2 (4.0)	25 (50.0)	23 (46.0)	18 (36.0)	21 (42.0)	2 (4.0)	4 (8.0)	48 (96.0)	46 (92.0)
χ^2 value	/									5.851	7.816
P value	/									< 0.05	< 0.05

Table 2.
Comparison of Various Symptom Scores before and after Treatment in the Two Groups (points, $\bar{x} \pm s$)

Symptom	Before treatment		After treatment	
	Control group	Study group	Control group	Study group
Facial color	0.68 \pm 0.18	0.71 \pm 0.19	0.08 \pm 0.01 ^a	0.01 \pm 0.01 ^a
Lips	0.98 \pm 0.27	1.11 \pm 0.31	0.28 \pm 0.06 ^a	0.04 \pm 0.01 ^{ab}
Sleep	1.24 \pm 0.35	1.14 \pm 0.32	0.44 \pm 0.11 ^a	0.28 \pm 0.06 ^a
Urination	0.84 \pm 0.23	0.98 \pm 0.27	0.28 \pm 0.06 ^a	0.24 \pm 0.05 ^a
Hand-foot-heart-chest	0.81 \pm 0.22	1.14 \pm 0.32	0.41 \pm 0.10 ^a	0.28 \pm 0.06 ^a
Appetite	0.74 \pm 0.20	1.04 \pm 0.29	0.31 \pm 0.07 ^a	0.08 \pm 0.01 ^{ab}
Halitosis	1.44 \pm 0.41	1.24 \pm 0.35	0.81 \pm 0.22 ^a	0.38 \pm 0.09 ^{ab}
Abdominal distension and abdominal pain	1.24 \pm 0.35	1.41 \pm 0.40	0.71 \pm 0.18 ^a	0.34 \pm 0.08 ^{ab}
Defecation duration	2.54 \pm 0.74	2.21 \pm 0.64	1.88 \pm 0.54 ^a	0.88 \pm 0.24 ^{ab}
Defecation difficulty	3.41 \pm 1.00	3.28 \pm 0.96	1.74 \pm 0.50 ^a	0.68 \pm 0.18 ^{ab}
Defecation frequency	3.88 \pm 1.14	3.58 \pm 1.05	2.01 \pm 0.58 ^a	1.08 \pm 0.30 ^{ab}
Stool property	4.08 \pm 1.20	4.01 \pm 1.18	2.28 \pm 0.66 ^a	1.34 \pm 0.38 ^{ab}

Note: compared with that before treatment, a $P < 0.05$, compared with study group, b $P < 0.05$.

Compare the changes of various symptom scores between the two groups

After treatment and during the follow-up, the scores of facial color, lips, sleep, urination, hand-foot-heart-chest, appetite, halitosis,

abdominal distension and abdominal pain, defecation duration, defecation difficulty, defecation frequency and stool property of the two groups were lower than those before treatment ($P < 0.05$). There was no significant difference in the

scores of facial color, sleep, urination and hand-foot-heart-chest symptoms before and after treatment of the control group and the study group ($P > 0.05$). There was no significant difference in the scores of facial color, lips, sleep, urination and hand-foot-heart-chest symptoms before treatment and during follow-up between the control group and the study group ($P > 0.05$). The scores of lip symptoms after treatment in the study group were lower than those in the control group ($P < 0.05$). The scores of appetites, halitosis, abdominal distension and abdominal pain, defecation duration, defecation difficulty, defecation frequency, stool property after treatment and during follow-up in the study group were lower than those in the

control group ($P < 0.05$). See Table 2 and Table 3 for details.

Compare the changes of primary symptom score, secondary symptom score and total score between the two groups

After treatment, the total score, the secondary symptom score and the primary symptom score at follow-up in the two groups were lower than those before treatment ($P < 0.05$). The total score, the secondary symptom score and the main symptom score after treatment and at follow-up in the study group were lower than those in the control group ($P < 0.05$). See Table 4 and Table 5 for details

Table 3.

Comparison of Various Symptom Scores before Treatment and During follow-up in the Two Groups (points, $\bar{x} \pm s$)

Symptom	Before treatment		At follow-up	
	Control group	Study group	Control group	Study group
Facial color	0.68±0.18	0.71±0.19	0.11±0.01 ^a	0.08±0.01 ^a
Lips	0.98±0.27	1.11±0.31	0.48±0.12 ^a	0.31±0.07 ^a
Sleep	1.24±0.35	1.14±0.32	0.44±0.11 ^a	0.24±0.05 ^a
Urination	0.84±0.23	0.98±0.27	0.41±0.10 ^a	0.38±0.09 ^a
Hand-foot-heart-chest	0.81±0.22	1.14±0.32	0.54±0.14 ^a	0.31±0.07 ^a
Appetite	0.74±0.20	1.04±0.29	0.34±0.08 ^a	0.11±0.01 ^{ab}
Halitosis	1.44±0.41	1.24±0.35	0.81±0.22 ^a	0.48±0.12 ^{ab}
Abdominal distension and abdominal pain	1.24±0.35	1.41±0.40	0.84±0.23 ^a	0.51±0.13 ^{ab}
Defecation duration	2.54±0.74	2.21±0.64	1.81±0.52 ^a	1.01±0.28 ^a
Defecation difficulty	3.41±1.00	3.28±0.96	2.08±0.60 ^a	1.01±0.28 ^{ab}
Defecation frequency	3.88±1.14	3.58±1.05	2.41±0.70 ^a	1.14±0.32 ^{ab}
Stool property	4.08±1.20	4.01±1.18	2.14±0.62 ^a	1.61±0.46 ^{ab}

Note: compared with that before treatment, aP < 0.05, compared with study group, bP < 0.05.

Table 4.

Primary symptom Score, Secondary Symptom Score and Total Score between the Two Groups before Treatment and after Treatment (points, $\bar{x} \pm s$)

Group	Number of cases	Total score		Secondary symptom score		Primary symptom score	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group	50	21.88±5.78	11.21±2.90 ^a	8.01±1.73	3.41±0.93 ^a	13.98±2.04	7.98±1.97 ^a
Study group	50	21.84±5.63	5.88±1.01 ^a	8.84±1.13	1.88±0.37 ^a	13.11±2.92	4.00±0.59 ^a
T value		1.155	16.449	1.945	12.649	1.982	15.091
P value		>0.05	<0.05	>0.05	<0.05	>0.05	<0.05

Note: compared with that before treatment, aP < 0.05.

Table 5.

Comparison of Primary symptom Score, Secondary Symptom Score and Total Score between the Two Groups before Treatment and during Follow-up (points, $\bar{x} \pm s$)

Group	Number of cases	Total score		Secondary symptom score		Primary symptom score	
		Before	At follow-up	Before	At follow-up	Before	At follow-up

		treatment		treatment		treatment	
Control group	50	21.88±5.78	12.41±2.93 ^a	8.01±1.73	4.01±0.94 ^a	13.98±3.04	8.51±2.09 ^a
Study group	50	21.84±5.63	7.11±1.92 ^a	8.84±1.13	2.38±0.42 ^a	13.11±2.92	4.84±0.73 ^a
T value		1.155	16.402	1.945	12.749	1.982	14.785
P value		>0.05	<0.05	>0.05	<0.05	>0.05	<0.05
Note: compared with that before treatment, ^a P < 0.05.							

DISCUSSION

Constipation in children is often accompanied by poor appetite. If the child patient fails to receive timely and effective treatment, it will seriously affect the physical development of the child patient, which is not conducive to the daily nutritional intake of the child patient. In recent years, the incidence of constipation in children is increasing, while conventional drug therapy is not highly targeted. It is urgent to find an effective treatment method to reduce the recurrence rate after drug withdrawal and accelerate the relief of constipation symptoms⁴. With the increasing importance of traditional Chinese medicine in clinical practice, more and more studies have been done on the treatment of constipation in children by traditional Chinese medicine. Constipation in children belongs to the category of difficult defecation, yin constipation and yang constipation in TCM theory, weak spleen and qi in children, weak spleen, delicate zang-fu organs, insufficient chemical source, no right to mobilize, the condition of spleen deficiency, reducing the power of large intestine conduction, accumulating stagnation and stopping the accumulation, injuring the gastrointestinal tract, causing the loss of intestinal conduction and finally becoming constipation, which is the main pathogenesis of constipation in children^{5,6}.

Therefore, invigorating the bowels, invigorating the spleen and invigorating the qi and eliminating food stagnation are the main principles of Chinese medicine in treating constipation in children.

Shenqi Runchang Tongbian Decoction is composed of Radix Rhubarb, Hawthorn, Semen Trichosanthis, Radish Seeds, Angelica Sinensis, Mangnolia Officinalis, Aurantii Fructus Immaturus, Rhizoma Atractylodis, Radix Astragali, and Radix Pseudostellariae. Among them, Rhubarb has the function of dispelling stagnation, purging fire and clearing away heat; Hawthorn and Radish Seeds have the function of eliminating stagnation and

regulating qi; Semen Trichosanthis and Angelica Sinensis have the function of relaxing defecation, moistening dryness and nourishing blood; Mangnolia Officinalis can warm stomach and moderate, relieve fullness and swelling, lower qi and eliminate phlegm, relieve cold-qi, disperse wind and pathogen, relieve pain, moisturize intestine and abdomen; Aurantii Fructus Immaturus can strengthen the peristalsis of stomach and intestine, eliminate stagnation of food and regulate qi; Rhizoma Atractylodis and Radix Astragali can moisten intestines, replenish qi, invigorate spleen and replenish qi; Radix Pseudostellariae has the functions of moistening dryness, invigorating qi and invigorating spleen. The combination of these traditional Chinese medicines can exert the effects of eliminating food, promoting stagnation, expelling defecation, moistening intestines, invigorating qi and strengthening spleen^{7, 8}. Modern pharmacology shows that many kinds of organic acids in Hawthorn can decompose meat more easily, increase the decomposition of digestive enzymes and promote digestion. Radish Seeds can enhance the rhythmic contraction of intestinal tract, has the function of eliminating food and debulking, and promotes defecation better. Rhubarb can inhibit intestinal water absorption and increase intestinal peristalsis. The active ingredients of sennoside can facilitate smooth defecation. The laxative effect of Semen Trichosanthis is strong, because it is rich in fat oil and can alleviate the laxative effect after making frost, it still has certain laxative effect, but it will not be too strong^{9, 10}. Mangnolia Officinalis can promote gastrointestinal peristalsis. Aurantii Fructus Immaturus has the function of promoting gastrointestinal motility, increasing the contraction rhythm of gastrointestinal peristalsis, stimulating smooth muscle, and promoting the secretion of digestive juice. The ingested nutrients can be hydrolyzed by sufficient digestive enzymes, further making the

intestinal contents easier to be excreted, which can play the role of excretion, transportation, absorption and digestion, and can also play the role of regulating the gastrointestinal function^{11, 12}. Rhizoma Atractylodis can produce significant excitatory effect on intestinal smooth muscle. It is recommended to accelerate gastrointestinal motility and promote gastrointestinal peristalsis and secretion. Radix Astragali can enhance the movement and excitation of the small intestine, increase the smooth muscle tone and prolong the peak potential release time of the small intestine. Radix Pseudostellariae has the effect of regulating gastrointestinal motility, immune function and body stress state^{13, 14}. The combination of Shenqi Runchang Tongbian Decoction has obvious therapeutic effect on children constipation, can enhance the function of stomach and intestine, and can better promote the digestion of children.

In this study, the control group was treated with lactulose oral solution, and the study group was treated with Shenqi Runchang Tongbian Decoction. The results showed that the effectiveness of the study group after treatment and during follow-up was higher than that of the control group; the score of lips symptoms of the study group after treatment was lower than that of the control group; the score of appetite, halitosis, abdominal distension and abdominal pain, defecation duration, defecation difficulty, defecation frequency and stool property symptoms of the study group after treatment and during follow-up were lower than that of the control group; the total score, secondary symptom score and primary symptom score of the study group after treatment and during follow-up were lower than that of the control group. The results showed that Shenqi Runchang Tongbian Decoction could moisten intestines, replenish qi, invigorate spleen and replenish qi, improve the gastrointestinal peristalsis, promote gastrointestinal secretion, relieve defecation, moisturize dryness, nourish yin, supplement deficiency and benefit spleen, and promote the recovery of children^{15,16}.

In conclusion, the treatment of children with constipation with Shenqi Runchang Tongbian Decoction can improve the secondary symptoms

and primary symptoms of children and improve the comprehensive curative effect, especially in the aspects of improving appetite, halitosis, abdominal distension and abdominal pain, defecation duration, defecation difficulty, defecation frequency and stool property. It can effectively enhance the gastrointestinal function and promote the rehabilitation of children. It is worthy of being popularized in clinical practice.

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