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Observation of the Clinical Efficacy of Sanren Laxative Drink in the Treatment of Opioid-induced Constipation

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Abstract: ***Objective:*** *To observe the clinical efficacy and safety of Sanren Laxative Drink in the treatment of opioid-induced constipation in patients with cancer pain, to clarify its clinical value, and to provide a theoretical basis for the treatment of opioid-related constipation with traditional Chinese medicine.* ***Methods:*** *A total of 60 patients who met the inclusion criteria in the Department of Oncology of Wuhu Hospital of Traditional Chinese Medicine from December 2023 to December 2024 were randomly divided into control group and treatment group, with 30 cases in each group. The patients in the treatment group were treated with oral Sanren laxative drink on the basis of routine nursing, and the patients in the control group were given oral lactulose solution on the basis of routine nursing for 2 consecutive weeks, and the self-rating scale score, quality of life score and fecal trait score of constipation patients before and after treatment were compared between the two groups.* ***Results:*** *The effective rate of the treatment group was 90%, and that of the control group was 66.67%, and the patients in the treatment group were better than the control group in terms of constipation symptoms, quality of life and fecal characteristics, and the difference was statistically significant(P<0.05).* ***Conclusions:*** *Sanren laxative drink can help improve the fecal properties of OIC patients and assist patients in defecation, and can effectively improve the constipation symptoms and improve the quality of life of patients with cancer pain.*

Keywords: Sanren laxative drink, Opioid constipation, Clinical research**.**

1. Introduction

According to the World Health Organization [1], the incidence of malignant tumors worldwide is increasing year by year, with about 18 million new cases of malignant tumors every year, and this number is expected to increase to 23.6 million by 2030. As one of the most painful and common clinical symptoms of cancer patients [2], the prevalence of cancer pain in all stages is about 43% to 63% [3], which has a huge negative impact on the quality of life of cancer patients. Clinically, more than 90% of cancer pain can be effectively controlled by oral opioids [4], but while it exerts analgesic effects, it can also cause constipation, which is clinically called opioid-induced constipation (OIC). Constipation exists throughout the treatment of cancer, and it tends to worsen with the progression of the disease, which seriously affects the quality of life of patients and may induce serious cardiovascular and cerebrovascular events [5]. Therefore, the search for safe and effective methods for the treatment of OIC has become an urgent problem to be solved in clinical practice. At present, most of the treatments for OIC in Western medicine use interventions such as laxatives, prokinetic agents, enemas, and increasing the intake of soluble fiber, but their efficacy is not good, and the adverse reactions are obvious. As an in-hospital preparation of Wuhu Hospital of Traditional Chinese Medicine, Sanren Laxative Drink has good efficacy in clinical treatment, which is reported as follows.

2. Clinical Research

2.1 Clinical Data

A total of 60 patients who met the inclusion criteria were enrolled in the Department of Oncology of Wuhu Hospital of Traditional Chinese Medicine, Anhui University of Traditional Chinese Medicine from December 2023 to December 2024, and a total of 60 patients were randomly divided into treatment group and control group. The patients in the treatment group were orally administered Sanren laxative drink, and the control group was orally administered lactulose solution. There were 14 males and 16 females in the treatment group. age (52.20±9.925) years; Tumor categories: 11 cases of lung cancer, 8 cases of gastric cancer, 5 cases of breast cancer, 6 cases of esophageal cancer. There were 9 males and 21 females in the control group. age (51.50±5.178) years; Tumor category: 8 cases of lung cancer, 11 cases of gastric cancer, 7 cases of breast cancer, 4 cases of esophageal cancer. There was no significant difference in the general data of gender, age and tumor type between the two groups (P>0.05), which was comparable.

2.2 Inclusion Criteria for Cases

(1) Meet the 6 diagnostic criteria for malignant tumors and opioid constipation [6]; (2) Cancer patients who had no constipation before and recently developed constipation due to oral oxycodone hydrochloride extended-release tablets for pain relief; (3) Those who are lactose-free, galactose-free and fructose-intolerant; (4) Patients who have not received other drugs or treatments that affect bowel movement in the past month; (5) KPS score of 60 points or above; Expected survival of more than 3 months; (6) Be conscious, fluent and clear to express symptoms after taking medication; (7) Voluntarily participate in the experiment and sign the relevant informed consent form.

2.3 Case Exclusion Criteria

(1) Those who do not meet the diagnosis, inclusion criteria and have an unclear diagnosis; (2) Patients with habitual constipation, non-opioid-induced constipation and other diseases that may cause constipation; (3) Patients with obvious allergies to the drug components of this study; (4) Patients with severe systemic diseases and cardiorenal insufficiency; (5) Those who refuse to take Chinese medicine orally; (6) Those who cannot cooperate and pregnant or lactating women; (7) Observers who are participating in other clinical trials;

2.4 Treatment

Both groups were given the same routine care: that is, when the patients in the two groups started oral oxycodone hydrochloride extended-release tablets, the patients were instructed to eat more crude fiber food, eat a light diet, and get out of bed and walk around more when their physical strength allowed; Patients in the control group were given oral lactulose solution (Dandong Rehabilitation Pharmaceutical Co., Ltd.; 10ml/stick), dosage and usage: 10ml/time, 2 times/day, oral administration 30min before meals, for 2 weeks. Patients in the treatment group were given oral Sanren Laxative Drink (Wuhu Hospital of Traditional Chinese Medicine; 200ml/bottle), dosage and usage: 30ml/time, 2 times/day, oral administration 30min before meals, for 2 weeks.

2.5 Observation Indicators and Evaluation Criteria

2.5.1 Observation indicators

Constipation patients' symptom self-rating score, constipation patients' quality of life score, and stool trait classification score

2.5.2 Efficacy evaluation criteria:

Refer to the 2002 "Guiding Principles for Clinical Research of New Drugs of Traditional Chinese Medicine" to formulate efficacy evaluation criteria [7], as follows:

(1) Healing: All TCM syndromes disappeared or basically disappeared, and the total score decreased by ≥95%;

(2) Significant effect: TCM symptoms were significantly improved, 70% ≤ total score decreased by <95%;

(3) Effective: TCM symptoms have improved, 30% ≤ total points decreased by <70%;

(4) Ineffective: TCM symptoms did not improve, and the total score decreased by <30%.

Note: Calculation formula (nimodipine method) = (difference between pre- and post-treatment points ÷pre-treatment points) × 100%.

Total effective rate = (number of cures + effective number + effective number) / total number of cases.

2.6 Statistical Methods

Statistical analysis was performed by SPSS27.0, and the measured data were expressed as mean ± standard deviation (x±s), and data were processed using t-test or rank-sum test. The counts are described by chi-square test (2). The rank sum test is used for grade data. P<0.05 was statistically significant.

3. Test Results

3.1 PAC-SYM Scores

The symptoms of constipation were improved in both groups, but the improvement in the treatment group was significantly better than that in the control group. See Table 1 for details.

Table 1: Comparison of PAC-SYM scores of the two groups

Groups	Before treatment	After treatment	*t*	P
Treatment group	30.30±5.447	21.70±4.348	6.759	<0.001
Comparison Group	29.13±4.508	23.93±3.778	4.842	<0.001
t	0.904	-2.124		
P	0.370	0.038		

3.2 PAC-QOL Scores

The quality of life of constipation patients in both groups was improved, but the improvement in the treatment group was significantly better than that in the control group. See Table 2 for details.

Table 2: Comparison of PAC-QOL scores of the two groups

Groups	Before treatment	After treatment	*t*	P
Treatment group	79.77±5.049	56.03±5.353	17.67	<0.001
Comparison Group	78.17±5.167	64.33±6.222	9.369	<0.001
t	1.213	-5.539		
P	0.230	<0.001		

3.3 Stool Trait Typing Scores

The treatment group showed significant improvement in traits compared with the previous group, and the control group did not improve significantly compared with the previous group, and the treatment group was better than the control group, as shown in Table 3.

Table 3: Comparison of stool trait typing score of the two groups

Groups	Before treatment	After treatment	*Z*	*P*
Treatment group	2(1,3)	1(0,2)		
Comparison Group	2(1,3)	2(1,3)	-2.701	0.007
Z	-0.175	-2.150	-0.628	0.530
P	0.861	0.032		

3.4 The Clinical Efficacy of the Two Groups was Compared

Table 4: Efficacy comparison

Groups	works	effective	void	effective rate	Z	*P*
Treatment group	1	26	3	90%	-2.315	0.021
Comparison Grou	0	20	10	66.67%		

The effective rate of the treatment group was 90%, and the effective rate of the control group was 66.67%, and the

treatment group was better than the control group, and the difference was statistically significant, as shown in Table 4.

4. Discussion

Opioids are currently the most effective treatment for cancer pain, and most patients with cancer pain can improve their quality of life with opioids, but 90% of cancer pain patients experience constipation [8]. At present, Western medicine mostly uses laxatives, prokinetic drugs, secretagogues, opioid receptor antagonists and other drugs for its treatment, which can relieve constipation to a certain extent, but often induce a series of new adverse reactions, such as intestinal obstruction, perforation, nerve damage, etc [9]. In addition, constipation will occur throughout the treatment process, showing a progressive aggravation trend, which will seriously affect the quality of life of patients and may induce serious cardiovascular and cerebrovascular events [10]. Modern medicine suggests that opioids inhibit the agonistic effects of peripheral μ-opioid receptors in the gastrointestinal and enterenteric nervous system, thereby delaying gastric emptying, prolonging colonic transit time, altering anal sphincter tone, and inhibiting defecation [11]. Traditional Chinese medicine believes that opioid-related constipation is more complex than ordinary constipation, on the one hand, cancer consumes qi and hurts yin over time, and the deficiency of qi, blood and fluid leads to loss of conduction in the large intestine; Secondly, modern medical methods such as surgery, radiotherapy and chemotherapy will further damage the spleen and stomach, and if the spleen and stomach are abnormal, it will be difficult to infuse the fluid and the intestines will lose moisture and the stool will be dry; On the other hand, long-term oral administration of warm and dry opioids can aggravate fluid depletion, which can lead to the development of this disease, which can be attributed to the deficiency of the standard and the truth [12].

Sanren laxative drink is the hospital preparation of Wuhu Hospital of Traditional Chinese Medicine, the formula is cut by the addition and subtraction of Xiaochengqi decoction, the specific formula is angelica 15g, rehmannia 20g, rhubarb 9g, magnolia bark 9g, citrus aurantium 6g, hemp seed 10g, peach kernel 9g, almond 9g. This formula has the effect of nourishing yin and moistening the intestines and laxative. Specific analysis of the efficacy of traditional Chinese medicine: Rhubarb: bitter, cold, with the effects of diarrhea and accumulation, clearing heat and detoxifying, and reducing yellowness through menstruation. Relevant pharmacological studies have shown that rhubarb also has pharmacological effects such as laxative, anti-inflammatory, hepatorenal protection, anti-angiogenic and antitumor [13]. Citrus aurantium: bitter, bitter, sour, slightly cold, with the effect of breaking qi and dissipating accumulation, dissolving phlegm and removing ruffians. Modern studies have shown that it has the effects of regulating gastrointestinal function, anti-inflammatory, hepatoprotective and improving cardiovascular function [14]. Magnolia bark: bitter, bitter, warm, with the effect of dampness and phlegm, and the effect of removing the full qi. Pharmacological studies have shown that Magnolia officinalis has the effects of bidirectional regulation of gastrointestinal peristalsis, antibacterial and anti-inflammatory, antiviral, antidepressant and tumor growth [15]. Angelica sinensis: pungent, sweet and warm, it has the effect of replenishing blood and activating blood, regulating menstruation and relieving pain, and moistening the intestines and laxative. Modern studies have confirmed [16] that its components have analgesic, immune-enhancing and anti-tumor effects. Raw land: sweet, cold, with the effect of clearing heat and cooling blood, nourishing yin and nourishing Jin, moisturizing dryness and laxative. Modern pharmacological studies [17] have shown that it has anti-inflammatory, laxative, immunomodulatory, and antitumor effects. Hemp seeds: sweet, flat, with the effect of moistening the intestines and laxative, mostly used for the elderly frail or maternal blood deficiency and constipation. Studies have shown that its components have analgesic, cardioprotective activity, and antitumor effects [18]. Peach kernel: sweet, bitter, with the effect of invigorating blood and removing stasis, relieving cough and asthma, moistening the intestines and laxative. Pharmacological studies have confirmed that it has neuroprotective, anti-inflammatory, immunomodulatory and anti-tumor effects [19]. Almonds: slightly warm, bitter, slightly toxic, with the effect of reducing qi, relieving cough and asthma, moistening the intestines and laxative. Modern studies [20] have shown that its components have anti-inflammatory, analgesic, anti-fibrotic, immune-modulating, anti-digestive ulcer and anti-tumor effects.

According to the above data, the treatment group was significantly better than the control group in improving the quality of life of constipation, constipation symptoms and fecal characteristics of cancer patients ($P<0.05$). The total effective rate of the treatment group was 90%, and that of the control group was 66.67%, with a significant difference ($P<0.05$), indicating that Sanren laxative drink had significant efficacy in the treatment of constipation patients.

In summary, Sanren Laxative Drink can significantly improve the fecal characteristics of opioid-induced constipation, promote defecation, and also improve the constipation symptoms of cancer pain patients, improve their quality of life, and prolong survival.

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