



Clinical effectiveness of matrine sitz bath in treating perianal infection after chemotherapy for acute leukemia

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Background: Perianal infection is a common complication in patients with acute leukemia receiving chemotherapy. It usually manifests as a perianal mass, with redness/swelling, heat, and pain, and can affect physical and mental health in severe cases. The purpose of this study was to investigate the effectiveness of matrine sitz bath (MSB) in treating perianal infection after chemotherapy for acute leukemia.

Methods: A total of 216 acute leukemia patients with perianal infection that developed during chemotherapy were enrolled in this study and equally randomized into an MSB group and control group. The control group was treated with the conventional potassium permanganate sitz bath. After 14 days of treatment, the clinical efficacy and symptom/sign scores were compared between these 2 groups. The serum levels of high-sensitivity C-reactive protein (hs-CRP), tumor necrosis factor- α (TNF- α), interleukin-10 (IL-10), erythrocyte sedimentation rate (ESR), and prostaglandin E2 (PGE2) were detected by using enzyme-linked immunosorbent assay (ELISA).

Results: The clinical efficacy of MSB group was significantly superior to that of the control group ($P < 0.05$). The scores of anal pain, systemic symptoms, mass size, and mass texture were significantly decreased after treatment in both groups ($P < 0.05$), and they were significantly lower in the MSB group than in the control group ($P < 0.05$). After treatment, the serum levels of hs-CRP, TNF- α , ESR, and PGE2 in these 2 groups significantly dropped ($P < 0.05$), and they were significantly lower in the MSB group than in the control group ($P < 0.05$); IL-10 level significantly rose in both groups ($P < 0.05$), and it was significantly higher in the MSB group than in the control group ($P < 0.05$).

Conclusions: MSB is effective in treating perianal infection after chemotherapy for acute leukemia as it can effectively improve symptoms and signs and alleviate inflammatory reactions.

Keywords: Matrine; perianal infection; acute leukemia; sitz bath

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Introduction

Acute leukemia is a malignant transformation and proliferation of lymphoid progenitor cells. As a highly fatal condition, it accounts for about 3% of malignant tumors, with a mortality rate of 3.4 per 100,000 individuals (1,2).

Depending on the blood cells it affects, acute leukemia can be divided into acute myelogenous leukemia (AML) and acute lymphocytic leukemia (ALL). The currently available treatments for acute leukemia include chemotherapy, immunotherapy, and targeted therapy, with chemotherapy

Table 1 General data of the two groups

Variables	MSB group (n=108)	Control group (n=108)	Statistics	P value
Gender (n)				
Males	63	61	$\chi^2=0.074$	0.786
Females	45	47		
Age (years)	37.12±5.16	37.40±5.21	t=0.397	0.692
Disease course (months)	13.55±3.68	13.47±3.59	t=0.162	0.872
Leukemia type (n)				
Acute myeloid leukemia (AML)	59	60	$\chi^2=0.019$	0.890
Acute lymphocytic leukemia (ALL)	49	48		

being the most commonly used treatment. However, chemotherapy weakens the immune systems and causes bone marrow suppression (3,4), leading to complications such as bleeding and infection, among which perianal infection is one of the most common infectious complications. Perianal infection was caused by many factors, more than 90% of which originated from the anal gland infection between the sphincter. The incidence of perianal infection in Chinese patients with acute leukemia receiving chemotherapy was 13.9% (5), and perianal infection is also one of the main causes of death in patients with acute leukemia (6,7). At present, fumigation, physiotherapy and wet application are the main methods to treat perianal infection in leukemia patients. However, these treatment methods have the disadvantages of cumbersome operation, high cost and poor acceptance of patients. Patients with perianal infection usually have clinical symptoms such as perianal mass, redness/swelling, heat, and pain, which affect the efficacy of chemotherapy and lead to poor physical and mental health. Therefore, active prevention and treatment of perianal infection are particularly important for improving the physical and mental health of acute leukemia patients and increasing their survival rate. Traditional Chinese medicine sitting bath treatment of acute leukemia patients with perianal infection has a good effect, but it also has many disadvantages: the production method is complex, sitting bath liquid must be modulated, and the modulation method is not easy to grasp. This method not only brings great inconvenience to the patients, but also increases the workload of the medical staff. Matrine sitting bath (MSB) preparation method is simple. The purpose of our current study was to investigate the effectiveness of MSB in treating perianal infection after chemotherapy for acute leukemia

in terms of improving clinical symptoms and alleviating inflammatory reactions. We present the following article in accordance with the CONSORT reporting checklist (available at <http://dx.doi.org/10.21037/apm-20-912>).

Methods

Subjects

A total of 216 patients suffering from perianal infection during chemotherapy for acute leukemia in our center from June 2015 to December 2019 were enrolled in this study. Using the random number table method, they were equally randomized into two groups: the MSB group and the control group. The general data were matched between these two groups (all $P>0.05$) (Table 1).

The inclusion criteria were the following: (I) the patients met the diagnostic criteria for acute leukemia in the classification of myeloid tumors revised by the World Health Organization in 2008 (8); (II) the perianal infection met the diagnostic criteria (9) of swelling, redness, itching, tenderness during defecation, local pain in the perianal area, and a body temperature of >38.5 °C; (III) the patient's age was 18 to 65 years, with complete medical histories and clinical data; (IV) patients had received at least two cycles of chemotherapy for acute leukemia; and (V) all patients signed the informed consent.

The exclusion criteria included the presence of (I) other systemic infections; (II) the use of anti-infective drugs within 1 week before enrollment; (III) allergic conditions; (IV) mental disorders; or (V) other accompanying anorectal diseases.

This study was approved by the ethics committee of

our hospital [approval document number: (2015)KY037] and was conducted in accordance with the Declaration of Helsinki.

Treatment

During the treatment of the patients, the full-time deputy chief nurse gave technical guidance.

Control group

Patients in the control group were treated with a conventional potassium permanganate sitz bath, which was started 1 day before the patient received chemotherapy. An adequate amount of 1:5,000 potassium permanganate solution was added into the bathtub, and the bathtub temperature was adjusted to 40 °C. The perianal skin was routinely disinfected before the sitz bath. After the disinfection was completed, the patient was instructed to take off his/her clothes and sit in the bathtub. The patient's buttocks were completely soaked in the potassium permanganate solution. Each sitz bath lasted 20 minutes, and the treatment was performed 3 times a day (morning, noon, and night).

MSB group

Patients in the MSB group received MSB, which was also started 1 day before the patient received chemotherapy. An adequate amount of matrine solution (0.3 g/L) was added into the tub for treatment. The treatment method, duration, and frequency were the same as in the control group.

Patients in both groups were treated for 14 days. The clinicians adjusted the duration of the sitz bath according to the patient's perianal conditions during the treatment.

Response evaluation criteria

The clinical efficacies of the treatments were evaluated in accordance with the Criteria of Diagnosis and Therapeutic Effect of Diseases and Syndromes in Traditional Chinese Medicine (ZY/T001.1-94) (10). There were four treatment response levels: cured, markedly improved, improved, and no response. The response levels definitions follow below. Cured: the clinical symptoms, anal pain, and perianal mass have basically disappeared; markedly improved: the clinical symptoms, anal pain, and perianal mass have remarkably improved; improved: the clinical symptoms, anal pain, and perianal mass have somewhat improved; no response: the clinical symptoms, anal pain, and perianal mass have not

improved or have worsened.

Main measures

Scores of symptoms and signs

Anal pain, systemic symptoms, mass size, and mass texture were recorded in all patients before and after treatment, and each item was scored. Anal pain was rated on an intensity scale of 0= none, 2= mild, 4= moderate, or 6= severe. Systemic symptoms, mass size, and mass texture were rated on an intensity scale of 0= none, 1= mild, 2= moderate, or 3= severe. A higher score indicated a more serious condition.

Detection of inflammatory biomarkers

A total of 5 mL of fasting peripheral blood was drawn from the patients before and after treatment. The serum levels of tumor necrosis factor- α (TNF- α), interleukin-10 (IL-10), and prostaglandin E2 (PGE2) were detected according to the instructions of ELISA kits (Shanghai Yuan Ye Biotechnology Co., Ltd., Shanghai, China). The serum levels of high-sensitivity C-reactive protein (hs-CRP) was detected by turbidimetric scattering method with the Dade Behring Lmmage 800 special protein analyzer. The serum levels of Erythrocyte sedimentation rate (ESR) was detected by free sedimentation method with Italian Vital dc-10064 automatic blood sedimentation instrument.

Statistical analysis

Statistical analysis was performed using SPSS 22.0 software package. The measurement data are described as mean \pm standard deviation and were compared by using the t-test for two independent samples. The count data are presented with rates and percentages and were compared using chi-squared test and rank-sum test. A P value of less than 0.05 was considered statistically significant.

Results

Clinical efficacies in the two groups

The clinical efficacy was significantly higher in the MSB group than in the control group ($P < 0.05$) (Table 2).

Symptom/sign scores in the two groups before and after treatment

Before treatment, the scores of anal pain, systemic

Table 2 Comparison of clinical efficacy in the two groups (n, %)

Variables	Control group (n=108)	MSB group (n=108)	Statistics	P value
Cured	20 (18.52)	52 (48.15)	$\chi^2=26.876$	<0.000
Markedly improved	35 (32.41)	34 (31.48)		
Improved	35 (32.41)	13 (12.04)		
No response	18 (16.67)	9 (8.33)		

MSB, matrine sitz bath.

Table 3 Symptom/sign scores in the two groups before and after treatment ($\bar{x} \pm s$, points)

Item	Control group (n=108)	MSB group (n=108)	Statistics	P value
Anal pain				
Before treatment	3.82±0.79	3.95±0.82	t=1.187	0.237
After treatment	2.59±0.60	1.94±0.53	t=8.438	<0.000
Statistics	t=12.885	t=21.394		
P value	<0.000	<0.000		
Systemic symptoms				
Before treatment	1.27±0.24	1.30±0.25	t=0.900	0.369
After treatment	0.52±0.08	0.24±0.06	t=29.099	<0.000
Statistics	t=30.809	t=42.847		
P value	<0.000	<0.000		
Mass size				
Before treatment	2.33±0.56	2.45±0.42	t=1.782	0.076
After treatment	1.02±0.19	0.85±0.17	t=6.930	<0.000
Statistics	t=23.022	t=36.698		
P value	<0.000	<0.000		
Mass texture				
Before treatment	1.74±0.45	1.76±0.41	t=0.341	0.733
After treatment	0.70±0.09	0.52±0.07	t=16.406	<0.000
Statistics	t=23.551	t=30.982		
P value	<0.000	<0.000		

MSB, matrine sitz bath.

symptoms, mass size, and mass texture showed no significant difference between the MSB group and control group (all $P>0.05$). After the treatment, these scores significantly decreased in both groups (all $P<0.05$), and they were significantly lower in the MSB group than in control group (all $P<0.05$) (Table 3).

Inflammatory factor levels before and after treatment in the two groups

Before treatment, there was no statistical difference in serum hs-CRP, TNF- α , IL-10, ESR, and PEG2 levels between these two groups (all $P>0.05$). After treatment, the serum levels of hs-CRP, TNF- α , ESR, and PGE2 in these

Table 4 Inflammatory factor levels in the two groups before and after treatment ($\bar{x} \pm s$)

Item	Control group (n=108)	MSB group (n=108)	Statistics	P value
hs-CRP (mg/L)				
Before treatment	32.02±7.16	32.74±7.21	t=0.736	0.462
After treatment	11.56±2.13	6.29±1.67	t=20.235	<0.000
Statistics	t=28.464	t=37.141		
P value	<0.000	<0.000		
TNF- α (ng/mL)				
Before treatment	19.75±4.78	20.09±4.63	t=0.531	0.596
After treatment	16.18±4.21	14.06±3.89	t=3.844	<0.000
Statistics	t=5.825	t=10.363		
P value	<0.000	<0.000		
PGE2 (ng/mL)				
Before treatment	13.91±2.69	14.21±2.78	t=0.806	0.421
After treatment	11.98±2.15	10.47±2.04	t=5.295	<0.000
Statistics	t=5.824	t=11.272		
P value	<0.000	<0.000		
ESR (mm/h)				
Before treatment	49.23±8.37	49.86±8.67	t=0.543	0.588
After treatment	20.77±4.98	11.42±3.06	t=16.624	<0.000
Statistics	t=30.368	t=43.449		
P value	<0.000	<0.000		
IL-10 (pg/mL)				
Before treatment	15.03±4.39	14.72±4.25	t=0.527	0.599
After treatment	17.62±4.89	19.83±5.01	t=3.281	0.001
Statistics	t=4.096	t=8.083		
P value	<0.000	<0.000		

MSB, matrine sitz bath; hs-CRP, high-sensitivity C-reactive protein; TNF- α , tumor necrosis factor- α ; PGE2, prostaglandin E2; ESR, erythrocyte sedimentation rate; IL-10, interleukin-10.

two groups significantly dropped ($P<0.05$), and they were significantly lower in the MSB group than in the control group ($P<0.05$); IL-10 level significantly rose in both groups ($P<0.05$), and it was significantly higher in the MSB group than in the control group ($P<0.05$) (Table 4).

Discussion

Perianal infection is one of the most common complications in patients receiving chemotherapy for acute leukemia.

Clinically, it often manifests as perianal masses, redness/swelling, heat, and pain. In severe cases, it may result in defecation and urination disorders. The incidence of perianal infection is high in patients with acute leukemia receiving chemotherapy. Typically, it occurs during the myelosuppression period shortly after chemotherapy (11,12), which can cause serious damage to patients' quality of life and physical and mental health. The traditional treatments for perianal infection are often associated with significant pain, long wound-healing time, and unavoidable

complications such as perianal abscess. Matrine is a tetracyclic quinolizine alkaloid derived from the herb *Radix Sophorae flavescens* and has anti-inflammatory, anti-tumor, immune-regulating, antipyretic, analgesic, and nerve-stabilizing properties (13-17). As shown in our current study, MSB group had significantly better clinical efficacy than that of the control group, suggesting MSB has good clinical effectiveness in treating perianal infection in acute leukemia patients receiving chemotherapy as it can effectively improve the clinical symptoms and signs in these patients.

Perianal infections are mainly caused by bacterial infections and the common pathogenic bacteria include *Escherichia coli*, *Klebsiella pneumoniae*, and *Staphylococcus aureus*. Patients with perianal infections can experience both local problems such as perianal skin redness, swelling, and pain, and systemic symptoms including high fever and fatigue. We also compared the changes in symptoms and signs before and after treatment in the two groups. The results suggested that the anal pain, systemic symptoms, mass size, and mass texture were improved after treatment in both the MSB group and control group, and the improvements were more prominent in the MSB group than in the control group. This suggests that MSB can effectively alleviate anal pain and systemic symptoms and improve the size and texture of local masses. Chuang *et al.* (18,19) reported that matrine could kill a variety of pathogenic bacteria such as *Escherichia coli*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*, possibly by suppressing the biofilms of these pathogens (20). Therefore, matrine may inhibit the infections of pathogenic bacteria and contribute to alleviating anal pain and systemic symptoms, shrinking local masses, and lowering the symptom and sign scores in patients with acute leukemia receiving chemotherapy.

Perianal infection is an inflammatory disease in which inflammatory factors play various key roles. hs-CRP is an acute-phase reactant produced and secreted by the liver. It can participate in the inflammatory response by activating complements, binding to monocyte receptors, and secreting lymphokines. Its level in the human body increases with the severity of infection and thus is clinically valuable for detecting concurrent infections in patients with acute leukemia (21). TNF- α is a major pro-inflammatory cytokine involved in immune response and inflammatory events. Its level markedly increases under pathological conditions (22,23).

PGI₂ is an inflammation mediator that is widely present in human body. It participates in intestinal inflammation and is associated with the severity of certain diseases

(24,25). ESR is less specific in the diagnosis of infections but is highly sensitive in reflecting the occurrence and development of inflammation (26). The ESR level markedly increases in cases of infections (27). IL-10 is an anti-inflammatory cytokine. It can reduce inflammatory response by inhibiting the synthesis and release of various pro-inflammatory factors in the body (28). In our current study, the inflammatory response was significantly improved in both the MSB group and control group after treatment, and the improvement was more prominent in the MSB group, suggesting that MSB can effectively adjust the serum levels of hs-CRP, TNF- α , IL-10, ESR, and PEG2 and alleviate inflammatory response in patients with perianal infection after chemotherapy for acute leukemia.

Conclusions

MSB is highly effective in treating perianal infection in patients with acute leukemia receiving chemotherapy as it can effectively improve the symptoms and signs of these patients, decrease serum levels of proinflammatory factors (including hs-CRP, TNF- α , ESR, and PEG2), increase the levels of anti-inflammatory factor levels (e.g., IL-10), and alleviate inflammation.

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Footnote

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Data Sharing Statement: Available at <http://dx.doi.org/10.21037/apm-20-912>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/apm-20-912>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all

aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was performed in compliance with the ethical principles of the Declaration of Helsinki and was approved by the Ethics Committee of the Affiliated Hospital of Jiangnan University [(2015)KY037]. All subjects agreed and signed informed consent.

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