

# The Therapeutic Effects and Safety of Dioscorea Decoction Combined with Coix Seed in Treating Cancer Cachexia (Spleen-kidney Yang Deficiency Syndrome) in Malignant Tumor Patients

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**Abstract:** *Objective:* To investigate the therapeutic effects and safety of Dioscorea Decoction combined with Coix Seed in treating cancer cachexia (spleen-kidney Yang deficiency syndrome) in malignant tumor patients. *Methods:* A total of 90 patients with cancer cachexia admitted between June 2024 and June 2025 were randomly divided into a control group and a study group (45 cases each) using a random number generator. Both groups received antitumor therapy, oral megestrol acetate capsules, and conventional nutritional intervention. The study group additionally received oral Dioscorea Decoction combined with Coix Seed. Differences in TCM syndrome scores, nutritional indicators (serum albumin, hemoglobin), and adverse reactions were compared before and after treatment. *Results:* Baseline TCM syndrome scores and nutritional indicators were comparable between the two groups before treatment. After treatment, both groups showed significant reductions in TCM syndrome scores and increases in serum albumin and hemoglobin levels. The study group exhibited lower TCM syndrome scores and higher serum albumin and hemoglobin levels than the control group, with statistically significant differences. No significant difference in adverse reaction rates was observed between the two groups. *Conclusion:* Dioscorea Decoction combined with Coix Seed can further improve nutritional status, alleviate clinical symptoms, and demonstrate good safety in treating cancer cachexia patients.

**Keywords:** Dioscorea Decoction; Coix Seed; Cachexia; Malignant tumor

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## 1. Introduction

Cancer cachexia is a clinical syndrome characterized by persistent loss of skeletal muscle mass, most commonly seen in patients with lung cancer and digestive system tumors. It is often caused by an imbalance in energy

metabolism due to various reasons and clinically manifests as anorexia, weight loss, etc.<sup>[1]</sup> Epidemiological data shows that the incidence and mortality of malignant tumors are on the rise in China. In this context, the incidence of cachexia in patients with advanced malignant tumors can reach up to 80%, severely affecting the quality of life and prognosis of cancer patients and causing at least 22% of cancer deaths<sup>[2]</sup>. Conventional Western medicine and nutritional support interventions for cancer cachexia patients have limited effects and single targets, and may also increase the risk of liver and kidney function damage in patients. However, due to the anemia state of cancer cachexia patients, exercise therapy has significant limitations in the treatment of such patients. Therefore, it is necessary to explore a safe and effective method for comprehensive intervention in clinical practice<sup>[3]</sup>. Because of this, this study conducted research on 90 patients with cancer cachexia, including from June 2024 to June 2025, intending to investigate the therapeutic effect and safety of Dioscorea Decoction combined with Coix Seed on cancer cachexia (spleen and kidney Yang deficiency syndrome) in patients with malignant tumors.

## **2. Materials and methods**

### **2.1. General information**

Ninety patients with malignant tumor cachexia admitted to our hospital from June 2024 to June 2025 were selected and randomly divided into a control group and a study group, with 45 patients in each group using a computer random number generator. The study group consisted of 24 males and 21 females, aged between 37 and 77 years old, with an average age of  $(55.65 \pm 8.46)$  years old. The course of disease ranged from 1 to 5 years, with an average of  $(2.46 \pm 0.51)$  years. Among them, 27 patients were in stage III and 18 patients were in stage IV of TNM tumor staging. The control group consisted of 28 males and 17 females, aged between 35 and 79 years old, with an average age of  $(56.17 \pm 9.34)$  years old. The course of disease ranged from 1 to 5 years, with an average of  $(2.73 \pm 0.60)$  years. Among them, 31 patients were in stage III and 14 patients were in stage IV of TNM tumor staging. This study has been approved by the Medical Ethics Committee of XX Hospital, and all patients and their families involved in the trial were informed and signed consent forms.

### **2.2. Inclusion criteria**

- (1) Patients who meet the diagnostic criteria for cancer cachexia<sup>[4]</sup>;
- (2) Meet the diagnostic criteria for spleen and kidney Yang deficiency syndrome in the “Clinical Terminology of Traditional Chinese Medicine GB2019 Edition”<sup>[5]</sup>;
- (3) Aged between 18 and 80 years old;
- (4) Complete baseline data.

### **2.3. Exclusion criteria**

- (1) Patients with an estimated survival time of less than 3 months;
- (2) Patients with neurologic anorexia;
- (3) Women during pregnancy and lactation;
- (4) Patients with severe cardiac, liver, kidney diseases or infections;
- (5) Patients with autoimmune diseases;
- (6) Patients with severe benign gastrointestinal diseases;
- (7) Patients with poor compliance. Patients with severe benign gastrointestinal diseases.

## 2.4. Methods

Both groups of patients received concurrent anti-tumor therapy. They orally took Megestrol Acetate Capsules (Jiangsu Nhwa Pharmaceutical Corporation Limited, National Medical Approval Number H20010553, specification 80 mg/capsule), 160 mg per time, once a day, combined with conventional nutritional intervention, including health education, high-protein and high-nutrition diet, and symptomatic treatments such as enteral nutrition, intravenous injection of fat emulsion, antiemetic, and analgesic when necessary. In addition to the above treatments, the study group was given orally Shuyu Decoction combined with prepared Coix seed (the main ingredients include 23 herbs such as Chinese yam, *Codonopsis pilosula*, *Ophiopogon japonicus*, *Paeonia lactiflora*, and prepared Coix seed, decocted by the pharmacy of XX Hospital), one dose per day, taken once in the morning and once in the evening, for 2 months.

## 2.5. Observation indicators

### 2.5.1. TCM syndrome scores

Evaluated before treatment and after 2 months of treatment, respectively. Referring to the relevant standards of the “Guiding Principles for Clinical Research of New Chinese Medicines”<sup>[6]</sup>, the symptom scores include five aspects: emaciation, poor appetite, shortness of breath, fatigue, and abdominal distension. The higher the score, the more severe the symptoms.

### 2.5.2. Nutritional indicators

Evaluated before treatment and after 2 months of treatment, respectively. An automatic biochemical analyzer was used to measure patients’ serum albumin levels, and a hematology analyzer was used to measure patients’ hemoglobin levels.

### 2.5.3. Adverse reactions

The occurrence of adverse reactions such as gastrointestinal side effects, dizziness and headache, and abnormal liver function during the treatment process in both groups was observed.

## 2.6. Statistical methods

Data analysis was performed using SPSS 19.0 statistical software. After passing the Shapiro-Wilk test for normal distribution, the scores of traditional Chinese medicine (TCM) syndromes and nutritional indicators were expressed as mean  $\pm$  standard deviation (SD). Independent sample *t*-tests were used for comparisons between groups. Adverse reactions were expressed as rates (%), and differences between the two groups were compared using the  $\chi^2$  test or Fisher’s exact test.  $P < 0.05$  was considered statistically significant.

## 3. Results

### 3.1. Comparison of TCM syndrome scores between the two groups

There were no significant differences in TCM syndrome scores between the two groups before treatment (all  $P > 0.05$ ). After treatment, the scores decreased significantly in both groups (all  $P < 0.05$ ), and the scores in the study group were lower than those in the control group, with statistically significant differences (all  $P < 0.05$ ). See Table 1.

**Table 1.** Comparison of TCM syndrome scores between the two groups

Group	n	Weight Loss (kg)		Anorexia Score		Dyspnea Score		Fatigue Score		Abdominal Distension Score	
		Baseline	Post-Tx	Baseline	Post-Tx	Baseline	Post-Tx	Baseline	Post-Tx	Baseline	Post-Tx
Study	45	1.41 ± 0.36	0.79 ± 0.24*	1.21 ± 0.34	0.60 ± 0.14*	1.03 ± 0.32	0.51 ± 0.19*	1.47 ± 0.45	0.92 ± 0.23*	1.52 ± 0.37	0.96 ± 0.35*
Control	45	1.36 ± 0.40	0.94 ± 0.29*	1.27 ± 0.41	0.91 ± 0.25*	1.11 ± 0.39	0.86 ± 0.29*	1.56 ± 0.39	1.17 ± 0.34*	1.45 ± 0.43	1.16 ± 0.44*
<i>t</i> -value		0.623	-2.673	-0.756	-7.258	-1.064	-6.772	-1.014	-4.086	0.828	-2.386
<i>p</i> -value		0.535	0.009	0.452	< 0.001	0.290	< 0.001	0.313	< 0.001	0.410	0.019

Note: Compared with before treatment, \* $P < 0.05$ .

### 3.2. Comparison of surgical parameters between the two groups

There was no significant difference in serum albumin and hemoglobin levels between the two groups before treatment (all  $P > 0.05$ ). However, after treatment, both groups showed significant increases in these levels (all  $P < 0.05$ ). Moreover, the study group had higher levels of serum albumin and hemoglobin compared to the control group, with a statistically significant difference (all  $P < 0.05$ ). See **Table 2**.

**Table 2.** Comparison of nutritional indices between the two groups (mean ± SD)

Group	n	Albumin (g/L)		Hemoglobin (g/L)	
		Baseline	Post-Tx	Baseline	Post-Tx
Study	45	36.09 ± 6.58	42.43 ± 8.61*	101.65 ± 14.09	117.42 ± 14.34*
Control	45	34.96 ± 7.13	38.49 ± 6.82*	102.12 ± 13.35	111.06 ± 12.07*
<i>t</i> -value		0.781	2.406	-0.508	2.169
<i>p</i> -value		0.437	0.018	0.613	0.033

Note: Compared with before treatment, \* $P < 0.05$ .

### 3.3. Comparison of adverse reactions between the two groups

The study group only experienced dizziness and headache in one case each, and gastrointestinal side effects in one case. The control group had one case of gastrointestinal side effects. There was no statistically significant difference in the total incidence of adverse reactions between the two groups (4.44% vs 2.22%,  $P > 0.05$ ). See **Table 3** for details.

**Table 3.** Comparison of adverse reactions between the two groups (cases)

Group	n	Gastrointestinal reactions (n)	Dizziness/headache (n)	Total incidence (%)
Study	45	1 (2.22%)	1 (2.22%)	2 (4.44%)
Control	45	1 (2.22%)	0	1 (2.22%)
$\chi^2$				0
<i>p</i> -value				1



## 4. Discussion

From the perspective of traditional Chinese medicine, cachexia can be attributed to “deficiency and debilitation.” Traditional Chinese medicine oncology believes that the pathogenesis of tumor cachexia is similar to that of tumors, which is a mixture of deficiency and excess, with deficiency at the root and excess as the manifestation. For patients with spleen and kidney Yang deficiency syndrome, the treatment should focus on strengthening the body’s resistance to eliminate pathogens and nourishing the spleen and stomach, supplemented by promoting Qi and blood circulation, resolving phlegm, and detoxifying<sup>[7]</sup>. In this study, both groups of patients showed significant improvement in traditional Chinese medicine symptom scores and nutritional indicators after corresponding treatment. This is likely due to the use of megestrol acetate as the basic treatment in this study, which can inhibit inflammatory factors released in the tumor microenvironment to reduce systemic inflammatory response on the one hand, and act on the hypothalamus appetite center to increase hunger and food intake, thereby improving patients’ nutritional status on the other hand<sup>[8]</sup>. Dioscorea decoction is derived from Dioscorea Pill in “Synopsis of Golden Chamber” by Zhang Zhongjing. It mainly nourishes Qi and blood, dispels wind and eliminates pathogens, and can treat “various deficiencies of debilitation and hundreds of wind-induced diseases”. In this study, it was combined with Coix seed to enhance the effect of strengthening the spleen and promoting dampness elimination. The treatment effects are as follows:

After corresponding treatment, the scores of various traditional Chinese medicine symptoms in the study group were lower than those in the control group, and the levels of serum albumin and hemoglobin were higher than those in the control group, indicating that Dioscoreae Radix Decoction combined with processed Coix seed could further improve the nutritional status and reduce clinical symptoms of patients. Dioscoreae Radix Decoction uses Huai Shan Yao as the monarch drug to tonify the Qi and Yin of the triple warmer and rebuild the source of transformation for the spleen and kidney Yang deficiency syndrome of cachexia. With Si Jun Zi Tang, Si Wu Tang, *Ophiopogonis Radix*, and *Colla Corii Asini* as minister drugs, it can tonify the Qi of the spleen and lungs, assist the monarch drug to invigorate the middle warmer, nourish blood and essence, and nourish the organs. Assisted by drugs such as *Bupleuri Radix*, *Saposhnikovia Radix*, Medicated Leaven, and *Platycodi Radix* to eliminate pathogens and regulate the pivotal function. Finally, *Zingiberis Rhizoma Recens*, *Jujubae Fructus*, and prepared *Glycyrrhizae Radix Rhizoma* are used as envoy drugs to harmonize the various drugs while stimulating the spleen Yang to promote transportation and transformation, tonifying the spleen and nourishing the nutrients<sup>[9]</sup>. Processed Coix seed is made by processing Coix seed, which reduces its cold property and increases its function of tonifying the spleen and eliminating dampness. When used in combination with Dioscoreae Radix Decoction, it can break the difficulty of not being able to accept tonifying drugs due to internal dampness and turbidity<sup>[10]</sup>. Modern pharmacological experiments have shown that yam polysaccharide can promote fatty acid oxidation and inhibit excessive activation of mTOR, thereby blocking muscle protein breakdown<sup>[11]</sup>. Coix seed ester can reduce the activation of the ubiquitin-proteasome pathway and inhibit the expression of muscle atrophy factors (Atrogin-1/MuRF1). In addition, Coix seed has also been shown to reduce caspase-1-mediated IL-18 maturation by inhibiting NLRP3 inflammasome activation, thereby inhibiting inflammatory responses<sup>[12]</sup>. On the other hand, yam mucous protein can enhance the integrity of intestinal epithelial tight junctions and promote the repair of intestinal mechanical barriers<sup>[13]</sup>. The pachymic acid contained in Poria can reduce intestinal wall edema and improve absorption function by up-regulating the expression of aquaporin AQP3, thereby improving the nutritional status of patients<sup>[14]</sup>. There was no significant difference in the incidence of adverse reactions between the two groups of patients in this study, indicating that Dioscoreae Radix Decoction combined with processed Coix seed is safe for

the treatment of cachexia and does not increase the risk of adverse reactions.

## 5. Conclusion

In summary, the use of *Dioscoreae Radix* Decoction combined with processed Coix seed for the treatment of malignant tumor cachexia patients can further improve their nutritional status, reduce clinical symptoms, and has good safety. It is worthy of further promotion in clinical practice.

## Disclosure statement

The authors declare no conflict of interest.

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