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Danggui Buxue Oral Liquid Improves Chemotherapy-induced Myelosuppression, Nutritional Status and Reduces Infections in AIDS Patients with Lymphoma: A Retrospective Observational Study

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Research Article

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Abstract

Objective: This retrospective observational study aimed to evaluate the efficacy of Danggui Buxue Oral Liquid in clinical practice. We mainly observed its effects on mitigating chemotherapy-triggered myelosuppression, correcting malnutrition and cutting down secondary infection risks among AIDS patients with lymphoma who presented qi-blood deficiency pattern.

Methods: Clinical data of 96 eligible patients were collected and analyzed in this single-center retrospective observational study. All participants received standard combination antiretroviral therapy plus conventional chemotherapy during treatment. According to the adjuvant medications actually applied in clinical practice, enrolled individuals were divided into two groups, with 48 cases in each group. The combined treatment group took Danggui Buxue Oral Liquid 20 mL twice a day throughout four chemotherapy cycles, while the standard group received no additional traditional Chinese medicine intervention. After all treatment courses finished, we compared routine blood cell counts, myelosuppression grades assessed by CTCAE 5.0 criteria, nutritional risks screened via NRS2002 scale, as well as the incidence of secondary infections between the two cohorts.

Results: Baseline demographic information, laboratory indicators and clinical characteristics were well balanced between two groups, with no statistically significant differences ($P>0.05$). After four cycles of chemotherapy, white blood cell, hemoglobin and platelet counts rose obviously in patients using Danggui Buxue Oral Liquid. By contrast, these hematological indicators declined slightly in the standard treatment group ($P<0.05$). The occurrence rate of grade myelosuppression and bacterial infections was markedly lower in the combined group ($P<0.05$). Meanwhile, more patients in the combined group obtained NRS2002 scores below 3, which reflected obvious improvement in nutritional conditions ($P<0.05$).

Conclusion: As a feasible adjuvant remedy, Danggui Buxue Oral Liquid can effectively relieve severe myelosuppression caused by chemotherapy, improve patients' nutritional state and lower bacterial infection risks. It can also help AIDS patients complicated with lymphoma tolerate chemotherapy better. The combined regimen of Western medicine and traditional Chinese medicine had practical application value for immunodeficiency-related malignancies in clinical settings.

Introduction

The epidemic situation of acquired immunodeficiency syndrome (AIDS) had been well controlled in recent years. A statistical report released in 2024 showed that the number of people living with AIDS in China had reached around 1.355 million, and their average life span had gradually approached that of the general population [1]. The wide popularization of combination antiretroviral therapy (cART) plays a key role in prolonging the survival time of HIV-infected individuals. As survival time extends, non-AIDS chronic illnesses and malignant tumors have gradually become the main factors affecting the long-term prognosis of this patient population [2].

Lymphoma ranks as one of the most common malignant tumors among people living with HIV. Clinical observations found that most HIV-associated lymphoma cases are diagnosed at stage □ or □. This disease progresses rapidly and tends to invade extranodal tissues, including bone marrow (25%–40%), gastrointestinal tract (26%) and central nervous system (17%–32%) [3-4]. Different from lymphoma occurring in HIV-negative people, HIV-related lymphoma features stronger invasiveness. Many patients cannot complete full treatment courses due to poor physical conditions, which leads to unsatisfactory long-term survival outcomes [5].

Systemic chemotherapy remains the main treatment choice for HIV-associated lymphoma. However, multiple adverse factors will damage hematopoietic function in this group of patients. HIV infection itself can impair normal hematopoiesis; lymphoma cells may also infiltrate bone tissues and disrupt hematopoietic microenvironment. When combined with the cytotoxic effect of chemotherapeutic drugs, patients are highly likely to develop leukopenia, thrombocytopenia and anemia [6-8]. These hematological adverse events often interrupt scheduled chemotherapy. Considering the high aggressiveness of HIV-related lymphoma, clinicians usually adopt relatively intensive chemotherapy regimens, which further increases the risk of severe myelosuppression. Patients under such conditions are vulnerable to various life-threatening secondary infections [9].

In current clinical practice, hematopoietic growth factors and blood transfusion are commonly used to deal with chemotherapy-induced myelosuppression. Yet these conventional interventions can only produce temporary effects. Repeated medication and blood transfusion also bring heavy economic pressure to patients and their families. Traditional Chinese medicine (TCM) had formed a complete set of treatment ideas for chemotherapy-related complications. Guided by the syndrome differentiation theory focusing on qi, blood, yin, yang and zang-fu organs, TCM prescriptions can help restore hematopoietic function, adjust physical conditions and elevate overall quality of life.

Given the above clinical dilemmas, we carried out this retrospective observational study based on real clinical data. We collected medical records of AIDS patients with lymphoma who received standardized cART and chemotherapy in our hospital. Patients were grouped according to whether they received adjuvant Danggui Buxue Oral Liquid or not. We focused on observing changes in blood cell levels, myelosuppression severity, nutritional risks and infection incidence during chemotherapy. The research results are expected to provide practical reference for optimizing comprehensive treatment plans for this special patient group.

At present, few real-world studies have explored the adjuvant effect of this traditional Chinese medicine in this special patient group. This study fills this research gap and provides clinical evidence for combined therapy.

Materials and Methods

Study Design and Participants

This work was designed as a single-center retrospective observational study. We retrieved and sorted clinical data of qualified patients admitted to Chongqing Public Health Medical Center from January 2022 to December 2023. A total of 96 patients were included for final analysis. All participants were divided into two groups based on the actual adjuvant treatments they received during hospitalization and follow-up, with 48 patients in each group. All original data were extracted from the hospital's electronic medical record system.

This research was reviewed and approved by the Ethics Committee of Chongqing Public Health Medical Center (Approval No. 2024-042-01-KY). Considering the retrospective nature of this study, the ethics committee waived the requirement for written informed consent from individual patients. All personal information of enrolled patients was fully anonymized to protect privacy.

Inclusion and Exclusion Criteria

Inclusion criteria

1. Patients met the AIDS diagnostic standards issued by Chinese Center for Disease Control and Prevention (2021 version), with positive HIV antibody test results and HIV RNA load higher than 1000 copies/mL;
2. Lymphoma diagnosis was confirmed by pathological examination, which conformed to the 2016 WHO classification criteria for lymphoid neoplasms;
3. Age ranged from 18 to 65 years old, and Eastern Cooperative Oncology Group (ECOG) performance status score was no more than 2;
4. Patients had received continuous cART for over 3 months, and $CD4^+$T cell count remained stable above 50 cells/μL;
5. No severe dysfunction occurred in liver, kidney and heart organs, and patients had no contraindications to chemotherapy or oral TCM preparations;

6.Complete medical records and follow-up data were available to cover the whole four chemotherapy cycles.

Exclusion criteria

1.Patients suffered from other types of malignant tumors simultaneously;

2.Severe active infection or massive hemorrhage existed before chemotherapy initiation;

3.Individuals had a history of allergic reaction to any component of Danggui Buxue Oral Liquid;

4.Pregnant or lactating women;

5.Patients with incomplete medical records or lost follow-up during chemotherapy cycles.

Treatment Protocols

Both groups received standard cART and chemotherapy. The cART regimen was determined according to the patient's HIV drug resistance test results and clinical conditions, mainly including tenofovir disoproxil fumarate + emtricitabine + efavirenz, or tenofovir alafenamide + emtricitabine + dolutegravir. Chemotherapy regimens were selected according to the pathological classification of lymphoma. Patients diagnosed with diffuse large B-cell lymphoma received either the R-CHOP or R-DAEPOCH regimen. Those with Burkitt lymphoma were treated with the R-DAEPOCH regimen, and patients with Hodgkin lymphoma were administered the ABVD regimen. Each chemotherapy cycle lasted 21 days, and all patients completed four consecutive cycles of treatment.

Standard treatment group: Patients received cART and chemotherapy alone, without any additional TCM drugs during the whole treatment period.

Combined treatment group: On the basis of the above standard Western medical treatment, patients took Danggui Buxue Oral Liquid orally. The drug was produced by Zhengzhou Heda Pharmaceutical Factory, with national drug approval number Z10970001. The dosage was 20 mL each time, twice per day. Medication started on the first day of the first chemotherapy cycle and lasted until the end of the fourth cycle.

Outcome Measures

1.Baseline clinical data: We collected general information of all patients, including age, gender, HIV transmission route, $CD4^+$T cell count, HIV RNA load, pathological type of lymphoma and clinical staging.

2.Hematological indicators: Peripheral white blood cell (WBC), hemoglobin (Hb) and platelet (PLT) levels were detected before treatment and after four chemotherapy cycles. Dynamic changes of these indicators were recorded in detail.

3.Myelosuppression grading: We evaluated the severity of myelosuppression at the lowest point of each chemotherapy cycle in accordance with Common Terminology Criteria for Adverse Events (CTCAE) 5.0. The grade classification was set as follows:

Grade 0: No myelosuppression;

Grade Ⅰ: WBC 3.0–3.9×10^9/L, Hb 90–109 g/L, PLT 75–99×10^9/L;

Grade Ⅱ: WBC 2.0–2.9×10^9/L, Hb 80–89 g/L, PLT 50–74×10^9/L;

Grade Ⅲ: WBC 1.0–1.9×10^9/L, Hb 65–79 g/L, PLT 25–49×10^9/L;

Grade Ⅳ: WBC <1.0×10^9/L, Hb <65 g/L, PLT <25×10^9/L.

We calculated the incidence of myelosuppression at each grade.

4.Nutritional risk assessment: Nutritional status was assessed by Nutritional Risk Screening 2002 (NRS2002) scale before and after treatment[10]. A score equal to or higher than 3 suggested nutritional risk, while a score below 3 meant no obvious nutritional risk. We calculated the proportion of patients with NRS2002 score < 3 in each group.

5.Secondary infections: We recorded all kinds of secondary infections that occurred during chemotherapy, including bacterial infection, candida infection, other fungal infections, herpes virus infection and tuberculosis. The incidence of each infection type was calculated accordingly.

Statistical Analysis

Data were analyzed using SPSS 27.0 software. Continuous variables were expressed as mean ± standard deviation ($\bar{x} \pm s$), and the independent samples t-test was used for comparison between groups; categorical variables were expressed as n (%), and the chi-square (χ^2) test was used for comparison between groups. $P<0.05$ was considered statistically significant.

Table 1. CTCAE 5.0 Grading Criteria for Hematological Toxicity

Variable	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
White Blood Cell (×10⁹/L)	≥4	3.0-3.9	20-2.9	1.0-1.9	1
Hemoglobin (g/L)	≥110	95-109	80-94	65-79	65
Platelet (×10⁹/L)	≥100	75-99	50-74	25-49	25

Results

Baseline Clinical Characteristics

A total of 96 patients were included in this study, with 48 cases in each group. We compared age, gender composition, HIV transmission route, $CD4^+$T cell count, HIV RNA load, pathological type of lymphoma and clinical stage between two groups. No statistical differences were found in all above indicators ($P>0.05$), which proved good comparability of baseline conditions. Detailed data are shown in Table 2.

Table 2. Baseline Characteristics of Patients in the Two Groups [n (%)]

Variable	Total (n=96)	Combined Treatment Group (n=48)	Standard Treatment Group (n=48)	t/χ^2 Value	P Value
Age (years)▯	52.57±11.73	51.50±10.70	53.65±12.71	0.895	0.373
Male	87(90.63)	42(87.50)	45(93.75)	1.103	0.294
Infection Route					
Homosexual Contact	19(15.63)	11(22.92)	8(16.67)	0.591	0.442
Heterosexual Contact	77(84.37)	37(77.08)	40(83.33)		
CD4+T Cell Count (cells/μL)					
<200	72(75.00)	38(79.17)	34(70.83)	0.889	0.346
≥200	24(25.00)	10(20.83)	14(29.17)		
HIV RNA (copies/mL)					
<1000	29(30.20)	14(29.17)	15(31.25)	0.049	0.824
1000-100000	32(33.34)	15(31.25)	17(35.42)	0.188	0.665
≥100000	35(36.46)	19(39.58)	16(33.34)	0.405	0.525
Pathological Type					
Diffuse Large B-Cell Lymphoma	61(63.54)	28(58.33)	33(68.75)	1.124	0.289
Burkitt Lymphoma	6(6.25)	4(8.33)	2(4.17)	0.711	0.399
Hodgkin Lymphoma	9(9.38)	5(10.42)	4(8.33)	0.123	0.726
Others	20(20.83)	11(22.92)	9(18.75)	0.253	0.615
Staging					
Stage I-II	9(9.38)	5(10.42)	4(8.33)	0.123	0.726
Stage III	11(11.46)	7(14.58)	4(8.33)	0.924	0.336
Stage IV	76(79.17)	37(77.08)	39(81.25)	0.253	0.615

Note: ▯ Data are expressed as mean ± standard deviation ($\bar{x}\pm s$).

Changes of Hematological Indicators

Before treatment started, WBC, Hb and PLT levels showed no obvious differences between the two groups (P>0.05). After four chemotherapy cycles, the three hematological indicators all increased in the combined treatment group. In the standard group, these indexes presented a mild downward trend, and the within-group difference had no statistical significance. After treatment, WBC, Hb and PLT counts in the combined group were significantly higher than those in the standard group (P<0.05). Detailed data are listed in Table 3.

Table 3. Comparison of Changes in White Blood Cell, Hemoglobin, and Platelet Before and After Treatment Between the Two Groups ($\bar{x}\pm s$)

Group	n	Time Point	White Blood Cell ($\times10^9$/L)	Hemoglobin (g/L)	Platelet ($\times10^9$/L)
Combined Treatment Group	48	Before Treatment	5.20±3.18	81.53±18.41	95.31±38.93
	48	After Treatment	6.82±2.79[ab]	99.38±19.67[ab]	128.53±58.79[ab]
Standard Treatment Group	48	Before Treatment	5.40±3.49	91.53±23.29	110.78±72.80
	48	After Treatment	3.75±1.82[b]	75.31±15.87[b]	91.66±67.68[b]

Note: □ P<0.05,Compared with the same group before treatment;□ P<0.05, compared between the two groups after treatment.

Severity of Myelosuppression

We recorded myelosuppression grades at the lowest point of chemotherapy. The statistical results indicated that the incidence of grade □ myelosuppression for WBC, Hb and PLT was obviously lower in the combined treatment group (P<0.05). No significant differences were observed in the incidence of grade 0 to grade □ myelosuppression between two groups (P>0.05). Relevant data are presented in Table 4.

Table 4. Comparison of the Severity of Bone Marrow Suppression Between the Two Groups [n (%)]

Group	Bone Marrow Suppression Grade	White Blood Cell (n=48)	Hemoglobin (n=48)	Platelet (n=48)
Combined Treatment Group	Grade 0	10(20.83)	9(18.75)	12(25.00)
	Grade I	5(10.42)	8(16.67)	3(6.25)
	Grade II	9(18.75)	15(31.25)	15(31.25)
	Grade III	6(12.50)	7(14.58)	13(27.08)
	Grade IV	18(37.50)[a]	9(18.75)[a]	5(10.42)[a]
Standard Treatment Group	Grade 0	6(12.50)	8(16.67)	10(20.83)
	Grade I	2(4.17)	7(14.58)	4(8.34)
	Grade II	6(12.50)	10(20.83)	12(25.00)
	Grade III	6(12.50)	6(12.50)	12(25.00)
	Grade IV	28(58.33)[a]	17(35.42)[a]	10(20.83)[a]

Note: Compared between the two groups, □ P<0.05.

Nutritional Risk Assessment

Before treatment, up to 90.63% of all enrolled patients had NRS200 scores ≥ 3, which meant most patients faced nutritional risks. The inter-group difference at baseline had no statistical significance (P>0.05). After chemotherapy finished, the proportion of patients with NRS2002 score < 3 was much higher in the combined treatment group (P<0.05). The data are shown in Table 5.

Table 5. Comparison of NRS2002 nutritional risk scores between two groups [n (%)]

Nutritional Risk Score	Total (n=96)	Combined Treatment Group (n=48)	Standard Treatment Group (n=48)	χ^2 Value	P Value
Before Treatment					
≥3	87(90.63)	45(93.75)	42(87.50)	1.103	0.294
□3	9(9.37)	3(6.25)	6(12.50)		
After Treatment					
≥3	33(34.38)	10(20.83)	23(47.92)	7.804	0.005
□3	63(65.62)	38(79.17)	25(52.08)		

Incidence of Secondary Infections

Bacterial infection was the most common secondary complication during the whole chemotherapy period. Statistical results showed that the incidence of bacterial infection in the combined treatment group was significantly lower than that in the standard group ($P<0.05$). For candida infection, other fungal infections, herpes virus infection and tuberculosis, no obvious inter-group differences were found ($P>0.05$). The details are displayed in Table 6.

Table 6. Comparison of Secondary Infections Between the Two Groups [n (%)]

Item	Total (n=96)	Combined Treatment Group (n=48)	Standard Treatment Group (n=48)	χ^2 Value	P Value
Bacterial Infection	35(36.46)	12(25.00)	23(47.92)	5.441	0.020
Candida Infection	8(8.34)	3(6.25)	5(10.42)	0.545	0.460
Other Fungal Infections	15(15.63)	7(14.58)	8(16.67)	0.079	0.779
Herpes Virus Infection	6(6.25)	2(4.17)	4(8.33)	0.711	0.399
Tuberculosis	12(12.50)	5(10.42)	7(14.58)	0.381	0.537

Discussion

Continuous replication of HIV will gradually reduce the number of $CD4^+$T lymphocytes and damage cellular immune function. People living with HIV are more likely to develop opportunistic infections and malignant tumors. AIDS complicated with lymphoma is one of the most difficult complications in clinical work. Its morbidity and mortality are far higher than those seen in the general population [11]. In the early stage of HIV epidemic, the risk of non-Hodgkin lymphoma among AIDS patients was over 100 times higher than HIV-negative people [4].

After the wide application of cART, the life expectancy of HIV-infected people had been extended to 72–75 years, and the lifetime risk of malignant tumors reaches 25%–40%. Non-Hodgkin lymphoma is the leading type among these cancers [3]. By the age of 75, the cumulative incidence of non-Hodgkin lymphoma is 4.4% in HIV-positive population, while the figure is only 0.01% in ordinary people. Although the overall incidence of non-Hodgkin lymphoma had decreased by nearly 50% in the cART era, the disease burden of HIV-related Burkitt lymphoma and Hodgkin lymphoma had increased compared with the period before cART was widely used [12].

Even though the survival status of HIV patients had been improved greatly, chemotherapy-induced hematological damage and malnutrition remain major obstacles for continuous treatment. These problems often lead to treatment interruption, reduced curative effect and shortened survival time [13].

Therefore, exploring safe and effective adjuvant interventions to relieve chemotherapy-related adverse events had become an urgent clinical demand.

In clinical practice, treatment plans for HIV-related lymphoma are formulated according to pathological types, clinical stages, as well as patients' age, physical state and chemotherapy tolerance. Considering the high invasiveness of this disease, clinicians tend to choose relatively intensive chemotherapy regimens [14]. Relevant clinical data show that around 80% of tumor patients will suffer from myelosuppression of varying degrees after chemotherapy. HIV infection disturbs normal hematopoietic function, and lymphoma cell infiltration plus cytotoxicity of chemotherapeutic drugs will jointly cause peripheral blood cell decline [16]. Low blood cell counts raise the risks of infection and bleeding, which will affect chemotherapy progress and patients' quality of life seriously.

This retrospective study analyzed real clinical data from our hospital and explored the adjuvant value of Danggui Buxue Oral Liquid for AIDS patients with lymphoma during chemotherapy. The overall results proved that this TCM preparation could help raise peripheral blood cell counts, reduce severe myelosuppression, improve nutritional status and cut down bacterial infection incidence.

Danggui Buxue Decoction is a classic TCM formula for tonifying qi and nourishing blood. Its main active components include astragalus polysaccharide and angelica polysaccharide. Related pharmacological studies have confirmed that astragalus polysaccharide can promote the proliferation of hematopoietic stem cells. Angelica polysaccharide can stimulate the secretion of erythropoietin, and the two ingredients work together to accelerate the recovery of bone marrow hematopoietic function [17-18]. Astragaloside Ⅳ extracted from astragalus can enhance the phagocytic ability of macrophages via TLR4/NF-κB pathway. Ferulic acid from angelica can raise the proportion of $CD4^+$T cells and restore the balance between Th1 and Th2 cells, so as to improve overall immune function and reduce infection risks [19-20].

Chemotherapy often causes gastrointestinal dysfunction and metabolic disorders, which are important inducements of malnutrition. Our research found that Danggui Buxue Oral Liquid could effectively improve patients' nutritional state. This effect may be related to multiple mechanisms. Astragalus polysaccharide can activate mTOR signaling pathway and promote protein synthesis in hepatocytes. Calycosin from astragalus can protect intestinal barrier function and improve nutrient absorption efficiency [21-22]. For AIDS patients with inherent immune defects, the combined effects of this drug on hematopoiesis, immunity and nutrition bring obvious clinical benefits.

Limitations

Several limitations exist in this retrospective work. First, all data were collected from a single medical center, and the total sample size was only 96 cases. These factors may restrict the extrapolation of our research conclusions to wider patient groups. Large-sample and multi-center studies are required for further verification in the future. Second, retrospective observational research cannot completely avoid selection bias, even though baseline indicators were balanced between two groups. Third, we only

observed clinical outcomes within four chemotherapy cycles, and did not follow up long-term survival and tumor recurrence conditions. Fourth, our evaluation of nutrition and infection mainly depended on clinical scales and medical records, without combining quantitative biomarkers such as serum albumin and C-reactive protein, which may bring certain subjective deviation.

Conclusion

For AIDS patients with lymphoma who receive standard cART and chemotherapy, additional application of Danggui Buxue Oral Liquid can increase peripheral blood cell counts, reduce the occurrence of severe myelosuppression, improve nutritional conditions and lower bacterial infection rates. This TCM adjuvant treatment can help patients get through chemotherapy courses smoothly. The integrated therapy combining Western medicine and traditional Chinese medicine had unique advantages for treating immunodeficiency-related malignancies. More well-designed studies are needed to explore long-term efficacy and molecular mechanisms, so as to accumulate more clinical evidence for popularization.

Declarations

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Competing Interests

The authors declare that there is no conflict of interests regarding the publication of this article.

Author Contributions

Wei Zhang was responsible for data collection and manuscript drafting. Mingjun Li and Qisui Li participated in study design and statistical analysis. Jing Yuan took charge of overall research arrangement, manuscript revision and submission. All authors have read and approved the final version of the manuscript.

Data availability

The raw data supporting the conclusions of this article are available from the corresponding author upon reasonable request.

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