

Clinical study on the treatment of leukopenia after chemotherapy with leucogen tablets and Shengbai mixture

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Abstract: This prospective study evaluated the efficacy and safety of Paksun Combination in combination with lisdexamfetamine versus lisdexamfetamine monotherapy for the treatment of chemotherapy-induced leukopenia. A 12-month randomized controlled trial (January to December 2022) assigned 96 patients with leukopenia to two treatment groups by computer-generated block randomization. The intervention group (48 patients) received lisdexamfetamine (20 mg, TID) plus leucovorin (20 mL, TID), while the control group (48 patients) received lisdexamfetamine only. The primary outcomes included hematologic recovery parameters, TCM symptom improvement and immunologic indices. The combination therapy demonstrated significantly higher clinical response rates (93.75% vs 75.00%; $\chi^2=15.507$, $P<0.001$), with accelerated leukocyte recovery (5.46 ± 0.41 vs $4.07\pm0.50\times10^9/L$; $P<0.001$) and neutrophil restoration (2.78 ± 0.69 vs $2.17\pm0.73\times10^9/L$; $P=0.025$). Immunological improvements included increased IgG (20.81 ± 2.77 vs 17.95 ± 3.10 g/L; $P<0.001$) and IgM levels (1.59 ± 0.30 vs 1.07 ± 0.24 g/L; $P<0.001$). No significant difference in adverse events was observed between groups (10.42% vs 18.75%; $P=0.247$). The combination of Shengbai mixture and leucogen demonstrates significantly enhanced myeloprotective efficacy with safety profiles comparable to those of leucogen monotherapy, thereby underscoring its potential as a highly effective therapeutic modality.

Keywords: Adverse reactions; Chemotherapy; Immunoglobulin; Leukopenia; Shengbai mixture

Submitted on 13-05-2025 – Revised on 02-07-2025 – Accepted on 28-07-2025

INTRODUCTION

Leukopenia, a common hematological adverse event encountered in cancer patients post-chemoradiotherapy, not only substantially disrupts the continuity of anticancer therapy and undermines clinical outcomes but also elevates the risk of infectious complications and secondary morbidities (Blayney and Schwartzberg, 2022). Effective management of this condition is critical for optimizing patient prognosis and minimizing infection-related morbidity (Blayney and Schwartzberg, 2022). The taxane-anthracycline chemotherapeutic regimens demonstrate particular propensity for inducing leukopenia (Ahn *et al.*, 2024). Given the abbreviated peripheral lifespan of white blood cells (8-12 hours), chemotherapy-induced leukopenia frequently requires urgent clinical intervention (Ahn *et al.*, 2024).

Current Western therapeutic strategies predominantly utilize granulocyte colony-stimulating factor (G-CSF) to accelerate white blood cell (WBC) recovery, thereby maintaining scheduled chemotherapy cycles (Yang *et al.*, 2021). However, G-CSF administration remains restricted to grade III-IV leukopenia cases due to transient efficacy, substantial treatment costs and theoretical risks of

stimulating malignant cell proliferation (Yang *et al.*, 2021). Conventional leukopoietic agents including batyl alcohol, inosine and vitamin B4 demonstrate limited clinical efficacy in chemotherapy-associated leukopenia management, particularly among breast cancer populations (Ahn *et al.*, 2024).

Emerging evidence supports the integration of Traditional Chinese Medicine (TCM) with Western protocols for leukopenia management (Wang *et al.*, 2021; Zhang *et al.*, 2018; Wang *et al.*, 2024). TCM theory posits that post-chemotherapy leukopenia manifests through "blood deficiency" and "consumptive disease" patterns, originating from chemotherapy-induced deficiencies in qi, blood and spleen-kidney function (Wang *et al.*, 2022; Cao *et al.*, 2023). Therapeutic interventions therefore emphasize qi replenishment, blood nourishment and spleen-kidney reinforcement (Wang *et al.*, 2022; Cao *et al.*, 2023). Shengbai Mixture, a TCM formulation comprising multiple herbal components, exerts dual therapeutic effects through kidney-warming and blood-activating properties while restoring qi-blood balance (Wang *et al.*, 2021). Clinical evidence suggests that Shengbai Mixture not only elevates WBC counts but also enhances immune parameters, potentiates chemotherapeutic efficacy and improves long-term oncological outcomes (Yao *et al.*, 2022). Its favorable safety profile and suitability for

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extended administration further position it as a viable adjunctive therapy (Yao *et al.*, 2022).

Despite these documented benefits, comprehensive analyses quantifying Shengbai Mixture's effects on standardized TCM syndrome scores and specific immune markers remain limited. To address this knowledge gap, we conducted a 12-month randomized controlled trial (January-December 2022) evaluating 96 patients with chemotherapy-induced leukopenia at our institution. This investigation systematically assesses Shengbai Mixture's hematological recovery capacity, immunomodulatory properties and symptom-alleviating effects within an integrated therapeutic regimen.

MATERIALS AND METHODS

Study design

This randomized controlled trial was performed at a tertiary hospital from January 2022 to December 2022 to assess the efficacy of Shengbai Mixture—a traditional Chinese herbal formulation—in treating chemotherapy-induced leukopenia. Patients were randomly assigned using a computer-generated randomization table into two groups: the observation group ($n = 48$) received Shengbai Mixture in conjunction with Leucogen tablets. In contrast, the control group ($n = 48$) received only Leucogen tablets. Previous clinical studies with similar endpoints determined the sample size to ensure adequate statistical power.

Inclusion and exclusion criteria

Inclusion criteria

(1) confirmed diagnosis of chemotherapy-induced leukopenia; (2) age 18-65 years; (3) completion of ≥ 1 chemotherapy cycle as planned; (4) pre-chemotherapy peripheral white blood cell (WBC) count $\geq 4.0 \times 10^9/L$; (5) intact cognitive status and compliance; (6) complete clinical records; (7) informed consent. Exclusion criteria: (1) allergy to study medications; (2) comorbid aplastic anemia; (3) severe infections, immune disorders, or psychiatric diseases; (4) premature study withdrawal.

Diagnostic criteria

Western criteria

Patients met clinical criteria for drug-induced cytopenia (Baradaran *et al.*, 2022), with peripheral WBC count $< 4.0 \times 10^9/L$ (adults).

TCM criteria

Leukopenia was categorized into Qi-Yin (Blood) Deficiency Syndrome and Yang-Qi Deficiency Syndrome based on TCM pathophysiology. For Qi-Yin (Blood) Deficiency Syndrome, primary symptoms included fatigue, night sweats and dizziness; secondary symptoms included lumbar weakness, palpitations, heat intolerance and constipation. Tongue: red with thin coating; pulse: thready and rapid. Diagnosis required ≥ 2 primary and ≥ 1 secondary

symptoms, with corroborative findings on tongue and pulse. For Yang-Qi Deficiency Syndrome, primary symptoms included dizziness, fatigue, nocturia and loose stools; secondary symptoms included lumbar weakness, poor appetite, cold intolerance, pale and swollen tongue with tooth marks and deep-thready pulse. Diagnosis required ≥ 2 primary and ≥ 1 secondary symptoms, with supportive tongue and pulse signs.

Intervention

The control group received Leucogen Tablets (Jiangsu Jibeier Pharmaceutical Co., approval no H32025444, 20 mg/tablet), 1 tablet three times daily. The observation group received Shengbai Mixture (oral herbal formulation: 20 mL, three times daily after meals) alongside Leucogen. Shengbai Mixture components included *Polygonum cuspidatum*, *Spatholobus suberectus*, *Astragalus ligustrum lucidum*, *Polygonatum sibiricum*, *Cornus officinalis*, *Psoralea corylifolia*, *Epimedium*, *Angelica sinensis*, *Prunus persica*, *Carthamus tinctorius*, *Salvia miltiorrhiza* and *Panax notoginseng*. Its 13 herbs are purchased by the Chinese herbal pharmacy of Lishui People's Hospital from suppliers with Drug Operation License and GSP certification, with the hospital retaining the quality inspection report of each batch of herbs. The combination is prescribed by the hospital agreement, which is prepared according to the traditional method of decoction in water, containing about 60g of raw herbs per 100mL, sealed and packaged after autoclaving, stored in a cool and dry place ($2\sim 8^\circ C$), with a shelf-life of 7~14 days. Both groups received prophylactic antibiotics as needed and were treated for 42 consecutive days.

Evaluation criteria

Clinical Efficacy: Total effectiveness was graded as: (a) Markedly effective: symptom resolution, WBC $> 3.5 \times 10^9/L$, neutrophils $> 1.5 \times 10^9/L$; (b) Improved: symptom alleviation, WBC $> 3.0 \times 10^9/L$, neutrophils $> 1.5 \times 10^9/L$; (c) Ineffective: no improvement or worsening. Total effectiveness = (markedly effective + improved)/total cases $\times 100\%$. TCM Syndrome Scores: Symptoms (palpitations, night sweats, oral ulcers, constipation, irritability) were scored as 0 (none), 2 (mild), 4 (moderate), or 6 (severe); total scores were summed. Hematologic and Immune Parameters: Peripheral WBC, neutrophil counts, IgA/IgG/IgM levels and Karnofsky Performance Status (KPS) were measured pre- and post-treatment. Adverse Reactions: Incidence rates were recorded.

Statistical analysis

Data were analyzed using SPSS 26.0. Continuous variables are expressed as mean $\pm$ standard deviation and categorical variables as counts (%). Intergroup comparisons used t-tests or chi-square tests. Statistical significance was defined as $P < 0.05$.

RESULTS

Baseline characteristics

96 patients diagnosed with chemotherapy-induced leukopenia were enrolled in this prospective case-control study. Table 1 summarizes the baseline demographic and clinical characteristics of both groups. No statistically significant differences were observed in age, sex, duration of chemotherapy, or distribution of primary diseases between the groups ($P > 0.05$), confirming their comparability.

Comparison of total clinical efficacy

The observation group exhibited a significantly higher total clinical efficacy rate (93.75%) compared to the control group (75.00%) ($\chi^2 = 15.507$, $P < 0.001$) (Table 2).

Comparison of TCM syndrome scores

Baseline TCM syndrome scores did not differ significantly between the two groups ($P > 0.05$). However, at both 2 and 4 weeks post-treatment, the observation group exhibited substantially lower TCM syndrome scores compared to the control group (2 weeks: $t = 14.586$, $P < 0.001$; 4 weeks: $t = 8.247$, $P = 0.002$), as detailed in Table 3.

Comparison of peripheral blood cell counts

Peripheral WBC and neutrophil counts were significantly higher in the observation group compared to the control group after 6 weeks of intervention ($t = 13.107$, $P < 0.001$; $t = 5.138$, $P = 0.025$). No baseline differences were observed ($P > 0.05$) (Table 4).

Comparison of immunoglobulin levels

Following treatment, the observation group demonstrated significantly elevated serum levels of IgG and IgM compared to the control group ($P < 0.001$). In contrast, no significant differences in IgA levels were observed between the groups ($P = 0.745$), as presented in Table 5.

Comparison of karnofsky performance status (KPS)

The observation group showed significantly higher KPS scores at 2 and 4 weeks post-treatment compared to the control group ($t = 9.626$, $P = 0.010$; $t = 6.202$, $P = 0.030$). Baseline scores were comparable ($P > 0.05$) (Table 6).

Adverse reactions

The incidence of adverse reactions was 10.42% (5/48) in the observation group (dizziness/headache: 3; fatigue: 1; lumbar weakness: 1) and 18.75% (9/48) in the control group (dizziness/headache: 4; fatigue: 4; mild liver dysfunction: 1). No statistically significant difference was observed ($\chi^2 = 1.338$, $P = 0.247$).

DISCUSSION

TCM does not explicitly document leukopenia; on the contrary, according to clinical manifestations, this

condition is characterized by “blood deficiency.” According to TCM theory, the spleen is the root of the acquired constitution and the source of qi and blood production, while “the kidneys store the essence and the essence and blood are born from each other.” Under normal circumstances, the biochemical processes associated with blood production are inextricably linked to the functions of the spleen and kidneys. On the contrary, deficiencies of the spleen and kidneys impede the production of new blood, which may be considered as the pathogenic mechanism of leukopenia. Therefore, clinical treatment should focus on strengthening the spleen, warming the kidneys, activating the blood and nourishing the blood (Li *et al.*, 2018).

The Shengbai Mixture, developed by Professor Bai-Xian Chen from his clinical experience treating leukopenia, is an oral formulation composed entirely of Chinese herbal medicines. It contains 13 herbs: Astragalus membranaceus, Epimedium, Panax notoginseng, Cornus officinalis, Salvia miltiorrhiza, peach kernel, safflower, Angelica sinensis, Polygonatum, Psoralea corylifolia, Ligustrum lucidum, Spatholobus suberectus and Fallopia multiflora.

In this formula, Astragalus membranaceus and Epimedium serve as the principal herbs. Astragalus is renowned for its qi-tonifying and exterior-fortifying effects, which address deficiencies in qi, yin (or blood) and yang. Modern pharmacological studies indicate that Astragalus possesses antitumor properties, reduces the toxicity associated with chemotherapy and enhances immune function. Epimedium, characterized by its sweet taste and warm nature, enters the liver and kidney meridians to tonify the kidney and enhance yang. Together, these two herbs synergistically replenish qi and promote blood circulation (Wang *et al.*, 2020).

The ministerial herbs—Cornus officinalis, Panax notoginseng and Psoralea corylifolia—provide additional benefits. Cornus officinalis replenishes the liver and kidney while offering astringent effects that alleviate symptoms such as dizziness, tinnitus and soreness in the waist and knees; Panax notoginseng aids in hemostasis, promotes blood circulation and resolves blood stasis; and Psoralea corylifolia supports kidney and yang tonification as well as strengthens the spleen and stomach. Combined with the principal herbs, these components warm the kidney, reinforce yang and enhance the circulation of qi and blood (Zhang *et al.*, 2023).

The assistant and coordinating herbs in the formula include peach kernel, safflower, Ligustrum lucidum, Polygonatum, Spatholobus suberectus, Salvia miltiorrhiza and Angelica sinensis. Peach kernel, which enters the heart, liver and large intestine meridians, lubricates the intestines and relieves cough and asthma, thereby effectively improving symptoms of constipation and wheezing.

Table 1: Baseline characteristics of the study participants

Characteristic	Observation group (n=48)	Control group (n=48)	t/ χ^2	P
Age (years), mean $\pm$ SD	52.9 $\pm$ 4.6	53.6 $\pm$ 5.0	0.741	0.461
Sex, n (%)			0.087	0.768
- Male	30 (62.5%)	29 (60.4%)		
- Female	18 (37.5%)	19 (39.6%)		
Chemotherapy duration (months), mean $\pm$ SD	6.2 $\pm$ 0.7	6.9 $\pm$ 1.1	1.328	0.188
Primary disease, n (%)			1.024	0.959
- Gastric cancer	4 (8.3%)	3 (6.3%)		
- Rectal cancer	4 (8.3%)	5 (10.4%)		
- Colon cancer	5 (10.4%)	6 (12.5%)		
- Liver cancer	5 (10.4%)	6 (12.5%)		
- Lung cancer	15 (31.3%)	13 (27.1%)		
- Breast cancer	15 (31.3%)	15 (31.3%)		

Table 2: Comparison of total clinical efficacy between groups

Group	Markedly effective	Improved	Ineffective	Total effectiveness (%)
Observation	33 (68.75)	12 (25.00)	3 (6.25)	45 (93.75)
Control	19 (39.58)	17 (35.42)	12 (25.00)	36 (75.00)
χ^2	-	-	-	15.507
P	-	-	-	<0.001

Table 3: Comparison of TCM syndrome scores between groups ($\bar{x} \pm s$, points)

Group	Baseline	Week 2	Week 4
Observation	35.24 $\pm$ 3.05	22.75 $\pm$ 3.11	17.62 $\pm$ 1.98
Control	35.69 $\pm$ 3.14	25.80 $\pm$ 3.40	18.89 $\pm$ 1.85
t	0.712	14.586	8.247
P	0.478	<0.001	0.002

Table 4: Comparison of WBC and neutrophil counts between groups ($\bar{x} \pm s$, $\times 10^9/L$)

Parameter	Observation group (n=48)	Control group (n=48)	t	P
WBC				
- Baseline	3.19 $\pm$ 0.98	3.22 $\pm$ 0.66	0.176	0.861
- Post-treatment	5.46 $\pm$ 0.41	4.07 $\pm$ 0.50	13.107	<0.001
Neutrophils				
- Baseline	1.14 $\pm$ 0.52	1.15 $\pm$ 0.61	0.086	0.931
- Post-treatment	2.78 $\pm$ 0.69	2.17 $\pm$ 0.73	5.138	0.025

Table 5: Comparison of immunoglobulin levels between groups ($\bar{x} \pm s$, g/L)

Parameter	Observation group (n=48)	Control group (n=48)	t	P
IgA				
- Baseline	1.70 $\pm$ 0.44	1.73 $\pm$ 0.46	0.327	0.745
- Post-treatment	1.67 $\pm$ 0.31	1.65 $\pm$ 0.29	0.326	0.745
IgG				
- Baseline	16.31 $\pm$ 4.33	16.42 $\pm$ 4.50	0.122	0.903
- Post-treatment	20.81 $\pm$ 2.77	17.95 $\pm$ 3.10	14.278	<0.001
IgM				
- Baseline	1.04 $\pm$ 0.27	1.07 $\pm$ 0.34	0.479	0.633
- Post-treatment	1.59 $\pm$ 0.30	1.07 $\pm$ 0.24	12.173	<0.001

Table 6: Comparison of Karnofsky performance status between groups ($\bar{x} \pm s$, points)

Group	Baseline	Week 2	Week 4
Observation	53.78 $\pm$ 6.78	69.11 $\pm$ 4.13	76.12 $\pm$ 6.23
Control	54.11 $\pm$ 7.07	65.71 $\pm$ 4.62	71.25 $\pm$ 6.40
t	0.233	9.626	6.202
P	0.816	0.010	0.030

Safflower and Spatholobus suberectus, entering the heart and liver meridians, activate blood circulation, resolve blood stasis and alleviate pain, which in turn reduces palpitations and dizziness. Ligustrum lucidum primarily strengthens the middle burner, stabilizes the function of the five zang-organs and nourishes the spirit, mitigating symptoms associated with heart vexation. Salvia miltiorrhiza further promotes blood circulation, removes blood stasis, alleviates pain, calms the mind and dispels excess heat in the blood. Collectively, these herbs strengthen the spleen and warm the kidney, while consistently increasing leukocyte counts. Clinical research has demonstrated that the Shengbai Mixture effectively protects nuclear substances from radiation-induced damage, thereby promoting blood cell regeneration (Ma *et al.*, 2015).

Data from the current study demonstrated that the overall remission rate was considerably better in the observation group than in the control group after treatment ($P < 0.05$). Furthermore, TCM syndrome scores measured at 2 and 4 weeks post-treatment were significantly lower in the observation group than in the control group ($P < 0.05$). These results indicate that the Shengbai Mixture is more effective than conventional Western treatments for leukopenia, which is consistent with findings reported by Li Hao *et al.* (2024). In Moreover, comparing the peripheral blood leukocyte counts, neutrophil counts and immunoglobulin levels before and after treatment in the two groups, the levels of leukocytes, neutrophils, IgG and IgM were remarkably higher in the observation group after treatment ($P < 0.05$). These objective indicators of disease progression and patient prognosis indirectly support the therapeutic efficacy of Baisheng Combination. Additionally, the clinical benefit was further substantiated by the improvement in Karnofsky scores.

Given that patients undergoing tumor chemotherapy typically exhibit compromised physical function, the safety of any treatment regimen is a critical consideration. In this study, the incidence of adverse reactions did not differ significantly between the observation and control groups ($P > 0.05$). However, the severity of adverse reactions in the observation group was notably milder, with no serious complications such as liver or kidney dysfunction observed. The lack of significant differences in adverse reaction rates may be attributable in part to the relatively small sample size. Analysis suggests that the Shengbai Mixture, being a purely herbal formulation with a mild pharmacological profile, does not accumulate in the body. Furthermore,

considering the prolonged duration of tumor treatment and the substantial economic burden on many patients, the low cost of the Shengbai Mixture enhances treatment compliance (Li *et al.*, 2024).

CONCLUSION

Conclusively, due to the inherent toxicity of chemotherapeutic agents, oncology patients are at high risk of developing leukopenia during chemotherapy. If not managed promptly and effectively, this condition can adversely affect the chemotherapy process and lead to other health complications. Baisheng Combination is a purely herbal preparation that has demonstrated significant efficacy and safety in the treatment of chemotherapy-induced leukopenia. The sample size of this study was relatively small, however and further research is needed to confirm the efficacy and safety of Baisheng Combination in a larger and more diverse population.

Acknowledgment

Not applicable.

Author's contribution

Yuxiao Zeng and Yongwei Zhuang designed the study, Jian Li and Tao Lian collected the data, Jian Li analyzed the data, Yuxiao Zeng and Yongwei Zhuang prepared the manuscript. All authors read and approved the final manuscript.

Funding

There was no funding.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethical approval

The study protocol received approval from the Institutional Ethics Committee of Lishui People's Hospital (22-LS-102-EC) and written informed written consent was obtained from all participants.

Conflict of interest

The authors declared no conflict of interest.

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