Journal of Inflammation Research

Dovepress
Taylor & Francis Group

Open Access Full Text Article

ORIGINAL RESEARCH

Efficacy of *Sihuang Zijin* Powder Colloid in Treating Infusion Phlebitis in Patients with Tumors: A Randomized Controlled Study

Jian-Wen Hou, Ze-Ying Hu

Department of Head and Neck Surgery, Zhejiang Cancer Hospital, Hangzhou, Zhejiang, 310022, People's Republic of China

Correspondence: Ze-Ying Hu, Department of Head and Neck Surgery, Zhejiang Cancer Hospital, Hangzhou, 310022, People's Republic of China, Tel +86 13857102100, Fax +86 0571-88128221, Email huzeying1976@163.com

Objective: This study aimed to evaluate the efficacy of *Sihuang Zijin* powder colloid in the treatment of infusion phlebitis in patients with tumors.

Methods: In this randomized controlled trial, 110 patients with grade II–III phlebitis were randomly allocated to either of two groups: the experimental group and the control group. Patients in the experimental group received *Sihuang Zijin* powder colloid, and those in the control group were treated with a hydrocolloid. The severity of phlebitis was assessed using the Infusion Nurses Society grading criteria for phlebitis and the level of pain was assessed using a visual analog scale after 24 hours. Additional outcome measures included the duration required for pain relief, the time taken for resolution of the extent of redness and swelling, and patient satisfaction levels.

Results: Following 24 hours of treatment, there were notable differences between the two groups in the severity of phlebitis and pain scores. Patients in the experimental group exhibited a significantly shorter time to pain relief and resolution of swelling compared to those in the control group. Additionally, patient satisfaction was significantly higher in the experimental group.

Conclusion: *Sihuang Zijin* powder colloid was effective in the treatment of infusion phlebitis in patients with tumors, with treated patients demonstrating superior outcomes in terms of pain relief, resolution of swelling, and patient satisfaction.

Keywords: Chinese traditional medicine, colloids, medicine, phlebitis

Introduction

Nearly 20 million new cancer cases were reported in 2022, and 9.7 million people succumbed to the disease. It is estimated that nearly one-fifth of men and women will develop cancer during their lifetime, with cancer-related deaths among one in nine men and one in 12 women. Projections based on demographic trends suggest that the global incidence of new cancer cases will reach 35 million by 2050.[1]

Patients with cancers often have compromised physical health,[2] low immunity,[3] and elevated levels of specific inflammatory factors,[4] including hypercoagulable states and inflammatory mediators such as tumor necrosis factor-α (TNF-α) and interleukin-1β (IL-1β), which can indirectly damage vascular endothelial cells. In addition, some patients treated with radiotherapy and chemotherapy before surgery develop increased vessel wall fragility and a heightened risk of infusion phlebitis.[5]

Infusion phlebitis (IP) is an inflammatory response of the vasculature caused by irritation of the blood vessels from intravenous infusion.[6] It is one of the most common complications associated with intravenous infusion therapy,[7] characterized by redness, pain, localized cord-like and even indurated inflammatory changes in the veins, and inflammatory responses.[8] This condition is not only highly prevalent but also potentially harmful. When IP occurs in patients, it often necessitates the forced interruption of treatment, re-insertion of intravenous lines, increased healthcare costs, heightened infection risks, as well as other problems that compromise the effectiveness of treatment.[9]

Received: 14 March 2025
Accepted: 4 June 2025
Published: 19 June 2025

In modern medicine, the occurrence of IP is attributed to the properties of infused drugs, including extreme pH values, high plasma osmotic pressure, or the presence of particulate matter, which stimulate the vascular endothelium. These factors promote platelet aggregation, release prostaglandin E, increase vascular permeability, and trigger leukocyte infiltration, leading to inflammation. In addition, vascular injury induces histamine release, venous contraction, lumen narrowing, and reduced blood flow, all of which further exacerbate inflammation.[10]

In recent years, the external application of traditional Chinese medicine (TCM) has gained considerable attention for its role in managing IP. Transdermal absorption allows localized delivery of the externally applied TCM drug to the affected veins, maintaining a relatively stable local blood concentration. This approach has the effect of removing blood stasis, detumescence, and pain, all at a relatively low cost.[11]

Ruyi Jinhuang powder (RJP) is a classic TCM formulation that is widely used in clinical practice. RJP is effective in treating chemotherapeutic phlebitis with a high total effective rate of 96.97%. The study confirmed that 20 erysipelas patients with topical RJP and the total effective rate was up to 95%. It was discovered that RJP could significantly alleviating pain by reducing VAS score from 8 to 2.[12] Its anti-inflammatory properties have been demonstrated through the downregulation of inflammatory cytokines interleukin (IL)-1α, IL-1β, IL-6, and IL-10.[12] RJP has been shown to modulate the nervous and immune systems, participate in inflammatory responses, and influence cellular processes such as proliferation, differentiation, and apoptosis through specific mechanisms.[13] However, there are certain limitations associated with RJP, such as a low extraction rate of active ingredients, the potential for allergic reactions on affected skin, susceptibility to bacterial and mold contamination during storage, and a labor-intensive preparation process.

To address these issues, the pharmacy department of our hospital improved the RJP formulation by incorporating additional ingredients such as *Astragali radix* and *Arnebia euchroma*.

Astragali radix belongs to the lung and spleen meridians. The chemical components in Astragali radix include various components such as astragalus saponins, flavonoids, and polysaccharides. Modern pharmacological studies have shown that *Astragali radix* possesses a wide range of therapeutic effects, including anti-tumor, anti-inflammatory, immunomodulatory, anti-atherosclerotic, cardioprotective, anti-hypertensive, and anti-aging properties.[14] *Arnebia* euchroma belongs to the heart and liver meridians. The chemical components in Arnebia euchroma include quinones, flavonoids, phenolic acids, terpenoids, and polysaccharides, which have wound-healing, anti-microbial, and anti-bacterial properties, making it a valuable treatment option for several diseases.[15]

In the present study, a novel manufacturing process was used to enhance the formulation. Using medical hydrocolloid technology, the active components of the modified RJP were efficiently extracted and combined with hydrocolloid particles and an elastic polymer to produce *Sihuang Zijin* powder colloid. Hydrocolloids mainly include carboxymethyl cellulose and pectin, and the ingredients have been proven to be safe and reliable. Multiple studies have shown that hydrocolloids are safe and effective in clinical applications.[16–18] This improved preparation was administered to tumor patients with IP, yielding promising results.

Materials and Methods

Aims

The purpose of this study was to determine the clinical efficacy of *Sihuang Zijin* powder colloid in the treatment of IP, assess its feasibility, and provide new ideas and methods for the clinical treatment of IP. The objectives included reducing patients' pain and medical expenses, improving the quality of care, and analyzing the advantages of TCM while promoting TCM-based nursing practices and achieving improved social and economic outcomes.

Study Design

A parallel, double-armed, single-center, randomized controlled trial was conducted at the Zhejiang Cancer Hospital between August 20 and November 20, 2024. The study was registered on the Chinese Clinical Trial Registry (www.chictr.org.cn) under the registration number ChiCTR2400088521. Eligible participants were randomly assigned to the control group and experimental group in a ratio of 1:1.

The required sample size was determined using G*Power 3.1 software. The calculation indicated that for the examination of χ^2-tests with two groups, a minimum sample size of 88 was necessary to achieve a statistical power of 80.0% at an alpha level of 0.05 and an effect size (w) of 0.3. Considering a 20% attrition rate, a total of 106 participants were initially planned for inclusion in this study. The final number of participants included was 110 (Figure 1).

Participants

Inclusion Criteria Were as Follows

(1) Cancer patients diagnosed with grade II–III phlebitis occurring during or after infusion.

(2) Patients who received parenteral nutrition via peripheral vein infusion.

(3) Patients aged 18 years or older, with puncture sites located on the dorsum of the hand or forearm veins.

(4) Infusion rates were 40 to 70 drops per minute.

(5) Patients who were conscious and had stable vital signs.

(6) Participants who voluntarily took part in this study, consented to the use of topical medication, and signed informed consent forms.

Exclusion Criteria Were as Follows

(1) Patients with pre-existing vascular or coagulation system diseases.

(2) Patients with a history of previous vein injury or repeated punctures, which could increase the risk of additional vein damage.

(3) Patients receiving parenteral nutrition in combination with other irritant or corrosive drugs, which could exacerbate vein injury.

(4) Patients with known allergies to the experimental drug.

(5) Patients with upper limb edema, skin injuries, inflammation, or rashes.

Randomization and Blinding

Randomization

Patients were randomly assigned to the intervention and control groups using a computer-generated randomization program. Eligible patients were sequentially numbered based on the order of hospitalization and allocated to a group

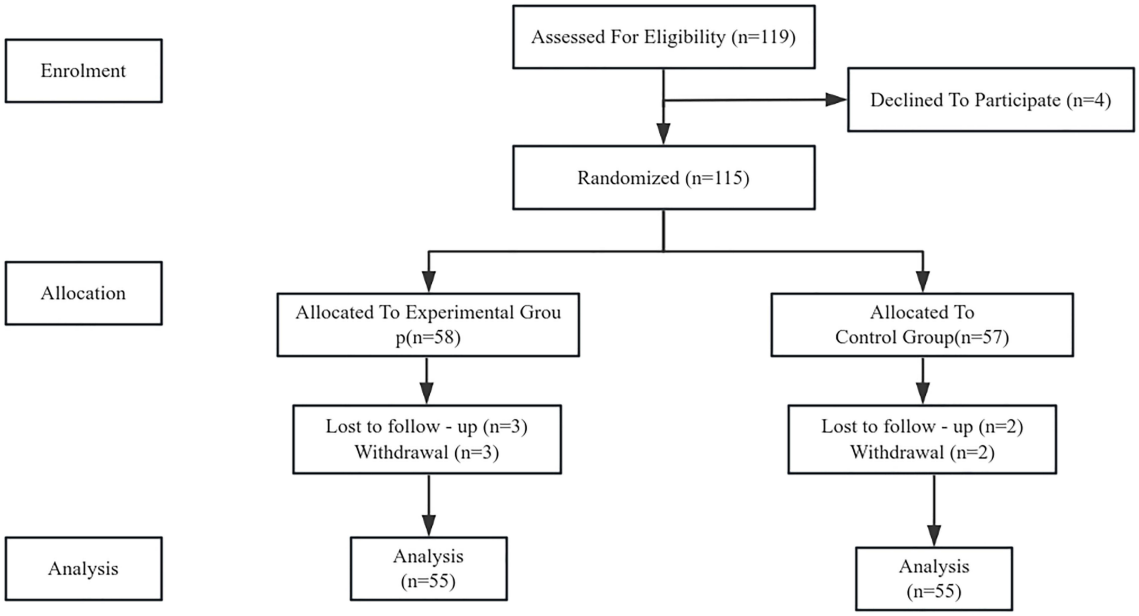

Figure 1 Flowchart illustrating the recruitment and allocation of participants in the study.

https://doi.org/10.2147/JIR.S528332

according to the corresponding number in the randomization table A total of 110 patients were included in the study, comprising 55 in the intervention group and 55 in the control group.

Blinding

Sihuang Zijin powder colloid is black, and the hydrocolloid is white. Due to this distinct appearance of the study materials, blinding of patients and the researcher administering the intervention was not feasible. However, to ensure impartial data analysis, the research data was coded in SPSS by an independent researcher, designating the intervention group as "A" and the control group as "B". The statistician analyzing the data was thus blinded to the group assignments. Upon completion of the study report, the codes were revealed by the researcher, with the letter "A" corresponding to the intervention group and "B" to the control group.

Ethical Considerations

This study was approved by the Institutional Review Board of the Zhejiang Cancer Hospital (Approval no. IRB-2023-1262) on December 26, 2023. Written informed consent and signature were obtained from each participant before the beginning of the study. All protected healthcare information was exclusively used for research purposes and safeguarded throughout the study.

Intervention Materials and Procedures

Preparation of the Drug

The key ingredients of the *Sihuang Zijin* powder colloid were as follows: *Astragali radix* (5 g), rhubarb (5 g), *Phellodendron chinensis* (5 g), *Coptis chinensis* (3 g), *Artemisia sinensis* (3 g), *Flos Lonicerae* (5 g), *Angelica dahurica* (5 g), *Atractylodes* (3 g), *Radix angelicae dahuricae* (5 g), *Paris polyphylla* (3 g), and licorice tablet (3 g). The preparation of Sihuang Zijin Powder Colloid is prepared by the Chinese Medicine Pharmacy of Zhejiang Cancer Hospital. The person in charge is a senior professional pharmacist. All raw materials comply with the standards of China Pharmacopoeia and are dry. These herbs were placed in a suitable container, and an appropriate quantity of water was added. The mixture was then heated until it boiled and maintained for 1 to 2 hours. After this, the solution was filtered, and the extract collected. The extract was then gradually incorporated into the hydrocolloid solution while stirring to ensure even distribution of the active components within the hydrocolloid. The quality of the prepared *Sihuang Zijin* powder colloid was evaluated for quality and approved for clinical use, with a shelf life of six months. The finished product of the four yellow purple gold hydrocolloid is 15cm long, 9cm wide and 0.5 mm thick (Figure 2).

Control Group

The hydrocolloid dressing was trimmed to fit the size and shape of the phlebitis area. It was placed on the affected area, extending 2 cm beyond the upper, lower, left, and right boundaries of the inflamed site. This dressing was replaced three times daily.

Experimental Group

The *Sihuang Zijin* powder colloid dressing was similarly tailored to the shape and size of the phlebitis area and placed on the affected area. It was applied to the affected region, covering 2 cm beyond the edges of the inflammation on all sides. The dressing was replaced three times daily. The *Sihuang Zijin* powder colloid dressing was replaced three times daily. A representative clinical presentation of phlebitis before and after treatment is illustrated in Figure 3, demonstrating the therapeutic effect of the intervention.

Outcome Indicators

Grading of Phlebitis

Phlebitis was graded as follows: Grade 0 indicated no symptoms. Grade I indicated localized pain, erythema, or edema without induration. Grade II indicated localized pain, erythema, or edema, with cord-like changes but no induration. Grade III indicated localized pain, erythema or edema, venous cord-like changes, and palpable induration. Grade IV indicated localized pain, erythema or edema, venous cord-like changes, palpable induration exceeding 2.5 cm, possibly with pus formation.

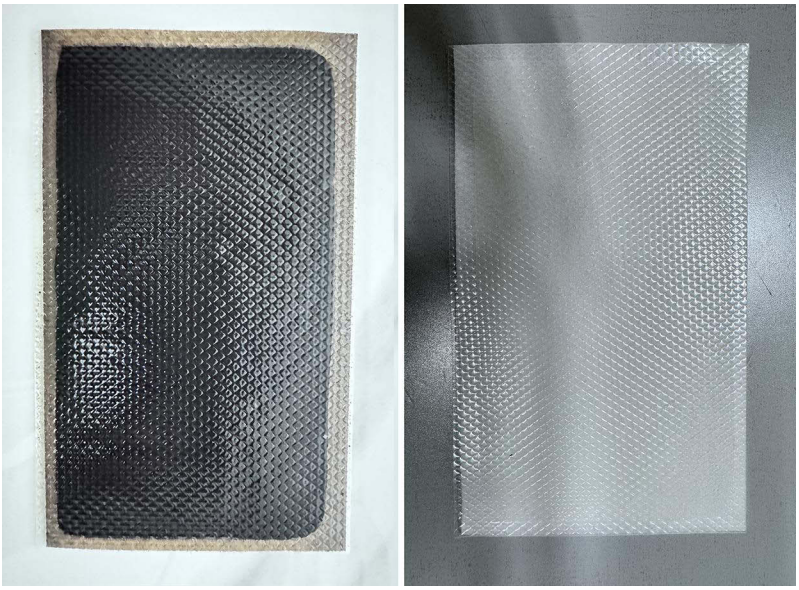

Figure 2 Comparison of the intervention material: *Sihuang Zijin* powder colloid (left) and hydrocolloid dressing (right).

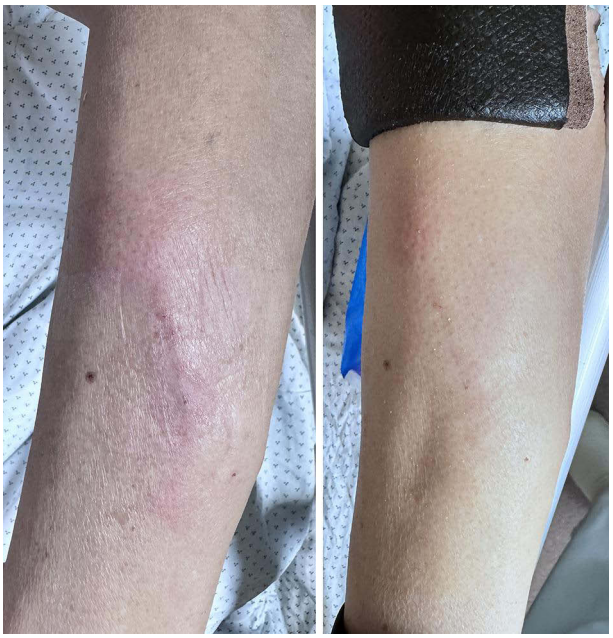

Figure 3 Clinical presentation of a limb with phlebitis before and after treatment with *Sihuang Zijin* Powder Colloid, before treatment (left), after treatment (right).

Evaluations of phlebitis grade were performed before treatment and 24 hours after treatment.

Pain Assessment

Pain severity was measured using a visual analog scale ranging from 0 to 10, where higher scores corresponded to greater pain intensity. A score of 0 represented the absence of pain, scores between 1 and 3 were categorized as mild pain, scores between 4 and 6 as moderate pain, and scores between 7 and 10 as severe pain.

Treatment Effectiveness

The effectiveness of the drug was measured by recording the time required for resolution of pain, redness, and swelling in both groups.

https://doi.org/10.2147/JIR.S528332

Patient Satisfaction

A specifically designed questionnaire was used to assess the satisfaction of patients with the phlebitis treatment. The scale had a total score of 100 points, and scores were categorized as follows: A score of ≥ 90 points was considered very satisfactory, a score of 80–90 points was considered satisfactory, and a score < 80 points was considered unsatisfactory. Total satisfaction = (very satisfactory cases + satisfactory cases) / total number of cases × 100%.

Data Collection

Before treatment, both groups reduced exercise, raised the affected limb, and disinfected the affected skin with iodophor, and dressings were retained for 8 hours per application. Therapeutic effects were assessed only once 24 hours post-treatment. All treatment and data collection were carried out in the wards of Zhejiang Cancer Hospital.

Data Analysis

SPSS for Windows (version 26; IBM) was used for data analysis. Descriptive statistics included the number, percentage, mean, standard deviation, minimum, and maximum values. The fitness of the data to normal distribution was evaluated using the Kolmogorov–Smirnov test. Parametric tests were used for normally distributed data. Independent samples *t*-test and the chi-squared test were used to compare group measurements. A *p*-value of < 0.05 was considered as indicating a statistically significant difference.

Results

Patients were enrolled in the study between August 20, 2024, and November 10, 2024. The flow diagram of participant allocation in the trial is presented in Figure 1. Of the 119 participants initially assessed for eligibility, 110 (92.4%) met the inclusion criteria and were randomized, with 55 participants allocated to the control group and 55 allocated to the experimental group. All patients completed the clinical trial.

Baseline Characteristics

Pre-intervention, the two groups were comparable in terms of baseline characteristics, with no statistically significant differences in the baseline demographic and clinical characteristics between the two groups of participants (Table 1). Overall, 53.6% of the participants had a history of smoking, 77.3% had a history of alcohol use, 79.1% had a single puncture, and 76.4% were diagnosed with grade III phlebitis prior to treatment.

Table 1 Baseline Demographic and Clinical Characteristics of Study Participants (n = 110)

Variables	Experimental Group (n = 55)	Control Group (n = 55)	χ^2/t	*P*
Gender, n (%)				
Male	31 (56.4)	32 (58.2)	0.037	0.847
Female	24 (43.6)	23 (41.8)		
Age, M ± SD	47.62 ± 5.33	49.35 ± 5.15	1.729	0.087
Height, M ± SD	167.04 ± 8.95	169.13 ± 8.87	1.231	0.221
Body weight, M ± SD	58.42 ± 5.72	60.80 ± 6.96	1.963	0.052
BMI, M ± SD	21.03 ± 2.30	21.27 ± 1.92	0.596	0.552

(*Continued*)

Table 1 (Continued).

Variables	Experimental Group (n = 55)	Control Group (n = 55)	χ^2/t	*P*
Smoking History, n (%)				
Yes	30 (54.6)	29 (52.7)	0.037	0.848
No	25 (45.4)	26 (47.3)		
Drinking history, n (%)				
Yes	46 (83.6)	39 (70.9)	2.536	0.111
No	9 (16.4)	16 (29.1)		
Number of punctures, n (%)				
Once	45 (81.8)	42 (76.4)	0.495	0.482
More than 1 time	10 (18.2)	13 (23.6)		
Nursing Unit, n (%)				
Head and neck neoplasm surgery	19 (34.6)	18 (32.7)	0.389	0.823
Thyroid neoplasm surgery	16 (29.1)	19 (34.6)		
Neurological neoplasm surgery	20 (36.3)	18 (32.7)		
Type of infusion, n (%)				
Lipophilic liquid	19 (34.6)	18 (32.7)	0.170	0.918
Highly concentrated electrolyte liquid	16 (29.1)	18 (32.7)		
High osmotic pressure liquid	20 (36.3)	19 (34.6)		
Puncture site, n (%)				
Back of the hand	25 (45.5)	22 (40.0)	0.334	0.563
Forearm	30 (54.5)	33 (60.0)		
Phlebitis Grading, n (%)				
Grade II	11 (20.0)	15 (27.3)	0.806	0.369
Grade III	44 (80.0)	40 (72.7)		
VAS, M ± SD	5.25 ± 1.10	5.22 ± 1.14	0.171	0.864

Note: Continuous variables were analyzed using the independent *t*-test, while categorical variables (n, %) were analyzed using the chi-squared test or Fisher's exact test.
Abbreviations: SD, standard deviation. BMI, body mass index. VAS, visual analogue scale.

Phlebitis Severity

Following 24 hours of treatment, the severity of phlebitis showed significant improvements in the experimental group: the prevalence of grade 0 phlebitis was 58.2%, grade I phlebitis was 38.2%, and grade II phlebitis was 3.6% in the experimental group. While in the control group, the prevalence of grade 0 phlebitis was 10.9%, grade I phlebitis was 67.3%, and grade II phlebitis was 30.9% (Table 2). These differences between the two groups were statistically significant ($p < 0.05$).

Table 2 Comparison of Phlebitis Grades Between the Interventional and Control Groups Following Treatment

	Experimental Group (n = 55)	Control Group (n = 55)	χ^2	*P*
Grade 0, n (%)	32 (58.2)	6 (10.9)	29.346	<0.001*
Grade I, n (%)	21 (38.2)	37 (67.3)		
Grade II, n (%)	2 (3.6)	12 (21.8)		

Note: *$P < 0.05$.

Table 3 Comparison of Pain Scores, Pain Relief Time, Time to Resolution of Redness and Swelling, and Satisfaction Levels Between the Interventional and Control Groups Following Treatment

	Experimental Group (n = 55)	Control Group (n = 55)	χ^2/t	*P*
VAS, M ± SD	0.53 ± 0.50	1.24 ± 0.69	6.138	<0.001*
Pain relief time (h, M ± SD)	18.31 ± 1.74	25.13 ± 1.68	20.908	<0.001*
Redness and swelling regression time (h, M ± SD)	14.05 ± 0.97	16.78 ± 1.05	14.157	<0.001*
Very satisfied, n (%)	41 (74.6)	29 (52.7)	9.815	0.007*
Basically satisfied, n (%)	14 (25.4)	19 (34.6)		
Not satisfied, n (%)	0 (0.00)	7 (12.7)		
Satisfaction rate, n (%)	55 (100.0)	42 (87.3)		

Note: Continuous variables were analyzed using the independent *t*-test, while categorical variables (n, %) were analyzed using the chi-squared test or Fisher's exact test. *$p < 0.05$.
Abbreviation: VAS, visual analogue scale.

Pain Scores and Recovery Outcomes

The pre- and post-treatment pain scores in the experimental and control groups were 0.53 ± 0.50 and 1.24 ± 0.69, respectively. The time to pain relief was 18.31 ± 1.74 in the experimental group compared to 25.13 ± 1.68 h in the control group. The time for resolution of redness and swelling in the experimental and control groups was 14.05 ± 0.97 and 16.78 ± 1.05 h, respectively. The differences between the two groups with respect to pain scores, time to pain relief, and time to resolution of redness and swelling were statistically significant ($p < 0.05$) (Table 3).

Patient Satisfaction

The patient satisfaction questionnaire recovery rate was 100%. Patient satisfaction rate regarding phlebitis treatment was 100.0% in the experimental group and 87.3% in the control group, and this difference was statistically significant ($p < 0.05$) (Table 3).

Discussion

Patients with tumors tend to have a higher incidence of IP due to several contributing factors, such as rapid infusion of intraoperative anesthetic induction drugs during surgery, quick fluid replacement, intraoperative blood transfusion, intraoperative hypothermia, as well as perioperative physical, chemical, and environmental stimuli.[10] Studies have reported an incidence of phlebitis ranging from 31% to 88% in patients with tumors.[7,19] Historically, corticosteroids or other anti-inflammatory and decongestant drugs have been used to treat IP. However, the clinical use of these drugs is limited by factors such as side effects, high costs, and complex administration procedures.[20]

From the TCM perspective, IP is similar to conditions such as "evil pulse", "red pulse", and "pulse arthralgia". This condition is believed to be located in the pulse, and is associated with the lung, liver, and spleen. It is posited in TCM theory that the lung governs the segment, the liver governs the catharsis, and the spleen governs the movement of the spleen. Therefore, in order to restore harmony within the meridians of the whole body, it is essential to focus on the lung, liver, and spleen. The pathogenesis of IP, as per TCM, involves the obstruction of blood, *qi*, blood toxins, heat, and stagnation in the pulse.

RJP is derived from Chen Shigong "Surgical Authenticity" from the Ming Dynasty and is included in the 2015 edition of "Chinese Pharmacopoeia". The ten different types of herbs that make up RJP are *Radix angelicae dahuricae, Rhubarb, Cortex magnoliae officinalis, Phellodendron chinensis, Pericarpium citri reticulatae, Rhizoma curcumae longae, Rhizoma atractylodis, Rhizoma arisaematis, Radix trichosanthis kirlowii, and Radix glycyrrhizae*. This formula has the efficacy of clearing heat and detoxification, removing blood stasis and relieving pain. It can inhibit bacterial infection, increase lysosomal content, enhance immune defenses, and inhibit inflammation.[21] In the clinic, RJP has been widely applied in treating different diseases. RJP has been used to treat serious inflammatory diseases, including sores, ulcers, psoriasis, acute mastitis and phlebitis.

The study results indicate that *Sihuang Zijin* powder colloid was more effective than hydrocolloid alone in treating IP. The *Sihuang Zijin* powder colloid was more efficacious in terms of reducing pain, redness, and swelling. This is because it aligns with the TCM treatment principles of treating phlebitis, and specifically, the formulation works to promote blood circulation, remove blood stasis, and reduce swelling.

The key ingredients of the *Sihuang Zijin* powder colloid were selected based on TCM's approach to addressing blood circulation and meridian health. *Astragali radix* targets the lung and spleen meridians, helping to alleviate joint pain, eliminate toxins and pus, and promote the flow of *qi* in these two meridians.[14] Rhubarb has the effect of purging heat toxins, as well as breaking stagnation and blood stasis in the liver and spleen meridians. It works synergistically with rhubarb to not only clear heat and detoxify the pulse poisoning heat stasis but also replenish *qi*, restore *yang*, and support the removal of pulse poisoning heat.[22] *Phellodendron chinensis, Coptis chinensis*, and honeysuckle are used to clear heat, dryness, and dampness, and purge fire and detoxify. These herbs contribute to reducing inflammation and managing excess moisture, which is central to the development of phlebitis. The combination of *Arnebia, Baiji, Angelica dahurica*, and *Zhonglou* helps to reduce swelling, relieve pain, cool the blood, and stop bleeding. *Atractylodes* is used to dry dampness and invigorate the spleen, thus further supporting the body's ability to expel excess fluids and facilitate healing, while licorice is added to harmonize the actions of the various herbs.[23] The formulation thus not only clears heat and removes blood stasis but also exposes evil *qi*, dry phlegm, and promotes blood circulation. It can effectively relieve pain and inhibit bacterial inflammation.

The Sihuang Zijin powder colloid is a specialized hydrophilic and hydrophobic polymer composed of hydrocolloid particles and an elastic polymer, prepared through a hydrocolloid preparation process. The material is thin, elastic, and can adapt to the movement of the skin. This formulation is designed to be thin, elastic, and adaptable to skin movements, offering enhanced comfort and flexibility. It features double stickiness, which helps it adhere firmly to the skin while allowing for a transparent polyurethane outer surface that is 25 μm thick. This outer layer is a semi-permeable membrane, providing a controlled environment that promotes healing and has several functions: it maintains low oxygen tension locally, which is essential for stimulating rapid capillary formation and improving local tissue microcirculation. This enhanced circulation aids in restoring the tissue to a normal physiological state, accelerating the absorption of exudate and facilitating the metabolism and absorption of toxins. As a result, the colloid significantly alleviates pain, reduces congestion, and promotes the reduction of local inflammation.[24]

In summary, *Sihuang Zijin* powder colloid was found to be effective in treating IP in patients with tumors. Treatment with the colloid was found to significantly reduce the severity of phlebitis, alleviate pain, and promote local absorption. Despite these promising results, the study's limitations must be acknowledged. This research was conducted in only two departments within a tumor hospital and involved a relatively small sample size. Additionally, no follow-up observations were carried out. Future studies should aim to address these limitations by enhancing the sample size, involving diverse clinical settings, and incorporating follow-up assessments. This would provide more robust and comprehensive evidence for the clinical application of *Sihuang Zijin* powder colloid in treating phlebitis.

Conclusion

The results of this single-blind, randomized controlled study provide evidence that *Sihuang Zijin* powder colloid is an effective treatment for infusion phlebitis in patients with tumors. It was found to effectively reduce pain, shorten the time to pain relief and the time to resolution of redness and swelling, while increasing patient satisfaction with treatment. These findings underscore the potential of the *Sihuang Zijin* powder colloid as an effective option for managing infusion phlebitis. This study also demonstrates the efficacy of traditional Chinese medicine treating inflammatory conditions, offering a valuable reference for integrating such treatments into modern clinical practice.

Abbreviations

IP, Infusion phlebitis; TCM, Traditional Chinese medicine.

Data Sharing Statement

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

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki (as was revised in 2013). The study was approved by Ethics Committee of the Zhejiang Cancer Hospital (Approval no. IRB-2023-1262). Written informed consent was obtained from all participants.

Clinical Trial Registration

https://www.chictr.org.cn/index.html, 2024-08-20, ChiCTR2400088521.

Acknowledgments

We are particularly grateful to all the people who have given us help on our article.

Funding

Health Commission of Zhejiang Province (2024ZL313).

Disclosure

The authors declare no conflict of interest.

References

1. Bray F, Laversanne M, Sung H, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin*. 2024;74:229–263. doi:10.3322/caac.21834
2. Chen Z, Hong B, He -J-J, Ye -Q-Q, Hu Q-Y. Examining the impact of early enteral nutritional support on postoperative recovery in patients undergoing surgical treatment for gastrointestinal neoplasms. *World J Gastrointest Surg*. 2023;15:2222–2233. doi:10.4240/wjgs.v15.i10.2222
3. Ashina S, Masuda A, Yamakawa K, et al. A comprehensive analysis of tumor-stromal collagen in relation to pathological, molecular, and immune characteristics and patient survival in pancreatic ductal adenocarcinoma. *J Gastroenterol*. 2023;58:1055–1067. doi:10.1007/s00535-023-02020-8
4. Bossi P, Delrio P, Mascheroni A, Zanetti M. The spectrum of malnutrition/cachexia/sarcopenia in oncology according to different cancer types and settings: a narrative review. *Nutrients*. 2021;13:1980. doi:10.3390/nu13061980
5. Sudhakar S, Jacob A, Hegde NN, Chaudhary RK, Mateti UV, Shetty V. Evaluation of chemotherapy infusion and phlebitis among cancer patients: a prospective observational single-center study. *J Oncol Pharm Pract*. 2023;29:1944–1950. doi:10.1177/10781552231161517
6. Guo J-L, Yan X-Y, Zhao Q-L, et al. Time to occurrence of phlebitis after continuous infusion of total nutrient admixture through peripheral veins: an experimental animal study. *J Inflamm Res*. 2022;15:205–215. doi:10.2147/JIR.S346186
7. Lv L, Zhang J. The incidence and risk of infusion phlebitis with peripheral intravenous catheters: a meta-analysis. *J Vasc Access*. 2020;21:342–349. doi:10.1177/1129729819877323
8. Manrique-Rodríguez S, Heras-Hidalgo I, Pernia-López MS, et al. Standardization and chemical characterization of intravenous therapy in adult patients: a step further in medication safety. *Drugs R D*. 2021;21:39–64. doi:10.1007/s40268-020-00329-w
9. Ní Chróinín D, Ray-Barruel G, Carr PJ, et al. The burden of peripheral intravenous catheters in older hospital inpatients: a national cross-sectional study part of the ONE MILLION GLOBAL PERIPHERAL INTRAVENOUS CATHETERS COLLABORATION. *Australas J Ageing*. 2023:42. doi:10.1111/ajag.13068
10. Zhu -L-L, Wang Y-H, Zhou Q. Progress in research on the mechanisms and interventions of phlebitis from the perspective of vascular endothelial cell and signaling pathway. *J Inflamm Res*. 2023;16:6469–6481. doi:10.2147/JIR.S450149

11. Yang J, Xu H. External application of herbal medicine to acupoints. *J Tradit Chin Med*. 2008;28:21–23. doi:10.1016/s0254-6272(08)60008-4
12. Wu M, Huang J, Shi J, Shi L, Zeng Q, Wang H. Ruyi Jinhuang powder accelerated diabetic ulcer wound healing by regulating Wnt/β-catenin signaling pathway of fibroblasts in vivo and in vitro. *J Ethnopharmacol*. 2022;293:115321. doi:10.1016/j.jep.2022.115321
13. Li X-Y, Zhang X-T, Jiao Y-C, et al. In vivo evaluation and mechanism prediction of anti-diabetic foot ulcer based on component analysis of Ruyi Jinhuang powder. *World J Diabetes*. 2022;13:622–642. doi:10.4239/wjd.v13.i8.622
14. Liu Y-X, Song X-M, Dan L-W, et al. Astragali Radix: comprehensive review of its botany, phytochemistry, pharmacology and clinical application. *Arch Pharm Res*. 2024;47:165–218. doi:10.1007/s12272-024-01489-y
15. Kumar A, Shashni S, Kumar P, Pant D, Singh A, Verma RK. Phytochemical constituents, distributions and traditional usages of Arnebia euchroma: a review. *J Ethnopharmacol*. 2021;271:113896. doi:10.1016/j.jep.2021.113896
16. Lamkhao S, Tandorn S, Thavornyutikarn P, et al. Synergistic amalgamation of shellac with self-antibacterial hydroxyapatite and carboxymethyl cellulose: an interactive wound dressing for ensuring safety and efficacy in preliminary in vivo studies. *Int J Biol Macromol*. 2023;253:126809. doi:10.1016/j.ijbiomac.2023.126809
17. Song H, Chen F, Cao Y, et al. Innovative applications of pectin in lipid management: mechanisms, modifications, synergies, nanocarrier systems, and safety considerations. *J Agric Food Chem*. 2024;72:20261–20272. doi:10.1021/acs.jafc.4c06586
18. Chamorro AM, Vidal Thomas MC, Mieras AS, Leiva A, Martínez MP, Hernández Yeste MMS. Multicenter randomized controlled trial comparing the effectiveness and safety of hydrocellular and hydrocolloid dressings for treatment of category II pressure ulcers in patients at primary and long-term care institutions. *Int J Nurs Stud*. 2019;94:179–185. doi:10.1016/j.ijnurstu.2019.03.021
19. Liu C, Chen L, Kong D, Lyu F, Luan L, Yang L. Incidence, risk factors and medical cost of peripheral intravenous catheter-related complications in hospitalised adult patients. *J Vasc Access*. 2022;23:57–66. doi:10.1177/1129729820978124
20. Kohno E, Murase S, Matsuyama K, Okamura N. Effect of corticosteroids on phlebitis induced by intravenous infusion of antineoplastic agents in rabbits. *Int J Med Sci*. 2009;6:218–223. doi:10.7150/ijms.6.218
21. Zhang X, Yu X, Yu Z, et al. Network pharmacology and bioinformatics to identify molecular mechanisms and therapeutic targets of Ruyi Jinhuang powder in the treatment of monkeypox. *Medicine*. 2023;102:e33576. doi:10.1097/MD.0000000000033576
22. Stompor-Gorący M. The health benefits of emodin, a natural anthraquinone derived from Rhubarb-a summary update. *Int J Mol Sci*. 2021;22:9522. doi:10.3390/ijms22179522
23. Wan Y. Observation for clinical effect of phellodendron wet compress in treating the phlebitis caused by infusion. *Pak J Pharm Sci*. 2018;31:1099–1102.
24. Modi D, Jonnalagadda S, Campbell GA, Dalwadi G. Enhancing oil solubility of BCS class II drug phenytoin through hydrophobic ion pairing to enable high drug load in injectable nanoemulsion to prevent precipitation at physiological pH with a potential to prevent phlebitis. *J Pharm Sci*. 2023;112:2427–2443. doi:10.1016/j.xphs.2023.03.012