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Review

Research Progress on the Basis and Clinical Applications of Peiyuan Anti-Cancer Decoction in the Treatment of Oncological Diseases

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Abstract: Malignant tumors represent a major global public health challenge, characterized by persistently high incidence and mortality rates that demand innovative therapeutic strategies. Peiyuan Anti-Cancer Decoction, a representative traditional Chinese medicine (TCM) formula in integrative oncology, has attracted considerable attention in both basic experimental research and clinical practice in recent years. Grounded in the TCM principle of strengthening the body's vital qi while eliminating pathogenic factors, this formula exerts anti-tumor effects through multi-target, multi-pathway synergistic mechanisms. These include modulation of immune function, regulation of tumor cell signaling pathways, enhancement of radiotherapy and chemotherapy efficacy with concurrent toxicity reduction, and improvement of patients' clinical symptoms and overall quality of life. Accumulating clinical evidence indicates that Peiyuan Anti-Cancer Decoction can augment the therapeutic effectiveness of conventional radiotherapy and chemotherapy, alleviate treatment-related adverse effects, and, to a certain extent, prolong survival in the comprehensive management of malignant tumors such as lung cancer and primary liver cancer. Its core therapeutic value lies in integrating the strengths of both medical systems by combining the Western medicine paradigm of direct tumor targeting with the TCM strategy of regulating the internal physiological environment, thereby establishing an integrated treatment model that harmonizes offensive and defensive therapeutic approaches. This paradigm aligns with the contemporary shift in oncology from single-target confrontation toward holistic balance. This article systematically reviews the mechanisms of action, clinical efficacy, and current research status of Peiyuan Anti-Cancer Decoction, and discusses future development directions, aiming to provide a valuable reference for optimizing integrative oncology treatment strategies.

Keywords: peiyuan anti-cancer decoction; integrative oncology; tumor microenvironment; chemotherapy; traditional chinese medicine

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1. Introduction

Currently, tumor therapy faces multiple challenges, including reduced efficacy of chemotherapy, immunosuppressive microenvironments, and treatment-related toxicities. Conventional Western medical approaches have limitations in improving patients' quality of life and long-term outcomes. Integrative medicine, guided by the core principle of "combining targeted tumor control with systemic support," overcomes the limitations of single-modality therapies through coordinated, multi-target strategies. Evidence indicates that Peiyuan Anti-Cancer Decoction can synergize with chemotherapy to significantly enhance objective response rates in advanced liver cancer. It inhibits tumor metastasis by modulating signaling pathways such as PI3K-AKT-mTOR and circ_SLIT3/NF-κB, reduces the incidence of radiation-induced lung injury, and markedly improves immune function and traditional Chinese medicine syndrome scores. This

formula integrates the precision of Western medicine in targeting tumors with the holistic balancing effects of traditional Chinese medicine, offering an innovative strategy to address the complexity of the tumor microenvironment and support long-term disease management. It highlights the translational value of integrative medicine in oncology.

2. Formula Composition and Traditional Chinese Medicine Theoretical Basis of Pei Yuan Anti-Cancer Decoction

Pei Yuan Anti-Cancer Decoction was formulated by Professor Li Renting, a renowned TCM expert from Shaanxi Province and a celebrated oncologist in the Sanqin region. Based on the therapeutic principles of strengthening the spleen, regulating qi, softening hard masses, and dispersing nodules, this formula consists of ingredients such as American ginseng, astragalus, atractylodes, poria, processed pinellia, coix seed, cardamom, white flower snake tongue grass, curcuma, roasted hawthorn, roasted medicated yeast, roasted malt, and tangerine peel, with clinical modifications made according to individual conditions. The formula emphasizes nourishing the foundational physiological integrity and supporting vital energy, prioritizing tonifying qi and reinforcing the body's defensive capacity while using pathogen-clearing and nodule-resolving actions as supplementary measures, reflecting the principle of "clearing pathogenic influences while preserving healthy qi, nurturing the root to support anti-cancer function." Astragalus tonifies the middle jiao, replenishes qi, strengthens physiological resilience, and supports tissue repair; it also promotes wound healing. American ginseng supplements qi and nourishes yin, clears deficient heat, and generates body fluids. As recorded in "Materia Medica Renewed", it can "nourish lung yin and quench thirst." White flower snake tongue grass clears heat, detoxifies, promotes diuresis, and alleviates urinary discomfort. When combined with American ginseng, one herb exerts a clearing action while the other provides supportive nourishment, synergistically enhancing the effects of tonifying qi, nourishing yin, activating blood, and resolving stasis. The combination of curcuma and turmeric creates a balance between warming and cooling properties, enhancing the ability to activate blood circulation, resolve stasis, and disperse nodules. Processed pinellia dries dampness, resolves phlegm, eliminates distension, disperses nodules, and stops vomiting—effectively removing damp-phlegm influences while augmenting curcuma's action against nodules. The spleen is the foundation of postnatal life and the source of qi and blood production. A robust spleen ensures adequate generation of qi and blood [1, 2]. Roasted atractylodes tonifies qi, strengthens the spleen, dries dampness, and promotes urination; poria promotes diuresis, reduces swelling, strengthens the spleen, and removes dampness. Together, they work synergistically to enhance spleen function and promote transformation and transportation, embodying the concept of "strengthening earth to generate metal." Coix seed promotes diuresis, removes dampness, strengthens the spleen, stops diarrhea, and detoxifies and disperses nodules. Cardamom transforms dampness, opens the stomach, regulates qi, and soothes the middle jiao. Combined, these two herbs—one sweet, one pungent—work together to strengthen the spleen, transform dampness, regulate qi, and harmonize the middle jiao. Supporting this are the "three roasted herbs" (roasted hawthorn, roasted medicated yeast, and roasted malt), which aid digestion, harmonize the spleen and stomach, eliminate stagnation, and protect the digestive functions of the middle jiao.

Pei Yuan Anti-Cancer Decoction is grounded in the traditional Chinese medicine principle that "when internal vital energy (zheng qi) is abundant, pathogenic influences cannot take hold," and centers on the therapeutic strategy of "supporting physiological integrity while clearing pathogenic influences." It exerts anti-tumor effects by regulating the balance of qi, blood, yin, and yang, and by improving the tumor microenvironment [3]. Ingredients such as American ginseng and astragalus, which tonify qi and nourish blood, enhance the body's "zheng qi"—that is, its capacity for physiological self-regulation, adaptation, and defense. Meanwhile, herbs like curcuma, which activate blood circulation and resolve stasis, and white flower snake tongue grass, which clears heat and detoxifies,

are combined to mitigate the influence of pathogenic toxins. Modern pharmacological studies have shown that compounds in white flower snake tongue grass, astragalus, curcuma, and other ingredients contain various anti-tumor active components—including polysaccharides, flavonoids, anthraquinones, and terpenoids—that exert anti-cancer effects through multiple mechanisms: inhibiting tumor cell proliferation and division, inducing apoptosis in cancer cells, suppressing tumor invasion and metastasis, improving the tumor microenvironment, enhancing host immune responses, reducing inflammation and oxidative stress, and increasing tumor cells' responsiveness to chemotherapy agents.

3. Advances in the Basic Research of Pei Yuan Anti-Cancer Decoction for Tumor Suppression

3.1. Induction of Tumor Cell Apoptosis and Autophagy

Autophagy is an evolutionarily conserved intracellular process of degradation and recycling in eukaryotic organisms. During this process, damaged proteins or organelles are engulfed by double-membrane structures called autophagosomes and then delivered to lysosomes (in animal cells) or vacuoles (in yeast and plant cells) for degradation and reuse. Autophagy plays a crucial role both in tumor cells and surrounding stromal cells, influencing tumor progression and response to therapy. The biological effects of autophagy depend on multiple factors, including tumor stage, specific oncogenic mutations, and cellular microenvironment. Given their critical roles in tumor biology, both autophagy and apoptosis have become important therapeutic targets in cancer treatment.

A hepatocellular carcinoma xenograft mouse model was established to investigate the mechanism by which Peiyuan Anti-Cancer Decoction inhibits liver cancer growth through modulation of autophagy via the circ_SLIT3/NF-κB axis. The experimental results showed that this traditional Chinese medicine formula significantly reduced tumor growth, and its mechanism involved activation of autophagy (elevated LC3 II/I ratio), promotion of apoptosis (upregulated Bax and Caspase-3 expression, downregulated Bcl-2 expression), and modulation of the circ_SLIT3/NF-κB signaling pathway [4].

Using the C57BL/6 mouse Lewis lung cancer xenograft model, researchers investigated the effects of Peiyuan Anti-Cancer Decoction on autophagy and tumor growth and metastasis in lung cancer. Based on traditional Chinese medicine theory and clinical experience, this study explored the therapeutic mechanisms of the formula for treating lung cancer. Results showed that Peiyuan Anti-Cancer Decoction improved the quality of life in mice and inhibited tumor metastasis, potentially through inhibition of the PI3K-AKT-mTOR signaling pathway and enhancement of autophagy levels in tumor cells [4, 5]. These findings highlight the unique advantages of traditional Chinese medicine in improving survival quality and mitigating metastasis in lung cancer.

3.2. Immunomodulatory Effects

The immune system functions as the body's intrinsic defense mechanism against tumorigenesis. Modulating immune responses to activate or augment endogenous immune activity enables effective recognition and elimination of tumor cells [6, 7]. The immunomodulatory effects of Peiyuan Anti-Cancer Decoction are primarily observed in two domains: enhancement of immune effector cell function and attenuation of the immunosuppressive tumor microenvironment.

3.2.1. Enhancing the Function of Immune Effector Cells

An H22 hepatocellular carcinoma mouse xenograft model was established and mice were assigned to blank control, tumor-bearing control, tegafur, Peiyuan Anti-Cancer Decoction, and combination therapy groups. After 14 days of oral administration, the Peiyuan Anti-Cancer Decoction and combination therapy groups exhibited significantly reduced tumor weights (tumor inhibition rates of 28.67%–33.27%), higher thymus and

spleen indices compared to the tegafur group, and decreased telomerase TERT protein expression (positive rates of 48.93%–46.64%, versus 57.29% in the tumor-bearing control group). Additionally, these treatments contributed to improved quality of life in the animal model. This study provides initial evidence that the herbal formula may inhibit tumor growth through modulation of telomerase activity while supporting immune organ function [8].

In a mouse model of colorectal cancer liver metastasis established by splenic injection of CT26 cells, Peiyuan Anti-Cancer Decoction significantly inhibited tumor growth (tumor inhibition rate 36%–40%), delayed tumor onset, and increased serum IL-12 levels, suggesting potential anti-tumor effects mediated via activation of innate immune responses, including NK cells and Th1 cells [2].

Multiple studies consistently report that this treatment increases peripheral blood CD3+ and CD4+ lymphocyte counts and the CD4+/CD8+ ratio, enhances NK cell numbers, mitigates chemotherapy-associated declines in immune function, and supports restoration of antitumor immune surveillance. These findings align the traditional Chinese medicine principle of 'supporting the body's vital energy' with contemporary immunological mechanisms, offering preliminary evidence for multi-target synergistic actions of compound herbal formulations.

3.2.2. Reversing the Immunosuppressive Microenvironment

A Lewis lung cancer mouse model was established to investigate the effects of Peiyuan Anti-Cancer Decoction. The decoction alone achieved a tumor inhibition rate of 23.72%, which increased to 71.15% when administered alongside cisplatin. Mechanistically, the combination treatment significantly reduced the proportion of myeloid-derived suppressor cells (MDSCs) in the spleen—from 28.5% in the model group to 15.97% in the combination group—increased the proportion of CD8+ T cells—from 5.43% to 14.55%—and downregulated expression of pro-tumor factors including VEGF, TGF-β1, and GM-CSF. These findings indicate that the compound formula contributes to anti-cancer activity by modulating immune cell composition and function, and demonstrate enhanced efficacy when used in conjunction with cisplatin.

3.3. Modulating the Tumor Microenvironment and Anti-Metastasis

The tumor microenvironment (TME) is a dynamic ecosystem comprising vasculature, immune cells, stromal cells, signaling molecules, and extracellular matrix, engaged in reciprocal interactions with tumor cells. Tumor cells actively remodel this environment to support proliferation—through secretion of factors that promote angiogenesis, restructure stromal components, and foster immunosuppression. Concurrently, immune effector cells and inflammatory mediators within the TME exert selective pressure, influencing tumor progression and adaptation. Targeting these interactions has therefore emerged as a central approach in anti-tumor therapy.

3.3.1. Inhibition of Tumor-Associated Fibroblast Activation

Cancer-associated fibroblasts (CAFs) are key components of the tumor microenvironment, contributing to tumor progression, angiogenesis, metastasis, and immune modulation through interactions with cytokines, growth factors, chemokines, and other effector molecules. Activation of CAFs within the tumor microenvironment represents a pivotal event in tumorigenesis and disease advancement, rendering CAF-targeted intervention a promising therapeutic approach.

In the H22 mouse hepatocellular carcinoma model, experimental studies demonstrated that Peiyuan Anti-Cancer Decoction indirectly modulates CAF activity by downregulating α-SMA and Vimentin expression, thereby attenuating tumor progression. α-SMA (alpha-smooth muscle actin) and Vimentin are proteins associated with the tumor microenvironment: elevated α-SMA expression in CAFs serves as a hallmark of their activated state, while Vimentin participates in cytoskeletal remodeling and pro-tumorigenic signaling. Additionally, the decoction suppresses secretion of CXCL1,

CXCL2, and CXCL8 by CAFs, elucidating a chemokine-mediated mechanism through which traditional Chinese medicine formulas influence the tumor microenvironment.

3.3.2. Regulation of Matrix Metalloproteinases and Invasion Metastasis

Matrix metalloproteinases (MMPs) are a family of zinc-dependent endopeptidases that play a central role in the degradation and remodeling of the extracellular matrix and are closely associated with tumor invasion and metastasis. Immunohistochemical analysis confirmed that Peiyuan Anti-Cancer Decoction exerts a synergistic inhibitory effect on MMP2 and MMP9 expression in the microenvironment of liver cancer lung metastasis. This indicates that the formula may suppress tumor invasiveness and metastatic potential through modulation of matrix metalloproteinase expression.

4. Clinical Application and Safety of Pei Yuan Anti-Cancer Decoction

According to the latest statistics from China's National Cancer Center, the incidence and mortality of malignant tumors in China continue to rise steadily. The 2024 National Cancer Report, based on 2022 data, identifies lung cancer, colorectal cancer, thyroid cancer, liver cancer, and stomach cancer as the five most common malignancies. Owing to its well-characterized anti-tumor mechanisms, Peiyuan Anti-Cancer Decoction has been widely integrated into clinical comprehensive cancer treatment regimens [9].

4.1. Lung Cancer

Pei Yuan Anti-Cancer Decoction is an empirical formula developed based on the traditional Chinese medicine theory of "lung obstruction," targeting the pathological characteristics of lung cancer—namely, deficiency of vital energy as the root cause and blood stasis with phlegm accumulation as the secondary manifestation [10, 11]. In this formula, Astragalus (Huang Qi) and Honeysuckle Herb (Bai Hua She Teng Cao) serve as the principal herbs; American ginseng (Xiyangshen), Atractylodes (Bai Zhu), Poria (Fu Ling), and Curcuma (Yu Jin) act as the secondary herbs; Curcuma Rhizome (E Zhu), Panax Notoginseng (San Qi), Pinellia (Ban Xia), Tangerine Peel (Chen Pi), and Magnolia Bark (Hou Po) are the assistant herbs; and Honey-fried Licorice (Zhi Gan Cao) functions as the messenger herb. Together, these ingredients work synergistically to strengthen the body's defenses, resolve phlegm, eliminate blood stasis, and disperse nodules and tumors.

Recent clinical studies have confirmed that Peiyuan Anti-Cancer Decoction, when combined with chemotherapy or chemoradiotherapy, provides significant comprehensive benefits in treating lung cancer, particularly in non-small cell lung cancer. In terms of objective therapeutic efficacy, the decoction demonstrates clear synergistic effects when used alongside various treatment protocols: when combined with platinum-based chemotherapy, it increases the objective response rate and improves one-year survival; when combined with NP protocol chemotherapy, the objective response rate ranges between 52.50% and 68.18%; when combined with TP protocol (paclitaxel plus cisplatin), the overall effective rate increases significantly; when combined with docetaxel plus cisplatin, the overall effective rate rises markedly; when combined with chemoradiotherapy, the clinical response rate shows a substantial increase; and when used with concurrent chemoradiotherapy for locally advanced lung cancer, the disease control rate reaches a high level. Regarding improvement of traditional Chinese medicine (TCM) syndromes, Peiyuan Anti-Cancer Decoction significantly reduces scores for TCM symptoms such as cough, sputum production, shortness of breath, hemoptysis, chest and flank distension, fatigue, poor appetite, and pallor, achieving a high overall effective rate for syndrome improvement. It is especially effective in alleviating spleen deficiency manifestations like lower back and knee weakness, poor appetite, general fatigue, loose stools, and edema, highlighting the distinctive advantages of holistic regulation in TCM. Furthermore, the formula shows clear efficacy against cancer-related fatigue—a common symptom among lung cancer patients—improving KPS scores substantially, significantly exceeding improvements observed with supportive therapy alone, while maintaining good safety. Regarding tumor markers, combined treatment with Peiyuan Anti-Cancer Decoction significantly reduces serum levels of multiple tumor markers including CEA,

CYFRA21-1, NSE, SCC-Ag, CA153, and CA125, reflecting reduced tumor burden and suppressed proliferation at the molecular level. In terms of toxicity reduction, the decoction significantly lowers the incidence of adverse effects caused by chemotherapy or chemoradiotherapy, such as myelosuppression, gastrointestinal reactions, liver and kidney function impairment, cytopenia, radiation pneumonitis, and radiation esophagitis, reducing the overall incidence of adverse events by approximately 17–25 percentage points and thereby improving patient tolerance to treatment. Additional benefits include ameliorating the hypercoagulable state in advanced lung cancer patients by lowering fibrinogen (FIB), D-dimer, and platelet levels, prolonging prothrombin time (PT) and activated partial thromboplastin time (APTT), with a high overall effective rate; regulating inflammatory cytokine balance by decreasing pro-inflammatory IL-6 and increasing anti-inflammatory IL-2 and IFN-γ; and significantly improving KPS scores and overall quality-of-life assessments. Improvements in immune function are positively correlated with objective therapeutic outcomes and symptom relief.

In summary, Peiyuan Anti-Cancer Decoction exerts a comprehensive effect in lung cancer treatment by enhancing therapeutic efficacy, reducing toxicity, modulating immunity, alleviating symptoms, and improving quality of life. It demonstrates clear clinical benefits when combined with various chemotherapy and chemoradiotherapy protocols, making it an effective herbal formula for integrative Chinese medicine and chemotherapy in treating lung cancer [12, 13].

4.2. Liver Cancer and Gastrointestinal Tumors

Peyuan Anti-Cancer Decoction, formulated based on the traditional Chinese medicine theory of 'strengthening the body's vital energy and eliminating pathogenic factors,' has demonstrated broad clinical value in the comprehensive treatment of gastrointestinal tumors. In terms of objective therapeutic efficacy, combining Peyuan Anti-Cancer Decoction with chemotherapy significantly improves response rates across various gastrointestinal cancers: the overall effective rate after surgery for colorectal cancer reaches 91.11%, the benefit rate for advanced colon cancer is 74.47%, the objective response rate for intermediate to advanced hepatocellular carcinoma ranges from 42.11% to 61.11%, and that for intermediate to advanced esophageal cancer reaches 71.15%, with a disease stabilization rate of 84.62%. When combined with immunotherapy plus chemotherapy, the effectiveness rate for esophageal squamous cell carcinoma can reach 100%, clearly demonstrating its synergistic enhancing effects on radiotherapy, chemotherapy, and immunotherapy. Regarding tumor markers, multiple studies consistently confirm that Peyuan Anti-Cancer Decoction significantly reduces levels of various tumor markers including CEA, CA19-9, CA72-4, AFP, SCC, and CYFRA21-1. It also downregulates molecular markers associated with tumor invasion and metastasis, such as VEGF, MMP-9, TGF-β1, VIM, GP73, CXCL1, and HMGB1, suggesting its potential role in inhibiting tumor angiogenesis, invasion, and metastasis. In improving traditional Chinese medicine syndrome patterns, the decoction effectively alleviates symptoms related to gastrointestinal tumors across different systems, including fatigue, loss of appetite, lower back and knee weakness, and diarrhea in gastrointestinal cancers; liver area pain and swelling, fatigue, shortness of breath, jaundice, and emaciation in liver cancer; and dry mouth, throat dryness, dysphagia, swelling, pain, and fatigue in esophageal cancer—highlighting the distinctive advantages of TCM's syndrome differentiation and holistic modulation. Moreover, Peyuan Anti-Cancer Decoction significantly improves cancer-related fatigue, with enhanced effects when combined with acupuncture therapy [14]. Regarding toxicity reduction, it markedly decreases the incidence of chemotherapy-related adverse reactions, including myelosuppression, gastrointestinal discomfort, hepatic and renal function impairment, and peripheral neurotoxicity—particularly showing outstanding efficacy in mitigating oxaliplatin-induced peripheral neuropathy. It also helps protect intestinal mucosal barrier function in colorectal cancer patients, thereby significantly improving their tolerance to chemotherapy. Notably, Peyuan Anti-Cancer Decoction is compatible not only with

various chemotherapy protocols—including FOLFOX4, FOLFIRI, DP, and TP—but also synergizes effectively with other treatments like radiofrequency ablation, acupuncture, and immunotherapy, demonstrating excellent compatibility and promising clinical prospects.

In summary, Peyuan Anti-Cancer Decoction exerts a comprehensive effect in the treatment of various gastrointestinal tumors—including colorectal cancer, gastric cancer, liver cancer, and esophageal cancer—by enhancing therapeutic efficacy, reducing toxicity, modulating immune function, alleviating symptoms, and improving quality of life. It is particularly suitable for middle- to late-stage patients with deficiency of vital energy, spleen-kidney insufficiency, or qi deficiency with blood stasis, and serves as an effective formula for integrative Chinese and Western medicine in treating gastrointestinal cancers.

4.3. Breast Cancer

Peyuan Anti-Cancer Decoction has demonstrated significant clinical value in the comprehensive management of mammary gland malignancy. Regarding objective therapeutic outcomes, clinical studies confirmed that combining Peyuan Anti-Cancer Decoction with trastuzumab-based targeted intervention or with cytotoxic therapy plus targeted intervention significantly improves response metrics: when combined solely with trastuzumab, the disease stabilization rate increased from 33.33% to 57.50%; when combined with cytotoxic therapy plus trastuzumab, the response rate rose from 43.33% to 70.00%, and the complete remission rate improved from 6.67% to 23.33%, clearly indicating enhanced effects on both targeted and cytotoxic interventions [15, 16]. In terms of tumor-associated biomarkers, both studies consistently showed that Peyuan Anti-Cancer Decoction significantly reduces levels of mammary gland malignancy–related markers such as CA125, CA153, and CEA, reflecting a reduction in tumor burden at the molecular level. Regarding improvement in traditional Chinese medicine (TCM) syndrome patterns, the decoction effectively alleviates symptoms associated with spleen deficiency and phlegm-dampness, including postprandial distension, abdominal fullness, poor appetite, chest tightness, epigastric oppression, loose stools, dizziness, and blurred vision, highlighting its TCM characteristics of strengthening the spleen, regulating qi, resolving phlegm, and dispersing nodules. In terms of quality of life, Peyuan Anti-Cancer Decoction significantly improves scores across multiple dimensions—including cognitive function, physical function, role function, and social function—helping patients better tolerate treatment. Regarding adverse effect mitigation, the decoction markedly decreases untoward reactions associated with trastuzumab and cytotoxic therapy, such as rash, gastrointestinal disturbances, leukopenia, and cardiac-related adverse events, reducing the overall incidence of adverse events by approximately 20–23 percentage points. Its protective effect against cardiac-related adverse events is particularly noteworthy, effectively mitigating cardiotoxicity associated with trastuzumab. Regarding long-term outcomes, combination therapy with Peyuan Anti-Cancer Decoction reduces the 12-month recurrence rate in patients with mammary gland malignancy, suggesting its potential role in inhibiting tumor recurrence and metastasis.

In summary, Peyuan Anti-Cancer Decoction exerts a comprehensive effect in mammary gland malignancy management by enhancing therapeutic outcomes and mitigating adverse effects, alleviating syndrome-related symptoms, improving quality of life, and lowering the risk of recurrence. It demonstrates clear clinical benefits when used in combination with targeted interventions such as trastuzumab and cytotoxic therapy, making it an effective formulation for integrative traditional Chinese and Western medical approaches in mammary gland malignancy management [16].

5. Challenges and Development Directions

5.1. Major Challenges Facing Current Research

Although Peiyuan Anti-Cancer Decoction has shown promising anti-tumor potential in both basic research and clinical applications, its further investigation and promotion still face numerous challenges. First, the depth of mechanistic research remains

insufficient. Most existing studies remain at the descriptive level, primarily observing the effects of this formula on biological behaviors such as tumor cell proliferation, apoptosis, and metastasis. However, research into specific molecular targets, signal pathway networks, and key active components is fragmented and lacks systematic mechanistic explanations. The multi-component, multi-target nature of traditional Chinese medicine (TCM) formulas inherently complicates their mechanisms of action, making it difficult to fully uncover their molecular basis for anti-tumor activity through single-pathway or single-target approaches. Second, the quality of clinical research needs improvement. Currently published clinical studies are mostly single-center, small-sample observational trials, with limited numbers of randomized controlled trials. Some studies suffer from methodological flaws, such as unclear randomization methods, improper blinding procedures, and inadequate sample size calculations, resulting in low-level evidence [2, 13]. Additionally, inconsistencies in TCM syndrome differentiation criteria, incomplete evaluation systems for therapeutic efficacy, and short follow-up periods limit the comparability and clinical applicability of study outcomes. Third, research on the material basis lags behind. As a TCM compound formula, the pharmacologically active constituents of Peiyuan Anti-Cancer Decoction have not yet been fully elucidated. Key scientific questions—such as the active components of individual herbs, interactions among these components, metabolic processes in vivo, and bioavailability—require deeper investigation. The lack of standardized quality control measures also hinders the formula's standardized production and clinical implementation. Fourth, the safety evaluation system remains incomplete. Although current clinical data suggest that Peiyuan Anti-Cancer Decoction is safe with a low incidence of adverse reactions, long-term, large-scale safety monitoring data are lacking. Potential risks—including hepatotoxicity, nephrotoxicity, and drug-drug interactions with chemotherapy agents—require systematic assessment.

5.2. Future Development Directions

To address the aforementioned challenges, future research can advance in the following directions: First, deepen the study of mechanisms of action and establish a multi-target network modulation model. By fully utilizing modern techniques such as systems biology, network pharmacology, and metabolomics, analyze the target points and signaling pathway networks of Peiyuan Anti-Cancer Decoction at a holistic level, elucidating its synergistic mechanism characterized by "multiple components, multiple targets, and multiple pathways." Simultaneously, employ serum pharmacology and plasma pharmacology methods to screen active constituents that enter systemic circulation, clarify the material basis of therapeutic effects, and provide scientific evidence for further development and application of this formula. Second, conduct high-quality clinical studies to enhance the level of evidence-based medicine. Design and carry out multicenter, large-sample, randomized, double-blind, controlled clinical trials in accordance with evidence-based principles, strictly adhering to CONSORT standards to ensure the authenticity and reliability of results. Establish unified standards for TCM syndrome differentiation and efficacy evaluation, using long-term outcomes such as quality of life and survival duration as primary endpoints to comprehensively assess the clinical value of Peiyuan Anti-Cancer Decoction. Meanwhile, actively conduct real-world studies to accumulate data on efficacy and safety under actual clinical conditions. Third, strengthen quality control research to promote standardization and normalization. Develop fingerprint-based quality control methods for Peiyuan Anti-Cancer Decoction, define the acceptable ranges of key marker compounds, and establish standardized preparation processes and quality specifications to ensure consistency and stability across different batches. Explore formulation innovations, such as granules and capsules, to improve patient compliance and facilitate clinical application [3]. Fourth, improve the safety evaluation system to ensure safe clinical use. Establish a long-term safety monitoring mechanism for Peiyuan Anti-Cancer Decoction, conduct large-scale, long-term follow-up safety studies, and systematically evaluate its potential impacts on liver

and kidney function, cardiovascular systems, and other aspects. Investigate interactions when this formula is used in combination with chemotherapy agents, targeted therapies, or immune checkpoint inhibitors, providing guidance for rational clinical use. Fifth, expand application areas and explore personalized treatment under precision medicine models. Building upon existing research, extend the investigation of Peiyuan Anti-Cancer Decoction to other cancer types such as gastric, pancreatic, and prostate cancers. Leverage the characteristics of TCM syndrome differentiation and treatment to develop precision therapy strategies integrating molecular subtyping with TCM syndrome patterns, identify optimal patient populations, achieve individualized treatment, and improve clinical outcomes. Sixth, strengthen translational research to accelerate the transformation of basic findings into clinical applications. Build a bridge between basic research and clinical practice, promptly translating identified effective targets and mechanisms into clinical treatment strategies, while feeding back clinical challenges to basic research, forming a positive feedback loop of "basic research--clinical application--basic research" to drive innovative development in integrative oncology.

6. Summary

Peiyuan Anti-Cancer Decoction, a representative formula in integrative oncology combining traditional Chinese medicine (TCM) and Western medicine, is formulated based on the TCM principle of "strengthening the body's defenses and eliminating pathogenic factors." With therapeutic principles focused on spleen tonification, qi regulation, softening hard lumps, and dispersing nodules, it has demonstrated unique advantages and broad application prospects in comprehensive cancer treatment. Basic research indicates that this formula exerts anti-tumor effects through multi-target, multi-pathway mechanisms, including immune modulation, induction of tumor cell apoptosis and autophagy, regulation of the tumor microenvironment, and inhibition of tumor angiogenesis and metastasis. Clinical evidence shows that when combined with radiotherapy, chemotherapy, targeted therapy, or immunotherapy, Peiyuan Anti-Cancer Decoction significantly improves objective response rates, alleviates clinical symptoms, enhances quality of life, and reduces treatment-related toxicities. It has shown clear clinical benefits across various malignancies, including non-small cell lung cancer, liver cancer, and gastrointestinal tumors. However, research and clinical application of this decoction still face challenges such as insufficient understanding of its mechanisms of action, low quality of clinical studies, unclear chemical constituents, and incomplete safety evaluations. Future efforts should focus on deepening basic research to clarify its mechanisms and active components, conducting high-quality evidence-based studies to strengthen clinical evidence, enhancing quality control and standardization, improving safety assessment systems, and exploring precision and individualized treatment models to advance the modernization and clinical application of this formula.

Integrative Chinese and Western medicine is a distinctive feature and strength in cancer treatment. Peiyuan Anti-Cancer Decoction, as a typical representative, embodies the core principles of traditional Chinese medicine—holistic view and syndrome differentiation—and aligns with the modern trend in oncology shifting from "single-target confrontation" to integrated physiological modulation. With ongoing research advancements and improvements in technical methods, Peiyuan Anti-Cancer Decoction is expected to play an increasingly important role in comprehensive cancer therapy, making greater contributions to improving survival rates and quality of life for patients.

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