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Research Progress on the Antitumor Effects and Clinical Applications of Yangzheng Xiaoji Capsules

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Abstract: ***Yangzheng Xiaoji Capsule is a modern compound preparation of traditional Chinese medicine (TCM) developed based on the TCM theories of "Fuzheng Quxie" (Strengthening the Body's Resistance and Eliminating Pathogenic Factors) and "Jianpi Xiaoji" (Strengthening the Spleen and Resolving Masses). It is widely used in the adjuvant therapy of tumors. Substantial basic and clinical research confirms that it not only exerts "Quxie" (Pathogen-Eliminating) effects by directly inhibiting tumor cell proliferation, inducing apoptosis, and suppressing invasion and metastasis but also achieves "Fuzheng" (Body-Resistance-Strengthening) effects by regulating the body's immune function, reducing the side effects of radiotherapy and chemotherapy, and improving cachexia. This article aims to systematically review the latest research progress regarding the antitumor mechanisms of Yangzheng Xiaoji Capsules (including inducing apoptosis and autophagy, inhibiting angiogenesis and metastasis, regulating the tumor microenvironment, immune regulation, chemosensitization, and toxicity reduction) and their clinical applications (its adjuvant therapeutic role in various solid tumors such as liver cancer, gastric cancer, lung cancer, colorectal cancer, and its impact on quality of life). It also provides an outlook on future research directions, hoping to offer a reference for in-depth study and rational clinical application of this drug.***

Keywords: Yangzheng Xiaoji Capsules, Antitumor effect, Mechanism of action, Clinical application, Integrated Traditional and Western Medicine, Review.

1. Introduction

Malignant tumors [1-2] are a major public health issue seriously threatening human health. Although modern medical approaches such as surgery, radiotherapy, chemotherapy, targeted therapy, and immunotherapy have made significant progress, problems including their side effects, drug resistance, and decreased patient quality of life remain prominent. In this context, TCM, with its concepts of holistic regulation, multi-target intervention, and "living with tumors," plays an increasingly important role in the comprehensive treatment of tumors.

Yangzheng Xiaoji Capsules [3] are a compound TCM preparation formulated based on the classic TCM principles of "Fuzheng Quxie" and "Jianpi Xiaoji," composed of multiple herbs including Astragalus (Huangqi), Ligustrum lucidum (Nüzhenzi), Ginseng (Renshen), Zedoary (Ezhu), Oldenlandia (Baihuasheshecao), Ganoderma (Lingzhi), Ground Beetle (Tubiechong), and Gynostemma (Jiaogulan). The formula aims to: supplement Qi and strengthen the spleen with herbs like Astragalus and Ginseng, supporting the body's vital energy (Zhengqi) and enhancing disease resistance, which constitutes "Fuzheng"; and attack the cancerous toxin directly by promoting blood circulation, removing blood stasis, clearing heat and toxins, and softening hard masses with herbs like Zedoary, Oldenlandia, and Ground Beetle, which constitutes "Quxie" and "Xiaoji". The entire formula simultaneously addresses both the root cause and symptoms, combining reinforcement and elimination, aligning with the core pathogenesis of deficiency of vital energy and internal accumulation of cancerous toxin in tumor patients.

In recent years, with in-depth modern pharmacological and evidence-based medical research, the antitumor value of Yangzheng Xiaoji Capsules has been widely confirmed [4-5]. This article intends to systematically review the relevant research progress from two aspects: its antitumor mechanisms and clinical applications.

2. Antitumor Mechanisms of Yangzheng Xiaoji Capsules

Modern research indicates that the antitumor effects of Yangzheng Xiaoji Capsules are not achieved through a single pathway but are the result of synergistic actions of multiple components, multiple targets, and multiple pathways, primarily manifested in direct antitumor effects and indirect regulation of the body's state.

2.1 Direct Antitumor Effects

2.1.1 Inhibiting Tumor Cell Proliferation and Inducing Apoptosis

Apoptosis is an important mechanism for the body to eliminate abnormal cells, and inducing tumor cell apoptosis is a core mechanism of many antitumor drugs. Numerous in vitro studies confirm [6] that Yangzheng Xiaoji Capsules and their active components can effectively inhibit the proliferation of various tumor cells and induce their apoptosis. Studies have found [7] that Yangzheng Xiaoji Capsules can upregulate the expression of pro-apoptotic proteins (such as Bax, Caspase-3, Caspase-9) while downregulating the expression of anti-apoptotic proteins (such as Bcl-2, Bcl-xl), thereby activating the mitochondrial apoptosis pathway. Furthermore, it can also affect the death receptor pathway (e.g., Fas/FasL) and regulate the activity of important

signaling molecules such as p53 and NF-κB, collectively promoting the initiation and execution of the apoptosis program. In models such as liver cancer HepG2 cells, gastric cancer SGC-7901 cells, and lung cancer A549 cells, Yangzheng Xiaoji Capsules have shown significant proliferation inhibition and pro-apoptotic effects. Its effects are dose- and time-dependent.

2.1.2 Inducing Tumor Cell Autophagy

Autophagy is a "double-edged sword," playing a complex role in tumor development. Under certain circumstances, excessive activation of autophagy can lead to type II programmed cell death. Research indicates [8] that Yangzheng Xiaoji Capsules can induce autophagy in tumor cells. The mechanism may be related to the regulation of the mTOR signaling pathway (mammalian target of rapamycin, a key negative regulator of autophagy). By inhibiting mTOR activity, it relieves the suppression of autophagy, thereby initiating the autophagy flux. This autophagic cell death is another important pathway for its direct killing of tumor cells.

2.1.3 Inhibiting Tumor Angiogenesis

Tumor growth and metastasis highly depend on the formation of new blood vessels, namely angiogenesis. Yangzheng Xiaoji Capsules [9-10] have been proven to have significant anti-angiogenic effects. This is primarily achieved by downregulating the expression of Vascular Endothelial Growth Factor [11] (VEGF) – one of the most potent pro-angiogenic factors – and its receptor (VEGFR). Inhibition of VEGF signaling directly hinders the proliferation, migration, and tube formation of endothelial cells. In tumor-bearing mouse models [12], it can reduce the microvessel density (MVD) within tumor tissue. This limits the nutrient supply to the tumor from the perspective of "starving" the tumor, curbing its growth and distant spread.

2.1.4 Inhibiting Tumor Invasion and Metastasis

Tumor invasion and metastasis are the main causes of treatment failure and patient death. Yangzheng Xiaoji Capsules can intervene in this process through multiple steps. Epithelial-mesenchymal transition (EMT) is a key step for tumor cells to acquire migratory and invasive abilities. Studies have found [13] that Yangzheng Xiaoji Capsules can upregulate the expression of epithelial markers (e.g., E-cadherin) and downregulate the expression of mesenchymal markers (e.g., N-cadherin, Vimentin), thereby reversing the EMT process and reducing cell invasiveness. Matrix metalloproteinases (MMPs) are key enzymes that degrade the extracellular matrix (ECM), "clearing the way" for tumor cell migration. Yangzheng Xiaoji Capsules can significantly inhibit the activity and expression of MMP-2 and MMP-9 [14], thereby weakening the ability of tumor cells to penetrate the basement membrane and ECM barrier.

2.2 Indirect Antitumor Effects and Holistic Regulation of the Body

2.2.1 Immunomodulatory Effects

The occurrence and development of tumors are often accompanied by suppression or disorder of the body's immune function. The "Fuzheng" effect of Yangzheng Xiaoji Capsules is largely reflected in its positive regulation of the immune system. This drug [15] can promote the proliferation and activation of T lymphocytes, particularly increasing the proportion and function of CD4+ helper T cells and CD8+ cytotoxic T cells, enhancing their ability to recognize and kill tumor cells. Simultaneously, it can activate natural killer (NK) cells and macrophages, which are the first line of defense in the body's antitumor immunity.

Yangzheng Xiaoji Capsules can promote the secretion of cytokines with antitumor activity (e.g., Interleukin-2, IL-2; Interferon-gamma, IFN-γ) [16], while inhibiting the expression of immunosuppressive factors (e.g., Transforming Growth Factor-beta, TGF-β; Interleukin-10, IL-10) [17], thereby improving the immunosuppressive state in the tumor microenvironment and creating favorable conditions for immune cells to function.

2.2.2 Chemosensitization and Toxicity Reduction

This is one of the most important values of Yangzheng Xiaoji Capsules in clinical combination therapy.

Studies indicate [18] that when combined with cisplatin, 5-fluorouracil, etc., Yangzheng Xiaoji Capsules can enhance the killing sensitivity of chemotherapy drugs to tumor cells by inhibiting the expression of multidrug resistance-associated proteins (e.g., P-gp) and synergistically inducing apoptosis, potentially helping to reverse or delay the occurrence of drug resistance. Radiotherapy and chemotherapy damage normal tissues, especially the bone marrow, digestive tract, and liver, while killing tumor cells. Yangzheng Xiaoji Capsules can significantly alleviate these toxic side effects. The mechanisms include: antioxidant stress, protecting the gastrointestinal mucosa, promoting the proliferation of bone marrow hematopoietic stem/progenitor cells, and stabilizing hepatocyte membranes [18-19]. Clinical observations have found [20] that combined application of this drug can effectively reduce the incidence and severity of leukopenia, thrombocytopenia, nausea, vomiting, and liver dysfunction in patients.

2.2.3 Improving Cancer Cachexia

Cancer cachexia is a syndrome characterized by progressive weight loss, muscle atrophy, and loss of appetite, severely affecting patients' quality of life and prognosis. The "Jianpi" (Spleen-Strengthening) efficacy of Yangzheng Xiaoji Capsules is highly relevant to this [21]. It can improve patients' appetite and nutritional status, increase body weight, especially lean body mass, and thus delay the progression of cachexia by regulating the neuroendocrine and inflammatory factor network (e.g., reducing Tumor Necrosis Factor-alpha, TNF-α levels).

3. Clinical Application Research of Yangzheng Xiaoji Capsules

3.1 Application in Primary Liver Cancer

Liver cancer is an area where research on Yangzheng Xiaoji

Capsules is relatively in-depth. Multiple clinical studies [22] show that in liver cancer patients receiving transarterial chemoembolization (TACE), radiofrequency ablation, or sorafenib targeted therapy, combining with Yangzheng Xiaoji Capsules can:

- Improve short-term efficacy [23]: The combination group showed better objective response rate (ORR) and disease control rate (DCR) than the Western medicine-alone group.
- Prolong survival: Combination therapy significantly prolongs median progression-free survival (PFS) and overall survival (OS) in patients.
- Improve liver function: Effectively reduce the incidence of post-TACE syndrome, protect liver function, and reduce serum ALT and AST levels.
- Enhance immune function: Increase the proportion of CD3+, CD4+ T cells and the CD4+/CD8+ ratio in patients.
- Improve quality of life: More significant improvement in Karnofsky Performance Status (KPS) and overall quality of life scores was observed in the combination group [24].

3.2 Application in Gastric Cancer

For patients with advanced gastric cancer, especially during postoperative adjuvant chemotherapy or palliative chemotherapy, adding Yangzheng Xiaoji Capsules can provide significant benefits.

- When combined with chemotherapy regimens such as FOLFOX or XELOX, it can improve the efficacy of chemotherapy and delay disease progression [25]. Effectively alleviate chemotherapy-induced myelosuppression (e.g., leukopenia, thrombocytopenia), gastrointestinal reactions (nausea, vomiting, diarrhea), and neurotoxicity, improving patients' treatment tolerance and compliance. It has a good improving effect on common symptoms in gastric cancer patients such as epigastric distension and pain, poor appetite, and fatigue, reflecting its "Jianpi Xiaoji" efficacy.

3.3 Application in Lung Cancer

In the treatment of non-small cell lung cancer (NSCLC), Yangzheng Xiaoji Capsules also show good auxiliary value.

- Combined with radiotherapy and chemotherapy: When used concurrently with platinum-based doublet chemotherapy or radiotherapy [26], it can enhance the antitumor effect while reducing radiation pneumonitis, radiation esophagitis, and chemotherapy-related hematological toxicity [27]. Maintenance therapy: For patients who have completed initial chemotherapy, using Yangzheng Xiaoji Capsules for maintenance therapy helps stabilize the condition and prolong survival, with good safety. Preliminary studies suggest [28] that combining Yangzheng Xiaoji Capsules with EGFR-TKI drugs (e.g., gefitinib, icotinib) may help delay the emergence of resistance and alleviate common adverse reactions to targeted drugs such as rash and diarrhea.

3.4 Application in Colorectal Cancer and Other Tumors

Clinical reports indicate that Yangzheng Xiaoji Capsules can also exert similar effects in the adjuvant treatment of malignant tumors such as colorectal cancer, pancreatic cancer, and breast cancer [29-31], including improving chemotherapy efficacy, reducing toxic side effects, and improving quality of life. Its potential role in regulating intestinal flora and improving intestinal barrier function also provides a new theoretical perspective for its application in colorectal cancer.

3.5 Improvement of Patient Quality of Life

This is an area where TCM treatment for tumors excels and a concentrated reflection of the clinical value of Yangzheng Xiaoji Capsules. Through systematic "Fuzheng" and "Quxie," this drug [32] can comprehensively improve clinical symptoms in tumor patients (such as pain, fatigue, loss of appetite, insomnia, etc.), stabilize mood, enhance physical strength, thereby improving their KPS scores and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) scores. This enables patients to better tolerate comprehensive treatment and achieve dignified, quality "living with tumors."

4. Discussion and Outlook

As a successful example of integrated Traditional Chinese and Western Medicine in antitumor research, the treatment principle of "Fuzheng Quxie" in Yangzheng Xiaoji Capsules coincides with the modern oncology emphasis on "regulating the tumor microenvironment" and "immunotherapy." Existing research has preliminarily elucidated its multi-target, integrated regulatory characteristics at the holistic, cellular, and molecular levels. However, some issues still require further exploration:

1) Active components and action targets need further clarification: Yangzheng Xiaoji Capsules are a complex system. Precisely which component groups play the core role, and how these components synergistically act on specific signaling pathways (e.g., PI3K/Akt, JAK/STAT) through a "network pharmacology" approach, still require systematic analysis using high-throughput technologies such as metabolomics and proteomics.

2) High-quality evidence-based medical evidence needs strengthening: Although there is a large amount of clinical research, multicenter, large-sample, randomized double-blind clinical trials (RCTs) are still relatively insufficient. In the future, more rigorous RCTs are needed to provide higher-level evidence for the application of Yangzheng Xiaoji Capsules in specific tumor types and specific treatment stages (e.g., neoadjuvant therapy, maintenance therapy).

3) Research on combination with cutting-edge treatment modalities: The potential of combining Yangzheng Xiaoji Capsules with modern immune checkpoint inhibitors (e.g., PD-1/PD-L1 antibodies), CAR-T cell therapy, and other

cutting-edge treatments deserves attention. Its role in regulating the immune microenvironment may provide new strategies for overcoming immunotherapy resistance or enhancing its efficacy.

4) Exploration of individualized medication and biomarkers: How to achieve precise and individualized application of Yangzheng Xiaoji Capsules based on patient characteristics such as genotype and TCM syndrome type is an important direction for future research. Finding biomarkers that can predict its efficacy will greatly promote rational clinical drug use.

5. Conclusion

In summary, Yangzheng Xiaoji Capsules [33-35], through dual mechanisms of directly inhibiting tumors (inducing apoptosis and autophagy, anti-angiogenesis, inhibiting invasion and metastasis) and indirectly regulating the body (immune regulation, chemosensitization and toxicity reduction, improving cachexia), demonstrate clear efficacy and unique advantages in the adjuvant treatment of various malignant tumors such as liver cancer, gastric cancer, and lung cancer. It can effectively enhance the efficacy of radiotherapy and chemotherapy, reduce toxic side effects, improve patient quality of life and immune function, and prolong survival, fully reflecting the value and potential of TCM in the comprehensive treatment of tumors. With the continuous deepening of modern research technologies and the ongoing expansion of clinical applications, Yangzheng Xiaoji Capsules are destined to play an even more important role in the battle against tumors.

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