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Antitumor Mechanisms and Clinical Applications of Shenqi Fuzheng Injection in Digestive System Cancers

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Abstract. Shenqi Fuzheng Injection (SFI) is a typical single compound from traditional Chinese medicine with a huge potential of SFI is mostly polysaccharide extracts of the substances of astragalus and Codonopsis, and the major three active components of SFI are astragalus polysaccharides, astragalosides and flavonoids. Molecular mechanisms of SFI have been extensively elucidated in gastric cancer, liver cancer, and other digestive system tumors based on recent basic and clinical studies. SFI interacts with multiple molecular pathways and molecular targets to achieve its therapeutic effects. The most prominent one is immune regulation, which is evidenced by the increased production of cytokines and chemokines and the alleviation of chemotherapy-induced immunosuppression. In the adjuvant treatment of digestive system cancers, SFI shows remarkable immunoregulatory and antitumor activities. Combining the SFI with immune checkpoint inhibitors and targeted therapies can be further explored to achieve synergistic antitumor effects based on the potential therapy effects of SFI. This review article summarizes the antitumor mechanisms of Shenqi Fuzheng Injection in digestive system cancers that are currently known, intending to help clinical use and future research directions.

Keywords: Shenqi Fuzheng Injection, digestive system malignancies, immunoregulation, clinical application

1. Introduction

Cancer has become one of the major killers globally. In 2020, new cancer cases totaled about 19.76 million worldwide, and cancer-related deaths were approximately 9.74 million. Digestive system cancers are a significant part of these diseases. For example, gastric cancer had about 1.098 million new cases and 690,000 deaths, while liver cancer contributed to 8.3% of all cancer-related deaths [1]. In Asia, especially in east Asian countries, both the gastric and liver cancers have much higher rates of illness and death than the world average. These statistics show that digestive system cancers are a serious global health problem. And the urgent need for early diagnosis, better supportive treatments, and improved survival and quality of life for patients. Traditional Chinese medicine (TCM) injections are used as supportive treatments for cancer and show special advantages due to the clear ingredients and quick effects. Shenqi Fuzheng Injection , an extract derived from Codonopsis pilosula and Astragalus membranaceus, is known to strengthen the body, improve

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immunity, and reduce the side effects of chemotherapy. SFI can enhance treatment efficacy and improve patient tolerance when used as an adjuvant in digestive system cancers. This review summarizes the main components, antitumor mechanisms, and clinical applications of Shenqi Fuzheng Injection to offer guidance for future clinical practice and scientific research.

2. Components of Shenqi Fuzheng Injection

The pharmacological basis of SFI originates from its primary herbal components, Codonopsis pilosula and Astragalus membranaceus. Codonopsis pilosula is the dried root of plants belonging to the Campanulaceae family, including Codonopsis pilosula, Codonopsis pilosula var. modesta, and Codonopsis tangshen. Astragalus membranaceus is the dried root of leguminous plants, including Astragalus membranaceus (Fisch.) Bge. and Astragalus mongholicus Bge. Both herbs are classified as Qi-reinforcing medicines in TCM, with the functions of invigorating Qi, supporting the spleen, and protect the body's surface from illness. The main antitumor constituents of Astragalus membranaceus include astragalus polysaccharides, astragalosides, and flavonoids [2]. These compounds cooperate to regulate the immune system and fight cancer by binding to different molecules and signaling pathways. Most of the active components of Codonopsis pilosula are carbohydrates, i.e. onosaccharides, polysaccharides, and oligosaccharides. Polysaccharides are the most notable ones, which have a variety of pharmacological activities like improving immunity, supporting blood production, lowering blood glucose, and slowing down aging [3]. These components together constitute the main material foundation of SFI in cancer treatment and provide fundamental support for its antitumor mechanisms.

3. Antitumor mechanisms of Shenqi Fuzheng Injection

Based on its the pharmacological properties of its components, SFI exerts antitumor effects through multiple pathways. The immune system can recognize and eliminate abnormally growing cells through multiple mechanisms, thereby inhibiting the forming and progress of tumors. However, tumor cells often create an immunosuppressive microenvironment by secreting immunosuppressive factors, which allows them to escape immune surveillance and elimination. Therefore, activating immune responses, promoting cytokine release, and restoring immune balance are very important in slowing down tumor growth and improving patient prognosis. Studies have shown that Codonopsis pilosula crude polysaccharide (CPCP) purified from SFI yields a purified polysaccharide (dCPP), composed of mannose, arabinose, rhamnose, xylose, galactose, and glucose. This substance can stop the growth of M2-like tumor-related macrophages caused by IL-4, help M1-like macrophages grow, and increase the levels of IL-1 and IL-6 mRNA, thereby reducing tumor volume in melanoma-bearing mice [4]. In addition, the injection can enhance the activity of natural killer (NK) cells and T lymphocytes, increase the levels of interleukin-2 (IL-2) and interferon-gamma (IFN-γ), improve the immune microenvironment, and strengthen the antitumor immune response [5]. Some clinical studies also found that when this injection is used together with chemotherapy, the number of $CD3^+$ and $CD4^+$ T cells in patients' peripheral blood significantly increases, while the level of $CD8^+$ T cells decreases. As a result, the $CD4^+/CD8^+$ ratio grows up, indicating that improve chemotherapy-induced immunosuppression by regulating the distribution of T-cell subsets [6, 7].

Although chemotherapeutic drugs can effectively kill tumor cells, they are often accompanied by side effects such as bone marrow suppression, nausea and vomiting, and hair loss. SFI can improve bone marrow hematopoietic function, promote the recovery of leukocytes and platelets, and reduce gastrointestinal toxic side effects, thereby enhancing patients' tolerance to chemotherapy. Both

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animal experiments and clinical studies have shown that combining Shenqi Fuzheng Injection with chemotherapy can increase the tumor remission rate and improve patients' quality of life [8]. Tumor recurrence and metastasis are closely related to the invasive behavior of tumor cells, which, in general, is a complex process that involves multiple factors. According to the results of an in vitro study conducted by Zhu Jiannan and colleagues, SFI motivated tumor cells to die by performing the following: reducing Bcl-2 and raising Bax and p53 expression [9]. The main enzymes that take part in the destruction of the extracellular matrix as well as the basement membrane are MMP-2 and MMP-9. These enzymes are over-expressed in different tumors and contribute to tumor cell invasion, metastasis, and angiogenesis. Astragaloside IV has the function of restricting the extracellular matrix melt that is performed by lessening MMPs level, therefore, it can slow down tumor cells spreading and metastasize abilities [5].

4. Clinical efficacy of Shenqi Fuzheng Injection

SFI has played a vital role in the clinical treatment of tumors in the digestive system, such as gastric cancer. The trial demonstrated that the combination therapy was more efficient in patients due to the lower levels of tumor markers like CYFRA21-1, TPS, NSE, and CA125 in the experimental group as compared to the control group, hence, it is quite clear that SFI can serve as an effective auxiliary therapeutic agent in gastric cancer [10]. Additionally, the experiments suggested that following combined treatment with SFI and FOLFOX6, the $CD4^+/CD8^+$ ratio in patients' peripheral blood elevated, T lymphocyte proliferation and differentiation were facilitated, and immune function got intensified [11].

In the case of liver cancer, SFI is typically employed in tandem with transcatheter arterial chemoembolization (TACE). Zhang Wei and his associates conducted an experiment in which 54 primary liver cancer patients were randomly divided into a treatment group (29 cases) and a control group (25 cases). On TACE day, Besides the standard treatment, SFI was administered to the patients in the treatment group. The findings showed that the patients' $CD4^+$ and the $CD4^+/CD8^+$ ratio were elevated while the increases of AST and ALT were not significant, thus, demonstrating that SFI can enhance immune function, protect liver function, and improve the quality of life of liver cancer patients [12]. In the treatment of intermediate and advanced liver cancer, interventional therapy is one of the most effective methods, however, it often causes adverse reactions such as fever, vomiting, and pain in the liver area. Di Ling et al. randomly divided 60 patients with advanced hepatocellular carcinoma into an experimental group (n=30) and a control group (n=30). The experimental group received SFI for five days prior to interventional therapy. The indocyanine green retention rate at 15 minutes (ICGR15) was measured before the first and second interventions and 30 days after the second intervention in both groups, and the post-embolization syndrome following chemoembolization was also observed. The results explained that the incidence of fever and abdominal pain in the experimental group was significantly lower than that in the control group. In addition, the ICGR15 value, which reflects liver function, was markedly decreased in the experimental group. Above findings suggest that Shenqi Fuzheng Injection can partially alleviate post-embolization syndrome following interventional therapy for primary liver cancer and help preserve hepatic reserve function [13].

Moreover, SFI may be used in combination with regular chemotherapeutic drugs such as fluorouracil, oxaliplatin, and epirubicin to bring about good results in the treatments of esophageal, gastric, liver, pancreatic, and colorectal cancers [14]. Zhang Xiaoyan and her team's research of 86 elderly patients with colorectal cancer arrived at the conclusion that the combination of SFI and XELOX chemotherapy enhances the immune status of the patients, therapeutic efficacy, quality of

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life, and reduces adverse effects associated with chemotherapy [15]. Combination therapy strategies are considered to help improve patients' tolerance to long-term chemotherapy and reduce the rate of treatment interruption caused by adverse effects.

5. Discussion

SFI is a multi-targeted regulator with immunomodulatory effects in both directions and of low toxicity. In addition to enhancing the immune function, it also moderates the adverse reactions caused by chemotherapy, thus, patients will be able to effectively complete their treatment regimens. However, most existing studies are single-center clinical trials with small sample sizes. Part of them have limitations in study design, and lack large-scale test, multicenter and double-blind randomized controlled trials. Furthermore, there are considerable differences in dosage and treatment duration among different studies, which may lead to inconsistencies in the evaluation of therapeutic efficacy. Subsequent studies should focus on exploring the optimal timing, dosage, and course of combination therapy between SFI and standard chemotherapy regimens such as FOLFOX and XELOX, in order to clarify its effects on long-term survival and recurrence rates. At the same time, molecular subtyping and immune status indicators can be used to identify the populations most likely to benefit, thereby promoting individualized treatment. In addition, its combination with immune checkpoint inhibitors and targeted therapies can be further explored to achieve synergistic antitumor effects.

6. Conclusion

SFI comes from two natural substances, i.e. Codonopsis pilosula and Astragalus membranaceus. The major biologically active components are polysaccharides, saponins, and flavonoids. The drug exploits different mechanisms to eliminate cancer cells, these are mainly immune regulation, antioxidation, tumor cell proliferation inhibition, apoptosis induction, and chemotherapy agent toxicity reduction. As a comprehensive treatment of digestive system malignancies such as gastric and liver cancers, SFI is an adjuvant that can increase therapeutic efficacy, enhance immune function, reduce side effects, and improve patients' quality of life. Although the current evidence needs large-scale, multicenter clinical trials for further confirmation, SFI is widely applicable in the integrated treatment of tumors and is expected to be the main factor that leads to increased chemotherapy compliance and better prognosis of patients.

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