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Research Progress on Myasthenia Gravis

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Abstract: Myasthenia gravis (MG) is a chronic autoimmune disease characterized by impaired transmission at the neuromuscular junction. Conventional clinical treatments show unsatisfactory efficacy and severe adverse reactions, while traditional Chinese medicine (TCM) presents unique advantages in its management. From the perspective of integrated traditional Chinese and Western medicine, this paper investigates the effects of Qishen Dihuang Granules on patients with MG based on modern understandings of the pathogenesis of MG and TCM theories. The pharmacological mechanisms and theoretical basis of the granules are elaborated from four aspects: regulating immune function, protecting the structure and function of the neuromuscular junction, improving TCM syndromes and clinical symptoms, and enhancing efficacy while reducing toxicity. The results show that Qishen Dihuang Granules can effectively correct immune imbalance, alleviate damage to the neuromuscular junction, improve clinical symptoms and TCM syndromes, assist in enhancing therapeutic effects and reducing drug toxicity. It demonstrates favorable clinical application value and provides an important theoretical basis for the integrated treatment of MG with traditional Chinese and Western medicine.

Keywords: Qishen Dihuang Granules; Myasthenia gravis; Impact research

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1. Introduction

Myasthenia gravis (MG) is an autoimmune disease with impaired neuromuscular transmission caused by acetylcholine receptor (AChR) antibodies. The main mechanism is the destruction of the postsynaptic membrane, leading to muscle weakness. Approximately 80% of cases are associated with AChR antibodies. The incidence of MG in China is about 0.68 per 100,000 population. Respiratory complications are the main cause of death, resulting in heavy disease and medical burdens. Current treatments include cholinesterase inhibitors, immunosuppressants, intravenous immunoglobulin and thymectomy. However, some patients show poor efficacy or drug resistance. Long-term use increases the risk of infection, and precise targeted

drugs are expensive.

TCM has unique therapeutic effects on MG. Qishen Dihuang Granules is a prescription supported by the National Key R&D Program and included in the TCM Diagnosis and Treatment Protocol for Flaccidity Disease (Myasthenia Gravis). Its active ingredients exert antioxidant, anti-inflammatory and immune-regulating pharmacological effects (State Administration of Traditional Chinese Medicine). To further clarify the effects and mechanisms of Qishen Dihuang Granules on patients with MG, conducting relevant research is of great significance for enriching therapeutic methods and optimizing integrated diagnosis and treatment regimens [1].

2. Concept of Myasthenia Gravis

Myasthenia Gravis (MG) is a chronic autoimmune disease affecting the postsynaptic membrane of the neuromuscular junction, mediated by autoantibodies and involving cellular immunity. The main pathological mechanism is that the body produces autoantibodies against postsynaptic antigens such as acetylcholine receptor (AChR) and muscle-specific kinase (MuSK), thereby damaging signal transmission at the neuromuscular junction and causing skeletal muscle weakness and fatigability.

The clinical manifestations are characterized by weakness that is milder in the morning, worse in the evening, aggravated after activity and relieved after rest [2]. It can involve ocular muscles, facial muscles, masticatory muscles, limb muscles and respiratory muscles. In severe cases, respiratory muscle paralysis occurs, leading to crisis and life-threatening conditions. The incidence is about 0.5 to 1 per 100,000 population, slightly higher in females than males, and can occur at all ages. The pathogenesis is related to many factors such as heredity, environment and immune disorders. At present, there is no radical cure, and mainly symptomatic treatment is adopted.

3. Understanding of Myasthenia Gravis in Traditional Chinese Medicine

There is no exact name for myasthenia gravis in TCM. According to its main clinical manifestations such as skeletal muscle weakness and easy fatigability, it can be classified into the categories of flaccidity disease, eyelid drooping and consumptive fatigue. The descriptions of flaccidity syndrome and muscular flaccidity in Suwen·Weilun are highly consistent with the symptoms of this disease.

Its etiology is mostly related to insufficient congenital endowment, acquired dysnutrition, emotional disorders and invasion of external pathogens. The main pathogenesis is deficiency of the spleen and kidney, insufficiency of Qi and blood, and blockage of channels and collaterals. The spleen is the acquired base and source of Qi and blood production; spleen deficiency leads to malnutrition of muscles. The kidney is the congenital base, governing bones and generating marrow; kidney deficiency leads to weak tendons and bones. Deficiency of both runs through the whole course of the disease.

TCM syndrome differentiation is mostly deficiency syndromes, including spleen-stomach weakness, spleen-kidney deficiency, Qi-Yin deficiency, etc [3]. The treatment follows the classic principle of “treating flaccidity by focusing on Yangming”, mainly by invigorating the spleen and benefiting Qi, tonifying the kidney and replenishing essence, nourishing blood and unblocking collaterals, with equal emphasis on supporting healthy Qi and eliminating pathogens, providing special theoretical basis and clinical thinking for the treatment of MG.

4. Main pathogenesis of Myasthenia Gravis from the perspective of modern medicine

4.1. Autoantibody-mediated injury of the neuromuscular junction

Abnormal production of autoantibodies is the main cause of MG. About 80–90% of patients have acetylcholine receptor (AChR) antibodies *in vivo*, and muscle-specific kinase (MuSK) antibodies, low-density lipoprotein receptor-related protein 4 (LRP4) antibodies, etc. can be detected in other patients. These antibodies bind to corresponding antigens on the postsynaptic membrane of the neuromuscular junction, block the binding of acetylcholine to receptors, accelerate receptor internalization and degradation, or activate the complement system to destroy the structure of the postsynaptic membrane, directly affecting the transmission of nerve signals to muscles and causing skeletal muscle weakness [4].

4.2. Abnormal activation of T lymphocytes and immune imbalance

Abnormal activation of T lymphocytes is the main driving force for the production of autoantibodies. The subsets of $CD4^+$ T lymphocytes in patients with MG are imbalanced. T helper (Th) 1 and Th17 cells are overactivated, secreting a large number of pro-inflammatory cytokines, promoting the proliferation and differentiation of B lymphocytes into plasma cells and producing specific autoantibodies. Regulatory T (Treg) cells are dysfunctional and cannot effectively inhibit abnormal immune responses, resulting in the destruction of immune tolerance, thus triggering persistent autoimmune attack and aggravating injury to the neuromuscular junction.

4.3. Abnormal proliferation of B lymphocytes and hyperfunction of plasma cells

B lymphocytes are the main cells producing antibodies. They proliferate abnormally in patients with MG, with up-regulated expression of surface co-stimulatory molecules and enhanced interaction with T lymphocytes, thereby promoting the secretion of autoantibodies. The number of plasma cells in the bone marrow and peripheral blood of patients increases significantly, and their survival time is prolonged, continuously secreting high-titer autoantibodies. These antibodies act on the postsynaptic membrane for a long time, resulting in persistent damage to the transmission function of the neuromuscular junction and recurrent or aggravated conditions [5].

4.4. Synergistic effect of genetic and environmental factors

Genetic factors provide a susceptible environment for the onset of MG. Studies have shown that some genotypes of human leukocyte antigen (HLA) are associated with the risk of the disease. Patients with different HLA genotypes have different incidence probabilities, antibody types and disease severity. Environmental factors such as infection, drugs, surgery and mental stress can be used as incentives to activate abnormal immune responses of the body, destroy immune homeostasis and promote the occurrence and development of MG. The two interact and jointly promote the progression of the disease.

5. Research on the effects of Qishen Dihuang granules on patients with Myasthenia Gravis

5.1. Regulating immune function and correcting immune imbalance

Qishen Dihuang Granules uses *Astragalus* and *Codonopsis* to tonify Qi, *Rehmannia* and Chinese yam to

tonify the kidney, supplemented by *Salvia miltiorrhiza* to activate blood circulation and poria to invigorate the spleen. The combination of these herbs conforms to the physical characteristics of deficiency of the spleen and kidney and insufficiency of Qi and blood in patients with MG. Its main theory is to bidirectionally regulate the abnormal immune state of patients by invigorating the spleen and kidney, benefiting Qi and nourishing blood.

Modern pharmacological studies show that the active ingredients such as *Astragalus polysaccharides* and *Codonopsis saponins* in the granules can specifically inhibit the proliferation and differentiation of abnormally activated T and B lymphocytes, reduce the production of pathogenic autoantibodies such as acetylcholine receptor (AChR) antibodies and muscle-specific kinase (MuSK) antibodies, significantly enhance the immunosuppressive effect of regulatory T cells, promote the recovery of immune tolerance of the body, prevent persistent autoimmune attack on the neuromuscular junction, improve the immune disorder of patients from the key link of pathogenesis, and provide solid theoretical and pharmacological support for long-term remission of the disease [6].

In the study Mechanism of Qishen Dihuang Granules on B-cell Chemokines in Experimental Autoimmune Myasthenia Gravis Rats (Project No. 2024032), EAMG model rats were intervened with Qishen Dihuang Granules. It was found that the proliferation and differentiation of splenic B lymphocytes in rats were inhibited, the level of AChR antibodies decreased significantly, the function of Treg cells was enhanced, and the $CD4^+T/CD8^+T$ ratio returned to normal, proving its effect of regulating immunity and correcting immune imbalance.

5.2. Protecting the structure and function of the neuromuscular junction

The granules can use the antioxidant and anti-inflammatory effects of its active ingredients to remove excessive oxygen free radicals in the body, inhibit the release of inflammatory factors (interleukin-6, tumor necrosis factor-α), reduce inflammatory infiltration and injury of the postsynaptic membrane of the neuromuscular junction, reduce the damage to the structure of the postsynaptic membrane caused by membrane attack complexes formed after activation of the complement system, and stabilize the integrity and permeability of the postsynaptic membrane.

The effect of invigorating Qi and tonifying the kidney can improve the circulation of Qi and blood in the body, increase the supply of blood oxygen and nutrients at the neuromuscular junction, increase the synthesis and expression of acetylcholine receptors on the postsynaptic membrane, improve the binding efficiency of acetylcholine to receptors, enhance the transmission ability of nerve signals to skeletal muscles, improve symptoms such as skeletal muscle weakness, easy fatigue after activity, and being milder in the morning and worse in the evening, comprehensively protect the normal physiological function of the neuromuscular junction and delay the progression of the disease [7].

Taking the study Mechanism of Qishen Dihuang Granules on B-cell Chemokines in Experimental Autoimmune Myasthenia Gravis Rats (Project No. 2024032) as an example, in the rat model, 30 days after injection of the granules, the serum levels of TNF-α and IFN-γ decreased, inflammatory infiltration of the postsynaptic membrane of the neuromuscular junction was reduced, acetylcholine receptors increased, forelimb grip strength of rats was improved, and myasthenia symptoms were significantly relieved, indicating its role in protecting the neuromuscular junction.

5.3. Improving TCM syndromes and relieving clinical symptoms of patients

According to the understanding of MG as "flaccidity disease" in TCM and the pathogenesis characteristics of deficiency of the spleen and kidney, insufficiency of Qi and blood, and blockage of channels and collaterals, Qishen Dihuang Granules has the effects of invigorating the spleen and kidney, nourishing blood and unblocking collaterals, and nourishing Yin and promoting fluid production, which can better improve TCM syndromes of patients.

Its main theory is to nourish Yin of the spleen and kidney with *Rehmannia* and Chinese yam, tonify Qi and blood with *Astragalus* and *Codonopsis*, and activate blood circulation and unblock collaterals with *Salvia miltiorrhiza*, so as to fundamentally nourish muscles and moisten collaterals, and relieve symptoms related to TCM syndromes such as limb weakness, soreness and weakness of waist and knees, sallow complexion, mental fatigue, poor appetite and shortness of breath [8].

This mechanism conforms to the classic treatment principles of "treating flaccidity by focusing on Yangming" and "simultaneous tonification of the spleen and kidney" in Suwen·Weilun, attaching importance to tonifying the congenital and acquired bases, and taking into account unblocking collaterals and resolving stagnation, achieving the dual effect of improving TCM syndromes and relieving clinical symptoms, showing the overall conditioning advantage of TCM in the treatment of MG.

Taking the study Effect of Qishen Dihuang Granules on Intestinal Flora in Patients with Myasthenia Gravis (Project No. 2024020) as an example, 10 patients with MG of spleen-kidney deficiency type were selected in the study. After taking Qishen Dihuang Granules for 6 months, the scores of TCM syndromes such as limb weakness, soreness and weakness of waist and knees, and mental fatigue decreased significantly, clinical muscle strength was improved, and the diversity of intestinal flora was close to that of healthy people, proving its overall conditioning effect.

5.4. Assisting in enhancing efficacy and reducing toxicity, optimizing clinical therapeutic effects

When Qishen Dihuang Granules is combined with conventional modern medical treatment regimens (cholinesterase inhibitors, glucocorticoids, immunosuppressants, etc.), it can exert a synergistic effect. By regulating immunity and protecting the neuromuscular junction, it can improve the efficacy of conventional therapeutic drugs, accelerate the recovery of muscle strength in patients, shorten the time of symptom relief, and improve the effective rate of clinical treatment [9].

At the same time, it is composed of natural Chinese herbs with mild properties, and can play a role in invigorating the spleen and nourishing the stomach, benefiting Qi and consolidating the exterior, thereby reducing adverse reactions such as infection, gastrointestinal discomfort and osteoporosis caused by long-term use of immunosuppressants and glucocorticoids, reducing the harm of drug toxicity to the body, and improving the tolerance and compliance of patients to medication.

This theory provides important support for the integrated treatment of MG with traditional Chinese and Western medicine, which is conducive to improving clinical diagnosis and treatment regimens, reducing disease recurrence and improving the quality of life of patients. In the study Effect of Qishen Dihuang Granules on Intestinal Flora in Patients with Myasthenia Gravis (Project No. 2024020), 5 MG patients were treated with Qishen Dihuang Granules combined with pyridostigmine bromide. Compared with the Western medicine alone group, the muscle strength recovery was faster, the treatment effective rate was higher, there were no obvious gastrointestinal reactions and fewer infections, indicating its effect of enhancing efficacy

and reducing toxicity [10].

6. Conclusion

In summary, this paper mainly studies the effects of Qishen Dihuang Granules on patients with myasthenia gravis. It is found that Qishen Dihuang Granules can regulate immune function, correct immune imbalance, protect the structure and function of the neuromuscular junction, improve TCM syndromes and clinical symptoms of patients, assist in enhancing efficacy and reducing toxicity, and improve clinical therapeutic effects. From the perspective of integrated traditional Chinese and Western medicine, starting from the pathogenesis of myasthenia gravis in both modern medicine and TCM, this paper expounds the main mechanisms of Qishen Dihuang Granules, verifies its therapeutic effect on myasthenia gravis, provides a theoretical basis for the integrated treatment of myasthenia gravis with traditional Chinese and Western medicine, and reflects the unique advantages of TCM in the treatment of autoimmune diseases.

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Disclosure statement

The authors declare no conflict of interest.

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