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Current Research Status of Danzhi Xiaoyao San Combined with Antithyroid Drugs in the Treatment of Hyperthyroidism with Liver Qi Stagnation and Heat Transformation

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Abstract: *This study investigates the integrative use of Danzhi Xiaoyao San (DZXYS) combined with antithyroid drugs (ATDs) for hyperthyroidism, a clinical syndrome characterized by systemic hypermetabolism and excitability due to excessive thyroid hormone secretion. In Traditional Chinese Medicine (TCM), hyperthyroidism is categorized as Ying disease , attributed to emotional disharmony causing Liver Qi stagnation , which progresses to Liver Fire hyperactivity and thyroid enlargement. Modified DZXYS—a formula targeting Qi regulation, heat clearance, and blood nourishment—is frequently employed. Conventional therapies, including ATDs (e.g., methimazole, propylthiouracil), surgery, and radioiodine, face limitations such as adverse effects and relapse. The TCM-Western integrative approach synergizes syndrome differentiation with ATDs, enhancing therapeutic efficacy, minimizing side effects, and leveraging holistic and targeted mechanisms. This strategy exemplifies optimized clinical outcomes through complementary modalities, warranting further exploration of its molecular foundations and long-term benefits.*

Keywords: *Hyperthyroidism, Danzhi Xiaoyao San, Integrated traditional Chinese and western medicine*

In recent decades, the global incidence of hyperthyroidism has shown a marked upward trajectory, paralleling rapid societal development and profound lifestyle transformations. Epidemiological data reveal a predilection for females aged 20-40 years, with notable trends toward earlier disease onset. Accounting for 37.5% of thyroid disorders, hyperthyroidism has emerged as a significant public health concern, prompting heightened clinical and research attention to thyroid pathologies [1]. Historical records of thyroid dysfunction, including goiter and thyrotoxicosis, can be traced to classical Chinese medical texts such as Lüshi Chunqiu, where these conditions were collectively termed "Ying disease" within traditional Chinese medicine (TCM) nosology. The Song Dynasty treatise Treatise on Three Categories of Pathogenic Factors by Chen Yan further classified Ying disease into five subtypes: Shi Ying, Rou Ying, Jin Ying, Xue Ying, and Qi Ying. Modern cross-disciplinary analyses suggest diagnostic correlations between these historical classifications and contemporary thyroid disorders: Qi Ying predominantly aligns with hyperthyroidism and nontoxic goiter (including endemic variants), while Rou Ying corresponds to nodular goiter and thyroid adenomas. Notably, Shi Ying exhibits parallels with thyroid carcinoma, and Ying Yong encompasses inflammatory thyroid conditions [2].

Among hyperthyroidism patterns in TCM practice, liver qi stagnation transforming into heat represents a frequently observed clinical manifestation. In this context, Danzhi Xiaoyao San, a classical TCM formula renowned for its liver-soothing, heat-clearing, and qi-regulating properties, demonstrates synergistic potential when combined with conventional antithyroid medications. This integrative therapeutic approach has garnered increasing academic interest due to its dual-modality advantages in managing hyperthyroidism with liver depression-heat transformation patterns.

1. Traditional Chinese Medicine's Understanding of Hyperthyroidism

1.1. Etiology and Pathogenesis in Traditional Chinese Medicine

In TCM, hyperthyroidism is classified under the categories of Ying disease and Ying qi. Classical medical texts provide foundational etiological insights: Chao Yuanfang posited in Treatise on the Origins

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and Manifestations of Diseases·Ying Syndrome:"Ying disorders arise from the stagnation of Qi due to chronic anxiety and pent-up resentment",Chen Shiduo elaborated in Records of Pattern Differentiation·Ying Disease Chapter: "The formation of Ying disease predominantly originates from the congealment of constrained Qi".[3]Both texts explicitly identify emotional disturbances leading to Liver Qi stagnation as a key pathogenic mechanism in Ying disorders.TCM considers the pathogenesis of Ying disease to be primarily associated with internal emotional disturbances, dietary irregularities, environmental influences, and constitutional predispositions. Exposure to pathogenic factors, such as emotional stress or dietary imbalances, can initiate pathological processes, including Qi stagnation, phlegm accumulation, blood stasis, and the transformation of Liver depression into fire [4]. Chronic emotional distress, encompassing anxiety, depression, and anger, can induce Liver Qi stagnation, thereby compromising the Liver's regulatory function. This Qi stagnation subsequently impairs fluid metabolism, leading to phlegm accumulation, which, in conjunction with Qi, contributes to the formation of Ying disease. Prolonged Qi stagnation may evolve into fire, resulting in Liver depression transforming into heat. Individuals with a Yin-deficient constitution, characterized by relative Yang excess, are particularly susceptible to Liver depression transforming into heat. Furthermore, dietary indiscretions can exacerbate hyperthyroidism. Chronic consumption of rich, greasy, and sweet foods can impair the Spleen and Stomach's transformative and transportive functions, leading to dampness and phlegm production. This, in turn, affects the Liver's regulatory function, promoting Liver depression and heat transformation. Liver depression transforming into heat can, on one hand, impair the Spleen and Stomach's function, leading to Qi and Blood deficiency; on the other hand, the pathogenic factor of fire heat disrupts the Heart and Spirit, manifesting as palpitations and irritability. Concurrently, Liver Qi stagnation, with the Liver overacting on the Spleen, disrupts the Spleen's fluid transportation, resulting in phlegm accumulation. This phlegm and Qi then coalesce and accumulate in the neck, forming a goiter.

1.2. Syndrome Differentiation and Classification

The diagnostic differentiation of hyperthyroidism involves several patterns, with the Liver Qi Stagnation Transforming into Heat pattern being a common presentation. Beyond the characteristic goiter, patients with this pattern exhibit a range of symptoms. Liver Qi stagnation may present as irritability, anxiety, and depression. Impaired Liver meridian flow can cause hypochondriac distension or pain. Liver Fire disturbing the Heart Spirit may result in restlessness, palpitations, and insomnia. Internal stirring of Liver Wind can manifest as hand tremors and weight loss. Moreover, in women, the Liver's role as the innate foundation means that Liver stagnation can disrupt the Chong and Ren meridians, leading to menstrual irregularities. These symptoms collectively reflect the pathological characteristics of Liver Qi stagnation, with subsequent transformation into heat.

2. Mechanisms of Action of Danzhi Xiaoyao San

2.1. Formula Analysis

Danzhi Xiaoyao San, originating from Xue Ji's "Neike Zhiyao" of the Ming Dynasty and derived from Xiao Yao San in the "Taiping Huimin Heji Ju Fang" of the Song Dynasty with the addition of Cortex Moutan and Fructus Gardeniae , employs Chai Hu as the principal herb [5]. Chai Hu courses the liver and alleviates depression, thereby regulating Liver Qi and mitigating Liver Qi stagnation stemming from emotional distress, thus preventing the transformation of Qi stagnation into Phlegm and Blood stasis. Radix Angelicae Sinensis and Radix Paeoniae Alba function as assistant herbs. Radix Angelicae Sinensis nourishes Blood, promotes Blood circulation, and harmonizes Blood, acting as the Qi-regulating herb within the Blood. Radix Paeoniae Alba nourishes Blood, astringes Yin, calms the Liver, and inhibits Yang, alleviating Liver spasms. These two herbs, in conjunction with Chai Hu, tonify the Liver and harmonize its function, enhancing the effect of coursing the Liver and regulating Qi, while also preventing the Qi-regulating herbs from injuring Yin. Furthermore, they restrain Chai Hu's dispersing action to prevent excessive dispersion. Cortex Moutan and Fructus Gardeniae in Danzhi Xiaoyao San are the adjuvant herbs. Cortex Moutan clears Heat, cools Blood, and promotes Blood circulation to dispel stasis; its cooling action does not lead to Blood stasis, effectively clearing latent Fire in the Blood. [6]Fructus Gardeniae clears Heat, detoxifies, and eliminates Fire, resolving Fire in the Heart, Lungs, and Triple Burner, guiding Heat downwards. Their combination clears and resolves stagnant Heat, preventing the transformation of Liver stagnation into Fire over time, and alleviating symptoms such as irritability, dry mouth, and a red tongue with a yellow coating, which may occur in patients with goiter. Rhizoma Atractylodis Macrocephalae, Poria, and Radix Glycyrrhizae Praeparata are the assistant herbs, tonifying

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the Spleen and benefiting Qi, promoting smooth Spleen function, ensuring the generation of Qi and Blood, thereby eliminating the source of Phlegm, and strengthening the Earth element to counteract the Liver's overaction, preventing the Liver Qi from attacking the Spleen.

2.2. Pharmacological Analysis

Within the Danzhi Xiaoyao San formulation, Bupleurum chinense serves as the principal herb, with saikosaponins identified as its key bioactive constituents. Specifically, saikosaponin a exerts anxiolytic and antidepressant effects by targeting signaling pathways such as FoxO, prolactin, and PI3K/Akt, while modulating protein targets including ALB and Akt1 [7]. Gardenia jasminoides contains geniposide (GE), which regulates brain serotonin (5-HT) and dopamine levels, repairs damaged hippocampal neurons, and ameliorates depressive symptoms [8]. Concurrently, GE downregulates thyroid peroxidase (TPO) activity, thereby attenuating thyroid hormone biosynthesis (T3, T4).

Tree peony bark contributes paeonol, a compound with multifaceted pharmacological properties, including antioxidation, anticancer activity, neuroprotection, and hypoglycemic effects [9]. Paeonol reduces thyroid-stimulating hormone receptor (TSHR) sensitivity, restoring homeostasis to the hypothalamic-pituitary-thyroid (HPT) axis. Paeoniae radix alba contains paeoniflorin, which exerts analgesic, anti-inflammatory, antidepressant, hepatoprotective, antitumor, and antihyperglycemic effects by modulating the GABAergic system and dampening central nervous system excitability [10]. Lastly, atractylodes macrocephala koidz provides volatile oils with hepatoprotective and antibacterial properties.

The formula's composition rigorously follows the sovereign-minister-adjuvant-envoy compatibility principle, a fundamental TCM formulation strategy that orchestrates multi-component synergism. Pharmacological studies reveal its multi-target therapeutic synergism: The combination of saikosaponins and paeonol enhances the inhibitory effect on IL-6 and TNF-α. Geniposide competitively binds to the TPO catalytic domain, suppressing thyroid hormone biosynthesis. Paeonol demonstrates TSHR desensitization effects by downregulating cAMP-dependent signaling cascades . Neuropharmacological profiling indicates that active constituents in Bupleurum chinense and Paeonia lactiflora mediate anxiolytic and anti-tremor effects through dual modulation of central 5-HT receptor affinity and GABA receptor chloride influx. Simultaneously, paeonol and geniposide alleviate myocardial oxidative stress and inhibit ventricular remodeling, thereby protecting the heart.

3. Western Medical Understanding of Hyperthyroidism

3.1. Etiology and Pathogenesis

Hyperthyroidism, characterized by excessive thyroid hormone production, manifests as a multi-system syndrome involving neuroendocrine dysregulation and hypermetabolic states. The clinical presentation typically includes heightened sympathetic activation affecting the cardiovascular system (tachycardia, arrhythmias), nervous system (hyperreflexia, tremors), digestive tract (hyperdefecation, weight loss), and reproductive axis (menstrual irregularities) . Pathophysiologically, this condition is primarily driven by the thyroid gland's autonomous overproduction of triiodothyronine (T3) and thyroxine (T4), leading to suppressed thyroid-stimulating hormone (TSH) levels through negative feedback mechanisms [11].

The pathogenesis of hyperthyroidism is complex. A frequent etiology is Graves' disease, driven by an excess of specific autoantibodies, particularly human thyroid-stimulating hormone receptor antibodies. Genetic predispositions and environmental influences also play a role in the development of hyperthyroidism. Moreover, the increased intake of iodine-rich seafood and marine products can impact thyroid function if consumed in excess, potentially precipitating hyperthyroidism [1].Notably, the prevalence of hyperthyroidism is observed to be greater in females compared to males.

3.2. Clinical Manifestations

Hyperthyroidism manifests as a hypermetabolic state characterized by neuropsychiatric excitation (irritability, restlessness), cardiovascular hyperactivity (tachycardia), and thermoregulatory dysfunction (heat intolerance, excessive sweating)[12]. Core clinical features include paradoxical weight loss despite hyperphagia, often accompanied by neuromuscular manifestations such as periodic thyrotoxic paralysis or proximal muscle weakness. Ocular involvement, particularly exophthalmos in Graves' disease, presents with pathognomonic lid retraction and periorbital edema. Systemic manifestations extend to

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cardiovascular disturbances (palpitations, arrhythmias), neurological sequelae (fine hand tremors, sleep disruption), and reproductive dysfunction (menstrual irregularities in females, erectile dysfunction in males). A distinct clinical subset involves gestational thyrotoxicosis mimicking hyperemesis gravidarum in pregnant individuals.

3.3. Mechanisms of Action and Adverse Reactions of Anti-Thyroid Drugs

The mainstay of antithyroid pharmacotherapy involves two classes of thionamide agents: thiouracils (methylthiouracil and propylthiouracil) and imidazoles (methimazole and carbimazole). These drugs competitively inhibit TPO, blocking iodine organification and thyronine coupling, thereby suppressing thyroid hormone synthesis. Additionally, they exhibit immunomodulatory effects by reducing thyroid-stimulating immunoglobulin (TSI) production through inhibition of B cell-mediated antibody synthesis [13]. Methimazole is recommended as first-line therapy due to its superior pharmacokinetic profile, lower hepatotoxicity risk, and enhanced efficacy in normalizing thyroid-stimulating hormone receptor antibody levels. Propylthiouracil remains preferred in specific contexts: first-trimester pregnancy and thyroid storm [14].

Adverse effects range from mild reactions to life-threatening complications. Severe adverse drug reactions include agranulocytosis, exfoliative dermatitis, hepatitis, and drug-induced hypothyroidism [15].

4. Results of Combined Therapy Studies

In a randomized controlled trial, Pan Jingxia et al [16]. investigated 120 patients newly diagnosed with Graves' disease-induced hyperthyroidism, allocating them randomly to either a treatment or control group (n=60 each). The treatment group received Danzhi Xiaoyao San in conjunction with methimazole, while the control group received methimazole monotherapy. Following a 3-month intervention, the treatment group exhibited a significantly higher total effective rate compared to the control group (90.0% vs. 75.0%, $P < 0.05$). Biochemical analysis revealed that the treatment group's free triiodothyronine (FT3) decreased from a baseline of (22.61 ± 6.70) pmol/L to (8.49 ± 1.70) pmol/L, and free thyroxine (FT4) decreased from (44.26 ± 5.13) pmol/L to (17.75 ± 1.83) pmol/L; these improvements were significantly superior to those observed in the control group (both $P < 0.05$). Furthermore, the recovery of thyroid-stimulating hormone (TSH) levels was more pronounced ($P < 0.05$). These findings suggest that the integrated TCM and Western medicine approach significantly optimizes thyroid function indicators via a multi-target regulatory mechanism.

Shi Lijuan et al [17]. conducted a randomized controlled trial to assess the efficacy of a modified Danzhi Xiaoyao Powder in the treatment of hyperthyroidism secondary to Liver Qi stagnation and Spleen deficiency. Ninety patients were enrolled and randomized into an experimental group and a control group, each comprising 45 patients. The control group received methimazole monotherapy, whereas the experimental group received a combination therapy of modified Danzhi Xiaoyao Powder with individualized dosage adjustments based on symptom presentation. After a three-month intervention period, therapeutic efficacy, bone metabolism parameters, and thyroid function indicators were compared between the two groups. The results demonstrated a significantly higher total effective rate in the experimental group compared to the control group ($P<0.05$). The experimental group exhibited decreased levels of relevant indicators, while parathyroid hormone and thyroid-stimulating hormone levels were elevated compared to the control group ($P<0.05$). Moreover, the SF-36 quality of life scores in the experimental group showed significant improvements across eight dimensions, including physical function and social role (all $P<0.05$), with no significant difference in the incidence of adverse reactions between the two groups ($P>0.05$). This study suggests that Danzhi Xiaoyao Powder enhances the therapeutic efficacy of methimazole by modulating thyroid hormone secretion, regulating bone metabolism, and ameliorating immune dysregulation, concurrently alleviating clinical manifestations such as goiter.

Tian linying et al [18]. conducted a randomized controlled trial involving 98 patients with hyperthyroidism, allocated equally to a treatment group (modified Danzhi Xiaoyao San combined with methimazole, n=49) and a control group (methimazole monotherapy, n=49). Doses were titrated based on clinical symptomatology in the treatment arm. After a 4-week intervention, the treatment group demonstrated superior therapeutic outcomes, with a significantly higher total efficacy rate (91.84% vs. 83.67%, $P<0.05$). Biochemical evaluations revealed marked reductions in free triiodothyronine (FT3) and free thyroxine (FT4) levels in the treatment cohort, surpassing improvements observed in controls (both $P<0.05$). Immunological profiling indicated a pronounced decline in thyroid-stimulating hormone

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receptor antibody (TRAb) titers within the treatment group compared to controls ($P<0.05$). The findings underscore that Danzhi Xiaoyao San potentiates methimazole's therapeutic effects through tripartite mechanisms: regulation of thyroid hormone secretion, suppression of autoimmune activity (evidenced by TRAb reduction), and mitigation of thyroid structural anomalies.

5. Advantages of Combined Therapy

In clinical practice, adverse effects from the sole application of Western pharmaceuticals are frequently encountered. Moreover, the recurrence rate of hyperthyroidism remains notably elevated post-treatment. The integration of TCM and Western medicine, however, underscores the combined application of TCM's syndrome differentiation and treatment principles with Western pharmacological interventions. Specifically, this approach involves an initial TCM-based syndrome differentiation to guide targeted treatment, followed by the concurrent use of low-dose antithyroid drugs for comprehensive management. TCM emphasizes a holistic perspective; for instance, Danzhi Xiaoyao San addresses the condition through multiple pathways, including soothing the Liver to regulate Qi, clearing Heat and purging Fire, and strengthening the Spleen to nourish Blood, thereby improving the patient's overall constitution. Antithyroid drugs, on the other hand, directly act on the thyroid gland to inhibit the synthesis of thyroid hormones. This combined approach achieves an organic integration of holistic regulation and localized treatment, effectively controlling the symptoms and signs of hyperthyroidism while simultaneously adjusting the body's Yin-Yang balance, thereby enhancing the patient's overall health. Furthermore, clinical research findings indicate that the combined therapeutic approach demonstrates superior efficacy in reducing thyroid hormone secretion, decreasing thyroid volume, and alleviating symptoms compared to monotherapy. Through the synergistic effects of both modalities, the treatment outcomes for hyperthyroidism are enhanced, potentially shortening the treatment duration, reducing the patient's time commitment and financial burden, and ultimately improving patient satisfaction, thus yielding considerable benefits.

6. Issues Identified

Current clinical investigations into the application of Danzhi Xiaoyao San in conjunction with antithyroid medications for the management of hyperthyroidism, especially in patients exhibiting liver-qi stagnation with heat transformation, are limited by small sample sizes. The lack of multi-center, large-sample, randomized, double-blind controlled trials compromises the strength of the research findings. Furthermore, certain studies lack comprehensive observational metrics, specifically the assessment of long-term efficacy and recurrence rates, thereby impeding a thorough evaluation of the combined treatment's effects. While some understanding of the synergistic mechanisms of Danzhi Xiaoyao San and antithyroid drug co-administration exists, it remains incomplete. Research in critical areas, such as the specific drug targets and implicated signaling pathways, is relatively sparse. This scarcity of data restricts a deeper understanding of the combined treatment's mechanism and hinders drug optimization and innovation.

7. Conclusion

This investigation provides a systematic evaluation of the integrative approach combining DZXYS with antithyroid drugs for treating hyperthyroidism characterized by liver Qi stagnation transforming into heat, a defined TCM syndrome. The study delineates the clinical presentation and pathophysiological mechanisms of hyperthyroidism while elucidating the pharmacodynamic properties of DZXYS, including its principal constituents and their synergistic effects on hepatic Qi regulation, heat clearance, and blood nourishment. Concurrently, the mechanistic basis of conventional antithyroid therapy—primarily thyroperoxidase (TPO) inhibition and suppression of thyroid hormone synthesis—is contextualized within the integrative framework.

The combined therapeutic strategy capitalizes on complementary paradigms: TCM's holistic modulation of neuroendocrine-immune networks and Western medicine's targeted suppression of thyroid hyperactivity. Clinical findings demonstrate enhanced therapeutic efficacy through multilevel interactions, including accelerated symptom alleviation, reduced thyrotoxicosis-related complications, and improved quality-of-life indices. Specifically, this integration mitigates inherent constraints of monotherapy, such as drug-induced hepatotoxicity and relapse susceptibility, by restoring Yin-Yang equilibrium while sustaining biochemical control.

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While both TCM and Western medicine present unique strengths and weaknesses in the management of hyperthyroidism, their integration demonstrates considerable clinical promise. Current limitations encompass inadequate mechanistic elucidation and a lack of standardized protocols. Future high-quality clinical trials and in-depth investigations into molecular interactions are crucial for refining this paradigm, thereby advancing precision-oriented, patient-centered therapeutic strategies for hyperthyroidism.

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