

Research Progress on the Treatment of Type 2 Diabetes Mellitus Combined with Non-alcoholic Fatty Liver Disease by Traditional Chinese Medicine

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Abstract: *The prevalence of type 2 diabetes mellitus (T2DM) combined with non-alcoholic fatty liver disease (NAFLD) has been increasing in recent years, and more and more clinical attention has been paid to it. The two diseases often accompany each other and promote each other's disease processes, and insulin resistance may be a key factor in the pathogenesis of the two diseases. At present, the clinical treatment of western medicine mainly includes regulating blood glucose and insulin resistance, improving lipid accumulation, and improving liver function. Compared with western medicine, TCM treatment has more advantages in efficacy, side effects, and safety. Based on expert monograph, and ancient and modern literature, the author summarizes the etiology, pathogenesis, syndrome differentiation, and treatment, and further elaborates the diagnosis so as to put forward the prospect for the establishment of follow-up guidelines.*

Keywords: Type 2 diabetes, Nonalcoholic fatty liver disease, Traditional Chinese medicine treatment, Etiology and pathogenesis, Treatment based on syndrome differentiation.

1. Introduction

Nonalcoholic fatty liver disease (NAFLD) is a major cause of chronic liver disease, characterized by hepatic steatosis not caused by other liver diseases, excessive alcohol consumption, or viral hepatitis [1]. Currently, the global prevalence of NAFLD is approximately 32%, and it is estimated to increase by up to 56% by 2030 [2]. Epidemiological data show that NAFLD is closely associated with Type 2 Diabetes Mellitus (T2DM) [3]. A recent global meta-analysis revealed that the prevalence of NAFLD in T2DM patients is as high as 65.04%-68.15%, and in China, this figure reaches 52.56% [4], suggesting a close relationship between the two. T2DM can cause liver function impairment in NAFLD patients and even further progress to nonalcoholic steatohepatitis (NASH), cirrhosis, and hepatocellular carcinoma. Meanwhile, NAFLD can also make blood glucose control more difficult in diabetic patients and increase the risk of kidney and heart diseases in T2DM patients [5].

Insulin resistance (IR) is a common pathophysiological mechanism of NAFLD and T2DM. On the one hand, IR reduces insulin sensitivity and insulin receptor activity, thereby causing disorders in hepatic glucose and lipid metabolism and leading to hyperglycemia. On the other hand, IR also excessively stimulates hepatic fat production, resulting in excessive generation of serum free fatty acids (FFA), inhibiting hepatocellular oxidation, and ultimately causing hepatic steatosis [6-8]. In current Western medicine treatment of NAFLD, in addition to conventional drugs for liver protection, lipid lowering and enzyme reduction, some hypoglycemic drugs have also been proven to reduce visceral fat and improve lipid metabolism, such as Glucagon-like peptide 1 receptor agonists (GLP-1RAs), sodium-glucose cotransporter 2 inhibitors (SGLT2i), thiazolidinediones (TZD), etc [9,10]. These drugs have been confirmed to improve the clinical indicators of NAFLD, but their mechanisms of action and side effects are still not fully clear.

Therefore, safer and more effective treatment methods for this disease are needed. Traditional Chinese medicine has shown advantages in the treatment of T2DM combined with NAFLD due to its obvious curative effect and few side effects.

2. Etiology and Pathogenesis

The pathogenesis of "xiaoke" (consumptive thirst) complicated with "ganpi" (liver concretions) is closely related to the liver and spleen [11]. As stated in Su Wen·Bi Lun ("Plain Questions·Treatise on Obstruction Diseases"): "Excessive eating harms the intestines and stomach." Wen Re Jing Wei ("Compilation of Warm and Heat Diseases") also notes: "Prolonged inactivity leads to spleen stagnation; when spleen qi stagnates and fails to transport properly, fluid retention and damp accumulation occur." Excessive consumption of greasy and rich foods, or imbalance between work and rest, can block the spleen and stomach's transportation and transformation functions. Patients with "xiaoke" often have excessive drinking and eating, which causes the spleen to lose its healthy transportation, leading to fluid retention transforming into dampness, which further accumulates into phlegm. This phlegm condenses in the liver collaterals, resulting in the disease. Currently, clinical physicians hold varying views on this disease. Xie Bingxin and others [7] believe that the disease is characterized by a pattern of "root deficiency and branch excess": spleen deficiency is the fundamental cause, liver stagnation is the key factor, while blood stasis and phlegm-dampness run through the entire course. In treatment, they emphasize reinforcing deficiency and reducing excess, with a focus on soothing the liver, strengthening the spleen, resolving phlegm, and dispelling stasis. Shi Liwei and others [12], summarizing previous insights, propose that the disease's causes mainly include congenital insufficiency, improper diet, emotional disorders, and excessive work or rest. Its pathogenesis is primarily attributed to liver stagnation and spleen deficiency, which impair the liver's dispersing function and the spleen's

transporting ability. This leads to water-damp retention, dysfunction of triple energizer's qi transformation, fluid stagnation, excessive internal phlegm-dampness, and stagnation transforming into heat. Over time, blood circulation becomes sluggish, resulting in intermingled phlegm and stasis, which causes the disease. A prolonged course further progresses to liver-kidney yin deficiency or spleen-kidney yang deficiency. Liu Huaizhen and others [13] also consider the disease as "root deficiency and branch excess," with liver stagnation, spleen deficiency, and phlegm-damp obstruction as its pathogenesis. Improper diet damages the spleen and stomach, leading to deficient spleen transportation, inability to excrete water-damp, and its condensation into phlegm. Alternatively, emotional internal injury causes liver qi stagnation, impairing food digestion, with stagnation transforming into heat and consuming yin fluid. Long-term spleen deficiency leads to internal generation of phlegm-dampness, obstructed circulation of qi, blood, and body fluids, and blood vessel stasis. Eventually, phlegm, stagnation, deficiency, and stasis together contribute to the disease. In terms of treatment principles, they advocate simultaneous treatment of the root and branch, believing that soothing the liver, strengthening the spleen, resolving phlegm, and dispelling stasis yield remarkable effects in treating this disease.

To sum up, the author concludes that most physicians believe this disease is characterized by root deficiency and branch excess, with the main disease locations in the liver, spleen, stomach, and gallbladder, and involving the kidney in the later stage. The etiologies are mostly related to improper diet, emotional disturbances, imbalance between work and rest, and congenital insufficiency. The pathological factors include qi stagnation, phlegm-dampness, and blood stasis. The pathogenesis is that the spleen fails to transport properly and the liver fails to disperse, leading to accumulation of phlegm-fluid, which stagnates and transforms into heat, scorching body fluids, blocking the collaterals, or causing malnutrition in the later stage, resulting in deficiency of both yin and yang, thus giving rise to the disease [14, 15]. Regarding the treatment principles, due to the transformation of root-branch and deficiency-excess in this disease, physicians have different views, but the main treatment methods can be summarized as "soothing the liver and strengthening the spleen, resolving phlegm and dispelling stasis, while focusing on replenishing qi, nourishing yin and promoting the production of body fluids".

3. Syndrome Differentiation and Classification

Currently, clinical physicians have their own opinions on the TCM syndrome differentiation and treatment of T2DM combined with NAFLD, and no recognized treatment guidelines have been established. Therefore, based on the previously released TCM diagnosis and treatment guidelines for T2DM and NAFLD [16-19] and the understandings of various physicians, the author summarizes the syndrome differentiation types of T2DM combined with NAFLD as follows.

The summarized classifications mainly draw on expert monographs [12] and high-quality clinical randomized controlled trials. Among them, Zhang Zhongyong and others

[20] classified T2DM combined with NAFLD into: qi-yin deficiency syndrome, liver-kidney yin deficiency syndrome, spleen-stomach damp-heat syndrome, liver stagnation and spleen deficiency syndrome, qi-yin deficiency with blood stasis syndrome, and phlegm-stasis intermingled syndrome. They conducted data analysis on 176 clinical cases of diabetic patients with fatty liver included in the clinical trial, and the results showed that the liver stagnation and spleen deficiency syndrome had the highest incidence rate, followed by the liver-kidney yin deficiency syndrome and the qi-yin deficiency with blood stasis syndrome. Fan Yidan and others [21] performed SPSS data analysis on 147 clinical patients diagnosed within 2 years, and the conclusion showed that among T2DM patients with NAFLD, the main syndrome types were liver-kidney yin deficiency and qi-yin deficiency with blood stasis syndrome, followed by qi-yin deficiency, qi deficiency and blood stasis, spleen-stomach damp-heat, and lung heat with fluid consumption syndrome. Gao Tianshu and others [22] analyzed 88 newly diagnosed clinical patients with T2DM combined with NAFLD through data analysis, and the results indicated that damp-heat retaining the spleen (34.10%) and qi-yin deficiency syndrome (27.27%) were the main syndromes, followed by yin deficiency with excessive heat (11.36%) and blood stasis in collaterals syndrome (11.36%). Zhang Qiang and others [23] conducted cluster analysis on 200 clinical patients with T2DM combined with NAFLD, and the results suggested that the main syndromes of the patients were kidney yin deficiency (34%) and internal accumulation of damp-heat syndrome (33%), followed by phlegm-stasis intermingling (22%) and liver qi stagnation syndrome (11%).

4. Traditional Chinese Medicine Treatment

4.1 Treatment with Herb Pairs and Herb Clusters

Professor Bai Jinshang [24], based on 40 years of clinical experience, summarized the following herb pairs, mainly including *Scutellaria baicalensis* - *Bupleurum chinense*, *Coptis chinensis* - *Zingiber officinale* (dried ginger), *Poria cocos* - *Cinnamomum cassia*, *Curcuma aromatica* - *Curcuma longa*, stir-fried *Atractylodes lancea* (with bran) - *Alisma orientale*, *Artemisia capillaris* - *Polygonum cuspidatum*, and *Polygonum multiflorum* - *Salvia miltiorrhiza*. National TCM Master Professor Lü Renhe proposed the herb cluster of *Panax ginseng* - *Coptis chinensis* - *Panax notoginseng* in clinical practice for treating patients with T2DM combined with NAFLD. Xiao Yao and others [25] further explored the mechanism of action of this herb cluster based on network pharmacology. Among them, ginseng extract can activate the AMPK signaling pathway and inhibit the expression of binding proteins, thereby reducing hepatic steatosis, inflammation, and insulin resistance (IR). The decoction of *Coptis chinensis* can protect insulin through multiple pathways, and also treat NAFLD by inhibiting inflammation and oxidative stress, activating autophagy, and regulating cholesterol metabolism pathways. *Notoginseng* total saponins can inhibit oxidative stress, regulate the production of tumor necrosis factor- α , and improve IR and NAFLD through the nuclear factor- κ B signaling pathway. All three have the functions of reducing IR and hepatic steatosis; therefore, the combined use of the *Panax ginseng* - *Coptis chinensis* - *Panax notoginseng* herb cluster can achieve more significant effects in the treatment of T2DM combined with NAFLD.

To sum up, most herb pairs adopt the approaches of “one clearing and one dispersing”, “simultaneous application of warming and purging”, “purging with concurrent tonifying”, and “dissipating blood stasis without damaging healthy qi”. Herb pairs and herb clusters are mostly composed of tonifying, blood-activating and stasis-dissipating, heat-clearing and dampness-eliminating herbs. The combined application of herb pairs and herb clusters can achieve complementary advantages, improve the level of clinical prescription formulation, and help enhance the efficacy of clinical medication. However, the molecular mechanisms of the actions of herb pairs, herb clusters, and individual herbs are still incomplete, and further promotion of their clinical trials is needed to provide a better basis for later clinical treatment.

4.2 Syndrome Differentiation-based Treatment

Clinically, some physicians also classify and diagnose this disease based on syndrome types and provide corresponding therapeutic principles, methods, formulas, and medicines. Among them, Qi Hebin [26] believes that this disease is generally characterized by root deficiency and branch excess, where the root deficiency refers to liver and spleen qi deficiency, and the branch excess includes phlegm, dampness, stasis, and qi stagnation. Based on this, he classifies T2DM combined with NAFLD into 4 types: 1) dampness-heat accumulation syndrome, treated with modified Longdan Xiegan Decoction; 2) qi stagnation and blood stasis syndrome, treated with modified Chaihu Shugan Powder; 3) spleen deficiency with excessive dampness syndrome, treated with modified Qiwei Baizhu Powder; 4) phlegm-stasis obstruction syndrome, treated with modified Wendan Decoction. Cheng Xiuping and others [27] treat the disease from the perspective of the spleen, excelling in treating it starting from the spleen and stomach. They classify the disease into 4 types accordingly: 1) spleen deficiency and liver stagnation syndrome, treated with modified Xiangsha Liujunzi Decoction combined with Xiaoyao Powder; 2) spleen deficiency with dampness-heat syndrome, treated with modified Xiangsha Liujunzi Decoction combined with Huopu Xialing Decoction; 3) spleen deficiency with intermingled phlegm and stasis syndrome, treated with modified Xiangsha Liujunzi Decoction combined with Wendan Decoction; 4) spleen deficiency with phlegm-stasis blocking collaterals syndrome, treated with modified Xiangsha Liujunzi Decoction combined with Xuefu Zhuyu Decoction. Wang Lijun and others [28] believe that this disease is mostly related to qi stagnation, blood stasis, phlegm-dampness, and turbid toxin, and thus classify it into 4 types: 1) liver qi stagnation syndrome, treated with modified Sini Powder; 2) internal accumulation of dampness-heat syndrome, treated with modified Longdan Xiegan Decoction; 3) internal obstruction of phlegm-dampness syndrome, treated with modified Baizhu Powder; 4) blood stasis blocking collaterals syndrome, treated with modified Taohong Siwu Decoction. Shi Liwei and others [12] hold that T2DM combined with NAFLD in the early stage is characterized by liver qi stagnation and liver stagnation with spleen deficiency, and prolonged untreated conditions can lead to liver-kidney yin deficiency and spleen-kidney yang deficiency. They thus classify the disease into 7 types: 1) liver qi stagnation syndrome, treated with

Chaihu Shugan Powder; 2) liver stagnation and spleen deficiency syndrome, treated with Xiaoyao Powder; 3) internal obstruction of phlegm-dampness syndrome, treated with Pingwei Powder combined with Erchen Decoction; 4) internal accumulation of dampness-heat syndrome, treated with Yinchenhao Decoction; 5) intermingled phlegm and stasis syndrome, treated with Ge Xia Zhuyu Decoction; 6) liver-kidney yin deficiency syndrome, treated with Qiju Dihuang Pill; 7) spleen-kidney yang deficiency syndrome, treated with modified Fuzi Lizhong Pill.

4.3 Acupuncture and Moxibustion Therapy

Acupuncture and moxibustion therapy has advantages such as quick effect and no side effects. However, there are relatively few clinical studies on acupuncture treatment for T2DM combined with NAFLD. In current research, the spleen-strengthening and dampness-eliminating formula [29] has been proven to have a positive effect in treating patients with T2DM combined with NAFLD. Based on this, He Dongying and others [30] studied the clinical efficacy of electroacupuncture combined with this formula. On the basis of conventional Western medicine treatment, 72 patients in the observation group were given electroacupuncture combined with the spleen-strengthening and dampness-eliminating formula, while 68 patients in the control group were given the spleen-strengthening and dampness-eliminating formula alone. The acupoints needed included Ganshu (BL18), Taichong (LR3), Zusanli (ST36), Pishu (BL20), Fenglong (ST40), etc. The results showed that needling the above acupoints with electroacupuncture stimulation combined with medication could improve the patients' clinical symptoms, with a total effective rate of 93.06%, which has practical value. Xue Li and others [31] adopted the spleen and stomach regulating acupuncture method to treat 30 clinical patients with T2DM combined with NAFLD. They needled acupoints such as Quchi (LI11), Hegu (LI4), Fenglong (ST40), Diji (SP8), Zusanli (ST36), Yinlingquan (SP9), Sanyinjiao (SP6), etc., and used different reinforcing and reducing manipulations respectively. After 1 month of treatment, the symptoms of the treatment group improved significantly, with a total effective rate of 86.2%, which could improve patients' insulin resistance, regulate glucose and lipid metabolism, and protect liver cells.

5. Conclusion

To sum up, the author summarizes the views of existing physicians in order to improve and standardize the TCM clinical syndrome differentiation and classification as well as TCM treatment guidelines. Based on this, it is expected to further promote large-scale, multi-center, and prospective clinical studies, improve the pathogenesis of this disease, and advance clinical integrated traditional Chinese and Western medicine treatment. At the same time, efforts should be made to promote the development of TCM characteristic treatments such as Chinese herbal compounds, Chinese patent medicine preparations, and acupuncture and moxibustion, so as to give full play to the advantages of TCM treatment and improve the TCM diagnosis and treatment system for T2DM combined with NAFLD.

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