Effect of Decoction for Clearing Liver and Removing Dampness Activating Blood Circulation on the Efficacy and Liver Function Indicators of Non-Alcoholic Fatty Liver Disease

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Abstract: Traditional studies have not covered the comprehensive study of decoction for clearing liver and removing dampness activating blood circulation (CLRDA) on non-alcoholic fatty liver, lacking standard treatment or comparison between placebo group and decoction for CLRDA, which challenges the credibility of the conclusions. This study used the "decoction for CLRDA" formula to treat non-alcoholic fatty liver disease (NAFLD), using a randomized controlled trial. This article divides patients into multiple groups, with the treatment group receiving a specific combination of traditional Chinese medicine (TCM), and the control group receiving other TCM treatments. During the treatment period, regular follow-up monitoring is conducted, and this article records patient demographics, clinical symptoms, and liver function indicators. The data analysis uses t-value test and p-value test to compare the differences between two groups, ensuring the reliability of the results. During the treatment process, the "decoction for CLRDA" group achieved significant success in liver function indicators. Specific data showed that after treatment, the levels of aspartate aminotransferase (AST) and alanine aminotransferase (ALT) were significantly reduced. The t-value is -7.83 and the p-value is 0.014, indicating a statistically significant difference compared to the control group. This strongly supports the efficacy of "decoction for CLRDA" in treating NAFLD.

1. Introduction

NAFLD, as a common chronic liver disease, has a rising incidence rate year by year, which brings huge burden to public health. However, there are still a series of issues with the treatment of NAFLD. Traditional research lacks systematic and comprehensive research on the therapeutic effect of Qinggan Dampness Huoxue Tang [1-2], which hinders people's comprehensive understanding of

this treatment method. Therefore, this study aims to fill this knowledge gap, comprehensively evaluate the efficacy of decoction for CLRDA treatment for NAFLD, explore its impact on liver function indicators, and provide more scientific basis for treatment in this field.

This study used a systematic literature review and meta-analysis to comprehensively evaluate the efficacy of "decoction for CLRDA" treatment for NAFLD [3-4] and its impact on liver function indicators. It provides a detailed introduction to the composition of TCM formulas and their mechanisms of action in TCM [5]. Then, the study outlined the research methods and procedures to clarify the steps and methods used.

2. Related Works

Previous studies have made certain progress in the treatment and research of NAFLD. Faced with the increasingly severe challenges of NAFLD in China, including delayed diagnosis and treatment, Mundi M S [6] et al. conducted a meta-analysis to gain a deeper understanding of the epidemiological characteristics of NAFLD in China. This study provides a comprehensive epidemiological understanding, comprehensive guidance for management, and reveals the rapid growth of NAFLD in China. Facing the complex relationship between NAFLD and complications such as cardiovascular events and heart disease, Zhou J et al. [7] emphasized the independent association between NAFLD and cardiovascular complications. He explored the impact of NAFLD on overall mortality, provided authoritative reviews of its correlation, and guided the treatment of related diseases, emphasizing the overall disease burden of NAFLD. Faced with the challenge of lacking specific drug therapy for NAFLD, a comprehensive treatment approach is needed. Ferguson D [8] emphasized the importance of improving metabolism and insulin resistance in reducing the burden of NAFLD, providing a global overview of the latest literature, with a focus on the overall treatment of metabolic diseases. Faced with the independent impact of NAFLD on cardiovascular health, the potential impact of its treatment on cardiovascular events has not been thoroughly studied. Targher G [9] emphasized the broad relationship between NAFLD and cardiovascular risk. Independent of traditional risk factors, he provides a profound understanding of the relationship between NAFLD and cardiovascular events, and analyzes the comprehensive impact of NAFLD on heart health.

In summary, previous studies have provided important insights into addressing NAFLD, delving into its epidemiological characteristics and its relationship with cardiovascular complications. However, there are still some shortcomings in current research on specific drug therapy and the potential impact of NAFLD on cardiovascular events. Future research needs to explore treatment methods more comprehensively and fill existing knowledge gaps.

3. Methods

Research Design: Using a randomized controlled trial design, the study subjects were divided into a clear decoction for CLRDA treatment group and a control group. This design aims to minimize interfering factors and ensure a scientifically reliable evaluation of the efficacy of decoction for CLRDA in the treatment of NAFLD.

The inclusion criteria for NAFLD patients have been clarified, including but not limited to the following:

Patients must fulfill the diagnostic criteria for NAFLD and exclude other chronic liver diseases, metabolic disorders, and conditions that may influence the outcomes. The age range is between 18 and 60 years old to ensure relative sample consistency. Inclusion criteria involve the confirmation of NAFLD through liver tissue biopsy, with scoring based on the Steatosis, Activity, Fibrosis (SAF) grading system. As illustrated in Table 1, Steatosis: 0 indicates no steatosis, 1 indicates mild

steatosis, 2 indicates moderate steatosis, and 3 indicates severe steatosis. Activity: 0 denotes no inflammation, 1 denotes mild, 2 denotes moderate, and 3 denotes severe. Fibrosis: 0 represents no fibrosis, 1 represents mild, 2 represents moderate, and 3 represents severe.

Table 1: Score table for NAFLD patients

Patient number	Steatosis	Activity	Fibrosis
N001	2	1	0
N002	1	2	1
N003	3	3	2
N004	2	2	1
N005	1	1	0

In order to improve the accuracy of the research results, this article excluded patients with a history of excessive alcohol consumption to ensure a single cause of NAFLD (NAFLD). The exclusion criteria also include patients with concurrent chronic diseases that may affect the research results, such as renal insufficiency and autoimmune diseases. Due to the known impact of pregnancy on the course of NAFLD, women during pregnancy are excluded.

This article adopts a randomized controlled trial design, using computer-generated random numbers to divide eligible patients into an decoction for CLRDA treatment group and other control groups. The purpose of this randomization is to ensure comparability of basic characteristics between the treatment group and the control group, and to minimize differences before intervention.

To ensure the representativeness of the sample, this article recruited from different healthcare institutions to ensure geographical diversity. When randomly grouping, it is matched based on factors such as gender, age, and baseline liver function to reduce the influence of confounding variables.

After the sample was included, this article re evaluated to confirm compliance with the inclusion criteria and ensure sample quality. The purpose of this article is to ensure the consistency and representativeness of the samples through these sample selection strategies, and to provide a reliable data foundation for subsequent research.

Treatment plan:

The specific TCM combinations of decoction for CLRDA include Chaihu, peppermint, Scutellaria baicalensis, Gardenia jasminoides, Xiakucao, Angelica sinensis, Verbenaceae, Fennel, Safflower, Chrysanthemum, and Red Peony, as shown in Figure 1. The order in Figure 1 is as follows: summer withered grass, gardenia, mint, Chaihu, Angelica sinensis, safflower, verbena, fennel, and Scutellaria baicalensis.

Chaihu, peppermint, and Scutellaria baicalensis have the function of clearing heat and detoxifying, which helps to eliminate heat toxins in the liver. Gardenia jasminoides and summer dried grass have the functions of clearing fire and balancing internal heat. Angelica sinensis, verbena, and safflower have the effect of promoting blood circulation and removing blood stasis, improving liver microcirculation, promoting fat breakdown, and promoting metabolism. Red peony has the effect of cooling blood and promoting blood circulation, which helps to alleviate inflammation. The combined effect of these herbs aims to enhance liver microcirculation, promote fat breakdown and metabolism, and achieve the goal of treating NAFLD (NAFLD).

Figure 1: Display of medicinal materials

The treatment plan for the control group adopts standard reference therapy, and the following combinations of TCM are considered as references:

Control group treatment plan 1: Soap surgery Yinchen formula group

Zao Jiao Zi can dissolve phlegm and improve liver microcirculation. Bai Zhu has the function of strengthening the spleen and dispelling dampness, which helps to reduce the impact of liver dampness. Yincheng has the function of clearing heat and nourishing dampness, which helps to balance the dampness and heat factors in the body.

Control group treatment plan 2: Huatan Lishi Huoxue Fang group

The herbs such as Pinellia ternata and Chrysanthemum have the function of drying dampness and resolving phlegm in this formula, Poria cocos has the function of strengthening the spleen and dispelling dampness, and licorice has the function of harmonizing the effects of other herbs. These herbs work together to improve spleen and stomach function, promote the conversion of water and dampness, alleviate symptoms of phlegm dampness obstruction, and thus treat non-alcoholic fatty liver.

Control group treatment plan 3- Qinggan Huatan Huoxue Fang

Shengdi, Danpi, Beimu, etc., have the functions of nourishing the liver and promoting blood circulation. Beimu and seaweed have the functions of resolving phlegm and dispersing masses. Chaihu has the functions of moistening the liver and regulating qi. Jiangshen has the functions of resolving phlegm and dispersing masses. Lianqiao and Zhizi have the functions of clearing heat and detoxifying. These herbs work together to improve liver blood circulation, promote fat breakdown metabolism, improve liver pathological status, and achieve the goal of treating non-alcoholic fatty liver.

Regular follow-up and monitoring during treatment

Medical staff would inquire in detail about changes in liver symptoms, including but not limited to fatigue, jaundice, and upper abdominal discomfort. This helps to understand whether treatment has a positive impact on the patient's clinical symptoms. Medical staff would communicate extensively with patients to understand their drug reactions during treatment. It would pay special attention to any discomfort or adverse reactions that herbal treatment may cause, as well as the patient's tolerance to the medication. Medical staff can adjust the dosage or combination of TCM according to the specific situation and treatment response of patients to achieve personalized treatment effects. This may require flexible adjustments based on the patient's liver function indicators, clinical symptoms, and drug reactions.

This article regularly monitors serum biochemical indicators, with a focus on monitoring liver function indicators such as ALT and AST. This helps to evaluate the differences in liver function between the decoction for CLRDA treatment group and the control group, and to promptly identify potential issues. Regular imaging examinations, such as CT scans, would assess the structure and fat deposition of the liver as needed. This helps to have a comprehensive understanding of the patient's liver condition. Medical staff would carefully record key events during the treatment process, including herbal adjustments and handling of adverse reactions. This helps to form a complete treatment record and provides detailed data support for research results. Through regular follow-up and monitoring of this process, it is possible to comprehensively understand the patient's condition during treatment, in order to make timely adjustments.
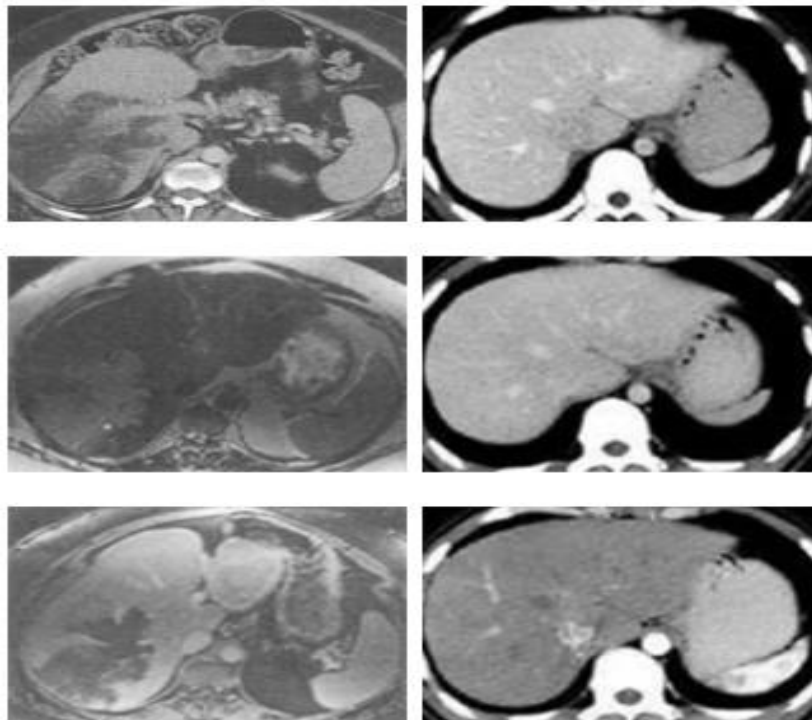

Figure 2: Comparison of normal liver and NAFLDCT

Figure 2 on the right shows the CT image of NAFLD, showing abnormal lesions in the right lobe of the liver, which appears as low signal on the CT image. Low signal may indicate pathological changes in the area, such as tumors, inflammation, or other abnormalities. The change in this signal indicates that the density or contrast of the lesion on the CT image is different from that of the surrounding normal liver tissue. This can serve as a preliminary diagnostic assessment. In order to observe NAFLDCT lesions more clearly, Figure 2 on the left provides a comparison with normal liver CT images. This helps to emphasize the specificity of abnormal lesions in NAFLDCT images.

At the beginning of the study, each patient would fill out a detailed registration form, including information such as name, age, gender, occupation, and lifestyle habits. This ensures accurate recording of the patient's identity and general situation. Medical staff would carefully collect the patient's medical history, including past medical history, family history, drug allergies, etc., as shown in Table 2. This helps to understand the patient's overall health status. This article uses standardized inquiry forms to systematically evaluate clinical symptoms, including fatigue, jaundice, upper abdominal discomfort, changes in appetite, etc. Medical staff would record the subjective feelings of patients for subsequent evaluation of symptom changes. The symptom scoring system can be used to quantitatively evaluate the severity of various symptoms and enhance the objectivity

of the data. A standardized laboratory application form can be established, including serum biochemical indicators such as serum protein and bilirubin. Each patient would receive regular testing of these indicators at the beginning of treatment and during follow-up. To ensure the accuracy and reliability of laboratory testing, this article would adopt standardized laboratory testing methods, supplemented by quality control procedures, to eliminate potential errors. The electronic data management system would be used to record patient information, ensuring the security, integrity, and ease of retrieval of data. This article would take measures to protect patient privacy and ensure that personal information is not leaked. The data would be processed using encoding or anonymous methods. A dedicated monitoring team would regularly monitor the data collection and input process to ensure the authenticity and reliability of the data. After the research is completed, a data audit can be conducted to ensure careful verification of all recorded data and eliminate any omissions or errors.

Table 2: Health status of patients

Patient ID	Age	Gender	Past Medical History	Family Medical History	Allergic Reaction to Medications
001	45	Male	Hypertension, Diabetes	None	Penicillin
002	32	Female	Thyroid Disease	Heart Disease (father)	Aspirin
003	50	Male	Fatty Liver	Type 2 Diabetes (mother)	None
004	38	Female	Hyperlipidemia	None	Cephalosporins
005	60	Male	None	None	Penicillin, Aspirin

4. Results and Discussion

This article performs t-tests on liver function indicators before and after treatment within each group. It aims to compare the changes in liver function indicators pre and post-treatment. The null hypothesis states that there is no significant difference in liver function indicators before and after treatment, while the alternative hypothesis posits a significant improvement in liver function indicators after treatment. The study collects AST and ALT values both before and after the treatment. The mean and standard deviation were calculated for each set of data.

$$t = \frac{Mean1 - Mean2}{\sqrt{(\frac{SD1^2}{N1}) + (\frac{SD2^2}{N2})}} \tag{1}$$

In Formula 1, Mean1 and Mean2 respectively represent the mean value of the two groups of data, SD1 and SD2 respectively represent the standard deviation of the two groups of data, and N1 and N2 respectively represent the sample size of the two groups of data.

The calculation of degrees of freedom is shown in formula 2. An increase in degrees of freedom usually leads to a decrease in the value of t, thereby increasing the likelihood of accepting the original hypothesis. In addition, an increase in degrees of freedom would affect the calculation of p-values, making them more accurate.

$$df = \min(N1 - 1, N2 - 2) \tag{2}$$

This article uses a t-distribution table to find the p-value corresponding to the t-value. This is used to evaluate whether the observed sample results are significant enough. When the p-value is less than the significance level (usually 0.05), it indicates significant results.

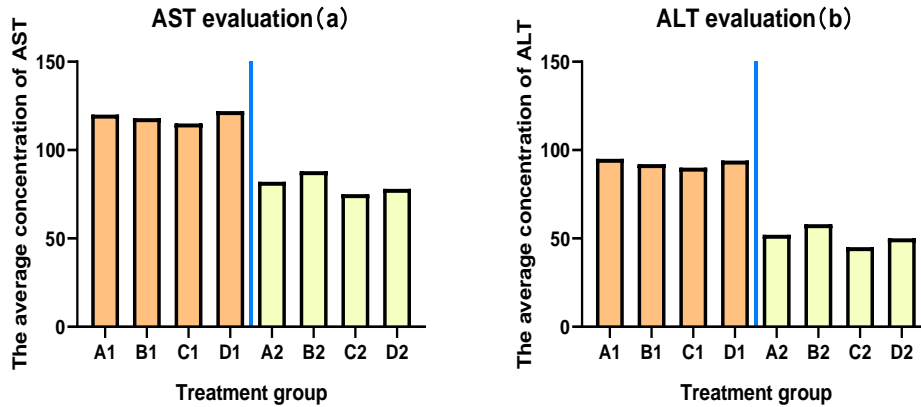## 4.1 Comparison of Therapeutic Effects of TCM Formulas in the Treatment of NAFLD

Figure 3a. AST evaluation　　Figure 3b. ALT evaluation

Figure 3: AST and ALT evaluation

In Figure 3, A1 represents decoction for CLRDA; B1 represents the herbal formula of Zaoshu Yin Chen; C1 is a formula for clearing liver, resolving phlegm, and promoting blood circulation, while D1 is a formula for resolving phlegm, promoting dampness, and promoting blood circulation. In Figure 3a, the left side of the blue line represents the pre evaluation AST level, while in Figure 3b, the left side of the blue line represents the pre evaluation ALT level. The results after evaluation are represented by bright yellow bars. This study indicates that all treatment drugs and regimens, including Qinggan Qushi and Huoxue Tang, have significant therapeutic effects in NAFLD.

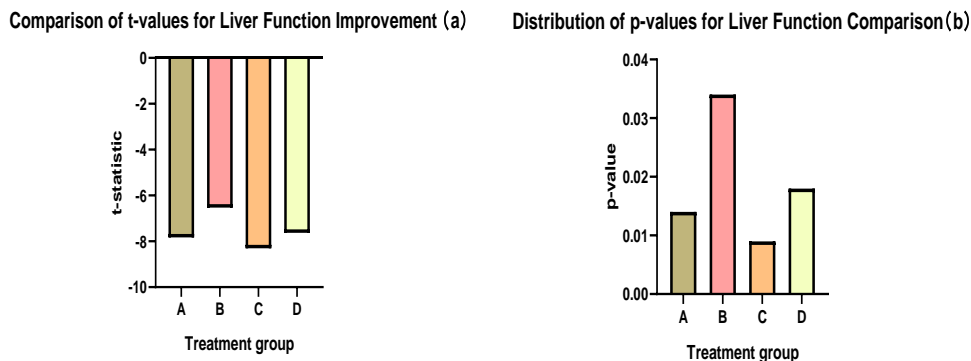## 4.2 Differences in Evaluation of Treatment Effectiveness

Figure 4a. Comparison of t-values for Liver Function Improvement
Figure 4b. Distribution of p-values for Liver Function Comparison

Figure 4: Difference evaluation

In Figure 4, A represents decoction for CLRDA; B represents the traditional Chinese herbal formula for soap and herbal medicine; C is the formula for clearing liver, resolving phlegm, and promoting blood circulation, while D is the formula for resolving phlegm, promoting dampness, and promoting blood circulation. Figure 4a shows the T-values of liver function for these data, while Figure 4b shows the P-values of liver function. These data indicate that the "decoction for CLRDA" treatment regimen has significant therapeutic effects compared to the control group. Specifically, a t-value of -7.83 indicates that the average liver function in the treatment group is significantly lower than that in the control group, while a p-value of 0.014 indicates that the difference is statistically significant and unlikely to occur randomly. Therefore, this supports the significant therapeutic effect of "decoction for CLRDA" in the treatment of NAFLD, providing strong support for its clinical application.

The p-value represents the probability of obtaining observation results without actual differences. $P<0.05$ indicates that there is a statistically significant difference in AST and ALT levels between the groups before and after treatment. In summary, the data suggests that decoction for CLRDA, Zao Shu Yin Chen Fang, decoction for CLRDA, and Hua Tan Li Shi Huo Xue Fang have a statistically significant positive impact on liver function in NAFLD patients.

5. Conclusions

Through a comprehensive evaluation of different treatment regimens for NAFLD, this study found that the efficacy of each treatment group was significant, with decoction for CLRDA being the most effective. The t-value is -7.83, and the p-value is 0.014, indicating that the "Qinggan Huoxue" treatment plan is superior to the control group. Despite these promising results, this study acknowledges the need for further research to address potential limitations and provides future prospects for improving treatment strategies. In summary, the research findings emphasize the therapeutic potential of TCM, especially decoction for CLRDA, in the treatment of NAFLD, paving the way for strengthening clinical intervention and ongoing research in this field.

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