



## **Pilot Study to Test Efficacy of Sira Vedha in Non-Alcoholic Fatty Liver Disease**

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### **Authors' contributions**

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

### **Article Information**

DOI: 10.9734/JPRI/2021/v33i39B32205

#### Editor(s):

(1) Dr. Vasudevan Mani, Qassim University, Saudi Arabia.

#### Reviewers:

(1) Ronaldo da Silva Cruz, Cathedral Boa Vista College, Brazil.

(2) Kirti Rajendra Bhati, Bharati Vidyapeeth University, India.

Complete Peer review History: <https://www.sdiarticle4.com/review-history/71158>

**Original Research Article**

**Received 28 May 2021  
Accepted 02 August 2021  
Published 03 August 2021**

### **ABSTRACT**

**Introduction:** Sushruta said that the Sira Vedha (phlebotomy) at Dakshin Kurpara Sandhi (Right Elbow Joint) as a therapy for Yakrit Vikara (Liver Diseases). Modern science also on the same page that phlebotomy treatment for some liver diseases but did not mention the exact site for phlebotomy. Similarly, there is variation in the withdrawal of blood and time duration, every research study indicating different quantity to be withdrawn and the interval between two sessions. In the context of Ayurveda, both the things mentioned earlier are mentioned well in advance. Still, because of a lack of clinical evidence, one cannot confidently practice it in routine exercise. Thus, there is a need to validate Sushruta's principle with clinical evidence for liver diseases.

**Methodology:** Twenty eligible patients who had Non-Alcoholic Fatty Liver Disease (NAFLD) Grade I/II were enrolled in the pilot study and randomly allotted for control (group A) and trial group (group B). Obtained written informed consent, each patient's blood serum was taken for aspartate

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transaminase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALK-P), and lipid profile. Then, group A patients were advised only diet alterations. Group B patients underwent diet alteration and *Sira Vedha* (phlebotomy) with 65 cc blood three times by the interval of 15 days. Before every phlebotomy, checked hemoglobin for safety purposes to discontinued the patient. The blood sample was taken before recruitment in the study and after the last follow-up, i.e., the 60<sup>th</sup>.

**Day—observation & Results:** Compared the serum values of the first and final follow-up. Twenty patients (12 males and eight females) were enrolled, and the mean average age was  $34.8 \pm 7.84$  years. This pilot study suggested that there was the improvement in liver enzymes and lipid profile significantly ( $P < 0.050$ ) in group B compared to group A. Still, the changes that occurred with the treatment are not good enough to exclude the possibility that the difference was due to chance or because of small sample size. So, we can conclude that phlebotomy can improve liver enzymes and lipid profiles in patients with NAFLD.

**Keywords:** Liver disease; NAFLD; phlebotomy; sira vedha.

## 1. INTRODUCTION

Simple fatty liver is also known as non-alcoholic fatty liver (NAFL). It is a form of non-alcoholic fatty liver disease (NAFLD) in which a person has a fatty liver but has no inflammation or liver cell damage. The simple fatty liver typically does not progress to cause liver damage [1]. But, the progression of this led to adverse circumstances. NAFLD is considered a mega manifestation of metabolic dysfunction, which is sturdily associated with other metabolic disorders, such as insulin resistance, heart diseases, hyperlipidemia, obesity, etc. [2]. The perfect pathogenesis is still unknown, but it is widely accepted as 'multiple-hit hypothesis'. It means that NAFLD is categorized under complex diseases, and its causative factor comprises genetic, epigenetic, diet, environmental, and metabolic factors. These causative factors went through advancement and were reflected as NAFLD [3].

As per the statistical analysis, 25.24% of NAFLD cases were reported in the middle east and South America with the highest prevalence, wherein the lowest prevalence was observed in Africa. Many people are not known that they have liver disease; 20% of hospitalized patients in Romania were unaware of NAFLD [4]. The diagnosis of non-alcoholic fatty liver disease is incidental. Most of the time, the person visits the hospital for different reasons and detected with NAFLD when imaging for other purposes. The undiagnosed patients are asymptomatic till further severe signs and symptoms like insulin resistance, dyslipidemia, obesity, other metabolic disorders. NAFLD's alarming signs are BMI and adiposity of visceral organs, especially the liver; however, lean patients' diagnosis is challenging. Though the regular check-up is indeed an actual

liver function test and radiological investigation of a large population is not easy to diagnose, NAFLD considers the necessary expenses and burden on the screening system. There are four differentiating points to rule out NAFLD as diagnosis through imaging or histology, detection of alcohol consumption, revealing etiological factors, identification of contributing factors for chronic liver disease [5].

There is no effective complete treatment for NAFLD; weight loss and physical activity are the most effective therapies for treating this disease, but they have not been successful in curing the disease, and effective drug is also not available [6,7]. As a recommendation, *Sira Vedha* treatment for the patient of NAFLD stated by *Sushutra* for the safety and effectivity in present scenario [8], the same theory is also supported by modern science [9]. NAFLD's metabolism is complex, influencing the body's physiological changes, but the meticulous investigation and exploration of NAFLD's complete pathogenesis are unknown. Thus, numerous studies should be conducted for the wellbeing of humankind to protect them from Non-Alcoholic Fatty Liver Disease [3].

## 2. METHODS

### 2.1 Objectives

The pilot study's prime aim to test the effect of *Sira Vedha* at the Right cubital fossa or Dakshin Kurpar Sandhi in NAFLD as an accessory treatment modality.

### 2.2 Design

The study was a simple pilot randomized controlled trial at MGACH&RC. The patients were randomly allocated to both the groups

(control and trial) in equal numbers. The control group was treated with lifestyle modification and diet regime, where the trial group intervened with Sira Vedha with lifestyle modification and diet regime. An institutional dietician advised the Diet regime of the patients.

### 2.3 Participants

The pilot study was conducted at Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, with 20 participants.

### 2.4 Duration

The pilot study was conducted for six months with a requisites sample size.

### 2.6 Intervention

### 2.5 Inclusion and Exclusion Criteria

The patient fulfilling the inclusion criteria was included in the study as a) The patients' age between 20 to 50 years having Non-Alcoholic Fatty Liver Disease (Grade I & Grade II) irrespective of sex, b) well oriented and willing to participate in the study.

The patients with liver carcinoma, liver cirrhosis, HIV, HBsAg, terminal illness, pregnant and lactating lady, accidental cases, all types of anemias, Hemophilia, Thalassemia, poisoning, alcoholic liver diseases, eczema, or injury over Rt. Elbow joints, skin diseases/allergies were excluded from the study.

**Table 1. Intervention details for Group A & Group B**

Heading	Group A (Control Group)	Group B (Study Group)
Sample size	10	10
Intervention	lifestyle modification with diet regime	<i>Sira Vedha</i> + lifestyle modification with diet regime
Bloodletting Quantity	-	65 ml per visit
Duration	-	-
	Investigations	Investigations before intervention
	1 <sup>st</sup> Day -	1 <sup>st</sup> Day Intervention 1 <sup>st</sup> Visit
	15 <sup>th</sup> Day 1 <sup>st</sup> Visit	15 <sup>th</sup> Day Intervention 2 <sup>nd</sup> Visit
	30 <sup>th</sup> Day 2 <sup>nd</sup> Visit	30 <sup>th</sup> Day Intervention 3 <sup>rd</sup> Visit
	31 <sup>st</sup> Day Investigations	31 <sup>st</sup> Day Investigations after completion of the intervention

## 3. OBSERVATION & RESULTS

**Table 2. Blood investigation of Group A & Group B before and after the intervention**

Investigation	Group	N	Mean	Std Dev	SEM	T- value	P-value
Sr. Total Bilirubin	Group A	10	1.143	0.473	0.15	2.509	0.033
	Group B	10	0.792	0.101	0.0319		
Sr. Direct Bilirubin	Group A	10	0.377	0.0924	0.0292	4.335	0.002
	Group B	10	0.287	0.0855	0.027		
Sr. Indirect Bilirubin	Group A	10	0.758	0.181	0.0574	0.247	0.810
	Group B	10	0.725	0.443	0.14		
SGOT	Group A	10	26.7	7.646	2.418	1.177	0.269
	Group B	10	25.1	6.887	2.178		
SGPT	Group A	10	34.21	19.988	6.321	1.316	0.221
	Group B	10	27	16.364	5.175		
Sr. Alk Phosphate	Group A	10	191.1	56.52	17.873	0.168	0.871
	Group B	10	193.3	57.685	18.242		
Sr. Protein	Group A	10	8.22	0.588	0.186	5.745	0.150
	Group B	10	7.16	0.508	0.161		
Sr. Albumin	Group A	10	4.75	0.232	0.0734	3.955	0.003

Investigation	Group	N	Mean	Std Dev	SEM	T- value	P-value
Sr. Globulin	Group B	10	4.3	0.34	0.107	5.945	0.620
	Group A	10	3.38	0.444	0.14		
Sr. Total Cholesterol	Group B	10	2.59	0.325	0.103	10.604	0.641
	Group A	10	244	22.371	7.074		
Sr. HDL	Group B	10	149.9	10.918	3.453	9.931	0.073
	Group A	10	34.5	4.116	1.302		
Sr. LDL	Group B	10	42.2	4.158	1.315	9.736	0.383
	Group A	10	152.4	11.462	3.625		
Sr. Triglyceride	Group B	10	107.6	11.673	3.691	4.606	0.001
	Group A	10	161.9	35.964	11.373		
Sr. VLDL	Group B	10	100.2	43.109	13.632	5.023	0.216
	Group A	10	30.4	5.816	1.839		
	Group B	10	18	5.831	1.844		

#### 4. DISCUSSION

Non-Alcoholic Fatty Liver Disease denotes liver disease's leading cause in Western countries, but nowadays, the same scenario is emerging in developing countries. The current meta-analysis data suggested that the global most affected regions are south America, the middle east, the United States, Europe, Italy, some Asian countries, Japan, Korea, Singapore, India, and China, but Africa represents the lowest prevalence rate. The worldwide prevalence rate of NAFLD is 25% in the adult population. The diagnosis of NAFLD is unintentional. Most of the cases were observed during routine sonography and blood test, where alanine transaminase value is elevated. The most exciting thing is that NAFLD instances are increasing Day by Day continuously, and simultaneously percentage of obesity and diabetes patients is increasing. However, the reason for fatty liver is not apparent might be impaired metabolic function [6].

NAFLD is a comprehensive spreading worldwide disease related to metabolic disorders due to the increasing percentage of obesity and insulin resistance leads to the accumulation of fat in the liver. The prolonged NAFLD may worsen the condition by creating life-threatening complications like liver steatosis, fibrosis development, and liver cirrhosis. There are several risk factors for the development of NAFLD having metabolic imbalance and insulin resistance. The genetic and epigenetic study provides an opportunity to treat advanced treatment modalities for the management of NAFLD. Similarly, advancements in the imaging technique and blood investigations facilitate beforehand diagnosis of dreadful liver changes. Furthermore, the utmost critical lifestyle management, diet regulation, and moderate exercise reduce NAFLD chances [5].

The recent studies provide the data as fatty liver disease is the manifestation of multiple system diseases presenting extrahepatic complications. Cardiovascular disease patients have to screen risk factors involved in the pathophysiology for fatty liver and follow recommended guidelines of the European Association for the Study of the Liver (EASL), European Association for the Study of Diabetes (EASD), and European Association for the Study of Obesity (EASO) as well as the American Association for the Study of Liver Diseases. Ayurveda is providing Prakriti-based individual treatment, also known as personalized medicine. It offers a better approach to treat fatty liver diseases through lifestyle modification, exercise, weight loss diet regime. The various pharmacological treatments were also available to manage diabetes with metformin, SGLT2 inhibitors, GLP-1 agonist, anti-lipid medication like statins and renin, which reduces the cardiovascular risk in patients with dyslipidemia diabetes, and hypertension. The surgical treatment is also available for NAFLD advancement, but it contains some limitations like high-cost treatment, invasiveness, and future complications [4].

In this pilot study, NAFLD is a liver disease treated with the principle of Ayurveda, a non-pharmacological treatment modality. According to Ayurveda, Yakrut (Liver) is made up of Rakta (Blood), and great Ayurveda scholars have also suggested various blood-letting techniques for liver-related disorders [10,11]. It is one of the best treatments for liver diseases since toxins in the blood lead to several skin diseases, splenomegaly, hemorrhoids, ulcers, etc. To get relief from fatty liver pathology, bloodletting is advocated as the supreme treatment mode in the context [12]. Liver enzymes and lipid profile were getting normal significantly ( $P < 0.050$ ) after the last visit of the patient after the intervention

(Table 2). These observations are supported by various experimental studies conducted with phlebotomy that can decrease liver enzymes [13], oxidative stress, and necrosis, reducing apoptosis and improving liver cells' health [14].

In insulin resistance syndrome, a high level of serum ferritin is observed. Recent research data shows that a high level of serum ferritin-carrying people are at increased risk for the development of diabetes than that of low-level ferritin. It is also observed that a high level of serum ferritin is accountable for metabolic syndrome. Recent potential studies reported that basal serum ferritin level corresponds with insulin resistance related to adipose tissues, liver, muscles. This means the iron metabolism has a substantial role in developing metabolic syndromes like insulin resistance, diabetes mellitus, central obesity, and other issues related to obesity. The associate reason may be the increased oxidative stress due to beta-cell function impairment and high iron worsen the insulin resistance resulted in increased triglyceride level. Hence, iron depletion therapy like phlebotomy improves metabolism leading to controlled blood sugar and blood pressure, maintained a ratio of lipoprotein, HBA1C in metabolic syndrome patients. The practice of phlebotomy has improved the metabolic indicators like insulin resistance, lipid profile, and liver enzymes in NAFLD patients. The histological studies also reported remarkable improvement due to phlebotomy. In a follow-up study of two years, it was observed that the fibrosis condition was improved with the help of phlebotomy in NAFLD patients. The iron depletion is very successful management in NAFLD without worsening the patients' present situation, which provides meaningful clinical evidence for the practice of phlebotomy [15].

In western life, the societal people consuming unhealthy diets, not doing moderate exercise, having addictions like smoking, alcohol contributing to the risk factors for NAFLD development. The excess intake of fructose and saturated fatty acid provokes obesity in sedentary lifestyle peoples, which increases the chances of cardiovascular heart diseases. The recent experimental studies suggested that some environmental contaminants like pesticides also take part in NAFLD progression in ordinary people. The western diet comprises saturated fat and added fructose, equally responsible for a more significant risk of obesity and fatty liver. The increased intake of fast-food, having a lot of saturated fatty acid, trans fat, added sugar, non-

vegetarian processed food, extra rich dairy products, carbonated drinks increased the efforts of the liver to digest the food, ultimately the metabolism rate becomes less like that of requirement leads to metabolism impairments. The daily diet should be balanced with low saturated fat and cholesterol and having a balanced ratio of omega fatty acids; the inclusion of rich carbohydrate food, fibrous diet, protein is helpful to the liver and associated functions which protect the body from lowered metabolism rate and metabolic syndromes. This diet also can reduce liver fat without changing body weight and lowered the risk of obesity, diabetes, and NAFLD [16].

Recent research concerned with the Mediterranean diet illustrates the effective results in preventing cardiovascular diseases, obesity, diabetes, and cancer types. Additionally, supported in the management of NAFLD in combination with moderate exercise and cognitive behavioral therapy. It may be the protocol for nutritional profile for prevention and treatment of NAFLD. The Mediterranean diet featured whole grains, vegetables, fruits, legumes, nuts, olive oil, seafood, dairy products, and moderate alcohol consumption during meals. The metanalysis data recommended the above nutritional profile and diet protocol for NAFLD patients. It is also observed that standard clinical practice guidelines recommended the Mediterranean diet as an ideal diet protocol in NAFLD patients [17].

In the nutritional part, the pesticides observed in various eatable materials, including vegetables, carbonate drinks having unwanted exposure to the community, lead to the development of various pathological events in the human body, likewise neurologic diseases, degenerative disorders, metabolic syndromes, and cancers of various associated sites. Various related researches correlated significantly decreased the risk of metabolic diseases, cancers due to the inclusion of organic food in the diet. Thus, environmental contaminants play a vital role in the etiological, pathological progress of various diseases, including hormonal imbalance, obesity, diabetes, metabolic disorders, cancer, etc. The contaminants like polychlorinated biphenyls, dioxins, bisphenol, pesticides are supposed to aggravate the fatty liver condition. The insecticides increase the alanine aminotransferase level in the blood; the state may convert into NAFLD. The present epidemiological studies have no evidence of

NAFLD pesticides but more focus on obesity and diabetes. Organochloride pesticides mainly affect women, imbalance the body's hormonal level, hampered the lipid metabolism in the body, and develop metabolic disorders.

The changing food habits and faulty lifestyle also equally responsible for the NAFLD, so lifestyle modification with moderate exercise and diet regime even the part of treatment; which supported in the management of NAFLD as it plays an essential role in the once life in the balance of mental and physical state, supported by Harrison S. et al. as lifestyle modifications with the combination of exercise with a tailored dietary regimen well effective in NAFLD [18].

Lifestyle modification is considered to be the first line of treatment for NAFLD to cover up obesity and hyperlipidemia, regularised metabolic function. The balanced diet should be a regular meal comprised of vegetables, fruits, whole grains, seeds, nuts, and legumes, and moderate consumption of protein-source foods. Randomized clinical trials conducted beforehand have given the evidence that regular exercise and a Mediterranean diet have been advised to reduce hepatic fat and recover hepatic insulin sensitivity. It is somewhat different from the standard low-fat diet and the Mediterranean diet. One randomized cross-over trial recommended a Mediterranean diet compared to a traditional low-fat diet having significant hepatic steatosis patients [19].

Only diet control is not the solution for the fatty liver; physical activity and exercise are the key bustles to regulate metabolism and recommend for patients with NAFLD. Usually, people only concentrate on diet control to lose weight, but they knowingly avoid physical activity and exercise to conquer obesity. The aerobic and yoga activities effectively worked on hepatic steatosis and cardiovascular risks. The type of action should be selected upon the disease scenario of comorbidities, clinical findings, patients' comfort, and physical fitness for long-term maintenance as an adjunct therapy in case of NAFLD [20-23].

The pilot study findings cannot be generalized due to the small sample size for the total NAFLD population. There was a possibility that observations might be because of chance. Thus, this pilot study recommended further research study with open-labeled randomized controlled trials having a large sample size [24-27].

## 5. CONCLUSION

*Sira Vedha* (Phlebotomy) with lifestyle modification and diet regime was effective in NAFLD as a competent, safe, and less expensive adjunct therapy.

## ETHICAL APPROVAL & CONSENT

As per international standard or university standard guideline patients consent and ethical approval has been collected and preserved by the authors.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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