Clinical Effect of Siravedha at Dakshin Kurpar Sandhi in the Management of Non-Alcoholic Fatty Liver Diseases - A Randomised Controlled Trial Protocol

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ABSTRACT

Background: *Sushruta* explained the *Sira Vedha* at *Dakshin Kurpara Sandhi* (Right Elbow Joint) as a remedy for *YakritVikara* (Liver Diseases), the same treatment was explained by modern science, but the exact site was not mentioned. Similarly, the amount to be withdrawn and interval also not revealed by previous researches. Although, in ancient science, the same was explained in the context, lack clinical evidence it was missing in the main stream. So, it is the need of time to study the principal of *Sushruta* regarding the treatment of liver diseases.

Objective: To study the effect of *Sira Vedha* at *Dakshin Kurpara Sandhi* (Right Elbow Joint) in the management of Non-Alcoholic Fatty Liver Diseases (NAFLD) as an adjuvant therapy

Material and Method: 120 patients will be randomly allotted to Group A and Group B having 60 patients in each group. Group A will be treated with only lifestyle modification and diet regime and Group B, *Sira Vedha* with lifestyle modification and diet regime. *Sira Vedha* will be done at three times by the interval of fifteen days and LFT, lipid profile and CBC investigations will be carried out concerning regular visit. The analysis will be done after the last visit of the patient for the anticipative outcome of the *Sira Vedha* in the present scenario.

Expected Results: The *Sira Vedha* with the minimum amount of bloodletting have better outcomes compared to only lifestyle management and diet regimen.

Key Words: *Sira Vedha*, Phlebotomy, NAFLD

BACKGROUND

SiraVedha (Venesection) is considered as half of the treatment of *Shalyatantra* itself, as like *BastiChikitsa* is considered in *kayachaikitsa*. *SiraVedha* is the treatment in which bloodletting is done.¹ Since many centuries' phlebotomy is practising as the most common invasive procedures in health care. In this process, blood is withdrawn by puncturing the vein to obtain a sample for analysis and diagnosis.² Which suggest that the *SiraVedha* described by *Sushruta* is same

as Phlebotomy in modern science. *SiraVedha* treatment is described by *Sushruta* in various diseases like *YakritVikar* (liver diseases). It is suggested that *Sira Vedha* should be performed at around the *Dakshin Kurpar Sandhi* (right elbow joint).³ But, the reason behind this is unexplored to date.

A research study conducted had proved that Phlebotomy is effective for non-alcoholic fatty liver disease (NAFLD) in decreasing liver cell damage and finally leads to an improvement of liver enzymes.⁴ On meta-analysis of clinical trials

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conducted by researchers proved that phlebotomy improved insulin resistance and the serum alanine aminotransferase (ALT) and HDL-C levels in NAFLD patients. The study suggested that phlebotomy can be considered as an alternative option in NAFLD patients in addition to lifestyle interventions (VeeravichJaruvongvanich, 2016).⁵ These researches on phlebotomy concerning observational parameters of liver function were carried out regarding liver enzyme irrespective to the site and interval of venesection and amount of bloodletting. *Sushruta* has mentioned the specific sites for *Sira Vedha* with respect to various diseases for treatment purpose. Regarding *YakrutVikara*, he had mentioned that *Sira Vedha* was performed at *Dakshin Kurpar Sandhi*. However, the exact *Sira* is not mentioned in the compendia.

Research evidence related to Phlebotomy about liver diseases is well established by the modern sciences. The site mentioned by WHO for phlebotomy is the median cubital vein. *Acharya Sushruta* has mentioned *Dakshin Kupar Sandhi* as a site of *Sira Vedha* in *YakritVikar* (Liver diseases). Considering the site of *Kurpar Sandhi*, the vein which is prominent and can be easily visible for puncture is the median cubital vein, which is like that mentioned by WHO. The difference lies only regarding the mention of the side (*Dakshin Kupar Sandhi*), considering the plane of the body. At the same time, the interval to withdraw the blood and quantity is not fixed or the elucidated quantity of blood in previous researches is too large to withdraw, which may directly influence on compliance rate of the patient. So, to overcome this conjugation gap in between the modern science and ancient system of Indian medicine, this study will be supportive in generating collateral evidence for the statement of *Sushruta* regarding *Sira Vedha* at *Dakshin Kupar Sandhi* in *YakritVikaras*.

MATERIALS AND METHODS

Objectives

The primary objective is to study the effect of *Sira Vedha* at Right Elbow Joint in the management of Non-Alcoholic Fatty Liver Diseases as adjuvant therapy. The secondary objectives are, a) To study the effect of *Sira Vedha* at Right Elbow Joint on Liver Function, lipid profile, CBC counting Non-Alcoholic Fatty Liver Diseases in the study group, b) To study the effect of *Sira Vedha* at Right Elbow Joint on Liver Function, lipid profile, CBC counting Non-Alcoholic Fatty Liver Diseases in the control group, c) To compare the effect of *Sira Vedha* at Right Elbow Joint by evaluating the values of Liver Function, lipid profile, CBC counting study and control group.

Design

The study will be a simple RCT at a single center institution. The patients will be equally allocated to both the groups i.e.

control and trial. There will be two groups: control that will be treated with lifestyle modification and diet regime and trial group with *Sira Vedha* and lifestyle modification and diet regime. In both groups, the diet review will be taken by an accredited dietician of the institute advising a reduced-fat low caloric diet (Figure 1). The intervention and investigation plan described as follows (Table 1)

Participants

The study will be commenced at Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha. A total of 120 patients will be recruited and allocated evenly into the two groups.

Duration

The study will be conducted for 18 months or until reached the total sample size required for the study.

Inclusion and Exclusion Criteria

Inclusion criteria for the study include a) All patients irrespective of sex-having age between 20 to 50 years with Non-Alcoholic Fatty Liver Disease (Grade I and Grade II fatty liver), b) able to give informed consent and willingness to participate in follow-up.

Exclusion criteria for the study include- patients with carcinoma of the liver, liver cirrhosis, HIV positive, HBsAg positive, terminal illness, pregnant and lactating lady, accidental cases, all types of anaemias, Hemophilia, Thalassemia, case of poisoning, alcoholic liver diseases, eczema over Rt. elbow joint, skin diseases/ allergy, injury at the right elbow joint (Figure 1).

Figure 1: Flow Chart- Methodology.

Table 1: Intervention and Investigation Plan

Heading	Group A (Control Group)		Group B (Study Group)	
Sample size	60		60	
Intervention	lifestyle modification with diet regime		<i>Sira Vedha</i> + lifestyle modification with diet regime	
Bloodletting Quantity	-		65 ml per visit	
Duration	Day 0	Investigations	Day 0	Investigations prior to intervention
	Day 1	-	Day 1	Intervention 1 st Visit
	Day 15	1 st Visit	Day 15	Intervention 2 nd Visit
	Day 30	2 nd Visit	Day 30	Intervention 3 rd Visit
	Day 31	Investigations	Day 31	Investigations after completion of intervention
Follow up	60 th day	Follow up investigations	60 th day	Follow up investigations
Total duration	120 days		120 days	

Risks for Study Procedure

There are negligible risks for this study. The *Sira Vedha* is a common procedure among the Ayurveda practice and the pre- and post-procedure care is standard as per WHO guidelines (Table 1).

Recruitment and Screening

The patients will be recruited from OPD and IPDat MGACH&RC, Salod (H), Wardha and screen with abdominal USG for Grade I & II fatty liver disease.

Patient's Evaluation and monitoring

Patients will be undergoing blood investigations before the intervention, during the intervention and at the last visit of the patients. Patient's compliance or the adverse event will be evaluated on each visit. Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Gamma-Glutamyl Transaminase, Albumin, Bilirubin, Hemoglobin, Platelet count, Serum Ferritin (SF), Transferrin Saturation, Erythrocyte Sedimentation Rate (ESR), C-Reactive Protein (CRP). Glycated Hemoglobin, Fasting Lipids, Glucose levels will be included in the blood investigations.

Informed consent process

After confirmation of the patient is appropriate for the study, informed consent will be taken for the enrollment. Prior in-

formation will be given to the patients regarding steps in the procedure, approximate recovery time after the procedure, and the follow-up visit. Probable risks and expected benefits of the *Sira Vedha* will be explained in advance, and if the patient wants, the alternative option will be given for the treatment.

The procedure of the enrolment

After obtaining informed consent and verifying inclusion-exclusion criteria, the participant will be enrolled for the study. Primary information of the patient with all investigations will be recorded in case record form concerning the patient's visit.

Randomization procedure

Concerning the suitability of the patient for enrollment in the study, the participants will be allotted randomly either to control or trial group using lottery method for randomization.

Adverse events

An adverse event means any unwanted medical state like life-threatening, fainting, shock or requires inpatient hospitalization, uncomplimentary or unintentional sign or symptom, or any observation related to the research study or not.

Sample size and Statistical analysis

Considering type II error of 10% (i.e., power of 90%) and using formal sample size calculations, a sample size of 60 patients for each group is fixed with the expected attrition rate of 10%. Pair and unpair t-test both statistical tests will be applied for the study data.

Confidentiality and storage

Ethics approval was obtained from the institutional ethics committee (IEC) at Datta Meghe Institute of Medical Sciences (Deemed to be University), Wardha. The patients will be recruited with specific code and their data will be kept confidential and will be stored in a secure system by the medical records department.

EXPECTED RESULTS

The *Sira Vedha* with the minimum amount of bloodletting has better outcomes compared to only lifestyle management and diet regimen.

DISCUSSION

The purpose of the present study is to evaluate the efficacy of *Sira Vedha* (phlebotomy) toward the improvement of liver enzymes, lipid profile and CBC related blood values

in patients with NAFLD. The results of this study will be expected to give a better outcome in the trial group, because of bloodletting in an organized manner. In the previous studies related to phlebotomy was done and have good results in NAFLD.^{6,7} But, the amount of blood and interval of bloodletting is different in the latest researches and not mentioned the fixed site of bloodletting also. This is a new pattern to study effectivity of *Sira Vedha* in controlled manner with the patients of NAFLD.⁸

Several articles related to liver health and hepatobiliary problems were reviewed. Gedam et al. studied psychiatric comorbidity, the severity of dependence and liver enzymes dysfunction among alcohol-dependent individuals.⁹ Jain et al assessed the magnitude of peripheral neuropathy in cirrhosis of liver patients from central rural India.¹⁰ Mittal and Chowdhary studied the normal measurements of the liver and spleen by ultrasonography.¹¹ Kirnake et al studied on invasive hepatic venous pressure gradient in cirrhosis.¹² Zawar et al reported a case of Management of Hepatitis B through Ayurved.¹³

CONCLUSION

The *Sira Vedha* with present methodology is the simple and cost-effective procedure for improving the status of Non-Alcoholic Fatty Liver Disease (NAFLD) with least duration.

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