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Case Report

Siddha makardwaja and bhumiamalaki (*Phyllanthus niruri*) can reverse the progression of Non Alcoholic Steato-hepatitis(NASH): Case study

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ABSTRACT

A 45-year male, a business man came to our general OPD with elevated liver enzyme with elevated fasting blood glucose report in his hand. The patient was further advised for fibro scan and his Liver stiffness measurement (LSM) was 11kPa with CAP score 264dB/m with negative virus panel. The patient was diagnosed as Non-Alcoholic Steato-hepatitis (NASH) based on his overweight and biochemical and radiological findings 3000mg *Bhumiamalaki* (*Phyllanthus niruri*) aqueous extract tablet (500mg) in two divided dose after food with luke warm water along with one tablet *Siddha Makardwaja* special Rasa 125mg twice daily before food triturate with honey for 10 minutes for six months. The symptom of dyspepsia and constipation were relieved in 1st month of treatment whereas mild change in liver fibrosis (LCM & CAP score) was observed in 1st three month of therapy and marked regression in liver stiffness was observed in after six months of therapy. The patient has no relapse of the liver fibrosis even after three years of observation. The patient had no adverse sign or symptom during medication and observed period. *Siddha Makardwaja* Rasa and *Bhumiamalaki* (*Phyllanthus niruri*) combination therapy can reverse the Progression of Non-Alcoholic Steato-hepatitis (NASH) in six months of therapy and sustain the amelioration liver tissue even after discontinuation of medication in long term follow up.

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1. Introduction

Non-Alcoholic Steato-hepatitis (NASH) is a type of liver disorder characterized by accumulation of fat (hepatic steatosis) and inflammation of liver cells without alcohol intake.¹ Some Non-alcoholic Fatty liver disease (NAFLD)/Metabolic associated fatty liver diseases (MAFLD) patients may progress to fibrosis, cirrhosis and hepato-cellular cancer. The progression of NAFLD to NASH is limited to 20%, whereas global and Indian incidence of NAFLD ranging from 30 to 32%.² Patients with NASH always associated with type two diabetics (T2DM), insulin resistance, obesity, hypertension and

atherosclerotic cardiovascular disease (ASCVD). The mechanism and cause for progression of NAFLD to NASH and NASH to further progress to Cirrhosis are not fully understood, but sedentary life style, genetic, metabolic, microbiome of gut, hypercholesterolaemia, immune system, release of inflammatory toxin (Cytokines), apoptosis and oxidative stress might be responsible for progression of NASH. NASH associated with hospitalisation, blood Investigations, radio diagnosis, fibro scan to predict progression to Liver cirrhosis, its morbidity and Liver transplant which severely impact on patient economy. Lifestyle intervention thorough diet, yogic practice and exercise with weight reduction have an impact on histological improvements in NASH. Fibrosis regression occurs in patients who manage to lose $\geq 10\%$ of their body

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weight although most find this difficult to achieve and sustain. Liver fibrosis, including cirrhosis, is proved to be potentially reversible through Ayurveda.³ The stages of NASH-related fibrosis range from absent (stage F0) to cirrhosis (stage F4). In general, fibrosis progression to cirrhosis and adverse liver-related outcomes in NASH is slow and unpredictable, with the actual fibrosis progression rate (FPR), however Liver stiffness measurement through fibro scan can be an accurate prediction of hepatic fibrosis.⁴

Bhumiamalaki (*Phyllanthus niruri*) is effective in reduction of fibrosis and metabolic markers in cirrhosis.^{5,6} *Bhumiamalaki* (*Phyllanthus niruri*) is effective in reduction of fibrosis and metabolic markers in cirrhosis.^{4,5} *Siddha Makardwaja* Rasa has effective as systemic anti-inflammatory by reducing pro inflammatory cytokines and used in compensated cirrhosis. *Siddha Makardwaja Rasa* (SMR) has effective as systemic anti-inflammatory by reducing pro inflammatory cytokines and used in compensated cirrhosis.^{6–8} Many anti-fibrotic drugs targeting hepatocytes, HSCs, and immune cells are being investigated in clinical trials. However, the results of many of these trials suggest that treatment with single agents is not sufficient to ameliorate advanced liver fibrosis. Therefore, *Siddha Makardwaja* Rasa and *Bhumi amalaki* combination therapy planned to targeting multiple mechanism of NASH resolution.

2. *Patient Information* – A 45-year male, a business man came to our general OPD with elevated liver enzyme with elevated fasting blood glucose report in his hand. His body weight was 76kg and his BMI was 29.7kg/m.² His complain was dyspepsia and weakness. The patient was sent for further investigation. He had no history of taking alcohol, nicotine and harmful medication or herb.

2. Clinical Findings

The clinical examination revealed that patient neither icterus nor pallor. His haemoglobin was 11.8mg/dl, HbA1c was 7.8%, Fasting blood glucose was 110mg/dl, PP sugar was 210mg/dl, total cholesterol 203mg/dl, Triglyceride was 330mg/dl, SGOT was 122mg/dl, SGPT was 75mg/dl, Alkaline phosphatase (ALP) was 102mg/dl, and other renal biochemicals and serum albumin were within normal level. The hepatitis virus panel test was negative. Ultrasound of whole abdomen revealed that increased echogenicity and poorly visualised intra hepatic vessels suggestive diffuse steatosis. The patient was further advised for fibro scan and his Liver stiffness measurement (LSM) was 11kPa with CAP score 264dB/m.

Time line	Intervention	Outcome
2/3/19	Patient came to OPD with elevated liver enzymes	
10/3/19	Patient came with all advised report Adv fibroscan	NA
15/3/19	Non-Alcoholic Steato-hepatitis (NASH) diagnosis 3 tab of <i>Bhumiamalaki</i> (500mg) twice daily after food one tablet <i>Siddha Makardwaja</i> special 125mg twice daily before food triturate with honey for 10 minutes.	
15/4/19	Three tab of <i>Bhumiamalaki</i> (500mg) twice daily after food. 2. One tablet <i>Siddha Makardwaja</i> special 125mg twice daily before food triturate with honey for 10 minutes	Remission of Dyspepsia and constipation
15/6/19	Same medication	Mild improvement
15/9/19	Same medication	Mark improvement
16/3/20	No medication	stable
20/3/23	No medication	Stable

3. Time line- Various timeline, intervention and outcome of the treated case

4. Diagnostic Assessment

The patient was diagnosed as Non-Alcoholic Steato-hepatitis (NASH) based on the biochemical, serological and radiological evidences. The patient was evaluated for Ayurveda parameter and diagnosed as *Yakrit dalludara*, The patient has *Kapha pitta prakruti*, and found *agnimandhya*(Low digestive power) and *krura kosta*(constipated) and treatment was designed to study the outcome based on published literature and experience. The patient was called for every month to know the compliance, but biochemical and radiological assessments were done in three-month, six month and medication was stopped. The patient was advised to do biochemical and radiological test in every year for three years.

5. Therapeutic Intervention

The patient was given oral medications for six months and the outcome was measured. 3000mg *Bhumiamalaki* (*Phyllanthus niruri*) aqueous extract tablet (500mg) in two divided dose after food with luke warm water along with one tablet *Siddha Makardwaja* special 125mg twice daily before food triturate with honey for 10 minutes. The patient was advised to walk for 45 minutes daily and avoid fast food and oils.

Table 1: The biochemical and radiological finding during follow up and observed period

Parameter	D0	D90	D180	One year	2 nd year	4 th year
Hb%	11.8	12.0	12.0	12.2	12.0	12.2
FBS mg/dl	110	90m	94	89	102	78
HBA1C %	7.8	7.2	6.8	6.2	6.2	5.8
TC mg/dl	203	180	152	162	162	154
TG mg/dl	330	270	170	170	170	160
SGOT(mg/dl)	122	103	27	37	39	38
SGPT(mdg/dl)	75	62	34	31	33	34
ALP	102	78	35	37	33	38
LSM KPa	11	10	6	6	6.2	6
CAP score	264 dB/m	250 dB/m	180dB/m	170dB/m	180dB/m	180dB/m

6. Follow up and Outcome

The patient was followed in every three months for six months and result was compared with baseline. The patient was followed for another three years in every year follow up without medication with restricted diet and exercise to study the relapse (Table 1). The symptom of dyspepsia and constipation were relieved in 1st month of treatment whereas mild change in liver fibrosis was observed in 1st three month of therapy and marked regression (reduction in LCM and CAP score) in liver stiffness was observed in after six months of therapy (Table 1). The patient has no relapse of the liver fibrosis even after three years of observation. The patient had no adverse sign or symptom during medication and observed period. The bio chemical tests for safety parameters were also within normal limits. So, the medication is completely safe for long term use.

7. Discussion

The patient was diagnosed as Non-Alcoholic Steato-hepatitis (NASH) as he is overweight and biochemical and radiological findings favors the discission. The intervention and dose were based on previous clinical study. The reduction of progression and reversal of fibrosis was observed in this case which is similar with our previous findings.⁹ Bhumi amalki has good antifibrotic effect in animal model, but no significant result in paklcebo control clinical trial.^{10,11} Siddha Makardwaja Rasa tritrate with honey for 10 minutes is the unique drug delivery method whereas SMR may reserve the pathway of NASH owing to their biocompatibility (bio-inertness, and low cytotoxicity), ability to chemically modify their surface by attaching multiple types of ligands, and their superior optical properties. It may regulate the metabolic pathway of hepatic lipid metabolism and alteration of parenchymal metabolism in liver.¹² Therefore, this combination therapy had promising antifibrotic effect to reduce liver fibrosis, reverse the fibrosis and sustain the amelioration liver tissue even after discontinuation of medication in long term follow up.

8. Conclusion

Siddha Makardwaja Rasa and Bhumiamalaki (Phyllanthus niruri) combination therapy can reverse the Progression of Non Alcoholic Steato-hepatitis (NASH) in six moths of therapy. Placebo controlled Clinical study is recommended.

8.1. Patient prospective and consent

The patient was bearded all cost of tests and medications. He had given his consent to publish his investigation reports and other related information in journal for academic purposes. The reduction of progression and reversal of fibrosis was observed in this case which is similar with our previous findings.³

9. Source of Funding

None.

10. Conflict of Interest

None


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