



ORIGINAL RESEARCH PAPER

Ayurveda

A STUDY ON EFFECT OF GOMUTRAHAREETAKI IN NON ALCOHOLIC STEATOHEPATITIS

KEY WORDS:

Gomutrahareetaki yoga, Non Alcoholic Steatohepatitis, SGOT, SGPT, Median stiffness of liver

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ABSTRACT
 Non-alcoholic Steatohepatitis (NASH) is characterised by fatty changes with lobular hepatitis in the absence of a history of alcoholism. It is included under a spectrum of diseases called Non Alcoholic Fatty liver disease (NAFLD). Epidemiological studies suggests that prevalence of NAFLD is around (9-32%) of population in India. The study was conducted in single group of 20 patients in Kayachikitsa OPD in Govt Ayurveda College Trivandrum. The study design was pre and post design. The trial drug Gomutrahareetaki was given to 20 subjects in tablet form in a dosage of 2 tablets thrice daily 30 minutes before food in empty stomach with hot water for 90 days. Periodical assessment of SGOT (Serum Glutamic Oxaloacetic Transaminase), SGPT (Serum Glutamate Pyruvate Transaminase), median stiffness of liver, and grading of fatty liver was done in 0th and 91st day. Statistical analysis showed that there was significant reduction in SGOT, SGPT, median stiffness of liver, and grading of fatty liver.

INTRODUCTION

Liver diseases are largely neglected health issue in developing countries, which carry highest burden but receive little attention. Over the years, increasing obesity, hypertension, and diabetes mellitus has led to higher incidence and prevalence of NAFLD & NASH. It is the emerging cause of liver related morbidity and mortality. According to Ayurveda, NASH may be correlated with a disease having santharpana janya nidana leading to medodhatwagnimandhya and sthanasamsraya in yakrit. Treatment with drugs having kaphahara medohara, lekhana, anulomana, deepana property and Srothosodhana property may correct dhatwagni mandhya from rasa to medus and prevent the progression of it into chronic liver diseases.

METHODOLOGY

Study design:

Interventional study – Pre & Post Test without control group.

Study setting:

Outpatient and Inpatient unit in the Department of Kayachikitsa, Govt. Ayurveda College Hospital, Thiruvananthapuram.

Study population:

Non-Alcoholic Steatohepatitis patients both male and female with age group between 20- 65 years.

Inclusion criteria:

Diagnosed cases of NASH, in both male and female patients in the specific age group of 20-65 years. (NAFLD with SGPT elevated 3 times the normal value)

Exclusion criteria:

1. Diagnosed case of Renal disorders, Ischemic heart disease and Congestive cardiac failure, esophageal varices, Liver cirrhosis, and Hepatocellular carcinoma, Acquired immune-deficiency syndrome, Tuberculosis, Bleeding disorders and Ascites.
2. Pregnancy and Lactation.
3. Prolonged medications for various systemic disorders.
4. Patients undergoing long term medications such as corticosteroid therapy.

Sample size was 20 cases, consecutive sampling satisfying the inclusion and exclusion criteria till attaining the sample size.

Data collected through history taking, clinical examination, detailed clinical research proforma and laboratory investigations..

Procedure:

Patients both male and female in the age group of 20-65 years satisfying the inclusion and exclusion criteria from the study setting was selected for the study. They was subjected to detailed clinical evaluation and investigations including, Fasting blood glucose (i.e., no caloric intake for at least 8hr), 2hr Post Prandial glucose level, HbA1c, Fasting lipid profile, TSH, LFT ,RFT, Serum Ferritin, Serum Ceruloplasmin and ANA was done. Informed and voluntary consent was obtained from the patient. The study was conducted in a single group. The data was recorded. Details regarding the study drug with pathya ahara and vihara were explained to the patient. The study drug was given to the patient for 90 days in the dose of 6 tablets per day. Each tablet weighing 1g was given to the patient in the dose of 2 tablets 3 times a day 30 minutes before food in the empty stomach. Patient was evaluated on the 0th, 91st day on the basis of laboratory findings and signs and symptoms. USG and Fibro scan was done before and after the study. The result obtained was statistically analyzed and concluded.

Quantitative Variables was expressed as mean, standard deviation, median and inter quartile range and qualitative variables will be expressed as proportion. Paired comparison of quantitative variable will be analyzed by Paired t test. A p-value of <0.05 will be considered as the level of significant. Data analysis will be performed using SPSS ver 22.0

DRUG REVIEW

The study drug *Gomutrahareetaki yoga* is mentioned in, ³Ashtanga hridayam chikitsa sthanam 16th chapter -Pandu chikitsa-slokam no:6, ⁴Ashtanga hridayam chikitsa sthanam 17th chapter-Sopha chikitsa- slokam no:3, ⁵Ashtanga Hridayam Chikitsa Sthanam Udara Chikitsa Adhyaya, slokam no.39 It consists of 2 drugs, *Gomutra* & *Haritaki*. The drug preparation and dose fixation were based on standards of Ayurveda pharmacopeia of India.

RESULTS

Distribution of patients according to the age

15% of patients were in both 20- 29 and 50-59 years of age, 30% of patients were in both 30-39 and 40-49 years of age and

10% of patients belong to 60-69 years of age.

Distribution of patients according to sex

85% of patients were males and 15% of patients were females.

Distribution of patients according to religion

90% of patients belong to Hindu religion. Christians and Muslims were 5% each.

Distribution of patients according to nature of occupation

55% of patients had sedentary job and 45% of patients had physical exertion during job.

Distribution of patients according to socio economic status

40% of patients were poor, 40% were from middle class, 10% were from upper middle class and 10% were from upper class.

II. DATA RELATED TO DIETARY HABITS

30% of patients had regular food habits and 70% of patients had irregular diet habit. 100% of patients were non vegetarians. 45% of patients had moderate intake of food and 55% of patients. 50% of patients regularly take meat, 85% of patients regularly take fish and 75% of patients regularly take egg. 35% of patients occasionally take meat, 15% of patients occasionally take fish and 25% of patients occasionally take egg. 20% of patients had no fast food intake, 80% of patients had habit of fast food intake.

Distribution of patients based on appetite

75% of patients had good appetite, 15% of patients had reduced appetite, 5% of patients had good appetite and 5% had excess appetite.

III. DATA RELATED TO THE GENERAL CONDITION OF THE PATIENTS

Distribution of patients based on exercise

50% of patients had no exercise, 45% of patients had moderate exercise and 5% of patients had mild exercise.

Distribution of patients based on BMI

55% of patients were overweight, 25% of patients were normal weight and 20% of patients had obesity G-1.

Distribution of patients based on prakrithi

50% of patients were kapha pita prakrithi, 25% of patients were Vatapitha prakrithi, 10% of patients were pita vata prakrithi, and 5% of patients were both pita kapha and kapha vata prakrithi.

IV. DATA RELATED TO NASH

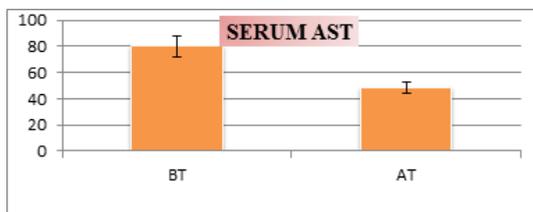
Among the patients, 50% of patients were asymptomatic, 50% of patients had fatigue, abdominal distension and abdominal discomfort. 20% of patients had loss of appetite and heart burn. 25% of patients had altered bowel habits.

V. DATA RELATED TO RESPONSE TO TREATMENT

DATA RELATED TO SERUM AST

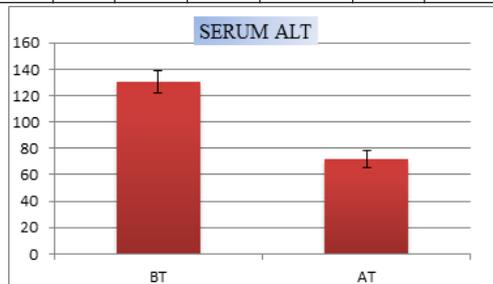
Variable	Test	Mean	SE	KS	T	P	Loss
Serum AST	BT	80.07	7.83	0.061 ^{NS}	7	.000*	39.11%
	AT	48.75	4.38	0.072 ^{NS}			

Paired t test showed that the treatment has significant effectiveness on reducing the serum AST (P<0.05). In the study group, the mean value of serum AST before treatment was 80.07+-7.83 IU/L which significantly reduced to 48.75+-4.38 IU/L with a reduction of 39.11 %.



DATA RELATED TO SERUM ALT

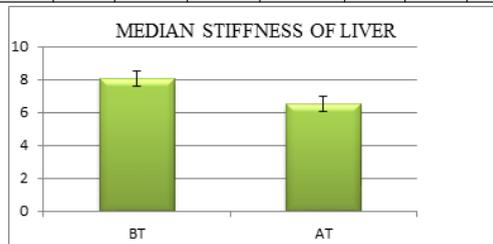
Variable	Test	Mean	SE	KS	T	P	Loss
Serum ALT	BT	130.75	8.36	0.200 ^{NS}	12.51	0.000*	45%
	AT	71.95	6.19	0.200 ^{NS}			



In the study group, the mean value of serum ALT before treatment was 80.07+-7.83 IU/L which significantly reduced to 48.75+-4.38 IU/L with a reduction of 39.11 %.

DATA RELATED TO MEDIAN STIFFNESS

Variable	Test	Mean	SE	KS	T	P	Loss
Median stiffness	BT	8.05	0.49	0.200 ^{NS}	6.27	.000*	19.25%
	AT	6.50	0.47	0.200 ^{NS}			



The mean value of median stiffness before treatment was 8.05+-0.49 kpa which significantly reduced to 6.50+-0.47 kpa with a reduction of 19.25%. P value is <0.05 and is statistically significant.

DATA RELATED TO LIVER SIZE.

Variable	Test	Mean	SE	KS	T	P	Loss
Median stiffness	BT	14.19	0.29	0.200 ^{NS}	3.28	.003*	2.46%
	AT	13.84	0.30	0.200 ^{NS}			

In the study group, the mean value of liver size before treatment was 14.129+-0.29 cm which significantly reduced to 13.84+-0.84 cm (p < 0.05) with a reduction of 2.46 %.

DATA RELATED TO GRADING OF FATTY LIVER

Transition	Percentage	P
Grade 1- mild fatty liver	22.2	0.005*
Grade 2-Grade 1 fatty liver	85.7	

By Wilcoxon's Signed Rank Test the treatment has significant effect in reducing the grade of fatty liver before and after the intervention (P<0.05). Due to the treatment 22.2% of patients changed from grade 1 fatty liver to mild fatty liver, while 85.7% of patients changed from Grade 2 to grade 1 fatty liver.

DISCUSSION

The results SGOT and SGPT were stable during the follow up period. According to Ayurveda NASH may be correlated with a disease having santharpana janya nidana leading to rasa dhatu dushti leading to formation of vitiated raktha dhatu with increase in sleshma bhava i.e., medodhatwagnimandhya and shanasamsraya in yakrit. The formation of medo dhatugata amapakavastha can be correlated to NASH.

The study drug gomutra haritaki have ama pachana, sroto sodhana, and lekhana, medohara, and Vatanulomana property. On analyzing the individual property of drugs, ⁶haritaki, has ⁷lavana varjitha pancha rasa, rooksha, ushna and laghu guna, ushna veerya and madhura vipaka, and acting as

tridosha hara.⁸It causes Agni deepana in koshta, bhoota, and dhatu level. It acts as ideal drug in avarana of vata by kapha, meda and ama.

⁹Gomutra has mainly katu and lavana rasa, it acts as kapha vata hara and Agni deepana and sroto sodhana. Along with this madhura rasa is also attributed to gomutra. So gomutra cause minimal level of pitha prakopa compared to other types of mutras. It has the capacity to potentiate the action of drug haritaki because it has teekshna and rooksha guna it adds to sroto sodhana property of the drug gomutra haritaki.

CONCLUSION

In a nut shell, the drug Gomutrahareetaki produced significant changes towards benefit in lab parameters SGOT & SGPT, and it reduces the median stiffness of liver and liver size of patients with NASH with trend to improvement in the disease condition which remained stable during the study period.

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