

## EFFECTIVENESS OF *PŪTIKA KṢĀRĀDI YOGA* AGAINST URSODEOXYCHOLIC ACID IN THE MANAGEMENT OF GRADE -2 NON-ALCOHOLIC FATTY LIVER DISEASE- A PRAGMATIC TRIAL.

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## ABSTRACT

Fatty liver disease is one among the common disease affecting liver. Non-Alcoholic fatty liver disease is a broad term which describes the buildup of excessive fat in the liver cell, in the absence of excessive alcohol intake. In Ayurveda It can be considered as a *Santharpanotha Vikara* with *Kapha Medo Dushti* with its *Sthānasamsraya* in *Yakrit*. In *Pūtika kshāradi yoga*, *Pūtika ksāra* has *Vāta kapha* and *Medohara* action, *Vida lavana* has *Anulomana* property, *Pippali* is *Oushadha* for *Yakrit* and *Plīha roga* and *Rasāyana*. Ursodeoxycholic acid is a naturally occurring bile acids with multiple hepatoprotective activities. In modern medicine it is used as wide range in hepatic related complaints. **Methodology:** Study design was Pragmatic clinical trial, done among 20 participants in each group for a period of 45 days in the age group of 30-60 years. Participants diagnosed as per diagnostic criteria and satisfying the inclusion criteria were selected conveniently in to two groups from the OPD of V.P.S.V. Ayurveda College Hospital Kottakkal and Gastroenterology OPD of Almas Hospital, Kottakkal respectively. Group 1 managed with *Pūtika ksāradi yoga* capsule 500mg thrice daily. Group 2 was treated with Ursodeoxycholic acid 150mg twice daily. Assessments were done based on blood parameters like AST & ALT on the 1st day before intervention and 45<sup>th</sup> day. No special diet modification or lifestyle change was advised during this period. **Result:** *Pūtika ksāradi yoga* was more effective than the Ursodeoxycholic acid in reducing the parameters AST and ALT in Grade -2 nonalcoholic fatty liver. **Conclusion:** *Pūtika ksāradi yoga* was more effective than Ursodeoxycholic

acid in reducing the parameters AST and ALT in Grade 2 non-alcoholic fatty liver. In the case of AST and ALT, they were significantly reduced in both groups after the intervention. While doing an independent sample test, statistically significant change between groups was observed in the case of ALT.

**Keywords:** Nonalcoholic fatty liver, *Pūthika kshārādi yoga*, Ursodeoxycholic acid

## INTRODUCTION

In the present scenario unhealthy lifestyles and food habits, lack of proper exercise had led to serious metabolic derangements in liver metabolism<sup>1</sup>. Fatty liver disease is one among the common diseases affecting liver. It includes alcoholic and nonalcoholic types. Non Alcoholic fatty liver disease is a broad term which describes the buildup of excessive fat in the liver cell, in the absence of excessive alcohol intake. Recent studies suggest the prevalence of NAFLD in Asian countries from 9-40%<sup>6</sup> and 60% has been reported among obese children from Kerala.<sup>2</sup> The disease is characterized by several histological changes which can be divided into Steatosis (fat accumulation) and Steatohepatitis (fat accumulation with inflammation with or without fibrosis), may lead to fibrosis and cirrhosis. There is no specific remedy in allied science for nonalcoholic fatty liver diseases. In Ayurveda It can be consider as a *Santharpanoṭha vikāra* with *Kapha Medo Dushti* with its *Sthānasamsraya* in *Yakrit*, which is said to be *Raktavaha srothomūla* and *Pitha sthāna*, the causative factor can be understood as *Agnimāndhya* leading to *āma* which is reflected in *Dhātagnimāndhya*. *Pūthika kshārādi yoga* contain *Pūthika* (*Chiuvilwa*)-*Holoptelea integrifolia*.(Roxb)Planch, *Vidalavana* and *Pippali*(*Piper longum*.Linn.) which is one among the formulations mentioned in *Plīha yakrit adhikāra*, in *Chakradhatta*.<sup>3</sup> Ursodeoxycholic acid a naturally occurring bile acids with multiple hepato protective activities. In modern medicine it is used as wide range in hepatic related complaints.<sup>4</sup>

## MATERIALS AND METHODS

**AIM OF THE STUDY:** To explore the scope of *Pānīya kshāra* in non-alcoholic fatty liver disease.

## OBJECTIVES OF THE STUDY

**Primary objective:** To compare the effectiveness of *Pūthika kshārādi yoga* against Ursodeoxycholic acid in grade 2 nonalcoholic fatty liver disease.

## STUDY DESIGN

Study design was Pragmatic clinical trial 20 participants in each group. Participants were selected conveniently into two groups from the OPD of V.P.S.V. Ayurveda College Hospital Kottakkal and Gastroenterology OPD of Almas Hospital Kottakkal respectively.

## DIAGNOSTIC CRITERIA

Prediagnosed cases of Nonalcoholic fatty liver grade 2 with elevated ALT and AST(ALT>45U/L, AST>35U/L)

## INCLUSION CRITERIA

- Subjects who fulfil the diagnostic criteria.
- Age group-30 -60 yrs.
- Those who are willing to provide written consent.

## EXCLUSION CRITERIA

- Subjects with Positive result of HBsAg, HCV and malignancies.
- Subjects with uncontrolled DM (HbA1c>6.5%)
- Uncontrolled HTN (Systolic>150mmhg, diastolic>100mmhg)
- *Kshāra* contraindicated diseases –*Jwara*, *Raktapitta*, *Pitha Prakruti*

## INTERVENTION OF STUDY

- Group A (Trial group) – *Pūthika kshārādi yoga* capsule 500 mg three times daily after food for a period of 45 days
- Group B (Control group) – Ursodeoxycholic acid capsule 150 mg two times after food for a period of 45 days
- Assessment will be conducted on day 1<sup>st</sup> and 45<sup>th</sup> day.

## ASSESSMENT TOOL

- Case proforma
- Objective parameters: AST, ALT, Assessment will be conducted on day 1<sup>st</sup> and 45<sup>th</sup> day.

## OUTCOME

- Trial drug was more effective than the control drug in reducing the parameters AST and ALT in Grade 2 nonalcoholic fatty liver disease.
- The following percentage of relief are noted in trial group-ALT (95%), AST (85%)
- The following percentage of relief are noted in control group-ALT (95%), AST (80%)
- The effectiveness of the trial procedure was found to be statistically significant.

## DISCUSSION

In Ayurveda NAFLD can be consider as a *Santharpanoṭha vikara* with *Kapha medo dushti* with its *Sthānasamsraya* in *Yakrit*. Excessive intake of *Sneha ahara* and less physical exercise led to *Kapha medo dushti*. Initial stage of disease vitiates the *Jataragni*, then *Medo-agni mandhya* occurs. *Agnimandhya* produces excess fat in the liver. Excess fat in the liver act as foreign body, it can trigger an inflammatory response as a natural defense mechanism. However, if the excess fat is not effectively removed, it can lead to chronic inflammation.

This chronic inflammation can disrupt the normal functioning of cells ,it may act as *Ama*. The presence of *Ama* can further exacerbate inflammation and this cycle repeats. It may correlate with steatosis. *Ama* can be formed in both *Koshta* and other parts of the body. *Ama* in *koshta* produce *Ajeerna*, *Agnimandhya* etc. When *Pitta* gets involved in the pathogenesis, inflammatory changes occur, which lead to the next stage of the disease, i.e., non-Alcoholic steatohepatitis (NASH). When *Vata* comes into the picture, fibrosis occurs, which may end up in Cirrhosis. The management should include the breakdown of pathological factors like *Agnivaigunya*, *Amavastha*, *Srotorodha*, *Kaphamedodushti* etc.

Here comes the importance of *Kshara Kalpana*. *Acharya Surutha* indicates *Paneeya kshara* in the

management of *Agnimandhya*, *Udara*<sup>5</sup>, etc. By using *Paniya kshara* for a short duration, we get *Ag-nidepana* and *Srothoshodhana* action. In *Chakradatta pleeha yakrit adhikra*, many *Kshara prayogas* are mentioned. *Yakrit* is *Agnyashaya* and *Mulasthan* of *Raktavaha srothas*. When *Agni* is correct, it may help to correct all metabolic activities, thus preventing lifestyle diseases like dyslipidemia, diabetes mellitus, etc. *Putika ksaradi* yoga contains *Pūtika ksara* (*Chiruvilwa-Holoptelea integrifolia*.(Roxb)Planch, *Pippali* (*Piper longum*.Linn.) and *Vida lavana*., which is one of the formulations mentioned in *Pleeha yakrit adhikra* in *Chakradhatta*<sup>3</sup>. *Vida lavana* was prepared by using common salt and *Amalaki*. The reference regarding preparation of *Vidalavana* mentioned in *Vaidya Yoga Ratnavali for Yakrit vridhi*. *Puthika* has *Lekhaneeya*, *Bheedaneeya* and *Vata kapha hara* property.<sup>6</sup> *Deepana pachana* properties of *Pippali* help to increase *Agni* and corrects the *Dhatu-parinama*. *Katurasa*, *Deepana* and *Pachana* acts as *Kledamedo upasoshanam* and disintegrates the obstruction of *Raktha vaha srothas* and thereby prevents the accumulation of excess *Medas* in the *Yakrit*. *Vidalavana* has *kapha vata hara* and *Anulomana* properties. All these properties of ingredients make it a suitable drug for *Ama pachana* and *Agnideepana*.it will help normal function of *Agniashaya* or Liver. *Puthika* made into *Kshara*, it is undergoing a *Sam-skara*, which results in *Gunatharadana*. So, it is the properties of *Kshara* that should be emphasized. *Paniya kshara* is *Tikshna* and *Pachana* and has properties like *Vilayana*, *Sodhana*, and *Lekhana*. *Teekshna* property helps the drug penetrate the tissue and act upon it. *Pachana* property helps correct the metabolic activity. *Vilayana* property helps in the disintegration of fat in the liver as well as anywhere in the body. *Sodhana* property clears the obstruction, and *Lekhana* property exerts a scraping action on the fatty liver. As per modern pharmacology, *Putika* is rich in phytochemicals, including alkaloids, saponins, flavonoids, tannins, fixed oils, etc<sup>7</sup>. It is well established that saponins are useful in preventing obesity, and flavonoids have potential antioxidant properties. Methanolic extract of *Putika* shows a significant

hepato-protective effect in reducing the liver injury induced by CCL<sub>4</sub> in mice. A study conducted by Ganie SA et.al reported that *Putika* has properties such as antidiabetic, anti-inflammatory, hepatoprotective, and hypolipidemic activities. As per modern pharmacology, *Pippali* improves the regeneration process by restricting fibrosis<sup>8</sup>. A study by Mariyam Thomas et al reported that The Oral administration of ethanol extract of *Pippali* significantly reduced the levels of AST and ALT in mice. Piperine acts as a significant protection against hepatotoxicity by reducing lipid peroxidation. A study by Khushbu c et al reported that *Pippali* has properties such as anti-inflammatory, anti-oxidative, hepatoprotective, hypocholesteremia, and immune modulatory activities. Piper longumine helps in the regeneration of hepatocytes. The effect of trial drug may be due to the hepatoprotective effects, lipid metabolism regulation, anti-inflammatory properties and gut microbiota modulations. Ingredients in the study drug possess antioxidant and anti-inflammatory properties, which can help protect liver cells from oxidative stress and inflammation-induced damage. Hepatoprotective activity of the study drug will help for restoring normal function of liver cells .All these results the decrease the value of AST and ALT.

## CONCLUSION

The following conclusions were evolved after conceptual compilation, critical review, clinical observations and discussions.

- The NAFLD is more common in the age group of 30-40 years.
- As per gender ,it is more common in males than females and seen more in participants with sedentary lifestyle.
- The majority of participants (90%) followed a mixed diet pattern and 88% of participants had poor appetite .

- NAFLD cannot be correlated to a single disease in Ayurveda. It can be considered as a *Santharpanotha vikara* with *Kapha medo dushti* with its *Sthānasamsraya* in *Yakrit*.
- The risk factors of NAFLD include *Vidahi abhishyandhi ahara* and *Vihara* which leads to *Kapha medo dushti* causes *Srotorodha*.
- Trial drug was more effective than the control drug in reducing the parameters AST and ALT in Grade 2 nonalcoholic fatty liver disease.
- The following percentage of relief are noted in trial group-ALT (95%), AST(85%)
- The following percentage of relief are noted in control group-ALT(95%), AST(80%)

The effectiveness of the trial procedure was found to be statistically significant.

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