Case Study

POTALA KATUROHINYADI KWATHA IN KAPHAJA YAKRIT DALLUDARA (NON-ALCOHOLIC FATTY LIVER DISEASE): A CASE STUDY

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ABSTRACT
Non-alcoholic fatty liver disease (NAFLD) is also otherwise termed as Hepatic steatosis and Kaphaja yakrit dalludara in Ayurveda. 34 years male patient, highly educated from a high socio-economic group of Non vegetarian diet habit came to hospital with complain of anorexia, indigestion and distention for three months. The clinical findings revealed that he is slightly obese, hyperglycaemia and dyslipidemia along elevated liver enzymes with fatty liver in USG and Fibro scan. The case was treated with Patolakaturohinyadi Kwatham (PKK) in the dose was 30ml Kasaya with equal quantity of luke warm water twice daily in empty stomach preferable morning and evening for six months. This study proved that PKK can significantly reduced blood sugar, serum Lipids and liver enzymes within three months along with reduction weight and BMI, but change in liver architecture required six months in this therapy. The patient was kept in observation for further one year without medication and advised to practice Yoga, exercise and low carbohydrate and fat diet to study the recurrence of disease. The liver architecture as well as biochemical profile of liver is maintained after one year also. PKK may correct the metabolic dysfunction by increase Agni, digest Ama which helped in the correction of hyperglycaemia and dyslipidaemia. PKK is safe in for six months of use in recommended dose (30ml BID) as there was no adverse sign and symptom observed and no change in biochemical and Haematological profile of Patients.PKK is safe and effective in this case of Kaphaja Yakrit dalludara (NAFLD). It can study further in large population to generated evidence for its efficacy and efficacy in larger group.

KEYWORDS: Kaphaja yakrit dalludara, Non-alcoholic fatty liver disease (NAFLD), Patolakaturohinyadi Kwatham (PKK).

INTRODUCTION
Yakrit dalludara is broad term in Ayurveda where the increase in size of Liver (Yakrit vridhi). When there is an increase of Kapha dosa leads to increase in size of Liver, then Kaphaja Yakrit dalludara takes place. Then it increase the Meda inside the Yakrit leads to Medaja Yakritdalludara[1]. Non-alcoholic fatty liver disease (NAFLD) is also otherwise termed as Hepatic steatosis and Kaphaja yakrit dalludara in Ayurveda, fat deposition in liver absence of excessive alcohol intake[2]. It is a global public health due to dietary hyper nutrition subsequent obesity, type-II diabetics and associated with smoking, hypertension and dyslipidaemia.

NAFLD is an umbrella term used to described a histological spectrum ranging from simple steatosis, a concentration of hepatic triglycerides (TGs) exceeding 5% of liver weight, to non-alcoholic steatohepatitis (NASH) characterized by hepatocellular damage, lobular necroinflammation, fibrogenesis resulting cirrhosis, and cancer[3]. The prevalence of NAFLD is 15-40% in Western countries and 9-40% in Asia. Recent studies from the Indian subcontinent recorded a NAFLD prevalence of 9–32% in the general population[4]. Metabolic perturbations, including insulin resistance, impaired glycaemic control, and altered lipid metabolism, have been hypothesized to contribute to the molecular pathogenesis of NAFLD and NASH[5]. Various pharmacological and non-pharmacological approaches seem to be non-effective and the patients are kept on long term treatment. Hence, even the highly educated patients reach to various traditional and alternative practitioners with an expectation of positive outcome[6]. Moreover, currently used medical treatment has been shown to be severe side effect and some have been associated with increased risk of certain type of cancer. Recent Randomised Clinical Trial demonstrated that phyto-medicine...
reduces steosis severity, liver ballooning and fibrosis and can be comparable with western medical system[7,8], Ayurveda medication in NAFLD is in conclusive[9,10] and limited to case studies[11] and literature review[12]. Although more than ten clinical trials of Ayurveda formulations are registered for NAFLD, yet more evidences required for the efficacy and safety of Ayurveda formulation in Non-alcoholic fatty liver diseases. Many patients demand for one poly herbal formulation which will be economic, no side effect and easy to take. Moreover, Potala katrohinyadi Kwatham is a known medicine for anorexia, vomiting, skin diseases, jaundice, viral infections and liver diseases phyto-chemical analysis is studied, [13,14]. Therefore, this case study is unique to study the safety and efficacy of Potala katrohinyadi Kwatham in Non-alcoholic fatty liver diseases primarily.

Clinical Findings
The case was having central obesity having 75kg weight and 163cm height (BMI-28.2). His viral hepati screening was negative antinuclear antibody, smooth muscle antibody, α-antitrypsin, ceruloplasmin, and thyroid-stimulating hormone levels were within normal limit. His fasting blood sugar is 122mg/dl, PPBS was 162mg/dl, HbA1c was 7.1 and fasting insulin was 30mlU/L. His serum total bilirubin was 1.0mg/dl with direct was 0.3mg/dl, SGOT was 54 U/L, SGPT was 45 U/L, alkaline phosphate 138u/l, GGT (Gamma-glutamyl transferase) was 64U/L (Normal range 03-60U/L), serum urea- 26.0mg/dl (normal range 13-45mg/dl), serum creatinine 0.62 (normal range 0.6-1.2mg/dl), total protein 6.2 and albumin was 4.2mg/dl, Serum cholesterol was 137mg/dl, TG was 227mg/dl, HDL was 38mg/dl, Haemoglobin was 12.8gm/dl, total thrombocyte (PLT) was 148x10^9/L, TLC-8700cells/cumm and ESR 1st hour was 06mm. He has elevated echo genicity and mild hepatomegaly in sonography report and mid line shift was 12 in liver electrography (Fibro scan).

The patient’s Dosha vidha Prikshya (Tenfold of comprehensive bio-psycho-spiritual clinical review) as Kapha Pitta prakruti, Kaphajavikruti Madyama sara, Madyamasamhana, Prabara satmya, Madyama Ahara Shakti and Vyayama Shakti, Madyama Vaya and Pramana. The Kosto (Bowel Habit) was Kruro (constipated). The patient’s Asta vidha Prikshya (eight fold examination) as Kapha pitta Nadi, normal Mutra and Mala, Ama lipta (coated) Jivha, Kapha predominant Shabda, Sargas and Drika, slightly central obesity in Akruti (general appearance).

Patient Information
A 34 years male patient, highly educated from a high socio-economic group of Non vegetarian diet habit came to hospital July 2018 with complain of anorexia, indigestion and distention for three months. He is a lawyer in profession and his father has been suffering from diabetic and dyslipidaemia. The patient gave the history of weight gain of 6kg within one year. No history of intravenous drug use, blood transfusion and unsafe sex practice.

The patient has taken modern appetizer, antacid and rapeprazole sodium for one month, but not satisfying with the relief. Therefore, he came for Ayurveda medication.

Time Line

| Time line | Clinical presentation | Medication |
|-----------|----------------------|------------|
| Before Jan 2019 | Asymptomatic | No medication |
| Feb 2019 | Heaviness, constipation | No medication |
| April 2019 | Anorexia, indigestion, distension of abdomen | modern appetizer, antacid and rapeprazole sodium for one months |
| May 2019(D0) | Anorexia, indigestion, distension of abdomen and came for Ayurveda treatment | NAFLD diagnosed & Potala Katrohinyadi Kwatham - 30ml BID with equal quantity of water in empty stomach |
| Jun 2019 (D30) | No symptom | Medication continued for another two month |
| July 2019 | No symptom and no improvement in USG and Fibroscan | Medication continued for another four month |
| October 2019 | No symptom and improved in fibro scan | Medication stopped |
| Sep 2020 | No symptom, Review and maintained health | Normal life without medication |
Diagnostic Assessment

The diagnosis of NAFLD requires the evidence of hepatic steatosis by imaging or by histology. Ultrasound is very effective in diagnosis steatosis where more than 33% hepatocyte are steatotic [15]. The SAF score in histology is encompassment of an assessment of steatosis (S), activity (A) and fibrosis (F) which has been introduced more recently to identify NASH (Non alcoholic Steato- hepatitis) which can progress to cirrhosis and end stage liver diseases [16]. The BARD score and NAFLD fibrosis score are simple non-invasive tests of fibrosis assessment calculated from specific software. Transient elastography (TE) provide the Liver stiffness measurement (LSM) using pulse -echo ultrasound as surrogate marker of fibrosis [17].

Therapeutic Intervention

Patolakaturohinyadi Kwatham (PKK) is a very famous Ayurvedic medicine in decoction form. It is used in the treatment of anorexia, vomiting, skin diseases, jaundice, viral infections and liver diseases. It is used in the treatment of fever and other diseases of Kapha and Pitta origin. It is also a potent antitoxic medicine used for liver detoxification. It is a potent antimicrobial medicine. The main ingredients of Patolakaturohinyadi kwatham are, Patola (Trichosanthes dioica), Katurohini (Picrorhiza kurroa), Chandana- Sandal wood (Santalam album), Madhusrava (Leptadenia reticulate), Guduchi (Tinospora cordifolia) and Patha (Cissampela spariera) [13]. The dose was 30ml Kasaya with equal quantity of lukewarm water twice daily in empty stomach preferable morning and evening. The treatment was given for three months initially and further extended for another three months. So total duration was done for 6 months.

Follow up and outcome

The patient was followed up in 30 days and 90 days, six month and observed for one year without medication. The patient has improved clinically and her haematological, biochemical and serological parameters gradually developed during the period of time (Table-2). The outcome was measured in terms of ultrasound and Fibro scan which showed improved in fibrosis score and not reappeared in one year of observed period.

After 30 days of treatment, his normal appetite was appeared and got relieved in abdominal discomfort, but he gained weight one kg and his blood sugar and other parameter was not changed significantly. As the patient relieved symptoms, felt good he wanted to extend his treatment, therefore the treatment was extended for further two months. There was a significant change in metabolic and liver function tests without changes in liver architecture in terms of ultrasound, fibrosis scoring and fibro scan after three months of treatment. The treatment schedule was further extended to another three months for better outcome and observed the change in fibrosis of liver. After six months of medication, there was a significant change in metabolic and liver function tests as well as liver architecture in terms of ultrasound, fibrosis scoring and fibro scan without any side effect. The BARD score changed from 4 to 2 and 0 after six month. NAFLD score <1.455 is F0 (no fibrosis). This case has mild fibrosis to no fibrosis after three month of therapy. The patient was kept in observation for further one year without medication and advised to practice yoga, exercise and low carbohydrate and fat diet to study the recurrence of disease. The liver architecture as well as biochemical profile of liver is maintained after one year also. The prescribed medication well tolerated as we were not observed adverse clinical sign and symptoms and there is no change in Haematological, renal and Liver profile.

Table 2: Hematological, Biochemical and Serological Parameters During the Treatment and Observed Period

| Lab parameters       | D0   | D30  | D90  | D180  | After one year without Rx |
|----------------------|------|------|------|-------|---------------------------|
| Weight (Kg)          | 75   | 76   | 73   | 71    | 66                        |
| BMI                  | 28.2 | 28.6 | 27.5 | 26.7  | 24.8                      |
| FBS (mg/dl)          | 122  | 120  | 84   | 78    | 82                        |
| PPBS (mg/dl)         | 182  | 178  | 123  | 118   | 123                       |
| HbA1C                | 7.1  | ---  | 6.4  | 6.2   | 5.8                       |
| Serum Insulin (Fasting) µU/ml | 30ml | ---  | 20   | 12    | 10                        |
| Total cholesterol    | 139  | 140  | 120  | 120   | 122                       |
Triglyceride 227 220 150 134 154
HDL Cholesterol 38 40 40 50 68
Haemoglobin (gm/dl) 11.7 11.6 12.4 12.6 11.8
ESR 1st hour 06 60 50 46 50
Platelet Count (10^9/L) 148 178 192 240 238
TLC 8700 8100 8000 7800 6800
Prothrombin Time Sec 11.4 11.4 10.2 10.2
Sr.Bilirubin (Total) mg/dl 1.0 0.8 1.79 1.2 1.0
Sr.Bilirubin (Direct) mg/dl 0.3 1.07 0.7 0.5 0.4
SGOT/ ALT(IU/L) 54 56 40 40 39
SGPT/AST(IU/L) 45 44 35 31 28
Alkaline Phosphatase (IU/L) 138 130 136 147 108
GGT( U/L) 64 63 40 40 35
Total protein 6.6 7.6 7.8 7.8 7.8
Albumin g/dl 4.2 4.2 4.6 4.6 5.2
Urea 26 18 28 30.6 27.2
Creatinine 0.62 0.60 0.65 0.76 0.5
Serum ferritin (ng/ml) 180 150 154 144 155
Ultrasound Mild - No change Normal Normal
BARD Score 04 04 02 00 00
NAFLD fibrosis Score -1.455 -0.91 -1.86 -3.00 -3.54
Fibroscan (Median stiffness) 12 --- 9.00 6.99 6.12

TLC: Total Leukocyte Count

SGOT (AST): serum glutamic-oxaloacetic transaminase; SGPT (ALT): serum glutamic-oxaloacetic transaminase; GGT: Gamma-glutamyl transferase; ANA: anti nuclear anti body,

DISCUSSION

The presented patient is Kapha pitta prakruti and other Ayurvedic parameters of examination were Kapha predominant. Therefore, it is suggested that Ayurvedic nomenclature for Non Alcoholic Fatty Liver diseases (NAFLD) may be Kaphaja Yakrit dalludara. Patolakaturohinyadi Kwatham (PKK) is indicated for Kapha pittaja disorders. PKK is already studied in Alcoholic liver diseases, where the study outcome was limited to diminished the liver enzymes without observing the liver architecture by fibrosis Score, Fibro scan and ultrasound. This study proved that PKK can significantly reduced blood sugar, serum Lipids and liver enzymes within 3 months along with reduction weight and BMI, but change in liver architecture required six months in this therapy. PKK may correct the metabolic dysfunction by increase Agni, digest Ama which helped in the correction of hyperglycaemia and dyslipidaemia. PKK is safe in for six months of use in recommended dose (30ml BID) as there was no adverse sign and symptom observed and no change in biochemical and Haematological profile of Patients. The patient was kept in observation for further one year without medication and advised to practice yoga, exercise and low carbohydrate and fat diet to study the recurrence of disease. The liver architecture as well as biochemical profile of liver is maintained after one year also. So PKK has corrected the metabolic error as NAFLD is said to metabolic associated fatty liver disease[18].

CONCLUSION

PKK is safe and effective in this case of Kaphaja Yakrit dalludara (NAFLD). It can study further in large population to prove its safety and efficacy in meaningful way.

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