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MANAGEMENT OF DYSLIPIDAEMIA WITH YAVALAUHA CHURNA (AN AYURVEDIC FORMULATION): A CASE REPORT

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ABSTRACT

Introduction: Dyslipidemia is abnormal levels of low density lipoproteins LDL, VLDL and low levels of HDL. The common causes include genetic factors, poor diet and sedentary life style, excessive alcohol intake, obesity, diabetes, kidney disease, hypothyroidism and certain drugs[1]. According to Ayurveda, it can be categorized under *Medovahasroto dushti*[2] or *Medodhatuagnimandya*. Several formulations were utilized for treatment of dyslipidemia. This study is unique by reporting the efficacy of *Yavalauhachurna* in the treatment of dyslipidemia. **Clinical findings:** A female patient aged 52 years complained of generalized weakness (*daurbalya*) associated with excess thirst (*ati-pipasa*), excess sleep(*nidra-aadhikya*) and excessive perspiration (*atisweda*). Laboratory investigations mentioned Hyperlipidemia with increased levels of total serum cholesterol (475.7 mg/dl), serum triglycerides (280.2 mg/dl), serum Low Density Lipoprotein (205.7 mg/dl), serum very Low Density Lipoprotein (89.1 mg/dl) and low High Density Lipoprotein (34.5 mg/dl). **Diagnosis:** The disease was diagnosed as *Medoroga* in Ayurveda and

Dyslipidemia as per contemporary science. **Therapeutic intervention and outcomes:** The intervention of trial drug – *Yavalauhachurna* lowered the various components of deranged lipid profile. The GCMS (Gas chromatography and mass spectrometry) study was conducted to understand the probable mode of action and validate the findings.**Conclusion:**The results will add on to the scientific literature by providing evidence based practice for tackling the condition of deranged lipids. This study paves the way for further larger clinical trials.

Key words: Dyslipidemia, *Yavalauhachurna*, Ayurveda, *Medoroga*, Randomised Controlled Clinical Trial, Case report

INTRODUCTION:

Dyslipidemia is the imbalance of lipids such as cholesterol, low-density lipoprotein cholesterol, (LDL-C), triglycerides, and high-density lipoprotein (HDL). This condition can result from diet, tobacco exposure, or genetic and can lead to cardiovascular disease with severe complications. Lipids, such as cholesterol or triglycerides, are absorbed from the intestines and are carried throughout the body via lipoproteins for energy, steroid production, or bile acid formation. Major contributors to these pathways are cholesterol, low-density lipoprotein cholesterol (LDL-C), triglycerides, and high-density lipoprotein (HDL). An imbalance of any of these factors, either from organic or nonorganic causes, can lead to dyslipidemia[3]. In India, the incidence of dyslipidemia is 10-13% as per various studies. Thus, the magnitude of this problem is an alarming sign for health of our country. Studies have shown that this is a more prevalent problem in Asian Indians as compared to white Caucasians in USA[4]. Dyslipidemia is a common pre-disposing factor as well as an outcome of many alarming problems of today's world like Diabetes mellitus, Cardiac ailments, metabolic syndrome, HTN, Obesity, etc. It affects both sexes and age groups between 20-60 yrs. Literature shows the use of statins has a risk of chronic toxic effect including carcinogenic, teratogenic and mutagenic changes over a life time of use [5]. Therefore, increasing prevalence made it necessary to explore dyslipidemia from literary as well as management point of view keeping in mind the scientific knowledge. The current intervention on the caseis significant as the formulation (*Yavalauhachoorna*) used is unique and proves efficacy in dyslipidemia, yielding a better choice in practice. *Yavalauhachoorna* acts against obesity (*sthoulya)*, diabetes *(prameha)* and worms

(krimi). Formulation is also known for its alleviation of kapha*(kaphahara)*, alleviation of medas*(medohara)*, cleansing of channels *(srotoshodana),* scrapping *(lekhana)* and absorbing *(grahi)* action. The ingredients include Embeliaribes (*Vidanga*), *Zingiber officinalis* (*Nagara*), Alkali of *Hordeum vulgare* (*Yavakshara*), Incinerated Iron ash (*Lauhabhasma*), *Hordeum vulgare* (*Yava*), and *Embilica officinalia* (*Amalaki*). Hence, they are very effective against *sthoulya* and *prameha*.

Patient Information:

A female patient aged 52 years weighing 69 kg and a height of 165 cm complained of generalized weakness (*daurbalya*) associated with excess thirst (*ati-pipasa*), excess sleep (*nidra-aadhikya*) and excessive perspiration (*atisweda*). Patient was free from serious ailments like IDDM or poorly controlled DM, MI, Cardiac failure, renal insufficiency, Hypothyroidism, gluco-corticosteroids induced dyslipidemia or was not under treatment with statins or any other drug. Patient reports to be a smoker with 1 pack (1 pack per year) 15 years before. Her family history was positive for hypertension, type 2 diabetes,and myocardial infarction (MI) (father at age 58 and mother at age 67). She was not under treatment from any system of medicine.

Clinical findings:

The patient was alert, orientated and cooperative. On physical exam, the patient had a regular heart rate and rhythm without a murmur, click or rub. Chest expansion was symmetric, her cardiac exam and peripheral pulses are both normal. Her anterior and posterior lung fields were clear to auscultation bilaterally. No peripheral edema was noted, and peripheral pulses were 2+ bilaterally. Hair growth was visualized to bilateral halluxes, and her monofilament and vibration exams were within reasonable limits. Foot exam was positive for dry skin but absent of cracks and sores. Height 164 cm (65th percentile), weight 98 kg (> 95th percentile), BMI 36.4 (> 99th percentile), blood pressure 136/76. No enlargement of the thyroid gland. Acanthosis nigricans on the posterior neck was absent.

Timeline:

Table 1: Timeline of the case

Year	Clinical events and intervention
2018	Patient started observing gaining of weight gradually
2019	Through controlling diet and physical exercise the weight was under control
2019-20	Patient was not under any treatment
2020	Condition (Generalized weakness, etc.) of patient worsening
15/09/2020	Patient arrived at the hospital for treatment.
15/09/2020	Clinical examination (Ayurvedic and modern) was conducted and the above mentioned observations were recorded.

15/09/2020	**Height and weight were assessed along with BMI. BMI derived indicated over weight. Laboratory investigations indicated an abnormally increased level of various parameters in lipid profile.**
15/09/2020	***Medovruddhilakshanas/ Medovahasrotodushtilaskshanas* observed and diagnosed as *Medoroga* in Ayurveda and Dyslipidemia in contemporary science.**
15/09/2020	**5 grams *Yavalauhachurna* was prescribed to the patient along with Honey twice daily.**
15/09/2020	**Patient instructed to come for the first follow up after one month**
20/10/2020	**Second visit of patient revealed remarkable changes in the symptoms specifically laziness and generalized weakness.**
20/10/2020	**Laboratory investigations mentioned an increased level despite certain levels of improvement. But, there was an increase of weight noted with change in BMI.**
20/10/2020	**Patient was informed to continue the medication and consult after one month along with laboratory investigation (Lipid profile)**
24/11/2020	**Third visit and after 2 months of treatment it was observed moderate to mild reduction and complete recovery of features. But, there was an increase of weight noted with change in BMI.**
24/11/2020	**Laboratory investigations mentioned remarkable levels of improvement.**

Diagnostic assessment:

Laboratory investigations mentioned an increased level of total serum cholesterol (475.7 mg/dl), serum triglycerides (280.2 mg/dl), serum Low Density Lipoprotein (205.7 mg/dl), serum very Low Density Lipoprotein (89.1 mg/dl) and low High Density Lipoprotein (34.5 mg/dl). Challenges were faced in identifying and eliciting history appropriately from the patient as the insight about the condition by the patient was least apart from gaining weight. The patient complained of generalized weakness(*daurbalya*) associated with excess thirst(*ati-pipasa*), excess sleep(*nidra-aadhikya*) and excessive perspiration(*atisweda*). By considering the constellation of signs and symptoms the disease was diagnosed as diseases of *medas* or lipids *(Medoroga)* (where the *medovahasrotodushtilakshanas* were observed). Components of pathogenesis *(samprapti)* was also understood and derived from the elicited signs and symptoms. Involvement of phlegm (*kaphadosha)*, lipids (*medodhatu),* lipid processing and circulating channels (*medovahasrotas)*, etc. where understood and was key in planning the formulation of choice.

Therapeutic intervention:

The selected formulation of choice was given to the patient after explaining in brief about the treatment approach and giving insight of the current condition of the patient followed by taking informed consent. The prescribed formulation – *Yavalauhachurna* was given for a period of 2 months. 5 grams *Yavalauhachurna* was prescribed to the patient along with Honey twice daily. The patient was assessed on thereafter and followed up again after one month. Patient

was advised to do consultation after 2 months with lipid profile test reports.

Table 2: Ayurvedic management of dyslipidemia

Intervention	Details of intervention	Dose	Anupana	Treatment duration
Oral medication: *Yavalauhachurna*	**Embeliaribes (*Vidanga*), Zingiberofficinalis (*Nagara*), Alkali of Hordeumvulgare (*Yavakshara*), Incinerated Iron ash *(Lauhabhasma)*, Hordeumvulgare *(Yava)*, and Embilicaofficinalia (*Amalaki*)**	**5 grams twice a day**	**Honey**	**2 months**

No concomitant allopathic medication was given during this whole treatment period. Lipid profile was the main objective criteria on which the patient was diagnosed and treated with the drug. Evaluation was done according to the values given by National Heart Lung and Blood institute; National Institute of Health (June 2005). [6, 7]

Table 3: Assessment criteria

Ayurveda	Contemporary
Pendulous buttock, abdomen and breast(*Chalasphikudarasthana*) **Lazy(*Alasya*)** **Generalized weakness(*Daurbalya*)** **Excessive thirst(*Atipipasa*)** **Excess sleep(*Nidradhikya*)** **Excess sweating(*Atisweda*)**	**Total Cholesterol** **<200 mg/dl - desirable** **200-239 mg/dl- borderline** **>240 high** **S.Triglycerides** **<150- desirable** **150-199 mg/dl- borderline** **>200- high** **S.HDL** **<40 – undesirable** **40-59- okay, but not optimal** **>60 mg/dl- good, desirable** **S.LDL** **<130- Good, normal** **130-159- borderline high** **160-189- high and undesirable** **>190- very high** **S.VLDL** **<40- normal** **40-120mg/dl- undesirable and high** **>120 – very high**
Grading: **Absence of symptoms – 0** **Mild degree of symptoms- 1** **Moderate degree of symptoms- 2** **Severe degree of symptoms – 3**	

Follow up and outcomes:

During the first visit, history taking was conducted and appropriate clinical examinations were performed along with mentioned laboratory investigations. Weight was recorded as 69 kg, height as165 cm. BMI derived as 25.3 kg/m^2 (indicating over weight). All the above mentioned tests such as total serum cholesterol, serum triglycerides, serum Low Density

Lipoprotein, serum very Low Density Lipoprotein and High Density Lipoprotein were conducted (total serum cholesterol (475.7 mg/dl), serum triglycerides (280.2 mg/dl), serum Low Density Lipoprotein (205.7 mg/dl), serum very Low Density Lipoprotein (89.1 mg/dl) and low High Density Lipoprotein (34.5 mg/dl)). Second visit (after 1 month) of patient revealed remarkable changes in the symptoms specifically laziness and generalized weakness along with improvement in objective parameters (such as total serum cholesterol (312.7 mg/dl), serum triglycerides (190.2 mg/dl), serum Low Density Lipoprotein (160.6 mg/dl), serum very Low Density Lipoprotein (68.1 mg/dl) and High Density Lipoprotein (38 mg/dl)).But, an increase in weight of 1 kg (70 kg) was seen in the patient with derived BMI of 25.7 kg/m^2.After 2 months of treatment there was remarkable levels of improvement with reference to subjective parameters such as moderate to mild reduction of pendulous buttock, abdomen and breast (*chalasphikudarasthana*), complete recovery from laziness (*alasya*), and generalized weakness (*daurbalya*). excess thirst (*atipipasa*) and excess sweating(*atisweda*) was not much improved. Excess sleep *(nidradhikya)* improved from moderate to mild degree. Objective parameters such as total serum cholesterol (200.3 mg/dl), serum triglycerides (119.7 mg/dl), serum Low Density Lipoprotein (121.1 mg/dl), serum very Low Density Lipoprotein (34.3 mg/dl) and High Density Lipoprotein (65.7 mg/dl).But, an increase in weight of 1 kg (71 kg) was seen in the patient with derived BMI of 26.1 kg/m^2. The patient was adherent to the prescription and tolerated the medicine. There were no adverse events or any unanticipated events suffered by the patient. Adherence was monitored by regularly updating the consumption of medicines to the consultant.

DISCUSSION:

The current evidence based case report is an example of prescribing a specific formulation for Dyslipidemia (*Medoroga*) and or Dyslipidemia patients. Formulation used here is *Yavalau hachurna*. Body humor (*Dosha*) is in intimate and inseparable relation (*samavayasam bandha*) with the disease. Interaction of body humor and the various tissues) is in *asamavayasam bandha* (separable relation (*Doshadushya samurchana*) with an ailment. Therefore for destroying the disease breaking the *doshadushyasamurchana* is the key. It is only possible by understanding the components of pathogenesis of a disease

(*sampraptighataka*). This can be discerned through the signs and symptoms (*lakshanas*) that are manifested in the patient. Administration of *yavalauhachurna* in this patient for the disease *medoroga* and or dyslipidemia is an excellent illustration of precise understanding of components of pathogenesis *(sampraptighataka)* in the patient and using a formulation that is alleviating abnormal phlegm (*kaphahara*), alleviating abnormal fat(*medohara*), alleviating obesity(*sthoulyahara*), and anti-diabetic (*pramehahara*) action. Studies prove *Embilica officinalia* (*Amalaki*)– one of the ingredients of *yavalauhachurna* producing significant hypolipidemic effect[8]. *Amla* contains high amounts of vitamin C in the natural form as well as cytokine-like substances identified as zeatin, Z-riboside, Z-nucleotide, flavonoids pectin, and 30% tannins. Tannins present in *Amlaki* retard the oxidation of vitamin C, while pectin has been reported to decrease serum cholesterol levels in human beings[9]. The flavonoid content of *Amla* was analyzed for its biological activity and found to possess a potent hypolipidemic effect[10]. Similarly,beneficial effects of ginger or Zingiberofficinalis(*Nagara*)[11]were observable in hyperlipidemia and diabetic subjects.It has been well demonstrated that ginger possesses antiobesity properties, leading to a reduction in BW and fat mass in various animal models[12-15]. Moreover, ginger was shown to be effective in reducing cardiovascular disease risk by ameliorating dyslipidemia in humans[16,17].Certain studies also reveal significant reduction of cholesterol by Alkali of *Hordeum vulgare* (*Yavakshara*)[18], similarly Incinerated Iron ash (*Lauhabhasma)* also is known for its hypolipidemic effect[19].Both Hordeumvulgare (*Yava*)[20], and Embilicaribes (*Vidanga*) possess the same outcome[21].On GCMS studies the Yava Lauha Churna showed alkaloids like Oxalic Acid, Acetic Acid, Tertaconasol, 3- Tretradecene, Hexaconasol. They have been reported to have hypolipidemic effects in various studies conducted earlier. Therefore it is helpful to understand the probable mode of action in contemporary language.

OXALIC ACID

A study found that oxalic acid suppressed in vitro lipid peroxidation in a concentration dependent manner. Furthermore, oxalic acid reduced the rate of ascorbic acid oxidation in the presence of hydrogen peroxide and Cu2+. These results suggest that oxalic acid is available as a natural antioxidant.[22]Another study concluded that lipase was strongly inhibited by furoic acid and oxalic acid of which inhibition by furoic acid was non-

competitive, while that of oxalic acid was competitive.[23]

ACETIC ACID

A study undertaken to evaluate in-vivo hypolipidemic activity of a novel series of 2-methyl-2-(substituted phenyl isoxazol) phenoxyacetic acid derivatives by triton induced hyperlipidemia in rats. The newly synthesized compounds 5a, 5d and 5g showed significant decrease in the serum TCH, TG, LDL and VLDL along with an increase in serum HDL levels as compared to standard drug Fenofibrate.Another study conducted to assess the Hypolipidemic Activity of Novel 2-(4-(2-Amino-6-(4-Substituted Phenyl) Pyrimidin-4-yl)-2-Substituted Phenoxy) Acetic Acid Derivatives using high fat diet induced hyperlipidemia in rats revealed that among the synthesized compounds, few derivatives were found to be the most hypolipidemic agent affording significant effects on the serum levels of CH, TG, LDL and HDL.[24]

TETRACONASOL

A study undertaken to investigate the hypolipidemic effect and potential mechanisms of *T. mongolicum* extracts. The results suggest that *T. mongolicum* is expected to be useful for hypolipidemic effects. Tetraconasole is one of the main bioactive compounds present in it along with linoleic acid and phytol, which are responsible for the said action.[25]

3-TETRADECENE

A study conducted to estimate the phytochemistry, pharmacology and traditional uses of Leptadenia pyrotechnica. Under phytochemistry section the hypolipidemic & antiatherosclerotic efficacy of methanolic extract of the aerial part of *L. pyrotechnica* in cholesterol fed rabbits was studied. The administration of *L. pyrotechnica* (250 mg/kg body weight per day orally) extract significantly ($p<0.001$) prevented the rise in serum total cholesterol, LDL-cholesterol, VLDL-cholesterol, triglycerides and atherogenic index. Hepatic and aortic total cholesterol, triglycerides and lipid peroxidation were also lowered significantly in the extract treated rabbits. 3-Tetradecene was one of the major constituent present in aerial part of tetradecene.[26]

HEXACOSANOL

A study conducted to estimate The Effect of Ethanolic Extract of Cassia Fistula Leaves on Triton X100 Induced Hyperlipidemic Male Albino Rats, has shown that the stem bark of Cassia fistula is also a potential source of lupeol, ß-sitosterol and hexacosanol. The result of this study showed that the ethanolic extract of Cassia fistula at various doses

ranging from 200mg/kg-600mg/kg hashypolipidemic properties.[27]

It was interesting to note that the patient reported weight gain and increase in BMI despite reduction of subjective features. This may be due to the redistribution of fat and nutritive action contributed from drugs like *amalaki*, etc. due to sweet taste post digestion (*madhuravipaka*), cold potency (*sheetaveerya*) and rejuvenating action (*rasayanakarma*). But the gain in weight cannot be considered as morbid rather it was at acceptable range.

Though mentioning its best part, there are certain flaws to be mentioned for conducting better interventions in future. Applicability of this formulation – *Yavalauhachurna* for other patients suffering from *Medoroga* and or dyslipidemia has to be studied, as Ayurveda believes in personalized medicine, where there are multiple confounding factors that may interfere with the outcome or efficacy of the treatment. These confounding factors are also to be considered and thereby removing any sort of bias. Such case series will yield more evidence to practice. Though the contemporary mentions the importance of EBM – Evidence Based Medicine, Ayurveda highlights PBM - Practice Based Medicine (i.e. a process of lifelong, self-directed, problem-based learning in which caring for one's own patients creates the need for clinically important information about diagnosis, prognosis, therapy and other clinical and health care issues[28]).

In spite of voluminous work done on it and its (*Medoroga*) management in Ayurveda, it still remains a common serious problem leading to fatal complications. This has encouraged coming up with this case report with Ayurvedic alternative to control the cholesterol levels. Therefore, in the present case study, an indigenous and cost effective drug "*Yavalauhachurna*[29]" has been evaluated for its efficacy on scientific line to check or reduce the incidence of dyslipidemia.

CONCLUSION:

Yavalauhachurna acts against the disease *Medoroga* due to its *dravya, guna* and *karmaprabhava* (impact of material, attribute and action) at various components of *sampraptighataka*.

Therefore, the appropriate use of *Yavalauhachurna* in similar manifestation or involvement of similar components of *samprapti* (pathogenesis) will provide better outcomes in clinical practice for *medoroga* spectrum disorders. The result of GCMS study explains the hypolipidemic effects of the compound in present study.

Patient perspective:

Patient reported significant relief in generalized weakness and improved from being lazy and reduction of excessive sleep. Physically the patient felt lite and enthusiastic in performing daily activities. Treatment also provided faith, optimism and hopes of the patient in Ayurveda system in curing ailments and maintains health.

Informed consent:

Informed consent was given by the patient to perform the intervention and report the efficacy in the form of case report.

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