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CASE REPORT

Effect of *Amalaki* (*Emblica officinalis* Gaertn) *swarasa bhavitha Haridra* (*Curcuma longa Linn.) churna* in Diabetic dyslipidemia - A case report

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Backround

Diabetic dyslipidemia is a cluster of lipoprotein abnormalities characterized by increased sugar levels, triglyceride, low-density lipoproteins (LDL) levels and with decreased high-density lipoprotein (HDL) particles in the body. The lipid changes associated with type 2 diabetes mellitus (T2DM) are attributed to increased free fatty acid flux secondary to insulin resistance. According to National Nutrition Monitoring Bureau (NNMB) 34% men and 33.6% women come under the category of both diabetic and dyslipidemia. Both diabetes and dyslipidemia are indeed common health concerns today. These are often linked and share risk factors and diabetes can lead to dyslipidemia over time.

Case presentation

A 55year old male patient presented with complaints of the numbness of left little toe, increased sweating and hunger. Preliminary assessment of blood sugar and lipid profile indicates a known case of diabetes mellitus and dyslipidemia. The patient was instructed to take two 500mg capsules of *Amalaki swarasa bhavitha Haridra churna* with lukewarm water after meals, twice a day, for a duration of 3 months. Assessment of FBS, PPBS and lipid profile were done at the end of each month. HbA1c was done prior to the treatment and after the completion of 3 months.

Conclusion

The combination of drug *Haridra* and *Amalaki* seems to be simple, safe and cost effective, easily available, without any adverse drug reactions (ADR) that can be administered in diabetic and dyslipidemic patients. The study drug was effective in reducing both the blood sugar levels and lipid profile value to a normal range in a patient with Diabetic dyslipidemia.

Introduction

Diabetic dyslipidemia, a common pattern of lipid abnormalities, includes hypertriglyceridemia, reduced high density lipoprotein (HDL)- cholesterol concentration and a shift towards small dense low-density lipoprotein (LDL).[1] Although not all patients with diabetes exhibit all manifestations, 60 to 70% of them present some lipid abnormalities.

Diabetes is a growing global concern due to its increasing prevalence. It is a well-established independent risk factor for cardiovascular disease (CVD). Both diabetes and dyslipidemia are common health concerns today, often linked and sharing common risk factors. Dyslipidemia is a major and probably the most critical link between diabetes and cardiovascular disease.[2] Over time, diabetes can lead to dyslipidemia.

Compared with non-diabetic individuals, diabetic patients have 2 to 4 times increased risk for stroke and death from heart diseases. A very common metabolic abnormality associated with diabetes is dyslipidemia, characterized by a spectrum of qualitative and quantitative changes in lipids and lipoproteins.[1]

The prevalence of dyslipidemia among diabetic patients at baseline was 85.5% among males and 97.8% among females. The most common pattern among both males and females was combined dyslipidemia with high LDL and low HDL, which affected 22.7% and 33% of diabetic patients with dyslipidemia, respectively.[3] As per the American Heart Association, at least 68% of people with diabetes aged 65 or older die of heart disease and 16% die of stroke.[4]

Reduction in serum LDL levels will reduce the circulating levels of smaller and denser LDL particles. Lowering LDL level is the first priority in treating Diabetic dyslipidemia. Diabetic dyslipidemia treatments can be divided into non-pharmacological and pharmacological. Non-pharmacological treatments include medical nutrition therapy, weight loss and physical activity. Pharmacological treatments include statins, cholesterol absorption inhibitors, niacin, fibrates, bile acid sequestrants (BAS) and omega-3 fatty acids. Statin can cause side effects like muscle pain and damage, liver damage, neurological problems of which myalgia (5%-10%) is the most common.[5]

Amalaki is botanically identified as *Emblica officinalis* Gaertn. belonging to *Euphorbiaceae* family having *tridoshahara, raktapittahara, swedahara*, *medohara, pramehaghna*, *sara, chakshushya, dahahara, rasayana and vayasthapana properties*[6,7,8]. *Haridra* botanically known as *Curcuma longa* Linn. is *kaphapittahara, mehaghni, vishahara, ruskha, ushna, kledamedohara, kushtaghna*, *vranahara* and *lekhana*.[9,10,11,12] Various studies of *Haridra* and *Amalaki* has significantly proved its anti-diabetic activity and reduces levels of lipids in serum. *Swarasa* (juice) of *Amalaki* and *churna* (powder) of rhizome of *Haridra* was taken and given *bhavana* (process of trituration) to increase the potency of the drug. Capsules were made with *bhavitha churna* (triturated powder) and administered to the patients. This case report describes the effect of *Haridra* and *Amalaki*, which are readily available and commonly used.

Materials and Methods

Preparation of drug

Fresh rhizomes of *Haridra* were washed thoroughly and sufficient amount of water was added and boiled until froth and fumes were released. Boiling was continued until a typical aroma and the rhizomes becomes soft. The rhizomes were then allowed to cool and spread over a mat and dried under the sun for 10-12 days[13,14]. Dried rhizomes were made into fine powder and sieved through mesh size 85.

The fresh fruits of *Amalaki* were purchased locally from the Kanjirapally market. They were washed, the fleshy part was removed using a clean knife, cut into small pieces, and then ground. It was then placed in a clean cloth, pressed and squeezed out through the cloth.The expressed juice was collected in a clean container.

Bhavana was given according to the reference of *Bhaishajya ratnavali*[15]. *Haridra churna* was evenly spread in a tray, and *Amalaki swarasa* was poured over it until it was completely absorbed. During the day, the tray was kept in sunlight, and at night, it was placed in the shade. This process was repeated for 7 days. After completely drying, the *churna* was ground again and sifted through a mesh size of 85. Then the *bhavitha haridra churna* was filled in gelatin capsule, each capsule containing 500 mg of *churna*. The clinical study was conducted using *bhavitha churna* of *Haridra* in capsule form.

Methodology

Patient satisfying the inclusion and exclusion criteria was selected from the Outpatient Department, Government Ayurveda Hospital, Trippunithura. The criteria are given below.

S.No	Inclusion criteria	Exclusion criteria
1.	Age: 30-70 yrs.	Known history of cardiac pathology, chronic kidney disease, liver pathologies and hematological disorders.
2.	FBS: between 110mg/dl and 200mg/dl.	Known history of any other endocrinological disease like hypothyroidism, aldosteronism etc.
3.	PPBS: between 140mg/dl and 240 mg/dl.	Pregnant and lactating females.
4.	HbA1c: between 6.5 -8.	Participants who are already administering medication for dyslipidemia and diabetes.
5.	LDL: 130mg/dl and above.	
6.	Individuals ready to follow all procedures.	

Assessment of blood sugar levels was done as per American Diabetes Association (ADA). FBS, PPBS, HbA1c and lipid profile were initially conducted at an authorized clinical laboratory and indicated a case of Diabetic dyslipidemia. When found to be in the inclusion criteria, liver function test, renal function test and thyroid function were done to exclude other pathological conditions. Blood sugar was checked through manual digital glucometer at the end of each month consecutively for 3 months. After the diagnosis, the subject was provided with *Amalaki swarasa bhavitha Haridra churna* capsules from the OPD after taking informed consent from patient. Participant was monitored for blood sugar levels and lipid profile before treatment, after 1 month, 2 month and after treatment. HbA1c was assessed before and after treatment to evaluate the effect of study drug in diabetes with dyslipidemia.

Case presentation

Patient information

A 55-year-old male patient residing in the rural area, from a middle-class family, completed his secondary education and working as a nursing staff visited the OPD with the complaints of tingling sensation of the left little toe and muscle cramps during night time. Also, he complained of increased sweating and increased hunger. The values of FBS, PPBS, HbA1c seems to be a known case of Diabetic mellitus. He was advised to do the lipid profile and the reports were found to satisfy the inclusion criteria of the study. Dietary history revealed excess intake of sugar items and the food pattern was regular. No comorbidities were present in the participant. He consulted a modern physician and was recommended to take Metformin tablet (500mg). Patient was not willing to take modern medicine, so he discontinued the medicine after 1week. And tried to control the disease by implementing dietary restrictions, such as reducing sugar intake and avoiding junk foods for 7 months. Additionally, he started walking for half an hour daily but the symptoms remained uncontrolled. The patient had strong positive family history of Diabetes mellitus, his mother had diabetic foot ulcer and undergone incision and drainage. He was advised to do liver function, renal function and thyroid function tests.

Clinical findings

Physical examination revealed a bodyweight of 63 kg, height of 168 cms, Pulse rate of 80/min, Blood pressure measures 132/88mm of Hg, Respiratory Rate of 17/min, Temperature of 94.2 F. The reports of Liver function tests, renal function and thyroid tests were normal. Laboratory investigations showed fasting blood sugar (FBS) - 162 mg/dl, Post prandial blood sugar (PPBS) - 191.2 mg/dl, HbA1c- 7.6 %, Serum cholesterol -233.0mg/dl, Serum triglyceride 159 mg/dl, HDL cholesterol- 45 mg/dl, LDL cholesterol 164.2 mg/dl, VLDL cholesterol- 23.8mg/dl. On clinical examination, the patient had a regular heart rate. Chest expansion was symmetric, clear and bilateral air entry present. He also complained of increased hunger and sweating. No edema present on the extremities and numbness present on the left little toe. The patient was alert, oriented and cooperative.

Therapeutic intervention

After explaining the condition and details of the drug used, the patient was given *Amalaki swarasa bhavitha Haridra churna* capsules (500 mg), 2 gm daily in divided doses. He was advised to take 2 capsules twice daily with lukewarm water, after food for a period of 3 months. Objective parameters such as blood sugar values in accordance with ADA guidelines and lipid profile were assessed at regular intervals. FBS, PPBS and lipid profile were evaluated at the end of each month. Additionally, HbA1c levels were measured before the treatment and after the completion of 3-month period.

Observation

Periodic assessment of blood sugar and lipid profile showed significant reduction in the values of FBS, PPBS, lipid profile and HbA1c of the patient. Before treatment the FBS (162mg/dl), PPBS (191.2mg/dl), LDL (164.2mg/dl), HDL (45 mg/dl), TG (159 mg/dl) were noticed. After 3 months of medication, the blood values reduced to FBS (102mg/dl), PPBS (112mg/dl), LDL (114mg/dl), HDL (52mg/dl0 and TG (121mg/dl) came within the normal limits. The value of HbA1c dropped from 7.6% to 6.2 %. Additionally, the patient reported reduced numbness in the left little toe and perspiration. All parameters returned to the normal range and showed significant improvement compared to pre-treatment values.

Assessment of Blood sugar levels and LDL cholesterol

	Before treatment	After 1 month	After 2 months	After 3 months
LDL	164.2	138	127	114
HDL	45	47.2	49.3	52
TG	159	155	136	121
FBS	162	143.1	123	102
PPBS	191.2	144.2	139	112

Assessment of HbA1c levels

	Before treatment	After treatment
HbA1c	7.6	6.2

Discussion

Insulin resistance is considered to be the core pathology of Type 2 Diabetes mellitus and is also associated with many other metabolic complications like dyslipidemia, obesity etc[1]. In Diabetic dyslipidemia controlling both glucose and lipid levels appears to be challenging and a drug addressing both the entities are necessary. The present study shows significant control over blood sugar level and lipid values.

Intake of *snigdha, madhura, guru, pichila ahara, nava annam, aanupamamsa, gorasa, guda* and those that increase *kapha* are some of the common *nidana* of *medoroga* and *prameha*. Along with that *divaswapna, avyayama* and *beejaswabhava* (hereditary factors) are other causes[16,17,18,19,20]. *Medoroga* and *prameha* are *santarpanajanya vyadhis* mainly with *medovaha srotodushti*[21]. *Medas* and *mamsa* are the *dushyas* involved in *medoroga*. As per *Bhavaprakasha, sthaulya* patients develops *prameha, kushta, visarpa,*etc.[22]

The capsule is the combination of two herbs *Haridra* (*Curcuma longa* Linn.) and *Amalaki* (*Emblica officinalis* Gaertn.). The *swarasa* (juice) of *Amalaki* and *Haridra churna* (powder) were used for the preparation of medicine. *Ashtanga Hridaya Uttarastanam* in the context of *Agroushadi* mentioned *Amalaki* and *Haridra* as the best remedy for *Prameha*[23]. *Haridra* is described as a *pramehaghna dravya* in all *Nighantu. Haridra* possess *tikta, katu rasa, ruksha guna, ushna virya* and *katu vipaka*[9,10,12]. *Amalaki* have *pancharasa* except *lavana*, *madhura vipaka, sheeta virya* and pacifies all the three *doshas* in the body[6,7,8]. *Tikta rasa* reduces *daha, trishna* and possess *lekhana, kledamedohara, sleshma upasoshana, ruksha* properties [24]. *Katu rasa* eliminates *sweda* and *kleda* from the body, reduces *sleshma* and *ruksha* in nature[25]. Also reduces excess *medas* in the body. Thus the combination of the drug acts on vitiated *Kapha, medas* and *kleda* which are the basic causes of *prameha* and excess *meda* in the body and acts as a potent *rasayana* drug. Due to *rukshata* of the drug, it reduces *ama* and *kleda* present in the body. This increases the *Agni* which helps to improve disturbed metabolism and *soshana* of *kleda* and *medas* which is useful in the *samprapti* of the disease.

Experimental studies shows that combination of this drug reported its efficiency as an anti-diabetic agent, inhibited lipid accumulation and the total cholesterol content. The formulation helped in overcoming the symptoms of pre-diabetes especially fatigue, increased thirst and hunger[26].

Curcuminoids in Haridra lowers lipid peroxidation by maintaining the activities of antioxidant enzymes and improves insulin resistance, decrease glucose and insulin levels thus possess potent anti diabetic action[27]. *Emblica officinalis* fruit juice is an effective hypolipidemic agent. It reduces aortic plaques and improves insulin sensitivity[28]. It is effective in low-density lipoprotein (LDL) oxidation and cholesterol levels thus preventing atherosclerotic changes[29]. The high amount of vitamin C content in the fruit of *Amalaki* reduces the sugar level in blood and flavonoids reduces the level of lipids in serum. It stimulates the islets of Langerhans i.e. the isolated group of cells which secrete hormone insulin.[30]

Conclusion

The administration of *Amalaki swarasa bhavitha Haridra churna* capsule at dose of 2 gm per day in divided dose (1gm BD) was significant in reducing both the blood sugar levels and lipid profile value to a normal range in a patient with diabetes and dyslipidemia. FBS was reduced from 162 mg/dl to 102 mg/dl, PPBS reduced from 191.2mg/dl to 112mg/dl, HbA1c from 7.6 % to 6.2% and LDL was reduced from 164.2 mg/dl to 114 mg/dl, HDL increased from 45 mg/dl to 52 mg/dl and TG from 159 mg/dl to 121 mg/dl. The patient complains of tingling sensation of left little toe and muscle cramps in the lower limbs, particularly at night. These symptoms have reduced after treatment. Also increased sweating and hunger have reduced.The probable mode of action of the drug is due to its *tikta, katu rasa, ruksha guna, ushna virya, katu vipaka, kleda medohara* properties. The drug possess *kaphahara* action which is the major cause of *prameha* and excess *medha* in the body. The study drug was significantly effective in reducing the blood parameters to normal limits. *Haridra* and *Amalaki* seems to be simple, safe and cost effective, easily available, without any adverse drug reactions (ADR) that can be administered in diabetes and dyslipidemic patients.

Patient perspective

Patient was satisfied with the treatment and assessment, and was relieved from the symptoms at the end of study period. He noticed a progressive improvement in his conditions. Patient was given full details about study and informed consent was obtained from him prior to beginning of study.

Ethical consideration

Ethical clearance (no. 04/DG/IEC/2022, dated 10/08/2022) was obtained from the Institutional Ethics Committee of Government Ayurveda College, Tripunithura. Patient was given details regarding the clinical trial and informed consent was obtained prior to the trial.

Conflict of interest

Nil.

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