

Clinical Evaluation of Antidyslipidemic Effect of Unani Polyherbal Formulation (*Habb-e-Sundrus*) - A Randomized Single Blind Standard Controlled Study

Barkati Md.Tarique ^{*1}, Mansoor Ahmad Siddiqui², Mohd Shahid³, Siddiqui Aafreen⁴

Assistant Professor, Department of Amraz-e-JildwaTazeeniyat, Yunus Fazlani Unani Medical College, Kujkheda, Kannad, Maharashtra, India¹

Director & HoD Department of Moalajat (Medicine), NIUM, Bengaluru, India²

Assistant Professor, Department of Moalajat, Markaz Unani Medical College, Calicut, Kerala, India³

PG Scholar, Department of Moalajat, NIUM, Bengaluru, India⁴

ABSTRACT: Background & Objective: Dyslipidemia is a major cause of atherosclerosis as it plays a pivotal role in its pathogenesis and related consequences. Deaths related to cardiovascular origin, especially from coronary heart disease is at the top globally. There are ample evidences determined which confirmed association between dyslipidemia and cardiovascular diseases. Hypolipidemic agents (statins) used in conventional medicine have low efficacy and produces intolerable or life-threatening adverse effects, primarily if they are used for a longer duration. In Unani system of medicine, the concept of *Dusumat-e-Dam* (lipid in blood/dyslipidemia) was lucubrated and managed extensively by single and compound drugs but not validated on scientific parameters. Hence, present study was designed to evaluate the efficacy and safety of *Habb-e-Sundrus* (Unani polyherbal formulation) in dyslipidemia.

Methods: Present study was single blinded, randomized, standard controlled clinical trial conducted at NIUM, hospital from March 2015 to December 2015 on sample size of 33 subjects. After taking written informed consent subjects were randomly allocated into two groups (22 in test group and 11 in control group). Test group was treated with powder of *Habb-e-Sundrus* (5gm twice a day) and control group treated with tablet atorvastatin (10 mg once a day) orally for 45 days consecutively. Subjective parameters (dyspnoea on exertion and fatigue) were assessed on each follow-ups (i.e. on 0th, 15th, 30th and 45th days) while objective parameters (lipid profile and BMI) were measured at 0th day and 45th day of trial. Results were analyzed using Student 't' test, Chi-square and Fisher Exact test.

Results: Serum triglyceride, Very low density lipoprotein, BMI and subjective parameters were shown statistically significant changes over time (45 days) in both test and control groups ($p < 0.05$). However, intergroup analysis revealed that differences in all investigated parameters were statistically non-significant. Safety parameters founds within the normal range.

Conclusion: It can be concluded that, use of either *Habb-e-Sundrus* or Atorvastatin is equally safe and effective in the management of dyslipidemia.

KEYWORDS: Dyslipidemia; *Siman-e-Mufrit*; *Habb-e-Sundrus*; Atorvastatin, Unani Medicine

I. INTRODUCTION

Dyslipidemia is basically a condition of abnormality of lipid levels measured in the blood, which includes either overproduction or deficiency of lipoproteins or both.^{1,2} It may manifest as an elevation of serum total cholesterol or triglyceride or both, or low density lipoprotein (LDL) and decrease in high density lipoprotein (HDL) concentration.^{3,4} It

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is a major health problem all over the world as it plays a pivotal role in development of coronary artery disease (CAD) and responsible for more than four million deaths annually and also accountable for developing IHD globally.^{5,6} In Asia, prevalence of coronary heart disease (CHD) is approximately four times higher as compared to the general population in the USA.⁴ If it is not monitored properly or left untreated, it affects overall health and could lead to catastrophic consequences like atherosclerosis, stroke and ischemic heart disease (IHD).⁷ Many studies have proved well established association between dyslipidemia and development of cardiovascular diseases.⁴ In Unani system, presence of lipids in blood is termed as *Dusumat-e-Dam* and was described elaborately about the ill effects with management, if fat is pathologically increased in blood.^{8,9,10} When these oily substances of blood reaches to different organs of the body, they start to deposit there in the form of fat (*Shahm*) due to *Barid Mizaj* (Cold temperament) of those organs.¹⁰ *Siman-e-Mufrit* (obesity) has also been discussed extensively and managed in Unani system of medicine (USM) since centuries.¹¹ The possible consequences of *Siman-e-Mufrit* like *Khafqan* (palpitation), *Salabat-e-Nabz* (Atherosclerosis), *Sakta* (Stroke), *Zeeq-un-Nafas* (breathlessness), Coma and Sudden death are very much similar with the signs, symptoms and complications of dyslipidemia defined in conventional medicine.^{9,12} Hence, *Siman-e-Mufrit* is a disease in which there is a deposition of *Barid Ratab Mad'da*¹³ (*Shahm/Lipid*) and it falls under the category of *Amraz-e-Balghamiya*.¹⁴

The basic principle of USM for treating the disease is *Ilaj-biz-Zid* (heteropathy) i.e., administration of drugs on the basis of *Mizaj* (temperament) opposite to particular disease and eliminating morbid matter from the body.¹⁵ As the collective *Mizaj* of ingredients present in *Habb-e-Sundrus* is *Haar* (hot) and possessing properties including *Muhaz'zil* (emaciating), *Mulat'tif* (demulcent), *Muhal'lil* (resolvent), *Mujaf'fif-e-Rutubat* (desiccant) and *Muqaw'wi-e-Kabid* (hepatotonic) which helps in *Ta'deel* (normalization of *Mizaj*) and *Tanqia-e-Madda* (elimination of morbid matter) from the body.^{16,17,18}

In conventional medicine, standard treatment of dyslipidemia includes dietary modifications, exercise and pharmacological therapy either alone or in combination. Hypolipidemic agents have low efficacy and produces intolerable or life-threatening adverse effects, primarily if they are used for a longer duration.¹⁹

In view of high burden possess by dyslipidemia on community and non-availability of safe and effective treatment, medical fraternity is looking for more efficient management of it. The USM may provide a solution for the above problem discussed. Keeping in view of *Ilaj-biz-Zid*, *Habb-e-Sundrus* was selected, as *Sue Mizaj Balghami* (immoderate phlegmatic temperament) is the main cause of *Dusumat-e-Dam* and *Siman-e-Mufrit*. Consequently, a randomised, single blind, standard controlled clinical trial has been designed to evaluate the safety and efficacy of *Habb-e-Sundrus* in dyslipidemia.

II. METHODOLOGY

Study design: A single blinded, randomized, standard controlled clinical trial was carried out in the Dept. of Moalajat (Medicine), National Institute of Unani Medicine Hospital, Bengaluru over a period of 10 months from March 2015 to December 2015. The study was conducted in accordance with Declaration of Helsinki (2013 version) and to GCP (Good Clinical Practice) guidelines after approval by institutional ethical committee. (IEC no: NIUM/IEC/2013-2014/003/MOAL/03). Total duration of clinical trial was 45 days.

Inclusion and exclusion criteria:

In this study, known cases of dyslipidemia with ≤ 3 years of disease chronicity, age between 20-60 years either gender and patients willing to give voluntary written informed consent were included. Whereas patients with history of IHD, stroke, diabetes mellitus, hypothyroidism and severe systemic illnesses, patients using oral contraceptive pills, pregnant and lactating women were excluded.

Sample size calculation:

In order to have a 83% chance of detecting a difference (at least 29 mg/dl) in mean cholesterol change with 10% drop outs at 5% level of significance and considering the standard deviation of total cholesterol as of 11.16 mg/dl with an experiment-wise error rate (EWER) of 0.050 (based on the achieved data from a previous similar study) using a one-

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sided **Microarrays - Two-Sample Analysis**, the sample size calculated was 22 and 11 in test and control groups (2:1) respectively by using **PASS Software by NCSS**.

Allocation of patients:

Out of 60 patients screened for the study 40 patients were fulfilled pre define criteria. Hence, they were subjected to clinical and laboratory investigations {Haemogram with ESR; Lipid Profile (S. cholesterol, S. Triglyceride, HDL, LDL and VLDL), RFT (S. urea & S. creatinine), LFT (SGOT, SGPT, Alkaline Phosphates) before (at 0th day) and after (at 45th day) completion of treatment. As per the exclusion criteria FB, ECG and TSH investigations were done during screening with aim to exclude the patients. Citing their personal reasons 7 participants declined to give written informed consent. Finally 33 subjects were enrolled and randomly assigned to either test group (n=22) or control group (n=11) by using lottery method. Test group was treated with *Habb-e-Sundrus* (5gm BD in powder form after meal) whereas control group with Tab. Atorvastatin (10mg OD after meal) orally for 45 days continuously with 3 follow-ups fortnightly. No Concomitant treatment was allowed to the patients other than test and control drug till the completion of study. Moreover, all patients were advised to take prescribed diet of 20-25 Kcal/kg body weight per day and brisk walk daily for 30 minutes along with the treatment in both groups. Two participants in test and one in control group did not turn up for the follow up and post test. Hence, they were assumed as lost to follow up (LFU). The details are depicted in flow chart (CONSORT).

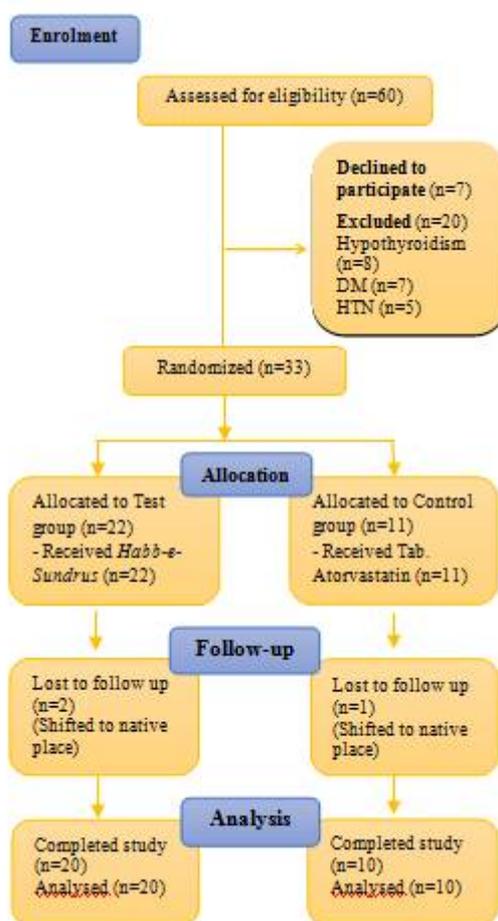


Fig. No. 1: CONSORT flow chart

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Table no. 1: Composition of Test drug (*Habb-e-Sundrus*):^{20,21}

Unani Names	Botanical Names	Quantity
<i>Sundrus</i>	<i>Trachylobium hornemannianum</i>	13.5 gram
<i>Luk-e-Maghsool</i>	<i>Coccus lacca</i>	4.5 gram
<i>Halela Siyah</i>	<i>Terminalia chebula</i>	4.5 gram
<i>Poast Halela Zard</i>	<i>Terminalia chebula</i>	4.5 gram
<i>Poast Halela Kabuli</i>	<i>Terminalia chebula</i>	4.5 gram
<i>PoastBalela</i>	<i>Terminalia bellirica</i>	4.5gram
<i>Aamla</i>	<i>Emblica officinalis</i>	4.5 gram
<i>ZeeraKirmani</i>	<i>Carumcarvi L.</i>	07 gram
<i>Namak Lahori</i>	<i>Sodium chloride</i>	3.5 gram

Intervention:

Good quality dried crude drugs (*table no. 1*) were procured from registered herbal shop in K.R market, Bengaluru and properly identified to ascertain its originality by the chief pharmacist of Dept. of IlmulAdvia NIUM, Bengaluru. After that, ingredients were cleaned by weeding out unwanted materials and grinded to make fine powder by following SOP's under the supervision of chief pharmacist as per the methods described in classical Unani texts and GMP. The test drug (*Habb-e-Sundrus*) was supplied as powdered (150 gram) in opaque, airtight plastic lock bags to test group subjects.

Dose: *Habb-e-Sundrus* (5 gm BD in powder form after meal) was prescribed to the test group whereas Tab. Atorvastatin (10 mg OD after meal) to the control group orally for 45 days continuously.

Blinding and Compliance to treatment: To ensure blinding, both test and control drugs were supplied in the visually identical forms (dispensed in opaque, airtight, self-locking packets). Compliance of intervention was monitored on every visit by dispensing remaining drug in empty packets. Patients were advised to maintain the notebook regarding calorie intake and minutes of brisk walk daily, as a part of fulfillment of protocol.

Efficacy and Safety Assessment:

The evaluation of efficacy in both groups was based on subjective and objective parameters. Subjective parameters (dyspnoea on exertion and fatigue) were assessed on each follow-ups (i.e. on 0th, 15th, 30th and 45th days) while objective parameters (lipid profile and BMI) were measured at 0th day and 45th day of trial. As these subjective parameters were differ in severity from patient to patient, for this purpose, an arbitrary grading scale was adopted for the assessment of subjective parameters in both groups (*table no.2*). The safety of the treatment was assessed by clinical symptoms at every visit of follow- ups and biochemical assessment at baseline (at 0th day) and after completion of treatment (at 45th day).

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Table no.2: Arbitrary grading scale

Sr.No.	Nature	Grade	Nature of severity
01	No	0	No symptoms
02	Mild	+	Mild symptoms but not enough to require remedial therapy to continue day to day activity
03	Moderate	++	Moderate symptoms which interfere in day to day activities and require remedial therapy to continue routine work
04	Severe	+++	Severe symptoms which do not allow to daily activities

Outcome measures: Primary outcome measures were changes in lipid profile. Secondary outcome measures were reduction in BMI.

Adverse events documentation: No adverse effect reported during the study in both test and control groups. Few patients had experienced mild gastric irritation after consuming test formulation although no one discontinued the trial.

Statistical Analysis:

Chi-square and Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. Student ‘t’ test (two-tailed) independent and dependent has been used to find the significance for inter and intra group analysis respectively. The statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data. Significance is assessed at 5 % level of significance with p value <0.05. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). P values of less than 0.05 were considered statistically significant.²²⁻²⁵

III. RESULTS

After screening 60 patients, a total of 33 consecutive patients were enrolled into the trial over a period of 10 months from March 2015 to December 2015 were randomly allocated into Test group (22 patients) and Control group (11 patients) respectively. Out of them, 20 patients in test and 10 patients in control group completed the course of treatment as 2 patients from test and 1 patient from control group were lost to follow-up.

Demographic characteristics of the two study groups are shown in table no.3.

Table no. 3: Demographic characteristics of study groups (expressed as Mean ± SD):

Parameters	Test group	Control group
Total no. (N)	20	10
Age	45.35±9.21	46.00±8.51
Gender (Male/Female)	13/7	6/4
Dietary Habits(Mixed/Veg.)	13/7	10/0

The mean age of the study population was 45.35±9.21 in Test group and 46.00±8.51 in control group. Majority of the individuals were in the age group of 31-40 years in both groups which coincides with the study conducted by

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Sawant²⁶, Ugwuja²⁷ and Okaka *et al.*,²⁸ who pointed out that prevalence of dyslipidemia is higher in 31-40 years of age group. In this study, 19 out of 30 patients were found males, whereas 11 were females. This data indicates that the prevalence of the disease is higher in males which correlates with the findings of studies conducted by Estariet *al.*²⁹ and Huanget *al.*³⁰ Likewise majority of patients i.e., 23 out of 30 patients were having mixed dietary habit, followed by 7 were pure vegetarian. The predominance of dyslipidemia in mixed dietary habit patients suggested that fatty diet, particularly non-vegetarian diet is one of the provocative factor for development of dyslipidemia. Present data is in conformity with the study conducted by Rasheed *et al.*³¹

There were no significant differences between both groups in age, gender and dietary habits. (Table no. 3).

Effect of drugs on objective parameters:

Effect on Serum Cholesterol: No significant differences were found in the mean cholesterol level at 45th day from baseline in both test and control group.

Effect on Triglycerides: Significant differences were found in mean triglyceride level at 45th day from baseline in both test and control groups with $p < 0.05$ but no significant difference found in between group analysis.

Effect on HDL: Significant difference found in the mean HDL-C at 45th day from baseline in control group ($p < 0.05$) but not in test group and inter group analysis.

Effect on LDL: Effect of drugs on LDL-C levels of both test and control groups were found statistically insignificant.

Effect on VLDL: Significant differences were found in the mean VLDL-C levels at 45th day from baseline in both test group and control group with $P < 0.05$ but no significant difference found in between groups.

Effect on BMI: Significant differences were found in the mean BMI at 45th day from baseline in both test and control group with $P < 0.05$ but no significant difference found in between groups.

Table 4: Effect of drugs on lipid profile and BMI (expressed as Mean ± SD)

Parameters	Test group (n=20)			Control group (n=20)		
	Before	After	P value	Before	After	P value
Cholesterol	201.45±38.08	193.80±32.85	0.382	202.60±32.32	178.80±41.29	0.186
Triglyceride	224.85±70.12	191.00±75.84	0.013 *	272.40±98.34	189.50±57.77	0.018 *
HDL-C	45.54±8.91	42.80±8.62	0.297	47.04±7.46	37.70±4.06	0.002*
LDL-C	111.67±38.13	114.30±30.12	0.772	95.18±34.74	99.50±25.99	0.728
VLDL-C	44.76±13.94	38.01±15.05	0.013*	54.32±19.68	37.76±11.60	0.019*
BMI	28.96±3.76	28.20±3.81	<0.001**	29.92±3.29	29.43±3.28	0.002*

Paired 't' test used for intra-group analysis and Unpaired 't' test for intergroup analysis

IV. DISCUSSION

A significant percentage of world population has raised plasma lipid level, resulting in an increased risk of coronary heart diseases (CHD).³² Researches over the past 4 decades has been consistently shows that the burden of dyslipidemia to be very high in terms of morbidity, mortality and medical costs. It is one of the important risk factor for coronary heart disease (CHD) which is the leading cause of death in United States. The World Health Organization (WHO) estimates that dyslipidemia is associated with more than half of worldwide cases of ischemic heart disease (IHD) and more than 4 million deaths per year.^{4,5,6} USM are being looked up as an alternate treatment for dyslipidemia due to long standing experience with them and failure of many conventional medicines. Keeping in view of the above problem discussed the hypolipidemic property of compound unani formulation (*Habb-e-Sundrus*) was examined in a randomized single-blind, standard-controlled, clinical trial in dyslipidemic patients.

Regarding the efficacy of test formulation on symptoms of dyslipidemia like dyspnoea on exertion and Fatigue which has been found to be highly significant ($p < 0.001$) can be due the properties of drugs present in the formulations. Most of the drugs are *HaarYabis* in *Mizaj* and having *Muhaz'zil* (Emaciating), *Muhal'lil* (Resolvent), *Mulat'tif* (Demulcent) and *Mujaf'fif-e-Rutubat* (Desiccant) properties.^{16,17,18} These properties of test formulation may have produced excessive

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Hararat in the *Kabid*(Liver) and might have rectified its metabolism, which in turn leads to decrease in serum lipids (Triglycerides and VLDL) at the end of treatment.

Individual drugs that constitute the ingredients of test formulation have been reported to have some interesting pharmacological effects that directly or indirectly support our contentions regarding the efficacy of the test formulation like Antioxidant, Hypolipidemic and Cardio tonic properties.³³⁻³⁶

β -sitosterol present in *Sundrus* (*Trachylobium hornemannianum*)³⁷ reduces serum LDL cholesterol level by competitively inhibiting intestinal cholesterol absorption.³⁸ Anthraquinones found in *halela*(*Terminalia chebula*)³⁹ inhibit absorption of cholesterol by increasing peristalsis in the intestine, boost the converting of cholesterol into the bile acid, and therefore increase the cholesterol excretion through the bile.³⁸ Active ingredient triterpenoid found in *halela*(*Terminalia chebula*)⁴⁰ have been reported to inhibit the endogenous synthesis of cholesterol.³⁸ Pectin found in *Aamla* (*EmbelicaOfficinalis*)⁴¹ may increase hepatic synthesis of bile acids and liver depletion of cholesterol resulting in Hypolipidemic effect.³⁸ furthermore hypolipidemic effect in this study may be related to some of the constituents such as carvacrol (polyphenol) and unsaturated fatty acids (UFA) present in *Zeera*(*Carumcarvi*).^{38,42}

The hypolipidemic effects of *Habb-e-sundrus* in present study may be due to the same above mentioned properties of the ingredients present in it. Thus, we can say that the scientific studies and reported effects of the individual ingredients of test drug are in conformity to a greater extent with that of our hypothesis as well as the inferences we drew out in the present study.

Overall effects of *Habb-e-Sundrus* were found quite significant in reducing important risk factors i.e. body weight and lipid profile specially serum triglycerides and VLDL in dyslipidaemic patients with the exception of serum cholesterol, LDL-C and HDL-C which did not changed noticeably.

Overall compliance to the study was good. The parameters related with the toxicity of drugs like Hb gm%, TLC, DLC, ESR, SGOT, SGPT, Alkaline Phosphate, Blood Urea and Serum Creatinine remained within normal limits in both groups before and after the intervention.

V. CONCLUSION

Obesity and hypertriglyceridaemia are considered important risk factors for dyslipidemia and the test formulation has shown significant hypotriglyceridaemic, VLDL lowering and anti-obesity effects without demonstrating any sign of toxicity or adverse effects. Thus, it may be concluded that *Habb-e-Sundrus* may have positive effects in the management of dyslipidemia.

Small sample size and short duration trial may be considered as the main limitations for this study. Hence, studies in more number of subjects are needed to explore the beneficial role of these ingredients of *Habb-e-Sundrus* on dyslipidemia.

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VII. CONFLICT OF INTEREST

The authors have no conflicts of interest that are directly relevant to the content of this study.

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