

CLINICAL EVALUATION OF UNANI DRUG SANDROOS, LIFESTYLE MODIFICATIONS AND YOGA IN HYPERLIPIDEMIA PATIENTS UNDER NPCDCS (UNANI) PROJECT

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ABSTRACT - Cardiovascular diseases (CVDs) are the leading cause of death among adults in the United States, and people with hyperlipidemia are at roughly twice the risk of developing CVD as compared to those with normal total cholesterol levels. Hyperlipidemia is a major metabolic disorder vastly seen in this era of modernization and fast life, living with stressful life and and fast foods having high calories and also has every comfort of living and not doing any kind of physical activity. A cluster of other metabolic risk factors are often found in association with this hyperlipidemia including obesity, Glucose intolerance, insulin resistance and hypertension Patients with familial hypercholesterolemia (FH) have an even greater risk of developing CVD at an earlier age; therefore, early detection and treatment are imperative to reduce cardiovascular events and premature death. Statins are the mainstay treatment for hyperlipidemia; however, the limitations of statins include treatment resistance, intolerance due to adverse events, and a lack of adherence which contribute to poor outcomes. For prevention and control of Non Communicable Diseases, a pilot project, Integration of Unani Medicine in National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS) was launched by Central Council for Research in Unani Medicine, Ministry of AYUSH, Govt of India at 17 CHCs and District Hospital Lakhimpur Kheri (UP). Under this pilot project this study conducted. In this study patients of Hyperlipidemia were divided in to two groups, Group A received Allopathic Medicine + Lifestyle interventions / *Ilaj bit Tadbeer* and Yoga while Group B received Unani drug *Sandroos* + Allopathic Medicine + Lifestyle interventions/ *Ilaj bit Tadbeer* and Yoga. There is a significant improvement occurred in the patients of Hyperlipidemia. In second group withdrawal of Allopathic medicines were also seen in some patients.

Key words: Hyperlipidemia, Yoga, Lifestyle interventions, *Sandroos*

INTRODUCTION

Hyperlipidemia is a major metabolic disorder vastly seen in this era of modernization and fast life, living with stressful life and and fast foods having high calories and also has every comfort of living and not doing any kind of physical activity. A cluster of other metabolic risk factors are often found in association with this hyperlipidemia including obesity, Glucose intolerance, insulin resistance and hypertension Patients with familial hypercholesterolemia (FH) have an even greater risk of developing CVD at an earlier age; therefore, early detection and treatment are imperative to reduce cardiovascular events and premature death. Statins are the mainstay treatment for hyperlipidemia; however, the limitations of statins include treatment resistance, intolerance due to adverse events, and a lack of adherence which contribute to poor outcomes. ¹

Hyperlipidemia (*Fart Tashahhum Al- Dam*) is a condition characterized by abnormally elevated levels of the lipids and/or lipoproteins in the blood. It makes the patients susceptible to accelerated atherosclerosis leading to cardiovascular diseases and stroke which are one of the major causes of premature deaths due to non communicable diseases (NCDs). As far as the concept of Hyperlipidemia in Unani Medicine is concerned physicians of Unani Medicine described hyperlipidemia as *Ghilzat-al-Dam* due to predominance of *Balgham* (phlegm). It causes narrowing of vessels (*Tazayyuq al- Uruq*) which effect the supply of *Rooh* to the vital organs like heart and brain resulting the disease of these organs. ²

Unani Concept of Hyperlipidemia

As far as the description of Hyperlipidemia in Unani Medicine is concerned, there is no detail as such in classical Unani literature. The concept of *Dusumat-e-dam* (presence of fatty material in blood circulation) exists in Unani literature. The ancient Unani physicians considered *Siman Mufrit* (obesity) and *Dusumat-e-dam* either as single disease or sequel of each other. It is evident from Unani literature that complications and clinical features mentioned by these prominent scholars and the description of *Dusumat-e-dam* gives an insight that they were aware of the concept of hyperlipidaemia and *Siman Mufrit* as are of the foremost causes of its pathogenesis. Fortunately, our distinguished physicians have extensively written on *Siman Mufrit*, its etiologies, pathogenesis, treatment, complication, and its prevention, which to a great extent, simulate with dyslipidaemia. *Buqrat* (Hippocrates, 460 BC) at first realized the complications of *Siman Mufrit* and its association with disease processes. He noted that it may lead to infertility, as well as obese persons are at greater risk of sudden death than the lean individuals.^{3,4}

Ibn Sina (980–1037 AD) devoted a special section on the consequences of *Siman Mufrit* and its proper management in his encyclopaedic book “*Al Qanoon fit Tibb*”.⁵

Worldwide, high cholesterol levels are estimated to play a role in 56% of ischemic heart disease events and 18% of strokes, amounting to 4.3 million deaths annually. In the United States, more than 100 million, or roughly 53% of adults, have elevated LDL-C levels. Yet, fewer than 50% of patients with high LDL-C receive treatment to reduce their levels and among those receiving treatment, fewer than 35% achieve adequate control. Further, approximately 31 million American adults have total cholesterol levels that exceed 240 mg/dL, placing them at about twice the risk of Atherosclerotic Cardiovascular Disease compared to those with total cholesterol levels that are at goal. Indian as a race are highly prone to premature atherosclerosis and coronary artery disease. Possible that Hyperlipidemia could be one of the major contributors of this epidemic of Coronary Artery Disease and associated metabolic disorders. Hyperlipidemia is divided in to two category^{6,7}

1. Primary Hyperlipidemia (Familial) is probably due to genetic causes
2. Secondary Hyperlipidemia (Acquired) is due to following conditions

Hypopituitarism, Hypothyroidism, Diabetes Mellitus, Obesity, Cushing’s syndrome, Chronic Renal failure, Chronic Liver Disease, Use of drugs, eg oral contraceptive pills (OCP), glucocorticoids, β Blocker and diuretics, use of diet rich in saturated fat and carbohydrates, Alcohol consumption, Deviation from Asbab Sitta Zarooriya (Six prerequisites of Healthy living).

The aim of treating hyperlipidemia is to prevent or reduce the risk and complications of CVD. Hyperlipidemia is a chronic disease caused by the genetic predisposition interacting with an individual’s diet and lifestyle. The caused like error in diet, regimen, and lack of exercise should be taken care of. So each case of hyperlipidemia is treated on its individual way with this most appropriate Unani remedy having lipid lowering activity.

As the prevalence of hyperlipidemia is increasing as well as hyperlipidemia is associated with complications such as Angina, Myocardial infarction, Stroke and allopathic treatment for hyperlipidemia causes adverse effects, while Unani Medicine and Yoga are safe for long term use. So a clinical study done on the patients of hyperlipidemia under NPCDCS AYUSH (Unani) project.

MATERIAL AND METHODS

In the present open label clinical study, patients were selected from OPDs of Community Health Centres (CHCs) of Lakhimpur Kheri (UP), under Integration of Unani Medicine in National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS). Integration of Unani Medicine in NPCDCS is joint pilot project of Ministry of AYUSH and Ministry of Health & Family welfare, Government of India. Detailed clinical examination was performed as per the Case Record Form (CRF). Written informed consent taken from the all the patients before enrollment in the study. The study was carried out during the year 2019-2020. Patients were selected in the study on the basis of the following criteria

Inclusion criteria

Patients were randomly selected in between the age group of 30 to 70 years of sex, religion and occupation, total Cholesterol \geq 240 mg/dl, LDL Cholesterol \geq 160, Serum Triglycerides \geq 200 mg/dl

Exclusion criteria

Pregnancy and Lactation

Any Major Systemic Illness (Malignancy, Cirrhosis of Liver, Liver failure, Renal failure etc)

Patients on corticosteroids and hormonal treatment.

Treatment schedule with dose and duration

All the patients of hyperlipidemia were divided in two groups. Group A received Allopathic Medicine + Lifestyle interventions / *Ilaj bil Tadbeer* and Yoga while Group B received Unani drug *Sandroos* 3gm/day + Allopathic

Medicine + Lifestyle interventions/ *Ilaj bil Tadbeer* and Yoga. First group of hypertension were also taking allopathic medicine (Atorvastatin) as prescribed by the Allopathic Medical officer of the concerned CHCs.

Sandroos (Trachylobium hornemannianum) is a resin obtained from Sal tree belongs to family *Fabaceae*, traditionally it is used in Unani System of Medicine as a drug of choice for the treatment of obesity and its associated disorders and almost all renowned physicians have described its therapeutic properties like *Muhazzil* (emaciating), *Mujafif* (dessicant), *Qate balgham* (mucolytic), *Mudir e boal* (Diuretic), *Munaqi e Akhlat e Barida* (Elimination of *Barid* humours).^{8,9,10,11}

Scientific study on *Sandroos* showed anti obesity effect without demonstrating any signs of toxicity or side effects.¹²

In lifestyle interventions/*Ilaj bit Tadbeer* patients were advised brisk walk 30 minutes at least 5 days in a week, low salt diet, low fat, sugar diet. Avoid junk and smoked foods, preserved foods, alcohol, carbonated drinks, etc. Avoid excess of non vegetarian diet.

In Yogic Management patients were advised selected practices of Common Yoga practises such as Sukshmayayama, Asanas (Tadasana, Katichakrasana, Vakrasana, Vajrasana, Pranayama (Nadi Suddhi, Bhrumari, Ujjayi) for 8 weeks.. All the yogic practices were advised by yoga instructor.²

Sample size

Total 78 patients of hyperlipidemia completed the follow up. In Group A 40 patients and in Group B 38 patients completed the follow up.

Duration of study

The total duration of treatment was 8 weeks

Follow up

Follow up of the patients done at the interval of every 2 weeks. On every follow up Vitals (Pulse, Blood Pressure, Temperature) and Signs and Symptoms recorded in the Case record Form.

Efficacy and safety parameters

Subjective parameters included Obesity, Fatigue and breathlessness assessed at baseline and after the completion of study using an arbitrary scale where in 0 stood for no symptom/sign, 1 stood for mild; 2 for moderate; 3 for severe condition. The objective parameters consisted of Body Mass Index (BMI), lipid profile including total cholesterol; triglyceride; HDL; LDL, and VLDL, Liver Function Test (S.Bilirubin, SGOT, SGPT) and Renal Function Test (Blood Urea, S. Creatinine), were performed at baseline and after completion of the study at 8 weeks.

Statistical analysis

Baseline and follow up values of clinical subjective parameters and objective parameters were statistically analyzed using Wilcoxon Signed-Rank, Student's paired t-test and Chi square test. The result was expressed as the Mean \pm SD. $P < 0.05$ has been considered as statistically significant and $p < 0.01$ and $p < 0.001$ have been considered as statistically highly significant

RESULTS AND DISCUSSION

Table 1: Age-wise distribution of the patients

Age Group(Years)	Group		Total (%)
	A (%)	B (%)	
30-40	14(35%)	14(36.84%)	28 (35.90)
41-50	15(37.5%)	14(36.84%)	29 (37.18)
51-60	9(22.5%)	7(18.42%)	16 (20.51)
>60	2(5%)	3(7.89%)	5 (6.41)
Total	40(100%)	38(100%)	78 (100.00)
Mean \pm SD	45.65\pm9.62	45.55\pm9.27	

Out of 78 patients of Hyperlipidemia, 28 (35.90%) patients were found in the age group of 30-40 years, 29 (37.18%) patients in 41-50 years, 16 (20.51%) in 51-60 years and 5 (6.41%) in the group of >60 years. These findings suggested that Hyperlipidemia is more common the age group of 30-50 years.

Table 2: Sex-wise distribution of the patients

Sex	Group		Total (%)
	A (%)	B (%)	
Male	22(55%)	23(60.53%)	45 (57.70)
Female	18(45%)	15(39.47%)	33 (42.30)
Total	40(100%)	38(100%)	78 (100.00)

Out of 78 patients of Hyperlipidemia 45 (57.70%) were male while 33 (42.30%) patients were female and it corresponds with previous studies ^{4,13}

Table 3 Dietary habit wise distribution of the patients

Dietary habit	A (%)	B (%)	Total (%)
Non Veg	22(55%)	24(63.16%)	46 (58.98)
Veg	18(45%)	14(36.84%)	32 (41.02)
Total	40(100%)	38(100%)	78 (100.00)

Out of 78 patients of Hyperlipidemia, 46 (58.98%) patients were Non vegetarian while 32 (41.02%) patients were Vegetarian. This suggested that hyperlipidemia is more prevalent in NonVegetarians and it corresponds with previous studies. ^{4,13}

Table 4: Mizaj-wise distribution of the patients

Mizaj	Group		Total (%)
	A (%)	B (%)	
<i>Damvi</i> (Sanguinous)	11(27.5%)	13(34.21%)	24 (30.76)
<i>Saudavi</i> (Melancholic)	0(0%)	0(0%)	0 (0)
<i>Safravi</i> (Bilious)	4(10%)	0(0%)	4 (5.12)
<i>Balghami</i> (Phlegmatic)	25(62.5%)	25(65.79%)	50 (64.12)
Total	40(100%)	38(100%)	78 (100.00)

Data revealed that out of 78 patients of hyperlipidemia, 24 (30.76%) patients belong to *Damwi Mizaj*, 4 (5.12%) *Safrawi Mizaj* and 50 (64.12%) *Balghami Mizaj*. This study showed that hyperlipidemia is more prevalent in *Balghami Mizaj* (Phlegmatic Temperament)

Table 5: Other Characteristic-wise distribution of the patients

Particular		Group		Total (%)
		A (%)	B (%)	
Family History	No	40(100%)	38(100%)	78 (100)
	Yes	0(0%)	0(0%)	0 (0)
Alcohol Use	No	36(90%)	36(94.74%)	72 (92.30)
	Yes	4(10%)	2(5.26%)	6 (7.70)
Tobacco use	No	26(65%)	24(63.16%)	50 (64.10)
	Yes	14(35%)	14(36.84%)	28 (35.90)
Physical Inactivity	No	35(87.5%)	32(84.21%)	67 (85.90)
	Yes	5(12.5%)	6(15.79%)	11 (14.10)

Out of 78 patients of hyperlipidemia, Family history of hyperlipidemia was not present in any patient, while Alcohol use present in 6 (7.70%) patients, Tobacco use present in 28 (35.90%) patients and physical inactivity was present in only 11 (14.10%) patients.

Table 6: Effect of combined therapy on subjective parameters

Subjective Parameters	Group									
	A		B		A			B		
	Mean ± SD				Mean change from BT	%	p- value	Mean change from BT		p value
	BT	AT	BT	AT				Mean	%	
Obesity	0.98±0.97	0.3±0.65	1.37±0.94	0.61±0.86	22.67	↓	<0.001	25.33	↓	<0.001
Fatigue	1.68±0.76	0.32±0.47	1.58±0.76	0.39±0.64	45.33	↓	<0.001	39.67	↓	<0.001
Breathlessness	1.02±0.92	0.22±0.48	1.05±0.73	0.13±0.34	26.67	↓	<0.001	30.67	↓	<0.001

*BT=Before Treatment /AT=After Treatment

In subjective parameters of Hyperlipidemia statistical analysis revealed that statistically significant improvement seen in Obesity, Fatigue and Breathlessness, p value is <0.001 in both the groups as shown in table 6.

Table 7: Objective Parameters-wise distribution of patients

Objective Parameters	Group									
	A		B		A			B		
	Mean ± SD				Mean % change from BT	p- value	Mean % change from BT		p value	
	BT	AT	BT	AT			Mean	%		
BMI	25.34±3.82	24.58±3.84	27.98±4.48	26.65±4.31	3.00	↓	0.00	4.75	↓	0.00
S Cholesterol	241.27±61.75	192.13±38.02	245.68±56.74	192.99±31.75	20.37	↓	0.00	21.45	↓	0.00
HDL	187.49±131.42	137.82±78.25	286.52±268.22	179.72±161.78	26.49	↓	0.00	37.27	↓	0.00
LDL	83.34±55.52	71.58±45.18	71.81±40.2	66.98±33.69	14.11	↓	0.00	6.73	↓	0.14
VLDL	100.63±54.16	82.31±45.34	98.66±57.66	82.09±48.19	18.21	↓	0.00	16.80	↓	0.01
Serum Triglycerides	129.4±118.79	90.04±70.28	179.61±148.65	115.73±91.72	30.42	↓	0.00	35.57	↓	0.00
Blood Urea	24.41±7.78	26.38±7.85	28.42±10.35	28.87±11.12	8.07	↑	0.12	1.58	↑	0.78
S Creatinine	0.77±0.19	0.8±0.31	0.8±0.18	0.8±0.24	3.90	↑	0.53	0.00	-	0.89
SGOT	38.98±24.92	38.09±20.77	32.12±11.55	35.99±13.12	2.28	↓	0.77	12.05	↑	0.09
SGPT	42.9±29.41	36.69±19.41	39.1±15.92	36.47±16.12	14.48	↓	0.03	6.73	↓	0.44
S Bilirubin	0.66±0.42	0.69±0.46	0.6±0.21	0.59±0.23	4.55	↑	0.75	1.67	↓	0.82

*BT=Before Treatment /AT=After Treatment

In Hypelipidemia Group A and Group B patients mean reduction is seen in Body Mass Index (BMI), Lipid Profile, p value is <0.05 result is statistically significant. In safety parameters (LFT and RFT) no significant changes seen ,p value >0.05 i.e. result is not statistically significant as shown in table 7. Reduction in BMI, S cholesterol and Triglycerides occurred due to effect of combined therapy (Unani drug *Sandroos* + Allopathic Medicine + Lifestyle interventions/ *Ilaj bit Tadbeer* and Yoga). β -sitosterol present in *Sandroos* (*Trachylobium hornemannianum*) reduces serum LDL cholesterol level by competitively inhibiting intestinal cholesterol absorption ^{14,15}

Table 8 Response of Treatment-wise distribution of the patients

Response	Group	
	A (%)	B (%)
<25% relief	4(10%)	2(5.26%)
25-50% relief	23(57.5%)	19(50%)
=>50 % relief	13(32.5%)	17(44.74%)
Total	40(100%)	38(100%)

As per the patients view on relief from the treatment, In Hyperlipidemia Group A out of 40 patients, 4(10%) patients got less than 25% relief, 23(57.5%) patients got 25-50% relief and 13(32.5%) patients got more than 50% relief. In Hyperlipidemia Group B out of 38 patients, 2(5.26%) patients got less than 25% relief, 19(50%) patients got 25-50% relief and 17(44.74%) patients got more than 50% relief.

Table 9 Overall response of the intervention on conventional treatment

S. No.	Overall response of the intervention	Number of Patients (%) in Hyperlipidemia Group A	Number of Patients (%) in Hyperlipidemia Group B
1.	Withdrawal of Allopathic medicine	0	5(13.15%)
2.	Partial reduction in dose/number of Allopathic medicine taken	7 (17.5%)	7(18.42%)
3.	No withdrawal/reduction in allopathic medicine taken	33 (82.5%)	26 (68.42%)
	TOTAL	40	38

Out of 40 patients of Hyperlipidemia Group A, no patient reported withdrawal of allopathic medicine after the intervention of combined therapy and 7(17.5%) patients reported reduction in dose/number of allopathic medicine taken. However, 33 (82.5%) patients reported no withdrawal/reduction of allopathic medicine.

Similarly out of 38 patients of Hyperlipidemia Group B, 5 (13.15%) patients reported withdrawal of allopathic medicine after the intervention of combined therapy and 7 (18.42%) patients reported reduction in dose/number of allopathic medicine taken. However, 26 (68.42%) patients reported no withdrawal/reduction of allopathic medicine. This reduction/withdrawal of Allopathic medicine is most likely due to cumulative effect of Unani/Allopathic Medicine, lifestyle modifications and yoga.

CONCLUSION

On the basis of above results it can be concluded that by comparing the overall response of intervention on conventional treatment in Hypertension Group A and Group B showed that withdrawal of allopathic medicine is seen in Hyperlipidemia Group B, so it revealed that by advising Unani Medicine and Yoga along with conventional treatment number /dose of allopathic drugs may be reduced and the patients of Hyperlipidemia may be prevented from the adverse effects of Allopathic drugs. Thus NPCDCS-AYUSH integration project is a model of successful operationalization of integration of AYUSH systems, in National Programme for prevention and control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS) for prevention and control of (NCDs).

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