Effect of Habbe Aftimoon in the Patients of Dyslipidemia with *Tasallube Sharaeen* (Atherosclerosis)

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Abstract

A randomized single blind standard controlled study was conducted to evaluate the efficacy of *Habbe Aftimoon* in the patients of dyslipidemia with Atherosclerosis. Thirty diagnosed patients were selected and randomly allocated to Control and Test groups (comprising 20 patients in Test group and 10 in Control group). *Habbe Aftimoon* in a dose of 4 Habb twice a day in Test group whereas Lipotab 2 tablets once a day was given in Control group for 60 days. All the patients were advised low fatty diet and moderate exercise. Before and after the treatment, both groups were assessed on subjective and objective parameters. The outcome of treatment were analyzed statistically by using Paired 't' test, Wilcoxon test, Friedman test with post test, one way ANOVA with post test and Kruskal Wallis test with Dunn's multiple compare test.

The Test drugs exhibited statistically significant result in subjective parameters (Palpitation and Body weight) in intra group and inter group comparison. In objective parameters, reduction in S. Cholesterol and increase in L ank ASI and ABI were observed, and this difference was found statistically significant in intra group comparison. The control drug exhibited significant improvement in palpitation and reduces body weight in intra and inter group comparison. In objective parameters, S. Cholesterol and S. Triglyceride were significantly decreased in intra group comparison, where as the changes in other subjective and objective Parameters were remain insignificant in both groups.

The study revealed that Test drug is effective in some objective and subjective parameters in patients of dyslipidemia with Atherosclerosis particularly in reducing body weight and S. Cholesterol level. No adverse effect and toxicity was seen during and after the study. Thus, it can be concluded that Test drug is effective and safe in the management of Atherosclerosis in dyslipidemic patients up to some extent. So, it may be recommended for delaying complications of Atherosclerosis.

Keywords: Atherosclerosis, Dyslipidemia, *Habbe Aftimoon*, Unani Medicine

Introduction

Tasallube Sharaeen (Atherosclerosis) is one of the commonest conditions which underlying pathologic process causes several cardiovascular and cerebrovascular complications. It is well known fact that Hyperlipidaemia and Obesity are two important risk factors associated with Atherosclerosis (Longo *et al.,* 2012).

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Since very beginning the concept of *Tasallube Nabz* also exist in Unani system of Medicine, as most of the ancient Unani scholars like Majoosi, Ibn Sina, Ibn Rushd, Ibn Zuhr and Samar Qandi have elucidated the cause of narrowing and stiffness of vessels in their treaties (Ibn Sina, 1993; Khawaja Rizwan, 2010; Majoosi, 1889; Ibne Zuhr, 1986) Now *Tasallube Sharaeen* is used as standard term for arteriosclerosis and atherosclerosis is main type of arteriosclerosis (Anonymous, 2012).

Atherosclerosis is predicted to become the leading cause of death in India by 2020 (Satishchandra *et al.,* 2011) Tobacco smoking, obesity, hypertension, diabetes mellitus, elevated plasma homocysteine and LDL are the principal factors responsible for deposition of lipid in large and medium sized arteries (Longe, 2002). Slow and progressive lipid deposition narrows down the arterial lumen by forming atherosclerotic plaque, which initially causes ischemia of the irrigated organs, but in advance stages results in peripheral vascular diseases, myocardial and cerebral infarction and stroke etc. (Nicholas *et al.,* 2006).

Now a day many pharmacological and non-pharmacological modes of treatment are available for prevention of atherosclerosis. Among non-pharmacological, life style modifications like decreasing daily calorie intake, and increase in physical activity is indeed helpful for most of the patients but in several circumstances pharmacological management of atherosclerosis is inevitable. For this purpose several cholesterol lowering agents such as Levostatin, Atorvastatin, Simvastatin, Clofibrate, Bezafibrate and Niacin etc are widely prescribed in conventional Medicine. But long term use of these drugs produces several adverse effects, such as Hepatotoxicity, Myopathy, Dyspepsia, Renal failure and Cholelithiasis. (Kumar, 2005; Goodman & Gillman, 2011)

High prevalence of the disease, multi factorial causes and life threatening complications and most important inability of contemporary system of Medicine to deliver safe and effective drug for the management of atherosclerosis effectively, warrant search of alternative treatment to alleviate such a complex disease of serious complications.

Unani system of Medicine offers different approach of treatment i.e. *Ilaj bil Ghiza (*Diet therapy), *Ilaj bit Tadbeer* (Regimental therapy) and *Ilaj bid Dawa (Pharmacotherapy)* (Kabeeruddin, 1954) which are the mainstay of treatment of hyperlipidaemia and atherosclerosis. These three could be used alone or in combination. Fundamentally, combination of *Ilaj bil Ghiza*, and Ilaj *bit Tadbeer* are very useful for the prevention of atherosclerosis. The principle of treatment should be to reduce caloric intake, to burn extra calories deposited in body, to eliminate *Mawade fasida* and correction of *Sue mizaj barid,* use of *Qalilul taghaziya kasirul kammiyat Ghiza* along with *Riyazate kasira* and *Hammam*

(Razi, 1997). Moreover, Unani physician also recommends *Ilaj bid Dawa* for the management of *Samne Mufrit*. A large number of, drugs available in Unani Medicine which possess action like *Muhazzil, Munzij, Mushil, Mufatteh, Jaali* and *Muhallil* properties could also be used for prevention of *Tasallube Sharaeen.*

Unfortunately, there is no convincing treatment available for the management of atherosclerosis in contemporary system of Medicine. Therefore, search of safe and effective drug for its management is quite necessary. In Unani system of medicine, *Habbe Aftimoon* is recommended for the treatment of *amraze balghamia* and *saudawia*. (Akbar Arzani, 2009) The ingredients of *Habbe Aftimoon* are Aftimioon (*Cuscuta reflexa* L.*),* Gule Surkh (*Rosa damascene* L.*),* Mastagi (*Pistacia lentiscus* L.*),* Post Halela Zard *(Terminalia chebula* L.*),* Bisfaij *(Polipodium vulgare* L.*),* Ustokhudoos *(Levendula stoechas* L.*)* and Namak Hindi *(sodium chloride)* (Kabeeruddeen, 2006).

Tasallube Sharaeen is also categorized as *amraze saudawia*. Thus this drug may be proven useful in this condition also, but its efficacy has not been evaluated on scientific parameters particularly for the management of Atherosclerosis. Therefore, a single blind randomized standard control clinical trial was designed to evaluate the efficacy of *Habbe Aftimoon* in the management of Atherosclerosis in dyslipidemic patients.

Methodology

A single blind standard controlled clinical trial was conducted from March 2012 to January 2013 in National Institute of Unani Medicine Hospital, Bangalore. The study protocol was designed according to the need of the trial, and approval was obtained by the Institutional Biomedical Ethics Committee of NIUM, Bangalore. After providing detailed oral information about the study, written consent was obtained from the participants. The patients belonging age of 20–65 years, having dyslipidemia with *Tasallube Sharaeen* (Atherosclerosis) were selected for the study. Diagnosis of Atherosclerosis was confirmed by computerised device (Atherowin & Canwin) on the basis of assessment of right brachial arterial stiffness index, left brachial arterial stiffness index, right ankle arterial stiffness index, left ankle arterial stiffness index, right brachial pulse wave velocity, left brachial pulse wave velocity, carotid femoral pulse wave velocity and ankle brachial index.

Individuals below 20 years and above 65 years of age , and those having history of AIDS, Tuberculosis, Hypothyroidism, uncontrolled Diabetes Mellitus, established I.H.D., advanced Kidney, Liver and Heart diseases and Pregnant and lactating women were not included to the study. According to subjective and objective criterion a total of 50 patients were registered for the study from

the OPD and IPD of NIUM Hospital. During screening 11 patients did not fulfil inclusion criteria and excluded from the study, remaining 39 patients were randomly allocated into Test (Group A) and standard Control (Group B) groups respectively by using simple randomization sampling method. In the Test group 4 tablets of *Habbe Aftimoon* twice a day (Each tablet contains 750 mg of Test drug) was given orally for 60 days whereas Lipotab 2 tab was administered once a day for the same duration. All the patients were advised low fatty diet with low caloric value (1600-200 kcal per day) and aerobic exercise for 30-45 minute per day (Agarwal, 2014). All patients were asked to come fortnightly for the assessment of progression or regression of symptoms. During the whole duration of protocol concomitant treatment was not allowed in both groups.

The assessment of efficacy of Test and Control drugs were carried out on the basis of subjective and objective parameters. Subjective parameters include symptoms like Palpitation, Xanthelesma, and *Nabz sulb* which were assessed at fortnightly, while other objective parameters i.e. body weight, lipid profile, arterial stiffness, pulse wave velocity and ankle brachial index were measured before starting treatment and after the completion of treatment.

In order to asses safety of the Test and Control drug , complete Haemogram (TLC, DLC, Hb%, ESR), Liver Function Test (S. Bilirubin, SGOT, SGPT, Alkaline Phosphates) and Kidney Function Test (Blood Urea & S. Creatinine) were also carried out before and after treatment .

During study seven patients from Test group and two patients from Control group were lost to follow-up, leaving behind 20 patients in Test and 10 patients in Control group. Therefore, statistical data were calculated on 30 patients only who were completed entire course of treatment. Data was statistically analyzed by paired't' test, Wilcoxon matched pair test and Friedman test for intra group comparison and one way ANOVA and Kruskal-Wallis test with Dunn's multiple pair comparison for inter group comparison

Results

Out of 30, 14 (46.66 %) are male and 16 (53.33 %) are female. 05 (25 %), 10 (50%), and 05 (25%) subjects in test group belongs to 20-35 year, 36-50 year, and 51-65 year age groups respectively, similarly 01 (10%), 04 (40%), and 05 (50%) subjects in standard control group belongs to 20-35 year, 36-50 year, and 51-65 year age groups respectively (Table 1).

The effect of Test and control drug on various subjective and parameters are depicted in Table 2 and 3A, 3B.

Table 1: Demographic Data

Factor		No. of patients		Total No. of Patients	Percentage (%)
		Test group	Control group		
Age	20-35	5	1	6	20
	36-50	10	4	14	46.7
	51-65	5	5	10	33.3
Sex	Male	9	5	14	46.67
	Female	11	5	16	53.33
Diet	Mixed diet	19	9	28	93.33
	Vegetarian	1	1	2	6.67
Socio-economic status	Upper (I)	0	0	0	0
	Upper Middle (II)	7	3	10	33.33
	Lower Middle (III)	4	2	6	20
	Upper Lower (IV)	8	5	13	43.34
	Lower (V)	1	0	1	3.33

Table 2: Effect of Drugs on Subjective Parameter

Parameter	Group	Assessment day					P value
		0 day	15th day	30th day	45th day	60th day	(a) P<0.01 with respect to zero days test group.
Palpitation	Control	3(1,4)	3(1,4)	2.5(1,3)	2(1,3)	$1^{*,\#,}$(1,2)	(b) P<0.01 with respect to 15 day test group.
	Test	3(2,4)	3(1,4)	3(1,3)	$1^{a,b,c}$ (1,3)	$1^{a,b,c}$ (1,3)	(c) P<0.01 with respect to 30 days test group.
Xanthelesma	Control	0(0,2)	0(0,2)	0(0,2)	0(0,2)	0(0,2)	* P< 0.01 with respect to zero day control group.
	Test	0(0,2)	0(0,2)	0(0,2)	0(0,2)	0(0,2)	
Nabz sulb	Control n=10	3(1,3)	2.5(1,3)	2.5(1,3)	2.5(1,3)	2.5(1,3)	# P<0.01 with respect to 15 days control.
	Test	2(1,3)	2(1,3)	2(1,3)	2(1,3)	2(1,3)	

After two months administration of *Habbe Afteemoon* and Lipotab, significant difference was observed only in body weight, total cholesterol, L ank ASI, and ABI in Test group, while in standard control group significant difference was observed only in body weight, total cholesterol and serum triglycerides. Whereas, no significance difference was observed in other objective parameters neither in test nor in standard control group.

Table 3A: Effect of drugs on objective parameter (20 in Test and 10 in Control group)

Parameters	Group	Assessment day		P value
		Before Treatment	After Treatment	
Body weight	Control(10)	83.8±4.15	81.9 ±4.2*	*→ P<0.01 with respect to before treatment in control group +→ P<0.01 with respect to before treatment in test group.
	Test(20)	79.0±2.4	76.8±2.6+	
S. Cholesterol	Control	205±8.93	180±9.35[a]	a→ P<0.05 with respect to before treatment in control group. b→ P<0.01 with respect to before treatment in test group. c→ p< 0.05 with respect to after treatment in control group.
	Test	215±8.73	195±5.93[b,c]	
Triglyceride	Control	274±25.7	214±28.9[d]	d→ P<0.01 with respect to before treatment in control group.
	Test	218±11.3	204±12.6	
Low Density Lipoprotein (LDL)	Control	92.7±11.9	89±10.3	P>0.05 Inter group comparison, with respect to before & after treatment in test & control group.
	Test	96.1±9.33	103.1±6.37	
High Density Lipoprotein (HDL)	Control	37.9±2.56	46.4±3.82	P>0.05 Inter group comparison, with respect to before & after treatment in test & control group.
	Test	51.1±3.5	44.4±2.32	

Furthermore, safety markers i.e. Haemogram (TLC, DLC, Hb%, ESR), Liver Function Test (S. Bilirubin, SGOT, SGPT, Alkaline Phosphates) and Kidney Function Test (Blood Urea & S. Creatinin) remained normal before and after treatment. (Table 4)

Discussion

Tasallube Sharain (Atherosclerosis) is one of the commonest causes of the premature vascular diseases, causing Ischemic Heart Disease, Cerebrovascular accidents, Stroke and Hypertension. Obesity and Hyperlipidaemia are two risks factor which are associated with atherosclerosis. In modern system of medicine several Hypolipidaemic agents are being used for the prevention of atherosclerosis. However, these drugs are neither drug of choice of Atherosclerosis nor producing convincing therapeutic effects. Furthermore, the side effects of these Hypolipidaemic agents are also causes of concern.

In view of the above facts, the development of Hypolipidaemic agents from herbal sources is quite necessary. There is no dearth of such drugs in Unani System of Medicine. *Habbe Aftimoon* is one of the compound formulations which is effective in the treatment of *Amraze Saudawia*. Apart from this the

Table 3B: Effect of drugs on objective parameter (20 in Test and 10 in Control group)

Parameters	Group	Assessment day		P value
		Before Treatment	After Treatment	
Right Brachial Arterial Stiffness Index (R Bra ASI)	Control	30±4.77	28.9±2.87	P>0.05 Inter group comparison, with respect to before & after treatment in test & control group.
	Test	24.4±1.66	23.3±2.31	
Left Brachial Arterial Stiffness Index (L Bra ASI)	Control	27±3.06	28.14±3.39	P=0.924 Inter group comparison, with respect to before & after treatment in test & control group.
	Test	28.04±2.42	28.07±3.77	
Right ankle Arterial Stiffness Index (R Ank ASI)	Control	42.08±3.29	42.08±2.82	P=0.66 Inter group comparison, with respect to before & after treatment in test & control group.
	Test	38.68±3.23	37.53±2.38	
Left ankle Arterial Stiffness Index (L Ank ASI)	Control	33.9±4.19	39.4±3.3	e'!P<0.05 with respect to before treatment in test group. Inter group comparison, p=0.09
	Test	31.5±2.04	35.9[e]±2.54	
Right Brachial Pulse Wave Velocity (R ba PWV)	Control	2344±359	2004±216	P=0.75 Inter group comparison, with respect to before & after treatment in test & control group.
	Test	1592±267	1966±180	
Left Brachial Pulse Wave Velocity (L ba PWV)	Control	1116±367	1426±188	P>0.05 Inter group comparison, with respect to before & after treatment in test & control group.
	Test	1058±295	1645±238	
Carotid Femoral Pulse Wave Velocity (C F PWV)	Control	1209±213	1229±142	P=0.62 Inter group comparison, with respect to before & after treatment in test & control group.
	Test	870±18	1270±119	
Ankle Brachial Index (ABI)	Control	1.11±.031	1.10 ±.031	f'!P<0.05 With respect to before treatment in test group.
	Test	1.01±.029	1.10[f]±.021	

ingredients of *Habbe Aftimoon* possess some important pharmacological properties such as Hypolipidaemic, Antioxidants, *Mohazzil* actions. These pharmacological actions are effective in the delaying process of Atherosclerosis. Therefore, A single blind standard control study was designed to evaluate the efficacy of *Habbe Aftimoon* in the patients of *Tasallube Sharain* (Atherosclerosis).

Table 4: Effect of Test and Control drugs on Safety parameters

Parameters		Test No=20		Control No=10	
		B.T	A.T	B.T	A.T
Hb% gm%		12.41±.31	12.46±.33	12.34±.41	11.92±.44
TLC cells/cu		8185±330	8062±386	8290±438	7170±480
DLC	P	57.6±1.6	57.3±1.4	58±1.5	59.4±2.45
	L	37.9±1.4	37.6±1.2	35.7±1.48	35.1±2.32
Cells/cu DLC	E	3.2±.18	3.5±0.23	4±.29	3.5±0.22
	M	2.2±.20	2.3±.21	2.3±0.21	2.3±0.21
Cells/cu	B	0±0.00	0±0.00	0±0.00	0±0.00
ESR (mm/1hrs)		27.4±4.2	27.5±4.6	21.5±4.18	23.6±5.20
FBS (mg/dl)		99±2.98	103±3.96	101±7.8	103±7.62
PPBS (mg/dl)		167±12.3	157.7±9.36	151±16.7	146±16.2
B. Urea (mg/dl)		31.3±1.6	29.1±1.5	29.3±2.42	35.5±2.75
S. Creatinin (mg/dl)		0.89±.02	0.84±0.03	0.85±0.02	0.94±0.05
S. Bilirubin (mg/dl)		0.64±0.05	0.65±0.05	0.52±0.04	0.52±0.05
SGPT(IU/L)		29.5±2.5	31.6±3.82	19.4±3.59	20.5±1.68
SGOT (IU/L)		25.1±1.8	23.7±1.6	20.5±1.7	18.7±2.34
Alkaline Phosphates (IU/L)		131±6.5	121±4.9	139±5.5	132±6.9

After 60 days treatment, significant improvement has been noticed in subjective and objective parameters such as S. Cholesterol, Left ankle Arterial Stiffness Index (L Ank ASI), Arterial Brachial Index (ABI), and body weight significantly in test group and total cholesterol, triglycerides, and body weight in standard control group respectively in atherosclerotic patients.

From above, it is evident that test drug is effective in intra group comparison. Such effect may be due to ingredients of test drug *Habbe Aftimoon* which contain antioxidant, Anti-atherosclerotic and Antioxidant properties. (Cheng *et al.,* 2003; Naik *et al.,* 2006; Lee *et al.,*1639; Naik *et al.,* 2004; Chang *et al.,* 2010; Selvaraj *et al.,* 2007) and hypolipidaemic properties of *Halela zard* (Chang *et al.,* 2010) Mastagi (Stella *et al.,* 2009; Xiuzhen Han *et al.,* 2007; Dedoussis *et al.,* 2004, Duke 2008) and *Ustukhodoos* (Nikolaevskii *et al.,* 1990; Yumi *et al.,* 2008; Parejo *et al.,* 2002; Ferreira *et al.,* 2006; Gulcin *et al.,* 2004).

This improvement may be due to *Muhallil* (Resolvent), *Mulattif* (Demulcent) and *Munzij balghame* wa *sauda* properties of *Ustukhudoos* (Kulkarni *et al.,*

2004; Ghani, 2010; Nabi, 2007) *Mufatteh*, *Muhallil* and *Mushile Balgham* wa *sauda* properties of *Aftimoon*, *Bisfaij*, *GuleSurkh*, *Mastagi,* and *Halela zard.* (Ghani, 2010; Nabi, 2007; Ibn Sina, 1993) These findings are in accordance with the description given by Razi, Ibne Sina, Ibne Baitar, N.Ghani, Mohd. Azam khan etc. Further, some recent studies revealed that *Mastagi* and *Ustukhodoos* possess anti atherosclerotic action. (Duke, 2008; Catherine *et al.,* 2001)

Individual drugs that constitute the ingredients of Test drugs have been reported to possess some interesting pharmacological effects that directly or indirectly support our contentions regarding the efficacy of the Test drugs. *Afteemoon Bisfaij*, *Halela zard, Ustokhudoos, Mastagi* possesses *Mufatteh sudad*, *Muhallil*, *Mulattif* and *Mushile sauda* wa *balgham* properties. (Ghani, 2010) *Ustokhodoos* (Catherine *et al.,* 2001) and *Halela zard* (Selvaraj *et al.,* 2007; Duke, 2002) possesses Anti-arteriosclerotic and hypolipidaemic properties, *Halela zard* (Prajapati *et al.,* 2005, Cheng *et al.,* 2003) *Gule Surkh*, (Prajapati *et al.,* 2005; Said, 1997; Boskabady, *et al.,* 2001) and *Mastagi* (Benhammou *et al.,* 2008; Tassou *et al.,* 1995) possesses antioxidant and cardiotonic properties. These effects are in the same line, as we have mentioned above that the drugs are producing effects because of hypolipidaemic, antioxidant and cardio tonic properties. Thus, on the basis of the scientific studies and the reported effects of the individual ingredients of Test drugs are in conformity to a greater extent with that of our hypothesis as well as the inferences we drew out of the present study.

In the light of above discussion, it can be concluded that the Test drugs produced significant hypocholesterolemic and anti obesity effect without demonstrating any sign of toxicity or adverse effect.

Although, the Test drug did not produces any significant effect in most of the objective parameters except body weight, S. Cholesterol, L Ank ASI, and ABI. However, the Test drug exhibited improvement in some objective parameter such as on Serum Cholesterol, body weight. Obesity and hypercholesterolemia are considered an important risk factor for development of atherosclerosis. The Test drug (*Habbe Aftimoon*) is quite effective in reducing body weight and serum Cholesterol level, thereby it may play pivotal role in delaying of atherosclerosis process. Therefore, it can be concluded that Test drug can be used for the prevention of atherosclerosis and delaying the progression of the disease. As a matter of fact, there is no curative treatment available in any system of medicine. The conventional system of medicine is using hypolipidaemic and thrombolytic agents for the prevention of atherosclerosis. (Goodman and Gillman, 2011) Hence, the Test drug *Habbe Aftimoon* can be safely used for the same purpose.

Conclusion

On the basis of above result and discussion, it can be concluded that the compound formulation *Habbe Aftimoon* is effective in reducing lipid profile in the patients of atherosclerosis associated with dyslipidemia. Hence, this drug could be effectively used for prevention of atherosclerosis and to reduce progression of its manifestation. Since the diverse mechanism is involved in the development of Atherosclerosis and disease is complex in nature. Therefore, some elaborate studies are required to ascertain other pharmacological action of Test drug relatively for longer duration.

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