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“Efficacy of Saboos-E- Asapghol (*Plantago Ovata*) and Kalonji (*Nigella Sativa*) in The Management of Hypertriglyceridemia.”

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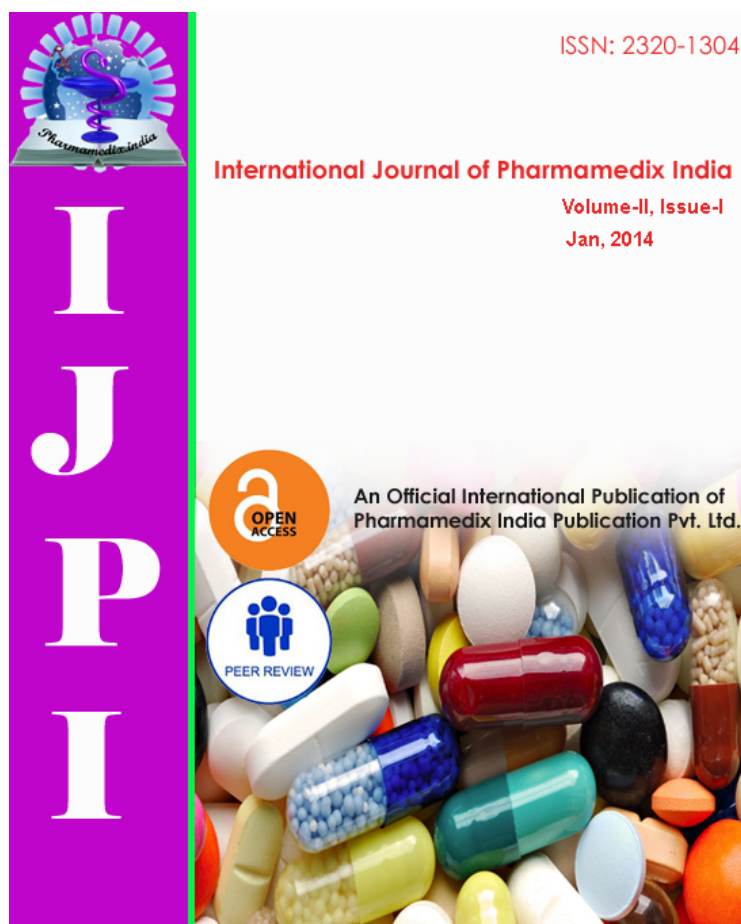
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Abstract:

World Health Organization has declared that cardiovascular diseases are number one leading cause of mortality globally e.g. an estimated 17.5 millions people died from cardiovascular diseases in 2005, representing 30% of all global deaths. Hypertriglyceridemia is increased day by day due to use of saturated fat, excessive alcohol and junk foods. Synthetic drugs are used in the modern system of medicine but induce adverse side effects. So, there is a need for safe and effective serum triglyceride lowering drugs. Saboos-e-Asapghol (*Plantago ovata*) and kalonji (*Nigella sativa*) are among these medicines. A clinical study was carried out in Ajmal Khan Tibbiya College Hospital on 60 patients of hypertriglyceridaemia. The diagnosis was based on inclusion and exclusion criteria. The Unani formulation Saboos-e-Asapghol (*Plantago ovata*) and kalonji (*Nigella sativa*) 4gm and 2gm respectively twice daily before meal were given for 90 days. Both the drugs were found to be significant in lowering the increased level of serum triglycerides. Therapeutic responses were evaluated through follow up observations at 45th day interval. The results were analyzed by biostatistical method with better efficacy.

Keyword: Cardiovascular disease, Hypertriglyceridaemia, Saboos-e-Asapghol, kalonji.

Introduction

Lipid disorders comprise the most prevalent serious disorders in industrialized nations and are a rapidly growing problem in developing nations, hypertriglyceridaemia are among them. The growing prevalence of obesity, type 2 diabetes mellitus, hyperlipidaemia and metabolic disorders which are important risk factors for atherosclerosis. Hypertriglyceridaemia is not a separate disease, it is included in hyperlipidaemia. The Hypertriglyceridaemic patients are continuously increasing because obese people tend to have

relatively high triglyceride and low HDL-cholesterol. High level of plasma triglycerides is also considered a risk factor for coronary heart disease. (Buriro A.M, Tayyab M, and Allah Dtta, 2011) Harrisons defines the hypertriglyceridaemia "In a practice Hyper triglyceridaemia is considered whenever the triglycerides level exceeds 2. 2 mmol/L (200 mg/dl)". (Ginsberg H.N and Goldberg 1994).

Unani physicians and scholars have briefly described the condition of obesity under the name of "*Saman-e-Mufrat*" which is almost

similar to hyperlipidaemia in all aspects as in etiology, clinical features, complications and management, and hypertriglyceridaemia is included in that. Therefore we can get valuable informations regarding hypertriglyceridaemia in the context of ‘*Saman-e-Mufrat*’ (obesity). Razi (885-925 AD) described the obesity in about sixty pages in his famous book ‘*Al Havi Fit-Tib*’ in Volume six. (Razi 1999) Sheikh Ibn-e-Sina (980-1030AD) in his famous book ‘*Al-Qanoon fit-Tib*’ has described the etiology, clinical features, complications and management of obesity in detail. (Sina 2010) Many Indian scholars like Akbar Arzani, Mohd Shareef, Mohd Qarshi, Ghulam Jeelani and Azam Khan have mentioned the disease obesity in their books. (Arzani 2010, Firozddin 1939, Jeelani n.a, Khan 1954, Qarshi 2011, Shareef 1931).

There is large number of single drugs and compound formulation are being used in Unani system of medicine in the context of *saman-e-mufrat* (obesity). There are various pharmacological studies are there in support of *kalonji* (*Nigella sativa*) and *Saboos-e-Asapghol* (*Plantago ovata*) in all lipid disorders. So, this study was designed to observe the effect of *Nigella sativa* and *Plantago ovata* husk in cases of hypertriglyceridaemia.

Triglyceride, Fats and Oils:

Fat is the name given to a class of triglycerides that appear as solid or semisolid at room temperature, fats are mainly present in animals. Oil is the name given to class triglycerides that appear as a liquid at room temperature, oils are mainly present in plants and sometimes in fish. Triacylglycerols are the products of a reaction in which three OH groups of glycerol are esterified with fatty acids.

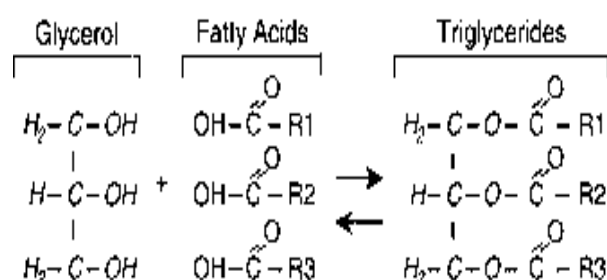


Figure 1: Structure of Glycerol & Triglycerides

A simple triacylglycerol is a triacylglycerol with three of the same fatty acid components. A mixed triacylglycerol is a triacylglycerol that contains two or three different fatty acid components and are more common than simple triacylglycerols”. (Bruice A Griffin 2009)

Unani concept of fat (Triglycerides):

Unani Scholars from very beginning have described two major types of fat:

1. *Sameen* (the liquefied fat)
2. *Rewaj* (the viscous and coagulated fat)

Ibn-ul Qif and Abu Sahel Maseehi have classified the fat according to the place where it is found e.g. fat which is found on muscles is called as “*Sameen*” and the one found on

places other than muscles is called as “*Sarb*”. (Qif Ibnul 1982) According to Majoosi: “*Sarb* is the name of fascia on which fat is found and the type of fat through which human body gets nourishment is referred to as “*Wadak*”. (Majoosi 2010) According to Abu Sahel Maseehi (970-1010 AD) fat is of two types:

1. *Sameen*: It is soft, semisolid and has less property to solidify.
2. *Shaham*: It is hard and is found in the body adherent to kidneys. “Both *shaham* and *sameen* are formed by that blood which has the property of ‘*Dasoomat*’ (meaning oily substance). (Nafees B 1954)

There is no any description of triglycerides in traditional Unani system of medicine, because it is a form of lipids. But triglyceride is being included in lipids or fat, we can get valuable information about triglycerides under the context of *shaham* in Unani system of medicine.

Materials and Methods

This study is a single blind control clinical trial on hypertriglyceridaemia. During the study all ICMR guidelines (Somsekhar Hemalatha 2008) were followed. The study was conducted on 60 patients comprising 30 patients in each group i.e. test group and control group respectively. Patients were randomly selected from Moalejat and Modern

Medicine OPD, Ajmal Khan Tibbiya College Hospital, AMU, Aligarh, India.

Those cases whose were having increased serum triglycerides were selected on the basis of inclusion and exclusion criteria. The patients selected for study were thoroughly examined and investigated. The patients were called for follow up at a certain interval i.e. 0 day, 45th day, 90th day. The patients below 21 years & above 60 years, Patients who fail to follow up and suffering from diabetes mellitus, hypothyroidism, acromegaly, cushing’s syndrome, nephrotic syndrome any other clinical illness were not included in the study, similarly those taking oestrogen containing oral contraceptive, alcohol, or any hypolipidaemic drugs or any system of medicine were excluded in the study.

Patients selected for hypertriglyceridaemia were asked the P.G. Laboratory, Department of Moalejat AKTC, AMU in a 12-14 hrs fasting state (water permitted) The samples were obtained in plain vials and centrifuged to obtain serum triglyceride level. Serum amylase, liver function tests, renal function tests and blood sugar (random) were done at the beginning of the study to exclude the causes of secondary hypertriglyceridaemia. Renal function test and liver function test were also repeated at the end of the study to access a safety profile of test drugs. Saboos-e-Aspaghol (*Plantago ovata*) and Sufoof-e-Kalonji (*Nigella sativa*) 4 gm and 2 gm twice

daily respectively before meal for 90 days. Atorlip-10 (Atorvastatin) 10 mg 1OD for 90 days as a standard drug. The patients were informed about the expected advantages and disadvantages of the drugs. No concomitant treatment was allowed. The individual assessment was carried out on the basis of physical examination and investigation. Observation were noted in the case report form, all the data were tabulated and statistically analyzed with the help of statistician by calculating mean and standard deviation followed by paired t-test and unpaired t-test, to the observations recorded at the end of the study (90 days).

Results and Discussion

As far as the age of the patients is concerned the maximum no. of patients in both the group were between 31-40 years of age that is middle age group and this is most prevalent age group for hypertriglyceridaemia and more prone for subsequent CAD and other vascular problems. (See table no.1)

When the gender distribution is concerned females were outnumbered which is a contradiction with other observations and findings in respect with hyperlipidaemia versus oestrogenaemia, the most probable reason is that females attending more in OPDs for their general clinical problems than males due to this reason the findings are not

in accordance with others and it is only by chance. (See table no.2)

As far as religious distribution is concerned Muslims were also outnumbered in both the group and it is mainly due to locality of our hospital and maximum attenders of OPD are Muslims but it is obvious that Muslims have more non-vegetarian habits and comparatively more frequently takes red meats than others. (Carl Mullar 1939, Joseph Goldstein, William R.H, Helmut G. Schrott and Arnog Motulsky 1973) (See table no.3 & 5) In middle income group the incident was noted as maximum, most probably their dietary habit and less calorie consciousness in these groups, while as in low income group, there is low calorie diet and in high income group the calorie conscious diet along with awareness on health subjects are the key factors for the low incidence. (See table no.4)

The efficacy of our drug was mainly observed on serum triglycerides are the main markers for abnormal lipids. The effect of test drug was highly significant in reducing the level of serum triglycerides, the most probable mechanism encountered in reducing serum triglycerides is presence of niacin (nicotinic acid) in Kalonji (*Nigella sativa*) which has lipid lowering property in general and serum triglycerides in particular. (See figure 2) The nigellin present in *Nigella sativa* seeds is also playing important role in reduction of abnormal lipid profile. At the same time there

is presence of omega-3 fatty acids as well as fractions of polyunsaturated fatty acids, which has well known effect on abnormal lipid. Nigella powder is also working as bile acid sequestrants which bind bile acids in the intestine and promotes the excretion of bile acids through stool.

During the study most of the patients of test group have complaints about gastrointestinal symptoms like bloating, abdominal fullness and loose stools, which was mainly due to excretion of fat contents through stool in form of steatorrhoea. The effect of drugs on serum triglycerides was highly significant ($t=8.9$, $p<0.001$). (See table no.6 & Figure 2).

Table No. 1: Distribution of Patients according to Age n=60		
Age groups	No. of Patients	%
21-30	10	16.66
31-40	21	35
41-50	18	30
51-60	11	18.33

Table No. 2: Distribution of Patients according to Gender n=60		
Gender	No. of Patients	%
Male	26	43.33
Female	34	56.66

Table No. 3: Distribution of Patients according to Religion n=60		
Religion	No. of Patients	%
Muslim	51	85
Hindu	6	10
Sikh	3	5

Table No. 4: Distribution of Patients according to Occupation n=60		
Occupation	No. of Patients	%

Business	10	16.66
Employee	17	28.33
Student	6	10
Housewife	27	45

Table No. 5: Distribution of Patients according to Dietary Habits n=60

Dietary Habits	No. of Patients	%
Vegetarian	11	18.33
Non-vegetarian	49	81.66

Table No.6: Effect of Drugs on Serum Triglycerides

Serum Triglycerides (in mg/dl)	Test Group N=30			Control Group N= 30		
	Before Treatment	After Treatment		Before Treatment	After Treatment	
Follow up	0 day	45 th day	90 th day	0 day	45 th day	90 th day
Mean	222.8	197.4	166.3	200.7	179.2	164.2
± S.D	± 48.2	± 47.0	± 30.4	± 36.0	± 36.2	± 28.2
P value (t-test paired)	t=8.9 , p <0.001			t=6.3, p <0.001		

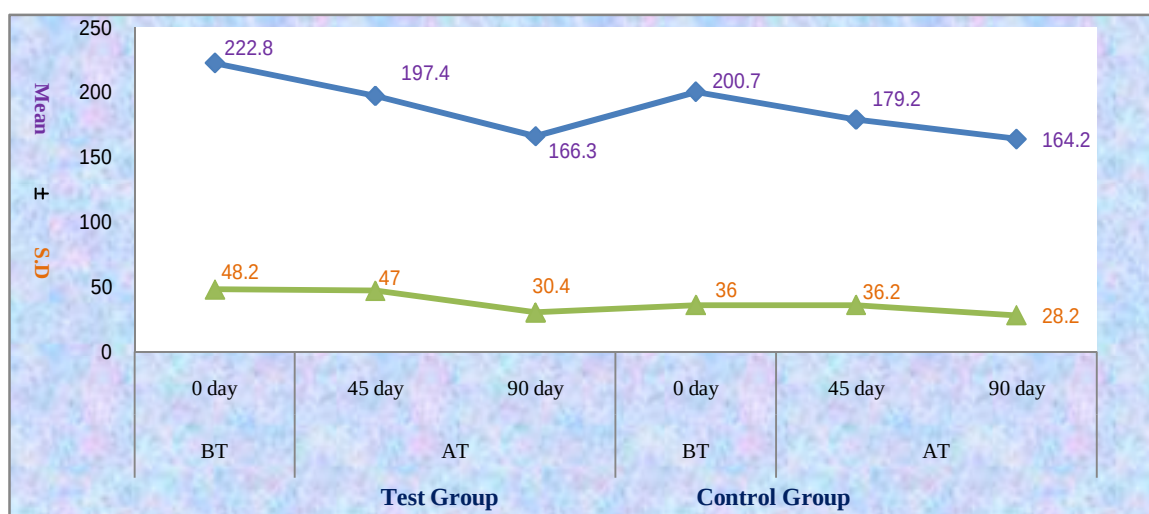


Figure 2: Effect of Drugs on Serum Triglycerides

During the study all the patients were advised to avoid saturated fat along with reduction of simple carbohydrates. Exercise particularly aerobic exercise was advised to all patients along with medications for both the groups during the study period.

Apart from these, the significant improvement was noted in general well being of the patients and the test drug was well tolerated by all the patients and there were no observable side effects was noticed except abdominal bloating, loose stool and frequent stool habit while as in control group the patients regularly complaint about fatigue, lethargy, muscular aches & cramps and nausea. The serum trans-amylases such as AST and ALT was also measured to see any observable effects particularly on liver as well as on skeletal muscles as a safety profile, it was found that the drug is completely safe for liver, muscles and no any nephrotoxic effect of test drug was noticed during the study period.

Conclusion

Hypertriglyceridemia is a part of hyperlipidaemia which is considered as risk factor for cardiovascular disease. So, safe, effective and lipid lowering agent is a sound of time. Our combination of drug of test group shows significant results in increased serum triglyceride level as compared to control drug, but no known observable side

effects was in test group as compared to control group.

Therefore we can propose the combination of test drug in increased serum triglyceride level, through this we can contribute for an important health risk factor responsible for atherogenesis and other cardiovascular disease in the advance global world.

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