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CLINICAL STUDY ON EVALUATION OF EFFICACY AND SAFETY OF UNANI FORMULATION IN OBESITY

Raheela Javaid[1]*, Asim Ali Khan[1], Rasikh Javaid[2], Mushtaq Ahmad Payer[1]

1. Department of Moalijat, Faculty of Medicine (U), Jamia Hamdard, New Delhi - 110062, India
2. Department of Ilmul Advia (Pharmacology), Faculty of Medicine (U), Jamia Hamdard, New Delhi - 110062, India.

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For Correspondence:

Raheela Javaid

Department of Moalijat, Faculty of Medicine (U), Jamia Hamdard, New Delhi - 110062, India

E-mail:

rahijavaid786@gmail.com

ABSTRACT

Obesity is introduced as a known risk factor of coronary artery disease (CAD) by the American Heart Association. It is known as one of the common metabolic disorders in man which has significantly increased in frequency in the last two decades. Body mass index (BMI) is an index used for the evaluation of body weight. In Unani literature there is a description of many drugs (single as well as compound formulation) used for the purpose of reducing weight and treating the obesity. Compound formulation of three drugs Zeera Siyah- *Carum carvi*, Ajwain- *Ptychotis ajowan* and Luk Maghsool- *Laccifer lacca*, being used by Unani physicians in reducing weight, was taken from Akseer-e-Azam. The formulation was found to be statistically significant in reducing BMI (p= 0.015).

INTRODUCTION

Obesity has reached global epidemic proportions in both adults and children and is associated with numerous comorbidities, including hypertension (HTN), type II diabetes mellitus, dyslipidemia, obstructive sleep apnea and sleep-disordered breathing, certain cancers, and major cardiovascular (CV) diseases[1,2,3,4]. It is a chronic disease and is epidemic in industrial countries due to the change of lifestyle it causes sudden death in 50% of men and 62% of women[5]. Because of its maladaptive effects on various CV risk factors and its adverse effects on CV structure and function, obesity has a major impact on CV diseases, such as heart failure (HF), coronary heart disease (CHD), sudden cardiac death, and atrial fibrillation, and is associated with reduced overall survival. Despite this adverse association, numerous studies have documented an obesity paradox in which overweight and obese people with established CV disease, including HTN, HF, CHD, and peripheral arterial disease, have a better prognosis compared with non overweight/non obese patients[2, 3, 4].

The Ancient Unani scholars like Hippocrates, Galen, Rhazes and Avicenna have described the condition, Saman-e-Mufrit (obesity) in their treatises and have mentioned the etiological factors, clinical features and complications of it. In Unani literature there is a description of many drugs (single as well as compound) used for the purpose of reducing weight and treating the obesity. Compound formulation of three drugs Zeera Siyah- *Carum carvi* (described as anti obesity[7], anti spasmodic[14], diuretic[11,12,13], expectorant, resolvent, anti inflammatory, galactogogue, emmenagogue etc as mentioned in Unani literature), Ajwain-*Ptychotis ajowan* (described as anticonvulsant, purgative, digestive, diuretic, appetizer etc as mentioned in Unani literature). Luk Maghsool-*Laccifer lacca* (described as anti obesity, emmemagogue, liver tonic etc as mentioned in Unani literature) being used by Unani physicians in reducing weight, was taken from Akseer-e- Azam[6].

METHODOLOGY

To evaluate the efficacy of Unani formulation of Zeera Siyah, Ajwain and Luk Maghsool in the ratio of 2:2:1 respectively, in the treatment of obesity the study was conducted at Majeedia Hospital, Jamia Hamdard, New Delhi. 60 patients were enrolled from the OPD of Majeedia Hospital. The trial was performed according to recommendations of the Helsinki Declaration & ICH- GCP & ICMR Ethical Guidelines. Proposal was submitted to the Institutional Ethical Committee of Jamia Hamdard, New Delhi for its approval and was approved. There were 30 patients in the Test Group and 30 patients in the Control Group. Either sex; patients between 18 to 70 yrs of age and patients who were who voluntarily

consented were included in the study and obese patients with Diabetes Mellitus, Hypothyroidism, patients taking oral contraceptive pills, hypolipidaemic drugs; clinically diagnosed for endocrine disorder (PCOD); Patients with liver and kidney insufficiency; Patients below 18yrs and above 70yrs of age; Pregnant and lactating women; patient who refuse to give informed consent and Terminally ill patients – (T.B; Hepatitis-B, C; HIV; acute & chronic cancers).were excluded from the study. Patient fulfilling the inclusion criteria were randomized into two groups, Test and Control. The Test Group was subjected to Unani formulation, composed of the above mentioned drugs (in the dose of 3.5 gm BD, powdered form) for a duration of 42 days. The Control Group was given the Statin-Atorvastatin (10mg/day) for 42 days. Both the groups were asked to follow the prescribed diet of approximately 1600 calories as well as exercise schedule. The patients were assessed clinically for efficacy and safety parameters at each follow up (21 days) and were investigated before and after the treatment for haematological and biochemical parameters in both the groups. The data emanated from the research work was subjected to statistical analysis by using T test (paired and unpaired).

OBSERVATION

Observation was made on following parameters:

1. Effect on Weight in the Study Population (Table & Graph -1)
2. Effect on BMI in the study population (Table & Graph-2)

RESULTS AND DISCUSSION

Weight

The mean value of weight before treatment in control group was 71.90 ± 2.365 and in test group was 78.60 ± 2.521. After treatment mean value of weight in control and test group was decreased to 69.63 ± 2.340 and 73.93 ± 2.447 respectively.

The percentage of reduction in weight was 3.16% in control group and 5.94% in test group. Which was extremely significant statistically in both the groups (p=< 0.0001). But when compared, the two groups did not show any statistically significant difference (p=0.209) in reducing weight. (Table & Graph -1)

BMI

The mean value of BMI in the control group before treatment was 29.1310 ± 0.8271 and after treatment was 28.2187 ± 0.8229. In the test group the mean value of BMI in the test group before treatment was 33.2297 ± 0.9108 after treatment was 31.2570 ± 0.8960. The percentage of improvement within the control group and test group was 3.13% and 5.93% respectively,

which was statistically extremely significant in both the groups (p=< 0.0001). Significant difference between the two groups was also observed statistically (p= 0.015). (Table & Graph-2)

The overall impression from the above data suggests that there is statistically significant result of Unani formulation in reducing obesity which is attributed to anti obesity effect of Luk Maghsool, Zeera Siyah, Ajwain [6,7,8,9,10]

Table-1 Effect on Weight in the Study Population

Weight	Control n=30		Test n=30		p value (T-test unpaired)
	Mean	SEM	Mean	SEM	
Before Treatment	71.90	2.365	78.60	2.521	0.057¥
After Treatment	69.63	2.340	73.93	2.447	0.209¥
% of Change	3.16		5.94		
p value(T-test paired)	< 0.0001***		< 0.0001***		

¥P>0.05 (NS), *P<0.05(S), **P<0.01(VS), ***P<0.001(ES)

Table-2 Effect on BMI in the Study Population

BMI	Control group n=30		Test group n=30		p value (T-test unpaired)
	Mean	SEM	Mean	SEM	
Before Treatment	29.1310	0.8271	33.2297	0.9108	.002
After Treatment	28.2187	0.8229	31.2570	0.8960	0.015*
% of change	3.13		5.93		
p value(T-test paired)	< 0.0001***		< 0.0001***		

¥P>0.05 (NS), *P<0.05(S), **P<0.01(VS), ***P<0.001(ES)

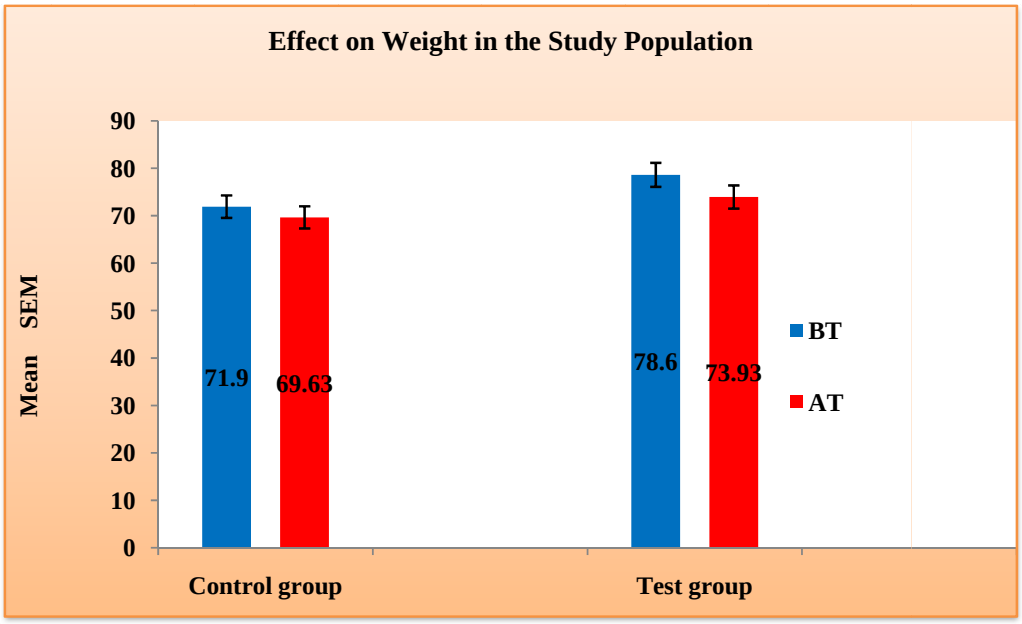

Figure-1

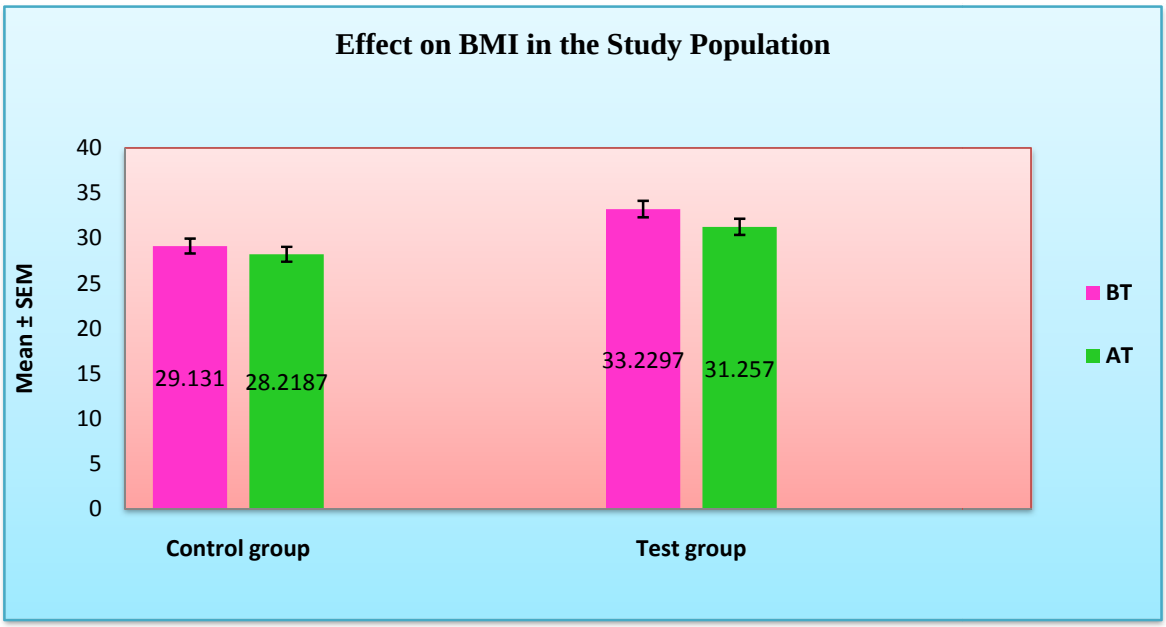

Figure-2

CONCLUSION

It may be concluded from the study that above said Unani formulation which has been used by the Unani Physicians from centuries for treating obesity has shown promising results in reducing weight in present clinical trial. The test drug was well tolerated and there were no side effect, therefore the test drug can be used for a long time and may prove beneficial in primary as well as secondary prevention of atherosclerotic diseases. Various aspects such as

reduction of the dose of test drug by concentration in the form of extracts, testing the three constituents of the test drug separately for their activity and combination with established Unani single drugs of strong antiobesity potential could be the preliminarily step towards this. Efficacy of test drug can be tested at various doses of test drug. A larger population study may be done to draw a reliable and conclusive evidence of the safety and efficacy of test drug.

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