ABSTRACT

Obesity is an independent risk factor for cardiovascular disease (CVD). Obesity is associated with an increased risk of morbidity and mortality as well as reduced life expectancy. The last two decades of the previous century have witnessed dramatic increase in health care costs due to obesity and related issues among children and adolescents. The emerging epidemics of obesity, CVD and diabetes form the crux of this phenomenal change. Among these entities, obesity has become a colossal epidemic causing serious public health concern and contributes to 2.6 million deaths worldwide every year.\(^{13}\) The open label randomized clinical trial on 60 diagnosed patients of obesity, aged between 20-50 years. An Unani formulation -compound of Luk Maghsul (\textit{Tachardia Laccca}), Ajwain Desi (\textit{Trachyspermum ammi}) & Zeera Siyah (\textit{Carum carvi}) is given for 90 days. The “P” value of each intervention groups on all parameters is \(P=0.001\).

**Keywords:** Samane Mufrit; Luk Mughsul; Ajwain Desi; Lac; Zeera Siyah.
INTRODUCTION
Pathologically obesity is not a disease, but it may be significant, because it may aggravate clinical conditions, such as hypertension, diabetes mellitus and heart disease. The fat in an obese is deposited in a subcutaneous, retroperitoneal, peritoneal tissues and omentum. In abnormal cases, fat may be deposited in the heart, pancreas, and liver etc\(^1\). The greed of man to consume excessive food in affluent societies has led to create the problem of obesity. Although, there are very many other causes of obesity which might not be influenced by diet itself. Yet over nutrition and physical under activity may be to any reason has gradually upset the balance between the calorie supply and the demand of the body. Obesity is also associated with serious disease like early phase of diabetes mellitus, hypertension and atherosclerosis, endocrinal disorders etc\(^2\).

In the Unani system of medicine there is a description of a number of effective drugs for obesity which possess quality medicines like Bisfaij (\textit{Polypodium vulgare} Linn), Zaranbad (\textit{Zingiber zerumbet}), Rasaut (\textit{Berberis arista}), Muquil (\textit{Commiphora mukil}), Magaz-e-tukhm-e-neem (\textit{Azadirachata indica}) Luk Mugshul (\textit{Tachardia lacca}), Marzanjosh (\textit{Origanum Vulgare} Linn), Karafs (\textit{Apium graveolens}), Juntiyana (\textit{Gentiana lutea}), Lehsan (\textit{Allium sativum}), Khatmi (\textit{Althaea officinalis}), Murmaki (\textit{Commiphora myrrha}), Zeera (\textit{Carum carvi}), Saunf (\textit{Foeniculm vulgare}), Sandroos (\textit{Trachelobium hornemanianum}) and Suddab (\textit{Ruta Graveolens} Linn) etc. These drugs probably act either by reducing absorption or increasing utilization of cholesterol in body by metabolism. Further these drugs have been demonstrated to possess Triglycerides reducing properties in them\(^3,4\).

Aim and Objectives
- To evaluate the efficacy of Unani formulation prepared from \textit{Luk Mughsul}, \textit{Zeera Siyah} and \textit{Ajwain Desi} in the management of obesity.
- To provide safe and cost-effective Unani treatment for obesity.
- To provide less harmful and herbal treatment of obesity.
- To develop a better understanding of the concept of obesity and their management, with relation to Unani as well as modern medicine.

MATERIALS AND METHOD
Thus, selection of Unani formulation (compound of \textit{Luk Mughsul, Ajwain Desi} & \textit{Zeera Siyah} is supported by unani literatures, which claim that it has good effect in the management of \textit{Samane Mufrit}\(^3\). The present study was designed as an open label randomized clinical trial in successive patients with obesity diagnosed on presentation, history and investigations. 60 diagnosed patients of age between 20-50 years. Who belongs to inclusion criteria were registered, and Unani
formulation (compound of *Luk Mughsul, Ajwain Desi & Zeera Siyah*) is given for 90 days. Complete physical examination & investigations of patients were done and follow-up planned prior of trial, 30th, 60th day and at the end of trial i.e. on 90th day. Low fat diet, moderate exercise, cut down sweets; alcoholic beverages and cessation of smoking were advised. Subjective, objective and safety parameter recorded. Complication and side effects treated accordingly and data collected. An official approval of study proposal was taken by the College and Hospital ethical committee; later on, by MUHS, Nashik (M.S.) before starting the trial. The statistical analysis of data has been done with the help of computer software “Statistical Package for Social Sciences”. Test of significant calculated by using paired “t” test.

RESULTS AND OBSERVATION

Interpretation of Weight

While analysing the weight at beginning of study the mean of weight was 76.9 with SD of 7.9 and the maximum value of weight 100, and minimum value was 62 was recorded. Then after the completion of 30th day on 2nd visit mean of weight gone down to 75.7 with 7.7 SD, and 97.2 was maximum value and minimum value was 61. Then after the completion of 60th day on 3rd visit mean of weight gone down to 74.3 with 7.5 SD, and 95 was maximum value and minimum value was 60.8, and after the completion of 90th day mean of weight was further gone down 72.9 with 7.1 SD and maximum value was 92.8 and minimum value was 60. While applying the paired “t” test difference between visit 1st – visit 2nd “t” paired value is 6.1 with 59 df “p” value is 0.001 that is statistically very significant. While applying the paired “t” test difference between visit 1st – visit 3rd “t” paired value is 20.6 with 59 df “p” value is 0.001 that is statistically very significant. While applying the paired “t” test difference between visit 1st–visit 4th “t” paired value is 23.8 with 59 df “p” value is 0.001 that is statistically very significant. The “P” value suggests that drug in the lowering of body weight is extremely significant.

The distribution of Weight at each follow-up
Interpretation of BMI
While analysing the BMI at beginning of study the mean of BMI was 28.1 with SD of 1.9 and the maximum value of BMI 33.8, and minimum value was 25.86 was recorded. Then after the completion of 30th day on 2nd visit mean of BMI gone down to 27.6 with 1.8 SD, and 32.87 was maximum value and minimum value was 25.65. Then after the completion of 60th day on 3rd visit mean of BMI gone down to 27.0 with 1.8 SD, and 32.16 was maximum value and minimum value was 25.27, and after the completion of 90th day mean of BMI was further gone down 26.5 with 1.7 SD and maximum value was 31.36 and minimum value was 25.

While applying the paired “t” test difference between visit 1st – visit 2nd “t” paired value is 16.7 with 59 df “p” value is 0.001 that is statistically very significant. While applying the paired “t” test difference between visit 1st – visit 3rd “t” paired value is 21.9 with 59 df “p” value is 0.001 that is statistically very significant. While applying the paired “t” test difference between visit 1st – visit 4th “t” paired value is 25.5 with 59 df “p” value is 0.01 that is statistically very significant. The “P” value suggests that drug in the lowering of BMI is extremely significant.

The distribution of BMI at each follow-up

Interpretation of Waist HIP Ratio
While analyzing the WHR at beginning of study the mean of weight was 0.92 with SD of 0.11 and the maximum value of WHR 1.07, and minimum value was 0.78 was recorded. And after the completion of the study i.e., after completion of 90 days mean of WHR was further gone down 0.91 with 0.10 SD and maximum value was 1.06 and minimum value was 0.78. While applying the paired “t” test difference between visit 1st – visit 4th “t” paired value is 4.1 with 59 df “p” value
is 0.001 that is statistically very significant. The “P” value suggests that drug in the lowering of WHR is extremely significant.

The distribution of WHR at follow-up

![Distribution of WHR](image)

CONCLUSION

Obesity is a major health problem throughout the world. In unani system of medicine also claimed the number of single and compound drugs to cure the obesity without causing any side effects. Therefore, it is an important need to provide safe and effective drug from Unani system of medicine for the long-term management of Obesity. So, keeping the fact in mind, the study entitled “A Prospective Open Label Randomized Clinical Study of Luk Mughsul (*Tachardia Lacca*), Ajwain Desi (*Trachyspermum ammi*) & Zeera Siyah (*Carum carvi*) in the cases of Samane Mufrit (obesity).” All patients received *Safoof* prepared from the drugs 05-gram BD with Luke warm water. As evidence of observation result and discussion of the study following conclusion can be drawn; After Intervention the safety parameters does not change significantly. It means the *safoof* does not act on our safety parameter. (ECG and BSL F and PP) On objective parameters, improvement is very significant. All the parameters in each intervention groups P=0.001. In weight “t” = -23.8 with 59 df “P”= 0.001, In BMI “t” = 25.5 with 59 df “P”= 0.001, In WHR “t”=4.1 with 59 df “P”= 0.001, In thigh circumference “t” = 4.8 with 59 df “P”= 0.001, In arm circumference “t” = 13.2 with 59 df “P”= 0.001, that is extremely significant. This result suggests that the effect of drug on the lowering of Weight, BMI, WHR, Thigh circumference and arm circumference. Therefore, it can be concluded that the drug formulation is safe and effective in the cases of Obesity. As literature shows, Obesity is a metabolic disorder & genetically inherited disease, therefore the long-term study is needed to explore other pharmacological action of drug, and not only this its specific ingredients or extracts’ possibly give better comparable impact on obesity.
than its crude form. Finally, as with any analysis, the potential for publication bias is of concern. Visual inspection of our analysis funnel plot could not rule out for publication bias. Obesity in adolescents and children has raised to significant levels globally with serious public health consequences. In addition to cardiovascular, emotional and social issues, it poses a serious hazard to the basic health care delivery system. Successful treatment of obesity requires multiple interventions. The choice of therapies should be guided by the initial assessment of a patient’s degree of obesity and comorbid condition, if present.

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