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A PROSPECTIVE OPEN LABEL RANDOMIZED CLINICAL STUDY OF LUK MUGHSUL (*TACHARDIA LACCCA*), AJWAIN DESI (*TRACHYSPERMUM AMMI*) & ZEERA SIYAH (*CARUM CARVI*) IN THE CASES OF *SAMANE MUFRIT* (OBESITY).

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ABSTRACT

The emerging epidemics of *Samane Mufrit* (obesity), cardiovascular disease (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.[1] The present study was designed as an open label randomized clinical trial in successive patients with obesity diagnosed on presentation, history and investigations. Sixty diagnosed patients of age between 20-50 years. And Unani formulation (compound of Luk Mughsul (*Tachardia Laccca*), Ajwain Desi (*Trachyspermum ammi*) & Zeera Siyah (*Carum carvi*) is given for 90 days. Subjective, objective and safety parameter recorded. The observation and results obtained in group have been discussed and compared with reference various known variables in the light of the text present in Unani as well as modern literature. distribution of base line characteristics like; Age, Sex, Mizaj, Diet, Anxiety, Habits, Hypertension, Past history, did not differ significantly between two intervention groups in other words groups are well matched and comparable. Objective Parameters: *Safoof* very effective on all objective parameters like Weight, BMI, WHR, Arm circumference and Thigh circumference. 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

Samane Mufrit is a common metabolic disease seen in clinical practice. The Hippocrate, Galen, Razes and Avicenna described the obesity (which is due to the excess of the phlegm (*Khilt-e-Balgham*). They describe the causes of that obesity are hereditary, lack of exercise (*Riyazat*) and luxurious life style, diet (*Ghiza*), excess of alcohol especially after meal and *Baroodat-e-mizaj*. *Samane Mufrit* is a predisposing factor of paralysis, stroke, narrowing of blood vessels, haemorrhage and sudden death. "Galen" recommended the main stay of treatment is to be evacuation (Istefragh by laxative), increasing body heat breath holding exercises and moderate amount of alcohol.

In India, obesity has reached epidemic in the 21st century, with morbid obesity affecting 5% of the country's population. Urbanization and modernization have been associated with obesity. In North India obesity was most prevalent in Urban population (men 5.5%, women 12.6%) followed by the Urban slums (men 1.9%, women 7.2%). Obesity rates were the lowest in rural population (men 1.6%, women 3.8%). Socioeconomic class also had an effect on obesity; women of high socioeconomic class had rates of 10.4% as opposed to 0.9% in women of low socioeconomic class.[2]

The prevalence of overweight and obesity is commonly assessed by using body mass index (BMI), defined as the weight in kilograms divided by the square of the height in meters (kg/m2). The calculation produces a figure that can be compared to various thresholds that define whether a person is underweight, of normal weight, overweight or obese. A BMI over 25 kg/m2 is defined as overweight and a BMI of over 30 kg /m2 as obese.[3,4,5,6]

Unani physicians described the mizaj (Temprament) of *Samane Mufrit* as a *Barid Ratab* (phlegam). People of

Baridul-mizaj probably have slower metabolic rate which leads to accumulation of fat and cause obesity. The Hippocrate, Rofas, Galen, Razes and Avicenna described the obesity, which is due to the excessive phlegm (*Khilt-e-Balgham*). They described obesity is a predisposing factor of paralysis, stroke, narrowing of blood vessels, haemorrhage and sudden death.[7,8,9]

The present study was designed as an open label randomized clinical trial in successive patients with obesity diagnosed on presentation, history and investigations. Sixty diagnosed patients of age between 20-50 years. Who belongs to inclusion criteria were registered, and Unani formulation-compound of *Luk Mughsul* (*Tachardia Laccca*), Ajwain Desi (*Trachyspermum ammi*) & Zeera Siyah (*Carum carvi*) 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. Subjective and objective Parameters, of *Safoof* very effective on all subjective and objective parameters like Weight, BMI, WHR, Arm circumference and Thigh circumference. The "P" value of each intervention groups on all parameters is P= 0.001.

MATERIAL AND METHODS

The study was approved by Institutional Ethical Committee and conducted during the session 2011-2014, and the study was designed as an open label randomized trial in successive patients with *Samane Mufrit* diagnosed on presentation, history, examination, and investigations. Sixty patients were selected by random sampling, of age between 20-50 years who were belonging to inclusion criteria registered. All patients were treated with the *Safoof* of medicine (trial drug) 5 gram daily, twice a day i.e. morning and night with Luke warm water, for a period of three months. The parameters of evolution were recorded prior of trial i.e. 0 day, 30th day, 60th day and 90th day of trial. For the assessment of safety E.C.G. & BSL (F & PP) were also carried out before starting the treatment at the end of the trial. A low-fat diet, moderate exercise, cutting down sweet, alcoholic beverages and cessation of smoking were advised. Subjective and objective parameters were recorded. Complication and side effects treated accordingly and data collected.

1. Criteria for Selection of the Patients (Inclusion Criteria):

- Patients having complain of obesity.
- Patients of both sexes will be selected for the study between the ages of 20-50 years.
- History of occupation & their life style (sedentary life style, worker or labour).
- History of socio-economic status and habits (particularly dietary habits, smoking and exercise)
- In case of females, only non-pregnant females.

2. Criteria for non-selection of patients (Exclusion Criteria)

- Patients with severe or obstructive liver diseases.
- Patients with hypothyroidism.
- Female patients who are on oral contraceptives.
- Patients with Nephrotic syndrome
- Pregnant ladies were excluded from the study.
- Patients who are taking diuretics and Beta-blockers.
- Patients having life threatening diseases.
- Patients with history of stroke with transient or permanent neurological deficit were also excluded from the study.

3. Diagnostic criteria: For the Diagnosis of *Samane Mufrit*, following history, clinical examination and biochemical investigation kept under consideration. In chief complaints and history of present illness particularly following history were interrogated and recorded in the case report form.

4. Subjective Parameters

- Joints pain
- Palpitation /Anxiety
- Dyspnoea on exertion
- Chest pain.

5. Objective Parameters

- Weight (Kilogram)
- Body Mass Index
- Waist Hip Ratio
- Thigh Circumference
- Arm Circumference

6. Safety measures

It includes routine investigation specially E.C.G. and BSL (F & PP)

OBSERVATION AND RESULTS

Distribution of base line characteristics like; Age, Sex, Mizaj, Diet, Anxiety, Habits, (Smoking, Alcohol and Tobacco) Hypertension, Past history, did not differ significantly between two intervention groups in other words groups are well matched and comparable.

- **Age:** In our observation, there is maximum number of patients in group was belonging from the age groups of 26-35 years. This finding suggests the possibility this obesity represent itself during these age groups.
- **Sex:** In our study, maximum number of patients that is 31 patients (i.e.51.7%) were male and 29 patients (i.e.48.3%) is female.
- **Mizaj:** In our observation there are 37 patients (i.e. 61.7%) found having *Balghami mizaj* whereas only 23 patients (i.e.38.3%) found having *Saudavi mizaj*, were as no patients found having *Safravi* and *Damvi mizaj*.
- **Diet Pattern:** In regard of dietary pattern, in our observation, maximum number 44 patients (i.e.73.3%) falls in Mixed diet pattern i.e. eat

vegetarian as well as Non-vegetarian foods and minimum number 16 patients (i.e.26.7%) were found vegetarian.

- **Habits**: During the study it is observed that in group 05 patients (i.e.8.3%) were tobacco user, 6 patients (i.e.10.0%) were smoker, and 01 patient (i.e.1.7%)
- **Past History:** In this study observation shows, out of 60 patients, 13 patients (i.e.21.7%) were found positive history of hypertension and 11 patients (i.e.18.3%) have the history of weight gain in group. No other past history found in group, those having other possible past history related to obesity like IHD, CVA, DM etc, they were not included in the study.

Effect on Subjective Parameter: Subjective parameters After Intervention, most of the subjective parameters like chest pain, palpitation, exertional dyspnoea, and joint pain improved significantly and while using chi-square test P value is <0.001 which is statistically very significant. Improvement of all subjective parameters differ significantly and its shows test drugs are very effective on clinical symptoms.

Effect on Objective Parameter

Table 01: Effects on Body Weight.

Parameters	Vis1t 1st	Visit 2nd	Visit 3rd	Visit 4th	Visit 1st vs Visit 2nd	Visit 1st vs Visit 3rd	Visit 1st vs Visit 4th
Mean	76.9	75.7	74.3	72.9	1.2	2.6	4
SD	7.9	7.7	7.5	7.1			
Maximum	100	97.2	95	92.8	2.8	5	7.2
Minimum	62	61	60.8	60	1	1.2	2
T paired					6.1 with 59 Df	20.6 with 59 Df	23.8 with 59 Df
P Value					0.001	0.001	0.001

Table 02: Effects on Body MASS INDEX (BMI).

Parameters	Vis1t 1st	Visit 2nd	Visit 3rd	Visit 4th	Visit 1st vs Visit 2nd	Visit 1st vs Visit 3rd	Visit 1st vs Visit 4th
Mean	28.1	27.6	27.0	26.5	0.5	1.1	2.6
SD	1.9	1.8	71.8	1.7			
Maximum	33.80	32.87	32.16	31.36	0.93	1.64	2.44
Minimum	25.86	25.65	25.27	25.0	0,21	0.59	0.86
T paired					16.7 with 59 Df	21.9 with 59 Df	25.5 with 59 Df
P Value					0.001	0.001	0.001

Table 03: Effects on Body Waist Hip Ratio (WHR).

Parameters	Vis1t 1st	Visit 4th	Visit 1st vs Visit 4th
Mean	0.92	0.91	0.01
SD	0.11	0.10	
Maximum	1.07	1.06	0.01
Minimum	0.78	0.78	0.o
T paired	4.1 with 59 Df		
P Value	0.001		

Table 04: Effects on Thigh Circumference.

Parameters	Vis1t 1st	Visit 4th	Visit 1st vs Visit 4th
Mean	54.9	54.1	0.8
SD	2.0	1.9	
Maximum	60	58.5	1.5
Minimum	52	51.5	0.5
T paired	4.8 with 59 Df		
P Value	0.001		

Table 05: Effects on Arm Circumference.

Parameters	Vis1t 1st	Visit 4th	Visit 1st vs Visit 4th
Mean	31.9	31.1	0.8
SD	2.5	2.4	
Maximum	38	38.5	+0.5
Minimum	29	28.0	1.0
T paired	13.2with 59 Df		
P Value	0.001		

Effect On Safety Parameter

1. ECG: While analysing the difference between Electro Cardio Gram (ECG) before starting trail and after completion of the trail, there are no significant changes found in the ECG. In Visit 1, 60 patients were with normal ECG (i.e.100%) where as in Visit 4, 60 patients were with normal ECG.

2. Blood Sugar Level Fasting (F): While analysing the BSL(F) at beginning of study the mean of BSL(F) was 94.7 with SD of 6.0 and the maximum value of BSL(F) was 108, and minimum value was 81 was recorded. And after the completion of the study i-e after completion of 90 days mean BSL(F) was 94.3 with 6.4 SD and maximum value was 105 and minimum value was 81 (Table No. 13 & Graph No.13.1).While applying the paired "t" test difference between visit 1st-visit 4th "t" paired value is 0.553 with 59 df "p" value is 0.582 that is statistically not significant.

3. Blood Sugar Level Post Prandial (PP): While analysing the BSL(PP) at beginning of study the mean of BSL(PP) was 147.2 with SD of 8.5 and the maximum value of BSL(PP) was 160, and minimum value was 131 was recorded. And after the completion of the study i-e after completion of 90 days mean BSL(PP) was 146.9 with 5.5 SD and maximum value was 158 and minimum value was 134 (Table No. 13 & Graph No.13.2).While applying the paired "t" test difference between visit 1st-visit 4th "t" paired value is 0.192 with 59 df "p" value is 0.849 that is statistically not significant.

DISCUSSION AND CONCLUSION

Samane Mufrit 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 *Samane Mufrit* 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 Laccca*), 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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Conflict of Interest

Nil.

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