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Clinical Study of Obesity (*Siman-E-Mufrat*) and Comparative Therapeutic Evaluation of Darchini and *Safoof-E-Muhazzil* in Its Management

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Abstract

Obesity (*Siman-e-Mufrat*) is nowadays becoming a challenging threat to clinician worldwide. Its prevalence is rapidly increasing. It is usually associated with other comorbidities such as Diabetes mellitus, Hypertension, Atherosclerosis, Cardiovascular and Cerebrovascular disease. There are various drugs in modern medicine that are used to treat obesity but having adverse effect so it is need of time to find out a drug from the system of Unani medicine with no adverse effect or minimal side effect. For this purpose A Randomized single blind study was designed to comparative clinical trial of *Darchini* and *Safoof-e-Muhazzil* for evaluation of efficacy of Darchini in comparison of *Safoof-e-Muhazzil* on obesity. Study was conducted in the Department of Moalejat, A.K.T.C Hospital. The protocol therapy duration was 90 days and follow up fortnightly. Cases are divided into two groups, test group (Group A), control group (Group B) comprising 30 patients in each group. Assessment of efficacy was done on the basis of objective parameters. The result of present clinical trial demonstrates that *Safoof-e-Darchini* is equally effective in comparison of *Safoof-e-Muhazzil*. *Safoof-e-Muhazzil* is also showing its effect on mild to moderate obesity like Darchini but both are ineffective in morbid obesity.

Keywords: Randomized single blind; Safoof-e-Muhazzil; Darchini; Obesity; Comorbidities; Objective parameters

Introduction

Siman-e-mufrat (Obesity) is a preventable disease and has reached epidemic proportion globally along with an adoption of westernized lifestyle characterized by a combination of excess food intake and inadequate physical activity. [1] Obesity is a complex trait with multifactorial aetiology, including behavioural, environmental and genetic factor. Obesity, a growing epidemic with a current prevalence is directly responsible for the rapidly increasing morbidity and mortality from insulin resistance and the metabolic syndrome, diabetes, cardiovascular disease, cancer, respiratory ailments, arthritis, reproductive challenges, and psychosocial problems. The dramatic rise in the prevalence of obesity is increasing day by day and has reached an alarming rate throughout world and became pandemic. In the USA the prevalence of obesity doubled during the past two decades and currently 35% of the US adult population is classified as obese. [2] Obesity can also be defined arbitrarily as an increase in body fat stores compared to lean body mass According to the first law of thermodynamics, the total the energy of a system plus surrounding is constant. [3] To prevent gradual weight gain over time, the 2005 Dietary guidelines for Americans recommended small decrease in energy from foods and beverages and increase in physical activity. For individuals who need to lose weight, the guidelines encourage a slow, steady weight loss by decreasing energy intake while maintaining an adequate nutrient intake and increasing physical activity. Individual strategies have typically used to reduce energy intake include limiting portion sizes, food groups, or certain macronutrients.4 Although the drugs currently available for the treatment of obesity are few in numbers and limited in efficacy such as Sibutramine and Orlistat [4-5].

Apart from modern medicine in unani system of medicine Siman-e-mufrat (Obesity) is a phlegmatic disease in which temperament of body becomes abnormally Barid and Ratab that results in excessive accumulation of fats (Sheham wa Sameen) leading to obesity. Unani physician like Ibn-e-Sina, DaudAntaki, Zakaria Razi, Ismail jurjani, Rabban Tabri described Historical background, aetiology, types, sign and symptoms, clinical diagnosis and management in detailed way [6-10]

In view of the above facts, it was envisaged to investigate the effect of test drug Darchini in comparison of Saffof-e-Muhazzil for its anti-obesity effect. This drug studied earlier and reported to have Musakhkhin (Calorific), Muharrik (Stimulant), Mufatteh-e-Sudad (Deobstruent), Hypoglycaemic and Hypolipidaemic effect and also have hot and dry temperament thus increases metabolic rate of body and burn excessive fat of body and hence causes in reduction of obesity. [11-15] and the control drug Safoof-e-Muhazzil has been proved as anti-obesity effect in unani pharmacopeia (Qarabadeen) because this unani formulation possess action like Muhazzil, Musakhkhin (Calorific), Mudir (Diuretic) and Mulattif (Demulcent) property due to its ingredients such as Zeera siyah (*Carum carvi*), Ajwain (*Trachyspermum ammi*), Marzanjosh (*Origanum majorana*), Badiyan (*Foeniculum vulgare*), LukMaghsool (*Cocoslacca*) Bura Armini(Sodium borate) and Suddab (*Ruta graveolens*)is beneficial in order to reduce obesity.

Materials and Methods

This Randomized single blind comparative clinical trial of Darchini and Safoof-e-Muhazzil for evaluation of efficacy of Darchini in comparison of Safoof-e-Muhazzil on obesity was conducted in

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Department of Moalejat, A.K.T.C Hospital, and Aligarh from July 2017 to May 2019. The protocol therapy duration was 90 days and follow up fortnightly. Cases are divided into two groups, test group (Group A), control group (Group B) comprising 30 patients in each group. The selection of patients and efficacy of test drug were assessed upon the basis of subjective parameters, objective parameters and laboratory investigations. The patients of both groups were kept under observation and advised dietary control and exercise (Brisk walking). Findings of test drug were recorded on designed CRF and inference was made by appropriate statistical analysis.

Criteria for selection of subjects

a) Inclusion Criteria

- Patient diagnosed with obesity from either sex
- BMI >25
- Waist circumference
- >102 cm in men
- >88 cm in women
- Patients, who are able to participate in study, agree to follow instruction and sign the consent form.
- Patients in age group of 20 to 60 years.
- Patients with complex symptoms that consist of dyspnoea, lethargy, weakness, palpitation, restricted movements and joint pain

b) Exclusion Criteria

- Patients below 20 years of age and above 60 years
- Patient who fail to give written consent
- Pregnant and lactating mother
- Patient who fail to follow up
- Patient using oestrogen containing contraceptive pills
- Patients of portal hypertension
- Patients suffering from Hypothyroidism, Diabetes Mellitus, chronic Renal Failure, Nephrotic Syndrome, HIV+ve, Cirrhosis of Liver, Chronic Alcoholism, Primary gout and Bleeding disorder

Investigations

Certain investigations carried out aiming

- As objective parameters
- To establish the safety of test drug
- To diagnose the patient of obesity due to any metabolic disorder for excluding from study

Following investigations were done in each and every patient

TLC, DLC, RBC, ESR, Hb%, RFT, LFT, Lipid Profile (Total cholesterol, Triglycerides and HDL), Blood Sugar (Random & Post Prandial) and Urine (Routine and Microscopic)

Above all investigations were done before starting the trial and also after completing the trial.

Thyroid profile, RBS, and ECG were done before starting the study trial for exclusion of other disease

Selection of subjects

The patients were selected on the basis of symptoms like increased body weight, palpitation, joint pain and restricted movement. After provisional diagnosis patients were subjected to laboratory investigations for confirmation of diagnosis. For selection complete history such as interrogation, history of present illness, past history, family history, general examination, physical examination and socioeconomic history. Kuppuswami socioeconomic status (2007) was used for detection of socioeconomic strata.

Informed consent

Patients who are fulfilling the inclusion criteria were given consent form sheet consisting detailed information about the nature of study, duration of study, drug to be used, side effects of drugs, methods of treatment. Patients were given every kind of freedom to ask any type of questions and enough times to take decision for participation in the study. If they were agreed then they asked to sign on the consent form.

Study Design

Randomized Single blind comparative clinical Trial

Sample Size

Total number of patients: 60

Allocation of Subjects

The 60 patients were randomly allocated by using lottery method into two groups comprising 30 patients for test group (group A) and 30 patients for control group (group B) respectively.

Assessment of Mizaj (Temperament)

Assessment of mizaj for the participant was done on the basis of Ajnas-e-Ashra that was given in classical unani literature. The parameters have been attached with case report form.

Method of Study

Diagnosed patient of Obesity qualifying the inclusion criteria was subjected for comparative clinical trial. Test drug Darchini 5gm in powder form with lukewarm water twice daily was given in Group (A) while Safoof-e-Muhazzil 5 gm orally was given in Group B patients.

Patients were advised for dietary regulation to consume less than 1300 calories per day with moderate exercise as 20-30 minutes morning or evening brisk walk.

No concomitant treatment was prescribed during trial period.

Drug Used

Group A

Trial Drug: Darchini (*Cinnamomum zeylanicum*)

Route of Administration: Oral, in Safoof form

Group B

Control Drug: Safoof-e-Muhazzil

The whole treatment plan for Siman-e-Mufrat is based on drug regimen, exercise (Brisk walk for 20-30 minutes according to the condition of patient) and the diet containing 1200-1300 kcal/day is advised. General total energy is calculated by basal energy need 1 kcal/kg/hour (Table 1).

Duration of protocol therapy: 3 months

Follow up

Table 1: Ingredients of *Safoof-e-Muhazzil*.

S. No.	Unani Name	Botanical Name	Quantity
1.	Ajwain Desi	*Trachyspermum ammi*	14 gm
2.	Zeera Siyah	*Carum carvi*	14 gm
3.	Tukhm-e-Badiyan	*Foeniculum vulgare*	14 gm
4.	Suddab	*Ruta graveolence*	14 gm
5.	Lukmaghsool	*Coccus lacca*	7 gm
6.	Marzanjosh	*Origanum majorana*	3 gm
7.	Bora Armani	*Sodium borate*	3 gm

90 days study was divided into 7 visits of follow up which were fortnightly. At every visit patients were asked about improvement in their symptoms and carried out examinations to assess clinical findings.

Assessment of Safety

All adverse events experienced by a patient or observed by the investigator were recorded at each visit. Adverse drugs reactions were assessed on Naranjo ADR probability scale and also on onset and severity classification.

Physical examinations including vitals were performed at the commencement of the trial and at each visit. Additional laboratory safety parameters like Haemogram (TLC, DLC, RBC, Hb%, ESR), LFT, RFT were also be carried out before and after completion of trial.

Assessment of Efficacy

The efficacy assessment in the test and control groups was done upon the basis of subjective and objective parameters. Symptoms like restriction of movements, joint pain breathlessness and palpitation were included in subjective parameters. Objective parameters include weight, waist circumference and BMI. The subjective and objective parameters were assessed at every visit while Haemogram, Urine (routine and microscopic), Blood Sugar (Fasting and Post parandial), RFT, LFT and Lipid Profile were carried out before and after completion of trial.

The subjective symptoms vary from patient to patient and also in severity so an arbitrary grading scale was designed. Total Sign and Symptoms Score were adopted for proper assessment and statistical evaluation of the efficacy of test and control drugs. The severity of 4 different sign and symptoms (Restriction of movement, Joint pain, Breathlessness, Palpitation) was rated on a 4 point scale (0, absent; 1, mild; 2, moderate; 3, severe) while the Values of Weight, Waist circumference and BMI were noted. After the completion of trial, the pre and post treatment values and scores were recorded and assessed. These are also subjected to comparison and statistical analysis was done to evaluate the efficacy of test and control drugs.

Objective Parameters

- Weight gain
- Waist Circumference
- BMI
- Lipid Profile

Withdrawal criteria

- If the subject is not willing to continue.
- The cases in which adverse reactions are noticed.
- Any acute systemic illness during the therapy.
- During intolerance protocol.
- Noncompliant with the study.

Outcome Measures

- Reduction in weight up to normal.
- Reduction in BMI to normal range.
- Reduction of waist circumference to normal range.
- Improvement in Lipid Profile.
- Improvement in clinical symptoms of Obesity.

Statistical analysis: Paired and unpaired students t-test was applied on subjective value parameters or other statistical test was applied as per requirement of data was expressed as mean ± SD& was considered significant at $p<0.05$(significance level of 5%).

Observation and Results

In this study out of 60 patients of Siman-e-mufrat (Obesity), 24 patients were 20-30 years of age, 15 patients were 31-40 years of age, 13 patients were 41-50 years of age, 8 patients were 51-60 years of age group. The highest prevalence was found in the age group of 20-30. The percentage of Male patient is 58.3% which was slightly higher than female patients e.g. 41.7%. All the demographic data of patients in both test and control groups are shown in (Table 2).

The effect of test drug on objective parameters i.e., Lipid profile (Serum Cholesterol, Serum Triglyceride, HDL), Body Weight and BMI are as follows:

Effect on Serum Cholesterol

In test group mean serum cholesterol level was 233.23 ± 64.08 mg/dl before treatment and at the end of study it was 194.1 ± 52.85 mg/dl, showing mean reduction was 39.23 ± 11.23 mg/dl and which was found to be significant ($P<0.001$) (Table 3).

In standard group mean serum cholesterol level was 204.03 ± 39.44 mg/dl before treatment and at the end of study it was 190.06 ± 37.24 mg/dl, showing mean reduction was 13.97 ±2.2 mg/dl and which was found to be significant ($P<0.0035$) (Table 3).

Effect on Weight of the Body

In test group mean body weight was 72.93 ± 9.32 mg/dl before treatment and at the end of study it was 67.91 ± 9.57 mg/dl, showing mean reduction was 5.02 ± 0.25 mg/dl and which was found to be significant ($P<0.001$) (Table 3).

In standard group mean body weight was 72.26 ± 6.39 mg/dl before treatment and at the end of study it was 68.77 ± 7.2 mg/dl, showing mean reduction was 3.49 ± 0.81 mg/dl and which was found to be significant ($P<0.001$) (Table 3).

Effect on Waist Circumference

In test group mean waist circumference was 96.5 ± 6.81 mg/dl before treatment and at the end of study it was 95.43 ± 6.2 mg/dl, showing mean reduction was 1.07 ± 0.61 mg/dl and which was found to be significant ($P<0.001$) (Table 3).

In standard group mean waist circumference was 95.4 ± 5.53 mg/dl before treatment and at the end of study it was 93.68 ± 5.5 mg/dl, showing mean reduction was 1.72 ± 0.03 mg/dl and which was found to be significant ($P<0.001$) (Table 3).

Effect on BMI

Table 2: Demographic Data of Patients in Test and Placebo group.

Age of Group	n	Percentage	Mizaj	n	Percentage
20-30	24	40	Balghami	47	78.3
31-40	15	25	Damvi	13	21.6
41-50	13	21.6	Safrawi	0	0
51-60	8	13.3	Saudavi	0	0
Gender			**Religion**		
Male	35	58.3		Muslim	43
Female	25	41.7		Non-Muslim	17
S.E.S			**Marital Status**		
Upper (I)	6	10	Married	41	68.3
Upper Middle (II)	13	21.7	Unmarried	19	31.7
Lower Middle (III)	16	26.7	**Dietary Habits**		
Upper Lower (IV)	14	23.3	Vegetarian	17	28.3
Lower (V)	11	18.3	Mixed	43	71.7

Table 3: Various Changes of Objective Parameters in Tests and Placebo Group n=60.

S. No.	Parameter	Group A			Group B		
		Before Treatment (Baseline)	After 90 Days	p- Value	Before Treatment (Baseline)	After 90 Days	p- Value
1.	Weight of the Body	72.93±9.32	67.91±9.57	<0.0001	72.26 ± 6.39	68.77±7.2	<0.0001
2.	Waist Circumference	96.5±6.81	95.43 ± 6.2	<0.0001	95.4 ± 5.53	93.68±5.5	<0.0001
3.	BMI	28.9±2.26	26.88±2.57	<0.0001	28.58 ± 1.95	27.21±2.18	<0.0001
4.	Serum Cholesterol	233.23±64.08	194.1±52.85	<0.0001	204.03±39.44	190.06±37.24	<0.0035
5.	Serum Triglyceride	188.56±28.16	164.46±29.64	<0.0001	181.4 ± 55.91	161.9±52.73	<0.0001
6.	HDL	28.43±5.88	41.1 ± 6.51	<0.0001	35.7 ± 6.68	44.16 ± 7.76	<0.0001

In test group mean BMI was 28.9 ± 2.26 mg/dl before treatment and at the end of study it was 26.88 ± 2.57mg/dl, showing mean reduction was 2.02 ± 0.31 mg/dl and which was found to be significant (P<0.001) (Table 3).

In standard group mean BMI was 28.58 ± 1.95 mg/dl before treatment and at the end of study it was 27.21 ± 2.18 mg/dl, showing mean reduction was 1.37 ± 0.23 mg/dl and which was found to be significant (P<0.001) (Table 3).

Effect on Serum Triglyceride

In test group mean serum triglyceride level was 188.56 ± 28.16 mg/dl before treatment and at the end of study it was 164.46 ± 29.64 mg/dl, showing mean reduction was 24.1 ± 1.48 mg/dl and which was found to be significant (P<0.001) (Table 3).

In standard group mean serum triglyceride level was 181.4 ± 55.91 mg/dl before treatment and at the end of study it was 161.9 ± 52.73 mg/dl, showing mean reduction was 19.5 ± 3.18 mg/dl and which was found to be significant (P<0.001) (Table 3).

Effect on HDL

In test group mean serum HDL level was 28.43 ± 5.88 mg/dl before treatment and at the end of study it was 41.1 ± 6.51 mg/dl, showing mean reduction was 12.67 ± 0.63 mg/dl and which was found to be significant (P<0.001) (Table 3).

In standard group mean serum HDL level was 35.7 ± 6.68 mg/dl before treatment and at the end of study it was 44.16 ± 7.76 mg/dl, showing mean reduction was 8.46 ± 1.08 mg/dl and which was found to be significant (P<0.001) (Table 3-5).

Discussion

Siman-e-mufrat is a condition which has association of several clinical conditions such as metabolic syndrome, Pre-diabetic, Pre-hypertensive as well as appearance of body figure moreover articular burden. Earlier it was considered as symbol of prosperity but now days it is supposed to be a curse due to its morbidity association. Obesity not only causes a burden of individual but also on the society. Unani scholars were well versed about morbidity associated with obesity therefore they have discussed planned regimens of diet as well as physical interventions. Many more drugs are also available both in single formulation as well as compound formulation to counter the obesity. The urbanization has provoked this condition and converted it into a pandemic worldwide. The modern classification in terms of body

Table 4: Safety Parameters (Test Drug).

Parameters		Assessments	
		BT	AT
		Mean±SEM	Mean±SEM
Hb%		12.03±1.55	12.34±1.07
RBC		4.25±0.78	4.32±0.75
TLC		7346.6±1395.5	7203.33±1090.5
DLC	**P**	65.23±5.05	67.56±3.88
	L	30.63±5.1	28.76±3.55
	B	0.2±0.4	0.1±0.3
	M	1.2±0.71	0.96±0.76
	E	2.8±1.8	3.13±2.09
ESR		29.53±9.59	24.43±5.81
S.Bilirubin		0.69±0.29	0.72±0.24
SGOT		35.23±5.25	31.63±4.82
SGPT		34.63±7.07	31.93±6.18
S.ALK Phosp		158.16±26.56	137.6±22.97
B.U		33.43±6.21	30.85±6.16
S.Cr		0.75±0.26	0.75±0.21
B.Sugar (F)		95.76±12.64	98±6.07
B.Sugar (PP)		128.7±14.96	127.06±13.72

Table 5: Safety Parameters (Control Drug).

Parameters		Assessments	
		BT	AT
		Mean±SEM	Mean±SEM
Hb%		12.00±1.38	11.91±1.23
RBC		3.89±0.84	4.02±0.75
TLC		8043.33±1751.6	7363.63±2105.5
DLC	P	63.7±6.84	66.56±5.12
	L	31.73±7.42	28.9±5.16
	B	0.4±0.49	0.43±0.5
	M	1.03±0.55	1.03±0.55
	E	3.06±1.81	3.06±1.83
ESR		32.7±10.18	28.7±7.77
S.Bilirubin		0.76±0.2	0.66±0.24
SGOT		35±8.89	30.3±7.94
SGPT		35.36±11.34	29.63±7.78
S.ALK Phosp		130.83±11.96	123.1±9.98
B.U		30.1±7.68	30.6±7.12
S.Cr		0.74±0.19	0.74±0.2
B.Sugar (F)		96.96±7.49	92.23±7.85
B.Sugar (PP)		136.53±12.61	137.36±9.4

mass index (BMI) is very relevant not only to categorize the obesity but also to understand the associated morbid conditions, treatment plans and interventions. In this study two unani drugs are comparatively evaluated in terms of clinical efficacy to counter the obesity as well as associated conditions.

The clinical study which is designed to evaluate the efficacy of two unani formulations which are time tested in terms of their efficacy to treat several metabolic conditions in which there are fatty deposition/ excessive accumulation of fat but there was no organized clinical study available to find its result both on subjective and objective parameters.

The observed response both in test group as well as in control group may be credited to Hot and Dry temperament of Test drug Darchini and majority of the ingredients present in the control drug formulation (Safoof-e-Muhazzil). By virtue of such temperament, these drugs might have increased the metabolism of liver by producing excessive hotness and dryness (Hararat and Yaboosat), and thus decrease is seen in the level of lipids like cholesterol, triglyceride, VLDL and LDL while improvement was seen in level of HDL. The observed results are in congruence with the description in the classical Unani literature, that excessive coldness and wetness (Baroodat and Ratoobat) in the body especially in liver, deranges metabolism leading to increased production of fat in the body and ultimately results in obesity while temperament such as hotness and dryness helps in the process of metabolism of fat and serves as a source of energy for the body and hence causes reduction of obesity.

As far as safety parameters are concerned, the difference in the haematological and biochemical parameters studied, before and after the treatment, was found to be statistically insignificant in both the groups. This signifies that both the drugs are safe with the respective doses.

For comparison of both the drugs, unpaired't' test was applied between the test and control group. No significant difference was found in the reduction of obesity. It can be concluded from above discussion that test drug having about same effect as control drug in improvement of all subjective and objective parameters.

Conclusion

The result of present clinical trial demonstrates that Safoof-e-Darchini is equally effective in comparison of *Safoof-e-Muhazzil*. *Safoof-e-Muhazzil* is also showing its effect on mild to moderate obesity like Darchini but both are ineffective in morbid obesity. As far as Hypolipidemic concern both are equally effective. All the safety parameters for both the groups show that they are safe and no adverse effects are found on hepato-renal markers. Both the formulations are recommended for such ailments but it will be better if carried out on different cross section of populations and on various centers to get multicentric data before recommending it for general population.

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