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 e fect so it is need of time to f nd out a drug from the system of Unani medicine with no adverse e fect or minimal side e fect. For this purpose A Randomized single blind study was designed to comparative clinical trial of *Darchini* and *Safoof-e-Muhazzil* for evaluation of e f cacy of Darchini in comparison of *Safoof-e-Muhazzil* on obesity. x. ᴰ ʊ Ꝍ sygnD ʊ MB t > ᴈ M B) comprising 30 patients in each group. Assessment of e f cacy was done on the basis of objective parameters. The result of present clinical trial demonstrates that *Safoof-e-Darchini* is equally e fective in comparison of *Safoof-e-Muhazzil*. *Safoof-e-Muhazzil* is also showing its e fect on mild to moderate obesity like Darchini but both are ine fective in morbid obesity.

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

I d c i

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. e 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 classi ed as obese. [2] Obesity can also be de ned arbitrarily as an increase in body fat stores compared to lean body mass According to the rst 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 e cacy 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 e ect of test drug Darchini in comparison of Sa of-e-Muhazzil for its anti-obesity e ect. is drug studied earlier and reported to have Musakhkhin (Calori c), Muharrik (Stimulant), Mufatteh-e-Sudad (Deobstruent), Hypoglycaemic and Hypolipidaemic e ect 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 e ect in unani pharmacopeia (Qarabadeen) because this unani formulation possess action like Muhazzil, Musakhkhin (Calori c), Mudir (Diuretic) and Mulattif (Demulcent) property due to its ingredients such as Zeera siyah (*Carum carvi*), Ajwain (*Trach spermum ammi*), Marzanjosh (*Origanum majorana*), Badiyan (*Foeniculum vulgare*), LukMaghsool (*Cocoslacca*) Bura Armini(Sodium borate) and Suddab (*Ruta graveolens*)is bene cial in order to reduce obesity.

Ma e ia a d Me h d

is Randomized single blind comparative clinical trial of Darchini and Safoof-e-Muhazzil for evaluation of e cacy 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. e 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. e selection of patients and e cacy of test drug were assessed upon the basis of subjective parameters, objective parameters and laboratory investigations. e 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.

C i e ia f ec i f bjec

a) I i C i e ia

- 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) E i C i e ia

- 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 su ering from Hypothyroidism, Diabetes Mellitus, chronic Renal Failure, Nephrotic Syndrome, HIV+ve, Cirrhosis of Liver, Chronic Alcoholism, Primary gout and Bleeding disorder

I e iga i

Ce ai i e iga i ca ied ai i g

- 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

F i g i e iga i e ed ei eacha d e e a ie

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

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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 ndings.

A e e f Safe

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 classi cation.

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 a er completion of trial.

A e e f E cac

e e cacy assessment in the test and control groups was done upon the basis of subjective and objective parameters. Symptoms like

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 signi cant (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 signi cant (P<0.001) (Table 3).

E ec Se T ig ce ide

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 signi cant (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 signi cant (P<0.001) (Table 3).

E ec 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 signi cant (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 signi cant (P<0.001) (Table 3-5).

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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 e cacy to counter the obesity as well as associated conditions.

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

e 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. e 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 di erence in the haematological and biochemical parameters studied, before and a er the treatment, was found to be statistically insigni cant in both the groups. is signi es 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 signi cant di erence was found in the reduction of obesity. It can be concluded from above discussion that test drug having about same e ect as control drug in improvement of all subjective and objective parameters.

C d i

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

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