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COMPARATIVE EFFICACY OF SAFOOF E MUHAZZIL AND ITS COMPRESSED TABLETS ON PARAMETERS OF WEIGHT REDUCTION

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Keywords:

Safoof e Muhazzil, Unani, BMI, Waist circumference, Waist hip ratio, obesity

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ABSTRACT: Background: To enhance patient compatibility *Safoof e Muhazzil* (powder) was compressed into tablets. **Objectives:** The present study was aimed at comparing the two dosage forms for any variations in the efficacy of *Safoof e Muhazzil*. **Method:** This triple-armed RCT was carried out on 90 patients after obtaining ethical clearance and written and informed consent. The study period was six weeks. Improvement was measured in terms of change in weight, BMI, waist hip ratio (WHR) and waist circumference (WC). 5g of powdered *Safoof e Muhazzil* (SMC) was given twice daily with water, whereas, 5 tablets of *Safoof e Muhazzil* (SMT) were given twice daily with water. The third group was given atorvastatin 10 mg once daily. **Result:** The study recorded a 20.03 % dropout. Most of the patients were non-alcoholic, non-smoker, non-vegetarian males above 45 years and had BMI between 25-30 kg/m². SMC and SMT gave similar results on all parameters of weight management with p<0.001. This can be attributed to the anti-oxidant and lipolytic properties of *Safoof e Muhazzil* per say and of its constituents. There was no significant difference between the two dosage forms on any of the parameters. **Conclusion:** The study concludes that the compression of the powder did not affect the drug's efficacy. This prompts further studies on the effect of this drug in weight-related co-morbidities. Other classical dosage forms should be tested in more patient friendly dosage forms. However, the short sample size was a restraint and warrants further studies on a bigger sample size.

INTRODUCTION: Being overweight and obese are defined as abnormal or excessive fat accumulation that presents a health risk. A crude population measure of obesity is the body mass index (BMI). A BMI of 30 or more is generally considered obese, whereas a BMI equal to or more than 25 is considered overweight ^{1,2}.

South Asians are at increased risk of developing type II diabetes and cardiovascular disease at lower BMI than other ancestral groups. Many factors contribute to this increased risk. Evidence suggests that Asian Indians manifest clustering of cardiovascular risk factors and T2DM even at lower levels of body mass index (BMI) compared to the age-matched white Caucasians ^{3,4,5}.

This is because Asian Indians characteristically have greater total, truncal, intra-abdominal, subcutaneous, and ectopic tissue fat at a given level of BMI than Caucasians ⁶. Obesity *per say* is not fatal but its co-morbidities like type II diabetes,

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cancer, hypertension, coronary artery diseases, congestive heart failure, pulmonary embolism, stroke, asthma, osteoarthritis, gall bladder diseases and chronic back pain are debilitating and, in some cases, fatal^{7, 8}.

It is probably the fastest-spreading epidemic the world faces, as its rise in low- and high-income countries is astounding. Worldwide more than 1.9 billion adults are overweight, out of which over 650 million have clinically relevant obesity, and the number of obese patients continues to rise globally¹. Almost 13–50% of the urban Indian population and 8–38% of the rural population suffers from obesity^{5, 9, 10}.

Attempts to control the ill effects of obesity with lifestyle measures and certain drugs like Orlistat, Liraglutide, Bupropion/naltrexon, Cathin, and other medications that curb appetite are currently in vogue¹¹. Antiobesity prescription drugs are relatively safe but are not free of adverse effects that can affect tolerability. Some antiobesity prescription drugs are known to cause bloating, diarrhea and fecal incontinence initially but subside later, whereas some are associated with dizziness, palpitations and hand tremors owing to their sympathomimetic properties. Besides, the FDA withdrew more than a dozen other drugs introduced for short- and long-term management of obesity because of their serious adverse effects¹². Apart from this the enormity of the problem and cost considerations of these drug therapies compels us to look for the alternative strategy. *Safoof e Muhazzil* is a classical pharmacopeial Unani drug of choice for obesity¹³. The phytoconstituents of the drug are anti-inflammatory, anti-obesity, antioxidant, diuretic, vaso-relaxant, antihypertensive and lipolytic^{7, 14, 15, 16}. But the dosage form is a bitter-tasting powder that is less palatable; hence its patient compliance is poor; therefore, an acute need was felt for a change in its dosage form. The present study aims to check the impact of change in

dosage form on efficacy regarding BMI, weight gain, waist circumference, and waist-hip ratio in a randomized, open-label, controlled clinical trial in hyperlipidemic individuals.

Body mass index (BMI) was considered the most popular weight status indicator. However, it fails to consider the fat distribution causing variations among individuals and populations. Therefore, waist circumference (WC), waist-hip ratio (WHR) and waist-height ratio (WHtR) are studied to calculate obesity-related risk as these take into consideration regional abdominal adiposity. Moreover, BMI should not be disregarded because of its limitations, as it essentially provides an initial indication that must be supplemented by further measurement of fat distribution, e.g., WC or WHtR¹⁷.

MATERIALS AND METHODS: The present study was conducted to compare classical dosage form of *Safoof e Muhazzil* (SMC) (powder) with compressed tablets of this powder on parameters of weight reduction i.e. BMI, waist circumference, and waist-hip ratio in a hyper-cholesteremic population through a randomized, open-label, standard controlled clinical trial at Majeedia Hospital of Jamia Hamdard in New Delhi.

On approval from the institutional ethics committee of Jamia Hamdard under No. DM/FOM/JH/Ethics Com/09, *Safoof e Muhazzil* of a single batch manufactured by GMP Complaint Company as per the National Formulary of Unani Medicine, Government of India and in accordance to the Drugs and Cosmetics act, Government of India 1945, amended from time to time as recent as 2020, was procured from the market. *Safoof e Muhazzil* is the powdered mixture of seven naturally occurring constituents, including five drugs of herbal origin, one of animal origin, and one of mineral origin **Table 1**^{13, 18}.

TABLE 1: CONSTITUENT OF SAFOOF E MUHAZZIL (IN EACH 5G)

| S. no. | Unani name | Botanical/Scientific name | Weight |
|--------|-----------------------|---|--------|
| 1 | Tukhm e Badiyan | seeds of <i>Foeniculum vulgare</i> Mill. | 1 g |
| 2 | Nankhwa (Ajwain Desi) | seeds of <i>Trachyspermum ammi</i> | 1 g |
| 3 | Zeera-e-Siyah | seeds of <i>Carum carvi</i> | 1 g |
| 4 | Sudab | leaves of <i>Ruta graveolens</i> | 1 g |
| 5 | Luk-e-Maghsool | Washed Lac (from insect <i>Coccus Lacca</i>) | 0.5 g |
| 6 | Marzanjosh | seeds of <i>Origanum vulgare</i> | 0.25 g |
| 7 | Bura Armani | <i>Armenian Bole</i> | 0.25 g |

A part of this powder was compressed into 1g tablets each. No excipients were added to the powder during compression. The disintegration time for the compressed tablets was 13 min at 37°

C. The results of the physiochemical and TLC analysis of the formulation are mentioned in **Table 2**⁷ and **Table 3**.

TABLE 2: PHYSIO-CHEMICAL CHARACTERIZATION OF THE TEST FORMULATION

| Appearance | Powder |
|---|-------------|
| Colour | Pale Brown |
| Smell | Aromatic |
| Taste | Mild Bitter |
| Loss of water on drying at 105 ⁰ | 3.8% |
| Successive extractions: | |
| Petroleum ether | 16% |
| Chloroform | 3.6% |
| Methanol | 8.72% |
| Water | 16.44% |
| pH of 10% | 7 |
| pH of 20% | 6.6 |
| Total Ash | 9.4-9.6% |
| Water insoluble Ash | 6.8% |
| Sulphated | 11.8% |
| Acid insoluble Ash | 12.2% |
| Volatile oil | 0.8 % vw |
| Monoterpenes | 9.73% |
| Sesquiterpenes | 73.03% |
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| Sesquiterpenes | 73.03% |

TABLE 3: TLC OF SAFOOF E MUHAZZIL

| Extracts | Solvent System | Spray/ Treatment | No. of spots | Rf. values |
|-----------------|--|---|--------------|------------------------------|
| Petroleum ether | Cyclohexane Ethyl acetate, (80:20) | Iodine vapour | 5 | 0.97, 0.92, 0.56, 0.44, 0.25 |
| | Petroleum ether Ethyl acetate, (24:1) | 5% ethnolic H ₂ SO ₄ | 4 | 0.98, 0.32, 0.23, 0.15 |
| | Chloroform, Ethanol (3:1) | Ceric ammonium Sulphate solution | 4 | 0.96, 0.79, 0.67, 0.12 |
| Chloroform | Benzene, Ethanol (4:1) | Iodine vapour | 4 | 0.93, 0.86, 0.82, 0.54 |
| | Cyclohexane, Ethyl acetate (80:20) | Iodine vapour | 1 | 0.25 |
| Ethanol | Amyl alcohol, Acetic acid, water (2:1:1) | 1% Neutral Fe Cl ₃ solution in ethnlol | | 0.92, 0.85, 0.77 |

The clinical study followed the guidelines of the Declaration of Helsinki and Tokyo for humans. The study adhered to guidelines of good clinical practices (GCP). 128 patients were screened, of which 113 fulfilled the inclusion criteria and were enrolled in the study after obtaining their written and informed consent.

They were randomized on pre-assigned case numbers of the computer-generated chart. This triple arm study had a sample size of 90 completed cases 30 in each group. 20-70 years hyperlipidemic (total cholesterol above 220 mg/dl) patients willing to sign the consent form were included in the study; whereas pregnant or diabetics or patients suffering from hepatic, renal or thyroid diseases were excluded.

The first group was given *Safoof e Muhazzil* in its conventional powdered form (SMC) 5g twice a day orally with water. The second group was put on compressed tablets of *Safoof e Muhazzil* (SMT) in the dosage of 5 tablets orally twice daily with water. The control group (Control) was prescribed Atorvastatin 10 mg orally once daily.

Since, atorvastatin is not the drug for weight management the effect of atorvastatin may be considered as placebo. Behavioral weight loss was planned hence all the subjects were advised to adhere to the 1600-calorie diet and half an hour of brisk walk.

The duration of protocol therapy was six weeks with follow-up at second, fourth and sixth week. Duration of study was 2 years. Assessment of efficacy was done at each follow-up.

Adverse effects, if any either reported or observed by the patient, were recorded in the clinical research file at each follow-up.

Assessment of results was done as per protocol using Graphpad Inst at 3.10 32 for windows created July 10, 2009 by using paired t-test and repeated measures ANOVA

Theory: A change in the dosage form could deliver the drug dose in a more structured form because the dosage for the powdered form may vary. Tablets are more palatable increasing patient compatibility, and may affect the efficacy positively. This study

could help those keen on losing weight but unable to take conventional drug. The results could prompt further studies on this drug's effect on weight-related co-morbidities like hypertension, CVD, arthritis, cancers, *etc.* Further, it also enhances the possibility of testing other classical dosage forms in more patient-friendly dosage forms.

RESULTS: The male-to-female ratio of the patients enrolled in the study in both the test and control groups was 3:2 and 2:3, respectively. A cross-sectional study on 572 individuals observed that men are more prone to weight gain and had a BMI of 27.4 kg/m². These correspond with our findings wherein most of the patients enrolled were males and most of them (43.33%) had a BMI between 25-30 kg/m²¹⁹.

The majority of the patients enrolled (81.11%) were non-vegetarian. A meta-analysis of 40 studies concluded that a vegetarian diet aids in weight loss as it tends to reduce energy, fat, protein, and cholesterol, and increased intake of carbohydrates and fiber²⁰.

Current smokers are 3.5-5 folds more at risk of obesity²¹. However, only 22.2% of smokers enrolled in our study. Alcohol intake increases calorie consumption; therefore binge drinking and high intake of alcohol raises the risk of obesity²². Despite this only 13.3% of alcoholics enrolled in our study.

Elevated levels of stress are a major predictor of weight gain²³; which is in concurrence to our finding as 25.56% patients enrolled in our study had positive history of stress. Of the enrolled patients 17.78% gave a positive family history for obesity.

SMC and SMT managed weight three to four times better than control on all four parameters. Four studies established the efficacy of *Safoof e Muhazzil* in obesity^{16, 24, 25, 26} as is also evident from our study. However, this is the first study that compares its efficacy with a changed dosage form. The compressed tablets managed weight almost just like the classical powder.

Both the test groups managed weight significantly, with $p < 0.001$ on all four parameters **Table 4**.

TABLE 4: EFFICACY

| Parameter | SMC | | | SMT | | | | |
|-----------|-------------------------|----------|-------------------------|----------|----------------------------------|------------|--|--|
| Parameter | BT vs AT (% difference) | p-value | BT vs AT (% difference) | p-value | Relative risk ratio (SMT vs SMC) | Odds ratio | | |
| BMI | 3.03 | ↑ <0.001 | 2.95 | ↑ <0.001 | 1.08 | 1.8 | | |
| Weight | 3.1 | ↑ <0.001 | 2.87 | ↑ <0.001 | 1.03 | 1.5 | | |
| WHR | 1.97 | ↑ <0.001 | 2.32 | ↑ <0.001 | 1.04 | 1.25 | | |
| WC | 3.06 | ↑ <0.001 | 3.53 | ↑ <0.001 | 0.967 | 0.64 | | |

The percentage difference (baseline and end of the study) between SMC and SMT is marginal (between 0.08- 0.47%) on all parameters. SMT exhibits protective activity superior to SMC against increase in weight, BMI and WHR. However, it was not so protective for increase in WC **Table 4**. The odds of weight management with SMT are similar to that of SMC.

DISCUSSION: Of the 113 patients enrolled in the study 23 patients were lost to follow up and 90 patients completed the study. The dropout rate was calculated as 20.35%. This RCT compared the difference in efficacy of the standard dosage form with that of compressed tablets of *Safoof e Muhazzil*. The findings were significant as they showed that the efficacy of the drug has been

unaltered due to change of dosage form and that its compression into tablets has no effect on its efficacy. This astounding effect of SMC and SMT can be attributed to the phyto-constituents of the drug *Safoof e Muhazzil* which are anti-inflammatory, anti-obesity, anti-oxidant, diuretic, vaso-relaxant, antihypertensive and lipolytic ¹⁴. Apart from this *in-vitro* and *in-vivo* studies have demonstrated *Safoof e Muhazzil* itself as anti-inflammatory, anti-oxidant and lipolytic ^{7, 16, 24, 25, 26, 27}.

The study was a comparative study between the dosage forms hence there was no need for control however, a control group was taken to reduce bias and to aid in getting a thorough association between the groups **Table 5**.

TABLE 5: MEAN WISE DISTRIBUTION

| Parameter | SMC | | SMT | | Control | |
|-----------|--------------------------|-----------------|--------------------------|-----------------|---------------------------|-----------------|
| | Mean difference (95% CI) | Margin of error | Mean difference (95% CI) | Margin of error | Mean difference (95% CI) | Margin of error |
| BMI | 0.85 [0.832 – 0.868] | ±0.0179 | 0.77 (0.752 – 0.788) | ±0.0179 | 0.22 (0.213 – 0.227) | ±0.00716 |
| Weight | 2.25 (2.218 – 2.282) | ±0.0322 | 2.05 (2.003 – 2.097) | ±0.0465 | 0.57 (0.566 – 0.574) | ±0.00358 |
| WHR | 0.019 (0.0165 – 0.0215) | ±0.00250 | 0.022(0.0216 – 0.0224) | ±0.00035 | 0.007 (0.00664 – 0.00736) | ±0.000358 |
| WC | 1.19 (1.187 – 1.193) | ±0.00283 | 1.46 (1.436 – 1.484) | ±0.0238 | 0.38 (0.377 – 0.383) | ±0.00283 |

Therefore, the control group was not included during analysis of results. However, the

demography of the control has been demonstrated **Table 6**.

TABLE 6: DEMOGRAPHIC DATA

| Parameter | SMC | SMT | Control |
|----------------------------|-------------|-------------|-------------|
| Gender | | | |
| Male | 18 (60%) | 18(60%) | 12 (40%) |
| Female | 12 (40%) | 12 (40%) | 18 (60%) |
| Average age | 45.2±1.91 | 45.86±2.01 | 46.63±2.27 |
| 20-29 | 1(3.33%) | 2 (6.66%) | 2 (6.66%) |
| 30-39 | 7 (23.33%) | 5 (16.66%) | 9 (30%) |
| 40-49 | 11 (36.66%) | 11 (36.66%) | 5 (16.66%) |
| 50-59 | 9 (30%) | 7 (23.33%) | 6 (20%) |
| 60-70 | 2 (6.66%) | 5 (16.66%) | 8 (26.66%) |
| Personal habits | | | |
| Smoking | 6 (20%) | 9 (30%) | 5 (16.66%) |
| Alcoholic | 4 (13.33%) | 5 (16.66%) | 3 (10%) |
| Non-vegetarian | 24 (80%) | 26 (86.66%) | 23 (76.66%) |
| Positive Family history | 10 (33.33%) | 2 (6.66%) | 4 (13.33%) |
| Positive history of stress | 10 (33.33%) | 10 (33.33%) | 3 (10%) |

| BMI | | | |
|-----------------------------|-------------|-------------|-------------|
| BMI <23 Kg/m ² | 3 (10%) | 3(10%) | 1 (3.33%) |
| BMI <25 Kg/m ² | 5 (16.66%) | 8 (26.66%) | 13 (43.33%) |
| BMI 25-30 Kg/m ² | 12 (40%) | 14 (46.66%) | 13 (43.33%) |
| >30 BMI Kg/m ² | 10 (33.33%) | 5 (16.66%) | 3 (10%) |

A pill is not the only solution to weight gain; a properly charted lifestyle alone can warrant sustained weight management²⁸. Hence a behavioral weight loss was planned, and accordingly, the patients in both groups were asked to follow a diet chart and physical activity plan. Being overweight and obese are the major underlying risk factors that promote the development of the metabolic syndrome. Limiting these can majorly impact curbing the cluster components of metabolic syndrome such as hyperlipidaemia, hypertension, and insulin resistance. Although obesity guidelines²⁸ stress the need for weight reduction using behavioral change to reduce caloric intake and increase physical activity. But when lifestyle modification fails, drug therapy may be recommended separately for each co-morbidity associated with weight gain like hyperlipidemia, hypertension, etc. Probably this is the strength of our study, as the study demonstrates that *Safoof e Muhazzil* not only possesses the anti-obesity effect but has been validated to be effective against associated risk factors vis-a-vis metabolic syndrome. Hence *Safoof e Muhazzil* can be prescribed as a standalone drug for managing obesity as well as its co-morbidities synergistically.

The limitations of the study were first, sample size was not calculated. Secondly, the study was not subsequent to in vivo study on the dose calculation of compressed tablets. The study was not preceded by a pre-clinical study on compressed tablets, as the same powder was compressed and dispensed in the same dosage. The powder of SMC was not divided according to the dose; however, the patients were educated about how to measure the powder hence the possibility of dosage variation cannot be ruled out in its classical form.

CONCLUSION: The study was conducted on 90 obese patients and had a 20.03 % dropout. The enrolled patients were non-alcoholic, non-smoker, non-vegetarian males above 45 years with BMI between 25-30 kg/m². *Safoof e Muhazzil* in both dosage forms has performed highly significantly in weight management. This can be attributed to the

anti-oxidant and lipolytic property of *Safoof e Muhazzil* per say and its constituents. The compressed tablet was almost similar to the classical form in weight management on all parameters viz BMI, waist circumference, hip waist ratio and weight. This proves that the compression of the powder had no significant effect on the drug's efficacy. However, the short sample size is a restrain in drawing conclusive results and warrants further studies on bigger samples. No adverse events were reported during the study.

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