Original Article

The Effects of Unani Formulation Jawarish Bisbasain Dyslipidaemia and Anthropometric Parameters Associated with Central Obesity: An Open-Label Clinical Trial

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Abstract

Jawarish Bisbasa, a Unani polyherbal formulation, is used traditionally in the clinical treatment of central obesity. It is a polyherbal semi-solid preparation of eleven medicinal herbs mainly used as spices.

Aim of the study: The main objective of this study was to evaluate the effect of Unani Formulation Jawarish Bisbasa and compare the changes in lipid profiles and Anthropometric Parameters before and after treatment in patients with hyperlipidaemia associated with central obesity.

Materials and methods: An open-label clinical validation study was conducted at the Regional Research Institute of Unani Medicine, Mumbai research OPD. The study included 120 cases of each gender with BMIs of 34.99 kg/m2 for men and 32.49 kg/m2 for women, while 88 cases completed the study. Enrolled cases received Unani Formulation Jawarish Bisbasa 7gm BD twice daily with warm water for 8 weeks. The pathological investigations and Anthropometric Parameters related to the study, particularly BMI, Waist Circumference, Waist to hip ratio, Saggital Abdominal Diameter, LDL, HDL, and VLDL values were statistically analysed at baseline, first, follow-up, and at the end of the study by using unpaired Student t-test and one-way analysis of variance. (ANOVA). Extremely significant BMI, Waist Circumference, Waist to hip ratio, Saggital Abdominal Diameter, and lowering of ESR, Total cholesterol, and Triglycerides when the values of before-treatment and after-treatment were analyzed in hyperlipidemia associated with central obesity. There were no side effects reported during the treatment.

Keywords: Central obesity (CO), Lipid Profile, BMI (Body Mass Index), Farte Tdassum Fid Dam (Hyperlipidaemia), JB (Jawarish Bisbasa).

Introduction

Obesity has become a significant public health issue worldwide over the last four decades.[1] It is caused by excess body fat accumulation, which is harmful to health. Obesity is defined by the World Health Organization (WHO) as body mass index

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(BMI) ≥30 kg/m2, while overweight is a BMI of ≥25 kg/m2.[2] The prevalence of overweight and obesity is increasing globally in both developing and developed countries in all age groups.[3] Since 1980, globally, its prevalence has almost doubled.[4] The WHO has reported that in 2016, more than 1.9 billion adults were overweight; among them, 650 million were overweight.[5]. World Health Organization defines obesity as "abnormal or excessive fat accumulation that may impair health. There are several causes of overweight and obesity, including lifestyle factors such as diet and physical activity; genetic factors such as parental obesity, underlying disease conditions, and medication use and demographic factors such as age, gender, place of habitat, education level, and income.[6-7], Nowadays, people are eating foods with highfat content, high sugar content, and often large-sized food causing overeating; combined with this sedentary behaviour, television watching and less physical activity cause a global rise in obesity.[1,6-7]

Unani concept:

The concept of Saman-e-Mufrat (Obesity) was initially described by Buqrat (Hippocrates: 460-370 BC) in his famous book "Fasool e Buqratia". He gave a detailed description of Saman-e-Mufrat (obesity) including its complications, prevention, and management. The all-time great philosopher of the medical system Ibne Sina (Avicenna: 980-1037 AD) has described the concept of end-organ damage in obesity[8]. Saman-e-Mufrat can be related to mortality, this was described by the great Unani scholar Jalinoos (Galen: 129-210 AD) who has mentioned that overweight individuals are more proneto early deaths in comparison to lean and thin persons [9].

Unani single drugs of *Jawarish Bisbasa* showed their cholesterol-lowering activity in different studies e.g. Heel Kalan (Amomum subulatum Roxb.) [10]; Bisbasa (Myristica fragrans Houtt.)[11]; Heel Khurd (Elettaria cardamomum (Linn.) Maton) [12]; Zanjabeel (Zingiber officinale Roscoe) [13]; Darchini (Cinnamomum zeylanicum Blume) [14]; Filfil Siyah (Piper nigrum Linn.) [15] & Qaranful (Syzygium aromaticum Merr. & L.M. Perry) [16].

Objective:

To evaluate the effect of Jawarish Bisbasa and compare the changes in lipid profiles and Anthropometric Parameters before and after treatment in patients with hyperlipidemia associated with central obesity

Material and Method

The study was designed as an open-label, single-arm, multicentric clinical trial carried out at three peripheral centers of the Central Council for Research in Unani Medicine, namely Central Research Institute of Unani Medicine, Lucknow, Regional Research Institute of Unani Medicine, Mumbai and Regional Research Institute of Unani Medicine, New Delhi. Patients were screened by the inclusion and exclusion criteria mentioned in the protocol.

A total of 120 patients fulfilling the selection criteria were recruited in the study from General& Research OPDs of the Regional Research Institute of Unani Medicine, Mumbai after obtaining their written informed consent. Out of them, 88 patients completed the study. The study was approved by the Institutional Ethics Committee and registered in CTRI with the reference number REF/2018/08/021125AU. Before enrolling in the study, a signed consent was obtained from eligible participants.

The laboratory tests including hemato logical, liver function test, kidney function test, Lipid profile, and Urine examination were done at the baseline and the end of the protocol therapy.

Ethical consideration:

The study was approved by the RRIUM's institutional ethics committee, F. No. 5-11/2011-12/ RRI/ALG/Tech/150, registered as CTRI with the reference number REF/2018/08/021125AU. Before enrolling in the study, a signed consent was obtained from eligible participants at registration.

Study design: An open-label clinical trial

Subject selection criteria:

Patients were enrolled based on the following inclusion and exclusion criteria.

Inclusion criteria:

Patients of either sex in the age group 18-65 years, BMI (Male=≤34.99 kg/m^2 and females ≤32.49 kg/m^2), Waist Circumference (>94 cms in Male and

>80 cm in Females), Waist-to-hip ratio between (≥80 cms to ≤ 1m), (Female 80 to 85 and Male >90 cm to < 1m), Sagittal Abdominal Diameter (SAD)> 25 cms. Cholesterol ≥200 mg/dl or serum triglycerides ≥150 mg/dl or low-density lipoprotein cholesterol levels≥130 mg/dl or high-density lipoprotein cholesterol <40 mg/dl were included in the study.

Exclusion criteria:

Medications causing secondary weight gain e.g. phenothiazines, sodium valproate, carbamazepine, lithium, glucocorticoids, thiazolidinediones, etc, and patients on oral contraceptive pills of hormone replacement therapy, patients having systemic illnesses requiring long-term treatment, patients unable to exercise, Pregnant, lactating excluded from the study. Patients with co-morbid condition like Diabetes mellitus, Hypertension, Cardiac Diseases and condition necessitating long term medical interventions were excluded from the study.

Drug, Dose, and mode of administration

Enrolled patients were given Jawarish Bisbasa in a dose of 7gm twice daily with lukewarm water after meals,for 8 weeks.

Table 1: Composition of *Jawarish Bisbasa*

S.N.	Ingredients (Unani name)	Botanical name/Scientific name	Part used	Quantity
1.	*Heel kalan*	*Amomum subulatum*	Fruit	50gm
2.	Bisbasa	*Myristica fragrans* Houtt.	Arillus	30gm
3.	Saleekha	*Cinnamomum cassia* Blume.	Stem bark	30gm
4.	Heel khurd	*Elettaria cardamomum* (L) Maton	Fruit	30gm
5.	Zanjabeel	*Zingiber officinale* Rosc.	Rhizome	30gm
6.	Daarchini	*Cinnamomum zeylanicum* Blume.	Stem bark	30gm
7.	Asaaroon	*Asarum europaeum* Linn.	Rhizome	30gm
8.	Filfil siyah	*Piper nigrum* Linn.	Fruit	20gm
9.	Qaranfal	*Syzygium aromaticum* (L.) Merr. L M Perry	Flower bud	15gm
10.	*Nabat safaid*	Sugar crystal		200gm
11.	*Qand safaid*	Sugar		800gm

Jawarish Bisbasa Manufactured following Good Manufacturing Practise (GMP) at Authorised Pharmacy of CCRUM, located at National Research Institute of Unani Medicine for Skin Disorders Hyderabad.

Efficacy and Safety Assessment:

The evaluation of efficacy was based on subjective and objective parameters. Subjective parameters viz. Heartburn, stomach fullness, breathing difficulties, Sleep apnea, and objective parameters Viz. Body mass index (BMI), Waist circumference, Waist Hip Ratio, Waist-to-height ratio (WHtR), and Sagittal abdominal diameter (SAD) were assessed on each follow-up (i.e. on baseline, 14th, 28th, 42^{nd,}and 56th days).

Criteria for assessment of safety: The safety of the treatment was assessed by clinical symptoms at every visit of follow-ups and biochemical evaluation at baseline (at the 0th day) and after completion of treatment (at the 56th day). No adverse effects were reported during the study.

Estimation of biochemical markers:

Kits purchased from Erba Mannheim manufactured by Transasia Biomedical Pvt Ltd India were used for the estimation of biochemical markers using the **ERBA-EM 200 Fully Automatic Biochemistry Analyzer**.

Outcome measures:

Primary outcome measures were reduction in Anthropometric Parameters-BMI, Waist

Circumference, Waist-to-hip ratio, Sagittalabdominal diameter, and symptomatic relief to the patients whereas secondary outcome measures were changes in the Lipid profile.

Statistical Analysis:

Results were statistically evaluated by applying the student's paired t-test. The result was expressed as the Mean±SD. The data were analyzed on Statistical Analysis System (SAS) (version 9.4) and MS Excel 2019. The test result was ranked as ns - Non significant, *P < 0.05 significant, **P < 0.01 very significant, ***P < 0.001 extremely significant

Results and Discussion

Demographic Study

The Present study evaluated the efficacy of a Unani pharmacopoeial formulation – Jawarish Bisbasa-in patients with *Siman Mufrit (*Central Obesity)(NUMC: M-37). A total of 120 patients were enrolled in this study, out of which 32 patients dropped out of the study. A total of 88 patients completed the study and were treated with ***Jawarish Bisbasa.***

Table 2: Gender-wise distribution of the patients (n=88)

Gender	Number of Cases	Percentage (%)	Mean ± SD
Male	12	13.64	47.69 ± 10.21
Female	76	86.36	37.89 ± 9.42
Total	88	100.0	39.67 ± 10.24

Generally, women have higher rates of obesity as compared to men.[31] In 2014 WHO estimated that 38% of men and 40% of women had BMI ≥25 kg/m2 and 11% of men and 15% of women had BMI ≥30 kg/m2[17]. In South-East Asia Regions, obesity among women is roughly double that of men. [18]

Table 3: Distribution of patients according to their Dietary habits (n=88)

Dietary	Number of Cases	Percentage (%)
Vegetarian	4	4.55
Non-vegetarian	84	95.45
Total	88	100

Table 3 shows that most% of the population i.e. 95.45% were taking a non-vegetarian diet followed by 4.55% of people taking a vegetarian diet. Non-vegetarians have high energy and fat content and thus may be associated with a higher risk of obesity. Similar observations had been reported by other workers [19-20].

Table 4: Therapeutic Response Concerning Clinical Parameters(n=88)

		Baseline	1st Follow-up	2nd Follow-up	3rd Follow-up	End of the treatment	P-value
Heart Burn	No	0(0%)	0(0%)	3(2.73%)	34(30.91%)	73(66.36%)	<0.001
	Mild	0(0%)	2(2.25%)	33(37.08%)	43(48.31%)	11(12.36%)	
	Moderate	8(5.93%)	64(47.41%)	49(36.3%)	10(7.41%)	4(2.96%)	
	Severe	80(75.47%)	22(20.75%)	3(2.83%)	1(0.94%)	0(0%)	
Fullness of Stomach	No	0(0%)	0(0%)	3(3.53%)	17(20%)	65(76.47%)	<0.001
	Mild	0(0%)	3(2.86%)	27(25.71%)	55(52.38%)	20(19.05%)	
	Moderate	2(1.36%)	68(46.26%)	58(39.46%)	16(10.88%)	3(2.04%)	
	Severe	86(83.5%)	17(16.5%)	0(0%)	0(0%)	0(0%)	
Breathing difficulties	No	1(0.69%)	2(1.39%)	18(12.5%)	49(34.03%)	74(51.39%)	<0.001
	Mild	1(1.01%)	17(17.17%)	42(42.42%)	29(29.29%)	10(10.1%)	
	Moderate	31(25%)	54(43.55%)	25(20.16%)	10(8.06%)	4(3.23%)	
	Severe	55(75.34%)	15(20.55%)	3(4.11%)	0(0%)	0(0%)	

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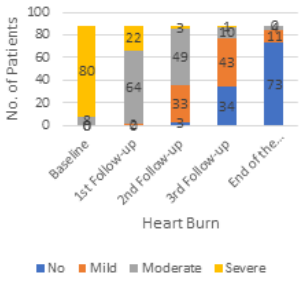
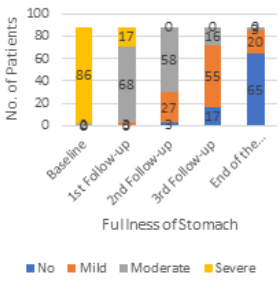
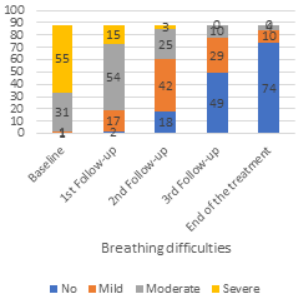
Sleep Apnea	No	11(5.19%)	21(9.91%)	37(17.45%)	65(30.66%)	78(36.79%)	<0.001
	Mild	9(10.59%)	17(20%)	34(40%)	17(20%)	8(9.41%)	
	Moderate	34(34.69%)	41(41.84%)	15(15.31%)	6(6.12%)	2(2.04%)	
	Severe	34(75.56%)	9(20%)	2(4.44%)	0(0%)	0(0%)	

Clinical features, including Heartburn, Fullness of the stomach, breathing difficulties, and Sleep apnea present at the baseline were significantly reduced (p<0.001) after the treatment of Unani Formulation Jawarish Bisbasa.







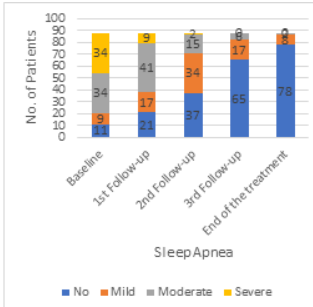
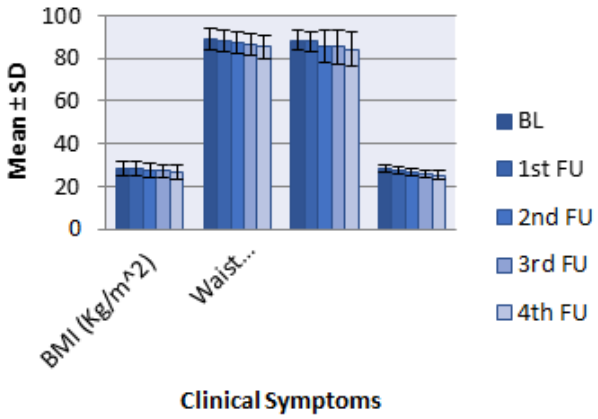


Figure 1: Therapeutic Response in Relation to Clinical Parameters

Table 5: Therapeutic Response in Relation to Anthropometric Parameters(n=88)

Anthropometric Parameters		Baseline	1st Follow-up	2nd Follow-up	3rd Follow-up	End of the treatment	P-value
BMI (Kg/m^2)	Mean ± SD	28.42 ± 3.33	28.43 ± 3.33	27.57 ± 3.21	27.16 ± 3.2	26.48 ± 3.28	<0.001
	Mean Change from Baseline	-	-0.01	0.85	1.26	1.94	
Waist Circumference	Mean ± SD	88.97 ± 5.19	88.16 ± 5.24	87.37 ± 5.04	86.32 ± 5.05	85.17 ± 5.24	<0.001
	Mean Change from Baseline	-	0.81	1.60	2.65	3.80	
Waist to hip ratio between (≥ 80 cm to ≤ 1 m)	Mean ± SD	88.32 ± 4.85	87.65 ± 4.74	85.47 ± 10.73	85.16 ± 7.85	84.12 ± 8.05	<0.001
	Mean Change from Baseline	-	0.67	2.85	3.16	4.20	
Sagittal Abdominal Diameter (SAD)	Mean ± SD	28.01 ± 1.78	27.52 ± 1.73	26.61 ± 1.8	25.89 ± 1.96	25.27 ± 1.89	<0.001
	Mean Change from Baseline	-	0.49	1.40	2.12	2.74	

Anthropometric parameters viz. BMI, Waist Circumference, Waist-to-hip ratio, and Sagittal abdominal diameter measured at the baseline were significantly reduced (p<0.001) after the treatment of Unani Formulation Jawarish Bisbasa.



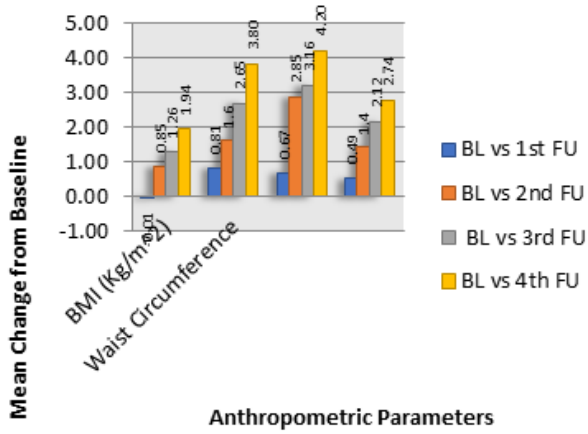


Fig: 2.1 Therapeutic Response in Relation to Figure 2.2: Mean Change from Baseline on Anthropometric Parameters Anthropometric Parameters

Analysis of Safety Parameters

Table 6: Effect on liver and kidney function tests (n=88)

Name of Parameter	Mean± SD		Range		P-value
	Before Treatment	After Treatment	Before Treatment	After Treatment	
S.Bilirubin (mg%)	0.41 ± 0.18	0.41 ± 0.19	0.18 - 1.03	0.1 - 0.89	0.954
SGOT IU/l	22.82 ± 5.93	24.1 ± 5.66	12.3 - 42.3	14.6 - 41	0.145
SGPT IU/L	22.23 ± 9.91	21.94 ± 7.25	8.7 – 70	11.4 - 45.4	0.828
Alkaline Phosphatase IU/L	85.75 ± 22.82	84.48 ± 26.53	45 – 142	30 - 170	0.734
Creatinine mg%	0.86 ± 0.14	0.77 ± 0.18	0.59 - 1.24	0.1 - 1.23	0
Blood Urea mg%	9.31 ± 2.64	9.31 ± 2.94	4.2 – 18	4.2 - 19.39	0.994

SGOT =serum glutamic oxaloacetic transaminase; SGPT =serum glutamic pyruvic transaminase; Alkaline Phosphatase (ALP)

Therefore, it can be inferred that the test drug Jawarish Bisbasa did not induce any adverse reaction. Thus, the drug's safety has been complied upon.

Table 7: Comparative change in Hemogram (n=88)

Name of Parameter			Mean ± SD		Range		Percentage of Increase (↑) / Decrease (↓)		Paired 't' test	
			Before Treatment	After Treatment	Before Treatment	After Treatment			Statistic value	P-value
HAEMOGRAM	Hb(gm/dL)		12.36 ± 1.49	12.25 ± 1.31	8.8 - 16.4	8.3 - 15.9	0.11	↓	0.52	0.601
	TLC(/mm^3)		7882.95 ± 1708.28	7965.91 ± 2250.41	2400 – 13000	3200 - 16400	82.96	↑	-0.28	0.783
	DLC	N (%)	56.02 ± 7.9	56.08 ± 9.14	30 – 86	30 - 82	0.06	↑	-0.04	0.965
		L (%)	33.78 ± 6.74	34.08 ± 8.22	12 – 57	15 - 59	0.3	↑	-0.26	0.795
		E (%)	8.49 ± 3.17	7.56 ± 4.15	1 – 15	0 - 16	0.93	↓	1.67	0.096
		M (%)	1.52 ± 0.88	1.61 ± 1.15	0 – 8	0 - 8	0.09	↑	-0.59	0.557
		B (%)	0 ± 0	0 ± 0	0 – 0	0-0	-	-	-	-
	ESR (mm) 1st Hr.		29.38±12.08	28.26±12.25	6-62	3-62	1.12	↓	1.12	0.264
	ESR (mm) 2nd Hr		41.20±10.23	38.67±13.27	0.36-65	0-64	0.28	↓	2.16	<0.05

No adverse effects of the study drug were reported by any of the patients over the treatment period and no statistically significant changes were observed in the values of pathological and biochemical parameters at the end of the treatment ($p>0.05$), which suggested that the study drug has no adverse effects.

Name of Parameter		Mean ± SD		Range		Percentage of Increase (↑) / Decrease (↓)		Paired 't' test	
		Before Treatment	After Treatment	Before Treatment	After Treatment			Statistic value	P-value
Lipid Profile	Serum Cholesterol	177.14 ± 35.96	173.41 ± 34.98	107 - 321	100 - 261	3.73	↓		<0.001
	HDL	49.63±13.24	52.85±8.60	33.3-146.8	35.5-83.8		↑	-2.56	<0.05
	LDL	112.42 ± 29.74	113.34 ± 30.89	22.6 - 201.9	51 - 174.8	0.92	↑	-0.2	0.841
	VLDL	25.15 ± 18.45	24.98 ± 10.74	9.9 - 142	10 - 57.74	0.17	↓	0.07	0.943
	Triglycerides	132.30±47.49	115.86±41.57	49.5-264.7	50-225.5		↓	5.09	<0.001

Table 8: Post-treatment change in lipid profile(n=88)

A significant reduction in mean serum Total cholesterol by 173.41 versus 177.14 was found significant (<0.001), In addition, the reduction in mean serum Triglyceride levels from 132.30 ±47.49 mg/dl at baseline to 115.86 ± 41.57 mg/dl post-treatment was found significant (<0.001, serum HDL cholesterol was raised by 52.85 ±8.60 versus 49.63 ±13.24 was found significant (<0.05) had been observed in Central Obesity treated with Unani pharmacopoeial formulation–Jawarish Bisbasa. This study assessed the tolerability, compliance, and systemic safety of the Unani pharmacopoeial formulation–Jawarish Bisbasa. We observed that all the participants in the treatment group who completed the study tolerated Jawarish Bisbasa well. During the research, none of the participants in the treatment reported any adverse medication responses or adverse events. Additionally, there was not a significant change in baseline values for any of the safety parameters, including hemoglobin percentage, total leucocyte count, differential leucocyte count, ESR, serum total bilirubin, SGOT, SGPT, ALP, serum urea, serum creatinine, fasting blood sugar, and urinalysis. As a result, Unani pharmacopoeial formulation–Jawarish Bisbasa was determined to be safe for humans. Similar observations had been reported by other workers[21]

Conclusion:

The present study concludes that Unani pharmacopoeial formulation–Jawarish Bisbasa is effective and safe in Central Obesity patients and substantially reduces major symptoms of Clinical Parameters viz, Heart Burn, Fullness of Stomach, Breathing difficulties, and Sleep Apnea. This medicine significantly reduces Anthropometric Parameters like Body mass index, Waist Circumference, Waist-to-hip ratio, Sagittal Abdominal Diameter (SAD), and serum Total cholesterol by 173.41 versus 177.14, serum Triglyceride levels by 115.86 versus132.30, serum HDL cholesterol was raised by 52.85 versus 49.63 from baseline to after 56 days of treatment. post-treatment was found significant. The outcomes of this study may support the use of Jawarish Bisbasa to treat central obesity and dyslipidemia in clinical practice.

We, therefore, recommend this drug for further investigations on a larger group of patients to develop a feasible herbal drug of choice to combat central obesity.

Conflict of Interest: There are no conflicts of interest

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