

Effect of life-style modification on postmenopausal overweight and obese Indian women: A randomized controlled 24 weeks preliminary study

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ABSTRACT

Aim: The aim of the following study is to evaluate the effect of life-style modification on postmenopausal (PM) overweight and obese Indian women in a randomized controlled 24 week study.

Materials and Methods: Two groups were formed Group I ($n = 30$) was designated as intervention (dietary and exercise group) and Group II ($n = 24$) served as control. Comparison of weight, waist circumference (WC) and body mass index (BMI) were made and compared among two groups at 4, 8, 16 and 24 weeks.

Results: Mean age at menopause was 48.35 years versus 49.65 years; mean number of menopausal symptoms were 5.70 ± 1.76 versus 5.10 ± 1.56 and mean duration since menopause was 2.70 versus 2.90 years in Groups I and II respectively. When the effect of Group I and control on weight was compared at 4, 8, 16 and 24 weeks, there was no significant difference between them up to 8 week. At 8 weeks Group I caused a significant decrease in weight ($P \leq 0.05$) when compared with control arm and which continued throughout the study period ($P < 0.05$) at both 16 and 24 weeks. Group I produced a significant reduction in WC from 8 weeks onwards up to 24 weeks ($P \leq 0.05$). BMI was statistically significant in Group I and the effect started at 4th week ($P \leq 0.05$) and the differences in BMI reduction were highly significant at 16th and 24th weeks ($P \leq 0.001$).

Conclusion: The results of the present study strongly recommend the life-style management to be incorporated in daily style of postmenopausal women under controlled supervision.

Key Words: Postmenopausal, obesity, overweight, life-style management

INTRODUCTION

Obesity is a public health problem and is reaching epidemic proportions. This problem poses an enormous burden on health care systems and has lowered the quality of life of affected individuals substantially. World Health Organization's latest projections indicate that by 2015 approximately 2.3 billion adults will be overweight and 700 million will be obese.^[1] Overweight individuals represent approximately 20% of the adult world population. Postmenopausal (PM) status is associated with higher prevalence of obesity, as 44% of postmenopausal women (PMW) are overweight, among whom 23% are obese.^[2] PMW has an increased tendency for gaining weight. It is as yet unclear whether the menopausal transition itself leads to weight gain, but is known that the physiological withdrawal

of estrogen brings about changes in fat distribution, together with physical inactivity, are probably the major causes of this phenomenon.^[3]

Obesity is an independent risk factor for more severe menopausal symptoms. Women with abdominal obesity compared with other women have, high vasomotor scores, personal life dissatisfaction, nervousness, memory loss, depression, flatulence, muscle and joint pains, sleeping disorders lack of energy.^[3] A sustained weight loss in obese patients has been shown to confer marked health benefits (metabolic and vascular) by various studies existing from western population.^[4-7] There is irrefutable evidence of

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the effectiveness of life-style management by regular physical activity and dietary management, in the primary and secondary prevention of several chronic diseases (e.g., cardiovascular disease [CVS], diabetes, cancer, hypertension, depression and osteoporosis) and premature death.^[8-10]

Sibutramine and rimonabant were withdrawn from the market recently. Moreover, no convincing data exist recommending the use orlistat in PM obesity as such. Hence, presently life-style modification at the transition and during of menopause will go a long way in preventing weight gain and related complications during this metabolically vulnerable period.

There are only few studies^[4-10] available from the western countries but no study is available from India to the best of our knowledge confirming the benefits of life-style management on weight reduction among PM Indian women.

MATERIALS AND METHODS

This study was conducted in the Postgraduate Department of Pharmacology and Therapeutics, in a tertiary care teaching Medical College of India over a period of 1 year. The study was approved by Institutional Ethics Board. Written informed consent was obtained from all the patients after explaining them the nature and purpose of the study. A total of 96 women attending the outpatient department were enrolled in the study. Out of 96 patients, a total of 60 meeting the inclusion criteria were randomized into two groups equally. Thirty patients in Group I and 24 patients in Group II completed the study.

Inclusion criteria

- Age: >45 years
- Sex: PM females
- Overweight: Body mass index (BMI): 25-29.9 kg/m²
- Obese: BMI >30 kg/m².

Exclusion criteria

- Hypertension.
- Cerebrovascular disease.
- CVS diseases such as ischemic heart disease and arrhythmias.
- Renal and hepatic disease.
- Type 1 and Type 2 diabetes mellitus.
- Psychosis.
- Thyroid disorder.
- Dyslipidemia.
- Use of medications known to affect body weight, e.g., drugs acting on central nervous system, cathartics, thyroid supplements, diuretics and selective serotonin reuptake inhibitors.

- A weight loss of 5 kg or more in preceding 6 months.
- Psychosocial contraindications such as bulimia nervosa, anorexia nervosa, substance abuse, clinically significant depression or under current psychiatric care.

Clinical evaluation with complete medical history, complete general physical examination and complete systemic examination was done. The following laboratory investigations were carried out at the time of screening:

- Hemoglobin, total leucocyte count, differential leucocyte count, erythrocyte sedimentation rate.
- Liver function tests.
- Renal function tests.
- Serum electrolytes (Na⁺, K⁺).
- Electrocardiography, X-ray, urine routine examination.

Specific investigations

- Weight, height, BMI, waist circumference (WC).
- Blood sugar (F), lipid profile (triglyceride, low-density lipoprotein-cholesterol and high-density lipoprotein-cholesterol), serum uric acid.

After screening all the patients were randomized into two groups with the help of the table of random numbers. Two groups were formed Group I was designated as the intervention group and Group II served as control. Each patient was followed-up for a period of 24 weeks. Both groups attended follow-up visits at 4, 8, 16 and 24 weeks of study.

Group I

Group I was advised life-style modification as follows:

Dietary interventions as per the diet chart prepared by dietician

Caloric restriction, consisting of 1300 kcal/day (25% total fat, 7% saturated fat, 100 mg of dietary cholesterol), eating calcium, flavonoid and antioxidant rich diet. They were encouraged intake of fiber, spinach, kale, cabbage, broccoli, tomatoes, beans, lentils, citrus fruits and a diet rich in phytoestrogens. All women were asked to avoid of fatty diet, sugars, salt, ghee, excess rice, potato and even honey.

Exercise/physical activity

Major recommendation was to exercise regularly, for at least 30-60 min on at least 5 days of the week or increased their physical activity expenditure (1000-1500 kcal/week). Controlled yoga and mind full exercises like meditation for 1 h on at least 5 days a week was compulsory. Any of the strength, resistance and stretching exercise training, aerobic such as walking, jogging, swimming, cycling, dancing, step ups and downs, brisk walking, lawn mowing were recommended to all. No fixed recommendations were made in the current study. The strict compliance to the

study protocol was assured. The highly motivated known women regularly visiting to yoga center of Medical College, premises, after two brief educative awareness sessions were included in the interventional group.

Group II

Group II was treated as control and was allowed to undertake their routine activity and diet of their own choice.

Efficacy assessments

Weight in kilograms was measured nearest to 0.1 kg (100 g) on insulin sensitivity index marked weighing machine with the subject ideally fasting, empty bladder, wearing only light clothing and without shoes. Height in meters was measured nearest to 1 mm.

BMI has been traditionally used to identify individuals who are most likely to be overweight and obese. It is calculated by dividing weight (in kg) by height (in m) squared:^[11]

$$\text{BMI} = \frac{\text{Weight}}{\text{Height}^2}$$

Body fatness in terms of BMI is classified as per consensus statement for diagnosis of obesity and metabolic syndrome for Asian Indian.^[12]

BMI (kg/m ²)	Category
Normal BMI	18.0-22.9 kg/m ²
Overweight	23.0-24.9 kg/m ²
Obesity	>25 kg/m ²

WC is considered to be a better assessor of metabolic risk than BMI because it is more directly proportional to total body fat and amount of metabolically active visceral fat.^[13] Normal WC measurements for men and women are ≤94 cm and ≤80 cm respectively. Metabolic risk is increased substantially if WC is ≥102 cm and ≥88 cm for males and females respectively.^[14]

Similarly, WC was classified as per consensus statement for diagnosis of obesity and metabolic syndrome for Asian Indian.^[12] For men: 90 cm and for women: 80 cm respectively to define obesity.

WC in inches was measured midway between the lower rib margin and iliac crest with a horizontal tape at the end of gentle expiration.^[14]

Statistical analysis

Data was analyzed with the help of Computer Software Microsoft Excel Windows. Mean ± standard deviation were calculated for quantitative variables for both groups. Statistical comparison of all the parameters viz., weight,

WC, BMI, was done by applying unpaired *t*-test for evaluation of intergroup significance and the intragroup significance was assessed using paired *t*-test. Minimum level of significance was taken as $P < 0.05$.

RESULTS

The baseline characteristics were comparable in both groups [Table 1]. The results obtained after evaluating the effects of both groups on various parameters are as under:

Efficacy assessments

Group I observed, reduced mean weight from 83.1 ± 7.64 kg at baseline to 80.2 ± 7.4 (−2.9 kg at 4 weeks, 73.2 ± 7.5 (−9.9 kg) at 8 weeks, 71.6 ± 6.46 (−11.5 kg) at 16 weeks and 71.2 ± 6.52 (−11.9 kg) at 24 weeks. The effect was found to be statistically significant at 4, 8, 16 and 24 weeks ($P \leq 0.001$) when compared with baseline [Table 2].

Similarly in Group I, a significant decrease in WC from 4th week onwards. There was a decrease from baseline score of 38.6 ± 2.33 inches to 37.3 ± 2.17 (−1.3 inches) with ($P \leq 0.001$) at 4 weeks, 34.9 ± 2.02 (−3.7 inch) at 8 weeks ($P \leq 0.001$), 34.56 ± 2.40 (4.04 inch) at 16 weeks and 34.02** ± 2.62 (−4.58) ($P \leq 0.001$) at 24 weeks. Maximum decrease was seen at 24 weeks [Table 2].

Intervention — Group I showed a significant decrease in BMI from 4th week. The decrease was observed from a mean baseline score of 30.6 ± 2.7 kg/m² to 29.5 ±

Table 1: Baseline characteristics of women

Parameter	Group I (n = 30)	Group II (n = 24)
Mean age at menopause	48.35 years	49.65 years
Mean no. of menopausal symptoms	5.70 ± 1.76	5.10 ± 1.56
Mean duration since menopause	2.70 years	2.90 years
Age (years) mean ± SD	55.63 ± 5.94	54.17 ± 5.60
Weight (kg) mean ± SD	83.1 ± 7.64	80.6 ± 8.83
Blood glucose (mg/dl) (F) mean ± SD	87.2 ± 5.91	88.83 ± 4.46
Height (cm) mean ± SD	164.3 ± 8.49	159.2 ± 9.22
BMI (kg/m ²) mean ± SD	30.6 ± 2.73	31.7 ± 3.25
WC (inches) mean ± SD	38.60 ± 2.23	38.66 ± 2.53
TG (mg/dl) mean ± SD	141.6 ± 17.96	150.79 ± 21.30
LDL (mg/dl) mean ± SD	128.9 ± 18.92	126.2 ± 25.8
HDL (mg/dl) mean ± SD	36.03 ± 5.9	38.7 ± 4.57
Uric acid (mg/dl)	5.40 ± 0.78	4.869 ± 0.89
HR (beats/min) mean ± SD	78 ± 7.17	78.7 ± 7.54
SBP (mg of Hg) mean ± SD	128.6 ± 6.12	124.75 ± 5.30
DBP (mm of Hg) mean ± SD	83.26 ± 5.03	80.25 ± 5.7

$P > 0.05$ of all parameters. SD: Standard deviation, BMI: Body mass index, WC: Waist circumference, TG: Triglycerides, LDL: Low-density lipoprotein, HDL: High-density lipoprotein, HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

2.62 (-1.1 inch) at 4 weeks ($P \leq 0.001$), 26.8 ± 2.5 (-3.8) at 8 weeks ($P \leq 0.001$), 26.3 ± 2.26 (-4) at 16 weeks ($P \leq 0.001$) and 26.1 ± 2.61 (-4.5) at 24 weeks ($P \leq 0.001$). Peak decrease was seen at 24 weeks [Table 2].

In the control arm, Group II mean weight reduced from baseline score of 80.6 ± 8.83 kg to 78.6 ± 9.06 (-2 kg), at 4 weeks, 77.2 ± 8.94 (-3.4 kg), 75.62 ± 8.87 (-4.98 kg) and 75.22 ± 6.88 (-5.38 kg), at the end of 4, 8, 16 and 24 weeks respectively [Table 3]. Mean WC at baseline was 38.6 ± 2.53 inches in the placebo arm. There was a decrease in WC to 37.7 ± 2.64 (-0.9 inches) at 4 weeks, 36.3 ± 3.45 (-2.3 inches) at 8 weeks, 35.91 ± 2.92 (-2.69 inches) at 16 weeks 35.24 ± 2.41 (-3.36 inches) at the end of 24 weeks ($P \leq 0.001$) [Table 3]. In the control arm BMI decreased from a mean 31.7 ± 3.25 kg/m² at baseline to 31.4 ± 3.69 (-0.3), 30.8 ± 3.3 (-1.09), 29.82 ± 3.206 (-1.88) and 29.58 ± 3.23 (-2.12) at 4, 8, 16 and 24 weeks [Table 3].

When the effect of Group I (intervention group) and control on weight was compared at 4, 8, 16 and 24 weeks, there was no significant difference between them up to 8 week. At 8 weeks Group I caused a significant decrease in weight ($P \leq 0.05$) when compared with the placebo arm and this significant difference in weight reduction continued throughout the study period ($P < 0.05$) at both 16 and 24 weeks. The maximum effect was seen at 24 weeks

[Table 4]. On comparing the effect of Group I and control WC at 4, 8, 16 and 24 weeks, the Group I in a similar manner produced a significant reduction in WC from 8 week onwards up to 24 weeks ($P \leq 0.05$). Maximum effect was seen at 24th week [Table 4]. On comparing the effect on BMI, fall in BMI was statistically significant in Group I and the effect started at 4th week ($P \leq 0.05$) and the differences in BMI reduction were highly significant at 16 and 24th week ($P \leq 0.001$) [Table 4].

DISCUSSION

Weight gain is a major health concern for women at midlife. Weight gain *per se* does not appear to be affected by the hormonal changes of the menopause. The fall in estrogen at menopause favors central abdominal fat accumulation. Other factors that may contribute to obesity in women include a low level of activity, parity, lower level of education, a family history of obesity, use of psychotropic drugs and chemotherapy. In addition to the adverse physical consequences of obesity, weight excess is a major risk factor for psychological distress, low self-esteem, depression and sexual dysfunction.^[3] Successful maintenance of weight loss during menopause involves life-style change. The result of the current study is in full accordance with these recommendations. As on comparison life-style modification produced significantly more reduction in weight, WC and BMI.

Table 2: Effect of life-style management on weight, WC and BMI (mean \pm SD) in over weight and obese women (N = 30)

Parameter	0 week	4 weeks	8 weeks	16 weeks	24 weeks
Weight (kg) mean \pm SD	83.1 \pm 7.64	80.2 \pm 7.41 (-2.9)**	73.2 \pm 7.56 (-9.9)**	71.6 \pm 6.46 (-11.5)**	71.2 \pm 6.52 (-11.9)**
WC (inches) mean \pm SD	38.60 \pm 2.23	37.3 \pm 2.17 (-1.3)**	34.91 \pm 2.09 (-3.7)**	34.56 \pm 2.40 (-4.04)**	34.02 \pm 2.62 (-4.58)**
BMI (kg/m ²) mean \pm SD	30.61 \pm 2.73	29.5* \pm 2.62 (-1.1)**	26.8 \pm 2.5 (-3.8)**	26.3 \pm 2.26 (-4.3)**	26.1 \pm 2.61 (-4.5)**

**Highly significant, $P \leq 0.001$ (Paired t-test) as compared to baseline, (-X)=Mean reduction from baseline. N: Number of patients, WC: Waist circumference, BMI: Body mass index, SD: Standard deviation

Table 3: Effect of control on weight, WC and BMI (mean \pm SD) in overweight and obese women (N = 24)

Parameter	0 week	4 weeks	8 weeks	16 weeks	24 weeks
Weight (kg) mean \pm SD	80.6 \pm 8.83	78.6 \pm 9.06 (-2)**	77.2 \pm 8.94 (-3.4)**	75.62 \pm 8.87 (-4.98)**	75.22 \pm 6.88 (-5.38)**
WC (inches) mean \pm SD	38.6 \pm 2.53	37.71 \pm 2.64 (-0.9)**	36.30 \pm 3.45 (-2.3)**	35.91 \pm 2.92 (-2.69)**	35.24 \pm 2.41 (-3.36)**
BMI (kg/m ²) mean \pm SD	31.7 \pm 3.25	31.41 \pm 3.69 (-0.3)**	30.82 \pm 3.33 (-0.9)**	29.82 \pm 3.20 (-1.88)**	29.58 \pm 3.23 (-2.12)**

**Highly significant, $P \leq 0.001$ (Paired t-test) highly significant when compared with baseline, (-X)=Mean reduction from baseline. N: Number of patients, WC: Waist circumference, BMI: Body mass index, SD: Standard deviation

Table 4: Comparative analysis of group I (N = 30) and group II (N = 24) on weight, WC and BMI in overweight and obese women

Time	Weight mean \pm SD		P value	WC mean \pm SD		P value	BMI mean \pm SD		P value
	Group I	Group II		Group I	Group II		Group I	Group II	
0 week	83.1 \pm 7.64	80.6 \pm 8.83	0.39	38.6 \pm 2.23	38.66 \pm 2.53	0.91	30.6 \pm 2.73	31.7 \pm 3.25	0.18
4 weeks	80.2 \pm 7.4	78.6 \pm 9.06	0.56	37.3 \pm 2.17	37.7 \pm 2.64	0.69	29.5 \pm 2.62	31.4 \pm 3.69	0.04*
8 weeks	73.2 \pm 7.43	77.2 \pm 8.94	0.05*	34.9 \pm 2.02	36.30 \pm 3.45	0.05*	26.8 \pm 2.5	30.8 \pm 3.33	0.001**
16 weeks	71.6 \pm 6.46	75.62 \pm 8.87	0.05*	34.5 \pm 2.40	35.91 \pm 2.92	0.05*	26.3 \pm 2.26	29.8 \pm 3.2	0.0001**
24 weeks	71.2 \pm 6.52	75.22 \pm 6.88	0.05*	34.02 \pm 2.62	35.24 \pm 2.41	0.05*	26.1 \pm 2.61	29.58 \pm 3.23	0.0001**

*Significant $P \leq 0.05$, **Highly significant. $P \leq 0.001$ using unpaired t-test. N=Number of patients, WC: Waist circumference, BMI: Body mass index, SD: Standard deviation

Reductions in weight, BMI and abdominal circumference have been associated with a reduction in vasomotor symptoms in overweight and obese women.^[4] The combination of dietary modification and exercise also has positive effects on health-related quality of life (HRQoL) and psychological health, which may be greater than that from exercise or diet alone.^[4] Improvements in weight, aerobic fitness and psychosocial factors may mediate some of the effects of these interventions on HRQoL.^[5] Weight loss in overweight and obese women improves psychological well-being, HRQoL, self-esteem and health practices.^[6,7] In addition, dietary weight loss and exercise exert a positive effect over insulin resistance in PMW, which together with a decrease in menopausal symptoms may potentially decrease cardiovascular risk.^[8]

The results of these studies^[4-8] are in accordance with our study as per beneficial effects of life-style modification is concerned on weight management of PMW, however the current study did not study the beneficial effects on various other parameters such as quality of life, symptom score and cardiovascular parameters.

Some of the recent studies^[15-17] are also in accordance with the current study. Dietary weight loss and exercise has been shown to improve body measures and biomarkers of glucose metabolism and inflammation independent of antidepressant use in overweight or obese, PMW in a 12-month randomized controlled trial.^[15] Similarly, caloric restriction, weight loss diet with or without exercise has been shown to reduce biomarkers of inflammation in PMW, with potential clinical significance for cancer risk reduction.^[16] Positive changes in depression, stress and social support have been shown to independently associated with increased HRQoL, after adjusting for changes in weight and aerobic fitness exercise group among overweight/obese PMW.^[5] Dietary weight loss, with or without exercise, significantly improved insulin resistance and older women have been shown to derive as much benefit as did the younger PMW in one of the recent study.^[16] The results of the present study are in accordance to our study, however our study was only planned to see the benefits on weight, BMI and WC among PM obese/overweight Indian women.

Thus, physical exercise and dietary changes are absolutely essential in the treatment of obesity particularly when existing literature fails to recommends the use of drugs for the effective and safe management of PM obesity.

There are few limitations of the study. First, it is a short-term study with less number of patients and effect of small sample size cannot be ruled out on results of the study as power of the study was not calculated before resuming

the current study. Thus, the highly encouraging results noticed in the current study need to be validated in larger Indian population. No biochemical markers, effects on menopausal symptoms, CVS parameters and impact on quality of life as a result of weight reduction were studied. Furthermore, highly motivated population included in the study retained these effects on long-term or not remains to be seen.

CONCLUSION

The results of the present study strongly recommend the life-style management to be incorporated in daily routine of PMW under the supervision and motivation/adherence to life-style management shall go a long way to avoid dual menace of obesity and its related complications.

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