OB-0095-Oligonol Supplementation Ameliorates Risk Factors of Type II Diabetes Mellitus in Overweight and Obese Saudi Females

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Introduction

Obesity is becoming a serious health problem that is increasing globally, especially in the last four decades. Indeed, the global prevalence of obesity has doubled between 1980 and 2014 [1]. The problem is even more critical in Saudi Arabia, with 36.9%, and 35.6% of the adults aged ≥ 30 years reported to be overweight, and obese respectively [2]. Obesity is associated with a variety of serious medical conditions and chronic diseases including dyslipidemia, type 2 diabetes mellitus, coronary heart disease, hypertension, stroke, osteoarthritis, and cancer [3]. Use of safe natural products to control obesity might be a possible effective alternative to the use of chemically prepared drugs with deleterious side effects [4]. Oligonol has been offered commercially as a new dietary ingredient, and has proved to be effective in other populations, but has not been tried on Saudi subjects.

Aim : To investigate the possible ameliorative effects of oligonol on blood pressure, measures of obesity, insulin resistance by (HOMA-IR), lipids profile, and leptin in healthy overweight and obese Saudi females.

Methods

A flow chart illustrating the study design, various stages of the study, and the measurements at these stages is presented in Figure 1.

CASE/ CONTROL-DOUBLE BLIND SYUDY

A total of 75 young healthy females (aged 20-34 years) were recruited, but only 60 overweight or obese females were chosen to be included.

- Blood pressure (BP), height, weight, waist circumference (WC) were measured by standardized methods, and BMI calculated
- Daily physical activity, medical history, dietary and sleeping habits were recorded by predesigned questionnaire
- Fasting blood samples were taken, serum was separated and kept at -80°C for later measurement of triglycerides, total and HDL- cholesterol, insulin and leptin.
- HOMA-IR were calculated by equation.

RANDOMIZATION based on BMI

Group (A): (N=30)

Mean Age $\pm$ SD=21.5 $\pm$ 4.1 years
Mean BMI $\pm$ SD=29.30 $\pm$ 3.97 kg/m²

Group (B): (N=30)

Mean Age $\pm$ SD=22.4 $\pm$ 4.0 years
Mean BMI $\pm$ SD=31.36 $\pm$ 4.27 kg/m²

All given a supply of capsules identical in appearance and instructed to take 2 capsules daily before the major meal, continue normal life routine and to come back for follow up and more capsules after 4 weeks to monitor changes in weight; and waist circumference

First Follow up evaluation after 4 weeks

1 subject dropped out for lack of noticeable effect noted after the first month,
1 subject dropped out for transportation difficulty
1 subject was excluded for pregnancy
No report of adverse effects
Remaining subjects = 27,
A fresh supply of capsules was given

First Follow up evaluation after 4 weeks

4 subjects dropped out for lack of noticeable effect noted after the first month
No report of adverse effects
Remaining subjects = 26,
A fresh supply of capsules was given

Second Follow up evaluation after 8 weeks

2 participants were excluded for lack of compliance-
No report of adverse effects
Remaining subjects = 25,
A fresh supply of capsules was given

Second Follow up evaluation after 8 weeks

4 participants dropped out for transportation difficulty-
No report of adverse effects
Remaining subjects = 22,
A fresh supply of capsules was given

Final visit after 12 weeks

- All 47 remaining subjects were reevaluated
- Blood pressure (BP), height, weight, waist circumference (WC) were measured, and BMI calculated
- Daily physical activity, medical history, dietary and sleeping habits, in addition to any noted side effects, physical or physiological changes were recorded
- Fasting blood samples were taken to measure all biochemical parameters

Biochemical measurements were performed on all blood samples in one batch to avoid variability. Following completion of all biochemical and statistical analysis, it was disclosed to the researchers that:

A was placebo

B was Oligonol

Figure 1: A flow chart illustrating the study design

Results

Some subjects were excluded for various reasons, leaving 25 in GA, and 22 in GB, Therefore, the two groups differed significantly in recalculated mean BMI at zero time (29.30 $\pm$ 3.97 for GA, and 31.63 $\pm$ 4.16 for GB, P=0.046) in table 1. No side effects or significant differences in diet or lifestyle were found at the end of the study. Results of all measured parameters are presented in table 2 and figures 3 & 3.

Table 1: Changes in weight, BMI, and WC throughout the study period presented as Mean $\pm$ SD

	Group A (Mean $\pm$ SD)				P-Value	Group B (Mean $\pm$ SD)				P-Value
	1 st Visit	1 st follow up visit	2 nd follow up visit	Last visit		1 st Visit	1 st follow up visit	2 nd follow up visit	Last visit	
Weight (kg)	72.66 $\pm$ 10.8	73.56 $\pm$ 11.15	73.68 $\pm$ 10.99	73.52 $\pm$ 10.62	0.009	81.91 $\pm$ 13.2	82.15 $\pm$ 13.1	81.72 $\pm$ 13.6	81.29 $\pm$ 13.5	0.229
BMI (kg/m ²)	29.3 $\pm$ 3.97	29.66 $\pm$ 4.11	29.72 $\pm$ 4.09	29.65 $\pm$ 3.88	0.007	31.63 $\pm$ 4.16	31.81 $\pm$ 3.97	31.64 $\pm$ 4.13	31.4 $\pm$ 4.23	0.225
WC (cm)	82.3 $\pm$ 7.13	84.32 $\pm$ 6.6	85.54 $\pm$ 6.76	84.22 $\pm$ 7.28	0.000	91.06 $\pm$ 9.2	90.15 $\pm$ 7.63	90.88 $\pm$ 7.87	89.38 $\pm$ 8.3	0.058

Oligonol prevented weight gain in GB, unlike to that noted in control group (GA), which exhibited significant increase in mean weight (P= 0.036), WC (P=0.027), HC (P= 0.047), and leptin (P <0.001). Mean triglycerides was significantly increased in GA (P= 0.011), and decreased in GB (P= 0.008). Percentage of subjects with high diastolic BP (DBP) in GB decreased significantly from 36% to 9% (P=0.031) table 1 and table 2.

Table 2: Biochemical and endocrine parameters in the placebo group (Group A), and the oligonol group (Group B) before and after supplement, presented as mean $\pm$ SD

Variable	Group A (N= 25)			Group B (N= 22)		
	PRE-	POST	P- value	PRE-	POST	P- value
Insulin ($\mu\text{U/mL}$)	9.7 $\pm$ 4.8	8.3 $\pm$ 3.4	0.225	13.1 $\pm$ 6.9	12.9 $\pm$ 6.8	0.862
HOMA-IR	2.1 $\pm$ 1.2	2.0 $\pm$ 0.9	0.453	2.84 $\pm$ 1.53	2.71 $\pm$ 1.58	0.822
Leptin (ng/mL)	34.0 $\pm$ 12.1	43.1 $\pm$ 13.5	<0.001	37.7 $\pm$ 13.0	44.7 $\pm$ 14.0	0.067

Figure2: Lipid profile parameters and fasting blood glucose in the placebo group (Group A), before and after supplement

Figure3: Lipid profile parameters and fasting blood glucose in the oligonol group (Group B) before and after supplement

Discussion

In this double blind, case/control study we investigated the effect of oligonol supplementation on BMI, WC, HC, and percentage fat, as well as serum lipid profile, and various biochemical, and endocrine parameters reflecting adiposity and insulin resistance without change in diet or life style in overweight, and obese young healthy Saudi females. **In Conclusion** Oligonol supplement succeeded in ameliorating risk factors for T2DM in obese Saudi females by controlling abdominal obesity, and DBP, and decreasing hypertriglyceridemia without dietary restriction or lifestyle modification, and without any noted adverse side effects. Therefore, it could be suggested as safe future hypolipidemic and weight controlling agent for overweight and obese Saudi females.

References

[1] Global Health Statistics [Internet]. World Health Organization. 2014. Available from:

<http://www.who.int/gho/publications/worldhealthstatistics/2014/en/>.

[2] Al-Nozha MM, Al-Mazrou YY, Al-Maatouq MA, et al. Obesity in Saudi Arabia. Saudi Med J 2005; 26(5): 824-9.

[3] Memish ZA, El Bcheraoui C, Tuffaha M, Robinson M, Daoud F, Jaber S. Obesity and associated factors- kingdom of Saudi Arabia 2013. Prev Chronic Dis 2014; 11: E174.

[4] Haslam DW, James WP. Obesity. Lancet 2005; 366(9492): 1197-209.