Effects of Syzygium aromaticum in over weight and obese female patients with Polycystic Ovary Syndrome

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Abstract

Background: Polycystic Ovarian Syndrome is that the commonest reproductive endocrine disorder among women of reproductive age, affecting high of population worldwide. It’s the most typical multisystem endocrinopathy having diverse etiopathogenesis in women, causing menstrual irregularities, hirsutism and anovulatory infertility. Objective: To determine the effect of Clove, Syzygium aromaticum supplementation on body weight, BMI, Insulin level, insulin resistance indexes, fasting glucose level, LH level, Testosterone, androgen binding globulin and lipid profile in over weight and obese women patients with polycystic ovary syndrome (PCOS).

Methods: fifteen obese and overweight women with PCOS mean (BMI = 32) with mean (age = 29) were enrolled in the study, the clove group (n = 50 patients), who were received clove in a dose of 1000 mg daily) for three months. The parameters were measured before and after three months of treatment are: BMI, Fasting plasma glucose, Serum insulin levels, Insulin resistance indexes: (HOMA-B) (HOMA _IR) and (QUICKI). Lipid profile: serum cholesterol, triglycerides, VLDL-C, LDL-C and HDL-C, luteinizing hormone LH, testosterone and sex hormone binding globulin.

Results: Clove shows no significant decrease in weight, BMI, insulin level and serum cholesterol and QUICKI, with high significant decrease in values of glucose, HOMAB, HOMAIR, testosterone, LH, triglycerides, VLDL-C and LDL-C and highly significant increase in HDL-C and SHBG concentrations. Conclusion: Clove was helpful in management of patients with PCOS through their ability to decrease the glucose, insulin resistance, lipid profile, testosterone and LH and increase the HDL and SHBG.

Key words: Poly cystic ovary syndrome, Syzygium aromaticum, clove, obese, overweight, sex hormone binding globulin

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Introduction

Polycystic ovary syndrome (PCOS) is a complex condition described by elevated androgen levels, menstrual abnormalities, and/or small cysts on one or both ovaries. The disorder can be morphological (polycystic ovaries) or mainly biochemical (hyperandrogenemia). Hyperandrogenism, a clinical symbol of PCOS, can cause inhibition of follicular development, micro cysts in the ovaries, anovulation, and menstrual fluctuations (1).

PCOS is a heterogeneous disorder that affects at least 7% of adult women, the National Institutes of Health Office of Disease Prevention, reported that PCOS affects approximately 5 million women of childbearing age in the U.S. it is one of the leading causes of female infertility (2).

Research submits that 6% to 11% of females 18 to 44 years of age are affected by PCOS, production it the most common endocrine abnormality amongst women of reproductive age in the world. Women looking for help from health care professionals to resolve issues of obesity, acne, amenorrhea, excessive hair growth, and infertility often receive a diagnosis of PCOS. Women with PCOS have higher rates of endometrial cancer, cardiovascular disease, dyslipidemia, and type-2 diabetes mellitus (3).

It is a relationship between the presence of polycystic ovaries and signs of hirsutism, menstrual disturbances (e.g. amenorrhea, oligomenorrhea) and obesity (4).

Though PCOS could be a common disorder, the designation could also be unnoticed throughout adolescence as irregular menstruum with anovulatory cycles; obesity and skin disorder are frequent in adolescent girls (5).

Clove or Syzygium(S.) aromaticum, is a dried buds flower of Myrtaceae family that is original to the Maluku islands in Indonesia and farmed in different places worldwide (6,7).

Cloves are used for numerous medicinal purposes, and it is considered one of the spices and preservatives in many foods, due to their antioxidant and antimicrobial properties (7, 8).

Some reports have documented the antibacterial, antiviral, anticarcinogenic, and antifungal activities of clove, due to its potent antimicrobial and antioxidant activities the clove has gained much care among other spices (9).

The effective of clove in the inhibition of different degenerative diseases is due to the presence of various chemical constituents in high concentrations with antioxidant activity (10,11).
Clove essential oil (CEO) is traditionally used in the treatment of burns and wounds, and as a pain reliever in dental care as well as treating tooth infections and toothache. Cloves are used in Indian and Chinese traditional medicine as a warming and stimulating agent (6).

Cloves have been used for centuries in the treatment of vomiting; flatulence, nausea; liver, bowel and stomach disorders; and as a stimulant for the nerves. In Asia, cloves have been documented to relieve different microorganisms as scabies, cholera, malaria, and tuberculosis. As well, in America, clove has been used in inhibiting food-borne pathogens to treat viruses, worms, candida, and different bacterial and protozoan infections. Sesquiterpenes, isolated from clove were reported to have anti-carcinogenic activity (12).

Methods:

Patients
This prospective clinical trial was conducted during the period from July 2018 to August 2019. The Ethics Committee of the Al-Nahrain medical college approved this study. Women included in this study were among those who attended clinic of gynecology and obstetrics in Al -Imam Al-Kadhimiyain medical Teaching city; Baghdad, Iraq. Patients were selected randomly according to the day of presentation to the clinic. All participants were given informed consent before they were included in this study.

The patients were in reproductive age (18-40 years) the group (n=50) consists of 50 women diagnosed with ovarian polycystic syndrome. All the patients had at least 2 out of 3 of Rotterdam criteria.

Each patient was involved to detailed clinical history, physical examination and typical appearance of polycystic ovaries by ultrasound according to the criteria of Rotterdam consensus meeting 2003.

Safety Assessment
Safety assessment included medical history, physical examination, hormone level, and serum chemistry at all visits and the monitoring of drug-related adverse events by recordation in patient diaries.

Laboratory investigations
Weight, length Body mass index (BMI).

Hormonal assays include: Sex hormone binding globulin (SHBG), Testosterone, and luteinizing hormone (LH) by (TOSOH Corporation, Japan).

Fasting plasma glucose, Serum insulin levels Insulin resistance indexes HOMA-B, HOMA-IR and QUICKI, serum cholesterol, triglycerides, VLDL-C, LDL-C and HDL-C concentrations by Selectra pro, Elitech, France.

Study Design and Treatments
The enrolled patients were asked to take 2 capsule of clove (Nature company, USA) b.i.d (500 mg per capsule), orally for three months. Clinical examination, biochemical assay, and hormonal assay were performed at baseline and after three months of therapy. All patients provided their written informed consent and completed the entire trial.
Statistical analysis
The data were analyzed using Statistical Package for Social Sciences (SPSS) program version 25. Results were reported as mean ± S.D. The total variations were analyzed by performing the statistical design T-test. Probability levels of less than 0.05 were considered significant (13).

Results:
Clove treatment was well-tolerated by all patients. None of the subjects suspended the therapy due to side effects, although some experienced transient stomach upset during the first days of treatment. Effect on BMI for the mean duration of the study (3 months), clove was given to 50 patients. The mean weight and BMI nonsignificant decreased during the treatment time, from (84.93±13.63) to (82.92±12.14) mean BMI (31.53±5.14) to (30.79±4.64).

The results (Mean ±SE) of Glucose (mg/dL), HOMAB, HOMAIR comparison between the GLU group before and after treatment show highly significant decrease (p<0.001) in the values (105.36±9.00vs.91.94±7.52) (137.67±38.36vs.92.32±19.84) (2.74±0.51vs.2.36±0.35) respectively.

While on significant difference in insulin (uIU/ml), and QUICKI (10.52±1.55vs.10.40±1.30) (3.01±0.06vs.2.95±0.06) respectively.

In this study, results (Mean ±SE) before versus after 3 months of treatment with Clove of triglycerides, LDL, VLDL, LH and testosterone show highly significant decrease (p<0.001) in the values as (118.03±14.29vs.91.17±18.60) (105.53±10.13vs.95.83±8.94) (32.57±3.58vs.30.50±3.12) (20.20±3.85vs.14.83±3.33) (61.26±23.29vs.45.50±17.89) respectively. Where the results (Mean ±SE) before versus after 3 months of treatment with clove of HDL and SHBG show highly significant Increase (p<0.001) in the values as (44.23±4.26vs.57.33±3.99) (40.30±6.55vs.50.13±4.34) respectively.

Discussion
In the current study, the weight of patients CLOVES group and body mass index (BMI) before and after was appeared statistically no significance difference (p≥0.05). This results disagreement with another study was observed significant difference in BMI of all the experimental groups due to significant reduction in mean body weight of the diabetics after supplementation of cloves(14).

The supplemented with *S. aromaticum* decreased the body weight, suggesting its prospect as a natural anti-obesity supplement and its ability to decrease the hepatic lipid accumulation; it had efficiently inhibited the conversion of cells into adipocytes in a dose-dependent manner (15).

In the other side the study results agree with administration of eugenol for 30 days significantly improved glycemic control which prevented the loss of body weight and excess of food and fluid intake on in dose dependent manner (16).
The results (Mean ±SE) of Glucose (mg/dL), HOMAB, HOMAIR and QUICKI comparison between the clove group before and after treatment show highly significant decrease (p<0.001) in the values. These results in agreement with the effects of clove improve the role of insulin and lowering the blood glucose and decided that ingesting of clove improve glucose level in diabetic patients. All participants intake cloves daily expert significant improvements in cardiovascular effects, compared with those not taking cloves (17).

In our research regarding the results of insulin level, the results showed that no significant increase in insulin levels when compared to the level in diabetic control, clove may have exerted insulin mimetic effects in that way sparing serum insulin or may have contributed to increase insulin secretion and release (18).

But when we look at the results of insulin resistance parameters HOMAB, HOMAIR and QUICKI, we see a large statistical difference, and this explains the theory that the chemical components present in cloves are (dehydropunguelogen and dehydrodieugenol B) that had potent [PPAR-γ ligand-binding activity], therefore causing increased insulin sensitivity via muting the effect of lipotoxicity along insulin signaling pathway (19).

Dr- Khan in a study reported that *Syzygium aromaticum* has insulin-like action and improves insulin efficiency, the hypoglycemic effect of *Syzygium aromaticum* could be due to stimulation of functioning beta cells of pancreas to increase the release of insulin Or due to regeneration of beta cells (17,20).

*Syzygium aromaticum* has alpha-glucosidase inhibiting properties, it was predicted that anti hyperglycemic effect of clove may be due to its inhibitory action on alpha– glucosidase (21,22). In this study the PCOS patients women treated with clove showed significant differences in the mean values of TAG, LDL and VLDL. These parameters were decreased after three months of treatment while HDL levels were increase, since the total cholesterol value consists of the value of HDL, LDL and VLDL, the decrease in LDL and VLDL is offset by the increase in HDL, and therefore there is no statistical difference.

These results are agree with many studies and research that says the role of clove in decrease the bad fats and improve the good lipid and recommend its use as alternative natural source for management of hyperlipidemia (23,24,25).

Many studies reported the efficacy of *S. Aromaticum* extracts by reducing the serum triglycerides and cholesterol levels (26). The effect of clove as hyoplipidemic was showed after administration of clove powder with diet inhibited acetylcholine activity and lowered cholesterol level and this was in agreement with our study (25).
The anti-hyperlipidemic effect of clove can be described as a direct lowering in blood glucose level, cholesterol and TAG could also be due to regenerate pancreatic β-cells and a suppression of the hepatic fatty acid synthase, glucose-6-phosphate dehydrogenase (16,27).

The results of anti-hyperlipidemic effects of clove were showed that oral administration of clove decreases the levels of cholesterol, free fatty acids, triglycerides and the extent of lipid peroxidation in ethanol exposed rats (11,28)

This research is a novel due to first time studying the clove effects on patients women with PCOS, we see a significant statistical difference in the hormones levels testosterone, luteinizing hormone and sex hormone binding globulin in clove group before and after treatment (p≤0.001), The effects of the clove on the hormones were probably it is have hypoglycemic effect to lower blood glucose level and decrease the insulin resistance lead to decrease in ovarian androgen level ,free testosterone, increase SHBG , decrease hypothalamic GnRH pulses, and this lead to low in the LH level.

These results agree with the obesity and hyperlipidemia and lipid accumulation on ovary submits the inhibition of ovary function. So the administrations of clove, decrease in lipid peroxidation, and the increase of antioxidant enzymes in the ovaries, the low levels of testosterone also represent the estrojenic properties of clove administrations.(29)

The administration of EUG had significant antifertility activity, in this study revealed by (30) because of the presence of EUG in. The antifertility capacity of EUG was indirect evidence. However, more research is advised to fully establish the mechanism of the active constituent of this plant.

Clove was helpful in management of patients with PCOS throw their ability to decrease the glucose, insulin resistance ,lipid profile ,Testosterone and LH and increase the HDL and SHBG.

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