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Original Article

Effectiveness of Dietary Supplementation in women with PCOS: A randomized-controlled trial

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ABSTRACT

A well-known endocrine condition in women is polycystic ovarian syndrome. **Objective:** To evaluate the effects of Vitamin D in one hundred eighty girls with PCOS. **Methods:** The investigation is a randomized control trial that is double-blinded. The study took place at the Ali Medical Hospital in Islamabad. The goal of the study was still to determine how adding vitamin D affected the metabolic and endocrine parameter plasma glucose in females with polycystic ovarian syndrome. This experiment had a 24-week base period and a 12-week follow-up period. **Result:** In this trial, no important difference of Vitamin-D addition on main variable AUCgluc and additional secondary variables metabolic and endocrine parameters were observed. There was only exclusion of a substantial reduction in plasma glucose during OGTT after 1 hr. Moreover, no improvement in PCOS or menstrual frequency in experimental group was observed. **Conclusions:** The study found no substantial impact of Vitamin-D supplementation on plasma glucose and on metabolic or endocrine parameters but during OGTT plasma glucose was found to be reduced after 1 hour.

INTRODUCTION

Polycystic ovarian syndrome is a renowned endocrine disorder in women [1]. PCOS is a very complicated disorder and effects the metabolic and psychological factors [2]. On the other hand, deficiency of vitamin D is also common in population and in PCOS its occurrence rate is great [3-5]. Vitamin D is direct linked with sensitivity of insulin [6-8]. Vitamin D suppress the post inflammatory cytokines and enhance the insulin receptors and its release [5-9]. Insulin confrontation is linked with hazards of metabolic complications and cardiovascular disorders [10, 11]. Moreover, metabolic complications can lead to PCOS [12]. This is under light by the omnipresent qualities of vitamin D receptor within reproductive system of women [13-15]. The recent treatment choices for polycystic ovarian syndrome specifically depends on hormones and lifestyle [16]. High incidence o f deficiency of vitamin D in present in women with PCOS thus, supplementation of vitamin D could be an easy treatment to cure metabolic and endocrine problems

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[17]. Various studies including RCTs indicate that vitamin D intake shows positive outcomes in terms of metabolic and endocrine disorders. However the sample size in previous studies was not as large so the result may vary in large number of participants [18, 19]. The goal of the current research is to identify the effects of vitamin D in one hundred eight polycystic ovarian syndrome females. The principal purpose of the this project is to determine the outcome of vitamin D supplement as associated to dummy treatment on plasma glucose factor below the curvature AUGgluc as amount score of glucose. The goal of the present research was to evaluate the effects of Vitamin D in one hundred eighty girls with PCOS. This is to judge if Vit-D treatment as related to palliative has a control on plasma aldohexose space below the curvature (AUCgluc) as a live of aldohexose group. The study also tend to investigate the effect of Vitamin D supplement on many different metabolic and endocrine parameters, embody androgenic hormone humor levels and frequency of discharge amount.

METHODS

The study is double blinded and randomized control study. Study setting was Ali Medical Hospital, Islamabad. The study remained intended to identify the outcomes of Vitamin-D addition on metabolic and endocrine parameter, plasma glucose in polycystic ovarian syndrome female. This trial was based on 24 weeks with follow up interval of 12 weeks. Inclusion criteria was based on >18 year old females with PCOS and deficiency of Vitamin D 25(oh) d] serum levels < 75 nmol/l). PCOS diagnosis criteria was according to the Rotterdam criteria while Exclusion criteria was hormonal contraception within 3 months, hypercalcemia. Patients having symptom such as plasma metallic element concentrations, medicine effecting the sensitivity of internal secretion, regular cholecarciferol supplements over three months and different pathologies apart from PCOS, were excluded. All participants were informed about study and consent form was take. Subjects were allocated randomly. Sample size was conducted on base of pilot study. About 500 participant underwent the investigation and screening. And 180 patients fullfill the inclusion criteria for PCOS. Participants enrolled was increased from 150-180 to make sure to identify the difference of min outcome measure. Analysis for assessment was done through SPSS version 22.0.

RESULTS

In this trial, no important difference of vit-D addition on main variable AUCgluc and additional secondary variables metabolic and endocrine parameters were observed. There was only exclusion of a substantial reduction in plasma glucose during OGTT after 1 hr. Moreover, no improvement in PCOS or menstrual frequency in experimental group was observed. Out of 180, 123 subjects ended the trial and their mean age was 25.9 ± 4.7 years; Body mass index 27.5 ± 7.3 kg/m2; initial 25(oh)d 48.8 ± 16.9 nmol/L, and baseline abstinence aldohexose was 84 ± 8 mg/dL. Viosterol supplementation resulted in a major increase in 25(OH)D. However no noteworthy outcome on Aucgluc was observed. Subjects within the Vtamin-D cluster showed greater level blood serum aldohexose by sixty min throughout OGTT as associated to the palliative cluster. Every different parameters failed to show any vital improvement between the teams. There was no vital distinction of vitamin D supplement on plasma aldohexose at the top of 24 weeks path. The subdivision evaluated amongst members by initial 25(oh)d levels < fifty nmol/L (n = 60), vitamin D addition considerably lessened AUCgluc once twenty four weeks with an average management impact (95% CI) of 19.20 (– 35.45 to – 2.95, p = 0.021). Concerning subordinate result back factors, the study showed a major reduction in plasma glucose once sixty min throughout OGTT, Table 1.

Study Variables	Baseline	24th Week	p-value
fasting glucose meaure (mg/dl) Vit-D(n=81)84±8 Control(n=42)84±8 Glucose 30 minute OGTT(mg/dl)	82 ± 8 83 ± 7	– 1.2 (– 3.6 to 1.3)	0.353
Vit-D (n=80)133±24 Control(=42)128±25 Glucose 60 minutes OGTT(mg/dl).	130 ± 23 129 ± 26	– 1.6 (–10.0 to 6.8)	0.711
Vit-D (n = 80) 123 ± 39 Control (n = 42) 107 ± 31 glucose 120 min OGTT (mg/dL)	105 ± 31 107 ± 34	– 10.2 (– 20.2 to – 0.3)	0.045
Vit-D(n=81)98±24 control(n=42)93±24 hbA1c(mmol/mol)2	88 ± 24 85 ± 24	0.5 (– 7.6 to 8.6)	0.903
Vit-D (n = 74) 33 (31-35) Control (n = 38) 34 (32-35)	33 (32-35) 33 (32-35)	– 0.4 (– 0.9 to 0.2)	0.192
Vit-D (n=79)48.8±16.8 control(n=41)48.8±17.5 pth (pg/ml)*	90.2 ± 20.1 56.8 ± 29.5	33.4 (24.5 to 42.2)	<0.001
Vit-D (n = 81)41.9 (34.4-53.8) Control (n = 42)40.2 (33.0-51.4) 1,25(oh)2d	40.6 (32.4-51.1) 45.7 (37.6-55.5)	– 6.6 (– 11.3 to – 1.9)	0.004
(pmol/l)114 ± 48 Vit-D (n=75) control (n=41)110±43 calc(mmol/l)	141 ± 52 113 ± 48	27 (8 to 46)	0.006
Vit D(n=79)2.35±0.08 control(n=41)2.36±0.07	2.32 ± 0.07 2.32 ± 0.07	0.02 (– 0.00 3 to 0.05)	0.081

Table 1: Outcomes variables at baseline and end of 24 weeks

DISCUSSION

This study figured no noteworthy difference of Vitamin-D on main variable AUCgluc and added secondary variables metabolic and endocrine factors. There is only exemption of an important reduction in plasma glucose during OGTT after 1 hr. Moreover, we did not observe any improvement in PCOS or menstrual frequency in experimental group. Co-relation among Vitamin-D deficit and insulin resistance was not due to overweight. In some studies it is indicated to

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improve endometrial environment through cell Latinization [20]. In previous RCT researches, the part of Vitamin-D supplement remain unclear in the management of PCOS, whereas several researchers found noteworthy improvement in main features of polycystic ovarian syndrome. Jamilian et al., determined the impact of 100 IU of calciferol on daily basis vs control in 3 months trail of ninety female with polycystic ovarian syndrome [21]. They found significant reduction in serum insulin and fasting plasma glucose and noteworthy improvement in entire antioxidant capability [22]. Likewise, in another study, Maktabi et al., found significant reduction in fasting plasma glucose and plasma malondialdehyde in 70 females with PCOS [23]. On the other hand in another report did not reject the outcome of Vitamin-D supplement in a cohort study of polycystic ovarian syndrome females with insulin resistance [24]. Hence, in literature review many studies outcome overlap with the results of current study. Anyhow, our study still has many limitations. Major drop out can be the reason of interruption of result but still our study's sample size is large as compare to previous studies. As we did multiple testing to analyzed different measures of glucose metabolism. Thus the outcome of Vitamin-D supplement in females with polycystic ovarian syndrome having insulin resistance cannot be figured out.

CONCLUSION

The study did not found any substantial impact of Vitamin-D supplementation on plasma glucose and on metabolic or endocrine parameters but during OGTT plasma glucose was found to be reduced after 1 hour.

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