Project Report of UGC Minor Research Project No :23-1181/09(WRO)

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Title:- Diet and Chromium Supplementation as a treatment approach in Women with Polycystic Ovarian Syndrome

Duration of the study:- 2009-2010, 2010—2011

Amount Sanctioned:- Rs. 1,54,900/-

The project assessed different aspects of incidence of PCOS in young women with associated risks of metabolic syndrome, thyroid disorders, insulin resistance and also looked at therapeutic approach by diet modification, exercise ,and supplementation with Chromium piconilate.

The results are presented as follows:

PCOS is the most common endocrine disorder observed in women of reproductive age and a major cause of infertility. The cause of PCOS is not very clear but there is growing evidence of insulin resistance as a common finding.

Objectives: To study the effect of diet modification and chromium supplementation in management of PCOS.

Methodology: 60 women with PCOS and insulin resistance were divided into 3 groups:

Control group 1: Participants not on any medicines

Control group 2: Participants on biguanides (orally, 500mg/2 times a day)

Experimental group: Participants supplemented with chromium picolinate (orally, 200µgm/day)

Three groups were prescribed same diet modifications.

Result: 43.33 % of these women reported the presence of PCOS in the family.

Acanthosis nigricans was seen in 66.66% of the women. At the end of 4 months, the HOMA-IR decreased non significantly in the control group 1, significantly in control group 2 and experimental group. Thus, diet modification as an isolated therapy does not

appear to positively affect the insulin resistance. Whereas, chromium picolinate appears as effective as insulin sensitizer as they showed a similar decrease in HOMA-IR.

On the other hand, nutrition therapy affects other aspects of PCOS like reducing hyperandrogenism as reflected by a similar decrease in Free Androgen Index (FAI) in all 3 groups.

Women in all 3 groups also showed a significant decrease in weight, body fat% and waist circumference and BMI. However, there were no significant differences between the groups for body composition changes. It appears that diet modification may be responsible for these changes also.

Many amenorrheic women initiated menses, thus reflecting that PCOS was being managed and the ovarian effect for the same was being displayed. 9 women also achieved pregnancy after a weight loss of 4.5 to 5% of their initial weight.

Conclusion: These results demonstrated that in absence of national guidelines for managing PCOS, the health professionals should adopt integrated medical nutritional approach. This study provides basic information for better management of PCOS and demonstrates that nutrition should be mainstay of treatment. But for managing the insulin resistance, chromium supplementation seems to an effective treatment. However chromium needs to be studied for its long term side effects.

CONCLUSION:

These results from different dimensions i.e. anthropometric, biochemical and nutritional provides a rationale for employing different therapeutically options according to the existing condition in the women with PCOS and the required outcomes in the long-term, as PCOS is an umbrella with varied clinical and biochemical presentation. No two women have exactly the same symptoms (Balen A., 2004). A result that directs us

towards diagnosis of insulin resistance is that all women with biochemically identified insulin resistance may not particularly manifest acanthosis nigricans, a clinical sign of insulin resistance. Thus it may happen that an insulin resistant woman may go undiagnosed. Acanthosis nigricans thus can be an aid in screening but not a confirmed successful tool in all PCOS women with insulin resistance. The family history revealed that 43.33% of the women had existence of PCOS in the female relatives (mother/sister/grandmother). Thus family history can be an important predictive factor for PCOS and provide a chance of early management of PCOS.

The effort of this study draws us to the conclusion that for decreasing insulin resistance in women with PCOS chromium supplementation seems to be as effective as metformin (biguanide). The effect of chromium seen was at 200 microgram, however dose of chromium could be increased to 400, 600 and 1000 microgram depending on the level of insulin resistance and weight of the women. Though Chromium supplementation is an established line of treatment for NIDDM and it has shown positive results in PCOS patients, there is need for long term studies to determine the impact of chromium and its side effects in PCOS patients.

On the other hand, lifestyle modification as an isolated therapy does not seem to decrease the insulin resistance. But it does affect other aspects of PCOS like reducing hyperandrogenism as reflected by Free Androgen Index (FAI). It also changes the body composition favourably by decreasing the body fat along with the decrease in weight. Thus it uplifts the morale and self image of the women. Diet therapy can also form basis for other therapies as doses of many medications used today for management of PCOS are weight specific. Thus reducing the weight before starting the biguanide or chromium therapy may help the therapy to be more effective. However lifestyle modification may be associated with compliance problem in the patients. It was also interesting to observe

that many amenorrheic women initiated menses and towards the end of the study all the women on chromium picolinate and metformin had established a pattern of menstrual cycle. Thus reflecting that PCOS was being managed and the ovarian effect for the same was being displayed. 9 women also achieved pregnancy after a weight loss of 4.5 to 5% of their initial weight, thus bestowing the power of conceiving that was initially robbed by an unmanaged PCOS. After all, 'To be pregnant is to be vitally alive and thoroughly woman.' ~ Anne Buchanan & Debra Klingsporn. To sum up, the data demonstrates that nutrition should be the mainstay of treatment as it manages or positively improves a number of factors co existing in PCOS. However one should have diet modification approach integrated with other treatment strategies appropriate and specific to the existing condition, as it is very rightly said by *Prof. Norman* that *"Lifestyle modification is treatment – it is not avoiding treatment".*

Clinicians should be cautious in providing treatments or drugs. Absence of national guidelines makes it difficult to determine the treatment approach to be adapted.

The viscous cycle of PCOS and its outcome can be cracked with an integrated medical nutritional tactic which is the need of the hour as many women in reproductive age are affected with PCOS.

Polycystic Ovary Syndrome and thyroid dysfunction, the two endocrine anomalies have been linked to each other since several years, however most of the researchers have investigated the association between hypothyroidism and PCOS, an inverse relationship of PCOS leading to thyroid dysfunction is now being probed into. Thus this study aimed at looking into the possibility of development of thyroid dysfunction in women with PCOS. The other aspect of the study was to evaluate whether the presence of thyroid dysfunction influenced the already existing characteristics of PCOS. 25 women with PCOS were recruited from a clinic in Mumbai and were subjected to a preformed

questionnaire and were analyzed for their anthropometric, biochemical and dietary factors. A within group assessment of the above parameters was made between the women with PCOS and thyroid dysfunction and the women with PCOS alone to determine differences between the two. The thyroid function and thyroid antibody tests revealed elevated levels of thyroglobulin antibody in 24% patients, elevated levels of TSH in 8% women, elevated levels of TSH and the antibody in 4% women and elevated levels of T3 and T4 in another 4% women thus indicating a 40% prevalence of thyroid dysfunction in the study group. However only 10% of these women had a family history of thyroid dysfunction. Women with PCOS and thyroid dysfunction had significantly higher levels of TgAb ($t=1.803$, $p=0.05$), TSH ($t=6.361$, $p<0.05$) and LH: FSH ratio ($t=1.806$, $p<0.05$). No other parameters showed significant differences. Thus women with PCOS could be at a risk for development of thyroid disorders. And biochemical screening of all the thyroid parameters including that of thyroid autoantibodies is of utmost importance in such individuals as those with both PCOS and thyroid dysfunction may not show any obvious differences in the symptoms from their PCOS counterparts.

Few studies have determined metabolic syndrome incidence in women with and without PCOS and further research is required (Moran, Misso, Wild, Norman, 2010). Women with PCOS have many metabolic complications; metabolic Syndrome being a major threat. This study was an attempt to understand the risk and prevalence of metabolic syndrome in women with PCOS.

The study revealed a significant difference in the biochemical parameters, although other indictors of metabolic syndrome like WHR, Blood Pressure did not show a significant difference. Hyperinsulinemia often observed in women with PCOS was absent, which may be due to the age of the subjects. The participants were young with a mean age of 25.52 ± 4.94 years. Hence full blown consequences of PCOS like

hyperinsulinemia, insulin resistance might have possibly not set in as yet. But this does not rule out the possibility of future risk.

When women with PCOS were considered individually and screened for metabolic syndrome on the basis of NCEP, ATP III criteria, it was found that 50% of women were positively identified with metabolic syndrome, indicating a high prevalence of metabolic syndrome, while the remaining 35% of women with PCOS although did not fall into the category of metabolic syndrome, they had signs of possible progression to metabolic syndrome in near future, if immediate lifestyle modifications were not initiated.

The morbidity of metabolic syndrome & diabetes is well known. Therefore, all young women with PCOS should be screened for diabetes and metabolic syndrome and followed closely. Clinicians need to be aware of the risk factors for PCOS and intervene with a preventive approach of dietary and life style modifications, which may restore normal menstrual function, ovulation, and fertility for those desiring it. The prevention of the vicious cycle of PCOS and metabolic syndrome or limit the complications from which PCOS patients suffer, such as cardiovascular disease, diabetes mellitus, and increased risk for unopposed estrogen in necessary. In women desirous of fertility this takes on an even greater importance and should be a major facet of pre conceptional counseling.

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