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Metabolic Risk Assessment in Patients with and without Polycystic Ovarian Syndrome - A Cross Sectional Study

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ABSTRACT

Background and purpose of the study: Polycystic ovary syndrome (PCOS) is a hormonal disorder common among women of reproductive age. There is a greater risk of metabolic syndrome in women with PCOS imply on elevated risk for the development of cardiovasculardiseases. This study aimed to assess the metabolic risk between PCOD and non PCOD patients.

Methodology: It's a cross sectional study conducted among 57 PCOD and 68 Non PCOD patients in the Obstetrics and Gynaecology. Females above the age of 23 years were included. The data were collected from patients with their consent through an interview method based questionnaire is used to assess the metabolic risk factors among patients with and without PCOD. The collected data were analyzed with IBM.SPSS statistics software 23.0 version.

Results & Discussion: This study was conducted in 57 PCOD and 57 non PCOD patients, among 57 Non PCOS patients 17.5 % of patients were found to be at metabolic risk and 82.5% of patients were not at risk. Among 57 PCOS patients, 87.7 % of patients were found to be at metabolic risk and 12.3 % of patients were not at risk.

Conclusion: The result of this study concludes that women with PCOS have nearly 6 fold higher metabolic risk when compared with non-PCOS patients. These findings support the idea that PCOS should be consider a general health disorder with serious health implication and indicate that physician should comprehensively screen all women with PCOS for the metabolic risk.

Keywords: Metabolic syndrome, PCOS & non-PCOS patients, elevated body mass index, waist hip ratio, lipid profile, blood glucose and irregular menstrual cycle.

Introduction

Polycystic ovary syndrome (PCOS) is a condition that causes Ovulatory & Menstrual irregularity sub fertility and infertility, clinically evident hyperandrogenism and metabolic dysfunction in women. The lack of ovulation alters levels of estrogen, progesterone, FSH, and LH. Estrogen and progesterone levels are lower than usual, while androgen levels are higher than usual. Extra male hormones disrupt the menstrual cycle, so women with PCOS get fewer periods than usual [1].

The cause of obesity in the polycystic ovary syndrome remains unknown, but obesity is present in at least 30 percent of cases; in some series, the percentage is as high as ^[3]. Increased adiposity, particularly visceral adiposity that is reflected by an elevated waist circumference (>88 cm) or waist-to-hip ratio, has been associated with hyperandrogenaemia, insulin resistance, glucose intolerance, and dyslipidemia [2].

Most women with the polycystic ovary syndrome are able to compensate fully for their insulin resistance, but a substantial proportion have a disordered and insufficient b-cell response to mealsor a glucose challenge [3-6, 8]. Before the development of frank glucose intolerance, defects in insulin secretion may be latent and revealed only in circumstances that augment insulin resistance, as with the development of gestational diabetes in pregnancy or glucose intolerance associated with glucocorticoid administration [7].

Hypertension develops in some women with the polycystic ovary syndrome during their reproductive years, [9 - 10] and vascular endothelial dysfunction were noted in most, but not all, studies of women with the polycystic ovary syndrome [11 - 13]. Insulin-lowering therapies appear to improve the vascular endothelial dysfunction in patients with the syndrome polycystic ovary [14]. Hypertriglyceridemia, increased levels of very lipoprotein low-density and low-density lipoprotein cholesterol, and decreased levels of high-density lipoprotein cholesterol [15] also predispose patients to vascular disease in the polycystic ovary syndrome. Both insulin resistance and hyperandrogenaemia contribute to this atherogenic lipid profile. Testosterone lipoprotein lipase decreases activity in abdominal fat cells, and insulin resistance impairs the ability of insulin to exert its antilipolytic effects. Although these abnormalities would be expected to increase the morbidity and mortality from coronary artery disease and other vascular disorders in women with the polycystic ovary syndrome, this has been difficult to establish [16-18]. The assessment of the glycemic component of the metabolic syndrome in NHANES III, the cornerstones of treatment are management of weight and ensuring appropriate levels of physical activity." Lifestyle modification (diet and increased physical activity) may delay or prevent the development of metabolic syndrome [19-23].

Methodology

Study Design, Study Period and Study Populations

It's a Cross-sectional was study conducted to assess the metabolic risk in patients with and without PCOS in the in the Obstetrics and Gynaecology department, Sri Ramachandra Medical and Hospital for the period of 6 months.

Patient Selection criteria

Age > 23 years in Females with metabolic syndrome like thyroid disorders, diabetes, coronary heart disease, dyslipidemia, obesity and hypertension. For PCOD Patient Diabetes, Obese - BMI \geq 27.5 Kg/m2, Irregular Menstrual cycle, Thyroid Disorder, Dyslipidemia, Blood pressure &For Non -PCOD Patient - does not contain classical signs and symptoms of PCOD such as acne, facial hair growth, increases in weight, thinning of hair. Pregnant women, patients with psychiatric co morbidities, hypothyroidism and not willing to give informed consent were excluded from this study.

Sample size

The sample size was determined by using IBM.SPSS statistics software 23.0 Version with a power of 80 and the confidence interval level, 95 %, the calculated sample size was 57 patients in each group.

Ethical Approval

This study protocol is approved by the institutional ethics committee (IEC) before the commencement of the project. IEC No: CSP/19/NOV/81/412.

Data collection Procedure

The patients with and without PCOD will be interviewed with the questionnaire in the Department of Obstetrics and Gynaecology which includes both inpatients and out patients in G Block. Assessment of patient with and without PCOD by using Rhinessa women's questionnaire. It includes information regarding menstruation and menstruation related issues, gynecological problems & hormonal treatments. Assessment of metabolic risk by using Risk factors assessment and screening procedures which includes body mass index, Cholesterol level, blood pressure, waist hip ratio and sugar level.

Software used for analysis

The collected data will be analyzed with IBM SPSS statistic software 23.0. To describe about the data, descriptive statistic frequency analysis and percentage analysis categorical variables will be used. The mean and Standard deviation will be planned for continuous variables.

Data analysis and interpretation

The collected data were analyzed with IBM. SPSS statistics software 23.0 version. To

describe about the data, descriptive statistics frequency analysis, and percentage analysis were used as categorical variables, the mean & S.D were used as continuous variables. To find the significant difference between the bivariate samples in independent groups the unpaired sample t-test was used. We used Levens test to assess the equality of variance among the groups. To assess the relationship between the variables, pearson's correlation wasused. In both the above statistical tools the probability value of less than 0.05 is considered as significant level.

Results

S.No.	Metabolic RiskFactors	Total number of patients in groups (n=114)			
		Non- PCOD	PCOD	Р	
		(n=57)	(n=57)	Value	
	Systolic	BloodPressure (mn	nHg)		
1	<120	50 (87.7)	48 (84.2)	0.333	
2	120-139	1 (1.8)	0		
3	140-159	6 (10.5)	9 (15.8)		
	Diastolic	Blood Pressure (mr	nHg)		
4	<80	51 (89.4)	48 (84.2)		
5	>80	6 (10.5)	9 (15.8)	0.233	
	Tota	al cholesterol (mg/dl))	L	
6	<200	53 (.0)	31 (54.3)		
7	>200	4 (7)	26 (45.6)	0.042	
	Randor	n Blood Glucose (mg	g/dl)		
8	<200	55 (96.4)	48 (84.2)	0.022	
9	≥200	2 (3.5)	9 (15.8)	-	
Fasting Blood Sugar(mg/dl)					
10	<110	55 (96.4)	48 (84.2)	0.002	
11	110-125	3 (5.2)	9 (15.8)		
12	>126	2 (3.5)	0		
Postprandial Blood Glucose (mg/dl)					
13	<140	53	48 (84.2)	0.002	
14	140-199	2 (3.5)	9 (15.8)		
15	≥200	2 (3.5)	0		

 Table 1: Metabolic risk in non PCOD and PCOD patients

BMI					
16	<18.5	4 (7)	1 (1.8)		
17	18.6-22.9	44 (77.2)	12 (21.1)	0.031	
18	23.0-24.9	4 (7)	15 (26.3)	0.031	
19	25.0-29.9	2 (3.5)	18 (31.6)		
20	>30	3 (5.3)	11 (19.3)		
W/H Ratio					
21	<0.85	49 (86)	6 (10.5)	0.043	
22	0.86-0.90	3 (5.3)	0		
23	0.91-0.95	2 (3.5)	0		
24	>0.95	3 (5.3)	51 (89.5)		
Stress					
25	Yes	3 (5.2)	7 (12.3)		
26	No	54 (94.7)	50 (87.7)	0.003	

Table 2: Symptoms associated with metabolic syndrome in PCOS and non PCOS patients

S.No	Symptoms	Total number of patients in groups (n=114)		
		Non- PCOD	PCOD	
		(n=57)	(n=57)	
1.	Facial hair growth	2 (3.5)	28 (49)	
2.	Acne	17 (28.8)	39 (68.4)	
3.	Weight gain	13 (22.8)	42 (73.6)	
4.	Thinning of hair	0	7 (12.2)	
5.	>1 symptoms	21 (36.8)	47 (82.4)	

Table 3: Menstrual cycle for PCOD and non PCOD patients

S.No	Menstrual period	Total number of patients in groups (n=114)			
	(time interval)	Non- PCOD	PCOD	P value	
		(n -57)	(n-57)		
Interval between Periods					
1.	< 24 days	2 (3.5)	0		
2.	24-26 Days	7 (12.3)	1 (1.8)	0.031	
3.	27-29 Days	27 (47.4)	3 (5.3)		
4.	30-32 Days	14 (24.5)	0		
5.	33-35 Days	3 (5.2)	0		
6.	> 35 Days	4 (7)	53 (93.0)		
Periods in the Last 12 Months					
7.	Regular	50 (87.7)	4 (7)	0.004	
8.	Irregular	7 (12.3)	53 (93)		
Current Hormonal Treatments					
9.	Yes	5 (8.8)	21 (36.8)	0.026	
10.	No	52 (91.2)	36 (63.2)		

Discussion

Although many studies have demonstrated that the PCOS patients are at high risk of developing metabolic disturbances (Type II diabetes, Thyroid disorder) and cardiovascular disorders (Obesity, hypertension), it is difficult to estimate the prevalence and early detection of these risks in PCOS patients. This study was undertaken to clarify the relationship of metabolic risks in PCOS by comparing various parameters between PCOS and Non PCOS patients. The metabolic syndrome was defined by both lipid and non-lipid criteria that identify individual at increased risk for heart disease and Type II diabetes. We sought to identify and compare the factors that serve as predictors for the metabolic syndrome using data derived from groups having PCOS and Non PCOS patients.

The relevance of the study is in its attempt to provide insight regarding the risks developed by the PCOS patients and to focus on the early detection of risks in order to provide essential treatments rather treating the clinical signs and symptoms of PCOS patients.

This study included 114 patients who were enrolled from both outpatient and inpatient departments. In which 57 patients were found with PCOS and 57 patients were found with other gynecological problems. On comparing systolic blood pressure among 57 Non PCOS patients, 87.7% of patients had normal blood pressure and 1.8% of patients were found to be pre hypertensive and 10.5% of patients were found to have hypertension. Among 57 PCOS patients, 84.2 % of patients were found to have normal blood pressure, 15.8 % of patients were found to have hypertension. On comparing diastolic blood pressure, among 57 Non PCOS patients, 89.4% of patients were found to be normal and 10.5 % of patients were found to have hypertension.

Total cholesterol was compared between PCOS and Non PCOS patients. 100 % of Non PCOS patients were found to have normal level. Among PCOS patients, 71.9 % of patients were found to be normal and 28.1 % have abnormal levels. This is similar to the study conducted by Apridonidze T *et al.* [24] which concluded that there was a significant increase in total cholesterol among PCOS patients.

On assessing Diabetes, Random blood glucose (RBS), fasting blood glucose (FBS) and postprandial glucose (PPBS) levels were collected from the patient's case records. Among 57 Non PCOS patients, 96.4 % of patients were found to have normal RBS, FBS and PPBS.3.5 % of patients were found to be elevated levels. Among 57 PCOS patients, 84.2 % of patients were to have normal levels and 15.8 % of patients were found to have elevated RBS, FBS and PPBS. This is similar to the study by conducted Apridonidze T *et al.* [24] which reflects that there was high insulin resistance in patients with PCOS.

For the assessment of metabolic risk, obesity was used as a parameter in order to assess obesity, Waist hip ratio and BMI. On evaluating BMI, 7% of patients were found be lean, 77.2 % of patients were found to be normal, 7 % of patients were found to have overweight, 3.5 % of patients were classified as Obese I and 5.3 % of patients were classified as Obese II in Non PCOS group. Among 57 PCOS patients, 1.8 % of patients were to be lean, 21.1 % of patients were found to have overweight, 31.6 % of patients were classified as obese I and 19.3 % of patients was classified as obese II.

For W/H ratio, 86% of patients were found to have normal W/H ratio and 5.3% of patients were found to have increased W/H ratio in Non PCOS patients. Among 57 PCOS patients, 10.5 % of patients were to be normal, 89.5 % of patients were found to be have increased W/H ratio. This is similar to the study conducted by David A Ehrmann *et al.* [25] Apridonidze T *et al.* [24] and A Couto Alves *et al.* [26] and all these studies has shown that the PCOS patients who presented with the risk had obesity which is a predictor to assess the metabolic risks.

On comparing menstrual history among PCOS and Non PCOS patients, among Non PCOS patients, 36.8 % of patients were found to have irregular periods and 63.2 % of patients were found to have regular periods. Among PCOS patients, 93 % of patients were found to have irregular periods and 7 % of patients were found to have regular periods. On assessing stress, 12.3% of PCOS are found to be in stress. Eventually on assessing risk, among 57 Non PCOS patients 17.5 % of patients were found to be at risk and 82.5 % of patients were not at risk. Among 57 PCOS patients, 87.7 % of patients of them were found to be risk and 12.3 % of patients were not at risk (Table 1). Acne, facial hair growth and weight gain are the major symptoms seen in the PCOS patients. Majority of the PCOS patients observed with > 1symptoms (Table 2). 47.4 % of Non PCOS patients were found to have interval of 27-29 days between each menstrual cycle. 93 % of PCOS patients were found to have interval of more than 35 days between each menstrual cycle.87.7% of Non PCOS patients were found to have regular periods for the past one year. 93% of PCOS patients were found to have irregular periods for the past one year. 8.8% of Non PCOS and 36.8% of PCOS patients were on hormonal treatments. (Table 3). This study result shows the comparison of high risk score like waist /hip ratio, BMI, cholesterol level, blood glucose profile and stress. Thus, this risk score not only identify patients who are at high risk of developing metabolic risk and also stratify patients who are at verge of developing PCOS related metabolic outcomes.

Conclusion

Polycystic ovary syndrome (PCOS) is recognized as one of the most common endocrine/metabolic disorders in women. The relevance of the study is in its attempt to provide insight regarding the risks developed by the PCOS patients and to focus on the early detection of risks in order to provide essential treatments rather treating the clinical signs and symptoms of PCOS patients. Despite of all findings, this study concludes that, women with PCOS represent a population with a high incidence of metabolic disturbances and metabolic risk when compared with Non PCOS patients. The sign and symptoms, comorbidities, elevated body mass index, waist hip ratio, lipid profile, blood glucose and irregular menstrual cycle was significantly more frequent in PCOS patient. Therefore, PCOS does appear to increase the risk of MetS dependent of obesity. These findings support the idea that PCOS should be consider a general health disorder with serious health implication and indicate that physician should comprehensively screen all women with PCOS for the metabolic risk.

Declarations

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Conflict of interest: No conflict of interest

References

- 1. Christian, Dumesic, Behrenbeck, Oberg, Sheedy 2nd, Fitzpatrick. Prevalence and predictors of coronary artery calcification in women with polycystic ovary syndrome. J Clin Endocrinol Metab 2003;88(6): Page no. 2562-68.
- Talbott, Zborowski, Rager, Boudreaux, Edmundowicz, Guzick.Evidence for an association between metabolic cardiovascular syndrome and coronary and aortic calcification among women with polycystic ovary syndrome. J Clin Endocrinol Metab 2004;89(11): Page no. 5454 - 56.
- 3. Azziz R, Ehrmann D, Legro RS, et al. Troglitazone improves ovulation and hirsutism in the polycystic ovary syndrome: a multicenter, double blind, placebocontrolled trial. J Clin Endocrinol Metab 2001;86: Page no. 1626-32.
- Ehrmann DA, Sturis J, Byrne MM, Karrison T, Rosen field RL, Polansky KS. Insulin secretory defects in polycystic ovary syndrome: relationship to insulin sensitivity and family history of non-insulin-dependent diabetes mellitus. J Clin Invest 1995; 96: Page no. 520-26
- O'Meara NM, Blackman JD, Ehrmann DA, et al. Defects in beta-cell function in functional ovarian hyperandrogenism. J Clin Endocrinol Metab 1993; 76: Page no. 1241-7.
- Ehrmann DA, Breda E, Cavaghan MK, et al. Insulin secretory responses to rising and falling glucose concentrations are delayed in subjects with impaired glucose tolerance. Diabetologia 2002; 45: Page no. 509-17.
- 7. Ehrmann DA, Breda E, Corcoran MC, et al. Impaired beta-cell compensation to dexamethasone-induced hyperglycemia in

women with polycystic ovary syndrome. Am J Physiol Endocrinol Metab 2004;287: Page no. 241-246.

- Dunaif A, Finegood DT. b-cell dysfunction independent of obesity and glucose intolerance in the polycystic ovary syndrome. J Clin Endocrinol Metab 1996; 81: Page no. 942- 45
- 9. Glueck CJ, Papanna R, Wang P, Goldenberg N, Sieve-Smith L. Incidence and treatment of metabolic syndrome in newly referred women with confirmed polycystic ovarian syndrome. Metabolism 2003;52: Page no. 908-15.
- Zimmermann S, Phillips RA, Dunaif A, et al. Polycystic ovary syndrome: lack of hypertension despite profound insulin resistance. J Clin Endocrinol Metab 1992; 75: Page no. 508-13.
- Kelly CJG, Speirs A, Gould GW, Petrie JR, Lyall H, Connell JMC. Altered vascular function in young women with polycystic ovary syndrome. J Clin Endocrinol Metab 2002; 87: Page no. 742-6.
- 12. Paradisi G, Steinberg HO, Hempfling A, et al. Polycystic ovary syndrome is associated with endothelial dysfunction. Circulation 2001; 103: Page no. 1410-15.
- 13. Paradisi G, Steinberg HO, Shepard MK, Hook G, Baron AD. Troglitazone therapy improves endothelial function to near normal levels in women with polycystic ovary syndrome. J Clin Endocrinol Metab 2003; 88: Page no. 576-80.
- 14. Orio F Jr, Palomba S, Cascella T, et al. Early impairment of endothelial structure and function in young normal-weight women with polycystic ovary syndrome. J Clin Endocrinol Metab 2004; 89: Page no. 4588-93.
- 15. Talbott E, Guzick D, Clerici A, et al. coronary heart disease risk factors in women with polycystic ovary syndrome. Arterioscler Thromb Vasc Biol 1995; 15: Page no. 821-6.
- 16. Wild S, Pierpoint T, Jacobs H, McKeigue P. Long-term consequences of polycystic ovary syndrome: results of a 31-year followup study. Hum Fertil (Camb) 2000; 3: Page no. 101-5.

- 17. Talbott EO, Zborowski JV, Boudraux MY. Do women with polycystic ovary syndrome have an increased risk of cardiovascular disease? Review of the evidence. Minerva Ginecol 2004; 56: Page no. 27-39.
- Legro RS. Polycystic ovary syndrome and cardiovascular disease: a premature association? Endocr Rev 2003; 24: Page no. 302-12.
- 19. Kawadzki JK, Dunaif A: Diagnostic criteria for polycystic ovary syndrome: A rational approach in Polycystic Ovary Syndrome. Cambridge, MA, Blackwell 1992; Page no. 377-384.
- Eriksson KF, Lindgarde F: Prevention of type 2 (non-insulin dependent diabetes mellitus by detailed physical exercise: The 6-year Malmo feasibility study. Diabetologia 1991; 34: Page no. 891-898.
- 21. Pan XR, Li GW, Hu YM, et al: Effects of diet and exercise in prevention NIDDM in people with impaired glucose tolerance: The Da Qing IGT and diabetes study. Diabetes Care 1997; 20: Page no. 537-544.
- 22. Tuomilehto J, Lindstrom J, Eriksson JG, et al: Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 2001; 344: Page no. 1343-1350
- 23. Hu FB, Manson JE, Stampfer MJ, et al: Diet, lifestyle, and the risk of type 2 diabetes in women. N Engl J Med 2001; 345: Page no. 790-797.
- 24. Apridonidze. Prevalence and characteristics of the metabolic syndrome in women with polycystic ovary syndrome. J clinical endocrinology and met 2005; 90(4): Page no. 1929-1935.
- 25. David A Ehrmann. Prevalence and predictors of the metabolic syndrome in women with polycystic ovary syndrome. J clinical endocrinology and met 2006; 91(1): Page no. 48-53.
- 26. Couto Alves. Metabolic profiling of polycystic ovary syndrome reveals interactions with abdominal obesity. International Journal of Obesity 2017; 41: Page no. 1331–1340