1. INTRODUCTION

1.1 Definition and clinical feature

Polycystic ovary syndrome (PCOS) is an exceedingly prevalent metabolic disorder and possibly constitutes the most frequently encountered endocrinopathy to affect women. There is considerable heterogeneity of symptoms and signs among women with PCOS, and for an individual these may change over time. The extreme end of the spectrum, once known as Stein-Leventhal syndrome, encompasses the combination of hyperandrogenism (hirsutism, acne, alopecia and elevated serum testosterone concentrations), severe menstrual disturbance (amenorrhea or oligomenorrhea) and obesity (Stein IF and Leventhal ML 1935).

Due to its heterogeneous nature both in clinical presentation and laboratory manifestations the definition of the syndrome has been much debated. At present most accepted Rotterdam polycystic ovary syndrome diagnostic criteria for the diagnosis of PCOS states 2 of the following 3 features needs to be present to make the diagnosis and to establish diagnosis it is important to exclude other etiologies with similar clinical presentation (congenital adrenal hyperplasia, androgen-secreting tumors, Cushing’s syndrome) (Rotterdam ESHRE/ASRM-Sponsored _ PCOS _ Consensus _ Workshop _ Group 2004).

These features include:

i. Oligo or Anovulation

ii. Clinical and/or biochemical signs of hyperandrogenism and

iii. Polycystic ovaries (either 12 or more follicles measuring 2–9 mm in diameter, or an ovarian volume of >10 cm$^3$) (Balen AH, Laven JS et al. 2003).

Diagnosis of PCOS can be made first looking at the clinical symptoms followed by laboratory assessment (Figure 1):

1. Clinical Features:
a) Menstrual irregularities which could be oligomenorrhea, amenorrhea, dysfunctional uterine bleeding, with or without infertility.

b) Hyperandrogenism clinically assessed with the presence of hirsutism, Acne and male pattern alopecia.

2. Laboratory evaluation:

a) Polycystic ovaries seen in ultrasound scanning as presence of multi-follicles throughout the ovary measuring 2–9 mm in diameter and/or increased ovarian volume higher than 10 ml in at least one ovary.

b) Biochemical abnormalities that may include elevated LH: FSH ratio >2, elevated free testosterone, increased serum levels of Anti mullarian hormone and Insulin resistance with compensatory hyperinsulinemia.

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**Figure 1: Diagnosis and symptoms of PCOS**

<table>
<thead>
<tr>
<th>Clinical Features</th>
<th>Laboratory Evaluation</th>
<th>Long term Morbidity</th>
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<tbody>
<tr>
<td>• Menstrual Dysfunction</td>
<td>• Ultrasound scan</td>
<td>• Infertility/misscarriage</td>
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<tr>
<td>• Clinical Hyperandrogenism (Hirsutism, Acne, Alopecia)</td>
<td>• Hyperandrogenism (↑testosterone)</td>
<td>• Obesity</td>
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<tr>
<td>• Acanthosis nigricans</td>
<td>• ↑LH/FSH ratio</td>
<td>• Dyslipidemia</td>
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<td>• Insulin Resistance (HOMA, Glucose:Insulin ratio, euglycemic glucose clamp)</td>
<td>• Cardiovascular disorders</td>
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<tr>
<td></td>
<td>• ↑Anti-Mullerian Hormone</td>
<td>• Psychological concerns</td>
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<tr>
<td></td>
<td></td>
<td>(stress, anxiety &amp; low quality of life)</td>
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1.2 Burden

1.2.1 Global Prevalence

The prevalence seems to vary widely in different countries. In USA, two studies that used NIH criteria had documented prevalence rates of 4 percent in a population of 400 women (Azziz R, Woods KS et al. 2004) and 6.6 percent in women from a southeastern university. (Knochenhauer ES, Key TJ et al. 1998) Prevalence amongst women from other races appears to be similar. A study on 154 Caucasian women in Madrid, Spain, also found similar
prevalence rates of 6.5 percent. (Asuncion M, Calvo RM et al. 2000) Thus, it appears that the prevalence of clinically evident PCOS in women of reproductive age in Europe and America ranges from 6.5 to 8.0 percent using the 1990 NIH criteria and it raises two to three folds if the Rotterdam criteria are applied.

1.2.2 Asian Prevalence

The prevalence in Asian countries appears to be lower with a reported prevalence of 2.4 percent in China (Chen X, Yang D et al. 2008) and 6.3 percent in Srilanka (Kumarapeli V, Seneviratne RD et al. 2008) (Rotterdam’s criteria). There are no studies that have reported the prevalence of PCOS in India although there are studies on metabolic and other abnormalities in patients with PCOS in India. (Kalra P, Bansal B et al. 2009) One study on Indian women living in England has shown a high prevalence of 52 percent which does not seem to reflect the true prevalence of PCOS. (Rodin DA, Bano G et al. 1998) There are reports that Indian patients with PCOS have higher fasting insulin levels and greater IR compared to British and Australian white women with PCOS. (Norman RJ, Mahabeer S et al. 1995), (Wijeyaratne CN, Balen AH et al. 2002)

Thus, PCOS is the most common endocrine abnormality of reproductive-aged women today, affecting anywhere between 2% to 26% of the population based on the criteria used and therefore potentially represents a significant financial burden to our health care.

1.2.3 Economic burden of PCOS

Azziz et al, through a systematic review of the published medical literature identified the total cost of evaluating and providing care to reproductive-aged PCOS women in the United States is $4.36 billion. They estimated the mean annual cost of the initial evaluation to be $93 million (2.1% of total costs), that of hormonally treating menstrual dysfunction/abnormal uterine bleeding to be $1.35 billion (31.0% of total), that of providing infertility care to be
$533 million (12.2% of total), that of PCOS-associated diabetes to be $1.77 billion (40.5% of total), and that of treating hirsutism to be $622 million (14.2% of total). (Azziz R, Marin C et al. 2005)

India being the second most populous country in the world, with over 1.21 billion people (2011 census), more than a sixth of the world's population. Already containing 17.5% of the world's population, India is projected to be the world's most populous country by 2025, surpassing China, its population exceeding 1.6 billion people by 2050. India has more than 50% of its population below the age of 25 and more than 65% hovers below the age of 35. It is expected that, in 2020, the average age of an Indian will be 29 years, compared to 37 for China and 48 for Japan. (Census Population and Census of India, Retrieved 18 December 2008) Therefore, it points out to the need for precautionary health modalities rather than setting up budgets for multi-symptomatic complex disorders such as PCOS.

1.3 Pathophysiology of PCOS

Although the etiology and pathogenesis are not yet clearly delineated several factors such as high serum LH levels and altered LH: FSH ratio have been observed in PCOS females for a long time. This imbalance results in the failure of dominant follicle selection and leads to accumulation of small antral follicles giving the appearance of Polycystic Ovaries (PCO). In case of PCOS female, after the normal follicular growth up to the mid-antral stage, the maturation ceases and follicle undergoes atresia. After “mid-antral arrest”, there is progressive accumulation of follicular fluid that results in expansion of the antrum. As follicle enlarges, the granulosa cell layer degenerates, appears like a thin-walled cyst.

Furthermore, it has been observed that the altered growth and selection of dominant follicle which is traceable to altered sensitivity to FSH, could be due to (a) increased LH action due to early LH receptor gain or excessive LH production (Jakimiuk AJ, Weitsman SR et al. 2001) and/or (b) excessive production of Anti Mullerian Hormone (AMH), a local
inhibitor of FSH action (Franks S 1995) that has been found elevated in PCOS. Serum AMH levels are positively correlated with androgen levels. Since AMH inhibits FSH-induced aromatase activity in human granulosa cells, it may contribute to the characteristic high androgen levels in PCOS women. (Franks S 1995)

1.4 Need for present study:

It has been shown that the effects on physical appearance, including obesity, hirsutism, cystic acne, seborrhea and hair loss can cause psychological distress and decreased quality of life, possibly by influencing feminine identity (Kitzinger C and Willmott J 2002). Several studies have shown that PCOS women suffer from marked reductions in quality of life, impaired emotional well-being, and reduced sexual satisfaction (Bruce-Jones W, Zolese G et al. 1993; Eggers S and Kirchengast S 2001; Sills ES, Perloe M et al. 2001; Trent ME, Rich M et al. 2002; Coffey S and Mason H 2003; Elsenbruch S, Hahn S et al. 2003; Hashimoto DM, Schmid J et al. 2003; Rasgon NL, Rao RC et al. 2003; Trent ME, Rich M et al. 2003; Schmid J, Kirchengast S et al. 2004; Weiner CL, Primeau M et al. 2004; McCook JG, Reame NE et al. 2005). Adolescent girls with PCOS, who are at the height of identity development and awareness of body image and concern with social acceptance, develop a more significant disturbance in mood that potentially precipitate depression and social phobia (Farrell K and Antoni MH 2010). Also, there are studies suggesting that chronic stimulation of sympathetic activity, a result of stressful life style, can induce dysregulation of the Hypothalamus-Pituitary-Ovarian axis (HPO axis) in women with PCOS (Diamanti-Kandarakis E 2009). This points to the need for stress management based life style changes that reduce sympathetic tone and influence the HPO axis. Also, insulin sensitizing agents, Metformin and Thiazolidinediones which have been used extensively in the treatment of PCOS with mixed results, have short term benefits and side effects such as nausea, diarrhea and abdominal cramps (Li XJ, Yu YX et al. 2011). This has triggered researchers and patients to seek help through alternative non pharmacological therapies.
Short-term weight-loss (through dieting) intervention studies in PCOS women have shown decrease in abdominal fat (Andersen P, Seljeflot I et al. 1995; Holte J, Bergh T et al. 1995), hyperandrogenemia (Holte J, Bergh T et al. 1995), and lipid profile (Andersen P, Seljeflot I et al. 1995) with improved insulin sensitivity (Andersen P, Seljeflot I et al. 1995; Holte J, Bergh T et al. 1995). Also, addition of aerobic or combined aerobic-resistance exercise to an energy-restricted diet, improved body composition with no additional effect on insulin resistance and lipid profile (Thomson RL, Buckley JD et al. 2010). A more recent review of all exercise therapies (aerobics/or resistant) in PCOS showed that the most consistent improvements included improved ovulation, reduced IR and weight loss (Harrison CL, Lombard CB et al. 2011).

Yogic life style, a form of holistic mind-body medicine, developed thousands of years ago, is known to reduce stress (Sahajpal P and Ralte R 2000) and sympathetic tone (Manjunath NK and Telles S 2003 Jan). Although yoga as an intervention is not studied in PCOS, it is found to be effective in several associated conditions. Yogic intervention has shown to be effective in increasing insulin sensitivity (Chaya MS, Ramakrishnan G et al. 2008), reducing fasting blood glucose and improving lipid profiles (Singh S, Malhotra V et al. 2004). Improvement in quality of life has been observed in several chronic conditions such as chronic low backache (Tekur P, Chametcha S et al. 2010), osteoarthritis of knee joint (Ebnezar J, Nagarathna R et al. 2011), fibromyalgia (da Silva GD, Lorenzi-Filho G et al. 2007), rheumatoid arthritis (Haslock I, Monro R et al. 1994) and cancer (Raghavendra R, Nagendra HR et al. 2008).

Although there are studies which have shown the beneficial effects of yoga independently in many of the associated conditions of PCOS and also in reducing stress levels, to the best of our knowledge, there are no published studies on yoga in PCOS to-date. Hence the present study has been planned to study the efficacy of yoga in comparison to physical exercise intervention through a randomized control design in adolescent PCOS girls.