

Complete phenotypic and metabolic profiles of a large consecutive cohort of untreated Korean women with polycystic ovary syndrome

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Objective: To investigate the complete metabolic and phenotypic profiles of a large cohort of untreated, consecutively recruited Korean women with polycystic ovary syndrome (PCOS), for whom a registry for Korean women with PCOS was constructed.

Design: Observational study.

Setting: Three infertility clinics and 10 university hospitals.

Patient(s): Eight hundred sixty-five women with PCOS were recruited using the Rotterdam criteria.

Intervention(s): Standardized evaluation protocol and web-based case report form.

Main Outcome Measure(s): Metabolic and phenotypic profiles.

Result(s): The subjects with PCOS mainly consisted of young and nonobese women. The most problematic subjective symptom was menstrual disturbance or infertility, and, on average, the patients seemed to menstruate every 2 months. PCO morphology was observed in 96.5% of the patients. Although few women visited hospitals owing to HA symptoms alone, hirsutism was observed in one-third of the patients (33.9%) and half (47.4%) of the patients had biochemical HA. About one-fifth (20.1%) of the patients had generalized obesity, and one-third (33.2%) had central obesity. Prevalence of dyslipidemia, diabetes, hypertension, and metabolic syndrome were 35.7%, 3.5%, 4.0%, and 13.7%, respectively. Prevalence of prediabetes was 20.8%, and a substantial proportion of additional

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The first two authors contributed equally to this article.

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subjects with normal fasting plasma glucose or oral glucose tolerance tests were identified as having prediabetes by hemoglobin A_{1c} testing.

Conclusion(s): Our well-defined cohort provided comprehensive estimates of the features of metabolic and phenotypic profiles related to PCOS in Korean women. Further longitudinal follow-up studies are needed to investigate the changes in phenotypic and metabolic markers in this PCOS cohort. (*Fertil Steril*® 2014;101:1424–30. ©2014 by American Society for Reproductive Medicine.)

Key Words: Metabolic syndrome, phenotype, polycystic ovary syndrome, Rotterdam criteria, type 2 diabetes

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Polycystic ovary syndrome (PCOS) is one of the most common causes of endocrine dysfunction in women of reproductive age, with a prevalence that ranges from 11.9% to 19.9% by the Rotterdam criteria (1, 2). Metabolic disturbances, such as obesity, hypertension, dyslipidemia, insulin resistance, and glucose intolerance, are well-recognized clinical features of this syndrome. However, the available data depict considerable variation in PCOS phenotypes, and we reported that PCOS without hyperandrogenism (HA) is a more common phenotype in Korean women than in other populations (3–6). Phenotypic variation occurs even within the Asian populations, and South Asians in particular have a high prevalence of metabolic syndrome and a high risk of type 2 diabetes mellitus (4, 5).

Likewise, the phenotypic expression of this syndrome remains diverse, but to our knowledge, little is known about the basic and comprehensive data of Korean women with PCOS, such as PCOS-related symptoms, menstrual cycle pattern, prevalence of PCO morphology, lifestyle patterns, prevalence of metabolic abnormalities, and androgenic features. A registry for Korean women with PCOS was constructed at 13 reproductive endocrinology centers, and the current study focuses on a large cohort of untreated, consecutively recruited Korean women with PCOS.

MATERIALS AND METHODS

Subjects

From May 2010 to December 2011, women with PCOS were recruited at 13 centers in Korea; three were infertility clinics, and the remaining 10 were tertiary university hospitals. Standardized patient evaluation protocol was developed by investigators and was processed as a web-based case report form (CRF) using the data-management program iCReaT (<http://icreat.cdc.go.kr>), which was developed by the Korea National Institute of Health (KNIH; the flow-sheet and CRF are depicted in Supplemental Fig. 1 and the Appendix). The web-based CRF was 12 pages long (A4 size), and data entry was performed at each researcher's center. Validation of the entered data was done by both KNIH and the coordinating center (Seoul National University Hospital). All missing, extreme, and unsound input items were sent to each investigator as a query or a comment, and each investigator replied to the query and corrected errors if any.

A screening questionnaire was administered to determine eligibility, and among screened women ($n = 941$), 72 patients failed to meet eligibility criteria. Four patients declined to participate in the study, and 865 women with PCOS (18–40 years) were finally recruited using the Rotterdam criteria (7). Definitions of oligo- and/or anovulation, clinical and biochemical HA, and exclusion of other related disorders have been described elsewhere (3, 8, 9); a single investigator assessed the modified Ferriman–Gallwey (mF-G) score prospectively in 1,010 Korean women, and according to these data, a score of 6 or greater represented hirsute women in our population. Thus, clinical HA was defined as an mF-G score of 6 or greater (8). Biochemical HA was defined as an elevation of serum androgen levels beyond the 95% confidence limits measured in 89 ovulatory, nonhirsute controls who did not show PCO on ultrasound in our population (total T > 0.68 ng/mL, free T > 1.72 pg/mL, and free androgen index [FAI] > 5.36) (3). All patients with PCOS were screened to exclude hyperprolactinemia and thyroid dysfunction. Serum 17-hydroxyprogesterone (OHP) was also measured to exclude nonclassical adrenal hyperplasia, and if serum 17-OHP level was > 2 ng/mL, a repeat test was performed during the early morning follicular phase. Patients who showed continuous elevation of 17-OHP were excluded from the study group. To determine the distribution of the different PCOS phenotypes, patients with PCOS were divided into four subgroups: [1] the IM (irregular menstruation)/HA/PCO (polycystic ovary) group; [2] the IM/HA group; [3] the IM/PCO group; and [4] the HA/PCO group.

Information was collected by investigators at the time of the checkup related to smoking, exercise, medical disease diagnosed by physicians, and a history of cardiovascular disease, hypertension, diabetes, or dyslipidemia in a first-degree relative. The self-reported presence of acne was recorded, although no specific scoring system was applied. None of the patients with PCOS had taken combined oral contraceptives, lipid-lowering agents, or insulin sensitizers. The Institutional Review Board for human research of each of the centers approved this project, and written informed consent was obtained from each participant.

Clinical and Biochemical Measurements

Clinical variables, such as body weight, height, waist circumference, and blood pressure, were assessed in all of

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