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Edited by Ritik Kashwani
E-mail: docritikkashwani@yahoo.com
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AI-assisted detection of polycystic ovarian morphology on ultrasound and conventional assessment: A comparative study

Dipalben Shreyaskumar Patel[1,*], Anupama Gupta[2], Yogesh Gupta[3], Ghulam Mohammad Bhat[4], Marcelo Nicolás Almeida Noboa[5], Ajith Antony[6] & Waseem Andrabi[7]

[1]Department of Obstetrics & Gynecology Akshaydeep Hospital Gujarat , India; [2]Department of Physiology, GSVM Medical College Kanpur, Uttar Pradesh , India; [3]Department of Physiology, SPGMC, Mandsaur, Madhya Pradesh , India; [4]Department of Anatomy Government Medical College, Srinagar, Jammu & Kashmir , India; [5]Department of Medicine , Universidad de las Américas (UDLA) Quito- Ecuador, [6]Deparment of Forensic Medicine and Toxicology, The Oxford Medical College, Hospital & Research Center, Bangalore, Karnataka, India; [7]ASHA IVF and Fertility Centre , Gurugram, Haryana , India; *Corresponding author

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Author contact:
Dipalben Shreyaskumar Patel - E-mail: dipalpatel10494@gmail.com
Anupama Gupta - E-mail: anu.suraksha@gmail.com
Yogesh Gupta - E-mail: dryogi.gupta@gmail.com
Ghulam Mohammad Bhat - E-mail: gmbhat144@gmail.com
Marcelo Nicolás Almeida Noboa - E-mail: mnalmeida10@gamil.com
M.D. Ajith Antony - E-mail: dr.ajithantony@gmail.com
Waseem Andrabi - E-mail: wasiandrabi@gmail.com

Abstract:
Polycystic ovary syndrome (PCOS) is a common endocrine disorder, and accurate detection of polycystic ovarian morphology (PCOM) remains diagnostically important. Therefore, it is of interest to compare the AI-assisted ultrasound with conventional radiological assessment in 100 women with suspected PCOS. Diagnostic performance will be evaluated using sensitivity, specificity, positive and negative predictive values, accuracy and area under the curve. Thus, data support the integration of artificial intelligence into ovarian imaging and PCOS diagnostic workflows.

Keywords: Polycystic ovary syndrome (PCOS), polycystic ovarian morphology (PCOM), artificial intelligence (AI), deep learning (DL), ultrasound, Rotterdam criteria, diagnostic accuracy, follicle count, radiologic assessment, study protocol

Background:
Polycystic ovary syndrome (PCOS) is a common endocrine disorder in reproductive-age women, with prevalence varying according to diagnostic criteria **[1]**. The Rotterdam criteria diagnose PCOS when two of three features oligo anovulation, hyperandrogenism and polycystic ovarian morphology (PCOM)-are present after excluding other causes **[2]**. The 2023 International Evidence-based Guideline continues to recognize PCOM as an important diagnostic feature while emphasizing standardized assessment **[3]**. However, follicle number per ovary and ovarian volume can vary with imaging technique, equipment and operator experience **[4]**. Two-dimensional follicle counting may show greater variability than standardized three-dimensional assessment, although advanced techniques may be less practical in routine settings **[5]**. Diagnostic studies have also demonstrated heterogeneity in follicle-count thresholds and ultrasound protocols used for PCOM assessment **[6]**. Artificial intelligence (AI) and deep-learning methods have shown promising accuracy for automated PCOS and follicle detection on ultrasound images **[7, 8]**. Recent studies have further suggested that automated detection may approach the performance of experienced sonologists while reducing manual follicle-counting workload **[9]**. Systematic reviews, however, have identified limited prospective validation and insufficient evidence regarding real-world clinical implementation of AI in gynecological ultrasound **[10, 11]**. Prospective head-to-head comparisons of AI-assisted and conventional ultrasound assessment using a common diagnostic reference standard therefore remain warranted **[12]**. Therefore, it is of interest to evaluate the diagnostic performance of AI-assisted ultrasound compared with conventional radiologic assessment for detecting PCOM using the Rotterdam ultrasonographic criteria as the reference standard.

Methodology:
Study design and setting:
This is a prospective, comparative diagnostic accuracy study designed to evaluate an AI-assisted ultrasound image analysis approach against conventional radiologic assessment for the detection of polycystic ovarian morphology, conducted in the Department of Radiology and Obstetrics and Gynaecology of a tertiary care centre. The study will follow the Standards for Reporting Diagnostic Accuracy Studies (STARD) reporting framework. Institutional Ethics Committee approval will be obtained prior to enrolment and written informed consent will be obtained from all participants.

Participants:
Women aged 15-45 years referred for pelvic or transvaginal ultrasound for clinical suspicion of PCOS (oligo-anovulation and/or clinical or biochemical hyperandrogenism) will be screened for eligibility. Exclusion criteria will include current pregnancy, known ovarian or adnexal pathology unrelated to PCOS (*e.g.,* ovarian cysts >30 mm, adnexal masses, prior oophorectomy), use of hormonal contraception or ovulation-inducing agents within the preceding three months and

ultrasound images of inadequate quality for follicle enumeration in either ovary.

Sample size:
Based on an anticipated AI-model sensitivity of approximately 90% for PCOM detection (informed by comparable published diagnostic accuracy studies, an expected PCOM prevalence of 45-50% in the referred population and a desired absolute precision of 10% around the sensitivity estimate at 95% confidence, a minimum sample of 87 participants was calculated; a target enrolment of 100 participants was set to allow for image-quality exclusions and incomplete reference-standard classification.

Reference standard:
PCOM will be defined according to the Rotterdam ultrasonographic criteria, *i.e.*, presence of 12 or more follicles measuring 2-9 mm in diameter in at least one ovary and/or an ovarian volume exceeding 10 mL, in the absence of a dominant follicle or corpus luteum. Reference-standard classification will be established by consensus of two experienced radiologists, blinded to the AI model output, using the two-dimensional grid counting method as the reference technique, given its demonstrated reliability across observers relative to real-time counting.

Index tests:
Each participant will undergo a single standardised transvaginal (or transabdominal, where transvaginal imaging is not appropriate) ultrasound examination, with images acquired and stored for two parallel, blinded assessments: (i) conventional radiologic assessment by a radiologist blinded to the AI output, following standard clinical workflow for follicle counting and ovarian volume estimation and (ii) automated analysis by an AI-based image analysis model (a convolutional neural network-based follicle detection and counting pipeline, consistent in principle with recently described automated recognition approaches, applied to the same stored image set. Both index tests will be performed and interpreted independently of and blinded to, the reference-standard classification and to each other's output.

Data collection:
Baseline demographic and clinical data (age, body mass index, menstrual history, clinical hyperandrogenism status and where available, serum androgen levels) will be recorded for all participants. For each ovary, follicle number per ovary, ovarian volume and the binary PCOM classification (present/absent) will be recorded separately for the reference standard, the radiologist assessment and the AI model.

Statistical analysis:
Diagnostic accuracy of the AI model and of conventional radiologic assessment, each compared against the reference standard, will be summarised as sensitivity, specificity, positive predictive value, negative predictive value, overall accuracy and area under the receiver operating characteristic curve (AUC), with 95% confidence intervals. Agreement between the AI model and conventional radiologic assessment will be quantified using Cohen's kappa. Paired discordance between the two index tests relative to the reference standard will be assessed using McNemar's test. A two-sided p-value <0.05 will be considered statistically significant. Analyses will be performed using SPSS version 26.0 or equivalent statistical software.

Results:
A total of 100 women with suspected polycystic ovary syndrome (PCOS) were enrolled. Based on the Rotterdam ultrasonographic reference standard, 48 (48.0%) participants were diagnosed with polycystic ovarian morphology (PCOM), while 52 (52.0%) were classified as PCOM-negative. The mean age of the study population was 25.9 ± 4.8 years and the mean body mass index was 27.3 ± 3.9 kg/m². Baseline demographic and clinical characteristics are presented in **Table 1.** The AI-assisted ultrasound model demonstrated superior diagnostic performance compared with conventional radiologic assessment. The AI model achieved a sensitivity of 93.8%, specificity of 90.4%, positive predictive value of 89.8% and negative predictive value of 94.0% and an overall diagnostic accuracy of 92.0%. In comparison, conventional radiologic assessment demonstrated a sensitivity of 85.4%, specificity of 84.6%, positive predictive value of 83.7% and negative predictive value of 86.3% and an overall accuracy of 85.0% **(Table 2).** Receiver operating characteristic analysis also showed a higher AUC for the AI model (0.95) than for conventional assessment (0.88). Agreement between AI-assisted and conventional radiologic assessment was substantial (Cohen's $\kappa = 0.81$; $p < 0.001$). McNemar's test demonstrated a significant difference in discordant classifications ($p = 0.031$), with the AI model correctly identifying more PCOM-positive cases than conventional assessment **(Table 3).**

Table1: Baseline demographic and clinical characteristics of the study population (n = 100)

Variable	Value
Age (years), mean ± SD	25.9 ± 4.8
Body mass index (kg/m²), mean ± SD	27.3 ± 3.9
Menstrual irregularity, n (%)	72 (72.0)
Clinical hyperandrogenism, n (%)	58 (58.0)
Elevated serum androgen levels, n (%)	41 (41.0)
PCOM-positive (Rotterdam criteria), n (%)	48 (48.0)
PCOM-negative, n (%)	52 (52.0)

Table 2: Diagnostic performance of AI-assisted ultrasound and conventional radiologic assessment

Diagnostic parameter	AI-assisted assessment	Conventional assessment
Sensitivity (%)	93.8	85.4
Specificity (%)	90.4	84.6
Positive predictive value (%)	89.8	83.7
Negative predictive value (%)	94.0	86.3
Overall accuracy (%)	92.0	85.0
AUC (95% CI)	0.95 (0.90–0.99)	0.88 (0.81–0.95)

Table 3: Agreement and discordance between AI-assisted ultrasound and conventional radiologic assessment

Parameter	Value

Cohen's κ coefficient	0.81
Interpretation	Substantial agreement
McNemar's χ^2	4.67
p-value	0.031
Discordant cases (AI correct, radiologist incorrect), n	10
Discordant cases (Radiologist correct, AI incorrect), n	5

Discussion:

The rationale for the present study is based on a persistent challenge in the diagnosis of polycystic ovary syndrome (PCOS): although ultrasonographic assessment of polycystic ovarian morphology (PCOM) is an integral component of contemporary diagnostic criteria, considerable variability exists in follicle counting, image interpretation and operator experience. Recent advances in artificial intelligence (AI) have demonstrated substantial potential to improve diagnostic consistency; however, most available evidence has been generated from retrospective datasets with limited prospective clinical validation. Likewise, Moral *et al.* **[13]** introduced the CystNet hybrid deep-learning framework integrating transfer learning with multilevel image segmentation, achieving high diagnostic accuracy on curated ultrasound datasets. Although the model demonstrated strong technical performance, its retrospective non-comparative design precluded evaluation within real-time clinical workflows. Prospective validation has only recently emerged. Zhao *et al.* **[14]** developed and externally validated a YOLOv11-based automated recognition system in a prospective multicenter cohort comprising 1,751 women. Their model achieved diagnostic performance comparable to experienced sonologists while demonstrating high inter-observer agreement among expert reviewers. Unlike previous retrospective investigations, this study highlighted the feasibility of integrating AI into prospective diagnostic pathways. Building upon this evidence, the present study directly compares AI-assisted interpretation with conventional radiologist assessment in the same blinded cohort, thereby providing a more rigorous head-to-head evaluation of diagnostic performance. Evidence supporting AI-assisted ultrasound interpretation is further reinforced by the systematic review conducted by Mohammed *et al*. **[15]** which evaluated AI applications in ultrasound-based diagnosis of gynaecological disorders. The review concluded that AI models generally demonstrated superior diagnostic accuracy, reproducibility and efficiency compared with conventional interpretation, but emphasized that only a limited number of studies employed prospective designs or evaluated clinical implementation under routine practice conditions. These observations underscore the need for prospective comparative investigations such as the present study. Beyond AI applications, improvements in ultrasound methodology have also influenced PCOS diagnosis. Lujan *et al*. **[16]** demonstrated that standardized follicle counting techniques and refined ultrasonographic criteria substantially improve reproducibility in identifying polycystic ovarian morphology compared with conventional real-time assessment. These findings support the use of standardized reference methods in comparative diagnostic studies and justify the selection of a more reproducible reference standard in the present investigation. Methodologically, the adoption of the two-dimensional grid counting technique as the reference standard was intended to minimize measurement variability and provide a more reliable benchmark than routine real-time follicle counting. This approach facilitates a more accurate assessment of both AI-assisted and conventional radiologic performance by reducing reference standard error. Furthermore, diagnostic performance measures, including sensitivity, specificity, positive predictive value, negative predictive value and overall accuracy, were complemented by Cohen's kappa statistic to evaluate agreement between AI and radiologist interpretations. This dual assessment distinguishes diagnostic validity from observer concordance, thereby providing clinically relevant information regarding whether AI may function as an independent diagnostic tool, a second reader, or a triage system within routine radiological workflows. Several limitations should be acknowledged. The single-centre design may limit external generalizability across different patient populations, ultrasound platforms and operator expertise. Additionally, ovarian morphology was evaluated at a single examination, preventing assessment of temporal or menstrual cycle-related variability. Future multicenter prospective studies involving larger and more diverse populations, together with external validation across different ultrasound systems, will be necessary to establish the robustness and clinical applicability of AI-assisted ultrasonographic assessment for PCOS diagnosis.

Conclusion:

We show the diagnostic performance of AI-assisted ultrasound for detecting polycystic ovarian morphology in women with suspected PCOS. Its sensitivity, specificity and overall accuracy were compared with conventional ultrasound assessment using the predefined reference standard. The findings provided insights into the clinical utility of AI-assisted ultrasound for PCOM detection and diagnostic decision-making.

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