

Development of PCOD questionnaire original research

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ABSTRACT

Background: Polycystic ovarian disease (PCOD) is of clinical and public health importance, as it is very common, affecting up to one in five women of reproductive age, with 70% undiagnosed. ASRM/ESHRE criteria include ultrasound for diagnosis since 2003. Given limited diagnostic tools, a new PCOD scale or questionnaire is being developed to assess symptoms, aiming to enhance patient evaluation.

Objectives: The purpose of this study is to develop a new PCOD scale or questionnaire to assess patients, focusing on the symptoms of PCOD.

Methodology: 277 individuals received a Google Forms questionnaire, categorized into PCOD diagnosis and exclusion criteria, with 174 and 103 respondents respectively. Bio statistical analysis evaluated questionnaire reliability, content validity, sensitivity, and specificity.

Materials and methods: A Likert scale questionnaire, reviewed at Dr. B.R. Ambedkar Medical College, was sent to 277 women aged 18-45 via WhatsApp and email from August 1 to September 15, 2023. Bio statistical analysis on September 16, 2023, evaluated reliability, validity, sensitivity, and specificity, with 174 PCOD-diagnosed respondents

Result: The study confirmed the self-made PCOD diagnosis questionnaire's reliability (Cronbach's alpha: 0.890) and validity (96%). It showed high internal consistency and construct validity. Content validity met the satisfactory level at 96%. Sensitivity identified PCOD-positive cases, while specificity accurately detected PCOD-negative cases at 60.2%.

Conclusion: The study found that women using the self-made questionnaire for early PCOD diagnosis, can score up to 15.5 points, with surpassing 15.5 indicating a high likelihood of PCOD positivity.

Keywords: Early diagnosis, PCOD, Questionnaire

INTRODUCTION

In growing and evolved countries, the most common endocrine disorder in women of childbearing age is polycystic ovarian disease, affecting 5-10% of the population⁽²⁾. The disorder is associated with a variety of clinical features, including reproductive

disorders (infertility, hyperandrogenism, hirsutism), metabolic disorders (insulin resistance, glucose intolerance, type 2 diabetes), risk of cardiovascular events, and affects psychological

features ⁽¹⁾. The exact pathophysiology of PCOD is complex and largely unknown. PCOD may be misdiagnosed or underdiagnosed due to inconsistent diagnostic criteria, ignorance of medical professionals, and variability in her PCOD phenotype ⁽³⁾. Additionally, many women are unaware that they have PCOD and may not receive proper evaluation and treatment, putting them at risk for PCOD. ⁽¹⁾

The prevalence of PCOD has traditionally been estimated at 4-8% in studies in Greece, Spain, Australia, Asia, and the United States ⁽¹⁾. The prevalence of PCOD has increased with the use of different diagnostic criteria and was recently demonstrated to be 18% in the first community-based prevalence study based on current Rotterdam diagnostic criteria ⁽¹⁾. The main diagnostic steps to confirm PCOD are an ultrasound scan and a series of blood tests based on hormone levels ⁽³⁾. In addition, key clinical feature-based questionnaires and scales to identify PCOD would be useful in epidemiologic studies of female reproductive health ⁽³⁾. This is because such questionnaires can be distributed to large groups of women without the need for expensive hospital visits or diagnostic blood tests. The purpose of this study is to develop a scale or questionnaire to assess PCOD based on the first symptoms to assist women at risk of PCOD and increase public awareness of PCOD.

OBJECTIVE OF THE STUDY

The purpose of this study is to develop a new PCOD scale or questionnaire to assess patients, focusing on the symptoms of PCOD.

METHODOLOGY

Study design: survey study

Sampling method: purposive sample

Sample size: 277

Sample setting: online platform, via google forms.

MATERIALS AND METHOD

This self-designed questionnaire, employing a Likert scale, comprises five demographic questions, four preliminary questions, and 14 main questions related to PCOD symptoms. The 14 questions were formulated in reference to the Rotterdam criteria and existing PCOD-related questionnaires, covering topics such as irregular periods, weight gain, dermatological conditions, psychological symptoms, daily activities, and infertility, among others ⁽¹⁾. The questionnaire underwent a review process by experts in the field of obstetrics and gynaecology at Medical College and Hospital in Bengaluru, India on 19th July 2023. Suggestions provided by the experts were incorporated, and the final questionnaire was transformed into a Google Forms format. It was then distributed via WhatsApp and email to 277 women aged between 18-45 years, from 1st august 2023 to 15th September 2023 ensuring the consent from all participants. Out of this group, 174 women were diagnosed with PCOD, while 103 women were not diagnosed with PCOD. The collected data from the questionnaire were shared with a biostatistician on 16th September 2023 for statistical analysis to assess the reliability, content validity, construct validity, sensitivity and specificity of the self-designed questionnaire.

INCLUSION CRITERIA:

Age between 18 to 44 years
Women diagnosed with PCOD, not diagnosed with PCOD

EXCLUSION CRITERIA:

Age above 45
Post menopause

STATISTICAL ANALYSIS

Regarding the questionnaire instrument, Likert scale was employed. The rating required respondents to determine the level of a variable. The baseline data compares individuals with and without Polycystic Ovarian disease (PCOD) across key variables. On average, those with PCOD are younger (mean age 24.017 years) compared to those without PCOD (mean age 24.932 years). PCOD individuals tend to be shorter (average height 146.226 cm)

with greater variability, while non-PCOD individuals are taller (mean height 153.177 cm) with less variability. In terms of weight, PCOD individuals weigh more on average (mean weight 59.220 kg) with higher variability, whereas non-PCOD individuals weigh less on average (mean weight 54.068 kg) with lower variability. Age at menarche is also lower on average for PCOD individuals (mean age 13.063 years) compared to non-PCOD individuals (mean age 13.796 years).

Base line data		N	Mean	Std. Deviation
AGE	PCOD	174	24.017	5.883
	NO PCOD	103	24.932	5.375
HEIGHT	PCOD	174	146.226	51.876
	NO PCOD	103	153.177	16.979
WEIGHT	PCOD	174	59.220	17.718
	NO PCOD	103	54.068	10.766
AGE AT MENARCH	PCOD	174	13.063	2.006
	NO PCOD	103	13.796	1.599

Table 1: Showing baseline characteristics of the samples included

	Categories	PCOD		NO PCOD	
		Frequency	Percent	Frequency	Percent
Marital status	married	32	18.4	20	19.4
	unmarried	142	81.6	83	80.6
Occupation	a home maker	19	10.9	9	8.7
	student	116	66.7	85	82.5
	working womam	39	22.4	9	8.7
consult a doctor regarding your menstural abnormalities	No			97	94.2
	Yes	174	100.0	6	5.8
undergo ultrasound scan(USG) for the diagnosis of pcod	No			103	100.0
	Yes	174	100.0		

Table2:- Baseline

Among individuals with PCOD, 18.4% are married while 81.6% are unmarried, with 10.9% homemakers, 66.7% students, and 22.4% working women. Conversely, in the NO PCOD group, 19.4% are married, 80.6% unmarried, with 8.7% homemakers, 82.5% students, and 8.7% working women. Notably, all PCOD cases have consulted a doctor for menstrual irregularities, while 94.2% in the NO PCOD group have not sought medical advice, and only 5.8% have consulted a doctor. Additionally, all individuals with PCOD have undergone ultrasound scans for diagnosis.

RELIABILITY OF THE TOOL

In this study, a Cronbach's Alpha value of 0.878 suggests good internal consistency among the items, indicating that they reliably measure the same construct

CONSTRUCT VALIDITY

Exploratory factor analysis Result: The Kaiser–Meyer–Olkin measure of sampling adequacy is 0.890, well exceeding the minimum requirements for conducting Exploratory Factor Analysis. Factor loading represents the correlation coefficient between a variable and a factor, indicating the likelihood of variance explained as "not likely (1)," "somewhat likely (2)," and "very likely (3)." The data were subsequently analysed using SPSS 22 through Principal Component Analysis (PCA) to derive meaningful interpretations.

Questions	Factor loading
1) Do you have irregular period	0.593
2) Have you gained weight in last 3 months?	.777
3) Do you feel bloated often	.699
4) Is the fat around your abdomen more than other areas	.796
5) Do you have frequent facial acne	.603
6) Do you have excessive hairfall leading to baldness?	.544
7) Do you experience excessive hairgrowth on your body parts(on torso,on breast, on back ,on chin and upperlip	.733
8) Do you have dark patches around your neck, under arms,elbows or knuckles	.493
9) Do you feel hungry often	.842
10) Do you have constant craving for food	.788
11) Do you feel tired when you wake up in the morning	.749
12) Do you experience mood swings frequently	.662
13) Do you have lowerback pain frequently	.753
14) Do you exercise regulary?	.892

Table 3 Construct Validity

Most questions have factor loadings above 0.5, indicating a good correlation with the factor, except for Q8, which shows moderate correlation. The order of questions with high correlation to the factor is: Q14, Q9, Q4, Q10, Q2, Q13, Q11, Q7, Q3, Q12, Q5, Q1, Q6, and Q8.

CONTENT VALIDITY

Item level content validity index (96%) meet satisfactory level, and thus the scale of questionnaire has achieved satisfactory level of content validity.

Questions	inv1	inv2	inv3	inv4	inv5	inv6	Experts in agreement	I-CVI
1) Do you have irregular period	1	1	1	1	1	1	1	0.17
2) Have you gained weight in last 3 months?	1	1	1	1	1	1	6	1.00
3) Do you feel bloated often	0	1	1	1	1	1	5	0.83
4) Is the fat around your abdomen more than other areas	0	1	1	1	1	1	5	0.83
5) Do you have frequent facial acne	1	1	1	1	1	1	6	1.00
6) Do you have excessive hairfall leading to baldness?	1	1	1	1	1	1	6	1.00
7) Do you experience excessive hairgrowth on your	1	1	1	1	1	1	6	1.00

body parts(on torso,on breast, on back ,on chin and upperlip									
8) Do you have dark patches around your neck, under arms,elbows or knuckles	1	1	1	1	1	1	6	1.00	
9) Do you feel hungry often	1	1	1	1	1	1	6	1.00	
10) Do you have constant craving for food	1	1	1	1	1	1	6	1.00	
11) Do you feel tired when you wake up in the morning	1	1	1	1	1	1	6	1.00	
12) Do you experience mood swings frequently	1	1	1	1	1	1	6	1.00	
13) Do you have lowerback pain frequently	1	1	1	1	1	1	6	1.00	
14) Do you exercise regulary?	1	1	1	1	0	1	5	0.83	
Proportion relavance	0.86	1.00	1.00	1.00	0.93	1.00	5.79	0.96	

Table 4: - content validity

Test Result Variable(s): Total score

Area	Std. Error ^a	Asymptotic Sig. ^b	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.909	.018	.000	.874	.944

Table: - 5 Area under the curve

The Receiver operating characteristics (ROC) analysis evaluated the "Total score" variable's predictive performance for identifying Polycystic Ovarian disease (PCOD), yielding an Area under the curve (AUC) of 0.909, indicating strong discrimination between PCOD presence and absence. With a standard error of 0.018,

this AUC value provides a precise estimate of the variable's predictive ability. The highly significant p-value ($p = 0.000$) supports the "Total score" variable's statistical significance as a predictor of PCOD. The 95% confidence interval for the AUC is 0.874 to 0.944.

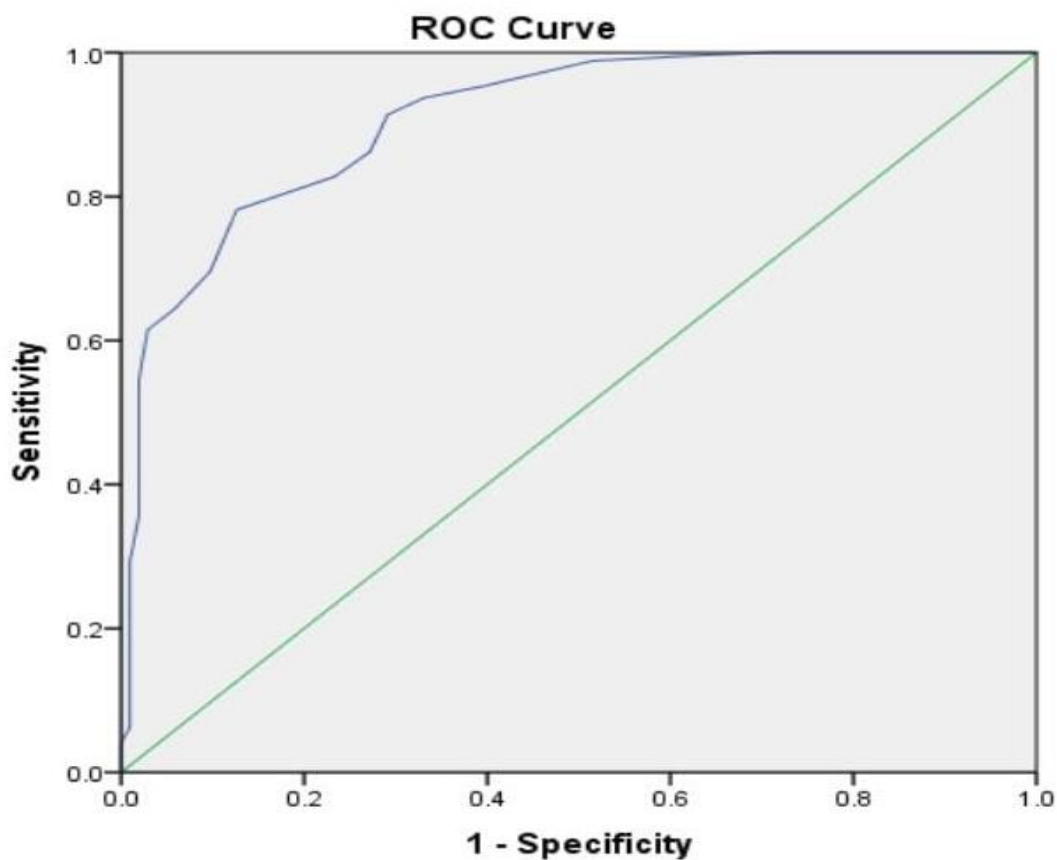


Figure 1: showing sensitivity and specificity

The sensitivity and specificity values, along with the specified cutoff value, provide additional insights into the performance of the diagnostic test for Polycystic Ovarian disease.

The sensitivity and specificity values, along with the specified cut off value, provide additional insight into the performance of the diagnostic test for PCOD.

Specificity: The specificity of 60.2% signifies that the test correctly identifies 60.2% of individuals who do not have PCOD. While this is relatively lower compared to sensitivity, it still suggests that the test has a moderate ability to correctly rule out PCOD in individuals without the condition.

Cutoff Value: The cutoff value of 15.5 is the threshold used to classify individuals into PCOD-positive or PCOD-negative groups based on the Total _score variable. Individuals with a Total _score above this cutoff is considered positive for PCOD, and those below are considered negative.

RESULT

Reliability of the tool: In this study, Cronbach's Alpha value of 0.878 suggests good internal consistency among the items, indicating that they reliably measure the same construct.

Construct validity: The Kaiser–Meyer–Olkin measure of sampling adequacy was 0.890, which is well above the minimum sampling adequacy requirements for conducting exploratory factor analysis.

Content validity: Item level content validity index (96%) meet satisfactory level, and thus the scale of questionnaire has achieved satisfactory level of content validity.

Sensitivity: The sensitivity value of 99.4% demonstrates the test's ability to accurately identify individuals with PCOD, reflecting a high true positive rate and effectiveness in detecting genuine case

Specificity: With a specificity of 60.2%, the test accurately identifies 60.2% of

individuals without PCOD. Although lower than sensitivity, it still indicates a moderate ability to rule out PCOD in those without the condition.

Cut off Value: The cut-off value of 15.5 distinguishes individuals into PCOD-positive or PCOD-negative groups based on the Total score variable. Scores above this threshold indicate PCOD positivity, while scores below signify PCOD negativity.

DISCUSSION

Polycystic Ovarian disease (PCOD) is a highly prevalent disorder, representing the single most common endocrine-metabolic disorder in reproductive-aged women. Polycystic ovarian disease is a highly inherited complex polygenic, multifactorial disorder. Women with PCOD are at increased risk for irregular menstrual cycle, hypertension, subfertility and Obstetric complications like endometrial atypia or carcinoma⁽⁴⁾ The prevalence rate of PCOD is high among Indian women.⁽⁵⁾ Because there was no Awareness or knowledge about PCOD in early stage and people are hesitant to disclose about PCOD. As ultrasound scan and Rotterdam criteria are the only two reliable tool for screening Of PCOD which is out of reach for most of the women in India, due to reasons like Socioeconomic status. As physiotherapist we assist women with PCOD diagnosed with their Weight loss exercise and physical activity regimen⁽⁶⁾, our aim was to develop a simple self-made questionnaire based on the major clinical symptoms of PCOD for feasible early Screening of PCOD.

This self-made questionnaire made using Likert scale pattern of 5 demographic questions, 4 Preliminary questions and 14 main questions related to PCOD symptoms in the following order irregular period, weight gain, mood swings, dermatological condition, infertility and so on this self-made questionnaire was then circulated among the experts in the field of Obstetrics

and gynecology from Dr.B.R. Ambedkar medical College and hospital Bengaluru, India for advice and review of the questionnaire. A few changes suggested by the experts Were made and then with their consent, questionnaire was circulated via Google forms to 277 women between the Age group of 18-45 years according to the inclusion and exclusion criteria, after which the samples were segregated to 174 women who were diagnosed with PCOD and 103 women who have not been diagnosed with PCOD further intervention the samples data collected was sent to the biostatistician for analysis of the self-designed questionnaire.

LIMITATION

Women are hesitant to disclose their medical conditions related to fertility and menstruation related problems.

RECOMMENDATION

1. Further study can be developed on individual domain of the symptoms determining diagnosis of PCOD.
2. A comparative study to detect PCOD in early stages using self-made PCOD questionnaire and ultrasound pelvic scan.

CONCLUSION

The study concludes that in the self-made questionnaire designed for early diagnosis of PCOD, women can achieve a maximum total score of 42. If the total score surpasses the cut-off value of 15.5, determined using the receiver operating curve, it is considered highly likely that the individual is positive for PCOD. In such cases, further medical interventions are recommended.

CONFLICT OF INTEREST

Authors declare no conflict of interest

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