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Development and Validation of Novel 'Polycystic Ovarian Syndrome' Diagnostic Questionnaire for the Females of Reproductive Age

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Abstract

Background: Polycystic ovarian syndrome (PCOS) is a complicated reproductive, metabolic, hormonal, and endocrine disorder that affects one in every five (20%) Indian women. As a result, detecting PCOS at a young age is critical. Currently, limited diagnostic tool exists to evaluate the risk and severity of PCOS in women of reproductive age. As a result, the focus of our research is on developing and evaluating the 'Novel PCOS diagnostic questionnaire', which will help both healthy people and PCOS patients determine their risk of getting PCOS and the severity of their illness respectively.

Method: Novel PCOS questionnaire was developed with questions related to demography, co-morbidity, symptoms, diet, and menstrual pattern. It was evaluated through theoretical validation, empirical validation, and reliability tests.

Results: The 'Novel PCOS diagnostic questionnaire' passes all the validation tests and it can be utilised further as diagnostic tool.

Conclusion: The preliminary development and validation of the Novel PCOS diagnostic questionnaire is highly relevant to be useful in the real-world. The validation of this questionnaire at a comprehensive spectrum is furtherly focussed.

Keywords: PCOS; validation study; questionnaire; risk and severity assessment

Abbreviations

PCOS- Polycystic ovarian syndrome, BMI- Body mass index, DHEA- Dehydroepiandrosterone-sulphate, ST- Serum testosterone, FT- Free testosterone, FSH- Follicle stimulating hormone, SHBG- Sex hormone binding globulin, FAI- Free androgen index, LH- Luteinizing hormone, TSH- Thyroid stimulating hormone, TPO-Ab- Thyroid-stimulating immunoglobulin antibody, FBG- Fasting blood glucose, FI- Free insulin, RBS- Random blood sugar, PPBS- Post prandial blood sugar, GI ratio- Glycaemic index, HOMA-IR- Homeostatic model assessment of insulin resistance, QUICKI- Quantitative insulin sensitivity check index, FBS/SI- Fasting blood glucose/Serum insulin, I-CVI- Item content Validity Index, S-CVI- Scale content Validity Index.

Introduction

PCOS is a hormonal or endocrine disorder which is common among the women who are in their reproductive ages [1]. The ovaries produce an excessively high number of androgens (male sex hormones), which are typically present in small amounts in women. This condition is typically regarded as a heterogeneous disorder [2, 3]. The polycystic ovarian syndrome is rightly called since it is marked by the presence of multiple tiny cysts (fluid-filled sacs) in the ovaries. However, not all women with this condition have cysts, and vice versa.

Amongst Indian adolescents, the general prevalence of PCOS is 9.13% [4], while in female with 15 to 19 year age and its prevalence is 22.6 percentage and 9.8 percentage as per Rotterdam criteria and AE-PCOS criteria respectively, which draws attention to the issue of early age occurrence [5]. Furthermore, the existence of diverse presenting signs and symptoms in different individuals makes it difficult for clinicians to diagnose PCOS.

The age of onset for PCOS is usually peri-menarchial (i.e., usually before 16 years of age). However, the diagnosis and clinical detection of the illness may be delayed as a result of the patient's failure to express concern over irregular menstruation, hirsutism, or any other symptoms. The syndrome may be unmasked in lean women with a genetic or hereditary predisposition to PCOS, when they subsequently gain weight [6]. Even after multiple healthcare visits, it remains undiagnosed in a large percentage of women. Also, despite being one of the major endocrine problems globally, PCOS is still not widely recognized as a serious health issue. Anovulation, microcysts in the ovaries, follicular development suppression, and irregular menstruation are all signs of hyperandrogenism, a clinical characteristic of PCOS [7].

After doing a thorough literature review, we discovered that there are a few questionnaires available that can predict the presence of PCOS. Predersen et al., for example, created a simple clinical instrument that can assist clinicians in diagnosing PCOS [8]. Second, Bedrick et al. designed a self-administering questionnaire to predict the presence of PCOS. Moreover, the most popular tool for assessing women with PCOS quality of life is the PCOSQ, a 26-item questionnaire [9].

Yet, currently, no diagnostic technique exists that can anticipate the severity of the PCOS condition. As a result, we embarked on this research project with the intention of benefiting society by making screening and diagnosis procedures for PCOS patients and the general community easier. Our Novel PCOS diagnostic questionnaire will assist both healthy people and patients in determining their risk of developing PCOS and the severity of their condition respectively. Hence the present study was conducted with a primary objective to develop and validate the 'Novel PCOS diagnostic questionnaire'. This questionnaire maybe helpful to determine the risk/severity of PCOS in women of reproductive age.

Materials and Methods

The primary objective of this research was to construct and validate the 'Novel PCOS diagnostic assessment questionnaire'

Development of the questionnaire

A comprehensive literature search was conducted to see whether any existing questionnaires for PCOS screening were available. There were various validated scientific questionnaires available for self-screening and evaluating PCOS patients' quality of life. The main downside was that no screening instruments or questionnaires were available to differentiate risk/severity into distinct categories such as mild, moderate, and severe. As a result, the 'Novel diagnostic questionnaire' capable of categorizing patients into these groups was developed and validated.

The questionnaire has 13 questions that were used to generate a score that was used to evaluate the participant. Each option selected by the participant has different score, varying from 0-3 (4-point Likert scale), thus the total score generated will depend on options selected by the participants. Here, 0 score denotes least risk and 3 score denotes the highest. Total score generated will be utilized to determine participant's risk/ severity level. The questionnaire has a total score of 39.

Aside from these 13 questions, participant's demographics, history, lifestyle choices, and lab data were collected, if available. This aided in a more accurate examination and analysis of the patient and the overall PCOS condition. The factors and parameters most associated with PCOS were addressed in our Novel questionnaire. The Novel questionnaire was designed to be filled by healthcare professionals i.e., it is an interviewing questionnaire.

All the questions listed in the questionnaire were filled via Google form. Prior to filling up the form, consent of each participant was taken on the participant consent form. 0, 1, 2 and 3 score was given for no risk, mild, moderate and high severity of PCOS. By default, the minimum score for all questions is 0. Interpretation of each question is described in ensuing paragraphs.

Many co-morbid conditions which act as risk factors have been reported to be significantly associated with PCOS. Hence, Question 1 is included in the questionnaire to identify all the risk factors previously diagnosed by healthcare professionals in participants. Maximum score for each sub-question is 3. It is further divided into 4 categories as:

Metabolic disorders (heart problem, high blood pressure ,diabetes, hyperlipidaemia, and hypoglycaemia) [10, 11]; psychiatric disorders (eating disorder, depression, anxiety, and sleep apnoea) [10, 12-14]; reproductive disorders (infertility and endometrial cancer/endometriosis) [10, 15] and others (bleeding or clotting disorder, stomach problems and thyroid problems) [16, 17].

Questions 4, 8, and 13 incorporate participant's personal information which includes participant's BMI [18, 19], sleep pattern [20, 21], smoking habit [22, 23]. Maximum score for this category of questions is 3.

Symptom based questions helps to determine the probable chances for development of PCOS and hence, questions 2, 9, 10, 11 and 12 were added in questionnaire to identify if the participant experiences any of the mentioned symptoms [1, 24-30]. Maximum score for each question in this category is 3.

It has been reported that diet [31-33] and exercise [34, 35] are major non pharmacological approaches for controlling the severity of PCOS. Hence, question 6 and 7 are intended to check the participant's dietary patterns with maximum score of 3 each; while question 3 and 5 were designed to examine participant's routine physical activity with maximum score of 3.

Menstrual irregularity is one of the most major and commonly seen symptoms in PCOS patients [26-28]. Therefore questions 11 and 12 were included in the questionnaire to check the participant's menstrual regularity. Maximum score for this category of questions is 3.

If available, apart from these questions, details regarding the ultrasound parameters and hormonal levels are also taken in the questionnaire, for the purpose of descriptive analysis only. Hormonal profile includes DHEA, ST, FT, FSH, SHBG, FAI, LH, Oestrogen, Progesterone, T3, T4, TSH and TPO Ab, FBG, FI, RBS, PPBS, GI ratio, HOMA-IR, QUICKI and FBS/SI. And, ultrasound profile includes no. of follicles, ovarian volume and size of cysts.

Evaluation of questionnaire

The questionnaire has a total score of 39. Higher the score, higher is the interpreted risk. The bifurcation of scoring range was based on pilot study results. The scoring was categorised in score 0-14, 15-23,24-34 and 32-39 for no, mild, moderate and high risk/severity respectively.

Validation Methods

The validity of any tool is ascertained how accurately it captures what it was intended to. The purpose of validation is to analyse whether the questionnaire is measuring what it is intended to measure of the evaluating parameters. The questionnaire was validated using different types of statistical approaches to ensure that it could be used effectively in the real world. Various methods for validating the questionnaire which were used are mentioned in Fig. 1.

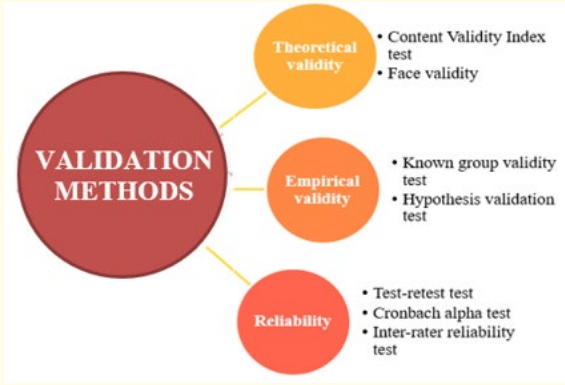

Figure 1: Validation methods for a questionnaire.

Theoretical validity

All the materials including validation report, consent form, questionnaire and all the details including description and interpretation of the questionnaire were provided to the experts for face and content validation. Following are the five stages for content and face validation process:

Step 1 Preparation of validation form

The drafting of a cover letter and response sheet is required to implement the validity form. The cover letter outlines the experts' roles in the assignment and the author's expectations. Name and address of author, brief study title and description, goal of study, and instructions to be followed were included in the cover letter. The rating scale, remarks, date of response and rater's name, qualification, years of experience, and profession were included on the response sheet.

Step 2 Selection of expert panel

Expert selection is critical for performing face and content validity; so, 12 experts were chosen who met the following criteria: a.) who had in-depth understanding of PCOS, b.) who had a minimum educational background of a PhD, & c.) who had a minimum of 2-3 years of teaching experience.

Step 3 Distribution and collection of validation form

Response of validation was collected through face- to-face meeting. Although all details pertaining to validation process was already included in cover letter, all experts were given a thorough explanation of the procedure and were requested for their qualitative input to add, delete, or alter any specific questions to make the questionnaire more comprehensible. Three weeks, were given to the experts to revert back with response form. In case of no response, a gentle reminder was given to them.

Step 4 Examining the completed form and compiling the responses

After the process of collection of forms was completed, forms were examined for completeness and presence of any missing data. Completed forms were compiled in result table with all verbal and written remarks.

Step 5 Percentage calculation

Content validation

It is measure to determine whether set of items included are adequate to tap the whole concept or not. For measuring content validity, I-CVI, S-CVI Average and S-CVI relevance value was determined. While S-CVI gauges the content validity of the entire scale, I-CVI evaluates the content validity of each individual item. The judgement of subject-matter experts is typically necessary to establish content validity because there is no specific statistical test to determine content area. Readability test that includes gunning fog and Flesch ease reading score was calculated.

Face validation

It is the quickest and quickest form to complete, but it also has the lowest level of validity because it solely rests on the assessor's knowledge and experience with PCOS. Face validity was calculated based on following two equations:

- (Number of agreed rater's per question/total number of rater's per question)*100.
- Sum of percentage of all questions/total number of questions.

Empirical validity

It helps to determine the accuracy of the construct. Here known- group validity test and hypothesis validity test were applied.

Known- group validity test

For this type of validation test, pilot study was conducted which included both PCOS and non-PCOS patients. Two groups were formed i.e. PCOS and non-PCOS group, and Chi-square test was applied.

i. Null hypothesis (H0): No difference is observed between PCOS and non-PCOS group.
ii. Alternative or research hypothesis (HA): Significant difference is observed between PCOS and non-PCOS group.

Hypothesis validity test

Hypothesis validity test enables us to determine whether the primary criteria (obesity, irregular menses, hirsutism) used are adequate to bifurcate severity into different levels. The hypothesis suggests that score obtained from the presence of primary criteria is directly proportional to the severity of the condition. For this type of validity testing, two group were formed as follows;

i. Group-I: Contains all 3 major symptoms of PCOS i.e. Hirsutism, Obesity and Irregular periods.
ii. Group-II: Contains either one or two of the three major symptoms of PCOS i.e. Hirsutism, Obesity and Irregular periods.

Here, Mann Whitney U test was applied.

Reliability

Reliability is calculated primarily to measure the trustworthiness of a research [36]. Reliability is mainly divided into two types as: i) Stability, and ii) Internal consistency reliability. Stability is defined as the ability of a measure to remain the same over time despite uncontrolled testing conditions or respondent themselves. It refers to how much a person's score can be expected to change from one administration to the next. A perfectly stable measure will produce exactly the same scores time after time. We performed test– retest, internal consistency reliability and inter-rater reliability test for our questionnaire.

1. *Test-retest reliability test*: To obtain the reliability coefficient i.e. repetition of the same measure on a second time, test-retest reliability test was performed. It assesses the external consistency of a test. The questionnaire was filled twice by the same participants after a gap of 2 weeks. The scores of time 1 and time 2 were evaluated to measure reliability coefficient of the questionnaire.

2. *Internal consistency reliability test*: To measure internal consistency of test; cronbach alpha was calculated. It is a function of the average inter-correlations of items, and the number of items in the scale. To measure equivalency of rating between different observers; individual participants were asked to fill up the questionnaire once.
3. *Inter-rated reliability test*: To measure the external consistency of test; Cohen's kappa reliability test was performed and Cohen's kappa co-efficient (k) was calculated (Table 4). It represents reliability the extent to which the data collected in the study are correct representations of the variables measured.

Statistical analysis

Data were analyzed using graph pad prism 8.01 and Microsoft excel and following statistics were performed for respective tests as mentioned in Fig. 2.

Test	Statistics
Theoretical validity	
Content validity Face validity	I-CVI and S-CVI Face validity %
Empirical validity	
Known group validity Hypothesis validity	Chi-square test Mann whitney U test
Reliability of the questionnaire	
Test- retest Inter-rater reliability Internal consistency reliability	Reliability coefficient Cohen's kappa coefficient (k) Cronbach alpha value

Figure 2: Analysis of pilot study results.

Results

We examined the metric features of a questionnaire developed to measure the severity or risk of PCOS in participants in this study. Majority of the validation tests were passed by the questionnaire. Measures of questionnaire reliability include consistency, accuracy, reproducibility, and research's credibility.

Content validity test

A test's content validity establishes whether it is representative of all aspects of the construct. To obtain accurate results, the content of a test, survey, or measuring procedure must encompass all crucial facets of the issue being measured. It is most often regarded as the interpretation of the questionnaire's assessment. The questionnaire passes this test, indicating that all of the items given in the questionnaire are reflective of the complete questionnaire. Theoretical validity of the questionnaire was examined using the face validity test, which also indicates that the questionnaire passes the test with 97.43% and no further revisions are required. The calculated I-CVI, S-CVI average and S-CVI relevance were 0.833, 0.974 and 0.846; which is higher than 0.78, which indicates excellent content validity of the questionnaire as described in Table 1.

Table 1. Results of content validity test

	DESCRIPTION	VALUE	INTERPRETATION
Sum of I-CVI	Item related content validity index	12.66666667	
S-CVI average	Scale level content validity index- average	0.974358974	
Sum of UA	Universal accepted	11	
S-CVI relevance	Scale level content validity index- relevance	0.846153846	> 0.78 = PASS
A PR	Average proportion of items judged as relevance across the 12 experts	0.974358974	

Readability test

Readability test was performed as a part of content validity test to determine whether the questionnaire is clearly legible and intelligible. The Flesch reading score and the Gunning fog score were determined, which indicated the questionnaire's standard/average and easy readability, respectively. The two tests denoted that the questionnaire is fairly easy to read (Fig. 3).

Face validity test

Theoretical validity can also be calculated using the face-validity test. The calculated face validity percentage is 97.43; which also suggests that the questionnaire has passed the test and no changes are required (Fig. 3).

Known group validity test

To investigate construct validity empirically, a known group validity test was performed using the chi square test. Except for the category for fast food intake, the majority of the items/categories included in the questionnaire revealed a significant difference between the two groups: case and control when chi-square test is applied as depicted Table 2. This is understandable given that there is no discernible variation in fast food eating patterns among any participant pool.

Hypothesis testing

Hypothesis validity test was performed using Mann- Whitney U test and significant difference (p value: 0.0012) was found between two groups, which denotes that pre-determined hypothesis passed the test. Thus, it indicates that questionnaire has good external validity.

Test- retest validity test

For the reliability of the questionnaire, test-retest was performed. The computed spearmen correlation coefficient calculated was 0.875; which is higher than 0.8. Thus, it indicates high dependability and very strong relationship as described in Fig. 3 and is considered acceptable.

Table 2. Known-group validity test

CATEGORY	SIGNIFICANT ?	P-VALUE
Comorbidities	Yes	<0.0001*
Symptoms	Yes	<0.0001*
Exercise	Yes	<0.0001*
BMI	Yes	<0.0001*
FG score	Yes	<0.0001*
Smoking	Yes	<0.0001*
Healthy practices	YES	0.0235
Stress	YES	<0.0001*
Sleep	YES	<0.0001*
Fast food intake	NO	0.613
Sugar rich food intake	YES	<0.0001*
Menstrual cycle symptoms	YES	<0.0001*
No. Of periods	YES	<0.0001*

NOTE:Chi Square test was applied.

**Significant difference between case and control group is observed.*

Internal Consistency Test

The questionnaire demonstrated high internal consistency and a very acceptable content validation score. The results of reliability test performed for the internal consistency of the questionnaire are described in Table 3. Internal consistency for all items on the questionnaire was more than adequate, indicating that this questionnaire measured the same construct and may be quite trustworthy in producing the same score each time an individual filled it out. The inter-item correlations in the questionnaire that determined how well the items theoretically fit together were focused, in order to evaluate internal consistency. Cronbach's alpha was used for this (α). An alpha of 0.70 to 0.95 was deemed appropriate. The calculated Cronbach's alpha was 0.827, which is greater than 0.8 and indicates that the questionnaire has acceptable internal consistency as described Fig. 3.

Table 3. Internalconsistency-Cronbach's alpha test results

VARIABLES	DESCRIPTION	VALUES	INTERNAL CONSISTENCY
K	# of times	13	
$?s^2y$	Sum of the item variance	42.64	
s^2x	Variance of total score	10.09	GOOD
?	Cronbach's alpha	0.83	

Table 4. Cohen's kappa observational table

		R2		T
		√	×	
R1	√	10	1	11
	×	0	1	1
T		10	2	12

R1= Rater 1, R2= Rater 2

Inter-rated reliability test

This test gives an idea about the external consistency of the questionnaire. Indicating moderate agreement between the two rater's, Cohen's kappa co-efficient (k) was calculated and found to be 0.63, which is higher than 0.6, as shown in Fig. 3.

Readability test results	
Flesch Reading Ease Score Gunning Fog	Standard/average Fairly easy to read

Interpretation of test-retest validity test	
<0.2	Very weak relationship
0.2 - 0.4	Weak relationship
0.4 - 0.6	Moderate relationship
0.6 - 0.8	Strong relationship
>0.8	Very strong relationship

Cronbach alpha result interpretation	
0.9 or above	Excellent
0.80 - 0.89	Good
0.70 - 0.79	Acceptable
0.60 - 0.69	Questionable
0.50 - 0.59	Poor
Below 0.5	Unacceptable

Interpretation of face validity test results		
% agreement	Strength of agreement per question or overall	Action for each question/entire tool
<80	Poor	Restructure
80 - 90	Substantial	Revise
90 - 100	Full	Retain

Interpretation of inter-rater reliability test		
Value	Level of agreement	% Data that is reliable
0 - 0.2	None	0 - 4%
0.21 - 0.39	Minimal	4 - 15%
0.40 - 0.59	Weak	15 - 35%
0.60 - 0.79	Moderate	35 - 63%
0.80 - 0.90	Strong	64 - 81%
> 0.90	Almost perfect	82 - 100%

Figure 3: Interpretation of validation test.

Discussion

PCOS is a complicated, widespread, and under-recognized condition. Even after visiting many healthcare centres, a huge percentage of women remain undiagnosed. In addition, despite being one of the world's most serious endocrine disorders, PCOS is still not widely recognized as a serious health issue [7]. As a result, the primary goal of this research was to create a questionnaire that would help women estimate their risk of getting PCOS, or the severity of the medical condition if they had already been diagnosed. As a result, the first step in achieving the goal was to develop and validate the 'Novel PCOS diagnostic questionnaire'. In the knowledge of authors this is the first questionnaire that will assist both healthy people and patients in determining their risk of developing PCOS and the severity of their condition respectively.

The validity of a research instrument determines how well it measures what it was supposed to measure and it is used to verify the accuracy of research findings. Validity in research involves two components: internal (credibility) and external (transferability). Internal validity indicates whether the results of the study are legitimate because of the way the groups were selected, data were recorded or analyses were performed. It refers to whether a study can be replicated. External validity determines if the study's findings may be applied to other groups of interest [37](non-random selection, heterogeneous groups). We have performed face validity, content validity and construct validation.

Validity assesses how effectively a measurement reflects the intended outcome and is used to confirm the accuracy of study findings [37]. A total of 13 questions were included in the questionnaire that were associated with PCOS condition based on review of literature as mentioned in the methodology section.

Conclusion

Development and preliminary validation of the Novel PCOS diagnostic questionnaire was found appropriate. It is a disease-specific measure for women with PCOS that explores the impact of the condition on diagnostic aspects of disease. The results of the validation of questionnaire on a smaller scale has shown outstanding initial validity and reliability results in a small clinical sample of women with and without PCOS in the Ahmedabad population. Yet, validation at a wider scale is required. Further research need to carry out to check the applicability of the questionnaire in a larger population.

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Conflict of interest

The authors declare no conflict of interest that could have influenced the submitted work.

Author contribution

All the authors have contributed equally to the present work. All have equally contributed in the process of designing, development, and validation of questionnaire, conduction of pilot study, analysis and interpretation of results& framing and writing of this research paper.

Ethics statement

A study protocol approved by Institutional Ethics Committee of L. M. College of Pharmacy, Navrangpura, Ahmedabad with Approval No. LMIEC/2021-22/PD/007.

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