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### RESEARCH ARTICLE

#### SIMPLER METHOD IN ASSESSMENT OF HIRSUTISM IN PCOS

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#### Abstract

**Introduction :** As the modified Ferriman–Gallwey (mFG) score is unsuitable for self-assessment and requires specialist training, a short, self-administered questionnaire to identify hirsutism was constructed and validated for large-scale application, particularly targeting population-based studies.

**Design:** A validation study was conducted to assess a new hirsutism questionnaire (NHQ).

**Material and Methods:** A total of 90 women aged 35-60 years who attended Chalmeda Anand Rao institute of medical sciences, Karimnagar and were diagnosed as PCOS were enrolled . A self-administered instrument containing four questions was designed to evaluate five body areas: upper lip, chin, chest, lower abdomen, and thighs with respect to the distribution of body hair. A score of 0–4 was attributed to each region based on drawings was provided in the instrument. An independent medical examination was conducted and compared the results to the gold standard modified Ferriman–Gallwey (mFG) score to test the reliability of this method.

**Results:** The area under the receiver operating characteristic curve was 0.93 (95% CI: 0.87–0.99). A cut-off score of 5 showed the best balance between sensitivity (85%) and specificity (90%), with 88.9% accuracy.

**Conclusion:** The accuracy and internal consistency of this self-administered questionnaire for the identification of hirsutism were good. Therefore, this questionnaire represents a useful tool for self-assessment of hirsutism in population-based studies.

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#### Introduction:-

Hirsutism is a common clinical condition defined by excess terminal body hair in androgen-dependent areas of the female body<sup>(1,2,3)</sup>. It may be present in polycystic ovary syndrome (PCOS), which is responsible for 60–85% of cases, in non-classical congenital adrenal hyperplasia (3–5%) and in idiopathic hirsutism (5–10%)<sup>(2,3,4,5)</sup>. Its occurrence is linked to an exaggerated androgenic effect that occurs through various mechanisms such as an increase in the production of ovarian or adrenal androgens<sup>(1)</sup>, greater enzymatic activity in the pilosebaceous units<sup>(4,7)</sup>, an increase in the proportion of free androgens<sup>(7)</sup>, and the use of exogenous hormones. Hirsutism is the most common manifestation of hyperandrogenism and the clinical criterion most commonly used to identify hyperandrogenic women<sup>(8)</sup>.

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The measurement of excess body hair has been the subject of major controversies. For decades, investigators have tried to establish a method of quantifying body hair that would result in a more precise diagnosis of hirsutism and reduce the inter-observer variations found with the subjective methods that have been proposed. Described by David Ferriman and John Gallwey in 1961, the scoring system that bears their names was originally designed to evaluate the amount of body hair in eleven regions of the body<sup>(9)</sup>. Following revisions introduced 20 years later, the modified Ferriman–Gallwey (mFG) score is currently the method most commonly used to identify hirsutism<sup>(10)</sup>. It consists of observing the quantity and distribution of terminal hair in nine body areas including the upper lip, chin, chest, upper and lower abdomen, back, sacroiliac region, thighs, and arms. These areas are given a score ranging from 0 to 4 according to quantity and density, with higher scores being indicative of a greater amount of body hair<sup>(8)</sup>. The sum of these values is classified according to varying cut-off points, the most commonly used being between 6 and 8 points<sup>(11)</sup>. Owing to its ease of application and low cost, the mFG is widely accepted. Nevertheless, the fact that this method is difficult to self-administer and requires specialist training<sup>(12)</sup> renders its use in studies involving a great number of participants largely unfeasible.

Objective methods of quantifying body hair by counting or weighing have been investigated; however, they appear to be more useful in the therapeutic control of hirsutism and are not recommended for use in diagnosis or for baseline quantification<sup>(13)</sup>.

Some androgenically sensitive areas are known to be more closely associated with hyperandrogenemia, hirsutism, and PCOS than others. The chin, submandibular region, upper lip, upper thighs, the midline of the abdomen, and the chest were identified as being the most sensitive areas<sup>(14)</sup>. The increase in body hair on the upper lip, the chin, and the lower abdomen proved to be better predictors of hirsutism<sup>(14,15)</sup>. A study conducted to determine the prevalence of PCOS<sup>(16)</sup> estimated that, of the nine areas investigated using the mFG score, only five were associated with a diagnosis of hirsutism and were predictive of the syndrome: the upper lip, chin, chest, lower abdomen, and thighs. Another study reported that, in body areas that are more sensitive to androgens, a strong correlation was found between the clinical evaluation and self- assessment of hirsutism<sup>(16)</sup>.

Hirsutism is an important element in the identification of PCOS, which, in turn, has been strongly associated with the occurrence of obesity, diabetes mellitus, and cardiovascular disease<sup>(16,17,18,19,20)</sup>. The pandemic of this triad has increased the interest of the scientific community in the subject of PCOS; however, adequate conditions must be created in order to conduct population-based studies.

The objective of this study was to construct and validate a simplified questionnaire to identify hirsutism that could be used in research studies, could be applied to large sample populations, and could be administered by the various means available, including the internet.

## **Materials And Methods:-**

### **Study design and population :**

This study was conducted in 90 women aged 35-60 years who attended Chalmeda Anand Rao institute of medical sciences, Karimnagar and were diagnosed as PCOS were enrolled. This limit was chosen because the full effect on androgens on the hair follicles is present in these age groups.

A short instrument containing few questions was developed with the aim of enabling it to be administered by the participant herself, and was named New Hirsutism Questionnaire (NHQ). It was based on the mFG score and was designed to evaluate the five body areas considered most sensitive to the circulating androgens associated with hirsutism and with a diagnosis of PCOS: i) upper lip; ii) chin and neck; iii) breasts and chest; iv) lower abdomen; and v) thighs. Drawings were elaborated to represent the different scores, ranging from 0 to 4 for each of the mentioned regions in accordance with the description of the score and the drawings provided previously in various papers published on this subject<sup>(9,10,21)</sup>. The participants were asked to answer questions on the current status of their body hair as it would be if they had not used any hair removal methods. Although written explanations were added to each one of the drawings in case the participants required further help, it was believed that the drawings alone would provide sufficient information to allow them to answer the questions.

This age limit was chosen because the full effect on androgens on the hair follicles is present in these age groups

### Inclusion Criteria

Women between age 35 – 60 years who were diagnosed as PCOS.

### Exclusion Criteria

1. Patients who were premenarchal or postmenopausal, had undergone prior hysterectomy, bilateral oophorectomy.
2. Hypothyroidism, hyperprolactinemia
3. Other causes of androgen excess like congenital adrenal hyperplasia, intersexual conditions.
4. Use of oral contraceptive pills/hormonal pills in the preceding three months.
5. Chronic diseases like SLE.
6. Any tumours causing androgen excess.

The participants completed the questionnaire privately and were then examined clinically and independently by one single investigator with a vast experience in applying the mFG score, which was the gold standard for validating the answers to this short-form questionnaire.

### Statistical Analysis

Linear regression estimated the proportion contributed by each area of the body to the variability in the overall score, when applying both the mFG and the NHQ. This was achieved by calculating  $R^2$ , i.e., the square of the correlation between the score found in the test and that found with the gold standard. For the contribution of each area in the final diagnosis of hirsutism,  $R^2$  was calculated within a logistic regression model.

For the validation study, sensitivity, specificity, and the percentage of classified tests (accuracy) were calculated using the various cut-off points suggested by the receiver operating characteristic (ROC) curve. In addition, the area under the ROC curve was calculated, showing the overall performance of the test. To define the cut-off value to be selected for the new instrument, limits were estimated with a view to maximising sensitivity and specificity. These analyses were performed using the cut- off points most commonly used in the mFG score <sup>(14)</sup>.

The tests were done using Microsoft excel 2010 and SPSS software.

### Results:-

The questionnaire was answered by 90 women aged 35-60 years (median: 50.5 years) and the participation refusal rate was 5.3%.

Mean scores, obtained by applying either the mFG or the NHQ questionnaire, did not vary significantly with age, parity, menstrual pattern. Mean scores differed as a function of BMI, although the differences were only of borderline significance (P=0.06 for the mFG and P=0.05 for the NHQ (Table 1).

**Table 1:-** Sociodemographic, reproductive, and anthropometric characteristics distributed according to the modified Ferriman– Gallwey (mFG) score and the proposed New Hirsutism Questionnaire (NHQ).

Variables	N(%)	mFG mean (S.D)	NHQ mean (S.D)
Age (years)			
35–44	19 (21.1)	5.48 (5.8)	4.27 (4.3)
45–54	49 (43.3)	3.54 (2.4)	2.63 (2.5)
55+	32 (35.6)	3.52 (2.9)	2.42 (2.5)
P-value		0.42	0.25
Parity			
0-2	70	3.83 (3.6)	2.86 (3.1)
>2	13	3.62 (3.2)	2.6 (2.5)
P-value		0.84	0.78
Menstrual dysfunction			
No	56 (66.7)	3.89 (3.9)	2.91 (3.1)
Yes	28 (33.3)	3.79 (2.9)	2.71 (2.7)
P-value		0.9	0.78
BMI (weight (kg)/height (m <sup>2</sup> ))			

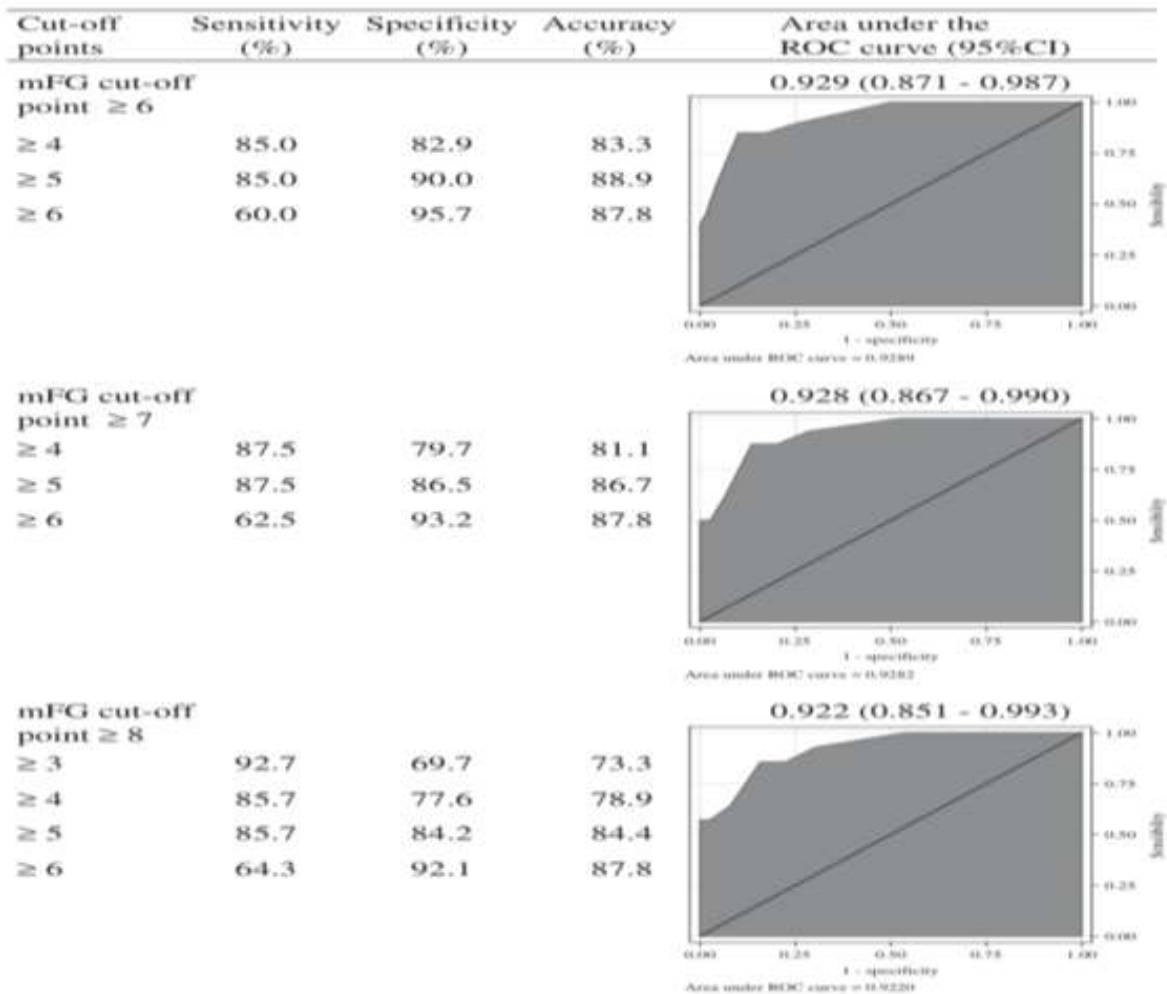
<25	40(48.2)	3.05(2.14)	2.08(1.8)
>25	44(51.8)	4.49(4.4)	3.42(3.7)
P-value		0.06	0.05

To analyse the performance of the test, the three most commonly used cut-off points for studies on hirsutism were applied (>6, >7 and >8). Analyses of the ROC curves showed that for both current and past body hair statuses evaluated according to the NHQ, the cut-off point of >5 points resulted in good accuracy, with very satisfactory sensitivity and specificity levels. The best performance of the NHQ questionnaire was found with an mFG cut-off point of >6, as shown by the area under the ROC curve for both moments in time (Fig. 1).

In the simple linear regression analysis, four of the five body areas used in the test were found to be better predictors of the total mFG score, as the predictive capacity of the chest was below the expected value. The thighs, upper lip, and chin were found to be the areas that most contributed toward the overall NHQ score. In the simultaneous multiple linear regression analysis, all the areas in the NHQ taken together were able to predict the total mFG score in 97% of cases (Table 2).

When the chest was excluded from the analysis, calculation of the area under the ROC curve showed an overall performance of the test of 0.9364 and accuracy of 90%, higher than that of the proposed instrument with five body areas, despite the slight decrease in its ability to predict the total mFG score.

**Figure 1:-** General performance of the NHQ (proposed test with five body areas) at the various cut-off points of the mFG score (gold standard) and analysis of the receiver operating characteristic (ROC) curves.



Considering hirsutism identified by the mFG as the dependent variable of the regression model, for all the cut-off points studied, the five areas that most contributed toward predicting this diagnosis were, in decreasing order, the upper lip, thighs, chin, lower abdomen, and sacroiliac region. Yet again, it was found that four of the areas evaluated in the proposed test (NHQ) were among them. The three regions of the body that most contributed to hirsutism identified according to the NHQ score at cut-off points of  $>4$  and  $>5$  were, also in decreasing order, the upper lip, thighs, and lower abdomen, differing from the cut-off point of  $>6$  in which this latter region was substituted by the chin (Table 2).

**Table 2:-** Proportion of prediction ( $R^2$ ) of each area for the overall score and for the diagnosis of hirsutism at the various mFG and NHQ cut-off points.

Body areas	MFG			NHQ			TOTAL	
	$>6$	$>7$	$>8$	$>4$	$>5$	$>6$	MFG	SMEH
	$R^2$	$R^2$	$R^2$	$R^2$	$R^2$	$R^2$	$R^2$	$R^2$
<b>Thighs</b>	0.38	0.43	0.33	0.39	0.36	0.36	0.55	0.56
<b>Upper lip</b>	0.48	0.56	0.50	0.45	0.44	0.44	0.53	0.62
<b>Chin</b>	0.26	0.19	0.19	0.19	0.20	0.28	0.51	0.38
<b>Lower abdomen</b>	0.23	0.17	0.22	0.23	0.27	0.10	0.44	0.34
<b>Chest</b>	0.08	0.04	0.07	0.22	0.21	0.21	0.25	0.29
<b>Upper abdomen</b>	0.11	0.14	0.17	-	-	-	0.41	
<b>Upper back</b>	0.04	0.05	0.06	-	-	-	0.36	
<b>Lower back</b>	0.17	0.24	0.21	-	-	-	0.31	
<b>Arms</b>	0.05	0.07	0.08	-	-	-	0.15	

### Discussion:-

The purpose of this paper is to present a short instrument for identifying hirsutism, which would be useful in scientific research, particularly in population-based studies. Compared with the gold standard, the sensitivity and specificity of this instrument were high at all the cut-off points evaluated. In addition, test-retest reliability was good, and the instrument was easily self-administered, showing that it is adaptable for use as an online research tool.

Based on the most commonly used scoring scale, the simplification of the test consisted of reducing the number of areas studied and its self-administration, which was made possible through the use of coloured, self-explanatory drawings designed to facilitate understanding and make it easier for the respondent to select a score for each body region.

### The performance of the test

The best evaluation of the validity of this instrument consisted of the combination of the cut-off points from the gold standard and the test:  $>6$  and  $>5$ , respectively, resulting in sensitivity of 85% and specificity of 90%, with a positive predictive value of 70.8% and a negative predictive value of 95.5%. This cut-off point also resulted in the highest proportion of correctly classified tests and the best overall performance of the test. These indicators of validity were higher than those reported in a US study proposing a simplified test in which only one of the two body areas was rated: the chin or the lower abdomen<sup>(13,22)</sup>. Additionally, the results obtained using the instrument presented in this study proved better than those reported in other recent studies in which simplified tests have also been proposed. One of those studies tested only three areas<sup>(23)</sup>, while another, which also evaluated three regions, used a cut-off point of  $>2$ <sup>(8)</sup>. As this latter study was conducted exclusively with Chinese patients, in whom the prevalence of hirsutism is extremely low compared with women in other countries, application of this instrument will probably be restricted to that population<sup>(8,16,24,25)</sup>.

### The challenge of identifying parts that represent the whole

The heterogeneity of the distribution patterns of body hair involves a multiplicity of combinations of sensitive regions. Women may have excess body hair in one, two, or several of these areas, thus determining various phenotypes. This makes it necessary to include the examination of various body regions in scores designed to quantify hirsutism. In this study, five areas were used that have also been thoroughly evaluated in scores proposed by another two investigators, with the present findings being consistent with their reports<sup>(3,26)</sup>. In this study, one important aspect is particularly noteworthy: of the five areas evaluated, four were found to be highly predictive of the total score (upper lip, chin, lower abdomen, and thighs), both with respect to the gold standard, whereas one (the

chest) contributed only modestly to the overall score. These data are consistent with findings reported by other authors<sup>(27)</sup>. When only these four areas were considered, using the same cut-off point, the number of correctly classified tests was greater.

#### **Self-administration: a desirable characteristic for large-scale use**

The feasibility of self-administration, one of the principal objectives behind the development of this questionnaire, was confirmed by the strong correlation between the test and the gold standard, in addition to the agreement level between the two instruments, which was three times that described in the literature<sup>(12)</sup>. In relation to the score attributed by the women themselves and that attributed by clinicians, another study reported a correlation that was much lower than that found in this study, even when the areas most sensitive to androgens were taken into consideration<sup>(28)</sup>.

In the evaluation of agreement between the test and the gold standard, one aspect merits particular consideration. The difference between the two measurements may result from the fact that the mFG establishes an overall score by grading nine body areas, whereas the NHQ measures only five of these areas. It is reasonable to believe that two methods with different spectrums of possible measurements (mFG: 0–36; NHQ: 0–20) will result in different scores, and it is possible that the mFG score is higher than that obtained with the NHQ. The difference of 0.966 shown in this study represents approximately one point and appears to be acceptable for the purpose of differentiating between hirsute and non-hirsute women.

#### **Conclusion:-**

The NHQ represents an important contribution to scientific research, not only with respect to hirsutism, but also principally to PCOS, offering a mechanism of large-scale quantification of a variable that is very important to identify and much more challenging to obtain. There are advantages such as the fact that it can be self-administered and that it presents good validity. As hirsutism is one of the diagnostic criteria for PCOS, identifying it at more advanced ages may allow studies of its association with cardiovascular disease to be conducted in the age group in which this outcome is most common. Therefore, this instrument may contribute to an advance in the study of PCOS and its consequences, benefiting the significant percentage of women affected by this condition.

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