Research articles

Validation of WHOQOL-BREF to measure quality of life among women with polycystic ovary syndrome

V Kumarapeli[1], R de A Seneviratne[2], C N Wijeyaratne[3]

Abstract

Introduction

Symptoms typically associated with polycystic ovary syndrome (PCOS) such as oligo/ amenorrhoea, hirsutism, obesity, subfertility lead to a significant reduction in quality of life (QOL). At present, no validated questionnaire exists to measure the QOL of women with PCOS. The study was carried out to validate WHOQOL-BREF before its application to assess quality of life in women with PCOS in Sri Lanka.

Methodology

The WHOQOL-BREF was validated on 130 women with PCOS attending an endocrine clinic at a tertiary care hospital and 130 community controls. Both convergent and discriminant validity of WHOQOL-BREF were measured simultaneously using the Multitrait-Multimethod Matrix technique in comparison with SF 36. Confirmatory factor analysis using principal component analyses was performed to test the construct validity. Reliability was measured by assessing internal consistency and test-retest reliability.

Results

Good convergent and discriminant validity was demonstrated by the WHOQOL-BREF for similar and different scales respectively in comparison with SF-36. Internal consistency measured using Cronbach's alpha exceeded Nunnaly's criteria of 0.7 for all except the social relationship domain in both groups while the test retest reliability measured using Pearson's correlation coefficients exceeded >0.7 ($p<0.01$) in all domains.

Conclusions

WHOQOL-BREF was found to be a valid and a reliable tool to assess QOL of women with PCOS. It showed good convergent validity, discriminant validity and reliability in all except the social relationships domain.

Key words

validation, quality of life, MTMM, factor analysis

Introduction

Polycystic ovary syndrome (PCOS) is the commonest reproductive endocrine disorder affecting approximately 5%-10% of women of reproductive age. The women affected with PCOS face psychological and social consequences including affect on mental health and quality of life. Literature reveals that limited research had been carried out to assess the impact that symptoms of PCOS have upon quality of life (QOL) of women with the condition (1). At present no validated instrument is available to measure QOL of women with PCOS. The instruments such as the Nottingham Health Profile that measure impairment of daily activities and disability or functional status, do not assess QOL per se (2).

The WHOQOL-BREF is the abbreviated 26-item version of the WHOQOL-100. It has been recommended for use among women with reproductive morbidities especially gynaecological morbidities (2). WHOQOL-BREF contains four domains related to quality of life (QOL) i.e. physical health, psychological health, social relationships and environment and one facet on "overall quality of life and general health". The answers to all questions in WHOQOL-BREF are recorded on a 5 point Likert scale. Raw score for each domain is transformed into a 0-100 linear score. High values represent a better quality of life. Each question assesses QOL in respect of the preceding 2 weeks (3).

Abramson and Abramson (4) have highlighted that validations done outside the study setting suffices only if the researcher is certain that the study populations and circumstances are similar to the new study, so that the methods, results and application will be valid in the new setting too. Hence, the primary objective of the study was to test the validity of WHOQOL-BREF prior to its use among women with PCOS in Sri Lanka. Validation was done in accordance with the guidelines given by the WHO (3).

Methodology

WHOQOL-BREF had been translated into Sinhala according to guidelines given by WHO (5), by the field centre at Faculty of Medicine, University of Ruhuna. Therefore, it was used without modification in the study after obtaining permission from the field centre.

1. Medical officer (Rabies control), Public Health Veterinary Services, Ministry of Health.
2. Professor in Community Medicine, Department of Community Medicine, Faculty of Medicine, University of Colombo.
3. Professor in Reproductive Medicine, Department of Obstetrics & Gynaecology, Faculty of Medicine, University of Colombo.

Study population
The study was carried out using two groups of eligible women – cases and controls. The cases consisted of women of 15-39 years, newly diagnosed with PCOS and community controls who were women in the same age group without symptoms of oligomenorrhoea and amenorrhoea or clinical signs of hyperandrogenism.

Sample size
The sample size for the validation was first calculated based on the assessment of construct validity (factor analysis). However, the appropriate sample size for factor analysis is debatable. A sample size of 100 is considered acceptable (10). A minimum of five subjects per each item in the multivariate statistical model is considered to generate stable reliability and validity estimates for factor analysis. Thus, the minimum sample size for this 26 item instrument is 130. Secondly, it was calculated based on the assessment of convergent and discriminant validity. The formula used is given below (Hully and Cummings 1988).
The study was carried out using two groups of eligible women – cases and controls. The cases consisted of women of 15-39 years, newly diagnosed with PCOS and community controls of women in the same age group without PCOS.

$$N = \{(z_\alpha + z_\beta)/c\}^2 + 3$$
$$C = 0.05\ ln\ \{(1+r)/(1-r)\}$$
C=correction factor
r =expected correlation coefficient
N=total number of subjects required

The sample size thus calculated using the above formula was 113 (11). The largest sample size so derived i.e., 130 cases and 130 controls was used.

Sampling
A consecutive sample of women with PCOS was selected among women who came for treatment to the endocrine clinics at the De Soyza Maternity Hospital, a referral centre and a teaching hospital in Colombo. As the comparison group, 130 eligible women were selected from the MOH area Mirigama using cluster sampling.

Data collection
Short Form Health Survey 36 (SF 36), is another instrument that measures self assessed general health status which has been validated and used in Sri Lanka (5). SF36 has 8 domains of functional status on a multi-item multi-domain scale, some of which are comparable with domains of WHOQOL-BREF. These include physical health, psychological health and social relationships.

WHOQOL-BREF and SF 36 were incorporated sequentially into one questionnaire. The selected women were requested to fill the questionnaire by themselves. Two weeks later the same questionnaire was mailed with a stamped self addressed envelop addressed to the principal investigator, to a randomly selected group of women, 25 each from cases and controls.

Method of validation
A "gold standard" measure for general assessment of health and well being or of health related quality of life cannot be defined and thus criterion validity cannot be proven for this measure. Therefore, the following method was carried out to assess the validity of WHOQOL-BREF.

A. Judgemental validity
Judgemental validity assesses whether or not the conceptual definition has been appropriately translated into operational terms (4). Face validity, content validity and consensual validity are assessed by judgement.

A panel comprising experts in the field of community medicine, clinical medicine and psychological medicine assessed the judgemental validity. Appraising the relevance of the tool to the domains under investigation assessed face validity. Content validity was assessed by checking whether or not all aspects of the measure were covered, and consensual validity was determined by assessing the agreement of the experts on whether or not the conceptual definition has been translated appropriately into operational terms in the tool.

B. Convergent and discriminant validity
Convergent and discriminant validity assesses the validity of a tool against another known measure of the same variable or a closely related one which is known to measure the same concept and when it is not known which one is superior (4).

Convergent validity is the degree to which concepts in the two measures that are related theoretically are interrelated in reality. Discriminant validity is the degree to which concepts that are not related theoretically are, in fact, not interrelated in reality. If valid, this should show strong correlations with related measures (convergent validity) and not show strong correlations with unrelated measures (discriminant validity) (4).

SF 36 was used to assess convergent and discriminant validity which were measured simultaneously using the Multitrait-Multimethod Matrix technique (MTMM) (6).
In the interpretation, following basic principles were used:

- Correlations between measures of the same domains assessed using different instruments are **validity coefficients**. If the measure being validated is showing convergent validity, the calculated validity coefficients should be of high values showing strong correlations. If the measure being validated is showing discriminant validity, the validity coefficients that differ in, both domains and the instrument should be the lowest in the matrix.

In addition, discriminant validity was also assessed by two other methods as recommended by the WHO (7).

a. It was assessed by comparing the mean scores for the four domains in cases and controls to see the ability to discriminate between the two groups.

b. The mean scores for the four domains in groups generated by a median split on the item 1 and item 2 of WHOQOL-BREF were tested for significance in cases and controls separately.

C. Construct validity

Confirmatory factor analysis using principal component analyses was performed to test whether the data fits a hypothetical model. If WHOQOL-BREF is a valid measure of the domains within it, these domains emerge from a factor analysis of the data from the population that is being validated and items relating to a particular domain should be grouped together within a single factor (8).

D. Reliability

Reliability was assessed by two methods: internal consistency and test-retest reliability.

Internal consistency

Internal consistency measures the extent to which similar questions produce consistent answers. Cronbach's alpha coefficient, which is the measure of the overall correlation between items within a domain, was used to assess reliability (8). It was measured for each domain of WHOQOL-BREF in cases and controls to see whether it exceeded the commonly accepted minimal standard or the Nunnally's criterion of 0.70 (9).

Test-retest reliability

The test-retest reliability measures the stability or consistency of information. It is the extent to which similar information is gathered when measured more than once. A group of 50 subjects (25 cases and 25 controls) whose health status was unlikely to change substantially over the course of two weeks, was followed up and retested (3). The test-retest coefficients were calculated for each domain (Pearson r) and for the facet 1-"overall QOL and general health" facet (Spearman's r).

Results

Women in the two groups were comparable in basic socio-demographic characteristics. Frequency distributions of the four domains (mean, median and mode) for WHOQOL-BREF for the two groups were symmetrical.

Convergent and discriminant validity

Multitrait Multimethod Matrix (MTMM) of correlation coefficients for WHOQOL-BREF and SF 36 in the two groups are shown in Table 1 and 2. In the assessment of the two instruments for the cases, the highest validity coefficients (Pearson's r) were observed for the physical (0.625) and psychological (0.517) health domains (Table 1 and 2). This provided evidence for convergent validity. A similar pattern was seen among the comparison group (Table 2). The correlations for the social domains between the two instruments

Table 1 – MTMM of correlation coefficients for WHOQOL-BREF and SF 36 for women with PCOS (Pearson's r)

	WHOQOL-BREF			SF 36		
	Physical health	Psychological health	Social relationship	Physical functioning	Mental health	Social functioning
WHOQOL-BREF						
Physical health						
Psychological health	.633**					
Social relationship	.586**	.641**				
SF 36						
Physical functioning	**.625***	*.048*	*.121*			
Mental health	*.229***	**.517****	*.292**	.139		
Social functioning	*.269***	*.258***	**.276****	.203*	.457**	

** Correlation is significant at the 0.01 level (2-tailed).
*Correlation is significant at the 0.05 level (2-tailed).

Table 2 – MTMM of correlation coefficients for WHOQOL-BREF and SF 36 for the control group (Pearson's r)

	WHOQOL-BREF			SF 36		
	Physical health	Psychological health	Social relationship	Physical functioning	Mental health	Social functioning
WHOQOL-BREF						
Physical health						
Psychological health	.554**					
Social relationship	*.316***	.416**				
SF 36						
Physical functioning	**.613***	*.160*	*.140*			
Mental health	*.370***	**.449****	*.246***	.129		
Social functioning	*.529***	*.371***	**.268****	.148	.408**	

** Correlation is significant at the 0.01 level (2-tailed).
*Correlation is significant at the 0.05 level (2-tailed).

(0.276 and 0.268) were significant but were moderate for both groups. Correlations that differ in both, dimension and the instrument (in italics) were the lowest in the matrix confirming that the measure being validated is showing discriminant validity.

The discriminant validity was further assessed by comparing the mean scores for the four domains of WHOQOL-BREF obtained by cases and controls (Table 3). Highly significant differences ($p<0.001$) were found between the scores of the two groups for the physical health and psychological health domains while differences found in the scores for social relationships and environment domains were not significant.

The subgroups distinguished by a median split on item 1, self assessed 'overall quality of life' and item 2, self assessed 'general health' were also tested for significance within the groups. The scores for item 1 and item 2 were split into two, below and above the median and with the median itself included in the lower half. The lower half (indicating poor QOL) generated by the median split on item 1 among cases was compared with the lower half in controls (Table 4). The controls gave higher scores than cases in all the domains in the lower half where 'overall quality of life' was poor. A significant difference ($p<0.001$) was found only between the scores of the physical health domain.

The upper halves were analysed in a similar manner (Table 4). The controls gave higher scores than case subjects in all the domains in the upper half where the 'overall quality of life' was better. Highly significant differences ($p<0.001$) were found between the scores of the physical health and psychological health domains.

A similar analysis was performed by a median split on item 2 in the two groups. When the lower halves were compared none of the scores in the domains were found to be significantly different ($p>0.05$). When the upper halves were compared significant differences ($p<0.001$) were found between the scores of physical health and psychological health domains.

Construct validity

Confirmatory factor analysis using principal component analyses was performed on both groups. The anti-image correlation matrices

Table 3- Mean scores for WHOQOL-BREF for women with PCOS and for the control group

Domain of WHOQOL-BREF	Women with PCOS Mean	SD	Control group Mean	SD	Significance Z test
Physical health	64.1	16.5	76.7	13.6	SND=6.68 p=<0.001
Psychological health	65.1	16.2	74.4	13.9	SND =4.97 p=<0.001
Social relationship	65.8	20.3	69.9	18.6	SND =1.67 p=.096
Environment	65.4	16.5	67.8	16.2	SND =1.19 p=.232

Table 4 - Mean scores for the two groups generated by a median split on item 1 in WHOQOL-BREF for women with PCOS and the control group

Domain of WHOQOL-BREF	Women with PCOS lower half n=81		Control group lower half n=53		Significance Z test
	Mean	SD	Mean	SD	
Physical health	61.2	17.2	70.9	14.2	SND =11.65 P<0.001
Psychological health	61.3	16.9	65.4	13.1	SND =2.24 p=0.137
Social relationship	62.4	20.5	62.3	18.8	SND =0.00 p=0.977
Environment	61.8	17.0	58.8	13.8	SND =1.15 p=0.285
	upper half n=49		upper half n=77		
Physical health	69.0	14.2	80.6	14.2	SND =19.98 p<0.001
Psychological health	71.3	13.1	80.6	13.1	SND =15.09 p<0.001
Social relationship	71.5	18.8	75.1	18.8	SND =1.10 p=0.296
Environment	71.3	13.8	74.0	13.8	SND =1.15 p=0.286

revealed that measure of sampling adequacy for all variables were well above the accepted level of 0.5. Bartlett's test of sphericity for both groups were significant (p<0.001). The Kaiser- Meyer Olkin measure was 0.826 for women with PCOS and was 0.825 for comparison group. These confirmed the factorability of the data. The factors were selected depending on the Eigenvalues. The factors were considered relevant only if its Eigenvalue exceeded 1.0. Varimax rotation

Table 5– Factor coefficients of items in WHOQOL-BREF after Varimax rotation for women with PCOS

Item in WHOQOL-BREF	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
Item 3	-.219	.176	**.602**	.440	.221	-.035
Item 4	.305	-.111	.330	**.627**	.069	.087
Item 5	.426	**.562**	-.105	.487	.012	.057
Item 6	.422	**.586**	-.032	.367	-.067	.032
Item 7	.384	**.532**	.104	.012	.054	.064
Item 8	.253	**.714**	.046	.082	.141	.085
Item 9	.012	**.719**	.284	.039	.218	-.062
Item 10	.311	.330	**.541**	.112	.182	.106
Item 11	.453	.307	**.456**	-.145	-.025	.114
Item 12	**.647**	.323	.075	.224	.024	.013
Item 13	**.743**	.162	.177	.206	.206	-.074
Item 14	.088	.348	-.008	.000	**.864**	-.081
Item 15	.367	.088	.081	**.515**	.166	-.034
Item 16	.298	.004	.276	.067	**.766**	.136
Item 17	.373	.231	**.635**	.201	.306	.023
Item 18	.294	.244	**.689**	.179	.009	-.059
Item 19	.470	**.518**	.393	.054	-.180	.087
Item 20	**.614**	.266	.200	.028	.059	.075
Item 21	.011	.070	-.004	.006	.025	**.995**
Item 22	**.700**	.096	.219	.103	.187	-.057
Item 23	.066	**.609**	.379	.053	.176	-.025
Item 24	.429	**.553**	.171	.150	.010	-.044
Item 25	**.623**	.348	-.153	.222	.163	.117
Item 26	.025	.217	.106	**.819**	-.085	-.027

Table 6– Distribution of the items in the four domains of WHOQOL-BREF according to the factors identified by CFA for women with PCOS

WHOQOL-BREF	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
Physical health domain						
Item 4			.627			
Item 15			.515			
Item 16					.766	
Item 10		.541				
Item 3		.602				
Item 17		.635				
Item 18		.689				
Psychological health domain						
Item 5	.562					
Item 6	.586					
Item 7	.532					
Item 19	.518					
Item 11		.456				
Item 26		.819				
Social relationships domain						
Item 20				.614		
Item 21						.995
Item 22				.700		
Environment domain						
Item 8	.714					
Item 9	.719					
Item 23	.609					
Item 24	.553					
Item 14					.864	
Item 12				.647		
Item 13				.743		
Item 25				.623		

technique was used (8).

The factor analysis for women with PCOS identified six relevant factors. The Eigenvalues ranged from 8.19 to 1.12. The questions that are related to a particular construct are highlighted under each factor (Table 5). Each item had a loading (factor coefficient) greater than 0.5 only in the factor that it belonged to.

The distribution of the items in the four domains of WHOQOL-BREF were grouped against the factors identified by confirmatory factor analysis

Table 7– Internal consistency (Cronbach's alpha) of WHOQOL-BREF among women with PCOS and the control group

Domains of WHOQOL-BREF	Women with PCOS	Control group
Physical health	0.7907	0.6775
Psychological health	0.7883	0.7321
Social relationship	0.5605	0.5416
Environmental	0.8276	0.8088

for cases (Table 6). Items in domains of psychological health and social relationships have each separated into two. One item each from the physical domain and the environment domain has combined to form a separate factor (factor 5) while separating the rest of the items into 2 components.

A similar analysis was carried out for the comparison group. It identified five relevant factors. The Eigenvalues ranged from 6.37 to 1.08. When the distribution of the items in the four domains of WHOQOL-BREF were grouped against the factors identified by confirmatory factor analysis, all four domains had separated into two components each.

Internal consistency (Cronbach's alpha)

The Cronbach's alpha exceeded Nunnaly's criteria of 0.7 for all except the social relationship domain in both groups (Table 7). The correlations between questions 1 and 2, questions 2 and 3, questions 1 and 3 of the social domain were analysed separately. There was poor correlation between item 1 and 2 (Cronbach's alpha =0.2368) and item 2 and 3 (Cronbach's alpha =0.3816).

Test-retest reliability

Test-retest coefficients (Table 8) were calculated for each domain (Pearson r) and for the item 1 and item 2 (Spearman's s). All correlations were significant at $p<0.01$. Test retest Pearson's r were >0.7 for all the domains in both groups.

Discussion

The validation of WHOQOL-BREF was carried out prior to its use to assess QOL among women with PCOS in Sri Lanka. A "gold standard" measure for general assessment of health related QOL cannot be defined and thus criterion validity cannot be proven for this measure.

The validity coefficients (Pearson's r) were highest for physical and psychological domains while the social domain showed moderate correlations for both groups. The validity coefficients for the social domain in other studies have shown similar results (13, 14).

When the mean scores for the four domains of WHOQOL-BREF obtained by the two groups were tested for significance, highly significant differences ($p<0.001$) were found between the scores for the physical health and psychological health domains while the differences in the social relationships and environment domains were not significant.

The inability of the social relationships and environment domains of WHOQOL-BREF to discriminate between cases and controls have been reported elsewhere (3, 13, 15). The inability of the environment domain to discriminate between cases and controls may be due to the fact that environment domain is like a socio-demographic composite index. It includes physical safety, financial resources, home and physical environment and health service attributes. Since the two groups were comparable i.e. statistically there were no significant differences in the basic socioeconomic indices, no difference may be seen in the scores for this domain. As a result, the domain was not different between the two groups.

When the subgroups distinguished by a median split on item 1 and 2 among cases and controls were analysed, it differed significantly in physical health and psychological health domains in the 'upper halves' where QOL was better (Table 5). The social relationships and the environment domains did not show significant differences in all comparisons. This may show that physical and psychological domains of WHOQOL-BREF have better discriminant validity at the upper end of the spectrum. This observation was similar to that seen by Murphy *et al.* (14) where the physical health domain showed discrimination well across the full health spectrum from "healthy" to 'very ill'. The psychological, social and environment domains could not discriminate at the bottom end

Table 8 – Teat-retest reliability of WHOQOL-BREF among women with PCOS and the control group

Dimensions of WHOQOL-BREF	Women with PCOS	Comparison group
Physical health[1]	0.833**	0.944**
Psychological health[1]	0.756**	0.725**
Social relationships[1]	0.741**	0.704**
Environment[1]	0.845**	0.802**
Item 1-QOL[2]	0.603**	0.676**
Item 2-General Health[2]	0.677**	0.654**

n= 130 [1] Pearson's r [2] Spearman's s

** Correlation is significant at the 0.01 level (2-tailed).

of the spectrum i.e. between 'ill' and 'very ill' where QOL was poor.

The WHO study group (3) has reported that factor analysis has confirmed the comparative fit of the 4 domain model to the construct of QOL. Yao *et al* (16) have found similar results. In the present study confirmatory factor analysis identified six and five factors (domains) for the cases and the controls respectively. Ohaeri *et al* (17) have also reported that WHOQOL-BREF contains heterogeneous items that do not encompass the logical construct of QOL; instead they have obtained an eight domain model from the factor analysis.

Among cases, four items (enjoy life, feel life to be meaningful, ability to concentrate, satisfaction with self) from psychological health domain and four items (feeling safe in daily life, healthy physical environment, condition of the living place, access to health services) from environment domain which appears to contribute to psychological health have combined to form factor 1. Similarly, four items (have enough energy for daily life, physical pain prevents activities, ability to perform daily living activities, satisfaction with capacity for work) from physical health domain and two items (ability to accept bodily appearance, having negative feelings) from the psychological health domain have combined to form factor 2 which seem to go together. Item 4 (need treatment to function daily) and item 15 (ability to get around) which are related to functional ability have separated out from the physical domain.

It appears that in the patients with PCOS four major constructs have emerged. Factor 1 is mainly related to psychological health, factor 2 is mainly related to physical health, factor 3 is mainly related to functional ability and factor 4 is mainly related to social functioning. The separation seen in the social domain is similar in both cases and controls, i.e. item 21 has separated out and has emerged as a single factor while items 20 and 22 have remained together in both groups. This may be partly attributed to the fact that nearly half the population were unmarried in both groups which resulted in an unanswered item, no. 21, which refers to satisfaction with the sex life.

Cronbach's alpha exceeded Nunnaly's criteria of 0.7 for all domains except the social relationship domain in both groups. Similar results have been reported from the various national versions of the WHOQOL-BREF (alpha ranged 0.55-0.74) (18). It suggests that the three items in the social domain did not form a uni_dimensional scale. Since alpha is a function of inter-item correlation and the number of items (Cronbach 1951), the lower value obtained for the social domain could be partly due to the shorter scale length. There was poor correlation between items 1 and 2 (Cronbach's alpha = 0.2368) and items 2 and 3 (Cronbach's alpha =0.3816) showing that the difficulty was due to the item 2 which assessed person's satisfaction with sex life. Nelson and Lofty (18) has noted that statistics of the social domain should be interpreted with caution since it is usually recommended that a minimum of four items should be included in a domain.
The test retest reliability (Table 8) of the four domains was high (Pearson's r = 0.6 to 0.9) after testing over a two week period. The lower but significant correlations for the item 1 and 2 are to be expected since they are single item analyses.

Conclusions
WHOQOL-BREF was found to be a valid and a reliable tool to assess QOL of women with PCOS. It showed good convergent validity, discriminant validity and reliability in all except the social relationships domain.

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