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Psychometric properties of the Iranian version of modified polycystic ovary syndrome health-related quality-of-life questionnaire

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STUDY QUESTION: Can the modified polycystic ovary syndrome health-related quality-of-life questionnaire (MPCOSQ) be validated in Iranian patients with polycystic ovary syndrome (PCOS) to provide an instrument for future outcome studies in these patients?

SUMMARY ANSWER: We show initial reliability and validity of the Iranian version of the MPCOSQ as a specific instrument to measure health-related quality of life (QOL) in patients with PCOS in Iran.

WHAT IS KNOWN ALREADY: The prevalence of PCOS in Iran is relatively high and studying QOL in these patients is important. The PCOSQ has previously been translated and validated in Iran but no studies had examined the psychometric properties of the MPCOSQ in Iran.

STUDY DESIGN, SIZE, AND DURATION: This was a cross-sectional study. After linguistic validation of the Iranian version of MPCOSQ, an expert panel evaluated the items by assessing the content validity index (CVI) and content validity ratio (CVR). Then a semi-structured interview was conducted to assess face validity. Consequently, exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were performed to indicate the scale constructs ($n = 200$). In addition, reliability analyses including internal consistency and test–retest analysis were carried out.

PARTICIPANTS/MATERIALS, SETTING, AND METHODS: This study was carried out on women with PCOS ($n = 200$) who attended two private gynecology clinics in Kashan, Iran. Patients were eligible if they met each of the following criteria: 15–40 years of age; married; not having non-classic adrenal hyperplasia, thyroid dysfunction and hyperprolactinemia; Iranian; not having problems in speaking or listening; having two of the following Rotterdam diagnostic criteria: (i) polycystic ovaries visualized on ultrasound scan (presence of 12 follicles or more in one or both ovaries and/or increased ovarian volume >10 ml), (ii) clinical signs of hyperandrogenism (the hirsutism score based on the Ferriman–Gallwey score >7 or obvious acne) and/or an elevated plasma testosterone (normal range testosterone <2 nmol/l), (iii) having an interval between menstrual periods >35 days and/or amenorrhea as the absence of vaginal bleeding for at least 6 months, i.e. 199 days.

MAIN RESULTS AND THE ROLE OF CHANCE: CVI and CVR scores for MPCOSQ were 0.96 and 0.92, respectively. A six-factor solution (emotional disturbance, weight, infertility, acne, menstrual difficulties and hirsutism) emerged as a result of an EFA and explained 0.64% of the variance observed. The result of the EFA supported the item 'late menstrual period' being placed in the menstrual rather than the emotional subscale. The results of the CFA for six-factor model for MPCOSQ indicated an acceptable fit for the proposed model. Additional analyses indicated satisfactory results for internal consistency (Cronbach's alpha ranging from 0.76 to 0.92) and intraclass correlation coefficients (ranging from 0.71 to 0.92). Moving 'late menstrual period' from the emotional to the menstrual subscale significantly improved the reliability coefficient for both subscales.

LIMITATIONS, REASONS FOR CAUTION: Study of patients with PCOS attending two private gynecology clinics may limit generalization of the findings to the entire population with PCOS. All patients in this study were married for cultural reasons in Iran. Therefore, the results of the present study have to be interpreted with some caution.

WIDER IMPLICATIONS OF THE FINDINGS: The Iranian version of the MPCOSQ will fill an important gap in measuring the QOL in patients with PCOS in the research and community settings in Iran.

STUDY FUNDING/COMPETING INTEREST(S): The authors declare that they have no conflict of interest.

Key words: health-related quality-of-life questionnaire / modified polycystic ovary syndrome health-related quality-of-life questionnaire / Iran / reliability / validity

Introduction

Polycystic ovary syndrome (PCOS) is the most common endocrine disorder in women of reproductive age. It is estimated that 5–10% of women suffer from the disease (Ehrmann, 2005). The symptoms typically associated with PCOS, including amenorrhea, oligomenorrhea, hirsutism, obesity, infertility, anovulation and acne, can lead to a significant reduction in female quality of life (QOL), cause mood disturbances including symptoms of depression, marital and social maladjustment and impair sexual functioning (Hahn *et al*., 2005).

The issue of the QOL of patients with PCOS is very often overlooked in the clinical practice (Hahn *et al*., 2005). One reason for such limited focus on QOL in patients with PCOS might be the fact that while there are a number of general instruments to measure health-related quality of life (HRQOL), only one specific instrument exists to measure QOL in this population, that is the PCOS health-related quality-of-life questionnaire (PCOSQ; Jones *et al*., 2002). The PCOSQ was developed by Cronin *et al*. (1998) and contains 26 items that measure 5 PCOS-related subscales namely emotional disturbances, hirsutism, weight difficulties, infertility and menstrual difficulties. It has good reliability (Guyatt *et al*., 2004; Jones *et al*., 2004; McCook *et al*., 2005), but its validity showed controversial results. Thus, the PCOSQ was modified by Barnard *et al*. (2007) and four additional items were added to the original questionnaire in order to measure issues related to acne and its effect on patients' QOL. This modified version (MPCOSQ) therefore contains 30 items that includes 6 subscales (Barnard *et al*., 2007).

The prevalence of PCOS in Iran is relatively high (11.4%; Ramezani Tehrani *et al*., 2011) and studying QOL in these patients seems important. Since previously the PCOSQ has been translated and validated in Iran (Amini *et al*., 2011), we decided to set up a study to examine the psychometric properties of the MPCOSQ in Iran. To our best knowledge, apart from the original study by Barnard *et al*. (2007), this is the first study that reports on psychometric properties of the MPCOSQ. We thought this might contribute to the existing knowledge on the topic and would provide an instrument for future outcome studies in these patients in Iran.

Methods

The questionnaire

As briefly explained, the modified PCOS quality-of-life questionnaire (MPCOSQ) is a 30-item questionnaire that contains 6 subscales: emotional disturbances (8 items), hirsutism (5 items), infertility (4 items), weight (5 items), menstrual (4 items) and acne (4 items). Response categories are rated on a seven-point Likert scale where a score of 7 suggest no problems or difficulties and 1 indicates maximum impairment on that item. Scores for the emotional disturbance, hirsutism, infertility, weight, menstrual and acne subscales are 8–56, 5–35, 4–28, 5–35, 4–28, and 4–28, respectively (Cronin *et al*., 1998; Barnard *et al*., 2007).

Translation and cultural adaptation

After permission from the author of the MPCOSQ, a forward–backward procedure was applied to translate the English version of the MPCOSQ into Persian (the Iranian language). Two independent professional translators produced two forward translations. Both translators were asked to aim for conceptual rather than literal translation. Together with one of the authors, the translators compared their translations and produced a single draft of the questionnaire. Totally blind to the original version, two other professional translators back translated the provisional Persian questionnaire into the English language. The two translators were not aware of the questionnaire. Finally, an expert team comprising the translators, the researchers and one specialist in psychometrics reviewed all the translation and cultural adaptation processes. They also evaluated the final English version with the original questionnaire. Agreement in terms of semantic, idiomatic and conceptual equivalence was reached and a final version of the questionnaire was provided. In general, the original questionnaire remained unchanged except for one minor modification in item 'felt unsexy because overweight' that was changed to 'felt not having sexy attractiveness because overweight' to adapt to the Iranian culture.

Design and data collection

This was a cross-sectional study of women with PCOS who attended two private gynecology clinics in Kashan, Iran. Women who had been previously diagnosed with PCOS and were scheduled for a routine follow-up appointment were invited to participate. After the study was explained and written consent to participate was obtained from each patient, they were requested to complete a detailed health survey and MPCOSQ, while they were waiting for scheduled consultations with their physician. Patients were eligible if they met each of the following criteria: being 15–40 years of age; married; not having non-classic adrenal hyperplasia, thyroid dysfunction and hyperprolactinemia; Iranian; not having problems in speaking or listening; having two of the following Rotterdam diagnostic criteria: (i) polycystic ovaries visualized on ultrasound scan (presence of 12 follicles or more in one or both ovaries and/or increased ovarian volume, i.e. >10 ml), (ii) clinical signs of hyperandrogenism (the hirsutism score based on the Ferriman–Gallwey score >7 or obvious acne) and/or an elevated plasma testosterone (normal range testosterone >2 nmol/l), (iii) having an interval between menstrual periods >35 days and/or amenorrhea, defined as the absence of vaginal bleeding for at least 6 months (i.e.199 days).

Statistical analysis

(i) Content validity: an expert panel of 10 specialists in gynecology and midwifery was asked to comment independently on necessity in order to calculate the content validity ratio (CVR) and relevancy, clarity and simplicity in order to calculate the content validity index (CVI) of the items. The necessity of the items was assessed using a three-point rating scale: (i) not necessary, (ii) useful, but not essential, (iii) essential. Following the experts' assessments, a CVR for the total scale was computed. According to the Lawshe table, an acceptable CVR value for 10 expert panels is 0.62 (Lawshe, 1975). Based on the proportion of experts who rated each item, the CVI was calculated. Polit and Beck (2004) recommended 0.80 as the acceptable lower limit for the CVI value (e.g. 8 out of 10 experts should rate 3 or 4).

(ii) Face validity: it is concerned with how appropriate, relevant and understandable the items on a questionnaire are to the focus or aim of the questionnaire (Jenkinson and McGee, 1998). Although on its own face validity does not determine the true validity of a questionnaire, it is important to be done as it can improve the assistance of respondents completing a questionnaire, identify any ambiguities in the wording of items and identify any inappropriate items (Jenkinson and McGee, 1998; Kline, 2000). To test face validity, the MPCOSQ was administrated to 30 patients with PCOS to ensure the linguistic and conceptual equivalence of the translations.

(iii) Factor analysis: to verify the factor structure of the MPCOSQ subscales, factor analysis was used. Factor analysis is a statistical method which enables the underlying subscales of a questionnaire to be determined (Kline, 2000). Factor structure of the MPCOSQ was extracted using exploratory factor analysis (EFA), utilizing principal component analysis with varimax rotation. To assess how well the EFA-extracted model fitted the observed data, we conducted confirmatory factor analysis (CFA). The method of estimation was weighted least squares. The asymptomatic covariance matrix was considered as a weighted matrix. The input matrix was covariance matrix of data. Fit indices and acceptable values of these indices for CFA were considered as $\chi^2/df < 5$, the root mean square error of approximation <0.08 and the comparative fit index >0.9 (Bentler and Bonett, 1980).

(iv) Reliability: reliability of the questionnaire measured the variance in a score which reflects the true score, rather than random error; that is, the extent to which measures give consistent or accurate results. Two common forms of reliability are internal consistency and test–retest reliability methods. The internal consistency of a scale relates to its homogeneity. The higher the coefficient value, the higher the reliability and the lower the standard error of measurement. The internal consistency was assessed with the Cronbach's alpha coefficient that ranges from 0 to 1, and values equal to or >0.70 indicate satisfactory internal consistency for a scale (Cronbach, 1951). Test–retest reliability measures stability over time, by administering the same test to the same subjects at two points in time. In order to carry out the test–retest reliability a total of 30 patients, randomly selected from the original group, completed the Persian MPCOSQ again 2 weeks later, in the same manner as the first one. The test–retest reliability of the scale was estimated by intraclass correlation coefficient (ICC). The following category was selected to interpret the agreement levels: 00–0.2 as small, 0.21–0.40 as fair, 0.41–0.60 as moderate, 0.61–0.80 as substantial and 0.81–1 as almost perfect (Landis and Koch, 1977).

Statistical analysis was performed using Statistical Package for the Social Sciences 15.0 (SPSS, Inc., Chicago, IL, USA) and LISREL 8.80 (Scientific Software International, Inc., 2007). *P*-values <0.05 were considered as significant.

Ethics

The Ethics Committee of the Tarbiat Modares University approved the study. All patients give informed consent.

Results

Participants

In all 200 women with PCOS were included in the study. The mean age of patients was 28.02 (SD = 6.11) years. Sociodemographic and clinical characteristic of the patients are presented in Table I.

Content validity

The CVR in this study for the total scale was 0.92, indicating a satisfactory result. The CVI for the scale was found to be 0.96 suggesting that it had a good content validity. Moreover, items were slightly modified based on expert reviews.

Face validity

Almost all patients indicated that the questionnaire was easy to read and understand. Minor wording changes were done according to patient's suggestions to improve clarity.

Table I Sociodemographic and clinical characteristic in Iranian patients with PCOS (*n* = 200).

Variable	
Age (years), mean ± SD	28.02 ± 6.11
Education, *n* (%)	
Guidance school or less	44 (22)
Completed high school	103 (51.5)
College	53 (26.5)
Occupation, *n* (%)	
Employment	39 (19.5)
Housewife	160 (80)
Hirsutism (FG > 7), mean ± SD	8.39 ± 4.28
Having acne, *n* (%)	121 (60.5)
Interval between menstruation (days), *n* (%)	
<21	48 (24)
21–34	53 (26.5)
35–60	19 (9.5)
>199	12 (6)
Changeable	68 (34)
Diagnosis of infertility, *n* (%)	135 (67.5)
BMI (kg/m^2), *n* (%)	
<25	81 (40.5)
25–30	87 (43.5)
>30	32 (16)

FG, Ferriman–Gallwey score.

Table II Descriptive statistics, Cronbach's alpha and ICC of the MPCOSQ subscales.

Subscales	Cronbach's alpha		Mean ± SD	ICC
	Alpha of subscales as originally assigned by Cronin et al. (1998)[a]	Alpha of subscales with one item exchanged[b]		
Acne		0.92	6.34 ± 1.35	0.71*
Menstruation	0.73 (4-item)	0.76 (5-item)	4.18 ± 1.70	0.92*
Weight	0.78	0.78	6.20 ± 1.01	0.72*
Hair	0.89	0.89	5.24 ± 2.21	0.74*
Infertility	0.89	0.89	4.33 ± 1.95	0.80*
Emotion	0.77 (8-item)	0.83 (7-item)	5.85 ± 1.33	0.71*

[a]Without acne subscale.
[b]Last menstrual period.
*P-value < 0.05.

Reliability

Cronbach's alpha for the scale as a whole was 0.84, indicating good reliability, and for each subscale the data are presented in Table II. One item originally assigned by the developers to the emotional subscale was 'last menstruation period'. This item seemed better placed in the menstrual subscale and moving the item from the emotions to the menstrual subscale significantly improved alpha reliability coefficient for both subscales. The ICC for the MPCOSQ subscales was satisfactory (ICC ranged from 0.71 to 0.92; $P < 0.05$; Table II).

Factor analysis

The MPCOSQ was analyzed by principal component factor analysis with varimax rotation. The overall Kaiser-Meyer-Olkin measure of sampling adequacy was 0.78. The Bartlett's test of sphericity was significant ($P < 0.001$), indicating that the variables correlated with one another. Hence, our preliminary analyses confirmed the appropriateness of principal components factor analysis for the data. The MPCOSQ was found to have six factors. The percentage variance explained for rotated factor matrices ranged from 8 to 12% per factor, with six factors explaining 64% of the overall variance. Consideration of each factor revealed the following (percentages refer to the variance explained by each factor): emotional disturbance 12.57%, hirsutism 12.23%, infertility 10.45%, acne 10.38%, weight 9.44% and menstrual difficulties 8.98%. Table III depicts the factor loading after rotation of each item. The factor loadings of the items all exceed 0.386. Item 'last menstrual period' loaded on the menstrual factor, again. The results of CFA for six-factor model for MPCOSQ (moving the item 'late menstrual period' from the emotions to the menstrual subscale) indicate acceptable fit of the proposed model (Table IV, Fig. 1).

Discussion

This study is the first to describe the psychometric properties of the MPCOSQ in another language. While generic questionnaires exist to measure HRQOL, they do not have the ability to capture information on all the areas of well-being and performance that may be important to women with PCOS. For example, infertility and hirsutism can place a considerable strain on the emotional well-being and personal relationships of women with PCOS. This paper reports the translation procedure, structure, validity and reliability findings of the MPCOSQ in Iran. In general, our results support the initial reliability and validity of the Iranian version of MPCOSQ.

Translation of an existing instrument into another language is not a simple translation of words and it requires broad developmental research to produce a culturally comparable form of the instrument plus psychometric testing to establish equivalence (Jones et al., 2001; Jones et al., 2006). In the present research, cultural and conceptual equivalence were obtained. In the translation process, we followed the guidelines for cross-cultural adjustment of psychometric measurements. The Iranian MPCOSQ version was culturally applicable and relayed the intent of the original English MPCOSQ.

In terms of face validity, the women interviewed felt that, on the whole, the questionnaire was addressing the issues which are relevant to PCOS. In previous studies, the lack of questions about acne was raised as a serious error (Jones et al., 2004). The finding that 60% of respondents in the study suffered from acne, supported the fact that acne is a common symptom of the PCOS and suggests that the addition of a new acne subscale to the PCOSQ by Barnard et al. (2007) is important for using the MPCOSQ in a clinical setting. In this study this dimension accounted for 10.38% of the variance.

The test–retest reliability of the Iranian language version of the MPCOSQ was found to be high. All subscales achieved high correlations >0.7, which indicates that the questionnaire produces constant results from subjects at different times, when no evidence of change in health status exists. This level of test–retest reliability is comparable to a previous study (Jones et al., 2004). Based on these studies we can conclude that Iranian MPCOSQ has been validated. The internal reliability of the MPCOSQ was found to be high, with all the scales exceeding the accepted value of 0.8. Our results were also comparable to those in the studies of Jones et al. (2004) and McCook et al. (2005) in which the internal consistencies were between 0.7 and 0.9. The item 'last menstrual period' originally assigned by the developers to the emotional subscale, seemed better placed in the menstrual subscale and moving the item from the emotion to the menstrual subscale significantly improved the reliability coefficient for both subscales. Moreover, in our factor analysis, this item loaded on

Table III Factor loadings from the MPCOSQ principal component analysis.

Item[a]	Factor					
	1	2	3	4	5	6
E7: worried about having PCOS	**0.855**	0.093	0.030	0.146	0.004	0.052
E8: self-conscious as a result of having PCOS	**0.836**	0.138	0.029	0.148	0.014	0.039
E5: low self-esteem as a result of PCOS	**0.757**	0.077	0.031	0.070	0.049	0.053
E4: moody as a result of having PCOS	**0.747**	0.076	0.016	0.116	0.101	0.127
E3: tired easily	**0.637**	0.097	0.090	0.191	0.140	0.153
E2: depressed as a result of having PCOS	**0.590**	0.146	0.077	0.069	0.156	0.038
E6: afraid of getting cancer	**0.386**	0.196	0.156	0.014	0.098	0.227
H1: growth of visible body hair	0.087	**0.866**	0.044	0.011	0.126	0.104
H3: growth of visible hair on your face	0.137	**0.856**	0.085	0.050	0.104	0.101
H2: growth of visible hair on upper lip	0.149	**0.853**	0.002	0.031	0.094	0.036
H5: embarrassment about excessive body hair	0.037	**0.780**	0.072	0.076	0.012	0.048
H1: growth of visible hair on chin	0.112	**0.760**	0.091	0.120	0.032	0.015
I2: afraid of not being able to have children	0.013	0.035	**0.904**	0.035	0.112	0.152
I4: Sad because of infertility problems	0.037	0.009	**0.881**	0.004	0.029	0.118
I1: Concerned about infertility problems	0.035	0.059	**0.833**	0.017	0.010	0.149
I3: lack of control over the situation with PCOS	0.054	0.136	**0.791**	0.070	0.090	0.059
A3: felt unattractive because of acne	0.215	0.099	0.026	**0.847**	0.194	0.003
A1: acne	0.109	0.111	0.003	**0.847**	0.032	0.077
A2: acne[b]	0.160	0.018	0.002	**0.840**	0.070	0.143
A4: depressed as a result of acne	0.206	0.076	0.088	**0.802**	0.192	0.055
W3: frustration in trying to lose weight	0.089	0.082	0.133	0.018	**0.766**	0.157
W1: concerned about being over weight	0.0007	0.103	0.115	0.064	**0.762**	0.180
W5: difficulties staying at your ideal weight	0.095	0.122	0.007	0.007	**0.757**	0.003
W2: trouble dealing with weight	0.200	0.065	0.015	0.087	**0.652**	0.063
W4: felt unsexy because overweight	0.087	0.011	0.017	0.371	**0.633**	0.008
M1: headaches[b]	0.102	0.111	0.015	0.088	0.082	**0.760**
M3: abdominal bloating[b]	0.013	0.106	0.031	0.079	0.150	**0.752**
M2: irregular menstrual periods[b]	0.046	0.079	0.216	0.081	0.109	**0.724**
M4: menstrual cramps[b]	0.163	0.146	0.057	0.164	0.015	**0.617**
E1: last menstruation period[b]	0.083	0.156	0.255	0.036	0.066	**0.606**

[a]Items E: emotional disturbance; H: hirsutism; I: infertility; A: acne; W: weight; M menstrual. Item numbers refer to question number in the original questionnaire.
[b]Refers to the last menstruation.

Table IV Results of confirmatory factor analysis for the six-factor model.

Model	χ^2	df	χ^2/df	RMSEA	CFI
As originally assigned by Cronin *et al.* (1998)	767.84	390	1.96	0.070	0.91
With one item exchanged	734.99	390	1.88	0.067	0.92

RMSEA, root mean square error of approximation; CFI, comparative fit index; df, degree of freedom.

the menstrual factor. In the study of Barnard *et al.* (2007) and Jones *et al.* (2004), this item loaded in menstrual predictability not emotional subscale. To confirm the results of our EFA we utilized CFA. The CFA analysis showed that moving this item to the menstrual factor provided a better fit to the data (Table IV).

Our study confirmed that the Iranian MPCOSQ has six factors. All contributed to only one factor having a factor loading of >0.38, thus satisfying the criteria that predictive items have loadings (Streiner and Norman, 2003). The items loading on each factor are very similar to those identified by Barnard *et al.* (2007) and Jones *et al.* (2004). The discrepancy was 'last menstrual period' which loaded on the menstrual factor in the current study whereas in studies of Barnard *et al.* (2007)

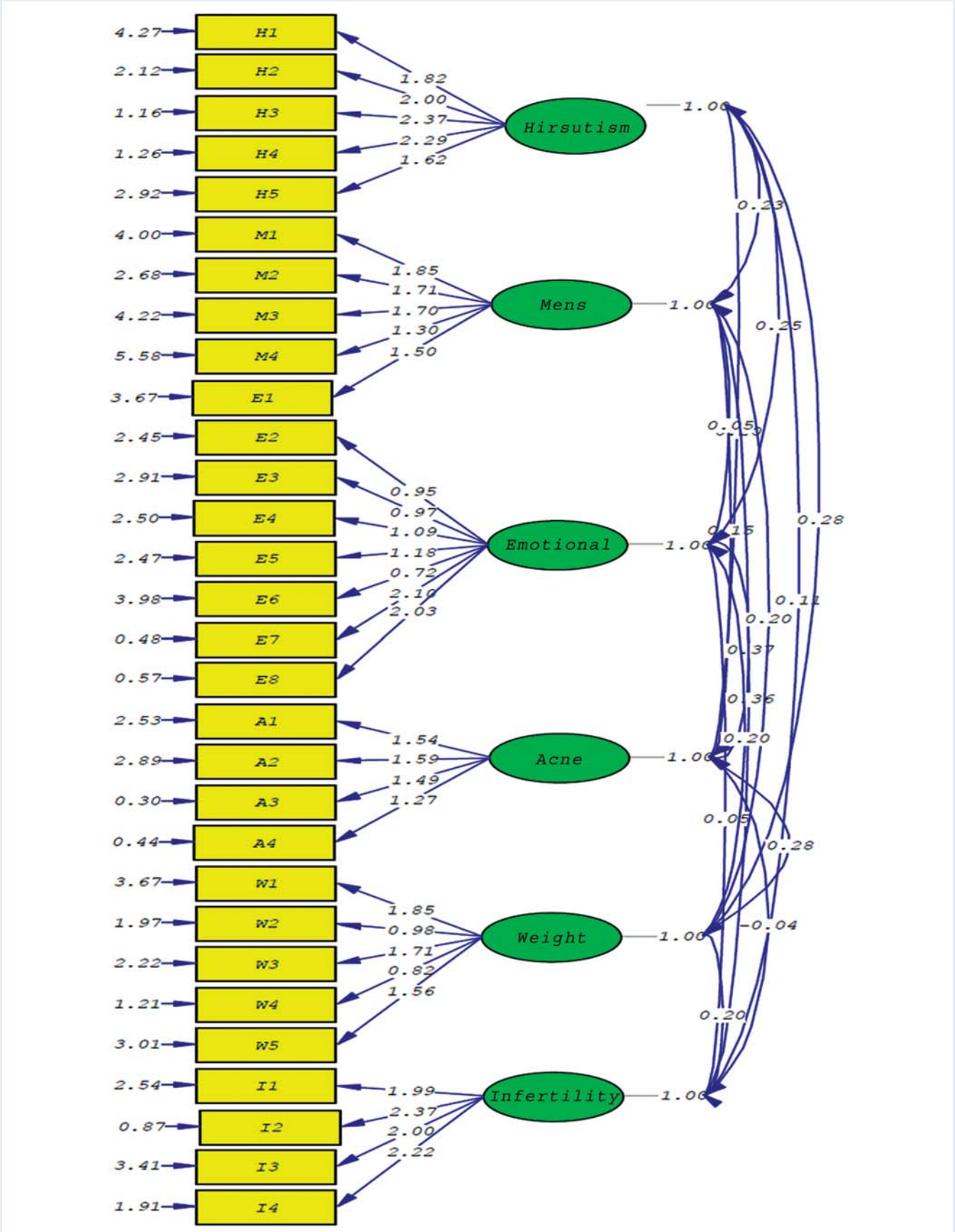

Figure 1 CFA of the six factor model of the MPCOSQ.

and Jones *et al*. (2004) loaded in the menstrual predictability, or in the Guyatt *et al*. (2004) study it loaded on the emotional subscale.

The Iranian MPCOSQ structure was further supported by the strong relationships observed among the subscales, suggesting perfect relations between factors (Fig. 1). On this basis of our research, it is possible to suggest that the center of each of the six subscales identified across all samples is really similar, although particular discrepancies do in fact exist. This indicates that the underlying conceptualization of the subscales of QOL is universal.

In summary, the present study confirmed the six factor structure, content and face validity and reliability of the Iranian version of MPCOSQ. However, it should be noted that it has certain limitations. The study of patients with PCOS who were attending two private gynecology clinics may limit generalization of the findings to the entire PCOS population. Moreover, patients were recruited from a gynecology clinic and the patient population undergoing or seeking medical treatment is known to differ in a number of sociocultural and psychological parameters compared with a community sample. Consequently, it could be argued that there was a bias towards patients with PCOS with menstrual disturbance and infertility and not those presenting with other PCOS-related conditions (i.e. weight increase and acne) who are often referred to endocrinology and dermatology clinics. However, it was felt that sufficient patients with complaints of a dermatological or endocrinological nature to allow us to validate the MPCOSQ were seen in the gynecology clinics. Furthermore, all of the patients in this study were married for cultural reasons in Iran. Some items in MPCOSQ related to sex and infertility, and in the Iranian culture having sex outwith marriage is illegal. Therefore, the results of the present study have to be interpreted with some caution. Further studies using the Iranian MPCOSQ are now needed with regard to larger samples, including community participants, and other regions in Iran. Such studies will extend the generalizability of the Iranian MPCOSQ.

The value of including HRQOL instruments to evaluate treatment from the patient's perspective and to investigate clinical interventions over time has been established (Mant and Fowler, 1990; Streiner, 1995; Colwell *et al*., 1998). The MPCOSQ is a good screening tool which health-care providers can use to help prioritize health-related concerns from the patient's prospective.

Conclusion

Our findings demonstrate the initial reliability and validity of the Iranian version of the MPCOSQ as a measure of specific HRQOL in Iranian patients with PCOS. The Iranian version of the MPCOSQ will fill an important gap in measuring the QOL for patients with PCOS in research and community settings in Iran.

Authors' roles

All authors were involved in designing of the study, data collection and analysis, interpretation of results and manuscript preparation. All authors read and approved the final manuscript.

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Conflict of interest

None declared.

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