ORIGINAL ARTICLE

The Validity and Reliability of the Indonesian Version of Fertility Quality of Life (FertiQoL) Questionnaire

Achmad Zulfa Juniarto[1], Faizah Fulyani[1], Eka Chandra Herlina[1], Prasasya Paramesthi[2], Mahayu Dewi Ariani[1], Aulia Iskandarsyah[3]

[1] Medical Biology and Biochemistry, Department Faculty of Medicine, Diponegoro University, Semarang, Indonesia
[2] Faculty of Medicine, Diponegoro University, Semarang, Indonesia
[3] Faculty of Psychology, Padjajaran University, Bandung, Indonesia

ABSTRACT

Introduction: Quality of life among infertile patients can be measured using a tool has been developed. The tool is The Fertility Quality of Life (FertiQoL). This tool has been translated into 45 languages, and its validation has been studied in some of them. FertiQoL has been translated into Bahasa Indonesia, and reported based on a limited number of female samples.This study used a larger sample size, which consisted of male and female patients to further validate FertiQoL both internally and externally using WHOQoL-BREF questionnaire. **Methods:** The FertiQoL questionnaire was distributed in three private hospitals, one private obstetrician and gynaecologist clinic through purposive sampling method between March 2017 and April 2018. A package containing demographic questions and FertiQoL questionnaire was distributed to patients who met the inclusion criteria and one third of them were asked to filled in the WHOQoL-BREF questionnaire for convergent validation. **Results:** Demographic and FertiQoL were completeted by 614 patients, whereas 217 patients filled in additional WHOQoL-BREF. Significant positive correlations were found on all FertiQoL subscales through convergent validation with WHOQoL-BREF. Intra-correlation of each question in FertiQoL was found to correspond the highest to its intended subscale. The alpha coefficient of FertiQoL subscales was between 0.11-0.85. Omitting reverse-worded questions from the questionnaire increased FertiQoL alpha coefficient to 0.60-0.87. **Conclusion:** In the Indonesian language, FertiQoL was an internal and external tool that valid and reliable to assess the quality of life of infertile patients. However, further evaluation is needed to increase reliability on the relational and social subscale.

Keywords: Validity, Reliability, Infertility, Quality of Life

Corresponding Author:
Achmad Zulfa Juniarto, PhD
Email: zulfa_juniarto@fk.undip.ac.id
Tel: +62-24-76928010

INTRODUCTION

Reproductive problems characterized by the inability of fertile pregnancies after 12 months or more where intercourse is carried out regularly without contraception in a stable relationship is called infertility (1). There are two kinds of infertility, primary and secondary. A phenomenon in which fertile pregnancy has never been achieved is called primary infertility. Secondary infertility is when a couple has had a fertile pregnancy prior but unable to achieve fertile pregnancy again. Factors that cause infertility can be from female or male, both or due to idiopathic causes (2). About 9% of the world's population is estimated to suffer from infertility (3). Combined primary and secondary infertility in Indonesia in 2012 within married females aged 15-45 is estimated at 22.3% (4). Indonesia in 2013 has a population 238 million and en estimated prevalence of infertility is 21,3% (5). The desire of having children among Indonesian marriage couples is very strong, especially with the culture that a family must have children (6). Researchers have found that in developing countries, the negative consequences are much stronger than in western countries. In contrast, the availability and accessibility of fertility treatment are insufficiently met in poor-resource areas (7). Recent studies have reported that infertility (8), decreases life's overall satisfaction and well-being (9), the success of treatment (10), willingness to continue therapy (11), and treatment evaluation (12).

In recent years, clinicians are demanded to avoid measuring the effect of an illness only through the aspect of mortality and morbidity. They are advised to consider the psychosocial effect of a disease towards patients, such as behaviour, daily activity, perception towards their illness, and inability to function. World Health Organization (WHO) defines Quality of Life (QoL) as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns" (13). WHO developed WHOQoL-100,

an instrument to measure QoL, giving clinicians an instrument to deliver a treatment plan through a holistic approach. WHOQoL-100 is a generic instrument, with 100 questions and measures 24 facets. WHOQoL-BREF, was developed as a brief version of WHOQoL-100. WHOQoL-BREF has 26 questions. The 24 questions represented each facet from WHOQoL-100 with two additional general questions. WHOQoL-BREF have four measurement domains, there are physical health, psychological, social relationship and environment. Although generic instruments are applicable to a broad population, condition-specific instruments are more adjusted toward a disease, thus giving a better measurement predictor (13).

Fertility Quality of Life (FertiQoL) has been developed by the international collaboration between European Society for Human Reproduction and Embryology (ESHRE), American Society for Reproduction Medicine (ASRM) and Merck-Serono, Geneva, Switzerland, a condition-specific instrument which is used to measure quality of life among infertile patients. WHOQoL development protocol was used in the development of FertiQoL. FertiQoL has good psychometric properties and has been translated into 45 languages by the FertiQoL team with the approval of two local fertility experts (14). Indonesian FertiQoL has been previously translated and studied (15), although a convergent validation study has not been established, which is vital to validating any instrument. Since, infertility has a strong psychosocial impact that need to be managed, there is a need to provide a valid and reliable instrument to assess emotional, physical, and cognitive aspect of an individual's fertility-specific quality of life in Indonesian version that can be used in research and clinical setting.

MATERIALS AND METHODS

Patients recruited using purposive sampling method from two private Women's and Children's hospitals in Semarang and Tegal and one private obstetrics and gynecology clinic in Semarang, Central Java between March 2017 and April 2018. Inclusion criteria were: (1) patients who visited a specialist for infertility and screened by an obstetrician and gynecologist or an andrologist in charge (2) has an adequate command of the Indonesian Language, and (3) willing to participated. Eligible patients were referred to an on-site surveyor. Both the patient and his or her partner were invited to fill the questionnaires. Patients were asked to fill the questionnaires on the spot or take the questionnaires home. Questionnaire package taken home was accompanied by a stamped return envelope addressed to the researcher. Each patient was required to sign an informed consent and was assigned a code that referred to the location of which the questionnaires were distributed, a unique number, and the surveyor's initials to ensure anonymity. Ethical approval was obtained from the Komisi Etik Penelitian Kesehatan dan Kedokteran FK UNDIP/RSUP Dr. Kariadi (KEPK) for this research to proceed.

The questionnaire package consists of one page of (i) demographic questionnaire, (ii) FertiQoL questionnaire, and over two hundred patients also received (iii) WHOQoL-BREF questionnaire and (iv) blank page for comments regarding the study. All questionnaires were written in Indonesian. Surveyors were invited to test the questionnaire at the beginning of the study. Researchers decided to alter the word infertility ("kemandulan") to fertility ("kesuburan") in questions 1 and 20. Indonesian word of infertility "Kemandulan" is inappropriate for this study as it is a terminology for sterility rather than infertility. FertiQoL scoring system followed the manual available on www.fertiqol.org. WHOQoL-BREF questionnaire and its scoring system was obtained from www.who.int. Both questionnaires are scaled to fit 0-100 scoring system.

SPSS version 23.0 was used to compute the data. Cronbach-alpha was calculated to show reliability of each subscale/domain of the questionnaires. Inter-correlation study was done using Pearson's correlation. Kolmogorov-Smirnov test is used to test the abnormality distribution data on FertiQoL and WHOQoL-BREF set. The result of the data were not normally distributed, the Spearman correlation is used to calculate between FertiQoL and WHOQoL-BREF. The value obtained is p<0,05. The value is statistically significant.

RESULTS

Participants
In total, 629 patients participated in this research. Due to the incompletion of the questionnaire, 15 questionnaires were excluded, resulting in 614 FertiQoL, 217 among them also filled the WHOQoL-BREF questionnaire. Both men and women filled the questionnaires with a similar distribution of both sexes. The mean age of participants was 32.4 (SD 5.7). Even though the sample size for convergent validation of FertiQoL was considerably smaller, both groups' demographic distributions were similar (Table I). As term 'infertility' refers to the inability of sexually-active couples of opposite sexes, the validity and reliability of Indonesian FertiQoL was not tested separately based on the respondents sex.

FertiQoL psychometric properties
Cronbach alpha for FertiQoL subscales is presented in table II. Cronbach alpha of the subscales was between 0.11 – 0.80. The mean total score of FertiQoL among Indonesian infertile patients is 72.7 (SD 14.9).

FertiQoL internal validation
Each question in the FertiQoL questionnaire has its highest significant correlation within its intended subscale (Table III). Questions 4, 11, 14, 15 and 21 (Q4R, Q11R, Q14R, Q15R, Q21R) are correlated

Table I. Respondents characteristics[a,b]

Variable	FertiQoL only[c,d,e]	FertiQoL and WHOQoL-BREF-[f,g,h]
Demographics		
Men, % (n)	46.6 (286)	44.2 (96)
Women, % (n)	53.4 (328)	55.8 (121)
Age (y), mean (SD)	32.4 (5.7)	32.9 (5.4)
Residence		
Urban, % (n)	66.0 (405)	59.9 (130)
Rural, % (n)	33.6 (206)	39.2 (85)
Education		
Elementary/Secondary, % (n)	4.2 (26)	6.0 (13)
High school, % (n)	23.9 (147)	27.6 (60)
University, % (n)	71.0 (436)	65.9 (143)
Employment		
Employed, % (n)	82.4 (506)	77.4 (168)
Reproductive characteristics		
Years infertile, mean (SD)[d]	4.8 (3.8)	5.1 (3.6)
Parenthood, % (n)[b]	12.9 (81)	12.0 (28)
Health insurance		
Insured, % (n)	66.3 (407)	63.6 (138)

[a] Sample sizes varies per variable
[b] Current marriage. Due to Indonesian norm and cultural belief, couples treated for infertility are assumed to be in a legally- or religiously-binding relationship
[c] Data used in reliability and internal validity of FertiQoL
[d] Sample size 614
[e] Missing data: 3 samples from residence, 5 from education
[f] Data used in external validity of FertiQoL
[g] Sample size 217
[h] Missing data: 2 samples from residence, 1 sample from education

Table II. Psychometric properties of core FertiQoL in Indonesian population[a]

FertiQoL Scale	Number of items	Mean score (SD)	Cronbach's α	Cronbach's α after omitting reverse-scoring items
Emotional	6	68.5 (19.7)	0.74	0.87
Mind/Body	6	70.3 (18.4)	0.80	0.80[b]
Relational	6	79.5 (15.6)	0.11	0.60
Social	6	72.4 (18.4)	0.59	0.77
Total core score	24	72.7 (14.9)	0.85	0.92

[a] Sample size 614
[b] There is no items with reverse-scoring in mind/body subscale
α >0.7 deemed reliable

negatively due to their nature of reverse scoring in the FertiQoL questionnaire.

FertiQoL convergent validation against WHOQoL-BREF
It can be inferred from table IV, each subscale in the FertiQoL questionnaire is positively and significantly correlated to WHOQoL-BREF domains, ranging from 0.16 (between emotional subscale and environment domain) and 0.46 (between emotional subscale and physical health.

DISCUSSION

This study finds a significant positive relationship between FertiQoL and WHOQoL-BREF within all subscales. The higher the QoL scores in said subscales correspond to a higher quality of life, vice versa. Each question in FertiQoL has the strongest significant correlation within its respected subscales. Cronbach alpha within FertiQoL subscales was between 0.11-0.80; relational and social subscales were found to have Cronbach alpha <0.70. Omitting reverse-scoring items from all subscales raised FertiQoL's Cronbach-alpha to 0.60-0.87.

The highest correlation was found on the emotional subscale when calculated against WHOQoL-BREF. The emotional subscale measures the negative feelings caused specifically by infertility (e.g. Apakah anda merasa sedih dan depresi dengan masalah kesuburan anda?) hence it can be concluded that infertility most heavily impacts one's emotions, thus declining his/her quality of life. Another interpretation of this finding is one's physical health is an indicator of which further decreases one's emotion.

The social subscale was found to be significant when tested against WHOQoL-BREF domains, and its calculated Cronbach-alpha was 0.59. The social subscale measures the impact of social aspects, such as social inclusion, expectation, and support from society. A prior Indonesian FertiQoL study that involved a smaller number of patients also reported the relational subscale being the lowest subscale of the whole questionnaire with an alpha coefficient of 0.66 and has the lowest Pearson correlation compared to other subscales.

While significant when correlated to WHOQoL-BREF domains, relational subscale was found to have the weakest reliability within all FertiQoL subscales with Cronbach alpha of 0.11. The relational subscale measures the impact of infertility towards one's partnership, such as the effect of sexuality, communication, and commitment. While the relational subscales' mean score appears to be the highest out of all the subscales, the result does not seem to illustrate the case as this subscale has very poor reliability.

Low alpha coefficients found within the relational and social subscales indicate that subscales have very poor reliability within the FertiQoL questionnaire. This finding can be caused by either the FertiQoL questionnaire itself or the characteristics of Indonesian patients. Firstly, it is important to note that the FertiQoL questionnaire was initially written in English and was developed with Western culture in mind. Indonesian women reported difficulty in accessing infertility treatments due to low confidentiality within the services, perceived treatment failure, shame, and fear of being diagnosed with infertility (16). The field surveyors reported that some patients showed rather low-spirited emotions by the time they finished the questionnaire. Some even asked why such private information was necessary to be disclosed. Q6 (Are you satisfied with your sexual relationship even though you have fertility problems?) emphasized

Table III: Pearson's correlation between each questions and core FertiQoL subscales. (n = 614)

		Domain				
		Emotional	Mind/Body	Relational	Social	Total core FertiQoL
Emotional	Correlation Q4R	**-0.39****	-0.16**	-0.29**	-0.17**	-0.31**
	p-value	**<0.01**	<0.01	<0.01	<0.01	<0.01
	Correlation Q7	**0.74****	0.58**	0.33**	0.57**	0.68**
	p-value	**<0.01**	<0.01	<0.01	<0.01	<0.01
	Correlation Q8	**0.80****	0.57**	0.33**	0.57**	0.68**
	p-value	**<0.01**	<0.01	<0.01	<0.01	<0.01
	Correlation Q9	**0.82****	0.66**	0.26**	0.62**	0.73**
	p-value	**<0.01**	<0.01	<0.01	<0.01	<0.01
	Correlation Q16	**0.81****	0.69**	0.26**	0.64**	0.75**
	p-value	**<0.01**	<0.01	<0.01	<0.01	<0.01
	Correlation Q23	**0.75****	0.66**	0.34**	0.61**	0.73**
	p-value	**<0.01**	<0.01	<0.01	<0.01	<0.01
Mind/Body	Correlation Q1	0.53**	**0.72****	0.17**	0.46**	0.58**
	p-value	<0.01	**<0.01**	<0.01	<0.01	<0.01
	Correlation Q2	0.54**	**0.75****	0.25**	0.41**	0.60**
	p-value	<0.01	**<0.01**	<0.01	<0.01	<0.01
	Correlation Q3	0.51**	**0.78****	0.25**	0.42**	0.60**
	p-value	<0.01	**<0.01**	<0.01	<0.01	<0.01
	Correlation Q12	0.53**	**0.61****	0.41**	0.57**	0.65**
	p-value	<0.01	**<0.01**	<0.01	<0.01	<0.01
	Correlation Q18	0.64**	**0.73****	0.32**	0.61**	0.71**
	p-value	<0.01	**<0.01**	<0.01	<0.01	<0.01
	Correlation Q24	0.50**	**0.65****	0.34**	0.48**	0.60**
	p-value	<0.01	**<0.01**	<0.01	<0.01	<0.01
Relational	Correlation Q6	0.19**	0.19**	**0.48****	0.29**	0.34**
	p-value	<0.01	<0.01	**<0.01**	<0.01	<0.01
	Correlation Q11R	-0.15**	-0.19**	**-0.65****	-0.21**	-0.34**
	p-value	<0.01	<0.01	**<0.01**	<0.01	<0.01
	Correlation Q15R	-0.08*	-0.12**	**-0.65****	-0.15**	-0.28**
	p-value	0.04	<0.01	**<0.01**	<0.01	<0.01
	Correlation Q19	0.48**	0.46**	**0.63****	0.44**	0.60**
	p-value	<0.01	<0.01	**<0.01**	<0.01	<0.01
	Correlation Q20	0.42**	0.42**	**0.64****	0.47**	0.58**
	p-value	<0.01	<0.01	**<0.01**	<0.01	<0.01
	Correlation Q21R	-0.16**	-0.18**	**-0.67****	-0.18**	-0.34**
	p-value	<0.01	<0.01	**<0.01**	0.00	<0.01
Social	Correlation Q5	0.17**	0.19**	0.25**	**0.43****	0.31**
	p-value	<0.01	<0.01	<0.01	**<0.01**	<0.01
	Correlation Q10	0.65**	0.56**	0.30**	**0.75****	0.70**
	p-value	<0.01	<0.01	<0.01	**<0.01**	<0.01
	Correlation Q13	0.52**	0.53**	0.24**	**0.74****	0.62**
	p-value	<0.01	<0.01	<0.01	**<0.01**	<0.01
	Correlation Q14R	-0.23**	-0.26**	-0.45**	**-0.50****	-0.43**
	p-value	<0.01	<0.01	<0.01	**<0.01**	<0.01
	Correlation Q17	0.64**	0.60**	0.25**	**0.78****	0.70**
	p-value	<0.01	<0.01	<0.01	**<0.01**	<0.01
	Correlation Q22	0.59**	0.55**	0.27**	**0.73****	0.65**
	p-value	<0.01	<0.01	<0.01	**<0.01**	<0.01

R Items marked with an R are treated as reversed-items and utilized the reverse of the response scale.
*Correlation is significant at the 0.05 level (two-tailed).
** Correlation is significant at the 0.01 level (two-tailed).

that discussing marital issues (especially sexual matters) is still widely avoided within the Indonesian culture. The relatively uncommon questions found in FertiQoL questionnaire may bring up the possibility of social desirability (SD) bias within Indonesian patients. SD is an attempt for an individual to gain self-protection, avoid criticism, and gain social conformity and social approval within a community (17). SD bias can also be augmented when a questionnaire is completed using pen-and-paper (18) and with a surveyor (19); as 93.2% of valid responses were answered through this method, SD bias poses a significant problem in this research. Similarly, prior FertiQoL validation study conducted in Taiwan (20) and Iran (21) also reported low Cronbach-

Table IV: Psychometric properties and Spearman's correlation of FertiQoL subscales and WHOQoL-BREF domains in Indonesian population[a]

| | Scale | Number of items | Mean score | Cronbach's α | WHOQoL-BREF | | | |
					Physical health	Psychological	Social relation-ship	Environment
FertiQoL	**Emotional**	6	67.9 (20.3)	0.77	0.46** <0.01	0.42** <0.01	0.29** <0.01	0.16* <0.05
	Mind/Body	6	69.2 (19.1)	0.81	0.43** <0.01	0.40** <0.01	0.33** <0.01	0.21** <0.01
	Relational	6	76.5 (16.8)	-0.08	0.33** <0.01	0.33** <0.01	0.38** <0.01	0.28** <0.01
	Social	6	71.4 (19.2)	0.57	0.39** <0.01	0.40** <0.01	0.35** <0.01	0.22** <0.01
	Total core score	24	71.3 (16.1)	0.86	0.48** <0.01	0.46** <0.01	0.39** <0.01	0.25** <0.01
WHO-QoL-BREF	**Physical health**	8	70.6 (10.6)	0.69	n.a.	n.a.	n.a.	n.a.
	Psychological	6	66.9 (11.6)	0.72	n.a.	n.a.	n.a.	n.a.
	Relationship	3	66.6 (14.8)	0.70	n.a.	n.a.	n.a.	n.a.
	Environment	8	67.6 (12.0)	0.82	n.a.	n.a.	n.a.	n.a.

[a] Sample size 217
*Correlation is significant at the 0.05 level (two-tailed).
** Correlation is significant at the 0.01 level (two-tailed).
n.a. Not available

alpha from the relational and social subscales when compared to other subscales within core FertiQoL. This finding indicates the influence of culture and social norms is a significant deciding factor that skews the reliability in FertiQoL questionnaire.

Secondly, numerous researches have pointed out reverse-worded question within a questionnaire poses significant bias which further reduces the scale of validity and reliability. Moreover, reverse-worded questions frequently form a separate method factor that does not appear substantively meaningful (22, 23). The problem in reverse-worded questions can be pinpointed at patients' failure to notice the reverse-wording of the questions, thus respond the same way to all items (23). Prior researches recommend completely removing reverse-worded questions within a questionnaire (22). FertiQoL utilizes 5 reverse-worded questions out of 24, meaning the lower respondents scored on the scale reflects higher quality of life. Removing Q11R, Q15R, and Q21R (Are you and your partner affectionate with each other even though you have fertility problems? Have fertility problems strengthened your commitment to your partner? Are you content with your relationship even though you have fertility problems?) from the relational subscale due to their usage of reverse-worded questions resulted in a dramatic improvement of Cronbach alpha from 0.11 to 0.60. It is important to note that the value of Cronbach alpha is predicted to rise as the number of items in the calculation is increased. With only three items being calculated, alpha coefficient of 0.60 can be considered as acceptable (24). An introduction to psychological tests and scales (2 ed). Similarly, removing Q14R (Do you feel your family can understand what you are going through?) from the social subscale raised its Cronbach alpha from 0.59 to 0.77. Moreover, removing all reverse-worded questions from core FertiQoL (Q4R, Q11R, Q14R, Q15R, Q21R) yields even higher Cronbach-alpha within the range of 0.60-0.87 (Table II).

FertiQoL and WHOQoL-BREF have similar outcomes. Both questionnaires can be measured individually as subscales or as a whole item. Both questionnaires are not tools to distinguish psychopathology from normal functions, thus having no cut-off value. Both have four scoring aspects, and the average scores for both questionnaires were similar to each other. Even though some questions belong to a different measurement group, the theme of questions was relatable, albeit FertiQoL's specificity towards infertility.

This study has important strengths. This study is the first FertiQoL to report on the relationship between FertiQoL and WHOQoL-BREF. While a pilot study has been done prior in the Indonesian population involving 128 women, this is the first study to report on the convergent validation of Indonesian FertiQoL. The mean score of Indonesian FertiQoL was found to be higher compared to the development study of FertiQoL. Although the value of Cronbach's alpha was found to be lower, especially in the relational and social subscales, the alpha coefficient for the total core score of FertiQoL was satisfactorily high at 0.85, which further confirms the validation of Indonesian FertiQoL. The involvement of large numbers of both female and male patients also represents the Indonesian population's spread.

This study has some limitations. This study did not consider what kind of treatments the patients were receiving. Thus the impact of a specific treatment could not be measured. 93.2% of questionnaires were done through a self-administration method using pen-and-paper with the presence of a field surveyor which may in turn resulted in SD bias. To measure the quality of life FertiQoL dan WHOQoL-BREF can be used, although the

total combined questions add up to 50 questions. The similarity of both questionnaires may be burdensome to some patients. However, the high response rate does not support this limitation. This research was conducted in three private hospitals and one private specialist clinic, with limited support from the insurance company towards infertility treatments and personal health care services; this study does not necessarily represent the Indonesian population.

CONCLUSION

FertiQoL has a very high potential of being a staple tool in fertility clinics to provide medical professionals with information regarding infertility, thus adjusting treatment modality that focuses on the patients' well-being. While the development of Indonesian FertiQoL is in the right direction, further evaluation needs to be done to increase the relational and social subscales' reliability.

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