Research Article

Validation and Reliability Test of Indonesian Version of The Haemo-QoL Questionnaire

Putri Khaerani,* Ellyana Sungkar, Dian M. Sari

Department of Physical Medicine and Rehabilitation
dr. Hasan Sadikin Hospital, Bandung, Indonesia

*Corresponding author: pkhaerani4681@gmail.com

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Abstract

Hemophilia, blood clotting disorder that requires multidiscipline treatment is a chronic condition which limit the child's ability and reduce quality of life. Quality of life can be measured by Haemo-QoL, the first hemophilia questionnaire, produced 3 sets versions of psychometric. The aim of this study is to obtain a measuring tool to assess the quality of life in children with hemophilia in Indonesia using the Indonesian version of Haemo-QoL questionnaire. This is a cross sectional–observational analysis study, involved 105 hemophilia patients as respondents, aged 4-16 years. Acquisition data was conducted on April to July, 2018 in Bandung. Haemo-QoL was translated into Indonesian and then back translated, further is cognitive debriefing and afterward was tested on each subject. There are several invalid questions in each age group due to lack of respondents and inconsistencies in filling. This inconsistency caused by using Indonesian as a second daily language by more than 50% of respondents. Cronbach's alpha for all types of questionnaires has a r–coefficient ≥ 0.5 which means that the Haemo-QoL reliability in Indonesian for all categories has been tested with good results and it can be used to assess the quality of life of hemophilia patients.

Keywords: *Haemo-QoL Indonesian version, reliability, validity, quality of life.*

Uji Validasi dan Reliabilitas Kuesioner Haemo-QoL Versi Bahasa Indonesia

Abstrak

Hemofilia adalah kelainan pembekuan yang memerlukan penanganan multidisiplin; bersifat kronik dan membatasi kemampuan anak sehingga menurunkan kualitas hidup. Haemo-QoL merupakan kuesioner hemofilia pertama yang memiliki 3 set versi kuesioner psikometri. Tujuan penelitian ini untuk mendapatkan alat ukur dalam menilai kualitas hidup anak hemofilia menggunakan kuesioner Haemo-QoL versi Bahasa Indonesia. Penelitian menggunakan desain observasional analitik potong lintang yang melibatkan 105 responden berusia 4-16 tahun. Pengambilan data dilakukan pada bulan April - Juli 2018 di Bandung. Haemo-QoL diterjemahkan ke bahasa Indonesia kemudian diterjemahkan kembali ke bahasa Inggris dan dilakukan cognitive debriefing. Selanjutnya dilakukan pengujian pada setiap subjek menurut kelompok usia. Pada penelitian ini didapatkan hasil yang tidak valid pada masing-masing kelompok usia karena kurangnya jumlah responden dan ketidakkonsistenan dalam pengisian antara lain disebabkan penggunaan Bahasa Indonesia sebagai bahasa kedua oleh lebih dari 50% responden. Cronbach's alpha untuk semua jenis kuesioner memiliki nilai koefisien r ≥0,5 sehingga reliabilitas baik, yang berarti kuesioner Haemo-QoL dalam Bahasa Indonesia ini dapat digunakan untuk menilai kualitas hidup pasien hemofilia.

Kata kunci: *Haemo-QoL versi Indonesia, reliabilitas, validitas, kualitas hidup.*

Introduction

Hemophilia patients registered in Indonesia based on 2011 data is reaching 1,388 patients. Association of Indonesian Hemophilia Society/ *Himpunan Masyarakat Haemofilia Indonesia* (HMHI) predicts the number of hemophilia patients in Indonesia has reached 20,000 people. In West Java, there were 289 patients, with 55 patients of them were in city of Bandung, 25 in county of Bandung, and 17 in West Bandung county.[1,2]

Hemophilia, a chronic blood clotting disorder, is caused by lack of blood clotting factors; factor VIII is around 80-85% and factor IX.[3,4] Patients with severe hemophilia have the risk of experiencing various types of bleeding both spontaneously or trauma. The most common types of hemorrhage are hemarthrosis (70-80%), hematoma, and arthropathy. Hemarthrosis and recurrent hematoma, as with pain cause restrictions on the locomotor system and decrease physical ability.[4-7] Children with hemophilia will limit their movement and undergo sedentary lifestyles, which can cause decreasing in cardio-pulmonary function and increasing in body mass index. Arthropathy will cause the limited range motion of the joints, so activities that require full range motion of the joints cannot be done.[3,8,9]

Quality of life is a subjective perception of satisfaction or happiness in life and it is an important domain for individuals.[10] The important thing for children in the early years of life is to provide a real opportunity for using their ability to learn, develop, and having fun during those years. Chronic conditions in children, such as hemophilia, will be able to limit their ability and therefore, reducing their quality of life.[9]

Health conditions are quite important aspects that contribute in quality of life. Another definition, namely the quality of life related to health, is health related quality of life (HRQoL). Child's HRQoL is also influenced by other factors such as the ability to participate in peer groups and the ability to compete according to the level of development. Assessment in quality of life is known as a measurement of important health outcomes in the management of the health sector, which can help optimize the management according to the patient's needs. Disease-specific HR-QoL instruments have been developed by hemophilia children, Haemo-QoL (Haemophilia Quality of Life Questionnaire).[10-12]

Haemo-QoL is the first hemophilia questionnaire consist of 3 sets of versions of the psychometric questionnaire that were tested for three age groups of children as well as their parents. This questionnaire has been validated in Germany, France, Italy, Spain, Netherlands, England and translated into 30 languages, not including Indonesia.[11,12]

As a communication tool, language has a very vital role in human life. The use of Indonesian language in daily life is important to support community life activities. Indonesian citizens, in general, are often to use regional languages. Indonesian language is understood and spoken by more than 90% of citizens in Indonesia, but it is not primary language. Indonesian citizens use one of 748 regional languages in Indonesia as primary language to communicate mostly in informal setting and sometimes in formal setting. There are positive and negative impacts for using regional languages. Positive impacts are Indonesian has a lot of vocabularies, as a wealth of Indonesian culture, as the identity and characteristics of a tribe and region and causing familiarity in communication. Negative impacts are difficulty for one region to understand other regions, foreign who wants to learn Indonesian found it difficult because of too many vocabularies, people become less familiar in using standard Indonesian.

Based on the background above, the aim of this study is to obtain standardized measurement tools to assess the quality of life of hemophilia children in Indonesia using the Indonesian version of the Haemo-QoL questionnaire.

Methods

This study used a cross sectional research design. The target population was hemophilia pediatric patients in Bandung. Inclusion criteria are hemophilia patients, aged 4-16, understand Indonesian, and have good ability to carry out the instructional procedures. Exclusion criteria are hemophilia patients with cognitive impairments and mental health disorders.

The first stage of initial characteristic study was carried out on 20 subjects who could use Indonesian language well. In the second stage of final characteristic study was carried out on 35 subjects for each category. This study used consecutive sampling and took 35 patients for each category. The data was taken from the results of filling out the HaemoQol questionnaire by hemophilia pediatric patients during April-July 2018.

This study was conducted to test the validity and reliability of the Haemo-QoL questionnaire in English into Indonesian using the interview analytical method or filling out questionnaires for hemophilia patients. This study was conducted in 6 steps as written in the flow chart at the Figure 1. The author of Haemo-QoL must give review in every step. The final version of the instrument was tested in 35 patients using SPSS version 24.0 software. The internal consistency of each statement is assessed by the Cronbach's alpha coefficient.

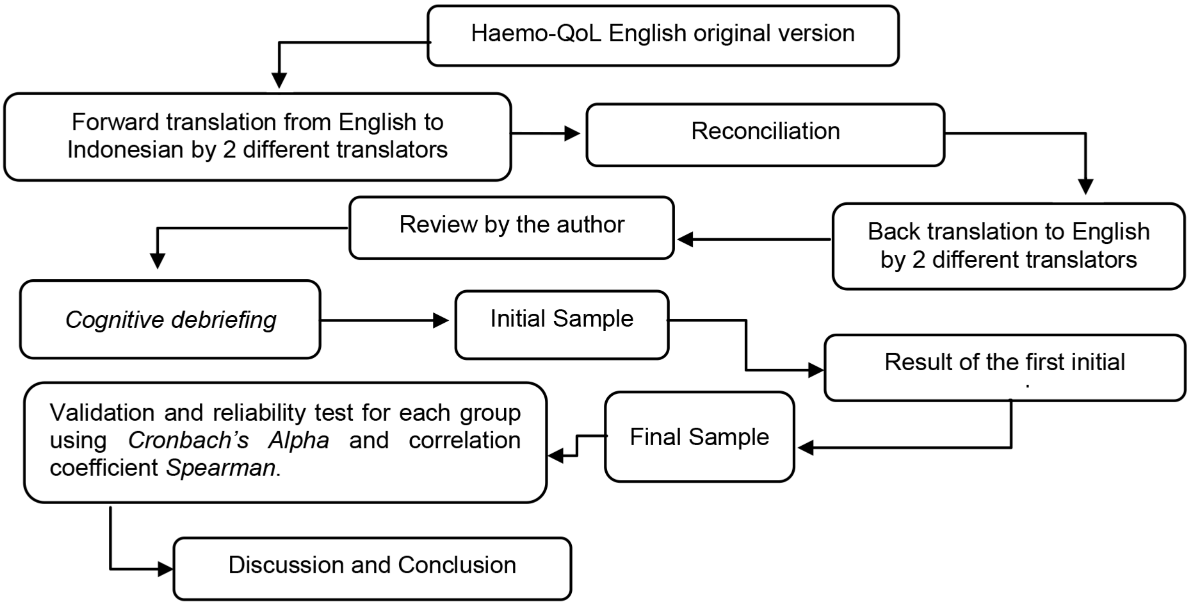

Figure 1. Study Flowchart

Validity shows the extent to which instrument measures what will be measured. A valid instrument means that the measuring instrument used to obtain the data is valid. The step in testing the validity of the questions on the questionnaire is looking for *r* count (Pearson correlation number).[13,14] Reliability test is used to measure instrument which is an indicator of a variable. Reliable means that it can be trusted and relied on, so with several times repeated the results will remain the same (consistent). Questionnaire is reliable if the answer of a sample to a statement is consistent or stable from time to time. The authors used one shot method for measuring the level of reliability, to test the questionnaire just asking one-time questions. Reliability testing used the alpha cronbach technique for interval data types.[13,14]

Descriptive analysis techniques is a technique of measuring instrument using questionnaires to determine the perceptions of respondents regarding the attractiveness of a variable. Each question is accompanied by 3-5 possible answers that must be considered and chosen by the respondent. The answers chosen are then compiled assessment criteria for each question item based on continuum values and percentage: 20-36% is very low, >36-52% is low, >52-68% is average, >68-84% is high, and >84-100% is very high.[1,13,15]

Results

Subject Characteristics

Table 1 describes the characteristics of the subject according to age, education, hemophilia type, and severity. Age has an average of 10.16 ± 4.0 years. Children in kindergarten are 9 (8.6%), in playgroup are 14 (13.3%), in elementary are 48 (45.7%), junior high school are 17 (16.2%) and senior high school are 17 (16.2%). Hemophilia A is 88 (83.8%) and Hemophilia B is 17 (16.2%).

Table 1. Subjects Characteristics

Characteristics	n (%)
Age (year)	
Mean±Std	10.16 ± 4.0
Median	10
Range (min-max)	4.0-16.0
Education	
Kindergarten	9 (8.6)
Playgroup	14 (13.3)
Elementary	48 (45.7)
Junior High School	17 (16.2)
Senior High School	17 (16.2)
Hemophilia Type	
A	88 (83.8)
B	17 (16.2)
Level of Severity	
Mild	13 (12.4)
Moderate	16 (15.2)
Severe	76 (72.4)

Table 2 explains the comparison between duration of questionnaire based on daily language used in the age group 4-7 years, 8-12 years, and 13-16 years. The average for children who use Indonesian in group 4-7 years is 19.6 ± 11.0 minutes while for children who use Sunda is 31.2 ± 11 minutes. The average for children who use Indonesian in group of 8-12 years is 18.5 ± 5.9 minutes while children who use Sunda is 31.5 ± 12.0 minutes. And the average for group of 13-16 years who use Indonesian is 15 minutes while for children who use Sunda is 28.2 ± 9 minutes. The results of the statistical test of all groups obtained p value was <0.05 on the variable duration of questionnaire meaning there is significant difference between the variables in groups of children who use Indonesian and Sunda.

Table 2. Duration of Questionnaire Based on Daily Language Used by Age Group

Age Group	Daily Language		p value
	Indonesia	Sunda	
4-7 years	n=16	n=19	0.002*
Mean ± Std	19.6 ± 11.0	31.2 ± 11.0	
Median	15.5	30	
Range (min-max)	10.0-45.0	15.0-45.0	
8-12 years	n=11	n=24	<0.001
Mean ± Std	18.5 ± 5.9	31.5 ± 12.0	
Median	19	30	
Range (min-max)	10.0-31.0	15.0-60.0	
13-16 years	n=-11	n=24	<0.001
Mean ± Std	15.0	28.2 ± 9.0	
Median	15.0	27	
Range (min-max)	15.0	15.0-60.0	

Validity and Reliability Test

To determine the validity of the items on the questionnaire, a person product moment correlation test was conducted. The number of subjects taken in the questionnaire trial was suggested by 30 people if n ≥10. With the number of subjects (n)=35 people, the correlation table (r table) was 0.3. Some questions in each instrument are invalid (r-count <0.3).

Testing reliability is done by internal consistency or the degree of accuracy of answers. Instrument is reliable if the coefficient r ≥0.5. If the instrument has a coefficient of r <0.5, the measuring instrument is not reliable. Table 3 shows that all the questionnaire instruments are reliable because (r >0.5).

Table 3. Reliability Test Result Based on Aged Group

Age Group	Cronbach's alpha	Cronbach's alpha based on standardized items	n of Items
4-7 year	0.857	0,5	48
8-12 year	0.931	0,5	105
13-16 year	0.928	0,5	119

Discussion

This study had 105 subjects of hemophilia children. No subjects were excluded on the assessment day. This study had 31.4% less than estimated of the required sample of 51 children in the age group. Ferreira et al[16] regarding validation tests in the city of Brazil stated that the number of subjects obtained was 39 people with hemophilia children and adults. Taha[17] managed to gather 45 hemophilia children and Mercan[18] managed 39 hemophilia children. These three studies showed that the Haemo-QoL questionnaire in their respective language versions is reliable and can be used as benchmark for the quality of life for hemophilia patients in their country. All research met the same problem regarding difficulty to get the subject. Short time research period was also problem in this study.

The results of this validation test were not in accordance with validation tests in several previous countries.[3,17,18] There were several questions in each questionnaire that give constant results, so they could not be calculated statistically and were invalid. This invalidity and statistically, did not change the validity of the entire questionnaire content, because content validation had been done before by the founder of questionnaire.[19,20]

Validation tests were conducted on 20 subjects for each age group first. In the first validation test, the results obtained were valid for each question. Then a validation test was performed on a larger group, 105 subjects. The results of cognitive debriefing showed no grammatical understanding or the meaning of the whole sentence. The results of cognitive debriefing indicated that the child could understand the question and no one felt or said that the written vocabulary needed to be changed.

The results of the validation test for ages 4-7 have 3 invalid questions from 51 questions. Nineteen children from 35 used Sunda as a daily language and Indonesian as second language. There were differences in terms of time and understanding in reading the writing which written in second language.

One of the questions in the 4-7 years Haemo-QoL questionnaire was about “injections” that was invalid because the results were constant, so it could not be calculated statistically. Injections could be performed by other doctors, or by nurse or parents, but at the interview, it was found that parents had not dared to inject their children in the age of 4-7 years and in the clinic, all injections for children were carried out by doctors.

Questionnaire results for ages 8-12 years, obtained 5 items from 106 questions were invalid. The question about "joint bleeding" asked "whether you need to keep quiet, for example lying in bed, when you experience bleeding" showed an invalid result. Gunter et al[21] wrote that the treatment of joint bleeding in hemophilia was by injecting a substitute for factors and handling the pain. All children knew that if they had bleeding event, all they had to do was having an injection.

The item on "hemophilia and body health" asked whether a month ago, their joints felt stiff. In cognitive debriefing interview, subjects said that they understood the phrase "stiff in the joint". Most subjects felt pain instead of stiff. The question about "exercise and school", was "I have to do more indoor activities than other children due to my hemophilia", said to be invalid. This is because many children had the same answer and giving small point in result. The question of "overall health" gave invalid results because of the data obtained, 22 subjects from 35 subjects (63%) filled out questionnaires when their health conditions were not good, because of being treated for bleeding or getting an injection for bleeding handling.

The results for ages 13-16 have 5 items out of 119 questions that were invalid. In the 5 items of this question, a small value was obtained so that the results were invalid. Ten children from 32 children used Sunda as a daily language and Indonesian as the second language. Statistically invalid was also due to incompatibility or consistent with other items.

Author suggests for further research to assess the Indonesian version of Haemo-QoL in wider population by homogenizing the subject. Another research in other site is needed for further assessment about impact of Indonesian as second language to see daily language factors. Standardized assessment of the level of cognition of children is needed, to avoid bias results because of the cognitive inability of children to understand the questions. Standardized assessment of the mental health of children is needed to avoid biased results because children experience mental health problems.

The Indonesian version of Haemo-QoL, as a standardized clinical measurement tool, can be used in assessing the quality of life of hemophilia children in Indonesia so that it can assist in evaluating the results of rehabilitation programs. Further research needs to be done with a validated questionnaire to analyze correlations between dimensions in Indonesia.

Conclusion

Haemo-QoL for 4-7 years age group has 3 invalid question items, 8-12 years age group has 5 invalid items, and 13-16 years age group has 5 invalid question items. The three Haemo-QoL questionnaires had proven to have good reliability. Haemo-QoL questionnaire Indonesian version can be used to assess the quality of life of hemophilia patients.

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