

Validity and Reliability Test of Rome IV Functional Dyspepsia Diagnostic Questionnaire (R4-FDDQ) on Indonesian Population

Prueba de validez y confiabilidad del Cuestionario de diagnóstico de dispepsia funcional de Roma IV (R4-FDDQ) en la población de Indonesia

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SUMMARY

Introduction: Currently there has not been a specific instrument to assess the presence of functional dyspepsia, which is specially designed for the Indonesian population. The main objective was to determine the validity and reliability of the Indonesian version of the Rome IV Functional Dyspepsia (FD) Questionnaire Criteria. **Methods:** A total of 80 participants (age ≥ 21 years) with a complaint of dyspepsia were recruited. The Kruskal-Wallis test is used to analyze the difference between demographic data and the type of FD. Pearson's product-moment correlation and Cronbach's alpha tests were used to assess the validity and reliability. **Results:** The participants were mostly dominated by females (66.75 %), with an age average of 43.26 ± 12.692 , obese (41.25 %), and Javanese (92.50 %). Most

participants are classified as not having functional dyspepsia (77.50 %). Based on the questionnaire, most participants that fulfill the criteria for functional dyspepsia sub-type are classified into postprandial distress syndrome (8.8 %). There were no significant differences between gender, age, BMI, and ethnicity with the type of FD, with each of them indicating $p > 0.01$. The validity test was confirmed valid with the r-value greater than the r-table ($r > 0.26$, $p < 0.01$). The translated questionnaire also confirmed an acceptable reliability level ($\alpha = 0.79$). **Conclusion:** The Indonesian version of the Rome IV Functional Dyspepsia Questionnaire Criteria was valid and reliable and can be used as a screening tool in diagnosing functional dyspepsia in the Indonesian population.

Keywords: Functional dyspepsia, Rome IV, validity, reliability, human and disease.

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RESUMEN

Introducción: Actualmente no existe un instrumento específico para evaluar la presencia de dispepsia funcional, el cual está especialmente diseñado para la población indonesia. El objetivo principal fue determinar la validez y confiabilidad de la versión indonesia de los criterios del cuestionario de dispepsia funcional (FD) de Roma IV. **Métodos:** Se reclutaron un total de 80 participantes (edad ≥ 21 años) con queja de dispepsia. La prueba de Kruskal-Wallis se utiliza para analizar la diferencia entre los datos demográficos y el tipo de DF. Se utilizaron la correlación producto-momento de Pearson y las pruebas alfa de Cronbach para evaluar la validez y confiabilidad. **Resultados:** Los participantes fueron mayoritariamente femeninos (66,75 %), con edad promedio $43,26 \pm 12,692$, obesos (41,25 %) y javaneses (92,50 %). La mayoría de los participantes se clasifican como sin dispepsia funcional (77,50 %). Según el cuestionario, la mayoría de los participantes que cumplen los criterios para el subtipo de dispepsia funcional se clasifican en el síndrome de malestar posprandial (8,8 %). No hubo diferencias significativas entre sexo, edad, IMC y etnia con el tipo de DF, indicando cada uno de ellos una $p > 0,01$. La prueba de validez se confirmó como válida con un valor de r mayor que la tabla de r ($r > 0,26$, $p < 0,01$). El cuestionario traducido también confirmó como nivel de confiabilidad aceptable ($\alpha = 0,79$). **Conclusión:** La versión indonesia de los Criterios del Cuestionario de dispepsia funcional de Roma IV fue válida y confiable y puede usarse como una herramienta de detección para diagnosticar la dispepsia funcional en la población indonesia.

Palabras clave: Dispepsia funcional, Roma IV, validez, fiabilidad, humano y enfermedad.

INTRODUCTION

Functional dyspepsia (FD) is defined as a group of symptoms that causes uncomfortable feelings in the upper abdominal in which the type of cause can be divided into postprandial distress syndrome (PDS) and epigastric pain syndrome (EPS) (1). The estimated global prevalence of FD ranges between 4.8-7.2 % (2). To this date, there has not been a specific study about the prevalence of FD in Indonesia. While the proposed mechanisms of FD are suspected to involve multiple mechanisms, it is commonly associated with psychosocial aspects and decreased quality of life (3,4). While symptom assessment is crucial

and further testing available in primary care is sometimes only *Helicobacter pylori* testing, the diagnosis can't be definitive yet (5). The gold standard to diagnose FD remains only by endoscopy, and a normal result characterizes it, sometimes accompanied by gastric hyperemia and without any organic lesion (6,7).

Over the past decade, development in the field of FD has led to an increase in questionnaires used for diagnosis establishment. The Rome IV Functional Dyspepsia Diagnostic Questionnaire (R4-FDDQ) is a to-the-point 7-item questionnaire developed to help diagnose FD (8). It has been used in various clinical studies (9,10). The R4-FDDQ can help establish the diagnosis of FD compared to the diagnosis by gastroenterologists (11). It can also help rule out the differential diagnosis of FD. Thus, it may help to evaluate the treatment given to the patients (12). The questionnaire has been translated into several languages, including Arabic, Cantonese Chinese, Japanese, Spanish, and Portuguese (13-16), yet to be translated into Bahasa Indonesia. Indonesia is a country consisting of multi-ethnicity, so a simple translation could not be performed without considering cross-cultural factors (17). This study aimed to determine the validity and reliability of the Indonesian-translated version of R4-FDDQ.

METHODS

Translations and cultural adaptations

The English version of the Rome IV Functional Dyspepsia Diagnostic Questionnaire (R4-FDDQ) consists of 7 questions assessing the frequency, uncomfortable feeling, and pain in the upper abdominal pain which can be present in dyspepsia patients. The translated questionnaire maintained the original structure to assess the type of functional dyspepsia in the patients. The translation process was conducted with self-translating. There was a modification after the translation process, reducing the questions to 6 questions because of the ambiguity and similarity of one question with another question. Based on the Rome Foundation scoring algorithm for R4-FDDQ, this specific question doesn't indicate any significance in affecting the result.

Study design and population

The study was prospective and involved 80 participants (21 years and older) with a complaint of dyspepsia in the inpatient and outpatient gastroenterology clinic of Siti Khodijah Sepanjang Hospital Sidoarjo from November 2021 until August 2022. The presence of uncomfortable feelings and pain in the abdomen was definitive in suspecting dyspepsia. None of the participants are excluded. All participants are recruited through their medical records. The participants filled out the R4-FDDQ through offline and online interviews. Demographic data (gender, age, and ethnicity) and body mass index (BMI) were collected from all participants. The BMI is classified based on Asia-Pacific classification as follows: <math> < 18.5 \text{ kg/m}^2 </math> (underweight), $18.5\text{-}22.9 \text{ kg/m}^2$ (normal), $23\text{-}24.9 \text{ kg/m}^2$ (overweight), $\geq 25 \text{ kg/m}^2$ (obese) (18). The type of functional dyspepsia is divided into postprandial distress syndrome (PDS) and epigastric pain (EPS) (19). Informed consent was obtained from all participants, and Research Ethical Committee approved the ethical clearance of this study of Siti Khodijah Sepanjang Hospital Sidoarjo by the letter number 030KET-KEPK/IX-2021.

Statistical analysis

Mean (\pm standard deviation), number (n), and percentage (%) are used to analyze the descriptive analysis. The Kruskal-Wallis test was used to analyze the difference between gender, age, BMI, and ethnicity with the type of FD. For the validity test, the Pearson product-moment correlation test was used to assess the validity by comparing the correlation value (r-count) to the correlation table value (r-table) and observing the significance value (p-value) ($r > 0.26$, $p < 0.01$). Cronbach's alpha was used to assess the reliability by observing the alpha's value. The interpretation of the alpha's value can be evaluated as follows: excellent (> 0.9), good (> 0.8), acceptable (> 0.7), questionable (> 0.6), poor (> 0.5), and unacceptable (< 0.5). All statistical analysis was processed with IBM SPSS Statistics version 25.0.

RESULTS

Table 1 shows that participants are mostly dominated by females (66.75 %), followed by males (33.75 %). The participant's age average at 43.26 ± 12.69 . The participant's age is classified into 17-25 years old (10 %), 26-35 years old (18.75 %), 36-45 years old (30 %), 46-55 years old (25 %), 56-65 years old (13 %), and > 65 years old (2.5 %). The participant's BMI average at 24.59 ± 4.12 . The participant's BMI is classified into underweight (7.5 %), normal (32.5 %), overweight (18.75 %), and obese (41.25 %). Most participants are also classified as Javanese (92.5 %), followed by non-Javanese (7.5 %).

Table 1 also shows that most participants were not classified into functional dyspepsia (77.5 %). Based on the questionnaire result, most sub-type of functional dyspepsia is dominated mainly by the postprandial distress syndrome sub-type (8.8 %). For 62 participants that were classified as not FD, they were dominated by females (64.5 %), with age ranges between 36-45 years old (35.5 %) and a mean and SD value of 44.15 ± 11.86 , obese (40.3 %) with mean and SD value of 24.59 ± 4.01 , and Javanese (93.5 %). For 7 participants that were classified as PDS, they were dominated by females (71.4 %), with age ranges varying from 17-25 years old, 26-35 years old, and 36-45 years old, with each of the age groups having 2 participants, with a mean and SD value of 34.29 ± 8.9 , obese (57.1%) with a mean and SD value of 25.37 ± 4.53 , and Javanese (85.7 %). For 5 participants that were classified as EPS, they were dominated by females (80 %), with age ranges between 17-25 years old (40 %) with a mean and SD value of 39.2 ± 21.97 , normal (100 %) with a mean and SD value of 20.78 ± 0.87 , and Javanese (80 %). For 6 participants that were classified as overlapping between PDS and EPS, they were dominated by females (66.7 %), with age ranges between 46-55 years old (50 %) with a mean and SD value of 48 ± 13.45 , obese (66.7 %) with a mean and SD value of 26.83 ± 5.08 , and Javanese (100 %). There were no significant differences between gender ($p = 0.900$), age ($p = 0.203$), BMI ($p =$

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Table 1. Characteristics of the study participant

Characteristic	Mean ± SD (n = 80)	Not classified as FD (n = 62)	PDS (n = 7)	EPS (n = 5)	Overlap between PDS and EPS (n = 6)	p-value
Gender						0.900
Male	27 (33.75 %)	22 (35.5 %)	2 (28.6 %)	1 (20 %)	2 (33.3 %)	
Female	53 (66.25 %)	40 (64.5 %)	5 (71.4 %)	4 (80 %)	4 (66.7 %)	
Age	43.26 ± 12.69	44.15 ± 11.86	34.29 ± 8.9	39.2 ± 21.97	48 ± 13.45	0.203
17-25 years old	8 (10 %)	4 (6.45 %)	2 (28.6 %)	2 (40 %)	0 (0 %)	
26-35 years old	15 (18.75 %)	10 (16.1 %)	2 (28.6 %)	1 (20 %)	2 (33.3 %)	
36-45 years old	24 (30 %)	22 (35.5 %)	2 (28.6 %)	0 (0 %)	0 (0 %)	
46-55 years old	20 (25 %)	16 (25.8 %)	1 (14.3 %)	0 (0 %)	3 (50 %)	
56-65 years old	11 (13 %)	9 (14.5 %)	0 (0 %)	1 (20 %)	1 (16.7 %)	
>65 years old	2 (2.5 %)	1 (1.55 %)	0 (0 %)	1 (20 %)	0 (0 %)	
BMI	24.59 ± 4.12	24.59 ± 4.01	25.37 ± 4.53	20.78 ± 0.87	26.83 ± 5.08	0.079
Underweight	6 (7.5 %)	5 (8.1 %)	1 (14.3 %)	0 (0 %)	0 (0 %)	
Normal	26 (32.5 %)	19 (30.6 %)	1 (14.3 %)	5 (100 %)	1 (16.65 %)	
Overweight	15 (18.75 %)	13 (21 %)	1 (14.3 %)	0 (0 %)	1 (16.65 %)	
Obese	33 (41.25 %)	25 (40.3 %)	4 (57.1 %)	0 (0 %)	4 (66.7 %)	
Ethnicity						0.542
Javanese	74 (92.5 %)	58 (93.5 %)	6 (85.7 %)	4 (80 %)	6 (100 %)	
Non-Javanese	6 (7.5 %)	4 (6.5 %)	1 (14.3 %)	1 (20 %)	0 (0 %)	

SD, standard deviation; BMI, body mass index; FD, functional dyspepsia; PDS, postprandial distress syndrome; EPS, epigastric pain syndrome.

0.079), and ethnicity (p = 0.542) with the type of FD. All of them indicate p >0.05.

Table 2 showed a valid result from the validity test of the Indonesian version of R4-FDDQ. From the 6 questions, 3 questions show a moderate correlation (question 1 = 0.622; question 5 = 0.647; question 6 = 0.616). The other 3 questions show a strong correlation (question 2 = 0.802; question 3 = 0.763; question 4 = 0.759). The validity of the Indonesian version of R4-FDDQ is demonstrated by the fact that the r-count of each question is higher than the r-table and the

significance value is less than 0.01 (r >0.26, p <0.01).

Table 3 showed a reliable result from the reliability test of the Indonesian version of R4-FDDQ.

The result indicates a Cronbach's alpha value of 0.79. This can be interpreted as a reliable questionnaire because Cronbach's alpha value is more than 0.7. The level of reliability of this questionnaire indicates acceptable reliability. This finding shows that the Indonesian version of R4-FDDQ is reliable.

Table 2. Pearson correlation coefficient of the Indonesian version of R4-FDDQ

Item	r	α
Question 1 In the last 3 months, how often did you feel so full after a regular-sized meal (the amount you normally eat) that it interfered with your usual activities? Selama 3 bulan terakhir, seberapa sering Anda merasa sangat kenyang setelah memakan makanan dengan porsi normal (jumlah yang biasa Anda makan) sehingga mengganggu aktivitas Anda?	0.622	<0.01
Question 2 Has it been 6 months or longer since you started having these episodes of fullness after meals that were severe enough to interfere with your usual activities? Apakah sudah 6 bulan atau lebih sejak Anda mulai merasakan kekenyangan setelah memakan makanan yang cukup berat sehingga mengganggu aktivitas Anda?	0.802	<0.01
Question 3 In the last 3 months, how often were you unable to finish a regular-sized meal because you felt too full? Selama 3 bulan terakhir, seberapa sering Anda tidak dapat menghabiskan makanan dengan porsi normal karena merasa terlalu kenyang?	0.763	<0.01
Question 4 Has it been 6 months or longer since you started having these episodes of feeling too full to finish regular-sized meals? Apakah sudah 6 bulan atau lebih sejak Anda mulai merasa terlalu kenyang untuk menghabiskan makanan dengan porsi normal tersebut?	0.759	<0.01
Question 5 In the last 3 months, how often did you have pain or burning in the middle part of your upper abdomen (above your belly button but not in your chest), that was so severe that it interfered with your usual activities? Selama 3 bulan terakhir, seberapa sering Anda merasakan nyeri atau rasa terbakar di bagian tengah perut bagian atas (di atas pusar, tetapi tidak di dada), yang cukup berat sehingga mengganggu aktivitas Anda?	0.647	<0.01
Question 6 Has it been 6 months or longer since you started having this pain or burning in the middle part of your upper abdomen? Apakah sudah 6 bulan atau lebih sejak Anda mulai merasakan nyeri atau rasa terbakar di bagian tengah perut bagian atas tersebut?	0.616	<0.01

r, Pearson correlation coefficient; α , p-value

Table 3. Cronbach's alpha of the Indonesian version of R4-FDDQ

Question	Cronbach's alpha
Question 1 In the last 3 months, how often did you feel so full after eating a normal portion of food (the amount you normally eat) that it interfered with your activities? Selama 3 bulan terakhir, seberapa sering Anda merasa sangat kenyang setelah memakan makanan dengan porsi normal (jumlah yang biasa Anda makan) sehingga mengganggu aktivitas Anda?	0.79
Question 2 Has it been 6 months or more since you started feeling full after eating food that was heavy enough to interfere with your activities? Apakah sudah 6 bulan atau lebih sejak Anda mulai merasakan kekenyangan setelah memakan makanan yang cukup berat sehingga mengganggu aktivitas Anda?	
Question 3 In the last 3 months, how often did you not finish a normal portion of food because you felt too full? Selama 3 bulan terakhir, seberapa sering Anda tidak dapat menghabiskan makanan dengan porsi normal karena merasa terlalu kenyang?	
Question 4 Has it been 6 months or more since you started feeling too full to finish these normal portions of food? Apakah sudah 6 bulan atau lebih sejak Anda mulai merasa terlalu kenyang untuk menghabiskan makanan dengan porsi normal tersebut?	
Question 5 During the past 3 months, how often did you have pain or burning in the center of your upper abdomen (above the belly button, but not in the chest), which was severe enough to interfere with your activities? Selama 3 bulan terakhir, seberapa sering Anda merasakan nyeri atau rasa terbakar di bagian tengah perut bagian atas (di atas pusar, tetapi tidak di dada), yang cukup berat sehingga mengganggu aktivitas Anda?	
Question 6 Has it been 6 months or more since you started experiencing this pain or burning in the center of the upper abdomen? Apakah sudah 6 bulan atau lebih sejak Anda mulai merasakan nyeri atau rasa terbakar di bagian tengah perut bagian atas tersebut?	

DISCUSSION

Statistical analysis shows a valid result of the Indonesian version of R4-FDDQ. The reliability test shows acceptable reliability. According to reports, using a standard instrument is crucial for creating clinical research. Many issues in primary healthcare can be evaluated by certain questionnaires, which can also help to establish the diagnosis of the disease (9,19). R4-FDDQ evaluates symptoms and quality of life in the dyspepsia patient. The subscale of the question determines the type of functional dyspepsia. The symptoms of functional dyspepsia are evaluated by the onset and frequency of postprandial fullness, early satiation, and epigastric pain in the patients (20).

The validity of a questionnaire analyzes whether the questionnaire measures what it is intended to (21). The Indonesian version of R4-FDDQ indicates a valid result. Several factors may affect the result of the validity, which are the demographic distribution, the interview dynamics with the participants, and the status of the participants, which are hospitalized participants (inpatients and outpatients) (22). Each of the questions tested has a moderate to strong correlation. The highest correlation coefficient is from question 2. This can be interpreted that these questions represent how well it is to fit the diagnostic criteria of functional dyspepsia. This result is also similar to another study that reported R4-FDDQ could be used to diagnose functional dyspepsia in a large population (23). This finding suggests that the Indonesian version of R4-FDDQ can be used as a valid instrument to help establish the diagnosis of FD in the Indonesian population.

The reliability of a questionnaire measures how consistent the questionnaire's results are (21). The Indonesian version of R4-FDDQ indicates an acceptable reliable result. Several factors may affect the result reliability, which are the language used in the questionnaire, the psychological and physical factors of the participants, and how trained the interviewer is (24). The acceptable reliability of the questionnaire indicates how reliable it is in measuring the patient's symptoms, which is based on the questionnaire to help establish the diagnosis of functional dyspepsia. This result is similar to another study that reported

R4-FDDQ could be relied on to help establish the diagnosis of functional dyspepsia (25). This finding suggests that the Indonesian version of R4-FDDQ can be relied on to help establish the diagnosis of FD in the Indonesian population.

A total of 80 participants were involved in this research. The participants well demonstrated the Indonesian population as this research was dominated by Javanese, which is the most common ethnic group in Indonesia (26). Most participants are also dominated by females. This finding was also reported in another study (27). Most participants are also mostly classified as 36-45 years old. However, this finding was slightly different in another study which reported that most FD patients are classified as 46-60 years old, followed by 31-45 years old (19). Most participants are also classified as obese. This finding was also reported in another study (28). The findings of this report suggest that dyspepsia patient is more common in females, aged around 36-45 years old, people with obesity, and come from Java.

This study had several limitations. The sample size was relatively too small. Because of the cross-sectional design, the ability of the translated version of R4-FDDQ to assess the diagnosis after endoscopy could not be evaluated. The translation process merely depended on the self-translating rather than comparing the results between re-translated and post re-translated versions of this questionnaire. Lastly, the symptoms present when the participant answered the questionnaire could affect the questionnaire result.

CONCLUSION

This study confirmed that translated version of R4-FDDQ is valid and reliable. The questionnaire can be used as a screening tool for diagnosing functional dyspepsia. Endoscopy examination remains a definitive examination in diagnosing functional dyspepsia.

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Conflicts of Interest

The authors declare no conflict of interest.

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