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Adaptación cultural y validación de la versión indonesia del QUALEFFO-41 en pacientes con osteoporosis

Pandji Winata Nurikhwan[1], Zairin Noor[2]

[1]General Physician. Faculty of Medicine and Health Sciences. Lambung Mangkurat University.
[2]Department of Orthopaedic and Traumatology. Faculty of Medicine and Health Sciences. Lambung Mangkurat University - Ulin General Hospital. Kalimatan Selatan, Indonesia

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Correspondence: Pandji Winata Nurikhwan. Faculty of Medicine and Health Sciences. Lambung Mangkurat University. Kalimatan Selatan, Indonesia
e-mail: pandji.winata@gmail.com

ABSTRACT

Background: osteoporosis represents a growing public health concern in Indonesia, contributing to substantial morbidity through pain, functional decline, and vertebral or non-vertebral fractures. Despite the widespread use of the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41) internationally, a fully validated Indonesian version has not been previously available. This study aimed to conduct a rigorous cultural adaptation and psychometric validation of the Indonesian QUALEFFO-41.

Methods: a cross-sectional study was conducted among 204 Indonesian-speaking patients diagnosed with osteoporosis or osteopenia. The cross-

cultural adaptation followed Beaton's standardized guideline, including forward-backward translation, expert panel review, and cognitive debriefing. Psychometric evaluation included internal consistency (Cronbach's alpha), test-retest reliability (Intraclass Correlation Coefficient; ICC), convergent validity (Average Variance Extracted and Composite Reliability), and construct validity using Confirmatory Factor Analysis (CFA).

Results: internal consistency was excellent for Pain (α = 0.93) and physical function (α = 0.90), acceptable for social function (α = 0.73), moderate for mental function (α = 0.79), and marginal for general health perceived (α = 0.65). Test-retest reliability demonstrated good to excellent ICC values across domains (0.66-0.87), with an exceptionally high ICC for the total score (0.999). Convergent validity was satisfactory across all domains (AVE > 0.50; CR > 0.70). CFA showed perfect model fit for general health perceived, marginal fit for adl and jobs around the house, and poorer fit for pain, mobility, social function, and mental function.

Conclusion: the Indonesian QUALEFFO-41 demonstrates robust reliability and satisfactory validity, supporting its use as a culturally relevant instrument for assessing quality of life in Indonesian patients with osteoporosis. Although several domains showed suboptimal CFA fit likely reflecting cultural and linguistic influences the instrument remains psychometrically sound for clinical practice and research. Further longitudinal and multi-group analyses are recommended to refine factor structure and evaluate responsiveness across diverse Indonesian populations.

Keywords: Osteoporosis. Quality of Life. QUALEFFO-41. Reliability. Validation.

RESUMEN

Antecedentes: la osteoporosis constituye un creciente problema de salud pública en Indonesia, que contribuye de manera significativa a la

morbilidad a través del dolor, el deterioro funcional y las fracturas vertebrales o no vertebrales. A pesar del uso generalizado del Cuestionario de Calidad de Vida de la Fundación Europea para la Osteoporosis (QUALEFFO-41) a nivel internacional, hasta ahora no se disponía de una versión indonesia completamente validada. Este estudio tuvo como objetivo realizar una rigurosa adaptación cultural y validación psicométrica del QUALEFFO-41 indonesio.

Métodos: se llevó a cabo un estudio transversal con 204 pacientes de habla indonesia diagnosticados con osteoporosis u osteopenia. La adaptación transcultural siguió la guía estandarizada de Beaton, que incluye traducción directa-inversa, revisión por panel de expertos y entrevistas cognitivas. La evaluación psicométrica incluyó consistencia interna (alfa de Cronbach), fiabilidad test-retest (Coeficiente de Correlación Intraclase; ICC), validez convergente (varianza media extraída y fiabilidad compuesta) y validez de constructo mediante Análisis Factorial Confirmatorio (AFC).

Resultados: la consistencia interna fue excelente para dolor (α = 0,93) y función física (α = 0,90), aceptable para función social (α = 0,73), moderada para función mental (α = 0,79) y marginal para percepción de salud general (α = 0,65). La fiabilidad test-retest mostró valores ICC buenos a excelentes en todos los dominios (0,66-0,87), con un ICC excepcionalmente alto para la puntuación total (0,999). La validez convergente fue satisfactoria en todos los dominios (AVE > 0,50; CR > 0,70). El AFC mostró un ajuste perfecto para el dominio de percepción de salud general, un ajuste marginal para actividades de la vida diaria y tareas del hogar, y un ajuste pobre para dolor, movilidad, función social y función mental, consistente con los hallazgos de estudios de validación en Corea, Israel, Serbia y Malasia.

Conclusión: el QUALEFFO-41 indonesio demuestra una sólida fiabilidad y una validez satisfactoria, lo que respalda su uso como instrumento culturalmente relevante para evaluar la calidad de vida en pacientes indonesios con osteoporosis. Aunque varios dominios mostraron un ajuste subóptimo en el AFC, probablemente reflejando influencias culturales y

lingüísticas, el instrumento sigue siendo psicométricamente sólido para la práctica clínica y la investigación. Se recomiendan análisis longitudinales y multigrupo adicionales para refinar la estructura factorial y evaluar la capacidad de respuesta en diversas poblaciones indonesias.

Palabras clave: QUALEFFO-41. Validación. Fiabilidad. Calidad de vida. Osteoporosis.

INTRODUCTION

Osteoporosis is a major and growing public health concern in Indonesia. The progressive loss of bone mass and the deterioration of bone microarchitecture characteristic of osteoporosis lead to increased fragility and fracture risk, imposing substantial clinical, social, and economic burdens. National estimates have reported osteoporosis prevalence rates of 28.8 % in men and 32.3 % in women in early Indonesian studies (Anasulfalah et al., 2023). In addition, vertebral fracture prevalence among Indonesian women in Southeast Asia has been estimated at approximately 9 % (Ferreira et al., 2013). Given the rapid growth of the ageing population and the projected rise in fracture incidence with predictions that half of all osteoporotic hip fractures will occur in Asia by 2050 (International Osteoporosis Foundation, 2020). The burden of osteoporosis in Indonesia is expected to continue increasing.

Within this context, measuring health-related quality of life (HRQoL) in patients with osteoporosis becomes critically important. Conventional clinical parameters such as bone mineral density (BMD) or fracture counts capture structural changes but often fail to reflect the broader impact of osteoporosis on pain, functional limitations, social participation, and psychological well-being. Disease-specific patient reported outcome measures (PROMs) therefore play a crucial role in assessing the subjective burden of osteoporosis, evaluating treatment effects, and monitoring longitudinal changes. However, the use of PROMs in Indonesia has been constrained by a lack of validated, culturally adapted instruments. While

generic HRQoL tools are available, disease-specific, locally validated measures remain limited within the Indonesian language and cultural context.

One of the most widely applied osteoporosis-specific PROMs is the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41). Developed by the European Foundation for Osteoporosis (now the International Osteoporosis Foundation), the QUALEFFO-41 consists of 41 items across five domains: pain, physical function, social function, general health perception, and mental function (Lips et al., 1997; De la Loge et al., 2005). This questionnaire has been translated into numerous languages and has demonstrated clinical utility in populations with vertebral fractures and osteoporosis (Choo et al., 2024).

A recent systematic review assessing the measurement properties of QUALEFFO-41 found that the quality of evidence supporting structural validity, reliability, responsiveness, and cross-cultural validity ranged from very low to moderate (Choo et al., 2024). Despite the appearance of a Bahasa Indonesia version in certain instrument repositories, no peer-reviewed publication has documented a full psychometric validation of the Indonesian QUALEFFO-41, including appropriate translation and adaptation procedures, evaluation of factor structure, reliability testing, construct validity, measurement error, and responsiveness. This methodological gap limits the confidence with which QUALEFFO-41 can be used in clinical practice and research in Indonesia.

Therefore, the aim of the present study is to conduct a comprehensive cultural adaptation and psychometric validation of the QUALEFFO-41 into Bahasa Indonesia for use among Indonesian patients with osteoporosis, with or without vertebral fractures. By adhering to internationally accepted methodological guidelines for cross-cultural adaptation (Beaton et al., 2000) and applying rigorous psychometric evaluation, this study aims to produce a validated Indonesian QUALEFFO-41 capable of reliably assessing HRQoL among Indonesian patients with osteoporosis.

METHODS

Study design

This study employed a cross-sectional design to translate, culturally adapt, and psychometrically validate the Indonesian version of the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41). The study followed the cross-cultural adaptation process recommended by Beaton et al. (2000) and psychometric evaluation guidelines proposed by Nunnally and Bernstein (1994) and Hair et al. (2019).

Participants

A total of 204 participants diagnosed with osteoporosis or osteopenia were recruited from outpatient clinics and community health centers in Indonesia. Participants were aged 61-77 years and were able to read and understand the Indonesian language.

Instrument

The QUALEFFO-41 is a disease specific quality of life questionnaire originally developed by the International Osteoporosis Foundation (IOF) to assess the health related quality of life in patients with vertebral fractures and osteoporosis. It comprises 41 items grouped into five domains:

1. Pain,
2. Physical Function,
3. Social Function,
4. Mental Function, and
5. General Health Perception.

Each item is scored on a 5 point Likert scale, with higher scores indicating poorer quality of life.

Translation and cross-cultural adaptation

The translation and cultural adaptation of the QUALEFFO-41 into Indonesian were conducted according to the standard Beaton et al. (2000) six step process:

1. Forward Translation: Two independent bilingual translators (translated the original English version into Indonesian).
2. Synthesis: Both translated versions were compared and synthesized into a single reconciled version after discussion among translators and researchers.
3. Backward Translation: Two additional translators, blinded to the original instrument, translated the Indonesian version back into English to ensure conceptual equivalence.
4. Expert Committee Review: A multidisciplinary committee (methodologists, clinicians, and linguists) reviewed all versions to evaluate semantic, idiomatic, experiential, and conceptual equivalence, producing a pre-final version.
5. Pre-testing: The pre-final version was administered patients to evaluate clarity, relevance, and cultural appropriateness through cognitive debriefing interviews.
6. Final Version: Minor linguistic adjustments were made based on feedback, and the final Indonesian version was approved by the original instrument's developer (IOF).

Cross-cultural adaptation and linguistic validation

The cross-cultural adaptation of the QUALEFFO-41 questionnaire into Indonesian was conducted in accordance with internationally accepted guidelines for the adaptation of health-related quality of life instruments. Two independent bilingual translators whose mother tongue was Indonesian performed forward translations of the original English version into Indonesian. One translator had a medical background, while the other had no clinical background to ensure both conceptual and lay-language equivalence. The two translated versions were then synthesized into a single reconciled Indonesian draft after discussion and consensus between translators and the research team. Subsequently, backward translation was performed by two independent professional translators who were blinded to the original instrument and had no prior knowledge of

QUALEFFO-41. The purpose of back-translation was to ensure semantic and conceptual equivalence with the original version.

The committee evaluated semantic, idiomatic, experiential, and conceptual equivalence and produced the pre-final Indonesian version. Cognitive debriefing (pilot testing) was conducted among osteoporosis patients to assess clarity, comprehensibility, and cultural relevance. Minor wording adjustments were made based on participant feedback.

During the validation phase, participants completed only the Indonesian version of the QUALEFFO-41 questionnaire. No dual-language (English and Indonesian) administration was performed, and the same respondents did not complete both language versions. This approach was chosen to reflect real-world clinical use in the Indonesian population.

Data collection procedure

Data were collected in Indonesia. Participants completed the Indonesian QUALEFFO-41 during their routine clinical visits, either independently or with minimal assistance from trained research staff. To evaluate test-retest reliability, a subsample of 60 participants completed the questionnaire again after a two-week interval, during which no clinical changes were expected. Sociodemographic data were also collected.

Statistical analysis

Psychometric analyses were conducted to assess the reliability and validity of the Indonesian QUALEFFO-41. Statistical analyses were performed using IBM SPSS Statistics version 26.0, SmartPLS 4.0, and AMOS 24.0.

Reliability

Internal consistency reliability was assessed using Cronbach's Alpha (α). Coefficients of $\alpha \geq 0.70$ were considered acceptable, $\alpha \geq 0.80$ good, and $\alpha \geq 0.90$ excellent. Test-retest reliability was examined using the Intraclass Correlation Coefficient (ICC) with a two-way mixed-effects

model and absolute agreement definition. ICC values ≥ 0.75 indicated good reliability, and ≥ 0.90 excellent reliability.

Convergent validity

Convergent validity was evaluated through factor loadings, Average Variance Extracted (AVE), and Composite Reliability (CR). AVE ≥ 0.50 and CR ≥ 0.70 were interpreted as satisfactory evidence of convergent validity.

Construct validity

Construct validity was examined via Confirmatory Factor Analysis (CFA) using maximum likelihood estimation in AMOS. Model fit was assessed using χ^2/df, CFI, TLI, GFI, AGFI, and RMSEA. The model was considered acceptable when χ^2/df < 3.0, CFI and TLI ≥ 0.90, GFI ≥ 0.85, and RMSEA ≤ 0.08.

RESULTS

Sociodemographic and clinical characteristics of participants

(Table I)

Table I. Sociodemographic and clinical characteristics of participants

Characteristics	Category	Frequency (*n*)	Percent (%)
Type of subject	Pre-validation Study	50	24.5
	Control	88	43.1
	Case	66	32.4
Current age of subject (years)	60-64	13	6.4
	65-69	112	54.9
	70-74	57	27.9
	≥ 75	22	10.8
Onset age of osteoporosis (years)	≤ 59	7	3.4
	60-62	89	43.7
	63-65	81	39.7
	≥ 66	27	13.2
Body mass index (kg/m²)	< 18.5 (underweight)	0	0.0
	18.5-22.9 (normal)	98	48.0
	23.0-24.9 (overweight)	77	37.7
	≥ 25 (obese)	29	14.2

Level of education	No formal education	42	20.6
	Primary School	43	21.1
	Secondary School	71	34.8
	Tertiary School	48	23.5
Marital status	Married	98	48.0
	Widowed	106	52.0
Employment status	Working	39	19.1
	Retired	165	80.9

Note: Percentages are calculated based on valid responses (n = 204).

Results of translation and adaptation of the QUALEFFO-41 questionnaire into Indonesian

General Information

The original QUALEFFO-41 (Quality of Life Questionnaire, 1997) was translated, adapted, and validated into Indonesian by ZN, and PWN. The translation was acknowledged and approved by the International Osteoporosis Foundation (IOF) on June 16th, 2019.

Structure of the questionnaire

The Indonesian version of QUALEFFO-41 comprises 41 items divided into five domains, identical to the original version. The questionnaire used in this study consists of several main domains that describe various aspects of the respondents' condition. The pain domain includes 5 items assessing the frequency, duration, and intensity of back pain. The physical function domain is divided into three sub-domains. The activities of daily living sub-domain consist of 4 items evaluating the respondents' ability to dress, bathe, use the toilet, and maintain sleep quality. The household work sub-domain contains 5 items covering activities such as cleaning, cooking, washing dishes, shopping, and lifting objects. The mobility sub-domain includes 8 items assessing the ability to stand, bend, climb stairs, walk, and maintain posture. Social function domain consists of 7 items measuring respondents' participation in hobbies, sports activities, cinema/theatre visits, and other social engagements. The general health perception domain includes 3 items reflecting respondents' perceptions of their overall health and quality of life and the mental function domain

comprises 9 items evaluating feelings of fatigue, hopelessness, loneliness, mood, and levels of optimism.

Translation and cultural adaptation

The translation process emphasized semantic, idiomatic, experiential, and conceptual equivalence with the original instrument. Several linguistic and cultural adaptations were applied to ensure clarity and relevance for respondents. Lexical adjustments and simplifications were made to improve readability, while unfamiliar or technical terms were replaced with more commonly understood expressions. Cultural adaptations were incorporated for items that may not fully match the local context, such as activities involving cinema or theatre. Clarifying examples were added to enhance comprehension, particularly for items involving specific weights or tasks. Semantic refinement was also carried out to preserve the intended psychological meaning of key terms, ensuring that translated items accurately reflected the constructs measured in the source version.

Scoring and Interpretation

All response options were standardized according to the IOF scoring algorithm (2017):

1. Most items are rated from 1 (best quality of life) to 5 (worst quality of life).
2. Items 33, 34, 35, 37, 39, and 40 are reverse-scored.
3. Domain scores are calculated as the mean of all items in the domain, then converted to a 0-100 scale.
4. If more than 30 % of items are left unanswered, the result is considered invalid.

Validation notes

1. The translation included the official IOF scoring and conversion algorithm, ensuring methodological consistency.

2. The Indonesian version maintains the original structure and psychometric intent, while ensuring linguistic and cultural equivalence.
3. Official authorization was obtained from the International Osteoporosis Foundation confirming the validity and appropriateness of this adaptation.

The Indonesian version of the QUALEFFO-41 demonstrates semantic and conceptual equivalence with the original English instrument, with minor linguistic simplifications and contextual adjustments to accommodate Indonesian cultural norms. This version is suitable for assessing quality of life among Indonesian-speaking patients with osteoporosis.

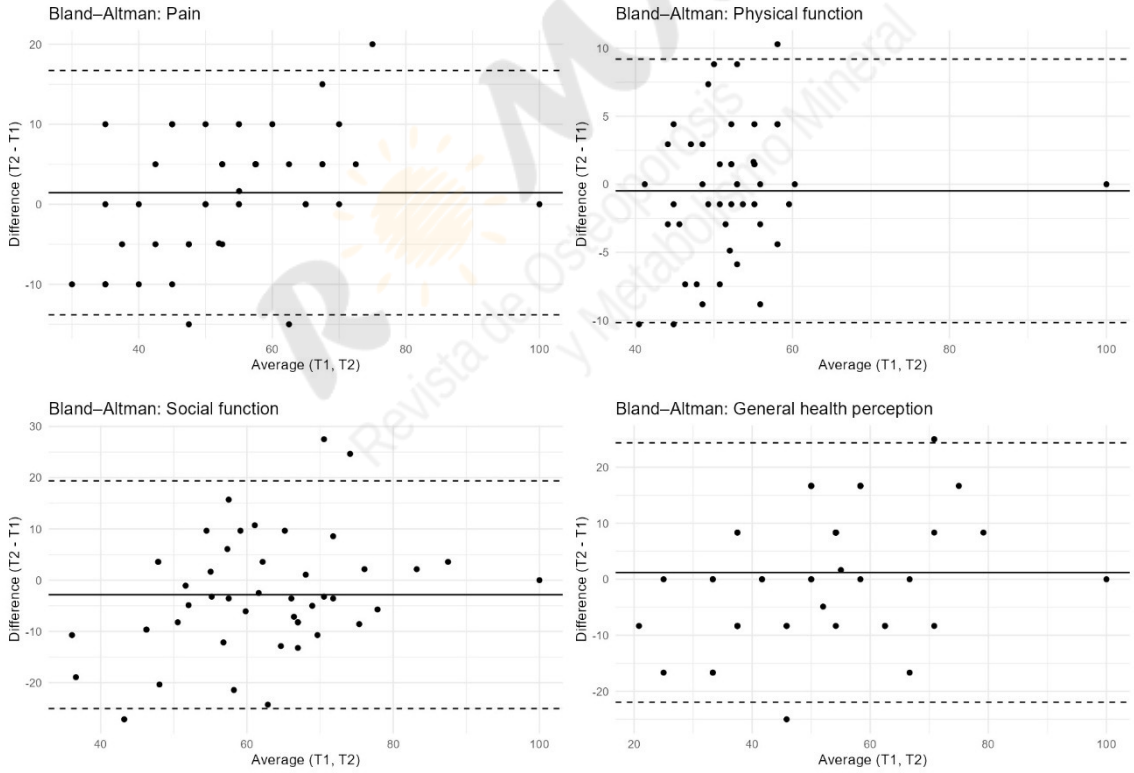
Table II presents the internal consistency reliability of each domain as measured by Cronbach's alpha. The Pain domain, with five items, demonstrated excellent reliability ($\alpha = 0.930$). The Physical Function domain, consisting of 17 items, also showed a high level of reliability ($\alpha = 0.902$). The Social Function domain achieved acceptable reliability with an alpha value of 0.725. The General Health Perceived domain exhibited marginal reliability ($\alpha = 0.653$), indicating that internal consistency was lower compared to other domains. Meanwhile, the Mental Function domain demonstrated moderate reliability with an alpha of 0.794. Overall, most domains achieved satisfactory levels of internal consistency.

Table II. Integrated analysis of internal consistency, test–retest reliability, and construct validity across questionnaire domains

Domain		Number of items	Cronbach's Alpha (α)	Alpha interpretation	*n* (test-retest)	Time interval	ICC	ICC interpretation	AVE	CR	Validity interpretation
Pain		5	0.930	Highly reliable	60	14 days	0.8378	Good	0.721	0.928	Valid
Physical function	**Activities of daily living**	4	0.902	Highly reliable	60	14 days	N/A	N/A	0.831	0.980	Valid
	Household work	5					0.8510	Good			
	Mobility	8					N/A	N/A			
Social function		7	0.725	Acceptably reliable	60	14 days	0.6604	Moderate	0.584	0.787	Valid
General health perceived		3	0.653	Marginally reliable	60	14 days	0.7572	Good	0.695	0.830	Valid
Mental function		9	0.794	Moderately reliable	60	14 days	0.8664	Excellent	0.716	0.907	Valid
Total score		-	-	-	60	14 days	0.9994	Excellent	-	-	-

Source: Authors' primary data (2025).

Test-retest reliability results using the Intraclass Correlation Coefficient (ICC) over a 14-day interval with a subsample of 60 participants. The Pain domain showed good stability over time (ICC = 0.8378), while the Physical Function domain also demonstrated good reliability (ICC = 0.8510). The Social Function domain had a moderate level of reliability (ICC = 0.6604). General Health Perception produced good reliability (ICC = 0.7572). The Mental Function domain achieved excellent test-retest reliability (ICC = 0.8664). Furthermore, the total score exhibited an exceptionally high ICC of 0.9994, indicating nearly perfect temporal stability. The Bland-Altman plot used to evaluate the consistency of measurement results between the first test and the retest, thus providing an overview of the level of agreement on the total QUALEFFO-41 score, is shown in figure 1.



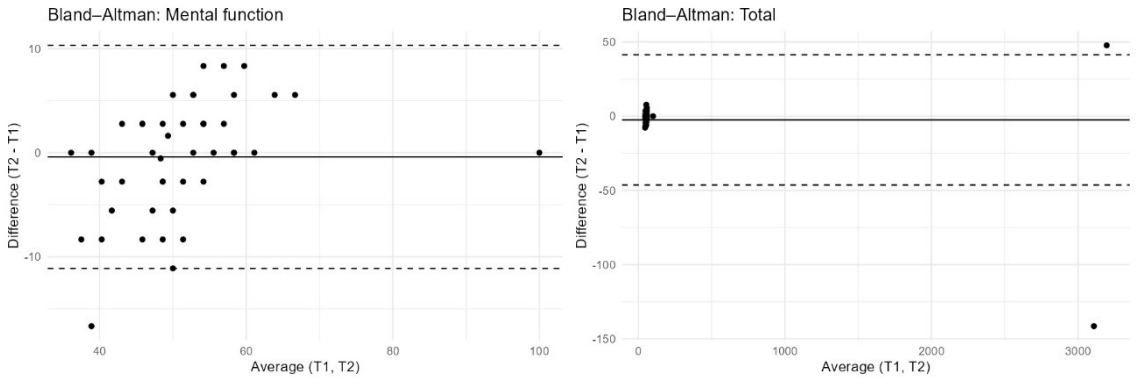


Figure 1. Bland-Altman Plot for QUALEFFO-41 Scores.

Convergent validity of each domain using Average Variance Extracted (AVE) and Composite Reliability (CR). All domains met the standard criteria for convergent validity, with AVE values exceeding 0.50 and CR values above 0.70. Specifically, the Pain domain demonstrated strong convergent validity (AVE = 0.721, CR = 0.928). Social Function (AVE = 0.584, CR = 0.787), General Health Perceived (AVE = 0.695, CR = 0.830), Mental Function (AVE = 0.716, CR = 0.907), and Physical Function (AVE = 0.831, CR = 0.980) also displayed satisfactory convergence. These results confirm that the items within each domain adequately represent their respective latent constructs.

Table III presents the results of the Confirmatory Factor Analysis for each construct. The Pain construct showed poor model fit based on indices such as GFI, AGFI, CFI, TLI, and RMSEA. Within the Physical Function domain, the ADL (Activities of Daily Living) and Jobs Around the House sub-constructs demonstrated marginal fit, whereas Mobility showed poor fit across all indicators. The Social Function and Mental Function constructs also indicated poor fit, suggesting substantial deviations from ideal measurement model assumptions. In contrast, the General Health Perceived construct exhibited perfect fit, indicating that the measurement model aligned fully with the observed data. Overall, the CFA results highlight variability in construct validity across domains, with some requiring further refinement. A Structural Equation Model (SEM) Path Diagram depicting the relationships between latent constructs and the contribution of each indicator to the overall model is shown in figure 2.

This diagram provides a visual understanding of the direction and strength of the structural relationships tested in the study. Meanwhile, a Confirmatory Factor Analysis (CFA) model for the QUALEFFO-41 latent construct, which displays the factor loading values of each item and the model's fit to the theoretical structure. These three complementary figures help explain the results of the psychometric analysis and provide visual support for the interpretation of the results in the discussion is shown in figure 3.

Table III. Construct validity (Confirmatory Factor Analysis - CFA)

Construct		χ^2/df	GFI	AGFI	CFI	TLI	RMSEA	RMR	Fit conclusion
Pain		32.13	0.771	0.314	0.840	0.680	0.392	0.083	Poor fit
Physical function	**Activities of daily living**	8.19	0.963	0.815	0.969	0.906	0.188	0.059	Marginal fit
	Household work	7.49	0.941	0.822	0.935	0.871	0.179	0.101	Marginal fit
	Mobility	11.00	0.783	0.609	0.693	0.570	0.222	0.222	Poor fit
Social function		11.236	0.821	0.642	0.662	0.493	0.225	0.173	Poor fit
General health perceived		–	1.000	–	1.000	–	–	0.000	Perfect fit
Mental function		34.434	0.585	0.308	0.462	0.283	0.406	0.242	Poor fit

Source: Authors' primary data (2025).

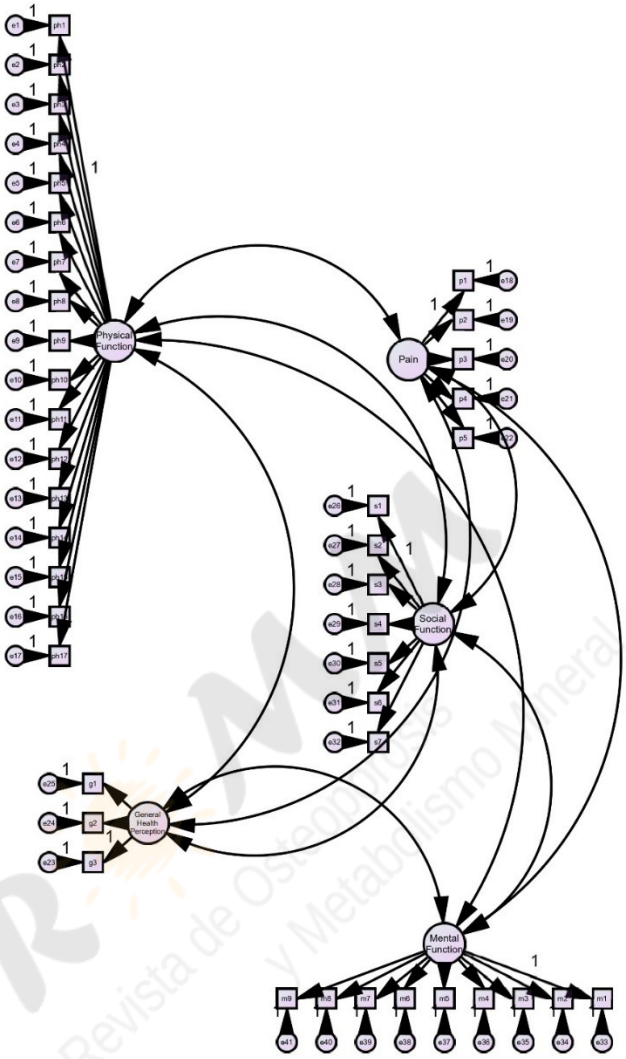
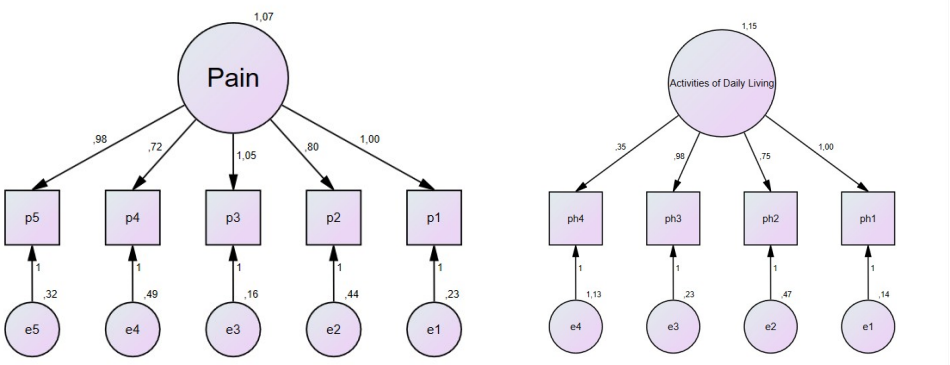


Figure 2. Structural Equation Model (SEM) Path Diagram.



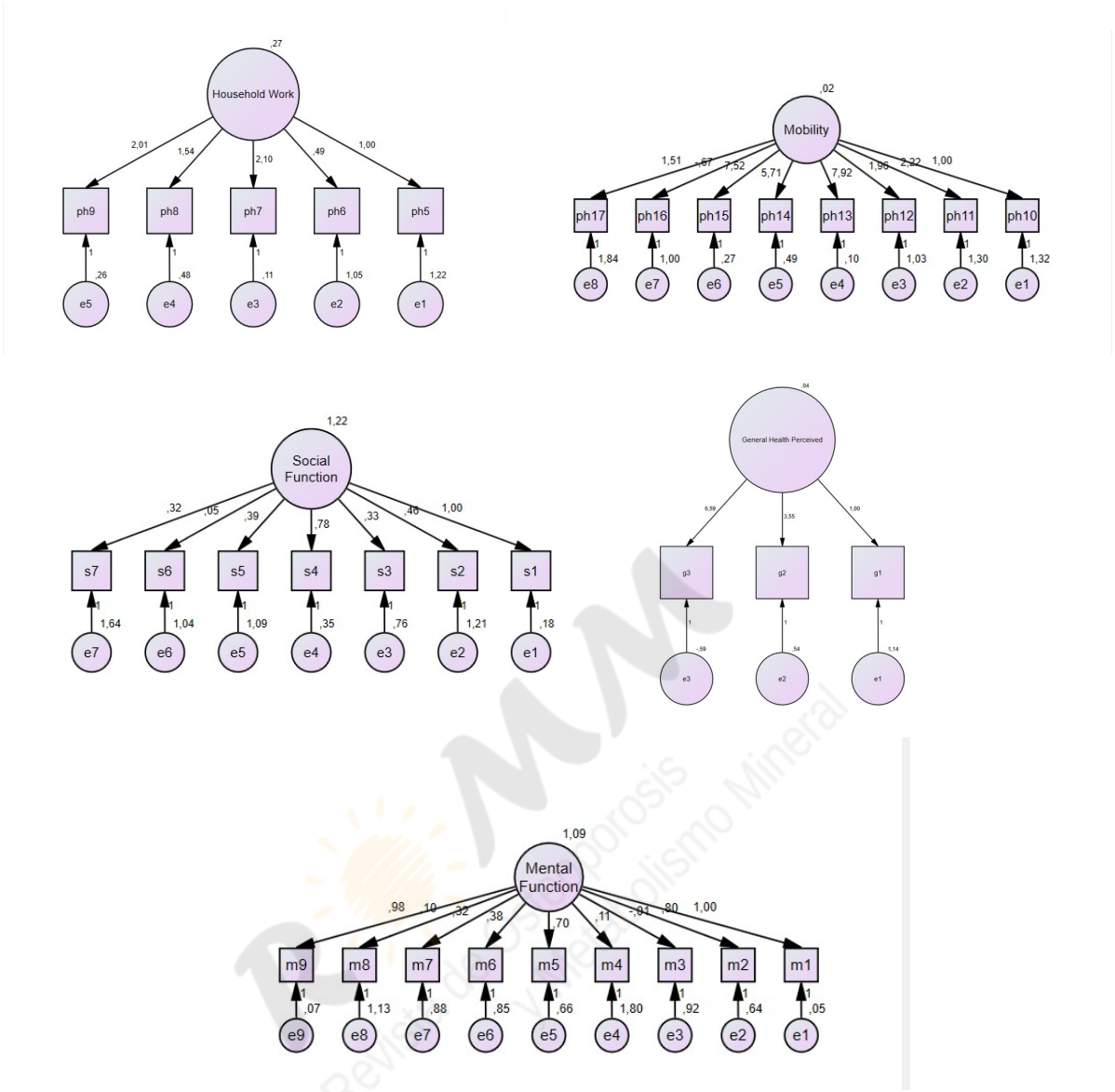


Figure 3. Confirmatory Factor Analysis (CFA) model for the latent construct QUALEFFO-41.

DISCUSSION

The validation results of the Indonesian version of QUALEFFO-41 in this study demonstrate a relatively good psychometric profile. The high internal consistency in domains such as Pain (α = 0.93) and Physical Function (α = 0.90) reflects that the items within these domains are highly cohesive and consistently measure the intended constructs. This finding is consistent with the Korean adaptation, in which the Cronbach's alpha of QUALEFFO-41 ranged from 0.733 to 0.942, indicating adequate reliability in the Korean local population (Lee et al., 2019).

Although internal reliability was very strong in several domains, the Confirmatory Factor Analysis (CFA) results showed that not all domains perfectly followed the original factor structure. The General Health Perceived domain demonstrated very good model fit, whereas other domains such as Pain, Social Function, Mobility, and Mental Function showed low to marginal fit based on indices such as CFI, TLI, and RMSEA. This indicates that although the items are internally consistent, the theoretically assumed latent structure (factors) may not fully align with the data from Indonesian respondents. The discrepancy between high internal reliability (α) and suboptimal CFA model fit can be explained by understanding that Cronbach's alpha measures item homogeneity, whereas CFI, TLI, and RMSEA assess how well the factor structure (latent dimensions) fits the empirical data. In other words, items may be very coherent with one another but do not necessarily fit well within a hypothesized single-factor structure. This phenomenon was also reported in a recent systematic review: according to a 2024 review, evidence for construct validity is relatively strong, but there are limitations in cross-cultural validity and factor structure (Choo et al., 2024).

Cross-cultural comparisons are highly relevant to interpreting these results. For example, in the Hebrew-language adaptation study for postmenopausal women in Israel, QUALEFFO-41 showed internal reliability (α = 0.88) and adequate construct validity, but several domains (especially cognitive/mental and social) required refinement to be relevant within the Israel societal context (Masharawi et al., 2025). Similarly, the Serbian adaptation of QUALEFFO-41 also demonstrated challenges in translation and cultural adaptation despite the use of methodologically rigorous forward-backward procedures (Tadic et al., 2012). In Malaysia, the Malay version of QUALEFFO-41 showed good internal consistency (0.752-0.925), but the social activity domain obtained a lower alpha (0.692), possibly reflecting differences in social perception in the Malay cultural context (Nagammai et al., 2015).

Cultural and linguistic factors are likely major contributors to these differences. For example, the interpretation of household tasks in

Indonesia may differ significantly from Europe or Western contexts Indonesian households often distribute such tasks among extended family members, which may cause respondents to rate household burden differently from how it is conceptualized in the original QUALEFFO framework. Additionally, expressions such as “social function” and “mental function” may carry different nuances in the Indonesian language; idiomatic expressions, emotional communication, and social roles (e.g., family roles, social support) are greatly influenced by local cultural values. A linguistic adaptation that is not sensitive to these nuances can lead to item cross-loading (items loading onto multiple latent factors) or high error covariance, which subsequently affects CFA model fit.

High reliability results and convergent validity (such as adequate AVE and composite reliability in the main domains) indicate that the Indonesian version of QUALEFFO-41 remains highly useful as a disease specific quality of life measurement tool for the local osteoporosis population. Good internal consistency means that respondents answered items in a stable pattern, while convergent validity indicates that the domains indeed reflect the constructs they are intended to measure and correlate with related theoretical constructs. These findings collectively support the use of the Indonesian QUALEFFO-41 as an important instrument in clinical research, epidemiological surveys, and monitoring outcomes in osteoporosis patients in Indonesia.

The importance of the Indonesian version of QUALEFFO-41 cannot be overstated as a locally adapted and validated instrument, it allows for a more sensitive and contextually appropriate assessment of quality of life compared to generic instruments (such as EQ-5D) within the Indonesian population, which may have unique perceptions of pain, mobility, social activities, and mental health. This provides practical benefits for clinical practice (e.g., rehabilitation management and interventions), research (measuring the effects of therapy or rehabilitation), and policy (e.g., identifying the burden of osteoporosis-related quality-of-life impairment in developing countries).

This study reinforces the position that health-related quality of life (HRQoL) constitutes a critical clinical outcome in the management of osteoporosis, particularly among patients with vertebral fractures. Osteoporosis should not be conceptualized solely as a reduction in bone mineral density (BMD), but rather as a chronic, multifactorial condition with profound physical, psychological, and social consequences. From a global epidemiological perspective, osteoporotic fractures represent a substantial and growing public health burden, particularly in ageing populations (Cooper, Harvey & Dennison, 2008). Vertebral fractures, although frequently underdiagnosed, are associated with chronic back pain, progressive kyphotic deformity, impaired mobility, reduced pulmonary function, and increased fall risk. These sequelae collectively contribute to long-term deterioration in HRQoL, often exceeding what can be captured through radiological findings or densitometric parameters alone (Chandran et al., 2023).

The development of the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) marked a paradigm shift in osteoporosis outcome assessment by emphasizing patient-reported outcomes (Lips et al., 1997). Unlike generic instruments, QUALEFFO was specifically designed to detect the multidimensional impact of vertebral fractures, including pain severity, physical functioning, social participation, mental health, and general health perception. Subsequent validation studies confirmed its internal consistency, construct validity, and discriminative capacity in distinguishing patients with and without vertebral fractures (Lips et al., 1999). The shortened version, QUALEFFO-41, further improved feasibility in both clinical and research settings without compromising psychometric robustness.

Previous studies consistently demonstrate that vertebral fractures constitute a pivotal determinant of HRQoL impairment. Oleksik et al. (2000) reported that postmenopausal women with low BMD and prevalent vertebral fractures experienced significantly lower HRQoL compared to those without fractures. Similarly, Jahelka et al. (2009) found that patients with osteopenia or osteoporosis but without fractures exhibited relatively

preserved quality of life compared to fractured patients. These findings suggest that vertebral fracture represents a clinical turning point in the trajectory of osteoporosis, underscoring the importance of fracture prevention strategies.

Instruments such as QUALEFFO demonstrate superior sensitivity compared to generic measures in detecting clinically meaningful differences and post-treatment changes. Badia et al. (2001) showed that QUALEFFO possessed strong discriminative ability in women with vertebral fractures when compared with the Osteoporosis Quality of Life Questionnaire (OQLQ). Furthermore, Yilmaz et al. (2014) demonstrated that disease-specific instruments exhibit higher responsiveness indices than generic tools in evaluating therapeutic interventions. This is particularly relevant in clinical trials assessing pharmacological agents, physical rehabilitation, or combined interventions.

The association between HRQoL and functional parameters further strengthens the clinical relevance of disease-specific assessment. Bergland, Thorsen and Kåresen (2011) demonstrated significant correlations between HRQoL scores and measures of mobility and balance among women with osteoporosis and vertebral fractures. Spinal deformity and chronic pain not only impair physical performance but also increase fall risk, creating a vicious cycle of disability and further fracture risk. Therefore, integrating HRQoL assessment with functional mobility evaluation provides a more comprehensive framework for patient-centered osteoporosis management.

Rehabilitation guidelines also emphasize the importance of quality of life monitoring as part of therapeutic evaluation (Smits-Engelsman, Bekkering & Hendriks, 2005). Treatment success should not be restricted to improvements in BMD but should also encompass functional recovery and psychosocial well-being. This reinforces the clinical utility of QUALEFFO beyond research applications, positioning it as a valuable decision-support tool in routine care. HRQoL in osteoporosis is inherently multidimensional. Physical domains particularly pain and activity limitation often exert the greatest influence on total scores; however, psychological and social

domains also significantly contribute to overall health perception (Lips et al., 1999; Oleksik et al., 2000). Chronic pain, fear of falling, reduced autonomy, and social withdrawal collectively shape the lived experience of osteoporosis. Consequently, a biopsychosocial framework is essential in interpreting HRQoL outcomes.

However, several limitations need to be acknowledged. First, the study sample may have been dominated by women, limiting generalization to male osteoporosis populations. Gender differences in social roles, household responsibilities, and pain perception may lead to different response patterns. Second, this study used a cross-sectional design, which does not permit the analysis of changes in quality of life over time (responsiveness) or causal inference. Third, although a test–retest assessment was conducted, long-term temporal stability (e.g., over months or years) and measurement invariance across subpopulations (e.g., by age, gender, geographic region) were not analyzed. Without invariance analysis, it is difficult to confirm whether the QUALEFFO-41 factor structure remains consistent across various Indonesian population segments. A subgroup analysis based on T-score severity and fracture type was not conducted due to limited statistical power. Future studies with larger samples are recommended to explore the discriminative capacity of the Indonesian QUALEFFO-41 across clinical severity groups.

Recommendations for future research include: (1) conducting item-level analyses (e.g., item response theory or communalities analysis) to identify problematic items (cross-loading, redundant, or culturally irrelevant); (2) performing cognitive interviews with respondents from diverse cultural and social backgrounds to ensure item meaning is fully understood as intended; (3) considering adjustments to the factor structure (possibly dividing domains or subscales) based on local data and cultural theory; (4) conducting multi-group CFA to test measurement invariance across groups (gender, region, age), and (5) implementing longitudinal studies to evaluate responsiveness (sensitivity to change) and temporal stability of the Indonesian QUALEFFO-41.

Overall, although not all domains demonstrated perfect model fit in CFA, the strengths in internal reliability and convergent validity make the Indonesian version of QUALEFFO-41 a highly valuable, relevant, and contextual instrument for assessing quality of life in osteoporosis patients in Indonesia. Further adaptation and validation will continue to strengthen its utility in clinical research, population studies, and osteoporosis management interventions in the country.

CONCLUSION

This study demonstrates that the Indonesian version of the QUALEFFO-41 is a valid and reliable instrument for assessing health related quality of life in patients with osteoporosis, showing a stable factorial structure and satisfactory internal consistency across domains. The CFA results indicate acceptable model fit, and the reliability coefficients support the robustness of the scale within the Indonesian cultural context. Careful linguistic and cultural adaptation ensured that the instrument captures patients' lived experiences more accurately than non-localized measures. Although the study is limited by its cross-sectional design, predominantly female sample, and absence of test-retest evaluation, the findings provide a strong methodological basis for the clinical and research application of the QUALEFFO-41 Indonesia. Future research should explore its longitudinal responsiveness and applicability in more diverse osteoporosis populations.

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